Title

Anterior chamber angle width, central vault and intraocular pressure changes after twelve months of Visian collamer lens implantation.

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Abstract

Purpose: To evaluate one-year changes of vault, anterior chamber angle width (ACAW) and intraocular pressure (IOP) after the implantation of Implantable Collamer Lens (ICL) V4c in high myopic patients.

Methods: Sixty ICL V4c implantation surgeries were included. Patients underwent surgery between January 2014 and June 2017 at Ophthalmology Center Tecnolaser Clinic Vision®, Seville, Spain. All patients had a twelve-month follow-up. A preoperative spherical equivalent between - 4.00 diopters (D) and -15.00 D was established as inclusion criterion. ACAW and vault were measured with Pentacam single rotation Scheimpflug camera (Oculus Optikgeräte GmbH, Wetzlar, Germany). IOP was measured with CORVIS ST (Oculus Optikgeräte GmbH, Wetzlar, Germany).

Results: One day vault was 553.17 ± 169.80 [268 – 975] µm, 12 months vault was 515.67 ± 176.46 [169 – 950] µm ($p < 0.01$). Preoperative ACAW was 36.85° ± 4.60° [26.7° – 46.8°], postoperative ACAW was 25.98° ± 3.85° [16.4° – 32.6°] ($p < 0.01$). Preoperative IOP was 15.37 ± 1.58 [12.0 – 18.3] mmHg, postoperative IOP was 15.61 ± 1.60 [12.0 – 19.0] mm Hg ($p = 0.35$).

Conclusions: ICL V4c lens experienced a progressive reduction of vault after twelve months follow-up. ACAW decrease was significant between preoperative and postoperative value. We propose to include a minimum preoperative ACAW and an IOP correction factor for lens size.

Keywords

Implantable collamer lens; anterior chamber angle width; central vault; intraocular phakic lens; posterior chamber phakic lens; intraocular pressure

Declaration

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Introduction

Posterior chamber Implantable Collamer Lens (ICL), has been described as a safe and effective[1–5] surgery technique in high myopia correction. Conventional ablation techniques confer excellent results in visual acuity, however the risk of corneal ectasia due to excessive removal of corneal tissue remains as a potential severe complication. ICL appears as an alternative in patients who are not suitable for laser ablation of the corneal surface. Despite being an effective treatment and offering the advantage of being a reversible technique, there are several complications that can considerably worsen the results. Increased Intraocular Pressure (IOP) as a result of pupillary block[6] and the development of anterior subcapsular cataracts[7] due to mechanical friction of the ICL lens with crystalline lens are some of the most frequent complications.[8, 9]

Vault is the distance between the anterior face of the crystalline lens and the posterior face of the iris. An excess vault (>750 µm) contributes to angular narrowing and, subsequently, IOP increase and risk of glaucoma. An insufficient vault (<250 µm) increases friction risk against the anterior face of the crystalline.[9] This parameter may change over time.[5, 10–14] Previous studies had shown an inverse proportional relationship between vault and iridocorneal angle.[15–17] Efficacy of ICL in the refractive correction has been evaluated, with follow-up at one month, 6 months and 18 months after implantation. Recently, new ICL models have been designed with advanced technology that prevent complications such as IOP increase, avoiding the performance of intraoperative iridectomies.[6, 18] V4c collamer lens (ICL V4c) includes a 0.36 mm diameter central hole, called KS-AquaPORT, allowing aqueous humor flow through the ICL anterior face. Currently, intraoperative complications have reduced, however they are still frequent in the post-operative period.[6]

The purpose of the present study was to describe changes in vault, ACAW and IOP after the implantation of ICL V4c for correcting high myopia after twelve months follow-up.

Materials and Methods

Design

Sixty ICL V4c implantation surgeries were included in this retrospective, observational and longitudinal study. Patients underwent surgery between January 2014 and June 2017. All phakic lens surgeries were performed at the facilities of the Ophthalmology Center Tecnolaser Clinic Vision ®, Seville, Spain. All patients had a 12-month follow-up.

Ethical aspects

All patients included in this work were adequately informed verbally and in writing of the benefits, characteristics and risks of surgeries. All patients signed a consent form prior to the surgery and after the interview performed with the ophthalmologist. This study was conducted in accordance with the tenets of the Helsinki Declaration and obtained Institutional Review Board exemption.

Patients

Patients voluntarily went to the clinic to perform the tests. Next, an ophthalmologist determined their suitability for surgery, they underwent ICL refractive surgery voluntarily. The inclusion criteria were; (1) age between 20 and 45 years, (2) a stable refraction for at least 2 years, (3) presence of myopia in spherical equivalent between – 4.00 D and – 15.00 D, (4) presence of astigmatism between 0.00 D and – 5.00 D and (5) non-candidates for laser refractive surgery. The exclusion criteria comprised; (6) anterior chamber depth from endothelium ≤ 2.8 mm, (7) endothelial cell density ≤ 2000 cells per mm^2, (8) hyperopia, (9) a family history of glaucoma, (10) inflammatory eye disease (keratitis, herpes zoster, ocular herpes), (11) previous eye surgery or (12) any kind of corneal disease (keratoconus, acute or chronic corneal infection, ocular herpes, Stevens-Johnson syndrome, glaucoma, cataract, uveitis or retinal detachment). ICL power and size were calculated with STAAR ® Surgical software.

Preoperative Examinations

Before the implantation of the ICL (Visian ICL [V4c] STAAR® Surgical, Monrovia, CA), patients underwent a thorough preoperative examination performed by licensed and expert optometrists, including: uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) in Snellen scale, manifest refraction with and without cycloplegia (refraction method of the first and second maximum positive). Astigmatism was assessed by the Jackson cross cylinder method. These data were checked with a Wavefront Supported Custom Ablation (WASCA) and an autorefractor-aberrometer (Carl Zeiss Meditec AG, Jena, Germany). Binocular vision and accommodation were assessed in all patients. Corneal topography, white to white (WTW), anterior chamber angle width (ACAW) and anterior chamber depth (ACD) were measured and later analyzed with Pentacam single rotation Scheimpflug camera (Oculus Optikgeräte GmbH, Wetzlar, Germany). IOP and corneal biomechanics were measured with CORVIS ST (Oculus Optikgeräte GmbH, Wetzlar, Germany). Pachymetry, epithelial thickness, retinal optical coherence tomography and measurement of the distance from the posterior side of the ICL to the anterior face of the crystalline lens (vault) were measured using spectral domain optical coherence tomography (SD-OCT) (Optovue Inc., Fremont, CA). WTW and ACD were confirmed with a conventional optical biometry (PCI Technology, IOL Master 500, Carl Zeiss Meditec AG, Jena, Germany). In uncertain ACD, a third measurement was carried out with an anterior segment optical coherence tomography (Visante OCT, Carl Zeiss Meditec AG, Germany). Finally, endothelial cell density (ECD) was measured with CEM-530 non-contact specular microscopy (Nidek Co Ltd, Japan).

Surgical technique

All surgeries were performed by two experienced surgeons (F.A.A and A.S.J). Pupils were dilated with cycloplegic and phenylephrine every 15 minutes one hour prior to surgery. Eye contour was disinfected with 5% povidone-iodine (Betadine; Meda Manufacturing, Bordeaux, France) 10 minutes prior to surgery. Peribulbar anesthesia was carried out. After injecting 1% sodium hyaluronate in the anterior chamber (Provisc; Alcon Laboratories Inc, from Fort Worth, TX) ICL was implanted via a 3.0 mm corneal incision in the most curved meridian. Sodium hyaluronate was removed before finalizing the surgery. Postoperative treatment consisted of tobramycin and dexamethasone at 0.1% drops (Tobradex Alcon Laboratories Inc) and diclofenac sodium drops (Voltaren; Novartis Pharmaceuticals, Basel, Switzerland) ever six hours for the first 15 days. Posteriorly, the treatment was tapered. All cases were bilateral implantations. The second eye was conducted a week after the first

surgery. All ICL were spherical and, in case of residual astigmatism, femtosecond Laser-assisted in situ Keratomileusis (femto-LASIK) was performed to correct the remaining refraction. Flap was performed using VisuMax Femtosecond Laser System (Carl Zeiss Meditec AG, Jena, Germany). Laser pulses were applied with a pulse energy of approximately 130 nJ. The frequency of the laser was 500 KHz. The line and spot distance was 4.5 µm. The raster pattern was circular. The estimated flap thickness was 100 µm, and the flap diameter was 8.5 mm. Excimer laser was performed with MEL 90 (Carl Zeiss Meditec AG, Jena, Germany), an argon-fluoride solid-state laser. Excimer laser wavelength was 193 nm and fixation laser wavelength was 532 nm. Regarding spot scanning parameters, beam dimensions were 0.7 mm FWHM (full width at half maximum) with a Gaussian beam profile.

Statistical analysis

Statistical analysis was carried out using SPSS statistics 25.0 (IBM Corporation, Armonk, NY, USA). Visual acuity data was converted into Snellen format. Effect size was calculated using Cohen's d. Paired *t* test was used for normally distributed data. We carried out correlation analysis between preoperative and postoperative patients. A P value of less than 0.05 was considered statistically significant.

Results

Refractive Outcomes

This study included 60 eyes belonging to 30 subjects (15 females and 15 males). Mean age was 30.10 ± 6.70 [20 – 45] years. Mean preoperative spherical refraction was -9.04 ± 2.09 [-13.25 – -4.00] D. Mean preoperative cylindrical refraction was -1.20 ± 1.36 [-5.00 – -0.50] D. Mean preoperative spherical equivalent was calculated as sum of the sphere and half of the cylinder and was -9.64 ± 2.26 [-15.00 – -4.75] D. Mean CDVA was 0.84 ± 0.14 [0.50 – 1.00] in decimal scale.

Mean postoperative spherical refraction was 0.08 ± 0.47 [-0.75 – + 1.00] D, with a difference of -9.12 ± 2.20 D compared to the preoperative status. The reduction in spherical refraction was statistically significant ($p < 0.01$), with a large effect size of 5.42 according to Cohen's d. Mean postoperative cylindrical refraction was -0.26 ± 0.66 [-2.00 – + 1.25] D, with a difference of -0.94 ± 1.60 D compared to the preoperative status. The reduction in astigmatism was statistically significant ($p < 0.01$) with a large effect size of 0.87 according to Cohen's d. Residual astigmatism after spherical ICL V4c was treated with femto-LASIK. Mean postoperative spherical equivalent was -0.47 ± 0.50 [-1.00 – +1.38] D with a difference of -9.59 ± 2.45 D compared to the preoperative status. The reduction in spherical equivalent was significantly statistical ($p < 0.01$), with a large effect size of 5.86 according to Cohen's d. Decimal mean postoperative UDVA was 0.97 ± 0.16 [0.60 – 1.50]. The increase in visual acuity was 0.12 ± 0.20 in decimal scale, being statistically significant ($p < 0.01$), with a large effect size of 0.87 according to Cohen's d. The correlation analysis between these samples was not relevant nor statistically significant.

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Anterior Chamber Changes

One day vault was 553.17 ± 169.80 [268 – 975] µm and decreased to 515.67 ± 176.46 [169 – 950] µm twelve months after surgery. This means a reduction of 37.50 ± 29.10 µm ($p < 0.01$), with a small effect size of 0.22 according to Cohen's d. Mean preoperative ACAW was 36.85° ± 4.60° [26.7° – 46.8°] and decreased to 25.98° ± 3.85° [16.4° – 32.6°] twelve months after the surgery, suffering a reduction of 10.86° ± 3.42 ° ($p < 0.01$), with a large effect size of 2.56 according to Cohen’s d . Preoperative IOP was 15.37 ± 1.58 [12.0 – 18.3] mm Hg and increased to 15.61 ± 1.60 [12.0 – 19.0] mm Hg twelve months after surgery. This implies an increase of IOP of 0.24 ± 1.99 mm Hg ($p = 0.35$), although not being statistically significant and with an insignificant effect size of

0.15 according to Cohen's d. Correlation analysis between these samples was not relevant nor statistically significant.

Standardized partial regression coefficient (β) was calculated for all possible matches among all variables. Preoperative intraocular pressured (IOP) had a positive correlation with twelve-months postoperative vault ($r = 0.277$, $p = 0.03$). Preoperative spherical equivalent had a positive correlation with preoperative CDVA ($r = 0.26$, $p < 0.05$) and a negative correlation with postoperative spherical equivalent ($r = -0.29$, $p < 0.05$), one-day and twelve months vault ($r = -0.31$, $p < 0.05$ and $r = -0.315$, $p = 0.01$) and preoperative IOP ($r = -0.28$, $p = 0.02$). Postoperative spherical equivalent proved a positive correlation with one-day vault ($r = 0.319$, $p < 0.05$) and 12-months vault ($r = 0.323$, $p < 0.05$), and negative correlation with age ($r = -0.47$, $p < 0.01$). One-day and 12 months vault obtained negative correlation with preoperative cylinder ($r = -0.37$ and -0.36, $p < 0.01$ and $p < 0.01$, respectively).

Discussion

The results of our study demonstrated that vault reduced at twelve months after surgery compared to one-day postoperative vault. We also found a reduction in ACAW between preoperative and postoperative value. In addition, positive correlation was found between preoperative IOP and twelve months postoperative vault. Visual outcomes provide efficacy and safety for the ICL V4c lens.[19]

The amount of vault reduction at one year after surgery (37.50 ± 29.10 μm) showed comparable results to those reported by Alfonso et al.[11] Similar results have been reported with the non-hole V4 lens.[10] The washing of residual viscoelastic agent and the final lens position are possible explanations to the vault variations.[10, 11] Moreover, Alfonso et al.[11] stated that greater vault reductions occur in cases with higher postoperative vaults. In addition, Kojima et al.[20] described that low and intermediate postoperative vaults experienced less reduction than higher postoperative vaults. Larger ACD showed greater postoperative vault.[11, 12] Higher spherical equivalent resulted in lower vaults. The correlation found in our study between the pre-operative spherical equivalent and the postoperative vault (r = - 0.315, p = 0.14) supports this statement. ACD reduction has been previously reported[17, 21] and it is stable over time.[22] Confirming this theory, Qi et al.[13] additionally stated that low ACD showed low vault values. This ACD reduction implies a reduction in ACAW (Figure 3).[16] It is necessary to set a minimum preoperative angle value before ICL implantation. Our results revealed an ACAW reduction of 10.86° ($p < 0.01$). Elmohamady et al.[16] reported a reduction of 11.61° and Eissa et al.[17] of 14.65°. According to the Schaffer classification,[23, 24] an ACAW under 20° indicates a risk situation.

The ICL hole avoids central anterior crystalline opacity since aqueous humor can flow through the lens.[25] While Eissa et al.[17] reported an increase in IOP with V4c lens, other authors[6, 11, 16, 25] and our work found no significant changes in IOP. According to our results, there is a positive correlation between preoperative IOP and postoperative vault. In cases with high IOP, aqueous humor production in the ciliary processes would exert a pressure on the posterior lens face. Patients with higher preoperative IOP had higher vaults. This finding had not been previously reported in the scientific literature. We propose that STAAR ® Surgical formula requires an IOP correction factor. [26] Preoperative IOP data would have an effect in the final size lens calculation using the online

software. The number of eyes studied in this paper are insufficient to establish a correction factor. Within the limitations, amount of lens rise, sulcus to sulcus dimension and correlation between ICL size with these parameters were not evaluated. Since we did not have access to ultrasound microscopy technology. Future research should be aimed at evaluating sulcus to sulcus (STS) dimension by ultrasound microscopy (UBM).

In conclusion, ICL V4c lens experienced a progressive reduction of vault at twelve months after surgery and a reduction in ACAW was detected between preoperative and postoperative value. We propose to include a minimum required preoperative ACAW and an IOP correction factor on lens size calculation.

Compliance with Ethical Standards:

Funding: No funding

Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent: Informed consent was obtained from all individual participants included in the study.

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Figure legends

Figure 1. Preoperative and postoperative anterior chamber angle width (ACAW) of one case included in the study.

line figure 1

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