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VIsual outcomes in manual small incision cataract surgery versus phacoemulsification: A prospective comparative data analysis

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VISUAL OUTCOMES IN MANUAL SMALL INCISION CATARACT SURGERY VERSUS PHACOEMULSIFICATION: A PROSPECTIVE COMPARATIVE DATA ANALYSIS

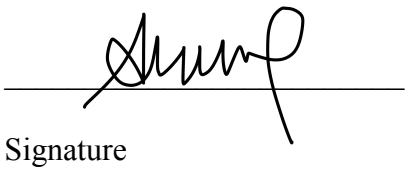
Sanushka Moodley

A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Master of Medicine in the branch of Ophthalmology.

Johannesburg, May 2019

DECLARATION

I, Sanushka Moodley, declare that this research report is my own, unaided work. It is being submitted for the Degree of Master of Medicine at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.



Signature

30th day of May 2019 in Johannesburg

ABSTRACT

Purpose:

The aim of the study was to compare the visual outcomes, namely surgically induced astigmatism and visual acuity, of phacoemulsification cataract surgery with manual small incision cataract surgery (MSICS).

Method and Design:

The study design was a prospective comparative interventional cohort study. Patients were collected over a 13-month period - September 2016 to October 2017. Participants were patients routinely booked for elective cataract surgery at the Helen Joseph Hospital. Patients were assigned to either receiving phacoemulsification or manual small incision cataract surgery depending on the maturity of their cataract – as is routinely done. Keratometry was measured preoperatively and 6 weeks post-operatively, and visual acuity was assessed at 6 weeks post-operatively.

Results:

100 eyes from 92 patients were enrolled in the study, 48 patients in the MSICS group and 44 patients in the phacoemulsification group. Surgically induced astigmatism was comparable between the two groups with a median value of 0.95 dioptres in the phacoemulsification group and 1.13 dioptres in the MSICS group ($p= 0.25$) when assessed with a univariate median regression. The p-values became even less significant when a multivariate median regression was performed using surgically induced astigmatism as the outcome and type of surgery, age and gender as the predictors.

Uncorrected visual acuity 6 weeks post-operatively was comparable between the two groups ($p =0.24$). Best corrected visual acuity at 6 weeks was also comparable, ($p =0.07$).

Conclusion:

There was no statistical difference in the visual outcomes between phacoemulsification and manual small incision cataract surgery. The teaching of manual small incision cataract surgery should be promoted in the public health system to replace large limbal extracapsular cataract extraction as its outcomes are comparable to phacoemulsification- the gold standard. In doing so, this could increase our cataract surgery rate and reduce patient follow up time.

AKNOWLEDGEMENTS

To Dr Kerry Alberto (Supervisor and the Head of the Ophthalmology Department at Helen Joseph Hospital), thank you for your unconditional support and especially for embracing manual small incision cataract surgery and encouraging it in your department.

To the Consultants, registrars, medical officers and optometrists at Helen Joseph Hospital – thank you for your participation and assisting me with data collection.

Dr Naseer Ally, Consultant at St John Eye hospital – Thank you for all your help and guidance with the statistics.

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LIST OF ABBREVIATIONS

WHO	World Health Organisation
ECCE	Extracapsular cataract extraction
MSICS	Manual Small Incision Cataract Surgery
SIA	Surgically Induced astigmatism
IQR	Interquartile range
Phaco	Phacoemulsification

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1.0 CHAPTER 1 – INTRODUCTION

1.1 Background

Cataract is one of the leading causes of blindness in South Africa[1]. It is responsible for about 50% of the prevalence of blindness and is a national health priority.[1] Globally, the incidence of poor vision due to blinding cataract is at least 25 million eyes per year [2]. An age-related cataract occurs when the natural lens in the eye becomes opacified over time, its starts off with mild blurring of the vision and progresses to a point where hand movements and sometimes only light is perceived by the eye – this is referred to as a dense, blinding cataract.

"Vision 2020 – the right to sight", a joint program by the World Health Organisation (WHO) and the International Agency for the Prevention of Blindness, aims to eliminate blindness due to cataract by reducing the backlog of cataract surgery in a sufficient and sustainable manner by the year 2020. In order for this to be achieved, the number of operations per year need to keep up with the incidence of operable cataracts. Also, in order to achieve sustainability, the cost of surgery should be kept as low as possible without jeopardising visual outcome[2].

Many of the elderly patients requiring surgery are not situated in urban areas and are being serviced by outreach programs. With ongoing urbanisation, the demand for cataract surgery at secondary and tertiary centres has increased and will continue to do so. We know that in tertiary settings such as ours, increasing the amount of staff to deal with the increasing number of patients isn't always feasible. We could however increase our surgical capacity to eradicate the burden of blinding cataracts.

Cataracts can only be managed surgically. Extracapsular cataract extraction (ECCE) is the main type of cataract surgery done worldwide. This is where the lens capsule is opened anteriorly, the cataract removed and an artificial lens is placed and left in the capsular bag - closest to its normal anatomical position. An ECCE can either be manual or automated. The manual techniques require a manual wound construction, manual cataract retrieval and manual intraocular lens

insertion. Phacoemulsification is the automated technique where incisions are just big enough to pass the phacoemulsification probe into the eye (2.5-4mm), the cataract is then grooved allowing it to be cracked into smaller pieces and these are extracted by the phacoemulsification probe, a foldable intraocular lens is injected into the capsular bag where it unfolds.

Phacoemulsification is currently the gold standard across the globe, and in our public hospital setting, is the method of choice for removing less mature cataracts which are not necessarily blinding but symptomatic. It can be used to removed hard cataracts but if it's not done by a skilled surgeon with the additional tools and consumables required, it can result in significant corneal endothelial cell loss which ultimately leads to corneal decompensation and opacification of the cornea.

Manual extracapsular cataract extraction is the method of choice in our setting for removing hard dense cataracts and is still routinely done with the conventional large (10-12mm) limbal-based incision at many institutions. It is cheaper than phacoemulsification but the surgery takes longer. Because sutures are placed to close the wound, the patients follow up for quite some time as sutures are removed at 3 months post-operatively and the patient will only have their final refraction 6 weeks after that. Manual small incision cataract surgery (MSICS) has shown to be far better in terms of visual outcomes in comparison to the conventional "limbal-based" ECCE as the cataract is removed manually through a smaller self-sealing wound. Sutureless surgery also reduces surgery time. This type of surgery therefore allows low-cost, high-volume surgery vs the conventional "limbal-based" ECCE and has been shown to have similar visual outcomes to phacoemulsification [3–9]. Studies also show that post-operative astigmatism and endothelial cell counts are comparable between the two types of surgery.[3–5,10,11]

Many patients with dense blinding cataracts in our Ophthalmology department undergo the conventional "limbal –based" ECCE and intraocular lens implantation due to surgeon preference. Because of its wider incision and sutures it requires a longer time to visual rehabilitation and higher degrees of post-operative surgically induced astigmatism. MSICS has shown to be superior

"limbal-based" ECCE in this regard[12,13]. In certain areas like the rural Eastern Cape, MSICS was introduced to the local surgeons as a means to cope with cataract backlog providing a low-cost, high- turnover service, which also reduces patient follow up visits and hence travel costs to the patients. At institutions such as the Tilganga Eye Hospital in Kathmandu, Nepal, experienced surgeons do 8-10 MSICS per hour and up to 2000 operations a week [4].

According to the WHO, the required surgery rate target should be 2000 per million population per year. This was reduced by local authorities to 1500 in 2010 as targets weren't being met [1]. Reducing the target doesn't help in eradicating blinding cataracts, it only worsens the load. Because MSICS is a quick effective procedure, it is ideal for high-volume surgery in places with a huge cataract burden like South Africa.

1.2 Advantages of MSICS

- Small incision with self-sealing wound
- Less surgical-induced astigmatism
- Use of a low cost intraocular lens
- Short duration of surgery
- Fast turnaround time for high volumes
- Low cost in terms of equipment
- Successful visual recovery
- Can be done on all types of cataract

1.3 Disadvantages of MSICS

- Requires larger incision than phacoemulsification
- Not suitable for keratorefractive surgery patients

1.4 MSICS versus Limbal-based ECCE

Studies have shown that MSICS is significantly superior to limbal-based ECCE in terms of surgically induced astigmatism.[10,14,15] Best corrected visual acuity at 6 weeks is also better in MSICS as well as Day 1 post-operative uncorrected vision. Limbal-based ECCE is more time consuming as it requires suturing.[3,13] The sutureless nature of MSICS shortens surgical time and reduces time to visual rehabilitation.[10,13] Economically, both of these surgeries come in at just under $16 per case.

1.5 MSICS versus Phacoemulsification

Although phacoemulsification is the modern way of doing cataract surgery with impressive post-operative visual outcomes, MSICS has been shown to provide similar outcomes more cost-effectively – making it ideal for low-income settings.[4–8,10] Some studies found no difference in visual outcomes between the two procedures. [4–8]

Results from a South African randomised control trial showed better unaided visual acuity in phacoemulsification patients at 8 weeks postoperatively but at 8 months, visual acuity was comparable between the two operations.[6] Surgically induced astigmatism was found to be far less in phacoemulsification in a meta-analysis involving 1315 eyes.[5] It has also been suggested that MSICS is superior to phacoemulsification for hard age-related cataracts, as the increased phaco power needed to remove them and the resultant longer time spent in the anterior chamber causes more endothelial cell loss than with routine MSICS.

1.6 Null Hypothesis

There is no statistically significant difference between the surgically induced astigmatism and 6-week post-operative visual acuity between phacoemulsification and manual small incision cataract surgery.

1.7 Study Objectives

The primary objective is to analyse and compare surgically induced astigmatism at 6-weeks post-operatively between MSICS and phacoemulsification by comparing pre-operative keratometry with post-operative keratometry in each group. The secondary objective would be to compare post-operative visual acuity, both uncorrected and best corrected, at 6-weeks post-operatively.

2.0 CHAPTER 2: METHODOLOGY

2.1 Study design

This was a prospective comparative interventional cohort study. The study was based at Helen Joseph Hospital's Eye Department. Patients were consented for participation on their pre-operative visit if they met the criteria. The first 50 of these patients to complete 6-week follow-up in each group were included in the study. Data collection commenced in September 2016 and was completed in October 2017.

2.2 Ethical considerations and Approval

Ethical approval was granted by the Human Research Ethics Committee of the University of Witwatersrand. (Ethics approval number M160820 – See Appendix A).

Permission to conduct research at Helen Joseph Hospital was granted by Dr M Mukansi -Chairperson of the Helen Joseph Hospital Ethics and Research committee, as well as Dr Kerry Alberto – Head of the Ophthalmology Department at Helen Joseph Hospital.

The patients' names and folder numbers were kept confidential by the primary investigator.

2.3 Study population

Participants were from the Helen Joseph Hospital drainage area. Patients were from all ethnicities. All cataract patients above the age of 18 were eligible for participation unless they met the exclusion criteria.

The exclusion criteria included:

- Any other known pathology contributing to visual impairment such as corneal pathology, glaucoma, high refractive error, amblyopia, retinal pathology or optic neuropathy (in the cases where there was no preoperative view of the fundus, a postoperative pathological fundus finding resulted in exclusion from the study despite initial enrolment)
- History of refractive surgery
- Poor post-operative treatment compliance or follow-up compliance
- Intraoperative/ post-operative complications such as capsular tear, vitreous loss, no intraocular lens insertion, post-operative severe inflammation, severe post-operative corneal oedema.
- Suturing of surgical incisions

2.4 Method

Patients were routinely booked for elective cataract surgery after being examined by a consultant or registrar in the clinic as is normally done. At this initial visit they were assigned to either phacoemulsification or MSICS based on the

surgeon's clinical discretion. Essentially, hard dense cataracts were booked for MSICS, softer less mature cataracts were booked for phacoemulsification as is routinely done. It is important to note that severity of the cataract has no gross effect on visual outcome if the patient has no other ocular pathology. Patients came for the usual pre-operative assessment the day before surgery to ensure everything is in order for surgery the following day. On this pre-operative assessment patients were informed of the study if they met the pre-operative criteria and upon agreeing, signed the consent for participation.

Surgeons included medical officers, registrars and consultants. Phacoemulsification was done with a 2.8mm clear corneal incision, main incision placement was at the surgeon's discretion. MSICS was done with either straight or frown scleral incision superiorly. Surgery had to be uneventful with no post-operative complications and good follow-up compliance to be included in this study.

The study didn't require any additional visits, patients were routinely seen at 1 or 2 weeks post-operatively (at the surgeon's discretion) and then at 6 weeks for post-operative refraction. For the study, data was collected on the pre-operative visit and at the 6-week post-operative visit. MSICS patients were excluded at the first postoperative visit if it was found that they had posterior segment pathology contributing to poor visual acuity that couldn't be seen preoperatively.

Initial preoperative keratometry was obtained from optical biometry measurements done with the Carl Zeiss IOL Master ®. At the 6-week visit, visual acuity was measured with a Snellen Chart and post-operative keratometry was measured with the NIDEK ARK-510A.

2.5 Data collection

Data collection commenced in September 2016 and ran until October 2017. The initial pre-operative data was captured on the collection sheet by the medical officers admitting the patients for surgery. The patients' names and folder numbers were recorded on the data sheet purely to prevent duplication and were

not used in the study. The type of surgery was recorded along with the which eye was being operated. The Surgeon's name and competency level was purposefully not recorded. The date of the surgery was also noted. The pre-operative IOL Master® keratometry readings were transcribed from the biometry measurements and a short questionnaire regarding the exclusion criteria was completed on the data sheet by the admitting doctor. At the 6-week post-operative visit, patients were refracted by the optometrists and uncorrected and best corrected visual acuities were recorded. The optometrists also remeasured keratometry using the NIDEK ARK-510A autorefractor/ keratometer. The optometrists captured this 6-week data onto the collection sheet and the completed data collection sheets were kept in a folder for the primary investigator. While analysing the data collection sheets, participants were removed from the study at the 6-week visit if they had an intraoperative or post-operative finding that met the exclusion criteria. Data was captured onto an excel spreadsheet by the primary investigator. The pre and post-operative cylinder and axis (amount of astigmatism) from the keratometry readings were recorded for each patient. The surgically induced astigmatism was calculated with the SIA Calculator Version 1.0 - a free mobile application developed by Yor. This calculator has been programmed to calculate the amount of astigmatism induced by cataract surgery by means of vector analysis. It requires the pre-operative and post-operative keratometry power and axis readings. The calculated surgically induced astigmatism was recorded for each patient on the excel spread sheet.

2.6 Statistical analysis

The sample size was calculated using an independent t-test, a difference of astigmatism of 0.5 Dioptres and a standard deviation of 0.8 Dioptres. Assuming 80% power and a type-1 error rate of 0.05, we calculated that we would need 84 patients in total or 42 in each group to achieve significance. If you assume a 20% dropout rate this would take us to 100 participants. We thus decided on 50 patients per group.

Descriptive statistics such as median and interquartile range (IQR) were used for non-normally distributed data. The Wilcoxon Rank Sum test was used to assess if there was a statistically significant difference between the two groups for continuous variables. Spearman's correlation coefficient was used to assess if there was any relationship between surgically induced astigmatism and uncorrected visual acuity in each group.

A univariate median regression analysis was performed with surgically induced astigmatism as the outcome and the two groups as the predictor. A multivariate median regression analysis was also performed with the two operation groups, age and gender as predictors and surgically induced astigmatism as the outcome. The STATA version 15.1 (StataCorp Texas USA) software program was used to analyse the data. Snellen visual acuity was converted to LogMar visual acuity for the sake of statistical analysis. (See Table 1) Astigmatism was recorded in dioptres (D). A p-value of <0.05 was used for significance.

SNELLEN VISUAL ACUITY	LogMar VISUAL ACUITY
6/6	0
6/7.5	0.1
6/9	0.2
6/12	0.3
6/15	0.4
6/18	0.5
6/24	0.6
6/30	0.7
6/36	0.8
6/60	1.0

Table 1. Visual acuity conversion table

3.0 CHAPTER 3 – RESULTS

3.1 Participation

After consenting to participation, the first 50 eyes to have uncomplicated cataract surgery in each group and successfully complete their 6-week follow-up were included in the study if they met the criteria. 100 eyes of 92 patients were enrolled in the study –48 in the MSICS group and 44 patients in the phacoemulsification group. Eight of these patients had both eyes included in the study.

The mean age of the MSICS group was 67.48 years with a range of 48 -86 years. The mean age in the phacoemulsification group was 71 with a range of 51 -89 years. (see table 2) This was not a statistically significant difference (p=0.07)

GROUP	MEAN (SD)	95% CI
MSICS	67.48 (9,84)	64,68 – 70,28
Phaco	71 (9,38)	68,30 – 73,69

Table 2. Age analysis

With regards to gender, eight patients in each group did not have their gender recorded but according to our sample size calculations this did not affect our statistical tests. The MSICS group had 35 females and 17 males. The phacoemulsification group had 30 females and 12 males. The difference in distribution between the two group in terms of males and females was not statistically significant (p=0.03) There were however statistically more females in the study than males. (see table 3)

GROUP	FEMALE	MALE
MSICS	83%	17%
Phaco	71%	29%

Table 3. Gender distribution between groups

3.2 Surgically Induced Astigmatism

Astigmatism was measured by doing pre and post-operative keratometry and was recorded in Dioptres as mentioned. (See figures 1 and 2 for data distribution in each group) The median (IQR) value for MSICS surgically induced astigmatism was 0.91 (0.66-1.31) Dioptres and 0.76 (0.37-1.27) Dioptres in the Phacoemulsification group. When comparing the surgically induced astigmatism between the two groups the p-value was 0.04, and while this is statistically significant, there is no real clinical significance as the difference between the two medians is 0.15D. A univariate median regression analysis was performed and showed a median surgically induced astigmatism of 1.13 Dioptres for MSICS and 0.95 Dioptres for the phacoemulsification group (p=0.253). The interpretation of this was that the median surgically induced astigmatism between the two procedures was not statistically significant.

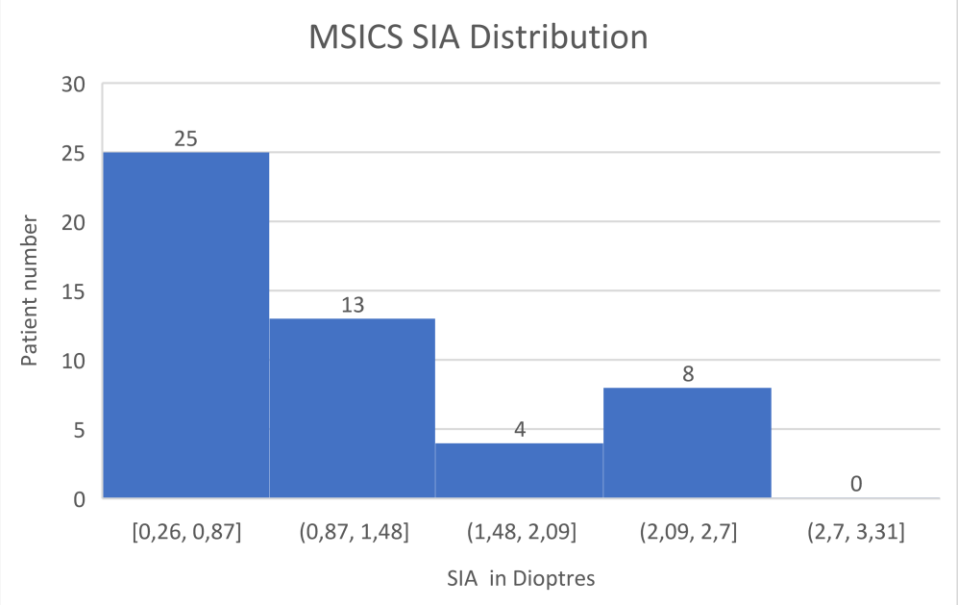


Figure 1. Distribution of Individual SIA results –MSICS group

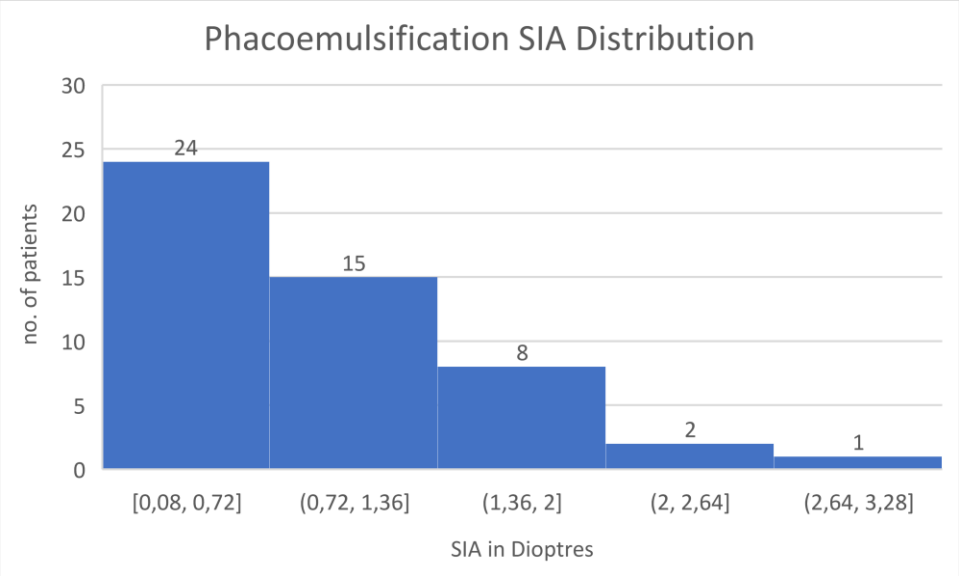


Figure 2. Distribution of Individual SIA results – Phacoemulsification group

3.3 Visual Acuity

Visual acuity, converted to LogMar, was analysed as mentioned. (See figures 3 to 6 for data distribution for each group)

The median (IQR) values for uncorrected and best corrected visual acuity for the MSICS group were 0.30 (0.20-0.50) and 0 (0.00-0.20) LogMar respectively. The median (IQR) values for the uncorrected and best corrected visual acuity in the phacoemulsification group were 0.30 (0.20 – 0.50) and 0 (0.00 – 0.10) LogMar respectively. When comparing the two groups, there was no statistically significant difference between them in both uncorrected and best corrected visual acuity – the p-values were 0.24 and 0.07 respectively.

When looking at the relationship between uncorrected visual acuity and surgically induced astigmatism, the Spearmann's coefficient was applied. The results were R=0.19 (p=0.19) for MSICS and R=0.13(p=0.38) for phacoemulsification. In other words, the uncorrected visual acuity was not statistically related to the amount of surgically induced astigmatism – the strength of correlation was very weak and not statistically significant.

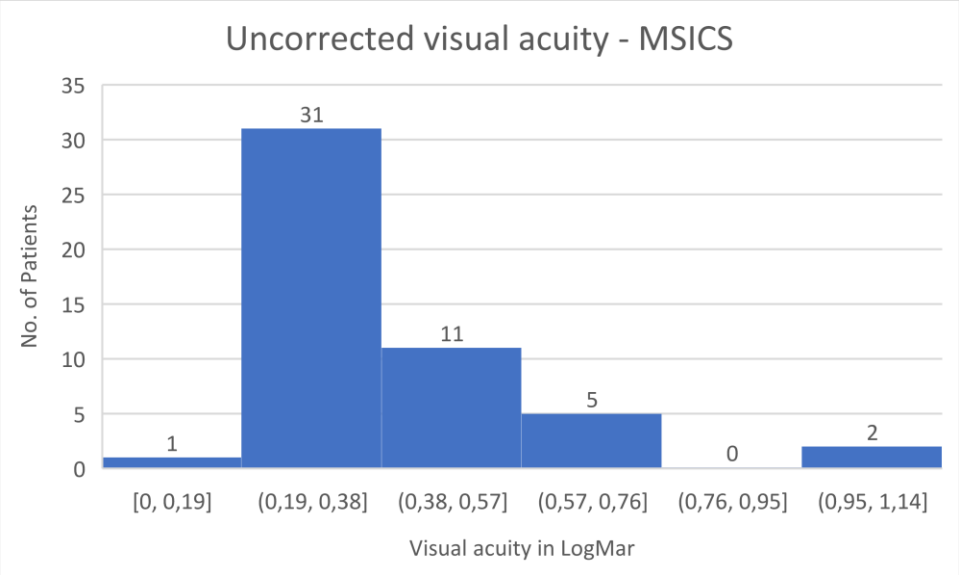


Figure 3. Distribution of Uncorrected visual acuity – MSICS group

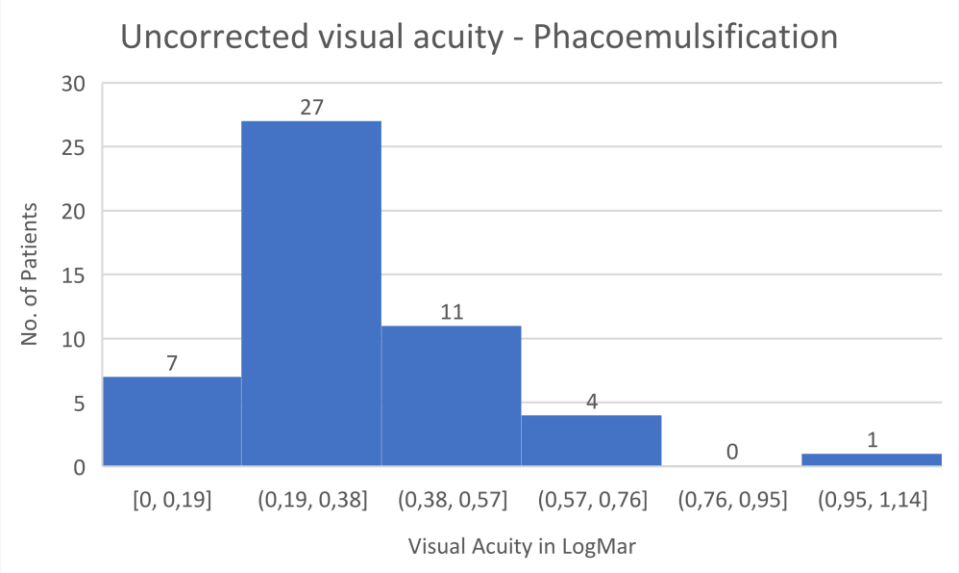


Figure 4. Distribution of Uncorrected visual acuity – Phacoemulsification group

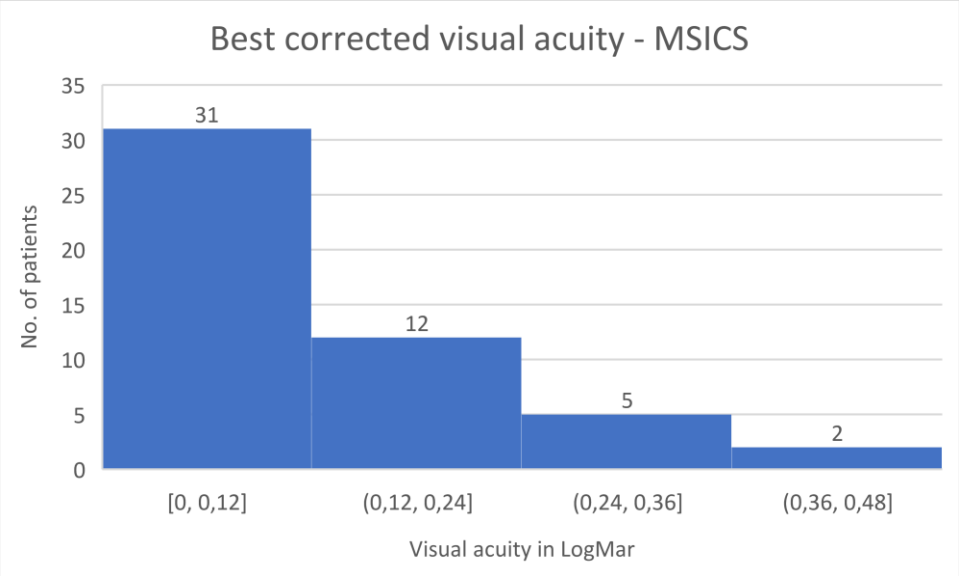


Figure 5. Distrubution of Best corrected visual acuity – MSICS group

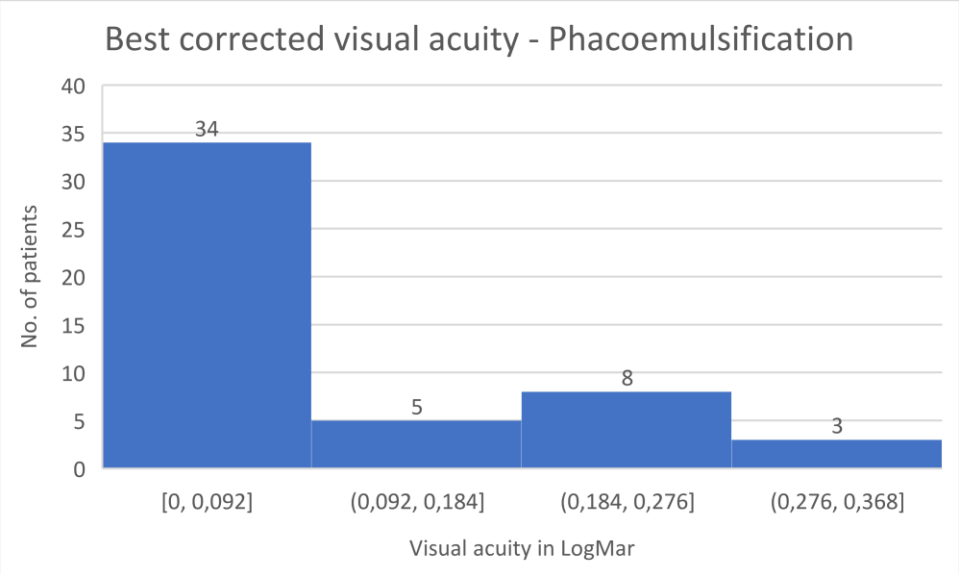


Figure 6. Distribution of Best corrected visual acuity – Phacoemulsification group

3.4 Multivariate median regression analysis

Although this was not one of the outcomes in the study objectives, we did a multivariate median regression to assess if there was any effect on surgically induced astigmatism by predictors such as type of surgery, age and gender. None

of the predictors had a statistically significant effect on the outcome. In fact, the p-value became even less significant showing less of a difference between the surgical groups.

4.0 CHAPTER 4 – DISCUSSION AND CONCLUSIONS

4.1 Discussion

In this study there was no statistically significant difference, in both surgically-induced astigmatism and visual acuity, between the two surgical procedures. We therefore failed to reject the null hypothesis. The fact that surgeons of different surgical competence levels, ranging from consultants to medical officers, did these operations is a true reflection of the possible outcomes in training centres where there are different skill levels. A limitation of this study however is that it is a hospital-based study and not population based.

While there are other factors that can influence surgically-induced astigmatism such as main incision size, type and placement. A study in Helsinki comparing different incision types in MSICS showed no statistical difference between straight and frown incisions with regards to surgically induced stigmatism.[16] As is well-known, surgically induced astigmatism from phacoemulsification can be reduced by making smaller clear corneal incisions and making your main incision on the steep axis of the cornea thus flattening it.[17] However, in our training institution registrars are first taught to do phacoemulsification incisions in the superior half of the cornea and once comfortable with the surgery can refine it by operating on the steep axis. This is why the primary investigator did not include these parameters in the data collection as surgeons at different skill levels will have their own incision preferences. Ideally, one could analyse the outcomes of a single surgeon doing both operations to get a more accurate impression of surgically induced astigmatism or have all surgeons making the same size and type of incisions in the same position.

Ideally, the keratometry measurements should be done with the same machine for both pre and post-operative measurements. A study by Laursen et al however showed that there was no statistical significance between the IOL Master and Nidek-ARK in precision of corneal power measurement. [18]

Previously, cataract surgery was purely rehabilitative but is now also seen as a form of refractive surgery, therefore surgically induced astigmatism becomes more and more important as it is a cause of poor uncorrected visual acuity in otherwise uneventful surgery. The fact that there was no statistically significant difference in this study between the two operations in terms of surgically induced astigmatism means that the patient will be happier with the refractive outcomes of both procedures. The mean values of both procedures show that the induced astigmatism can be corrected with spectacles or contact lenses post-operatively with good tolerance as the values are not high. Uncorrected visual acuity in both procedures was 6/12 and this is also an acceptable result for those patients that cannot afford spectacles or contact lenses, unlike limbal based ECCE where the SIA is intolerably high making uncorrected visual acuity a lot poorer. [10,14,15]

4.2 Conclusion

In our setting where we require high-volume, cost effective surgery with also minimal cost to patients in terms of follow-up, MSICS is ideal method of removing hard mature cataracts. It is superior to limbal ECCE as shown in the literature but more importantly (as shown in this study) has similar visual outcomes to the gold standard, phacoemulsification, and should be the preferred method of removing advanced cataracts in our institution.

APPENDIX A – Ethics Clearance Certificate

R14/49 Dr Sanushka Moodley

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M160820

NAME: (Principal Investigator)	Dr Sanushka Moodley
DEPARTMENT:	Ophthalmology Helen Joseph Hospital
PROJECT TITLE:	Visual Outcomes in Manual Small Incision Cataract Surgery versus Phacoemulsification: A Prospective Study
DATE CONSIDERED:	26/08/2016
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr Kerry Alberto
APPROVED BY:	Professor P Cleaton-Jones,Chairperson, HREC (Medical)
DATE OF APPROVAL:	26/09/2016

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 10004, 10th floor, Senate House/3rd Floor, Phillip Tobias Building, Parktown, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in August and will therefore be due in the month of August each year.

Principal Investigator Signature _____ Date _____

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX B – Permission to conduct research: Helen Joseph Medical Advisory Chair

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

Helen Joseph Hospital
Enquiries: Dr. M. Mukansi
Research Committee - Chairperson
Tell: 011 489 0306/1087
Fax: 011 489 1038
Email: murimisi.mukansi@wits.ac.za

To whom it may concern
Date: 27 July 2016

SUBJECT: **HELEN JOSEPH HOSPITAL RESEARCH COMMITTEE**
Protocol Title: Visual outcomes in manual small incision cataract surgery versus phacoemulsification: A prospective study
Protocol Ref No: Not applicable
Ethics Clearance: Pending
Principal Investigator: Dr. Sanushka Moodley
Department: Ophthalmology

Committee Recommendations
Committee approval is provisional. Pending HREC of the University of the Witwatersrand.

Thank you in anticipation

Dr. M. Mukansi
Chairperson of the HJH Ethics and Research Committee

APPENDIX C – Permission to conduct research: Helen Joseph Hospital Department of Ophthalmology HOD

Consent to Allow for Collection of Data for the Purposes of Research

To whom it may concern,

This document hereby serves as permission for Dr. Sanushka Moodley, student number 1528115, to collect the relevant data needed to complete the research intended under the title:

Visual outcomes in manual small incision cataract surgery versus phacoemulsification: A prospective study

Data will be collected from the Ophthalmology department at Helen Joseph Hospital, Johannesburg.

Data that would be needed for this study:

- Post-operative visual acuity
- Pre and post-operative keratometry

All data will be collected prospectively as per the submitted protocol, and will remain strictly confidential to the author. All data collection will be performed after approval by the Human Research Ethics Committee of the University of the Witwatersrand.

The intended research will be fully funded by the applicant and will not interfere with the daily running of the hospital or hospital equipment.

Head of Department Ophthalmology, Helen Joseph Hospital, Johannesburg:

Name Dr Kerry Alberto Date 22/7/2016

Signature

APPENDIX D – Consent Form

Consent Form: Use of Clinical Information for Research

Dear Patient,

You will be undergoing an operation to treat your cataract. The ophthalmology department not only renders treatment but is also actively involved in conducting research aimed at improving the quality of care that we deliver. Such research involves the use of patient records from which information is extracted. The use of such information is subject to the following:

1. Approval from the Human Research Ethics Committee (Medical) of the University of the Witwatersrand. 2. Identity of a patient from whose file information is extracted is never revealed to anyone but the researcher unless specific consent is obtained to do so. The information gathered does not contain the name of the patient but only a coded number to maintain anonymity.

We would like to obtain your consent to use information from your file for the purpose of research, subject to the conditions. If you choose not to give consent, this will not compromise your treatment in any way. If at any time you choose to withdraw consent you are free to do so and will not be prejudiced in any way.

Should you wish to contact us at any stage regarding consent, contact Dr S Moodley at 011 993 8783/ 8774. Cell: 0824698582

A. Consent Given

I_____ hereby give consent for my records to be used as per the above-mentioned conditions for the purposes of research:

PATIENT: _____ DATE: _____

B. Consent Not Given

I _____ do not give consent for my records to be used:

PATIENT: _____DATE: _____

APPENDIX E – Patient Information Sheet

PATIENT INFORMATION SHEET:

Study title:

Visual outcomes in manual small incision cataract surgery versus phacoemulsification: A prospective study

Good day and thank you for your time. My name is Dr Sanushka Moodley and I will be conducting the above-mentioned study. Please read through this document carefully and feel free to direct any questions to us at the eye clinic at Helen Joseph Hospital. If you prefer for this document to be read in the language of your choice, an interpreter will be provided for you.

Introduction:

We, the Department of Ophthalmology at the University of the Witwatersrand, are doing research on cataract surgery outcomes/results. Research is just the process to learn the answer to a question, it helps us to gather evidence to prove or disprove ideas that we as researchers have with regards to medical care and it updates us with evidence-based medicine.

In this study we want to learn which type of cataract operations benefit our patients more. We would like you to have the best visual outcomes so that your eyes recover faster and with fewer clinic visits so that it doesn't cost you a lot to come to your checkups.

There are many different operations to remove a cataract from the eye. These two methods that we chose are the better ways to remove your specific cataract according to other studies and we are hoping to prove it with this study in our setting. We will need your operation information and your postoperative vision and measurements to prove that these are better surgical methods to encourage all training eye doctors at University of the Witwatersrand to learn how to do these operations.

We are inviting you to take part in this research study so that we can gather information to improve the quality of our service to our patients and reduce patient post-operative hospital visits.

What is involved in the study?

You will be booked for routine cataract surgery via the normal booking route at the eye clinic. You will have your biometry done (this is the eye measurement that

tells us what size artificial lens to replace your lens with) You will then have one of two operations depending how bad your cataract is.

When you do your 6-week checkup, we will check your vision, and recheck your eye measurements as well as do a glasses test- these are all things that we routinely do after you have had an eye operation, the only difference is that we will use this information to help us in our research project.

What we would require from you in the study is your preoperative eye measurements and post-operative eye and vision measurements. Whether or not you chose to participate in this study does not disadvantage or advantage you in any way. All these measurements are done on every patient that undergoes a cataract operation- whether they participate.

Your personal information is not needed for our research and will not be published in our results. The information that we need from you will be gathered at your routine checkups, so you are not required to make any additional visits to the hospital at extra cost to you.

Should you choose to participate, you may withdraw at any time should you change your mind.

Risks: There are no risks in being involved in this study, you will follow the same procedure for cataract surgery and post-operative visits whether you chose to participate or not.

Benefits: There are no direct benefits to you as a patient. The information gathered will be of benefit to future patients whose doctors will be learning to do these operations.

Confidentiality:
As mentioned above, personal information will not be disclosed in the study. Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the Research Ethics Committee and the Medicines Control Council (where appropriate).

Contact details of researcher:
Please direct any study-related questions to us.
Dr S Moodley/ Helen Joseph Hospital Eye clinic: 011 489 0824

To report any problems or complaints, please contact the Human Research Ethic Committee:

Prof P Cleaton- Jones: Tel: 011 717 2301 **email:** peter.cleaton-jones@wits.ac.za

Administrative Officers
Ms Z Ndlovu **Email:** zanele.ndlovu@wits.ac.za
Mr Rhulani Mkansi **Email:** rhulani.mkansi@wits.ac.za
Mr Lebo Moeng **Email:** lebo.moeng@wits.ac.za
Tel: 011 717 2700/2656/1234/ 1252

Once again, thank you for taking the time to go through this information sheet. If there is anything that is unclear, please don't hesitate to ask us.

APPENDIX F – Data Collection Sheet

Data collection sheet Dr S Moodley

Pt name: Folder no.

Type of surgery: Date of Surgery:

Pre-op information:

	RIGHT	LEFT
PRE-OP K's		

Does the pt have any of the following?

1. Vision loss secondary to:
   Corneal pathology
   Glaucoma
   Refractive error: High Myopia
   Amblyopia
   Retinal pathology including ARMD and Diabetic maculopathy
   Optic neuropathy

2. History of refractive surgery

6-week post-operative information:

	RIGHT	LEFT
6 Week UCVA		
6 WEEK BCVA		
6 Week K's		

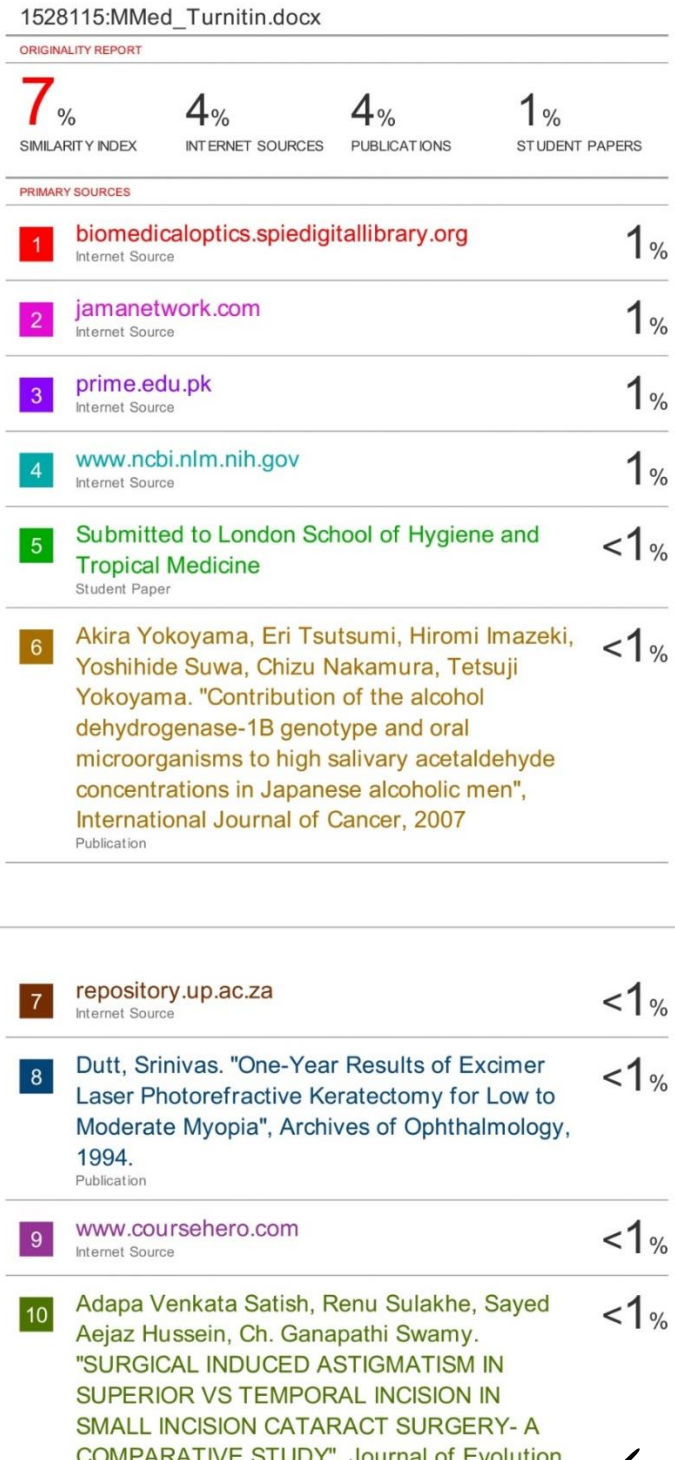
1. Was the patient compliant with post-operative care and follow up?

2. Did the patient have any immediate post-operative complications? E.g. TASS, severe corneal oedema

3. Did the surgery require suturing?

4. Were there any intraoperative complications noted?

APPENDIX H – TURNITIN REPORT



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Acknowledged by Dr Kerry Alberto (Supervisor): _____

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