

Posterior chamber phakic intraocular lens (ICL) for hyperopia: Ten-year follow-up

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PURPOSE: To evaluate the long-term safety, efficacy, predictability, and stability of implantation of a Collamer implantable contact lens (ICL) (Staar) to correct hyperopic refractive errors.

SETTINGS: Ophthalmology Department, Santa Rita Hospital, Vercelli, Italy.

METHODS: Fifty-nine eyes of 34 patients with hyperopia had implantation of an ICL. Patients were examined preoperatively (baseline) and 1 day, 1 week, 1, 3, and 6 months, and 1, 2, 4, 6, 8, and 10 years postoperatively. Main outcome measures were subjective and objective refractions, uncorrected visual acuity, best corrected visual acuity (BCVA), variation in intraocular pressure (IOP), anterior chamber depth (ACD), variation in endothelial cells, adverse events, and patient satisfaction.

RESULTS: Nine patients had ICL implantation in 1 eye and 25 patients, in both eyes. Preoperatively, the spherical equivalent (SE) was between +2.75 diopters (D) and +11.75 D and astigmatism was between +0.50 D and +1.00 D. The mean SE of the manifest refraction was $+0.07 \pm 0.54$ D; refraction stabilized quickly and remained stable throughout the follow-up period. At 10 years, the safety index was 111 and the efficacy index, 96.8. Of the eyes, 86.5% had a change in SE refraction within ± 0.50 D; 1.6% lost 1 Snellen line of BCVA. The mean endothelial cell loss was 4.7%, which remained almost unchanged throughout the follow-up period. The mean variation in ACD was -14.9% and in IOP, $+5.3\%$.

CONCLUSIONS: The results confirmed the long-term safety, efficacy, accuracy, and predictability of ICL implantation for hyperopia. The Collamer material was well tolerated in all eyes.

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The initial goal of refractive surgery was to move the focal point on the retinal plane in ametropic eyes. Today, however, refractive surgeons face the additional challenge of providing good quality of vision and thus a better quality of life.¹ At a time when most refractive procedures, with the exception of Baikoff anterior chamber phakic intraocular lens (pIOL) implantation, were targeted to correct refractive errors on the cornea,² technological advancements and the development of advanced chemical polymers led to a new class of material for pIOLs. Collamer,

comprising collagen copolymer 0.4% stabilized by poly(hydroxyethyl methacrylate) 60%, water 37.5%, and benzophene 3.3%,^{3,4} is probably the best example of the new generation of pIOL materials. Many ophthalmologists began using Collamer pIOLs because of the material's safety and the eye's tolerance of it in the posterior chamber.⁵

Experience implanting Baikoff single-piece poly(methyl methacrylate) anterior chamber pIOLs in myopic patients gave us an appreciation of the procedure's safety, high level of predictability, and stability of refractive results. In 2003, Sanders and Vukich⁶ concluded that pIOLs have optical advantages over keratorefractive surgery for high to moderate myopia.

In May 1998, we began implanting version 4 (V4) of a Collamer implantable contact lens (ICL) (Staar). The ICL has a plate design and is available in 4 standard overall lengths ranging from 11.0 to 12.5 mm. All models have a 5.5 mm diameter optic that is meniscus shaped, with a concave posterior surface and a convex anterior surface. This study evaluated the outcomes of

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implantation of 50 V4 Collamer ICLs and 9 earlier models to correct hyperopia.

PATIENTS AND METHODS

This study comprised 59 eyes (34 patients) that had implantation of an ICL for hyperopia. It included patients who were initially scheduled for keratorefractive procedures, such as radial keratotomy (RK), laser in situ keratomileusis (LASIK), or photorefractive keratectomy, but for whom the procedures were considered contraindicated. It also included 3 eyes with progressive hyperopia after RK and 3 eyes with significant hyperopia after LASIK for myopia. All patients received an explanation of the procedure and signed a consent agreement form before surgery.

Inclusion criteria included proper motivation, no evidence of previous ocular pathology, preoperative hyperopic spherical equivalent (SE) between +2.50 diopters (D) and +11.75 D, astigmatism less than 1.00 D, unsuccessful contact lens use, request for a better quality of life, certain occupations (eg, firefighter, snow-skiing instructor, forest ranger), participation in agonistic sports (eg, soccer, basketball), certain hobbies, and age between 30 years and 55 years. In patients older than 50 years, the clinical condition of the eye was assessed to ensure the ICL procedure was appropriate; these patients were asked to sign an additional consent form detailing all alternative surgical choices and their advantages and disadvantages. Exclusion criteria were uveitis, diabetic retinopathy, endothelial cell count less than 2000 cell/mm², lens opacities, glaucoma, and an anterior chamber depth (ACD) less than 2.7 mm.

After a detailed medical history and current medical status were obtained, the following were performed: an orthoptic examination, slitlamp anterior segment evaluation, refractive measurements and tests, autorefractometry with an undilated pupil, subjective and objective (cyclopentolate hydrochloride 1%) refractions, automated and manual keratometry, measurement of best spectacle-corrected visual acuity (BSCVA) with a vertex distance at 12.0 mm (soft contact lens of a known power and curvature used in some cases), applanation tonometry, ultrasound corneal pachymetry, echo biometry of the anterior and posterior chambers, photopic and scotopic pupil diameters (Colvard and Plusoptix CR03 pupillometers) under slitlamp light, vitreous and retinal examination, and if necessary, fluorangiography and visual field evaluation. Computerized corneal topography (EyeSys, CSO, Orbscan) was also performed to measure the largest corneal diameter and anterior chamber angle opening, horizontal white-to-white (WTW) distance, sagittal depth, and distance from the corneal apex to the limbus. Endothelioscopy (Conan) was performed to obtain a quantitative cell count and a qualitative analysis of the morphology of the inner corneal layer.

The ICL power was calculated using the Staar Surgical Customer Service Department formula, which uses the ACD, mean corneal K-reading or central corneal thickness (simulated keratometry), central corneal pachymetry, horizontal WTW distance, and refraction 12.0 mm from the corneal vertex or with a contact lens.

In the early years of the study, the length of the ICL was determined by comparing the horizontal limbus WTW measurement with the results obtained with the Orbscan device and caliper and following the nomogram minus 0.5 mm. In the last years of the study, an analysis of retrospective results enabled creation of a nomogram that considers ACD, corneal

curvature, and configuration of the chamber angle. In some cases in which a median WTW value was available, the smallest ICL (11.0 mm) was chosen, especially in eyes in which the WTW distance was 11.75 mm.

Hyperopic eyes require cautious treatment given their risk for developing acute pathology of their hydrodynamics (closed-angle glaucoma).⁴ Thus, the biometric evaluations were used to identify eyes with excessively flat corneas and limited angular spaces, particularly in younger patients.

The quality of vision was evaluated preoperatively and 6 months and 1 year postoperatively by asking patients to complete a questionnaire about their satisfaction as well as their jobs and hobbies. The questionnaire included questions regarding (1) day-driving vision (with glasses and contact lenses), (2) night-driving vision (with glasses and contact lenses), (3) distance and near vision in strong natural light, and (4) distance vision in dim illumination. The postoperative questionnaire included additional questions about halos, glare, blurred vision, and other visual disturbances.

Surgical Technique

In almost all cases, at least 1 week before ICL implantation, 2 neodymium:YAG (Nd:YAG) laser peripheral iridotomies, separated by 60 to 80 degrees, were made in the upper quadrant.⁷ The upper quadrant was chosen to avoid the risk for monocular diplopia or ghost images and for aesthetic reasons, especially in eyes with a blue or gray iris. The iridotomies were positioned in the more peripheral areas of the iris (basal), 0.5 to 1.0 mm from the limbus, because the posterior chamber is wider in those zones and the risk for cataract is reduced. One hour before and just prior to surgery, 2 drops of apraclonidine 0.5% were applied to avoid postoperative intraocular pressure (IOP) rises and rupture of the blood-aqueous barrier. One or 2 drops of pilocarpine 2% solution were instilled every 10 minutes starting 20 to 30 minutes before the laser surgery.

In 8 cases, the eyes were very brown and had thick irises; in these cases, a single classic intraoperative iridectomy was made. At the end of surgery, after pharmacologic miosis, the iridectomy was positioned peripherally at 12 o'clock with a 0.12 mm forceps and iris scissors. The opening was large enough (at least 1.0 mm) to permit good aqueous flow and prevent the footplate from occluding it.

All the procedures were performed by the same surgeon (P.M.P.) with the same disinfecting, draping, and eye stabilizing techniques used in normal cataract surgery. Particular care was taken to isolate the eyelashes from the operating field; the edges of the polyethylene drape were cut after the eyelids were cleaned with sponges soaked in povidone-iodine 5% (Oftasteril or diluted Betadine). The conjunctival sac was washed with the same substance for at least 5 minutes.

In the first 3 procedures, regional intraorbital anesthesia was used and the ICL was implanted with a forceps through a 3.4 to 3.5 mm main incision. Subsequently, topical anesthesia and 2 side-port incisions of approximately 1.0 mm were used.

Preservative-free lidocaine 1% or lidocaine 4% eyedrops were mixed with 3 parts balanced salt solution (BSS) and injected into the anterior chamber. A cohesive ophthalmic viscosurgical device (OVD) (sodium hyaluronate 1.0% [Provisc]) was then injected; care was taken not to overfill the chamber and to keep the cannula near the limbus to

avoid touching the lens capsule or endothelium. A temporal side self-sealing near-to-clear 3.0 mm incision was made. This approach was chosen to prevent an increase in astigmatism and to avoid rotating the ICL, thus reducing the amount of manipulation in the narrow chamber of the hyperopic eyes. All ICL loading procedures were done by a trained surgical assistant (M.P.G.), who took care to check the following landmarks: the 2 small dots next to the optical zone and the 2 holes on the footplates (distal right and proximal left), which indicate the anterior side of the ICL.

Insertion of the cartridge inside the corneal tunnel was done with the open part of the exit aperture facing downward until the edge of the tunnel aperture just exceeded Descemet's membrane. The piston of the injector was gently pushed or rotated. As the ICL unfolded, the surgeon confirmed proper ICL positioning by making sure the circular reference hole on the haptic wings was visible on the right distal part of the ICL. If the reference mark was not in the correct position, the surgeon rotated his wrist a maximum of 180 degrees to advance the ICL and prevent it from compressing or wrinkling during its delivery.

Extreme mydriasis was not required as a pupil diameter of 10.0 to 10.5 mm was sufficient. The retropupillary positioning was performed with a rapid maneuver. The footplates were placed behind the iris through the side-port incisions with a smooth capsule polisher (Janach). The OVD was completely removed under pupil mydriasis. Next, acetylcholine chloride (Miochol), usually between 0.3 mL and 0.6 mL, was injected into the chamber. A bimanual irrigation/aspiration cannula was inserted, preventing chamber collapse and excessive pressure and turbulence in the BSS infusion flow. Normally, sutures were not used for incisions smaller than 3.2 mm; with stromal hydration of the edges, there was a higher chance the incision would remain closed.

Preoperative and Postoperative Pharmacological Regimen

The pharmacological treatment was based on the rationale of the surgical procedure; that is, to avoid reactive or septic inflammation and pupillary block glaucoma.⁸ A broad-spectrum antibiotic with nonsteroidal antiinflammatory drugs (NSAIDs) was administered at the end of surgery. The OVD was irrigated from the eye using BSS mixed with a diluted solution of vancomycin or gentamicin.

Two days before and 7 days after ICL implantation, patients received 1 to 2 drops of tobramycin-dexamethasone (TobraDex) and sodium diclofenac (Voltaren Ofta) 4 times a day. In addition, 2 tablets of acetazolamide (Diamox) were given immediately after surgery and another tablet 12 hours later. If subsequent therapy was required, a mineral salt integrator such as Polase (potassium aspartate and magnesium aspartate) was given.

Outcome Measures

The 2 main outcome measures were the safety and efficacy of ICL implantation. Complications were evaluated by dividing patients into 2 groups based on the ICL model: Group A (models V1, V2, and V3), which comprised 9 implantations performed from the beginning of the study in February 1995 to May 1998, and Group B (model V4), which comprised 50 implantations performed after May 1998.

RESULTS

The mean age of the patients at the time of ICL implantation (primary eye in bilateral procedures) was 38.41 years \pm 4.9 (SD) (range 31 to 55 years). Twenty-five patients (64.1%) were men and 14 (35.9%), women.

Preoperative

Preoperatively, the mean manifest SE refraction was $+5.78 \pm 2.54$ D (range $+2.50$ to $+11.75$ D), the mean best corrected visual acuity (BCVA) 0.58 ± 1.21 (range 0.2 to 1.0), and the mean ACD 2.94 ± 0.27 mm (range 2.69 to 3.27 mm). The mean photopic pupil diameter was 3.29 ± 0.42 mm (range 2.95 to 4 mm) and the mean scotopic pupil diameter, 5.67 ± 0.80 mm (range 5.25 to 6.5 mm). The mean endothelial cell density (ECD) was 2696 ± 298 cells/mm² (range 2321 to 3376 cells/mm²) and the mean IOP (applanation), 13.36 ± 0.53 mm Hg (range 9 to 18 mm Hg).

Follow-up Compliance

All patients attended the 2-year and 6-year follow-up visits and 89%, the last control. Ten years after the first ICL implantation, 96% of patients (57 eyes) were examined. The mean follow-up for the first ICLs implanted (in 1995) was 46 months (range 6 months to 10 years).

Postoperative

All postoperative data are from the 10-year follow-up. The mean manifest SE refraction was $+0.07 \pm 0.50$ D (range -1.00 to $+1.50$ D). The SE refraction was within ± 0.50 D in 81% of eyes, within ± 1.00 D in 96%, and within ± 1.50 D in 100% (Figures 1 and 2). The BCVA was 20/20 or better in 56.45% of eyes, 20/40 or better in 95.17%, and 20/70 or better in 100%. The BCVA was unchanged in 64.4% of eyes, improved by 1 Snellen line in 15.2%, improved by

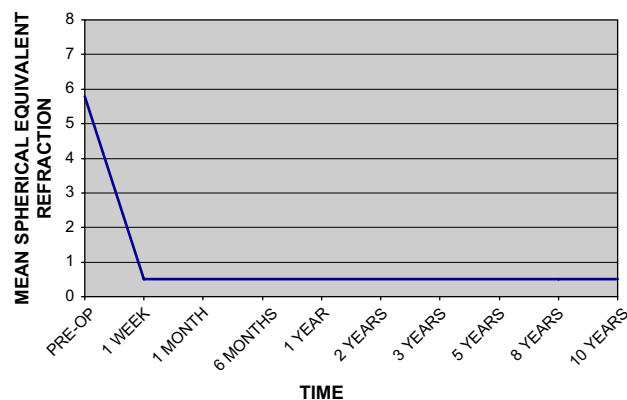


Figure 1. Spherical equivalent refraction from baseline to 10 years after ICL implantation.

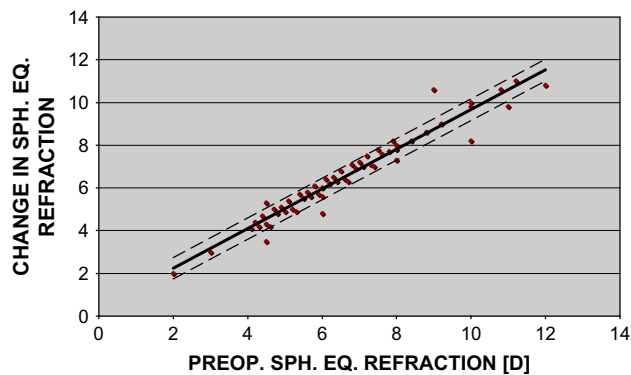


Figure 2. Change in SE refraction.

2 Snellen lines in 8.3%, improved by 3 Snellen lines in 8.3%, and reduced by 1 Snellen line in 8.3% (Figure 3). The UCVA was 20/20 or better in 49.78% of eyes, 20/40 or better in 87.58%, and 20/70 in 100%.

The mean ECD was 2437 ± 243 cells/mm². Endothelial cell loss was 4.7%, which remained unchanged throughout the follow-up (Figure 4). The mean ACD was 2.38 ± 0.23 mm (-14.9%) and the mean IOP, 15.16 ± 1.84 mm Hg (+5.3%). The mean photopic pupil diameter was 3.89 ± 0.53 mm (+9.5%) and the mean scotopic pupil diameter, 5.81 ± 0.87 mm (+2.9%).

Questionnaire

On the questionnaire, 29 patients (89%) stated their quality of vision was very good and their quality of life had greatly improved. One patient (3%) would not consider ICL implantation in the contralateral eye (acute glaucoma due to pupillary block). Most said they would repeat the surgery and would recommend it to a friend. Twenty-six patients said their quality of uncorrected vision was good and 4 (14%) said it was excellent; the remainder of the patients said it was

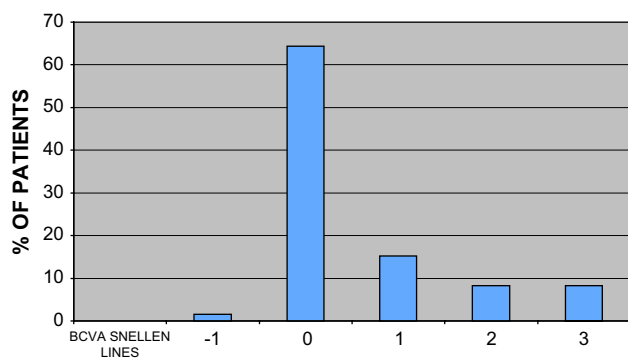


Figure 3. Lost and gained BCVA lines after ICL implantation.

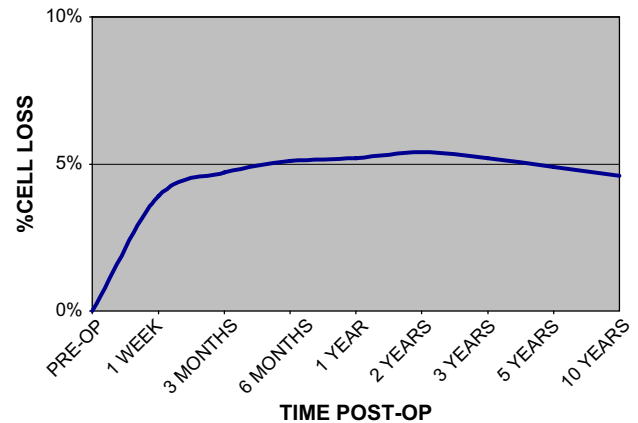


Figure 4. Endothelial cell variation over 10 years.

moderate with the possibility of improvement. Twenty-three patients (70%) reported seeing halos under scotopic light at the 6-month follow-up visit; 2 (6%) reported bothersome halos at the 1-year follow-up. Other patients reported this sensation decreased until it resolved. The worst reports of halos, glare, and a painful eye sensation (heavy eye) were by 2 patients in whom the ICL was overly vaulted (central distance between posterior surface of the ICL and anterior capsule of the crystalline lens).

Complications

Group A In Group A (ICL models V1, V2, V3), a 47-year-old man with a 12.0 mm ICL developed pupillary block glaucoma due to overcrowding of the anterior chamber. The patient had anisometropia, a manifest refraction of $+6.00 +0.50 \times 85$, an amblyopic eye, a BSCVA of 0.4, an ACD of 2.87 mm, and a WTW distance of 12.3 mm. Thirty-six hours after implantation, the ICL was removed because timolol 0.5% eyedrops, which contain a topical β -blocker; oral carbonic anhydrase inhibitors; and intravenous mannitol 18%, gave temporary results. The BCVA returned to the preoperative level in 5 months, and normal pupil function was restored in 7 months.

In a 38-year-old man, the ICL was inadvertently placed upside-down. The ICL (ICHL2020) was one of the first implanted with an injector. The surgery was uneventful; however, the day after, the UCVA and BSCVA were significantly worse than expected. The ICL was removed and reimplanted with a forceps. Postoperatively, the BCVA was 0.9 with $+0.75 \times 95$ and the UCVA was 0.7; there was no loss of vision.

A 43-year-old woman developed a small anterior paracentral nonprogressive subcapsular opacity in the crystalline lens. This was caused by the surgical procedure and was evident the day after the ICL was

implanted. Over the follow-up, the patient lost 1 Snellen line of BCVA.

Group B In Group B (ICL model V4), there were no cases of acute pupillary block glaucoma in eyes with double peripheral Nd:YAG laser iridotomies or in eyes with a classic 12 o'clock iridectomy.

A complete anterior subcapsular cataract developed in a 47-year-old man. The cataract, which was first noted 4 years after ICL implantation, developed rapidly. Before the cataract developed, inadequate vaulting of approximately 100 μm was noticed. The patient was told the ICL might require explantation and replacement with a longer model to prevent cataract formation. The patient refused as visual acuity was good at that time; he agreed to have cataract extraction with IOL implantation if a cataract developed.

Three years after ICL implantation, a nuclear and subcapsular cataract developed in both eyes of a 51-year-old man; the ICL vaulting (approximately 100 μm) was inadequate. The patient had phacoemulsification cataract extraction with IOL implantation. The patient lost no lines of Snellen BCVA in either eye and reported being very satisfied.

A 34-year-old man temporarily lost 2 lines of Snellen BCVA as a result of retinal edema and pupil mydriasis. The temporal distal haptic footplate was dislocated in the anterior chamber after trauma caused by a punch to the eye. The ICL was repositioned with a spatula through a clear corneal paracentesis. Iris functionality and BCVA were restored within 6 months.

In the last 2 years of the study, excessive vaulting occurred in 1 eye of 2 patients who had bilateral ICL implantation. Both patients reported persistent pain and a weight sensation in the eye with the excessively vaulted ICL and glare and halos. There was no increase of IOP, although iris chafing and mobilization of the pigment were seen.

Patient 1 was a 38-year-old woman who had excessive vaulting (approximately 1.0 mm) of a +9.00 D, 12.0 mm ICL in the right eye. Preoperatively, the manifest refraction was +5.25 +0.25 \times 175, the ACD 2.89 mm, and the WTW distance 11.7 mm. Postoperatively, the manifest refraction was +0.25 +0.25 \times 78 and the IOP 9 mm Hg.

Patient 2 was a 43-year-old woman who had excessive vaulting (more than 1.0 mm) of a +8.00 D, 13.0 mm ICL in the left eye. The overvaulting was the result of underestimation of the WTW distance during the Orbscan evaluation. Preoperatively, the manifest refraction was +4.00 sphere, the ACD 2.76 mm, the WTW distance 12.8 mm, and the IOP 11 mm Hg. Postoperatively, the manifest refraction was +0.25 sphere and the IOP 12 mm Hg.

During the initial follow-up period, the patient Nd:YAG laser iridotomies in both eyes were enlarged to ensure the best possible hydrodynamics. Two months after ICL implantation, the heavy-eye sensation was still present in both patients. After the patients provided informed consent, the ICL was explanted under topical anesthesia and a shorter ICL (+9.00 D, 11.5 mm in patient 1; +8.00 D, 12.0 mm in patient 2) was implanted through the same 3.0 mm incision. No lines of Snellen BCVA were lost, and the discomfort and pain resolved. No additional iris chafing or pigment mobilization occurred. After the ICL exchange, the manifest refraction was +0.25 +0.50 \times 85 and the vaulting approximately 500 μm in patient 1 (Figure 5). In patient 2, the manifest refraction was +0.50 D and the ICL vaulting was 400 μm (Figure 6).

Both Groups No progressive pigment dispersion or significant increase in the mean IOP occurred in either group.

DISCUSSION

Our study shows that ICL implantation is a procedure with complications that are easily treatable and do not result in a loss of Snellen lines of BCVA in most cases. In addition, potential complications of intraocular surgery, such as infection, bleeding, endothelial damage, retinal detachment, are rare. In our experience with implantation of all types of pIOLs (myopic, hyperopic, toric), no intraocular infections occurred. Perhaps this is a result of meticulous asepsis; during preparation

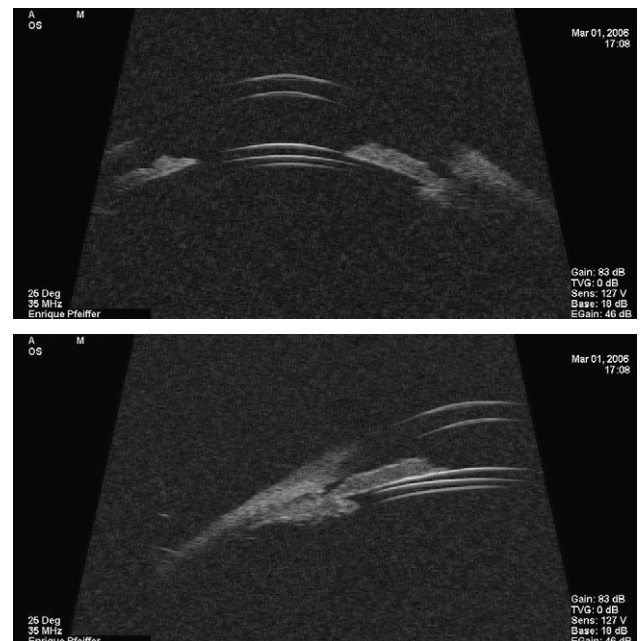


Figure 5. The new ICL is well positioned and adequately vaulted.

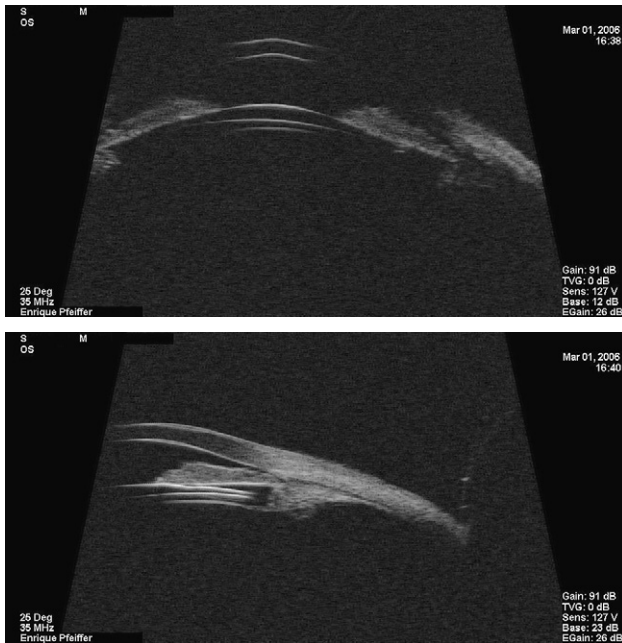


Figure 6. The new ICL is well positioned and adequately vaulted.

for surgery, the edge of the eyelid is thoroughly cleaned with sponges soaked in povidone-iodine 5% solution, the conjunctival sac is washed with povidone-iodine 5% for at least 5 minutes, and the eyelashes are isolated from the operating field.

Postoperatively, the quality of vision in our hyperopic patients was very good and, as reported in other studies,^{9–11} there was less spherical aberration than in eyes treated with LASIK. In addition, the complications of ICL implantation (cataract, acute pupillary block glaucoma) are easier to resolve than LASIK complications (decentered ablation, interface epithelization, ectasia). Cataract formation is perhaps the main concern with ICL implantation.¹² Theoretically, the risk is higher in hyperopic eyes than in myopic eyes because of the reduced space in the anterior chamber. Although cataract secondary to ICL implantation is a risk, the incidence was low in our study. In 1996, the ICL Users Group (ICL Users Meeting, Interlaken) hypothesized that the positive shape of the hyperopic ICL played an important role in avoiding iatrogenic cataract formation. From our study, we believe a cataract forms when the aqueous flow between the ICL and the crystalline is blocked or is significantly reduced, which results in loss of nutrition to the crystalline. In our study, we did not observe contact between the anterior surface of the crystalline lens and the

posterior surface of the ICL in any eye. Vaulting, even if small (between 100 μ m and 150 μ m) was always present. Thus, we concluded that more time and investigation are needed to draw conclusions about the mechanisms of cataract formation.

Experienced cataract surgeons have the skills to perform ICL implantation. However, there is a learning curve for those who want to master this delicate surgical technique

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