

**SAFETY AND VISUAL OUTCOMES OF NOVEL ABEXTERNO AKREOS® SINGLE PASS METHOD OF
TRANSSCLERAL SUTURED POSTERIOR CHAMBER IOL IMPLANTATION
FOR SCLERAL FIXATION OF IOL**

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Abstract

We present the safety and efficacy of a novel transscleral sutured posterior chamber intraocular lens (TSSPCIOL) implantation approach utilizing 25 gauge vitrectomy and a foldable posterior chamber intraocular lens implant (AKREOS AO60, Bausch & Lomb). 80 consecutive eyes that underwent single surgeon TSSPCIOL implantation between October 2008 and July 2012 at a referral-based retina institution were analyzed for best spectacle-corrected visual acuity (BCVA) and safety indicators. Postoperative complications included retinal detachment in 2 eyes (2.5%), Irvine-Gass cystoid macular edema in 3 eyes (3.75%), with 2 of those cases occurring late, persistent postoperative corneal edema in 1 eye (1.25%), hyphema in 2 eyes (2.5%) and 1 case of postoperative vitreous hemorrhage with spontaneous clearing. The modified external approach with AKREOS® TSSPCIOL placement with 25 gauge vitrectomy has relatively few complications, improves visual acuity in patients requiring TSSPCIOL, and offers several advantages over traditional anterior chamber or conventional scleral sutured techniques.

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Introduction

Surgical management of intraocular lens implantation in the absence of capsular support is challenging and associated with operative and postoperative complications.

A number of surgical options exist for optical rehabilitation in the presence of inadequate posterior capsular support. Anterior Chamber Intraocular Lenses, while easily placed, are inherently associated with optical aberrations including aniseikonia, magnification, lens-edge glare, increased rates of pseudophakic bullous keratopathy, restricted pupil movement, intraocular inflammation, and glaucoma¹⁻⁴. Their use is undesirable in cases of preexisting uveitis, corneal decompensation, or glaucoma, and their placement may not be possible in cases of insufficient iris.

Iris-sutured PCIOL have reduced operating times³ over trans-scleral techniques, but are associated with iris atrophy, pigment dispersion, uveitis, cystoid macular edema, and limited pupillary mobility^{3,5} and likewise cannot be performed in the presence of significant iris defects.

When placed properly, TSSPCIOL avoids contact with the iris avoiding risks of pigment dispersion, endothelial dystrophy, aniridia, iris defects, and glaucoma associated with ACIOLs¹. However, TSSPCIOL has been associated with increased surgical time given the greater technical complexity, and may carry the risk of complications such as suprachoroidal hemorrhage and retinal detachment. Suture erosion or lysis continues to be a serious long-term risk in these patients¹.

We describe a novel approach utilizing a foldable posterior chamber intraocular lens (PCIOL) implant (AKREOS® AO60, Bausch & Lomb) with stable four-point trans-scleral fixation. This has achieved a reliable and reproducible operation with improved anatomic and visual outcomes, reduced complications and decreased surgical times.

Patients and Methods

A retrospective review of 80 consecutive patients who had undergone single surgeon TSSPCIOL implantation (DAA) between October 2008 and July 2012 at a referral-based retina institution was conducted.

Medical charts were reviewed for patient demographics, baseline preoperative best spectacle-corrected visual acuity (BCVA), postoperative best spectacle-corrected visual acuity, date of and indication for surgery, surgical technique, operative time, intraoperative or postoperative complications, any subsequent surgical procedures required, and date of last follow-up.

Indications for surgery were all attributed to aphakia due to complex retinal detachment repair, complex cataract surgery, complex IOL exchange, or trauma; retained lens/lens fragment due to complex cataract surgery; dislocated/subluxated crystalline lens due to trauma or Marfan syndrome; dislocated/subluxated PC IOL due to complex retinal detachment repair (**figure 1**), complex cataract surgery, complex IOL exchange, trauma, pseudoexfoliation (**figure 2**), Axenfeld syndrome, or other causes; exchange of ACIOL due to UGH syndrome (**figure 3**); and traumatic cataract (**table 1**).

The rate of our intraoperative and postoperative complications was compared to studies that have analyzed TSSPCIOL and iris-sutured PCIOL.

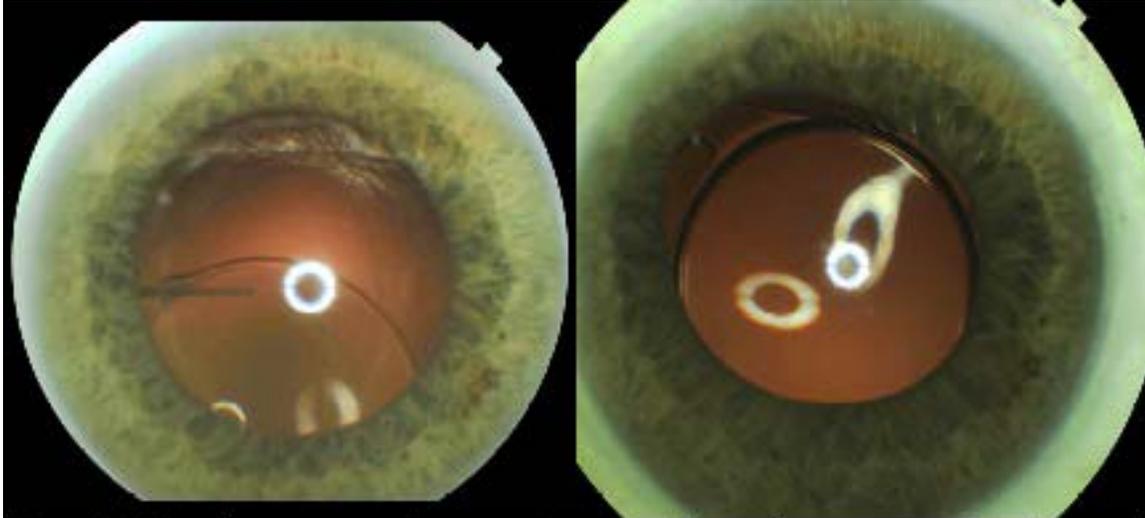


Figure 1. Anterior segment photograph, pre- and 1 week post trans scleral sutured posterior chamber intraocular lens with AKREOS® A060 in a patient presenting with dislocated posterior chamber intraocular lens due to complex retinal detachment repair.

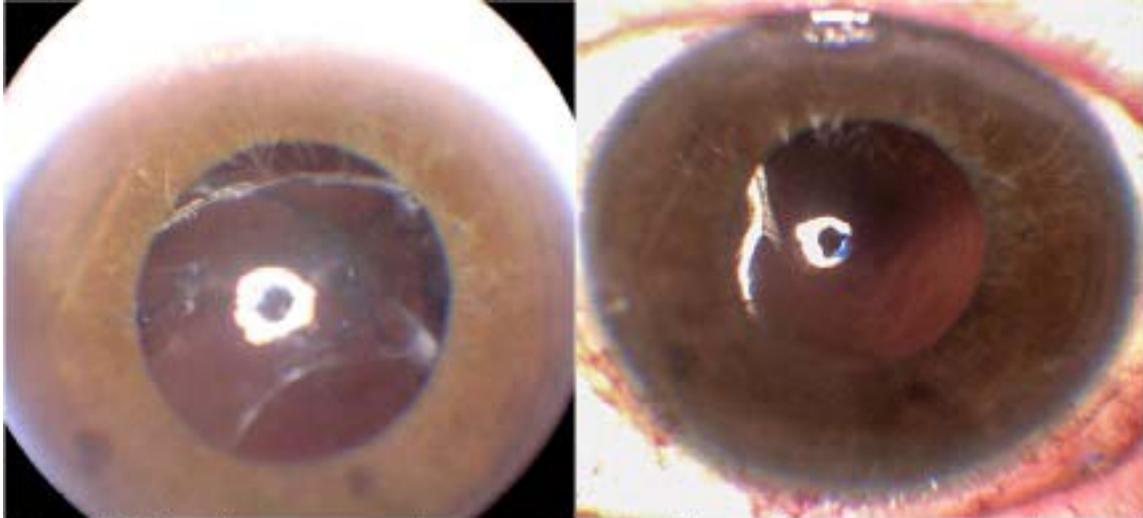


Figure 2. Anterior segment photograph, pre- and 1 week post trans scleral sutured posterior chamber intraocular lens with AKREOS® A060 in a patient presenting with subluxated posterior chamber intraocular lens due to pseudoexfoliation syndrome.



Figure 3. Anterior segment photograph, pre- and 1 week post trans scleral sutured posterior chamber intraocular lens with AKREOS® AO60 in a patient with an anterior chamber intraocular lens and uveitis-glaucoma-hyphema (UGH) syndrome.

Table 1. Indications for transscleral sutured PC IOL		
Diagnosis	Eyes, n	%
Aphakia		
Post complex RD repair	7	8.8
Post complex cataract sx	12	15.0
Post complex IOL exchange	1	1.3
Trauma	5	6.3
Retained Lens/Lens Fragment		
Post complex cataract sx	7	8.8
Dislocated/subluxated crystalline lens		
Trauma	2	2.5
Marfan	1	1.3
Dislocated/subluxated PC IOL		
Post complex RD repair	13	16.3
Post complex cataract sx	3	3.8
Post complex IOL exchange	1	1.3
Trauma	3	3.8
Other	18	22.5
Pseudoexfoliation	3	3.8
Axenfeld Syndrome	1	1.3
Exchange of ACIOL		
Secondary to UGH syndrome	1	1.3
Traumatic cataract	2	2.5
AC=anterior chamber; IOL=intraocular lens; PC=posterior chamber; RD=retinal detachment;		

Analyses were conducted for all 80 eyes of 77 patients with a mean follow-up of 249.7 days. Visual acuity was measured using the Snellen chart. Intraocular pressure was measured by applanation. New-onset glaucoma was defined as an increase of intraocular pressure requiring treatment in a patient with no prior history of glaucoma. Macular optical coherence tomography was utilized to confirm cystoid macular edema when suspected. Preoperative and postoperative anterior segment photography was obtained in some patients. Postoperative anterior segment ultrasound biomicroscopy was also obtained in some patients.

Surgical Technique

The surgical technique included a complete 25 gauge pars plana vitrectomy including elevation and subsequent removal of the posterior hyaloid. After the vitrectomy, all nuclear and cortical fragments as well as capsular remnants and dislocated intraocular lens implant if present were removed converting the eye to aphakia. An AKREOS® AO60 (Bausch & Lomb) was implanted in all eyes and fixated to the sclera with 9-0 prolene. The single-piece PCIOL has a 6.0 mm optic, up to 11 mm overall length, and 4 closed eyelets at the distal end of the haptics. The surgery steps were as follows:

1. The cornea is marked in the periphery at two points 180 degrees apart in the horizontal meridian with a corneal marker and sterile intraoperative marking pen.
2. A conjunctival peritomy is then made adjacent to the two cornea marks.
3. A rectangular scleral groove is made 3.0 to 3.5 mm posterior to the limbus and a tunnel is created to produce a scleral flap at both the 3:00 and 9:00 position.
4. Two 25g microcannulas are placed under each scleral flap. The punctures are made 4.0 mm apart, 2.0 mm posterior to limbus.
5. A complete 25g vitrectomy is then performed. An external to internal pass of a 25g forcep with a 9-0 prolene suture is made without a needle, through the temporal sclerostomy #1 into the posterior chamber. It is visualized through the pupil and elevated to the plane of the iris.
6. This suture is handed off to a 20g forcep placed through a limbal incision and the suture is removed through the limbus.

7. This suture is then passed through both eyelets on the temporal haptic side of an AKREOS PCIOL.
8. A 20g forcep with the original suture is passed through the limbal incision and into the iris plane and is handed off to a 25g forcep which has been introduced through the temporal sclerostomy #2 (**figure 4**). The 25 gauge forcep was introduced external to internal through the fellow, adjacent puncture of the original entry point of the suture.
9. The 25g forcep is removed through the temporal sclerostomy externalizing the prolene suture. The procedure is then repeated for the nasal sclerostomy with a separate, additional 9-0 prolene suture.
10. A viscoelastic injection into the anterior chamber is used to protect the corneal endothelium and deepen the anterior chamber.
11. The IOL is folded using folding forceps, and transferred to an IOL insertion forcep for implantation. The IOL is inserted and unfolded in the posterior chamber. 12. The temporal and nasal sutures are tightened and adjusted to achieve optimal centration of the IOL before the sutures are than permanently tied (**figure 5**).
12. After verifying the correct IOL position, the scleral flaps are closed and rarely, sutured if necessary.
13. Intravitreal injection of triamcinolone acetonide 4.0 mg is delivered.
14. The conjunctiva is closed with 9-0 vicryl sutures and the limbal incision is closed with a single X-type 9-0 nylon suture.

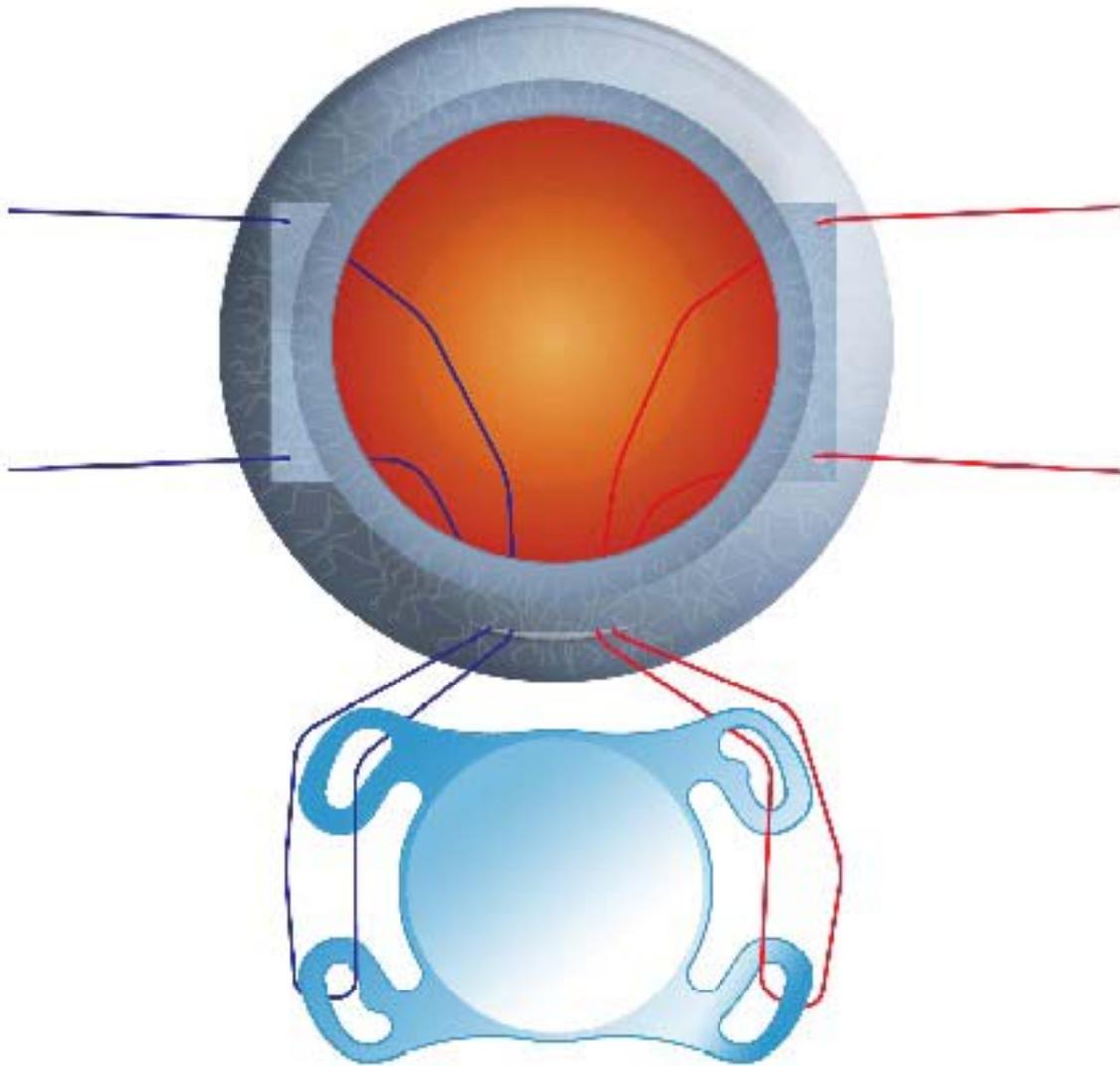


Figure 4. Abexterno pass of 9-0 prolene suture is made into the posterior chamber, and removed through the limbal incision. This suture is then passed through both eyelets on the temporal haptic side of an AKREOS PCIOL, passed through the limbal incision and externalized through the temporal sclerostomy.

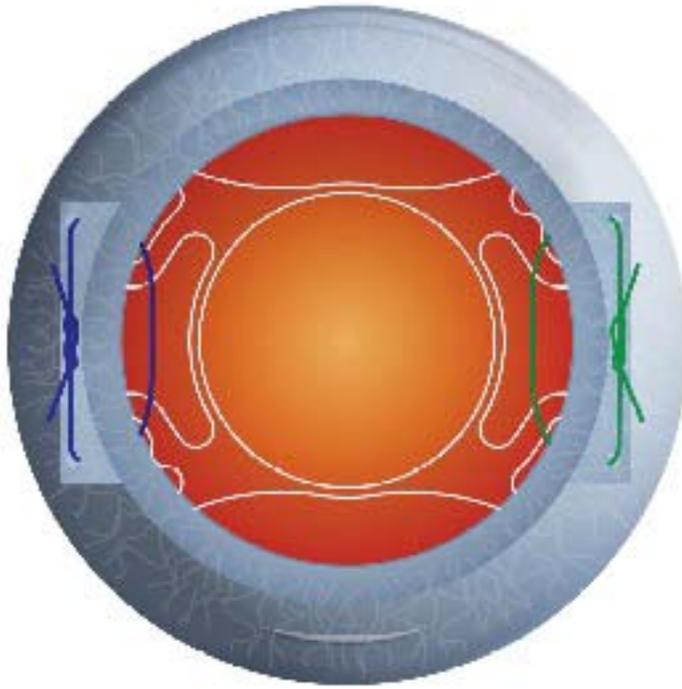


Figure 5. The sutures are adjusted to achieve optimal centration of the IOL before being permanently tied.

Results

80 eyes of 77 patients (43 men, 34 women) were included. Mean age was 68.2 years \pm 14.9 (SD) (range 24-99). Mean follow-up was 8.8 \pm 8.4 months (range 1-41 months). Preoperative diagnoses of 80 eyes shown in **table 1**.

Preoperative best corrected visual acuity (BCVA) was 20/40 or better in 9 eyes (11.3%), between 20/40 and 20/100 in 13 (16.3%), and worse than 20/100 in 58 (72.5%). Preoperative visual acuity ranged from 20/25 to LP.

Postoperative BCVA was 20/40 or better in 33 eyes (41.3%), between 20/40 and 20/100 in 20 eyes (25%), and worse than 20/100 in 27 eyes (33.8%). Postoperative visual acuity ranged from 20/15 to LP. 78 of 80 eyes maintained or improved their vision, and 2 had worse postoperative BCVA (**table 2**).

Sample pre and post op photos demonstrate well centration of the lens under various preoperative diagnoses with preservation of iris anatomy (**Figure 1, Figure 2, Figure3**).

No patient was observed to have postoperative subluxation or dislocation. Postoperative vitreous hemorrhage with spontaneous clearing was noted in one patient (1.25%). A postoperative (47 days) rhegmatogenous retinal detachment was successfully repaired in one patient (1.25%). Late cystoid macular edema was treated with topical therapy in two patients (2.5%). Optic opacification was observed in one patient (1.25%).

22 of the 27 eyes with postoperative BSCVA worse than 20/100 had significant comorbidities preoperatively, including prior retinal detachment (3), cystoid macular edema (2), epiretinal membrane (2), retinal scar (2), uveitis-glaucoma-hyphema syndrome (1) pseudoexfoliation (1), glaucoma status-post trabeculectomy (1), macular hole (1), corneal scar (1), retinoblastoma status-post radiation therapy (1), uveitis (1), Axenfeld-Rieger syndrome (1), proliferative diabetic retinopathy (1), status-post Descemet's stripping endothelial keratoplasty (1), and trauma (3).

Preoperative Diagnosis	Post BCVA, n (%)					
	20/40 or better	20/50 to 20/100	Worse than 20/100	Improved	No Change	Worse
Aphakia						
Post complex RD repair	0	1	6	5	2	0
Post complex cataract sx	6	5	1	11	1	0
Post complex IOL exchange	1	0	0	1	0	0
Trauma	2	2	1	4	1	0
Retained lens/Lens Fragment						
Post complex cataract sx	1	2	4	6	1	0
Dislocated/subluxated crystalline lens						
Trauma	0	0	2	1	1	0
Marfan	1	0	0	1	0	0
Dislocated/subluxated PC IOL						
Post complex RD repair	6	3	4	11	1	1
Post complex cataract sx	1	2	0	2	1	0
Post complex IOL exchange	0	1	0	1	0	0
Trauma	1	0	2	3	0	0
Other	10	4	4	14	3	1
Pseudoexfoliation	2	0	1	3	0	0
Axenfield syndrome	1	0	0	1	0	0
Exchange of ACIOL						
Secondary to UGH syndrome	0	0	1	0	1	0
Traumatic cataract	1	0	1	2	0	0
Total	33 (41.3%)	20 (25%)	27 (33.8%)	66 (82.5%)	12 (15%)	2 (2.5%)

AC=anterior chamber; IOL=intraocular lens; PC=posterior chamber; RD=retinal detachment; BCVA= best corrected visual acuity

Discussion

Transscleral suture fixation of PCIOLs have played an important role in the visual rehabilitation of aphakic eyes in the absence of capsular support. The current strategy involves the insertion of a large-diameter optic (6.5 or 7.0mm), single-piece PMMA IOL with large modified C-shaped haptics into the ciliary sulcus.

We have found numerous advantages to this novel technique with the AKREOS® lens in a variety of complex ocular conditions associated with aphakia or the absence of capsular support (**table 1**).

The AKREOS® is extremely deformable, tear-resistant and easy to fold, eliminating the need to enlarge the limbal incision on implantation, thus reducing final corneal astigmatism, reduced operative time and accelerated vision recovery.

Posterior IOL tilt reported in two-point fixation techniques can result in significant visual disturbances including uncorrectable coma aberration, myopic shift and oblique astigmatism⁶. One unique feature of this technique is the immediate stable four-point fixation that is possible utilizing the suture eyelets in the AKREOS®.

Optical decentration is a known complication of TSSPCIOL surgery, inducing lateral shift of focus and radial astigmatism⁷. The mechanical resistance of the hydrophobic acrylic component of the AKREOS® allows the lens to rapidly regain form, and the loop haptic shape allows immediate centration. We find the four-point fixation aids in centration. Additionally, the aberration neutral optics platform of the Advanced Optic (AO) AKREOS reduces the risk of optical complications in mild decentration.

A possible limitation of the lens is the hydrophilic component used for compressibility to allow the lens to fit in microincisions. It is a known problem for hydrophilic acrylic lenses to be prone to opacification (Park, Mak). Specifically, recent reports indicate that the use of air/gas bubbles is associated with opacification of hydrophilic acrylic lenses (Fellman, Werner). Clinicians should be aware of this association for future procedures utilizing air/gas bubbles in these patients.

Late breakage of suture is a serious, well-published complication leading to displacement and further surgery. We typically use a heavier 9-0 prolene as an alternative suture to reduce the risk of breakage. Numerous reports in transscleral sutured C-shape haptic IOLs describe variations of cow-hitch knot fixation techniques that avoid intraocular knots with free suture ends to address the risk of knot slippage and iris chafing⁸⁻¹¹.

However, cow-hitch suture fixation may still allow slack and prolene suture slip along the haptic and unravel over the haptic end if there is no secure knot.

In our technique, passing the suture through the closed 4-point haptic design of the AKREOS® lens eliminates the need for cow-hitch creation or knot modification altogether, decreasing operative time and reducing the manipulation of the prolene suture which may also lead to suture compromise.

In cases of dislocated IOL, various retrieval techniques have been advocated to secure the existing IOL including suture fixation to sclera, to iris, and sutureless transscleral fixation with the canalization of ciliary sulcus-based sclerotomy¹². These techniques do not account for the wide variety of dislocated PCIOL and associated haptic designs from decades of prior cataract surgery that could be incompatible or suboptimal for rescue and successful suture fixation or stabilization. Further these techniques require more difficult maneuvers of retrieval and stabilization prior to subsequent fixation. We advocate the conversion of all cases to aphakia and an identical technique for TSSPCIOL implantation with the same AKREOS IOL. The reduced complexity of surgical decision making is an important advantage of our technique as it is applicable to a wide variety of disorders.

Another important advantage of this technique is the use of 25 gauge vitrectomy and associated instrumentation. The use of 25 gauge trochar microcannulas allows more controlled and possibly less trauma to the peripheral retina and ciliary sulcus. Further, these microcannulas allow the suture to be precisely placed with a 25 gauge forcep without more difficult and potentially risky needle passes to introduce and retrieve the suture.

The low rate of intra- and post-operative complications should also be noted. Of note, no patient was observed to have postoperative subluxation, dislocation, or suture slippage/breakage. As noted previously, postoperative vitreous hemorrhage with spontaneous clearing was seen in one patient (1.25%), postoperative (47 days) rhegmatogenous retinal detachment was successfully repaired in one patient (1.25%), late cystoid macular edema was treated with topical therapy in two patients (2.5%), and Optic opacification was observed in one patient (1.25%). In comparison, Grigorian et al. reported vitreous hemorrhage with spontaneous clearing in 3 of 24 eyes (12.5%), proliferative vitreoretinopathy with retinal detachment in 2 eyes (8.3%), and cystoid macular edema in 1 eye (4.2%) with their technique. Monteiro et al. reported macular edema in 4 of 15 eyes (26.7%), hyphema in 2 eyes (13.3%) while observing no IOL tilt or dislocation. In a retrospective review of 208 cases of TSSPCIOL, Hannush et al. reported a similar complication profile with 12(6%) cases of cystoid macular edema, 18(9%) cases of increased intraocular pressure, and loss of visual acuity in 8(4%) eyes. While no statistical analysis was performed comparing techniques directly, the similar side effect profiles highlight the safety and viability of our technique that also offers a mean operative time of 40 minutes.

Conclusion

This procedure allows for a technically efficient, reliable and reproducible procedure, with intraoperative time reduced compared to previously reported techniques. Anatomic outcomes are excellent with encouraging visual results and low complications. Long term postoperative dislocation remains a serious potential and indeterminate risk.

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