Implantable Collamer Lens - Morphological changes induced in the anterior segment

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PURPOSE: To evaluate the changes induced in the anterior segment after implantation of a STAAR® Implantable Collamer® contact lens (ICL) and to develop mathematical models for predicting these changes.

METHODS: Eighty-two eyes of 52 patients had implantation of an ICL at the Ophthalmology Department, Egas Moniz Hospital (Lisbon, Portugal). Patients were examined preoperatively and at months 1, 6, 12, 24 and 36 postoperatively. The anterior segment was evaluated using a Scheimpflug photography system.

RESULTS: The mean vault values after the first month were 349.93 μm. They remained stable during the first 24 months of the follow-up period, with a slight tendency to decrease at 36 months which was not statistically significant. We observed a reduction in the anterior chamber angle, depth and volume of 14.23°, 167 μm and 60.44 mm³, respectively. This reduction remained stable during the follow-up period. Linear regressions performed for anterior chamber angle, depth and volume in function of the vault generated R² values of 0.12, 0.12 and 0.49, respectively.

CONCLUSION: The anterior segment stabilizes at the first month postoperatively. Linear mathematical models proved inadequate in predicting the changes induced by this intraocular lens.

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INTRODUCTION

The most common refractive surgery performed today is laser-assisted in situ keratomileusis (LASIK). This technique, as with all keratorefractive procedures, has severe limitations in high myopes as well as in patients with thin corneas, since it can cause iatrogenic keratectasia.

The second major issue with keratorefractive procedures is that they can deteriorate the optical qualities of the cornea, having an impact in the quality of vision.

Whenever keratorefractive surgery is deemed inappropriate, two options remain: phakic intraocular lens (pIOL) implantation and refractive lens exchange (RLE).

RLE is a safe and effective option for the correction of high ametropias, especially in the presbyopic age group.

With respect to pIOLs, one model that has been extensively studied and reported as being safe and predictable in correcting moderate to high ametropia is the VISIAN implantable collamer lens (ICL) (Staar Surgical Co).

The ICL is made from a collamer, which is comprised of collagen copolymer 0.4%, polyhydroxyethyl methacrylate 60%, water 37.5% and benzophene 3.3%. This material is highly biocompatible and has proven to be safe after implantation in the posterior chamber.

The first ICL surgery was performed in 1993. After the first surgeries, and because there was extensive contact between the IOL and the lens, its design was progressively revised in successive generations. The V1 model had a constant optic zone diameter with variable...
footplate dimensions. In the V2 model, it was the optic zone which had variable dimension, with the footplates remaining constant. In the third generation, the optic diameter was optimized.

In the V4 model, introduced in 1998, the radius of the posterior concave surface was changed to 11 mm, increasing the final distance between the apex of the lens and the apex of the posterior curvature of the ICL (central vault). A variation of this model (V4B) was subsequently introduced. This variation differs from its predecessor mainly because it incorporates full thickness holes on footplates, both proximally and distally (four in total) in order to improve aqueous humour circulation. More recently a new model, V4C, was presented at the ESCRS meeting in Vienna 2011. It was designed with a small orifice over the visual axis, which prevents pupillary block while maintaining the optical qualities of the IOL.

The choice of ICL size is a critical step in preoperative planning, as it determines the stability and position of the ICL. If the ICL is too large, it causes mechanical stress on the ciliary sulcus, increased peripheral lens touch, forward displacement of the peripheral iris, chafing of the iris and pigment dispersion. Conversely, a lens which is too small will have a small vault and increased central lens touch, as well as decreased stability.

As a consequence of its positioning as well as its design, the ICL induces profound changes in the anterior segment which are not fully understood. The purpose of this study was to understand these changes as well as to develop mathematical models to help to predict them.

**METHODS**

Patients undergoing ICL implantation between April 2008 and February 2011 were retrospectively evaluated. Only patients with regular postoperative visits with a minimum of 6 months (M) follow-up were included.

All the patients provided informed consent. The study adhered to the principles of the Declaration of Helsinki. Institutional Review Board approval was not required.

Power calculations for the ICLs were performed by the manufacturer, using a modified vertex formula. The size of the ICL was chosen by adding 0.5 mm to the white-to-white distance obtained with calipers. Only version 4B of the ICL was used.

Surgery was performed under topical anaesthesia. Patients selected for toric ICL implantation had the horizontal meridian marked at the slit lamp before entering the operating room.

After full pharmacological mydriasis, one 1.5 mm clear cornea incision was created at the 12 o’clock meridian and the anterior chamber was filled with a cohesive viscosurgical device (Healon® - Abbott Medical Optics, Inc.). A 3 mm clear cornea incision was then performed at the temporal end of the horizontal meridian. Next, the ICL was introduced in the anterior chamber through the second incision, using the injector. Following this manoeuvre, the footplates were placed in the ciliary sulcus using the recommended manipulator. The toric ICL were then rotated to the recommended meridian. The remaining viscosurgical device was subsequently washed out of the anterior chamber with a balanced salt solution, and acetylcholine chloride 10mg/mL was instilled into the eye (Miocol®, Novartis). Finally, a surgical iridectomy was performed using iris scissors.

All patients were observed preoperatively, as well as at months 1, 3 and 6. At months 12, 24 and 36, 64, 37 and 10 patients were evaluated, respectively.

Each visit included a complete clinical evaluation as well as Scheimpflug photography (Oculus Pentacam HR®).

The morphometric values of the anterior segment were obtained automatically using Pentacam® software (v. 6.03r02) and compared longitudinally. The same investigator performed all Scheimpflug examinations. The vault value was the only variable calculated manually. It was obtained using the calipers provided by the software to measure the pupil centre (with the patient dilated) on the image of the horizontal meridian. This measurement was always carried out by the same investigator and taken three times. The coefficient of repeatability of the vault value for this observer was 7.84 μm. The mean of the three measurements was used in the statistical analysis.

All statistical analyses were performed on JMP 8.0.2 for Macintosh (SAS Institute Inc.) The results are expressed as mean ± SD. A p value less than 0.05 was considered statistically significant.

**RESULTS**

Eighty-two eyes of 52 patients (34 women, 18 men) were evaluated. Of the 82 ICLs implanted, 55 (67.1%) were toric and 27 (32.9%) were spheric.

The baseline demographic data for the studied sample is shown in Table 1.

The morphometric data for the anterior segment collected during the follow-up visits is presented in Table 2.

We first compared the anterior segment morphometric values for toric and spheric lenses. As we found no statistically significant differences during follow-up, we grouped toric and spheric lenses for statistical analysis.

We compared the vault values longitudinally. No significant differences were found between M1 and M6 (p=0.56, t-Student), M1 and M12 (p=0.52), M1 and
M24 (p=0.85), and M1 and M36 (p=0.61). Although no statistically significant difference was found, there seemed to be a slight decrease in vault at M24 and M36, especially concerning the upper values, as illustrated in Figure 1.

In order to clarify this matter further, we performed Bland-Altman analysis of the data, comparing M1 with M24 (only 10 patients were available for this comparison at month 36) (Figure 2). This analysis revealed no systematic evolution of the data and we could not establish a greater decrease in the higher initial vault values as some authors have suggested.

To try to understand the decrease of 42.43 μm observed from M24 to M36, we analyzed the subgroup of 10 patients with a follow-up of 36 months. These patients had a vault value of 281 ± 244.98 μm at M1, 278 ± 240.3 μm at M24 and 290.44 ± 230.45 μm at M36. No statistically significant differences were found between these observations.

We also compared the remaining morphometric variables longitudinally.

Table 1. Patient Demographic data.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>Mean ± SD: 34.18 ± 6.94</td>
</tr>
<tr>
<td></td>
<td>Range: 18 to 49</td>
</tr>
<tr>
<td>Sex (% female)</td>
<td>65.9</td>
</tr>
<tr>
<td>Follow-Up (Months)</td>
<td>Mean ± SD: 21.59 ± 9.43</td>
</tr>
<tr>
<td></td>
<td>Range: 7 to 41</td>
</tr>
<tr>
<td>Central Corneal Thickness (μm)</td>
<td>Mean ± SD: 525.5 ± 30.19</td>
</tr>
<tr>
<td></td>
<td>Range: 430 to 593</td>
</tr>
<tr>
<td>Keratometry Reading (D)</td>
<td>Mean ± SD: 43.96 ± 2.1</td>
</tr>
<tr>
<td></td>
<td>Range: 36.2 to 50.2</td>
</tr>
<tr>
<td>Anterior Chamber Depth (mm)</td>
<td>Mean ± SD: 3.15 ± 0.26</td>
</tr>
<tr>
<td></td>
<td>Range: 2.67 to 3.73</td>
</tr>
<tr>
<td>Anterior Chamber Volume (μm³)</td>
<td>Mean ± SD: 191.55 ± 31.77</td>
</tr>
<tr>
<td></td>
<td>Range: 98 to 253</td>
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</tbody>
</table>

Table 2. Morphometric data for the anterior segment during follow-up.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Pre-op</th>
<th>M1 (n=82)</th>
<th>M6 (n=64)</th>
<th>M12 (n=37)</th>
<th>M24 (n=10)</th>
<th>M36 (n=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior Chamber Angle (°)</td>
<td>38.55 ± 6.28</td>
<td>24.91 ± 8.02</td>
<td>23.86 ± 8.19</td>
<td>23.68 ± 11.41</td>
<td>22.11 ± 12.06</td>
<td>28.63 ± 4.65</td>
</tr>
<tr>
<td>Anterior Chamber Volume (μm³)</td>
<td>191.55 ± 31.77</td>
<td>131.11 ± 25.55</td>
<td>126.88 ± 30.24</td>
<td>119.94 ± 36.58</td>
<td>127.28 ± 37.73</td>
<td>134.48 ± 15.3</td>
</tr>
<tr>
<td>Anterior Chamber Depth (μm)</td>
<td>315 ± 6</td>
<td>298 ± 57</td>
<td>297 ± 58</td>
<td>282 ± 68</td>
<td>283 ± 78</td>
<td>297 ± 4</td>
</tr>
<tr>
<td>Vault (μm)</td>
<td>-</td>
<td>349.93 ± 232.05</td>
<td>349.41 ± 231.08</td>
<td>345.62 ± 247.49</td>
<td>332.87 ± 255.11</td>
<td>290.44 ± 230.45</td>
</tr>
</tbody>
</table>
With respect to the anterior chamber angle, we observed a reduction of 14.23 degrees between the preoperative observation and M1 (p<0.001, t-Student). No statistically significant differences were found between M1 and M6 (p=0.899), M1 and M12 (p=0.6), M1 and M24 (p=0.8), and M1 and M36 (p=0.31).

As regards the anterior chamber depth, we observed a reduction of 167.7 μm between the preoperative observation and M1 (p=0.0121, t-Student). No statistically significant differences were found between M1 and M6 (p=0.86), M1 and M12 (p=0.18), M1 and M24 (p=0.0875), and M1 and M36 (p=0.28).

The volume of the anterior chamber decreased 60.44 mm³ (p<0.001, t-Student) from the preoperative evaluation to the first month post-op. We did not observe any statistically significant changes in this variable between M1 and M6 (p=0.18), M1 and M12 (p=0.073), M1 and M24 (p=0.28), and M1 and M36 (p=0.59).

We can thus conclude that in our sample, the morphometric characteristics of the anterior segment stabilize at the first month postoperatively.

In trying to systematically describe the morphometric changes in the anterior segment, we considered the vault value as an independent variable in linear regressions performed for anterior chamber depth, volume, and angle at M6 (Figure 3, 4 and 5). The R² values for the aforementioned variables were 0.12, 0.49 and 0.12, respectively.
DISCUSSION

In the current study we found that the vault value remained stable from M1 up to M36 after surgery. This result contradicts the findings of other series published in the literature, namely those by Gonvers et al. (using V3 and V4 ICL models) and Alfonso et al. (using the V4 model). The difference in behaviour found may be due to the different design of the IOL we used (model V4B).

We should point out that our vault values were obtained manually (although always by the same investigator), which carries the risk of decreased accuracy and bias. Furthermore, we only evaluated the central vault and not the peripheral one as other authors have done.

Despite our previous statement, we found a tendency towards a reduction in vault after M24, although it was not statistically significant. We did not observe any systematic reduction either for the upper or lower bounds of the dispersion. We can probably interpret this decrease in the context of a selection bias—the 10 patients compared were the first implanted in our department and had lower vault values when compared to the rest of the sample from M1 onwards. Thus, the decrease of 42.43 μm in vault value was probably the result of bias. The apparent increase in anterior chamber angle and volume observed at M36 is also likely to be the result of the lower vault values in this patient subset.

For the morphometric parameters of the anterior segment, we found significant changes induced by the implantation of the ICL, namely a substantial reduction in anterior chamber depth, volume and angle. These changes stabilized by the first month postoperatively.

After considering the vault as an independent variable, we tried to establish a mathematical model that would predict the changes in the anterior segment. The model that had the closest resemblance to our sample distribution was a linear one, so we decided to perform linear regressions. These revealed an inverse relationship between the aforementioned variables and the vault value. We also found these models to be lacking in adjustment to our data, with low R² values, the greater of which corresponded to the anterior chamber volume, although even then it was only 0.48. This led us to the conclusion that in our sample the dispersion of data cannot be modelled adequately using a linear paradigm. We attribute this fact to the high interindividual variability that characterizes many biological variables.

A thorough analysis of the data also revealed an apparent contradiction in our results. We obtained a reduction of 167.7 μm in the anterior chamber depth and a vault of 349.93 μm at M1. Part of this difference can be explained by ICL thickness alone. We also used automatic software measurements for anterior chamber depth while manually calculating the central vault. However a doubt remains. The investigators feel that since the changes induced in the anterior chamber are so profound, it is likely that given its positioning, the ICL may also influence the effective position of the zonula and the lens, perhaps accounting for some of the discrepancy observed. We would like to see this matter further clarified in a subsequent study.

In conclusion, the ICL induces profound changes in the anterior segment which cannot be fully modelled. These stabilize by the first month. Further studies with a larger sample, longer follow-up and other imaging techniques, namely ultrasound biomicroscopy, are required to further clarify these matters.

REFERENCES