Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Prospective Study of Incision Characteristics for Surgically Induced Astigmatism in Small Incision Cataract Surgery at Tertiary Rural Centre

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Abstract

Introduction: Cataract is a major cause of blindness in developing countries. The developing countries cannot afford expensive modern technologies to treat these poor patients. Therefore a cost effective, fast, machine independent procedure is necessary. Manual sutureless small incision cataract surgery is comparable to other relative new techniques and has been increased in popularity.

Materials and Methods:
- This prospective, non comparative, observational hospital based study enrolled 350 eyes of 329 cases over 4 years and 6 months from August 2011 to March 2016
- It was carried out at the department of Ophthalmology, R.D Gardi Medical College, Ujjain, (M.P.)
- All the patients of cataract where manual, sutureless, small incision cataract surgery was possible, were included
- The pre-operative refraction, keratometry, autoref Keratometer (Nidek), A-scan (Sonomed) and intraocular lens calculation was done accordingly
- Post-operative results recorded on second and seventh post-operative day and 4 and 8 weeks from surgery.

Results: Correlation of surgically induced astigmatism (SIA) and wound size: Mean (SD) was 0.76 (0.44) for 7 mm and 0.48 (0.41) for 6mm group. S.I.A. of 6 and 7 mm groups was significantly different (P = 0.0002) (95% C.I. = −0.50–−0.25). Correlation of SIA and wound shape: Mean (SD) was 0.95 (0.39) for straight and 0.46 (0.39) for frown group. S.I.A. of straight and frown incision groups was significantly different (P < 0.0001) (95% C.I. = −0.75–−0.5). S.I.A: 79.42% had S.I.A. <1.00 D, 12.85% had S.I.A. 1.25 D–2.00 D, 7.73% had nil.

Conclusions: Manual small incision cataract surgery is a safe and effective procedure with good overall outcomes resulting in rapid visual rehabilitation. Post-operative astigmatism was significantly more in straight (P < 0.0001) and 7 mm incision (P= 0.0002) as compared to frown and 6 mm incision.

Key words: Incision, Small incision cataract surgery, Surgically induced astigmatism

INTRODUCTION

Cataract, a major cause of blindness in developing countries, contributing to over 90% of the total disability adjusted life years[1] and is a big health morbidity. Although cataract surgery is the most cost effective intervention, its delivery in developing country has many issues and challenges.[2] The developing countries cannot afford expensive modern technologies to treat these poor patients. Therefore, a cost effective, fast, machine independent procedure is necessary.

This prospective, non-comparative, and observational hospital-based study enrolled 350 eyes of 329 cases over 4 years and 6 months in central part of Indian, Ujjain.

Access this article online

www.ijss-sn.com

Month of Submission : 07-2021
Month of Peer Review : 08-2021
Month of Acceptance : 08-2021
Month of Publishing : 09-2021

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MATERIALS AND METHODS

Study Site and Setting

- This prospective, non-comparative, observational hospital-based study enrolled 350 eyes of 329 cases over 4 years and 6 months from August 2011 to March 2016
- It was carried out at the Department of Ophthalmology, R.D Gardi Medical College, Ujjain, (M.P.) a tertiary, referral and teaching hospital, receiving patients from semi-urban and rural populations.

Inclusion Criteria

All the patients of cataract where manual, sutureless, and small incision cataract surgery (MSICS) was possible were included in the study. Same surgeon was operator in all.

Exclusion Criteria

Any other ocular co-morbidities as pterygium, corneal degeneration and dystrophy, ocular injuries, uveitis, retinal detachment and vitreous hemorrhage, congenital cataract, high myopia, and lens induced glaucoma were excluded from the study.

Data Collection Techniques

All datum was entered in pro forma (Excel) and was analyzed statistically with GraphPad Prism 6 version 6.02. Demographic particulars, presenting complaint, general, systemic, and detailed ocular examination (visual acuity, anterior segment torch light, and slit lamp) were performed and intraocular pressure (applanation tonometry); ophthalmoscopy direct and indirect were done.

The pre-operative refraction, keratometry, axial length of eye was recorded with the help of autoref Keratometer (Nidek), A-scan (Sonomed). IOL calculation was done accordingly. B-scan was done whenever indicated.

The operative procedures were recorded with specific reference to the type of procedure done, size and shape of wound and any intra-operative complication noted. The post-operative results were recorded on 2nd and 7th post-operative day and 4 and 8 weeks from surgery.

The post-operative results were recorded next which included the visual acuity, slit lamp examination, refraction, post-operative keratometry using same keratometer, intra-ocular pressure measurement, fundus examination. Special attention was given to the amount of astigmatism induced postoperatively, which was calculated by simple subtraction method. Detailed analysis of all datum was done.

Statistical Analysis

Unpaired *t*-test was applied using GraphPad Prism 6 version 6.02. $P < 0.05$ is considered statistically significant.

Ethical Consideration

- Project proposal was submitted and approved by the college Research and Ethics Committees. The decision to admit and treat was based on clinical grounds/investigations and not for the sake of the study. Informed consent was obtained from patients after explaining the objectives and protocol of the study.

RESULTS

Correlation of SIA and Wound Size (6 mm and 7 mm) (Figure 1)

147 and 203 cases had wounds of 7 & 6 mm; respectively. The Mean (SD) was 0.76 (0.44) for 7mm and 0.48 (0.41) for 6mm group, their respective medians being 0.75 & 0.50. S.I.A. was not normally distributed and unpaired t test (two tailed) was applied. S.I.A. of 6 & 7 mm groups was significantly different (*p=0.0002*) {95% C.I. = -0.50 to -0.25}. So, it can be concluded that there is a *strong association between the size of the wound and the S.I.A.*

Correlation of SIA and Wound Shape (Straight and Frown) (Figure 2)

95 and 255 cases had straight & frown incisions; respectively. The Mean (SD) was 0.95 (0.39) for straight and 0.46 (0.39) for the frown group, their respective medians being 0.1 & 0.5. S.I.A. was not normally distributed and unpaired t test (two tailed) was applied. S.I.A. of straight & frown incision groups was significantly different (*p< 0.0001*) {95% C.I. = -0.75 to -0.5}. Thus, there is a *strong association between shape of the wound and the S.I.A.*

Comparative assessment of Pre and post operative amount of astigmatism: (n=350) (Table 1)

Pre-operatively 191 cases had astigmatism upto 1 D, while post operatively 221 were having it. Pre-operatively 25 cases had more than 2 D, while postoperatively only 3 cases had more than 2D ($P < 0.01$, Unpaired T test).

Comparative assessment of Pre and post operative type of astigmatism: (n=350) (Table 2)

Pre-operatively 112 cases had against the rule astigmatism, while post operatively 206 were having it. Pre-operatively 66 cases had no astigmatism, while postoperatively only 7 had it ($P < 0.05$, Chi square test).

S.I.A. {Surgically Induced Astigmatism} : (Table 3) (Figure 3)

79.42% had S.I.A. < 1.00D, 12.85% had S.I.A. 1.25D to 2.00D and none > 2.00D. 7.73% cases had nil.

Post-op unaided Visual acuity at 8 week: (Table 4)

92% had unaided visual acuity better than 6/18, with only 8% less than 6/18.

Operative Procedures

All the incisions were superiorly placed and around 2.5mm away from limbus.

In our study, size of incision was 7mm in 42% eyes and 6mm in 58% (Table 5).

Shape of incision was frown in 72.85% and remaining had straight incision (Table 6).

DISCUSSION

Modern cataract surgery, aims to achieve a better unaided visual acuity with rapid post-surgical recovery and minimal surgery related complications. Early visual rehabilitation, better unaided visual acuity and surgical safety can be achieved in a great measure by reducing the incision size. Incision size depends on the mode of nucleus delivery and the type of intraocular lens used.

In this study, we have tried to assess the surgical outcome in terms of visual recovery, induced astigmatism in eyes undergoing cataract surgery by the technique of MSICS. Post-operative astigmatism plays an important role in the evaluation of final outcome of surgery. Astigmatic outcomes (amount and type) were studied in detail as primary outcome of interest of sutureless small incision cataract surgery (SICS).

SICS in Different Types of Cataract

There were no major appreciable differences in type of cataract with predominance of nuclear cataract (38%), combined (cortical, nuclear, and posterior subcapsular cataract) being 31%, cortical 22%, and posterior subcapsular cataract 9%. We found that MSICS can be done in almost all types of cataract with good visual outcome. Thomas *et al*.[3] also found that manual small incision technique is utilized to achieve the desired outcome as often as possible and for all types of cataracts.

Singh *et al*.[4] did a prospective randomized controlled trial, involving 93 patients and concluded that SICS with implantation of rigid PMMA lens is a suitable surgical technique for immature cataract in developing countries. A study of 100 eyes where, 16 had intumescent, 67 mature, and 17 hypermature cataract concluded that MSICS proves to be safe and efficacious alternative for white cataracts.[5]

Pre-operative Astigmatism

Type of astigmatism

In our study, against the rule astigmatism was seen in 32%, with-the-rule in 25%, oblique in 24%, and nil in 19%. We observed that pre-operative assessment plays important role in determining the amount of astigmatism postoperatively. Ernest *et al*. in a multifactorial, multivariate study of 426 patients analyzing factors influencing axis of the induced astigmatism, most important for a postoperative astigmatism against the rule is using the no-stitch-technique and a pre-operative astigmatism against the rule.[6]

Nielsen in 1995 did prospective evaluation of SIA and astigmatic keratotomy effects of various self-sealing small incisions. He concluded that if pre-operative astigmatism is considered in selecting incision type and location for SICS, one can minimize post-operative keratometric astigmatism.[7]

Operative Procedures

Wound construction

In cataract surgery, incision size determines various factors such as wound stability, corneal curvature changes, post-operative induced astigmatism, and visual rehabilitation.[8]

In our study, size of incision was 7 mm in 42% eyes and 6 mm in 58%; while shape of incision was frown in 73% and remaining had straight incision. All the incisions were superiorly placed and around 2.5 mm away from limbus. We found that frown incision induces less astigmatism and smaller the incision; less will be the induced astigmatism, this being in accordance with the literature.

Singer developed frown incision in 1991 and a series of 62 eyes with 6 mm and 7 mm incisions were prospectively evaluated for induced astigmatism. They propounded that frown incision provided many benefits.[9]

Huang and Tseng in 1997 did the corneal topographic analysis of small incision and concluded that smaller produces less astigmatism, faster post-operative recovery and more stable refraction.[10]

Anwar[11] in 1999 studied the changes in SIA after Extra-capsular Cataract Extraction. Post-operative astigmatism was more when extraction is done through the incision and more anterior incision having greater induced astigmatism.

Burgansky *et al*. (2002) found that the 7.0 mm group had statistically significantly greater induced astigmatism than the 5.0 mm group ($P = 0.01$, simple subtraction; $P = 0.002$, vector analysis).[12]

Haldipurkar *et al*.[13] suggested that the basis of MSICS is the tunnel construction for entry to the anterior chamber. The parameters important for the structural integrity of the tunnel are the self-sealing property of the tunnel, location with respect to the limbus and shape of the wound.

POST-OPERATIVE RESULTS

Post-operative type of astigmatism

In our study, postoperatively, 59% had against-the-rule astigmatism, 29% had oblique, 20% had with-the-rule, and 2% had no astigmatism, as we had superiorly placed incisions ($P < 0.05$). Our results are in accordance with Nielsen[14] who did astigmatic keratometric evaluation of the incisions and found temporal resulted in with-the-rule induced change and superior ones against-the-rule.

Oshika *et al.* found superior incision had slight against-the-rule astigmatic changes, whereas slight with-the-rule astigmatism in the temporal incision. Amount of irregular astigmatism 1 day after surgery being significantly greater than pre-operative ($P < 0.001$), but not thereafter.[15]

Post-operative amount of astigmatism

In this study, postoperatively, majority of patients (63%) had amount of astigmatism <1.00D, while 34% patients had astigmatism in between 1.25D and 2.00D and only 1% had being more than 2.00D. The mean post-operative corneal astigmatism was 0.92 ($P < 0.01$) at the end of 8 weeks which was comparable to Ang *et al.*[16] in whom the mean post-operative astigmatism was significantly higher than preoperatively (1.40D vs. 0.99D, $P = 0.02$).

Gogate *et al.* (2003) found that the corneal astigmatism was (1.01 ± 0.97) D ($n = 95$) 1 week postoperatively and (0.62 ± 0.53) D ($n = 90$) at 1 month ($P < 0.01$).[17]

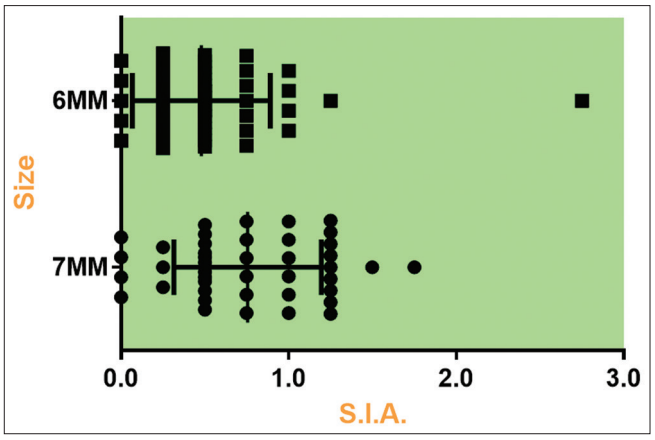
Gokhale and Sawhney (2005) propounded mean astigmatism induced by surgery was 1.28 D × 2.9 degrees for superior incision.[18]

In a non-randomized interventional case series of 102 patients with BBC undergoing cataract extraction by MSICS, superior scleral tunnel was employed in 30.4%, and had post-operative astigmatism of –1.08 D.[19]

SIA

In our study, 79% had SIA <1.00D with only 14% patients had SIA in between 1.25D and 2.00D and no one more than 2.00D. About 7% patients had no SIA. The mean (SD) was 0.76 (0.44) for 7 mm group and 0.48 (0.41) for the 6 mm group. The mean (SD) was 0.95 (0.39) for straight group and 0.46 (0.39) for the frown group.

The results were encouraging and in accordance with the world literature, as discussed below.



Figures 1: Unpaired test data of the surgically induced astigmatism of the two wound sizes

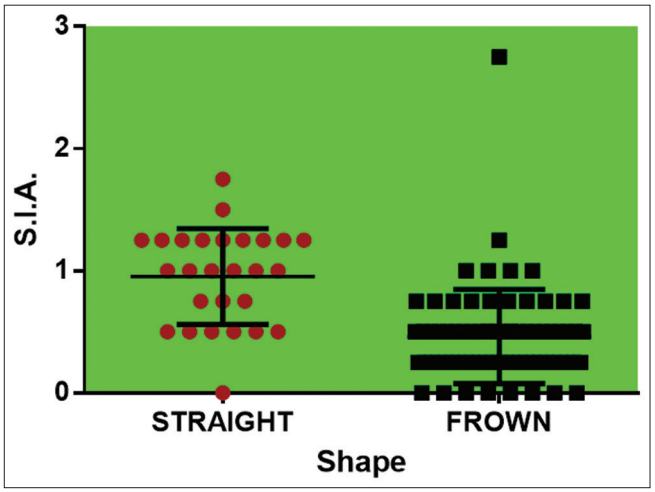


Figure 2: Unpaired test data of the surgically induced astigmatism of the two wound shapes

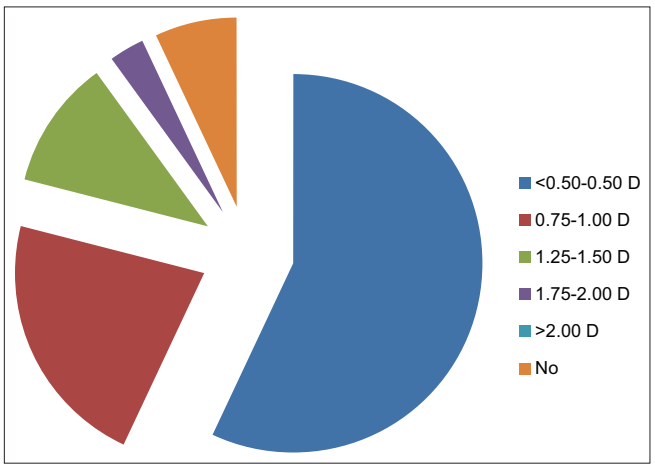


Figure 3: Surgically Induced Astigmatism encountered in the study

Singer did vector analysis calculations of diopters (D) of mean induced keratometric astigmatism for the frown incision versus the scleral pocket incision groups were 0.80 D versus 1.19 D ($P = 0.0263$) at 1 day; 0.74 D versus 1.03 D

Table 1: Comparative assessment of pre- and post-operative amount of astigmatism: (*n*=350)

Amount of astigmatism	Pre-operative	Post-operative
Nil	66	7
0.25–1.00 D	191	221
1.25–2.00 D	68	119
>2.00 D	25	3

Table 2: Comparative assessment of pre- and post-operative type of astigmatism: (*n*=350)

Type of astigmatism	Pre-operative	Post-operative
With the rule	88	70
Against the rule	112	206
Oblique	84	67
No	66	7

Table 3: SIA found in the study (*n*=350)

SIA (at 8 week)	No. of Eyes	Percentage
0.25–0.50 D	201	57.42
0.75–1.00 D	77	22
1.25–1.50 D	37	10.57
1.75–2.00 D	8	2.28
>2.00 D	0	0
No	27	7.73
Total	350	100

SIA: Surgically induced astigmatism

Table 4: The post-operative unaided visual acuity at 8th weeks (*n*=350)

Post-operative visual acuity	No. of eyes	Percentage
6/9 or better	147	42
6/12–6/18	175	50
6/24–6/36	28	8
Total	350	100

Table 5: Size of incision (*n*=350)

Size of wound	No. of Eyes	Percentage
7 mm	147	42
6 mm	203	58
Total	350	100

Table 6: Shape of incision (*n*=350)

Shape of wound	No. of Eyes	Percentage
Straight	95	27.14
Frown	254	72.85
Total	350	100

($P = 0.0547$) at 1 week; 0.71 D versus 1.07 D ($P = 0.0057$) at 4 weeks; 0.84 D versus 1.15 D ($P = 0.0072$) at 6 months; and 0.82 D versus 1.30 D ($P = 0.0144$) at 1 year.[9]

Steinert *et al.*[20] evaluated induced astigmatism and postoperative wound stability in a randomized prospective study of 130 patients. Vector analysis calculations of prism D of mean post-operative-induced keratometric astigmatism for the small incision versus conventional incision groups were, at day 1, 1.54 D versus 3.07 D ($P < 0.0001$); at weeks 1 to 2, 1.00 D versus 2.43 D ($P < 0.0001$); at 1 month, 0.98 D versus 1.44 D ($P = 0.004$); and at 3 months, 0.82 D versus 1.03 D ($P = 0.089$).

Uusitalo *et al.*[21] in 1993 studied the outcomes of SICS. Less initial induced astigmatism was demonstrated at day 7 with a 4.0-mm incision (0.1 ± 0.53 D) compared with a 7.5-mm incision (1.90 ± 1.97). The low amount of induced cylinder, rapid stabilization of the wound, and faster visual rehabilitation confirms the advantage of small-incision cataract surgery to large-incision surgery.

Uusitalo and Tarkkanen found that mean SIA in all eyes was 0.2 D ± 0.7 (SD); 91.2% were within ±1.0 D of preoperative values. Improvement after first-eye surgery was: Snellen visual acuity (95.0%), VF-14 score (89.4%), satisfaction with vision (80.1%), self-reported trouble with vision (75.8%), and cataract symptoms (75.1%).[22]

Archana *et al.* observed that SIA was 1.85 ± 0.62 D, 1.56 ± 0.54 D, 1.35 ± 0.49 D, and 1.34 ± 0.45 D at 1 week, 2 weeks, 4 weeks, and 8 weeks postoperatively. Surgically-induced astigmatism is significantly higher in clear corneal MSICS than in sclero-corneal. Thus, the study confirmed the safety and improvement in acuity after small-incision cataract surgery using sclero-corneal tunnel incision.[23]

Thus, our results are in accordance with the world literature.

Post-operative Unaided Visual Acuity

In our study, majority of the patients (91%) had unaided visual acuity better than 6/18, with only 9% of patients <6/18. Our results are comparable with the world literature, as mentioned below. Wright *et al.* where 56% and 70% of patients had unaided visual acuities of 6/12 or better at 3 weeks and 3 months, respectively.[24] Mpyet *et al.* found that on 5th day and 6 weeks uncorrected visual acuity (UCVA) was good in 43.7% and 69.0%, respectively.[25] Venkatesh *et al.* found that on the 40th post-operative day, 78.4% achieved UCVA of 6/18 or better and 97.1% best-corrected visual acuity of 6/18 or better.[19]

Singh *et al.* in 2009 did a study where in SICS group ($n = 89$), more than three quarters of the patients had good visual outcome (6/6-6/18) on 1st post-operative day ($P = 0.065$).[4]

Trivedy[26] in 2011 carried out a retrospective interventional study. Out of 368 subjects, 81.8% of the patients achieved post-operative UCVA of 6/18 and better by the 4th week. Fifteen patients were found to have posterior capsular

opacification and had the UCVA between 6/24 and 6/60. The study results show that high quality cataract surgery can be attained in a high volume setting.

Sherwin *et al.* found that without correction (uncorrected VA), nearly 80% (78.7%) achieved a "good" outcome (VA 6/6-6/18), 19.8% were "borderline" (VA <6/18-6/60), and 1.5% had a poor (VA <6/60) outcome. With pinhole-correction, the proportion of good outcomes increased to 89.4%, and poor outcomes decreased to 0.9%. Poor outcomes were most commonly due to ocular co-morbidities (54.5%) and refractive error (36.4%). Older age and pre-operative blindness were strongly associated with borderline or poor visual outcomes.[27]

Some studies like Sadiq *et al.* got UCVA of 6/6, on 1st post-operative week in 8.3% cases. By the end of 12th post-operative weeks, 34.5% had the same. About 66.7%, 75%, and 83.3% eyes had best correctable visual acuity of 6/6 after 4 weeks, 8 weeks, and 12 weeks, respectively.[28]

Murthy *et al.*[29] found among cataract-operated eyes, 18.7% presented with VA > or = 20/32 and 18.0% were <20/200. With best-corrected acuity, the corresponding percentages were 55.7% and 11.0%.

CONCLUSIONS

MSICS is a safe and effective procedure with good overall outcomes and results in rapid visual rehabilitation and can be done in almost all types of cataract with good visual outcomes.

The amount of post-operative astigmatism was significantly more in straight incision ($P < 0.0001$) and in 7 mm (longer) incision ($P = 0.0002$) as compared to frown incision and 6 mm incision.

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How to cite this article: Mahadik S, Singh G. Prospective Study of Incision Characteristics for Surgically Induced Astigmatism in Small Incision Cataract Surgery at Tertiary Rural Centre. Int J Sci Stud 2021;9(6): -58.

Source of Support: Nil, **Conflicts of Interest:** None declared.