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Comparison of intraoperative vs postoperative optical coherence tomography measurement of implantable collamer lens vaulting

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Purpose: To compare intraoperative vs postoperative optical coherence tomography (OCT) measurements of implantable collamer lens (ICL) vaulting.

Setting: American University of Beirut Medical Center, Beirut, Lebanon.

Design: Prospective observational cohort study.

Methods: Patients with myopia or myopic astigmatism undergoing ICL insertion in which intraoperative OCT measurements were obtained were included. Exclusion criteria included coexisting ocular problems and previous ocular surgery. The outcome measures were ICL vaulting as determined by OCT intraoperatively and postoperatively at 1 day, 1 week, 1 month, and 3 months.

Results: Forty-five eyes of 26 patients were included. Mean age was 27.23 ± 6.47 years (range 17 to 48 years), and mean manifest refraction spherical equivalent was −10.20 ± 3.92 diopters (D) (range −20.50 to −4.50 D). Mean ICL vaulting measured 731 ± 215 µm intraoperatively, 648 ± 219 µm at 1 day, 640 ± 204 µm at 1 week, 628 ± 212 µm at 1 month, and 632 ± 210 µm at 3 months postoperatively (P = .0009, with all postoperative vaulting measurements statistically similar to each other, but significantly different from the intraoperative measurement). However, intraoperative ICL vaulting had high predictability of postoperative vaulting at 3 months with r^2 = 0.81 (P < .0001), and Bland–Altman analysis demonstrates a relatively constant difference between the 2 measurements as plotted against their mean with a bias of 98.27 µm and tight 95% limits of agreement range.

Conclusions: Intraoperative ICL vaulting measured by OCT correlated highly with postoperative OCT vaulting and can be considered a reliable tool to predict the final ICL vault.

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Implantable collamer lenses (ICLs) are phakic sulcus-supported intraocular lenses (IOL) intended to correct refractive errors. They have proven efficacy and safety, especially the latest iteration, which has a central port to facilitate flow of aqueous over the crystalline lens and minimize the incidence of acute angle-closure glaucoma in the early postoperative days.[1–8]

One of the last unconquered challenges of ICL implantation is accurate prediction of the implant vaulting. The latter is the distance between the posterior border of the ICL and the anterior surface of the crystalline lens. Optimal vaulting is key to the success of the procedure.[9] In fact, excessive vaulting can cause pupillary block, iris touch, and angle-closure glaucoma, whereas low vaulting can create anterior lens opacification and induce early cataract.[10–12] Proper vaulting is roughly estimated to be close to the central corneal thickness with an upper limit at around 1000 µm and a lower limit set around 50 to 250 µm, especially due to the improved safety imparted by the central port in the latest ICL models.[13] Very high or very low vault can be an indication for ICL exchange.[14] Despite the best efforts to order a perfect-fit lens, around 2.6% of eyes implanted with ICLs are observed to have inappropriate vaulting requiring ICL exchange.[8,15–18] White-to-white determination, performed manually with calipers and with imaging systems, or sulcus-to-sulcus measurement with high-frequency ultrasound biomicroscopy, have been the mainstay in postoperative vault prediction, along with internal anterior chamber depth measurement.[4,19] Preoperative anterior segment optical coherence

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tomography (OCT) to determine the crystalline lens rise and the angle-to-angle distance have been described as additional ancillary tests to optimize vault prediction.[20–22]

The introduction of intraoperative OCT systems built into the operating microscope provides a unique opportunity for the surgeon to assess the intraoperative vaulting and accordingly make clinically relevant decisions. It has successfully been used in various types of intraocular surgeries such as corneal transplantation, glaucoma, and retinal surgeries.[23–25] This prospective study compared the ICL vaulting measured by OCT intraoperatively and postoperatively up to 3 months to evaluate the usefulness of the former in predicting the actual postoperative vaulting.

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METHODS

This was a prospective study involving patients who were planned for ICL insertion at the American University of Beirut Medical Center in Beirut, Lebanon, between November 2017 and October 2018. This study was approved by the Institutional Review Board at the American University of Beirut and adhered to the tenets of the Declaration of Helsinki. Patients were excluded if the OCT acquisition was of poor quality (not allowing adequate ICL vaulting measurement) and if they had any coexisting ocular problem or any previous ocular surgery. Preoperative assessment included measurement of uncorrected distance visual acuity (UDVA), manifest refraction spherical equivalent (MRSE), corrected distance visual acuity (CDVA), and a complete ophthalmological examination including intraocular pressure measurement, slitlamp biomicroscopy, and dilated fundus examination. In addition, the internal anterior chamber depth from the corneal endothelium, the simulated keratometry, and the white-to-white distance were recorded before surgery using dual Scheimpflug–Placido tomography (Galilei, Ziemer Ophthalmic Systems AG), and the latter was also measured manually using calipers. Spectral domain OCT of the anterior chamber (Cirrus HD-OCT, Model 5000, Carl Zeiss Meditec AG) was performed preoperatively. Intraoperative OCT measurements of the ICL vault were performed using RESCAN 700 intraoperative OCT (Carl Zeiss Meditec AG) before and after ophthalmic viscosurgical device removal. Postoperatively, UDVA, CDVA, and ICL vaulting measurements on OCT were performed at 1 day (except for CDVA), 1 week, 1 month, and 3 months, with the OCT operator being blinded to any intraoperative findings.

Surgical Procedure

All procedures were performed under topical anesthesia by the same surgeon (S.A.). Pupil dilation was initiated with phenylephrine 2.5%, tropicamide 1%, and indomethacin 0.1% eye drops instilled twice, 10 minutes apart. Two limbal paracentesis incisions were made at 12 o'clock and 6 o'clock followed by intracameral injection of 1% preservative-free lidocaine, followed by 1.0% sodium hyaluronate ophthalmic viscosurgical device (OVD) injection. The toric V4c EVO ICL, (STAAR Surgical) which comes with a central aquaport, was then introduced via a 3.2 mm temporal incision. Subsequently, the 4 haptics were tucked under the iris, and the ICL was rotated to the desired meridian, followed by intraoperative OCT measurement. Capture acquisition was performed with the narrowest angle scan available. The OVD was then squeezed out by gentle irrigation around the sides of the ICL by an irrigation cannula while pressing on the posterior lip of the side port to enhance OVD ejection and avoid marked fluctuation in anterior chamber depth. The side ports and main wound were then gently hydrated. Intraoperative OCT measurement was performed again after making sure that the anterior chamber was close to physiological depth. If there was a need for intracameral miotics (carbachol 0.01%), it was diluted 1:3 and injected after all OCT measurements were performed at the very end of the procedure.

Measurement of Intraoperative ICL Vaulting

The RESCAN 700 intraoperative OCT platform does not provide any form of caliper. Hence, to calculate intraoperative vault, the narrowest angle scan was selected to avoid any distortion errors introduced by wide-angle scans, which could affect measurements (Figure 1). The central thickness of each ICL on the first postoperative visit was measured using the built-in caliper of Cirrus 5000 SD-OCT software. The intraoperative OCT image was then loaded into AutoCAD software (Autodesk), and using the known central ICL thickness in each eye, an image scale in micrometers was devised via which the intraoperative vaulting was calculated.

Statistical Analysis

Descriptive statistics were used to quantitatively summarize data using mean values, standard deviations, and range. Preoperative UDVA and CDVA and intraoperative ICL vaulting were compared with their respective postoperative values at the different time points using the Mann–Whitney *U* test for unpaired data, the Wilcoxon matched-pairs signed-rank test for paired data, and the analysis of variance with Tukey correction for multiple comparisons, where applicable. Linear regression was used to evaluate the relationship between intraoperative and postoperative ICL vaulting at 3 months. Bland–Altman plots with 95% limits of agreement were used to analyze the difference between intraoperative and postoperative ICL vaulting at 3 months to the average of these 2 measurements. Statistical significance was set at $P < .05$.

RESULTS

Forty-five eyes of 26 patients were included. Mean age was 27.23 ± 6.47 years (range 17 to 48 years), and mean MRSE was −10.20 ± 3.92 D (range −20.50 to −4.50 D) with a preoperative CDVA of 0.11 ± 0.18 logarithm of the minimum angle of resolution (logMAR) (range 0.00 to 0.50 logMAR). At 3 months postoperatively, MRSE was −0.04 ± 0.55 (range −1.00 to +0.75), which was significantly different from its preoperative value ($P < 0.0001$), and UDVA tended to be slightly better at 0.04 ± 0.08 logMAR (range 0.00 to 0.30 logMAR) compared with the preoperative CDVA ($P = 0.06$). Baseline and postoperative characteristics are summarized in Table 1. The average thickness of the ICL as measured by OCT postoperatively was 244.70 ± 27.39 µm. No eye underwent ICL exchange or explantation.

Vault Measurement

In 33 eyes (73.3%) that had intraoperative OCT measurement before and after OVD removal, ICL vaulting was 879 ± 174 µm and 746 ± 184 µm, respectively ($P < .0001$) with a correlation coefficient of 0.87 ($P < .0001$) (Figure 2). Mean intraoperative ICL vaulting after OVD removal for all eyes was 731 ± 215 µm, whereas the postoperative mean ICL vaulting measurements were 648 ± 219 µm at 1 day, 640 ± 204 µm at 1 week, 628 ± 212 µm at 1 month, and 632 ± 210 µm at 3 months (ANOVA $P = .0009$) (Figure 3). One eye measurement was excluded at day 1 due to subpar ICL vault imaging quality. Although no significant differences were noted among all postoperative measurements, they were each significantly different from the intraoperative ICL vaulting on multiple comparisons analysis (all pairwise $P < .001$). Linear regression analysis of postoperative ICL

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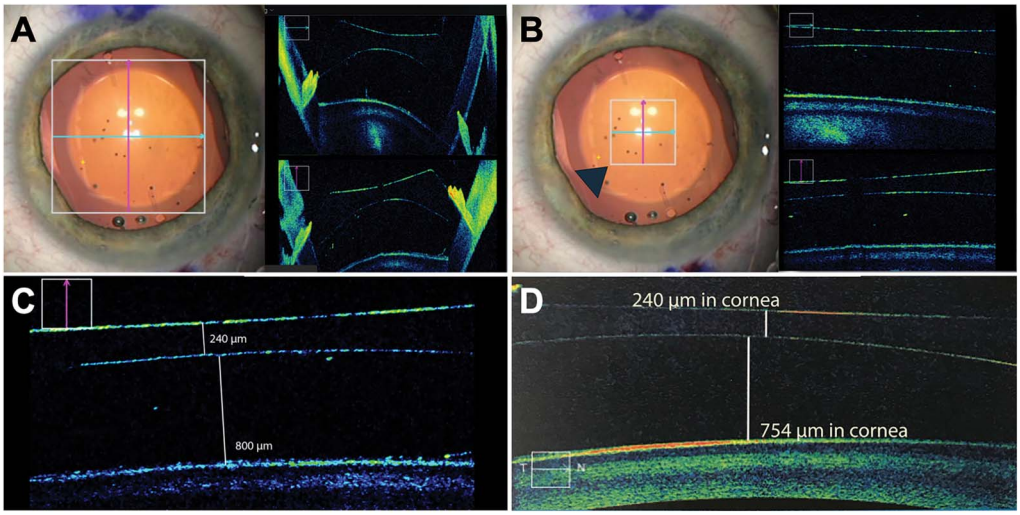

Figure 1. (*A*) Wide-angle intraoperative OCT scan by the RESCAN 700. The OCT image on the right hand side looks distorted. (*B*) Narrow-angle intraoperative OCT scan by the RESCAN 700 showing distortion-free image (*black arrowhead*). (*C*) ICL lens vault intraoperatively using the RESCAN 700. (*D*) Three-month postoperative ICL vault by the Cirrus 5000 SD–optical coherence tomography. The ICL thickness is measured and used to back-calculate the exact vault on the OCT image taken intraoperatively using image analysis software (ICL = implantable collamer lens; OCT = optical coherence tomography).

vaulting at 3 months against intraoperative ICL vaulting yielded a very good fit with an $r^2 = 0.81$, a slope of 0.88, and an intercept of −9.9 ($P < 0.0001$) (Figure 4). A Bland–Altman plot showed a relatively constant and systematic bias of 98.27 µm more in the intraoperative compared with the 3-month postoperative OCT measurements of ICL vaulting with 95% limits of agreement of −90.67 µm and +287.20 µm (Figure 5). A total of 45 eyes were included in the Bland–Altman analysis, and 41 eyes (91.1%) fell within the 95% limits of agreement. There were no differences in the ICL vaulting among fellow eyes, neither when measured intraoperatively (mean difference −37.84 ± 135.80 µm, $P = .50$) nor at 3 months postoperatively (mean difference 6.74 ± 72.17 µm, $P = .90$).

DISCUSSION

Recent advances in ICL phakic IOL technology, such as better IOL shape and the addition of a central aquaport, made the procedure safer.[9] Nevertheless, adequate vaulting remains the main challenge to the refractive surgeon aiming to avoid IOL exchange and potential complications such as cataract and glaucoma. Despite the best preoperative efforts to determine the ideal IOL size by combining white-to-white, internal anterior chamber depth, and sulcus-to-sulcus measurements, vaulting surprises still occur and can lead to IOL exchange in approximately 2.6% of operated eyes.[8,16–18,26]

This study shows a systematic difference of about 100 µm more between the intraoperative ICL vaulting compared with the postoperative measurements. The correlation between the 2 measurements was excellent with tight limits of agreement, indicating that intraoperative OCT can be used to predict postoperative vaulting. The difference in measurements is likely due to residual OVD presence after manual irrigation and the fact that the pupil is still pharmacologically dilated when the OCT measurement is taken intraoperatively. In comparison, postoperative OCT measurements were taken on a physiological pupil, which is usually smaller, and ICL vaulting with aquaport has been shown to be sensitive to pupil size, with lower vaulting associated with smaller pupil sizes.[27] However, pharmacological constriction of the pupil before intraoperative OCT measurement would have resulted in an anterior push of the lens–ciliary body diaphragm complex and subsequent lower implant vault that is not correlated with the one of the postoperative physiologic pupils. In addition, the surgeon's decision to explant or exchange the ICL, in the event the intraoperative vault was deemed unacceptable, would rather be taken before pupil constriction. Possible inherent differences in measurements between the 2 OCT systems and errors from image caliper measurements could have also contributed to the difference observed, albeit to a lesser extent.

Image distortion from the wide-angle scan mode is also likely to introduce errors in intraoperative vault measurement and is one of the reasons a caliper is not provided in the RESCAN 700 platform. We had circumvented this issue by recording the image of the narrowest scan mode. A

Table 1. Baseline and postoperative characteristics.

Characeteristic	Mean ± SD (Range) N = 45 Eyes/26 Patients
Age (y)	27.23 ± 6.47 (17, 48)
Sex (female, %)	16 (61.54%)
Preoperative MRSE (D)	−10.20 ± 3.92 (−20.50, −4.50)
Preoperative astigmatism (D)	−2.82 ± 1.92 (−6.00, −0.50)
Preoperative CDVA (logMAR)	0.11 ± 0.18 (0.00, 0.50)
Preoperative WTW (by tomography) (mm)	12.24 ± 0.35 (11.72, 13.03)
Preoperative ACD (mm)	3.32 ± 0.25 (2.90, 3.77)
Preoperative simK (D)	44.27 ± 1.49 [39.72, 46.26]
Postoperative MRSE* (D)	−0.04 ± 0.55 (−1.00, +0.75)
Postoperative UDVA* (logMAR)	0.04 ± 0.08 (0.00, 0.30)
ICL thickness (µm)	244.70 ± 27.39 (178, 305)

ACD = anterior chamber depth; CDVA = corrected distance visual acuity; ICL = implantable collamer lens; logMAR = logarithm of the minimum angle of resolution; MRSE = manifest refraction spherical equivalent; simK = simulated keratometry; UDVA = uncorrected distance visual acuity; WTW = white-to-white
*At 3 months

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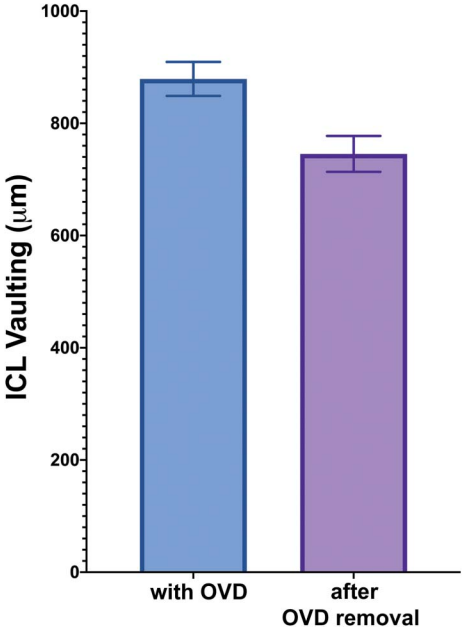

Figure 2. ICL vaulting (mean ± scanning electron microscopy, µm) before and after ophthalmic viscosurgical device removal (n = 33) (ICL = implantable collamer lens; OVD, ophthalmic viscosurgical device).

study by Titiyal et al. found only 7 µm of mean difference between intraoperative ICL vaulting and vault at 3 months postoperatively.[28] However, the figures provided in their study featured wide-scan mode with distorted images, and the ICL thickness was not measured and used as a scale reference to eliminate distortion bias. In addition, it was not mentioned whether a miotic agent was used before intraoperative measurements were performed, which could also decrease intraoperative vaulting.

Based on our results, we believe that ICLs with extreme intraoperative vault readings should be explanted during the same surgical session. In addition, the ability to have direct access to the same power IOLs with a size that is one step larger and one step lower would ensure same-session IOL exchange without necessitating another surgical

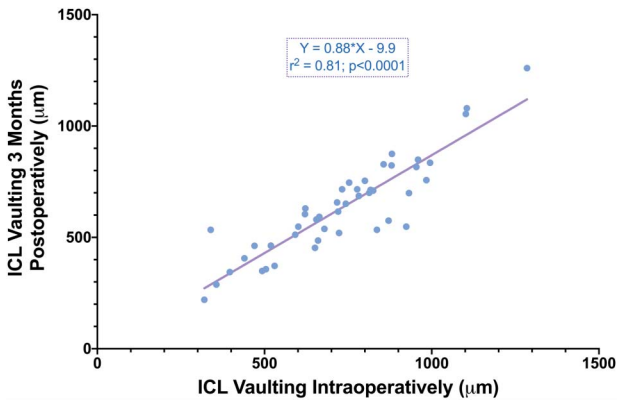

Figure 4. Linear regression analysis of postoperative ICL vaulting at 3 months as a function of intraoperative ICL vaulting (ICL = implantable collamer lens).

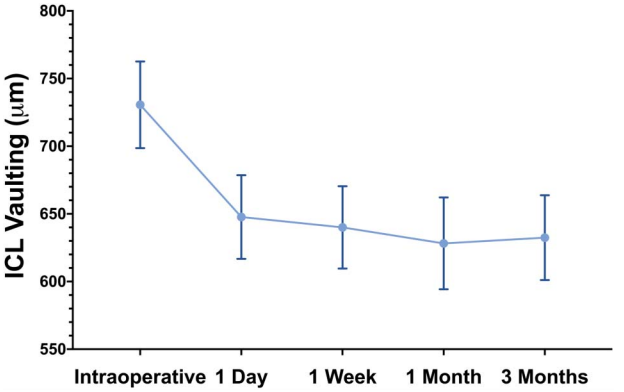

Figure 3. ICL vaulting (mean ± scanning electron microscopy, µm) intraoperatively after ophthalmic viscosurgical device removal and postoperatively at 1 day, 1 week, 1 month, and 3 months (n = 45) (ICL = implantable collamer lens).

procedure, hence ensuring optimal patient safety and satisfaction. Also, for surgeons performing bilateral surgeries, a good intraoperative vault measurement in the first eye would allow the surgeon to proceed with the fellow eye with greater confidence, as concordance rates of the ICL vaulting between the two eyes were very high both intraoperatively and postoperatively. At present, using the Zeiss RESCAN 700 technology, the surgeon can estimate the intraoperative vaulting by comparing the ICL thickness, which in myopia with or without astigmatism averages around 250 µm. Some available intraoperative OCT technologies do provide a caliper, whereas most are expected to offer it in the near future.

This prospective study has a relatively short follow-up time period, but its main aim was to assess the feasibility of predicting ICL vault in the early postoperative phase from the intraoperative measurement. Also, only patients with myopia were enrolled, and hence, the findings cannot be extended to the hyperopic population. It is well known that ICL vaulting decreases over time due to increased crystalline lens thickness associated with age. Studies have

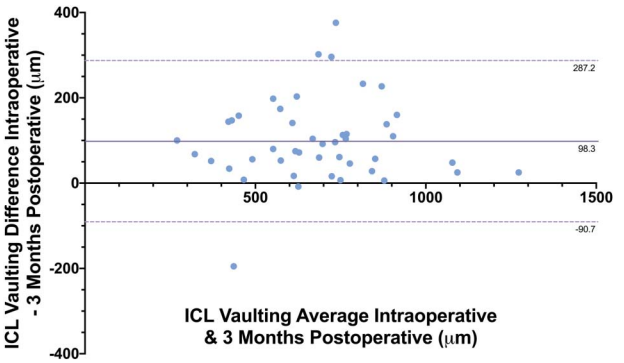

Figure 5. Bland–Altman analysis of the difference between intraoperative and 3-month postoperative ICL vaulting (µm) plotted against the mean of the 2 measurements for the 45 eyes (*dashed lines,* represent 95% limits of agreement, in which 91.1% of eyes fall; *solid line,* bias) (ICL = implantable collamer lens).

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shown that ICL vaulting in patients with myopia progressively decreases over a 12-year period.[13] This should be taken into consideration vis-a-vis the postoperative data.

In summary, intraoperative OCT measurements of ICL vaulting highly correlated with postoperative measurements at 3 months. ICL vaulting prediction has not improved markedly over the past 2 decades despite the use of ultrasound biomicroscopy to estimate the sulcus-to-sulcus distance and OCT technology to evaluate the crystalline lens rise. A disruptive technology that would accurately predict postoperative vaulting from preoperative data does not seem likely in the near future. On the other hand, OCT is arguably the fastest-adopted imaging technology in the history of ophthalmology, and it stands a great chance to be integrated in most surgical microscopes in the next few years. Hence, we forecast a promising role for intraoperative OCT to better predict and optimize postoperative vaulting and subsequently enhance patient safety and satisfaction.

WHAT WAS KNOWN

- Despite the best preoperative efforts to determine the ideal implantable collamer lens (ICL) size, vaulting surprises still occur and can lead to lens exchange or removal in 2.6% of cases. However, with intraoperative optical coherence tomography (OCT) now available, it can be used to estimate ICL vaulting intraoperatively.

WHAT THIS PAPER ADDS

- Intraoperative OCT can be easily used to estimate ICL vaulting, even without a built-in caliper. These measurements correlate highly with postoperative vaulting and can be used to guide the surgeon about the expected postoperative course.

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