·Clinical Research ·

Comparison of Artisan iris-claw intraocular lens implantation and posterior chamber intraocular lens sulcus fixation for aphakic eyes

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Abstract

- AIM: To compare the efficacy and complications of Artisan iris-claw intraocular lens (IOL) implantation and posterior chamber IOL sulcus fixation for the treatment of aphakic eyes without capsular support after vitrectomy.
- METHODS: A prospective study of 45 cases was conducted. Forty -five eyes without sufficient lens capsule support following pars plana vitrectomy (PPV) combined lens extraction were divided into two groups. Group A: 25 eyes received Artisan iris -claw IOL implantation. Group B: 20 eyes received posterior chamber IOL sulcus fixation. The corrected distance visual acuity (CDVA) and intraocular pressure (IOP), corneal endothelial cell loss rate, surgical time and complications were compared between the two groups. Pigment changes of trabecular meshwork and anterior chamber depths were measured at each time point in Artisan group.
- RESULTS: The mean surgical time of Artisan group was significantly shorter (P<0.05). No statistically significant difference in endothelial cell loss rate was noted between two groups at any time point (P>0.05). CDVA of Artian group was better than that of the sulcus fixation group 1d after surgery (P<0.05) and there was no statistically significant difference 1 and 3mo after surgery (P>0.05). Mean IOP showed no significant differences between groups before and after surgery. The postoperative complications of Artisan group were anterior uveitis, iris depigmentation, pupillary distortion and spontaneous lens dislocation. The complications of sulcus fixation group include choroidal detachment, intraocular haemorrhage, tilt of IOL optic part and retinal detachment.
- CONCLUSION: Secondary Artisan IOL implantation can

be performed less invasively and in a shorter surgical time period with earlier visual recovery after surgery compared to transscleral suturing fixation of an IOL. This technique is an effective and safe procedure. It is a promising option for the treatment of aphakic eyes without capsular support after vitrectomy.

• **KEYWORDS:** iris-claw intraocular lens; aphakic eye; vitrectomy

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INTRODUCTION

S everal surgical options are available to correct aphakia in those who have pars plana vitrectomy (PPV) and lens extraction due to various reasons. In the absence of adequate capsule support, anterior chamber intraocular lens (ACIOL) implantation or posterior chamber intraocular lens (PCIOL) sulcus fixation can be performed.

Previously, ACIOL implantation has rarely been used due to the long-term complications like secondary glaucoma, corneal decompensation and severe uveitis [1]. 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 complications^[2].

The Artisan IOLs, one of the latest versions of the iris-fixated ACIOL, have a substantially different lens design than previous generations of iris fixated IOLs and also are associated with fewer complications^[3]. They are easy to place and are associated with a good visual outcome and a low incidence of intraoperative and postoperative complications. Artisan phakic IOLs have been widely used for the correction of high myopia, and the access of safety and efficacy has passed the United States FDA certification^[4].

Many reported cases of Artisan IOL implantation have had good clinical outcomes ^[5-8]. However, comparison of Artisan iris-claw IOL implantation and PCIOL sulcus fixation for the treatment of aphakic and vitrectomized eyes is scarce. In this

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Group	n -	Sex		Age	Preop. pupil shape	
Group		M	F	$(a, \overline{x} \pm SD)$	Round	Deformation
Artisan group	25	15	10	63.16±16.72	11	14
Sulcus fixation group	20	12	8	66.25 ± 17.50	9	11
Test value		0.0	00^{a}	-0.60^{b}	0	.005 ^a
P		1.0	00	0.55	(0.95

^a Chi-square test, ^b Two-independent *t*-test.

prospective study, we compare the efficacy and complications of Artisan iris-claw IOL implantation and PCIOL ciliary sulcus suture fixation for the treatment of aphakic eyes without capsular support after vitrectomy.

SUBJECTS AND METHODS

Subjects The study protocol and informed consent forms were obtained from all the participants and followed the tenets of the Declaration of Helsinki. A prospective study was conducted. Forty-five eyes of 45 cases were included from September 2008 to September 2012 in Tianjin Medical University Eye Centre, all the cases were aphakia without sufficient lens capsule support following PPV and lensectomy. Eyes had vitrectomized in previous 4-12mo for various reasons such as trauma and operation complications. The patient age ranged between 15-81y, mean age $65.25 \pm$ 17.50y. The inclusion criteria included preoperative corrected distance visual acuity (CDVA) >0.15, anterior chamber depth >3.2 mm, no serious iris damage and endothelial cell density > 900/mm². The patients were divided into two groups according to the residual capsule condition (Table 1). Group A: 25 eyes without residual capsule limitation received Artisan iris-claw IOL implantation, which is a concave convex, polymethylmethacrylate (PMMA) IOL with an 8.5-mm length, 0.90-mm maximum height, and 5.4-mm optical zone. Group B:20 eyes with residual capsule <180° received implantation of a foldable hydrophilic acrylic PCIOL(SuperFlex620H; Rayner Intraocular Lenses Ltd, East Sussex, United Kingdom) with an optic diameter of 6.25 mm and overall length of 12.5 mm by transscleral suturing fixation. Preoperative pupil shape rules for round 20 eyes (group A: 11 eyes, group B: 9 eyes), different degree of deformation in 25 eyes (group A: 14 eyes, group B: 11 eyes). All the patients were followed up for 1y.

Methods

Artisan iris -claw intraocular lens implantation All procedures were performed by the same consultant surgeon using a standardised technique that, in summary, comprised: a 5.2 mm chord length half-thickness limbal section, creation of two small corneal paracenteses at 3 and 9 o'clock, followed by full thickness completion of the superior corneal incision; injecting intracameral 1% acetylcholine chloride, then cohesive viscoelastic into the anterior chamber;

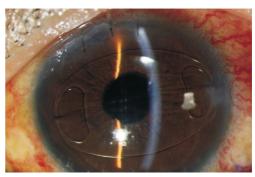


Figure 1 Anterior segment photograph of Artisan iris-claw IOL implantation.

implanting the lens with the help of viscoelastic agent; rotating the IOL so that the claw haptics are orientated dependant on the amount of iris tissue present; enclavation of the iris between the claws; creation of a superior peripheral iridotomy; suturing the corneal wound with two interrupted 10-0 nylon sutures; and washing out the viscoelastic agent (Figure 1).

Posterior chamber intraocular lens ciliary sulcus suture **fixation** First, PPV perfusion was performed in all eyes. Before a 3.5- to 4.0-mm-wide clear corneal incision at the 12-o'clock position was created, vertical paracentral paracenteses at the 3- and 9-o'clock positions were performed. An additional conjunctival peritomy around the 4- and 10-o'clock quadrants was performed. After blunt dissection of the episcleral tissue and slight cauterization of the surgical field, two triangular scleral flaps were constructed at positions 180° apart. Polypropylene suture (10-0) was introduced through the scleral flaps into the anterior chamber and guided outside through the clear corneal incision at the 12-o'clock position. Both haptics of the IOL were tied with 10-0 polypropylene suture, and the IOL was folded with lens forceps and inserted into the posterior chamber through the clear corneal incision. The 10-0 polypropylene suturing was performed tightly enough not to loosen under the scleral flaps. The clear corneal incision was closed without sutures by stromal hydration. Finally, the scleral flaps were closed with 10-0 nylon and interrupted sutures with 8-0 bicryl were used to close the conjunctival peritomy.

Evaluation CDVA and intraocular pressure (IOP) were examined preoperatively and at 1d, 1 and 3mo

Table 2 Comparison of mean CDVA of the two groups over time

Groups	Preop.	1d	1mo	3mo
Artisan group	0.40 (0.15, 0.80)	0.40 (0.12, 0.80)	0.40 (0.15, 0.80)	0.50 (0.20, 1.00)
Sulcus fixation group	0.45 (0.15, 0.80)	0.30 (0.08, 0.60)	0.45 (0.12, 0.60)	0.40 (0.15, 0.80)
Z	-0.28	-2.16	-0.56	-0.73
P	0.78	0.03	0.58	0.47

Table 3	Comparison of corneal endothelial cell loss rate of the two groups over time

Groups	Preop.	3mo	6mo	1a
Artisan group	1872.8±510.0	4.39±1.85	4.76±2.06	6.30±2.71
Sulcus fixation group	1756.3 ± 528.0	3.92 ± 1.85	4.33±1.80	5.73 ± 2.12
t	0.69	0.77	0.66	0.69
P	0.49	0.44	0.52	0.50

postoperatively. Corneal endothelial cell loss rate was examined and compared 3, 6 and 12mo postoperatively. Operation time and complications were compared between the two groups. Pigment changes of trabecular meshwork were measured by gonioscopy at each time point in Artisan group and anterior chamber depths (the distance between the midpoint of cornea posterior surface and the midpoint of Artisan IOL anterior surface) measured by Pentacam anterior segment analyzer were also recorded.

Statistical Analysis Descriptive statistics was used to report demographic characteristics by means of SPSS package version 17.0. Two-independent ℓ -test was used to compare patients' CDVA, IOP, corneal endothelial cell loss rate and surgical time between two groups. The values are expressed as the mean \pm SD. P <0.05 was considered statistically significant.

RESULTS

Visual Recovery No statistically significant differences in CDVA were noted between the two groups before surgery. CDVA of Artisan group was significantly better than the sulcus fixation group 1d after surgery. No statistically significant differences were noted between the two groups 1mo and 3mo after surgery (Table 2).

Corneal Endothelial Cell Loss Rate No statistically significant differences in corneal endothelial cell loss rate were noted between the two groups before surgery. And no statistically significant differences were noted between the two groups 3, 6 and 12mo after surgery (Table 3).

Intraocular Pressure Mean IOP showed no statistically significant differences between groups before and after surgery (Figure 2).

Surgical Time The mean surgical time in the Artisan group (11.23 ± 1.54) min was significantly shorter than that in the transscleral suturing fixation group (31.68 ± 3.15) min (t = -26.60, P = 0.000).

Complications All eyes achieved the desired anatomic results and no intraoperative complications occurred in any of our cases. Postoperative complications are shown in detail in Table 4.

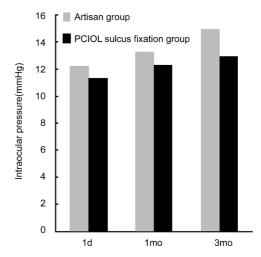


Figure 2 Comparison of mean IOP of the two groups over time.

Table 4 Postoperative complications of 31 aphakic eyes with insufficient capsular support that underwent IOL implantation

Complication	Artisan group	PCIOL sulcus fixation group
Hypotony	2	6
Choroidal detachment	0	2
IOL tilt	0	1
Cystoid macular edema	0	2
IOL dislocation	1	0
Rentinal detachment	0	1
Uveitis	4	0
Pupillary distortion	4	0
Pigmented precipitates	5	0
Iris depigmentation	3	0
Hyphema	0	1
Vitreous haemorrhage	0	1

Artisan Iris-claw Intraocular Lens Implantation Group

No chronic inflammation was seen in any of the eyes in Artisan group. Spontaneous lens dislocation was seen in 1 case 7mo postoperatively, which underwent emergency reposition. No pigment deposition on trabecular meshwork and pigment dispersion glaucoma was found in Artisan group. The mean anterior chamber depth was 2.98 ± 0.14 mm 1d after surgery, 3.05 ± 0.14 mm 3mo postoperatively, 3.04 ± 0.06 mm 6mo postoperatively and 3.00 ± 0.08 mm 1y postoperatively. The anterior chamber depths of all the

patients in Artisan group were >2.6 mm at any time point.

Posterior Chamber Intraocular Lens Sulcus Fixation Group Clinical cystoid macular edema and choroidal detachment faded by conservative management. Retinal detachment was observed in 1 case 3mo postoperatively and was successfully reattached. The preoperative residual capsule range >120 degrees in 6 cases, one of which (16.67%) developed IOL tilt 11mo after surgery. No pupillary distortion was found in any case.

DISCUSSION

At present, PCIOL ciliary sulcus suture fixation is more commonly used in the correction of aphakic eyes without sufficient capsular support after vitrectomy, and some scholars accept it as the mainstream operation method for this kind of patients. However, it has some limitations. The operation procedures rely on the estimation of the relationship between corneal limbus and the adjacent tissue instead of under direct vision, which is blind in some way. The technique requires a longer surgical time and leads to a incidence of intraoperative and postoperative high complications such as lens tilting, decentration, choroidal haemorrhage, retinal detachment (RD), and cystoid macular edema (CME)[9]. Besides, because the anterior chamber and the vitreous cavity are filled with liquid after vitrectomy, the anterior chamber stability is poor, the eyeball is easy to collapse, which increases the operation difficulty and the occurrence of severe complications. Meanwhile, the IOL is prone to tilt without the support of vitreous.

Vote et al [10] and Bading et al [11] 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. In our study, 1 case (7.69%) of RD was found 3 mo postoperatively. Transient hyphema and vitreous haemorrhage was observed in 2 cases (15.38%). No choroidal haemorrhage was found in our study, the reasons might be the combination of pars plana vitrectomy perfusion which effectively maintains the dynamic balance of intraocular pressure. Hypotony was found in 3 cases and subsequent choroidal detachment was seen in 1 case, this presumably occurred due to inevitably intraocular fluid overflow which caused by long-time complicated operation. One case developed IOL tilt 11mo after surgery, we consider the contraction of the residual posterior capsular was the possible cause for the tilt occurred in the late postoperative period

By comparison, Artisan iris-claw IOL implantation has the advantages of simple operation procedure, short surgical time and minor intraocular harassment.

The mean surgical time in the Artisan group was significantly shorter than that in the transscleral suturing fixation group. We believe fewer operation steps are the main cause.

In our study, no statistically significant differences were noted between the two groups in mean IOP and CDVA after surgery except CDVA of Artisan group was significantly better than the ciliary sulcus fixation group 1d after surgery. Artisan IOL implantation in vitrectomized eyes showed good efficacy in visual outcomes. Güell et al [5] reported satisfactory results of Artisan IOL implantations in 16 aphakic patients. After 36mo follow-up, CDVA was 20/40 or better in 31.25% and mean SE was 0.46D.Lorencová et al [7] performed Artisan IOL implantation in 51 aphakic eyes, also showed good visual outcome after 13mo period of follow up. Postoperative high IOP is a commonly seen complication in ACIOL implantation, the main reasons include pupillary block, angle structural damage, inflammatory material blocking angle or incomplete removal of viscoelastic agents. We performed prophylactic peripheral iridectomy in Artisan group, effectively avoided the occurrence of postoperative pupillary block. Because the full-length of Artisan IOL is 8.5mm, which ensures no harassment to the anterior chamber angle, the incidence of postoperative high intraocular pressure is greatly reduced compared to the angle supported ACIOL implantation. No pigment deposition on trabecular meshwork and pigment dispersion glaucoma was found in Artisan group.

Endothelial cell loss occurred predominantly during the first year ^[6]. No statistically significant differences were noted in corneal endothelial cell loss rate between the two groups at any time point 1y after surgery. And corneal endothelial cell loss rate of Artisan group was similar to that of routine cataract operation ^[12]. The anterior chamber depths are more adequate in aphakic cases. In our study, the anterior chamber depths of all the patients in Artisan group were >2.6 mm at any time point. The volume of the later generations of iris-claw-fixated ACIOL in phakic eyes only accounted for about 30% of anterior chamber space, and the minimum distance to the corneal endothelium is greater than 1.5 mm, which can avoid the direct friction with corneal endothelium. Qasem *et al* ^[13] reported that endothelial cell loss rate was negligible 5y after Artisan IOL implantation.

Most complications of Artisan IOL implantation in the present study were mild and transient. At present, no studies have shown iris-claw ACIOL implantation may cause postoperative persistent iris depigmentation, but it was reported the incidence rate of postoperative acute iritis in ACIOL implantation was 3.4% -10.7% [12]. The design of Artisan lens avoids the direct contact with the iris except the clamping positions, which reduces the incidence of iris inflammation after operation. In our study, the postoperative iris injury mainly included early postoperative iritis and mild iris depigmentation, no serious complications such as iris synechiae, iris perforation or necrosis occurs. The

accumulation of pigmented precipitates on IOL's surface is also a reported complication. The cause of these pigmented cell precipitates is unknown, but multiple factors like inflammatory reactions, surgical manipulation of the iris, hypotony have been suggested. Fortunately all of 4 eyes responded well to corticosteroid. Skillful operation and gentle manipulation were important, repeated tensile stimulation of iris should be avoided. Pupillary distortion was seen in 4 cases, the possible reasons include asymmetric clamp or great difference of clamped iris tissue volume. Surgeons should pay attention to make both claws clamp the symmetric position of iris, and the volume of clamped iris tissue should be equal. Spontaneous lens dislocation is an important complication of iris-fixated IOL implantation. We consider the insufficient volume of clamped iris tissue was the possible cause. By adjusting the manipulation procedure and ensuring enough iris tissue clamped, the complication can be avoided. We suggest the volume of clamped iris tissue should be 1.5-2 mm to ensure the IOL fixation and decrease the incidence of lens dislocation. Otherwise, reposition of Artisan IOL is much simpler.

In summary, despite the patients in case of anterior chamber depth less than 3.2 mm or severe iris damages or iris atrophy were not suitable for the implantation of Artisan iris-claw ACIOL. The results suggest that secondary Artisan implantation is an effective and safe procedure and offers favorable visual outcomes and a low incidence of intraoperative and postoperative complications and are easier to remove or replace if necessary^[14]. It can be performed less invasively and in a shorter surgical time period with earlier visual recovery after surgery compared to transscleral suturing fixation of an IOL. This technique is a promising option for the treatment of aphakic eyes without capsular support after vitrectomy. Further studies with a larger number of patients and a longer follow-up observation and comparison between two surgical methods are necessary.

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Conflicts of Interest: Teng H, None; Zhang H, None. REFERENCES

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