Repositioning of in-the-bag Dislocated Intraocular Lenses: A Randomized Clinical Trial Comparing Two Surgical Methods

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Keywords
In-the-bag dislocated intraocular lens · Intraocular lens repositioning · Intraocular lens tilt

Abstract

Introduction: The aim of this study was to evaluate intraocular lens (IOL) tilt, IOL-induced astigmatism (IIA), refractive change, and impact of capsular fibrosis on IOL position after scleral fixation of dislocated IOL using two methods: ab externo scleral suture loop fixation (group A) and a modification, embracing the continuous curvilinear capsulorhexis (group B). Methods: In this prospective randomized clinical trial conducted at St. Erik Eye Hospital, 117 patients with dislocated IOL were randomized to group A (n = 61) or B (n = 56). Patients with ordinary pseudophakia (n = 60) served as controls. IOL tilt was measured three-dimensionally with anterior segment optical coherence tomography (AS-OCT). Results: The median IOL tilt was similar with both methods (A: 7.8°; B: 8.3°; p = 0.51) but higher than in ordinary pseudophakia (5.4°; p < 0.001). Both groups showed a myopic shift, p < 0.001. In cases without capsular fibrosis, the median IOL tilt was 15.5° in group A (n = 7) and 7.0° in group B (n = 5), p = 0.19. For each degree of IOL tilt, IIA increased by 0.075 D (p < 0.001). IOL position could be measured with AS-OCT in all patients given that the IOL was visible in the pupil. Conclusion: After IOL fixation surgery, IOL tilt is higher than in normal pseudophakia. A study involving more patients without capsular fibrosis could clarify whether IOL position is better with method B in this subgroup. IAA is low, but myopic shift is common. AS-OCT is useful for IOL tilt assessment after IOL fixation surgery.

Introduction

One of the complications of cataract surgery is late intraocular lens (IOL) dislocation. Either the whole IOL-capsular bag complex dislocates (in-the-bag dislocation; about 80–90% of cases) or a dislocated IOL is not surrounded by a capsular tissue (out-of-the-bag dislocation; about 10–20% of cases) [1, 2]. Surgical techniques for in-the-bag dislocations usually use capsular tissue, e.g., in the standard approach “ab externo scleral suture loop fixation” [3], the capsule-IOL complex is sutured to the sclera with polypropylene loops around the IOL haptics through the capsular bag. The results are usually good, but the IOL position is sometimes not optimal [3–7]. With this method, the status of capsular bag might be important. Possibly, only fibrotic bags can keep the suture in place, whereas if the bag is not fibrotic, passing a needle could be impossible.

Trial registration number: NCT04150263.
through both layers of the capsular bag may cause the suture to cut through the capsule tissue with subsequent IOL decentration and/or tilt. As the suture loop includes the haptic as well, it is unlikely that the IOL will dislocate entirely; however, even partial tears of the bag may cause IOL decentration. For this reason, we evaluated a modified method “embracing the continuous curvilinear capsulorhexis (CCC),” developed by LA. In this method, the CCC is embraced (i.e., the suture loop goes around the CCC; Fig. 1). We hypothesize that the CCC opening, even in capsular bags without fibrosis, is sufficiently tear resistant to hold the suture and thereby the IOL-capsule complex in place. Gimbel et al. [8] suggested suturing through the rim of the CCC (i.e., CCC is perforated); however, this method works only when the CCC is fibrotic.

IOL position and IOL-induced astigmatism (IIA) are outcomes of IOL repositioning surgery. IIA was previously estimated in theoretical models but not in humans [9, 10]. Automated measuring of three-dimensional (3-D) IOL position was described in ordinary pseudophakia [11] but not after IOL fixation surgery. Previous studies relied on IOL position assessment with subjective slit-lamp examination or indirectly as a change in best corrected visual acuity (BCVA), refraction, and total ocular astigmatism [3–5, 7, 12–17] or included other...
methods, such as IOL Master, ocular coherence tomography, ultrasound biomicroscopy, or Purkinje reflexes [18–24]. Previous studies aiming for 3-D IOL position assessment used reconstructed models that required additional calculations [21, 22, 24]. Overall, randomized trials evaluating surgery of dislocated IOL are few [17].

In this prospective randomized clinical trial, we evaluated 3-D IOL position, IIA, and refractive change after IOL fixation to the sclera with two methods: ab externo scleral suture loop fixation (group A) and a modification, embracing the CCC (group B). We also evaluated whether the absence of capsular fibrosis and Soemmering’s ring (S-ring) affects the IOL position postoperatively with these two surgical methods. Finally, we evaluated the usefulness of swept-source anterior segment coherence tomography (Casia 2, Tomey, Japan) for automatically assessing the 3-D IOL position after IOL fixation surgery.

Materials and Methods

This prospective randomized parallel group study followed the tenets of the Declaration of Helsinki and was approved by the Regional Ethics Committee in Stockholm, Sweden. The study was registered at ClinicalTrials.gov (identifier, NCT04150263). Written consent was obtained from all patients between October 2018 and October 2020.

Patients with a dislocated IOL were referred to St. Erik Eye Hospital, a tertiary referral center. The inclusion criteria were in-the-bag IOL dislocation ≥6 months after the cataract surgery, intact CCC, willingness to participate in the study, IOL visible in the pupil, and an IOL design with 2 open-loop haptics. The exclusion criteria were inability to cooperate, a completely dislocated IOL, IOL re-dislocation, and ectopia lentis because of Marfan’s syndrome. In bilateral cases, only the eye operated first was included. The main outcome was the 3-D IOL position at 6-month follow-up.

Patients with ordinary pseudophakia (n = 60) were identified as eligible in the Swedish National Cataract Register and were recruited as controls (the Pseudophakic group), which served as a reference for “normal IOL position.” The inclusion criteria for the controls were uneventful phacoemulsification with IOL implantation performed 7–10 years before the data collection, age ≥75 years, and a well-centered IOL on the date of examination. The exclusion criterion was a history of any other intraocular surgery.

A flowchart is presented in Figure 2. During the specified period, 294 referred patients had in-the-bag IOL dislocation that required surgical approach. 117 were enrolled in the study and were randomized either to IOL suturing by the traditional ab externo scleral suture loop fixation method (group A, n = 61) or by the modification embracing the CCC (group B, n = 56). A number of cards were apportioned for each type of procedure by 1:1 and placed into opaque sealed envelopes. Just before the surgery, a random envelope was chosen for assignment, without replacement. Participants got routine information about IOL repositioning but were masked to the type of surgery. One surgeon (LA) made all enrollments, performed all surgeries, and assessed outcomes, at the latter stage masked to the type of surgery during the data collection: first, all data except the type of surgery were gathered in an Excel sheet; the type of surgery was included last, just before statistical analyses. The original study protocol included 3 follow-up visits: 1, 6, and 18 months, of which the latter was canceled because of the corona pandemic.

Examinations and Measurements

The main outcome 3-D IOL position (magnitude and direction of IOL tilt in degrees) was quantified with Casia 2 after pupil dilation (online suppl. Fig. 1; for all online suppl. material, see www.karger.com/doi/10.1159/000529506) and compared between the three study groups. To evaluate whether the presence/absence of capsular fibrosis impacts IOL position, IOL tilt was calculated in patients without fibrosis and S-ring and in patients with fibrosis and/or S-ring and compared within and between the groups A and B. Fibrosis intensity was graded as none (capsular bag was clear), moderate (the bag was slightly white), and advanced (the bag was intensely white) on slit-lamp examination and confirmed during the surgery, as well as presence/absence of S-ring.

The Casia 2 usefulness for measuring IOL position was evaluated by the number of patients in whom the IOL position could be assessed. Refraction and keratometry were obtained by auto-keratorefractometry (Auto Ref/Keratometer Nidek Co., ARK-1), and IIA was calculated as follows:

Total ocular astigmatism (by autorefractometry) – total corneal astigmatism, the latter by Casia 2, which also measures posterior corneal astigmatism.

IIA was calculated with a method similar to that proposed by Naeser [25]. Total astigmatism (T), angle of cylindrical axis, corneal astigmatism (C), and angle of the astigmatic steep axis were converted to two astigmatic power vectors, KP0 and KP45, separately for the (T) and (C): KP0 = T (or C)*cos (2*angle), KP45 = T (or C)*sin (2*angle). Thereafter, the IIA was calculated in polar values by subtracting KP0 (T) from KP0 (C) and KP45 (T) from KP45 (C); IIA (KP0) = KP0 (T) – KP0 (C) and IIA (KP45) = KP45 (T) – KP45 (C). Thereafter, the IIA in polar values was reconverted to cylindrical values by the formula: \[ \sqrt{IIA (KP0)^2 + IIA (KP45)^2} \]. Finally, the quantitative relationship between IOL tilt and IIA was calculated by linear regression model.

BCVA was assessed with Snellen chart and converted to logarithm of the minimal angle of resolution values for statistical analyses. Intraocular pressure (IOP) was measured with Goldmann applanation tonometry.

The change in spherical equivalent (SE) was calculated as the difference between the SE ≥1 year prior to the IOL dislocation and the SE 6 months after the surgery. The presence of macular edema was determined by optical coherence tomography (TOPCON 3D OCT-2000; Topcon Corporation, Japan).

Participants from the Pseudophakic group (n = 60) underwent dilated slit-lamp examination; IOL tilt was measured with Casia 2 and compared with groups A and B. In analyzing the IOL tilt and refraction outcomes at 6 months, we employed the “last observation carried forward” method for the reoperated cases, using 1-month outcomes of these cases in the 6-month analyses.

Surgery

Schematic illustration of surgery is shown in Figure 1. Duration of the surgery was from placing until removal of the drape. 1 case...
was performed under general anesthesia, the rest under local anesthesia (topical, subtenon, and intracameral). Pupils were dilated with topical cyclopentolate 1% and phenylephrine 10%. Three 2-mm corneal incisions were placed, and the anterior chamber (AC) was filled with viscoelastic (1% sodium hyaluronate, Z-Hyalin plus 15 mg/mL, Zeiss, Inc.). Two conjunctival peritomies and two scleral grooves of half the scleral thickness were fashioned at the 6 and 12 o’clock positions, 2.5 mm behind the limbus. If the IOL haptics were not positioned at 6–12, the IOL was rotated.

In group B, a 27-gauge needle was passed through the scleral groove, perforated the posterior layer of the capsular bag peripherally under the haptic, and entered into the bag “cavity,” leaving the bag between the IOL optic and the capsulorhexis. In group A, the needle instead perforated both layers of the capsular bag (Fig. 1). Thus, in both groups, the loop always included the IOL haptic; in group B, it also included the CCC edge. The needle was then exited through the corneal incision. A long, straight needle with 10-0 polypropylene (Ethicon, 1713, Prolene Non-Absorbable Sutures, STC-6) was docked into the 27-gauge needle, and the complex was retracted through the scleral groove. The procedure was repeated, with needles passing through the ciliary sulcus but without entering the capsular bag. Lastly, the same procedure was repeated on the opposite side. Needles were cut off and sutures were tightened until a slight fold was seen in the CCC edge (group B) and tied in the scleral groove; knots were rotated into the sclera. The conjunctiva was sutured with 7-0 vicryl (Ethicon, vicryl 7-0, Diegem, Belgium). Acetylcholine hydrochloride (Miochol-E; Bausch & Lomb, Irvine, CA, USA) was injected into the AC, and any vitreous was removed from the AC. Sodium hyaluronate was removed and moxifloxacin (Vigamox 1 mg/mL, 0.2 mL) was injected into the AC. All patients were given 250 mg acetazolamide once and received topical therapy with dexamethasone (Isopto-Maxidex 1 mg/mL) 4 times daily, tapered over 4 weeks.

**Statistical Methods**

Power analysis showed that 27 cases in each group could detect a 5-degree difference in IOL tilt between the treatment groups with 95% power at $\alpha = 0.05$, expected standard deviation of 5.0, and ratio between the groups 1:1. Based on our clinical experience, a high proportion of patient loss was expected during follow-up; therefore, we decided to recruit 61 patients in each group.

Statistical analysis was performed using the software IBM SPSS version 27 (IBM Corp., Armonk, NY, USA). Non-normally distributed data are presented as medians and interquartile ranges (IQRs), and for statistical calculations, nonparametric tests were used as appropriate. For normally distributed quantitative data, parametric statistics was employed, and data are presented as means ± standard deviations. A 95% confidence interval (CI) is

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**Fig. 2.** CONSORT flowchart presenting 6 months of follow-up. *Number of patients with available data for the main outcome IOL tilt.
provided for group comparisons of BCVA and for the IIA/IOL tilt in linear regression model.

## Results

Baseline characteristics of 117 randomized patients (groups A and B) and 60 pseudophakic controls are shown in Table 1. A summary of the outcomes is presented in Table 2.

Six months after the surgery, a total of 87 patients in groups A and B were analyzed. The IOL tilt did not differ between groups A (7.8°) and B (8.3°), but each group differed significantly from the pseudophakic controls (5.4°) (Table 2). The mean difference between the pseudophakic and the dislocated group (groups A + B) was 3.75°, CI = 2.54°–4.95°, *p* < 0.001. IOLs were predominantly tilted toward the inferotemporal quadrant, both in groups A and B and in the Pseudophakic group (Table 2; Fig. 3). In cases without fibrosis and S-ring, the median tilt in group A was 15.5° and 7.0° in group B; this difference did not reach statistical significance, possibly due to the low number of cases (Table 2). Presence of S-ring did not impact IOL tilt in any analyses.

In the Pseudophakic group, the highest value for IOL tilt was 9.1°. In groups A and B, a total of 18 patients had IOL tilt ≥15°. Five patients were re-operated before the 6-month visit: 3 in group A and 2 in group B (here, one IOL was twisted by gas under retinal detachment surgery). The IOL was exchanged in 2 cases. In other 3 cases, additional prolene suture was placed around the CCC using method B; the mean IOL tilt diminished from 18.7° to 9.8° after the reoperation. According to linear regression, the IIA increased by 0.075 D with increase of each degree of IOL tilt (*p* < 0.001, 95% CI = 0.035–0.115).

BCVA improved significantly, but a myopic shift was observed in both groups (Table 2). In the entire group with dislocated IOL, BCVA of 0.5 (Snellen chart) was achieved in 71 out of 87 cases (81.3%) at 6 months, reoperated patients were excluded, and a myopic shift was seen in 86% of cases.

The median time of surgery was 22 min (range 13–42), slightly longer in group B (Table 2). Complications are listed in Table 2. Measuring IOL position with Casia 2 was possible in all patients but 2 cases in group A at 1 month, where the IOL was not visible in the pupil due to pronounced dislocation.

### Conclusion

Here, we report on the 3-D IOL position after IOL fixation to the sclera. Our study shows that Casia 2 is useful for 3-D measuring of IOL tilt after IOL fixation. We also report that feasibility of IOL fixation using the capsular bag might depend on the level of capsular fibrosis.

Other previously proposed modifications of the original method for scleral IOL fixation included usage of the CCC, which, however, require fibrosis of the CCC [8, 26]. Capsular fibrosis does not always develop; 11% of eyes in our study had no detectable capsular bag fibrosis or S-ring.

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**Table 1.** Baseline characteristics of patients operated for IOL dislocation with the ab externo scleral suture loop fixation method (group A) and a modification, embracing the CCC (group B) and controls with normal pseudophakia

<table>
<thead>
<tr>
<th></th>
<th>Group A (n = 61)</th>
<th>Group B (n = 56)</th>
<th>Pseudophakic group (n = 60)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age, years</td>
<td>81.4±6.7 (66–94)</td>
<td>81.4±5.1 (71–99)</td>
<td>78.8±3.2 (75–87)</td>
</tr>
<tr>
<td>Females/males, %</td>
<td>56/44</td>
<td>63/36</td>
<td>67/33</td>
</tr>
<tr>
<td>Right eyes</td>
<td>34 (56%)</td>
<td>28 (50%)</td>
<td>31 (52%)</td>
</tr>
<tr>
<td>Left eyes</td>
<td>27 (44%)</td>
<td>28 (50%)</td>
<td>29 (48%)</td>
</tr>
<tr>
<td>Glaucoma or OHT diagnosis</td>
<td>17 (28%)</td>
<td>21 (38%)</td>
<td>5 (8%)</td>
</tr>
<tr>
<td>IOP, mm Hg</td>
<td>15 (13–20)</td>
<td>17 (14–20)</td>
<td>–</td>
</tr>
<tr>
<td>ARMD</td>
<td>8 (n = 59*)</td>
<td>9</td>
<td>0 (n = 40*)</td>
</tr>
<tr>
<td>Other</td>
<td>1 macular pucker</td>
<td>1 central venous occlusion with macular edema, 1 macular hole</td>
<td>–</td>
</tr>
<tr>
<td>Mean BCVA (logMAR)</td>
<td>0.65±0.70</td>
<td>0.70±0.91</td>
<td>–</td>
</tr>
</tbody>
</table>

Data are presented as medians and interquartile ranges (IQRs) unless stated otherwise. ARMD, age-related macular degeneration; BCVA, best corrected visual acuity; IOP, intraocular pressure; OHT, ocular hypertension; logMAR, logarithm of the minimal angle of resolution. *Available data in medical charts or Swedish National Cataract Register.
The method here presented does not require a capsular bag, CCC fibrosis or S-ring, and results in good IOL position, comparable with the standard method. In patients without capsular fibrosis and S-ring, the IOL tilt was smaller in group B (7.0°) than in group A (15.5°), albeit without statistical significance, probably because of the

All results are presented in medians (interquartile range) unless otherwise stated. Exclusions from analyses were due to missing data (patients lost to follow-up, measurements not performed) or missing documentation of data. BCVA, best corrected visual acuity in logMAR; CCC, continuous curvilinear capsulorhexis; CI, confidence interval; IOL, intraocular lens; post-op, postoperatively; IIA, IOL induced astigmatism; SE, spherical equivalent; S-ring, Soemmering’s ring; SD, standard deviation. aLast observation carried forward (LOCF) method employed for 5 reoperated patients. bFive reoperated patients excluded. cSubgroup analyses at 6-month follow-up was not possible to perform due to missing data; therefore, we here present outcomes from 1-month visit. dA total of 47 patients in group A and 41 in group B had moderate fibrosis. According to multivariate regression model, the presence/absence of S-ring did not impact IOL tilt neither within nor between groups A and B, p = 0.721. Advanced fibrosis was seen in 4 (group A) and 5 (group B) patients. *Mann-Whitney U test. **Paired-samples t test. ***t test. ****Paired-samples Wilcoxon test. #In 2 patients in group A (1 patient in each subgroup), IOL tilt was impossible to measure because the IOL was located behind the iris. Therefore, the tilt was estimated to 30°.

The method here presented does not require a capsular bag, CCC fibrosis or S-ring, and results in good IOL position, comparable with the standard method.
small size of these subgroups. As mentioned, to find a difference of 5° IOL tilt would require 27 patients in each group. A study with more patients without capsular fibrosis is needed to elucidate whether “embracing the CCC” may be superior to the standard method in cases without capsular fibrosis. To prove long-term tear

Fig. 3. Directions and magnitudes of IOL tilt. The polar coordinates show the direction, and the Cartesian coordinates show the magnitude of IOL tilt from the visual axis 6 months after surgery. Upper figure shows outcomes of groups A and B: group A (red), group B (green-blue). Lower figure: pseudophakic control group. Note that the IOLs were predominantly tilted inferotemporally (with the inferotemporal border of the IOL tilted posteriorly and the superonasal border tilted anteriorly) in all groups: 42 cases out of 48 (87.5%) in group A, 34 out of 39 (87%) in group B, and 52 out of 60 (87%) in the Pseudophakic control group.
resistance of the CCC may also require a longer follow-up. However, this modification may be useful in early in-the-bag dislocation directly after cataract surgery of a loose crystalline lens, when capsular fibrosis has not yet developed. Furthermore, as “embracing the CCC” employs capsule tissue only, it may be applied in fixing a dislocated plate-haptic or similar IOLs because the haptics of such IOLs are not suited for suture loop fixation. The modified method can be used as additional technique to other surgical methods, as shown in 3 reoperations in our study. Limitations of “embracing the CCC” include the need for an intact CCC and a sufficiently large CCC opening. If these requirements are not fulfilled (there were no such patients in this study), it is preferable to fixate the IOL by the traditional ab externo method.

The current study shows that overall IOL position after IOL fixation to the sclera is good, although significantly different from that in ordinary pseudophakia. The 3.75° difference in IOL tilt from normal pseudophakia in our study might be of less clinical importance, as linear regression results show that IOL-related astigmatism is very low. Previous data based on theoretical ray-tracing model indicate that IOL tilt may induce even less astigmatism [9]. Furthermore, there is mirror symmetry between right and left eyes, and the direction of IOL tilt resembles that in normal pseudophakia [11, 27, 28] in our material. Thus, the IOL tilt after IOL fixation surgery with current methods may be seen as acceptable, even in cases with more substantial IOL tilt.

Kimura et al. [11] presented the use of Casia 2 for assessing the 3-D IOL position in ordinary pseudophakia. So far, no studies have been published on IOL position using the Casia 2 after IOL fixation surgery. We here show that Casia 2 is useful for also quantifying larger IOL tilt, e.g., after scleral IOL fixation. Accuracy and repeatability of the measurements are subjects for future research.

The refractive predictability was low in this study: 86% of eyes had a myopic shift postoperatively, explained by an anterior shift of the IOL. In our material, the IOL was sutured 2.5 mm behind the limbus, which is larger distance than the 1.8–2.0 mm used in another study that also reported a myopic shift [17]. The ideal distance to enter the ciliary sulcus is reported to be 3 mm from the limbus [29], which may reduce the risk for myopic shift. In the present study, 81.3% of cases reached a visual acuity of 0.5 or more, which matches or supersedes the results reported in other studies [3, 17].

Limitations of the study are as follows. The planned follow-up was 18 months, but the last visit had to be cancelled due to the corona pandemic. Six months is, however, a reasonable end point for evaluation of this type of surgical procedure and matches other comparable publications [3, 12, 14, 17, 19]. Evaluation of the level of capsular fibrosis in this study may seem inaccurate, but differentiating a completely clear capsular bag from the one with fibrosis and/or S-ring was straightforward.

In conclusion, suture fixation of a preexisting IOL to the sclera without IOL exchange appears to be a simple, rapid, and uncomplicated procedure, in most cases possible to perform under local anesthesia. The modification “embracing the CCC” offers one more alternative for repositioning of in-the-bag dislocated IOL. Our study also shows that AS-OCT can be used to compare the results from different surgical approaches for IOL fixation. This knowledge can be of value in future studies aiming to further improve the results after IOL fixation surgery.

Statement of Ethics

The research was conducted ethically in accordance with the World Medical Association Declaration of Helsinki. This study protocol was reviewed and approved by the Regional Ethics Committee in Stockholm, Sweden, approval number 2018/1838-31/2. A written informed consent was obtained from all participants to participate in the study.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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No funding was received for this study.

Author Contributions

L.A. was responsible for the conceptualization of the study, performance of the study, data management, statistics, and manuscript writing. A professional statistician was consulted regarding statistical analyses. A.B. was responsible for the supervision, validation of the study, and manuscript writing. Both authors provided a final review and approved the manuscript before submission.

Data Availability Statement

The datasets generated and analyzed during the current study are not publicly available due to restrictions in our ethical approval but are available from the corresponding author on request from editor to verify the results of the study.