Evaluation of a new scleral fixation foldable IOL in the absence of capsule support


INTRODUCTION

The technique of scleral fixation of intraocular lenses (IOLs) has changed over the past 20 years [1]. When visual correction in an aphakic eye by means of contact lenses or glasses is not possible or not desired, we can implant a secondary IOL to correct the ametropia [2]. There are several ways to proceed with the secondary implantation: (1) introducing an IOL, either angle-supported or iris-fixed; (2) suturing a PC IOL to the iris; and 3) suturing a PC IOL transscerally. The major limitation of sulcus-fixed posterior chamber IOLs is that they require posterior capsule support. In some eyes, however, there is no support because of previous surgery: intracapsular cataract extraction, capsule rupture that occurred during phacoemulsification or epinucleus aspiration, or total lens removal resulting from vitrectomy. However, generally speaking, if there is no capsule support, the transscerally sutured PC IOL offers several advantages in certain eyes: because of its anatomic situation, there is less endothelial decompensation, chronic inflammation, and less peripheral anterior synechia, glaucoma, narrow anterior chamber, or cystoid macular edema [3-7]. Histological studies of the anterior segment showed that the best method in these eyes is sulcus fixation [8-12]. This fixation method stabilizes the IOL loop, which borders
regards efficacy, surgical complications, advantages, disadvantages, and surgery costs in cases with no capsule support.

Material and Methods: This was a retrospective study conducted on 24 patients (24 eyes), 14 of whom had traumatic cataract, six had postphacoemulsification complications, two were aphakic, and two had lens luxation. The patients were divided into two groups: group I, scleral fixation foldable IOL, and group II, scleral fixation rigid IOL, made up of 12 patients each, during a study period lasting 20 months. The procedures were performed under topical plus subconjunctival anesthesia in group I, under general anesthesia in group II, all by the same surgeon. The IOL scleral fixation technique used in both groups was the scleral incision technique.

Results: The mean age of group I patients was 57.8 years (range, 24-75 years), and in group II patients 50.3 years (range, 7-75 years). The average duration of the surgical intervention was significantly lower in the group I: 32.5 min (±0.19) versus 43.4 min (±0.4.2) in the group II (p<0.001). The incision required for the Ophtec PC 425Y 6/13.5 foldable intraocular lens was less than half the length needed for the other rigid intraocular lens (3.2 mm versus 7.0 mm). In group I, the patients reported no discomfort intraoperatively or postoperatively, and none required intravenous sedation. The mean duration of the convalescence period showed a statistically significant difference between the two groups: 3.8 (±0.45) weeks for group I and 12.5 (±0.90) weeks for group II (p<0.001). Group I achieved a Best optical Correction Visual Acuity (BCVA) of 0.57 (±0.17) at the 1st week postoperatively, whereas group II achieved a BCVA of 0.44 (±0.19). The difference was statistically significant (p<0.05). In the 1st postoperative month, group I presented a mean posterior astigmatism of –0.88 D (±0.42) and group II presented a mean postoperative astigmatism of –2.42 D (±0.60). The difference was statistically significant (p<0.05).

Conclusion: In this study, the scleral fixation of the foldable IOL Ophtec PC 425Y 6/13.5 with the scleral incision technique took less time, needed a smaller incision and provided a better visual outcome, suggesting that this could be the alternative to the conventional scleral fixation rigid IOL.

Key-words: Scleral fixation foldable IOL Ophtec PC 425Y 6/13.5, scleral fixation rigid IOL Alcon CZ 70 BD, scleral incision technique.

PATIENTS AND METHODS

Patients

We studied and operated on 24 patients (24 eyes), examined in the Department of Ophthalmology, São João University Hospital (Oporto, Portugal), that had no capsule support. Fourteen of them had traumatic cataract, six had postphacoemulsification complications, two were aphakic, and two had lens luxation. The patients’ demographic characteristics are summarized in table I. These patients were divided randomly into two groups: group I (Ophtec PC 425Y 6/13.5, scleral fixation foldable IOL) and group II (Alcon CZ 70 BD, scleral fixation rigid IOL). Each group included 12 patients with identical pathologies, with 10 males and 2 females in group I and 9 males and 3 females in group II. No restrictions concerning age or sex were made. The study was conducted over 20 months. Preoperatively, all patients had a complete ophthalmologic examination including best-corrected visual acuity (BCVA), slitlamp evaluation of the anterior segment, Goldmann applanation, tonometry, fundus assessment after pharmacologic pupil dilation, and B-mode ultrasound. Biometry was done using contact A-scan ultrasound axial length measurements and by keratometry with a RK-8100 P Kerato refractometer. The IOL power was calculated using the SRK II formula. All procedures were performed by the same surgeon (MMM). The procedures were performed under topical anesthesia supplemented with 0.15 mL of subconjunctival local anesthesia induced by lidocaine 2% in group I and under general anesthesia in group II. After complicated phacoemulsification occurred and the remaining capsule support was considered insufficient for conventional implantation, we removed the remaining capsule; anterior vitrectomy was performed with an automated vitrector and the scleral fixation of the IOL was performed using our scleral-fixation technique with scleral incision [16]. A timer measured surgical time in both groups. Any complications were recorded at post-

<table>
<thead>
<tr>
<th>Demographic characteristics.</th>
<th>Group I</th>
<th>Group II</th>
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<tbody>
<tr>
<td>Number of eyes</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Average age (years)</td>
<td>57.8</td>
<td>50.3</td>
</tr>
<tr>
<td>Age limit (years)</td>
<td>24-75</td>
<td>7-75</td>
</tr>
<tr>
<td>Sex (♂/♀)</td>
<td>10: 2</td>
<td>9: 3</td>
</tr>
</tbody>
</table>

Table I
operative day 2, 1 week, 2 weeks, then at 1 month, 3 months, and 4 months.

**Scleral fixation technique with scleral incision**

All patients had identical preoperative pharmacologic preparation with cyclopentolate 1%, phenylephrine 10%, ofloxacin, diclofenac 0.1% drops administered three times at 10-min intervals and stopped 45 min before the procedure. Group I patients received the same systemic sedatives (oral diazepam 10 mg) 45 min before starting surgery. The infusion cannula was placed in the anterior chamber through clear cornea, 1 mm from the limbus in the inferotemporal quadrant and maintained intraocular pressure (IOP) during surgery in two aphakic eyes. The surgical technique was identical in all eyes and comprised a tight limbus conjunctival flap at 5 o’clock and 11 o’clock. A radial scleral incision was made 3 mm perpendicular to the limbus and as deeply as possible at 5 o’clock and 11 o’clock (fig. 1a), followed by a scleral layer cauterization. A scleral layer pathway was made 1.5 mm behind the posterior surgical limbus with a 30-gauge needle. The 10-0 Prolene needle extremity was passed opposite the pointed one through this scleral pathway until it was seen in the pupillary area (fig. 1b). We then pulled the Prolene thread externally through the 7-mm-long clear corneal incision and the haptic extremity could then pass through the interior of the foldable IOL with its haptic hole, so that the lens’s haptic extremity was brought through the haptic hole, so that the lens’s haptic extremity was then pulled through the haptic hole and extracted the Prolene needle by reversing it through the incision. The extremity of the folded thread was brought through the haptic hole, so that the lens’s haptic extremity could then pass through the interior of the foldable IOL (sailor’s stitch) (fig. 2). The Ophtec PC 425Y 6/13.5 scleral-fixated foldable IOL was inserted into the posterior chamber through a clear corneal incision made with a standard 3.2-mm steel blade, using an IOL folding forceps. The Alcon CZ 70 BD scleral fixation rigid IOL was inserted into the posterior chamber through the 7-mm-long clear corneal incision and the haptics was placed in the ciliary sulcus, with IOL scleral fixation through a stitch made on the side of the scleral incision outwardly so as to have an intrascleral suture (fig. 3). A scleral incision suture was made with 7-0 Dexon followed by a conjunctival flap suture. Residual vitreous and viscoelastic material was removed from the anterior chamber, and the pupil constricted with aceytlocholine. In group I, ten corneal incisions self-sealed with corneal stroma hydration; in two eyes with inadequate wound sealing, a 10-0 nylon suture was performed. In group II, all corneal wounds a 10.0 nylon suture was performed. A balanced salt solution was injected from the corneal side port to control intraocular pressure and detect wound adaptation. Dexamethasone sodium phosphate and gentamicin antibiotic was injected subconjunctivally at the end of the procedure. The postoperative doses of topical dexamethasone, ofloxacin, and flurbiprofen were instilled three times daily during the 1st month after surgery.

**Intraocular lenses**

In group I, we used the Ophtec PC 425Y 6/13.5 scleral-fixated foldable IOL comprising three parts: the optic diameter was 6.0 mm, made of highly purified polysiloxane, and two PMMA haptics were perforated in the extremities (total diameter, 13.5 mm). This IOL is formed by an optically transparent polysiloxane elastomer with a UV absorber conveniently connected. It registers light transmittance in the visual spectrum in 90%, has a 1.431 (35°) refraction index and an approximate contrast of 117.2. In group II, we used the Alcon CZ 70 BD scleral-fixated rigid IOL comprising three parts: the optic disc, 6 mm in diameter, and two PMMA haptics (total diameter, 13.5 mm).

**Follow-up and statistical analysis**

Postoperatively, patients were examined at day 2, 1 week, 2 weeks, 1 month, 3 months and 4 months. The examinations included BCVA, keratometry with an RK-8100 P Kerato refractometer, slitlamp evaluations, Goldmann applanation tonometry, and fundus evaluation.

SPSS program was used for statistical analysis. The numeric variables were compared by the "T test" and the categorical ones by the "Fisher exact test". An explicative model was built using logistic regression.

**RESULTS**

We studied 24 eyes of 24 patients. There were no significant age differences between the two groups. The mean age of the 19 men and 5 women in the study was 54.0 years (range, 7-75 years) (table I). The mean age of group I was 57.8 years (range, 24-75 years), and of group II was 50.3 years (range, 7-75 years) (table I). No significant differences were found concerning age, sex, and systemic or ocular antecedents. Each of the IOLs was tested on the same number of cases. The mean follow-up was 11.5 months (range, 4-20 months). There was no difference between the proportion of patients who received topical anesthesia supplemented with 0.15 mL of subconjunctival local anesthesia induced by lidocaine 2% in group I and under general anesthesia in group II. Postprocedure hospitalization was significantly higher in group II. Although the number of cases studied (12 in each group) is insufficient to reach statistical significance, no differences were found concerning the number of peroperative surgical complications. Hyphema was found in 2 patients in group I versus 3 patients in group II; vitreous hemorrhage or choroidal hemorrhage did not occur in either group.

On the 2nd postoperative day, all corneas remained clear with only a mild inflammatory reaction in the anterior chamber, the pupils were centred, and there were no cases of IOL decentration or choroidal or retinal...
detachment. Intraocular pressure was less than 22 mmHg with topical medications.

Late postoperative complications (after 3 months of follow-up) such as lens decenteration, lens tilt, and retinal detachment did not occur either.

Differences were found concerning the average visual acuity in the two groups. Group I achieved a best optical correction visual acuity (BCVA) of 0.57 (±0.17) at week 1 postoperatively, whereas group II achieved a BCVA of 0.44 (±0.19). In the 1st postoperative month, the

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**Figure 1:** (a) Scleral incision. (b) Introduction of the Prolene needle into the eyeball.

**Figure 2:** Fixation of the Prolene thread to the lens haptics.

**Figure 3:** Scleral lens fixation.
average visual acuity was 0.75 (±0.21) in group I (0.75 versus 0.56) (fig. 4), whereas group II only achieved a BCVA of 0.67 (±0.25) (fig. 4) at the end of the 3rd postoperative month. While allowing for this difference, the number of cases we studied, 12 in each group, is still insufficient to reach any broad statistical significance. In the 3rd postoperative month, average visual acuity was similar in both groups (0.75 versus 0.67) (fig. 4). In the 1st postoperative month, group I presented a mean postoperative astigmatism of –0.88 D (±0.42) and group II presented a mean postoperative astigmatism of –2.42 D (±0.60). The difference was statistically significant (p<0.05).

As regards the incision needed for the intervention, there was a significant difference between both groups: the incision required for the Ophtec PC 425Y 6/13.5 foldable intraocular lens was less than half the length needed for the other rigid intraocular lens (3.2 mm versus 7.0 mm). The average duration of the surgical intervention using the foldable intraocular lens was significantly lower when compared to the other rigid intraocular lens (table II).

As for the duration of convalescence (days of absence from work), we observed a statistically significant difference between the two groups: the duration of convalescence averaged 3.8 (±0.45) weeks for group I and 12.5 (±0.90) weeks for group II. During the follow-up, there were two cases of cystoid macular edema in group I and four cases in group II. There were no cases of choroidal displacements, recurrent hemorrhages, or endophthalmitis.

### DISCUSSION

In the past few years, we have been modifying our anesthesia and surgical techniques and using topical plus subconjunctival anesthesia as an alternative to traditional retrobulbar, peribulbar, or general anesthesia for scleral fixation of secondary IOL implants. Nevertheless, it must be noted that in limbal anesthesia the anesthetic agents may also reach the iris and ciliary body by the conjunctival-scleral route with iris and ciliary body anesthesia [17]. In our study, topical plus subconjunctival anesthesia and oral sedation were used in group I; general anesthesia was used in group II. None of the patients in group I experienced discomfort during the procedure and none required additional anesthesia to complete surgery safely. This method avoids the risks associated with peribulbar, retrobulbar, or general anesthesia, such as periocular bruising or swelling, ptosis, optic nerve injury, orbital hemorrhage, central retinal artery or vein occlusion, brain-stem anesthesia, and even death [18-20]. We believe that topical plus subconjunctival anesthesia is sufficient for scleral fixation of secondary foldable IOL implants. It is also less time-consuming and more cost-effective. In addition, because the eye is left unpatched, postoperative visual recovery is immediate and ocular motility normal [19]. It is a challenge for surgeons to treat patients with scleral fixation of secondary IOL implants because the analysis of the data demonstrates that topical plus subconjunctival anesthesia is a technique that is safe and effective.

Scleral fixation of the Alcon CZ 70 BD scleral-fixated rigid IOL requires an incision of at least 7.0 mm for implantation. Use of the Ophtec PC 425Y 6/13.5 scleral-fixated foldable IOL is increasing as small-incision surgery gains greater acceptance. We use our IOL scleral fixation technique, which is easy, effective, and has obvious advantages: it does not make the sclera fragile, lowers the percentage of intraoperative and late complications, and increases the resistance of the fixation thread because it uses a double thread and the suture is passed from the external surface to the inside of the eye only once. We bury the free ends of the Prolene suture between the two edges of the scleral incision. Moreover, the duration of the procedure using the scleral incision technique is significantly lower than that using the scleral flap technique and prevents unnecessary trauma to the eye.

The Ophtec PC 425Y 6/13.5 IOL with the haptics perforated in the extremities, inserted through a smaller incision (3.2 mm), provides two important advantages. First, patients who have scleral-fixated rigid IOL implantation usually have significant astigmatism from their previous surgery. The figure for postoperative astigmatism depends on the number, depth, tightness, and location of the sutures in large-incision surgery. Performing IOL scleral fixation through a sutureless 3.2-mm incision instead of a 7.0-mm or longer incision lowers

### Table II

<table>
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<tr>
<th>IOLs</th>
<th>Duration of intervention (Mean±SD) (min)</th>
<th>P value</th>
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<tr>
<td>Foldable IOL</td>
<td>32.5±4.0</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Rigid IOL</td>
<td>43.4±4.2</td>
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the risk of additional astigmatism because of the incision width and because the wound can be left sutureless in many cases [21]. In the 1st postoperative month, group I presented a mean postoperative astigmatism of –0.88 D (±0.42) and group II presented a mean postoperative astigmatism of –2.42 D (±0.60). The patients operated on though a small incision present rapid stabilization of the corneal wound and early recovery of visual acuity [21]. Group I achieved a best optical correction visual acuity (BCVA) of 0.57 (±0.17) at the 1st week postoperatively, very similar to that reported by Yosuke [21], whereas group II achieved a BCVA of 0.44 (±0.19).

The second advantage of the small corneal incision is that it is performed in a relatively closed system, preventing intraoperative hypotony and thus enabling the surgeon to work more comfortably as well as lowering the risk of related complications such as suprachoroidal hemorrhage. It also decreases the incidence of clinically apparent cystoid macular edema (CME) [22-24]. The mean duration of the procedure with the corneal small incision (3.2 mm) was significantly lower, namely because of the absence of corneal suture. Patients operated on through a small incision present rapid stabilization of the corneal wound and early recovery of visual acuity [21]. When the remaining capsular support was considered insufficient for conventional implantation, we removed the remaining capsule, and anterior vitrectomy was performed with an automated vitrector in order to facilitate the implantation of the IOLs and to minimize late complications as regards retinal displacement and CME, as recommended by Nabors and collaborators [25].

In addition to the early recovery of visual acuity and the lower keratometric change, one of the most important differences between these two techniques is the average duration of convalescence: group II took three times longer to convalesce than the group in which foldable IOLs were used. This proves that scleral lens fixation surgery can and should be performed using small incision techniques using the Ophtec PC 425Y 6/13.5 scleral-fixated foldable IOL with two PMMA haptics perforated in the extremities.

CONCLUSION

Our experiment demonstrates that our IOL scleral fixation technique with topical plus subconjunctival anesthesia provides a safe and comfortable surgical environment for an experienced surgeon and can be considered a progressive and valid alternative to the multiple preoperative administration of anesthesia. Scleral fixation of the foldable IOL Ophtec PC 425Y 6/13.5 is an option that is foldable, haptics-perforated, effective, safe, and comfortable for the surgeon, less time-consuming, and one that provides the opportunity of working in a closed system. There are fewer intraoperative complications; however, the surgeon’s experience remains a concern. Because of the small study population, it is recommended that a large number of patients be evaluated over the long term.

We would like to thank Mr. Pinto Hespanhol MD PhD for his contribution to the statistical analysis.

REFERENCES


