Secondary Artisan–Verysise aphakic lens implantation

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PURPOSE: To evaluate efficacy, predictability and safety of Artisan–Verysise intraocular lens (IOL) secondary implantation for aphakia correction.

SETTING: Instituto de Microcirugía Ocular, and Autonoma University of Barcelona, Barcelona, Spain.

METHODS: Uncorrected visual acuity, best spectacle-corrected visual acuity (BSCVA), manifest refraction, endothelial cell count, and clinical complications were evaluated. Sixteen consecutive eyes of 14 patients with aphakia were submitted to surgery. Postoperative examinations were done at 6 weeks, 6 months, 1 year, and every year for at least 3 years. An iris-supported Artisan–Verysise IOL was implanted for aphakia correction.

RESULTS: Thirty-six months after Artisan–Verysise lens implantation, BSCVA was 20/40 or better in 6 eyes (37.5%). Preoperatively, 5 eyes had the same BSCVA (31.25%). Mean postoperative spherical equivalent (SE) was 0.46 diopter (D). Mean endothelial cell loss was 10.9% 36 months postoperatively. The cell loss occurred predominantly during the first year (7.78%). Cystoid macular edema was observed in 2 cases, 1 of them associated with chronic unresponsive low intraocular pressure. No other serious complications were observed.

CONCLUSION: Artisan–Verysise IOL implantation seems a safe, predictable, and effective option for aphakic eyes without capsule support.

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The surgical correction of aphakic eyes without capsule support usually poses a difficult management problem. Most of these situations include posttraumatic or spontaneous dislocations of the crystalline lens as well as capsule loss during cataract extraction. The classic options for secondary intraocular lens (IOL) implantation include ciliary sulcus fixation and angle-supported implantation.[1,2] Posterior chamber IOL scleral fixation is the preferred procedure by most surgeons because the IOL position preserves the anatomy of the eye better than anterior chamber IOLs and they are theoretically safer long term because of the more adequate preservation of the corneal endothelium.[3,4] Nevertheless, complications such as ciliary choroidal body hemorrhage; retinal detachment, sometimes with giant retinal break; cystoid macular edema (CME); vitreous prolapse into the anterior chamber; and conjuctival erosion by transscleral sutures with associated endophthalmitis risk have been described.[5–7] Meanwhile, different results have been reported using anterior chamber angle-supported IOLs, depending on the preoperative status of the eye, surgical technique, and lens style. Associations with corneal edema, CME, glaucoma, IOL instability, lens decentration, pupil distortion, and retinal detachment have been described with both the flexible open–loop anterior chamber IOL and Kelman tripod lens.[8–10]

In the early 1980s, an iris-fixated IOL was first introduced by Worst et al.[11,12] The Artisan–Verysise lens was fixed to the midperipheral iris and centered over the pupil. This IOL does not interfere with the physiologic vascularization and does not effect mydriasis or angle structures.[13] Some studies have already indicated favorable visual outcomes and a low incidence of intraoperative and postoperative complications with the current model.[14]

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In this retrospective study, we evaluated the efficacy, predictability, and safety of Artisan–Verysise lens implantation for aphakic correction during 3 years.

PATIENTS AND METHODS

This retrospective study comprised 16 eyes of 14 patients with ages ranging from 36 and 74 years, who had Artisan–Verysise aphakic IOL (Ophthec BV) implantation by the same surgeon (J.L.G.) between December 1997 and February 1999 at IMO, Instituto de Microcirugía Ocular, Barcelona, Spain. Eight eyes had complicated cataract surgery with extensive capsule rupture and vitreous loss at least 1 year before secondary IOL implantation; 3 eyes had congenital cataract extraction through a manual dissection–aspiration technique; 2 eyes had penetrating ocular trauma; 2 eyes had combined surgery, penetrating keratoplasty, and angle-supported anterior chamber IOL exchange; and 1 eye, had anterior vitrectomy and IOL exchange after a nontraumatic posterior chamber lens subluxation (Figure 1).

Indications for surgery were unsatisfactory correction with spectacles or contact lenses for medical, professional, or personal requirements; chronic corneal edema, CME; vitreous–endothelial touch; and posterior chamber IOL subluxation.

Exclusion criteria for IOL implantation were an endothelial cell count less than 1800 cells/mm^2, anterior chamber depth less than 3.0 mm (i-Scan Ophthalmic Ultrasound Mode B scan.OTI Ophthalmic Technologies Inc.), glaucoma, recurrent uveitis history, proliferative diabetic retinopathy, and age–related macular degeneration. All patients were fully informed of the details and possible risks of the procedure in accordance to Helsinki declaration, and a written informed consent was obtained from each patient.

Preoperative and postoperative evaluations included subjective refraction, uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), Javal keratometry, slitlamp examination, Goldmann applanation tonometry, indirect fundus examination (fluorescein angiography when necessary), endothelial cell count, and morphologic evaluation by specular microscopy (Konan, Noncon ROBO). Postoperative examinations were done at 1 day, 6 weeks, 6 and 12 months, and every year for at least 3 years.

The Artisan–Verysise lens is a biconvex poly(methyl methacrylate) (PMMA) IOL with an 8.5 mm length, a 1.04 mm maximum height, and a 5.0 mm optical zone. The A-constant was 115, and the SRK/T formula[15] was used to calculate IOL power.

Surgical Technique

Under retrobulbar anesthesia (4 cc of a proportional combination of mepivacaine 2% and bupivacaine 0.75%), the first plane of a 5.2 mm long posterior vascular corneal incision and 2 vertical paracentral paracentesis (at 10 and 2 o'clock positions) were performed. After an intracameral injection of acetylcholine 1% (Acetilcolina 1%) and viscoelastic material through the paracentesis, the second plane of the incision was performed. The IOL was then inserted, rotated with a hook into a horizontal position, and centered over the pupil always under viscoelastic material protection. A lens fixation forceps was introduced through the large incision. At the same time, through the paracentral paracentesis, a modified blunt 36-gauge blended needle was introduced and a 1.0 mm iris fold was picked up and pulled through the "claw" into the haptic. The maneuver was then repeated on the other side, achieving perfect IOL centration over the pupil. This IOL fixation system was surgeon dependant, which is 1 of its main advantages. A peripheral slit iridotomy at 12 o'clock was then performed. Finally, all the viscoelastic material was carefully removed through an automated irrigation/aspiration system and the large incision was closed with 4 or 5 single 10-0 nylon sutures. Bimanual anterior vitrectomy was performed before IOL insertion, if needed, with a vitrector (Accurus, Alcon) and indirect intraocular illumination. Lighting was the only way to properly evaluate a clean anterior chamber before lens implantation. In 2 cases, penetrating keratoplasty with anterior vitrectomy were simultaneously performed and an angle-supported anterior chamber lens was exchanged through an open-sky technique. In another case, a posterior chamber subluxated lens was removed at the time of anterior vitrectomy and then the Artisan–Verysise lens was implanted (Figure 2).

RESULTS

Efficacy, Predictability, and Stability

Preoperative BSCVA was 20/40 or better in 5 eyes (31.25%) and postoperatively in 6 eyes (37.5%). Postoperative UCVA was equal to or better than preoperative BSCVA in 50% of eyes (8 of 16 eyes) at 36 months follow-up (Figure 3 and Table 1).

The goal refraction was emmetropia or slight residual myopia. Mean preoperative spherical equivalent (SE) refraction was +7.60 diopters (D) (range +4.75 to +14.50 D); this refraction decreased to a mean SE of –0.53 D (range –3.75 to +5.25 D), –0.51 D (range –3.00 to +5.00 D), and –0.46 (range –2.75 to +5.0 D) 3, 12, and 36 months after surgery, respectively. These results indicate stability in refractive outcome since the third month (Figure 4). In 56.25% of eyes (7 of 16 eyes) at 3 months, 62.50% of them (10 of 16 eyes) at 12 months, and

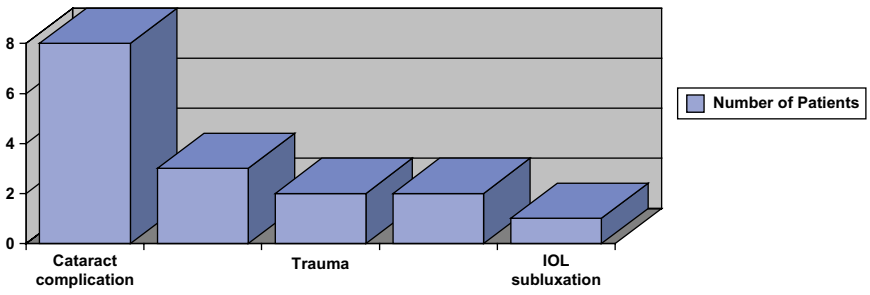

Figure 1. Indications for secondary Artisan–Verysise lens implantation.

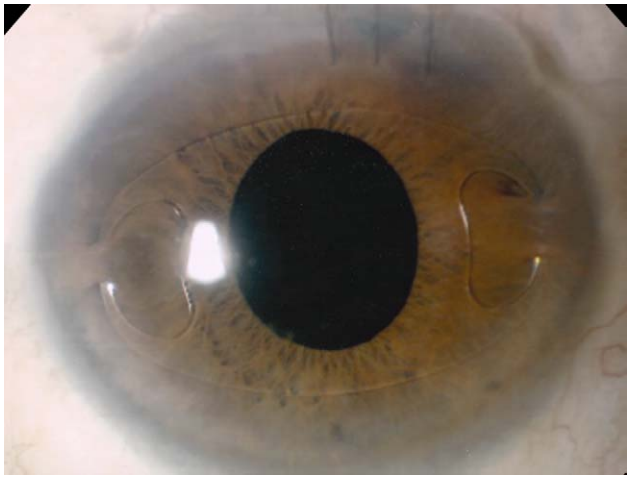

Figure 2. Artisan–Verysise lens in an aphakic eye with previous posterior chamber lens subluxation.

68.75% of eyes (11 of 16 eyes) at 36 months, the postoperative SE was within ±2.00 D of emmetropia. In 31.25% (5 of 16 eyes) at 3 months, 43.75% (7 of 16 eyes) at 12 months, and 43.75% (7 of 16 eyes) at 36 months, the postoperative SE was within ±1.00 D of emmetropia.

Corneal Endothelium

Preoperative mean cell density was 2345 cells/mm^2 (range 1934 to 2874 cells/mm^2). This wide range is related to the varied corneal status of patients in this series. Twelve months after surgery, mean endothelial cell density was 2167 cells/mm^2 (range 1422 to 2681 cells/mm^2), and at 36 months it was 2089 cells/mm^2 (range 1308 to 2480 cell/mm^2). Mean endothelial cell loss during the first 12 months after the surgery was 7.78%. During the next 2 years, the loss was 3.12%, with a cumulative loss for the first 3 years of 10.9% (Table 1).

Complications

During the surgery, the only complication observed was positive vitreous pressure and vitreous prolapse in 4 eyes (25%), all of which had previous complicated cataract extraction (3 eyes were very short and highly hyperopic). Significant postoperative flare was found in 6 eyes (60%); these eyes had an extensive anterior vitrectomy and iris manipulation, but they responded adequately to topical steroid treatment. An elevated intraoperative pressure (IOP; more than 20 mm Hg), probably steroid induced, was found in 3 eyes (18.75%) during the first 6 weeks after surgery. Once the steroids were discontinued, IOP decreased to normal values. Two patients complained of intermittent halos, and 1 patient had trauma history and an irregular pupil (Figure 5).

Postoperative CME was observed in 2 eyes (both were present preoperatively) (Figure 6), but both eyes responded angiographically well to subTenon's triamcinolone 40 mg (Trigon Depot) within 10 weeks after injection. In the second eye, visual acuity did not improve, probably because of chronic unresponsive low IOP.

DISCUSSION

During the past 2 decades, many surgeons have still been reluctant to perform secondary IOL implantation in aphakic eyes because of the associated risk for decreasing BCVA.[16] The main causes have been corneal edema and retinal complications.[17]

Several studies have focused on 2 secondary IOL designs: angle-supported anterior chamber IOLs[1,5,10,16,17] and scleral-sutured lenses.[3,5,6,18–20] There is no preference for either lens type at this time. Some individual factors such as age, ocular history, anatomic abnormalities, corneal status, and patient co-morbilities are taken into account to make the best choice for each patient. The general consensus is to use an anterior chamber IOL in patients older than 60 years with good endothelial cell counts and normal pupils, especially if health problems contraindicate prolonged

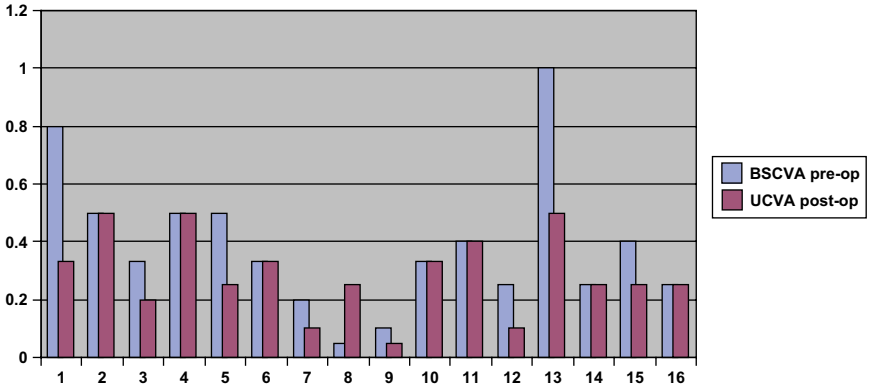

Figure 3. Preoperative BCVA and postoperative UCVA at 36 months.

Table 1. Preoperative and postoperative visual acuities and endothelial cell counts.

Patient	Preoperative Status	BSCVA Preop	BSCVA Postop 36 Months	UCVA Postop 36 Months	Endothelial Cell Count Preop (cells/mm^2)	Endothelial Cell Count 12 Months (cells/mm^2)	Endothelial Cell Count 36 Months (cells/mm^2)	Variation Preop 36 Months (%)
1	Complicated cataract	20/25	20/30	20/60	2135	1954	1935	9.36
2	Complicated cataract	20/40	20/30	20/40	2514	2584	2350	6.52
3	Complicated cataract	20/60	20/60	20/100	2165	2014	1950	9.93
4	Complicated cataract	20/40	20/40	20/40	2605	2384	2360	9.40
5	Complicated cataract	20/40	20/40	20/80	2036	1422	1308	35.75
6	Congenital cataract	20/60	20/50	20/60	2674	2526	2480	7.25
7	Ocular trauma	20/100	20/80	20/200	2834	2522	2388	15.73
8	Angle-supported lens*	20/400	20/60	20/80	2112	2006	1908	9.65
9	Ocular trauma	20/200	20/200	20/400	2253	1982	1950	13.44
10	Congenital cataract	20/60	20/60	20/60	2353	2162	2068	12.11
11	Congenital cataract	20/50	20/35	20/50	2655	2410	1368	48.47
12	Angle-supported lens*	20/80	20/80	20/200	1934	1895	1886	2.48
13	Complicated cataract	20/20	20/25	20/40	2023	1833	1713	15.32
14	Subluxated lens†	20/80	20/80	20/80	2874	2681	2656	7.58
15	Complicated cataract	20/50	20/60	20/80	2028	1980	1908	5.91
16	Complicated cataract	20/80	20/80	20/80	2332	2252	2208	5.31

BSCVA = best spectacle-corrected visual acuity; UCVA = uncorrected visual acuity
*Removal of the angle-supported lens and penetrating keratoplasty
†Removal of the lens and anterior vitrectomy

surgical procedures or when there is an increased bleeding risk. Sulcus-fixated posterior chamber IOLs are preferred in younger patients, especially those with a low endothelial cells count; scleral suture fixation depends on the amount of capsule support.

In this series, we studied the iris-fixated Artisan–Verysise used as a secondary IOL in aphakic patients. The mean postoperative refraction at 36 months of –0.46 D was moderately predictable and highly stable compared that in with other published series of secondary IOL implantation in aphakic eyes.[5,8] Best spectacle-corrected visual acuity improved in most eyes except, temporarily, in 2 eyes with postoperative CME. Both patients subjectively observed similar clinical complaints, but at different postoperative time points: 4 weeks and 14 weeks, at which time visual acuity was clearly reduced over a period of 2 to 3 days. Both eyes regained 50% of the visual acuity loss during the first 2 weeks. The first eye resolved completely after 4 months. The second eye did not resolve, probably because of secondary chronic unresponsive low IOP.

Endothelial cell loss during the first 3 years in this study was 10.9%, which is similar to other studies[21,22] examining the phakic Artisan–Verysise lens. On the other hand, some authors[23] have not found any difference respect to endothelial cell loss and endothelial morphometric values between anterior chamber IOL implantation and sutured-fixated posterior chamber IOL implantation. Nevertheless, a greater endothelial attrition at 1 and 2 years after sutured posterior chamber lens implantation has been studied.[24] The greatest decrease in endothelial cell density is observed during the first 12 months (7.78%) and therefore most likely relates to the surgery.[21] During anterior chamber lens implantation in phakic eyes, the highest surgical risk for the endothelium is contact between

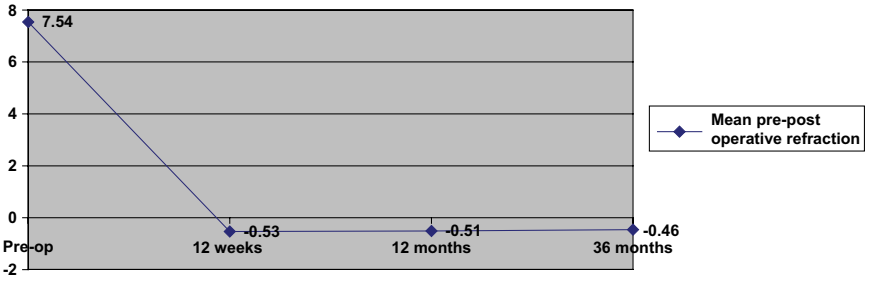

Figure 4. Refraction stability 12 weeks postoperatively.

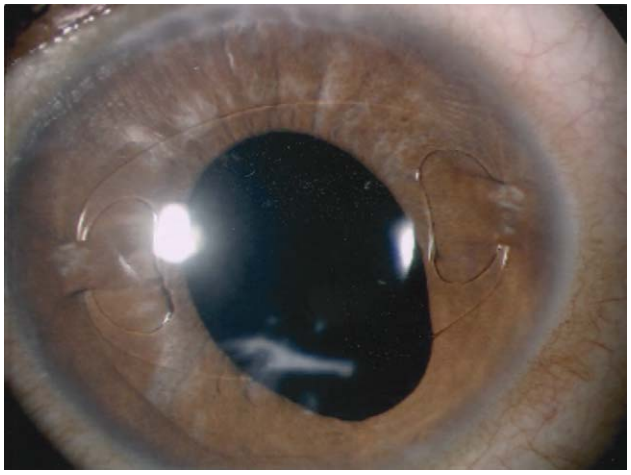

Figure 5. Artisan–Verysise lens in an aphakic eye with trauma history and irregular pupil.

the endothelium and the IOL or surgical instruments. This is also true in aphakic eyes, although from our point of view factors such as anterior chamber collapse because of aphakic low scleral rigidity and the turbulence during the anterior vitrectomy maneuvers are more important. Two potheses describe how an iris-claw lens may induce postoperative endothelial cell loss. The mechanical hypothesis has different implications on aphakic eyes versus phakic eyes. While the distance between IOL and endothelium is more than adequate in aphakic cases (above 3.5 mm, including those associated with penetrating keratoplasty), there is likely more movement or IOL donesis than in phakic eyes. The inflammatory hypothesis involves biological mediators as an etiology in chronic cell loss and CME. Endothelial cell counts criteria in aphakic IOL implantation are quite different than the criteria used in phakic IOL implantation studies. This is a consequence of the very different population who are typical candidates for secondary implantation. Most of them are older and have had at least 1 previous intraocular surgery, both factors contributing to the low preoperative endothelial cell counts.[25–27] In 1 eye in our study, we observed a postoperative increase in central cell density. This may be related to the discontinuation of an aphakic soft contact lens used before surgery, perhaps to a repopulation of the central corneal endothelium with cells from the periphery, or both.

The complication rate reported in previous studies with angle-supported or sulcus-sutured lenses is higher than in this study, although it is very difficult to properly compare these different groups because of the diversity of pathology and the varied number of eyes. Although it is difficult to learn proper surgical technique for Artisan–Verysise lens implantation, fixation, and centration,[22] we think that it will result in fewer complications for an experienced surgeon than other styles of secondary implantation, including pupillary distortion, CME, retinal detachment, and vitreous hemorrhage.

More data are required to evaluate the mid- and long-term safety of this lens style for secondary implantation. Nevertheless, the simplicity of the procedure compared with transscleral sutured techniques, the reversible-adjustable fixation, and centration characteristics and the relatively low rate of associated complications, compared with angle-supported anterior chamber lenses, make the Artisan–Verysise lens an attractive alternative.

The main disadvantage thus far has been wound size because the Artisan–Verysise lens is a single-piece PMMA lens.

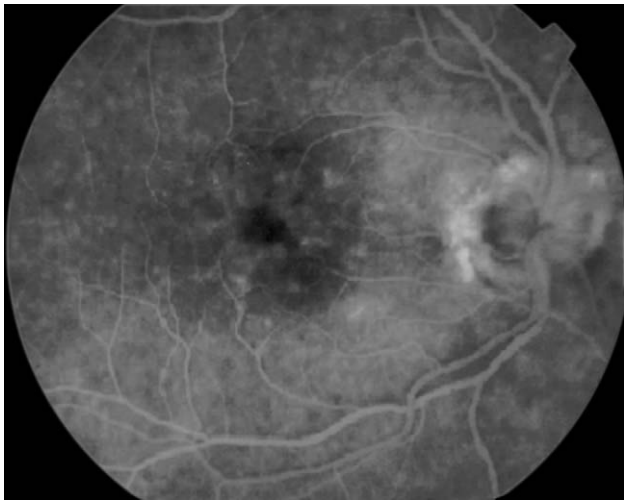

Figure 6. Cystoid macular edema following Artisan–Verysise lens implantation.

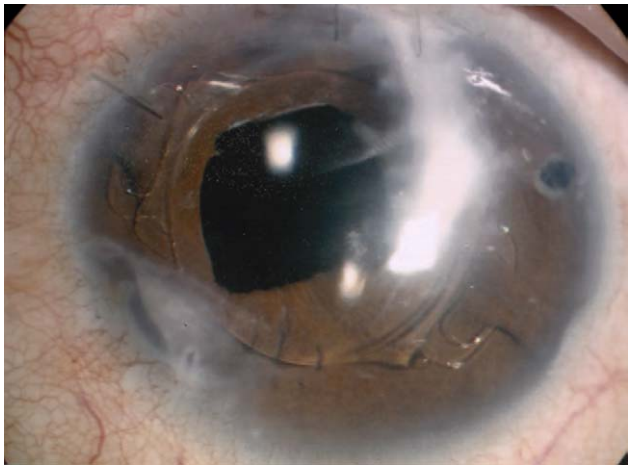

Figure 7. Foldable Artiflex lens in an aphakic eye.

We have just started with the Artiflex project (Figure 7), a soft silicone iris fixated IOL that may be introduced through a 2.75 to 3.2 mm incision. Although it is too early for any clinical evaluation, this project might significantly improve our clinical and refractive results in both phakic and aphakic eyes.

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