Comparison of Two ICLs

Data suggests both designs are comparable across a variety of optical metrics.

BY JASON P. BRINTON, MD

INTRAOCULAR PRESSURE AFTER IMPLANTATION OF THE VISIAN IMPLANTABLE COLLAMER LENS WITH CENTRAFLOW WITHOUT IRIDOTOMY


Abstract summary. Higueras-Esteban et al retrospectively compared intraocular pressure (IOP) after implantation of the Visian Implantable Collamer Lens (Visian ICL; STAAR Surgical) V4c and V4b designs in 17 and 18 eyes, respectively, over a 3-month period. The presence of a central 360-µm hole, the KS-Aquaport, differentiates the V4c (hole ICL; Figure 1) from the V4b (conventional ICL; Figure 2). According to the company, its KS-Aquaport Centraflow technology allows a more natural flow of aqueous humor, eliminating the need for a laser iridotomy or surgical iridectomy.

The investigators implanted the IOLs between September 2011 and May 2012. Eyes in the conventional ICL group received two Nd:YAG laser iridotomies 2 weeks before surgery.

Three months postoperatively, the mean logMAR distance UCVAs in the hole and conventional ICL groups were -0.07 ±0.11 and -0.09 ±0.12, respectively. One or more lines of distance BCVA were gained in 44.4% of eyes in the hole ICL group versus 52.9% of eyes in the conventional ICL group. According to the study, only one of 35 eyes did not achieve an outcome within ±0.50 D of the target refraction.

The mean IOP showed a mild transient increase during the first month in both groups, from 11.9 ±2.7 and 11.5 ±2.8 mm Hg preoperatively in the hole and conventional ICL groups, respectively, to 13.8 ±2.2 and 12.4 ±1.8 mm Hg 3 months postoperatively, respectively. There was no significant difference between pre- and postoperative IOP values. At 3 months, the mean vault was 528 ±268 µm (95% CI, 354–635 µm) in the hole ICL group and 557 ±224.4 µm (95% CI, 442–672 µm) in the conventional ICL group (P=.73). There were no significant differences in IOP within or between groups during follow-up (P>.05 for all comparisons).

On a subjective questionnaire, five patients in the hole ICL group reported transient increases in halos in the early postoperative period that significantly decreased by 1 month after surgery.

VISUAL QUALITY COMPARISON OF CONVENTIONAL AND HOLE-VISIAN IMPLANTABLE COLLAMER LENS AT DIFFERENT DEGREES OF DECENTERING


Abstract summary. Pérez-Vives et al used an adaptive optics visual simulator (crx1; Imagine Eyes) to simulate and compare the visual acuity provided by conventional and hole ICLs at different refractive powers (-3.00, -6.00, and -12.00 D) and at different degrees of decentration (centered, decentered by 0.3 mm, and decentered by 0.6 mm) in the presence of 3- and 4.5-mm pupils in one eye of 15 patients. According to the authors, this method allows evaluation of visual quality without the need for Visian ICL implantation as well as analysis of the effect of each Visian ICL model and its decentring effects. The investigators measured contrast sensitivity and high-, medium-, and low-contrast visual acuities for three spatial frequencies: 10, 20, and 25 cycles/degree.

According to the investigators, the simulation did not reveal a significant difference in visual acuity or contrast sensitivity between the two groups at any ICL power, decentred position, pupillary size, or spatial frequency.

COMPARATIVE STUDY OF TWO TYPES OF IMPLANTABLE COLLAMER LENSES; ONE WITH AND ONE WITHOUT A CENTRAL ARTIFICIAL HOLE

Huseynova T, Ozaki S, Ishizuka T, et al

Abstract summary. Huseynova et al compared the outcomes between hole (n=44 eyes) and conventional ICLs (n=21 eyes) after implantation. The investigators examined patients pre- and postoperatively to assess changes in visual acuity, endothelial cell density (ECD), manifest refraction, and objective scatter index (OSI); they also assessed higher-order aberrations (HOAs) in eyes with 4- and 6-mm pupils preoperatively and for 3 months postoperatively. The
preoperative mean manifest refraction spherical equivalent was -9.32 ±4.02 D (range, 6.75 to-16.50 D).

According to the investigators, there were no statistically significant differences postoperatively in distance UCVA ($P=81$), distance BCVA ($P=.24$), manifest refraction spherical equivalent ($P=.18$), and ECD ($P=.76$) between the groups. At 3 months postoperatively, the efficacy indices for the conventional and hole ICL groups were 1.01 and 1.03, respectively. No difference in OSI ($P=.32$) or HOAs was found, but there was a statistically significant improvement from preoperative to 3-month postoperative logMAR distance BCVA for both groups (conventional ICL, $P=.0005$; hole ICL, $P<.0001$).

**DISCUSSION**

The peer-reviewed literature has consistently demonstrated that phakic IOL implantation is safe and effective for the correction of myopia and astigmatism. Barsam and Allan examined three prospective, randomized, controlled trials comparing phakic IOL implantation to excimer laser vision correction in 228 eyes of 132 consecutive patients (myopic range, -6.00 to -20.00 D). They reported that, although the percentage of eyes with a distance UCVA of 20/20 or better 12 months postoperatively was comparable for both cohorts, the phakic IOL group scored significantly better on safety, contrast sensitivity, and patient satisfaction metrics. Additionally, data recently presented by STAAR Surgical on the Visian Toric ICL to the US Food and Drug Administration (FDA) Ophthalmic Devices Panel set a new benchmark for efficacy in an FDA refractive surgery trial, with 47.2% of 194 eyes gaining at least 1 line of distance UCVA compared with preoperative distance BCVA and 76.8% of eyes gaining 1 or more lines of distance BCVA.

Notwithstanding these data, there are barriers to phakic IOL adoption. A 2013 survey of members of the International Society of Refractive Surgery reported that 47% versus 38% of respondents would choose excimer laser vision correction versus phakic IOL implantation for a 30-year-old patient with -10.00 D of myopia. Additionally, the requirement of a laser iridotomy or surgical peripheral iridectomy before Visian ICL implantation is notable for its effects on patient comfort and convenience and for its associated cost. Obviating this step with the hole ICL simplifies the implantation procedure and eliminates the risk of complications associated with an iridotomy.

The first hole ICL was implanted by Erik L. Mertens, MD, FEBOphth, in June 2011. Over the past 3 years, the literature has established this lens to be safe, efficacious, and predictable. Questions remain, however, about the effects of the central artificial hole on IOP, ECD, vault, and various measures of optical quality, including contrast sensitivity, OSI, and HOAs.

Although conventional ICL implantation induces fewer HOAs than wavefront-guided LASIK, the same has not yet been demonstrated with the hole ICL. Additionally, because the ciliary sulcus is not precisely aligned with the visual axis, it unclear whether Visian ICL decentration could adversely affect visual acuity or contrast sensitivity with the hole versus the conventional ICL.

The three studies discussed herein report several important findings about implantation of the hole ICL. Implantation of this lens:

- produced minimal to no increase in IOP;
- was associated with a stable ECD in the early preoperative period;
- led to vaults comparable with those of the conventional ICL;
- caused no change in contrast sensitivity or OSI; and
- did not degrade visual acuity or contrast sensitivity with lens decentration of 300 or 600 µm.

Ultimately, for all of the optical metrics evaluated in these three studies, there were no significant differences between the hole and conventional ICLs. As an additional benefit, the rate of postoperative cataract formation with the hole ICL may be lower than in the conventional ICL due to the natural flow of aqueous across the face of the crystalline lens. After 569 hole Visian ICL implants, Dr. Mertens has reported zero incidence of cataract, IOP elevation, or acute angle-closure to date (personal communication).

**TAKE-HOME MESSAGE**

- There were no significant differences in IOP within or between the hole and conventional ICL groups over a 3-month period, according to Higuera-Esteban et al.
- A simulation performed by Pérez-Vives and colleagues revealed no difference in visual acuity or contrast sensitivity between the two groups at any ICL power, decentered position, pupillary size, or spatial frequency.
- A comparative study by Huseynova et al. found no statistically significant differences between the two Visian ICL lenses in postoperative distance UCVA and BCVA, manifest refraction spherical equivalent, ECD, OSI, or HOAs.
- A significant benefit of the hole ICL is that a laser iridotomy or surgical iridectomy is not required in advance of ICL implantation.

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A limitation of the studies discussed herein is their small cohorts and limited follow-up time. Metrics such as ECD require longer observation to establish stability. Further studies are needed to show that these findings are durable.

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