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Research Article

Artisan and artiflex phakic intraocular lenses for high ametropia: long-term results

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Abstract

Objective: To evaluate the long-term refractive and visual outcomes in patients undergoing Artisan or Artiflex phakic intraocular lens (pIOL) implantation for high ametropia.

Methods: A retrospective cohort study. Myopic and hyperopic patients seeking refractive correction who could not undergo or could not have fully correction with corneal refractive surgery were submitted to pIOL implantation. Baseline characteristics and postoperative outcomes were reported for patients who completed the minimum follow-up of twelve months between January 1999 and December 2018. The report included refractive outcomes and spherical equivalent (SE) power, surgeries performed to achieve emmetropia, endothelium cell density and complications.

Results: The study evaluated 195 eyes, with a mean follow-up of 84.86 ± 56.19 months. The majority of patients underwent myopic correction (175/195, 89.74%). Fifty-six (56/175, 30%) and 6 (6/20, 30%) patients underwent corneal refractive surgery after pIOL (Bioptics) to correct any residual refractive errors in the myopic and hyperopic groups, respectively. The mean pre-operative SE was -13.06 ± 3.64 D in the myopic and +8.01 ± 2.55 D in the hyperopic group. A final SE of ± 2.0 diopters (D) was achieved in 91.4% and 95% of the myopic and hyperopic groups, respectively. Cataract was the most frequent complication, followed by glaucoma and uveitis. There was significant endothelial cell loss in the myopic patients ($p<0.001$), although no clinical corneal edema had developed by the time of the follow-up.

Conclusion: Phakic intraocular lenses are effective in refractive corrections and can be an invaluable option for patients meeting the inclusion criteria.

Keywords: Phakic intraocular lens, Myopia, Hyperopia, Artisan, Artiflex

Introduction

Phakic intraocular lenses have been available as an option for the treatment of refractive errors in eyes whose corneal surgical procedures such as photorefractive keratectomy (PRK), laser in situ keratomileusis (LASIK) or small incision lenticule extraction (Smile) are formally contraindicated or unacceptable [1-3]. Although corneal refractive surgery offers a suitable quality of vision and more predictable correction for low and moderate levels of ametropia [2,3], corneal surgery for higher levels of ametropia has inadequate results in terms of performance and visual quality because of significant changes in corneal curvature (excessive flattening or steepness) and the consequent high order aberrations. The loss of accommodation in young patients and the significantly higher risk of retinal detachment in myopic patients set the clear lens extraction as not the first option for visual correction in patients without cataracts [3-5].

The available options for phakic intraocular lenses, there were the angle-supported anterior chamber which have been discontinued; the posterior chamber lenses or pre-crystalline intraocular 'contact lenses' (ICL), that may be associated with higher incidence of cataracts; and iris-fixated lenses (e.g., Artisan and Artiflex), which are fixated in the middle periphery of the iris, with a safe distance from corneal endothelium and crystalline lens [2,6-9]. Artisan is a single piece PMMA lens with an optical zone of 5.0 or 6.0 mm and a total diameter of 8.5 mm (Figure 1). The lens power ranges from +1.00 D to +12.00 D for hyperopia and from -3.00 D to -23.50 D for myopia [10,11]. The Artisan implant is a rigid lens and requires a large incision depending on the optical zone. The foldable model, the Artiflex, has an optic composed of hydrophobic polysilicone and PMMA haptics with a 6.0 mm optic zone and 8.5 mm total diameter, and it is implanted through a 3.2 mm incision (Figure 2). It is only available for myopic correction with a lens power ranging from -2.00 D to -14.50 D [2,10]. It is also possible

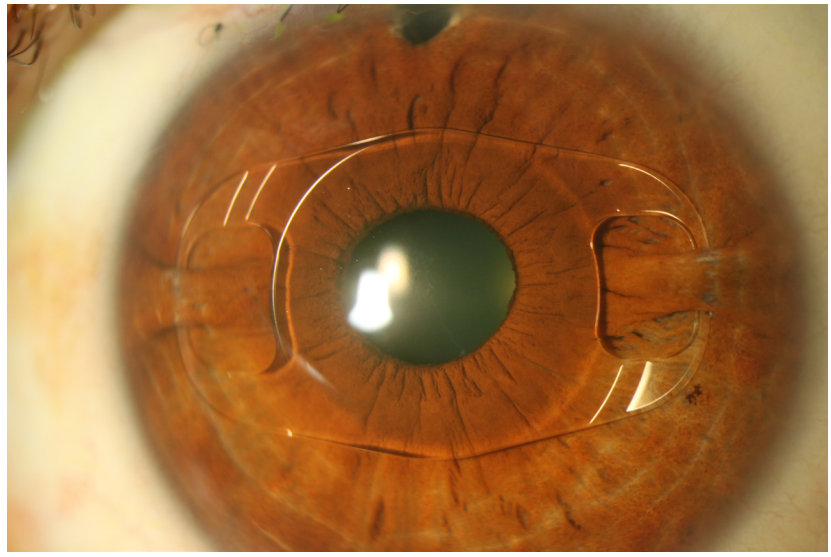

Figure 1: Artisan phakic intraocular lens: one month postoperative.

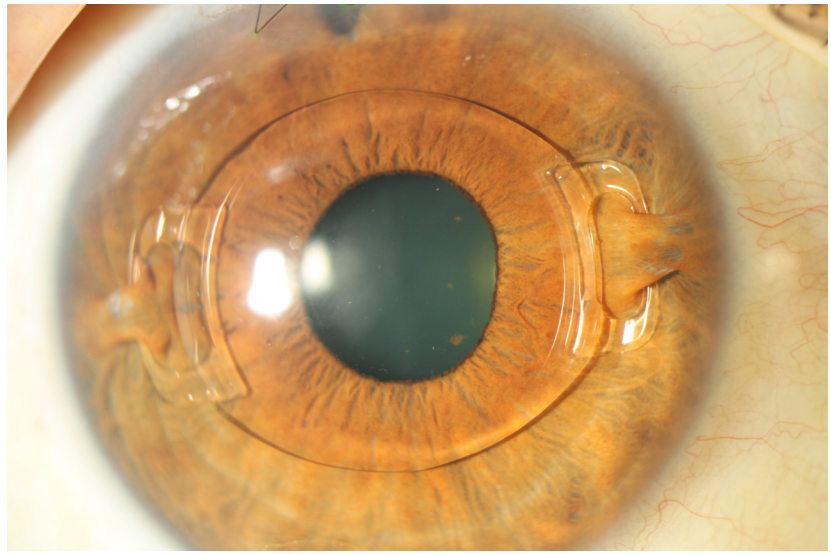

Figure 2: Artiflex phakic intraocular lens: one month postoperative.

to complement a residual post-operative refraction with a corneal refractive surgery after pIOL implantation, the Bioptics [12], first described by Zaldivar in 1999. In this study, we report our long-term results of Artisan and Artiflex implantations.

Patients and Methods

This is a retrospective observational cohort study. It included patients who underwent surgical implantation of an Artisan or Artiflex pIOL for high ametropia correction (myopia or hyperopia) between January 1999 and December 2018 in a private ophthalmology clinic in Porto Alegre, Brazil. Patients were evaluated pre- and postoperatively up to 10 years after implantation. The study was performed according to the tenets of the Declaration of Helsinki, and informed consent was obtained from all participants. The patients enrolled all met the clinical criteria for pIOL implants: minimum anterior chamber depth of 3.0 mm (from corneal endothelium to anterior capsule of crystalline lens), pupil size in scotopic conditions smaller than the pIOL optic zone, and endothelial cell counts above the 90% confidence interval for the age. Patients with previous intraocular or refractive surgery, incomplete medical records, or those whose follow-up period was shorter than twelve months were excluded from the analysis.

Pre- and postoperative assessments included Snellen's uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA); manifest refraction; slit lamp examination; anterior segment measurement; specular microscopy (Konan® and Nidek®); corneal topography (Tomey®) between 1999 and 2012 or corneal tomography (Orbscan® and/or Pentacam®) for patients included after 2013, and a retinal evaluation prior to the procedure. Complications were all reported.

Surgical technique

All surgeries were performed by a single surgeon (S.K.) on an outpatient basis, with local anesthesia (peribulbar blockage). Two paracenteses were performed at ten and two o'clock, and an ophthalmic cohesive viscoelastic device was injected into the anterior chamber. For the foldable model, Artiflex, a 3.2 mm clear cornea incision was made, and for the rigid model, Artisan, a 5.2 mm or a 6.2 mm scleral tunnel was performed, depending on the pIOL optical zone diameter. The lens was inserted using proper material (Operaid Artiflex Implantation Spatula; Ophtec®). After positioning the pIOL, the iris tissue was grasped and enclavated into the haptics at the 3 and 9 o-clock positions with proper forceps (Operaid Artisan/ Artiflex Enclavation Needle, Ophtec®). Peripheral iridectomy was performed surgically at the 12 o'-clock position. The incision was sutured with 10-0 nylon.

The pIOL calculation was performed using the Van der Heijde formula, which includes refraction, keratometry and the adjusted depth of the central anterior chamber measured by ultrasound [13]. The target refraction was emmetropia in all cases.

Miotic drops were used immediately before the surgery to reduce the risk of crystalline lens touching during implantation and to facilitate haptic enclavation. Postoperatively, 1% prednisolone and 0.3% gatifloxacine eye drops were used every 3 hours for 10 days.

Statistical analysis

The data collected were analyzed with IBM Statistical Package for the Social Sciences (SPSS) software, version 23.0. Categorical variables were described by frequencies and percentages, and quantitative variables were described by means and standard deviations. The visual acuity was converted to the logarithm of the minimum angle of resolution (logMAR) units for the statistical analyses. The Kolmogorov-Smirnov test was used to evaluate the normality of the variables. Mann–Whitney U-test was used to compare the means of quantitative variables between categories of dichotomic qualitative variables. Pre- and post-data were compared by Student's t-test for paired samples. Comparisons of pairs of the means of quantitative variables were performed by the two-way Friedman test followed by the Wilcoxon signed-rank test. The level of statistical significance was set at $P<0.05$.

Results

Data of 195 eyes from 120 patients were evaluated. The baseline characteristics of patients are presented in Table 1. The majority of

Table 1: Baseline characteristics in patients prior phakic intraocular lens (pIOL).

	Mean ± SD, n(%)		*P value*
	Myopia	**Hyperopia**	
	n=175	n=20	
Age, n=120	33.07 ± 8.68	38.10 ± 13.56	0.147‡
	(18 – 52)	(20 – 58)	
Gender, n=120			
Female	71 (65.7)	6 (50)	0.281†
Male	37 (34.3)	6 (50)	
Eye, n=195			
Right	90 (51.4)	11 (55.0)	0.762†
Left	85 (48.6)	9 (45.0)	
pIOL lens			
Artisan	119 (68.0)	20 (100.0)	0.003†
Artiflex	56 (32.0)	0 (0.0)	
logMAR UDVA	1.19 ± 0.29	1.21 ± 0.22	0.972‡
	(0.10 – 1.30)	(0.70 – 1.30)	
logMAR CDVA	0.25 ± 0.24	0.32 ± 0.26	0.061‡
	(0 – 1.30)	(0 – 1.30)	
Spherical error (D)	-12.16 ± 3.63	9.11 ± 2.19	0.000‡
	(-24.00 to -6.00)	(6.00 – 14.00)	
Refractional cylinder (D)	-1.77 ± 1.41	-2.20 ± 1.96	0.556‡
	(-5.50 to 0)	(-7.00 to 0)	
Spherical equivalente (D)	-13.06 ± 3.64	+8.01 ± 2.55	0.000‡
	(-25.00 to -6.65)	(+3.50 to +14.00)	
ECD	2515.46 ± 371	2556.40 ± 456.87	0.933‡
	(1278 - 3443)	(1910 – 3494)	

SD: Standard Deviation; UDVA: Uncorrected Distance Visual Acuity; CDVA: Corrected Distance Visual Acuity; D: Diopter; ECD: Endothelium Cell Density (cells/mm²); †Pearson's chi-square test; ††Fisher's exact test; ‡Mann-Whitney U test.

patients were female, with a mean age of 33.59 ± 9.38 years. Myopic eyes account for 89.74% (175/195) of the cases. There were no statistically significant differences between the baseline characteristics in both groups except for the type of lens and spherical power – that were reported with the negative lens power for myopia correction and the positive lens power for hyperopia correction. The mean preoperative spherical equivalent (SE) was -13.06 ± 3.64 D and +8.01 ± 2.55 D in the myopic and hyperopic groups, respectively.

The final outcomes are shown in Table 2. In the myopic group, 69.7% (122/175) of eyes achieved the final results with a single procedure, the pIOL. Fifty-three (53/175, 30.3%) received corneal refractive surgery, LASIK or PRK, after the pIOL to correct residual ametropia or astigmatism. In the hyperopic group, 70% (14/20) achieved the final correction with pIOL, and 6 eyes (6/20, 30%) underwent either LASIK or PRK. In the myopia group, 72% (126/175) of eyes that underwent to phakic IOL implantation with or without Bioptics achieved SE at the ±1.00 D interval, and among the hyperopic eyes, 65% (13/20) achieved ±1.00 D. UDVA improved from 1.19 ± 0.29 logMAR (Snellen equivalent 20/295) preoperatively to 0.19 ± 0.24 (Snellen equivalent 20/30) postoperative (p<0.001) in the myopic group and from 1.21 ± 0.22 logMAR (Snellen equivalent 20/324) to 0.22 ± 0.19 (Snellen equivalent 20/33) in the hyperopic group (p=0.001). The cumulative Snellen visual acuity after the final procedure is show in Figure 3.

Corneal refractive surgery was performed in 59 eyes – LASIK in 50 eyes and PRK in 9 eyes – within 3 months after pIOL implantation to correct residual ametropia. Of these patients, 89.83% (53/59) were myopic before pIOL implantation. In the myopic group, the post-pIOL mean SE decreased from -1.39 ± 1.27D to -0.17 ± 0.77D (p<0.001) after excimer laser correction, with 90.5% of eyes (48/53) reaching ±1.00 D of SE and 86.5% (45/53) reaching ±0.50 D of SE. The mean preoperative UDVA was 1.23 ± 0.27 logMAR (Snellen equivalent 20/340) and improved to 0.28 ± 0.22 logMAR (20/40) (p<0.001) after pIOL implantation. After the final correction of residual ametropia with the excimer laser, the mean UCVA improved to 0.21 ± 0.32 logMAR (Snellen equivalent 20/32) (Table 3). Among the hyperopic patients, UCVA improved from 1.15 ± 0.30 logMAR (Snellen equivalent 20/280) preoperatively to 0.30 ± 0.29 logMAR (20/39) after the pIOL implants (p = 0.039) and to 0.27 ± 0.26 (20/37) after the cornea refractive surgery (p=0.391) (Table 3). Astigmatism was the main factor responsible for the post-pIOL residual refraction in both groups, with a mean cylinder ranging from -4.17 ± 1.63 D to -0.46 ± 0.71 D in the hyperopic pre- and post-excimer laser correction, respectively.

A significant reduction in the endothelial cell count was observed in the myopic group, from 2515 ± 371 to 2377 ± 353 cells/mm^2 (p<0.001), with a 5.48% reduction in endothelial density over the follow-up period (84.86 + 56.19 months, 0.78%/

Table 2: Final outcomes in Myopic and Hyperopic patients.

	Mean ± SD, n(%)	Mean ± SD, n(%)		*P value*
		Myopia	Hyperopia	
	Total=195	n=175	n=20	
Follow-up time (months)	84.86 ± 56.19	82.93 ± 53.24	101.75 ± 77.12	0.157
Procedures performed				0.355†
Single pIOL	136 (69.75)	122 (69.7)	14 (70.0)	
Bioptics	59 (30.25)	53 (30.3)	6 (30.0)	
logMAR UDVA	0.19 ± 0.24	0.19 ± 0.24	0.22 ± 0.19	0.258‡
logMAR CDVA	0.13 ± 0.17	0.12 ± 0.17	0.20 ± 0.19	0.056‡
Spherical error (D)	-0.39 ± 1.27	-0.43 ± 1.31	-0.10 ± 0.83	0.914‡
Refractional cylinder (D)	-0.80 ± 0.88	-0.78 ± 0.83	-0.98 ± 1.25	0.561‡
Spherical equivalent (D)	-0.80 ± 1.33	-0.82 ± 1.36	-0.59 ± 1.11	0.859‡
±0.5 D	106 (54.4)	97 (55.4)	9 (45.0)	
±1.0 D	139 (71.3)	126 (72.0)	13 (65.0)	
±2.0 D	179 (91.8)	160 (91.4)	19 (95.0)	
ECC	2377.47 ± 353	2368.06 ± 373.06	2436.80 ± 190.06	0.422‡
	(1000 – 3060)	(1000 – 3060)	(2102 – 2878)	
Complications N(%)	24 (12.3)	21 (12.0)	3 (15.0)	
Cataract	15 (7.7)	13 (7.4)	2 (10)	0.683††
Glaucoma	7 (3.5)	7 (4.0)	0 (0)	0.999††
Traumatic displacement of pIOL	2 (1.0)	1 (0.6)	1 (5.0)	0.195††
Spontaneous displacement of pIOL	6 (3.0)	5 (2.9)	1 (5.0)	0.482††
Anterior uveitis	8 (4.1)	8 (4.6)	0 (0)	0.451††
Retina detachment	2 (1.0)	2 (1.1)	0 (0)	0.999††

SD: Standard Deviation; pIOL: Phakic Intraocular Lens; UDVA: Uncorrected Distance Visual Acuity; CDVA: Corrected Distance Visual Acuity; D: Diopter; ECD: Endothelium Cell Density (cells/mm^2); †Pearson's chi-square test; ‡Mann-Whitney U test; ††Fisher's exact test

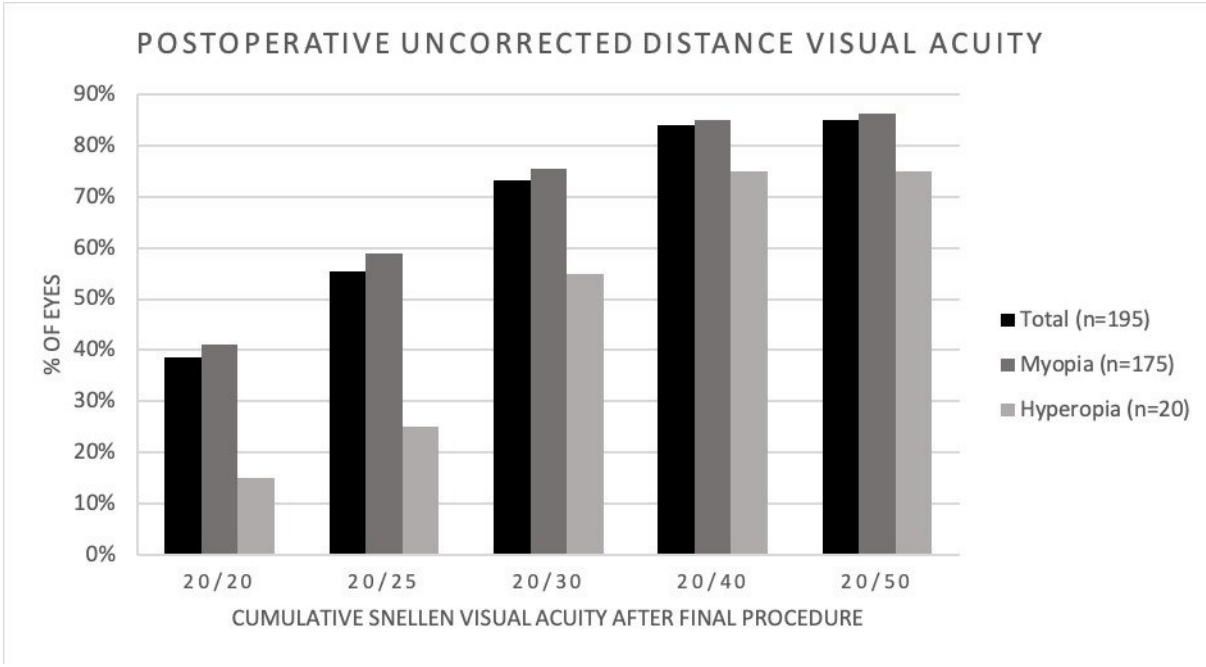

Figure 3: Postoperative uncorrected distance visual acuity.

Table 3: Outcomes in myopic and hyperopic patients undergoing Bioptics.

	Myopia Mean ± SD, n(%)					**Hyperopia Mean ± SD, n(%)**				
	Before pIOL	**After pIOL**	**After Bioptics**	***P value***	****P value***	**Before pIOL**	**After pIOL**	**After Bioptics**	***P value***	****P value***
	n=53	n=53	n=53			n=6	n=6	n=6		
Manifest refraction										
Sphere (D)	-11.43 ± 3.36	-0.47 ± 1.31	0.01 ± 0.84	<0.001†	0.007†	8.37 ± 2.03	1.00 ± 2.91	-0.45 ± 0.51	<0.0011†	0.244†
Cylinder (D)	-2.72 ± 1.57	-1.85 ± 0.94	-0.38 ± 0.58	<0.001†	<0.001†	-4.45 ± 1.86	-4.16 ± 1.63	-0.45 ± 0.71	0.002†	0.005†
Spherical equivalent (SE)	-12.79 ± 3.25	-1.39 ± 1.27	-0.17 ± 0.77	<0.001†		6.15 ± 2.50	-1.08 ± 3.63	-0.69 ± 0.79	0.001†	0.690†
±0.5 D	-	9 (17.0)	45 (86.5)			-	0 (0.0)	3 (50.0)		
±1.0 D	-	18 (33.9)	48 (90.5)			-	0 (0.0)	4 (66.7)		
±2.0 D	-	43 (81.1)	52 (98.1)			-	2 (33.3)	6 (100.0)		
logMAR CDVA	0.27 ± 0.23	0.14 ± 0.18	0.12 ± 0.16	<0.001†	0.099†	0.30 ± 0.10	0.28 ± 0.19	0.21 ± 0.21	0.259†	0.372†
logMAR UDVA	1.23 ± 0.27	0.28 ± 0.22	0.21 ± 0.32	<0.001†	<0.001†	1.15 ± 0.30	0.30 ± 0.29	0.27 ± 0.26	0.039†	0.999†
ECD	2487.61 ± 381		2463.57 ± 356	0.647		2593.83 ± 445		2372.17 ± 144	0.248	

SD: Standard Deviation; pIOL: Phakic Intraocular Lens; D: Diopter; UDVA: Uncorrected Distance Visual Acuity; CDVA: Corrected Distance Visual Acuity; ECD: Endothelium Cell Density (cells/mm^2); *P value: Statistically significance to Bioptics procedure (before pIOL-after Bioptics); **P values: Statistically significance to corneal refractive procedure (after pIOL-after Bioptics); †Student's t-test for paired samples; ‡Friedman test of related samples.

year). In the hyperopic group, there was no significant endothelial cell loss, ranging from 2556 ± 456 preoperatively to 2436 ± 190 postoperatively (p=0.302).

A multiple linear regression was calculated to predict postoperative endothelial cell density based upon their pre-operative cell count and time of follow up. Preliminary analyses were performed to ensure there was no violation of the assumption of normality, linearity and multicollinearity. A significant regression equation was found (F (2,143) = 12.51, p<001), with an R^2 of 0.137. The postoperative endothelial cell density's predictive is equal to 1567.338 -0.612 (follow-up), + 0.417 (pre-operative EC) where follow up in measure in months and postoperative ECD is measured in cells/mm^2 and. Endothelial cells decreased 0.612 each month of follow-up and both pre-operative and time of follow up were significant predictors of final endothelial cell density.

The follow-up period ranged from 12 to 209 months, with the majority of patients being followed over five years. Six (3.1%) eyes were followed for 12 months, 30 (15.2%) eyes over one and up to 2 years, 48 (24.26%) over 2 years, 48 (24.6%) over 5 and 63 (32.3%) over 10 years.

Complications are described on the bottom of Table 2. The most frequent complication was cataract in 7.69% of eyes (15/195). The majority of cases (13/15) were in the myopia group, and 73.3% (11/15) occurred after 3 years of follow-up. Postoperative high intraocular pressure was present in 4.0% (7/175) of myopic cases and none of the hyperopic and the cases were all treated with topical medication. Anterior uveitis/iritis was present in 8 eyes (4.6%) after pIOL implantation in the myopic group, 2 (1.4%) with the Artisan implant and 6 (10.7%) with the Artiflex implant (Artisan=139, Artifex=56; p=0.003), and the cases were all treated adequately with eye drops. There were three eyes that developed cataract following iritis, and they were submitted to phacoemulsification surgery. There were six (6/195; 3.07%) cases of spontaneous displacement of pIOL, 5 in myopic eyes. The displacements were surgically corrected. Two eyes (2/195; 1.02%) had retinal detachment (RD), both in the myopic group. One of them had a preoperative SE of -22.75, and the -16.75, and both had this complication 11 months after Artisan implantation.

Discussion

Ametropia reduction was achieved in both myopic and hyperopic eyes. In the myopic group, 78% of eyes that were submitted to a single procedure with pIOL implantation achieved SE within ±1.00 D, and the same occurred in 90.5% of patients in the myopic Bioptics group. The decrease in manifest refraction and spherical equivalent occurred in agreement with the improvement of corrected and uncorrected visual acuity. We found a significant improvement of CDVA and UDVA in the myopic group and UDVA in the hyperopic group. These findings agree with studies that have shown that patients with pIOL implants had a significant improvement in visual acuity, both with and without glasses [14,15]. There was no statistically significant difference, however, in CDVA pre- and postoperatively in the hyperopic group, which may be partially explained by the lower refraction error in this group and minor aberrations due to high positive lunettes when comparing to the myopic one. Similar to the literature [16-18], postoperative refraction stability was found in most cases, with an average spherical equivalent within ±2.00D in both myopic and hyperopic cases during the mean follow-up period.

The complication rate was low. Fifteen eyes (7.7%) developed cataract during the follow-up period, which occurred three years after pIOL implantation in the majority of cases (11/15). Chen et al. [9] showed a 1.11% incidence of cataract formation, with an average time of 37.65 months after pIOL implantation. It is known that patients with high myopia have a higher incidence of early cataracts, so it is difficult to determine whether the cataract development was due only to the pIOL implantation [2,9]. In our study, 4.1% of eyes presented with anterior uveitis and iritis, and we found a higher correlation between it and the Artiflex implant than with the Artisan implant (p=0.003). The occurrence of iritis after pIOL is a well-known complication that may affect up to 7% of patients [6,15], which could be treated with topical eye drops or possibly lens removal [19]. A multicenter study with 2-year follow-up results described that pigmented precipitates appear to occur more frequently in eyes with Artiflex implants than in eyes with Artisan implants, persisting until the first 3 months after surgery (n=49; 16.9%) [20]. Pigment dispersion and inflammatory reactions subsequent to the Artisan/Artiflex IOL implant can be explained by the pressure caused in the iris through the crystalline lens and the pIOL, and may be more for Artiflex implants because it introduces a vault between the optic-haptic junction and the plane of the iris smaller than that of the Artisan [21,22].

A transient increase in intraocular pressure was present in the immediate postoperative period in 3.5% of cases and was probably due to residual viscoelastic in the anterior chamber and/or secondary to the use of topical corticosteroids. Other studies have shown similar rates of transient ocular hypertension [17,18] or higher, such as 26% [23]. We did not find any significant correlation between the previous ametropia and complications, probably due to a small hyperopic subgroup.

The combination of pIOL and corneal excimer laser surgery has been used to treat cases of extreme ametropias. The use of this strategy in cases of high myopia can improve refractive predictability, safety, and quality of vision and it is also a good option for correcting astigmatism [24]. There are few studies reporting the use of the pIOL associated with excimer laser treatment for hyperopia [21,23], with postoperative SE usually higher than for treatments for myopia [25]. In our study, 66.7% of the hyperopic eyes followed by the Bioptics protocol reached a range of ±1.00 D SE after the final procedure, and 83.3% had Snellen vision equal or better than 20/40, compared to 90.6% within the myopic patients. Bioptics is useful and concise and can lead to more accurate results, especially for the astigmatism corrections when comparing to toric pIOL [26]. Furthermore, residual refractive surgery would be preferable and more predictable to correct astigmatism than a large incision as the one needed for Artisan, due to the fact that toric Artiflex is not available in Brazil.

Despite having designs that support a large vault, Artisan and Artiflex lenses can cause corneal endothelium damage, either due to surgical trauma or the presence of the implant in the anterior chamber. Previous studies have shown a rate ranging from zero [14,27] to 11.9% of reduction in endothelial cell count [28,29] and various mechanisms have been proposed and investigated to explain the possible occurrence of corneal endothelium cell loss in the presence of pIOL. The surgical procedure itself can cause a decrease in endothelial cell density and the mechanical friction between the endothelium and the IOL has also been postulated to possibly cause cell detachment in patients who often rub their eyes or sleep face

down. In a theoretical mathematical model for eyes with pIOL, Davvalo et al. [30] found that when a pIOL is implanted, aqueous flow is diverted toward the periphery of the anterior chamber and glucose concentration may decrease in the region anterior to the pIOL. Thus, implantation of a pIOL would significantly affect nutrient transport processes to the corneal endothelium, especially during sleep. The present study found different results between the myopic and hyperopic groups, with myopic eyes presenting with a statistically significant reduction in corneal endothelium cells. Despite this statistical reduction of cell counts in the myopic group, clinical corneal edema was not observed in any eye during the follow-up period. Furthermore, the multiple linear regression suggested that pre-operative ECD and time of follow-up might be responsible for up to 13.7% of variation on the postoperative result. Thus, the result of the comparative pre- and final follow-up visit should not be used as s single information, at the hand of the natural ECD loss - that ranges about 0.5% a year in healthy and treatment naïve eyes and cannot be inconsiderable. Tahzib et al., in a 10-year follow-up study, showed a reduction of 8.86% ± 16.01% over the period, and no case of corneal decompensation was reported [28], which agrees with the theory that in regards to ECD, a statistically significant loss might not impact directly on the clinical results although it is a good reason to keeping caring about.

We recognize the limitations of a retrospective study and the possibility of bias, especially in a long-term follow-up. Nonetheless, the results showed that the iris-claw pIOLs are safe and might be an excellent and reversible alternative for the correction of high ametropias. Further studies are needed to better evaluate the variables associated with poorer outcomes and possible improvements, especially for hyperopic patients.

Author Contribution

S.K., G.M.Z, and S.B.M contributed to the design and implementation of the research, to the analysis of the results and to the writing of the manuscript.

Conflicts of Interest

The authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest in the subject matter or materials discussed in this manuscript.

Declarations

Not applicable.

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