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# Late In-the-Bag Intraocular Lens Dislocation

## *A Randomized Clinical Trial Comparing Lens Repositioning and Lens Exchange*

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***Purpose:*** To compare the efficacy and safety of 2 operation methods for late in-the-bag intraocular lens (IOL) dislocation.

***Design:*** Prospective, randomized, parallel-group surgical trial.

***Participants:*** Patients referred to Oslo University Hospital (tertiary referral center).

***Methods:*** We randomly assigned 104 patients (104 eyes) either to IOL repositioning by scleral suturing (n = 54) or to IOL exchange with retropupillary fixation of an iris-claw IOL (n = 50). One surgeon performed all operations. Patients were evaluated comprehensively before surgery, and most patients (82%) attended an examination 6 months after surgery.

***Main Outcome Measures:*** Best-corrected visual acuity (BCVA) 6 months after surgery.

***Results:*** The mean postoperative BCVA was 0.24±0.29 logarithm of the minimum angle of resolution (logMAR) units (range, −0.18 to 1.16 logMAR) in the repositioning group and 0.35±0.54 logMAR (range, −0.20 to 3.0 logMAR) in the exchange group ($P = 0.23$). A BCVA of 20/40 or better (Snellen) was reached by 61% and 62% of the patients, respectively ($P = 0.99$). The mean postoperative corneal cylinder was 1.2±1.0 and 1.2±0.8 diopters, respectively ($P = 0.84$), and the postoperative endothelial cell density changes were −3±10% ($P = 0.07$) and −10±14% ($P = 0.001$), respectively (group difference, $P = 0.04$). Repositioning had a longer mean surgical time than exchange ($P < 0.001$). There were 2 (4%) and 0 cases of perioperative fluid misdirection syndrome, respectively. Postoperative complications were intraocular pressure (IOP) increase (n = 12), cystoid macular edema (CME; n = 3), and nonarteritic anterior ischemic optic neuropathy (n = 1) in the repositioning group, and IOP increase (n = 9), pupillary block (n = 1), choroidal effusion (n = 2), CME (n = 4), and redislocation (n = 1) in the exchange group.

***Conclusions:*** We found satisfactory and not significantly different outcomes for BCVA 6 months after surgery in the 2 groups. Both operation methods seemed safe, with low frequencies of serious perioperative and postoperative complications. However, some of the observed differences in complications should be taken into consideration when selecting the most suitable method in clinical practice. *Ophthalmology 2016;■:1–9 © 2016 by the American Academy of Ophthalmology. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).*

In-the-bag intraocular lens (IOL) dislocation is considered a late complication of cataract surgery and is diagnosed an average of 6 to 9 years after in most cases uneventful surgery.[1–7] Dislocation of the IOL–capsule complex was almost nonexistent and not recognized until the advent of continuous curvilinear capsulorrhexis and was first described in 1993.[8] Several studies have reported an increasing trend in recent years.[1,7,9–11]

Pseudoexfoliation syndrome (PEX) has been established as an important risk factor for late in-the-bag IOL dislocation.[1,3–7,11–14] Pseudoexfoliation syndrome is associated with weak zonulae and contraction of the anterior capsule, which gradually may result in loosening of the IOL–capsule complex and eventually dislocation.[1,5,8,15] Pseudoexfoliation syndrome has a high prevalence in Scandinavian countries, and previous studies have detected pseudoexfoliative material in 11% to 17% of the patients referred to our department for cataract surgery.[16–18] Other conditions shown to predispose patients to late in-the-bag IOL dislocation, presumably through loosening of the zonulae, are previous vitreoretinal surgery,[1,2,19] myopia/increased axial length,[2,10,12] uveitis,[1,3] retinitis pigmentosa,[2,12] trauma,[1–3] and certain connective tissue disorders.[20]

The optimal management for late in-the-bag IOL dislocation is still being questioned. In principle, there are 2 different surgical approaches: repositioning of the existing IOL by fixating it either to the scleral wall or to the iris, or exchanging the IOL–capsule complex with a new IOL. Although different operating techniques have been compared previously, these studies have applied mainly a retrospective research design and most have included few patients.[2–4,6,7,11,12,14,21–23] To the best of our knowledge, no other randomized clinical trial comparing surgical



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treatment methods for late in-the-bag IOL dislocation has been conducted previously. In the present trial, we compared, by randomization of study participants, IOL repositioning by scleral suturing versus IOL exchange with an iris-claw lens. The aim was to compare the efficacy and safety of these 2 principally different operation methods.

## Methods

We performed a randomized clinical trial of patients referred to the Department of Ophthalmology at Oslo University Hospital (tertiary referral clinic) with late in-the-bag IOL dislocation between January 2013 and December 2015. Referred patients were considered consecutively for eligibility.

The inclusion criteria were as follows: IOL dislocation more than 6 months after cataract surgery, IOL inside the capsule and visible in the pupillary area in the supine position, eligibility for both operation methods, ability to cooperate fairly well during the examinations, and willingness to participate in the study. Repositioning surgery was considered unsuitable when a suture loop around the haptic could not be made (such as plate−haptic IOLs without holes in the peripheral part) or in patients requiring a change in IOL refraction. Exchange with an iris-claw IOL was not considered a proper technique in eyes with active uveitis; in the presence of a pathologic iris, such as large defects, much atrophy, or pronounced iridodonesis; or in eyes that previously had undergone Descemet's stripping automated endothelial keratoplasty. Totally dislocated IOLs into the posterior segment of the eye requiring pars plana vitrectomy were not included. We also did not include patients who before cataract extraction had a subluxated lens in need of surgery with a Cionni capsular tension ring (e.g., Marfan syndrome patients with ectopia lentis), because resuturing of the ring was considered the most appropriate operation method in these cases. For patients with dislocated IOLs in both eyes during the study period, only the first operated eye was included.

As shown in Figure 1, a total of 175 patients (180 eyes) with late in-the-bag IOL dislocation were referred in the specified period. Of these, 104 patients (104 eyes) were enrolled. We used a computer program for randomization that provided random permuted blocks. An optometrist who did not take part in the evaluation of eligibility or the surgery assigned patients to treatment groups. Enrolled patients were randomized (1:1) either to IOL repositioning with suturing of the haptics to the scleral wall (n = 54) or to removal of the IOL−capsule complex followed by replacement with a retropupillary iris-claw IOL (n = 50). Reasons for exclusion are presented briefly in Figure 1.

### Preoperative Examination

Time since cataract surgery and predisposing conditions were registered before surgery. Pseudoexfoliation syndrome status was determined based on the presence of dandruff-like material on the pupillary edge or if PEX was noted in the patient medical records before cataract surgery. Refraction and measurement of the best-corrected visual acuity (BCVA) were performed applying the Early Treatment Diabetic Retinopathy Study visual acuity chart with standardized lighting conditions in the room. In cases of substantially dislocated IOLs, a correction for aphakia was performed during visual acuity measurement. Best-corrected visual acuity values were converted to logarithm of the minimum angle of resolution (logMAR) values for statistical analysis and are presented as logMAR values unless otherwise stated. Goldman applanation tonometry was conducted before pupillary dilation.

The degree of IOL dislocation was evaluated with slit-lamp examination and photography of the anterior segment. We used the following classification: grade 1, small decentration with the optic of the IOL still covering the visual axis, often with pseudophakodonesis and a gap between the pupillary edge and the IOL; grade 2, the equator of the optic approximately in the visual axis; and grade 3, the IOL more decentered than grade 2, but at least 1 haptic still visible in the pupillary area. There was uncertainty about the BCVA measurement in several cases with dislocation grade 2 or 3 because of visual interference from the IOL edge or the haptics or nontransparent material in the superior part of the capsule.

### Surgical Procedure

All operations were performed using retrobulbar anesthesia by the same surgeon (L.D.), who has long experience with both surgical procedures. The pupil was dilated with cyclopentolate 10 mg/ml and phenylephrine 100 mg/ml twice 5 minutes apart, 30 to 60 minutes before surgery. The size of the pupil was measured with a strabismus caliper at the start of surgery. A cohesive viscoelastic (Healon GV OVD, Abbott Laboratories Inc., Abbott Park, IL) was used and removed at the end of surgery. Thereafter, 1 mg cefuroxime was installed into the anterior chamber. If present, vitreous strands were removed from the incision wound by a cellulose sponge applied externally followed by gently cutting with scissors, as well as internally sweeping possible incarcerated vitreous from the wound (termed *removal of vitreous strands from the incision*). In very old patients with liquefied vitreous humor, this procedure often was judged as sufficient. Otherwise, anterior vitrectomy was performed, if necessary, using the Stellaris Vision Enhancement System phacoemulsification machine (Bausch & Lomb, Rochester, NY). We recorded the surgical time (from the first incision to the removal of the surgical drape at the end of the operation). The clock was stopped if the surgeon had to wait for unpacking of instruments that were not prepared on the instrument table. We also registered whether a capsular tension ring was present, the type of IOL, and any perioperative complications.

**Suturing of the Haptics to the Scleral Wall (Repositioning).** Repositioning surgery was performed using the ab externo suture loop closed-system fixation technique, which has been used by several other investigators and is illustrated and described in detail by Chan et al.[24] Iris hooks were used if the haptics could not be identified. A scleral triangular flap was made behind the limbus corresponding to the superior haptic location, followed by a limbal incision approximately 180° apart. A straight needle on a 10-0 Prolene suture (Ethicon, Sommerville, NJ) was introduced through the limbal incision. Thereafter, a bent 27-gauge cannula was introduced under the scleral flap, through the scleral wall, beneath the middle part of the haptic, through the capsule, and into the straight needle, followed by retraction of the needle−cannula complex from the scleral incision port. This procedure was repeated with the cannula in front of the IOL−capsule complex, making a loop around the haptic. Then the entire procedure was repeated at the opposite site. For exactly 180° alignment of the 2 Prolene sutures, a Mendez degree gauge, which is a measuring instrument with 10° increments, was used to mark the limbus to avoid tilt and decentration of the IOL. For the same reason, the sutures were adjusted before tightening the knots. In cases of 3 closed haptics, 3 loops were made. The sutures were placed 1 to 2 mm behind the limbus to ensure that the haptics within the capsular bag were anchored away from the posterior iris to avoid friction. Finally, the scleral flaps were placed over the suture knots. The conjunctiva was sutured with 10-0 nylon.

**Replacing the Intraocular Lens−Capsule Complex with a Retropupillary Iris-Claw Intraocular Lens (Exchange).** The IOL−capsule complex was luxated into the anterior chamber using cohesive viscoelastics and the viscoelastics cannula, followed by explantation through a 5.5-mm scleral pocket arcuate incision at the