Peripheral Arterial Disease in Diabetes - Aspects of preventable foot loss in KwaZulu-Natal.

by

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Supervisory Approval

As the candidate's supervisor, I have approved this thesis for submission.

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As the candidate's co-supervisor, I have approved this thesis for submission.

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B. Zipfel

Dedication

To Ida Frances Oates Pataca,
whose prescience and trust allowed her granddaughter, aged 5,
to "treat" her corns with Grandpa's shaving blade.

Declaration

I, Anette Telmo Thompson, declare that

(i) The research reported in this dissertation is (except where otherwise indicated) my original work.

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ANETTE TELMO THOMPSON

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Lastly, to my colleagues and family whose unfailing support has not gone unnoticed. Thank you.

Overview of the thesis

While the researcher acknowledges the many risk factors for diabetes-related amputation, this study looked at peripheral arterial disease (PAD) in particular, since it is a condition frequently seen by podiatrists who assess and treat patients with diabetes.

Foot pathology such as ulceration in diabetes needs adequate blood supply to heal. Without adequate blood flow, tissue necrosis leads to amputation. Thus, all possible means to prevent PAD become vital to prevent amputations. Education on lifestyle changes, diet and hydration combined with exercise are some of the preventative measures, but these are not achievable if patients have painful feet. In addition, ischaemia or poor blood supply will itself cause nerve damage (neuropathy), which can manifest as pain and paresthesia in the foot. The current thesis will document that preventive measures, intensive patient education on feet and footwear, as well as dedicated foot screening, foot risk classification and podiatric foot care need to start immediately at the time of diagnosis of diabetes.

This study consists of nine chapters. Chapter One presents the introduction to the thesis. Chapters Two to Eight are grouped thematically into three parts. Part One contains Chapters Two to Four on the theme of screening for PAD in patients with diabetes. Part Two contains Chapters Five to Seven on aspects of anatomical, physiological and footwear risk factors for PAD. Part Three contains Chapter Eight and relates to costs of diabetic lower limb amputations and the missing role of podiatry in KwaZulu-Natal. Chapter Nine presents the thesis discussion and conclusion.

Part One explores the theme of screening for PAD in patients with diabetes in three chapters. Chapter Two contains the published manuscript for a scoping review that investigated what was known about the ankle-brachial index (ABI) as a method of screening for PAD. It focused on such studies concerned with the lower limb in patients with diabetes in low- and middle-income countries. South Africa, a middle-income country according to the International Diabetes Federation (IDF), had previously only reported one pedal study in 2004 in which ABI and

manual palpation of foot pulses was performed. The scoping review revealed that many low- and middle-income countries routinely incorporate the ABI in clinical screening for PAD in patients with diabetes. No evidence was found of large-scale clinical implementation of ABI to screen for lower limb PAD in the diabetic population in the context of prevention of diabetic foot disease in South Africa.

After conducting the scoping review, a journal article was found which called the use of the ABI into question. The abstract of that article was considered sensationalist and misleading. Chapter Three contains the researcher's published letter to the editor in rebuttal.

Prevalence of PAD specific to the lower limb in the diabetic population in KwaZulu-Natal is poorly documented. To assess the prevalence of PAD in KwaZulu-Natal, Chapter Four describes a test study performed on a patient population attending a diabetes outpatient clinic in uMgungundlovu district. Patients were examined employing a truncated but comprehensive podiatric clinical foot assessment which included automated ABI and hand-held Doppler vascular examination. The assessments enabled individual limb risk classification and informed on the previously unknown incidence of diabetes patients presenting with ischaemia and peripheral vascular disease. Established and early signs of peripheral arterial disease were found in 94% of the sample.

The theme of Part Two addresses aspects of lower limb anatomy, physiology and footwear risk factors for the development of PAD. Since prior clinical observation among other patients with diabetes had noted the concurrent presentation of anomalous foot biomechanics, Chapter Five explored the literature concerning blood flow to the calf muscle "pump" as a result of the windlass mechanism. During the literature review prior to writing Chapter Five, an aspect of foot haemodynamic research was found that supplanted medical teaching prior to 2010. This meant that the foot venous "pump" had more importance in vascular return than previously had been ascribed to it.

This aspect to haemodynamics in the foot enabled a synergistic relationship to be described between the description of the function of the venous valve-less reservoir in the foot and the action of the hallux in the phases of gait. While the function of the venous foot pump is being

modelled to construct replicating devices, very little attention has been drawn to the implications for patients with diabetes. This finding alone deserves attention in academic teaching and further study in biomechanical models.

Since dorsiflexion of the hallux is required for a functional windlass, Chapter Six describes how the metatarsal parabola can influence hallux dorsiflexion. Incomplete parabolae influence gait and have relevance to metatarsalgia and diabetic ulceration prevention. It suggests that foot assessment in diabetes should in future include manual palpation to determine the presence or incompleteness of a metatarsal parabola, in order to institute treatment and preventative measures for callus and biomechanical imbalance.

Clinical observation of patient footwear revealed that footwear appeared to be implicated in forces of pressure that caused callus. The researcher considered whether there could be a mismatch in the location of flexion function of footwear to that of feet.

Chapter Seven contains a published manuscript on the author's study on metatarsal lengths and mismatched footwear. Since flexion at the hallux was shown in the current study to be necessary for haemodynamic function in the foot, the manuscript describes the investigation carried out into the position of flexion in footwear. The results showed that footwear flexion position might not match the anatomical flexion position of a patient. Mismatched footwear flexion impedes hallux dorsiflexion. This yielded information that will need to be included in future guidelines on clinical foot examination and patient education, since mismatched flexion in footwear constitutes a risk factor for ulceration in patients with diabetes.

It has been clear to many health professionals for some time that a strong workforce of podiatry is urgently needed to prevent amputations in patients with diabetes. This has been communicated to the researcher by many endocrinologists, vascular and general surgeon colleagues as well as family health physicians. It was felt that since health policy decisions are driven by many factors, the important one to address was cost. The researcher thus undertook the process of calculating some of the costs of diabetes-related lower limb amputations. This will enable policymakers to juxtapose such costs against the costs to position podiatry in the framework for national health and thus deploy qualified podiatrists in KwaZulu-Natal.

Chapter Eight presents the published manuscript of a draft cost analysis study of 660 lower-limb diabetes amputations from 2013 to 2017 at a single hospital. It extrapolates these costs across KwaZulu-Natal and all provinces. The cost analysis also presents what the budgeted amount would have been for podiatric care, to show that it is and would have been a fraction of the non-reversible and preventable losses represented by lower-limb amputations in diabetes.

The multi-disciplinary team (MDT) approach to diabetes care and ulcer prevention is also presented, with supportive literature providing the evidence base of the value of podiatry, especially in the multi-disciplinary team approach to diabetes amputation prevention.

The current study undertook to investigate aspects of preventable foot loss in patients with diabetes. In the final discussion of the total thesis in Chapter Nine, findings are summarised together with recommendations for various stakeholders based on the findings therein. In summary, podiatric care for patients with diabetes has the potential not only to contribute to the efficient use and saving of medical and financial resources but also, in conjunction with the team approach, to save the feet of diabetic patients and improve their quality of life.

Keywords: diabetic foot assessment, peripheral arterial disease, windlass mechanism, foot venous pump, metatarsal parabola, footwear, lower limb amputation, health care costs, podiatry, diabetes multi-disciplinary team approach

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List of acronyms and abbreviations

ABI	Ankle-brachial index (also known as ankle-brachial pressure index)
ABPI	Ankle brachial pressure index
COPD	Chronic outpatients department
CT	Computerised Tomography
DFU	Diabetic Foot Ulcer
DOPD	Diabetes outpatient department
DVT	Deep vein thrombosis
DX	Diagnosis
DDX	Differential diagnosis
ECQ	Edinburgh Claudication Questionnaire
FIP-IFP	International Federation of Podiatrists
HX	History
IDF	International Diabetes Federation
IPJ	Inter-phalangeal joint
IWGDF	International Working Group on the Diabetic Foot
LIRI	Leather Industries Research Institute
MRI	Magnetic Resonance Imaging
MTPJ	Metatarsophalangeal Joint
NICE	National Institute for Health and Care Excellence (United Kingdom)
NIDDM	Non-Insulin dependent diabetes mellitus (also Type II diabetes mellitus)
NRF	National Research Foundation
OPD	Outpatients department
PAD	Peripheral Arterial Disease
PUVA	Psoralen and Ultraviolet A therapy
PVD	Peripheral Vascular Disease
SEMDSA	Society for Endocrinology Metabolism and Diabetes South Africa
SIGN	Scottish Intercollegiate Guidelines Network
SOPD	Specialised outpatient department
TBI	Toe brachial pressure index
THRIP	Technology and Human Resources in Industry Program
TX	Treatment
WHASA	Wound Healing Association of South Africa

Co-author Contribution Statements

Authorship guidelines were followed as set out by the Committee on Publication Ethics (COPE) [1]. The co-authors of the publications in the current thesis fulfil the criteria for authorship recommended by the International Committee of Medical Journal Editors (ICMJE) [2] as stated:

1. "Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; and
2. Drafting the work or revising it critically for important intellectual content; and
3. Final approval of the version to be published; and
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved."

Clinical observation of peripheral vascular disease in patients living with diabetes prompted a number of avenues of investigation – how is it screened in South Africa; what was the extent of peripheral arterial disease in a population living with diabetes; were there any further aspects of physiology, anatomy and footwear implicated in its pathogenesis; and what was it costing in terms of amputations and poor utilisation of the discipline of podiatric medicine?

Thompson AT, Pillay S, Aldous C. The use of ABI in screening for diabetes-related lower limb peripheral arterial disease in IDF middle- and low-income countries: a scoping review. Int J Diabetes Dev Ctries 2020; 40, 4–11. https://doi.org/10.1007/s13410-019-00753-y

This first paper was a joint effort by the authors, with a substantial contribution from Professor Aldous regarding the structure and approach of a scoping review. Doctor Pillay suggested that the question should profile countries with poor resources. All three authors participated in identifying the research question to compile the search string for study acquisitions. The team equally shared the task of reviewing the 400 records identified, to sift and select the final reported studies based on relevance to the research question. As the main author, I collated,

summarized the search and selection findings and reported the results in both a descriptive and numerical summary of the data and thematic analysis. Both co-authors provided final approval of the article via email prior to journal submission. This specific journal was chosen as it represents one of the countries with limited medical resources. Both co-authors contributed to efforts that lasted ten months to elucidate the reviewers as to the different nature of a scoping review.

Thompson AT. On the Ankle Brachial Index. Scand J Clin Lab Invest. 2019;79(5):281-282. https://doi.org/10.1080/00365513.2019.1569717

Soon after the first paper was submitted, this letter to the editor was conceptualized and written by the primary author alone. It served as a rebuttal to the suggestion put forward in an article by Trevethan [3] that the ABI should possibly be discarded in clinical practice. I undertook this letter to the editor since our team had conducted the scoping review on the use of ABI and our conclusions were contrary to those put forward in the disputed article. Both authors of the scoping review article were appraised and supported my intention to write a rebuttal.

The next part of my approach used a test study to screen a sample patient population for peripheral arterial disease.

Thompson A T, Pillay S, Zipfel B, Singh D, Aldous C. Prevalence of Peripheral Arterial Disease in a diabetes patient population attending Edendale Hospital in Pietermaritzburg. Journal of Endocrinology, Metabolism and Diabetes of South Africa. (submitted 27 October 2020).

Prevalence of PAD specific to the lower limb in the diabetic population in KwaZulu-Natal is poorly documented. In order to assess prevalence of PAD in KwaZulu-Natal, I collaborated with Dr Somasundram Pillay in a test study performed on a patient population attending a diabetes out-patient clinic in uMgungundlovu district. Over three hundred patients were examined by me using a truncated but comprehensive podiatric clinical foot assessment which included automated ABI and hand-held Doppler vascular examination of both feet. These data were combined with same day vital signs and other clinical data as recorded by the attending diabetes clinic physicians. The podiatric assessments enabled individual limb risk classification and informed on the previously unknown incidence of diabetes patients presenting with ischaemia

and stages of peripheral vascular disease. Owing to the large size of data, and my lack of advanced training in statistical analysis, Mr. Deepak Singh of the Durban University of Technology was engaged to structure the database and provide the statistical analysis conducted on IBM SPSS v26 ®. Doctor Bernhard Zipfel critically revised this manuscript for intellectual podiatric content. Professor Aldous provided critique on overall content. All authors critically reviewed the manuscript and provided email approval prior to submission.

My attention was then focused on haemodynamics in the foot – what aspect of known biomechanics could improve blood flow or work against haemodynamics in the foot? The following two manuscripts are reviews that found physiological and anatomical relationships to biomechanics and thus will influence how exercise is optimized.

Thompson AT, Zipfel B, Aldous C. The relationship of the windlass mechanism to venous flow in the foot in diabetes – what should we know? – a two-pronged literature review. Journal of Endocrinology, Metabolism and Diabetes South Africa (submitted 6 November 2020).

This review originally began with the need for more detail on haemodynamics to support current literature on the need for exercise in the treatment of diabetes. While much was found regarding the role of the calf muscle pumps, it was only when studies were found that explained dissection study findings on the anatomy and physiology of the foot venous pump that the correlation to foot biomechanics and the diabetic foot was found. It was drafted by me as the main author with inputs and critique from co-authors Professor Aldous and Dr Zipfel.

Thompson AT, Zipfel B, Aldous C. The dysmorphic metatarsal parabola in diabetes clinical examination and management: a narrative review. Journal of Endocrinology, Metabolism and Diabetes South Africa (submitted 11 November 2020)

Observation in clinical practice directed this line of investigation, documented in this manuscript. Many patients with diabetic foot ulcers over the lesser metatarsal joints also presented with brachymetatarsia of the first metatarsal. This dermatological aspect to an incomplete metatarsal parabola is particularly important in patients with diabetes. An incomplete metatarsal parabola may cause imbalance, disruption of foot posture and forefoot function. The resultant focal

increased plantar pressure can lead to the formation of pre-ulcerative hyperkeratosis or callus in patients with diabetes. Manuscript content was critically reviewed for intellectual content by both Dr Zipfel and Professor Aldous.

Clinical observation indicated that some footwear was implicated in pathology of the foot and this was investigated with some preparatory discussions with members of the local footwear industry.

Thompson AT, Zipfel B, Muzigaba M, Aldous CM. Flexion location of the first metatarsophalangeal joint and the location of forefoot bend in general purpose women's footwear. Foot Ankle Surg. 2019;25(3):340-347. https://doi.org/10.1016/j.fas.2018.01.001

In my research preparations, I consulted with a last maker regarding flexion position built into footwear lasts. Information came to light at that meeting that prompted the further analysis of a foot measurement database, to assess whether there could be a mismatch in flexion positions. I recruited Dr Muzigaba to discuss how best to present the statistical analysis. Dr Muzigaba worked with me to refine and run the analyses, as well as collaborate and edit the explanatory text. The article was critically revised for intellectual content by both Dr Zipfel and Professor Aldous. All authors provided final approval of the article via email prior to journal submission. The journal required precise descriptive language, and all three authors were involved in these changes before publication.

Finally, the following manuscript records the study conducted into costs of peripheral arterial disease.

Thompson AT, Bruce JL, Kong VL, Clarke DL, Aldous C. Counting the cost of preventable diabetes related lower limb amputations at a single district hospital in KwaZulu-Natal – what this means, what can be done? Journal of Endocrinology, Metabolism and Diabetes of South Africa. https://doi.org/10.1080/16089677.2020.1782007 Published Volume 25, 2020 - Issue 2, 44-50.

This portion of the study was originally prompted during a doctors' guild meeting in Durban in 2014 in which it was suggested to me that, despite all the medical evidence on prevention of

diabetes-related lower limb amputations (DMLLA), only a costing exercise could be powerful enough to stimulate healthcare policy amendments necessary to implement the measures needed to prevent DMLLA. In discussions with Dr Somasundram Pillay, he suggested that I approach Professor Clarke of the Pietermaritzburg Metropolitan Trauma Service (PMTS) and the Pietermaritzburg Surgical Service (PMSS) at Greys Hospital, to pursue data on DMLLA. Collaborative meetings were held with all authors. To overcome the challenges of distance and conflicting schedules, a WhatsApp group called 'Project: Diabetic Foot' was formed by Professor Clarke, that linked continued communication between all the authors and enabled arrangements for meetings, questions and exchange of information. Dr Bruce interrogated the database and provided input regarding the psychological and mental state of the surgical team in respect of the increasing non-traumatic amputation load. Dr Kong provided input for methods of compiling and presenting the data. Detailed assistance was provided on specific aspects by Professor Clarke and Professor Aldous. I undertook data input supervision and cross-checking. The text draft, data analysis and interpretation were performed by me with critical intellectual inputs from all authors. All authors provided email approval prior to submission.

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3. Trevethan R. Subjecting the ankle-brachial index to timely scrutiny: is it time to say goodbye to the ABI? Scand J Clin Lab Invest. 2018;78(1-2):94-101. https://doi.org/10.1080/00365513.2017.1416665

Peripheral Arterial Disease in Diabetes - Aspects of preventable foot loss in KwaZulu-Natal.

Anette Telmo Thompson

Abstract

This study in three parts aimed to investigate what could still be learnt about foot-related aspects of peripheral arterial disease (PAD) in patients with diabetes in KwaZulu-Natal. The structure followed a number of avenues:- how it is screened in South Africa; what is the extent of PAD in our diabetes patient population; are there further related or contributory aspects in foot physiology, anatomy and footwear; and lastly how much is it costing in terms of amputations and the poor implementation and utilisation of the specialty of podiatric medicine?

The first part examined screening for PAD and revealed that both Ankle Brachial Index (ABI) and handheld doppler ultrasonography were little used for general screening in South Africa. A foot assessment study was undertaken of a patient population not exposed to podiatric care (n=302) and showed that those with previously unknown early signs as well as established PAD represented 94% of patients.

The second part of this study investigated anatomical, physiological and footwear risk factors for PAD. A chapter describes how the function of the dorsiflexion of the hallux was found to be linked to the function and phases of venous return in the foot via the foot venous pump. The study further examined how a dysmorphic metatarsal parabola can influence hallux dorsiflexion and thereby venous return. Results suggested that diabetic foot assessments should now include methods to test for the presence or incompleteness of metatarsal parabola. A further chapter examined metatarsal lengths from 3-dimensional measurement data to compare to data used for footwear manufacture. Mismatched footwear flexion impedes hallux dorsiflexion and thereby foot haemodynamics. Results showed that footwear flexion position often does not match the anatomical flexion position of a patient.

The third part of the study assessed what the absence of Podiatry and thereby poor delivery of diabetic foot care is costing the country. An audit of diabetes-related lower limb amputations at Greys Hospital estimated an extrapolated cost of some R70 billion per annum for South Africa.

The results of the study can inform national and provincial healthcare policy in respect of Podiatry, future guidelines on clinical foot examination, patient education and footwear design.

Iqoqa

Lolu cwaningo olunezingxenye ezintathu kuhloswe ngalo ukuphenya okusangafundwa ngezingxenye i*peripheral arterial disease* (PAD) ezigulini ezinesifo sikashukela KwaZulu-Natali. Umumosakhiwo ulandele izingxenye ezimbalwa: - ukuthi kuskrinwa kanjani eNingizimu Afrika; ifinyelela kuphi i-PAD eqoqweni leziguli zethu zesifo sikashukela; ngabe kukhona okunezelelayo okuhlobene nefiziyoloji yonyawo, i-anathomi kanye nezicathulo; okokugcina ngakube kubiza malini ukunqunywa kanye kokuqalisa ukusebenza okungekho ezingeni nokusebenzisa imithi yokwelapha ekhethekile?

Ingxenye yokuqala ihlole ukuskrinela i-PAD yase iveza ukuthi kokubili i-*Ankle Brachiak Index* (ABI) kanye ne*doppler ultrasonography* ephathwa ngesandla zasetshenziswa kancane ukuskrina okwejwayelekile eNingizimu Afrika. Ucwaningo lokuhlola unyawo lwenziwa eqoqweni leziguli ezingasondelene nokunakekelwa kwezinyawo (n=302) nokwakhombisa ukuthi lokho kanye nezimpawu zasekuqaleni ezingaziwa kanye ne-PAD esunguliwe kumele iziguli ezingama-94%.

Ingxenye yesibili yalolu cwaningo iphenye imithelela ingozi mayelana ne-PAD ngokwe-anathomi, ifiziyoloji kanye nezicathulo. Isahluko sichaza ukuthi umsebenzi we*dorsiflexion* ye-hallux kwatholakala ukuthi uxhumene nomsebenzi nezigaba zalapho kuguquka khona umthambo onyaweni ngephampu yomthambo wonyawo. Ucwaningo lwaphinde lwahlola ukuthi i*dysmorphic metatarsal parabola* ingaba nomthelela kwi*hallux dorsiflexion* nokujika komthambo.

Imiphumela yaphakamisa ukuthi ukuhlolwa kwezinyawo ezidalwa yisifo sikashukela kumele manje kufake izindlelakwenza zokuhlola ubukhona noma ukungapheleli kwe*metatarsal parabola*. Esinye isahluko sahlola ubude bama*metatarsal* asukela kwimininingo yokukala emacala ma-3 ukuqhathanisa imininingo esetshenziswe ekwakhiweni kwezicathulo. Iflekshini engahambisani yezicathulo inqinda i*hallux dorsiflexion* bese kuba ne*haemodynamics* yezinyawo. Imiphumela yakhombisa ukuthi umumo weflekshini yezicathulo awuvamisile ukuhambisana nomumo weflekshini ye-anathomi yesiguli.

Ingxenye yesithathu yocwaningo yahlola ukuthi ukungabi khona koKwelashwa kwezinyawo okube sekudala ukungalethwa ngendlela konakekelo lonyawo oludalwe yisifo sikashukela kulibiza imali enkulu izwe. Ukubhekisiswa kokunqunywa kwezinyawo ngenxa yesifo sikashukela eGreys Hospital kulinganiselwa esambeni esingama-70 *billion* ngonyaka eNingizimu Afrika.

Imiphumela yocwaningo ingaba nomthelela kwinqubomgomo kazwelonke neyesifundazwe mayelana nokwelashwa kwezinyawo, imigomo yasesikhathini esizayo ekuhlolweni kwezinyawo, ukufundisa iziguli nomumosakhiwo wezicathulo.

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Chapter One: Introduction

There is an increasing complexity to certain human diseases that simultaneously draws the attention of all medical disciplines yet provides the stimulus to each field to expand the common base of knowledge. Diabetes mellitus is such a disease. It demands attention due to the devastating complications that the inflammatory processes cause in multiple systems within the human body. In the lower limb, atherosclerotic plaque formation, arteriosclerotic narrowing of the vascular lumen and ischaemia are progressive aspects of peripheral arterial disease (PAD), directly implicated globally in foot and lower limb amputations [1−5].

Podiatry is the specialty of health sciences concerned with the research, prevention, diagnosis and treatment of deformities, pathologies and injuries of the foot and associated structures – in relation to the body as well as the manifestations of systemic diseases – by all appropriate systems and technologies using scientific and professional specialised knowledge [6−8]. As such, demand for podiatrists for their important role in diabetes care is increasing worldwide. Podiatric medicine plays a role in the prevention of lower limb complications such as diabetic foot ulcers (DFU) through examination, education and treatment. It also provides advanced wound care (through debridement, total contact cast, among others), custom offloading, microbiological testing, vascular, musculoskeletal and neurological screening. It coordinates patient care according to each patient's foot risk status.

It has been apparent for some years that, at the same time as enormous strides have been made in formulating and revising the national guideline for care in diabetes [9−10], studies underscoring the lack of foot care in diabetes in South Africa have been escalating. These studies highlight inter alia the lack of patient awareness of diabetes foot disease and the lack of dedicated preventative foot care. [11−19]. South African studies now call for healthcare improvement and podiatrists to prevent amputations due to foot disease in diabetes [20−22]. It must be noted that the local authors of these studies are not podiatrists but represent other medical disciplines.

Since lower limb ischaemia is one of the causes in diabetes of ulceration [23-30] and non-healing lower limb lesions which precede amputations, my current work set out to investigate what could

still be learnt about foot-related aspects of PAD in patients with diabetes in South Africa. The structure of this investigation would follow a number of avenues:- how it is screened in South Africa; what is the extent of PAD in our diabetes patient population; could there be further related or contributory aspects in foot physiology, anatomy and footwear; and lastly how much is it costing in terms of amputations and the poor implementation and utilisation of the discipline of podiatric medicine?

In screening for PAD, hand-held doppler ultrasonography and the calculation of the ankle brachial index (ABPI or ABI) forms part of medical training in South Africa, including that of podiatrists. To investigate what had been published about the use of the ABI in screening for lower limb PAD, the first exercise of the current study was to compile a scoping literature review. A scoping review is an approach to knowledge synthesis that focuses on key concepts and assists in identifying gaps in the research body of knowledge [31]. In the current study, the scoping review identified publications that described the use of the ankle-brachial index (ABI) in screening for diabetes related lower limb peripheral arterial disease in IDF middle- and low-income countries. The International Diabetes Federation (IDF) classifies South Africa as a middle-income country [32]. The scoping review manuscript was published in the International Journal of Diabetes in Developing Countries. It reveals that the ABI remains a widely accepted method to screen for peripheral arterial disease, in conjunction with hand-held doppler ultrasonography and physical examination in resource-poor settings. It also revealed the lack of published population comprehensive studies using ABI in South Africa [33].

Shortly after completing the scoping review, I found an article calling the ABI into question and suggesting its discontinuation [34]. I submitted a letter to the Editor in rebuttal [35], based on the results of the scoping review carried out in the current study that supported its use in resource-poor settings, together with hand-held doppler ultrasonography.

In countries that may lack enough podiatrists to assess diabetic patients, it is important that technology is used by members of the multi-disciplinary team to achieve early identification of the at-risk lower limb. Such technology is invaluable to determine the prevalence of certain lower limb risk factors within the diabetic population. Data, pertinent to each region, can then be used for health care planning purposes in the deployment of podiatrists. In order to find out what data on

peripheral arterial disease would result from the deployment of a podiatrist, the next step in the current work was to conduct a test study.

The test study took place at a diabetes outpatient clinic of a regional hospital in the uMgungundlovu health district. As a qualified podiatrist, I used a condensed podiatric foot assessment tool with low-cost technology devices to carry out individual limb risk classification. This exercise aimed to find the incidence of diabetes patients presenting with ischaemia and PAD. Vascular examinations were carried out by clinical assessment as well as by hand-held doppler ultrasonography and automated ankle-brachial equipment. At the same encounter, by including a truncated but comprehensive podiatric foot assessment that included musculo-skeletal, dermatological, neurological and footwear examination, a lower limb risk classification was also carried out. The risk classification placed the assessed patients into Low, Medium, High Risk and Active foot disease categories as per the 2017 national guidelines of the Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA) [9].

The next two aspects that warranted investigation in the current study were related to musculo-skeletal haemodynamics. Inclusion of this direction of enquiry in the thesis structure was prompted by a period of my clinical observations in which a pattern of poor hallux function was seen in patients presenting with a short first metatarsal (SFM). Some of these patients concurrently presented with peripheral vascular disease (PVD).

The first aspect concerned the extent to which lower limb haemodynamics could be affected by biomechanical dysfunction of the windlass function at the first metatarsophalangeal joint. This is related to an aspect of metatarsal structure (the relative lengths of the metatarsals that form a complete or incomplete metatarsal parabola). A literature review was conducted to set out the relationship between the windlass mechanism and calf muscle (leg) haemodynamics. During this process, new information regarding foot haemodynamics was found. This new information is shown to correspond to the biomechanical function of the foot in the phases of gait, with specific implications for the foot in diabetes. This finding can direct new studies to inform new approaches to improve haemodynamics in the lower limb in diabetes. A second literature review was conducted relating to the concept of the metatarsal parabola, methods of measurement and relationship to foot function and pathogenesis in diabetes.

The third aspect I investigated was whether footwear could enable or block the windlass function necessary for haemodynamics in the lower limb. A published manuscript details further research that was carried out in this regard [36]. I analysed a three-dimensional database of foot measurements to find whether the flexion characteristic is correctly positioned in general purpose women's footwear. An oral presentation on the same analysis was delivered to the World Congress of Podiatry in late 2019. This investigation yielded important information for patients with diabetes and medical practitioners in South Africa.

Globally, wherever podiatric medicine is part of diabetes foot care, it has been documented that podiatrists play an important role in the prevention of lower limb complications. Health care planning must be updated to include Podiatry. This is necessary for National Health to correct the error of white paper omission of Podiatry that took place circa 1994.

How much is the cost of prevention compared to the sequela of lower limb disease in diabetes, namely amputation?

In the final section of the current study, a draft analysis of the cost of amputations in South Africa was carried out. Retrospective data on diabetes-related lower limb amputations (for the five years between 2013 and 2017 at the surgical unit of Grey's Hospital) was analysed to quantify financial and other drains on the healthcare system from preventable diabetes-related amputations. A prospectively maintained real-time database was analysed to quantify the immediate diagnostic imaging, laboratory costs, theatre and ward costs for these patients. Since many of the amputees are transferred back to their referring base facility, costs were outlined that include costs of transportation, estimates for hospital ward care back at the referring facility, follow up care after surgery, specialised wound care, podiatric care, orthotics and therapeutic footwear, physical therapy, mobility aids such as crutches, artificial limbs, walking frames and wheelchairs. In addition, socio-economic costs are outlined that include personal financial loss, psychological costs such as patient loss of self-worth, loneliness and depression; costs to the family, the community and industry [37-47] In addition, the cost to the country of loss of taxable income as well as the psychological factors affecting health care workers are noted. These include a growing loss of morale affecting surgeons and support personnel who face excessive and increasing numbers of amputations in their work, in the knowledge that these could have been prevented.

The multi-disciplinary team approach to the care of diabetes patients is described. It profiles the in-depth foot screening, assessment, treatment and education provided by podiatry as a role player in the team for prevention of diabetes amputations. The costs of ZAR 348 million for 660 diabetes-related amputations in Pietermaritzburg are compared to suggested costs of ZAR 10 million for instituting podiatric care for those 660 diabetes patients. The expenditure on podiatry is justified given that a recent systematic review with meta-analysis has shown that podiatry in the MDT can decrease diabetes amputations by more than half [48].

In the closing section, the preceding chapters are summarised, but attention will focus on pertinent and urgent issues. These include but are not limited to the urgent establishment of at least one medical school department for the discipline of Podiatric Medicine in the province of KwaZulu-Natal. In the state health sector, posts should now be opened at Tertiary, Regional and District Hospitals to attract existing unemployed qualified podiatrists before they are lured into overseas posts. Since Podiatry in South Africa is now a scarce skill, The Health Professions Council of South Africa (in addition to the efforts of the Board for Physiotherapy, Podiatry and Biokinetics) should be mandated by the Department of Health to facilitate and expedite the application of immigrant and returning qualified podiatrists from English speaking countries who are keen to work in state health, should posts be opened.

Until further training and formation of diabetes team units, which include podiatrists are created, different approaches to diabetic foot assessment, foot education and foot treatment will be necessary. These may include, among others, group teaching and education to all health professionals as to the scope and training of podiatric medicine, which includes treatment of complex issues relating to structural and functional defects of the foot and lower limb. Such education as to the role of podiatry in diabetes care is necessary to avoid any professional stereotyping that may detract from effective health delivery. For example, opinions that may still exist in the medical profession such as “podiatrists just cut toenails” are the result of professional ignorance and lack of education at medical school on the training and scope of practice of podiatric medicine.

Multi-disciplinary diabetes treatment teams need to be correctly funded at both state and private health levels. Both podiatrists and specialised diabetes nurse educators are under-provided for in terms of necessary patient time by many of the private medical insurers, including that of

government itself. Lack of education among insurers regarding podiatric training and scope of practice reveals itself in the unwillingness of some insurers to reimburse podiatrists for diabetes wound care, and lack of reimbursement for custom prescription in-shoe orthoses at equitable rates to those of orthotist/prosthetists.

An additional challenge is for the syllabus at medical schools to include updated interdisciplinary education on podiatric medicine, such that each medical discipline can better recognise symptomatic concerns warranting timely referral, as well as reinforce the recommendations for annual podiatric foot assessment that have been shown globally to substantially lower the risk of lower limb complications for diabetic patients.

Approaches such as telehealth in the age of smartphone cameras should be explored in future studies. These could support specially trained primary healthcare workers to send diabetic foot assistance enquiries with or without images to Tertiary and Regional-based podiatric medicine facilities. This would not only assist with supportive knowledge for remote wound care but also to appropriately refer patients for treatment to the podiatrists. Remote wound care is particularly important in a time of Covid-19 when routine visits to hospitals by at-risk diabetes patients should be restricted. State health mobile podiatry clinics could be created, with rosters to call on outlying areas for scheduled follow-up and education. Educational and motivational support messages could be forwarded to each patient's mobile telephone, as a follow up to clinical education and support. State television, radio and print media diabetes education in English should be translated into each official language, for local dissemination. The life skills curriculum for school students should include basic education on diabetes so that young people are empowered with knowledge to support their family members, contribute to prevention of complications and embrace lifestyle changes for their own prevention and control of the disease.

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Part One: Screening for peripheral arterial disease in patients with diabetes mellitus

Studies show that lower limb amputations in patients with diabetes can often be traced back to a foot lesion [1-5]. Diabetic vasculopathy, neuropathy, increased plantar pressure, formation of callus, ulceration and morbidity are linked [6-8]. Prevention of plantar foot ulcers is vital to reduce the incidence of lower limb amputations, poor patient outcomes, and the consequent socio-economic burden [9-13].

Diabetic foot screening, foot assessment and education are an integral part of foot ulcer preventative measures. Podiatric clinical foot screening (accompanied by simultaneous verbal educational interaction with the patient) progresses through an examination of the musculoskeletal structure, dermatology, neural and vascular testing, as well as the patient's footwear. Risk factors arising from the examination are collated, and the patient is recorded as being at low risk, medium risk or high risk of lower limb complication, according to a set protocol [14]. An example of a foot screening sheet may be found in Appendix 12. In this way, patients can be accurately and timeously referred or scheduled for further treatment and management by the appropriate discipline within the diabetes multi-disciplinary team, to prevent lower limb complications with potential progression to amputation.

Discussions with Dr Somasundram Pillay (Endocrinologist) at Edendale Hospital and Dr Damian Clarke (Surgeon) at Greys Hospital, concerning the rate of lower limb amputations in Pietermaritzburg suggested that a high (hitherto unquantified) proportion of patients with diabetes have vascular insufficiency of the lower limb, leading to non-healing of lower limb lesions.

At a state health medical encounter, if feet of the diabetic patient are indeed examined, perfusion to the foot would be determined by palpation of pedal pulses. My concern is that simple palpation of pedal pulses may not be accurately interpreted compared to Doppler vascular waveforms, to provide a necessary alert to the beginning of PAD. Studies have shown that lack of pedal palpation consensus among clinicians results in substantial observer error [15-17]. These studies advocate Doppler measurement, particularly in clinic environments in which there are different levels of experience and hurried conditions [18-19]. A study that examined males only (but failed to state

this in the incomplete manuscript title) recorded a high level of false-positives in pedal palpation of obese patients, indicating that obesity may jeopardise the reliability of pulse palpation [20].

In considering methods of screening for peripheral arterial disease (PAD) in the lower limb, two of the low-cost methods that form part of podiatry training (and are used by podiatrists in multi-disciplinary teams) are the handheld Doppler ultrasound device and the ankle-brachial index (ABI, also known as ABPI). Both handheld doppler and ABPI are used in conjunction with podiatric clinical examination to enable early-stage detection of ischaemia in the foot. This is supported by a 2018 survey of podiatric practice in the United Kingdom which found that the use of hand-held Doppler ultrasonography and ABPI was practiced by those podiatrists who had received training thereon and who regularly saw more than 20 patients with diabetes per week [21].

As a method of gaining insight into the extent of published work on the screening usage of the ankle-brachial pressure index, a scoping literature review approach was selected. The focus would be in screening for lower limb PAD in low to middle-income countries (countries as defined by the International Diabetes Federation) which include South Africa.

The scoping review forms Chapter Two of Part One; the manuscript was accepted by the International Journal of Diabetes in Developing Countries in May 2019 and was first published online.

While the results of the scoping review were being compiled (before publication), I came across an abstract of an article published in the Scandinavian Journal of Clinical and Laboratory Investigation in which the author questioned whether it was “time to say goodbye to the ABPI” [22]. I had completed the documentation of the scoping review a few weeks earlier (which revealed how important the ABPI remains in resource-limited settings). I therefore objected to what was considered to be the misleading nature of the abstract title, as well as the lack of material therein regarding automated ABPI. My published rebuttal letter to the Editor forms Chapter Three of Part One.

The scoping review did not find a published podiatric or foot-related study in South Africa that screened for lower limb PAD using the ankle-brachial index. To conduct screening and collect evidence on the lower limb status of a sample of patients with diabetes, ethics clearance from the University of KwaZulu-Natal was obtained. In addition, permission from both the Department of

Health and the management of Edendale Hospital in Pietermaritzburg was granted to conduct podiatric foot screening (which included hand-held Doppler ultrasound and automated ankle-brachial index) on patients attending the diabetes outpatients' clinic at Edendale Hospital. The description and results of this foot screening test study are contained in Chapter Four of Part One.

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Chapter Two: The use of ABI in screening for diabetes-related lower limb peripheral arterial disease in IDF middle- and low-income countries: a scoping review

In discussing methods of screening for peripheral arterial disease (PAD) in the lower limb, two of the low-cost methods that form part of podiatry training (and are used by podiatrists in multi-disciplinary teams) are the handheld doppler ultrasound device and the ankle-brachial index (ABI, also known as ABPI). Both handheld doppler and ABPI are used in conjunction with podiatric clinical examination to enable early-stage detection of ischaemia in the foot.

I led a small team to conduct a scoping literature review to find what has been published about the use of the ankle-brachial pressure index. The focus would be in screening for lower limb PAD in low to middle-income countries (countries as defined by the International Diabetes Federation) which include South Africa.

The scoping review forms Chapter Two of Part One; the manuscript was accepted by the International Journal of Diabetes in Developing Countries in May 2019 for online publication, followed by the actual print in 2020 as detailed below.

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REVIEW ARTICLE

The use of ABI in screening for diabetes-related lower limb peripheral arterial disease in IDF middle- and low-income countries: a scoping review

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Abstract

Background The burden of disease from diabetic foot ulcers linked to peripheral arterial disease (PAD) is complicated by limited resources in low- to middle-income countries (LMIC). This precludes the widespread use of sophisticated imaging methods. Screening for PAD can include the use of low-cost tests such as the ankle brachial index (ABI). A scoping review was performed to identify what is known about the use of ABI in screening for diabetes-related PAD in LMIC.

Methods LMIC were defined as per the International Diabetes Federation Atlas. The following databases were searched using a comprehensive search term: Cochrane Library, EbscoHost, PubMed, Web of Science, Science Direct, Scopus, and Google Scholar. A total of 400 records were gleaned. The publication abstracts were screened through several rounds to select only those in which ABI was used in the context of screening for PAD to prevent diabetic foot disease.

Results Twenty publications were included, from MLIC countries such as Brazil, Nigeria, Kenya, Uganda, South Africa, India, China, Singapore, Korea, Taiwan, Hong Kong, Indonesia, Thailand, and the Philippines. Ten ancilliary publications were identified.

Conclusions The widespread reporting and large scale use of ABI in PAD screening in Asia are evident, compared to fewer reports from Africa and South America. Many Asian publications report using faster, automated ABI equipment in conjunction with handheld Doppler evaluation of flow signals. Despite concerns regarding the potential for false elevations secondary to vessel calcification and non-compressibility, ABI remains a useful first encounter test in screening for PAD. Asian publications endorse and report the use of ABI firmly within the core clinical examination and consideration of other risk factors for PAD. No publications were found on large-scale use of automated ABI in the South African or greater African context of diabetic foot screening.

Keywords Diabetic foot screening · PAD · Ankle brachial index · Scoping literature review · MLIC

Abbreviations

ABI	Ankle brachial index
ABPI	Ankle brachial pressure index
CT	Computerized tomography
ECQ	Edinburgh Claudication Questionnaire
IDF	International Diabetes Federation
IWGDF	International Working Group on the Diabetic Foot
MRI	Magnetic resonance imaging
NICE	National Institute for Health and Care Excellence (England)
NIDDM	Non-insulin dependent diabetes mellitus (also known as type II diabetes mellitus)
PAD	Peripheral arterial disease
PVD	Peripheral vascular disease
SEMDSA	Society for Endocrinology Metabolism and Diabetes South Africa
SIGN	Scottish Intercollegiate Guidelines Network
TBI	Toe brachial pressure index
WHASA	Wound Healing Association of South Africa

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Background

Peripheral arterial disease (PAD) is a known risk factor for diabetic foot ulceration [1–5]. PAD can be variously described as peripheral vascular disease (PVD) or lower limb (ischemia). In high-income countries such as the UK, the 2018 NICE guidelines update for assessment of PAD-added new recommendations to the 2016 guidelines [3]. In 2018, the use of ABPI for screening (not as a pure diagnostic tool) is retained after reviewing the evidence on test and screening modalities [6]. In low- to middle-income countries, health resources are limited and thus preclude large-scale use of costly MRI or CT modalities. The costs of PAD in diabetes and related lower limb amputations in KwaZulu-Natal, a province of South Africa, encompass not only human suffering but increasing drain on fiscus [7]. Screening for PAD remains an important tool to reduce the burden of social inequality on health.

Clinical signs of diminished blood flow to the lower limbs may be seen as dry, shiny, hairless skin; brittle and rigid nails; elevated pallor; and dependent rubor due to the loss of the veno-arteriolar reflex and loss of skin temperature sensation. Pain may or may not be present. It must be noted that in the African or Indian populations, elevation pallor and dependent rubor may be obscured by skin pigmentation. Vascular examination of all peripheral pulses consists of palpation of pedal pulses as well as the brachial, radial, femoral, popliteal, dorsalis pedis, and posterior tibial arteries. According to the Wound Healing Association of South Africa (WHASA), lower limb clinical vascular examination should include an examination of the skin, surface temperature, pedal pulses, capillary refill time, ABI, and a grading based on the examination. [4] In a small 2019 study from the University of Malta which compared different screening modalities in the detection of PAD in primary care settings, pulse palpation, wave-form analysis, ankle brachial pressure index, absolute toe pressure, toe brachial pressure index, and transcutaneous oxygen pressure were compared. The highest percentage of participants who had PAD was for the Doppler Waveform (93.0%). This was followed by TBPI (72.0%), ABPI (57.0%), ATP (35.0%), TCPO (30.0%), and pulse palpation (23.0%). The study demonstrated the existence of inconsistencies between the six different modalities used and advocated not only awareness among clinicians but the need for more studies with a view to provide evidence as to which screening modality yields the most valid results [8] .

As patients with diabetes often present atypically, and may have non palpable pedal pulses, handheld Doppler evaluation of flow signals provides the next level of non-invasive clinical assessment.

Quality of Doppler signals can be graded as:

- Triphasic: normal arterial flow; usually associated with a palpable pulse
- Biphasic: mild to moderate PAD
- Monophasic or absent: severe PAD
- Bounding biphasic or monophasic pulses indicate stenotic vessels.

The ABI is a test conducted using a sphygmomanometer with appropriate cuffs for the ankle and the brachial (arm) pulses. The index is a calculated ratio of the systolic blood pressure at the ankle versus that in the upper arm. The use of a handheld Doppler instrument greatly facilitates the location of atypical pulses. Automated ABI machines incorporate both ankle and brachial cuffs such that measurement of both lower limbs is conducted at the same time. Interpretation of ABI is shown in Table 1.

Aim

This scoping review set out to find what has been published on the usage of the ankle brachial pressure index (ABPI) test in screening for diabetes-related lower limb peripheral arterial disease in middle- and low-income countries as defined by the World Health Organization.

Methods

Scoping reviews differ from literature reviews and systematic reviews. Recently scoping reviews have emerged as an alternative method to synthesize literature on a given topic. Scoping reviews generate descriptive narratives that review the sources of available evidence. The work of Arksey and O'Malley [10] and that of Levac et al. [11] outlined six stages of a scoping study or scoping review. The present review followed the methods outlined for the first five of those stages.

The research team was established by approaching fellow academics with expertise in the area to be scoped (stage 1). The first team meeting decided on a pertinent research question "What is the usage of ABPI in screening for diabetes-related lower limb peripheral arterial disease in resource limited settings?" (stage 2). Whereas TBPI, ATP, palpation, and TcPO2 have been documented as alternative screening methods [8], our study chose to only search for ABPI.

Criteria for inclusion or exclusion of studies (stage 3): a search was conducted online for key word synonyms in order to anticipate different terms that might be used in the literature. For example, "resource limited settings" could be expressed as "third world" or "developing world" or "MLIC" middle- to low-income countries." Boolean operators were used to include all the synonyms in the first search term to prepare as comprehensive a sweep of the literature as possible.

To establish which countries were resource-limited, the team used the IDF classification of limited resource countries

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Table 1 Ankle brachial index interpretation [9]

ABI value	Interpretation
> 1.3	False elevation; heavy vessel calcification
0.9 1.29	Normal range
0.5 0.89	Peripheral artery disease, associated with intermittent claudication
< 0.5	Critical limb ischemia; associated with ulceration and rest pain

as found in the IDF World Atlas [12]. By using the IDF website's interactive filter for economic development, an atlas for each of low-income countries and middle-income countries was generated (Figs. 1 and 2).

Search term and data sources

The following search term was developed to list specific country or continent names and applied to the Cochrane Library, EbscoHost, PubMed, Web of Science, Science Direct, Scopus and Google Scholar databases: ("diabetes mellitus") AND ("peripheral arterial disease") AND ("ankle brachial index") AND (Africa OR "South America" OR Brazil OR Mexico OR Russia OR India OR China OR Philippines).

It must be noted that the search term for Web of Science was identical but needed insertion of a TS Field tag to denote topic. (TS = (diabet* AND "peripheral arterial disease" AND ("ankle brachial index") AND ("Africa" OR "South America" OR Brazil OR Mexico OR Russia OR India OR China OR Philippines)).

The search across the Cochrane database yielded one result [13].

Study selection, data collection, and interpretation (stage 4): the search across the remaining databases identified 400 records. Since PAD in diabetes mellitus places patients at significant risk for cardiovascular, ocular, and renal damage in addition to limb loss, these records included references in which the focus was not strictly that of screening for PAD in the lower limbs. Once duplications, indices, and abstract lists for conferences were deleted ($n = 161$), abstracts were screened by the team to eliminate records with obvious focus on PAD in areas other than the lower limb (Fig. 3).

Full texts of the 24 core papers were requested from the university library services. On receipt of these, it was found that two abstracts related to the same paper as one database had

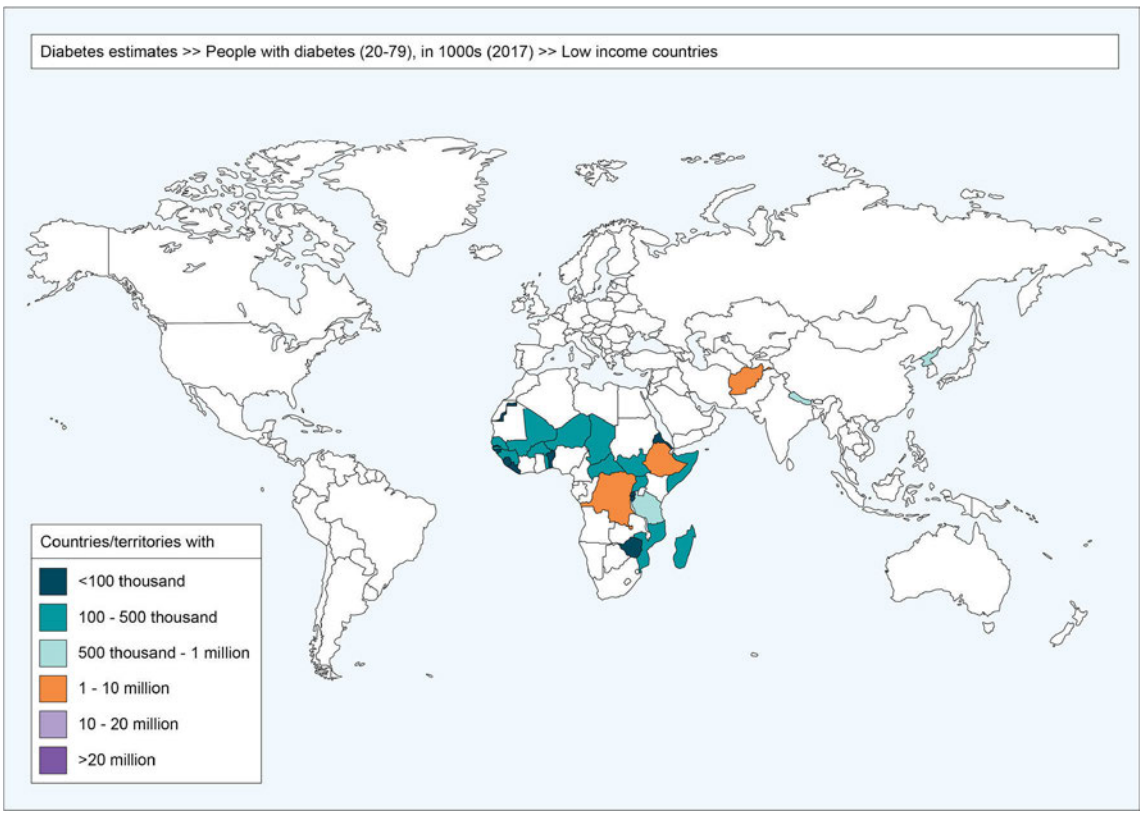

Fig. 1 IDF estimates of diabetes prevalence in low income countries (Africa, Madagascar, Afghanistan, Nepal, and North Korea) [12] (Reprinted with permission)

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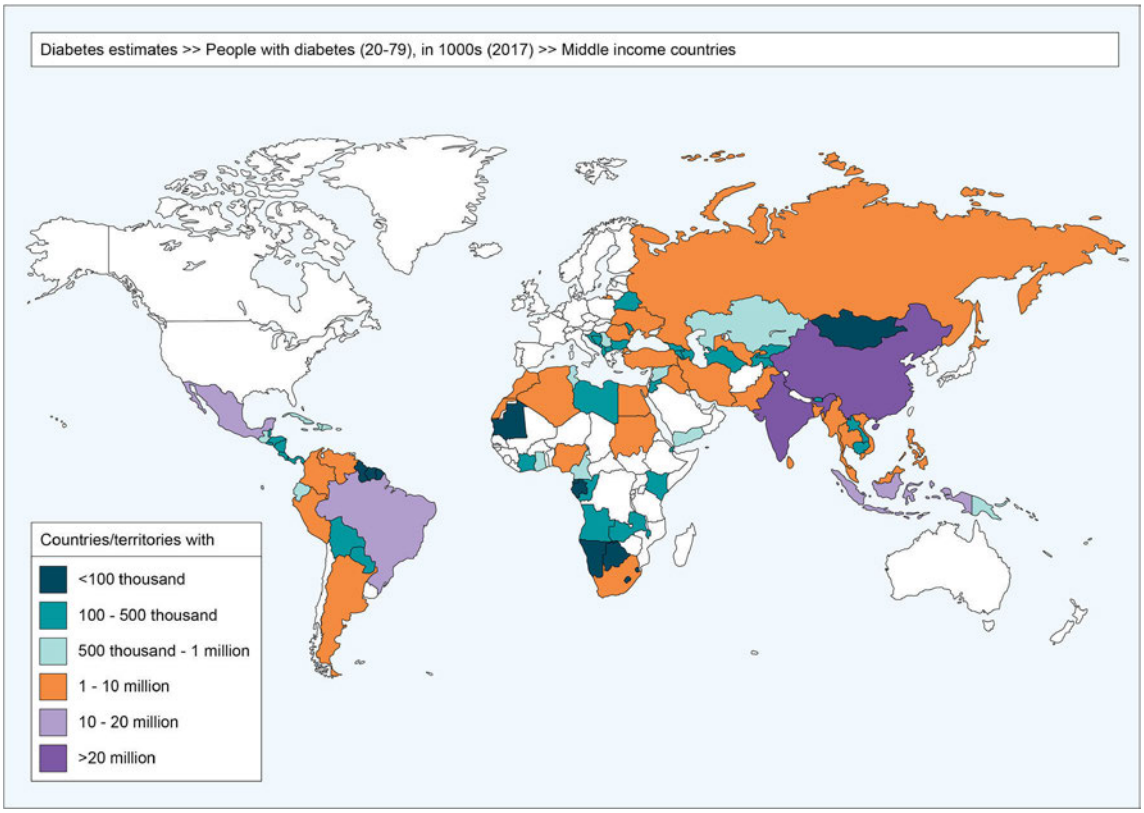

Fig. 2 IDF estimates of diabetes prevalence in middle-income countries (Mexico, South America, Africa, India, Russia, China, the Philippines) [12] (Reprinted with permission)

referenced the Chinese author's first name as his surname. Three papers were found to have English abstracts but foreign language texts (Mexican Spanish and African French) and were, regretfully, discarded since none of the team members had sufficient fluency in these languages. The single Cochrane review, together with the remaining 20 core papers, was then examined.

The Cochrane review included a single Spanish prospective study that compared the manual Doppler method of obtaining an ABI with the automated oscillometric method [13] and thus was not included in this review as Spain is classified as a high-income country by the IDF. Furthermore, the Cochrane review excluded screening studies in which patients were asymptomatic (did not present with exertional leg pain) and in which angiography or duplex ultrasonography was excluded. Of note, however, the review discussion acknowledged that systematic review of studies using ABI in alternative patient groups such as high-risk patients without leg pain and patients with atypical leg pain is required. It also endorsed that primary studies that include patients not previously diagnosed with PAD and asymptomatic patients with comorbidities such as diabetes mellitus are also required.

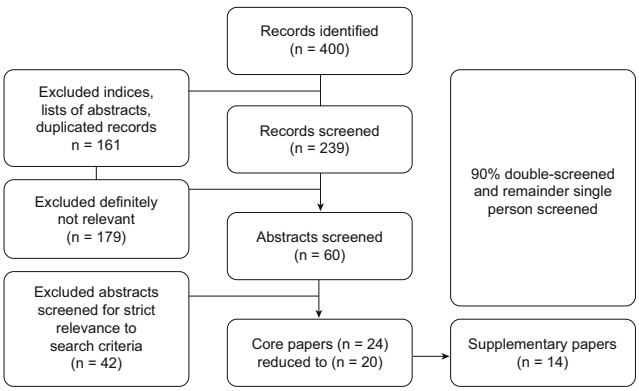

Fig. 3 Flow diagram showing process of eliminating duplications and irrelevant records from the total number of records identified from abstracts (study identification and selection)

Data synthesis

Extracted data were synthesized descriptively with studies grouped by commonly reported themes. Simple summation was used in MS Excel to provide quantitative data (stage 5).

Results

As per the Arksey and O'Malley framework for conducting a scoping review, "a thematic construction is used to provide an overview of the breadth of the literature but not a synthesis" [11]. Results are thus presented as a numerical analysis of the extent and nature of studies

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using tables or charts, together with common thematic groupings and/or analysis.

Countries identified

The 20 core papers emanated from countries using ABI in their screening process to detect peripheral vascular disease in patients with diabetes. They included Brazil, Nigeria, Kenya, Uganda, South Africa, India, China, Singapore, Korea, Taiwan, Hong Kong, Indonesia, Thailand, and the Philippines.

Number of patients screened

The total number of patients reported by the 20 core papers [14–33] was 35,340. Within these papers, published in this century with one exception [23], their analyses of results present common statements regarding risk factors for PAD, correlations to hypertension, age, duration of diabetes, systolic blood pressure, dyslipidaemia, gender, smoking, HbA1c levels, ethnic differences, as well as endorsement for the use of ABPI as a reasonable screening tool, noting its simplicity and low cost of examination.

Nature of clinical operators

Among the core papers, the ABI test was variously carried out by vascular surgeons [14], medical doctors or interns [17–19, 22–31, 33], experienced technician under supervision of a physician [15], trained examiner [16], trained physician [32], and trained personnel [21] .

With one exception [14], all papers excluded other types of diabetes mellitus and reported only on non-insulin dependent diabetes mellitus (NIDDM) participants.

Types of ABI equipment

While most studies in this review used conventional sphygmomanometer cuffs together with a handheld 8 MHz Doppler ultrasound probe, others used automated ABI measurement devices [26, 29, 32]. Automated ABI measurement was used on 17,906 (50.7%) of the 35,340 patients reported in the records selected by this scoping review.

Two studies of case control design, 18 cross sectional studies

Two papers [15, 31] studied patients with NIDDM and control groups without diabetes. The paper by Binu et al. in South India [15] excluded symptomatic, cardiovascular and smokers from the diabetic group and excluded hypertensive, smokers, coronary artery disease, and metabolic syndrome from the control group. They found an asymptomatic (no exertional leg pains) PAD prevalence of 24% in the diabetic group compared to 4% in the non-diabetic group. The other case control paper reported on a larger study carried out at the National Diabetes Management and Research Centre in Ghana in which the ECQ assessment was used to differentiate the participants into those with no exertional leg pains, atypical exertional pains, pain at rest, and "classical" intermittent claudication. They found that 18.6% of participants with diabetes had an ABI less than 0.9, compared to 8.1% of those without diabetes.

Age and gender data

Although increased age was stated as an expected risk factor, a number of studies in India, China, and Singapore found that male patients displayed PAD at a younger age than females [12, 18–20]. Some studies found females to be more at risk than males [11, 14, 16, 17, 20, 22, 23, 28] while others found males to be more at risk than females [15, 21, 26, 29] and a number of studies found gender not to be significant [12, 13, 27, 30].

Two papers were gender specific: Rheeder et al. [27] examined only female South African patients while Sarkar et al. [28] examined only male patients in Eastern India. Both studies administered the WHO questionnaire developed by Rose et al. [34] to test for exertional symptoms and to grade intermittent claudication where present. Both studies were too small to draw inferences on their larger diabetic population. The paper by Rheeder et al. was aimed at finding concordance between ABI and toe brachial index (TBI) and correlations to pedal pulse palpation and radiographic evidence of medial artery calcification [27]. Unfortunately, although it was population group-specific (black South Africans), it did not report on the clinical data collected.

Unusual reported risk factors for PAD

Among the expected risk factors for PAD documented by the 20 core papers (see Table 2) were some noteworthy data. In the Kenyan study [24], foot deformities were found to be a risk factor for PAD while in the Ugandan study, glibenclamide a sulfonylurea drug was found to be associated with a higher incidence of peripheral arterial disease [25]. No distinction was made as to whether only glibenclamide was associated with an increased risk of PAD or whether all sulfonylureas or other medications were implicated.

Body mass index

Obesity screening yielded unexpected associations in that heavier BMI was only found to be a risk factor in a few papers [15, 31, 33] while others found that leaner patients (low BMI) were at risk [18, 19, 26, 29] and some found BMI to have no significance [16, 21, 23–25, 30, 32].

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Table 2 Summary of data in 20 core studies screened (N/S denotes not significant, shaded blocks indicate data not collected/reported). Bullets indicate data collected/reported

Authors	Countries	Number of participants	NIDDM duration	Age group	Gender	HBP	Systolic BP	Lipidaemia	HbA1C	BMI	Diff in Pop Groups	Smoking	Neuropathy
Andrade et al [14]	Brazil	236	longer	older	Female	•	•						
Binu et al [15]	India	100		M Y	N/S	•		•		heavier			
Do N Sales et al [16]	Brazil	73	longer	older	N/S	•	•			N/S		N/S	
Eshcol et al [17]	India	2493	longer	older	Female>	•	•	•	N/S			•	
Ghosh et al [18]	India	84	shorter	N/S	Male >	•	•	•		Leaner		male	
Guan et al [19]	China	1397	longer	older	Female	•	•	N/S	•	Leaner		•	
Khurana et al [20]	India	200	longer	Older	Female			•	•				
Narayanan et al [21]	Singapore	521	longer	Older	Male Y	•		•	N/S	N/S	•	•	•
Li et al [22]	China	3924	M ≠ F	Older	Male Y	N/S		•	•	•		•	•
Mohan et al [23]	India	4941	Longer	M Y	Female>	•	•	•	•	N/S		N/S	
Mugambi et al [24]	Kenya	218	Longer	Older	Male>	•	•			N/S		N/S	•
Okello et al [25]	Uganda	229	N/S	Older	Female>	•	N/S	N/S	N/S	N/S		N/S	
Rhee et al [26]	Korea, Indonesia, Thailand, Taiwan, China, Hong Kong	6625	longer	Older	Female>	•		•	•	Leaner	•	•	
Rheeder et al [27]	S Africa (*gender specific)	85	longer		Female*						•		
Sarkar et al [28]	India (*gender specific)	31	longer	Older	Male*		•						
Sosale et al [29]	India	600	shorter	older	Male	•		•	N/S	leaner			
Umuerri et al [33]	Nigeria	380	longer	older	N/S	•		N/S		heavier		N/S	
Wang et al [30]	China	2010	Longer	older	N/S	•		N/S		N/S	•	•	•
Yeboah et al [31]	Ghana	485		older	Female	•				heavier		N/S	
Zhang et al [32]	China	10681		older	Male	•		•	•	N/S		•	•

Ethnic and/or population differences

Ethnic and population prevalence differences were noted in the large PAD-Search study across six countries in Asia [26] as well as between the three population groups in Singapore [21]. All the African studies only measured the black population group [24, 25, 27, 31, 33] and thus did not report on prevalence in other population groups.

Discussion

Macrovascular diabetes-related complications like PAD and resulting lower limb amputations place a strain on the economies of developing countries. One of the major goals in addressing the burden of lower limb complications in diabetes should be the detection of PAD by simple non-invasive means. Risk stratification by means of ABI is one such option allowing for prioritization of resources to high-risk populations in order to have the greatest impact.

It can be difficult to provide in-depth preventative screening for every patient owing to resource constraints in low-and middle-income countries. Automated ABI measurement devices have been used for large PAD screening studies since they offer cost reductions in terms of improved accuracy, time taken to test, and human resources.

Screening for PAD in Africa using ABI remains a conundrum. Our review showed that, although some countries in Africa have reported using ABI in screening for lower limb PAD, there has been no report of large-scale implementation of ABI in the diabetic population to screen for lower limb PAD in the context of diabetic foot disease in South Africa. In contrast, the low- and middle-income countries in Asia and South America already actively include ABI in their clinical screening of patients with diabetes.

Limitations of ABI testing for diagnosis of PAD include concerns that have been raised in connection with ABI results above 1.3 as these are considered to be indicative of stenotic vessels. It has been argued that, because of vessel stenosis, normal readings could represent low readings elevated by stenosis. This would only apply in the case of using an ABI test in isolation and no publication reported this. The use of exercise modifiers and the background data from a complete physical examination which must include identification of known risk factors is as much a part of the search for PAD as the ABI screening test.

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It is hoped that the advent of low-cost automated ABI used in conjunction with handheld Doppler equipment will allow more low-resource health systems, particularly those in Africa, to close the gap in large scale screening for PAD so as to prevent the costly sequelae of diabetic foot disease.

Authors' contributions ATT was the project lead in the scoping review. CA provided background research on scoping review methodology. ATT, SP, and CA participated in the iterative record selection process. Each author read a set number of abstracts and contributed to the final selection of included records.

ATT wrote the first draft of the article and prepared the tables and figures. SP and CA participated in revising the article through several iterations providing critical intellectual content. All the authors have read and approved the final manuscript.

Compliance with ethical standards

Ethics approval was obtained from the Biomedical Research Ethics Committee, University of KwaZulu-Natal number BE264/17. This article does not contain any studies with human participants performed by any of the authors.

Conflict of interest The authors declare that they have no conflict of interest.

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Chapter Three: On the Ankle Brachial Index

After conducting the scoping review (as described in Chapter Two), a journal article was found which called the use of the ABI into question. The abstract of that article was considered sensationalist and misleading. Sections of the article did not take automated ABPI technology into account. Chapter Three contains the researcher's letter to the editor in rebuttal.

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LETTER TO THE EDITOR

Check for updates

On the Ankle Brachial Index

Anette Telmo Thompson

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Dear Editor,

Having just served on a team that compiled a scoping review on the use of the ankle-brachial index (ABI) in screening for peripheral arterial disease (PAD) in diabetes patients in middle and low income countries (as defined by the International Diabetes Federation Atlas) [1], we note the difference between first world medical resources and the limited medical resources in the rest of the world. Our team works in a province of 10 million people, of whom 1.5 million are registered diabetes patients in state health [2] (excluding a further 0.4 million in private health). We have very limited resources to screen for PAD in order to help prevent the many lower limb amputations taking place [2,3].

Your journal recently published an article by Dr Robert Trevethan entitled 'Subjecting the ABI to timely scrutiny: is it time to say goodbye to the ABI?' [4].

We believe that the abstract is misleading. It states there are only reservations (concerning ABI) 'now' and that 'qualifying empirical evidence' suggests it might be advisable to abandon it. What is not clarified is that such 'evidence' includes studies reporting on the manual method of obtaining an ABI, such that the 'issues that call it into question' which include inconsistent procedural practices largely fall away when using newer time-saving automated ABI equipment.

The publications used to provide evidence are similarly misleading when describing the role of the ABI. For example, the first report authored by Hinchliffe [5] is a report from the International Working Group on the Diabetic Foot which clearly states that the ABI is first, a screening tool (not diagnostic) to be used in conjunction with thorough clinical examination of the lower limb. Despite this, Dr Trevethan refers to the poor 'diagnostic accuracy of the ABI' as indicated by the research of Tehan [6]. This again is misleading since ABI is not a diagnostic tool. This error is again repeated by quoting Al-Qaisi et al. stating that it can be 'non-diagnostic altogether'.

The author referred to a Cochrane review [7] finding 726 records in the second refined round of that literature search in order to illustrate how much has been written about ABI. It is curious that Dr Trevethan highlights that much research has methodological deficiencies yet did not pick up on the glaring deficiency of that specific Cochrane review. The authors of that Cochrane review found little evidence in favour of ABI – but simply because the review was limited to studies on ABI on patients with exertional leg pain (which possibly should have been stated clearly in the review's title). It then reported the paucity of these studies, even though, as Dr Trevethan correctly points out, it had found 746 papers in a 'second, refined, round of a literature search'. More studies are needed, both in the group with exertional leg pain, the asymptomatic but high risk patient, the patient with atypical leg pain, those not previously diagnosed with PAD and the asymptomatic patient with comorbidity such as diabetes mellitus – these form a much larger group than that particular Cochrane review chose to address.

Our scoping review found that researchers in Brazil, Nigeria, Kenya, Uganda, South Africa, India, China, Singapore, Korea, Taiwan, Hong Kong, Indonesia, Thailand and the Philippines conducted studies which use ABI as part of their screening and clinical diagnostic protocol. Almost half of these studies eliminated the procedural irregularities of manual ABI measurement by screening with low cost automated devices plus handheld Doppler ultrasonography in conjunction with all the clinical examinations necessary to inform on an eventual diagnosis.

Dr Trevethan argued for the use of toe-brachial index (TBI) screening. It is possible that the stated potential procedural irregularities of manual ABI would also be applicable to manual TBI screening. We question whether TBI would be necessary when a handheld Doppler ultrasound indicating pedal pulse waveforms is included in the screening process.

The studies in our scoping review contributed to the existing knowledge base of low and middle income nations in surprising ways: researchers in Asia found that the clinical profile of PAD in non-insulin dependent diabetes showed differences to that of European populations such as presenting in leaner patients and that those leaner patients were more likely to be male rather than female [8–10]. Researchers in India have found PAD in patients with shorter diabetes duration compared to what we have been led to expect with longer diabetes duration [9–11]. A further study found ethnic differences in PAD presentation [8].

These studies endorse the use of ABI as a reasonable screening tool, noting its simplicity and low cost of

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examination, when used in conjunction with handheld Doppler ultrasonography, and taken as a part of the total clinical examination [11–21]. Alternative imaging investigations as used in the United Kingdom and the USA are not readily available in low-middle income settings where there are large geographic distances between rural hospitals and clinics. We agree that arterial calcification using ABI can be a challenge if ABI is used alone but not when in conjunction with handheld Doppler ultrasound screening. Some of the low-middle income studies with very large samples (example 'PAD-search') in which new diagnoses of PAD were made would not have been possible without the use of the faster automated ABI plus Doppler ultrasonography screening [8,10,14] as part of the clinical workup.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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Chapter Four: Prevalence of Peripheral Arterial Disease (PAD) in a diabetes patient population attending Edendale Hospital in Pietermaritzburg

Prevalence of PAD specific to the lower limb in the diabetic population in KwaZulu-Natal is poorly documented. In order to assess prevalence of PAD in KwaZulu-Natal, we describe a test study performed on a patient population attending a diabetes out-patient clinic in uMgungundlovu district. Patients were examined by means of a truncated but comprehensive podiatric clinical foot assessment which included automated ABI and hand-held Doppler vascular examination. The assessments enabled individual limb risk classification and informed on the previously unknown incidence of diabetes patients presenting with ischaemia and peripheral vascular disease.

Recommendations include support for the multi-disciplinary approach to diabetes care, with the inclusion of podiatric medicine; amendments to the national guidelines on diabetes care and heightened need for education, assessment and treatment of the lower limb in diabetes for prevention of complications.

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Abstract

Background: Prevalence of lower limb peripheral arterial disease (PAD) within the diabetic population in KwaZulu-Natal has been poorly documented.

Objectives: This study was conducted to determine the prevalence of PAD in a state health patient population in KwaZulu-Natal, as well as individual foot ulcer risk classifications.

Setting, Materials and Methods: 301 patients living with diabetes (PLWD) attending the SOPD diabetes clinic at Edendale Hospital volunteered for foot examination. The examining podiatrist employed a truncated but comprehensive podiatric clinical foot assessment which included automated ABI and handheld Doppler vascular examination. The data were combined with general clinical and demographic data from patient examinations on the same day.

Outcome measures: These assessments enabled individual limb risk classification as per SEMDSA guidelines and informed on the previously unknown incidence of PAD in PLWD presenting with ischaemia and peripheral arterial disease.

Results: Based on Doppler waveform findings, 94% (n = 283) of the patients examined presented with degrees of PAD. Risk classification based on foot assessments placed 90.0% (n = 271) at high risk, 9.3% (n = 28) at moderate risk and only 0.7% (n = 2) at low risk. Further, the podiatric assessments found evidence in the feet and lower limbs of 68% of patients examined (n = 205) that warranted further investigation and treatment by podiatrists, cardiologists, vascular surgeons, endocrinologists and other disciplines in the multi-disciplinary team.

Conclusions: Vascular risk for ulceration is not detected in time for effective prevention measures. Pedal pulse palpation together with Doppler ultrasonography is recommended for PLWD. Obesity and lack of exercise form a vicious cycle in diabetes foot care. Evidence is shown of the physical and emotional need for podiatric care of PLWD throughout the health system. Conclusive evidence is presented to question the clinical value of “60-second” screenings of the foot. Further study directions are indicated.

Keywords: Peripheral arterial disease; handheld Doppler ultrasonography; automated ankle-brachial index; risk classification; diabetic foot ulcer; foot assessment; podiatry; podiatric medicine.

Background

Lower limb complications in people living with diabetes (PLWD) progress to amputation as a result of a multitude of factors [1-5]. One such risk factor for amputation is vascular disease which results in ischaemia. This then translates into poor wound healing of the initial lesion despite wound care efforts.

The podiatric protocol for assessment of PLWD includes a vascular examination of pedal pulses with handheld doppler ultrasound. The doppler results are reported according to waveform presentation. If the doppler results indicate ischaemia, arrhythmia and/or suspected medial arterial calcification or atherosclerosis, the patient is referred to either cardiology or vascular departments for further imaging and management. Additional clinical vascular examinations performed by the attending podiatrist include assessment of skin temperature, colour, capillary refill time, presence or absence of claudication, rest pain and the ankle-brachial index (ABPI) test. Since vasculopathy in diabetes may exist on its own, or in combination with neuropathy, a neurological foot examination is also conducted. The podiatrist's foot assessment is completed by evaluating the patient for musculoskeletal, dermatological and footwear risk factors for ulcer formation. This is accompanied by interactive patient foot care and footwear education.

At present, there is only one podiatrist based at Grey's Hospital who serves the podiatric needs of the entire uMgungundlovu district, a district which contains more than ten district hospitals, 78 provincial clinics, and at least three community health centres [6]. Consequently, the podiatric medicine component of the multi-disciplinary team of the diabetes clinic service at Edendale Hospital cannot adequately be sustained at this time. To this end, a study was carried to assess and screen the PLWD attending the Edendale Hospital outpatient clinic as would be done by a podiatry service.

Objectives

1. To determine the prevalence of peripheral arterial disease and early signs thereof by means of podiatric assessment and non-invasive screening of a convenience sample of PLWD attending the outpatient diabetes service at Edendale Hospital, Pietermaritzburg, South Africa.

2. To determine the diabetic foot risk profile of the patients assessed, according to the 2017 Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA) guidelines.

Materials and methods

Setting

Edendale Hospital (Pietermaritzburg) is a provincial, regional training hospital located within the uMgungundlovu District of KwaZulu-Natal. The Edendale diabetes service is a weekly clinic operating from 8 am until 1 pm, at which PLWD are first assessed by a team of nursing sisters who examine their seated and standing blood pressure, resting pulse rates, random blood glucose (glucometer), weight (in kilograms), height (in meters) and electronically calculated body mass index. Thereafter, patients are seated awaiting their clinician consult from 8 am with one of two doctors who may each have an intern doctor assisting with the patient load.

The podiatric assessment was carried out on volunteer participating patients in a separate adjoining recovery room, equipped with privacy curtain, a standard examination bed or plinth and a bedside instrument trolley on wheels. The ambient temperature of the room was controlled to 22 degrees centigrade so that all vascular tests were carried out at the same temperature

The examiner was a qualified podiatrist, with 18 years' experience in patient assessment, trained and experienced in the equipment used.

Ethics approval

Ethical approval to collect and utilise data was granted by the Department of Health, Management of Edendale Hospital and the Biomedical Research Ethics Committee of the University of KwaZulu-Natal, BREC reference BE264/17.

(A) Patient Education and Consent

Large colour posters in both English and isiZulu were prepared. These posters were mounted on vertical surfaces facing the waiting patients. These posters described the research project and called for their voluntary participation (see Figure 4.1).

As patients were seated waiting for the doctors, they were each handed a printed copy of the patient information sheet and consent forms in either English or isiZulu according to their language of choice. To convey the research project to those older isiZulu patients who were unable to read, the senior nursing sister spoke to the group in isiZulu and explained the project. Only those patients who volunteered to be assessed took part in the project. A total of 301 participants volunteered and were evaluated during the 15 weeks that took place between September 2018 and February 2019.

The examiner had no instruction in isiZulu prior to the project but learnt some isiZulu to greet patients and ask them to lie down on the examination bed. Basic medical isiZulu phrases and possible responses were learnt to enable the assessment process and to re-assure non-English speaking patients.

Figure 4.1: English and isiZulu versions of foot research project poster (Source A T Thompson)

(B) Instruments

The data recording sheet was prepared by the researcher after the style of the form originated by the Centre for Diabetes and Endocrinology, used with permission. The data recording sheet was designed so that it could be completed by a qualified examiner within 15 minutes, for reasons that will be elaborated on in the discussion. Data was recorded by circling the applicable findings.

Automated ankle-brachial pressure measurement was performed using an automated ABPI machine, using either large or medium size cuffs, depending on the stature of the patient (MESI ™ Slovenia).

An 8 MHz wide beam vascular probe on a model DMX digital Doppler ultrasound device (Huntleigh Healthcare Limited ™, United Kingdom) with water-based ultrasound gel, was used to perform an assessment of dorsalis pedis and tibialis posterior arterial pulses in the foot. Waveforms were displayed on the digital screen (Figure 4.2) accompanied by audible signals.

Figure 4.2: DMX digital doppler ultrasound device
featuring large digital screen with waveform display. (Source: A T Thompson)

PAD is often given attention and explained in clinical literature by the signs that constitute end-stage disease. These signs (some or all) include critical limb ischaemia, claudication (exertional pain), absent pulses, pale feet or purplish colour, cold feet, calf muscle atrophy, narrowing of the arteries (atherosclerosis) and calcification of the arteries (arteriosclerosis).

However, the essential definition of PAD is damage to or dysfunction of the arteries outside the heart resulting in reduced blood flow. On this basis, in early PAD, some or all the later signs of

disease may not be present, except for reduced blood flow. Handheld Doppler ultrasonography is (thus) essential to support clinical suspicion in early PAD and has the greatest diagnostic accuracy [7].

(C) Infection Control

As per standard podiatry clinical practice, the examiner disinfected and cleaned all examination surfaces with 90% alcohol mixed with 3% chlorhexidine gluconate (Biotaine ™) solution before and after each session. Hospital cleaners cleaned the floor with proprietary cleansers prior to each session. The patients removed their shoes and hosiery before the examination, and a disposable paper/plastic linen saver was used under their feet for each patient. The examiner wore a fresh set of latex gloves to examine each patient.

Disposable 10g monofilaments were used, and the contact surfaces of the doppler probe, the tuning fork base and ABPI cuffs were sprayed or wiped with Biotaine and disposable paper tissue between patients. Ultrasound gel was wiped off the skin with a disposable paper tissue.

(D) Vascular screening

Once the patient was comfortably supine and unshod on the examination bed, the pressure cuffs of the Mesi ABPI device were placed on the patient but not inflated (as per the images in Figure 4.1).

Foot assessment on both feet was performed in a specific sequence, such that a minimum of 10 minutes rest elapsed before the automated ABPI test was conducted, although manufacturer instructions state that minimal rest time is necessary before testing since three pulses are measured simultaneously.

Conductive ultrasound gel was placed on the mid dorsum and sub medial malleolus of each foot. Handheld Doppler ultrasonography was performed using a handheld DMX digital doppler ultrasound device with inbuilt waveform display (Huntleigh Healthcare Limited, United Kingdom). Waveforms were recorded as either Triphasic, Biphasic, Monophasic, or Triphasic bounding, Biphasic bounding, or Monophasic bounding, arrhythmic or absent.

The temperature difference of the foot relative to the lower leg was subjectively performed by examiner palpation. Simultaneously, observations were made on the colour of the perfused foot

compared to the perfused colour of the rest of the limb. The patient was questioned as to whether they experienced foot pain during the day or night.

The test for capillary refill time was performed by gently squeezing the hallux nail for 5 seconds to reduce capillary perfusion such that, on release, visual returning perfusion to the digit could be timed in seconds. Capillary refill time greater than two seconds was previously considered an indication of poor perfusion, but its evidence base, reliability and validity when compared to laser Doppler flowmetry is now questioned [8]. It was nonetheless included in the current study's assessment to assess in future analyses whether any relationship exists between it and the Doppler and/or ABPI findings.

(E) Neurological screening

The patient was probed to ascertain whether they experienced numbness and/or pain in the feet (burning or sharp). A basic neurological examination was performed using the tests for vibration sense (128 Hz tuning fork) and light touch (10g Semmes Weinstein monofilament) as illustrated in figures 4.4 and 4.5 (reproduced with permission from the International Diabetes Federation).

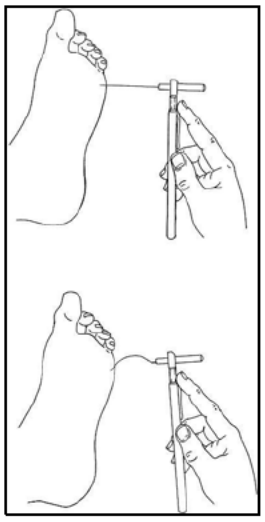

Figure 3: 10g Monofilament test

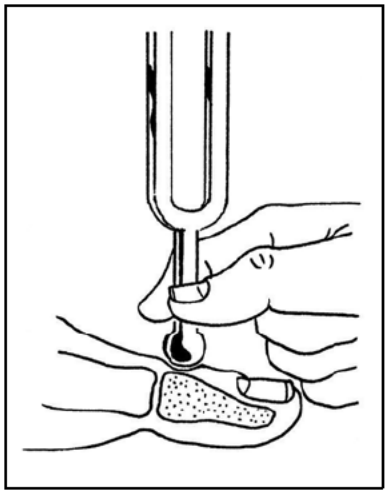

Figure 4: Tuning fork 128 Hz vibration test

(images for academic publication courtesy of the International Diabetes Federation)

(F) Dermatological screening

The patient was questioned and examined for evidence of previous or current ulcers of the lower limb. The presence of skin and/or toenail infection such as onychomycosis, tinea pedis or other infection were noted and recorded. The presence and location of fissures, helomata (corns) and callus (hyperkeratosis) were also noted and recorded.

(G) Musculoskeletal screening

The patient was examined for musculoskeletal foot and ankle deformities such as hallux valgus, digital deformities (such as clawing, hammertoes, nail loss or deformities amongst others), and the presence of prominences or anatomical anomalies in the foot such as brachymetatarsia. Mobility level of the patient was recorded as well as any history of previous lower limb amputations, current or former ulcerations.

Footwear was assessed as either acceptable or non-acceptable for low- and moderate-risk feet, according to the characteristics previously researched and published by the examiner [8], shown in Table 4.1. In addition, three attributes of non-acceptable footwear were recorded for planned future interaction with the footwear industry (narrow, pointy, slip-on).

Table 1: Seven characteristics for acceptable footwear in low-risk feet in diabetes [9]

Footwear for Low-Risk Feet in Diabetes
The seven characteristics of acceptable footwear are:
1. Flexibility
2. Appropriate upper contact (and fastening)
3. Full heel contact
4. Toe-shaped shoes
5. Fixation at heel
6. Appropriate in-flare (shape of the shoe)
7. Low heel height

(H) Additional screening notes

The base of the form was used for inserting additional notes.

(I) Data collection for analysis

Demographic data (as recorded by SOPD nursing support personnel as well as doctors' notes) were combined in a single spreadsheet (Microsoft Excel™ 2010) together with the patient data collected from 301 assessment reports completed by the podiatrist's foot examinations. The data were then

imported into a statistics software package (SPSS™ v25) to prepare the dataset used for database queries and analyses.

A total of 209 variables were extracted from the data collected. Clinical and demographic data from the patient's hospital file, as well as calculated values thereon, yielded 21 variables. The podiatric examination and assessment data, in addition to calculated or grouped values thereon, formed the remaining 188 variables.

Body mass indices (BMI) were further grouped into five sub-classification variables:

- Underweight Below 18.5
- Normal weight 18.5 to 24.9
- Overweight 25.0 to 29.9
- Class I Obese 30.0 to 34.9
- Class II Obese 35.0 to 39.9

(J) Doppler waveforms defined for peripheral arterial disease

In the current study, three basic arterial waveforms in Doppler ultrasonography were recorded (triphasic, biphasic and monophasic), with further subdivisions into continuous and absent as illustrated in Table 2.

Table 2: Doppler waveform characteristics in the study

Doppler waveform	**Waveform characteristic on screen**
Triphasic	1. forward flow in systole 2. reverse flow in late systole / early diastole 3. forward flow in late diastole
Biphasic	1. reverse flow in diastole 2. forward flow in systole (i.e. no forward flow in diastole)
Biphasic continuous	1. reverse flow in diastole 2. steady positive flow in diastole
Monophasic	1. single flow with either low or high velocity ("bounding")
Absent waveform	No waveform display but single audible signal elicited by using one's left hand to compress dorsalis pedis at the proximal ankle, between tibia and fibula, while holding Doppler in the right hand.

Triphasic doppler ultrasound waveforms in pedal arteries reflect unobstructed blood flow. In this study, Doppler ultrasound waveforms less than triphasic (i.e. biphasic, monophasic, continuous, absent) were considered indicative of degrees of ischaemia and thus interpreted as positive for

peripheral arterial disease, whether this was established peripheral arterial disease or early signs thereof. Both feet were examined. If either foot presented with a less than triphasic flow, the patient (as a whole) was recorded as positive for peripheral arterial disease. Bounding pulses were interpreted as a sign of the presence of stenotic narrowing and/or calcification in the arteries.

(K) ABPI indices defined for peripheral arterial disease

The ABPI device test results were indicated by ABPI index numbers for each foot, as well as brachial pressure in terms of systolic and diastolic (mm/Hg), heart rate (beats per minute). Since the automated ABPI machine displayed results for each foot, if results other than normal were shown for either foot, the whole patient was classified as presenting with peripheral arterial disease. Screen band highlights were displayed on the device, as shown in Table 4.3.

Table 3: Mesi device classification of ABPI values
source: MESI Slovenia - https://www.mesimedical.com/overview-of-pad-guidelines/

ABPI value	Interpretation	Recommended action
1.41 and higher values	Non-compressible	Refer to vascular specialist
1.4 – 1.0	Normal range	No action
0.99 – 0.91	Borderline	Assess/treat risk factors
0.90 – 0.40	Abnormal	Refer to vascular specialist
0.40 or less	Severe	Refer to vascular specialist

The ABPI automated machine displays results in colour bands. Green was displayed for values between 1.4 and 1.0, and yellow for 0.99 to 0.90. For values above 1.41 and below 0.89, this was displayed as a red band together with the written message within the display, indicating that PAD was present either due to weak pulses or non-compressible arteries. In this study, for reasons of time and equipment constraints, waveform records were not printed out but recorded manually on the Assessment Report form.

(L) Definition of categories of foot risk

The diabetic foot risk profile of the patients was determined by assessing the risk profile as set out (see Table 4.4) by the Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA) 2017 guidelines.

Table 4: Categorisation grid for foot risk in PLWD [10]

Category	Risk Profile	Frequency of foot examinations and/or level of care
Low risk	People with no risk factors and no previous history of foot ulcer or amputation	General foot care and education; annual examination at primary care
Moderate risk	People with one risk factor (neuropathy, peripheral arterial disease or foot deformity) and no previous history of foot ulcer or amputation	Every visit Secondary level care
High risk	People with two or more risk factors (neuropathy, peripheral arterial disease or foot deformity) and/or a previous history of foot ulcer or amputation	Every visit Tertiary level care
Active foot problem	People with ulceration or spreading infection or critical limb ischaemia or gangrene or suspicion of an acute Charcot neuro-arthropathy, or an unexplained hot, red, swollen foot with or without pain.	Every visit

(M) Factors affecting frequency counts

Data for the podiatrists' examination and assessment of both left (L) and right (R) feet per patient was captured on the datasheet and entered onto the spreadsheet, except in cases of amputee patients in which data for the missing foot could not be collected.

Results

The results of all assessments consisted of medical, sociodemographic and foot assessment variables. Together, these resulted in a dataset containing a total of 211 variables per patient, with data for each foot, except in the case of amputees.

The medical and sociodemographic profiles for the 301 patients assessed are shown in Table 4.5.

Table 4.5. Medical and sociodemographic profile of the patient sample.

VARIABLES (n = 301)	Characteristics	Frequency	Percent (%)
Number of **years since diagnosis of diabetes**	1 to 5	86	28.6
	6 to 10	64	21.3
	11 to 15	62	20.6
	16 to 20	28	9.3
	21 to 25	16	5.3
	26 to 30	11	3.7
	31 to 35	8	2.7
	Missing entries	26	8.6
Type of diabetes mellitus	Type I	39	13.0
	Type II	251	83.4
	Missing entries	11	3.7
Family history	No	87	28.9
	Yes	150	49.8
	Missing entries	64	21.3
Gender	Male	78	25.9
	Female	219	72.8

	Missing entries	4	1.3
Ages (grouped)	10 - 19	8	2.7
	20 - 29	10	3.3
	30 - 39	27	9.0
	40 - 49	46	15.3
	50 - 59	84	27.9
	60 - 69	86	28.6
	70 - 79	31	10.3
	80 - 89	7	2.3
	90 - 99	2	0.7
Employed	No	95	31.6
	Yes	44	14.6
	Pensioner	72	23.9
	Scholar	8	2.7
	Prisoner	1	0.3
	Missing entries	81	26.9
Racial composition	Black African	291	96.7
	White African	1	0.3
	Indian heritage	4	1.3
	Mixed heritage	4	1.3
	Missing entries	1	0.3
Body Mass Index	Underweight	4	1.3
	Normal weight	30	10.0
	Overweight	58	19.3
	Class I obese	75	24.9
	Class II obese	104	34.6
	Missing entries *	30	10.0
Hypertensive	No	56	18.6
	Yes	233	77.4
	Missing entries	12	4.0
Hyperlipidemic	No	33	11.0
	Yes	255	84.7
	Missing entries	13	4.3
eGFR (grouped)	<60	88	29.2
	≥ 60	179	59.5
	Missing entries	34	11.3

Note: * “Missing entries” in Table 4.5 represent data not recorded by attending doctors.

Results for Objective1: Prevalence of peripheral arterial disease as per non-invasive screening

Doppler waveform frequencies per left and right feet, by pedal pulse, were calculated. The right foot results are shown in Table 6, in which 10.7% of right feet showed monophasic waveforms for both pedal pulses, while 75.7% of right feet accounted for two grades of biphasic waveforms in dorsalis pedis and 80.4% in tibialis posterior. Only 8.7% (n = 26) presented both right foot pedal pulses displaying normal triphasic waveforms.

Table 6: Doppler waveforms for right (R) foot pulses
Dorsalis pedis (DP) and Tibialis posterior (TP)

Doppler R DP	Frequency	Percent
Triphasic	40	13.3
Monophasic	32	10.7
Biphasic	224	74.4
Biphasic Bounding	4	1.3
Missing (amputee)	1	0.3
Total	301	100
Doppler R TP	Frequency	Percent
Triphasic	26	8.7
Monophasic	32	10.6
Biphasic	180	59.8
Biphasic Bounding	62	20.6
Missing (amputee)	1	0.3
Total	301	100

Similarly, the left foot results are shown in Table 7, in which 10.6% of left feet showed monophasic waveforms for dorsalis pedis and 11.3% for tibialis posterior, while 71.0% of left feet accounted for two grades of biphasic waveforms in dorsalis pedis and 79.7% in tibialis posterior. Only 8.6% (n = 26) presented both left foot pedal pulses displaying normal triphasic waveforms.

Table 7: Doppler waveforms for left (L) foot pulses
Dorsalis pedis (DP) and Tibialis posterior (TP)

Doppler L DP	Frequency	Percent
Triphasic	41	13.6
Monophasic	45	15.0
Biphasic	138	45.8
Biphasic Bounding	76	25.2
Missing (amputee)	1	0.3
Total	301	100
Doppler L TP	Frequency	Percent
Triphasic	26	8.6
Monophasic	34	11.3
Biphasic	183	60.8
Biphasic Bounding	57	18.9
Missing (amputee)	1	0.3
Total	301	100.0

Results for both pedal pulses were combined into a single doppler result per foot, as per Table 8.

Table 8: Combined pedal pulse waveforms for each foot

Doppler R	Frequency	Percent
Triphasic	18	6.0
Monophasic	45	15.0
Biphasic	179	59.5
Biphasic Bounding	58	19.3
Missing (amputee)	1	0.3
Total	301	100.0
Doppler L	Frequency	Percent
Triphasic	19	6.3
Monophasic	56	**18.6**
Biphasic	148	49.2
Biphasic Bounding	77	25.6
Missing (amputee)	1	0.3
Total	301	100.0

In the final calculation of the doppler results, the criterium was followed that triphasic waveforms were negative for peripheral arterial disease but that degrees of waveform loss were positive for progressive stages of peripheral arterial disease. The total doppler results showed that only 6% (n = 18) are free from PAD. In comparison, almost 20% (18.6%, n = 56) had monophasic waveforms, and a total of 94% (n = 282) of the patients assessed had peripheral arterial pathology in one stage or another (Table 9).

Table 9: Combined doppler results for positive or negative PAD.

Doppler R PAD	Frequency	Percent
Negative for PAD	18	6.0
Positive for PAD	283	94.0
Total	301	100.0
Doppler L PAD	Frequency	Percent
Negative for PAD	19	6.3
Positive for PAD	282	93.7
Total	301	100.0

The automated ABPI results (Table 10) approximated the doppler monophasic waveform results closely, showing 17.3 % positive results for severe peripheral arterial disease, (n = 52 ABPI red band values both **above 1.41 and below 0.4**), compared to Doppler monophasic waveforms (severe PAD) of 18.6% (n = 56) as seen previously in Table 8.

Table 10: Automated ABPI results for severe PAD or stenosis (**values < 0.89 and > 1.41**)

ABPI R PAD	Frequency	Percent
Negative for PAD	250	83.1
Positive for PAD	51	**16.9**
Total	301	100.0
ABPI L PAD	Frequency	Percent
Negative for PAD	249	82.7
Positive for PAD	52	**17.3**
Total	301	100.0

Results for Objective 2: To determine each patient's Diabetes Foot Risk category as per SEMDSA guidelines.

Frequency counts of individual right (R) and left (L) feet, placed into SEMDSA categories of low risk, moderate risk and high risk for diabetic foot ulceration (DFU) ascribed a risk category to each of the 301 patients (Table 11). The results show that only two patients were at low risk of ulceration in both feet, 28 patients had moderate risk in both feet, and 271 patients (90% of the sample) were at high risk of DFU when combining results from both feet.

Table 11: Frequencies of risk per category, for individual feet and combined left and right feet.

Risk Categories	**Frequencies**			**Percentages**		
	Yes	**No**	**Total**	**Yes**	**No**	**Total**
Low risk R	4	297	301	1.3	98.7	100
Low risk L	2	299	301	0.7	99.3	100
Low risk L + R	**2**	299	**301**	**0.7**	99.3	**100**
Moderate risk R	28	273	301	9.3	90.7	100
Moderate risk L	29	272	301	9.6	90.4	100
Moderate risk L + R	**28**	273	**301**	**9.3**	90.7	**100**
High risk R	271	30	301	90.0	10.0	100
High risk L	272	29	301	90.4	9.6	100
High risk L + R	**271**	30	**301**	**90.0**	**10.0**	**100**

Although the two research questions had been answered, the enormity and implications of the answers to those questions prompted further investigation into the data, with the hope that this would provide more insight into the multi-faceted medical picture of these PLWD.

The frequencies of known diabetes foot ulcer risk factors in the assessed sample (n = 301) were tabulated and combined with the results of both feet (table 13 overleaf).

Table 13. Frequencies of known DFU risk factors in the sample

Known DFU Risk factors	**Frequencies in sample n = 301**	**Percentages in sample n = 301**
Visual impairment	3	1.0
Previous ulcers/amputations	27	9.0
Renal impairment eGFR<60	88	29.2
Incorrect footwear	96	31.9
Dermatological pathologies	144	48.0
Deformities and/or prominences	206	68.4
Loss of protective sensation	229	74.8
Peripheral arterial disease (doppler)	283	94.0

Once these frequencies were established, the data were interrogated to find any possible relationships between the demographic and clinical variables in the one hand, to known DFU risk factors on the other. In this way, it was hoped to reveal possible associated variables, not only to indicate directions for further future investigation but also to signpost diagnostic and treatment pathways. This was carried out by a Fisher's Exact test on the categorical values, while the numerical dependent values were one-way ANOVA derived, from routines run from within the statistical software (Table 14).

Table 14. Relationship between demographic/clinical variables to known DFU risk factors (significance shown in p-values set at 95% confidence interval, n = 301)

Known risk factors for DFU	**Age**	**Sex**	**Diabetes Type**	**Years since diagnosis**	**Family history of DM**	**Hypertension**	**Hyperlipidemia**	**Employed**	**BMI > 26**	**eGFR <60**
Visual impairment	0.661	1.000	0.353	0.069	1.000	1.000	1.000	0.531	0.273	0.553
Previous ulcers/amputations	0.146	1.000	1.000	0.423	0.241	0.798	0.103	0.587	0.356	0.237
Renal impairment eGFR<60	**0.000**	0.021	**0.000**	**0.000**	0.460	**0.000**	0.547	**0.000**	0.164	---
Incorrect footwear	0.221	**0.025**	0.857	0.804	1.000	0.528	0.115	0.954	0.912	0.676
Dermatological infections	**0.004**	0.281	0.000	0.652	0.054	**0.009**	0.055	**0.018**	**0.004**	0.499
Dermatological fissures	0.294	0.625	0.287	0.691	0.861	0.463	**0.005**	0.515	**0.041**	1.000
Dermatological hyperkeratosis	**0.006**	**0.007**	**0.012**	0.358	1.000	**0.032**	0.184	0.230	0.112	0.346
Deformities and/or prominences	0.066	**0.000**	**0.016**	0.797	0.395	0.113	**0.024**	0.105	0.733	0.256
Loss of protective sensation	**0.000**	**0.000**	**0.001**	0.000	0.174	**0.003**	**0.016**	**0.002**	0.469	0.068
Peripheral arterial disease (doppler)	0.105	**0.010**	0.261	0.433	0.776	**0.028**	1.000	0.013	0.284	1.000

Note: Significant values (p-value equal or less than 0.05) are shown in bold face in Table 14.

Having seen the associations between variables and noting that many participants volunteered that their (over)weight prevented them from exercising, data was further explored. Binary logistic regression analysis was used to predict the odds of being a (positive) case based on the values of the independent variables (predictors).

In the first example, we considered the independent variable BMI (in its various grades, represented by a coded number) against whether the patient had a history of previous ulcers (yes/no). The regression analysis also adjusted for factors such as HbA1c, age, gender and population group, considered to be 'confounder' variables.

An Omnibus test of model coefficients produced a chi-squared value that showed that the relationship between BMI and history of previous ulcers was not significant as the p-value was 0.810. This was also verified by the Nagelkerke R Square test result of 0.015 for the model.

However, when this was adjusted by the confounder variables of HbA1c, Sex(1=male), Age group (>50) and Population group then it can be seen that HbA1c is significant (p = 0.030) and results in 1.2 times the odds (High HbA1c to Low HbA1c) of being associated with a history of previous ulcers. Male sex, although not significant when compared to the female sex, conferred 3.3 times the odds of having had a previous ulcer. Similarly, the variable Age grouped (>50) is significant (p-value 0.037) with odds of 5.099 times compared to younger than age 50, of having had previous ulcers (Table 15).

Table 15. Odds ratios on a history of previous ulcers being associated with BMI alone, and adjusted for the confounder variables of HbA1c, Sex, Age >50 and Population group.

Dependent variable "history of previous ulcers" compared to Independent variable BMI and confounder variables in the equation	Unadjusted values			Adjusted for confounders		
	B	Wald	Sig.	Exp(B) odds	95% confidence interval. for EXP(B)	
					Lower	Upper
BMI coded		2.630	0.621			
BMI coded (1) underweight	-18.342	0.000	0.999	0.000	0.000	
BMI coded (2) overweight	-1.054	1.227	0.268	0.349	0.054	2.250
BMI coded (3) Obese class I	-0.782	0.720	0.396	0.457	0.075	2.786
BMI coded (4) Obese class II	-0.079	0.008	0.927	0.924	0.170	5.033
HbA1c	0.249	4.702	**0.030***	**1.283**	1.024	1.606
Sex (1) Male	1.213	3.382	0.066	**3.364**	0.923	12.255
Age grouped >50	1.629	4.346	**0.037***	**5.099**	1.102	23.588
Population group		0.000	1.000			
Population group (1)	-19.821	0.000	1.000	0.000	0.000	
Population group (2)	-18.972	0.000	0.999	0.000	0.000	
Population group (3)	-19.229	0.000	0.999	0.000	0.000	
Constant	-6.036	13.266	0.000	0.002		

In a similar way, models were constructed to find the odds ratios between the binary independent variable BMI (in its various grades) and loss of sensation (peripheral neuropathy); BMI and PAD (as per doppler) for the left foot and right foot. Each of these odds ratios was calculated alone, and adjusted for the variables of HbA1c, age grouped, gender and race.

Tables 16 through 18 reflect only the results that reflected significant p-values and adjusted odds ratios that were found in each model. Values that are both significant and reflect high odds ratios are shown in bold font.

Table 16. Odds ratios on **loss of sensation** being associated with BMI alone, and adjusted for the confounder variables of HbA1c, Sex, Age >50 and Population group.

Dependent variable "loss of sensation" compared to Independent variable BMI and confounder variables in the equation	Unadjusted values			Adjusted for confounders		
	B	Wald	Sig.	Exp(B) odds	95% confidence interval. for EXP(B)	
No association found with BMI alone						
Age grouped >50	1.936	28.572	**0.000**	**6.932**	3.408	14.097
Note: confounder variables of Sex and Population group indicated neither significance nor odds						

Table 17. Odds ratios on **abnormal PAD (Right foot)** associated with BMI alone, and adjusted for the confounder variables of HbA1c, Sex, Age >50 and Population group.

Dependent variable "PAD right foot" compared to Independent variable BMI and confounder variables in the equation	Unadjusted values			Adjusted for confounders		
	B	Wald	Sig.	Exp(B) odds	95% confidence interval. for EXP(B)	
					Lower	Upper
BMI overweight	0.409	0.236	0.627	1.505	0.290	7.821
BMI Obese class I	0.023	0.001	0.978	1.023	0.201	5.218
BMI Obese class II	0.113	0.019	0.890	1.119	0.228	5.504
HbA1c	0.134	1.070	0.301	1.144	0.887	1.475
Age grouped >50	1.225	4.171	**0.041**	**3.406**	1.051	11.041
Note: confounder variables of Sex and Population group indicated neither significance nor odds						

Table 18. Odds ratios on **abnormal PAD (Left foot)** being associated with BMI alone, and adjusted for the confounder variables of HbA1c, Sex, Age >50 and Population group.

Dependent variable "PAD left foot" compared to Independent variable BMI and confounder variables in the equation	Unadjusted values			Adjusted for confounders		
	B	Wald	Sig.	Exp(B) odds	95% confidence interval. for EXP(B)	
					Lower	Upper
BMI (overweight)	0.344	0.171	0.679	1.411	0.276	7.210
HbA1c	0.043	0.126	0.723	1.044	0.824	1.322
Age grouped >50	1.363	5.494	**0.019**	**3.908**	1.250	12.217
Note: confounder variables of Sex and Population group indicated neither significance nor odds						

When one of us (ATT) set out to collect foot assessment data on PLWD, she anticipated that examination might reveal some patients who would need onward referral, as per podiatric training. A total of 205 patients (68% of the sample of 301 patients) presented with clinical signs or symptoms that required further clinical attention, of whom 82% (n = 168) needed further treatment and management by a podiatrist. The need for further skilled treatment by a podiatrist was thus present in 56% (n = 168) of the total sample.

These 205 patients were grouped into the following categories: 63 patients who presented with severe skin and/or nail pathologies; 71 with vascular or cardio-vascular anomalies; 57 with musculoskeletal pathologies and 14 neural conditions that were neuro-vascular or neuro-muscular, requiring attention to detail on medication, and treatment to return to function. Tabulated data of the incidental clinical findings and the researcher's path of referral are presented in Table 12 (overleaf).

Table 12. Summary of incidental clinical findings, dangers and referral path taken by researcher during foot assessment study.

Key: Hx (history), Dx (diagnosis), DDx (differential diagnosis), Tx (Treatment), DOPD (diabetes out-patient department), DVT (deep vein thrombosis), PUVA (Psoralen and ultraviolet A), IPJ (inter-phalangeal joint), MPJ (metatarsophalangeal joint).

Skin and Nails Incidental presentations	n	Danger	Suggested management	Referred to	Escalation Discipline(s)
Hippocratic nails hx smoking	1	Potential sign of pulmonary pathology	screening chest radiograph	DOPD doctor	Radiology
Hyperhidrotic feet (untreated)	1	Risk factor for fungal infection or pitting keratolysis, community infective risk	Prescription strength antiperspirant preparation, education re dietary restrictions, podiatry treatment	DOPD doctor	Podiatry
Incurvated nails hx DVT	4	If not corrected, nail encircles nail tuft, resultant ischaemic tip, gangrene	Regular preventative treatment by podiatrist to re-shape nail margins; nail plate 'Keriflex' type nail prosthetic made by podiatrist to guide straight nail growth	DOPD doctor	Podiatry
Indurated skin at ankle	1	Lipodermatosclerosis	Compression therapy arterial status permitting, Fibrinolytic medication cardiac status permitting, potent anti-inflammatory topicals and steroids such as clobetasol propionate	DOPD doctor, Podiatrist at Greys	Podiatry Vascular Nurse
Non-healed amputation site (> 1year duration)	2	Receded blood flow	Vascular workup, patient wound care education, follow-up? should be offloading e.g. on crutches	Podiatrist at Greys	Podiatry Vascular Nurse
Pre-tibial necrobiosis lipoidica diabeticorum	3	High risk of broken skin, ulceration	Topical retinoids, topical steroids, PUVA light therapy	DOPD doctor	Dermatology
Severe anhidrosis despite use of basic emollients	5	Dry, broken skin increases risk of infection; investigate neural involvement (sympathetic nervous system)	Next level keratinolytic balms (podiatrist to advise compounding pharmacist in hospital), education e.g. no foot soaking, neural supportive medication/supplementation	Podiatrist at Greys	Podiatry
Severe callus, corns or grossly thickened nails	14	11 times more likely to ulcerate	Debridement, reduction, offloading device or intervention, education of patient and medical personnel, footwear assessment	Podiatrist at Greys	Podiatry
Skin and nail pathology (severe)	15	11 times more likely to ulcerate	Reduction, prevention of ulceration on IPJs, MPJs, plantar surface	Podiatrist at Greys	Podiatry
Ulcer open (patient aware) but no dressing used, no offloading	3	Infection, amputation	Debridement by podiatrist, reduction, offloading device or intervention, education of patient and medical personnel, footwear assessment	Diabetes OPD doctor, Podiatrist at Greys	Podiatrist
Ulcer under foot, no dressing used, no offloading	3	Infection, amputation	Debridement by podiatrist, reduction, offloading device or intervention, education of patient and medical personnel, footwear assessment	Diabetes OPD doctor, Podiatrist at Greys	Podiatrist
Ulcer, medial heel, no ulcer dressing or pressure relief	1	high risk amputation	Wound care education, follow up? should be on offloading on crutches or moon boot	Diabetes OPD doctor, Podiatrist at Greys	Podiatrist
Ulcer, new, amputee, dressed by Eshane Clinic but no offloading	1	impeded healing, amputation	Debridement by podiatrist, reduction, offloading device or intervention, education of patient and medical personnel, footwear assessment	Diabetes OPD doctor, Podiatrist at Greys	Podiatrist, Vascular

Table 12. (continuation)

Skin and Nails Incidental presentations	n	Danger	Suggested management	Referred to	Escalation Discipline(s)
Ulcer, untreated under 5th MTPJ (patient unaware)	1	high risk amputation	Debridement by podiatrist, reduction, offloading device or intervention, education of patient and medical personnel, footwear assessment	Diabetes OPD doctor, Podiatrist at Greys	Podiatrist
Ulcer untreated under 1st MTPJ (patient unaware)	3	high risk amputation	Debridement by podiatrist, reduction, offloading device or intervention, education of patient and medical personnel, footwear assessment	Diabetes OPD doctor, Podiatrist at Greys	Podiatrist
Ulcer: dry gangrene (unprotected)	1	high risk amputation	Offloading device or intervention, education of patient and medical personnel, footwear assessment, protective device, vascular investigation	Diabetes OPD doctor, Podiatrist at Greys	Podiatrist, Vascular
Ulcers, plantar, patient unaware therefore untreated	4	high risk amputation	Debridement by podiatrist, reduction, offloading, education, footwear assessment	Diabetes OPD doctor, Podiatrist at Greys	Podiatrist

Cardio-Vascular Incidental presentations	n	Danger	Suggested management	Referred to	Escalation Discipline
Abnormal pulsatile waveforms on doppler	1	thrombus formation	ECG, bloods and medication review	Diabetes OPD doctor	Cardiology Vascular
Arrythmia or abnormal pulsatile waveforms	11	thrombus formation	ECG, medication review	Diabetes OPD doctor	Cardiology Vascular
BPM < 40	2	cardiac arrest	Evaluate if candidate for pacemaker, revise meds, admit to high care	Diabetes OPD doctor	Cardiology Vascular
Fem pop artery biphasic continuous (hot painful knee but cold monophasic foot)	2	fem pop thrombus/blockage	refer for angiogram lower limb; re-vascularise	Diabetes OPD doctor	Cardiology Vascular
Medial arterial calcification ABPI reading > 1.4, doppler waveform biphasic continuous	4	strong predictor for future cardiovascular event,	Refer for X-ray confirmation, supplementation Vit K2, revise anticoagulant therapy, low dose vit D, phosphate binders	Diabetes OPD doctor	Cardiology Vascular
Medial arterial calcification, severe	4	strong predictor for future cardiovascular event,	Refer for X-ray confirmation, supplementation Vit K2, revise anticoagulant therapy? low dose vit D, phosphate binders?	Diabetes OPD doctor	Cardiology Vascular

Table 12. (continuation)

Cardio-Vascular Incidental presentations	n	Danger	Suggested management	Referred to	Escalation Discipline
Monophasic pedal pulses yet compression hose was dispensed for varicose leg pain at Embalenhle Clinic	1	Compression in presence of ischaemia can cause gangrene	(Re-)Education of clinic staff that only once doppler ultrasound indicates good arterial supply can compression hose be dispensed. Refer to vascular for full dopplex exam	Diabetes OPD doctor, DoH Management	Nursing, Podiatrist, Vascular
Pain in arms when lifting the arms	2	Rotator cuff disease or peripheral vascular disease; tendinitis, bursitis; nerve impingement	Investigation - orthopaedics, vascular, neurology	Diabetes OPD doctor	Vascular, Neurology, Orthopaedics
Pain in chest when lifting arms above shoulders	1	Thoracic outlet syndrome??	Investigation - cardiology	Diabetes OPD doctor	Cardiology Vascular
Pain on leg elevation	3	Peripheral arterial disease; Nerve impingement	Investigation - vascular, neurology	Diabetes OPD doctor	Vascular, Neurology
Painful oedema of the feet	8	indicator for cardiac failure; lymphedema; renal disease	Investigate low protein levels; medications (side effect?); venous insufficiency;	Diabetes OPD Doctor	Cardiology, Vascular Nephrology
Pedal pulses monophasic or biphasic continuous	10	High risk of non-healing pedal tissue	refer for angiogram lower limb; re-vascularise	Diabetes OPD Doctor	Cardiology Vascular
Post stroke	3	High fall risk	refer to podiatrist re footwear, occupational therapy for devices	Podiatrist	Podiatry, Occupational Therapy
Weak bpm (hx stroke)	1	potential cardiac failure	refer to cardiology, suitable patient for pacemaker?	Diabetes OPD Doctor	Cardiology Vascular
Tachycardia (>100 bpm resting)	7	If prolonged, syncope, cardiac failure, thrombus formation	Medication review (HBP), check electrolytes, cardiovascular workup?	Diabetes OPD Doctor	
Unilateral calf pain	5	potential thrombus	refer for angiogram lower limb; re-vascularise	Diabetes OPD Doctor	Cardiology Vascular
Unilateral knee pain, hot to touch (leg wrapped with tight hose at the knee)	4	potential thrombus	refer for angiogram lower limb; re-vascularise	Diabetes OPD Doctor	Cardiology Vascular
Gait imbalance with leg pain	2	unable to ambulate or exercise	investigate musculoskeletal, biomechanics, gait function	Podiatrist	Podiatrist

Table 12. (continuation)

Musculoskeletal Incidental presentations	n	Danger	Suggested management	Referred to	Escalation Discipline
Gait imbalance due to lumbar and unilateral leg pain	1	fall risk	Work up by podiatrist, imaging, in-shoe prescription insole	Podiatrist (Greys)	Podiatrist, Podiatry orthotics lab
Mallet toes	1	ulcer risk	Work up by podiatrist, conservative treatment with custom toe props fabricated in clinic from two-part silicone.	Podiatrist (Greys)	Podiatrist, Podiatry orthotics lab
Metatarsus adductus (uncorrected)	3	callus formation due to shoe misfit, ulcer risk	Work up by podiatrist, templates by podiatrist for custom prescription shoe insert with components built in to support lateral borders of foot and prevent ulceration	Podiatrist (Greys)	Podiatrist, Podiatry orthotics lab
Pain under the 1st MTPJ, history stumbled and fell	1	DDX: plantar plate injury, sesamoiditis, bursitis, ischaemia, ulcer risk	imaging investigation, work up by podiatrist, offloading in shoe device made by podiatrist	Podiatrist (Greys)	Podiatrist, Podiatry orthotics lab
Severe plantar fasciitis with suspected calcaneal spur	1	inability to exercise, decreased blood supply, musculoskeletal compensatory fatigue, pain syndrome, inability to work	refer for x-ray confirmation, send for in-shoe correction to be made by podiatrist, followed by physiotherapy once patient is pain free.	Podiatrist (Greys)	Podiatrist, Podiatry orthotic lab, Physiotherapy
Shoes: High heels, biphasic pulses	2	callus formation, decreased blood supply, ulcer risk	Work up by podiatrist, patient education, follow up	Podiatrist (Greys)	Podiatrist
Short first metatarsal (bilateral) with hallux rigidus, painful/symptomatic	38	callus formation, musculoskeletal deformation (toes); ulcer risk	Work up by podiatrist, templates by podiatrist for custom prescription shoe insert with components built in to re-establish metatarsal parabolic action; patient education	Podiatrist (Greys)	Podiatrist, Podiatry orthotics lab
Unilateral ankle pain	8	unable to exercise, impacts vascular, impacts quality of life, ulcer risk	imaging investigation, work up by podiatrist, offloading in shoe device made by podiatrist	Podiatrist (Greys)	Podiatrist MSK Vascular
Unilateral knee imbalance	1	unable to exercise, impacts vascular, impacts quality of life, ulcer risk	imaging investigation, work up by podiatrist, offloading in shoe device made by podiatrist	Podiatrist (Greys)	Podiatrist, Podiatry orthotics lab
Unilateral short first metatarsal and back pain	1	unable to exercise, impacts vascular, impacts quality of life, ulcer risk	In-shoe device for correction of gait imbalance	Podiatrist (Greys)	Podiatrist, Podiatry orthotics lab

Table 12. (continuation)

Neurological Incidental presentations	n	Danger	Suggested management	Referred to	Escalation Discipline
Gait anomaly hx TB spine	1	fall risk	Supply crutches/walking aids, physiotherapy, podiatry in-shoe orthotics	Diabetes OPD doctor	Podiatrist, Podiatry orthotics lab
Gait imbalance post stroke (has no crutches or walking aid)	1	fall risk	Supply crutches/walking aids, physiotherapy, podiatry in-shoe orthotics	Diabetes OPD doctor	Podiatrist, Podiatry orthotics lab
Hand paresthesia as well as lower limb paresthesia	1	fall risk	Assess Vit B12 levels, Rx medication for neuropathic pain, physiotherapy, occupational therapy	Diabetes OPD doctor	Podiatry, Physiotherapy, Occupational Therapy
Ineffective pain medications given for neuropathic pain	1	Patient risks toxicity by self-medication dosage increase.	Pt had been given Tramadol, suggest rather Carbamazepine or newer Duloxetine	Diabetes OPD doctor	Endocrinology
Pain in feet hx meningitis with temporary paralysis	1	Fall risk due to painful gait, loss of quality of life	Assess Vit B12 levels, Rx medication for neuropathic pain, physiotherapy	Podiatrist (Greys)	Podiatrist, Podiatry orthotics lab, Physiotherapy
Retracted extensor tendons in presence of sensory neuropathy	3	High risk for ulcer under MTPJs, DDX rhabdomyopathy	Neural support e.g. Vit B12, physiotherapy. Ulcer prevention for metatarsophalangeal joints, podiatry work-up and podiatry orthotics	Podiatrist (Greys)	Podiatrist, Podiatry orthotics lab, Physiotherapy
Shoe coring exposed (patient neuropathic and unaware)	1	Exposed holes can damage skin, ulcer risk	Patient education, clinic personnel education, podiatry offloading intervention	Podiatrist (Greys)	Podiatrist, Podiatry orthotics lab
Shoes too small - patient unaware	3	Neuropathy causes patient to wear tighter shoes to increase diminishing sensation; ulcer risk	Patient education, clinic personnel education, podiatry foot protection intervention	Podiatrist (Greys)	Podiatrist, Podiatry orthotics lab
Feet as cold as ice, not wearing socks	2	high risk DFU, or burn risk	Refer for duplex doppler, review medications, patient education, clinic personnel education	Diabetes OPD doctor	Vascular, Podiatrist
Total patients with incidental findings needing podiatric care/management/referral	205				

Discussion

The high numbers of diabetes-related amputations in KwaZulu Natal [13-14] are linked to diabetic foot disease, and this, in turn, is related to the rate and risk of ulceration.

There is a very high prevalence of peripheral arterial disease in the cohort assessed (94%) and a lack of corresponding clinical notation thereof in patient's files. It may thus appear that the vascular risk for diabetic foot ulceration is not being detected in time for more effective prevention measures.

The percentage in the sample of patients classified at high risk of DFU (90%, n = 271) is alarming.

Accurate, thorough testing and documentation are vital for identification of risk. Some clinical records, as completed by the doctors on duty, indicated that pedal pulses were "weak", or "strong", based on manual palpation. Doppler ultrasonography of the same patients on the same day and within minutes of each examination showed that these recorded outcomes of manual palpation of pedal pulses showed little relationship to the actual doppler ultrasonography. For example, a recorded "strong" (palpated) pulse was frequently a stenotic 'bounding' pulse as indicated by the doppler waveforms. This would suggest that the 2017 SEMDSA guidelines which state that:

> "at diagnosis and annually thereafter, a trained healthcare worker (podiatrist, nurse, doctor, community health worker) must examine patient's feet without socks or bandages to determine risk status**:** Inspect for foot deformities, skin and nail abnormalities; Inspect footwear; Test sensation (monofilament, 128 Hz tuning fork or "touch the toe" and *"**Palpate** dorsalis pedis and posterior tibial pulses"*

is inadequate in scope, since this study has shown that palpation is an unreliable method to inform on arterial flow or waveforms that require intervention in PLWD. See Appendix 20 for the conference presentation on pedal pulse palpation as investigated in this study.

Obesity and lack of exercise – a vicious cycle

Almost 80% of patients assessed did not have normal body mass. Over one-third (n = 104) were class II obese or morbidly obese patients who required physical assistance to mount the step to lie on the examination plinth, and for whom extra-large ABPI cuffs were needed. Participants understood that the Doppler audible signal was their pulse, reflecting "their heart-beat in their feet". The researcher felt obligated by professional ethics to explain to a PAD-positive patient whenever their blood flow was sub-optimal. She showed them how calf muscle pump exercises would increase blood flow to the feet. Patients reported that they had not been exposed to the calf-muscle explanation so had not understood about walking as exercise "medicine" nor had those who were unable to walk been shown the alternative seated heel raise exercises.

Incorrect footwear was statistically associated (p= 0,025) to a single variable, namely (female) sex but not to any other socio-medical variable. Podiatrists are aware of the contribution of incorrect footwear in the female population to foot distortion and dysfunction, which forms part of the podiatric diabetes patient education that these patients had not received.

With regard to the risk factors for DFU of foot skin conditions such as infections, fissures and callus or hyperkeratosis, increased age was associated with infection and formation of callus but surprisingly not with fissures which form as a result of moisture imbalances, both in skin too moist and skin too dry. Yet fissures were statistically associated with hyperlipidaemia and a BMI >26. Obesity may have a mechanical shear effect on the plantar skin of the foot, but further study is needed to investigate why hyperlipidaemia is associated with (moisture imbalances that precipitate) fissures.

Skin infections in the sample, mostly fungal, were statistically associated with increasing age, hypertension, employed status and obesity. Is age a factor because of decreased immune response? Or could older people or old shoes have been exposed to fungal elements for longer? Could decreased hepatic function or uptake of nutrients in advancing age be a factor? Is the association to employment related to work footwear, i.e. occlusive safety shoes?
Further links to skin infections revealed by the Fisher's and ANOVA tests are that of hypertension, employment and obesity, which form a basis for future studies.

The formation of callus or hyperkeratosis is shown to be significantly associated with age, gender (female), type of diabetes (II), and hypertension. However, although increased pressure and friction are implicated in the formation of callus, the callus is not significantly associated

with increased BMI >26. The unexpected association between callus and hypertension, as shown in Table 14 forms yet another subject for future study.

Further findings shown in Table 14 include the result that deformities and/or prominences are statistically associated with gender (female), type of diabetes (II), and hyperlipidaemia. Forces from footwear aside, how do excess lipids in (younger) type II diabetes females in this population affect the foot structure to cause deformities or prominences? This is yet another question for future investigation that will require research into female patient hormonal data, lipid and collagen levels and their influence/impact on foot anatomy. Temporary ligamentous and joint changes due to physiological changes in hormones during the menstrual cycle have been well documented [14]. However, permanent deformity/prominence as found in our sample in younger hyperlipidemic black African diabetes females requires further study. Such studies should encompass investigation of footwear, activity, lower-limb biomechanics and of neuromuscular control in addition to female hormonal markers.

Peripheral arterial disease (by handheld doppler ultrasonography) was shown to be statistically significant only to sex (female, p-value 0.010) and hypertension (p-value 0.028). This finding is most relevant for both the pathways for clinical treatment as well as for podiatric patient education on additional non-pharmacological means of preventing and reducing hypertension.

Relationship between demographic/clinical variables to known DFU risk factors

Surprisingly, as can be seen from Table 14, neither visual impairment nor a history of previous ulcers or amputations were significantly associated with any of the demographic or medical variables. On the other hand, renal impairment (indicated by an eGFR<60) was significantly associated with increased age, type of diabetes, duration of diabetes, hypertension and employment.

Similarly, hypertension in this population is significantly associated with renal impairment, and this is in keeping with the known relationship between renal dysfunction, causing increased hypertension and hypertension accelerating loss of kidney function [11].

Evidence of the need for podiatric care

More than half of the 301 sampled patients (56%, n = 168) were found to need specific podiatric care to prevent further complications. There is only 1 state health podiatrist in Pietermaritzburg, based at Greys Hospital. This finding provides support for the opening of multiple podiatrist posts in the uMgungundlovu district. A study in 2015 found that the uMgungundlovu district had an estimated diabetes prevalence of 39.9% [12]. Statistics South Africa estimated that the population of KwaZulu-Natal was some 11.2 million people by mid-2019 [15]. The uMgungundlovu district population represents approximately 9.9% of the province in a 2018 report [16]. Assuming an unchanged estimated diabetes prevalence of 39,9% for the district of uMgungundlovu, means that there are at least 442 092 PLWD in uMgungundlovu district. Thus, if 56% of these patients (as per Edendale Hospital statistics) need specific podiatric care, this would translate into some 248 000 PLWD in the district for whom there exists a need for specialised podiatrist care. Based on the researcher's experience in private practice, one podiatrist is needed for approximately every 960 PLWD who are on a 6-month clinic rotation, or for every 480 PLWD who are on a 3-month clinic rotation. This is required in order to fulfil the national guidelines for diabetic foot assessments, patient education and actual clinical treatment for patients in different risk categories.

Utilising the 2017 estimates for the lifetime incidence of diabetes foot ulcers of between 19% to 34% [17], then of the estimated total of 442 092 PLWD in the uMgungundlovu district, between 84 000 and 150 000 patients would, in the normal course of the disease, develop a DFU requiring podiatric care. The review published in 2017 [17] states that there is a strategy for overall preventive management to prevent foot ulcer recurrence. The strategy requires good diabetes control, ongoing professional foot care at intervals of 1 to 3 months (dependent on risk classification). It also requires modifications to achieve properly fitting footwear or in-shoe intervention that can be shown to relieve plantar pressure. Foot temperature should also be monitored, and patients educated to report for additional foot care on signs of inflammation. Patient education should be delivered by the team approach to promote patient compliance or adherence, not just at a single visit. Vascular surgery is needed to restore vascular flow where possible. Escalation to orthopaedic surgery may be necessary to achieve biomechanical protection should all possible conservative (non-surgical) treatments be exhausted [17].

Team role played by the podiatrist

It must be noted that many of the incidental clinical foot findings (as per Table 12) were made after the patient had already been seen by the diabetes clinician or intern on duty. The podiatrist felt ethically obligated to send the patient back to the clinician or refer to another department so that the patient could receive further attention to these findings.

Evidence to guide the minimum duration of a comprehensive foot assessment

In contrast to private practice, in which new patient assessments require 30 to 45 minutes to allow for simultaneous interactive in-depth education and basic urgent treatment care, this study showed that it is clinically impossible to conduct the comprehensive assessment portion alone in under 15 minutes. As such, this study provides solid conclusive evidence that the "60-second diabetic foot screening" as proposed by Sibbald [18] cannot be considered of clinical value since some findings could be missed. The researcher suggests that it should be removed from wound care and nursing guidelines until adequately revised. Handheld Doppler ultrasonography (with visual waveforms) alone will take up 60 seconds per foot.

The emotional and psychological effect on patients of their podiatric examination

Many of the patients who volunteered for foot assessment asked the researcher about her podiatric work. They were astonished and even angry to learn that an entire medical discipline exists to assess, diagnose and treat feet; to provide ongoing foot care for those with diabetes and educate them on how to prevent amputation. They felt deprived and neglected by the Department of Health system. They expressed sadness when they learnt that one of us (ATT) could not return to continue their care, and she found this emotionally disturbing.

Other matters that were found to be of concern included patients arriving with open ulcers on their feet, some were aware of them, others unaware but none understood the danger of open ulceration, nor that they should be seeking assistance with wound care. It is unknown whether the community clinics provide diabetes-specific pressure offloading wound care.

Another disturbing statistic was the low number of amputees attending the SOPD clinic, given the known high numbers of amputations. Amputees are high-risk patients and should be attending every month as per the SEMDSA guidelines [10]. We were unable to determine whether amputees had been lost to follow up or why there was such poor attendance of amputees.

Limitations of the study

Since a minimum of 300 records were required for statistical analysis, logistics and planning for the assessments to take place over a given 3-month or 12-week patient return cycle meant that approximately 25 patients were planned to be assessed in one session of four hours. Since many patients arrived fasting in order to have blood samples taken after seeing the doctors, there were many who did not volunteer for assessment as they were keen to have their blood tests done first and then leave to eat.

Many patients would arrive early and wait from 05:00 am onwards. Since only one podiatrist examiner was assessing the patient output of up to four doctors, the examiner fell behind in the intake. The examining podiatrist then began foot assessments at 07:00 am, to "be ahead of" the doctors who started at 08:00 am. Despite this initiative, the required number of 25 patients per day for assessment was not achieved in the period before year-end. Assessments, therefore, continued through a new cycle after year-end but avoided duplication of those returning patients who had already been assessed.

The majority (96.7%, n = 291) of subjects are of black African descent. In the absence of similar data for other population groups, no comparisons can yet be made in respect of other population groups attending state health diabetes clinic facilities in uMgungundlovu district.

Further study directions

Since a total of 188 podiatric assessment variables were collected, together with 21 clinical variables, the calculation of further odds ratios could form the basis of a future extended study, to include the additional clinical variables of blood test results. These were not available at the time but could form the basis of future studies.

Future study could pursue the hypothesis, for example, that a lifetime medication load might be one of the contributors to the association of renal impairment with age, type of diabetes and duration of diabetes

The statistical association of renal impairment to employment is an unexpected one that raises questions for future study – what can be hypothesised? Is there inadequate opportunity/education on the need for hydration during working hours? Is there a difference in sodium/potassium levels

in food consumed by employed persons (i.e. “fast” or pre-packaged or street vendor food) compared to sodium levels in the food of those who are unemployed? Salt-sensitivity and blunted renal autoregulation are known to characterise second stage hypertension which other studies indicate is more likely to be found in people of African origin, in severe obesity/metabolic syndrome and in participants with gout or hyperuricemia [19].

Another statistically significant group of associations that will require future study was that of loss of protective sensation (peripheral neuropathy) associated with increasing age, gender (female), type of diabetes (II), hypertension, hyperlipidaemia and employment.

Recommendations

In the uMgungundlovu district, only Edendale Hospital approaches the basics of a multi-disciplinary team (MDT) for diabetes outpatient management. However, it lacks the on-site disciplines of podiatry, vascular surgery, and prosthetics for which patients must go to Grey’s Hospital. The MDT approach for diabetes management at Edendale is thus incomplete. The MDT approach can work well in our African culture, which understands that it “takes a village” to raise a child. Similarly, it takes a team to educate and empower each PLWD and their family with knowledge and treatment to take control of their disease.

The patients who took part in the study asked questions and were open to explanations, to a demonstration of blood flow linked to calf muscle action and diabetes foot education. Many were older patients accompanied by daughters, sons or grandchildren. I believe that group education provided by their own language speaking podiatrist will be well received by patients as well as all medical members of the MDT. Education on foot care, on the neglected but vital role of foot exercise and what footwear to avoid, will contribute to the prevention of many risk factors.

There is only one podiatrist based at Grey’s Hospital serving the uMgungundlovu district which contains more than 10 district hospitals, 78 provincial clinics, and at least three community health centres. It is recommended that posts for podiatrists must be created in order to assist the Department of Health in diabetes amputation prevention efforts.

As explained in the preceding discussion, the national SEMDSA foot assessment guidelines should be amended in future revisions to replace 'palpation of pedal pulses' with "handheld Doppler audible ultrasonography with visual waveforms".

In many low resource settings, (as seen in the studies examined in the scoping review in Chapter Two, cheaper handheld Doppler instruments are of the more basic auditory type, without visual waveforms. Instead of waveforms, they display arrows indicating increased or decreased pulsatile strength. This type of cheaper doppler is often used with cuff and stethoscope to manually perform the ABPI calculation (systemic ankle pressure divided by systemic brachial pressure). The Doppler ultrasonography model used in the study displays waveforms on a screen. In Table 10 herein, results show that the automated ABPI (used in the study) approximated the Doppler monophasic waveform results (17.3% for severe PAD on ABPI compared to 18.6% severe PAD on Doppler). As such, the results of the Doppler were used to indicate the presence of PAD.

In clinical private practice in Umhlanga, for example, vascular surgeons carry the portable handheld Doppler ultrasound waveform device in their pockets, reserving the automated ABPI for use in clinics in which their support staff can run the ABPI device without extensive training.

Ultimately the decision to use one or both in South Africa is a question of cost. DMX doppler requires training and experience but is one-quarter of the price of an automated ABPI machine that requires no training or experience.

Since the subject sample in this study was predominantly black African (96.7%, n = 291), further studies are needed to sample the other population groups adequately. Such studies could yield weighting of risk factors specific to each population group to suggest further investigation and prevention strategies.

There is abundant literature on treating established peripheral arterial disease [20-27]. Although such research may be helpful for medical practitioners it would seem more logical and in keeping with provincial and private health mission statements that emphasis be placed on *prevention* - preventive education, podiatric prevention and treatment of foot complications.

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Part Two: Anatomical and footwear risk factors for PAD

In this introduction to Part Two of the thesis, I provide some background about my personal training and experiences that brought me to this section of the current study.

In 2002, my undergraduate work (in podiatric medicine) investigated whether an unshod childhood results in increased forefoot width in a multi-ethnic adult sample [1].

Two years later, private practice raised more questions regarding the role of ill-fitting footwear in causing foot pathology. I found that the South African footwear industry used morphological guidelines that were not representative of the total population in its ethnic variety. The Leather Industries Research Institute (LIRI, attached to Rhodes University until 2000) conducted the last measurement survey of female feet in 1954 on a sample which contained only 'white' participants [2].

In 2004, for my post-graduate Masters' degree study, I carried out the first three-dimensional female foot measurement survey in South Africa. The project received DTI support via a National Research Foundation (NRF) Technology and Human Resources in Industry (THRIP) grant. THRIP grants incorporate a project relationship with financially contributing industry partners, during which time the grant recipient works to transfer knowledge to industry and, in turn, receives technical training from industry.

The THRIP grant enabled me to travel to Colchester, Vermont in the United States of America and receive training in operating a FastScan three-dimensional laser scanner. During 2005 and 2006, I set up portable laser scanning at both the University of Johannesburg (Doornfontein campus) and at the Westville and Howard College campuses of the University of KwaZulu-Natal. Data collection resulted in the first South African database of three-dimensional images of female feet, stratified across ethnic and age groups, with derived linear measurements. Outcomes of the study satisfied the footwear industry partners but the thesis discussion indicated that further work should be carried out to achieve further refinements in the investigation of foot geometry and thus, function. Certainly, the average width fitting across the measured sample was wider than the industry standard at that time, so that some manufacturers began to make wider fitting shoes on my recommendation.

In May 2007, I presented my work at the FIP-IFP International Podiatry Congress in Copenhagen, Denmark, at which I attended a presentation by Dr Dominguez-Maldonado who had found differences in metatarsal parabolae between male and female subjects. This was one of the catalysts for clinical observation and the line of enquiry that is documented in the current study.

During the following four years, I worked as an intern and in-house research podiatrist for one of the industry partners and relocated from Johannesburg to Durban. The complexity of technical shoe manufacture knowledge and experience gained, thereby enabled me to apply anatomical and podiatric 'insight' to guide the design of footwear products. Thereafter I founded a multi-practitioner private podiatry practice in Durban, with a special interest in diabetes, in order to mentor fellow young podiatrists with similar interests, while still maintaining my links to the footwear industry.

Anomalies of foot anatomy and physiology of the foot, combined with unforgiving footwear, can be a devastating combination for the foot of a person living with diabetes. The following three chapters set out both the foot and calf-muscle "vascular pumps" (including new evidence that has come to light in the last decade – and therefore post-dates my training and it is suspected, a good proportion of medical doctors in practice); how the anatomy and physiology is now linked to the biomechanical "windlass mechanism" of the foot; the osseous metatarsal "parabola" and pathways for pathogenesis when the "parabola" is incomplete; the peripheral vascular implications of the presence or absence of forefoot flexion in footwear; and an original research manuscript on metatarsal lengths related to mismatched footwear, with an Appendix containing the subsequent conference presentation on how this impacts on feet in diabetes.

Every one of these aspects has an implication for function of the foot in diabetes. There is a dermatological aspect to an incomplete metatarsal parabola which is particularly important in patients with diabetes. The metatarsal parabola serves a 'roll over' function at hallux dorsiflexion in the heel lift phase of gait. An incomplete metatarsal parabola may cause imbalance, disruption of foot posture and forefoot function. The resultant focal increased plantar pressure can lead to the formation of pre-ulcerative hyperkeratosis or callus in patients with diabetes. It has been documented that patients with diabetes with callus are 11 times more likely to ulcerate than people without diabetes [3].

The patients described in the previous Part One Chapter Four desperately needed (and wanted) to be able to walk in order to mechanically improve their lower limb circulation. In the vicious cycle of obesity and lack of exercise, these patients complained that their feet hurt and that shoes hurt their feet. In South Africa, very few patients with diabetes can afford or have access to properly fitted athletic footwear, let alone therapeutic footwear, so it is not unusual to find high risk patients with diabetes wearing general purpose footwear, some of which appears to only suit the foot morphology of other populations. My clinical observation (in private practice) of the locations of diabetic foot ulcers, together with examination of the patient's footwear, generated further questions. Was foot flexion at the first MTP joint related to haemodynamics in the foot in diabetes? Was there a relationship between hallux deformities and dysfunctional metatarsal parabolae? Were the flexion positions built into footwear mismatched to some feet in the population?

Part Two Chapter Five was submitted as a manuscript in November 2020 and awaits publication. It consists of a double review of literature, firstly on the anatomy and physiology of the windlass mechanism in the foot and secondly, on the current knowledge of the anatomy and physiology of the venous foot pump (after 2009). It confirms a synchronicity incorporating hallux dorsiflexion in gait, with the start of venous flow from the foot to the calf muscle pumps. Further discussed are the implications of these findings for diabetes care, prevention of venous stasis, and design of both footwear and in-shoe therapeutic devices, as well as future research directions.

Part Two Chapter Six was submitted as a manuscript in November 2020 and awaits publication. It consists of a narrative review to describe dysmorphism of the metatarsal parabola and the effect this can have on hallux dorsiflexion and thus on the function/dysfunction of the venous foot pump. The chapter reviews methods of measuring the metatarsal parabola, dysfunction of the foot due to a dysmorphic metatarsal parabola; clinical examination and treatment in resource-limited diabetes care.

Part Two Chapter Seven is a published manuscript that describes the further analysis of a three-dimensional foot measurement database (resulting from my Masters' degree work) to find the fulcrum location of the first metatarsophalangeal joint in terms of percentage of total overall foot length. The location of the first metatarsophalangeal joint ranged from 70% to 79% of total foot length which did not match the flexion position in shoe and sandal manufacture of 63% to 66% respectively. These results suggest that patients as well as the

medical community need to be informed to select and check the flexion fit of footwear, as failure to do so could potentially result in increased forces of shear and torque from a mismatched shoe fulcrum at the first metatarsophalangeal joint.

The content in Part Two will also suggest the need for podiatric screening of metatarsal parabolae in patients with diabetes to prevent unevenly distributed plantar pressure. Podiatric treatment to prevent the risk of ulceration could take the form of, for example, inexpensive podiatric prescription shoe inserts (fabricated by podiatrists) that provide non-surgical restoration of forefoot parabolic balance. The chapters in Part Two provide some of the reasons to encourage diabetes lower limb vascular function through exercise while wearing correctly fitted and flexing footwear.

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Chapter Five: The relationship of the windlass mechanism to venous flow in the foot in diabetes – what should we know?

The function of the hallux in walking in relation to haemodynamics of the lower limb is poorly documented. The current research project sought to find and synthesise present knowledge of foot venous return, combined with known gait dynamics concerning hallux dorsiflexion in the windlass mechanism so that the findings may be applied in clinical practice of diabetes care.

The study presents evidence that hallux dorsiflexion is an essential component of the windlass mechanism. Documented further is how the functioning of the windlass mechanism will shorten the plantar fascia and thereby provide a compressive lift into the plantar structures of the medial longitudinal arch. The basic elements of the phases of gait are described in relation thereto.

In the investigation into present knowledge of foot venous return, literature is presented that documents the current knowledge of the "reservoir" nature of the plantar valve-less veins. This is antithetical to the "sponge-like" venous network that formed the basis of previous medical teaching. Not only is the extraordinary reservoir structure evident, but current knowledge of the physiology and venous lateral to medial haemodynamics in the plantar foot is described.

Parallels in function and physiology of both systems become apparent. This paper suggests that the two systems are inter-dependent. Further discussed are the implications of these findings for diabetes care, prevention of venous stasis, and design of both footwear and in-shoe therapeutic devices, as well as future research directions.

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The relationship of the windlass mechanism
to venous flow in the foot in diabetes – what should we know? –
a two-pronged literature review

Abstract

Background

Lower limb haemodynamic function is essential in diabetes to prevent vasculopathy, support neural function and promote healing. Hallux function in gait in relation to haemodynamics of the lower limb is poorly documented. Current knowledge of foot venous return dynamics must be synthesised with known gait dynamics concerning hallux dorsiflexion so that the findings may be applied to diabetes care.

Aims

1. To describe and discuss the relationship of the windlass mechanism to current knowledge on venous flow in the plantar foot by means of twin literature searches.
2. To present the findings in the form of a review, synthesising previously published information.
3. To present the implications for foot care in diabetes and suggest further research directions.

Methods

Search terms were refined after trial electronic searches. Two record searches were conducted across three electronic medical databases and across all the databases incorporated into the University of KwaZulu-Natal's access to WorldCat.org.

Results

Considerable evidence exists to support the concept of synergy of the current knowledge on the anatomy and physiology of the foot venous pump, to the arch compressive function brought about by hallux dorsiflexion in gait.

Discussion

Any impairment of the venous foot pump becomes an important risk factor for chronic vascular disease. Static foot disorders, rigid or poorly flexible footwear or foot dysmorphism

can reduce the efficacy of the foot venous pump that, in turn, can influence the efficacy of the proximal calf and thigh venous pumps.

Conclusion

The ejection fraction of blood produced by the foot venous pump as a result of hallux dorsiflexion and plantar compression should be promoted for foot health in patients at risk of peripheral vascular disease. Any plantar in-shoe device or item of footwear should be manufactured to promote the function of the venous foot pump.

Key words

Hallux dorsiflexion; venous foot pump; peripheral vascular disease; foot haemodynamics, shoe manufacture, orthosis and orthotic manufacture.

Introduction

Patients with diabetes need to safeguard their lower limb haemodynamic function in order to support healing and prevent complications. Venous dysfunction can, for example, impact on neuropathy as well as ankle mobility [1]. Aside from work on ankle flexion, little has been published prior to 2007 regarding the function of the plantar foot in gait in relation to haemodynamics of the lower limb [2]. This review sought to find and synthesise the present knowledge of foot venous return, combined with known gait dynamics concerning hallux dorsiflexion so that the findings may be highlighted for application in diabetes clinical practice.

The "windlass mechanism" concept in the foot

A functional medial longitudinal arch is one in which the arch is raised by means of the windlass mechanism (Figure 5.1), as first proposed in the seminal work by Hicks [3].

A windlass is so-called as it consists of two rigid segments, that can be visualised joined by a pin that allows rotation between the two segments (Figure 5.1). One of the segments has a drum attached to it with a handle. A tension band is run between the two segments and attached to the drum. When the handle is raised, the band is wound up the drum, and the segments are raised.

In the foot, the bones of the arch form the two segments. The tension band is the medial plantar fascia or aponeurosis band which originates from the base of the calcaneus and inserts at the sesamoid bones of the first metatarsophalangeal joint and the base of the proximal phalanx of the hallux [4].

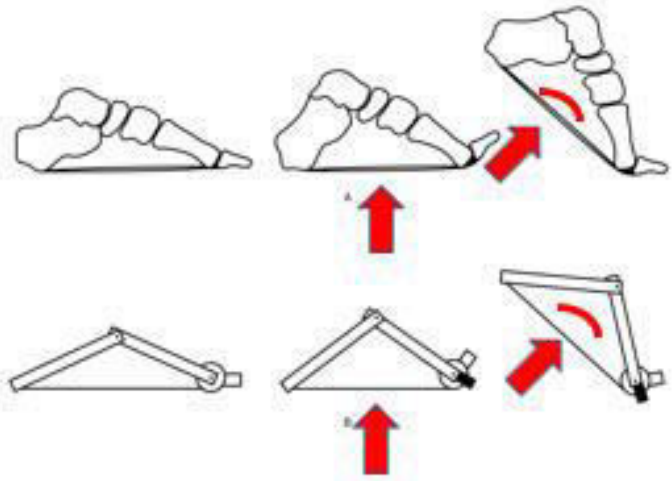

Figure 5.1: The windlass mechanism of the foot.
Illustrations at A show the progression of the foot from midstance to terminal stance with dorsiflexion of the hallux resulting in tightening of the plantar fascia, elevation of the medial longitudinal arch and compression of the soft tissues within the arch by the fascia. Illustrations at B illustrate the windlass tensioning of the plantigrade band on elevation of the distal lever, resulting in shortening of the band and raising of the segments. (redrawn after Hicks [3]).

The venous muscle pump concept

The physiological action of muscle contraction on the adjoining venous structures is descriptively termed a "venous pump". Venous pump mechanisms in the lower limb are known to exist in the foot, the calf, the thigh, and the pelvis [5]. Studies tend to focus on the function and importance of the (relative large volume) calf muscle pump with respect to hemodynamics in the lower limb [6-9]. The powerful calf muscles as shown in figure 5.2 (soleus in the leg pump and gastrocnemius in the popliteal pump) assist by compression in the ejection movement of blood upwards to the thigh, the pelvis and upper body onwards to the heart. However, the calf muscle pump cannot work in isolation, hence the search for more information on haemodynamics relevant to the foot.

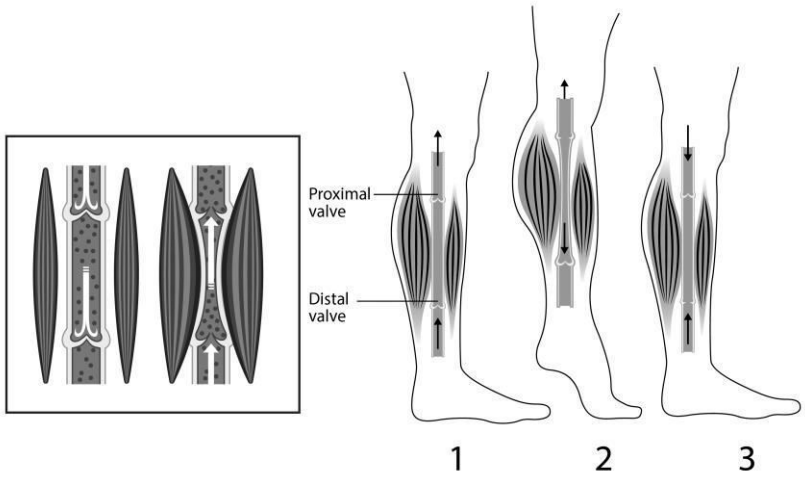

Figure 5.2: Calf muscle contraction needed for venous ejection fraction
(adapted from Diabetes South Africa and University of Arizona patient handouts)

1. Proximal and distal venous valves open to receive venous ejection fraction from the foot pump prior to heel lift
2. Contraction of calf muscles at heel lift causes ejection fraction to move to the thigh
3. Proximal valves shut to prevent backflow

Aims

1. To describe and discuss the physiological relationship of the "windlass mechanism" to current knowledge on the physiology of venous flow in the foot by means of twin literature searches.
2. To present the findings in the form of a review, as a synthesis of previously published information.
3. To present the implications thereof for the care of the foot in diabetes and suggest further research directions.

Methods

Trial advanced searches were conducted to refine the Boolean search terms used. Two differently themed searches were conducted across three electronic medical databases together with the 87 databases represented on the University of KwaZulu-Natal's WorldCat and WorldCat.org databases. Advanced searches used the key phrases "windlass mechanism", "foot windlass" for the first search, followed by "foot venous pump" "venous foot pump" for the second. Purely searching for 'windlass' for example, would yield irrelevant results, for example, the surgical 'windlass tourniquet'. "Foot pump" would yield irrelevant results concerning artificial inflation or compression devices and were excluded

from the searches. Once the updated material on the anatomy and physiology of the plantar venous pump was found, the searches were limited to the period 2010 to 2020 to find literature that postdated those findings [10-13].

Two groups of searches were conducted to collate the findings of literature retrieved from electronic databases together with hand searches and searches in authoritative texts. The databases, terms and Boolean operators used for this process are listed in Table 5.1. Duplicate records were removed. Abstracts and documents were read to assess relevance to the physiological/ structural/ gait/ biomechanical intent of the research questioning and to extract relevant information. Pertinent references in those records were also read. Records that purely concerned surgical correction methods or surgical devices were removed. Records that confused or propounded outdated data, for example, 'plantarflexion of the ankle as the mechanism for foot vascularity' were excluded from the records found.

Table 5.1. Databases searched in the study

Databases	**Search terms Group One (2010 to July 2020)**	**Search terms Group Two (2010 to July 2020)**
PubMed	((English[Language]) AND (Foot[Title/Abstract])) AND (windlass mechanism[Title/Abstract])	((English[Language]) AND (venous foot pump[Title/Abstract])) ((English[Language]) AND (foot venous pump[Title/Abstract]))
World Cat (online university library)	ti:(foot) AND ti:(windlass mechanism) AND ln:(English) AND (yr:2010..2020)	ti:(foot venous pump) OR ti:(venous foot pump) AND ln:(English) AND (yr:2010..2020)
Google Scholar	'Foot' AND 'windlass' (yr:2010..2020)	'Foot venous pump' OR 'Venous foot pump'(yr:2010..2020)
Cochrane Library	'Foot' AND 'windlass mechanism'	'Venous foot pump' OR 'foot venous pump'

Results

In Group One, a total of 68 Records were found. Abstracts were read to set aside those records concerning surgical devices, osseous corrective methods or surgical complications. In Group Two, a total of 44 records were found. Abstracts were read to eliminate those records concerning use of devices to artificially replicate the venous circulation in the foot, or to prevent thrombosis. However, five abstracts concerning foot pump devices were retained for information on the physiological foot pump. A total of 28 duplicated records were eliminated.

Full texts were sourced for the 22 remaining 'core' records (Table 5.2), as well as the five 'foot pump' device records. References within found texts were also read for relevance.

Table 5.2

Databases	**Records for Group One**	**Selected**	**Records for Group Two**	**Selected**
PubMed	42	19	7	2
World Cat databases	13	12	11	8
Google Scholar	10	6	9	7
Cochrane Library	3 trials (muscle strength testing, plantar fasciitis)	0	2 reviews (devices for surgical recovery)	0
Sub-totals	68	37	44	14
	Less duplications	16	Less duplications	12
Totals		20		2

The "Windlass mechanism" requires hallux dorsiflexion

During walking, there are two fulcra (or fulcrums) within the foot: at the ankle joint and across the five metatarsophalangeal joints [4]. Contraction of the triceps surae muscles shortens the Achilles tendon which produces plantar flexion of the foot, thereby causing heel lift. Forward momentum and body weight shift distally to the next fulcrum at the metatarsophalangeal joints. At heel lift, the windlass mechanism of the foot shortens the plantar fascia by means of the dorsiflexion moment at the hallux [3]. The shortening and lifting of the plantar fascia act as compression to the plantar structures dorsal to the fascia.

The venous foot pump: previous teaching versus current knowledge

Regarding the foot, however, controversial opinions existed regarding the "lesser" importance of the deep versus the superficial drainage systems and their functional mechanisms. Older literature presented the concept of 4 venous systems in the foot (Lejar's plantar venous network, the supra-fascial dorsal venous network, the dorsal veins of the foot, and the medial and lateral plantar veins) [14]. It was previously thought that Lejars' 'rete' or network of plantar veins [15] formed a type of "sponge" that constituted the reservoir of venous blood in the foot. The controversy was also noted as to whether weight-bearing compression or muscular contraction constituted the dominant mechanisms of creating flow in the foot venous pump [16-20]. Early work in high compression (125mmHg) foot

compression pumps showed improved venous return and wound healing in people with diabetic foot wounds [18].

The previous concept of the venous sole of the foot has now been shown to be incorrect. In 2009 the first of many papers from the Sorbonne University detailed the extensive anatomical dissections that rewrote the anatomy books on the plantar venous system in the foot. [10-13, 5]. Subsequently, in Ireland, Corley and colleagues [21] reviewed the literature concerning the anatomy and physiology of the venous foot pump, the general features of which are illustrated in Figure 5.3. Cadaveric dissections in their study confirmed the presence of the "previously unreported" secondary deep plantar arch, together with a deep venous network which enabled more detailed descriptions of patterns of doubling and branching of the primary veins of the foot [21].

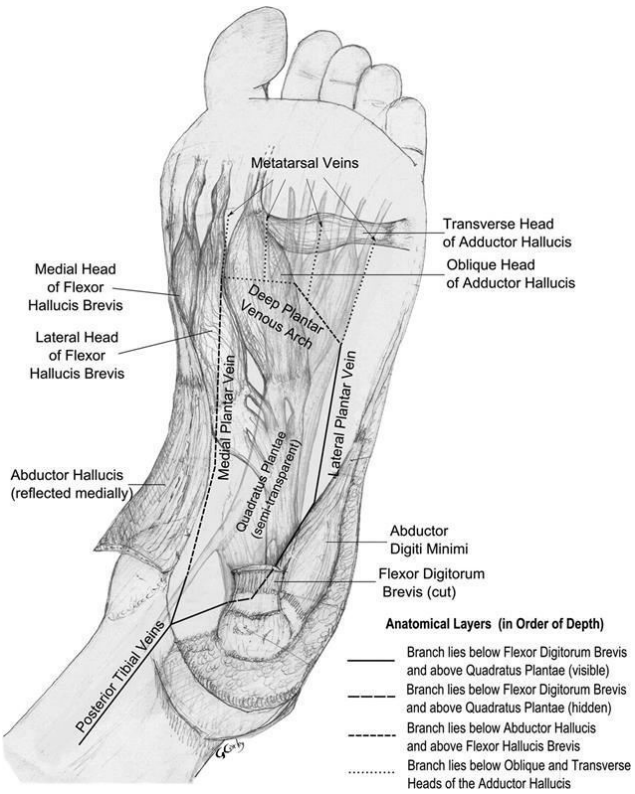

Figure 5.3. Illustration of the general features of the plantar venous plexus.
(Drawing is not to scale). Source: Corley et al [21] reproduced with permission

Pre-dating Corley, the early pivotal and subsequent works of Uhl and Gillot [10-13, 5] show that there is a venous reservoir located deep in the valve-less plantar veins between the plantar muscles. Their studies show that pressure on the lateral heel and dorsiflexion of the

ankle joint at heel strike moves venous blood from the lateral calcaneus to the lateral plantar veins of the supinated foot; as the foot then reaches mid-stance, the compression on the lateral border of the midfoot moves venous blood medially. These converge from deep medial plantar veins proximal to the metatarsal joints to superficial medial marginal veins via medial perforators as a result of both weight-bearing and muscle action on the deep plantar veins during walking, which moves the plantar blood reservoir of between 25 to 35 millilitres upwards to the calves [12]. Their work showed that venous flow is directed from deep to superficial, lateral to medial, which directs flow in the foot posteriorly to the medial calcaneal plexus and from there to the posterior tibial veins, upwards to the calf muscle pump. Their study showed that distal venous flow starts from the foot and from there to the muscular pumps in the calf, thigh and pelvis.

In 2019, Horwood detailed a gait model of flow from the venous foot pump to the calf muscle pump in duplicated papers [22-23]. However, Horwood placed most emphasis on weight-bearing compressive forces and omitted the role of hallux dorsiflexion in muscular contraction of the plantar aponeurosis and musculature under the arch. Recommendations in the Horwood papers were to redesign compression hose, even though it was acknowledged that the natural foot pump could produce more flow than compressive devices, but this was not further explored in terms of diabetes nor converted into clinical advice for the patient with diabetes. [22-23].

Florence University researchers in Italy also carried out a study that confirmed the venous physiology of lateral to medial arch flow [24] as seen simplistically in figure 5.4.

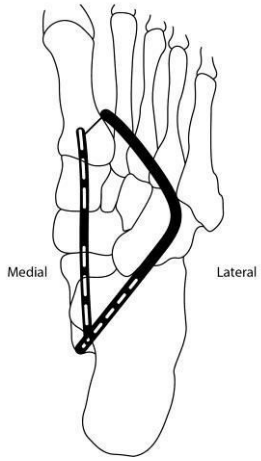

Figure 5.4: Medial venous arch (simple illustration redrawn after Ricci et al [24].

The foregoing findings point to the extraordinary reservoir structure and update our knowledge of the physiology and venous lateral to medial haemodynamics in the plantar foot. Parallels in function and physiology of both systems become apparent.

Discussion

Uhl and Gillot stated that any impairment of the foot pump becomes an important risk factor for chronic vascular disease, for example, in static foot disorder [12]. In 2015, Uhl and Gillot reiterated their prior statement that any foot dysmorphism such as a flat foot (lack of, or reduced medial longitudinal arch) can reduce the efficacy of the foot venous pump and that this, in turn, would impact on the efficacy of the calf venous pump [5]. From this statement, it can be understood that Uhl and Gillot consider a functional medial longitudinal arch necessary for the hemodynamic function of the venous foot pump. More importantly, the dorsiflexion moment of the hallux increases the tension in the plantar fascia, shortening the fascia and lifting the fibrous band into the medial longitudinal arch, thus compressing the deep venous reservoir. This biomechanical action is thus integral to the foot "venous pump" action.

If hallux dorsiflexion is reduced or absent, then shortening of the medial band of the aponeurosis will be negatively affected, while the central band and lateral band may yet partially function. Lack of medial band shortening, in turn, may reduce compression of the medial arch plantar veins, and thus reduce foot venous return. Similarly, if ankle flexion is reduced, the soleus leg pump and gastrocnemius popliteal pump may produce reduced calf muscle venous return.

Surgeons, faced with the objective to prevent venous stasis in the lower limb after surgical procedures, would be the driving force to find technical solutions, particularly in the absence of post-surgical ambulation. A Cochrane review found that intermittent pneumatic compression (IPC) devices mimic the squeezing action on the veins by the foot or calf muscles when walking [25]. Devices have been favoured after surgical procedures to prevent blood stasis complications [26]. In keeping with Uhl and Gillot's findings that the foot venous pump ejects 25 to 35 ml while the calf muscle pump ejects 50 to 60 ml, this gradient finds a parallel in the reported performance rate of calf-thigh devices compared to plantar (foot) compression devices [25].

A foot pump device produces compression by means of a small balloon-like structure plantar to the medial foot. The plantar reservoir ejection fraction of 25 to 35 ml is not unimportant since studies have shown that compression of the foot pump (by a replicating device) is superior to molecular-weight heparin in the prevention of post-surgical thrombosis in the lower limb [27-30].

Of interest to physical anthropology is the now established understanding that the 'start' of venous flow is in the foot venous 'pump'. Ontogenetic development of the lateral column of the foot as described in evolutionary studies [31-33] may have been necessary to enable the compressive flow from lateral to medial, from deep to superficial that evolved into the haemodynamics necessary for sustained bipedal (upright) walking.

Recommendations

The relationship of the venous foot pump to haemodynamics in the foot has received less attention in practical recommendations to patients with diabetes. Extrapolating from the now established relationship of enabled hallux dorsiflexion to foot venous pump-action, several implications for the care of the foot in diabetes arise.

1. ***Avoid mechanisms that reduce foot venous return in diabetes***

Any condition or mechanism that reduces foot venous return and/or impacts negatively on calf venous return will be of special concern to patients with diabetes, given that the necessary cardiovascular (CV) pressure gradients at various segments of the CV system will be compromised. This would apply to all footwear, compression hosiery and in-shoe appliances that could inhibit hallux dorsiflexion necessary to elevate the medial longitudinal arch.

2. ***Find mechanisms to improve foot venous return in diabetes***

Uhl and Gillot suggest treatment (of a foot that lacks a functioning medial longitudinal arch) with a (prescription) inner sole to improve venous flow [5], but they do not describe the structural characteristics of such an inner sole. It is not stated whether it would contain an arch component to produce the necessary medial arch compression and/or other components to provide compression proximal to the lesser metatarsal heads in the location of the deep

plantar veins. Their suggestions require further investigation in future studies using in-shoe components to produce compression of the plantar structures involved in normal gait.

3. Avoid inhibition of intrinsic muscles that are needed for arch elevation

Intrinsic muscle activity occurs at the same time as metatarsophalangeal joint dorsiflexion, as the centre of mass moves anterior to the metatarsophalangeal joint. Inactivity of the intrinsic muscles will lead to wasting of the muscles and loss of strength.

Footwear that restricts the action of the intrinsic musculature of the foot by way of a narrow toe box or mismatched toe box shape can prevent the function of the intrinsic muscles.

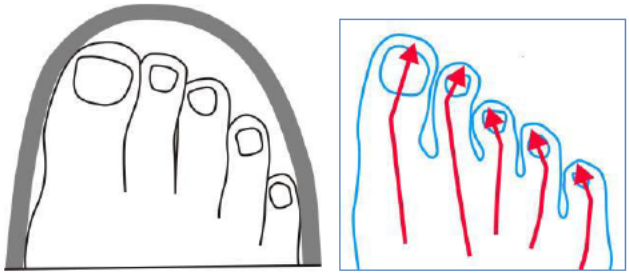

Figure 5.5. Shape mismatch: crowding of toes in a narrow toe box (Source: AT Thompson)

Crowding of the toes in narrow or mismatched toe boxes (Figure 5.5) can cause transverse plane curvature of the toes. It is entirely feasible that this curvature in the transverse plane can inhibit the sagittal plane action of the intrinsic muscles attached to the phalanges.

The interossei and lumbrical (intrinsic) muscles combined with the adductor hallucis muscle are responsible for bracing the longitudinal and transverse arches of the foot [34-36]. The function of the toes is to plantarflex to relieve ground reaction force on the metatarsal heads (Figure 5.6), provide grip and help maintain balance at heel raise [34].

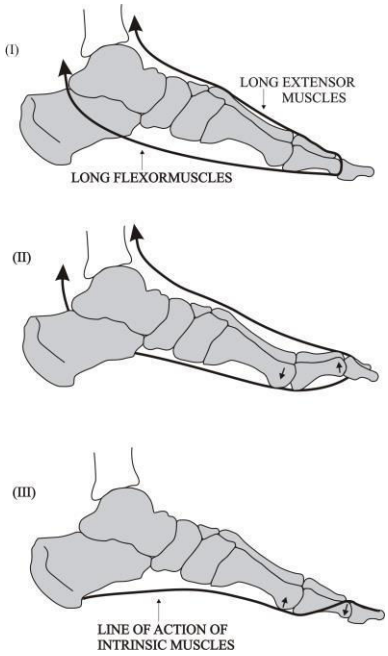

Figure 5.6. Arch bracing action of interossei and lumbrical muscles (redrawn after Stamm [34])

Plantarflexion of the toes results from the combined contraction of the long flexors, interossei and lumbricals (Figure 5.6.i and 5.6.iii). If the interossei and lumbricals are weak and unable to maintain the phalangeal joints in extension (Figure 5.6.ii), then contraction of the long flexors alone would bring the apices of the toes to the ground, thus diminishing their arch bracing action [34].

While it was previously thought that intrinsic muscles of the foot (the abductor digiti minimi, abductor hallucis, extensor digitorum brevis, flexor digitorum brevis, and flexor hallucis brevis) are inactive during the initial part of the stance phase and contract in the latter half of this phase [35], electromyography and MRI have shown that postural demand can influence intrinsic foot muscle activity during stance [37-38]. Disruption of the function of the intrinsic muscles has also been shown to result in a decrease in arch height, as shown in a study on the effect of fatigue on navicular drop [39]. However, in the latter study, no provision was made for the ejection fraction of venous blood from the dorsiflexed foot to continue to the calf muscle pump, then to the thigh muscle pump and into the pelvis. Since the vascular system is continuous, that study's methodology may, in turn, have influenced arterial supply to the muscles, and the reported 'fatigue'.

The relationship between intrinsic muscle weakness and toe deformities and sequelae thereof has been shown in other studies [40-41]. Lack of a functioning windlass has been linked to other sagittal plane pathologies such as hallux limitus and hallux rigidus [42-46] as well as hallux abducto valgus. These deformities and dysfunctions are known risk factors for ulceration in the national guidelines on diabetes care [47].

4. ***Recommend haemodynamic friendly footwear to support neural function in diabetes***

It is important that footwear shape, enhanced footwear flexibility and physical activity promote intrinsic muscle strength to support the arch function in foot haemodynamics. Studies suggest that nerves can regenerate if they are stimulated by physical activity. One study showed that physical activity is associated with reduced odds of peripheral neuropathy among diabetics with normal HbA_1C. Physical activity, together with glycaemic control, is associated with less neuropathy [48]. Voluntary exercise has been shown to positively affect neuronal biology [49-50]. Furthermore, exercise is associated with improvement in neural function [51].

A noteworthy study that investigated clawed toes in the diabetic foot looked at neuropathy, intrinsic muscle volume and plantar aponeurosis thickness [52]. It found that neuropathic feet with claw toes have less intrinsic muscle volume and a thicker plantar aponeurosis. Intrinsic muscle volume could be reduced by as much as 50% [53]. A radiographic study of the windlass mechanism in patients with diabetes mellitus and peripheral neuropathy showed impaired ability to raise the arch from the toe-flat to toe-extended positions [54]. Further studies found that engagement of the windlass mechanism increases the compliance of the arch-spanning structures [55-56].

Further studies are needed to quantify the neural effect of improved foot haemodynamics, together with the stimulus of foot flexibility (hallux dorsiflexion). Such studies could shed light on the potential improvement of neural function in the foot as well as prevention of neuropathy in patients with or without diabetes, through improved flexibility of footwear.

In the PREVUE study [57] plantar resistance exercise was found to be a successful therapy for venous dysfunction. In another study, the extension of the hallux was found to occur during both active walking as well as passive flexion [58]. Considering the findings of the

current review, future studies could investigate the combination of prescription in-shoe inserts with compressive components in combination with or without plantar resistance exercise.

Current footwear design for DFU prevention and/or rehabilitation tends to focus on plantar pressure reduction. Such studies use 200 kPa as a target for peak plantar pressure [59]. However, these design directions may be missing the opportunity to incorporate features to assist foot venous return and thereby, foot haemodynamics. In view of these concerns, particularly since good haemodynamics are necessary for healing and prevention of DFU, further studies are needed to pursue footwear design investigation for patients with diabetes.

Concerning internal construction in shoes for persons with diabetes, further haemodynamic studies are needed to quantify the difference between the venous foot pump blood ejection volume with and without contoured arch filler materials of various densities. This is necessary to pursue the suggestion made by Uhl and Gillot [12] that 'arch support' would be useful to promote the haemodynamic function of the foot venous pump. The location of the venous medial functional unit described by Uhl and Gillot (Figure 5.7) is shown below.

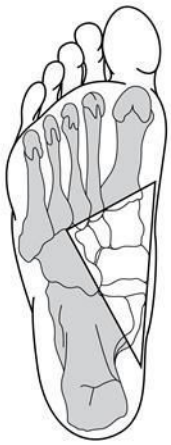

Figure 5.7. Location of the venous medial functional unit (unshaded triangle) as per Uhl and Gillot [12]

Studies have investigated the role of foot posture on the functioning of the windlass mechanism [60-61] while new evidence has been brought in 2020 that it is not the windlass mechanism that converts the foot into a rigid lever, but active muscle contraction [62]. The

function of the intrinsic muscles as shown in studies [63-66] represents another aspect that has direct implications on design and manufacture of footwear to support foot function.

Conclusions

The "medial functional unit" of the venous foot pump described by Uhl and Gillot [12] is mirrored in the phases and dynamics of gait as well as the windlass mechanism in biomechanical function in the foot. This relationship has been established as inter-related processes.

In the interest of exploring all avenues that promote good vascular return in the diabetic foot, it is recommended that the patient's footwear should be examined for the characteristics described herein. As part of a comprehensive diabetes foot assessment and patient education, the examination of shape and flexibility in a patient's footwear, low heel elevation as well as the correct match of first metatarsal flexion position to the corresponding position in the shoe, should be considered.

Studies should be conducted to investigate evidence of the haemodynamic function (if any) of in-shoe components such as an arch filler or a plantar metatarsal pad (shaped bulk placed proximal to the four metatarsal heads in order to provide compression and/or elevation to the metatarsal shafts) and other similar components specifically for patients with diabetes. This aspect of foot function, in its simplicity, has been neglected and deserves more attention, given its relevance to the promotion of blood flow in the foot in diabetes.

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Chapter Six: The dysmorphic metatarsal parabola in diabetes, clinical examination and management: a narrative review

Foot posture is important in diabetes, particularly since the neuropathic diabetic patient may present with motor neuropathy in addition to sensory neural deficits. Examination of anatomical components of the foot can offer insight into the architecture of the forefoot static stance that enables or disables the load-bearing and balancing function of the human foot. An examination that does not feature in guidelines on assessment of the diabetic foot is that of assessing whether a metatarsal parabola is present or malformed.

The metatarsal 'parabola' (in the transverse plane) is so-called since the cascade of the differing lengths of the metatarsals form a parabola, defined as the intersection of an arc with a flat (plantar) surface. The parabola serves a function in the rollover motion or forefoot rocker of the foot at terminal stance before heel rise, as well as providing stability and balance in static stance. A further function is ensuring that the lever-action at the first metatarsophalangeal joint takes place, at dorsiflexion of the hallux.

The purpose of this paper is to summarise the literature regarding methods of measuring the metatarsal parabola, dysfunction of the foot due to a dysmorphic metatarsal parabola; clinical examination and management in resource-limited diabetes care.

Publication details

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Abstract

Foot posture and function is important in diabetes, particularly since neuropathy in diabetes may present with motor in addition to sensory neural deficits. Examination of anatomical components of the foot can inform on the architecture of the forefoot that enables or disables the load-bearing and balancing function of the human foot. An examination that does not feature in guidelines on assessment of the diabetic foot is that of assessing whether a metatarsal parabola is present or malformed.

The metatarsal 'parabola' (in the transverse plane) is so-called since the cascade of the differing lengths of the metatarsals form a parabola, defined as the intersection of an arc with a flat (plantar) surface. The parabola serves a function in the rollover motion or forefoot rocker of the foot at terminal stance before heel rise, as well as stability and balance in static stance. A further function ensures that the lever-action at the first metatarsophalangeal joint takes place, on dorsiflexion of the hallux.

This narrative review summarises the literature regarding methods of measuring the metatarsal parabola, dysfunction of the foot due to a dysmorphic metatarsal parabola; clinical examination and management in resource-limited diabetes care. It documents the short first metatarsal (SFM) as a risk factor for diabetic foot ulceration. Examination for identification and management of dysmorphic metatarsal parabolae is recommended for foot examinations in diabetes care.

Keywords: brachymetatarsia; short first metatarsal; SFM; metatarsalgia; foot examination; podiatry; prescription innersole; custom orthosis; Morton's extension; shoe insert.

1. Introduction

Archimedes is recorded as having said, "Give me a place to stand, and with a lever, I will move the whole world" [1]. Lower limb amputations in diabetes can be traced back to a foot lesion, which if untreated, can progress to an ulcer and consequent morbidity [2]. A clear link between diabetic neuropathy, increased plantar pressure, formation of callus and ulceration has been shown [2−4]. Prevention of plantar foot ulceration is therefore paramount to prevent lower limb amputations and reduce the resultant socio-economic burden [5-6]. Global and local guidelines on the management of diabetes note that callus formation

develops in response to pressure and/or friction and should be referred to a podiatrist or foot team for removal, investigation of aetiology and prevention of recurrence [5-10].

Foot posture is important in diabetes, particularly since the neuropathic diabetic patient may present with motor neuropathy in addition to sensory neural deficits. Examination of anatomical components of the foot can offer insight into the architecture of the forefoot static stance that enables or disables the load-bearing and balancing function of the human foot. One such examination (that has not yet featured in guidelines on assessment of the diabetic foot) is that of determining the presence or absence of a functional metatarsal parabola.

The metatarsal 'parabola' is so called since the cascade of the differing lengths of the metatarsals as they touch the plantar surface forms a parabola, defined as the intersection of an arc with a flat surface. The parabola serves a function in the rollover motion or forefoot rocker of the foot at terminal stance before heel rise, as well as the provision of stability and balance in static stance. A further function is ensuring that the lever-action at the first metatarsophalangeal joint (MTPJ-1) takes place, i.e. that the hallux can dorsiflex.

An example of an incomplete metatarsal parabola is one in which there is either brachymetatarsia of the first metatarsal (short first metatarsal or SFM or 'Index minus foot'), or a longer first metatarsal ('Index plus foot') such that the medial arc of the parabola (formed by the lesser metatarsophalangeal joints) does not pass through the first metatarsophalangeal joint, as shown in Figure 6.1.

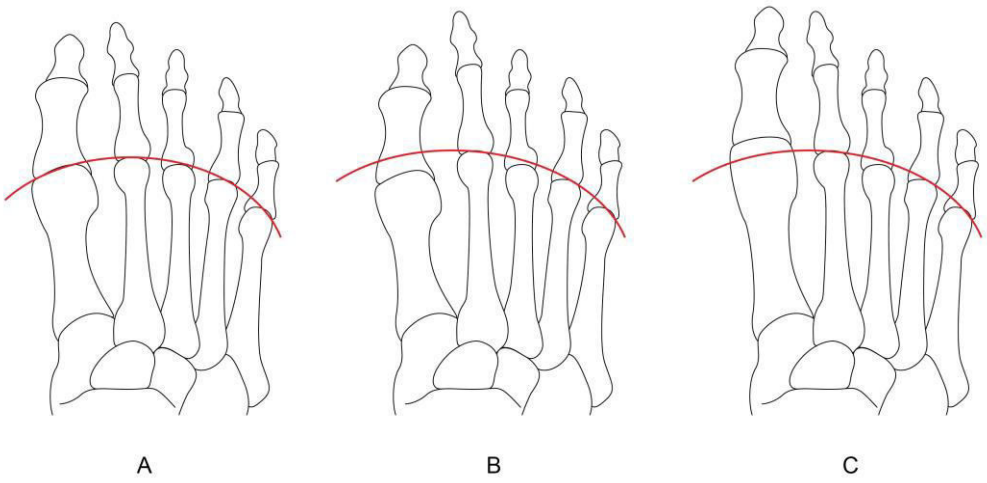

Figure 6.1. Balanced parabola, short first metatarsal, long first metatarsal.

2. Review method

Trial advanced searches were conducted beforehand to refine the Boolean search terms. Record searches were conducted across three electronic medical databases together with the 87 databases represented on the WorldCat and WorldCat.org databases. Advanced searches used the key phrases “metatarsal parabola”, “brachymetatarsia”, “metatarsal protrusion”, “short first metatarsal” and “short first ray”. The databases and Boolean terms used for this process are listed in Table 6.1. The searches returned a total of 3988 records. Records that purely concerned surgical correction techniques were removed. Duplicate records were then removed. Abstracts were read to assess relevance to the research aims. In reading the remaining records, those records concerning methods of metatarsal length measurement and associated references and their references were also read for relevance and inclusion.

Table 6.1. Databases searched to the year 2020.

Databases	**Search terms**
PubMed	((((((English[Language]) AND (metatarsal parabola[Title/Abstract]) OR (brachymetatarsia [Title/Abstract]) OR (metatarsal protrusion[Title/Abstract]) OR (short first metatarsal[Title/Abstract]) OR (short first ray[Title/Abstract]))))
World Cat (online university library)	ln:(English) AND ti:(metatarsal parabola) OR ti:(brachymetatarsia) OR ti:(metatarsal protrusion) OR ti:(short first metatarsal) OR ti:(short first ray)
Google Scholar	"metatarsal parabola" OR "short first metatarsal" OR "Metatarsal protrusion" OR "short first ray" OR "brachymetatarsia"
Cochrane Library	"metatarsal parabola" OR "short first metatarsal" OR "Metatarsal protrusion" OR "short first ray" OR "brachymetatarsia"

3. Measurement methods used to define the metatarsal parabola

Studies that have looked at the relative lengths of all metatarsals have explored the measurement of the “metatarsal parabola” [11-12]. Methods for measuring metatarsal lengths may utilise x-ray examinations, direct bone measurements and clinical palpation. X-ray examinations are costly, require primary care patients to travel to x-ray facilities, result in absence from work and decreased productivity, and involve ionising radiation exposure.

Direct bone measurements preclude living subjects as these can only be done on osseous material, which could be affected by necrosis. Studies have shown that palpation-based methods are simple, cheap and non-invasive, in addition to having a high degree of reliability [13-14].

Viladot investigated metatarsalgia caused by biomechanical anomalies in the forefoot [15]. In 1973, he classified the forefoot by relative toe and metatarsal lengths. He used the description "Greek foot" to describe a foot in which the second toe is longer than the first [15]. The metatarsal length formulae are index plus 1>2>3>4>5; index plus-minus 1≥2>3>4>5; and Index minus 2>1>3>4>5. In a study of 1000 (presumably European) feet, Viladot recorded 16% index plus, 26% index plus-minus and 56% index minus [16]. The terminology of "Index plus, index plus-minus and index minus" is still used in the current orthopaedic surgical literature.

Controversy exists as to what quantifies or defines the shortness to be termed a "short first metatarsal". Several authors have published what they consider to be the point of difference between the length of the first metatarsal and some other reference point for the first metatarsal to be termed "short". A short first metatarsal has been defined as one that is shorter in relative length of articulation than the second metatarsal by more than 3 millimetres [13]. Hardy and Clapham had arrived at a mean protrusion of 4 mm between the first metatarsal to second metatarsal [17]. Different authors have used terms such as "Morton's foot", 'Index minus foot', and 'short first metatarsal' to refer to brachymetatarsia of the first metatarsal. Figures 6.2 and 6.3 illustrate the different measurement approaches taken by studies over a period of more than 80 years.

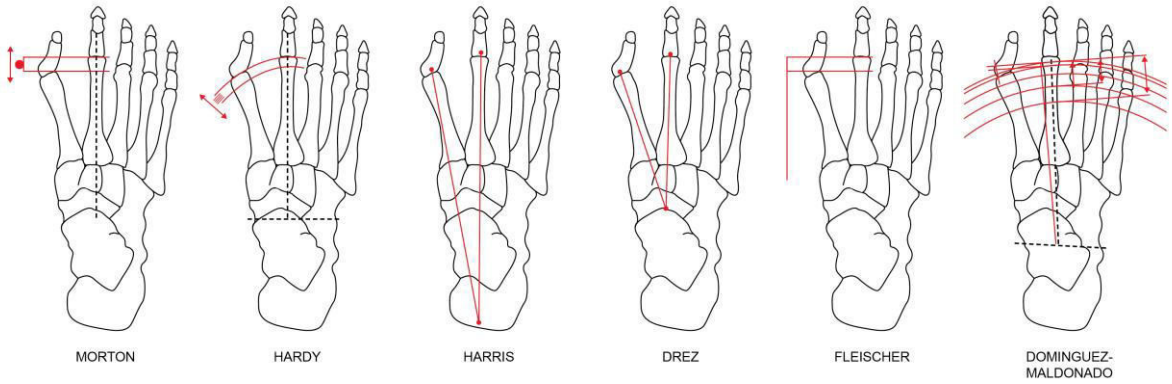

Figure 6.2. Approaches to measurement of first metatarsal relative length (re-drawn) Morton [18] 1935, Harris [19] 1949, Hardy [17] 1951, Drez [20] 1980, Dominguez-Maldonado [11] 2014 and Fleischer [21] 2017.

Figure 6.3. Nilsonne metatarsal protrusion index [21]

The approach by Fleischer, based on Nilsson's measurement method [21] gave rise to the measurement techniques of Maestro and Barroco. Their methods also rely on radiography and are being used by surgeons who advocate a simplistic metatarsal length correction such that 1=2>3>4>5 [22-24]. This approach echoes the opinion expressed by Morton that "one of the requirements for the ideal foot function is an equidistance of the heads of the first and second metatarsal bones from the heel", although the point at the heel from which to take this measurement was not defined [18].

4. Consequences of a dysmorphic metatarsal parabola

4.1 Imbalance in load distribution, poor foot alignment

In a 1987 study, Cavanagh refuted what he referred to as a theory of tripod load distribution in favour of a six-point load distribution under the forefoot, consisting of the two sesamoids under the MTPJ-1 and the four lesser metatarsal heads [25]. He found that variations in the length of the first and second metatarsals (metatarsal protrusion) could alter foot alignment during stance. A study in 2009 on the role of the first metatarsal and hallux in balance

showed that malfunction of the hallux in flexion would cause dysfunction of the foot by interfering with balance and therefore causing pressure shifting in the foot [26]. This is particularly important in diabetes care since balance deterioration can also be present in plantar surface sensory dysfunction [26-27].

4.2. Disruption of the windlass mechanism

A short first metatarsal (SFM) structural attribute can disrupt the windlass mechanism of the first metatarsophalangeal joint (MTPJ-1) and affect foot posture [29-31]. One of the compensations for SFM is an abducted foot posture which can result in transfer hyperkeratosis ('callus') or helomata dura ('corns') overlying the second or lesser metatarsals, in response to increased pressure or friction. Another possible compensation is a flexion moment on the interphalangeal joint of the hallux (more distal to the MTPJ-1 and therefore an attempt to move the non-functioning fulcrum of the MTPJ-1 to that of the IPJ-1). This results in increased pressure and a diagnostic clue in the form of transfer hyperkeratosis on the medial and plantar surface of the proximal IPJ-1 and phalanx of the hallux. These are common sites of hallux ulceration in diabetes.

4.3. Joint stresses and instability

Dudley Morton considered that the metatarsal parabola functions to provide stability during the stance and propulsive portion of gait, as weight is transferred to the metatarsal heads [18]. In a person with SFM, during weight transfer to the forefoot (the metatarsophalangeal joints), Morton stated that the gradual cascade of transfer was disrupted. If the first metatarsal was too short, Morton believed that it could not assume the body weight in a balanced way and that compensatory changes in foot posture might occur. In support of Morton's concept of lateral movement of pressure, one study [32] found that patients with a Morton's foot registered higher pressures beneath the second metatarsal (mean of 320 kPa) compared to a non-Morton foot control group (mean 243kPa). Another study found that 60% of patients who presented with metatarsalgia displayed lesser metatarsophalangeal joint instability [33]. A further study considered that the aetiology of lesser metatarsophalangeal joint symptoms was a deficit in first ray weight-bearing [34]. In a 2006 critical analysis of Morton's concepts, Glasoe and Coughlin conducted a review which found support for Morton's notion that weight can shift laterally in individuals who have a short first ray [35].

Dudley Morton, with limited technology, postulated various other concepts such as the "axis of balance", hypertrophy of the second metatarsal and separation between the medial cuneiforms as indicators of increased mobility of the first ray. Glasoe and Coughlin found little scientific evidence to support these concepts [35]. They noted that Morton did not adequately consider the influence of the plantar aponeurosis in the stabilisation of the forefoot [35]. Medial longitudinal arch height and calcaneal inclination are two indicators of muscle balance in foot posture, yet these were not measured by Morton.

4.4. *Pathologies found in association with SFM or Index minus feet*

On examination in routine Podiatric practice in South Africa, some patients present with painful foot pathology related to a faulty metatarsal parabola, more commonly termed a 'short first metatarsal' (SFM) or "Index minus" foot. Transfer metatarsalgia can occur as the lesser metatarsal heads assume the body weight, with resultant overlying formation of callus (hyperkeratosis) and/or corns (helomata dura).

SFM is commonly found in conjunction with metatarsalgia, plantar hyperkeratosis, plantar heloma durum [36] and may be associated with pathologies related to compensatory altered gait such as acquired pes planus, hallux valgus and hallux limitus or rigidus.

In some instances, compensation for the lack of function of the MTPJ-1 fulcrum may result in hyper-dorsiflexion of the distal hallucal phalanx. The resultant jamming of the articular surfaces at MTPJ-1 can result in limitation of joint range of motion and lead to the condition called hallux limitus, or as the condition progresses, hallux rigidus. The 'jamming' of the articular surfaces of the first metatarsal and the proximal phalanx may give rise to articular capsule thickening of the MTPJ-1, often mistaken by patients as a "bunion" or hallux valgus.

SFM may relate to the compensations for the altered MTPJ-1 fulcrum position and function (loss of moment at MTPJ-1). Since the fulcrum of MTPJ-1 in SFM is more proximal than that of MTPJ-2, one of the compensations could be increased flexion of the first ray for MTPJ-1 to become plantigrade. Another compensation could be the abduction of the foot in order to shift the fulcrum laterally over the second metatarsal head, leading to callus and helomata (corn) formation due to overload of the lesser metatarsal structures. Compensatory abduction of the forefoot, combined with rotation over the second metatarsal may increase pronatory rotational forces over the first metatarsal head, increasing the risk of hallux valgus

formation in a foot at risk of hallux valgus (due to other inherent and hereditary anatomical risk factors such as rounded articular facets) [37].

Lack of a functioning fulcrum at MTPJ-1 will restrict the windlass mechanism as previously described [38]. The windlass mechanism forms the primary part of the sagittal plane foot function, stability, and propulsive gait. A restricted windlass mechanism may be implicated in the development of acquired pes planus. Although SFM may be implicated in the development of such pathologies as acquired pes planus, hallux valgus, hallux limitus and hallux rigidus, an investigation into the relationship of SFM and these latter pathologies is outside the scope of this study.

4.5 Impact on the foot venous pump mechanism

Importantly, extrapolating from what is now known regarding the inter-linked windlass mechanism (via hallux dorsiflexion) and the foot venous pump [39-40], a non-functioning windlass will impact negatively on foot venous return.

5: Clinical examination and non-surgical management in resource-limited diabetes care.

5.1. Palpation method for measurement of metatarsal head positions

Podiatric clinical palpation technique is taught to identify, inter alia, the position of the metatarsal heads. The simple approach is a plantar palpation and marking method (Figure 6.4).

Figure 6.4. Plantar palpation and marking of metatarsal heads (centre of joint capsule) to identify first metatarsal brachymetatarsia.

Note in Figure 6.4. above, the metatarsal parabola is dysmorphic, hence tension on the joint resulted in hallux limitus, compensatory callus on the distal IPJ and heel enthesitis due to increased torsion on the plantar aponeurosis due to compensatory abductory gait.

A study in 1994 established the validity and reliability of the dorsal palpation technique taught in the United Kingdom when compared to radiographic measures [14]. Two decades later, another study established intra-observer reliability of measuring first and second metatarsal protrusion by means of dorsal palpation [13].

5.2. Prevalence in a KwaZulu-Natal sample diabetic population

Studies suggest different prevalence figures of SFM/Index minus/Morton's foot in different populations [17, 19-21]. It is not well documented whether patients with diabetes who present with transfer callus on the lesser metatarsophalangeal joints, may also present with a short first metatarsal (SFM). In a sample of 301 patients with diabetes examined by metatarsal palpation in KwaZulu-Natal, South Africa, [41] the frequency of SFM with hyperkeratosis was 24.6% (n = 74) for the right foot and 24.3% for the left foot (n = 73 excludes an amputee) as shown in table 6.2.

Table 6.2. Frequencies of SFM and signs of MTPJ-1 dysfunction in diabetes [41]

Signs of MTPJ-1 pathology (n = 301)	**Frequency right foot**	**Frequency left foot**
Short first metatarsal (SFM)	24.6%	24.3%
Hallux abducto valgus (HAV)	8.0%	8.3%
Prominent MTPJ-1 (pathognomonic of SFM, Hallux limitus, Hallux rigidus)	28.6%	28.2%
Hyperkeratosis (Corns and callus)	36.2%	36.2%

Glasoe and Coughlin made the statement that "problems associated with the Morton Foot are not common" [35]. The data in table 6.1 would appear to refute that statement, although not all hyperkeratosis aetiology can be ascribed to pressures from imbalance since incorrect footwear may also play a role. In 2017 a study associated a 2 to 5 times higher risk of plantar plate pathology of the second metatarsophalangeal joint, with shortness of the first metatarsal greater than 4mm relative to the length of the second metatarsal [21].

5.3 Podiatric non-surgical treatment modalities

Dudley J Morton (not to be confused with Thomas G Morton after whom the condition known as Morton's neuroma in the foot is named) recorded and measured brachymetatarsia of the first metatarsal in an African sample [18], which he termed a "short first metatarsal" (SFM). Morton believed that SFM gives rise to different leverage stresses and changes to structural stability [18]. As treatment, Morton suggested the use of a "compensating insole" containing a platform beneath the head of the short first metatarsal which would extend the length of the hallux [18]. This is different to the construction method employed by South African-trained podiatrists, in which the extension pad (or "Morton's extension") does not necessarily extend the entire length of the hallux (Figure 6.4).

Orthopaedic surgeons may elongate the first metatarsal by means of distraction osteogenesis or may shorten the diaphysis of the longer second metatarsal [42−43]. In contrast, podiatrists gradually remove the dermal hyperkeratosis by sharp debridement followed by low-speed

dermabrasion. This is followed by a clinical biomechanical examination. The podiatrist will thereafter construct a functional in-shoe device to correct the faulty biomechanics of the first metatarsophalangeal joint and/or related structures that may have become dysfunctional due to compensatory forces. A recessed 'kinetic wedge' component is fabricated, based on a field of study within biomechanics called sagittal plane biomechanics (the study of foot function related to the sagittal plane) [30]. This is paired with a 'Morton's extension' for the hallux embedded within an orthosis or prescription innersole to be worn inside suitably flexible footwear (Figure 6.5). Prescription inserts are usually affixed with Velcro ® as this enables the insert to be removed and re-positioned in different pairs of a patient's footwear.

Figure 6.5. Medial, plantar and dorsal views of a custom prescription innersole as used in conservative treatment of brachymetatarsia of the first metatarsal with heel enthesitis caused by torsional strain on the plantar fascia.

The prescription innersole pictured in Figure 6.4. incorporates sagittal plane offloading of the MTPJ-1, a Morton's extension for the hallux, offloading of the calcaneal insertion of the plantar aponeurosis, a medial longitudinal arch component, medial heel wedging to relieve tissue stress and a plantar metatarsal pad beneath the metatarsal diaphyses 2-4 to correct excessive plantarflexion of the metatarsals and restore the transverse arch.

The hallux extension component serves to move the fulcrum of the first metatarsophalangeal joint distally and restore the lever arm of the first ray to the hallux [44] while the kinetic

wedge excavation creates a ‘pocket’ for the first metatarsophalangeal joint. This creates a counteracting moment against the flexor tendon from the valgus (arch) component proximally, thus overcoming the tension on the joint and allowing it to flex.

The MTPJ-1 in a dysmorphic metatarsal parabola may articulate when non-weight-bearing. When a dysmorphic parabola is noted in conjunction with over-pronation, a Hubscher Manoeuver (a.k.a ‘Jack’s test’) can establish the degree to which the hallux can dorsiflex on weight-bearing [45]. The Hubscher Maneuver or Jack’s test is performed with the patient unshod, relaxed weight-bearing, head up and facing forward. The patient is asked to not assist with foot motion in any way. The examiner grasps the proximal phalanx of the hallux and manually attempts to dorsiflex the hallux at the MTPJ-1. The test can reveal joint stiffness, limitation in joint range of motion (functional hallux limitus) and inability to flex (functional hallux rigidus).

6. Implications for practice

In conjunction with the Jack’s test for hallux dorsiflexion while weight-bearing, palpation and skin mapping of the metatarsal heads to establish the presence of a functional metatarsal parabola or absence thereof, can be taught to all members of the multi-disciplinary team in resource-limited diabetes care. This is particularly important since patients with diabetic neuropathy may not present with protective metatarsalgia sensation preceding ulceration. Paper mapping can enable patient education and improved comprehension of footwear and footwear insert guidelines.

Both surgical and conservative approaches satisfy the objective of re-distributing plantar pressure across dysmorphic metatarsal formulae to reduce hyperkeratosis but differ markedly in terms of complexity, cost, and suitability for low-resource diabetes care [46]. The orthopaedic approach is invasive and progresses through radiological imaging, surgery, post-operative recovery and rehabilitation. The podiatric approach is non-invasive and progresses through non-invasive examination, pen-and-paper mapping, custom made or individualised in-shoe devices, fitting and patient education.

7. Discussion

Compensatory abduction and thereby hyper-pronation due to a dysmorphic curve in the metatarsal parabola is implicated in the reduction or loss of hallux dorsiflexion in gait [45].

Many studies have supported the biomechanical effect of either a long or short first metatarsal in the aetiology of forefoot pathology such as hallux limitus, hallux rigidus, forefoot plantar pressure, Morton's neuroma, abductory dysfunction resulting in functional pes planus and potential for calcaneal enthesitis due to torsional forces acting on the plantar aponeurosis [16, 47-53].

We are unaware of any other studies documenting the SFM as a risk factor for diabetic foot ulceration. Since almost a quarter of the patients with diabetes examined in a South African 2019 study presented with SFM with hyperkeratosis, with a potential increase of hyperkeratotic build-up and potential progression to ulceration, this should be considered a risk factor for DFU [41]. As such, we recommend that manual examination for identification and management of dysmorphic metatarsal parabolae should form part of foot examinations in diabetes care.

Authorship

ATT conceptualised and carried out the literature searches and prepared the first draft of the manuscript. BZ provided critical input and revision in the drafting of specific sections, CA provided direction and overall critical review.

Conflicts of interest

The authors state that they have no conflicts of interest, neither individually nor collectively.

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Chapter Seven: Peripheral vascular implications - undesirable footwear characteristics

Since hallux dorsiflexion in the windlass mechanism has been shown to be an integral part of the foot venous pump action, this concept underscores further insights into characteristics of footwear that can be considered undesirable for good haemodynamic foot function.

7.1 Inflexible footwear can inhibit hallux dorsiflexion

Rigidity and inflexibility of foot coverings are used to restrict joint movement [1]. Similarly, immobilization may be required for the management of pathologic states of the first metatarsophalangeal joint [2]. Thus, it is entirely feasible that rigid or inflexible footwear soles could decrease the medial functional unit of the foot venous pump by preventing or inhibiting dorsiflexion of the hallux and lesser toes. This, in turn, will inhibit the windlass mechanism such that medially compressive muscular action in the foot could diminish, and venous foot return be impaired.

7.2 Rocker bottom footwear can prevent hallux dorsiflexion range of motion

Rigid soled or thick soled shoes that cannot flex at a matching position for the flexion of the metatarsophalangeal joints can inhibit hallux dorsiflexion and thus reduce the arch raising function of the windlass mechanism. One answer to promoting ankle flexion in, for example, thick inflexible soled shoes, is to form a “rocker bottom” or exaggerated toe-spring within the sole. While this allows the ankle to act as a fulcrum, the windlass mechanism in the foot is impaired since hallux dorsiflexion range of motion is substantially reduced [2]. Deep midfoot muscular action is prevented since the foot is passively rocked forward by momentum rather than windlass muscular compression.

The rocker sole was the most reported design feature in a recent systematic literature review on footwear and insole design features [3]. It reported many configurations of apex position, apex angle, rocker angle, rigidity and hardness in order to reduce peak pressure. However, alternative methods of offloading pressure that would yet retain or promote the haemodynamic function of the foot venous pump are yet to be considered. Further studies are needed into specific types of shoe inserts in conjunction with variations of rocker soles that would interface more closely with the foot to assist compression of the foot venous pump

7.3 Mismatched flexion position in footwear can inhibit dorsiflexion of the hallux

A further reduction or limitation of venous foot return can be found in the construction of footwear in which the built-in flexion position in the shoe does not match the flexion position of the first and lesser metatarsophalangeal joints. Mismatched flexion points in footwear can inhibit dorsiflexion of the hallux and thereby impact negatively on the windlass mechanism. In the present work, a study on metatarsal lengths and mismatched footwear forms the published manuscript in this chapter. The results were also presented as a potential DFU risk factor at the World Congress of Podiatry in 2019 (Appendix 18).

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Flexion location of the first metatarsophalangeal joint and the location of forefoot bend in general purpose women's footwear

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ABSTRACT

Background: General purpose footwear could have a built-in flexion location which may not match the anatomical fulcrum location for an individual's foot. Mismatched fulcra impact on joint function, and may delay healing of an injured first metatarsophalangeal joint (first MP joint). This study compared the location of the first MP joint in an asymptomatic sample of the South African female population to the bend location set within the lasts (used by footwear manufacturers) to find whether mismatches of the flexion locations of the joint to the bending location of the footwear were likely.
Methods: The study used a three dimensional foot measurement database of 453 female participants to find the fulcrum location of the first MP joint. The distance between the heel and the first MP joint was expressed as a percentage of the overall length of the unshod foot. Similar measures for sandals and closed shoes were derived, and all were compared to manufacturer last data.
Results: The location of first MP joint ranged from 70% to 79% of total foot length, significantly different from last design specifications of 63% or 66% ($p < 0.0001$). The range of first MP joint fulcrum locations in the same size feet occurred in a wide 24 mm mediolateral band under the forefoot, termed a flexion zone.
Conclusions: The first MP joint cannot properly function as a fulcrum unless footwear has a matching flexion location. Footwear designs should incorporate a wide flexion zone located under the forefoot to permit the range of first MP joint flexion locations. Recommendations to patients are to select appropriate flexible footwear to prevent shear forces, reduce strain, prevent injury and enable range of motion function and healing of injury.
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1. Introduction

Although some work has been reported on specialized footwear for post-operative orthopaedic recovery [1,2], little is found to connect orthopaedic foot knowledge to the parameters that footwear manufacturers use to make general purpose footwear. The function of the first metatarsophalangeal joint (first MP joint) is adversely affected when the fulcrum of the shoe does not match the fulcrum location of the joint [3]. Adequate range of motion of the first MP joint is dependent on adequate dorsiflexion [4]. The location of flexibility in the shoe is important to allow for a natural range of motion dorsiflexion during the propulsion phase of gait. We thus investigated whether actual foot measurements support the specifications presently used to manufacture general purpose footwear.

In footwear design, last designers position a set location for the flexion location of the first MP joint. European guidelines position the fulcrum at 66% of overall last length for sandals as well as shoes [5,6]. North American last-making guidelines place the fulcrum at 63% of overall last length [7].

Since patients either wear closed shoes or sandals post-operatively, we investigated for differences between sandal as well as closed shoe last lengths. It was found that, for cosmetic appearances, shoe manufacturers allow less toe space beyond the distal ends of the toes to the end of footwear in an open sandal than in a closed toe shoe [7]. The result is that the last for a sandal is shorter compared to that of an open shoe, yet the location of the forefoot bend for a shoe or sandal is set at the same percentage of overall last length. This results in a different bend location from shoe to sandal. To illustrate this, assume a shoe last length of 170 mm. The bend location for the first MP joint would thus be located at 112 mm (using 66% of overall last length). The corresponding sandal last would be 163 mm long in which 66%

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of overall last length would place the bend location for the first MP joint at 108 mm, resulting in a variance of 4 mm from that of the closed shoe in this example.

The first question asked was whether the actual location of the first MP joint in an unshod measured sample was significantly different from the flexion point location of the first MP joint as set by footwear manufacturers for sandals and closed shoes. The second question asked was whether other variables such as population group, age, weight, foot breadth (at the metatarsal break) and forefoot girth are significantly associated with the location of the first MP joint.

2. Participants and methods

The primary author (ATT) developed a three dimensional (3D) database of foot measurements by laser and point scanning of the right foot of 510 female participants [8]. Participants were randomly selected from a large volunteer pool of working women at the University of Johannesburg and the University of Kwa-Zulu Natal over a period of four months. In addition, a convenience sample of female crew members from the national airline, a national media broadcaster and a church group was included. In descriptive summary, participants' ages ranged from 21 to 69 years, their weight from 34.7 kg to 150.9 kg and their Body Mass Index (BMI) from 13 to 56 BMI. An earlier foot measurement survey in 1954 had addressed a limited group of South African white female adult feet [9]. To rectify the lack of population group representation in the older study, all four major population groups were represented in the new study as required by South African government statistics so that historical inequalities of focus can be redressed [10]. The names given to these population groups for statistical research purposes are Black African, White, Indian/Asian and Coloured (a local distinct population who have ancestry from African [Khoisan and Bantu], European and Asian [Austronesian and South Asian] ethnic groups) [11]. A pilot study on 10 participants was undertaken to establish inter-rater reliability and to verify the reproducibility of the scanner and stylus instrumentation.

A hand-held laser scanner (FastScan, USA) captured a 3D image of the right foot of each participant by means of successive scanning sweeps. A special platform positioned the foot during scanning. Each participant's foot was guided into a block of orthopaedic impression foam in relaxed calcaneal stance position in one-legged weight bearing [12] and kept immobile. The negative foam impression of the plantar surface of the foot was scanned after a dorsal surface foot scan and digital stylus marking of bony landmark points. Post-processing custom software (Telmo, USA) digitally combined the dorsal and plantar scans to form a 3D image of the foot (Fig. 1).

Linear measurements were derived using custom software. Data for 53 of the 510 participants were excluded due to scanning inclusion errors flagged by the post-processing software. The dataset extracted for this study included data for selected palpated bony landmarks, gender, population group, age, weight, height, calculated BMI, foot length, foot breadth and forefoot girth.

2.1. Ethics

The study was conducted in accordance with the Helsinki Declaration. The Biomedical Research Ethics Committee of the University of KwaZulu Natal, College of Health approved the current analytical study via Ethics Clearance BCA058/17 dated 27th March 2017. Informed consent was obtained for data collection from 510 adult female participants under the prior Ethics Clearance Certificate EC212004/009 from the University of Johannesburg.

2.2. Variables

Each landmark point captured (as shown in Fig. 2) is an X, Y, Z coordinate. Cartesian arithmetic was used to derive the linear distances between selected landmark points.

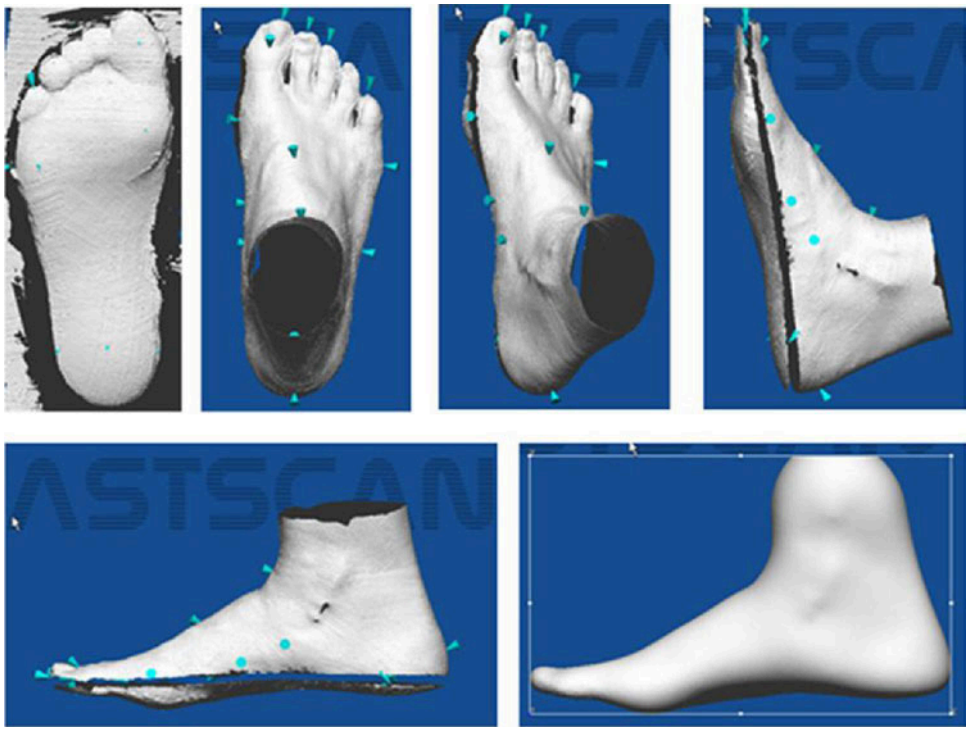

Fig. 1. Three dimensional foot surface data capture. Positive scan halves are fused by custom software into one three-dimensional object surface; blue cones indicate stylus point marking of bony landmarks (Thompson [8]). (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

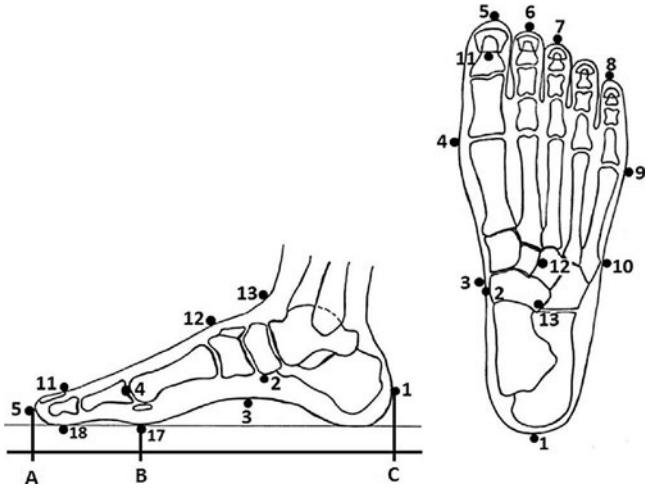

Fig. 2. Medial and dorsal representation of 18 surface palpated landmark points for stylus point data capture (Thompson [8]). Landmark points were used to derive Foot Length (A–C) and Heel to first metatarsophalangeal joint Length (C–B).

For the purposes of this study, the selected measurements were foot length (from landmark 1 to 5) and heel to first MP joint distance (from landmark 1 to 17), which we term Heel-1MPJ length. Based on landmark data, Fig. 2 illustrates the derived foot length (distance A–C) and the Heel-1MPJ length (distance B–C).

- Foot length (mm)—defined as the distance from the most proximal surface of the heel to the distal tip of the hallux or longest toe.
- Heel-1MPJ length (mm)—defined as the distance from the most proximal surface of the heel to the first MP joint landmark in a medial view.
- Heel-1MPJ expressed as a percentage of foot length (%)—calculated as $\frac{\text{Heel 1MPJ length}}{\text{Foot length}} \times 100\%$

To postulate what would occur in lasts for both types of footwear across the sample of feet, 8 mm and 15 mm was added to each foot length (represented by the dotted lines in Fig. 3) to obtain the theoretical last lengths for a sandal (A_1 to C in Fig. 3) and a closed shoe (A_2 to C in Fig. 3), respectively. The location of each first MP joint was then re-calculated as a percentage of overall last length for the two types of lasts.

The following variables were investigated in the study:-

Heel-1MPJ % of sandal length (%)—calculated as $\frac{\text{Heel 1MPJ length}}{\text{Foot length}+8} \times 100$.

Heel-1MPJ % of closed shoe length (%)—calculated as $\frac{\text{Heel 1MPJ length}}{\text{Foot length}+15} \times 100$.

Gender (F)—this study included only female participants.

Population group—participants self-identified their ethnicity based on the four population groups as previously defined in the South African governmental census: Black, Indian or Asian, White and Coloured [10,11]. Each participant was allocated to one of four sub-samples based on their self-identification, and random selection continued until each sub-sample contained at least 125 participants.

Age (years)—as self-reported by the participant.

Weight (kg)—as measured on a medical digital scale (Beurer, Germany).

Height (m)—as measured using a digital stadiometer (Seca, Germany).

Body Mass Index (BMI)—calculated as $\frac{\text{Weight}}{\text{Height}^2}$.

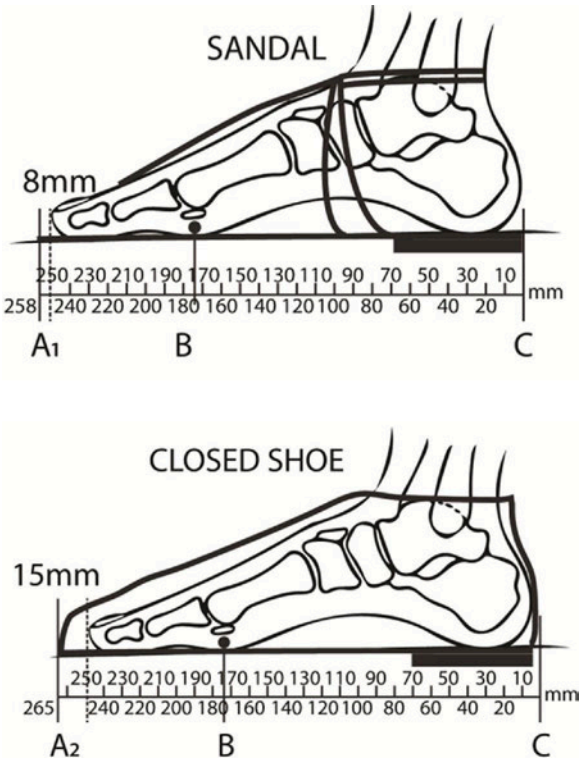

Fig. 3. Example sandal last above allows 8 mm toe clearance ahead of toes ($B–A_1$) while corresponding closed shoe last below allows 15 mm toe clearance ($B–A_2$). Thus the example closed shoe last is 265 mm long while the sandal last is 258 mm long. Yet the lasts for either variation place the flexion location at the same fixed percentage of overall last length, instead of using a measure related to the foot.

Foot breadth (mm)—width of the metatarsal break or the linear distance between landmark points 4 and 9 (Fig. 2).

Forefoot girth (mm)—tape circumference around the first and fifth metatarsophalangeal joints, manually measured around landmarks 4 and 9.

Concept of a zone width of possible first MP joint fulcrum locations whether in sandals or closed shoes (mm) —it is impractical for footwear manufacturers to make footwear for all first MP joint fulcrum locations in different footwear styles. Instead, an analogous design concept to describe the largest variation that could exist may be useful, to describe a zone into which most fulcrum points fall for sandals and closed shoes. The extent in width of this zone is based on max(Heel 1MPJ%of sandal length) and min(Heel 1MPJ%of closed shoe length).

The variable zone width of possible first MP joint fulcrum locations from sandals to closed shoes (mm) is calculated as:

$$\left(\frac{\text{foot length} \times \max(\text{Heel 1MPJ\% ofsandal length})}{100}\right) \left(\text{foot length} \times \frac{\min(\text{Heel 1MPJ\%of closed shoe length})}{100}\right).$$

This variable is also referred to as the zone width variable, or flexion zone (conceptually depicted in Fig. 4).

2.3. Statistical analyses

Data analyses were performed in a statistical software package (R, version 3.3.2). Continuous variables were first tested for normality using the Shapiro–Wilk and Shapiro–Francia tests. In order to assess the distribution of non-parametric continuous variables, Median and Interquartile Ranges (IQRs) as well as the minimum and maximum values were computed.

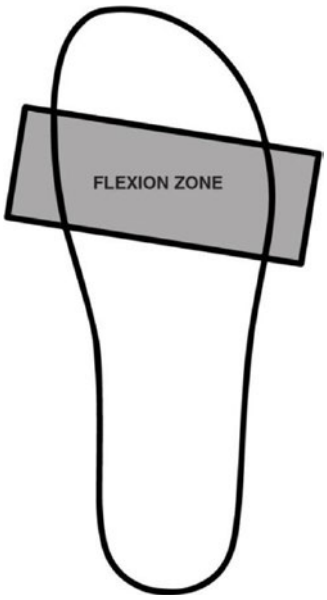

Fig. 4. Variation in location of first metatarsophalangeal joints requires matching variation in footwear flexion, conceptualized as a zone of flexion or flexion zone.

To determine the distribution of the Heel-1MPJ % of foot length (%) and Heel-1MPJ % of sandal length (%) among study participants and show whether this deviated from the North American (USA) and South African (SA) industry parameters, we produced scatter plots with horizontal lines running through the data to indicate the location of mean values. A one sample t-test was run to determine whether the Heel-1MPJ % of foot length (%) and Heel-1MPJ % of sandal length (%) among study participants were different from the USA and SA industry parameters.

We used inferential statistics to assess whether the distribution of the variable zone width of possible first MP joint fulcrum locations from sandals to closed shoes (mm) differed by population group. This involved using the Kruskal–Wallis test which tested whether the mean ranks of this variable were the same in all four population groups. A Dunn's test [13] was computed to test the median differences between multiple pairwise comparisons of population groups following a Kruskal–Wallis test. The median differences between groups and the associated IQRs were plotted using a boxplot with jitters. In order to assess the strength of the relationship between the variable zone width of possible first MP joint fulcrum locations from sandals to closed shoes (mm) and other continuous variables (age, weight, foot breadth and tape forefront girth), Spearman's correlation tests were performed. The two-way correlations between these variables were plotted using a scatter plot matrix. A visual inspection of the relationship between the response variable and each predictor variable adjusted for other predictor variables was achieved by plotting Multivariate Lowess Smooths [14]. By simultaneously computing the smooth of the response variable on all predictor variables, this non-parametric multiple regression method is able to adjust each smooth for the others. Throughout the analysis the level of statistical significance was set at $p < 0.05$.

3. Results

This study found that the bending position in footwear made according to South African and USA last parameters does not match the average first MP joint location in the measured sample. The mean Heel-1MPJ length, expressed as a percentage of sandal last length (72%) was significantly higher than the stated South African (66%; $p < 0.0001$) and North American (63%; $p < 0.00001$) industry measurements. Similarly, the mean Heel-1MPJ length expressed as a percentage of closed shoe length (70%) among study participants was significantly higher than the stated South African 66% ($p < 0.00001$) and North American 63% industry measurements ($p < 0.0001$). This means that the forefoot flexion location of most subjects is more distal to that which is built in to footwear made according to either South African or USA industry parameters. Fig. 5 illustrates these differences.

The extent of the possible first MP joint fulcrum locations in the sample and extrapolated between what it would be in sandals and secondly, what it would be in closed shoes was found to be a median of 24 mm wide and could range from 21 mm to 29 mm in zone width (Table 1).

When investigating whether other variables were associated with the location of the first MP joint, the analysis found that the variables of population group, weight, foot breadth and forefoot

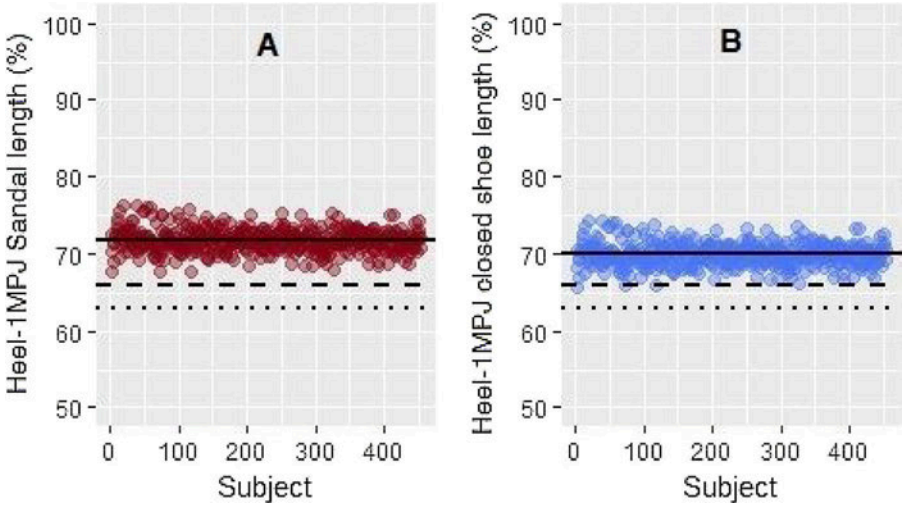

Fig. 5. Two-way scatter plots showing the mean of the distance heel to first metatarsophalangeal joint (Heel-1MPJ) as a percentage of sandal length (Fig. 6A) and Heel-1MPJ in closed shoe length (Fig. 6B) among study participants, compared to the mean estimates recommended by the South African (SA) and United States of America (USA) industry parameters. It is seen in both graphs that the mean estimates in the study sample fall outside the means recommended by both the SA and USA footwear industries. Note: solid lines = observed means for the study sample; dashed line = mean for SA industry; dotted line = mean for USA industry.

Table 1
Distribution of continuous variables in the study sample (N = 453). Note: Heel-1MPJ denotes heel to first metatarsophalangeal joint length. Foot breadth denotes maximum breadth or width across the forefoot.

	Median	IQR	Min	Max
Age (years)	39	[30–52]	21	69
Height (meters)	1.62	[1.56–1.67]	1.42	1.8
Weight (kg)	68.4	[43.9–122.9]	34.7	150.9
Body Mass Index (BMI)	26	[23–30]	13	56
Foot length (mm)	239	[231–248]	206	285
Maximum foot breadth across forefoot (mm)	92	[89–97]	77	110
Tape forefoot girth at metatarsal joints (mm)	232	[222–242]	180	288
Heel-1MPJ % of foot length (%)	74	[73–75]	70	79
Heel-1MPJ % of sandal length (%)	72	[70.7–72.7]	67.7	76
Heel-1MPJ % of closed shoe length (%)	70	[68.9–70.82]	65.8	74
Zone width of possible first MP joint fulcrum locations between sandals and closed shoes (mm)	24	[21.5–27.7]	21	29

girth (but not age) were significantly associated with the location of the first MP joint. The bivariate correlation containing age, weight, foot breadth, forefoot girth and zone width is shown in Table 2. The table shows that at univariate level, the flexion zone width was positively and significantly correlated with tape forefoot girth ($p < 0.001$), foot breadth ($p < 0.001$), and body weight ($p < 0.001$) but not with age.

The comparison of the four population groups in respect of the zone width of possible first MP joint fulcrum locations whether in sandals or closed shoes showed statistically significant differences ($p < 0.001$). Fig. 6 shows that the median flexion zone was highest among white South Africans, followed by black South Africans, with Indian South Africans showing the smallest median.

Table 2
Bivariate correlation between age, weight, foot breadth, forefoot girth and flexion zone (N = 453).

Variable	1	2	3	4	5
1. Age	1.000				
2. Weight	0.177**	1.000			
3. Foot breadth	0.073	0.409***	1.000		
4. Forefoot girth	0.144*	0.533***	0.739***	1.000	
5. Flexion zone width	0.045	0.435***	0.624***	0.514***	1.000

' ' $p > 0.05$.
* $p < 0.01$.
** $p < 0.001$.
*** $p < 0.0001$.

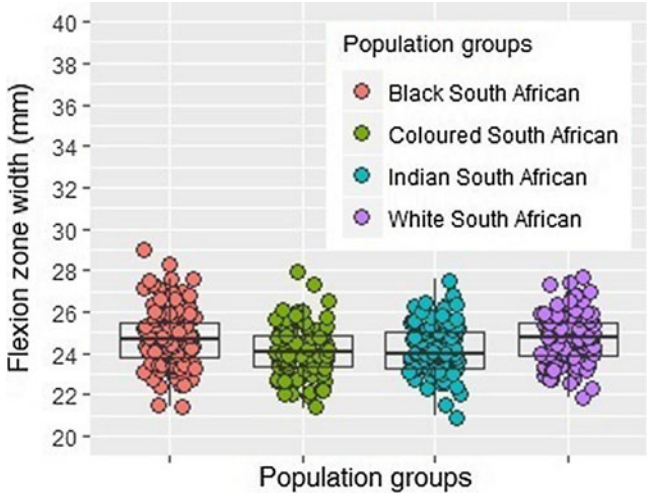

Fig. 6. The comparison between population groups based on the extent of the flexion zone width in millimetres (extent of possible locations for the first metatarsophalangeal joint between the minimum 66% in a closed shoe length and maximum 76% for a sandal length). The graph shows that the median flexion zone was widest among white South Africans, followed by black South Africans, with Indian South Africans showing the smallest median flexion zone extent.

The Black South African and White South African population groups had the highest median Zone widths of possible first MP joint fulcrum locations in both types of footwear. Post hoc comparison of different pairs of population groups based on the zone width variable (Zone width of possible first MP joint fulcrum locations from sandals to closed shoes) used Dunn's multiple pairwise comparison test and showed that South African Indians have smaller median zone widths which were statistically different from Black South Africans ($p < 0.001$) and White South African ($p < 0.001$), but not from South African Coloureds ($p = 0.373$). South African Coloureds had smaller zone widths that were statistically different from White South Africans ($p < 0.001$) and Black South Africans ($p < 0.001$). Lastly, Black South Africans were not statistically different from White South Africans ($p = 0.343$) regarding the extent of the zone width variable.

The multivariate Lowess Smooths of the zone width and each of the four predictor variables (age, weight, foot breadth, and forefoot girth) adjusted for others is shown in Fig. 7.

At multivariate level, the negative correlation between flexion zone width and age showed that age is not statistically significant, but the flexion zone width is positively correlated with weight, foot breadth and forefoot girth, as seen by the Spearman's rho coefficient and associated p values.

4. Discussion

Since we found that the first MP joint was more distal than the location of flexion in footwear, this study raises important concerns regarding the potential of ill-fitting footwear to cause harm, particularly when worn post-operatively. Surgical procedures are routinely performed for congenital and acquired conditions affecting the first MP joint including arthritis, hallux valgus, hallux rigidus, and disease of the hallucal sesamoids. Poor healing may occur after surgery [15–17] and we postulated whether unmatched foot to shoe flexion locations as observed clinically could be a factor not previously considered.

A systematic review of the characteristics of foot structure and footwear associated with hallux valgus [18] found that a long first metatarsal and ill-fitting footwear, inter alia, to be factors that increase the risk of hallux valgus development. Other studies have shown that a first MP joint fulcrum which is located proximal to the fulcrum location in the shoe may lead to hallux valgus formation [19,20].

Studies of the relationship between foot measurements have looked at the primary differentiators of foot length, width and girth [21–23]. Few studies have highlighted first MP joint morphometric differences in the sagittal plane [24,25] although a substantial body

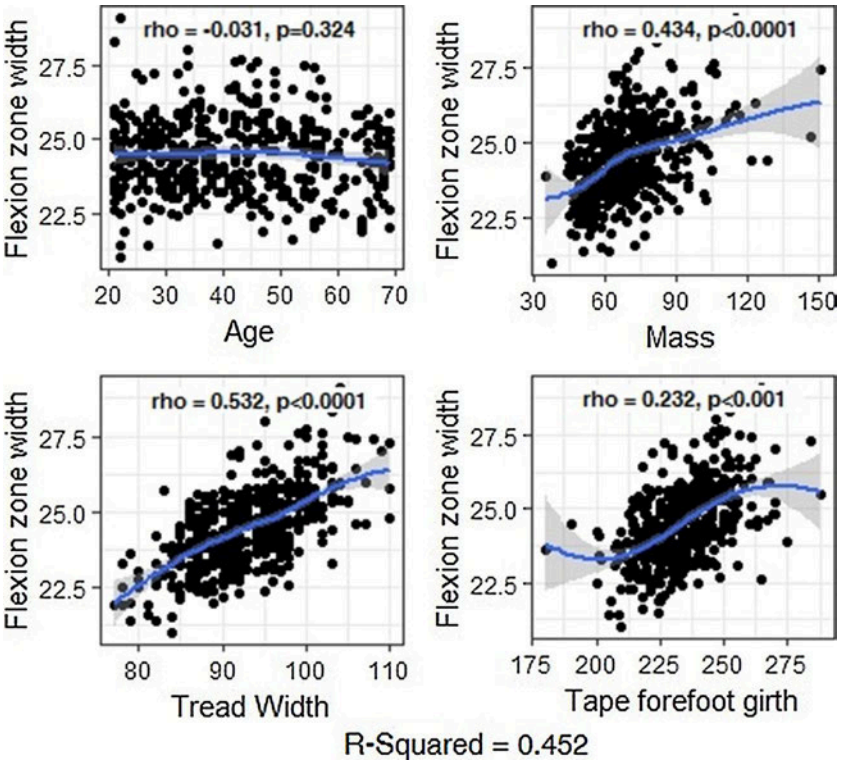

Fig. 7. Multivariate lowess smooths of the flexion zone width and each of the four predictor variables (age, weight, foot breadth and forefoot girth) adjusted for others, and Spearman's rho coefficients and p values associated with each predictor variable. The lack or presence of statistically significant relationships can also be seen from the adjusted smoothed lines running through the fitted values. The figure shows that at multivariate level, the correlation between flexion zone width and age is not statistically significant, but there is positive correlation with weight, foot breadth and forefoot girth.

of work has drawn attention to pathologies due to such disorders [19,26,27]. A first MP joint fulcrum which is located distal to the fulcrum location in the shoe (Fig. 8) will result in forces on the joint, reducing the ability of the hallux to function and is implicated in hallux rigidus [19,20]. In the absence of a functioning fulcrum at the first MP joint, compensatory abduction of the foot may take place; this would place increased force and flexion moments on the lateral four digits and metatarsals, the abnormal stresses of which may lead to fatigue fractures [28]. These considerations are important in light of recent work by Michelson et al. [29] concerning first metatarsal head morphology in hallux rigidus and hallux valgus.

Our sample included both underweight and obese subjects (BMI 13–BMI 56). The obese subjects (BMI > 30) may have exerted greater downward force on the medial longitudinal arch, thereby decreasing the height of the arch [30] thereby lengthening the arch, which might shift the first MP joint to a more distal location. However, the mean variance occurred near the 75 kg marker and one could argue that this weight is not generally considered an obese body weight in average height adult women in South Africa.

The present study was limited in that only female subjects were measured and it is anticipated that male foot measurement data will be examined in future.

The current study measured participants unshod (zero heel elevation). Since the plantar fascia shortens in heel elevation, the percentage of overall foot length represented by the heel to first MP joint segment may vary at differing heel elevations. Our foot segment percentages cannot therefore be used for sandals or shoes with heel elevation. We suggest that future investigation determine the impact of varying degrees of heel elevation on the length calculation of heel to first MP joint (due to shortening of the plantar fascia in heel elevation), so as to complete the data on Heel to first MP joint length in footwear.

We note that, with the exception of surgical fusion of the first MP joint that would require immobilization of this joint via a rigid sole in footwear, most clinical conservative as well as surgical interventions aim to restore flexion function of the forefoot structures.

5. Conclusion

We found evidence that a multi-ethnic population contains individuals whose first MP joint fulcrum location does not match the footwear fulcrum location found in sandals or closed shoes made according to either South African or North American last industry parameters. Furthermore, we calculated that the grouping of such different first MP joint locations would represent a band or zone across the metatarsal spread at least 24 mm wide in the sagittal plane (proximal to the distal foot) in order to accommodate most of the first MP joint locations.

It is impractical for footwear manufacturers to make individual footwear with specific flexion points for all the different first MP joint fulcrum locations within the same size. Since a first MP joint position which may fall outside the set flexion point in a shoe cannot properly function as a fulcrum, it is suggested that medical consultants to footwear manufacturers advise on forefoot flexibility requirements and characteristics to allow for the range of first MP joint fulcrum locations in the population.

We conclude that the results of this study suggest that the public as well as the medical community be informed (Fig. 8) to select and check the flexion fit of footwear, particularly pre- and post-operatively. Failure to do so could potentially result in increased forces of shear and torque from a mismatched shoe fulcrum at the first metatarsophalangeal joint. We believe such forces need to be considered in the risk factors for musculoskeletal as well as skin pathology and non-healing, particularly with pre-existing risk

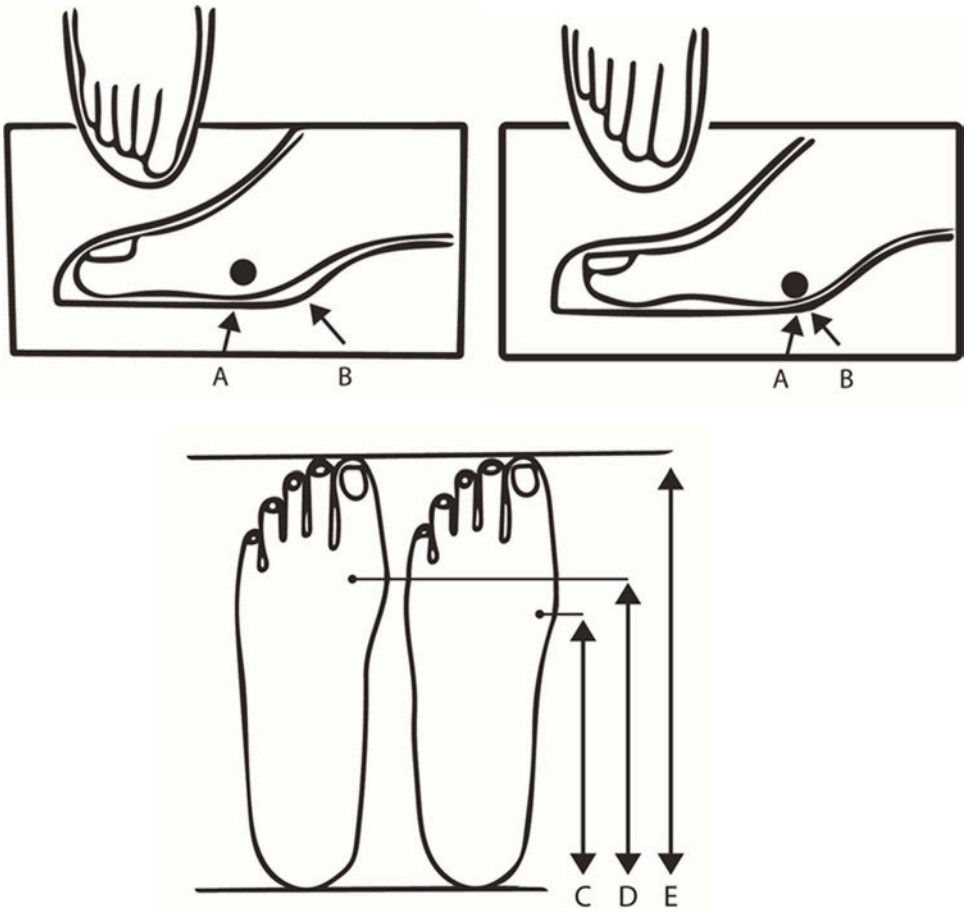

Fig. 8. Explanatory illustration suggested as a clinical informative tool to prevent fulcrum mismatch. Arrows on top left indicate mismatch of first metatarsophalangeal (MP) joint fulcrum A to flexion location B built into a shoe, while arrows on right indicate congruency of flexion location between shoe and foot. C and D indicate potential for variance in location of first MP joint in feet of equal length E.

factors such as diabetic peripheral neuropathy and/or peripheral vascular disease.

Contributions of authors

ATT initiated and planned the study, formulated the methodology, and wrote the core manuscript, CMA and BZ provided input and editing of the manuscript. MM performed the statistical analysis and provided the description of data analysis approach.

Conflict of interest and funding

No conflict of interest declared. The Technology and Human Resources in Industry Program (THRIP) of the National Research Foundation of South Africa, the University of Johannesburg, the South African Footwear and Leather Industries Association and Michelle Footwear provided financial grants to support the cross-sectional data capture project. The entities acknowledged did not plan, gather data, perform analyses, interpret data or otherwise contribute to this manuscript.

This article has not been previously submitted for publication.

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Part Three: Diabetes linked lower limb amputations in KwaZulu-Natal

A misinformed criticism often levelled at podiatrists, which I personally have experienced, is one of perceived cost. How much is the cost of prevention compared to the cost of the sequela of PAD, namely amputation?

Since health policy decisions are driven by many factors, among which are costs, I undertook to begin the process of calculating some of the costs of diabetes-related lower limb amputations so that policy makers could juxtapose such costs against the cost of increased deployment of qualified podiatrists in KwaZulu-Natal.

Chapter Eight presents a manuscript published in the Journal of Endocrinology, Metabolism and Diabetes of South Africa entitled, "Counting the cost of preventable diabetes related lower limb amputations at a single district hospital in KwaZulu-Natal – what this means, what can be done?". The manuscript details the draft cost analysis of 660 lower-limb diabetes amputations from 2013 to 2017 at a single hospital and extrapolation of these costs across the province and the nation. Within those costs, I present what the budgeted amount would have been for podiatric care in order to show that it is a fraction of the non-reversible and preventable losses represented by lower limb amputations.

The multi-disciplinary approach to diabetes care and ulcer prevention is presented, with supportive literature providing the evidence base of the value of podiatry in the MDT approach to diabetes amputation prevention.

Particularly at present in the COVID-19 pandemic, it is important to avoid diabetes complications that would result in casualty/emergency room visits and hospitalization at a time when the health care system is stretched, and resources may have been re-deployed. Telehealth and combination home health or home care strategies should be considered and modelled.

Appendix 19 contains the presentation at Northdale Hospital, Pietermaritzburg, requested by Dr Somasundrum Pillay of Edendale Hospital, attended by district Department of Health coordinators and local state health doctors in July 2019.

Chapter Nine contains the discussion of the total work in this thesis and puts forward recommendations to various stakeholders based on its findings.

Chapter Eight: Counting the cost of preventable diabetes related lower limb amputations at a single district hospital in KwaZulu-Natal – what this means, what can be done?

In discussing the lack of an adequate podiatry presence in state health and the sequelae thereof with Dr Somasundrum Pillay, I expressed the opinion that the endpoint of such lack of care was diabetic lower limb amputation (DLLA). Although some research had highlighted the growing numbers of DLLA, no study had yet explored the financial and mental cost to state health of such preventable amputations.

This chapter contains a published manuscript that details my draft cost analysis of 660 lower-limb diabetes amputations from 2013 to 2017 at a single hospital and extrapolation of these costs across the province and the nation. It presents what the budgeted amount would have been for podiatric care in order to show that it is a fraction of the non-reversible and preventable losses represented by lower limb amputations.

The chapter presents the multi-disciplinary approach to diabetes care and ulcer prevention, with supportive literature providing the evidence base of the value of podiatry in the MDT approach to diabetes amputation prevention.

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Counting the cost of preventable diabetes-related lower limb amputations at a single district hospital in KwaZulu-Natal: what does this mean, what can be done?

AT Thompson , JL Bruce , VY Kong , DL Clarke & C Aldous

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ARTICLE

Counting the cost of preventable diabetes-related lower limb amputations at a single district hospital in KwaZulu-Natal: what does this mean, what can be done?

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Background: Healthcare policy decisions are driven by many factors, including cost, hence the need to show costs of diabetes mellitus-related lower limb amputations (DMLLA) to inform amendments to health care. Substantial decreases in amputation rates are associated with specialised podiatry foot clinics and ongoing foot education, as per national guidelines on the multidisciplinary team approach (MDTA) to diabetes health care. There are only two podiatry posts in KwaZulu-Natal (KZN) state health department (DoH).
Objectives: Aims were to draft the medical costs for 660 DMLLA at Greys Hospital for the period 2013–2017; to extrapolate costs on annual DMLLA in KZN; to outline socio-economic costs for future investigation; to present evidence that podiatry in the MDTA can decrease numbers of DMLLA.
Methods: A retrospective review on clinical data captured in real time and maintained by the Pietermaritzburg Metropolitan Trauma Service (PMTS) and Surgical Service (PMSS) was performed. Costs were analysed on data for 660 patients' DMLLA at Greys Hospital between 2013 and 2017, and psychological and socio-economic costs via literature review.
Results: Medical care at Greys Hospital for 660 DMLLA in the five years cost in excess of ZAR 213 million. Extrapolated to the 1 231 diabetic amputations (2014) equals an annual cost to KZN DoH in excess of ZAR 398 million. Personal, family loss and socio-economic costs are estimated in excess of ZAR five million per amputee, resulting in further cost of ZAR 6.155 billion per annum to KZN. Extrapolation across 11 provinces signifies a national cost of at least ZAR 68 billion.
Conclusions: We present a gauge of the cost of DMLLA to KZN and national health. Substantial possible socio-economic losses compound these. The role of podiatrists within MDTA teams has an evidence base to prevent DMLLA.

Keywords: diabetes mellitus, public health, podiatry, prevention of foot and limb loss, socio-economic cost

Background

In resource-limited environments in low- and middle-income countries, lower limb amputations due to the complications of diabetes are costly to fiscus. It is important to note that there is a marked decrease in amputation rates associated with specialised podiatry foot clinics and ongoing patient foot education.[1] Albeit that the thrust of primary care is prevention, provision of such primary prevention care for diabetic foot complications is difficult to implement in the face of other demands for hospital and trauma care. Cost calculations of preventable diabetes-related amputations in South Africa are required in order to inform policy-makers regarding the importance of training and placement of podiatrists throughout the healthcare system. Podiatrists are needed in the primary health care sector for screening, assessment, semi-surgical and other treatment in the management of diabetic foot health, as well as the provision of in-depth patient foot education.

A study in 2015 noted that KwaZulu-Natal (KZN) had 1.28 million people registered with diabetes in the public sector, which translates into a mean diabetes prevalence of 12.5%, although some districts exceeded 35%.[1] The same study found that the District Health Information System (DHIS) registered 2 323 diabetic lower limb amputations carried out in state health facilities in KZN during the period 2013–2014.

Several research outcomes have led to the International Diabetes Federation's statement that all people with diabetes should have a foot assessment that places them in the appropriate risk stratification to indicate the clinical pathway for foot disease prevention and treatment. A multidisciplinary team approach, with the inclusion of podiatry in treating the diabetic foot, is central for good outcomes, to protect the diabetic foot from breakdown, preventing foot ulceration and lower limb amputations. Podiatry takes preventive measures early in the disease process such that treating the foot in the early risk categories prevents patients from becoming high risk.[2] Although the value of podiatry and the approach of a multidisciplinary team in diabetes care has been widely acknowledged,[3 20] very few such teams that include podiatry are in place in state health. Healthcare policy decisions are driven by many factors, including cost, hence the need to begin the process of calculating the costs of diabetes-related lower limb amputations. Since lower limb amputations in diabetes are largely preventable, they are a measure of inadequate care on the part of any healthcare service.

The study aimed to produce a draft cost calculation in respect of patients with diabetes-related complications who were referred to the surgical service at Greys Hospital, Pietermaritzburg for lower limb surgery such as amputation, stenting, skin grafting or revisionary amputation of a previous amputation. These costs are extrapolated across the total number of annual amputations in KZN province. An outline of the socio-economic costs or so-called 'hidden costs' is added, based on a review of psychology and legal literature. For the purposes of a draft calculation, comparable costs and amputations are assumed equally across all 11 provinces.

Ethical approval was granted by the Biomedical Research Ethics committee under the reference BCA058/17.

Methods and materials

A retrospective review of data captured on a prospectively entered electronic registry was performed. Clinical data are captured in real time and maintained by the Pietermaritzburg Metropolitan Trauma Service (PMTS) and the Pietermaritzburg Surgical Service (PMSS) in KwaZulu-Natal province, South Africa. All patients who underwent diabetes-related lower limb surgery or amputation at Greys Hospital in the calendar years 2013–2017 were identified and selected for analysis. Clinical data for a total of 660 digital records were exported from the databases to spreadsheets. Since compound clinical data were in descriptive text form, 'unpacking' or manual conversion of the textual data into numerical coding was carried out to facilitate quantitative analysis.

Tables were prepared of cost driver formulae, after the methods developed in previous studies that have used data from the PMTS.[21 23] Costs were obtained from the radiology manager and hospital financial management (see Tables 2 and 3). In addition, in-hospital ward costs were estimated, based on the average of medical aid rates across two of the largest private hospital groups in KwaZulu-Natal and as per Allied Health tariffs published by the Discovery Health Medical Scheme.[24]

'Hidden costs' are the socio-economic costs of diabetes-related lower limb amputations, which form a backdrop of concern to the overall mental health of health workers; to amputees themselves and their families; and to the social and economic welfare of individuals, affected communities, industry and national fiscus. These were sourced from review of the literature that included the quantum of typical legal settlements in respect of personal injury claims involving loss of the lower limb.[25]

Results

Calculations across cost drivers resulted in a total cost of ZAR 213.456 million (albeit incomplete) for 660 diabetic amputations, broken down by categories of costs. Costs were calculated from data on types of diagnostic imaging, laboratory tests requested, transportation to and from the referring facility, theatre time, post-surgery instructions, prognosis, outcome, ward type and ward stay duration. This total is incomplete as it does not include items such as food, dietitian consultations, nursing consumables and all hospital staff remuneration. While the amounts for podiatry foot care and podiatry orthotics or shoe modifications are shown, they do not form part of the total estimates since only two podiatrists are deployed in state health in KZN.[1] However, the relevance of the podiatry cost estimates will be covered in the discussion.

The data revealed that patients who underwent diabetes-related lower limb amputations are often sent to the PMSS by ambulance from as many as 20 other state hospitals in the province. It was noted that patients are often returned to their base facility for nursing once they have been stabilised after surgery due to crowding and lack of ward beds at Greys Hospital. Running costs for ambulance vehicles are available from the Automobile Association of South Africa[26] and are presented below.

Transportation

Table 1 outlines only the running costs for such transportation. The vehicle running cost consists of maintenance and fuel for an example Volkswagen Crafter 2.0 L diesel ambulance[26] and excludes costs of staffing, personal protective equipment (PPE), mobile and telecom communications, vehicle purchase/lease, vehicle depreciation, vehicle insurance, signwriting, training, medical liability insurance, medical equipment, medical equipment depreciation, medical consumables, security tracking, management overheads and any other aggregate costs, which will need to form part of an internal audit not included in the present study. Also excluded from the transportation costs are costs incurred by those 110 patients (in Table 1) who used other transportation (referring health facility: GP private, Greys Hospital, Private transport, Unknown, Walk-in) for whom transportation costs were not available or not recorded.

Table 1 lists the ambulance running costs as per the Automobile Association[26] of return trips from referring health facilities, in descending order of cost, for diabetes amputation patients at Greys hospital for the five years from 2013 to 2017.

Diagnostic imaging

Diagnostic imaging forms a large segment of costs for amputation surgery, including leg, cardiovascular and other systems imaging since morbidity of the entire patient is assessed before surgery (Table 2).

Standard and routine diagnostic laboratory investigations

The cost of standard and routine laboratory tests (full blood count, electrolytes, kidney function, liver function, blood gas, etc.) was obtained from the hospital laboratory and estimated as a total of ZAR 2 650, applied across all diabetic amputation patients, per surgical encounter.

As may be seen in Table 3, base tariffs were used to estimate post-surgical costs such as hospital care back at the referring facility, physiotherapy, rehabilitation, podiatry care and podiatry orthotics for the contralateral foot, prosthetic limbs and mobility aids.

The calculations across the cost driver formulae (as per Table 3) resulted in the line totals presented in Table 4.

Hidden costs to Department of Health

A decline in quality health care has caused the public to lose trust in the healthcare system.[27] The medical response is thus compromised by delays in treatment due to ignorance and mistrust.[27] Patients with compromised limbs who are referred to Greys Hospital inevitably lose those limbs, which all too often reinforces patients' beliefs due to so many patients presenting late with limbs that cannot be salvaged. Patients do not have foot care intervention or in-depth foot education from podiatrists carried out early enough to effect prevention.[1]

Table 1: Running cost estimate of transporting diabetes patients for amputation and amputation-related surgery (n = 660) to and from Greys PMSS between 2013 and 2017

Referring base health facility ranked by cost	Category	Km to Greys	AA cost at ZAR 7/km per round trip	No. of patients	ZAR total
Newcastle Hospital	Regional	265	3710.00	116	430 360.00
Church of Scotland Hospital Tugela Ferry	District	121	1 694.00	98	166 012.00
Vryheid Hospital	District	301	4 214.00	37	155 918.00
Greytown Hospital	District	75	1 050.00	89	93 450.00
Emmaus Hospital, Winterton	District	149	2 086.00	39	81 354.00
Appelbosch Hospital, Ozwatini	District	69	966.00	68	65 688.00
Estcourt Hospital	District	144	2 016.00	22	44 352.00
Montebello Hospital, Ozwatini	District	68	952.00	21	19 992.00
Ladysmith Hospital	Regional	157	2 198.00	9	19 782.00
Madadeni Hospital, Newcastle	Regional	268	3 752.00	4	15 008.00
Inkosi Albert Luthuli Hospital	Central	77	1 078.00	13	14 014.00
Dundee Hospital	District	226	3 164.00	2	6 328.00
Nkonjeni Hospital, Mahlabathini	District	318	4 452.00	1	4 452.00
Christ the King Hospital, Ixopo	District	122	1 708.00	2	3 416.00
EG Usher Hospital, Kokstad	District	237	3 318.00	1	3 318.00
Edendale Hospital	Regional	11	154.00	11	1 694.00
St Apollinaris Hospital, Makholweni	District	120	1 680.00	1	1 680.00
Addington Hospital	Regional	84	1 176.00	1	1 176.00
Life Entabeni	Private	79	1 106.00	1	1 106.00
King Edward VII Hospital	Tertiary	79	1 106.00	1	1 106.00
St Augustine Netcare Hospital	Private	79	1 106.00	1	1 106.00
Clinic local	Clinic	10	140.00	3	420.00
Mediclinic Howick	Private	26	364.00	1	364.00
Northdale Hospital	District	5	70.00	5	350.00
Greys Pain Clinic	Clinic	5	70.00	1	70.00
Orthopaedic centre	Tertiary	5	70.00	1	70.00
St Anne's Netcare Hospital	Private	4	56.00	1	56.00
GP private *	Private	0	0.00	25	0.00
Greys Hospital *	Tertiary	0	0.00	31	0.00
Private transport *	Private	0	0.00	22	0.00
Unknown *	Private	0	0.00	30	0.00
Walk in *	Private	0	0.00	2	0.00
Sub-total running and fuel costs only				660	ZAR 1 132 642.00

Note: * Cost of transportation missing for 110 patients. It is unknown why a regional hospital with its own surgeons, for example in Newcastle, would need to send surgical cases to Greys Hospital.

Another hidden loss is that of medical personnel's loss of morale and loss of sense of purpose. The vast load of amputations has negative psychological consequences for surgeons since it is demoralising and energy draining to be removing limbs that cannot be salvaged, in the full knowledge that the amputation could have been prevented. Mental fatigue is experienced since staff feel that they are constantly 'swimming upstream'.

Table 2: Individual diagnostic imaging cost drivers

Imaging cost drivers	ZAR per investigation (2019 values)
Radiograph: chest	650
Radiograph: per lower limb	470
CT scan: pelvis un-contrasted	2 750
CT scan: pelvis pre- and post-contrast	7 200
CT scan: lower limbs to feet	6 200
CT angiogram: lower limb	13 000
Ultrasound: lower limb	1 300
Ultrasound: Doppler echo per lower limb	2 300

Hidden indirect socio-economic costs

In conducting a review of personal accident legal cases in which there was a loss of limb, loss descriptions are listed below and suggest a framework for future quantitative and qualitative investigations. A typical possible amount awarded in legal settlement for loss of limb in comparable personal injury cases is ZAR 5 million,[25] which does not factor in losses to society or to national fiscus.

Losses to the individual:

- Emotional aspects in addition to pain and suffering.[28]
- Loss of body image and body image dissatisfaction.[29,30]

Table 3: Summary of individual hospital cost driver formulae

Cost drivers	Formulae
Cost of EMS transportation	Total costs of EMS transportation as per Table 1
Cost of analgesia	ZAR 75 per day × number of days for the number of patients
Cost of antibiosis	ZAR 700 per day × number of days for the number of patients
Cost of imaging studies	ZAR costs as per drivers in Table 2 × applicable patients
Cost of laboratory tests	ZAR 2 650 per patient × number of patients
Cost of an operating theatre	Cost per minute (225 ZAR) × time (minutes)
Cost of surgical ICU	ZAR 18 000 per day × number of applicable days
Cost of acute/high care	ZAR 10 500 per day × number of applicable days
Cost of surgical ward stay	ZAR 3 800 per day × number of applicable days
Estimated ward stay on return to the referring facility	ZAR 3 800 per day × average 14 days × number of patients
Estimated postoperative physiotherapy at Greys Hospital	ZAR 325 per day × 6 047 ward days for 660 patients
Estimated physiotherapy/occupational therapy rehabilitation at the referring facility, including crutches	ZAR 325 average per day × 14 ward days for 660 patients
	ZAR 280 for a pair of crutches × 660 patients
Cost of (absent) podiatry care and ongoing assessment as per SEMDSA guidelines (in this case, all 660 were high-risk patients)	ZAR 614 every 3 months × 660 patients over the 5 years
Cost of (absent) podiatry orthotics/shoe modification to save the contralateral limb, prevent future ulceration	ZAR 3 600 per patient × 660 patients
Cost of prosthetic limbs, estimated for 50% of patients	ZAR 160 000 × 330 patients, plus ZAR 140 000 for revisions
Cost of mobility aids (wheelchair) for rehabilitation	ZAR 9 000 per wheelchair × 660 patients
Cost of qualified counselling	ZAR 508 per 60-minute session × 20 sessions × 660 patients

- Grief and anger, often directed inwards with changes in self-identity.[31]
- Loss of income due to loss of employment or decreased working life.
- Depression and the consequences of depression such as poor coping.[29]
- Lack of adequate readjustment.[28]
- Loss of perceived status to other individuals, stigma.[31]
- Loss of quality of life; home care often unaffordable.[28]
- Increased risk of second amputation.[32]
- Increased risk of earlier mortality.[32]
- Loss of trust in health care system.[27]

Losses to the family unit:

- Disruption of family life.[33]
- Financial and physical cost of home care.[33]
- Negative impact on family member who becomes caregiver.[33]
- Loss of income and quality of life.[34]

Table 4: Total ZAR costs for Greys Hospital as per cost driver formulae in Table 3

Greys Hospital – costs for 6 047 ward days, 660 amputations (five years 2013–2017)	Total ZAR at 2019 values
EMS patient transportation*	1 132 642
Analgesia (IV and oral)	453 525
Antibiosis (IV and oral)	4 232 900
Imaging studies	1 156 630
Laboratory tests	1 754 300
Operating theatre time (32 322 minutes)†	7 272 450
Cost of surgical ICU‡	15 264 000
Cost of acute/high care‡	18 354 000
Cost of surgical ward stay‡	11 924 400
Estimated cost of return stay at referring hospital (average 14 days)	35 112 000
Estimated cost of physiotherapy at Greys Hospital over total ward days	1 965 275
Estimated cost of physiotherapy/occupational therapy rehabilitation at referring facility	3 003 000
Cost of crutches for 660 patients	184 800
Estimated cost of podiatry treatment over 5 years for 660 patients (care not provided)§	**(8 104 800)**
Estimated cost of podiatric orthotics/shoe modifications (care not provided)§	**(2 376 000)**
Cost of wheelchairs for 660 patients	5 940 000
Cost of prosthetic limbs for 50% of patients	99 000 000
Estimated cost of counselling for 660 patients	6 705 600
Total Greys Hospital costs for 660 diabetes amputations§ (excluding podiatry not provided)	213 455 522

Notes: *Transportation excludes costs of staffing, personal protective equipment (PPE), mobile and telecom communications, vehicle purchase/lease, vehicle depreciation, vehicle insurance, signwriting, training, medical liability insurance, medical equipment, medical equipment depreciation, medical consumables, security tracking, management overheads and any other aggregate costs. †Operating theatre cost excludes the cost of stock, consumables and staff remuneration. ‡ICU, acute/high care and general ward stay duration are not indicative of actual needed days due to crowding and lack of beds; the patient is often transported after surgery back to a hospital ward at the referring facility. §Food, dietitian consultations, nursing consumables and all hospital staff remuneration is excluded, as is podiatry, which level of care was not provided.

- Psychological losses such as depression, hopelessness.[31]
- Anxiety, grief and suffering by family members.[35]
- Loss of trust and anger against healthcare system.[27]

Losses to society:

- Decreased working life.
- Loss of skills and knowledge.
- Cost of replacement skills training.
- Loss of production.
- Loss of mentorship capacity.
- Loss of continuity.
- Anger against healthcare system.[27]
- Loss of trust in healthcare system.[27]
- Early deaths.[32,36] [38]

Losses to fiscus:

- Direct healthcare costs of amputation.
- Future healthcare costs.
- Increase in disability grants.

- Cost of replacement skills training.
- Loss of PAYE.
- Loss of taxable production.
- Loss of VAT on lost production.

Discussion

The quantum of ZAR 213.456 million (albeit incomplete) for 660 diabetic amputations and amputation-related surgeries at a single surgical and tertiary hospital unit in KwaZulu-Natal (between 2013 and 2017) is alarming. This represents an average (incomplete) hospital cost of ZAR 323,418 per diabetes-related amputation. If this figure is multiplied by the 1 231 diabetes-related amputations in 2014 as reported in 2015,[1] this brings the cost to ZAR 398 million in one year for KZN – on preventable lower limb complications of this non-infectious disease.

The possible indirect costs to individuals, society and the national fiscus are incalculable. Socio-economic costs include losses to the individual, to the family, the community, the economy and fiscus through lost production and lost taxation. Legal settlements in cases of personal injury from comparable lower limb loss are typically calculated in the region of ZAR 5 million each and this is only in respect of projected medical costs, loss of income, reduced life span, pain and suffering.[25] Legal settlement calculations do not take into consideration the loss to society or to fiscus that diabetes-related amputations cause.

Ignorance and neglect precede diabetes lower limb amputations. In 2019, a foot assessment study was carried out by a podiatrist researcher on a cohort of 301 patients attending the Edendale chronic outpatient diabetes clinic.[28] Patients expressed anger on discovering that an entire medical discipline exists to prevent foot complications in diabetes but is not available to them.[28] Their anger was directed at lack of care and information so that, 'if they had known earlier', complication outcomes may have been prevented.[28] A random survey of 18 community health centres in the Western Cape in 2008 found that only 11.3% of patients with diabetes had a recorded foot examination.[29] Five years later, a study in KZN reported that the recording of foot examinations in patient records was only 6%.[30] A further study in 2013 assessed the awareness and performance of prescribed diabetic foot care practices in a Gauteng Hospital.[31] It was found that not only were the practices inadequate, but 94% of patients had never been referred to or made use of a podiatrist. In 2016, a study set out to determine the awareness of diabetic foot disease among patients with type II diabetes mellitus at a regional hospital in Durban. It found that more than 90% of participants had not received any previous form of diabetic foot care education from any source.[32] Yet national guidelines for diabetes care are clear on the role of in-depth foot care to assess risk and direct the pathways of care to prevent amputations.[33]

Given the high mortality rate after amputations, there is a moral imperative to prevent amputations, not only because of the enormous one-way drain on finances but because the whole fabric of society is affected.

The psychological value to the patient of an immediate in-depth foot assessment, with identification of the at-risk foot, with foot care education, footwear examination and education, cannot be over-emphasized. Podiatrists, as specialised diabetic foot health practitioners, impart a medical identity and mission that promotes the importance of the feet in diabetes. While medical staff who treat diabetes according to national guidelines are aware of the value of podiatry, there remains an insufficient number of state health podiatry posts across KZN.

Currently, there are only two podiatry posts in state health in KZN for a registered diabetes population of close on 1.3 million patients. The authors of the 2015 audit postulated that at least 350 podiatrists were needed to assess and educate the numbers of diabetes state health patients in KZN.[1] As far back as 2005, it was highlighted that a major barrier to addressing the skills shortage of such practitioners is the lack of additional training institutions for podiatric medicine on the African continent.[34] This paper makes a further call for expanded training of the discipline of podiatric medicine at medical schools, particularly within KwaZulu-Natal where it is absent.

Podiatry as a discipline needs to be firmly positioned within the healthcare system in order to reduce the number of diabetes-related amputations. A recent systematic review and meta-analysis states that 'healthcare systems can expect a 39–56% amputation rate reduction after implementing a multidisciplinary amputation prevention programme that includes podiatry'. The costing exercise in this paper showed some ZAR 10 million that should have been used for podiatric care. Applying the percentages given by the systematic review and meta-analysis means that if podiatric care and devices had been implemented for the 660 patients in this study, 39% to 56% of the amputation costs of ZAR 213.456 million, i.e. between ZAR 83 million and ZAR 119 million, could have been saved for Pietermaritzburg alone.

By counting the rising numbers of diabetes-related amputations at a single hospital over a period of five years, and applying those data for the province, we have provided a gauge of what diabetes-related amputations mean in terms of annual costs to KZN and National Health. At a second level and compounding these costs are substantial possible socio-economic losses. The role of podiatrists within multidisciplinary diabetes teams is an evidence-based means of decreasing diabetes-related amputations.[35 46]

Author contributions

ATT conceptualised, conducted the literature reviews, converted data to code to perform data analysis and wrote the manuscript; JLB extracted and facilitated the raw clinical text data from the registry databases and provided insight into the state of surgical staff morale; VYK provided cost driver design and analysis framework; DLC provided pertinent stylistic edits and directional encouragement; CA supplied critical revision and approved the version to be published.

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Chapter Nine: General Discussion

12.1 Peripheral arterial disease in diabetes: A podiatrist's perspective

Diabetes mellitus is a devastating systemic disease. While there is certainly merit in pursuing knowledge of individual aspects of the disease, nothing in this disease behaves in isolation – everything is connected. Each medical discipline that takes specialized care of their aspect of the multi-faceted care of the diabetes patient may believe that their own discipline deserves paramount attention. Yet all their efforts are overcome by the time a patient loses their toe, foot or leg, since vascular damage is not usually isolated to the lower limb.

Diabetic foot complications can range from cellulitis to chronic osteomyelitis and critical ischaemia. These complications can arise with localized trauma in the presence of neuropathy, peripheral vascular disease, and immunosuppression. Diabetic foot infections are the most common skeletal and soft-tissue infections in patients with diabetes. Both types of diabetes mellitus confer a higher risk of lower extremity amputation due to infection compared to patients without diabetes. Prevention, early recognition, and early treatment have been shown to protect from amputations [1-3]. Many developed countries recognize the value of podiatric medicine in reducing the costs of diabetes-related amputations [3-7].

In clinical practice as a podiatrist, it is frustrating to be presented with a diabetic foot ulcer that is non-healing due to ischaemia and peripheral arterial disease (PAD). This study aimed to find the extent or prevalence of PAD in one area of the province of KwaZulu-Natal. It looked at known risk factors and questioned whether there could be any other foot related risk factors that had not received attention or been investigated? Other questions to potentially improve patient care were: "Could there possibly be other foot-related aspects missing in the care approach? What evidence might the journey in this study bring to show that podiatric input, inter alia, is needed in South Africa to prevent diabetes-related foot complications?

12.2 Peripheral arterial disease in diabetes: risk factors

In simple terms, peripheral arterial disease in diabetes mostly results from denaturing of the smooth walls of blood vessels. Apart from risk factors that cannot be changed such as

increasing age (over 50 years of age) and a previous family history, most risk factors are preventable. High blood glucose levels cause the denaturing process of glycosylation of protein in vessel walls. Studies show an association between elevated HbA1c levels (high average blood glucose levels, hence elevated glycosylation) and PAD. Atherosclerosis or the formation of plaque on vessel walls is another cause of arterial disease, due to inflammation and weakness of the blood vessels in the presence of elevated lipid levels. High cholesterol levels, particularly elevated triglycerides, cause elevated levels of circulating lipoproteins that affect endothelial function in the arteries. Smoking reduces oxygen levels in the blood, necessary for cellular repair mechanisms. Hypertension or elevated blood pressure results in distention strain on blood vessels, potentially damaging them. Obesity increases pressure on blood vessels, so exercise, diet and hydration are important in obesity prevention.

In the current study, the pursuit of clinical and other information on peripheral arterial disease enabled me to investigate related aspects in which I could look beyond what I know.

12.3 The vicious cycle: lack of exercise and obesity – role of podiatry treatment?

Podiatric treatment is a vital aspect of care to address the vicious cycle of obesity and lack of exercise. This is particularly pertinent when obese patients blame their painful feet for their lack of exercise. Podiatric measures include biomechanical examination, reduction of painful callus, education, custom exercise prescription and in-shoe custom correction to re-balance the feet, reduce pain and enable exercise.

Podiatric and footwear knowledge and skills enabled investigation into pathways that could potentially improve blood circulation. The current study found that haemodynamics research in the last decade contributed new information on the anatomy and physiology of the foot venous muscle pump [8-10].

The current study found a link between foot dysfunction and haemodynamics [11.]

This dysfunction can be related to external influences on the foot such as inflexible footwear or footwear with a mismatched flexion zone [12].

12.4 The importance of in-depth screening for prevention of complications

Scrolling back along the timeline from when diabetes is first diagnosed, it is now clear that in-depth detection of risk factors for lower limb complications ought to play a crucial role in any medical interventions, whether at primary, secondary or tertiary level, not only for prevention of complications but also to reduce the earlier mortality associated with lower limb complications.

Key findings from Statistics South Africa [13] show an evidence-based pattern in the increase of deaths from diabetes complications. Despite the slight decline in 2016 in overall deaths, diabetes mellitus was the second leading natural cause of deaths after tuberculosis, ahead of other forms of heart disease, cardiovascular disease and human immunodeficiency virus disease [13]. Most female deaths were attributable to diabetes mellitus. Non-communicable disease is increasing, underpinning the urgent need for evidence-based decisions and planning to provide appropriate public health education, preventive services and interventions. This is most true of the provisioning of podiatric medical personnel throughout all three levels of health care and, particularly, the establishment at district level of multi-disciplinary teams that include podiatry.

12.5 Multi-disciplinary Team Approach to Diabetes Care

Studies show that the implementation of a team-based approach to diabetes care and management (incorporating collaborative care across many specialties and disciplines) results in fewer hospitalizations, lower risks of diabetes complications and decreased health care costs [14-17]. Cost-effective diabetes team care is a result not only of intensive clinical management but also of patient education to prevent disease and promote health [18-20].

A diabetes multi-disciplinary team (MDT) will include physicians such as endocrinologists, cardiologists and vascular specialists together with the core allied disciplines of podiatry, diabetes educators, dieticians and specialized nurses. Further disciplines that support the patient with diabetes are pharmacy, ophthalmology, neurology, psychology, dentistry, home care nursing and social work [5, 14-15, 18].

12.6 The role of podiatry in the multi-disciplinary team care of Diabetes

Podiatry is a specialized discipline for the care of the foot and ankle. As such, podiatrists are trained to conduct in depth foot examinations and risk assessments of patients with diabetes. In the United States of America, studies confirm that podiatric care for patients with diabetes is cost effective and essential for reducing amputations [4, 14-15]. In patients suffering from diabetes, an in-depth clinical foot examination is the single most important factor in preventing foot ulceration and potential subsequent foot or limb loss [21]. A recent systematic review combined with meta-analysis asserts a reduction in diabetes amputations of between 39% to 56% with the inclusion of podiatric care in a multi-disciplinary team [1].

The patient's ability (and willingness) to exercise is becoming more important as studies show that exercise both lowers lipid levels and levels of free glucose in the blood. The current study showed another benefit of exercise, specifically that of promoting positive haemodynamics by engaging the foot venous pump as well as the calf muscle pump.

While many studies have described the benefits of physical activity in diabetes, [22-28] there is a vast difference in motivation for a patient who is simply "told to exercise" and the patient who is shown educational material and physical demonstrations about the working of the foot and calf muscular "pumps". In clinical practice, patients who understand how these "muscle pumps" work are more motivated to institute self-care measures such as daily exercise. The value of physical activity such as walking is not limited to an improvement in haemodynamics. Good haemodynamics are needed for cardiovascular and whole-body vascular function. In addition, studies have shown neural improvement related to increased levels of physical activity [29-32].

Resource-limited medicine as experienced in South Africa will need to use less expensive technology to adequately screen for prevention. The use of automated ABPI and the handheld Doppler ultrasound device avoids the information-gap on arterial waveform properties conferred by manual palpation methods, as previously discussed in Part One. These devices provide early signaling that peripheral arterial disease has begun and needs more specific attention and intervention. An audible Doppler signal (that the patient can hear) is of specific value in assisting to educate and motivate the diabetes patient on the value of lower limb exercise.

In order to empower patients to overcome diabetes ignorance in respect of the feet, the interaction with a podiatrist is invaluable. The use of handheld Doppler ultrasonography, with the audible signal enabled, had a startling effect on many state health patients (as described in Part One of the current study) when they understood that the sound was the beat of their heart in their feet. To show and then educate the patient about the action of the calf muscle "pump" is invaluable. This is done by asking the patient to grasp their calf muscle and dorsiflex the ankle to feel the gastrocnemius muscle contracting beneath their hands. This demonstration not only educates patients about the action of the foot and calf muscle "pumps" (as in the simple act of walking) but is vital to an understanding and internalization of the patient's desire and motivation to walk and exercise for better blood circulation.

The fact that patients can understand that an entire medical discipline exists to take care of the foot and ankle, serves to emphasize the importance of foot care to the diabetes patient. This has psychological value beyond the foot-related messages that other members of the medical team may give. All the "take home" messages from a patient-podiatrist interaction underpin the concept of prevention.

In the study into the prevalence of PAD in the cohort of outpatient diabetes patients at Edendale Hospital (described in Part One Chapter Four), the results support the need for full foot assessments, preferably by trained and qualified podiatrists so that a holistic picture of patient foot-related health is obtained. Accurate and early detection of risk factors is necessary to classify diabetes patients into risk categories and implement corrective preventative measures including timeous and appropriate patient education, as per national guidelines.

Part Three in the current study presented some of the evidence supporting the value of diabetes multi-disciplinary teams and podiatric medicine as an essential component thereof. In a 2016 study at the Edendale Hospital diabetes outpatient clinic, in which a podiatrist was included, there was measurable improvement in patient outcomes [33].

In the current study in which data was collected by means of detailed foot screening and assessment, the presence of a working podiatrist (the researcher) also resulted in timeous referrals for vascular imaging, cardiology, orthopaedics and physiotherapy. In the total of 301 patients assessed, 66 patients were referred for further vascular imaging; 12 patients were found to have undiagnosed cardiac arrhythmia and/or tachycardia on Doppler examination by the podiatrist and were referred for ECGs which confirmed cardiac anomalies. In addition,

the researcher who solely conducted the examinations referred 135 at-risk patients to the solitary podiatrist at Greys Hospital for urgent podiatric intervention and treatment, in addition to that podiatrist's existing extraordinary workload.

12.7 Synergy between haemodynamics and lower limb biomechanics: new insight

Part Two Chapter Five on haemodynamics produced information from the works of Uhl and Gillot, Corley and others [8-10, 34]. This led to the synergy between the physiology and biomechanics of the phases of gait to be presented with specific implications for the foot in diabetes. By meticulous dissection of hundreds of cadavers, Uhl and Gillot showed a pattern and structure to the movement of venous blood that replaced previous teaching [10]. Certainly, the content of instruction to students in lower limb anatomy who qualified prior to 2010 is now replaced by evidence of a system that fits the physiology of gait. In other words, dorsiflexion of the hallux causes the tightening of the plantar fascia, to lift it into the arch structure in the windlass mechanism, compress the valve-less venous reservoir and result in the ejection fraction to the calf muscles necessary to prevent venous stasis and negative haemodynamics.

This synergy is most important for further investigation in diabetes. Future studies should explore the extent to which foot interface devices such as molded orthotics and prescription innersoles with components such as lateral pads, plantar metatarsal pads and valgus pads alter haemodynamics, particularly in feet in which the venous foot pump is dysfunctional. Individualized shoe insert interventions may be shown to improve venous return, reduce oedema and assist the patient with diabetes to feel comfortable enough to embark on or increase their amount of exercise.

Depending on the results of such studies, in-shoe interventions could impact on the efforts of health care organisations to alter the lifestyle, diet and exercise habits of insulin resistant patients or populations at risk of developing diabetes.

12.8 Status of provision of qualified foot care for patients with diabetes

In 2015, a five-year retrospective study [35] of the District Health Information System (DHIS) was done on the number of registered diabetic patients and working podiatrists in the

public health sector of KZN. It was found that there are insufficient numbers of podiatric practitioners to meet the basic foot care needs of patients in the public health sector. According to the data collected from the DHIS, a normalised average of 1 288 973 existing state health diabetic patients was found on record in the province of KZN, the majority of which are found in the more urbanised districts of eThekwini, iLembe, uMgungundlovu, uThungulu and Ugu. A two-year normalised average of 14 901 patients was recorded as newly diagnosed diabetic patients.

As at the time of writing in 2020, the KZN Department of Health (DoH) has only two podiatrists employed, one each in the public health sectors of the eThekwini and uMgungundlovu districts. The podiatrists are positioned at Grade 1 and 2, with the other levels of practitioner hierarchy such as supervisors, policy makers and directors unoccupied. The Sahadew 2015 study calculated that, theoretically, a maximum of 8 032 patients could have been seen by the existing two podiatrists resulting in a shortfall in the province of 1 280 941 patients that did not and could not receive podiatric care and/or education [31].

Hospital admissions (including surgery) are the top cost in health care, accounting for over one-third of payments from private medical insurers [36]. During the period 2013 – 2014, KwaZulu-Natal Department of Health facilities carried out a total of 2 323 diabetic lower limb amputations [35]. By implementing a multi-disciplinary team approach including Podiatry, it is entirely feasible that a 56% reduction in amputations of this number may have resulted in saving 1 301 limbs/feet and the associated financial and psychosocial costs during that period, calculated at ZAR 6.155 billion as described in the manuscript in Part Three hereof.

A further five years have since passed since the figures profiled in the Sahadew study. While the burden of diabetes-related amputations in developed countries is decreasing, data from a 2018 study in KwaZulu-Natal shows that the incidence of lower limb amputations from 2013 to 2017 is on an upward slope in both regional and tertiary hospitals [37].

uMgungundlovu Health District in KwaZulu-Natal covers an area of 9 189 square kilometres. It is comprised of seven municipalities namely uMshwathi, Umgeni, Mpofana, Impendle, Msunduzi, uMkhambathini and Richmond. uMgungundlovu Health District has 9 hospitals (Table 1), 3 community health centres, 46 fixed clinics, 17 Mobile Clinics and 1 state aided clinic, serving an estimated population of 1.1 million inhabitants (1,095 million as at 2016 with growth of 1.9 % annually [38]

The KZN Department of Health Mission Statement for uMgungundlovu as per its website states that their mission is "To achieve such excellence in service delivery that all individuals in the uMgungundlovu District remain in better health, thus becoming the leading District in the country". Their vision is "Better health, Better life through Courage and Excellence" [39].

As at 2020, there are only two podiatry posts in the entire public sector for KwaZulu-Natal. No new state health podiatry posts have been created, yet the uMgungundlovu Health District was selected as a Pilot District to prepare for the implementation of National Health Insurance (NHI). Only one podiatrist is in uMgungundlovu district, based at Greys Hospital, as seen in Table 12.1.

Table 12.1: Podiatrist posts in uMgungundlovu district: Hospitals/Community Health Centres as at December 2019.

Hospitals in uMgungundlovu District	**Community Health Centres**
Appelbosch Hospital – nil podiatrists	Bruntville CHC (Mpofana) – nil podiatrists
Edendale Hospital – nil podiatrists	East Boom CHC (uMsunduzi) – nil podiatrists
Doris Goodwin Hospital – nil podiatrists	iMbalenhle CHC (iMbali) – nil podiatrists
Fort Napier Hospital – nil podiatrists	
Grey's Hospital – **1 podiatrist**	
Northdale Hospital – nil podiatrists	
Richmond Hospital – nil podiatrists	
Townhill Hospital – nil podiatrists	
uMgeni Hospital – nil podiatrists	

12.7 State Health and Private Medical Insurers (see also 12.12)

The MDT approach to diabetes care, including podiatry, has been implemented in the private healthcare sector by CDE (Centre for Diabetes and Endocrinology) who partnered with medical schemes to identify health care practitioners from all the disciplines required for the MDT. Currently, Discovery Health, a private Medical Scheme, launched its own diabetes care program for members, which includes provision for podiatry assessment and some treatment, although extended care for moderate, high risk and active foot disease is still inadequate, according to national guidelines. Today, with hindsight, it seems incredible that 25 years ago, private care medical insurers did not acknowledge the role of the podiatrist in

preventative foot care. Medical insurers at that time also dismissed the role of the registered dietician in diabetes as unimportant [36].

The current utilisation of an MDT with the inclusion of a podiatrist in the treatment of diabetes at public health institutions has not yet been implemented. Compliance with diabetic guidelines remains very poor, as found by a study conducted at a regional KZN hospital to assess compliance, that only 6% of 750 diabetes patient records noted foot examinations [40].

Multi-disciplinary diabetes teams need to be correctly funded at both state and private health levels. Both podiatrists and specialized diabetes nurse educators are under-provided for in terms of necessary patient time by many of the private medical insurers, including that of government itself. Lack of education among insurers regarding podiatric training and scope of practice reveals itself in the unwillingness of some insurers to reimburse podiatrists for diabetes wound care, and lack of reimbursement for custom prescription in-shoe orthoses at equitable rates to those of orthotist/prosthetists.

12.9 Health care should engage all professional skills to achieve local goals

According to the World Health Organisation's (WHO) framework document [41], the organisation and its partners ‘recognize inter-professional collaboration in education and practice as an innovative strategy that will play an important role in mitigating the global health workforce crisis’. It states that inter-professional education is a necessary step in creating a health workforce that is better prepared to collaborate and thereby respond to local health needs. The WHO framework document further suggests that health workers should engage any individual professional whose skills can help achieve local health goals. It lists a range of mechanisms that can shape effective inter-professional education. These include supportive management practices, i.e. identifying and supporting champions, the resolve to change the culture and attitudes of health workers, a willingness to update, renew and revise existing curricula, and developing and enforcing appropriate legislation that eliminates barriers to collaborative practice.

Masoetsa's unpublished 2005 dissertation on “Positioning of podiatric medicine within the South African healthcare system” notes the long history of attempts to reinstate podiatry into

the public health sector, military and correctional services, due to the error of omission of the discipline of podiatry in the post-1994 white paper on national health [42].

12.10 Lack of inter-professional teaching about role of podiatry in diabetes

Podiatric Medicine is a surgical discipline in its training and scope of practice. The discipline is represented on the joint board of Physiotherapy, Podiatry and Biokinetics at Health Professions Council of South Africa. Whereas medical doctor students are exposed to the role of physiotherapy, inter-professional teaching concerning podiatric medicine is absent at medical schools throughout South Africa.

An additional challenge is thus for the syllabus at all medical schools to include updated education about podiatric medicine, the depth of podiatric education and scope of practice, such that each medical discipline can better recognize symptomatic concerns warranting timely referral to podiatrists. This would reinforce annual diabetes foot assessment recommendations that have been shown globally and locally to lower the risk of serious lower limb complications in diabetes patients.

12.11 Recommendations to increase the number of podiatrists

The unpublished Masoetsa study highlighted the fact that a major barrier to addressing the vast under-supply of such practitioners is the lack of additional training institutions on the African continent and made a call for more podiatry training [42].

The University of Johannesburg (UJ) is the only institution in Africa providing training to podiatrists. UJ has an enrolment (first year) class of approximately 40 students and from 2015 – 2019, an average of 20 podiatrists qualified per year. There is a need for more universities with medical schools to offer qualifications in podiatric medicine; this would contribute to the adequate distribution of podiatrists and assist in meeting the growing demand from the rest of Africa for student enrolment places to study Podiatry.

Most of the subjects, equipment and resources used to train podiatrists already exist at medical schools. In recent years, academic advancement in podiatry has escalated, as a new

policy adopted by UJ requires all lecturers to hold a minimum of a master's degree, preferably a PhD. While planning is necessary, a Durban-based course in Podiatry within a medical school or within a faculty of health sciences would greatly contribute to correcting the poor distribution of podiatric diabetes services, reduce the number of lower limb amputations and associated costs to the state, as well as improve the quality of life of the increasing diabetic population. Bursaries and scholarships would not only offer opportunities to young adults to pursue tertiary education but also improve awareness of podiatry. Un-freezing or creation of new podiatry posts within public health facilities should be urgently considered. There are qualified podiatrists currently in private practice in KZN who have expressed willingness to work in state health. These podiatrists could begin the transition to a podiatric clinic within a diabetes multi-disciplinary team approach in each hospital.

The low numbers of podiatrists in KwaZulu-Natal, while statistically vast, can be remedied. It is recommended that an assessment of current tertiary medical and other healthcare institutions and their current syllabi is undertaken with the aim to introduce knowledge about podiatry's scope of practice and application into the inter-professional education models. Further, the call for more podiatry training must be urgently considered to address the vast shortage of practitioners. In the short term, collaboration between the HPCSA, private podiatry regulatory boards, existing practitioners, the DoH and tertiary institutions is required to strategize correcting the distribution of podiatrists and the appropriate management of diabetic patients.

12.12 Recommendations on approaches for preventative foot care in diabetes

Innovative approaches to diabetic foot assessment, foot education and foot treatment will be necessary until more structures which include podiatrists are created. These may include group teaching and group education to other health professions as to the nature and scope of podiatry to avoid stereotyping [43]. Podiatry includes treatment of complex issues relating to structural and functional defects of the foot and lower limb. Such education as to the role of podiatry in diabetes care is necessary to avoid any professional stereotyping that will detract from effective health delivery (for example, "podiatrists just cut toenails") that may exist as a result of ignorance.

New approaches such as telehealth and digital technology can support educational outreach by texts/SMSs to groups of patients; as well as support visual requests for podiatrist opinion or guidance on treatment where no podiatrist can be reached. Mobile phones can send visuals as a form of triage, to support referrals of patients for treatment to podiatrists at posts to be created at district, regional and tertiary care hospitals.

Healthcare can and must embrace technology to reach as many patients as possible. A study in India using mobile phones to enable a weekly coaching program by means of weekly messages to patients [44]. It contained an application that enabled tracking their weight, physical activity and diet, along with 12 weekly video lessons, and resulted in significantly ($p<0.01$) greater weight loss in the experimental group than in the control group who received usual care [44]. In another study, intermittent calf muscle electrical stimulation had a positive outcome on walking capacity in patients with diabetes suffering from claudication (calf muscle pain on walking) [45]. In Scotland, the Royal Free hospital podiatry team have started a Virtual Review Clinic to support teams working in community clinics and on home visits in North Central London. Full colour visuals are received from community workers in real time by the specialist podiatrist reviewer at the hospital. The initiative is intended to help reduce the number of times that patients with foot ulceration must visit the hospital, especially those needing to self-isolate during the time of COVID-19. For people with diabetes and foot ulceration this provides essential access to expert review whilst continuing to receive care in the most appropriate setting to save limbs and lives [46]. Health care will need to consider whether to postpone wound-related surgical procedures. Telehealth and combination home health and home care strategies are important new models to shift care away from hospitalization [47-53].

In South Africa, an approach using mobile phone technology could be used to educate and support community nurses and even registered and licensed traditional healers. These could be used to roll out in-depth educational material. Training workshops are needed for helpers to recognise the risk factors and warning signs preceding foot ulceration. Assessment of traditional healer knowledge regarding diabetes and diabetes foot care could provide valuable information about how to use their strength and influence in the community. Inclusion of traditional healers could broaden the base of timeous recognition and referral of warning signs for foot ulceration. Referral to clinics that, in turn, have been specifically trained and are equipped with the medical knowledge and ability to access expert podiatric virtual review from a hospital base, would enable prevention of complications that lead to amputations.

Similar training workshops for traditional healers regarding pharmacology in diabetes have taken place in Mamelodi [54]. During these workshops, traditional healers were trained about what their behavior should be, their roles in the community, how to work with the police and councillors and how to refer their patients to the clinic for further attention [54].

The Society of Endocrinology, Metabolism and Diabetes of South Africa designs and distributes a guideline for the management of diabetes, engineered to accommodate developing countries and their unique health circumstances. These include limited available medical resources, high levels of poverty, high burden of complications and poor patient compliance. The current 2017 guidelines (no updates have been published since 2017) are available as both a comprehensive manual and an easy-to-use reference sheet. The guidelines state that foot examinations by (suitably trained) healthcare providers must be an integral component of diabetes management to identify persons at risk for ulceration and lower-extremity amputation [55].

A diabetic patient is required to have an annual comprehensive foot screening by a podiatrist or suitably trained healthcare provider. The foot assessment must include a formal assessment for skin, bone and joint, nerve and vascular abnormalities as outlined in their Appendix 21.2 of the SEMDSA 2017 guidelines [55]. It is recommended that these guidelines in future include detailed education on and examination of footwear, in the light of the findings in this study in Part Two.

The SEMDSA national guidelines further state that all patients with type 2 diabetes must have their feet examined at least annually (more frequently in those at moderate and high risk for ulcers) in the protocol to prevent foot ulceration. All patients with type 2 diabetes should receive education on good foot care practices and ulcer prevention. People at high risk of foot ulceration and amputation should receive more frequent and intensive foot care education; and be referred to healthcare professionals trained in foot care management, such as podiatrists. Patients with a plantar foot ulcer, critical limb ischaemia, gangrene or Charcot foot must be referred urgently for specialist care to a centre with multidisciplinary care (i.e. including a podiatrist) [55].

12.13 Peripheral arterial disease: morbidity, shortened working life and mortality

It may be assumed, given the high numbers of diabetes-related amputations that, in the absence of more amputation prevention efforts, there are elevated numbers of patients at high risk. Widespread peripheral vascular disease has correlations to cardio-vascular and renal disease. Economically, many of these patients can no longer work. This non-employment imposes a high level of dependency among adults who are still of working age. It also shortens the period during which workers can contribute to fiscus and social security mechanisms, which are then inadequate. In a research report in 2019, this shortening of working life in South Africa for both men and women is high: time spent out of employment (all causes) is 33% in the case of men and 43% for women. Mortality is another factor that shortens South African life – only 44% of men aged 15 reach age 65 and 53% of women [56].

12.14 Direct and indirect costs of diabetes-related lower limb amputations

What is the cost to South Africa of podiatric care being such a poorly implemented skill in the healthcare system, even though podiatry is a registered discipline at Health Professions Council of South Africa?

By counting the rising numbers of diabetes-related amputations at a single hospital over a period of five years, and applying that data for the province, a gauge has been provided to indicate how much diabetes-related amputations mean in terms of annual costs to KZN and National Health. Compounding these costs are substantial socio-economic losses. The current study has shown that the role of podiatrists within multi-disciplinary diabetes teams is an evidence-based, affordable means of preventing a large percentage of diabetes-related amputations and their related costs.

A recent study (as at time of writing) compares the five-year mortality and direct costs of treating diabetic foot complications to those of cancer. It showed that, except for lung cancer, chronic limb ischaemia and all lower limb amputations (minor and major) were the highest causes of five-year mortality and costs were comparable to those for cancer [7].

The current study presents costs of amputation that are conservative, and the overall cost may be incalculable. At the time of writing, South Africa has the added burden of the COVID-19 pandemic. Human pathogenic coronaviruses bind to target cells via angiotensin-converting enzyme 2 (ACE2), normally expressed by epithelial cells of the lung. Patients with diabetes normally produce increased ACE-2. Treatment with ACE-inhibitors, especially in hypertension results in upregulation of ACE-2 that has been hypothesized to potentially facilitate infection with COVID-19 [57-58]. It is suggested that investigation of this hypothesis should encompass both the effects of therapy and genetic ACE-2 polymorphisms [57].

In another study on COVID-19 patients who had been discharged or died in Wuhan, China, 48% of patients had an existing co-morbidity. Of these, hypertension represented 30%, diabetes 19% and coronary heart disease 8% [59]. Since these three conditions are frequently simultaneously present in patients with diabetes, it is unknown how these were individually counted. Suffice to say that diabetes and its co-morbidities are now considered risk factors [59].

12.15 Summary

While acknowledging the many risk factors for diabetes-related amputation, this study focused on PAD since it is a condition frequently seen by podiatrists who assess and treat patients with diabetes. The examination of PAD by means of two electronic portable devices was used to collect data on a patient population attending a diabetes out-patient clinic in uMgungundlovu district. Early signs and established PAD were found in 94% of the sample, comprised of 96.7% black African patients. In a study published in the second semester of 2020, diabetes patients of ('black') African descent were associated with an increased risk of major amputation compared with 'whites' [60].

Since foot pathology such as ulceration needs adequate blood supply to heal, all possible means to prevent PAD become vital to prevent amputations. Education on lifestyle changes, exercise, diet and hydration are part of the preventative measures but none of this is possible if patients have painful feet. Ischaemia or poor blood supply will itself cause nerve damage (neuropathy), which can manifest as pain and paresthesia. Preventive measures, intensive foot

and footwear education, foot risk classification and foot care need to start immediately at diagnosis.

A synergistic relationship was found between the description of the function of the venous valve-less reservoir in the foot and the action of the hallux in the phases of gait. This aspect alone deserves attention in academic teaching and further study in biomechanical models. This study also presented the reasons why foot assessment in diabetes should include manual palpation to determine the presence or incompleteness of a metatarsal parabola, to institute callus and biomechanical imbalance prevention measures. Research carried out in the current study into the position of flexion in footwear, necessary for haemodynamics, yielded information that will need to be included in future medical curricula as well as guidelines on clinical examination and patient education.

Lastly, as shown in the draft cost analysis on diabetes-related amputations, engagement of podiatry in the MDT approach to diabetes care is affordable compared to the cost of amputations. Podiatry care for patients with diabetes has the potential not only to contribute to the efficient use and saving of medical and financial resources, but also, in conjunction with the team approach, to save the limbs of diabetic patients and improve their quality of life.

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Appendix 1-A: The Original Study Protocol – March 2017

University of KwaZulu-Natal
College of Health Sciences
School of Medicine

Relative metatarsal lengths and hyperkeratosis: Plantar screening in the prevention of Diabetic Foot Ulcers in KwaZulu-Natal

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EXECUTIVE SUMMARY

Statement of Purpose

The purpose of this quantitative, observational, comparative and analytical study is three-fold:

1. To analyse metatarsal lengths in a database of an asymptomatic population in order to compare metatarsophalangeal joint flex positions to the flex position built into footwear;

2. To clinically examine patients attending diabetes clinics at Edendale Hospital and RK Khan Hospital in a 3-month cycle (coinciding with patient therapeutic visits) in 2017 so as to categorise foot risk;

3. At the same time, to use a photographic instrument to record their plantar foot images. Post collection digital examination of these images will determine relative metatarsal lengths, bony protuberances and hyperkeratosis. The digital results will be compared with the clinical examination results, as well as the asymptomatic data from the first section.

Overview

Studies show that lower limb amputations in patients with diabetes can often be traced back to a foot lesion. Diabetic neuropathy, increased plantar pressure, formation of callus, ulceration and morbidity are clearly linked (Singh, Armstrong *et al*. 2005, Pavicic and Korting 2006, Sun, Cheng *et al*. 2011). Prevention of plantar foot ulcers is vital to reduce the incidence of lower limb amputations, poor patient outcomes, and the consequent socio-economic burden (van Netten, Price *et al*. 2016).

Diabetic foot screening and foot assessment are an integral part of foot ulcer preventative measures. Early detection of risk factors such as bony protuberances or irregular bone structure as well as hyperkeratosis (callus) can alert healthcare workers to the presence of pressure so that treatment can be scheduled. In the case of patients with

diabetes who are neuropathic or have poor vascular supply, such treatment is essential to prevent ulceration and potential amputations.

Among the osseous structural anomalies that warrant attention is brachymetatarsia of the first metatarsal or a short first metatarsal (SFM). This structural attribute can disrupt foot posture, resulting in transfer hyperkeratosis (callus) or helomata dura (corns) overlying the second or lesser metatarsals. Similarly, a longer first metatarsal which projects beyond the metatarsal parabola, in combination with incorrectly fitting footwear that abducts the hallux, has been implicated in the aetiology of hallux valgus. Bony protrusions, relative lengths of metatarsals and plantar hyperkeratosis will form the focus of this study.

Podiatry in South Africa is a scarce skill. For example, in Kwa-Zulu Natal, some 1.3 million people with diabetes were registered in the public healthcare sector for the period 2013/2014 (Sahadew, Singaram 2016). In 2016, there were only two podiatrists serving the public sector for this province.

It is necessary and important to find low cost examination and treatment pathways for diabetics who may present with transfer callus on the lesser metatarsophalangeal joints in the presence of anomalies of metatarsal lengths. Ideally, such examination and screening tools could be used by any medical personnel at primary care level for early identification of these risk factors among diabetic patients presenting with neuropathy and/or peripheral arterial disease. This study will use a photographic examination tool in addition to clinical examination. Since the images collected are digital, these could potentially be transmitted to a centrally located facility for confirmation of diagnosis by a podiatrist, followed by digital re-transmission of treatment instructions. Treatment instructions may include immediate referral to the podiatrist, or onward transmission of measurements for the fabrication or supply of in-shoe devices which will offload pressure, or footwear instructions – the treatment ramifications themselves are extensive and do not form part of this study.

Since an individual's footwear is the immediate environment around their feet, callus can also be caused by the pressure and friction of an incorrect flexion position at the metatarsal heads. It is important to ascertain whether footwear manufacture standards are congruent with the metatarsal flexion positions in the local population.

Aims of the study

1. Analyse a database of measurements of an asymptomatic adult multi-ethnic population to determine the relative metatarsal lengths of the first and fifth metatarsals.

2. Perform clinical assessments so as to do foot risk categorisation on a cohort of diabetes patients at two regional hospitals in KwaZulu-Natal. These clinical assessments will note the presence of bony protrusions such as any beneath the metatarsal heads, as well as the presence and location of plantar hyperkeratosis.

3. At the same time, capture photographic foot images of the same cohort of diabetes patients so as to subsequently compare the digital images with the results of the clinical assessment.

Objectives of the study

1. a. Measure the positions of MTPJ1 and MTPJ5 in a database of asymptomatic adults and express these as a percentage of the length of the foot in millimetres;

   b. Compare the anatomical location of the metatarsal heads to the fixed flexion position built into footwear by the footwear industry to determine whether congruence exists.

2. a. Carry out clinical foot assessments on a cohort of state health patients attending diabetic clinics at two different regional hospitals in KwaZulu-Natal. These manually recorded assessments will include musculoskeletal, dermatological, vascular (Doppler ultrasound) and neural examinations, utilising a modified Centre for Diabetes and Endocrinology (CDE) assessment form with permission.

   b. Perform risk categorisation according to the Society for Endocrinology Metabolism and Diabetes of South Africa (SEMDSA) 2016/2017 guidelines.

c. Establish the prevalence of peripheral neuropathy and peripheral arterial disease in the sample.

d. Provide patients with written information in either English or Zulu on prevention of foot ulcers in the presence of peripheral neuropathy and/or peripheral arterial disease.

3. a. At the same time as the clinical assessment, use a portable platform instrument for non-invasive photographic imaging of the foot to create Digital Imaging and Communications in Medicine (DICOM) compliant images and data for use in standard medical picture archiving and communication systems (PACS) workflows.

b. After data capture, examine and measure the images digitally in order to compare to physical clinical assessment data in respect of bony protuberances, disparate metatarsal lengths and plantar hyperkeratosis.

Project outputs

These will include:

a) The doctoral thesis, consisting of

Chapter One: Introduction – including a review on the diabetic foot

Chapter Two: Manuscript for publication detailing the results of the comparison of anatomical flex positions at the metatarsophalangeal joints in an asymptomatic (general) population to the flex positions built into footwear.

Chapter Three: Manuscript for publication documenting the prevalence of peripheral neuropathy and peripheral arterial disease in a sample of patients attending diabetic clinics in two regional hospitals in KwaZulu-Natal.

Chapter Four: Manuscript for publication documenting the prevalence of bony protuberances and hyperkeratosis in the study's diabetic cohort.

Chapter Five: Manuscript for publication documenting the comparison between the "hands-on" clinical assessment of bony protuberances and hyperkeratosis with a photographic method.

Chapter Six: Manuscript for publication reviewing the at-risk diabetic foot and comparing the results of the analysis of anatomical flex positions at the metatarsophalangeal joints in a diabetic population to the flex positions built into footwear with specific focus on at-risk diabetic foot needs.

Chapter Seven: General Discussion

b) Two local conference presentations: Centre for Diabetes and Endocrinology Annual Forum, August 2017 or South African Foot Surgeons Conference 2017; Podiatry Association of South Africa Biennial Congress Aug 2017.

c) One international conference presentation (Footwear and Biomechanics Symposium, Australia 2017, hosted by Griffith University, or RSSDI (Research Society for the Study of Diabetes in India) Congress in India in 2017, or FIP (Federation Internationale des Podologues) World Congress of Podiatry in 2019).

Relevance

The immediate impact of the project will take the form of the publications and dissemination of the results.

The knowledge to be gained from this study has the potential to prevent costly foot and lower limb complications in at-risk diabetic patients, particularly since undetected areas of potential pressure can result in ulceration, potentially leading to loss of limbs and mortality.

Should the photographic image findings correlate well to the clinical examination method, the photographic method can be suggested as a tool for use in community clinics which do not have a podiatrist or doctor on duty.

The results will inform footwear manufacture, not only in South Africa but in other footwear manufacturing countries who supply South Africa. It will add South African

data to the body of knowledge on foot morphology, anatomy and physiology as it pertains to footwear manufacture standards and guidelines.

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1 DEFINING THE RESEARCH PROBLEM

In patients suffering from diabetes, the clinical foot examination is the single most important factor in preventing foot ulceration and potential subsequent amputation. Global guidelines on diabetes care state that callus formation develops in response to pressure and/or friction and should be referred to a podiatrist, a foot specialist or foot team for removal and prevention of recurrence (Amod, Ascott-Evans *et al*. 2012, Naude, Smart *et al*. 2015, Bus, van Netten *et al.* 2016, NICE 2016, WHO 2016).

Since Kwa-Zulu Natal only has two podiatrists in the public sector, there are insufficient podiatrists to serve the 1,288 million registered diabetics in the public health system (Sahadew, Singaram 2015). Plantar pressure overload in the form of hyperkeratosis or helomata dura overlying the lesser metatarsals are risk factors for ulceration in persons suffering from peripheral neuropathy in diabetes mellitus. Prevention of plantar foot ulcers is important to reduce the incidence of lower limb amputations, poor patient outcomes and the consequent socio-economic burden (van Netten, Price *et al.* 2016) .

In the absence of sufficient podiatrists, it is important to find low cost examination and treatment pathways for diabetics who may present with transfer callus on the lesser metatarsophalangeal joints due to the presence of bony protuberances and length anomalies of the first metatarsal. Such an examination and screening method could be used be medical personnel at primary care level for early identification of these risk factors in neuropathic diabetic patients.

Since an individual's footwear is the immediate environment around their feet, callus can also be caused by pressure and friction of an incorrect flexion position of the shoe at the individual's metatarsal formula. It is important to ascertain whether footwear manufacture standards are congruent with the metatarsal flexion positions in the local population.

Aims of the study

1. Analyse a database of measurements of an asymptomatic adult multi-ethnic population to determine the relative metatarsal lengths of the first and fifth metatarsals.

2. Perform clinical assessments so as to do risk categorisation on a cohort of diabetes patients. These clinical assessments will note the presence of bony protrusions such as any beneath the metatarsal heads, as well as the presence and location of plantar hyperkeratosis.

3. At the same time, capture photographic foot images of the same cohort of diabetes patients so as to compare the digital images regarding relative metatarsal lengths and the presence of hyperkeratosis with the results of the clinical assessment.

Objectives of the study

a. Measure the positions of MTPJ1 and MTPJ5 in a database of asymptomatic adults and express these as a percentage of the length of the foot in millimetres;
b. Compare the anatomical location of the metatarsal heads to the fixed flexion position built into footwear by the footwear industry to determine whether congruence exists.

b. Carry out clinical foot assessments on a cohort of state health patients attending diabetic clinics at two different regional hospitals in KwaZulu-Natal. These manually recorded assessments will include musculoskeletal, dermatological, vascular (Doppler ultrasound) and neural examinations.
c. Perform risk categorisation according to the SEMDSA 2012 guidelines.
d. Establish the prevalence of peripheral neuropathy and peripheral arterial disease.
e. Provide patients with written information on prevention of foot ulcers in the presence of peripheral neuropathy and/or peripheral arterial disease.

f. At the same time as the clinical assessment, use a portable platform instrument for non-invasive photographic imaging of the foot to create Digital Imaging and Communications in Medicine (DICOM) compliant images and data for use in standard medical picture archiving and communication systems (PACS) workflows.

g. Post data capture, examine and measure the images digitally in order to compare to physical clinical assessment data in respect of bony protuberances, disparate metatarsal lengths and plantar hyperkeratosis.

2 FIRST PAPER: DOES THE FLEX POSITION OF THE FIRST METATARSOPHALANGEAL JOINT CORRELATE TO THAT OF GENERAL PURPOSE FOOTWEAR?

PLEASE NOTE: The database for this first paper carries BREC approval BCA058/17

2.1 Background and Literature Review

The function of the first metatarsophalangeal joint (MTPJ1) is adversely affected when the fulcrum of the shoe does not match the fulcrum location of the joint (Kleindienst, Morrison *et al.,* 2008). Adequate range of motion of the MTPJ1 depends on adequate dorsiflexion (Bojsen-Møller and Lamoreux 1979). The flex area is important to allow for a natural dorsiflexion during the propulsion phase of gait.

Since an individual's footwear is the immediate environment around their feet, callus can further be caused by pressure and friction of an incorrect flexion position at the metatarsal formula (Singh, Bentley *et al*. 1996, van der Zwaard, Vanwanseele *et al*. 2014, Bus, van Netten *et al.*, 2016). It is important to ascertain whether footwear manufacture standards are congruent with the metatarsal flexion positions in the local population.

A last is the solid model foot form around which a shoe is shaped and finished in the shoe making process (Figure 1).

Figure 1: A pair of lasts (green) showing a shoe fabricated around the last.
(source: collection A.T. Thompson)

Last designers locate a set position for the flex point of the MTPJ1. European guidelines position the flex point at 66 per cent of overall last length for sandals and shoes (Koleff, 1997). North American last-making guidelines are similar, placing the fulcrum at 63 per cent of overall last length (Adrian 1991).

Although some work has been reported about specialized footwear for post-operative orthopaedic recovery (Strauss 2005; Kurup *et al*., 2012), little is found to connect orthopaedic foot knowledge to the standards used by the footwear industry to make general purpose footwear. We thus question whether actual foot measurements support the last standards presently used to manufacture general purpose footwear.

An earlier foot measurement survey in South Africa addressed a limited group of female adult feet (Hill, 1954). In 2006, a new 3D database of foot measurements was created by laser and point scanning of the right foot of 510 female participants (Thompson, 2006). An extract of these measurement data will be used in this study.

We will investigate how the position of MTPJ1 in the unshod foot, in sandals and in closed shoes compares to the two MTPJ1 positions assumed by last makers. We will further ask if other measures are related to the position of the MTPJ1, and if the MTPJ1 positions can be translated into a design suggestion for footwear.

The first question to be asked is whether the actual position of MTPJ1 in the measured sample is significantly different from the flex point positions of the MPTJ1 as used by the footwear industry.

The second question to be asked is whether any other variables such as population group, age, weight, height, foot tread width and forefoot girth are significantly associated with the position of MTPJ1.

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2.3 Aims

This study aims to:-

a. Compare the location of flexure of MTPJ1 to flexion position parameters used in footwear manufacture.

b. Determine whether variables such as population group, age, weight, height, foot tread width and forefoot girth are significantly associated with the position of MTPJ1.

2.4 Objectives

a. In an extant database of female foot measurements, calculate the position of MTPJ1 in millimetres so as to express these lengths as a percentage of the length of the foot;

b. Compare the position of MTPJ1 in the sample to the metatarsal flex position built into footwear made according to industry guidelines for South Africa and the United States of America.

2.5 Materials

Participants for the extant database were randomly selected from a large volunteer pool of working women at the campuses of two national universities, the University of Johannesburg, and the University of KwaZulu-Natal. In addition, a convenience sample of female crew members from the national airline, a national media broadcaster and a church group was included. In descriptive summary, participants' ages ranged from 21 to 69 years, their weight from 34.7 kg to 150.9 kg and their BMI from 13 to 56.

2.6 Methods

A laser scanner captured a 3D image of the right foot of each participant. A special platform positioned the foot during scanning. Each participant's foot was guided into a block of orthopaedic impression foam in a relaxed calcaneal stance position (Evans

2003). Successive passes of the handheld scanner created the scanned surfaces (Figure 2). The negative foam impression of the plantar surface of the foot was scanned after the dorsal surface foot scan, and post-processing software digitally "stitched" the dorsal and plantar scans to form a point cloud 3D image of the foot.

Figure 2: Successive scanning sweeps of a dorsal scan of the foot and ankle (Source: A T Thompson)

While the foot was positioned for scanning, palpation of the foot confirmed bony landmark points, which were then marked by a digital stylus to provide precise positioning data. Software was written to build three dimensional foot shapes and to derive the linear measurements between the landmark points. Data for 53 of the 510 participants were excluded due to scanning inclusion errors flagged by the post-processing software. The dataset extracted for this study will include data for selected landmarks, gender, population group, age, weight, height, tread width and forefoot girth.

2.7 Validity

A pilot study on ten participants was undertaken to establish inter-rater reliability and to verify the repeatability of the scanner and stylus instrumentation.

2.8 Data selection and statistical analysis

Data analysis will be performed using three statistical software packages namely: Stata Version 13, R-studio Version 3.3.2, and Tableau Version 10. The three software

packages have unique features which allow for data manipulation, analytics and presentation.

Continuous variables will be tested for normality using the Shapiro-Wilk and Shapiro-Francia tests which will determine whether parametric or non-parametric tests can be used for inferential statistical analyses.

To assess the distribution of continuous variables, Median and Interquartile Ranges (IQRs) or Mean and Standard Deviation will be computed. To determine the distribution of the Rear foot % of Foot length (%) and Rear foot % of sandal length (%) among study participants and show whether this deviated from the U.S. and South African industry standards, a scatter plots with horizontal lines running through the data to indicate the location of mean or median values will be plotted. A one sample t-test or its non-parametric equivalent will be used as applicable to determine whether the Rear foot % of Foot length (%) and Rear foot % of sandal length (%) among study participants are different from the USA and SA industry measures.

Inferential statistical tests will be used to assess whether the distribution of the variable "Zone width of possible MTPJ1 fulcrum positions from sandals to closed shoes (mm)" differs by population group. This analysis will involve the Kruskal-Wallis test or the one-way ANOVA. The median and/or mean differences between groups and the associated IQRs will plotted using a boxplot with quantile plot overlays. To assess the strength of the relationship between the variable "Zone width of possible MTPJ1 fulcrum positions from sandals to closed shoes (mm)" and other continuous variables (age, weight, height, tread width and tape forefront girth), Spearmen's or Pearson's correlation tests will be performed as applicable. A visual inspection of the relationship between the response variable and each predictor variable adjusted for other predictor variables will be achieved by plotting Multivariate Lowess Smooths using the mlowess command (Royston and Cox, 2005) in Stata. By simultaneously computing the smooth of the response variable on all predictor variables, this non-parametric multiple regression method can adjust each smooth for the others. Throughout the analysis the level of statistical significance will be set at $p<0.05$.

2.9 Ethical considerations

Informed consent was obtained from 510 adult female participants under the prior Ethics Clearance Certificate EC212004/009 from the University of Johannesburg.

The present study will be conducted in accordance with the Helsinki Declaration.

Ethics Clearance for this study has been granted from the Biomedical Ethics Committee of the University of KwaZulu-Natal, College of Health under BREC approval BCA058/17.

3 SECOND PAPER: PREVALENCE OF PERIPHERAL NEUROPATHY AND PERIPHERAL ARTERIAL DISEASE IN A SAMPLE OF DIABETIC PATIENTS AT TWO REGIONAL HOSPITALS IN KWAZULU-NATAL

3.1 Background and Literature Review

Studies have shown that lower limb amputations in diabetes can be traced back to a foot lesion, which if untreated, can progress to an ulcer and consequent morbidity (Singh, Armstrong *et al*. 2005). A clear link between diabetic neuropathy, increased plantar pressure, formation of callus and ulceration has been shown (Singh, Armstrong *et al*. 2005, Pavicic and Korting 2006, Sun, Cheng *et al*. 2011). Prevention of plantar foot ulcers is important to reduce their socio-economic burden and prevent lower limb amputations (van Netten, Price *et al.* 2016).

In patients suffering from diabetes, the clinical foot examination is the single most important factor in preventing foot ulceration and potential subsequent foot or limb loss (Clarke and Tsubane 2008). Global and local guidelines on the management of diabetes state that callus formation develops in response to pressure and/or friction and should be referred to a podiatrist or foot team for removal and prevention of recurrence *(*Amod *et al.* 2012, Naude, Smart *et al.* 2015, Bus, van Netten *et al*. 2016, NICE 2016, WHO 2016).

Diabetes care guidelines endorse the annual (or more frequent) examination of the foot to prevent pedal complications of diabetes such as ulceration and amputation (Mayfield, Reiber *et al*. 1998, Lavery, Hunt *et al.* 2010, Amod *et al.* 2012, Bus, van Netten *et al*. 2016, WHO 2016).

Foot screening methods such as Sibbald's 60-second screen for the high risk diabetic foot may record callus (hyperkeratosis) but may lack specific detail about the callus and if found, suggest onward referral to a podiatrist, foot specialist or foot team (Sibbald, Ayello *et al.* 2012, Kuhnke, Botros *et al*. 2013).

Several studies have led to the World Health Organisation statement that a multi-disciplinary team approach, with the inclusion of podiatry in treating the diabetic foot, can reduce amputations by up to 85% (WHO, 2015).

According to a recent study by Sahadew, Kwa-Zulu Natal, a province of South Africa, has some 1,28 million people registered with diabetes in the public sector which translates into a diabetes prevalence of 12.5% (Sahadew, Singaram *et al*. 2016). As at 2016, there are only two podiatrists serving the public sector for this province, and 13 podiatrists serving the private sector in KwaZulu-Natal. Until this deficit of podiatric care is corrected in the healthcare system, it is important to find alternative examination and treatment pathways for diabetics who may present with ulceration risk factors such as metatarsals of anomalous length and transfer hyperkeratosis overlying the lesser metatarsophalangeal joints.

The study by Sahadew found that there were 2,323 diabetic lower limb amputations carried out in DoH facilities in Kwa-Zulu Natal during the period 2013-2014, but the dermal etiology of these was not documented (Sahadew, MSc UKZN thesis 2016).

It is proposed that the feet of diabetic patients presenting at two regional hospitals, namely Edendale in Pietermaritzburg and R K Khan in Chatsworth be examined and recorded utilising the CDE (Centre for Diabetes and Endocrinology) Foot Assessment Form, as used in private health care (Appendix 4). Permission to use this examination format has been granted by CDE (Appendix 5). The examination will record the presence and location or absence of plantar bony protrusions and hyperkeratosis, as well as the neurological and vascular status of the patients' feet.

Permission to conduct the study will be obtained from the Department of Health and Hospital authorities once BREC provisional approval is obtained.

Volunteer patients will be asked in either English or Zulu for their consent to be examined.

Data analysis will determine the prevalence of peripheral neuropathy and peripheral arterial disease and assign foot risk as per SEMDSA guidelines (see section 3.4).

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3.3 Aim

Perform CDE clinical foot assessments on a cohort of diabetes patients presenting at two regional hospitals in KwaZulu-Natal over a 3-month period. These clinical assessments will record the presence of bony protrusions such as any beneath the metatarsal heads, as well as the presence and location of plantar hyperkeratosis, in addition to signs of peripheral neuropathy and angiopathy.

3.4 Objectives

a. Carry out clinical foot assessments on a cohort of state health patients attending diabetic clinics at two different regional hospitals in KwaZulu-Natal. These manually recorded assessments will include musculoskeletal, dermatological, vascular (Doppler ultrasound) and neural examinations.
b. Perform risk categorisation according to the SEMDSA 2012 guidelines.

Table 1: SEMDSA Risk Categorization System for diabetic feet (Amod *et al*., 2012)

Category	**Risk profile**	**Follow-up frequency**
0	No sensory neuropathy and no PAD	Once a year
1	Sensory neuropathy present but no foot deformity or PAD	Once every six months
2	Sensory neuropathy and signs of foot deformity and PAD present	Once every three months
3	Previous ulceration or amputation	Once every one to three months

c. Analyse the assessment data to determine the prevalence of peripheral neuropathy and peripheral arterial disease.
d. To determine any predictors of peripheral neuropathy and peripheral arterial disease in the study sample.
e. Provide patients with written information on prevention of foot ulcers in the presence of peripheral neuropathy and/or peripheral arterial disease with foot deformity.

3.5 Materials – Participants

Participants who will be asked to volunteer will be state health patients attending diabetic clinics at two regional hospitals - Edendale Hospital (Pietermaritzburg) and RK Khan Hospital (Chatsworth) in KwaZulu-Natal.

3.6 Instrument

The diabetic foot assessment tool that will be used is a modified version of the 2015 issue of the Centre for Diabetes and Endocrinology (CDE) Foot Assessment Form (Appendix 6). Permission has been granted by CDE to use this form for purposes of the research study (Appendix 7).

3.7 Methods

Participants will be asked to sit upright on an examination plinth with their legs and feet extended on the plinth. The PI will sit on a chair facing the participant's feet.

Musculoskeletal examination will consist of conventional medical palpation, rotation of joints and observation. Dermatological examination will be carried out by palpation and observation. Vascular examination will be performed by palpation, visual observation and auscultation of Doppler ultrasound waveforms. Neurological sensory examination will use a 10g Semmes Weinstein monofilament, a NeuroTip instrument, a TipTherm instrument, a 125Hz Tuning fork. In addition, two reflexes will be tested, namely the ankle and patella reflexes. Footwear will be assessed as suitable or unsuitable. Detailed description of the examination methods may be found in Appendix 8.

3.8 Validity

Inter- and intra- rater reliability of Doppler use:

For this part of the study the inter- and intra-rater reliability of performing a Doppler ultrasound assessment of the dorsalis pedis and posterior tibial arteries and the ability to interpret their results (i.e., use of the Doppler) will be investigated. Ten participants will be placed in a horizontal supine position and rested for at least 5 minutes prior to the assessment. To assess inter-rater reliability of clinical use of the Doppler, the PI and her assistant podiatrist will be required to independently assess dorsalis pedis and posterior

tibial arterial flow using a Huntleigh Multi Dopplex II bi-directional Doppler (Huntleigh, UK) and ultrasound transmission gel (Mista Surge, South Africa). All testing equipment will be new at the beginning of the study. Based on the audio and visual waveforms produced by their own Doppler assessments, the podiatrists will then grade Doppler waveforms as absent, monophasic or multiphasic. The participants will return one week later to the same measurement locality. Following the same test protocol, each participant will have their waveforms obtained and graded again by one of the podiatrists from their previous testing session using the same procedure described previously.

Depending on funding, the PI may have the option to record Doppler waveforms (using the Dopplex Reporter Software).

3.9 Statistical analysis

Data analysis will be performed using three statistical software packages namely: Stata Version 13, R-studio Version 3.3.2, and Tableau Version 10. The three software packages have unique features which allow for data manipulation, analytics and presentation.

Patient demographic and clinical characteristics, including the presence of orthopaedic, dermatological, vascular, and neurological, will be summarised using descriptive statistics such as frequencies/ proportions and percentages. The results will be tabulated by regional hospital.

The prevalence of peripheral neuropathy and peripheral arterial disease will be computed as composite metrics and presented graphically using bar graphs with percentages and counts. Exploratory bivariate analysis will involve cross tabulation of dependant variables (presence of peripheral neuropathy and peripheral arterial disease) and independent variables including age, gender, diabetes mellitus, ethnic group, presence of hypertension, aspirin therapy, history of renal failure, smoking status, anthropometrics indices, dyslipidaemia and ACE-I/Other Rx, etc. Chi-square or Fisher's Exact test will be used to assess if there are statistically significant associations between these variables.

The independent variables with p-value less than 0.25 during bivariate analysis will be selected as candidates for multivariate analysis which will seek to determine the predictors of peripheral neuropathy and peripheral arterial disease in the study sample. Association between the dependent and independent variables will be assessed using Odds Ratios (ORs) and 95% Confidence Intervals (CI). The ORs and CIs will be plotted using a forest plot and/or profile plots to enhance visual inspection of the relationships between the independent and dependent variables. Statistical association will be considered significant if p-value is <0.05. Multi-collinearity between variables will also be checked in the adjusted model.

4 THIRD PAPER: METATARSAL ARCHITECTURE AND PLANTAR HYPERKERATOSIS IN AT-RISK DIABETIC PATIENTS PRESENTING AT TWO REGIONAL HOSPITALS IN KWAZULU-NATAL: A COMPARATIVE ANALYSIS OF TWO METHODS

4.1 Background and Literature Review

Areas of high pressure under the neuropathic or angiopathic diabetic foot are risk factors for ulceration. While electronic pressure mat systems or force platforms can map areas of high pressure under the foot, these take up space and at a cost in excess of R200 000 are too costly to deploy at primary care level in KwaZulu-Natal. One of the clinical signs of pressure is transfer callus on the lesser metatarsophalangeal joints because of length anomaly of the first metatarsal. It is important to find alternative examination and treatment pathways for diabetics who may present with signs of high pressure areas. Such an examination and screening method may be used by non-podiatric medical personnel at primary care level for early identification of neuropathic diabetic patients who are at increased risk of ulceration.

A low-cost method of simultaneously recording plantar surface anatomy and pathology in such a way that it can be digitally transmitted onwards for central assessment, which at the same time serves as the template for fabrication and provision of a non-invasive method of treatment, is needed in the current South African health context to help prevent diabetic ulceration.

Dudley J Morton was one of the earliest researchers to describe brachymetatarsia of the first metatarsal and to postulate atavism or similarities to evolutionary traits (Morton 1927). He believed that a short first metatarsal derived from a past in which man's ancestors were both arboreal and terrestrial.

Morton recorded and measured brachymetatarsia of the first metatarsal in an African sample (Morton 1935), which he termed a "short first metatarsal" (SFM). He believed that SFM gives rise to different leverage stresses and changes to structural stability. As treatment, Morton suggested the use of a "compensating insole" containing a platform

beneath the head of the short first metatarsal which would extend the length of the hallux. This is different to the construction method employed by South African-trained podiatrists, who place an extension pad to fit the parabola formed by the lesser metatarsals but not extending the entire length of the hallux. Figure 3 illustrates a normal metatarsal parabolic 'curve' which passes through all five of the metatarsophalangeal joints.

Figure 3: Radiographic foot bone image with superimposed normal metatarsal parabola.

(Source: collection A T Thompson)

Different authors have used terms such as "Morton's foot", 'Index minus foot', and 'short first metatarsal' to refer to brachymetatarsia of the first metatarsal. Controversy exists as to what quantifies or defines the shortness of a "Short first metatarsal", hereafter to be called "SFM". This project will explore whether these terms describe the same anatomical concept. It will also present the literature on what different authors consider to be the point of difference between the length of the first metatarsal and another reference point in order to be termed "short".

Viladot classified the forefoot by relative toe and metatarsal lengths. He used the description “Greek foot” to describe a foot in which the second toe is longer than the first and “Egyptian” foot to describe a foot in which the first toe is longest (Viladot 1973). In describing metatarsals, the metatarsal length formulae are index plus 1>2>3>4>5; index plus minus 1≥2>3>4>5; and Index minus 2>1>3>4>5. In a study of 1000 (European?) feet, Viladot recorded 16% index plus, 26% index plus minus and 56% index minus (Viladot 1982). The terminology of “Index plus, index plus minus and index minus” is still used in current orthopaedic surgical literature.

4.2 Studies of measurement

Methods for measuring metatarsal lengths may use x-ray examinations, direct bone measurements and clinical palpation. X-ray examinations are costly, require primary care patients to travel to x-ray facilities, result in absence from work and decreased productivity, and involve ionising radiation exposure. Direct bone measurements preclude living subjects as these can only be done on osseous material, which could be affected by necrosis. Studies have shown that palpation-based methods are simple, cheap and non-invasive, in addition to having a high degree of reliability (Spooner, Kilmartin *et al*. 1994, Martínez-Cepa, Zuil-Escobar *et al*. 2014).

A short first metatarsal has been variously defined as one that is shorter in relative length of articulation than the second metatarsal by more than 3 millimetres (Martínez-Cepa, Zuil-Escobar *et al.* 2014). Hardy and Clapham arrived at a mean protrusion of 4 millimetres between first metatarsal to second metatarsal (Hardy and Clapham 1951).

Studies suggest different prevalence figures of SFM/Index minus/Morton’s foot in different populations (Harris and Beath 1949, Hardy and Clapham 1951, Drez, Young et al. 1980, Viladot 1991).

Further, studies that have looked at the relative lengths of all metatarsals have explored the measurement of the “metatarsal parabola” (Valley and Reese 1991, Dominguez-Maldonado, Munuera-Martinez et al. 2014). The metatarsal ‘parabola’ is so called since the cascade of the differing lengths of the metatarsals as they touch the surface is similar to a parabola, namely the intersection of an arc with a flat surface.

4.3 Studies of functional stability

Dudley Morton considered that the parabola functions to provide stability during the stance and propulsive portion of gait, as weight is transferred to the metatarsal heads. What happens in SFM is that during weight transfer to the forefoot (the metatarsophalangeal joints), the gradual cascade of transfer is disrupted. If the first metatarsal is too short, he believed it could not assume the body weight and compensatory changes in foot posture might occur. In support of Morton's concept of lateral movement of pressure, a subsequent study (Rodgers and Cavanagh 1989) found that patients with a Morton foot registered higher pressures beneath the second metatarsal (mean of 320 kPa) compared to a non-Morton foot control group (mean 243kPa). A study presented to the American Orthopaedic Foot and Ankle Society (Coughlin and Jones 2005) found that 60% of patients who presented with metatarsalgia displayed lesser metatarsophalangeal joint instability. Researchers further considered that the etiology of lesser metatarsophalangeal joint symptoms was a deficit in first ray weight bearing (Grimes and Coughlin 2006). In a 2006 critical analysis of Morton's concepts, Glasoe and Coughlin conducted a review which found support for Morton's notion that weight can shift laterally in individuals who have a short first ray (Glasoe and Coughlin 2006).

Dudley Morton, with limited technology, postulated various other concepts such as the "axis of balance", hypertrophy of the second metatarsal and separation between the medial cuneiforms as indicators of increased mobility of the first ray. Glasoe and Coughlin found little scientific evidence to support these concepts. They noted that Morton did not adequately take into account the influence of the plantar aponeurosis and muscles in stabilization of the forefoot. Medial longitudinal arch height and calcaneal posture are two indicators of muscle balance in foot posture, yet these were not measured by Morton. These indicators can be determined from the images to be collected in this study, although the data and reporting thereon will form the basis for a post-doctoral study.

Examination of static stance offers an insight into the architecture that enables the load-bearing and balancing function of the human foot. In a 1987 study, Cavanagh refutes

the prior theory of tripod load distribution in favour of a six-point load distribution under the forefoot, consisting of the two sesamoids under the first metatarsophalangeal joints and the four lesser metatarsal heads (Cavanagh, Rodgers *et al*. 1987). Variations in divergence of the first and second metatarsals (metatarsal protrusion) may alter foot alignment during stance.

4.4 Pathologies found in association with Index minus and Index plus feet

On examination in routine podiatry practice in South Africa, some patients present with painful foot pathology related to a faulty metatarsal parabola, commonly termed by podiatrists as a 'short first metatarsal' (SFM) and by the orthopaedic community as an Index minus foot. Transfer metatarsalgia can occur as the lesser metatarsal heads assume the body weight, with resultant overlying formation of callus (hyperkeratosis) and/or corns (helomata dura).

SFM is commonly found in conjunction with metatarsalgia, plantar hyperkeratosis, plantar heloma durum (Espinosa, Brodsky *et al*. 2010) and may be associated with pathologies related to compensatory altered gait such as acquired pes planus, hallux valgus and hallux limitus or rigidus.

SFM may relate to the compensations for the altered MTPJ1 fulcrum position and function (loss of moment at MTPJ1). Since the fulcrum of MTPJ1in SFM is more proximal, one of the compensations could be increased flexion of the first ray in order for MTPJ1 to 'reach the ground'. Another compensation could be abduction of the foot in order to shift the fulcrum laterally over the second metatarsal head, leading to callus and corn formation due to overload of the dermal structures. Compensatory abduction of the forefoot, combined with rotation over the second metatarsal may increase pronatory rotational forces over the first metatarsal head, increasing the risk of hallux valgus formation in a foot at risk of hallux valgus (due to other inherent and inherited structures such as rounded articular facets). Lack of a functioning fulcrum at MTPJ1 will restrict the windlass mechanism as described in the seminal work by Hicks (Hicks 1954). A restricted windlass mechanism can be implicated in the development of acquired pes planus. In some instances, compensation for the lack of function of the MTPJ1 fulcrum may result in hyperflexion of the proximal hallucal phalanx and

hyperextension of the distal hallucal phalanx (Figure 4 II). The resultant jamming of the articular surfaces of MTPJ1 can result in hallux limitus and hallux rigidus.

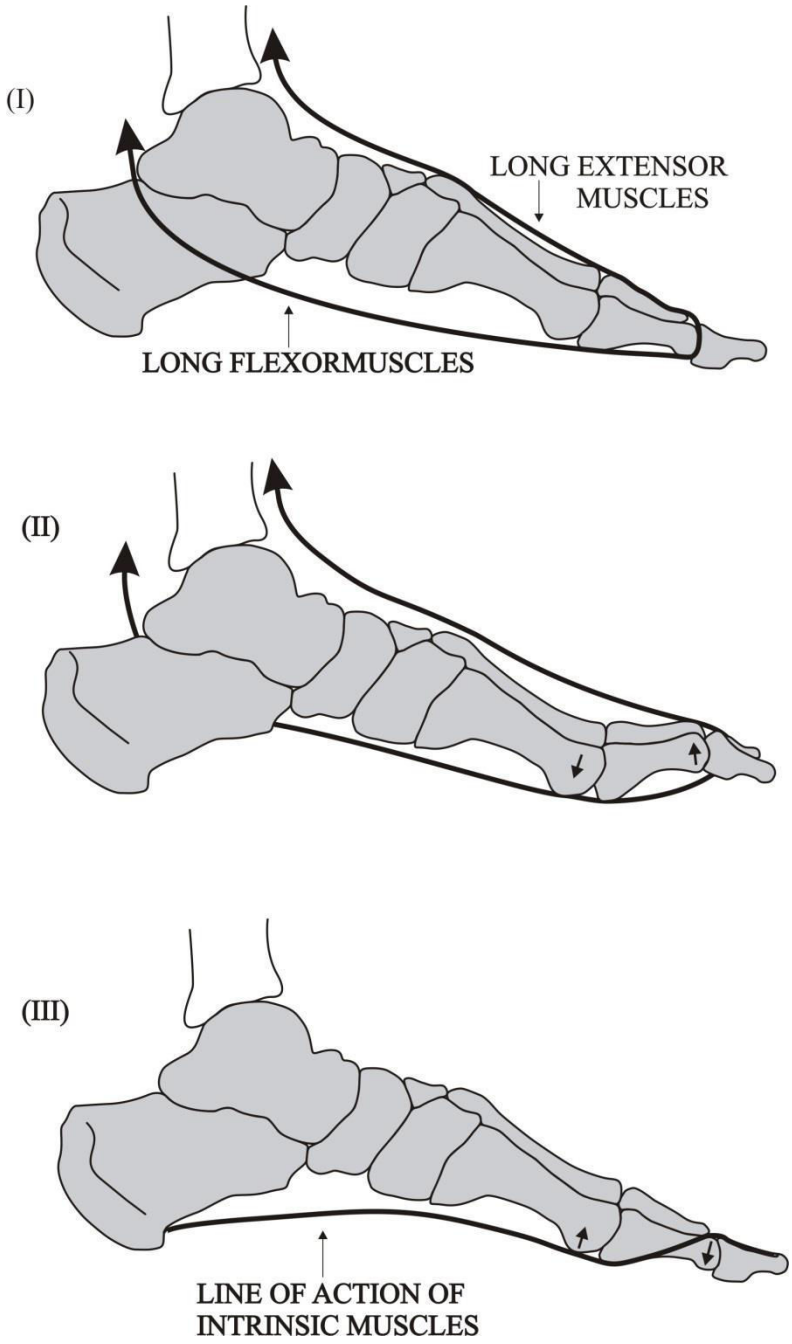

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Figure 4: Action of muscles on toes (After Stamm, 1964)

Glasoe and Coughlin made the statement that “problems associated with the Morton Foot are not common” (Glasoe and Coughlin 2006). This study may support or refute that statement.

Although anomalies of hallux length are thought to be implicated in the development of such pathologies as acquired pes planus, hallux valgus (Mancuso *et al*., 2003), hallux limitus and hallux rigidus, an investigation into the relationship of metatarsal lengths and these latter pathologies is outside the scope of this study.

4.5 Palpation method for measurement of metatarsal head position

Podiatric clinical palpation technique is taught to identify, inter alia, the position of the metatarsal heads. A study in 1994 established the validity and reliability of the dorsal palpation technique when compared to radiographic measures (Spooner, Kilmartin *et al*. 1994).

Two decades later, another study established intra-observer reliability of measuring first and second metatarsal protrusion by means of palpation (Martínez-Cepa, Zuil-Escobar *et al*. 2014).

In South Africa, the method taught is a plantar palpation method. This consists of passively dorsiflexing the metatarsophalangeal joint with one hand, while palpating the plantar joint margins with the other. The examiner marks what is perceived to be the most distal end of the metatarsal head with an appropriate pen.

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4.7 Aim

Capture photographic foot images of a cohort of diabetes patients on the same day and immediately after their clinical foot assessment, and thereafter assess if there is a level of agreement in the measurement data taken using both types of assessment.

4.8 Objectives

Examine the digital images post-capture in order to

a. measure relative metatarsal lengths
b. assess whether hyperkeratosis can be seen to be present
c. compare these data with the results of the clinical assessment to establish the agreement in both methods.

4.9 Materials

Participants who will be asked to volunteer will be state health patients attending diabetic clinics at two regional hospitals - Edendale Hospital (Pietermaritzburg) and RK Khan Hospital (Chatsworth) in KwaZulu-Natal.

4.10 Instrument

The study will use a low cost portable clinical instrument for non-invasive photographic imaging of the foot. The instrument consists of a low frame assembled from structural profiled aluminium, constructed in such a way as to support a 12 millimetre toughened transparent safety glass platform that is certified to support 150 kilograms. Attached to the aluminium frame are fixtures to support the camera elements and cabling to connect to a laptop personal computer.

Custom software for this process will create Digital Imaging and Communications in Medicine (DICOM) compliant images and data for use in standard medical picture archiving and communication systems (PACS) workflows.

4.11 Method

Participants will lie supine on an examination plinth for the plantar foot examination and marking. As per podiatric training and using a fresh pair of surgical gloves for each examination, the metatarsophalangeal joint area will be palpated until the location of the most distal, palpable aspect of the metatarsal head is identified. The plantar location of the metatarsophalangeal joints will be marked with a non-toxic surgical marking pen.

Participants will be assisted to step unshod onto the measurement platform. (The measurement platform and examination plinth will be sprayed and wiped down with an alcohol antiseptic solution in between each participant's use).

On the measurement platform, the participant's feet will be photographed in weight bearing stance position in medial, rear, dorsal and plantar views.

The participant will be assisted off the platform and the skin markings will be removed with cotton wool and baby oil or alcohol (depending on which pen type is sourced).

After data collection, software will be used to examine the images of the plantar, medial dorsal and rear surface of the participants' feet to extract measurements which will comprise the data that will be analysed. The method of calcaneal bisection will be performed as per the method validated in a previous study (Robinson, Dyson *et al*. 2001).

4.12 Views of the feet, surface marks, camera positions and post capture measurements

Medial view: Each foot will be palpated and marked with a surgical pen at the medial joint line of the first metatarsophalangeal joint (MTPJ1), as well as the most medial point of the tuberosity of the navicular bone (NAV) (Figure 5) prior to photography (Figure 6).

Figure 5: Marking of medial tuberosity of navicular and first metatarsophalangeal joint.

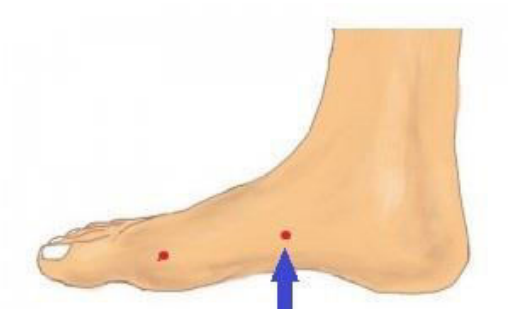

Figure 6: Camera should be positioned with 'line of sight' aimed at the navicular mark.

After image collection, digital measurement will measure the overall length of foot in millimetres, length of the foot from the most distal part of the back of the heel to the most distal point of the longest toe, and medial longitudinal arch height measured from the navicular tuberosity to the horizontal plane of the plantar surface (Figure 7).

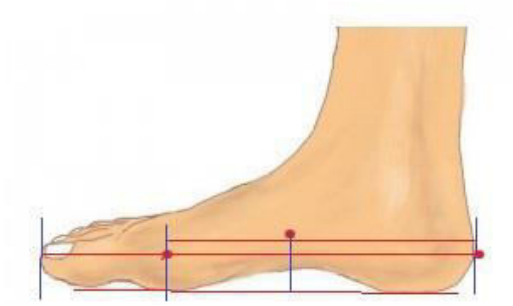

Figure 7: Measurements to be extracted from medial view.

Each foot will be palpated and marked with a surgical pen at the joint line of each metatarsophalangeal joint 1 through 5 (Figure 8).

Figure 8: Plantar view of marked feet

After image collection, digital measurement by means of the software will measure

- overall length of foot in millimetres, i.e., length of the foot from the most distal part of the back of the heel to the most distal point of the longest toe, and
- relative lengths of the metatarsals by measuring from the most distal part of the back of the heel to the palpated centre of joint for each of the five metatarsophalangeal joints (figure 9).

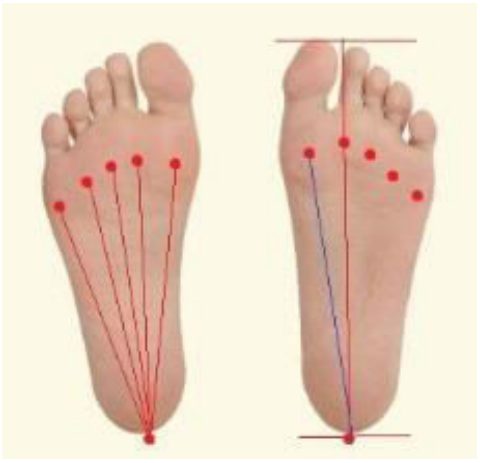

Figure 9: Measurements to be extracted from plantar view.

For the rear view, the camera should line up midway between the two feet (figure 10). This corresponds to the line of sight used by a clinician in visual examination.

The camera can be aimed at the horizontal surface – these images below seem to be from a 35º to 40 º elevation.

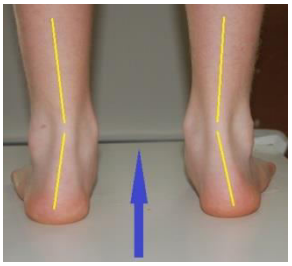

Figure 10: Mid foot placement of camera focus

It is important to capture at least 10 centimetres of the leg above the ankle (lower third of the leg) so that the bisection lines can be digitally inserted post data capture.

Software will calculate the angle formed by the two lines (Figure 11).

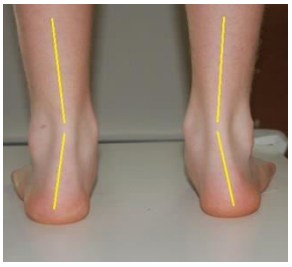

Figure 11: Lines used by software to calculate angles.

4.13 Validity

The platform instrument will be validated by means of a small test group of patients for whom there are existing weight bearing radiographs of their feet (anterior-posterior and lateral views). These patients will be asked to volunteer for foot measurement using the platform instrument. The patients will recline in a supine position on an examination plinth. They will present the plantar surface of their feet for palpation and marking of their metatarsal heads with a non-toxic skin pen (as per the method taught in Podiatric Medicine training in South Africa – see section 4.11). Participants will stand upright in relaxed stance so that the dorsal creases of their flexed metatarsal joints and navicular tuberosity can be palpated and surface marked with the same pen according to the technique validated by Spooner (Spooner, Kilmartin *et al*. 1994). They will be assisted onto the platform by the PI or an assistant.

The dorsally palpated marked positions and the plantar palpated marked positions of their metatarsals will be compared to the images of the metatarsals in the radiographs to establish which of the two methods (dorsal or plantar) has greatest validity and reliability.

In order to control for internal validity in the collection of SFM data, the testing will be performed, using the platform instrument, connected to a computer, in order to collect the data variables. The custom software will provide for calibration of the instrument before data collection.

4.14 Data analysis

Data analysis will be performed using three statistical software packages namely: Stata Version 13, R-studio Version 3.3.2, and Tableau Version 10. The three software packages have unique features which allow for data manipulation, analytics and presentation.

The distribution of relative metatarsal lengths and other measurements will be examined using means and standard deviations or median and interquartile based on parametricity of the data. In order to compare the photographic foot imaging technique and the clinical assessment in terms of their agreement in generating comparable measures, the Bland-Altman test and plots will be used, with 2-standard deviations and confidence intervals. This method will test the hypothesis that the relative metatarsal length measurement with the photographic foot imaging technique will have clinically acceptable agreement with the measurement using the clinical assessment. A Bland-Altman analysis has been accepted as the standard statistical approach to assess the agreement between two methods of clinical measurement (Altman and Bland, 1983; Bland and Altman, 1986; Mantha *et al*, 2000)

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5 PARTICIPANT SELECTION AND SAMPLING STRATEGY

A convenience sample of known adult diabetic patients will be recruited from Edendale Hospital, Pietermaritzburg and asked to volunteer. Similarly, a convenience sample of known adult diabetic patients will be recruited from RK Khan Hospital, Chatsworth and asked to volunteer. These two hospitals have been selected because they are the only ones that currently have podiatric service so that, should the study reveal that a patient needs urgent podiatric care, they can be immediately referred. This would not be the case at any other regional hospital in the province where there is currently no podiatric care available.

Participants will be asked to sign consent once the procedure has been explained to them.

6 RECRUITMENT

Informative posters will be placed at both venues. Permission from Department of Health and from each Hospital Manager will be sought once BREC approval is obtained.

7 STUDY SETTING

The study will take place in an examination room at each diabetic clinic.

8 ETHICAL CONSIDERATIONS

Anonymity and confidentiality will be protected during analysis of the database of a stratified sample population at UJ and UKZN since records are numbered and carry no associated names or identities.

Consent will be obtained by means of a signed consent form in either English or Zulu, which will identify the researcher and the institutional association of the researcher, as well as of her supervisor; it will explain that participation is voluntary; that responses will be treated in a confidential manner; that anonymity will be ensured because participant names will be replaced by numbers. The consent form will explain that participants are free to withdraw from the research at any time without any negative or undesirable consequences to themselves. Further, participants will be advised that there are no personal benefits to be received as a result of their participation in the research.

Collection of data will respect the Helsinki guidelines for human research.

Approval will be requested from the Biomedical Research Ethics Committee of the University of KwaZulu Natal, College of Health Sciences (see Appendix: Ethical).

9 DATA SELECTION

The variables to be collected from the diabetic patients are in three clusters: demographic and medical status, clinical foot assessment results and photographic image results.

DEMOGRAPHIC, MEDICAL STATUS VARIABLES	VALUES
Date of birth/age	Integer
Gender	M or F, convert to 1,2
DM type I or II	1 or 2
Ethnic group	Black, White, Indian/Asian, Coloured convert to 1,2,3,4
Hypertensive	Yes/No, convert to 1,2
Aspirin therapy	Yes/No, convert to 1,2
Dislipidaemic	Yes/No, convert to 1,2
Renal failure	Yes/No, convert to 1,2
Latest T-cholesterol	Integer with decimal point
ACE-I/ARB Rx	Yes/No, convert to 1,2
Smoker	Yes, Used to, Never, convert to 1,2,3
Latest HBA1c	Integer with decimal point
Height	Metres, Integer with decimal point
Weight	Kilograms, Integer with decimal point
Calculate Body Mass Index	(weight (kg) / [height (m)]2)

	FOOT ASSESSMENT VARIABLES	VALUES
Musculoskeletal 1	Deformity	Yes/No, convert to 1,2
Musculoskeletal 2	Bony prominences	Yes/No, convert to 1,2
Musculoskeletal 3	Joint mobility	Yes/No, convert to 1,2
Musculoskeletal 4	Amputations	Yes/No, convert to 1,2
Footwear 1	Footwear Style	Acceptable/Unacceptable
Footwear 2	Footwear Cushioning	Present/Absent
Derm 1	Ulcers	Yes/No, convert to 1,2
Derm 2	Infection	Yes/No, convert to 1,2
Derm 3	Fissures	Yes/No, convert to 1,2
Derm 4	Corns	Yes/No, convert to 1,2
Derm 5	Callus	Yes/No, convert to 1,2
Vascular 1	Doppler dp	Mono, Bi, Tri-phasic, bounding, convert to integers
Vascular 2	Doppler Post tibialis	ditto
Vascular 3	Temperature	Too warm, normal, too cold – convert to integers
Vascular 4	Colour	Inflamed, normal, pale – convert to integers
Vascular 5	Capillary refill time (seconds)	Integer, if less than 2 = Negative, if> 2 = positive
Neuro 1	Monofilament	Sensate Yes/No, convert to 1,2
Neuro 2	Light dull touch	Yes/No, convert to 1,2
Neuro 3	Hot cold	Yes/No, convert to 1,2
Neuro 4	Sharp blunt	Yes/No, convert to 1,2
Neuro 5	Vibration	Yes/No, convert to 1,2
Neuro 6	Patella reflex	Yes/No, convert to 1,2
Neuro 7	Ankle reflex	Yes/No, convert to 1,2
	Sensory Neuropathy	Calculation based on variables results
		If any of Neuro1 to 7 are positive
	Angiopathy (PAD)	Calculation based on variables results
		If any 3 of vascular results are positive
	Foot risk Category	Calculation based on SEMDSA classification

Category	**Risk profile**
0	No sensory neuropathy and no PAD
1	Sensory neuropathy present but no foot deformity or PAD
2	Sensory neuropathy and signs of foot deformity and PAD present
3	Previous ulceration or amputation

PHOTO IMAGE VARIABLE	VALUES
Photo Arch height	Integer millimetres (mm)
Photo Foot length	Integer mm
MTPJ1 to heel (length)	Integer mm
MTPJ2 to heel (length)	Integer mm
MTPJ3 to heel (length)	Integer mm
MTPJ4 to heel (length)	Integer mm
MTPJ5 to heel (length)	Integer mm
Photo visible deformity	Yes/No, convert to 1,2
Photo visible bony prominence	Yes/No, convert to 1,2
Photo visible fissures	Yes/No, convert to 1,2
Photo visible corns	Yes/No, convert to 1,2
Photo visible callus	Yes/No, convert to 1,2
Calculate Short first metatarsal	If MTPJ1 to heel length < MTPJ2 to heel length
Calculate Long first metatarsal	If MTPJ1 to heel length > MTPJ2 to heel length

10 BUDGET

Item	Item Description	Detail	Rand Totals
1	Statistical consultation	Waived in lieu of stats authorship	---------- -----
2	Graphic support to prepare explanatory figures	10 hours at R600 per hour	6000
3	Inter-library loans – fees for articles/books not in the library	Unknown, estimated	200
4	Publication costs	R5000 per manuscript x 3	15000
5	Printing/photocopying of Patient Information Sheet, posters	4 sheets x 400,	1083
6		4 posters, mounted	900
7	800 pairs of surgical gloves, for PI and assistant (2 prs x 400 patients)	Mista Surge (wholesaler)	1160
8	Supply of 10 litres Hibitaine spray	Mista Surge	832
9	1 x Huntleigh MD2 bi-directional hand Doppler foot assessment kit + software	Canonbury UK at research price	18000
10	50 x Semmes Weinstein 10g monofilaments (use each 10 times)	From MedisMedical Cape Town at wholesale	5793
11	1 x TipTherm instrument	From Leoto Supplies, Cape Town at wholesale	734
12	Supply of NeuroPen and 500 neurotips	From Leoto, Cape Town at wholesale	2000
13	Supply of Tuning Fork 125 hz	Leoto supplies	780
14	Supply of Patella hammer	Leoto supplies	355
15	Supply of 800 linen savers	Mista Surge wholesalers	1320
16	Surgical marker pens	Richard-Allan surgical pens	1200
17	Travel local CDE annual conference in August 2017	Travel - flights	2400
		Accommodation	4000
		Conference Fee	2800
18	Travel local PASA annual conference in August 2017	Travel - flights	2400
		Accommodation	4000
		Conference Fee	3200
19	Local travel to Pietermaritzburg and Chatsworth.	Fuel cost, own vehicle. Estimated at 500 km per week x 12 weeks	4800
20	Technical support	Custom made cases on wheels for equipment	6000
	Totals		75035

11 CONTRIBUTORS AND AUTHORSHIP

Name	Department	Contribution	Author or acknowledgements
C Aldous	University of KwaZulu-Natal	Constructive input and editing	Co-author
B Zipfel	University of Witwatersrand	Constructive input and editing	Co-author
M Muzigaba	Enhancing Care Foundation	Data analysis and textual input	Co-author
V Pataca	Telmo Medical	Technical consultation	Acknowledgement

Appendix 1-B: Revised Executive Summary – August 2018

APPENDIX 1 A: THE UPDATED STUDY PROTOCOL

Global prevalence of diabetes is stated by world bodies to be in the region of six percent, whereas research in KwaZulu-Natal, South Africa in 2015 found a prevalence of five times that figure. A study in 2019 showed that lower limb amputations due to diabetes lower limb complications are on the increase in this province.

Since lower limb ischaemia is one of the causes of the non-healing lower limb lesions in diabetes (which are known to precede amputations), this study will use detailed podiatric foot assessment and low cost technology to determine the incidence of diabetes patients presenting with ischaemia and peripheral vascular disease at a diabetes outpatient clinic of a regional hospital in the uMgungundlovu health district.

In the first part of this work, a scoping literature review will be compiled. It will identify publications that describe the use of the ankle-brachial index (ABI) in screening for diabetes related lower limb peripheral arterial disease in IDF middle- and low-income countries.

A sample of patients attending the diabetes outpatient clinic at Edendale Hospital will be assessed using handheld doppler ultrasonography and automated ankle-brachial equipment. By including a complete podiatric foot assessment that will include musculo-skeletal, dermatological, neurological and footwear examination, a risk classification will also be performed. The risk classification will place the assessed patients into Low, Medium, High Risk and Active foot disease categories as per the 2017 guidelines of the Society for Endocrinology, Metabolism and Diabetes of South Africa. Initially the study protocol requested permission to examine two patient populations, one in Chatsworth and the other in Pietermaritzburg. Due to reorganizational changes at RK Khan Hospital, only Edendale Hospital was accessed.

A further consideration that impacts on vascular return in the lower limb is both musculo-skeletal and concerns footwear. This relates to an aspect of metatarsal structure (relative metatarsal lengths that form a complete or incomplete metatarsal parabola) as well as the role of footwear in enabling or hindering foot flexion necessary for vascular return. In part two of this work, insights into haemodynamics of the lower limb that were published within the past 10 years will be presented in relationship to the biomechanical ‘windlass mechanism’ in the foot; physical concepts that impact on vascular supply to and from the foot. Since footwear is the immediate environment to the shod foot, this work will document the characteristics of footwear that enable the function of anatomical mechanisms that promote blood flow in the foot.

There is a dermatological aspect to an incomplete metatarsal parabola which is particularly important in patients with diabetes. The metatarsal parabola serves a ‘roll over’ function for the foot in the heel lift phase of gait. An incomplete metatarsal parabola may cause disruption of foot posture, balance, forefoot function and increased

plantar pressure that can lead to the formation of pre-ulcerative hyperkeratosis or callus in diabetes patients.

The study will analyse a three-dimensional foot measurement database to find the fulcrum location of the first metatarsophalangeal joint with which to compare to the flexion position in shoe and sandal manufacture.

In part three, retrospective data on diabetes related lower limb amputations (for the five years between 2013 and 2017 at the surgical unit of Grey's Hospital) will be prepared for analysis to quantify the diagnostic imaging, laboratory costs, theatre and ward costs for these patients. Further medical costs and socio-economic costs will be quantified and extrapolated across the province. Evidence will support the call for podiatry care to decrease the amputation rate in diabetes, as well as support for the multi-disciplinary team approach to the care of diabetes patients.

In the closing section, I will discuss pertinent and urgent issues. These include but are not limited to the suggested urgent establishment of a university department for the discipline of Podiatric Medicine in the province of KwaZulu-Natal. In the state health sector, posts should be opened at Tertiary and Regional Hospitals to attract both South African unemployed qualified podiatrists before they are lured into overseas posts, as well as podiatrists returning from overseas and foreign podiatrists and podiatric surgeons who wish to work in podiatric medicine in South Africa. Until further training and formation of combined units which include podiatrists are created, different approaches to diabetic foot assessment, foot education and foot treatment will be necessary. These may include, inter alia, group teaching of patients by podiatrists and education to health professionals as to the nature of podiatric medicine, which includes treatment of complex issues relating to structural and functional defects of the foot and lower limb. Such education as to the role of podiatry in diabetes care is vital to avoid any professional stereotyping that may detract from effective health delivery (for example, "podiatrists just cut toenails") that may still exist in the medical profession as a result of professional ignorance.

An additional challenge is for the syllabus at medical schools to include updated inter profession education on podiatric medicine, such that each medical discipline can better recognize symptomatic concerns warranting timely referral, as well as reinforce the recommendations for annual podiatric foot assessment that have been shown globally to lower the risk of serious lower limb complications for diabetic patients.

An educational program for primary care nurses in respect of the diabetic foot needs to be written, preferably by a podiatrist, with measurable performance by means of knowledge testing. Approaches such as telehealth in the age of smart phone cameras should be explored in future studies. These could support the specially trained primary healthcare worker to send assistance enquiries with or without images to Tertiary and Regional-based podiatric medicine facilities, to appropriately refer patients for treatment to those podiatric facilities.

Appendix 2: BREC Ethical Approval BCA058/17

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Tel: 27 31 2604769 - Fax: 27 31 260-4609
Email: BREC@ukzn.ac.za
Website: http://research.ukzn.ac.za/ResearchEthics/BiomedicalResearchEthics.aspx

30 November 2017

Dr ALT Thompson
Discipline of Podiatric Medicine
School of Clinical Medicine
Anette.thompson@telmo.co.za

Dear Dr Thompson

Protocol: South African Female adults foot measurement 2016.
Degree: Post-Doctoral Fellow
BREC reference number: BCA058/17

Your correspondence received on 27 November 2017 requesting approval to interrogate a database containing data on diabetic amputations carried out at Greys Hospital since 2012 (collected by Dr Damian Clarke) has been **noted and approved** by a sub-committee of the Biomedical Research Ethics Committee.

This approval will be ratified by the committee at its next meeting taking place on 12 December 2017.

Yours sincerely

[redacted]

Mrs A Marimuthu
Senior Administrator: Biomedical Research Ethics

cc supervisor: Aldousc@ukzn.ac.za

Appendix 3-A: BREC Provisional Approval BE264/17

UNIVERSITY OF
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Website: http://research.ukzn.ac.za/ResearchEthics/BiomedicalResearchEthics.aspx

10 May 2017

Mrs ALT Thompson (215082336)
Discipline of Podiatric Medicine
School of Clinical Medicine
anette.thompson@telmo.co.za

Dear Mrs Thompson

Title: Relative metatarsal lengths and hyperkeratosis: Plantar screening in the prevention of diabetic foot ulcers in KwaZulu-Natal.
Degree: PhD
BREC Ref No: BE264/17

PROVISIONAL APPROVAL

A sub-committee of the Biomedical Research Ethics Committee has considered your application received on 13 April 2017.

The study is given **PROVISIONAL APPROVAL** subject to the response to the following:

1. Hospital and DOH approval to be submitted to BREC.

Please could each query be responded to separately e.g. BREC Query 1: (List the query) and below the query state the Answer to Query 1. A tabulated response is not acceptable.

All changes to the text must be highlighted and the relevant pages of the research application form resubmitted. Only one copy of the responses and amended pages needs to be submitted.
Only when full ethical approval is given, may the study begin. **Full ethics approval has not been given at this stage.**

PLEASE NOTE: Provisional approval is valid for 6 months only - should we not hear from you during this time the study will be closed and reapplication will need to be made.

Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2015), South African National Good Clinical Practice Guidelines (2006) (if applicable) and with UKZN BREC ethics requirements as contained in the UKZN BREC Terms of Reference and Standard Operating Procedures, all available at http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx.

BREC is registered with the South African National Health Research Ethics Council (REC-290408-009). BREC has US Office for Human Research Protections (OHRP) Federal-wide Assurance (FWA 678).

Yours sincerely

[redacted]
Mrs A Marimuthu
Senior Administrator: Biomedical Research Ethics

cc supervisor: aldousc@ukzn.ac.za
cc postgraduate administrator: scmpg@ukzn.ac.za

Appendix 3-B: BREC Approval BE264/17

UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

25 July 2017

Mrs ALT Thompson (215082336)
Discipline of Podiatric Medicine
School of Clinical Medicine
anette.thompson@telmo.co.za

Dear Mrs Thompson

Title: Relative metatarsal lengths and hyperkeratosis: Plantar screening in the prevention of diabetic foot ulcers in KwaZulu-Natal.
Degree: PhD **BREC Ref No:** BE264/17

EXPEDITED APPLICATION: APPROVAL LETTER

A sub-committee of the Biomedical Research Ethics Committee has considered and noted your application received on 13 April 2017.

The study was provisionally approved pending appropriate responses to queries raised. Your response received on 03 July 2017 to BREC letter dated 10 May 2017 have been noted by a sub-committee of the Biomedical Research Ethics Committee. The conditions have now been met and the study is given **full ethics approval** and may begin as from 25 July 2017. Please ensure that site permissions are obtained and forwarded to BREC for approval before commencing research at a site.

This approval is valid for one year from **25 July 2017.** To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to BREC on the appropriate BREC form 2-3 months before the expiry date.

Any amendments to this study, unless urgently required to ensure safety of participants, must be approved by BREC prior to implementation.

Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2015), South African National Good Clinical Practice Guidelines (2006) (if applicable) and with UKZN BREC ethics requirements as contained in the UKZN BREC Terms of Reference and Standard Operating Procedures, all available at http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx.

BREC is registered with the South African National Health Research Ethics Council (REC-290408-009). BREC has US Office for Human Research Protections (OHRP) Federal-wide Assurance (FWA 678).

We wish you well with this study. We would appreciate receiving copies of all publications arising out of this study.

Yours sincerely

[redacted]
Prof D Wassenaar
Deputy Chair: Biomedical Research Ethics Committee

cc supervisor: aldousc@ukzn.ac.za
cc postgraduate administrator: scmpg@ukzn.ac.za

Appendix 4: BREC Approval extension BE264/17

UNIVERSITY OF
KWAZULU-NATAL
INYUVESI
YAKWAZULU-NATALI
RESEARCH OFFICE
Biomedical Research Ethics Administration
Westville Campus, Govan Mbeki Building
Private Bag X 54001
Durban
4000
KwaZulu-Natal, SOUTH AFRICA
Tel: 27 31 2604769 - Fax: 27 31 2604609
Email: BREC@ukzn.ac.za
Website http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx

20 August 2018

Mrs ALT Thompson (215082336)
Discipline of Podiatric Medicine
School of Clinical Medicine
anette.thompson@telmo.co.za

Dear Mrs Thompson

Title: Relative metatarsal lengths and hyperkeratosis: Plantar screening in the prevention of diabetic foot ulcers in KwaZulu-Natal.
Degree: PhD
BREC Ref No: BE264/17

RECERTIFICATION APPLICATION APPROVAL NOTICE

Approved:	25 July 2018
Expiration of Ethical Approval:	24 July 2019

I wish to advise you that your application for Recertification received on 31 July 2018 for the above protocol has been **noted and approved** by a sub-committee of the Biomedical Research Ethics Committee (BREC) for another approval period. The start and end dates of this period are indicated above.

If any modifications or adverse events occur in the project before your next scheduled review, you must submit them to BREC for review. Except in emergency situations, no change to the protocol may be implemented until you have received written BREC approval for the change.

The committee will be notified of the above approval at its next meeting to be held on 11 September 2018.

Yours sincerely

[redacted]

Prof V Rambiritch
Chair: Biomedical Research Ethics Committee

cc supervisor: aldousc@ukzn.ac.za
cc postgraduate administrator: scmpg@ukzn.ac.za

Appendix 5: Edendale Hospital permission

health
Department:
Health
PROVINCE OF KWAZULU-NATAL

DIRECTORATE: CHIEF EXECUTIVE OFFICER

Physical Address: No.89 Selby Msimang Road, Pietermaritzburg, 3216
Postal Address: P/Bag X 509, PLESSISLAER, 3216
Tel: 033 395 4040 Fax: 033 395 4087 Email: [redacted]
www.kznhealth.gov.za

EDENDALE HOSPITAL

Enquiries: Ms. H.G Mkhize- Grace
Ext: 4040
Date: 09 June 2017

Mrs ALT Thompson
Discipline of Paediatric Medicine
School of Clinical Medicine

Dear Mrs Thompson

RE: RELATIVE MATATARSAL LENGTHS AND HYPERKERATOSIS: PLANTAR SCREENING IN THE PREVENTION OF DIABETIC FOOT ULCERS IN KZN".

Your request dated 09 June 2017 is acknowledged and refers.

I have pleasure in informing you that permission has been granted to you by Edendale Hospital to conduct research.

Please note the following:

1. Please ensure that you adhere to all the policies, procedures, protocols and guidelines of the Department of Health with regards to this research.
2. Please ensure this office is informed before you commence your research.
3. The Hospital will not provide any resources for this research.
4. You will be expected to provide feedback on your findings to Edendale Hospital.

Yours Sincerely

[redacted]

MRS ZSI NDWANDWE
CHIEF EXECUTIVE OFFICER
EDENDALE HOSPITAL

Appendix 6: RK Khan Hospital permission

health
Department:
Health
PROVINCE OF KWAZULU-NATAL

R.K KHAN HOSPITAL

Postal Address: Private Bag X004, Chatsworth, 4030
Physical Address: 336 R. K. Khan Circle, Croftdene,
Chatsworth, 4030
Tel.: 031-459 6001
Fax: 031-401 1247
Email: siphephelo.mabatha@kznhealth.gov.za

OFFICE OF THE CEO

ENQUIRIES: DR T. MAYISE

6 June 2017

Mrs ALT Thompson
(UKZN)

Dear Madam

RE: PERMISSION TO CONDUCT RESEARCH: RELATIVE METATARSAL LENGTHS AND HYPERKERATOSIS: PLANTAR SCREENING IN THE PREVENTION OF DIABETIC FOOT ULCERS IN KWAZULU-NATAL

Permission is granted to conduct the study at this institution.

Please note the following:

1. Please ensure that you adhere to all the policies, procedures, protocols and guidelines of the Institution with regards to this research.

2. Please ensure this office is informed before you commence your research and your University's Ethics approval must be attached.

3. You will be expected to provide feedback on your findings to this institution.

4. You will be liaising with : Dr J. Mulla
   : Head of Department: Medicine
   Tel.: 031 459 6172

Yours faithfully

[redacted]

DR T. MAYISE
ACTING HOSPITAL CEO

Appendix 7: English Information Sheet

UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

INFORMATION SHEET FOR PARTICIPANT
(ISIZULU NGEMUVA)

College of Health Sciences
School of Clinical Medicine
September/October/November 2018

Hello!

My name is Anette Thompson. I am a qualified medical foot practitioner called a podiatrist. I am a doctoral student at the University of Kwa-Zulu Natal. If you need, you can telephone me at work on 031-201 9907 or email me at anette.thompson@telmo.co.za.

You are invited to consider participating in a study to research the diabetic foot in KwaZulu-Natal. The aim and purpose of this research is to find out how common it is to find diabetic patients with the type of foot bone structure and hard skin under their feet, which could be a risk factor for foot ulcers. Foot ulcers can lead to amputation.

The study is expected to enrol about 350 participants in total. Patients will be measured at the diabetes clinic in Edendale Hospital in Pietermaritzburg. The study will take place over a period of three months. Each patient will have their feet examined for bony protuberances and hard skin, blood circulation by means of a Doppler Ultrasound device, a special ankle and arm blood pressure test as well as two small touch tests. There will be no blood tests taken. These are all standard examinations and are not painful.

The duration of your participation if you choose to enrol and remain in the study is expected to be a maximum of 12 minutes while I carry out the examinations. The study is self-funded by the researcher.

The study does not anticipate any risks or discomforts to you. We hope that it will benefit you by providing an updated assessment of your feet to doctor. This research will serve to suggest a way in which other patients at primary care clinics could benefit from foot screening.

This study has been ethically reviewed and approved by the UKZN Biomedical research Ethics Committee (Ref. BE264/17).

In the event of any problems or concerns/questions you may contact the researcher at telephone 031-2019907 or the UKZN Biomedical Research Ethics Committee, contact details as follows:

BIOMEDICAL RESEARCH ETHICS ADMINISTRATION Research Office, Westville Campus Govan Mbeki Building Private Bag X 54001 Durban 4000 KwaZulu-Natal, SOUTH AFRICA Tel: 27 31 2604769 - Fax: 27 31 2604609 Email: BREC@ukzn.ac.za

Appendix 8: English Consent Form

PARTICIPANT

INFORMED CONSENT

My name is Anette Thompson and I am a qualified podiatrist conducting research for my doctoral degree at the University of KwaZulu-Natal. My supervisor is Professor Colleen Aldous (tel. 031-2604124). I am investigating the foot in diabetic patients and I will also be measuring how well the nerves and blood vessels work in your feet. I will be touching your feet to examine them in the normal clinical way. There will be no blood taken.

If you agree to participate, it will take a few minutes. We will use small items to touch your feet to test your nerves. This is painless. We will use a Doppler ultrasound machine and a special blood pressure machine to listen to your heartbeat in your feet. Your identity will be kept confidential.

You are under no obligation to take part in this study and are free to leave it at any time should you so wish. There are no personal benefits to be received as a result of your participation in the research except if my examination finds something that needs urgent medical attention in which case you will be referred to the medical team at the clinic. Your information will be kept in a password protected computer.

I, Anette Thompson (researcher) have fully explained the purpose of the study, and the type of examination that will be used. I have assured the subject of safety and confidentiality. I have asked whether questions have arisen regarding the examination and have answered to the best of my ability.

Researcher's signature: _____

Date: _____

Subject number allocated to participant
for data collection purposes

NUMBER_____

I _____
(name) have been informed by Anette Thompson about the diabetic foot study to assess my feet and also photograph my feet.

I understand the purpose and procedures of the study. I have been given an opportunity to ask questions about the study and have had answers to my satisfaction.

I declare that my participation in this study is entirely voluntary and that I may withdraw at any time without affecting any treatment or care that I would usually be entitled to.

If I have any further questions/concerns or queries related to the study I understand that I may contact the researcher at telephone 031-2019907 or 111 Musgrave Park, 18 Musgrave Road, Durban.

If I have any questions or concerns about my rights as a study participant, or if I am concerned about an aspect of the study or the researchers then I may contact:

BIOMEDICAL RESEARCH ETHICS ADMINISTRATION Research Office, Westville Campus, Govan Mbeki Building, Private Bag X 54001 Durban 4000 KwaZulu-Natal, SOUTH AFRICA

Tel: 27 31 2604769 - Fax: 27 31 2604609
Email: BREC@ukzn.ac.za

_____ _____

Signature of Participant Date

_____ _____

Signature of Dr S Pillay Date

_____ _____

Signature of Translator Date

Appendix 9: IsiZulu Information Sheet

INCWAJANA YOLWAZI FOR PARTICIPANT (ENGLISH ON REVERSE)

College of Health Sciences

Isikole sodokoteala

September/October/November 2018

Sawubona!

Igama lami ngingu-Anette Thompson. Ngingudokotela wezinyawo ngiqhuba imfundo yami ephakeme enyuvesi yakwazulu Natal. Uma uthanda ukuxhumana nami ungafonela kulenamba elandelayo 031 201 9907 noma kulomchafazo othi anette.thompson@telmo.co.za

Uyamenywa ukuthi ube yinxenye yalolucwaningo lwezinyawo zabantu abaphethwe ushukela lapha KwaZulu Natal. Isizathu sokwenza lolucwaningo ukuthola ukuthi kuvame kangakanani ukuthola iziguli eziphethwe ushukela ezinezinyawo ezibukeka kabi Kanye nesikhumba esiqinile ngaphansi kwezinyawo, lokho okungaba imbangela yokuthi bathole izilonda ezinyawni ezingabangela ukuthi ugcine kunqunywe izinyawo.

Lolucwaningo kufanele lumbandakanye abantu abangamakulu amathathu namashumi ayisishanu. Bazohlolwa emtholampilo kashukela e-Edendale Hospital e-Pietermaritzburg. Lolucwaningo luzothatha izinyanga ezintathu. Isiguli ngasinye sizohlolwa izinyawo ukuba izinyawo zabo zibukeka kanjani nokuthi igazi lihamba kanjani emzimbeni ngokusebenzisa uhlelo lobucwephwshe i-doppler ultrasound, kuzophinde kusebenziswe izinto ukubheka ukuthi imizwa isasebenza kahle ezinyaweni. Awekho amagazi azothathwa. Kuzoba indlela ejwayelekile yokuhlola izinyawo futhi angeke ibe buhlungu.

Lolucwaningo luzothatha imizuzu engekho ngaphezulu kweyamashumi amathathu lapho uzohlolwa khona izinyawo. Lolu cwaningo lukhokhelwe umcwaningi.

Lolucwaningo angeke lukubeke engozini noma lukuzwise ubuhlungu. Sinethemba lokuthi uzosizakala ngokuhlolwa kwezinyawo zakho. Lolucwaningo luzokhombisa ukuthi iziguli zingathola usizo ngokuhlowa kwezinyawo zabo emtholampilo.

Lolucwaningo lubhekiwe lwavunyelwa yi-UKZN Biomedical Research ethics committee (inamba BE264/17).

Uma unenkinga noma imibuzo ungathintana nomcwaningi kulenamba elandelayo 031 201 9907 noma i-UKZN Biomedical Research Ethics Committee Kulemininingwane elandelayo.

BIOMEDICAL RESEARCH ETHICS ADMINISTRATION Research Office, Westville Campus Govan Mbeki Building Private Bag X 54001 Durban 4000 KwaZulu-Natal, SOUTH AFRICA Tel: 27 31 2604769 - Fax: 27 31 2604609 Email: BREC@ukzn.ac.za

Appendix 10: IsiZulu Consent Form

PARTICIPANT INFORMED CONSENT

Igama lami ngingu-Anette Thompson Ngingudokotela wezinyawo ngenza ucwaningo lobudokotela lwemfundo ephakeme e-UKZN. Usuphavayiza wami ngu-Professor Colleen Aldous (031-2604124). Ngihlola ukuma kwezinyawo ezinoshukela ngizophinde ngibheke ukuthi igazi lihamba kanjani ezinyaweni nokuthi imizwa isebenza kahle. Sizothinta izinyawo zakho ngendlela ejwayelekile yokuhlolwa kwezinyawo. Akukho magazi azothathwa.

Uma uvuma ukuba yinxenye kuzokuthatha imizuzu embalwa. Sizosebenzisa izinto ezincane ukuhlola imizwa ezinyaweni zakho, lokhu angeke kube buhlungu. Sizosebenzisa umshini omncane obizwa nge-doppler ukuhlola ukuhamba kwegazi ezinyawo kanjalo nalokhu angeke kube buhlungu. Ukuba yinxenye yalolucwaningo kuzoba imfihlo.

Awuphoqiwe ukuba yinxenye yalolulwaningo futhi ungaphuma uma ungasathandi ukuba yinxenye yalolucwaningo. Azikho izinto eziyinzuzo ozozithola ngokuba yinxenye yalolucwaningo kodwa uzosizakala ngokuthi uzokwazi ukuthi izinyawo zakho zikusiphi isimo futhi sizokwazi ukukudlulisela kwabanye odokotela uma kukhona esikubonayo. Ulwazi lonke luzogcinwa kwikhompuyutha enemfihlo.

Mina Anette Thompson ngichazile inhloso yalolucwaningo nendlela yokuhlolwa ezosentsenziswa. Ngibazisile ukuthi akukho bungozi nokuthi imininingwane yabo izoba yimfihlo. Ngibuzile ukuthi ingabe ukhona onemibuzo ngaphendula ngemizamo yami yonke

Isiginasha yomcwaningi _____

Usuku _____

Inamba enikeziwe _____

Inamba _____

Mina _____
(faka igama) ngichazelwe nguAnette Thompson ngocwaningo lwezinyawo ezinoshukela ukuhlola izinyawo.

Ngiyaqonda inhloso Kanye nenqubo yalolucwaningo. Nginikiwe ithuba lokubuza imibuzo ngalolucwaningo futhi nganikezwa izimpendulo ngendlela egculisayo.

Ngiyaqinisekisa ukuthi angiphoqiwe ukuba yinxenye yalolucwaningo nokuthi ngingaphuma noma ngabe yinini ngaphandle kokuhlangabezana nezinkinga ngokulahlwa noma ukunakekelwa engijwayele ukukuthola.

Uma nginemibuzo noma okuthile okumayela nalolucwaningo ngiyaqonda ukuthi ngingaxhumana nomcwaningi enambeni ethi 031 201 9907 noma 18 Musgrave Road, Suite 111 Musgrave Park.

Uma nginemibuzo noma okuthile okumayelana nalolucwaningo noma umcwaningi ngingaxhumana:

BIOMEDICAL RESEARCH ETHICS ADMINISTRATION Research Office, Westville Campus, Govan Mbeki Building, Private Bag X 54001 Durban 4000 KwaZulu-Natal, SOUTH AFRICA

Tel: 27 31 2604769 - Fax: 27 31 2604609
Email: BREC@ukzn.ac.za

_____ _____

Isiginesha yalowo oyinxenye Usuku

_____ _____

Isiginesha Dr S Pillay Usuku

_____ _____

Isiginesha yohumushayo Usuku

Appendix 11: Permission from Centre for Diabetes and Endocrinology

Anette Thompson

From: Michael Brown (CDE) <michaelb@cdediabetes.co.za>
Sent: Friday, January 27, 2017 3:49 PM
To: Anette Thompson
Subject: RE: Anette Thompson PhD study

Importance: High

Dear Anette

Thank you for your request. I apologise for the delay in getting back to you – I had to check with both the clinical and business arms of the CDE.

We are happy for you to reference the tool with appropriate acknowledgement. We hope that your studies are going well!

God bless

Michael

Michael Brown
Head - CDE Media & Publishing / Clinical Consultant
(Direct) +27 (11) 712-6006
(Cell) +27 82 494-4165
(Direct) +27 86 607-9355
MichaelB@CDEDiabetes.co.za

CDE - Your Partner in Diabetes™
81 Central Street, Houghton Estate, 2198 /
PO Box 2900, Saxonwold, 2132
Johannesburg, South Africa
+27 (11) 053-4400
+27 (11) 728-6661
www.cdediabetes.co.za

Centre for Diabetes & Endocrinology (Pty) Ltd
Reg. No.: 1994/001693/07 / VAT No.:4900141757

CONFIDENTIALITY NOTICE
This e-mail may contain confidential information and is intended for the use of the recipient named above.
Should you receive this email in error, please forward it to the intended recipient and delete it from your mail system.
Any disclosure, copying, distribution or action on the contents of this e-mail is strictly prohibited.

From: Anette Thompson [mailto:anette.thompson@telmo.co.za]
Sent: Friday, 13 January 2017 16:41
To: Michael Brown (CDE)
Subject: Anette Thompson PhD study

Dear Michael and all at CDE,

My PhD work is, among other aspects, looking at what diabetic foot assessment and/or screening methods are being used at two district hospitals in KwaZulu-Natal.

I should like permission to include and refer to the Podiatric Foot Assessment as used by CDE.

Many thanks, Anette

Appendix 12: Diabetic Foot Assessment Data Collection Instrument

DIABETIC FOOT ASSESSMENT REPORT

After style of CDE,Copyright 2015
Modified with permission

PATIENT NUMBER	**MALE FEMALE**	**EDENDALE HOSPITAL**
DATE		
PODIATRIST EXAMINER	**Anette Thompson**	**Tel 031-201 9907**

Ethnicity: ***black African*** ***white African*** ***Asian Indian*** ***Mixed heritage***

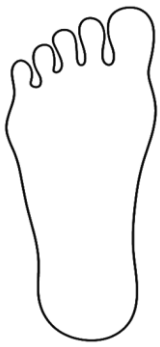
Age		**Weight**		**Height**	
Date of Birth		**Type Diabetes**		**Year Diagnosed**	
Hypertension		**ACE-I / ARB Rx**		**Aspirin therapy**	
Dislipidaemia		**Lipid therapy**		**Latest T cholesterol**	
Renal Failure		**Smoking**		**Latest HbA1c**	

√ = **NORMAL** (NAD-no abnormality demonstrated) X = **ABNORMAL** *(comment in the space provided)*

SCREENING(encircle applicable)	**PREVIOUS FOOT PROBLEMS ?**	**NO**	**YES**	**SYMPTOMS OF NEUROPATHY ?**	**NO**	**YES**	**INTERMITTENT CLAUDICATION ?**	**NO**	**YES**

RIGHT FOOT / lower limb	**REPORT**	**LEFT FOOT / lower limb**
	ORTHOPAEDIC	
NONE HAV TOES BUNIONETTE ANKLE CHARCOT	Deformities	NONE HAV TOES BUNIONETTE ANKLE CHARCOT
NONE MPJ1 TOE IPJS MPJ5 STYLOID PROCESS NAVICULAR SHORT 1ST METATARSAL OTHER	Prominences	NONE MPJ1 TOE IPJS MPJ5 STYLOID PROCESS NAVICULAR SHORT 1ST METATARSAL OTHER
Ambulatory Wheelchair Crutches	Mobility	Ambulatory Wheelchair Crutches
YES NO	Previous amputations	YES NO
Acceptable Not acceptable Narrow Pointy Slip on	Footwear	Acceptable Not acceptable Narrow Pointy Slip on
	DERMATOLOGY	
YES NO	Previous ulcers	YES NO
NONE O/M TINEA PEDIS Other	Infections	NONE O/M TINEA PEDIS Other
NONE Heel PMA Interdigital Other	Fissures	NONE Heel PMA Interdigital Other
NONE PMA 1 2 3 4 5 Digits dorsal/plantar HEEL	Corns and Callouses	NONE PMA 1 2 3 4 5 Digits dorsal/plantar HEEL
BP	**VASCULAR**	
ABPI	ABPI	ABPI
BPM PAD		PAD
Pulses too weak		Pulses too weak
Incompressible arteries		Incompressible arteries
Doppler u/s Triphasic Biphasic Mono phasic Bounding Absent	Dorsalis pedis *pulse*	Doppler u/s Triphasic Biphasic Mono phasic Bounding Absent
Doppler u/s Triphasic Biphasic Mono phasic Bounding Absent	Post tibialis *pulse*	Doppler u/s Triphasic Biphasic Mono phasic Bounding Absent
Normal Cold Hot	Temperature	Normal Cold Hot
Paler or darker than rest of limbs	Colour	Paler or darker than rest of limbs
2 secs greater than 2 secs	Capillary refill time(CRT)sec	2 secs greater than 2 secs
	NEUROLOGICAL	
YES ABSENT	Monofilament 0.05g	YES ABSENT
YES ABSENT	Vibration 125Hz tuning fork	YES ABSENT
YES NO	Paresthesia /cramps	YES NO
NO YES	**Sensory Neuropathy**	**NO YES**
SEMDSA 1 2 3 4	**FOOT RISK**	SEMDSA 1 2 3 4

NOTES AND COMMENTS



Appendix 13: Raw Data example (collected at Edendale Hospital)

UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

DIABETIC FOOT ASSESSMENT REPORT

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After style of CDE, Copyright 2015
Modified with permission

PATIENT NUMBER 510226 MALE (FEMALE) EDENDALE HOSPITAL

DATE 13/2

PODIATRIST EXAMINER Anette Thompson Tel 031-201 9907

Ethnicity: *black African* / *white African* / *Asian Indian* / *Mixed heritage*

Age		Weight		Height	
Date of Birth		Type Diabetes		Year Diagnosed	
Hypertension		ACE-I / ARB Rx		Aspirin therapy	
Dislipidaemia		Lipid therapy		Latest T cholesterol	
Renal Failure		Smoking		Latest HbA1c	

√ = **NORMAL** (NAD-no abnormality demonstrated) X = **ABNORMAL** (*comment in the space provided*)

SCREENING (encircle applicable)	PREVIOUS FOOT PROBLEMS ?	NO YES	SYMPTOMS OF NEUROPATHY ?	NO YES	INTERMITTENT CLAUDICATION ?	NO YES

RIGHT FOOT / lower limb	**REPORT**	**LEFT FOOT / lower limb**
	ORTHOPAEDIC	
(NONE) HAV TOES BUNIONETTE ANKLE CHARCOT	Deformities	(NONE) HAV TOES BUNIONETTE ANKLE CHARCOT
NONE MPJ1 (TOE IPJS) MPJ5 STYLOID PROCESS NAVICULAR SHORT 1ST METATARSAL OTHER	Prominences	NONE MPJ1 (TOE IPJS) MPJ5 STYLOID PROCESS NAVICULAR SHORT 1ST METATARSAL OTHER
(Ambulatory) Wheelchair Crutches	Mobility	(Ambulatory) Wheelchair Crutches
YES (NO)	Previous amputations	YES (NO)
(Acceptable) Not acceptable Narrow Pointy Slip on	Footwear	(Acceptable) Not acceptable Narrow Pointy Slip on
	DERMATOLOGY	
YES (NO)	Previous ulcers	YES (NO)
NONE O/M (TINEA PEDIS) Other	Infections	NONE O/M (TINEA PEDIS) Other
(NONE) Heel PMA Interdigital Other	Fissures	(NONE) Heel PMA Interdigital Other
(NONE) PMA 1 2 3 4 5 Digits dorsal/plantar (HEEL)	Corns and Callouses	(NONE) PMA 1 2 3 4 5 Digits dorsal/plantar (HEEL)
BP	**VASCULAR**	
ABPI	ABPI	ABPI
BPM (PAD)		(PAD)
(Pulses too weak)		Pulses too weak
(Incompressible arteries)		Incompressible arteries
Doppler u/s Triphasic (Biphasic) Mono phasic Bounding Absent	Dorsalis pedis *pulse*	Doppler u/s Triphasic (Biphasic) Mono phasic Bounding Absent
Doppler u/s Triphasic Biphasic (Mono phasic) Bounding Absent	Post tibialis *pulse*	Doppler u/s Triphasic (Biphasic) Mono phasic Bounding Absent
Normal (Cold) Hot	Temperature	Normal (Cold) Hot
(Paler or darker) than rest of limbs	Colour	(Paler or darker) than rest of limbs
2 secs (greater than 2 secs)	Capillary refill time(CRT)sec	(2 secs) greater than 2 secs
	NEUROLOGICAL	
YES (ABSENT)	Monofilament 0.05g	YES (ABSENT)
YES (ABSENT)	Vibration 125Hz tuning fork	YES (ABSENT)
(YES) NO	Paresthesia /cramps	(YES) NO
NO (YES)	**Sensory Neuropathy**	NO (YES)
SEMDSA 1 2 (3) (4)	**FOOT RISK**	SEMDSA 1 2 (3) (4)

NOTES AND COMMENTS

ref for vasc. pain, pallor, (R) leg at risk

Appendix 14: Raw Data example (patient SOPD record)

EDENDALE DIABETES SERVICE

HEALTH
KwaZulu-Natal

Name	(NAME WITHHELD)			Age	59	Gender	F
DOB / Folder Number	590804						

History	Diet	(Y)	N	Exercise	(Y)	N	Home Glucose Monitoring	(Y)	N	
Current	Year of 1st Diagnosis DM	2012		FHx of DM	Mother ✓	Brother ✓	Grandmother			
					Father ✓	Sister ✓	Grandfather			
Past Medical History					Current Smoker	Ex Smoker	Alcohol			

T1DM ☐ T2DM ☑ HPT ☑ CKD ☐ OA ☐ CVA ☐ IHD ☐ MI ☐ CABG ☐ OTHER ☑ Epilepsy

RVD Y	RVD N	Year Of Δ	Year Of ARV Initiation	Names of ARV	CD4
✓		1997	1997	AZT 3TC / EFV	

Any Changes Of Meds Y ✓ N ✓ Name and Old Dosage: Furosemide 60mg BD

Employed ☐ Unemployed ☐ Pensioner ☐ MISSING

Examination	BP: Sitting	166/84	P	67	GLUC 8.4	Wt	70
	Erect BP	175/95		71		Ht	156
	Dipstix	NAD				BMI	28
CVS ✓		Carotid Bruit Y/N				Waist circ	107
RESP ✓		Fundi ordered			R	L	
ABDO ✓		Glaucoma Y ☐ N ☐					
NOT ACCURATE A Thompson		Cataract Y ☐ N ☐					
		Non Prolif Retinopathy Y ☐ N ☐					
		Prolif D.R Y ☐ N ☐					

Feet NAD — Injection sites: NAD — Lipodystrophy ☐ Lipoatrophy ☐ Cellulitis ☐

Ulcer ☐ T.pedis ☐

		R	L
Thyroid ✓	Sensory Neuro * Y ☐ N ☒	Paresthesia!	Paresthesia! *
ENT	Pulses DP + PR * Y ☑ N ☐	Biphasic!	Biphasic! *

A Thompson, podiatrist

Date of Bloods									
GFR	>60	TRIG	6.09 *	TSH	1.53	Urine PCR			
Creat	84	TOTAL CHOL	6.90 *	Hba 1c (NGSP)	7.8	CMP	2.31	0.73	0.93
LDL-CHOL	Trigs ↑	HDL CHOL	1.04	Vit B12	288				

Date of ECG: 29/8/19

Prescription

1. Metformin 1g TDS	500mg PO	9. Furosemide	40mg PO ~~BD~~ TDS
2. Pioglophane	24u flt nocte	10. HCTZ	12.5mg OD PO
3. Glimepiride	4mg PO OD	11. Accucheck strips	
4. Epilim CR 1g	BD	12. Atorvastatin	40mg PO nocte
5. Aspirin	150mg PO daily	13.	
6. Amlodipine	10mg OD PO	14.	
7. Enalapril	10mg BD PO	15.	
8. ~~Furosemide~~		16.	

PLAN: Meds Adj ☐ Bloods ☑ ECG ☐ Eye Clinic ☑ SOPD ☐ OTHER ☐ NEXT APP: 6/12

Dietician ☐ Podiatrist ☐ ? A Thompson - pt needs referral please.

NAME: ZALGAONKAR SIGNED: DATE: 13/02/19

uMnyango Wezempilo, Departement van Gesondheid
Fighting Disease. Fighting Poverty, Giving Hope

HME STICKER: Urine PCR available BLOOD STICKER:

Appendix 15: Raw Data example
(single PMSS data base entry)

RAW DATA (Example of a single PMSS database entry)

Patient Reference Number ID	**Time Admission**	**Date Admission**
312	23:51:38	20-12-2012
Threatened Airway	**Airway Intervention**	**Trachea Central**
No	Face mask oxygen	Yes
O2 Saturation	**Respiratory Rate**	**Respiratory Intervention**
94	28	None
Pulse Rate	**Systolic BP**	**Diastolic BP**
130	155	83
MAP	**Vascular Access**	**Intravenous Fluids**
107		
Volume IVI Fluids Infused	**Admission GCS**	**Temperature**
	14	38.4
Referred Higher Centre	**Required ICU Admission**	**Required HCU Admission**
Yes	No	No
Duration ICU	**Duration HCU**	**Outcome**
0	0	Survived
Expected Death?	**Cause of Death**	**Date Discharge**
		24-12-2012
Unit	**Diagnosis**	**Investigations**
	# Poorly controlled diabetic # Bilateral tibio-peroneal peripheral vascular disease # Necrotic left big toe	Hb: 8.9 WCC: 15.42 Plt: 357 INR: 1.19 UCE: 134/3.8/105/17/16/4.6/126
Surgery	**Clinical Course**	**Problems**
Left toectomy	Healing well TMA stump healing well	Nil
Plan on Discharge	**SOPD Follow Up**	**Discharge Medication**
Analgesia, dressings at NDH	TFU on the 14/01/2013 TFU at NDH for Meloderm dressings every 3 days	Panado 1g tds po and chronic meds
Discharging Doctor	**OP Number**	**Discharging Doctor**
Steenkamp	421112	Steenkamp
IP Number	**Pregnant**	**Age**
421112	NA	70
History	**Examination**	**Adjuncts**
		Transurethral catheter, ECG
Urine Output	**Antibiotics Administered**	**Analgesia Administered**
1	Yes	Yes
Investigations Laboratory	**Investigations Imaging**	**pH**
ABG, HGT, FBC, U+E, CMP, LFT, Type and Screen, INR, Urine dipstick	CXR, formal U/S	7.53
pCO2	**pO2**	**HCO3**
3.1	9.6	22.8
BE	**Lactate**	**Na**
-2.7	1.2	131
K	**Cl**	**Urea**
4.1	101	4.7
Creatinine	**HGT**	**WCC**
106	11.4	13
HGB	**PLT**	**INR**
9	302	
ABG	**U+E**	**FBC**

0	0	0
Senior Registrar Informed	**Time Senior Registrar Informed**	**Imaging Positive Findings**
Yes	23:00:00	CXR: Patchy infiltrates bilaterally in hilar regions, no pleural effusions or fluid in fissure, U/S calcification
Assessment	**Management Plan**	**Operative Intervention and Findings**
70-year old male patient known with COPD, DM which is poorly controlled and clinically bilateral tibio-peroneal peripheral vascular disease with non-healing right TMA stump and necrotic left big toe	Maintain O2 sat monitoring while on 40% Face mask oxygen A-B-S nebulization 6hrly Insulin sliding scale IV fluid N/S at 100ml/hr IV ABx Analgesia Keep NPO Chase blood results that were repeated For theatre tonight for right toectomy +/- TMA +/- BKA Consult with ICU	
Admitting Doctor	**Shock Present**	**Examination General**
Eksteen		Brought in on stretcher with non-functioning IVL and no urine catheter. Low oxygen saturation initially (90%) but came up to 98% on 40% FM oxygen
Examination Neurology	**Examination Cardiovascular**	**Examination Pulmonary**
GCS 14/15- E4 V4 M6, no focal signs, PEARL	no pitting oedema, JVP not raised, pulse regular Apex normal and normal heart sounds, no evidence CCF	Airway self maintained but audible expiratory wheeze Initial low oxygen saturation which improved on FM oxygen Hyper-inflated chest Trachea central Decreased air entry bilaterally with expiratory wheeze in upper airways No dullness on percussion
Examination Abdomen	**Examination Other**	**History Presenting Complaint**
soft non tender but increased BMI No organomegaly	Right foot: TMA stump mal-odorous, poor healing with black edges but no pus draining Dorsalis pedis pulse not felt but popliteal pulse present	Referred from NDH known with COPD, Diabetes Mellitus, Peripheral vascular disease at tibio-peroneal level on right leg. Previous TMA of right foot done in December 2011 with poor healing of stump. Now presenting with necrosis and wet gangrene of big toe on left foot but poor anaesthetic candidate for surgical intervention at NDH
History Previous Medical History	**History Previous Surgical History**	**History Current Medications**
Poor historian as not accompanied and GCS 14/15: COPD-? what treatment DM? OHG or insulin, HPT	TMA of right foot	Not in referral letter and patient unable to give clear answer
History Social	**History Allergies**	**Hospital**
allegedly non-smoker and non-	NIL	Greys

drinker but COPD!!		
Drug1	**Drug2**	**Drug3**
Insulin sliding scale	Augmentin	Normal Saline
Drug4	**Drug5**	**Admission Type**
Keep NPO	A-B-S nebulization	Emergency
Classification Of Death	**Discharging Firm**	**Admitting Firm**
NA	Firm 4	Trauma
X-Rays	**Contrast Studies**	**Contrast study finding**
Extremity		
Ultrasound	**U/S finding**	**Computed Tomography**
Left foot	ischaemia	
CT finding	**Formal Angiography**	**Formal angio finding**
On-table angiography	**OT Angio finding**	**Magnetic Resonance Imaging**
MRI finding	**MAP Calc**	**Average Age**
	107	48.15
Base Health Facility	**Symptom onset Admission**	
Northdale		
Discharge Creatinine	**Peak Creatinine**	**Patient Details Date Birth**
		12-11-1942
Patient Details Name	**Patient Details Race**	**Patient Details Sex**
Withheld by researcher	Asian	Male
Patient Details Surname		
Withheld by researcher		
OP NOTES DATABASE – LOCATED AND MATCHED TO ABOVE PATIENT RECORD		
Patient Reference Number ID	**Urgency**	**Autotransfusion**
312	Emergency - Not damage control	
Start Time	**Date**	**Upper Limb Procedure**
10:00:00	21-12-2012	
Lower Limb Procedure	**Upper Limb Access**	**Lower Limb Access**
Amputation – toectomy (single digit)		
Blood Loss	**Wound Risk**	**Surgeon**
50	Dirty	Benamro F
Assistant1	**Anaesthetist**	**Anaesthetic**
Dr Zanati	Dr Vickery	Regional anaesthesia (spinal)
Closure	**Drains**	**Prosthesis**
Skin left open		
Specimens	**Post-Operative Instructions**	**Duration**
	FWD, antibiotics, analgesia open wound on Sunday, chest physio, start Clexane tonight	00:30:00
Assistant2	**Finish Time**	**Antimicrobials Administered**
	10:30:00	0
Antimicrobials	**Operation Notes**	**Hospital**
	cleaned and draped, circular incision around the joint then disarticulation of the joint then excision of the metatarsal bone by bone cutter. removal of all slough tissue. good haemostasis. good washing of the stump by normal saline. dressing with jelonet, plastic gauze then creb (sic)-	Greys

	bandage.	
Admitting Firm	**OP Number**	**IP Number**
Firm 1	421112	421112
Operative Access Calculation	**Operative Procedure Calculation**	**Operative Findings**
	Amputation – toectomy (single digit)	
Total Operations	**Procedure**	**Intervention**
19190		
Histopathology Report	**Microbiology Number**	**Histopathology Number**

Appendix 16: What is a Podiatrist?

WHAT IS A PODIATRIST?

Podiatric Medicine is that discipline of health sciences concerned with the research, prevention, diagnosis and treatment of deformities, pathologies and injuries of the foot and associated structures – in relation to the body as well as the manifestations of systemic diseases – by all appropriate systems and technologies using scientific and professional specialised knowledge [1].

A podiatrist is thus a health professional who is concerned with the assessment, diagnosis and management of foot disorders and related lower limb disorders [2]. Podiatrists treat and advise on foot problems in areas ranging from disorders in children to sports injuries, to the management of foot problems in older people and people with disabilities or systemic illnesses affecting the foot. Podiatry also involves the diagnosis, treatment and prevention of common dermatological foot problems such as corns, callouses, plantar warts, ingrown nails and athlete's foot. Podiatrists receive training in anatomy, lower limb dissection, physiology, microbiology, podiatric medicine, dermatology, clinical medicine and pharmacology, as well as biomechanical theory, sports medicine, orthosis theory and manufacturing, as well as theory and in-theatre observation of orthopaedic surgery [2]. Podiatric training encompasses wound care, wound debridement and specialised dressings, especially in the realm of wound care in diabetes [2].

Podiatrists are trained to perform skin and nail surgery, whether under general anaesthesia in theatre [2] or under local anaesthesia utilising sterile packs in the consulting room. Specialised surgical stainless-steel instruments are used by podiatrists for nail surgery.

Many problems in the foot are related to more complex issues relating to structural and functional defects of the foot and lower limb. Podiatrists in South Africa are trained to fabricate custom moulded in-shoe orthoses from raw materials as well as softer prescription innersoles in order to effect offloading of tissue stress, re-alignment of the foot or provide accommodative support [2].

The combination of surgical training, clinical medicine and ability to prescribe and fabricate in-shoe devices to effect offloading is important in prevention and treatment of, for example, the diabetic foot ulcer. Podiatrists also deliver valuable patient education in diabetes care, including exercise therapy, monitoring of vascularity and nerve function in the foot.

Some podiatrists may choose to focus on specific areas of interest, for example, advanced techniques in diabetic wound offloading and care, or sports podiatry, or footwear research and design. Podiatric medicine (podiatry) in South Africa is a scarce skill due to lack of training departments within existing medical schools.

References

1. International Federation of Podiatrists https://www.fip-ifp.org/what-we-do/what-is-podiatry/
2. University of Johannesburg, Department of Podiatry https://www.uj.ac.za/faculties/health/Podiatry/Pages/default.aspx

Appendix 17: Some isiZulu phrases learnt during the study

Some isiZulu phrases learnt during the study

As an unwilling casualty of apartheid, I never learnt a black African language. It simply was not available, and enquiries were repressed. I regret the missed opportunity to learn in my youth with the gift of time and the facility of a younger mind. However, I did try thanks to Mr. Mandla Shabangu (Ops Manager, Edendale Hospital), nursing sisters and patients who generously corrected my pronunciation. These are some of my notes made during data collection.

Hello/Good morning – Sawubona

How are you – Unjani

I am learning isiZulu – Ngiyafunda isiZulu

Slowly – kancane

Do (you) feel (this) – uyukuzwa?

Can you feel now? – uyeswa manje?

Do your feet hurt? – Izinyawo azibuhlungu?
Do you have cramps - Amacramps?

Cold – kuyabanda?

Hot – kuyashisa?

Vibration – ukuqhaqhazela (pronounced ugu ghla ghla zela)

Ngiyakuthinta yebo noma cha

Do you feel vibration – uyukuzwa ukuqhaqhazela?

Today – namhlanje

Next (person) – Olandelayo

Please lay down – ngicela lala phansi

Do not move – musu ukusukuma (pronounced musu ugu shu kuma)

We are done – sesiqedile (pronounced sessi cle dile)

Thank you – ngiyabonga

Dust – uthuli

Appendix 18: FIP-IFP International Conference presentation

Appendix Eighteen

Abstract and slides of an Oral presentation delivered to the Global Podiatry Congress of the International Podiatry Federation 14-17 November 2019 (Miami, USA)

Placement of forefoot bend in women's shoes – a risk factor for ulceration in diabetes?

Anette Telmo Thompson[1], Bernhard Zipfel[2], Colleen M Aldous[1]

[1] School of Clinical Medicine, University of KwaZulu-Natal, Durban, South Africa

[2] Evolutionary Studies Institute and School of Geosciences, University of Witwatersrand, Johannesburg, South Africa

Keywords: Diabetes mellitus, metatarsals, hallux valgus, footwear, forefoot flexion, hyperkeratosis, shear force, ulcer prevention

Abstract

Background – Therapeutic footwear or footwear as used by diabetic patients could have a specific location of sole flexibility under the metatarsal formulae which may be unsuited to the actual anatomical fulcrum location in their feet. Mismatched fulcrum positions impact on joint fulcrum function and may be implicated in both formation of hyperkeratosis and reduced function of the foot venous pump by inhibiting the raising of the plantar fascial arch via the windlass effect.

This study compared the location of the first metatarsophalangeal (MP) joint fulcrum in a multi-ethnic sample of the South African female population to the forefoot flexion position located in the lasts (used by footwear manufacturers) to find whether mismatches of anatomical flexion of the joint to the flexion or fulcrum location of the footwear were likely.

Methods - The study used laser scanned three-dimensional foot measurement images of 453 female participants to establish the location of the first metatarsophalangeal joint.

The length in millimeters between the participant's heel and the first metatarsophalangeal joint was expressed as a percentage of the overall length of the measured foot. Corresponding measures were taken for sandals and closed shoes, and values derived were compared to last manufacture parameters.

Results - This study found that the flexion or bending position in footwear made according to UK and USA last parameters does not match the average first MP joint location in the measured sample. The locations of first MP joint ranged from 70% to 79% of total foot length, significantly different from last design parameters placing flexion at 63% or 66.6% ($p<0.0001$). The range of first MP joint fulcrum locations in same size feet were distributed in a wide 24.4 mm mediolateral band under the forefoot.

Discussion - We found evidence that a multi-ethnic population in South Africa contains individuals whose first MP joint fulcrum location does not match the footwear fulcrum location found in sandals or closed shoes made according to either UK or USA last parameters. The first MP joint cannot properly function as a fulcrum unless footwear has a matching flexion location. Mismatched fulcra can result in forces on the joint, reducing the ability of the hallux to function and is implicated in hallux rigidus. Without a functioning fulcrum at the first MP joint, compensatory abduction of the foot may take place; this would

place increased force and flexion moments on the lateral four digits and metatarsals, the increased pressure of which is a risk for diabetic ulceration. Absence of forefoot flexion will prevent the raising of the arch in ambulation, limiting venous return from the foot venous pump. Footwear designs should incorporate a wide flexion range or zone located under the forefoot to permit the range of first MP joint flexion locations. Recommendations to patients with diabetes are to select appropriate flexible footwear to prevent shear forces, reduce strain, prevent hyperkeratosis and enable range of motion function to engage the foot vascular pump.

Placement of forefoot bend in women's shoes – a risk factor for ulceration in diabetes?

Anette Telmo Thompson[1]
Bernhard Zipfel[2],
Colleen M Aldous[1]

[1] School of Clinical Medicine,
University of KwaZulu-Natal, Durban, South Africa
[2] Evolutionary Studies Institute and School of Geosciences,
University of Witwatersrand, Johannesburg, South Africa

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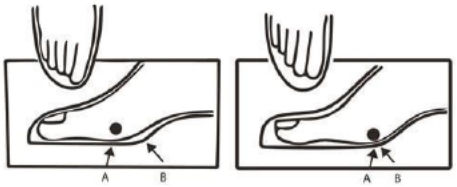
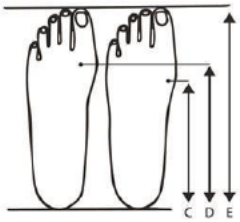
1

Background: Clinical observations

- First metatarsophalangeal joint (MTPJ-1)
- Biomechanical fulcrum in gait
- Variation in position in same length feet
- Dorsiflexion of the hallux may be reduced if fulcrum mismatch between foot and footwear

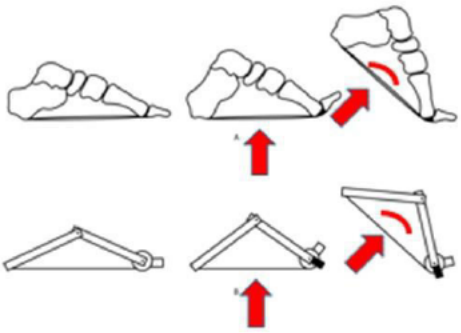




2

Importance of hallux dorsiflexion

- Dorsiflexion at terminal stance
- Tightens plantar fascia
- Elevates medial longitudinal arch "Windlass mechanism"

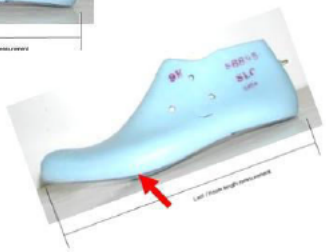


- *Facilitates heel lift*
- *Compression of soft tissues in the arch by the lifted fascia*

3

Footwear lasts fulcrum location

- Last makers parameters
- British guidelines
  66 % of overall last length
- North American guidelines
  63 % of overall last length.
- Fulcrum is same for
  sandal or shoe lasts



4

Aims of the study

- Determine the extent of mismatches between anatomical MTPJ-1 and the fulcrum in footwear
- Determine whether age, BMI, foot width or foot girth were predictor variables

5

Method

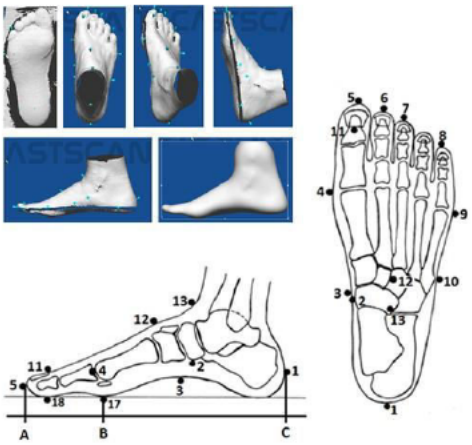
- Compare foot measurements to industry last parameters
- Find whether age, BMI, foot width or foot girth were predictors of "mismatch"

6

Materials and Methods

- n = 453 South African female participants
  (no exclusions for systemic illness)
- 3-D foot scans
- Palpated bony landmarks
- Stylus point XYZ co-ordinates

- Length of the foot (A to C)
- Length from the heel to MTPJ-1(C to B)



7

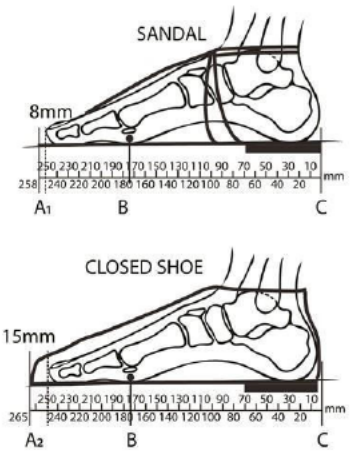
Method

Compare feet to lasts for sandals and shoes

Toe extension
is 8mm in a sandal last

Toe extension
is 15mm in a closed shoe last

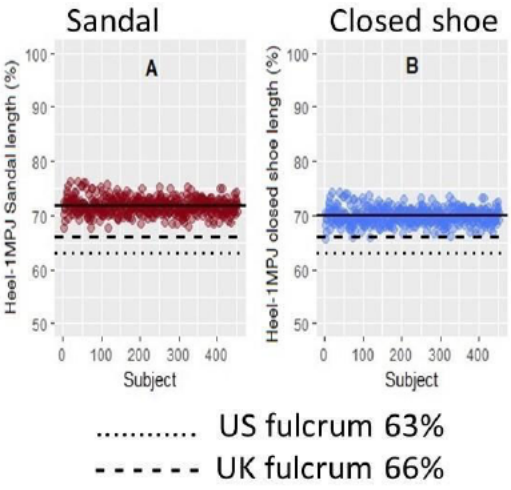
Yet lasts for either variation place flexion
at the same fixed percentage
of overall last length.



8

Results

- The locations of MTPJ-1 ranged from 70% to 79% of total foot length
- This anatomical fulcrum is significantly different from both last design parameters ($p<0.0001$)



9

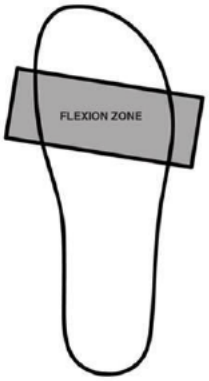
Results

The range of MTPJ-1 fulcrum

in same size feet

occurs in a wide 24.4 mm

band under the forefoot



10

Results – distribution of continuous variables

	Median	IQR	Min	Max
Age (years)	39	[30-52]	21	69
Height (meters)	1.62	[1.56-1.67]	1.42	1.8
Weight (kg)	68.4	[43.9-122.9]	34.7	150.9
Body Mass Index (BMI)	26	[23-30]	13	56
Foot length (mm)	239	[231-248]	206	285
Maximum foot breadth across forefoot (mm)	92	[89-97]	77	110
Tape forefoot girth at metatarsal joints (mm)	232	[222-242]	180	288
Heel-1MPJ % of Foot length (%)	74	[73-75]	70	79
Heel-1MPJ % of sandal length (%)	72	[70.7-72.7]	68	76
Heel-1MPJ % of closed shoe length (%)	70	[68.9-70.82]	66	74
Zone width of possible first MP joint fulcrum locations between sandals and closed shoes (mm)	24	[21.5-27.7]	21	29

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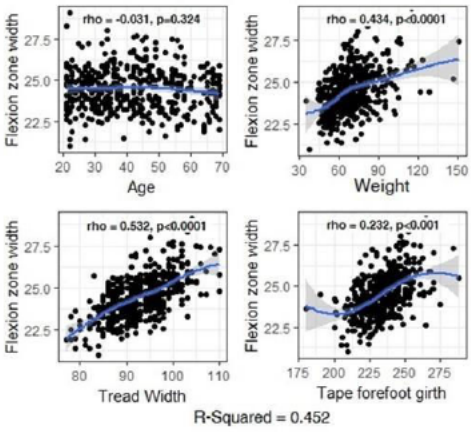
Results: predictors

- 'Flexion zone width' to 'age' not statistically significant
- Positive correlation
  - weight,
  - foot breadth
  - and forefoot girth.



12

Discussion

- Mismatch to either UK or USA parameters
- Possible reasons ?
- Have feet changed since last foot measurement surveys ?
- Previous foot survey in South Africa 1954
- Anthropometric changes in body shape in different populations
- Last surveys elsewhere – uk, Japan and Germany

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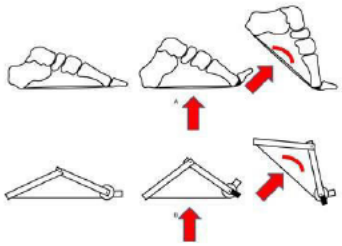
Discussion

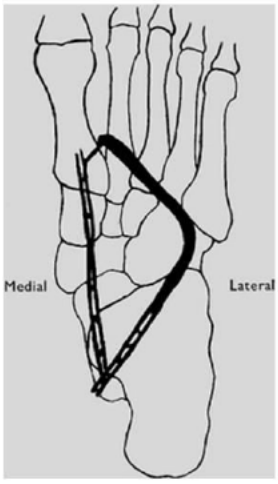
- BMI
- Foot Width
- Foot girth
- Wide band of MTPJ-1 fulcra
- Influence of increased BMI on fulcrum?
- Wider and more "fleshy" feet?
- 1<2>3>4>5 ?
- 1>2>3>4>5?
- Is this similar in other populations?

14

Implications for vascular return

Absence of forefoot flexion will prevent the raising of the arch in gait, limiting compression in arch for the foot venous pump.





16

Vascular implications for diabetes patients

9 million diabetes patients in South Africa

Use general purpose footwear (per UK or US)

Potential vascular return impairment?

17

Implications to prevent "mismatch" shear forces, pressure and friction in diabetes

- Callus is sign of pressure and/or friction

  ... deformity (congenital, acquired)
  ... prominence
  ... poorly fitting footwear
  ... faulty gait (neuro, muscular, trauma)
  ... faulty biomechanics

- Callus *increases* pressure and risk of ulceration
  11 times more than without callus.
- Callus not implicated in ulceration in non-diabetics

18

Biomechanical implications

- Non-functioning MTPJ-1
  so fulcrum may be attempted at IPJ-1
- Compensatory abduction
- Increased force and flexion moments
  on metatarsal heads/digits 2/3/4/5
- Increased pressure = dermal breakdown
- Dermal breakdown = ulceration

19

Conclusion

A South African population contains individuals whose MTPJ-1 fulcrum location does not match the fulcrum location in footwear.

Diabetes patients in this population who use general purpose footwear made on UK or US parameters which do not match their foot anatomy may risk ulceration.

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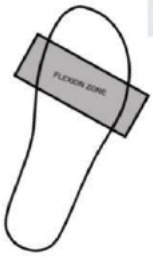
Recommendations

- **Footwear design**
  - enable complete metatarsal range of motion
  - enable ease of flexibility at forefoot
  - incorporate flexion zone
- **Diabetes patients**
  - select appropriate footwear with a zone of flexion



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Thank you

Appendix 19: MDT Presentation: Northdale Hospital

Why is it that, when podiatrists are integrated in the MDT, amputations and mortality are reduced?

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Anette Thompson
M Tech Podiatry (University of Johannesburg)
Clinical Medicine PhD 2020, UKZN Medical School

SEMDSA
Society for Endocrinology, Metabolism and Diabetes of South Africa

In people with diabetes,
foot examinations by healthcare providers
must be an integral component of diabetes management
to identify persons at risk
for ulceration and lower-extremity amputation.

International Diabetes Federation

IDF urges all health care practitioners
to identify, assess, treat or **refer** patients ***earlier***
in the "Window of Presentation"
between when neuropathy is diagnosed
and prior to developing an ulcer.

IDF Foot Z-Card 2017 https://www.idf.org/e-library/guidelines.html

LOW RISK treatment plan

- Referral for patient foot education – to whom?
- Referral for routine foot care – to whom?
- Patient to carry out daily foot inspection
- Patient to wear proper footwear
- Patient to exercise tight glycaemic control

- Omits a baseline examination of the patient to determine predisposing biomechanical imbalance.

Identify, assess, treat or refer

- Steps to prevent amputation should begin on diagnosis.
- Systematic review reveals reduction in HBA1C for those receiving diabetes self-management education compared to those who did not.

Chrvala CA, Sherr D, Lipman RD. Diabetes self-management education for adults with type 2 diabetes mellitus: A systematic review of the effect on glycemic control. Patient Educ Couns. 2016 Jun;99(6):926-43.

Identify, assess, treat or refer

- Psychological value of an immediate in-depth foot assessment, with foot care education, footwear examination and education
- Cannot be a 60 second medical intervention (as suggested by Sibbald, 2012) because there is no time for patient interaction…
- Need interactive time for patient foot education…
- Need interactive time to examine or discuss footwear…
- Need time to evaluate foot imbalances…

Podiatrist in the team…

Psychological value – ⬆ focus
Educational value
Practical value
Becomes a specialised support for the patient

Identify, assess, treat or refer

- Referral to the podiatrist should begin on diagnosis.
- Systematic review reveals that plantar pressures can be reduced – if such an intervention takes place…

- *S A Bus; G D Valk; R W van Deursen; D G Armstrong; C Caravaggi; P Hlaváček; K Bakker; P R Cavanagh The effectiveness of footwear and offloading interventions to prevent and heal foot ulcers and reduce plantar pressure in diabetes: a systematic review.Diabetes/Metabolism Research and Reviews, v24 nS1 (May/June 2008): S162-S180*

Recognise limb length discrepancy

- Limb length discrepancy (LLD) has a biomechanical influence on foot pressures
- May not present any clinical symptoms
- Uneven shoe wear, callus on one foot only
- Functional vs Anatomical length difference
- Can lead to plantar ulceration

R B Masoetsa; D Goven; A Sayed; E Modimakwane; T Juma. Does leg length discrepancy predict which foot will ulcerate in a patient with diabetes mellitus? : original research Wound Healing Southern Africa, v3 n1 (2010): 24-26

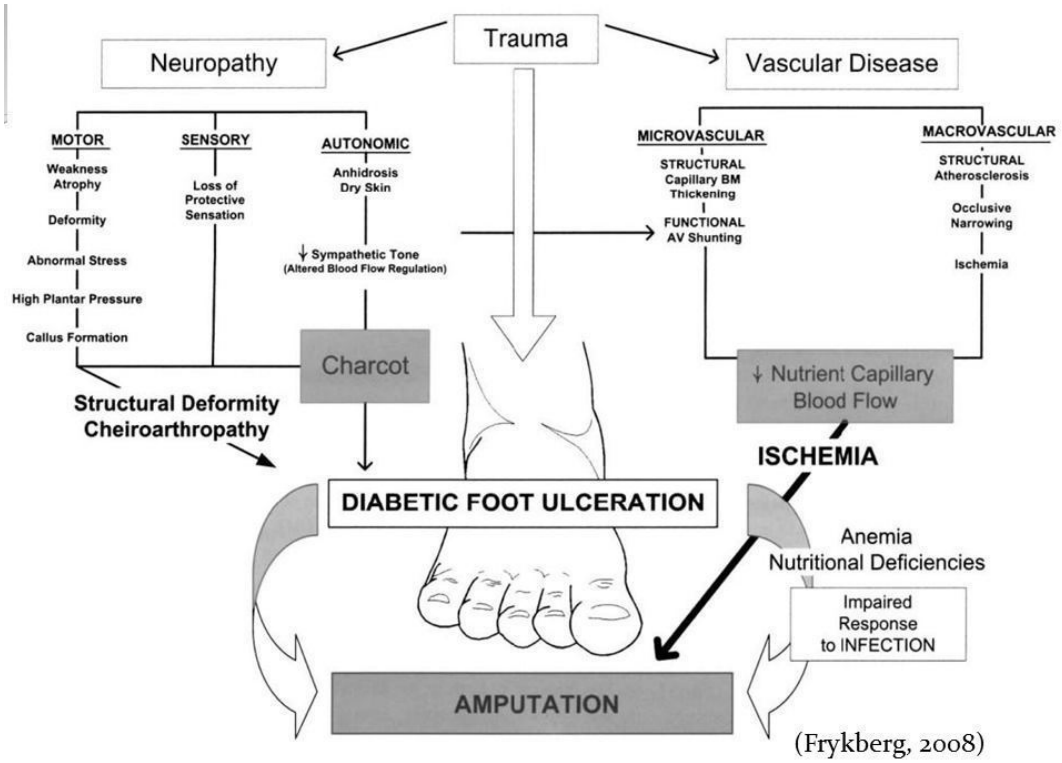
Red flags – refer for podiatry

- pressure callus or corns;
- altered biomechanics (varus or valgus foot)
- limited joint mobility
- bony deformity or bony prominence
- severe nail pathology
- peripheral neuropathy;
- peripheral vascular disease; and/or
- a history of ulcer or amputation.

and other Red flags…

- Strong correlation with elevated serum creatinine levels
  (Akha O, Kashi Z and Maklough A 2010 Correlation between amputation of diabetic foot and Nephropathy. Iraninan Journal of Kidney Diseases Vol 4(1) p27-31

- Lack of foot care education – explaining the "why"
- Lack of foot specific exercise education
- Lack of education on footwear
- Lack of education on pernio (chilblains)
- Podiatry to assist obese patients to exercise
- Ignorance of the role of the foot and calf muscle pumps

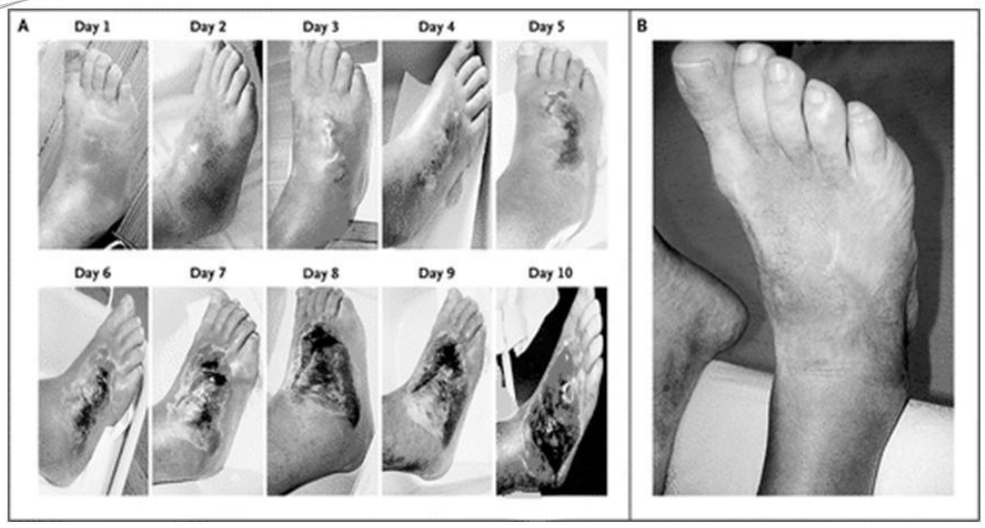


(Frykberg, 2008)

What precedes amputation?

Skin breakdown in the foot (DFU)
- Peripheral neuropathy
- Peripheral Vascular Disease
- Trauma (accidental, footwear, MSK deformity)
- Infection
- Frostbite, Pernio (chilblains)

- Post surgical embolus
- Renal disease
- ***Ignorance and neglect***



IGNORANCE **10 Days ulcer progression in a patient who didn't know he was diabetic.. Source: New England Journal of Medicine 2013**

Ignorance and neglect

2008 – Survey of 18 CHCs in W. Cape
11.3% of patients recorded foot exams…
(Steyn et al 2008)

2011 – Regional Gauteng Hospital
94% of diabetic patients no foot exam
(Dikeukwu Thesis Wits 2011)

2013 – Regional Hospital in KwaZulu-Natal
6% of patients recorded foot exams…
(Igbojiaku et al 2013)

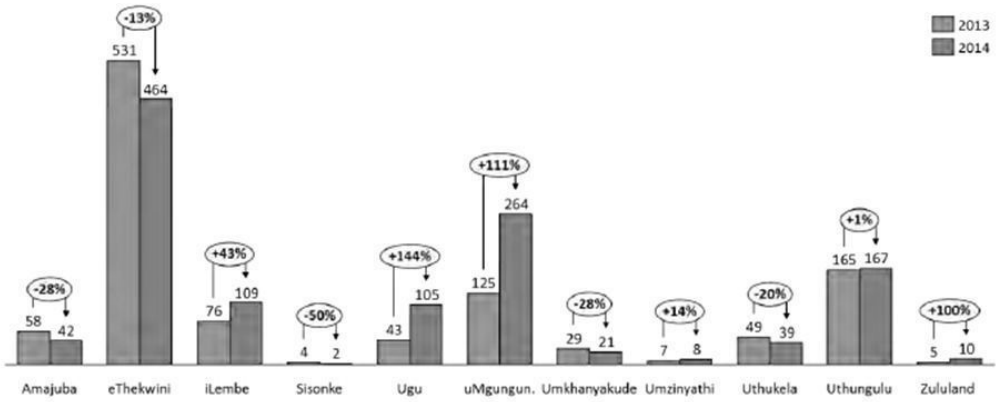
Ignorance and neglect

2015 – Diabetes in public health sector KwaZulu-Natal
14.3% higher than national prevalence estimates.

38% of cases in highly urbanised eThekwini.
1 329 275 diabetic patients recorded .
2 podiatrists work in KZN public health sector.
2,323 diabetic related amputations recorded…

Source: Sahadew N. 2015 An explorative review of the distribution, incidence, prevalence, diabetes related amputations and defaulters of patients with diabetes mellitus and podiatrists in the public health care sector of KwaZulu-Natal. Thesis UKZN.

Distribution of diabetes related amputations in districts of KZN



Sahadew N, M Med Thesis UKZN 2015

Positive impact of MDTA

Role of podiatrist in management of DFU
(Clarke and Tsubane, 2008)

Podiatric DFU intervention using TCC in Eastern Cape
(Howard, 2012)

Statistically significant improvements noted
Edendale regional hospital KZN, MDTA including
Podiatrist foot exams and education
(Pillay et al 2016)

Edendale podiatry research

Statistical analysis still ongoing but some early data:-

Only 40 patients out of 302 had triphasic (normal) arterial flow in both pedal pulses (Doppler readings)

Automated ABPI correlated well with Doppler

Significant correlation between MSK risk and Type I

Foot ulcers and mortality

- 4 out of 10 people with a history of a diabetic foot ulcer (DFU) are likely to be dead in 10 years time than with diabetes alone.

International Diabetes Federation and International Working Group of the Diabetic Foot. Diabetes and Foot Care: Time to Act, Fourth Edition. IDF

Iversen MM, Tell GS, Riise T, et al. History of foot ulcer increases mortality among individuals with diabetes: ten-year follow-up of the Nord-Trondelag health study, Norway. Diabetes Care. 2009;32(12):2193-9.

Amputation and again …

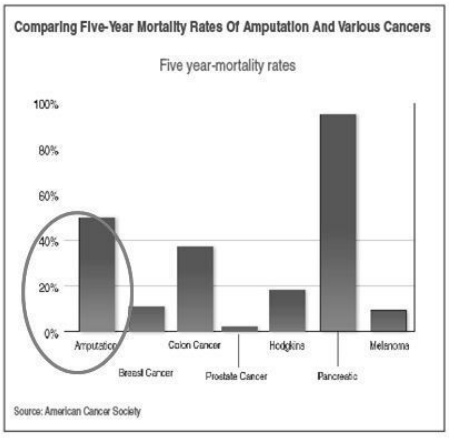
- Following a lower extremity amputation (LEA), nearly 7 out of 10 patients will lose the contra-lateral limb within five years.

Rogers LC, Lavery LA, Armstrong DG. The right to bear legs — an amendment to healthcare: how preventing amputations can save billions for the U.S. health care system. J Am Podiatric Medical Association. 2008;98(2):166-168.

Five year mortality rate

After amputation, five year mortality rate (50%) is greater than cancer of the breast, colon , prostate, Hodgkins, and Melanoma.

Only Pancreatic cancer has a higher five year mortality rate (90%).



Liswood, P J What Studies Reveal About the Preventive Value of Podiatric Care for Patients with Diabetes, Podiatry Today; Vol 25 (7) 2012

Literature on ‘proper’ MDTA

- 19. Lavery LA, Hunt NA, LaFontaine J, et al. Diabetic foot prevention. Diabetes Care 2010;33:1460–2. Abstract/FREE Full Text Google Scholar
- 20. Ronnemaa T, Hamalainen H, Toikka T, et al. Evaluation of the impact of podiatrist care in the primary prevention of foot problems in diabetic subjects. Diabetes Care 1997;20:1833–7. Abstract/FREE Full Text Google Scholar
- 21. Plank J, Haas W, Rakovac I, et al. Evaluation of the impact of chiropodist care in the secondary prevention of foot ulcerations in diabetic subjects. Diabetes Care 2003;26:1691–5. Abstract/FREE Full Text Google Scholar
- 22. Sowell RD, Mangel WB, Kilczewski CJ, et al. Effect of podiatric medical care on rates of lower-extremity amputation in a medicare population. J Am Podiatr Med Assoc 1999; 89:312–17. PubMed Web of Science Google Scholar
- 23. Fylkesnes K. Determinants of health care utilization—visits and referrals. Scand J Public Health 1993;21:40–50. Abstract/FREE Full Text Google Scholar
- 24. Adamson J, Ben-Shlomo Y, Chaturvedi N, et al. Ethnicity, socio-economic position and gender—do they affect reported health—care seeking behaviour? Soc Sci Med 2003;57:895–904. CrossRef PubMed Web of Science Google Scholar
- 25. Leese GP, Schofield CJ. Amputations in diabetes: a changing scene. Prac Diabetes Int 2008;25:297–9. Google Scholar
- 26. El Sakka K, Fassiadis N, Gambhir RP, et al. An integrated care pathway to save the critically ischaemic diabetic foot. Int J Clin Pract 2006;60:667–9. CrossRef PubMed Web of Science Google Scholar
- 27. Dargis V, Pantelejeva O, Jonushaite A, et al. Benefits of a multidisciplinary approach in the management of recurrent diabetic foot ulceration in Lithuania: a prospective study. Diabetes Care 1999;22:1428–31. Abstract/FREE Full Text Google Scholar
- 28. Van Gils CC, Wheeler LA, Mellstrom M, et al. Amputation prevention by vascular surgery and podiatry collaboration in high-risk diabetic and nondiabetic patients. The Operation Desert Foot experience. Diabetes Care 1999;22:678–83.Abstract/FREE Full TextGoogle Scholar
- 29. Meltzer DD, Pels S, Payne WG, et al. Decreasing amputation rates in patients with diabetes mellitus. An outcome study. J Am Podiatr Med Assoc 2002;92:425–28. PubMed Web of Science Google Scholar
- 30. Larsson J, Apelqvist J, Agardh CD, et al. Decreasing incidence of major amputation in diabetic patients: a consequence of a multidisciplinary foot care team approach? Diabet Med 1995;12:770–6. CrossRef PubMed Web of Science Google Scholar
- 31. Frykberg RG. Team approach toward lower extremity amputation prevention in diabetes. J Am Podiatr Med Assoc 1997; 87:305–12. PubMedWeb of Science Google Scholar
- 32. Patout CA, Birke JA, Horswell R, et al. Effectiveness of a comprehensive diabetes lower-extremity amputation prevention program in a predominantly low-income African-American population. Diabetes Care 2000;23:1339–42. Abstract/FREE Full Text Google Scholar
- 33. Lipscombe J, Jassal SV, Bailey S, et al. Chiropody may prevent amputations in diabetic patients on peritoneal dialysis. Perit Dial Int 2003;23:255–9. Abstract/FREE Full Text Google Scholar

Cost savings implications

Studies have been conducted outside of Africa which show cost savings implications of podiatric integration in the MDTA

Carls GS, Gibson TB, Driver VR, et al. The economic value of specialized lower-extremity medical care by podiatric physicians in the treatment of diabetic foot ulcers. J Am Podiatr Med Assoc. 2011;101(2):93-115

Savings per patient equivalent to over R250 000

Studies have indicated that a multidisciplinary approach to the diabetic foot, including a podiatrist, can reduce amputations by as much as 85% (Clarke and Tsubane, 2008; Tudhope, 2009).

What do podiatrists do?

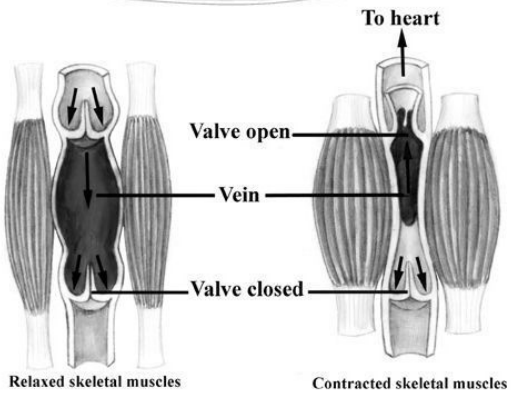
- Diabetic foot screenings and full assessments
- Foot risk identification
- Diabetic patient empowerment education – specific to that patient
- Enable patient to formulate a foot care "action plan"
- Management of non-ulcerative foot pathologies
- Management of ulcerative foot and ankle pathologies
- Biomechanical Components (shoes and In-shoe components)

PODIATRY ASSOCIATION OF SOUTH AFRICA

Pan - African Diabetic Foot Study Group

Source IWGDF (PADFSG)

- Exercise prescription and goals (esp. show calf muscle 'pump')
- Early warning signs – referrals to team members
- Set a follow up date for podiatry treatment (according to risk evaluation) of non ulcerative and ulcerative pathology



Podiatrists impart a medical identity and mission that promotes the importance of the feet in diabetes

Diabetic Foot Assessment

Six Parts:

1. Musculoskeletal
2. Dermatological
3. Vascular
4. Neurological
5. Footwear
6. Education

Exercise for high risk patients

- Physiological and psychological challenges
- Adaptation of upright exercises to supine bed exercises
- Assisted exercise (involve family)
- Group therapy
- Psychology support

Ryan T Crews; Kristin L Schneider; Sai V Yalla; Neil D Reeves; Loretta Vileikyte; et al. Physiological and psychological challenges of increasing physical activity and exercise in patients at risk of diabetic foot ulcers: a critical review. Diabetes/Metabolism Research and Reviews, v32 n8 (November 2016): 791-804

Musculoskeletal assessment

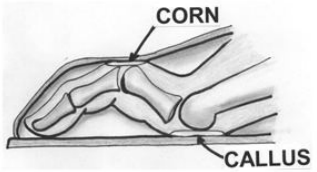
- Joint mobility (ROM)
- Deformities/ prominences
- Abnormal pressure
- Prior amputations

SHOULD INCLUDE

- Biomechanics (eg. varus/valgus imbalance, LLD, patient Hx)

Dermatological Assessment

- Ulcers
- Infections
- Fissures
- Blisters
- Texture
- Anhidrosis
- Hyperhidrosis
- Corns/Callus
- Nails



Callus increases DFU risk x11

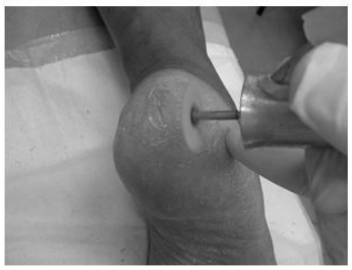
Callus increases the pressure on the plantar aspect of the foot and the risk of ulceration 11 times more than if the patient had no hyperkeratotic build up.

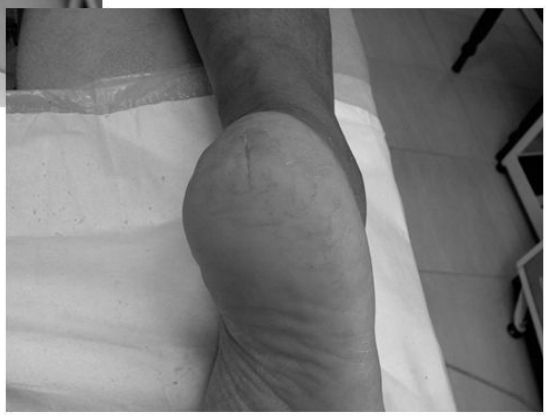
A Practical Manual of Diabetic Footcare, Edmonds, 2008

Interdigital corn

Custom silicone spacer device made in consult

Heel fissures
before and after
sharp scalpel debridement
and dermabrasion with
vacuum drill instrument
and sterile medium grit disk





Restoring diabetic skin texture

Name of Product	Keratolytic concentration	Anti-fungal ingredient
Clicks Nourishing Heel Balm	25% urea	None
Dr Sole Cracked Heel Repair Cream	25% urea	Tea Tree
Effectunol	25% urea	None
Eulactol Heel Balm	25% urea	None
Heels	25% urea	Tea Tree
Dr Sole Treatment Heel Balm	20% urea	Tea Tree
Froggie Heel Balm	20% urea	Tea Tree
Oh So Heavenly Heel Balm	20% urea	none
Hydra Aqueous Plus	11% urea	none
Epi-Max Plus	10% urea	none
Nutraplus	10% urea	none
Pedi-Cydin	5% urea	none
Pedi-Relax Diabetic Foot care cream	5% urea	Piroctone olamine
Recharge Diabetic Herbal Foot Cream	Vitamins E & A	Silver citrate

Early ACUTE Charcot foot

- Acute or sub-acute inflammation of all or part of the foot in people with diabetes
  complicated by distal symmetrical neuropathy,
  with or without fracture or dislocation
  that cannot be explained by recent trauma, and
  without preceding ulceration of the adjacent skin

- Temperature difference between feet > 2° centigrade
- Technetium-99 scan to confirm

Jeffcoate, W. The diabetic foot Vol 7 No 4 2004

Vascular Assessment

- Temperature
- Dorsalis pedis pulse
- Post tibialis pulse,
  popliteal pulse
- Colour
- Capillary Refill Time (CRT)
- Doppler ultrasound exam
  (can we afford to wait until
  pulses are absent???)
- Intermittent claudication
- Automated ABPI
- Exercise history and plan

Footwear Assessment

FOOTWEAR ASSESSMENT TABLE If any answer in the table is No, the patient must be referred to a follow up appointment with a podiatrist for footwear and in-depth gait analysis/measurement for prescription of appropriate interventions such as custom insoles/orthoses, as well as further education/prescription of preventative/corrective footwear or footwear modification		
Footwear accommodates shape, length, width and depth of feet, with sufficient toe room?	Yes	No
Footwear accommodates foot deformities?	Yes	No
Footwear protects the toes?	Yes	No
Footwear fits well and does not cause either bulging of skin nor red marks on the skin?	Yes	No
Widest flex area of footwear is aligned with widest flex area of the MTP joints?	Yes	No
Is there at least 1cm space between the distal tip of the longest toe and the innermost distal end of the shoe? (Alternatively, foot should be able to push forward into the shoe, revealing a 1 cm palpable gap at the back of the heel)	Yes	No
Does all of the patient's footwear have fastening over both the dorsum of the foot as well as the back of the heel?	Yes	No

Footwear Assessment

Does the patient know why to avoid using backless styles, thong styles (strap between the toes), pointed toed shoes or oval pointed shoes?	Yes	No
Is the footwear upper made of natural material (leather, suede, cotton, wool, bamboo)?	Yes	No
Does the patient know to avoid non-breathable, inelastic materials such as vinyl, plastic, polyurethane (PU) and PVC?	Yes	No
Does the neuropathic patient know why to avoid shoes that have innersoles with bubbles, stipples, textured surface, so called "massage points"?	Yes	No
Is the heel elevation of the footwear lower than or equal to 25mm?	Yes	No
Is the surface contact area of the heel at least 75% of the heel of the foot?	Yes	No
Is the footwear adjustable (laces, Velcro, buckles, elastic gusset)?	Yes	No
Does the footwear have any cushioning of the insole?	Yes	No
Is the insole of the shoe removable and replaceable/washable?	Yes	No
Is the footwear free from foreign objects?	Yes	No
Is the footwear free from breaks, torn lining or worn cushioning?	Yes	No
Is the footwear internally free from rough seams, prominent stitching, glue patches, ridges or wrinkles or any type of surface which could chafe?	Yes	No
Is the footwear free from wear that might compromise the patient's biomechanics? (Place shoe on flat surface and examine whether it is distorted from vertical or does not make contact with the ground surface in any area, e.g. over worn heels)	Yes	No

Neurological Assessment

- Semmes Weinstein Monofilament
- Light/dull touch
- Hot/cold (TipTherm)
- Sharp/Blunt (Neurotip)
- Vibration
- Proprioception test
- Patellar reflex
- Ankle reflex
- Symptoms of neuropathy (burning feet, sharp pain, "pins & needles" paresthesia
- Neuropathy disability score
- VAS pain score

Foot risk evaluation: low foot risk

- *Low foot risk* is normal sensation and circulation with no deformity, no previous ulcer oramputation

Podiatrist carries out patient education, interactive history/lifestyle discussion, dietary habits, physical activity levels, knowledge of what exercise does to blood glucose levels, daily work challenges, glucometer knowledgeable or glucometer ignorant, footwear examination and education on what to look for in a shoe. Re-affirmation of multi-disciplinary approach.
Full report (copy to doctor/team) becomes baseline for next year's full re-assessment.

Foot risk evaluation: Moderate risk

- *Moderate foot risk* is any ONE of Foot deformity/prominence; loss of sensation or PAD

  Podiatrist patient education is more specific to risks of foot injury, interactive work on tight blood glucose control, diet esp Vit B12, physical activity levels, knowledge of what exercise does to blood circulation (to support nerves), physical examination to check proprioception/balance; footwear examination and testing biomechanics (prescription footwear or inserts may be needed in cases of amyotrophy/deformity)

  Full report (copy to doctor) becomes baseline for follow up re-assessment in 3 to 6 months.

Foot risk evaluation: High risk

- *High foot risk* is previous ulcer or amputation, OR 2 or more of: foot deformity/prominence, LOPS, PAD, visual impairment, eGFR less than 60 or on renal replacement

Podiatrist will conduct Doppler and obtain vascular consultation for patient. Patient education is more specific to in depth interactive work on tight blood glucose control, tight cholesterol control, healthy diet, physical activity levels, specific exercises, physical examination to check skin texture, footwear examination and testing biomechanics (prescription footwear or inserts with cushioned Poron memory foam needed for microvascular and neural stimulation), education why to stop smoking, etc.....
Full report (copy to doctor) becomes baseline for follow up Re-assessment every 1 to 2 months. These patients should not cut their own nails.

Clinical finding: active foot disease

- Any of: Active foot ulcer; gangrene; spreading infection; critical limb ischaemia; charcot foot

Podiatrist management:

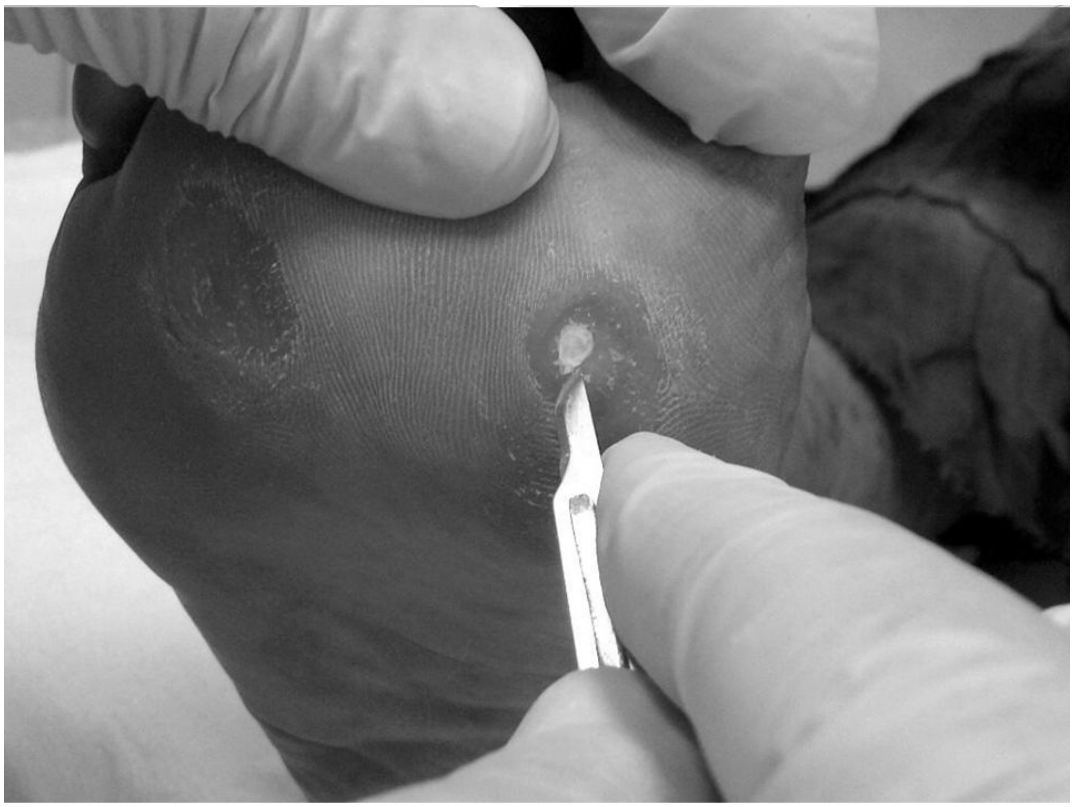
- Wound care, foot examination at every visit (example: debridement, wound therapy, total contact cast)
- Multi-disciplinary referral within 24 hours, co-ordinated by senior diabetes consultant
- Management of contralateral foot/prevention

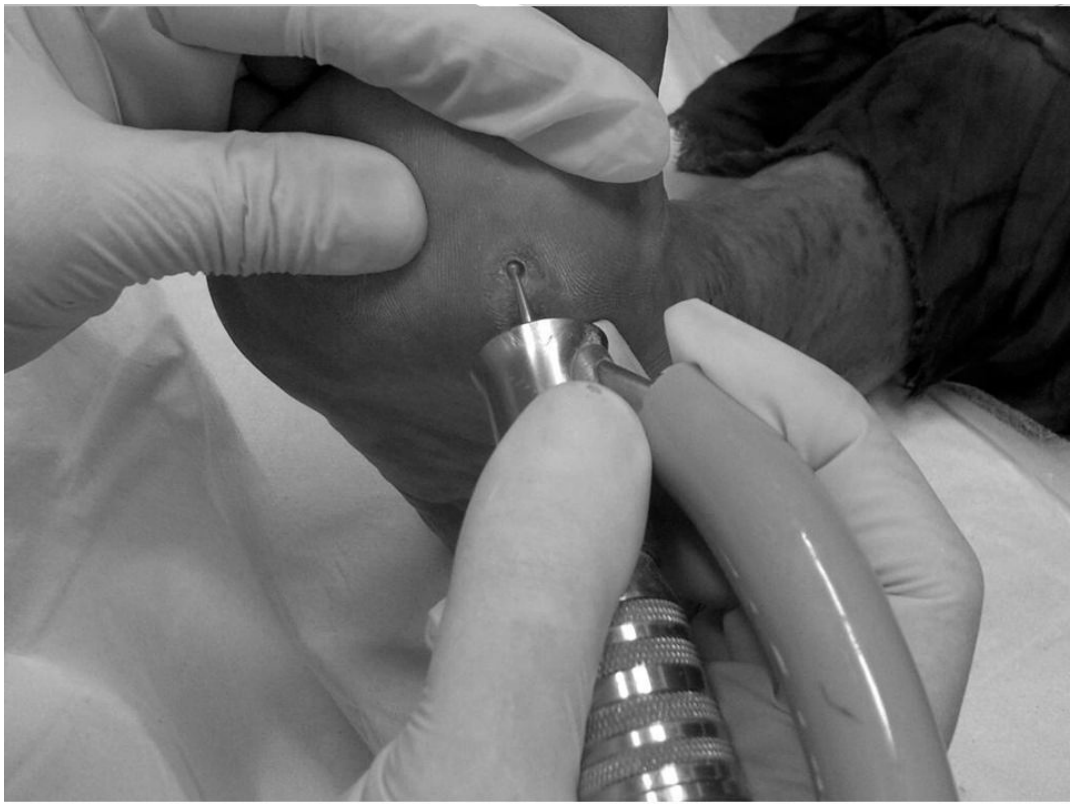
Example Podiatry Treatment: musculoskeletal

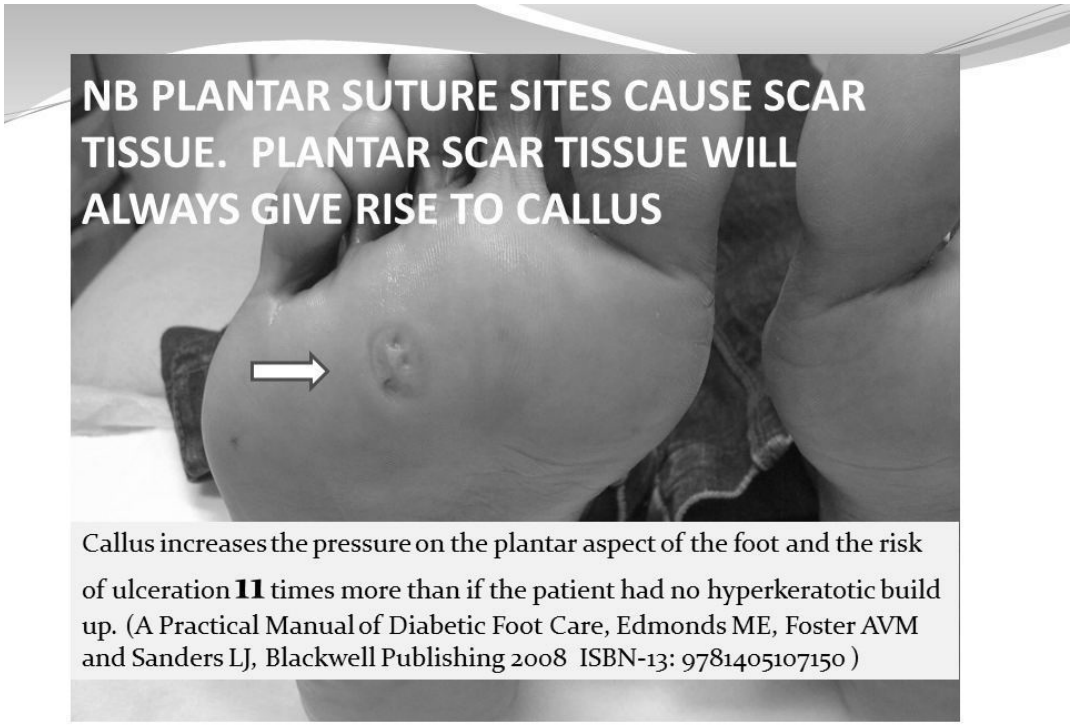
- Address the pathologies which were found in the assessment
- Example: Musculoskeletal
  Hallux valgus (bunion) – potential future ulcer site
  1. If flexible, do workup to determine suitability for day and/or night splints
  2. Biomechanical examination
     find varus/valgus imbalance points which need prescription insole correction to prevent progression.
  3. Footwear – education, modification, prescription

Podiatry Treatment: Dermatological

- Address pathologies ex the assessment
- Example: Hyperkeratosis (callus) under PMA – future ulcer site
  1. Sharp debridement
  2. Dermabrasion
  3. Find the cause – anatomical, biomechanical, neurological, incorrect footwear, etc…
  4. Address the cause
     e.g. congenital short 1st metatarsal
     Template and prescription for Rx insoles
     Counselling and education re footwear

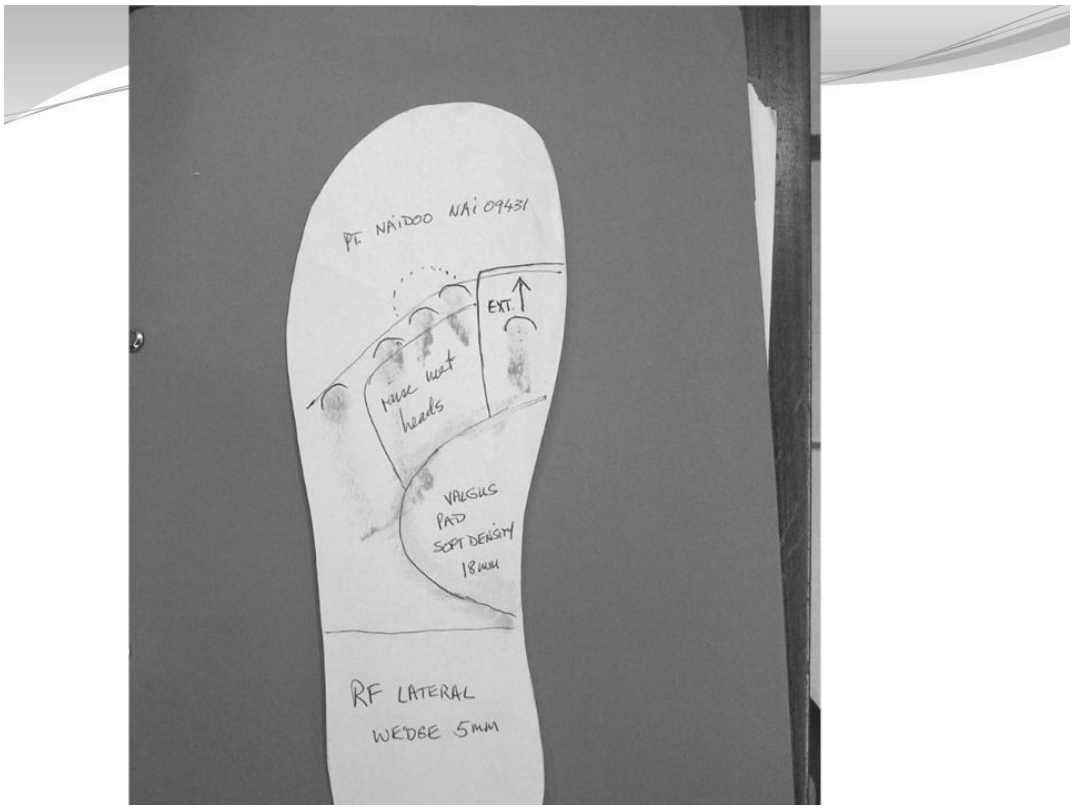






Callus increases the pressure on the plantar aspect of the foot and the risk of ulceration **11** times more than if the patient had no hyperkeratotic build up. (A Practical Manual of Diabetic Foot Care, Edmonds ME, Foster AVM and Sanders LJ, Blackwell Publishing 2008 ISBN-13: 9781405107150)

EXT.


Pt NAIDOO NAi 09431
EXT.
MAKE MET HEADS
VALGUS PAD SOFT DENSITY 18MM
RF LATERAL WEDGE 5MM

Note on callus

- Callus increases the pressure on the plantar aspect of the foot and the risk of ulceration **11 times more** than if the patient had no hyperkeratotic build up.

A Practical Manual of Diabetic Foot Care, Edmonds ME, Foster AVM and Sanders LJ, Blackwell Publishing 2008 ISBN-13: 9781405107150

Podiatry tx: Rx insoles/orthotics

No two diabetic feet are the same.

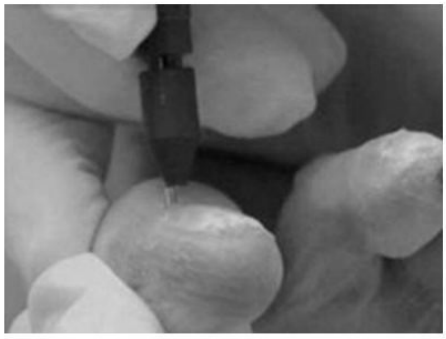
Pre-formed orthotics are not ideal.

Podiatry special shoes and inserts

Podiatry Treatment: Dermatological

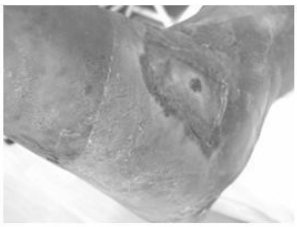
- Address the pathologies found in the assessment
- Example: Fungal nail infection

1. Specimen sampling
2. Dermabrasion of nail thickness
3. PAS stain to confirm infection
4. Doppler to confirm blood flow, then LASER treatment to kill fungal infection + topical Amorolfine/oral meds plus Fungisolve shoe/ hosiery treatment to break cycle of re-infection



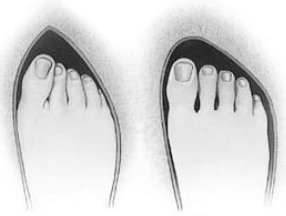
Podiatry treatment: Vascular

- Investigations: ABPI test
- Doppler Ultrasound test
- Education
- Rx, dispensing and how to education of compression hose
- 3-part compression bandaging for venous ulcers
- Total Contact Cast for DFU
- DFU Wound management
- Referral to vascular surgeon for angiogram – revascularise
- Specific exercise instruction tailored to the patient



Podiatry treatment: Neurological

- Referral and interaction with primary physician/endocrinologist re neuropathic pain control
- Investigation, Rx and administration of Vitamin B12 injection if levels are low
- Increase exercise even if pulses palpable
- **High risk foot**: Rx Footwear/orthotics
  exercise strategies to prevent ulcers
  MONTHLY CHECKS BY PODIATRIST
- **Medium risk foot**: Advice on footwear/
  exercise strategies to prevent ulcers
  3-6 MONTH CHECK BY PODIATRIST
- **Low risk foot**: biomechanical examination,
  education, education, education *ANNUAL FOLLOW UP*



Summary

- Diabetes : expensive, devastating, prevalent in SA
- Podiatrist diabetes care: essential, improves outcomes and saves money.
- Podiatry value important: new healthcare delivery models.
- Early referral of patients: essential
- Educate medical aids and State health
- Lobby for new Departments of Podiatry at universities
- Lobby and motivate for posts at all hospitals
  to prevent podiatric brain drain.
- Medical curriculum to include knowledge of podiatry

Thank you

Appendix 20: Presentation at CDE Forum November 2020

"Palpation of the foot in diabetes – what are we missing?"

Palpation of the foot in diabetes – what are we missing?

Anette T Thompson
FFPM RCPS (Glasgow) M Tech Podiatry (UJ)

CDE Forum November 2020

1

Disclosure

- I have no conflict of interest in relation to this presentation.
- Research Support: BBF Safety Footwear, Telmo Applied Science.

This presentation is in two parts.

All references and further reading are shown at the end of the presentation, to avoid excessive content on the slides.

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2

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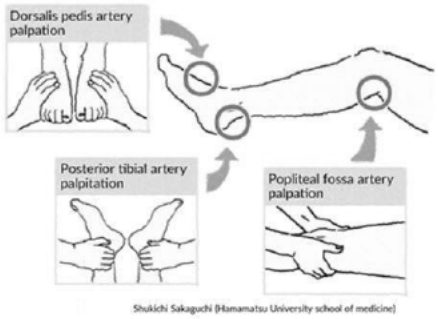

Palpation of the peripheral arterial pulses
in a patient with strong systolic blood pressures,
by an experienced clinician,
is an important and reliable skill.

PART ONE: Palpation of peripheral pulses

BY NC ND

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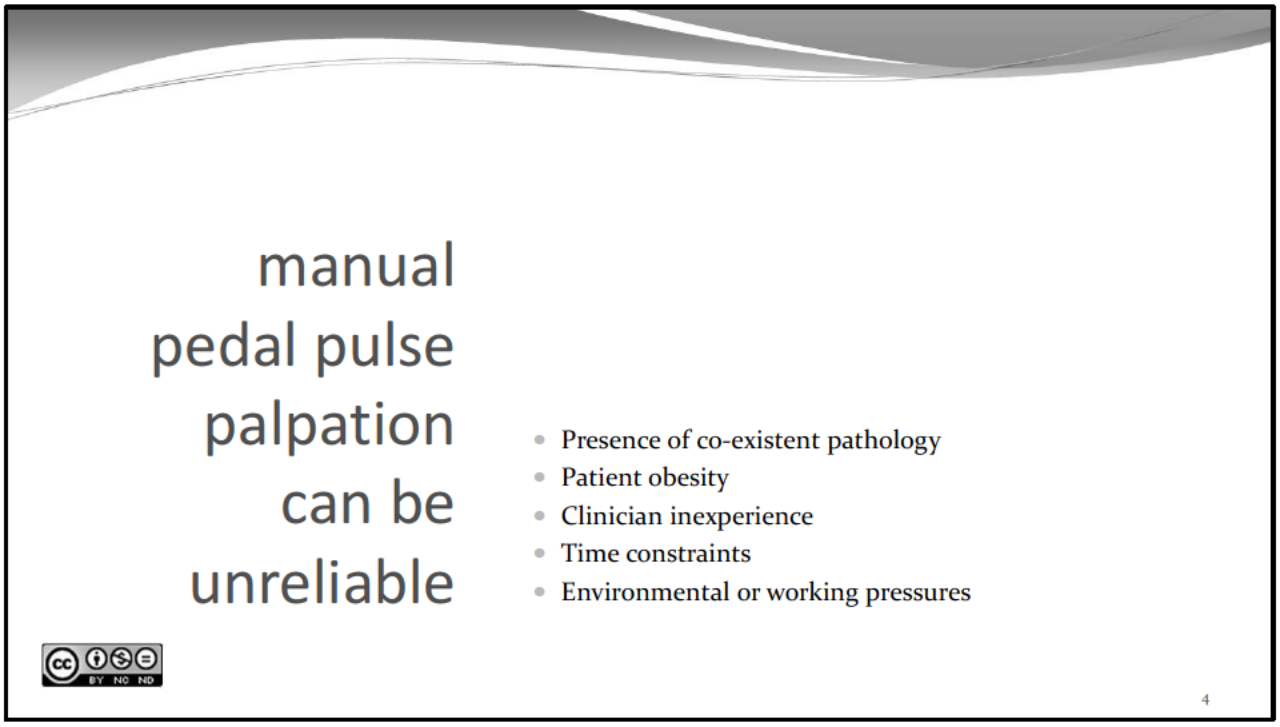
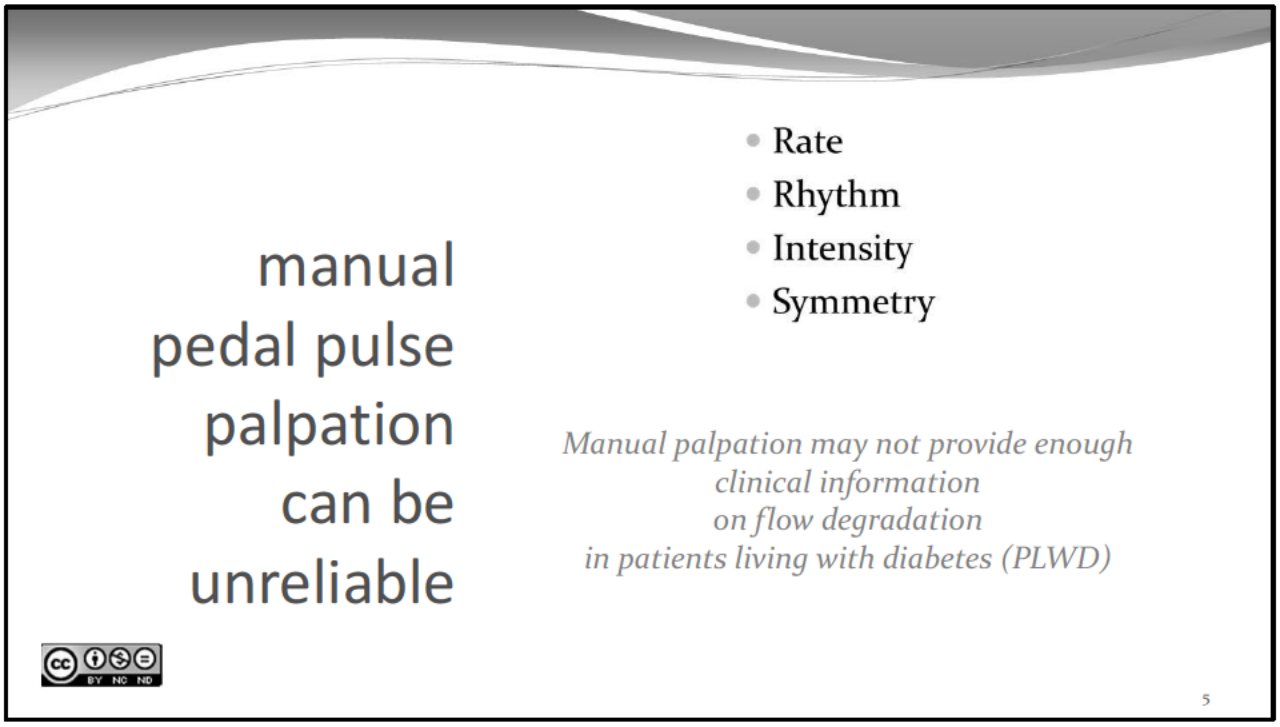
Part One concerns peripheral arterial pulses.
In a patient with strong systolic blood pressures
carried out by an experienced clinician,
palpation of pulses is an important and reliable skill.



However, numerous studies show that simple manual palpation of pedal pulses can yield erroneous results.
Reasons on the patient side include co-existing pathology or patient obesity
The examiner may lack experience, lack of enough time, or there may be environmental or working pressures in busy practices.



Since palpation can only inform on rate, rhythm, intensity and symmetry, this may not be early enough detection of flow degradation in patients living with diabetes.

Motivation and Objective

- Early detection of lower limb peripheral arterial disease (PAD) allows for timeous therapeutic and lifestyle interventions.
- The aim was to determine whether palpation of pedal pulses in a typical South African diabetes clinic is accurate for the early detection of PAD.

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Finding the early stages of peripheral arterial disease allows for timeous therapeutic and lifestyle interventions.

The question asked was whether pedal pulse palpation in a typical South African diabetes clinic
was accurate for the early detection of PAD?

Method

Doppler waveform	Waveform characteristic on screen
Triphasic	1. forward flow in systole 2. reverse flow in late systole / early diastole 3. forward flow in late diastole
Biphasic	1. reverse flow in diastole 2. forward flow in systole (i.e. no forward flow in diastole)
Biphasic continuous	1. reverse flow in diastole 2. steady positive flow in diastole
Monophasic	1. single flow with either low or high velocity ("bounding")
Absent waveform	No waveform display but single audible signal elicited by using one's left hand to compress dorsalis pedis at the proximal ankle, between tibia and fibula, while holding Doppler in the right hand.

Triphasic = unobstructed blood flow
= no pathology

Biphasic waveform
Biphasic continuous
Monophasic
Absent waveforms
} degrees of PAD

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This study defined unobstructed blood flow as the presence of triphasic doppler ultrasound waveforms in pedal arteries.
Waveforms less than triphasic (i.e. biphasic, monophasic, continuous, absent) were considered indicative of degrees of PAD, whether established PAD or early signs thereof.

Both feet were examined. If either foot presented with less than triphasic flow, the patient (as a whole) was recorded as positive for PAD.

Method

- N = 301 patients living with diabetes ages 17 to 92, av. age 55
- Public health care diabetes clinic (uMgungundlovu district KwaZulu-Natal)
- *Ethics approval granted by the Department of Health, Management of Edendale Hospital and the Biomedical Research Ethics Committee of the University of KwaZulu-Natal, BREC reference BE 264/17.*
- Dorsalis pedis (DP) and tibialis posterior (TP) examined on each limb
- Doppler ultrasound – researcher reported as waveforms
- Pedal pulse palpation - attending doctors, reported as present or absent.

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With the relevant ethics approval, 301 patients living with diabetes, attending a public health care diabetes clinic were examined by both the researcher and the attending doctor.

Both pedal pulses on both limbs were examined. The researcher used handheld Doppler ultrasonography while the doctors reported on present or absent pedal pulses.

Results

- Prevalence of PAD by Doppler exam was 94% (n=283)
- Practically ***half*** of patients had doppler-based evidence of PAD despite a palpable DP (58.1% vs 47.8%, left vs right DP)
- More than half of patients had doppler based evidence of PAD despite a palpable TP (58.9% vs 59.3%, left vs right TP)

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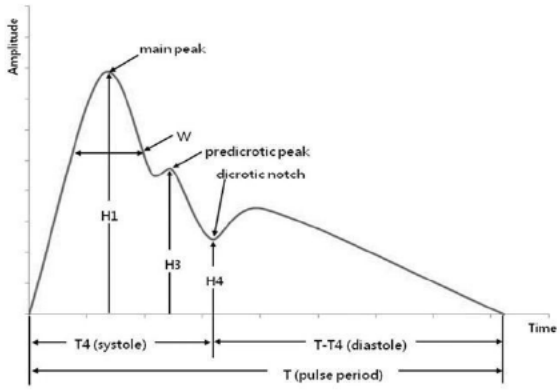
The results showed a prevalence of peripheral arterial disease of 94%

Practically half of the patients had doppler evidence of PAD
despite a palpable dorsalis pedis pulse

More than half of patients had doppler evidence of PAD
despite a palpable tibialis posterior pulse.

Results



- In the study cohort, a proportion of patients had ***normal triphasic*** Doppler readings.
- Within these, there were patients recorded as having ***non-palpable DP pulses*** (7.32% vs 7.5% left vs right DP)
- … and patients recorded as ***non-palpable TP pulses*** (7.69% in both left vs. right TP)

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Conversely, Doppler revealed normal triphasic readings in almost 20 patients for whom the doctors had recorded non-palpable DP pulses.

Conclusions

- Pulse palpation is not reliable for the early detection of PAD when compared to hand-held Doppler ultrasonography.
- When used in isolation, pulse palpation can lead to a large proportion of patients with PAD being missed.
- Absent palpable pulses may not be indicators of diminished flow.

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The study concluded that pulse palpation is not reliable for the early detection of PAD when compared to hand-held Doppler ultrasonography.

When used in isolation, pulse palpation can lead to missing a large proportion of patients with PAD

Absent palpable pulses may not be indicators of diminished flow.

Recommendation

Based on the findings, it is proposed that SEMDSA guidelines regarding foot examination be amended.

- Guidelines should include ***both*** clinical foot pulse palpation ***and*** hand-held doppler ultrasound to improve earlier diagnosis of PAD in PLWD.

Category	Risk Profile	Frequency of foot examinations and/or level of care
Low risk	People with no risk factors and no previous history of foot ulcer or amputation	General foot care and education; annual examination at primary care
Moderate risk	People with one risk factor (neuropathy, peripheral arterial disease or foot deformity) and no previous history of foot ulcer or amputation	Every visit Secondary level care
High risk	People with two or more risk factors (neuropathy, peripheral arterial disease or foot deformity) and/or a previous history of foot ulcer or amputation	Every visit Tertiary level care
Active foot problem	People with ulceration or spreading infection or critical limb ischaemia or gangrene or suspicion of an acute Charcot neuro-arthropathy, or an unexplained hot, red, swollen foot with or without pain.	Every visit

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Based on the findings, it is proposed that national guidelines be amended to include both manual pulse palpation and hand-held doppler ultrasound to improve earlier diagnosis of PAD in persons living with diabetes.

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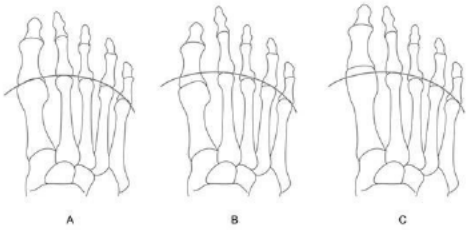
These are the references and further reading for Part One

PART TWO – an osseous risk factor for diabetic foot ulceration



- Brachymetatarsia of the first metatarsal or Short First Metatarsal (SFM)
- Hereditary osseous presentation
- Produces an imbalanced metatarsal parabola.
- Numerous gait compensations for inability to roll over MTPJ-1

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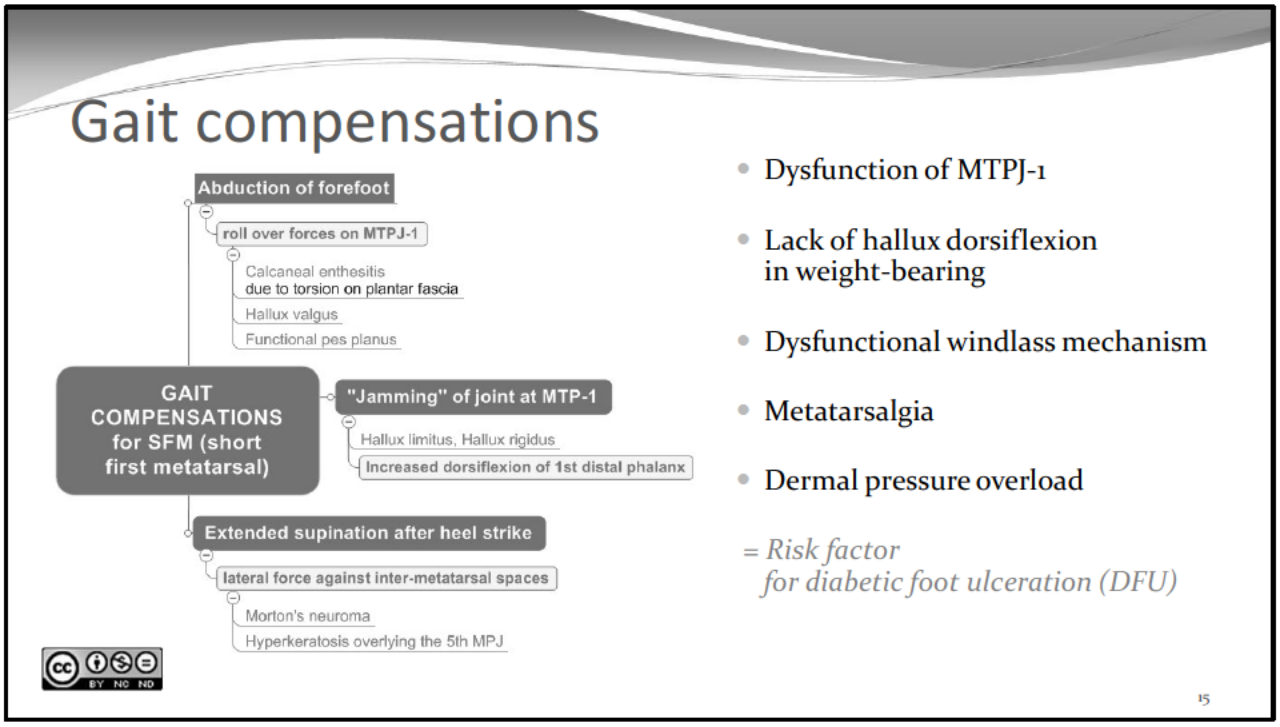
Part Two concerns evidence that palpation can alert the clinician to a skeletal risk factor for diabetic foot ulceration.

Brachymetatarsia of the first metatarsal (illustration B) or Short first metatarsal (SFM) is a hereditary osseous presentation.

As shown, it produces an imbalanced metatarsal parabola, resulting in inability to roll over MTPJ-1



Gait compensations include abduction of the forefoot, jamming of the joint at MTP-1 and extended supination after heel strike.

These lead to dysfunction of the first metatarsophalangeal joint, a lack of hallux dorsiflexion in weight bearing.
That in turn leads to a dysfunctional windlass mechanism with implications for decreased venous return.
The venous foot pump partially depends on the windlass mechanism to eject the portion of venous blood from the foot to the calf muscle pump.

Since the first MP joint is forced to have reduced articulation, there is jamming of the joint itself,
resulting in an enlarged joint capsule, and development of hallux limitus and hallux rigidus.

Abduction of the forefoot often results in extended supination after heel strike,
so that lateral forces can produce an intermetatarsal neuroma and/or hyperkeratosis overlying the 5th MP joint.

Resultant dermal pressure or overload from SFM, whether at the hallux joint, the distal phalanx of the hallux,

or any of the lesser metatarsal heads makes this presentation a risk factor for a DFU.

How prevalent is SFM in diabetes?

Signs of MTPJ-1 pathology (n = 301)	Frequency right foot	Frequency left foot
Short first metatarsal (SFM)	24.6%	24.3%
Hallux abducto valgus (HAV)	8.0%	8.3%
Prominent MTPJ-1 (pathognomonic of SFM, Hallux limitus, Hallux rigidus)	28.6%	28.2%
Hyperkeratosis (Corns and callus)	36.2%	36.2%

SFM in **25%** of patients examined at a diabetes state health SOPD in 2019.

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How often could you see this in patients with diabetes?

Well, SFM was found to be present in 25% of patients examined at a state health SPOD in 2019.

Identification -pathognomonic signs

- Enlarged MTPJ-1 (*similar to a bunion bump but the hallux is straight, not deviated*)
- Upturned distal phalanx of the hallux
- Hyperkeratosis on medial border of the hallux

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What are the main signs of a SFM?
An enlarged first MTP joint – this may not be a bunion, there is no valgus
An upturned distal hallux phalanx.
Hyperkeratosis on the medial border of the hallux
(feel for roughness and ask as some female patients may file it down)

Identification -pathognomonic signs

Additional plantar signs/symptoms

- Hyperkeratosis at proximal IPJ (attempt to shift fulcrum distal of MTPJ-1)
- Hyperkeratosis over MTPJ-5

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Additional signs include hyperkeratosis at the proximal IPJ
and variable hyperkeratosis over the fifth MPJ,
depending on how much supinatory abduction the patient does in compensation.

Identification -pathognomonic signs

Additional signs/symptoms

- Ingrown toenail in conjunction with medial hyperkeratosis of the hallux (*indicates medial pressure against nail bed*)

BY NC ND

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On the left you can see the upturned distal phalanx with medial hallux hyperkeratosis
The hallux nail plate is deformed in response to the medial pressure against that phalanx

On the right, on presentation to my rooms, this patient had already lost his ingrown nail to his GP but the medial pressure against the distal phalanx was unresolved, and the growing MTPJ-1 joint capsule enlargement is visible.

Identification -pathognomonic signs

Additional signs/symptoms

- Metatarsalgia
- Hyperkeratosis or helomata over lesser MTPJs, esp. 2nd or 3rd
- + - Heel pain

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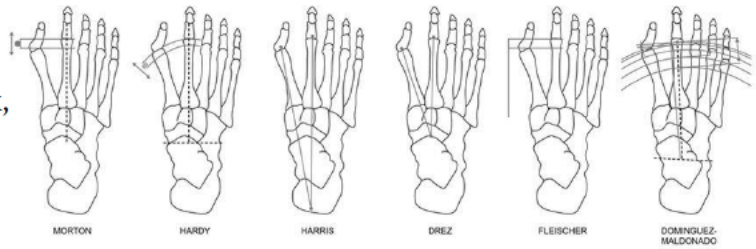
Metatarsalgia may be absent in the patient living with diabetic neuropathy.
Hyperkeratosis may or may not be seen over the lesser metatarsophalangeal joints, depending on footwear, activity levels.
In the photo on the left, the interphalangeal joint of the hallux takes the pressure.
In the photo on the right, the patient recalls ulcers under both hallux joints.
He lost the left hallux completely and a fusion was done to the right hallux.
This now results in excess pressure on the metatarsophalangeal joint.

Identification – measurement methods

- Radiography is costly
- Travel, absence from work, decreased productivity, radiation exposure, time consuming.
- Palpation-based methods are simple, cheap, non-invasive, high degree of reliability.



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Studies have put forward many measurement methods based on x-rays.
X-rays cost money and are time consuming, among other factors.
Palpation-based methods are simple, cheap, and have a high degree of reliability as shown in peer-reviewed academic studies.

Materials and Method

- Patient to lie supine on a plinth
- Reassure patient that measurement and marking is painless.
- *Instruments:*
  1. *Gentian violet surgical marking pen*
  2. *Gloves*

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Have the patient lie supine on the examination bed, and reassure them that marking is painless.
You will need gloves and a surgical marking pen.

Materials and Method

- Face the plantar surface of the patient's feet
- Articulate each MTP joint, dorsiflexing and plantarflexing, while palpating both the dorsal and plantar surfaces of the joint capsule with forefinger and thumb

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Face the patient's feet.
Flex each metatarsophalangeal joint dorsally and plantarly,
while you palpate both the dorsal and plantar surfaces with forefinger and thumb.
For larger patients use forefinger and third finger.

Materials and Method

- Mark the palpated centre of each joint capsule

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Lightly mark the palpated centre of each joint capsule on the plantar surface.

Materials and Method

- Join the joint centres from the fifth MTP joint to the second MTP joint

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Join the dots but start from the outside of the foot,
beginning at the 5th MP joint. You are going to create a continuous curve or parabola

Materials and Method

- Extend the curve to the medial border to form a parabola
- This assists in visualizing the short first metatarsal (SFM)

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Extend the curve to the medial border of the foot.
If there is SFM, the curve so formed will not pass through the mark on the first MP joint.

Notes on method

- Can perform same measurement on existing radiographs (if available)
- 4mm (or more) shorter than second metatarsal = SFM

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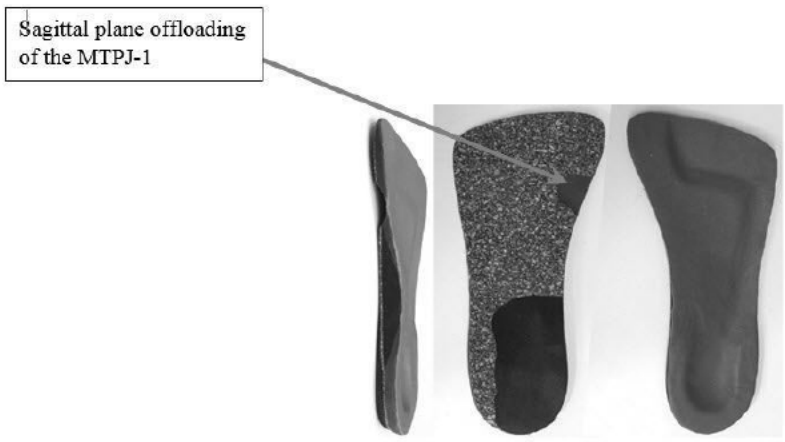
Of course, you can insert the curve onto x-rays, if available.

Note that literature states that a first metatarsal that 4mm or more, shorter than the second metatarsal, is a short first metatarsal

Example Podiatric non-invasive treatment



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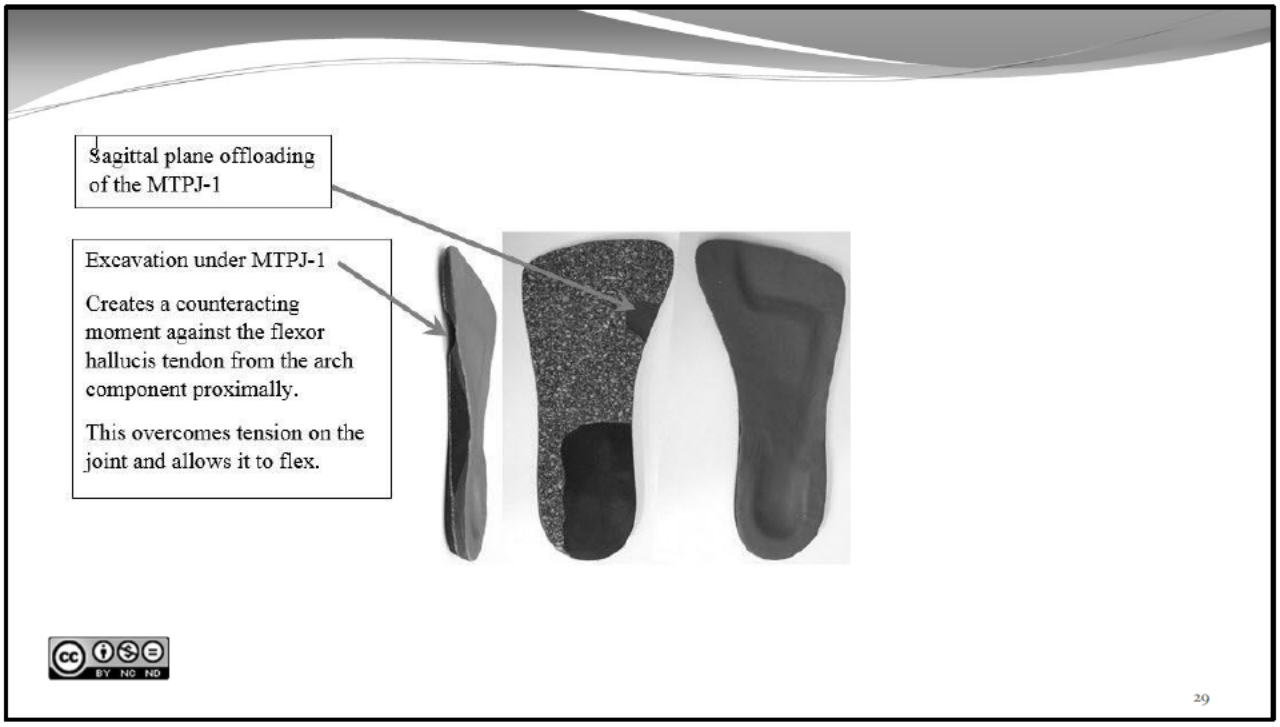
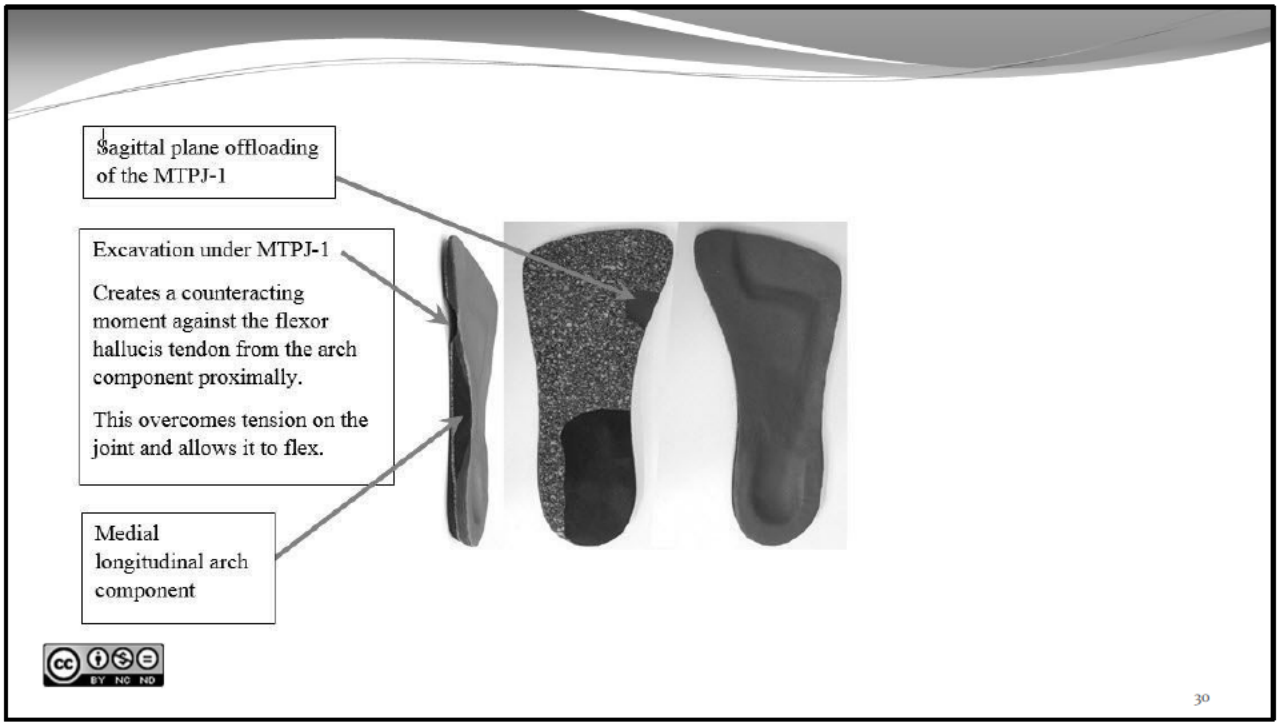
Time does not allow for a full exposition of podiatric skill in this area.

Here is one example of non-invasive treatment, as used by podiatrists.
It is based on the field of study within biomechanics called sagittal plane dynamics.

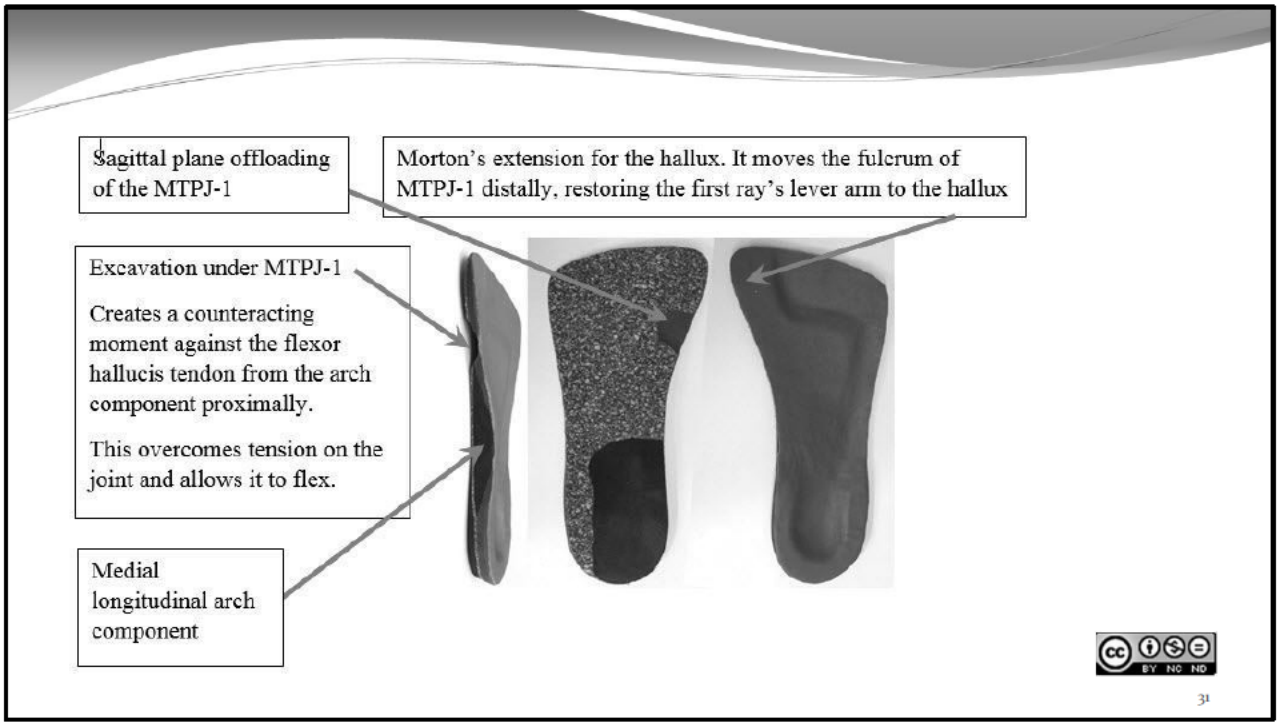
A hollow is formed in a custom shoe insert into which the first MP joint can rest on memory foam.



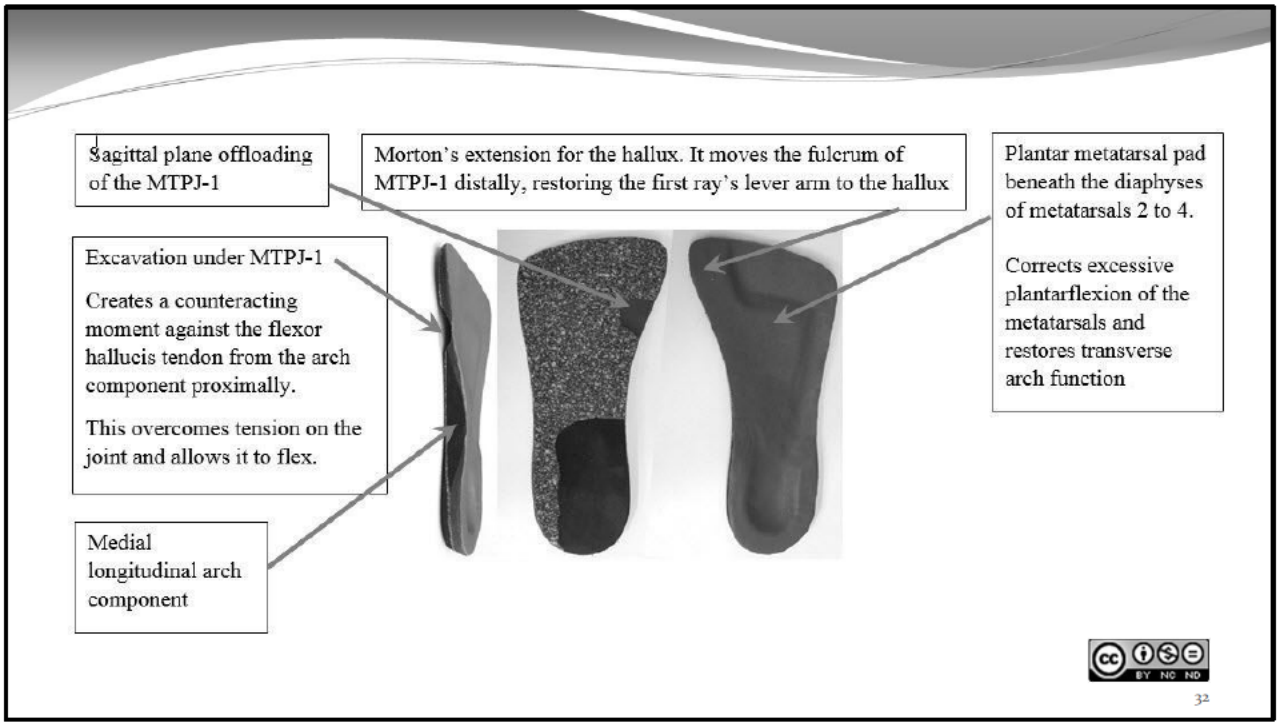
The hollow or excavation creates a counteracting moment against the flexor tendon from the higher arch component proximally. This overcomes tension on the joint and allows it to flex in rollover



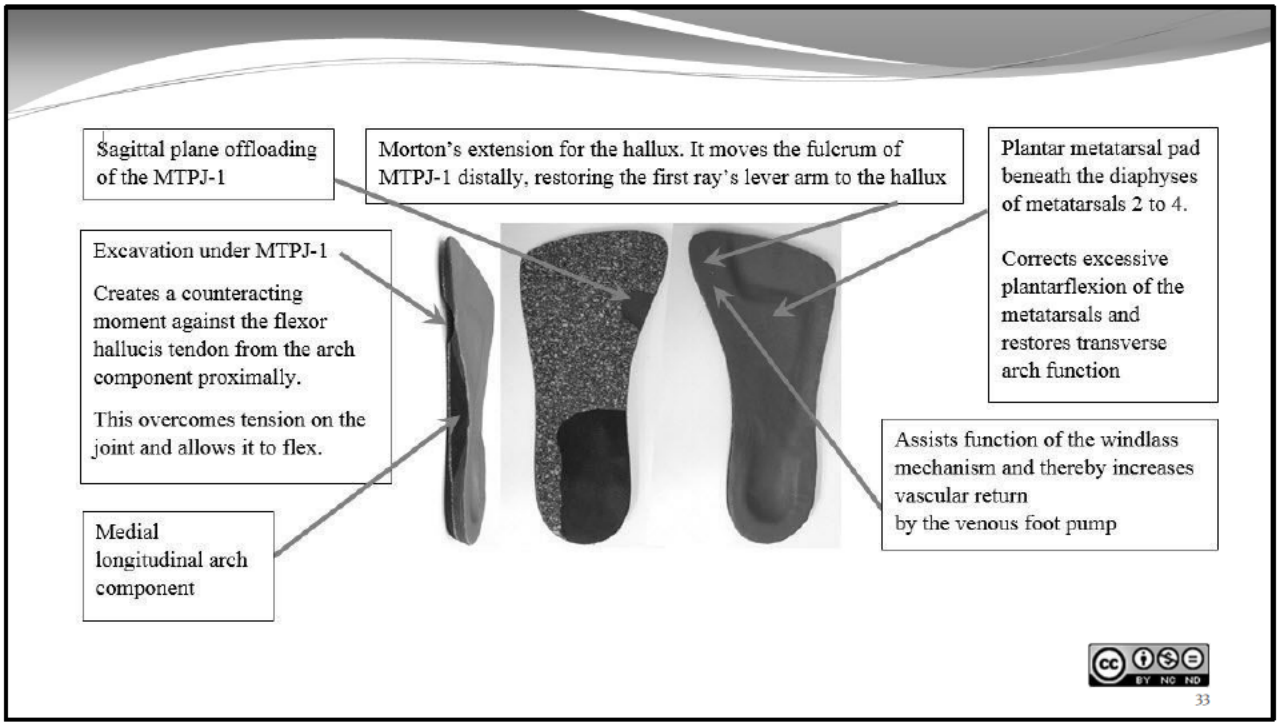
The medial arch component must be accurately positioned in 3 planes.



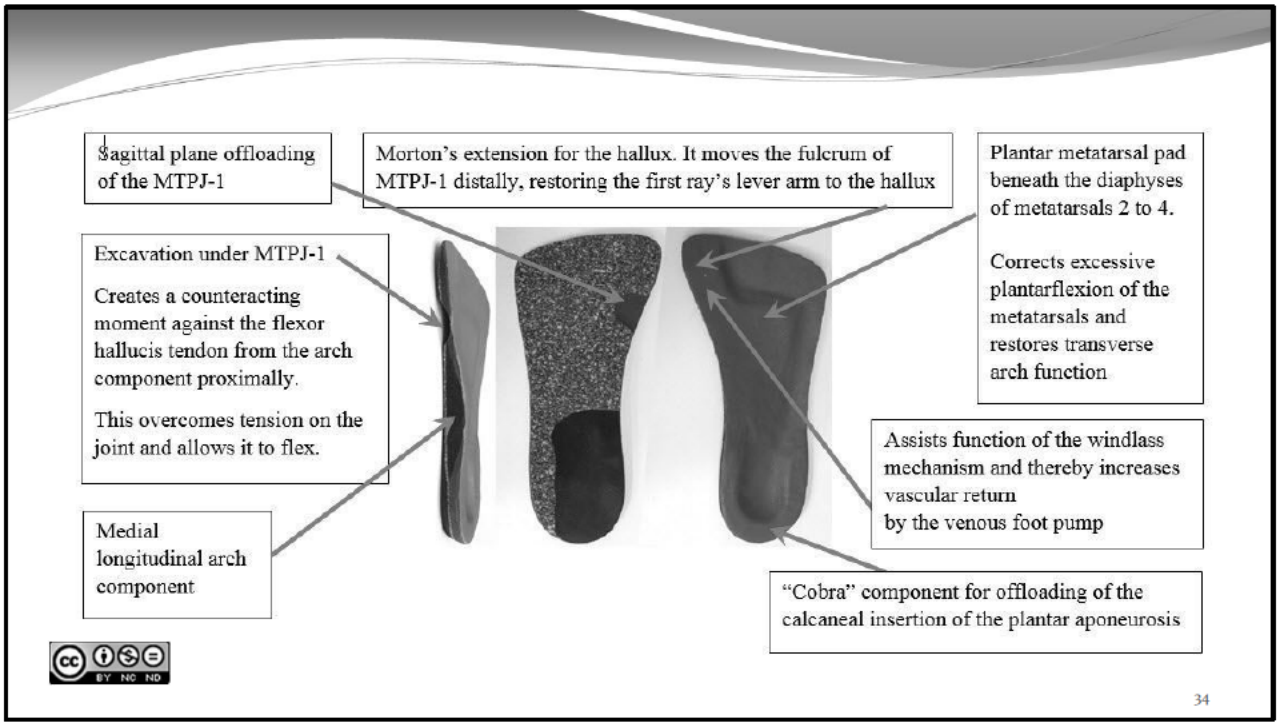
Dudley J Morton (not Thomas G Morton after whom the neuroma is named) proposed what is today called a Morton's extension. This component moves the fulcrum of the first MTP joint and this restores the lever arm to the hallux.
Another variation on the Morton's extension id a Cluffy Wedge, named after Dr James Clough in the USA – however, there may not be sufficient room in a shoe for this variant.



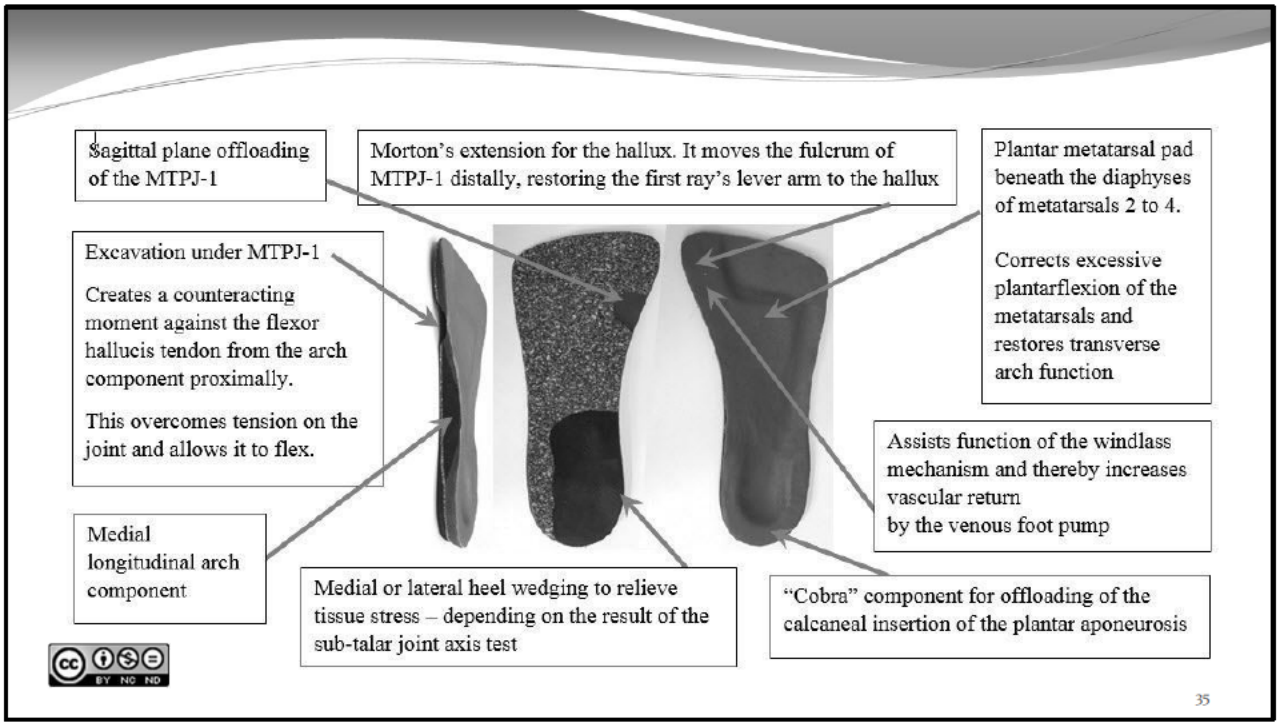
Since compensatory abduction of the foot causes strained interosseous and lumbrical muscles, the metatarsals become plantarflexed and supinated. A plantar metatarsal pad under their diaphyses corrects this.



The Morton's extension also assists function of the windlass mechanism, thereby restoring function to the foot venous pump by facilitating hallux dorsiflexion.



Podiatrists call the concave heel component a "cobra pad" – it offloads the calcaneal insertion of the plantar aponeurosis.

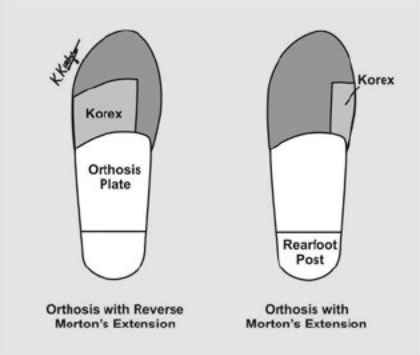


Based on the result of the sub-talar axis test included in the biomechanical examination, it is necessary to add medial or lateral wedging to relieve tissue stress in the heel and ankle structures.

These will have come about through years of compensation for the SFM.

Podiatric treatment and prevention

- Goal is patient mobility
- Conduct a clinical exam of the foot - ROM, dermal condition…
- Conduct a biomechanical exam – gait imbalance, timing, sub-talar axis, torsion, tone ….
- There are many treatment variants – custom cast orthotic (if patient > 60Kg)



https://www.facebook.com/kevinakirbydpm/posts/use-of-mortons-extensions-and-reverse-mortons-extensions-on-foot-orthoses

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Our goal is patient mobility, given that exercise is medicine in diabetes care.

Podiatrists carry out clinical examinations, testing ranges of motion, dermal condition overlying bony structures…

A biomechanical exam is carried out to assess static and dynamic gait for imbalance, timing, sub-talar axis, torsion and muscle tone, among other elements.

There are many treatment variants for the SFM. This illustration is taken from media published online by Prof Kevin Kirby of Sacramento University in California.
Note that densities of orthoses are dependent on patient body weight.

Before

After

Hand crafted silicone devices are useful adjuncts to wound care.

Silicone devices offload pressure until such time as custom orthotics can be fabricated by the podiatrist.

May also be used in conjunction with in-shoe orthotics.

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When ulceration is already present, then the use of custom silicon devices made at the bedside can offload wounds until such time as wounds have healed or the orthosis has been produced.

Recommendations for palpation of SFM

- Examine the foot in diabetes for signs of the SFM.
- Confirm the diagnosis by means of the palpation/marking method or weight-bearing radiographs if affordable.
- Refer to your nearest podiatrist

N.B.
For distant practices - should some of your patients with diabetes present with SFM, you should be able to arrange for a podiatrist to travel to your rooms to assess and treat them in a multiple patient visit coordinated for the same day.

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It is recommended that all members of the diabetic team look at the diabetic foot for signs of the SFM.
You can confirm the diagnosis by the palpation/marking method shown
or by marking weightbearing x-rays if these are affordable.

If found, refer to your nearest podiatrist for further clinico-biomechanical examination and treatment.

Note that most podiatrists will travel for groups. There are podiatrists who work with occupational health doctors and have regular travel to remote locations in Botswana, to Eskom Tutuka in Mpumalanga, to Kumba in Sishen in the northern Cape, to name a few. It is cost-effective to see a group of patients. Should you have a number of patients presenting with SFM, contact your nearest podiatrist and coordinate a multiple patient visit for the same day.

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Thank you, here are the references and further reading for Part Two.

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Thank you

Appendix 21: Challenges, limitations, opportunities and upliftment

Appendix 21: Challenges, limitations, opportunities and upliftment

When I began this particular academic path a few years ago, I could not have foreseen the ways in which people and events would shape this doctoral experience and continue to exert influence on what I acknowledge to be my nature to continue to look for the "why" and the "how"?

Why are there gaps in medical training concerning podiatric medicine?

Why aren't podiatrists training side by side with interns in South African hospitals?

Why is the epidemic of diabetes not receiving more attention?

How can I make a difference?

The above list could run into hundreds of lines. Certainly, the selected aspects addressed in this thesis provide more than enough material for future and ongoing research.

For the benefit of the many podiatrist colleagues that I hope will follow this direction, there were, of course, challenges along the way. My path to receiving an accepted study proposal ran through seventeen iterations. I had originally hoped to collect data at two hospitals with the aid of a new photographic platform, but lack of funding and development time meant that I had to re-focus and re-direct.

The financial challenge was posed by the fact that, due to the delays caused by time taken to prepare new proposals, the access window to National Research Funding had expired.

Limitations consisted mostly of time limitations and physical fatigue since study and research had to proceed side by side with earning a living, taking care of home and family, my patients and home care of an aged frail parent.

None of the challenges nor limitations would weigh up to the opportunities and upliftment that provided motivation - direction and encouragement from my supervisors. Respect and academic camaraderie freely given by medical colleagues. Supportive sharing of ideas and strategies for coping and growing from fellow doctoral students and academic thought leaders. University initiatives in training workshops on, for example, statistical software. So much upliftment came from Professor Aldous and her doctoral student group – all professionals with similar challenges and limitations.

The strength of many minds sharing ideas helps us harness our energy in ways that not even a disastrous global virus could shake. Lockdown this year meant that, more than ever, we embraced virtual collaboration, virtual resources and the inspired time/work capsule provided by the pomodoro technique.

Durban, South Africa
November 29, 2020.