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EFFICACY OF HORIZONTAL STITCH IN EYES UNDERGOING MANUAL SMALL INCISION CATARACT SURGERY – A COMPARATIVE STUDY.

Ophthalmology

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ABSTRACT

Purpose: To determine whether eyes undergoing manual small incision cataract surgery (MSICS) have better uncorrected distance visual acuity (UCDVA) and lower postoperative astigmatism with a horizontal stitch compared to phacoemulsification and MSICS without this suture.
Methods: Participants with uncomplicated cataract were offered phacoemulsification or MSICS. Those who opted for MSICS were randomly assigned to get the horizontal stitch at the end of the cataract surgery. The primary outcome measure was the UCDVA between three groups.
Results: Seventy-five eyes of 75 patients were recruited, 25 in each group. At 6 weeks, 56% eyes in MSICS with horizontal stitch and 52% in phacoemulsification group had UCDVA of 6/6 compared to only 16% in MSICS group. The spherical equivalent for the MSICS group (-0.78 ± 0.76D) was significantly higher than MSICS with horizontal stitch (0.32 ± 0.30) and phacoemulsification (-0.28 ± 0.21) ($p<0.05$ for both), though there was no difference between the latter two groups.
Conclusion: Adding a horizontal stitch to MSICS significantly improves uncorrected vision and reduces postoperative astigmatism and visual results are comparable to phacoemulsification.

KEYWORDS

Manual small incision cataract surgery, phacoemulsification, horizontal stitch, astigmatism.

INTRODUCTION

Cataract is the most common cause of reversible blindness across the globe, especially in the developing world.[1,2] Manual small incision cataract surgery (MSICS) has been shown to be an effective way to tackle this huge backlog of cataract surgeries.[3-6] Many randomized controlled trials have clearly demonstrated the safety and efficacy of MSICS compared to phacoemulsification in restoring vision at 6 weeks postoperative follow up.[7,8,9] The main advantage of MSICS over phacoemulsification is the faster surgical time, non-dependence on expensive equipment and consumables thereby leading to reduction in cost per surgery, shorter learning curve and ability to perform MSICS in eyes with brown, black and white cataracts,[9,10] which are prevalent in the developing world.[4,11]

Despite these advantages, phacoemulsification is still the preferred choice for cataract surgery worldwide because the incision sizes are much smaller leading to minimal post-operative surgically induced astigmatism and excellent uncorrected visual acuity. Indeed, most clinical trials comparing phacoemulsification and MSICS have shown poorer uncorrected visual acuity in the MSICS group compared to phacoemulsification attributable to the surgically induced astigmatism following MSICS.[7,9] For these reasons MSICS is currently performed for patients who cannot afford phacoemulsification such as those below poverty line and those attending free and charitable eye camp surgeries. This cohort of patients is least likely to wear spectacles postoperatively and rely on uncorrected vision. Hence, it is imperative that MSICS be performed with the least possible surgically induced astigmatism which will ensure better postoperative vision.

There have been some modifications to the MSICS technique to achieve minimal astigmatism such as shifting the surgical tunnel temporally or along the steep axis, reducing the size of the incision and fragmenting the nucleus[12] either before delivery using prechoppers, snares etc., or during delivery within the tunnel and making frown incisions instead of straight incisions.[13] In this study, we performed a horizontal stitch at the MSICS surgical tunnel at the end of the procedure and compared the postoperative astigmatism with eyes that underwent MSICS without the horizontal stitch as well as with eyes that underwent phacoemulsification.

Methods

Subjects

The study was approved by the institutional ethics committee and was performed as per the tenets of Declaration of Helsinki. An informed written consent was obtained from participants before enrolment.

Consecutive patients >18 years of age presenting to our outpatient department with defective vision attributable to cataract were offered participation in the study. Eyes with very dense or mature white cataract and other ocular comorbidities such as corneal opacity, pseudoexfoliation, glaucoma, macular and optic nerve pathologies that could interfere with visual outcomes were excluded. Similarly cataract following ocular trauma, eyes that had previous intraocular surgery and those with maximum mydriasis < 5mm were also excluded.

Allocation and masking

There were three study groups i.e. MSICS alone, MSICS with horizontal stitch and phacoemulsification. Once included in the study, patients were offered phacoemulsification or MSICS surgery as per routine hospital protocol. Those who opted for MSICS were randomly assigned to get the horizontal stitch at the end of the cataract surgery. The randomization sequence was generated using a DOS-based software program and allocation codes were placed in small envelopes and sealed. These codes were opened in the operation theatre after placement of the intraocular lens and those assigned to the horizontal stitch group received the suture. Those who had posterior capsular rent or premature corneal entry were not excluded but data was analysed using intention to treat methods.

An independent examiner evaluated the patients pre and postoperatively and was masked to the type of surgery performed. He was not allowed to raise the upper eye lid during the study visit so that placement of the horizontal stitch was not revealed. Optometrists assisting with visual acuity and keratometry were also masked to the type of surgery performed.

Sample size calculation
Assuming 1:1 randomization, 90% power (a Z .05), and a precision error of 5% to detect a difference of 30% or more in uncorrected postoperative visual acuity between the MSICS groups with and without a horizontal switch, the required sample size was calculated to be 25 in each group. A similar number (n=25) of eyes from age-matched patients was recruited for eyes receiving phacoemulsification.

Preoperative evaluation
All patients had a thorough preoperative evaluation by an independent investigator. The examination included uncorrected (UCDVA) and best corrected distance visual acuity (BCDVA), dilated slit lamp evaluation of the anterior segment using the LOCSIII system, thorough fundus evaluation, measurement of intraocular pressure using Goldmann applanation tonometry, A-scan biometry for axial length and measurements of keratometric values in the steepest and flattest meridians using the Bausch and Lomb keratometer.

Surgical technique
The MSICS was performed under peribulbar anaesthesia. Standard operating techniques were used as described before.[6] In summary, a superior straight scleral tunnel incision measuring 6mm in horizontal length was fashioned, capsulorrhexis was completed, nucleus was prolapsed into the anterior chamber after hydrodissection and delivered outside the section using an irrigating vectis. Following cortical clean up, a single piece rigid PMMA IOL (Appalens, Appasamy associates India) was inserted into the bag and stromal hydration was performed at the main tunnel and paracentesis incisions. In the horizontal stitch group, a 10-0 nylon suture was passed along the left and right side of the posterior lip of the incision followed by passing the needle along the right and left side of the anterior lip of the incision, such that a purse string like effect was produced to secure the horizontal scleral tunnel. The horizontal stitch was tightened such that it helped to approximate the anterior and posterior lips of the scleral tunnel without causing corneoscleral folds. Phacoemulsification was performed using the peristaltic phacoemulsification system (Visalis 100 Zeiss, Germany) using superior 2.8mm clear corneal tunnel incision, a foldable hydrophobic acrylic IOL (Aurovue, Aurolab India) was placed in the bag and the corneal tunnel was secured by stromal hydration.

Postoperative follow up
An independent investigator performed examinations 1 day and 6 weeks postoperatively. Snellen UCDVA and BCDVA were recorded at all visits. A complete ophthalmic examination, including slit lamp evaluation, fundus evaluation, keratometry and refraction, was performed at the final visit at 6 weeks follow up.

Outcome measure
The primary outcome measure was the UCDVA between the three groups. Secondary outcomes assessed were BCDVA and refractive error at the last follow up.

Statistical analysis
Continuous variables were expressed as means with standard deviation and categorical variables were expressed as proportions. Visual acuity was converted into logarithm of minimum angle of resolution (logMAR) for statistical analysis. Spherical equivalent was calculated for refractive correction at last follow up using the formula: spherical equivalent = sphere + ½ cylinder. Differences in continuous variables between two groups were analyzed using the student t test or Wilcoxon rank-sum test. The ANOVA or Kruskal Wallis test was used to identify group differences between three groups. The chi square or Fisher's exact test was used to identify group differences between categorical variables. A comparison between pre and postoperative characteristics was done using the paired t test.

All data was stored in Microsoft Excel and was analyzed using STATA statistical software package, version 12.1 I/c (STATA, Fort worth, Texas, USA). All p values less than 0.05 were considered statistically significant.

Results
Seventy-five eyes of 75 patients were recruited for the study, 25 each in the MSICS group, MSICS with horizontal stitch group and phacoemulsification group. The mean age of participants was 64.2 years and 56% were men. A comparison of baseline characteristics between the groups is shown in table 1. Eyes in the MSICS group had significantly greater IOL power compared to the phacoemulsification group but not compared to the horizontal stitch group. Eyes were comparable in other preoperative metrics. None of the study eyes suffered any intraoperative complications.

At 6 weeks, the UCDVA was significantly better in eyes that received phacoemulsification and MSICS with the horizontal stitch compared to eyes that had MSICS alone. The UCDVA was 6/9 or better in more than 90% eyes receiving phacoemulsification compared to only 20% in eyes receiving only MSICS. There was no difference in UCDVA in eyes with phacoemulsification vs. MSICS with horizontal stitch. Similarly, the spherical equivalent was significantly lower in eyes with phacoemulsification and MSICS with horizontal stitch compared to MSICS alone ([table 1].

Table 1: The distribution of pre-op and post-op parameters between three study groups.

Parameters		MSICS (n=25)	P*	H-Stitch, (n=25)	P **	Phaco (n=25)	P #
Pre-op	IOL Power	23.3 ± 2.4	0.90	22.9 ± 1.9	0.09	21.7 ±1.9	0.03
	K1	43.3 ± 1.6	0.86	42.9 ± 1.9	0.23	43.9 ± 1.6	0.50
	K2	43.1 ± 1.5	0.99	43.0 ± 1.9	0.09	44.2 ± 1.7	0.09
Post-op	K1	43.3 ± 1.5	0.79	42.9 ± 1.9	0.11	44.0 ± 1.8	0.35
	K2	42.9 ± 1.9	0.45	43.5 ± 1.8	0.61	44.1 ± 1.8	0.08
	UCDVA						
	6/6	4 (16.0)	0.001	14 (56.0)	0.36	13 (52.0)	0.001
	6/9	1 (4.0)		9 (36.0)		11 (44.0)	
	6/12	11 (44.0)		2 (8.0)		0	
	>6/12	9 (36.0)		0		1 (4.0)	
	Refraction						
	Sph equivalent	-0.78 ± 0.76	0.009	-0.32 ± 0.30	0.99	-0.28 ± 0.21	0.006
	Axis	68.3 ± 36.8	0.07	42.9 ± 30.9	0.51	30.2 ± 28.9	0.004

Values on vision are n (%). The rest of the values are Mean ± Standard Deviation. MSICS: Manual small incision cataract surgery, UCDVA: uncorrected distance visual acuity, H – stitch: Horizontal stitch, Phaco: Phacoemulsification, IOL: intraocular lens. Sph: Spherical

* p values comparing MSICS alone with horizontal stitch, ** p values comparing horizontal stitch with phacoemulsification, # p values comparing MSICS only with phacoemulsification.

Comparing keratometric values showed that there was no statistically significant change in K1 and K2 before and after surgery except for K2 in the horizontal stitch group [table 2].

Table 2: The within-group statistical comparison of pre-op and post-op parameters between three study groups.

	MSICS only (n=25)			MSICS-Horizontal Stitch (n=25)			Phacoemulsification (n=25)		
	Pre-op	Post-op	P-value	Pre-op	Post-op	P-value	Pre-op	Post-op	P-value
K1	43.3 ± 1.6	43.3 ± 1.5	0.893	42.9 ± 1.9	42.9 ± 1.9	0.059	43.9 ± 1.6	44.0 ± 1.8	0.084
K2	43.1 ± 1.5	42.9 ± 1.9	0.361	43.0 ± 1.9	43.5 ± 1.8	0.003	44.2 ± 1.7	44.1 ± 1.8	0.875

Values are Mean ± Standard Deviation. P-values by paired 't' test.

Figure 1: Distribution of keratometric values (K1) with standard error

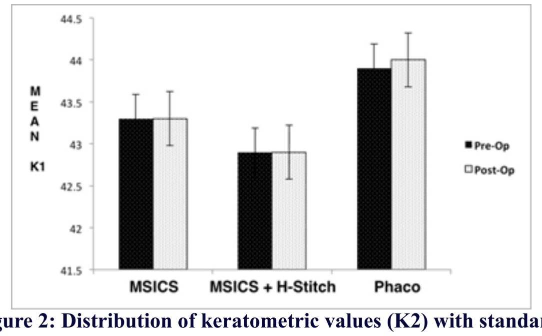
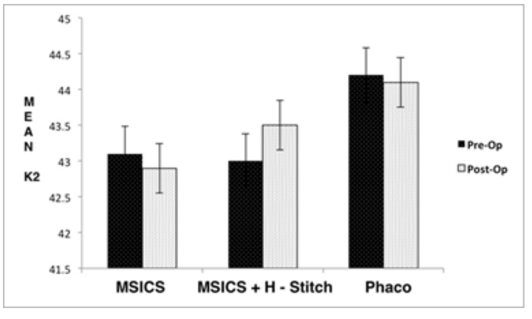


Figure 2: Distribution of keratometric values (K2) with standard error



DISCUSSION

MSICS has been shown to be a safe and effective technique for performing cataract surgery with reasonably good visual outcomes.[5,6,8] However, compared to phacoemulsification, the larger surgical incision means that it leads to significant residual astigmatism after wound healing. Unless this aspect of MSICS is addressed, its widespread adoption remains doubtful despite its cost effectiveness. We performed a study to address this issue and found that eyes receiving MSICS with a horizontal stitch yielded better UCDVA and lower postoperative spherical equivalent compared to eyes receiving MSICS alone. Additionally, we also found that the horizontal stich improves vision and residual astigmatism to a level comparable with phacoemulsification.

Sutures to cataract surgical incisions have been utilized in the past to reduce surgically induced astigmatism.[14-17] The “X” pattern sutures have been most commonly employed by previous studies, most dating back to the late 90's. Davison operated 276 eyes with the scleral tunnel phacoemulsification and equally divided them into either receiving either 4 mm or 5.5 mm surgical incisions that were all approximated using two X-pattern sutures.[14] The average astigmatism at 1-year was −0.34 ± 0.91 for the 4.0 mm group and −0.23 ± 1.01 for the 5.5 mm group. We found similar results in our group with phacoemulsification without sutures, though we performed the surgery via a 2.8mm incision. Similarly Azar et al conducted a randomized controlled trial with 131 eyes receiving either three, one of no sutures after a 5.5mm phacoemulsification.[15] They employed radial 10-0 nylon sutures and found that compared with sutureless surgery, the one-suture surgery resulted in less against the rule shift.

Conversly, fewer studies have reported on astigmatic benefits of the horizontal suture. Storr-Paulsen analyzed postoperative astigmatism after phacoemulsification in 32 eyes with a 4 mm scleral tunnel incision and a single, horizontal stitch technique, similar to our technique.[16] The mean astigmatism was −0.01 D at 1-year, and −0.07 D at 3 years postoperatively. More recently, Eslami et performed a prospective nonrandomized study comparing surgically induced astigmatism between horizontal and X-pattern sutures in the scleral tunnel incisions for MSICS.[17] They had 32 eyes in each group and reported that X-pattern sutures were preferred to the horizontal sutures in the patients without significant preoperative steepening in line with the central meridian of the incision and in the cases with significant preoperative steepening, sutureless surgery or horizontal sutures were preferred. They also confirmed that corneal astigmatism in the patients undergoing MSICS was stable at 6 weeks after the surgery.

The mechanism of induced astigmatism after larger incisions, particularly in MSICS, is not well understood. Du et al studied the corneal incision in 68 eyes undergoing phacoemulsification using confocal microscopy and reported that reduction of endothelail cell density and the histocytological changes at the corneal incision were associated with postoperative astigmatism.[18] It is generally believed that there may be loosening and disorganization of stromal collagen due to the corneal incision leading to increased steepening of the axis at which the incision is made. Horizontal stitch applied to the corneal incision may act as a purse string and help tighten the stroma at the incision site thus preventing the induced astigmatism during wound healing.

The strength of our study is the comparison of MSICS with horizontal stitch with eyes undergoing MSICS alone as well as those having phacoemulsification. Group – wise comparisons were useful in delineating the beneficial effects of the horizontal stitch well. We also randomly assigned eyes receiving MSICS into surgery with and without the horizontal stitch. The drawbacks are the small sample size and the limited follow up period.

In conclusion, we found the adding a horizontal stitch to MSICS significantly improves uncorrected vision and reduces astigmatism in the postoperative period. Future studies may consider understanding cellular mechanisms of surgically induced astigmatism and how sutures at the incision may help in minimizing astigmatism, particularly in eyes undergoing MSICS.

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