

# The Literature

BY JASON P. BRINTON, MD

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

Higuera-Esteban A, Ortiz-Gomariz A, Gutiérrez-Ortega R, et al<sup>1</sup>

### ABSTRACT SUMMARY

Higuera-Esteban et al retrospectively compared the IOP after implantation of the Visian Implantable Collamer Lens (ICL; STAAR Surgical) V4c design (n = 17 eyes) with CentraFlow technology versus the conventional ICL V4b model (n = 18 eyes) over a 3-month period. (Figures 1-3) The presence of a central 360- $\mu\text{m}$  hole, called the KS-Aquaport, differentiates the ICL V4c (hole ICL; not available in the United States) from the ICL V4b (conventional ICL). According to STAAR, its 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 group received two YAG laser iridotomies 2 weeks before surgery.

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

The mean IOP showed a mild transient increase during the first month in both groups from  $11.9 \pm 2.7$  and  $11.5 \pm 2.8$  mm Hg preoperatively in the hole and conventional groups, respectively, to  $13.8 \pm 2.2$  and  $12.4 \pm 1.8$  mm Hg 3 months postoperatively. There was no significant difference between pre- and postoperative IOP values. At 3 months, the mean vault was  $528 \pm 268$   $\mu\text{m}$

(95% CI, 354-635  $\mu\text{m}$ ) in the hole group and  $557 \pm 224.4$   $\mu\text{m}$  (95% CI, 442-672  $\mu\text{m}$ ) in the conventional group ( $P = .73$ ). There were no significant differences in IOP within or between groups during the follow-up period ( $P > .05$  for all comparisons).

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

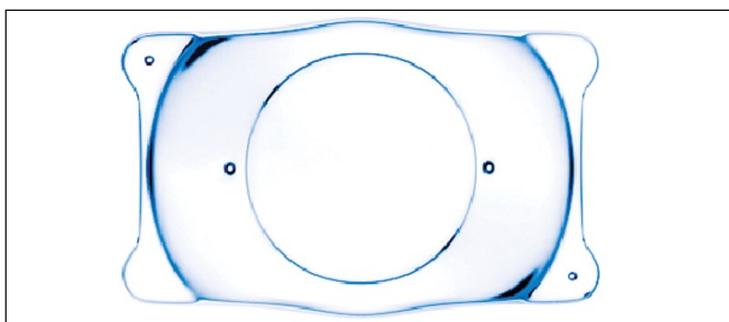


Figure 1. The ICL V4b IOL.

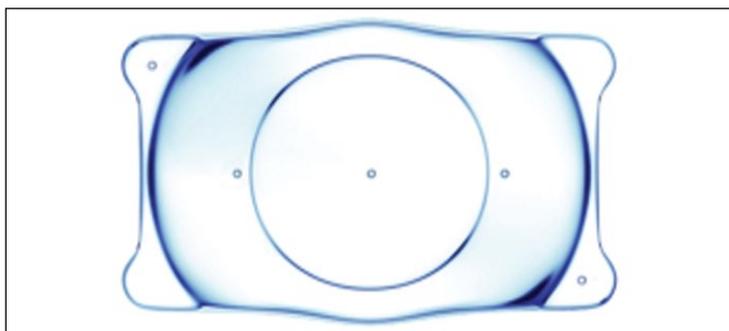


Figure 2. The ICL V4c IOL.

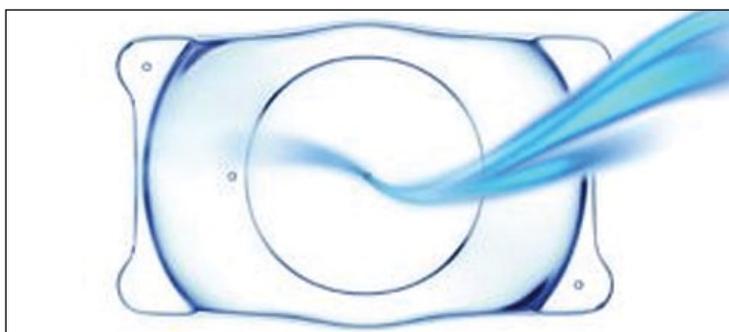


Figure 3. The ICL V4c IOL. The KS-Aquaport is designed to restore a more natural aqueous flow and eliminate the need for an iridotomy.

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

Pérez-Vives C, Ferrer-Blasco T, Madrid-Costa D, et al<sup>2</sup>

#### 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 subjects. According to the authors, this method allows for an evaluation of patients' visual quality without the need for ICL implantation as well as an analysis of the effect of each ICL model and the ICL decentering effect. 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, decentered 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<sup>3</sup>

#### ABSTRACT SUMMARY

Huseynova et al compared the outcomes between the hole (n = 44 eyes) and conventional ICL (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 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 uncorrected distance visual acuity ( $P = .81$ ), corrected distance visual acuity ( $P = .24$ ), manifest refraction spherical equivalent ( $P = .18$ ), and ECD ( $P = .76$ ) between the groups. The efficacy index for the conventional and hole ICL groups 3 months postoperatively was 1.01 and

1.03, respectively. Also, no difference in OSI ( $P = .32$ ) or HOAs was found. There was, however, a statistically significant improvement in the preoperative and 3-month postoperative LogMAR corrected distance visual acuity for both groups (conventional,  $P = .0005$ ; hole,  $P < .0001$ ).

#### DISCUSSION

The peer-reviewed literature has consistently demonstrated that phakic IOL implantation is safe and effective for the correction of myopia and astigmatism.<sup>4-8</sup> 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).<sup>9</sup> They reported that, although the percentage of eyes with an uncorrected distance visual acuity 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 patients' satisfaction metrics. Additionally, data recently presented by STAAR Surgical on the Visian Toric ICL to the 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 uncorrected distance visual acuity compared with preoperative corrected distance visual acuity and 76.8% of eyes gaining 1 or more lines of corrected distance visual acuity.<sup>10</sup>

Notwithstanding these data, there are barriers to phakic IOLs' 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.<sup>11</sup> Additionally, the requirement of a laser iridotomy or surgical peripheral iridectomy before ICL implantation is notable for its effects on patients' 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.<sup>12-18</sup>

The first hole ICL was implanted by Erik L. Mertens, MD, in June 2011. Over the past 3 years, the literature has established this lens to be safe, efficacious, and predictable.<sup>19,20</sup> Questions have remained, 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,<sup>21</sup> the same has not yet been demonstrated with the hole IOL. Additionally, because the ciliary sulcus is not precisely aligned with the visual

axis, it has been unclear whether ICL decentration could adversely affect visual acuity or contrast sensitivity with the hole versus conventional ICL.

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

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

Ultimately, for all of the optical metrics evaluated in these three studies, there was no significant difference between the hole and conventional ICL. As an additional benefit, the rate of postoperative cataract formation with the hole ICL may be lower than with the conventional ICL due to the natural flow of aqueous across the face of the crystalline lens.<sup>22-25</sup> After 569 hole ICL implants, Dr. Mertens has reported a zero incidence of cataract, IOP elevation, or acute angle closure to date (Erik Mertens, MD, personal communication, 2014).

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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