

## SMALL INCISION CATARACT SURGERY VERSUS PHACOEMULSIFICATION FOR IMMATURE CATARACT: A SINGLE BLIND RANDOMIZED CONTROLLED TRIAL

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**ABSTRACT: BACKGROUND:** Manual small incision cataract surgery (SICS) has given visual results almost equivalent to Phacoemulsification but limited studies are available regarding the efficacy of small incision cataract surgery in phaco suitable immature cataracts. **OBJECTIVE:** To compare manual small incision cataract surgery and Phacoemulsification in immature cataracts. **MATERIALS AND METHODS:** A single blind randomized controlled trial was conducted with 105 eyes each for small incision cataract surgery and Phacoemulsification. **RESULT:** Mean IOL power was similar in both Phacoemulsifications as well as SICS. Four cases of posterior capsular rupture occurred in Phacoemulsification while one case of zonular dialysis occurred in SICS. Uncorrected visual acuity was good (6/6-6/18) in 80.0 % of the phaco and 93.33 % of the SICS group. **CONCLUSION:** SICS surgical technique resulted in significantly better visual acuity on the 1<sup>st</sup> postoperative day in comparison with phaco. Hence, SICS with rigid PMMA IOL implantation being a cheaper, faster and easier technique, may be recommended for immature cataract surgery in the developing countries.

**KEYWORDS:** Phacoemulsification, Small Incision Cataract Surgery

**INTRODUCTION:** An estimated 180 million people worldwide are visually disabled, of whom nearly 45 million are blind, and of which 80% are living in the developing countries.<sup>1</sup> World-wide as well as in developing countries including India the most common cause of blindness is cataract. In India 62.6% of blindness is caused by cataract. Cataract is defined as any opacity in the lens or its capsule, whether developmental or acquired. The word cataract has been derived from the Greek word 'Katarraktes' which means waterfall.<sup>2</sup>

When cataract develops patient complains of blurring of vision, uniocular diplopia, coloured halos, and distortion of image and loss of vision.<sup>3</sup> Once it is confirmed that loss of vision is due to cataract and there are no other co-existing problems in the eye, the patient can be taken for surgery. There has been tremendous improvement in the techniques of cataract surgery. Now-days, Manual small incision cataract surgery (SICS) and Phacoemulsification are the two most important surgical techniques.

Small incision cataract surgery (SICS) was developed in USA and Israel. It became very popular because of its merit over conventional ECCE as well as Phacoemulsification. In this technique, intraocular lens (IOL) implantation is performed through a sutureless self-sealing valvular sclero – corneal tunnel. Phacoemulsification is presently the most popular method of extracapsular cataract extraction (ECCE). In this technique the corneo scleral incision required is very small (3 mm).

Therefore, sutureless surgery is possible with a self-sealing scleral tunnel or clear corneal incision made with a 3 mm keratome.

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But it is costly, instrument dependent and requires skilled surgeon. Initially, manual SICS was considered a poor cousin of Phacoemulsification till a randomized controlled trial demonstrated it to be not only economical but almost as effective as Phacoemulsification.<sup>4,5</sup>

There is a difference of 0.3 - 0.5D of astigmatism between SICS and Phaco but a substantial difference in the cost. Whether a large cataract surgery programme should bear this extra cost for a marginal visual benefit is a matter of question. It is believed that SICS is the appropriate technique for mature cataract and Phacoemulsification is more suitable for immature cataract. Moreover, some cataracts such as grossly subluxated lenses, very hard cataracts or those with poor endothelial counts are better removed through small incision cataract surgery.<sup>6</sup>

Several studies have shown similar visual outcome following these two surgical techniques. But none of these studies have compared these two surgical techniques among the phaco suitable immature cataracts. Hence the present RCT was conducted to compare the efficacy of SICS with Phaco among phaco-suitable immature cataracts in a developing country.

**METHODS:** A single blind randomized controlled trial was conducted in the Department of Ophthalmology, Agartala Government Medical College (AGMC) during 1<sup>st</sup> October 2013 to February 2014 among 210 patients having immature senile cataract. Adequate sample size required for the study was calculated to be 210 considering 1:1 randomization, 80% power ( $z_{(1-\beta)} = 0.8416$ ), 5% level of significance ( $z_{(1-\alpha/2)} = 1.96$ ) and an ability to detect a difference of 20% or more uncorrected visual acuity between the two groups on the 1<sup>st</sup> postoperative day.

The patients were randomly allocated into two groups: Group A for Phacoemulsification and group B for SICS. Primary outcome measure was uncorrected visual acuity on the 1<sup>st</sup> postoperative day. The allocation was decided by a senior resident one day prior to the surgery. He randomly picked up envelopes containing written type of surgery to be done on the next patient. These envelopes contained pre sequenced allocations regarding the type of surgery using randomization in blocks of 4 and were kept in the operating room.

Surgeon was blinded of the randomization sequence. Patients were informed about the method of surgery but the ophthalmic assistants and nurses, who tested and recorded the postoperative visual acuity, were blinded about the surgery undertaken. Prior permission for conducting the study was obtained from the competent authority of the institute and informed written consent was obtained from each of the study participants.

Immature cataract was defined as nuclear sclerosis up to 2+, cortical cataract 2+ and posterior sub capsular cataract of any grade. All other types of cataracts were excluded from this study. Informed consent was obtained from all the patients before enrolling them in the study. All were properly examined with slit lamp biomicroscopy, tonometry, syringing, fundus examination with 90D. IOL power was calculated with A-scan biometry. Random blood sugar, ECG and physician check-up was undertaken in all the cases.

Topical tropicamide 1% and non-steroidal anti-inflammatory eye drops was instilled every 15 minutes for 1 hour before surgery. All patients were operated under peri-bulbar anesthesia. All the surgeries were performed with temporal approach. The group A patients were operated by Phacoemulsification with phaco chop technique. The PMMA IOL with 5 mm optic was implanted after enlarging the incision to 5 mm. The group B patients were operated by SICS with fish hook technique.

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In group A four patients had posterior capsular rupture and were managed by implanting PMMA IOL in the sulcus. All patients were given subconjunctival injection of Gentamicin-Dexamethasone.

The surgical time was measured starting from the making of sclerocorneal incision till pushing the subconjunctival Gentamicin - Dexamethasone injection. Surgical time and intraoperative complications were recorded. Postoperative complications, postoperative UCVA, and surgically induced astigmatism were calculated on the first postoperative day.

**RESULT:** Out of 210 patients, 105 were operated with Phacoemulsification and another 105 with Manual Small Incision Cataract Surgery. Data were analyzed using intention to treat analysis.

Table 1: Baseline characteristics of the study subjects			
Variables	Group A (Phaco)	Group B (SICS)	P - value
Age, mean (SD)	57 (8.21)	58 (6.41)	0.3264
Gender	Male	66 (51.56)	0.6713
	Female	39 (47.56)	
Visual acuity	6/18 - 6/60	27 (45.76)	0.5391
	< 6/60 – FC	78 (51.65)	

Table 1: Shows that both the study and control groups were identical in terms of age, gender and preoperative visual acuity.

The mean IOL power was almost similar in both the groups. In group 'A' it was  $21.02 \pm 1.31$  D and in group 'B' it was  $21.2 \pm 1.8$  D. In group A, four patients had posterior capsular rupture in which PMMA IOL was implanted in sulcus with care. One of them had posterior vitreous loss, which was managed by anterior vitrectomy and PMMA IOL in the sulcus. One of them also had posterior capsular rupture with nucleus drop, which was referred to vitreoretinal surgeon and was managed by removal of nucleus and PMMA IOL implantation in the sulcus.

In group B, one patient had zonular dialysis during dialing of the nucleus. In group A, 89.5% and in group B, 14.2% cases took surgical time more than 6 minutes. On the 1<sup>st</sup> postoperative day, eye pad was removed at 7 a.m. and eye was examined under slit lamp. On postoperative day 1, three patients in group A and four in group 2 had corneal edema. One patient had increased anterior chamber reaction in both the groups. Uncorrected visual acuity was measured.

Table 2: Uncorrected visual acuity on the 1 <sup>st</sup> postoperative day				
Groups	Good (6/6 - 6/18)	Borderline (6/24-6/60)	Poor (< 6/60)	P-value
A (Phaco)	84 (80.0)	18 (17.14)	08 (2.86)	0.0020
B (SICS)	98 (93.33)	6 (5.71)	01 (0.6)	

Table 2: shows that in Phaco group 84 (80.0%) and in SICS group 98 (93.33%) of the patients had good (6/6-6/18) postoperative visual acuity and it was statistically significant ( $p = 0.0020$ ).

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**DISCUSSION:** Most of the patients included in this study had travelled long distance from remote areas of Tripura. It is our common observations that though we advise our patients for review, most of the patients who have good vision do not come for follow up. Due to this, long term follow up outcome could not be evaluated in this study. Operated patients were advised to apply antibiotics and steroid eye drops regularly on tapering regime for six weeks.

In our study we tried to compare Phacoemulsification and SICS for immature cataracts. Phacoemulsification was in group A and SICS was in group B. Mean intraocular power was similar in both groups. During the operation in phaco group, 4 patients complicated with posterior capsular rupture with vitreous loss in one case and nucleus drop in another case. In SICS group, only one patient had zonular dialysis.

Hence, complications during operation were more in phaco group than SICS group. Mean surgical time was more in phaco group than in SICS group. Mean surgery time of more than 6 minutes was observed in 89.5% of patients in group A and 14.2% of patients in group B. So, SICS require shorter surgical time. On postoperative day 1, corneal edema was present in 3 patients in group A and 4 patients in group B. Anterior chamber reaction was present in one patient in both groups.

On the basis of early postoperative complications, Phacoemulsification and SICS, both have similar complications. UCVA was good (6/6-6/18) in nearly three quarters of patients in both groups. So, SICS had given visual results better than Phacoemulsification. Phacoemulsification has long learning curve, requires expensive equipment's, has a high consumable cost and needs expensive foldable lenses to maximize the benefit associated with the small incision.<sup>7</sup>

Despite these facts, there is a growing demand for phaco surgery in developing world and many patients are willing to pay for it. To meet the demand and to make it affordable to people of all socioeconomic levels, Phacoemulsification is being performed with implantation of foldable and rigid IOLs as well in developing countries.

**CONCLUSION:** SICS surgical technique resulted in significantly better visual outcome on the 1<sup>st</sup> post-operative day in comparison with phaco. Hence, SICS with rigid PMMA IOL implantation being a cheaper, faster and easier technique, may be recommended for immature cataract surgery in the developing countries.

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