Multicenter study of the Artisan phakic intraocular lens

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ABSTRACT

Purpose: To assess the Artisan intraocular lens to correct myopia in phakic eyes.

Setting: European multicenter study sponsored by Ophtec BV, Groningen, The Netherlands.

Methods: In this prospective multicenter clinical study, the Artisan lens was implanted in 518 eyes between September 1991 and October 1999. The power of the lenses ranged from −5.0 to −20.0 diopters (D). Follow-up examinations were performed at 6 months and 1, 2, and 3 years. Follow-up ranged from 6 months (n = 454) to 3 years (n = 249). The preoperative uncorrected visual acuity (UCVA) was not recorded but was estimated to be worse than 0.1. The preoperative mean best spectacle-corrected visual acuity (BSCVA) was 0.67 ± 0.26 (SD). Endothelial cell counts were done at 6 months and 1, 2, and 3 years in a subgroup of 129 eyes.

Results: A UCVA of 20/40 or better was observed in 76.8% of eyes regardless of the postoperative goal. A BSCVA of 20/40 or better was observed in 93.9% of eyes and remained stable throughout the follow-up. Of the eyes with extremely high myopia (>−15.0 D), 63.3% gained 2 or more lines of BSCVA; of those with moderate myopia (−5.0 to −10.0 D), 23.5% gained 2 or more lines. The mean endothelial cell density change was 4.8% at 6 months, 2.4% at 1 year, 1.7% at 2 years, and 0.7% at 3 years. The incidence of persistent adverse events at 3 years was relatively low. Secondary surgical interventions included repositioning of the lens because of poor initial placement and lens exchange because of preoperative power calculation errors. Glare and halo effects during night driving were noted and were related to large pupils in young patients.

Conclusion: The Artisan lens is a safe, stable, efficacious, and predictable method to correct −5.0 to −20.0 D of myopia. This study suggests that the corneal endothelial cell loss is stabilized to the physiologically normal level after 3 years. *J Cataract Refract Surg 2000; 26:1163–1171 © 2000 ASCRS and ESCRS*

Spectacles and contact lenses have long been the only means of correcting myopia. Today a variety of alternatives are available. Radial keratotomy (RK) has been used to correct low degrees of myopia from −1.0 to −6.0 diopters (D). Some major problems are undercorrection, lack of predictability, and late hyperopic shift.

Currently, photorefractive keratectomy (PRK)[1] and laser in situ keratomileusis[2] are at the center of interest. Lack of long-term predictability and stability and haze in the short-term follow-up (PRK) are the predominant

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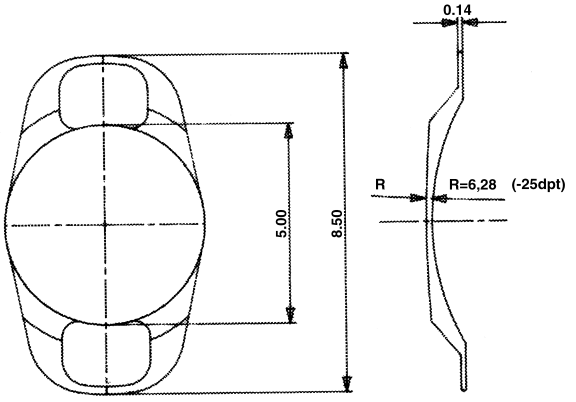

Figure 1. (Budo) The Artisan phakic lens.

concerns. Epikeratoplasty and lamellar onlays have been used for myopia as well as aphakia, keratoconus, and hyperopia. Results in myopic eyes have not been encouraging. High-refractive-index polysulfone inlays (keratophakia) have been used experimentally. Hydrogel corneal implants have also been used to correct myopia, but the long-term results have not been good. No significant clinical studies of this concept have been conducted, but predictability and, perhaps, stability are likely to be major problems.

Recently, the intracorneal ring (ICR) was introduced to correct myopia up to −4.5 D (T.E. Burris, MD, D.K. Holmes-Higgin, MD, P. Asbell, MD, "Corneal Asphericity in Phase II ICR Patients"; D.S. Durrie, MD, P.A. Asbell, MD, T.E. Burris, MD, D.J. Schanzlin, MD, "Reversible Refractive Effect: Data from the Phase II Study of the 3600 ICR in Myopia Eyes," presented at the Symposium on Cataract, IOL and Refractive Surgery, Seattle, Washington, USA, June 1996). No long-term data are available. Clear lensectomy[3] via extracapsular cataract extraction or phacoemulsification with an intraocular lens (IOL) may be an option. The potential of posterior capsule opacification requiring neodymium:YAG laser treatment, the loss of accommodation in the younger age group, and the propensity of myopic eyes toward retinal detachment are matters of concern.

Research on modern phakic IOLs began in 1986 and now includes 3 major designs: (1) posterior chamber lenses (ICL, Fyodorov)[4,5]; (2) anterior chamber angle-supported lenses (Nuvita, Baikoff)[6,7]; and (3) iris-stroma-supported lenses (Artisan, Worst).[8–18] The Artisan lens is the subject of this European multicenter study.

Patients and Methods

The Artisan phakic lens is positioned in the anterior chamber and held in place by fixation to the midperipheral iris stroma, creating a bridge over the optical axis. Lens model 206 has a 5.0 mm optic (clear optical zone), is 8.5 mm in overall length, has a vault of 0.8 mm, and is available in powers from −5.0 to −20.0 D (Figure 1). Before 1997, the lens was available in only 1.0 D power increments; since 1997, it has been available in 0.5 D increments. Schematic drawings of the Artisan lens with 2 dioptric powers (Figure 2) suggest the clearance be-

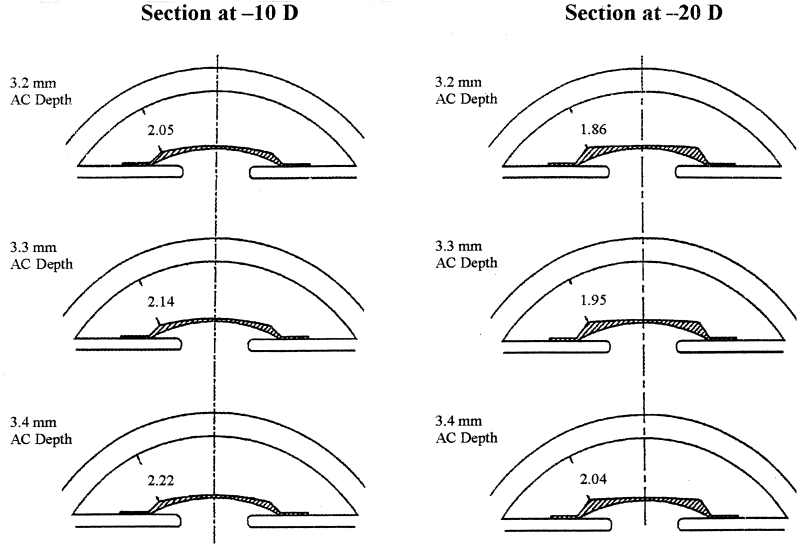

Figure 2. (Budo) Anteroposterior and peripheral space at 2 lens powers. Drawings should show the phakic condition, but for the overview the natural lens was not drawn.

tween the lens and the endothelium that can be obtained.

Patients

Between December 1991 and July 1999, a total of 518 eyes (335 patients) with myopia from −5.0 to −20.0 D received an Artisan lens. Two hundred forty-nine eyes (48.1%) were available for analysis at 3 years; 154 eyes (29.7%) were not due for the 3 year evaluation; 17 eyes (3.3%) were discontinued and 98 eyes (18.9%) lost to follow-up.

Two hundred five patients (61.2%) were women (308 eyes [59.5%]) and 130 (38.8%), men (210 eyes [40.5%]). The mean age was 36.4 years ± 9.7 (SD) (range 18.2 to 65.2 years). The inclusion criteria were a stable refraction for the previous 24 months; an anterior chamber depth (ACD) of 3.0 mm or more; an endothelial cell count of 2000 cells/mm^2 or more; and myopia between −5.0 and −20.0 D. Patients were excluded if they had an abnormal iris, cornea, pupil, or retinal condition; early cataract formation; a family history of retinal detachment; chronic or recurrent uveitis; an endothelial cell count less than 2000 cells/mm^2; intraocular pressure (IOP) greater than 21 mm Hg; a fixed pupil size greater than 4.5 mm; or pre-existing macular degeneration or retinopathy.

A signed informed consent describing the risks and benefits of the procedure was obtained from each patient prior to surgery.

Preoperatively, the mean refractive error was −12.95 ± 4.35 D (range −5.0 to −20.0 D), the mean best spectacle-corrected visual acuity (BSCVA) 0.67 ± 0.26, the mean cylinder 1.23 ± 1.13 D (range 6.0 to 0.0 D), the mean ACD 3.38 ± 0.71 mm, and the mean endothelial cell count 2876 ± 410 cells/mm^2. The preoperative uncorrected visual acuity (UCVA) was not recorded, but given the mean preoperative spherical equivalent (SE) (−12.95 D), the value was estimated to be less than 0.1.

The refractive errors were divided into 3 groups: Group 1, moderate myopia (−5.0 to −10.0 D); Group 2, high myopia (−11.0 to −15.0 D); and Group 3, extremely high myopia (>15.0 D).

All patients were evaluated preoperatively to determine baseline statistics and then postoperatively at 1 to 6 days, 2 to 3 weeks, 4 to 8 weeks, 4 to 6 months, 7 to 11 months, 12 to 14 months, 24 to 26 months, and 36 to 38 months. Standardized case report forms were used to collect data at each site and were then relayed to the study sponsor.

Statistical analysis of the results was performed using Student *t* tests. A *P* value of 0.05 was considered statistically significant.

Surgical Procedure

The lens power was calculated using the van der Heijde formula,[12] which uses the mean corneal curvature (K), adjusted ACD (ACD − 0.8 mm), and SE of the patient's spectacle correction at a 12.0 mm vertex.

Several variations of the surgical technique (developed by J.G.F. Worst) were used to implant the lens. Preoperatively, patients were prepared as for standard cataract surgery, with the addition of miotic drops (pilocarpine 1% to 2% or acetylcholine chloride) to prepare the iris for lens fixation, reduce the risk of lens touch during implantation, and facilitate centration of the lens.

Ocular anesthesia was general, retrobulbar, or peribulbar depending on patient needs and surgeon preference. Eyes were prepared by cleaning the area with povidone–iodine (Betadine®), isolating the lashes, and inserting a lid speculum.

Typically, a 5.5 mm primary incision was made at 12 o'clock (for inserting the lens) and 2 paracenteses were made at 10 and 2 o'clock (for instrument access to fixate the lens). Several incision types were used by the surgeons: a corneal incision in ±19% of the cases; a corneoscleral incision in ±12%; a limbal incision in ±44%; and a scleral tunnel incision in ±25%.

Instillation of a cohesive viscoelastic material (sodium hyaluronate [Healon®/Healon GV® or Amvisc®/Amvisc®Plus]) through the paracenteses and primary incision was mandatory to maintain sufficient ACD, protect the endothelium, and facilitate adjusting the lens within the eye during fixation. All viscoelastic material was removed by manual irrigation in front of the IOL at the end of the procedure.

Results

Safety

The safety of the Artisan lens was evident within the first 6 months. The mean BSCVA improved to 0.87 ± 0.20 at 6 months, 0.88 ± 0.19 at 1 year, 0.88 ± 0.19 at

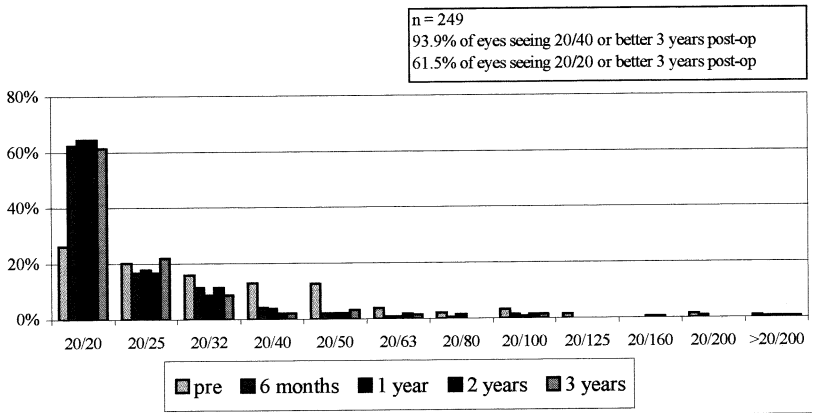

Figure 3. (Budo) Best spectacle-corrected visual acuity at 3 years (N = 249).

2 years, and 0.87 ± 0.20 at 3 years. A BSCVA of 20/40or better was reported in 93.9% of eyes at 3 years (Figure 3).

The BSCVA remained the same or improved in 95.8% of eyes. Three eyes (1.2%) lost 2 or more lines of acuity (1 was due to a developing nuclear cataract and 2 were for no definite reason but probably involved naturally occurring macular myopic degeneration) (Figure 4). In terms of lines gained, the BSCVA was significantly different among the 3 myopia groups. In Group 1, 23.5% gained 2 lines or more; in Group 2, 43.7%; and in Group 3, 63.3% (Figure 5).

The safety index (ratio of mean postoperative BSCVA to mean preoperative BSCVA) was 1.31.

Efficacy

The mean UCVA was 0.66 ± 0.28 at 6 months, 0.67 ± 0.28 at 1 year, 0.67 ± 0.28 at 2 years, and 0.68 ± 0.29 at 3 years. It was 20/40 or better in 76.8% of eyes at 3 years and 20/20 in 33.7% (Figure 6).

The efficacy index (ratio of mean postoperative UCVA to mean preoperative BSCVA) was 1.03.

Predictability—Spherical Equivalent

The deviation of the achieved SE correction from the calculated refractive SE correction was calculated. After 3 years, 142 eyes (57.1%) were within ±0.5 D of the desired refraction and 196 eyes (78.8%), within ±1.0 D (Table 1). Figure 7 shows the deviation from intended correction in each eye.

Predictability—Astigmatic Correction

The mean postoperative cylinder was 0.84 ± 0.85 D (range 5.0 to 0.0 D). The reduction in absolute astigmatism was 0.39 D (Table 2).

Stability

Improvements in UCVA and BSCVA were statistically significant ($P < .05$), yet there was no significant difference between the individual follow-up intervals af-

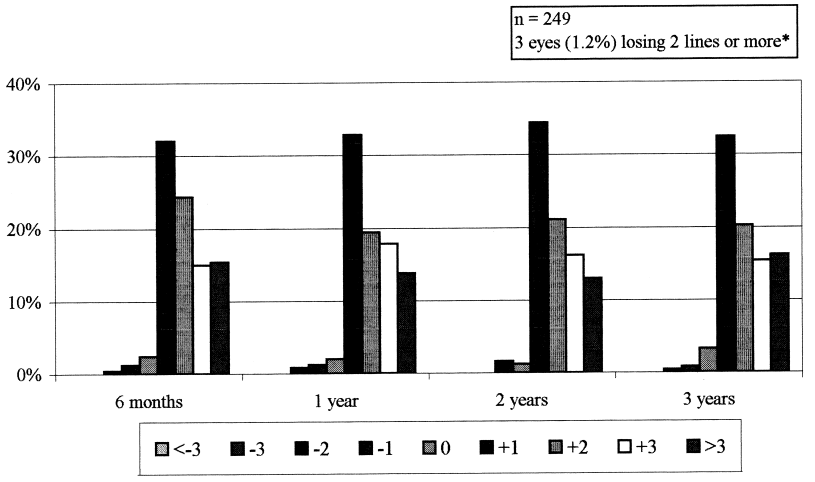

Figure 4. (Budo) Best spectacle-corrected visual acuity, lines gained or lost over 3 years (N = 249). Reasons for losing 2 lines or more were no definite reason (1); nuclear cataract (1); eye had received IOL before (1).

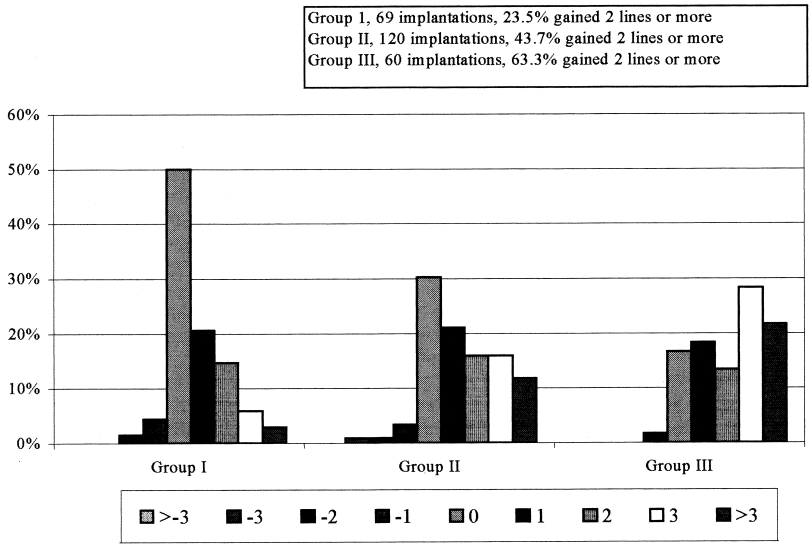

Figure 5. (Budo) Best spectacle-corrected visual acuty, lines gained or lost over 3 years; comparison per group (N = 249).

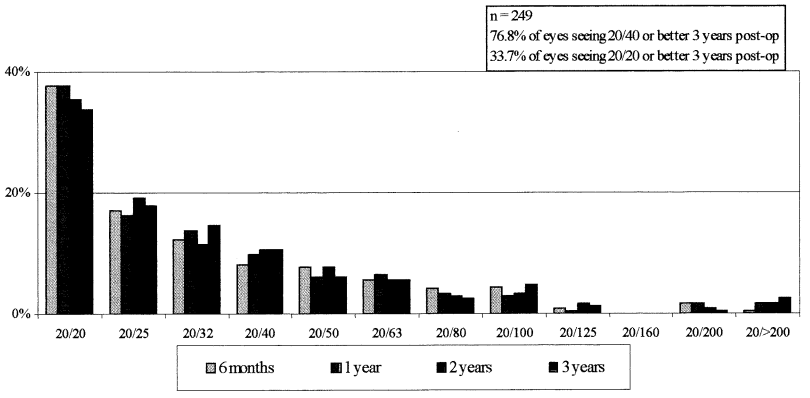

Figure 6. (Budo) Uncorrected visual acuity at 3 years (N = 249).

Table 1. Refractive outcome—deviation from the goal at 3 years (N = 249).

Deviation (D)	Number of Eyes	Percentage
±0.5	142	57.1
±1.0	196	78.8
±1.5	223	89.7
±2.0	233	93.6

ter surgery, confirming the stability of visual acuity after surgery (Figure 8).

Intraoperative Problems and Adverse Events

Intraoperative problems and adverse events are shown in Tables 3 and 4, respectively.

Secondary Surgical Intervention

Twenty-two eyes required a secondary intervention (Table 5).

Other Complications

The incidence of other complications was relatively low (Table 6).

Halos

Because halos are "edge effects" and high-power IOLs are expected to show more prismatic effect, the reports of halos in the 3 myopia groups were compared. A significant difference was shown between Group 1 (moderate myopia) and Group 3 (very high myopia), 7.2% and 10.0%, respectively (Table 7).

Endothelial Cell Loss

The degree of endothelial cell loss was confirmed in a subgroup of 129 eyes with a follow-up of 3 years. Postoperatively, the mean cell density change was 4.8% (2739 ± 431 cells/mm^2) at 6 months, 2.4% (2672 ± 386 cells/mm^2) at 1 year, 1.7% (2626 ± 424 cells/mm^2) at 2 years, and 0.7% (2607 ± 442 cells/mm^2) at 3 years (Figure 9).

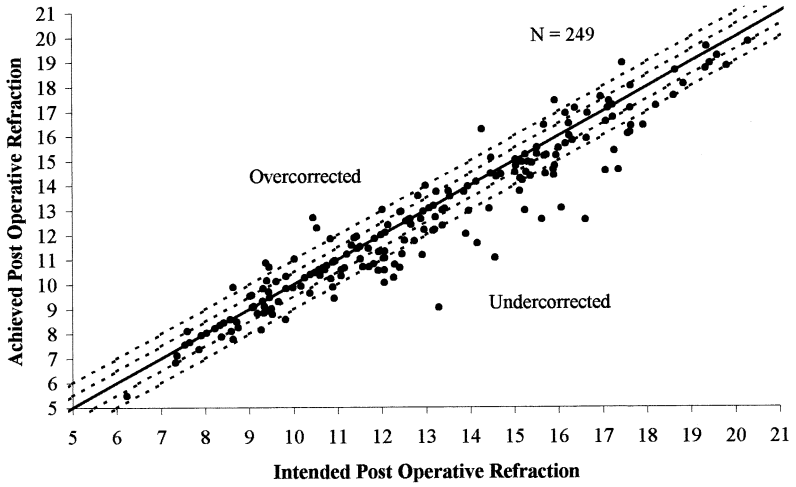

Figure 7. (Budo) Intended versus achieved postoperative refraction at 3 years (N = 249).

Table 2. Refractive astigmatism (N = 29).

Investigator	Astigmatism (D)		Induced (+)/ Reduced (−) (D)
	Preop	At 3 Years	
A	−1.07 ± 1.20	−0.52 ± 0.75	−0.55
B	−1.50 ± 1.26	−0.83 ± 0.70	−0.67
C	−1.32 ± 1.00	−0.61 ± 0.44	−0.71
D	−1.32 ± 1.22	−0.81 ± 0.84*	−0.50
E	−1.26 ± 1.01	−1.26 ± 0.72	0.00
F	−1.37 ± 1.33	−1.70 ± 1.99	0.33
G	−1.10 ± 1.43	−0.44 ± 0.52	−0.66
H	−1.03 ± 0.87	−0.43 ± 0.55*	−0.60
I	−1.22 ± 1.09	−1.21 ± 0.90	−0.01
Total	−1.23 ± 1.13	−0.84 ± 0.85	−0.39

*Based on 2 year data as 3 year data were not available.

Discussion

Postoperative uncorrected and corrected visual acuity results of this study demonstrate the safety, efficacy, predictability, and stability of the Artisan phakic lens to correct high to severe myopia. Significant gains in UCVA and BSCVA were achieved. The results were not surprising based on the history of poly(methyl methacrylate) IOLs used to correct aphakia following cataract surgery.

Safety of the surgical procedure and long-term biocompatibility have long been the primary concerns about the use of these devices. In this 3 year study, the intraoperative problems were minimal and typically related to the short learning curve required to master the special implantation technique for the Artisan lens. Increased experience by a greater number of surgeons using the lens, introduction of modified techniques, better training, and refinement of individual technique have reduced this learning curve.

Postoperative complications such as glare/halos were related to poor centration of the lens during surgery or implanting the lens in eyes in which the scotopic pupil was larger than the lens optic diameter. Experience

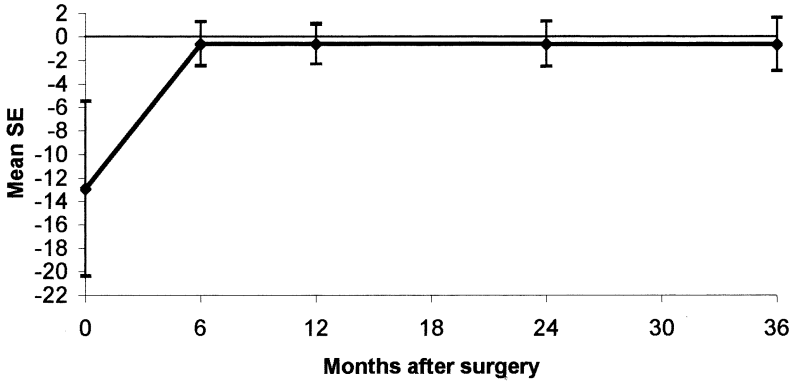

Figure 8. (Budo) Change over time in mean SE of manifest refraction (error bars ±2.0 SD) (N = 249).

Table 3. Intraoperative problems (N = 518).

Problem	Number of Eyes	Percentage
Hemorrhaging (wound)	10	1.9
IOL corneal touch	14	2.7
Difficulty centering lens	2	0.4
Iris prolapse	1	0.2
Potential surgical iris trauma	2	0.4
Difficult wound closure	1	0.2
Difficulty enclavating IOL	1	0.2
Difficulty fixating IOL	1	0.2
Anterior capsule touch	1	0.2
Positive IOP during surgery	1	0.2

Table 4. Adverse events (N = 249).

Adverse Event	Number of Eyes	Percentage
Persistent corneal edema	2	0.8
Persistent iris atrophy	1	0.4
Persistent IOL not well centered at surgery	3	1.2
Cumulative hyphema	4	1.6
Cumulative IOL not well centered at surgery	22	8.8
Cumulative pupillary block	2	0.8
Cumulative retinal detachment	2	0.8

Table 5. Secondary surgical intervention (N = 249).

Secondary Surgical Intervention	Number of Eyes	Percentage
Repositioning of decentered lens	5	2.0
IOL removal*	7	2.8
IOL replacement (exchange)	8	3.2
Repositioning iris hernia	1	0.4
Correcting astigmatism with PRK	1	0.4

PRK = photorefractive keratectomy

*Wide pupil diameter (1); critical endothelial cell count (1); trauma (punch on eye), leading to loosening of the claws (2); posterior capsule opacification followed by cataract formation (3)

Table 6. Other complications at 3 years (N = 249).

Complication	Number of Eyes	Percentage
Glare	12	6.0
Halo, rings	22	8.8
Age-related cataract formation	6	2.4
Other complications	10	4.0

Table 7. Recorded halo 3 years postoperatively (N = 249).

IOL Power (D)	Number of Eyes	Halos Recorded	Percentage
−5.00 to −10.00	69	5	7.2
−10.01 to −15.00	120	11	9.2
−15.01 to −20.00	60	6	10.0

increases the ability to accurately center the lens and postoperative recentering is always an option, as the fixation is reversible.

Pérez et al.[14] studied the centration of the iris-claw lens with digital system measurement. They reported that decentration with respect to the pupil in a group of 22 eyes was 0.47 ± 0.29 mm and concluded that for a standard 4.0 mm entrance pupil, a slight decentration should not cause serious visual problems. Larger pupils, however, can cause visual impairment such as halos.

The Artisan model 206 with a 5.0 mm optic was used exclusively during this study. In 1997, a new model with a 6.0 mm optic was introduced to address potential glare/halos in patients with larger pupils. This model is more forgiving when the lens is somewhat decentered. A 6.5 mm primary incision is needed for this design. In the future, "foldable" Artisan lenses could reduce the incision size.

Non-lens-related (surgery-related) complications such as transient corneal edema (following corneal touch during surgery), transient rise in IOP, or pupillary block (insufficient removal of viscoelastic material) and hyphema (insufficient surgical experience for this technique) were experienced infrequently and successfully resolved.

Secondary surgical intervention in 22 cases included repositioning the lens, IOL replacement for a lens of different power, and IOL removal due to trauma. Endothelial cell loss stabilized to a mean physiological loss of 0.7% per year between 2 and 3 years following a mean loss of 7.1% during the first year, possibly associated with the initial surgery.

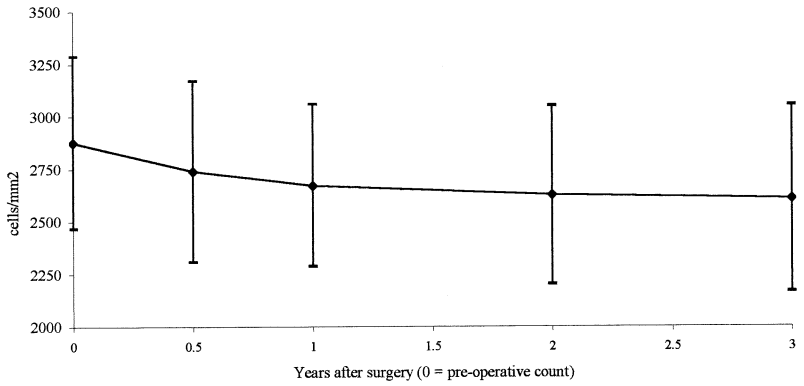

Figure 9. (Budo) Mean (SD) endothelial cell density over 3 years (error bars ±1.0 SD) (N = 249).

No rotation of the IOL, pupil ovalization, uveitis, or persistent corneal dystrophy was reported.

The results of this study demonstrate stability, good predictability, and accuracy, similar to the results reported by other authors using the Artisan lens.[8–18]

Conclusion

Spectacles and contact lenses for the correction of moderate to severe myopia are well established and the current standard of care. While these modalities incur minimal risk to patients, they often result in inferior optical images (aberrations and miniaturization), negative cosmetic appearance, and significant inconvenience.

The risk/benefit ratio of implanting the Artisan phakic IOL may be an acceptable alternative to spectacles and contacts by providing better image quality, reduced reliance on external devices, and a high level of convenience. The efficacy and short-term safety of the lens are supported by this multicenter study. Continued monitoring of patients is needed to establish the long-term safety.

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Dr. Worst holds a patent for the design of the Artisan lens, and Dr. Budo is medical monitor and consultant to Ophtec BV. None of the other authors has a financial interest in any product mentioned.