Iris-claw intraocular lenses to correct aphakia in the absence of capsule support

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PURPOSE: To evaluate the indications, postoperative visual efficacy, and complication rate after intraocular implantation of an iris-claw aphakic intraocular lens (IOL).

SETTING: Oxford Eye Hospital, Oxford, United Kingdom.

DESIGN: Case series.

METHODS: This chart review comprised eyes with no capsule support that had anterior iris-fixation IOL implantation for aphakia between 2001 and 2009.

RESULTS: The study comprised 116 eyes (104 patients). Iris-claw IOLs were inserted during primary lens surgery in 18 eyes (15.5%), during an IOL exchange procedure for dislocated posterior chamber IOLs in 19 eyes (16.4%), and as a secondary procedure in 79 eyes (68.1%). The mean follow-up was 22.4 months (range 3 to 79 months). The final corrected distance visual acuity (CDVA) was 6/12 or better in 68.9% of all eyes and in 47 of 53 eyes (88.7%) with no preoperative comorbidity. Complications included wound leak requiring resuturing in 2.6% of eyes, postoperative intraocular pressure rise in 9.5% of eyes (glaucoma escalation 0.8%), and cystoid macular edema in 7.7% of eyes (0.8% chronic). Iris-claw IOL subluxation occurred in 6.0% of eyes from 5 days to 60 months postoperatively; all the IOLs were repositioned. Corneal decompensation occurred in 1.7% of eyes; 0.8% had retinal detachments.

CONCLUSIONS: Iris-claw IOL implantation for aphakia gave a good visual outcome and can be used for a wide range of indications. Postoperative complication rates were comparable to, if not better than, those with conventional anterior chamber IOLs. Correct implantation technique is critical in avoiding postoperative IOL subluxation.

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With the development of modern cataract surgery and the excellent visual outcomes obtained with posterior chamber intraocular lenses (PC IOLs), the problem of aphakia correction is less commonly encountered.[1] However, complicated cataract surgery, trauma, and crystalline lens dislocation, such as in cases of Marfan syndrome, may leave inadequate capsule support for IOL implantation in the bag or ciliary sulcus. Correction of aphakia in the absence of capsule support can be achieved by several methods of IOL implantation, such as those using open-loop anterior chamber IOLs (AC IOLs), transsclerally sutured PC IOLs, iris-sutured PC IOLs, or iris-fixated AC IOLs.

The first iris-claw IOL was introduced by Worst et al. in 1972,[2] and a modification of this became the Artisan lens (Ophtec BV). This IOL design incorporates a claw that is fixed to the immobile mid-peripheral portion of the iris; thus, it was suggested that the IOL did not disrupt the normal physiology of the iris or angle structures. The bridging arc of the IOL was also said to eliminate erosion of the pupil border, which occurs with traditional pupil-supported IOLs.[3] It was suggested that the initial biconvex model increased the risk for pseudophakic bullous keratopathy (PBK). A modified convex–concave version was introduced in 1996 to increase the distance between the IOL and the corneal endothelium; this model has since been in common use. Subsequently, in 2005, the Verisyse iris-claw IOL (Abbott Medical Optics, Inc.) became available.

The published literature on iris-claw IOLs in aphakia is limited to a few case series, most of which

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include relatively small numbers of patients.[4–8] In this retrospective study, we evaluated the indications, visual outcomes, and safety of iris-claw IOL implantation for aphakia. We believe that our series of 116 eyes is the largest reported series examining iris-claw IOL use for the treatment of aphakia.

PATIENTS AND METHODS

This retrospective case series comprised patients who had implantation of an Artisan or Verisyse iris-claw IOL at Oxford Eye Hospital from 2001 to 2009 because of a lack of posterior capsule support. Data were obtained from case-note review, and only patients who had at least 3 months of follow-up at Oxford Eye Hospital were included. All patients were fully informed of the risks and benefits of surgery, and written consent was obtained from them in accordance with good medical practice.

Preoperative information recorded included demographic data, Snellen visual acuity, intraocular pressure (IOP), preexisting pathology, and cause of the lack of capsule support. Intraoperative and postoperative information obtained included final corrected vision, postoperative IOP, and incidence of complications. Final visual acuity was taken as that at discharge or at the most recent clinic appointment. The postoperative refractive outcome was analyzed after the individual spherocylinders of refraction in each eye were converted into power vectors.[9]

Surgical Technique

Surgeries were performed by consultants, fellows, and experienced residents. Anesthesia was general, sub-Tenon, or topical depending on the patient's needs and the surgeon's preference. The A constant used was 115.0. A superior 5.5 mm clear corneal incision was made with paracenteses at 10 o'clock and 2 o'clock. Sodium hyaluronate 1.0% (Healon) was instilled through the primary incision to maintain sufficient anterior chamber depth (ACD) for endothelial protection and to facilitate lens manipulation. The IOL was inserted vertically and rotated into a horizontal position. The IOL was held with a pair of curved Clayman forceps (Micra Instruments), which has an elongated inferior leg to provide maximum IOL stability. Enclavation of the iris into the IOL claw was performed using an Artisan enclavation needle (Ophtec BV). An adequate iridectomy or iridotomy was performed (if not already present) to avoid postoperative pupil block, and 10-0 nylon sutures were used to close the wound. All ophthalmic viscosurgical device material anterior to the IOL was removed after completion of the procedure.

At the end of surgery, 2 mg betamethasone and 20 mg gentamicin were injected subconjunctivally or 1 mg cefuroxime was injected intracamerally. Topical dexamethasone 0.1% and chloramphenicol were applied every 6 hours for 3 weeks.

Anterior vitrectomy was performed before IOL insertion if required. Penetrating keratoplasty (PKP) was performed in conjunction with IOL insertion in some cases.

RESULTS

The study comprised 116 eyes (104 patients), 63 of which had implantation of an Artisan iris-claw IOL and 53 of which had implantation of a Verisyse iris-claw IOL. In 5 eyes, PKP was performed in conjunction with Artisan IOL implantation. The mean age of the patients at surgery was 61.2 years (range 21 to 97 years). The mean follow-up was 22.4 months ± 18.0 (SD) (range 3 to 79 months).

Indications for Iris-Claw Intraocular Lens

Table 1 shows the indications for iris-claw IOL implantation. The IOLs were inserted during primary lens surgery in 18 eyes (15.5%), during an IOL exchange procedure for dislocated PC IOLs in 19 eyes (16.4%), and as a secondary procedure in 79 eyes (68.1%).

Visual Acuity

The median final corrected distance visual acuity (CDVA) (Snellen) was 6/9 (Figure 1). Eighty eyes (68.9%) had a final CDVA of 6/12 or better.

Table 2 shows the ocular pathology present before iris-claw IOL insertion that might have limited the final vision; a significant number of eyes had such pathology. Thus, the results in eyes with no previous comorbidity that might limit final vision were evaluated. In this group of 53 eyes, the median final CDVA was 6/7.4 (Figure 2). Forty-seven eyes (88.7%) in this group achieved a final CDVA of 6/12 or better, with 20 eyes (37.7%) achieving a final CDVA of 6/6 or better.

The refractive outcome was available for 35 of the 53 eyes with no comorbidity that might limit final visual acuity. The goal of refraction was emmetropia or slight myopia. The mean final postoperative spherical equivalent refraction was +0.12 ± 1.76 diopters (D) (range −2.00 to +1.62 D).

Evaluation of the constituent components of refraction using power vector analysis showed a mean sphere of −0.17 ± 0.61 D and a mean cylinder of +0.58 ± 2.29 D at mean axis of 97.1 ± 22.5 degrees. This is consistent with the relatively large superior

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Table 1. Indications for iris-claw IOL implantation.

Indication	Eyes (n)
During primary lens surgery	
Marfan syndrome/ectopia lentis	11
Preop zonular dehiscence/trauma	4
Zonular dehiscence during surgery	3
Posterior chamber IOL dislocation	
Comorbidity	
Pseudoexfoliation syndrome	1
Previous vitrectomy	7
Previous trabeculectomy	1
Congenital cataract surgery with secondary PC IOL	1
Zonular dehiscence during phacoemulsification	1
None noted	8
Secondary insertion for aphakia	
Complicated cataract surgery	31
Lensectomy for congenital cataracts/ICCE	16
Previous trauma	13
Retinal detachment repair with silicone oil tamponade	14
Lensectomy for subluxated lenses (Marfan)	3
Vitrectomy for proliferative diabetic retinopathy	1
IOL explantation for endophthalmitis	1

ICCE = intracapsular cataract extraction; IOL = intraocular lens; PC = posterior chamber

Table 2. Ocular pathology present before iris-claw IOL insertion that might limit potential vision.

Comorbidity	Eyes (n)*
Previous RD surgery	17
Glaucoma	17
Previous trauma	14
Retinal vascular disease	3
AMD	9
Optic nerve disease	2
Amblyopia	2
Corneal decompensation	5
CME	2
Endophthalmitis	1
Previous macular hole surgery	1

AMD = age-related macular degeneration; CME = cystoid macular edema; RD = retinal detachment
*Some eyes had multiple pathologies

corneal incisions made for iris-claw IOL insertion and that many eyes also had corneal incisions during previous surgery. However, because reliable refractions were available for 35 eyes only, no definitive comment on the refractive outcome can be made.

Not all aphakic patients had a preoperative refraction recorded; thus, it was difficult to accurately evaluate preoperative to postoperative improvement in visual acuity.

Complications

Table 3 shows the postoperative complications. The most frequent complication was elevated IOP, which included immediate postoperative to chronic elevation. In the majority of eyes, the IOP was well controlled with topical medication. One eye with IOP elevation showed progression of glaucoma. This patient had a complex ocular history with previous failed trabeculectomy in that eye and subsequently required Molteno tube insertion. Of the eyes with cystoid macular edema (CME), 1 had chronic CME (0.8%) that did not respond to treatment; this eye had CME preoperatively.

DISCUSSION

There is as yet no established consensus on the best treatment of aphakia in the absence of capsule support. Options include open-loop angle-supported AC IOLs, sulcus-sutured PC IOLs, iris-sutured PC IOLs, and iris-fixated AC IOLs.[10] In this series, we reviewed the use of iris-claw IOLs for the treatment of aphakia in the absence of capsule support for a wide range of indications; the majority of cases were secondary IOL insertion.

Sixty-eight percent of all eyes in our series achieved a final CDVA of 6/12 or better, and 88.7% of eyes with no other pathology limiting vision achieved this level. This is comparable to results in a previous

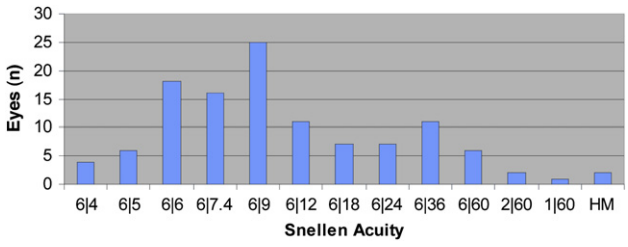

Figure 1. Final Snellen CDVA (116 eyes) (HM = hand motions).

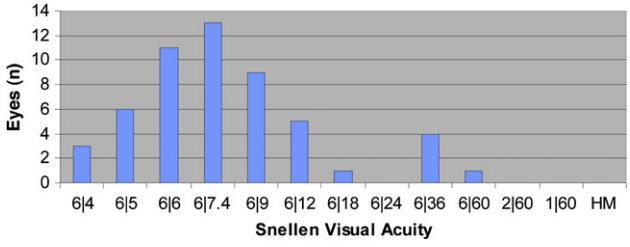

Figure 2. Final Snellen CDVA in eyes with no preoperative ocular comorbidity (53 eyes) (HM = hand motions).

Table 3. Postoperative complications.

Complication	Eyes, n (%)	Comments/Management (Number of Eyes)
Early		
Wound leak	7 (6.0)	Conservative treatment (4); resuturing (3)
Iris prolapse	1 (0.8)	Wound resutured
Vitreous band to wound	2 (1.7)	Nd:YAG vitreolysis (1); anterior vitrectomy (1)
Hyphema (from PI)	2 (1.7)	Observation
Vitreous hemorrhage (from PI)	3 (2.6)	Observation
Iris-claw IOL dislocation	2 (1.7)	At 5 d (1), at 14 d (1); both repositioned
Intermediate		
Elevated IOP	11 (9.5)	Steroid response (3); pupil block due to nonpatent iridectomy, required Nd:YAG PI (1); topical medication (6); required Molteno tube (1)
Cystoid macular edema	9 (7.7)	Topical treatment (5); sub-Tenons triamcinolone (1); intravitreal triamcinolone (1); preop CME, 3× sub-Tenons triamcinolone, failure to resolve (1)
Retinal tear	1 (0.8)	Marfan syndrome, pneumatic retinopexy
Retinal detachment	1 (0.8)	Vitrectomy
Astigmatism requiring surgery	3 (2.6)	LRIs (2); LASIK (1)
Iris-claw IOL dislocation	1 (0.8)	Repositioned at 3 mo
Late		
Raised IOP	1 (0.8)	Noted at 34 mo, topical treatment
Corneal decompensation	2 (1.7)	At 26 mo (1), at 56 mo (1); conservative treatment, poor visual prognosis (both eyes)
Epiretinal membrane	1 (0.8)	Conservative treatment
Iris-claw IOL dislocation	4 (3.4)	From 7 to 60 mo; all repositioned

CME = cystoid macular edema; IOL = intraocular lens; IOP = intraocular pressure; LASIK = laser in situ keratomileusis; LRIs = limbal relaxing incisions; Nd:YAG = neodymium:YAG laser; PI = peripheral iridotomy; PKP = penetrating keratoplasty

study of iris-claw IOLs[4] and in studies using secondary open-loop AC IOLs (60% to 77% eyes with a CDVA of 20/40 or better[11,12]), secondary sulcus-sutured PC IOLs (53.8% to 77.8%[13,14]), or secondary iris-sutured PC IOLs (60% to 67%[15,16]). However, when reviewing the literature, it is often difficult to accurately assess the visual outcomes with each of these IOL types because the eyes in which they are implanted often had complicated cataract surgery, which may itself limit final visual acuity or cause complications.

The most common complications in our series were wound leak (total 6%; requiring resuturing 2.6%), iris-claw IOL dislocation (total 6%), elevated IOP (total 9.5%, glaucoma escalation 0.8%), and CME (total 7.7%, chronic CME 0.8%). The incidence of wound leak is not unexpected in this population; many had multiple previous surgeries, and the 5.5 mm incision for iris-claw IOL insertion is often made through previously incised cornea. The 3 cases of wound leak that required resuturing were relatively early in our case series and highlight the need to take extra care when closing the corneal incision in this potentially friable tissue. In view of this, corneal sutures were left in situ for approximately 3 months (mean 13.1 weeks) before their removal to ensure adequate corneal healing.

Most alternative methods of IOL insertion in the absence of capsule support require a corneal incision similar in size to that required for iris-claw IOLs. An exception is the comparatively new method of glued PC IOLs,[17] in which a foldable IOL can be used. However, this technique is not in common use at present.

Iris-claw IOL dislocation (total incidence 6%) occurred from 5 days to 60 months after insertion. The 2 cases of early decentration were likely related to insertion technique. Of those with late dislocation, 1 was traumatic and the others occurred spontaneously. All dislocated IOLs were repositioned. Iris-claw IOL dislocation tended to occur in IOLs inserted earlier in the series rather than in later cases, suggesting a learning curve.

With respect to elevated IOP, the incidence of glaucoma escalation in our series was comparable to that with secondary AC IOL insertion (0% to 7%[12,18]) and better than that with secondary sulcus-sutured PC IOL insertion (0% to 30.7%[8,13]) and secondary iris-sutured PC IOL insertion (5% to 30%[15]). Iris-claw IOLs may be particularly useful in eyes with a compromised angle, in which an AC IOL may not be suitable. The design of the iris-claw IOL ensures that it is fixed to the midperipheral iris, and results in a recent study using anterior segment optical

coherence tomography[6] indicate a consistent central and peripheral ACD.

Regarding CME, the literature reports a wide variation in the incidence of CME with other secondary IOLs. With the use of secondary open-loop AC IOLs, the CME rate varied from 0% to 33%, with higher incidences in series examining secondary AC IOL insertion after complicated cataract surgery than in those after uncomplicated intracapsular cataract extraction.[12,19] The incidence of CME after sulcus-sutured PC IOLs was 0% to 7.6%[8,13] and after iris-sutured PC IOLs, 0% to 16.7%.[16] Thus, the total rate of 7.7% in our series, with a chronic CME incidence of 0.8%, is comparable, if not better than, the figures for other IOLs.

A common concern with the use of angle-supported AC IOLs is the development of PBK (incidence reported from 0% to 14%[11,18] and from 0% to 18%[20,21] in the presence of PKP). In our series, only 2 eyes (1.7%) developed corneal decompensation over 3- to 79-month follow-up (mean 22.4 months). One eye had PKP at the time of iris-claw IOL insertion. However, a limitation of our study is that corneal endothelial cell counts (ECCs) were not measured in all patients preoperatively and sequentially after surgery. Patients with iris-claw IOL insertion in our unit now have an annual ECC. Of the 6 most recent cases in the series reported in this paper, the mean ECC was 2189 cells/mm^2 a mean of 9.7 months postoperatively. Others[7] report a 7.78% cell loss within the first year postoperatively and 10.9% over the first 36 months, suggesting that most endothelial cell damage occurs intraoperatively. Another study[8] found no significant endothelial cell loss over a 22-month follow-up.

A recent study of 39 eyes with Artisan IOL implantation for aphakia[4] reports no cases of hyphema, postoperative glaucoma, CME, or corneal decompensation over a mean follow-up of 17.3 months, with all cases performed by the same surgeon. Our series includes the first cases of iris-claw IOL insertion for aphakia at our center, and surgery was performed by consultants, fellows, and experienced residents. Thus, the complications in our series likely reflect the learning curve associated with iris-claw IOL insertion, although it is important to be aware of these rates.

To our knowledge, this is the largest reported series of iris-claw IOL insertion for aphakia for a wide range of primary and secondary indications for insertion. We report visual outcomes and complications that are comparable to, if not better than, alternative IOL types. We found a small learning curve in terms of correct method of insertion and careful suturing of the wound to prevent early IOL dislocation and wound leaks. Although there is still no consensus on the best IOL to implant in the absence of capsule support, we believe iris-claw IOL implantation is a safe and efficacious option.

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