Toric Implantable Collamer Lens for Correction of Myopia and Astigmatism in Keratoconus

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28.1 Introduction

Phakic refractive IOLs are becoming more and more popular because of the ease of implantation and the predictability of refractive and visual results.

Myopia and astigmatism are often associated with keratoconus, and patients with keratoconus often ask for refractive surgery. In such eyes, when corneal topography shows a keratoconic aspect or suggests a keratoconus fruste, implantation of a refractive IOL may be considered to avoid a postoperative fragile cornea. Moreover, the indication is easily considered because the anterior chamber depth is usually greater than 3.00 mm in such cases [1].

Phakic IOLs (PIOLs) allow correction outside the limits of the corneal refractive surgery [1]. The insertion of an implant in a phakic eye preserves accommodation and is reversible. Current IOL choices include AC PIOLs; angle-supported or iris-fixated models; and PC PIOLs, sulcus-fixated or free-floating models.

Historically, the idea of curing refractive problems by means of built-in or integrated additional optics (built-in glasses or contact lenses) sounds logical; however, even the great surgeons of our time failed initially with this approach that dates back to the late 1950s.

Despite the well-known setbacks of Strambelli [2–4], individual scientists never allowed the idea of PIOL implantation to die. Three different scientists pursued three different anatomic concepts for PIOLs at roughly the same time: Baikoff saw a solution in the angle-supported anterior chamber lens [5].

Fechner developed another solution in the modification of Worst's iris fixated lobster claw IOL and Fyodorov implanted a silicon lens into the posterior chamber [6].

The Baikoff design, angle-supported PIOLs evolved from 4-point fixation polymethyl methacrylate (PMMA) versions [5] to three-point PMMA versions, and then to foldable IOLs to decrease induced astigmatism. The PMMA versions failed basically due to endothelial cell loss, pupil ovalization, and induced astigmatism. To overcome these problems, the material was changed from PMMA to hydrophilic acrylate or hydrophobic acrylate. However, severe complications such as

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endothelial decompensation [7] and pupil ovalization [8] after implantation of an anterior PIOL have resulted in several European countries having recalled these lenses for the correction of refractive errors [9].

The iris-fixated PIOL for the correction of myopia was introduced in 1986 as a rigid single-piece PMMA model with a 5.0- or 6.0-mm optic. The iris-fixated PIOL has been implanted for more than 20 years through a 5.0- to 6.0-mm incision. The goal of reducing surgically induced astigmatism was achieved with the development of the foldable iris-fixated model with silicone optic and PMMA haptics introduced in 2003.

The foldable design makes implantation possible through a 3.2-mm incision. However, this PIOL may be associated occasionally with recurrent intraocular inflammation, enhanced iris dispersion with posterior synechiae [10], and lenticular glistering [11].

The posterior chamber PIOLs to correct myopia was introduced first by Fyodorov in 1986 [6]. The first-generation Fyodorov PC PIOL was a one-piece silicon lens fixated by a haptic in the PC. In 1990, this lens was replaced by a second-generation model. Using knowledge of the early model of silicon posterior PIOL designs as a basis, two manufacturers, i.e., Medennium Inc., Irvine, CA, USA and STAAR Surgical Co., Monrovia, CA, USA, currently are researching and marketing posterior PIOL designs.

28.2 The Implantable Collamer Lens (ICL) (STAAR Surgical Co.)

The ICL has undergone many modifications in design since 1993. The latest model, V 4c, developed in 2011, made significant improvement in the amount of vaulting over the anterior lens capsule from the previous model [1]. The lens has a one-piece plate design with a rectangular shape, 7.5–8.0 mm wide, available in four standard overall lengths: 11.5–13.5 mm for myopic lenses and 11.0–13.0 mm for hyperopic lenses to adapt to eyes of different sizes.

The diameter of the optic zone is 4.65–5.5 mm in the myopic lenses, based on the desired dioptric power, and 5.5 mm for hyperopic ICLs.

Available powers for myopic lenses range from −3.0 to −22.0 D and from +3.0 to +20.0 D for hyperopic lenses [12].

The lens is introduced by means of a STAAR microinjector.

The proximity of the ICL to the crystalline lens, a dynamic phenomenon, has been postulated to be a risk factor for cataract development, which has been the main concern with this lens, and a greater vault would be expected to decrease ICL–crystalline lens contact [1, 12]. However, it is also possible that interference with lens nutrition instead of IOL contact of the crystalline lens may be the cause of cataract [13].

The main differences between the ICL and the phakic refractive lens (PRL) are the lens material and lens dynamics. The ICL is made of a collamer, which is hydrophilic acrylic with some cross-linked porcine collagen [13].

The PRL is made of hydrophobic silicone and rests on the zonulas and floats in the PC, whereas the ICL is fixated and supported in the ciliary sulcus. Cataract formation has been reported less frequently with the PRL [14]. However, rotation of the PRL in the PC excludes the possibility for cylinder compound whereas the ICL has the toric alternative for myopic eyes with astigmatism [15].

28.2.1 Device Description

The STAAR Surgical Visian ICL (Implantable Collamer Lens) is an intraocular implant manufactured from a proprietary hydroxyethyl methacrylate (HEMA)/porcine-collagen based biocompatible polymer material. The Visian ICL contains a UV absorber made from a UV absorbing material. The Visian ICL features a plate-haptic design with a central convex/concave optical zone and incorporates a forward vault to minimize contact of the Visian ICL with the central anterior capsule.

The Visian ICL features an optic diameter with an overall diameter that varies with the dioptric power; the smallest optic/overall diameter being 4.9 mm/12.1 mm and the largest 5.8 mm/13.7 mm. The lenses are capable of being folded and inserted into the posterior chamber through an incision of 3.2 mm or less.

The Visian ICL is intended to be placed entirely within the posterior chamber directly behind the iris and in front of the anterior capsule of the human crystalline lens when correctly positioned, the lens functions as a refractive element to optically reduce moderate to high myopia.

28.2.2 Material

Collagen—Copolymer (Collamer™) Biocompatible, Refractive index 1.45 at 35 °C, optically clear, UV Absorbing (10% transmission).

28.2.3 Manufacture

Lathe cut, Laser engraved, Hydrated, Steam Sterilized, Single—Piece Design.

28.2.4 Different Versions of the Toric ICL

The development of the toric ICL has passed by many modifications since the first version in 1993 with appearance of the V family of the lens in 2007 which was stored in NaCl container and has no holes which necessitates making a peripheral iridotomy to help prevent pupillary block, in 2010 the improved version V4b came with two perioptic holes to facilitate removal of viscoelastic material behind the lens and the lens was stored in BSS not NaCl as before, in 2013 the newer version V4c was introduced with a central hole which allowed for the implantation of the lens without the need for the peripheral iridotomy (see Figs. 28.1, 28.2, and 28.3).

28.2.5 Recommended Criteria for the Toric ICL Implantation in KC Patients

- Normal systemic history and normal physical examination results.
- Absence of any history or physical signs of ocular disease with the exception of keratoconus and myopia.
- Age between 20 and 45 years.
- Best Spectacle Corrected visual acuity of 0.3 (20/60) or better in the eye to be treated.
- Stable refraction for at least 12 months after corneal collagen cross-linking.
- Clear central cornea.
- Normal anterior segment with an anterior chamber depth of at least 2.80 mm.
- Normal intraocular pressure.

28.2.6 Preoperative Assessment of Patients

- Manifest (Subjective) and Cycloplegic (Objective) refraction.
- Best spectacle corrected visual acuity:

Every single measure should be used to verify the subjective refraction before the calculation of the ICL power. The accurate subjective refraction in these cases is defined as the lowest sphere and cylinder values that give the best spectacle corrected visual acuity. These values together with the exact axis of the cylinder should be properly determined using all the available optometric tricks. The subjective refraction that gives the best spectacle corrected visual acuity should be checked in three consecutive monthly visits after at least 9 months of the CXL to get sure of the stability of refraction. The stability of the subjective refraction over the monthly visits is one of the most important parameters before planning to implant a toric ICL (TICL) for those patients. It indicates the stability of the keratoconic state after the CXL, hence the stability of the visual outcome after the TICL implantation. One of the

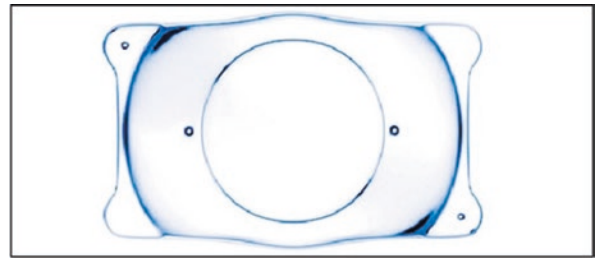

Fig. 28.1 Different periods of vaulting of the implanted toric ICL

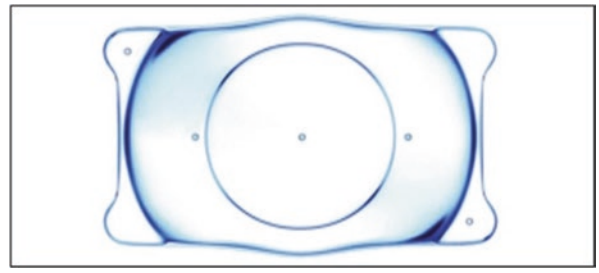

Fig. 28.2 The ICL V4b IOL

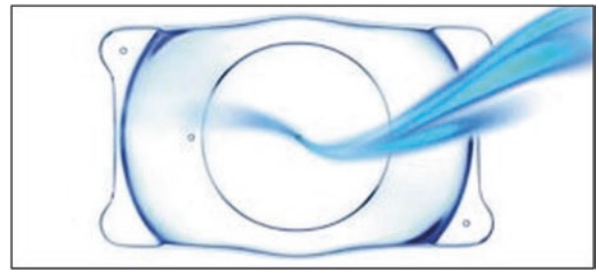

Fig. 28.3 The ICL V4c iol

useful clinical tricks is to prescribe glasses for those patients and encourage them to wear their glasses for at least 2 weeks before ordering the ICL. Patient's satisfaction and fair visual performance with the glasses before the TICL implantation are very good indicators of a good postoperative visual performance. Again, it is to be noted that there is usually a discrepancy between the value of the subjective and cycloplegic refraction in keratoconic eyes as a result of the corneal multifocality induced by the keratoconus [16].

Verification of the power of the sphere together with the power and exact axis of the cylinder give the best subjective spectacle corrected visual acuity is the key point of the success of the TICL implantation to give visual performance satisfaction for those patients.

- Anterior chamber depth using IOL Master (Carl Zeiss, Jena, Germany), a Scheimpflug anterior segment imaging (e.g., Pentacam), or anterior segment OCT.
- Corneal Curvature information (*K* readings).
- White-to-white measurement using a Caliper and/or IOL Master (Carl Zeiss, Jena, Germany).
- Assessment of anterior, posterior corneal surfaces and Anterior Chamber using a Scheimpflug camera system (e.g., Pentacam, Oculus Inc).
- The ICL power can be calculated using the software ICL POWER CHOICE OF STAAR SURGICAL. The verified stable subjective refraction, as described earlier, is the one that is used to calculate the TICL power.

28.3 Surgical Technique

- In order to dilate the pupil of the eye to be operated, 1 h before surgery, a Tropicamide 1 % (Mydriacyl, Alcon laboratories, Inc. Fort Worth, USA) and phenylephrine® ophthalmic solution 2.5 % (Alcon laboratories, Inc. Fort Worth, USA) are instilled every 15 min.
- Marking the exact horizontal and vertical axes of the cornea at the slit lamp with a pen marker.
- Checking and confirming that the pupil is fully dilated.
- Confirmation of the received TICL power and diameter.
- Reviewing the orientation diagram supplied by the manufacturer and establishing the implantation direction.
- Cleaning of the operative site with Povidone Iodine (Betadine®).
- Draping the patient and the operative site with sterile towels.
- Preparing the TCL for loading into the injector cartridge:
  - Open the lens container
  - Hydrate the micro-Staar foam tip (STAAR Surgical) inside the ICL container
  - Wet the inside of the micro-Staar injector with BSS.
  - Lubricate the inside of the cartridge with viscoelastic Healon® (10 mg/mL Sodium hyaluronate; Abbott).
  - Getting the ICL from its container using the foam tip
  - Loading the ICL inside the cartridge under the microscope on the side table using the foam tip and the coaxial forceps (Janach, J3864.1, sold by STAAR)
  - Insertion of the foam tip inside the micro-Staar injector.
  - Finally load the cartridge inside the injector.
- Cutting of the drape and exposing the operative eye with a self-retaining speculum.
- Bores and Mendez tool is used to determine the proper axis for the lens position as indicated by the implantation diagram.
- Marking the axis on the limbus using a surgical pen marker.
- Performing two sideport incisions (paracentesis) one at 12:00 o'clock and one at 6:00 o'clock.
- Temporal clear corneal tunnel of 3.00–3.2 mm with a disposable keratome after fixing the globe with 0.12 fixation forceps.
- Injection of viscoelastic in the anterior chamber.
- Insertion of the ICL using the injector.
- Injection of viscoelastic on top of the lens in the anterior chamber.
- Manipulating the distal haptic under the edge of the iris through the side port using an ICL special manipulator.
- Manipulation of the proximal haptic under the iris edge through the main 3.2 mm incision.
- ICL centration and rotation as necessary referring to the implantation guide.
- Removal of the viscoelastic using Simcoe irrigation/Aspiration cannula.
- Constriction of the pupil using Miochol-E (acetylcholine chloride intraocular solution) 1:100 with Electrolyte Diluent (Novartis, Switzerland).
- Surgical iridectomy after pupil constriction is achieved using Vitrectomy cutter in case of implanting the V4b version of the ICL (not necessary in the new version of V4c ICL as it has a central hole).
- Checking for wound leakage.
- Instillation of antibiotic eye drops.
- Removal of the drapes.
- Antibiotic and corticosteroid drops four times daily for 10 days.
- In cases of bilateral implantation, the second eye can be operated upon within the first postoperative week of the fellow eye.
- Postoperative follow up should include; uncorrected visual acuity (UCVA), CDVA, slit-lamp examination, Manifest and Cycloplegic refraction, funduscopy, and IOP measurements.
- Assessment of the postooerative ICL vaulting should be done using the slit lamp, the anterior segmant OCT and/or a Scheimpflug camera system (Pentacam, Oculus Inc.).

28.4 Clinical Results

In a study that was conducted by our team [16] to assess the use of the toric ICL to correct the ametropia in the stable keratoconus patients after corneal collagen cross-linking, a prospective interventional clinical study included 16 eyes that we followed for more than 3 years which is considered the longest follow-up period for this technique in published data.

The results demonstrate the efficacy of the technique in restoring a good visual acuity for those patients having residual high sphere and cylinder after corneal collagen cross-linking.

28.4.1 Visual Acuity

- Table 28.1 presents the different periods of the CDVA after the corneal cross-inking and ICL implantation, as noticed, the mean CDVA improved from 0.56 before cross-linking to >0.8 after 1 week of the ICL implantation, and this improvement was maintained throughout the follow-up period. The beta type 2 error was 0.0987.
- Table 28.2 presents the difference between the CDVA before the surgery and the postoperative UDVA demonstrating a significant improvement in the visual acuity as the mean for the preoperative CDVA was 0.63 ± 0.14 and the mean of the postoperative UDVA was about 0.8 at 1 week and maintained throughout the rest of the follow-up or even got slightly better. The beta type 2 error was 0.0842.

28.4.2 Refraction

Considering the sphere, the preoperative mean was about −6.00 ± 4.00 D, which improved to almost undetectable levels postoperatively. Preoperatively, the mean cylinder was about −5:00 ± 1.50 D, and this improved to 0.0 D postoperatively; the spherical equivalent preoperatively was −8.50 ± 4.00 D, and this improved postoperatively to less than −0.25 D. The beta type 2 error was 0.0835.

Table 28.1 Different periods of the CDVA after the corneal cross-linking and ICL implantation

CDVA	Before cross-linking	Before ICL	After 7 days	After 1 month	After 6 months	After 1 year	After 3 years
Range	0.40–0.80	0.40–0.80	0.60–1.20	0.60–1.20	0.60–1.20	0.60–1.20	
Mean ± SD	0.56 ± 0.13	0.63 ± 0.14	0.82 ± 0.16	0.87 ± 0.15	0.89 ± 0.17	0.89 ± 0.17	0.89 ± 0.17
Median	0.60	0.60	0.85	0.85	0.90	0.90	0.90
F (*p*)							
Mean difference (p_1)		0.063* (0.002)	0.256* (<0.001)	0.306* (0.028)	0.325* (<0.001)	0.325* (<0.001)	0.325* (<0.001)
Mean difference (p_2)			0.194* (0.002)	0.244* (<0.001)	0.263* (<0.001)	0.263* (<0.001)	0.263 (<0.001)
Mean difference (p_3)				0.050* (0.032)	0.069 (0.139)	0.069 (0.139)	0.069 (0.139)
Mean difference (p_4)					0.019 (1.000)	0.019 (1.000)	0.019 (1.000)
Mean difference (p_5)						0.0 (–)	0.0 (–)
Mean difference (p_6)							0.0 (–)

p_1, Bonferroni-adjusted *P* value for comparison between pre-cross-linking with each other period; p_2, Bonferroni-adjusted *P* value for comparison between pre-ICL with each other period; p_3, Bonferroni-adjusted *P* value for comparison between after 7 days with each other period; p_4, Bonferroni-adjusted *P* value for comparison between after 1 month with each other period; p_5, Bonferroni-adjusted *P* value for comparison between after 6 months with each other period; p_6, Bonferroni-adjusted *P* value for comparison between after 1 year and after 3 years

*Statistically significant at $P \leq 0.05$

Table 28.2 Difference between the CDVA before the surgery and the postoperative UDVA

UCVA	CDVA before ICL	After 7 days	After 1 month	After 6 months	After 1 year	After 3 years
Range	0.40–0.80	0.60–1.20	0.60–1.20	0.60–1.20	0.60–1.20	0.60–1.20
Mean ± SD	0.63 ± 0.14	0.79 ± 0.16	0.83 ± 0.16	0.85 ± 0.15	0.88 ± 0.18	0.88 ± 0.18
Median	0.60	0.80	0.80	0.80	0.85	0.85
F (*p*)			43.022* (<0.001)			
Mean difference (p_1)		0.169* (0.002)	0.206* (<0.001)	0.250* (<0.001)	0.250* (<0.001)	0.250* (<0.001)
Mean difference (p_2)			0.038 (0.135)	0.081* (0.042)	0.081* (0.042)	0.081* (0.042)
Mean difference (p_3)				0.044 (0.210)	0.044 (0.210)	0.044 (0.210)
Mean difference (p_4)					0.0 (–)	0.0 (–)
Mean difference (p_5)						0.0 (–)

p_1, Bonferroni-adjusted *P* value for comparison between pre-ICL with each other period; p_2, Bonferroni-adjusted *P* value for comparison between after 7 days with each other period; p_3, Bonferroni-adjusted *P* value for comparison between after 1 month with each other period; p_4, Bonferroni-adjusted *P* value for comparison between after 6 months with each other period; p_5, Bonferroni-adjusted *P* value for comparison between after 1 year and after 3 years; UCVA, uncorrected distant visual acuity
*Statistically significant at $P \leq 0.05$

The preoperative manifest refraction is used to calculate the TICL power. The beta type 2 error was 0.0762.

28.4.3 Vaulting of the TICL

The mean values were 539.13 ± 161.94 μm, 524.88 ± 151.61 mm, 509.12 ± 121.7 mm, 508.75 ± 132.4 μm, 508.90 ± 111.6 μm, and 507.12 ± 117.3 μm for the 1-week; 1-, 3-, 6-, 12-month; and 3-year postoperative periods of the follow-up, respectively (see Fig. 28.4).

28.4.4 Intraocular Pressure

The mean values were 12.0 ± 1.03 mmHg, 14.38 ± 2.45 mmHg, 13.0 ± 1.51 mmHg, 12.19 ± 1.33 mmHg, 11.94 ± 1.12 mmHg, and 11.94 ± 1.12 mmHg for the 1-week; 1-, 3-, 6-, 12-month; and 3-year postoperative periods of the follow-up, respectively.

28.4.5 Endothelial Cell Count

The mean preoperative endothelial cell count was 2850 cells per square millimeter; after 1 year, it was 2705 cells per square millimeter (–5.08 % cell loss). After 2 years, it was 2650 cells per square millimeter (–7.01 % cell loss), and after 3 years, it was 2594 cells per square millimeter (–8.89 % cell loss).

No complications occurred during the surgical procedures.

No eye needed explantation or repositioning of the TICL. Decentration of the TICL optic was not observed, and no case of pupillary block was detected.

28.5 Discussion

Refractive surgical correction of ametropia in patients with keratoconus remains challenging.

Progressive thinning and subsequent anterior bulging of the cornea can lead to high astigmatism

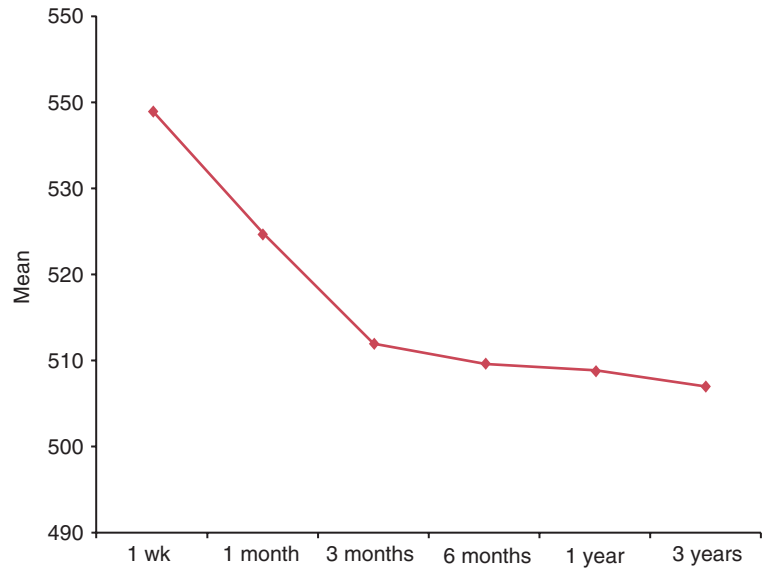

Fig. 28.4 The ICL V4c IOL. The KS-Aquaport is designed to restore a more natural aqueous flow and eliminate the need for an iridotomy

that is often accompanied by myopia and sometimes central scarring, resulting in mild-to-marked impairment in the quantity and quality of vision [17, 18].

Spectacles and contact lenses are the usual optical treatment options in the early stages of keratoconus [19].

In more advanced cases with severe corneal astigmatism and stromal opacity, patients may not tolerate contact lenses or there may be no improvement in visual acuity on using contact lenses. In these cases, a penetrating keratoplasty (PKP) or a deep anterior lamellar keratoplasty is necessary to restore visual function [20].

Collagen cross-linking using riboflavin and UV light was lately introduced [21]; however, cross-linking alone stabilizes and stiffens the cornea by inducing more corneal collagen cross-links of keratoconus, and the remaining refractive errors will still need to be corrected.

Our prospective nonrandomized clinical interventional study of 16 eyes, aimed to determine whether the implantation of a TICL in corneas that had been cross-linked and showed refractive stability for at least 12 months is safe, predictable, and effective in correcting different ranges of myopia and astigmatism in eyes with early stage keratoconus [16].

We obtained very satisfactory refractive outcomes in predictability with all the eyes being within 0.5 D of the intended spherical equivalent; the mean spherical equivalent was <0.25 D 3 years after the surgery. In addition, the astigmatism decreased significantly to nearly clinically insignificant values. Regarding visual outcomes, the efficacy was good with >81 % of the eyes having a postoperative UDVA of ≥0.8 and all the operated eyes maintaining a CDVA or gaining multiple lines of CDVA [16]. All the studied cases demonstrated line(s) gain in their postoperative BCVA. The improvement of the postoperative visual performance of these patients is attributed to many optical factors: The effect of the CXL on regularization of the corneal surface and relative recentering of the cone and then the correction of the remaining refractive error by the ICL which provides a magnification of image and improvement of the image details by correcting the refractive error at a level near to the nodal point. We think that the above-mentioned factors are responsible for the superior visual performance of the cross-linked keratoconic eyes after implantation of Toric ICL to correct their ametropia.

The efficacy and predictability of posterior chamber phakic toric IOLs in the treatment of different degrees of myopia combined with low to high astigmatism in virgin ametropic eyes are

supported by many reports [15, 22–25]. Some studies demonstrated the efficacy and predictability of these lenses to treat similar refractive errors in stable keratoconic eyes [26]. Their long-term stability was also reported in our study [16].

The most commonly reported postoperative complications of the ICL implantation are anterior subcapsular cataract [27–29] and increased IOP [30, 31].

Sanders [32] reported that anterior subcapsular opacities and cataract occurred 5 years after surgery in the Food and Drug Administration trial.

Although approximately 6–7 % of eyes developed anterior subcapsular opacities ≥7 years after phakic IOL implantation, the opacity progressed to a clinically significant cataract in only 1–2 % during the same period, with most cases being observed in older patients and in eyes with very high myopia.

There were no cases of chronic increased postoperative IOP or anterior subcapsular cataract in our study.

Another concern is the degree of vaulting of the implanted ICL and how it changes over time; a study performed by Kojima et al. [33] 1 year after ICL implantation in 36 eyes showed that the mean vault was 0.53 ± 0.25 mm. A result consistent with the results in our study, which showed a mean vault of 0.509 ± 0.141 mm at 1 year postoperatively.

We also demonstrated that a high vault gradually decreases over time. The reason for the decrease in the initial vaulting measures especially from the 1-week to 1-month period of the postoperative follow-up may be related to the residual viscoelastic material that was present between the ICL and the crystalline lens, although meticulous irrigation/aspiration was performed.

A complete irrigation is often difficult because of the presence of a narrow space between the crystalline lens and the ICL.

It is preferable that TICL implantation not be performed until refraction and keratometry are stable after corneal collagen cross-linking. We prefer to wait for a least 1 year of the CXL to insure the stability of the refraction in those eyes.

The recommended indications for TICL implantation in keratoconus are as follows:

CDVA ≥20/60, clear central cornea, stable refraction at least 12 months after cross-linking and those patients who are satisfied with their spectacles prescription after CXL. Of course all measures should be exhausted to provide the best subjective spectacle corrected visual acuity before ordering the spectacles after stabilizing the cornea. If these criteria were not met, TICL is not considered as a good tool for ametropia correction and visual rehabilitation in keratoconic eyes a kind of keratoplasty would probably provide better visual outcomes.

In other words, TICL implantation should not be considered a true alternative to keratoplasty but rather an alternative treatment in cases of early-to-moderate stages of keratoconus with a relatively low irregular/regular astigmatism. The key point of success with this modality is to base the TICL power calculation on the subjective best spectacle correction refraction. This value should be meticulously verified and approved by both the patient and surgeon prior to TICL calculation, ordering, and implantation. A keratoconus patient who is happy with his glasses after CXL will be almost sure after TICL implantation as a result of the optical correction of his refractive error on a plane nearer to the nodal point by the ICL. We advise waiting for at least 1 year after the CXL to implant the TICL to get sure of the stability of the refraction and corneal state.

Refraction stability could be verified by 3 monthly consecutive visits in which the subjective refraction value that guarantees the best spectacle corrected visual performance is revised each time to insure stability before ordering and implanting the TICL.

All intraocular procedures entail some degree of endothelial cell loss, and insertion of a phakic IOL induces between 2.1 and 7.6 % [34]. Postoperative endothelial loss is also an important issue. For the ICL, the 1-year endothelial

cell loss rate was 5.17 % in one study [35] and, in another, a cumulative decrease of 7.7 % was seen in the endothelial cell density over 5 years [36].

The reason for the discrepancy is possibly because of chronic low-grade inflammation [37].

28.6 Conclusion

Correction of spherical and cylindrical refractive errors in keratoconic eyes by TICL implantation after cross-linking seems to have significantly good outcomes, particularly in the astigmatic component of refraction. The significant visual improvement after this procedure could be attributed to two factors: the effect of the cross-linking on flattening/regularizing the cornea and the correcting effect of the TICL on a plane near the nodal point of the line of sight.

It is recommended to meticulously repeat the refraction of these eyes to obtain the subjective refraction that provides the best spectacle corrected visual performance and to calculate the ICL power using it to target postoperative emmetropia.

28.7 Example of a Clinical Case from Our Study

A 26-year-old female patient with progressing keratoconus who had corneal collagen cross-linking of her both eyes and showed refractive stability after 12 months. (Fig. 28.5 shows Pentacam study before CXL and 12 months after CXL.) The refractive stability was verified over the last 3 monthly visits of the patient. The patient had a BCVA of 0.4 (OD) and 0.8 (OS) with the subjective refraction of −9.50 −4.00×46 and −4.50 −3.50×138, respectively. The patient was given glasses to wear them over 2 months and she was very satisfied with them. A pair of toric ICLs was ordered for her based on the subjective refraction. The IOL Master (Zeiss, Germany) was used to provide values of the *K* readings, anterior chamber depth, and white-to-white measurements of both eyes (Fig. 28.6). Bilateral toric ICL implantation was performed 14 months after the CXL according to the provided data and the implantation forms provided by the manufacturer (Figs. 28.7 and 28.8). One month after the surgery the UCVA was 0.7 (OD) and 1.2 (OS) with a quite bilateral anterior segment, normal bilateral IOP, and an ICL central vault of 600 μm bilaterally as

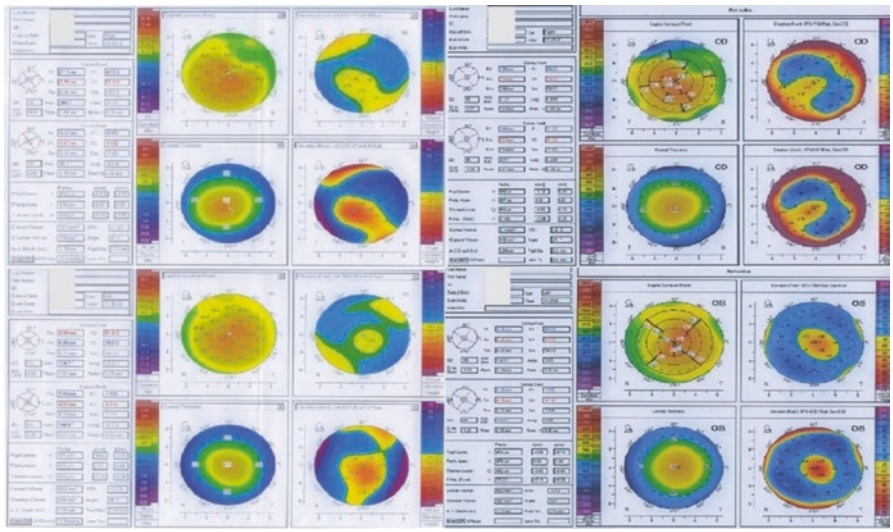

Fig. 28.5 Bilateral Scheimpflug images pre and 12 months postcorneal collagen cross-linking

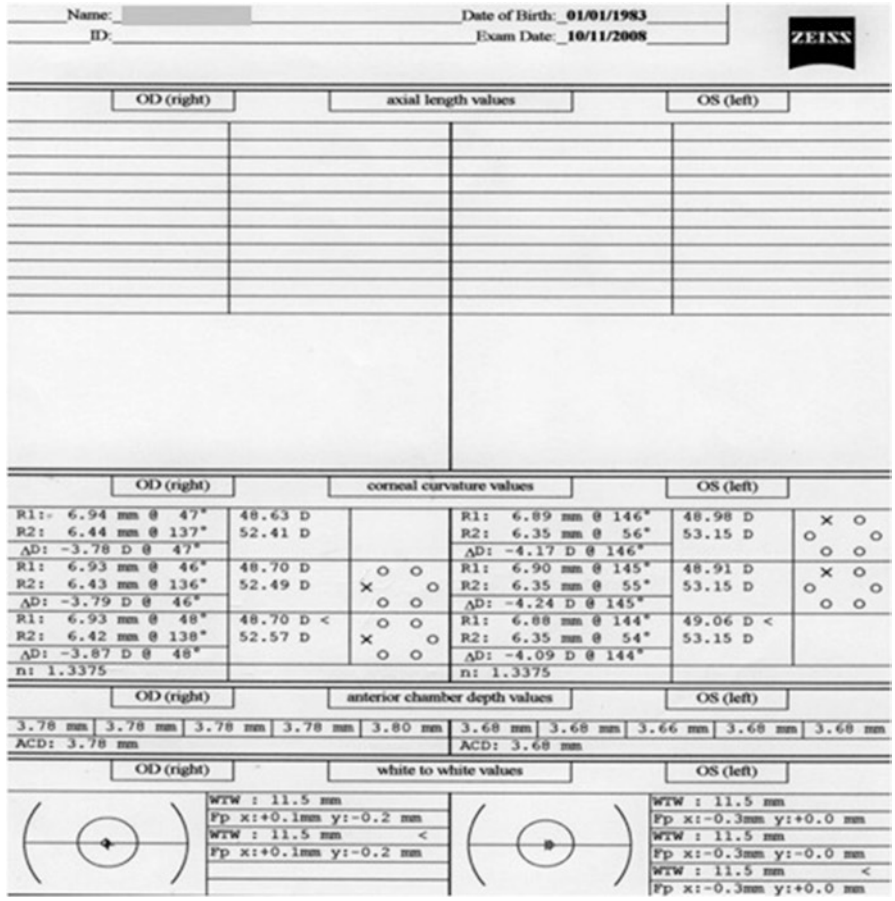

Fig. 28.6 Bilateral corneal curvature data, anterior chamber depth, and white-to-white measurements as measured using the IOL Master® (Zeiss, Germany))

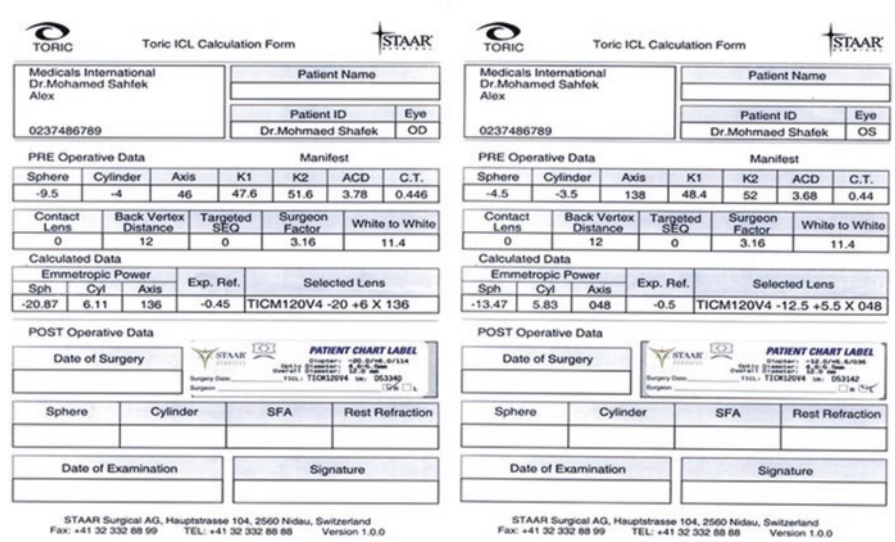

Fig. 28.7 Bilateral toric ICL calculation form provided by STAAR surgical

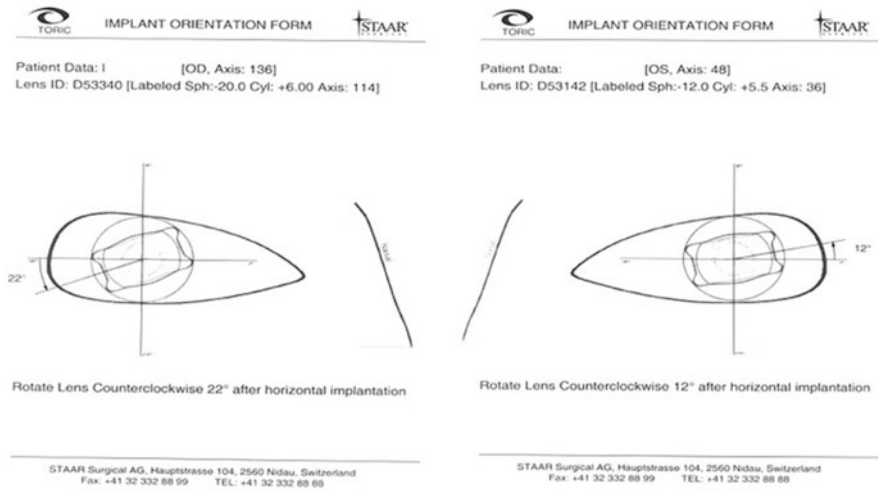

Fig. 28.8 Bilateral toric ICL implantation form provided by STAAR surgical

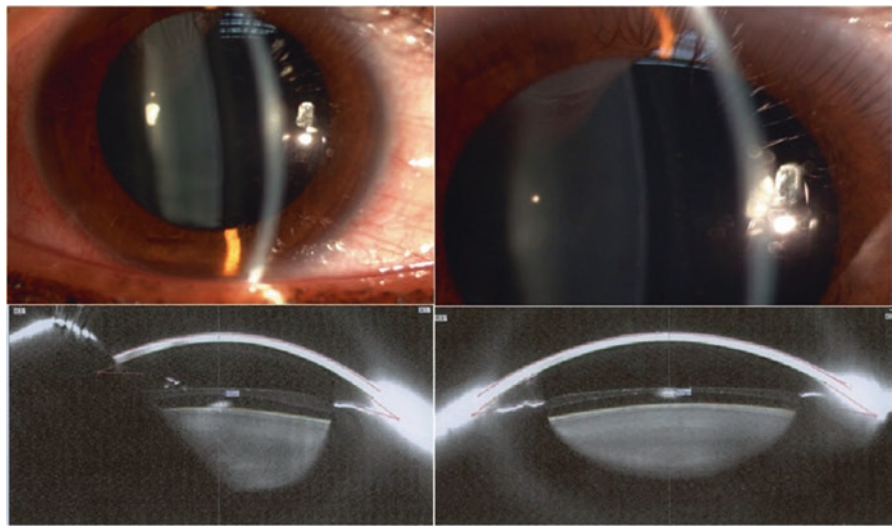

Fig. 28.9 Bilateral slit lamp and anterior segment Scheimpflug images of the toric ICL in place

measured by the anterior segment Scheimpflug imaging provided by the Pentacam (Fig. 28.9).

Compliance with Ethical Requirements Mohamed Shafik Shaheen and Hussam Zaghloul declare that they have no conflict of interest.

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national and with the Helsinki Declaration of 1975, as revised in 2000. Informed consent was obtained from all patients for being included in the study.

No animal studies were performed by the authors for this chapter.

Financial disclosure: None of the authors has financial interest.

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