UNIVERSITY OF KWAZULU-NATAL

College of Law and Management Studies and School of Law

An Investigation into critical Legal Issues surrounding Dental Botox

Dr M S Pillay

8421596

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Supervisor: Professor Ann Strode and Ms Sheetal Soni

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ABSTRACT

An unnaturally expressionless, vapid face with skin that appears to be drawn way too tight, is often the image that flashes to mind when we hear the word "Botox". Yet when done correctly, this aesthetic procedure guarantees to soften wrinkles and brighten the skin, hence it is a popularity among celebrities looking to maintain a youthful appearance.

From the ceaseless stream of smooth jawlines and chiselled cheekbones to celebrity plastic surgeons posting images of their work, the age of continuous self-documentation has impelled a unique set of beauty ideals and an intense increase in cosmetic procedures. Whilst most doctors suggest focusing on skin integrity by advising on appropriate beauty regimens, there *are* exceptions. 'Botox' is the exception. Botox (onabotulinumtoxinA), also called botulinum toxin type A, is made from the bacteria that causes botulism. Botox treatments are becoming more extensive and recognised and to some it seems to be an acceptable way to elude the signs of aging. Botox works by relaxing the contraction of muscles by blocking nerve impulses which results in muscle relaxation and softening of wrinkles.

According to the American Society of Plastic Surgeons, in 2015, more than 6.7 million Botox procedures were executed, making it the most popular minimally invasive cosmetic procedure.

In South Africa Botox is recognised as a prescription-only drug which requires that it should be prescribed by a doctor and administered by a suitably trained and qualified clinician. It is therefore illegal for a person who does not have the requisite qualification, skills and knowledge to administer Botox is a neurotoxin which can cause serious adverse effects if used incorrectly.

Before 2007, controversy existed regarding the suitability of Botox in dentistry. Dentists were accused of abandoning their conventional roles of fixing gums and teeth and venturing into administering Botox. There are circumstances when the use of Botox and similar treatments can be deemed to be related to the practice and scope of dentistry. Thus the aim of this thesis is to investigate the critical, legal issues surrounding Dental Botox.

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and actions that helped me with the analysis and eventual attainment of the objective, I personally want to extend my gratitude and appreciation, for now and always.

Doctor MS Pillay

Table of Contents

LIST OF ABBREVIATIONS

BT	Botulinum Toxin
DPS	Dental Protection Society
USA	United States of America
UK	United Kingdom
FDA	Food and Drug Administration
TMD	Temperomandibular Joint Dysfunction
TMJ	Temperomandibular Joint
HPCSA	Health Professions Council of South Africa
SADA	South African Dental Association
GDC	General Dental Council
RBA	Risks, benefits and alternatives
RBQA	Risks, benefits and alternatives and questions answered
GP	Golden Proportion
BDD	Body Dysmorphic Disorder
BDA	British Dental Association
NHS	National Health Service
HEE	Health Education England
OSCE	Objectively Structured Clinical Examinations
CPD	Continuous Progressive Development
ADA	American Dental Association
COMAR	Code of Maryland Regulations
AAFE	American Academy of Facial Aesthetics
MDPB	Medical and Dental Professional Board
MHRA	Medicines and Healthcare Regulatory Agency

CHAPTER ONE: INTRODUCTION AND LITERATURE REVIEW

1.1. Introduction

This chapter presents the problem and research questions on which this study focuses and reviews the relevant literature.

Medical and dental technology is rapidly advancing, resulting in the development of new procedures to improve aesthetic and functional disorders with greater ease. Patients' awareness of these expanding alternatives has resulted in increasing demand for this growing range of new treatments. Treatments based on the administration of botulinum toxin (BT), commonly known as 'Botox', provide temporary, less invasive and relative risk free alternatives that have been demonstrated to be effective in the management of a wide range of dental disorders and aesthetic conditions, including temporomandibular disorders, bruxism, clenching, masseter hypertrophy, deep nasolabial folds, radial lip lines, high lip line and black triangles between teeth.[1] Botox has thus expanded the range of treatment options which could potentially be offered by dentists; however, the regulatory environment governing the practice of dentistry does not address the use of Botox directly, leaving the question of whether, and to what extent, it can be used in dentistry in a grey area.

1.2. Statement of the problem

A wide range of positions exist on the question of whether or not it is ethical for dentists to conduct cosmetic procedures at all and, if so, to what extent and whether the practice is adequately regulated.[2] In South Africa, dentists are limited to the scope of practice defined by the Health Professions Act[3] which, in Section 33, stipulates that "a dentist can perform a cosmetic procedure on a patient to the oral and perioral area."[4] This is a very general guideline and it is unclear whether it includes the administration of Botox.

[1] D Mostafa 'A successful management of severe gummy smile using gingivectomy and botulinum toxin injection: A case report' (2018) 42 *International Journal of Surgery Case Reports*, 169-174.
[2] Ibid.
[3] The Health Professions Act 56 of 1974.
[4] 'Health Professions Council of South Africa: Policy and Guidelines', available at *https://www.hpcsa.co.za/PBMedicalDental/Guidelines* , accessed on 12 May 2018.

While Botox is administered by dentists for lip augmentation as an adjunct to denture therapy or solely to enhance the lips, it has been argued that dentists are better qualified than other professional health care providers to administer Botox safely and effectively to other areas of the face as well.[5] While Botox treatment is not included in the undergraduate curriculum for dentistry, the specialised training which dentists receive for the head and neck area in their undergraduate training in anatomy, physiology and pharmacology[6], in addition to the training and experience acquired during their postgraduate training, results in dentists developing a high level of expertise appropriate to the administration of both aesthetic and therapeutic Botox.[7]

As members of the Dental Protection Society (DPS), dentists enjoy professional indemnity which covers malpractice and medico-legal risks. However, in its 2017 annual report the Health Professions Council of South Africa[8] indicated that the number of complaints and legal cases relating to medical negligence and malpractice are rising annually. The Dental Protection Society reports that complaints and litigation against dentists relate to one of the following four issues:

- failure to inform the patient adequately as to the expected aesthetic result or possible adverse effects, resulting in the patient's consent being inadequately informed;
- discontentment with the outcome of the aesthetic procedure, frequently associated with a disproportionate outcome and 'lumping' in the case of dermal fillers;
- hypersensitive reactions resulting in anaphylaxis;
- post-operative pain and skin discoloration.[9]

While dentists may possess the necessary expertise to administer Botox, the rise in the number of reports by dental patients of medical negligence and malpractice highlights the importance of dentists exercising due diligence for the benefit of their patients as well as to uphold the reputation of their profession.

[5] 'Should-dentists-be-allowed-to-administer-botulinum-toxin' available at *https://www.omicsonline.org*/ -, accessed on 24 November 2018.
[6] 'Academic Programmes' – University of Pretoria, available at *http://www.up.ac.za/en/odontology/article/22379/academic-programmes*, accessed on 12 May 2018.
[7] Ibid.
[8] 'HPCSA_annual_report 2017 2018 pdf,' available at *http://www.hpcsa.co.za/Uploads/editor/UserFiles/downloads/publications*, accessed on 26 November 2018.
[9] 'Academic Programmes' – University of Pretoria, available at *http://www.up.ac.za/en/odontology/article/22379/academic-programmes*, accessed on 12 May 2018.

1.3. Purpose of the study

Against this background, this study investigates the critical and legal issues surrounding dental Botox. In particular, the study explores whether the administration of Botox falls within the scope of practice of dentists in South Africa and, if so, whether this includes treatment to the face. It also explores the regulatory framework which governs the administration of Botox by dentists and examines whether legal or policy reform is needed in this area.

This study aims to answer the research questions by examining the scope of practice of dentists with regard to the use of Botox. The study will:

(i) examine the scope of other professions with regard to the administration of Botox;
(ii) examine medical malpractice in the context of the administration of dental Botox;
(iii) investigate possible medical negligence/liability with regard to dentists who administer Botox elsewhere on the face; and
(iv) based on the findings, make recommendations to improve the administration of Botox to dental patients.

1.4. Research questions

This study investigates the following research questions:

(i) Does the administration of Botox fall within the scope of practice of dentists in South Africa?
(ii) Does the administration of Botox to a patient's face fall outside of the scope of practice of a dental surgeon and thus constitute medical malpractice?
(iii) Does a regulatory framework exist which governs the administration of Botox by dentists?
(iv) Is there a need for legal or policy reform with regard to the administration of Botox by dentists?

1.5. Structure of the dissertation

The dissertation comprises four chapters which are structured as follows:

Chapter One: This chapter provides a background to the research topic, identifies the research problem and the significance of the study, reviews the literature relevant to the study and presents the aims and expected outcomes of the study.

Chapter Two: This chapter investigates the legal issues surrounding Botox in South Africa. The issues of standards of dental care, medical malpractice and negligence are explored.

Chapter Three: This chapter explores a study in which the United States of America (USA) and the United Kingdom (UK) identified and addressed legal issues arising from the use of dental Botox.

Chapter Four: This chapter presents a summary of the findings of the study and provides recommendations informed by these findings.

1.6. Literature review

This section presents academic views and findings in the literature addressing the critical legal issues surrounding the use of Botox in dentistry.

1.6.1 Development of Botox

1.6.1.1 Botulinum toxin

Botulinum toxin is a neurotoxin produced by the Gram-positive bacterium *Clostridium botulinum* under anaerobic conditions.[10] Botulinum is one of the most fatal toxins known and has found applications in bioterrorism as well.[11] If foods containing this toxin are consumed, the toxin spreads to the peripheral cholinergic nerve endings, inhibiting the release of acetylcholine, a neurotransmitter which triggers muscle contraction and glandular secretion, resulting in the bilaterally symmetric descending neuroparalytic illness[12] botulism, first described by Kerner.[13]

1.6.1.2 Acceptance for therapeutic use

[10] D Truong, D Dressler & M Hallett *Manual of Botulinum Toxin Therapy* 2 ed (2009) 10.
[11] SS Arnon, R Schechter, TV Inglesby, et al. 'Botulinum Toxin as a Biological Weapon: Medical and Public Health Management' (2001); 285(8) *Journal of the American Journal Association* 1059–1070.
[12] Ibid.
[13] D Truong, D Dressler & M Hallett. *Manual of Botulinum Toxin Therapy* 2 ed (2009) 10.

Botulinum toxin (BT), or 'Botox', is the first toxin to be accepted for therapeutic uses.[14] The therapeutic use of the toxin was pioneered by German physician Justinus Kerner.[15] Kerner reported that "the toxin intercepted the signal transmission within the peripheral sympathetic nervous system, allowing the sensory transmission to remain unhindered."[16] Botulinum toxin's potential to restrict acetylcholine release at the neuromuscular junction has been used extensively in medical conditions which manifest increased muscle movement.[17]

The mechanism of action for Botox is fairly simple.[18] On the administration of Botox into the muscles of the face the neurotransmitter that innervates the muscles are affected and blocked.[19] Patients may become partially or completely immune to repeated injections due to antibodies that neutralise the neurotoxin.[20] The incidence of immune resistance differs for each patient depending on study modulation and treatment indicators; complexing proteins may increase the immune response by acting as adjuvants. The complexing proteins are vital in "neutralising and non-neutralising antibodies in the response to botulin toxin."[21] Despite the fact that it is a lethal toxin, compared to other treatment options Botox treatment is relatively safe.[22] Botox treatments are the most frequently conducted minimally invasive aesthetic procedure in North America.[23]

1.6.1.3 Composition

Different compositions of botulin toxin (BT) have been produced. [24] The primary commercially available preparations of botulinum toxin are Botox (onabotulinumtoxin A; manufactured by Allergan, Inc. in Ireland); Dysport (abobotulinumtoxin A; manufactured by Ipsen Ltd in the UK); and Xeomin (incobotulinumtoxin A; botulinum toxin type A [150 kD], free from complexing proteins; 'NT 201;" (Merz Pharmaceuticals GmbH, Germany)."[25] The new botulinum toxin is used to assist with the reduction of immune resistance in people with long

[14] A Azam, S Manchanda, S Thotapalli & SB Kotha 'Botox Therapy in Dentistry: A Review' (2015) 7(2) *Journal of International Oral Health* 103–105.
[15] Ibid.
[16] Ibid.
[17] Ibid.
[18] Ibid.
[19] Ibid.
[20] Ibid.
[21] Ibid.
[22] Ibid.
[23] Ibid.
[24] Ibid.
[25] Ibid.

term ailments.[26] BTs can be differentiated into seven types, from A to G,[27] however commercially available variants are purified exotoxin and only BT type A (BTA) and BT type B (BTB) are promoted by a range of brand names. BTA is promoted as 'Botox in' the USA; 'Dysport' in the UK and Europe; 'Xeominin' in Germany; and 'Prosigne' in China.[28] 'Botox' is a trade name for botulinum toxin, which is in the form of a purified protein.[29]

In 2008, nearly 2.5 million cosmetic procedures were conducted using Botox, accounting for a quarter of all cosmetic procedures that year.[30] Although Botox has been mostly associated with therapy for purposes of achieving cosmetic results, its benefits and uses go beyond such cosmetic applications[31] and include facial dystonia, spasticity, salivary flow, non-dystonic disorder, sweating disorders, fistula treatment and temperomandibular discomfort.[32] Since the first therapeutic use for strabismus, the spectrum of therapeutic applications of BTs has expanded to include its injection into extra ocular muscles as an alternative to strabismus surgery.[33] It is argued that for almost thirteen years—until Botox Cosmetic was introduced in 2002—the only use of Botox accepted by the United States Food and Drug Administration (FDA) was for "crossed eyes and abnormal muscle spasms of the eyelids."[34]

1.6.1.4 Treatment procedure

Treatment with botulinum toxin A involves a simple procedure. The toxin is injected into the facial muscles. Within a few hours, it begins to attach to the nerve endings of the motor muscles, blocking the transmission of signals from nerves to these muscles.[35] As 'dynamic wrinkles' result from the contraction of muscles under the skin[36], when these motor muscles are unable to contract[37] they become smooth.[38] Full efficacy is reached within two to ten days.[39]

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[26] Ibid.
[27] P Nayyar, P Kumar, PV Nayyar & A Singh 'BOTOX: Broadening the Horizon of Dentistry' (2014) 8(12) *Journal of Clinical and Diagnostic Research* 25 – 29.
[28] Ibid.
[29] Ibid.
[30] Ibid.
[31] Ibid.
[32] Ibid.
[33] S Srivastava, S Kharbanda, U S Pal & V Shah 'Applications of botulinum toxin in dentistry: A comprehensive review'. (2015) 6 *National Journal of Maxillofacial Surgery* 152- 9.
[34] P Nayyar, P Kumar, PV Nayyar & A Singh 'BOTOX: Broadening the Horizon of Dentistry' (2014) 8 (12) *Journal of clinical and diagnostic research* ZE25-29.
[35]American Academy of Facial Aestheics: 'Frown Lines and how Botulin Toxin can help', available on *https://www.facialesthetics.org/frown-lines/*, accessed on 23 November 2018.
[36] M Naumann, A Albanese & F Heinen 'Safety and efficacy of botulinum toxin type A following long-term use' (2006) 13(4) European *Journal of Neurology* 35- 40.
[37] Ibid.
[38] Ibid.
[39] Ibid.

The patient experiences no loss of sensation during treatment with Botox.[40] The effects of Botox last for around three to four months, depending on factors such as the dose of toxin administered and the patient's metabolism and lifestyle choices.[41] When the wrinkles begin to reappear another treatment can be administered.

Before administration of Botox, the doctor should review the patient for any possible adverse side effects that may occur and notify the patient of all treatment options available. The doctor must then obtain voluntary consent from the patient detailing all the information which the patient needs to know. The consent form must be secured and evidenced by the signatures of the patient, the doctor and a witness.[42]

1.6.2 Side effects

While Botox is widely used, it is not without side effects. These may include acute pain, ischemia, bruising, swelling, local muscle weakness, fever and flu-like symptoms, as well as muscle atrophy after prolonged use, heart palpitations, tingling sensations and nausea.[43] Side effects are rare, however, and typically disappear within one to two days.[44] Allergic reaction to the botulinum toxin and an existing infection are contraindicated for the administration of Botox.[45] The administration of Botox has serious adverse effects in pregnancy, lactating mothers and patients with neurological disorders. The toxin is further contraindicated in cases of flu, colds, infection and dermatitis.[46]

1.6.3 Cosmetic use of Botox to mitigate physiological changes resulting from aging

1.6.3.1 The effects of aging on facial bone, muscle and fat

[40] American Academy of Facial Aestheics: 'Frown Lines and how Botulin Toxin can help', available on *https://www.facialesthetics.org/frown-lines/*, accessed on 23 November 2018.
[41] American Academy of Facial Aestheics: 'Frown Lines and how Botulin Toxin can help', available on *https://www.facialesthetics.org/frown-lines/*, accessed on 23 November 2018.
[42] Kyung-Soo Park, Chi-Heun Lee, and Jung-Woo Lee 'Use of a botulinum toxin A in dentistry and oral and illofacial surgery ' (2016) 16(3) *Journal of Dental Anaesthesia and pain medicine 151-157.*
[43] A Sinha A, M Hurakadli,PYadav. 'Botox and derma fillers: The twin face of cosmetic dentistry.' (2015) *Int J Contemp Dent Med Rev*. 27.
[44] Ibid.
[45] 'BOTOX' (Onabotulinum toxin A) Medication Guide: Initial U.S Approval. (1989) , available at *https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/103000s5215lbl.pdf* , accessed on 12 May 2018.
[46] Ibid.

Throughout the ages, beauty has been associated with a youthful appearance.[47] Facial bone structure has an immense influence on a person's physical appearance.[48] A significant component of a youthful appearance is a fine facial skeleton that is well supported. In youth, the bone structure is defined by full, high cheeks, distinct brow bones and reduced depression in the orbital region.[49] Youthful skin is defined by softness, suppleness, smoothness and hydration.[50]

Aging occurs at every layer of the facial structure, affecting bone, muscle, fat-pads and skin.[51] The effects of the progression of aging are more profound than the facial wrinkles and lines which appear on the skin. The facial bone composition is responsible for shaping an individual's distinctive facial structure and contours.[52] While the facial skeleton continues to grow throughout a person's life,[53] selective resorption takes place in targeted areas of the facial bone as part of the aging process.[54] There are specific areas that are susceptible to bony resorption in the human facial bone structure and these relate to the *obicularis oculi* which cover the lateral brow, the lateral orbital 'crow's feet' areas and the inferolateral orbital rim.[55] In addition, the movement necessary for the functioning of the specific facial areas is anatomically linked to a reduced ligamental attachment of the soft tissues to the bone. This means that the joining of the "muscles and ligament to the bone" in these regions experiences less stress.[56] The absence of stress may influence bone loss in these regions. Bone loss alters the size and contours of the face, enlarging the peri-orbital areas, decreasing the angle of the brow bone and lessening the sculpture of the mandible.[57]

The width and area of the orbital aperture increases with age.[58] Kahn and Shaw found substantial decline of the contralateral aspects of the orbital rim in conjunction with aging for

[47] S Lanigan 'Anti Aging Treatments Don't Need Knife', available at *http://EzineArticles.com/expert/* , accessed on 4 May 2018.
[48] Ibid.
[49] Ibid.
[50] Ibid.
[51] 'Facial Structure: Understanding how the face ages,' available at *https://www.sfbaycosmetic.com/skin-tightening/facial-structure-understanding-face-ages/*, accessed on 12 April 2018.
[52] Ibid.
[53] B Mendelson, CH Wong 'Changes in the facial skeleton with aging: implications and clinical applications in facial rejuvenation' (2012) 36 (4) *Aesthetic Plastic Surgery* 753-60.
[54] Ibid.
[55] Ibid.
[56] Ibid.
[57] Ibid.
[58] DM Kahn & RB Shaw Jr 'Aging of the bony orbit: A three-dimensional computed tomographic study' (2008) 28 (3) *Aesthetic Surgery Journal* 258-264.

both men and women.[59] This results in recession of those particular areas, although the changes transpire at different rates. During middle age, there are signs of the inferolateral orbital rim and recession of the superomedial quadrant. There is further recession of the inferomedial quadrant of the orbit in old age, primarily amongst males.[60] Mendelson & Wong found that the superomedial and inferolateral orbital areas have the highest affinity to resorb during orbital aging.[61]

The medial together with middle third of the facial skeleton is made up of the maxilla, and the lateral third of the facial structure includes the body and arch of the zygoma.[62] Resorption of the bone in the mid-section of the face does not occur at a constant rate. The jaw bone has a higher tendency toward age-related loss than the zygoma.[63] Mendelson & Wong note that deepening of the jaw bone (maxilla) results in "posterior positioning of the nasolabial crease and the upper lip."[64] The jaw continues to enlarge with age.[65] The changes that occur in the bony 'foundation' which supports the nose in youth, the bone in the nasal area and the ascending processes of the maxilla precipitate changes in the soft tissue in the nose area with age.[66]

Facial bones provide a foundation for muscle, fat-pads, and skin on the face.[67] Enlargement of the peri-orbital bone structure results in greater prominence of the medial fat pad, elevation of the medial brow and lengthening of the lip–cheek junction, resulting in 'crow's feet'.[68] The facial muscles which lie below the facial fat pads are in repetitive movement as one eats, laughs, smiles, and frowns.[69] The aging process results in facial fat loss and this, coupled with gravity and repeated muscle movement, may lead to deep facial wrinkles.[70] This results in the formation of 'crow's feet' at the outer corners of the eyes and the formation of creases between the brows.[71]

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[59] Ibid.
[60] Footnote 53 supra.
[61] Footnote 53 supra.
[62] Footnote 53 supra.
[63] Footnote 53 supra.
[64] Footnote 53 supra.
[65] Footnote 53 supra.
[66] Footnote 53 supra.
[67] 'Facial Structure: Understanding how the face ages,' available at *https://www.sfbaycosmetic.com/skin-tightening/facial-structure-understanding-face-ages/*, accessed on 6 May 2018.
[68] Ibid.
[69] Ibid.
[70] Ibid.
[71] Ibid.

Studies show that the facial muscles weaken with the passage of time.[72] Loss of muscle tone and thinning skin may contribute to a flaccid, drooping look to the face where the jaw line loses its contour and leaves a less distinct profile. Sagging can also occur as a result of the skin's failure and loss of ability to recoil as it did in youth.[73] The fat pads which provide volume, facial contour and fullness become thinner and move downwards as one ages. The loss of facial glands leads to decreased oil production in the skin.[74]A previously firm and rounded face, which epitomised youthfulness, begins to show noticeable changes such as hollows which may form below the eyes, deeper lines around the nose and mouth, flaccid skin due to a drooping jaw line, and a double chin caused by fat beneath the chin.[75] The resulting changes in appearance, such as sunken eyes and sagging skin, contribute to the formation of marked lines around the nose and mouth.[76] The loss and descending movement of fat pads can cause the face to look shrunken and hollow in the cheek area.[77]

1.6.3.2 Prevention and treatment modalities

Literature suggests that methods intended to control or prevent aging were in existence in ancient human civilisations.[78] Anti-aging treatments were used in ancient Egypt by Cleopatra, the Egyptian queen and ruler, who cleansed her skin with donkey's milk.[79] In the seventeenth century, Elizabethan women used raw meat whilst the French used red wine to reduce wrinkles.[80] Egg whites were applied to the skin as skin exfoliators.[81] Most of these methods for slowing down the aging process did not prove to be beneficial in the long term, however.

Anti-aging treatment modalities include both prevention and treatment. Preventative medicine focuses on lifestyle modification such as avoidance of pollution, radiation, smoking and improved nutrition and exercise.[82] Treatment choices include cosmetological care, which

[72] Ibid.
[73] Ibid.
[74] Ibid.
[75] Ibid.
[76] Ibid.
[77] Ibid.
[78] MA Flatt, RA Settersten, Jr, R Ponsaran, &JR. Fishman 'Are "Anti-Aging Medicine" and "Successful Aging" Two Sides of the Same Coin? Views of Anti-Aging Practitioners' (2013) 68 (6) *The Journals of gerontology: Series B* 944-55.
[79] 'Curious History,' available at *https://www.curioushistory.com/ancient-egyptian-beauty-secrets-of-queen-cleopatra*, accessed on 23 November 2018.
[80] GA Bubenik & SJ Konturek 'Melatonin and Aging: Prospects for Human Treatment' (2013) 68(6) *The Journals of Gerontology: Series B* 944- 955.
[81] Ibid.
[82] R Ganceviciene, A Liakou, A Theodoridis, E Makrantonaki,& C Zouboulis 'Skin anti-aging strategies' (2012) 4(3) *Journal of Dermatoendocrinology* 308 – 319.

include daily skin care, sun protection and aesthetic non-surgical procedures.[83] Topical agents such as cell regulators and systemic agents such as hormone replacement therapy and antioxidants are also used.[84] More invasive procedures are also available, which include chemical peels, visible light therapy, ablation procedures, radio frequency, injectable bio-stimulation and rejuvenation, redistribution and restoration of fat and volume loss and skin enhancement and shaping.[85]One of the most controversial treatment modalities is the use of botulinum toxin, commonly known as 'Botox'.[86]

1.6.4 Dental applications for Botox

The use of Botox has been extended to dentistry where it has been found to be an effective and less invasive procedure for both aesthetic dental conditions, such as deep nasolabial folds, radial lip lines, high lip line and black triangles between teeth, as well as in the management of disorders of the mouth and its underlying structures, such as temporo-mandibular disorders, bruxism, clenching and masseter hypertrophy.[87] Botox has been used to correct the parafunctional clenching, extra-capsular temporomandibular disorder (TMJ), trismus and headaches which accompany these conditions.[88] A number of studies have documented the efficacy of Botox in patients with hemi-masticatory spasm.[89] Botox is also used in orthodontic cases where facial muscles need to be retrained.[90] Botox can be used for dental implants and surgery and, in cases of gummy smile, masseter enlargement, and various myofacial pains.[91] Freund and Schwartz found that whilst treating patients for facial lines with Botox injections there was marked recovery from migraine symptoms among patients who had received dismal results using traditional methods.[92]

As dental surgeons receive extensive training in the anatomy of the facio-maxillary region, minimal training is required to make use of Botox while substantially increasing the range of

[83] Ibid.
[84] Ibid.
[85] Ibid.
[86]A Azam, S Manchanda, S Thotapalli & S B Kotha 'Botox Therapy in Dentistry: A Review' (2015) 7(2) *Journal of International Oral Health* 103 – 105.
[87] P Nayyar, P Kumar, PV Nayyar & A Singh 'BOTOX: Broadening the Horizon of Dentistry' (2014) 8(12) *Journal of Clinical and Diagnostic Research* 25 – 29.
[88] Ibid.
[89]MG Cersósimo, A Bertoti , CU Roca & F Micheli 'Botulinum toxin in case of hemimasticatory spasm with severe worsening during pregnancy.' (2004) (27) *Clinical Neuropharmacology* 6-8.
[90] Ibid.
[91] Ibid.
[92] Ibid

invasive procedures at their disposal.[93] The application of Botox for dental treatment is gaining momentum and Botox is viewed by dentists worldwide as relatively safe for use.[94]

1.6.4.1 TMJ, bruxism and pathological clenching

One important application of Botox is as an accessory in cases of temporomandibular joint (TMJ), bruxism and pathological clenching, especially for those who are affected by chronic TMJ and facial pain. Intensive night clenching or grinding of teeth, which in acute cases may appear as dystonic bruxism, leads to TMJ dysfunction and, in addition, can result in damage to teeth, bone, joints and gums.[95] In untreated cases of excessive pathologic clenching, the resultant fracturing of the enamel may result in tooth decay and recession of the gums.[96] Because parafunctional clenching results in periodontal trauma, restricting biting forces before and after pre-periodontal surgery can be vital to the healing process.[97] Pathological clenching can be reduced by administering small quantities of botulinum toxin Type A.[98]

Bruxism is a disorder characterised by excessive eccentric grinding of the teeth which can impact the involved muscles and may also lead to the development of TMD which, in turn, may result in joint impairment.[99] Chronic patients present with headaches, bruxism-induced TMJ derangement or arthritis and find it difficult to speak, swallow, or chew.[100] The condition is exacerbated by factors such as fatigue, stress and emotional distress.[101] If sleep bruxism is evident, an intra-oral guard may be required to protect the teeth, however such an occlusal covering appliance only halts the bruxism for an interval, providing temporary relief from headaches and bruxism-induced TMJ derangement or arthritis.[102] Due to the many appearances of bruxism, standard treatments which are available have irregular results and do not show universal success.[103] Botulinum neurotoxin has exhibited great potential in minimising bruxism symptoms.[104] As Botox is a muscle relaxant, a relatively low dose can achieve substantial

[93] S Srivastava, S Kharbanda, US Pal & V Shah 'Applications of botulinum toxin in dentistry: A comprehensive review'. (2015) 6(2) *National Journal of Maxillofacial Surgery* 152-9.
[94] Ibid.
[95] Ibid.
[96] Ibid.
[97] Ibid.
[98] Ibid.
[99] M Van Zandijcke M, MM Marchau. 'Treatment of bruxism with botulinum toxin injections' (2010) Journal *of Neurosurg Psychiatry* 53.
[100] Ibid.
[101] Ibid.
[102] Ibid.
[103] Ibid.
[104] Ibid.

reduction of the severity of muscle contractions causing TMJ and facial pain, alleviating pain significantly in patients with TMJ who otherwise would have undergone full mouth reconstructions.[105]

Temperomandibular joint dysfunction (TMD) is caused by dysfunction of the muscles required for chewing, resulting in a litany of chewing and digestive disorders[106] as well as pain in the facial area, around the joints, the area adjacent to the ears and radiating into the neck.[107] Disease of the occlusion and the periodontium having an aetiology in dysfunction of the muscles of mastication are the fundamental constituents of temperomandibular dysfunction.[108] Common factors of TMD include muscular spasticity, which is associated with bruxism, mandibular dystonia, external stresses and psychomotor behaviours, among others.[109] As extra-capsular TMD is often temporary, the least invasive management options are preferable, however most of the methods currently in use are minimally effective. If mild relaxation of the muscles can be achieved, the reflex action of clenching can be completely avoided without affecting the patient's ability to chew and swallow.[110] The masticatory musculature treatment approach of TMD has been limited to supportive care. In more acute cases, interventions by physiotherapists, oral medication and other management methods have been used but these usually achieve temporary and insufficient relief. [111]Prolonged use of oral medication is unsuccessful because of the modest progression and regular side effects.[112] Muscle relaxants such as diazepam can limit patient activities. However, for patients who have not been successful with the usual treatment techniques, the administration of Botox injections into the aching masticatory muscles can offer relief of difficult symptoms.[113]

1.6.4.2 Masseteric hypertrophy

[105] Ibid.
[106] Ibid.
[107] Ibid.
[108] Ibid.
[109] Ibid.
[110] Ibid.
[111] Ibid.
[112] Ibid.
[113] Ibid.

Dental patients who habitually clench their jaws tend to suffer more often from masseteric hypertrophy.[114] The enlargement of the muscles manifests in the appearance of the patient's face: for example, the jaw may look inflamed and distorted. Traditional treatment methods entail a surgical resection which frequently results in extensive contraction.[115] A number of studies have found, however, that small quantities of Botox injections into the masseter muscles were effective in reducing masseter hyperactivity.[116]

1.6.4.3 Gummy smile

The exposure of excessive gingival tissue in the maxilla when smiling, a condition which is referred to colloquially as a 'gummy smile', is a health and aesthetic issue which is not easily treated.[117] Excessive gum display occurs when there is over-contraction of the upper lip muscles, in particular the levator labii superioris alaeque nasi."[118] Procedures that have been developed for the treatment of hyper-functional upper lip elevator muscles, such as the Rubinstein and Kostianovsky, Miskinyar and Rees and Latent techniques,[119] have not proven successful in the management of this condition. The most frequent methods presently used are the LeFort I maxillary osteotomy, used in cases of impaction for skeletal vertical maxillary excess, and the gingivectomies for delayed passive dental eruption with excessive gingival display."[120] A less invasive method is preferable to reduce muscular over-contraction.

If administered in small doses, Botox has been found to uniformly compromise these muscles, decreasing the extent of the gummy smile. In a study conducted by Polo, five patients with intense gingival display due to hyper-functional upper lip elevator muscles were treated with Botox under electromyographic guidance.[121] Each patient was administered 0.25 U injections per muscle on both sides into the levator labii superioris, superioris labii alaeque nasi, and at the overlap areas of the levator labii superioris and zygomaticus minor muscles.[122] The average

[114]P Gupta, K. Yadav & V Sharma 'Applications of Botulinum Toxin: A review of literature' (2016) (1) *Journal of Advanced. Res. Dent. Oral Health* 3-4.
[115] Ibid.
[116] Ibid.
[117] M Polo 'Botulinums type A (BOTOX) for the neuromuscular correction of excessive gingival display on smiling (gummy smile).' (2008) 2(133) *American Journal OrthodDentofacial*. 195-203.
[118] Ibid.
[119] S Silberstein, N Mathew, J Saper J, SS Jenkins 'Botulinum toxin type A as a migraine preventive treatment.' (2000) June (40) 6 *For the BOTOX Migraine Clinical Research Group* 445-450.
[120] LC Jeynes & CA Gauci 'Evidence for the use of botulinum toxin in the chronic pain setting-a review of the literature.' (2008) 8 (4). *Pain Practice* 269-276.
[121] M Polo 'Botulinum toxin type A (Botox) for the neuromuscular correction of excessive gingival display on smiling (gummy smile)' (2008) 133 (2) *American Journal of OrthodDentofacialOrthop*. 195–203.
[122] Ibid.

increase in upper lip length upon smiling was 124.2%; the duration of the effect ranged from 3 to 6 months and no negative effects were observed or reported during this time."[123] The patients were content with the results.[124]

1.6.4.4 Dermal filler therapy

Another significant application of Botox is its use in tandem with dermal filler therapy as a non-invasive alternative in treatment of high lip-lines.[125] Dental training includes a surgical procedure that involves the periodontal flap.[126] When using Botox therapy and lip enhancement with dermal fillers, the muscles around the lips become weakened, limiting the elevation of the lip while retaining complete function.[127] This process must be carried out carefully to ensure that the patient maintains adequate lip proficiency for speech, eating and facial expression.[128] An advantage of treatment with Botox and dermal fillers is that results can be achieved nearly instantly in one session, with no extraction.[129] The shortcoming is that treatment must be repeated two to three times annually and the costs are excessive.[130]

1.6.5 Regulatory context for dental application of Botox in South Africa

In South Africa, dentists are required to register with a number of statutory bodies, including the Health Professions Council of South Africa (HPCSA), the South African Dental Association (SADA) and the Dental Ombudsman. These statutory bodies govern the scope of dental practice, thus protecting the interests of the patient. Section 22A (5) (f) of the Medicines and Related Substances Act[131] states that a practitioner, nurse or a person registered under the Health Professions Act[132], "other than a medical practitioner or dentist, may prescribe and apply, only within his/her scope of practice and subject to the indication for the use of such substances and medicines and to the conditions determined by the Medicines Control Council, to patients under his/her care."

[123] Ibid.
[124] Ibid.
[125] Ibid.
[126] Ibid.
[127] Ibid.
[128] Ibid.
[129] Ibid.
[130] Ibid.
[131] Act 101 of 1965.
[132] The Health Professions Act 56 of 1974.

Dentists who act beyond the scope of their training are subjected to disciplinary action such as suspension from practice, dismissal or criminal charges.[133] As Botox treatment is not specifically addressed in the training of dental surgeons, this raises the question whether the administration of Botox can be considered to fall within the scope of a dentist's qualification or not.

The South African Health Professions Act 56 of 1974, section 33(1), read with section 61(2), of the Health Professions Act (Act No. 56 of 1974) as amended by Act 29 of 2007, sets out the scope of practice of the dentist as follows: [134]

> (a) The physical clinical examination of the oral, maxillofacial and related structures of a person;
>
> (b) making a diagnosis of diseases, injuries and conditions of the oral, maxillofacial and related structures, including determining the relevance of systemic conditions, and/or giving advice on such conditions;
>
> (c) performing dental procedures and/or prescribing medicines aimed at managing the oral health of a patient, including prevention, treatment and rehabilitation;
>
> (d) performing any procedure on a patient aimed at fitting or supplying a dental prosthesis or appliance; and
>
> (e) performing any aesthetic or cosmetic procedure on a patient pertaining to the oral and perioral area.[135]

1.6.5.1 Limitation of administration of Botox to specific health care practitioners

According to the Health Professions Council of South Africa (HPCSA) Guidelines (Addendum 2) of the Medicines Control Council of South Africa, scheduled substances used for cosmetic medical procedures may only be administered by a doctor or other qualified professional registered with the HPCSA who is adequately trained in the relevant anatomy, physiology and pharmacology, including the management of potential side effects and complications.[136] Administration of scheduled substances to patients by non-registered persons is deemed illegal

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[133] The Health Professions Act 56 of 1974.
[134] Ibid.
[135] Ibid.
[136] 'Aesthetic and Anti-aging Medicine of South Africa ,' available at *https://www.aestheticdoctors.co.za/content/page/about-us*, accessed on 5 May 2018.

and is grounds for criminal prosecution.[137] What is not clearly established is whether dental surgeons fall within the ambit of adequately qualified medical professionals or not.

1.7 Medical malpractice and or negligence

Medical malpractice may be defined as bad or wrong practice resulting in loss of limb by amputation, deformity, serious injury to health, or even death.[138] Medical malpractice is a far more expansive term than medical negligence because it includes negligent and intentional acts or omissions.[139] 'Medical negligence' refers to the failure of practitioners to perform with adequate competency in their sphere of the profession.[140] 'Negligence' signifies conduct and relates to how practitioners use their minds to execute what they know to be illegal.[141] Negligent acts or failure to act which can result in criminal prosecution include performing an operation and causing brain damage to a patient or failing to obtain informed consent from a patient.[142] Intentional acts or omissions that may result in legal recourse include knowingly breaching confidentiality or otherwise violating a patient's privacy, or intentionally failing to obtain an informed consent, which is classified as 'assault'.[143] The question of whether or not a patient was issued an informed consent is regularly highlighted in cases of medical malpractice and medical negligence.[144]

[137] Ibid.
[138] 'Textbook of Medical Jurisprudence and Toxicology,' available at *https://www.amazon.com/Text-Book-Medical-Jurisprudence-Toxicology-Classic/dp/B008XDVQ72*, accessed on 9 July 2018.
[139] J McQuoid-Mason 'What constitutes medical negligence?' (2010) (7) A *current perspective on negligence versus malpractice SA Heart* 248-251.
[140] Ibid.
[141] Ibid.
[142] Ibid.
[143] Ibid.
[144] Ibid.

CHAPTER TWO: THE LEGAL FRAMEWORK GOVERNING THE ADMINISTRATION OF BOTOX BY DENTISTS IN SOUTH AFRICA

2.1. Introduction

The previous chapter provided an introduction to this thesis. It provided the background to the study, deliberated on the academic views and studies on Botox and described the research questions. The literature indicates many of the complexities of administrating Botox, including legal issues. This chapter addresses the legal framework governing the administration of Botox in South Africa, the standard of dental care, medical malpractice and informed consent.

According to the Health Professions Council of South Africa, Act 56 of 1974, section 33, the scope of practice of the dentist entails the following;[1]

(a) The physical clinical examination of the oral, maxillofacial and related structures of a person;

(b) Making a diagnosis of diseases, injuries and conditions of the oral, maxillofacial and related structures, including determining the relevance of systemic conditions, and/or giving advice on such conditions;

(c) Performing dental procedures and/or prescribing medicines aimed at managing the oral health of a patient, including prevention, treatment and rehabilitation;

(d) Performing any procedure on a patient aimed at fitting or supplying a dental prosthesis or appliance; and

(e) Performing any aesthetic or cosmetic procedure on a patient pertaining to the oral and perioral area.[2]

Dentists who practice outside this scope of their dental license are in violation of the Health Professions Act[3] and the HPCSA regulations.[4] Medical malpractice involves all acts that are in violation of not only the law but medical practice in general as prescribed by the HPCSA.[5] Medical malpractice includes delayed diagnosis and is the most common reason for claims against registered practitioners. It includes failure to diagnose, exclusion of revision of an

[1] Health Professions Act 56 of 1974.
[2] Ibid.
[3] Ibid.
[4] Ibid.
[5] Ibid.

incorrect diagnosis even when new evidence is produced, examined or investigated. The underlying factor is evident in the break in communication, either with the patient or with colleagues, or all parties. The quantity and cost of clinical negligence claims in South Africa has been escalating at a rapid rate.[6]A doctor does not only stand to face a civil claim if his or her practice fails to meet the required standards but may also undergo disciplinary proceedings initiated by the Health Professions Council.[7]

The HPCSA identifies the following acts as forms of medical malpractice: unlawful advertising; over-servicing of patients; criminal convictions; engaging in an inappropriate relationship with a patient; unacceptable behavior; conducting a procedure without a patient's informed consent; releasing information about a patient without his or her authorization; managing a patient incompetently; demanding exorbitant remuneration for services provided, inadequate patient care; demonstrating racial prejudice; insolence to patients; writing prescriptions for patients who are habitual drug users; perverse incentives; accepting bribes; and treating intoxicated patients.[8]

2.2. Medical malpractice in relation to the administration of dental Botox: Negligence and application by the courts

There is no law presently in South Africa which specifically addresses legal claims in the medical field; claims established on the grounds of medical negligence or malpractice are thus dealt with under common law.[9] Medical malpractice can lead to a common law delictual claim for damages in terms of South African private or civil law.[10]

It is important to clarify the difference between medical malpractice and medical negligence. Medical malpractice is defined as "any act or omission by a physician during treatment of a patient that deviates from the accepted norms of practice in the medical community and causes

[6] J. Malherbe ' Leading Research Impacting Clinical Care in Africa' (2013) 103 (2) *South African Medical Journal* 83-84.
[7] HPCSA – 'Professional Conduct and Ethics,' available at *https://www.hpcsa.co.za/conduct*, accessed on 20 October 2018.
[8] HPCSA – 'Professional Conduct and Ethics,' available at *https://www.hpcsa.co.za/conduct*, accessed on 20 October 2018.
[9] Suing a doctor or hospital in South Africa : 'What is your rights?' available at *https://www.dsclaw.co.za/articles/suing-a-doctor-or-hospital-in-south-africa-what-are-your-*, accessed on 28 November 2018.
[10] L. C. Coetzee & Pieter Carstens, Medical Malpractice and Compensation in South Africa, (2011) (86) *Chicago Kent Law Review*. 1263 -1271.

an injury to the patient."[11] As such, malpractice is the umbrella term that encompasses both intentional and negligent conduct by a medical practitioner that causes injury or harm to a patient, including acts or omissions. Negligence, on the other hand, arises when a medical practitioner performs his or her job in a way that differs from this approved and appropriate medical standard of care.[12] If a patient suffers damage or loss resulting from a doctor or hospital's failure to take reasonable care, the doctor or hospital may be found liable for negligence.[13] Medical negligence is considered medical malpractice when the medical practitioner's negligent treatment causes unwarranted injury to the patient; for example, if it worsens the patient's state of health, initiates unnecessary and unforeseen complications or requires further medical treatment.[14]

2.2.1 Medical malpractice

Medical malpractice arises when a health care professional neglects to administer proper treatment, excludes the correct action, or provides substandard treatment that culminates in danger or injury to a patient or results in the patient's death.[15] Under the law of delict, doctors and hospitals have a duty to provide acceptable care to eliminate any harm to their patients.[16] South Africa derives its medical malpractice law from English common law which forms the basis of jurisprudence in most Commonwealth countries and in the United States.[17] Common law refers to law that is established by precedent in court cases rather than through a legislative process.[18] As such, this section will refer to case law on delictual claims on medical malpractice.

It is important to note that a doctor or hospital that deliberately breaches a patient's confidentiality may be deemed liable for injuria.[19] In South African law, the medical doctors

[11] B.S Bal. 'An introduction to medical malpractice in the United States.' (2009) 467(2) *Journal of Clinical Orthopoedic Related Research*. 339-47.
[12] Ibid.
[13] Ibid.
[14] Ibid.
[15]Medical News Today- Medical Practice: What does it involve? available at *https://www.medicalnewstoday.com/articles/248175.php*, accessed on 6 October 2018
[16] Ibid.
[17] Ibid.
[18] Ibid.
[19] Ibid.

may encounter liability if they do not properly implement their legal duty towards a patient, resulting in harm. [20] The negligent conduct of the medical doctor will result in delictual liability if all the elements of delict are met. The elements of delict are harm, conduct, causation, fault and wrongfulness.[21]All these elements must be proven for medical malpractice.

In the context of dentistry, malpractice includes the breach of confidentiality, the failure to receive valid informed consent, the issue of fraudulent medical certificates, claiming for unrendered medical services and not abiding by regulations which govern the dental profession. [22] The failure to adhere to norms and standards of the dental profession is the major cause of malpractice together with the failure to obtain the desired therapeutic goals.[23] Thereafter, it must be demonstrated that the dentist had a license to practice, as this would mean that they had a professional obligation to render appropriate care to the patient. If a surgeon was found to be unlicensed, this would constitute a criminal offence. Secondly, it must be shown that the dentist failed to discharge their professional duty through error and substandard care. Thirdly, it must be demonstrated that this error resulted in injury; and, fourthly, that the injury led to damages.[24] The damage may be physical harm, such as scarring, injury to teeth and or oral structures, permanent loss of teeth or disability, or could involve other costs, such as lost productivity at work and wages or emotional trauma.[25]

The case law which has the greatest relevance for medical practitioners is obtained from civil claims declaring medical negligence; the most relevant of these are those that define a violation of duty of care or causation.[26] In a negligence claim, the plaintiff will succeed on a balance of probabilities that the defendant failed in a presumptuous duty of care that was owed by the defendant to the plaintiff and there was a violation of that duty which resulted in harm.[27] For

[20] Footnote 8 supra.
[21] M Loubser, R Midgley, A Mukheibir, L Niesing and D Perumal . *The Law of Delict in South Africa* 2ed (2012) 15.
[22] NL Makwakwa, PD Motloba 'Dental Malpractice in South Africa (2007- 2016),' 2019 74(6) *South African Dental Journal* 310-315.
[23] Ibid.
[24] Ibid.
[25] Ibid.
[26]'Medical Protection,' available at *https://www.medicalprotection.org/southafrica/advice-booklets/common-problems-managing-the-risks-in-general-practice-in-south-africa/case-law* , accessed on 20 October 2018.
[27] Ibid.

delictual claims, the court requires a complainant to prove that the actions of the defendant were not seen as being reasonable in accordance with the law.

In the case of dental Botox, the court would need to determine that the treatment of dental problems using Botox was conducted properly, within the scope of dentistry and in accordance with the prescribed guidelines of the Health Professions Council. If that the first criterion is confirmed (which is usually the case), the plaintiff must then render persuading evidence that the healthcare professional involved could reasonably have foreseen the consequences of his or her action and did not protect against such an eventuality; moreover, it must be shown that the practitioner's actions fell short of the standards that the law considers reasonable. The test for reasonable conduct was set out in the judgment of a 1924 case where it was argued that it does not always follow that a breach of duty of care results in harm to a patient.[28] There may be situations in which the outcome would have been the same for the patient whether the breach of duty to care had transpired or not. For example, a diagnostic delay in a present incurable tumor is unlikely to influence patient outcome. This is where the testimony and evidence by proficient witnesses is critical for contending the causation constituent of a claim. What it often leads to is if the judge chooses one expert's view over another's.[29] In deciding what is justifiable, the court will have to consider the skill, expertise and conscientiousness held and used at any time by the members of the professional body to which they belong.[30] This also extends to the branch of dental Botox. This means that if a doctor's treatment of a patient is regarded as justifiable by the regulatory association of his or her colleagues, or through the testimony of a practitioner in his or her capacity as an expert witness before the courts, a court would be unlikely to find him or her guilty of negligence.

The question arises whether, in the case of dental Botox, a surgeon or a dentist can be considered an expert witness by the courts. Based on the theory of the scope of practice in the administration of dental Botox, a dental surgeon may provide expert testimony as an expert witness provided that the practitioner administered the Botox in accordance with the scope of practice for dentists. If, for instance, the Botox was administered by the dentist outside the peri-oral region, the dentist would be assessed against the standards of a practitioner who is authorised to administer Botox in these areas of the body, such as a plastic surgeon. The expert

[28] *Van Wyk v Lewis* (1924) AD 438.
[29] Ibid.
[30] Ibid.

witness, in that case, would be a plastic surgeon. The plaintiff's case would only be successful if the court found that a contravention of duty caused harm to the patient.

The quantity and cost of clinical negligence claims brought in South Africa has escalated in recent years.[31] General practitioners who conduct surgery should be aware that they are more prone to legal action and must proceed with caution. In cases of an emergency they should only take on procedures that are clinically necessitated, act within their field of competency, obtain informed consent and work within their scope of care.[32]

In a medico-legal survey conducted in the USA concerning dental malpractice, approximately one-quarter of the malpractice claims reported were made on the basis of complications resulting from minor and major oral surgery.[33] A fifth of the claims related to endodontic treatment. Rehabilitative procedures such as implants, crowns and bridges that resulted in injuries or fractures formed another quarter of the complaints. The rest of the complaints dealt with complications arising with braces, severe infections and diagnostic failures.[34]

The HPCSA and the Scope of the Professions of Dentistry in the Health Professions Act specify that, except in an emergency, a practitioner shall only execute a professional act for which they are suitably qualified and adequately experienced. In cases where a practitioner is not suitably qualified and adequately experienced, the practitioner must communicate and collaborate with appropriately qualified health practitioners in the management of a patient. The onus is, therefore, on the practitioner to ensure that they have an adequate education, training and experience in the implementation of any procedure.[35] If they fail to meet this standard they could be liable if sued for medical malpractice.

2.2.2 Medical negligence

As mentioned earlier, one form of medical malpractice is medical negligence. Sir William Blackstone, an English jurist, coined the phrase 'medical negligence' in 1768, noting that it

[31]Suing a doctor or hospital in South Africa : 'What is your rights?' available at *https://www.dsclaw.co.za/articles/suing-a-doctor-or-hospital-in-south-africa-what-are-your-*, accessed on 28 November 2018.
[32] Footnote 23 supra.
[33]L M Sykes, A Harryparsad, W.G. Evans, F Gani. 'Social Media and Dentistry: Part 8: Ethical, legal, and professional concerns with the use of internet sites by health care professionals.' (2017)72 (3) *South African Dental Journal* 132-136.
[34] What constitutes Dental Malpractice?' – available at *https://www.google.com/search?q=Legalbeagle.com*., accessed on 16 May.
[35] Ibid.

was "how trust is broken between the patient and the practitioner". According to Carstens and Pearmain, the first mention of medical negligence in South Africa was in an 1877 case in which Judge de Villiers defined 'medical negligence' as follows:

> …there can be no doubt that a medical practitioner, like any professional man, is called upon to bring to bear a reasonable amount of skill and care in any case to which he has to attend: and that where it is shown that he has not exercised such skill and care, he will be liable in damages.[36]

Liability for omissions in the practice of medicine was acknowledged in the courts in the case of *Kovalsky v Krige*[37] in which the plaintiff declared *inter alia* that the doctor was negligent in not waiting with the patient until it was safe for the patient to be left alone. The court ruled that a surgeon is required to demonstrate reasonable care and proficiency in patient management.[38]

The case of *Kruger v Coetzee* [39] set an important precedent in terms of how negligence is handled. In this case, the court adopted the criterion of an impartial standard of the reasonable person. To this end the court said that, for the purposes of liability, culpa arises if:

> (a) A diligens paterfamilias in the position of the defendant- (i) would foresee the reasonable possibility of his conduct injuring another in his person or property and causing him loss; and (ii) would take reasonable steps to guard against such occurrences; and (b) the defendant failed to take such steps. . . . An action for damages alleged to have been caused by the defendant's negligence, culpa arises, for the purposes of liability, only if a diligens paterfamilias in the position of the defendant not only would have foreseen the reasonable possibility of his conduct injuring another in his person or property and causing him patrimonial loss, but would also have taken reasonable steps to guard against such an occurrence, and if the defendant failed to take such steps.[40]

2.3. Standard of dental care

[36] P. Carstens, & D Pearmain (2007) *Foundational Principles of South African Medical Law*. Durban: Lexusnexis.
[37] *Kovalsky v Krige* (1910) 20 CTR 822.
[38] Ibid.
[39] *Kruger v Coetzee* 1966 (2) SA 428 (A).
[40] Ibid.

2.3.1 Duty of care

A duty refers to 'an obligation to do' or 'avoidance of doing something'. If we have a duty to another person it means we are obligated to that person in some respect and for some reason while he or she holds a corresponding right or claim against us.[41] According to the HPCSA, "duty of care encompasses duties to patients, colleagues, and other health care practitioners, duties to themselves, duties to society, the health care profession and lastly, duties to the environment."[42] The broad principle of duty of care to the patient entails taking into consideration the best interests and wellbeing of the patient; acting with objectivity and integrity; providing secure access to care; treating the patient with respect; involving the patient in the management of his or her health; upholding the patient's privacy; obtaining informed consent, and preventing conflict of interest.[43]

In the context of dentistry, an important aspect of duty to care is the use of extreme caution in the administration of medicines or drugs which may have adverse effects or be contraindicated for patients.[44] Patel advises that dentists should avoid administering Botox to mentally unstable patients or patients with unrealistic expectations and that in the event that a dentist decides to treat such a patient, they should proceed with extreme caution. [45] Barbano recommends that Botulinum A should not be administered to patients such as celebrities or actors whose livelihood is linked to some extent to their physical appearance, because contraindications or side effects of the drug could potentially alter their appearance in undesirable ways.[46] In addition, Patel proposes that Botox should not be used in dental or cosmetic surgery for the following categories of patients without extreme caution: [47]

i. Patients with neuromuscular disorders (e.g. myasthenia gravis, Eaton-Lambert syndrome) and who have allergies and allergic to any of the constituents of Botulin Toxin A or Botulin Toxin B (i.e. BTX, human albumin, saline, lactose and sodium succinct).

[41] Ibid.
[42] Health Professions Council of South Africa: Policy and Guidelines,' available at *https://www.hpcsa.co.za/PBMedicalDental/Guidelines* , accessed on 12 May 2018
[43] Ibid.
[44] Dr. D Patel, Dr.F Mehta, Dr. R Trivedi, Dr. SJ Suthar 'Botulinum Toxin and Gummy Smile- A Review' (2013) 4 (1) *Journal of Dental and Medical Sciences* 1-5.
[45] Ibid.
[46] R Barbano 'Risks of erasing wrinkles: buyer beware' 2006 Nov 28;67 (10): *Neurology*.17-18
[47] Ibid.

ii. Patients who are on medications which can affect the neuromuscular impulse transmission and exacerbate the effects of BTX (e.g. amino glycosides, penicillamine, quinine, and calcium blockers).

iii. Pregnant patients or lactating mothers (BTXs are classified as pregnancy category C drugs)

Providing an adequate standard of care to dental Botox patients involves prioritising each patient's interests, listening carefully to their wishes or concerns and considering their preferences.[48] Also, patients have expectations of being regarded as individuals and having their cultures and values respected and expect that all members of the dental team will possess honesty and reliability.

Dentists administering dental Botox need to ensure that they have considered all aspects of their patients' health and well-being.[49] Standard of care for Dental Botox patients also involves treating patients in a hygienic and risk free setting, coupled with sound corrections or alterations for any disabilities. Furthermore, dentists practicing dental Botox need to put the interests of their patients first before financial gain and business need.[50] Standard of care further extends to managing dental pain and anxiety appropriately and providing redress to patients who suffer harm during dental treatment. Patients require information which is complete, well defined and precise before, during and after care in order to make informed decisions.[51] Patients require proper details of the treatment, possible results, costs and any changes likely to occur. The standard of care also includes a dentist being able to keep patients' records updated, complete, distinct, precise and readable. This includes ensuring that the personal information of their patients are kept confidential; failing to do so represents medical malpractice.[52]

2.4. Negligence

People of the State of California v. Conrad Robert Murray[53]

In 2011, Dr Conrad Murray was sued for "grossly negligent and reckless behaviour" after he allegedly administered harmful doses of the anaesthetic Propofol to popstar Michael Jackson,

[48]A Blitzer , MF Brin, PE Greene, S Fahn'Botulinum Toxin Injection for the treatment of Oromandibular Dystonia.' (1989) 98 (2) *Ann Otol RhinolLaryngol* 93- 97

[49]D Mock. (2009) 'Botulinum Toxin and Dentistry. Ensuring Continued Trust, Royal College of Dental Surgeons of Ontario: Ensuring Continued Trust:' Dispatch.1–4.

[50] Ibid.

[51] Ibid

[52] Ibid

[53]*California_v_Murray* (2011) CA2/7

resulting in his death.[54] In this case, Murray's administration of the anaesthetic outside of the clinical setting and without appropriate monitoring facilities and equipment was considered by the court to be "direct evidence of wilful reckless conduct."[55] The court ruled that Murray did not give adequate consideration to the risks related to the administration of anaesthesia outside of an appropriate clinical setting; i.e. a hospital. Such conduct, under criminal law, can be regarded as "reckless and a gross deviation from the standard of care."[56] Following a six-week trial, the jury found Murray guilty of involuntary manslaughter. He was sentenced to four years in prison but served two years in prison.[57] This prominent case determined that recklessness in medical practice must be criminally prosecuted.

2.4.1 Administering Botox outside of the dental scope of practice

A dentist may be deemed negligent if they administer Botox outside of their scope of practice. In South Africa, Botox is scheduled as a prescription-only drug. It must be prescribed and administered by an appropriately trained and qualified doctor.[58] It is therefore illegal for a person who does not have the requisite qualification, skills and knowledge to administer Botox. As a neurotoxin, Botox can have serious harmful effects if used incorrectly.

In the United Kingdom (UK), registered dentists are recognised as "appropriate practitioners" and are permitted under Section 58(2) of the Medicines Act to "procure, prescribe, dispense or administer, prescription-only medicines (POMs) in connection with the practice of dentistry."[59] Botulinum toxin is one such medicine. By specifying that these activities are allowable within the practice of dentistry, the General Dental Council (GDC) in the United Kingdom may have had the effect of preventing registered dentists from procuring, supplying, administering or dispensing products containing botulinum toxin when they are using these products for cosmetic purposes beyond the practice of dentistry, rather than therapeutically as part of dental treatment.[60] The GDC's long-standing guidance, as set out in the 'Red Book' and later in *Maintaining Standards*, had always made it clear that registered dentists who prescribed drugs for patients other than in connection with the 'above board' course of dental treatment were liable to be found guilty of serious professional misconduct.[61] The fine detail of this specific

[54]Minc, Falkoff & Wolff (2016) , LLP posted in Medical Malpractice on Saturday, February 20, 2016
[55] Ibid
[56] Ibid
[57] Ibid
[58] Medicines and Related Substances Act 101 of 1965
[59] Ibid.
[60] Ibid.
[61] Ibid.

guidance was lost in the transition to the Standards for Dental Professionals,[62] but in the Council's latest October 2013 guidance on prescribing Medicines in its *Standards for the Dental Team* its position is described as follows:[63]

> Dentists must not remote prescribe (for example via telephone, email, or a website) for non-surgical cosmetic procedures such as the prescription or administration of Botox or injectable cosmetic medicinal products.[64]

2.4.2 Administering Botox in dentistry while lacking adequate competence

According to the HPCSA guidelines, dental Botox needs to be practiced by a registered specialist who has received training from an examination body accredited by the Board.[65] It is therefore medical malpractice for a dentist to delegate the administration of Botox to a practitioner without the requisite competencies.[66] In the case of the *South African Dental Association v Minister of Health,*[67] the court declared that it was illegal for a qualified dentist to delegate his or her duties, especially when specialist skills and medicine were involved, to dental assistants. In a challenge where the South African Dental Association (SADA) sought to legalise the exception to the general rule to have dental assistants recognised as professionals, SADA argued that the traditional practice of training dental assistants in the workplace adequately equipped them to prescribe dental medicines and conduct surgery. SADA argued that as dental assistants assist dentists extensively with dental procedures that require contact with patients they acquire the necessary expertise to perform some procedures without supervision. The court dismissed the case with costs and maintained that dental assistants may only perform specialist procedures such as dental surgery, including the administration of Botox, in the presence and under the guidance of a qualified, experienced and registered dentist. The court further maintained that the role of dental assistants must be restricted to the duties specified under the Health Professions Act 59 of 1974[68], which covers preparing and managing the dental clinical setting before, during and after patient care; sterilising medical instruments; sanitising clinical work areas; ensuring strict infection control

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[62] *Standards for Dental Professionals*. (2005) General Dental Council.
[63] Scope of Practice of Dentists available at *https://www.google.com/search?q=scope+of+practice+of+dentists+gdc&oq=scope+of+practice+of+dentists+gdc&aq* , accessed on 15 November 2018
[64] Ibid.
[65] Health Professions Council of South Africa' available at *https://www.hpcsa.co.za/Public* accessed on 15 March 2018.
[66] Ibid.
[67] *South African Dental Association v Minister of Health* (2014) (20556)
[68] Ibid.

practices are adhered to; preparing dental materials and instruments (including dental hand pieces) to be used in clinical techniques; assisting with patients' requests and care during dental treatment; keeping accurate records and assessments of patients; processing radiographs; and assisting the dental practitioner during dental procedures and emergencies.[69]

The outcome of *South African Dental Association v the Minister of Health*[70] implies that it is unlawful for a registered and qualified dentist to delegate duties, including administering Botox during surgery or in another context, to an assistant. Penalties may be imposed on a qualified and registered dentist who delegates their duties to someone whose qualifications, skills and competencies are not recognised by the HPCSA to administer certain drugs – worse still, to perform specialised dental surgery.

A doctor is also required to take a proper patient history. According to the Consumer Protection Act of 1986 in India, administration of dental Botox without thoroughly conducting patient medical history constitutes a segment medical malpractice.[71] The Supreme Court of India, for example, has declared that it is imperative for a medical doctor of any speciality to conduct thorough investigation into the patient's past and medical history. This will aid in supporting their case in the event of a claim of medical negligence. In the case of *Dr. Suresh Gupta* v. *Govt of NCT Delhi*[72], the Supreme Court of India stressed the importance of gathering medical evidence to ascertain the patient's past and present medical history; failure to do so was considered medical malpractice.[73]

Legally, a dentist commits medical malpractice if he or see undertakes to do a task for which he or she lacks professional competence. Competence does not only involve attaining a qualification, however, but also involves continually staying abreast of developments in the field and ensuring that one has the necessary skills and training to perform new or updated procedures. Thus most medical professional bodies, such as the HPCSA, mandate that all of their members update their skills and attend continuous professional development courses in their areas of specialisation on a regular basis.[74] In the context of dental Botox, this involves

[69] Ibid.
[70] Ibid.
[71] M.S Pandit, &S Pandit, 'Medical negligence: Criminal prosecution of medical professionals, importance of medical evidence: Some guidelines for medical practitioners.' (2009) 25(3) Indian *Journal of Urology: IJU: Journal of the Urological Society of India*, *25*(3), 379–383.
[72] *Suresh Gupta* vs. *Govt of NCT Delhi* (2004)6 SCC 42.
[73] *Suresh Gupta* vs. *Govt of NCT Delhi* (2004)6 SCC 42.
[74] HPCSA guidelines.

dentists attending lectures and courses and staying abreast of research to ensure that their knowledge of developments and improvements in the administration of Botox in dentistry is up-to-date. Given that it is standard practice that medical practitioners continually upgrade their knowledge and skills in order to maintain competence, it could be argued that incompetence can constitute a form of negligence.

In addition, the fact that the person performing a procedure has a recognised qualification does not exonerate him or her from medical liability concerning the procedure. In the sphere of medical law ignorance is not a defence. By keeping updated with modern trends and developments in the administration of Botox in dentistry, dentists are better positioned to minimise the potential for litigation that is related to intentional or unintentional acts [75]

2.4.3 Administering Botox in excess of prescribed limits

As mentioned above, one way in which a dentist could be guilty of negligence is by administering a dose of Botox in excess of safe limits. Botox is a neurotoxin which, if ingested, can interact with vital muscles in the body, causing paralysis and potentially resulting in fatality. When injected in minute doses into marked areas identified for Botox, however, it can effectively and safely inhibit signals between the nerves and muscles, effecting relaxation of the muscles. It is therefore crucial that Botox be administered in extremely low doses. A dentist commits an offence if he or she administers Botox above the prescribed limit. Thus administering of Botox in doses above the prescribed limit constitutes a serious form of medical malpractice and violates foundational tenets of medical law.[76] The estimated lethal dose for human beings is approximately 3,000 U.[77] "For cosmetic use, the typical Botox dosages should be less than 100 U." "Optimal pH of the solution is between 4.2 and 6.8, and vials should be stored at or below −5°C." These guidelines needs to be strictly adhered to and failure to adhere to professional guidelines on dosage would be a form of negligence, as dentists are required to act in accordance with professional and ethical guidelines.[78]

2.4.4 Failing to obtain informed consent

[75] HPCSA guidelines.
[76] A Azam,A., S Manchanda,., S Thotapalli,. and SBKotha, ' Botox Therapy in Dentistry : a Review' (2015) 7(2) *Journal of International Oral Health* 103- 105.
[77] Ibid.
[78]M.Van Zandijcke, M.M Marchau. 'Treatment of bruxism with botulinum toxin injections.' (1990) 53(6) *Journal of Neurology, Neurosurg Psychiatry*. 530.

The Dental Protection Board, of which South Africa is a member, publishes statistics on complaints related to dental Botox for each member country.[79] The four most common types of complaints are the following:

- Shortcomings in the consent process; particularly, failure to adequately inform the patient about the expected outcomes and potential negative outcomes of the procedure.[80]
- Dissatisfaction with the outcome of the cosmetic procedure (often related to asymmetry and 'lumping' in the case of dermal fillers)[81]
- Hypersensitive reactions (leading, in one case, to anaphylaxis)[82]
- Postoperative pain, discomfort and bruising.[83]

In the case of *Castell v Greef*,[84] the Supreme Court of South Africa established the standard of a "reasonable patient" when it comes to a medical practitioner's disclosure and obtaining informed consent. The case involved a prophylactic subcutaneous double mastectomy and simultaneous breast reconstruction with the use of silicone implants involving a transpositional flap procedure.[85] The medical procedure had a 50% chance of complication. In this case, the court ruled that a patient's consent would amount to a justification to the wrongfulness and consequences of a medical procedure or an operation and its consequences, if the medical practitioner has a duty to warn the consenting patient of a material risk that comes with the proposed treatment; and further that such a risk is "material" if, in the circumstances of the particular case: (a) "a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it; or (b) the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it."[86]

Glick argues that it is necessary to draw attention to the fact that the use of botulinum toxin is not always for cosmetic/aesthetic purposes, but also for dental procedures.[87] There are many well-recognised therapeutic uses for this substance, not least in conjunction with the treatment

[79] LB Rao R Sangrur, P Singh. 'Application of Botulinum Toxin Type A: An arsenal in dentistry' (2011) (22) Indian *Journal of Dental Research* 440-445
[80] Ibid.
[81] Ibid.
[82] Ibid.
[83] Ibid.
[84] *Castell v de Greef* 1994 (4) SA 408 (C).
[85] Ibid.
[86] Ibid.
[87] K Glick. 'Cosmetic dentistry is still dentistry' (2000) (66) *Journal Canadian Dental Association* 88–89.

of temporomandibular joint (TMJ) disorders and other forms of facial pain, in special care and paediatric dentistry and in certain procedures within the field of oral and maxillofacial surgery.[88] The use of botulinum toxin to reduce dysfunctional muscular activity alongside conventional orthodontic treatment has also been documented.[89] The author further states that Dental Healthcare Professionals are in a more advantageous position than many other health care professionals to conduct these procedures risk free and with a successful outcome due to their knowledge and training in anatomy, physiology and pharmacology, their technical skills and expertise in the control of infection, and their competency to cope with a medical emergency.[90]

Key aspects of informed consent

(i) Information

Informed consent requires a dentist to explain the risks, benefits and alternatives to a procedure to the patient. The dentist is responsible for informing the patient themself and ensuring that the patient understands what has been explained to them.[91] Various allegations founded on lack of informed consent usually claim that a physician failed in his duty to provide the patient with all the information about the risks and possible substitutions for the recommended treatment, or that a physician administered treatment which was unauthorised by the patient.[92] In a case in India, *Dr. Shyam Kumar v Rameshbhai Harmanbhai Kachhiya*,"[93] an operation performed for glaucoma and cataract resulted in a weakened retina and loss of vision. The National Commission of India ruled that undertaking an operation without obtaining informed consent was improper. In this case, the medical records were not produced, and it was further decided that a patient cannot be deprived of such information and was entitled to claim compensation.[94]

The practice of treating patients without disclosing potential risks is akin to securing consent of the patient by misrepresentation. In the case of *Salgo v Leland Stanford University Hospital*[95] in California, a patient became paralysed as a result of a new diagnostic treatment. The patient claimed that the doctor had failed to inform him of the risk of paralysis associated with the

[88] Ibid.
[89] Ibid.
[90] Ibid.
[91] Ibid.
[92] W. Moore., M.N Slabbert 'Medical information therapy and medical malpractice litigation in South Africa' (2013) 6 (2) *South African Journal of Bio ethics and Law*.
[93] *Dr.Shyam Kumar* vs. *Rameshbhai Harmanbhai Kachhiya,* I(2006)CPJ16(NC).
[94] Ibid.
[95]*Salgo v Leland Stanford University Hospital* (1957) 154 Cal. App. 2d 564.

procedure.[96] In another disclosure cased in the United States, *Natanson v Kline*, a woman sued for malpractice after she suffered burns during cobalt radiation therapy following her mastectomy. The doctor conceded that while the patient had consented to the therapy, she had not been adequately informed of the risks.[97] South African courts regard medical misrepresentation of facts to be a serious criminal offence.[98]

The administration of Botox in dentistry can result in a wide range of side effects. These must be discussed thoroughly with prospective patients prior to obtaining consent so that they are able to make informed decisions about treatment with Botox. states that

> systemic side effects of administering Botox in dentistry include anxiety, dizziness, drowsiness, headache, dry mouth and eyes, pharyngitis, dysphagia, facial pain, symptoms of flu, failure to focus eyes, drooping eyelid or eyebrow, unclear vision, sensitivity to light, nausea, sweating, fever, chills, allergic reaction like rash, itching, dyspnoea, tightness of chest, facial oedema, hoarseness of voice, respiratory infection, anaphylaxis, urticarial, erythema multiforme, pruritus, no bladder control, loss of strength, paralysis and seizures. The side effects at the injection site involve pain, redness, tingling, and bruising, swelling, tenderness, stiff or weak muscles at or close to the bleeding site.

Informed consent involves more than adequate informing the patient of outcomes and risks and asking the patient to sign a consent form. The medical practitioner is obligated to disclose all relevant information about his or her competency and expertise to conduct the procedure or offer the appropriate care so that the patient is adequately equipped to make an informed decision. The medical practitioner is also required to accurately reflect the patient's oral health care needs to the patient. The South African Dental Act states that compelling a patient to undergo a procedure by distorting the value of the procedure or the patient's need for the financial gain of the practitioner violates trust in the patient-doctor relationship and constitutes medical malpractice.

(ii) <u>Appreciation and agreement</u>

[96] Ibid.
[97] *Natanson v. Kline* (1960) 41, 476 350 P. 2d 1093.
[98] A.Azam., S. Manchanda, S., Thotapalli and SB Kotha, ' Botox Therapy in Dentistry : a Review' (2015) 7(2) *Journal of International Oral Health* 103- 105.

The consent form must contain all information relevant to the procedure expressed in clear and simple terms. The HPCSA recommends that the consent form which has been prepared for a procedure should be read aloud to the patient by the practitioner. Sillis states that the discussion of risks, benefits and alternatives (RBA) should be noted in a chart as "RBA discussed and questions answered" or "RBAQA." To prove the discussion had taken place, dentists are advised to develop a custom and a practice: that is, a habit in the way they practice. While a dentist may have issues recalling the details of a certain case, they can communicate the typical protocol that they would usually employ for the procedure.[99] The HPCSA advises dentists that although informed consent discussions differ depending on the individual requirements of a patient, the clinician must ensure that the nature of the recommended treatment, the risks, complications and benefits of the recommended treatment, alternatives to the treatment and the treatment plan and anticipated order of events are explained in detail to the patient.[100] After the patient has had an opportunity to ask any questions they may have and has agreed to the procedure, both patient and clinician must sign the consent form.[101]

Sillis describes a case in which a dentist was prosecuted for damage to the inferior alveolar nerve during a wisdom tooth extraction. The dentist had used a standard informed consent form that merely informed the patient of potential nerve during the procedure but failed to include the term 'permanent injury to the nerve.'[102] It was ruled that the mere inclusion of the term 'permanent' would have saved him from liability.[103]

In another legal matter, a patient claimed the dentist performed root canal therapy which was unwarranted. The teeth in question had received several restorations for persistent dental caries. Though the risk of pulpal involvement was possible due to the extent of the old restorations, the dentist failed to use a consent form nor did he note that he had communicated this option to the patient.[104] The teeth continued to be symptomatic and necessitated root canal therapy and the patient proceeded with litigation. The dentist could have avoided litigation by obtaining

[99] 'Pennsylvania Dental Association Insurance Services,' available at *http://www.pdais.com/articles/articles-general-liability/informed-consent/* accessed on 20 October 2018.
[100] Health Professions Council of South Africa available at *https://www.hpcsa.co.za/downloads/conduct_ethics/rules/generic_ethical_rules/booklet_9_informed_consent.pd*, accessed on 28 November 2018.
[101] Ibid.
[102] 'Pennsylvania Dental Association Insurance Services,' available at *http://www.pdais.com/articles/articles-general-liability/informed-consent/* accessed on 20 October 2018.
[103] Ibid.
[104] L M Sykes, A Harryparsad, W.G. Evans, F Gani. 'Social Media and Dentistry: Part 8: Ethical, legal, and professional concerns with the use of internet sites by health care professionals.' (2017) 72 (3) *South African Dental Journal* 132-136.

an informed consent which included the use of additional treatment up to and including extraction and discussing the patient's total care with him.[105]

According to the HPCSA, discussions around 'informed consent' are often difficult due to language problems. If the patient is deaf, the dentist must provide a sign language interpreter; if the patient speaks a language different from that spoken by the dentist the insurance provider must provide a translator.[106] For minor children, the dentist must involve the parent in this discussion.

In the USA, the cost of provision of a sign language interpreter must be covered by the dentist and cannot be transferred to the patient. For divorced parents, the parent with legal custody may give informed consent. Minors who are emancipated can give their own informed consent.[107]

Although patients ultimately decide which treatment options to take, their signed consent forms are not always enough to safeguard a dentist from liability should a dentist provide care which is below the acceptable standard.[108] Informed consent does not offer protection against malpractice. On the contrary, a dentist should not proceed to treat patients who persistently refuse the suggested treatment.[109]

Making an informed decision is the right of every patient, but it is the responsibility of the dentists to ensure that the patient is given all of the information necessary to exercise this right —including information about risks, benefits and other treatment options.[110]

The South African National Health Act[111] states that it is a criminal offence to provide a health service to a patient without the patient's informed consent. The Act protects the right of competent patients to consent to health services and treatment and obligates health service

[105] 'Informed Consent:More than just a form,' available at *https://www.cda.org/news-events/informed-consent-more-than-just-a-form*, accessed on 20 October 2018.
[106] Health Professions Council of South Africa available at *https://www.hpcsa.co.za/downloads/conduct_ethics/rules/generic_ethical_rules/booklet_9_informed_consent.pd*, accessed on 28 November 2018.
[107] 'Pennsylvania Dental Association Insurance Services,' available at *http://www.pdais.com/articles/articles-general-liability/informed-consent/* accessed on 20 October 2018.
[108] S. Naidoo, K Moodley (2009) Ethics and the Dental Team. Schaik V, editor. Hatfield, Pretoria: Van Schaik; 136.
[109] Ibid.
[110] Ibid.
[111] National Health Act 61 of 2003.

providers to "take all reasonable steps to obtain the [patient's] informed consent".[112] Section 8 of the Act specifically provides that "health care users have the right to participate in decisions affecting their health and treatment" and, to this end, it mandates health service providers to share relevant information with users who lack the capacity to make decisions, unless the disclosure of such information would be contrary to the user's best interests.[113]

2.5. Failure to behave in a paternalistic and professional way

The next aspect of professional behaviour is balancing paternalism with patient autonomy.[114] Paternalism implies an "authoritarian attitude," knowing the best course of action and unilateral decision-making without patient involvement.[115] Taking paternalism further would lead to assertiveness or a belief in a particular treatment regimen, withholding information about negative consequences of a specific treatment/procedure, compulsion, and swaying for a favourable acceptance from a patient who has inadequate knowledge; this is unlawful.[116] Another illegal aspect is a situation whereby dentists engage in intense marketing tactics such changing outcomes and benefits of dental Botox for the sake of ensuring that a patient accepts treatment; this is unlawful and results in professional legal liability on the part of the medical professional.[117]

Patient autonomy refers to a patient's right to request a treatment procedure that may be against a clinician's will. If a patient requests a cosmetic procedure which goes against the clinician's professional judgement, the patient must be aware that they are fully responsible for the decision to treat, that such treatments are not bound by the ethics of medical and dental boards and that if any complications arise they have no recourse whatsoever.[118] After the clinician explains the reasons for and against the procedure, it is the patient's prerogative to make a decision;[119] the clinician, however, also has the right to refuse to perform procedures which

[112] National Health Act 61 of 2003.
[113] Ibid.
[114] J. Hartshorne, TK Hasegawa. '*Overservicing in dental practice – ethical perspectives*.' (2003) (58) *South African Dental Journal* 364–369.
[115] Ibid.
[116] Ibid.
[117] Ibid.
[118] SG Schanschieff, DS Shovelton, JK Toulmin. (2014) *Report of the Committee of Inquiry into Unnecessary Dental Treatment*. London: HMSO.
[119] Ibid.

they consider a violation of professional conduct. In such a case, the patient is at liberty to seek treatment elsewhere.[120]

As clinicians, dentists have the responsibility to prepare treatment plans that support 'professionalism' (educating the patient) and 'patient autonomy' (respecting patient wishes), and are followed by scientific credibility; it is essential to ensure that the operator has the ability to perform and provide what is being recommended.

2.6. Medical ethics in the context of Botox treatment

Medical ethics is defined as "a system of moral principles that apply values to the practice of clinical medicine and in scientific research." [121] Medical ethics is based on a set of values that professionals can refer to in situations which are ambiguous or in which a conflict of interest has arisen.[122] Ethics encompass four primary principles: non-malfeasance, beneficence, autonomy, and justice.[123] While ethical compliance requires that all four of these principles be satisfied, in reality one or more element is often given preference over the other. This may be due to conflicting views between a patient and clinician, with one party being more dominant.[124] In cosmetic dentistry, ethics is usually fairly straightforward and situations often can be clearly judged as 'right' or 'wrong': if a decayed tooth is restored to health and function it is considered ethically 'right';[125] if a professional model requests the removal of a healthy molar so that her facial features are accentuated to give her a better appearance it is regarded as ethically 'wrong.'[126] The ethical position in these examples is fairly obvious and most practising clinicians would be in agreement.

In aesthetic dentistry, however, subjectivity can outweigh objectivity.[127] Clinicians in their daily practice are faced with problems and challenges regarding treatment management. The role of a dentist in providing cosmetic procedures or aesthetic treatment is threefold: professional, clinical and profit-based. In some situations two or more of these roles may be in

[120] Ibid.
[121] 'Medical Ethics,' available at *https://en.wikipedia.org/wiki/Medical_ethics* accessed on 20 October 2018.
[122] Ibid.
[123] Ibid.
[124] Ibid.
[125] MG Kelleher, S Djemal & N. Lewis 'Ethical marketing in'aesthetic' ('esthetic') or'cosmetic dentistry'. (2012) 39 (5) *Journal of* Dental Update. 313-6, 318-20, 323-4.
[126] I Ahmad 'Risk management in clinical practice. Part 5. 'Ethical considerations for dental enhancement procedures' (2010) 2 09 (5) *British Dental Association* 207-214.
[127] Ibid.

conflict with each other.[128] In such a case, the dentist must ensure that they honour all four principles of ethics in their duty of care.

2.7. Legal issues surrounding administration of dental Botox

There are legal implications surrounding the administration of dental Botox which are applicable to the wider medical profession: such as medical malpractice cases, a Botox procedure gone wrong, issues of negligence which encompass failure to exercise duty of care, or failure to obtain informed consent. Such legal implications as delictual claims against dentists arising from medical negligence due to failure to exercise the duty of care between the dental surgeon and the patient are to be considered.

Demonstrating cause

As mentioned previously, medical negligence or culpa must be proved against a dentist who administers Botox to a dental patient using the reasonable person test established in *Kruger v Coetzee*[129]. The reasonable person test requires that the dentist administering Botox ought to have foreseen, in his capacity as a dentist (given his training, skills and expertise), that his conduct (through an act of commission or omission) would have caused harm or injury to the patient. Common law requires a link between the action of the dental surgeon and the harm caused to the patient. This link is causation. For medical negligence, as discussed earlier, the dentist's action must be demonstrated to be the cause of the patient's injury or harm: in the case of the administration of Botox, either through incompetence by acting outside of the scope of his or her practice; administering a dose beyond the prescribed limit; failing to obtain informed consent; or through failure to exercise any other duty of care. Without demonstrating causation it is difficult to prove negligence. Equally important is the non-applicability of the doctrine of *res ipsa loquitur* which was rejected by South African courts in *Mitchell v Dixon*[130], especially in medical malpractice cases. The argument against this doctrine is that the facts do not necessarily speak for themselves: for example, the fact that a patient develops injuries or gets worse immediately after a Botox procedure is not *prima facie* proof that the dentist was negligent. The court would determine whether negligence or failure to exercise the duty of care were the cause of injury in the case.

[128] Ibid.
[129] Footnote 41 supra.
[130] Footnote 45 supra.

Performing cosmetic procedures

The question whether it is ethical for dentists to conduct procedures purely for aesthetic reasons is a critical one.[131] In practice, medical or dental professionalism is defined as "a combination of vocation and enhancing health and function."[132] Cosmetic procedures, however, because they do not necessarily have health or functional benefits, lie outside the scope of professional practice.[133] A client seeking cosmetic therapy from a dentist or medical practitioner must understand that the ethical standards that apply to professional medicine or dentistry will not apply to the cosmetic procedure. While the client of a professional service provider may bring a lawsuit against them for failure to comply with the standards of their profession, for the client of a non-professional practitioner such as a hairdresser or tattoo artist personal litigation is the only recourse.[134] In effect, the patient cannot have it both ways: on the one hand expect fiduciary judgment from a professional, and on the other dictate the treatment they want for non-health purposes.[135] A dental surgeon who administers cosmetic services should also reduce his or her rate for these services as he or she is effectively providing them as a 'skilled trader' rather than as a 'professional'.[136] Both parties must be aware that the patient cannot hold the dental surgeon responsible ethically for his or her cosmetic work, and the dental surgeon cannot claim professional status while performing a cosmetic service because it is a business, rather than a professional transaction.[137]

A variety of arguments are made to justify the value of cosmetic dentistry; some of these have greater validity than others. Most commonly, the client requesting cosmetic dentistry is seeking to whiten or straighten his or her teeth or to close gaps due to missing teeth.

One argument for cosmetic dentistry is that it aids the 'psychological healing" of the client. This argument lacks validity, however. Firstly, few dental surgeons are psychologists; an attempt to dabble in psychology thus involves practising beyond the scope of dentistry.[138] Secondly, while the argument is made that improving a smile can increase self-esteem and confidence and benefit social interactions or career opportunities, these possible gains are, in

[131] Ibid.
[132] Ibid.
[133] Ibid.
[134] Ibid.
[135] Ibid.
[136] Ibid.
[137] Ibid.
[138] Ibid.

fact, ethereal.[139] Dentists are not qualified to assess or address the emotional needs of a client.[140] In addition, a failed cosmetic procedure can negatively impact the very emotional or social aspects of the client's life which they sought to improve.[141] Thirdly, studies have demonstrated that a number of aesthetic procedures are merely fads and provide a client a passing sense of gratification with no lasting value. [142]Finally, if a client makes the case that they require the procedure for their mental health, it raises the question whether the client is in sound mind to give informed consent for the procedure.[143] Informed consent is only valid if the person (or surrogate) is of sound mind and has been presented with the potential side effects and success rates associated with the prospective treatment.[144] When a dentist presents images showing only the most successful outcomes of the procedure, they are not adequately informing the patient.[145]

Another argument made for aesthetic dentistry is the 'golden proportion' (GP).[146] The GP is a framework for natural beauty. However, if all plant and animal species complied with the GP they would be mere replicas of each other.[147] The argument can be made that beauty lies not in conformity to the GP, but in diversity.[148] Many lecturers, however, have a fondness for the GP and thus promote cosmetic dentistry to their students.[149] Pursuing the GP as an ideal, however, is not in the interests of the dental health of clients – although it may promote monetary gain for the practitioner.[150] Studies have shown, for example, that the maxillary anterior teeth comply with the GP in only 17% of the population.[151] If one were to accept the idea that the GP represents the single standard of 'perfect' beauty, it would follow that the majority of the population is imperfect in this regard. If this was the case, damaging the enamel and dentine of one's teeth would be the only way to attain 'ideal' beauty. This leads to larger debates around whether it is ethical to use genetic engineering to create 'designer' human beings.[152]

[139] Ibid.
[140] Ibid.
[141] Ibid.
[142] Ibid.
[143] Ibid.
[144] Ibid.
[145] Ibid.
[146] Ibid.
[147] Ibid.
[148] Ibid.
[149] Ibid.
[150] Ibid.
[151] Ibid.
[152] Ibid.

Recently, there has been a trend to market extensive posterior and anterior restorative work on cosmetic grounds. After carrying out a detailed occlusal analysis, the practitioner informs the patient of various occlusal problems such as defective contacts, grinding patterns, TMJ and clicking. To address these problems, a full mouth rehabilitation is presented as the only solution. Most dental surgeons understand occlusion as unexplained, and lecturers of aesthetic dentistry manipulate this weakness for advising on veneers and crowns, which is more gain for them.[153] This faulty logic argues that achieving perfect occlusal relationships will resolve occlusal problems. However, why should an imperfect occlusal relationship be addressed if it is causing no discomfort to the client? If patients have defective contacts, grinding patterns, wear facets or TMJ clicking without deleterious clinical findings or symptoms, it cannot be justified to propose the more destructive course of action of providing veneers or crowns. Many patients have occlusal irregularities which cause them no difficulties; however, clinical intervention could introduce new issues which the patient had not experienced before.[154]

Regardless of the aesthetic goal or proposed procedure, the clinician bears an obligation to advise the client of the least invasive and optimal options which are supported by scientific research and have acceptable endurance with minimal risk of complications. Pincusone, one of the 'godfathers' of aesthetic dentistry, advised that: "There is nothing permanent in dentistry."[155] If a minimal or least invasive procedure is performed, the chances of success and longevity are greatest. More invasive procedures are typically accompanied by greater risk of complications.[156] As all treatment modalities have advantages and disadvantages a compromise is often necessary. It may be best to sacrifice the most optimal aesthetic outcome to achieve better function and a longer duration of benefit. It is essential that all possible advantages and disadvantages of each alternative procedure are thoroughly discussed with the patient.

Performing procedures beyond the scope of dentistry

If a procedure is unrelated to dentistry and beyond the scope of practice, it can be argued that a dentist should not perform it, irrespective of the training or certification the dentist has obtained. Thus it would be illegal and unethical for a dentist trained or certified to administer Botox treatment for procedures that are either beyond the scope of dentistry or unrelated to dentistry. There is, however, need to clarify circumstances in which the use of botulinum toxin

[153] Ibid.
[154] Ibid.
[155] Ibid.
[156] Ibid.

A and related treatments is linked to the practice and scope of dentistry. The peri-oral area, including the lips, cheeks and jaw, falls within the scope of dentistry but parts of the face outside these areas do not.[157] The HPCSA guidelines dictate that dental Botox may only be practiced by a registered specialist who has received training from an examination body accredited by the Board.[158]

Until 2007, there was disagreement regarding the suitability of Botox in dentistry.[159] Ramphora notes that dentists who began to administer Botox were sometimes accused of abandoning their traditional role of repairing gums and teeth.[160] Botox, which had quickly gained popularity, was criticised as a money making technique which fell outside the scope of dentistry.[161] Dentists who performed Botox were accused of being materialistic and self-serving, as well as showing little concern for the welfare of patients.[162]

It is safe to say that the HPCSA accepts that the provision of Botox for non-therapeutic cosmetic treatments is within the scope of the practice of dentistry, thus there are no legal restrictions prohibiting dentists from administering Botox in South Africa.[163] Although the use of Botox falls within the scope of legal practice of dentists, it does present some legal issues. Opinions regarding the legality of dentists administering Botox to their patients are varied. One of the opinions is that if a procedure goes beyond the scope of dental tuition, it cannot be undertaken by a dental surgeon, irrespective of the training or certification he or she has received.[164] Thus it would be illegal and unethical for a trained or certificated dentist to administer Botox treatment for procedures that are either beyond the scope of dentistry or are unrelated to dentistry.[165] There is, however, a need to clarify circumstances when the use of botulinum toxin A and similar treatments can be deemed to be related to the dental arena. It may be debated that aesthetic dental procedures involving peri-oral regions such as the lips,

[157] Ibid.
[158] HPCSA guidelines
[159]Ramphoma, K. J 'Oral Health in South Africa: Exploring the Role of Dental Public Health Specialists' (2016) 71 (9) South *African Dental Journal* 402 – 403.
[160] Ibid.
[161] Ibid.
[162] Ibid.
[163] HPCSA guidelines available at *https://www.hpcsa.co.za/downloads/conduct_ethics/rules/generic_ethical_rules/booklet_1_guidelines_good_prac.pdf*, accessed on 20 October 2018
[164] SJ Lee et al 'Effect of Botulinum Toxin on Nocturnal Bruxism: A randomized control trial" (2010) 89(1) *American Journal of Physical Medicine and Rehabilitation* 16-23.
[165] Ibid.

cheeks or jaw would be associated, but procedures beyond those selected areas would not be considered within the scope of dentistry.[166]

There is no law in South Africa that expressly restricts dentists from administering Botox. The safety and wellbeing of patients must be the principal consideration, and the patient's right to choose their treatment and practitioner is vital to patient autonomy. However, many of these procedures may carry risks which are inherent to the procedures, result from the ignorance of the clinician or relate to the individual physiology of the patient.[167] Some patients may even present with a true body dysmorphic disorder (BDD) which a dental practitioner may not have the training or experience to recognise.[168] In addition, the expectations of patients of the outcome may be unrealistic. Thus it is vital that the consent process be carried out in all cosmetic procedures.[169]

[166] Ibid.
[167] Lewis, 'Dento-legal aspects of non-surgical facial aesthetic procedures' (2014) 5 (2*) Faculty Dental Journal* 68-73.
[168] Ibid.
[169] Ibid.

CHAPTER THREE: EXPLORING LEGAL ISSUES WHICH HAVE ARISEN IN THE USE OF BOTOX BY DENTISTS IN THE UNITED KINGDOM AND THE UNITED STATES OF AMERICA

3.1. Introduction

This chapter focuses on the way in which the United Kingdom (UK) and the United States of America (USA) have identified and addressed legal issues arising from the use of dental Botox. This chapter also explores methods for increasing the competency of dentists in the administration of Botox.

3.2. Administration of Botox by dentists practising in the United Kingdom (UK)

This section examines the management of dental Botox by the UK, including the principles of care established by the General Dental Council, the training of dentists and the overseeing of their competency.

3.2.1 Governance of dentistry in the UK

Dental practice in the UK is regulated by the General Dental Council (GDC),[1] a regulatory body which is the counterpart of the HPCSA in South Africa, albeit with a specific focus on dentistry. The GDC was founded in 1956 with the primary objectives of establishing and maintaining standards to regulate dentistry in the UK for the protection and benefit of both practitioners and patients.[2] The GDC maintains a current register of all qualified dental care professionals which kept up to date, as the council aims take the lead in UK's health care regulation and seeks to promote and instil general public's confidence in the dental profession.[3] The GDC facilitates practitioners' maintenance of current knowledge and skills, controls the quality of dental education in the UK that patients receive from dental professionals and provides assistance to patients in terms of answering questions or attending to their complaints.[4] The Council liaises between government, practitioners and the public.[5]

In the UK, legal challenges related to dentistry typically arise from complaints (usually against an individual practice but also, on occasion, against the Dental Complaints Service itself);

[1] 'General Dental Council,' available at *https://www.gdc-uk.org/professionals/standards*, accessed on 9 November 2018.
[2] Ibid.
[3] Ibid.
[4] Ibid.
[5] Ibid.

claims for compensation (with or without the involvement of solicitors and/or issuance of legal proceedings); the involvement of the General Dental Council (GDC) or other agencies; or a combination of these processes and redress mechanisms for victims.[6]

In 2008, the GDC announced that the administration of Botox and dermal fillers away from the perioral or immediate perioral area does not fall within the practice of dentistry.[7] This means that any practitioner found to have performed a non-cosmetic procedure using Botox outside the perioral area is liable for prosecution. The GDC states that 'unconventional or complementary' therapies which are not provided in combination with, or related to, a patient's dental treatment must be conducted separately from the practice of dentistry.[8]

3.2.2 Principles of care prescribed by the GDC

The principles of care outlined by the GDC cover the following areas: prioritising patients' interests; communicating effectively with patients; securing valid patient consent; maintaining and protecting patients' information; establishing an effective complaints procedure; ensuring that the clinical environment supports patients' best interests; ensuring that dental professionals uphold, progress, improve and work according to their professional expert knowledge and proficiencies; highlighting and addressing concerns around risk to patients; and ensuring patients' confidence in practitioners and in the dental profession.[9]

3.2.3 GDC guidelines and dental Botox

Dental practitioners who wish to offer Botox or other non-surgical cosmetic procedures outside their scope of practice should be cognisant of the fact that the GDC requires that they maintain a high standard of care irrespective of the type of treatment they offer patients. Practitioners are required to restrict the services they offer to their areas of expertise to ensure that they have the necessary competence to exercise good judgement. Dental practitioners are required to maintain a professional standard when promoting Botox services and ensure that indemnity accompanies Botox procedures. The GDC's Guidance on Direct Access states that:

> The administration of Botox is not the practice of dentistry and so it does not appear in the GDC's Scope of Practice document. However Botox is a

[6] Ibid.
[7] Ibid.
[8] Ibid.
[9] Ibid.

prescription-only medicine (POM) and needs to be prescribed by a registered doctor or dentist who has completed a full assessment of the patient.[10]

3.2.4 The British Dental Association (BDA)

The British Dental Association (BDA) is a professional association and a registered trade union which represents dentists in the United Kingdom. Its mission is to "encourage the interests of members, enhance and develop the realm of dentistry with the ultimate aim of improving the nation's oral health."[11] The organisation represents practitioners at the national and local levels. The mandate of the BDA is to promote safe, appropriate practice and patient management; it provides professional guidance to its members in all matters in order to facilitate ongoing professional development.[12] The organisation also promotes advanced standards (often in collaboration with other institutions) and fosters advances in the oral health of the United Kingdom.

3.2.4.1 The policy of the BDA with regard to the use of Botox in dentistry

As the GDC does not view the administration of Botox as falling within the scope of dentistry, it is not addressed in the dental curriculum at an undergraduate level.[13] The BDA is silent on whether dentists may administer of Botox and provides no guidance on whether dentists may carry out other similar procedures, including preparations that currently do not fall within the scope of dentistry.[14] The BDA does, however, provide strong recommendations which include that dentists performing Botox or other related procedures must have adequate training and competency in this area of practice.[15] Any practitioner administering Botox must ensure that he or she has received training of an adequate standard, secure informed consent from patients and ensure that his or her duty of care is adequately met.[16] A patient wishing to undergo Botox treatment must secure professional indemnity beforehand.[17]

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[10] K Lewis 'Dento Legal aspects of non-surgical facial aesthetic procedure (2014) *Faculty of Dental Journal* 39 68.
[11] British Dental Association availble at *https://bda.org/*, accessed on 8 November 2018.
[12] British Dental Association availble at *https://bda.org/*, accessed on 8 November 2018.
[13] Botox – British Dental Association available at https://bda.org/dentists/policy-campaigns/public-health-science/public-health/position-statements/Pages/botox-position.aspx, accesssed on 20 November 2018.
[14] Ibid.
[15] Ibid.
[16] Ibid.
[17] British Dental Association – Wikipedia available at *https://en.wikipedia.org/wiki/British_Dental_Association#History*, accessed on 5 October 2018.

3.2.5 Competency of dentists in the UK

In the UK, opinions on whether or not registered dentists should be permitted to provide facial aesthetic procedures, and the extent to which such procedures should be regulated, range widely.[18] The use of injectable materials such as collagen by dentists began to increase in the late 1980s but has never become widespread.[19] The use of Botox in the field of maxilla-facial aesthetics has gained momentum in the last two decades with the small but increasing number of dentists who have ventured into the field of facial aesthetics using injectable dermal fillers and Botox.[20] In some cases, these procedures are being undertaken for the purpose of changing a patient's appearance only. In other instances, they are being used as a secondary procedure to support other dental procedures of a non-aesthetic nature. An example is treatment involving dermal fillers or botulinum toxin which is carried out alongside the provision of conventional dentures for purposes of improving the overall aesthetic appearance of the patient.[21]

3.2.6 Qualifications and training for the administration of Botox

The Constitution of the National Health Service (NHS) of England provides regulating principles and outlines the rights and responsibilities of various role players in health care.[22] In 2013-2015, Health Education England (HEE), with the authorisation of the Department of Health, worked with industry and professional experts to "review the credentials required for non-invasive cosmetic procedures and the professional qualifications required to be appropriate prescribers, and generate recommendations on the accreditation of qualifications and curriculum provision."[23]

The Keogh Review, which describes the outcome of the first phase of this programme, noted that currently there are no criteria for who may conduct non-cosmetic procedures and no accredited training programme exists and points out that as a patient's decision to undergo a cosmetic procedure can impact their health and wellbeing, it is important that they select a practitioner who has adequate training and expertise.[24] The report recommends that

[18] K. Lewis 'Dento-legal aspects of non-surgical facial aesthetic procedures' (2014) 5 (2) FDJ 68- 73.
[19] Ibid.
[20] Ibid.
[21] Ibid.
[22] Healthcare in England available at *https://en.wikipedia.org/wiki/NHS_Constitution_for_England* accessed on 19 November 2018.
[23] Ibid.
[24]Review of the Regulation of Cosmetic Interventions (2013), available at *https://www.gov.uk/government/uploads/system/uploads/attachment* data/file/192028/ accessed on 11 November 2018.

requirements for training be developed by various professional groups and portions of the curriculum which have been covered prior to the training and those courses which are to follow should be identified in order to complete the training.[25] This means that these professional groups would not go into the training at the same time and, further, that professional training may be provided to practitioners with no previous experience. The report also recommends that each practitioner wishing to offer this range of medical procedures acquire the necessary skills and expertise to do so in a manner that is safe and meets professional standards.[26] The report further recommends that the curriculum and training requirements must be subjected to regular reviews to guarantee that all practitioners are acceptably trained in new techniques.[27]

Stemming from the Keogh Review, a wide range of dental courses are offered at present in the UK. For the administration of Botox, the Foundation Botox Dermal Filler training course or the Level 7 Certificate in Botox and Dermal Fillers is recommended, and this recommendation is confirmed by the recommendations contained in the NHS report published in 2014.[28] *Foundation Botox and Dermal Filler* is a one day introductory course designed to provide the dentist with foundational skills in both the Botox and dermal filler techniques and provides a certificate of attendance which is recognised by all major insurance companies.[29] The *Level 7 Certificate in Botox and Dermal Fillers* is a comprehensive 277 hour accredited training course in medical aesthetic techniques which includes practical group work and one-on-one workshops, online training and objectively structured clinical examinations (OSCEs) which all culminate into a recognised qualification.[30] All courses are continuous progressive development (CPD) certified and enable the dentist to obtain indemnity to start practising immediately. Continuous support is also offered after completion of course work as part of this course package.[31]

3.3. Governance of dentistry in the United States of America (USA)

[25] Ibid.
[26] Ibid.
[27] Ibid.
[28] Ibid.
[29] Cosmetic Courses: Teaching in medical aesthetics available on *https://www.cosmeticcourses.co.uk/who-we-train/botox-training-for-dentists/* accessed on 5 October 2018
[30] Ibid.
[31] Ibid.

Legal issues surrounding Botox are derived from the code of conduct governing all dental practitioners in the USA. [32]

Dentists in the USA, irrespective of their area of specialisation, are guilty of committing an offense if they are found to have administered Botox without first obtaining informed consent from their patients.[33] A general guideline as to what constitutes informed consent is provided by the American Dental Association.[34] Statements that should be excluded include those that contain a material misrepresentation of fact; exclude a fact necessary to declare the whole statement not materially false; are planned or are expected to construct an untenable expectancy about outcomes that a dentist is able to accomplish; and those that contain a material, unbiased representation, whether communicated or inferred, that "the marketed services are of higher quality to those of other dentists, if that representation is not subject to acceptable authentication."[35]

In the USA, biased statements regarding the quality of dental services can also constitute an ethical issue.[36] Statements of personal views may be considered to constitute misinformation if they are not objectively grounded, if they misrepresent the qualifications of the professional or the basis of the opinion, or if the patient reasonably interprets them as implied statements of fact.[37] Claims against such statements are assessed case by case with consideration for how a patient might reasonably be expected to be affected or to react to the advertisement in its entirety.[38]

While dental practice in the US is regulated on a state-by-state basis, across the board candidates for a dental license must first meet three prerequisites: complete an accredited training programme; pass a formal written examination; and pass a clinical examination.[39] In

[32] American Dental Association: Principles of ethics and codes available at *https://www.ada.org/en/about-the-ada/principles-of-ethics-code-of-professional-conduct/veracity*, accessed on 12 July 2019.
[33] K.I. Reid 'Informed consent in dentistry' (2017) 45(1) *Journal of law and medicine ethics* 77-94.
[34] American Dental Association: Principles of ethics and codes available at *https://www.ada.org/en/about-the-ada/principles-of-ethics-code-of-professional-conduct/veracity*, accessed on 12 July 2019.
[35] Ibid.
[36] Ibid.
[37] Ibid.
[38] Ibid.
[39] American Dental Association : State Licensure for US Dentists available at *https://www.ada.org/en/education-careers/licensure/state-dental-licensure-for-us-dentists*, accessed on 12 July 2019.

each state, a dental practice act establishes boards comprised of practitioners and clients.[40] These boards are responsible for licensing, regulating and disciplining medical professionals in accordance with their scope of practice.[41] The state's practice act mandates that only licensed practitioners may perform the procedures or services specified for a particular profession. This serves to protect the profession from incompetency and unethical, illegal or deceitful practices. Although statutory law differs in each state, the dental practice acts of various states restrict the dentist to procedures in the oral cavity which include the teeth, gums and jaws.[42]

In thirteen states, the Dental Practice Act prohibits the practice of specialist dentistry by medical practitioners without a dental license.[43] The fact that medical practice acts include oral health management and treatment indicates that medical practitioners are allowed to provide services that previously fell within the purview of a dentist's scope of practice as long as it is authorised by the state dental practice act.[44] Certain dental practice laws permit dental practitioners to extract teeth, with the exception of one state which prohibits dentists from creating or restoring lost or missing teeth.[45] Since 2005, Maine has permitted primary care doctors to obtain training to undertake dental extractions and perform other basic dental procedures due to a shortage of dentists in the state. The School of Medicine at the University of New Mexico also provides a one year placement program for dentists and medical residents and doctors are permitted to undertake studies in fundamental dentistry.[46]

Scope of practice curtails the growth of dentistry in the US as dental practitioners who perform procedures outside of the defined scope of their practice risk criminal action and face financial penalties. In the event that a licensing board learns that an individual is performing services outside the scope of the practice for which he or she is licenced, it can launch investigations and level charges against the individual for unauthorised practice where necessary. As a result, medical practitioners are most often cautious to undertake any procedures in accordance with their scope of practice and they exercise caution in expanding their scope of practice, unless such expansion of the scope of practice has been previously determined and sanctioned.[47]

[40] R.J Manski, D. Hoffmann, & V Rowthorn, 'Increasing Access to Dental and Medical Care by Allowing Greater Flexibility in Scope of Practice' (2015) 105 (9) American *journal of public health* 1755-62.
[41] Ibid.
[42] Ibid.
[43] Ibid.
[44] Ibid.
[45] Ibid.
[46] Ibid.
[47] Ibid.

While medical and dental practice acts define the scope of practice of each profession, there are areas, such as medical emergencies and patient screening, where the practice acts are ambiguous.[48]

US law mandates that the prescription of botulinum toxin for therapeutic purposes may only be done by a qualified practitioner. Attaining this level of qualification requires a substantial amount of study time.[49] However, Botox may only be administered by a qualified dental practitioner. **Non-prescribing nurses may not administer dental Botox even if a qualified dental practitioner is present. Delegating the administration of Botox by a dental practitioner to a less qualified dental assistant is illegal in the USA and is deemed unsafe for the patient.[50] This corresponds with the position of the HPCSA in South Africa discussed in Chapter** 1, as well as the ruling in the case of *South African Dental Association v Minister of Health* [51] that it is illegal for dentists to delegate their duties to dental assistants, especially in instances where skills and medicine are involved.

The American Dental Association (ADA) does not specifically deal with facial cosmetic surgery or treatment, however it defines the scope of dentistry as being limited to the "human teeth, oral cavity, alveolar process, gums, jaws, or directly related and adjacent masticatory structures".[52] Dentists who possess an ADA specialisation for oral and maxillofacial surgery, however, are authorised to engage in a greater scope of work. This incorporates the diagnosis, surgical and secondary treatment of diseases, injuries and flaws, including the "functional and the cosmetic features of both the hard and soft tissues of the oral and maxillofacial areas".[53] The ADA Board declares that the use of facial aesthetic methods external to the stomatognathic system is outside the scope of practice for a dentist without a specialisation in oral and maxillofacial surgery. The stomatognathic system is an anatomic system which involves the teeth, jaws and related soft tissues; its functions include speech, mastication and deglutition.[54] Any dentist in the USA who administers Botox outside of this system is therefore guilty of a

[48] Ibid.
[49] 'State by State Dental Botox regulations in the US,' *available on https://dentox.com/state-by-state-dental-botox-regulations/*, accessed on 20 November 2018.
[50] Dental Legal Update Newsletter available on *http://jeanine.com/files/DentalLegalNewsletter/FinalDentalAdvertisingRulesNewsletter.pdf*, accessed on 18 November 2018.
[51] *South African Dental Association v Minister of Health* (2014) (20556).
[52] Footnote 34 supra.
[53] Ibid.
[54] Ibid.

criminal offence and may face prosecution.[55] The use of Botox for separate aesthetic reasons is specifically allowed for dentists who hold a specialisation in oral and maxillofacial surgery.[56]

3.3.1 Selected state laws governing dental botox

In the USA, laws governing the use of Botox and dermal fillers vary from state to state.[57] In most states, a dental board regulates general dentistry and provides specific guidance on the administration of dental Botox.[58] Medical practitioners including plastic surgeons, nurses, internal medicine physicians, ophthalmologists, dermatologists, podiatrists, dentists, obstetricians, medical aestheticians, and physician's assistants may issue Botox as per the provisions of each state's laws. Although the pioneer of Botox usage in all facial treatment, Dr. Howard Katz, is a professional dental practitioner, outdated regulations that do not allow dentists to administer Botox are still applicable certain states.[59]

In the states of Mississippi and Virginia, the use of Botox in dentistry is restricted to oral and maxillofacial surgeons who possess the required professional qualifications.[60]

In Arkansas and Louisiana, use of Botox by dentists requires that a dentist complete a course offered by an accredited program of the American Dental Association and/or the dental board of the state.[61] These two states further require that such a training course should cover such topics as patient consultation and patient assessment; uses and contraindications of Botox; potential risks and side effects associated with Botox and related treatments and how to manage them; preparation and administration of the injections; therapeutic uses of the drugs; and hands-on training with actual patients.[62] Dentists are required to administer Botox exclusively in their dental offices and are prohibited from allowing support staff, such as dental nurses and hygienists, to administer Botox on their behalf.[63]

The states of Massachusetts, New Mexico, Pennsylvania, South Carolina, South Dakota, and Wyoming do not currently regulate the use of Botox by dentists. However, many malpractice

[55] Ibid.
[56] Ibid.
[57] H. Katz' (2014) State by State by State Dental Botox Laws in the US,' available on http://dentox.com/state-by-state-dental-botox-regulations/, accessed on 20 November 2018.
[58] Ibid.
[59] Ibid.
[60] Ibid.
[61] Ibid.
[62] Ibid.
[63] Ibid.

insurance carriers still require that anyone administering Botox or dermal fillers complete an appropriate training course.[64] Some of these states are beginning the process of putting regulations in place.[65]

The Board of Dentistry and Dental Hygiene in Delaware refuses to take a position on whether dentists may administer Botox. Delaware considers possible violations regarding dentists administering Botox on the merits of each case.[66]

Dentists in Alaska are permitted to perform any cosmetic procedure on the condition that the procedure is part of a patient's dental treatment plan.[67]

The dental board in Connecticut allows dentists to undertake Botox procedures only insofar as such procedures relate to the mouth and its structures, including the jaw.[68] This is similar to Texas, where the Dental Board does not specifically regulate cosmetic procedures but confines the scope of dentistry to procedures that involve the teeth, mouth, gums, jaws and related structures.[69]

In Idaho, the Board notes that the dental practice law is broad enough in scope to allow dentists to administer Botox and dermal fillers.[70] The Board also mandates that practitioners bear a responsibility to obtain adequate training to ensure their competence for any procedure they perform.[71]

In Iowa, the law limits dentists to the provision of treatments as specified by the scope of practice of dentistry. For example, dentists are permitted to examine, diagnose and treat patients suffering from ailments or deformities and defects in and around the mouth, which include the teeth, gums, jaws and associated structures and tissue.[72] Appropriate treatments may be carried out for such ailments and deformities, including the administration of medications, appliances or surgery; however the methods must relate to the practice of dentistry and the dental practitioner is required to be in possession of adequate training and expertise for

[64] Ibid.
[65] Ibid.
[66] Ibid.
[67] Ibid.
[68] Ibid.
[69] Ibid.
[70] Idaho State Board of Dentistry , available on https://isbd.idaho.gov/IBODPortal/Home.aspx, accessed on 20 November 2018.
[71] Ibid.
[72] H. Katz' (2014) State by State by State Dental Botox Laws in the US,' available on http://dentox.com/state-by-state-dental-botox-regulations/, accessed on 20 November 2018.

the methods used.[73] A dental examination must be undertaken and the medical history of the patient must be obtained before prescribing or administering any medication to the patient.

With reference to these laws, the Board's stance is that dentists may use Botox and dermal fillers only if such use has a direct bearing and relevance to the dental practice and provided that the practitioner has acquired relevant and suitable training in this field of practice.[74] These laws allow only those dentists who have completed the required program accredited by the American Dental Association, which includes the administration of Botox and the use of dermal fillers in the curriculum, to undertake Botox procedures.[75] This provision is similar to the laws passed by the dental board of Louisiana wherein licenses are not necessarily granted for Botox usage or dermal fillers but the dental board clearly defines specific obligations. For instance, before using Botox or dermal fillers, the dentist ought to have successfully undergone training issued by an accredited institution recognized by the Commission on Dental Accreditation of the American Dental Association or a continuing education course addressing the relevant topics. This requirement for training also extends to the state of Maryland where dentists can authorise medicines for treatments that are within their scope of practice and must also obtain adequate training in the administration of Botox and other medications in accordance with the Code of Maryland Regulations (COMAR).[76]

The same provisions are applicable in New Hampshire, where dentists may conduct procedures which are within the scope of practice as defined by NH RSA 317-A:20 on condition that they possess the necessary skills and expertise to perform such procedures.[77]

In Kansas, the dental board has prohibited dentists from the administration of injections which are expected to diminish signs of aging and has argued that such procedures are inappropriate to the practice of dentistry. To this end, dentists who administer injections for purposes other than dental purposes can be subjected to disciplinary action.[78]

The Michigan Board of Dentistry issued a statement on Botox in 2012 allowing the use of Botox, derma fillers and neurotoxins by dentists on the proviso that they have been properly

[73] Ibid.
[74] Ibid.
[75] Ibid.
[76] Ibid.
[77] Ibid.
[78]Dental Boards Organization (2012).Dentists' Botox Use Laws, available on , from https://www.dentalboards.org/PDFS/2012BackgroundBotox.pdf, accessed on 19 November 2018.

trained in this area of practice and on provision that such use is within the dentist's scope of work (defined by MCL 333.1101).[79] The Board observed that such use, when administered by dentists who are not properly trained or those who practice outside the scope of dental practice, puts patients' lives at risk. The Board further noted that the scope of dental practice applicable to general dentists excludes administration of injections of these constituents for aesthetic reasons.[80] The Board's position does not constitute a statute or administrative code rule, however: it is not binding and therefore cannot be enforced.[81] In civil cases where it has to be determined whether the use of Botox, derma fillers and neurotoxins falls within a general dentist's scope of work, the statement made by the Board may be submitted and admitted as evidence, however the court is under no obligation to support the position of the statement.[82] The Board's Botox statement can, however, serve as a warning to dentists who routinely use these substances without proper training or outside of their scope of practice.

In Arkansas and Louisiana, the dental boards require dentists wishing to administer Botox to obtain training from an institution accredited by the Commission on Dental Accreditation of the American Dental Association. The course content must include, "directives on patient consultation and assessment when using Botox and dermal fillers, positive effects and contraindications for dental Botox, safety and risks involved, the technique on the use of dermal fillers to enhance and complete cosmetic dental treatment, how to use Botox to treat disorders of the temporomandibular joint and teeth grinding and to identify and control harmful reactions and treatment of possible complications."[83] These two states also allow the administration of Botox and dermal fillers only at dental practices that observe universally acceptable precautions as outlined by the Federal Centers for Disease Control.[84]

3.3.2 Training and certification of dentists for the use of Botox

The American Academy of Facial Aesthetics (AAFE) is the only available training institution offering a non-surgical, minimally invasive facial injectable program for clinicians in various

[79] Ibid.
[80] Ibid.
[81] Ibid.
[82] Ibid.
[83] Arkansas . State Board of Dental Examiners available at *https://www.asbde.org/licensure* accessed on 12 July 2019.
[84] Ibid.

states. Three levels of training are offered which include theory, practice monitoring and evaluation.[85]

In the US, it is argued that dentists are qualified to administer Botox, provided that they have received comprehensive training in head and neck function, have an in-depth knowledge of the pharmacology and are experienced in the administration of Botox.[86] Benninger *et al*[87] argue that the dental curriculum in the US adequately equips dentists to administer Botox. Students receive "an accelerated clinical anatomy course below the head and neck and an 11 to 12 week specific course of head and neck anatomy compared to their medical colleagues who receive on average 2 to 3 weeks of head and neck anatomy education during their first 4 years of prequalification training".[88] Benninger *et al* highlights that dental students administer between 3000 and 4000 injections "at multiple sites intra and extra orally" during their four years of training in dentistry.[89] Benninger *et al* argue that training in general dentistry provides the "fundamental knowledge and clinical skills" required for the administration of Botox.[90]

3.4. Conclusion

It is evident that in the USA there are many states where it is considered completely acceptable for general dentists to administer Botox and dermal fillers in the oral and maxillofacial areas from chin to top of the forehead. However there are some states that may allow one form of treatment and not the other, and there are states where dentists are not allowed to conduct these therapies at all. There is no question that there is greater demand for the administration of Botox to be accepted nationwide, with more state dental boards allowing these procedures. It is appropriate for dentists to use Botox and dermal fillers for dental uses within the scope of dentistry as defined by the state practice act.[91]

The practise of Botox in dentistry in the United Kingdom is grounded in the safety and welfare of patients as the superseding consideration, with the patient's right to choose what treatment they wish to receive, when, and from whom, as principal to patient autonomy. However, it is

[85] American Academy of Facial Aesthetics available at *https://www.facialesthetics.org/courses-events/* accessed on 12 July 2019.
[86] B. Benninger B, A Ross (2012) Should Dentists be Allowed to Administer Botulinum Toxin? Dentistry 2:135. doi:10.4172/2161-1122.1000135.
[87] Ibid.
[88] Ibid.
[89] Ibid.
[90] Ibid.
[91] ' Dentists doing Botox. Its about time!' , available on *https://www.facialesthetics.org/blog/dentists-botox-time/, a*ccessed on 3 Sept 2019.

imperative to bear in mind that patients may well have different levels of expectation and willingness to accept a sub-optimal aesthetic outcome. In all 'cosmetic' cases the consent process is crucially important, yet it is sometimes encumbered by forthcoming difficulties. Nevertheless, the need for Botox is increasing and dentistry, properly regulated and practised, can and should be given the control.[92]

[92] 'Cosmetic Dentistry and the booming business of botulinum toxin,' available on *http://www.theyoungdentist.com/uk/features/articles/14-the-botulinum-toxin-business-is-booming, accessed on 2 Sept 2019.*

CHAPTER 4: SUMMARY OF FINDINGS AND RECOMMENDATIONS

4.1. Introduction

This paper has lent itself to the wider discussion and debate on whether dental practitioners should be allowed to administer Botox. This determination is critical, especially in light of the multiple uses of Botox in the modern era as enabled by the current demand for youthfulness and treatments to curb ageing, on the one hand, and the technological advances in the field of medicine, on the other.

To combat ageing and treat other cosmetic and dental-related ailments botulinum toxin, also known as Botox, is increasingly being used.[1] As this study has highlighted, Botox has gained wide acceptance for its therapeutic characteristics which have come to overshadow its more lethal and life-threatening elements. Small doses of botulinum toxin are considered to be safe.[2] These multiple modern day uses of Botox have widened the scope of its application and administration to the field of dentistry where Botox is considered a less-invasive treatment of 'muscle-generated' dental ailments such as temporomandibular disorders (TMD), bruxism and clenching, among others.[3] As with any other medical treatment and procedure, use of Botox also has its side effects, including pain at the site where injection is administered and weakening of muscles that are injected with Botox; sometimes flu-like symptoms and nausea may also be experienced by patients after a Botox procedure.[4] However, the benefits of the use of Botox as a therapeutic and dental treatment have been established as outweighing the side effects highlighted in this study.

Of particular importance to this study is the fact that in such jurisdictions as the United States of America, dental surgeons receive extensive training which encompasses administration and use of Botox as part of their scope of practice and, due to this intensive training, they need limited additional training to enhance their skills in this field.[5] In light of such developments in the USA, this study probes whether in South Africa the scope of practice for dentists

[1] A Azam, S Manchanda, S Thotapalli, S B Kotha 'Botox Therapy in Dentistry: A Review' (2015) 7(2) *Journal of International Oral Health* 103 – 105.
[2] http://www.healthline.com/health/botox-poison, *accessed 29 November 2018*
[3] P Nayyar, P Kumar, PV Nayyar, A Singh 'BOTOX: Broadening the Horizon of Dentistry.
[4] https://www.accessdata.fda.gov/drugsatfda_docs/label/2002/botuall041202LB.pdf, *accessed on 20 July 2018*.
[5] Ibid.

currently includes a role for their administration of Botox. In simple terms, the main question that this study aims to answer is whether dentists can administer Botox or not in South Africa.

In South Africa, the field of dentistry, just like any other medical profession, is governed by the Health Professions Act.[6] The Act also determines the scope of practice for dentists.[7] Section 33 of the Health Professions Act[8] specifically provides that dentists can "perform any aesthetic or cosmetic procedure on a patient to the oral and peri-oral area". Questions exist as to whether the prescribed scope of practice includes all administration of Botox by dentists. The provisions of the Act and the guidelines for the dentists' scope of practice are unclear as to whether it includes the administration of Botox. Furthermore, as it is the case with other medical procedures, there are legal implications that are attendant to the administration of Botox, notwithstanding whether this is done by a dentist or a cosmetic surgeon. Improper administration of Botox can give rise to delictual claims against a dentist. The guidelines of the Health Professions Council of South Africa (HPCSA) for good practice in the health care profession require, for instance, that a medical practitioner ensure that the medical procedure performed is within their scope of practice and, further, that they have appropriate training not just to administer, but also to mitigate, this medical procedure's potential adverse effects.[9]

In light of these developments, the study specifically sought to respond to the questions: whether the administration of Botox falls within the scope of practice of dentists in South Africa; whether it constitutes medical malpractice if a dentist administers Botox to a patient's face outside of their scope of practice; whether there is a regulatory framework regarding the administration of Botox by dentists; and, lastly, whether law or policy reform is needed on the administration of Botox by dentists. The next section will discuss key findings from this study.

4.2. Summary of findings

The key findings of the study will be presented according to the four questions of the research study highlighted in the study and the introduction above.

4.2.1. Does the administration of Botox fall within the scope of practice of dentist in South Africa?

[6] The Health Professions Act 56 of 1974.
[7] https://www.sada.co.za/scope-of-practice/Health Professions Act 56 of 1974, accessed on 3 March 2018.
[8] The Health Professions Act 56 of 1974.
[9] HPCSA Guidelines.

With regards to whether the administration of Botox falls within the scope of dentists' practice, this study points out that registered dentists are identified as 'appropriate practitioners' and, in terms of Section 58(2) of the Medicines Act, they can "procure, prescribe, dispense or administer, prescription-only medicines" as part of their scope of practice in the field of dentistry.[10] The HPCSA guidelines require that dental Botox be administered by a "specialist who has received training from an examination body accredited by the Board".[11] According to Addendum 2 of the Medicines Control Council of South Africa, injections are to be administered by a doctor or a professional registered with the HPCSA.

The literature engaged in this study has also highlighted that dentists are in a more advantaged position than other medical practitioners when it comes to effectively carrying out treatment and procedures on facial areas.[12] This is largely due to their undergraduate training in anatomy, physiology and pharmacology which specialises in the head and neck area.[13] Furthermore, the regulations defining the Scope of the Professions of Dentistry under the Health Professions Act provide that a practitioner "shall only perform, except in an emergency, a professional act for which he or she is adequately qualified and sufficiently experienced".[14]

It is further highlighted in this study that it is a requirement for medical practitioners who use substances for aesthetic medical procedures on patients to also have the capacity to manage the potential side effects, reactions and complications that may be resultant to administering such substances during medical procedures.[15] The practitioner therefore bears the burden of proof to ensure that they have had adequate education, training and experience in the performance of any procedure, including the administration of Botox.[16] The HPCSA makes it compulsory for all members of the medical profession, in their respective areas of specialisation, to continuously update their skills and to attend continuous professional development courses. This this applies to dentists who administer Botox.

[10] Medicines and Related Substances Act 101 of 1965.
[11] Health Professions Council of South Africa' available at http://isystems. hpcsa.co.za/iregister/, *accessed on 15 March 2018.*
[12] https://www.omicsonline.org/should-dentists-be-allowed-to-administer-botulinum-toxin-2161-1122.1000135.php?aid=7215, *accessed on 24 November 2018.*
[13]http://www.up.ac.za/en/odontology/article/22379/academic-programmes, *accessed on 12 May 2018.*
[14] HPCSA Guidelines.
[15] https://www.aestheticdoctors.co.za/content/page/about-us , *accessed 5 May 2018.*
[16] D Mostafa, 'A successful management of sever gummy smile using gingivectomy and botulinum toxin injection: A case report' (2018) 42. *International Journal of Surgery Case Reports* 169-174.

The study further highlights that although Botox treatment does not form part of the curriculum for undergraduate studies in dentistry. The readiness, qualification and skill of dentists to administer Botox can be easily addressed through adequate training and exposure that can be undertaken in the post graduate years, rendering a dentist a master in the fields of aesthetic and therapeutic Botox treatment, building onto the specialised foundation phase of his studies.[17] The study further deduced that it is medical malpractice for a dentist to delegate or authorise someone without the requisite competencies to administer Botox in dentistry.[18] In *South African Dental Association v Minister of Health*[19] the court ruled that it is illegal for a qualified dentist to delegate their duties to dental assistants, especially when specialist skills and medicine are involved. This is the same standard used in the USA, where administration of Botox can only be done by a qualifying dental practitioner and not by any non-prescribing staff member. In the context of the USA, a nurse cannot administer Botox even when this is being done in the presence of a dental practitioner.[20]

In answering the highlighted question, although not expressly provided, it would seem that given the wide application of the scope of practice for dentists as prescribed by South Africa's Minister of Health and various legislative and regulatory measures, registered doctors do act within their scope of practice to administer Botox. It also follows that dentists who are not registered with the HPCSA cannot administer Botox, as this would amount to performing this procedure illegally, which can lead to criminal prosecution.[21]

4.2.2. Is it medical malpractice if a dentist administers Botox to a patient's face outside of their scope of practice?

The study has defined medical malpractice as 'any act or omission by a physician during treatment of a patient that deviates from accepted norms of practice in the medical community and causes an injury to the patient'. The study further made a distinction between malpractice and negligence, and observed that while malpractice refers to both intentional and negligent acts committed by medical practitioners, negligence constitutes malpractice when the medical practitioner's negligent treatment causes undue injury to the patient. The study went to define malpractice in dentistry as 'treatment which is provided by a dental care professional that is found to be below the acceptable standard of care expected from a dentist, that results in serious

[17] https://www.up.ac.za/odontology/article/22379/academic-programmes accessed on 12 May 2018.
[18] Ibid.
[19] *South African Dental Association v Minister of Health* (20556/2014) [2015] ZASCA 163 (24 November 2015)
[20] Footnote 39 supra.
[21] Footnote 5 supra.

personal injuries sustained by the patient'.[22] In highlighting the requirements for proving a delictual claim against a dentist arising from a Botox procedure gone wrong, the study has highlighted that a patient must prove the following: that the dentist was licensed and registered as required by the Health Professionals Act; that they suffered harm; that the dentist failed to exercise the duty to care through mistakes and poor treatment; that the mistake or poor treatment caused an injury; and that the injury resulted in damages.[23]

The HPCSA highlights medical malpractice as including, *inter alia*, operational procedure without the consent of the patient, incompetence in providing treatment to patients and insufficient care to patients.[24] As highlighted in answering question 1 above, the HPCSA regulations provide that a practitioner can only perform a professional act for which he has received adequate qualification and sufficient experience, with an exception of emergency situations. The study findings point to the fact that in the event where a dentist administers Botox to a patient's face when they do not possess the requisite training in this area, they act outside the scope of their practice. This is in line with the provisions of the HPCSA guidelines and the Health Professionals Act.[25] This conduct further amounts to malpractice. The onus is on the practitioner to ensure that they have adequate education, training and experience in the performance of a Botox procedure.[26] In instances where a dentist does not possess such adequate training or sufficient experience in performing a Botox procedure, the practitioner has a duty to communicate and work with appropriately qualified health practitioners in the treatment of a patient. If a dentist fails to meet this standard they could be sued for medical malpractice. In other words, a dentist commits medical malpractice for undertaking certain tasks for which they lack professional competence. This also extends to a qualified professional failing to update themself regarding modern trends in the profession. As was pointed out in Chapter 1, the HPCSA makes it mandatory for all members of the medical profession, in their respective areas of specialisation, to continuously update their skills and to attend continuous professional development courses.

Furthermore, the study has highlighted medical negligence as a form of medical malpractice, which is failure on the part of the medical practitioner to exercise 'a *reasonable* amount of skill

[22] http://malpracticecenter.com/dental-malpractice/ accessed on 12 October 2018.
[23]Legalbeagle.com.What Constitutes Dental Malpractice? Accessed on: 16-05-2017; legalbeagle.com/5446060-constitutes-dental-malpractice.html.
[24] http://www.hpcsa.co.za/conduct, *accessed on 20 October 2018*.
[25] Section 22(5)(f) and section 33 of the Health Professionals Act 56 of 1974.
[26] D Mostafa, 'A successful management of sever gummy smile using gingivectomy and botulinum toxin injection: A case report' (2018) 42. *International Journal of Surgery Case Reports* 169-174.

and care' during the medical procedure being undertaken, which renders them liable for delictual claims for damages.[27] For delictual claims, the courts will require the aggrieved party to prove that the medical practitioner's conduct fell short of the reasonable standards expected from someone in their profession. In establishing the 'reasonable man' test, which is the yardstick for proving a delictual claim for medical negligence, in *Kruger v Coetze*[28] the courts found that it is a case of medical negligence if a *diligens paterfamilias* in the position of the defendant not only would have foreseen the reasonable possibility of their conduct injuring another in their person or property and causing them patrimonial loss, but would also have taken reasonable steps to guard against such an occurrence, and if the defendant failed to take such steps. In deciding what is 'reasonable', the court will therefore consider the level of skill and diligence possessed and exercised at the time by the members of the branch of the profession to which the practitioner (in this case, a dentist) belongs.

With regard to the duty of care, the study has established that in the field of dentistry dental practitioners administering Botox to their patients have a duty to take the welfare of their patients into consideration. As with any other medical practitioner, dentists too have a duty to exercise extreme caution in administering medicines or drugs that have adverse effects to their patients. The study further has established negligence as a form of medical malpractice in three instances: namely, when the dentist acts outside the scope of his or her practice by administering Botox; when the dentist is incompetent in administering Botox in dentistry (that is when he or she administers Botox without having received the necessary training from an examination body accredited by the Board); and when a dentist administers excess dosage of Botox above the prescribed limits (which constitutes an offence).

In conclusion, the study has clearly highlighted that it is, in fact, medical malpractice when a dentist administers Botox outside the scope of his practice, whether intentionally or negligently, unless this procedure is conducted in an emergency situation.

4.2.3. Is there a regulatory framework regarding the administration of Botox by dentists?

This study found that the health profession within which dentists practice is regulated. The Health Professions Act[29] provides for the establishment of the Health Professions Council of

[27] P Casterns & D Pearmain 'Foundational Principles of South African Medical Law' (2007). Durban. Lexis Nexis.
[28] Footnote 41 supra.
[29] The Health Professions Act 56 of 1974.

South Africa (HPCSA), the statutory regulatory body responsible for, *inter alia*, controlling and exercising "authority in respect of all matters affecting the training of persons in, and the manner of the exercise of the practices pursued in connection with, the diagnosis, treatment or prevention of physical or mental defects, illnesses or deficiencies in humankind." In terms of the Act, no person may practise within the Republic of South Africa as a medical practitioner unless he or she is registered in terms of the Act.[30]

The Act also provides for control over the education, training, registration, and practices of a variety of health professionals.[31] Furthermore, the Health Professions Act prohibits any person from practising within any health profession outside the scope which has been defined by the Minister, unless they are registered in terms of the Act in respect of such profession, and contravention of this provision amounts to an offence.[32] Such offence of acting outside the scope defined for such a profession within the medical or health professional field is punishable by means of a fine or imprisonment for a period not exceeding twelve months, or both a fine and such imprisonment.[33]

The study has established that the Medical and Dental Professional Board (MDPB) is responsible for all registered medical and dental practitioners, including their training and that of medical and dental students. The MDPB falls under the control of the HPCSA, although it functions somewhat independently.

The dental administration of Botox is, therefore, regulated, by virtue of the provisions of the Health Professions Act, the regulations, the HPCSA guidelines and the Medicines Control Act. However, the provisions of the legislative framework are not explicit and the determination of the scope of practice of dentists, in particular, is construed to be wide enough to extend to the administration of Botox by dentists. The arguments made in question 1 and 2 infer the existence of this regulatory framework.

4.2.4. Is law or policy reform needed on the administration of Botox by dentists?

As highlighted in the study, botulinum toxin is a lethal poison with life-threatening consequences when not administered properly. Within the context of Botox administration procedures, the study has gone to considerable lengths to highlight, on the one hand, the uses

[30] Section 17(10(a) of the Health Professions Act 56 of 1974.
[31] Section 3 of the Health Professions Act 56 of 1974.
[32] Section 34(2) of the Health Professions Act 56 of 1974.
[33] Section 39(2) of the Health Professions Act 56 of 1974.

and benefits of Botox both in therapeutic, dental and aesthetic treatment procedures and, on the other hand, the importance of administering proper dosages of Botox, especially given its poisonous characteristics.

Botox has certainly been demonstrated to have significant value in the dentistry field, especially as a less invasive treatment for dental problems. As has been earlier stated, there is currently no legislation governing medical malpractice cases, including cases where a Botox procedure as a non-invasive dental treatment goes wrong. While common law, through delictual claims, has provided recourse for victims of medical negligence and medical malpractice, these cases are on the rise. The medical field is well-regulated and the scope of any field within the medical practice is provided for by the Minister, as this study found.

Although this study has established that dentists have the expertise, through their training, to administer Botox, and the benefits of Botox as a non-invasive measure for dental procedure, it revealed the uncertainty that persists in practice specifically in terms of the scope of practice of dentists in administering Botox. Firstly, there is no express provision giving dentists a green light in performing Botox procedures. Secondly, the provisions for dentists' scope of practice have not been clearly articulated to include administration of Botox. Dentists' suitability and competence is therefore deduced from a wider application of the existing legislation and regulations promulgated by the Minister.

In light of the lack of specific and explicit policy or legislative provisions on whether dentists can administer Botox, this study therefore recommends a policy that will regulate Botox procedures, with a specific focus on various practitioners who have undertaken training in areas of their medical field that are adequate for administering Botox. Dentists in South Africa would fall under this category of trained medical practitioners with adequate training to administer Botox. This policy could also outline the various uses of Botox, which go beyond the cosmetic or aesthetic purposes. The policy could go further to mandate that dentists undertake continued learning courses periodically, to upskill themselves and familiarise themselves with new innovations and new developments in the field. The policy could also provide express provisions for the scope of practice, the training and skills required and the certification needed for dentists to administer Botox for dental-related purposes.

The study therefore proposes a legal or policy reform regarding the administration of Botox by dentists. This policy could borrow heavily from the practice in the United States of America, as highlighted in Chapter 3 above, of incorporating

4.3. Recommendations

In light of the findings of the study, it is recommended that South Africa, through its regulatory body of medical practitioners, the HPCSA, apply itself to clarifying its position on whether dentists can administer Botox under the scope of their practice. Comparative analysis in Chapter 3 has clarified the position in the UK, where the Medicines Act regards dentists as 'appropriate practitioners' when it comes to procuring, prescribing and administering Botox.[34] In the United States of America, the Medicines and Healthcare Regulatory Agency (MHRA) regulates the use of Botox. There is therefore a strong precedent for the HPCSA to address the administration of Botox within the dental practitioners' scope in the South African framework and regulatory landscape. This study therefore recommends that the HPCSA uses its current regulatory mandate which is already wide and flexible enough, to promulgate regulations or guidelines that focus specifically on the following:

a. *The scope of practice, and its attendant parameters for dentists to administer Botox.*
b. *The extended curriculum, provided through under-graduate, post-graduate or further professional development courses that is necessary to ensure that dentists are adequately trained in the administration of Botox to patients.*
c. *The continued review of the curriculum on the administration of Botox to ensure that dentists and other practitioners whose scope of practice covers the administration of Botox are constantly updated with regard to new procedures and new innovations in this field.*

The study has already established that dentists' practice puts them at an advantaged position when it comes to providing treatment and in administering injections to the human face. It therefore follows that dentists should be recognised explicitly, through guidelines or policy considerations, as medical practitioners who can administer Botox in terms of the South African medical standards as set out by the HPCSA.

[34] Section 58(2) of the UK Medicines Act, see in K Lewis, 'Dento legal aspects of non-surgical facial aesthetic procedure (2014) 5(2) 39 68.

As this study has detailed comprehensively, the HPCSA also regulates education and training in the health professions, including the continuing professional development of medical practitioners to foster compliance with healthcare standards. Taking the cue from the UK and USA cases, this study further recommends the need for the HPCSA to police a high standard of care and safety in the administration of Botox by allowing privileges to dentists specifically to administer Botox through making it compulsory for dentists to undertake regular continuing dental/medical education courses during the course of their practice. This would facilitate safe dental treatment to patients using Botox, and would ensure that dentists continuously update their basic science knowledge and clinical skill levels, especially in terms of the administration of Botox. This would further lead to a decrease in medical malpractice cases against medical practitioners, and the number of medical malpractice cases arising from negligence in the administration of Botox by dentists would also decrease.

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Kovalsky v Krige 1910 (20) CTR 822.

Kruger v Coetzee 1966 (2) SA 428 (A).

Mitchell v Dixon 1914 AD 519.

Natanson v Kline 1960 41, 476 350 P. 2d 1093.

Salgo v Leland Stanford University Hospital 1957 154 Cal. App. 2d 564.

South African Dental Association v Minister of Health (20556/2014) [2015] ZASCA 163 (24 November 2015.

Van Wyk v Lewis (1924) AD 438.

SECTION 2: PROJECT DESCRIPTION

Please do *not* provide your full research proposal here: what is required is a short project description of not more than two pages that gives, under the following headings, a brief overview spelling out the background to the study, the key questions to be addressed, the participants (or subjects) and research site, including a full description of the sample, and the research approach/ methods

2.1 Project title

An investigation into the critical legal issues surrounding Dental Botox

2.2 Location of the study *(where will the study be conducted). Briefly describe the study setting (socioeconomic status; urban/rural).*

A detailed literature search was done on the legal issues surrounding Dental Botox.

2.3 Objectives of and need for the study
(Set out the major objectives and the theoretical approach of the research, indicating briefly, why you believe the study is needed.)

Dentists have the necessary experience and expertise to do Botox,however there has been a rise in medical malpractice. This study aims to investigate the critical and legal issues surrounding dental Botox.

Objectives of the study

(i) To examine scope of other professionals regarding Botox.

(ii) To examine medical malpractice on the administration of dental Botox.

(iii) To investigate possible medical negligence/liability of dentists who do Botox elsewhere on the face.

(iv) Based on the findings to make recommendations on improving the administration of Botox on dental patients.

2.4 Questions to be answered in the research

(Set out the critical questions which you intend to answer by undertaking this research.)

This thesis aims to answer the following research questions:

i) Does the administration of Botox fall within the scope of practice of dentist in South Africa?

(ii) Is it medical malpractice if a dentist administers Botox, to a patient's face outside of their scope of practice?

(iii) Is there a regulatory framework regarding the administration of Botox by dentists?

(iv) Is law or policy reform needed on the administration of Botox by dentists?

2.5 Research approach/ methods

(This section should explain how you will go about answering the critical questions which you have identified under 2.4 above. Set out the approach within which you will work, and indicate in step-by-step point form the methods you will use in this research in order to answer the critical questions – including sample description, sampling strategies, data collection methods, and data reduction strategies.**A concise literature review is required (no more than 800 words).**

For a study that involves surveys, please append a provisional copy of the questionnaire to be used. The questionnaire should show how informed consent is to be achieved, as well as indicate to respondents that they may withdraw their participation at any time, should they so wish

Data collection

The data was collected by literature search. Information was obtained from government publications, case laws, journals, periodicals ,books and internet articles.

The data reduction strategy

The data was reduced to focus primarily on the use of Botox by Dentists.

Literature Review

This literature review provides an analysis of the literature and academic views on the investigation into the critical legal issues surrounding the use of Botox in dentistry by dentists.

'Botulism' is a life-threatening disease first described by Kerner.[1] It is caused by botulinum toxin (BT) also known as botulinum neurotoxin developed under anaerobic conditions

[1] D Truong, D Dressler, & M Hallett, *Manual of Botulinum Toxin Therapy* 2 ed (2009) 10.

SECTION 3: ETHICAL ISSUES

The UKZN Research Ethics Policy applies to all members of staff, graduate and undergraduate students who are involved in research on or off the campuses of University of KwaZulu-Natal. In addition, any person not affiliated with UKZN who wishes to conduct research with UKZN students and / or staff is bound by the same ethics framework. Each member of the University community is responsible for implementing this Policy in relation to scholarly work with which she or he is associated and to avoid any activity which might be considered to be in violation of this Policy.

All students and members of staff must familiarise themselves with, AND sign an undertaking to comply with, the University's "Code of Conduct for Research".

QUESTION 3.1

Does your study cover research involving:	**YES**	**NO**	**MAYBE / UNKNOWN**
Children		✓	
Persons who are intellectually or mentally impaired		✓	
Persons who have experienced traumatic or stressful life circumstances		✓	
Persons who are HIV positive		✓	
Persons highly dependent on medical care		✓	
Persons in dependent or unequal relationships		✓	
Persons in captivity		✓	
Persons living in particularly vulnerable life circumstances		✓	

If "Yes", indicate what measures you will take to protect the autonomy of respondents and (where indicated) to prevent social stigmatisation and/or secondary victimisation of respondents. If you are unsure about any of these concepts, please consult your supervisor/ project leader.

QUESTION 3.2

Will data collection involve any of the following:	**YES**	**NO**
Access to confidential information without prior consent of participants		✓
Participants being required to commit an act which might diminish self-respect or cause them to experience shame, embarrassment, or regret		✓
Participants being exposed to questions which may be experienced as stressful or upsetting, or to procedures which may have unpleasant or harmful side effects		✓

Is this research supported by funding that is likely to inform or impact in any way on the design, outcome and dissemination of the research?	YES	NO ✓

If yes, this needs to be explained and justified.

If yes, please indicate what the conditions are.

QUESTION 3.10

Do you, or any individual associated with or responsible for the design of the research, have any personal, economic, or financial interests (or any other potential conflict of interests) that could reasonably be regarded as relevant to this research project?

NO

If you answered YES to Question 3.10 please provide full details:

The use of stimuli, tasks or procedures which may be experienced as stressful, noxious, or unpleasant		✓
Any form of deception		✓

If "Yes", explain and justify. If appropriate, indicate what steps will be taken to minimiseany potential stress/harm.

QUESTION 3.3

Will any of the following instruments be used for purposes of data collection:	**YES**	**NO**
Questionnaire		✓
Survey schedule		✓
Interview schedule		✓
Psychometric test		✓
Other/ equivalent assessment instrument		✓

If "Yes", attach copy of research instrument. If data collection involves the use of a psychometric test or equivalent assessment instrument, you are required to provide evidence here that the measure is likely to provide a valid, reliable, and unbiased estimate of the construct being measured. If data collection involves interviews and/or focus groups, please provide a list of the topics to be covered/ kinds of questions to be asked.

QUESTION 3.4 Note - This question is not applicable to the study

Will the autonomy of participants be protected through the use of an informed consent form, which specifies (in language that respondents will understand):	**YES**	**NO**
The nature and purpose/s of the research		
The identity and institutional association of the researcher and supervisor/project leader and their contact details		
The fact that participation is voluntary		
That responses will be treated in a confidential manner		
Any limits on confidentiality which may apply		
That anonymity will be ensured where appropriate (e.g. coded/ disguised names of participants/ respondents/ institutions)		
The fact that participants are free to withdraw from the research at any time without any negative or undesirable consequences to themselves		
The nature and limits of any benefits participants may receive as a result of their participation in the research		
Is a copy of the informed consent form attached?		

If NO to any of the above: (a) please justify/explain, and (b) indicate what measures will be adopted to ensure that the respondents fully understand the nature of the research and the consent that they are giving.

QUESTION 3.5

Specify what efforts have been made or will be made to obtain informed permission for the research from appropriate authorities and gate-keepers?
Not applicable

QUESTION 3.6

STORAGE AND DISPOSAL OF RESEARCH DATA:
Please note that the research data should be kept for a minimum period of at least five years in a secure location by arrangement with your supervisor.

How will the research data be secured and stored? When and how (if at all) will data be disposed of?

Secured offices located at work premises in address below

227 Main Road , Malvern, 4093

QUESTION 3.7

In the subsequent dissemination of your research findings – in the form of the finished thesis, oral presentations, publication etc. – how will anonymity/ confidentiality be protected?
How will you give feedback to your research participants?

Not applicable to the study

QUESTION 3.8

3. SUPERVISOR/ PROJECT LEADER DETAILS

NAME	TELEPHONE NO.	EMAIL	SCHOOL / INSTITUTION	QUALIFICATIONS
3.1 Professor Ann Strode	+27 - 33- 260 5731	StrodeA@ukzn.ac.za	UKZN	BA, LLB, LLM (Natal) PHD (UKZN)
3.2 Professor MS Soni	+27 - 33- 260 5383	Sonish@ukzn.ac.za	UKZN	LLB, LLM

SECTION 4: FORMALISATION OF THE APPLICATION

APPLICANT

I have familiarised myself with the University's Code of Conduct for Research and undertake to comply with it. The information supplied above is correct to the best of my knowledge.

NB: PLEASE ENSURE THAT THE ATTACHED CHECK SHEET IS COMPLETED

DATE: ..... SIGNATURE OF APPLICANT.....

SUPERVISOR/PROJECT LEADER/DISCIPLINE ACADEMIC LEADER

NB: PLEASE ENSURE THAT THE APPLICANT HAS COMPLETED THE ATTACHED CHECK SHEET AND THATTHE FORM IS FORWARDED TO YOUR SCHOOL RESEARCH COMMITTEE FOR FURTHER ATTENTION

DATE: 4/6/19

SIGNATURE OF SUPERVISOR/PROJECT LEADER/DISCIPLINE LEADER

_____

RECOMMENDATION OF SCHOOL RESEARCH ETHICS COMMITTEE/HIGHER DEGREES COMMITTEE

The application is (please tick):

	Recommended and referred to the Human and Social Sciences Ethics Committee for further consideration
	Not Approved, referred back for revision and resubmission
	Other: please specify:

NAME OF CHAIRPERSON:

Name_____**SIGNATURE:**_____

DATE .....

RECOMMENDATION OF UNIVERSITY RESEARCH ETHICS COMMITTEE (HUMAN AND SOCIAL SCIENCES)

NAME OF CHAIRPERSON:_____**SIGNATURE**_____

DATE.....

CHECK SHEET FOR APPLICATION

PLEASE TICK	
1. Form has been fully completed and all questions have been answered	✓
2. Questionnaire attached (where applicable)	n/a
3. Informed consent document attached (where applicable)	n/a
4. Approval from relevant authorities obtained (and attached) where research involves the utilisation of space, data and/or facilities at other institutions/organisations	n/a
5. Signature of Supervisor / project leader	✓
6. Application forwarded to School Research Committee for recommendation and transmission to the Research Office	✓