

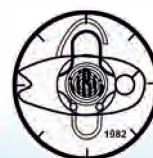
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Indian Journal of Cataract and Refractive Surgery

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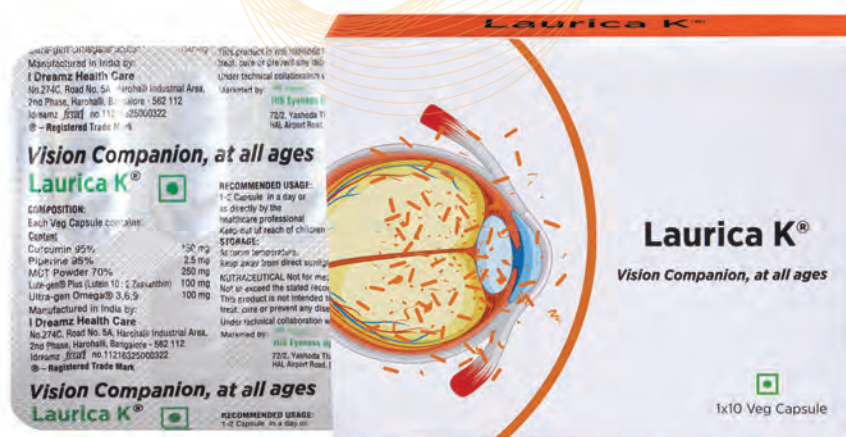
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Inaugural Editorial *Indian Journal of Cataract and Refractive Surgery*

Cyres Mehta, Editor-in-Chief of the new *Indian Journal of Cataract and Refractive Surgery* (IJCRS), has invited me to write the inaugural editorial for the journal. It is a daunting task to write an inaugural editorial for a new journal with the lofty goals of IJCRS. What can I say?

Another journal to read! Sometimes, we all feel inundated with new journals, mostly emanating from for-profit businesses canvassing potential authors to submit articles that undergo only summary reviews. Alternatively, there has been no increase in first-rate peer-reviewed journals, in which articles undergo serious scrutiny before publication. It is very difficult to start such a journal, where being accepted and published is itself an academic achievement. Even established medical journals are undergoing challenging times, as authors will often accept the easier path of acceptance in less strictly peer-reviewed journals, requiring fewer rounds of editing, and the rampant proliferation of questionable information on-line are making the review and editorial process more difficult.

Should India be the source of a new academic journal? India is a “different country.” I have made over 15 trips to take part in academic meetings in India, a number exceeding any destination outside my North American home. My first and most memorable trip was by invitation of Dr. Keiki Mehta to speak at the Indian Intraocular Implant Society and the immediately subsequent All India Ophthalmological Society, in (then) Bombay in January and February of 1995. I recall fabulous hospitality, and being asked to take a seat at the podium as soon as I walked through the door, to help chair a session. I recall, exploring Bombay, meeting families of some of my Toronto patients, and finding many aspects of India to be lagging North America: the functioning of the Indian electrical and telephone systems, the health safety of street food, the extent to which Indian surgeons had adopted phacoemulsification, and to a Canadian, the unbelievable population density of Bombay and the wild rides on tuk-tuks. My hosts were gracious enough to teach me a lot about India and its culture. Many of my interpersonal discussions that trip consisted of very thoughtful, gentle lectures to help me understand a culture which predates all Western societies, and therefore, seems wildly incomprehensible to a Western Judeo-Christian initiate to India. I made some life-long friends on that trip, both inside and outside of medicine. On my flight home, relaxing in the luxury of my Air Canada flight, I simply felt like a better person for having been to India and having

engaged with Indian ophthalmologists and the diverse people that I met, trying to grasp some idea of their existence and issues through my foreign eyes. India had penetrated my soul, as my patients had warned it would. I am forever deeply indebted to my wonderful friend Keiki Mehta, who introduced me to India and initiated me to having numerous fascinating, educational, and deeply moving experiences, there over the subsequent 30 years. I continue to marvel at the hospitality I am shown on every trip, and I am amazed at the voracious Indian hunger for learning that I see at every meeting I attend in India and elsewhere.

It has been a remarkable experience to observe the rate of modernization on every visit to India, in retrospect fitting for a country with an incredible academic history. Not only is India the source of the root language of all Indo-European languages, Sanskrit, but it is also the source of the decimal system, the zero, much of the basis of all our mathematics, as well as numerous games from chess to card games, etc. Innovation in science is not new to India. Maharishi Kaṇāda (~400 BCE), founded the Vaisheshika school of Indian philosophy that also represents the earliest Indian physics. He proposed the first theory of atomism, with paramāṇu being tiny indivisible particles of matter. He described them to be eternal and to combine with each other in different ways to make up all matter. This description sounds rather modern, whereas it was stated over 2000 years ago. Furthermore, around 600 BCE Sushruta, who lived just north of Delhi, and is recognized as the father of Indian surgery, was the first in the world to describe a method of cataract surgery (couching). We, in the West, are latecomers to India's academic parade in science and ophthalmology.

I have been privileged to have been invited, over many years, to review articles for the *Indian Journal of Ophthalmology* and that journal generously placed my name on its masthead for longer than I deserved. I have reviewed articles for multiple journals, mostly Western based, and I have been very aware of the rapid improvement in the quality and academic level of the IJO. The IJO was the logical place for Indian ophthalmology to start to mark its academic presence globally. At present, every cataract and refractive meeting globally sees its award ceremonies dominated by Indian authors and producers. I believe that India now has more academic ophthalmology training programs than all the Western countries in the world combined. These programs train the largest number of educated youth available in any country globally. India now performs

a full 1/3 (~8.5 million) of global cataract surgical procedures (26 million). Just that number justifies India's own journal of cataract and refractive surgery. Cyres Mehta, the son of my initial Indian ophthalmic host, Keiki Mehta, has assembled an editorial board of esteemed Indian cataract and refractive surgeons, to embark with him, on the new IJCRS. India's past record, current surgical volume, and achievements in academic cataract and refractive surgery demand local control of destiny. The IJCRS will provide a vehicle of information exchange in the same way the IJO provided one when Indian ophthalmology needed a venue for Indian general ophthalmology in 1953, and thereafter.

The (other) *Journal of Cataract and Refractive Surgery* began as a newsletter in 1975, quickly evolved into the *Journal of The American Intraocular Implant Society*, and adopted its current name in 1986. Its origin was due to the disrespect shown by American Academic Ophthalmology toward the then-recent rapid evolution in cataract surgery, by surgeons often deemed to be "cowboys" by the American ophthalmic academic elite. JCRS turned out to be a wonderful venue for the exchange of ideas and collaboration among cataract and refractive surgeons globally and played a significant role in the past 50 years of incredible progress in cataract and refractive surgery. Indian cataract and refractive surgery, evidenced by the sheer volume and Indian domination of achievement awards globally, is now in a position to demand hitherto unawarded respect and to gain more rapid publication of Indian ideas to the most appropriate audience. IJCRS can and surely will deliver this. The dawning of the IJCRS is an opportunity for Indian cataract and refractive surgeons to unite in discussion and show the world how much has been achieved and

how much more can be achieved in the future. Even a cursory perusal of the table of contents of the inaugural issue shows active discussion of wide-ranging important topics in current cataract and refractive surgery. I congratulate you all on this momentous achievement. Like many other Western ophthalmologists, I can hardly wait to return to India to learn from your doctors and allow Indian culture to again pull at my soul. There is definitely something mystical, alluring, and enduring about "Mother India." Congratulations!

Steve A. Arshinoff

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Lens Exchange with Implantation of a Bitoric Intraocular Lens in Eyes with Significant Astigmatism after Previous Corneal Surgeries: Analysis of Bitoric Intraocular Lens Implantation after Previous Corneal Surgery

Dimitrii Dementiev^{1,2}, Anna Shipunova¹, Konstantin Zhukov¹, Olga Kukleva¹

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ABSTRACT

The purpose of this study was to evaluate the clinical outcomes of cataract surgery with implantation of a bitoric intraocular lens (IOL) in eyes with significant amounts of astigmatism after previous corneal surgery. This was a prospective study including 35 eyes of 33 patients with high astigmatism after previous corneal surgery: 19 eyes of 19 patients (age, 33–51 years) with previous penetrating keratoplasty (PKP), 8 eyes of 7 patients (age, 31–37 years) with previous photorefractive keratectomy (PRK), and 7 eyes of 7 patients (age, 37–47 years) with previous radial keratotomy (RK). Phacoemulsification surgery was performed in all cases with implantation of the bitoric IOL AT TORBI 709M IOL (Carl Zeiss Meditec). Postoperative follow-up ranged from 20 to 68 months. Uncorrected distance visual acuity (UDVA) improved significantly with surgery ($P \leq 0.016$), with a significant reduction of the associated cylinder ($P \leq 0.018$). Likewise, a significant improvement was observed in corrected distance visual acuity (CDVA) after surgery in the PKP ($P < 0.001$) and RK groups ($P = 0.025$). Postoperatively, 89.5%, 62.5%, and 100% of eyes gained lines of CDVA in the PKP, PRK, and RK groups, respectively. The postoperative spherical equivalent was within ± 2.00 D in 47.4% of eyes in the PKP group. It was within ± 1.50 D in all eyes in the PRK and RK groups. Cataract surgery with implantation of the bitoric AT TORBI 709M IOL seems to be a useful option for an effective visual rehabilitation in eyes with previous corneal surgery and significant amounts of corneal astigmatism. Predictability seems to be more limited after PKP.

KEYWORDS: Bitoric intraocular lens, corneal abnormalities, high astigmatism

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INTRODUCTION

Laser refractive surgery was proposed several years ago as an effective and safe option to correct residual astigmatism after corneal surgical procedures, such as radial keratotomy (RK) and penetrating keratoplasty (PKP).^[1-3] Difficulties arise when this type of patient develops cataract and phacoemulsification surgery with implantation of an intraocular lens (IOL) is required.^[4] The use of adequate IOL power calculation formulas and the selection of an appropriate IOL design are crucial for a successful outcome providing spectacle

independence.^[4] Toric IOLs have been suggested to be a good option in those cases of previous corneal surgery with significant amounts of residual astigmatism and in need of cataract surgery.^[5-10] However, the scientific evidence of the use of this type of implant in such cases is very limited.^[5-10]

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In 2011, a new bitoric IOL was commercially released, the AT TORBI 709M/MP IOL (Carl Zeiss Meditec, Jena, Germany), providing an extensive range of diopter combination possibilities, allowing customization of the implant in the most complex cases. This IOL has been shown to provide excellent results in cases of regular corneas with low to high corneal astigmatism^[11-16] but also in some cases of high astigmatism in irregular corneas, such as keratoconus.^[17,18] The aim of the current study was to evaluate the clinical outcomes of cataract surgery with implantation of this bitoric IOL in eyes with clinically significant astigmatism after previous corneal surgery, including RK, PKP, and photorefractive keratectomy (PRK).

METHODS

Patients

Patients with high astigmatism after previous corneal surgery and undergoing cataract surgery were included in the study. Phacoemulsification surgery with implantation of the bitoric IOL AT TORBI 709M IOL (Carl Zeiss Meditec, Jena, Germany) was performed in all cases. Inclusion criteria for the study were the presence of cataract or sclerotic changes of the patient's crystalline lens affecting visual acuity significantly (0.2 logMAR or below), patients of at least 21 years, previous RK, PRK, or PKP surgeries leaving significant amounts of corneal astigmatism (more than 2.5 D), and patients willing and able to return for the scheduled follow-up examinations. The following conditions were defined as the exclusion criteria for the study: previous corneal or intraocular surgeries except RK, PRK, or PKP, active ocular disease, diabetic or hypertensive patients with clinical evidence of retinal pathology, pregnancy, macular degeneration, zonular instability, corneal or intraocular opacities, history of steroid-responsive episodes, glaucoma, pupil dilation of <6.0 mm, and participation in other ophthalmic drug or device clinical trials during our clinical investigation.

Clinical protocol

A complete preoperative examination was performed in all cases, including medical history, measurement of uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA), slit-lamp examination, optical biometry (IOL-Master 500, Carl Zeiss Meditec, Jena, Germany), Goldmann applanation tonometry, pachymetry and anterior segment analysis (Visante OCT 3.0.1.8, Carl Zeiss Meditec, Jena, Germany), corneal topography (ATLAS Revision 3.0.0.39, Carl Zeiss Meditec, Jena, Germany), and funduscopy under pupil dilation. Postoperatively, different examinations were performed at 1 day, 1 week, 1 month, 3 months, and

12 months after surgery. Further follow-up visits took place annually. All visits included slit-lamp examination, corneal topography, measurement of UDVA and CDVA, manifest refraction, and tonometry.

Surgical technique

The surgical interventions were performed by the same expert surgeon (DD) using topic anesthesia (lidocaine 2%). A manual marking of the 0° and 180° axes was performed under the slit lamp in sitting position just before the surgery to keep the marks visible. All incisions were temporal (180° ± 15°), with a size between 1.5 and 2.4 mm. The general surgical procedure was followed including these sequential steps: injection of viscoelastic in the anterior chamber, capsulorrhexis (5.0–6.0 mm), hydrodissection, nucleus removal by phacoemulsification, irrigation/aspiration of cortical material, viscoelastic injection in the capsular bag, IOL implantation, and viscoelastic removal. Each patient received a local antibiotic and anti-inflammatory prophylaxis and a postsurgical therapy with topic nonsteroidal anti-inflammatory drugs for 1 month, including cortisone and antibiotic drops (1 drop 4 times daily for the first 4 days and then 1 drop 3 times daily for the following 7 days).

Data analysis

Data analysis was performed with a commercially available software package (SPSS for Mac, Version 20.0; IBM Corporation, Armonk, NY, USA). The normality of data samples was evaluated by means of the Kolmogorov–Smirnov test. When parametric analysis was possible, the Student's *t*-test for paired data was used for comparisons between groups, whereas the Mann–Whitney test was applied to assess the significance of such differences when parametric analysis was not possible. For the analysis of differences between preoperative and postoperative visits in each group, the Student's *t*-test for paired data or the Wilcoxon ranked sum test was used depending if the samples were distributed normally or not, respectively. For all statistical tests, *P* < 0.05 was considered statistically significant.

RESULTS

Thirty-five eyes of 33 patients with a mean age of 39.9 years (standard deviation [SD]: 5.5, median: 39, range: 31–51 years) were included in the study. Three subgroups were defined according to the prior corneal surgery: PKP group, including 19 eyes of 19 patients with an age range from 33 to 51 years, PRK group, including 8 eyes of 7 patients between 31 and 37 years old, and RK group, including 7 eyes of 7 patients with an age range from 37 to 47 years. Table 1 summarizes the preoperative

data in the three groups of the current study. As shown, there were statistically significant differences between groups in terms of preoperative refraction ($P \leq 0.029$). For this reason, the results of each group were analyzed separately. The mean follow-up was 31.1 (SD: 11.2, median: 29, range: 16–63 months), 35.0 (SD: 7.1, median: 35, range: 22–46 months), and 31.0 months (SD: 6.9, median: 28, range: 20–38 months) in the PKP, PRK, and RK groups, respectively ($P = 0.201$). Table 2 summarizes the postoperative outcomes. The mean interval between the previous corneal surgery and the toric IOL implantation was 11.5 years, ranging from 1.5 to 25 years.

Penetrating keratoplasty group outcomes

A significant improvement in UDVA with surgery ($P < 0.001$) associated with a significant reduction of cylinder and spherical equivalent was observed ($P < 0.001$). Postoperative UDVA of 20/40 or better was found in 73.7% (14/19) of eyes [Figure 1]. Likewise, a significant improvement was observed in CDVA after surgery ($P < 0.001$) with 89.5% (17/19) of eyes gaining lines of CDVA [Figure 2]. The postoperative spherical equivalent was within ± 2.00 D in 47.4% (9/19) of eyes [Figure 3].

Photorefractive keratectomy group outcomes

LogMAR UDVA improved significantly with surgery ($P = 0.010$), accompanied by a significant reduction of cylinder ($P = 0.012$). Postoperative UDVA of 20/25 or better was observed in all eyes (8/8) [Figure 1]. Likewise, a significant improvement was found in CDVA

after surgery ($P = 0.025$), with 62.5% (5/8) of eyes gaining lines of CDVA [Figure 2]. The postoperative spherical equivalent was within ± 0.50 D in 87.5% (7/8) of eyes, and the postoperative cylinder was within ± 1.00 D in 75.0% (6/8) of eyes [Figure 3].

Radial keratotomy group outcomes

Manifest cylinder was reduced significantly with surgery ($P = 0.018$), with significant improvement of UDVA ($P = 0.016$) and CDVA ($P = 0.014$). Postoperative UDVA of 20/25 or better was found in 71.4% (5/7) of eyes [Figure 1]. Likewise, all eyes gained lines of CDVA postoperatively [Figure 2]. The postoperative spherical equivalent and cylinder were within ± 1.00 D in all eyes (7/7) [Figure 3].

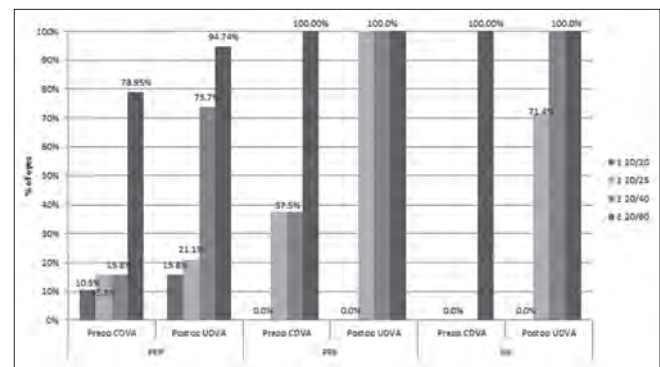


Figure 1: Distribution of postoperative uncorrected distance visual acuity compared to the distribution of preoperative corrected distance visual acuity in the three groups of eyes. CDVA: Corrected distance visual acuity, UDVA: Uncorrected distance visual acuity, PKP: Penetrating keratoplasty, PRK: Photorefractive keratectomy, RK: Radial keratotomy

Table 1: Preoperative data in the three groups evaluated

Mean±SD/median (range)	Preoperative data			P
	PKP group	PRK group	RK group	
LogMAR UDVA	1.05±0.32/1.00 (0.40–1.52)	0.93±0.52/1.30 (0.20–1.30)	1.20±0.30/1.00 (1.00–1.80)	0.776
Manifest sphere (D)	-2.64±2.57/-2.50 (-8.25–1.50)	0.53±2.03/1.25 (-4.00–2.25)	-1.18±3.65/-1.50 (-7.00–3.00)	0.029
Manifest cylinder (D)	-9.08±1.92/-9.00 (-12.00–6.00)	-4.67±1.36/-5.00 (-6.00–2.50)	-6.04±1.21/-6.50 (-7.00–3.75)	<0.001
Manifest SE (D)	-7.18±2.86/-8.00 (-12.50–1.50)	-1.80±2.37/-0.75 (-7.00–0.075)	-4.20±3.89/-5.00 (-10.25–0.25)	<0.003
LogMAR CDVA	0.42±0.21/0.50 (0.00–0.80)	0.35±0.21/0.50 (0.10–0.50)	0.49±0.04/0.50 (0.40–0.50)	0.587

UDVA: Uncorrected distance visual acuity, SE: Spherical equivalent, CDVA: Corrected distance visual acuity, SD: Standard deviation, PKP: Previous penetrating keratoplasty, PKP: Penetrating keratoplasty, PRK: Photorefractive keratectomy, RK: Radial keratotomy, LogMAR: Logarithm of the minimum angle of resolution

Table 2: Postoperative data in the three groups evaluated

Mean±SD/median (range)	Postoperative data			P
	PKP group	PRK group	RK group	
LogMAR UDVA	0.29±0.21/0.30 (0.05–1.00)	0.12±0.03/0.10 (0.10–0.17)	0.20±0.07/0.17 (0.10–0.30)	0.018
Manifest sphere (D)	-1.41±1.70/-0.50 (-5.00–0.50)	-0.09±0.42/0.00 (-1.00–0.50)	-0.39±0.20/-0.50 (-0.50–0.00)	0.132
Manifest cylinder (D)	-3.00±1.60/-3.00 (-6.00–0.00)	-0.94±0.73/-0.88 (-2.00–0.25)	-0.79±0.17/-0.75 (-1.00–0.50)	0.003
Manifest SE (D)	-2.91±2.05/-2.75 (-7.50–0.00)	-0.56±0.60/-0.44 (-2.00–0.13)	-0.79±0.20/-0.88 (-1.00–0.50)	0.004
LogMAR CDVA	0.07±0.04/0.10 (0.00–0.10)	0.01±0.00/0.01 (0.01–0.01)	0.08±0.03/0.10 (0.05–0.10)	0.088

UDVA: Uncorrected distance visual acuity, SE: Spherical equivalent, CDVA: Corrected distance visual acuity, SD: Standard deviation, PKP: Previous penetrating keratoplasty, PKP: Penetrating keratoplasty, PRK: Photorefractive keratectomy, RK: Radial keratotomy, LogMAR: Logarithm of the minimum angle of resolution

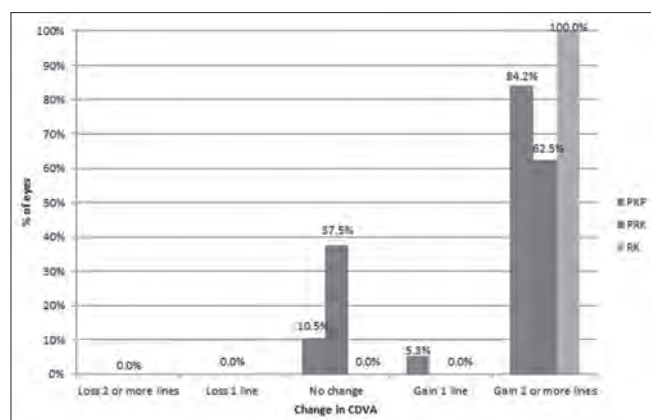


Figure 2: Distribution of the change in lines of corrected distance visual acuity with surgery in the three groups of eyes. CDVA: Corrected distance visual acuity, PKP: Penetrating keratoplasty, PRK: Photorefractive keratectomy, RK: Radial keratotomy

Complications

No IOL rotation was observed. Two patients had an elevated IOP at 1 month after surgery that was solved with antihypertensive drops. Two eyes of two patients required a YAG laser capsulotomy at 6 months after surgery due to the presence of a significant posterior capsular opacification leading to visual deterioration.

DISCUSSION

The bitoric IOL evaluated in the current study has been shown to significantly improve uncorrected vision and reduce the refractive cylinder in corneas with prior PKP. This is consistent with the results of other studies showing the benefit of the use of toric IOLs in postkeratoplasty eyes with significant amounts of corneal astigmatism.^[5-8,10,19-21] As expected, in spite of the visual improvement achieved with the bitoric IOL evaluated, the predictability of the astigmatic correction had some limitations, as shown in previous series evaluating other toric IOLs in postkeratoplasty eyes.^[5-8,10,19-21] In our series, the postoperative spherical equivalent was within ± 2.00 D in approximately half of the evaluated sample, with a mean postoperative value of -2.91 ± 2.05 D. Lockington *et al.*^[19] reported a similar postoperative refractive outcome with 2 other types of toric IOLs in postkeratoplasty eyes, with the mean refractive cylinder decreasing significantly from -5.49 ± 3.72 to -2.61 ± 2.10 D. However, in our series, the mean preoperative astigmatism was higher, with a mean value of -9.08 D. Thomas *et al.*^[7] reported a median reduction of astigmatism by 70.59% with a specific type of toric IOL in eyes with postkeratoplasty astigmatism ranging from -2.00 to -17.00 D. According to our outcomes and the previous scientific evidence, there is a trend to undercorrection of astigmatism with toric IOLs in eyes after PKP. Several factors may account for this, such

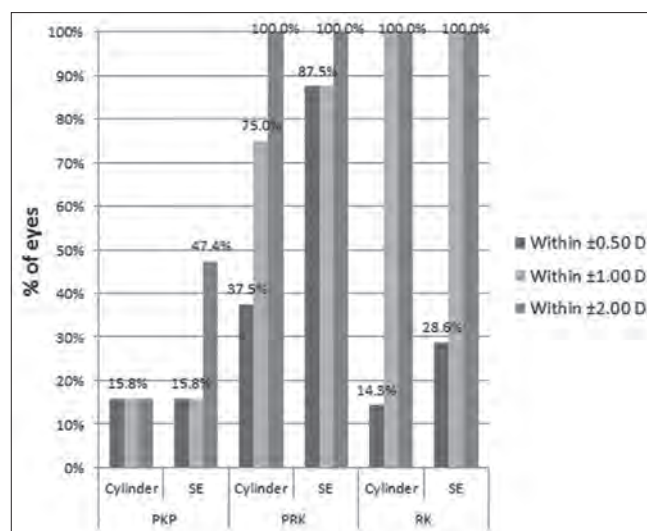


Figure 3: Distribution of postoperative cylinder and spherical equivalent in the three groups of eyes. PKP: Penetrating keratoplasty, PRK: Photorefractive keratectomy, RK: Radial keratotomy, SE: Spherical equivalent

as the potentially significant effect of posterior corneal astigmatism after PKP that is not considered in IOL power calculations, the unpredictable effect of corneal incision due to the altered biomechanical behavior of the postkeratoplasty cornea, or the contribution of small IOL misalignments or rotations. This last factor seems to have a minimal contribution as the IOL misalignment and rotation of the evaluated bitoric IOL have been shown to be limited. Kretz *et al.*^[12] reported a mean absolute IOL misalignment of 3.5° , with values ranging from 0° to 10° . Bascaran *et al.*^[14] found a mean axis rotation for the AT TORBI 709M IOL of $4.42^\circ \pm 4.31^\circ$, with 86% of the lenses rotating $<10^\circ$. In contrast, several studies have shown an increase in posterior corneal astigmatism and irregularity after PKP, with the potential of generating an impact on visual performance.^[22] Future studies should aim to refine IOL power calculations in postkeratoplasty eyes.

In the current study, a significant visual improvement with reduction of refractive cylinder was obtained after the implantation of the bitoric IOL in eyes with significant amounts of astigmatism after PRK and RK. Postoperative UDVA of 20/25 or better was observed in 100% and 71.4% of eyes in the PRK and RK groups, respectively. Likewise, the postoperative spherical equivalent was within ± 1.00 D in all eyes of both groups. These results are similar and even better than those found in eyes without previous corneal surgery with the same type of bitoric IOL.^[11-16] Kretz *et al.*^[12] found in 41 eyes with preexisting corneal astigmatism of 0.75 D and implanted with the bitoric IOL AT TORBI 709M that 97% of eyes had a

postoperative spherical equivalent within ± 1.00 D of emmetropia. Bascaran *et al.*^[14] reported in 48 eyes implanted with the same bitoric IOL that UDVA was 20/40 or better in 88.1% of eyes and 20/25 or better in 61.9%. Compared to other studies evaluating the results of toric IOLs in eyes with previous RK, the results in our sample of 7 eyes are similar or even slightly better.^[23,24] Studies with larger sample sizes are needed to confirm the results in eyes with prior PRK and RK.

CONCLUSIONS

Cataract surgery with implantation of the bitoric IOL AT TORBI 709M seems to be a useful option for an effective visual rehabilitation and refractive correction in eyes with prior corneal surgery and significant amounts of residual corneal astigmatism. More studies are needed to confirm the potentially significant contribution of posterior corneal astigmatism to total corneal astigmatism in postkeratoplasty eyes in order to refine algorithms of IOL power calculations in such eyes.

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Conflicts of interest

There are no conflicts of interest.

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Cataract Surgery in Patients with Previous Penetrating Keratoplasty

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ABSTRACT

Cataract surgery in patients with previous penetrating keratoplasty (PK) presents additional challenges. A thorough evaluation of the patient is required before surgery to determine the feasibility and difficulty of the procedure. In these cases, calculating the intraocular lens power is more complicated. The phacoemulsification technique is considered the preferred method, although, in cases of advanced cataracts, extracapsular extraction may be a good alternative. During surgery, specific details such as the location of incisions must be taken into account, and maneuvers should be attempted to preserve the corneal endothelium to the maximum extent possible. Although there is a risk of graft rejection, cataract surgery in patients with previous keratoplasty has been shown to be safe and effective in several studies. In conclusion, cataract surgery in patients with PK is safe and provides satisfactory visual outcomes when a careful evaluation of the patient is performed before surgery.

KEYWORDS: *Cataract surgery, corneal transplant, specular microscopy*

INTRODUCTION

Cataract surgery is a common and highly effective procedure for treating lens opacity. However, in patients who have previously undergone corneal transplants, cataract surgery may present additional challenges. In Spain, the history of corneal transplants dates back to the mid-20th century. In 1940, Professor Ignacio Barraquer performed the first one in Spain.^[1] Corneal transplant is the most common transplant worldwide;^[2] therefore, we are increasingly encountering patients with cataracts who have previously undergone penetrating keratoplasty (PK) in our daily practice.

SPECIAL CONSIDERATIONS

Before surgery, a thorough assessment of the patient is important under the slit lamp, to observe the condition of the cornea, iris, iridocorneal angle, presence of anterior or posterior synechiae, stability of the zonule, and lens hardness, which can provide information about the difficulty of surgery and the likelihood of preserving the transplanted cornea.

When calculating the power of the intraocular lens (IOL) in cataract surgery following PK, compared

to a triple procedure, we will have information on corneal refractive power, anterior chamber depth, and axial length, which are key factors for calculating the IOL power to be implanted.^[3] If we add to that the use of advanced diagnostic equipment and the use of newer generation formulas, we can achieve a refractive outcome closer to the desired one.

Currently, phacoemulsification cataract surgery has been shown to be safer and to have better visual outcomes than extracapsular extraction.^[4] Therefore, it should be our technique of choice when approaching cataract surgery in patients with previous PK. However, in cases of complicated surgery, especially if it is a hard cataract, extracapsular extraction has shown less endothelial cell loss compared to phacoemulsification in these patients.^[5]

Regarding special considerations during surgery, it is important to consider the incisions. Make them as peripheral as possible, away from the graft edges and sutures, if present. Capsulorhexis may be hindered

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by poor visualization of the capsule, either due to inadequate graft transparency or irregularities on its surface. In such cases, emphasize the use of abundant viscoelastic and dyeing the capsule if necessary. It is important to perform phacoemulsification using the minimum possible energy to preserve the corneal endothelium and, consequently, the transparency of the transplanted cornea to the maximum extent possible. If possible, the use of a femtosecond laser would be interesting to ensure a round and centered capsulorhexis and for nucleus prefragmentation, as it allows for less ultrasound use and reduces endothelial damage.^[6] However, it may not always be possible to have this technology available, and even if available, it may not always be feasible due to media opacity, and sometimes, the femtosecond laser may not adapt perfectly to the irregularities of a transplanted cornea.

Although the risk of graft rejection exists, there are studies demonstrating that cataract surgery following PK is a safe and effective procedure, with a low risk of corneal graft failure.^[3,7] In our experience, our results are quite consistent with those found in the medical literature, even having operated on patients who underwent corneal transplants more than 50 years ago and maintained corneal transparency after cataract surgery.

CONCLUSIONS

Cataract surgery in patients with PK may have certain special considerations; however, it is currently a safe procedure that allows for fairly acceptable visual outcomes for the patient. Therefore, our recommendation

is not to be afraid of surgery in these cases, as the likelihood of graft survival is high, especially if we perform early surgery with a less rigid lens.

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Conflicts of interest

There are no conflicts of interest.

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Comparative Analysis of the Effectiveness of Different Methods of Intracorneal Segments Calculation in Patients with Pellucid Marginal Degeneration

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ABSTRACT

The purpose of this study was to perform a comparative analysis of the effectiveness of different methods of intracorneal ring segments (ICRS) calculation for implantation in patients with pellucid marginal degeneration (PMD). Forty-two patients (42 eyes) c PMD underwent ICRS implantation. There were 22 patients (22 eyes) in the 1st group where our own method of calculation was implemented. The second group consisted of 20 patients (20 eyes) where the Keraring Calculation Guidelines (Mediphacos, 2008) were used. Values of visual acuity (VA) and five refractive indices have been examined preoperatively, on the 1st day and 3 months after the procedure. Maximal dynamics of Irregular astigmatism (IR) manifested as its median decrease by 6 D in comparison with preoperative values was observed in the eyes of the 1st group ($P < 0.05$), while twice less effect was noticed in the 2nd group ($< 3D$). The greatest rise of uncorrected VA occurred in the 1st group, its median has increased by three times in comparison with the initial and 1.5 times with the 2nd group. Distance-corrected VA turned out to be statistically higher right after operation in the eyes of the 1st group ($P < 0.05$), while remained almost the same in the 2nd group compared to initial values ($P > 0.05$). The method of calculation of Intracorneal ring segments (IRCS) parameters for implantation in patients with PMD, developed by our team of doctors, showed high effectiveness since it allowed a decrease of IR median by 6.0 D without change of spherical components of refraction. We consider ICRS as one of the most effective treatment alternatives in the management of patients with PMD. It is a safe technique that normalizes the morphological alterations present in the cornea, thus improving the VA and the quality of life of patients with PMD.

KEYWORDS: *Intracorneal ring segments, irregular astigmatism, pellucid marginal degeneration*

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INTRODUCTION

Correction of refractive abnormalities in patients with keratectasia can be considered the main task for ophthalmologists, at the same time presenting a row of significant difficulties due to a high degree of irregular astigmatism (IA).^[1-3] Thus, spectacles and contact lenses (CL), being the traditional method of optic correction of refraction abnormalities, are very limited and can be used only at initial stages of corneal diseases, pellucid marginal degeneration (PMD) in particular.^[4-7]

Although correction with hard corneal, scleral, or hybrid CL is the most helpful nonsurgical method of IA correction at keratectasia, Prescription and production together with fitting of the lens in the patient's eye are rather challenging in the majority of PMD cases.^[8,9]

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Besides, there is always a possibility of direct contact of ectasia with the posterior surface of CL, which can cause destructive changes not only of epithelium but of stroma as well, and CL presence in the conjunctival sac increases the risk of infectious processes and dry eye disease occurring.^[6,10,11]

Among different methods of refractive surgery, implantation of intracorneal ring segments (ICRS) which allows an effective decrease of IR degree can be considered a preferable technique.^[12,13] Meanwhile, implementation of this technology at PMD involves certain difficulties with the calculation of ICRS parameters due to the absence of clinical recommendations.^[12,14-16]

It is quite evident that the search for an optimal method of ICRS parameters calculation is very important for providing maximal vision acuity in patients with PMD.

Purpose

The purpose of this study was to perform a comparative analysis of the effectiveness of different methods of ICRS calculation for implantation in patients with PMD.

METHODS

Forty-two patients (42 eyes) with PMD who underwent ICRS implantation were under observation. The presence of IA 3.5 D and more and keratopachymetry parameters no <400 µm, measured using Optical coherent tomography (OCT), were established as selection criteria.

Patients with corneal scars, cataracts, glaucoma, and macula dystrophy were not included in the study.

According to the peculiarities of performed treatment, all patients were divided into two groups. The 1st group consisted of 22 patients (22 eyes) to whom our own method of ICRS parameters calculation was applied, and in the 2nd group which totaled 20 patients (20 eyes), the “Keraring Calculation Guidelines” nomogram was used for the same purpose.

Our own method of calculation assumed that weakening of cornea refraction in its exterior and interior sectors requires strengthening of refractive force in the upper and lower sectors by means of implantation segment 120° long in the upper sector and 90° long in the lower sector [Figure 1].

Besides, for the calculation of ICRS height, we initially figured out the difference between the optic power of the horizontal meridian with refraction in the upper and lower parts of the vertical meridian in the 5-mm area [Figure 2].

Then, based on the received values of IA in the upper and lower parts of the cornea, the height of the upper and lower segments was additionally calculated [Table 1].

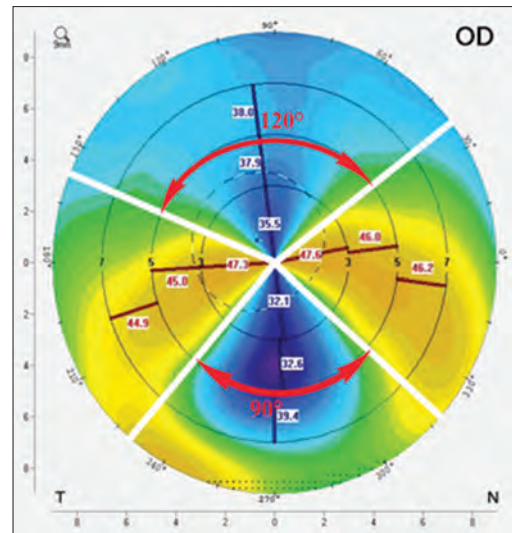


Figure 1: Intracorneal ring segments length and localization for implantation at pellucid marginal degeneration. OD: Oculus dexter

Table 1: Calculation of intracorneal ring segments thickness

IA, D	ICRS thickness (µm)
3.0–4.0	150
>4.0–6.0	200
>6.0–9.0	250
>9.0	300

IA: Irregular astigmatism, ICRS: Intracorneal ring segments

In all cases, surgery was performed under local anesthesia using 0.4% Inokain drops (oxybuprocaine hydrochloride 0.4%), Promed exports, India. A circle corneal tunnel with an inner diameter of 4.8 mm has been formed on femtosecond laser VisuMax 500 (Carl Zeiss, Germany) using the ICR program. The width of the tunnel was calculated on the basis of the following formulae: $C = A + B$, where C is the width of the tunnel in mm, A – the width of the segment basis, and B – the height of the segment (in mm). The outer diameter of the tunnel was defined as the sum of the inner diameter (4.8 mm) and 2C. Calculation of the depths of the tunnel was performed depending on keratopachymetry in the area of implantation so that it is located on 70%–80% of corneal thickness with no <120 µm residual stroma. Two linear incisions were also done in the projection of the tunnel in the inner and outer sections of the horizontal meridian using a femtosecond laser.

In all cases, either one or two IRCS made by NEP “MG” (Russia) have been implanted. Its design has a semi-sphere cross-section shape with a 5.0 mm inner diameter and 6.2 outer diameter of various arc height and length.

Segments have been implanted into the corneal tunnel using forceps and spatula. Postoperative treatment

included 0.5% levofloxacin drops four times a day for 7 days and 0.1% dexamethasone sodium phosphate drops for 4 weeks.

Baseline evaluation was performed initially, on the 1st postoperative day and 3 months later, and included examination of uncorrected distance visual acuity (VA); corrected distance VA (CDVA), spherical components of subjective refraction (SCSR) and spherical components of objective refraction (SCOR), cylinder components of subjective refraction (CCSR) and cylinder components of objective refraction (CCOR). SCOR and CCOR were evaluated using an NRK-8000 refractometer («Nikon», Japan). K_{max} was defined in the same terms using

Pentacam HD (Oculus, Germany) anterior segment analyzer.

Minimal pachymetry was measured before the procedure using the RtVue xR Avanti system (Optovue, USA), Cornea Line regimen.

The number of patients who preoperatively used spectacles for IA correction was established. Three months later, the patients were examined to identify the number of people in need of residual ametropia correction and able to tolerate it.

Statistical analysis was performed using *R* version 4.1.2 (*R* core team [2021]. <https://www.R-project.org/>) and IBM SPSS statistics, version 20, (IBM Corporation, Chicago, Illinois, USA) version 20.

Mean and standard deviations were used to present quantitative data for the analysis of the study as *me* (Q25; Q75), где *Me*—median, Q25, Q75—25th и 75th quantile. In all tests, $P < 0.05$ was considered statistically significant.

RESULTS

All operations passed uneventfully; postoperative period was unremarkable. Pre- and postoperative functional and refractive values in patients with PMD are presented in Table 2.

Analysis of data, presented in Table 2, showed that at the comparison of all initially similar indices, statistically significant intergroup differences of IR, uncorrected VA (UCVA), CDVA, CCSR, and CCOR values were found at all postoperative terms of observation ($P < 0.05$).

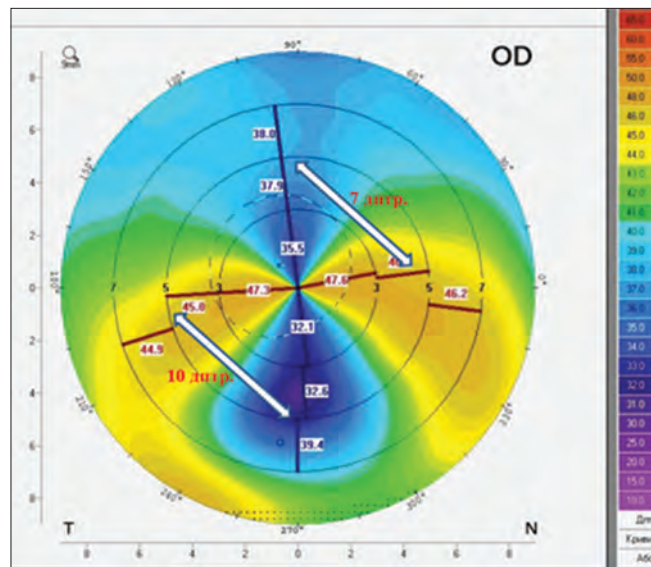


Figure 2: The difference of corneal optic power in vertical and horizontal meridians. OD: Oculus dexter

Table 2: Pre- and postoperative functional and refractive values in patients with pellucid marginal degeneration

Indices	Group	Terms of observation, median (Q25–Q75)		
		Preoperatively	1 st postoperative day	3 months
IR, D	1 (n=22 eyes)	7.75 (6.5–9.75)	1.75 (1.5–2.0)*	1.75 (1.5–2.0)*
	2 (n=20 eyes)	7.25 (5.5–9.25)	4.38 (3.63–6.75)	4.5 (3.0–6.25)
UCVA	1 (n=22 eyes)	0.08 (0.03–0.1)	0.3 (0.2–0.5)*	0.4 (0.25–0.6)*
	2 (n=20 eyes)	0.1 (0.05–0.2)	0.2 (0.1–0.3)	0.1 (0.1–0.25)
DCVA	1 (n=22 eyes)	0.5 (0.2–0.6)	0.6 (0.5–0.7)*	0.7 (0.6–0.8)*
	2 (n=20 eyes)	0.5 (0.3–0.6)	0.5 (0.4–0.6)	0.6 (0.4–0.7)
CCSR, D	1 (n=22 eyes)	–6 (–7–4)	0 (–1–0)*	0 (–1–0)*
	2 (n=20 eyes)	–5 (–6–4)	–3.25 (–4–2.5)	–3.25 (–4–2.5)
CCOR, D	1 (n=22 eyes)	–7 (–8.5–6)	–1.5 (–2–1)*	–1.5 (–2–1.5)*
	2 (n=20 eyes)	–6.5 (–8.5–5)	–4 (–6.25–3)	–4.5 (–5.75–3)
SCSR, D	1 (n=22 eyes)	–0.5 (–3–1)	0 (–2.5–0)	0 (–2–0)
	2 (n=20 eyes)	–1.75 (–3–0)	0 (–1–0)	0 (–1.5–0.75)
SCOR, D	1 (n=22 eyes)	–0.5 (–3.5–1)	–0.5 (–2.5–1)	–0.5 (–2.5–1)
	2 (n=20 eyes)	–1.75 (–3–0.75)	0 (–1.5–1)	0.5 (–1.5–1.5)

*Statistically significant intergroup differences ($P < 0.05$). CCSR: Cylinder components of subjective refraction, CCOR: Cylinder components of objective refraction, SCSR: Spherical components of subjective refraction, SCOR: Spherical components of objective refraction, UCVA: Uncorrected visual acuity, DCVA: Distance-corrected visual acuity, IR: Irregular astigmatism

The study of IR dynamics in both groups was considered the main criterion in the evaluation of treatment effectiveness. Analyzing this value, it was evident that the maximum reduction of IR median on 6D in comparison with preoperative figures happened in the eyes in the 1st group ($P < 0.05$), meanwhile decrease of IA median <3 D was found in the 2nd group ($P < 0.05$) [Figure 3]. IA median remained unchanged at the following observation terms in both groups.

Achieved refractive effect led to increase of vision acuity, but gradient of values differed among groups.

The 1st postoperative day after segment implantation was marked with UCVA elevation in both groups ($P < 0.05$). The maximal increase of UCVA had a place in the 1st group, where the UCVA median turned out to be three times greater in comparison with the initial value, and 1.5 times higher in the 2nd group ($P < 0.05$) [Figure 4].

UCVA dynamics differed in both groups in the subsequent observation terms. Thus, 3 months after the surgery, this index increased in the 1st group but remained unchanged in the 2nd group ($P > 0.05$). UCVA median was two times higher in the 1st group in comparison with the second by the end of observation.

A statistically significant increase of CDVA ($P < 0.05$) occurred in the eyes of the patients in the 1st group, while CDVA remained unchanged in the second group in comparison with initial data [Figure 5]. Both UCVA and CDVA values immensely heightened ($P < 0.05$) in the 1st group 3 months later, although the 2nd group did not show a statistically significant increase of the above-mentioned parameter ($P > 0.05$).

Change of IA values led to legitimate modifications of refractive parameters of operated eyes. Thus, a relevant decrease of CCSR on the 1st postoperative

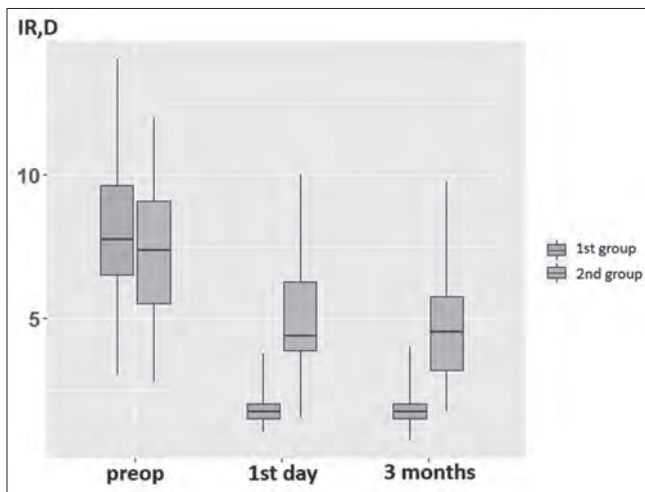


Figure 3: IR values before and after treatment. IR: Irregular astigmatism

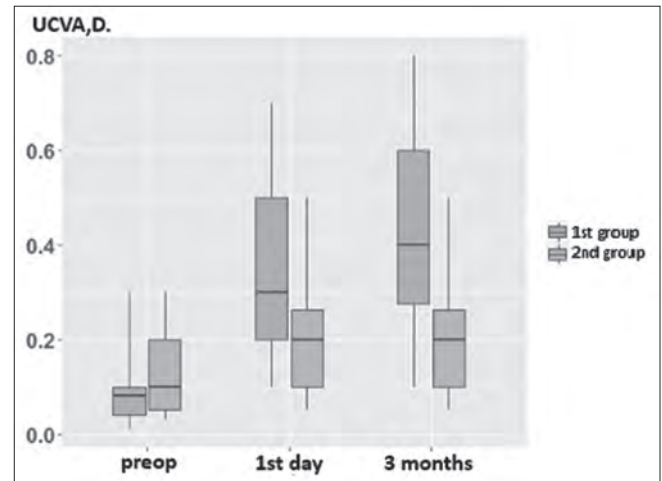


Figure 4: Uncorrected visual acuity values before and after treatment. UCVA: Uncorrected visual acuity

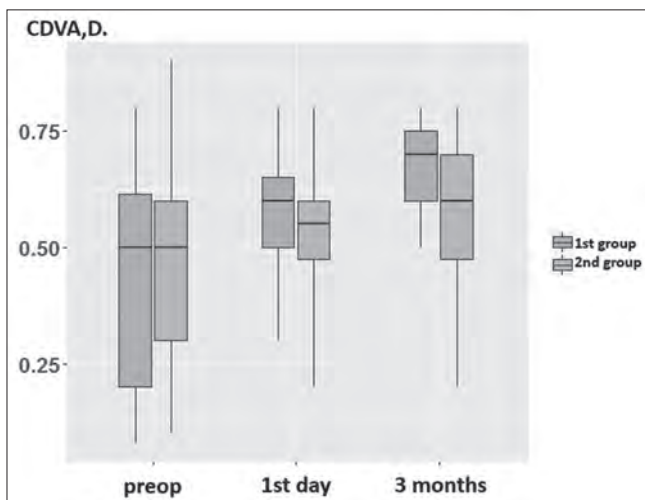


Figure 5: Corrected distance visual acuity values before and after treatment. CDVA: Corrected distance visual acuity

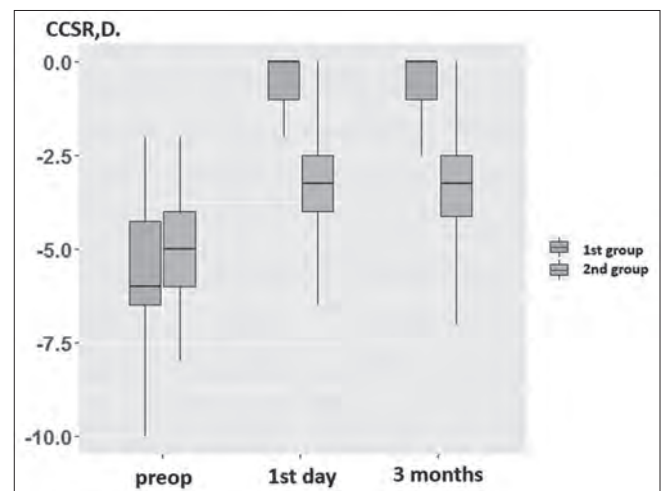


Figure 6: Cylinder components of subjective refraction values before and after treatment. CCSR: Cylinder components of subjective refraction

day was found in both groups ($P < 0.05$), but not commensurably [Figure 6]. Hence, if the median difference made 6D in the 1st group, resulting in the presence of almost physiological astigmatism, this parameter decreased only by 2.75 D in the second group ($P < 0.05$). CCSR values remained stable in both groups during the following terms of observation ($P > 0.05$).

The greatest decrease of CCOR values took place in the eyes of the 1st group on the 1st postoperative day [Figure 7], as the median differed with preoperative by 5.5 D in the 1st group and by 2.5 D in the 2nd group ($P < 0.05$). Furthermore, CCOR parameters have not changed ($P > 0.05$).

We did not reveal statistically significant differences between SCSR and SCOR values observed during all examination periods in the 1st group ($P > 0.05$) [Figures 8 and 9]. Nevertheless, a meaningful hyperopic shift of both refractive components was noticed on the 1st postoperative day after ICRS implantation in the second group ($P > 0.05$) in the absence of any considerable dynamic ($P > 0.05$).

Special attention was devoted to the aspect of the tolerance of spectacle correction by patients with PMD. Although all patients demanded spectacles for IA correction before the operation, only 19 (45.2%) patients could use them due to anisometropia and a high degree of IA. By the end of the observation period, 7 (14.2%) patients from the 1st group and 14 (70%) patients from the 2nd group required glasses correction, but only 5 (71%) patients of the 1st group and 8 (57.1%) patients of the 2nd group could tolerate them well.

The following cases are presented to prove the above-mentioned results.

Clinical case 1

Patient K., male, 42-year-old, Diagnosis: PMD OU.

Preoperatively: Vis OS = 0.05 sph-1.0 D cyl-6.0 D ax 90° = 0.2, Refractometry: Sph-1.5 D cyl-9.5 D ax 87°, Keratometry = 10.5 D IR.

The patient has undergone implantation of two ICRS, our own method was applied for calculation (120° - 300 mcm, 90° - 300 mcm).

Three months later: Vis OS = 0.2 sph-1.5 D = 0.7, Refractometry: Sph-1.75 D cyl-1.5 D ax 85°.

According to the topographic map, IA values decreased by 8.7 D compared to preoperatively examined [Figure 10].

Clinical case 2

Patient G., female, 57-year-old, Diagnosis: PMD OU.

Preoperatively: Vis OS = 0.05 sph-3.0 D cyl-4.5 D ax 95° = 0.4, Refractometry: Sph-4.75 D cyl-6.5 D ax 97°, Keratometry: 7.0 D IR.

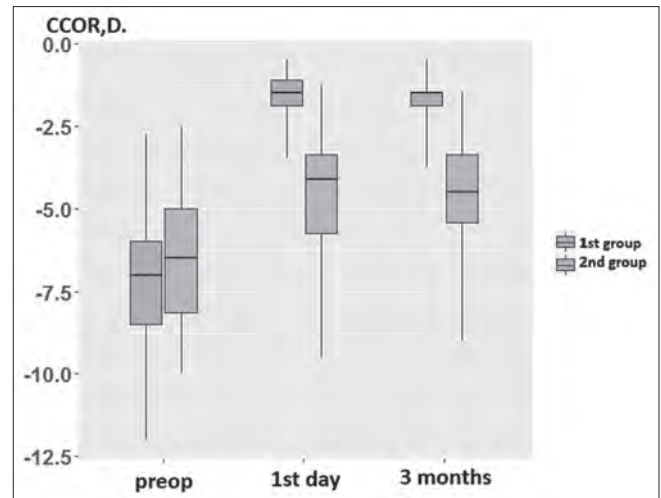


Figure 7: Cylinder components objective refraction values before and after treatment. CCOR: Cylinder components objective refraction

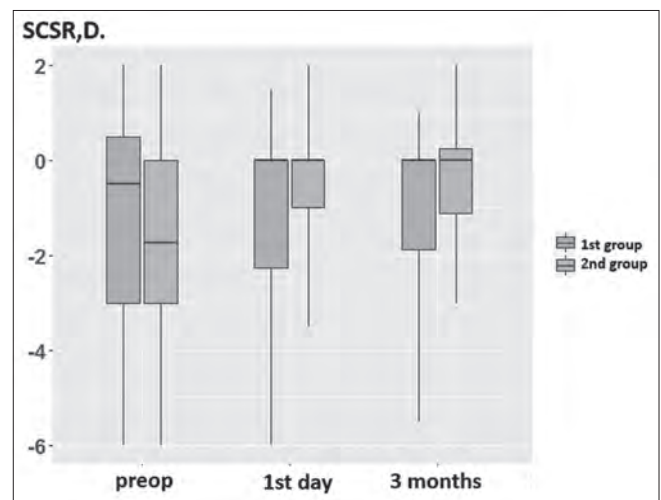


Figure 8: Spherical components of subjective refraction values before and after treatment. SCSR: Spherical components of subjective refraction

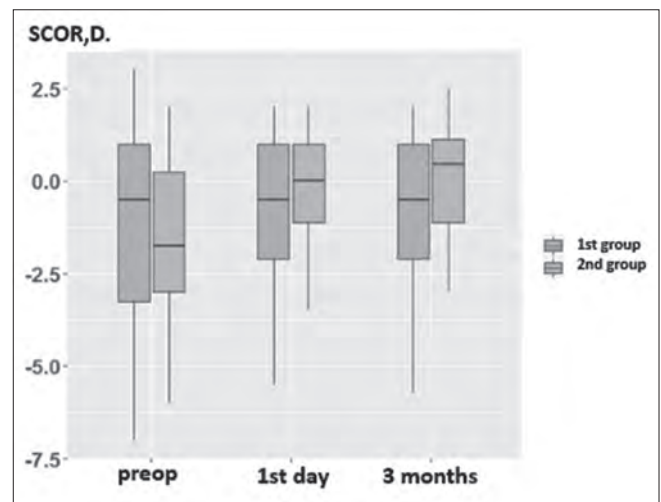


Figure 9: Spherical components of objective refraction values before and after surgery. SCOR: Spherical components of objective refraction

The patient has undergone implantation of one IRCS with length 210° and height 250 mcm, Mediphacos nomogram was applied for calculation.

Three months later: Vis OS = 0.2 Sph-1.0 D cyl-4.5 D ax 100° =0.5, Refractometry: sph-1.5 D cyl-5.5 D ax 105°.

IA values decreased by 0.3 D compared to preoperatively examined according to topographic map [Figure 11].

DISCUSSION

In summary, first of all, it is necessary to point out that the maximal number of patients ill with PMD have participated in the conducted research and were divided into two groups for performing a comparative analysis of the results of treatment. Only Kubaloglu *et al.*, in 2010,^[17] reported in their study about 16 eyes of 10 patients,

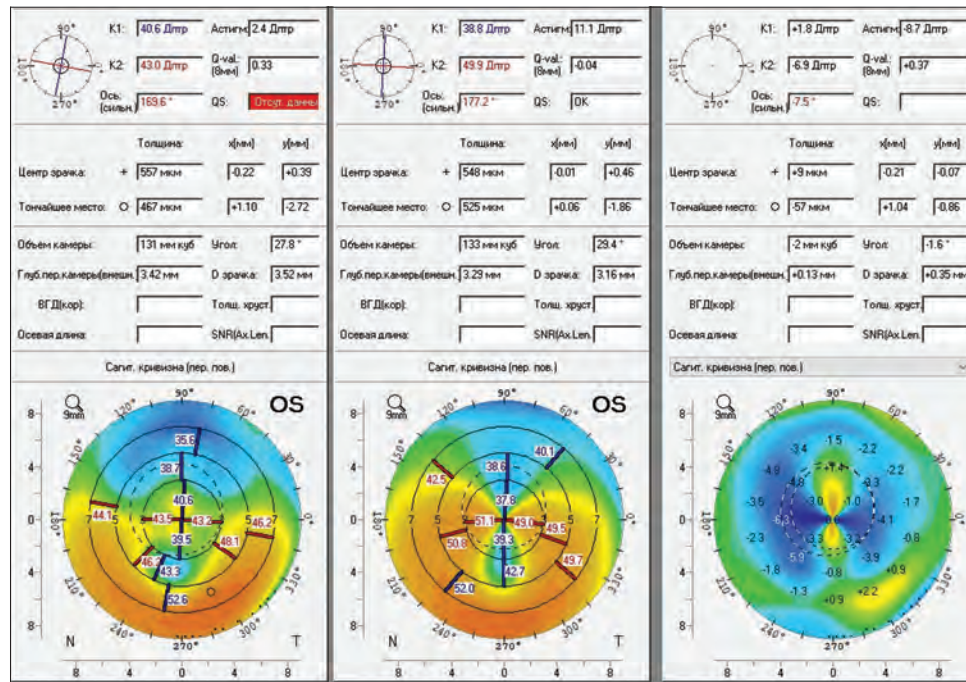


Figure 10: Topographic map of patient K. OS: Oculus sinister

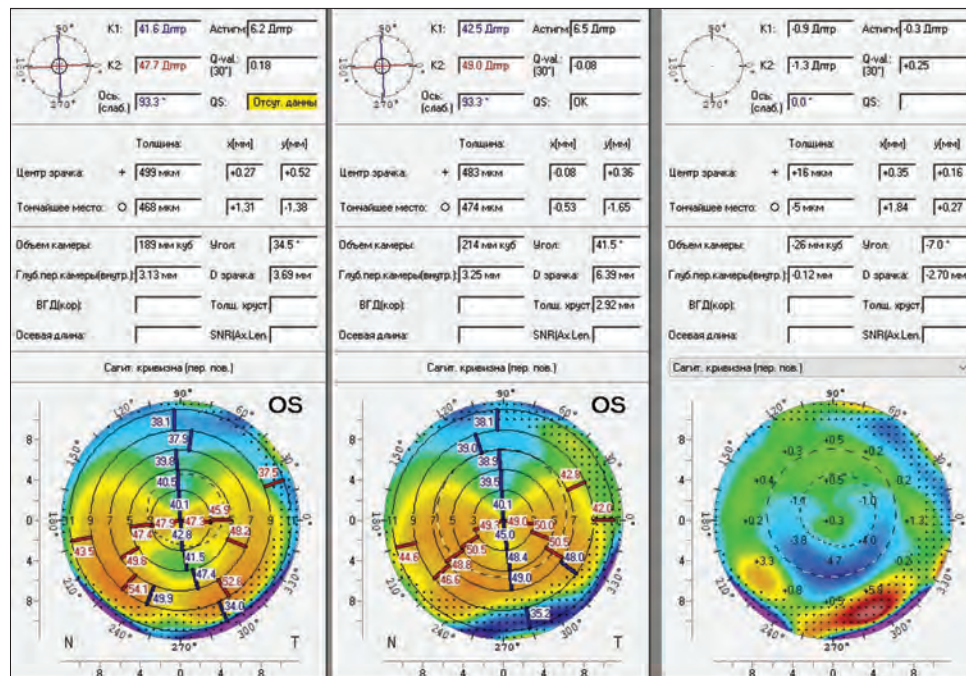


Figure 11: Topographic map of patient G. OS: Oculus sinister

which is the largest number of eyes, previously analyzed. However, neither in this nor in other works devoted to this topic, there is no comparative analysis of the effectiveness of various methods for calculating the parameters of IRCS calculation. The decrease of IR degree and increase of VA were considered the main factors of IRCS implantation effectiveness. At comparable preoperative indices, statistically significant intergroup differences of IR, UCVA, DCVA, CCSR, and CCOR values ($P < 0.05$) have been found on the 1st postoperative day and 3 months later segments implantation. This fact was the evidence of various efficiency of methods used for IRCS calculation.

As an example, the 1st postoperative day was marked by maximal lowering of IR value (decrease of median by 6 D) in the eyes of the 1st group ($P < 0.05$), while in the 2nd group, the same parameter decreased by <3 D only, compared to initial. The achieved refractive effect proves the rightness of our view on an optimal calculation of the number, thickness, and location of segments.

VA dynamic directly depended on postoperative refraction, which is why UCVA elevated in both groups on the 1st postoperative day. However, the maximal increase occurred in the 1st group, where the median of this index turned out to be three times higher compared to the initial and 1.5 times higher than in the 2nd group ($P < 0.05$).

Statistically significant almost immediate postoperative elevation of DCVA ($P < 0.05$) was also noticed in the eyes of patients of the 1st group, while the same value did not meaningfully differ from preoperative in the 2nd group ($P > 0.05$). In our opinion, this fact can be explained by the amount of postoperative astigmatism.

At analyzing the received results, such peculiarity as an increase of both UCVA and DCVA values in the eyes of the 1st group 3 months later, the performed treatment drew our attention. This phenomenon happened due to better neurosensory adaptation of patients from Group 1 against the background of less values of postoperative IR in comparison with Group 2.

All presented data concerning the dynamics of the main investigated indices testify to the greater efficacy of our own method of IRCS calculation in comparison with the Mediphacos nomogram. It can be additionally proved by the fact that the predictability of refractive effect was higher in the 1st group as we have not noticed a significant deviation of SCOR and SCSR values ($P > 0.05$), whereas both values had an obvious hyperopic shift in the eyes of patients from the 2nd group ($P < 0.05$).

CONCLUSION

1. The method of calculation of IRCS parameters for implantation in patients with PMD, developed by our team of doctors, showed high effectiveness since it allowed a decrease of IR median by 6.0 D without change of spherical components of refraction. Meanwhile, the same value dropped by 2.77 D with a hyperopic shift in the eyes where the Mediphacos nomogram was used for calculation ($P < 0.05$).
2. Newly achieved refractive status of the operated eyes allowed a significant improvement of UCVA in both groups and DCVA in the 1st group in comparison with initial values ($P < 0.05$).
3. IRCS implantation in the eyes with PMD can be considered a safe method of treatment due to the sustainability of postoperative refraction, the uneventful course of the postoperative period, and the stable position of segments in the cornea.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Impact of the Femtosecond Laser Compared to the Microkeratome in LASIK on Corneal Regularity

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ABSTRACT

Aims: Investigation of corneal parameters and regularity in the setting of laser *in situ* keratomileusis (LASIK) using a femtosecond laser and a microkeratome.

Settings and Design: This was a prospective, randomized, paired-eye comparative study.

Subjects and Methods: Ninety-six eyes of 46 patients underwent bilateral LASIK. In each patient, one eye was randomly treated with the femtosecond laser and the other eye with the microkeratome. The central evaluation was based on corneal irregularity, higher-order root mean square (HO-RMS), and other corneal parameters.

Statistical Analysis Used: IBM® SPSS Statistics version 22.0.0.0 was used to analyze the data and determine the statistical evidence.

Results: At each follow-up time point, the irregularity index for the femtosecond laser group was stable within the 3- and 5-mm zones ($P = 0.596$ and $P = 0.139$, respectively), while it was unstable in the microkeratome group ($P = 0.03$ and $P = 0.047$). Regarding the HO-RMS, there was no statistically significant difference ($P = 0.493$) before surgery. After 3 months, there was an increase in HO-RMS in the femtosecond laser group from 0.401 ± 0.179 (range: 0.11–0.89) to 0.423 ± 0.152 (range: 0.17–0.88), which was not significant ($P = 0.079$). In the microkeratome group, the HO-RMS increased from 0.415 ± 0.175 (range: 0.13–0.94) to 0.573 ± 0.242 (range: 0.13–0.94) which is significant ($P < 0.001$). The difference in HO-RMS after 3 months between the groups was also significant ($P < 0.001$).

Conclusions: The femtosecond laser induces significantly less corneal irregularities and less HO-RMS compared to a microkeratome. This potentially leads to better quality of visual acuity in the femtosecond group and better predictability.

KEYWORDS: Corneal irregularity, femtosecond laser, higher-order root mean square, microkeratome

INTRODUCTION

Refractive surgery is increasingly gaining acceptance thanks to its safety and accuracy. Laser *in situ* keratomileusis (LASIK) has widely contributed to this success, with rapid visual rehabilitation and limited postoperative discomfort (usually not more than 6–10 h). Higher refractive errors can also be corrected very well because of the high refractive power of the cornea.^[1–4]

LASIK is a corneal refractive surgical procedure that is suitable for the correction of various refractive errors such as myopia, hyperopia, regular and irregular astigmatism, and the treatment of presbyopia. A lamellar incision is

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made in the upper corneal stroma using a mechanical microkeratome or a femtosecond laser. The flap is then opened, with a hinge often located superiorly or nasally. Using an ablative laser, particularly the excimer laser, the precalculated correction profile is performed by ablation of the corneal stroma. The corneal flap is then folded back in place. Conventional LASIK with mechanical microkeratomes is now regarded as a safe and established procedure. However, even with the latest generation of microkeratomes, some inaccuracies in flap creation cannot be completely avoided, such as deviations in flap geometry, especially flap thickness.^[4] On the one hand, thick flaps can result in decreased residual stromal thickness after tissue ablation with the excimer laser, leading to an increased risk of iatrogenic keratectasia.^[5] On the other hand, mechanical microkeratomes can also produce very thin cuts or a cutting failure. This usually leads to aberrations that need to be corrected later in a further step, in addition to the correction of aberrations to improve outcomes. There are major differences between the manufacturers of mechanical microkeratomes. A few direct comparative studies between femtosecond lasers and mechanical microkeratomes can be found in the literature, but reproducibility with femtosecond lasers is significantly higher than with microkeratomes. It should be noted that in these comparative studies, the mean flap thickness selected with femtosecond laser is often significantly lower than with mechanical microkeratomes and is closer to the target value.^[4] The differences between femtosecond technology and mechanical microkeratomes in flap creation for LASIK have already been investigated, particularly with regard to the precision of the flap cut. Flap thickness is more accurate, predictable, and reproducible with femtosecond laser.^[4,6,7] However, fewer comparative paired-eye studies investigated the influence of these techniques on corneal behavior after LASIK.

The aim of this study was to evaluate important topographic parameters of the cornea after LASIK treatment during a follow-up period of 6 months and to investigate potential advantages and/or disadvantages of both flap creation technologies.

SUBJECTS AND METHODS

All procedures were performed at the ORASIS Eye Clinic in Reinach AG, Switzerland. The study was approved by the Cantonal Ethics Committee (LDV number 2006/11, Aargau) and complies with the principles of the Declaration of Helsinki. All patients gave written informed consent. We included 44 patients with 88 eyes in the study who underwent bilateral LASIK in the same session.

This was a prospective, randomized, blinded, paired-eye comparative study. We included patients with the following refractive errors: myopia from -0.75 to -7.0 ; hyperopia; and astigmatism $<+4.0$ D. Central corneal thickness was at least $520\text{ }\mu\text{m}$ or more. All patients included in the study were 21 years old or older, had normal corneal topographical findings with no suspicion of corneal ectatic diseases, and showed a stable refraction of ± 0.5 D within the last 2 years before surgery. They were excluded if they had prior cataract or refractive surgery, dry-eye syndrome, and/or amblyopia. In this study, one eye from each patient was randomly selected to undergo Femto LDV-assisted LASIK treatment (LDV), while the fellow eye was operated using the Amadeus II microkeratome (SIS Amadeus®; Ziemer Ophthalmic Systems AG).

All patients underwent baseline examinations including slit-lamp examination, manifest refraction, objective refractometry (Topcon, Tokyo, Japan), pupillometry (Procyon Instruments Ltd, London, UK), wavefront aberrometry (ZyWave, Bausch and Lomb Zyoptix; Bausch and Lomb Incorporated, Bridgewater, NJ, USA), and corneal topography (Orbscan® II version 3.0; Bausch and Lomb Zyoptix; Bausch and Lomb Incorporated, Bridgewater, NJ, USA). Patients were examined preoperatively and postoperatively at regular intervals, i.e., 1st day, 1st week, 1st month, 3rd month, and 6th month after surgery.

Optical coherence pachymetry (Technolas Perfect Vision GmbH) and confocal laser microscopy (Heidelberg Retinal Tomograph II; Heidelberg Engineering GmbH, Heidelberg, Germany) were used, respectively, to assess corneal morphology intraoperatively directly after the flap was repositioned in place and at the 1st week postoperatively. Central corneal thickness was measured using corneal topography (Orbscan II version 3.0; Bausch and Lomb Zyoptix).

Statistical analysis

Statistical Package for the Social Sciences (SPSS), International Business Machines (IBM) was used for statistical analysis. Nonparametric tests were applied whenever data were not distributed normally per Shapiro–Wilk and Kolmogorov–Smirnov tests. We applied repeated measures ANOVA test. Whenever ANOVA was significant, different groups were compared using multiple paired *t*-tests with a Bonferroni correction. The significance threshold was 5%. We used Pearson's correlation coefficient to assess linear correlations between sets of data. If not stated otherwise, data are shown as mean \pm standard deviation.

RESULTS

The preoperative mean keratometries in the LDV

and microkeratome groups were 43.8 ± 0.21 (43.4, 44.2; 95% confidence intervals, 95 CI) and 44 ± 0.24 D (43.5, 44.4), respectively. On the 1st day after surgery, they were 41.2 ± 0.4 D (40.4, 42) and 41.3 ± 0.35 D (40.5, 42). There was a statistically significant decrease in the overall keratometry postoperatively with both techniques when compared to baseline, and this was visible as early as 1 day after surgery (all $P < 0.001$). The behavior of corneal mean *K*-values remained significantly stable during the postoperative course, from day 1 to the end of follow-up, both for LDV ($P = 0.36$; repeated measures analysis of variance) and microkeratome ($P = 0.087$), in comparison to the baseline mean *K*-values. However, the femtosecond laser allowed a more stable performance between the 1st and 6th months compared to microkeratome (mean *Ks* increase by 0.21 ± 0.061 D (0.19, 0.4; $P = 0.021$), which corresponds to a 0.5% rise. We used mean differences to determine variations of the amplitude of keratometry. Delta between actual and calculated thickness during follow-up ranged from -35% to 12% (LDV) and -37% to 15% (SIS) of the difference between the preoperative and day-1 postsurgical keratometry. However, none of these values, except for the aforementioned ones, were included in either strictly positive or negative 95 CI. Furthermore, the mean postoperative keratometeries strongly correlated with the sphere power treatment data in the LDV and microkeratome groups ($P < 0.001$). Regression lines were homogeneous (Equations [1] and [2], $P = 0.184$).

$$\hat{y}_{LDV} = 43.287 + 0.916x \quad (1)$$

$$\hat{y}_{SIS} = 43.593 + 1.036x \quad (2)$$

Equations 1 and 2: Linear equations describing the correlation between predicted mean *Ks* (*y*) and laser set sphere power (*x*) during follow-up.

Sphere means power in the SIS group moderately correlated with the keratometric data preoperatively ($r = 0.310$, $P = 0.04$), and it lost this association after surgery. Conversely, in the LDV group, the mean keratometry has shown to be inversely correlated with sphere mean power from the day after surgery ($r = -0.453$, $P = 0.002$) up until 6-month postsurgical follow-up ($r = -0.571$, $P < 0.001$), even though a correlation before surgery was not found. A correlation between the keratometry and cylindrical mean power or their respective axes was not present in either group.

Irregularity index changed between the preoperative and postoperative periods in both groups. In the LDV group, the preoperative and 1st-day postoperative mean corneal 3-mm irregularity index were $\pm 1.07 \pm 0.33$ D (0.5, 2.1) and $\pm 1.77 \pm 0.73$ (0.8, 3.8), respectively. In the

microkeratome group, they were $\pm 1.12 \pm 0.36$ D (0.5, 2.0) and $\pm 1.82 \pm 0.66$ (0.7, 3.5). The differences were significant in both groups (all $P < 0.001$). The 5-mm zone increased more $\pm 1.44 \pm 0.38$ D (0.9, 2.5) and $\pm 2.72 \pm 1.18$ D (1.1, 5.2) for LDV and $\pm 1.59 \pm 0.87$ D (0.9, 5.9) and $\pm 2.53 \pm 1.12$ D (0.9, 6.1) in the microkeratome group (all $P < 0.001$). Throughout follow-up, the index did not change significantly within the 3-mm zone for patients treated with the LDV. The same effect was observed in the 5-mm area. For eyes treated with microkeratome, these zones were significantly less stable over time. In the central 3 mm, the index varied between the 1st day and the 1st week (-21.5%, $P = 0.006$) and between the 1st week and the 1st month (+15.1%, $P = 0.028$). Up to the 1st month, the highest gap between two successive follow-up intervals was 0.28 D ($P = 0.006$), versus 0.037 D in the femtosecond laser group ($P = 0.5$), for the 3-mm area. Beyond the 3-mm mark, the index decrease remained stable by the end of the 1st postoperative week ($P = 0.01$).

The mean higher-order root mean square (HO-RMS) preoperatively was 0.401 ± 0.179 (range: 0.11–0.89) for the femtosecond laser group and 0.415 ± 0.175 (range: 0.13–0.94) for the microkeratome group. There was no significant difference ($P = 0.493$). After 3 months, there was an increase in HO-RMS in the femtosecond laser group to 0.423 ± 0.152 (range: 0.17–0.88), which was not significant ($P = 0.079$). In the microkeratome group, the HO-RMS increased to 0.573 ± 0.242 (range: 0.13–0.94) which is significant ($P < 0.001$). The difference in HO-RMS after 3 months between the groups was also significant ($P < 0.001$).

The calculated ablation depth was not equal to the effectively ablated tissue during observation time, both for the SIS and LDV groups (both $P < 0.0001$). The LDV seemed more precise than the SIS, although not statistically significant, being 4% (1st day) and 11% (6 months) closer to the calculated ablation depth on average. Indeed, in the LDV group, the actual ablation represented -35.3% (-52.9, -21.8) of the calculated thickness against -39.4% (-57.9, -25.1) in the SIS at baseline, and -45.8% (-62, -33.5) against -57% (-74.8, -43.3) at 6 months. However,

Table 1: Pearson's correlation coefficients between calculated ablation thickness and actual thickness at postoperative day 1 and month 6

	1 day		6 months	
	LDV	SIS	LDV	SIS
Pearson correlation	0.559	0.753	0.660	0.798
<i>P</i>	<0.001	<0.001	<0.001	<0.001

LDV: Femto LDV-assisted lasik treatment, SIS: Sis amadeus, ziemer ophthalmic system

the correlation of actual thickness with calculated thickness remained strong in both groups throughout follow-up [Table 1]. There was a significant trend in all patients of an initial decrease in the difference between actual and calculated thickness, up until the 1st week, before linearly increasing during the rest of the follow-up.

In the femtosecond laser and microkeratome groups, minimal corneal thickness was observed at the end of the 1st week $506.5 \pm 9.9 \mu\text{m}$ (486.4, 526.6), and $518.3 \pm 8.5 \mu\text{m}$ (501, 535.6), respectively). The difference between the groups was not statistically significant ($P = 0.499$). Figure 1 shows how the minimal corneal point increases progressively after the 1st week, in both groups. In the LDV group, this progression was very stable. A slight increase of $8.9 \pm 1 \mu\text{m}$ was noted between the 1st week and the 6th month (0.005, 17.8; $P = 0.0498$), against $13.4 \pm 1 \mu\text{m}$ in the SIS group (4.9, 22; $P = 0.0003$). No other significant differences were seen between follow-up intervals (minimal $P = 0.562$). At 6 months, the corneas' thickness of patients who underwent SIS had significantly increased in comparison to all follow-up intervals (all $P < 0.05$). Furthermore, the thinnest point at the 6-month postsurgical follow-up was identical to the one obtained 1 day after surgery in the LDV group ($515.5 \pm 9.1 \mu\text{m}$ [496.9, 534], and $514.1 \pm 10.8 \mu\text{m}$ [492.2, 536], respectively; $P = 0.1$) while it significantly increased in the SIS group ($531.7 \pm 7.2 \mu\text{m}$ [517.1, 546.3], and $521.6 \pm 8.9 \mu\text{m}$ [503.5, 539.8], respectively; $P = 0.015$). With respect to paired t -tests, both comparisons of means

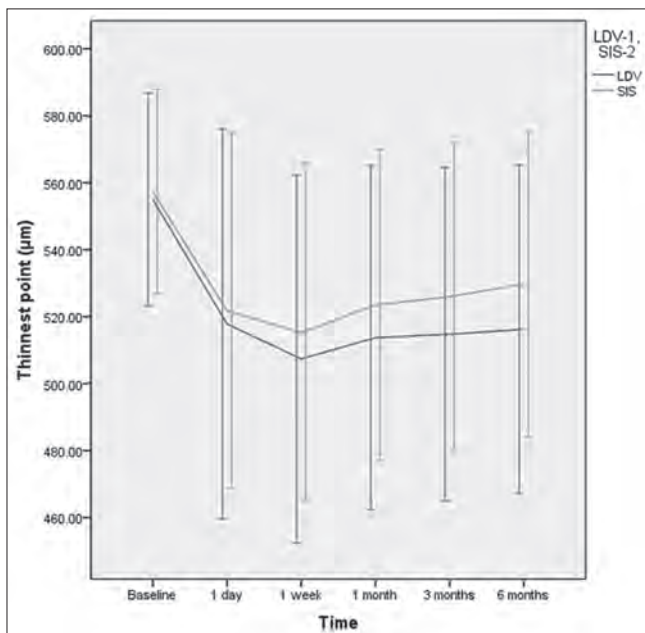


Figure 1: Evolution of the corneal thinnest point at each follow-up interval. LDV: Femto LDV-assisted lasik treatment, SIS: Sis amadeus, ziemer ophthalmic system

between the SIS and the LDV groups were similar until the 1st month, following which the thickness in the SIS group gradually increased ($P = 0.018$). The abscissa and ordinate of the thinnest points did not significantly change in this study ($P = 0.14$ and $P = 0.51$, respectively), both during the intervention and during the follow-up: respective means were $-0.005 \pm 0.1 \text{ mm}$ ($-0.2, 0.2$) and $-0.17 \pm 0.06 \text{ mm}$ ($-0.29, -0.05$), at baseline, $0.15 \pm 0.05 \text{ mm}$ ($0.05, 0.26$) and $-0.22 \pm 0.05 \text{ mm}$ ($-0.31, -0.13$), at 6 months; all $P = 0.1$. When confronting the two groups, we found the same results.

Mean kappa angle measurements at baseline and 6 months were $4.89 \pm 0.6^\circ$ (3.3, 6.5) and $4.86 \pm 0.54^\circ$ (3.5, 6.2), respectively, in the LDV group, and $5.8 \pm 0.5^\circ$ (4.6, 7.1), and $5.8 \pm 0.5^\circ$ (4.5, 7.1), at 6 months. There were no significant differences both inside the LDV and SIS groups ($P = 0.97$ and $P = 0.45$, respectively).

DISCUSSION

The thinnest areas of the cornea changed significantly during the follow-up examinations in the microkeratome group, while they remained stable in the femtosecond laser group. The coordinate system indicating the position of these points did not change throughout this study with either technique. Within the same follow-up interval, the effectively ablated tissue of all patients strongly matched the calculated ablation depth of these patients. However, the effectively ablated tissue of the same eye at each follow-up interval was never equal to the calculated ablation depth for that eye. There are no differences between groups. There are no differences in the ablation depth between the groups, as the ablation depends mainly on the excimer laser. Due to the incision and the initial hydration of the stromal bed, a relative interface edema is created. This is the case for most applications. However, if a patient has only relatively small correction, for example, a correction of 2 D and a calculated ablation of $20 \mu\text{m}$, it is quite possible that the edema initially masks the treatment-related loss of corneal tissue. However, this changes in the postoperative course as shown in our study. After the 1st week, the resorption of edema could explain the increase between actual and calculated thickness in both groups. The postoperative changes in corneal thickness in the microkeratome group show a possible effect of mechanical stress on the remodeling and proliferation phase of the cornea. The clear consistency of the kappa angle demonstrates the precision and stability of the excimer laser in creating an accurate ablation profile. The use of one of the two flap creation techniques had no influence on this value.

In addition to keratometry, irregularity index is another important parameter in the examination of corneal

topography. Irregularity index is calculated within the most important visual areas of the cornea, i.e., the zones with a diameter of 3 mm and 5 mm. These indices are measured with the corneal topography Orbscan II. Within the central zone of 3 mm, the anterior and posterior surfaces of the cornea are physiologically almost parallel. This characteristic makes it easier and more accurate to measure corneal thickness from the anterior radius of curvature alone.^[8] The 5-mm area is equated to the optical zone, which corresponds to the part of the eye that first receives all light rays relevant to vision. It lies above the entrance pupil of the iris and is 5.4 mm. This limit results from the Stiles–Crawford effect of the first kind, which describes that the relative light sensitivity of the photoreceptors of the retina decreases as one approaches the edges of the pupil.^[9]

The minimal changes in the mean keratometry values in the postoperative course compared to the surgical results showed quite stable conditions after LASIK. Minor fluctuations in the first postoperative period are caused on the one hand by the LASIK incision itself but also by excimer laser shots.^[10] The closer we get to the center of the cornea, the more unstable the 3–5-mm irregularity index becomes in the microkeratome group, and the greater the differences between the two groups.

Corneal irregularity, as we measured it topographically, accordingly, leads to increased HO-RMS even after 3 months postoperatively, but it was not significant in the femtosecond group, whereas it was highly significant in the microkeratome group. There was a significant difference between the groups in the femtosecond laser group after 3 months. This may be due to the different corneal irregularities of the two groups. Other studies confirm these results that the HO-RMS is lower in the femtosecond laser group than in the microkeratome group.^[11–13]

Both the microkeratome group and the femtosecond laser group led to very good clinical results. However, it was found that corneal irregularity and HO-RMS were significantly lower with femtosecond laser compared to microkeratome, potentially leading to better clinical outcomes with femtosecond laser.

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Conflicts of interest

There are no conflicts of interest.

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Corneal Cross-linking Combined with Refractive Surgery for the Comprehensive Management of Keratoconus: Cross-linking Plus

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ABSTRACT

The past two decades have witnessed an unprecedented evolution in the management of keratoconus that demands a holistic approach comprising inhibiting the ectatic progression as well as visual rehabilitation. The advent of corneal cross-linking (CXL) in the late 1990s resulted in long-term stabilization of the ectatic cornea along with limited reduction in corneal steepening and regularization of corneal curvature. However, CXL as a standalone procedure does not suffice in rehabilitating the functional vision, especially in patients who are unwilling or intolerant toward contact lenses. The concept of “CXL plus” was proposed which incorporates adjunctive use of refractive procedures with CXL in order to overcome the optical inefficiency due to corneal irregularity, decrease the irregular astigmatism, correct the residual refractive error, and improve functional visual outcome in keratoconus. Several refractive procedures such as conductive keratoplasty, photorefractive keratectomy, transepithelial phototherapeutic keratectomy, intrastromal corneal ring segment implantation, phakic intraocular lens implantation, and multiple other techniques have been combined with CXL to optimize and enhance the CXL outcome. The current review aims to summarize the different protocols of CXL plus, provide guidelines for selection of the optimum CXL plus technique, and aid in decision-making for the comprehensive management of cases with primary keratoconus in addition to discussing the future and scope for innovations in the existing treatment protocols.

KEYWORDS: *Corneal cross-linking plus, corneal irregularity, functional vision, keratoconus, refractive*

INTRODUCTION

Keratoconus in the past was considered a hindrance to complete visual rehabilitation and surgeons around the world resorted to spectacles, contact lenses, and corneal transplantation which were the only options available until recently.^[1] Being a noninflammatory corneal ectatic condition, it is characterized by progressive thinning of corneal stroma and central or paracentral corneal steepening leading to induced regular or irregular astigmatism and a decrease in visual acuity.^[2,3] The past two decades have witnessed an unprecedented evolution in the management of this disease with the help of advanced diagnostic techniques and newer treatment protocols.^[3] The

concept of corneal cross-linking (CXL) as a minimally invasive procedure to stabilize corneal ectatic disorders was introduced in the late 1990s.^[4] Wollensak *et al.* in 2003 reported CXL as a potential treatment for halting the progression of keratectasia and alleviating the need for corneal transplantation in keratoconus.^[5] CXL constitutes the use of riboflavin and ultraviolet A light to increase the biomechanical corneal stability and halt ectatic progression in keratoconus.^[4-7] Numerous studies have reported long-term stabilization of the

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ectatic cornea, reduction in corneal steepening, and regularization of corneal curvature with the use of CXL in keratoconus.^[7-11]

CONCEPT OF CROSS-LINKING PLUS

Management of keratoconus demands a holistic approach that comprises inhibiting the ectatic progression along with visual rehabilitation. Thus, several concerns which need to be sequentially addressed in keratoconus to ensure visual recovery include halting the keratectasia, reducing or rectifying irregular astigmatism, and correcting the residual refractive error. CXL as a standalone procedure without subsequent use of contact lenses does not suffice in overcoming the optical inefficiency due to corneal irregularity and achieving a satisfactory visual outcome. Adjunctive use of refractive procedures with CXL was proposed so as to regularize and reshape the cornea and improve functional vision in keratoconic patients.^[12,13] The term “CXL plus” coined by Kymionis in 2011 incorporates such adjuvant therapies to CXL which offer both stability and functional vision in keratoconus.^[12] Various refractive procedures targeting the corneal curvature, corneal irregularity, irregular astigmatism, and residual refractive error have been combined with CXL to optimize and enhance the CXL outcome in keratoconus. Combinations of CXL with conductive keratoplasty (CK), photorefractive keratectomy (PRK), transepithelial phototherapeutic keratectomy (t-PTK), intrastromal corneal ring segment (ICRS) implantation, phakic intraocular lens (PIOL) implantation, and multiple other techniques have been studied and suggested. The current review aims to summarize the different protocols of CXL plus, provide guidelines for selection of the optimum CXL plus technique, and discuss the future and scope for innovations in keratoconus management. This study attempts to elucidate the rationale and indication for each of the recommended CXL plus techniques and intends to aid in decision-making for the comprehensive management of cases with primary keratoconus while excluding eyes with postsurgical ectasia and other corneal ectatic diseases.

CONDUCTIVE KERATOPLASTY WITH CROSS-LINKING

CK has been described for the treatment of irregular corneas in keratoconus.^[14] This noninvasive technique involves no corneal incision.^[15,16] It works on the principle of corneal remodeling through heating of collagen fibrils at a specified temperature with radio frequency current (350 kHz) applied to selective spots in the peripheral corneal stroma at a depth of 500 μm in order to achieve the intended correction.^[15,16] Kato

et al. reported regression of visual acuity and corneal topography to the preoperative state following CK in advanced keratoconus.^[17] Kymionis *et al.* reported the combined effect of CK and CXL procedures in two patients with advanced keratoconus.^[18] CK was applied on topographically more flattened areas of the corneal periphery to steepen them and decrease the irregular astigmatism.^[18] The number of spots applied in each case depended upon the severity of irregularity and the topography.^[18] The CXL procedure was performed 24 h later in the first patient and immediately after CK in the second patient aiming to stabilize the corneal remodeling effect of CK.^[18] Nevertheless, corneal remodeling was found to be temporary despite post-CK application of CXL and regression was noticed 3 months postoperatively.^[18] This study concluded that although combining CXL with CK offered theoretical advantage, no added benefit of this combination was observed over CXL alone due to potential regression.^[18] However, Sinjab *et al.* in a retrospective exploratory cohort study noted that combined apical placement spots CK and epi-on CXL after 24 h provided a most consistent visual outcome over time.^[19]

PHOTOREFRACTIVE KERATECTOMY WITH CROSS-LINKING

The very first attempt to seek the benefits of CXL plus by conjunction of excimer laser technology with CXL was accomplished by combining topography-guided (topo-guided) PRK and CXL [Table 1]. Initially, a two-step sequential approach was presented by Kanellopoulos and Binder.^[20] The authors reported a case of keratoconus who was treated with CXL and after 1 year of corneal stability underwent sequential topo-guided PRK resulting in significant clinical improvement.^[20]

Despite the promising results of this case report, there were several limitations with this two-step approach. The ablation rate might be different in a cross-linked than in a nonoperated, virgin cornea leading to unpredictable refractive results and possible limited effectiveness of PRK. The risk of post-PRK haze formation is higher since the anterior stroma is repopulated by new keratocytes 6 months after CXL. Finally and probably, the most significant limitation of this approach is that the second-step PRK removes part of the cross-linked corneal tissue, thereby potentially decreasing the stiffening effect of CXL.

On account of these limitations, it was anticipated that simultaneous topo-guided PRK followed immediately by CXL so as to strengthen the cornea at a targeted and uniform depth may be a better approach to optimize

Table 1: Summary of outcomes with combined photorefractive keratectomy and corneal cross-linking

Author	Study design	Surgical procedure (number of eyes)	Follow-up	Outcomes
Kanellopoulos and Binder ^[20]	Case report	CXL followed by topo-guided PRK 12 months later (1)	18 months	Significant clinical improvement and stability; no complications observed
Kymionis <i>et al.</i> ^[21]	Pilot study (prospective)	Simultaneous topo-guided PRK followed by CXL (14)	10.69±5.95 months (range: 3–16 months)	Significant improvement in UDVA, CDVA, SE, defocus, and keratometry readings; no complications observed
Kanellopoulos ^[22]	Retrospective, comparative study	Sequential CXL with delayed PRK and simultaneous topo-guided PRK followed by CXL (127 and 198, respectively)	36±18 months (range: 24–68 months)	Simultaneous group performed better in all parameters (UDVA, CDVA, keratometry, SE, corneal haze); significant haze noted in 19 eyes (17 of sequential and 2 of simultaneous group)
Krueger and Kanellopoulos ^[23]	Case series	Simultaneous topo-guided PRK and CXL (2)	36 and 30 months	Reduction of spherocylindrical refraction and improvement in functional vision; no complications observed
Stojanovic <i>et al.</i> ^[24]	Case series	Topography-guided transepithelial custom ablation followed by CXL (7)	12 months	Visual, refractive, and topographic improvement; no complications observed
Kymionis <i>et al.</i> ^[25]	Prospective case series	Simultaneous topo-guided PRK followed by CXL (31)	19.53±3.97 months, (range: 12–25 months)	Significant improvement in UDVA, CDVA, SE, and keratometry; no progression of keratoconus; 16 of 31 eyes showed posterior linear stromal haze
Tuwairqi and Sinjab <i>et al.</i> ^[26]	Prospective, nonrandomized, noncontrolled study	Simultaneous topography-guided PRK and CXL (22)	12 months	Significant improvement in all study parameters (UDVA, CDVA, sphere, SE, manifest and topographic astigmatism, keratometry); no complications observed
Alessio <i>et al.</i> ^[27]	Prospective, nonrandomized clinical trial	Simultaneous transepithelial topo-guided PRK and CXL versus CXL only (17 in each group)	24 months	PRK-CXL provided better UDVA/CDVA and lower SE, spherical/cylindrical power, and keratometric values than CXL; no complications observed
Kontadakis <i>et al.</i> ^[28]	Prospective, comparative case series	Simultaneous topo-guided PRK and CXL versus CXL only (60)	39±11 months	Significant improvement in UDVA, CDVA, keratometry, SE, and defocus equivalent with significant corneal flattening in PRK-CXL group
Kanellopoulos <i>et al.</i> ^[29]	Prospective	Simultaneous topo-Guided Partial-Refraction PRK and CXL (144)	128±4 months (range: 120–146 months)	Significant and stable improvement in UDVA, CDVA, and keratometry
Kanellopoulos and Asimellis <i>et al.</i> ^[30]	Case series	Simultaneous topo-guided PRK and high-fluence CXL (231)	36 months	Visual (UDVA and CDVA) and topographic improvement; no complications observed
Kaiserman <i>et al.</i> ^[31]	Retrospective, case series	Epithelial PRK and accelerated CXL (20)	822.5±336.7 days (range: 266–1749 days)	Significant improvement in UDVA, CDVA, and keratometry; no complications observed
Shetty <i>et al.</i> ^[32]	Prospective, case series	Combined same-day topography-guided custom ablation treatment (T-CAT) followed by accelerated CXL (2)	6 months	Improvement in UDVA, CDVA, and keratometry
Shetty <i>et al.</i> ^[33]	Prospective, comparative case series	Simultaneous topo-guided PRK followed by enhanced-intensity CXL (29)	12 months	Improvement in visual and keratometric parameters

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Table 1: Contd...

Author	Study design	Surgical procedure (number of eyes)	Follow-up	Outcomes
Fadlallah <i>et al.</i> ^[34]	Retrospective, nonrandomized study	Nontopo-guided PRK and CXL (140)	24 months	Significant improvement in UDVA, SE, and mean cylinder; four eyes developed mild haze
Al-Amri ^[35]	Prospective, interventional, nonrandomized, noncontrolled case series	Nontopo-guided PRK and CXL (60)	68.20±4.71 months (range: 60–106 months)	Significant improvement in UDVA, CDVA, SE, and keratometry
Shaheen <i>et al.</i> ^[36]	Prospective uncontrolled interventional case series	CXL followed by WFG PRK 12 months later (34)	12 months	Significant improvement in UDVA, CDVA, manifest sphere, and cylinder as well as ocular HOAs
Gore <i>et al.</i> ^[37]	Prospective case series	Simultaneous transepithelial WFG PRK and accelerated CXL (47)	24 months	Significant improvement in CDVA, keratometric parameters, and coma; one eye lost ≥2 lines of CDVA
Abou Samra <i>et al.</i> ^[38]	Prospective	Simultaneous WFG PRK and accelerated CXL versus sequential WFG PRK 6 months after CXL (62)	12 months	Significant improvement in visual, refractive, keratometric, and aberrometric parameters with no significant difference between the 2 groups
De Rosa <i>et al.</i> ^[39]	Retrospective interventional study	Topo-guided PRK with 0.02% MMC immediately followed by standard CXL (15)	24 months	Promising procedure in mild-to-moderate KC, no serious complications noted

PRK: Photorefractive keratectomy, CXL: Corneal cross-linking, UDVA: Uncorrected distance visual acuity, CDVA: Corrected distance visual acuity, SE: Spherical equivalent, Topo-guided: Topography guided, HOAs: Higher-order aberrations, WFG: Wavefront-guided, MMC: Mitomycin C, T-CAT: Topography-guided custom ablation treatment

the benefits of this combined treatment. This technique was performed for the first time by Kymionis *et al.* on a contact lens-intolerant patient with pellucid marginal corneal degeneration.^[40] Kymionis *et al.* subsequently applied the simultaneous topo-guided PRK-CXL approach on patients with progressive keratoconus and reported significant improvement in all evaluated parameters including spherical equivalent (SE), defocus, uncorrected and corrected distance visual acuity (UDVA and CDVA), and keratometric values.^[21] The PRK treatment was modified (e.g. attempted correction, optical zone, and percentage of topographic customization) based on the preoperative corneal thickness (CT), corneal higher-order aberrations (HOAs), and manifest refraction to limit the maximum ablation depth at 50 µm; expected thinnest pachymetry after PRK was aimed at more than 400 µm.^[21]

The simultaneous technique seemed to overcome the drawbacks of the initial two-step CXL-PRK procedure due to its main advantage that laser ablation does not interfere with already cross-linked corneal tissue. This consideration was also confirmed with the comparative clinical study by Kanellopoulos which showed that same-day simultaneous topo-guided PRK-CXL is more effective than sequential CXL with delayed (6 months or more) PRK.^[22] Kanellopoulos recommended 70% treatment of cylinder and up to 70% treatment of

sphere so as not to exceed an ablation depth of 50 µm and achieve an expected CT of no <350 µm after PRK.^[22] The simultaneous approach was reported to be superior on account of three factors: patients' comfort, minimization of the potential stromal scarring, and preservation of cross-linked corneal stromal tissue.^[22] In another case series, Krueger and Kanellopoulos presented two cases of keratoconus who underwent simultaneous topo-guided transepithelial PRK followed by CXL and showed stability and progressive improvement over a long observation period of at least 30 months; the technique was named "Athens protocol" by the authors.^[23]

Several other studies confirmed the safety and efficacy of the simultaneous topo-guided PRK-CXL technique in keratoconic patients. Stojanovic *et al.* performed topo-guided custom surface ablation followed by CXL using transepithelial approach so as to avoid potential custom ablation planning error due to epithelial remodeling observed after traditional manual epithelial debridement.^[24] This study recommended the maximum ablation depth of 60 µm with minimum postoperative CT of 400 µm and reported stability over a period of 12 months.^[24] Kymionis *et al.* presented the long-term results of simultaneous topo-guided PRK after epithelial removal with t-PTK followed by CXL and showed significant topographic and clinical improvement

that remained stable throughout the follow-up period.^[25] Tuwairqi and Sinjab reported significant visual, refractive, and topographic improvement after simultaneous topo-guided PRK-CXL in patients with low-grade keratoconus.^[26] The ablation depth was targeted to achieve ± 1.00 diopter of emmetropia and to preserve 400 μm of stroma before proceeding with CXL, taking into account the normal thickness of corneal epithelium as 50 μm .^[26]

Two studies compared the long-term clinical outcomes of simultaneous transepithelial topo-guided PRK followed by CXL with the outcomes obtained by CXL treatment alone and reported significant improvement in UDVA, CDVA, and keratometric values in the PRK-CXL group.^[27,28] Alessio *et al.* also analyzed the corneal HOAs and showed a better reduction in root mean square values after topo-guided PRK-CXL (with a planned ablation stromal depth between 18 and 49 μm) than after CXL alone.^[27] Kontadakis *et al.* reported a keratometric improvement in both PRK-CXL and CXL alone groups, but corneal flattening was more prominent in the PRK-CXL group.^[28] Recently, Kanellopoulos confirmed the long-term safety and efficacy of topo-guided PRK-CXL (6 mW/cm^2) in a 10-year follow-up study.^[29] The significant improvement in visual acuity noticed at the 1st postoperative year was reported to be stable at the 10-year evaluation.^[29] The accelerated CXL technique used concurrently with topo-guided PRK was also reported to provide long-term stability in keratoconus.^[30,31]

Shetty *et al.* reported the results of combined same-day topography-guided custom ablation treatment followed by accelerated CXL in keratoconic patients with different types of cones and asphericities.^[32] The treatment protocol described by the authors was based on the correlation between corneal asphericity (Q) and cone location in keratoconus and was targeted to achieve the desired postoperative corneal asphericity with the stromal ablation restricted to a depth of 40 μm .^[32] Subsequently, Shetty *et al.* also evaluated the impact of keratoconus cone location on the change in refraction, corneal aberrations, and biomechanics after simultaneous topo-guided PRK and enhanced-intensity CXL (30 mW/cm^2) by comparing two groups: Group 1, cone located within the central 2-mm zone and Group 2 outside the central 2-mm zone.^[33] The authors concluded that cone location affected only visual acuity and biomechanics and reported a better improvement in CDVA in Group 1 than in Group 2.^[33]

Several studies have evaluated the efficacy of PRK (after mechanical epithelial removal) using a

nontopo-guided approach combined with CXL and have reported significant visual improvement in patients with early-stage keratoconus.^[34,35] It is also worth noting that the combination of sequential or simultaneous wavefront-guided PRK and CXL has also been studied.^[36-38]

It is palpably clear from the aforementioned studies that several recommendations in the planning of the PRK-CXL technique have been reported regarding the maximal ablation depth and the estimated postoperative CT. However, another issue that still remains a debate is the use of mitomycin C (MMC) after PRK and before CXL. In several studies, MMC has not been used (or its use is not mentioned) during PRK-CXL.^[23,26,28,29,32-34] Kymionis *et al.* have described a desolation effect of CXL on the keratocyte population in the anterior stroma with *in vivo* confocal microscopy.^[41] This effect which reduces, at least theoretically, the possibility of haze formation is considered the main reason for avoiding the use of MMC. Interestingly, De Rosa *et al.* showed a promising result in a 2-year follow-up study on 15 eyes who underwent TG-PRK with 0.02% MMC application immediately followed by standard CXL.^[39] Furthermore, other studies have described this combined technique with the use of MMC.^[21,24,25,27,30,31,35]

Recently, Kanellopoulos *et al.* introduced a novel technique based on the combined higher fluence CXL with customized PRK (Athens protocol) using ray tracing from artificial intelligence that combined data from wavefront, Scheimpflug tomography, and interferometry axial length measurements which proved to be safe and effective for managing progressive keratoconus in young adult patients.^[42]

Rationale and indication

Based on the published data, the topo-guided PRK-CXL treatment aims to stabilize the disease progression as well as normalize the corneal surface in keratoconic eyes by reducing the irregular astigmatism and potentially reducing the refractive error.^[21-23] This customized approach thus attempts to reverse the impact of corneal irregularity on visual performance of the patient. The combined topo-guided PRK-CXL treatment can be performed in keratoconic patients who have sufficient CT that allows stromal ablation at a depth within the recommended maximum limit.^[21-23] The ablation performed is used for therapeutic correction of corneal topographic irregularities and is not targeted for refractive correction; however, partial correction of refractive error can be attempted based on preoperative CT.

TRANSEPITHELIAL PHOTOTHERAPEUTIC KERATECTOMY WITH CROSS-LINKING (CRETAN PROTOCOL)

According to the conventional CXL protocol, removal of corneal epithelium is an essential step which is traditionally performed by mechanical debridement.^[5] However, corneal epithelium during CXL can also be removed by alternative techniques such as t-PTK [Table 2]. In 2010, Kymionis *et al.* were the first to describe the combination of t-PTK and CXL in a keratoconic patient resulting in significant visual and topographic improvement.^[43] The aim of t-PTK was not only to remove the corneal epithelium for the following cross-linking process but also to regularize the anterior irregular cornea.^[43] This combined technique of t-PTK-CXL has been called “Cretan protocol.”^[54] This protocol constitutes epithelial

removal by t-PTK ablation at an intended depth of 50 μm in a 6.5–7.0 mm zone; the de-epithelialized area is then enlarged by mechanical debridement till the targeted diameter of 8.0–9.0 mm followed by CXL.^[44,45]

After the first report, Kymionis *et al.* compared the two techniques for epithelial removal during CXL between two well-matched groups and showed that t-PTK-CXL resulted in better visual and refractive outcomes than conventional CXL.^[44] The improvement in UDVA, CDVA, steep keratometry, and corneal astigmatism was reported to be significant in the t-PTK-CXL group at 12 months postoperatively.^[44] In the following study, the initial encouraging outcomes of this protocol were confirmed in the long term, and significant improvement was reported at all postoperative intervals.^[45]

Table 2: Summary of outcomes with combined transepithelial phototherapeutic keratectomy and corneal cross-linking

Author	Study design	Surgical procedure (number of eyes)	Follow-up	Outcomes
Kymionis <i>et al.</i> ^[43]	Case report	t-PTK followed by CXL (1)	6 months	Visual and topographic improvement; no complications observed
Kymionis <i>et al.</i> ^[44]	Prospective, comparative, interventional case series	t-PTK (group 1) and mechanical epithelial debridement (group 2) during CXL (38)	12 months	Significant improvement in UDVA, CDVA, steep keratometry, and corneal astigmatism with t-PTK epithelial removal; no complications observed
Kymionis <i>et al.</i> ^[45]	Prospective case series	t-PTK followed by CXL (23)	33.83 \pm 10.82 months (range: 24–56 months)	Significant improvement in UDVA, CDVA, keratometric values, and corneal astigmatism; no complications observed
Kapasi <i>et al.</i> ^[46]	Retrospective, comparative	t-PTK during CXL (PTK group) and mechanical epithelial removal during CXL (mechanical group) (34)	1 month	Significant improvement in SE and astigmatism in PTK group compared to mechanical group; no complications observed
Kapasi <i>et al.</i> ^[47]	Comparative	t-PTK during CXL (PTK group) and mechanical epithelial removal during CXL (mechanical group) (34)	12 months	Significant improvement in CDVA and gain of CDVA lines in PTK group; no complications observed
Gaster <i>et al.</i> ^[48]	Retrospective, comparative study	Manual epithelial debridement and ablation via PTK followed by CXL (339)	24 months	Equivalent visual, refractive, and keratometric outcomes between the two techniques
Grentzelos <i>et al.</i> ^[49]	Prospective, comparative, interventional case series	t-PTK (Cretan protocol group) and mechanical epithelial debridement (Dresden protocol group) during CXL (30)	4 years	Significant and faster improvement in visual, refractive, and keratometric values in Cretan protocol group; no complications observed
Chen <i>et al.</i> ^[50]	Retrospective case series	t-PTK followed by high-intensity CXL (46)	21.0 \pm 7.6 months (range: 10–43 months)	Significant improvement in CDVA and keratometric values and decrease in corneal HOAs; three eyes lost ≥ 2 lines of CDVA
Shetty <i>et al.</i> ^[51]	Case report	t-PTK with topography-based ablation followed by accelerated CXL (3)	3 months	Significant improvement in CDVA in 2/3 eyes, topography-based t-PTK technique ablated less stroma and achieved comparable outcomes
Grentzelos <i>et al.</i> ^[52]	Prospective case series	t-PTK followed by simultaneous PRK and CXL (55)	12 months	Significant improvement in UDVA, CDVA, SE, and keratometry; no complications observed
Grentzelos <i>et al.</i> ^[53]	Prospective interventional case series	Simultaneous t-PTK and conventional PRK followed by CXL: Cretan protocol plus (31)	36 months	Improvement in mean UCVA, BCVA, spherical equivalent, reduced corneal astigmatism, no complications observed

t-PTK: Transepithelial phototherapeutic keratectomy, CXL: Corneal cross-linking, UDVA: Uncorrected distance visual acuity, CDVA: Corrected distance visual acuity, SE: Spherical equivalent, HOAs: Higher-order aberrations, PRK: Photorefractive keratectomy, BCVA: Best corrected visual acuity

Several other studies followed and evaluated the combination of t-PTK and CXL. Kapasi *et al.* in a short-term comparative study showed early results corresponding to the previous studies.^[46] Subsequently, another study by the same authors indicated better visual outcome 12 months after treatment with t-PTK-CXL technique.^[47] MMC was used following t-PTK ablation in both of these studies.^[46,47]

Gaster *et al.* on the contrary reported equivalent outcomes up to 24 months with both t-PTK and mechanical debridement during CXL.^[48] Despite the comparable outcomes, the improvement in CDVA in the t-PTK-CXL group was reported to be significant at the last follow-up.^[48,55] Recently, Grentzelos *et al.* in a prospective comparative long-term study confirmed the outcomes of previously published reports and concluded that t-PTK-CXL is advantageous over mechanical epithelial removal during CXL.^[49]

The effectiveness of the Cretan protocol encompassing the combination of t-PTK and accelerated CXL treatment instead of conventional CXL has also been evaluated. Chen *et al.* confirmed the efficacy of the t-PTK-CXL technique using high-intensity CXL (18 or 15 mW/cm²).^[50] Moreover, they evaluated the epithelial thickness profile and showed a more uniform regional epithelial thickness distribution after the combined treatment.^[50] Shetty *et al.* reported three cases of keratoconus management using topography-based removal of corneal epithelium combined with accelerated CXL (9 mW/cm²) and showed promising results.^[51]

Cretan protocol could also be extended and combined with conventional PRK in cases with adequate CT. Thus, in a procedure called Cretan protocol plus, t-PTK was performed as described previously in the Cretan protocol while conventional PRK was limited to a maximum ablation depth of 50 µm in a maximum zone of 5.5 mm which was immediately followed by CXL.^[52] No eye was estimated to have a CT <350 µm after combined t-PTK-PRK.^[52] In a long-term 3-year case series, Cretan protocol plus revealed a favorable outcome with improvement in postoperative logMAR mean UCVA, BCVA, reduction in mean SE, and corneal astigmatism.^[53]

The authors concluded that Cretan protocol plus is a promising alternative surgical approach in keratoconic patients with adequate CT.^[52]

Rationale and indication

As it has been thoroughly described in the published studies, t-PTK during CXL actually acts as a treatment customized for irregular corneas in keratoconus. Reinstein *et al.* have demonstrated an epithelial doughnut pattern in keratoconic corneas characterized by

localized central thinning surrounded by an annulus of thickened epithelium.^[56] Due to the epithelial doughnut pattern, t-PTK in Cretan protocol uses patient's own epithelium as a masking agent and facilitates the removal of small quantity of anterior stromal tissue on the cone apex along with the epithelium.^[44,45,56] Therefore, t-PTK during CXL additionally targets to smoothen the irregular anterior corneal stroma, decrease the corneal astigmatism, and enhance the postoperative outcome.^[44,45] It is also worthwhile to note that Cretan protocol can be performed in any case of CXL, even in those in which combined PRK-CXL procedure, could not be an option due to low CT.

INTRASTROMAL CORNEAL RING SEGMENTS WITH CROSS-LINKING

ICRS implantation, either manual or femtosecond laser assisted, aims for flattening and regularization of central cornea and therefore acts as a potential treatment option for keratoconus.^[57] In general, ICRSs induce more flattening of the corneal curvature as their thickness increases and placement gets more proximal to the visual axis.^[58,59] Due to the asymmetric cornea commonly present in keratoconus, a combination of thick (placed at the steep areas, usually inferiorly) and thin (placed at the flat areas, usually superiorly) segments may be implanted in order to gain significant corneal surface regularization.^[60] On the contrary, equal-thickness segments are suggested for managing central cones.^[61]

Even though ICRS may improve corneal irregularity and provide patients with improved visual performance, they do not consist of a "true" treatment for keratoconus, as they do not interfere with the pathophysiology of the condition.^[13] Hence, combining CXL with ICRS implantation may lead to keratoconic corneal stiffening and inhibition of ectatic progression in addition to improvement of the irregular cornea.^[13,57-61]

Several studies have reported the use of ICRS adjuvant to CXL in keratoconic patients [Table 3]. The combination of ICRS implantation and CXL was demonstrated to result in comparable or better refractive and topographic outcomes than ICRS insertion alone.^[62-64] In a study by El-Massry *et al.* femtosecond laser-assisted keraring ICRS insertion and simultaneous epi-off accelerated CXL showed a continuous improvement over 1 year.^[77]

The safety and efficacy of CXL and single or paired ICRS used adjunctively were assessed by many studies, and significant improvement was reported in UDVA, CDVA, and manifest refraction along with a significant reduction in cylinder and keratometry.^[59,65-71] A recently published clinical trial reported an improvement

Table 3: Summary of outcomes with combined intrastromal corneal ring segment implantation and corneal cross-linking

Author	Study design	Surgical procedures (number of eyes)	Follow-up	Outcomes
Chan <i>et al.</i> ^[62]	Retrospective, comparative	Intacs alone/Intacs and CXL (12/13)	102±39 days/97±38 days	Intacs with CXL showed a significantly greater reduction in cylinder, topographic lower-upper ratio, and steep and average keratometry, no complications observed
Renesto <i>et al.</i> ^[63]	Randomized clinical trial with 2 groups	Riboflavin only and ICRS 3 months later/CXL followed by ICRS 3 months later (19/20)	24 months	No significant difference was identified between groups in UDVA, CDVA, SE, and spherical or cylindrical components; no complications observed
Legare <i>et al.</i> ^[64]	Retrospective, comparative	ICRS and same-day CXL/ICRS alone (66)	12 months	Significant improvement in UDVA, CDVA, sphere, cylinder, SE, keratometry, and total HOAs in both the groups; no complications observed
Hersh <i>et al.</i> ^[59]	Prospective randomized clinical trial	ICRS with concurrent CXL/ICRS followed by CXL 3 months later (104/94)	6 months	Substantial improvement in corneal topography with no significant difference between the sequential and concurrent groups, thicker segment size, and single segment placement showed greater topographic improvement
Henriquez <i>et al.</i> ^[65]	Prospective	CXL followed by Ferrara ICRS 6 months later (9)	6 months	Significant visual improvement, reductions in SE and keratometry readings; no complications observed
El-Raggal ^[66]	Prospective, comparative	KeraRing insertion followed by CXL with a 6-month interval/2 step same-day procedure (9/7)	12 months	No significant differences in UDVA, CDVA, refractive error; however keratometric values showed greater reduction in the same-day group; no complications observed
Saelens <i>et al.</i> ^[67]	Case series	Same-day Ferrara ICRS implantation and CXL (7)	12 months	Significant improvement in SE and keratometry; inferior ring had to be removed in 1 patient because of implant migration
Ertan <i>et al.</i> ^[68]	Case series	ICRS followed by transepithelial CXL, 3.98-month interval (25)	3 months	Additional improvement in UDVA, CDVA, sphere, cylinder, and keratometry; no complications observed
El Awady <i>et al.</i> ^[69]	Prospective	KeraRing implantation followed by CXL at least 3 months later (21)	5.67±1.89 months	All outcome measurements (UDVA, CDVA, SE, cylinder, and keratometry readings) were improved after KeraRing implantation and showed further improvement after CXL; no complications observed
Sharma <i>et al.</i> ^[70]	Prospective randomized	CXL alone/CXL combined with simultaneous ICRS implantation (20/18)	12 months	CXL with ICRS yielded additional improvement in UDVA with a significant reduction in cylinder and SE; no complications observed
Yeung <i>et al.</i> ^[71]	Retrospective comparative case series	Single or paired ICRS implantation with CXL (85)	12 months	Outcomes were equivalent with single and paired implantation; no complications observed
Greenstein <i>et al.</i> ^[72]	Prospective, randomized clinical trial	Same session Intacs and CXL/sequential, Intacs followed by CXL 3 months later (158)	6 months	Total anterior corneal HOA including vertical and horizontal coma significantly improved, spherical anterior corneal HOAs increased postoperatively with no change in trefoil
Coskunseven <i>et al.</i> ^[73]	Prospective, comparative, randomized	CXL followed by ICRS (group 1)/ICRS followed by CXL (group 2); mean interval: 7±2 months (48)	13±1 months	Group 2 showed more improvement in CDVA, SE, and mean keratometry than group 1; 8 eyes had slight corneal edema with stromal opacities, which disappeared within 3 months
El-Raggal ^[74]	Comparative case series	Femtosecond-mediated channel creation using 1.5, 1.6, and 1.7 mJ power settings for ICRS insertion 6 months after CXL (15)	6 months	Although channel for ICRS can be created after CXL by modifying the femtosecond laser power, channel dissection and ICRS implantation should be performed before or concurrent with CXL; corneal haze in all eyes resolved within 6 weeks

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Table 3: Contd...

Author	Study design	Surgical procedures (number of eyes)	Follow-up	Outcomes
Kılıç <i>et al.</i> ^[75]	Case series	Same-day combined ICRS and transepithelial CXL procedure, with 20% alcohol application and riboflavin injection into the corneal channel (131)	7.07±4.66 months (range: 1–25 months)	Refractive and keratometric measurements improved in all cases; no complications observed
Alió <i>et al.</i> ^[76]	Retrospective, comparative, nonrandomized	ICRS followed by CXL (3–12 months later) either with epithelial debridement (classic group) or intrastromal pocket for riboflavin delivery (pocket group) (16/11)	12 months	No statistically significant differences between the 2 groups in any of the parameters measured (UDVA, CDVA, sphere, cylinder, and keratometry values, corneal aberrations, and corneal pachymetry); significant corneal haze in all cases which resolved over time
El-Massry <i>et al.</i> ^[77]	Retrospective noncomparative interventional study	Femtosecond laser-assisted kerating intrastromal corneal ring segment insertion and epi-off accelerated CXL (30)	12 months	Improvement in visual, refractive, and topographic; no serious complications

The Intacs and Intacs SK are manufactured by Addition Technology, Lombard, IL. The Ferrara ICRS is manufactured by Ferrara Ophthalmics Ltda, Belo Horizonte, Brazil. The KeraRing is manufactured by Mediphacos, Belo Horizonte, Brazil. ICRS: Intrastromal corneal ring segment, CXL: Corneal cross-linking, CDVA: Corrected distance visual acuity, SE: Spherical equivalent, UDVA: Uncorrected distance visual acuity, HOAs: Higher-order aberrations

in anterior corneal HOAs after ICRS implantation and concurrent or sequential CXL.^[72] However, no correlation was established between the improvement in HOAs and subjective or objective visual performance.^[72]

Several other studies with conflicting data have also been published, with respect to the optimal sequence and timing of ICRS and CXL, with the main argument being which combination may achieve superior outcomes in terms of maximizing corneal flattening.^[64-67,73-75] It seems that ICRS implantation followed by same-session or delayed CXL offers superior corneal flattening, whereas ICRS implantation following CXL (two-step procedure) limits the flattening capabilities of the ring segments as the cornea has already been fixed into a suboptimal configuration after the induced CXL stiffening.^[59,64-67,73-75] Variations in the CXL technique such as the use of transepithelial approach with application of riboflavin in the corneal channel or an intrastromal corneal pocket have also been evaluated.^[68,75,76]

A significant advantage of ICRS is the procedure's reversibility. ICRS can be safely and easily explanted from keratoconic eyes with previous CXL.^[78] Although there is a reversal of refractive outcomes, some of the topographic benefits gained from implantation may persist after explantation.^[78]

Rationale and indication

Based on the above studies, ICRS implantation followed by CXL improves the corneal curvature, decreases the irregular astigmatism, retards disease progression, and rehabilitates functional vision. This combined

approach is indicated in keratoconic patients with low spectacle-assisted CDVA due to decentered cones and high corneal irregularity.

PHAKIC INTRAOCULAR LENS IMPLANTATION WITH CROSS-LINKING

Studies have reported the use of PIOL following CXL as an alternative approach for the correction of moderate-to-high refractive error in patients with progressive keratoconus intolerant to contact lenses.^[79,80] The types of PIOL that have been implanted in keratoconic patients include both iris-fixated and posterior chambers [Table 4].^[81-87] This two-step approach was reported for the first time in 2011 by Kymionis *et al.* in a 29-year-old woman with progressive keratoconus and high myopic astigmatism who underwent toric implantable collamer lens (ICL) implantation 12 months after CXL.^[81] Significant improvement was noticed in UDVA and CDVA 3 months postoperatively and the short-term results of this combined approach were reported to be encouraging.^[81]

Two studies reported the outcomes of iris-fixated PIOL implantation following CXL.^[82,83] Izquierdo *et al.* studied the safety and efficacy of foldable anterior iris-claw PIOL implanted 6 months after CXL in eyes with progressive keratoconus.^[82] Güell *et al.* also performed toric Artiflex/Artisan PIOL implantation following CXL and confirmed the long-term stability of this combined treatment.^[83]

Other studies reported short- to long-term outcomes of Visian ICL implantation following CXL.^[84-87]

Table 4: Summary of outcomes with combined corneal cross-linking and phakic intraocular lens implantation

Author	Study design	Type of PIOL (number of eyes)	Interval between CXL and PIOL (duration of follow-up)	Outcomes
Kymionis <i>et al.</i> ^[81]	Case report	Posterior chamber: Toric Visian ICL (1)	12 months (3 months)	Improvement in UDVA and CDVA; no complications observed
Izquierdo <i>et al.</i> ^[82]	Prospective	Iris claw: Artiflex (11)	6 months (12 months)	Significant visual and refractive improvement with very low residual refractive error; no complications observed
Güell <i>et al.</i> ^[83]	Case series	Toric iris-fixated: Artiflex/artisan (17)	3.9±0.7 months; range: 3.1–5.5 months (36.9 months±15.0; range: 14–58 months)	Significant visual and refractive improvement, 94% of eyes achieved UDVA of 20/40 or better and none of the eyes lost lines of CDVA; no complications observed
Fadlallah <i>et al.</i> ^[84]	Retrospective	Posterior chamber: Toric Visian ICL (16)	6 months (6 months)	Significant visual and refractive improvement; no complications observed
Kurian <i>et al.</i> ^[85]	Prospective, case series	Posterior chamber: Visian ICL (5)	11.4±7.7 months (6 months)	Significant visual and refractive improvement; 2 eyes required adjunct ICRS implantation with CXL
Antonios <i>et al.</i> ^[86]	Retrospective	Posterior chamber: Toric Visian ICL (30)	6 months (2 years)	Significant visual and refractive improvement; no complications observed
Shafik <i>et al.</i> ^[87]	Prospective, interventional case series	Posterior chamber: Toric Visian ICL (16)	12 months (3 years)	Significant visual and refractive improvement; no complications observed

The Visian ICL is manufactured by STAAR Surgical, Monrovia, CA. The Artiflex and Artisan are manufactured by Ophtec BV, Groningen, The Netherlands. CXL: Corneal cross-linking, PIOL: Phakic intraocular lens, ICL: Implantable collamer lens, UDVA: Uncorrected distance visual acuity, CDVA: Corrected distance visual acuity, ICRS: Intrastromal corneal ring segment

Kurian *et al.* reported that although it is possible to safely correct the refractive error in keratoconus with posterior chamber PIOL, the aberrations associated with it are uncorrected by the PIOL.^[85] Antonios *et al.* evaluated the long-term clinical outcome of Visian toric ICL insertion after CXL in progressive keratoconus.^[86] Although significant visual improvement was maintained throughout the follow-up, a small hyperopic shift was observed at 2 years which did not affect the visual outcome.^[86] Shafik *et al.* evaluated the predictability, efficacy, and long-term stability of toric Visian ICL implanted 12 months after CXL and reported significant visual improvement.^[87] None of the eyes needed explantation or repositioning of the ICL during the 3-year follow-up.^[87] The decrease in endothelial cell count that was observed in the long-term studies was not significant.^[83,87] However, yearly monitoring of endothelial cell count has been recommended.^[79]

Rationale and indication

After achieving stability of ectatic progression with CXL, PIOL implantation can be performed in selective keratoconic patients having good or acceptable spectacle-assisted CDVA in addition to high refractive error with or without anisometropia. All of the aforementioned studies have reported PIOL implantation after a minimum of 3 months following CXL.^[81-87]

COMBINATION OF MULTIPLE TECHNIQUES

The combination of CXL with a single refractive procedure may sometimes lead to a partial gain of

functional vision. Therefore, surgeons have proposed combinations of two or more of the above-mentioned modalities with CXL so as to maximize the visual outcome. A multimodal approach serves to combine the desirable attributes of each of the included procedures while minimizing their individual limitations. The following combinations of multiple procedures have been reported [Table 5].

1. CXL with PRK and ICRS implantation
2. CXL with PRK and PIOL implantation
3. CXL with ICRS and PIOL implantation
4. CXL with t-PTK and ICRS implantation
5. CXL with ICRS, PIOL, and PRK (Quadruple approach).

The combination of ICRS and PRK incorporates the synergistic use of a tissue-sparing procedure and a tissue-removing procedure with CXL. PRK and CXL may be performed either sequentially or simultaneously with ICRS implantation to address the mild residual refractive error encountered following ICRS insertion in keratoconic patients.^[88-93] Despite the variations in the timing and the interval between each of the three procedures, this technique has been reported as safe and effective in providing functional visual acuity to patients with low-to-moderate keratoconus.^[88-93]

Another study evaluated the combination of Athens protocol (PRK with CXL) followed by PIOL implantation to treat the high residual refractive error

Table 5: Summary of outcomes with combinations of multiple techniques and corneal cross-linking

Author	Study design	Combined procedures (number of eyes)	Order of the procedures (duration of follow-up)	Outcomes
Kremer <i>et al.</i> ^[88]	Case series	ICRS, PRK, and CXL (45)	ICRS implantation followed by (6 months later) simultaneous wavefront-guided PRK and CXL (12 months)	Significant improvement in UDVA, CDVA, and keratometry values; no patient lost any line of CDVA; no ECD changes; Epithelial hyperplasia in 4 of 45 eyes
Coskunseven <i>et al.</i> ^[89]	Prospective	ICRS, CXL and PRK (16)	ICRS implantation followed by CXL followed by transepithelial topography-guided PRK with an interval of 6 months between each procedure (6 months)	UDVA, CDVA, SE, and keratometry values showed significant improvement; no eye lost any line of CDVA; no complications observed
Dirani <i>et al.</i> ^[90]	Retrospective	ICRS, CXL and PRK (17)	ICRS implantation followed by CXL with a 4-week interval followed by nontopography-guided PRK 6 months later (6 months)	UDVA, CDVA, SE, and keratometry values showed significant improvement; no complications observed
Al-Tuwairqi <i>et al.</i> ^[91]	Prospective	ICRS, CXL and PRK (41)	ICRS implantation followed by (6 months later) simultaneous topography-guided PRK and CXL (12 months)	Significant improvement in UDVA, SE, and keratometry values, 85% of eyes maintained or gained multiple lines of CDVA; no complications observed
Lee <i>et al.</i> ^[92]	Retrospective	ICRS, PRK, and CXL (23)	ICRS implantation followed by combined corneal WFG-PRK (transepithelial) and high-fluence accelerated CXL 1 month later (6 months)	Significant improvement in UDVA, CDVA, SE, keratometry values, and HOAs; no complications observed
Koh <i>et al.</i> ^[93]	Prospective	ICRS, PRK, and CXL (30)	ICRS implantation followed by (3 months later) simultaneous wavefront-guided PRK and CXL (12 months)	UDVA, CDVA, SE, and keratometry values improved with a reduction in HOAs; no complications observed
Assaf and Kotb ^[94]	Prospective nonrandomized	CXL, PRK, PIOL (22)	Topography-guided PRK followed by same-day CXL (Athens protocol), followed by iris claw or angle-supported PIOL implantation 2–4 months later (6 months)	Significant improvement in CDVA, SE, and keratometry values; no complications observed
Coşkunseven <i>et al.</i> ^[95]	Case series	ICRS, CXL and PIOL (14)	ICRS implantation followed by CXL (>6 months) and then toric PIOL implantation (>6 months) (12 months)	Significant improvement in UDVA and CDVA in keratoconic eyes with high refractive error; no complications observed
Dirani <i>et al.</i> ^[96]	Retrospective	ICRS, CXL and PIOL (11)	ICRS implantation followed by CXL (4-week interval) and then toric PIOL implantation 6 months later (12 months)	Significant improvement in UDVA, CDVA, SE and keratometry; no complications observed
Abdelmassih <i>et al.</i> ^[97]	Consecutive case series	ICRS, CXL and PIOL (16)	ICRS implantation followed by CXL (4-week interval) and then toric PIOL implantation 6 months later (24 months)	Significant improvement in UDVA, CDVA, SE, and keratometry; no complications observed
Yeung <i>et al.</i> ^[98]	Retrospective case series	t-PTK, ICRS and CXL (16)	Same-day t-PTK followed by single ICRS implantation and CXL (6.9±4.6 months)	Significant improvement in UDVA, CDVA and mean and steep keratometry values; no complications observed
Rocha <i>et al.</i> ^[99]	Prospective case series	t-PTK, ICRS and CXL (55)	ICRS implantation, followed by CXL and PTK (6 months)	Significant improvement in UDVA, CDVA sphere, and cylinder; no complications observed
Coskunseven <i>et al.</i> ^[100]	Retrospective interventional case series	ICRS, CXL, PIOL, PRK (11)	ICRS implantation, followed by CXL followed by PIOL followed by topography-guided PRK with interval of 6 months between each procedure (12 months)	Significant improvement in UDVA, CDVA, SE, and astigmatism; no complications observed

CXL: Corneal cross-linking, ICRS: Intrastromal corneal ring segment, PRK: Photorefractive keratectomy, UDVA: Uncorrected distance visual acuity, CDVA: Corrected distance visual acuity, PIOL: Phakic intraocular lens, SE: Spherical equivalent, ECD: Endothelial cell density, t-PTK: Transepithelial phototherapeutic keratectomy, HOAs: Higher-order aberrations, WFG: wavefront-guided

and reported improved and stabilized visual performance in keratoconic patients.^[94]

Several studies have confirmed the safety, efficacy, and long-term stability of PIOL implantation following sequential ICRS insertion and CXL in patients with moderate-to-severe keratoconus.^[95-97] PIOL implantation was targeted to correct the moderate-to-severe ametropia persistent after the initial procedures and improve the visual outcome.^[95-97]

The combination of ICRS implantation with CXL and t-PTK performed on the same day has been demonstrated as safe, effective, and predictable in patients with moderate keratoconus.^[98,99]

A recent retrospective interventional study evaluated a four-stage combined treatment comprising ICRS, CXL, PIOL, and PRK performed sequentially in the same order and confirmed the safety and efficacy of this combined approach in suitable keratoconic patients.^[100] All eyes in this series had low preoperative spectacle-assisted CDVA which improved significantly after ICRS implantation compared to improvement in UDVA.^[100] The patients underwent CXL treatment followed by PIOL implantation with an interval of 6 months between each of the procedures to correct the high residual refractive error which led to a significant improvement in UDVA and SE.^[100] The eyes were later subjected to topo-guided PRK treatment which resulted in added improvement in these parameters.^[100] The end result after the four-stage procedure showed significant improvement in visual acuity, with all eyes achieving better postoperative UDVA than preoperative spectacle-assisted CDVA.^[100]

LASER *IN SITU* KERATOMILEUSIS XTRA, SMALL INCISION LENTICULE EXTRACTION XTRA, AND PHOTOREFRACTIVE KERATECTOMY XTRA

Laser *in situ* keratomileusis (LASIK) Xtra is a modified procedure that combines LASIK with prophylactic accelerated CXL for the correction of refractive error in an attempt to decrease the risk of postoperative corneal ectasia. Similarly, the combination of small incision lenticule extraction (SMILE) and PRK with CXL termed as SMILE Xtra and PRK Xtra, respectively, has also been reported with the same rationale. These procedures are mainly used in patients with high refractive error or borderline corneal parameters seeking refractive correction and therefore have not been extensively discussed as it is beyond the scope of the current study.

Several studies reported comparable results in terms of safety, efficacy, and predictability between LASIK Xtra and conventional LASIK [Table 6].^[101-105] Despite

the initial supportive evidence, long-term studies are required to determine whether LASIK Xtra is beneficial in preventing postoperative keratectasia.^[103,105] Tomita *et al.* demonstrated insignificant changes in corneal biomechanics after LASIK Xtra as compared to LASIK.^[101] Kohnen *et al.* reported topographic and refractive stability with no signs of keratectasia at 12 months postoperatively in both LASIK Xtra and conventional LASIK groups and showed no advantage of LASIK Xtra over LASIK.^[104] Taneri *et al.* reported a case of unilateral corneal ectasia that developed 2 years after LASIK Xtra.^[111]

Studies have evaluated the initial safety and efficacy of SMILE Xtra at 1–2 years postoperatively.^[106-108] In a comparative study, a slight trend toward myopic shift after SMILE Xtra has been reported.^[107] Although SMILE Xtra has been safely used in forme fruste keratoconus, the authors have mentioned the need for longer duration of follow-up and larger sample size to fully confirm these findings.^[109] Sachdev *et al.* demonstrated the initial safety and efficacy of PRK Xtra in myopic eyes with thinner pachymetry and tomographic abnormalities at 1 year postoperatively.^[110]

Rationale and indication

Although the use of adjuvant accelerated CXL after LASIK, SMILE and PRK in eyes with thin corneas, borderline topography and high refractive error has been presented in several aforementioned studies, there is no long-term evidence supporting their role in the prevention of keratectasia. As a result, due to the paucity of long-term studies and lack of conclusive evidence regarding the efficacy of these protocols in preventing ectasia, currently, PIOL implantation may be preferred over corneal procedures in such susceptible eyes for refractive correction.

GUIDELINES FOR SELECTION OF CROSS-LINKING PLUS TECHNIQUE

In patients with documented keratoconus progression, CXL is required in order to increase the corneal biomechanical stability and thus halt the ectatic process. Although CXL alone might improve the vision and few corneal parameters to some extent, the majority of patients, with moderate to advanced keratoconus, will still require adjunctive refractive therapies for resolving the corneal irregularities and enhancing the visual outcome. For this reason, combined CXL treatments (CXL plus) are gaining more ground and popularity in order to provide a better quality of life to keratoconic patients.

To date, no algorithm exists for determining the most efficient and effective CXL plus protocol for

Table 6: Summary of outcomes with laser *in situ* keratomileusis Xtra, Small incision lenticule extraction Xtra, and photorefractive keratectomy Xtra

Author	Study design	Surgical procedure (number of eyes)	Follow-up	Outcomes
Tomita <i>et al.</i> ^[101]	Contralateral eye, comparative case series	LASIK in one eye and LASIK Xtra in contralateral, nondominant eye (24)	12 months	No significant differences in UDVA, CDVA, MRSE, ECD, CH, and CRF were found between the 2 procedures
Wu <i>et al.</i> ^[102]	Prospective controlled clinical trial	LASIK Xtra versus LASIK (96)	6 months	No statistically significant differences in UDVA, CDVA, MRSE, keratometry, pachymetry, and ECD; 2 eyes lost one or more lines in the LASIK-Xtra group
Low <i>et al.</i> ^[103]	Retrospective	LASIK Xtra versus LASIK (100)	5.7 months (range: 1.5–13.3 months)	No significant difference in UDVA and efficacy and safety indices between the 2 groups
Kohnen <i>et al.</i> ^[104]	Prospective, randomized, fellow eye-controlled clinical trial	LASIK Xtra versus LASIK (52)	12 months	No statistically significant differences in UDVA and MRSE between the 2 procedures
Seiler <i>et al.</i> ^[105]	Prospective, comparative study	LASIK Xtra versus LASIK (152)	12 months	One month postoperatively, 5 eyes in LASIK Xtra group lost 1 line of CDVA compared with 1 eye in LASIK only group; refractive improvement was similar
Ganesh and Brar ^[106]	Prospective	SMILE Xtra (40)	12 months±28.12 days	No complications like haze, keratitis, ectasia, or regression were observed; no eye-loss lines of CDVA
Ng <i>et al.</i> ^[107]	Prospective, comparative interventional	SMILE Xtra/SMILE (21/32)	6 months	No eye lost ≥1 line of CDVA with good safety and efficacy indices in SMILE Xtra
Osman <i>et al.</i> ^[108]	Retrospective, comparative interventional	SMILE Xtra/SMILE (30/30)	24 months	Significantly higher UDVA, CDVA, MRSE, and CRF in SMILE Xtra group
Graue-Hernandez <i>et al.</i> ^[109]	Prospective, interventional, case series	SMILE Xtra in forme-fruste keratoconus (15)	24 months	No intraoperative or postoperative complications observed
Sachdev <i>et al.</i> ^[110]	Interventional comparative case series	PRK Xtra/PRK (109/118)	12 months	No iatrogenic ectasia or hyperopic shift noted in the PRK Xtra group; no significant difference in CDVA or incidence of haze

LASIK: Laser *in situ* keratomileusis, SMILE: Small incision lenticule extraction, PRK: Photorefractive keratectomy, UDVA: Uncorrected distance visual acuity, CDVA: Corrected distance visual acuity, MRSE: Manifest refraction spherical equivalent, ECD: Endothelial cell density, CH: Corneal hysteresis, CRF: Corneal resistance factor

each individual patient. The treatment needs to be planned and customized after taking into consideration many parameters such as patient's age, refractive status, personal needs, stage of keratoconus, disease progression rate, corneal irregularity, and willingness or tolerance toward spectacle and contact lenses.^[112] Combined CXL treatment protocols are indicated in patients with documented progression of the disease showing unsatisfactory visual function or aversion/intolerance toward contact lenses and spectacles. In eyes with cones located within the central 2-mm zone, the combination of CXL with topo-guided PRK and/or t-PTK appears to be the most appropriate treatment approach in an attempt to both stabilize keratoconus progression and regularize the anterior corneal surface.

The prerequisites for combining CXL with laser ablation techniques are maximum stromal ablation depth of up to 50 µm and predicted postoperative thinnest pachymetry of more than 400 µm.^[21,24] In more advanced cases where the safety requirements regarding CT are not met and in eyes with cones located outside the central 2-mm zone, simultaneous ICRS implantation and CXL seem to provide satisfactory results in terms of disease stabilization, corneal reshaping, and reduction of irregular astigmatism. In addition, the two-step approach of CXL followed by PIOL implantation after an interval of 3–6 months offers a promising alternative for patients with high residual refractive errors (myopia and regular astigmatism) and ectatic progression. The aforementioned combined treatment techniques may

also be used in stable keratoconic cases or keratoconus suspects with nonsatisfactory visual function (contact lens/spectacle intolerance, irregular astigmatism, high refractive error, etc.) in order to improve their refractive profile without causing biomechanical destabilization of the cornea. Finally, in order to further enhance refractive outcomes of CXL plus, a triple or quadruple approach can also be performed by combining multiple refractive techniques with CXL. Nevertheless, further studies are required in order to draw definite conclusions regarding their safety, efficacy, and long-term stability.

FUTURE OF CROSS-LINKING PLUS

Although CXL remains the gold standard for halting the ectatic process, it does not offer the advantage of fully addressing the refractive component of keratoconus. For this reason, a plethora of combined treatment protocols, as presented above, have been introduced in clinical practice, but no definitive management strategy has been described yet. Several parameters need to be further explored in order to standardize treatment planning and improve predictability, especially that of combined CXL and laser ablation techniques. Till date, no algorithm has been developed that takes into account all the possible factors (patient's age, refractive status, personal needs, keratoconus stage, etc.) affecting the final refractive outcome of combined CXL protocols. The future aim is to develop nomograms that can incorporate all the aforementioned parameters and help in achieving highly accurate and predictable refractive results. Further prospective long-term randomized controlled studies are required for the development of customized CXL plus techniques that can be individualized as per each patient's status and needs.

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There are no conflicts of interest.

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Conversion of a Foldable Intraocular Lens into a Scleral Dumbbell Tuck Lens for Aphakia

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I read with interest and surprise an article on the comparative study of the visual outcome of a newly designed scleral tuck lens and suture-fixated lens for the rehabilitation of aphakia by Shah *et al.*^[1] as I was contemplating the creation of the same lens.

Carleval intraocular lens (IOL) for sutureless scleral fixation inspired in me the idea of a “trans-scleral plug” creation in any foldable IOL which can be suspended with the sclera without any sutures.

SURGICAL TECHNIQUE OF CREATING A DUMBBELL SUTURE TUCK FOLDABLE INTRAOCULAR LENS

Any single-piece foldable lens can be used for this lens creation. The surgical steps are simple and are very repeatable and reproducible in minutes on the OT table when you encounter a large posterior rent with vitreous loss and inadequate capsular support for a posterior chamber IOL. This IOL is very useful in eyes where there is traumatic aphakia with extensive loss of iris tissue, hence an iris-claw or anterior chamber IOL (ACIOL) insertion is not possible.

This involves creating a hole in the haptic of a single-piece acrylic IOL using 5/0 prolene suture needle. A 4-mm length of suture is cut to create a plug with a bulbous tip created with a heat cautery (pre-Yamanization of haptics) on both ends of the haptics of the single-piece acrylic IOL. This modified IOL with the dumbbell plugs on each haptic is folded and loaded in a butterfly cartridge.

The foldable modified lens is inserted into the anterior chamber using an IOL injector over the iris diaphragm after an adequate anterior vitrectomy is performed. Then, one tip of the bulbous dumbbell plug is pulled out with 23G forceps inserted from the 3 o'clock sclerotomy using a handshake maneuver [Video 1]. The dumbbell single knob is gingerly out through a beveled scleral opening 1 mm posterior to the limbus at 3 and 9 o'clock on both sides. The two plugs are covered by the scleral flaps without any sutures and the conjunctiva is apposed over. The two plugs hold the lens like a hammock tied to the tree and lie a two struts for the scleral fixation of the IOL.

This technique shows the ease of creation of a novel scleral tuck lens from any single-piece foldable lens which can be used in the management of complications of a posterior capsular rent (without capsular support for IOL insertion) when backup lenses are not available.

The similar creation of dumbbell tacks is easier in a PMMA scleral support IOL with two holes in the haptic for 4/0 prolene suture insertion and the creation of dumbbell knobs using a heat cautery.

ADVANTAGES

1. Any single-piece foldable IOL can become a scleral tuck lens (except the Rayner design of foldable IOL)

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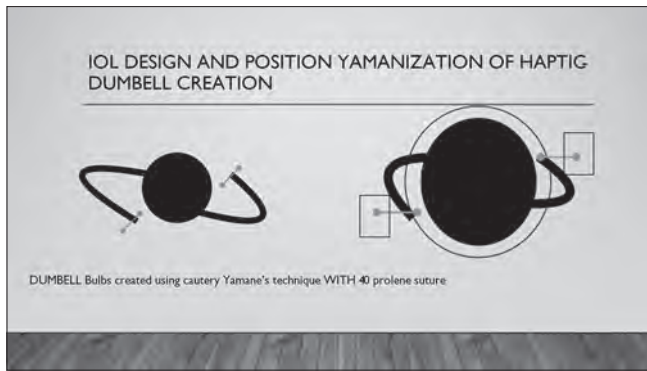


Figure 1: Acrylic IOL

2. A three-piece IOL is not needed for standby for the Yamane technique, nor is the need for an iris-claw and ACIOL backup lenses
3. There is no learning curve for this procedure and no necessity for extra instruments other than a 23G max grip vitreoretinal forceps
4. A good anterior vitrectomy and exact markings

of 3 and 9' o clock at 1 mm from the limbus are extremely important to prevent lens tilt

5. The IOL lies in the ciliary sulcus; hence, the iris chafing is not a complication
6. The polene bulbs are subsceral in location.

CONCLUSION

This new IOL creation is a simple and reproducible technique for scleral dumbbell suture support IOL. [Figure 1]

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Conflicts of interest

There are no conflicts of interest.

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Lens Status: A Protective Factor for Endothelium during Phacofragmentation Following Posterior Nucleus Drop during Phacoemulsification

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ABSTRACT

Purpose: The purpose of the study was to evaluate the effect of phacofragmentation on the corneal endothelium following complicated phacoemulsification surgery and to compare the endothelial cell loss between eyes with aphakia and pseudophakia during the procedure.

Materials and Methods: This is a prospective interventional comparative case series. Patients who were referred to our center for phacofragmentation with nucleus drop following complicated phacoemulsification surgery were recruited. They were divided into two groups: Group 1 included patients in whom an intraocular lens (IOL) was placed in the sulcus during the primary cataract surgery and Group 2 included those who were left aphakic. Corrected distance visual acuity (CDVA), intraocular pressure (IOP), corneal clarity, and endothelial cell count (ECC) were recorded before and after phacofragmentation and were analyzed.

Results: Pre-phacofragmentation CDVA, IOP, and ECC were comparable between the two groups. Endothelial cell loss at 1 week, 1 month, and 3 months was 4.01%, 6.14%, and 7.99% in Group 1 and 6.39%, 8.68%, and 10.66% in Group 2 patients, respectively. Severe corneal edema was seen on day 1 postoperative period in nine patients in Group 2 compared to 3 in Group 1. Significant IOL decentration was seen in two patients in Group 2 and none in Group 1.

Conclusion: Patients who were pseudophakic during phacofragmentation had significantly less endothelial cell loss and better corneal clarity. IOL decentration was common when IOL was inserted during the phacofragmentation procedure. Hence, it is advisable to place the IOL whenever possible during the primary surgery before referring the patient to a vitreoretinal surgeon.

KEYWORDS: *Complicated cataract surgery, nucleus drop, phacofragmentation*

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INTRODUCTION

Posterior dislocation of the lens is the complete dislocation of the crystalline lens or its fragments from the patellar fossa into the vitreous cavity. It is one of the major intraoperative complications of phacoemulsification surgery.^[1] It can also be encountered in other types of cataract surgeries also, but the rate has increased significantly in the past two decades as more surgeons have converted to phacoemulsification surgery. Surgeons are particularly prone to this complication during the learning

curve^[2] as the incidence of the dropped nucleus with experienced surgeons is significantly less than that with inexperienced surgeons.^[3,4] Posteriorly, dislocated lens matter could be just cortical matter, nuclear fragments, or the entire nucleus or lens. Cortical matter drop produces a higher grade of inflammation but gets

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absorbed on its own and surgical intervention is not required in most cases. On the contrary, pure nucleus matter produces minimal inflammation and stays in the vitreous cavity for a very long time, and can lead to complications such as cystoid macular edema and retinal detachment. The nucleus or nuclear fragment dislocation is a potentially serious complication of phacoemulsification.^[5,6] Two studies from India have reported 0.4%^[3] and 0.8%^[4] incidence of nucleus drop following phacoemulsification. Risk factors predisposing to nucleus drop are posterior polar cataracts, hard cataracts (Grade 3 or 4), total cataracts, radial tears in capsulorhexis, surgeries performed under topical anesthesia, vitrectomized eyes, and high myopia.^[4] The aim of managing a posteriorly dislocated lens is to improve the visual acuity of the patient and reduce intraocular inflammation, corneal edema, and prevent glaucoma. Spontaneous resorption occurs in small cortical or nuclear fragment drops (<25% of the lens material).^[7] Surgical management is the mainstay of treatment in most cases of the posteriorly dislocated lens.

Phacofragmentation provides a significant gain in visual acuity in cases of posteriorly dislocated lens unless complications occur during the procedure. Increased endothelial cell loss is common in these cases due to complicated primary cataract surgery and multiple subsequent intraocular procedures. The surgeon aims to minimize endothelial cell loss as much as possible. Hence, the objective of our study was to analyze the endothelial cell loss in patients who were pseudophakic or aphakic at the time of the phacofragmentation and the role of intraocular lens (IOL) insertion at the time of primary complicated cataract surgery.

MATERIALS AND METHODS

It is a prospective interventional comparative case series conducted at a tertiary eye care center. Ethical clearance was obtained from the institutional review board (Ref No. IESC/T-106/February 25, 2015, RT-24/July 22, 2015), and the study was conducted in accordance with the tenets of the Declaration of Helsinki. Patients referred to our center following complicated phacoemulsification with a nucleus drop were recruited. Patients below the age of 18 years, traumatic or other secondary cataracts, associated ocular comorbidities such as glaucoma or endothelial dystrophies, the interval between cataract surgery and phacofragmentation more than 3 weeks, severe corneal edema, and an IOL placed other than in sulcus during primary surgery (anterior chamber IOL, Iris claw lens, scleral-fixated IOL) were excluded from our study.

Patients were divided into two groups based on their IOL status, and written informed consent was obtained from all patients. Group 1 had patients in whom three-piece IOL was placed in the sulcus during the time of the primary phacoemulsification surgery and then referred for phacofragmentation. Group 2 included patients who were left aphakic during the primary complicated cataract surgery.

Preoperative assessment was made following admission to our center. The intraoperative details of the primary cataract surgery, such as intraoperative cumulative dissipated energy during phacoemulsification and vitreous loss during the surgery, were not available. Data gathered for analysis were age, sex, and the interval between complicated cataract surgery and phacofragmentation. All patients had a complete ophthalmic examination which included preoperative corrected distance visual acuity (CDVA), intraocular pressure (IOP) using noncontact tonometry, detailed slit-lamp examination, and indirect ophthalmoscopy. The grade of the nucleus was recorded from the previous records. The size of the dropped nucleus was determined as a comparison to the total size of a nucleus, and media haze was recorded according to the endophthalmitis vitrectomy study as visualized through indirect ophthalmoscopy.^[8] Endothelial cell count (ECC) was measured using noncontact specular microscopy (SP 3000P, Topcon Medical Systems, Inc.) the day before the surgery.

Surgical technique

All patients underwent 23-G three-port pars plana vitrectomy with phacofragmentation (Constellation, Alcon Laboratories, Inc.). Pars plana vitrectomy with phacofragmentation was done by an experienced vitreoretinal surgeon. Routine vitrectomy steps, such as core vitrectomy followed by triamcinolone-assisted posterior vitreous detachment and peripheral shave vitrectomy, were performed. Perfluorocarbon liquid around the macula was used in all cases to protect the macula from lens fragments and ultrasonic energy. 20-gauge phacofragmotome was inserted into the eye through a separate 20-G microvitreoretinal blade entry that was made superiorly. The 20-G port was closed with Vicryl sutures immediately after the removal of all lens matter, and the remaining steps of the surgery were carried out. A foldable, hydrophobic, acrylic, three-piece IOL (AcrySof MA60AC, Alcon Laboratories, Inc.) was placed in the sulcus in all patients who were aphakic (Group two patients) during phacofragmentation surgery after completing vitrectomy and removing the fragments. All patients were left under air tamponade at the end of surgery.

Postoperative evaluation

Postoperative CDVA, IOP, and slit-lamp examination were done on day 1, 1 week, 1 month, and 3 months. Corneal edema on day 1 was graded according to the Oxford Cataract Treatment and Evaluation Team (OCTET) grading.^[9] Corneal edema was defined as an increase in central corneal thickness with or without Descemet folds. The OCTET grades corneal edema as transient corneal edema (+), transient corneal edema with Descemet membrane folds of <10 (++), and transient corneal edema with Descemet membrane folds of >10 (+++). ECC was done at 1 week, 1 month, and 3 months to determine the percentage of endothelial cell loss over time. IOL decentration was noted by slit-lamp retroillumination, and the visibility of any edge of the optic in an undilated pupil was considered a significant amount of decentration.

Statistical analysis

The abovementioned data were entered in Microsoft Excel 2007 spreadsheet and were analyzed using SPSS for Windows software (SPSS version 23.0, International Business Machines Corp. Armonk, New York, USA). The mean, median, mode, standard deviation data, maximum, and minimum of each variable were calculated, and differences between groups were tested using the two-sample *t*-test for parametric data and two-sample Wilcoxon rank-sum test (Mann–Whitney) for nonparametric data. The level of statistical significance was $P < 0.05$.

RESULTS

The study comprised a total of 40 patients of which 20 patients had IOL implanted during their primary complicated cataract surgery and now underwent phacofragmentation surgery (Group 1) and 20 patients who were left aphakic during the primary surgery and underwent vitrectomy with phacofragmentation surgery and IOL implantation (Group 2). CDVA, IOP, corneal edema, and ECC have been recorded pre- and postphacofragmentation surgery and were analyzed.

The mean age of the patients in Group 1 was 62.55 ± 6.29 years (range: 48–76 years) and in Group 2 was 62.8 ± 6.81 years (range: 50–77 years). The two groups were comparable in terms of age with $P > 0.05$ (0.90 with *t*-test). There were 10 women (50%) and 10 men (50%) in Group 1 and 11 women (55%) and 9 men (45%) in the second group. The interval between the primary phacoemulsification surgery and the phacofragmentation surgery was 12.95 ± 5.66 days in Group 1 and 13.1 ± 5.7 days in Group 2. The difference was not significant between the two groups ($P = 0.96$). The media haze, size of the dropped nucleus, and grade of the nucleus were comparable in both groups [Table 1].

Endothelial cell loss after phacofragmentation at 1 week, 1 month, and 3 months was 4.01%, 6.14%, and 7.99% in Group 1 and 6.39%, 8.68%, and 10.66% in Group 2 patients ($P = 0.0014$, 0.0016, and 0.0031), respectively. CDVA and IOP did not significantly differ between the groups at a 3-month follow-up. Table 2 shows the comparison between the pre- and postphacofragmentation CDVA, IOP, specular count, and endothelial cell loss between the groups.

Transient corneal edema with Descemet membrane folds of >10 (+++) based on OCTET grading was noted in nine patients in Group 2, whereas only in three patients in Group 1. Table 3 shows the comparison of 1st postoperative day corneal clarity between the groups. Significant IOL decentration was noted in two patients in Group 2 [Figure 1], whereas no patients had IOL

Table 1: Preoperative parameters - media haze, size of the dropped nucleus, and grade of the nucleus

Parameter	Group 1 (n=20)	Group 2 (n=20)	P
Media haze			
0	2	3	0.72
1	3	6	
2	7	6	
3	8	5	
Size of nucleus			
¼	5	5	1
½	8	8	
¾	3	4	
Total	4	3	
Grade of nucleus			
2	8	7	0.83
3	10	9	
4	2	4	

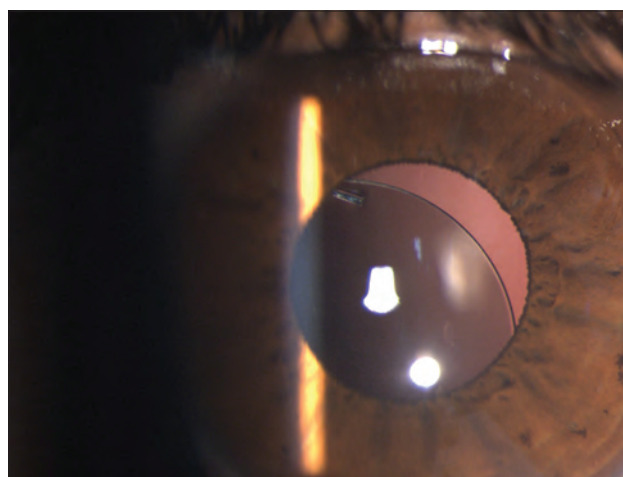


Figure 1: Clinical photograph of decentred three-piece intraocular lens (IOL) in a patient who underwent IOL implantation during the phacofragmentation surgery. We can see the optic edge in an undilated pupil suggesting significant decentration

Table 2: Pre- and postoperative corrected distance visual acuity, intraocular pressure, specular count, and endothelial cell loss

Parameter	Group 1	Group 2	P
Preoperative CDVA (LogMAR)	1.152±0.63	1.37±0.68	0.29
3 rd month CDVA (LogMAR)	0.25±0.14	0.312±0.20	0.34
Preoperative IOP (mmHg)	21±12.9	17.75±7.23	0.75
3 rd month IOP (mmHg)	15.6±3.57	15.1±2.71	0.62
Preoperative specular count (cells/mm ³)	2470.65±171.77	2443.95±317.01	0.74
Specular count at 1 week (cells/mm ³)	2370.9±158.18	2291.1±326.74	0.33
Specular count at 1 month (cells/mm ³)	2317.95±149.88	2236.05±324.94	0.31
Specular count at 3 months (cells/mm ³)	2272.95±158.14	2187.95±320.06	0.29
Endothelial cell loss at 1 week (%)	4.01±1.01	6.39±3.3	0.0014
Endothelial cell loss at 1 month (%)	6.14±1.53	8.68±3.06	0.0016
Endothelial cell loss at 3 months (%)	7.99±1.66	10.66±3.39	0.0031

CDVA: Corrected distance visual acuity, IOP: Intraocular pressure, LogMAR: Logarithm of the minimum angle of resolution

Table 3: Postoperative day 1 corneal clarity (Oxford cataract treatment and evaluation team grading)

OCTET	Group 1 (n=20)	Group 2 (n=20)
+	Four patients	Three patients
++	13 patients	Eight patients
+++	Three patients	Nine patients

+ transient corneal edema; ++ transient corneal edema with DM folds <10; +++ transient corneal edema with DM folds >10 OCTET: Oxford cataract treatment and evaluation team

decentration in Group 1. No other complications were noted in either group.

DISCUSSION

Endothelial cell loss and corneal decompensation are common complications following complicated cataract surgeries with subsequent multiple intraocular surgeries. The effect of placing the IOL during the primary complicated cataract surgery and its benefit of protecting the corneal endothelium during the subsequent phacofragmentation surgery has been analyzed in our study.

The baseline parameters (age, sex, the interval between the two surgeries, IOP, and ECC) between the groups were comparable. The grade of corneal edema, size of the dropped nucleus, and the grade of the nucleus, which could affect the energy dissipated during the phacofragmentation and the duration of phacofragmentation surgery, was also found to be comparable between the groups. In our study, the final visual outcome of the two groups was comparable to both pre- and postphacofragmentation. A study by Lashgari *et al.*^[10] concluded that those with better previtrectomy visual acuity and patients who were left aphakic at the time of cataract surgery were associated with good visual outcomes postoperatively. However, this difference was not found in our study. The 1st-day

specular count could not be measured in most cases due to corneal edema. The mean endothelial cell loss in the 1st week was 5.21%. Endothelial cell loss in aphakic group patients was significantly more compared to that of the pseudophakic at 1 week, 1 month, and 3 months. Similar findings were reported by Takkar *et al.*,^[11] in which the endothelial cell loss following vitreoretinal surgeries was evaluated. Other studies have also concluded increased endothelial loss without a physical barrier between the anterior segment and the vitreous cavity.^[12,13] Rofagha and Bhisitkul^[14] concluded that the primary intraoperative goals of the cataract surgeon in a complicated cataract surgery must be the removal of accessible lens material from an anterior approach, removal of the vitreous from the anterior segment, and to place an anterior or posterior chamber IOL in the same setting as emphasized in our study.

In our study, we have hypothesized that the lens acts as a physical barrier between the anterior and posterior segments, preventing the fluid currents and ultrasonic power of the phacofragmentation probe from disperse to the anterior segment, thereby affecting the corneal endothelium. Second, manipulations in the anterior chamber while inserting the IOL following phacofragmentation also add insult to the endothelium. In a study by Binkhorst,^[15] they had discussed profound aqueous turbulence by saccadic ocular movements because of the lack of stabilizing effect of the lens-zonule barrier. They also discussed “turbulence endotheliopathy” in eyes that underwent intracapsular cataract extraction and the role of endophthalmodiodesis in corneal endothelial insult. Although our study evaluated phacofragmentation in the presence of posterior chamber IOL, other studies have shown combined pars plana vitrectomy and phacofragmentation with ACIOL or iris claw lens also to be effective with good results, but long-term results were lacking.^[16,17] A

study by Margherio *et al.*^[18] concluded that BCVA in eyes undergoing vitrectomy for retained lens fragments with posterior chamber IOL *in situ* were better than those with ACIOL which was better than the aphakic eye.

IOL decentration was more common in the second group due to the presence of air tamponade in these patients, which tends to push the IOL inferiorly. IOL insertion during the primary surgery could achieve centration as the primary surgeon could exactly manipulate the IOL over the sulcus and fibrosis starts to set in, leading to minimal disturbance in the position of IOL during the second surgery.

None of our patients in either group had cystoid macular edema. Although, a study by Cohen *et al.*^[19] showed that the sulcus placed IOL at the time of cataract extraction, which was associated with a reduced risk for CME. The mean time to development of CME in their series was 4 months.

CONCLUSION

Endothelial decompensation is an important complication following complicated cataract surgery and vitrectomy surgery. The presence of an IOL seems to be one of the most important factors for endothelial protection. IOL placement by the primary surgeon not only decreases the surgical time and surgical manipulation during phacofragmentation surgery but also decreases the occurrence of IOL decentration.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Effortless Endocapsular Nucleus Scooping Technique of Soft Cataract Phacoemulsification

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ABSTRACT

Purpose: The purpose of the study was to evaluate the safety and efficiency of innovative techniques of performing hydrodelineation for phacoemulsification of the nucleus and visco-assisted hydrodissection for aspiration of epinucleus in the management of soft cataracts.

Design: This study involves a retrospective study in a tertiary eye care center.

Materials and Methods: Medical records of 22 eyes from 22 patients with a clinical diagnosis of soft cataract (lens opacities classification system <2), who underwent phacoemulsification with hydrodelineation and visco-assisted (2% hydroxypropyl methylcellulose) hydrodissection, were reviewed. Centurion phacoemulsification system (Alcon Laboratories, Inc.) with active fluidics and active sentry handpiece was used with vacuum parameters at 80–575 mm Hg and an aspiration flow rate of 12–45 mL/min all in linear mode. The primary outcome measures were cumulative dissipated energy (CDE), ultrasound time (UST), amount of fluid used, and surgical complication of posterior capsular tear.

Results: All 22 cases were completed successfully without any complications and intraocular lens implantation in the bag. The mean CDE was 1.12 ± 1.38 , with mean total UST for phacoemulsification 8.88 ± 9.52 s. No case observed any intraoperative complications.

Conclusion: Phacoemulsification with hydrodelineation and visco-assisted hydrodissection in soft cataracts is a nonfragmentation/nonchopping technique. It is a simple, safe, faster, surgeon-friendly technique for soft to mildly denser cataracts and can be practiced by novice surgeons.

KEYWORDS: *Fast, low vacuum, novice surgeon, phacoemulsification, soft cataract*

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INTRODUCTION

Phacoemulsification has been the most accepted and commonly practiced surgery for cataract extraction with various modifications since its introduction in 1967 by Kelman.^[1] To enhance the safety and effectiveness of the procedure, considerable advancements in phacoemulsification procedures and technology have taken place.

Phacoemulsification utilizes ultrasound energy to break the nucleus into emulsate for aspiration, making cataract extraction possible through a small incision.^[2] The most important step in the surgery associated with the use of phaco energy is the nucleus breakdown, initially termed

“nucleofractis” by Gimbel, who devised the “divide and conquer” technique.^[3] Since then, various modifications of the technique have been made according to the hardness of cataracts and surgeon practices. Various fragmentation or cracking techniques have been described for all grades of cataract, but chopping soft cataracts can be challenging due to relatively smaller, less dense endonucleus, lack of rigid cleavage planes, and abundant sticky soft cortical components.^[4] Therefore, several nonfragmentation approaches for soft

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lens extraction have been described, requiring different maneuvers, and customized instruments.^[5-11]

We describe a simple technique for nucleus emulsification and en masse epinucleus removal in soft cataract.

MATERIALS AND METHODS

This was a single-centered observational study conducted at a tertiary care-level hospital. The protocol adhered to the tenets of the Declaration of Helsinki and received approval from the institutional ethics committee. Written informed consent was taken from all patients for the surgery.

Surgical technique

This technique was applicable for soft cataracts graded lens opacities classification system III nuclear opalescence and nuclear color 2 or less, any grade of posterior subcapsular cataract or cortical cataract.

All surgeries were performed by a single experienced cataract surgeon (A.K.J) under topical anesthesia. The surgeries were performed using the centurion phacoemulsification system (Alcon Laboratories, Inc., Fort Worth, TX, USA). Initial steps were the same as the standard phacoemulsification procedure, including two side port incisions and one main port incision using 1.2 mm and 2.2 mm keratome, respectively. The anterior chamber was formed using a dispersive viscoelastic agent and 5.0 mm capsulorhexis was made. Hydrodissection was done to separate the cortex from the capsule, followed by complete hydrodelineation, cleaving the epinucleus from the cortex with a [Figure 1a]. Limited

visco-dissection was done using 2% hydroxypropyl methylcellulose. The phaco tip was introduced into the anterior chamber in the bevel up position, and the superficial cortex and the epinucleus at the central 5 mm are aspirated. Then, a 45° bent Kelman phaco tip was embedded in the center of the endonucleus using a low vacuum (80 mmHg, linear mode) [Figure 1b] and the nucleus separated from epinucleus assisted by spatulated side instrument [Figure 1c]. The endonucleus was then phacoemulsified in the bag, leaving a cushion formed by the continuous rim of the soft epi nucleus behind it, decreasing the risk of damage to the posterior capsule. The parameters used were 380 mmHg vacuum and 40 mL/min aspiration flow rate in linear mode with torsional phacoemulsification. The epinucleus layer was removed en masse [Figure 1d] using the phaco tip assisted by a side instrument under low vacuum (220 mmHg) and low flow rate along with low power (up to 20% torsion) settings, which might be used only a few times, though. Then, cortical material removal and polishing of both anterior and posterior capsules were done, followed by intraocular lens (IOL) implantation in the bag, visco-aspiration, and hydration of ports [Video 1].

RESULTS

A retrospective analysis of the first 22 eyes with soft cataracts undergoing phacoemulsification between October 2021 and August 2022 was performed.

All cases were completed successfully by the above-described technique without any complication and IOL implantation in the bag.

The mean cumulative dissipated energy was 1.12 ± 1.38 . The mean total ultrasound time for phacoemulsification was 8.88 ± 9.52 s. The total estimated fluid aspirated was 72.05 ± 26.52 mL. The average total case time was 13.03 ± 8.07 min. No case was observed of any intraoperative complications such as anterior capsule tears, posterior capsule ruptures, or zonulysis. No case reported any postoperative complications. No case required conversion to another phacoemulsification technique.

DISCUSSION

Soft cataract extraction can be challenging and may not be as straightforward as it first appears, especially for beginners who may face some difficulties in surgery and might end up with unexpected complications.

Our technique offers the advantage of in-the-bag phacoemulsification with minimal damage to the corneal endothelium, minimal use of ultrasound energy, less time

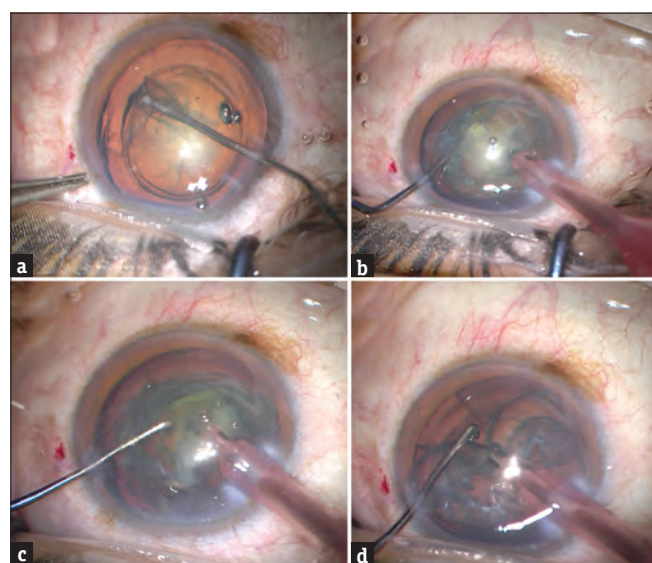


Figure 1: (a) Hydrodelineation and a complete hydrodissection; (b) Nucleus impaled with phaco tip; (c) Nucleus scooped out in the bag only and separated from epinucleus using a second instrument; (d) En masse epinucleus aspiration

consuming, no risk of posterior capsular rupture without any stress on zonular apparatus, and easy cataract extraction that can be practiced even by novice surgeons.

Phacoemulsification of soft cataracts by routine nucleotomy techniques such as stop and chop, divide, and conquer, and direct chop is challenging as chopping is not attained easily in these cataracts. The fragmentation requires a good hold of tissue to chop or divide it, but in soft cataracts, due to a less dense endonucleus and softer cortex, the phaco tip cuts through the nucleus, leading to early break of occlusion and nucleus aspiration, leading to the formation of undivided nuclear bowl, with increased risk of phaco tip hitting posterior capsule.^[2,3]

Various surgical strategies have been described to deal with these issues. Mechanical fragmentation techniques, including hydro-chop, visco-fracture, and V-slice techniques, have been described to cleave soft nuclei before phaco power is required to reduce overall phaco energy. However, complete nuclear division might not be achieved in all cases, limiting the use of these techniques.^[12-14] In the “Tilt and crush” technique, the whole nucleus is engaged with a phaco probe under a high vacuum and is tilted vertically in the anterior chamber followed by mechanical crushing between the second instrument and the phacoemulsification tip which might cause damage to corneal endothelial cells.^[11]

The above technique is a safe and effective method for soft cataract removal. It requires adequate hydrodissection and hydrodelineation that delineates the nucleus from the thick epinucleus, allowing appropriate management of both layers. There is lesser consumption of phaco power as a small nucleus, which has already been outlined, is gripped with a phacoemulsification tip under a low vacuum setting, scooped out using a blunt spatulated manipulator, and then phacoemulsified. Corneal endothelial damage is also minimal because of lower ultrasonic energy usage, lesser ultrasound energy time consumption, safe zone in-the-bag phacoemulsification, and maintaining a distance from endothelium. Moreover, there is no risk of posterior capsular tear/rupture during nucleus maneuvering as there is no direct chopping or sculpting, non-usage of sharp instruments, and the formation of a thick epinuclear shell cushion behind it that protects the posterior capsule. Furthermore, the risk of hitting the anterior capsule and extension of capsulorhexis generally associated with traditional chopping techniques is not there.

Several other nonfragmentation and nonchopping techniques have been reported [Table 1]. Phaco rolling and windmill techniques both use high vacuum for nucleus emulsification.^[6,10] All these procedures impose a greater risk to posterior capsular integrity.

Table 1: Comparison of various soft cataract phacoemulsification techniques

Technique	Capsulorhexis size	Hydrodis section	Hydrodelineation	Sculpting	Technique	Plane of phacoemulsification	Vacuum
Our technique	5 mm	Yes	Yes	No	En masse nondividing technique	Endocapsular	Low (380)
RAPID	5 mm	Yes	No	No	En masse nonfragmentation technique	Multiplanar	Routine (475)
Phaco rolling	>5 mm	Yes	Yes	No	Nonfragmentation/ nonchopping	Endocapsular	High
Bowl and Snail	>5 mm	Yes	Yes	Required	Nonchopping	Endocapsular	Very low (120)
Rock “n” roll		Yes	Yes	Required (fan-shaped)	Nonchopping	Suprascapular/ pupillary plane	Routine
Endocapsular carousel technique	5 mm	Yes	Yes	No	Carouseling with a specialized phaco tip	Endocapsular	High (425)
Phaco windmill	5–5.5 mm	Yes	Yes	No	Nonfragmentation/ nonchopping	Endocapsular	Moderate to high (350–500)
Onehanded revolving technique	5.5 mm	Yes	No	No	Nonfragmentation/ nonchopping	Endocapsular	Routine
Tilt and crush	Oval	Yes	No	No	Modified chopping technique	Suprascapular	High
Stop and press	-	Yes	No	Central groove	Occlusion-free modified stop-and-chop technique	Endocapsular	Low

Sculpting approaches such as “bowl and snail,” and “Rock n roll” techniques employ sculpting a deep central bowl followed by emulsification of a C-shaped nuclear rim with rotation and fan-shaped sculpting of the nucleus followed by flipping and posterior surface emulsification, respectively.^[4,5] One-handed revolving technique requiring only a phaco tip without a side port includes endonucleus removal followed by piecewise epinucleus removal after creating multiple peripheral grooves using a phaco tip with a limitation of at least 5 mm of capsulorhexis for this method.^[9] A recently described “RAPID” technique requires coordinated maneuvering of phaco probe impaled nucleus in a circular manner to move it out of the bag away from the posterior capsule into the anterior capsule plane or iris plane with feasibility only in soft cataract and adequate sized capsulorhexis.^[8] The “Stop and Press” technique is a modification of the stop and chop method where the nucleus is cracked into two hemisections after making a central groove, and each hemisection is chopped without using occlusion by ultrasound power but by stabilizing the nucleus between phaco tip and capsule.^[15]

CONCLUSION

This is a simple, effective, and safe phacoemulsification technique, especially for soft-to-mild denser cataracts with good reproducibility.

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Conflicts of interest

There are no conflicts of interest.

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Quantification of Anterior Chamber Angle in North Indian Population Using Scheimpflug-based Corneal Tomographer

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ABSTRACT

Objectives: Primary angle closure glaucoma shows faster clinical progression as compared to open-angle glaucoma. Hence, its early diagnosis is crucial so that prophylactic peripheral iridotomy can be done. The current gold standard for anterior chamber angle (ACA) assessment is gonioscopy but is invasive and requires skilled operators, limiting its widespread use. The objective of this study is to evaluate Sirius⁺ Scheimpflug tomographer as a screening method for the diagnosis of gonioscopically narrow ACA.

Materials and Methods: A comparative cross-sectional analysis of ACA and related parameters among glaucoma patients using dual Scheimpflug analyzer Sirius⁺ was done. Sirius⁺ measurements were correlated with gonioscopically closed angle and open angles to determine statistical significance. This clinical study included 80 eyes of 40 patients reporting to the ophthalmology department with raised intraocular pressure.

Results: The mean ACA recorded for open-angle eyes was $39.05^\circ \pm 5.91^\circ$ and was $25.92^\circ \pm 4.46^\circ$ for narrow-angle eyes ($P < 0.0001$). The Pearson correlation coefficient revealed a significant correlation of Sirius⁺ parameters (ACA, anterior chamber volume [ACV], aqueous depth, horizontal anterior chamber diameter, and lens rise) with gonioscopically closed angles (Shaffer's grade 2 or below) which was further confirmed by receiving operator characteristic analysis wherein areas under curve revealed excellent discriminant power of ACA, ACV, lens rise, and aqueous depth in detecting closed angles.

Conclusions: Scheimpflug-based tomography offers objective measurements, enhancing the reliability of ACA evaluation. The study employed the technology to quantify the ACA and highlighted the statistically significant Sirius⁺ parameters that can be exercised for screening and early diagnosis for patients with angle closure glaucoma.

KEYWORDS: Angle closure, anterior chamber angle, glaucoma, gonioscopy, Scheimpflug, Sirius⁺, tomography

INTRODUCTION

The anterior chamber angle (ACA) is a critical anatomical structure in the eye responsible for the outflow of aqueous humor, the fluid that nourishes and maintains the intraocular pressure (IOP). A wide and open ACA is typically indicative of normal ocular physiology and function, reducing the risk of angle-related complications. Primary angle closure glaucoma (PACG) shows faster progression clinically as compared to

primary open-angle glaucoma (POAG).^[1] Diagnosis of PACG relies on early examination and identification of iridotrabecular contact in individuals with raised IOP so that prophylactic laser peripheral iridotomy can be done.^[2] Thus, assessment of ACA is important to determine the type of glaucoma.^[3]

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Traditionally, the evaluation of ACA has relied on invasive techniques such as gonioscopy, which involves direct visualization of the angle structures using a specialized contact lens. While gonioscopy remains the gold standard for ACA assessment,^[3] its invasiveness and requirement for skilled operators limit its widespread use, particularly in primary care settings. As a result, there is a growing demand for noninvasive imaging modalities that can provide accurate and reproducible measurements of ACA parameters. Imaging devices, such as anterior segment optical coherence tomography (AS-OCT), ultrasound biomicroscopy (UBM), and Scheimpflug imaging, have been used to grant a more impersonal and precise assessment of the ACA.^[4-6]

In recent years, Scheimpflug-based corneal tomography has emerged as a promising tool for anterior segment imaging. This technology utilizes a rotating camera system to capture high-resolution images of the cornea and anterior chamber, allowing for the precise measurement of various anterior segment parameters, including ACA width, depth, and morphology. Sirius+ combines Placido Disk topography with Scheimpflug tomography of the anterior segment providing information on pachymetry, elevation, curvature, and dioptric power of both corneal surfaces over a diameter of 12 mm.

Several studies have demonstrated the utility of Scheimpflug-based corneal tomography in assessing ACA parameters in different populations and clinical settings. For example, a 2014 study investigated the repeatability and reproducibility of ACA measurements obtained using a Scheimpflug-based device and found excellent agreement between repeated scans, highlighting the reliability of this technology for clinical use.^[7] Similarly, a 2015 study evaluated the diagnostic performance of noncontact screening methods for detecting narrow angles and angle-closure disease, reporting high sensitivity and specificity compared to gonioscopy.^[8]

Despite the growing body of evidence supporting the use of Scheimpflug-based corneal tomography in ACA assessment, there remains a paucity of data regarding its application in specific populations, such as patients in North India. The Indian subcontinent is known for its diverse genetic makeup, environmental factors, and socioeconomic disparities, which may influence ocular anatomy and physiology. Furthermore, the prevalence of certain eye diseases, including angle-closure glaucoma, varies across different regions of India, underscoring the importance of region-specific studies to guide clinical practice and public health interventions.

This study aims to address this gap in knowledge by conducting a comprehensive clinical investigation to quantify ACA parameters using Scheimpflug-based corneal tomography among patients in North India. By characterizing the normative values and variability of ACA parameters in this population, we seek to enhance our understanding of ocular anatomy and pathology in the region, ultimately improving diagnostic accuracy, treatment outcomes, and vision-related quality of life for individuals at risk of angle-related eye disorders.

MATERIALS AND METHODS

The aim of this study is to evaluate Sirius+ Scheimpflug tomographer as a screening method for the diagnosis of gonioscopically narrow ACAs. A comparative cross-sectional analysis of ACA and related parameters among glaucoma patients in North India using dual Scheimpflug analyzer Sirius+ was done at a tertiary care eye center from May 2023 to January 2024 (9 months) after taking institutional-based ethics clearance. All the patients with IOP = or >20 mmHg (unknown/known cases of glaucoma – NTG/POAG/PACG) with age more than 21 years, and having a family history of glaucoma were included as the study population. Exclusion criteria included history of any intraocular surgery, anterior segment laser treatment in the past, secondary glaucoma, neovascular glaucoma, or patients with limbal defects and other disorders limiting the observation of peripheral anatomy of the anterior segment. Certain strategies were adopted to eliminate confounding error:

1. Gonioscopy performed by a single examiner masked to Scheimpflug findings
2. Dual Scheimpflug analyzer Sirius+ was used in all cases
3. Only topical anesthetic drops and hypromellose were used for gonioscopy.

Data collection

Adult patients were enrolled from a general ophthalmology office, and all subjects signed a written informed consent form. The Sirius+ Scheimpflug analyzer was used to automatically measure the mean ACA, anterior chamber volume (ACV), aqueous depth, horizontal anterior chamber diameter (HACD), pupil diameter, lens rise, central corneal thickness (CCT), minimum corneal thickness, and corneal volume. Findings were recorded on an Excel sheet.

Gonioscopy was performed with a Goldmann 3-mirror lens at $\times 16$ magnification with a 1 mm beam and a very narrow slit with the lowest illumination to allow appropriate identification of the structures. The ACA in every quadrant was classified based on the Shaffer grading system. A narrow angle was defined when the

posterior trabecular meshwork was not visualized in more than 180° of the angle (Shaffer 2 or less).

Sample size

Sample size calculated keeping 80% power and 5% significance level (significant at 95% confidence level).

$$\text{Sample size, } n = \frac{\left(Z_{1-\alpha/2} + Z_{1-\beta} \right)^2 \times 2pq}{(p_1 - p_0)^2}$$

$Z_{1-\alpha/2}$ is the value of α error taken at 5% and is 1.96.

$Z_{1-\beta}$ is the value of β error taken at 20% (0.2) and is 0.84. p_0 (prevalence of patients) was assumed to be 50% or 0.5. Relative Risk (RR) is the minimum detectable risk and is taken as 0.25 (considering that it would be worthwhile if angle closure is found in at least 25% of the patients undergoing screening).

Thus, this clinical study included 80 eyes of 40 patients.

Statistical analysis

SPSS 29 v statistical software (Manufactured by International Business Machines (IBM) located at Chicago, IL) used for data analysis. Comparisons of the means of normally distributed data were performed with Student's unpaired *t*-test (Wilcoxon test for skewed distributions). Continuous variables were reported as the mean \pm standard deviation. The correlation coefficient among parameters obtained by Sirius and Shaffer's grade, as determined by gonioscopy, was assessed with Spearman's correlation coefficient. For this study, a *P* value below 0.05 was acknowledged as statistically significant.

Receiving operator characteristic (ROC) curves were adopted for studying the efficacy of the Sirius⁺ measurements in correlating with their chances of closed angle as determined by Gonioscopy. ACA, ACV, anterior chamber depth (ACD), and other parameters were individually interpreted in those analyses.

Ethical issues

All the aspects of the study and its methods were vetted by the institutional ethical committee. All included patients signed an informed consent.

RESULTS

The mean age of the patients was 46.67 ± 12.34 years [Figure 1] with a range of 25–69 years. The female-male ratio was 36:44.

The study included 66 (82.5%) eyes of patients graded as open angle and 14 (17.5%) eyes as narrow angle, based on gonioscopy. The average ACA of all study

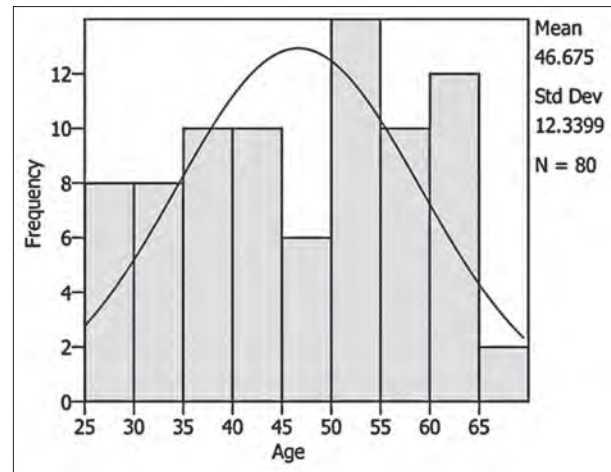


Figure 1: Depicting the age-wise analysis of all the participants included in this study

participants as demonstrated by Sirius⁺ was $36.76^\circ \pm 7.57^\circ$ (range: 19.4° – 53.6°). The mean ACA recorded for open-angle eyes was $39.05^\circ \pm 5.91^\circ$ and was $25.92^\circ \pm 4.46^\circ$ for narrow-angle eyes ($P < 0.0001$) [Figure 2].

The Sirius⁺ Scheimpflug analyzer was used to automatically measure the mean ACA, ACV, aqueous depth, HACD, pupil diameter, lens rise, CCT, minimum corneal thickness, and corneal volume in all the study participants [Table 1].

The correlation coefficient between closed angle as determined by gonioscopy (Shaffer's grade 2 or below) and the parameters obtained by Sirius was assessed with Pearson correlation coefficient wherein ACA, ACV, aqueous depth, HACD, and lens rise revealed significant correlation [Table 2].

The efficacy of the Sirius⁺ parameters to screen out the narrow-angle eyes, as defined above, was further analyzed using ROC curves. The areas under the curve (AUC) in ROC analysis revealed very good discriminant power of many of the parameters studied in detecting narrow angles [Table 3].

According to the ROC curves [Figure 3], the narrow angles can most effectively be diagnosed with ACA, ACV, lens rise, and aqueous depth among all nine parameters recorded in this study, thus further confirming our findings of Pearson correlation.

DISCUSSION

The ACA plays a crucial role in the pathophysiology of various ocular conditions, particularly glaucoma. Quantification of the ACA is essential for diagnosing and managing such conditions effectively. In this study, we utilized Sirius⁺ Scheimpflug Tomographer to quantify the ACA in the North Indian population.

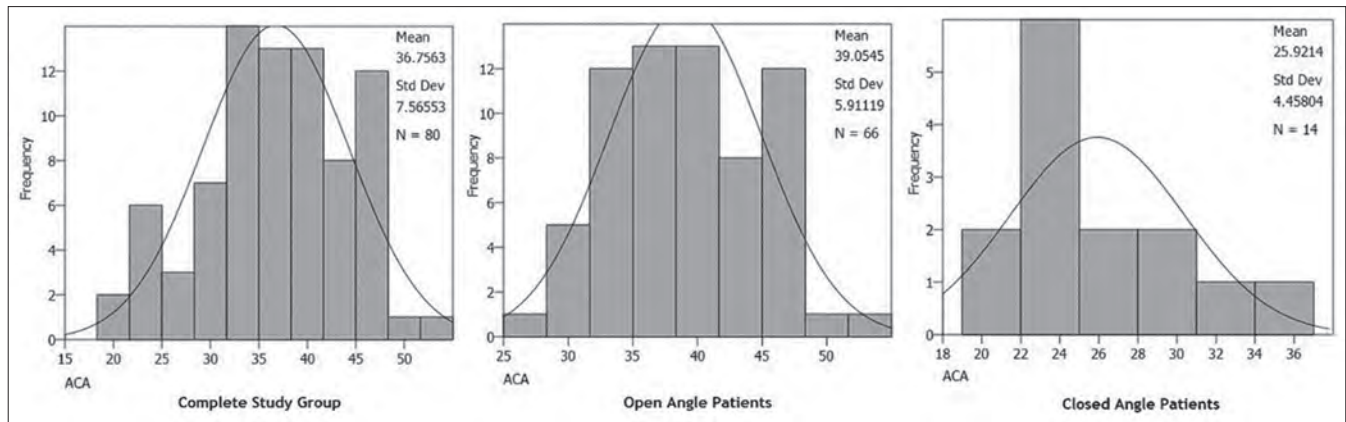


Figure 2: Graphical representation of anterior chamber angle of all the participants versus open angle and closed angle patients. ACA: Anterior chamber angle

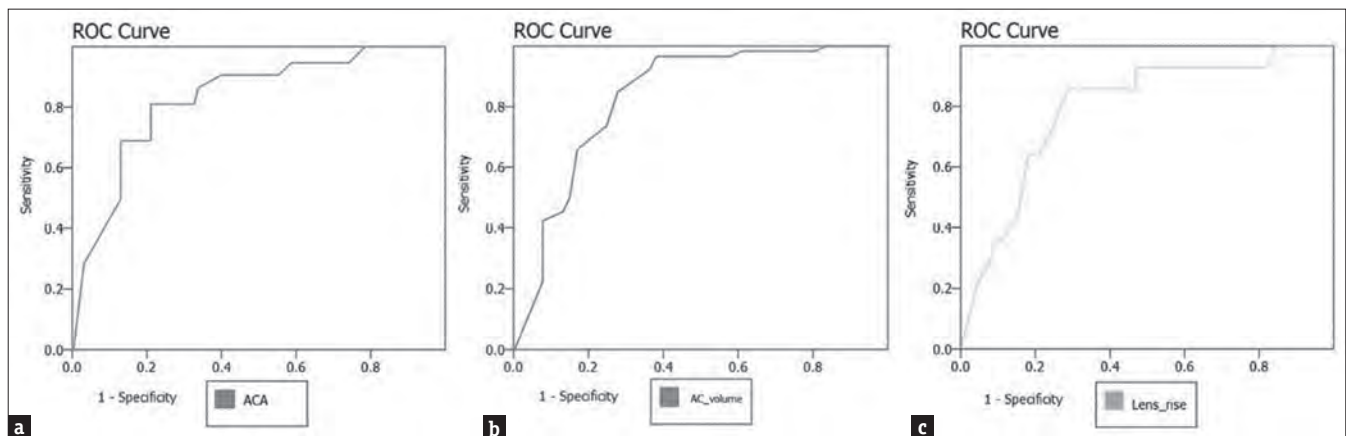


Figure 3: Receiving operator characteristic curves of the Sirius+ parameters (a) Anterior chamber angle, (b) Anterior chamber volume, (c) Lens rise to discriminate eyes with an angular width of Shaffer's Grade 2 or less. ACA: Anterior chamber angle, ROC: Receiving operator characteristic

Table 1: Sirius+ parameters (mean±standard deviation) and their comparison between open- and narrow-angle patients along with its statistical relevance

Parameters	Open angle (n=66)	Narrow angle (n=14)	Mean difference	P
ACA (°)	39.05±5.91	25.92±4.46	13.13	<0.0001
ACV (mm ³)	165.88±25.55	106.06±18.40	59.82	<0.0001
Aqueous depth (mm)	2.85±0.39	2.42±0.30	0.43	<0.0001
HACD (mm)	11.49±0.51	11.03±0.44	0.46	0.025
Pupil diameter (mm)	3.09±1.17	2.86±0.94	0.23	0.114
Lens rise (mm)	-0.07±0.33	0.25±0.12	-0.32	0.0007
CCT (μm)	519.20±30.06	525.71±25.11	-6.51	0.134
Min corneal thickness (μm)	505.55±35.55	509.29±32.68	-3.74	0.235
Corneal volume (mm ³)	53.25±3.23	53.49±3.19	-0.24	0.657

ACA: Anterior chamber angle, ACV: Anterior chamber volume, HACD: Horizontal anterior chamber diameter, CCT: Central corneal thickness

Currently, the gold standard method to assess ACA is gonioscopy, which helps to accurately assess the iridocorneal angle and diagnose possible variations in normal angle structures. However, its reproducibility and effectiveness as a screening method for the general population are compromised as the examination involves direct contact with the cornea.^[9,10]

Additional imaging tools, including AS-OCT and UBM, have been employed to provide a more accurate and holistic evaluation of the ACA. In clinical practice, all of these technologies are valuable and complementary, especially when one approach is difficult to use or the results are questionable. However, UBM necessitates direct contact with the eye, which besides being uncomfortable for the patient, needs a trained

Table 2: All the parameters with their Pearson correlation coefficient

Parameters	Pearson correlation	Significant (one-tailed)
ACA (°)	0.678 ^a	0.0001
ACV (mm ³)	0.741 ^a	0.0001
Aqueous depth (mm)	0.597 ^a	0.0001
HACD (mm)	0.376 ^a	0.0015
Pupil diameter (mm)	0.139	0.109
Lens rise (mm)	-0.415 ^a	0.0002
CCT (μm)	-0.148	0.095
Min corneal thickness (μm)	-0.096	0.199
Corneal volume (mm ³)	-0.042	0.354

ACA: Anterior chamber angle, ACV: Anterior chamber volume, HACD: Horizontal anterior chamber diameter, CCT: Central corneal thickness

Table 3: Areas under the curve for the parameters studied

Variable under test	Area under the curve
ACA	0.88
ACV	0.85
Aqueous depth	0.80
HACD	0.73
Pupil diameter	0.42
Lens rise	0.82
CCT	0.59
Minimum corneal thickness	0.58
Corneal volume	0.50

ACA: Anterior chamber angle, ACV: Anterior chamber volume, HACD: Horizontal anterior chamber diameter, CCT: Central corneal thickness

operator as well. When it comes to quantitative ACA measurement and screening for narrow angles, optical coherence tomography and UBM have demonstrated equivalent strong screening abilities in previous studies.^[11]

The Scheimpflug imaging system is a noninvasive optical system that allows a complete evaluation of the anterior segment. It collects various data on several structures such as corneal thickness, anterior and posterior corneal curvature, corneal topography, corneal volume, ACD, and horizontal and vertical limbus-to-limbus distance. Some recent previous studies have shown good reproducibility of the parameters obtained with the Scheimpflug analyzer, which offers the advantages of a more unbiased, reproducible, objective, and noncontact tool, for rapid imaging and quantitative analysis.

Our findings revealed several important insights into the ACA characteristics of the study population. The results revealed that Sirius+ parameters such as ACA, ACV, lens rise, and aqueous depth have a good correlation with the gonioscopy Shaffer grade and are effective in identifying

narrow angles (Shaffer II or less). These results are consistent with earlier research that used the Pentacam to investigate the same parameters.^[12]

In this study, when assessed using the Pearson correlation coefficient, the Sirius+ parameters with promising results to screen out narrow angles were the ACA, ACV, aqueous depth, HACD, and lens rise. The AUC in ROC curves (0.88 for ACA, 0.85 for ACV, 0.82 for Lens rise, and 0.80 for ACD) reaffirmed the results. Kurita *et al.*^[6] found similar results while analyzing the Pentacam measurements. These parameters are thus critical for assessing the risk of angle closure and glaucoma development. Our study contributes to the existing literature by providing normative data specific to the North Indian population, which can serve as a reference for future research and clinical practice.

Despite the strengths of our study, several limitations should be acknowledged. The data recorded were correlated with gonioscopy (current gold standard), which may induce misclassification, it is a subjective examination. Furthermore, relatively small sample size limits the generalizability of our findings. Future studies with larger and more diverse populations are warranted to validate our results using Partition analysis so as to determine the threshold value of the most efficient parameter of Sirius+ to distinguish between open and narrow angles. In addition, studies comparing Sirius+ with other anterior segment imaging technologies in detecting narrow angles should also be undertaken in future.

This study does not claim that imaging with Sirius+ can fully replace gonioscopic examination of the ACA, which gives a direct anatomical view, because Scheimpflug systems do not allow light to enter through the angle recess, making it impossible to visualize the ACA directly. Thus, evaluation of the ciliary body's features and interaction between the iris and ciliary body is not possible. Furthermore, it is not able to assess the angle's degree of pigmentation, distinguish between nonsynechial appositional closure, or identify peripheral anterior synechiae.

Our results highlight the importance of utilizing advanced Scheimpflug imaging technology for accurate and reproducible quantification of the ACA. Traditional methods of ACA assessment, such as gonioscopy, are subjective and reliant on examiner experience. In contrast, Scheimpflug-based tomography offers objective measurements, enhancing the reliability of ACA evaluation.

To the best of our knowledge, this is the first study to evaluate the performance of Sirius+ Scheimpflug

analyzer as a screening method for narrow angles. Our study provides valuable insights into the quantification of the ACA in the North Indian population using Scheimpflug-based corneal tomography. The findings contribute to our understanding of ethnic variations in ACA morphology and have implications for the diagnosis and management of glaucoma and other ocular conditions.

CONCLUSIONS

Scheimpflug-based tomography offers objective measurements, enhancing the reliability of ACA evaluation. The study employed the technology to quantify the ACA and highlighted the statistically significant Sirius⁺ parameters that can be exercised for screening and early diagnosis for patients with angle-closure glaucoma. The quantitative data obtained from our study provide valuable insights into ACA dimensions and highlight the utility of advanced imaging technologies for objective and reproducible assessment of the ACA. The findings contribute to the existing literature and emphasize the need for further research to validate our results and explore longitudinal changes in ACA parameters. Overall, our study advances our understanding of ACA morphology in the North Indian population.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Understanding the Role of Ayushman Bharat Pradhan Mantri Jan Arogya Yojana in Improving Access to Eye Surgeries: A Retrospective Study at a Tertiary Eye Care Institute in North India

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ABSTRACT

Purpose: The purpose of the study was to estimate the utilization of the Ayushman Bharat insurance scheme among patients with eye diseases in a tertiary care hospital in North India.

Methods: Retrospective medical chart review of patients availing of the Pradhan Mantri Jan Arogya Yojana (PM-JAY) scheme for the treatment of their eye diseases. The study was approved by the institutional ethics committee. Patient demographics, type of surgery, and outcome data were collected from medical records and transcribed into Microsoft Excel. For comparison, based on location, patients were divided into rural and urban groups, as well as home districts and other districts.

Results: A total of 15,274 eye surgeries were performed during the study period; of them, 3458 (22.6%) patients availed PM-JAY scheme. There were 1844 males (53.3%) and 1614 females (46.7%). Of all, 2713 (78.5%) patients availed Ayushman benefits for cataract surgery. The average age of male patients was 58.5 ± 11.3 years, and of female patients was 57.2 ± 10.4 years. A total of 826 (30.5%) patients had a history of systemic diseases. A history of systemic disease was present in 537 (28.4%) rural patients and 289 (35%) urban patients. A total of 2149 (62.1%) belonged to the home district, and 1309 (37.9%) belonged to other locations. A total of 368 (28.1%) patients who belong to other districts had undergone procedures other than cataracts, as compared to 377 (17.5%) patients of the home district.

Conclusion: This scheme reduces out-of-pocket expenses and helps to overcome financial barriers to availing eye care services. The implementation of PM-JAY requires further enhancement through public awareness campaigns.

KEYWORDS: *Ayushman Bharat health scheme, cataract surgery, eye diseases, Pradhan Mantri Jan Arogya Yojana, Tertiary Eye Care Institute*

INTRODUCTION

India spends only 4% of its Gross domestic product (GDP) on health care, with the government funding only 1.4% (about £4 billion).^[1] For the health system, strengthening health expenditure by the government will increase as a percentage of GDP from the existing 1.15% to 2.5% by 2025.^[1] To transform India's health-care system, the Central Government of India started the Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (PM-JAY) program in 2008. It is the world's

largest wholly government-funded health insurance plan. This program is aimed at about 100 million economically disadvantaged and vulnerable families. It consists of two key health programs: the establishment of Health and Wellness Centres and the National Health Protection

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Scheme. This has been the most ambitious health-care effort ever undertaken to obtain universal health coverage.^[2]

The PM-JAY aims to protect the financial health of 500 million of India's most disadvantaged citizens.^[3] It has helped to halt the slide of the 50–60 million Indians who would fall into poverty annually as a result of medical-related expenditures.^[3] PM-JAY targets offering institutional treatment to 0.5 million families living below the poverty line (BPL). This program provides relief to an underprivileged population by providing free health care.^[4] Before this, most of the population had no national health protection scheme. For ophthalmic surgeries, PM-JAY has several potential benefits. PM-JAY beneficiaries can access any public as well as private eye care facilities.^[4]

To achieve the goal of eliminating avoidable blindness, a concerted effort has been made to increase eye care service utilization.^[5] However, several barriers to eye care service utilization have been reported, including low socioeconomic status.^[5] Financial reasons have been identified as one of the major barriers to availing eye care services in India. At present, most of the significant ocular morbidities requiring secondary and tertiary care have been covered for BPL families under PM-JAY.

We found it interesting to look at the demographic and disease profile of patients who availed of the PM-JAY scheme, who were visiting our institute as both walk-in or through an extensive rural outreach program, who were availing both paying as well as nonpaying services as per their social strata. The aim was to understand the social and clinical factors that may be influencing the utilization of the scheme from an eye care perspective. This study attempts to analyze the utilization of the PM-JAY scheme by patients with eye diseases. The service utilization of this scheme at a tertiary eye care institute from January 2020 to December 2021 is presented in the manuscript.

METHODS

A retrospective review of patients' details who availed of benefits of the PM-JAY scheme from January 2020 to December 2021 (COVID-19-era). The study was approved by the institutional ethics committee. The research adhered to the principles of the Declaration of Helsinki. The sampling method is universal sampling. All the patients admitted with eye diseases were taken as samples/study subjects, and the information was collected from the medical records department with prior permission from the concerned authority. All the relevant information was taken from the records of the patients admitted to the hospital during the study period. Demographic data, including age, gender, location, the month of presentation, and treatment, was recorded. The statistical analysis was performed with SPSS 17.0 software (IBM, Armonk, New York, USA). Microsoft Excel (Microsoft Corp., Redmond, WA, USA) was used to generate graphs and tables. Descriptive statistics were obtained to determine the frequency and proportions. Mean and standard deviation were calculated for continuous variables. The Chi-square test was used to compare identified variables between the two groups. $P < 0.05$ were considered statistically significant.

RESULTS

A total of 3458 patients availed of the PM-JAY health scheme during the study period. Out of them, 53.3% (1844) were males, and 46.7% (1614) were females, with a statistically significant difference ($P = 0.00$) based on a one-sample binomial test. The mean age of the patients was 54.8 ± 13.5 years, ranging from 4 to 96 years.

The patients were distributed across different age groups as follows: 0.7% (23) were below 10 years old, 1.7% (59) were between 10 and 19 years old, 2.9% (100) were between 20 and 29 years old, 6.1% (212) were

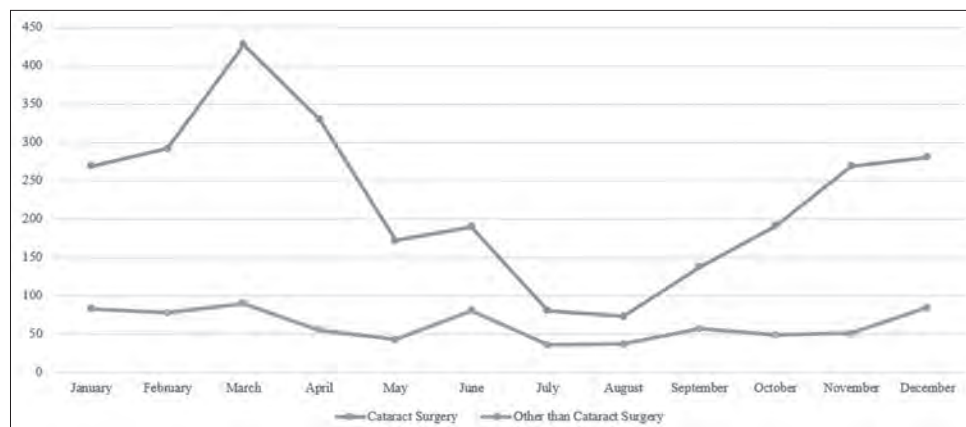


Figure 1: Monthly trend of patients who availed Pradhan Mantri Jan Arogya Yojana scheme

between 30 and 39 years old, 17.9% (619) were between 40 and 49 years old, 30.4% (1052) were between 50 and 59 years old, and 37.7% (1393) were 60 years or above. The gender distributions according to age groups are presented in Table 1.

All patients who availed of PM-JAY benefits had undergone surgeries or laser procedures. Among them, 78.5% (2713) of patients availed benefits for cataract surgery. Monthly trend of patients who availed Pradhan Mantri Jan Arogya Yojana scheme is presented in Figure 1. Details of other procedures can be found in Annexure 1. In terms of location, 62.1% (2149) of patients belonged to the home district, while 37.9% (1309) belonged to other locations. A total of 368 (28.1%) patients from other districts had undergone procedures other than cataracts, compared to 377 (17.5%) patients from the home district, which was statistically significant [$P = 0.001$, Chi-square test, Table 2].

The average age of patients who underwent cataract extraction was 57.9 ± 10.9 years. Out of them, 46.6% (1265) were female, and 53.4% (1447) were male. The average age of male patients was 58.5 ± 11.3 years, while that of female patients was 57.2 ± 10.4 years ($P = 0.002$).

Among the cataract surgery patients, 69.6% (1888) belonged to rural locations, and 30.4% (824) were from urban locations. A total of 826 (30.5%) patients had a history of systemic diseases, with 537 (28.4%)

being rural patients and 289 (35%) being urban patients [$P = 0.001$, Figure 2].

At the presentation, 2.6% (71) patients had vision $<6/60$ in both eyes, with 1.6% (45) patients having vision $<3/60$ in both eyes. The presenting uncorrected visual acuity is shown in Table 3.

After cataract surgery, at the final follow-up, the vision of the operated eye was $>6/12$ in 85.8% (2330) patients, between 6/12 and 6/18 in 7.5% (206) patients, between 6/18 and 6/60 in 4.1% (111) patients, 6/60–3/60 in 0.6% (17) patients, and $<3/60$ in 1.7% (48) patients [Table 4]. The underlying causes of poor postoperative vision ($>3/60$ in 48 patients) are presented in Table 5. A total of 25 patients who had a postoperative vision of $<3/60$ were undergone a second surgery. The details of the surgery are included in Annexure 2. After surgery, vision was improved in 17 patients.

DISCUSSION

In 1976, to reduce the blindness backlog and build eye care infrastructure and human resources, India launched a centrally sponsored National Program for Control of Blindness (NPCB).^[6] District Blindness Control Society (DBCS) has been formed for the implementation of the NPCB. The main objective of DBCS is to achieve maximum reduction in avoidable blindness through optimal utilization of available resources within that district. During the 11th 5-year plan DBCS under NPCB has also been merged with the District Health Society under the National Rural Health Mission.^[7] DBCS also involves non-government organizations for eye care delivery by supporting eye surgeries performed by them. Despite this, the cataract surgery backlog continues to grow, necessitating more innovative schemes by the government.^[8]

In India, approximately 65% of surgeries are performed in the private and voluntary sectors.^[9] International non-governmental Organizations (INGOs) also provide

Table 1: Gender distribution of AB-PMJAY patients according to their age groups

Age category (years)	Gender		Total	P
	Female	Male		
Below 10	4	19	23	<0.0001
10–19	26	33	59	
20–29	34	66	100	
30–39	100	112	212	
40–49	317	302	619	
50–59	516	536	1052	
60 above	617	776	1393	
Total	1614	1844	3458	

AB-PMJAY: Ayushman Bharat Pradhan Mantri Jan Arogya Yojana

Table 2: Cross-tabulation of AB-PMJAY patient locations and surgical procedures

Patient district	Procedure details		Total	P
	Cataract	Other than cataract		
Home district	1772	377	2149	<0.0001
Other district	941	368	1309	
Total	2713	745	3458	

AB-PMJAY: Ayushman Bharat Pradhan Mantri Jan Arogya Yojana

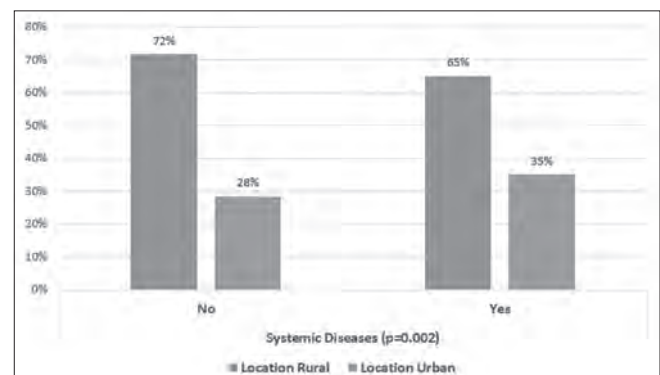


Figure 2: Systemic diseases among rural and urban patients

Table 3: Cross-tabulation showing presenting uncorrected visual acuity of patient undergone cataract surgery

Preoperative UCVA	Fellow-eye UCVA						Prosthetic eye	Total
	>6/12	6/12–6/18	6/18–6/60	6/60–3/60	<3/60	NA		
>6/12	293	25	17	4	13	0	1	353
6/12–6/18	351	215	45	9	14	6	0	640
6/18–6/60	336	191	197	11	25	5	0	765
6/60–3/60	89	50	50	18	17	1	0	225
<3/60	375	94	116	45	80	19	0	729
Total	1444	575	425	87	149	31	1	2712

UCVA: Uncorrected visual acuity, NA: Not available

Table 4: Cross-tabulation showing improvement in uncorrected visual acuity after cataract surgery

Preoperative UCVA	Postoperative UCVA					Total
	>6/12	6/12–6/18	6/18–6/60	6/60–3/60	<3/60	
>6/12	338	13	1	0	1	353
6/12–6/18	592	34	11	2	1	640
6/18–6/60	656	75	26	4	4	765
6/60–3/60	188	16	18	0	3	225
<3/60	556	68	55	11	39	729
Total	2330	206	111	17	48	2712

UCVA: Uncorrected visual acuity

Table 5: Underlying causes of poor visual outcome

Cause	Frequency (%)
Retinal detachment	16 (33.33)
Corneal scar- leukomatous	4 (8.33)
GOA	4 (8.33)
Macular scar	3 (6.25)
Diabetic retinopathy	4 (8.33)
Vitreous hemorrhage with tractional retinal detachment	2 (4.17)
Corneal scar	1 (2.08)
ERM, CME, posterior uveitis	1 (2.08)
Foveal atrophy	1 (2.08)
Malignant glaucoma	1 (2.08)
Myopic macular degeneration	1 (2.08)
Myopic maculopathy with choroidal nevus	1 (2.08)
Neovascular glaucoma	1 (2.08)
Optic atrophy	1 (2.08)
Severe NPDR	1 (2.08)
Vasculitis dispersed vitreous hemorrhage	1 (2.08)
Vitreous hemorrhage	1 (2.08)
Not having any specific underlying cause	4 (8.33)

NPDR: Nonproliferative diabetic retinopathy, ERM: Epiretinal membrane, CME: Cystoid macular edema, GOA: Glaucomatous optic atrophy

valuable resources, tools, and funding for eye care delivery. These organizations operate through a variety of approaches, from supporting individual projects to integrated national eye care programs.^[10] Many of these INGOs partner with eye institutes to support them in eye care delivery in that region by providing infrastructure, equipment, training, and human resources.^[10] This also includes direct support for performing eye surgeries. All these resources are available

to protect economically weaker sections of society from financial liabilities arising out of hospitalization and to make eye care services available.

In PM-JAY, all the significant ocular morbidities requiring secondary and tertiary care have been covered. Enrolled patients can access any approved eye care facility, whether government or private. At our institute, significantly more males have benefited from this scheme as compared to females. Our findings are in keeping with observations from previous studies.^[11-16] According to these reports, males have more access to eye treatments.^[11-16] A previous study on PM-JAY utilization has also reported more utilization by male patients.^[17] According to our results, even free health coverage has not been able to overcome gender inequality. The indirect cost of treatment may have been playing a significant role in gender inequality. The average age of male patients undergoing surgery was significantly higher than that of female patients. This may be due to men postponing surgery for fear of losing their livelihood in earning years. Globally, older people, women, and people with lower socioeconomic levels have a higher cataract burden.^[18]

In our study, significantly more patients from the rural population have availed of PM-JAY benefits. This was due to our outreach team, including vision technicians and community eye health workers, have been creating PM-JAY awareness in rural cadres and bringing patients to our institute to be operated on while the urban patients were mostly walk-ins. There was a seasonal trend in patients availing of PM-JAY for cataract surgeries. In

North India, eye care facilities experience seasonal patterns in patients availing eye care services. These facilities see significantly more patients from November to March than other months. This is attributed to some cultural beliefs regarding avoiding elective surgeries in the summer months.

The majority (more than 35%) of patients belonged to more than 60 years of age. This can be related to the disease profile of PM-JAY patients. Most of them had undergone cataract surgeries. At present, PM-JAY covers six packages for cataract care varying by the technique used to remove the cataract and the severity of the condition. Phacoemulsification and small incision cataract surgery are the two most widely offered packages for cataracts.^[19]

In India, according to the National Family Health Survey, more than 55% of households in India do not seek healthcare from the public sector.^[20] More than 50% of total health expenditure is household pocket expenditure.^[21] However, in the state of Uttar Pradesh, significantly higher utilization of Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB-PMJY) for cataract surgery was reported by private institutes than by government entities.^[19] Less than one-third (29%) of households have at least one member covered under health insurance or health scheme.^[21] This is also overcome by the introduction of the PM-JAY scheme, as all people belonging to the BPL category are insured for their hospitalization expenses.

Other ocular surgical procedures covered under PM-JAY were dacryocystectomy, pterygium excision, iridectomy, vitrectomy, retinal detachment surgery, etc.,. Significantly, more patients availed specialty services (other than cataracts) from adjoining districts than in hometowns. This may be due to the nonavailability of tertiary eye care services in these districts.

CONCLUSION

Significantly, more male patients availed benefits of PM-JAY, cataract surgery was the most frequent procedure, and patients from other districts had undergone significantly higher procedures other than cataracts compared to the home district. Increasing awareness about the Ayushman Bharat scheme and its benefits for eye care can significantly contribute to overcoming the backlog in eye care services for underprivileged communities. Tertiary care hospitals that offer super-specialty eye services and have access to vision technicians, vision centers, and outreach services can play a pivotal role in bridging the gap between PM-JAY scheme beneficiaries and eye care facilities. By working in synchronization with

government schemes, such as PM-JAY, health-care providers can achieve financial sustainability for hospitals and ensure that much-needed eye care reaches those in need. This study encourages the adjustment of the community ophthalmology service provider model to effectively connect PM-JAY beneficiaries with eye care services, ultimately leading to improved accessibility and success of government health-care schemes.

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Conflicts of interest

There are no conflicts of interest.

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Annexure 1: Details of surgeries and procedures availed	
Procedure	Frequency (%)
Vitreoretinal surgery (with SOI)	72 (9.66)
Pterygium + conjunctival autograft	46 (6.17)
Pterygium + conjunctival autograft	39 (5.23)
PRP	37 (4.97)
Dacryocystectomy with implants	36 (4.83)
SOR	31 (4.16)
Iridectomy - laser	28 (3.76)
Vitrectomy + retinal detachment surgery	28 (3.76)
Capsulotomy (YAG)	26 (3.49)
Iridectomy	26 (3.49)
Dacryocystorhinostomy without silicon tube/stent	25 (3.36)
For retinal tear repair per eye per sitting	25 (3.36)
PRP - retinal laser including 3 sittings	22 (2.95)
Corneal ulcer management	20 (2.68)
Glaucoma surgery (trabeculectomy only) with or without Mitomycin C, Phaco emulsification with foldable hydrophobic acrylic IOL	19 (2.55)
Corneal grafting	16 (2.15)
Laser for retinopathy (per sitting)	16 (2.15)
Retinal detachment surgery	16 (2.15)
Capsulotomy (YAG)	14 (1.88)
Endophthalmitis (excluding vitrectomy)	14 (1.88)
Squint correction (per muscle)	13 (1.74)
Lensectomy/pediatric lens aspiration, vitrectomy	12 (1.61)
Vitrectomy	12 (1.61)
Corneal grafting	10 (1.34)
Corneo/scleral/corneo scleral tear repair	10 (1.34)
Dacryocystorhinostomy without silicon tube/stent, entropion correction	9 (1.21)
Minor - upto 2 muscles	8 (1.07)
Corneal grafting, cataract with foldable hydrophobic acrylic IOL by Phacoemulsification	7 (0.94)
Entropion correction, dacryocystorhinostomy without silicon tube/stent	7 (0.94)
Vitrectomy, lensectomy/pediatric lens aspiration	7 (0.94)
Glaucoma surgery (trabeculectomy only) with or without Mitomycin C	5 (0.67)
Pediatric membranectomy anterior vitrectomy	5 (0.67)
Cyclocryotherapy/cyclophotocoagulation	4 (0.54)
Entropion correction	4 (0.54)
GA/EUA, Major - 3 or more muscles	4 (0.54)
Glaucoma surgery (trabeculectomy only) with or without mitomycin C	4 (0.54)
Lensectomy/pediatric lens aspiration	4 (0.54)
Secondary IOL/IOL exchange/explant	4 (0.54)
SFIOL (inclusive of vitrectomy)	4 (0.54)
SFIOL (inclusive of vitrectomy), vitreoretinal surgery (with SOI)	4 (0.54)
Conjunctival tumor excision + AMG	3 (0.40)
Corneal ulcer management, endophthalmitis (excluding Vitrectomy)	3 (0.40)
Major - 3 or more muscles, GA/EUA separate add-on package	3 (0.40)
Pediatric lensectomy	3 (0.40)
Pediatric lens aspiration with posterior capsulotomy anterior vitrectomy	3 (0.40)
Small tumor of lid - excision + lid reconstruction	3 (0.40)
Vitrectomy (S300027), Cataract with foldable hydrophobic acrylic IOL by Phacoemulsification	3 (0.40)
Canaliculo dacryocystorhinostomy without silicon tube/stent	2 (0.27)
Chalazion removal	2 (0.27)
Cyclocryotherapy/cyclophotocoagulation	2 (0.27)
SOR, Phaco emulsification with foldable hydrophobic acrylic IOL	2 (0.27)
Unspecified surgical package	2 (0.27)
Conjunctival tumor excision, including amniotic membrane graft	1 (0.13)

Contd...

Annexure 1: Contd...

Procedure	Frequency (%)
Conjunctival tumor excision, including amniotic membrane graft, pterygium + conjunctival autograft	1 (0.13)
Corneal/scleral patch graft, iris prolapse repair	1 (0.13)
Corneal graft	1 (0.13)
Corneal grafting, limbal dermoid removal	1 (0.13)
Cyclocryotherapy/cyclophotocoagulation, conjunctival tumor excision, including amniotic membrane graft	1 (0.13)
GA/EUA	1 (0.13)
GA/EUA, corneo/scleral/corneo scleral tear repair	1 (0.13)
GA/EUA separate add-on package, vitreoretinal surgery (with SOI)	1 (0.13)
Iris cyst removal	1 (0.13)
Lid abscess drainage	1 (0.13)
Lid tear repair	1 (0.13)
Lid tumor excision + lid reconstruction	1 (0.13)
Major - 3 or more muscles	1 (0.13)
Orbitotomy	1 (0.13)
Pediatric glaucoma surgery	1 (0.13)
Scleral buckling surgery	1 (0.13)
Small tumor of lid - excision + lid reconstruction, limbal dermoid removal	1 (0.13)
Surgical membranectomy, vitrectomy	1 (0.13)
Vitrectomy + retinal detachment surgery (preauth required), lensectomy/pediatric lens aspiration	1 (0.13)
Vitreoretinal surgery (with SOI), SFIOL (inclusive of vitrectomy)	1 (0.13)
PRP: Pan retinal photocoagulation, SOI: Silicone oil injection, SOR: Silicon oil removal, GA/EUA: Examination under Anesthesia, IOL: Intraocular lens, AMG: Amniotic membrane grafting, YAG: Yttrium aluminium garnett, SFIOL: Scleral fixated Intraocular lens	

**Annexure 2: Distribution of second surgery in patients
with poor postoperative vision of <3/60**

Surgery	Frequency (%)
PPV + MP + FAE + EL + C3F8 gas injection + avastin injection	4 (16.0)
PPV + BB + MP + PFCL + EL + SOI	2 (8.0)
PPV + BB + MP + PFCL + EL + SOI	2 (8.0)
PPV + MP + EL + SOI	2 (8.0)
PPV + BB + FAE + EL + SOI	2 (8.0)
Phacoemulsification + IOL	1 (4.0)
PPV + BB + FAE + EL/TSC + C3F8/SOI	1 (4.0)
AC wash + vitreous biopsy + IOAB	1 (4.0)
Left eye PPV + BB + FAE + EL/TSC + C3F8/SOI	1 (4.0)
Phacoemulsification + IOL + trabeculectomy	1 (4.0)
PK + cataract + IOL	1 (4.0)
PPV + BB + MP + PFCL + EL + SOI	1 (4.0)
PPV + MP + FAE + EL	1 (4.0)
PPV + MP + FAE + EL + SOI 1000 CS	1 (4.0)
PPV + MP + FAE + EL SOI	1 (4.0)
PPV + MP + FAE + EL + C3F8 gas injection	1 (4.0)
PPV + MP + FAE + EL + C3F8 gas injection + avastin injection	1 (4.0)
YAG capsulotomy	1 (4.0)
Total	25

SOI: Silicone oil injection, PPV: Pars plana vitrectomy, MP: Membrane peeling, FAE: Fluid air exchange, EL: Endolaser, PFCL: Per fluoro carbon liquid, IOL: Intra ocular lens, IOAB: Intraocular antibiotic, BB: Belt Buckle, PK: Penetrating Keratoplasty, TSC: Transscleral cryotherapy, YAG: Yttrium Aluminium Garnett

Code to Crack Nucleus: An Innovation in Phacoemulsification

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ABSTRACT

Code to crack nucleus is a concept that aims to understand the basic process responsible for the evolution of nuclear crack. This understanding would help surgeons in achieving successful nucleotomies, especially in harder cataracts. Furthermore, it would be a summation of different techniques into one concept. While practicing different styles and machine combinations, we would be able to realize the key constituents of nuclear dehiscence in phacoemulsification.

KEYWORDS: *Code to crack nucleus, nucleotomy, nucleus chopping, phacoemulsification*

INTRODUCTION

Phacoemulsification is one of the most common types of cataract surgery done in Bharat. Nucleotomy is a day-in and day-out procedure for Indian ophthalmologists, which can be described as subdividing the nucleus into smaller pieces for efficient emulsification. There is an armada of modern-day machines that can achieve the aforementioned process successfully. Likewise, enormous techniques and different instrumentation combinations have been able to achieve the same. Since the instrumentation and techniques are available to all, this begs one to think that the code to crack the nucleus lies somewhere else!

The safety and efficacy profile of this surgical technique is quite reliable. An interesting finding to note is that all the techniques have a common final step, lateral separation, as described in nucleofractis techniques by the American Academy of Ophthalmology.^[1] To facilitate a smooth and a good nucleotomy, one should understand the process of lateral separation.

It is of utmost importance to understand the anatomy of the structure that is being operated upon; hence, one should remember the lamellar structure of the human lens, which persists even in mature cataracts.^[2] Sometimes, there is a steady accumulation of chromophores and complex, insoluble crystalline aggregates in the lens nucleus, which leads to the formation of brown nuclear cataracts. This process is homogeneous, and the gross morphology of the lens

fibers remains as it was before.^[3] The suture lines would be the preexisting lines for the evolving cracks, and lateral separation is the key process involved. Herein, we describe a code to crack the nucleus of the lens to have universal placement of incisions in both eyes with the same set of instruments and reproducibility.

SURGICAL TECHNIQUE

Code to crack depends on the understanding that lamellar pattern persists in cataracts and lateral separation is the key force responsible to achieve it. In this technique, the initial incisions are placed universally at 10:30 o'clock and 1:30 o'clock h. There is a preference to use a Sinskey hook rather than a chopper for the nucleus fragmentation process, as the sharpness of the second instrument would not matter in inducing lateral separation. Once the initial crack is induced using the concept of lateral separation, postocclusion of the nuclear matter, the phaco probe is rotated in a circular motion (by pronation), to extend the crack to a deeper plane [Video Clip 1]. The mechanism behind using this technique is based on the fact that the circular vector, if split, has a vertical component, and if acted on this plane, it creates a force directed posteriorly to the line of separation; thus, the crack goes deeper without much tangential stretch, a force seen usually with cracks dependent on only lateral separation.

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There are advantages of learning this concept. Understanding the basic concept of fragmentation of the nucleus would dissolve the confusion arising out of different tips, choppers, and techniques. The crack would be induced by uniplanar force; thus, the amount of tangential traction required will be drastically reduced. This concept has attracted a lot of peer attention in various discussions and on various platforms. To our understanding, the limitation of this technique includes a good hold of the nuclear substance on the phaco tip and hence, would be better appreciated in harder cataracts.

Note: Rotating phaco tip is difficult with the traditional grip used by most of the phaco surgeons. The grip used by most of the surgeons can be called as a “Pen Grip”. Instead, we apply Chopstick Grip (Chaturvedi Chopstick grip) which is based on the grip described by Machemer for the vitrectomy probe. It facilitates handpiece maneuvering and achieves deeper surgical movements. This would also compensate for the need to have curved tips.

Phaco surgery is an interdependent plan of incision orientation, clockwise location and the follow-up surgical maneuver, thus making a composite mental picture is important. For example making a two port phaco, angled at 120°, sitting superiorly with chopstick

grip and code to crack coupled with coaxial aspiration is one set of interdependent sequences.

CONCLUSION

A surgeon should always remember that the lamellar pattern would persist in cataractous lenses. Lateral separation is the key force responsible for nucleotomy. Three-dimensional thinking would help in getting the actual line of crack (you would get, what you want), hence understanding the mechanical concept behind the technique. Finally, adding rotation (Pronation) while doing lateral separation would give depth to the crack without much tangential traction.

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Conflicts of interest

There are no conflicts of interest.

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VISCO – Assisted Modified Tilt-and-tumble Nucleotomy – A Technique for Safe Nuclear Emulsification in Soft Cataract

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ABSTRACT

We present a method for phacoemulsification in soft cataract, in which gentle hydrodelineation is done first for nuclear manipulation to prolapse one pole of endonuclease out of the bag. The prolapsed endonuclease is maneuvered vertically with viscoelastic agent and its cannula. The viscoelastic agent serves a dual purpose of coating endothelium and providing a viscous medium, wherein, the endonuclease is supported vertically. Subsequently, a chopper is introduced through a side-port to support it from behind to prevent its fall back into the nuclear bed. This step is followed by the introduction of phaco probe and impaling of endonuclease with aspiration mode. This step further continues as routine chopping technique. We introduce it as VISCO – Assisted modified tilt-and-tumble nucleotomy in soft cataract phacoemulsification.

KEYWORDS: Nucleotomy, soft cataract, tilt, tumble

INTRODUCTION

The phacoemulsification procedure for cataract extraction was first described by Charles D. Kelman in 1967.^[1] Newer innovations, both in techniques and technology of phacoemulsification, have increased the efficacy and safety of this procedure.^[2] The commonly used techniques for cataract extraction by phacoemulsification are “divide-and-conquer,” “stop-and-chop,” and “phaco chop.”^[3] Soft cataract (lens opacities classification system III, grades 1) is characterized by a minimally dense endonuclease with abundant sticky soft cortical matter.^[4,5] During nuclear fragmentation of the soft nucleus in phacoemulsification, the Ultrasonic tip (US) tip tends to aspirate and perforate soft nuclear matter, making it difficult to achieve and sustain occlusion. Novice surgeons are cautious of penetrating the nucleus and subsequent, posterior capsular rupture (PCR). Therefore, the phaco tip is embedded quite superficially during the chopping procedure. An undivided bowl of nucleus is quite common in a novice surgeon's hand. The second instrument, chopper, often causes “cheese wiring” through the nucleus during nuclear fragmentation.^[6] Bowl-and-snail,^[7] tilt-and-crush,^[8] zero phaco,^[9] phaco rolling technique,^[10]

hydro-chop,^[11] and VISCO-fracture^[12] are several phacoemulsification techniques described in the literature for soft cataract emulsification. We are presenting an easy and safe modified technique of “VISCO – Assisted Tilt-and-Tumble nucleotomy” in soft cataract phacoemulsification.

SURGICAL TECHNIQUE

This section describes the VISCO – Assisted modified tilt-and-tumble nucleotomy technique. Soft cataract cases of grade 1 were performed by a single surgeon using the above technique, since January 2023. The patient's consent was taken for a recording of surgery, teaching, and publication. The phacoemulsification machine used to perform these surgeries was Galaxy Pro Orbit. All cases were performed under topical anesthesia.

A 2.8 mm temporal clear corneal incision was made. A continuous curvilinear capsulorhexis of approximately 5 mm was performed with a bent 26G needle. Hydrodissection was not performed. A gentle hydrodelineation was performed [Figure 1a]. End-point

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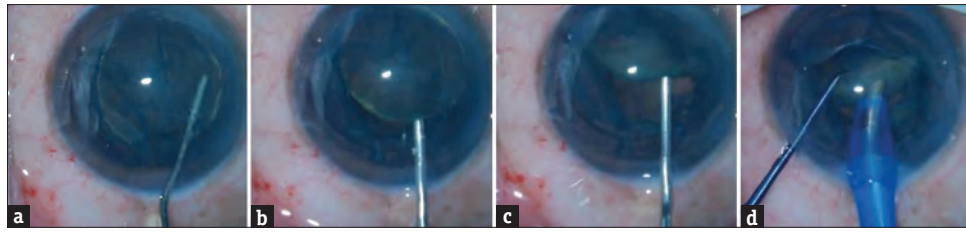


Figure 1: (a) Hydrolinelineation was performed; end-point was golden ring formation, (b and c) Flow of viscoelastic and push of VISCO-cannula is used very gently to tilt the endonuclease vertically, (d) Chopper is introduced through side-port to support it from behind to prevent its fall back into nuclear bed

was a golden ring formation. The hydrodissection cannula was reintroduced at 9° to the axis of the main wound at the rim of the golden ring. Injection of fluid is continued until the opposite pole of the nucleus prolapses out of the capsulorhexis rim into the anterior chamber. A viscoelastic agent is injected above and beneath the prolapsed pole. The endothelium of the cornea is coated with viscoelastic adequately. The flow of viscoelastic and push of VISCO-cannula is used very gently to tilt the endonuclease vertically [Figure 1b and c]. endonuclease is bathed in the “Sea of Viscoelastics” [Video 1a]. Subsequently, a chopper is introduced through a side-port to support it from behind to prevent its fall back into the nuclear bed [Figure 1d]. This step is followed by the introduction of phaco probe and impaling of endonuclease with vacuum only. This step further continues as routine chopping technique [Video 1b]. High vacuum and low US power were used to emulsify the endonuclease. In some cases of very soft nuclei, vacuum only was used to aspirate the endonuclease. Rest of the steps were similar to routine phacoemulsification procedures.

No case of PCR or corneal-related complications were observed intraoperatively.

On follow-up, on the 7th day, all cases had clear cornea.

DISCUSSION

Nuclear fragmentation is tough in soft cataract due to the lack of a rigid cleavage plane. Repeated break of occlusion following aspiration and perforation of nuclear matter is a common occurrence. Chopper frequently causes cheese-wiring of soft nucleus instead of cracking it into smaller pieces.^[6] Sticky nucleus resist rotation by dialler.^[9]

Techniques such as bowl-and-snail,^[7] tilt-and-crush,^[8] zero phaco,^[9] phaco rolling technique,^[10] hydro-chop,^[11] and VISCO-fracture^[12] yield successful outcome in soft nuclei. Tilt and tumble is considered to be an effective technique in very soft cataract.^[13]

The VISCO – assisted modified tilt-and-tumble nucleotomy technique developed is quite safe, effective,

and easy to learn. Owing to its reproducibility and simplicity, this procedure has become our routine emulsification technique in soft nucleus.

The nucleus is prolapsed and vertically tilted into the anterior chamber with viscoelastic agent and cannula. It is stabilized by the second instrument and the routine steps of emulsification are done.

Why this modification was needed?

In our experience of soft cataract emulsification, the moment the phaco probe was introduced through the main wound, the tilted endonuclease used to fall back into nuclear shell under the influence of positive pressure of an irrigating fluid. In a novice surgeon's hand, emulsifying an endo nucleus in its shell comes with all risks of complications.

This technique is safer in handling soft nucleus than the traditional chopping techniques in the following ways.

The divide-and-conquer technique of nuclear fragmentation is challenging in soft nuclei owing to the risk of perforation of the soft nucleus, leading to an increased chance of PCR during sculpting.^[14]

In our technique, first, a chopper is mainly used to prevent fall back of soft endonuclease back into the nuclear shell. Vertically inclined endonuclease is impaled with a vacuum of phaco probe effectively. Therefore, cheese wiring of the soft nucleus with a chopper is effectively handled.

Second, PCR risk is minimized as lens is tilted away from the posterior capsule during emulsification.

Third, high vacuum, minimal US power usage, and adequate coating with viscoelastic agent ensure the safety of endothelium.

We had clear cornea in all cases on the postoperative day 7. Thus, it is a safe procedure.

Why this modification is an easy skill to acquire?

Prolapse of one pole of endonuclease in the anterior chamber, VISCO-manipulation, and chopper supporting the vertical tilt of endonuclease are the basic steps

learned by all surgeons during manual small incision cataract surgery procedures.

CONCLUSION

Nuclear segmentation techniques for soft cataract are quite challenging for newer surgeons. Our VISCO – Assisted tilt-and-tumble nucleotomy is simple and reproducible. The skill for this technique can be easily acquired by a novice surgeon.

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Nil

Conflicts of interests

There are no conflicts of interest.

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Comparative Analysis of Postoperative Astigmatism Following Two Different Manual Methods of Corneal Marking for Toric Intraocular Lens Implantation

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ABSTRACT

Objectives: Astigmatism correction has become an increasingly important component of cataract surgery. The primary objective of the study is to compare the residual astigmatism after toric intraocular lens (IOL) implantation in cataract surgery using two manual methods of corneal marking. The secondary objectives are to compare postoperative uncorrected distance visual acuity (UCDVA) and accuracy of toric IOL alignment in both the groups.

Materials and Methods: This was a comparative prospective analysis of postoperative refractive outcome after toric IOL implantation during cataract surgery using manual methods of corneal marking. The first group underwent slit-lamp-assisted corneal axis marking. The second group underwent preoperative reference marking with bubble marker followed by intraoperative axis marking (two-step procedure). This clinical study included 80 eyes of 74 patients undergoing cataract surgery with coexisting corneal astigmatism.

Results: The mean postoperative UCDVA at postoperative day 01 for the first group was 0.295 ± 0.14 logMAR (range from 0 to 0.8 logMAR) and for the second group was 0.328 ± 0.22 logMAR (range from 0 to 1.0 logMAR). The difference was not statistically significant ($P = 0.441$). The mean postoperative UCDVA at postoperative day 28 for the first group was 0.205 ± 0.13 logMAR (range from 0 to 0.6 logMAR) and for the second group was 0.283 ± 0.19 logMAR (range from 0 to 1.0 logMAR). This difference was statistically significant ($P = 0.045$).

Conclusions: Slit-lamp marking gave better postoperative results as compared to toric bubble marker in terms of better postoperative visual outcome and lesser mean postoperative IOL misalignment following toric IOL implantation in astigmatic patients undergoing cataract surgery.

KEYWORDS: Astigmatism, bubble marker, cataract, corneal, marking, slit lamp, toric intraocular lens

INTRODUCTION

Cataract surgery, nowadays is more of a refractive surgery.^[1] During cataract surgery, achieving the postoperative highest level of uncorrected distance visual acuity (UCDVA) is the ultimate desired goal of any cataract surgeon. Astigmatism correction has become an increasingly important component of cataract surgery as 30% of patients with cataract have preexisting astigmatism of over 0.75 D, 8% of the eyes have corneal

astigmatism of over 2.00 D, and 2.6% of the eyes have corneal astigmatism of over 3.00 D.^[2]

Since postsurgical residual astigmatism can compromise UCDVA, taking care of corneal astigmatism during

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cataract surgery is critically important. To address this, several surgical techniques were used including steep meridian incision, limbal relaxing incisions, peripheral corneal relaxing incisions, and excimer laser surgery.^[3] First toric intraocular lens (IOL) was developed by Shimizu *et al.*, in 1992, as 3-piece nonfoldable polymethyl methacrylate implants, to be inserted through a 5.7 mm incision.^[4,5] Since then, toric IOLs have proven to be the most effective method in providing spectacle independence to astigmatic patients undergoing cataract surgery [Figure 1].^[6]

The alignment and placement of toric IOL depends on the axis of preoperative astigmatism; hence, this axis needs to be delineated precisely for both intraoperative assistance and for postoperative refractive correlation. The fundamentals for proper alignment of toric IOL are^[7] identifying the steep meridian using topography;^[8] toric IOL calculation considering anterior and posterior corneal astigmatism, surgically induced astigmatism, effective lens position, and clear corneal incision facilitating the main port;^[9] pre/intraoperative corneal marking; and finally, positioning the IOL that involves gross alignment and removal of viscoelastic and final alignment of IOL.^[10]

Misalignment of a toric IOL, defined as the difference between the desired implantation meridian and the final achieved position of the IOL,^[11] occurs during:

1. Preoperative assessment: Errors during preoperative assessment are due to tilting of the patient's head during preoperative corneal topography causing inaccurate preoperative prediction of the correct axis for IOL alignment^[12]
2. Intraoperatively: The causes of intraoperative misalignment are an error in corneal marking for desired meridian of implantation and/or intraoperative misalignment of the IOL with the target meridian^[13]
3. Postoperatively: Rotation of IOL postoperatively within the capsular bag, which occurs in a small percentage and may be corrected by early surgical repositioning.

Preoperative corneal marking is, therefore, of the utmost importance in preventing IOL misalignment. According to Hill and Potvin, every 1° where the toric IOL is “off axis” will yield a 3.3% reduction in cylinder correction. If IOL is 10° off the target axis, the patient already loses one-third of the astigmatism correction that was intended.^[14] Thus, a toric lens, if placed 30° off-axis, loses 100% of its optical effectiveness.

Toric marking

To avoid cyclotorsion, the eye should be marked while the patient is seated upright, as cyclotorsion of the eye

occurs approximately 2°–4° (sometimes up to 15°) when a patient lies supine.^[15] Although the accuracy of manual marking methods is high, computer-guided methods have also been employed by some surgeons.^[16] Manual methods commonly used preoperatively include surgeon's direct visual marking, bubble marker-assisted method, slit-lamp marking, pendular marker-assisted method, and tonometer marking.

Previous studies to compare and assess the various manual methods have demonstrated the mean error of alignment ranging from 3° to 7°. Igarashi *et al.* assessed the horizontal meridian misalignment of limbal marking under a slit-lamp microscope and showed the axis misalignment by an average of 3.4° to 6.9°.^[17] A study conducted by Dr. Bhaskar Ray Chaudhuri on “A new slit lamp based method for corneal marking for toric IOL implantation and a comparative series of 60 eyes comparing the results of the new and conventional marking techniques” revealed favorable outcomes for slit-lamp-based method.^[18]

Majority of the eye centers in India performing toric IOL implantation are still dependent on manual methods of corneal marking only. There are very few studies comparing the manual methods of corneal marking, and to the best of our knowledge, only one study conducted by Dr. Bhaskar Ray Chaudhuri^[18] compares the efficacy of slit-lamp marking with bubble marker. Herein, we will compare the preoperative reference corneal markings using slit lamp (as a one-step method), which also eliminates the need of placement of a second axis mark on the table, with that of marking using bubble marker (a two-step method), in cataract patients undergoing toric IOL transplantation.

Aim

The aim of this study was to compare the postoperative residual astigmatism after cataract surgery with toric IOL implantation using slit-lamp-based corneal marking versus using bubble marker for preoperative corneal marking.

Objectives

1. The primary objective of the study is to compare the residual refractive astigmatism in both the groups
2. The secondary objectives are to compare:
 - (a) UCDVA
 - (b) Accuracy in toric IOL alignment or the degree of misalignment in both the groups.

MATERIALS AND METHODS

Duration of study

The duration of this study was from July 2020 to June 2022 (24 months).

Study design

Randomized control trial

This was a comparative prospective analysis of postoperative residual astigmatism after toric IOL implantation in patients undergoing cataract surgery using two different manual methods of corneal marking.

The first group included subjects who underwent manual slit-lamp-assisted preoperative corneal marking. The second group underwent corneal marking with intraoperative bubble marker.

Group 1: In this method, the patient sits at the slit-lamp before surgery with proper head positioning to account for any cyclotorsional movement. Marking is performed as a one-step procedure:

The patient looks into the slit-lamp light, and the beam is narrowed to a thin slit and aligned to the desired axis for IOL placement (as dictated by enVista Toric online calculator) using the rotator switch. The beam is then moved up or down until it passes through the bright first Purkinje image [Figure 2]. Once alignment is achieved, with the patient maintaining steady fixation, peripheral cornea is marked using a gentian violet marker or sterile 26G needle on a 2 mL syringe, where the slit beam cuts the limbus. The site of incision for main port entry as preferred by a surgeon is then marked by realigning the slit beam.

Group 2: It consists of patients undergoing cataract surgery with toric IOL implantation using bubble marker for preoperative corneal marking. Marking is performed as a two-step procedure:

- Preoperative reference marking: Using bubble marker outside the operating room before surgery to identify the 0°, 90°, and 180° on the eye [Figure 3]
- Using the pre-operative reference marks at 0°, 90° and 180° to gauge proper alignment, intra-operative marking for final axis of placement of Toric IOL, as estimated by Toric IOL calculator, is done on the operating table with patient in supine position [Figure 4].

Study sample

Inclusion criteria

- Both male and female patients undergoing cataract surgery with toric IOL implantation
- Corneal astigmatism more than 1 diopter (as calculated by IOLMaster)
- Patients more than 21 years of age on the day of surgery.

Exclusion criteria

- Patients having any anterior segment disorders, e.g., pterygium, corneal dystrophy, scarring, ectasia,

glaucoma, and uveitis

- Patients having any posterior segment disorder
- Irregular astigmatism
- Ocular surface disease or prior refractive surgery.

Strategies to remove confounding

- All cases performed by the same surgeon (right handed)
- Continuous curvilinear capsulorhexis kept uniform between 5 and 5.5 mm in diameter
- enVista toric IOL (Bausch and Lomb) implanted in all cases
- The eyes were randomized to ensure matching
- IOLMaster® 500 from ZEISS used for both the groups for IOL power calculations
- All surgeries carried out using topical anesthesia and with a 2.8 mm main entry port.

Data collection

Preoperative evaluation: 1–2 days before surgery. It included examination of anterior and posterior segments, keratometry, biometry, tonometry, and ultrasound B-scan in cases with media opacity. Corneal astigmatism and K-values were assessed for comparison.

Postoperative follow-up was done for 1 month, consisting of three visits. The first visit on the day following the surgery, the second visit after 1 week, and the third visit after 4 weeks of surgery. Patients' UCDVA, residual refractive astigmatism, and the amount of toric IOL misalignment (in degrees) were noted.

Sample size

The sample size was calculated keeping 80% power and 5% significance level (significant at 95% confidence level).

$$\text{Sample size, } n = \frac{\left(Z_{1-\alpha/2} + Z_{1-\beta} \right)^2 \times 2pq}{(p_1 - p_0)^2}$$

$Z_{1-\alpha/2}$ is the value of α error taken at 5% and is 1.96.

$Z_{1-\beta}$ is the value of β error taken at 20% (0.2) and is 0.84.

p_0 is the prevalence of patients undergoing cataract surgery with toric IOL implantation using any method of corneal marking for preoperative astigmatism and is estimated to be 50% or 0.5.

$$p_1 = \frac{(p_0) \times RR}{[1 + p_0(RR - 1)]} = \frac{0.5 \times 0.25}{[1 + 0.5(0.25 - 1)]} = 0.2$$

$$p = \frac{p_0 + p_1}{2} = \frac{0.5 + 0.2}{2} = 0.35$$

RR is the minimum detectable risk and is taken as 0.25 (considering that it would be worthwhile only if



Figure 1: Toric intraocular lens with reference marks indicating the cylindrical axis



Figure 3: Preoperative reference marking using the bubble marker outside the operating room

postoperative astigmatism is found in maximum 25% of the patients undergoing toric IOL implantation using either of the methods of corneal marking).

$$\text{Hence, } n = \frac{(1.96 + 0.84)^2 \times 2 \times 0.35 \times 0.65}{(0.2 - 0.5)^2} = 39.63$$

A sample size of 40 patients was taken for each study group and a total of 80 patients were selected for this study.

This clinical study included 80 eyes of 74 patients undergoing cataract surgery with coexisting corneal astigmatism.

Statistical analysis

Data analyses was performed using commercial software (SPSS Version 21.0; SPSS, Inc., Chicago, IL, USA). Comparisons of the means of normally distributed data were performed with Student's unpaired *t*-test. Postoperative mean UCDVA and misalignment of toric IOL were compared between the two groups. Percentages of cases with postoperative UCDVA >6/12 (logMAR 0.3) were calculated for both the groups. Percentages of cases with postoperative refractive cylinder <0.5 D were



Figure 2: Slit-lamp marking when the beam passes through the bright first Purkinje image

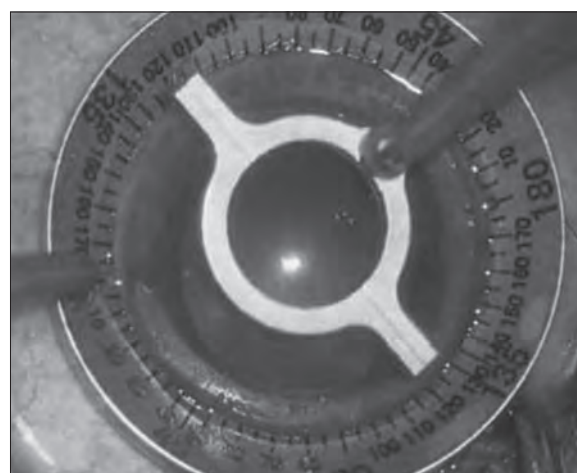


Figure 4: Intraoperative marking of the desired axis on the OT table

also calculated. $P < 0.05$ was considered statistically significant.

Ethical issues

All the aspects of the study and its methods were vetted by the Institutional Ethical Committee. The study was also approved by the Scientific Research Committee of the institution. All included patients signed an informed consent.

RESULTS

The mean age of the first group (with marking on slit lamp) was 66.5 ± 16.82 years ($n = 40$, range 48–83 years). The mean age of the second group (marking with bubble marker) was 63.23 ± 20.40 years ($n = 40$, range 49–90 years). There was no statistically significant difference between the two groups ($t = 1.992$, $P = 0.124$). The first group included 19 males and 21 females, while the second group included 17 males and 23 females.

The mean preoperative corneal astigmatism for the first group was 2.09 ± 0.88 D (range from 1.11 to 4.83 D) and for the second group was 2.18 ± 0.84 D (range from 1.04 to 4.40 D). There was no statistically significant difference between the two groups ($t = 1.991$, $P = 0.650$).

Postoperative day 1

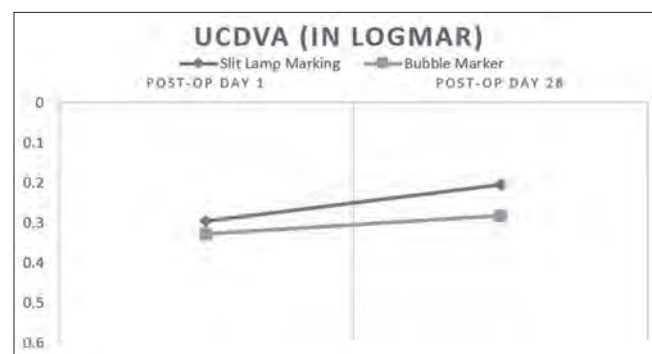
The mean postoperative UCDVA for the first group was 0.295 ± 0.14 logMAR (range from 0 to 0.8 logMAR) and for the second group was 0.328 ± 0.22 logMAR (range from 0 to 1.0 logMAR), as shown in Table 1. The difference was not statistically significant ($P = 0.441$).

The mean postoperative residual refractive cylinder, as shown in Table 2, for the first group was 0.71 ± 0.33 D (range 0.0–1.75 D) representing 66.23% of reduction in the astigmatism from preoperative levels. The mean postoperative residual refractive cylinder for the second group was 0.87 ± 0.62 D (range 0.0–2.50 D) representing 60.13% of reduction in the astigmatism from preoperative levels. This difference was not statistically significant ($P = 0.150$).

The mean postoperative toric IOL misalignment measured by the slit lamp was 5.2 ± 2.32 (range from 0 to 10) for the first group and was 7.0 ± 2.79 (range from 3 to 15) for the second group. This was statistically significant ($P = 0.002$). Postoperative toric IOL misalignment of 7° or less occurred in 35 eyes (87.5%) of the first group in comparison to 24 eyes (60%) of the second group, as shown in Table 3.

Postoperative day 28

The mean postoperative UCDVA for the first group was 0.205 ± 0.13 logMAR (range from 0 to 0.6 logMAR) and for the second group was 0.283 ± 0.19 logMAR (range from 0 to 1.0 logMAR), as shown in Graph 1. The difference was statistically significant ($P = 0.045$). As shown in Table 1, in the first group, 37 eyes (92.5%) had postoperative UCDVA of 0.3 logMAR or better. In the second group, 29 eyes (72.5%) had postoperative UCDVA of 0.3 logMAR or better. For both the groups,



Graph 1: Comparison of mean uncorrected distance visual acuity on postoperative days 1 and 28. UCDVA: Uncorrected distance visual acuity

no eyes lost lines of visual acuity. All eyes in both the groups had a best-corrected distance visual acuity of 0.2 logMAR or better.

The mean postoperative residual refractive cylinder, as shown in Table 2 and Graph 2, for the first group was

Table 1: Uncorrected distance visual acuity (comparison on postoperative days 1 and 28)

UCDVA (logMAR)	Postoperative day 1		Postoperative day 28	
	Group 1	Group 2	Group 1	Group 2
0.0–0.2	16	17	28	23
0.3–0.5	23	18	11	14
0.6–0.8	1	4	1	2
0.9–1.1	0	1	0	1

UCDVA: Uncorrected distance visual acuity

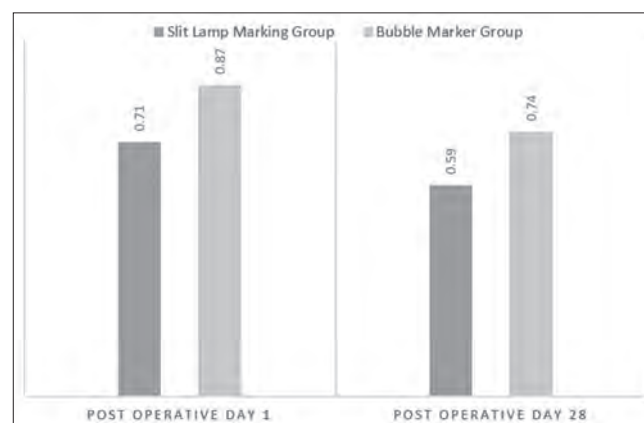
Table 2: Residual astigmatism (comparison on postoperative days 1 and 28)

Cylinder (diopters)	Postoperative day 1		Postoperative day 28	
	Group 1	Group 2	Group 1	Group 2
0.00–0.50	19	16	20	20
0.75–1.00	19	13	19	14
1.25–1.50	1	5	1	2
1.75–2.00	1	3	0	2
>2.25	0	3	0	2

Table 3: Toric intraocular lens misalignment (comparison on postoperative days 1 and 28)

Toric IOL misalignment ($^\circ$)	Postoperative day 1		Postoperative day 28	
	Group 1	Group 2	Group 1	Group 2
0–2	5	0	5	0
3–5	16	12	18	13
6–8	16	19	14	18
9–11	3	5	3	6
>12	0	4	0	3

IOL: Intraocular lens



Graph 2: Comparison of mean residual astigmatism on postoperative days 1 and 28

0.59 ± 0.28 D (range 0.0–1.25 D) representing 71.61% of reduction in the astigmatism from preoperative levels. The mean postoperative residual refractive cylinder for the second group was 0.74 ± 0.51 D (range 0.0–2.25 D) representing 65.86% of reduction in the astigmatism from preoperative levels. This difference was not statistically significant ($P = 0.11$).

The mean postoperative toric IOL misalignment measured by the slit lamp was 5.05 ± 2.24 (range from 0 to 9) for the first group and was 6.88 ± 2.92 (range from 3 to 16) for the second group, as shown in Table 3 and Graph 3. This was statistically significant ($P = 0.002$). Postoperative toric IOL misalignment of 7° or less occurred in 35 eyes (87.5%) of the first group in comparison to 26 eyes (65%) of the second group.

Thus, the mean postoperative toric IOL misalignment was comparable within each of the groups on postoperative days 1 and 28 certifying the rotational stability of IOL. However, the difference between the two groups remains statistically significant on both occasions.

DISCUSSION

As the phacoemulsification technique has improved, astigmatic error is one of the most important causes of low UCDVA after cataract surgery. Thus, an effort to reduce preoperative corneal astigmatism while undergoing cataract surgery will significantly improve the UCDVA. Implantation of a toric IOL is the best option for correction of coexisting corneal astigmatism.

Newly developed IOLs have better rotational stability and predictability.^[19] Villegas *et al.* mentioned that correcting corneal astigmatism of <0.50 D does not improve visual outcome after the cataract surgery.^[20] Holland *et al.* stated that patients with >0.75 D of corneal astigmatism had better visual outcomes with implantation of toric IOLs than

with implantation of monofocal IOLs.^[21] In the current study, selected patients had >1 D of corneal astigmatism.

Accurate alignment of toric IOL to steep corneal astigmatic axis is important to achieve effective postoperative results. Deviation from the median can be attributed to several mistakes, including inaccurate preoperative prediction of the correct axis for IOL alignment, inaccurate preoperative marking of the horizontal meridian, and inaccurate surgical implantation or postoperative IOL rotation. Preoperative corneal marking is generally the most crucial step in preventing IOL misalignment. Therefore, we aimed to determine the degree to which corneal marking methods would impact residual astigmatism and IOL misalignment.^[22]

Residual astigmatism

As regards the refractive outcome, both the groups in the current study showed a marked reduction of preoperative astigmatism around 66%–72% with no statistically significant difference between the two groups. As shown in Table 4, the percentage of patients with postoperative residual refractive astigmatism <0.5 D after toric IOL implantation represented 50% in both the groups compared to 25% to 100% of the cases reported in the literature.^[23,24]

Uncorrected distance visual acuity

Patients with slit-lamp marking showed a clinically better visual outcome as regards mean postoperative UCDVA and the percentage of cases with UCDVA >0.3 logMAR. This difference was statistically significant on the third follow-up visit 4 weeks postsurgery. As shown in Table 5, in the current study, patients achieving



Graph 3: Comparison of mean toric intraocular lens misalignment on postoperative days 1 and 28. IOL: Intraocular lens

Table 4: Residual astigmatism (comparison with previous studies)

Residual refractive astigmatism (diopters)	Slit-lamp marking	Bubble marker
Present study		
Mean	0.59 ± 0.28	0.74 ± 0.51
<0.50 D (%)	50	50
Previous studies		
Mean (range)	0.35–0.65	0.40–0.87
<0.50 D (%)	40–100	25–100

Table 5: Uncorrected distance visual acuity (comparison with previous studies)

UCDVA	Slit-lamp marking	Bubble marker
Present study		
Mean	0.205 ± 0.13	0.283 ± 0.19
0.3 logMAR or better (%)	92.5	72.5
Previous studies		
0.3 logMAR or better (%)	70–100	70–95

UCDVA: Uncorrected distance visual acuity

postoperative UCDVA >0.3 logMAR represented around 92.5% of the cases in slit-lamp marking as against 72.5% in the bubble marker group. The reported percentage of patients achieving postoperative UCDVA >0.3 logMAR after toric IOL implantation represented 70% to 100% of the cases with slit-lamp marking as against 70% to 95% with bubble marker as per the literature.^[25,26]

Postoperative toric intraocular lens misalignment

The slit-lamp marking group showed a statistically significant better outcome in terms of mean postoperative toric IOL misalignment which was $5.05^\circ \pm 2.24^\circ$ (previous studies ranged from 2.40 to 6.85) compared to $6.88^\circ \pm 2.92^\circ$ in the second group using bubble marker (wherein previous studies ranged from 2.85 to 7.42), as shown in Table 6. Postoperative toric IOL misalignment of 7° or less occurred in 35 eyes (87.5%) of the first group in comparison to 26 eyes (65%) of the second group on the third follow-up visit 4 weeks postsurgery.

Other aspects

Realignment of a significantly misaligned toric IOL should be done within the first few weeks of surgery because the adhesions that form between the capsular bag and the lens can pose difficulties to the second intervention.^[27]

In our study, the same right-handed surgeon marked both the right and the left eyes while using his dominant hand, a factor that may be pondered upon for the degree of axis misalignment between the left and right eyes. Likewise, the placement of the incision hand relative to the marking might have resulted in some variability between the right and left sides which has not been studied.

CONCLUSIONS

Slit-lamp marking gave better postoperative results in terms of visual outcome and mean postoperative toric IOL misalignment following toric IOL implantation in cataract surgery. The difference of the uncorrected visual acuity (logMAR) between the two groups 4 weeks postoperatively has occurred because of the higher mean postoperative toric IOL misalignment in the bubble marker group.

In our study, the results and outcome postslit-lamp marking technique (as a one-step method) for corneal

marking before toric IOL implantation were better and statistically significant as compared to marking with bubble marker.

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Conflicts of interest

There are no conflicts of interest.

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A Rare Case of Bilateral Pyramidal Cataracts in a Pediatric Patient Requiring Surgical Precision

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ABSTRACT

Bilateral pyramidal cataracts in pediatric cases present complex diagnostic and management challenges, necessitating meticulous surgical techniques and close monitoring to prevent visual impairment and amblyopia. This case report aims to present a comprehensive analysis of a challenging pediatric case involving bilateral pyramidal cataracts, enhancing diagnostic and management insights for anterior polar pyramidal cataracts, and exploring potential strategies for improved surgical precision and safety. A detailed account of the case of a 7-year-old Caucasian female with bilateral pyramidal-shaped capsulolenticular opacification obstructing the visual axis is provided, highlighting the diagnostic process, surgical intervention, and postoperative outcomes. The surgical intervention, involving meticulous capsulorhexis, lens opacity removal, and intraocular lens implantation, led to substantial improvement in visual acuity without notable complications, underscoring the importance of early diagnosis and precise surgical management. The presented case underscores the significance of early intervention to prevent amblyopia in pediatric patients with pyramidal cataracts, emphasizing the necessity of meticulous surgical techniques and consistent follow-up to detect and address potential complications. Further research and experience sharing can contribute to improved outcomes in managing this rare condition.

KEYWORDS: *Amblyopia, anterior polar cataract, congenital cataract, pyramidal cataract, surgical management, visual acuity*

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INTRODUCTION

Congenital cataracts manifest either at birth or during the initial decade of life, exerting a substantial impact on the pediatric population worldwide. The prevalence of bilateral blindness resulting from cataracts in children exceeds 14 million cases, constituting more than half of all instances of global blindness. It is noteworthy that approximately half of these cases are of hereditary origin, frequently associated with nearly 200 distinct genetic disorders.^[1]

While anterior polar cataracts are relatively frequent, pyramidal cataracts represent a rare form of capsulolenticular cataracts characterized by conical opacities projecting into the anterior chamber from the anterior capsule of the lens. These types of lesions may be unilateral or bilateral with varying degrees of cortical

opacity surrounding them. Although they have a similar site of origin to common anterior polar lens opacity, pyramidal cataracts are larger in diameter and elevation. Their etiology is not well understood, and little data exists regarding their clinical course.^[2]

Despite being uncommon, pyramidal cataracts pose challenges during surgical intervention due to their size and degree of extension into the anterior chamber.^[3] Capsulorhexis in pediatric cases can be particularly challenging due to high capsular elasticity frequently leading to oversized anterior capsulorhexis.^[4] Moreover, spontaneous dehiscence or separation from the lens capsule during surgical maneuvers has been reported for these types of lesions.^[5,6]

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Given this context, we present a unique case involving bilateral pyramidal cataracts that highlights both diagnostic and management considerations associated with anterior polar pyramidal cataracts. By documenting our patient's experiences through clinical presentation and treatment course, we aim to contribute further knowledge on this rare condition while discussing potential solutions to improve precision and safety during surgery.

CASE REPORT

A 7-year-old female patient of Caucasian descent was referred to the cornea clinic due to a noticeable decline in visual acuity in both eyes. The patient had no previous medical history, ongoing medication use, or history of surgical procedures. Her prenatal and neonatal periods were uneventful, and there were no noteworthy familial medical conditions.

On thorough examination, the patient exhibited reduced visual acuity (20/63) in both eyes. Auto refractometric measurements were unreliable during the ophthalmic evaluation. Slit lamp biomicroscopy examination revealed white pyramidal-shaped capsulolenticular opacification extending into the anterior chamber, surrounded by a clear lenticular zone in both eyes. The base diameter of the pyramidal cataract was measured as 1.1 mm in the right eye and 1.2 mm in the left eye, causing bilateral obstruction of the visual axis. The fundus examination did not reveal any abnormalities. Intraocular pressure measurements remained within the normal range for the patient's age group. To further investigate the lesions and their potential connections, color anterior segment photography [Figure 1] and Scheimpflug's corneal topography were performed.

After obtaining informed consent from the parents of the child, cataract extraction surgery was performed in both eyes a few months apart under general anesthesia. The same surgical technique was applied to both eyes as follows. A 2.2 mm biplanar superior clear corneal incision was created, utilizing a bimanual technique through paracenteses made on either side. To safeguard

the endothelium, a sterile air bubble was injected into the anterior chamber, while trypan blue was employed to reduce the elasticity and tension of the pediatric lens capsule. Cohesive viscoelastic material was introduced into the anterior chamber. Subsequently, an anterior capsular flap was fashioned, followed by the execution of a 5.0 mm continuous curvilinear capsulorhexis. The pyramidal lens opacity, which remained attached to the anterior capsular flap, was meticulously removed using capsulorhexis forceps. The lens material was aspirated using the bi-manual irrigation aspiration method. To mitigate early inflammatory reactions and postoperative inflammatory complications, enoxaparin sodium (Clexane; Aventis Pharma, Surrey, England, United Kingdom) was added to the irrigation solution of the phacoemulsification device. A single-piece hydrophobic acrylic intraocular lens designed for the posterior chamber was inserted into the capsular bag, with the power adjusted to achieve a targeted hyperopic value of +0.75 D in the postoperative period. The anterior and posterior capsules were meticulously polished to prevent early-onset posterior capsule opacification. Given the patient's good cooperation during the procedure, posterior capsulotomy was not performed; however, neodymium-doped yttrium aluminum garnet-laser posterior capsulotomy was scheduled for future follow-up visits if deemed necessary [Supplementary Video 1]. The patient's postoperative progression exhibited no notable complications after receiving a treatment regimen primarily involving topical moxifloxacin, dexamethasone, and tropicamide eye drops. At the 1-month follow-up, there was a substantial improvement in unassisted visual acuity, reaching 20/40 in both eyes. However, bilateral corneal astigmatism was detected. Assisted visual acuity was 20/32 in the right eye (with a prescription of $-0.50 + 2.00$ at 90°) and in the left eye (with a prescription of -2.50 at 90°). Autorefractive readings were $(-0.75 + 3.00$ at $100^\circ)$ in the right eye and $(-0.25 + 3.23$ at $89^\circ)$ in the left eye.

DISCUSSION

Congenital anterior lens opacities manifest as a white opacity that either involves or resides just below the anterior lens capsule. These opacities are estimated to represent approximately 14% of all cases of congenital cataracts.^[7] The development of congenital anterior lens opacities is believed to arise from mesodermal tissue that becomes trapped within the lens capsule during embryological development.^[8] In general, these opacities are nonprogressive and frequently present bilaterally, with a diameter rarely exceeding 3 mm. Conventionally, they have been considered to have minimal impact on visual function.^[7,9] Congenital anterior cataracts can be

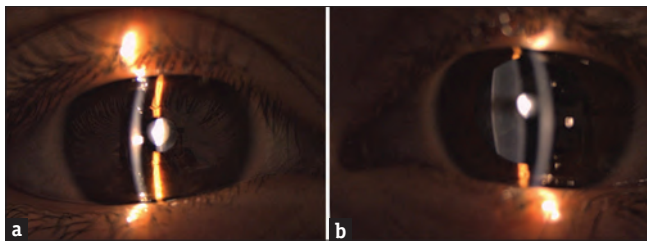


Figure 1: Preoperative anterior segment photos of both eyes. Slit lamp optical section showing the pyramidal extension in the right eye (a) and in the left eye (b)

further categorized into three primary subtypes: polar, subcapsular, and pyramidal.^[8] Among the subtypes of congenital anterior lens opacities, the pyramidal subtype is notably associated with a risk of amblyopia exceeding 90%.^[10] Furthermore, a correlation between anterior lens opacities and corneal astigmatism has been observed.^[11] In addition, anterior lens opacities have been linked to conditions such as keratoconus, corneal opacities, and other congenital anomalies, supporting the aforementioned developmental theory.^[12] In line with the literature, the pyramidal anterior polar cataract was bilateral in the presenting case and corneal astigmatism (+3.98 at 102° in the right eye and + 5.09 at 91° in the left eye preoperatively) existed.

Despite their small size, anterior lens opacities pose a significant risk of amblyopia. The obstruction caused by the cataract, hindering the passage of light, can result in stimulus deprivation amblyopia. While surgical intervention for these opacities is uncommon, there are cases where surgery becomes necessary, especially in instances of the pyramidal subtype or cortical changes that heighten the risk of progression. Besides, anisometropia, a condition characterized by significant differences in refractive error between the two eyes, is the primary cause of amblyopia in patients with anterior lens opacities. Therefore, regular monitoring of patients with anterior lens opacities is crucial to detect the development of anisometropia and amblyopia.^[13] In cases where children do not exhibit significant amblyopia, a conservative approach is preferred for the management of congenital anterior lens opacities. For those with unilateral pyramidal cataracts, occlusion therapy is the preferred treatment strategy. On the other hand, children with bilateral pyramidal cataracts are closely monitored until there is evidence of cataract progression the development of amblyopia, or both. When amblyopia occurs or the lens opacities are deemed to be amblyogenic, surgical intervention becomes the primary treatment option.^[2] Our patient underwent uneventful cataract surgery in both eyes. The surgical approach for pyramidal cataracts should focus on meticulous capsulorhexis and removal of the lens opacity while ensuring the safety of the surrounding structures. Intraoperative techniques play a vital role in achieving successful outcomes during cataract surgery. Various approaches can be employed, such as the utilization of trypan blue to reduce capsular elasticity and tension, or the addition of enoxaparin sodium to the irrigating solution to minimize postoperative inflammatory reactions. These techniques contribute to optimizing surgical procedures and improving overall outcomes.

Pyramidal cataracts, though rare, can significantly impact visual acuity in pediatric patients and necessitate early intervention to prevent amblyopia. Surgical management of pyramidal cataracts requires meticulous capsulorhexis and removal of the lens opacity, considering the challenges posed by the size and extension of the cataract. Regular monitoring and follow-up are vital to detect anisometropia, amblyopia, and other potential complications. The presenting case highlights the importance of early diagnosis and appropriate management to prevent visual impairment and amblyopia associated with this condition.

Authors' contributions

All authors collected the study data and wrote, revised, and approved the manuscript.

Availability of data and material

The authors confirm that the data supporting the findings of this study are available within the manuscript.

Standards of reporting

CARE guidelines were followed in this study.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the legal guardian has given his consent for images and other clinical information to be reported in the journal. The guardian understands that names and initials will not be published and due efforts will be made to conceal the identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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Rhexis Stress Rip Sign

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ABSTRACT

Secondary rhexis tears occur in intact primary capsulorhexis due to sharp instruments or phaco probes tearing the anterior capsule in the usual surgical scenario. We report a series of secondary rhexis tears during cataract surgery associated with congenital iridofundal colobomas. Here, the tear happens in the coloboma area due to stress exerted on the capsulorhexis margin by a blunt force from within or from the outside. The tear may even propagate to the posterior capsule, making the surgery complicated. We presume that this splitting of the capsule could be due to the unusually fragile nature of capsule and the lack of zonular support in the colobomatous area.

KEYWORDS: *Blunt stress, coloboma, rhexis rip*

INTRODUCTION

Cataract surgery in eyes with iridofundal colobomas is challenging due to poor pupillary dilatation, zonular weakness, phacodonesis, dense cataracts, and a crowded anterior chamber.^[1,2] The chances of primary rhexis extension are very high in such eyes in the colobomatous area. Initiating rhexis in the area of intact zonules and making it smaller in the colobomatous area ensure an intact capsulorhexis.^[3] Herein, we report five cases of “rhexis stress rip sign” where secondary rhexis tears were noted in the colobomatous area during surgery due to the exertion of blunt stress from within or externally on the rhexis margin.

CASE REPORTS

Cases 1, 2, and 3

Three cases of “rhexis stress rip sign” were noted in Manual small incision cataract surgery (MSICS) after delivery of hard nuclei (Grade 4 nuclear sclerosis). Nucleus delivery was performed using the bimanual technique. In this technique, a cyclodialysis spatula was inserted under the nucleus using the nondominant hand after gentle hydro dissection, and the nucleus was wheeled out of the capsular bag using a Sinskey hook. In all the cases, following the bimanual technique, a rhexis tear was noted in the colobomatous area with posterior extension and posterior capsular tear (PCR) [Figure 1]. Vitreous disturbance was absent. Rigid

three-piece intraocular lens (IOL) was implanted in the sulcus in all the cases, with single-point haptic fixation to the iris in two cases.

Here, the stress exerted at the inner rhexis margin from within while wheeling out the bulky nucleus caused the ripping of the thin anterior capsule in the colobomatous area. We suggest making a large eccentric capsulorhexis larger in the area of intact zonules to avoid capsulorhexis rip in cases of dense cataracts associated with iris coloboma while performing MSICS [Figure 2]. In cases of small pupil, iris hooks may be placed superiorly to aid in the creation of a large rhexis. In cases of severe micro cornea, intentional cuts or capsulotomies may be placed to avoid capsular rip extending posteriorly and to maintain posterior capsule integrity.

Case 4

The third case of “rhexis rip sign” was observed in a case of phacoemulsification of a cataract of Grade 3 nuclear sclerosis while inserting capsular hooks in the colobomatous area for capsular support before initiating nucleus disassembly. The blunt stress exerted on the rhexis margin from outside while placing the capsular hooks caused the rhexis rip in this case. Phacoemulsification was continued, and there was no posterior extension of the tear. A foldable three-piece

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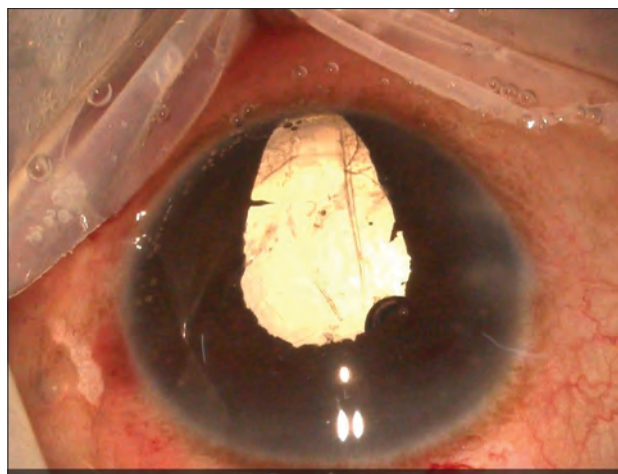


Figure 1: Inferior “Rhexis Stress Rip,” noted after nucleus delivery. Note the posterior extension with posterior capsular rent without vitreous disturbance

IOL was placed in the sulcus vertically with haptic in the area of the rhexis rip, and haptic fixation to the iris was done inferiorly. A bent 9-0 Prolene straight needle was inserted through the corneal tunnel, passed through one margin of the colobomatous iris, brought under the haptic in the colomatous rip area, and passed through the other colobomatous iris margin and brought out. Suture loop was brought out, and fixation was performed using the 4-throw pupilloplasty technique. This also serves the purpose of iris coloboma repair in such cases.

The authors recommend judicious use and careful insertion of capsule hooks in coloboma eyes. Excessive tightening or jerky movements during the insertion of hooks can tear the fragile capsule in the colobomatous area. Iris hooks are not recommended for stabilizing the bag inferiorly in these cases, as iris hooks being sharper increases the risk of rhexis tear.

Case 5

The fourth case of “rhexis rip sign” was noted in a case of phacoemulsification in a mature cataract during the insertion of capsular tension ring (CTR). The timing of placement of CTR was after cortex wash, before placement of IOL. Superior phacoemulsification was performed in this case and CTR was inserted from the side port incision placed at the 3 o’clock position. As the CTR was being dialed into the bag, the blunt stress exerted by the CTR on the outer edge of rhexis margin caused a sudden rip in the colobomatous area, without posterior extension. CTR was explanted in this case, and iris fixation of haptic of a foldable three-piece IOL was performed inferiorly.

DISCUSSION

“Rhexis stress rip” is an uncommon occurrence during

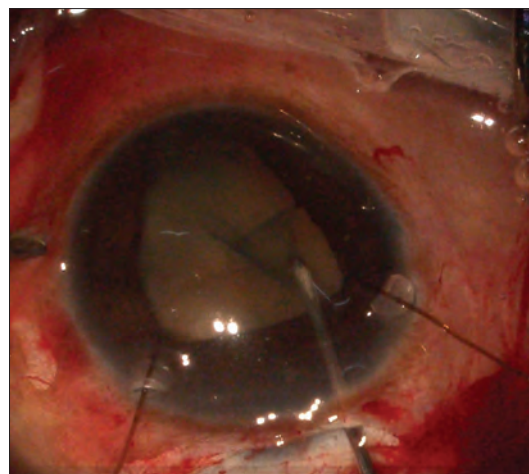


Figure 2: Creation of a large eccentric rhexis, larger in the area of intact zonules in a patient with microcornea, iridofundal coloboma

cataract surgery in eyes with iridofundal colobomas. It is characterized by the secondary tear in the rhexis margin inferiorly in the colobomatous area as a result of blunt stress being exerted from within or from outside. We presume that this happens due to the abnormally fragile nature of the anterior capsule in the colobomatous area and the lack of zonular support in this area.

In patients undergoing MSICS, it is most commonly observed after delivery of a bulky nucleus. These cases are often associated with posterior extension of the rip and PCR. We recommend using iris hooks superiorly and making a large eccentric rhexis to avoid this scenario. In case of the severe micro cornea, intentional cuts in the capsulorhexis can avoid rhexis rip.

In patients undergoing phacoemulsification, the incidence of “rhexis stress rip” is comparatively less and often is caused due to stress exerted on the rhexis margin from outside, as during the insertion of capsular hooks or CTR. These cases are not associated with posterior extension or PCR.

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Conflicts of interest

There are no conflicts of interest.

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A Big Astigmatic Refractive Surprise Corrected by Flipping the Custom Toric Intraocular Lens

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ABSTRACT

Refractive surprises in regular Toric IOLs are usually due to rotation of the IOL, incorrect IOL placement or misalignment, unexpected surgically induced astigmatism or inaccurate IOL power calculation. These can be corrected postoperatively by redialing the IOL, exchange of IOL or laser corneal refractive procedures. Newer Custom Toric IOLs are now being used to correct high astigmatism(>6D). We hereby report a case of a big astigmatic refractive surprise after cataract surgery with a well aligned Custom Smart Toric IOL due to inadvertent IOL flip during implantation. This was corrected by flipping back the IOL on post operative day three.

KEYWORDS: *Big astigmatic refractive surprise, custom toric intraocular lens, flip, toric intraocular lenses*

INTRODUCTION

Toric intraocular lenses (IOLs) are the IOLs of choice for implantation in refractive cataract surgeries with corneal astigmatism. Regular toric IOLs would correct astigmatism up to 6 diopters in the IOL plane.^[1,2] Custom toric IOLs are lenses which are specially made for high corneal astigmatism (>6D).^[1,2] Newer IOLs such as Ultima Smart Toric ([UST], Care Group, India) have an inbuilt axis and they must be aligned along the 0°–180° axis.^[1,2]

The common causes of refractive surprise after toric IOL implantation are the rotation of the IOL, incorrect IOL placement or misalignment, unexpected surgically induced astigmatism, or inaccurate IOL power calculation.^[2,3] These refractive surprises can be corrected by understanding the cause and choosing an appropriate surgical method^[4] such as redialing the IOL, exchange of IOL, or laser corneal refractive procedures.^[2,3]

The purpose of our case report is to highlight the inadvertent flip of IOL during implantation as one of the causes of big refractive surprises in custom toric IOL which is corrected by flipping back the IOL.

CASE REPORT

A 53-year-old female came to our outpatient department in

January 2023 with complaints of decrease in vision in Left eye (LE) with uncorrected visual acuity (VA) of 3/60. She had a history of high refractive error in LE since childhood with no improvement with glasses. No previous records were available. Her keratometry values were K₁ 43.25D at 68° and K₂ 50.75D at 158° showing an astigmatism of 7.5D and autorefractometer values [Table 1] showed an astigmatism of around 8D. The radius of curvature of the anterior and posterior cornea was 7.27 mm and 6.39 mm, respectively. On detailed examination, a diagnosis of LE cataract with stable keratoconus with high corneal astigmatism with amblyopia was made.

As the corneal astigmatism was more than 6.0D, a decision to implant customized smart toric IOL was taken. IOL power was calculated using IOL Master 700 and planning was done on Verion Image Guided system.^[2,3] A custom toric IOL (UST) of 13.5 D/Cyl: 12D at 158° was planned [Figure 1a].

LE uneventful phacoemulsification surgery was performed. The custom toric IOL was implanted as planned and aligned at 0°–180° axis, but to our surprise, the immediate postoperative autorefractometer reading showed a big astigmatic surprise [Table 1]. Instead of correcting the

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Figure 1: (a) Toric intraocular lens (IOL) plan on Verion Image Guided system, (b) Customized Ultima Smart Toric IOL

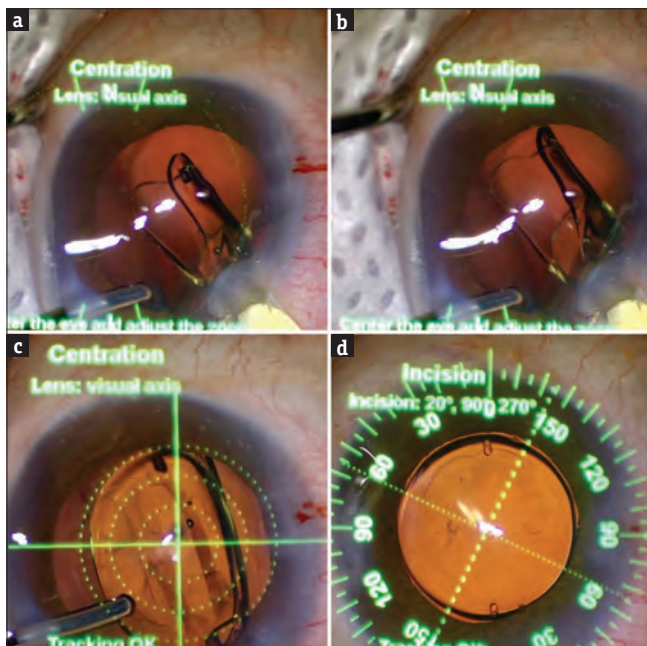


Figure 2: (a and b) Leading haptic with the hole opening toward right side instead of left side, (c) Flipped intraocular lens (IOL), (d) Well-aligned IOL after intraoperative flip

preoperative high cylindrical values, we ended up with increased postoperative cylindrical values [Table 1].

On careful review of the surgical video [Figure 2], we realized that the IOL had flipped during implantation. Hence, the next day, the patient along with relatives were informed and explained about the situation. The patient was taken to the operation theater on the 3rd day for flipping the IOL back to correct the cause.

Methods – Flipping of IOL,^[5] [Figure 3].

Under topical anesthesia, side ports were opened and the IOL was lifted from the capsular bag in the anterior chamber with the help of viscoelastic (methylcellulose). Then, with the help of two Sinskey Hooks, IOL was flipped 180° so the anterior surface with the inbuilt

Table 1: Pre- and postoperative, and postflip autorefractometer value and visual acuity

Values	AR	UCVA
Preoperative	+0.50D/−8.00D at 70°	3/60
Postoperative (immediate)	+1.00D/−11.25D at 51°	3/60
Postflipping (POD)		
POD 1	+0.25D/−0.75D at 68°	6/18
POD 1 month	+0.50D/−0.75D at 70°	6/12
POD 6 months	+0.50D/−0.50D at 69°	6/12

AR: Autorefractometer, UCVA: Uncorrected visual acuity, POD: Postoperative day

toricity came to lie anteriorly. The IOL was then repositioned in the bag and thorough viscoelastic removal was done and the markings were aligned at 0°–180° with the help Verion Image Guided system. Side ports were closed.

Immediate postoperative autorefractometer showed that astigmatism was corrected, and the VA improved to 6/18 on postoperative day (POD) 1 [Table 1]. As a result of preexisting amblyopia, the final VA is 6/12, which is stable POD6 months [Table 1].

DISCUSSION

This custom toric IOL is a plate haptic, planar, biconvex IOL with toricity inbuilt on the anterior surface and must be aligned 0°–180°. It has two holes which are diagonally placed on the two opposite plate haptics [Figure 1b]. The IOL should be loaded in such a way that the leading haptic with the hole should open on the left side of the surgeon operating from the temporal side. In our case, the IOL flipped and opened on the right side acting as a mirror image, shifting the toric axis at 22° [Figure 2]. The toricity thus shifted anti-clockwise, 44° away from the intended 158° axis. The reported data shows 1%–1.3% frequency of reversed implantation of IOLs which can be recognized only after the optic has unfolded within the eye,^[5] so, it can be missed.

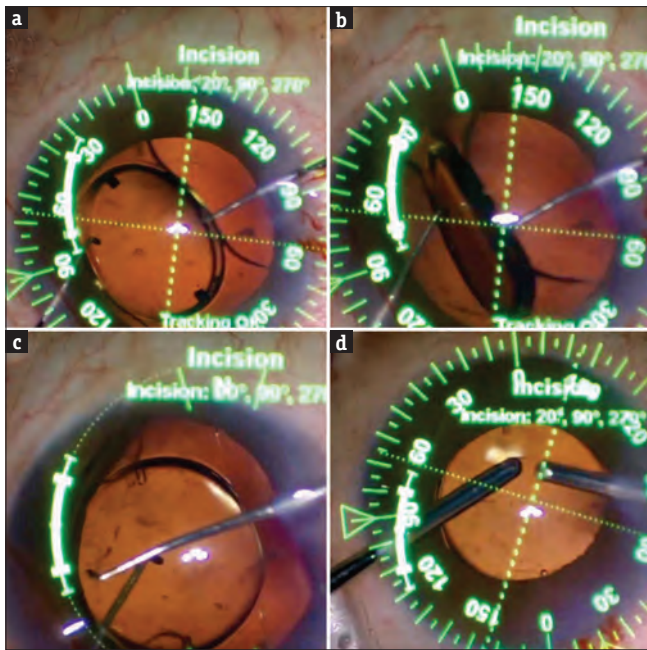


Figure 3: (a) Lifting intraocular lens (IOL) in anterior chamber, (b and c) flipping back the IOL by 180° with the help of 2 Sinsky Hooks, (d) Well-aligned flipped back IOL with corrected toricity

Toric IOL loses its toricity if it rotates more than 30° and further rotation will increase astigmatism by about 3.3% per degree. As the IOL was reversed and misaligned by 44°, it induced more astigmatism [Table 1].^[2] clockwise rotation by 44° will bring the IOL to the intended axis of 158° but it will not give full toric correction as the high toric power is now placed posteriorly in the bag due to flip.

As the cause of this surprise was clear, there was no need to explore other options such as Astigmatismfix.com^[2,3] and Assort.com. Hence, the simple solution was to correct the cause^[4] and flip the IOL back and align at 0°–180° [Figure 3].

To the best of our knowledge and literature search, we did not find any reported case of intraoperative IOL flip of a custom toric IOL leading to a big astigmatic surprise, but we could find few case series regarding the use of custom toric IOLs to correct high astigmatism in

pellucid marginal corneal degeneration and keratoconus patients with cataract.^[1,6] Hence, we can say that ours is a special case which needs to be mentioned.

CONCLUSION

We would like to conclude that the intraoperative flip of custom toric IOL with plate haptics can be one of the causes of a big astigmatic surprise which can be corrected by flipping it back.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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Peripheral Sterile Corneal Infiltrate Status Postfemto-laser *In situ* Keratomileusis

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ABSTRACT

Peripheral sterile corneal infiltrate status postlaser *in situ* keratomileusis (LASIK) is a relatively rare complication. A 26-year-old female who underwent uneventful femtosecond laser-assisted LASIK developed unilateral peripheral, multifocal corneal infiltrate along the flap margin on postoperative day 4 and responded to topical steroids and oral doxycycline resulting in complete resolution on postoperative day 9, with best-corrected visual acuity 6/6. Early diagnosis and appropriate management can result in quick resolution without compromising visual outcome.

KEYWORDS: Corneal infiltrate, laser *in situ* keratomileusis, peripheral, sterile

INTRODUCTION

Laser *in situ* keratomileusis (LASIK) is one of the most widely performed ophthalmic surgical refractive procedures in the world. It includes both conventional microkeratome LASIK and femtosecond laser-assisted LASIK (femto-LASIK).

Although rare, peripheral infiltration can be a complication status post-LASIK in the early postoperative period, and if the entity and its likely immune etiology is in knowledge of the refractive surgeons, it can abate the need for further investigations like flap lift and culture for microbiology. Although meticulous examination and close follow-up to rule out the possibility of infectious keratitis cannot be undermined at the same time.

This is a case report of a peripheral sterile infiltrate status postfemto-LASIK.

CASE REPORT

A 26-year-old female with bilateral high myope presented for evaluation and refractive surgery. Her uncorrected visual acuity (UCVA) was counting fingers 3 m in both eyes. Her best-corrected visual acuity was 6/6 in both eyes. She was accepting -9 DS/-2.5 DC × 70 in the right eye and -7 DS/-1.5 DC × 110 in the left eye. After a thorough refractive surgery workup, implantable collamer lens (ICL) implantation was done

in the right eye under topical anesthesia, followed by left eye femto-LASIK after 1 week with a superior hinge (FS200, Alcon, Germany). The surgery was uneventful, without signs of bleeding from the flap edge before and after the surgery. The patient was prescribed topical 1% prednisolone acetate three hourly in tapering dose, 0.5% moxifloxacin eye drop three hourly and lubricants, and oral doxycycline 100 mg twice daily for 1 week. On postoperative (postoperative) day 1, UCVA in the left eye was 6/6. LASIK flap was *in situ*, and the interface was clear. On regular follow-up on postoperative day 4, UCVA in the left eye was 6/6. The patient was asymptomatic, but on slit-lamp examination; peripheral marginal inferior subepithelial infiltrate near the flap margin at 5 o'clock and 7 o'clock positions was noted [Figure 1]. There was no epithelial defect or anterior chamber reaction. Tobramycin eye drop, eight hourly, was added; rest treatment was continued. On postoperative day 5, the peripheral infiltrate was noted to be less intense. Subjacent to the previous lesion minimal cellular infiltration as diffuse lamellar keratitis was noted [Figure 2]. The frequency of steroids was hiked up to one hourly dosage. On postoperative day 6, left eye peripheral activity decreased significantly. On postoperative day 9, left eye peripheral activity

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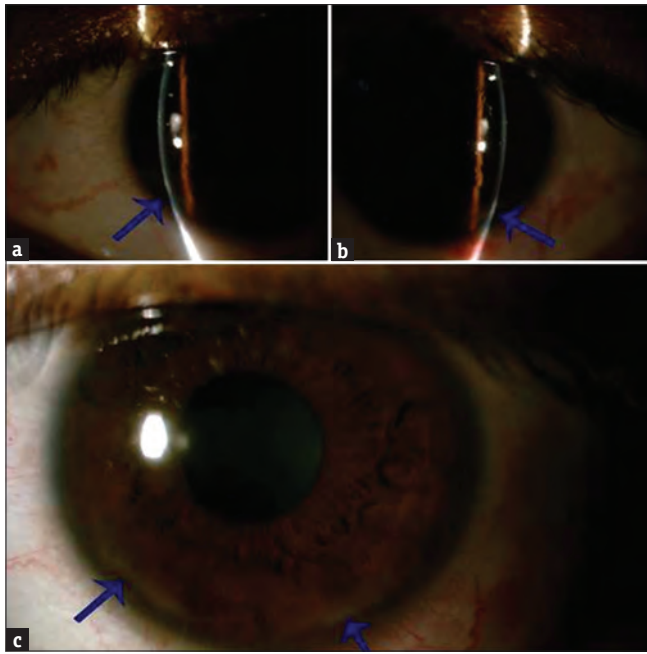


Figure 1: (a and c) Corneal infiltrate in periphery along the flap margin at 7 o'clock position on postoperative day 4, (blue arrow) (b) Corneal infiltrate in periphery along the flap margin at 5 o'clock position on postoperative day 4 (blue arrow)

resolved completely with minimal peripheral residual scar [Figure 3] with UCVA of 6/6. Topical steroids were tapered weekly.

DISCUSSION

Peripheral corneal infiltrate status post-LASIK is a very rare complication. Immune-mediated etiology appears to be more commonly associated, but at the same time, one needs to have a strong suspicion of infectious etiology till ruled out with investigations or based on clinical response. Common associations with peripheral sterile infiltrate are blepharitis, staphylococcal hypersensitivity infiltrate, acne rosacea, hypercholesterolemia, use of topical nonsteroidal anti-inflammatory drugs, patching eye with bandage contact lens causing hypoxia, topical anesthetic abuse, and autoimmune/collagen vascular disorder.^[1] In our case, none of the identifiable risk factors were present. The absence of symptoms, along with no circumciliary congestion, no anterior chamber reaction, no epithelial defect, and no response to topical steroids, was strongly suggestive of noninfectious, sterile nature of infiltrate in our case. In the literature, so far, only seven published case reports/series are there for peripheral sterile infiltrate status post-LASIK.^[2-8] In all previous studies, peripheral infiltrates were responsive to topical steroids, leading to complete resolution of peripheral infiltrate with minimal residual scarring, except Lifshitz *et al.*, who used oral steroids in two cases for significant circumferential infiltrate with a

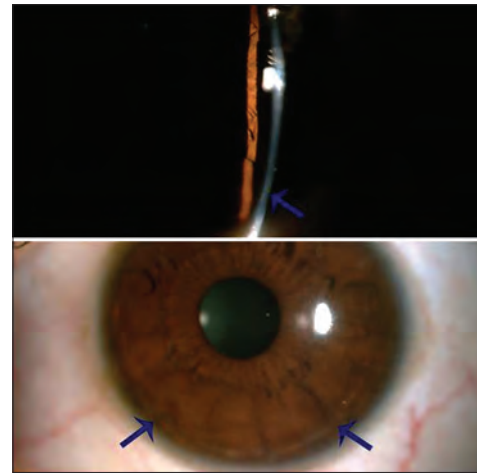


Figure 2: Slit-lamp photo of the left eye on postoperative day 5, showing resolving peripheral sterile infiltrate

dose of 1 mg/kg for 2 weeks.^[2] In the literature search, resolution was noted to vary from postoperative day 4 to as late as 7 weeks.^[2,3] In the case report of Yu *et al.*, delayed resolution of infiltrate in the 7th week can be attributed to the use of low-strength steroids in the form of fluorometholone 0.1%.^[3] None of the cases reported so far was started on systemic doxycycline from the day of operation, except our case as doxycycline is a part of our routine postoperative regimen. This can be the reason for less intense infiltrate at presentation in our case compared to most of other cases. Only Lifshitz *et al.* used doxycycline in one of their cases with meibomian gland disorder after noting peripheral infiltrate and observed complete resolution on the 4th day.^[2] Doxycycline has an established multipronged anti-inflammatory action.^[9] We strongly feel that its use can be corroborative to the steroids in the treatment of peripheral sterile infiltrate. Although its use in routine postoperative regimes needs to be further studied.

In conclusion, recognizing peripheral sterile infiltrate is important for appropriate and early management for a good outcome. Nevertheless, it is very important to maintain a high degree of suspicion for infectious keratitis because management and potential outcomes are very different for both entities.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given her consent for her images and other clinical information to be reported in the journal. The patient understands that her name and initials will not be published and due efforts will be made to conceal her identity, but anonymity cannot be guaranteed.

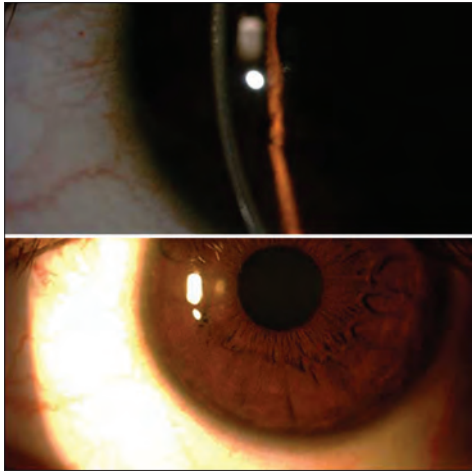


Figure 3: Slit-lamp photo of the left eye on postoperative day 9, showing resolved peripheral infiltrate with minimal residual scar

Financial support and sponsorship

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Conflicts of interest

There are no conflicts of interest.

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Rare Presentation of Bilateral Sturge–Weber Syndrome with Glaucoma

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ABSTRACT

Sturge–Weber syndrome (SWS) or encephalotrigeminal angiomas is a congenital disorder of phacomatoses. The diagnostic triad of skin-unilateral facial port-wine staining involving the ophthalmic division of trigeminal nerve, central nervous system-intracranial leptomeningeal venous angiomas, and ocular-vascular abnormalities of the eyelid, conjunctiva, episclera, ciliary body, choroid, retina, and orbit. Bilateral SWS is rare. We describe the case of a 53-year-old female presented with bilateral SWS with late-onset glaucoma. Surgical treatment with combined phacoemulsification and foldable lens and trabeculectomy with mitomycin C in both eyes was carried out to achieve control of intraocular pressure.

KEYWORDS: *Glaucoma, port-wine stain, Sturge–Weber syndrome*

INTRODUCTION

Sturge–Weber syndrome (SWS) is a nonfamilial, nonhereditary disorder of unknown etiology. It is diagnosed by the triad of unilateral facial port-wine staining (PWS) (nevus flammeus), involving the ophthalmic division of trigeminal nerve, leptomeningeal venous angiomas, and ocular vascular abnormalities.^[1] Incidence is 1 per 50,000 live births with no racial or gender predilection.^[2] Bilateral PWS can be seen in 10% to 30% of cases involving both ophthalmic and maxillary trigeminal nerve distributions. Glaucoma occurs in 30%–70% of SWS individuals^[3] with higher incidence with ipsilateral eyelid PWS and severe vascular anomalies of conjunctiva and episclera. Glaucoma is usually unilateral and diagnosed in infancy, but in 40% of cases, it can occur later in adolescence or adulthood. Bilateral glaucoma can occur when bilateral facial hemangiomas are present. This case report shows a rare case of bilateral SWS (Type II) with late-onset glaucoma without neurological involvement.

CASE REPORT

A 53 year Female presented with a complaint of progressive diminution of vision in both eyes for the past 3 years with irritation and increasing redness. There is no history of seizures, weakness, or mental retardation.

On examination, the patient showed bilateral capillary hemangioma involving the upper two-thirds of the

face on the right side and nearly full face on the left side with involvement of both eyes including upper and lower eyelids [Figure 1a]. The lower lip was protruding and hypertrophied, more on the left side [Figure 1b]. At the intraoral examination, we observed a hemangioma in the retromolar trigone and in the lower surface of the tongue, seen as purplish red spots without symptomatology [Figure 1c]. Gingiva's color and texture were normal, not revealing any signs of hyperplasia. The best-corrected visual acuity was 6/24, N8 in both eyes. Anterior segment examination showed a clear cornea, normal anterior chamber depth, and operable cataracts in both eyes. There was episcleral telangiectasia in the inferonasal quadrant of the right eye. While findings in the left eye were more prominent with 360° episcleral telangiectasia. Intraocular pressure (IOP) measured with applanation tonometer was 40 mmHg and 36 mmHg with the central corneal thickness of 497 μ 484 μm in the right and left eye, respectively. The gonioscopy showed open angles with no angle anomaly. A dilated fundus examination of the right eye showed a medium-sized disc with a deep cup of 0.8 thin neuroretinal rim with an inferior notch. While the left eye had a medium-sized disc

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Figure 1: (a) Bilateral port wine stain. (b) Lesion in vermilion border of the lower lip. (c) Lesion in the lower side of the tongue. (d) Both eyes postoperative appearance. (e) Right eye under speculum showing conjunctival hemangiomas, elevated bleb at 12 o'clock, and pseudophakia. (f) Left eye under speculum showing conjunctival hemangioma on lower part, flat bleb, and pseudophakia

with a large excavated cup of around 0.95 with very thin neuroretinal rim and normal retinal vasculature in both eyes. Humphrey visual field (HVF) analysis on 24-2 showed correlating field defects of upper arcuate scotoma in the right eye [Figure 2a] and double arcuate scotoma showing marked constriction of visual fields with only a small central island of vision in the left eye [Figure 2b]. There was one point fixation threat on the central 10-2 fields of both eyes [Figure 2c and d]. Retinal nerve fiber layer (RNFL) thickness analysis with optical coherence tomography (OCT) showed inferior thinning in the right and involvement of all three quadrants except nasal in the left eye of the optic disc [Figure 2e]. A diagnosis of both eyes operable nuclear cataracts with secondary open-angle glaucoma with Type II SWS was made on the basis of clinical cutaneous and ocular findings and the absence of any neurological symptoms and signs. The patient was started on oral and topical medical therapy for the control of IOP and inflammation and combined cataract and glaucoma surgery with mitomycin C performed in both eyes. Postoperative follow-up up to 12 months in both eyes showed good results, postoperative anterior segment photo [Figure 1d-f] with best-corrected visual acuity 6/6 and N6 and IOP 13 and 14 mmHg, respectively, and stable HVF and OCT reports.

DISCUSSION

SWS is a rare sporadic syndrome characterized by nevus flammeus (port-wine stain-PWS) in the trigeminal nerve distribution, brain leptomeningeal hemangioma, and diffuse choroidal hemangioma. The distribution of PWS along the branches of the trigeminal nerve determines the severity of associated neurological deficits and glaucoma. Hennedige *et al.*

reported that patients with V1 dermatome had a 6.7% risk of glaucoma and a 26.7% risk of neurologic association. Patients with only V2 dermatomes involvement reported no risk of glaucoma and 3.1% neurological involvement when both the V1 and V2 dermatomes were involved; risk was much higher for both glaucoma (31.8%) and neurologic manifestations (54.5%). If all three dermatomes (V1, V2, and V3) were involved, the risk of neurologic manifestations was four times.^[4] Bilateral lesions present in 7%–26% of cases and, compared to unilateral lesions, are usually accompanied by more severe neurological symptoms.^[5] Neurological deficit is caused by the intracranial vessel malformation, and imaging findings can be cortical calcifications, tram line calcifications (30%), cortical atrophy, pial angiomatosis and enlarged ipsilateral choroid plexus, eye manifestations includes glaucoma (30%–70%), choroidal angioma, episcleral/conjunctival angiomas, heterochromia of the iris, and dilated retinal veins and optic atrophy.^[6] Facial nevus flammeus involving the palpebral area is a strong indicator of choroidal hemangioma. Glaucoma is a prominent feature of SWS and bilateral glaucoma is seen in about 45% of patients of bilateral SWS. The episcleral vessel tortuosity in SWS, probably resulting from arteriovenous shunts within the episcleral hemangiomas, causes raised episcleral venous pressure. The various mechanisms suggested for glaucoma are elevated episcleral venous pressure, premature aging of the trabecular meshwork, and Schlemm's canal complex causing early-onset chronic open-angle glaucoma. The oral lesions that can occur in SWS 40% of cases include gingival hemangioma, gum hypertrophy, and asymmetric jaw growth.^[7] Medical therapy for glaucoma is mostly

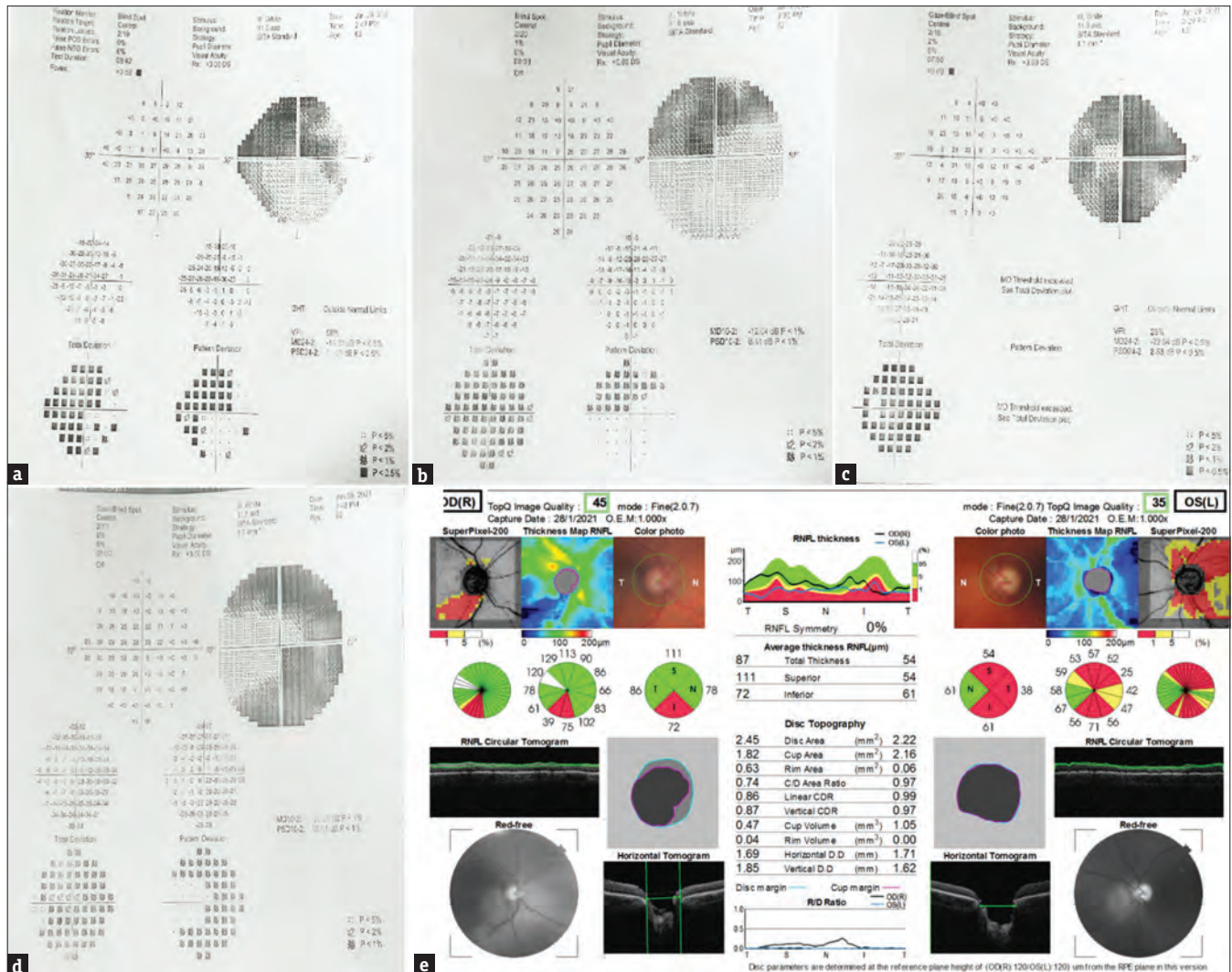


Figure 2: (a) Perimetry report 24-2 right eye showing upper arcuate field defect. (b) Perimetry report 10-2 right eye showing one point fixation threat. (c) Perimetry report 24-2 left eye showing Biarcuate scotoma. (d) Perimetry report 10-2 left eye showing one point fixation threat. (e) Optical coherence tomography report right eye showing inferior Retinal nerve fiber layer (RNFL) loss, left eye three quadrant RNFL loss except nasal quadrant

inadequate and patients require surgical intervention to control IOP. Trabeculectomy is associated with a number of complications like choroidal effusion^[8] though goniotomy and trabeculotomy can be tried for early-onset glaucoma. Many reports suggested lesser complications with glaucoma drainage devices^[9] and choice of procedure as the primary treatment modality in the management of glaucoma in SWS. The Roach scale^[10] is used for classification:

- Type I: Both facial and leptomeningeal angiomas; may have glaucoma
- Type II: Facial angiomas alone; may have glaucoma
- Type III: Isolated leptomeningeal angiomas; usually no glaucoma.

The current case is Type II SWS presented with bilateral episcleral malformations, nevus flammeus on both eyelids, but no choroidal hemangioma with advanced

glaucoma in both eyes. Although there was no retinal arteriovenous malformation and no clinical evidence of neurological deficit.

CONCLUSION

Bilateral Port wine stain in SWS with late-onset glaucoma is rare. The SWS presents with a wide spectrum of clinical manifestations and treatment, as well as prognosis, depends on the nature and severity of clinical features. The presence of port wine stain can cause deep psychological trauma to the patient and development of personality is affected. Glaucoma management in such cases can be challenging; our case highlights good results with combined phacotrabeculectomy mitomycin C.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have

given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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Small Incision Lenticule Extraction Surgery as an Effective Strategy to Treat Megalocornea

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ABSTRACT

Megalocornea is a developmental defect in which the entire anterior segment is enlarged bilaterally. Megalocornea is associated with Marfan syndrome and other ocular and systemic congenital defects. One may suppose that in situations of megalocornea, there may be abnormal collagen production, abnormal collagen tissue/cross-linking, a risk of corneal ectasia, and the presence of secondary glaucoma or cataracts, which may serve as the factors for not considering refractory surgeries. We report a case of megalocornea that was successfully treated with small incision lenticule extraction surgery. The patient noticed considerable improvement, and no further complications were observed during the follow-up.

KEYWORDS: *Cataract, glaucoma, laser surgery, megalocornea, small incision lenticule extraction*

INTRODUCTION

Megalocornea is a developmental defect in which the entire anterior segment of the cornea enlarges bilaterally in a nonprogressive manner.^[1]

Astigmatism from an enlarged cornea can cause impaired vision, and the disorder is typically asymptomatic in children. Adults may develop premature cataracts, usually between the ages of 30 and 50 years.^[2] Some individuals with congenital megalocornea may not have any symptoms; as a result, the diagnosis may not be discovered until difficulties develop. There is no cure or therapy for enlarged corneas seen in megalocornea because the underlying anatomical problem is irreversible. We report a case of megalocornea that was successfully treated with small incision lenticule extraction (SMILE) using the VisuMax (ZEISS AG, Jena, Germany).

CASE REPORT

A 31-year-old male sought consultation for refractive surgery of his myopic status, in November 2018. At the time of examination, he had best-corrected visual acuity of 6/6 in his right eye with -2.50 D Sph and 6/6 in his left eye with -1.75 D sph/-2.25 D cyl × 155°. IOP in the right eye was 17 mm and in the left eye was 16 mm.

Further evaluation under slit lamp revealed that the patient had bilateral megalocornea (white-to-white distance of 14.8 mm), with a clear cornea and a pachymetry of 413 and 401 microns in the right and left eye, respectively. Anterior segments were deep, iris was normal in appearance, and the lens also appeared normal.

Preoperative corneal topography showed a simulated keratometry reading of the right eye -40.73 D (8.29 mm) at 177°/41.35 D (8.16 mm) at 87° and left eye -40.18D (8.40 mm) at 150°/41.83 D (8.07 mm) at 60° [Figure 1a and b].

The patient wanted an improved quality of life by becoming spectacle free as he was a swimmer and a sportsman, hence was very keen on refractive surgery. The lack of evidence in the literature to support refractive surgery and the hazard of performing refractive surgery on a patient with megalocornea were explained to the patient. After obtaining appropriate informed consent, the patient was taken up for lenticule extraction procedure with SMILE on November 06, 2018.

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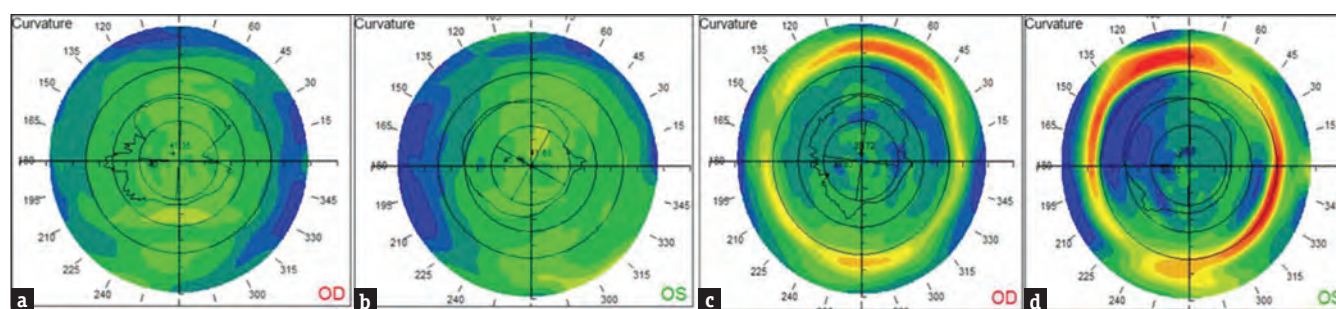


Figure 1: (a and b) Preoperative computerized corneal topography of both eyes. (c and d) Postoperative computerized corneal topography of both eyes

Surgical procedure

The VisuMax500 kHz femtosecond laser system (Carl Zeiss Meditec, Jena, Germany) was used. The SMILE/lenticule extraction procedure was performed in the operating room in sterile conditions by an ophthalmic surgeon. Topical anesthesia was used with three instillations of 2 drops of proparacaine at 30 s intervals followed by a drop of povidone-iodine 10% solution (Wokadine, Dr. Reddy's Laboratories, Ltd., India) in both eyes and scrubbing of the eyelids with the same solution.

To keep the eye open and in position during the laser treatment, an eyelid speculum was utilized, and a curved interface was placed on the VisuMax femtosecond laser platform for alignment with the corneal surface. The patient was instructed to gaze at the blinking green light to achieve optimal centration. The laser procedure began by applying suction and creating the posterior surface of the refractive lenticule, followed by the 90° side cut and cap cut. Next, the entry cut was made at 135°, extending 3.5 mm in length. After the laser treatment, a SMILE dissector specially designed by Geuder Germany was used to dissect the stromal lenticule in two sweeps: one superficial and one deep. Finally, the lenticule was removed using lenticule extraction microforceps (Indo-German). The treatment data for SMILE and the parameters for the procedure are mentioned in Tables 1 and 2.

The patient was discharged with appropriate follow-up advice. He was followed up regularly. On November 13, 2018, his refraction was emmetropic. Slit-lamp pictures 6 months after the SMILE procedure are presented in Figure 2. Nearly 4 years postrefractive procedure, on June 08, 2022, he reported for a follow-up. He underwent repeat investigations. The patient continues to be emmetropic.

Pachymetry of both eyes preoperatively using Optovue showed cornea to be OD 473 μ m and OS 472 μ m. The thinnest measurements were OD 409 μ m and OS 395 μ m [Figure 3] postoperatively.

Table 1: Treatment data for ReLEx small incision lenticule extraction

	Right eye	Left eye
Treatment pack size	S	S
Suction time	00:00:33	00:00:32
Cap data		
Diameter (mm)	8.00	7.70
Thickness (μ m)	130	120
Side cut angle (°)	90	90
Incision position (°)	140	135
Incision angle (°)	43	45
Incision width (mm)	3.00	3.00
Lenticule data		
Optical zone (mm)	6.70	6.50
Transition zone (mm)	0.10	0.10
Thickness (μ m)	Minimum - 25; maximum - 83	Minimum - 15; maximum - 96
Side cut angle (°)	90	90
Refractive correction		
Sphere (D)	-2.75	-2.25
Cylinder (D)	-0.60	-3.00
Axis (°)	60	155
Expected result		
Sphere	0.00	0.00
Cylinder	0.00	0.00
Axis	60	155
RST (μ m)	260	256

RST: Residual stromal thickness

Table 2: Parameters for the procedure

Parameter	Lenticule	Lenticule side	Cap	Cap side
Scan mode	Single	-	Single	-
Scan direction	Spiral in	-	Spiral out	-
Energy (nJ)	28	28	28	28
Track distance (μ m)	4.0	4.0	4.0	4.0
Spot distance (μ m)	2.0	2.0	2.0	2.0

Postoperative corneal topography showed a simulated keratometry reading of the right eye -38.53 D (8.76 mm) at 173°/39.72 D (8.5 mm) at 83° and the left eye -38.15 D (8.85 mm) at 179°/38.5 D (8.77 mm) at 89° [Figure 1c and d].

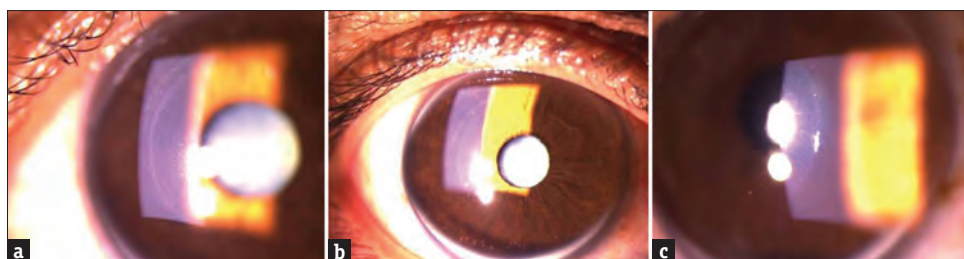


Figure 2: (a-c) Slit-lamp pictures 6 months after small incision lenticule extraction

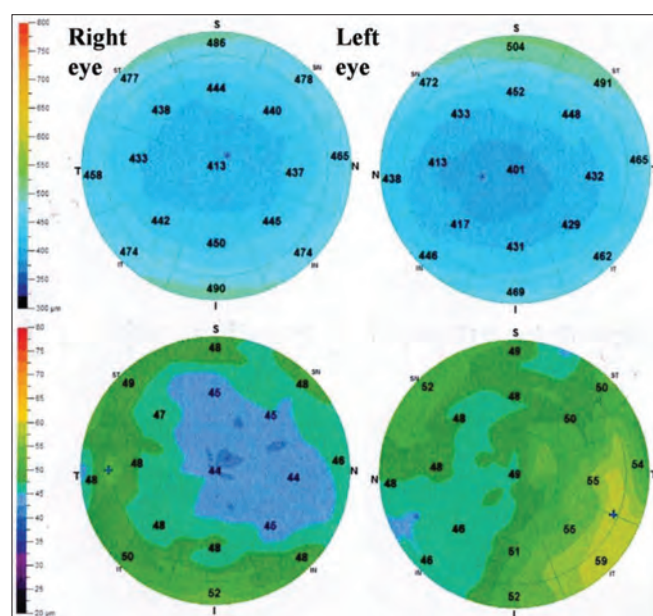


Figure 3: Pachymetry findings of both eyes

DISCUSSION

In megalocornea, two clinical presentation patterns were observed. Isolated megalocornea, known as primary megalocornea, lacks any accompanying ocular or systemic symptoms. Megalocornea, along with various ocular and systemic abnormalities, is the second most common clinical manifestation.^[2] The case described is of primary or isolated type of megalocornea as the patient had no other associated features or presentations.

SMILE is a variation of the refractive lenticule extraction technology and is a less invasive method of laser vision correction for various ocular diseases.^[3,4] SMILE was found to be superior to femtosecond-LASIK/LASIK in terms of preserving corneal biomechanical strength after surgery.^[5]

To treat megalocornea, ophthalmologists usually refuse to perform corneal refractive surgery. Due to the rarity of megalocornea, LASIK or PRK results may not be as predictable as they would be in eyes without this disorder. However, because megalocornea is linked to Marfan syndrome and other ocular and systemic congenital defects, one may suppose that in situations

of megalocornea, there may be abnormal collagen production, abnormal collagen tissue/cross-linking, and a risk of corneal ectasia. Only after verifying that corneal stiffness and hysteresis were normal during testing with the Ocular Response Analyzer is PRK suggested as a therapy option.^[6] To the best of our knowledge, refractive surgery has not been tried as a treatment modality in managing patients with megalocornea.

The presence of secondary glaucoma or cataract in these cases would also be a factor for not considering refractory surgeries in such cases, but our patient did not have any of these issues, and the LASIK treatment option was not opted for because of the flat cornea in this patient.

CONCLUSION

Considering the 4 days of pain and blurred vision, PRK was not the choice to treat this patient. Hence, the SMILE surgery was considered, which proved to be beneficial as the patient noticed considerable improvement without any complications during follow-up. However, further efficacy may be established after SMILE surgery in clinical trials with larger samples of similar cases reported here.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given his consent for his images and other clinical information to be reported in the journal. The patient understands that his name and initials will not be published and due efforts will be made to conceal identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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