

Extent of multifocality with corneal manipulation in manual small incision cataract surgery with monofocal posterior chamber intraocular lens implantation

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Purpose: To compare the visual outcome in terms of multifocality in Manual Small Incision Cataract Surgery (MSICS) with and without intraoperative manipulation of corneal curvature. **Methods:** This was a prospective study on 80 subjects (80 eyes) who underwent MSICS with monofocal posterior chamber intraocular lens (PCIOL) implantation between January 2018 and October 2019. Intraoperative manipulation of corneal curvature using viscoelastics was performed during MSICS in 40 subjects (cases) while this intraoperative manipulation was not performed in the remaining 40 subjects (controls). Uncorrected distance visual acuity (UDVA) and uncorrected near visual acuity (UNVA) were compared at day 1, 7, 30 and 180 postoperatively. **Results:** At 1 month and 6 months of follow up, UDVA was comparable in the 2 groups. UNVA was better in cases than controls at 1 month and 6 months ($P < 0.001$). At 6 months of follow up, 76% of cases with UDVA of 6/9 or better had UNVA of N8 while only 15% of controls with UDVA of 6/9 or better had UNVA of N8 ($P < 0.001$). Mean near add requirement to achieve a best corrected near vision (BCNV) of N6 at 6 months was significantly lesser ($P = 0.002$) in cases (+2.05 D) compared to controls (+2.43 D). **Conclusion:** MSICS with intra operative manipulation of corneal curvature resulted in better unaided near visual acuity compared to that without intra operative manipulation of corneal curvature, without compromising unaided distant visual acuity.

Key words: MSICS, monofocal PCIOL, multifocality, corneal stretching

Nowadays cataract surgery aims at restoring good vision without requiring refractive correction. Monofocal IOLs provide excellent distant vision^[1] but fail to provide desired near vision.^[2]

Currently, multifocal IOLs provide good distant, intermediate, and near vision.^[3,4] However, the optical side effects reported with multifocal IOLs limit their routine usage.^[5-10] Refractive corneal surgeries like conductive keratoplasty create multifocal corneal effects, yielding good distant and near vision in presbyopic subjects.^[11,12] Hence, there is need to see if the use of monofocal IOLs along with the principles of refractive corneal surgery, properties of corneal biomechanics,^[13] and Gauss's law of physics by stretching the cornea horizontally in cataract surgery enables multifocality.

Manual small-incision cataract surgery (MSICS) is known to provide good postoperative vision and has emerged as a cost-effective technique of cataract surgery. MSICS can be combined with the technique of stretching the peripheral cornea and using Gaussian curvature theory^[14] of alteration of vector forces in a nearly closed chamber to create multifocality.

This study was undertaken to compare the multifocality (visual outcomes for distance and near) in two groups of patients undergoing MSICS—one with the proposed technique

of corneal manipulation and the other without corneal manipulation.

Methods

This was a prospective, randomized comparative interventional study conducted on patients undergoing MSICS between January 2018 and October 2019 in a tertiary care hospital attached to the medical college. All patients provided written informed consent and the study was conducted in accordance with the Declaration of Helsinki.

Inclusion and exclusion criteria

Eligible patients with senile cortical cataract and nuclear opacity of grade 1 to grade 3 (LOCS III) during the study period were included in the study. Patients with age less than 45 years, pseudoexfoliation syndrome, grade 4 and 5 nuclear opacity (LOCS III), astigmatism more than 2.5D by keratometry, retinal pathologies, and patients who were one eyed were excluded.

Preoperatively, all the study subjects underwent visual acuity testing, refraction, slit lamp examination, fundus examination with direct and indirect ophthalmoscope, IOP measurement, lacrimal sac syringing, keratometry, ultrasound

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biometry, gonioscopy in relevant cases, and IOL power calculation using SRK T formula.

Sample size

A total of 80 patients were enrolled and categorized as follows: 40 patients as cases who underwent MSICS with intraoperative manipulation of corneal curvature and 40 patients as controls who underwent only MSICS without intraoperative manipulation of corneal curvature.

Before commencing the study, a pilot study was conducted to evaluate the visual outcomes for both distant and near in a similar set. Based on the difference seen in visual outcome between the cases and controls in the pilot study, a difference of 40% was taken as the effect size, and calculation of sample size was done as follows:

$$n = \frac{\left\{ z_1 \sqrt{2P(1-P)} + z_2 \sqrt{[P_1(1-P_1) + P_2(1-P_2)]} \right\}^2}{(P_1 - P_2)^2}$$

The following parameters were considered for estimating the sample size:

1. The level of significance " α " (P value) considered was 5% (i.e. $P \leq 0.05$)
2. Power of the study " $1 - \beta$ " considered was 90%
3. $P_1 = 70\%$, $P_2 = 30\%$
4. Expected difference in the proportion of improvement in visual outcome was $P_1 - P_2 = 40\%$.

For an " α " value of 5%, the two-tailed Z_α value was 1.96 and for power of 90% ($1 - \beta$) Z_β value was -1.28.

Submitting these values in the above formula, the sample size obtained was $N = 37$.

Accounting for the loss to follow-up, 40 subjects were enrolled in each group.

Surgical technique

Sub-Tenon's anesthesia [Video 1] was used as it allowed movements of eye to facilitate intraoperative keratoscopy. The block consisted of 1.5 ml mixture of 2% lignocaine with adrenaline (adrenaline avoided in hypertensives) and 0.5% bupivacaine with hyaluronidase 10 units per ml.

Operative procedure in cases

All surgeries were performed by a single surgeon (Dr. PB).

Following a thorough wash of conjunctival cul de sac with saline, the shape of the mires on cornea was assessed through a hand-held keratoscope. Superior frown-shaped scleral incision, 6 mm in size and 1.5 mm away from limbus, was made. The size of the incision was prefixed for all 40 cases and a marker was used to ensure the correct size of the incision. A sclerocorneal tunnel was made using a crescent blade. A 2-mm sized entry was made in the inner lip of the sclerocorneal tunnel using a 2.8-mm sized keratome. Trypan blue was used to stain the anterior capsule. An anterior chamber was formed with a viscoelastic substance (hydroxypropyl methyl cellulose 2%). The same viscoelastic substance was injected using specially made 25-gauge metal cannula (with two apertures with one aperture of metal cannula along the bore and another aperture facing toward the cornea) into the periphery of the anterior chamber to stretch the horizontal meridian of the cornea at the 3 and 9 o'clock position

As a result of stretching of cornea, the appearance of horizontally oval mires was noted through the hand-held keratoscope intraoperatively. Continuous curvilinear capsulorhexis of 5.5 to 6 mm size was made using a 26-gauge cystitome. The main port entry in the inner lip of sclerocorneal tunnel was extended using the keratome. Rest of the procedure was that of the routine MSICS with hydrodissection followed by nucleus delivery using irrigated vectis. Simcoe's cannula was used to aspirate cortical matter and also as an AC maintainer while implanting IOL. Subconjunctival injection of gentamycin and dexamethasone were performed.

Controls underwent the same procedure detailed as above except for the intraoperative corneal stretching. Mires were assessed intraoperatively before incision, after incision, and at the end of procedure.

Postoperative examination

Follow up examinations were performed on day 1, 7, and 30 and 6 months after surgery. At each visit, refraction was done along with the assessment of distant and near visual acuity using Snellen chart. Keratometry was also performed during each postoperative visit.

Outcome measures

Primary outcome measures were UDVA (uncorrected distant visual acuity) and UNVA (uncorrected near visual acuity).

Statistical analysis

Data was entered into Microsoft excel and was analyzed using IBM SPSS version 22. Continuous variables were described using mean and standard deviation and categorical variables were described as proportions. Appropriate statistical tests were used to compare the outcome measures between the two groups. A P value < 0.05 was considered statistically significant. Surgically induced astigmatism (SIA) was calculated using an SIA calculator v 2.1.

Results

The mean age of the patients was similar between the two study groups. A UDVA of 6/18 or better was seen in 77.5% and 87.5% of patients in cases and controls, respectively, at 1 month of follow up. This was statistically comparable. A UDVA of 6/18 or better was seen in 97.5% of cases and 100% of controls at 6 months of follow up with no statistically significant difference [Fig. 1]. At 6 months of follow up, an UDVA of 6/9 or better was seen in 53% of cases and 32% of controls.

An UNVA of N8 or better was seen in 65% of cases and 20% of controls at 1 month of follow up. This was statistically significantly greater ($p < 0.001$) in the cases compared to controls. At 6 months of follow up, 75% of cases had an UNVA of N8 or better as compared to only 17.5% of controls ($p < 0.001$) [Fig. 2].

Comparison of UDVA and UNVA

A total of 72% of cases with UDVA of 6/18 or better had a UNVA of N8 whereas 70% of the controls with a UDVA of 6/18 or better had a UNVA of N10 at 6 months of follow up. A total of 76% of cases with a UDVA of 6/9 or better had a UNVA of N8 while only 15% of controls with a UDVA of 6/9 or better had a UNVA of N8 at 6 months of follow up ($p < 0.001$).

Refraction

The median cylinder required in cases at 1 month follow up was -1D (range: -1.44 to -0.75) as compared to -1.25D (range:

-1.50 to - 0.88) in controls, which was statistically not significant. The median cylinder required in cases at 6 months follow up was - 0.50 D (range: -1 to - 0.50) as compared to - 1D (range: -1 to - 0.50) in controls, which was statistically significant (p = 0.026).

Near add required

At 1 month of follow up, cases and controls requiring mean near add to achieve best-corrected near visual acuity of N6 were +2.23D and +2.55 D, respectively (p < 0.001). At 6 months of follow up, cases and controls requiring mean near add to

achieve best-corrected near visual acuity of N6 were +2.05 D and +2.43D, respectively (p = 0.002) [Table 1].

Surgically induced astigmatism (SIA)

The mean SIA at 1 month in cases and controls was 1.09D and 1.06 D, respectively, and the mean SIA at 6 months in cases and controls was 1.13D and 1.06D, respectively, with no statistically significant difference.

Mires through intraoperative hand-held keratoscope

In the cases, 68% had horizontally oval mires after stretching and 47.5% had horizontally oval mires at the end of procedure. This was responsible for good uncorrected near visual acuity in cases [Fig. 3]. In the controls, 83% had vertically oval mires after incision and 63% had vertically oval mires at the end of procedure [Fig. 3].

Intraoperative mires noted at the end of procedure was correlated with postoperative UNVA at 6 months of follow up. Among 30 cases with a UNVA of N8 or better, 56.67% had horizontal mires and 40% had circular mires. Among 33 controls with a UNVA of N10 or worse, 66.67% had vertically oval mires [Table 2].

Discussion

The present study found that MSICS with intraoperative manipulation of corneal curvature had better unaided near-visual acuity when compared to that without intraoperative manipulation of corneal curvature. The exact principle behind the multifocality following the method of intraoperative manipulation of corneal curvature is not known, but the possible hypothesis could be the following. According to Gauss’s law of elastic domes, for every change in the curvature of one meridian, there is an equal and opposite change 90 degrees away.^[15] The horizontal meridian of cornea is stretched intraoperatively using viscoelastics before extending the inner lip of the sclerocorneal tunnel which leads to the steepening of the vertical meridian of cornea.

When incision is made on this steepened vertical meridian, the upper half of the vertical meridian flattens while the lower half of the vertical meridian remains steep providing multifocality. To check for the steepening of the vertical meridian of cornea before and after the stretching of horizontal meridian using viscoelastics, a hand-held keratoscope was used intraoperatively. The end point of horizontal meridian stretching was achieved when the horizontally oval mires or at least circular mires were seen through the keratoscope.

In the present study, a UDVA of 6/18 or better was seen in 77.5% and 87.5% in cases and controls at 1 month, respectively. In a previous study by Gogate *et al.*, a UDVA of 6/18 or better at postoperative 6 weeks was seen in 71.1% of individuals.^[16]

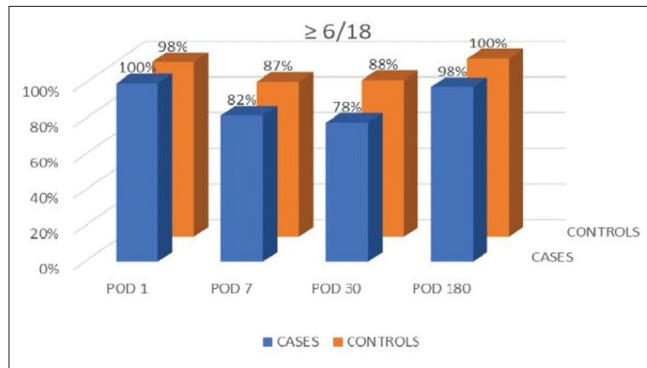


Figure 1: Comparison of UDVA ≥ 6/18 at postoperative day 1, 7, 1 month, and 6 months between cases and controls (N = 80)

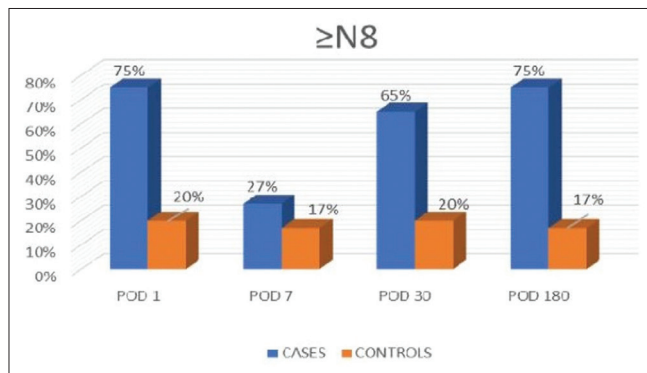


Figure 2: Comparison of UNVA ≥ N8 at postoperative day 1, 7, 1 month, and 6 months between cases and controls (N = 80). Others – circular and oblique mires

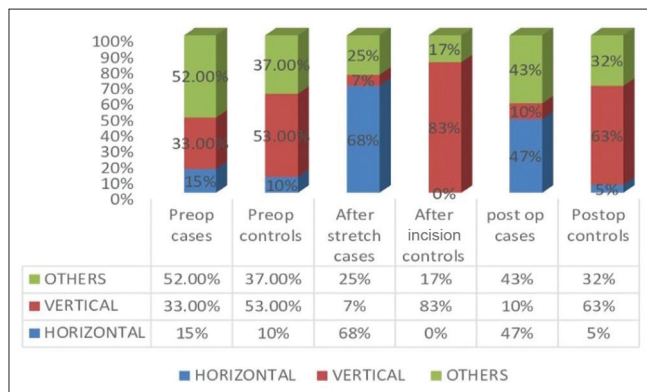


Figure 3: Cluster bar chart showing the comparison of preop mires, mires after stretch, and postop mires in cases and controls

Table 1: Comparison of the near add at different follow up periods between two groups (n=80)

Postoperative	Cases (n=40)	Controls (n=40)	P
Day1	1.95±0.71	2.5±0.52	<0.001
Day7	2.49±0.56	2.58±0.56	0.487
Month 1	2.23±0.34	2.55±0.38	<0.001
Month 6	2.05±0.55	2.43±0.47	0.002

All values represent mean±standard deviation

Table 2: Comparison of post-operative mires in cases and controls at 6 months after surgery according to the UNVA criteria

Postoperative mires	Cases (n=40)		Chi square	P	Controls (n=40)		Chi square	P
	≥N8 (n=30)	≤N10 (n=10)			≥N8 (n=7)	≤N10 (n=33)		
Horizontal	17 (56.67%)	2 (20%)	7.633	0.022	0 (0%)	2 (6.06%)	**	**
Vertical	1 (3.33%)	3 (30%)			3 (42.8%)	22 (66.67%)		
Others	12 (40%)	5 (50%)			4 (57.1%)	9 (27.27%)		

**No statistical test was performed due to 0 subjects in one of the cell. Others -circular and oblique

Another study by Venkatesh *et al.* reported a UDVA of 6/18 or better at 6 weeks in 82% of subjects and these results were comparable to our study.^[17]

In the present study, a UDVA of 6/18 or better was seen in 97.5% of cases and 100% of controls at 6 months. This is similar to a previous study by Ruit *et al.* which reported a UDVA at 6 months of 6/18 or better in 89% of subjects who underwent MSICS.^[18]

In the present study, a UNVA of N8 or better was seen in 65% of cases and 20% of controls at 1 month and in 75% of cases and 17.5% of controls at 6 months of follow up.

In the present study, there were no intraoperative and postoperative complications noticed in either of the groups upto 6 months of follow up. This implies that intraoperative manipulation of cornea, that is stretching of the horizontal meridian of cornea with a viscoelastic substance, is unlikely to have any adverse effects.

Mild intraoperative iris floppiness was noted during surgery after the stretching of cornea using viscoelastics in most of the cases. However, this did not cause any adverse effects on the postoperative outcome.

One of the limitations of our study was the exclusion of hard cataracts (grade 4 and 5 nuclear opacity). This was done in order to avoid any untoward effect on zonules while stretching cornea using viscoelastics. Therefore, caution has to be exercised when extrapolating the results of the current study to surgery in hard cataracts.

Conclusion

MSICS with intraoperative manipulation of corneal curvature had better unaided near-visual acuity compared to that without intraoperative manipulation of corneal curvature, without compromising unaided distant visual acuity.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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