New Phakic Implants

Surgeons share their experiences with the Visian ICL V4c and the AcrySof Cachet.

BY ERIK L. MERTENS, MD, FEOPTH; ANTONIO TOSO, MD; AND SIMONETTA MORSELLI, MD

The V4c for Correction of Myopia and Astigmatism

By Erik L. Mertens, MD, FEOPTH

More than 1 year ago, I started to implant the latest Visian ICL model, the V4c (STAAR Surgical), with a 0.36-mm port located in the center of the optic. This KS-Aquaport, which is designed to restore more natural aqueous flow and eliminate the need for an iridotomy, sets the Visian ICL V4c apart from the earlier model, the V4b. Because I no longer have to perform an iridotomy prior to lens implantation or an iridectomy intraoperatively in dark brown irides, the V4c is my first choice for the correction of myopia with or without astigmatism or for the correction of mixed astigmatism. This article presents some of my experiences implanting the V4c. A video demonstration can be viewed at eyetube.net/?v=nebod.

LENS DESIGN

In addition to the aquaport in the center of the ICL, the V4c also has two 0.36-mm ports located just outside the optic. Designed to simplify the removal of ophthalmic viscosurgical device (OVD) after surgery, these holes also allow aqueous to flow over a wider surface area of the crystalline lens.

Inclusion of the KS-Aquaport and the two additional ports gives the surgeon a greater safety net and patients better surgical results. Specifically, the aquaport eliminates the need to perform Nd:YAG iridotomy or peripheral iridectomy before implantation of the ICL and, therefore, eliminates the issues associated with these procedures.

SURGICAL APPROACH

Because the Nd:YAG iridotomy step has been eliminated with the V4c, the overall procedure is more in line with a LASIK procedure. Implantation of the V4c can be performed on the same day as the preoperative examination.

At the start of surgery, I load the V4c into an injector and fill the cartridge with an OVD. I then use forceps to pull the V4c into the tip of the cartridge until I can see all three holes. This will ensure that the lens will be delivered into the anterior chamber safely and accurately. Once the lens is in place, I irrigate the OVD from the anterior chamber, maneuvering the V4c to make space and directing the irrigation port toward the aquaport. The OVD migrates from the anterior chamber, where it can then be aspirated safely. For a video demonstration of OVD removal, visit eyetube.net/?v=fohos.

One day after surgery, the aquaport is still visible and can be found slightly temporal to the pupil center. Typically, the edges of the lens optic are not visible, and therefore glare is minimized. To date, there has been no induction of higher-order aberrations after V4c implantation. We have not had to change our nomogram for the lens.

In my experience, there have been no rises of intraocular pressure (IOP), no change in refractive outcome, and no patient complaints or visual symptoms after surgery.

OUTCOMES

I reviewed the charts of 68 patients who underwent implantation of the V4c Visian ICL model for myopia and myopic astigmatism correction. The inclusion criteria were preoperative distance BCVA of 20/40 or better, stable refraction, and a clear central cornea. The exclusion criteria included age less than 22 years, anterior chamber depth less than 2.8 mm from endothelium, endothelial cell density less than 2,000 cell/mm², cataract, history of glaucoma or retinal detachment, macular degeneration or retinopathy, neuro-ophthalmic diseases, and history of ocular inflammation. Before implantation, patients had a complete ophthalmic examination including refraction, keratometry, corneal topography, endothelial cell count, pachymetry, slit-
lamp biomicroscopy, Goldmann applanation tonometry, and binocular indirect ophthalmoscopy. The targeted refraction was emmetropia.

A total of 130 eyes were included in this analysis. Follow-up ranged from 3 to 6 months. No peripheral iridotomy was performed prior to or during implantation. Mean patient age was 31.66 ±7.4 years, mean preoperative spherical equivalent was -6.15 ±2.72 D (range, -15.75 to -1.25), and mean cylinder was -1.11±1.24 D (range, -6.00 to 0.00). Main outcome measures evaluated during a 6-month follow-up included UCVA, refraction, BCVA, vault, IOP, and adverse events.

In this series, no intraoperative complications occurred. At 6 months, the mean Snellen decimal UCVA was 1.10 ±0.14, and mean BCVA was 1.11 ±0.14 (Figure 1). The efficacy index was 1.05, and the safety index was 1.06. The mean spherical equivalent decreased from -6.15 ±2.72 to -0.01 ±0.06 D (range, -0.25 to 0.25) at 6 months. Additionally, 96.2% of eyes were within ±0.50 D of attempted correction and 100% were within ±1.00 D at 6 months (Figure 2). IOP was maintained and stable throughout follow-up. Mean postoperative ICL-to-lens distance (vault) was 560 µm (range, 400–800). No eye experienced pupillary block (Figure 3) or elevated IOP, and no eye required peripheral iridotomy or explantation.

CONCLUSION

Short-term assessment of this new lens design, which incorporates a central port, showed good efficacy, predictability, and safety up to 6 months postoperative for the correction of myopia and astigmatism. IOP was maintained and stable, demonstrating the performance of the central port.

With the Visian ICL V4c, these patients were happy with their visual outcomes, and I was happy that the procedure took less time and was easier to perform than in the past. The combination of the KS-Aquaport in the center of the optic to alleviate the need for iridotomy and the additional ports outside the optic to ease removal of the OVD makes the V4c my first choice for patients who are considering a phakic IOL.

Erik L. Mertens, MD, FEBOphth, is Medical Director of Medipolis, Antwerp, Belgium. Dr. Mertens is a Chief Medical Editor of CRST Europe. He states that he is a consultant to STAAR Surgical. Dr. Mertens may be reached at tel: +32 3 828 29 49; e-mail: e.mertens@medipolis.be.
Distance Variation During Accommodation With the AcrySof Cachet

By Antonio Toso, MD; and Simonetta Morselli, MD

The AcrySof Cachet phakic IOL (Alcon Laboratories, Inc.) is designed to ensure safe and easy implantation. It is made of the same soft, flexible hydrophobic acrylic material as other AcrySof IOLs, which allows the lens to be folded and inserted through a small incision of 2.6 mm. Use of the AcrySof Cachet requires careful patient selection and IOL calculation. This article describes our experience with anatomic and functional results after implantation.

We conducted a study to evaluate whether this IOL is likely to move into the eye, changing the distances between the IOL and the endothelium and crystalline lens during accommodation. These positional changes could modify the relative position of the phakic IOL with respect to the corneal endothelium and crystalline lens, which could have the potential to induce cataract or endothelial cell loss. Imaging technologies such as optical coherence tomography (OCT) allow visualization and characterization of changes in the anterior segment in eyes implanted with IOLs. The aim of our study was to use anterior segment OCT (Visante; Carl Zeiss Meditec) to evaluate the safety distance and stability of this angle-supported phakic IOL in the anterior segment during accommodation.

This observational study included 29 eyes of 15 patients (mean age, 29.28 ±8.99 years) with moderate to high myopia who were implanted with an AcrySof Cachet phakic IOL. The preoperative mean myopic spherical equivalent was -13.03 ±1.54 D, and the postoperative mean spherical equivalent was -0.62 ±0.35 D.

SURGICAL TECHNIQUE AND POSTOPERATIVE TREATMENT

All patients underwent general anesthesia with laryngeal mask without a curare-like drug. A 2.6-mm clear corneal incision was made on the steepest meridian. A sideport incision was created, and a mild solution of a miotic drug was injected into the anterior chamber. A low molecular weight OVD (hyaluronic acid 0.85%) was injected into the anterior chamber.

Before the lens was loaded and delivered, the Monarch III P-Cartridge (Alcon Laboratories, Inc.) was filled completely with OVD. The correct position of the IOL in the cartridge was verified under the microscope.

The lens was delivered into the anterior chamber, and correct IOL position was verified. The OVD was easily removed with a passive system using a Sauter cannula. Balanced saline solution was injected at the 6-o’clock position, and the cannula was used to push down the optic and the inferior edge of the main incision. The incision was hydrated with cefuroxime and balanced saline solution, and no suture was applied.

Five hours after surgery, IOP was measured, the position of the phakic IOL was checked, and the patient was discharged from the hospital. The day after surgery, visual acuity and IOP were measured.

POSTOPERATIVE EXAMINATIONS

The position, stability, and safety distances of the phakic IOL were evaluated with the Visante 30 days after surgery. All patients were examined without accommodation and during accommodation. Accommodation was induced by changing the focus of the internal fixation target of the Visante using a negative lens addition (-3.00 D). The software enables the surgeon to choose among different refractive powers (Figure 4).

We measured the distance between the anterior surface of the phakic IOL and the corneal endothelium at the central point. This distance was measured over a line perpendicular to the curvature of the posterior cornea (central cornea–phakic IOL distance). We also measured the distance from the vertex of the anterior surface of the crystalline lens to the posterior surface of the phakic IOL (crystalline lens–phakic IOL distance) over a line perpendicular to the surface of the phakic IOL.

RESULTS

Regarding the position of the phakic IOL in the anterior chamber, a small change was observed in the
distance between the center of the cornea at the endothelial plane and the anterior surface of the phakic IOL during accommodation. The same was observed with the distance between the posterior surface of the phakic IOL and the anterior surface of the crystalline lens. The baseline values with no accommodation were 0.79 ±0.05 mm (crystalline lens–phakic IOL distance) and 1.86 ±0.12 mm (phakic IOL–central cornea distance). During accommodation, these values were 0.69 ±0.11 mm and 1.78 ±0.08 mm, respectively. Figure 5 shows OCT images of measurements of these parameters.

During accommodation, the distance between the endothelium and the anterior surface of the phakic IOL decreased by about 3.5%, and the distance between the posterior surface of the phakic IOL and the crystalline lens decreased by 11%, compared with the US Food and Drug Administration (FDA)-recommended safety distance values of ratios 2:3 and 1:3 (Figure 6).

**DISCUSSION**

Some questions remain about the potential long-term risks to anterior segment structures after implantation of an angle-supported phakic IOL. Phakic IOLs should be well positioned with adequate stability so that they do not damage the corneal endothelium or the anterior lens capsule. Therefore, the distances of the phakic IOL in relation to these intraocular structures are key in obtaining good performance over time.

Several authors have demonstrated that this angle-supported phakic IOL demonstrates excellent intraocular behavior after pupil dilation, with no shortening of the distance between the phakic IOL and central corneal endothelium. A change in phakic IOL position can lead to complications such as endothelial damage and cataract formation. We used anterior segment OCT to evaluate the safety distances of this angle-supported phakic IOL during accommodation. The mean distance between the posterior surface of the AcrySof Cachet lens and the anterior surface of the lens decreased during accommodation, as did the mean distance between the anterior surface of the phakic IOL and the endothelium. The reduction of these distances during accommodation is close to the FDA-recommended safety distances. This anatomic evidence supports the safety of the AcrySof Cachet because this phakic IOL never touches the lens during accommodation, and it maintains a safe distance from the corneal endothelium (Figure 7).

Simonetta Morselli, MD, is Chief of the Ophthalmic Unit, San Bassiano Hospital, Bassano del Grappa, Italy. Dr. Morselli is a member of the CRST Europe Editorial Board. She states that she has no financial interest in the products or companies mentioned. She may be reached at e-mail: simonetta.morselli@gmail.com.

Antonio Toso, MD, is a Consultant and Vitreoretinal Specialist, Ophthalmic Unit, San Bassiano Hospital, Bassano del Grappa, Italy. Dr. Toso states that he has no financial interest in the products or companies mentioned. He may be reached at e-mail: antonio.toso@gmail.com.

---