

A Comparative Study of 5.5mm Temporal Sclerocorneal Manual Small Incision Cataract Surgery Versus 5.5mm Temporal Clear Corneal Extended-incision Phacoemulsification with Implantation of a 5.25mm Rigid pmma Intraocular lens in the Bag

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Abstract

Objective: Aim of the study is to Compare the astigmatism induced by a reduced temporal sclerocorneal tunnel incision manual small incision cataract surgery with an extended temporal clear corneal Phacoemulsification of similar width .

Methods: A Prospective, randomised controlled study was carried out in 224 selected patients who were again divided into two groups - Group A (112 patients) and Group B (112 patients). Group A patients underwent temporal manual small incision cataract surgery with a 5.5 mm sclerocorneal incision and Group B underwent phacoemulsification by a 2.8 mm clear corneal temporal incision which was extended to 5.5 mm before IOL implantation. In both groups, a 5.25 mm rigid PMMA IOL was implanted in the bag. UCVA and BCVA of both group of patients was quantified and analyzed at 1 week and at 6 weeks

Observation: It was seen that the mean surgically Induced astigmatism in group A (N=112) was 0.5625D , which was slightly lesser than that in Group B (N=112) which was 0.65D, although the p-value of 0.26 indicated that there was statistically no significant difference in visual outcomes between the two groups of patients. Here, a p-value of < 0.05 was considered statistically significant.

Conclusion: In Skilled and Safe hands, refractive outcomes following performing a 5.5mm temporal sclerocorneal frown-incision manual small incision cataract surgery and a phacoemulsification procedure by a 2.8mm temporal clear corneal incision extended to 5.5mm for implanting a 5.25mm rigid PMMA IOL , are comparable.

Keywords: Manual Small Incision Cataract Surgery, Phacoemulsification, Astigmatism, Sclerocorneal, Temporal, Clear Corneal, Rigid PMMA Intraocular lens

Introduction

Among the teeming Population of our country , 77.5% of preventable blindness according to NPCB (2006-2007) is due to Cataract in India [1]. Evolution of techniques of cataract surgery from Couching to ICCE, ECCE, SICS, Phacoemulsification and Femto second laser-assisted cataract surgery have all targeted better visual outcomes than the patients' existing vision. During the financial year 2007-2008, 5.4 million cataract surgeries were performed in India [1].

Every passing day, we realise that cataract surgery is more of a refractive surgery today, than a normal cataract surgery a couple of decades back, and that the expectations of patients have skyrocketed,

at times, beyond the surgeons' means.

Working in an NGO Hospital I realized, where high-volume cataract surgery is being performed on a regular basis, the basic pre-requisites for a fruitful surgical outcome were 'Proper' selection of patients following a good pre-op. evaluation with proper funduscopy , good Biometry, a faster surgery with minimal tissue-handling and the most important and modifiable determinant parameter was a 'closer-to-an-astigmatically-neutral' incision.

A temporal sclerocorneal SICS incision induces lesser SIA than a superior one and so does a clear-corneal temporal phaco incision than a superior sclerocorneal phaco incision [1-2]. It occurred to me to combine the two concepts in our setting, where a vast majority of footfalls is of the poorer sections of society.

Way back in 2006, a question was asked in the editorial column of Ophthalmology Times which later became World Ophthalmology Report - 'Is it cheating to give a hard lens to a phaco patient'? My answer was 'Yes', and it was duly published by the editor Dr. Sashi Kapoor, MD, in the subsequent edition.



During my Phaco Fellowship I was initiated into Phaco with a temporal clear-corneal incision. Fellows were allowed to perform surgery on 'free' patients brought through 'outreach camps'. Before IOL implantation, the 2.8 mm wound used to be extended to 5.5 mm to allow a single piece 5.25 mm rigid PMMA IOL to pass through and a single or double 10-0 suture used to be given for reinforcing the wound. It intrigued me- were these the few 'lucky' patients who would be getting better vision over their not-so-fortunate SICS fellow patients? Was I really correct in saying so at that point of time? This thought made me embark on comparing the visual outcomes in patients by performing both Manual SICS & Phacoemulsification in 2 sets of patients keeping similar parameters as far as the 'incision' factor was concerned.

I was about to join a reputed institute in South India several years back but was somewhat apprehensive as to how demanding the patients there were & what protocols were being followed there. I asked a colleague and he replied that surgical 'Packages' varied according to the 'IOL' type being implanted and not on the 'type of surgery'. A surgeon could perform 'phaco' or manual 'SICS' according to his own discretion, but implant an IOL of the patients' choice.

I have seen a large numbers of patients who have been operated as 'phaco' cases spending a large amount of money in the process, but have had a 'rigid' IOL implanted in them. I have also seen a large no. of patients who have and are still undergoing manual SICS followed by implantation of a 'foldable' IOL. This study is a special tribute to these bewildered surgeons regarding the encouraging outcomes of two known surgical procedures with a slight twist in the approaches, so that a large number of patients undergoing surgery for cataract can benefit, albeit in good hands, and transparency in services can be maintained and surgical and medicolegal complications can be avoided.

Still, this study gives us a clear take home message that in cases where a surgeon performs a phacoemulsification procedure and then implants a rigid PMMA IOL after extending the incision, the choice of surgery in the very first instance can go in favour of a 5.5mm temporal sclerocorneal tunnel incision manual SICS with acceptable and competitive visual outcomes.

The only factors to be considered during choice of surgery would be the grade of the cataract, intra operative complications, stage of surgery and the surgeons' skill and surgical experience.

Considering the fact that there is a huge backlog of cataract cases despite having almost 210,730 ophthalmologists worldwide, the present and urgent need is restoring quality vision to the teeming millions at an affordable price. Approximately 20 million cataract surgeries are performed each year globally but the number of patients handicapped due to cataract increases each year with an increasing aging population, so we are left with 20 million people blinded by cataract. More than 95% live in developing nations where cataract surgery is hampered by insufficient manpower and surgical means [1].

Materials and Methods

Patients were brought from Outreach Camps following initial screening during the period from May 2014 to August 2014 as per the following guidelines, to our Base Hospital, in clusters, out of which 224 patients were finally selected for the study.

Inclusion Criteria for Selection of Patients

- Visual Impairment for daily activities with a BCVA in the better eye of $\leq 6/36$ caused by cataract only, family h/o ocular disease was taken.
- Patients with concurrent/known ocular disease were eliminated Age > 50 years < 75 yrs.
- Pre-existing regular astigmatism of $< 1.5D$ in the steep axes
- Patients with cataracts having preferably NS GrII, III and IV were selected.

Exclusion Criteria of Patients

- Patients with Grade V+/ hard cataracts and Morgagnian cataracts were excluded from the study.
- Patients having high corneal astigmatism/ corneal pathology/ posterior segment pathology were excluded.
- Patients having concurrent DM, HTN, Cardiac ailments, COPD, severe kyphosis / bony osteoarthopathy, BHP, or other Systemic diseases were eliminated.

After arrival at the Base hospital, patients were evaluated as follows Preoperative Evaluation

- Uncorrected & Corrected Visual Acuity (ETDRS-Snellen Eye Chart)
- Refraction trial (Canon/ Nidek Autorefractometer)
- Keratometry (Appasamy Keratometer)
- Intra Ocular Pressure measurement (NCT-Reichert / AT- Inami)
- Syringing of Nasolacrimal passage of selected eye
- Slit Lamp Biomicroscopy (Zeiss)
- Biometry -Immersion biometry - Biomedix and Appasamy - SRK-T Formula
- Dilated Fundoscopy -with 90 D and Indirect Ophthalmoscopy
- B-Scan USG of the selected eye -Appasamy B-Scan
- General Medical checkup by the Hospital Physician, with ECG.
- PPBS and Conjunctival Swab C/S of the eye to be operated.

Methodology

A Prospective, randomized, controlled study was carried on a total of 224 patients. These patients were divided into two groups randomly. Gr. A consisted of 112 patients who underwent Manual SICS with a 5.5 mm sclerocorneal Temporal tunnel incision. Gr. B consisted of 112 patients who underwent a 2.8 mm clear corneal temporal incision which was extended to 5.5mm following phacoemulsification. In both groups, following cataract removal, a 5.25 mm rigid PMMA intraocular lens was inserted. Visual outcomes in the two groups

were recorded at 1 week, and at 6 wks. Informed consent was taken for every patient pre-op. The collected data was sampled and analyzed.

Surgical Technique

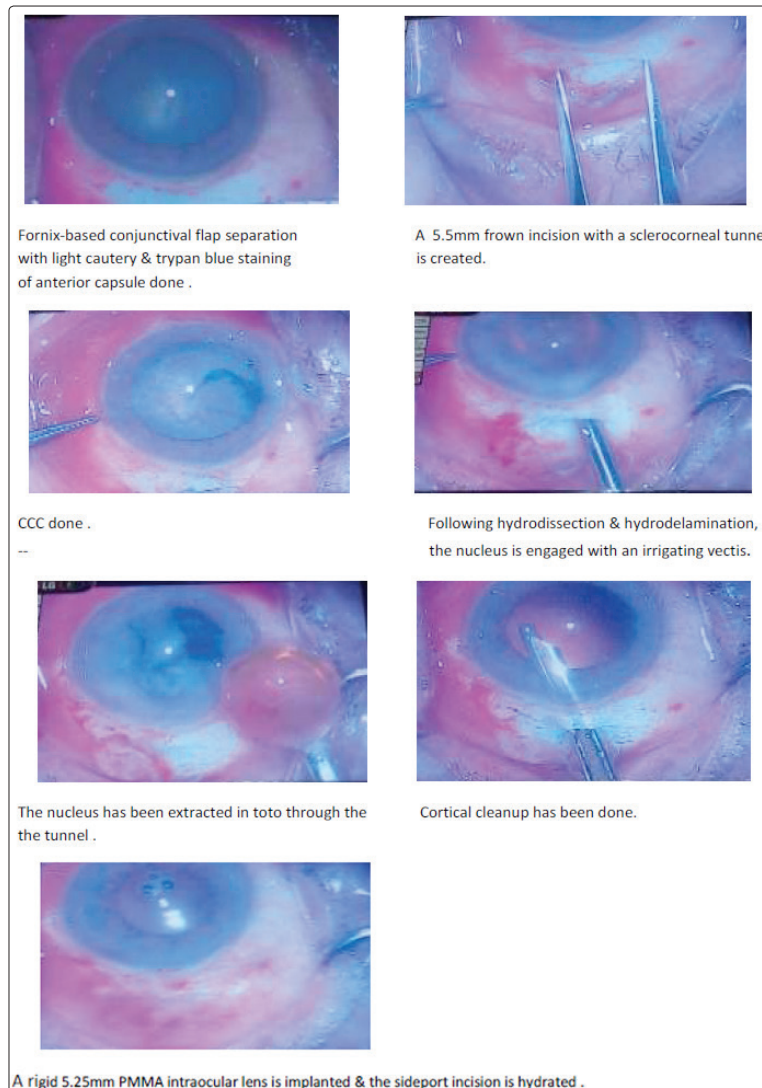
The patients were advised to come after proper scrubbing of their faces, hands and feet and after applying Vigamox eye drops qid plus Nevanac eye drops tid in both eyes since 04 days before surgery. After proper instillation of Vigamox eye drops hourly for 3 consecutive hours along with Betadine eye drops and topical proparacaine eye drops, the patients were subjected to perbulbar block with 2% Xylocaine + 0.5% Bupivacaine + Hynidase. Care was taken not to make the eye hypotonic because if the tunnel gets ragged at times in a hypotonic eye, it induces more astigmatism. Also expression of the nucleus from the bag becomes difficult in case of a manual small incision cataract surgery. Half of the patients Group A (112 patients) underwent manual small incision surgery with a 5.5 mm temporal sclerocorneal tunnel from incision.

The depth of the incision was kept at 0.3mm. A 5.5mm continuous curvilinear capsulorhexis was done. After hydrodissection and

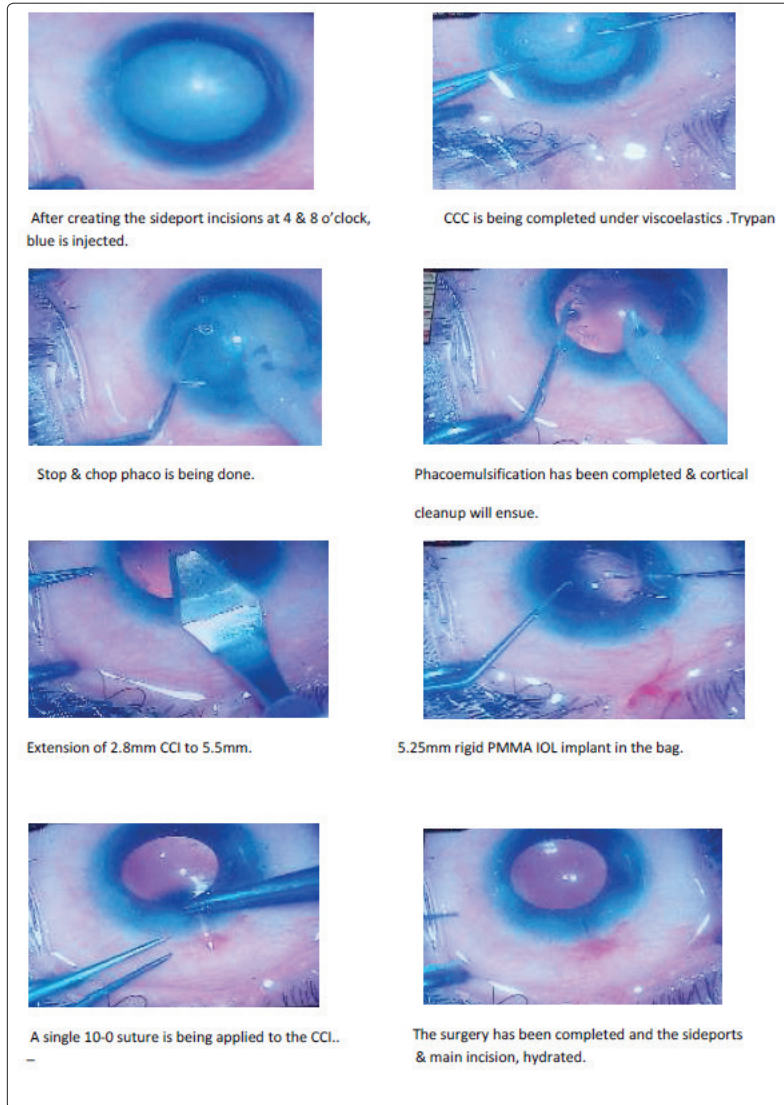
hydrodelamination, the nucleus was dialled out of the capsular bag by a sinsky hook/dialler. The nucleus was removed with the help of an irrigating vectis. Cortex was removed with a 2-way simcoe cannula, visco was injected in the A/C & in the bag and a 5.25mm rigid intraocular lens was inserted in the bag. The sideport was hydrated and 0.1ml intracameral preservative-free Vigamox was given.

The other half (112 patients) Group B underwent phacoemulsification following a 2.8 mm clear corneal temporal incision. Following CCC, hydrodissection and hydrodelamination, direct chop phacoemulsification was performed. In this group, before IOL implantation, the 2.8 mm incision was increased to 5.5mm with a 5.2 mm steel keratome. After IOL implantation, a single 10-0 suture was applied in the clear corneal phaco patients. In both the groups, a 5.25 mm rigid PMMA intraocular lens was implanted. The patients were discharged the following day and were advised to follow up after 07 days, 3 weeks and 6 weeks. At each follow-up their UCVA, BCVA, refraction, K-readings, IOP measurements by NCT, Slit lamp exam and undilated fundus exam were done and the findings were noted down.

GROUP A Surgery



GROUP B Surgery



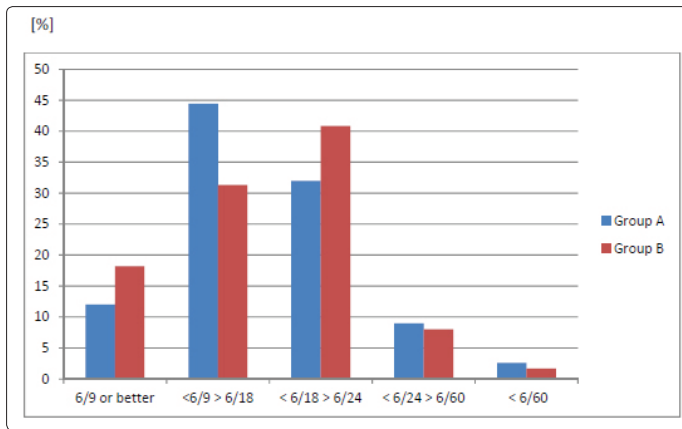
Outcome

Uncorrected and best-corrected Visual Acuity in both the groups at 1 wk, 3 wks and at 6 wks were recorded, sampled and analysed. Although a modest degree of induced astigmatism is evident from the analytical results, the actual amount of astigmatism induced is quite nominal with a 5.5mm temporal sclerocorneal tunnel incision compared to an extended temporal clear corneal incision.

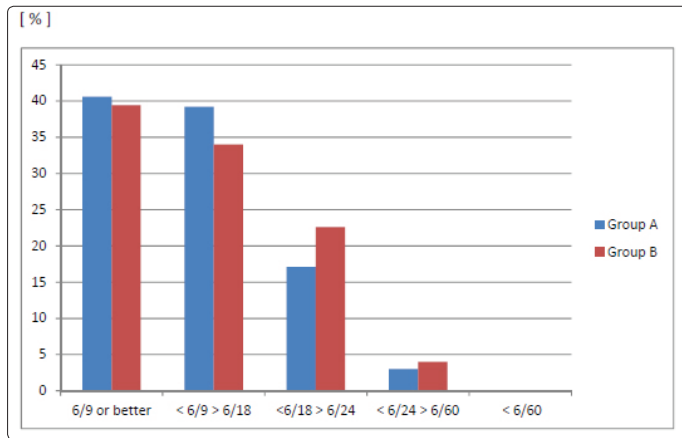
Post- operative UCVA	1 week		3 weeks		6 weeks	
	Group A	Group B	Group A	Group B	Group A	Group B
6/9 or better	12%	18.2%	39.4%%	37.0%	40.6%	39.4%
<6/9 > 6/18	44.4%	31.3%	38%	33.2%	39.22%	34%
<6/18 > 6/24	32%	40.8%	15.9%	23.8%	17.10%	22.6%
<6/24 >6/60	09%	08%	05%	06%	03%	04%
< 6/ 60	2.6%	1.7%	1.7%	--	0.08%	--

[%]

UCVA in Group A (SICS) and Group B (PHACO) at 1 week post-op

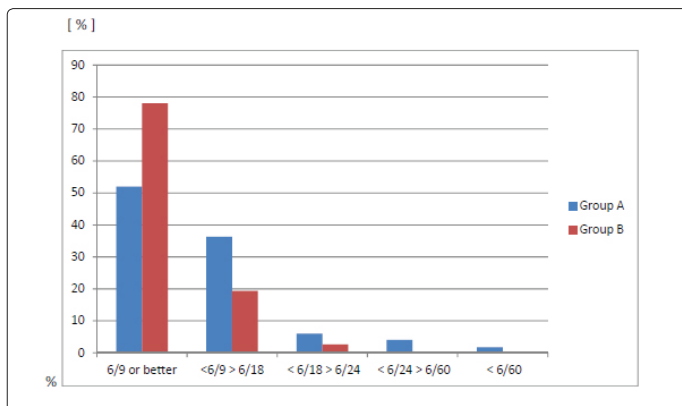


UCVA of Group A (SICS) & Group B (PHACO) at 6 weeks Post-op

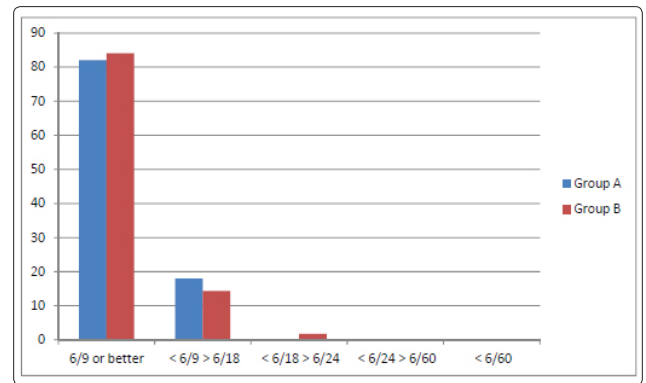


Post-operative BCVA	1 week		3 weeks		6 weeks	
	Group A	Group B	Group A	Group B	Group A	Group B
6/9 or better	52%	78%	81.22%	82.2%	82%	84%
<6/9 > 6/18	36.3%	19.4%	18.7%	16.1%	17.92%	14.3%
<6/18 > 6/24	06%	2.6%	--	1.7%	--	1.7%
<6/24 > 6/60	04%	--	--	--	--	--
<6/60	1.7%	--	0.08%	--	0.08%	--

BCVA of Group A(SICS) & Group B (PHACO) at 1 week post-op



BCVA of Group A (SICS) & Group B (PHACO) at 6 weeks post-op



Per-operative Complications In the manual SICS group A

- 4 patients (0.03%) had a ragged and slightly torn external sclerocorneal incision margin but with no damage to the internal lip of the incision.
- 3 (0.02%) patients had grade1 hyphaema (OCTET Grading I) which stopped on hydration of the sideport incision and raising the IOP.
- 6 patients (0.05%) had descemet's stripping near the internal lip of the incision.
- None of the patients had a posterior capsular rent.

Of the phaco group B

- 1 patient (0.008%) had a posterior capsular rent during Sculpting, without vitreous prolapse, in 1 patient who had a gr. 4 nuclear cataract (OCTET Grading II) and
- 1 patient (0.008%) had descemet's stripping at the internal lip of the phaco incision.

Complications of Group A(SICS) Vs Group B(PKE) on the 1st post-op. day were

	Corneal Striae +	Corneal Striae ++	Corneal Striae +++/++++	Descemet's Stripping	Posterior capsular rent without vitreous loss
GROUP A	30	15	3	2	1
GROUP B	12	5	1	1	1

Average time taken for surgery

For Group A (SICS) patients	7 mins. +/- 1.8 mins.
For Group B (Phaco) patients	12 mins. +/- 2.2 mins.

At 6 weeks, two patients in Group A had a BCVA <6/60 due to pseudophakic bullous keratopathy (1.7%), & in Group B, one patient (0.008%) had a decentred IOL following a PCR , with high surgically induced astigmatism . All group B patients were doing well at 6 weeks, with no significant post-op. complications.

Analysis

It has been seen that a temporal 3.0 mm clear-corneal incision induced between 0.28D and 0.53D of temporal flattening, with no effect on the nasal corneal curvature [3]. Greater corneal flattening is seen with longer corneal incisions [4]. Topography has also shown that the temporal flattening of a 5.0mm incision is in the 0.50-1.75D

range, with less dramatic nasal flattening of 0.25-0.75D and vertical steepening of 0.25-0.75D [5].

Corneal Topography could be used to quantify corneal changes at both nasal and temporal meridians, but due to unavailability of corneal topography in our institution, we could not do so.

Singer used the frown incision where the arc length was either 6.0 or 7.0mm and the apex of the crown was 1.5mm posterior to clear cornea. A rigid 6.0-7.0 mm intraocular lens was implanted followed by a single 10-0 nylon mattress suture. He noted that this incision induced lesser surgical astigmatism than a standard scleral pocket incision at 6 months post-op [6].

In my study, the calculated mean induced astigmatism in Group A patients was 1.0D and in Group B patients this was 1.25D. The mean resultant astigmatism in Group A patients was 0.5625D +/- 0.50, and that in Group B patients it was 0.65D +/- 0.54. Statistical analysis was done using the Pearson Chi-squared test of significance.

$$\chi^2_c = \sum \frac{(O-E)^2}{E}$$

Where O = Observed frequency E = Expected frequency and a p-value of < 0.05 was considered statistically significant.

The 2 tailed p-value in the two groups of patients was 0.26, which was much higher than 0.05 and hence was not statistically significant enough.

But at the conclusion of my study I found that the mean resultant astigmatism figures of 0.5625D +/- 0.50 for Group A patients and the corresponding values of 0.65D +/- 0.54 for Group B patients aptly correlates the comparable visual outcomes in the manual small incision cataract surgery patients done with a temporal sclerocorneal incision. A large number of studies have shown comparable visual outcomes of small incision cataract surgery and phacoemulsification (Gogate et al., 2007, Ruit et al, 2007). This held true for the 2 groups of patients in our study .

The slightly higher resultant surgical induced astigmatism in the phacoemulsification group occurred because here the incision size was extended to 5.5mm and also a single 10-0 suture had been applied in all phaco patients, both resulting in higher WTR astigmatism [7]. Nevertheless, further studies on larger population groups and through a longer time span, are necessary to consolidate the findings of this study.

Discussion

A temporal incision is typically used if against the rule astigmatism is present before surgery. The opposite-shaped frown incision theoretically offers the greatest support and induces the least amount of astigmatism (2). Induced astigmatism is estimated to be proportional to the cubic length of such incisions, i.e. Corneal astigmatism is directly proportional to the cube of the length of the incision and is inversely proportional to the distance the incision is placed from the limbus [9,10]. Increased internal opening increases the induced astigmatism [8]. In our study , the average keratometric astigmatism was 0.5625D in the SICS group and 0.65D in the extended incision phaco group.

Time trials significantly went in favour of the manual SICS group over the phaco group with an average case-plus-turnover-time

of 7 mins. +/- 1.8mins. for SICS versus 12 mins +/- 2.2 mins for phacoemulsification.

Vector analysis was not performed as only average pre-op keratometric data was recorded and this showed significantly that visual recovery rates aside, manual small incision cataract surgery proved to be a much faster and less expensive surgical technique for advanced cataracts of the rural population, compared to phacoemulsification. In the study done by Malik et al., they have found that the temporal incision in manual SICS does not cause any significant drag on the incision due to eyelid blink and gravity, rather these forces are neutralised better by being parallel to the vector of the forces. Now, as because most elderly patients with cataract have pre-operative ATR , WTR astigmatism which is induced by any temporal incision is somewhat neutralised [11]. The differences in SIA in our study groups is mainly due to the increased flattening with clear corneal extended-incisions which are closer to the visual axis than the sclerocorneal incisions which are farther away.

According to Jacobeic Surgically-induced astigmatism according to incision length after cataract surgery' was [12].

	Type of Incision	Incision length	SIA
(a)	Scleral tunnel incision	5.0 – 5.5 mm	0.50D – 0.90D
(b)	Clear corneal incision	5.0 – 5.5 mm	0.60 D– 1.25D

In a study done by Kohnen, Dick and Jacobi in July 1995, they compared the surgically induced astigmatism after 3.5 mm, 4.0 mm, and 5.0 mm temporal corneal tunnel incisions over six months and observed that temporal corneal tunnel incisions induced clinically minimal astigmatism over six months postoperatively depending on incision size [7].

Archana, Khurana A K , Chawla U, in their study in 2011 had compared the outcomes of performing manual small incision cataract surgery by a 6mm straight temporal sclerocorneal tunnel incision & a temporal 6mm curvilinear clear corneal incision & the results were as expected [13].

Another study by S RUIT, G Tabin, David Chang, Shreshtha and others have concluded in their study that 'Both phacoemulsification and MSICS achieved excellent visual outcomes with low complication rates. SICS is significantly faster, less expensive, and less technology dependent than phacoemulsification. SICS may be the more appropriate surgical procedure for the treatment of advanced cataracts in the developing world'.

But my study is unique in that here a comparison has been made between acceptable and slightly predictable means of surgical procedures being performed randomly in our country and may be elsewhere, results of which even surgeons performing them haven't bothered to evaluate. Here the incision for the SICS group is a 5.5mm frown temporal sclerocorneal one, whereas that for the Phaco group is a routine 2.8mm clear corneal one which has been extended to 5.5mm only following completion of the phacoemulsification surgery and prior to IOL implantation. In both the groups the lens has been implanted in the bag to avoid bias. The results showed that temporal 5.5mm sclerocorneal manual SICS has competitive refractive outcomes compared to a 5.5mm clear corneal Phacoemulsification procedure after implantation of a 5.25mm rigid PMMA intraocular lens in the bag. Moreover, implantation of a

foldable IOL through a widely extended incision than 2.8-3.5mm, causes a viscoelastic like methylcellulose to egress out of the anterior chamber shallowing it and causing more damage to the corneal endothelium, difficulty in placing the IOL in the bag increasing the likelihood of IOL decentration. If at all a cartridge is to be used, the wound must be shortened by sutures increasing surgical time.

Conclusion and Recommendations

WHO defines visual impairment as vision worse than 20/60, considering this, both procedures gave satisfactory visual outcomes, and this we all know, but that was not the aim of our study. It may be recommended that an additional take home message for those surgeons who have had the misfortune of having to convert to manual SICS surgery during a clear-corneal phacoemulsification procedure is that, if the size and texture of the nucleus and the stage of the surgery warrants that the nucleus or the nuclear fragments can be delivered following extending the incision to 5.5mm keeping a stable anterior chamber, do so and give 1 or 2 sutures at the end of the surgery. If adequate support of the capsular bag is present a foldable IOL can be implanted, else a rigid multipiece IOL of 6.0 X 12.5/13.0mm can be placed in the sulcus, albeit with a higher surgically- induced astigmatism. In most other cases, a wiser move would be to put a single suture to the clear-corneal incision and create a separate temporal sclerocorneal tunnel incision of 5.5-6.0 mm with an internal lip of 6.5mm and implant a rigid PMMA IOL in the sulcus and complete the surgery safely because chances of inducing an unacceptable amount of residual astigmatism is lesser than an extended clear corneal incision or a superior sclerocorneal incision in a case of pre-existing ATR astigmatism. Here also the presence/ absence of a posterior capsular rent/ zonular dialysis, vitreous loss etc. i.e the stage of surgery and anterior chamber stability would all be deciding factors as to the choice of the conversion surgery.

To conclude, in the words of Dr. Natchiar of Aravind Eye Care system- 'The increasing cost of surgery due to the use of costly equipments supported by commercial forces is not easily affordable by most patients and most surgeons. This is contrary to the community need for quality care at low cost to deal with the magnitude of blindness due to cataract. Manual SICS provides quality care with advantages of sutureless stable incision and shorter learning curve at an affordable cost. It therefore appears to be the answer for community need and the cataract backlog' [14]. This study is different from similar to her studies done by various authors regarding surgically induced astigmatism by either comparing the location of incisions or the length of incisions, mostly the results of which most phaco surgeons have already known all these years. But the practicality of this study lies in its relevance to the day to day procedures many of us are performing, especially in developing countries such as India, be it intentionally or inadvertently without paying heed to the surgical or medico legal pitfalls we may be implicated in.

We must also take into account the fact that Rigid PMMA IOL's remain clear throughout life whereas some Foldable IOL's, even belonging to reputed companies, have been reported to have opacified with time, albeit to varying degrees, for which a second and at times a difficult IOL Exchange surgery, has had to be done.

In conclusion, it can be said that, as a 5.5mm temporal MSICS procedure results in acceptable post-op. Va, is not technology and machine-dependent, it can be used globally in any eye care facility in our fight to clearing the vast cataract backlog, increasing the

CSR and CSC of many countries and contribute productively in the 'VISION 2020: The right to sight' program of the WHO and IAPB.

I have always learnt two very vital things during my residency days from my professor and those are- ' Safe surgery is the best surgery' and 'A good surgeon must know when to leave the patient' so..... let good sense prevail [15-17].

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