

Implantation of a posterior chamber phakic intraocular lens on Bruch's membrane opening-minimum rim width, retinal nerve fiber layer, and macular thickness

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Abstract

• **AIM:** To assess whether the implantation of a posterior chamber phakic intraocular lens produces changes in optical coherence tomography (OCT) measurements of macular thickness (MT) and two parameters that define the structure of the optic nerve, the peripapillary nerve fiber layer (RNFL) and the Bruch's membrane opening-minimum rim width (BMO-MRW).

• **METHODS:** This nonrandomized prospective pre-post study included 86 eyes of 48 patients (age, 20-47y; axial length: 23.10-28.95 mm) scheduled for myopia or myopic astigmatism correction with implantation of the implantable collamer lens (ICL). Eyes with glaucoma or any other ocular disease that could alter OCT results were excluded. RNFL, BMO-MRW and MT were measured preoperatively, and at 1 and 6mo after surgery using spectral-domain OCT. Changes between preoperative and postoperative values were evaluated.

• **RESULTS:** There was a significant increase in BMO-MRW at 1mo (mean change: $3.48 \pm 15.07 \mu\text{m}$, $P=0.041$). No significant changes were found during the rest of follow-

up (1-6mo postop., $P=0.623$). There was also a significant increase in RNFL thickness at 1mo after surgery ($1.45 \pm 2.18 \mu\text{m}$, $P<0.001$), but with a significant reduction from 1 to 6mo postoperatively ($P=0.002$). Regarding MT, it increased significantly at 1mo ($2.46 \pm 3.76 \mu\text{m}$, $P<0.001$), with a significant decrease afterwards ($P=0.048$). Measurements of the three parameters at 6mo were slightly superior to preoperative values ($P<0.01$).

• **CONCLUSION:** Minimal changes are induced in BMO-MRW, RNFL and MT after ICL implantation in healthy eyes, confirming the safety of the surgical procedure regarding the structure of the optic nerve head and the macula, and indicating that this phakic intraocular lens seems to have a slight impact on OCT measurements.

• **KEYWORDS:** implantable collamer lens; phakic intraocular lens; posterior chamber; macular thickness; macular edema; optical coherence tomography

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INTRODUCTION

Posterior chamber phakic intraocular lenses (pIOLs) are an effective surgical option for the correction of refractive errors, with some advantages over excimer laser correction^[1]. The most widely studied pIOL is the EVO Visian implantable collamer lens (ICL; Staar Surgical AG, Nidau, Switzerland)^[2], with a great number of clinical studies confirming the efficacy and safety of this implant for the correction of refractive errors^[3-8], even in the long-term^[9-11]. As the implantation of this pIOL is a safe procedure, complications are not very common, being coincident with those that can be found after any intraocular surgical procedure^[2,12-14]. However, low rates of complications have been reported, such as early development

of cataract, pigmentary dispersion syndrome, acute pupillary block, glaucoma, or pIOL decentration^[2,12].

Concerning the increase in intraocular pressure (IOP) after implantation of ICL, most of published studies have demonstrated that this parameter does not experience significant changes in the medium and long term^[11,15-18]. It should be mentioned that this finding has been reported with ICL models with^[15,17-18] and without AquaPort, (Staar Surgical AG, Nidau, Switzerland)^[11,16], which is a central hole included in the most recent models of ICL that facilitates aqueous humor flow and prevents pupillary block. On the contrary, a small number of studies has reported a significant increase in IOP in 5%-10% of eyes after ICL implantation^[19-20]. The main causes of early IOP increase are viscoelastic retention, steroid response and pupillary block, whereas the causes of mid-to-long term IOP rise are pigmentary dispersion and angle closure^[19-21]. It should be noted here that there are some factors that are associated with an increased risk of IOP rise after ICL implantation, such as the presence of a high vault or a narrow anterior chamber^[22-23]. Despite the potential risk of an IOP elevation after this procedure, there is a lack of scientific evidence on its safety regarding the optic nerve head (ONH) structure.

Besides potential changes in IOP, as any other intraocular surgery, ICL implantation can cause some degree of inflammation which may have an impact on the macular structure. There are very few previous studies investigating the presence of potential changes in retinal and choroidal structure measured by optical coherence tomography (OCT), showing some level of thickening of choroidal thickness, with more subfoveal choroidal changes in those eyes with a higher degree of myopia^[24-26]. In addition to this, one case has been reported showing the development of a cystoid macular edema two weeks after the surgery of ICL implantation^[27].

The objective of this study was to assess whether ICL implantation produces changes in OCT measurements of macular thickness (MT) and two parameters that define the structure of the ONH, the peripapillary nerve fiber layer (RNFL) and the Bruch's membrane opening-minimum rim width (BMO-MRW).

PARTICIPANTS AND METHODS

Ethical Approval A full explanation of the procedure and the nature of the study was provided to each patient prior to their enrolment. Written informed consent was obtained from each subject after receiving such detailed explanation and answering all potential doubts. The study was approved by the ethics committee of Hospital Universitario de Gran Canaria Dr. Negrín (Code: CEIm HUGCDN 2021-049-1) and was performed in compliance with the tenets of the Declaration of Helsinki.

Study Design This study was a nonrandomized prospective pseudoexperimental pre-post study that included patients scheduled for myopia or myopic astigmatism correction with implantation of ICL in Vithas Eurocanarias, Las Palmas de Gran Canaria, Spain.

Participants Inclusion criteria were moderate to high myopia or myopic astigmatism, age from 20 to 50 years old and indication of pIOL implantation due to the impossibility of performing an excimer laser procedure with safety. Exclusion criteria were previous ocular surgery, anterior chamber depth of less than 2.8 mm measured from endothelium, corneal endothelial cell count below 2300 cells/mm², crystalline lens opacity, more than 0.5 D of change in manifest sphere or cylinder in the last year, pregnancy, hypersensitivity to collagen, history of any systemic or ocular diseases (e.g. glaucoma, ocular hypertension, age-related macular degeneration), conditions that could alter OCT results such as peripapillary atrophy, difficulties in fixation, and corneal opacities, low quality OCT images (image quality under 15), and intraoperative or postoperative complications.

Examination Protocol A complete ophthalmologic examination was performed preoperatively in all cases including refraction, keratometry, monocular uncorrected and corrected distance visual acuity, Goldmann applanation tonometry, slit lamp examination, corneal topography (Pentacam Scheimpflug Image System, Oculus Inc. Wetzlar, Germany), optical biometry (IOL Master[®] 700, Carl Zeiss Meditec, Jena, Germany), funduscopy and retinal and ONH analysis by OCT (Spectralis-Glaucoma Module Premium Edition, Heidelberg Engineering, Carlsbad, USA). Circle and radial scans were acquired to provide RNFL and BMO-MRW measurements, respectively, as well as horizontal scans to provide MT measurements. The circle and radial scans were centered on the Bruch's membrane opening. Likewise, all scan types were aligned according to the fovea-to-BMO-center axis using the automated anatomical positioning system scan feature. Manual correction of the automated segmentation was not performed in any case. The analysis of MT, RNFL and BMO-MRW was selected as it allows a characterization of the structural status of the macula and the ONH. It should be considered that the Bruch's membrane opening was recently found to be the true anatomical border of the optic disc, being the parameter BMO-MRW an accurate measurement of the neuroretinal rim and consequently a key parameter to detect structural damage in the ONH^[28-29].

All patients underwent comprehensive visual acuity, refraction and slit lamp examination one day, one week, one month, and six months after surgery. Likewise, automated anatomical positioning-based OCT scans were repeated one month and six months after surgery using the automatic "follow-up" mode

to obtain MT, RNFL and BMO-MRW measurements. This mode was used to ensure that all postoperative measurements were done in the same position as preoperatively. Furthermore, IOP was assessed by Goldmann tonometry one month and six months after surgery.

Surgical Procedure All pIOL implantations were performed by the same experienced surgeon under topical anaesthesia. After sterilization of the periocular skin and conjunctival sacs using diluted iodine povidone, preparation of the pIOL and introduction into the cartridge, a paracentesis was done at 90°, lidocaine (dilution 1%) was introduced through this incision and then the viscoelastic agent to fill the anterior chamber. Then, a 3-mm clear corneal incision was performed temporally. After this, the extreme of the cartridge was introduced through the incision and the pIOL was then unfolded in front of the iris. With the use of a Romano manipulator, the haptics of the pIOL were placed carefully behind the iris, initiating this procedure for the more distal haptics. In case of toric ICL, Verion image-guided system (Alcon Laboratories, Inc., Fort Worth, USA) was used to achieve the desired positioning. After ensuring a proper positioning of the pIOL, the viscoelastic agent was completely aspirated with the irrigation/aspiration handpiece and intraoperative miosis was induced with the use of intracameral acetylcholine. Finally, intracameral antibiotic was instilled (cefuroxime 1 mg/0.1 mL in patients without allergy to penicillin and vancomycin 1 mg/0.1 mL in case of allergy) and corneal incisions were hydrated. A postoperative prophylactic treatment was prescribed in all patients consisting of topical application of antibiotic (ofloxacin 3 mg/mL eyedrops 4 times a day for 10d), nonsteroidal antiinflammatory drugs (bromfenac 0.9 mg/mL eyedrops twice a day for 1mo), steroid (dexamethasone 1 mg/mL eyedrops 4 times a day for 10d, twice a day for 7d, once a day for 7d), and artificial tears.

Statistical Analysis The statistical data analysis was performed using the software SPSS version 22.0 for Windows (SPSS, Chicago, Illinois, USA). Normality of all data distributions was initially evaluated by means of the Kolmogorov-Smirnov test. For all measured variables, average (mean value), standard deviation (SD), median and minimum and maximum values were provided. The paired Student *t*-test was used to assess the significance of differences between consecutive visits if data samples were normally distributed. Otherwise, the Wilcoxon ranked sum test was used to assess such significance. A *P*<0.05 was considered as the criterion for statistical significance.

RESULTS

A total of 86 eyes (44 right and 42 left eyes) of 48 patients with mean age of 32.2±6.2 (median: 31.5, range: 20 to 47y) were enrolled. The sample comprised 11 males (22.9%) and 37 females (77.1%). Toric models of the pIOL implanted were

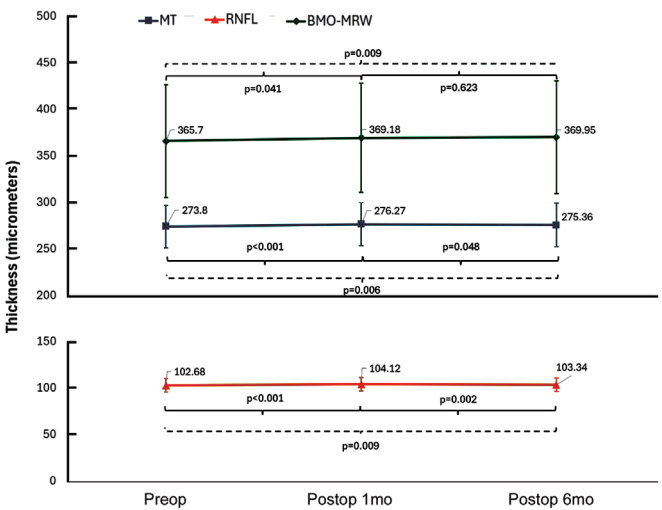


Figure 1 BMO-MRW, RNFL and MT at all visits in the sample evaluated BMO-MRW: Bruch's membrane opening minimum rim width; RNFL: Peripapillary retinal nerve fiber layer; MT: Macular thickness; Preop: Preoperative; Postop: Postoperative. Data are reported as mean±SD.

Table 1 Summary of preoperative data of eyes included and evaluated in the current study

Parameters	Mean±SD	Median (range)
Age (y), n=48	32.2±6.2	31.5 (20 to 47)
Manifest sphere (D)	-6.62±2.69	-6.38 (-12.50 to 0.00)
Manifest cylinder (D)	-1.23±0.91	-1.00 (-3.75 to 0.00)
CDVA logMAR	0.01±0.04	0.00 (0.00 to 0.22)
IOP (mm Hg)	14.0±2.7	14.0 (9.0 to 21.0)
AXL (mm)	25.88±1.18	25.94 (23.10 to 28.95)
ACD (mm)	3.76±0.30	3.75 (3.28 to 4.56)
Spherical power pIOL implanted (D)	8.68±2.82	8.50 (0.50 to 15.50)
Cylinder power pIOL implanted (D)	0.77±1.08	0.00 (0.00 to 4.00)
pIOL diameter (mm)	12.87±0.37	13.20 (12.1 to 13.2)

SD: Standard deviation; D: Diopters; CDVA: Corrected distance visual acuity; IOP: Intraocular pressure; AXL: Axial length; ACD: Anterior chamber depth; pIOL: Phakic intraocular lens.

needed in 36 eyes (41.9%). Table 1 shows the preoperative characteristics of the sample evaluated.

At the end of the follow-up, there was a significant reduction of manifest refraction (*P*<0.001) and a small in magnitude but statistically significant improvement in corrected distance visual acuity (postop logMAR value: mean 0.00, SD 0.03, median 0.00, range: 0.00 to 0.22, *P*=0.02). Likewise, IOP at 6mo after surgery was significantly lower than preoperatively although the magnitude of the difference was small (postop IOP: mean 13.3 mm Hg, SD 3.0, median 13.0, range: 8.0 to 22.0 mm Hg, *P*=0.003). Mean vault of the pIOL evaluated at 6mo after its implantation was 0.49 mm (SD: 0.21, median: 0.47, range: 0.10 to 1.02 mm).

Regarding changes in OCT parameters, they are represented in Figure 1. There was a significant increase in BMO-MRW at 1mo after surgery (*P*=0.041), although the magnitude of the

Table 2 Summary of changes detected in the OCT parameters evaluated during the follow-up

Mean±SD; median (range)

Parameters	Change preop-1mo	$P_{\text{preop-1mo}}$	Change postop 1mo-6mo	$P_{\text{preop-6mo}}$	P (change postop 1mo-change postop 6mo)
MT (μm)	2.46±3.76; 3.00 (-6.00 to 12.00)	<0.001	1.55±4.05; 1.50 (-6.00 to 13.00)	0.006	0.062
RNFL (μm)	1.45±2.18; 1.00 (-3.00 to 6.00)	<0.001	0.70±1.98; 1.00 (-5.00 to 5.00)	0.010	0.002

SD: Standard deviation; MT: Macular thickness; RNFL: Peripapillary retinal nerve fiber layer; Preop: Preoperative; Postop: Postoperative.

change was small. No significant changes were found during the rest of follow-up (postop. 1-6mo, $P=0.623$). There was also a significant increase in RNFL thickness at 1mo after surgery ($P<0.001$), but with a significant reduction from 1 to 6mo postoperatively ($P=0.002$). Regarding MT, a similar behaviour was observed; there was a significant increase in MT at 1mo postoperatively ($P<0.001$), and a significant decrease afterwards ($P=0.048$). At 6mo, measurements of BMO-MRW, RNFL and MT remained slightly over baseline measurements. These small differences were statistically significant as well ($P<0.01$; Figure 1).

Table 2 shows the mean changes detected in BMO-MRW, RNFL and MT at 1 and 6mo after surgery. As shown, mean magnitude of changes was small although most of them reached statistical significance. There was an increase during the first month in BMO-MRW, RNFL and MT ($P=0.041$, $P<0.001$, and $P<0.001$, respectively), and there was an increase as well after 6mo ($P=0.009$, $P=0.010$, and $P=0.006$, respectively), which was less pronounced than that observed after the first month. The measurements of the three parameters at 6mo were slightly superior yet almost identical to baseline measurements.

DISCUSSION

Several studies have demonstrated that some changes can occur in OCT parameters after intraocular surgery such as cataract surgery with IOL implantation^[30-34]. Specifically, our research group found in previous studies a slight increase in the measurements of BMO-MRW, RNFL and MT at 1 and 6mo after femtosecond laser-assisted cataract surgery (FLACS) and concluded that this surgical procedure did not have a negative impact on the ONH structure^[30,32]. Likewise, the same trend was observed in eyes undergoing conventional cataract surgery^[30]. Both in the case of FLACS and in the case of conventional cataract surgery, the increase observed in the three OCT parameters after surgery was more pronounced than that observed after ICL implantation in the present study. However, more research is needed in terms of the impact of other refractive intraocular surgeries, and specifically on the impact of different types of IOLs, such as pIOLs, on retinal, ONH and choroidal structure. It should be noted that this type of implants is commonly used in highly myopic eyes that are predisposed to the development of some retinal problems as well as glaucoma^[21,35-36]. To this date, some studies have reported some macular and choroidal changes after

implantation of ICL, especially in eyes with higher degree of myopia^[24-26], but potential changes in RNFL and BMO-MRW had not been analysed. The current study was aimed at investigating such changes, with a comprehensive analysis of longitudinal changes in MT, RNFL and BMO-MRW during a 6mo follow-up after ICL implantation.

In our series, a mean increase in MT of 2.46±3.76 and 1.55±4.05 μm was observed at 1mo and 6mo after ICL implantation, being these increases statistically significant. These changes were slightly higher than those reported on average by Zhu *et al*^[25] who evaluated retinal changes during a 3-month follow-up after ICL implantation using another OCT technology in a sample of younger subjects. Several factors may account for this increase in MT such as a minimal or subclinical inflammatory response after surgery. Yu *et al*^[37] proved that some degree of flare can still be found months after cataract surgery, indicating that this procedure causes a mild inflammatory response that lasts not only in the short-term but also in the mid-term. Furthermore, Xu *et al*^[38] carried out some research in an experimental rodent model, finding out that cataract surgery elicited pro-inflammatory gene expression and protein secretion in the posterior segment of the eye. This could explain, at least partially, the changes in MT observed after cataract surgery^[37-38]. Different types of intraocular surgery may cause different degrees of postoperative inflammation. FLACS seems to cause less inflammatory response than conventional cataract surgery^[37,39]. To date, this has not been investigated after ICL implantation. Nevertheless, some degree of flare should be expected after ICL implantation as well, though it might be of lower intensity. This could justify the fact that the present study found the same trend in postoperative measurements of MT—initial increase and then a slow decrease towards baseline values—as previous studies performed in eyes undergoing cataract surgery, with a difference only in the magnitude of the change. It should be considered that an additional lens with a specific refractive index has been introduced within the eye that might modify the calculations performed to obtain the measurements obtained with this optical method. Comba *et al*^[40] found that the mean signal strength index of the peripapillary and macular scans obtained in the eyes implanted with both monofocal and trifocal IOLs were statistically less than those found in a control group. However, achieving correctly focused OCT scans in myopic eyes may be facilitated by the reduction

of diopters caused by the implantation of a pIOL, and this may have an influence on the quality of these scans. More research on the optical impact of IOLs on OCT scans should be performed to extract more consistent conclusions. A similar trend to small but significant increase in MT was also reported by our research after cataract surgery, although the magnitude of changes was somewhat higher^[30,32].

Concerning RNFL, a mean increase of 1.45 ± 2.18 and 0.70 ± 1.98 μm was observed at 1mo and 6mo after ICL implantation in our series. Although these changes were statistically significant, they were of small magnitude and within the measurement error range of the instrument. It should be considered that the test-retest variability for the Spectralis OCT RNFL measurements is 4.95 μm ^[40]. Potential contribution of a subclinical inflammatory process may have also contributed to this RNFL thickening^[41]. It should be noted here that RNFL changes following the same trend reported here have been also found after cataract surgery, although the magnitude of the variation was higher compared to that found in the current study. Our research group^[30] reported a mean increase in RNFL thickness of 1.88 μm (1.33 to 2.42) and 4.72 μm (2.5 to 6.94) in eyes undergoing FLACS and conventional cataract surgery, respectively. Nevertheless, it should also be considered that crystalline lens is removed and the IOLs implanted are different, moreover, in some cases they can be multifocal, and this may be related to the greater magnitude of the changes seen after cataract surgery. To the best of our knowledge, only one study has addressed this topic, concluding that a trifocal IOL caused a greater postoperative change in RNFL than a monofocal IOL^[33].

Finally, changes in BMO-MRW were also investigated as it provides valuable information on the structural status of the ONH^[28-29]. According to some authors, this OCT parameter is able to detect minimal changes in the ONH structure, allowing the identification of incipient glaucomatous damage even earlier than the RNFL^[42]. In our sample, a mean increase of BMO-MRW of 3.48 ± 15.07 and 4.25 ± 11.80 μm was observed at 1mo and 6mo after ICL implantation, respectively. This increase in BMO-MRW is less pronounced than that reported after FLACS and conventional cataract surgery, with a mean magnitude of change over 12 μm ^[30,32]. As previously mentioned, this minimal trend to thickening could be the result of some level of subclinical intraocular inflammation and related to the fact that an IOL has been implanted. However, the range of measurement error of this parameter should be also considered. Park *et al*^[43] evaluated the reproducibility of BMO-MRW measurement with same OCT technology used in the current series and found mean intravisit repeatability indices of 2.94 and 3.70 μm in healthy and glaucoma patients, respectively. The change detected in our series is somewhat

higher than the repeatability coefficient, suggesting that the trend to an increase in BMO-MRW is real. In addition to this, and accordingly to the postoperative changes observed in RNFL and MT, the fact that 6mo after surgery, when postoperative inflammation is deemed to be resolved, the OCT measurements remained slightly over baseline values, may be related to the optical properties of the IOL implanted. Also, the postoperative changes in IOP must be considered. Glaucoma surgery usually causes drastic reductions in IOP, and this can lead to changes in the appearance of the optic disc called “optic disc cupping reversal”. It has been proposed that the cause of the increase in BMO-MRW found after cataract surgery could be the decrease in the IOP observed postoperatively, as it may have some expanding effect on the neuroretinal rim similar - though less marked - to that observed after glaucoma surgery^[30,32]. In those studies, the IOP decreased after cataract surgery between 2.39 and 2.93 mm Hg. Despite the lack of clinical relevance of this change, the possibility of a slight but actual impact on OCT measurements could not be ruled out. Nonetheless, in the present study, the IOP decrease after surgery was minimal (from the preoperative mean of 14.0 ± 2.7 mm Hg to the postoperative mean of 13.3 ± 3.0 mm Hg). Therefore, the chances of this IOP reduction to be the cause of any changes in OCT measurements are very small.

The present study is the first to investigate the changes in BMO-MRW, RNFL and MT after ICL implantation. The fact that in most of the comparisons the differences reached statistical significance indicates that small changes in these OCT parameters do occur postoperatively. A longer follow-up would be desirable, as well as an objective measurement of the postoperative inflammation (*e.g.* postoperative cells and flare), and also studies comparing the postoperative behavior of OCT measurements after implantation of different types of IOL.

In conclusion, the implantation of the posterior chamber pIOL ICL does not seem to cause any deterioration in the structural status of the macula and ONH in healthy eyes, confirming the safety of the surgical procedure. Slight increases were detected in BMO-MRW, RNFL and MT compared to the preoperative values. Further studies are necessary to assess potential long-term changes in these three parameters after ICL implantation and to define the exact relationship between different types of IOL and postoperative changes in OCT measurements.

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