Needle versus VacuFix enclavation of iris fixated intraocular lenses

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PURPOSE: To compare needle enclavation to the newer VacuFix enclavation of iris fixated intraocular lenses in terms of visual/refractive outcomes, ease of positioning, postoperative pigment dispersion onto the lens surface, amount of horizontal iris capture and lens/iris distance.

SETTING: Instituto de Microcirugía Ocular (IMO), Barcelona, Spain.

METHODS: Prospective, interventional, comparative study. Patients were assigned to have intraocular lens (IOL) transplant using the enclavation needle in one eye and the VacuFix system in the other. The number of attempts needed to enclavate the haptics during the procedure was noted. Postoperatively, all eyes were followed up at one day, one week and three months. At follow-up, refraction, uncorrected/best-corrected visual acuities, anterior chamber flare and cells, and cells present on the surface of the IOL were noted. Three months postoperatively, anterior segment optical coherence tomography was performed to assess both the amount of tissue included in the enclavation (iris bridge), and the distance of the posterior surface of the IOL from the anterior surface of the iris (lens/iris distance).

RESULTS: Forty eyes of twenty patients were included. Postoperative mean uncorrected distance visual acuity (UDVA) was 0.11 ± 0.23 logMAR and 0.12 ± 0.20 logMAR (p = 0.99), and postoperative spherical equivalent (SE) was −0.06 ± 0.71 and +0.10 ± 1.28 (p = 0.72) with 100% and 88.9% of eyes within ±1 dioptre (D) of the intended postoperative refraction in the needle and VacuFix groups, respectively. Both enclavation techniques were equal in terms of pigment deposition on the IOL, postoperative inflammation, lens/iris distance and ease of enclavation. Iris-bridge was statistically greater (267.2 ± 63.4 μm; p < 0.01) but more inconsistent (range 224 - 332 μm) in the needle group than in the VacuFix group (232.4 ± 17.8 μm; range 222 - 241μm).

CONCLUSION: VacuFix enclavation of iris-fixated IOLs is as safe and efficient as the needle fixation technique. Iris-bridge was statistically greater and less consistent in the needle than in the VacuFix group.

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Early attempts at using iris-fixated intraocular lenses (IOLs) in the 1950s and 60s were quickly abandoned due to safety issues1,2. Three decades later, however, improvements in lens design have allowed for the resurgence of iris-fixated IOLs3-5.

Artisan*/Artiflex® iris-fixated IOLs (Ophtec, Groningen, the Netherlands) have demonstrated their safety and efficacy in the correction of various spherical refractive errors6,7, and more recently, their ability to correct astigmatism of varying degrees, with the introduction of the toric versions of these lenses8.

The precise placement of the Artisan*/Artiflex® lenses is of utmost importance. Decentered IOLs have reduced effectiveness, and can cause glare as well as other troublesome aberrations. Inadequate enclavation of iris tissue can cause iris chafing with subsequent pigment dispersion, which if severe can lead to IOL subluxation/dislocation9. Moreover, with the toric design, imprecise haptic enclavation will reduce the efficacy of the lens in correcting the pre-existing astigmatism. Numerous studies have clearly shown that off-axis rotation of a toric IOL by just one degree results in a 3.3% loss of astigmatic correction10,11.
NEEDLE VS VACUFIX ENCLAVATION FOR IRIS-FIXATED IOLS

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Iris enclavation of iris-claw IOLs is generally performed using one of two surgical techniques. In the first, an enclavation needle (Figure 1; provided by the manufacturer) is introduced through two obliquely fashioned side-ports. In the second, the procedure is carried out using small gauge vitreo-retinal forceps introduced through two side ports situated 90 degrees from the main incision, in a manner similar to standard phacoemulsification surgery. These techniques for implantation of iris-fixated IOLs are time honored, and many papers have been previously published demonstrating their efficacy and safety.12-14

Most novice surgeons find the enclavation step the most technically difficult part of the procedure. The new BO150 VacuFix (Ophtec, Groningen, The Netherlands) is a system consisting of two color-coded handpieces (purple for the right haptic and orange for the left one) that resemble the traditional enclavation needle but differ in that they end in a blunt tip with an oval aperture on its underside. This aperture is used to aspirate the iris tissue through activation of a vacuum using a foot pedal, allowing enclavation of a reproducible amount of iris tissue between the haptics of the lens every time. The new system is designed to be compatible with nearly all phacoemulsification machines, and could be used to enclavate all iris-claw lenses (Figure 2).

The objective of this study was to assess if the new VacuFix enclavation system performs as well as the needle enclavation technique, and to determine if the VacuFix offers any added value to the ophthalmic surgeon.

PATIENTS AND METHODS

Patient Population

Forty eyes of twenty patients were assigned to receive an iris fixated IOL. One eye was to have the IOL enclavated using the specifically designed needle, while the new VacuFix enclavation system was to be used in the contralateral eye.

Inclusion and Exclusion Criteria

Inclusion criteria for the phakic eye group were myopia or compound myopic astigmatism, an endothelial cell count (ECC) of ≥ 2300 cells/mm² and an anterior chamber depth (ACD) (distance from anterior lens capsule to the corneal endothelium) of ≥ 3.0 mm. In the aphakic eye group, the inclusion criteria were an ECC of ≥ 2300 cells/mm², ACD of ≥ 3.0 mm and an intact iris architecture that would allow an adequate/stable IOL enclavation. Eyes with preoperative cataract, glaucoma, ocular surface disease, uveitis, retinal disease or inadequate iris tissue that would not allow for adequate/stable IOL enclavation were excluded from this study.

Patient Assessment

Preoperative refraction, corneal tomography (Orbscan II, Bausch & Lomb, Technolas, NY, USA) and ECC (Topcon SP2000P; Topcon, Nishinomiya, Hyogo, Japan) were determined in all eyes. All patients were followed up at one day, one week and at three months postoperatively; refraction, uncorrected visual acuity (UCVA) and best-corrected visual acuity (BCVA), anterior chamber flare and cells, deposits on the surface of the IOL and any other complications were noted at each visit. Anterior segment optical coherence tomography (AS-OCT Visante, Carl Zeiss Meditec Inc., Dublin, CA, USA) was performed at three months postoperatively to assess both the amount of tissue included in the enclavation (iris-bridge) and the distance of the posterior surface of the lens from the anterior surface of the iris (lens-iris distance) in the area just adjacent to the enclavation site (Figure 3).
The Intraocular Lenses

The Artisan® phakic IOL is a single piece lens made of PMMA manufactured with compression-molding technology. It has an overall diameter of 8.5 mm and a convex-concave optical zone of 6.0 mm. The Artiflex® phakic IOL is a 3-piece lens, again with an overall diameter of 8.5 mm. It has a convex-concave 6.0 mm optic made of silicone and the haptics made of PMMA, thus allowing the IOL to be inserted through a 3.2 mm incision (Figure 4).

The Artisan® lens aphakia is a monofocal 1-piece convex-concave PMMA IOL with an 8.5 mm length and a 5.0 mm optical zone (Figure 5). The toric models of the Artisan® and the Artiflex® have their cylindrical component either parallel or perpendicular to the long axis of the IOL.

Lens power for the phakic group was calculated using the van der Heijde formula, while for the aphakic group, regular biometric formulas such as the SRK/T were used. All surgeries were performed under topical anesthesia by the same surgeon (JLG). A single plane posterior corneal incision was centered at 12 o’clock, and two vertical paracentesis were performed located at 2 and 10 o’clock and directed to the point where enclavation was desired. After intra-cameral injection of acetylcholine and viscoelastic material, the lens was introduced in a single step (to avoid any contact between the front part of the IOL and the crystalline lens) and thereafter rotated 90 degrees into a horizontal position from 3 to 9 o’clock. Toric IOLs had their enclavation sites centered at the pre-marked axis. The IOLs were then either fixed with an enclavation needle with a bent tip that pushes the iris into both claws of the haptic, or the BO150 VacuFix handle was introduced into the eye via the paracentesis while holding the Artisan®/Artiflex® lens with the holding forceps. While holding the VacuFix flat onto the iris surface underneath the slit in between the haptics, vacuum was engaged by depressing the phaco-machine footswitch until the maximum level (±200 mmHg) of vacuum was reached. At that point the haptics were pressed downward over the VacuFix tip, enclavating the IOL to the iris. The centration of the IOL over the pupil was checked. All manipulations were performed under viscoelastic protection. Finally, a peripheral slit iridotomy was performed at 12 o’clock; the viscoelastic material was exchanged with balanced salt solution using the irrigation/aspiration (I/A) of the phaco machine, and the incision was closed with as many interrupted 10 - 0 nylon sutures needed to close the incision completely with minimal tension. The tension of the sutures was subjectively checked with a Maloney keratoscope.

Statistical analysis

Data analysis was performed using the software SPSS for Windows version 19.0 (IBM, Armonk, NY, USA). Normality of data samples was evaluated by means of the Kolmogorov-Smirnov test. Mean, standard deviation, median and range was provided for all parameters measured in the analyzed sample. When parametric analysis was possible, the Student t test for unpaired data was used for comparisons between groups (needle vs. VacuFix), while the Mann-Whitney U test was applied to assess the significance of such differences when parametric analysis was not possible. Furthermore, statistical analysis of differences in frequencies or percentages, as well as in categorical data was performed using the Chi-square test. A p-value of less than 0.05 was considered statistically significant for all tests.
Table 1. Preoperative and postoperative visual and refractive data.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Needle</th>
<th>VacuFix</th>
<th>p-value</th>
<th>Needle</th>
<th>VacuFix</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LogMAR</td>
<td></td>
<td>-</td>
<td>-</td>
<td>0.11 (0.23)</td>
<td>0.12 (0.20)</td>
<td>0.99</td>
</tr>
<tr>
<td>UDVA</td>
<td>-5.05 (7.21)</td>
<td>-7.04 (7.06)</td>
<td>0.88</td>
<td>-5.11 (0.82)</td>
<td>0.29 (0.43)</td>
<td>0.78</td>
</tr>
<tr>
<td>Sphere (D)</td>
<td>-8.37 (-15.00 to +12.00)</td>
<td>-9.00 (-16.50 to +13.00)</td>
<td>0.92</td>
<td>-5.11 (0.82)</td>
<td>0.29 (0.43)</td>
<td>0.78</td>
</tr>
<tr>
<td>Cylinder (D)</td>
<td>-1.13 (-7.00 to 0.00)</td>
<td>-1.25 (-5.00 to 0.00)</td>
<td>0.97</td>
<td>-0.06 (0.71)</td>
<td>0.12 (0.58)</td>
<td>0.72</td>
</tr>
<tr>
<td>Spherical equivalent (D)</td>
<td>-7.83 (6.59)</td>
<td>-7.72 (6.88)</td>
<td>0.97</td>
<td>-0.06 (0.71)</td>
<td>0.12 (0.58)</td>
<td>0.72</td>
</tr>
<tr>
<td>J0 (D)</td>
<td>-0.25 (0.63)</td>
<td>-0.12 (0.62)</td>
<td>0.57</td>
<td>-0.06 (0.71)</td>
<td>0.12 (0.58)</td>
<td>0.72</td>
</tr>
<tr>
<td>J45 (D)</td>
<td>-0.33 (-1.25 to +0.86)</td>
<td>0.00 (-1.25 to +0.87)</td>
<td>0.69</td>
<td>-0.06 (0.71)</td>
<td>0.12 (0.58)</td>
<td>0.72</td>
</tr>
<tr>
<td>B (D)</td>
<td>9.77 (2.94)</td>
<td>9.95 (2.59)</td>
<td>0.84</td>
<td>0.00 (0.98 to +1.00)</td>
<td>0.00 (-1.73 to +0.77)</td>
<td>0.17</td>
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<tr>
<td>LogMAR</td>
<td>0.04 (0.06)</td>
<td>0.05 (0.06)</td>
<td>0.95</td>
<td>0.00 (0.00 to 0.22)</td>
<td>0.00 (0.00 to 0.30)</td>
<td>0.81</td>
</tr>
<tr>
<td>CDVA</td>
<td>0.05 (0.00 to 0.22)</td>
<td>0.05 (0.00 to 0.22)</td>
<td>0.95</td>
<td>0.00 (0.00 to 0.22)</td>
<td>0.00 (0.00 to 0.30)</td>
<td>0.81</td>
</tr>
</tbody>
</table>

UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity; J0 and J45, astigmatic power vector components; B, overall blur strength; SD, standard deviation.

Table 2. Postoperative visual outcomes.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Needle</th>
<th>VacuFix</th>
</tr>
</thead>
<tbody>
<tr>
<td>UDVA ≤ 0.00</td>
<td>70.0%</td>
<td>55.6%</td>
</tr>
<tr>
<td>UDVA ≤ 0.10</td>
<td>85.0%</td>
<td>77.8%</td>
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<tr>
<td>UDVA ≤ 0.20</td>
<td>90.0%</td>
<td>83.3%</td>
</tr>
<tr>
<td>UDVA ≤ 0.30</td>
<td>90.0%</td>
<td>88.9%</td>
</tr>
<tr>
<td>UDVA ≤ 0.00</td>
<td>85.0%</td>
<td>83.3%</td>
</tr>
<tr>
<td>UDVA ≤ 0.10</td>
<td>90.0%</td>
<td>94.4%</td>
</tr>
<tr>
<td>UDVA ≤ 0.20</td>
<td>100.0%</td>
<td>94.4%</td>
</tr>
<tr>
<td>UDVA ≤ 0.30</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity; SD, standard deviation.

Figure 6. Distribution of the type of IOL implanted in each group.

Figure 7. Distribution of postoperative visual outcomes.

Figure 8. Distribution of postoperative spherical equivalent.
RESULTS

Demographic data

A total of 39 eyes from 20 patients with a mean age of 35.5 years (SD: 8.6; median: 35.5; range: 23 to 49 years) were included in the study. This sample was comprised of 19 right eyes (48.7%) and 20 left eyes (51.3%) of 8 males (40.0%) and 12 females (60.0%). The two groups were differentiated according to the method used for iris enclavation: the needle group included 20 eyes (51.3%) of 20 patients, and the VacuFix group included the 19 contralateral eyes (48.7%) of the same 20 patients. The type of IOL implanted in each group is shown in Figure 6.

No statistically significant differences were found between groups in the percentage of eyes implanted with each type of IOL (p = 0.91). There were no statistically significant differences in age between groups (36.7 ± 8.3 vs. 36.2 ± 9.4, p = 0.70).

Visual and refractive outcomes

Table 1 summarizes the preoperative and postoperative visual and refractive data in the analyzed sample. No eye lost lines of LogMAR CDVA in the needle group, whereas 1 eye (5.3%) lost 1 line of LogMAR visual acuity in the VacuFix group.

Figure 8 displays the distribution of the postoperative spherical equivalent in the two groups of the analyzed sample.

Table 3 summarizes the preoperative and postoperative visual and refractive data in those eyes implanted with toric IOL models, as the number of eyes implanted with the Artisan®/Artiflex® (myopia) and the Artisan®Aphakia was insufficient to use inferential statistics. As shown, no statistically significant differences were found between groups in visual and refractive data, either preoperatively (p ≥ 0.295) or postoperatively (p ≥ 0.459).

Ease of enclavation

Mean number of captures required during the surgical procedure was 3.3 (SD: 1.6; median: 3.0, range: 2 to 9) and 2.9 (SD: 0.9, median: 3.0, range: 2 to 4) in the needle and VacuFix groups, respectively. This difference was not statistically significant (p = 0.64). It is important to note that in the subgroup of aphakic eyes, the average number of captures needed to enclavate the haptics of the IOL using the VacuFix and needle was 2 and 3.5, respectively.
Postoperative biomicroscopic signs

At 3 months postoperatively, neither flare nor cells in the anterior chamber were detected in either of the two groups evaluated. Deposits were present on the surface of the IOL in a total of 7 (35.0%) and 6 eyes (31.6%; p = 0.823) in the needle and VacuFix groups, respectively (Figure 9).

Optical coherence tomography analysis

At three months postoperatively, AS-OCT analysis was performed to assess both the amount of tissue included in the enclavation (iris bridge) and the distance from the posterior surface of the IOL to the anterior surface of the iris (iris-lens distance).

The iris-lens distance was slightly higher in the VacuFix group compared to the needle group, although the difference did not reach statistical significance (p = 0.09). In contrast, the iris bridge was significantly higher in the needle group compared to the VacuFix group (p < 0.01) (Figure 10).

Complications

The only complication encountered during this study was the development of cataract in one eye in which the IOL was enclavated using the VacuFix system. The cataract was not related to the surgical procedure; at the time of writing the patient’s other eye had also developed nuclear sclerosis and needed IOL explantation and phacoemulsification.

DISCUSSION

Iris-fixated IOLs have demonstrated their efficacy and safety in correcting variable types and degrees of ametropia over the last couple of decades. Postoperative refractive predictability and stability, together with an increase in the safety profile of these lenses have made them the most popular method of correcting ametropia outside the limits of corneal refractive surgery. Problems related to these lenses, such as accelerated endothelial cell loss with subsequent corneal decompensation, glaucoma and cataract have largely been overcome with strict patient selection criteria, modern anterior segment imaging technology and improvements in implantation techniques.

One of the main problems with implanting these lenses is the difficulty faced, especially by novice surgeons, in enclavating the haptics of the lens to the iris. A relatively steep learning curve is required, during which inaccurate and inconsistent IOL implantation can lead to postoperative refractive inaccuracies and complications.

Iris-fixated IOLs were traditionally enclavated either using specially designed enclavation needles or using micro-forceps, but because these methods were deemed difficult by some surgeons, a newer enclavation system relying on vacuum was produced. The potential benefits of this new system include precise enclavation of the haptics, which is of utmost importance especially when implanting the toric model, increased ease of enclavation, especially in aphakic eyes that are notoriously difficult due to posterior iris bowing, and a consistent, reproducible amount of iris tissue enclavated into the haptics, which could potentially translate into more consistent placement of the IOL in the anterior chamber, resulting in more accurate postoperative refractive outcomes.

Table 4 shows the refractive and visual outcomes of iris-fixated IOLs in studies with the longest
follow-up period. In our study, the refractive and visual outcomes between the needle and VacuFix were comparable. The mean preoperative spherical equivalent for all eyes recruited was $-7.83 \pm 6.59$ D and $-7.72 \pm 6.88$ D in the needle and VacuFix group, respectively ($p = 0.97$), which is slightly lower than that published by other authors. Postoperative spherical equivalent in our study was $-0.06 \pm 0.71$ D and $0.10 \pm 1.28$ D in the needle and VacuFix groups, respectively ($p = 0.459$). As regards the cylindrical component in these eyes, preoperative cylinder was $-1.46 \pm 0.53$ D ($-0.75$ to $-2.50$) and $-1.73 \pm 1.12$ D ($-0.75$ to $-5.0$) ($p = 0.689$) and postoperatively was $-0.29 \pm 0.34$ D and $-0.77 \pm 1.23$ D ($p = 0.531$) in the needle and VacuFix groups, respectively (see Table 3).

Iris-fixated IOLs may be complicated by iris pigment dispersion, which if severe, can precipitate on the surface of the IOL, causing decreased visual acuity and potentially increasing intraocular pressure. This phenomenon is particularly noted with the flexible models of these lenses, as their optics are made of silicone and not PMMA. Baikoff et al. demonstrated that pigment dispersion at the pupillary border might be related to a crystalline lens rise (defined as the distance between the anterior pole of the lens and a hypothetical line connecting the 3 and 9 o’clock angle recesses) of $\geq 600$ μm. In our study, we attempted to determine whether there was a relationship between the distance of the posterior surface of the IOL to the anterior surface of the iris (lens-iris distance) in the area just adjacent to where the iris is enclavated and the occurrence of pigment deposits on the surface of the IOL, and to see if this distance differed between the needle and VacuFix groups. The iris-lens distance was slightly lower than that reported in the literature.

Table 5 shows the refractive and visual outcomes of the Artiflex IOL in previously published peer-reviewed articles. With respect to the subset of eyes implanted with the Artiflex Toric (n = 25), in our study the mean preoperative spherical equivalent was $-9.69 \pm 3.31$ D and $-9.93 \pm 2.07$ D in the needle and VacuFix groups, respectively ($p = 0.936$), with a postoperative spherical equivalent of $0.16 \pm 0.46$ D and $0.34 \pm 1.56$ D in the needle and VacuFix groups, respectively ($p = 0.475$). As regards the cylindrical component in these eyes, preoperative cylinder was $-2.13 \pm 1.12$ D ($-1.0$ to $-5.0$) ($p = 0.689$) and postoperatively was $-0.98 \pm 1.07$ D ($p = 0.891$) in the needle and VacuFix groups, respectively (see Table 3).
higher in the VacuFix group (155.9 μm) compared to the needle group (148.9 μm), although the difference did not reach statistical significance (p = 0.09). With respect to the presence of deposits on the surface of the IOL, a total of 7 (35.0%) and 6 eyes (31.6%) showed this sign in the needle and VacuFix groups, respectively (p = 0.823); their occurrence showed no relationship to the iris-lens distance.

Another part of our AS-OCT analysis was the amount of iris tissue enclavated in the IOL haptics (iris-bridge). This value was significantly higher (267.2 μm) in the needle group when compared to the VacuFix group (232.4 μm) (p < 0.01), although the amount of tissue was more consistent in the VacuFix group. We are unsure if this finding has any clinical implications.

The surgeon (JLG) experienced no complications in either group during the course of this study, except for one patient who developed a visually debilitating cataract at the 3-month visit that necessitated IOL removal and cataract extraction. The occurrence of the cataract in this patient was not related to the method of IOL implantation, as the patient’s other eye also developed cataract a few months after the conclusion of this study. No IOL tilt, decentration nor dislocation was encountered in any of the eyes in either the needle or the VacuFix groups.

In the aphakic eyes, the surgeon (JLG) noted that iris enclavation was more easily achieved with the VacuFix compared to the needle (average 2 vs. 3.5 attempts). However, due to the low number of aphakic eyes recruited in this study, we cannot safely conclude that the VacuFix system is more efficient in these eyes.

In summary, our findings clearly demonstrate that the new VacuFix enclavation system performs equally as well as the well-studied and time-honored needle technique. The latter procedure, however, is notoriously difficult to perform, so further studies are warranted to determine whether the novice surgeon would find the VacuFix system easier to use. Larger studies on aphakic eyes are also required to show if this new system is more efficient in such eyes.

REFERENCES


