Iris-claw Phakic Intraocular Lens for High Myopia

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ABSTRACT

PURPOSE: To evaluate the efficacy, safety, predictability, and stability of implanting a polymethylmethacrylate (PMMA) phakic intraocular lens (PIOL) (the Artisan myopia lens) to correct high myopia.

METHODS: An Artisan myopia lens was implanted in 78 consecutive eyes of 49 patients with preoperative myopia that ranged from -6.25 to -28.00 D. Mean patient age was 42.4 years. Mean follow-up was 10.7 months and all patients were followed for at least 6 months; 45 eyes had follow-up of 12 months, and 10 eyes had 24 months. The desired outcome was emmetropia in all eyes except for those eyes with preoperative myopia greater then -23.00 D.

RESULTS: Fifty-three eyes (67.9%) had a postoperative refraction at the last follow-up examination within ±1.00 D of emmetropia, and 39 eyes (50.0%) had a postoperative refraction ±within 0.50 D of emmetropia. The postoperative refraction remained stable during the entire follow-up period. Mean spectacle-corrected visual acuity improved from 20/32 preoperatively to 20/25 postoperatively. Mean postoperative uncorrected visual acuity was 20/32. There was no significant change in endothelial cell density from baseline. We did not encounter major complications.

CONCLUSION: Implantation of the Artisan myopia lens to correct high myopia resulted in a stable and fairly predictable refractive outcome. A significant endothelial cell change was not detected. [*J Refract Surg* 2001;17:634-640]

Since the renewed introduction of phakic intraocular lenses (PIOLs) to correct high myopia, several models have been developed and studied. Basically, three models exist currently—iris-fixated, angle-supported, and posterior chamber lenses. The iris fixated Artisan myopia lens is a phakic intraocular lens that was introduced in 1986 by Worst and Fechner.[1,2] At that time, the lens had a biconcave optic 4.5 mm in diameter, and was called the Worst-Fechner Claw lens. In 1991, the optic changed to a convex-concave model 5 mm in diameter, and since 1998 the diameter of the optic has also been available in a 6-mm size. All three types of lenses have been implanted successfully, with good refractive results.[1-3] In the series of eyes we reported in 1995, the surgeon was different and the sclerocorneal incision was measured according to the size of the lens. Because of the general safety concern about PIOLs, we thought it was important to report the results of our patient population, even though follow-up in this study is not extensive. We began to implant the Artisan myopia lens in January 1997, and we report here data collected until March 1999.

PATIENTS AND METHODS

Patients

A total of 91 eyes of 47 patients were operated between January 1997 and March 1999. We included all eyes with follow-up of at least 6 months: a total of 78 eyes (85.7%) of 39 patients is reported. All eyes were operated consecutively by the same surgeon (GL) and examined postoperatively at our department. Each patient was informed of the investigative nature of the procedure and a detailed oral and written informed consent was obtained, in accordance with the Helsinki Declaration.

Patient Examination

A complete preoperative ocular examination was performed on each patient, including A-scan biometry (Alcon, Irvine, CA), applanation Goldmann tonometry (Haag Streit, Bern, Switzerland), keratometry, and endothelial cell count (Topcon sp2000-p, Tokyo, Japan). The preoperative refraction required for calculating the power of the intraocular lens was performed with and without cycloplegia. Visual acuity was converted from Snellen notation to the logarithmic scale, logMAR

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notation. Best spectacle-corrected visual acuities were measured before and after surgery. Follow-up examinations were performed at 24 hours, 1 week, 2 to 4 weeks, 2 to 4 months, 6 months, and 12 months. After that, patients were examined annually. Patients with complications were examined more frequently.

Specular microscopy was performed after 2 to 4 months, at 6 and 12 months, and then annually. Postoperatively, examinations included slit-lamp biomicroscopy, applanation tonometry, manifest refraction, and best spectacle-corrected and uncorrected visual acuity.

Artisan Myopia Lens

The Artisan myopia lens is made of ultraviolet-absorbing clinical quality polymethylmethacrylate with a convex-concave optic. The overall size of the lens is 8.5 mm in length. The optic can be manufactured in diameters of 5 mm and 6 mm. The 6-mm lens has been available since 1998 and is manufactured from -3 to -15.50 diopters (D) in half-diopter steps. The 5-mm lens is available from -3.00 to -23.00 D in half-diopter steps. The limitation in lens power available for the 6-mm lens is because in higher powers, the shoulder of the lens is too close to the corneal endothelium. Both lens designs are exactly the same and differ only in optical diameter and effective optical zone size. Total height of either lense does not exceed 0.95 mm. Because the 6-mm lens was only available later in the study, only ten of the myopic eyes with preoperative myopia less than -15.50 D were implanted with this size PIOL. The power of the lens was calculated with the Van der Heijde[4] formula:

$$\text{Power} = \frac{n}{[n/k + Ps]} + \frac{n}{[n/k] - d}$$

Where: k = keratometric value of the cornea (diopters); Ps = equivalent spectacle power of the corneal plane (diopters); d = distance between the IOL plane and the corneal plane (meters); n = refraction index of aqueous (1.336). Because the distance between the crystalline lens and the PIOL is 0.8 mm, the d value was corrected with this number.

In most cases, surgery was performed under local retrobulbar anesthesia with 2.5 ml of marcaine and 2.5 ml of lidocaine with Hyason (hyalorunidase 150 I.U., Organon, Oss, The Netherlands); in some cases surgery was performed under general anesthesia. The Honan balloon was used for at least 10 minutes. One drop of 4% pilocarpine was instilled in the eye the morning before surgery and 30 minutes prior to surgery. The day before surgery, patients instilled gentamycin ointment in the eye to be operated.

The surgical protocol was the same for all eyes. After opening the conjunctiva at 12 o'clock, depending on the size of the PIOL, a 5 or 6-mm corneoscleral beveled two-step tunnel incision was made without entering the anterior chamber. Two paracenteses at 10 o'clock and 2 o'clock were made. The anterior chamber was irrigated with a solution of 0.04% pilocarpine, after which the anterior chamber was filled with Healon (Pharmacia and Upjohn, Uppsala, Sweden). The incision was than perforated.

The Artisan myopia lens was than introduced toward the 6 o'clock position, using special forceps designed for the claw lens. With a lens rotator, the PIOL was rotated in such a way that the haptics were at the 3 and 9 o'clock positions. The PIOL was than held with a Budo forceps at the outer part of the optic and enclavated to the iris with enclavation needles (Ophtec, Groningen, The Netherlands) through the paracenteses. To enclavate, the needle was put under the opening of the haptic at the site of the iris where the haptic should be fixated. Then a fold of iris tissue was gently pushed up, while with the other hand the Budo forceps held the lens, pushing it over the needle with the fold of iris. A peripheral crescent iridotomy was performed with vannas scissors. A 10-0 nylon running suture was placed, and before the knot was tied all the Healon was removed by irrigation with balanced salt solution. The suture was than knotted, and gentamycin ointment was administered. Postoperatively, dexamethasone 0.1% was prescribed four times daily for 1 month.

We present data according to standardized guidelines for reporting on refractive surgical procedures.[5] For statistical analysis, we used SPSS version 8.0 (SPSS Inc., Chicago, IL). A two-tailed probability of less than .05 was considered statistically significant.

RESULTS

Our patient population included three men and 26 women, with a mean age of 42.2 years (SD = 11.1, range 19 to 61 yr). The mean follow-up period was 10.7 months for all patients. All 78 eyes were followed for 6 months, 45 eyes for 12 months, and 10 eyes for 24 months. Preoperative myopia ranged from -6.15 to -28.00 D. The baseline refractive

Table 1
Postoperative Refraction in Eyes After Implantation of the Artisan Myopia Lens

Preoperative Refraction (D)	No. Eyes	Postoperative Refraction ±1.00 D of Emmetropia (% eyes)
-6.25 to -10.00	27	77.7
-10.12 to -20.00	40	57.5
-20.12 to -28.00	11	63.6

groups are represented in Table 1. The anterior chamber depth ranged from 2.9 mm to 4.5 mm and the axial length from 24.8 mm to 34.6 mm.

When considering predictability (Fig 1), 50% (39 eyes) were within ±0.50 D, 67.9% (53 eyes) were within ±1.00 D, and 89.7% (70 eyes) were within ±2.00 D of emmetropia. By refractive group (Table 1), postoperative refraction was within ±1.00 D of emmetropia in 77.7% of eyes in the -6.25 to -10-D group, 57.5% of eyes in the -10 to -20-D group, and 63.6% of eyes in the over -20-D group. The postoperative refraction remained stable during the entire follow-up period (Fig 2). There was an apparent small hyperopic shift between 6 and 12 months, but only 45 eyes were examined at 12 months, versus 78 eyes at 6 months. None of the eyes had a change of more than 1.00 D in refraction between 6 and 24 months.

Mean spectacle-corrected visual acuity improved from 20/32 preoperatively to 20/25 postoperatively. Mean uncorrected visual acuity postoperatively was 20/32. The cumulative number of eyes with an uncorrected visual acuity was 20/20 or better in 23 eyes (29.5%), 20/25 or better in 35 eyes (44.3%), 20/30 or better in 51 eyes (64.5%), and 20/40 or better in 58 eyes (73.4%). Spectacle-corrected visual acuity was 20/20 or better in 44 eyes (55.7%), 20/25 or better in 59 eyes (74.7%), 20/30 or better in 68 eyes (86.1%), and 20/40 or better in 70 eyes (88.6%). The coefficient of efficacy ([average postoperative uncorrected visual acuity divided by average preoperative best spectacle-corrected acuity] multiplied by 100%) was 91%.

In two eyes, there was loss of best spectacle-corrected visual acuity of two Snellen lines, and in five eyes the loss was one Snellen line (Fig 3). Most eyes had an improvement in best spectacle-corrected visual acuity. The coefficient of safety ([average postoperative best spectacle-corrected visual acuity divided by average preoperative best spectacle-corrected visual acuity] multiplied by 100%) was 121%.

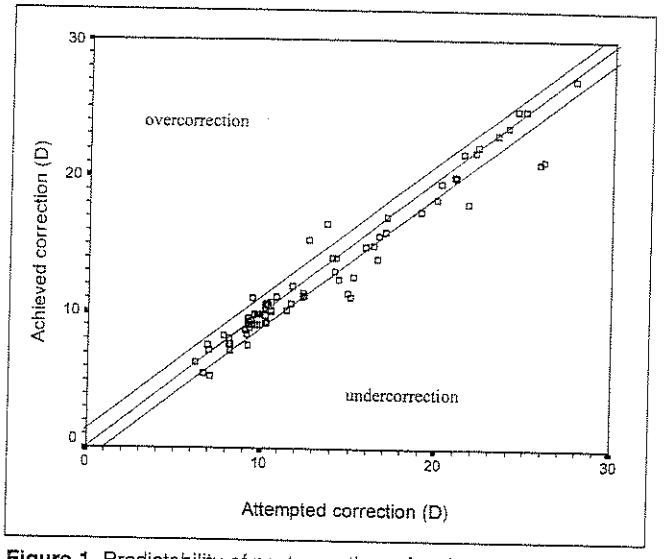

Figure 1. Predictability of postoperative refraction of all eyes at last follow-up examination after implantation of an Artisan myopia lens (iris-claw phakic intraocular lens).

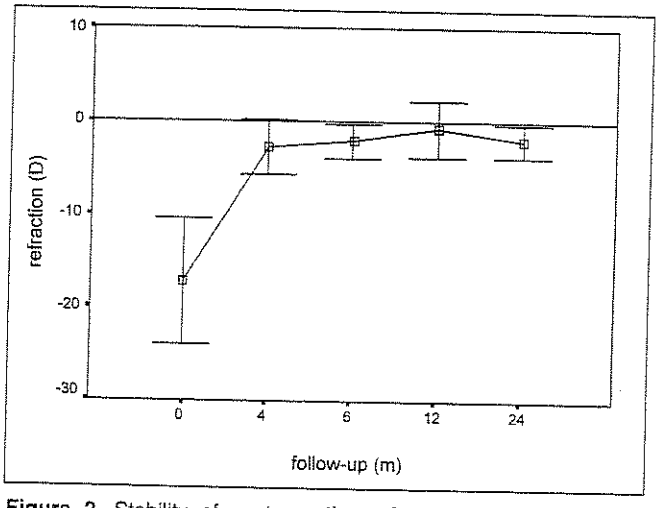

Figure 2. Stability of postoperative refraction during the entire follow-up period (Analysis of variance [ANOVA] $P > .05$) after implantation of an Artisan myopia lens (iris-claw phakic intraocular lens). Error bars show standard deviation of 5.44 at 0 months, 1.3 at 4 months, 1.06 at 6 months, 1.48 at 12 months, and 1.65 at 24 months.

Concerning corneal endothelial cell count, the change in percentage showed a gain in endothelial cell density postoperatively (Fig 4). Mean cell density was 2875 cells/mm^2 preoperatively, 2935 cells/mm^2 at 2 to 4 months, 2958 cells/mm^2 at 6 months, 3014 cells/mm^2 at 12 months, and 3049 cells/mm^2 at 2 years.

Complications

In Table 2 we describe postoperative problems reported in the literature. In our study, in 10 eyes (12.8%) of five patients, halos and glare were

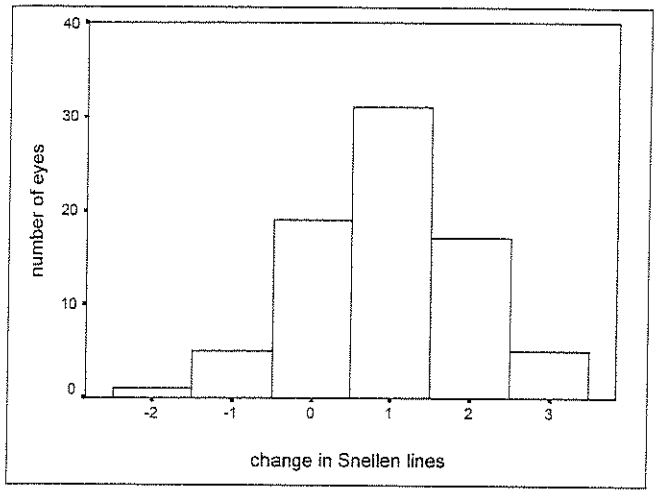

Figure 3. Change in best spectacle-corrected visual acuity at the last follow-up examination after implantation of an Artisan myopia lens (iris-claw phakic intraocular lens).

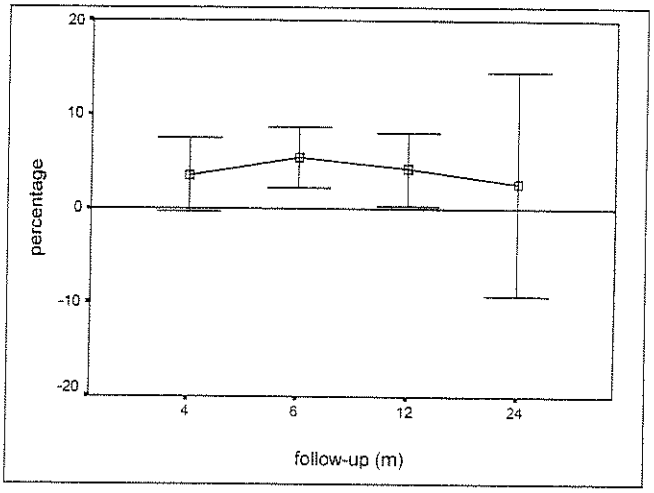

Figure 4. Percent change in endothelial cell density after implantation of an Artisan myopia lens (iris-claw phakic intraocular lens). Error bars show standard deviation at 4 months is 12.88, at 6 months is 11.89, at 12 months is 11.57, and at 24 months is 11.33.

encountered. In eight eyes this problem occurred with the 5-mm optic lens. In three eyes (3.85%) this complication was disturbing; one patient had so much hindrance that in both eyes the lens was replaced with a 6-mm optic Artisan myopia lens 1 year after the initial implantation. Another patient with a 6-mm optic Artisan myopia lens reported having problems with glare when driving into tunnels, in particular the transition when entering a tunnel from the outside.

We saw conjunctival bleb formation in three eyes immediately after surgery, in which there was some wound leakage under the conjunctiva. The blebs did not result in significantly low intraocular pressure and resolved postoperatively.

Anterior uveitis occurred in three eyes and resolved with topical treatment. In both eyes of one patient (59 years of age) nuclear cataract formation occurred, which was actually present in mild form preoperatively but increased postoperatively. Therefore, cataract extraction was performed 1 year after implantation of the Artisan myopia lens. Phacoemulsification was performed during the same surgery after the PIOL was removed, and through the same incision, which was shortened with a suture.

Four Artisan myopia lenses were replaced, the two mentioned above, and the other two because of undercorrection. In one eye, a -20.00-D lens was replaced with a -23.00-D lens, 4 months after surgery. The preoperative refraction in this patient was S-24 = C -0.50 x 110°; with the -20.00-D lens the refraction was S-6.5 = C -1.50 x 95°, and with the -23.00-D lens it was S-3 = C -1.00 x 100°.

In one eye of another patient, a -7.00-D PIOL was replaced with a -8.00-D lens 6 months after the first surgery. The preoperative refraction in this eye was S-6.75 = C -0.75 x 180°; after the first surgery it was S-1.0 = C -0.25 x 165°, and with the -8.00-D lens, S-0.25 = C -0.50 x 170°.

DISCUSSION

Correcting high myopia with phakic intraocular lenses offers a predictable and stable refractive result, especially for patients with moderate and high myopia. This has been described for the iris-fixated PIOLS[6,7], angle-supported PIOLs[8,9], and posterior chamber PIOLs.[10-13] In comparison with keratorefractive procedures, predictability is much more accurate with PIOLs, especially for myopia of more than -10.00 D (Table 2).[14-17] Another modality that produces accurate refractive results is clear lens extraction.[18,19] The drawback of this technique is loss of accommodation, formation of posterior capsule opacifications, and the risk of retinal detachment.

Although there are well-described advantages that favor the use of PIOLs, all potential risks must be evaluated before using these lenses on a large scale. Concerns about damaging anterior chamber structures—especially the corneal endothelium—and creating subclinical intraocular inflammation have been described.[20]

The minimal recommended anterior chamber depth was 3.2 mm, although in two eyes of one patient this was less (2.9 mm and 3.1 mm).

Table 2
Review of Reported Postoperative Results and Complications

Authors	No. Eyes	Preoperative Myopia (D)	Follow-up	Percent ±1.00 D of Emmetropia	Regression	Complications
Photorefractive Keratectomy						
Piovella et al (1997)[14]	56	-5.75 to -24.5	mean 32.1 mo	48.1 up to -10 D	3.4% up to -10 D	Severe haze, 19.6%; halos, 51.2%
Hersh et al (1998)[15]	105	-6 to -14	up to 6 mo	57.4	mean 0.89 D	Haze (3+), 4.4%
Laser in situ Keratomileusis						
Hersh et al (1998)[15]	115	-6 to -15	up to 6 mo	40.7	mean 0.55 D	Flap related problems in three cases
Knorz et al (1998)[16]	8 10 19	-5 to -19 -10 to -14.9 -15 to -29	12 mo	100 60 38.9	0 10% 21.2%	Reoperation in 4.3%
Maldonado-Bas et al (1998)[17]	138 91 43	-6.25 to -10 -10.25 to -15 -15 to -25.5	6 to 25 mo	63 51.16 32.5	mean 0.64 D mean 1.38 D mean 0.5 D	None reported
Clear Lens Extraction						
Colin et al (1997)[18]	49	>-12.00	4 yr	56.1	none	Retinal detachment in 1.9%, YAG capsulotomy in 36.7%
Jimenez-Alfaro et al (1998)[19]	26	mean -20.85 ±5.48	12 mo	76.91	---	CD* 3 eyes, IOP > 25 mmHg (19.23%), PCO† in 15.38%
Posterior Chamber Phakic Intraocular Lens						
Marinho et al (1997)[10]	38	-7 to -28	3 to 24 mo	71	none	One case of hypopyon, corneal edema and rotation; severe glare in one case
Rosen et al (1998)[11]	16	-5.5 to -14.5	3 mo	69	none	not reported
Sanders et al (1998)[12]	10	-7.25 to -9.37	6 mo	100	not reported	not reported
Zaldivar et al (1998)[13]	124	-8.5 to -18.63	1 to 36 mo	69	not reported	not reported
Anterior Chamber Phakic Intraocular Lens						
Menezo et al (1997)[6]	94	-7 to -24	3 to 74 mo	79.8	not reported	After 5 years, 17.9% cell loss, glare 3.2%, iris damage 4.25%
Baikoff et al (1998)[8]	134	-7 to -18.8	1 to 3 yr	66 after 1 yr 51.4 after 3 yr	0.37 D	Endothelial cell loss 4.5% (yr), 5.5% (yr), halos/glare 12.5%, iris retraction 27.5%, IOL displacement 6%, RD§ in one case
Alio et al (1999)[9]	263	-10 to -20	up to 7 yr	not reported	not reported	RD 3%, halos or glare in 10%
Fechner et al (1999)[7]	127	-5 to -31.75	up to 8 yr	62.1	not reported	RD in one case, corneal decompensation in four cases

*Choroidal detachment
†Posterior capsule opacification
§Retinal detachment

As for the corneal endothelial cell change in this study, we found a gain in cell density instead of a loss. This remarkable finding is probably due to the large variation in measuring cell density with the Topcon 2000 specular microscope. Variation in cell density measurement of three measurements in healthy eyes varied between 1.4% and 14.3%, with a mean of 6.2% (unpublished data). Therefore, small changes in cell density cannot be measured accurately with this specular microscope. Also, our sample size was small enough so that large variations could occur. This does not explain our finding of a tendency toward increase in cell density. Therefore, we cannot come to a conclusion about endothelial cell density change. We found a significant endothelial cell loss in four eyes of 12.4% after 6 months, of 10.1% and 23.8%, respectively, after 12 months, and 11.2% after 24 months. On the other hand, we found a significant gain in cell density of more than 10% in 17 eyes. No conclusion can be drawn from our endothelial cell density data.

Reports on endothelial cell change with iris-claw PIOLs vary. Fechner and colleagues[7] reported endothelial decompensation in four eyes with the biconcave Worst-Fechner PIOL; Menezo and colleagues[6] did not find progressive endothelial cell loss 4 years after implantation of the iris-claw PIOL. Recent studies on newer models of angle-supported PIOLs reveal a stabilization of cell loss in the second year after surgery[8], whereas early models caused severe endothelial cell loss.[21]

Fixation of the Artisan PIOL on the midperipheral iris tissue does not damage the iris, provided that the enclavation has been performed properly, with as little trauma as possible. In angle-supported PIOLs, damage to the iris, such as pupil ovalization with anterior synechia and iris atrophy, has been described.[9] We did not encounter any pupil ovalization or iris atrophy. We did not have to explant any of the lenses because of tissue damage to the iris, whereas with the angle-supported PIOL, an explantation rate of 4.8% has been described.[9]

We explanted the PIOL in both eyes of one patient, 59 years of age, who had nuclear cataract 2 years postoperatively. We do not think that the cataract was caused by the PIOL itself, but rather that the cataract was already present preoperatively. The explantation of the Artisan myopia lens and phacoemulsification in this patient was uneventful.

Chronic elevated postoperative intraocular pressure has not been found in our patient population, but has been described for the angle-supported PIOL. To prevent pupillary block, we began to make a peripheral iridectomy, and later, a crescent iridotomy. In earlier studies, pupillary block occurred both in iris-fixated[7] and angle-supported PIOLs.[22] These high intraocular pressures in the immediate postoperative period might also be caused by incomplete removal of the viscoelastic material used during surgery.

Another important complication associated with PIOLs is retinal detachment. In our study we have not encountered any retinal detachment, but other studies on iris-fixated and angle-supported PIOLs have reported an incidence of 0.8%[7] and 3.0%[9], respectively. This complication is also one of the potential hazards in clear lens extraction, where an incidence of 1.9 %[8] has been reported.

Halos and glare remain a concern with this type of lens. In our study it seems that the 5-mm optic Artisan myopia lens was associated with more glare disturbance and halos than the 6-mm lens. The number of 6-mm Artisan myopia lenses (10 of the total 68) that we implanted is too small to make any statistical comparison between these two optic sizes. Menezo and colleagues[6] found a similar rate of significant glare (3.2%) with the iris-fixated Worst-Fechner lens. Another important cause of halos and glare is the presence of a large iridectomy, which is why we began performing an iridotomy instead. Reports on the incidence of significant halos or glare in angle-supported PIOLs were 12.5% after 3 years[8] and 10% after 7 years.[9]

Our experience with correcting high myopia using the Artisan myopia lens yielded satisfactory refractive results. We did not encounter major complications, although we realize that the follow-up in this study is limited.

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