Artiflex Phakic Intraocular Lens Implantation After Corneal Collagen Cross-linking in Keratoconic Eyes

Abstract

PURPOSE:

To evaluate the safety, efficacy, and stability of the Artiflex (Ophtec BV) foldable anterior iris-claw phakic intraocular lens (PIOL) following corneal collagen cross-linking (CXL) in select cases of progressive keratoconus.

METHODS:

This prospective, comparative study, conducted between March 2007 and June 2008, involved 11 eyes with progressive keratoconus. Inclusion criteria were progressive keratoconus (Amsler-Krumeich classification grades I and II) with no corneal opacities, corneal thickness >450 µm, endothelial cell count >2500 cells/mm 2, anterior chamber depth >3.2 mm, spherical equivalent refraction >4.50 diopters (D) (with a cylinder component <2.00 D), and no other treatment for keratoconus other than contact lens. Each patient underwent CXL in the keratoconic eye with implantation of the Artiflex IOL 6 months thereafter. Uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), and refraction and topographic profiles were examined at 1, 6, and 12 months after the CXL procedure.

RESULTS:

All eyes achieved UDVA of 0.3 logMAR or better. Final spherical and cylindrical error ranged from 0 to -1.50 D and 0 to -1.75 D, respectively. No eyes lost lines of preoperative CDVA. Statistically significant reductions in mean maximum (2.14 D, *P*<.001) and minimum (1.17 D, *P*=.02) keratometry values were present 12 months after the CXL procedure. No complications were observed.

CONCLUSIONS:

Combined CXL and Artiflex implantation was a safe and effective treatment in this subset of eyes with progressive keratoconus. Good results in terms of visual acuity, postoperative residual refractive error, and keratometry values were identified.

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AUTHOR CONTRIBUTIONS

Study concept and design (L.I.); data collection (M.A.H.); analysis and interpretation of data (M.A.H., M.M.); drafting of the manuscript (L.I., M.A.H.); critical revision of the manuscript (L.I., M.A.H., M.M.); administrative, technical, or material support (M.A.H.); supervision (L.I., M.A.H.)

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Keratoconus is a noninflammatory disorder in which the central or paracentral cornea undergoes progressive thinning and bulging, eventually resulting in corneal ectasia. 1 It is associated with decreased biomechanical strength of the tissue, which is likely caused by diminished intra- and interfibrillar cross-linking of the collagen fibers. 2

Corneal collagen cross-linking (CXL) using a photosensitizer, riboflavin, and ultraviolet A (UVA) light has been shown to result in increased stiffness of the cornea, 3–8 improved biomechanical strength, 3–8 keratocyte apoptosis, 3 and increased resistance to enzymatic digestion. 8,9 As a result of these effects, the procedure has been used to limit the progression of keratoconus. 10–12

The phakic intraocular lens (PIOL) has been demonstrated to correct moderate and high refractive errors, resulting in good visual quality, especially in myopic patients. 13–16 The foldable, iris-fixated Artiflex PIOL is the new version of the Artisan lens (Ophtec BV, Groningen, The Netherlands). An identical IOL manufactured by Ophtec BV called Verisyse (distributed by

Abbott Medical Optics Inc, Abbott Park, Illinois) was approved by the US Food and Drug Administration (FDA) for highly myopic eyes. 17

The aim of this study was to assess the safety and efficacy of CXL combined with Artiflex PIOL implantation for the treatment of select cases of progressive keratoconus.

Patients and Methods

This prospective, single center study was conducted at the Oftalmosalud Institute de Ojos, Lima, Peru, between March 2007 and June 2008, and included 11 progressive keratoconic eyes of 11 patients (6 men and 5 women). Each patient received CXL by UVA/riboflavin to the eye with progressive keratoconus. Six months after CXL, an Artiflex PIOL was implanted.

Keratoconus progression was defined by at least one of the following: an increase in maximum keratometry (K1) of 1.00 diopter (D) or more in 1 year, patient complaints of deteriorating visual acuity (excluding possible noncornea-related reasons for deterioration), or the need for new contact lens fitting more than once in the previous 2 years.

Inclusion criteria were diagnosis of keratoconus (Amsler-Krumeich classification grades I and II), progressive keratoconus, absence of corneal opacities or scarring on slit-lamp examination, central corneal thickness (CCT) >450 µm (measured by ultrasonic pachymetry), endothelial cell count >2500 cells/mm 2 measured on the central part of the cornea, anterior chamber depth >3.2 mm from epithelium to anterior capsule measured by IOLMaster V.2.1 (Carl Zeiss Meditec, Jena, Germany), spherical equivalent refraction >4.50 D (with a cylinder component <2.00 D), low quality of vision, and contact lens intolerance (defined as comfortable wearing time <8 hours per day). Contact lens use was discontinued for at least 3 weeks for rigid lenses or 1 week for soft lenses before corrected distance visual acuity (CDVA) assessment was performed.

Exclusion criteria were any previous or current treatment for keratoconus except contact lens use and the inability to understand the nature of the study or provide informed consent for any reason.

Uncorrected distance visual acuity (UDVA), CDVA, manifest refraction, maximum and minimum keratometry measurements (Keratron Scout; OPTIKON 2000, Rome, Italy), CCT (Ophthasonic A-Scan/Pachometer III; Accutome, Malvern, Pennsylvania), and endothelial cell counts (noncontact specular microscope; Topcon Corp, Tokyo, Japan) were taken 6 months after the CXL procedure and 6 months after Artiflex PIOL implantation.

The study was approved by the ethics committee of Oftalmosalud Instituto de Ojos under the principles of the Helsinki Declaration. Informed consent was obtained from all study participants.

Preparation of 0.1% Riboflavin Solution

Dilute vitamin B2-riboflavin-5-phosphate 0.5% (G Streuli & Co AG, Uznach, Switzerland) was compounded with dextran T500 (Roth AG, Karlsruhe, Germany) to create a 0.1% riboflavin solution. The solution was protected from light and used within 24 hours.

Cross-Linking Procedure

Topical anesthesia was achieved by applying proparacaine hydrochloride 0.5% (Alcaine; Alcon Laboratories Inc, Ft Worth, Texas) drops on the eye every 5 minutes for three doses immediately prior to the procedure. After positioning the patient under the operating microscope, a lid speculum was inserted and the central 9-mm corneal epithelium was removed with a blunt spatula (AE2766; Asico LLC, Westmont, Illinois). The riboflavin solution was instilled every 5 minutes for 30 minutes until the riboflavin penetrated the cornea. The required irradiance from the ultraviolet (UV) lamp (UV-X illumination system, version 1000; IROC AG, Zurich, Switzerland) of 3.0 mW/cm 2 was calibrated prior to each treatment using a UVA meter (LaserMate-Q; LASER 2000, Wessling, Germany) at a working distance of 5 cm. The UV radiation was then focused on the apex of the cornea at a distance of 5 cm for a total of 30 minutes, providing radiant energy of 3.0±0.3 mW/cm 2. During UVA administration, riboflavin drops were applied to the cornea every 5 minutes or sooner if the corneal surface appeared visibly dry. After treatment, the eye surface was washed with 5 mL balanced salt solution and two drops of ofloxacin 0.3% (Oflox; Allergan Inc, Irvine, California) were instilled, followed by placement of a bandage soft contact lens (SofLens 59 +0.50 D; Bausch & Lomb, Rochester, New York).

Postoperatively, patients received acetaminophen 500 mg twice daily for 3 days, one drop of 0.3% ofloxacin six times daily for 7 days to the operative eye, along with one drop of 0.5% ketorolac tromethamine (Acular, Allergan Inc) four times daily for 5 days, followed by one drop of 0.1% fluorometholone (FML, Allergan Inc) twice daily for 5 weeks starting at postoperative day 5. The bandage contact lens was removed on postoperative day 4, and the was eye examined by slit-lamp microscopy to confirm the presence of complete corneal reepithelialization. Routine follow-up was performed at 1, 6, and 12 months postoperatively.

Artiflex Iris-Claw Phakic Intraocular Lens

The Artiflex PIOL is the foldable version of the Artisan PIOL introduced in 2003. The design

incorporates a foldable 6.0-mm silicone optic and polymethyl methacrylate (PMMA) haptics that allow for implantation through a 3.2-mm incision.

Artiflex Implantation

Lens power was calculated using Van der Heijde's formula, 17 which includes the patient's manifest refraction, topographic keratometry, and adjusted ultrasound central anterior chamber depth.

Topical anesthesia was achieved by instilling proparacaine 0.5% hydrochloride (Alcaine) on the eye every 5 minutes for two doses immediately prior to the procedure. A 3.2-mm limbal tunnel incision was made at 12 o'clock (all patients had with-the-rule astigmatism) and two lateral paracentesis ports were created in the cornea at 10 o'clock and 2 o'clock with a width of 1.5 mm. Carbachol intraocular solution 0.01% (Miostat, Alcon Laboratories Inc) was injected, and the anterior chamber was filled with a cohesive ophthalmic viscosurgical device (sodium hyaluronate 1.4% [Healon GV, Abbott Medical Optics Inc]). The IOL was inserted with its injector at 12 o'clock and rotated into a horizontal position. The lens haptic was enclavated to a fold of midperipheral iris stroma using an enclavation needle at the 3- and 9-o'clock meridians to achieve perfect IOL centration. A peripheral surgical iridotomy was made at the 12-o'clock meridian. All ophthalmic viscosurgical device material was carefully removed by manual irrigation, 0.1 mL (1 mg) intracameral cefuroxime was instilled, and the incision was closed with hydration of the stroma. Postoperative treatment included 3 mg topical ciprofloxacin hydrochloride and 1 mg dexamethasone (Sophixin DX Ofteno; Laboratorios Sophia SA De CV, Guadalajara, Mexico) one drop every 4 hours for 2 weeks.

Statistical Analysis

Statistical analysis was performed with SPSS version 12 (SPSS Inc, Chicago, Illinois). Comparisons of means were performed using the Student *t* test. Normality of data distribution was evaluated using the Kolmogorov-Smirnov test. The chi-square test was used to evaluate proportional differences between follow-up examinations.

Results

Demographics

Mean patient age was 29.09±4.54 years (range: 23 to 31 years). One (9.09%) patient was 25 years old, six (54.54%) were between 26 and 29 years, and four (36.36%) were over 30 years. The latter four patients had progressive keratoconus grade II and their fellow eye had been previously treated for advanced keratoconus (two had intrastromal corneal rings and two underwent penetrating keratoplasty). The stages of keratoconus were 18.2% (2/11) stage I and 81.8% (9/11) stage II.

Visual Acuity

Mean preoperative UDVA was 1.40±0.40 logMAR. Postoperative UDVA 6 months after CXL was 1.16±0.46 logMAR and 0.16±0.06 logMAR 6 months after Artiflex PIOL implantation, which shows a statistically significant reduction between the pre- and postoperative follow-up periods (*P*=.04 and *P*<.001, respectively). Compared with preoperative UDVA, a postoperative (6 months after Artiflex implantation) UDVA gain of 5 or more lines was found in 11 (100%) eyes. All eyes achieved 20/40 or better 6 months after last treatment.

Mean preoperative CDVA was 0.14±0.06 logMAR and at 6 months after CXL was 0.12±0.06 logMAR, which was not statistically significant (*P*=.16). Corrected distance visual acuity at 6 months after Artiflex implantation was 0.04±0.05 logMAR, which was statistically significant compared with the preoperative value (*P*<.001). Corrected distance visual acuity was unchanged or improved in all eyes compared with preoperative levels, and seven (63.63%) eyes gained one or more lines of CDVA. The shows pre- and postoperative UDVA and CDVA for each study eye.

Table: P
Visual
Keratome

Keratometry

Compared with preoperative levels, mean maximum keratometry was reduced by 1.27 D 6 months after CXL and by 2.14 D 6 months after Artiflex implantation, which was statistically significant (*P*=.02 and *P*<.001, respectively). Mean minimum keratometry when compared with preoperative levels increased by 0.24 D at 6 months after CXL (*P*=.63) and then reduced by 1.17 D 6 months after Artiflex implantation (*P*=.02). No progression of the cone in 11 (100%) eyes was noted. The shows pre- and postoperative keratometry measurements for each study eye. Figure shows mean keratometry (K1 and K2) at 6 months after CXL and Artiflex implantation, respectively.

Figure 1. Pre- (K1) and postoperative (K2) keratometry values during follow-up. Preop = preoperative visit, Post CXL = postoperative follow-up 6 months after the cross-linking procedure, Post pIOL = postoperative follow-up 6 months after Artiflex phakic intraocular lens implantation

Refractive Outcomes

Compared with preoperative levels, the mean spherical value decreased 0.45 D and 5.43 D 6 months after CXL and Artiflex inplantation, respectively, which was statistically significant (*P*=.03 and *P*<.001, respectively). In terms of the cylinder value, a nonsignificant reduction of 0.16 D was observed 6 months after CXL (*P*=.13). However, a statistically significant reduction of 0.55 D 6 months after Artiflex implantation was observed (*P*=.04). The and Figure show pre- and postoperative refractive errors.

Figure 2. Pre- and postoperative refractive errors during follow-up. Preop = preoperative, Post CXL = postoperative follow-up 6 months after the cross-linking procedure, Post pIOL = postoperative follow-up 6 months after Artiflex phakic intraocular lens implantation, SE = spherical equivalent refraction

Endothelial Cell Count

Mean preoperative central endothelial cell count was 2759.64±159.84 cells/mm 2. Postoperative central endothelial cell count 6 months after CXL was 2739.09±156.99 cells/mm 2, which was not statistically significant (*P*=.46), and 6 months after Artiflex PIOL implantation was 2668.82±133.17 cells/mm 2, which was statistically significant (*P*=.03).

Adverse Effects and Postoperative Complications

No intraoperative or serious postoperative complications occurred in this series of patients. Mild haze was present in two patients that resolved after 15 days (without any change in postoperative medications).

Discussion

Refractive results following riboflavin/UVA CXL have been reported to show a decrease of 0.93 to 1.42 D in mean spherical equivalent refraction. [12,18–20] In terms of corneal curvature, previous studies describe a postoperative reduction of mean keratometry from 0.92 to 2.10 D after 6 months [21] and between 1.45 and 2.68 D after 1 year. [18–21]

Phakic IOL implantation is proven to be effective, stable, and safe in patients with a high refractive error, [13–17,22,23] as well as in patients with keratoconus. [24,25] Other authors obtained the same or better UDVA values after implantation of the Artisan/Verisyse [16,26–28] or Artiflex [14] PIOLs in 93.3% to 100% of patients and the same or better CDVA values with the Artisan/Verisyse [13,15,17] in 82% to 97.2% with follow-up from 6 months to 10 years. However, these results were for CXL or PIOL implantation alone. There are no published data describing the combination of these two procedures for treatment of keratoconus. Results from the current study demonstrated improved refractive outcomes for patients undergoing both riboflavin/UVA CXL and Artiflex PIOL implantation, with a reduction of 5.43 D mean spherical equivalent refraction and 2.12 D central keratometry 6 months after the last surgery, with no progression of the cone in any patient.

The main concern with PIOLs is long-term tolerance of the corneal endothelium. Mean endothelial cell loss was 3.29% (including a physiological 0.6% annual loss) 1 year after the CXL procedure and 6 months after Artiflex implantation. Similar results after only PIOL implantation were found at 6 and 12 months postoperatively, with mean endothelial cell loss ranging from 0.05% to 5.5% and from 1.79% to 7.21%, respectively. [13,14,25,29–31] Data from the European multicenter study of the Artiflex PIOL [14] and the FDA Artisan/Verisyse study [17] show that implantation of the Artisan iris-claw PIOL did not result in significant loss of endothelial cell density up to 2 years postoperatively. The largest reduction in endothelial cell density occurred during the first 6 months

postoperatively and the rate of cell loss diminished by 4- and 5-year follow-up. 16 Data from the literature 18,19 describe no significant changes in endothelial cell count before and after CXL. Our findings suggest that performing both CXL and PIOL implantation together do not result in additional endothelial cell loss beyond performing the individual procedures alone. Longer follow-up will be required to confirm the stability of these results and to characterize endothelial cell loss over time.

We performed corneal collagen CXL first because the literature 19,21 has shown that CXL produces statistically significant reductions in keratometric values and refractive errors with time. We wait 6 months after CXL before implanting the Artiflex IOL to consider the changes produced by the CXL procedure on refractive errors and keratometric values, which affect the calculation of PIOL power. In addition, we believe a longer time interval shows a greater change in spherical equivalent refraction and keratometry, and because our patients do not want to wait a long time for a final result we chose 6 months after CXL to implant the PIOL as our study protocol.

The toric Artisan lens has shown good results in patients with high myopia and astigmatism, 32 and it could represent an option in this combined procedure. We decided to use the Artiflex instead of the Artisan or toric Artisan because these lenses require an incision of 5.2 to 6.2 mm and we wanted to preserve corneal biomechanical integrity in these already compromised keratoconic eyes. At the moment, the toric version of Artiflex allows correction of myopia up -14.00 D and it is inserted through a 3.2-mm incision. In the future, this may be a good option for patients with keratoconus and a high cylinder error when combined with the stabilizing CXL procedure.

Based on the available data and results of our current study, we suggest that PIOL implantation after corneal collagen CXL in patients with keratoconus would have a similar refractive effect with nonkeratoconic eyes. An additional benefit is provided by CXL in reducing corneal steepening and limiting the progression of keratoconus, thereby improving the two principal problems of refractive error and progression of the disease.

Combining CXL with Artiflex PIOL implantation appears safe and efficacious for the treatment of select cases of progressive keratoconus and results in significant improvements in visual acuity, keratometry, and refractive error.

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