Astigmatism and Refractive Outcome After Late In-The-Bag Intraocular Lens Dislocation Surgery: A Randomized Clinical Trial

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PURPOSE. To compare surgically induced astigmatism (SIA) and refractive outcomes between two operation methods for late in-the-bag IOL dislocation.

METHODS. In this prospective, randomized, parallel-group clinical trial, 104 patients (eyes) were assigned to IOL repositioning by scleral suturing 1.5- to 2-mm posterior to limbus (n = 54) or IOL exchange with a retropupillar iris-claw IOL using a 5.5-mm scleral pocket incision (n = 50). The SIA was determined by vector analysis through conversion of corneal cylinders to Cartesian coordinates, and is presented as magnitude in diopters @ direction in degrees (D @ °). Follow-up was 6 months.

RESULTS. The SIA was 0.24 D @ 8° for IOL repositioning and 0.65 D @ 171° for IOL exchange, which was a nonsignificant group difference (X coordinate: P = 0.08; Y coordinate: P = 0.16). Mean SIA magnitude was 0.60 ± 0.50 D and 1.12 ± 0.85 D, respectively (P < 0.001). Mean postoperative spherical equivalent was −1.6 ± 1.6 D after IOL repositioning and −0.5 ± 1.0 D after IOL exchange (P < 0.001). For IOL repositioning, this represented a mean myopic shift of −0.7 ± 1.1 D compared with before the IOL dislocation (P < 0.001). For IOL exchange, it was within ±1 D of target refraction in 83% of the patients.

CONCLUSIONS. Surgically induced astigmatism was modest in both operation groups, albeit with a tendency of being more pronounced for IOL exchange. Repositioning surgery led to a myopic shift, whereas exchange surgery provided good refractive predictability.

Keywords: randomized clinical trial, intraocular lens dislocation, surgically induced astigmatism, refractive outcome

Late in-the-bag IOL dislocation occurs on average 7 to 10 years after cataract surgery,1-4 and it has become more frequent in recent decades.3,5,6 The condition has been treated with various surgical techniques and placements of the IOL, indicating that there is no clear consensus on the optimal operation method.7

In principle, the dislocated IOL can be either repositioned or exchanged, and studies have shown similar visual outcomes for these operation methods.1,3,6,8,9 In exchange surgery, a nonfoldable IOL is often implanted, either in the anterior chamber or behind the iris. An advantage of this operation method is the ability to adjust the refraction. However, a large incision is usually required, and IOL exchange has therefore been associated with quite pronounced surgically induced astigmatism (SIA), especially if a corneal or limbal incision is chosen.10-12 Intraocular lens repositioning requires smaller incisions. However, with this method the refractive outcome is dependent on where the haptics are sutured, and thus, whether the IOL-capsule complex is repositioned back to its original position or not.

Despite its importance for daily life activities, only a few studies have compared refractive outcomes between different operation methods for late in-the-bag IOL dislocation,5,11-14 and to our knowledge, no previous randomized trial has been conducted. Because a consensus on the surgical technique has not yet been established, nor with regard to refractive outcomes, we considered it of clinical relevance to perform such a comparison. In the present trial, we randomized patients to IOL repositioning by scleral suturing or IOL exchange with a retropupillar iris-claw IOL. The aims of the present article were to compare SIA and refractive outcomes between these two operation methods.

MATERIALS AND METHODS

This prospective, randomized, parallel-group clinical trial of late in-the-bag IOL dislocation surgery was conducted at the Department of Ophthalmology at Oslo University Hospital, with patient inclusion between January 2013 and December 2015. The research adhered to the tenets of the Declaration of Helsinki, Regional Ethics Committee approval was obtained, and all study patients provided written informed consent. The study has been registered at ClinicalTrials.gov (identifier, NCT01784926). The sample size calculation of this randomized trial was performed with postoperative corrected distance visual acuity (CDVA) as the efficacy variable.1

Referred patients were considered consecutively for eligibility, and 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, IOL fixed to capsular remnants, both eyes of the patient had visual acuity (CDVA) of at least 0.3, and no history of implantation in the capsular bag or the use of an anterior chamber lens.
eligibility for both operation methods, ability to cooperate fairly well during the examinations, and willingness to participate in the trial. For patients with dislocated IOLs in both eyes during the study period, only the first operated eye was included. A total of 104 patients with late-in-the-bag IOL dislocation were considered eligible for enrollment in the study. They were randomized (1:1) either to IOL repositioning by scleral suturing (n = 54) or to IOL exchange with a retropupillary fixated iris-claw IOL (n = 50). A more detailed description of the inclusion and exclusion criteria and a flow chart of the allocation process have been presented elsewhere.1

Preoperative Examination

A comprehensive evaluation of all study patients was conducted before surgery. An optometrist performed the subjective refraction and the CDVA measurement by using a manual phoropter and applying the Early Treatment Diabetic Retinopathy Study visual acuity chart with standardized lighting conditions in the room. Patients who experienced no visual improvement from attempted correction were registered with a value of 0 for sphere and cylinder. For a few patients, severe visual interference from the dislocated complex made subjective refraction impossible to perform (visual acuity of 2 or 3 logMAR), and they were registered without any refraction values.

Keratometry was performed with Scheimpflug topography (Pentacam HR; Oculus Optikgeräte GmbH, Wetzlar, Germany), whereas optical biometry was performed with IOLMaster (Carl Zeiss Meditec AG, Jena, Germany) or ALScan (NIDEK CO., LTD, Aichi, Japan). In a few cases, optical biometry was not successful because of severe interference from the dislocated complex, and ultrasound biometry was performed. The SRK/T formula and an A-constant of 116.9 was used, consistent with another study.15 The appropriate IOL power for exchange patients was selected by taking into consideration the refractive power of the IOL-capsule complex with a retropupillary fixated iris-claw IOL (Verisyse VRSA54; Abbott Laboratories, Abbott Park, IL, USA). A 5.5-mm scleral pocket arcuate incision was made at the 12-o’clock position (90°). Running two-cross sutures were passed through the sclera at an attempted distance of 8 mm apart. The alignment of the sutures in the same meridian was conducted to avoid tilt and decentration of the IOL, and for the same reason, the sutures were adjusted in the axis as described by Holladay and colleagues.19,20

Postoperative Examination and Surgically Induced Astigmatism

An examination was performed 6 months after surgery with measurement of the same parameters as before surgery, except for biometry. Altogether 85 of 104 (82%) study patients participated. The reasons for loss to follow-up were serious illness (cancer, stroke, dementia) and one death.

Jackson cross cylinder power vectors for the astigmatism (I0 and J45) were determined as described by Thibos et al.17,18 Simulated keratometry (SimK) readings were provided by the Scheimpflug topography, and the corneal cylinder was calculated as K2 - K1. The net astigmatism of an eye is given by the astigmatic magnitude (M) in diopters (D) and the direction @ in degrees (°), presented as M @ @. In this study, SIA was determined from the corneal cylinders by vector analysis using the method with Cartesian coordinates and doubling of the axis as described by Holladay and colleagues19,20 Calculations were performed in accordance with the following equations (x is the steepest meridian of the net astigmatism [M] in degrees),19,20

$$x = M \times \cos(2 \times \alpha)$$

$$y = M \times \sin(2 \times \alpha)$$

The SIA was calculated by first subtracting the preoperative value from the postoperative value for the x and y coordinates separately. Values within each operation group were then averaged, before reconversion to the ordinary cylinder notation (M @ @) as previously described.19 To verify the results, vector analysis of the SIA was also performed with the polar value method as described by Nesper and colleagues,21,22 which is supposed to yield the same results.23 In the present study, 90° was chosen as the reference meridian.

In addition to presenting the SIA as a cylinder notation value (M @ @), the arithmetic mean magnitude of the SIA was also calculated for each operation group, consistent with presentations by Alpins24 and others.25

Refractive Predictability

The refractive predictability of the two surgical techniques was assessed by comparing the spherical equivalent 6 months after surgery with the target refraction. The difference between these refractions was termed the prediction error. For IOL exchange, target refraction was determined by the preoperative biometry. For IOL repositioning, the surgical technique aimed for a lens position, and thus refraction, close to before the IOL dislocation. The refraction measured at the preoperative examination was, because of the downward dislocation and possible tilt of the IOL, not considered to be accurately representative of this predislocation refraction. We managed, however, to gather information about the subjective refraction before the IOL dislocation from most patients in the repositioning group (45/54, 83%). This spherical equivalent was for the purpose of analysis defined as target refraction in the repositioning group. The refractive predictabilities have been presented with recommended standard graphs.26

From the preoperative measures and the refractive outcomes of the IOL exchange patients in the present study with a postoperative best-corrected visual acuity (BCVA) of 20/40 or better, we calculated an optimized A-constant for retropupillary positioning of the iris-claw IOL by using a software for IOL
calculation (Verion Image Guided System; Alcon Laboratories, Inc., Fort Worth, TX, USA).

**Statistical Methods**

The computer software SPSS (version 23.0; IBM Corp., Armonk, NY, USA) was used for statistical analysis, continuous data were assessed for normal distribution, and the two operation groups were compared with independent samples t-test, a nonparametric test (Mann-Whitney U), or $\chi^2$ test. For analysis of change within each group, we used paired samples t-test. Two-sided significance testing and a significance level of 5% were applied throughout. Results have been presented as mean $\pm$ SD or number (%).

**RESULTS**

Baseline characteristics are presented in Table 1.

**Surgically Induced Astigmatism**

Different measures of astigmatism after 6 months follow-up are presented in Table 2. The postoperative change in the mean corneal cylinder regardless of axis was not significant in either of the groups (repositioning: $P = 0.81$; exchange: $P = 0.40$), and there was also no significant difference for this change between the groups ($P = 0.53$). The postoperative corneal astigmatism had a $J_0$ power vector of $-0.01 \pm 0.64$ D in the repositioning group and $-0.20 \pm 0.51$ D in the exchange group.

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**Table 1.** Late In-The-Bag Intraocular Lens Dislocation: Baseline Characteristics and Target Refraction in the 2 Operation Groups

<table>
<thead>
<tr>
<th></th>
<th>Repositioning Group ($n = 54$), Mean $\pm$ SD or n (%)</th>
<th>Exchange Group ($n = 50$), Mean $\pm$ SD or n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>81.1 $\pm$ 9.4</td>
<td>82.3 $\pm$ 6.2</td>
</tr>
<tr>
<td>Sex, male/female</td>
<td>20 (37)/34 (63)</td>
<td>21 (42)/29 (58)</td>
</tr>
<tr>
<td>Eyes, right/left</td>
<td>31 (57)/25 (45)</td>
<td>27 (54)/25 (46)</td>
</tr>
<tr>
<td>Spherical equivalent, all‡ D</td>
<td>0.84 $\pm$ 4.08 (n = 52)</td>
<td>3.11 $\pm$ 5.50 (n = 45)</td>
</tr>
<tr>
<td>Spherical equivalent, adjusted† D</td>
<td>$-0.76 \pm 1.31$ (n = 43)</td>
<td>$-0.78 \pm 1.32$ (n = 29)</td>
</tr>
<tr>
<td>Axial length, mm</td>
<td>24.8 $\pm$ 2.6 (n = 52)</td>
<td>24.3 $\pm$ 1.3 (n = 49)</td>
</tr>
<tr>
<td>IOL and target refraction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Power of the new IOL, D</td>
<td>-0.88 $\pm$ 1.52 (n = 45)</td>
<td>-0.73 $\pm$ 0.83 (n = 50)</td>
</tr>
</tbody>
</table>

* All patients with a preoperative refraction included in the calculation. Independent samples t-test, $P = 0.03$. Nonparametric test (Mann-Whitney $U$), $P = 0.07$.
† Analyzed with the SimK values from corneal topography.
‡ The SIA for IOL exchange was 0.65 D @ 172° if operations with a limbal incision were excluded from the analysis.

**Table 2.** Astigmatism in the Two Operation Groups: Intraocular Lens Repositioning Versus Intraocular Lens Exchange

<table>
<thead>
<tr>
<th></th>
<th>Repositioning Group, Mean $\pm$ SD or n (%)</th>
<th>Exchange Group, Mean $\pm$ SD or n (%)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preoperative</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corneal cylinder,* D</td>
<td>1.21 $\pm$ 0.87 (n = 49)</td>
<td>1.12 $\pm$ 0.62 (n = 42)</td>
<td></td>
</tr>
<tr>
<td>$J_0$ power vector</td>
<td>0.16 $\pm$ 0.60</td>
<td>0.16 $\pm$ 0.48</td>
<td></td>
</tr>
<tr>
<td>$J_{45}$ power vector</td>
<td>-0.07 $\pm$ 0.41</td>
<td>-0.02 $\pm$ 0.40</td>
<td></td>
</tr>
<tr>
<td><strong>Preoperative net astigmatism by vector analysis</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corneal cylinder and meridian, D @ *</td>
<td>0.34 @ 78</td>
<td>0.32 @ 87</td>
<td></td>
</tr>
<tr>
<td><strong>Postoperative</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corneal cylinder,* D</td>
<td>1.18 $\pm$ 1.03 (n = 40)</td>
<td>1.22 $\pm$ 0.83 (n = 39)</td>
<td>0.84</td>
</tr>
<tr>
<td>$J_0$ power vector</td>
<td>-0.01 $\pm$ 0.64</td>
<td>-0.20 $\pm$ 0.51</td>
<td>0.22</td>
</tr>
<tr>
<td>$J_{45}$ power vector</td>
<td>-0.03 $\pm$ 0.45</td>
<td>0.09 $\pm$ 0.50</td>
<td>0.19</td>
</tr>
<tr>
<td><strong>Postoperative net astigmatism by vector analysis</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corneal cylinder and meridian, D @ *</td>
<td>0.07 @ 33</td>
<td>0.43 @ 168</td>
<td></td>
</tr>
<tr>
<td><strong>Surgically induced astigmatism†</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Subtraction method</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corneal cylinder change (D) from preoperative to postoperative visit</td>
<td>$+0.02 \pm 0.48$ ($P = 0.81$) (n = 37)</td>
<td>$+0.12 \pm 0.81$ ($P = 0.40$) (n = 32)</td>
<td>0.53</td>
</tr>
<tr>
<td>Vector analysis (Cartesian coordinates)</td>
<td>(n = 37)</td>
<td>(n = 32)</td>
<td></td>
</tr>
<tr>
<td>Δ X coordinate</td>
<td>0.23 $\pm$ 0.51</td>
<td>0.62 $\pm$ 1.03</td>
<td>0.08</td>
</tr>
<tr>
<td>Δ Y coordinate</td>
<td>0.07 $\pm$ 0.54</td>
<td>$-0.19 \pm 0.73$</td>
<td>0.16</td>
</tr>
<tr>
<td>SIA, D @ *</td>
<td>0.24 @ 8</td>
<td>0.65 @ 171†</td>
<td></td>
</tr>
<tr>
<td>Mean SIA magnitude, D</td>
<td>0.60 $\pm$ 0.50</td>
<td>1.12 $\pm$ 0.85</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

* Cylinder magnitude averaged regardless of axis.
† Analyzed with the SimK values from corneal topography.
‡ The SIA for IOL exchange was 0.65 D @ 172° if operations with a limbal incision were excluded from the analysis.
Repositioning Group (n = 43),
Mean ± SD or n (%)  | Exchange Group (n = 42),
Mean ± SD or n (%)  | P Value
---|---|---
Target refraction,* D | −0.89 ± 1.54 (n = 57) | −0.76 ± 0.87† (n = 42) |
6 months after surgery |  |  |
SE, D | −1.58 ± 1.58 (n = 43) | −0.46 ± 0.97 (n = 42) | <0.001 |
SE within ±0.5 D from target refraction | 13/37 (35) | 25/42 (60) | 0.04 |
SE within ±1 D from target refraction | 21/37 (57) | 35/42 (83) | 0.01 |
Prediction error‡ | −0.74 ± 0.97 (n = 37) | +0.29 ± 0.86 (n = 42) | <0.001 |
Optical biometry | +0.34 ± 0.91 (n = 34) |  |  |
Ultrasound or other eye | +0.10 ± 0.64 (n = 83) |  |  |
J0 power vector | −0.21 ± 0.50 (n = 43) | −0.23 ± 0.41 (n = 42) | 0.28 |
J45 power vector | −0.04 ± 0.35 | 0.05 ± 0.32 | 0.07 |
Change from preoperative to postoperative visit |  |  |
SE change,§ D | −0.68 ± 1.14 (P = 0.002) (n = 33) | +0.44 ± 1.25 (P = 0.09) (n = 25) | 0.001 |

* Mean for patients with information and that attended the 6-month postoperative visit. Target refraction defined for the repositioning group as the subjective refraction measured before dislocation of the IOL, and for the exchange group as the target refraction calculated from the preoperative biometry.
† Six of the patients had a target refraction more myopic than −2 D (reading myopia).
‡ Difference between the postoperative spherical equivalent and the target refraction.
§ There were 28/34 (82%) within ±1 D from target refraction.
| There were 7/8 (88%) within ±1 D from target refraction. Target refraction determined from ultrasound biometry and/or based on optical biometry of the other eye.

Refractive Outcome

Refractive outcomes are shown in Table 3 and Figure. The mean spherical equivalent 6 months after surgery was −1.58 ± 1.58 D in the repositioning group and −0.46 ± 0.97 D in the exchange group (P < 0.001). This was within ±1 D of target refraction for 57% and 83% of the patients, respectively (P = 0.013), albeit with different definitions for target refraction in the two groups. Mean prediction error of optical biometry for IOL exchange was −0.74 ± 0.97 D (P < 0.001, n = 57 with complete information).

Discussion

This randomized clinical trial compared IOL repositioning by scleral suturing and IOL exchange with a retropupillar iris-claw IOL in patients with late-in-the-bag IOL dislocation. In a previous article, we showed that both operation groups experienced few serious peri- and postoperative complications in a 6-month follow-up period, and more than 60% of the patients reached a postoperative CDVA of 20/40 or better, with no significant group difference. In the present article, we have shown that IOL exchange was statistically more successful than IOL repositioning in terms of target refraction and astigmatism.

In two retrospective studies of IOL dislocation surgery, mean SAs of 0.6 and 0.7 D after IOL repositioning, and 0.7 and 1.1 D after IOL exchange with a corneal incision was found. Also other IOL dislocation studies have shown increased astigmatism after exchange surgery. Further-
more, an increased refractive astigmatism of approximately 1.0 D after implantation of an iris-claw IOL in aphakic eyes have been reported. One such study claimed, however, that they applied an astigmatism-neutral corneal incision. The quite modest induced astigmatism for IOL exchange in our study was likely related to the use of a scleral pocket arcuate incision with a suture that was not particularly tightened and not removed. Compared with a large corneal incision, the scleral pocket arcuate incision has the additional advantage of being self-sealing with minimal risk of postoperative fluid leakage and hypotony.

Our results showed a more negative value for the J0 power vector after surgery, especially in the exchange group, indicating a group tendency toward inducing against-the-rule astigmatism. A clinical implication from this result is that exchange surgery may be beneficial in patients that have with-the-rule astigmatism before surgery, in contrast to patients with against-the-rule astigmatism.

As expected, our results showed that IOL exchange had significantly better refractive predictability than IOL repositioning (Fig.). The postoperative spherical equivalent was within ±1 D of target refraction in 85% of the patients in the exchange group. This is higher than other IOL dislocation studies that have implanted iris-claw IOLs, and it is comparable to previous benchmark studies of standard cataract surgery. Although more recent studies on cataract surgery have shown even better outcomes, it must be taken into account that biometry measurements can be difficult in eyes with late in-the-bag IOL dislocation because of optical interference from the dislocated complex. Thus, our results were evaluated as satisfactory.

There was, however, a tendency for a more hyperopic outcome than intended after IOL exchange, with a mean optical biometry prediction error of +0.34 D. It therefore seems that the applied A-constant of 116.9 was too low. Previous studies that have implanted a retropupillar iris-claw IOL for various indications have applied an A-constant between 116.5 and 117.5, and the refractive outcomes have differed. Based on the prediction error and the performed A-constant optimization calculation in the present study, we suggest an A-constant of 117.3 for optical biometry and a slightly lower constant (e.g., 117.1) for ultrasound biometry for a Verisyse aphakic iris-claw IOL fixated retropupillary with the concavity forward.
The refraction of eyes operated with IOL repositioning for late in-the-bag IOL dislocation can, at least in theory, be adjusted by deliberate positioning of the scleral sutures, and hence the IOL-capsule complex. Forward movement of an IOL provides a myopic shift and a backward movement a hyperopic shift, and it has been suggested that 1-mm change in anterior chamber depth corresponds to 1.5 D change in refraction. However, while the IOL was sutured to the other studies that have used the same surgical technique, the limbus. This is similar to, or slightly more posterior, than in 1.5 mm and preferably 1.8- to 2.0-mm posterior to the pierced through the sclera at an attempted distance of more than the IOL position to reach a specific target refraction in each individual case. In our study, the surgical technique, therefore, aimed to suture the complex close to the assumed physiological position. However, the refractive outcome showed that the repositioning group experienced a myopic shift, indicating that these IOLs were, on average, positioned more anterior after surgery than before the dislocation.

With the applied scleral suturing technique, the needle was pierced through the sclera at an attempted distance of more than 1.5 mm and preferably 1.8- to 2.0-mm posterior to the limbus. This is similar to, or slightly more posterior, than in other studies that have used the same surgical technique. However, while the IOL was sutured to the limbus in some of those patients, this was not the intention in our study with only in-the-bag IOL dislocations. Our findings indicate that the scleral sutures for IOL repositioning need to be positioned slightly more anterior from the limbus if one intends to obtain a refraction similar to before the IOL dislocation. This is consistent with a previous study that identified sulcus-positioned haptics as far as 2 mm behind the limbus. However, a more posterior scleral suturing of a loose IOL-capsule complex may possibly affect the stability of the complex, and lead to IOL tilt.

A clinical implication from the present study is that in terms of refractive outcomes after late in-the-bag IOL dislocation surgery, exchange surgery with an iris-claw lens fixated retropupillary is favorable compared with IOL repositioning by scleral suturing. Exchange surgery should therefore be strongly considered in cases requiring a specific postoperative refraction, or in cases where a myopic shift should be avoided (e.g., due to risk of inducing unacceptable anisometropia). However, other differences between the operation methods must also be taken into account in the choice of operation method in clinical practice.

The present study has several strengths, which include the randomized research design, enrollment of a fairly high number of patients with late in-the-bag IOL dislocation and that one experienced surgeon performed all the operations. Limitations include that the sample size may have been too small to reach an adequate statistical power in the comparison of SIA. Furthermore, the vector analysis was based on the assumption that all study eyes had regular astigmatism, which may not have been correct in every case. For analysis of induced astigmatism, the position of the main surgical incision is often chosen as the reference meridian, especially in corneal refractive surgery. In this study, the surgical meridian was not equal for all patients, neither was it exactly defined in every case, and the treatment was not targeted to reduce astigmatism. Thus, astigmatism analysis with Cartesian coordinates and $90^\circ$ as a reference meridian for the polar value method was considered an adequate compromise.

In conclusion, this randomized clinical trial showed modest SIA both for IOL repositioning by scleral suturing and for IOL exchange with a retropupillary fixated iris-claw lens. The scleral pocket arcuate incision used for IOL exchange thus appears to provide beneficial outcomes in terms of induced corneal astigmatism. Furthermore, exchange surgery showed good refractive predictability, although the applied A-constant seems to have been too low. For repositioning surgery, a myopic shift must be expected if the scleral fixation technique with the usual position for the sutures is used in eyes with late in-the-bag IOL dislocation.

Acknowledgments

An abstract with the main results has been accepted for an oral presentation at the upcoming annual meeting for the European Society of Cataract and Refractive Surgeons (ESCRS2017, Lisbon, Portugal, October 2017).

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