• Clinical Research •

Comparison of preoperative simulated and postoperative real safety distances using anterior segment OCT in patients with phakic IOL according to iris configuration

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Abstract

● **AIM:** To compare the simulated safe distance (SSD) preoperatively versus real safe distance (RSD) postoperatively in patients with iris-claw phakic intraocular lens (pIOL) implantation according to iris configuration.

● **METHODS:** Totally 60 eyes of 60 patients underwent pIOL implantation for surgical correction of myopia. Anterior chamber depth (ACD) was measured with the IOLMaster 700, and nasal and temporal safety distances (SD) were measured pre- and postoperatively using Anterior Segment Visante-OCT. SD was defined as a line measured between the edge of the optic or its simulated image to the endothelium. Eyes were divided into 3 groups: convex, concave, and plane according to preoperatory iris configuration. Statistical analysis was performed using the R program, for the comparison of independent groups and multiple comparisons, the Kruskal-Wallis test and the Dunn test were used respectively.

● **RESULTS:** Mean difference between nasal preoperative SSD and postoperative RSD was -0.36±0.38, -0.29±0.48, and -0.18±0.30 mm in the concave, convex, and plane group, respectively. Mean difference between temporal SSD and RSD was -0.36±0.37, -0.14±0.38, and -0.24±0.33 mm in the concave, convex, and plane group, respectively. There were statistically significant differences between SSD and RSS for both nasal and temporal sides in the concave and plane group (P<0.002).

● **CONCLUSION:** Preoperative SSD and postoperative RSD for iris-claw pIOL shows significant differences in patients with concave and plane iris.

● **KEYWORDS:** simulated safe distance; refractive surgery; refractive phakic intraocular lens; anterior segment OCT

INTRODUCTION

The implantation of phakic intraocular lens (pIOL) has become a popular surgical technique for treating refractive errors due to the reversibility of the procedure[1], excellent refractive and visual results[2-3], easy handling of residual postoperative error[4], and safety[5]. Yet, the potential damage for endothelial cells is a major concern in this type of pIOLs; while the normal endothelial cells loss per year is 0.6%±0.5%[5] in long-term studies evaluating the efficacy and safety of the Artiflex pIOL, the total endothelial cell loss (ECL) can be considerable, reaching up to 21.5% in 10y postoperatively[6-9]. Corneal decompensation has been reported after pIOL implantation, related to the considerable ECL[10-12], likewise, ECL has been reported to be the second cause of explantation of pIOL[13].

Nowadays, several inclusion criteria have been suggested to preserve endothelial cell count (ECC) after implantations, such as central anterior chamber depth (ACD) greater than 2.8 mm (from endothelium to anterior surface of crystalline lens)[14], 3.2 mm[15] or 3.35 mm[16], central ECC greater than 2300 cells/mm^2, and for myopic artisan endothelial safe distance or peripheral endothelial clearance greater than 1.5 mm[15].

The peripheral endothelial clearance or safe distance is the distance from the endothelium to the peripheral edge of the iris-claw pIOL. It can be assessed in two ways: preoperatively (simulated safe distance, SSD) using a software that simulates the pIOL before surgery with anterior segment optical coherence tomography (AS-OCT) or Scheimpflug devices[15], and postoperatively (real safe distance, RSD) measuring in real time the pIOL in the eye. In some studies, safe distance was measured using the template of the AS-OCT system

for preoperative simulation; those studies have shown no significant differences from the preoperative simulation to the corresponding postoperative measurements when the simulator was placed on the middle of the iris tissue, suggesting that pIOL template of the AS-OCT system for preoperative simulation of iris-fixated pIOLs improves the criteria for patient selection[15]. To the best of our knowledge there is no information about testing the results accuracy in different types of iris configuration.

The purpose of this study is to assess the compatibility between the SSD and RSD in patients with concave, plane and convex iris after pIOLs implantation.

SUBJECTS AND METHODS

Ethical Approval This was a prospective, cohort study that included 60 eyes of 60 patients who underwent iris-claw pIOL implantation (Artisan, Ophthec) for surgical correction of myopia at Oftalmosalud Instituto de Ojos, Perú, between July 2016 to July 2018. The study complied with the Declaration of Helsinki. The ethics committee and Institutional Review Board of Oftalmosalud approved the study. Written informed consent was obtained from all patients agree to participate in the study protocol.

Inclusion criteria were ACD greater than 3.2 mm (measured from the corneal epithelium to the lens), stable refraction (less than 0.5 D change in 6mo), endothelial cell density greater than 2300 cells/mm^2, mesopic pupil less than 6.0 mm, patient age 18 years or older, no contact lens use, no previous ocular surgeries or laser treatments, no ocular trauma, no corneal abnormalities or other ocular pathologies (dry eye, corneal ectasia, glaucoma, cataract, history of retinal detachment *etc.*), and no systemic diseases. If patients had bilateral implantation only one eye randomly selected was included in the study. Preoperatively, all subjects underwent a complete ophthalmologic examination at pre- and 3mo postoperatively including: uncorrected and best corrected distance visual acuity (UCVA and BCDVA respectively), manifest and cycloplegic refraction, slit-lamp evaluation, corneal topography and pachymetry (Galilei G6 Port, Switzerland, software version V6.4.2), specular microscopy (SM-NIDEK CEM-530; Gamagori, Aichi, Japan, software version V1.11.02), optical biometry (IOLMaster 700, Carl Zeiss Meditec AG, Jena, Germany, software version 1.70.12.53128) and AS-OCT (VISANTE model 1000; Carl Zeiss Meditec, Dublin, CA, USA, software version 3.0.1.8). All examinations were performed by the same researcher (Camino-Quezada M). pIOL power calculations were performed using the Van der Heijde formula[7]. ACD was measured with the IOL Master 700 (Carl Zeiss Meditec AG, Jena, Germany).

Measurement of the Safety Distance and Iris Configuration The safety distance was defined as the distance between the edge of the optic to the endothelium (expressed in mm) using AS-OCT Visante software calipers at 45°. Temporal and nasal safe distances were recorded separately. Preoperatively, pIOL simulation was performed using the pIOL template of the AS-OCT system. The Artisan simulator was placed in the middle of the iris tissue and the posterior surface of the haptic was placed halfway between the anterior border of the iris (line passed anteriorly from thinnest portion of iris) and the posterior pigmented epithelium. Using the software calipers, the SSD assessed preoperatively and postoperative RSD (at 1mo postoperative) were measured. All surgeries were performed by the same surgeon (Izquierdo L Jr). Comparisons were performed between the SSD and the RSD for both nasal and temporal sides.

Iris configuration was measured preoperatively, with AS-OCT Visante at 0°-180° and classified into 3 groups: convex, concave, and plane. As the iris configuration may vary from frame to frame in different image capture, the midpoint between the iris root and the iris tip was selected as the reference landmark, in order to reduce the measurement variability of iris bowing[8]. Iris bowing was defined as the perpendicular distance from the iris pigment epithelium to a midpoint between the iris root and the iris tip. If the measurement line coincides with the horizontal line from the scleral spur to the scleral spur with the pigment epithelium of the iris (Figure 1A) the iris was considered as plane; if the line of measurement was posterior to the iris pigment epithelium (Figure 1B), the iris bowing was considered as positive, and the iris was convex. If the line of measurement was anterior to the iris pigment epithelium (Figure 1C), the iris bowing was considered as negative, and the iris was concave[8]. All examinations were performed by the same researcher.

Statistical Analysis The R version statistical package 3.4.1 [Freely available software under the terms of the Free Software Foundation's General Public License (https://www.r-project.org/)] was used for the statistical analysis. For the comparison of independent groups, the Kruskal-Wallis test was used. The Dunn test was used for multiple comparison tests after the Kruskal-Wallis test, differences were considered statistically significant at a P value <0.05.

RESULTS

The average patient age was 31.75y (range 20-46y). There were 24 males (40%) and 36 females (60%). Table 1 shows the preoperative and postoperative data of the studied population.

According to preoperative evaluation, there were 26.6% (16/60), 18.33% (11/60), 55% (33/60) eyes in the concave, convex and plane group respectively. Preoperative temporal SSD was 1.79±0.37 mm and postoperative RSD was 1.55±0.31 mm (P<0.001). Preoperative nasal SSD was 1.75±0.38 mm and postoperative RSD was 1.48±0.29 mm (P<0.001).

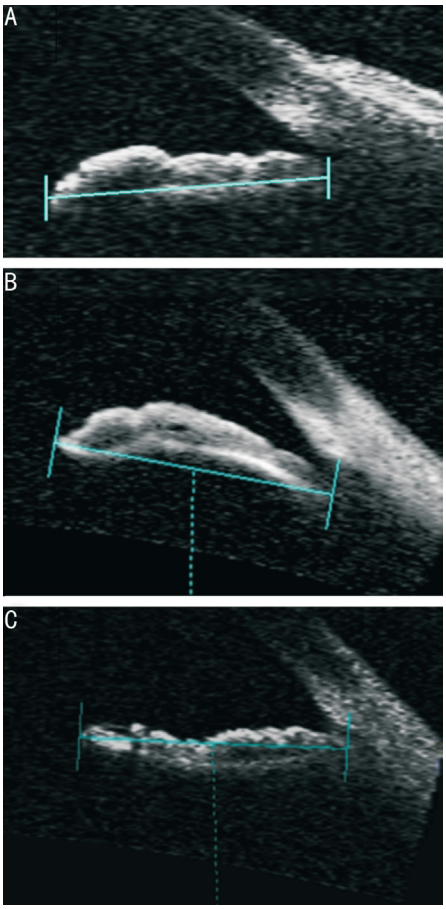

Figure 1 Example of iris configuration assessment A: Iris plane, line coincides with the horizontal line from the scleral spur to the scleral spur with the pigment epithelium of the iris; B: Iris convex, the line of measurement was posterior to the iris pigment epithelium; C: Iris concave, line of measurement was anterior to the iris pigment epithelium.

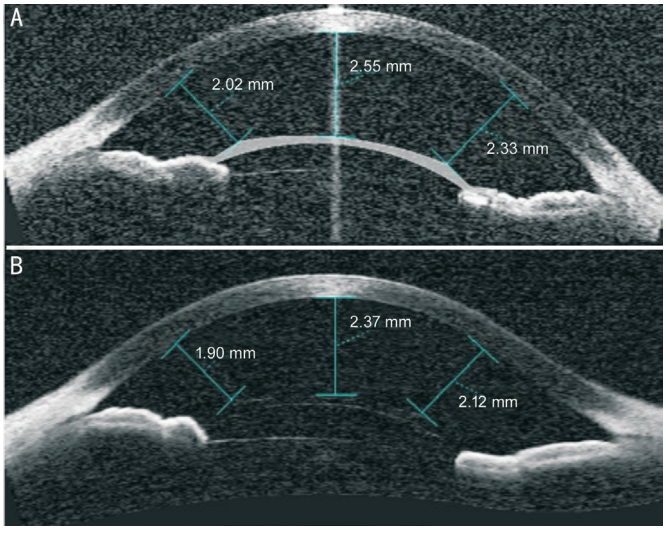

Figure 2 Simulated safe distance (A) and real safe distance (B) in a patient with concave iris Nasal preoperative SSD was 2.02 mm and postoperative RSD was 1.90 mm. Temporal preoperative SSD was 2.33 and postoperative RSD was 2.12 mm.

Mean difference between temporal SSD and RSD was -0.36±0.37, -0.14±0.38, and -0.24±0.33 mm in the concave, convex, and plane groups, respectively. Mean difference between nasal SSD and RSD was -0.36±0.38, -0.29±0.48, and -0.18±0.30 mm in the concave, convex, and plane groups, respectively. Statistically significant differences between SSD and RSD (for both nasal and temporal) were found in the concave and plane groups. Table 2 shows pre- and postoperative safe distances for each group and Figure 2 shows SSD and RSD in a patient with concave iris, in which nasal postoperative RSD was 120 μm lower than preoperative SSD and temporal postoperative RSD was 210 μm lower than preoperative SSD.

Table 1 Pre- and postoperative values of each variable in the studied population

Parameters	Preop.	Postop.	[a]*P*
Age (y)	31.75±7.58	31.75±7.58	-
ACD (mm)	2.19±0.36	2.10±0.39	0.2878
CCT (μm)	524.57±34.07	514.30±36.96	0.1416
Sphere (D)	-9.78±4.43	0.10±0.49	<0.001
Cylinder (D)	-2.16±1.32	-1.00±1.12	<0.001
ECC (cells/mm^2)	2723.60±226.62	2494.85±316.83	<0.001

ACD: Anterior chamber depth; SSD: Simulated safe distance; RSD: Real safe distance; CCT: Central corneal thickness; ECC: Endothelial cells count; [a]Wilcoxon rank sum test.

Table 2 Preoperative simulated and postoperative real safe distance in the studied groups mean±SD, mm

Iris configuration	Preop. simulation	Postop. real	Mean difference	[a]*P*
Nasal				
Concave	1.96±0.29	1.60±0.27	-0.36±0.38	0.001
Convex	1.61±0.49	1.32±0.30	-0.29±0.48	0.322
Plane	1.69±0.34	1.51±0.28	-0.18±0.30	0.002
Temporal				
Concave	2.05±0.35	1.69±0.34	-0.36±0.37	0.001
Convex	1.57±0.35	1.43±0.34	-0.14±0.38	0.322
Plane	1.76±0.31	1.52±0.28	-0.24±0.33	0.001

Preop.: Preoperative; Postop.: Postoperative. [a]Wilcoxon signed rank test with continuity correction.

Table 3 shows the lower coefficient of correlation of concordance found for all groups, meaning that SSD change after pIOL implantation. Figure 3 shows Bland Altman plots for the differences between the SSD and RSD in eyes with iris concave, plane and convex respectively.

ECC had a significant decrease in all groups, Table 4 shows the mean decrease in ECC in each group; it was 305.6±348.4, 197.2±185.9, and 204.8±192.9 μm in the concave, convex and plane group respectively.

DISCUSSION

According to the European Multicenter Study of Artisan

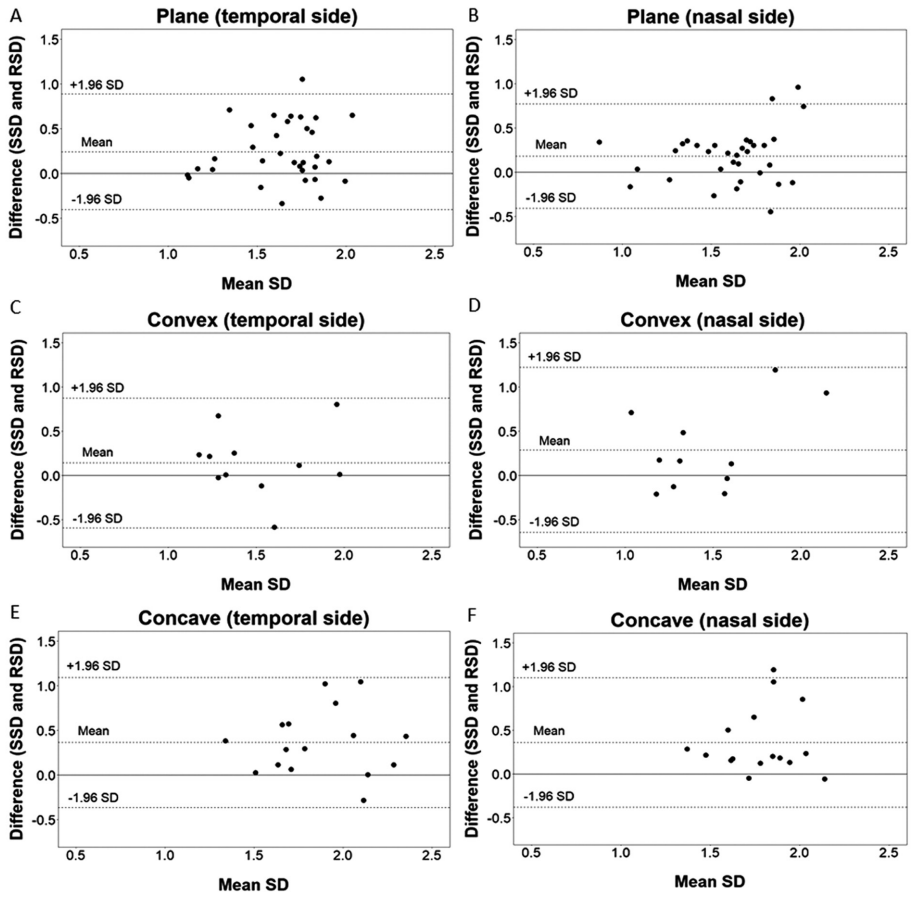

Figure 3 Bland Altman plots, for the differences between SSD and RSS for iris concave, plane, and convex.

Table 3 Lin's concordance correlation coefficient for preoperative simulated safe distance and postoperative real safe distance

95%CI

Iris type	Nasal SSD *vs* RSD CCC	Temporal SSD *vs* RSD CCC
Concave	0.053 (-0.221, 0.319)	0.257 (-0.072, 0.536)
Convex	0.240 (-0.210, 0.606)	0.367 (-0.213, 0.756)
Plane	0.458 (0.193, 0.660)	0.282 (-0.026, 0.503)

CCC: Lin's concordance correlation coefficient; SSD: Simulated safe distance; RSD: Real safe distance.

Table 4 Mean decrease on endothelial cells count in each group according to iris configuration

μm

Iris configuration	Mean decrease	Range	*P*
Concave	305.6±348.4	65-989	0.003
Convex	197.2±185.9	87-567	0.002
Plane	204.8±192.9	126-682	<0.001

pIOL[4] and to the U.S. Food and Drug Administration Ophtec Study[4], the rate of ECL after iris-claw pIOL implantations is not significantly different from the normal ECL of 0.6% per year[6]. However, recent studies with long term follow up showed a significant loss of endothelial cells 2.9% to 9.1% at 6y, and 12% at 10y after pIOL implantations[5-6]. ACD is one of the main factors in central ECC decay after anterior chamber pIOL implantations[16-19].

In 2006, Baïkoff[20] proposed that the minimum safe distance between the edge of the optical zone of the pIOL and the endothelium, as measured by AS-OCT, should be greater than 1.5 mm to minimize the risk of ECL. In fact, in myopic Artisan pIOL, the peripheral endothelial clearance or safe distance seems to be more important than the ACD because the thickness of iris-fixated pIOLs differs according to their power[17].

Peripheral endothelial clearance can be assessed pre- and postoperatively; preoperatively (SSD) using a template that simulated the future position of the pIOL. Studies have been conducted to test if the software or template is effective in predicting the postoperative peripheral RSD with different results. Doors *et al*[6] used the Visante AS-OCT system in 60 eyes for preoperative simulation, they placed the pIOL simulator in the middle of the iris tissue and found that the measured edge distances were significant smaller in the preoperative simulation than in the postoperative images. Fallah Tafti *et al*[15], using AS-OCT compared preoperative simulation versus real postoperative measurements after iris-fixated pIOL using two different techniques for positioning the template: in one the simulator was placed on the posterior pigmented epithelium of the iris and in the other the simulator was placed in the middle of the iris tissue and found that

only when the simulator was placed in the middle of the iris tissue the results were not statistically different from the corresponding postoperative measurements. These differences could be a result of not only the localization of the pIOL template over the iris (middle versus posterior), but also due to the iris configuration of the patients.

In our study we implemented the technique of placing the simulator on the middle of the iris, in which no differences were found between pre- and postoperative evaluation as Fallah Tafti *et al*[15] suggested, however, we found that SSD overestimated the RSD in 0.26 mm (range 0.14-0.36 mm). Significant differences were found between preoperative SSD and RSD for both nasal and temporal sides in eyes with iris concave and plane.

Considering that significant statistical differences were found only in the plane and concave iris groups, and not in the convex iris group, we can hypothesize that our results are associated with the behavior of the iris when the pIOL is implanted. Thus, we believe that in cases of plane or concave irises, the traction created by the pIOL can change the position of the iris to be more anterior. This phenomenon could not happen with a convex iris because it has an anterior configuration. Our results show a greater change in the concave iris group than in the plane iris group; safe distance was reduced in the plane iris group by -0.18±0.30 and -0.24±0.33 mm in the nasal and temporal sides, whereas in the concave group the safe distance was reduced by -0.36±0.38 and -0.36±0.37 mm in the nasal and temporal sides, reinforcing our hypothesis. Also, despite all groups had significant decrease on ECC, the group with higher amount of decrease was observed in the concave group followed by the plane group and the convex group.

Our study has some limitations: the caliper for RSD measurements was placed manually. However, the same operator performed all measurements and followed the same measurement criteria (45 degrees) to minimized errors in the measurements. Also, our study has a small sample size. We are collecting more data for subsequent analysis. However, our results show that the SSD assessed preoperatively by AS-OCT can be overestimated in patients with concave and plane iris configuration and this must be taken in consideration when forming an inclusion criterion for pIOL implantation. We recommend surgeons to be aware of the SSD in this group of patients and evaluate the RSD in the short postoperative follow-up.

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Conflicts of Interest: Henriquez MA, None; **Camino-Quezada M,** None; **Ben-Shaul O,** None; **Izquierdo L Jr,** None.

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