# Adjustable Refractive Surgery: 6-mm Artisan Lens Plus Laser In Situ Keratomileusis for the Correction of High Myopia

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**Purpose:** To evaluate efficacy, predictability, stability and safety of adjustable refractive surgery (ARS) by combining a phakic intraocular lens (IOL) (Artisan lens 6-mm optical zone [OZ]) and laser in situ keratomileusis (LASIK) (6.5 mm OZ) for the correction of myopia greater than -15.00 diopters (D).

**Design:** Noncomparative interventional case series.

**Participants:** Twenty-six eyes of 18 patients with a preoperative spherical equivalent between -16.00 and -23.00 D.

**Methods:** First surgery: An 8.5/9.5-mm flap was created and a 6-mm optic iris claw phakic IOL of -15.00 D was inserted in the anterior chamber through a posterior corneal incision. The second surgery was performed once refraction and topography were stable, between 3 and 5 months later. Second surgery: LASIK enhancement (6.5-9.2 OZ); the flap was relifted, and the residual refractive error was corrected.

Main Outcome Measures: The main parameters in this study were uncorrected visual acuity, best-corrected visual acuity (BCVA), refraction, contrast sensitivity, endothelial cell count (ECC), and subjective response.

**Results:** Twenty-eight months after both surgeries, 80.70% of the eyes were within 0.50 D of emmetropia and 100% within 1.0 D. Twenty-six percent of the eyes gained 3 or more lines from their preoperative BCVA, and 42% gained 2 or more lines. There was no visual loss in any eye from 6 weeks to 24 months after LASIK enhancement (second surgery) and refraction, and visual acuities remained stable. Two subjects (11%) had some subjective disturbances at night. There was a 0.61% mean loss of ECC during the first 12 months and a 0.60% loss during the next 16 months. No serious complications were observed.

**Conclusions:** ARS with the combination of a 6-mm optic, 15 D Artisan lens, and LASIK appears to be a safe and highly predictable method for the correction of myopia greater than −15.00 D. It is the best approach with the technology currently available. *Ophthalmology 2001;108:945–952* © *2001 by the American Academy of Ophthalmology.* 

Today, one of the goals of refractive surgery for both the surgeon and the patient is not only emmetropia but also a superior quality of vision at any time during the day or night.

Keratorefractive procedures such as epikeratoplasty, <sup>1,2</sup> in situ keratomileusis, <sup>3</sup> excimer laser photorefractive keratectomy, <sup>4</sup> and more recently laser in situ keratomileusis (LASIK)<sup>5,6</sup> have all been used to correct high myopia. So far, the best results have been obtained by LASIK. The complications that have been reported for high myopic correction, such as unpredictability, regression, and, mainly, poor quality of vision under dim illumination, are conditions probably related to both the change of the corneal contour and the small optical zone (OZ) used.

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Among the intraocular procedures, we may include the phakic intraocular lenses (IOLs),<sup>7</sup> lenses used to correct ametropia on a phakic eye, and clear lens extraction (CLE) with IOL implantation, 8,9 a procedure that has been criticized because of a theoretical greater incidence of postoperative retinal detachment and accommodation loss in young subjects. 10,11 Similar to corneal refractive surgery, phakic IOLs need to be built with a smaller OZ, as the degree of myopia to be corrected is higher. However, when correcting very high myopia, the small OZ may produce a suboptimal visual acuity in dim illumination conditions because of large pupils, halo effects, and poor night vision.<sup>12</sup> The rationale of combining a phakic IOL (the Artisan lens, Ophtec B.V., Groningen, The Netherlands) and LASIK was to improve the quality of vision in this group of high myopic subjects. This visual improvement could not be achieved by other more common methods of correction such as LASIK or phakic IOL implantation alone. To diminish glare, halos, and other common complaints subjects have under dim illumination, the largest possible OZ was used in both the IOL and the stromal ablation.

The adjustable refractive surgery (ARS) approach consisted of performing the lamellar cut before the IOL implantation. This method was used to avoid any possible contact between the corneal endothelium and the anterior chamber IOL during the microkeratome pass.

This is a prospective study of high myopic eyes that were corrected with the ARS method, combining a -15.00 diopter (D), 6-mm OZ Artisan lens, and LASIK with a 6.5-mm OZ. LASIK was performed as the second procedure to correct the residual ametropia, and this assured us of a more predictable outcome.

## **Patients and Methods**

Twenty-six eyes of 18 patients were enrolled in this prospective study (8 men, 10 women), consecutively, with ages ranging from 28 to 35 years (31.30  $\pm$  2.20), from December 1996 to March 1997. The preoperative refractive error ranged from -16.0 D to -23.0 D (mean,  $-18.42 \pm 2.73$ ). Patients with or without astigmatism were included. Preoperative uncorrected visual acuity (UCVA) was less than 0.063 in all of the eyes; preoperative best-corrected visual acuity (BCVA) was 0.39 ± 0.16 (range, 0.10-0.50) (20/200-20/40) (contact lens overrefraction). All the surgeries were performed by the same surgeon (JLG) at Instituto de Microcirugia Ocular de Barcelona. The surgical procedure consisted of two main steps. First, before IOL implantation, the suction ring of the microkeratome was centered on the pupil at the sclerocorneal limbus, and a flap was obtained. The interface was cleaned, the flap was replaced, and the 6-mm Artisan lens was then implanted. Residual refractive myopia and astigmatism were corrected by LASIK, which was performed 3 to 5 months after the first surgery, similar to a standard LASIK enhancement.

# Patient Selection

Patients older than 28 years, with stable myopia for at least 1 year and greater than -15.00 D of spherical equivalent refraction who also had an otherwise normal ophthalmologic examination and unsatisfactory correction with spectacles or contact lenses for medical, professional, or personal requirements were included. All patients were fully informed of the details and possible risks of the two procedures, and written consent was obtained.

Exclusion criteria were anterior segment pathologic condition, inadequate eyelid closure, uveitis, previous corneal or intraocular surgery, monocular status, systemic diseases (such as autoimmune, connective tissue disease, atopia, or diabetes), chronic treatment with corticosteroids or any immunosuppressive treatment or state, pregnancy, endothelial cell counts of less than 2000 cells/mm² and an anterior chamber depth less than 3 mm.

## **Preoperative Examination**

Preoperative examinations were performed by a team of optometrists who were trained and supervised by the investigators of this study. Preoperative evaluation included UCVA and BCVA (contact lens overrefraction), manifest and cycloplegic refractions, slit-lamp examination, applanation tonometry, keratometry (Javal, Spain), and indirect ophthalmoscopy.

The subjective response for satisfaction was rated on a scale from 1 to 5, 1 = very poor, 2 = poor, 3 = moderate, 4 = good, and 5 = excellent. The symptoms such as glare, halos, pain, itching, and foreign body sensation were rated as 1 = very intense, 2 = intense, 3 = moderate, 4 = few and 5 = none.

The following complementary examinations were performed: videokeratography (EyeSys Corneal Analysis System, Houston, TX), central corneal pachymetry (Accutome, Kremer Corneometer, Broomal, PA), axial length and anterior chamber depth with our ultrasonic biometer (CompuScan LT Model No. 1000, Storz, St Louis, MO), endothelial cell count (Topcon SP, 1000 noncontact specular microscope and the Imaginet Analysis System from Topcon, Spain) and contrast sensitivity (CSV-1000, Dayton, OH).

#### Worst Iris Claw Phakic IOL

A convex-concave, iris-claw fixated IOL, designed by Jan Worst (Ophtec B.V, Groningen, The Netherlands) with a 6-mm OZ and -15.00 D was used in all of the study subjects. To maintain a 6-mm OZ and at the same time work within safe limits, it was critical not to overpass a -15.00 D correction. The biomaterial of this one-piece compressing molding lens is polymethylmethacrylate. The total length was 8.5 mm; the peripheral height was 0.96 mm (which was the maximal height allowed in the study) with a standard lens power of -15.00 D. The dioptric power of these lenses is calculated with the patient's refractive error, the anterior chamber depth, and keratometric values (Van der Heijde formula). Nevertheless, for this study it was not necessary to calculate the exact power of the IOL, because the expected residual error was going to be corrected with LASIK.

## Surgical Procedure

Retrobulbar anesthesia (4 ml of a proportional combination of mepivacaine 2% (Mepivacaina 2%, Braun, Spain), bupivacaine 0.75% (Bupivacaina 0.75%, Braun), and mucopolisacaridase (Thiomucase, Funk, Spain) was used for the procedure. Before IOL implantation, the suction ring of the microkeratome ALK-E (Automated Corneal Shaper, Chiron Vision, Clairemont, CA, with serial number 286) or Hansatome (serial number 2966), was centered on the pupil at the sclerocorneal limbus, and the guides and corneal surface were moistened (Fig 1). The lamellar flap (160  $\mu \rm m$ ) was obtained and folded over the nasal side of the eye using the LASIK retreatment spatula (ASICO). The interface was cleaned, the flap replaced, and its borders were carefully dried with microsponges.

After confirming adequate adhesion of the flap edges, we proceeded with the implantation of the Artisan lens<sup>14</sup> (Fig 2).

Between 2 and 4 months after IOL implantation, once all the sutures had been removed and the residual cylinder was stable for at least 4-weeks, LASIK was programmed. The patient was given oral diazepam (5–10 mg) orally, and topical anesthesia (tetracaine and oxibuprocaine) was used at a rate of one drop every 2 minutes for 6 minutes before surgery.

A third-generation excimer laser system, the Keracor 117 CT, 50 Hz Planoscan (Chiron Technolas) was used. The main features of this laser system are a 2-mm beam size, a beam energy density of 120 mJ/cm², a pulse frequency of 50 Hz, and a maximum treatment OZ for myopia of 8.5 mm. The software used was the V 2.67 subgroup 036, with an OZ of 6 mm and a peripheral treatment zone from 6 to 8.5 mm.

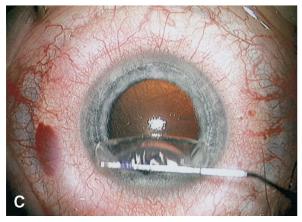
LASIK was performed with topical anesthesia. After dissecting the peripheral edge of the flap with the LASIK retreatment spatula (ASICO), the flap was lifted, and the ablation was performed (Fig 3).

## Follow-up

Postoperative evaluations were programmed at 24 hours, 1 and 3 months after IOL implantation. During the first 3 months and







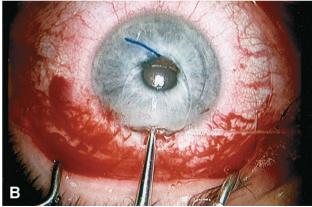
**Figure 1.** First Surgery: Microkeratome cut. It is extremely important to first check the quality and dimensions of the flap.

starting at the fourth week visit, suture removal was performed with the patient's astigmatism taken into account using videokeratography control. With the exception of the first day postoperatively, a complete ophthalmologic examination, as previously described, was performed at each visit.

After the LASIK procedure, each patient was examined the first day postoperatively and at 1, 3, 6, 12, 18, and 24 months. Again, with the exception of the first postoperative day, a complete examination was performed.

Each patient was encouraged to return for follow-up and was given complete information emphasizing the impor-





**Figure 2.** First Surgery: Artisan intraocular lens (IOL) introduction. Note that the IOL must be completely introduced in only one step to eliminate the risk of IOL-crystalline contact.

tance of doing so. All the patients enrolled returned for followup.

# Statistical Analysis

Data for analysis were obtained from data forms previously designed by the authors for refractive procedures. When both eyes of a patient were used for the study (8 patients), they were analyzed separately. Student's t test for paired data was used (Microsoft Excel 97). The differences were considered statistically significant when the probability value was less than 0.05.

# **Results**

A summary of the results is shown in Table 1.

## Visual Acuity

Pre-LASIK UCVA ranged from less than 0.063 to 0.32 (0.11  $\pm$  0.10). One, 12, and 24 months after LASIK, UCVA ranged from 0.16 to 0.70 (0.50  $\pm$  0.15), from 0.25 to 0.63 (0.51  $\pm$  0.14), and from 0.25 to 0.63 (0.51  $\pm$  0.14), respectively. Postoperative UCVA was significantly better than preoperative values at 1, 12, and 24 months (Student's t test for paired data, P < 0.001).

Postoperative best spectacle-corrected visual acuity (BSCVA) ranged from 0.25 to 1.00 (0.55  $\pm$  0.16) and from 0.25 to 1.00 (0.59  $\pm$  0.17) at 1 and 12 months after LASIK, with no changes at 24 months. Contact lens overrefraction was not used to check visual acuity postoperatively. When comparing preoperative BSCVA with 1-month, 12-month, or 24-month values, the differences were found to be statistically significant (Student's t test for paired data, P < 0.001).

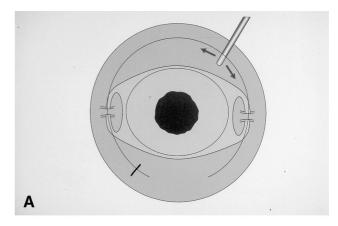
Seventy-seven percent of the eyes (20 eyes) achieved UCVA of 20/40 (0.5) or better. None achieved UCVA better than 20/25 (0.8) or worse than 20/200 (0.1).

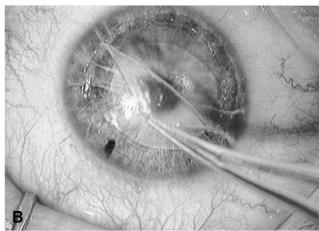
Preoperatively, no eyes had a BSCVA of 20/25 (0.8) or better (Fig 4). No eyes lost a single Snellen line of SCVA, but 30.70% of the eyes gained 1 line of BSCVA, 15.38% gained 2 lines, and 26.90% gained 3 or more lines of vision after the LASIK procedure compared with the first preoperative control (Fig 5).

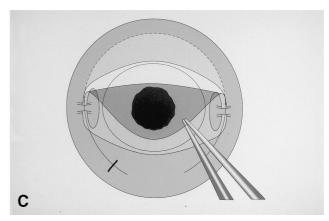
#### Refraction

Twenty-four months after LASIK, all of the eyes were within  $\pm 1.00$  D of emmetropia, and 21 eyes (80.7%) were within  $\pm 0.50$  D (Fig 7).

Sixty-five percent of the eyes were within ±1.00 D of astigmatism before IOL implantation. After LASIK, this percentage







**Figure 3.** Second Surgery: Laser in situ keratomileusis enhancement. Dissection of the edge of the flap and exposure of the corneal stroma.

increased to 84.60% at 3 months, and it remained unchanged for the rest of the follow-up period.

# Contrast Sensitivity

Contrast sensitivity was measured using the CSV-1000 test, and there were no statistically significant differences between preoperative and postoperative contrast sensitivity values at the 3rd and 24th month after LASIK at all spatial frequencies (Student's t test for paired data, P > 0.05).

Table 1. Preoperative and Postoperative Results of the Adjustable Refractive Surgery (6-mm Artisan Phakic Intraocular Lens + Laser in situ Keratomileusis) Approach

	Preoperative	1 mo	12 mo	24 mo
UCVA	< 0.063	$0.50 \pm 0.15$	$0.51 \pm 0.14$	$0.51 \pm 0.14$
BSCVA	$0.39 \pm 0.16$	$0.55 \pm 0.16$	$0.59 \pm 0.17$	$0.59 \pm 0.17$
±1.00 D of emmetropia (%)	_	92.30	100	100
±0.50 D of emmetropia (%)	_	80.76	80.76	80.76
UCVA ≥20/40		73.07	77	77
Loss ≥2 lines BSCVA	_	0	0	0
Gain ≥1 line BSCVA	_	65.38	72.98	72.98

BSCVA = best spectacle-corrected visual acuity; D = diopter; UCVA = uncorrected visual acuity.

# Subjective Response

At 24 months postoperatively, using the scale previously mentioned, the mean overall subjective response was 4.0. This subjective response included symptoms such as glare, halos, and other grievances such as pain, itching, and foreign body sensation.

#### Corneal Endothelium

The mean preoperative endothelial cell density was  $2782 \pm 392$  cells/mm² (1937–3225). Twelve months after IOL implantation, the mean endothelial density slightly decreased to  $2765 \pm 389$  cells/mm² (1925–3201). Twenty-eight months after IOL implantation, the endothelial cell count remained relatively stable,  $2749 \pm 388$  cells/mm² (1915–3181). No statistically significant differences in endothelial cell counts were found throughout follow-up (Student's t test for paired data, P > 0.05). There was a 0.61% mean loss of endothelial cells during the first 12 months and a 0.60% loss during the next 16 months after IOL implantation.

#### Complications

Of the 26 eyes operated on, there were no serious complications during the follow-up period.

There were a few complications related to the microkeratome, which included one case of a free cap measuring 8 mm in diameter, one case involving a traumatic flap dislocated 1 day after surgery, and one case of a short flap with a 3-mm hinge and a horizontal stromal space of 7.7 mm.

During the first week after IOL implantation, 19.23% of the eyes were found to have mild elevation of intraocular pressure.

No lens opacification, pigmentary dispersion, pupillary block or retinal complications occurred during the follow-up period.

## **Discussion**

The correction of high myopia is controversial. Corneal refractive surgery cannot adequately correct high myopia. Intraocular refractive surgery (lens extraction with IOL implantation or phakic IOL implantation) is a more suitable option for the correction of high myopia.

It is extremely important to maintain a minimal OZ size of 6 to 6.5 mm for corneal ablation procedures and for IOL implantation in phakic eyes when correcting high myopia of a spherical equivalent greater than -12.00 D. It is difficult to work with large OZs when attempting to correct high myopia because of excessive ablation and the increased peripheral height of phakic IOLs, which can cause damage to the surrounding tissues.

This was the reason to combine a 6-mm OZ Artisan IOL and a 6.5-mm OZ LASIK procedure for the correction of high myopia. LASIK was performed second, because the outcome was more predictable by doing it last. The term ARS was used for all the cases; we had planned on combining corneal refractive surgery with intraocular surgery. The rationale in performing the flap first during the intraocular surgery was to avoid any possibility of contact between the endothelium and the IOL during the suction and cut with the LASIK procedure.

#### Efficacy of the ARS procedure

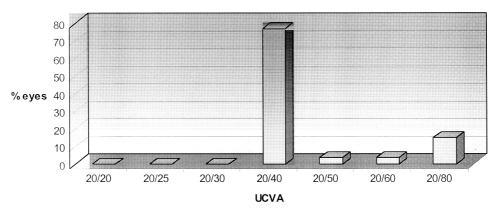


Figure 4. Efficacy of the adjustable refractive surgery (6-mm Artisan phakic intraocular lens + laser in situ keratomileusis) procedure.

#### Safety of the ARS procedure. Change in BSCVA at 24 months postoperatively

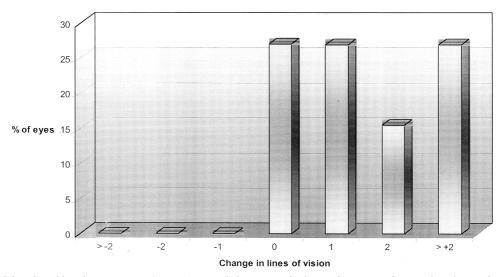


Figure 5. Safety of the adjustable refractive surgery (6-mm Artisan phakic intraocular lens + laser in situ keratomileusis) procedure.

The ideal refractive procedure is one that could be adjustable. Theoretically, the ARS concept could be applied to any kind of refractive surgery, for example, an ideal IOL able to be changed in power once in place with laser.<sup>14</sup>

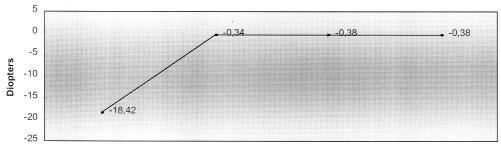
The refractive results of our study were excellent after both surgeries. All of the eyes were within  $\pm 1.00$  D of emmetropia, and 80.70% (21 eyes) were within  $\pm 0.50$  D. These results are better than those of previous studies, in which only the implantation of the Artisan lens was used for correcting high myopia. <sup>15,16</sup> Perez Santonja et al. <sup>17</sup> and Krumeich et al. <sup>18</sup> whose results resemble ours, have reported a postoperative spherical equivalent refraction within  $\pm 1.00$  D in 91% and 95% of the eyes they operated on, respectively.

Zaldivar et al<sup>19</sup> introduced the term "bioptics" to describe the combination of LASIK and IOL implantation in patients who had spherical equivalents of -18.00 D or greater, subjects with high levels of preoperative astigmatism (greater than -2.00 D), and patients whose lens power availability was a problem. In a group of 67 myopes who underwent the "bioptics" procedure, <sup>20</sup> the mean postoperative spherical equivalent and cylinder power at their last examination after LASIK were  $-0.20 \pm 0.90$  and  $-0.50 \pm 0.50$  D, respectively. In this group of patients, 85% (57)

eyes) achieved a postoperative spherical equivalent refraction within  $\pm 1.00$  D and 67% (45 eyes) within  $\pm 0.5$  D of emmetropia at the time of their last examination. The mean follow-up was 3 months after the LASIK procedure (range, 1 day-6 months).

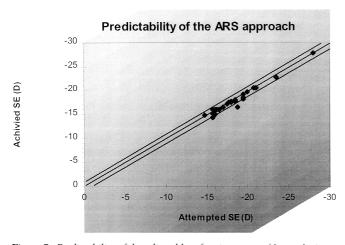
In our study, 100% of the patients were within  $\pm 1.00$  D of emmetropia and 80.70% within  $\pm 0.50$  D. The complications in the series of Zaldivar et al<sup>20</sup> series were cataract formation (1 eye) and macular hemorrhage (1 eye). The IOL they used had an OZ of 4.8 mm. Our goal in this study was to maintain an OZ of 6 mm. Seventy-three percent of the eyes in this study gained 1 or more lines of their preoperative BCVA. Other authors<sup>17,21</sup> have reported this gain in visual acuity caused by the increase in the size of the retinal image; however, they did not use contact lens over refraction preoperatively. We think it is important to perform contact lens overrefraction to avoid overestimation in actual gain in visual acuity.

All the patients who undergo LASIK or any other "phakic" IOL surgery alone for the correction of high myopia usually complain of nocturnal halos and notice a decrease in the quality of vision in dim illumination. Only two patients in our study experienced visual disturbances at night. These complaints were drastically reduced, because we used a



Time after surgery: Preop-1m-12m-24m

**Figure 6.** Stability of the adjustable refractive surgery (6-mm Artisan phakic intraocular lens + laser in situ keratomileusis) procedure.



**Figure 7.** Predictability of the adjustable refractive surgery (6-mm Artisan phakic intraocular lens + laser in situ keratomileusis) procedure.

larger (6-mm) OZ with the iris claw IOL, and the final visual acuity was not altered by such phenomena.

The main risk with posterior chamber IOLs is cataract formation and in anterior chamber IOL implantation damage to endothelium. We observed a slight decrease of the endothelial cell count (a 0.61% mean loss during the first 12 months and a 0.60% loss during the next 16 months). This could be a result of the surgery itself or of the presence of a foreign body in the anterior chamber. The mean endothelial cell loss reported in this study is lower than that reported by other authors. 15,21-23 A more extensive follow-up should be done to determine the stability of endothelial cell counts in these subjects. One of the main advantages of using ARS is that it avoids the risk of endothelial to IOL touch during the microkeratome cut. A previous report,<sup>24</sup> which used the combined surgical technique (not ARS) showed the mean endothelial cell count after the Artisan lens implantation and before LASIK as  $2629 \pm 366$ ; even though this number was similar to the endothelial cell count measured after 12 months after the LASIK procedure (2612  $\pm$  347), we prefer to create the flap before the IOL implantation to eliminate any risk of damage to the endothelium. We use this technique as standard. This factor becomes critical when dealing with angle-fixated anterior chamber IOLs. In this case, it is highly recommended that the flap be performed before the implantation of the IOL, especially if an enhancement procedure is necessary in the near future. When implanting posterior chamber phakic IOLs, the main advantage of ARS is to avoid the possible luxation of the lens into the anterior chamber during the microkeratome cut from a dilated pupil.

As with other series, no postoperative glaucoma had been observed with the exception of a mild, transient episode of elevated intraocular pressure, which disappeared when corticosteroids were discontinued. 17,18

The complications reported in the literature with the Artisan lens implantation but not found in this study are lens decentration, <sup>25</sup> retinal complications, <sup>21,25,26</sup> cystic wounds, <sup>25</sup> Urrets/Zavalia syndrome, <sup>25</sup> lens opacity, <sup>17</sup> and ischemic optic neuropathy. <sup>27</sup> Perez Torregrosa et al, <sup>28</sup> using the Imaginet analogue digital system, measured its position-

ing and found no decentration more than 1 mm in any of the eyes. Fechner et al<sup>25</sup> referred to difficulty in centrating the lens initially with severe exudative iritis in eight eyes, which required repeated incarceration to fixate the IOL. We had no clear decentration measured at the slit lamp. Again, a much longer follow-up is necessary to be sure about the long-term possible fixation problems, although we strongly suggest that surgeons include at least 1.5 mm of folded iris inside the claw, because poor fixation has probably been the cause of most of those IOL decentration and/or luxations.

A possible disadvantage of ARS (although we did not see this in our series) is the risk of an increased rate of epithelial ingrowth at the interface, a description found in any LASIK retreatment series.<sup>29</sup>

Another option for patients with high myopia (>-12.00D) is CLE. It is less predictable than our ARS approach, and there is an increased risk of retinal detachment when doing this procedure. Colin et al<sup>30</sup> reported 59.1% of patients with preoperative myopia greater than −12.00 D who underwent CLE were within ±1.00 D of emmetropia and 85.7% were within  $\pm 2.00$  D at 7-year follow-up. They also reported the incidence of retinal detachment after CLE was nearly double that estimated for people with myopia greater than -10.00 D, who do not undergo surgery. Of course, this item must be adequately studied with a properly selected control group. We are confident in this combined procedure because of the excellent optical results in using larger OZs. Preservation of accommodation in young patients, quality of vision in dim illumination, predictability, and safety<sup>31</sup> should be considered when evaluating the options for subjects with high myopia. ARS appears to be a suitable option for subjects with myopia greater than -15.00 D, who otherwise have normal ophthalmologic examinations.

Even though our present endothelial cell count numbers are close to the expected physiologic endothelial change values one would normally see, it would be interesting to have a more complete follow-up of these patients (5–10 years) and compare them with an age-matched control group. This information could be critical in accepting any "phakic" IOL surgery for high myopia as standard.

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