

Original article

A Study of efficacy, safety and visual outcome of Toric implantable Collamer Lens implantation for patients with Myopic Astigmatism

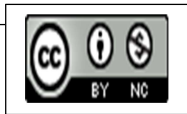
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ABSTRACT

In this study was investigate that the Study of efficacy, safety and visual outcome of Toric implantable Collamer Lens implantation for patients with Myopic Astigmatism. In astigmatism, refraction varies in different meridians; consequently, the rays of light entering the eye cannot converge to a point focus but form focal lines. It was a prospective study in which patients suffering from myopic astigmatism were treated by using toric implantable collamer lens (ICL) was enrolled. Fifty eyes of 23 patients with myopic astigmatism underwent toric ICL Implantation. Pre and post operatively spherical equivalent, UCVA, BCVA, IOP, topography, astigmatism, corneal thickness, keratometry, posterior segment examination & anterior chamber depth were recorded for all patients. Toric implantable collamer lens implantation was performed for all patients. Mean pre-operative best corrected visual acuity was 6/9 (0.65 +/- 0.22 in decimals) was compared with mean post operative best corrected visual acuity at 6 months which was 6/6 (0.96 +/-0.11 in decimals). The difference in the value was found to be statistically significant. In conclusion, the results of the current study suggest that the toric ICL performs well in correcting myopic astigmatism and also suggest that toric ICL implantation may become a viable alternative to corneal refractive procedures.

Key Words: Myopic Astigmatism, Collamer lens, pre and post operative

Introduction

In astigmatism, refraction varies in different meridians; consequently, the rays of light entering the eye cannot converge to a point focus but form focal lines. Astigmatism can be classified into two types. They are regular and irregular astigmatism [1]. In regular astigmatism, which was first described by Donders in 1864, the meridians of the greatest and least curvatures are at right angles, and the refractive power differs uniformly from one meridian to another. Regular astigmatism may be corneal, due to abnormality of the corneal curvature, or lenticular, due to lenticonus or subluxation of the lens. Depending on the axis, regular astigmatism may be 'with the rule', in which the two principle meridians occur at right angles to one another and the vertical meridian is more curved than the horizontal, 'against the rule', in which the two principle meridians occur at right angles to one another and the horizontal meridian is more curved than the vertical meridian, and oblique, in which the two principle meridians are not horizontal or vertical although they are at right angles to each other [2].

Regular astigmatism may also be simple, in which the rays are focussed on the retina in one meridian and either anterior or posterior to the the retina in the other meridian (for example, simple myopia or simple hypermetropia), compound, in which the rays of light in both meridians are focussed either anterior to or posterior to the retina (for example, compound myopia or compound hypermetropia), or mixed, in which the light rays in one meridian are

focussed anterior to, and in the other meridian posterior to, the retina (here, the eye is myopic in one meridian and hypermetropic in the other) [3].

Irregular astigmatism is characterized by an irregular change of refractive power in different meridians, and there are multiple meridians.

With reference to the frequency of occurrence of astigmatism, it is important to remember that almost all individuals have a minor degree of physiological astigmatism, astigmatism exhibits no gender specificity (occurs equally both in males and females), about 60% of refractive errors have astigmatism and the most common type of astigmatism is compound myopic astigmatism.

Myopic astigmatism is a common refractive error characterized by a combination of nearsightedness and irregular curvature of the cornea or lens, resulting in blurred and distorted vision. Traditional corrective methods such as spectacles and contact lenses are effective but may not be ideal for all patients, particularly those seeking permanent correction or those intolerant to external aids [4]. Refractive surgery, including laser-assisted procedures like LASIK, offers another alternative; however, limitations exist for individuals with high refractive errors, thin corneas, or dry eye symptoms [5].

The Toric Implantable Collamer Lens (TICL) has emerged as an advanced surgical option designed to address both myopia and astigmatism simultaneously. Unlike corneal refractive procedures, the TICL is placed behind the iris and in front of the natural lens, preserving corneal structure and biomechanical stability (Sanders et al., 2007). Its unique collamer material offers excellent biocompatibility and optical quality, contributing to improved postoperative outcomes.

Several studies have demonstrated the efficacy, safety, and predictability of TICL implantation for correcting moderate to high myopic astigmatism [6]. Visual outcomes such as uncorrected distance visual acuity (UDVA), best corrected distance visual acuity (CDVA), and refractive stability have been consistently favorable, with high patient satisfaction rates reported. Nevertheless, long-term studies and continued evaluation of potential complications such as cataract formation, intraocular pressure elevation, and rotational stability are essential to ensure optimal patient care [7].

Materials and Methods

This study was done at Cornea Clinic of Institute of Ophthalmology, Joseph Eye Hospital, Trichy between April 2012 and May 2013. It was a prospective study in which patients suffering from myopic astigmatism were treated by using toric implantable collamer lens (ICL) was enrolled. As per the inclusion and exclusion criteria in our study, we included fifty eyes of twenty nine patients. This study was approved by the Institutional Ethics Committee.

A standard protocol was used to collect and document all the details regarding the cases included in the study. Detailed information about history, complaints, occupation of the patient was taken. This included type of visual problem, duration of symptoms, duration of wearing glasses/contact lens, frequency of changing glasses, any prior corneal surgery, trauma, any prolonged use of topical medications and any history of systemic disease.

A complete ocular examination was done for each patient which included UCVA- uncorrected visual acuity, BCVA, corneal topography, slit lamp examination, cycloplegic refraction, ultrasound pachymetry. pupillary size, non contact tonometry, white to white measurement of cornea, slit lamp biomicroscopy with +90D, indirect ophthalmoscopy.

Results

Demography of patients

Age distribution:

The age of patients included in this study ranged between 18-40 years. There were 29 patients in the range of 18-25 years age, 16 patients ranged between 26-30 years age, five patients in the range of 31-40 years age. The average age in the study was 25.8 years. Most patients were in the range of 18-25 yrs age (Tab-1).

Table 1. Patients' age distribution with myopic astigmatism undergoing toric implantable collamer lens implantation at a tertiary eye care hospital.

AGE GROUP	NO. OF EYES
18-25 YRS	29
26-30 YRS	16
31-40 YRS	5

Gender Distribution

Of the 50 patients enrolled in the study, 31 were males and 19 were females (Tab-2). There were 20 males & nine females were in the range of 18-25 years, 6 males and 10 females were in the range of 26-30 years age and 5 males in the range of 30-40 years age group.

Table 2. Gender distribution of patients with myopic astigmatism undergoing toric implantable collamer lens implantation at a tertiary eye care hospital.

GENDER	NO. OF EYES
Male	31
Female	19

3. Laterality of Eyes:

Twenty one patients underwent toric ICL implantation in both eyes; one patient underwent toric ICL implantation in right eye alone and seven patients underwent toric ICL implantation in the left eye alone. (Table-3)

Table 3. Laterality of eyes with myopic astigmatism undergoing toric implantable collamer lens implantation at a tertiary eye care hospital.

LATERALITY	NO.OF EYES
RT eye	1
LT eye	7
Both eyes	21

4. Pre-Operative Uncorrected Visual Acuity

In this study, all patients had pre-operative uncorrected visual acuity(UCVA) uncorrected between 6/36 and 2/60. Twelve patients had pre-operative visual acuity between 6/36 and 6/60, 36 patients had UCVA ranged between 5/60 and 3/60 before surgery and two patients had pre- operative UCVA less than 3/60. The mean UCVA before surgery was about 5/60 (0.078+/-0.02 in decimals)

5. Post-Operative Uncorrected Visual Acuity

Post operative uncorrected visual acuity at 1st week ranged between 6/60 and 6/6 with a mean of 6/6 P(0.82+/-0.24 in decimals), the difference between mean pre-operative UCVA and mean post- operative UCVA at 1 week was found to be significant statistically such that $p < 0.001$ by paired 't' test.

Post-operative uncorrected visual acuity at 1st month ranged between 6/18 and 6/6 with a mean of 6/6 P(0.84+/-0.20 in decimals); the difference between mean pre-operative UCVA and mean post-operative UCVA by paired 't' test was found to be statistically significant such that p value less than 0.001 at 1 month.

Post-operative uncorrected visual acuity at 3 months ranged between 6/18 and 6/6 with a mean of 6/6 (0.90 \pm 0.19 in decimals); the difference between mean pre-operative UCVA and mean post-operative UCVA were compared at 3 months by paired 't' test and it shows that $p < 0.001$ which was significant statistically.

Post-operative uncorrected visual acuity at 6 months ranged between 6/18 and 6/6 with a mean of 6/6 (0.9 \pm 0.18 in decimals); the difference between mean pre-operative UCVA and mean post-operative UCVA at 6 months was found to be significant statistically and p value is less than 0.001 by paired 't' test (Tab-4).

Table 4: Pre-operative and post-operative mean uncorrected visual acuity in patients with myopic astigmatism undergoing toric implantable collamer lens implantation at a tertiary eye care hospital.

Time of Examination	Mean UCVA +/- SD	Statistical Analysis (paired t' test')
Pre-operative	0.0788 \pm 0.02	---
1 week Post op	0.8192 \pm 0.24	$t = 21.64^{\wedge} *$; $p < 0.0001$
1 month Post op	0.843 \pm 0.20	$t = 25.83^{**}$ $p < 0.0001$
3 months Post op	0.9014 \pm 0.19	$t = 29.15^{\wedge} ***$ $p < 0.0001$
6 months Post op	0.9074 \pm 0.18	$t = 31.50^{\wedge} ****$; $p < 0.0001$
Abbreviation: Post op = Post-operative; UCVA Uncorrected Visual acuity; d.f.=degree of freedom. *Mean Pre-operative versus mean post-operative (1 week) UCVA **Mean Pre-operative versus mean post-operative (1 month) UCVA ***Mean Pre-operative versus mean post-operative (3 months) UCVA ****Mean Pre-operative versus mean post-operative (6 months) UCVA		

Discussion

Overall, many reports [8, 9] have shown excellent outcome in regards to the efficacy, safety, predictability and visual outcome in correcting myopic astigmatism. In the current study, the stability of vision was maintained throughout the six months follow up in all patients. In current study, the pre operative mean UCVA of 5/60 (0.778 in decimals) was found to have improved to 6/6p (0.9074 in decimals) post operatively at 6 months (Table-4). Similar study was done by Shimizu et al., 2016⁶, which included one hundred and twelve patients with myopia between - 2.75 and - 19.50D and astigmatism of -2 to -4 D with toric ICL implantation. The mean preoperative UCVA improved from 0.01 \pm 0.04 to 0.75 \pm 0.22 and the mean pre operative spherical equivalent reduced from -10.56D to 1.25D.

Similarly, [10] evaluated the 3-year clinical outcomes after toric implantable collamer lens implantation for the management of moderate to high myopic astigmatism in 34 eyes of 20 patients. Improvement in UCVA, manifest spherical and cylindrical refraction was observed at one week, and remained stable even after three years. The spherical equivalent was within ± 0.50 D. There was no complications post-operatively and all patients had good visual outcome at all visits.

Studied among patients of myopic astigmatism on 56 eyes of thirty two persons. In this study, the mean spherical equivalent ranged between -4D and -17.25D. The astigmatism ranged between -0.75D and -4 diopters [12]

All the patients were preceded with toric implantable collamer lens implantation. The mean astigmatism was reduced to -0.35D. Improvement in UCVA, manifest spherical and cylindrical refraction was observed at one week and remained stable after 3 years, studied 77 eyes with moderate to high myopic astigmatism who underwent implantation with toric implantable collamer lenses. At 12 months, mean astigmatism was found to have decreased to -0.44 D from -2.38 (before surgery). Almost 99% of the eyes had post-operative better best corrected V/A when compared to pre-operative best corrected V/A. There were no vision-threatening complications [11].

Studied among 43 eyes of twenty three persons with toric ICL implantation in the treatment of myopic astigmatism. Pre-operatively the spherical equivalent (mean) was -4.9D. The pre-operative astigmatism (mean) was -2.62 [14].

After one year he found out that pre-operative mean UCVA was improved from -0.87 (in decimals) to -0.94 post-operatively. He also found out that spherical equivalent was drastically reduced post-operatively when compared to pre-operative spherical equivalent. 98% of patients were within +/-1 diopter of spherical equivalent. He also showed that use of toric ICL implantation to correct myopic astigmatism was excellent and it is highly safe, effective and had good predictability. There was no significant post-operative complications noted over 1 year of follow up period.

Reviewed the evaluation of visual outcome and safety of PIOL implantation and LASIK in the treatment of myopic astigmatism. He concluded that PIOL had better visual outcome than LASIK and PRK (photorefractive keratectomy). The posterior chamber ICLs resulted in better UCVA post-operatively when compared with LASIK and PRK. He also found that PIOL had lower risk of retinal detachment than any other surgeries. They also concluded that there was no post-operative complications [15].

In 3 years, [16] studied 361 eyes, of which 178 eyes received toric ICL implantation while the remaining 183 eyes received LASIK for myopic astigmatism. These authors reported that after implantation, BCVA improved from 20/40 to 20/25; hence, the authors showed that toric implantable collamer lens implantation had better visual outcome and were safe. They also concluded that ICL placement is highly predictable for treatment of myopic astigmatism.

Conducted a study of toric ICL implantation among 10 persons for the treatment of myopic astigmatism. In this study patients had a pre-operative spherical equivalent with a mean of -12.1D, the pre-operative mean astigmatism was 3.00 diopters. Three eyes had vision of 6/6 with no refractive correction [17]. More than 70% of patients had aa vision (UCVA) of 6/6. All patients had reduced cylindrical value post-operatively. In this study the efficacy was good in all cases. The author finally concluded that toric ICL implantation was safe procedure in treating refractive errors.

Evaluated the safety, efficacy, predictability, stability and complications after implantation of toric phakic IOLs for the treatment with PIOLs for myopic astigmatism among seventy eyes of fifty three persons. Pre-operatively the patients had a mean spherical component of -8.90 +/- 4.52 D and cylinder between -1.50 and -7.25 D.

These authors also found that post-operatively, 46 eyes gained 1 or more lines when compared to the preoperative BCVA. There was a significant reduction in spherical errors and astigmatism in all cases. All eyes were within +/- 1.00D of astigmatism. No serious complications were observed and the refractive error was stable at 6 months after surgery.

A study with comparing the visual outcomes and safety profile after toric ICL implantation and with implantation of iris fixated toric PIOLs. Thirty eyes underwent toric ICL procedure and thirty one eyes underwent iris fixated toric PIOL. The author measured uncorrected visual acuity and best corrected visual acuity pre-operatively and post-operatively at 1, 3 and 6 months [18].

He noted that post-operatively after 6 months the astigmatism correction was good in toric ICL group. And there was a significant difference of astigmatism in the two groups, such that better in toric ICL group than in iris fixated toric PIOL. Post operatively, the vision was stable over a period and there was no complications in the toric ICL group.

The author concluded that the toric ICL. implantation presented with a good visual outcome and safety profile was also good in toric ICL implantation.

In another study, [19] compared toric ICLs and photorefractive keratectomy (PRK) for moderate to high myopic astigmatism. These authors concluded that the toric implantable collamer lens resulted with good visual outcome when compared to PRK patients in all aspects. Stability of vision was maintained over a long period in toric ICL implantation group. So they concluded it is a good alternative corrective procedure among other refractive procedures.

A another study conducted by Sheng et al 2012¹⁵ among 122 eyes with myopic astigmatism implanted with toric ICL. with mean pre- operative spherical equivalent of -12.2 \pm 3.37D and mean astigmatism of - 3.1 \pm 1.7D. ICL patients were reviewed at 1 day, 1 week, 1, 3, 6 months post-operatively. After 6 months 100% patients were within \pm 1.00Dspherical equivalent with mean astigmatism reduced to 0.21D: These authors concluded that toric ICL, was safe and effective.

A study among 63 eyes of 36 patients with toric ICL implantation for patients of myopic astigmatism with a mean pre-operative spherical equivalent of 10.71 \pm 3.55D, with a mean cylinder of -3.60 D. More than 90% of eyes had a spherical equivalent within \pm 1.00 D pos- operatively at 6 months. Astigmatism also reduced with a mean of 0.38D post-operatively at 6 months and the authors concluded that implantation of toric ICL was an effective procedure and also safe and had good predictability [20].

In the current study there were no intra-operative complications. Post operatively, at 1 week, three eyes of three patients had corneal edema which subsided spontaneously within 1 month, and their BCVA was 6/6. One patient had iritis post-operatively and he was treated with topical steroids and cycloplegics and the iritis resolved. At 3 months and at 6 months two eyes of one patient had increased IOP, which was treated with topical anti glaucoma medications; There are no serious complications resulted during their follow up. Importantly, safety profile of toric implantable collamer lens in this study was found to be excellent.

Conclusion

In conclusion, the results of the current study suggest that the toric ICL performs well in correcting myopic astigmatism. In addition, neither significant IOP rise, nor vision-threatening complications occurred throughout the follow-up time. These findings suggest that toric ICL implantation may become a viable alternative to corneal refractive procedures.

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