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CATARACT

# Visual outcomes and complications following posterior iris-claw aphakic intraocular lens implantation combined with penetrating keratoplasty

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**Abstract**
*Background* To evaluate the indication, visual outcome, and complication rate after implantation of a posterior iris-claw aphakic intraocular lens (IOL) during penetrating keratoplasty.
*Methods* This retrospective study comprised 23 eyes (23 patients) without adequate capsule support undergoing posterior iris-claw aphakic IOL implantation (Verisyse™/Artisan®) during penetrating keratoplasty between 2005 and 2010. Mean follow-up was 18 months (range from 12 to 37 months).
*Results* The IOLs were inserted during an IOL exchange in 17 eyes and as a secondary procedure in six aphakic eyes. Pseudophakic bullous keratopathy with corneal scar after anterior chamber intraocular lens (ACIOL) was the main indication for penetrating keratoplasty in 16 eyes (69.6 %). The final corrected distance visual acuity (CDVA) in logMAR (mean 1.0±0.46) improved significantly ($p<0.05$) compared to the preoperative CDVA (mean 1.8±0.73). Twenty eyes (86.9 %) had a final visual acuity in logMAR better than the pre-operative CDVA. The mean postoperative IOP 16.3 mmHg±4.0 was not significantly ($p>0.05$) higher compared to the preoperative IOP 15.6 mmHg±5.1. Complications included slight temporary pupil ovalization in three eyes (13.0 %) and iris-claw IOL sublocation in three eyes (13.0 %); all IOLs could be easily repositioned. Cystoid macular edema occured in one eye (4.3 %) 8 weeks after primary surgery. All grafts remained clear without any sign of graft rejection.
*Conclusions* Retropupillar iris-claw IOL during penetrating keratoplasty provides good visual outcomes with a favorable complication rate, and can be used for a wide range of indications in eyes without adequate capsule support.

**Keywords** Aphakia · Bullous keratopathy · Penetrating keratoplasty · Iris-claw · Retropupillar · Verisyse · Artisan

## Introduction

In spite of decreased usage of angle-supported anterior chamber intraocular lenses (ACIOLs) and other lens types associated with pseudophakic bullous keratopathy [1], persistent corneal edema remains a significant indication for full-thickness penetrating (PKP), Descemet-stripping automated endothelial (DSAEK), and Descemet membrane endothelial keratoplasty (DMEK) [2, 3]. During keratoplasty, it is generally desirable to leave the eye pseudophakic, given the optical advantages of intraocular lenses (IOLs).

Frequently, the lack of adequate capsular support complicates intraocular lens implantation at the time of penetrating keratoplasty. In these cases, an angle- or iris-supported (e.g. iris-claw) anterior chamber intraocular lens (ACIOL), a trans-sclerally sutured, fibrin glue-assisted sutureless or iris fixated posterior chamber intraocular lens (PCIOL) can be implanted [4, 5]. ACIOLs can be associated with complications including corneal endothelial cell loss, leading to pseudophakic bullous keratopathy, iris sphincter erosion, secondary glaucoma, chronic inflammation, and hyphema [6]. Trans-sclerally fixated IOLs are associated with disadvantages such as difficult suture technique, longer surgical

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time, IOL decentration, hypotony, possible intraoperative bleeding and damage to the ciliary body [7, 8]. The ideal position of the intraocular lens (IOL) remains behind the iris plane [9]. Therefore, retropupillar iris-claw lens implantation seems to be an ideal alternative.

In the present study we describe our experience with the retropupillar Artisan® aphakia iris-claw lens during penetrating keratoplasty.

## Patients and methods

### Subjects

All cases of Artisan®/Verisyse™ PCIOL (Ophtec BV, Groningen, The Netherlands, Advanced Medical Optics, Inc. (AMO), Santa Ana, CA, USA) implantation during penetrating keratoplasty in eyes with aphakic or pseudophakic bullous keratopathy with corneal scar over a 5-year period (December 2005–2010) at Charité University Hospital Berlin were identified from the operating theatre logbook and reviewed. All patients were operated by two experienced surgeons (PR, EB) using the same surgical protocol in all cases. The retrospective study concerned 23 eyes of 23 patients [nine women and 14 men; mean age ± standard deviation (SD), 72.3±9.0; range 54 to 84 years] without adequate capsule support undergoing posterior iris-claw aphakic IOL implantation (Verisyse™/Artisan®) during penetrating keratoplasty. Follow-up ranged from 12 to 37 months, mean 18 months.

The aetiology of bullous keratopathy and IOL dislocation was identified in each case. Pre- and postoperative evaluation included CDVA (corrected distance visual acuity), Goldmann's applanation tonometry, slit-lamp examination, fundus examination, endothelial cell densitiy (ECC), number of topical antiglaucomatous drugs taken and complications. Visual acuity was converted to logMAR values for statistical analysis [10], which was performed using Student's *t*-test.

### Verisyse lens

The Verisyse™/Artisan® aphakia iris-claw lens is a PMMA IOL with an 8.5-mm length, a 1.04-mm maximum height, and a 5.0-mm clear optical zone. In 1971, Worst presented the "Iris-Claw Lens" (a biconvex PMMA IOL fixated above the iridal plane at the mid-periphery of the iris) at a meeting in Paris. In 1986, a modified biconcave phakic version of the Artisan was first implanted by Feschner for refractive surgery purposes. The aphakic model was redesigned in 1996 (convex/concave). The optic power was calculated by using the SRK/T formula. The manufacturer's recommendation for anterior fixation is 115.0. We assumed a surgeon's factor A constant of 117.0 for posterior fixation. IOL calculations were performed for all patients before surgery.

### Surgery

All procedures were performed by two surgeons (PR, EB) using the same surgical protocol in all cases. Details of the surgical technique have been published [4, 9, 11]. Under local (peribulbar) or general anaesthesia, all patients underwent corneal trephination after placing cohesive viscoelastic material in the anterior chamber. After removal of the IOL and synechiolysis of the angle if necessary, the iris-claw IOL was inserted with the open sky technique. Then the PC IOL was rotated with a hook into a horizontal position from 3 to 9 o'clock and centered behind the pupil using the Purkinje images in the reversed position. Acetylcholine chloride 1 % (Miochol) was injected following IOL insertion behind the pupillary plane. Enclavation of the iris into the IOL claw was performed using an enclavation needle. Peripheral slit iridectomy was not performed at all. The typically 0.25–0.5 mm oversized corneal donor tissue was then sutured to the host bed with double running sutures (Nylon 10–0, Nylon 11–0) and all viscoelastic material was removed. Gentamicin and prednisolone acetate 1 % drops were prescribed after surgery and slowly reduced over time. All patients received topical steroids 5 times daily after the surgery for prophylaxis of graft rejection and/or macular edema. Prednisolone acetate drops were tapered one drop per month, and continued once daily after. No systemic immunosuppressive agents have been used at all.

In all cases, anterior open-sky vitrectomy was performed, except for cases with a history of anterior or pars plana vitrectomy.

## Results

The IOLs were inserted during an IOL exchange in 17 eyes (73.9 %) and as a secondary procedure in six aphakic eyes (26.1 %) during penetrating keratoplasty (PKP). Pseudophakic bullous keratopathy (PBK) with corneal scar after anterior chamber intraocular lens (ACIOL) was the main indication for penetrating keratoplasty in 16 eyes (69.6 %).

Penetrating keratoplasty was combined with IOL exchange in 14 eyes with PBK and subluxated ACIOLs (82.3 %), in two eyes with bullous keratopathy (Fuchs' endothelial dystrophy) and subluxated PCIOLs due to pseudoexfoliation syndrome (11.8 %) and in one eye with subluxated PCIOL and bullous keratopathy after multiple glaucoma surgeries due to congenital glaucoma (5.9 %).

Penetrating keratoplasty was combined with retropupillar iris-claw IOL implantation as a secondary procedure in three aphakic eyes after trauma (50 %), in two aphakic eyes with PBK after ACIOL explantation (33.3 %) and in one aphakic eye with culture confirmed Acanthamoeba keratitis (16.7 %).

The postoperative corrected distance visual acuity (CDVA) in logMAR (mean 1.0±0.46) of all eyes at last follow-up improved significantly ($p<0.05$) compared to the preoperative CDVA (mean 1.8±0.73) 1 day before surgery (Fig. 1). Fifteen eyes (65.2 %) even gained more than 2 lines after surgery. Only three eyes (13.1 %) achieved a final visual acuity equal to that measured pre-operatively. No loss in visual acuity was recorded despite 13 patients suffering from glaucoma preoperatively. The mean postoperative IOP 16.3 mmHg±4.0 did not significantly ($p>0.05$) change compared to the preoperative IOP 15.6 mmHg±5.1 in all patients. In addition, the mean postoperative IOP (16.0 mmHg±3.9) of 13 patients suffering from glaucoma preoperatively did not change significantly ($p>0.05$) change compared to the preoperative IOP (16.8 mmHg ±5.8). No worsening of glaucoma was observed and the amount of antiglaucomatous eye drops taken did not significantly change (preoperative: mean 2.0±1.01 drugs, postoperative: mean 1.96±0.98 drugs). The mean endothelial cell densitiy (ECD) at last follow-up (mean 18 months) was 1319±211 cells/mm$^2$ (Fig. 2). The mean preoperative ECD was 2325±240 cells/mm$^2$.

All eyes achieved the desired anatomic results. No intraoperative complications were observed. Postoperative complications are listed in Table 1. In the early postoperative period (<1 week), three eyes (13.0 %) developed slight temporary pupil ovalization, which tended to normalize over time. Three eyes (13.0 %) showed a partial dislocation of one haptic of the Artisan®/Verisyse™ PCIOL due to loosening of the enclavation in median 2 weeks postoperatively; all IOLs could be easily repositioned by re-enclavation of the loosened haptic. Cystoid macular edema (CME) occured in one eye (4.3 %) 8 weeks after primary surgery. CME was detected clinically by funduscopy and verified by spectral domain optical coherence tomography (SD-OCT). CME was successfully treated with systemic carbonic anhydrase inhibitors (acetazolamide) and topical non-steroidal anti-inflammatory eye drops (ketorolac). All grafts remained clear without any sign of graft rejection.

## Discussion

Pseudophakic bullous keratopathy (PBK) secondary to an anterior chamber lens (ACIOL) is still an indication for full-thickness penetrating keratoplasty (PKP) in the case of a dense corneal scar, and represents a surgical challenge involving a triple procedure: PKP, IOL explantation, and secondary IOL implantation. At present, DSAEK and DMEK are the

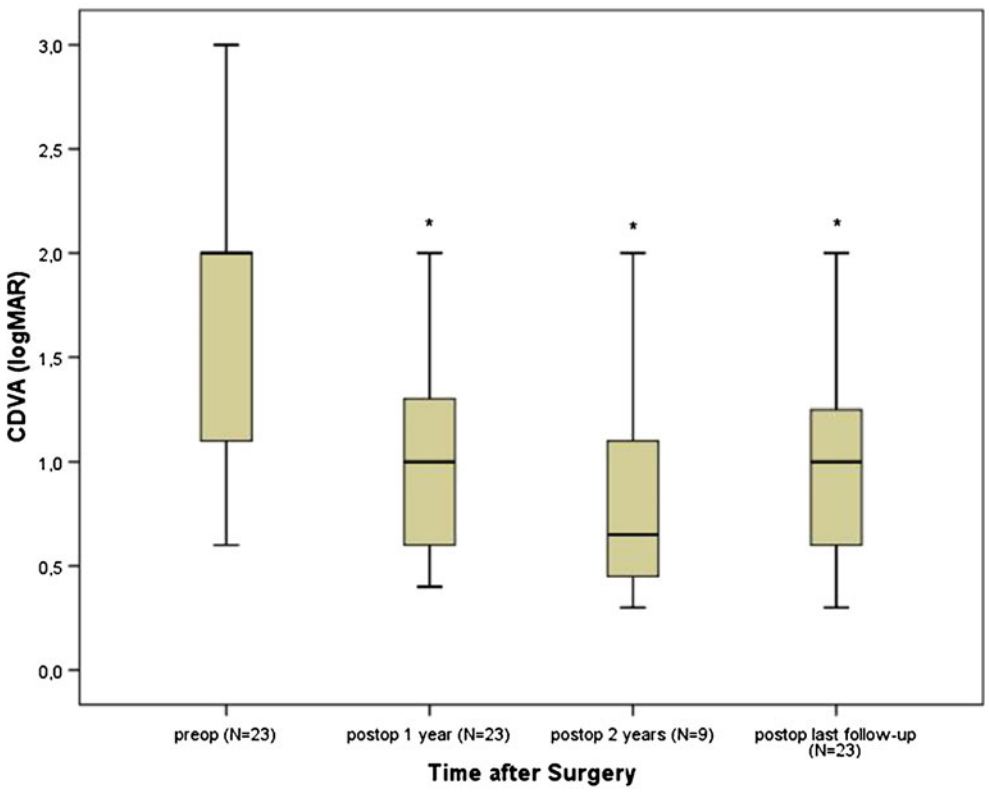


**Fig. 1** CDVA (corrected distance visual acuity) in logMAR, * $p<0.05$ (pre- to postoperative)

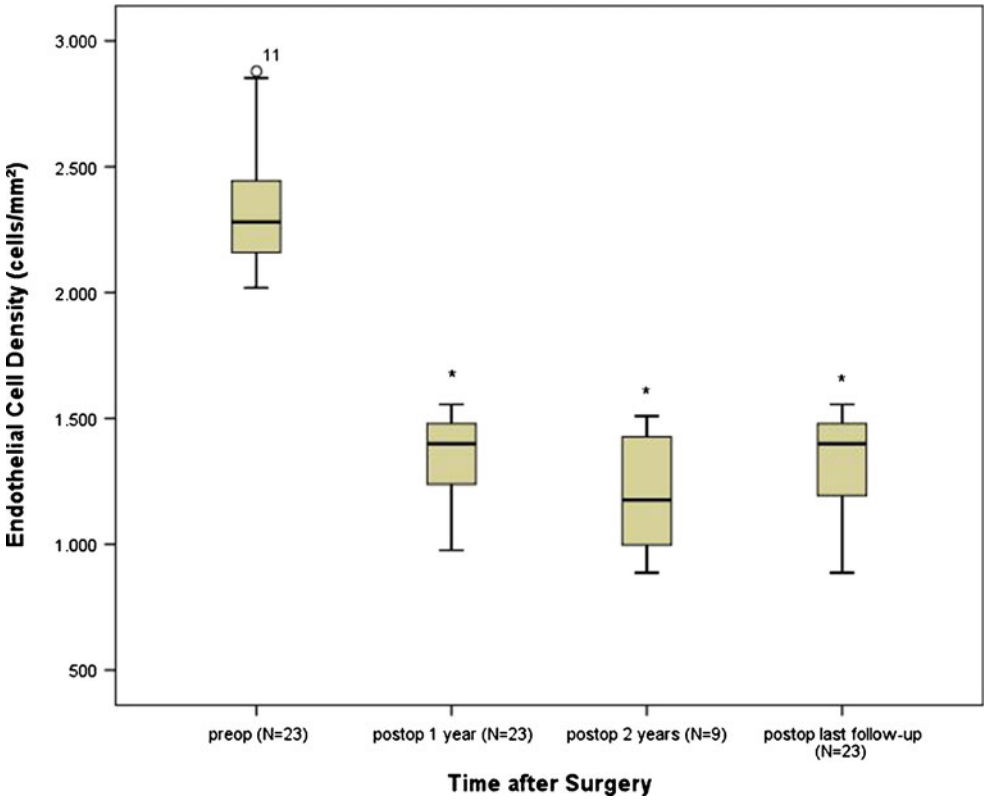


**Fig. 2** ECD (endothelial cell density, cells/mm$^2$), * $p<0.05$ (pre- to postoperative)

procedure of choice to manage endothelial diseases such as Fuchs endothelial dystrophy, PBK, and endothelial graft failure. The advantages of DSAEK/DMEK over PKP include lack of induced astigmatism, increased wound stability, and faster visual recovery [12]. However, in the presence of a dense corneal scar, PKP is the only surgical option because the visual axis clarity is inadequate for DSAEK/DMEK.

The most appropriate method of secondary intraocular lens implantation (or exchange) at the time of penetrating keratoplasty (PKP) in the absence of capsular support is not known. The safety and long-term efficacy of a transsclerally sutured PCIOL are less than satisfactory [13–15]. The transsclerally sutured IOL is associated with a steep learning curve, and requires special steps that an anterior segment surgeon may not use routinely. In a previous study [15], ultrasound biomicroscopy showed that transscleral suturing of an IOL was associated with problems relating to accurate suturing at the ciliary sulcus. In addition, there are issues with IOL iris contact, pigment dispersion, high aqueous flare, cystoid macular edema, difficult suture technique, longer surgical time, IOL decentration, hypotony, possible intraoperative bleeding and damage to the ciliary body, vitreous incarceration, and up to 20 % of IOL dislocation [7, 8, 16].

**Table 1** Complications

| Type of complication | Eyes (*n*) | Percentage of total |
|---|---|---|
| Pupil ovalization | 3 | 13.0 % |
| IOL dislocation | 3 | 13.0 % |
| Macular edema | 1 | 4.3 % |

The first study of anterior fixation of an iris-claw IOL in aphakia in combination with penetrating keratoplasty was published by Rijneveld et al. in 1994 with 19 eyes [17]. Visual acuity improved in 83 % of their patients. Complications such as pigment dispersion, glaucoma, peripheral synechiae, and lens decentration were rare. Although the difference between anterior and posterior fixation was not statistically significant, the authors prefered the anterior fixation technique.

Mohr et al. published the first study on retropupillary iris-claw IOL fixation in 48 aphakic patients [4]. No major complications were observed and the new retropupillary technique was shown to be superior (simplicity, reliability, and best anatomical results) to other techniques.

Kanellopoulos studied Artisan® anterior iris-fixated IOL implantation associated with PKP for managing aphakic keratopathy in 11 patients [18]. Kanellopulos and in 2006 Dighiero et al. stated that the retropupillar fixation technique would better preserve the anatomy of the anterior segment. This would explain the lower complication rate of endothelial cell loss and lower incidence of macular edema [19].

Gicquel et al. analyzed anterior (13 eyes) or posterior (14 eyes) iris fixation of Artisan®/Verisyse™ for the treatment of pseudophakic bullous keratopathy (PBK) using ultrasound biomicroscopy [9]. Anterior IOL fixation led to more

major complications including iridal synechias, endothelium–IOL contact, higher endothelial cell loss, and iridocorneal angle closure.

Another new surgical technique for managing bullous keratopathy secondary to anterior chamber intraocular lens (ACIOL) comprises femtosecond laser-assisted penetrating keratoplasty and ACIOL exchange with fibrin glue-assisted sutureless posterior chamber intraocular lens (PCIOL) implantation ("glued IOL") [20]. However this technique has only been published in a small case series of three patients.

To our knowledge this is the largest case series of Artisan®/Verisyse™ retropupillar iris-fixated IOL combined with PKP. In our study we found a significant improvement ($p<0.05$) of the postoperative corrected distance visual acuity (CDVA) in logMAR (mean 1.0±0.46) of all eyes compared to the preoperative CDVA (mean 1.8±0.73). Visual acuity improved in 86.9 %, which is similar to previous studies [17, 19]. Even 65.2 % gained more than 2 lines after surgery. Only 13.1 % eyes achieved a final visual acuity equal to that measured pre-operatively. No loss in visual acuity was recorded despite though 13 patients suffering from glaucoma preoperatively. But the rather low postoperative visual acuity in general could be explained by optic nerve atrophy. The mean postoperative IOP (16.0 mmHg± 3.9) of 13 patients suffering from glaucoma preoperatively did not change significantly ($p>0.05$) change compared to the preoperative IOP (16.8 mmHg±5.8). No worsening of glaucoma was observed.

The Artisan® Aphakia iris-claw IOL has a substantially different lens design than previous generations of iris-fixated IOLs, which also were associated with complications [21]. The Artisan lenses are anchored to the midperiphery of the iris. They have a vaulted design. This provides optimal clearance between iris and IOL. Except at the fixation points under the iris, they are slightly raised below the iris plane, which prevents them from interfering with the normal physiologic features of the iris [9]. We did not expect to see secondary pupillary blocked glaucoma. Therefore, we did not have a preference for peripheral iridectomy.

The mean endothelial cell density at last follow-up (mean 18 months) was 1,319±211 cells/mm$^2$. This is comparable to previous studies with lower patient numbers using posterior Artisan® Aphakia iris-claw IOL combined with PKP. Gicquel et al. showed 1 year after combined Artisan Aphakia Iris-claw IOL a significant lower endothelial cell count in 13 eyes with anterior iris-claw IOL (ECC=mean 1,185±222 cells/mm$^2$), compared to 14 eyes with posterior fixated iris-claw IOL (ECC=mean 1,426±215 cells/mm$^2$) [9]. Dighiero et al. obtained an endothelial cell count in mean 1,487 cells/mm$^2$ 6 months after surgery [19].

All eyes achieved the desired anatomic results. In the early postoperative period (< 1 week) three eyes (13.0 %) developed slight temporary pupil ovalization, which tended to normalize over time. Pupil ovalization can occur if the fixation of the haptics is performed asymmetrically or to tight. This is not a common complication, although it has already been reported after iris-claw IOL implantation [21, 22], and is an acceptable complication considering the severity of the initial disease [17]. Three eyes (13.0 %) showed a postoperative partial dislocation of one haptic of the Artisan PCIOL due to loosening of the enclavation in mean 2 weeks (range 1–2 weeks) after surgery. This rare complication had been reported [23]. Haptic repositioning is easily achieved through small incisions using local anesthesia. Posterior fixation has the advantage over anterior fixation, because if one haptic becomes disenclavated (bilateral disenclavation has not been reported yet), no contact with the endothelium is possible. Cystoid macular edema occured in one eye (4.3 %) 8 weeks after primary surgery. This rate is lower than the 14 % and 10 % rates reported in the largest series on ACIOLs [24] and scleral-fixated PCIOLs [16] implanted during PKP.

In our study, all grafts remained clear, without any sign of endothelial decompensation or graft rejection. All complications associated with the retropupillary fixation technique seem acceptable considering the severity of the initial disease. However, limitations of our retrospective, non-comparitive cohort study are the rather short follow-up. Moreover, determination of small differences in visual outcome or complication rates when compared to other existing techniques will require a large prospective randomized clinical trial. Although there is still no consensus on the best IOL to implant in the absence of capsule support, we believe retropupillar iris-claw IOL implantation is an effective, well-evaluated and interesting option during PKP.

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**Conflict of interest** None to declare.

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