Long-Term Outcomes and Safety of the Phakic Visian Toric Implantable Collamer Lens in Eyes with Non-Progressive Keratoconus

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ABSTRACT

Study Design: Retrospective

Background: Keratoconus is a bilateral condition that affects 0.09–0.22% of the population and involves a progressive thinning of the cornea. This thinning results in a corneal bulge, which leads to irregular astigmatism and visual function impairment. Vision is generally correctable in the early stages of keratoconus with glasses. To evaluate the long-term outcomes and safety of phakic Visian toric implantable collamer lens (ICL) implantation in eyes with stable keratoconus.

Methods: This retrospective records review included patients with stable keratoconus who underwent phakic Visian ICL implantation and had been followed for at least 5 years following surgery. Keratometry, visual acuity, and refractive error were examined to evaluate outcomes. The Amsler-Krumeich classification system was used to determine disease stage. Adverse events were also examined to evaluate treatment safety.

Results: A total of 52 eyes (35 patients) with Stage I-III keratoconus were included in this study. Average subject age was 28.1 ± 4.3 years. Prior to ICL implant, logMAR uncorrected visual acuity (UCVA) and best-corrected visual acuity (BCVA) were 1.093 ± 0.343 (Snellen equivalent: 20/248) and 0.026 ± 0.041 (20/21), respectively. Additionally, the spherical and cylindrical refractive errors averaged -6.688 ± 3.810 and -2.168 ± 0.747 D, respectively. The maximum keratometry reading (k_{max}) averaged 47.5 ± 1.951 D. Five years after surgery, uncorrected logMAR visual acuity had significantly improved to 0.073 ± 0.057 (20/24, p = <0.001).

Conclusion: The Visian toric ICL is an effective and safe treatment option for improving visual acuity in eyes with stable keratoconus.

Keywords: Keratoconus, Vision, Eyes, Lens

INTRODUCTION

Keratoconus is a bilateral condition that affects 0.09–0.22% of the population and involves a progressive thinning of the cornea. This thinning results in a corneal bulge, which leads to irregular astigmatism and visual function impairment. Vision is generally correctable in the early stages of keratoconus with glasses. However, as the disease progresses, corneal reshaping with contact lenses becomes necessary to obtain optimum vision. Though the disease generally stabilizes in the third or fourth decade of life[1-7], many cases will progress to the point where a corneal transplant is indicated.

Myopia and uneven astigmatism cause keratoconus, a gradual non-inflammatory corneal thinning condition, which reduces visual acuity. Although corneal collagen cross-linking (CXL) can effectively prevent the disease's progression the procedure's poor visual outcomes persist. Following corneal CXL, further procedures are frequently required in patients who are intolerant to rigid gas permeable contact lenses in order to improve their vision[8,9].

Treatments to stabilize the cornea and correct vision have recently been used to treat advanced cases of keratoconus and, if effective, avoid corneal transplant. Stabilizing treatments include corneal cross-linking (CXL) procedures and intracorneal ring segment implantation. These treatments have been shown to stabilize corneal shape in many cases, but a large amount of spherical error and an irregular astigmatism can remain. Therefore, the implantable collamer lens (ICL) has been used to correct vision in eyes with stable keratoconus. Prior studies have shown short-term (within 1 year of implant) efficacy of the ICL for correcting both moderate[8-13] and severe[8,11,13-16] refractive error in eyes with stable keratoconus. Long-term studies have also shown that both vision and refractive error remain stable 2 years[10,11], 3 years, and 4 years after ICL implant. One recent study showed long-term stability of both vision and refractive error over a 5-year follow-up period. The aim of the study was to evaluate the long-term outcomes and safety of phakic Visian toric implantable collamer lens (ICL) implantation in eyes with stable keratoconus.

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METHODS

This study was reviewed and approved by the private hospital Institutional Review Board (IRB) and all study conduct adhered to the tenets of the Declaration of Helsinki. This retrospective study was given exempt status by the IRB, waiving the requirement of informed consent.

Study Subjects: This study included subjects with stable keratoconus who had undergone implantation of the Visian toric ICL at private hospital (Abha, Saudi Arabia) between January 2010 and June 2018. All subjects were at least 21 years of age and had been followed for at least 5 years after toric ICL implantation. Eyes that had a history of ocular disorders or ocular surgery were excluded from analyses.

Implantable Collamer Lens Implantation: All included subjects underwent implantation of the phakic Visian toric ICL (STAAR Surgical, Monrovia, CA). Prior to surgery, patients underwent refraction (subjective refraction), keratometry (Pentacam HR system (Oculus, GmbH, Wetzlar, Germany). All toric ICL power calculations were performed using software provided by the ICL manufacturer, with a target refraction of emmetropia. Additionally, the manual caliper was used for white-to-white diameter measurements was used to determine ICL size.

Following instillation of topical anesthesia (0.4% benoxinate HCl, Benox®, EIPICO, Egypt), a 3.2 mm clear corneal incision was made and the anterior chamber was filled with 1% sodium hyaluronate. The ICL was than loaded into the manufacturer-provided injection cartridge and inserted into the posterior chamber. The ICL was positioned in the sulcus and oriented along the proper refractive axis. All hyaluronate was flushed from the anterior chamber with a balanced salt solution and [miotic agent name and %] (manufacturer, manufacturer location) was instilled to induce miosis. The surgical incision was self-sealing and no sutures were required. Surgical wound closure was confirmed in all cases. Following surgery, all subjects used a topical VIGAMOX® (0.5% Moxifloxacin HCl ophthalmic solution, Alcon Lab. Inc., Fort Worth, TX, USA) and a topical steroid 1% Prednisolone acetate eye drops (Pred Forte, Allergan, Ireland) were administered in all patients four times a day for 2 weeks.

Clinical Examinations: All subjects underwent thorough ophthalmic examinations prior to surgery and throughout the 5-year postoperative period. At the preoperative and 5-year examinations, subjects underwent slit-lamp examination and measurement of intraocular pressure (IOP), uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA), refractive error, and keratometric values. Visual acuity measurements were obtained using a standard Snellen chart and recorded as decimal visual acuity. Manifest refractions were manually obtained using a standard phoropter and IOP measurements were obtained using applanation tonometry.

Data Analyses: Continuous data are presented as mean ± standard deviation. All visual acuity data were converted to the logarithm of the minimum angle of resolution (logMAR) before performing data analyses. Two-tailed, paired Student's t-tests were used to examine differences between preoperative and 5-year postoperative measures. All statistical analyses were performed using Microsoft Excel (Microsoft Corporation, Redmond, WA) and a commercially available statistical software package (SPSS for Windows version 20, SPSS, Inc., Chicago, IL). Statistical significance was defined as $p < 0.05$.

RESULTS

A total of 52 eyes of 35 subjects were included in this study. Subjects had an average age of 28.1 ± 4.4 years and 18 were male. A total of 23 right eyes and 29 left eyes were included. Prior to surgery, logMAR UCVA was 1.093 ± 0.343 (Snellen equivalent: 20/200 and logMAR BCVA was 0.026 ± 0.041 (20/22). The spherical and cylindrical refractive errors averaged -6.688 ± 3.810 and -2.168 ± 0.747 D, respectively. Prior to surgery, k_1 and k_2 were 44.873 ± 1.809 and 44.774 ± 2.650 D, respectively. The k_{max} averaged 47.552 ± 1.951 D and IOP averaged 14.7 ± 3.8 mmHg.

The refractive error remained significantly lower than preoperative values after ICL implantation. Five years after surgery, the mean spherical error was 0.620 ± 0.444 D and the mean cylindrical error was 0.475 ± 0.301 D. Additionally, the spherical equivalent (SE) of the refractive error was -0.069 ± 0.165 D at 5 years. All 52 eyes (100%) included in this study had a postoperative SE of less than 0.5 D and 46 eyes (88.5%) had an SE of less than 0.25 D. The logMAR UCVA also significantly improved from preoperative values and was 0.073 ± 0.057 (20/24) at 5 years ($p < 0.001$). Best-corrected visual acuity did not change from baseline values and remained at 0.022 ± 0.033 (20/21, $p = 0.206$).

Keratometry measurements were not significantly affected by ICL implant. Following surgery, k_1 and k_2 were 44.873 ± 1.809 and 44.562 ± 1.920 D, neither of which was significantly different from preoperative measurements ($p = 0.500$ and 0.344, respectively). The postoperative k_{max} was 47.356 ± 1.920 D, which was also not significantly different than the preoperative value ($p = 0.303$).

The safety index (mean postoperative decimal BCVA/preoperative decimal BCVA) was 1.01 ± 0.06. Additionally, IOP was 14.7 ± 3.8 mmHg 5 years after ICL implantation, which was not significantly different than preoperative values ($p = 0.625$). No intraoperative complications occurred in any of the 52 eyes included in this study. However, minor postoperative complications occurred in a total of 4 eyes (0.08%) of 2 patients (0.06%). These included mild dryness (n = 2 eyes) and mild anterior uveitis which persisted for 2 months postoperatively (n = 2 eyes). No serious complications occurred and none of the implanted ICLs were explanted.

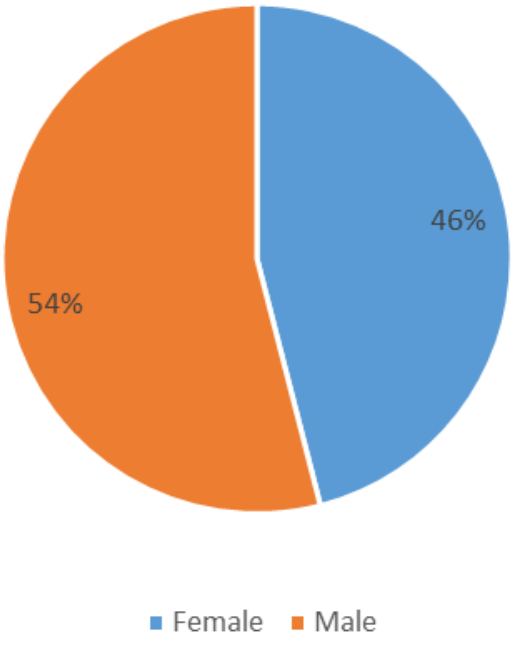

Figure 1: Gender distribution

Table 1: Pre and post comparisons

	Mean ± S.D		Mean ± S.D	p-values
Age	28.3 ± 4.5			
PreOp Sph	- 6.68 ± 3.81	post op Sph	0.60 ± 0.441	0.00001
PreOp Cyl	- 2.16 ± 0.747	post op Cyl	0.475 ± 0.301	0.00001
K1 pre	44.87 ± 2.64	post op k1	44.87 ± 1.80	0.5
K2 pre	44.7 ± 2.64	post op k2	44.56 ± 1.91	0.34
k max	47.55 ± 1.95	post op k max	47.35 ± 1.91	0.303
va	0.102 ± 0.06	best va	0.94 ± 0.082	0.00001
post op VA	0.85 ± .10	post op BEST VA	0.95 ± 0.10	0.0001

DISCUSSION

The current analyses showed that uncorrected visual acuity and refractive error remain stable up to 5 years following phakic toric ICL implantation in eyes with stable keratoconus. Furthermore, at 5 years, 100% of included patients had a residual SE of less than 0.5 D and 88.6% of included patients had a residual refractive error of less than 0.25 D. Additionally, keratometric changes did not occur following ICL implant[12-16].

The findings of the current study are in agreement with prior studies that examined visual and refractive outcomes following phakic toric ICL implantation in eyes with stable keratoconus. The ability of phakic toric ICLs to correct myopic and astigmatic refractive errors has been well established in eyes with stable keratoconus. Over the short-term (≤1 year), the toric ICL has been shown to markedly reduce refractive error and improve UCVA when implanted at least 6 months following corneal collagen crosslinking[11] or intracorneal ring segment placement[9,14]. In one study, both CXL and ICRS placement were performed in one procedure. Fewer studies have examined longer-term outcomes, but refractive stability has been shown 2 years[17], 3 years[18-20], and 4 years[21,22] following ICL implant. Only a single study (23 eyes, 13 subjects) examined 5-year outcomes[23]. That study found that refractive error correction and UCVA improvements persisted through the full 5-year follow-up period. The results of the current study are in agreement. Five years following ICL implant, both SE (-0.069 ± 0.165 D) and logMAR UCVA (0.073 ± 0.057 [20/24]) were markedly and significantly improved over preoperative values (average SE: -7.772 ± 3.354 D, average logMAR UCVA: 1.093 ± 0.343 [20/248]; both $p < 0.001$). Therefore, the current study further supports using phakic toric ICLs to correct even severe refractive errors in eyes with stable keratoconus[21-23].

The safety index of ICL implantation in the 52 eyes included in this study was 1.01 ± 0.06 and pre- and postoperative IOP were not significantly different from each other. These measures indicate that ocular health did not decline and aqueous outflow pathways remained unobstructed following ICL implant. Additionally, no intraoperative complications occurred and only minor postoperative complications were observed during the follow-up period (i.e., [list of complications here]). Postoperative complications associated with the ICL implant include cataract formation[24], an increase in IOP[25], and night vision disturbances[25]. None of these were observed in any subject.

Our study had several limitations related to its retrospective design. Additionally, this study only examined 5-year outcomes. Therefore, it cannot tell us how refractive error and visual acuity changed over time during the post-operative period.

CONCLUSION

Future prospective studies that include uniform measurements in the early and late postoperative periods are needed to confirm our findings and to better understand refractive and visual changes that may occur over time. In conclusion, the phakic Visian toric ICL is safe and effective over the long-term for correcting refractive error in eyes with stable keratoconus.

Authorship Contribution: All authors share equal effort contribution towards (1) substantial contributions to conception and design, acquisition, analysis and interpretation of data; (2) drafting the article and revising it critically for important intellectual content; and (3) final approval of the manuscript version to be published. Yes.

Potential Conflicts of Interest: None

Competing Interest: None

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