

Secondary Artisan– Verysise intraocular lens implantation for aphakic correction in post-traumatic vitrectomized eye

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CLINICAL STUDY

Abstract

Purpose To evaluate the efficacy and safety of Artisan–Verysise intraocular lens (IOL) secondarily implanted for aphakic correction in post-traumatic vitrectomized eyes.

Methods Postoperative outcomes of secondary implantation of an iris-supported Artisan IOL in 17 unilateral aphakic patients with previous pars plana vitrectomy secondary to posterior segment trauma were evaluated prospectively. Eyes had vitrectomized in previous 6–60 months. After complete ophthalmologic examination, IOL implantation was performed through a scleral tunnel incision. Patients were followed for visual outcome, endothelial cell density (ECD) and occurrence of complications. Uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA), spherical equivalents (SE), and ECD were compared before and after IOL insertion.

Results Patients' postoperative mean follow-up were 14.65 ± 5.21 months. UCVA improved in all patients. (0.03 ± 0.1 preoperatively vs 0.45 ± 0.29 postoperatively, $P = 0.0001$). However improvement of BCVA was not significant. Mean postoperative SE was 0.84 ± 1.32 D, whereas it was 10.85 ± 1.70 D preoperatively ($P = 0.0001$). SE was within ± 2.00 D of emmetropia in 16 eyes (94.1%). Mean endothelial cell loss was 8.1% in first 6 postoperative months. All eyes achieved the desired anatomic results. No intraoperative complications occurred in any of our cases. Complications were transient pigmented precipitates (three cases), choroidal detachment (one case), and transient vitreous haemorrhage (one case).

Conclusion Secondary Artisan IOL implantation is an effective and safe procedure to correct aphakia in vitrectomized eyes without capsular support after trauma. Considering good visual rehabilitation and low rate of complications, this procedure is recommended in vitrectomized eyes.

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Introduction

It is not uncommon for penetrating ocular injuries to involve the anterior and posterior segments simultaneously. Several surgical options are available to correct aphakia in those who have had pars plana vitrectomy (PPV) and lensectomy due to trauma. In the absence of adequate capsule support, an angle or iris supported anterior chamber intraocular lens (ACIOL)¹ and a trans-sclerally sutured posterior chamber intraocular lens (PCIOL)² can be implanted.

Due to several long-term complications like corneal decompensation, cystoid macular oedema (CME), secondary glaucoma, lens decentration, and retinal detachment (RD), placement of an ACIOL has been reduced considerably.³ Trans-scleral fixation of a PCIOL, while preserving the anatomy of the eye and causing less corneal endothelial damage, is technically more challenging, requires more surgical time, and is associated with a high incidence of intraoperative and postoperative

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complications such as lens tilting, decentration, choroidal haemorrhage, RD, and CME.^{2,4}

The Artisan IOLs, one of the latest versions of the iris-fixated anterior chamber IOLs, have a substantially different lens design⁵ than previous generations of iris fixated IOLs and also are associated with fewer complications. They are easy to place and are associated with a good visual outcome and a low incidence of intraoperative and postoperative complications.⁶

Many reported cases of Artisan IOL implantation have had good clinical outcomes^{1,7–11}; however, despite more than 10 years of favourable clinical experience with this IOL, experience in the literature with implantation of this lens in aphakic and vitrectomized eyes secondary to trauma is scarce. Insertion of Artisan IOL in an eye without vitreous poses challenges, especially when a large incision is required.

In this prospective study, we evaluated the efficacy and safety of secondary Artisan–Vervysise lens implantation for aphakic correction in post-traumatic vitrectomized eyes.

Materials and methods

In this prospective non-randomized consecutive clinical study we evaluated postoperative outcomes of secondary implantation of an iris-supported Artisan–Vervysise IOL in vitrectomized traumatic eyes in Farabi Eye Center, between May 2005 and March 2007. 18 unilateral aphakic patients (15 men and 3 women) with previous PPV and lensectomy secondary to posterior segment trauma were enrolled. One diabetic patient was excluded from the study because of premacular fibrosis developed during follow-up. Eyes had been vitrectomized 6–60 months before IOL implantation. The study was reviewed and approved by the ethics committee of the Medical Faculty of Tehran University of medical sciences and written informed consent was obtained from each patient before IOL implantation.

Preoperatively all patients underwent complete ophthalmologic evaluations including subjective refraction, uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA), keratometry, slit-lamp examination, Goldmann applanation tonometry, indirect fundus examination, endothelial cell densitometry (ECD), and morphologic evaluation by specular microscopy. Patients with PPV in recent 6 months, with uncontrolled glaucoma, with severe iris damages, and whose ECD was less than 1000 cells/mm² were excluded. Axial length was measured using A scan (Nidek Echoscanner US-2500, Tokyo, Japan). In those who had silicone in their eyes, axial length measurement was performed by partial coherence laser interferometry (IOL

Master, Carl Zeiss Jena). The SRKII formula was used to calculate IOL power.

Surgery

All procedures were performed by two surgeons using the same surgical protocol in all cases. Under general anaesthesia a 5.5 mm, scleral tunnel incision was made 1 mm posterior to limbus and two paracentesis were performed at 10 and 2 o'clock positions. Then acetylcholine 1% was injected to constrict the pupil and the anterior chamber was filled with an ophthalmic viscosurgical device and an Artisan IOL was inserted in the anterior chamber, rotated with a hook into an appropriate position, and centred over the pupil. The iris was hooked between the claw-like footplates to achieve perfect IOL centration over the pupil. Then a peripheral iridotomy was performed at 12 o'clock position and the viscoelastic material was carefully removed. Finally, the incision was closed with three interrupted 10–0 nylon sutures.

When silicone removal was needed, the pupil was fully dilated preoperatively. An incision was made at the inferotemporal limbus. An infusion cannula was inserted into the eye through the paracentesis. Infusion was opened and with depressing posterior lip of scleral tunnel, silicone oil was removed before insertion of IOL. Gentamicin and dexamethasone were injected subconjunctivally. Dexamethasone and Chloramphenicol drops were prescribed postoperatively, tapered, and then discontinued after 1 month.

Postoperative follow-up examinations were done at 1 day, 1 week, 6 weeks, 3 months, and thereafter the patients followed at 6-month intervals. During each visit, ophthalmologic examinations identical to those performed preoperatively were performed except for ECD, which was re-evaluated once after 6 months. Main outcome measures were included UCVA, BCVA, spherical equivalents (SE), endothelial cell loss, and occurrence of complications.

Statistical analysis

Descriptive statistics was used to report demographic characteristics; by the means of SPSS package version 14.5. Non-parametric test (Wilcoxon signed ranks) was used to compare patients' UCVA, BCVA, SE, and ECD before and after Artisan IOL implantation.

Results

A total of 17 eyes (13 OD and 4 OS) of 17 patients were included in our study. Age of the participants ranged

Table 1 Patients' ophthalmic history, visual acuity, and endothelial cell density before Artisan IOL implantation

Patient	Sex	Age (years)	OD/OS	Previous surgery	Time of Previous Surgery (month)	UCVA	BCVA	Spherical equivalent	ECD (cells/mm ²)
1	M	22	OD	PPL, PPV, EB, FB removal, SF6	14	20/1000	20/100	+ 8.75	2054
2	M	28	OS	PPL, PPV, EB, EL, silicone	6	20/800	20/70	+7	1824
3	F	65	OD	PPL, PPV	6	20/600	20/70	+ 12.25	2470
4	M	18	OD	PPL, PPV, FB removal, silicone	6	20/500	20/25	+ 12.5	2453
5	M	36	OD	PPL, PPV	18	20/400	20/40	+9	2127
6	M	28	OD	PPL, PPV	6	20/800	20/30	+ 11.25	2332
7	M	25	OD	PPL, PPV, EB, FB removal, EL, SF6	6	20/600	20/25	+ 10.75	1614
8	M	24	OS	PPL, PPV, FB removal, SF6	14	20/600	20/100	+ 11.5	1395
9	M	22	OD	PPL, PPV	6	20/1000	20/100	+ 12	1211
10	F	14	OD	PPL, PPV, EB	26	20/800	20/70	+ 13.25	2429
11	M	21	OD	PPL, PPV, FB removal, silicone	7	20/500	20/40	+ 11	1814
12	M	25	OD	PPL, PPV, FB removal, SF6	7	20/800	20/40	+ 10	1626
13	M	40	OD	PPL, PPV, EB	24	20/800	20/25	+ 12.5	2236
14	M	24	OS	PPL, PPV	9	20/500	20/40	+ 9.5	1529
15	M	16	OS	PPL, PPV	8	20/400	20/30	+ 11.25	1352
16	M	19	OD	PPL, PPV, EB	60	20/600	20/30	+ 9.25	1917
17	F	19	OD	PPL, PPV, EB	6	20/400	20/70	+ 12.75	1846

Abbreviations: BCVA, best-corrected visual acuity; EB, encircling band; ECD, endothelial cell density; EL, endolaser; F, female; FB, foreign body; IOL, intraocular lens; IOP, intraocular pressure; M, male; OD, right eye; OS, left eye; PPL, pars plana lensectomy; PPV, pars plana vitrectomy; UCVA, uncorrected visual acuity.

from 14 to 65 years (mean, 27.7 ± 13.3); 14 (82.4%) were men and 3 (17.6%) were women. All patients had a history of PPV and cataract extraction due to posterior segment trauma in previous 6–60 months (mean, 13.4 ± 13.6). The preoperative ophthalmic history and findings are shown in Table 1.

Patients' postoperative mean follow-up time was 14.65 ± 5.21 months (9–24). UCVA improved in all patients (0.03 ± 0.1 preoperatively vs 0.45 ± 0.29 postoperatively, *P* = 0.0001). UCVA was 20/40 or better in seven eyes postoperatively, where preoperatively in none. However, improvement in BCVA was not significant (0.48 ± 0.22 preoperatively and 0.52 ± 0.24 postoperatively, *P* = 0.94). After surgery BCVA remained the same or became better in 15 eyes (88.8%).

Mean postoperative SE was 0.84 ± 1.32 D, whereas it was 10.85 ± 1.70 D preoperatively (*P* = 0.0001). Absolute mean of refractive errors was 1.14 D. At near 14 months follow-up, the postoperative SE was within ± 2.00 D of emmetropia in 16 out of 17 eyes (94.1%). In 10 eyes (58.1%), postoperative refractive errors were within ± 1.00 D of emmetropia. Excluding patients with concomitant silicone removal, mean postoperative SE was 0.66 D. Severe hyperopia (>4 D) developed in one eye (No. 11), in which silicone oil removal had performed with IOL insertion.

Mean preoperative ECD was 1895.8 ± 405.1 cells/mm² and mean ECD 6 months postoperatively was 1742.2 ± 405.6 cells/mm² (*P* = 0.00). Mean endothelial cell loss was 8.1% (153.6 cells/mm²) in first 6 postoperative months (Table 2).

Complications

All eyes achieved the desired anatomic results and no intraoperative complications occurred in any of our cases.

The mean early postoperative IOP was 17.8 mm Hg (range, 5–24 mm Hg). With respect to early postoperative complications, an IOP of more than 20 mm Hg was observed in two patients (11.1%) that was transient and responded to topical medication. Scleral tunnel insufficiency with anterior chamber leakage and subsequent choroidal detachment was seen in one eye (5.5%), requiring secondary suture of the tunnel. Choroidal detachment reduced after a week with conservative management, but secondary glaucoma developed due to peripheral anterior synechiae. It was controlled with antiglaucoma medications. Transient hyphema and vitreous haemorrhage was observed in one patient. The source was possibly bleeding from scleral tunnel after a period of hypotony. One diabetic patient developed premacular fibrosis, which might be a complication secondary to the underlying ocular pathologic features and not related to IOL. He needed reoperation and was excluded from the study.

Pigmented precipitates on posterior surface of IOL were observed in three cases, but were transient and responded well to corticosteroid. Two of three eyes had concomitant silicone oil removal. No other serious postoperative complications were observed. No acute or chronic inflammation, clinical CME, RD, or endophthalmitis were seen in any of the eyes. Except

Table 2 Postoperative visual acuity and endothelial cell loss

Patient	UCVA	BCVA	Spherical equivalent	ECD (cells/mm ²)	Comments, Complications	F/U (month)
1	20/70	20/70	0	1760	—	18
2	20/30	20/30	-0.75	1831	Silicone oil removal, IOL precipitation	22
3	20/70	20/70	+1.25	2218	—	11
4	20/70	20/70	+1	2450	Silicone removal	12
5	20/70	20/40	+1.25	2005	—	20
6	20/25	20/25	+2	2045	IOL Precipitation	15
7	20/25	20/25	+0.5	1230	—	14
8	20/70	20/70	+0.5	1342	Leaking wound, choroidal detachment, glaucoma	15
9	20/200	20/100	+0.75	1010	—	24
10	20/50	20/40	-0.25	2331	VH	12
11	20/200	20/100	+4.5	1725	Silicone oil removal, IOL precipitation	15
12	20/100	20/50	-1.5	1510	—	10
13	20/25	20/25	+1	2011	—	9
14	20/70	20/40	+1.25	1374	—	10
15	20/20	20/20	0	1333	—	9
16	20/25	20/25	+0.62	1736	—	24
17	20/200	20/40	+2.25	1708	—	9

Abbreviations: BCVA, best-corrected visual acuity; ECD, endothelial cell density; IOL, intraocular lens; UCVA, uncorrected visual acuity; VH, vitreous haemorrhage.

secondary suture of the tunnel in one patient, no patient required secondary surgery to reverse complications.

Discussion

Vision

Artisan IOL implantation in vitrectomized eyes, secondary to trauma, showed good efficacy in visual outcomes and low complications. At the last follow-up, most patients regained significant visual acuity. UCVA improved in all patients and nearly one third of the patients achieved a visual acuity of 20/40 or better. BCVA remained the same or became better in 88% of eyes. These results are favourably comparable with the results in the other published series in which 19–80% of cases had a final visual acuity of 20/40.^{1,7,9–12}

The Artisan IOL have been used safely for secondary implantation in adults and children with aphakia.^{1,7,9–12} They have also been used after traumatic injuries to the globe.^{9–12} Güell *et al*⁷ reported satisfactory results of Artisan IOL implantations in 16 aphakic patients. After 36 months follow-up, BCVA was 20/40 or better in 31.25% and mean SE was 0.46 D. Lorencová *et al*¹¹ performed Artisan IOL implantation in 51 aphakic eyes, 33% of which were post traumatic. They also showed good visual outcome after 13 months period of follow-up. In both of the mentioned studies, most of the aphakic eyes had had no previous PPV. van der Meulen *et al*¹ in a case-control study on 13 patients, who had previous PPV for retained lens fragments with Artisan IOL implantation, reported various complications. However PPV in their series was performed simultaneously with

IOL implantation and the cases were not traumatic. Condon *et al*¹³ have recently reported visual outcomes and complications of a new modified McCannel iris suture fixation of small-incision foldable IOL for aphakia. Although 2 of their 46 cases had IOL dislocation, they noted this method as an effective technique with few severe adverse events.

In this study, postoperative refractive errors were within ± 2.00 D of emmetropia in more than 94.1%. Severe hyperopia developed in only one eye. However, postoperative refractive error was more than previous reports of either Artisan IOL^{1,7,12} or iris fixated PCIOL.¹³ One reason might be inaccurate keratometry in most of our cases due to irregular astigmatism caused by previous repaired corneoscleral laceration. The other reason might be use of SRK II formula for IOL calculation. Although axial length in all of our patients was in normal range (20.5–23.7 mm), using newer formulas might improve postoperative refractive error. Accuracy was also lower in cases with concomitant silicone removal. The results would be better if these cases are excluded.

Complications

Most postoperative complications in the present study were mild and transient. We excluded the patients with traumatic aniridia or severe iris damage. In our cases we had no problem in IOL centration and fixation. In all of them IOL remained well centred until the end of the follow-up period. After scleral fixation, suture erosions have been noted in 7.8–27.9% cases after 5 years that leads to decentred IOLs required reoperation.^{14,15} Subluxation of the Artisan aphakia has been reported

to be lower (up to 2%),¹² therefore in younger patients, Artisan implantation might be preferred to correct aphakia, surgically.

The accumulation of pigmented precipitates on IOL's surface is a reported complication of some intraocular surgeries.¹⁶ These precipitates have been reported with the use of both polymethyl methacrylate and silicone IOLs. In some cases, these precipitates are visually significant, and although topical corticosteroids can reduce them, they tend to recur once the steroids are stopped.^{16,17} The cause of these pigmented cell precipitates is also unknown, but multiple factors like inflammatory reactions, IOL design, surgical manipulation of the iris, hypotony, and medication (pilocarpine, intracameral acetylcholine) have been suggested.¹⁶ To the best of our knowledge, this is the first study to report this complication in Artisan IOL implantation. Two of three eyes with pigmented precipitates had concomitant silicone oil removal, and thus had more iris trauma and more prolonged surgery. This may be an explanation for this complication. Intracameral acetylcholine might be another reason. Fortunately in only one case it was visually significant and all of three eyes responded well to corticosteroid.

CME has been reported in secondary Artisan IOL implantation for aphakic correction and is associated with chronic low IOP.⁷ Similar to Lorencová study,¹¹ none of our cases developed clinical CME. The reason might be previous PPV that might reduce risk of chronic inflammation and macular oedema.

The most serious complication may be RD in a traumatized eye. Fortunately none of our patients developed it during follow-up. Although the problem may be reduced visualization of retina, especially in traumatic patients with posterior segment injury, it has been noted that the Artisan implantation does not significantly interfere with adequate visualization of peripheral retina for vitreoretinal surgery.¹⁸ However, given the limited support provided by the iris, the presence of gas in the vitreous cavity can lead to the anterior displacement of the lens. van der Meulen¹⁸ suggested that corneal endothelial touch can be prevented by the use of Healon.

Vote¹⁵ and Bading¹⁴ found a rate of 6.3–8.2% for RD and 3.2% for choroidal haemorrhage in their cases after the implantation of a trans-sclerally sutured PCIOL. These complication rates were considered to be adequately high for a significant fraction of trauma cases or eyes that required complex retinal surgeries before IOL implantation and might be attributed to scleral fixation. Implantation of a scleral-fixated IOL in the posterior chamber has been reported to bear certain risks, such as vitreous haemorrhage and retinal breaks with consequent RD.^{19,20} Güell⁷ and Lorencová¹¹ didn't

observe any RD and choroidal haemorrhage in their cases after secondary implantation of Artisan. We had only one case of choroidal detachment due to anterior chamber leakage and one case of hyphema and vitreous haemorrhage possibly from bleeding of the wound. Both of these complications seem to be related to the wound insufficiency, not to the IOL fixation.

Several studies of Artisan iris-fixated IOL implantation have reported endothelial damage and cell loss.^{6,7} Consistent with previous reports on phakic and aphakic eyes,^{6–8} Artisan IOLs in our study induced a mean corneal endothelial cell loss of 8.1% in first 6 months of follow-up. Some limitations of our study were short follow-up for ECD measurements, and lack of data about other important parameters like coefficient of variation and percentage of hexagonal cells. Concomitant silicone oil removal in some of our patients might exacerbate corneal endothelial cell loss, although sample size was not enough for statistical analysis.

There is no study to compare endothelial cell loss in Artisan *vs* sutured fixated PCIOL implantation. Endothelial cell loss of 10.3% in aphakic eyes with sutured fixated PCIOL implantation was reported.²¹ Cell loss occurred predominantly during the first year⁷; however, continuous endothelial cell loss was observed previously after Artisan implantation^{7,8} as well as PCIOL.²² Although the distance between IOL and endothelium is more adequate in aphakic cases, there is likely more movement or IOL decentration than phakic eyes.^{7,23} Moreover, endothelial cell loss in post-traumatic aphakic IOL implantation may be more important than other settings of IOL implantations. These patients are relatively younger, have various previous traumas, and have experienced at least one previous intraocular surgery contributing to the preoperative ECD. Considering the importance of endothelial cell loss in this group, more surgical precaution seems to be required.

In summary, despite the severe underlying pathologic features in many of our patients, the results suggest that secondary Artisan implantation is an effective and safe procedure to correct aphakia in vitrectomized eyes without capsular support after trauma. Because of good visual rehabilitation, and low rate of complications, we recommend this procedure in vitrectomized patients to avoid the potential complications after implanting ACIOLs, or trans-sclerally sutured PCIOL. Further studies with a larger number of patients and a longer follow-up are needed to determine the long-term visual outcomes, ECD as well as probable long-term complications.

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