A Randomized Paired Eye Comparison of Two Techniques for Treating Moderately High Myopia

LASIK and Artisan Phakic Lens

François J. Malecaze, MD, PhD,1 Hervé Hulin, MD,1 Pascal Bierer, MD,1 Pierre Fournié, MD,1 Hélène Grandjean, MD, PhD,2 Claire Thalamas, MD,3 José L. Guell, MD, PhD4

Objective: To compare refractive performance and safety of laser in situ keratomileusis (LASIK) and Artisan phakic intraocular lens (PIOL) for moderately high myopia.

Design: A prospective, randomized trial with paired eye control.

Participants: Twenty-five patients with myopia ranging from −8.00 to −12.00 diopters (D).

Intervention: For each patient, one eye received LASIK and the other one was implanted with an Artisan phakic intraocular lens. The treated eye and the surgical technique were randomized.

Main Outcome Measures: Primary outcome measure was spherical equivalent refraction. Main secondary outcome measures were the change of two or more lines and safety index (ratio postoperative to preoperative best-corrected visual acuity).

Results: One year after surgery, the mean spherical equivalent refraction was −0.74 ± 0.67 D for LASIK-treated eyes and −0.95 ± 0.45 D for Artisan-treated eyes, and the majority of LASIK-treated eyes (64%) and Artisan-treated eyes (60%) were within ±1.00 D of the intended result. At 1 month, the mean spherical equivalent refraction was −0.28 ± 0.71 D for LASIK and −1.07 ± 0.59 D for Artisan (P < 0.01). The changes of two or more lines were in favor of Artisan (P < 0.05). The safety index was significantly better for Artisan (1.12 ± 0.21) than for LASIK (0.99 ± 0.17) at 1 year (P < 0.02).

Conclusions: In cases of moderately high myopia, LASIK and Artisan phakic intraocular lenses seemed to produce a similar predictability. The best-corrected visual acuity and subjective evaluation of quality of vision were better for Artisan. Ophthalmology 2002;109:1622–1630 © 2002 by the American Academy of Ophthalmology.

Today a variety of surgical alternatives are available for correcting myopia. For low myopia, photorefractive keratectomy and laser in situ keratomileusis (LASIK) are currently the most popular techniques.1,2 In high myopia correction (≥−15D), the surgical modalities are also well established. An unavoidable conclusion nowadays, was that LASIK must no longer be performed for high myopia because of several complications.3 An option for this range of myopia is clear lensectomy, but the loss of accommodation and the possibility of retinal detachment is a matter of concern.4 Therefore, more and more workers in the field accept that the main actual alternative for very high myopia is the phakic intraocular lens (PIOL), which can be chamber angle-supported5,6 or iris-supported,7,8 or it can be located in the posterior chamber.9,10 Thus, the choice of the appropriate technique is easy for low and high myopia. However, for moderately high myopia, the choice is much more difficult. Currently, the usual technique for this grade of myopia is LASIK,11 even though it does not provide optimal results. Thus, it is a very important issue to know if PIOL, although apparently a more “aggressive” technique normally used for high myopia, would not also be justified for moderately high myopia. Until now, there have been no prospective studies comparing this option with LASIK. Therefore, we performed a prospective, randomized bilateral study comparing the refractive optical performance and safety of a phakic iris-supported lens (Artisan lens) and LASIK for the treatment of −8 to −12 diopters (D) of myopia.

Patient and Methods

Patient Population

During approximately 1 year, all patients from the clinical practice of the two participating surgeons (FJM in Purpan Hospital, Tou-
louse, France, and JLG in Instituto de Microcirugia, Barcelona, Spain), were invited to participate in the study. Among them, 25 myopic patients fulfilled the criteria (described as follows) and elected to participate in the study.

All patients included in this study had stable myopia for 2 years and unsatisfactory correction by glasses and contact lenses. They had bilateral myopia between −8 and −12 D with an astigmatism <1.5 D. For all eyes, the anterior chamber depth was ≥3.0 mm, the endothelial cell count was ≥2000 cells/mm², the corneal thickness was ≥530 µ, and the mean keratometry was between 42 and 45 D.

Exclusion criteria were as follows: patients under the age of 30 years, corneal disease including keratoconus suspect in videokeratography, glaucoma, uveitis, or a history of retinal detachment.

Each patient received LASIK in 1 eye (LASIK-treated eyes) and Artisan PIOL in the other eye (Artisan-treated eyes) by the same surgeon (FJM or JLG). The order of the two methods and the eye treated were randomized using a random number table at the inclusion visit. The study was approved by the ethical committees of Toulouse 2 and Barcelona (Autonoma University), and informed consent was obtained from each patient.

Patient Examinations

The evaluators (HH and PB) did not participate in the surgical process. The analysis was performed in a double-blind fashion. Both evaluators worked independently from any objective testing, such as slit-lamp examination and corneal topography, which could have unmasked the surgical procedure. For this purpose, independent evaluators performed objective tests. Patients were examined preoperatively and also postoperatively by 1 day, 1 month, 3 months, 6 months, and 1 year.

All the analyses described as follows were also performed postoperatively.

On postoperative day 1, only uncorrected visual acuity 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, applanation tonometry, and corneal topography (EyeSys Corneal Analysis System, Houston, TX). In addition, at 3 months and at 1 year postoperatively, an endothelial evaluation using a noncontact specular microscope (Topcon SP 2000 P; Topcon, Nishinomiya, Hyogo, Japan) and contrast sensitivity (CSV 1000 Vector Vision, Dayton, OH) were performed.

At 6 months postoperatively, the laser flare meter (Kowa FM 500i; Kowa Optimed Inc., Torrance, CA) was used only in a selected subset of patients (n = 10) because of a limited availability of the apparatus.

At 12 months postoperatively, a subjective response for satisfaction was recorded on a scale of 1 to 5 (1 = very poor, 2 = poor, 3 = moderate, 4 = good, and 5 = excellent), and glare and halos were also scored on a scale of 1 to 5 (1 = very intense, 2 = intense, 3 = moderate, 4 = few, and 5 = none).

In addition, for the last 11 patients, an analysis of binocular vision both preoperatively and 1 year postoperatively was added to the protocol. We analyzed retino-cortical correspondence (normal, abnormal), heterophoria (prism cover test), fusion (prism and synoptophore), and stereoscopy using the Lang stereotest (Lang, Forch, Switzerland) and the TNO stereotest (Laméris, Nieuwegein, Netherlands).

Surgical Technique

Whatever the technique, the target of surgery was emmetropia in both LASIK-treated eyes and Artisan-treated eyes.

LASIK Procedure. Patients received diazepam (5 mg) orally and topical anesthesia (oxibuprocaine, 0.4%), one drop every 2 minutes starting 6 minutes before surgery. The Keracor Technolas 217 C (Bausch & Lomb Surgical, Claremont, CA) was used. The system was calibrated before each procedure using a calibrated test film. The software used was version 2.67, subgroup 036, with an ablation zone diameter of 5 mm and a peripheral treatment zone from 6 to 8.5 mm.

The suction ring of the microkeratome, the Hansatome (Bausch & Lomb Surgical, Claremont, CA), was centered on the pupil at the sclerocorneal limbus, and the guides and corneal surface were moistened. Once the lamellar flap (160 µ) was made, it was folded using a spatula maintaining thestromal bed without any extrahydration or desiccation for approximately 15 seconds with active fixation by the patient. The helium neon aiming beam of the laser was focused on the center of the pupil, and the active Eye Tracker System was placed; the ablation was then performed. After ablation, the stromal bed was rinsed with saline solution (Ringer lactate), the flap was placed in its original position, and its border was carefully dried with microsponges. To confirm adequate adhesion, the peripheral cornea was indented with forceps to check for the presence of striae passing from the periphery into the flap. Thereafter, the lid speculum was carefully removed and one drop each of gentamicin and diclofenac were instilled. A topical broad-spectrum antibiotic three times per day was prescribed during the first week.

Artisan Procedure. The Artisan phakic intraocular lens, a convex-concave, iris claw-fixed PIOL with a 6-mm optical zone diameter (Artisan lens; Ophtec B.V., Groningen, Netherlands), was used. This single-piece lens composed of polymethyl methacrylate was manufactured using compression molding technology. Patient refractive error, anterior chamber depth, and keratometric values (Van der Heijde formula) were used to calculate the diopteric power of the lens. The power of the lens was chosen to obtain emmetropia. When the emmetropic lens was not available (it must be remembered that 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.

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 encavlation area. After an intracamer al 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° into a horizontal position from 3- to 9-o’clock. The PIOL was fix ed with an enclavation needle having a bent tip, pushing the iris into both claws. All maneuvers 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 5 or 6 interrupted 10–0 nylon sutures to completely close the incision with minimal tension. The tension of the sutures was checked with standard qualitative Maloney keratomecope.

Postoperatively, prednisolone and chloramphenicol ointment were used four times per day during the first 15 days and then tapered over the next week. Beginning at week 4, over a period of 3 months sutures were selectively removed, depending on the patient’s astigmatism as measured by videokeratography.

Outcome Measures and Statistical Analysis

The primary outcome measure was the refractive outcome (i.e., the postoperative spherical equivalent refraction at 1 year). According to the data in the literature, we could predict that at 1 year...
after LASIK approximately 55% of the eyes would be within ±1.00 D of the desired result. The number of subjects for each method was determined with the objective of achieving a percentage of 80% within ±1.00 D for Artisan, and for a unilateral test with an alpha level of 5% and a power of 70%. The secondary outcome measure was safety, estimated by the percentage of eyes losing two or more Snellen lines of spectacle-corrected visual acuity, and the safety index, which is commonly used as a measure of safety.13

Comparison for percentages was performed using the chi-square test and McNemar’s test when comparing results on the same patient. Concerning quantitative data, the comparisons between the preoperative and postoperative periods, as well as those between the two eyes, were performed using the Wilcoxon sign-rank test, a nonparametric test for matched samples.

Results

All patients completed the study as planned and were included for analysis of the primary and secondary outcome measures, although five patients could not be assessed at the 6-month visit.

Patient Population

There were 8 male and 17 female patients, ranging from 31 to 52 years (38.4 ± 7.6 years). There were no statistically significant differences in the baseline ophthalmic characteristics of the LASIK and Artisan-treated eyes. The baseline parameters were a mean spherical equivalent refraction of −9.39 ± 1.47 D (range, −8.9−12 D) for LASIK and −10.19 ± 1.56 D (range, −8−12 D) for Artisan, a mean baseline refractive cylinder power of 0.83 ± 0.75 D (range, 0−1.50 D) for LASIK and 0.73 ± 0.76 D (range, 0−1.50 D) for Artisan, and a mean baseline keratometric power of 43.44 ± 1.32 D (range, 41−46.25 D) for LASIK and 43.52 ± 1.39 D (range, 41−46.50) for Artisan.

Refractive Outcome

The mean spherical equivalent refraction at 1 year postoperatively was −0.74 ± 0.67 D (range, 0−2 D) in the LASIK-treated eyes and −0.95 ± 0.45 D (range, 0−1.6 D) in the Artisan-treated eyes, a difference which was not statistically significant. As shown in Figure 1 A, B, in scattergrams of changes achieved at 1 year versus intended refraction, LASIK and Artisan-treated eyes exhibited similar patterns of refractive changes, with very few overcorrections and the quasi majority of refractive outcomes ranging from plano to a slight undercorrection. As shown in Figure 2, depicting the refractive outcomes in small steps, at 1 year the majority of both LASIK-treated (64%) and Artisan-treated (60%) eyes were within ±1.00 D of the intended result.

The optimal refractive correction appeared very early for both techniques (Fig 3). For Artisan, the 1-year values had already been obtained as early as the first month and remained stable. For LASIK, it was at the first month that the results were the best with a mean spherical equivalent refraction of −0.28 ± 0.71 D. They were then significantly superior (P < 0.01) to those of the Artisan-treated eyes in which the mean spherical equivalent refraction was −1.07 ± 0.59 D. However, this difference was no longer apparent after 3 months.

The refractive cylinder results differed for the two techniques. For LASIK, the mean cylinder power fell from 0.83 ± 0.75 D preoperatively to 0.29 ± 0.34 D at 1 month and 0.42 ± 0.55 D at 1 year. Conversely, for Artisan there was no reduction of the astigmatism, with values of 0.73 ± 0.76 D preoperatively to 0.97 ± 0.97 D at 1 month and 0.74 ± 0.56 D at baseline at 1 year. Thus, the results concerning astigmatism were significantly better with LASIK at each postoperative period (P < 0.01).
Visual Acuity Outcome

The two techniques showed no statistically significant difference in efficacy (Table 1). At 1 day, one third of the eyes had an uncorrected visual acuity of 20/40 or better with both procedures. The maximal efficacy was obtained as soon as the first month. At 1 year, a slight superiority in the results using LASIK was found, although this difference was not statistically significant ($P = 0.13$).

Table 1. Efficacy of Laser in Situ Keratomileusis and Artisan*

<table>
<thead>
<tr>
<th></th>
<th>1 Day (%)</th>
<th>1 Month (%)</th>
<th>3 Months (%)</th>
<th>6 Months (%)</th>
<th>1 Year (%)</th>
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<tbody>
<tr>
<td>UCVA ≥20/25</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Artisan</td>
<td>2/25 (8)</td>
<td>3/25 (12)</td>
<td>5/25 (20)</td>
<td>2/20 (10)</td>
<td>5/25 (20)</td>
</tr>
<tr>
<td>$P$</td>
<td>0.55</td>
<td>1.00</td>
<td>0.44</td>
<td>0.21</td>
<td>0.73</td>
</tr>
<tr>
<td>UCVA ≥20/40</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LASIK</td>
<td>9/25 (36)</td>
<td>19/25 (76)</td>
<td>17/25 (68)</td>
<td>16/20 (80)</td>
<td>20/25 (80)</td>
</tr>
<tr>
<td>Artisan</td>
<td>8/25 (32)</td>
<td>15/25 (60)</td>
<td>16/25 (64)</td>
<td>12/20 (60)</td>
<td>15/25 (60)</td>
</tr>
<tr>
<td>$P$</td>
<td>0.76</td>
<td>0.23</td>
<td>0.76</td>
<td>0.17</td>
<td>0.12</td>
</tr>
<tr>
<td>Efficacy index</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>LASIK</td>
<td>0.71 ± 0.26</td>
<td>0.64 ± 0.24</td>
<td>0.76 ± 0.27</td>
<td>0.75 ± 0.25</td>
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<tr>
<td>Artisan</td>
<td>0.67 ± 0.22</td>
<td>0.72 ± 0.22</td>
<td>0.71 ± 0.21</td>
<td>0.71 ± 0.24</td>
<td></td>
</tr>
<tr>
<td>$P$</td>
<td>0.57</td>
<td>0.24</td>
<td>0.43</td>
<td>0.59</td>
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</tbody>
</table>

*Efficacy index is the ratio of the mean postoperative UCVA to the mean preoperative BSCVA.

BSCVA = best spectacle-corrected visual acuity; LASIK = laser in situ keratomileusis; UCVA = uncorrected visual acuity.
with either of the techniques. In particular, no flap or interface abnormalities or decentered ablation were observed in the LASIK-treated eyes. Flare values of the LASIK-treated eyes were 9.82 \pm 0.9 photon counts per millisecond preoperatively and 10.48 \pm 1.2 photon counts per millisecond postoperatively ($P = 0.31$).

Concerning the intraocular pressure (IOP), Artisan surgery led to no modification of the IOP (15.3 \pm 2.4 mmHg preoperatively, 14.2 \pm 4.2 mmHg at 1 month postoperatively, 13.8 \pm 2.25 mmHg at 3 months postoperatively, 13.2 \pm 2.9 mmHg at 6 months postoperatively, and 13.4 \pm 4.4 mmHg at 1 year postoperatively). The LASIK procedure was associated with a significant decrease ($P < 0.001$) in IOP, which was seen as early as the first month and persisted at 1 year (preoperative IOP, 15.1 \pm 2.7 mmHg; 1-month postoperative IOP, 8.7 \pm 1.8 mmHg; 3-month postoperative IOP, 9.4 \pm 2.3 mmHg; 6-month postoperative IOP, 8.2 \pm 2.9 mmHg; and 1-year postoperative IOP, 8.0 \pm 2.3 mmHg).

In patients for whom we were able to study the flare, we did not observe any significant difference between the preoperative and postoperative periods. Flare values of the LASIK-treated eyes were 9.82 \pm 0.9 photon counts per millisecond preoperatively and 11.16 \pm 1.5 photon counts per millisecond postoperatively ($P = 0.08$), and those of the Artisan-treated eyes were 9.76 \pm 1.0 photon counts per millisecond preoperatively and 10.48 \pm 1.2 photon counts per millisecond postoperatively ($P = 0.31$).

**Safety**

Measurements of the best spectacle-corrected visual acuity (BSCVA) showed a difference between LASIK and Artisan. As shown in Table 2, the safety index (ratio of mean postoperative BSCVA over mean preoperative BSCVA) was significantly higher in the Artisan-treated eyes than in the LASIK-treated eyes at all periods, except at 1 month.

Visual acuity was evaluated in terms of loss of two lines or more (Fig 4) and a difference between LASIK and Artisan eyes was confirmed. There was no loss of two lines in eyes treated by Artisan compared with loss of two in three eyes treated by LASIK. In addition, there were six cases of improvement in Artisan-treated eyes versus only two cases in LASIK-treated eyes ($P = 0.08$).

Comparing the results of the two techniques in the same patient (Fig 5), there were identical results in 10 cases, superior results for LASIK in 3 cases, and superior results for Artisan in 12 cases. This difference is statistically significant ($P < 0.05$).

There were no significant complications during or after surgery with either of the techniques. In particular, no flap or interface abnormalities or decentered ablation were observed in the LASIK-treated eyes and no uveitis in the Artisan-treated eyes.

<table>
<thead>
<tr>
<th>Table 2. Comparison of the Safety Index for Laser in Situ Keratomileusis and Artisan</th>
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<tbody>
<tr>
<td>Safety index            </td>
</tr>
<tr>
<td>LASIK</td>
</tr>
<tr>
<td>Artisan</td>
</tr>
<tr>
<td>$P$</td>
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*Safety index = ratio of the mean postoperative BSCVA over the mean preoperative BSCVA.

BSCVA = best spectacle-corrected visual acuity; LASIK = laser in situ keratomileusis.

**Contrast Sensitivity**

As shown in Table 3, at the 1-year follow-up visit, although the contrast sensitivity values were slightly modified in the LASIK-treated eyes and were improved in the Artisan-treated eyes, there were no statistically significant differences between the two methods at all four spatial frequencies ($P = 0.66, 0.70, 0.06$, and 0.29 for 3, 6, 12, and 18 cycles per degree cyc/deg, respectively).

**Subjective Evaluation and Quality of Vision**

Considering the subjective responses reported by the 25 patients in the LASIK-treated eyes, 8 moderate halos were reported before the operation and 13 moderate halos after the operation. In the Artisan-
treated eyes, the figures were 10 moderate halos before and 12 moderate halos after the operation. In the LASIK-treated eyes, 7 cases of glare were reported (including 1 severe case) before treatment, and 13 cases of glare were reported (including 3 severe) after treatment. Among these last three, only two appeared postoperatively, and these two eyes had no specific clinical picture. In the Artisan-treated eyes, 9 cases were reported before treatment and 14 after treatment. Only one eye presented a severe glare preoperatively and postoperatively. Thus, there is a slightly increased frequency of halos ($P = 0.05$ for LASIK and $P = 0.19$ for Artisan) and glare ($P = 0.02$ for LASIK and $P = 0.01$ for Artisan) after surgery, but there is no significant difference between the two techniques ($P = 0.30$ for halos and $P = 0.20$ for glare).

As an additional way of assessing the two techniques, satisfaction ratings were noted, and the patients were asked which technique they preferred. The satisfaction levels were not statistically different ($P = 0.40$) between the two methods, and overall they were correct because the score was inferior to 4 in only five cases in LASIK-treated eyes and three cases in Artisan-treated-eyes. Concerning the preference for one of the techniques, 4 of 25 patients preferred LASIK, 11 of 25 preferred Artisan, and 10 of 25 had no preference.

**Binocular Vision**

Only one case had previous strabismus with abnormal retinocortical correspondence. He did not have any change in his sensory status after surgery, and he did not experience diplopia. The other
cases had various physiologic preoperative phorias (5 exophorias, 5 orthophorias). No noticeable change after surgery was noticed in prism cover test measures. Stereoscopy and fusion amplitude were in a normal range and were not affected by surgery.

Discussion

In 2001, there was still an ongoing debate concerning the choice of the appropriate surgical technique for moderately high myopia from approximately −8 to −12 D. Two completely different surgical refractive alternatives are more extensively used in young patients; the corneal refractive procedure (ie, LASIK and the intraocular lens surgery). The choice between the two techniques is still a matter of debate because they do not have the same advantages and disadvantages. A major concern with LASIK is its risk of corneal ectasia14,15, whereas with Artisan, endothelial cell loss is feared.16 However, an accurate comparison between these two techniques for this range of myopia has never been published to our knowledge. Therefore, we decided to conduct a trial comparing these two techniques for this level of myopia with two major questions in mind. (1) Which one has the better refractive performance? (2) Which is safer in the long-term?

This trial was planned with two main objectives: (1) to try to answer as specifically as possible the two questions that were raised previously, and (2) not to incur any risk to the patient. A bilateral design, with similar myopia in both eyes of a given patient, comparing LASIK in one eye with a phakic intraocular lens in the other eye seemed to satisfy these two criteria. Indeed, this preoperative, randomized bilateral study largely reduces the variability introduced by interindividual differences and differences in surgeons that linked to outcome measures, but it also allows a better statistical evaluation with each patient serving as his own control.

<table>
<thead>
<tr>
<th>Spatial Frequency</th>
<th>Preoperative</th>
<th>1-Year</th>
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<tbody>
<tr>
<td></td>
<td>Laser In Situ Keratomileusis</td>
<td>Artisan</td>
</tr>
<tr>
<td>3 cyc/deg</td>
<td>1.62 ± 0.27</td>
<td>1.50 ± 0.44</td>
</tr>
<tr>
<td>6 cyc/deg</td>
<td>1.15 ± 0.67</td>
<td>1.21 ± 0.65</td>
</tr>
<tr>
<td>12 cyc/deg</td>
<td>0.89 ± 0.77</td>
<td>0.83 ± 0.70</td>
</tr>
<tr>
<td>18 cyc/deg</td>
<td>0.68 ± 0.63</td>
<td>0.74 ± 0.55</td>
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control. Thus, for an identical number of cases, the paired methodology allowed us to define small quantitative differences more clearly. Furthermore, concerning the important problem of risks for the patient, because the long-term outcome of both techniques was unknown, our choice of performing a bilateral study balanced the potential risk for the patient.

In addition, the inclusion of the patients was conducted with the knowledge of the potential risks of these two techniques by selecting patients whose characteristics, particularly cornea and anterior chamber depth, were deemed suitable for surgery.

Concerning the choice of the PIOL for the comparison with LASIK, we preferred the Artisan lens, which was already being used routinely by both surgeons, because of its position in the eye far from the endothelium and the natural lens, the large optical zone (6 mm) and the adjusted, surgeon achieved centration of the PIOL over the pupil.

The primary outcome measure selected in this study was the refractive outcome. Its overall trend was toward similar results for LASIK and Artisan for myopia between −8 and −12 D. At 1 year, no statistically significant difference was found in the refractive outcome between the LASIK-treated and Artisan-treated eyes, as determined by the postoperative spherical equivalent refraction, the percentage of eyes within ±1.00 D of the desired result (slightly higher than predicted based on the literature), and the efficacy index. Both LASIK and Artisan-treated eyes were on average undercorrected. This undercorrection was slightly higher for Artisan, probably because of a tendency of both surgeons toward a slight residual myopia in the intended correction of this new technique. It is important to note that this residual myopia is more easily manageable thereafter in the Artisan-treated eyes than in the LASIK-treated eyes because it is easy to perform a laser excimer for a slight residual myopia in the Artisan-treated eyes, whereas in the LASIK-treated eyes, the residual stromal bed can rule out a retreatment as was observed for one patient in our study.

Even if the overall tendency in terms of refractive outcome is similar for both procedures, there is an advantage in favor of LASIK for the following reasons. First, LASIK is temporarily better, because at 1 month the mean spherical equivalent refraction is statistically better for LASIK ($P < 0.01$). Second, at 2 years the percentage of eyes with an uncorrected visual acuity $> 20/40$ was higher with LASIK, although this difference was not statistically significant perhaps due to the small sample size. Finally, in terms of astigmatism, even though not of great clinical importance, the results were statistically better for LASIK.

The second main objective when starting this study was to appreciate which of the two strategies was safer. At the 1-year follow-up, the analysis showed that there was a significant difference in the change of BSCVA. Figures 4 and 5 clearly show that this difference is explained by two undeniable trends, a greater proportion of gain of BSCVA with Artisan and a greater loss of BSCVA with LASIK. The high percentage of loss of BSCVA in LASIK-treated eyes, which is higher than the one reported in the literature, was not caused by a flap abnormality, a photoablation decentration, or a low keratometric power, and this may be artifactually high because of the small sample size of our study.

To appreciate the safety of these two techniques, a laser flare meter was performed in 10 of 25 patients, and no statistically significant difference was found between LASIK and Artisan. This is in agreement with previous reports, including our own, of the absence of subclinical inflammation after Artisan implantation.

In contrast, a decrease of intraocular pressure after LASIK was noted. This lowered intraocular pressure has already been described by several authors. The cause of this decrease is probably related to the system of measurements that becomes no longer adapted to a thinner cornea.

No statistically significant difference was observed when comparing the preoperative and postoperative endothelial cell counts in the LASIK and Artisan-treated eyes. A limitation of our study was the short follow-up (only 1 year), and further examinations must be carried out to compare in each patient the effect of the two procedures on the endothelium, which is presently the object of contradictory opinions.

Concerning patient satisfaction, the majority of patients stated that they were satisfied with both eyes. However, when asked which eye they preferred, the majority of these patients expressed a preference for Artisan. It is not possible to correlate these results with the primary outcome measure, because the minimal residual myopia was too slight to be clinically visible. We did not observe a significant correlation between satisfaction levels and glare and halos ($P$ range, 0.10–0.73). If an attempt is made to compare the satisfaction levels with the objective change of BCVA, in 13 cases patient satisfaction was in accordance with these results, 9 patients had no preference (although there was a difference of at least one line of BCVA on one side), and 3 patients preferred the technique which had the lower objective results. Thus, it is likely that the factors influencing the degree of satisfaction vary from one patient to another, and the sample size of this study is too small to perform a broader analysis. It is also interesting to note that the binocular vision was not affected by the conjunction of corneal and intraocular refractive procedures. This seems logical, as ametropias and accommodative effort were almost symmetrical in both eyes of the patients, before and after surgery. The visual improvement had no effect on binocularity; however, this may have been because the patients in this study had no previous asthenopic troubles. Perhaps a different result would have been obtained if the previous state of binocularity had been more fragile (e.g., in high unilaterial myopia). Nevertheless, one can remark that the only patient with previous strabismus had no change in the postoperative tests. In this study, it has been shown that in symmetrical myopia, if preoperative binocular vision is correct, the use of the two different techniques (corneal or intraocular refractive surgery) on either of the eyes had no effect on binocularity, and the tremendous difference in keratometry power was well tolerated.

We are aware that the small sample size of this study does not allow definitive conclusions, but it is interesting to note that the main outcome measure (i.e., the refractive outcome) is similar with both techniques. It is temporarily
better with LASIK; however, for us this has a lesser clinical importance than the better recovery of baseline spectacle-corrected visual acuity with Artisan.

All things considered, when trying to make the best choice for a patient with moderately high myopia, the individual parameters of the cornea and the anterior chamber depth must first be taken into account. From a general point of view, although Artisan surgery is more aggressive and not yet commonly performed, we believe that it presently represents the better choice for the patient because there is a better recovery of baseline best-corrected visual acuity, some reversibility, and easy management of postoperative residual refractive error. We also believe that Artisan surgery probably has a better quality of vision because of preservation of the original optics of the eye.

Conversely, wavefront technology could be applied either to the optics of the IOL taking advantage of the fixation of the IOL, or with minimal adjustment laser ablation after IOL implantation. However, today’s opinion needs to be confirmed by a longer term follow-up (i.e., by several years).

References