



CODEN [USA]: IAJPBB

ISSN: 2349-7750

INDO AMERICAN JOURNAL OF PHARMACEUTICAL SCIENCES

<http://doi.org/10.5281/zenodo.1420189>

Available online at: <http://www.iajps.com>

Research Article

RANDOMIZED CONTROLLED TRIAL OF SURGICAL DATA MAKING THE COMPARISON OF POST OPERATIVE ASTIGMATISM WITH OPENING OF 3.5MM VS 6MM AFTER STITCH LESS CATARACT REMOVAL SURGERY

¹Maria Javed, ²Hafiz Mirza Muhammad Zeshan, ³Zobia Shahid

¹Mayo Hospital Lahore

²Services Hospital Lahore

³Mayo Hospital Lahore

Abstract:

Objective: Use of surgical data making the comparison of post-operative astigmatism with opening of 3.5mm vs 6mm after stitch less cataract removal surgery

Background: Cataract surgery with small and big opening is beneficial due to less instrumental expenses and Disposability. At the moment for advanced and mature cataract it appears a better and suitable treatment. Declaring of surgically induced astigmatism (SIA) superior has become a public health problem, so the comparative study of surgically induced astigmatism is much important. By keeping in view the limitations of such studies in Pakistan this study is designed to compare the post-operative SIA with stitch less 3.5mm & 6mm incision surgery that is SICS (Small Incision Cataract Surgery).

Methods: Study design: Randomized Controlled Trial.

Setting: LRBT Free Secondary Eye Hospital North Karachi.

Duration: 6 months' duration.

Procedure: For the astigmatism and surgical efficiency and related adverse effects after stitch less cataract extraction Post-Operative cataract patients were examined by means of:

(a) With cut size 3.5 mm or more

(b) With cut size 6 mm or more

The segregation criteria include all patients with past surgical history, heart disease, renal failure and all other eye diseases whereas all the patients were above 18 years of age and included both male and female with stitch less cataract extraction surgery. **Results:** Via hospital record system the records of total 140 patients were collected. The average age of the patients was 54 ± 9 . 25 of the patient were between the ages of 36 years to 45 years. The visual activity was measured as zero when it was less than 1/60, as one when it is less than 3/60 to 1/60, as two when it is less than 6/60 to 3/60, as three when it is Less than 6/18 to 6/60 and four when it is 6/6 to 6/18. Post operatively with repeated visits the uncorrected visual acuity has increased and the maximum of the increase was observed in group 1 patients with 3.5 mm opening. **Conclusion:** It might be concluded that SIA is less likely to be occurring in the stitch less 3.5mm surgery. However, 6mm SICS is more cost effective.

Keywords: stitch less surgery SICS (Small incision Cataract Surgery), Cataract, surgically induced astigmatism (SIA).

*** Corresponding author:**

Maria Javed,
Mayo Hospital,
Lahore

QR code



Please cite this article in press Maria Javed et al **Randomized Controlled Trial of Surgical Data Making the Comparison of Post Operative Astigmatism with Opening of 3.5mm Vs 6mm after Stitch less Cataract Removal Surgery., Indo Am. J. P. Sci, 2018; 05(09).**

INTRODUCTION:

One of the leading causes of blindness in the world is cataract. According to various studies out off various developing countries India has almost 13 million blind people from which 60% to 80% are due to the cataract. In addition to the said figure increase of 4 million patients were reported yearly with blindness and out of them 3 million patients were treated with cataract surgery yearly. The cataract surgery is limited to day care surgery only as by the invention of phacoemulsification. Phacoemulsification is only opted in big cities and institutions due to its high cost. On this base, in developing countries, stitch less cataract surgery i.e SICS becomes a ray of hope as a treatment of cataract burden.

Cataract surgery is a big benefit for the patients due to its less instrumental expenses, cost and disposability of small and big incision. Now here for advanced and mature cataract it appears a better and suitable treatment. Once the surgery is completed the scleral tunnel is usually sealed without stitches or may be some time with stitches in a different way. Now a day the cataract surgery becoming a refractive surgery and on the yearly bases the refractive procedures are increasing worldwide. Declaring of surgically induced astigmatism (SIA) superior has become a public health problem, so the comparative study of surgically induced astigmatism is much important. By keeping in view the limitations of such studies in Pakistan this study is designed to compare the post-operative SIA with stitch less 3.5mm & 6mm incision surgery that is SICS (Small Incision Cataract Surgery).

MATERIAL AND METHODS:

For the current research the study design was opted is on experiential retrospective, where the astigmatism and surgical efficiency and related adverse effects

after stitch less cataract extraction Post-Operative cataract patients were examined by means of

- (a) With incision size 3.5 mm
- (b) With incision size 6 mm

The duration of the study was six months. The study venue was LRBT Free Secondary Eye Hospital North Karachi. The exclusion criteria include all patients with past surgical history, heart disease, renal failure and all other eye diseases whereas all the patients were above 18 years of age and included both genders with stitch less cataract extraction surgery. The data of the patients was collected who were admitted for surgery in hospital, history details of demographic and diagnostic were noted through anterior segmental examination. The details regarding intra ocular pressure was also noted. Also took into consideration the results of intraocular lens power and scan unit. From the patients or attendant of the patient an informed consent was also taken. By taking approval from Hospital Ethical Committee ethical consideration was taken in to account.

Statistical analysis:

All the collected information was stored by electronic means and analyzed by using SPSS version 20. To calculate average and standard deviation descriptive figures were applied. For qualitative variables like gender Frequency distribution and percentages were calculated.

RESULTS:

Via hospital record system the records of total 140 patients were collected. The average age of the patients was 54 ± 9 with range 18-60. 25 (31.3%) of the patient were between the ages of 36 years to 45 years. Whereas 15 (18.7%) belong to 18 years to 35 years and 40(50%) were above or equal to 45 years of age. 52(65%) of the patients were male and 28 (35%) were females. More of the patients characteristics were given below in table 1.

Table No 1: The baseline characteristics of HE patients.

Characteristic	n(%)
Number of patients	140
Male to female Ratio	2:01
Mean Age +SD	54±9
Low Socioeconomic Status	60%
Middle Socioeconomic Status	31%
High socioeconomic level	9%
Illiterate	3(3.7%)
Up to matriculation	65(81.3%)
Above Matriculation	12(15%)

The visual activity was measured as zero when it was less than 1/60 to PL+, as one when less than 3/60 to 1/60, as two when less than 6/60 to 3/60, as three when it is Less than 6/18 to 6/60 and four when it is 6/6 to 6/18. Post operatively with repeated visits the uncorrected visual acuity has increased and the maximum of the increase was observed in group 1 patients with 3.5 mm incision. More details are appended below in table number 2.

Table No 2: Summary of BCVA and UCVA

Post op Visits	BCVA		P-value	UCVA		P-value
	Group A	Group B		Group A	Group B	
I	2.34± 1.1	2.72±1.0	0.21	2.4 ± 1.1	2.6 ± 1.0	0.54
II	3.21± 1.2	3.77±0.20	0.3	2.70 ±1.2	3.3 ± 0.45	0.25
III	3.50± 1.13	3.8±.2	0.5	3.26 ± 1.1	3.7 ± 0.42	0.321
IV	4± 0	3.81±.24	0.46	3.20 ± 0.45	3.69 ± 0.46	0.29

* BCVA best corrected visual acuity

** UCVA: Uncorrected visual acuity

The comparative summary of SIA can be observed in the figure 1.

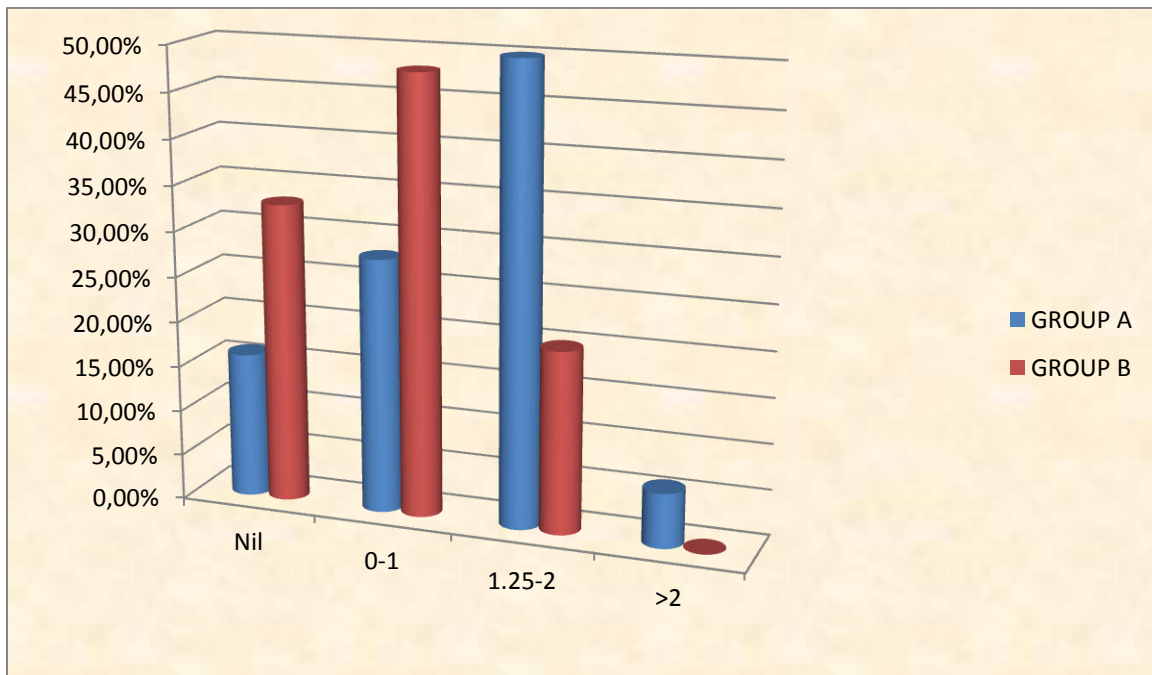


Figure 1: Mean SIA in different incision groups at 4th week postoperatively

DISCUSSION:

To compare the SIA with suture less 3.5mm and 6mm incision surgery (SICS) this study was conducted. It was observed in our study that SIA is less likely to appear in group 1 (incision size 3.5mm that is phacoemulsification cataract surgery). In earlier published studies the visual rehabilitation was observed. The restoration is attributable to less tenderness and low SIA. Patients with fewer complaints were also been observed like redness or foreign body sensation and pain. According to a

study that was conducted by Zawar et al they found that 93.4% of eyes achieved a final BCVA better than 6/12 at 6wk postoperatively. The earlier said achievement was also claimed by few other studies. In this study, Group B has 33% of the patients with no post-operative astigmatic error whereas SIA up to 1D was highly observed in this group. The study of Renderi et al also supports the findings of this study. In this study, maximum patients showed SIA of less than 1D in 3.5 mm incision group. Another research with central 3.5 mm incision has declared SIA of less

than 1D in only 25% patients, with maximum patients had SIA between 1.25D to 2D. The surgical procedure is better than opted in group A as the findings of this study reported the group B with minimum SIA. In this area this study is first of its kind, as work is not much available with a comparative suitable option. The limitations of study may include the less sample size and lack of extended follow up.

CONCLUSION:

It is concluded that SIA is less likely to be occurring in the stitch less 3.5mm surgery. However, 6mm SICS is more cost effective than 3.5mm phacoemulsification cataract surgery because we live in developing country. Moreover, the results were insignificant so we can apply 6mm in future.

REFERENCES:

- Gogate P, Deshpande M, Nirmalan PK. Why do phacoemulsification? Manual small-incision cataract surgery is almost as effective, but less expensive. *Ophthalmology*. 2007; 114(5):965–968.
- Haripriya A, Chang DF, Reena M, Shekhar M. Complication rates of phacoemulsification and manual small-incision cataract surgery at Aravind Eye Hospital. *J Cataract Refract Surg*. 2012;38(8):1360–1369.
- Khanna RC, Kaza S, Subash P, Shantha G, Sangwan VS. Comparative outcomes of manual small incision cataract surgery and phacoemulsification performed by ophthalmology trainees in a tertiary eye care hospital in India: A retrospective cohort design. *BMJ Open*. 2012;2.
- Ravindra MS. Nucleus management in manual small incision cataract surgery by phacosection. *Indian J Ophthalmol*. 2009; 57:41–3.
- Zawar SV, Gogate P. Safety and efficacy of temporal manual small incision cataract surgery in India. *Eur J Ophthalmol*. 2011; 21(6):748–753.
- Tabin G, Chen M, Espandar L. Cataract surgery for the developing world. *Curr Opin Ophthalmol*. 2008; 19(1):55–59.
- Ruit S, Tabin G, Chang D, Bajracharya L, Kline DC, Richheimer W, et al. A prospective randomized clinical trial of phacoemulsification vs manual sutureless small-incision extracapsular cataract surgery in Nepal. *Am J Ophthalmol*. 2007; 143(1):32–38.
- Khanna R, Pujari S, Sangwan V. Cataract surgery in developing countries. *Curr Opin Ophthalmol*. 2011; 22(1):10–14.
- Pershing S, Kumar A. Phacoemulsification versus extra capsular cataract extraction: where do we stand? *Curr Opin Ophthalmol*. 2011;22(1):37–42.
- Ruit S, Tabin G, Chang D, Bajracharya L, Kline DC, Richheimer W, et al. A prospective randomized clinical trial of phacoemulsification vs manual sutureless small-incision extracapsular cataract surgery in Nepal. *Am J Ophthalmol*. 2007; 143:32–8.
- Gogate P, Ambardekar P, Kulkarni S, Deshpande R, Joshi S, Deshpande M. Comparison of endothelial cell loss after cataract surgery: Phacoemulsification versus manual small-incision cataract surgery: Six-week results of a randomized control trial. *J Cataract Refract Surg*. 2010; 36:247–53.
- Gogate P, Deshpande M, Nirmalan PK. Why do phacoemulsification. Manual small-incision cataract surgery is almost as effective, but less expensive? *Ophthalmology*. 2007; 114:965–8.
- Gogate PM, Kulkarni SR, Krishnaiah S, Deshpande RD, Joshi SA, Palimkar A, et al. Safety and efficacy of phacoemulsification compared with manual small-incision cataract surgery by a randomized controlled clinical trial: Six-week results. *Ophthalmology*. 2005; 112:869–74.
- Hepsen IF, Cekiç O, Bayramlar H, Totan Y. Small incision extracapsular cataract surgery with manual phacotrisection. *J Cataract Refract Surg*. 2000;26:1048–51.
- Bayramlar H, Cekiç O, Totan Y. Manual tunnel incision extracapsular cataract extraction using the sandwich technique. *J Cataract Refract Surg*. 1999;25:312–5.
- Gogate PM, Deshpande M, Wormald RP, Deshpande R, Kulkarni SR. Extracapsular cataract surgery compared with manual small incision cataract surgery in community eye care setting in western India: A randomised controlled trial. *Br J Ophthalmol*. 2003;87:667–72.
- Bond BF. The small incision phaco section planned extracapsular manual technique. *Highl Ophthalmol*. 1997;25:15–25.
- Singh P, Singh S, Bhargav G, Singh M. Conjunctival flap in manual sutureless small-incision cataract surgery: A necessity or dogmatic. *Int Ophthalmol*. 2012;32:349–55.
- Gokhale NS, Sawhney S. Reduction in astigmatism in manual small incision cataract surgery through change of incision site. *Indian J Ophthalmol*. 2005;53:201–3.
- Merriam JC, Zheng L, Merriam JE, Zaider M, Lindström B. The effect of incisions for cataract

- on corneal curvature. *Ophthalmology*. 2003;110:1807–13.
21. Yi K, Li Q. Unfolded intraocular lens implantation through a 6 mm sutureless incision. *Yan Ke Xue Bao*. 1999;15:262–4.
 22. Azar DT, Stark WJ, Dodick J, Khoury JM, Vitale S, Enger C, et al. Prospective, randomized vector analysis of astigmatism after three-, one-, and no-suture phacoemulsification. *J Cataract Refract Surg*. 1997;23:1164–73.
 23. Vass C, Menapace R, Rainer G. Corneal topographic changes after frown and straight sclerocorneal incisions. *J Cataract Refract Surg*. 1997;23:913–22.
 24. Sadiq MN, Pai A, Kurup PM. Cataract surgeries by phaco-sandwich technique through sclerocorneal tunnel, a cohort study in Oman. *J Ayub Med Coll Abbottabad*. 2006;18:53–7.
 25. Storr-Paulsen A, Henning V. Long-term astigmatic changes after phacoemulsification with single-stitch, horizontal suture closure. *J Cataract Refract Surg*. 1995;21:429–32.