Longitudinal corneal endothelial cell loss after corrective surgery for late in-the-bag intraocular lens dislocation: a randomized clinical trial

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Short title: Long-term endothelial cell loss in IOL dislocation surgery

SYNOPSIS:

This randomized clinical trial of late in-the-bag IOL dislocation revealed similar long-term endothelial cell loss after IOL exchange with a retropupillary iris-claw lens compared with IOL repositioning with scleral sutures.

ABSTRACT

Purpose: To compare safety in terms of longitudinal corneal endothelial cell (EC) loss after intraocular lens (IOL) exchange versus IOL repositioning for late in-the-bag IOL dislocation.

Setting: Patients with late in-the-bag IOL dislocation referred to Oslo University Hospital.

Design: Prospective, parallel group, randomized clinical trial (RCT).

Methods: During a 3-year period, 104 patients were randomly assigned to groups receiving either IOL exchange with retropupillary fixation of an iris-claw lens (n = 50) or IOL repositioning by scleral suturing (n = 54). All operations were performed by one surgeon with an anterior approach. Endothelial cell density (ECD) and central corneal thickness (CCT) were measured preoperatively and at 6 months, 1 year, and 2 years after surgery. A linear mixed model was applied for the longitudinal analysis, where patients with at least one ECD measurement were included (n = 44 exchange; n = 50 repositioning). The main outcome measure was 2-year longitudinal EC loss in IOL exchange compared to IOL repositioning.

Results: The longitudinal EC loss was similar between the IOL exchange and IOL repositioning groups during the 2 years of follow-up (17.5% vs. 15.3%, p = .15). A subgroup analysis found no reason to advise against either method for patients with low preoperative ECD (< 1500 cells/mm²). The mean CCT was similar between the two groups and remained stable over 2 years of follow-up.

Conclusions: This RCT of late in-the-bag IOL dislocation surgery revealed that exchanging the IOL is as safe as repositioning in terms of 2-year longitudinal EC loss.

INTRODUCTION

Cataract surgery with phacoemulsification of the crystalline lens and replacement with an artificial intraocular lens (IOL) in the lens capsule (in-the-bag) provides excellent visual prognosis for most patients.¹ However, despite uncomplicated surgery, a spontaneous late in-the-bag IOL dislocation may occur. In regions with high prevalence of pseudoexfoliation syndrome (PEX), the reported 20-year cumulative incidence is 3.0%,² and there is an 6-10 years average interval between cataract surgery and the IOL dislocation.^{3,4} There are several acknowledged surgical approaches to treat this condition, in principle variants of either repositioning of the existing IOL or to exchange it for a new one. However, there is no clear consensus on which method is favorable, and there has been a lack of prospective studies of late in-the-bag IOL dislocation.

An important safety measure for this type of surgery is corneal endothelial cell density (ECD), which decreases with age.⁵ After cataract surgery, the reported endothelial cell (EC) loss is 2.5% per year, which is up to 8 times more than in a healthy unoperated eye.^{5,6} For IOL dislocation surgery, there have been concerns that IOL exchange might result in more EC loss than IOL repositioning as it is considered being a more traumatic procedure for the corneal endothelium.^{3,4,7}

In 2013, the authors initiated a randomized clinical trial (RCT) on late in-the-bag IOL dislocation to evaluate IOL repositioning with scleral sutures versus IOL exchange with a retropupillary iris-claw lens. Preoperative characteristics, operative data and medium-term outcomes (6 months) have been previously reported.^{3,8-11} A recent report included long-term visual outcomes and complications.¹² The medium-term analysis revealed a borderline more pronounced EC loss in the exchange group.³ The aim of the present study was to examine whether there was a difference in corneal ECD between IOL exchange and repositioning of the existing IOL with two sutures in a 2-year longitudinal analysis after surgery for late in-

the-bag IOL dislocation. The secondary aim was to elucidate whether preoperative ECD should be a decisive factor for the surgical approach.

METHODS

Between January 2013 and December 2015, patients with late-in-the-bag IOL dislocation who were suitable for both surgical techniques were invited to participate in the study. The inclusion and exclusion criteria have been published previously and there were no restrictions on preoperative ECD.³ The participants comprised 104 patients (104 eyes) randomly assigned in two patient groups: an IOL exchange group or an IOL repositioning group. The exchange surgery involved explanting and replacing the IOL and capsule for an aphakic iris-claw IOL (Verisyse, VRSA54; Abbott Laboratories, Inc., Abbott Park, Illinois, USA) retropupillary enclavated to the iris. Repositioning surgery involved two 10-0 Prolene sutures (Johnson & Johnson Medical, Birdsboro, Pennsylvania, USA) through the capsular bag around each haptic and fixation to the scleral wall. In cases of vitreous loss, the surgeon either removed the vitreous strands from the incision by using cellulose sponges and scissors, or if needed, an automated vitrectomy was performed (Stellaris Vision Enhancement System phacoemulsification machine; Bausch & Lomb, Rochester, New York, USA). A previous paper describes the surgical procedures and design of the dislocated IOL in further detail.³ The study adhered to the Declaration of Helsinki, it was approved by the Regional Committees for Medical and Health Research Ethics (2012/1981), and was registered at clinicaltrials.gov (NCT01784926) before the inclusion. All patients provided written informed consent for the treatment and participation in the research project.

One surgeon (L.D.) with experience in both methods conducted all operations. Among the 86 patients who were still alive at 2 years after surgery, 66 (77%) completed the 2 years of follow-up. A flow-chart and more details on patients lost to follow-up have been previously published.¹² The present analysis included all patients with at least one ECD measurement during the study period (n = 44 for IOL exchange; n = 50 for IOL repositioning).

Pre- and postoperative examinations: The same ophthalmologists (M.D., O.K.) and optometrists performed a thorough ophthalmological examination at the preoperative visit, and at 6 months, 1 year, and 2 years after surgery.

Measurements: The highest preoperative intraocular pressure (IOP) between the diagnosis of late-in-the-bag IOL dislocation and the preoperative visit was included in the analysis, as it was considered to be more correlated with EC loss than the IOP at later postoperative visits where the mean values were within normal limits for both treatment groups.¹² The ECD was measured preoperatively, and at 6 months, 1 year and 2 years after surgery with a non-contact confocal microscope (ConfoScan 4; Nidek Technologies Srl, Padova, Italy). Measurements were not feasible in all cases or at all time points due to poor cooperation or technical problems.

The images were obtained from the central cornea, and by default, the program automatically counted cells within a rectangular area of 0.0935 mm². The image used was the clearest one at each time point, and the median of three automatic counts was chosen for semi-manual count, with the researcher masked to the group affiliation. The semi-manual counting was performed by manual marking of all whole cells and partially visible cells in the upper and left frame edges, followed by the software calculation of the ECD measured in cells/mm². Compared with semi-manual counts, the automatic counts gave up to 30% higher values due to a software tendency to double count cells, especially for low ECD counts. Therefore, automatic counts were disregarded, and the analysis includes only the semi-manual ECD counting, as also recommended by others.¹³ The central corneal thickness (CCT) and the anterior chamber depth (ACD) were measured with Scheimpflug topography (Pentacam HR: Oculus Optikgeräte GmbH, Wetzlar, Germany).

Statistical methods: This trial used visual acuity as the primary outcome measure, and the sample size calculations required a minimum of 28 individuals in each group at the final

observation.³ A substantial loss to follow-up was anticipated as a consequence of the high mean age at inclusion, hence it was decided to include more patients. The present study considers a secondary outcome from the same trial with the aim to evaluate any differences between the two different surgical approaches regarding the longitudinal effect on ECD.

To account for the unbalanced preoperative ECD and repeated measurements within each individual (correlated data), a linear mixed model with a random intercept was used.^{14,15} To evaluate whether the time effect was different between the two treatment groups, the model included an interaction term between group and time, together with the main effects of group and time. Furthermore, fixed effects for the following variables were considered; preoperative age, gender, preoperative dislocation grade (1-3),¹² highest preoperative IOP, preoperative ACD, CCT (time-dependent covariate), complications (time-dependent covariate), and need for postoperative surgery.

The multivariable model included variables with a p-value < 0.2 from univariable models. Multicollinearity did not appear. A stepwise backward selection was performed where variables with a p-value of > 0.2 were excluded from the final model. Moreover, to account for the longitudinal design, a first-order autoregressive (AR-1) covariance structure for each treatment group was used. The validity of the model was checked by plots of standardized residuals versus predicted values and by normal probability plot of standardized residuals. The results presented are beta-coefficients with 95% confidence intervals and p-values. In addition, the longitudinal changes of ECD and CCT in the two treatment groups are presented graphically.

Two subgroup analyses examined the two treatment groups for i) patients with low versus high EC loss, and ii) patients with low preoperative ECD (< 1500 cells/mm²). A third subgroup analysis examined the effect of automated anterior vitrectomy on EC loss.

All statistical analyses were performed using Stata (StataCorp. 2017. *Stata Statistical Software: Release 15*. College Station, TX: StataCorp LLC).

Table 1. Preoperative characteristics and parameters included in the analysis comparing the longitudinal effect on ECD from either IOL exchange or IOL repositioning in treatment of late in-the-bag IOL dislocation.		
Included eyes	Repositioning (n = 50) Mean $\pm$ SD (range) or n (%)	Exchange (n = 44) Mean $\pm$ SD (range) or n (%)
Preoperative values		
Age (years)	80.8 $\pm$ 9.5 (56-94)	81.8 $\pm$ 6.3 (63-95)
Males / Females	19 (38%) / 31 (62%)	18 (41%) / 26 (59%)
PEX	39 (78%)	39 (87%)
Glaucoma or high IOP	28 (56%)	29 (66%)
IOP highest preoperative (mmHg)	22.2 $\pm$ 8.9 (9-46)	24.2 $\pm$ 11.4 (8-57)
ECD (cells/mm ²)	1912 $\pm$ 431 (1091-2855) (n = 46)	1682 $\pm$ 452 (770-2790) (n = 40)
Anterior chamber depth (mm)	4.44 $\pm$ 0.38 (3.31-5.22) (n = 45)	4.30 $\pm$ 0.43 (3.33-5.11) (n = 38)
CCT (μ m)	563 $\pm$ 48 (472-722) (n = 46)	554 $\pm$ 47 (465-642) (n = 38)
Dislocation grade		
Grade 1	21 (42%)	12 (27%)
Grade 2	13 (26%)	9 (20%)
Grade 3	16 (32%)	23 (52%)
Number of ECD measurements		
4 of 4 time points	22 (44%)	21 (48%)
3 of 4 time points	11 (22%)	7 (16%)
2 of 4 time points	6 (12%)	10 (23%)
1 of 4 time points	11 (22%)	6 (14%)
Complications (peri- and postoperative) *	10 / 50 (20%)	12 / 44 (27%)
Postoperative surgery †	5 / 50 (10%)	4 / 44 (9%)
CCT: central corneal thickness. CME: cystoid macular edema. ECD: endothelial cell density. IOL: intraocular lens. IOP: intraocular pressure. PEX: pseudoexfoliation syndrome.		
* Complications included: iris injuries, intraocular bleeding, fluid misdirection syndrome, CME, retinal tear and redislocations.		
† Postoperative surgery: 1 patient in each group had redislocation surgery; 3 patients in each group had filtering surgery in treatment of high IOP; 1 patient in the repositioning group had postoperative pars plana vitrectomy.		

RESULTS

In total, the 94 patients had 275 observations during the study period. On average, there were 2.9 observations per patient (range 1-4). Table 1 shows a detailed description of the observations and preoperative characteristics.

Main analysis

As shown in Table 2, the longitudinal analysis revealed a highly significant negative main effect of time, meaning that the exchange group had a significant reduction in ECD during the study period. There was also a significant difference in ECD between the two treatment groups preoperatively. However, there was no significant interaction between time and group, meaning that the influence of time was similar in the two treatment groups. Thus, the repositioning group also had a reduction in ECD during the study period.

The exchange group had an EC loss of 17.5% during the 2-year period, while the repositioning group had an EC loss of 15.3% (Figure 1). A borderline significant trend was found towards a lower ECD with increasing age. Gender, dislocation grade, highest preoperative IOP, preoperative ACD, CCT, peri- and postoperative complications or the need for postoperative surgery were not associated with EC loss. Accordingly, the final model did not include these variables. Further, the AR-1 covariance structure revealed rho estimates of 0.35 and 0.80 for the exchange and the repositioning group, respectively.

One patient in the repositioning group had a perioperative complication (fluid misdirection syndrome) which led to an early severe EC loss and corneal decompensation.¹² The CCT remained stable for both groups during the 2 years of follow-up (Figure 2).

Subgroup analyses

The first sensitivity analysis was performed on EC loss for the 71 patients with preoperative and at least one postoperative ECD measurement. For these patients, comparisons were made between the upper and lower quartiles of EC loss relative to preoperative ECD (Table 3). Patients with high EC loss (upper quartile) showed a tendency of low preoperative ECD in both treatment groups. For other covariates with a possible negative effect on ECD, the treatment groups did not show important differences.

The second sensitivity analysis investigated the possible difference in EC loss between the treatment groups for patients with low preoperative ECD. The preoperative ECD was below 1500 cells/mm² for 24 patients, of which 20 patients had at least one postoperative ECD measurement. In this subgroup analysis, both groups had a mean follow-up of approximately 20 months. In the exchange group (n = 13) the preoperative ECD was 1213 cells/mm² (95% CI 1095, 1331) and the EC loss was 260 cells/mm² (95% CI -420, -99). In the repositioning group (n = 7) the preoperative ECD was 1345 cells/mm² (95% CI 1214, 1476) and the EC loss was 428 cells/mm² (95% CI -639, -217).

Among patients with preoperative and at least one postoperative ECD measurement automated anterior vitrectomy was used in 17 (49%) out of 35 eyes in the exchange group. As vitrector was not used in any cases in the repositioning group, the third sensitivity analysis compared eyes within the exchange group according to the use of automated anterior vitrectomy (Table 4).

Figure 1. Age-adjusted mean corneal ECD during 2 years of follow-up after IOL exchange (n=44) or IOL repositioning (n = 50) for late in-the-bag IOL dislocation. Error bars: 95% confidence interval. ECD: endothelial cell density. IOL: intraocular lens.

Figure 2. Age-adjusted mean CCT during 2 years of follow-up after IOL exchange (n=44) or IOL repositioning (n = 49) for late in-the-bag IOL dislocation. Error bars: 95% confidence interval. CCT: central corneal thickness. IOL: intraocular lens.

x

Table 2. Longitudinal analysis on corneal endothelial cells in a randomized clinical trial comparing IOL exchange and IOL repositioning after surgery for late in-the-bag IOL dislocation. Linear mixed model with endothelial cell density as the outcome variable. *

Fixed effects	β -coefficient (95% confidence interval)	P-value
Treatment group Exchange Repositioning	Ref. 213 (22 to 405)	.029
Time Preoperative	Ref.	
6 months	-174 (-244 to -105)	< .001
12 months	-253 (-338 to -169)	< .001
24 months	-298 (-387 to -209)	< .001
Interaction term: group*time		.15 [†]
6 months	90 (-2 to 182)	.056
12 months	5 (-113 to 124)	.93
24 months	1 (-133 to 135)	.99
Age (years)	-11 (-23 to 0)	.059

IOL: Intraocular lens.

* Final model: $ECD = \beta_0 + \beta_1\text{group} + \beta_3\text{time6} + \beta_3\text{time12} + \beta_4\text{time24} + \beta_5\text{group*time6} + \beta_6\text{group*time12} + \beta_7\text{group*time24} + \beta_8\text{age} + \text{random intercept and AR-1 covariance structure (per treatment group) of the residuals}$

[†] The overall p-value of the three interaction terms

Table 3. Eyes in the upper and the lower quartile of postoperative corneal endothelial cell loss after surgery for late in-the-bag IOL dislocation with either lens exchange or lens repositioning.

Quartiles	Repositioning Mean (95% CI) or n (%)	Exchange Mean (95% CI) or n (%)
Upper quartile (EC loss > 23.5%)	n = 10	n = 7
Preoperative ECD (cells/mm ²)	1518 (1298 to 1737)	1472 (1065 to 1879)
CCT central (μm)	579 (554 to 631) (n = 9)	530 (474 to 613) (n = 7)
Last observation 6 / 12 / 24 months (n)	0 / 2 / 8	1 / 0 / 6
CCT central at final visit (μm)	562 (531 to 593) (n = 9)	520 (488 to 553) (n = 7)
ECD at final visit (cells/mm ²)	920 (763 to 1076)	835 (539 to 1132)
ECD change preoperative to final (cells/mm ²)	-598 (-871 to -325)	-637 (-865 to -408)
Lower quartile (EC loss < 6.0%)	n = 13	n = 5
Preoperative ECD (cells/mm ²)	2092 (1906 to 2278)	1608 (1173 to 2043)
CCT central (μm)	559 (535 to 584) (n = 13)	542 (512 to 571) (n = 4)
Last observation 6 / 12 / 24 months (n)	2 / 2 / 9	3 / 0 / 2
CCT central at final visit (μm)	544 (524 to 565) (n = 12)	551 (497 to 605) (n = 3)
ECD at final visit (cells/mm ²)	2092 (1930 to 2254)	1603 (1216 to 1990)
ECD change preoperative to final (cells/mm ²)	0 (-56 to 57)	-5 (-87 to 77)

CCT: central corneal thickness. EC: endothelial cell. ECD: endothelial cell density. IOL: intraocular lens.

Table 4. Sensitivity analysis within the IOL exchange group: corneal endothelial cell loss according to the use of vitrector or not.¹

Included eyes	Use of vitrector (n=17) Mean (95% CI)	No vitrector used (n=18) Mean (95% CI)	P-value ²
EC loss to final observation (cells/mm ²)	-346 (-518 to -174)	-227 (-297 to -158)	0.17
Last observation 6 / 12 / 24 months (number)	4 / 1 / 12	2 / 2 / 14	

EC: endothelial cell. IOL: intraocular lens.

¹ Preoperative and at least one postoperative endothelial cell density measurement required for analysis.

² Independent samples t test for comparison between groups

DISCUSSION

This RCT is the first to perform a longitudinal analysis on corneal EC loss after two different surgical approaches for late in-the-bag IOL dislocation. The analysis revealed similar corneal EC loss in eyes undergoing IOL exchange with a retropupillary iris-claw lens in comparison to those treated with repositioning of the existing IOL by scleral suturing. A longitudinal study on the effect on corneal ECs and corneal thickness from different types of IOLs and surgical procedures in IOL dislocation operations has been called for.¹⁶ In particular, since the EC loss from surgery seems to be more pronounced for IOL exchange,³ a longitudinal study is of paramount importance because a potential long-term group difference would have implications in choosing the surgical method. Thus, this study provides important clinical information.

The longitudinal analysis over 2 years showed no significant group difference and nearly linear EC loss for both surgical approaches, as shown in Figure 1. The analysis found significant main effects of time and group. However, there was no combined effect from the interaction term (treatment group and time), so the observed difference between the groups reflects a preoperative difference. Thus, the groups had similar time development.

At the medium-term follow-up (after 6 months), the mixed model showed a trend towards a more pronounced EC loss in the exchange group, which is in line with a previous report on 6-month follow-up data.³ This indicates a more pronounced EC loss shortly after IOL exchange surgery, explained by the larger intraocular trauma with manipulation close to the corneal endothelium compared to IOL repositioning. Nevertheless, over a longer time period, this group difference seems to be offset by a similar long-term EC loss. Furthermore, it seems that the cornea remains clear over a 2-year period with both surgical approaches and thereby contributes to the overall favorable visual outcome reported recently.¹²

Generally, intraocular surgery leads to EC loss,⁵ and only a few studies have evaluated EC loss after IOL dislocation surgery.¹⁷⁻²⁰ These studies were retrospective and showed EC loss varying from 11 to 21% (mean follow-up: 3-12 months) using different surgical approaches.^{17,18} Since IOL repositioning involves minimal intraocular manipulation in the anterior chamber, one could assume that this approach is less harmful for the corneal endothelium, compared with the exchange technique, where the ECs could suffer from touch by instruments or by the IOL explant and implantation.^{7,17-19} Nevertheless, with a scleral tunnel incision and the use of a sufficient amount of viscoelastic material, the EC loss could remain within an acceptable degree, even in exchange procedures.²¹ The present longitudinal analysis revealed no significant difference between the groups, and the mean EC loss over 2 years was 17.0% for the exchange group and 15.3% for the repositioning group. Additional surgical interventions during the follow-up period had no significant effect on ECD, which may relate to the few re-operations.¹²

The main analysis revealed some variation in EC loss, and therefore an explorative sensitivity analysis was performed to compare patients with high EC loss (upper quartile) versus low EC loss (lower quartile). For both treatment groups, low preoperative ECD tended to lead to more EC loss. In addition, a sensitivity analysis was performed on patients with preoperative ECD < 1500 cells/mm², to investigate whether a low preoperative ECD should indicate the surgical method of choice. Due to the small samples in this sensitivity analysis, one should be careful to draw conclusions, but the data suggest that IOL exchange with a retropupillary iris-claw lens is as safe as repositioning even when the preoperative ECD is low. The third sensitivity analysis revealed a possible association between the use of automated anterior vitrectomy and EC loss within the exchange group. Probably, the use of anterior vitrectomy may reflect increased intraocular manipulation, with subsequent increased EC loss.

In IOL exchange surgery, the iris-claw lens used in this trial is only one out of several options for a new posterior chamber (PC) IOL. Alternatives include several sclerotomy techniques developed over the last decade, such as sutureless intrascleral tunnel fixation,²² fibrin glue-assisted intrascleral fixation,²³ or flanged IOL fixation.²⁴ However, from the authors experience, the implantation of an iris-claw IOL is less of technical difficulty than other approaches. Furthermore, it is time-efficient,^{3,10} and the implantation of the new IOL requires only minor intraocular manipulation.

The iris-claw IOL can be placed in the anterior chamber (AC) or retropupillary in the PC.^{25,26} Concerns have arisen regarding potential long-term differences in EC loss for these two placements,²⁷ and several studies have indicated that PC placement may be preferable.^{18,21,27,28} Nevertheless, these studies have important differences regarding indications for surgery and patient characteristics. Furthermore, the study designs have limitations to conclude about the preferred placement of an iris-claw IOL for aphakic use.

In the present trial, the iris-claw lens was enclavated retropupillary, as also preferred by others.^{18,21,27,28} A retropupillary placement is more physiological and preserves a deeper ACD compared to an anterior enclavation.²⁷ It may also be favorable in cases of redislocation (disenclavation) as usually one enclavation usually still fixates the IOL and can be re-enclavated relatively easily without harming the corneal endothelium.²⁶

The Artisan aphakia IOL is identical to the Verisyse iris-claw lens used in the present trial. It was originally made for phakic use and is not approved for aphakia in the United States (US). However, an ongoing clinical trial (NCT01547429) aims for an approval of aphakic use from the US Food and Drug Administration (FDA). There have been concerns about its long-term effect on the corneal endothelium.²⁹ Nevertheless, they are not necessarily applicable for the pseudophakic eye, and the iris-claw IOL for secondary implantation has increased in popularity, at least in Europe.^{26,28,30} For iris-claw IOL in phakic eyes, the ACD is

an important risk factor for long-term EC loss.²⁹ However, the present trial shows that the EC loss is not dependent on ACD in pseudophakic eyes with a retropupillary IOL.

One of the main strengths of this study is the randomized design, and it is the first longitudinal analysis to evaluate the impact on the corneal endothelium from two different surgical approaches for late in-the-bag IOL dislocation. Analyzing repeated correlated data using a linear mixed model is preferable for several reasons. It is flexible, it enables the use of all collected data, and it adjusts for preoperative differences with a random intercept added to the model.^{14,15} Hence, the mixed model improves the validity and gives more certain estimates for the included population as a whole compared to longitudinal analysis of covariance or analysis of changes.^{14,15}

The analysis included 94 (90.4%) out of 104 randomized patients and the ECD measurements involved semi-manual counting, which is more accurate than automatic counting, in particular for low cell counts. Even though ECD measurement was not feasible for all patients at every time point, and the missing data represent a limitation, the linear mixed model yielded a mean of 2.9 ECD observations from 94 patients, and comparable group sizes. Patients may have low ECD when they present with late in-the-bag IOL dislocation, and ECD studies often exclude patients with low ECD, low ACD, or glaucoma.^{16,19,25,29,30} This study, however, had no restrictions on preoperative ECD, glaucoma, or other ocular diseases, and the rather broad inclusion criteria improve the external validity. Yet the results are limited to elderly patients with late in-the-bag IOL dislocation. The authors suggest, however, that the results for the exchange group may also apply to some extent for patients beyond in-the-bag IOL dislocation in need of exchange surgery (e.g. aphakic) where a retropupillary iris-claw IOL is chosen.

This RCT of surgery for late in-the-bag IOL dislocation revealed that the 2-year longitudinal EC loss is similar in IOL exchange with a retropupillary iris-claw lens as in IOL

repositioning with scleral sutures. Despite low preoperative ECD in quite a few participants and a considerable long-term EC loss, the risk of corneal decompensation is low from a 2-year perspective. In conclusion, with the surgical techniques applied in the present trial, exchanging the IOL is as safe as repositioning in terms of longitudinal EC loss.

VALUE STATEMENT

What was known:

- A healthy endothelium is crucial for a clear and transparent cornea.
- Corneal endothelial cell density is decreased by increasing age, and the yearly cell loss is higher in pseudophakic than phakic eyes.
- For late in-the-bag IOL dislocation, there have been concerns that IOL exchange surgery may give higher endothelial cell loss compared with IOL repositioning.

What this paper adds:

- Despite low preoperative corneal endothelial cell density, the long-term risk of corneal decompensation is low for the two surgical approaches used in this trial.
- The long-term endothelial cell loss is not higher in IOL exchange with a retropupillary iris-claw lens compared with IOL repositioning with scleral sutures in treatment of late in-the-bag IOL dislocation.

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