Phakic intraocular lenses to correct high myopia: Adatomed, Staar, and Artisan

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Purpose: To evaluate the feasibility and safety of using phakic intraocular lenses (IOLs) to correct high myopia by comparing 3 IOL models: Adatomed, Staar, and Artisan.

Setting: La Fe University Hospital, Department of Ophthalmology, and the Fundación Oftalmológica del Mediterráneo, Valencia, Spain.

Methods: In this prospective comparative study, a phakic IOL was implanted in 217 highly myopic eyes (118 patients). Fifty-nine eyes received an Adatomed IOL, 21 eyes a Staar IOL, and 137 eyes an Artisan IOL. The mean preoperative spherical equivalent was −15.39 diopters (D) ± 2.83 (SD), −16.00 ± 5.05 D, and −16.17 ± 2.75 D in the Adatomed, Staar, and Artisan groups, respectively. The mean follow-up was 32.4 months (range 19 to 46 months) in the Adatomed group, 18.3 months (range 11 to 21 months) in the Staar group, and 121.4 months (range 38.4 to 154.3 months) in the Artisan group. At the follow-up examinations, intraocular pressure (IOP), IOL pigment deposits, cataract formation, and visual acuity were evaluated.

Results: The best corrected and uncorrected visual acuities improved in all eyes. No significant differences in visual acuity improvement were observed with the 3 materials, although the improvement was somewhat greater in eyes with the Artisan and Staar IOLs. The difference in mean IOP between preoperatively and the last follow-up examination was 1.5 mm Hg in the Staar group, 1.3 mm Hg in the Adatomed group, and 1.7 mm Hg in the Artisan group ($P = .36$, $P = .26$, and $P = .32$, respectively). The incidence of pigment deposits was similar in the Adatomed and Staar groups, with deposits in 32 eyes (54.23%) and 8 eyes (38.1%), respectively. Anterior cataract formation was higher in the Adatomed group (44.06%) than in the Staar group (9.52%); nuclear cataract developed in 2 Adatomed eyes (1.46%) only.

Conclusions: There was a higher incidence of anterior subcapsular cataract formation in the Adatomed group than in the Staar group. Delayed cataract development and the cataract type in patients with Artisan IOLs indicate that age and axial length may be prognostic factors. Factors such as IOL design, material, and placement probably affect cataract formation in eyes with posterior chamber IOLs for high myopia, particularly the Adatomed IOL.

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Refractive surgery attempts to confer freedom from the use of spectacles and contact lenses in most cases. The best indication for refractive surgery is a desire to be less dependent on glasses or contact lenses.

The current refractive surgery techniques include intraocular procedures and methods that alter the cornea.[1] The intraocular procedures comprise lens extraction with or without implantation of an intraocular lens (IOL) and IOL implantation in phakic eyes in the anterior and posterior chambers.[1–6]

Phakic IOLs are increasingly popular with refractive surgeons because of good refractive results and few serious complications. This study compared different types

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Table 1. Characteristics of the 3 IOL types.

Characteristic	Adatomed	Staar	Artisan
Material	Polydimethylsiloxane	2-hydroxyethyl methacrylate	Poly(methyl methacrylate)
Amount of collagen	NP	Less than 1%	NP
Length, mm	11.5–13.0	12.0–13.0	8.5
Width, mm	6.5	6.0	5.0/6.0
Optical zone	Biconcave	Concave–convex	Concave–convex
Optical zone diameter, mm	5.5	4.5–5.5	5.0–6.0
Refractive index*	1.41	1.45	NP
Optic thickness, mm	0.8–1.3	NP	NP
Haptic thickness, mm	0.15	NP	NP
Water content, %	≤1	38	NP
Currently available	No	Yes	Yes
Location	PC	PC	AC
Design	Single piece	Single piece	Single piece
Myopic power, D	−8 to −21	−3 to −20	−5 to −20
Model	094M-1	ICM series	—
Microinjector	No	Yes	No

AC = anterior chamber; NP = not provided by manufacturer; PC = posterior chamber
*Index refraction at 35°C

of phakic IOLs in surgical technique, refractive outcomes, and complications. It looked at the feasibility of using IOLs to treat high myopia, comparing the Adatomed, Staar, and Artisan IOLs.

Patients and Methods

The study comprised 217 eyes of 118 patients scheduled for implantation of a phakic IOL to correct high myopia in 1 or both eyes (99 patients and 19 patients, respectively) from March 1992 to December 2001 at the Service of Ophthalmology, La Fe University Hospital, Valencia, Spain. All patients had clear crystalline lenses with no evidence of cataract before surgery. The exclusion criteria included visually significant cataract, glaucoma, previous trauma, diabetic retinopathy, capsule pseudoexfoliation, and advanced systemic disease.

Before surgery, patients were given detailed explanations of the medical implications and the implantation technique for each phakic IOL. All signed a written consent form in accordance with the Helsinki Declaration. No institutional review board approval was required for this study.

Three types of phakic IOLs were evaluated: Adatomed (not commercially available), Staar (Staar Surgical AG), and Artisan (Ophtec) (Table 1). The Adatomed IOLs were implanted from June 1994 to June 1997.

The Adatomed IOL (094M-1) (Figure 1) is a boat-shaped, single-piece lens with plane haptics composed of polydimethylsiloxane, a thermostable, high-grade silicone elastomer with a low water content (hydrophobic). The posterior surface of the optic is concave with a radius of 9.9 mm. The posterior surface of the optic is formed so it touches the anterior curvature of the crystalline lens. The anterior curvature is also concave; the radius depends on the dioptric power.

The Staar IOL was designed to provide space between the posterior chamber phakic IOL and the anterior surface of the crystalline lens so they do not touch but allow fluid exchange between them. The single-piece, soft, elastic, and hydrophilic collagen/HEMA copolymer (Collamer) IOL (Staar ICM 120V2-4) is composed of a polymer and porcine collagen (less than 0.1% collagen). The IOL is presented as a single piece or monoblock (Figure 2). The posterior chamber Staar IOL has undergone many design modifications. The models used in this study were the ICM series: V2 (n = 8 eyes), V3 (n = 7 eyes), and V4 (n = 6 eyes).

The Artisan is a concave–convex phakic IOL designed to be supported by the mid-iris tissue (iris claw) (Figure 3, *left*). This iris-claw phakic IOL, designed by Jan Worst, was manufactured from a single piece of Perspex CQ-UV in combination with poly(methyl methacrylate). The IOL has 2 flexible claws, which are designed to attach to the iris tissue in the midperiphery.

A complete ophthalmologic examination, including the anterior segment and retina, was done in all patients. In

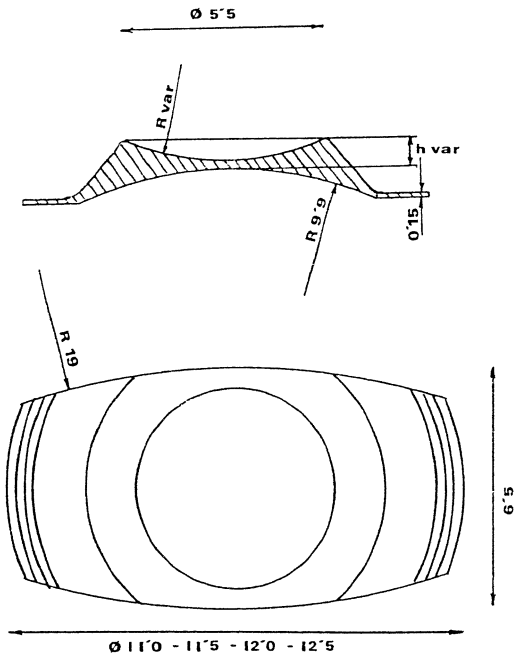

Figure 1. (Menezo) Schematic drawing of the Adatomed posterior chamber phakic IOL for high myopia. The optic is 5.5 mm in diameter.

19 eyes with high-risk peripheral retinal degenerations, argon laser prophylactic photocoagulation was performed. Anisometropia (defined as a difference of more than 3.0 diopters [D] between the 2 eyes) was observed in 36 eyes (16.59%) and amblyopia (defined as a visual acuity worse than 20/29), in 9 eyes (4.14%). The anterior chamber depth was determined with an echograph A-ultrasound pachymeter (Nidek Echo-Scan U8-100 and DGH Ultrasonic). Central keratometry was performed over the 2 principal meridians using a calibrated Haag-Streit keratometer.

The power of the IOL (Adatomed) was determined with the MYOPIOL program, provided by Adatomed GmbH. The calculations were based on 4 IOL models and 8 refractive surfaces studied by Haigis[7] to establish the algorithm that provided results close to emmetropia. The results for emmetropia produced by other algorithms, such as that developed by van der Heijde and coauthors,[8] are identical. The parameters required for calculation with the latter formula are indicated in Table 2. After this information was processed, the dioptric power of the IOL and the possible residual refraction were displayed.

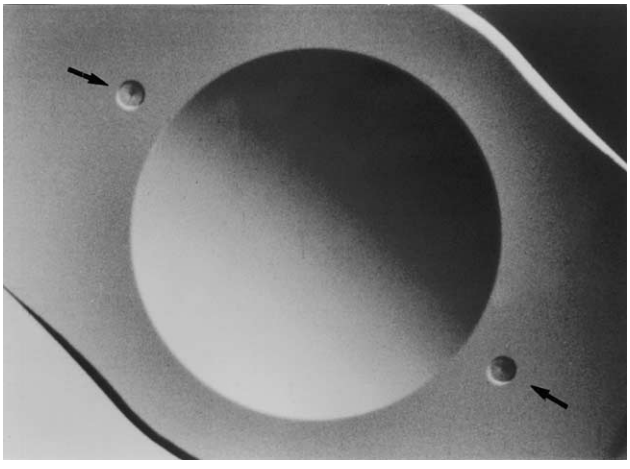

Figure 2. (Menezo) The Staar IOL. Note the positioning holes in the haptic portion (arrows).

The length of the Adatomed and Staar IOLs were determined by the horizontal corneal diameter (white to white). The IOL size was chosen to be the horizontal corneal diameter plus 1.0 mm rounded to the nearest 1.0 mm increment. The corneal diameter was measured preoperatively with the computerized calipers on the videokeratoscope (EyeSys Laboratories, Inc.). The goal was to implant an IOL that was slightly larger than the ciliary sulcus to provide secure fixation. The IOL power was determined using a proprietary formula. The independent variables in the formula are preoperative spherical equivalent (SE) refraction, keratometric power, vertex distance, actual anterior chamber depth, and corneal thickness. The final power calculation incorporated the surgeon's personal constant.

All IOLs were implanted by the same surgeon (J.L.M.). One hour before surgery, the pupil was dilated with a mydriatic cocktail (homatropine 2%, tropicamide 2%, and phenylephrine 2.5%) in the Adatomed and Staar cases. It was constricted with pilocarpine 2% in the Artisan cases. A Honan balloon was placed for 10 minutes (30 mm Hg) with the 3 IOL types.

Adatomed Implantation Procedure

A partial-thickness vertical limbal incision of 5.5 to 6.0 mm was made superiorly from the 11:30 to the 12:30 meridians. A temporal anterior chamber paracentesis was performed in all cases to introduce a spatula to facilitate IOL placement between the iris and the anterior capsule. The anterior chamber was filled with sodium hyaluronate 1% to maintain adequate intraocular pressure (IOP) to facilitate implantation of the IOL in the sulcus. The IOL was positioned from 12 to 6 o'clock using a Fine forceps. A peripheral iridectomy was performed at the 12 o'clock meridian to decrease the likelihood of iridotomy occlusion by the IOL haptics. The limbal incision was then closed with 5 or 6 buried single 10-0 nylon sutures.

Staar Implantation Procedure

A clear corneal, single-plane, beveled 3.0 mm incision and superior paracentesis were performed. Sodium hyaluronate 1% was injected into the anterior chamber. Under direct visualization with the operating microscope, the IOL was positioned in the insertion cartridge. A 1.0 mm Merocel® microsurgical sponge (Medtronic Solan) was cut and placed

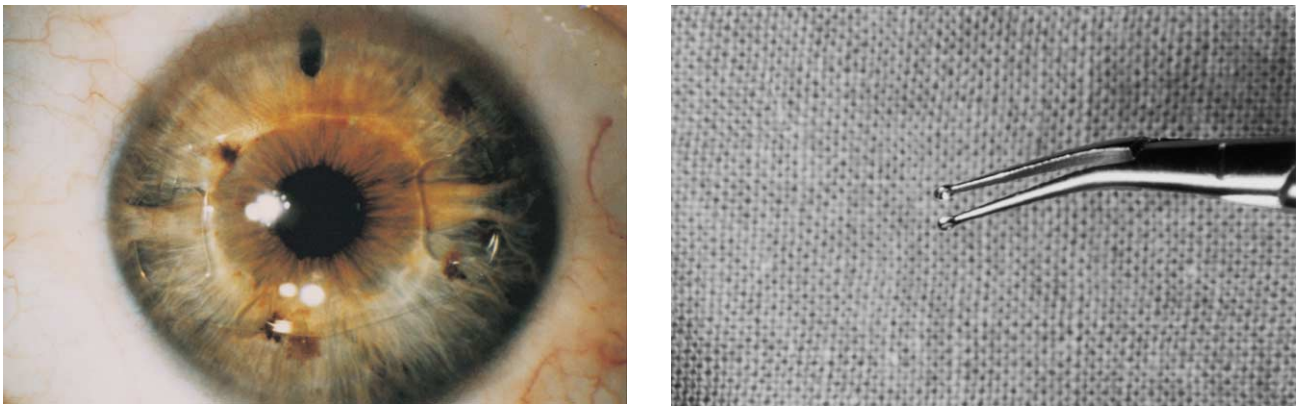

Figure 3. (Menezo) *Left:* Fixation of the Artisan IOL with small folds of paracentral iris tissue enclaved in the 2 haptics, showing a large pinch of iris and correct centration. *Right:* Fixation forceps.

behind the cartridge within the injector to protect the IOL from the injector arm. The IOL was then introduced into the anterior chamber with an injector cartridge designed by Staar Surgical.

The IOL has 2 dimples on the anterior surface that serve as positioning holes. One hole is located next to the distal footplate and the other, next to the proximal footplate. The peripheral plates of the IOL were placed under the iris using a spatula (P978B Deitz Tucker), being careful to avoid downward pressure and contact between the IOL and the crystalline lens. The IOL was centered, and the pupil was constricted with acetylcholine. The remaining viscoelastic material was then removed from the anterior chamber and exchanged for a balanced salt solution. To preclude the possibility of pupillary block after IOL insertion, a peripheral iridotomy was performed in the upper peripheral iris. The clear corneal incision was not sutured; it was self-sealing in all cases.

Artisan Implantation Procedure

The forceps technique was used to implant the Artisan IOL: Paracenteses were performed at 3 o'clock and 9 o'clock, and the main incision (5.5 mm or 6.5 mm depending on the IOL optic) was then performed at 12 o'clock. The anterior chamber was filled with a high-viscosity viscoelastic material. The Artisan IOL was introduced without a glide and rotated inside the eye until it was horizontal. Three interrupted nylon sutures were placed in the incision. Under a closed system, the IOL optic was fixated with a forceps at 12 o'clock and the iris was grasped at the 9 o'clock meridian (through 1 paracentesis) to enclave it in the claws of the Artisan IOL using a special fixation forceps designed by Menezo (Figure 3, *right*). (An appropriate amount of tissue must be grasped.) Afterward, a slit iridotomy was performed and the viscoelastic material aspirated. Two additional sutures were needed to close the wound.

Table 2. Clinical data used to calculate IOL power (217 eyes) (van der Heijde formula [Appendix]).

Parameter	Mean ± SD	Range
Axial length (mm)	28.98 ± 1.36	26.41 to 32.00
Anterior chamber depth (mm)	3.44 ± 0.32	3.09 to 4.01
Keratometry (D)	46.02 ± 1.35	40.5 to 47.5
Predicted IOL power (D)	−16.32 ± 2.31	−12.5 to −28.0
Actual IOL power (D)	−15.94 ± 2.39	−12.5 to −21.0

Immediately after surgery with all 3 IOL types, 20 mg of gentamicin with 2 mg of betamethasone were applied to the subconjunctiva. On the day of surgery, 80 mg of prednisone were administered orally and on the second day, 40 mg were administered. Topically, homatropine 10% was applied every 12 hours and dexamethasone 1% and gentamicin 3% were applied every 6 hours after the first postoperative day. The doses of these drugs were tapered after 3 days and stopped after approximately 30 days.

No criteria were used to determine which IOL the patient would receive. The indications for phakic IOL implantation were stable axial myopia (ie, the SE had not varied more than 0.50 D for 2 years) not treatable by another refractive surgical technique at the time of the surgical decision, age between 20 years and 50 years, and best spectacle-corrected visual acuity of at least 20/200.

Additional criteria for Artisan IOL implantation were an anterior chamber depth of at least 3.2 mm and a central corneal endothelial cell count of at least 2250 cells/mm^2. A noncontact specular microscope with a conventional slitlamp (Topcon SLF) was used to analyze the corneal endothelial cell density and morphometry. Patients receiving the Artisan IOL were examined preoperatively, 6 and 12 months postoperatively, and then annually. At each examination, 2 corneal areas (corresponding to the central and paracentral zones) were photographed and videotaped (Imaginet, Topcon Corp.). The endothelial cell density was determined from each image. The analysis was carried out semiautomatically

by the same researcher using appropriate software (endothelial cell analysis, Imaginet, Topcon Corp.) based on the cell contour quality.

Clinical Parameters

Four clinical parameters were evaluated to compare the 3 IOL types.

Intraocular Pressure. Intraocular pressure was determined preoperatively and postoperatively using a Goldmann tonometer mounted on a slitlamp. The average of 3 measurements was taken as the valid IOP.

IOL Pigment Deposits. Pigment deposits were evaluated after surgery on a qualitative basis only, considering the presence or absence of pigment in a luminous area 4.0 mm in diameter generated by the slitlamp on the IOL surface in the pupillary zone (without pharmacologically induced pupil dilation).

Cataract Formation. A single observer identified crystalline lens opacification with a slitlamp biomicroscope (Zeiss SLO-10) after adequate dilation. The appearance was described, although the corresponding degree was not established (in quantitative terms).

Visual Acuity. Distance visual acuity was determined using Snellen-type optotypes of capital letters in increasing size located 5 m from the patient. Near visual acuity was not evaluated in this study. Spectacle-corrected and uncorrected distance visual acuity were determined before and 6, 12, and 18 months after surgery in the 3 groups. Visual acuity was expressed on a decimal scale and measured in logMAR format.[9]

Statistical Analysis

Quantitative variables were expressed as the mean and standard deviation (SD) and qualitative variables, as percentages relative to the total number of cases. The statistical analysis of the results was performed by a paired Student *t* test for comparison of the means between groups. A *P* value less than 0.05 was considered statistically significant.

Results

The mean age of the 69 women (58.52%) and 49 men (41.47%) was 36.51 years (range 24 to 49 years). The demographic data are summarized in Table 3. The groups were comparable in SE, age, and sex.

Of the 217 eyes, 59 received an Adatomed IOL, 21 received a Staar IOL, and 137 received an Artisan IOL. The mean follow-up was 32.4 months (range 19 to 46 months) in the Adatomed group, 18.3 months (range 11 to 21 months) in the Staar group, and 121.4 months (range 38.4 to 154.3 months) in the Artisan group. The mean amplitude of the anterior chamber was 3.52 ± 0.31 mm, 3.45 ± 0.25 mm, and 3.41 ± 0.12 mm in the Adatomed, Staar, and Artisan groups, respectively. The mean axial length of the eyes was 29.12 ± 1.97 mm, 28.94 ± 1.36 mm, and 29.32 ± 0.92 mm, respectively.

Intraocular Pressure

The mean preoperative IOP was 17.5 ± 3.08 mm Hg, 16.54 ± 1.07 mm Hg, and 16.79 ± 2.07 mm Hg in the Adatomed, Staar, and Artisan groups, respectively. Intraocular pressure was determined at 1, 30, 90, and 180 days and 1, 2, and 3 years depending on the follow-up period. The mean IOP in the mean follow-up in each group was 19.00 mm Hg (Adatomed), 17.84 mm Hg (Staar), and 18.49 mm Hg (Artisan). These values were statistically similar to the mean preoperative values. The respective increases (1.30 mm Hg, 1.50 mm Hg, and 1.70 mm Hg) were not statistically significant in any group ($P = .36$, $P = .26$, and $P = .32$, respectively; paired Student *t* test).

IOL Pigment Deposits

The incidence of pigment deposits was similar in the Adatomed and Staar groups, with deposits in 32 (54.23%) of 59 eyes and 8 (38.1%) of 21 eyes, respectively. Pigmentation on the anterior capsule had 2 peculiar distributions: coronary, similar to Vossius' ring following blunt trauma (Figure 4, *left*), and diffuse, similar to the pigment dispersion syndrome (Figure 4, *right*). The incidence was lower in the Artisan group (9 [6.57%] of 137 eyes) and had a diffuse pattern.

Cataract Formation

Two basic cataract types, nuclear and anterior subcapsular, were found. Two (1.46%) of 137 eyes in 2 patients, 1 man and 1 woman, developed nuclear cataract (Figure 5, *left*) after Artisan IOL implantation. The mean time to nuclear cataract appearance after Artisan IOL implantation was 54.83 ± 22.12 months (range 35 to 99 months). Anterior subcapsular cataract developed with both types of posterior chamber phakic IOLs (26 eyes [44.06%] in the Adatomed group and 2 eyes [9.52%] in the Staar group; Figure 5, *right*). Both cases of anterior subcapsular cataract with the Staar lens were with the V3 model. (All cataract cases with the Staar IOL were with the V3 model.) Anterior subcapsular opacification in the Adatomed group developed more rapidly than in the Staar group. The mean

Table 3. Patient demographics.

Demographic	Adatomed	Staar	Artisan
Number of eyes	59	21	137
Sex			
Male	22	6	62
Female	37	15	75
Age (y)			
Range	39.1 ± 4.47	31.3 ± 9.6	36.2 ± 9.6
Mean ± SD	31 to 49	29 to 47	24 to 48
Follow-up (mo)			
Mean ± SD	32.4	18.3	96.2
Range	19 to 46	11 to 21	38 to 104
SE (D)			
Mean ± SD	−15.39 ± 2.83	−16.00 ± 5.05	−16.17 ± 2.75
Range	−10.5 to −18.25	−11.5 to −28.0	−7 to −21

SE = spherical equivalent

time to cataract appearance was 12.16 ± 3.66 months (Figure 4) and 20.00 ± 1.00 months (Figure 5, *right*), respectively. No eye that developed cataract after phakic IOL implantation had significant intraoperative or postoperative complications.

There were no differences between the Adatomed and Staar groups in the clinical appearance of the anterior subcapsular cataract. The cataract types were peripheral and concentric to the optical zone (Figure 4, *left*), central gray–white opacities in the pupillary zone (Figure 5, *right*), and diffuse and dense (Figure 4, *right*). All cataract types diminished visual acuity to some degree depending on their location in relation to the optical axis. In no opacified eye with the Adatomed and Staar IOLs was there a visible space between the posterior surface of the IOL and the crystalline lens. In eyes that developed cataract, the IOL was removed and the cataract extracted. On histopathologic examination, the anterior capsule crystalline lens (anterior subcapsular cataract) had a hyalinized laminate structure covered by a flat, smooth epithelium with thickened hyaline areas (Figure 6).

Visual Acuity Gain

The best corrected (BCVA) and uncorrected (UCVA) visual acuities improved in all eyes in the 3 groups. The mean UCVA before surgery was 0.03 (1.50 ± 0.62 logMAR) in the Adatomed group, 0.03 (1.52 ± 0.55 logMAR, counting fingers at 2 feet) in

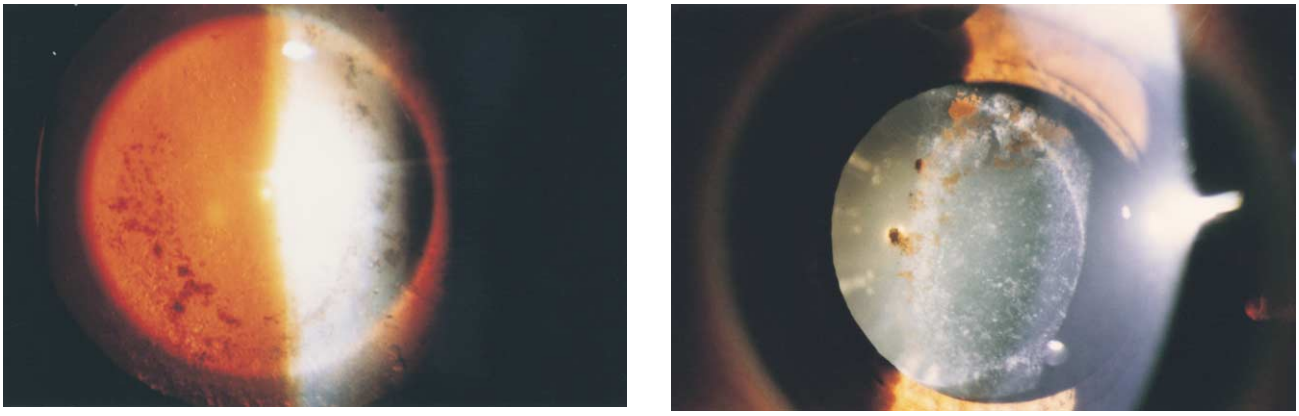

Figure 4. (Menezo) *Left:* Coronary pigment disposition over the Adatomed IOL. *Right:* Pigment dispersion over the anterior face of an Artisan IOL. There is a dense anterior subcapsular cataract, especially in the periphery. The Adatomed IOL was explanted without complications.

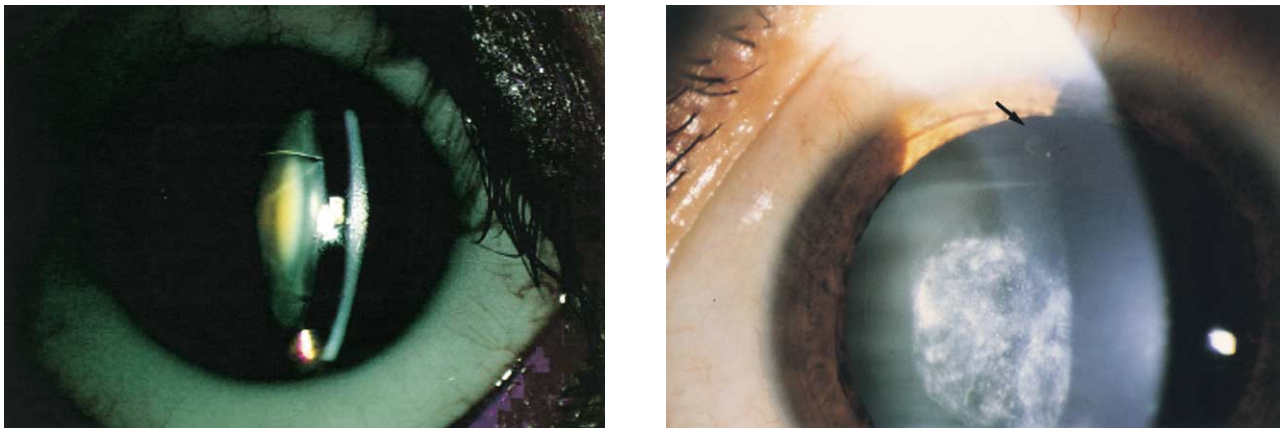

Figure 5. (Menezo) *Left:* Nuclear cataract 4 years after Artisan IOL implantation. *Right:* Central middle, densely speckled, anterior subcapsular cataract in an eye with the Staar IOL. This IOL can be easily identified by the characteristic positioning holes in the haptic (*arrow*).

the Staar group, and 0.014 (1.85 ± 0.40 logMAR, counting fingers at 1 foot) in the Artisan group. After surgery, the UCVA improved in the 3 groups and was slightly better in the Artisan group (Figure 7). At 18 months, the UCVA was 0.45 (0.35 ± 0.29 logMAR), 0.50 (0.3 ± 0.17 logMAR), and 0.51 (0.29 ± 0.29 logMAR) in the Adatomed, Staar, and Artisan groups, respectively. Although the improvement was slightly better in the Artisan group than in the Staar and Adatomed groups, the difference was not statistically significant ($P = .16$, $P = .19$, and $P = .21$, respectively; paired Student t test). At 18 months, the UCVA was ≥0.5 (20/40) in 39 eyes (66.10%) and 1.0 (20/20) in no eye in the Adatomed group, ≥0.5 in 16 eyes (76.19%) and 1.0 in no eye in the Staar group, and ≥0.5 in 111 eyes (81.02%) and 1.0 in 5 eyes in the Artisan group.

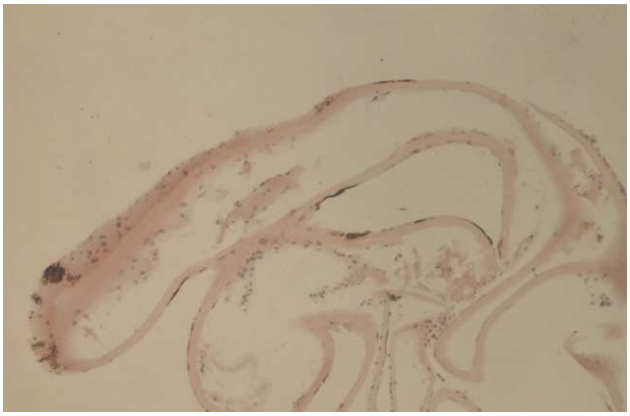

Figure 6. (Menezo) Histologic section of the anterior capsule of the crystalline lens shows a hyalinized laminate structure covered by a smooth epithelium with thickened hyaline areas. Note the pigment deposits (hematoxylin–eosin stain; original magnification ×50).

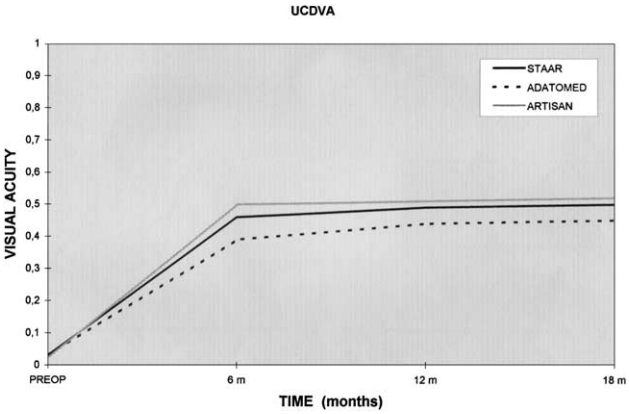

Figure 7. (Menezo) The mean UCVA with the Adatomed, Staar, and Artisan IOLs.

The mean BCVA before surgery was 0.49 (0.31 ± 0.19 logMAR) in the Staar group, 0.45 (0.34 ± 0.20 logMAR) in the Adatomed group, and 0.52 (0.28 ± 0.30 logMAR) in the Artisan group ($P = .64$). At 18 months, it improved in the 3 groups and was slightly better in the Artisan group (0.79 [0.10 ± 0.15 logMAR]) than in the Staar group (0.78 [0.11 ± 0.09 logMAR]) and the Adatomed group (0.66 [0.18 ± 0.12 logMAR]) ($P \leq .05$). Figure 8 shows that the BCVA stabilized 6 months after surgery in the 3 groups.

Figure 9 shows the safety of phakic IOLs in terms of the BCVA gain in the 3 groups. A gain of 2 or more lines occurred in 53.91% of the cases due to retinal image magnification but was an improvement in vision. Visual acuity was lost in 2 eyes (1.45%) in the Artisan group due to age-related macular degeneration and in 7 eyes (11.86%) in the Adatomed group because of the

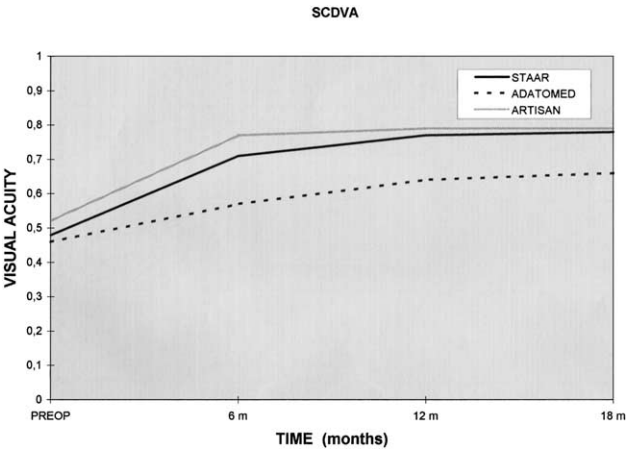

Figure 8. (Menezo) The mean best spectacle-corrected distance visual acuity with the Adatomed, Staar, and Artisan IOLs.

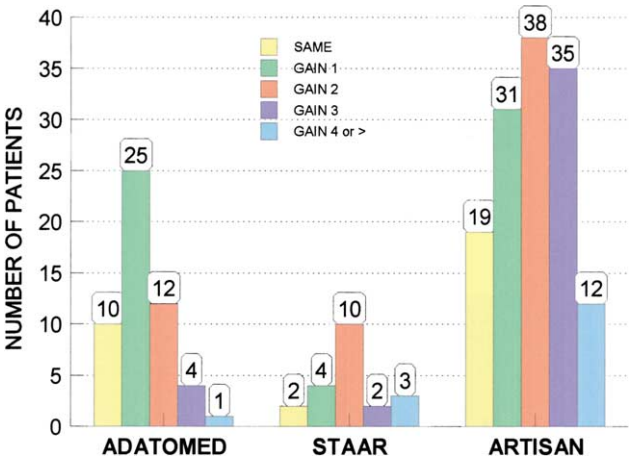

Figure 9. (Menezo) Gain of Snellen lines of BCVA by patients (shown as percentages) 18 months after IOL implantation.

beginning of anterior subcapsular opacification. No eye in the Staar group lost lines of vision.

Subjectively, most patients complained of some degree of nocturnal halos. No subjective differences were noted between the 3 IOL types.

Residual Spherical Equivalent

The mean SE decreased to −1.22 ± 0.93 D in the Adatomed group, −1.41 ± 1.03 D in the Staar group, and −0.85 ± 1.37 D in the Artisan group at 6 months; −1.32 ± 0.97 D, −1.51 ± 1.11 D, and −0.77 ± 1.33 D, respectively, at 1 year; and −1.40 ± 0.98 D, −1.60 ± 1.31 D, and −0.78 ± 1.21 D, respectively, at 2 years. The refractive differences were statistically significant at all examinations before and after surgery in the 3 groups ($P = .002$, $P = .021$, and $P = .03$, respectively; paired Student t test). There were no statistically significant differences between the 3 IOL types postoperatively ($P = .02$, $P = .021$, and $P = .19$, respectively). In refractive terms, the results exhibited a tendency toward undercorrection. An overcorrection was not observed in any eye.

Endothelial Cell Change

Endothelial cell changes were studied in the Artisan IOL group. The loss of endothelial cells was 3.30% at 6 months, 5.50% at 1 year, 7.63% at 2 years, and 10.51% at 5 years. Sixty-one eyes were evaluated at each interval.

Discussion

It is now well known that corneal surgery (laser in situ keratomileusis [LASIK] and photorefractive keratectomy [PRK]) for the correction of myopia has limits. Although no precise limits have been determined, most surgeons do not perform LASIK in eyes with myopia higher than −12.0 D.[10] The main advantage of corneal refractive surgery is minor invasiveness, with no need to open the eye.[11] The disadvantages include limited predictability, irreversibility, the effect of cicatrization on the optic zone, and postoperative pain. Preliminary studies show that leaving a cornea with a central thickness less than 400 μm may lead to corneal ectasia.[12]

Clear lens extraction followed by implantation of a low-power IOL[13, 14] is among the most controversial procedures in refractive surgery as it may increase the risk for retinal detachment.[4] The technique is invasive and leads to early loss of accommodation in relatively young patients.[15] However, it does provide stable correction of refractive defects with a high degree of predictability[16,17] and without affecting the clarity of the visual axis.

These facts have increased the interest of refractive surgeons in phakic IOLs. Phakic IOLs have become a viable option in highly myopic eyes because of the refractive predictability and stability and because they do not alter accommodation.[11] Our more than 10-year experience with implantation of IOLs to correct high myopia shows acceptable predictability and stability in the refractive outcome. Phakic IOLs have been implanted in the anterior and posterior chambers in highly myopic eyes. The complications observed after implantation of the first Worst-Fechner iris-claw IOL in phakic eyes made it necessary to explant most of them.[18] Cur-

rently, a new design of Worst-Fechner iris-claw IOLs is being implanted to treat high myopia[19–21] with good vision results but a potential endothelial cell loss of as much as 10% after 3 years.[20–23] We have used 2 types of iris-claw phakic minus-powered IOLs: the initial Worst-Fechner IOL (biconcave optic model) and a later model with a concave–convex profile.[22] However, no statistically significant differences in improved visual acuity, stability of the refraction, or endothelial cell loss were observed between the 2 types. In the current study, endothelial cell loss with the Artisan IOL was 3.30% at 6 months, 5.50% at 1 year, 7.63% at 2 years, and 10.51% at 5 years.

The idea of implanting an IOL in the posterior chamber to correct high myopia in phakic eyes was developed in Russia; in 1986, Fyodorov designed and began to implant silicone phakic IOLs for high myopia in the posterior chamber,[24,25] a procedure that avoided the endothelial decompensation problems posed by phakic IOLs implanted in the anterior chamber. The modern era of posterior chamber IOLs for high myopia began in 1977, when Pearce[23] designed an IOL for implantation in the posterior chamber. Fechner also implanted the Adatomed lens, using the phrase "posterior chamber myopia lens implantation in phakic eyes" to describe the procedure.[26]

The present study described our long experience using IOLs to correct high myopia and compared 3 models: Adatomed, Staar, and Artisan. In our experience, the 3 types provided a gain in both BCVA and UCVA. The gain in visual acuity was slightly better in eyes with Artisan IOLs than in those with Staar and Adatomed IOLs, although the gain was not statistically significant with any IOL. The visual acuity improvement is confirmed by other authors,[27,28] who relate it to loss of the minification effect of spectacles experienced by patients with extreme myopia.[29,30]

Hoffer[31] and more recently Colin[32] state that eyes with high myopia develop cataracts earlier than normal eyes. One complication posed by the implantation of a phakic IOL, especially a posterior chamber IOL, is the possibility of inducing cataract as a result of direct trauma or a later metabolic effect.

In our series, we found 2 basic cataract types: anterior subcapsular opacification and nuclear. Anterior subcapsular cataract appeared to be associated with posterior chamber phakic IOLs (Adatomed and Staar). This cataract type was less frequent with the Staar IOL (9.52%, all with the V3 model) than with the Adatomed IOL (44.06%). Cataract development with the Staar IOL was associated with the V3 model in both cases. The V3 is a nonvaulted flat design that is associated with cataract in several studies: Sanders and Vukich[33] (12.6%/2.9% with the V3/V4 designs) and Menezo and coauthors[29] (V3 in 2 of 3 cataract cases [16.6%] and V2 in 1 of 3 cases [8.33%]). The V3 model is no longer in use, but more vaulted models are being implanted. (The V4 model was recently designed and is presumed to offer better vaulting over the crystalline lens than the V3 model.) We obtained higher indices of anterior subcapsular cataract than other authors such as Fechner and coauthors[26] (17.7% of cases with Adatomed IOLs), Uusitalo and coauthors[30] (2.6% of cases with Staar IOLs), and Assetto and coauthors[10] (no cataract formation). This is probably attributable to the longer mean follow-up in our study. A longer follow-up would be required to more precisely establish the lens opacification capacity of Staar IOLs.

There are substantial differences in the design of the 2 posterior chamber IOL models, particularly the vault. The Staar IOL is vaulted, with no contact with the posterior iris and the crystalline lens, to avoid the possibility of late complications such as pigmentary dispersion syndrome and complicated cataract. The Adatomed IOL is no longer in clinical use. It was withdrawn in 1988 because of a high cataract incidence. Brauweiler and coauthors[34] report a higher incidence of cataract with Adatomed IOLs (89.1% of cases in a 2-year follow-up) than we found. There is significant concern about whether the posterior chamber phakic IOLs touches the crystalline lens. Deitz has stated that ultrasonography shows that the Staar IOL vaults over the crystalline lens without touching it (L. Sabbagh, "Lens Potential Looks Promising," Ophthalmology Times Weekly, November 13, 1995, page 12). However, Assetto and coauthors[10] report that because of the contact between the IOL and the crystalline lens and posterior iris, although not demonstrated in their study, the possibility of pigmentary loss and cataract formation must be considered. Our study did not demonstrate IOL–iris and IOL–crystalline lens touch, but clinical data indicate that these problems occur with both models. Slitlamp examination disclosed that in the opacified eyes with both IOL types, there was no visible space

between the posterior surface of the IOL and the crystalline lens.

Cataract development is more frequent in patients with high myopia than in the general population.[31,32,35] Reports show that the mean age for cataract surgery in patients with high myopia is 65 years. However, in eyes with axial lengths longer than 29.00 mm, the incidence is significant at 50 years. Our study found only 2 eyes in 2 patients developed nuclear cataract after Artisan IOL implantation. The age in these 2 patients at the time of implantation was 41 years and 43 years, and the axial length was 31.25 mm and 32.57 mm, respectively. The age at the time of cataract surgery was 53 years and 56 years, respectively. The relationship between phakic anterior chamber IOL implantation and cataract development has not been clearly established. A case in 1977 reports cataract development in a 62-year-old patient during the follow-up of Artisan IOL implantation.[14] These facts suggest that patient age at the time of implantation and high axial myopia are related to early development of nuclear cataract after Artisan IOL implantation. Delayed cataract development and cataract type (nuclear) in patients with Artisan IOLs suggest that age and axial lengths may be considered prognostic factors. However, factors such as IOL design, material, and placement probably affect cataract formation with posterior chamber IOLs for high myopia because of the weak correlation with age and axial length eye in these groups, especially the Adatomed group. Long-term follow-up is required to conclude whether the Staar IOL is safe relative to cataract formation in eyes with high myopia.

The intimate contact between posterior chamber IOLs (Adatomed and Staar) and the iris increases the possibility of pigment dispersion and the development of anterior subcapsular cataract.[14] Our study showed few differences in the presence of pigment deposits between the 2 posterior chamber IOL types. In a study of HEMA IOLs, Assetto and coauthors[10] observed no pigment dispersion in any case. However, Cisneros[15] reports pigment deposits in 32.83% of cases in his series of Adatomed IOL implantation. We observed no pigment dispersion in any case in the Artisan group.

Intraocular pressure modification is another complication. Postoperative IOP increases with both types of IOLs were statistically insignificant. No pupillary block was found, unlike the reports of phakic posterior chamber IOL implantation by other authors.[28]

Our study was a prospective comparative clinical evaluation of the biocompatibility and safety of the Adatomed, Staar, and Artisan IOLs for the correction of high myopia using 3 postoperative complications: IOP increase, IOL pigment deposits, and cataract formation. The visual acuity improvement with the 3 IOL types at 6, 12, and 18 months was also studied. The follow-up period was too short to draw firm conclusions about the long-term predictability with the Staar IOLs. However, the parameters evaluated may lack the sensitivity required to detect differences in viability between the 2 IOL materials. Further comparative studies of Artisan, Staar, Adatomed, and other phakic IOLs are thus needed. In our experience, the Artisan IOL afforded a slightly greater (although not statistically significant) improvement in visual acuity than the Staar and Adatomed IOLs. However, the Adatomed IOL appeared to produce fewer complications except for increased postoperative IOP and the presence of pigment deposits; these results were similar with both IOL types.

Because of the paucity of peer-reviewed articles about the position of the phakic IOL and its relationship to adjacent structures in the posterior chamber, there is controversy about the long-term safety, primarily in regard to the intimate contact between the IOL and the crystalline lens. The Artisan IOL, although requiring a more difficult surgical technique, can result in no complications if a refined surgical technique is used. However, endothelial cell loss is higher with this iris-supported IOL than with posterior chamber IOLs. None of the present phakic IOLs can be defined as ideal.

Appendix

Van der Heijde Formula

$$F_{IOL} = \frac{n}{\frac{n}{F_c'} - d} - \frac{n}{\frac{n}{F_c} - d}$$

with $F_c' = F_c + F_s'$ and $F' = F_s/(1 - t.F_s)$, where F_{IOL} is the power of the IOL, F_c the power of the cornea, F_s' the spectacle correction (F_s) at the corneal vertex, d the location

of the IOL, t the vertex distance of spectacles, and n the refractive power of the eye media (1.336).

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