

A MICROSCOPIC ANALYSIS OF SINGLE-USE VERSUS MULTI-USE PHACOEMULSIFICATION TUBING IN MAINTAINING STERILITY AND PATIENT SAFETY

by

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Submitted in partial fulfilment of the academic requirements

for the degree of MMed

in the Department of Ophthalmology

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Durban

2018

As the candidate's supervisor I have/~~have not~~ approved this thesis for submission.

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Declaration

I Dr L T Ndlovu declare that

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Dedication

I dedicate this research to my 3 children, Ralitsa Yumba, Raphy Yumba and Sisipho Yumba. They are my motivation.

Acknowledgements

Dr C. Kruse for his guidance.

Dr R. Rodseth for his valuable input in preparing the protocol.

Dr Tlou for data statistical analysis

Overview

Cataract is first of the five most common causes of blindness and vision impairment (poor night vision, fading colours and haloes around light) worldwide. It is followed by glaucoma, macular degeneration, diabetic retinopathy and trachoma. Prevention of blindness remains one of the most important areas of research in the medical field. A blind person becomes a burden in the family and the community at large, and blindness also shortens life span.

Cataract extraction with intraocular lens implant is the most common surgery worldwide. We live in a developing country where we need a balance between quality and safe health practises against cost-effective measures. We need to increase the number of cataract extractions in order to decrease vision impairment and blindness. At the same time, we need to find cost-effective ways so that this procedure does not deplete the health budget. One way of decreasing costs is to reuse equipment after cataract surgery.

Cataract extraction has evolved over many years. It is one of the oldest surgical procedures, first documented in the fifth century BC. The most significant change which marked a modern era victory was the introduction of phacoemulsification (phaco) in 1967. Phacoemulsification involves the breakdown of the nucleus using ultrasonography, irrigation and aspiration of the lens material. This technique has fewer complications including less wound problems, the procedure is sutureless and the risk of endophthalmitis and suprachoroidal haemorrhage is significantly decreased.

Two phacoemulsification tubes are connected to a phaco probe, one tube has fluid for irrigation and the other tube aspirates lens material and fluid. Both tubes do not enter the eye,

only the probe does. The phaco probe can therefore not be reused without being first sterilised. The tubes, however, should remain sterile and could potentially be reused. This study looks particularly at the sterility of the irrigation tube which carries BSS (Balanced Salt Solution) to the eye.

This observational descriptive prospective study was conducted at Edendale Hospital and Greys Hospital in the city of Pietermaritzburg (PMB). These hospitals are part of the PMB metropolitan complex in South Africa. In this complex there is no standard protocol with regards to whether we may reuse phaco tubing or not. Greys Hospital does not reuse tubing (they use one “phaco pack” per theatre case) whereas Edendale Hospital reuses the tubing: one tubing for 3 cases. For this study the tip of each tube was sent for culture to check for micro-organisms. Two unused phaco tubings were sent as controls. We used the same laboratory for all analyses.

Guidelines from the manufacturer state that phaco packs (the tubing is found inside this pack) are for single use only (1). There is, however, lack of scientific proof to back this guideline. We endeavoured to assess whether reusing phaco tubing has a negative impact on the sterility (and therefore safety) or not. If not, then reusing the phaco tubes could be widely adopted in an effort to save money while maintaining patient safety.

In summary, the aim of this observational descriptive prospective study is to assess if phacoemulsification tubing remains sterile during sequential phacoemulsification procedures. The objectives are to investigate whether there is a difference in growth of micro-organisms from phaco tubing that are used at the two sites; to investigate and compare micro-organisms, if

identified, from each specimen; and to gather evidence for a future protocol regarding reusing phaco tubing for sequential phacoemulsification.

More than half of all specimens in each group showed growth of the bacillus species and other organisms as a result of contamination. This study showed that there was a non-statistical difference between the contamination rates of the tubes from both hospitals. Although a statistical significance was not shown, this result is of great clinical significance. It highlights the need for further research into patient safety as our study showed significant contamination. Patient safety cannot be concluded from this study. A protocol to be followed by all the PMB complex hospitals cannot be drawn up as yet as further research into patient safety is warranted.

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CHAPTER 1: The Review of Literature

The practise of reusing single-use devices is done worldwide. In America it is subject to Food and Drug Administration oversight (1). Although it is anecdotally considered to be safe and effective, little published evidence is available on safety and efficacy (2). In Australia, a study by infection-control experts at the Woden Valley Hospital in Canberra indicated that reuse was occurring in 38% of all respondents (Med J Aust 1996; 164: 533-36)(3). Reuse occurred in more large metropolitan hospitals (in 64% of those with more than 300 beds) than in smaller metropolitan hospitals (in 41% of hospitals with fewer than 300 beds), or in private hospitals (32%) (4).

In a third world country like India, reuse of medical equipment marked for single-use is also quite common. A study was done in India which assessed if there was a correlation between reusing single-use devices and adverse effects in patients post percutaneous transluminal coronary angioplasty. The study took place in two hospitals, one with primarily high income earners and one with low income earners. Patients were admitted for the same indication. Adverse effects were categorised into serious (death, pyogenic infections and extended hospital stay) and non-serious (swelling, bleeding from site, haematoma, oozing from site) adverse effects. Anecdotal information suggests that hospitals with low income earners were found to reuse devices which were labelled as single use devices much more than hospitals with more high income patients.

There was, however, no difference in the number of adverse effects between the two hospitals, despite the significant difference in the number of single-use devices per procedure (5).

Post phacoemulsification endophthalmitis is one of the most severe complications of cataract surgery and it may lead to permanent blindness. Micro-organisms can be introduced in almost any step during surgery. Studies have found that wound incisions are the leading pathway for introducing flora into the eye (6). Lack of equipment sterility is an area where micro-organisms can be introduced. Sterile equipment is pre-packed to ensure quicker access and usage while maintaining sterility.

All state hospitals in the PMB complex utilize the Infinity™ system (Alcon Laboratories) which uses a single-use pack for each procedure. In the state phaco packs cost R656.67 per pack, the second most expensive consumable in our setting. Each sterile pack consists of a cartridge with irrigation fluid attachments (which fits into the phaco machine) as well as tubing, which fits into the autoclaveable hand piece. Only the hand piece is ever in contact with the patient's eye. The cartridge and tubing could therefore theoretically remain sterile for many cases if handled with care.

A study in the European Journal of Ophthalmology in 2012 aimed to determine if there was microbial contamination of the irrigating fluids at the time of phacoemulsification after the use of topical povidone-iodine and antibiotics prophylaxis (7). After each case fluid was collected and sent for microbiology analysis. Results showed that there was indeed contamination of irrigating

fluid but preoperative use of antibiotics decreased the rate of endophthalmitis infection to practically zero.

An article by Carol Rhuel, which was published in the Eucomed white paper in December 2009 explored whether outbreaks of Toxic Anterior Segment Syndrome (TASS) may be caused by contaminated devices (8). In this article, photos were taken with a scanning electron microscope and they were used to illustrate the increasing signs of degradation with continuous phaco tip reuse. The photos showed particulate matter which gathered on the phaco tip. This raised concerns about those small surgical devices that cannot be cleaned sufficiently for reuse without damaging them. The particulate matter on them can be introduced into the next patient's eye and could potentially also harbour micro-organisms.

There have been cases of postoperative endophthalmitis associated with equipment contamination. One study's purpose was to set up a model for the assessment, investigation and management of an atypical outbreak of infectious endophthalmitis of unknown cause in London in 2003 (9). A multidisciplinary infection control team was formed with the aim of identifying potential causative factors. These factors included analysing the theatre and its surrounding environment, pre-operative preparation, intra-operative theatre and surgical practices, post-operative practices, equipment maintenance guidelines, cleaning and sterilisation practices and microbiological screening. Five cases of endophthalmitis following uncomplicated phacoemulsification, by different surgeons, were noted over a 7-month period. Three cultures grew *Streptococcus viridans* of different strains, 1 culture grew *Staphylococcus aureus* and no organisms grew on the last culture. Without a single causative factor, it was postulated that it

was a combined effect of many possible factors that led to increased bacterial load and subsequent infection rate. Recommendations were made which included new cleaning protocols to prevent the build-up of debris on the phacoemulsification tubing.

In another article by Lesley et al (10) the importance of meticulous cleaning of phaco hand pieces to prevent endophthalmitis was elaborated. Automated flushing should be superior to manual cleaning of the instruments in preventing interpatient transfer of infection. Automated flushing did not, however, eliminate contamination but it only decreased it (11). In other branches of medicine manual cleaning and flushing of instruments with small lumens prior to sterilization proved more effective in eliminating inter-patient contamination.

Low temperature sterilization has been highlighted since the development of plastic single-use medical devices and the appearance of more sophisticated endoscopic tools whose constitutive materials could not bear high temperature processing (12). The criteria of gaseous proceedings, alkylating and oxidizing agents as well as new technologies based on the use of cold plasma, were reviewed. Drawbacks of alkylating agents include toxicity to staff, patients and environment, mutagenicity and dangers of handling. Drawbacks of oxidizing agents include corrosive effects on almost any material but with proper use they are promising. In recent years, their efficacy has been enhanced by using cold plasma to increase production of free radicals.

There are no studies that have looked specifically into re-using phacoemulsification irrigation tubing in isolation. A study was done in Brazil that looked into viral contamination during sequential phacoemulsification surgeries in an experimental model. The purpose of the study was to determine the incidence of Piry virus contamination among surgical instruments used with

disposable accessories for phacoemulsification during sequential surgeries (13). Four pigs eyes were contaminated with Piry virus and the other four eyes were not. Phacoemulsification surgeries were done on all eight eyes alternating between contaminated and non-contaminated eyes. The hand piece, irrigation and aspiration tubes were reused, the operating fields, gloves, scalpels, tweezers, needles, syringes, tip and bag collector from the phacoemulsification machine were exchanged. In their results they analysed specimens from the collector bags, the tips, irrigation and aspiration system. From their irrigation system, a sample from a non-contaminated eye (1/4) was positive and in their aspiration system two samples from non-contaminated eyes were positive. In the collector bag two samples from non-contaminated eyes were positive. At the tip two samples from non-contaminated eyes were positive. They also found two samples from the anterior chamber of non-contaminated eyes to be positive post-surgery. The conclusion was there was transfer of genetic material of Piry virus during sequential phacoemulsification where the tip, irrigation and aspiration systems were reused between surgeries (14).

There are studies that have looked into re-using extra ocular single-use devices. These studies include a study done in the UK, where they looked into re-using single-use laparoscopic instruments for cholecystectomy. This was a single published randomised controlled study which found no significant differences in outcome when comparing new and reprocessed single-use device laparoscopic instruments for cholecystectomy (15).

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CHAPTER 2: A submission ready manuscript.

TITLE: A microscopic analysis of single-use VERSUS multi-used phacoemulsification tubing in
maintaining sterility and patient safety

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Disclaimer: Views expressed in this article are my own and not official position of the institution or funder

Source of support: Mr Lance Steyn from Alcon Laboratories who donated some phaco packs for
microscopic analysis

Edendale Hospital and Greys Hospital theatre staff who were involved in the collection of specimens

Northdale Hospital laboratory staff for the processing the specimens

Original Research Article - full structure

Title: A microscopic analysis of single-use VERSUS multi-used phacoemulsification tubing in
maintaining sterility and patient safety

The Abstract

Background: The Pietermaritzburg complex in South Africa does not have a uniform protocol regarding reuse of phacoemulsification tubing. Each hospital in the complex has its own guidelines, based on manufacture recommendation and cost-saving measures. There is no definitive scientific evidence proving that reusing phaco tubing will harm patients.

Aim: To assess if phacoemulsification tubing remains sterile during sequential phacoemulsification.

Settings: The study was conducted at Edendale and Greys Hospitals in the Pietermaritzburg complex in KwaZulu-Natal, South Africa. At Greys Hospital new phacoemulsification tubing is used for each case. At Edendale Hospital, phacoemulsification tubing is reused on three sequential patients in one slate.

Method: This was an observational descriptive prospective study. It was done over 4 months. Data collection was from 31/03/2019 until 18/07/2019 from both hospitals. Routine phacoemulsification was done at each hospital as per hospital guidelines. At the end of the surgery, the tips of the tubing were cut off, placed in a sterile specimen container and sent to the laboratory for culture and microscopy. Results were compared as one hospital re-uses phaco tubings and the other one does not. Two unused tubings were also analysed as controls.

Results: A total of 26 single-use tubings were analysed. 12 out of 26 tubings (46.2%) grew no organisms; 5 out of 26 tubings (19.2%) grew bacillus species; a variety of other micro-organisms were found in less than 1% of tubings. A total of 41 multiple-use tubings were sent for analysis. 17 out of 41 tubings (41.5%) grew no organisms; 7 out of 41 (17.1%) tubings grew bacillus species. A variety of other micro-organisms were found in less than 5% of tubings. Pre-used tubings did not grow any micro-organisms.

Conclusion: A p value less than of 0.05% was accepted as statistically significant. Comparing the two hospitals, tubings which grew no organisms were 46.2% (single-use) versus 41.5% (multiple-use). This gives a statistically non-significant p value of 0.70394. Tubing which grew bacillus species were 19.2% (single-use) versus 17.1% (multiple-use) ($p = 0.82588$). Comparing a variety of other micro-organisms also gives a p value of 0.75656. This implies that phacoemulsification tubing is significantly contaminated after just one use. Although no statistical difference was found between the two groups, a contamination rate of over 40% is of great concern. There are contributing factors which may have influenced this result including the fact that our specimen containers, even though they are the standard specimen containers in our hospitals, are not really sterile. Specimen handling in theatre and in the laboratory could also have contributed to contamination. In our setting, phaco tubing does not seem to remain sterile during cataract surgery. Further research needs to be done in order to gain more insight on patient safety.

Introduction

The Pietermaritzburg complex comprises of three hospitals. Two of them participated in the study. The third one did not offer phacoemulsification at the time of the study. The hospitals do not have a uniform protocol regarding reuse of phacoemulsification tubing. Each hospital bases its protocol either solely on manufacture recommendation or a combination of manufacture recommendation and cost-saving measures. Theatre staff from Greys Hospital follows the manufacturer guidelines: Phaco packs are sold as single-use items.

It is a directive from the provincial Department of Health (DOH) to save costs. One solution is to buy cheaper equipment or to opt to perform surgical techniques that do not require expensive equipment. There is a suggestion from DOH to the ophthalmology departments to rather perform more extracapsular lens extractions, which cost less than phacoemulsification. A secondary objective of this study is to make a protocol with regards to reusing items labelled by the manufacturer as single-use. Hopefully this study will form a basis for more research into reusing items labelled as single use items by the manufacturer.

There is little scientific evidence evaluating whether reusing phaco tubing will harm patients. A previous study found that micro-organisms could be transferred from infected to non-infected eyes during sequential phacoemulsification but they only analysed probes, irrigation and aspiration fluids. There is no published directive regarding re-use of single-use phaco packs.

The aim of the study is to assess if phacoemulsification tubing remains sterile during sequential phacoemulsification. The objective is to investigate if there is growth of micro-organisms from phaco tubings at the two sites and to compare the micro-organisms after single vs multiple use.

In this study the phaco probes are autoclaved before being reused but the tubing are not. Microscopic analysis of the tubing should serve as evidence for drafting a standard protocol for the Pietermaritzburg complex and assess patient safety in general.

Research method and design

Study design and setting

This was an observational descriptive prospective study. It was done over 4 months from 31/03/2019 until 18/07/2019. It was conducted at Greys Hospital and Edendale Hospital. Routine phaco procedure was done. Drapes, blades, knives and phaco probes were all sterilised before being reused. Re-used tubing was not sterilized between cases. Slates and procedures were not altered for the study. We used these two hospitals because they currently have different protocols on used phacoemulsification tubing. At Greys Hospital new phacoemulsification tubing was used for each case. At Edendale Hospital, phacoemulsification tubing was reused on three sequential patients on one slate. At the end of the case(s), just before the tubing was discarded (after each case at Greys Hospital and at the end of every third case at Edendale Hospital), a 5cm piece of irrigation tubing tip was cut off, placed in a sterile specimen container and sent to the laboratory for investigation. Two unused irrigation tubings were also sent to the laboratory for testing as controls. At the laboratory the specimens were incubated in a broth medium overnight then transferred on to Agar plates for culture.

Study population and sampling strategy

Theatre cases were booked as per standard departmental theatre slates. Slates are often booked months in advance. Specimens were collected as they become available at the end of the procedure(s). Unused irrigation tubing was also sent as specimen at the beginning of the study.

Inclusion criteria: all irrigation tubing used during that period, to be kept sterile and reach the laboratory in a sterile specimen container.

Exclusion criteria: any other techniques of cataract extraction including lens washout, extracapsular lens extraction and intracapsular lens extraction; known contaminated or known unsterile tubing.

The intended sample size was 76 phacoemulsification tubing from three hospitals in the PMB complex. This was an estimated number of phacoemulsification surgeries done in the PMB complex in one month. One hospital did not offer the procedure at the time of the study due to lack of a surgeon so only two hospitals collected specimens and the sample size was decreased to 67. Collection took longer than one month due to unforeseen circumstances: These included lack of phaco packs at Greys Hospital in that period and theatre ran out of colour coded specimen bottles at Edendale Hospital. 41 irrigation tubings from Edendale Hospital were analysed and 26 tubings from Greys Hospital. Two unused and sterile tubings were donated by the manufacturer, Alcon Laboratories. The accuracy of our estimated average and range was calculated using statistical analysis.

Data collection

Standard specimen bottles and laboratory forms were left in theatre. Surgery was performed by different surgeons. Before discarding the tubing, the surgeon cut the 5mm piece with unused sterile scissors and inserted it into the specimen container. The specimen and the laboratory request forms were placed in clear laboratory plastic bags. Plastic bags, specimen bottles and request forms for the study were colour coded for easy identification of the hospital it originated from. Unused irrigation tubings were prepared by the author under sterile conditions, in the similar manner as the used irrigation tubings and labelled as “control”. All phacoemulsification irrigation tubing was cultured and microscopically analysed.

Data analysis

Data analysis was done with the statistician. The Z test, the difference of two proportions, was used for statistical analysis. A p-value of less than 0.05% was taken as statistically significant. We calculated the confidence level using the formula confidence level = $P \pm 1.96 (P)(1-P)/n$.

Ethical considerations

Patients were not enrolled for the study. No patient consent or record was required. The state laboratory was used to analyse our phacoemulsification tubing. Future patients could benefit because recommendations will be made to improve patient safety and/or improve cost-effectiveness. Conflict of interest may be present, as this study is done towards a degree.

BIOMEDICAL RESEARCH ETHICS COMMITTEE



NAME OF RESEARCHER: Dr Lungile Thandeka Ndlovu

DEPARTMENT: Ophthalmology

TITLE OF STUDY: A microscopic analysis of new VERSUS used phacoemulsification tubing in maintaining sterility and improving patient safety

ETHICS REFERENCE NO: BE450/16

DATE OF ETHICAL APPROVAL OF STUDY: 11/01/2017

DATE OF AMENDMENTS: 10/04/2017

AMENDMENTS REQUESTED:

Protocol states: in 4.5.2 (sample size)

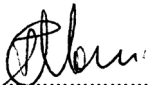
A total sample size is estimated at about 76 phacoemulsification tubing which will be microscopically analysed. About 12 tubing will be collected from Northdale Hospital, 28 tubing from Greys Hospital and 40 tubing from Edendale Hospital.

Amendment requested

Removal of Northdale Hospital as one of the participants in this study.

Reason for amendment

This amendment is necessary as Northdale Hospital has suspended all ocular surgery as from 01/04/2017. No phacoemulsification procedures will be done until a permanent doctor is employed by the hospital or Greys Hospital Eye Clinic has enough staff to send a doctor to Northdale to assist with ocular surgery. This study will then only compare two hospitals, Greys Hospital and Edendale Hospital. This will not affect the study negatively as Edendale Hospital just like Northdale Hospital reuses phacoemulsification tubing.

SIGNATURE OF PRINCIPAL RESEARCHER:.....DATE: ...10/04/2017.....

Results

Phacoemulsification irrigation tubing was sent for microscopic analysis to show whether they remain sterile during sequential phacoemulsification. Results from specimen sent as controls showed no growth of micro-organisms. The results from single-used and multi-used tubings, as shown in table 1 and table 2, show that not all tubing remains sterile after phacoemulsification. Less than half of the tubings stay sterile as no micro-organisms were found in 41.5% (Edendale) and 46.2% (Greys). Tubings that did not remain sterile, grew a variety of micro-organisms as shown in table 1 and table 2. Most types of micro-organisms grew on only one or two tubing in each hospital. Bacillus species grew in multiple (5 or more) tubings. In comparing the two hospitals, clinically, Greys Hospital had more tubings which showed no growth of micro-organisms than Edendale Hospital, but the difference was only 4.7%.

The Z test, the difference of two proportions, was used for statistical analysis. The p value of less than 0.05% was taken as statistically significant. We calculated the confidence level using the formula $\text{Confidence level} = P \pm 1.96 (P)(1-P)/n$.

Comparing the two hospitals, tubing which grew no organisms were 46.2% (single-use) versus 41.5% (multiple-use). This gives a statistically non-significant p value of 0.70394. Tubing which grew bacillus species were 19.2% (single-use) versus 17.1% (multiple-use) ($p = 0.82588$), confidence level of 17.1% to 19.2% (single-use), versus confidence level of 14.52% to 19.68%

(multiple-use). Tubings which grew bacillus species give a p value of 0.82588. In comparing a variety of other micro-organisms also gives a p value of 0.75656 which is statistically also not significant. The 95% confidence level gave us a true value of an unknown population.

Table 1: Organisms cultured per study site

Organism	Greys Hospital (single-use)		Edendale Hospital (multiple-use)	
	n	%	N	%
acinobacter baumannii complex	-	-	2	4.9%
bacillus species	5	19.2%	7	17.1%
coagulase neg staphylococcus and micrococcus	-	-	1	2.4%
corynebacterium species	1	3.8%	1	2.4%
granulicatella adiacens	1	3.8%	-	-
klebsiella pneumonia	-	-	2	4.9%
micrococcus luteus	-	-	2	4.9%
micrococcus species and bacillus species	1	3.8%	-	-
myroides species	-	-	1	2.4%
pantoea species	-	-	1	2.4%
pseudo stutzeri and coaguase neg staphylococcus	1	3.8%	-	-
rhizobium radiobacter	1	3.8%	-	-
serratia plymuthica	1	3.8%	-	-
sphingomonas paucimobilis	-	-	2	4.9%
staphylococcus aureus and staphylococcus lentus	-	-	1	2.4%
staphylococcus capitis	-	-	1	2.4%
staphylococcus cohnii	1	3.8%	-	-
staphylococcus epidermidis	1	3.8%	-	-
staphylococcus hominis and sphingomonas paucimobilis	-	-	1	2.4%
staphylococcus warneri	-	-	1	2.4%
streptococcus salivarium	1	3.8%	1	2.4%
No growth	12	46.2%	17	41.5%
TOTAL	26	100%	41	100%

Discussion

The first documented complete surgical extraction of the lens from the eye was in 1748 in Paris(1). Over the past few decades major improvements were done by removing the cataract and leaving an intact posterior capsule behind(2). Wound reduction and introduction of sutures greatly improved results. The introduction of phacoemulsification has shortened surgery time and improved wound healing, but the costs of each surgery have risen drastically.

The question of whether irrigation tubing remains sterile during sequential phacoemulsification tubing in our setting seems to have been answered. More than half of all phaco tubing is contaminated after use, even after only a single patient. This could be due to a variety of factors: Contamination of the tubings could have occurred during surgery or handling, from the time the tubings were opened for surgery to the time they were prepared for microscopy in the laboratory.

Bacillus species was the most prevalent contaminant. All other species identified have never been associated with endophthalmitis. Bacillus species have been known as opportunist pathogens since the late nineteenth century. Isolation of this pathogen cannot be taken in isolation without taking the clinical picture into account (3). Certain subtypes of bacillus like bacillus anthrax and bacillus cereus are associated with terminal illnesses. B cereus causes destructive intraocular damage, severe keratitis, conjunctivitis, iridocyclitis, panophthalmitis, dacrocystitis and orbital abscess.

Staphylococcus epidermidis has previously been regarded as an innocuous commensal microorganism on the human skin but nowadays it is seen as an important opportunistic pathogen. It is now the most frequent cause of nosocomial infections, at a rate about as high as that due to its more virulent cousin *Staphylococcus aureus* (4). Staphylococcus epidermidis is the most common source of infections on

indwelling medical devices. This results from the fact that it is a permanent and ubiquitous colonizer of human skin, and the device gets contaminated during use (5). Staph epidermidis infections only rarely develop into life-threatening diseases.

Corynebacterium diphtheria is linked to epidemic outbreaks in Russia in the 1990s. It has since seen a decline. Today, the more common scenario is non-diphtherial corynebacterial bacteremia associated with device infections (venous access catheters, heart valves, neurosurgical shunts, peritoneal catheters), as well as meningitis, septic arthritis, and urinary tract infections (6).

More than half of our single- used and multi-used tubings were contaminated after surgery. This is clinically significant, even though many were “innocuous” micro-organisms. The results of single vs. multiple-use devices were however not statistically significant. Unused tubings were sterile as they did not grow any micro-organisms. These clinical results warrant further research in this field.

Strengths

The actual culture and microscopic analysis was done at a single recognized laboratory by qualified laboratory staff under the supervision of a qualified specialist microbiologist.

The study was done in a real-world setting without changes to any of the procedures or methods and therefore gives an accurate reflection of what is currently happening in our theatres.

Limitations

Sample size was kept small primarily due to cost and time constraints. A larger sample size could have had a more representative result. Duration was also a limiting factor, if more tubing were analysed over a long period a more representative result may have been seen.

Different laboratory staff analysed the specimens. This could mean different technique and lack of proper insight of the study by the different laboratory technicians.

Different theatre teams may also contribute to study limitation due to possible different specimen handling and sampling.

All tubings were from the same company, Alcon. A comparison of tubings from different companies may have showed a different result.

Implications and recommendations

This study has laid a foundation for future studies on re-using phacoemulsification tubing.

Phacoemulsification tubing seems to be contaminated even after only one use despite our efforts to keep the tips sterile during and between procedures. We recommend further research in this field with a larger sample size, one surgeon, use of one laboratory technician and microbiologist. This study has proven sterility of phaco tubings before use but has not proven sterility of phaco tubings even after single use, so safety of patients cannot be guaranteed. Further research in this field is warranted.

Conclusion

Microscopic analysis has shown that there may be growth of micro-organisms in tubings whether they have been used only once or multiple times. Unused tubings were confirmed sterile as no growth of micro-organisms were found. No statistically significant difference between single-used and multi-used tubing was found. Less than half of tubings remained sterile after single and multi-use. Clinically the high rate of contamination is of great concern. Based on this study, multiple re-use of phacoemulsification tubing does not put patients at a much higher risk of infection than post single use. With post single use and multiple re-use safety was not guaranteed due to the high contamination rate. Tested pre-used tubings were not found to be contaminated. Further studies need to be done to gain more insight into patient safety.

Acknowledgements

Dr C. Kruse for his guidance.

Dr R. Rodseth for his valuable input in preparing the protocol.

Dr Tlou for statistical analysis

Author: Dr L T Ndlovu

There are no conflicting interests.

Study was funded by the author.

Views expressed in this study are the authors own and not an official position of the department of health or the hospitals involved.

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Appendices

Appendix 1: The final Study Protocol

TITLE:

A microscopic analysis of single-use VERSUS multi-used phacoemulsification tubing in maintaining
sterility and patient safety

Degree: MMed Ophthalmology

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EXECUTIVE SUMMARY

Statement of purpose

The purpose of this comparative study is to evaluate the Pietermaritzburg guidelines regarding re-using the phacoemulsification (phaco) tubing after cataract surgery. Currently each hospital in the Pietermaritzburg complex has its own guideline. The current guidelines are influenced by understanding how the machine works, maintaining sterility, preventing cross infection and trying to keep the costs low. The manufacturer recommends one phaco tubing for one patient however that is controversial, internationally. These recommendations are not evidence based and may just be for sales. Internationally, the risk of infection and appropriate sterilization procedures for machines with internal tubing is a controversial matter.

In keeping with evidence based medicine, I am looking for microscopic evidence that will assist us in making standard guidelines based on scientific evidence. I will compare three groups from three hospitals in the Pietermaritzburg complex. One hospital uses new phaco tubing for each case, the second hospital changes the phaco tubing after three cases and the last one uses one phaco tubing for the whole slate (six patients or more). Before the tubing is discarded we will cut off a piece and send it to be tested for micro-organisms. This study will be conducted in 2016.

This project is necessary so as to have scientific evidence for choosing the specific guideline and set up a standard protocol. This study is looking at what the three hospitals have been doing for many years and finding common ground through scientific evidence. The results of this study will be relayed to the study hospitals and to other hospitals that offer phacoemulsification. In this way patient safety is improved.

1. DEFINING THE RESEARCH PROBLEM

A cataract is one of the leading causes of blindness worldwide. As a result the World Health Organisation put forward a target of how many cataracts need to be done per surgeon to eliminate blindness from cataract in 2020. This was termed “Vision 2020”.

To be in line with Vision 2020, high volume surgery centres have been set up.

High-volume-cataract surgery centres need to be able to provide quality, safe and fast turnover. Safety of patients, in terms of sterility of the equipment, is what this study will be looking at. We want to evaluate whether sterility is maintained when the phacoemulsification tubing is re-used between patients. Are patients who receive used phacoemulsification tubing in any danger of exposure to contaminated equipment? This is controversial because the tubing with irrigating fluid (ingoing fluid) is separate from the tubing (outgoing fluid) that aspirates the lens material and they are both connected to the sterilised/autoclaved re-usable phaco probe.

2. LITERATURE OVERVIEW AND MOTIVATION

For patients, cataracts mean blurry vision, poor night vision, fading colours and haloes around lights. Phacoemulsification has become the leading technique of cataract extraction worldwide.

Post phacoemulsification endophthalmitis is one of the severest complications of cataract surgery and it may lead to permanent blindness. Micro-organisms can be introduced in any step during surgery. Studies have found that wound incisions are the leading pathway for introducing flora into the eye (1). Equipment sterility is a wide area where micro-organisms can also be introduced. Equipment is often pre-packed to ensure quicker access and usage.

The phaco machine has irrigation tubing and separate aspiration tubing. A study in the European Journal of Ophthalmology in 2012 aimed to determine if there was microbial contamination of the irrigating fluids at the time of phacoemulsification after the use of topical povidone-iodine and antibiotics prophylaxis (2). After each case fluid was collected and sent for microbiology analysis. Results showed that there was contamination of irrigating fluid but preoperative use of antibiotics decreased the rate of endophthalmitis infection.

An article by Carol Rhuel, which was published in the Eucomed white paper in December 2009 explored whether outbreaks of Toxic Anterior Segment Syndrome (TASS) may be caused by contaminated devices (3). In this article, photos were taken with a scanning electron microscope and they were used to illustrate the increasing signs of degradation with continuous phaco tip reuse. The photos showed particulate matter which gathered on the phaco tip. This raised concerns about those small surgical devices that cannot be cleaned sufficiently for reuse without damaging them. The particulate matter on them can be introduced into the next patient's eye and could potentially also harbour micro-organisms.

There have been cases of postoperative endophthalmitis associated with equipment contamination. One study's purpose was to set up a model for the assessment, investigation and management of an atypical outbreak of infectious endophthalmitis of unknown cause in London in 2003 (4). A multidisciplinary infection control team was formed with the aim of identifying potential causative factors. These factors included analysing the theatre and its surrounding environment, pre-operative preparation, intra-operative theatre and surgical practices, post-operative practices, equipment maintenance guidelines, cleaning and sterilisation practices and microbiological screening. Five cases of endophthalmitis following uncomplicated phacoemulsification, by different surgeons, were noted over a 7-month period. Three cultures grew *Streptococcus viridans* of different strains, 1 culture grew *Staphylococcus aureus* and no organisms grew on the last culture. Without a single causative factor, it was

postulated that it was a combined effect of many possible factors that led to increased bacterial load and subsequent infection rate. Recommendations were made which included new cleaning protocols to prevent the build-up of debris on the phacoemulsification tubing.

In another article by Lesley et al (5) the importance of meticulous cleaning of phaco hand pieces to prevent endophthalmitis was elaborated. Automated flushing is superior to manual cleaning of the instruments in preventing interpatient transfer of infection. Automated flushing did not, however, eliminate contamination but it decreased it (6). In other branches of medicine manual cleaning and flushing of instruments with small lumens prior to sterilization proved more effective in eliminating inter patient contamination.

Studies have looked at cross infection from contaminated phaco hand pieces and irrigating fluid. There is no study that has solely looked at the role of tubing in isolation. One such study was done in 2014 at the University of Sao Paulo where they found viral contamination of phaco probes and tubing, gloves, surgical instruments and irrigating fluid after sequential phaco was done in contaminated and non-contaminated models(7).

2.2. References

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3. AIMS AND OBJECTIVES

3.1. Aim:

To assess if phacoemulsification tubing remains sterile during sequential phacoemulsification.

3.2. Objectives:

To draft a protocol regarding re-using phaco tubing during sequential phacoemulsification.

To investigate if there is growth of micro-organisms from phaco tubing that are re-used in sequential phacoemulsification at the two of three sites.

To investigate and compare micro-organisms, if identified, from each specimen (piece of sterile phaco tubing) that will be sent for culture

4. METHODS

The study will be conducted at Greys Hospital, Edendale Hospital and Northdale Hospital over a one-month period. Routine phaco procedure will be done as per hospital guidelines. Just before the tubing is discarded, a piece will be cut off, placed in a sterile specimen container and sent to the laboratory. At the laboratory it will then be incubated in a Broth medium overnight then transferred on to Agar plates for culture.

- We will use these three hospitals because they all currently have different protocols on used phacoemulsification tubing:
- At Greys Hospital new phaco tubing is used for each case.
- At Edendale Hospital, phaco tubing is reused on three sequential patients on one slate.

- At Northdale Hospital one phaco tubing is used for the entire slate of six patients.

Patient details will not be recorded.

4.1. Study Design

This is an analytical cross sectional study.

4.2. Setting

The study will be conducted at Greys Hospital, Edendale Hospital and Northdale Hospital in Pietermaritzburg, KwaZulu-Natal, South Africa.

Permission has not been granted yet - awaiting BREC approval.

4.3. Participant Selection

This is a study of a surgical device and not people. All used phacoemulsification tubing will be microscopically analysed.

4.4. Measurements

Each piece of tubing sent as a specimen will be incubated in a Broth medium and then transferred to Agar plate for culture. There are no studies done where irrigation tubing were cultured, one study that comes close was the study on CVP tips. CVP tips were cultured and compared with blood culture. In this study, the microscopic results from each piece of phaco tubing will be analysed. Bacteria that usually grow in tubes include Staphylococcus Epidermidis, Staphylococcus aureus and Pseudomonas. As this is sterile

tubing, no growth is expected on culture. Any growth will therefore be significant. Specimens from the different hospitals will be compared and so will the results. It will be interesting to note whether after six cases the density of growth or the number of micro-organisms will be more after six cases when compared to three or one case. Recommendations based on microscopic evidence will be made.

4.5. Data Selection and Statistical Analysis

Data selection

Phacoemulsification cases will be selected as per theatre booking. Before the tubing is discarded a piece will be cut and placed in a sterile bag before being sent to the laboratory. Data collection will start from 01/08/2016 until 31/08/2016.

Statistical analysis

We will report the incidence and 95% confidence interval of bacterial growth for each hospital. The difference in both incidence and density of growth will be analysed using Fisher exact test.

4.5.1. Data collection sheet

Table 1: Data Collection

Date sent	Hospital	Study Number of the tubule sent	Number of cataract cases done with that tubing	Culture results

4.5.2. Sample size

A total sample size is estimated at about 76 phacoemulsification tubing will be microscopically analysed. About 12 tubing will be collected from Northdale Hospital, 28 tubing from Greys Hospital and 40 tubing from Edendale Hospital. Statistical calculations will calculate the accuracy of our estimate of average and range.

5. ETHICAL CONSIDERATIONS

Patients will not be enrolled for the study. No patient consent or record is required. The state laboratory will be used to analyse our phacoemulsification tubing. Future patients will benefit because recommendations will be made to improve patient safety by maintaining sterility. Conflict of interest may be present as this study is done towards a degree.

6. BUDGET

Table 2: Budget

Item Description	Cost
stationery	R500
Petrol	R200
Northdale Hospital	R1200
Edendale Hospital	R4000
Greys Hospital	R2800
Total Project Cost	R8700

We have liaised with the Northdale Hospital Microbiology Laboratory and they will assist us with this study.

The author will not be seeking funding for this project.

7. TIME LINES AND PROJECT MANAGEMENT

Phacoemulsification is performed twice per week at Northdale Hospital and at Greys Hospital. It is performed daily at Edendale Hospital. Specimens will be collected by the surgeon, marked for the study and sent to the laboratory.

The collection of data will take place in August 2016 (pending bioethical approval). Write-up of the study will be completed before the end of 2016.

8. CONTRIBUTORS AND AUTHORSHIP

Table 3: Contributors and Authorship

Name	Department	Department	Author or acknowledgement
Dr L T Ndlovu	Ophthalmology	Principal Investigator	Author
Dr C Kruse	Ophthalmology	Supervisor	acknowledgement

9. APPENDICES

9.1. Ethics certificate



9.2. Curriculum Vitae (Principal investigator)

Lungile Thandeka Ndlovu
Address: 37 Forsdick Road
Glenmore
Durban
Cell 27828558797
Date of Birth 03rd October 1977
E-mail lungile.yumba@yahoo.com

EDUCATION

High School 1990 – 1994
University 1995 – 2002

Vukuzakhe High School
University of Cape Town

EMPLOYMENT

Present Position:

Registrar July 2012 – Present

Greys Hospital

Previous Positions held

Internship 2003 - 2004

Addington Hospital

Community Service 2004

King Edward Hospital

Medical Officer Jan 2005 – January 2006

Prince Mshiyeni

Hospital

Registrar Feb 2006 – June 2008

St Aidan's Hospital

Medical Officer July 2008 – June 2012 Prince Mshiyeni Hospital

QUALIFICATION

MBChB: University of Cape Town

Area of study: Ophthalmology

9.2. Curriculum Vitae (Supervisor)

Full name: Dr Carl-Heinz Kruse

Date of birth: 1975-06-29

Male/Female: Male

Telephone (Home): 031 811 8130

Telephone (Business): 033 897 3345

Cell: 084 011 0767

Fax No: 033 897 3111

E-mail Address: ruraleye@gmail.com

Current HPCSA No: MP 0532851

Present position: Head of Clinical Unit

Institution: Grey's Hospital

Department/Section: Ophthalmology

Nationality and Permanent residency: RSA

Previous positions held (last 10 years):

Principal Specialist: Ngwelezana Hospital (2008 – 2010)

Registrar: St Aidan's Hospital (2004 – 2007)

MO: Ermelo Hospital, Edendale Hospital (2002 – 2004)

Qualifications: MBChB: University of Pretoria 2000

MMed(Ophth): UKZN 2008

FCOphth: CMSA 2007

Area of study: Ophthalmology

Number of Postgraduate theses supervised (Masters): 4

Publication list over the past 3 years:

Kruse C. What is the ideal treatment of diabetic macular oedema? *S Afr J Diabetes Vasc Dis* 2013;**10**:120-121

Kruse C. The effects of systemic medication on diabetic retinopathy. *S Afr J Diabetes Vasc Dis* 2014;**11**:00–00

Details of all other research studies presently being conducted:

Appendix 2: The Guidelines for the African Vision and Eye Health Journal

Cover Letter

The format of the compulsory cover letter forms part of your submission. It is located on the first page of your manuscript and should always be presented in English. You should provide the following elements:

Full title: Specific, descriptive, concise, and comprehensible to readers outside the field, max 95 characters (including spaces).

Tweet for the journal Twitter profile: This will be used on the journal Twitter profile to promote your published article. Max 101 characters (including spaces). If you have a Twitter profile, please provide us your Twitter @ name. We will tag you to the Tweet

Full author details: The title(s), full name(s), position(s), affiliation(s) and contact details (postal address, email, telephone, highest academic degree, Open Researcher and Contributor Identification (ORCID) and cell phone number) of each author.

Corresponding author: Identify to whom all correspondence should be addressed.

Authors' contributions: Briefly summarise the nature of the contribution made by each of the authors listed.

Disclaimer: A statement that the views expressed in the submitted article are his or her own and not an official position of the institution or funder.

Source(s) of support: These include grants, equipment, drugs, and/or other support that facilitated conduct of the work described in the article or the writing of the article itself.

Summary: Lastly, a list containing the number of words, pages, tables, figures and/or other supplementary material should accompany the submission.

Anyone that has made a significant contribution to the research and the paper must be listed as an author in your cover letter. Contributions that fall short of meeting the criteria as stipulated in our policy should rather be mentioned in the 'Acknowledgements' section of the manuscript. Read our authorship guidelines and author contribution statement policies.

Original Research Article full structure

Title: The article's full title should contain a maximum of 95 characters (including spaces).

Abstract: The abstract, written in English, should be no longer than 250 words and must be written in the past tense. The abstract should give a succinct account of the objectives, methods, results and significance of the matter. The structured abstract for an Original Research article should consist of six paragraphs labelled Background, Aim, Setting, Methods, Results and Conclusion.

Background: Summarise the social value (importance, relevance) and scientific value (knowledge gap) that your study addresses.

Aim: State the overall aim of the study.

Setting: State the setting for the study.

Methods: Clearly express the basic design of the study, and name or briefly describe the methods used without going into excessive detail.

Results: State the main findings.

Conclusion: State your conclusion and any key implications or recommendations.

Do not cite references and do not use abbreviations excessively in the abstract.

Introduction: The introduction must contain your argument for the social and scientific value of the study, as well as the aim and objectives:

Social value: The first part of the introduction should make a clear and logical argument for the importance or relevance of the study. Your argument should be supported by use of evidence from the literature.

Scientific value: The second part of the introduction should make a clear and logical argument for the originality of the study. This should include a summary of what is already known about the research question or specific topic, and should clarify the knowledge gap that this study will address. Your argument should be supported by use of evidence from the literature.

Conceptual framework: In some research articles it will also be important to describe the underlying theoretical basis for the research and how these theories are linked together in a conceptual framework. The theoretical evidence used to construct the conceptual framework should be referenced from the literature.

Aim and objectives: The introduction should conclude with a clear summary of the aim and objectives of this study.

Research methods and design: This must address the following:

Study design: An outline of the type of study design.

Setting: A description of the setting for the study; for example, the type of community from which the participants came or the nature of the health system and services in which the study is conducted.

Study population and sampling strategy: Describe the study population and any inclusion or exclusion criteria. Describe the intended sample size and your sample size calculation or justification. Describe the sampling strategy used. Describe in practical terms how this was implemented.

Intervention (if appropriate): If there were intervention and comparison groups, describe the intervention in detail and what happened to the comparison groups.

Data collection: Define the data collection tools that were used and their validity. Describe in practical terms how data were collected and any key issues involved, e.g. language barriers.

Data analysis: Describe how data were captured, checked and cleaned. Describe the analysis process, for example, the statistical tests used or steps followed in qualitative data analysis.

Ethical considerations: Approval must have been obtained for all studies from the author's institution or other relevant ethics committee and the institution's name and permit numbers should be stated here.

Results: Present the results of your study in a logical sequence that addresses the aim and objectives of your study. Use tables and figures as required to present your findings. Use quotations as required to establish your interpretation of qualitative data. All units should

conform to the SI convention and be abbreviated accordingly. Metric units and their international symbols are used throughout, as is the decimal point (not the decimal comma).

Discussion: The discussion section should address the following four elements:

Key findings: Summarise the key findings without reiterating details of the results.

Discussion of key findings: Explain how the key findings relate to previous research or to existing knowledge, practice or policy.

Strengths and limitations: Describe the strengths and limitations of your methods and what the reader should take into account when interpreting your results.

Implications or recommendations: State the implications of your study or recommendations for future research (questions that remain unanswered), policy or practice. Make sure that the recommendations flow directly from your findings.

Conclusion: Provide a brief conclusion that summarises the results and their meaning or significance in relation to each objective of the study.

Acknowledgements: Those who contributed to the work but do not meet our authorship criteria should be listed in the Acknowledgments with a description of the contribution. Authors are responsible for ensuring that anyone named in the Acknowledgments agrees to be named.

Also provide the following, each under their own heading:

Competing interests: This section should list specific competing interests associated with any of the authors. If authors declare that no competing interests exist, the article will include a statement to this effect: The authors declare that they have no financial or personal relationship(s) that may have inappropriately influenced them in writing this article. Read our policy on competing interests.

Author contributions: All authors must meet the criteria for authorship as outlined in the authorship policy and author contribution statement policies.

Funding: Provide information on funding if relevant

Disclaimer: A statement that the views expressed in the submitted article are his or her own and not an official position of the institution or funder.

References: Authors should provide direct references to original research sources whenever possible. References should not be used by authors, editors, or peer reviewers to promote self-interests. Refer to the journal referencing style downloadable on our Formatting Requirements page.

Appendix 3: Ethical approvals



health

Department:
Health

PROVINCE OF KWAZULU-NATAL

GREYS HOSPITAL

OFFICE OF THE CEO

Private Bag X 9001, Pietermaritzburg, 3200

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Tel.: 033 - 897 3321 Fax: 033 - 8973398

To: Dr L.T. Ndlovu Department of Ophthalmology - Grey's Hospital cc: Mr. B. Bond - NY-ILS Laboratory — Grey's Hospital	
From: Mrs. K.T. McKenzie	Acting CEO - Grey's Hospital
Date: 9 November 2016	
Re: Request for permission to conduct research: A microscopic analysis of new versus multi-used phacoemulsification tubing in maintaining sterility and improving patient safety	

Dear Dr Ndlovu

Your request to conduct research at Grey's Hospital refers.

Permission to conduct the above study is hereby granted under the following conditions: ● Your provisional ethics approval and research protocol are assumed to be valid and final ethics approval is a prerequisite for conducting your study at our hospital. Once obtained from BREC, please submit a copy of the full ethics approval;

You are also required to obtain approval for your study from the Provincial Department of Health KZN Health Research Unit (HRKMU) prior to commencing your study at Grey's Hospital. You will find more information on their website: <http://www.kznhealth.gov.za/hrkm.htm>

Confidentiality of hospital information, including staff and patient medical and/or contact information, must be kept at all times; Patient records are not to be removed from the hospital premises nor are you allowed to photocopy/ photograph them.

You are to comply with the data collection process described in your attached email, and segregate research resources (tubing, laboratory specimens, etc.) from Grey's hospital's resources to avoid charges to the hospital. Non-compliance thereof will result in retraction of gatekeeper permission and reporting this to BREC and HRKMU. ● You are to ensure that your data collection process will not interfere with the routine services at the hospital;

Informed consent is to be obtained from all participants in your study, if applicable;

Policies, guidelines and protocols of the Department of Health and Grey's Hospital must be adhered to at all times;

Professional attitude and behaviour whilst dealing with research participants must be exhibited;

The Department of Health, hospital and its staff will not be held responsible for any negative incidents and/or consequences, including injuries and illnesses that may be contracted on site, litigation matters, etc. that may arise as a result of your study or your presence on site; ● You are required to submit to this office a summary of study findings upon completion of your research.

You are requested to make contact with the HCD of Surgery, Dr Govindasamy, at Grey's Hospital once you are ready to commence data collection.

Recommended by
Dr L Naidoo
Senior Manager- Medical Services

Approved by
Mrs. .T. McKenzie
Acting Hospital CEO



health

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PROVINCE OF KWAZULU-NATAL

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Edendale Hospital

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Date: 11 November 2016

Dr L.T Ndlovu
Discipline of ophthalmology
School of Clinical Medicine

Dear Dr Ndlovu

**REQUEST TO CONDUCT RESEARCH STUDY: A MICROSCOPIC ANALYSIS OF NEW
VS REUSED PHACOEMULSIFICATION TUBINGS IN MAINTAINING STERILITY AND
IMPROVING PATIENT SAFETY**

Your letter dated 29 August 2016 is acknowledged and refers.

I have pleasure in informing you that permission has been granted to you by Edendale hospital to conduct research.

Please note the following

1. Please ensure that you adhere to all policies, procedures, protocols and guidelines of the Department of Health with regards to this research.
2. Please ensure that this office is informed before you commence your research.
3. The hospital will not provide any resources for this research
4. You will be expected to provide feedback on your findings to the CEO/Medical Manager's office at the end of your research.

Yours Sincerely

Dr O.G Ojo
Acting Chief Executive Officer
Edendale Hospital



UNIVERSITY OF
KWAZULU-NATAL
INYUVESI
YAKWAZULU-NATALI

19 July 2016
Dr Carl-Heinz Kruse
Dept. of Ophthalmology

MMED PROTOCOL: "A microscopic analysis of new VERSUS multi-used phacoemulsification tubing in maintaining sterility and improving patient safety"

Student: Dr LT Ndlovu, Student Number: (Department of Ophthalmology)

I am pleased to inform you that the abovementioned protocol has been approved.

Please note:

The Academic Leader: School Research must review any changes made to this study.

The study may not begin without the approval of the Biomedical Research Ethics Committee.

, A copy of the full ethics approval letter should be forwarded to the Postgraduate Office.

May I take this opportunity to wish the student every success with the study.

Yours sincerely

Lushy Konar

Postgraduate Administrator

Biomedical Research Ethics Committee

Westville Campus

Postgraduate, Higher Degrees & Research

School of Clinical Medicine, NRMSM Campus

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1910 - 2010

100 YEARS OF ACADEMIC EXCELLENCE

Founding Campuses: Edgewood Howard College

Medical Woo!

Pietermaritzburg

Westville

BIOMEDICAL RESEARCH ETHICS COMMITTEE



NAME OF RESEARCHER: Dr Lungile Thandeka Ndlovu

DEPARTMENT: Ophthalmology

TITLE OF STUDY: A microscopic analysis of new VERSUS used phacoemulsification tubing in maintaining sterility and improving patient safety

ETHICS REFERENCE NO: BE450/16

DATE OF ETHICAL APPROVAL OF STUDY: 11/01/2017

DATE OF AMENDMENTS: 10/04/2017

AMENDMENTS REQUESTED:

Protocol states: in 4.5.2 (sample size)

A total sample size is estimated at about 76 phacoemulsification tubing which will be microscopically analysed. About 12 tubing will be collected from Northdale Hospital, 28 tubing from Greys Hospital and 40 tubing from Edendale Hospital.

Amendment requested

Removal of Northdale Hospital as one of the participants in this study.

Reason for amendment

This amendment is necessary as Northdale Hospital has suspended all ocular surgery as from 01/04/2017. No phacoemulsification procedures will be done until a permanent doctor is employed by the hospital or Greys Hospital Eye Clinic has enough staff to send a doctor to Northdale to assist with ocular surgery. This study will then only compare two hospitals, Greys Hospital and Edendale Hospital. This will not affect the study negatively as Edendale Hospital just like Northdale Hospital reuses phacoemulsification tubing.

SIGNATURE OF PRINCIPAL RESEARCHER:.....DATE: ...10/04/2017.....



health

Department:
Health
PROVINCE OF KWAZULU-NATAL

330 Langalibalele street,
Private Bag X9051 PMB, 3200
Tel: 033 395 2805/3189/3123 Fax: 033 394 3782
Email: hrkm@kznhealth.gov.za
www.kznhealth.gov.za

DIRECTORATE:

Health Research & Knowledge
Management (HRKM)

Reference: HRKM420116

KZ-2016RPO 15

13 December 2016

Dear Dr L T Ndlovu
(University of KwaZulu-Natal)

Subject: Approval of a Research Proposal

The research proposal titled 'A microscopic analysis of new VERSUS reused phacoemulsification tubing in maintaining sterility and improving patient safety' was reviewed by the KwaZulu-Natal Department of Health (KZN-DoH).

The proposal is hereby approved for research to be undertaken at Greys, Northdale and Edendale Hospitals.

You are requested to take note of the following:

Make the necessary arrangement with the identified facility before commencing with your research project.

Provide an interim progress report and final report (electronic and hard copies) when your research is complete.

Your final report must be posted to HEALTH RESEARCH AND KNOWLEDGE MANAGEMENT, 10-102, PRIVATE BAG X9051, PIETERMARITZBURG, 3200 and e-mail an electronic copy to hrkm@kznhealth.gov.za

For any additional information please contact Ms G Khumalo on 033-395 3189.

Yours Sincerely

Dr E Lutge
Chairperson, Health Research Committee

Date: U 21/16.

Appendix 4: Raw data (example)

NATIONAL HEALTH
LABORATORY SERVICE

Practice Number 5200296

NORTHDALÉ LABORATORY

Private Bag X 9006, Pietermaritzburg, KZ, 3200

Tel : 033 387 2502, Fax: 033 387 9035

pg 1 of 1

FULL FINAL LABORATORY REPORT

LAB NUMBER: E1 01334461

PATIENT :

REPORT TO:

Control 3 PHACO STUDY

DOB not stated Sex -

Sample Ref :

ABCU0572D

DR NDLOVU

Collected:

18/04/2017 2

Received :

18/04/2017 10:10

Study: Dr LT Ndlovu

1st Print:

23/04/2017 16 :20

37 Forsdick Road

Reprint :

06/06/2017 14:23

Carrington Heights

KwaZulu-Natal 4001

Patient Location:

Study: Dr LT Ndlovu, -

FOR ENQUIRIES AND FOLLOW-UP TESTS, PLEASE QUOTE PATIENT'S MRN NUMBER MRN70490666

MICROBIOLOGY

Specimen received: Miscellaneous Tests requested: Cult

Bacterial Culture :

No growth after 2 days

Authorised by: ZS zwane (Medical Technologist) Cult

--End of Laboratory Report--

FULL FINAL LABORATORY REPORT

LAB NUMBER: EI 01334460

PATIENT :

REPORT TO:

Control 4 PHACO STUDY

DOB not stated Sex -

Sample Ref : ABGU0573D

DR NDLOVU

Collected: 18/04/2017 2

Received : 18/04/2017 10:42

Study: Dr LT Ndlovu

1st Print: 23/04/2017 16 :20

37 Forsdick Road

Reprint : 06/06/2017 14:24

Carrington Heights

KwaZulu-Natal 4001

Patient Location: Study: Dr LT Ndlovu, -

FOR ENQUIRIES AND FOLLOW-UP TESTS, PLEASE QUOTE PATIENT'S MRN NUMBER MRN70490576

MICROBIOLOGY

Specimen received : Miscellaneous Tests requested: Cult

Bacterial Culture:

No growth after 2 days

Authorised by: ZS Zwane (Medical Technologist) Cult

--End of Laboratory Report--