INTRODUCTION

Until the 1980s, the intracapsular method was the method of choice, but quickly the extracapsular method became progressively more popular. With the intracapsular method, intraocular lens (IOL) implantation in the sulcus was impossible, which was also true when the extracapsular method had zonular dehiscence complications or large fissures in the posterior capsule. Today there are many fewer cases of traumatized eyes, ectopic lenses, or pediatric lensectomies that present without capsular support. In cases of limited zonular dehiscence, the intraocular lens can be placed in the capsular bag using a capsular tension ring, without compromising stability [1].

There are several causes for zonular and capsular support loss: trauma, complicated surgeries, zonule weakness, and secondary and congenital capsule weakness. The lens can be damaged by a variety of physical, electric, thermal, and chemical factors, but the penetrating and contusing forces are those that truly compromise the zonular and capsular support. Closed trauma has been referred to as the cause of posterior capsule rupture, typically circular or oval and centered. Deforming forces can also stretch the zonule and cause dehiscence. Penetrating lesions cause direct ruptures in the anterior and/or posterior capsule. During extracapsular cataract extraction,
Material and Methods: This was a retrospective study conducted on thirty patients (30 eyes), ten of whom were aphakic, eleven had traumatic cataract, seven had post-phacoemulsification complications, and two had lens luxation. The patients were divided into two groups (I – scleral incision technique and II – scleral flap technique) of fifteen patients each, during a study period lasting eighteen months. The great majority of the procedures were performed under general anesthesia and by the same surgeon. Statistical analysis was done using SPSS. The numerical variables were compared using the t test and the categorical ones using the Fisher exact test. We performed multifactorial analysis to build a model that could predict and compare the complications associated with each technique. An explicative model was built using logistic regression.

Results: We observed a threefold higher rate of complications associated with the scleral flap technique when compared to the scleral incision technique. This difference was particularly relevant as regards the occurrence of free scleral flap and hyphema. No statistically significant differences were observed regarding vitreous hemorrhage, choroidal hemorrhage, retinal detachment, difficulty in the external pulling of the Prolene suture, breaking of the Prolene suture, and anterior chamber collapse. We found a significant association between intraoperative complications and the technique used (higher number of complications with the scleral flap) and also with some systemic diseases (patients with hypertension had more intraoperative complications). The number of late complications resulting from the scleral flap technique was much higher than those observed with the scleral incision technique; however, the number of the cases we studied is insufficient to reach statistical significance.

Conclusion: The duration of the procedure using the IOL scleral incision technique is significantly lower than using the scleral flap technique. Intraoperative complications were significantly associated with the technique used: more frequent with scleral flap. Late complications were mainly associated with systemic and previous ocular diseases.

Key-words: New IOL scleral incision fixation technique, scleral flap technique.
A stitch made on the side of the scleral incision outwardly so as to have an intrascleral suture knot (fig. 5). A scleral incision suture was made with Dexon 7.0 followed by a conjunctival flap suture.

The scleral flap technique (group II) consisted of a 4- and 10-o’clock superior conjunctival peritomy followed by placement of a 3-mm-long and 2-mm-wide triangular scleral flap at 4 and 10 o’clock (two flaps) (fig. 6). We made a 7-mm scleral-corneal opening after anterior vitrectomy. A 10.0-G straight Prolene needle was introduced through the scleral layer, 1.5 mm posterior to the limbus, parallel to the iris, until the end could be seen in the pupillary area (fig. 7). A 28-G needle was introduced into the eye through the opposite scleral layer, in order to canalize the 10.0 Prolene straight needle in its lumen (fig. 8). The 28-G needle was removed from the eye as well as the straight needle, allowing the polypropylene 10.0-G suture to cross the eye from one scleral layer to the other (fig. 9). Using a Sinskey hook, the suture thread was removed through the superior corneoscleral wound (fig. 10). The thread was cut and each extremity was attached to an IOL haptic (fig. 11).

The IOL was placed in the ciliary sulcus and the sutures were attached to the scleral flap layer (fig. 12).

A second 10.0-G polypropylene thread was attached to the scleral flap layer in order to attach the fixation...
thread to the lens followed by a conjunctival and scleral flap suture.

A timer measured surgical time in both techniques. Every complication was recorded at postoperative day 2, day 15, then at 1 month, 3 months and 6 months.

**Statistical analysis**

Statistical analysis was done using the SPSS program. The numeric variables were compared using the t test and the categorical variables using the Fisher exact test. We conducted a multifactorial study to evaluate the complications associated with each technique. An explicative model was built using logistic regression.

**RESULTS**

We studied thirty eyes of thirty patients. The patients’ demographic characteristics are summarized in table I. There were no significant age differences between the two groups. Each of the techniques was tested on the same number of cases. The rate of ocular antecedent occurrences in the patients was not significantly different. We observed a threefold higher rate of complications associated with the scleral flap technique than in the scleral incision technique (fig. 13). However, the number of cases we studied, 15 in each group, is insufficient to reach statistical significance.

Free scleral flap was recorded only when group II’s technique was used. The number of hyphemas was
higher when the scleral flap technique was used (five versus two), as was the case with the collapse of the anterior chamber (three versus two) and problems with the external pulling and breakage of the Prolene suture (one versus none). No differences were found concerning vitreous hemorrhage, choroidal hemorrhage, and retinal detachment. The number of late postoperative complications following the scleral flap technique was much higher than with our IOL scleral fixation technique. Differences were found concerning the occurrence of lens tilt and luxation. Cystoid macular edema occurred in four patients in each group. The duration of the conjunctival opening was significantly higher using the scleral flap technique.

Figure 9: External pulling of the Prolene needle.
Figure 10: External pulling and cutting of the Prolene thread.
Figure 11: Prolene thread fixation to the lens haptics.
Figure 12: Lens scleral fixation.
The scleral flap, cauterization, and insertion of the needle into the globe took significantly longer when using the two-point fixation and scleral flap technique. The time spent in the fixation, insertion, and scleral suture of the lens was not significantly different between the two techniques, nor was there any significant difference concerning the conjunctival suture.

The average duration of the surgical intervention using the scleral incision technique was significantly lower when compared to the other technique table II.

On the 2nd postoperative day, every eye presented transparent cornea, a centered pupil, a mild inflammatory reaction in the anterior chamber, ocular tension <20 mmHg, and centered intraocular lenses. In the 3rd and 6th postoperative months, the average visual acuity was similar in both groups. Twenty eyes presented the best optical correction of at least 20/40 (or better) and the rest presented a visual acuity of <20/100 and <20/40 due to macular changes.

In order to identify the main determinants of the complications observed, they were classified according...
the time of occurrence into preoperative and late complications. We performed a multivariate analysis to identify the variables most associated with the occurrence of complications table III and IV. We found a significant association between preoperative complications and the technique we use (more with the scleral flap) and systemic diseases (patients with hypertension). The number of late complications following the scleral flap technique was much higher than what was observed with the scleral incision technique; however, the patient sample was too small for statistical significance. Late complications were mainly associated with systemic and previous ocular diseases.

**DISCUSSION**

The ciliary sulcus is a slightly avascular area and intraocular lens placement in this anatomic area is only slightly stable because of the surrounding structures. There are also complications that occur with anterior chamber lenses such as corneal endotheliitis, secondary glaucoma, and acute iritis [16, 18, 19]. An anatomic study developed by Duffey and collaborators concluded that the location of the ciliary sulcus in relation to the posterior surgical limbus is 0.94 mm in the vertical meridian and 0.50 mm in the horizontal meridian [8]. Clinical studies concluded that locating the ciliary sulcus still frequently fails when using the external method. Belluci and others conducted ultrasonic biomicroscopy in 16 eyes of 12 patients after scleral lens fixation and found that of 18 haptics sutured 2–3 mm behind the posterior surgical limbus, 16 were posterior to the ciliary sulcus [20]. When that distance was reduced to 1.5-2 mm, six haptics were in the ciliary sulcus, six in the pars plana, and two in the iris rout. This shows how difficult it is to determine the position of the fixation sutures precisely.

In the IOL scleral fixation technique, we have always used the distance of 1.5 mm behind the posterior surgical limbus to place the Prolene suture in the scleral pathway, for it seemed to be the most probable location of the ciliary sulcus, as was shown by Richard’s experiments [21]. In addition to the limbus suture distances, other variables contribute to correctly localizing the haptic in the sulcus, such as the needle angle as it penetrates the sclera and the secondary anatomic variations in cataract extraction. Other operative factors seem to be important in localizing the ciliary sulcus, including the needle penetration with the eye closed and the use of appropriate lens size [22].

### Table III

Intraoperative complications: multifactorial analysis.

<table>
<thead>
<tr>
<th>Intraoperative complications</th>
<th>Coef.</th>
<th>S.E.</th>
<th>Wald</th>
<th>DF</th>
<th>p</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technique</td>
<td>-4.893</td>
<td>2.413</td>
<td>4.112</td>
<td>1</td>
<td>0.043</td>
<td>0.001 0.849</td>
</tr>
<tr>
<td>Systemic antecedents</td>
<td>-3.640</td>
<td>1.709</td>
<td>4.538</td>
<td>1</td>
<td>0.033</td>
<td>0.001 0.747</td>
</tr>
<tr>
<td>Constant</td>
<td>18.855</td>
<td>9.139</td>
<td>4.256</td>
<td>1</td>
<td>0.039</td>
<td></td>
</tr>
</tbody>
</table>

### Table IV

Late complications: multifactorial analysis.

<table>
<thead>
<tr>
<th>Late complications</th>
<th>Coef.</th>
<th>S.E.</th>
<th>Wald</th>
<th>DF</th>
<th>p</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ocular antecedents</td>
<td>1.156</td>
<td>0.579</td>
<td>1.990</td>
<td>1</td>
<td>0.046</td>
<td>0.195 2.292</td>
</tr>
<tr>
<td>Systemic antecedents</td>
<td>2.682</td>
<td>1.177</td>
<td>2.280</td>
<td>1</td>
<td>0.023</td>
<td>0.375 4.989</td>
</tr>
<tr>
<td>Constant</td>
<td>0.827</td>
<td>6.572</td>
<td>0.130</td>
<td>1</td>
<td>0.900</td>
<td></td>
</tr>
</tbody>
</table>
The number of hyphemas was higher when using the scleral flap technique, probably because of the greater manipulation of the eyeball, the needle penetration angle in the eye, and the use of higher-caliber needles. The free scleral flap was only observed in the technique used in group II, because scleral incision was performed in group I. In addition to freeing the scleral flap and the time spent in that procedure, there can also be erosion of the suture knot in the sclera in 27% of the cases, as Bellucci has proved [18], resulting from scleral flap atrophy, although in our patients none has irritated through the conjunctiva in 45 months. Suture exposure can lead to endophthalmitis, even after several years [16, 23].

Since we did not study a large number of clinical cases, no statistically significant differences were observed relating to anterior chamber collapse, vitreous hemorrhage, choroidal hemorrhage, retinal detachment, difficulty in external pulling, and Prolene suturing. The number of late complications are well described in the scleral flap technique, namely cystoid macular edema [12, 23, 24] and lens decentration, probably due to the greater manipulation of the eye and the scleral fixation technique. We found a threefold higher rate of complications associated with the scleral flap technique when compared to the scleral incision technique. Again, this was not statistically significant because of the sample size, fifteen cases studied in each group.

The mean duration of the procedure with the scleral incision technique was significantly lower, namely in the conjunctival opening, the scleral flap, the scleral layer cauterization, the introduction of the Prolene thread into the eye, the thread fixation to the lens, the scleral lens fixation, and the scleral flap suture. There were no statistical differences regarding late surgical complications and visual acuities.

**CONCLUSION**

Our IOL scleral fixation technique has obvious advantages: it does not make the sclera fragile, it lowers the percentage of late and intraoperative complications, it 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 one time only. Moreover, the duration of the procedure using the scleral incision technique is significantly lower than using the scleral flap technique. It does not cause pigment dispersion in the iris and the type of thread fixation to the lens increases its stability. The incision scleral technique offers a simplified and elegant method for fixation of IOLs and other intraocular devices.

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**REFERENCES**