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Scleral Fixation Using a Hydrophilic Four-haptic Lens and Polytetrafluoroethylene Suture: A Phase I Clinical Trial

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Keywords: Scleral fixation, Aphakia, Gore-Tex suture, IOL Akreos AO60

Abstract

Purpose: To assess the safety of scleral fixation using Akreos AO60 IOL and Gore-Tex suture.

Methods: Prospective evaluation of 20 patients who underwent scleral fixation of Akreos AO60 with Gore-Tex. Patients presenting with aphakia or dislocated IOL without capsular support were enrolled in the study. Main outcome measures included visual acuity, endothelial cell density, and postoperative complications over 6 months of follow-up.

Results: Mean ± SD uncorrected logMAR visual acuity improved from 1.92 ± 0.23 (20/1600 Snellen equivalent) preoperatively to 0.80 ± 0.56 (20/125) post-surgery ($p < 0.001$). Mean ± SD BCVA logMAR was 0.43 ± 0.23 preoperatively and 0.37 ± 0.24 (20/50) post-surgery ($p = 0.312$). Exposure of suture occurred in 8/20 (40%) eyes over the 6 months of follow-up. The mean ± SD endothelial cell density was 1,740.50 ± 522.92 cells/mm^2 and 1,187.19 ± 493.00 cells/mm^2 ($p < 0.001$) pre and postoperatively, respectively. Mean ± SD postoperative spherical equivalent was -1.12 ± 1.50D. Postoperative complications included hypotony in 15% of the patients, ocular hypertension and transient vitreous hemorrhage in 10%, and retinal detachment and transient lens opacification in 5%.

Conclusion: Scleral fixation with an Akreos AO60 and Gore-Tex appears safe. However, caution must be taken regarding suture exposure, and scleral flaps can be a technique to reduce the risk of this complication. Phase II studies are needed.

INTRODUCTION

In the context of inadequate capsular support, surgical options for intraocular lens (IOL) implantation include insertion of an anterior chamber IOL (ACIOL), iris fixation of an ACIOL, iris fixation of a posterior chamber IOL (PCIOL), and scleral fixation (with or without suture) of a PCIOL.

Technique selection is often influenced by the patient's age, anatomical factors (e.g., previous trauma with loss of iris tissue), other ocular comorbidities (such as glaucoma), and, finally, surgeon preference.

Older ACIOLs have been associated with higher rates of ocular hypertension, loss of endothelial cells, pupillary block, cystoid macular edema, and uveitis-glaucoma-hyphema syndrome, when compared to PCIOLs.[1, 2] Further, with PCIOLs, the position of the lens is closer to the natural lens location, probably offering refractive benefits.[1]

Iris fixation has been associated with higher rates of iris atrophy, pigmentary dispersion syndrome, uveitis, and pseudophacodonesis when compared to scleral fixation.[3] However, the scleral fixation technique is also not without complications. Retinal detachment, IOL inclination, vitreous and suprachoroidal hemorrhage, endophthalmitis, and suture erosion/breakage have all been reported and can result in permanent loss of sight.[4, 5]

Uncertainties regarding the erosion and breaking of thread sutured to the sclera and the PCIOL have received special attention. Concerns about the half life of commonly used polypropylene thread have been raised. Some scleral fixation techniques without suture have been suggested,[6, 7] as well as alternative suture materials, such as Gore-Tex or larger diameter polypropylene (9-0),[4, 5, 8] to minimize the risk of suture-related complications.

In 2014, Khan et al.[1] described a modified technique for scleral fixation at two points of a CZ70BD IOL (Alcon, Fort Worth, TX, USA) using Gore-Tex suture, a non-absorbable monofilament polytetrafluoroethylene (PTFE) thread. With increased experience, the technique proposed by Khan et al.[1] has undergone modifications. The main adjustment was the use of an Akreos AO60 IOL with a four-haptic design that enables excellent centralization and stabilization of the IOL through four-point fixation.[9] Recent studies using this technique have been published, although none were prospective.[5, 7, 9-13]

The objective of the current study was to evaluate the safety of Akreos AO60 scleral fixation using Gore-Tex suture, in the absence of capsular support, associated with pars plana vitrectomy (PPV), when necessary.

METHODS

Study design

This prospective, single-center, phase-1 clinical trial adhered to the principles of the Declaration of Helsinki and was approved by the local research ethics committee of the Ribeirão Preto Medical School of the University of São Paulo (reference number: 03907418.5.0000.5440). Trial registration number: RBR-6qvmjs (09/02/2020).

All aphakic patients and those with dislocated or subluxed IOLs, without capsular support, treated at the Clinical Hospital of Ribeirão Preto Medical School, between February and May 2019, were invited to participate in this study. Written informed consent was obtained from all participants.

Study population

Inclusion criteria were as follows: patients aged ≥ 18 years, with aphakia or decentralized/dislocated IOL; absence of reliable capsular support in the surgeon's opinion; best-corrected visual acuity (BCVA) at least 5 letters better than uncorrected visual acuity.

Exclusion criteria included the presence of capsular support that would render it possible to implant an IOL without scleral fixation, ocular comorbidities that could be aggravated by surgery, such as advanced glaucoma and corneal disease, endothelial cell counts with densities less than 1,000, and the presence of systemic comorbidities contraindicating the surgical procedure.

Baseline and follow-up evaluations

Patients underwent comprehensive ophthalmological evaluations at baseline, one day after surgery, one week after surgery, and after 1, 2, 3, and 6 months post-surgery. The baseline assessment included uncorrected and best-corrected visual acuity measurements, applanation tonometry, slit-lamp biomicroscopic examination, indirect fundus examination, specular microscopy and pachymetry (ICONAN - Konan Specular Microscope Sp-5500, Irvine, CA, USA), and immersion biometry.

Preoperative lens calculations were carried out using immersion ultrasonography (Alcon OcuScanRxP, Fort Worth, TX, USA). The SRK-T (axial length greater than 26 mm), Hoffer-Q (axial length less than 22 mm), or Holladay 1 formulas were used, depending on the obtained value. The calculation was made for the implantation of an IOL in the topography of the capsular bag. The target postoperative refraction average was -0.40 diopter spherical equivalent.

At all visits, we measured uncorrected visual acuity and intraocular pressure (IOP) and performed slit-lamp biomicroscopic and indirect fundus examinations. Optical coherence

tomography (SD-OCT; Heidelberg Engineering, Germany) was carried out in cases that the postoperative BCVA was worse than 20/40 and there was a suspicion of epiretinal membrane (ERM) or cystoid macular edema (CME) by fundus biomicroscopy. Refraction, specular microscopy and pachymetry were performed between 3 and 6 months after surgery, when BCVA was verified.

Snellen visual acuities were converted into mean logMAR equivalents for statistical analysis; counting fingers (CF) at 3 meters was converted into 1.85, CF at 2 meters to 1.9, CF at 1 meter and CF at 30 cm to 2.0, and hand motion to 2.1. Hypotony was defined as the new onset of an IOP less than 5 mmHg at any postoperative visit, and ocular hypertension was characterized by an IOP higher than 25 mmHg at any visit.

Surgical technique

Two conjunctival peritomies are created 180° apart nasally and temporally, followed by cauterization in order to obtain hemostasis. A 23-gauge inferior sclerotomy is performed for infusion. Four additional sclerotomies are created: two temporal and two nasal, 2.5 mm above and below the midline using a trocar blade, at a distance of 3 mm from the limbus. A pars plana vitrectomy was performed, if needed.

Afterward, the needles of the 7-0 CV-8 Gore-Tex suture (WL Gore & Associates, Newark, DE, USA) are discarded, and the suture thread is cut in two halves. Each end of the thread is then passed through the two adjacent holes in the IOL.

The anterior chamber can then be accessed through the previously created corneal wound (if cataract surgery was recent) or by constructing a new upper corneal incision using a 2.75-mm blade. The incision can be enlarged to 3.5-4.0 mm.

Each end of the Gore-Tex thread is passed into the anterior chamber and removed from the corresponding sclerotomy using flat intraocular forceps. The Akreos A060 IOL (Bausch & Lomb, Rochester, NY, USA) is folded and placed through the corneal wound into the posterior chamber of the eye, and the four extremities of the thread are then pulled.

Next, the trocars are removed, and the threads are tied. It is important to first center the IOL and then gradually adjust the thread tension at the nasal and temporal extremities before tying the permanent knot. The threads are cut, leaving a long enough tip, which, theoretically, can help reduce the risk of future Gore-Tex unfolding and conjunctiva erosion.

In order to avoid postoperative hypotonia, leaking sclerotomies can be sutured with 7-0 polyglactin 910 (Vicryl, Ethicon, NJ, USA). The corneal wound is closed using 10-0

nylon suture. Finally, the conjunctival peritomy is also closed, ensuring that the external Gore-Tex thread is completely covered.

Statistical analysis

Data analysis was carried out using the IBM SPSS Statistics software (Statistical Package for Social Sciences, version 23.0), where data frequency and descriptive measures were applied. A p-value < 0.05 was considered statistically significant.

The Kruskall-Wallis and Mann-Whitney tests were used to compare means and times, and the non-parametric Wilcoxon test was used to verify the existence of significant differences considering paired data.

RESULTS

A total of 20 patients were included in the current study. Their mean age ± SD at the time of surgery was 64 ± 10 years (range: 39 - 84 years). The study sample comprised 8 women (40%) and 12 men (60%), and the eyes that underwent surgery were 9 right eyes (45%) and 11 left eyes (55%). Indications for secondary IOL surgery included: dislocated or subluxed crystalline lens after trauma in 7/20 patients (35%); dislocated crystalline lens after complicated cataract surgery in 3/20 (15%); aphakia after complicated cataract surgery in 6/20 (30%), three of which had a history of trauma; and dislocated or subluxed IOL in 4/20 (20%), one of which took place after complicated cataract surgery and another after blunt trauma (Table 1).

Table 1. Baseline patients' characteristics

Characteristics	Data
Gender, no. (%)	
Male	**12 (60%)**
Female	**8 (40%)**
Age (years) (mean ± SD)	**64,20 ± 10,75**
Eyes, no. (%)	
Right eye	**9 (45%)**
Left eye	**11 (55%)**
Surgical indication, no. of eyes (%)	
Dislocated or subluxed crystalline lens after trauma	**7 (35%)**
Aphakia after complicated cataract surgery	**6 (30%)**
Dislocated or subluxed IOL	**4 (20%)**
Dislocated crystalline lens after complicated cataract surgery	**3 (15%)**

Ten of the 20 (50%) patients underwent scleral fixation alone, while the other ten eyes underwent concurrent 23-gauge PPV. Of the patients with combined surgery, 4/20 (20%) underwent IOL explantation, 4/20 (20%) lens fragmentation, 1/20 (5%) ERM peeling, and 1/20 (5%) removal of silicone oil and prolene mesh (Table 2). No intra-operative complications were noted.

Table 2. Surgical characteristics

Surgery performed	**Data**
1) Scleral Fixation, no. (%)	**10 (50%)**
Previous surgery:	5 (25%)
Complicated cataract surgery	4 (20%)
PPV + Endophacofragmentation	1 (5%)
PPV + Lensectomy + removed IOFB	
2) PPV + explant of IOL + scleral fixation	**4 (20%)**
3) PPV + lens fragmentation + scleral fixation	**4 (20%)**
4) PPV + ERM peeling + scleral fixation	**1 (5%)**
5) Removal of silicone oil + scleral fixation	**1 (5%)**

ERM - Epiretinal membrane
IOFB - Intraocular foreign body

Outcome measures

Visual acuity

Mean ± SD uncorrected logMAR visual acuity was 1.92 ± 0.23 (20/1600 Snellen equivalent) preoperatively, which improved significantly to 0.81 ± 0.54, 0.78 ± 0.47, 0.79 ± 0.46, and 0.80 ± 0.56 (20/125 Snellen equivalent) at 1, 2, 3, and 6 months postoperatively, respectively (Wilcoxon-test = -3.76; p-value < 0.001).

Mean ± SD best-corrected logMAR visual acuity was 0.43 ± 0.23 (20/50 Snellen equivalent) preoperatively and 0.37 ± 0.24 (20/50 Snellen equivalent) postoperatively (Mann Whitney-test = -0.66; p-value = 0.531 and Wilcoxon-test = -1.01; p-value = 0.312). BCVA was verified between 3 and 6 months after surgery.

Anterior segment changes

On the first day after surgery, 15/20 (75%) patients had corneal edema. After one week, this number decreased to 5/20 (25%), at one month to 3/20 (15%), and at two months to 2/20 (10%). After three months of follow-up, none of the patients had corneal edema.

As for anterior chamber cells/flare, 6/20 (30%) were positive for this parameter on the first day, 4/20 (20%) on the seventh postoperative day, and 1/20 (5%) at one month and two months. At three months and six months of follow-up, none of the patients were noted to have anterior chamber cells.

A Seidel-positive corneal incision was noted in 1/20 (5%) patient in the first week after surgery. Spontaneous resolution occurred after two weeks.

Adverse events

The second leading postoperative complication found in the present study, after corneal edema, was conjunctival erosion with exposure of the Gore-Tex suture (Figure 1); 8/20 (40%) patients exhibited suture exposure throughout the six months of follow-up, decreasing to 6 cases after conducting procedures on two of them (the exposed tip was cut in one case, and the conjunctiva was resutured in another). Three of the 20 (15%) operated eyes presented with suture exposure in the first week, 4/20 (20%) at two months, and 6/20 (30%) at three months after surgery.

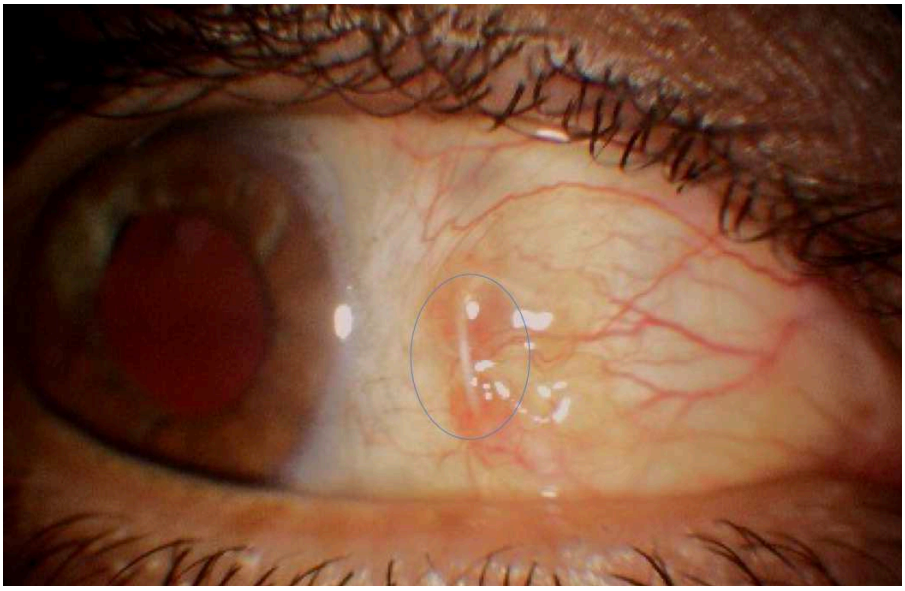

Figure 1. Gore-Tex suture exposure after surgery. In this case, the suture, not the knot, eroded the conjunctiva 7 days after surgery.

Iris synechiae were observed in the corneal incision in 4/20 (20%) patients at the end of the follow-up, and 2/20 (10%) of them had edema in the upper cornea, but with a free visual axis.

Four months after surgery, 1/20 (5%) patient exhibited cellularity in the anterior chamber with opacification of the lens; there was an almost complete improvement in lens

opacification and vision after using topical corticosteroids. The patient had a previous history of recurrent anterior idiopathic uveitis (Figures 2a and 2b).

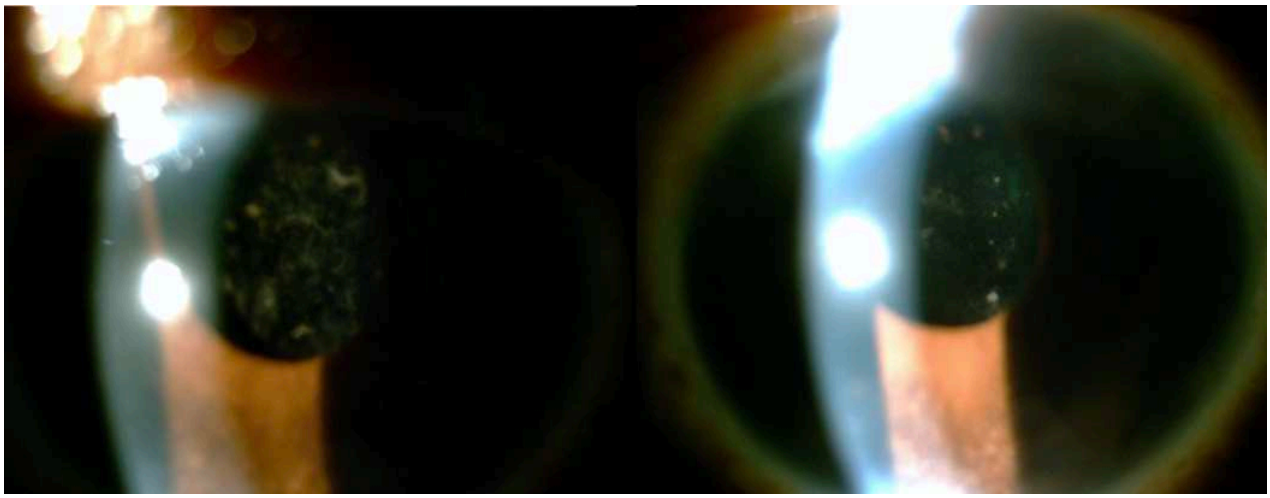

Figure 2. (a) Akreos intraocular lens opacification four months after surgery; (b) Improvement in lens opacification two months after treatment with topical corticosteroids. The patient had a previous history of recurrent anterior idiopathic uveitis.

On the first postoperative day, 1/20 (5%) patient presented with macular intraretinal hemorrhage. OCT was performed 4 months postoperatively after refraction (BCVA was 20/200) and demonstrated disorganization of the outer retina. One case of probable toxic anterior segment syndrome (TASS) presented on the first postoperative day. Due to the possibility of endophthalmitis, intravitreal antibiotic injection was performed, and the patient presented good evolution (final BCVA was 20/40). Three patients (3/20; 15%) evolved with cystoid macular edema (CME) and 2/20 (10%) with epiretinal membrane (ERM); both pathologies were noted after six months of follow-up.

Two patients (2/20; 10%) had transient vitreous hemorrhages (resolution within one month), while 1/20 (5%) presented recurrence of a retinal detachment (RD), which was observed 20 days after the placement of the secondary IOL. This patient had had RD about 10 years before that. Complete repair occurred after pneumatic retinopexy, and sessions of laser were performed to block the retinal rupture. Corneal deepithelialization was observed after the laser and herpetic keratitis developed few weeks later. After treatment, the patient evolved with central corneal opacity and BCVA of 2.1 logMAR.

Specular microscopy

Mean ± SD endothelial count was 1,740.50 ± 522.92 cells/mm^2 (range: 1,019.00 - 2,849.00) preoperatively and 1,187.19 ± 493.00 cells/mm^2 (range: 657.00 - 2,262.00)

postoperatively (Mann Whitney-test = -3.18; p = 0.001 and Wilcoxon-test = -3.52; p < 0.001). Specular microscopy and pachymetry were performed at baseline and 3 to 6 months after surgery.

Mean ± SD pachymetry was 562.00 ± 62.07 µm (range: 439.00 - 687.00) preoperatively and 564.65 ± 65.71 µm (range: 450.00 - 741.00) after the surgery (Mann Whitney-test = -0.30; p = 0.775 and Wilcoxon-test = -0.45; p= 0.653). The endothelial cell count and the pachymetry after surgery was possible to be performed in 16 of the 20 patients due to factors that hampered evaluation, such as corneal opacity.

Intraocular pressure and IOP-lowering therapy

Mean ± SD intraocular pressure (IOP) was 14.95 ± 3.14 mmHg at baseline and was 11.40 ± 5.64 mmHg on day 1, 14.25 ± 5.31 mmHg after one week, 15.10 ± 4.48 mmHg after one month, 14.75 ± 5.96 mmHg after two months, 15.35 ± 5.09 mmHg after three months, and 15.15 ± 4.06 mmHg after six months of surgery (Kruskall Wallis-test: p = 0.493).

Another adverse event observed was hypotony (IOP < 5 mmHg) in 3/20 (15%) patients on the first postoperative day. After one week, all three patients had normalized intraocular pressure. No complications of ocular hypotony were identified.

Preoperatively, none of the patients had IOP > 25 mmHg, and 3/20 (15%) were using ocular hypotensive medication. Over the course of the 6-month follow-up, 2/20 (10%) patients exhibited ocular hypertension. At the 6-month evaluation, none of them had an IOP > 25 mmHg, and 5/20 (25%) were using ocular hypotensive agents. Nine of the patients (9/20; 45%) showed an increase of at least 5 mmHg throughout the follow-up compared to baseline.

Refractive changes

In the pre and postoperative periods, respectively, the mean ± SD sphere power in diopters was +11.76 ± 3.00D (range: +1.25 - +15.00) and +0.46 ± 1.34D (range: -1.50 - +3.0) (Mann Whitney-test = -5.25; p < 0.001); the mean ± SD cylinder power was -1.32 ± 1.60D (range: -6.0 - 0) and -3.21 ± 1.57D (range: -1.0 - -6.0) (Mann Whitney-test = -3.61; p < 0.001); and the mean ± SD spherical equivalent was +11.06 ± 3.06D (range: +0.25 - +14.75) and -1.12 ± 1.50D (range: -4.25 - +1.0) (Mann Whitney-test = -5.25; p < 0.001).

DISCUSSION

New scleral fixation techniques have recently been described using alternative sutures, foldable lenses, and smaller caliber instruments.[1, 6, 14-21] Retrospective studies have shown good results of scleral fixation using the Akreos AO60 lens and Gore-Tex suture.[5, 7, 9-13] To our knowledge and based on a computerized search of the Medline database, this is

the first prospective study of Akreos A060 scleral fixation with Gore-Tex suture and it confirms that the technique is safe and promotes good visual results.

Fixing an IOL at two points can cause IOL tilting or decentralization.[22] The Akreos AO60 design facilitates centralization and decreases inclination, thus reducing induced astigmatism and high-order aberrations. Also, it is easily foldable, allowing a smaller corneal incision, which maintains the stability of the anterior chamber and prevents intraoperative hypotony. Su et al. (2019)[13] compared the fixation of the Akreos AO60 lens (46 eyes) with that of the enVista MX60 lens (8 eyes) and found a similar induced astigmatism in the two models. Moreover, since it is an aspherical lens, free from aberrations, the Akreos AO60 can provide superior quality vision, which is not affected by decentralization or pupil size.[8] This constitutes an additional advantage in eyes with traumatic mydriasis, a relatively common condition in patients undergoing scleral fixation of an IOL. Also, because it is hydrophilic acrylic, it is associated with less inflammation when compared to hydrophobic acrylic lenses.[23]

As for the type of suture, prolene was the most used thread for scleral fixation. However, due to complications related to the thread, Gore-Tex suture is being used more and more for this procedure, as it provides advantages such as greater resistance to traction and small memory, which facilitates manipulation and causes a minimal inflammatory response.[20] Khan et al. (2014[1], 2016[7], 2018[9], and 2019[5]) did not report complications related to the suture in their publications. An alternative includes scleral fixation without the use of sutures, which has also been described with favorable visual results.[6, 17, 18]

Khan et al. (2018)[9] placed sclerotomies 3 mm posterior to the limbus and separated sclerotomies by 5 mm to decrease the risk of contact with the iris, permit a more reliable centralization of the IOL due to the anatomical position being closer to the capsular bag, and decrease the risk of folding of the haptic. Given these benefits of Khan's technique, we also placed our sclerotomies 3 mm posterior to the limbus and 5 mm between them.

In the present study, all patients were followed-up for at least six months. One of the most important parameters to assess the safeness of the technique is visual acuity. We obtained a best-corrected final visual acuity that was very similar to the preoperative value, 0.43 at baseline and 0.37 after surgery ($p = 0.531$). There was, in fact, a slight improvement (Figure 3). In 2018, Patel et al.[20], in a retrospective series of 49 eyes which underwent scleral fixation of IOLs using Gore-Tex suture, reported final visual acuity of 0.5 (20/63 Snellen equivalent), a value very close to that found herein. In 2016, Khan et al.[7] published

the results obtained from 85 eyes that underwent scleral IOL fixation using Akreos AO60 or Alcon CZ70BD lenses and Gore-Tex suture; the mean final visual acuity was 20/63 in the Akreos AO60 group and 20/112 in the CZ70BD group.

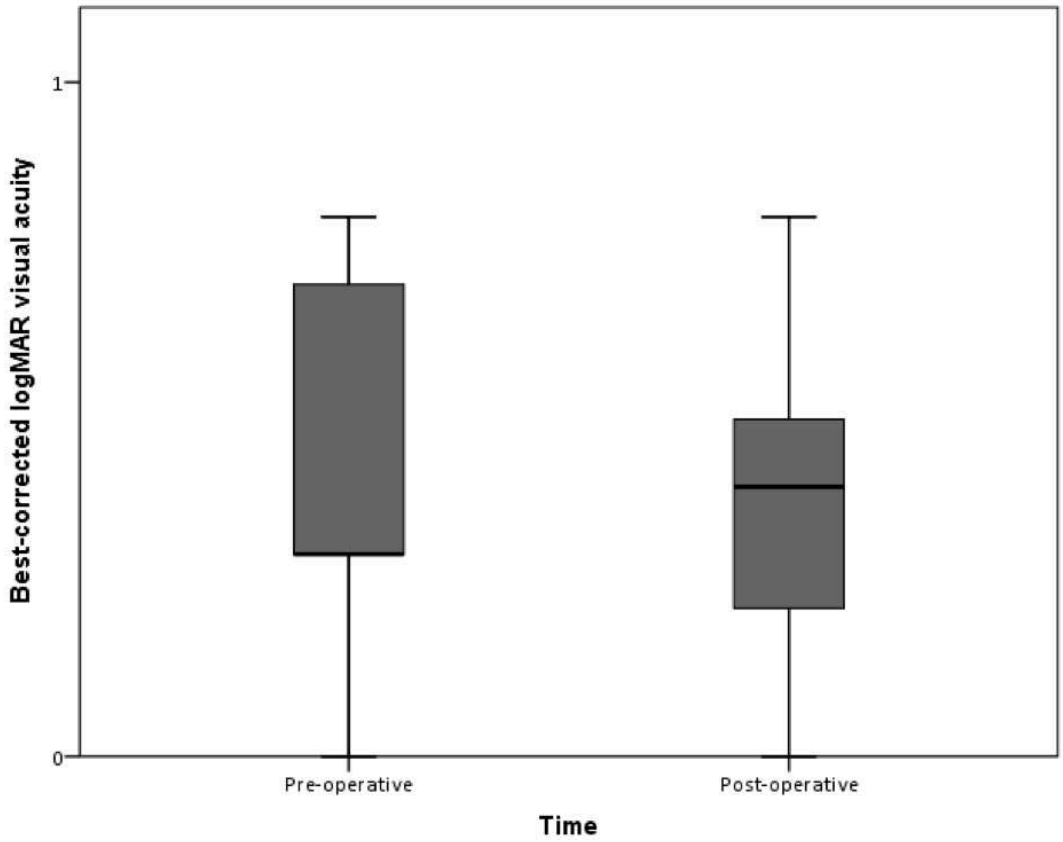

Figure 3. Box plot graphics showing the similarity in best-corrected visual acuity at baseline (preoperative: mean logMAR BCVA: 0.43) and 3-6 months after surgery (postoperative: mean logMAR BCVA: 0.37). Middle line represents the median, the square represents the mean, the 25th and 75th percentiles determine the box and the 5th and 95th percentiles determine the whiskers.

Malamud et al. (2016)[19] and Khan et al. (2019)[5] reported outcomes in series of 57 and 63 eyes, respectively, undergoing PPV with ACIOL or scleral-sutured PCIOL placement; they obtained similar visual results to those in our study: 20/60 (ACIOL group) and 20/40 (CZ70BD group) in Melamud et al.; 20/50 (ACIOL group) and 20/46 (Akreos AO60 group) in Khan et al. No differences in visual acuity were found between groups; however, the ACIOL group were noted to have more complications, such as epiretinal membrane (ERM) in the study by Melamud, and transient corneal edema in the study by Khan. Importantly, Khan et al. (2019)[5] and Melamud et al. (2016)[19] stated that eyes with significant ocular history or visually significant macular pathologies were excluded. Therefore, complications and visual results may not represent the “real world”, since patients who undergo fixation

commonly have other eye diseases, as observed in some of our patients. In the present study, 18/20 (90%) patients exhibited improvements in visual acuity when comparing the uncorrected visual acuity before and after surgery, achieving visual stability in the first month (Figure 4), and 14/20 (70%) had equal or better final visual acuity when comparing the pre and postoperative corrected acuities.

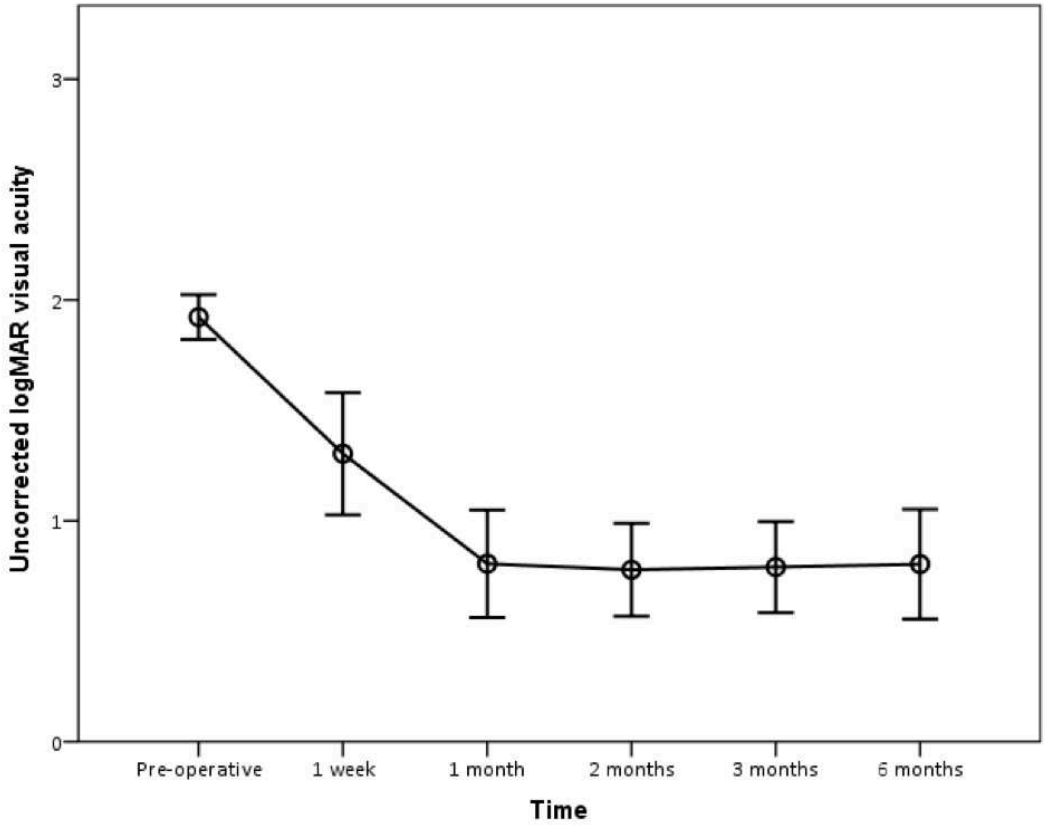

Figure 4 The mean uncorrected logMAR visual acuity during all follow-up visits (1.92 pre-operative, 1.30 in 1 week, 0.81 in 1 month, 0.78, 0.79 and 0.8 in 2, 3 and 6 months). There was significant improvement in uncorrected visual acuity after IOL scleral fixation in all study periods when compared to baseline values ($p \leq 0.001$). Improvement steadiness occurred 1 month after surgery.

In this study, corneal edema was the most frequent complication in the immediate postoperative period (75% on day 1). However, it was a transient condition; none of the patients had corneal edema after three months. Khan et al. (2019)[5] reported transient corneal edema (less than one month) in 12 (19%) eyes; Patel et al. (2018)[20] found significant persistent corneal edema (longer than one week) in 4/49 (8.2%), and one case with a predisposition to endothelial disease developed prolonged edema

Another important consideration is anterior segment inflammation. We observed that the presence of cells in the anterior chamber was an uncommon event (20% of patients on the

seventh postoperative day), that had a maximum duration of three months. This information is not usually mentioned in studies on scleral fixation with Akreos AO60, although it is relevant, since, theoretically, this hydrophilic acrylic lens causes less inflammation than hydrophobic acrylic, and silicone lenses.[23] Khan et al. (2016)[7] reported a range between 1.1% and 5.4% of anterior uveitis in cases of iris fixation, scleral fixation, and anterior chamber IOLs reported in other studies.

A positive Seidel test (wound leakage) was observed in only one patient on the first postoperative day. This may have occurred due to the need to expand the corneal incision in this case for IOL explantation. The evolution of cataract surgery to smaller corneal incisions due to the use of folding IOLs and the ease of cutting these explanted IOLs would be expected to decrease the risk of wound leakage. In 2016, Terveen et al.[10] performed scleral fixation of Akreos with Prolene or Gore-Tex sutures in 35 patients, with a mean follow-up of six months, and described the occurrence of iritis in 2 (5%) eyes and wound leakage in 1 eye (3%).

A frequent postoperative complication in the present study was conjunctival erosion with suture exposure; 8/20 (40%) patients exhibited Gore-Tex exposure throughout the 6-month follow-up period. We chose not to rotate and bury the suture due to the risk of displacing the on piece IOL, a fact that may have led to the higher rate of suture exposure in our study compared to in other studies. In 2020, Bonnell et al.[21] reported suture exposure in 1/15 (7%) patient, and in 2018 Patel et al.[20] reported one case with Gore-Tex suture erosion with purulent scleritis, even though the thread was rotated during the sclerotomy. Rotating the suture may warp this soft lens, especially if the suture is too tight.27 Because of that, we recommend to bury the knot under a flap to reduce this complication, as reported by Fass et al. (2010)[14]. This group used a similar technique to that employed herein although, in addition to using prolene, they created scleral flaps, which can be a technique to reduce the risk of conjunctival erosion by the suture. Similarly, Goel et al. (2018)[11] stated that the use of scleral flaps and the rotation of the suture knots decrease the risk of suture erosion. In their 2015[7] and 2018[9] publications, Khan et al. did not observe any suture-related complications, including rupture, erosion, IOL dislocation or inclination, endophthalmitis, or persistent postoperative inflammation.

As for lens-related complications, one patient presented with cells in the anterior chamber and lens opacification in the fourth month after surgery. Opacification of the Akreos AO60 and other such hydrophilic IOLs, due to gas tamponade, is an occurrence reported in

the literature;[24] therefore some surgeons have changed their preferred IOL to hydrophobic acrylic IOL's, but unfortunately there is no hydrophobic 4-point IOL available in the Brazilian market. In our case, no gas was used intraoperatively, and there was an improvement in the anterior chamber inflammation and lens opacification after using topical corticosteroids. Of note, this patient had a previous history of recurrent anterior idiopathic uveitis.

An occurrence that is not frequently described in scleral fixation studies is the observation of retinal changes in the immediate postoperative period. In our study, a patient presented on the first postoperative day with macular intraretinal hemorrhages, which may have been caused by the trauma during lens fragmentation. Four months after surgery, we noted a disorganization of the outer retina on the OCT, which probably explains the final visual acuity of 1.0 logMAR (20/200 Snellen equivalent).

Two (10%) patients in our study had transient vitreous hemorrhages (VH), with resolution within one month. The VH probably be related to scleral wound sutures and hypotony at the end of surgery. In one of these two eyes, retinal detachment (RD) was observed 20 days after the surgery. Following pneumatic retinopexy, the retina was successfully attached, but after a laser session, the patient developed corneal deepithelialization, herpetic keratitis, and corneal opacity (2.1 logMAR final acuity). Khan et al. reported VH in 7%, 7.1%, and 9.5% in their 2014[1], 2018[9], and 2019[5] publications, respectively, but no cases of RD. Patel et al. (2018)[20] reported VH in 5/49 (4.8%) patients and one case of postoperative RD. The incidence of VH varied from 0 to 12.2% in studies comparing other IOL implantation techniques.[7]

After 6 months of follow-up, 2 (10%) of our patients were noted to have ERM and 3 (15%) had CME. In the current study, since OCT was not routinely performed in all patients, it is not possible to determine with certainty when during the postoperative period the ERM and CME developed, or whether these retinal findings were already present prior to surgery. Preoperative OCT was not possible due to media opacity, such as retained lens material. In 2017, Khan et al. reported CME in 4.8% of patients; they observed this complication in patients who underwent pars plana lensectomy concomitantly with phacofragmentation for traumatic cataracts, subluxed crystalline, or retained lens material.

We observed a statistically significant variation in the endothelial cells count among our patients (mean of 1,740.50 cells/mm^2 preoperatively to 1,187.19 cells/mm^2 postoperatively; $p < 0.001$). Specular microscopy data are not routinely discussed in previous

series of scleral fixation, even though such information constitutes an important factor related to the risk of corneal decompensation. None of the patients in our study developed chronic corneal edema, but all of our patients had an endothelial count above 1,000 cells/mm^2 at baseline. Despite the reduction in the endothelial count between pre and postoperative periods, there was no significant change in the pachymetry values (mean of 562µm preoperatively to 564µm postoperatively; $p = 0.775$), consistent with the absence of any cases of chronic edema.

Three of the 20 (15%) eyes presented with hypotony (IOP < 5 mmHg) on the first postoperative day, without secondary complications. This may have been caused by leakage of the sclerotomies, which were sutured at the end of the procedure only when necessary. At one week after surgery, all IOPs had normalized, probably due to sclerotomy healing.

Methods to decrease the risk of postoperative hypotony include performing a fluid-air exchange at the end of surgery (although this increases the risk of lens opacification) and using smaller gauge instruments. In 2014, Khan et al.[1] observed transient hypotony in 9.4% of their patients, but in their 2018 study there was no cases of hypotony; 23-gauge and 23 or 25-gauge instruments were used, respectively. Patel et al. (2018)[20] used 23 or 25-gauge instruments and reported ocular hypotony (IOP ≤ 5 mmHg) in 6/49 (12.2%) patients.

Throughout the 6-month follow-up, 2/20 (10%) patients presented with ocular hypertension (Table 3). At the 6-month evaluation, none of the patients had IOP ≥ 25 mmHg, and 5/20 (25%) used IOP-lowering medication. Ocular hypertension was a finding described in all recent studies of scleral fixation with sutures, with the reported proportion of affected patients being 3.6%,[9] 7%,[1] 7.9%,[5] 16.3%,[20] and 24%.[10] In their 2016 report, Khan et al.[7] compared sutureless scleral-fixated, iris-fixated, and anterior chamber lens implantation from other studies; reported rates of transient ocular hypertension ranged from 4% to 12.4%. However, the measurement of IOP alone does not reflect all cases of elevated IOP. The proportion of patients using ocular hypotensive agents and IOP variation comprise two other important considerations. Twenty percent of our patients were taking hypotensive eye drops after six months of follow-up, despite having normalized IOPs, and 45% showed an IOP increase of at least 5 mmHg over the course of follow-up when compared to baseline.

Table 3. Postoperative complications

Postoperative Complications	No. of eyes (%)	Date of the first and last observation of the occurrence	Therapy / Outcome
Corneal edema	15 (75%)	1 day - 60 days	Observation / Resolution
Exposure of suture	8 (40%)	7 days - 6 months	-
ACR	6 (30%)	1 day - 60 dias	Observation / Resolution
Ocular hypotony	3 (15%)	1 day	Observation / Resolution
CME	3 (15%)	After 6 months	In treatment
ERM	2 (10%)	After 6 months	-
Vitreous hemorrhage	2 (10%)	1 day - 7 days	Observation / Resolution
Ocular hypertension	2 (10%)	1 week - 3 months	Topical Hypotensive Drugs
Opacification of IOL	1 (5%)	120 - 150 days	Topical corticosteroids
TASS	1 (5%)	1 day - 7 days	ATB + Dexa IV
Retinal detachment	1 (5%)	21 days - 30 days	C3F8 + laser / Resolution

ACR - Anterior chamber reaction
CME - Cystoid macular edema
TASS - Toxic anterior segment syndrome

In spite of the safety and favorable visual results associated with scleral-fixated IOL implantation, little is known regarding the refractive outcomes of scleral-fixated IOLs and the optimal IOL calculation formula for use with these lenses.[6] Many studies do not describe the sclerotomy position or the applied IOL calculation formula, thus limiting comparisons. In 2016, Terveen et al.[10] reported results from 37 eyes who underwent scleral fixation of Akreos A060 with 9-0 Prolene or Gore-Tex, and the refractive results of 18 patients were analyzed. The mean postoperative spherical power was +0.08 ± 1.31D (SD) (range -2.75 to +2.00 D), which is comparable to the mean postoperative spherical power in our study (was also +0.46 ± 1.34D [SD] [range -1.50 to +3.0]).

In the present study, the mean postoperative spherical equivalent (SE) ± SD and the mean residual SE (postoperative SE minus target refraction) were -1.12 ± 1.50D and -0.72D,

respectively, values that are similar to other studies. In 2019, Botsford et al.[12] reported results from 31 patients who underwent scleral fixation of Akreos A060 or CZ70BD lenses with CV-8 Gore-Tex suture, 3 mm posterior to the limbus. The mean postoperative SE ± SD was -0.79 ± 0.95D. Mean residual SE was -0.19D, indicating a tendency towards slightly myopic results. Postoperative keratometry values to assess corneal astigmatism were not determined, although scleral tunnels were performed. Other authors have also described a greater myopic tendency than planned; Fass et al. (2010)[14] reported results from 9 eyes who underwent scleral fixation of Akreos A060 with 9-0 or 10-0 Prolene; the mean postoperative residual SE was -0.40D. Su et al. (2019)[13] analyzed the results of 55 patients who underwent scleral fixation with Gore-tex suture and Akreos A060 or enVista MX60 lenses. The mean postoperative SE ± SD was -0.99 ± 1.00D, and the mean residual SE was -0.64D. Typically, when placing sclerotomies 2 mm posterior to the limbus, a sulcus-based calculation is carried out, which involves reducing the IOL power by 0.5 to 1.0D.

In 2017, Theodoulidou et al.[25] reported the surgically induced astigmatism (SIA) of twenty publications of eyes who underwent cataract surgery with phacoemulsification and described values that ranged from 0.24 to 1.65D depending on the size and location of the incision. In 2019, Su et al.[13] found a mean SIA of 0.77D, a much lower value than that found herein, which was -3.21 ± 1.57D (range: -1.0 - -6.0). It is noteworthy that, in general, astigmatism is lower in more recent studies, such as that by Su et al. (2019)[13]. Since the new lenses are foldable, such as Akreos A060, it is possible to make smaller corneal incisions. However, incision expansion may be required for IOL explantation. In the present study, 6 patients underwent IOL explantation, a procedure that has declined in frequency due to the availability of more adequate instruments, such as scissors to cut the lens.[26] We also observed a greater postoperative astigmatism after complicated cataract surgery. Theoretically, making scleral tunnels can lead to less induced astigmatism, and may be an alternative in cases that a new incision should be created.

Limitations of the present study include its limited sample size, and relatively short duration of follow-up. Longer-term follow-up is warranted to evaluate such potential complications as suture breakage and dislocation of the lens.

Another limitation of this study is that other surgical techniques were not evaluated, thus hampering comparison. Also, pre and postoperative keratometry were not analyzed for comparison and to define corneal astigmatism. However, we observed greater total astigmatism in patients who had an IOL explant. Further, the rates of postoperative

complications and the final visual acuity may have been influenced by posterior segment pathology. It would have been interesting to perform OCT before and after surgery in all patients, throughout the follow-up, to identify retinal changes and correlate them with visual acuity. However, preoperative OCT was not possible due to media opacity, such as retained lens fragments.

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Figures

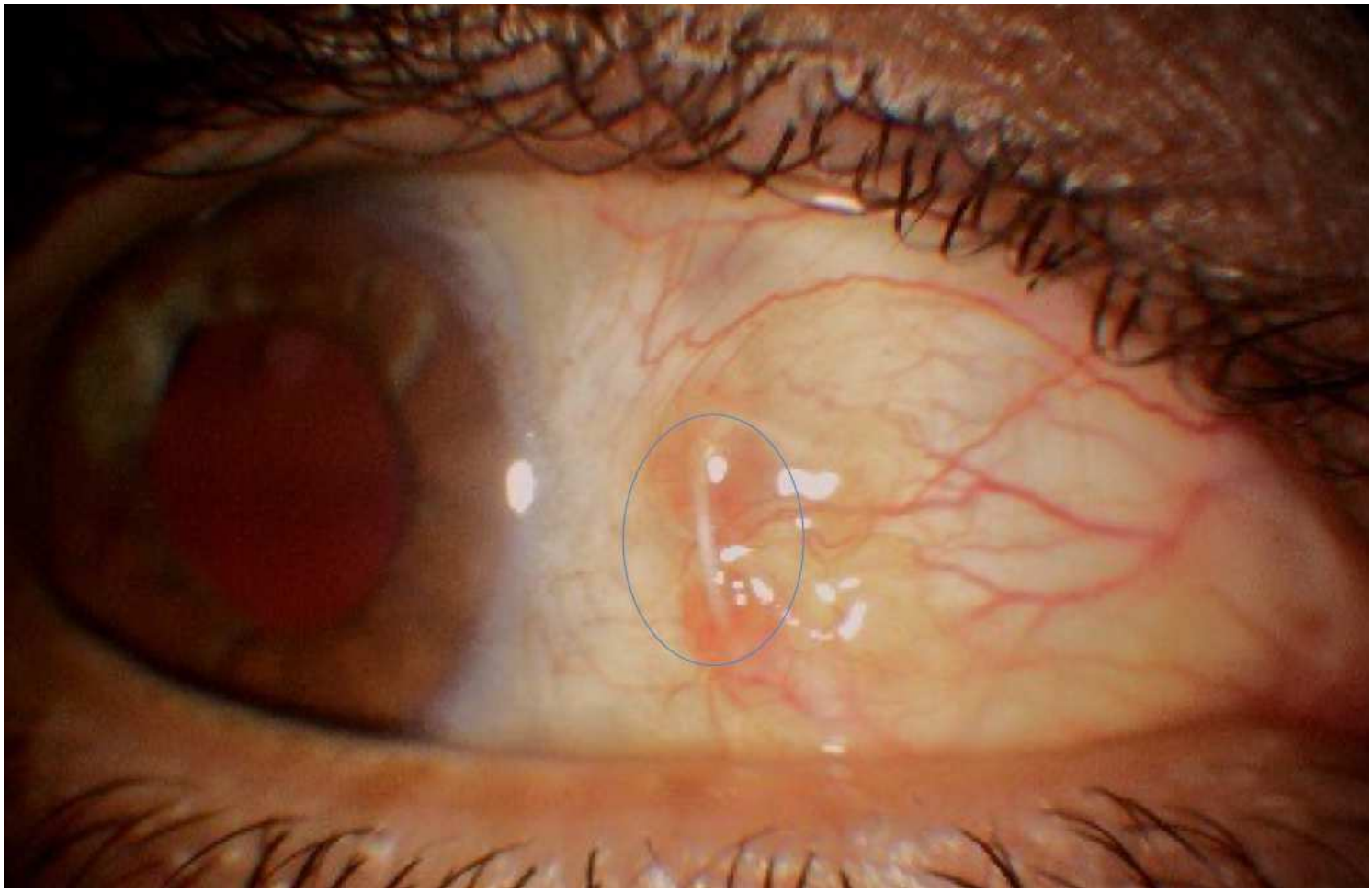

Figure 1

Gore-Tex suture exposure after surgery. In this case, the suture, not the knot, eroded the conjunctiva 7 days after surgery.

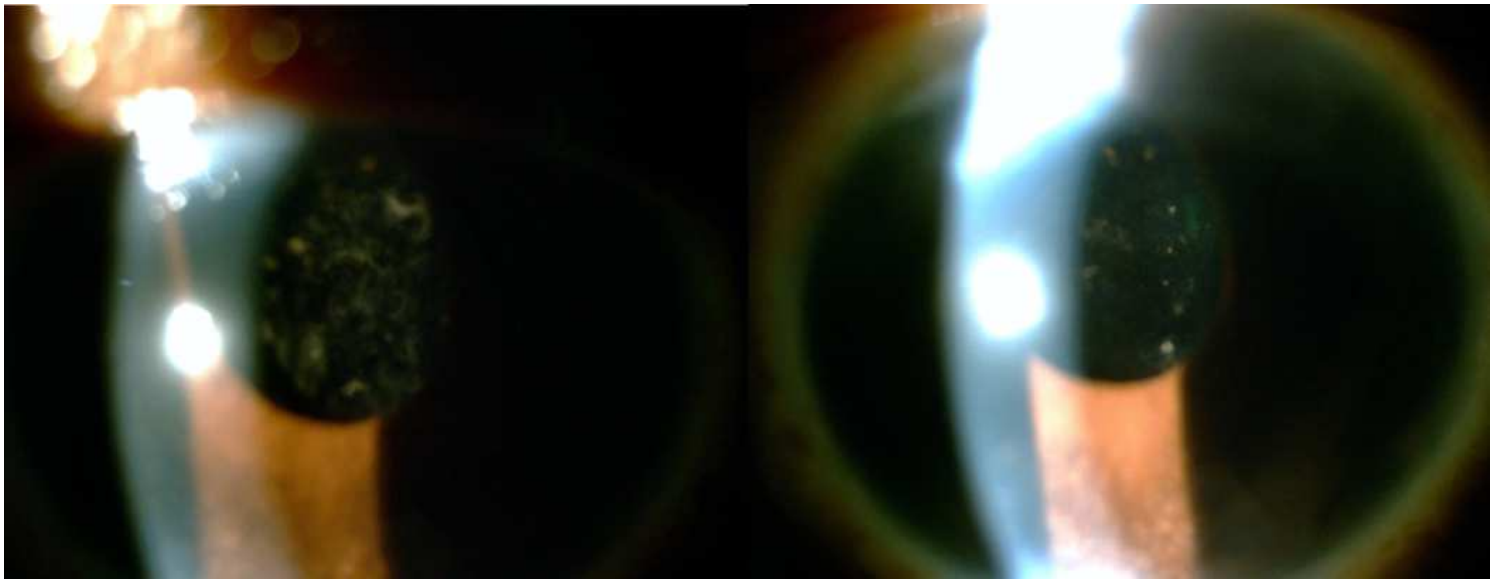

Figure 2

(a) Akreos intraocular lens opacification four months after surgery; (b) Improvement in lens opacification two months after treatment with topical corticosteroids. The patient had a previous history of recurrent anterior idiopathic uveitis.

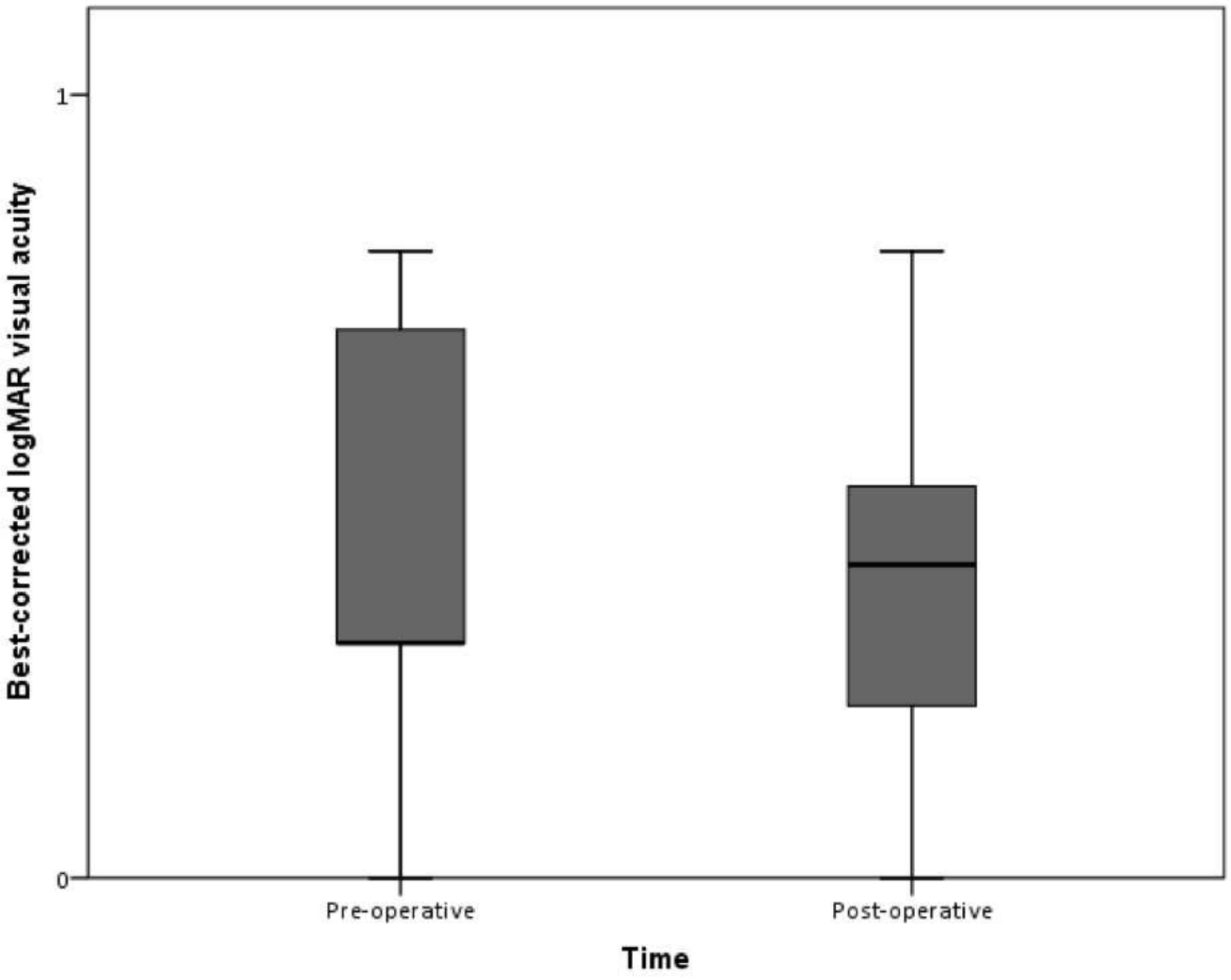

Figure 3

Box plot graphics showing the similarity in best-corrected visual acuity at baseline (preoperative: mean logMAR BCVA: 0.43) and 3-6 months after surgery (postoperative: mean logMAR BCVA: 0.37). Middle line represents the median, the square represents the mean, the 25th and 75th percentiles determine the box and the 5th and 95th percentiles determine the whiskers.

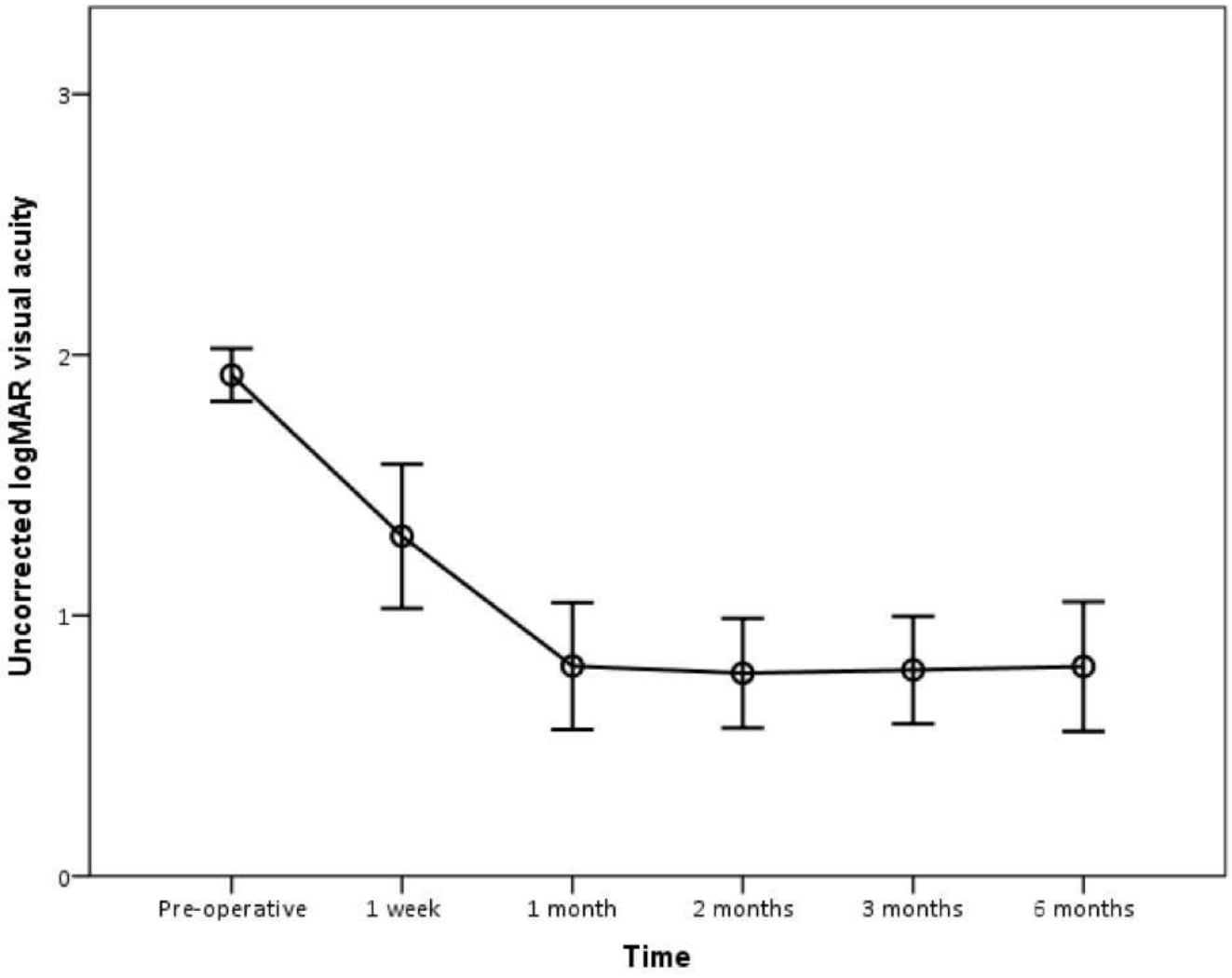

Figure 4

The mean uncorrected logMAR visual acuity during all follow-up visits (1.92 pre-operative, 1.30 in 1 week, 0.81 in 1 month, 0.78, 0.79 and 0.8 in 2, 3 and 6 months). There was significant improvement in uncorrected visual acuity after IOL scleral fixation in all study periods when compared to baseline values ($p \leq 0.001$). Improvement steadiness occurred 1 month after surgery.