Iris-supported Phakic Lenses (Rigid vs Foldable Version) for Treating Moderately High Myopia: Randomized Paired Eye Comparison

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• PURPOSE: To compare refractive performance of Artisan (Ophtec, Groningen, The Netherlands) or Verisyse phakic intraocular lens and its foldable version, Artiflex (Ophtec), for the correction of moderately high myopia.
• DESIGN: Randomized pilot study.
• METHODS: SETTING: Institutional practice. PATIENT POPULATION: Thirty-one patients with myopia that ranged from −6 to −14 diopters (D). INTERVENTIONAL PROCEDURE: One eye was implanted with an Artisan phakic intraocular lens (PIOL) and the other with an Artiflex PIOLs. MAIN OUTCOME MEASURES: Primary outcome measure was the percentage of eyes with uncorrected visual acuity (UCVA) of >20/40 at one year after the operation. Main secondary outcome measures were the safety index, the change of two lines or more of best spectacle-corrected visual acuity (BSCVA) and the endothelial cell count.
• RESULTS: No intraoperative complications were noticed. One year after surgery, the percentage of eyes with UCVA of >20/40 was 51.6% (16/31 patients) for Artisan-treated eyes and 77.4% (24/31 patients) for Artiflex-treated eyes ($P = .033$). One month after surgery, this same percentage was 42.9% (13/31 patients) and 77.4% (24/31 patients), respectively ($P = .004$). The safety index at one year was 1.13 ± 0.24 for Artisan-treated eyes and 1.12 ± 0.21 for Artiflex-treated eyes, which is a difference that was not statistically significant ($P = 0.742$). At one year after surgery, the changes of two lines or more of BSCVA and the endothelial cell loss were similar for both groups.
• CONCLUSION: To correct moderately high myopia, the Artiflex lens provides a faster visual recovery and a better UCVA than does the Artisan lens. The safety of the lens should be supported by an enlarged sample size and a longer follow-up period. (Am J Ophthalmol 2006; 142:909–916. © 2006 by Elsevier Inc. All rights reserved.)

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MODERATELY HIGH MYOPIA FROM −6 TO −14 DIopters (D) currently is corrected surgically by laser in situ keratomileusis (LASIK) or phakic intraocular lens (PIOL).[1]

In this range of nearsightedness, we previously reported that LASIK and PIOL (Artisan [Ophtec, Groningen, The Netherlands] lens also called Verisyse lens) produce a similar predictability in the refractive outcome. Conversely, better best-corrected visual acuity and quality of vision were obtained with Artisan lens.[2]

However, a 6.2-mm posterior corneal incision is needed for the Artisan implantation procedure because of the polymethylmethacrylate (PMMA) material. Thus, a postoperative astigmatism may be induced by this technique. For these reasons, a new foldable version of Artisan, called Artiflex (Ophtec), has been created recently. This lens can be inserted through a 3.2-mm incision with a surgical procedure that normally does not require sutures. This, in turn, reduces the induced astigmatism.

We therefore performed a prospective and randomized pilot study comparing the refractive performance of these two iris-supported PIOLs, Artisan and Artiflex, for the surgical correction of moderately high myopia, through an original paired-eye design.

METHODS

• PATIENT POPULATION: During an approximate two-year period, all patients from the clinical practice of the participating surgeons (F.M.,J.C. in Purpan Hospital, Toulouse, France; J.-.L.G. in Instituto de Microcirugìa Ocular, Barcelona, Spain) were invited to participate in the study.

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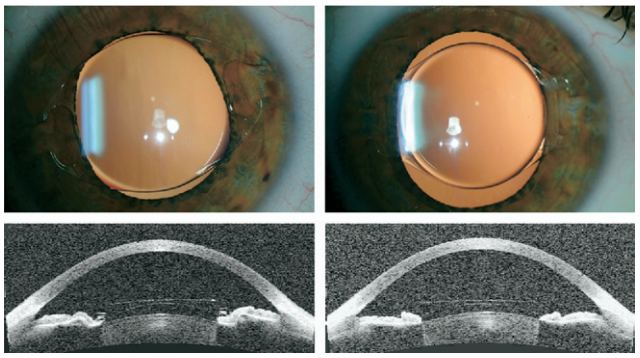

FIGURE 1. Artisan and Artiflex phakic intraocular lenses (PIOLs) in both eyes of the same patient. Slit-lamp photographies and anterior segment optical coherence tomography (OCT) images of Artisan (Top left and Bottom left) and Artiflex (Top right and Bottom right) at one year after the operation.

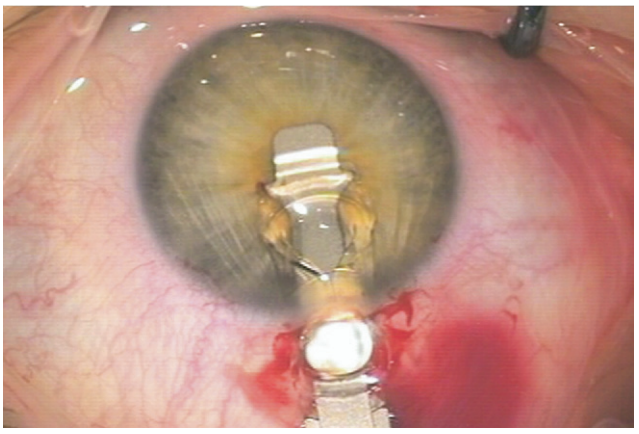

FIGURE 2. Artiflex folded through a 3-mm incision.

Among them, 31 patients with myopia fulfilled the criteria and elected to participate in the study. Each patient who was included in this study had stable myopia for two years and a contact lenses-wearing intolerance. Each patient had bilateral myopia between −6 and −14 diopters (D), with astigmatism no greater than 2 D. For all eyes, the anterior chamber depth was ≥3.2 mm, and the central endothelial cell count (cECC) was ≥2200 cells/mm^2. Exclusion criteria were patients who were <30 years old, corneal disease that included keratoconus that was suspect in videokeratography (TMS-4; Tomey Corporation, Nagoya, Japan), cataract, glaucoma, uveitis, ocular surface disease, or a history of retinal detachment. Each patient received Artisan PIOL in one eye (Artisan-treated eyes) and Artiflex PIOL in the other (Artiflex-treated eyes) by the same surgeon (F.M.,J.C. or J.-.L.G.; Figure 1). The order of the two methods and the eye that was treated were randomized with the use of a random-number table at the inclusion visit. The study and data accumulation were carried out by approval from the appropriate Institutional Review Board as the ethical committees of Toulouse 2 and the Autonoma University of Barcelona. Informed consent was obtained from each patient. The study was in adherence to the tenets of the Declaration of Helsinki.

• **PATIENT EXAMINATIONS:** The analysis was performed in a double-blind fashion. Both evaluators worked independently from any objective testing, such as slit-lamp examination, which could have unmasked the surgical procedure. For this purpose, independent evaluators performed visual tests. Patients were examined before and also after the operation at one day and one, three, six, and 12 months. Patients were examined in both sites (France and Spain) under the same photopic conditions and visual decimal charts about the visual performances. The analyses were also performed before the operation.

One day after surgery, only uncorrected visual acuity (UCVA) and biomicroscopic examination were recorded. At all other testing intervals, a complete ophthalmic examination was performed, which included uncorrected and spectacle-corrected visual acuity, refraction, slit-lamp microscopy, and applanation tonometry. Despite the lack of a laser flare-meter based study, the postoperative anterior chamber inflammation was graded with a slit-lamp examination.

To assess the surgical-induced astigmatism (SIA) in both groups, a calculation that was based on a 10-step vectorial analysis, as described by Holladay and associates,[3,4] and that used the keratometry readings vertexed to the corneal plane, was performed. To report the aggregate results of the SIA in each group in a clinically meaningful way, doubled-angle polar plots were used as previously described.[5] In this article, the SIA is reported in the positive cylinder notation so the values that are shown on the polar plots indicate the meridian at which the cornea steepened after surgery.

In addition, at three and 12 months after surgery, an endothelial evaluation with a noncontact specular microscope (Topcon SP 2000 P; Topcon, Nishinomiya, Hyogo, Japan) was performed. We evaluated the ECC at the center (triplicate measurement), which determined the cECC value.

Contrast sensitivity testing (CSV 1000; Vector Vision, Dayton, Ohio, USA) was also performed at the same periods. In addition, a subjective response for satisfaction was recorded on a scale of 1 to 5 (1 = very poor; 2 = poor; 3 = moderate; 4 = good; 5 = excellent), and glare and halos were also scored on a scale of 1 to 5 (1 = none; 2 = few; 3 = moderate; 4 = intense; 5 = very intense). All the patients filled in this subjective questionnaire at the end of the postoperative period.

• **SURGICAL TECHNIQUE:** Calculation of lens power and the target of surgery was emmetropia for both Artisan-treated eyes and Artiflex-treated eyes. When the em-

TABLE 1. Paired-Eye Comparison of Visual Outcome and Efficacy Index at Each Milestone of the Follow-up, Between Artisan- and Artiflex-treated Eyes

Variable	Month 1 (%)	Month 3 (%)	Month 6 (%)	Year 1 (%)
Uncorrected visual acuity ≥ 20/25				
Artisan	6 (2/31)	13 (4/31)	20 (6/31)	19 (6/31)
Artiflex	42 (13/31)	45 (14/31)	33 (10/31)	30 (9/31)
*P**	.001	.005	.245	.373
Uncorrected visual acuity ≥20/40				
Artisan	43 (13/31)	56 (17/31)	57 (18/31)	52 (16/31)
Artiflex	77 (24/31)	84 (26/31)	73 (23/31)	7 (24/31)
*P**	.004	.013	.017	.033
Efficacy index†				
Artisan	0.56 ± 0.32	0.66 ± 0.34	0.63 ± 0.29	0.60 ± 0.29
Artiflex	0.83 ± 0.28	0.88 ± 0.25	0.82 ± 0.28	0.79 ± 0.26
P‡	.0001	.0001	.002	.0003

*Numbers in brackets show the number of eyes. Determined with a Chi-square test.

†Defined as the ratio of the postoperative uncorrected visual acuity over the preoperative best spectacle-corrected visual acuity.

‡Determined with a Wilcoxon signed-rank test.

metropic lens was not available (we have 0.50 D steps and not 0.25 D steps), our choice was to favor a slight residual myopia, as opposed to a slight residual hyperopia. Ophtec (Groningen, The Netherlands) has established a calculation of lens power with the van der Heijde formula, which uses the corneal curvature, the anterior chamber depth and the spheric equivalent (SE) of the patient's subjective refraction. The adjusted anterior chamber depth calculation has been changed slightly for Artiflex by the manufacturer.

The Artisan PIOL, a convex-concave, iris claw-fixated PIOL with a 6-mm optical zone diameter, was used. This single-piece lens that was composed of PMMA was manufactured with compression-molding technology. The Artisan implantation procedure was done under peribulbar anesthesia. A two-plane, 6.2-mm long, posterior corneal incision was centered at 12 o'clock, and two vertical paracenteses were performed located at 2 and 10 o'clock and directed to the enclavation area. After an intracameral injection of acetylcholine and viscoelastic material, the lens was introduced in one step (to avoid any contact between the front part of the PIOL and the crystalline lens) and thereafter rotated 90 degrees into a horizontal position from 3 to 9 o'clock. The PIOL was fixed with an enclavation needle that had a bent tip and pushed the iris into both claws. The centration of the PIOL over the pupil was checked. All manipulations were performed under viscoelastic protection. Finally, a peripheral slit iridotomy was performed at 12 o'clock; the viscoelastic material was exchanged with balanced salt solution, and the incision was closed with five or six interrupted 10–0 nylon sutures to close the incision completely with minimal tension. The tension of the sutures was checked with standard qualitative Maloney keratoscope. Beginning at week 4, over a period of three months sutures were removed selectively, depending on the patient's astigmatism as measured by videokeratography.

The Artiflex lens is also a convex-concave, iris claw-fixated PIOL with a 6-mm optical zone diameter. It is a three-piece lens that consists of a flexible optical part made of ultraviolet-absorbing silicone and rigid haptics made of PMMA. The Artiflex lens was inserted with the use of a special-designed spatula that allows the surgeon to fold and insert the lens through a 3.2-mm incision (Figure 2). Similar to the Artisan procedure, this small incision was centered at 12 o'clock. It was not located at the steepest meridian, to compare the induced-astigmatism of both groups strictly, with this identical location in all cases. The incision was usually watertight, and suturing was not necessary. For the enclavation, special curved forceps that hold the base of the PMMA body were used.

After the operation, in both techniques, prednisolone and indomethacin-gentamycin drops were used four times per day during four weeks.

• **OUTCOME MEASURES AND STATISTICAL ANALYSIS:** The primary outcome measure was the postoperative UCVA, more specifically the percent of eyes with UCVA of >20/40 at one year after surgery. As we previously reported, the expected percent of eyes with UCVA of >20/40 for Artisan-treated eyes was 60% at one year after the operation.[2] After Artiflex implantation, a lower refractive cylinder power could be expected and, consequently, a better UCVA and efficacy index. Thus, the number of subjects for each method was determined with the objective of achieving a postoperative percent of eyes with UCVA of >20/40 at one year of 90% for Artiflex lens and for a unilateral test with an alpha level of 5% and a power

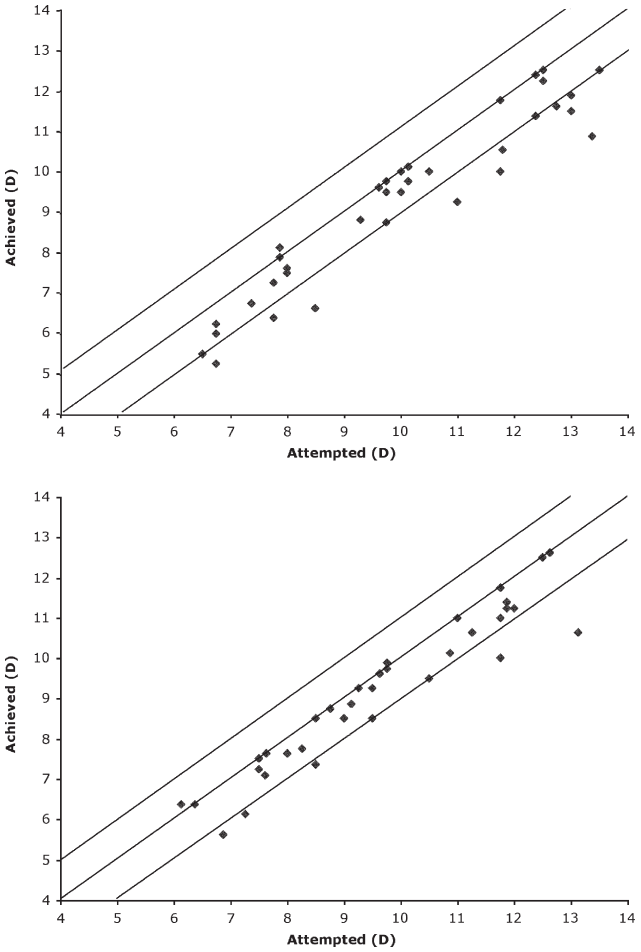

FIGURE 3. Scattergrams show the preoperative manifest spheric equivalent refraction vs the induced change one year after Artisan (Top) and Artiflex (Bottom) in 31 pairs of eyes in the same patients. D = diopters.

of 80%. Thus, the calculated sample size (31 subjects) was statistically sufficient to draw reliable conclusions concerning the paired eye efficacy comparison of both PIOLs.

The secondary outcome measure for both lenses was the safety index[6] and was defined as the ratio postoperative best spectacle-corrected visual acuity (BSCVA)/preoperative BSCVA. We also recorded the percent of eyes that lost two or more Snellen lines of BSCVA.

Other outcome measures that were also considered were the mean refractive cylinder power, the SIA, the changes in BSCVA, the efficacy index, the intraocular pressure, and the endothelial cell loss. The *mean refractive power cylinder* was defined, in our work, as the mean objective ocular astigmatism. Standard descriptive statistics, concerning the SIA calculation (means, median, [standard deviations] SDs, and [confidence intervals] CIs), were applied after conversion of the data to a Cartesian coordinates (x–y) system. The *efficacy index* was defined as the ratio postoperative UCVA/preoperative BSCVA. Concerning the safety parameters of the lens (cECC, intraocular pressure, inflammation, and deposits), the calculated sample size did not allow any definitive conclusions to be drawn concerning the occurrence of rare complications.

Comparison for percents was performed with the Chi-square test and Fisher exact test when appropriate. The comparisons between the preoperative and postoperative periods and comparisons between the two eyes were performed with the Wilcoxon signed rank test, a nonparametric test for matched samples. Statistical calculation was performed with StatView software (SAS Institute Inc, Cary, North Carolina, USA).

RESULTS

ALL PATIENTS COMPLETED THE STUDY AND WERE INcluded for analysis of the primary and secondary outcome measures.

• **PATIENT POPULATION:** There were 31 patients, whose age ranged from 31 to 59 years (median, 37.8 ± 9.0 years). There were no statistically significant differences in the baseline ophthalmic characteristics of both groups. The preoperative SE value was −10.3 ± 3.2 D (range, −14 to −6.50 D) for Artisan-treated eyes and −9.5 ± 2.2 D (range, −13 to −6 D) for Artiflex-treated eyes ($P = .076$). No statistically significant difference was noticed in the mean preoperative keratometry of the two groups (43.5 ± 1.5 D for Artisan and 43.5 ± 1.7 D for Artiflex; $P = .685$). The mean baseline refractive cylinder power was −1.15 ± 0.67 D (range, −2.0 to 0 D) for Artisan-treated eyes and −0.93 ± 0.53 D (range, −2.0 to 0 D) for Artiflex-treated eyes, which was a slight difference that was close to statistical significance ($P = .056$).

• **VISUAL ACUITY OUTCOME:** One year after surgery, the percent of eyes with UCVA of >20/40 was 51.6% for Artisan-treated eyes (16/31 eyes) and 77.4% for Artiflex-treated eyes (24/31), a difference that was statistically significant ($P = .033$). The difference of the percent of eyes with UCVA of >20/25 between Artisan and Artiflex-treated eyes was statistically significant at one month and three months after surgery (respectively, 6.4% vs 41.9% at one month [$P = .001$] and 12.9% vs 45.1% at three months [$P = .005$]). At one year after surgery, the percent of eyes with UCVA of >20/25 was 19.3% for Artisan-treated eyes (6/31 eyes) and 29.0% for Artiflex-treated eyes (9/31 eyes), but this difference was not statistically significant ($P = .373$). The mean efficacy index was significantly better ($P = .0003$) for Artiflex-treated eyes than for Artisan-treated eyes at each milestone of the follow-up, respectively 0.79 ± 0.26 and 0.60 ± 0.29 at one year after surgery (Table 1).

• **REFRACTIVE OUTCOME:** The mean postoperative SE at one year after the operation was significantly lower ($P =$

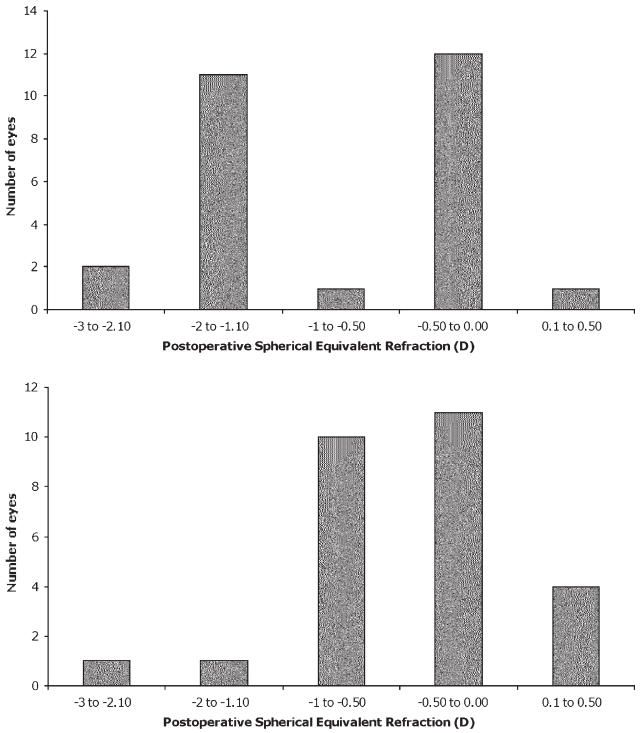

FIGURE 4. The bar graph presents the postoperative spheric equivalent refraction in small steps one year after Artisan (Top) and Artiflex (Bottom) in one eye of the same patient. D = diopters.

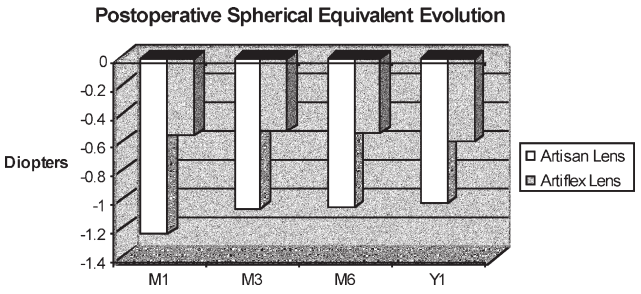

FIGURE 5. Spheric equivalent refraction at various intervals after Artisan and Artiflex on both eyes of the same patient.

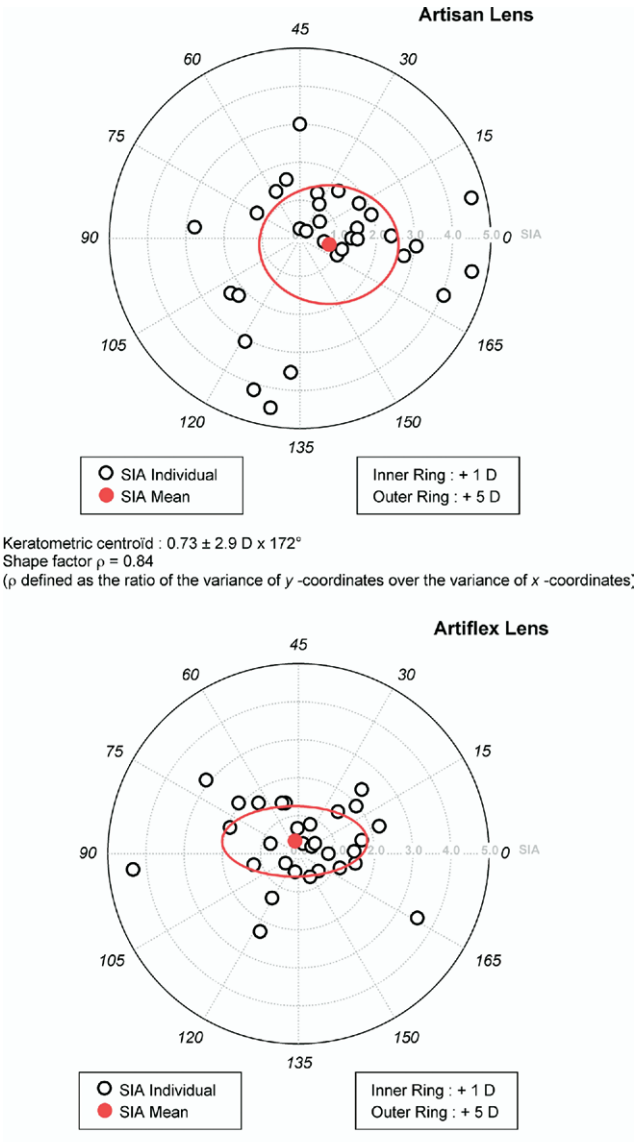

FIGURE 6. Modified double-angle polar plot representation of surgical-induced astigmatism (SIA) at one year after surgery, after Artisan (Top) and Artiflex (Bottom) on both eyes of the same patient. The circle shows the keratometric centroid of the surgical-induced astigmatism in each group. The graphic representation of the surgical-induced astigmatism in the Artiflex group appears less scattered and associated with a marked elliptic-shaped centroid that conveys a low percentage of postoperative oblique astigmatism. D = diopters.

.0005) in the Artiflex-treated eyes, with a mean SE of −1.01 ± 0.69 D for Artisan and −0.58 ± 0.55 D for Artiflex.

At one year after the operation, 83.9% of Artiflex-treated eyes (26/31 eyes) were within ±1 D of the intended emmetropia vs 58% of Artisan-treated eyes (18/31 eyes), which was a difference that was statistically significant ($P = .015$). In scattergrams of changes that were achieved at one year vs emmetropia, Artisan and Artiflex exhibited similar patterns of refractive changes (Figure 3).

The postoperative SE values at one year, which were depicted by the refractive outcomes in small steps, were clustered around emmetropia for Artiflex-treated eyes and scattered for Artisan-treated eyes (Figure 4). The optimal refractive results appeared as early as the first month for both techniques (Figure 5). The postoperative SE refraction remained stable during the follow-up in both groups and in the Artisan group between the first and the third month (on the removal of the sutures). The mean refractive cylinder power at one year was significantly lower ($P = .001$) for Artiflex, with −1.02 ± 0.63 D for Artisan-treated eyes and −0.56 ± 0.47 D for Artiflex-treated eyes.

TABLE 2. Paired-Eye Comparison of the Safety Index Between Artisan- and Artiflex-treated Eyes in the Postoperative Period

Safety Index*	Month 1	Month 3	Month 6	Year 1
Artisan	1.08 ± 0.28	1.05 ± 0.26	1.11 ± 0.25	1.13 ± 0.24
Artiflex	1.13 ± 0.14	1.09 ± 0.19	1.11 ± 0.44	1.12 ± 0.21
$P^{\dagger}$	.171	.204	.411	.742

*Defined as the ratio of the postoperative best spectacle-corrected visual acuity over the preoperative best spectacle-corrected visual acuity.

†Determined with Wilcoxon signed-rank test.

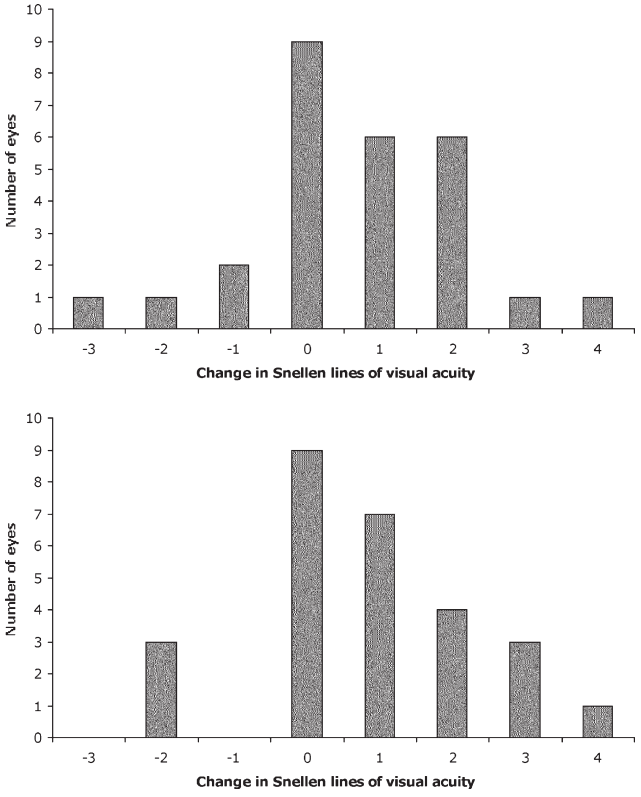

FIGURE 7. The bar graph depicts the change in best spectacle-corrected visual acuity (BSCVA) from the preoperative examination to the one-year postoperative examination in terms of the number of Snellen lines changed. (Top) Artisan-treated eyes; (Bottom) Artiflex-treated eyes.

In the Artisan group, the mean of SIA at one year after surgery was 0.73 ± 2.9 D, which was 172 degrees from the meridian of the incision, whereas in the Artiflex group, it was 0.29 ± 1.67 D, which was 51 degrees from the meridian of the incision. The SIA lowering of 0.44 D for Artiflex-treated eyes was close to statistical significance, with the use of a paired comparison ($P = .072$). Although not significant, the study probably did not have the power to draw any conclusions. With respect to the doubled-angle polar plots representation, it appeared more scattered for Artisan-treated eyes than for Artiflex-treated eyes (Figure 6).

• **SAFETY:** There was no statistically significant difference in the safety index for both groups at all periods (Table 2). Safety was also evaluated in terms of changes in best spectacle-corrected visual acuity (BSCVA) from baseline to postoperative follow-up times (Figure 7). There was a similar percent of loss of two lines or more for Artisan and Artiflex groups, respectively 6.4% (2/31 eyes) and 9.7% (3/31 eyes). Similarly, the gain of one line or more of BSCVA was identical for both techniques, 14 and 15 eyes, respectively.

There were no significant complications during or after surgery with either of the techniques, particularly no uveitis in any group. The injection of the foldable lens through a 3.2-mm incision was easy in all cases, without corneal or iris traumatisms. The fixation and the centration over the pupil of the Artiflex lens were as reproducible as with the Artisan lens. Despite the lack of a slit-lamp-based quantitative image analysis, we did not observe a clinically significant higher incidence of pigment or non-pigment deposits in either of the techniques. In addition, Artisan and Artiflex led to no significant modification of the intraocular pressure (respectively, 14.8 ± 2.7 mm Hg and 14.3 ± 2.6 mm Hg, before surgery; 14.4 ± 2.4 mm Hg and 14.2 ± 2.8 mm Hg at one year after surgery).

We also did not find any statistically significant difference in the endothelial tolerance between the two groups. The values of cECC for Artisan-treated eyes and Artiflex-treated eyes were, respectively, 2638 ± 421 cells per mm^2 and 2654 ± 398 cells per mm^2 before surgery and 2473 ± 416 cells per mm^2 and 2405 ± 456 cells per mm^2 at one year after surgery. The percent of central endothelial cell loss at one year after surgery was 9.4% for Artisan-treated eyes and 9.0% for Artiflex-treated eyes, which was a difference that was not statistically significant.

• **QUALITY OF VISION AND CONTRAST SENSITIVITY:** We did not find any statistically significant difference between the two lenses at all four spatial frequencies (3, 6, 12, and 18 cycles per degree; Table 3). A subjective evaluation of the quality of vision (halos and glare) during scotopic and

TABLE 3. Contrast Sensitivity Data Before and 1 Year After Phakic Intraocular Lens Implantation

Spatial Frequency	Preoperative			Year 1		
	Artisan	Artiflex	P*	Artisan	Artiflex	P*
3 Cycles per degree	4.5 ± 2.3	4.7 ± 2.2	.967	4.7 ± 1.8	4.5 ± 1.6	.670
6 Cycles per degree	3.2 ± 2.2	3.4 ± 1.9	.663	2.7 ± 1.9	3.4 ± 1.9	.236
12 Cycles per degree	1.7 ± 1.8	2.0 ± 2.1	.271	1.8 ± 2.3	2.2 ± 2.4	.129
18 Cycles per degree	2.6 ± 2.4	2.1 ± 1.9	.359	1.4 ± 1.7	1.8 ± 2.8	.416

*Determined with a Wilcoxon signed-rank test.

mesopic conditions did not show any statistical significant differences between Artisan- and Artiflex-treated eyes. However, the satisfaction index was higher for Artiflex-treated eyes than Artisan-treated eyes (respectively, 3.9 ± 0.96 and 3.15 ± 1.03), which was a difference that was statistically significant ($P = 0.015$).

DISCUSSION

CURRENTLY TWO DIFFERENT SURGICAL TECHNIQUES (LASIK and PIOL, especially Artisan [also called Verisyse]) for correcting moderately high myopia are available and produce a similar predictability, as we previously reported.[2] Nevertheless, LASIK is not the best choice for myopia superior to −8 D, mainly because of the risk of corneal ectasia and impairment of the quality of vision.[1,2] In addition, the major concern with the refractive outcome for Artisan PIOL is the induced astigmatism that resulted from a 6-mm incision.[7] Thus, a foldable version of the lens has been generated. The Artiflex lens has been developed based on the Artisan concept, with the haptics and optic comparable with the conventional Artisan myopia lens. Although the haptics are still made of PMMA, the foldable optical zone is made of silicone and allows an insertion of the PIOL through a 3.2-mm incision. Consequently, the Artiflex lens theoretically represents an improvement of the iris-supported PIOL concept. Therefore, we performed a clinical evaluation of this latter lens, and to compare it with Artisan, we conducted a randomized, paired-eye study. Notably, this bilateral design with similar myopia in both eyes of a given patient (comparing Artiflex in one eye and Artisan in the other) reduced the variability introduced by interindividual differences and differences in surgeons. It also allows a better statistical evaluation, with each patient serving as his/her own control, and consequently accentuates the differences more clearly.

The primary objective of this study was to determine whether the reduction of astigmatism because of the small incision led to better visual results. The primary outcome measure that we selected was the mean postoperative UCVA, particularly the percent of eyes with UCVA of >20/40, which is a parameter that is influenced directly by the degree of defocus and astigmatism. At one year after surgery, the percent of eyes with UCVA of >20/40 was statistically better for Artiflex ($P < .05$). The efficacy index was significantly higher for Artiflex-treated eyes during the follow-up period. These improved values for Artiflex are in close relationship with the lowering of the postoperative induced astigmatism. When the percent of eyes with UCVA of >20/25 between both groups were compared, the visual accuracy of Artiflex-treated eyes was significantly higher in the early postoperative period. Nevertheless, this study did not highlight this significant difference beyond month 3. This is probably the result of the reduction of corneal astigmatism for the Artisan group on the removal of the sutures. Even if these results that concerned UCVA >20/25 tend to demonstrate a progressive reduction of the difference between both lenses in terms of efficacy, they illustrate also the faster and better visual recovery for Artiflex-treated eyes during the early postoperative period. This observation probably accounts for the significantly higher level of patient satisfaction for the Artiflex group (see "Quality of Vision and Contrast Sensitivity"). Although this study suggested an optimal UCVA for Artiflex, we also observed an unexpected improvement of refractive outcome parameters. Postoperative residual SE and percentage of eyes within ±1 D of emmetropia were significantly better for Artiflex, although the target of Artisan and Artiflex lenses power calculation was identical in all patients (ie, emmetropia). When the attempted and achieved correction for both lenses were compared, the predictability of Artiflex remained unchanged, regardless of the preoperative SE value (Figure 4). These results were unexpected, because such a difference cannot be explained by the variation of the width of the incision. Because of the "coupling effect" (curvature changes in the incised meridian and the unincised orthogonal meridian), there should be no change in SE refraction.[8] A reasonable hypothesis is that the predictability of the Artiflex has been enhanced because of a better accuracy of the lens power calculation by the manufacturer. This increased precision of the power calculation of Artiflex lens could be explained by the modification of the adjusted anterior chamber depth value (see "Surgical Technique").

The second main objective of this study was to compare the safety of both lenses. There was no statistical difference in the safety index between Artiflex- and Artisan-treated eyes at each milestone of the follow-up period. The gain and the loss of lines of BSCVA were very similar for both groups. These results suggested that there is no adverse event during the whole follow-up because of the new Artiflex material, even if the sample size of the studied Artiflex-treated eyes may be statistically insufficient to detect rare complications. The foldable characteristic of Artiflex lens could have decreased the tolerance of the endothelium because of the unfolding and/or a potential postoperative mobility of the flexible optic. This study brought reassuring data with similar cECC and central endothelial cell loss values at one year follow-up in the Artisan- and Artiflex-treated eyes. The postoperative results of the cECC and endothelial cell loss values in both groups are similar to those of a previous Food and Drug Administration Artisan evaluation.[9] Furthermore, the ECC evolution of the superior corneal quadrant, in a paired-eye comparison, was similar for both eyes (data not shown), which suggested that there is no superior endothelial touch during the unfolding of the lens. Further examinations must be carried out to confirm the endothelial tolerance of Artiflex during a long-term follow-up period. The optic silicon material that was used in Artiflex, despite a well-established biocompatibility in previous pseudophakic PIOLs,[10,11] could have increased the incidence of pigment and nonpigment deposits after surgery.[12] A cautious examination under the slit-lamp did not show an adverse event for Artiflex-treated eyes. The use of an intensive combination of steroid and nonsteroid drops during the first month after surgery could explain that this potential complication was not observed in our study. The comparable postoperative intraocular pressure level between both groups is an additional argument in favor of the satisfactory biocompatibility of Artiflex lens.

With respect to the quality of vision, the objective evaluation that was performed in this study, based on contrast sensitivity, did not outline any difference between both lenses, despite the diversity of their optic material. When we compare the subjective satisfaction, most of the patients expressed a strong preference for Artiflex, particularly because of the rapid visual recovery and the improved UCVA. Notably, there is no difference between halos and glare in Artisan- and Artiflex-treated eyes. This result is not surprising because of the similar 6-mm optic zone and edge designs, and an achieved optimal centration over the pupil for both lenses.

In summary, when Artisan vs Artiflex lenses are compared with the aim of correcting moderately high myopia that ranged from −6 to −14 D, the best PIOL choice appears to be the Artiflex lens, rather than the Artisan lens. Because of its foldable optical zone, the Artiflex lens provides a faster visual recovery and better visual outcomes that result from a lower postoperative induced-astigmatism and an increased refractive accuracy. Furthermore, this foldable silicone version seems to be as safe as PMMA. Nevertheless, this observation has to be supported by a larger cohort of patients and a long-term follow-up period.

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Biosketch

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