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ORIGINAL RESEARCH

Clinical Outcomes of Implantable Collamer Lenses for the Treatment of Myopia in Eyes with Anterior Chamber Depth (<3.0 mm) at a Single Center in the United States

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Purpose: To report the clinical outcomes of ICL implantation for the treatment of myopia in American patients at a single center with central internal anterior chamber depth (ACD) less than the FDA-approved 3.0 mm.

Patients and Methods: Data was retrospectively obtained from 943 eyes of 560 patients between 4/6/2022 and 7/15/2024 which included 231 eyes of 120 patients with internal central ACD of <3.0 mm and 712 eyes of 440 patients with internal central ACD of ≥3.0 mm as measured by the Pentacam AXL (OCULUS, Wetzlar, Germany). Demographics, biometry, postoperative vault, and any complications were recorded. Patients were seen 1 day, 1 month, and 2 months, and followed regularly by their primary eyecare provider with instructions to return in the event of any problems. Rates of ICL explantation were statistically compared using the Fisher's Exact test. Postoperative vault and IOP were compared using the Student's *t*-test.

Results: Of the 231 eyes with ACD < 3.0 mm, 0.4% (1/231) required intraocular surgical intervention including ICL explant, exchange, or toric lens repositioning at some point in the postoperative period or were clinically judged to have a vault requiring an exchange compared to 3.7% (26/712) eyes with ACD ≥ 3.0 mm ($p = 0.0103$). Average postoperative vault for the eyes with ACD < 3.0 mm was 437.22 ± 191.93 microns compared to 560.73 ± 193.65 in eyes with ACD ≥ 3.0 mm ($p < 0.001$). IOP and visual acuity at 1 month were similar between the groups.

Conclusion: Outside the US, the lower limit of ACD is 2.8 mm for myopia correction. This single center study demonstrates that ICL surgery in American eyes with ACDs < 3.0 mm may also be safe and result in excellent outcomes with comparable rates of exchange or enhancement to eyes meeting the FDA guidelines.

Keywords: refractive surgery, vision correction, phakic IOLs, vault, sizing

Introduction

Implantable Collamer® Lenses (ICLs, STAAR Surgical Company, Monrovia, CA, USA) have consistently demonstrated an excellent safety profile with outcomes for refractive correction of myopia with and without astigmatism.[1–3] Preoperative diagnostic evaluation and ICL lens size selection are critical to avoid complications including narrowing or closure of the iridocorneal angle causing intraocular pressure (IOP) problems, endothelial cell loss, and for older, pre-EVO ICL models a risk of anterior subcapsular cataract formation.[4,5]

Due to their anatomical location in the eye, implantation with ICLs is known to narrow angles but in the overwhelming majority of patients, especially those who are myopic, this is tolerated without complication or issue.[6] Central, interior chamber depth (ACD), sometimes called "aqueous depth" as measured from the endothelium to the anterior

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crystalline lens surface, is an excellent measure of available space in the anterior chamber and can easily be obtained with the Pentacam or Pentacam AXL and ACD (int) (OCULUS, Wetzlar, Germany). ICLs in patients with low ACDs (generally defined as central, internal ACD < 3.0 mm) has been shown to be safe, but vault typically is lower than in those with deeper ACDs, which is an important consideration as vault generally decreases over time.[7,8]

Outside the US, the ICL indications for myopia include preoperative ACD 2.8 mm or greater, but this is outside the approval range in the USA with a minimum ACD of 3.0 mm per the US Food and Drug Administration (FDA) guidelines.[9] Results internationally strongly support that ICL implantation in those with ACDs of 2.8 mm or greater are safe and it is possible the FDA criteria excludes patients that are otherwise good candidates for ICL except for the ACD indication.[10–12]

In our practice, patients are rarely excluded based on FDA approval range alone, and instead a holistic view of their eye is taken with multiple diagnostic modalities including Pentacam and very high frequency ultrasound biomicroscopy. If we determine that it would be safe to implant ICLs in patients with ACDs < 3.0 mm, as measured by the Pentacam, we proceed with surgery after patient consent. In this paper, we report results from nearly 1000 consecutive ICL cases to compare outcomes between patients with ACDs (<3.0 mm) and ACDs (≥3.0 mm).

Materials and Methods

This single center retrospective study, which was conducted at Parkhurst NuVision in San Antonio, TX, analyzed myopic ICL procedures between 4/6/2022 and 7/15/2024. Follow-up was 1 day, 1 month, 2 months, and then regular annual exam with their primary eyecare provider with instructions to return with any problems noted by the patient or primary eyecare provider. Thus, the follow-up for complications is indefinite. Advarra Institutional Review Board (Columbia, USA) approved the study as exempt from the need for IRB oversight and was conducted in accordance with the tenets of the Declaration of Helsinki and adherent to all HIPAA regulations. This includes adequate provisions to maintain the confidentiality of any identifiable data collected in this retrospective study. Consent to review patient medical records was not required by the IRB due to the minimal risk imposed by evaluating existing de-identified data. Nine hundred and forty-three total eyes of 560 patients were included in the study. Two hundred and thirty-one eyes of the 943 eyes met the inclusion criteria of ICL implantation with internal central ACD of <3.0 mm as measured by the Pentacam AXL. Seven hundred and twelve eyes of 943 patients met the inclusion criteria of ICL implantation with internal central ACD of ≥3.0 mm as measured by the Pentacam AXL. Demographics, biometry, 1 day postoperative vault, postoperative vision, 1-month IOP, and any complications reported between the surgery and publication of this work were recorded. Rates of explantation were statistically compared using Fisher's Exact tests. Postoperative vault, IOP, and vision were compared using Student's t-tests.

Surgical Protocol

The ICL procedures were planned and performed in the typical manner. Younger patients were generally targeted for a spherical equivalent outcome of +0.12 D, moving closer to plano by age 50. For those older than 40–45, blended vision was offered and frequently implemented, adjusting the non-dominant eye closer to −1.50 D after assessing tolerance prior to surgery. The manufacturer's Online Calculation and Ordering System (OCOS) was used for these calculations. In eyes where ACD measurement was below the FDA indication of 3.0 mm or greater, clinical judgement was used to assess safety, and a "one eye at a time" approach was employed in lieu of same day immediately sequential bilateral surgery as appropriate, especially for patients with ACDs < 2.8 mm. The shallowest ACD in the analysis was 2.54 mm. The EVO+ lens was the primary choice, and the EVO lens was chosen when necessary, when the EVO+ was not available due to lens power. The ICLs were implanted through a 3.0 mm incision. The majority of the cases were bilateral, same-day except when it was decided to perform the cases one eye at a time due to ambiguity in sizing or ACD < 2.8 mm. Each bilateral procedure was immediately sequential with separate sets of sterile instruments and medications from separate lot numbers between cases. A brief exam was performed 1 hour after surgery to check IOP and wound closure. For additional consideration of lens size selection, the London Vision nomogram was used with data from the Arcscan (Arcscan, Broomfield, CO, USA). All ICLs in this study were sized using this method. Generally, if the Arcscan is down for maintenance, we use the Sonomed Escalon (Escalon Medical, Wayne, PA, USA) and Parkhurst Nomogram. For additional information on the surgical techniques, the authors use, please consult the video library we put together for ICL surgery at: https://refractivefoundations.com/icls/.

Diagnostic Modalities

Pre-operative biometric data, including central internal ACD, were obtained using the Pentacam AXL (Oculus Optikgeräte GmbH, Wetzlar, Germany). Parameters for lens size selection were primarily obtained using the Artemis Insight 100 VHF digital ultrasound device (ArcScan, Inc). The combination of diagnostic modalities in addition to the visual exam informed clinical judgement on when to implant the ICLs with ACDs outside of the FDA-approved depth. Postoperative vault was measured on post-operative day 1 using Zeiss Cirrus 5000 Anterior segment optical coherence tomography (Carl Zeiss Meditec, Dublin, CA, USA).

Results

Table 1 summarizes the baseline characteristics of the two groups: eyes with ACD < 3.0 mm (231 eyes of 120 patients) and eyes with ACD ≥ 3.0 mm (712 eyes of 440 patients). The demographics were comparable except for patients with shallower ACDs being older, which may be due to changes in anatomy over time. The shallowest ACD included in the study was 2.54 mm. Of the 231 eyes with ACD < 3.0 mm, 0.4% (1/231) required intraocular surgical intervention in the postoperative period or were clinically judged to have a vault requiring an exchange compared to 3.7% (26/712) of eyes with ACD ≥ 3.0 mm (p = 0.0103). Average postoperative vault for the eyes with ACD < 3.0 mm was 437.22 ± 191.93 microns with a range of 26 microns to 886 microns. Average postoperative vault for the eyes with ACD ≥ 3.0 mm was 560.73 ± 193.65 microns with a range of 54 microns to 1290 microns ($p \leq 0.0001$). Average 1-month postoperative IOP for the eyes with ACD < 3.0 mm was 14.78 ± 4.24 mmHg. Average 1-month postoperative IOP for the eyes with ACD ≥ 3.0 mm was 14.86 ± 3.88 mmHg ($p = 0.2851$). Average postoperative VA for the eyes with ACD < 3.0 mm was −0.0035 ± 0.14 logMAR. Average 1-month visual acuity for the eyes with ACD ≥ 3.0 mm was −0.05 ± 0.07 logMar ($p = 0.1391$). Table 2 summarizes the clinical outcomes.

Table 1 Baseline Patient Demographic Data

Parameters	ACD < 3.0 (n = 231)	ACD ≥ 3.0 mm (n = 712)	P-value
Age, years	36.52 ± 6.87	32.98 ± 7.12	*0.0001*
Sex, %			0.2449
Male	12.55% (29)	15.87% (113)	
Female	87.45% (202)	84.13% (599)	
Race, %			0.4898
Caucasian	37.66% (87)	42.13% (300)	
Hispanic	43.72% (101)	38.48% (274)	
Asian	9.96% (23)	9.41% (67)	
Black	8.66% (20)	9.97% (71)	
ACD Range	2.54–2.99	3.00–4.21	
ICL Vault (μ) Range	26–886	54–1290	
Average internal ACD (mm)	2.85 ± 0.10	3.20 ± 0.27	*<0.0001*
Preoperative spherical equivalent (D)	−8.01 ± 3.07	−7.71 ± 2.94	0.1831
Toric ICL	54.5% (126/231)	57.2% (407/712)	0.4937
ICL size, %			
12.1	23.38% (54)	6.6% (47)	
12.6	52.8% (122)	56.3% (401)	
13.2	23.8% (55)	35.8% (255)	
13.7	0% (0)	1.26% (9)	

Notes: All values are provided in mean ± standard deviation unless otherwise indicated. Student's t-tests were used to compare continuous data. Fisher's Exact or Chi-Square tests were used to compare categorical data.
Abbreviations: ACD, internal anterior chamber depth; ICL, implantable Collamer lens.

Table 2 Outcomes of ICLs Implanted in Eyes with ACD < 3.0 mm Compared to Eyes with ACD ≥ 3.0 mm

Outcome	ACD < 3.0 mm (n = 231 Eyes of 120 Patients)	ACD ≥ 3.0 mm (n = 712 Eyes of 440 Patients)	P-value
Explantation/ Exchange	0.4% (1/231)	3.7% (26/712)	*0.0103*
ICL Vault (μ) Average	437.215 ± 191.93	560.7303 ± 193.65	*<0.0001*
IOP (mmHg)	14.780 ± 4.2426	14.8561 ± 3.8751	0.2851
UCDVA (logMAR)	0.00 ± 0.14	−0.05 ± 0.07	0.1391

Notes: All values are provided in mean ± standard deviation unless otherwise indicated.
Abbreviations: ACD, internal anterior chamber depth; ICL, implantable Collamer lens; UCDVA, uncorrected distance visual acuity.

Table 3 Eyes with High or Low Postoperative Vault with ACD < 3.0 mm Compared to Eyes with ACD ≥ 3.0 mm

Outcome	ACD < 3.0 mm (n = 231 Eyes of 120 Patients)	ACD ≥ 3.0 mm (n = 712 Eyes of 440 Patients)	P-value
<100 μm	2.2% (5/231)	0.1% (1/712)	*0.0041*
>900 μm	0.0% (0/231)	5.6% (40/712)	*<0.0001*

Notes: All values are provided in mean ± standard deviation unless otherwise indicated.
Abbreviation: ACD, internal anterior chamber depth.

Table 3 summarizes the number of eyes with high or low vault in each group. Interestingly, there were significantly more eyes with postoperative vault < 100 µm in the <3.0 mm ACD group and more eyes with postoperative vault > 900 µm in the ≥3.0 mm ACD group.

Discussion

In this paper, we report our outcomes from nearly 1,000 consecutive ICL cases at a single institution. We found that outcomes after ICL implantation in patients with ACDs <3.0 mm and ACDs ≥3.0 mm were comparable, and ICLs in those with smaller ACDs were extremely safe and effective. One eye (0.4%) in the shallow group required explantation/exchange compared to 3.7% of those with ACDs ≥ 3.0 mm. While this result is statistically significant, it is not likely clinically meaningful beyond the conclusion that shallower ACDs are as safe as those with deeper ACDs. It is unlikely that ICLs in this population would actually be safer with a lower explantation/exchange rate except that possibly these patients had an even more thorough review to select the appropriate ICL size. Lower postoperative vault in the shallow ACD group is consistent with existing literature and importantly, the mean vault for this group was also comfortably within the recommended vault range of 250–750 µm.[10] Postoperative IOP and visual acuity were excellent and better than 20/20 Snellen equivalent in both groups and statistically comparable. For the one eye in the shallower ACD group that required explantation, postoperative vault was 848 but the narrowing of the angle was judged to be too shallow to safely allow the ICL to remain in place despite using the 12.1 size, so it was explanted without difficulty or subsequent complications. Lastly, there were more eyes with shallow postoperative vault (<100 µm) in the <3.0 mm ACD group and more eyes with high postoperative vault (>900 µm) in the ≥3.0 mm ACD group. This is likely a function of the clinical decision to "hedge down" sizes when ACD < 3.0 mm. In this study, the lowest internal ACD was 2.54 mm but for interest the lowest ACD we have done outside the context of this study is 2.42 mm which also was a successful, safe outcome.

For the majority of international governing bodies including Europe, the approval cutoff is for an internal ACD of 2.8 mm.[13,14] Since the implant is the same, there is considerable evidence in the published literature demonstrating safety of the lens in these cases. For this reason, we did not feel any hesitation, ethically or otherwise, proceeding with ICL implantation in patients with ACDs <3.0 mm, especially since we always obtain informed consent. Although these cases were "off-label" in the United States, off-label use is common when based on use is based on "sound scientific evidence and sound medical opinion".[15] In addition to international governing bodies finding ICL implantation in eyes with ACDs < 3.0 mm to be safe, this is also well supported in the literature with safety and efficacy findings similar to our reported results.[6,10,11,16,17]

Limitations to this study include the limited sample size, although we do include nearly 1,000 eyes. Additionally, this was not a double-blinded or randomized trial. The shallower ACD patients were carefully chosen for surgery, and there are potential factors where other patients with a shallow ACD would be recommended for a different vision correction procedure instead (eg, narrow angles by Arcscan). Our preoperative demographics were comparable between groups except for age with the shallow ACD group being slightly older likely due to the natural decrease in ACD with time.[18] Future studies can include a larger sample of ACDs <3.0 mm to further elucidate the safety and efficacy in this population. Lastly, ACD in this study was measured using the Pentacam platform, and the results of this study may not translate to other methods of measurement.

ICLs are a lifechanging surgery not just for those who cannot safely benefit from laser-based ablative surgery, but they can also provide superior vision in some patients compared to contact lenses, glasses, or laser vision correction. Therefore, ICLs should be made available to as many people as possible if clinical judgement determines the procedure is an appropriate option. In consideration of the FDA approved indications, we routinely implant ICLs in eyes with ACDs less than 3.0 mm and our outcomes as reported here are excellent and comparable to those with ACDs of ≥3.0 mm. The FDA indications are reflective of the clinical trials in the United States and do not necessarily restrict clinical decision-making nor make a substitute for surgeon judgement. As ICLs continue their rapid adoption in the United States, it is possible that the FDA approval indications will expand to be commensurate with international guidelines and common clinical use.

Conclusion

In summary, we have found that in this United States study population the use of ICLs in eyes with ACDs < 3.0 mm can be safe with excellent outcomes.

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Disclosure

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