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REVIEW ARTICLE

Implantable Contact Lenses in Keratoconus

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ABSTRACT

Keratoconus is a progressive inherited disorder with varying economic and social consequences. Varying modalities of visual rehabilitation such as spectacles, contact lenses, surgical treatment in the form of corneal collagen cross-linking to arrest progression, and surface refractive procedures such as photorefractive keratectomy, implantation of phakic intraocular lenses (IOLs), or Intacs have been undertaken with varying results. This review article focuses on the introduction of phakic IOLs/implantable contact lenses in keratoconus. Thorough research was made on PubMed, Google, HINARI, and related sites for all related material, and it was thoroughly studied to draft this article.

Keywords: Corneal collagen cross-linking, Implantable contact lens, Keratoconus, Toric.

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INTRODUCTION

Keratoconus is a noninflammatory, progressive ectatic disorder of the cornea, thus inducing myopic irregular astigmatism causing a decrease in visual acuity.[1,2] Visual rehabilitation in the form of spectacles and contact lenses is given with varying success at the different stages of the disease. To halt the progression of the disease, corneal collagen cross-linking (CXL) is the only option available. Various studies have established the role of CXL to prevent the progression of keratoconus.[3-7] Cross-linking has been used as the modality to prevent progression of keratoconus alone or in combination with photorefractive keratectomy (PRK),[8,9] Intacs,[10,11] implantable contact lenses (ICLs),[12,13] etc. Phakic intraocular lens (PIOL) or ICL has been introduced as a treatment option to correct the refractive error to the optimal in keratoconus patients. This review article discusses the ICL, their risks and benefits, and results in keratoconus patients in various situations.

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IMPLANTABLE CONTACT LENSES

Phakic IOLs or ICLs are a special kind of intraocular lenses behind the natural lens of the patient to treat myopic, hyperopic, or astigmatic refractive errors to provide high-quality vision to the patient. They are of various types: Anterior chamber, angle-supported, or posterior chamber ICLs. The Visian ICL (implantable collamer lens) marketed by STAAR Surgical is a posterior chamber PIOL, meaning it is positioned behind the iris and in front of the natural lens. It received Food and Drug Administration (FDA) approval in 2005 for correcting nearsightedness ranging from –3.00 to –20.00 D (diopters). The Artisan/Verisyse (Abbott Medical Optics) is an anterior chamber PIOL, meaning it is positioned in front of the iris. Artisan lenses were polymethylmethacrylate made iris-fixated PIOLs, whereas Artiflex is the newer foldable version of the Artisan IOLs. In 2004, the Verisyse PIOL received FDA approval for correcting moderate to severe nearsightedness within the range of –5.00 to –20.00 D. Phakic IOLs have not received FDA approval for hyperopia or astigmatism yet. Also pending FDA approval is the AcrySof Cachet angle-supported PIOL (Alcon). The Cachet is a soft acrylic lens positioned in front of the iris and secured in the angle of the anterior chamber of the eye where the cornea and iris meet.

Preoperative concerns:

- Age more than 21 years
- Stable refraction
- No ocular surface or intraocular disease
- Corneal endothelial cell count more than 2,000 cells per cubic millimeter.
- Anterior chamber depth of at least 3 mm.

Advantages of PIOLs or ICLs:

- Able to correct high degrees of nearsightedness that cannot be corrected with other surgical procedures.
- May be performed in patients who are not candidates for LASIK due to corneal irregularity or thinness.
- Less likely to cause or contribute to dry eyes.
- May be surgically removed.

Disadvantages of PIOLs or ICLs:

- Postoperative induction of astigmatism due to large incision.
- Development of cataract, especially if vault is low. According to FDA, approximately 6 to 7% of eyes develop anterior subcapsular opacities at 7+ years following ICL implantation and 1 to 2% progress to

clinically significant cataract during the same period, especially very high myopic and older patients.[14,15]
- Increase in intraocular pressure postoperatively either because of retained viscoelastic substance or because of increased vault of the IOL causing pupillary block.
- Can cause glare and haloes.
- Endothelial cell loss annually. A study observed a continual steady loss of endothelial cells of –1.8% per year.[14]

ICL IN KERATOCONUS

The use of ICL in keratoconus started in 2008. In an early study conducted on two patients having contact lens intolerance, stable topography, and refraction, phakic toric ICL implantation improved the uncorrected and best spectacle–corrected visual acuity (UCVA and BSCVA) markedly. Preoperatively, the manifest refraction was –10.00 –6.00×100 in case 1 and –8.00 –2.75×100 in case 2. Postoperatively, the manifest refraction was +0.50 –1.00×90 in case 1 and –0.25 –1.25×100 in case 2. No progression of keratoconus was observed till 1 year of follow-up.[16] In a prospective, noncomparative interventional case series, significant increase in BSCVA was observed after implantation of STAAR collamer posterior chamber PIOL. This established the fact that ICL implantation can be considered as a safe, effective, and predictable procedure for the correction of refractive error in keratoconus patients.[17] In further prospective study conducted on 30 eyes of 21 patients, it was well established that toric ICL implantation is a predictable, effective procedure to correct ametropia in eyes with keratoconus. Results were fairly stable up to a follow-up of 12 months. Preoperatively, the mean spherical equivalent (SE) in the 30 eyes (21 patients) was –5.38 D ± 3.26 (standard deviation, SD) (–13.50 to –0.63 D) and the mean cylinder –3.48 ± 1.24 D (–1.75 to –6.00 D). At 12 months, 86.7% of the eyes were within ± 0.50 D of the attempted refraction and all eyes were within ±1.00 D.[18]

In another study conducted on 27 keratoconus patients with implantation of toric ICL STAAR surgical, it was observed that throughout a period of 6 months follow-up, toric ICL implantation was good in terms of safety, predictability, efficacy, and stability. All patients had mild keratoconus with SE of –10 ± 2.46 D and astigmatism of –3 ± 1.58 D. LogMAR UCVA and logMAR BSCVA values were –0.09 ± 0.16 and –0.15 ± 0.09 respectively, 6 months after surgery. The safety and efficacy indices were 1.12 ± 0.18 and 1.01 ± 0.25. At 6 months, 85 and 96% of the eyes were within ± 0.5 and ± 1.0 D, respectively, of the targeted correction.[19] Similar lens was evaluated in another subset of keratoconus patients conforming the previous results. In this study, 22 eyes of 14 patients were evaluated. The mean preoperative SE and cylinder changed from –4.98 ± 2.63 DS and –2.77 ± 0.99 DC to –0.33 ± 0.51 DS and –1.23 ± 0.65 DC respectively at the end of 6 months. Before the surgery, the mean Snellen decimal visual acuity was 0.63 ± 0.20. The mean unaided vision and visual acuity changed to 0.76 ± 0.23 and 0.85 ± 0.21 respectively at the end of 6 months. The mean safety and efficacy indices were 1.40 ± 0.32 and 1.24 ± 0.34 respectively.[20] In another study with a long follow-up of 3 years, it was observed that toric ICL implantation is a good treatment option with safety, efficacy, and predictability. Results were stable over follow-up of 3 years. This was a retrospective study conducted on 21 eyes of 11 patients with SEs of –9.70 ± 2.33 D (mean ± SD) and astigmatism of –3.21 ± 1.56 D. At 3 years, 67 and 86% of the eyes were within ± 0.5 and ± 1.0 D respectively of the targeted correction.[21]

Efficacy of toric ICL implantation has been evaluated even in keratoconic eyes after CXL. In a case report evaluating ICL implantation subsequent to CXL after 6 months, it was observed that collamer lens implantation in a two-step procedure seems to be an effective method for correcting keratoconus in patients with high myopia and astigmatism. In this study, a 22-year-old female patient underwent posterior chamber PIOL implantation, 12 months after CXL. It was observed that 3 months after the surgery, UCVA improved from counting fingers to 20/40 and corrected distance visual acuity (CDVA) improved from 20/100 to 20/30.[22] In another prospective study evaluating keratoconus patients undergoing topography-guided PRK with CXL, followed by implantation of iris claw or angle-supported PIOLs, it was established that combining the two procedures improved the visual performance in keratoconus patients. In this study, 22 eyes of 14 patients, who underwent PIOL implantation 3 to 4 months after simultaneous topography-guided PRK and CXL, were evaluated. The mean SE was significantly reduced from –9.08 ± 2.5 to –0.69 ± 0.67 D, $p \leq 0.001$. The mean UCVA improved from 1.24 ± 0.49 to 0.37 ± 0.08 logMAR. The mean CDVA (logMAR) improved from 0.69 ± 0.3 preoperatively to 0.35 ± 0.01 postoperatively ($p \leq 0.001$). At last follow-up, all eyes could achieve CDVA of 0.3 or better.[23] Implantation of toric ICL in keratoconus patients has been evaluated even for the residual refractive error after Intacs implantation and CXL, suggesting that ICL can serve as a good treatment option for the residual refractive error in such patients.[24,25] In another study conducted on 16 eyes with keratoconus ICL implantation after CXL, results were observed to be fairly stable even after long-term follow-up of 3 years, with no significant endothelial cell loss. The mean Snellen decimal CDVA improved from 0.56 ± ($p < 0.0001$). The mean UDVA also improved significantly from 0.63 ± 0.14 before ICL

implantation to 0.88 ± 0.18 after 3 years of follow-up ($p < 0.001$). The endothelial cell count loss after 3 years was –8.98%.[26] Angle-supported PIOLs were also evaluated in keratoconus stages I and II. This study was conducted on 12 eyes of 8 patients. The UCVA was 20/40 or better in all cases. The BSCVA was equal or improved in all cases. The safety index (postoperative BSCVA/preoperative BSCVA) was 1.18; the efficacy index (postoperative UCVA/preoperative BSCVA) was 0.77.[27] It was observed that angle-supported PIOLs serve as an effective treatment option for early stage keratoconus. In another study involving combined implantation of kerarings and Artisan/Artiflex PIOLs in patients with varying causes of corneal ectasia such as keratoconus, pellucid marginal degeneration resulted in visual and refractive improvements. This study involved 10 eyes of 8 patients, and it was observed that mean UDVA improved from 0.02 ± 0.10 preoperatively to 0.11 ± 0.06 after Keraring implantation and to 0.54 ± 0.18 after PIOL implantation ($p < 0.001$ for all). Mean CDVA improved from 0.18 ± 0.12 preoperatively to 0.39 ± 0.13 after Keraring implantation and to 0.66 ± 0.18 after PIOL implantation ($p < 0.001$ for all). Mean MRSE reduced from –12.50 ± 6.31 D preoperatively to ±12.08 ± 5.17 D after Keraring implantation ($p = 0.10$) and to –0.10 ± 0.84 D after PIOL implantation ($p < 0.001$).[28] Another study stated that in keratoconus visual and refractive improvement by the sequential implantation of Intacs intracorneal ring segments (ICRS) and Artisan/Artiflex, toric IOL is a safe and predictable procedure. This study evaluated 21 eyes of 16 patients, and it was observed that mean UDVA 12 months after ICRS and PIOL implantation increased from 2.0 ± 0 to 0.25 ± 0.22 logMAR (Snellen 20/2,000 to 20/35) ($p < 0.001$). The mean CDVA increased from 0.31 ± 0.13 to 0.13 ± 0.13 logMAR (Snellen 20/40 to 20/25) ($p = 0.039$). Predictability of refractive results was good, with SE refraction within ± 0.50 D of the attempted correction in 13 eyes (61.9%) and within ± 1.00 D in 19 eyes (90.5%).[29] Implantation of ICL has been considered as an option to correct residual refractive error after penetrating or deep anterior lamellar keratoplasty. In this study 7 eyes of 7 patients who had undergone keratoplasty with contact lens intolerance underwent posterior chamber PIOL implantation. A significant ($p < 0.01$) improvement was observed postoperatively in mean UCDVA (1.18 ± 0.4 *vs* 0.2 ± 0.1), spherical refraction (–5.89 ± 3.43 *vs* 0.53 ± 0.75), cylindrical refraction (–4.39 ± 0.75 *vs* –1.74 ± 0.84), and refractive spherical equivalent (–8.09 ± 3.77 *vs* –0.33 ± 0.54). The BCDVA changes were not significant (0.09 ± 0.11 *vs* 0.05 ± 0.08).[30] In another study undertaken on 20 eyes of 14 patients who underwent collamer lens implantation for keratoconus with a follow-up of 1 year, it was observed that 90% of the eyes had refractive cylinder of <1.0 D ($p = 0.003$) and 100% of eyes were within ± 0.75 D of sphere at 1 year ($p = 0.0085$). The safety index at 12 months was 1.2.[31]

CONCLUSION

Keratoconus with high myopic and irregular astigmatism causes a lot of visual morbidity to the patients. Various treatment options have been provided for the visual rehabilitation of keratoconus patients. Implantable contact lenses have emerged as a good treatment option for such patients with high degree of efficacy, safety, and predictability. Various studies have established this fact. Implantable contact lenses have been implanted in keratoconus patients in various combinations with CXL, Intacs, or after keratoplasty to provide optimal visual rehabilitation in such patients.

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