COMPARISON BETWEEN ACRYSOF TORIC IOLS AND LIMBAL RELAXING INCISIONS FOR MANAGEMENT OF PREOPERATIVE ASTIGMATISM IN CATARACT PATIENTS

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ABSTRACT

Purpose: The aim of this work is to compare toric intraocular lens (IOL) implantation, and limbal relaxing incisions to treat astigmatism during phacoemulsification.

Design: Prospective randomised comparative study.

Methods: 60 eyes of 60 patients were devided into 2 equal groups. 30 eyes were offered phacoemulsification with toric IOL implantation and 30 were implanted spherical IOLs with limbal relaxing incisions. Postoperative astigmatism and UCVA were measured and compared during week 1 and month 1 and after 3 months.

Results: The mean preoperative BCVA was 0.1 ± 0.15 in toric subgroup, 0.15 ± 0.15 in LRI subgroup. The mean preoperative astigmatism was -2.4 + /-0.7 & -2.7 + /-0.7 respectively. At the first week: The mean postoperative UCVA at one week was 0.72 ± 0.12 , 0.61 ± 0.09 , in each group respectively. The mean postoperative astigmatism in the first week was -0.5 + /-0.3 & -1.27 + /-0.5 respectively. The mean postoperative UCVA at 1 month was 0.89 ± 0.14 , 0.58 ± 0.1 . The mean postoperative astigmatism was -0.55 + /-0.35 & -1.37 + /-0.5 respectively. In the 3 months follow up visit the mean for the postoperative UCVA was 0.9 ± 0.13 and 0.59 ± 0.16 for each subgroup respectively. The mean postoperative astigmatism was -1.25 + /-0.25 & -1.6 + /-0.5 respectively. There was a highly significant statistical difference between the result of UCVA preoperative and the results of UCVA at the early and last postoperative follow up. The average change of corneal astigmatism in the LRI group 1.1 + /-0.6 Dioptres at three months.

Conclusion: From our results, it is evident that LRIs are safe, predictable, and effective method for treating preexisting astigmatism in cataract surgery. However, regression may occur after surgery. Toric IOL implantation has recently become available as a means of treating astigmatism. Toric IOL implantation was proven to be very effective, stable and safe

INTRODUCTION

In recent years, our aim with cataract surgery has changed from a simple extraction to achieving improved visual acuity (VA) without correction with glasses or contact lenses either for near or far. This is why it can now be considered as «refractive cataract surgery». This change has been possible thanks to the integration of technical advances driven by the increasing demands of ophthalmologists and patients.

This means that, when planning a cataract surgery, we must take into account both the spherical and the astigmatic components to achieve the objective of emmetropia.¹

The spherical component is compensated by implanting an intraocular lens (IOL), for which all factors will be analyzed in order to choose the type of lens and power according to the biometrical data obtained with good apparatus and a skilled technician, appropriate formula and constant, as well as patient characteristics and those of surgical technique chosen.¹

The astigmatic component is planned according to corneal topography and keratometry primarily but other factors also need to be taken into account, such as age, contralateral eye, corneal characteristics.²

Although the advent of phacoemulsification, foldable intraocular lenses, (IOLs), and improved incision designs has decreased the incidence and extent of surgically induced astigmatism in cataract patients.², approximately 10% to15% of cataract patients has more than 1.5 D of

keratometric astigmatism, refractive astigmatism or both.²

Interest in correcting pre-existing astigmatism simultaneously with cataract surgery has grown in recent years. There are a variety of strategies for reducing preexisting corneal astigmatism at the time of cataract surgery. These can be divided into strategies, including corneal on meridian incisions, limbal relaxing incisions (LRIs), opposite clear corneal incisions (CCIs), arcuate keratotomies (AKs), and lens strategies. Corneal strategies have one advantage: They usually involve only knives, which are immediately available. However, because we are acting on biological tissue, there is always some degree of unpredictability relating to the wound-healing response.3

As a result of the unpredictability and lack of comfort with corneal approaches to astigmatism correction, many cataract surgeons have been pleased with the recent availability of toric IOLs.

PATIENTS AND METHODS

Before initiating this study, the protocol, the informed consent form and any other written information to be given to patients was reviewed and approved by the Ethics Committee of the Zagazig University Hospital. **Center:**Zagazig University Hospital-Ophthalmology Department.

- **Study sample:** 60 eyes of 60 patients
- **Inclusion Criteria-:** Cataract patients with 1.0 to 4.0 D astigmatism
- Exclusion Criteria:Previous corneal surgery,irregular astigmatism, concurrent

posterior segment disease, Corneal opacities and occurrence of intraoperative complication e.g. vitreous loss

All patients were subjected to complete medical assessment. A complete general ophthalmic examination was done including uncorrected visual acuity (UCVA), best corrected visual acuity(BCVA) , refraction (Nidek AR-1 Autorefractometer and retinoscopy), Slitlamp , retinal evaluation, tonometry , corneal topography (Topcon CA-200F Corneal Analyser) & biometry (Zeiss IOL master).

The power of the steep and flat corneal meridians was determined from both topography and IOL master. The difference between the two meridians is the amount of corneal astigmatism and its axis is the axis of the steep meridian (i.e. axis of plus cylinder).

Planning the surgery

Group 1

The data collected from the preoperative assessment were used in planning the surgical procedure. We used the online toric IOL calculator (www.acrysoftoriccalculator.com) to determine the model & power of the IOL to be used and plan the axis to be implanted on. In all cases we used the steep meridian for the main incision.

Group 2

The data collected from the preoperative assessment were used in planning the surgical procedure. We used the online LRIs calculator (www.lricalculator.com) to determine the length & site of the incision. The site of the main incison was also suggested from the calculator so as not to interfere with the site of the LRIs.

In both groups the surgically induced astigmatism was calculated as 0.5 dioptre in the online calculation form .This was calculated before from the previous surgical outcome of the surgeon using the online surgically induced astigmatism calculator. (www.sia-calculator.com).

On the day of the operation

Both groups

90 minutes preoperatively, the pupils were dilated by topical application of a combination of tropicamide 1%, phenylephrine hydrochloride 10 % and Flurbiprofen 0.03 %.Before attempting the surgery, a marker was used to put an orientation mark at the 3 and 9 O"clock position at the limbus while the patient is sitting. This is particularly important for fear of head tilting or cyclotorsion that may occur following lying flat or after injection of anesthesia. All cases were done under peribulbar anesthesia performed by ophthalmic surgeon using a mixture of lidocaine

hydrochloride 20 mg/ml (xylocaine 2 %) and hyaluronidase 1.500 IU/ampule (Hyalase).

After disinfection and draping, the operative procedure began by application of a wire speculum. The steep corneal meridian as indicated by the corneal topography was identified and marked at the beginning of surgery, using a marking pen. A clear corneal tunnel incision was done by an angled keratome. The entry site into the cornea was just in front of the limbal capillaries .The incision was completed into a tunnel of 2.0 mm in length. Sodium hyaluronate 1.35% was injected through the main incision to fully inflate the anterior chamber. Two side port paracentesis were done at about 90° or 4 clock hours on either side of the main incision using a continuous blade 15°.A curvilinear capsulorhexis was performed using a cystotome or capsulorehxis forceps. Hydrodissection was done using a 27 gauge flattened tip cannula, followed by rotation of the nucleus. We used phaco machine (Alcon infinity) to perform phacoemulsification in the posterior chamber with a stop and chop technique in all cases- After phacoemulsification of the nucleus, the cortex was removed by automated I/A.

Group 1

Then the bag and the anterior chamber were refilled with the same viscoelastic material. Then, marking the axis of implantation using a Mendeez ring according to the toric IOL calculator. The Acrysof IQ toric IOL models SN6AT3, SN6AT4, SN6AT5, SN6AT6 & SN6AT7 were used. Implantation of IOL using a lens injector and C shaped cartridge. Rotation of the IOL to Just off the desired orientation followed by removal of the viscoelastic from the anterior chamber and behind the IOL simultaneously with rotation to the desired position is a crucial step when implanting a toric IOL to minimize the chance of the IOL rotation. This was followed by stromal hydration of the wound. No sutures were taken in any case.

Group 2

The bag and the anterior chamber were refilled with the same viscoelastic material. Implantation Acrysof SA60ATT IOL was done .Implantation of IOL using a lens injector and C shaped cartridge The steep corneal meridian as indicated by the corneal topography, identified and marked based on the reference markers done at the beginning of surgery, using a marking pen with the guide of a degree marker. LRIs were done using a disposable silicone knife (Beaver-Visitec International). A 600 µm fixed depth knife, specially designed for LRIs was used in all cases. The length of the arc of LRI was

determined according to the preoperative corneal cylinder and made according to the Donnenfield nomogram used in the online LRI calculator for the correction of pre-existing astigmatism with cataract surgery. The LRIs were placed 1.0 mm from the limbus toward the center of the cornea. They should be regular in shape and all the time concentric with the limbus. According to the amount of preoperative astigmatism and age, paired limbal relaxing incisions were made. The LRIs were always centered over the steep corneal meridian and always trying to be steady in depth and following the curvature of the limbus.It was reasonable to place the LRIs at the conclusion of surgery, in the event that a complication necessitates a modification to the phaco-incision. They were done after the IOL implantation and just before removal of viscoelastic. This helped to keep the tension for better incision control. After the LRI has been completed, thorough wash of the incision using a blunt cannula was done in order to remove any blood clots which may affect the healing process and so the resultant astigmatism.

Also sweeping of the incision with the calibre was done. Followed by removal of the viscoelastic from the anterior chamber and behind the IOL. This was followed by stromal hydration of the wound. No sutures were taken in any case.

The postoperative treatment was as follows: Topical prednisolone acetate 1% eye drops 6 times daily for 1 week then tapered to 4 times / day for the next 2 weeks then 2 times / day for the next 2 weeks. Topical ofloxacin 0.3% eye drops 6 times daily for 1 week.

The patients were examined on the slit lamp for follow up 24 hours, 1 week, 1 month, 3 months after surgery during which UCVA,BCVA,Refraction and dilated slit lamp exam were done to determine if IOL had undergone any rotation. The disadvantage of this technique is that its relative accuracy is subject to the observer's experience and bias.

Results were collected and statistically analysed. Using IBM professional SPSS software package, Paired t test was calculated to compare the preoperative and post-operative data.

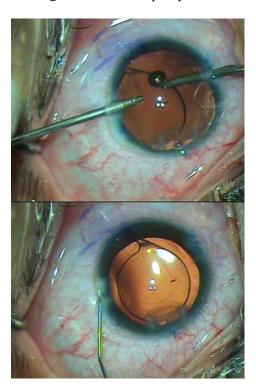


Figure 1: Summery of steps of toric IOL implantation

Figure 2: LRI calculator form

RESULTS

Group 1

This study group included 30 eyes of 30 patients 12 of which were males and 18 patients were females with mean age of 64.8 years old. The preoperative corneal astigmatism ranged between 1.5 and 3.75 diopters with 50% of cases (15 eyes) having astigmatism between 1.5-<2.25 dioptres, 23.3% of cases (7 eyes) with astigmatism between 2.25-<3.00 diopters and 26.7% (8 eyes) having astigmatism equals or more than 3 dioptres.

Dilated examination of the cases in the first day to determine if there is significant rotation of the IOL was done. None of the cases required re-entry to the theatre to readjust the position of the IOL. The mean error in placement was less than 2 degrees.

The mean preoperative UCVA was 0.1 ± 0.15 (Log MAR +1) while the mean postoperative UCVA at one week, one month and three months was 0.72 ± 0.12 (Log MAR +0.16), $0.89 \pm$ 0.14(Log MAR +0.05) & 0.9±0.13(Log MAR +0.05) respectively. There was highly significant statistical difference between preoperative and postoperative UCVA at the final follow up (t = 18.7563.the two-tailed P value is less than 0.0001) The mean preoperative astigmatism was -2.4 ± 0.7 while the mean postoperative astigmatism on 1 week, one month and three months was -0.5 ± 0.3 , -0.55 ± 0.35 and -0.75 ± 0.25 respectively. There was highly significant statistical difference between preoperative and postoperative astigmatism at the final follow up (t = 8.4169.the two-tailed P value is less than 0.0001).

The mean preoperative BCVA was 0.325 ± 0.157 (Log MAR +0.5) while the mean postoperative BCVA at three months was 1.2 ± 0.2 (Log MAR -0.1). There was highly significant statistical difference between preoperative and postoperative

UCVA at the final follow up (t = 18.7563.the two-tailed P value is less than 0.0001).

IOL rotation

At each visit remarking the axis of astigmatism was done then dilated examination slit lamp photography was performed. The IOL axis of orientation is evaluated against the red reflex and calculation of any rotation. At three months the mean rotation was 3.8 degrees.

Group 2

This study group included 30 eyes of 30 patients 16 of which were males and 14 patients were females with mean age of 66.2 years old. The preoperative corneal astigmatism ranged between 1.75 and 4.5 dioptres with 26.7% of cases (8 eyes) having astigmatism between 1.5-<2.25 dioptres, 33.3% of cases (10 eyes) were having astigmatism between 2.25-<3.00 dioptres and 40% (12 of 30) cases having astigmatism equals or more than 3 dioptres.

The mean preoperative UCVA was 0.15 ± 0.15 (Log MAR +0.8) while the mean postoperative UCVA at one week, one month and three months was 0.61 ± 0.09 (Log MAR +0.2), 0.58 ± 0.1 (Log MAR +0.22) & 0.59 ± 0.16 (Log MAR +0.23) respectively. There was highly significant statistical difference between preoperative and postoperative UCVA at the final follow up (t = 11.5099.the two-tailed P value is less than 0.0001).

The mean preoperative BCVA was 0.387 ± 0.146 (Log MAR +0.4) while the mean postoperative BCVA at three months was 0.843 ± 0.125 (Log MAR +0.1). There was highly significant statistical difference between preoperative and postoperative BCVA at the final follow up (t = 14.4107.the two-tailed P value is less than 0.0001).

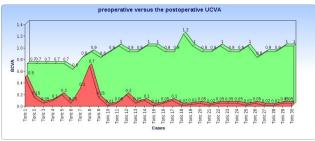


Figure 3 Graph representing the preoperative versus the postoperative mean UCVA. (Toric group)

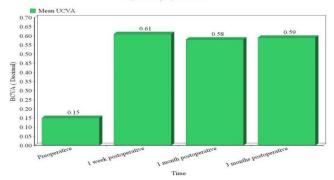


Figure 4 Graph representing the preoperative versus the postoperative mean UCVA. (LRI group)

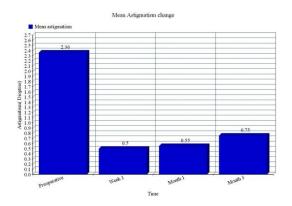


Figure 5 Preoperative versus postoperative mean astigmatism. (Toric group)

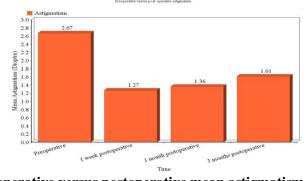


Figure 6 Preoperative versus postoperative mean astigmatism. (LRI group)

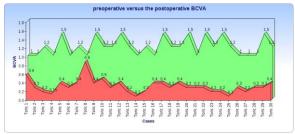


Figure 7 Graph representing the preoperative (red) versus the postoperative (green) BCVA. (Toric group)

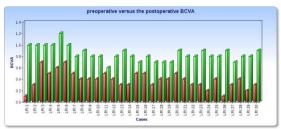


Figure 8 Graph representing the preoperative (red) versus the postoperative (green) BCVA. (LRI group)

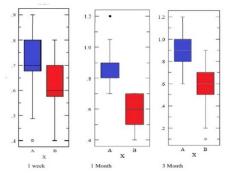


Figure 9 BOX Plot comparing mean UCVA of the 2 groups (Toric blue. LRIs red)

DISCUSSION

There are several approaches for reducing preexisting astigmatism during cataract surgery. Broadly these can be devided into corneal and lenticular approaches. Budak and coworkers reported that patients with more than 1.50 to 2.00 D of astigmatism are generally considered candidates for some form of surgical astigmatic correction⁴.

On this basis, our inclusion criteria required that both the corneal and refractive cylinder should be 1.5 to 4.00 D before surgery.

Toric pseudophakic intraocular lenses (IOLs) are increasingly used in cataract surgery. They offer patients the opportunity to correct corneal astigmatism at the time of cataract surgery and achieve spectacle independence for distance vision. Now, we have multifocal toric IOLs which provide spectacle independence not only for distance vision but also for near and intermediate vision.

IOL type

In our study we used the alcon acrysof toric IOL with the following models used SN6AT3, SN6AT4, SN6AT5, SN6AT6, and SN6AT7.

Both Holland et al., and Bauer et al., investigated toric acrysof IOLs .They concluded that implantation of the AcrySof® toric IOL proved to be an effective, safe, and predictable method of managing corneal astigmatism in cataract patients. ^{5,6}

Inclusion and exclusion criteria

In our study we have included cases with regular astigmatism only although Visser et al.,reported 2

cases in which cataract extraction with foldable acrylic toric IOL implantation was used to correct corneal astigmatism (irregular) in patients (age > 60 years) with keratoconus and cataract. Refractive astigmatism decreased by 70% in both eyes.⁷

Measurement of preoperative astigmatism

We used K readings from IOL master (Zeiss) in selection of IOL power and model .The axis of corneal astigmatism was determined from both topography and IOL master. In our hands this was found to be accurate and this was supported by results from Hill et al., who evaluated simulated clinical outcomes in patients with toric IOLs calculated on the basis of dual-zone automated keratometry from an integrated optical biometer relative to manual keratometry with equivalent accuracy obtained.⁹

Planning of incision

We used the steep meridian for the main incision (2.8 mm in all cases) in all cases.0.5 dioptre of surgically induced astigmatism was compensated in the online calculation form. We have taken into consideration studies performed on the phaco incisions by Borasio et al ¹⁰ and Masket et al ¹¹.

Pre-operative Marking Techniques

In our study we used the 3 step marking technique with a mean error slightly less than 2 degrees in IOL placement .This was better than the results reported by Visser et al. who reported a mean total error in toric IOL alignment of $4.9 \pm 2.1^{\circ}$ with the 3-step ink-marker procedure 12

Intraoperative alignment

We used the preoperative reference markings and intraoperative Mendez ring to determine the axis of IOL implantation which was aligned according to these marks without any aid of any special techniques. Osher described an iris finger printing technique, in which a pre-operative detailed image of the eye is obtained, in which the alignment axis is drawn. A printout of this image is used during surgery to align the toric IOL based on iris characteristics. ¹³

Post-operative Alignment Measurement

In our study we used the Slit lamp observation method in assessing the IOL alignment after the surgery with this simple and cheap method we reported misalignment of less than 2 degrees .This was comparable to the results of Carey et al., who assessed the validity of an internal optical path difference map of a refractive power/corneal analyzer system in determining the alignment of toric IOLs. They concluded that both refractive power/corneal analyzer system and slit lamp observation were reliable and predictable methods of assessing IOL alignment.¹⁴

Clinical Results

Our results indicated a highly significant improvement in the UCVA postoperative. The mean preoperative UCVA was 0.11 ± 0.15 , while the mean postoperative UCVA at the last follow up (3 months) was 0.88 ± 0.12 (log MAR 0.05). Our results were better than study conducted by Kim and coworkers in 2010.We think this was attributed to high percentage of patients who undergone rotation after implantation (42%). 15

While our results were comparable to the results of Holland et al, ¹⁶ and Ahmed et al. ¹⁷.

Misalignments & Rotation

In our study,at the 3 months follow up, 26 IOLs out of 30 (87%) rotated less than 5 degrees from the intended axis. Four IOLs rotated between 5 and 10 degrees. The mean IOL rotation was 3.8 degrees in the last follow up. No attempts to readjust the IOLs were made as the four cases with significant rotation.>5° were accompanied by capsular opacification and fibrosis. YAG capsulotomy was performed and refractive correction was offered.

This was comparable to the results reported by Chang et al., who concluded that based on the mean axis deviation and the number of IOLs rotating 5° or more, the AcrySof SN60T toric IOL showed statistically better rotational stability. 18

LRI group

In our evaluation of (LRIs) as a relatively easy inexpensive method for correction of corneal astigmatism, we recorded keratometric astigmatism before and after LRI in the last follow

up. We used corneal topography for the preoperative evaluation of corneal astigmatism and in assessment of the postoperative results.

Analysis of our results showed a significant reduction of the preoperative corneal astigmatism in most of the cases. In a study conducted by Bayramlar they showed significant reduction of the preoperative keratometric astigmatism with a mean reduction of 37% ¹⁹. This result was comparable to our results. (Mean reduction in our cases 39%) Also Mingo had similar results with a mean reduction of 29% ²⁰. Higher reduction was shown by Fouda in 2010 ²¹. This may be partly because he used another nomogram (modified gills nomogram) and the different technique in LRI creation with a depth of 90% of the thickness of the cornea based on pachymetry.

Regression

In order to study the regression effects of LRIs i.e. the stability of the incision during postoperative course, we evaluated the mean postoperative refractive astigmatism at 1 week, 1 month, and 3 months. It was -1.27 ± 0.50 D, $-1.37 \pm$ 0.50D, $-1.61 \pm 0.51D$ respectively. The results indicated regression of some refractive astigmatism within the first 3 months of about 30 % of astigmatic correction. Regression was also noted by different surgeons .Mingo showed that preoperative refraction was reduced from -2.17±1.03D to postoperative refraction of - $1.3\pm0.60D^{20}$.

We thought this regression might be due to the healing process of the wound. recommended for increasing the efficacy of LRIs in the postoperative period when some regression was noted or when the initial refractive effect was small, to increase the postoperative steroid dose as it retards the healing process and allows sometime for incision to be gapped and filled with scar tissue²². The resulting under correction might be explained by many factors including the degree of preoperative astigmatism, and the occasional placement of the incisions very peripheral. Other factors that might explain the under correction in some of our patients include irregular contour or depth of the incision especially when working on soft tension at the end of the surgery. In addition, the use of fixed depth (600µm) incision in all patients; although not all patients have the same corneal thickness at the periphery can be considered a factor. Thicker corneas will have a relatively decreased incision depth consequently decreased efficacy of the incision.

CONCLUSION

Our study was based on comparing between these two different modalities in correction of

preexisting astigmatism with cataract surgery (toric IOL implantation and LRIs). From our comparison between the two groups, we found that, there was a highly significant improvement in the UCVA postoperatively in all the study groups, However there were much better results in the toric IOL group in comparison to the LRI group with 27% % of the patients who were implanted with toric IOL achieving UCVA of 1.0 or better while none of patients who undergone LRI achieved this. Also UCVA of 0.7 or better was observed in 97% of patients' toric subgroup and only 30 % in LRI subgroup. To conclude the discussion from our study, we reached an understanding that the toric IOL group were much more stable, effective and predictable way to correct astigmatism than the LRIs group that showed regression and fewer efficacies along the postoperative follow up period.

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