Combined treatment for keratoconus

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In keratoconus there are two main problems that need to be resolved. We have to improve vision and stop progression. The first line of treatment for keratoconus, rigid contact lenses, does not always work for every patient and so in these exceptions there are a few surgical alternatives available. However, patient expectations are raising and the consequences of surgery could be unpredictable, both anatomically and functionally.

In short...

There have been, in recent years, some technological advances that have led us to two approaches: (a) corneal regularization based either on intracorneal ring (ICR) implantation\(^5\) or limited topography-guided excimer laser customized ablation treatment (T-CAT)\(^6\) or toric phakic intracorneal lenses (IOLs); (b) corneal stabilization using corneal collagen crosslinking (CXL)\(^7\)

We performed a study to see if a three-step procedure (Figure 1) would be effective at stopping progression and improving visual and refractive results in patients with keratoconus and extreme myopia and astigmatism. In our research, we used a posterior chamber toric implantable collamer lens (IOLs) (Visian ICL; STAAR Surgical, Monrovia, California, USA) post implantation of an intrastromal corneal ring segment (ICRS) (Keraring; Mediphacos, Belo Horizonte, Brazil) using a femtosecond laser (IntraLase, Irvine, California, USA). Then we performed CXL on the study group and examined the outcomes to see if this approach is an efficient one.

The study

In our study we examined nine keratoconic patients (14 eyes) [3 males (6 eyes) and 6 females (8 eyes)] who all completed at least one year of follow-up. Uncorrected visual acuity (UCVA), best spectacle corrected visual acuity (BSCVA), refraction, topographic findings, and adverse events were assessed.

All procedures were performed by the same surgeon (Efekan Coskunseven) at Dunya Eye Hospital, Istanbul, Turkey. The mean patient age was 25.21±1.76 years (range, 22 to 28 years) All patients demonstrated clear central corneas and contact lens intolerance. Corneal thickness was at least 400 micron at the thinnest corneal point. Patients were excluded if any of the following criteria applied after the preoperative examination:

- If there is no increase in visual acuity after RGP or hybrid contact lens trial. Even if the patient has contact lens intolerance we must try the contact lenses just to see how much the visual acuity will increase.
- The ACD (from endothel) is less than 2.8 mm. Mostly high myopic cases have deep anterior chamber but we should always consider the fact that after ICR implantation ACD will decrease.
- Other exclusion criteria are history of herpes, keratitis, corneal dystrophies, diagnosed autoimmune disease, systemic connective tissue disease, acute or grade IV keratoconus, and endothelial cell count of less than 1000 cells/mm\(^2\). The mean interval between ICR and CXL was 7 months and the mean interval between CXL and ICL toric implantation was 8.4 months. Preoperative and postoperative visual acuity, refraction, pachymetry and topography results were evaluated and the mean follow-up period was 7.2 months.

ICR implantation: The implantation of small arc-like polymethyl methacrylate (PMMA) segments is a minimally invasive surgical option for keratoconic corneas or ectatic corneas occurring after laser in situ keratomileusis. There are different types of intracorneal rings, depending on their curvature, width and zone of implantation. Kerarings (Mediphacos, Belo Horizonte, Brazil) are newly developed segments made of PMMA that are characterized by a triangular crosssection that induces a prismatic effect on the cornea. Their apical diameter is 5 mm and the flat basis width is 0.6 mm with variable thickness (0.15 to 0.30 mm thickness with 0.5 mm steps) and arc lengths (90, 120, 160 and 210 degrees). The optical zone provided by Keraring segments is 5.0 mm in diameter. Today 6 mm optical zone Keraring Si6 new segment is also available with 6 mm optical zone to avoid halo and glare.

The surgical procedure was performed under sterile conditions and topical anaesthesia. Purkinje reflex was chosen as the central point and was marked using a Wavelength Allegretto Biomicroscope (Allegretto 400 Hz laser platform, WaveLight Laser Technologie AG). A 5 mm marker was used to locate the exact ring channel. Corneal thickness was measured during surgery using ultrasonic pachymetry (Sonogage, Cleveland, Ohio, USA) along the ring location markings. Tunnel depth was set at 80% of the thinnest corneal thickness on the tunnel location in the femtosecond laser. An incision was made on the steepest topographic axis.

One or two segments were implanted according to the distribution of the ectatic area on the corneal surface, whereas the thickness of the segment was determined using the distribution of the ectatic area and the spherical equivalent (SE).

It is known that spherical and astigmatic correction need to be considered when implanting phakic toric IOL lenses. So, we planned to regularize corneal irregularity not to correct spherical refraction in our study. We evaluated the corneal thickness to choose the appropriate ring thickness. A 60 kHz IntraLase Femtosecond Laser (Abbott Medical Optics, Santa Ana, California, USA) was used to create the ring channels. The mean interval between ICR and CXL was 7 months.

CXL with riboflavin and UVA

CXL with riboflavin and UVA is a new technique of corneal tissue strengthening that combines the use of riboflavin as a photo sensitizer and UVA irradiation. The treatment procedure was conducted under sterile conditions in an operating theatre. Topical anaesthetic eye drops were applied.

After abrasion of the corneal epithelium of 7 mm, 0.1% riboflavin solution in 20% dextran (PESCHKE Meditradte, Huenenberg, Switzerland) was applied on the cornea every 3 minutes for 30 minutes. The saturation of the
Toric Visian ICL implantation: IOL selection was made at 6 months post-CXL treatment. To control for potential cycloplegia on being supine, we measured the zero horizontal axis at a stilt탑 while the patient was sitting upright. Each patient received two peripheral incisions one week before the surgery using a neodymium:yttrium–aluminium–garnet (Nd:YAG) laser. ICLs were sized according to corneal white-to-white and anterior chamber depth (AOD) measurements taken by the Orbscan II (Bausch + Lomb Inc., Salt Lake City, Utah, USA).

Results

No intraoperative and late postoperative complications were found in this series of patients. At the last postoperative examination, there was a statistically significant reduction in the spherical equivalent refractive error compared with that observed at the examination before all surgeries (Figure 2). The results were as follows:

- Mean SE; six months after ICR implantation decreased from -16.40±3.56 to -9.61±2.71 and six month after CXL treatment decreased to -9.56±2.74 and one year after ICL toric IOL implantation decreased to -9.90±1.02.
- Mean astigmatism; six months after ICR and CXL treatment decreased from -4.73±1.32 to -2.36±0.58 and six month after CXL treatment decreased to -1.88±1.63 and one year after ICL toric IOL implantation decreased to -0.96±0.35.
- Mean flat K; after ICR implantation decreased from 56.1±2.40 to 54.78±2.20 and six month after CXL treatment decreased to 53.54±2.24 and one year after ICL toric IOL implantation decreased to 53.57±2.28.
- Mean steep K; after ICR implantation decreased from 60.57±2.14 D to 56.76±2.17 D and six month after CXL treatment decreased to 54.61±2.74 D and one year after ICL toric IOL implantation decreased to 54.48±3.07 D. As you can see here after Keraring implantation the decrease in step K values is 60.57 - 56.41 = 5.96 D, however, the decrease in flat K values is about 56.16 - 54.78 = 1.38 D.
- Mean K; after ICR implantation decreased from 58.36±2.18 to 55.77±2.17 and six month after CXL treatment decreased to 54.07±1.22 and one year after ICL toric IOL implantation decreased to 54.03±2.19.
- Mean UCVA; after ICR implantation decreased from 0.01±0.01 to 0.06±0.05 and six month after CXL treatment increased from 0.08±0.04 and one year after ICL toric IOL implantation increased to 0.46±0.11 (Figure 3).
- Mean BCVA; after ICR implantation increased from 0.16±0.09 to 0.41±0.12 and six months after CXL treatment increased to 0.48±0.11 and one year after ICL toric IOL implantation increased to 0.58±0.09 (Figure 3).

Discussion

We are now expected to improve both the visual acuity and keratoconic corneal progression in keratoconus patients. Today many authors present CXL with phoric ICL implantation, however, the studies showed that CXL was effective in halting the progression of keratoconus over a period of up to four years. In the last CXL meeting, a case report was presented and showed that up to 6 D regression was achieved. However, the published studies also revealed a reduction of max K readings by more than 2 D, while the postoperative SEQ was reduced by an average of more than 1 D, and the refractive cylinder decreased by about 1 D (Figure 2). It was also found that CXL treatment was effective at reducing corneal and total wavefront aberrations. A primary intervention such as CXL should be considered to potentially increase the biomechanical stability of the corneal tissue. Only the CXL and toric IOL combination can be effective, allowing a maximum of 2 D decrease in regularity through CXL and up to -18 D in spherical and 5 D in astigmatic corneal correction as a result of toric ICL.

The efficacy of the 5 mm optical zone Keraring in diopters, according to corneal thickness, is about 7 D. The inhibiting effect of ICR to keratoconus progression is still unclear. Our studies showed that ICR and CXL combined treatment is safe and effective to stop progression and visual correction in keratoconic patient. But if the patient still needs spherical or astigmatic correction phoric toric IOL can be used.

Conclusion

Combined posterior chamber toric phoric Visian ICL implantation after Keraring ICR implantation followed by CXL in a three-step procedure is an effective treatment sequence that can stop progression and improve visual and refractive results in patients with keratoconus with extreme myopia and astigmatism. However a long-term follow-up of a larger population study is required to validate these findings.

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Management of Corneal Endothelial Decompensation Caused by Iris-Fixated Phakic Intraocular Lenses With Descemet Stripping Automated Endothelial Keratoplasty

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INTRODUCTION

Iris-fixated phakic intraocular lens (pIOL) implants have become a viable alternative to laser refractive surgery for the correction of myopia.1–2 In addition to providing a high quality of vision, the procedure preserves the innate thickness of the cornea and has the potential to correct a wider range of refractive errors.3–6

The literature describes a number of postoperative complications from pIOL implantation, including acute glaucoma because of pupillary block, chronic glaucoma, uveitis, infectious endophthalmitis, cataract formation, and corneal endothelial cell loss.7 Endothelial changes including eventual decompensation necessitate regular follow-up and, if warranted, explantation and/or keratoplasty.8 As the most commonly performed form of endothelial keratoplasty, Descemet stripping endothelial keratoplasty (DSEK)/Descemet stripping automated endothelial keratoplasty (DSEAK) has become the current standard for treating endothelial failure.9

We report 2 iris-fixated pIOL implanted eyes in 2 patients who developed corneal decompensation and were managed with DSEAK and explantation of the pIOL.

CASE REPORTS

Case 1

A 37-year-old woman presented with a 2-month complaint of worsening blurry vision and discomfort in the left eye. Two years prior, while still living in Vietnam, she underwent implantation of an Artisan iris-fixated pIOL (Ophtec B.V., Groningen, The Netherlands) in the left ambylopic eye for high myopia.

The uncorrected visual acuity (UCVA) was 20/20 in the right eye and count fingers (no improvement on pin hole) in the left eye. Slit-lamp examination in the left eye revealed 1+ scleral injection and 3++ corneal edema. A large epithelial defect covering about 80% of the cornea was evident. Gonioscopic examination revealed moderate-thickness enclavation sites well centered nasally and temporally on the iris with a superior iridectomy present. The left crystalline lens was noted to have a 1+ nuclear sclerotic cataract.

A clinical diagnosis of corneal decompensation with bullous keratopathy was made, and DSEAK surgery was discussed and agreed upon. Surgical protocol was as follows: a 6-mm, biplanar, temporal corneal incision was made, and DSEAK surgery was discussed and agreed upon. Surgical protocol was as follows: a 6-mm, biplanar, temporal corneal incision was made. The crystalline lens was noted to have a 1+ nuclear sclerotic cataract.

A clinical diagnosis of corneal decompensation with bullous keratopathy was made, and DSEAK surgery was discussed and agreed upon. Surgical protocol was as follows: a 6-mm, biplanar, temporal corneal incision was made. The crystalline lens was noted to have a 1+ nuclear sclerotic cataract. The surgeons were then used to close the wound to approximately 4 mm in.

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length. The anterior chamber was reformed with a viscoelastic material. The host Descemet membrane was then stripped, and an 8.0 mm DSAEK donor graft was inserted through the superior incision. The surgical wound was completely closed with 2 additional interrupted 10-0 nylon sutures. The anterior chamber was then completely filled with air for 10 minutes, and the patient was sent to the recovery area, where the bubble was reduced to 50% by release through a paracentesis at the slit lamp. Postoperative treatment included Zymar (Allergan, Irvine, CA) 4 times daily and Pred Forte 1% (Allergan) 4 times daily.

One day after the procedure, the patient had no complaints. The wound was intact and 1+ corneal edema was noted. The anterior chamber had 1+ cell and flare. UCVA was 20/200. Topical corticosteroids were tapered over 6 months.

At 12-month follow-up, the patient continued to have no subjective complaints and was satisfied with the complete resolution of the pain. The wound was intact with no evidence of corneal edema, and the graft was well centered with an anterior chamber that was deep and quiet. Best-corrected visual acuity (BCVA) was noted to be 20/60. All treatment was discontinued, and the patient was scheduled for routine follow-up.

**Case 2**

A 67-year-old woman presented with a complaint of progressive blurred vision in the left eye over a period of 3 months. Her history revealed severe bilateral myopia with mild myopic retinal degeneration (−20.5 diopter (D) OD and −21.0 D OS) for which she had Verisyse (AMO, Santa Ana, CA) lens implanted OU 3 years previously. In addition, before implantation, she had 2 episodes of retinal detachment in the left eye treated successfully with a scleral buckling procedure without intravitreal gas injection.

On examination, the BCVA was 20/40 OD and 20/400 OS. Intraocular pressure was 18 mm Hg OU. Slit-lamp examination revealed a clear cornea on the right side with a well-positioned Verisyse lens. The left eye revealed the central corneal edema with diffuse thickening, evidence of micrystic changes, and presence of scattered, intermittent, old posterior synechiae. The lens showed 1+ nuclear changes in the right eye, whereas the left lens demonstrated 2+ nuclear sclerosis and anterior subcapsular cataract. Endothelial cell count in the right eye was 2374 cells per square millimeter and in the left eye was 617 cells per square millimeter in an area that could be measured adjacent to the edema.

Given a diagnosis of pseudophakic bullous keratopathy and early cataractous changes in the left eye, a DSEAK and a cataract extraction with implantation of a posterior chamber intraocular lens (IOL) were discussed and agreed upon. Surgical protocol was similar to case 1, with the addition of phacoemulsification and posterior chamber lens implantation with a 5.0-D acrylic IOL (MA60MA; Alcon, Inc, Fort Worth, TX) before DSAEK.

One day after the procedure, UCVA was noted to be 20/300 OS. The graft and posterior chamber IOL were well positioned. At 1-week follow-up, UCVA in the left eye had improved to 20/70. The wound was intact with no evidence of corneal edema, and the graft was noted to be well centered.

At 12-month follow-up, the patient continued to have no subjective complaints of blurred vision or pain. BCVA was noted to be 20/40 at last visit, and all treatment was discontinued.

**DISCUSSION**

pIOL implantation has emerged as an effective option in refractive surgery. However, concerns about endothelial decompensation beyond the annual physiologic loss of 0.6% are compelling. In a short-term study, Stulting et al found the endothelial cell density loss rate to be 11.3%. Another 3-year multicenter study by the US Food and Drug Administration found that the mean change in endothelial cell density (ECD) from baseline to 3 years was 4.8% to 7.8%. Furthermore, a 2-year follow-up by Moshirfar et al found a 3.3% and 6.5% decrease in endothelial cell density over respective 1- and 2-year intervals. However, more recent findings by Budo et al (0.7%) and Pop and Payette (0.78%) reveal insignificant annual loss rates. A recently completed long-term study depicted a 0.6% annual loss rate, typical of age-related change. In addition, the authors found no correlation between corneal decompensation and preoperative anterior chamber depth (ACD), although anatomically the ACD should be an important risk factor for potential decompensation. Nonetheless, given the presence of conflicting data, it is essential to monitor the long-term health of the endothelium after iris-fixed pIOL placement.

Although the exact mechanism of decompensation is unknown, many theorized mechanisms exist. During lens implantation, surgical endothelial trauma may cause a more than desirable loss of endothelial cell layers predisposing to decompensation. Another cause may be related to poor enclavation technique causing a loose-fitting implant to either dislocate or intermittently come into contact with and irritate the endothelium. Postoperative inflammatory changes such as diffuse peripheral anterior synechiae may decrease the ACD and predispose to mechanical trauma of the endothelium. Other causes include Urrets-Zavalia syndrome or early postoperative elevated intraocular pressure that may similarly compromise the ACD. It may be possible that some patients may inherently react to a pIOL implant with a chronic inflammatory reaction, thereby causing endothelial dysfunction. Another cause for concern should be pIOL properties that may inherently react to controversial data, it is essential to monitor the long-term health of the endothelium after iris-fixed pIOL placement.

In the event of endothelial decompensation, definitive management involves explantation of the pIOL implant and
surgical transplantation of corneal tissue. A 2009 Ophthalmic Technical Assessment review confirmed DSEK/DSAEK to be the current consensus for managing endothelial disease. Although DSEK does introduce a new set of adverse events such as failed adherence of the donor graft, it is established that most of these complications do not affect eventual visual recovery.

In patients older than 50 years, we also recommend consideration of cataract extraction at the time of DSEK. In a recent review by Price et al, it was found that DSEK, similar to other keratoplasty techniques, accelerates the rate of cataract formation because of the use of posttransplantation topical corticosteroids. Furthermore, a significant increase was found in those individuals older than 50. Relative to the baseline rate of cataracts (3% to 4%), they report a rate of 42% within the same 43- to 64-year age group. Given the risk of graft failure with subsequent cataract surgery, it is prudent to consider concomitant extraction as a benefit to the patient.

**CONCLUSIONS**

Although iris-fixated pIOLs are a viable option for refractive correction, clinicians should be aware of the possible complications including endothelial decompensation warranting endothelial keratoplasty and pIOL explantation. Furthermore, in patients older than 50, a combined cataract extraction should be considered.

**REFERENCES**

Intracorneal Ring Segments and Phakic Intraocular Lens

To the Editor:

We read with interest the article by Cakir and Utine regarding the results of combined intracorneal ring (KeraRing; Mediphacos Ltd, Belo Horizonte, Brazil) and anterior chamber, iris-fixated, phakic intraocular lens (IOL) (Artisan/Artiflex; Ophtec BV, Groningen, The Netherlands) implantation in patients with keratoctasia, which appeared in the February 2011 issue of the Journal of Refractive Surgery, and would like to comment that the results and the conclusions coincide with those presented by Navas. In their work, Navas et al conducted a similar evaluation on seven eyes of six patients with keratoconus who underwent sequential intracorneal ring: six eyes received Intacs (Addition Technology Inc, Des Plaines, Illinois) and one eye corneal rings (Visiontech Medical Optics Ltd, Belo Horizonte, Brazil), and posterior chamber Implantable Collamer Lens (Visian ICL; STAAR Surgical, Monrovia, California). Four eyes were implanted with the toric ICL and three eyes with the spherical ICL (Fig).

In our study, mean uncorrected distance visual acuity (UDVA) improved from 0.05±0.03 preoperatively to 0.57±0.13 after both procedures (P=.0001 for all). Mean manifest refraction spherical equivalent (MRSE) decreased from −11.03±4.80 diopters (D) preoperatively to −0.46±0.52 D after both procedures (P=.0003). All patients had a noticeable subjective improvement. Similar results were reported by Cakir and Utine, who found visual and refractive improvements after both procedures. We noticed a slightly better postoperative mean UDVA. However, Cakir and Utine reported a better postoperative MRSE with a high standard deviation.

We used 6.0-mm optic diameter intrastromal rings in six cases and 5.0-mm in one case, without any difference in the final outcome. Other authors have reported good results with combined intracorneal ring segments...
and anterior chamber, iris-fixated, phakic IOLs in keratoconus eyes, with good results; however, this may be technically challenging and the non-flexible version requires implantation through a scleral tunnel. \(^3\)

We prefer posterior chamber phakic IOLs due to the quality of the optics and the stability that the toric version offers for the treatment of high astigmatism, as optical correction of stable keratoconus with phakic toric IOLs has been reported previously. \(^4\)

Overall, we agree with Cakir and Utine that the combined implantation of intracorneal ring segments and phakic IOL for the treatment of keratoconus is a safe and effective bioptic procedure, which has proven to be both predictable and accurate.

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The authors have no financial interest in the materials presented herein.

REFERENCES


Reply:

We appreciate the comments of Navas et al regarding our article. \(^1\) They present similar results in patients with keratoconus, where sequential intracorneal ring and posterior chamber phakic intraocular lens (IOL) implantation led to improvement in visual acuity and reduction in refraction. Although the rationale of their treatment is similar to ours, there are differences in the tools used.

It has been demonstrated that the closer the implanted intracorneal ring is to the visual axis, the greater the corneal flattening and refractive correction effect. \(^2\) Furthermore, in case of an unsatisfactory result, penetrating keratoplasty would be technically easier when the diameter of the implanted intracorneal ring segment is smaller compared to larger. We also believe that posterior chamber phakic IOLs should be used with caution due to the possibility of lenticular complications and the impact of rotation on refractive result; whereas the “one-size-fits-all” characteristics of iris-fixated, anterior chamber IOLs create an advantage in keratectatic eyes with deep anterior chambers.

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The authors have no financial interest in the materials presented herein.

REFERENCES


Subjective Refraction Before LASIK Enhancement in Bioptics Procedures With Refractive Multifocal Intraocular Lenses

To the Editor:

In the so-called bioptics approach, a secondary excimer laser procedure is performed for residual ametropia after primary intraocular lens (IOL) implantation. \(^1\) Recently, three patients presented who developed a hyperopic defect following LASIK for residual ametropia after cataract surgery with a refractive multifocal IOL. Subjective refraction before LASIK ranged between \(-1.00\) and \(-1.50\) diopters (D), with corrected distance visual acuity (CDVA) ranging between 20/32 and 20/25. After uneventful myopic LASIK in one eye of each patient, all three eyes presented a hyperopic outcome of \(+2.50\) D with CDVA of 20/20 in every case. Retrospective examinations of ablation reports in all three eyes excluded any possible source of error.

A likely explanation for the hyperopic surprise found in these patients is presented herein: subjective refraction for CDVA was obtained using the near focus of the multifocal IOL, therefore, the eyes were not myopic of \(-1.00\) to \(-1.50\) D, but hyperopic of \(+1.00\) to \(+1.50\) D. Hence, the myopic ablation resulted in a more hyperopic residual defect.

Distance vision in an eye implanted with a multifocal IOL can be corrected by using either of the two principal foci of the IOL, but only if the far focus is in-focus for far vision, will the near focus be useful for near vision. The Figure shows the typical defocus curve of a
refractive multifocal IOL. Given an eye with an actual residual hyperopia of +1.00 D after refractive multifocal IOL implantation, CDVA can be obtained using the real ametropia of +1.00 D (point A in the Figure: far focus in-focus for far and near focus in-focus for near) or −1.25 D (point B in the Figure: far focus out-of-focus for far and near focus in-focus for far and out-of-focus for near). Before any secondary intervention, it is necessary to confirm that the far focus of the multifocal IOL is being used for distance subjective refraction. This can be done by any of the following tests:

- Once CDVA has been determined, distance-corrected near visual acuity should be measured and it should be similar or slightly inferior to CDVA, depending on the multifocal IOL model.
- A −2.25- or −2.50-D lens should be placed on top of the refraction for CDVA, and far vision should be measured again to show a slight decrease, because the near focus of the IOL is being used for distance vision.

Unexpected outcomes in any of the three tests indicate the possibility of having used the near focus of the refractive multifocal IOL for far vision, leading to a false diagnosis of myopia in an eye that actually presents with low hyperopia.

Pseudomyopia in eyes with multifocal refractive IOLs has been reported using automatic refraction, and therefore, autorefractometers are not helpful in this situation. Careful subjective refraction before LASIK enhancement in bioptics using refractive multifocal IOLs is mandatory.

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