COMPARISON OF THE REFRACTIVE OUTCOME FOLLOWING CORNEAL SECTION PHACOEMULSIFICATION VERSUS BLUMENTHAL TECHNIQUE OF MANUAL SMALL INCISION CATARACT SURGERY AT 6 WEEKS

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BONAFIDE CERTIFICATE

This is to certify that this dissertation entitled "'COMPARISON OF THE REFRACTIVE OUTCOME FOLLOWING CORNEAL SECTION PHACOEMULSIFICATION VERSUS BLUMENTHAL TECHNIQUE OF MANUAL SMALL INCISION CATARACT SURGERY AT 6 WEEKS' done towards fulfilment of the requirements of the Tamilnadu Dr. MGR Medical University, Chennai, for the M.S. Branch III (Ophthalmology) examination to be conducted in March 2013 is a bonafide work of Dr. Rashmi Mittal, postgraduate student in the department of ophthalmology, Christian Medical College, Vellore.

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CERTIFICATE

This is to certify that the subject matter of this thesis entitled, 'COMPARISON OF THE REFRACTIVE OUTCOME FOLLOWING CORNEAL SECTION PHACOEMULSIFICATION VERSUS BLUMENTHAL TECHNIQUE OF MANUAL SMALL INCISION CATARACT SURGERY AT 6 WEEKS' is the result of original work undertaken by Dr Rashmi Mittal under our supervision and submitted to the faculty of the Tamilnadu Dr. MGR Medical University, Chennai in partial fulfilment of the requirements of the M.S. Branch III (Ophthalmology) final examination to be conducted in March 2013.

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1 INTRODUCTION Cataract is one of the leading causes of blindness in India and cataract surgery is the most common and most successful surgery performed by all ophthalmologists which enables millions of people to restore or improve their vision (1)(2). Although cataract surgery has being performed since ancient times, the last half century has seen remarkable refinements of the procedure in order to achieve good and early visual rehabilitation. The procedure of cataract extraction has witnessed enormous evolution over time. Intracapsular cataract surgery with post operative aphakia was a commonly performed surgery in olden times but with the advent of intraocular lenses in 1940s...

INTRODUCTION

Cataract is one of the leading causes of blindness in India and cataract surgery is the most common and most successful surgery performed by all ophthalmologists which enables millions of people to restore or improve their vision (1)(2). Although cataract surgery has being performed since ancient times, the last half century has seen remarkable refinements of the procedure in order to achieve good and early visual rehabilitation.

The procedure of cataract extraction has witnessed enormous evolution over time. Intracapsular cataract extraction was a commonly performed surgery in olden times. Surgical aphakia was corrected with spectacles. But with the advent of intraocular lenses in 1940s extracapsular cataract extraction with rigid intraocular lens implantation became the surgical technique of choice. In late 1960 Charles Kelman came up with the idea of using ultrasonic sound waves to emulsify the lens material and then removing it through a very small incision, a technique referred to as phacoemulsification(3). Today "phacoemulsification" with foldable intraocular lens implantation is state of the art technique of cataract extraction.

Of the various modern cataract surgery techniques available to-date, Phacoemulsification with "foldable" intraocular lens implantation and Blumenthal technique of manual small incision cataract surgery(MSICS) with "rigid" intraocular lens implantation are most commonly performed in our institution. Phacoemulsification has several advantages like smaller incision size, less corneal complications, less post-operative discomfort, which leads to quicker visual recovery (4). But it is machine dependent, has a longer learning curve, not suitable for hard cataracts and also a costly affair. On the other hand MSICS is a safe, cost effective, faster technique which can be used for all types of cataracts (5).

Therefore, for a developing country like ours where the prevalence of cataract is still very high and where most people can't afford phacoemulsification, MSICS offers the advantages of sutureless cataract surgery as a low cost alternative to Phacoemulsification with the added advantages of having wider applicability and an easier learning curve (5).

The visual outcome of any cataract surgical technique can be assessed in terms of the residual refractive error which has a spherical and an astigmatic component. The spherical component depends on the lens power you aim for pre-operatively and can be predecided before surgery. It is the surgically induced astigmatism (SIA) which forms a major obstacle in achieving good unaided visual acuity. SIA necessitates spectacle use post operatively for good visual rehabilitation which is not desirable by most of the patients in view of the cost and convenience thereby leading to patient dissatisfaction. Studies have shown that SIA associated with phacoemulsification is definitely better than Blumenthal technique of MSICS (6) (7). But with the current improvements in the technique of MSICS and better training of ophthalmologists, SIA in this group of patients is also on a decrease. If this is the case then MSICS can boldly be described as an excellent alternative to phacoemulsification in developing countries where the burden of cataract blindness is still high.

With this background we decided to study the SIA following these two types of surgical techniques for cataract extraction in our institution. We also intend to compare the two techniques in terms of postoperative patient satisfaction and their effect on the endothelial count and central corneal thickness which can affect the long term visual outcome.

AIM AND OBJECTIVES

Aim:

To compare the refractive outcome following corneal section (CS) Phacoemulsification versus Blumenthal technique of manual small incision cataract surgery (MSICS) at 6 weeks.

Objectives:

- To compare unaided visual acuity following CS-Phacoemulsification versus Blumenthal technique of manual small incision cataract surgery.
- To compare surgically induced astigmatism (SIA) following CS-Phacoemulsification versus Blumenthal technique of manual small incision cataract surgery.
- To compare endothelial cell loss after cataract surgery – CS Phacoemulsification versus MSICS (Blumenthal technique).
- To compare the effect of surgical technique on the central corneal thickness – CS Phacoemulsification vs. MSICS (Blumenthal technique).
- To assess patient satisfaction in terms of improvement in visual function after cataract surgery – CS Phacoemulsification versus MSICS (Blumenthal technique)

REVIEW OF LITERATURE

Epidemiology:

Senile cataract is irreversible opacification of the lens or its capsule due to denaturation of the lens protein. It is usually a bilateral disease but can be asymmetric. It causes gradual, painless, progressive diminution of vision and is a potentially blinding condition (3).

With increasing longetivity of life in the modern era the prevalence of senile cataract associated visual impairment is also increasing and this can have a huge impact on the country's economy(7)(8). Moreover, if left untreated, cataract can lead to various complications like lens induced glaucoma and uveitis which can be a source of great nuisance to the patients and their families(9).

According to a recent survey, globally 285 million people are visually impaired, 246 million have low vision and 39 million people are blind. 65% of visually impaired people and 82% of all the blind are elderly i.e. 50 years and older. In India 62.619 million people are visually impaired, 54.544 million have low vision and 8.075 million people are blind, accounting for 20.5% of the global blindness burden. India is second only to China in the high prevalence of visual impairment and blindness (10).

The principle causes for visual impairment world-wide include uncorrected refractive errors (43%) and cataract (33%) (10). Globally senile cataract is also the leading cause for blindness except in the most developed countries (10)(3). It accounts for 48% of global blindness which represents 18 million people currently. It is also estimated that the current estimate of 20 million cataract blind will double by the year 2020 (3).

The burden of cataract blindness is highest in developing countries. In India alone an estimated 9 million people are cataract blind and additional 1.8–3.8 million go blind from cataract every year.(1)(11). But only 0.5 million cataract surgeries were performed in 1981-1982 and the numbers had increased to approximately 4.8 million in 2006.(11) 90% had intraocular lens implantation (11). Thus we see that India still needs to increase the cataract surgical rate to combat cataract blindness

Both refractive errors and cataract are treatable cause of blindness and much can be done to cure them. Other ocular pathologies like age related macular degeneration, glaucoma, trachoma and diabetic retinopathy contribute very little to the global burden of blindness and also they do not have any cost-effective treatment. Thus cataract and refractive errors are the major target diseases for all the blindness control programs all over the world.

Cataract surgical techniques:

Currently surgery is the only treatment option available once the vision is affected due to cataract formation (7). Surgery is indicated when the patients visual function drops to a level wherein it interferes with the patients quality of life (3). Cataract surgery will help restore the patients' eye-sight and the patient can enjoy the social and economic benefits of improved vision (12). This not only improves the quality of life of the patient and also indirectly improves the country's economic status. It is an extremely safe procedure with few major complications (13). It is the most common surgery performed by all ophthalmologists. The technique of cataract extraction has witnessed major advancements over time in order to improve the visual outcome.

A variety of surgical techniques are available for cataract extraction and then replacing it with an intraocular lens. These methods include phacoemulsification, extracapsular cataract extraction and intracapsular cataract extraction. Each method has many variations which undergoes further modifications depending on the surgeon preference.

In 1903, before the advent of intraocular lenses, Colonel Henry Smith developed the technique of intracapsular cataract extraction (ICCE) to deal with the high volume cataract surgery in India. In this technique the whole lens along with the capsule was removed through a large 12mm corneal incision which then required suturing. This resulted in unpredictably large surgically induced astigmatism and thus delayed visual rehabilitation. It was also associated with high rates of posterior segment complications like retinal detachment because of the pressure placed on the vitreous body during the procedure (14). The patients were left aphakic most of the times and the post operative residual refractive error were corrected with thick aphakic spectacles which suffered from poor image quality due to image distortion and magnification. But still this procedure was very popular in the developing countries in the past because it was quick and cost-effective. It did not require any sophisticated instrumentation and had a very short learning curve.

In 1960s the technique of cataract surgery was modified and extracapsular cataract extraction (ECCE) was introduced wherein the cataract was removed from the capsular bag. The posterior capsule was left behind for placement of posterior chamber intraocular lens in the capsular bag. The presence of an intact membrane between the aqueous and vitreous greatly reduces the incidence of post-operative complications like cystoid macular edema, retinal detachment, endophthalmodonesis and post operative glaucoma. ECCE is now the surgical technique of choice as it offers many advantages over ICCE. Since the many techniques of ECCE has been introduced and includes conventional ECCE, manual small incision cataract surgery, and phacoemulsification (3).

Conventional ECCE involves manual expression of the entire lens through a 10- 12mm corneal incision followed by implantation of intraocular lens in the capsular bag. The large corneal incision requires suturing which results in unwanted astigmatic errors. But the visual outcome in terms of image quality and clarity is much better after ECCE as compared to ICCE. Conventional ECCE is a cost effective procedure and can be performed for all grades of cataract.

The technique of "Phacoemulsification" was introduced by Kelman in the 20th century (15) and since then this has become the technique of choice where resources are available. In this procedure the lens is emulsified in the bag using ultrasonic waves and then removed piece-meal through a 3mm, self sealing corneal incision. A foldable IOL in then inserted through the same incision. This results in excellent visual outcome (3). The advantages of such a small incision include early visual rehabilitation, better unaided visual acuity and surgical safety. But the technique requires sophisticated instrumentation which makes it a costly affair and also it has a steep learning curve (16). Also it requires careful case selection as hard, hypermature and morgagnian cataracts might be difficult to handle with phacoemulsification resulting in higher rates of complications compared with surgery on an immature cataract.

In developing countries phacoemulsification is still not a popular method of cataract surgery in view of the cost of the procedure. As an alternative to phacoemulsification, another surgical technique has been developed that combines the advantages of phacoemulsification but without the accompanying costs. It is commonly referred as manual small incision cataract surgery (MSICS) (5). In manual SICS the cataractous lens is removed through a 5 to 6mm scleral incision. The scleral tunnel wound of MSICS has two incisions – external scleral incision and internal corneal incision. The scleral incision is either in shape of a frown or a straight scratch 5-6 mm in length, 1.5mm behind the limbus with or without, back cuts with side pockets. The internal incision is in the cornea and therefore does not lend itself to stretching. So it has to be large enough to allow expulsion of the entire nucleus from the eye and implantation of an IOL into the eye. 8-10mm internal wound, parallel to the limbus, usually suffices. So finally there is a relatively small external incision with a geometrical shape that lends itself to stretching and a tunnel that flares to a larger internal incision. This ensures the self sealing nature of a relatively large wound, thus avoiding any sutures and thereby minimizing post-operative astigmatic shift(5).

So we can see that the procedure of cataract surgery has taken major leaps over time which is still continuing (3). With so many options available one has to decide which cataract surgery technique to opt for. In less developed or developing countries with high prevalence of cataract blindness, the single most important factor that guides this decision is the cost effectiveness of the procedure.

A study done in southern-India has shown that the most cost effective technique of cataract surgery is sutureless MSICS. Societal cost i.e. the providers cost plus the patient/family cost of surgery was highest for phacoemulsification (1)(11). For the same reason sutureless MSICS is most commonly performed in India and phacoemulsification accounts for only about 10%. Phacoemulsification is slowly becoming the option of choice in urban settings (11).

Monitoring cataract surgical outcome:

The primary aim of cataract surgery is to visually rehabilitate the patient so as to improve their vision related quality of life and visual function and also to help them attain functional independence rapidly and this would indirectly help them contribute towards the country's economy (17). Therefore just expanding the cataract surgical services and increasing the cataract surgical rates is not enough. The focus should be more on postoperative visual outcome.

The visual outcome following any technique of cataract surgery can be assessed using various parameters like post operative visual acuity, contrast sensitivity, subjective improvement in vision as assessed by visual function score etc. Of this visual acuity assessment using Snellen's chart can be considered the best and quick method for objective assessment of visual outcome (17). Both unaided and best corrected visual acuity should be evaluated

World Health Organization (WHO) has laid down certain guidelines to help us to monitor the cataract surgical out-come. According to these guidelines "The visual acuity must be measured in each eye of all patients undergoing cataract surgery for age-related cataract, preoperatively and any time between discharge and 12 weeks post-operatively, using available correction and best correction (or pinhole correction). The following levels of visual outcome should be aimed for:"

Post-operative acuity	With available Correction	With best Correction
Good 6/6 – 6/18	>80%	> 90%
Borderline <6/18 – 6/60	<15%	<5%
Poor <6/60	<5%	<5%

Causes of poor visual outcome can be classified in four groups:

- Selection: due to pre-existing concurrent eye disease
- Surgery: due to surgery or immediate pre-or post-operative complications
- Spectacles: due to inadequate optical correction
- Sequels: due to late post-operative complications (posterior capsule opacification, retinal detachment, etc.)

If the WHO guidelines are not met then the visual outcomes after cataract surgery should be attempted to be improved by any measures that will:

- Improve case selection and avoid surgery in patients who will not benefit
- Improve the quality of surgery and avoid surgical complications
- Improve the operative (IOL) and/or post-operative correction of refractive error
- reduce late post-operative complications

Role of postoperative residual refractive error in patient rehabilitation:

With evolution of cataract surgery patient’s tolerance for post operative residual refractive error is also decreasing. Expecting spectacle independence after cataract surgery is very common (18). Need to wear glasses post operatively for clear visual acuity is often a source for patient dissatisfaction and complaint.

The residual refractive error after surgery has a spherical and an astigmatic component. With the advent of modern biometry techniques and latest generation formulas to calculate the intra-ocular lens power the spherical defects can be minimized. Thus control of the astigmatic component is becoming increasingly important to the refractive outcomes after cataract surgery (19).

Astigmatism is an optical defect in which the unequal curvature of one or more refractive surfaces of the eye prevents light rays from focusing clearly at a single point on the retina, thereby resulting in blurred vision. This may be due to an irregular curvature of the cornea or the lens. In pseudophakic eyes the lenticular component almost gets eliminated and hence the corneal curvature is responsible for most of the astigmatic effect (19). Astigmatism can be classified as regular, wherein the two principle meridians are perpendicular to each other, or irregular astigmatism (two principle meridians are not perpendicular). Regular astigmatism can be with-the-rule (vertical meridian is the steepest), against-the-rule (horizontal meridian is the steepest) or oblique type (the steepest curve lies in between 120 and 150 degrees and 30 and 60 degrees.

The amount of residual astigmatic error after cataract surgery is dependent on two factors:–

1) The preexisting astigmatism, intrinsic to the patient
2) The surgically induced astigmatism.

For best post operative visual outcome the surgically induced astigmatism should be minimal, and if possible favorable, to counteract the preexisting astigmatism.

Surgically induced astigmatism:

The change in astigmatism that follows any ocular surgery is known as surgically induced astigmatism (SIA). Change in corneal curvature is a well documented finding after cataract surgery and this induces a change in astigmatism which reflects the SIA. SIA is one of the major obstacles in achieving good visual rehabilitation because it necessitates spectacle wear for clear vision which is not desirable by most of the patients in view of the cost as well as the inconvenience. Though no one can see clearly at all distances (far, intermediate and near) without glasses after cataract, most patients desire optimal vision at least for distance and for this the amount of blur caused by the induced astigmatism must be minimal.

In order to control the post-operative astigmatism and to keep it at minimum one needs to know about the source of the astigmatism. It can be either preexisting or induced astigmatism. Total pre-existing astigmatism of the eye has a corneal and a lenticular component (20). But after cataract surgery, in pseudophakic eyes, the lenticular component is not significant and corneal component is responsible for most of the residual astigmatism. It can be measured by standard keratometry or corneal topography. The surgically induced astigmatism can be easily calculated based on the change in keratometry reading after surgery. There are a number of ways to calculate SIA as described below.

Calculation of surgically induced astigmatism

The amount of SIA, can be calculated by comparing pre- and postoperative keratometry values with vector or polar analysis (21) (22). Using standard keratometry as a sole guide to astigmatism planning can be at times misleading because it fails to identify any irregular astigmatism which can limit optimum surgical results. In such cases corneal topography would be the preferable (23).

Refractive data are usually consists of sphere, cylinder, and axis. This conventional format, which characterizes a single refraction, is not suitable for statistical analysis. The spherical component can be analysed without difficulty but the problem resides with the cylindrical component. The cylinder is denoted by a magnitude expressed in diopters and a direction reported in degrees. For statistical analysis of such directional data these values must be converted to vectors or as polar values (21) (24) .

- Vector analysis – In this method the cylinder is considered as a vector (magnitude and direction). The refractive error, which is expressed as sphere, cylinder, and axis, is converted to a vector and then the vectors can be compared (22).

- Polar analysis - This technique was specifically developed for analysis of the astigmatic component of refractive surgery. The refractive data is converted to polar values which characterizes regular astigmatism completely(24).

- Online calculators – most of these use the method of SIA calculation described by Holladay et al(22)**.**

Factors affecting surgically induced astigmatism:

SIA depends upon various factors like type of incision, size and location of the incision, placement of any suture, suture material used and technique of suturing , amount of scleral cauterization, use of steroids post operatively and also on the pre-existing astigmatism (25)(26)(27)(28)(29)(30)(31)(32)(33). Each of these factors play an important role in determining the final post operative residual astigmatism.

Incision characteristics are “the” most important factor in determining the amount of surgically induced astigmatism. In a cataract surgery an incision has to be described in terms of its position, location, distance from the limbus, size and distance from the limbus.

Studies show that 3.2mm clear corneal incision results in 0.5D of SIA(34). On further decreasing the length of incision to <2.5mm does not give any advantage in terms of astigmatic change because of the stretching of the wound during IOL placement. (34) (35)

Incisions made in cataract surgery can be corneal, limbal or scleral. Studies comparing SIA associated with each of these have shown that it is highest with corneal incisions, intermediate with limbal and minimum with scleral incisions.

Temporal scleral wounds are purported to cause less astigmatism than superior wounds as they are farthest away from centre of the cornea and therefore least likely to affect the corneal curvature in the visual asix (36). Temporal incisions also have a counterbalancing effect on the natural ATR shift that occurs with age. However, most surgeons are familiar with the superior location, and the larger wound size and conjunctival dissection in SICS make the temporal site less appropriate for wound placement.

An important concept in understanding incision design in SICS is that of the incisional funnel. This is an area bounded by a pair of curvilinear lines whose shape is based upon the relationship between astigmatism and two characteristics of the incision – length and distance from limbus. Incisions made within this funnel are astigmatically stable.

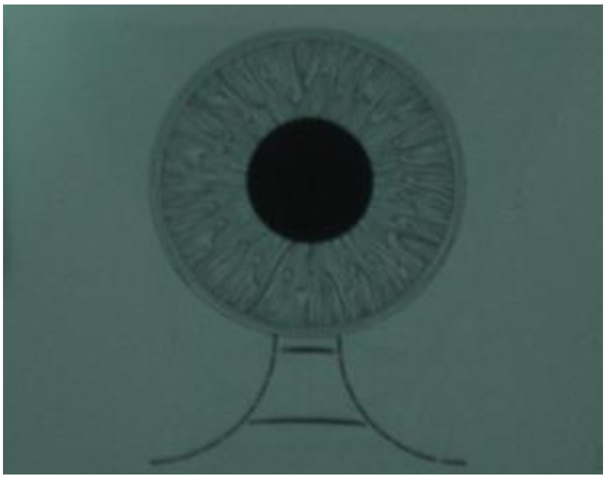


Diagram showing the astigmatic funnel

Short linear incisions made close to the limbus and longer incisions farther away are equally stable. The frown incision or the Chevrolet ‘v’ incision incorporate a larger incision into this funnel and hence are more desirable. Though moving farther away from the limbus makes an incision more stable, it increases the surgical difficulty by limiting access and maneuverability (37). Clear corneal tunnels have significant demerits – difficulty in obtaining square geometry due to limited length of tunnel, difficulty in anterior chamber manipulation , and less security due to long healing time and lack of fibrosis (37) .

It has been shown that a 3mm clean corneal incision correlated with least surgically induced astigmatism as compared to 2.5mm or 3.5mm incisions (26). There is no significant difference between SIA induced by 2.5mm and 3.5mm clear corneal incisions (27). Studies have also shown that clear corneal temporal incisions are associated with much less SIA as compared to nasal incisions (28).

In some studies left eye surgery is associated with higher SIA as compared to right eye, probably due to structural differences (29). But Rainer et al reported no significant difference between the two eyes. In their study right eye was associated with 0.85D ± 0.83D of SIA and left eye with 0.77 ± 0.35D, the difference between eyes not being statistically significant. (38). Another study reports SIA of 0.75 ± 0.49D after Superotemporal incisions and 0.71 ± 0.47D after superonasal incisions at one month which decreased to 0.6D ± 0.31D and 0.62 ± 0.29D at one year in the two groups respectively (39).

Presence of a large preoperative astigmatism, a low postoperative IOP, and high age, all results in more against-the-rule surgically induced astigmatism (30). It has also been shown that the postoperative astigmatic shift is same with both mersilene and nylon suture(31) (32). Use of scleral cautery at or 2mm within the limbus induces significant astigmatic change during cataract surgery (33). Therefore excessive, unnecessary cautery should be avoided intraoperatively.

Methods to control post operative residual astigmatism

The post op astigmatism can be minimized by intelligent preoperative planning, appropriate intraoperative interventions and post operative correction of any residual astigmatism. To be able to manipulate the astigmatic component one should be familiar with the SIA with that technique. Keeping a consistent technique allows the surgeon to have a reasonable estimation of SIA and thus plan to compensate for SIA and other astigmatic components. Some intraoperative manipulations that can help minimize astigmatism are as follows:

- *On axis incisions* – In this technique a single clear corneal cataract incision centered on the steepest meridian is made in order to flatten that meridian (40). Kauffamn et al have reported a flattening effect of 0.41D at 6 weeks and 0.35D at 6 months (40). Some others have reported that it can correct upto 1 dioptre of astigmatism (20). But certain incision positions might lead to a difficult and uncomfortable surgical experience. A study from China shows that on-axis clear corneal incision phacoemulsification was associated with better unaided and best corrected visual acuity and lesser surgically induced higher order aberrations as compared to clear corneal temporal incisions(41)

- *Peripheral corneal Relaxing incisions (PCRI)* – 90% deep diametrically opposite paired incisions are made in the peripheral cornea. Nomograms exist to specify the length of the incisions. The phacoemulsification incision is placed through one of the PCRIs. This technique is useful to treat 1-1.5D of astigmatism when a monofocal intraocular lens is planned. Beyond this the risks associated outweigh the benefit of the procedure due to the increased length of incision required. In such situations toric IOLs are a better option(20).

- *Compression sutures* – wound compression steepens the corneal curvature in that meridian (42) and this can be utilized to control astigmatism intraoperatively.

- *Toric IOLs* – These IOLs not only have a spherical power but also have an astigmatic component which cancels out the corneal astigmatism. But such a combination of two toric surfaces leads to unwanted image distortion post operatively. Upto 3 D of astigmatism can be corrected by toric IOLs. Present generation toric lenses have good rotational stability. It has many other advantages like it does not require any sophisticated instruments; it is a reversible procedure and can be easily performed by surgeons who are not so comfortable with corneal surgeries(20).

After all this if the patient is left behind with less than optimal astigmatic results then he can be planned for a keratorefractive surgery on follow-up.

Studies comparing surgically induced astigmatism after different techniques of cataract extraction:

New innovations in the technique of cataract surgery reflect an attempt to improve outcome of surgery by trying to reduce the SIA. Original intra and extra capsular cataract extraction techniques (ICCE and ECCE) which had large incisions and required sutures to close the wound induced unwanted change in the corneal curvature and hence were associated with high SIA. Thus cataract surgery wounds were modified to make them sutureless and with this there was a drastic decrease in SIA. The incision made in suture less cataract surgery is a three step wound involving the sclera and the cornea so that it is self sealing and also large enough to allow placement of a rigid intraocular lens. This technique of cataract extraction is known as manual small incision cataract surgery (MSICS). But the latest and gold standard of all cataract surgery techniques today is Phacoemulsification (PE) wherein an even smaller beveled wound is made in the cornea which is self sealing and adequate to insert a foldable IOL.

It has already been showed that there is significantly higher SIA after ECCE as compare to MSICS (43). But there have been only few studies to compare the SIA after phacoemulsification versus manual small incision cataract surgery.

According to a randomized controlled trial (RCT) from India, both MSICS and ECCE are safe and effective in community eye care settings. They studied 706 eyes and found that MSICS gives better uncorrected visual acuity than ECCE. 47.9% of patients in MSICS group achieved an unaided vision of 6/18 or better as compared to 37.3% in the ECCE group at 6 weeks. They did not comment on the surgically induced astigmatism. Also there was no significant difference in the complication rates between the two groups(44)

Another RCT from Nepal comparing visual outcomes of ECCE with MSICS in 100 eyes shows that uncorrected VA of 6/12 and better was achieved in 34% of the MSICS group and only14% in the ECCE group at six to eight weeks postoperatively. Astigmatism of ≥ 2D was 35.4% and 72.9% participants from MSICS and ECCE groups respectively at eight weeks. Thus they concluded that a better and rapid visual rehabilitation can be achieved with MSICS as compared to conventional ECCE (45)

A randomized control trial from India, done on 400 eyes, to compare the efficacy, safety and astigmatism after phacoemulsification and MSICS technique, showed that both the techniques are safe and effective for visual rehabilitation although phacoemulsification gives better uncorrected visual acuity in a larger proportion of patients at 6 weeks. 68.2% patients in the phacoemulsification group and 61.25% in the small-incision group had uncorrected visual acuity better than or equal to 6/18 at 1 week which improved to 81.08% and 71.1% at 6 weeks for the phacoemulsification and MSICS groups respectively. BCVA of 6/18 or better was seen in 98.5% of the patients in both groups. The mode of astigmatism was 1.5D for the MSICS group as compared to only 0.5D for the phacoemulsification group and the average astigmatism was 1.2 D and 1.1 D, respectively in the two groups. There was an intra-surgeon variation in astigmatism. They concluded that though both the techniques are safe and effective, phacoemulsification is associated with better unaided visual acuity at 6 weeks.(46)

Another randomized control trial from India , where they studied 186 eyes with visually significant cataract, showed the mean SIA to be 1.77D for the ECCE group, 1.17D for the SICS group and 0.77D for the PE group. SIA was significantly higher in the ECCE group but the magnitude of the difference between the SICS and the PE group was not statistically significant. But in this study phacoemulsification was performed through a 5.5mm scleral incision rather than a 2.8mm clear corneal incision which is the gold standard (6).

One other study from Nepal showed that both phacoemulsification and MSICS technique of cataract surgery achieve excellent visual outcomes with low complication rates and the averaged keratometric astigmatism was 0.7D and 0.88D in phacoemulsification and MSICS group respectively. But in this study vector analysis of the astigmatic change was not performed and also all the surgeries were performed through a temporal approach unlike most other places where a superior approach is favored (47)

<u>Endothelial cell loss after cataract surgery:</u>

Visual outcome after cataract surgery is also dependant on the postoperative corneal clarity which is the function of the endothelial cells. Therefore it is very important to protect the endothelial cells during surgery which can be achieved by intraoperative use of viscoelastics. But some amount of endothelial cell loss has been demonstrated after all techniques of cataract surgery

(48)(49)(50)(51)(52). Low endothelial cell density can lead to corneal oedema and, in extreme cases, pseudophakic bullous keratopathy which can negatively affect the visual outcome (48). But unless the endothelial count falls below a certain threshold corneal decompensation is unlikely (6)

The amount of endothelial cell loss depends on a number of factors which includes the preoperative endothelial cell count, associated medical comorbodities like diabetes, and the surgical technique used for cataract extraction. Loss varies with different techniques of cataract surgery. Many studies have been done in the past to compare the endothelial cell loss after different techniques of cataract surgery.

MSICS and phacoemulsification are associated with comparable endothelial loss (46) (6) (53). Gogate et al studied 400 patients and reported surgically induced endothelial cell loss of 474.2 cells/mm^2 after phacoemulsification and 456.1 cells/mm^2 after manual small incision cataract surgery at 6 weeks. The difference between the two groups was not statistically significant ($p = 0.98$) (46).

Another Indian study was done to compare the endothelial loss after Phacoemulsification and MSICS at 6 weeks. Endothelial cell count was done by both automated and manual methods. They concluded that there was no significant difference in endothelial damage between the two groups. Long term outcome was not looked at (52).

George et al studied 53 eyes with MSICS 60 eyes with phacoemulsification and have reported a mean percentage reduction in endothelial cell count of 4.21% after SICS and 5.41% after phacoemulsification (p = 0.85) (6).

Another recent study from Kerela also showed that MSICS is associated with lesser endothelial loss as compared to phacoemulsification, but the difference is not statistically or clinically significant (53).

Authors say that endothelial cell loss during surgery is significantly affected by the diabetic status of the patient (53) (54). In one study, in the diabetic group there was a 9.26 ± 9.55% drop in endothelial cell density as compared to only 7.67 ± 9.2 & drop in the control group. One other study also showed a statistically significant more surgically induced endothelial loss in diabetics than non-diabetics (p=0.05) (53).

Central corneal thickness after cataract surgery:

A post-operative decrease in endothelial count will lead to increase in the CCT which can lead to corneal decompensation thereby compromising the vision. It has been shown that an increase in immediate postoperative corneal thickness correlates strongly with the corneal endothelial damage after cataract surgery (55). It has also been shown that the central corneal thickness returns back to the preoperative levels within three to six months of surgery (56) .The same study also says that there is no correlation between moderate endothelial cell damage and change in central corneal thickness in long term (56).

Role of visual function assessment in cataract surgery:

In a patient with cataract the need for surgery is based on the visual disability caused by the cataract. Various techniques available for assessing visual disability include Snellen's visual acuity, near visual acuity, contrast sensitivity assessment, glare disability measurement and patients' perceived visual disability as quantified by a questionnaire (57). Visual acuity assessment alone may underestimate the value of cataract surgery as it ignores the overall postoperative functional improvement and patient satisfaction. But it still remains the most commonly used physiological measure for evaluating patients for cataract surgery because of its simplicity and ease of measurement (58). Vision of 6/12 or less is taken as an indication for cataract surgery in most centres (57) (59). It has been shown that presenting visual acuity correlates poorly with the subjective visual disability(57) (60). However binocular contrast sensitivity correlates well with the patients perceived visual disability (60). Thus contrast sensitivity measurement can provide useful information on need for cataract surgery in patients with reasonably good visual acuity. Near visual acuity has also been found to be a better predictor of patients' trouble with vision as compared to the Snellen's visual acuity (61). But use of near vision has rarely been used to predict cataract surgery outcome.

Success of cataract surgery depends not just on the enhanced postoperative visual acuity but also on the improvement in quality of life of the patient (7). It is well known that visual acuity does not correlate well with patient satisfaction. It is not unusual to come across a patient with good postoperative visual acuity but still highly unsatisfied with the visual outcome. Therefore patient perceived outcomes needs to be recognized as the most important tool for assessing visual outcome after cataract surgery.

Reporting of visual function is still not popular among ophthalmologists, though it is slowly gaining momentum. Significant progress has been made in the past few years to assess the patients' visual function. Several questionnaires have been designed that correlates well with the visual disability and also predict well the outcome of surgery (62).

Numerous scales that are available some of which includes activities of the daily vision scale, vision related daily sickness profile and the VF-14 scale (63) (57). Of these VF-14 is most popularly used. It is highly reliable, consistent, reproducible and internationally validated (57). It is a 14 items on its scale and the patients have to record their trouble with vision for each item on a 4-point Likert scale (none, little, moderate or great deal). This makes it very long and cumbersome (64) and therefore preventing its widespread everyday use. Therefore an attempt was made to reduce the items on the scale. Numerous scales with fewer items have been introduced since then (65). One of them is the VF-7 score which has been shown to be as effective as the longer VF 14 score in assessing patients' trouble with vision, visual function and visual satisfaction before and after surgery. The items on the scale are based on the population being tested to ensure its validity(57). Australian VF-7 and Finnish VF-7 are commonly used in practice. It takes less than 2 minutes to be administered.

Thus a reliable, easy-to-use and valid measurement of patients visual function would be the most accurate method to recognize patients for whom cataract surgery is needed and the improvements obtained after the surgery (57).

With this background we decided to compare corneal section phacoemulsification and Blumenthal technique of manual small incision technique of cataract surgery in terms of surgically induced astigmatism, endothelial cell loss, change in central corneal thickness and patient satisfaction. The surgically induced astigmatism will be calculated as described by Holladay et al (66) and improvement in visual function (patient satisfaction) will be assessed based on the visual function -7 score modified to meet our needs (57)

MATERIAL AND METHODS

Study design

This is a cross sectional observational study conducted in the department of ophthalmology (Schell eye hospital), Christian Medical College, Vellore from March 2012 - December 2012.

Subjects

Inclusion criteria:

- Visually significant cataract
- Grade of cataract - Nuclear sclerosis grade III or less
- Preoperative refraction should be possible
- No other co-existing ocular disease contributing to the low vision
- Patients willing to participate in the study

Exclusion criteria:

- Pre-existing corneal scar or a pterygium (can alter the surgically induced astigmatism)
- Axial length of the eyeball <20mm or >25mm
- Pre-existing high astigmatism (>3 Dioptre)
- Patients planned for a combined procedure i.e. some other surgery along with cataract surgery.

Patients fulfilling the inclusion and exclusion criterion and willing to participate in the study by signing consent were included in the study.

Method

196 patients planned cataract surgery who met our inclusion and exclusion criteria and who are willing to undergo the examination were invited to participate in the study.

Preoperative work-up - Informed consent in the local language was taken. Then the participants underwent objective and subjective refraction, automated keratometry, pachymetry and specular microscopy by trained optometrists and a detailed slit lamp examination by a trained ophthalmologist as a part of routine preoperative work-up. The participants were also asked to fill a visual function score sheet in order to assess their visual disability.

Surgical intervention - Participants underwent either corneal section Phacoemulsification with intraocular lens implantation or Blumenthal technique of manual small incision cataract surgery with intraocular lens implantation, as planed in the outpatient department. No randomization was attempted.

- Corneal section Phacoemulsification
    - 2.8mm corneal wound will be made anywhere between 9 – 3 ‘O’ clock area.

    - Foldable IOL will be implanted in the capsular bag.
- Blumenthal technique of MSICS
    - 5mm long scleral wound with 2-2.5mm back-cuts and 8-10mm internal wound will be made 1-2mm from the superior limbus.
    - Rigid PMMA IOL will be implanted.

The intra ocular lens (IOL) power will be calculated using SRK II formula and an IOL with power aiming for near emmetropia was implanted in the eye during the surgery. All surgeries were performed by experienced surgeons who have performed at least 500 cataract surgeries till date.

Follow up - Participants were followed up on day one, 1st week and at 6 weeks after surgery.

Objective and subjective refraction, automated keratometry, pachymetry and specular microscopy by repeated at 6 weeks by the same optometrists and a detailed slit lamp examination was done by an ophthalmologist. The participants were once again asked to fill the visual function score sheet in assess their current visual function.

All the data was recorded in a clinical research form and then entered in SPSS and the required analysis was done.

Institutional review board

The study protocol was approved by the institutional review board which constituted members outside the instution as per the ICMR guidelines required for any study conducted in the institution.

Outcomes measured

Primary outcome:

- Surgically induced astigmatism - This will be calculated from pre and post operative keratometric value at 6 weeks as described by Holladay et al.

Secondary outcomes:

- To compare the unaided postoperative visual acuity, endothelial cell loss, central corneal thickness following CS-Phacoemulsification and Blumenthal technique of MSICS at 6 weeks postoperatively.

- Patient satisfaction in terms of improvement in visual function after the cataract surgery – visual function was assessed by the VF-7 Scale (modified according to our social setting) pre- and post-operatively. The following 7 parameters were studied:
    1. Reading a newspaper or book
    2. Reading small prints - label on medicine bottle, telephone book, food label
    3. Seeing steps, stairs

4. Reading traffic/street/store signs
5. Doing fine handiwork, sewing, knitting, or carpentry
6. Cooking
7. Watching TV

The patients' difficulty, because of vision, with each of the above mentioned activities is given a numerical value

- No difficulty = 0
- A little = 75
- A moderate deal = 50
- A great deal = 25
- Unable to do activity at all because of vision = 0
- The score is left blank where the activity is not applicable to the patient

The composite score (0 to 100) is the average of all valid values

Sample size

Target sample size - 192 eyes

96 in Corneal section Phacoemulsification group and 96 in Blumenthal technique of manual small incision cataract group

Sample size calculation:

Two Means - Hypothesis testing for two means (equal variances)

Standard deviation in group I = .95

Standard deviation in group II = .65

Mean difference = .33

Effect size = 0.4125

Alpha Error (%) = 5

Power (%) = 80

Sided = 2

Required sample size per group = 96

At end of the study there were 99 eyes in the corneal section phacoemulsification group, but 79 eyes the Blumenthal technique of manual small incision cataract surgery group. This was because of the poor follow up n the MSICS group. More patients could not be recruited due to the time constraints.

Statistical Methods

Analysis was done using SPSS version 16

To find the associate between qualitative variables, the chi-square test was used.

To compare the risk factors quantitatively between the two groups the student's t-test was used.

RESULTS AND ANALYSIS

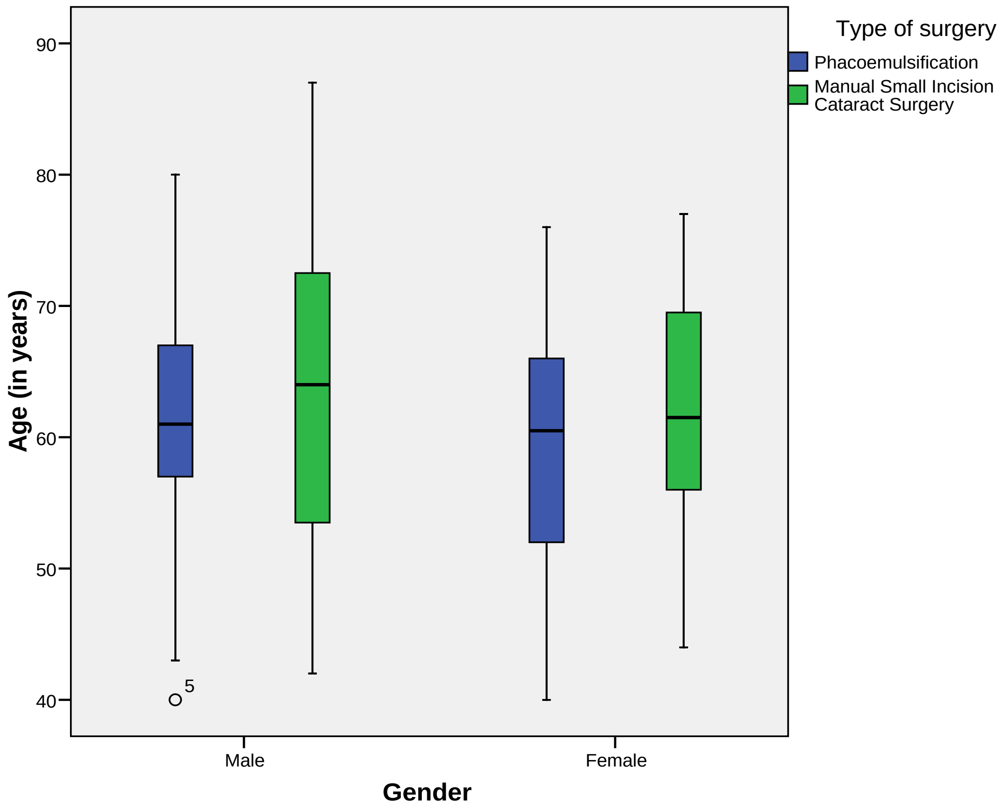
A total of 178 eyes were recruited for the study of which 99 eyes underwent corneal section phacoemulsification and 79 eyes Blumenthal technique of MSICS.

Characteristics	Phacoemulsification (N=99)	Manual small incision cataract surgery (N=79)
Age (in years)	59.9 ± 9.7	62.7 ± 9.7
Gender		
Male	37 (37.4%)	35 (44.3%)
Female	62 (62.6%)	44 (55.7%)
Operated eye		
Right	60 (60.6%)	53 (67.1%)
Left	39 (39.4%)	26 (32.9%)
Grade of nucleus		
Nuclear sclerosis grade 1	16(16.2%)	6 (7.6%)
Nuclear sclerosis grade 2	60 ((60.6%)	35 (44.3%)
Nuclear sclerosis grade 3	17 (17.2%)	37 (46.8%)
Only posterior subcapsular Cataract	6 (6.0%)	1 (1.3)
Other eye status		
Cataract	64 (64.7%)	58 (73.4%)
Pseudophakia	28 (28.3%)	15(19.0%)
Pseudophakia with posterior capsule opacification	5 (5.0%)	4(5.0%)
Clear lens	1 (1.0%)	1 (1.3%)
Other pathology	1 (1.0%)	1(1.3%)
Other eye vision		
6/6 to 6/18	50 (50.5%)	26 (33.3%)
6/24 to 6/60	41 (41.4%)	44 (56.4%)
5/60 to 3/60	5 (5.1%)	7(9.0%)
Less than 3/60	3(3.0%)	1 (1.3%)
Diabetics	36 (36.4%)	19 (24.0%)

Table 1: Demographic profile

DEMOGRAPHICS

Figure 1 - Age and gender distribution

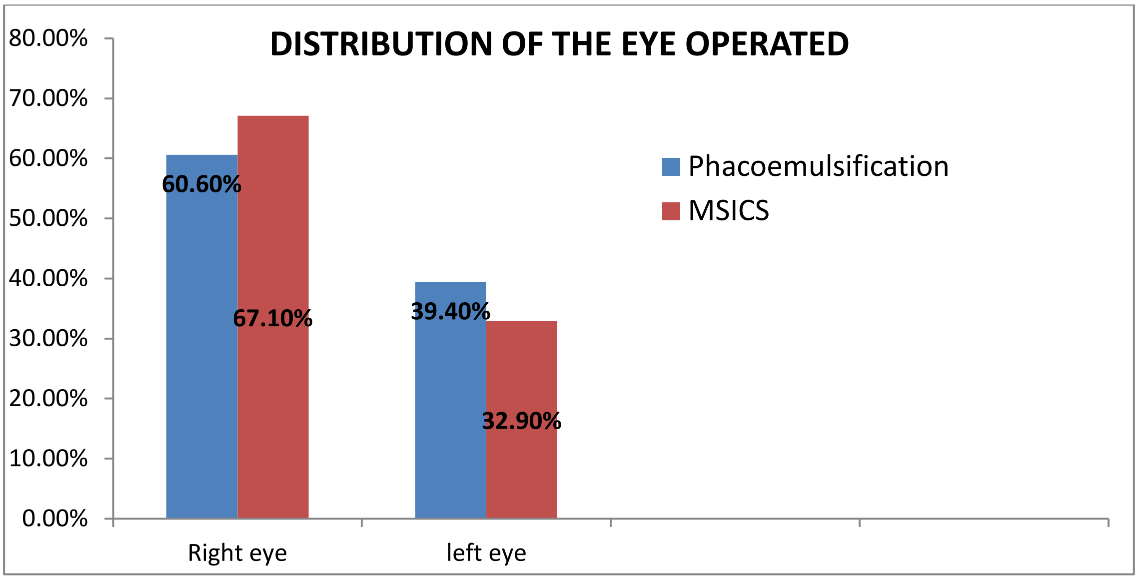


The age distribution in the two groups was analyzed using the independent t-test and the mean age difference between those who underwent phacoemulsification and MSICS was not statistically significant ($p = 0.06$).

Gender distribution in the two groups was analyzed using the chi-square test which showed that here was no statistically significant difference in the number of men and women who underwent phacoemulsification and manual small incision cataract surgery ($p = 0.361$).

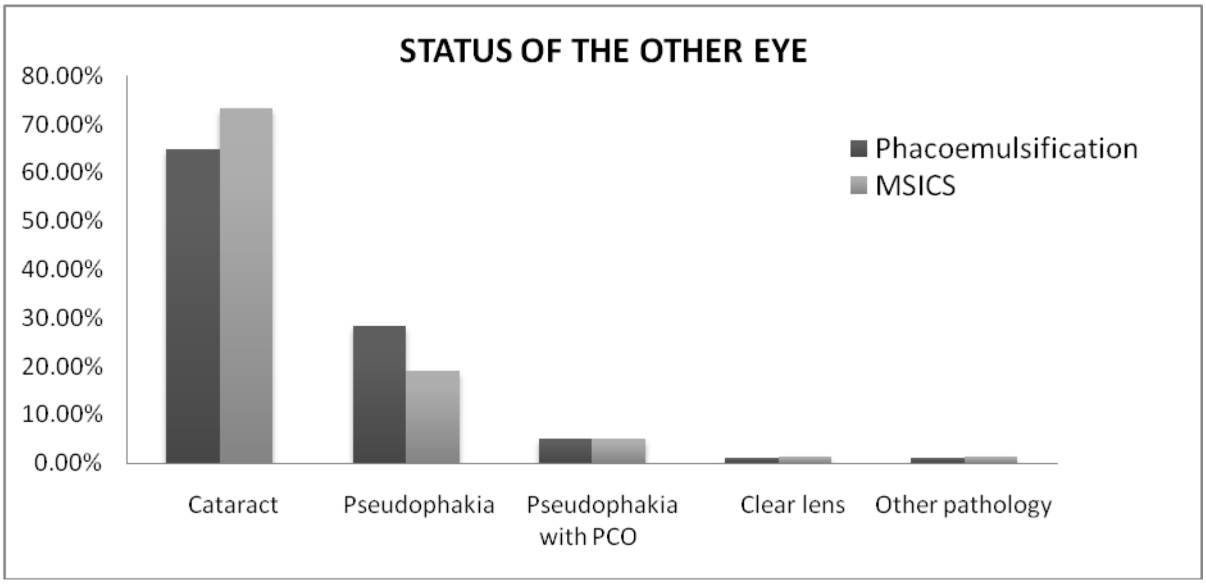
Thus the demographic profile of the eyes in the two study groups was comparable to each other.

Figure 2 – Comparison of the distribution of eye operated between the two groups



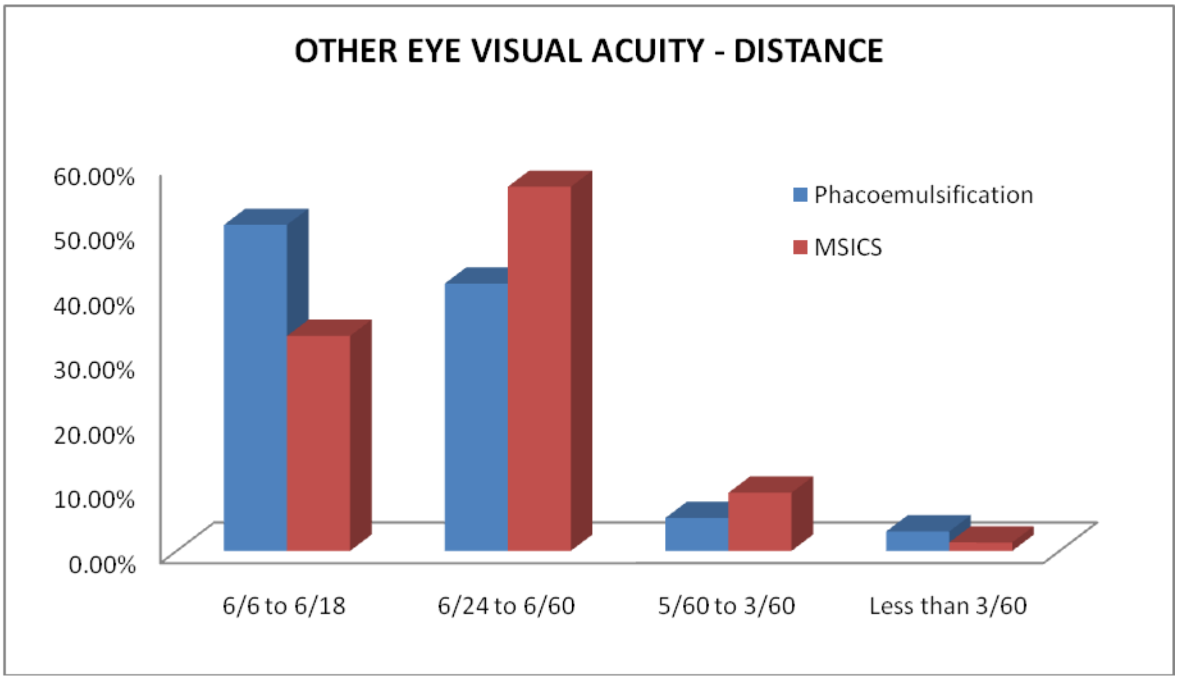
Distribution of eyes in the two groups was analyzed using chi square tests. The p value was 0.372 which suggested that there was no significant difference between the numbers of right or left eyes that were operated in the two groups.

Figure 3: Comparison of the other eye status between the two groups



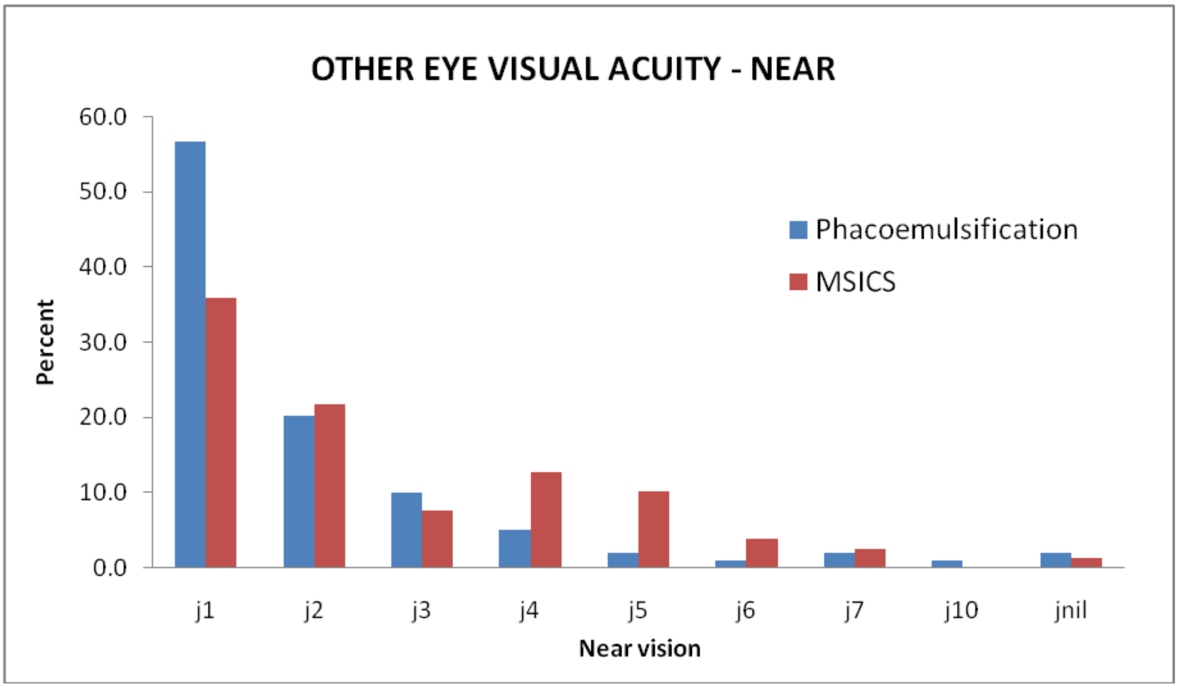
Status of the other eye was comparable between two groups (p-value 0.529).

Figure 4: Comparison of the other eye visual acuity for distance between the two groups



'p' value – 0.117

Figure 5: Comparison of the other eye visual acuity for near between the two groups

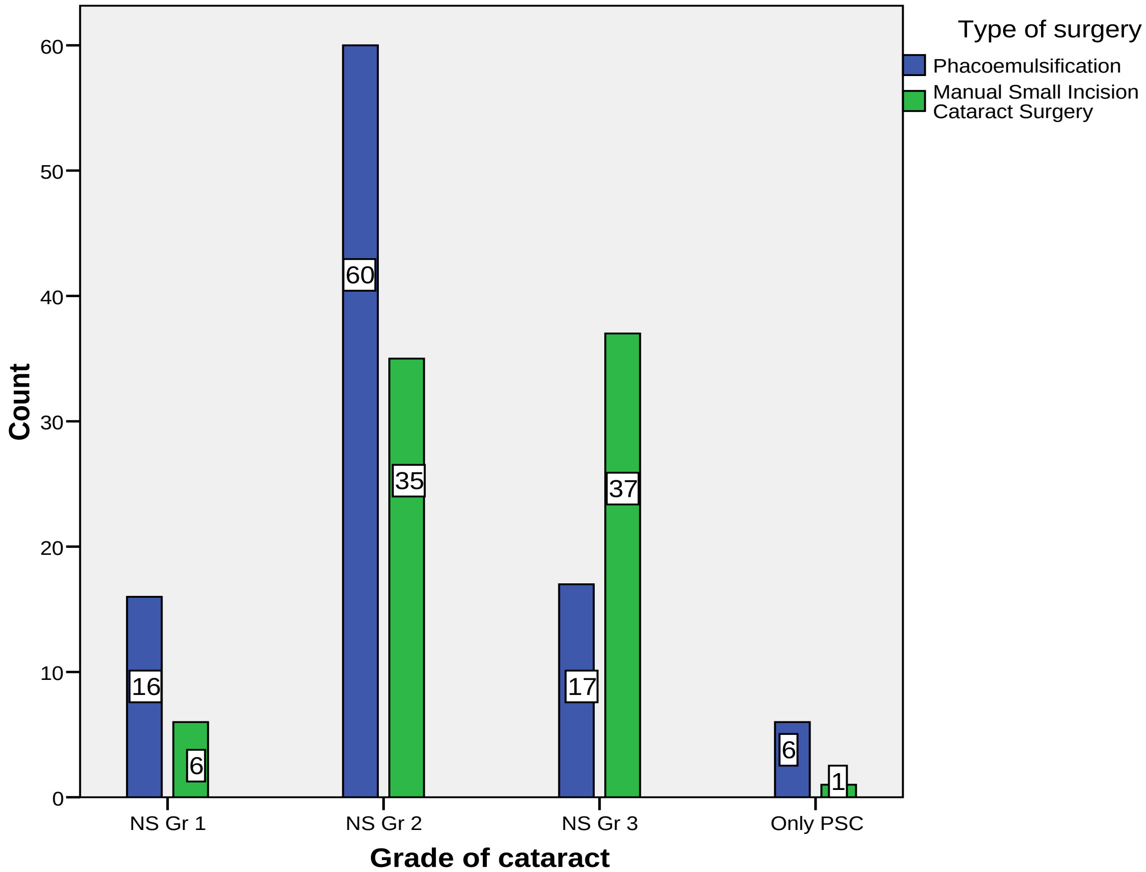


'p' value – 0.026

Table 2: Comparison of grades of cataract in the operated eye between the two groups

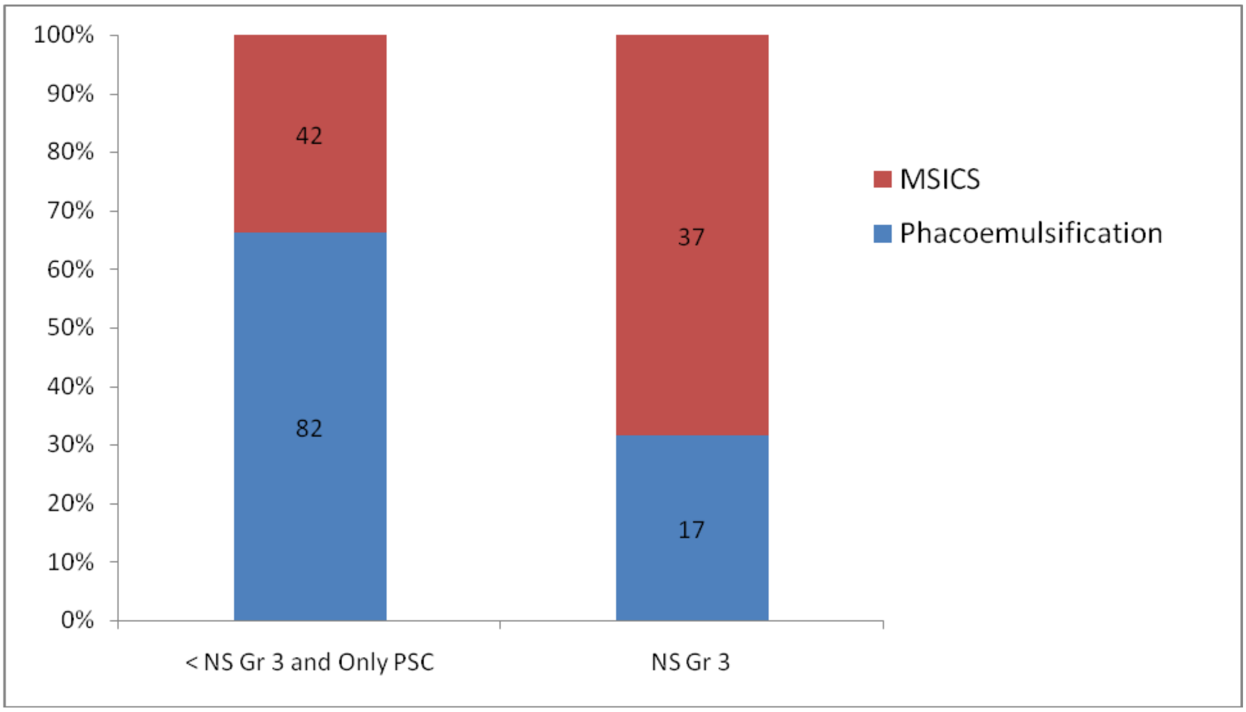
Grades of nucleus	Phacoemulsification N = 99		MSICS N = 79	
	n	%	n	%
Nuclear sclerosis grade 1	16	16.16	6	7.6
Nuclear sclerosis grade 2	60	60.60	35	44.30
Nuclear sclerosis grade 3	17	17.17	37	46.83
Posterior subcapsular cataract	6	6.06	1	1.27
	99	100	79	100

Figure 6: distribution of grades of cataract in the operated eye between the two groups



Eyes in the two study groups were subcategorized based on the cataract grade into hard cataracts and soft cataracts. Hard cataracts included nuclear sclerosis of grade 3 or more and the soft ones included nuclear sclerosis of grade 2 or less and/or posterior subcapsular cataracts.

Figure 7: Hard and soft cataracts in the two groups



The data was analyzed using chi-square tests and a significant difference was found in the grades of cataract that underwent CS-Phacoemulsification and Blumenthal technique of manual small incision cataract surgery. The phacoemulsification arm had more soft cataracts than the MSICS arm and the results were statiscally significant with a p-value <0.001.

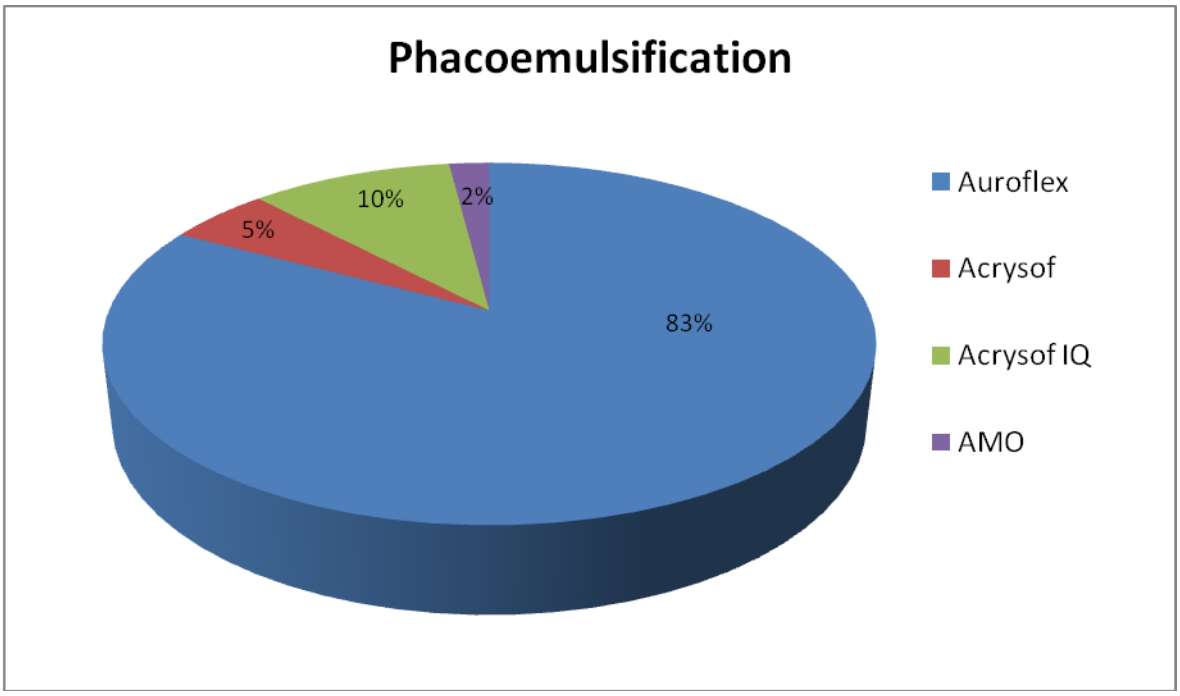
INTRAOCULAR LENS IMPLANTED

All eyes in the MSICS group had a rigid intraocular lens implanted, whereas foldable IOL was put in all eyes that underwent corneal section phacoemulsification. 2 foldable IOLs were placed in the ciliary sulcus due to posterior capsule rent during phacoemulsification.

Table 3: Different types of foldable IOL implanted after phacoemulsification

Type of lens	Phacoemulsification N = 99	
	N	%
Auroflex	82	82.8
Acrysof	5	5.1
Acrysof IQ	10	10.1
AMO	2	2
Total	99	100

Figure 8: Type of IOL implanted after phacoemulsification



VISUAL PROFILE

Our study shows that there was a definite improvement in visual status after cataract surgery. Though the pre-existing spherical error decreased with cataract surgery, an increase in the mean subjective cylinder was noted post-operatively. But this can be explained based on the fact that the surgical process by itself induces a certain amount of astigmatism (surgically induced astigmatism) which may add on or negate the pre-existing astigmatism. There was a concurrent increase in the keratometric astigmatism postoperatively signifying that some part of the surgically induced astigmatism may be because of the changes in the corneal curvature during and after surgery.

Table 4: Pre and postoperative patient visual data – "Phacoemulsification group"

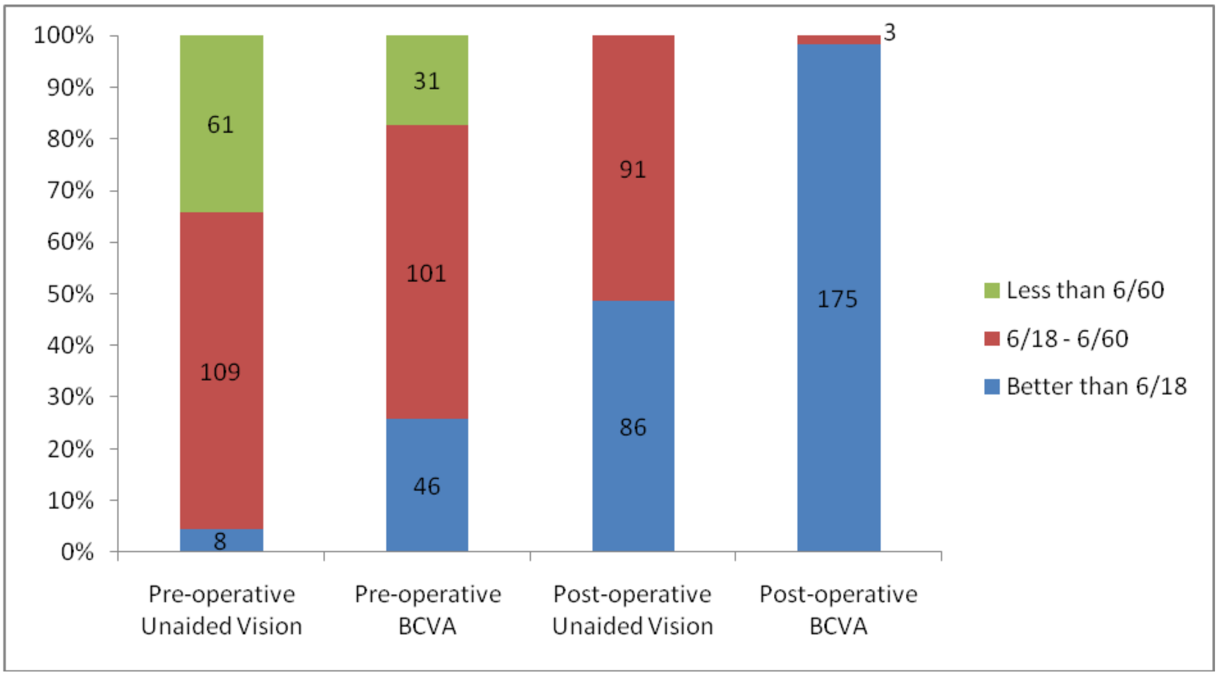
Parameter	Preoperative	Postoperative
BCVA		
Median	6/18	6/6
Range	6/9 or less	6/6 to 6/12
Sphere (D)		
Mean ± S.D	-1.49 ± 1.96	-0.26 ± 0.56
Range	-7.00 to +2.00	-3.50 to +1.00
Keratometric astigmatism (D)		
Mean ± S.D	0.86 ± 0.53	1.07 ± 0.64
Range	0.00 to +2.75	0.00 to +4.00
Mean minimum K (D) ± S.D	43.39 ± 1.66	43.25 ± 1.67
Mean maximum K (D) ± S.D	44.26 ± 1.87	44.32 ± 1.82

Table 5: Preoperative and post operative patient data – "MSICS group"

Parameter	Preoperative	Postoperative
BCVA		
Median	6/36	6/9
Range	6/9 or less	6/6 to 6/36
Sphere (D)		
Mean ± S.D	-1.68 ± 2.13	-0.30 ± 0.54
Range	-8.00 to +0.50	-2.50 to +0.75
Keratometric astigmatism (D)		
Mean ± S.D	0.79 ± 0.57	1.56 ± 0.82
Range	-0.50 to + 2.75	+0.05 to 4.50
Mean minimum K (D) ± S.D	43.87 ± 1.47	43.46 ± 1.59
Mean maximum K (D) ± S.D	44.66 ± 1.61	45.03 ± 1.65

On subdividing the data into the two study groups (Corneal section Phacoemulsification and Blumenthal technique of manual small incision cataract surgery) the results were as shown in the two tables above.

Figure 9: Gain in visual acuity after cataract surgery



* For one patient post operative unaided visual acuity was not recorded.

The above bar graph shows that there is definite improvement in both unaided and best corrected visual acuity after cataract surgery as one would expect. 46.3% of the patients achieved an unaided visual acuity of better than 6/18. But 98.3% of patients attained a BCVA better than 6/18 which is well within the guidelines laid down by WHO to monitor the cataract surgical outcomes.

On analyzing the phacoemulsification and the MSICS group separately it was revealed that eyes that underwent phacoemulsification had a better unaided visual out come as compared to MSICS. 60.6% of the eyes had an unaided vision of better than 6/18 in phacoemulsification group as compared to only 33.33% in the MSICS group. When BCVA was compared the numbers increased to 100 % for phacoemulsification group and 96.2% for the MSICS group. This signifies that the residual refractive error is more after MSICS.

Figure 10: Comparison of visual acuity at 6 weeks in eyes that underwent MSICS

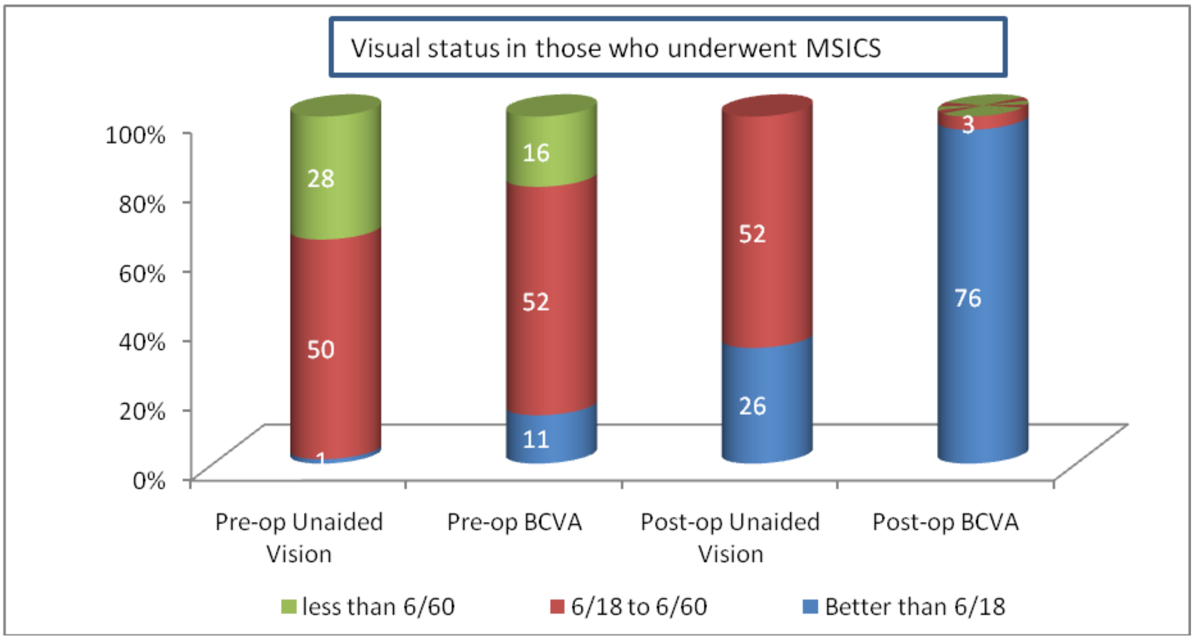


Figure 11: Comparison of visual acuity at 6 weeks in eyes that underwent Phaco

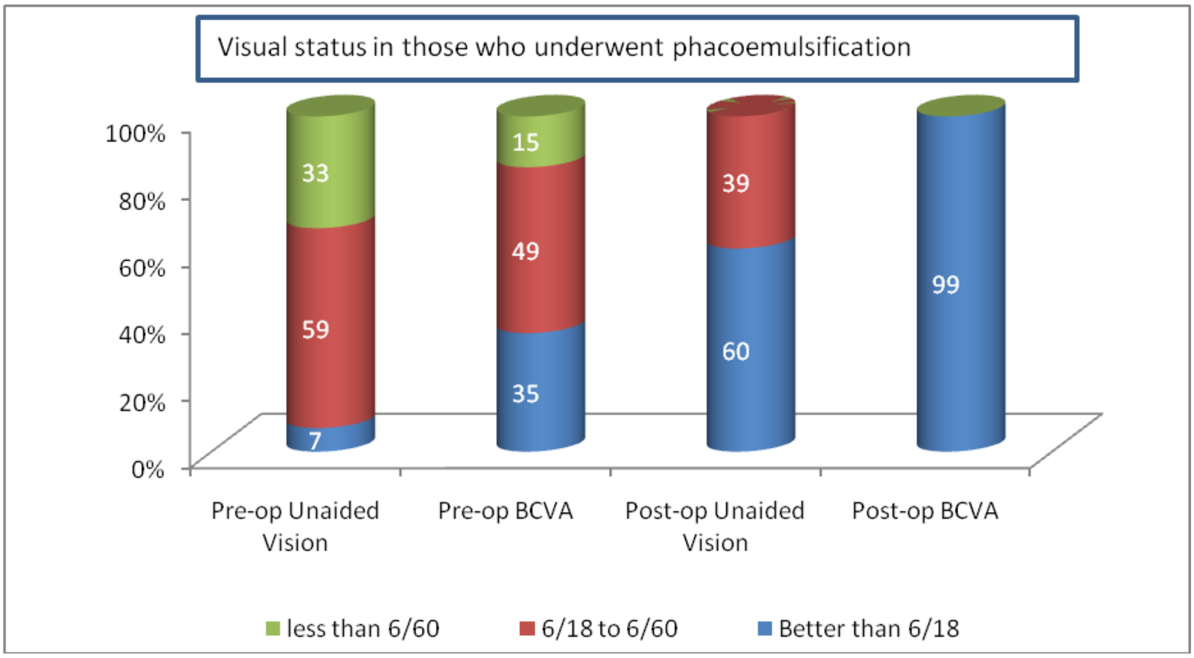


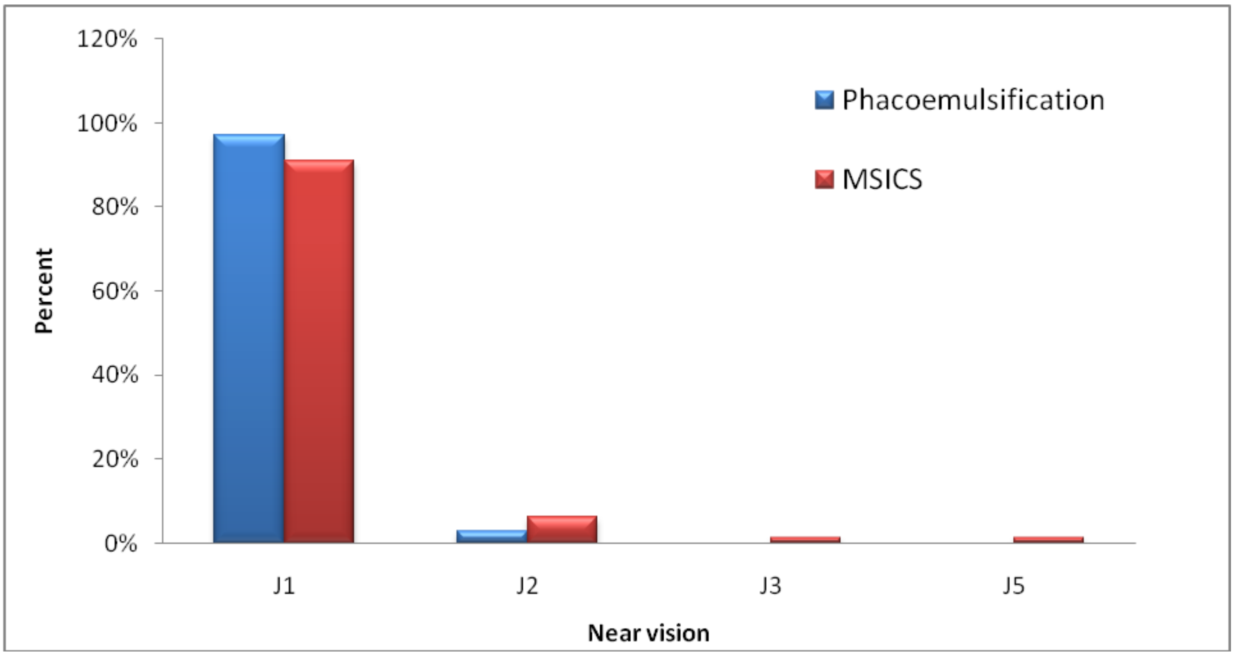
Table 6: Statistical analysis comparing the visual outcome in the two study groups

			Better than 6/18	6/18 to 6/60	Worse than 6/60	‘p’ value
Preoperative	Unaided vision	Phaco N=99	7	59	33	0.157
		MSICS N=79	1	50	28	
	BCVA	Phaco N=99	35	49	15	0.006
		MSICS N=79	11	52	16	
Postoperative	Unaided vision	Phaco N=99	60	39	0	**0.007**
		MSICS N=78	26	52	0	
	BCVA	Phaco N=99	99	0	0	0.27
		MSICS N=79	76	3	0	

Table 7: Comparison of post op BCVA for near at 6 weeks between the two groups

Near vision	Phacoemulsification N = 99		MSICS N = 79	
	n	%	n	%
J1	96	97	72	91.1
J2	3	3	5	6.3
J3	0	0	1	1.3
J5	0	0	1	1.3
	99	100	79	100

Figure 12: Post operative best corrected visual acuity for near at 6 weeks



Three patients had best corrected near vision of J2 after phacoemulsification. Of them one had foveal atrophy, other had ambyopia and no cause could be detected for the third case. In the manual small incision group three patients had PCO accounting for near vision of J5, J3 and J2. Others 5 eyes with J2 vision did not have any notable pathology.

Table 8: Comparison of the number of patients who bought spectacles after cataract surgery in the two groups

Post operative unaided VA	Phacoemulsification N=99		MSICS N=78	
	Bought glasses		Bought glass	
	Yes	No	Yes	No
6/6	6	11	0	2
6/9	11	9	2	9
6/12	10	13	2	11
6/18	4	13	0	21
6/24	7	9	4	15
6/36	2	3	2	7
6/60	1	0	0	3
TOTAL	41(41.41%)	58	10(12.82%)	68
P value	**0.48**		**0.42**	

In our study 41.41% of patients bought glasses after phacoemulsification whereas only 12.8% patients did the same after MSICS. This difference can be explained based on the differences in the socio-economic status, occupational needs, and status and visual acuity of the fellow eye in the two study groups.

There was no statistically significant correlation between the unaided visual acuity and the probability of buying spectacles in the two groups as analyzed by chi-square tests ($p>0.05$)

SURGICALLY INDUCED ASTIGMATISM (SIA)

Table 9: Comparison of SIA after Phacoemulsification & MSICS

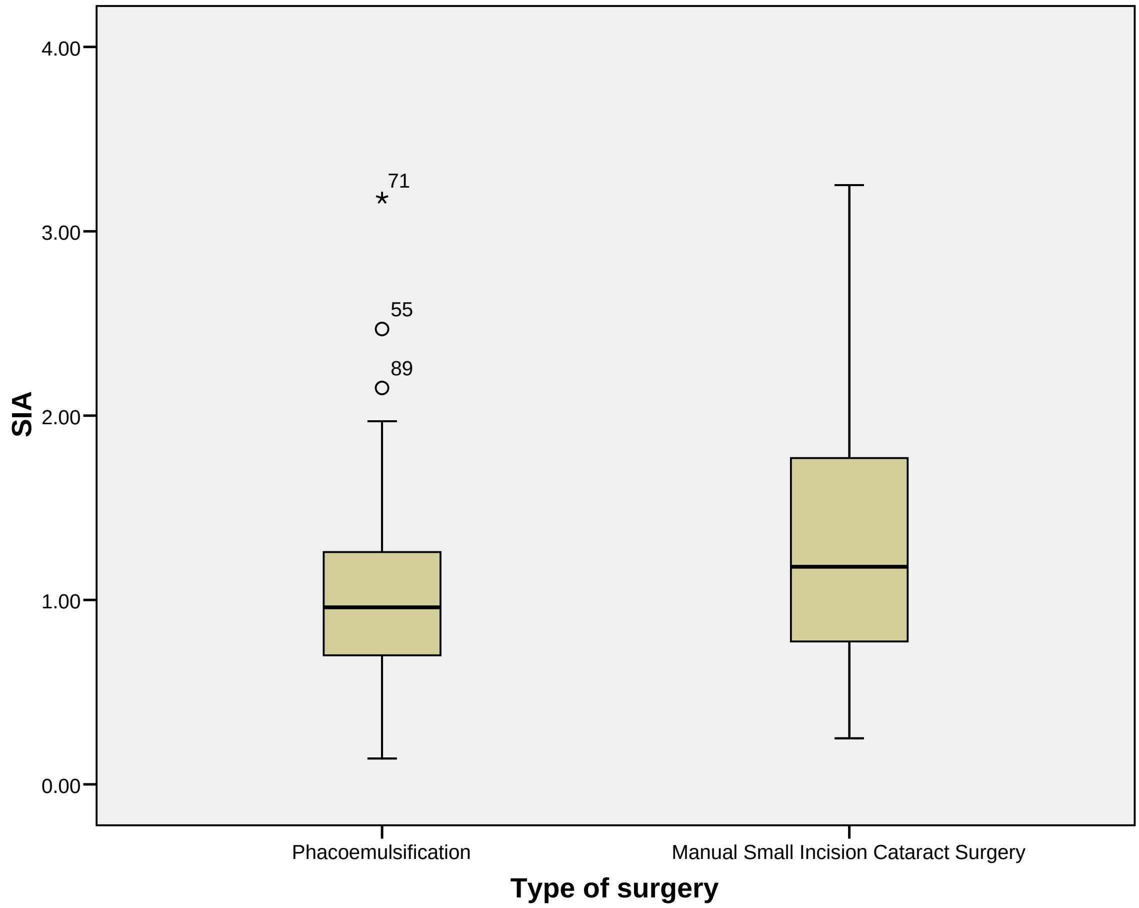
SIA	Phacoemulsification N= 99		MSICS N = 79	
	n	%	n	%
<0.5D	14	14.14	11	13.92
0.5 to <1.00D	38	38.38	19	24.05
1 to <2.00D	44	44.45	34	43.04
2 to <3.00D	2	2.02	14	17.72
3 to 3.50D	1	1.01	1	1.27

The distribution of surgically induced astigmatism after the two techniques of cataract surgery was as shown in the table above. Only two of the 99 patients in the corneal section phacoemulsification group had high surgically induced astigmatism of ≥ 2.0D. There was no notable cause for this extreme SIA in these eyes. Following Blumenthal technique of manual small incision cataract surgery 15 eyes had high astigmatism of ≥ 2.0D. In the MSICS group three patients had wound problems during the surgery. Scleral sutures were placed in two cases. At 6 weeks these eyes had SIA of 2.22D and 0.84D

Table 10: Statistical analysis of the SIA following phacoemulsification and MSICS

SIA	Corneal section Phacoemulsification	Blumenthal technique of manual small incision cataract surgery	P value
Mean	1.01 ± 0.49 D	1.29 ± 0.71 D	0.003
Median	0.96D	1.18D	
Minimum	0.14D	0.25D	
Mximum	3.18D	3.25D	

Figure 13: SIA after different techniques of cataract surgeries



The mean surgically induced astigmatism was calculated and compared between the two surgical groups using independent t-test. The mean SIA in those who underwent Phacoemulsification was 1.01 D ± 0.49 D and in those who underwent manual small incision cataract surgery was 1.29 D ± 0.71 D. There was a mean difference of 0.28 D surgically induced astigmatism between the 2 groups. Phacoemulsification induces 0.28 D astigmatism less than MSICS ($p<0.05$). This result though statistically significantly different may not be of much clinical significance.

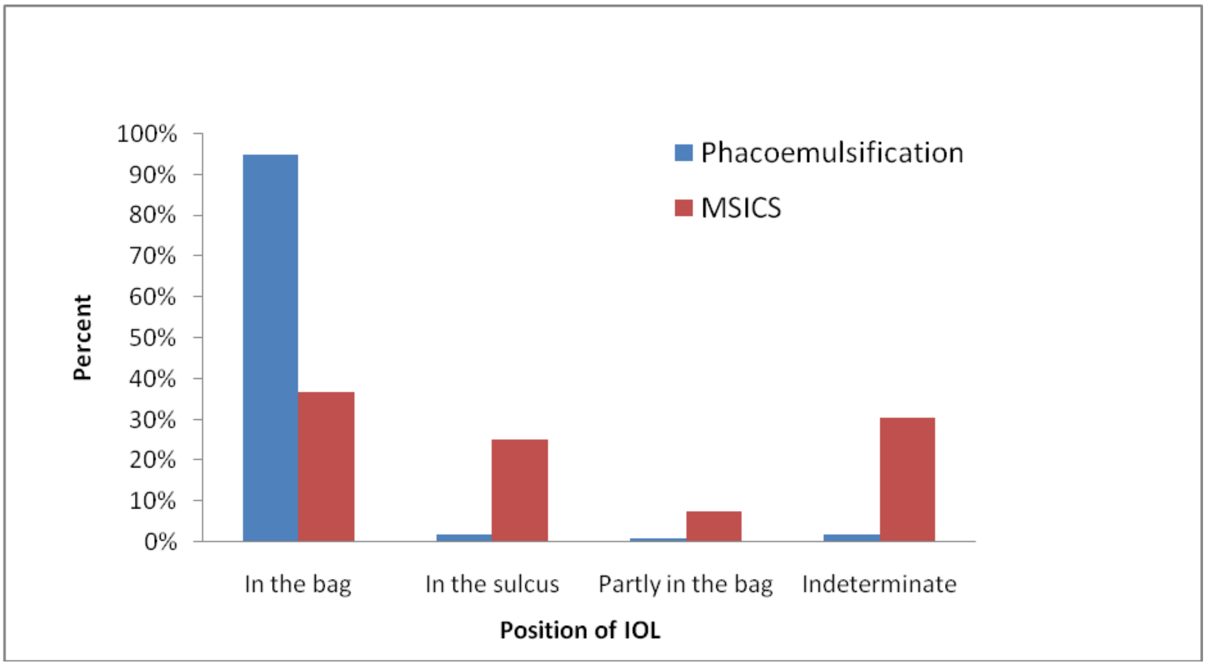
FACTORS AFFECTING SURGICALLY INDUCED ASTIGMATISM

Position of intraocular lens

Table 11: Comparison of the position of the IOL after the two surgical techniques

Position of IOL	Phacoemulsification N= 99		MSICS N = 79	
	n	%	n	%
In the bag	94	95	29	36.7
In the sulcus	2	2.0	20	25.3
Partly in the bag	1	1.0	6	7.6
Indeterminate	2	2.0	24	30.4
	99	100	79	100

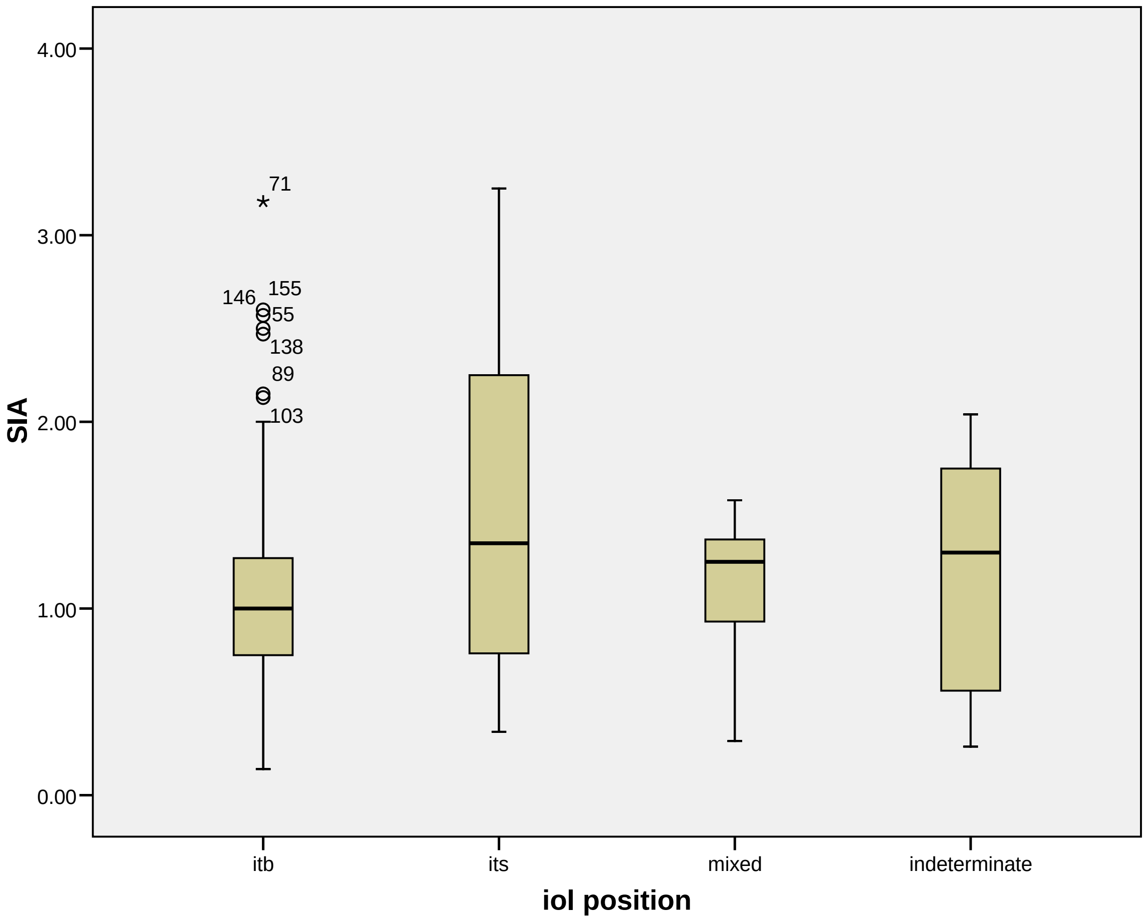
Figure 14: Comparison of the position of the IOL in the two study groups



In our study 95% of the eyes that underwent phacoemulsification were documented to have the foldable IOL in the capsular bag. In 2% of the eyes the IOL was purposefully put in the ciliary sulcus due to posterior capsule rent during the procedure.

Effect of the position of intraocular lens in the eye on SIA

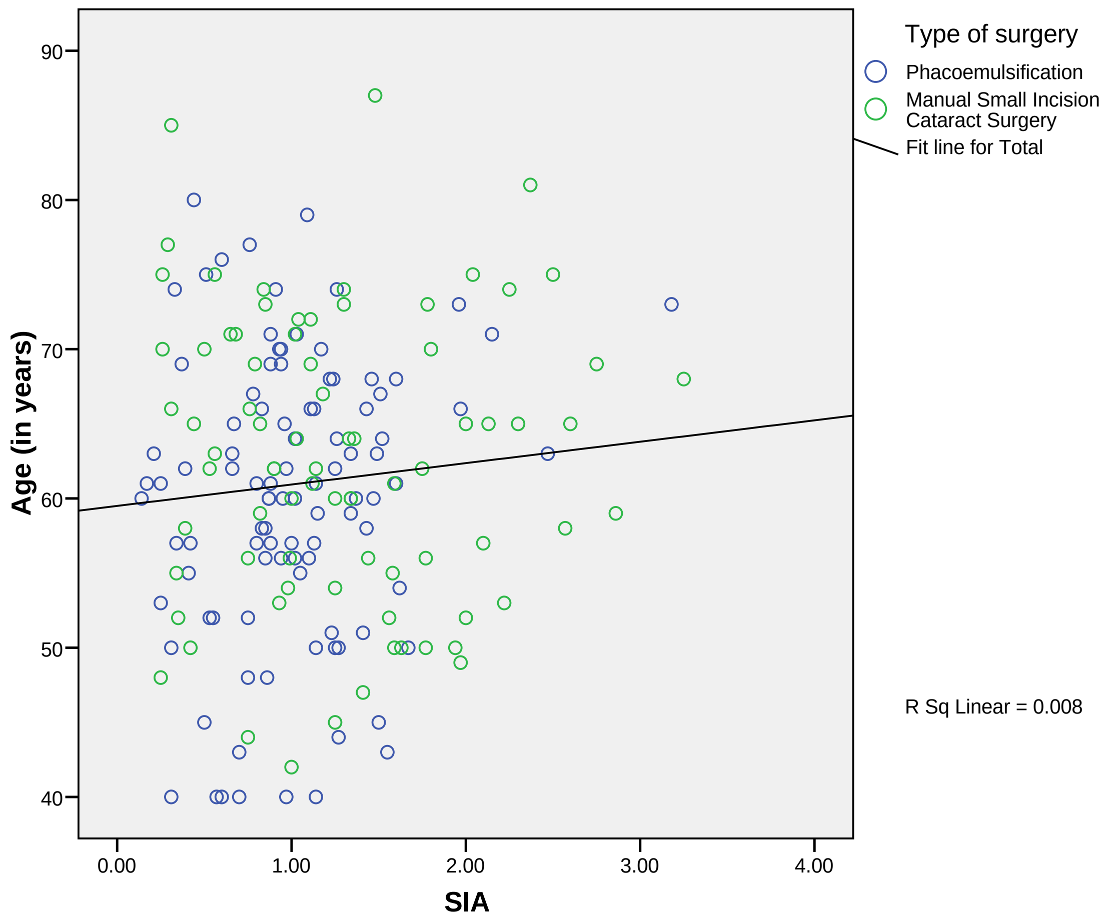
Figure 15: Comparison of SIA in eyes with different positions of IOL



In a cataract surgery the ideal placement of the IOL would be in the bag. But sometimes it may not be possible and the lens may be in the ciliary sulcus or partly in the bag and partly in the sulcus. In such situations one would expect induced lenticular astigmatism which can affect the SIA. There we analyzed our data using ANOVA test to compare the SIA with different positions of IOL. There is no statistically significant difference in the IOL position in affecting surgically induced astigmatism ($p>0.05$).

Effect of age on surgically induced astigmatism

Figure 16: effect of age on SIA in the two groups



With increasing age changes in corneal characteristics have been described in the past. Therefore we decided to study whether SIA differs with age in our patients or not. A regression analysis was done and a graph was plotted as shown above. Different values of SIA were seen to be equally distributed in all age groups in both phacoemulsification and MSICS arms. Thus it can be said that age does not affect SIA significantly.

Effect of position of the incision (Supero-temporal or Supero-nasal) on SIA in the Phacoemulsification group

In our study superior scleral section incision was made for all patients who underwent manual small incision cataract surgery. For phacoemulsification clear corneal section incision was made at 10:30 ‘O’ clock position for all patients. This meant that the incision was made superotemporally in the right eye and superonasally in the left eye. Superonasal incisions cause more surgical discomfort for the surgeon and therefore technically slightly more difficult. SIA has been described in literature to vary with the side operated (right or left eye). Therefore we subdivided out phacoemulsification arm into right and left eye and then further analyzed the SIA in the two subgroups.

Table 13: Comparison of SIA between the two eye following phacoemulsification

SIA	Right eye (Supero-temporal insicion) N= 60		Left eye (Supero-nasal incision) N = 39	
	n	%	n	%
<0.5D	10	16.67	4	10.26
0.5 to <1.00D	25	41.67	13	33.34
1 to <2.00D	24	40.00	20	51.28
2 to <3.00D	1	01.66	1	02.56
3 to 3.50D	0	00.00	1	02.56

Figure 17: Variation in SIA based on the difference in the site of incision between the two eyes in phacoemulsification

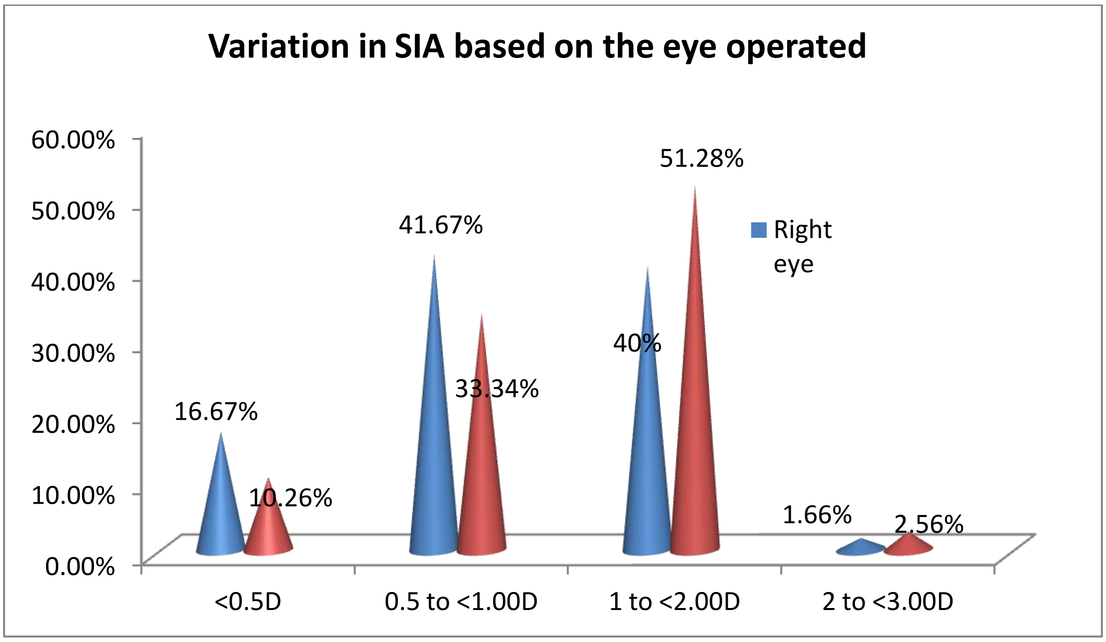


Table 14: Statistical analysis of the difference in astigmatism with change in site of the cataract incision

SIA	Right eye (Supero-temporal incision)	Left eye (supero-nasal incision)
Mean	**0.94D**	**1.11D**
Std. error of mean	0.059D	0.087D
Median	0.92D	1.02D
Mode	0.88D	1.14D
Std. deviation	0.45D	0.54D
Minimum	0.14D	0.31D
Maximum	2.47D	3.18D

'p' value – 0.09

In our study left eye had slightly more surgically induced astigmatism as compared to right eye. Mean SIA in the left eye was 1.11D as compared to only 0.94D in the right eye. Statistical analysis was done using the independent t-test test and the difference of means between the two eyes was found to be 0.17. This was statistically not significant.

CORRELATION BETWEEN SIA & POST OPERATIVE PRESCRIBED CYLINDER

Figure 18: Comparison of the prescribed cylinder at 6 weeks in the two arms

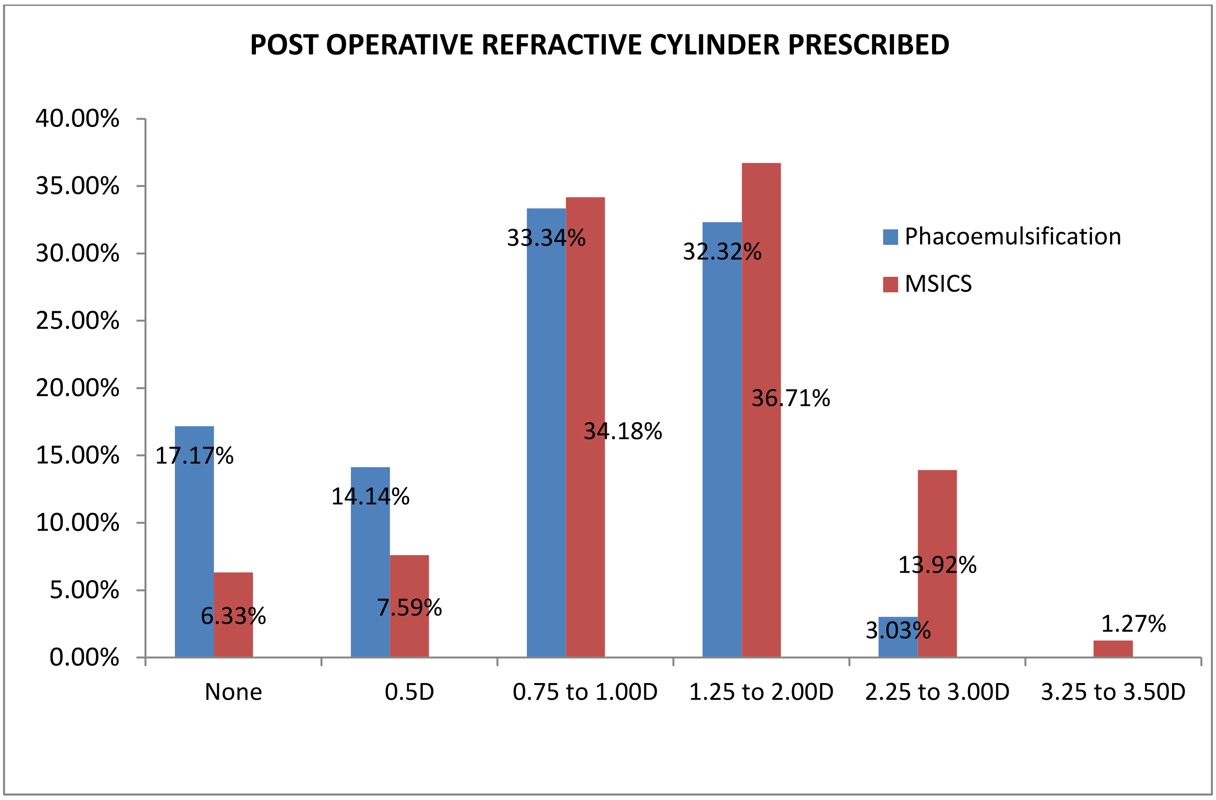


Figure 19: Comparison of the SIA in the two groups

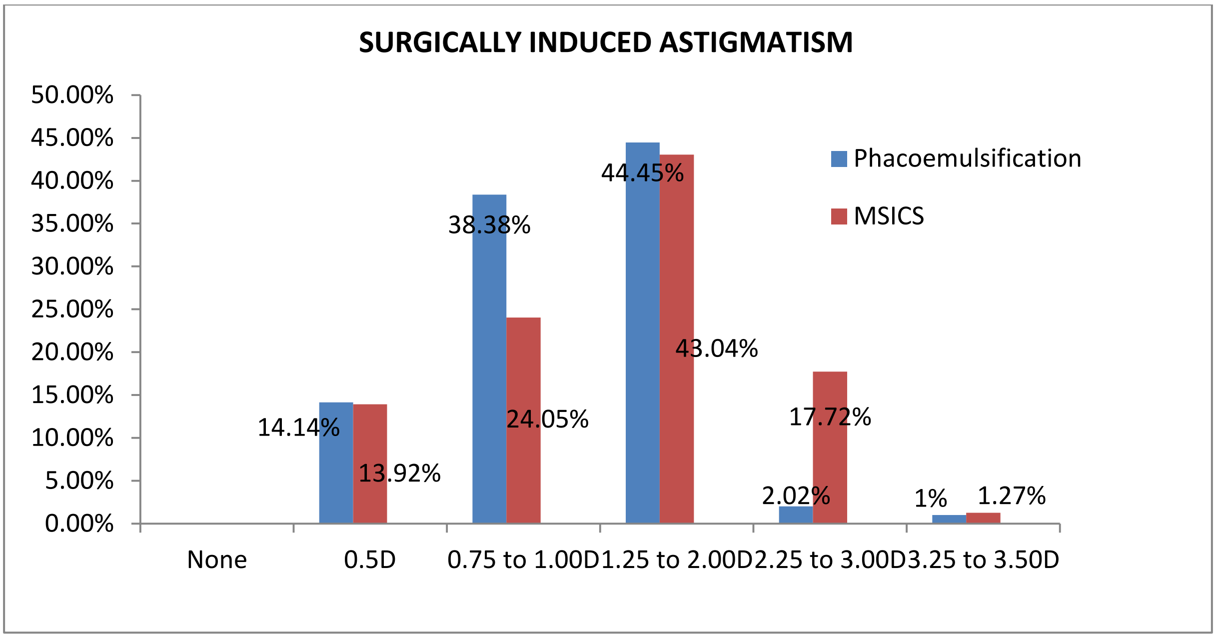


Table 15: Statistical comparison between the SIA and prescribed cylinder

	Phacoemulsification	MSICS	'p' value
Mean induced astigmatism	1.01D ± 0.49D	1.28D ± 0.70D	**0.003**
Mean of the magnitude of prescribed cylinder	-0.94 ± 0.63D	-1.36 ± 0.77D	**0.00**

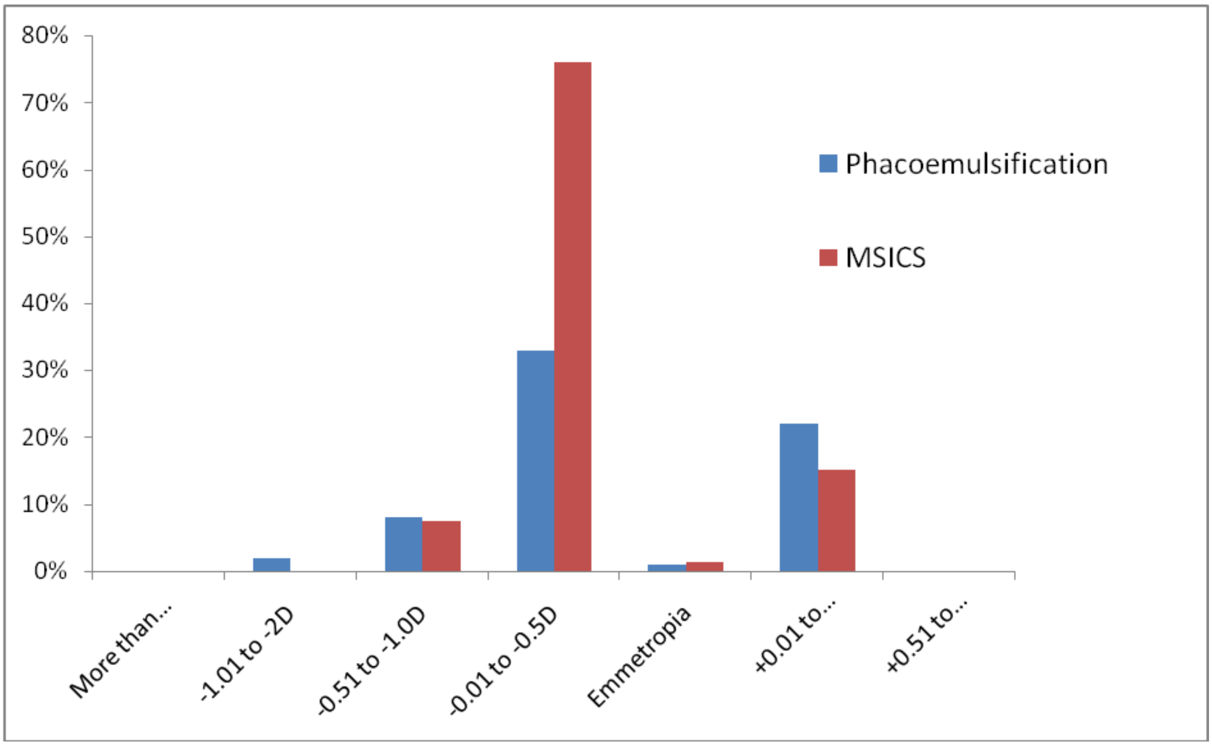
Mean SIA and mean of the prescribed cylinder in the two surgical groups was analyzed using Independent t-test and a significant statistical difference was noted.

TARGET SPHERICAL ERROR

Table 16: Pre operative target spherical error in the two groups

IOL power aim	Phacomemulsification N = 97		MSICS N = 79		P value
	n	%	n	%	
More than -2D	0	0	0	0	
-1.01 to -2D	2	2	0	0	
-0.51 to -1.0D	8	8	6	7.5	
-0.01 to -0.5D	**64**	**33**	**60**	**76**	
Emmetropia	1	1	1	1.3	
+0.01 to +0.5D	22	22	12	15.2	
+0.51 to +1.0D	0	0	0	0	
	97	100	79	100	
MEAN TARGET SPHERICAL ERROR	-0.19 ± 0.25D		-0.16 ± 0.21D		**0.50**

Figure 20: Target spherical error in the two study groups



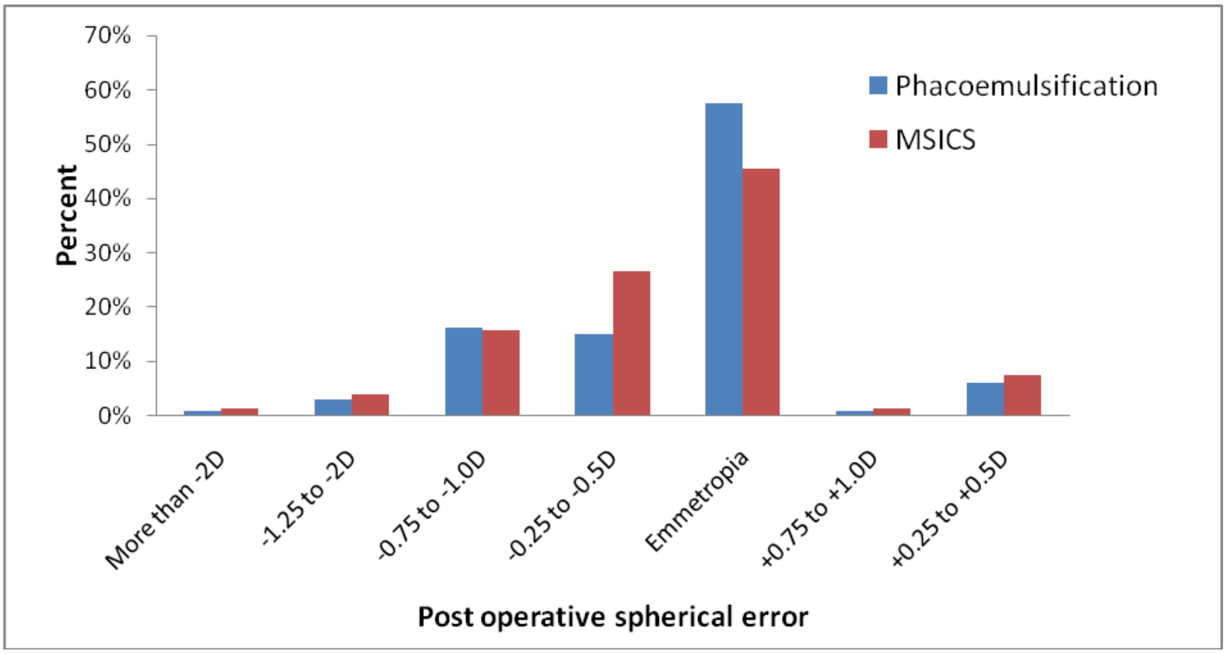
Target refraction was aimed within 0.5D of emmetropia for most of the patients in the study.

<u>**POST OPERATIVE SPHERICAL ERROR**</u>

Table 17: Post operative subjective spherical prescribed at 6 weeks

Spherical correction	Phacoemulsification N = 99		MSICS N = 79	
	n	%	N	%
More than -2D	01	1.0	01	1.3
-1.25 to -2D	03	3.0	03	3.9
-0.75 to -1.0D	16	16.2	11	15.9
-0.25 to -0.5D	15	15.2	21	26.6
Emmetropia	**57**	**57.6**	**36**	**45.6**
+0.75 to +1.0D	01	1.0	01	1.3
+0.25 to +0.5D	06	6.1	06	7.6
	99	100	79	100

Figure 21: Comparison of the spherical error prescribed at 6 weeks in the two groups



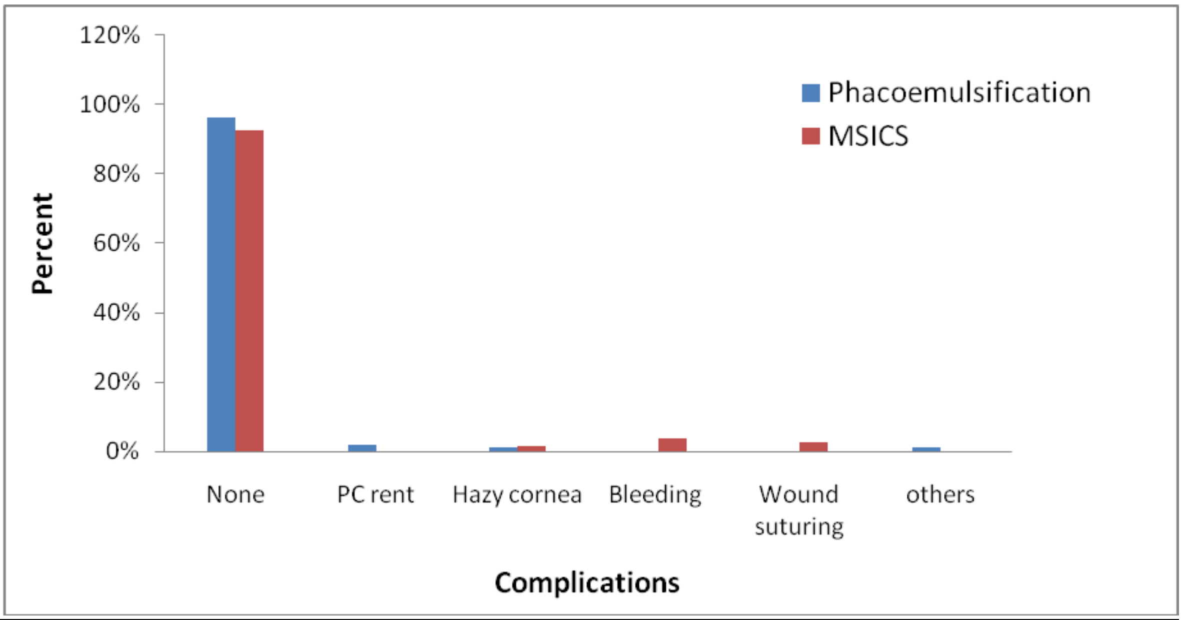
Emmetropia in terms of spherical error was achieved in majority of the eyes in our study

INTRA OPERATIVE COMPLICATIONS

Table 18: Comparison of intraoperative complications between Phaco and MSICS

Complication	Phacomemulsification N = 99		MSICS N = 79	
	n	%	n	%
None	95	96	73	92.4
Posterior capsule rent	2	2	0	0
Hazy cornea	1	1	1	1.3
Bleeding	0	0	3	3.8
Wound suturing	0	0	2	2.5
others	1	1	0	0
	99	100	79	100

Figure 22: Intraoperative complications



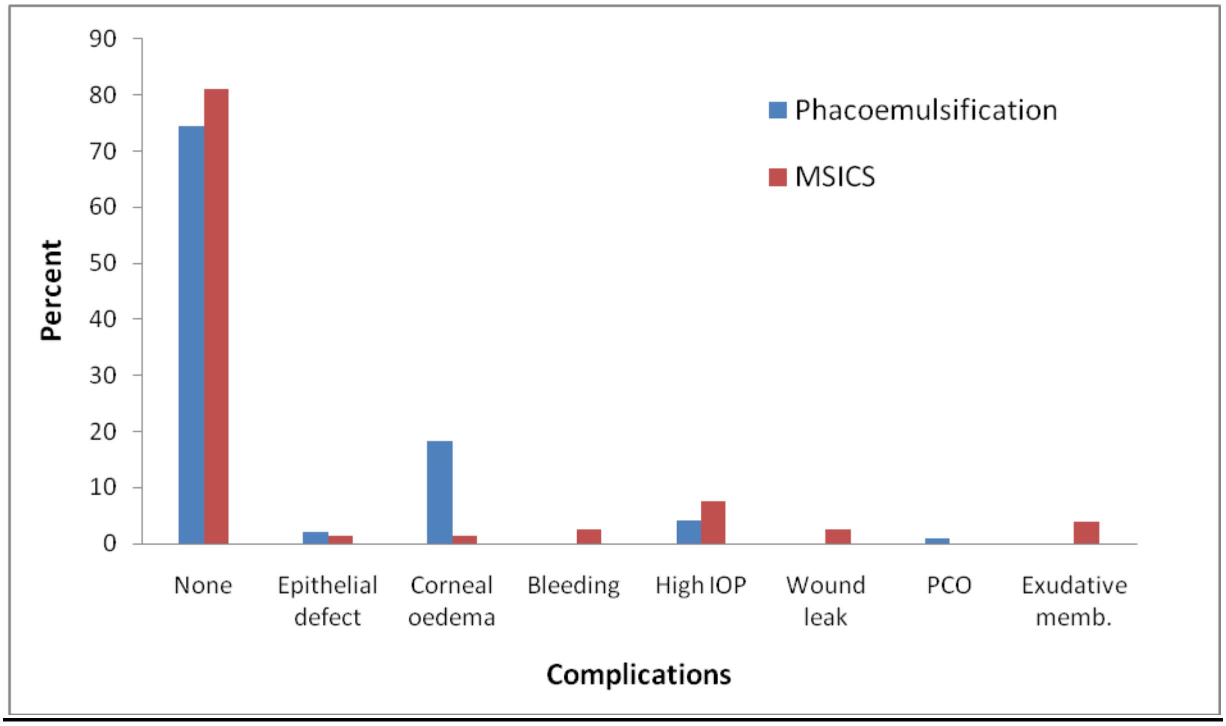
In our study more than 90% of patients in both groups had an uncomplicated surgery. One patient in the Corneal section phacoemulsification group had a rare complication of the superior haptic breaking inside the eye while injection the IOL. As the IOL was well centered in the bag no explantation was attempted. Post operative follow up was uneventful.

IMMEDIATE POST OPERATIVE COMPILCATIONS – DAY 1

Table 19: Comparison of immediate postoperative complications b/w Phaco & MSICS

Complication	Phacomemulsification N = 99		MSICS N = 79	
	n	%	n	%
None	74	74.47	64	81
Epithelial defect	2	2	1	1.3
Corneal oedema	18	**18.2**	1	**1.3**
Bleeding	0	0	2	2.5
High IOP	4	4	6	7.6
Wound leak	0	0	2	2.5
PCO	1	1	0	0
Exudative membrane	0	0	3	3.8
	99	100	79	100

Figure 23: Comparison of the immediate postoperative complications in the two groups



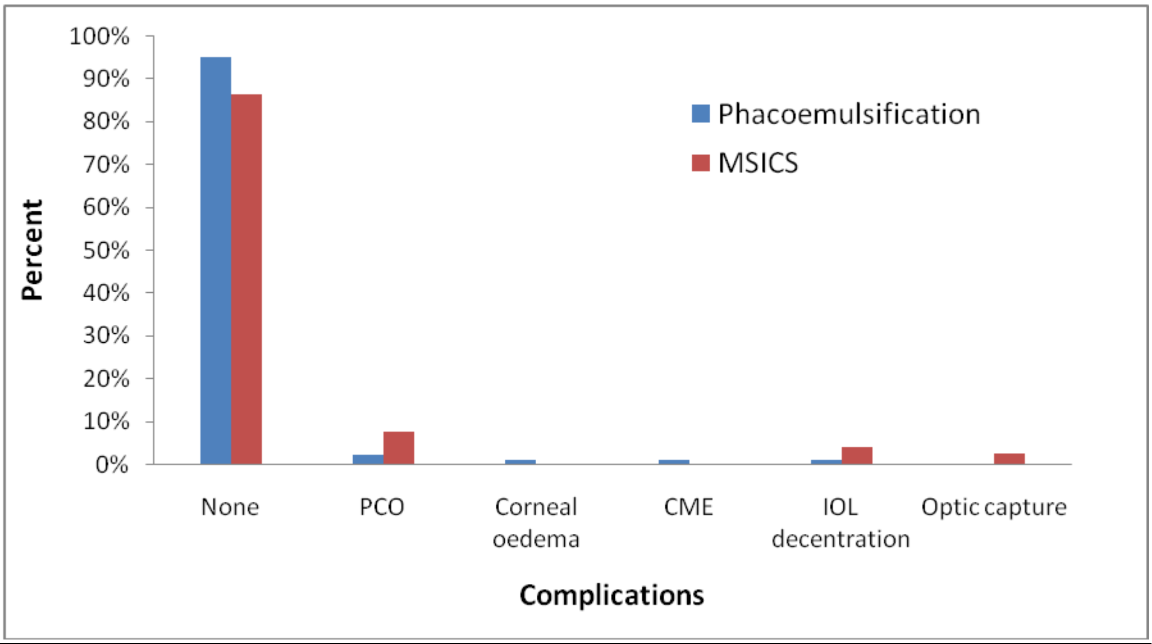
The higher incidence of post-operative corneal oedema after phacoemulsification may reflect transient endothelial damage due to the phaco power used during the procedure.

LATE POST OPERATIVE COMPLICATIONS – 6 WEEKS

Table 20: Comparison of late postoperative complications b/w Phaco & MSICS

Complication	Phacomemulsification N = 99		MSICS N = 79	
	n	%	N	%
None	94	95	68	86.1
Posterior capsule opacification	2	2	6	7.6
Corneal oedema	1	1	0	0
Cystoid macular oedema	1	1	0	0
IOL decentration	1	1	3	3.8
Optic capture	0	0	2	2.5
	99	100	79	100

Figure 24: Comparison of the immediate postoperative complications in the two groups



Corneal oedema that was noted on 1st post-operative day after phacoemulsification resolved in most of the cases by 6 weeks. Posterior capsule opacification was seen more with MSICS as compared with phacoemulsification. This may be related to the sulcus placement of the IOL in some of these cases. But more cases need to be studied and followed up for a longer duration to comment further.

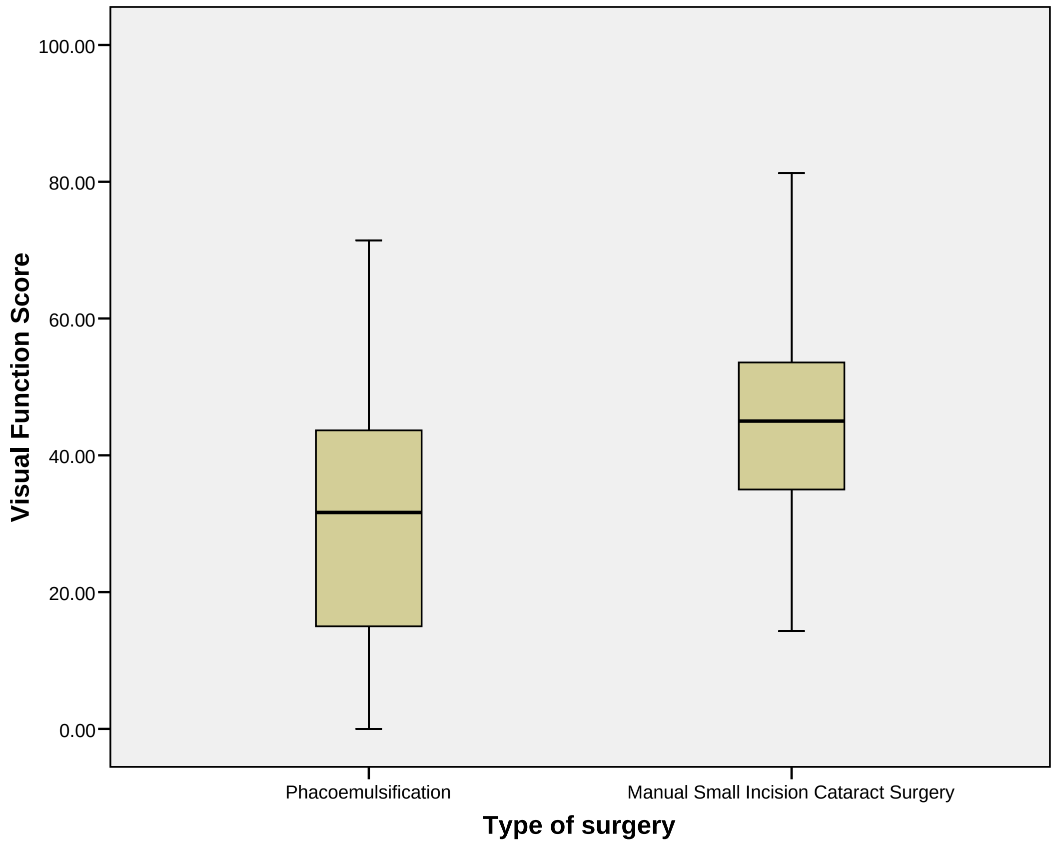
SUBJECTIVE VISUAL FUNCTION ASSESSMENT

Improvement in visual function after cataract surgery

(Visual Function Score)

Visual function score = Difference between the post and pre operative visual function

Figure 25: comparison of the subjective improvement in visual function in the 2 groups



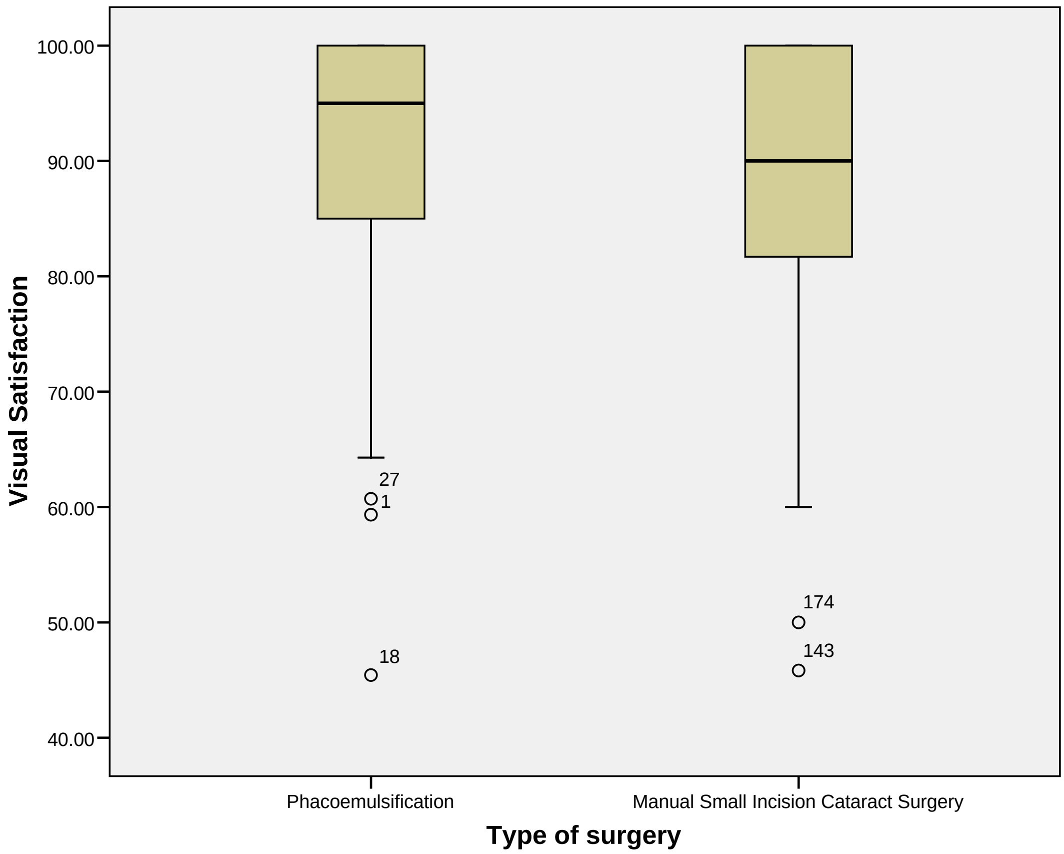
Visual function score was analyzed using the independent t-test. There was a statistically significant difference in the mean visual function score between phacoemulsification and manual small incision surgery ($p<0.001$). The subjective improvement in visual function was more dramatic after MSICS than Phacoemulsification

Postoperative visual function

Visual function score indicates the dramatic improvemant in the visual perception after cataract surgery and this is significantly dependent on the pre-operative visual disability. More the visual disability before surgery, better will be the VF-score.

Postoperative visual function is a better indicator of patient satisfaction as it tells about the final subjective visual function status as experienced by the patient

Figure 26: Comparison of the post-operative visual function in the two groups



On comparison of post-operative visual outcome between the 2 groups, phacoemulsification had a slightly better outcome, but this was statistically not significant ($p>0.05$).

ENDOTHELIAL CELL LOSS FOLLOWING CATARACT SURGERY

Valid endothelial cell count pre and post operatively was available only for 73 eyes in the phacoemulsification group and 44 patients in the MSICS group.

Table 21: Comparison of the endothelial cell loss following surgery in the two gropus

Endothelial cell loss	Phacoemulsification N = 73		MSICS N = 44	
	n	%	n	%
Less than 500	48	65.75	37	84.1
500 to less than 1000	15	20.55	5	11.36
1000 to less than 1500	5	6.85	2	4.54
More than 1500	5	6.85	0	0
	73	100	44	100

Figure 27: Comparison of the endothelial cell loss in the two groups

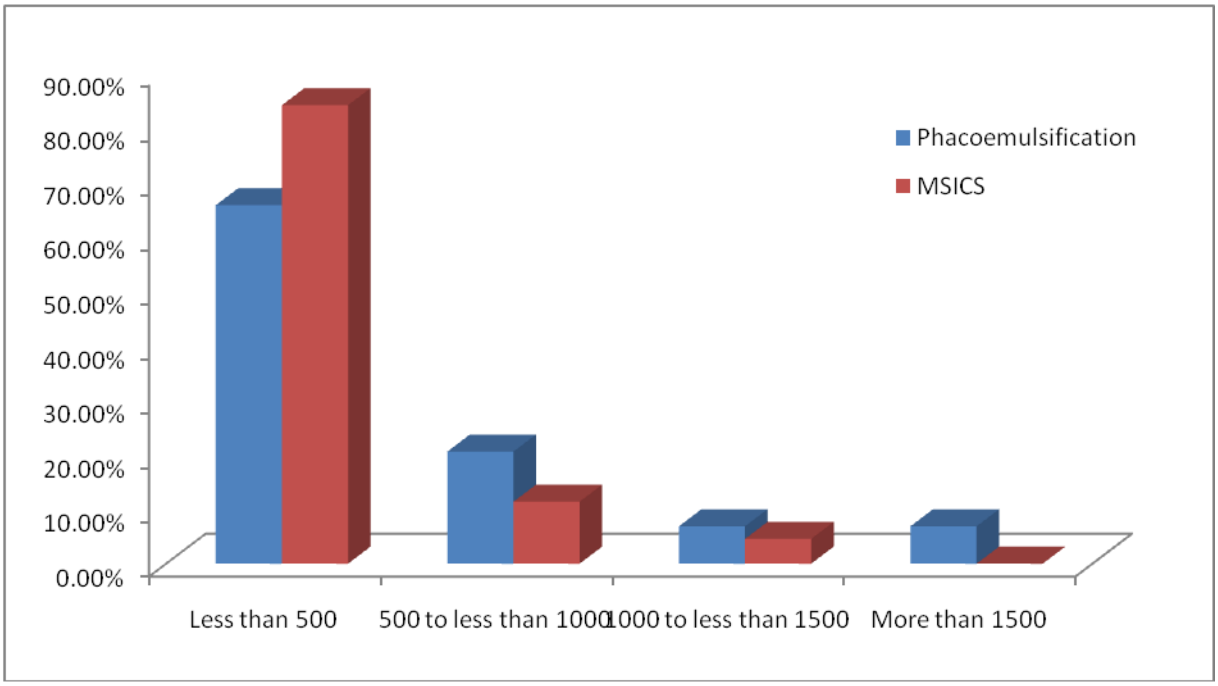


Table 22: Mean (SD) pre- and postoperative endothelial cell counts and surgically induced endothelial cell loss

	Phacoemulsification N = 73	MSICS N = 44	'p' Value
Preoperative mean – cells/mm^2 (SD)	2566.63 (374.94)	2522.43 (355.05)	0.530
Postoperative mean– cells/mm^2 (SD)	2039.71 (514.64)	2251.59 (335.90)	**0.008**
Endothelial cell loss – cells/mm^2 (SD)	526.91 (474.72)	270.84 (280.34)	**<0.001**
Percentage reduction - % (SD)	20.16 (17.43)	10.29 (9.90)	**0.001**

FACTORS AFFECTING THE EXTENT OF ENDOTHELIAL CELL DAMAGE DURINF CATARACT SURGERY

Technique of cataract surgery

Table 23: Comparison of the endothelial cell loss after Phacoemulsification & MSICS

Type of surgery	N	Mean (cells/mm^2)	Std. Deviation	Std. Error Mean	p-value
Phacoemulsification	73	526.92	474.73	55.56	**0.002**
MSICS	44	270.84	280.35	42.26	

The mean endothelial cell loss following corneal section phacoemulsification and Blumenthal technique of manual small incision cataract surgery was 527 cells/mm^2 and 271 cells/mm^2 respectively. This difference was analyzed statistically using the independent t-test and was found to be significant.

Diabetic status

Table 24: Comparison of endothelial cell loss in diabetics versus non diabetics

Diabetes	Group statistics				Independent samples test
	N	Mean (cells/mm^2)	Std. Deviation	Std. Error Mean	p-value
Yes	41	496.76	451.01	70.43	**0.223**
No	76	394.93	416.23	47.74	

There was no statistically significant effect of diabetes on the extent of endothelial cell damage during cataract surgery in our study

Grades of cataract

Endothelial cell loss in eyes with different grades of cataract was compared to each other using bonferroni test and no significant correlation could be appreciated ($p > 0.05$)

CHANGE IN CENTRAL CORNEAL THICKNESS AFTER CATARACT SURGERY

Table 25: comparison of changes in CCT following cataract surgery in the two groups

Change in central corneal thickness		Phacoemulsification N = 96		MSICS N = 77	
		N	%	N	%
Gain in CCT	Less than 10 microns	28	29.17	23	29.88
	10 to less than 20 microns	17	17.71	11	14.28
	20 to less than 30	7	7.29	5	6.49
	30 to less than 40	1	1.04	1	1.3
	More than 40	1	1.04	1	1.3
Loss in CCT		42	43.75	36	46.75
Total		96	100	77	100

For three patients in the phacoemulsification group and two in the MSICS group, central corneal thickness values could not be recorded.

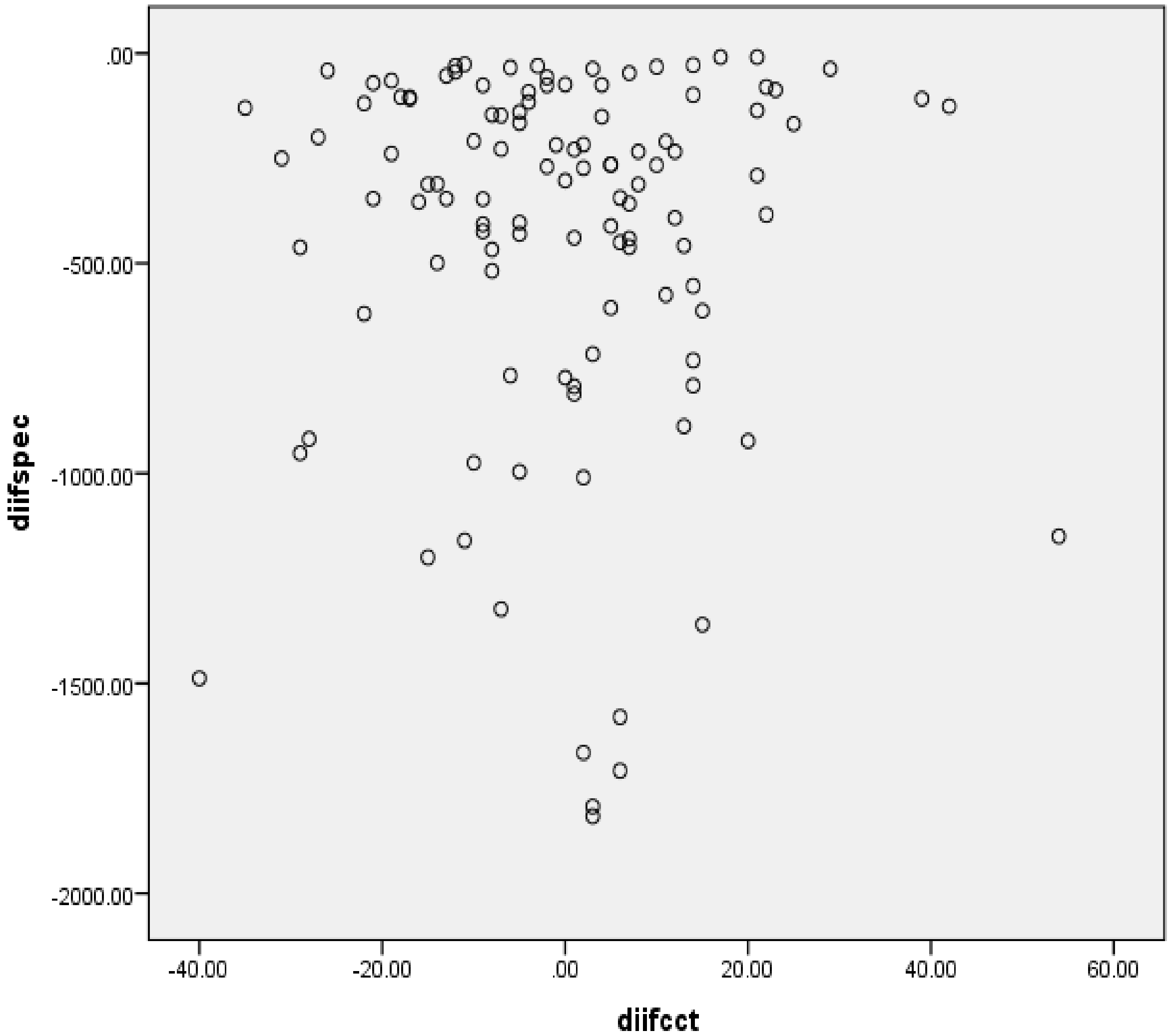
Table 26: Independent samples test

	N	Mean	Standard deviation	P value
Phacoemulsification	96	-0.22	18.61	0.904
MSICS	77	+0.10	16.05	

Statistical analysis using independent t-test showed no statistical difference in the change in mean central corneal thickness between the two groups.

CORRELATION BETWEEN ENDOTHELIAL CEL LOSS AND CHANGE IN CENTRAL CORNEAL THICKNESS

Figure 28: Correlation b/w endothelial cell loss and increase in CCT



On analyzing the correlation between endothelial cell loss and increase in corneal thickness there was no definite negative correlation that could be appreciated. This may be suggestive of clinical irrelevance of endothelial cell loss after uncomplicated cataract surgery. But more patients need to be studied for a longer duration of time to comment further.

DISCUSSION

In India cataract is still the leading cause of blindness. Surgery being the only treatment option available, low cost surgical techniques that are quick and easy to master are the demand of time. Manual small incision cataract surgery has emerged in a big way because it avoids the disadvantages of ECCE and at the same time enjoys the advantages of phacoemulsification. It is inexpensive, quick, has a shorter learning curve, can deal with all types of cataract, and relatively safe even in inexperienced hands. With improved instrumentation and technological advancements MSICS is slowly becoming the preferred surgical technique for most low cost, high volume surgical setups. The visual outcome following MSICS is slowly improving though not comparable to phacoemulsification. We did the study to compare the visual outcome following corneal section Phacoemulsification and Blumenthal technique of manual small incision cataract surgery.

In our study the demographic profile of the patient in terms of age and gender of the subjects in the two study groups was similar. This made the data in the two arms comparable.

Cataracts with nuclear sclerosis of grade three or less were only included in the study in order to avoid the grade of cataract as a confounding factor. On sub-grouping it was revealed that the corneal section phacoemulsification arm had more number of soft nuclei as compared to MSICS arm. On statistical analysis of the same, the difference was significant. This may indicate that surgeon’s preference regarding the technique of surgery to be undertaken is to some extent guided by the type and grade of cataract. Phacoemulsification is generally not preferred for higher grades of nuclear sclerosis. This bears a good clinical correlation because it is well known that phacoemulsificaion is more difficult in hard cataracts especially mature and hypermature (67). Difficulty in completing the continuous curvilinear capsulorhexis and emulsification of the hard nucleus makes the surgery challenging (68). The higher rates of intraoperative complications (69) may lead to surgeons erring on the side of MSICS rather than phacoemulsification for these cases. But studies have shown that phacoemulsification is quite safe and well tolerated procedure for all kinds of cataract in experienced hands (70) (69).

The post operative visual outcome was analyzed for the two surgical groups. In our study overall 48.6% of the patients achieved an unaided visual acuity of better than 6/18. On spectacle correction this figure improved to 98.31%. On analyzing the phacoemulsification and MSICS group separately, visual outcome following corneal section Phacoemulsification was better than Blumenthal technique of MSICS at 6 weeks. 60.6% of patients achieved uncorrected visual acuity of 6/18 or better after phacoemulsification as compared to only 33.33% in the MSICS group. Best corrected visual acuity of better than 6/18 was attained in 100% after phacoemulsification and 96.2% after MSICS. A study done by George et al, where they studied 62 eyes with phacoemulsification and 62 with MSICS, has shown that BCVA of better than 6/18 was achieved in100% of those who had Phacoemulsification and 98.2% of patients who had MSICS. They did not comment on the unaided visual acuity(6). Another Indian study reported unaided visual acuity of 6/18 or better in 47.9% of patients after MSICS at 6 weeks postoperatively (44). Our results are comparable with these studies.

Gogate et al studied 400 eyes and have reported unaided vision of 6/18 or better at 6 weeks in 81.08% of the cases who underwent phacoemulsification and 71.1%% of those who had

MSICS. After correction these numbers improved to 98.4% in both the groups (46). The difference in results may be due to the small sample size in our study.

It has been postulated in literature that Phacoemulsification results in better visual outcome due to lesser post operative residual refractive error (47) (46). A significant component of this residual refractive error is attributed to surgically induced astigmatism. Phacoemulsification has been shown to be associated with much less astigmatism as compare to MSICS (71). But with refinements in the surgical technique, SIA following MSICS is also declining (5).

In our study, in the phacoemulsification group, 2.8mm clear corneal incision was made at 10:30 ‘O’ clock hour position i.e. supero-temporal in the right eye and supero-nasal in the left eye. No attempt was made to alter the site of incision based on the preoperative keratometric values to counter astigmatism. Surgically induced astigmatism was calculated by the method as described by Holladay et al (22). 96 of the 99 patients in this group had SIA ranging from 0.14D to 1.97D. Only three patients had SIA more had 2.00D. The mean SIA after phacoemulsification was 1.00 ± 0.49D. The above mentioned values may be an exaggeration of the actual post-operative astigmatism seen clinically because in all the study patients the site of incision was fixed, unlike the actual clinical scenario where the incision site is modified according to the preoperative corneal topography so as to minimize the astigmatic shift and in some cases to negate the pre-existing astigmatism. Rainer et all have reported SIA of 0.81D at one month after phacoemulsification with similar clear corneal incision as ours (38). Another study reports SIA of 0.71D at 3 months after 3.2mm.superotemporal clear corneal incision (72).

We also compared the SIA between right and left eyes, to see if there was any notable difference between the two eyes. In our study the mean SIA in the right eye was 0.94D and left eye was 1.11D. The difference was statistically not significant.

Altan-Yaycioglu et al studied 182 eyes where clear corneal incisions were performed at the steep meridians i.e. superior, superotemporal, superonasal, nasal or temporal & reported that nasal & superonasal incisions are associated with highest astigmatic shift as compared to temporal or superotemporal clear corneal incisions. Our results are comparable to this study.

Another study reports SIA of 0.75 ± 0.49D after superotemporal incisions and 0.71 ± 0.47D after superonasal incisions at one month which decreased to 0.6D ± 0.31D and 0.62 ± 0.29D at one year in the two groups respectively (39).

Rainer et al have reported that right eye is associated with 0.85D ± 0.83D of SIA and left eye with 0.77 ± 0.35D, the difference between eyes not being statistically significant. (38).

On calculating the SIA after Blumenthal technique of MSICS in our study patients, 64 out of 79 eyes had SIA ranging between 0.25D and 1.97D. 15 out of 79 patients had SIA more had 2.00D. The mean SIA was 1.28 ± 0.71D. On comparison, the mean difference in surgically induced astigmatism between corneal section phacoemulsification and MSICS was statistically significant in our study. But this difference of 0.22D may not be clinically significant. This is in agreement with other studies(6).

Gogate et al have reported the post operative astigmatism of 0.5D after phacoemulsification and 1.5D for MSICS. But this was a direct comparison of post-operative cylinder and not a vector analysis(46).

In 2009 Gurung et al have reported astigmatism of ≥ 2D at 6 weeks in 35.4% who undergo MSICS (45). But in our study ≥ 2D was noted in only 19% of the cases. This may reflect on the improved surgical skills along with better instruments availability.

We compared SIA in patients with different position of IOL, in-the-bag, in-the-sulcus or part in and part out of the bag, to see if lenticular astigmatism affects SIA in any way in pseudophakic eyes. SIA was not influenced by the position of the IOL in our study.

Authors have previously looked to see if the type of surgery affects endothelial cell loss. It has been reported that both MSICS and phacoemulsification are associated with comparable endothelial loss (46) (6) (53). Gogate et al have studied 400 patients and reported an endothelial cell loss of 474.2 cells after phacoemulsification and 456.1 cells/mm2 after manual small incision cataract surgery at 6 weeks, the difference between the two groups not being statistically significant (p = 0.98) (46). In our study the measurement of endothelial cell count fully automated. The mean endothelial cell loss after phacoemulsification was 526.9 ± 474.72 cells/mm2 and that after MSICS was only 270.8 ± 280 cells/mm2. The differential endothelial cell loss was significant between the two groups (p=0.002). In our study endothelial cell loss after MSICS was significantly less.

The lower endothelial cell loss in the MSICS in our study can be explained based on the fact that the Blumenthal technique involves usage of anterior chamber maintainer throughout the surgery which prevents the anterior chamber from collapsing during the surgery. Moreover in this technique only one pole of the nucleus is prolapsed into the anterior chamber and then expressed through the corneo-scleral wound. This prevents significant contact between the nucleus and the endothelium and thus protects the corneal endothelium. Use of ophthalmic viscosurgical devices, minimal intraoperative manipulations, introduction of fewer instruments like vectis, ACM assisted delivery of nucleus and use of two side ports with formed anterior chamber for cortex aspiration may be few reasons for our good results.

George et al studied 53 eyes with MSICS 60 eyes with phacoemulsification and have reported mean percentage reduction in endothelial cell count of 4.21% after SICS and 5.41% after phacoemulsification (p = 0.85) (6). The actual number of endothelial cell loss is not mentioned in the study and the sample studied was small. Raju et al have reported similar results in which though MSICS is associated with lesser endothelial loss as compared to phacoemulsification, the difference is not statistically significant (53). But in our study the percentage mean endothelial cell loss after phacoemulsification was 20.16% and that after MSICS was 10.29%. The differential endothelial cell loss was significant between the two groups (p=0.002). Further studies are indicated to comment more.

We sub-classified the patients eyes based on the grade of cataract operated to see if that affects endothelial cell loss after cataract surgery. There was no significant difference between the two groups. This may be because of the exclusion of very hard cataracts (nuclear sclerosis grade 4 or more) from our study. Also the number of patients was small. Thus a larger study is needed to comment further on this.

We also compared endothelial cell loss in diabetics versus non-diabetics and there was no significant difference in the mean endothelial cell loss in the two groups. In our study the mean endothelial cell loss was 496 ± 451cells/mm2 in diabetic patients and 394.93 ± 416.23 cells/mm2 in non diabetics. This result was different from the results of other studies (53) (54). Mathew et al have reported that in diabetic patients there is a 9.26 ± 9.55% drop in endothelial cell density and 7.67 ± 9.2% drop in the control group after MSICS at 6 weeeks. Raju et al also showed a statistically significant more endothelial loss in diabetics than non-diabetics (p=0.05) (53). This difference in our study can be because of the low sample size and short follow up of our patients.

We also looked into the changes in central corneal thickness at six weeks after the two types of cataract surgery. There was no statistically significant change in central corneal thickness between the two groups (p=0.904). Thus in our study even though we showed more endothelial loss after Phacoemulsification, there was no corresponding increase in central corneal thickness. Therefore the endothelial loss may be clinically irrelevant. Further follow up of these patients will be required to comment further.

The results of catarct surgery are usually assessed clinically by an improvemant in snellen visual acuity. The assumption made here is that improvement in visual acuity is associated with an improvemant in visual function which will lead to better overall quality of life. But with changing times the trend these days is to give equal importance to patient perceived visual assessement as the objective assessment (17). In our study the subjective visual imppovement was analyzed based on the Visual Function score (VF-score). **Visual disability** was assessed beror and at 6 weeks after catarct surgery. **VF score** is the difference between the pre- and post operative visual disability score. VF score indicates the dramatic improvemant in the visual perception after cataract surgery and this is significantly dependent on the pre-operative visual disability. More the visual disability before surgery, better will be the VF-score. Postoperative visual disability score may be a better indicator of patient satisfaction as it tells about the final subjective visual function status as experienced by the patient.

On analysis of the VF-score in the two arms in our study, there was a statistically significant difference in the means. MSICS scored better on the VF scale as compared to phacoemulsification. But this needs to be interpreted cautiously because eyes in the MSICS group had a poorer preoperative vision to begin with. Therefore the improvement in visual function experienced by them was more dramatic. More studies need to be undertaken with comparable vision in the two arms to comment further.

But improvement in visual function i.e. VF-score cannot be equated to patient satisfaction. Instead patient satisfaction can be indirectly assessed by the postoperative visual disability score. It won't be incorrect to assume that a better post operative visual disability score signifies a visually more satisfied patient. Therefore postoperative visual disability score was compared and phacoemulsification scored slightly better than MSICS. The difference was statistically not significant. In other words after both types of surgery the patients were equally satisfied.

Thus in our study that though the improvement in visual function (VF-score) is more dramatic after MSICS, the ultimate postoperative visual function is comparable in the two groups.

CONCLUSIONS

1. 98.3% of patients achieved a BCVA better than 6/18 which is well within the guidelines laid down by WHO.

2. On analyzing the phacoemulsification and the MSICS group separately, BCVA of better than 6/18 was achieved in 100% of the eyes in phacoemulsification group and 96.2% in the MSICS group. However the difference was not statistically significant.

3. Corneal section phacoemulsification was associated with less SIA as compared to MSICS. The difference was statistically significant with a ‘p’ value of 0.003. The mean SIA after phacoemulsification was 1.01 ± 0.49D and after MSICS was 1.29 ± 0.71D.

4. The mean endothelial loss at 6 weeks was less with MSICS as compared to phacoemulsification. The difference was statistically significant with a ‘p’ value of <0.001. The mean endothelial cell loss was 271cells/mm^2 after MSICS and 527cells/mm^2 after phacoemulsification. It was not dependant on the grade of the nucleus or the diabetic status of the patient. However this did not have a direct bearing on the final visual acuity.

5. There was no significant change in central corneal thickness at 6 weeks following cataract surgery.

6. The grade of visual improvement after cataract surgery, as measured by Visual Function Score was better after MSICS. This is because the pre-operative visual acuity in MSICS group was worse.

7. Over all post-operative visual function score was better after phacoemulsification.

8. In our study left eye had slightly more surgically induced astigmatism as compared to right eye. This was statistically not significant with a ‘p’ value – 0.09.

9. There were no major complications and no significant difference in the complication rates between the two groups.

LIMITATIONS OF THE STUDY

1. The major limitation of our study was the small sample size and a short follow up of six weeks.

2. This was not a randomized controlled trial. Our study is a cohort study where a group of patients were followed up to six weeks. True randomization may not be possible because the choice of surgery and intraocular lens is largely governed by the socioeconomic status of the patient. Thus bias could not be completely avoided.

3. All eyes in the phacoemulsification group had a foldable IOL implanted where as eyes that underwent MSICS had rigid IOL implantation. This difference in the types of IOL used might have influenced postoperative visual function to some extent.

4. In our study no attempt was made to correct the pre-existing cylinder intra-operatively. But in real life practice every surgeon would try to decrease the post operative astigmatism by intraoperative wound modulation.

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ANNEXURE I

CLINICAL RESEARCH SHEET

PHACO / BLUMENTHAL

SERIAL NO: DATE:

NAME - HOSPITAL NUMBER- EYE OPERATED: R/L

AGE- GENDER- DIABETIC: Y/N\

Preoperative	Grade of cataract	
	Other eye status & vision	
	Lens booked	
	Power aimed	
Intraoperative	Complications	
Postoperatively (Day 1)	Complications	
Postoperatively (6 Weeeks)	Position of IOL	
	Complications	

Keratometry	K1	K2	Axis	SIA
Pre-operative				
6 Weeks Post-op				

	CCT	Endothelial count	VF Score
Pre-operative			
6-Weeks Post-op			

		Unaided VA	BCVA	Sphere	Cylinder	Axis
Pre-operative	Distance					
	Near					
6-Weeks Post-op	Distance					
	Near					

ANNEXURE II

INFORMED CONSENT

I ,…………………………..son/ daughter/ wife of ……………………………… have been explained in detail that a study “Comparison of refractive outcome following corneal section Phacoemulsification versus Blumenthal technique of manual small incision cataract surgery at 6 weeks” is being conducted by the Department of Ophthalmology ,CMCH ,Vellore.

I have been told that I shall be examined by the concerned doctor using noninvasive methods and that my vision will be recorded before and after the cataract surgery.

The liberty of withdrawing me from the study without any compromise of care from the hospital has also been explained.

The concerns about my participation in the study are explained and I have been told that the information shall be confidential.

I hereby give my full consent and cooperation for participating in the study.

Patient’s signature   Witness signature

Patient’s name   Witness’ name

Date   Date

ANNEXURE III

PATIENT INFORMATION SHEET

Opacification of the lens or its capsule is known as cataract and it is one of the leading causes for poor vision in adults in India. Vision can be restored surgically by removing the cataractous lens and replacing it with an artificial intraocular lens.

There are multiple techniques for cataract surgery, of which Blumenthal technique of manual small incision cataract surgery (MSICS) and Corneal section phacoemulsification (CS-Phaco) are most frequently done. MSICS is a type of sutureless cataract surgery wherein a 5mm long incision is made in the eye through which the cataract is removed and a rigid intraocular lens is placed. On the other hand CS-Phaco is a more advanced technique where an even smaller incision, 2.8mm long, is made and the cataract is removed after breaking it inside the eye using an ultrasonic probe, following which a foldable IOL is put. The small incision size is said to lead to better and faster visual rehabilitation. But CS-Phaco is a much more expensive procedure. Thus it cannot be afforded by all. Therefore, for a country like ours where the prevalence of cataract is still very high, we believe that MSICS offers the advantages of sutureless cataract surgery as a low cost alternative to CS-Phaco.

Therefore, in our institution, we are doing a study to compare the visual outcome and patient satisfaction after these two techniques of cataract surgery. In this study the patient will be examined by the principal investigator using non-invasive techniques as a part of routine preoperative work up. These tests will include will not cause any harm to the patient and they are done for all patients who are planned for cataract surgery. A similar examination will be repeated at 6 weeks after cataract surgery by the principal investigator. They will also be asked to fill up a form that will contain questions regarding their visual function before and after the surgery. No extra visits to the hospital by the patient will be required for the study purpose. The information obtained by the investigator regarding the participant will remain confidential throughout and the participants will have the liberty to withdraw from the study at any point in time without any compromise in hospital care.

The results of this study will help us to predict the unaided visual outcome better following these two techniques of cataract surgery.

For any queries contact DR. RASHMI MITTAL, mobile no. 9486722284, email -rashmimittal2002@gmail.com

ANNEXURE IV

VISUAL FUNCTION SCORE

PHACO / BLUMENTHAL

PREOPERATVE /POSTOPERATIVE

NAME HOSPITAL NUMBER DATE

Kindly score your difficulty, because of vision, with each of the below mentioned activities by giving a numerical value

No difficulty = 100

A little = 75

A moderate deal = 50

A great deal = 25

Unable to do activity at all because of vision = 0

Leave the score blank where the activity is not applicable to you

	SCORE
Reading a newspaper or book	
Reading small prints, such as labels on medicine bottles, a telephone book, or food label	
Seeing steps, stairs	
Reading traffic/street/store signs	
Doing fine handiwork, sewing, knitting, or carpentry	
Cooking	
Watching TV	
COMPOSITE SCORE	

ANNEXURE V

INFORMED CONSENT IN TAMIL

ஒப்புதல் படிவம்

நான் …………………………………… மகள்/மனைவி ……………………………… ஆகிய எனக்கு இரண்டு தொழில் நுட்பங்களை பயன்படுத்தி செய்யப்படும் புரை நீக்கும் அறுவை சிகிச்சையினால் 6 வாரத்தில் ஏற்படும் விளைவுகள் பற்றி ஆய்வை குறித்து எனக்கு வேலூரில் உள்ள கிருஸ்தவ மருத்துவக் கல்லூரியின் கண் பிரிவு ஆய்வாளர் தெரிவித்துள்ளார். இதன் மூலம் எனக்கு அறுவை சிகிச்சைக்கு முன்னும் பின்னும் ஏற்பட்டுள்ள விளைவுகளை மருத்துவ பதிவேட்டில் பதிவு செய்யப்படும்.

இந்த ஆய்வில் இருந்து நான் எப்பொழுது வேண்டுமானாலும் விலகிக் கொள்ளலாம் என்றும் அறிந்திருக்கிறேன்.

இந்த ஆய்வில் பங்குகொள்ளும்பட்சத்தில் என்னுடைய மருத்துவ விவரங்கள் பாதுகாப்பாக வைக்கப்படும் என்றும் அறிந்திருக்கிறேன்.

நான் இந்த ஆய்வில் பங்கேற்கவும், ஒத்துழைக்கவும் முழு மனதுடன் சம்மதிக்கின்றேன்.

நோயாளியின் கையொப்பம் :

நோயாளியின் பெயர் :

தேதி :

சாட்சியின் கையொப்பம் :

சாட்சியின் பெயர் :

தேதி :

ANNEXURE VI

PATIENT INFORMATION SHEET IN TAMIL

தகவல் பிரதி

கண்ணில் உள்ள லென்சின் மீது ஏற்படும் படலம் அல்லது கேப்ஸ்யூல் என்று சொல்லப்படும் நோய் கண்புரை என்று அழைக்கப்படுகிறது. இது நம் நாட்டில் (இந்தியாவில்) வயது முதிர்ந்தவர்களுக்கு பார்வை குறைவினால் ஏற்படுகிறது.

கண் புரையினால் பாதிக்கப்பட்டவர்களுக்கு அறுவை சிகிச்சையின் மூலம் லென்சை நீக்கிவிட்டு செயற்கை உள் விழி லென்சை பொருத்தி இழந்த பார்வையை மீண்டும் பெறச் செய்யலாம்.

கண் புரை அறுவை சிகிச்சையில் பல தொழில் நுட்பங்கள் உள்ளன. அதில் புளுமென்தால் எனப்படும் அறுவை சிகிச்சையும் (கண்ணில் சிறு கீறல் மூலம் செய்யப்படும் சிகிச்சை CS-Phaco எனப்படும் அறுவை சிகிச்சை முறையும் பிரதான சிகிச்சை முறைகளாகும். இதில் புளுமென்தால் அறுவை சிகிச்சையில் கண்ணில் 5 m.m (மி.மீ) அளவில் சிறிய கீறல் / துவாரம் செய்து அதன் வழியாய் பாதிக்கப்பட்ட லென்சை எடுத்துவிட்டு ஒரு திடமான செயற்கை உள் விழி லென்சை வைத்துவிடுவார்கள். இந்த அறுவை சிகிச்சையில் தையல் போடுவது தவிர்க்கப்படும். இரண்டாவது வகையான CS-Phaco என்பது 2.8 மி.மீ அளவில் சிறு கீறல் ஏற்படுத்தி அல்ட்ராசோனிக் (மீயொலி) பயன்படுத்தி லென்ஸ் நீக்கப்பட்டு உள் விழி லென்ஸ் வைக்கப்படுகிறது. இந்த 2 முறை அறுவை சிகிச்சை முறைகளும் நடைமுறையில் உள்ள முன்னேறிய தொழில் நுட்ப வகையை சார்ந்தவை. ஆனால் CS-Phaco முறை என்பது சற்று விலையுயர்ந்த அறுவைச் சிகிச்சையாகும்.

புளுமென்தால் அறுவை சிகிச்சை CS-Phaco என்னும் விலையுயர்ந்த அறுவை சிகிச்சைக்கு மாற்றாக குறைந்த செலவில் செய்யப்படுகிறது. நம் நாட்டில் அதிகமான மக்கள் புரை நோயால் பாதிக்கப்பட்டிருப்பதாலும் அதே நேரத்தில் எல்லோராலும் அதிக செலவு செய்து CS-Phaco அறுவை சிகிச்சை செய்ய முடியாது என்பதாலும் புளுமென்தால் (MSICS) அறுவை சிகிச்சை குறைந்த விலையில் செய்யப்படுகிறது.

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எனவே இந்த மருத்துவமனை மேற்கூறிய 2 தொழில் நுட்பங்களை பயன்படுத்தி அறுவை சிகிச்சை பெற்ற நபர்களை ஆராய்ந்து அதன் மூலம் அவர்களின் பார்வை மற்றும் அவர்களின் திருப்தியை ஒப்பிட்டு பார்க்க ஆய்வு செய்கிறோம். எனவே நோயாளியை பிரதான ஆய்வாளர் வழக்கமான சோதனைகளை செய்வார். அப்போது நோயாளியின் அறுவை சிகிச்சைக்கு முன் மற்றும் பின் அவர்களின் பார்வையின் செயல்பாடுகள் பற்றிய கேள்விகளுக்கு கொடுக்கப்பட்ட படிவத்தில் பூர்த்தி செய்ய கேட்கப்படுவர். (அறுவை சிகிச்சைக்கு முன் மற்றும் அறுவை சிகிச்சை முடிந்து ஆறு வாரங்கள் கழித்து)

நோயாளிகளின் மருத்துவ விவரங்கள் பாதுகாப்பாக வைக்கப்படும். அதே நேரத்தில் எந்த ஒரு நிபந்தனையில்லாமல் விலகிக் கொள்ளலாம். அதனால் அவர்களுடைய மருத்துவ சிகிச்சையில் எந்த வித பாதிப்பும் இருககாது.

இந்த இரு தொழில்நுட்பங்களை பயன்படுத்தி செய்யப்படும் ஆய்வில் கிடைத்த விவரங்களைக் கொண்டு கிடைத்த முடிவுகள் சிறந்த பார்வை பெறுவதற்கான சாத்தியக் கூறுகளை கண்டறியப்பயன்படும்.

இந்த ஆய்வைக் குறித்த விவரங்கள் அல்லது சந்தேகங்களை அறிய விரும்பினால். **டாக்டர் ரஷ்மி** என்பவரை. 9486722284 என்று செல்போனிலும் rashmimittal 2002 @ gmail.com என்ற மின்னஞ்சலிலும் தொடர்பு கொள்ளலாம்.

ANNEXURE VII

VF-SCORE IN TAMIL

பார்வை செயல்பாடுகள் குறித்த மதிப்பீடு

பேக்கோ / புளுமென்தால்

சிகிச்சைக்குமுன் / சிகிச்சைக்கு பின்

பெயர் மருத்துவமனை தொடர் எண் தேதி

கீழே கொடுக்கப்பட்டுள்ள நடவடிக்கைகள் குறித்து உங்கள் மதிப்பீட்டை கொடுத்தால் உங்களின் பார்வை. மற்றும் அதில் உள்ள சிரமம் குறித்து அறிந்து கொள்ளலாம்.

சிரமம் / கஷ்டம் இல்லை =100

சிரமம் / கஷ்டம் சிறிய அளவில் = 75

சிரமம் / கஷ்டம் மிதமான நிலையில் (பரவாயில்லை) = 50

சிரமம் / கஷ்டம் பெரிய அளவில (மிகவும் மோசமாக) = 25

பார்வை குறைபாடு அதிகமாக உள்ளதால் எந்த நடவடிக்கையும் செய்ய முடியவில்லை = 0

உங்கள் செயல்திறனுக்கு / நடவடிக்கைக்கு பொருத்தமானதாக இல்லையென்றால் காலியாக விட்டுவிடவும்

	மதிப்பீடு
பத்திரிக்கை / புத்தகம் படித்தல்	
சிறிய அச்சிட்ட எழுத்துக்கள், மருந்து பாட்டில்கள் மேல் ஒட்டப்பட்ட லேபிள்கள், தொலைபேசி புத்தகம் உணவுப் பொருட்கள் மீது உள்ள லேபிள்கள் போன்றவற்றை படித்தல்	
படிகட்டுகள் மற்றும் மாடிப்படிகளை பார்த்தல்	
போக்குவரத்து / தெரு / ஸ்டோர் போன்றவற்றில் உள்ள குறியீடுகளை படித்தல்	
கை வேலைபாடு, தையல், பின்னல் மற்றும் தச்சு வேலைகளை நன்றாக செய்ய முடிகிறது	
சமையல் வேலைகள்	
தொலைக்காட்சி பார்ப்பது	
மொத்த மதிப்பீடு	