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ORIGINAL RESEARCH

ICL Exchanges or Explants Due to Sizing in a United States High Volume Center

Matthew Hirabayashi[1], Gurpal Virdi[2], Taj Nasser[3], Lauren Libfraind[1], Eduardo Antonio Zapata[1], Andrew J Abramson[4], Gregory Parkhurst[1]

[1]Parkhurst NuVision LASIK Eye Surgery, San Antonio, TX, USA; [2]Mason Eye Clinic, Columbia, MO, USA; [3]Tylock George Eye Care and Laser, Irving, TX, USA; [4]Texas State University, San Marcos, Texas, USA

Correspondence: Matthew Hirabayashi, Parkhurst NuVision, 9725 Datapoint Dr Suite 106, San Antonio, TX, 78229, USA, Tel +1 314 578 2374, Email matthewhirabayashi@gmail.com

Purpose: To report the incidence, reasons, and outcomes for Implantable Collamer Lens (ICL) exchanges at a high-volume center in the United States.

Patients and Methods: A retrospective chart review was performed on 961 eyes of 484 patients who underwent ICL surgery in a commercial setting at Parkhurst NuVision from 04/06/2022 to 10/21/2024.

Results: 11 eyes of 8 patients out of the 961 commercial cases (1.1%) underwent ICL exchange at our institution due to sizing issues. Of these, only 5 cases (0.5%) were exchanged due to initial vault concerns with 6 cases (0.6%) exchanged due to rotated toric ICLs. Upon repeat review of these cases, we would have chosen a different size in 3 of them.

Conclusion: ICL implantation is remarkably safe, with an incredibly low exchange rate due to inappropriate sizing. The majority of these cases also involved clinically safe vault and the exchange only occurred due to rotation of a toric ICL.

Keywords: phakic IOL, ICL exchange, ICL vault, phakic IOL exchange

Introduction

Implantable Collamer Lenses (ICLs, Staar Surgical, California, USA) have consistently been demonstrated to be incredibly safe with excellent visual outcomes particularly since the advent of the EVO ICL® model with the central 0.36 mm KS-AquaPORT®.[1–3] This port appears to allow the eye to tolerate a wide range of postoperative vault, defined as the distance in microns between the anterior capsule of the natural crystalline lens and the posterior surface of the ICL through natural aqueous dynamics. This allows the ICL to continuously "float" on a layer of aqueous like a ball bearing.

Ideal vault is considered to be between 250 and 750 microns and sizing remains a critical component of ICL planning as inappropriate vault has historically been associated with early cataract formation, elevated IOP, or endothelial cell loss.[4,5] Inadequate vault-either too low or too high-can potentially lead to mechanical contact between the ICL and the crystalline lens (increasing the risk of anterior subcapsular cataracts) or anterior chamber angle narrowing, which may elevate intraocular pressure or compromise corneal endothelial health. The 4 EVO ICL sizes are based on diameter of a circle fully encompassing the ICL (essentially a diagonal measurement) and are 12.1 mm, 12.6 mm, 13.2 mm, and 13.7 mm (Figure 1). The current manufacturer nomogram is based on white-to-white (WTW) measurement, but increasing evidence supports the use of advanced imaging modalities-such as anterior segment optical coherence tomography (AS-OCT) and very high-frequency ultrasound biomicroscopy (UBM)-to directly visualize the sulcus, where the ICL resides, for more precise sizing. WTW can be obtained through various modalities ranging from caliper sizing to automated instruments such as the Pentacam (OCULUS, Wetzlar, Germany) but cannot provide the same critical information as UBM on the variability in anterior chamber angle, lens thickness, and sulcus measurements. There is growing evidence on the importance of dynamic vault with accommodation and pupil size which furthers the value of sizing accuracy.[6] At Parkhurst NuVision, we primarily use the London Vision nomogram with the Arcscan (Arcscan, Colorado, USA), the Parkhurst nomogram with the Sonomed Escalon (Escalon Medical,

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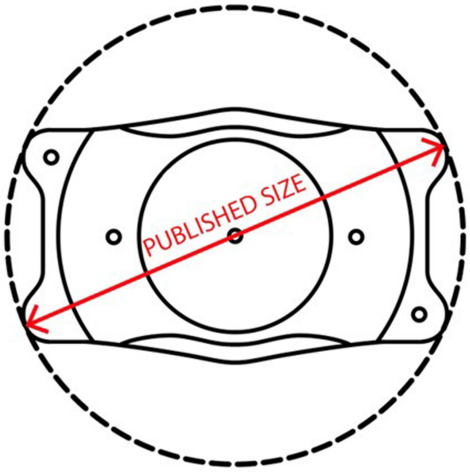

Figure 1 Diagonal measurement representing the EVO ICL sizes.

Pennsylvania, USA), and recently our bespoke AI sizing nomogram: VAULT.[7] This reflects a growing trend in refractive surgery toward data-driven, personalized sizing algorithms such as VAULT and other AI-based tools like ICLGuru.

Here, we share results from the rare cases of ICL exchange to provide perspective on how safe ICLs are, how confident surgeons can feel with sizing when moving beyond white-to-white alone, and how rare it is to perform an ICL exchange due to inappropriate vault.

Materials and Methods

Record Review

Parkhurst NuVision was one of the first sites to implant EVO ICL commercially after having been involved in the FDA clinical trial. We reviewed all records of commercial EVO ICL performed at Parkhurst NuVision from 04/06/2022 to 10/21/2024. Advarra Institutional Review Board (Columbia, USA) approved the study and was conducted in accordance with the tenets of the Declaration of Helsinki and adherent to all HIPAA regulations. It was determined to be exempt from IRB oversight and a waiver was granted because it imposes minimal patient risk due to its retrospective nature. Many steps were taken to ensure maintenance of patient data confidentiality throughout the study. Of the 961 eyes from 484 patients, we carefully analyzed the records from the 11 eyes of 8 patients who underwent EVO ICL exchange to a different size. We collected information including details of the procedure, ICL size and power, ACD, any complications, postoperative vault, and of course any need for exchange or explant in the postoperative period.

Sizing and Surgical Technique

As previously mentioned, in the majority of these cases the appropriate ICL size was determined using the London Vision nomogram with measurements from the Arcscan and Pentacam. The London Vision nomogram is an online tool where various caliper measurements from the Arscan are uploaded to yield vault predictions for each ICL size. In a minority of cases, we used the Parkhurst Nomogram with data from the Sonomed Escalon. This nomogram also relies on caliper measurements of the sulcus-to-sulcus space and the lens rise. Recently, we have begun using our bespoke, fully image-based AI nomogram VAULT to help provide additional data but this nomogram did not contribute to the data in this study. VAULT is a purely image-based machine learning model where images of UBMs or AS-OCTs are uploaded and analyzed by the AI algorithm to yield predicted vault for each ICL size.

For nomograms that provide predicted vault based on ICL size (ie, London Vision, VAULT), we targeted closest to 500 microns. In toric cases, we "hedged" to the larger size to create a more "snug" fit in the sulcus space and prevent rotation. While we have no specific criteria for this, an example is if 12.6 mm predicted a vault of 400 microns and 13.2 mm predicted a vault of 600 microns we chose 13.2 mm in toric cases. These decisions are made on a case-by-case basis.

A standard ICL surgical technique was used with a single 1.0 mm sideport incision and 3.0 mm main incision. Dispersive OVD was used to stabilize the eye and the ICL was inserted and tucked behind the iris without difficulty or complication in any case. The OVD was evacuated using BSS rinses. Detailed surgical technique online video series created by the authors are available at the Refractive Foundations ICL Workshop accessible at: https://refractivefoundations.com/icls/.

Results

Of the 961 commercial EVO ICL cases from 484 patients, 11 eyes of 8 patients (1.1%) underwent ICL exchange during the study period. Of these exchanges, only 5 cases (0.5%) of 4 patients were exchanged due to initial vault safety concerns with 6 cases (0.6%) of 4 patients exchanged due to rotated toric ICLs. In each of these 6 cases the initial vault was deemed to be clinically safe but exchanged to a larger size to improve fit in the sulcus space and reduce the likelihood of further rotation. All cases of exchanges/explant were initially sized using the London Vision nomogram and Arcscan.

There were 5 cases of 4 patients involving unsafe initial vault. One patient was found to have a central vault of 1126 microns on post-op day one. The IOP was never elevated, but on clinical exam the combination of the vault and appearance of the angles resulted in the decision to exchange the ICL with one size smaller within the first week. The other eye tolerated the initial size well without need for exchange or explant.

In the second patient, the post-op day 1 vault was 934 OD and 899 OS. The appearance of the angles on clinical exam and OCT lead to a decision to exchange to a smaller size in both eyes. In the right eye, the nasal and temporal angle was reduced from 33.53° and 34.13° to 19.70° and 12.3° respectively. In the left eye, the nasal and temporal angle was reduced from 43.63° to 46.47° to 15.63° and 17.70°, respectively. This is the only case of bilateral exchange or explant and was performed within the first week.

In the third case, the corneal diameter was large (WTW 12.4 mm) and the 13.2 mm ICL was exchanged for the 13.7 mm ICL within the first month. This size also was too small for the eye, and the ICL was visibly displaced inferiorly (Figure 2). The decision was ultimately made to explant this ICL over the course of a few months. The other eye tolerated the initial size well without need for exchange or explant.

In the fourth case, a 12.1 mm ICL was implanted with a postoperative vault of 848 μm. On exam, the iris was significantly anteriorly positioned and obvious narrowing of angles and intermittent headache symptoms reported by the patient. Since this is already the smallest ICL size the lens was explanted without difficulty in the first week. The other

Figure 2 The 13.7mm EVO ICL that was still too small for the patient's eye.
Notes: Photo Credit: Anthony Vanrachack, DO.

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Table 1 Summary of ICL Exchanges and/or Explants (n=961 Eyes of 484 Patients)

ICL Exchange/Explant Reason	Percent of Total ICL Cases
Total exchanges/explants, % (n)	1.1% (11/961)
Total exchanges, % (n)	1.0% (10/961)
Total explants, % (n)	0.2% (2/961)
Exchanges/explants due to sizing, % (n)	0.5% (5/961)
Exchanges/explants due to rotated toric ICL, % (n)	0.6% (6/961)
Exchange/explant cases where the surgeons would have chosen a different initial ICL size	0.3% (3/961)

Notes: Exchanges include the case of ICL exchange before ultimate explant.
Abbreviation: ICL, Implantable Collamer Lens.

eye tolerated the initial size well without need for exchange or explant. Notably in the latter two cases, the ICL remained in the other eye without difficulty and to the patient's satisfaction.

Additionally, 3 surgeons reviewed all these cases to see if now, with significantly more experience, the initial size choice would be different. The surgeons decided to choose a different ICL in only 3/11 (27%) of the cases.

A summary of this data is provided in Table 1 with a detailed review of the metrics, reasons for exchange, and ultimate outcome in Table 2.

Discussion

As ICLs have evolved, they have become more and more safe and tolerant to variations in sizing. The most recent model, the EVO ICL, appears to be the safest model yet. Parkhurst NuVision has extensive experience with EVO ICL, having participated in the clinical trial and being one of the first sites to implant a commercial EVO ICL. Of the nearly 1000 cases at the time of this study, only 11 have been exchanged or explanted due to sizing concerns. The majority of the exchanges are due to rotated toric ICLs, which were exchanged to the larger size so the tighter fit in the sulcus would prevent further rotation. These cases had clinically acceptable vault and had they been spheric ICLs likely would have never been exchanged. Interestingly, in nearly 1,000 cases only two eyes were outside the size range for the EVO ICL: one eye was too big and one eye was too small. Additionally, with a couple of years of additional experience with the EVO ICL, the surgeons at our practice decided to implant a different ICL in only 3 of the cases.

Having 5 eyes undergo exchange due to clinically unsafe vault out of nearly 1,000 cases is a strong testament to the safety profile of the EVO ICL platform but also an indication at the need to consider a staged, single-eye-at-a-time approach when working at the edge of sizing confidence. We attribute this extremely low 1.1% exchange/explant rate to our sizing methodology. While the only FDA-approved sizing method is the manufacturer nomogram which relies exclusively on caliper-measured white-to-white, we always obtain more data points. The Arcscan and London Vision nomogram assists with the majority of our sizing decisions and our in-house Parkhurst nomogram using the Sonomed and bespoke AI VAULT nomogram using AS-OCT have also proven extremely accurate. Occasionally, the manufacturer nomogram white-to-white recommendation conflicts with our methodology and in such cases we use ours instead. Emerging technologies like ICLGuru will also assist in minimizing the risk for mis-sized ICLs.

While this study is robust in the number of total ICL cases, the rarity of ICL exchange makes it difficult to draw meaningful conclusions about further limiting the outliers. We suspect that these rare cases may have something to do with caliper placement on the UBM machines which is why we are so passionate about our work with project VAULT and use of AI-based nomograms as the future of ICL sizing. The ability to eliminate user error and upload images will further standardize sizing and make these already rare ICL exchanges a thing of the past. In the case where the smallest ICL size, 12.1, was explanted due to overvault, some surgeons would opt to rotate the lens to a vertical orientation since there is evidence this can also reduce vault.[8] In 3/11 (27%) cases, it is possible that the exchange was not necessary but was only performed due to how early it was in the commercial EVO ICL release and hedging on the cautious side. More

Table 2 ICL Exchange/Explant Case Details

Patient	Eye	WTW	ACD	PreOP Angle N	PreOP Angle T	1st Size	1st Power	1st Toric	1st Axis	1st Vault	1st Angle N	1st Angle T	2nd Size	2nd Power	2nd Toric	2nd Axis	2nd Vault	Toric	Exchange/ Explant	Reason for Exchange	Surgeon would have Picked the Same Size
1	OD	11.7	3.32	40.633	40.433	12.6	−9.5	2	112	317	35.6	32	13.2	−9.5	2	129	602	Yes	Exchange	Rotated Toric	NO
2	OD	11.4	3.44	33.533	34.133	12.6	−9.5	1.5	88	934	19.7	12.3	12.1	−9.5	1.5	80	413	Yes	Exchange	Overvaulted	YES
2	OS	11.4	3.51	43.633	46.467	12.6	−9.5	1.5	88	899	15.633	17.7	12.1	−9.5	1.5	85	416	Yes	Exchange	Overvaulted	YES
3	OD	12.5	4.17	31.733	37	13.2	−14.5	1.5	89	704	N/A	N/A	13.7	−14.5	1.5	89	931	Yes	Exchange	Rotated Toric	YES
3	OS	12.7	4.21	54.833	56.267	13.2	−13	2.5	95	627	N/A	N/A	13.7	−13	2.5	95	902	Yes	Exchange	Rotated Toric	YES
4	OD	11.6	3.16	48.933	48.067	12.6	−6.5			1126	N/A	N/A	12.1	−6.5			467	No	Exchange	Overvaulted	YES
5	OS	12.4	3.31	43.7	56.033	13.2	−7.5	1.5	73	291	27.6	23.4	13.7	−7.5	1.5	73	54	Yes	Exchange, then explanted	Undervaulted	NO
6	OD	N/A	3.52	35.5	37.733	13.2	−13.5	1.5	113	733	25.067	22.867	13.7	−13.5	1.5	118	1078	Yes	Exchange	Rotated Toric	YES
6	OS	N/A	3.48	34.033	37.733	13.2	−14.5	2	65	800	25.1	24.3	13.7	−14.5	2	63	1030	Yes	Exchange	Rotated Toric	YES
7	OS	12.2	2.929	33.867	34	12.1	−5.5	1.5	56	346	N/A	N/A	12.6	−5.5	1.5	59	237	Yes	Exchange	Rotated Toric	NO
8	OD	10.7	2.743	33.5	32.467	12.1	−10	1.5	81	848	16.467	17.9						Yes	Explant	Overvaulted	YES

Notes: WTW and ACD from Pentacam AXL, Vault from ZEISS Cirrus, Angles from ArcScan.
Abbreviations: ICL, Implantable Collamer Lens; WTW, white-to-white, ACD, interior and central anterior chamber depth; N, nasal; T, temporal.

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data from ICL exchanges from more sites will be needed to draw meaningful conclusions about ICL exchanges, but this study certainly demonstrates how rare they can be. Lastly, our dataset is somewhat incomplete since we did not routinely collect all possible data at every possible visit. For example, if their vault after the exchange was reasonable and the slit lamp exam looked clinically safe, we did not necessarily repeat UBM. Future studies should aim to prospectively evaluate circumstances of exchanges/explants in a standardized manner using standardized sizing methods.

Since participating in the EVO ICL clinical trial, we have been implanting ICLs with great confidence and an extremely low exchange/explant rate of 1.1% due to sizing over the past several years. EVO ICLs are extremely safe and reliable. Especially when relying on more advanced imaging modalities, exchanges can be extremely rare.

Conclusion

ICLs are remarkably safe and effective with a size-related exchange or explant rate due to sizing at our institution of 1.1%. The majority of our exchanges are due to rotation of toric ICLs, not clinically unsafe vault. Only 0.5% of cases were ever exchanged due to clinically unsafe vault. We attribute this success to more advanced imaging modalities (eg, AS-OCT, UBM, etc.) instead of reliance on white-to-white alone.

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Disclosure

Drs. Hirabayashi, Nasser, Libfraind and Parkhurst are consultants for STAAR Surgical. The authors report no other conflicts of interest in this work.

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