Prevalence of cataract after collagen copolymer phakic intraocular lens implantation for myopia, hyperopia, and astigmatism

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PURPOSE: To evaluate the prevalence of cataract after Implantable Collamer Lens phakic intraocular lens (pIOL) implantation with different models at different ages and for different refractive powers.

SETTING: Fernández-Vega Ophthalmological Institute, Oviedo, Spain.

DESIGN: Retrospective nonrandomized clinical study.

METHODS: The pIOL (models V4, V4b, or V4c) was implanted in all cases.

RESULTS: The study included 3420 eyes (1898 patients). The mean patient age at surgery was 31.2 years ± 6.4 (SD) (range 18 to 50 years) and the mean spherical refractive error, −7.77 ± 5.24 diopters (D) (range −26.5 to 12.5 D). Twenty-one eyes (0.61%) of 15 patients had pIOL explantation (all model V4) because cataract developed. The mean age of the patients who had explantation was 39.43 ± 4.57 years; 7 were younger than 40 years, and 8 were 40 years or older. The mean spherical equivalent was −10.1 ± 5.41 D; 3 eyes had a pIOL power less than −10.50 D, 4 eyes between −10.50 D and −13.50 D, and 14 higher than −13.50 D. The mean time between pIOL implantation and cataract surgery was 4.2 ± 1.8 years. No eye with implantation of the latest models (V4b and V4c) developed cataract. The mean vault distance in eyes that developed cataracts was 103 ± 69 µm.

CONCLUSIONS: The incidence of cataract was low after pIOL implantation at the 6-year follow-up. The rate of cataract was higher in older patients and in those with high refractive errors.

Financial Disclosure: No author has a financial or proprietary interest in any material or method mentioned.

J Cataract Refract Surg 2015; 41:800–805 © 2015 ASCRS and ESCRs

Recently, the popularity of Implantable Collamer Lens phakic intraocular lenses (pIOLs) (Visian) has been growing for a wide range of patient ages. These pIOLs have shown to be an effective, safe, predictable, and stable way to correct high and low levels of myopia,1,2 hyperopia,3,4 and astigmatism.5,6 However, several studies1,2,7–13 have reported anterior subcapsular opacities, with some patients developing clinically significant cataract. The U.S. Food and Drug Administration (FDA) studies1,2 showed that the incidence of anterior subcapsular opacities was 2.1% within 1 year and 2.7% within 3 years after implantation of these pIOLs. Central or peripheral contact between the pIOL and the crystalline lens might be responsible for the development of an anterior subcapsular cataract. Eyes with insufficient vaulting (distance between posterior surface of the pIOL and anterior surface of the crystalline lens) were more predisposed to secondary cataract formation.12–16 Cataract development is more common in older patients and in patients with higher myopia; moreover, the incidence increases with the duration of the follow-up.15,14–16 Another cause of cataract formation is localized malnutrition caused by poor circulation of the aqueous humor.17
Different Implantable Collamer Lens pIOl designs were developed and have decreased the incidence of cataract formation. The basic difference between earlier designs and the V3 myopia design was the size of the optic, which was enlarged in the V3 design. The V4 pIOl model had an increase in forward vault to avoid pIOl-crystalline lens touch; the V3 model had less vaulting away from the crystalline lens and had a greater incidence of lens opacities.\(^8,10\) The V4b model introduced a new storage solution (a balanced salt solution), making the IOL power closer to the spectacle refraction. The latest model, the V4c, had a central hole to increase the aqueous humor perfusion and reduce the risk for cataract formation.\(^17,18\)

The present study evaluated the prevalence of cataract after implantation of models V4, V4b, and V4c of the Implantable Collamer Lens pIOl in a wide sample of eyes of patients of different ages and different refractive powers.

**PATIENTS AND METHODS**

This retrospective observational study comprised patients having Implantable Collamer Lens pIOl implantation at the Fernández-Vega Ophthalmological Institute, Oviedo, Spain, from January 2002 to August 2013. After being fully informed of the details and possible risks of the surgical procedure, all patients provided written informed consent. The study followed the tenets of the Declaration of Helsinki, and an institutional review board approved the study.

The inclusion criteria for pIOl implantation were a Snellen corrected distance visual acuity (CDVA) of 20/50 or better, a stable refraction, and a clear central cornea. The exclusion criteria were 18 years or younger, an anterior chamber depth (ACD) less than 2.8 mm, an endothelial cell density (ECD) less than 2000 cells/mm\(^2\), cataract, a history of glaucoma or retinal detachment, macular degeneration or retinopathy, neuro-ophthalmic disease, and a history of ocular inflammation.

**Patient Assessment**

Before pIOl implantation, patients had a complete ophthalmologic examination. The examination included the manifest and cycloplegic refractions, keratometry, corneal topography and pachymetry (Orbscan II scanning-slit device, Bausch & Lomb), ECD measurement (SP-3000P, Topcon Europe BV), slitlamp evaluation, Goldmannplanation tonometry, and binocular indirect ophthalmoscopy through a dilated pupil.

**Phakic Intraocular Lens Size and Power Calculation**

The pIOl diameter was individually determined based on the horizontal white-to-white (WTW) distance and ACD measured from the endothelium with the scanning-slit corneal topography device and following the pIOl manufacturer’s recommendations. For eyes with an ACD measurement of 3.5 mm or less, the pIOl size was calculated by adding 0.5 mm to the horizontal WTW measurement. For eyes with an ACD measurement greater than 3.5 mm, up to 1.0 mm was added to the WTW measurement. Calculated IOL sizes between the available IOL diameters (in 0.5 mm steps) were usually rounded down if the ACD was 3.5 or less and rounded up if the ACD was greater than 3.5 mm. The pIOl power was calculated using software provided by the manufacturer and a modified vertex formula. The target refraction was emmetropia in all cases.

**RESULTS**

The study comprised 3420 eyes of 1898 patients, of which 1176 were women (62%) and 722 men (38%). Table 1 shows the preoperative patient demographics. Of the eyes, 1531 (44.8%) received the V4 pIOl model (implanted between 2002 and 2008), 1108 (32.4%) the V4b model (implanted between 2008 and 2011), and 781 (22.8%) the V4c model (implanted between 2011 and 2013). The mean follow-up was 6 years ± 2 (SD) (range 1 to 12 years), 2.0 ± 0.5 years (range 1 to 3 years), and 6 ± 4 months (range 3 to 24 months), respectively.

Twenty-one eyes (0.61%) of 15 patients (4 women and 11 men) had pIOl explantation for cataract development. All pIOls explanted were the V4 model, the oldest version used in this study. Seven (47%) of the 15 patients were younger than 40 years old, and 8 patients (53%) were 40 years or older. Three eyes (14%) that developed cataract had a pIOl power less than −10.50 dioptrios (D), 4 eyes (19%) between −10.50 D and −13.50 D, and 14 eyes (67%) of more than −13.50 D. Table 2 shows the eyes with cataract as a function of pIOl power and vault.

Three eyes (14%) developed anterior and posterior subcapsular cataracts, 1 eye (5%) developed an anterior subcapsular and nuclear cataract, and 17 eyes (81%) developed anterior subcapsular cataracts. The mean age in eyes having pIOl explantation was 39.43 ± 4.57 years (range 29 to 46 years). Table 3 shows the visual acuity and refraction over time.
Table 1. Preoperative patient demographics.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Mean ± SD</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)</td>
<td>31.2 ± 6.4</td>
<td>18, 50</td>
</tr>
<tr>
<td>Refraction (D)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sphere</td>
<td>−7.27 ± 5.24</td>
<td>−26.50, 5.50</td>
</tr>
<tr>
<td>Cylinder</td>
<td>−1.58 ± 1.23</td>
<td>−7.25, 0.00</td>
</tr>
<tr>
<td>Keratometry (D)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flat</td>
<td>43.52 ± 1.88</td>
<td>32.75, 51.75</td>
</tr>
<tr>
<td>Steep</td>
<td>44.67 ± 2.03</td>
<td>33.25, 50.50</td>
</tr>
<tr>
<td>ACD (µm)</td>
<td>519.58 ± 43.38</td>
<td>335, 630</td>
</tr>
<tr>
<td>WTW (mm)</td>
<td>11.70 ± 0.38</td>
<td>10.50, 13.60</td>
</tr>
<tr>
<td>AL (mm)</td>
<td>26.80 ± 2.11</td>
<td>21.91, 36.31</td>
</tr>
</tbody>
</table>

ACD = anterior chamber depth; AL = axial length; WTW = white-to-white distance

The pIOL explantation and cataract surgery by phacoemulsification were successful in all eyes. Table 3 and Figure 1 show the mean final CDVA after IOL implantation. Figure 2 shows the changes in CDVA after pIOL implantation before the cataract surgery and after IOL implantation in all eyes that developed cataract. After pIOL implantation, in all eyes that did not develop a cataract that required removal, the CDVA remained the same or improved by 1 or more lines. However, when cataracts developed, 12 cases (57%) lost 2 or more lines of CDVA and none improved.

Figure 3 shows the central vault distance from the posterior pIOL optic to the anterior lens capsule. Peripheral vault is also important, especially when high refractive power pIOLs are implanted; the cataract in the major percentage of eyes developed because of peripheral contact in eyes with high myopia. The mean vault in eyes that developed cataracts was 103 ± 69 µm (range 40 to 270 µm); in 15 eyes (70%) the vault was less than 100 µm, and in 6 eyes (30%) the vault was between 100 µm and 270 µm.

The mean time between the pIOL implantation and cataract surgery was 4.2 ± 1.9 years (range 1 to 7 years). Most eyes (12 [58%]) developed cataracts between the third and fourth year after pIOL implantation (Figure 4). Four monofocal IOLs and 17 diffractive multifocal IOLs were implanted.

**DISCUSSION**

The aim of the present study was to evaluate the prevalence of cataract after implantation of the Implantable Collamer Lens pIOL in a wide sample of eyes with different refractive errors, ages, and pIOL models. This study determined which factors are related to the development of cataracts after pIOL implantation.

Several studies have analyzed the incidence of cataract development, lens opacities, and vaulting after pIOL implantation. The FDA studies analyzed the V4 model of the Implantable Collamer Lens pIOL in 523 eyes of 291 patients with 3.0 to 20.0 D of myopia who were 21 to 45 years old. The studies found good safety, efficacy, and predictability outcomes in the treatment of myopia. Nevertheless, anterior subcapsular opacities occurred in 11 cases (2.1%), although only 2 (0.4%) pIOL removals with cataract extraction and IOL implantation were performed at 1-year follow-up. After 3 years of follow-up, 14 eyes (2.7%) had anterior subcapsular opacities. Phakic IOL removal with cataract extraction was performed in 3 eyes (0.6%). Sanders and Vukich compared the incidence of lens opacities and clinically significant cataracts with 2 Implantable Collamer Lens pIOL designs. The V3 model was implanted in 87 eyes, and the V4 model was implanted in 523 eyes. They found that the incidence of anterior subcapsular opacities was significantly higher with the V3 model than with the V4 model (12.6% versus 2.9%). Furthermore, 9.2% of eyes with the V3 model and 0.8% of eyes with the V4 model had clinically significant cataract. This was because a greater proportion of eyes in the V3 group had poor vaulting. Sánchez-Galeana et al. found that the incidence of lens opacities was 8% (14 of 170) over a mean follow-up of 12.5 months; only 2 (1%) of 170 eyes required Implantable Collamer Lens pIOL explantation and cataract extraction. Patients with the V2 and V3 models had a higher incidence of lens opacities than the patients with the V4 model. Sarikola et al. studied the incidence of lens opacities after Implantable Collamer Lens pIOL implantation in 2 age groups. In Group 1, 26 eyes of 13 patients with clear lenses who were 45 years or younger had implantation of the V4 model; only 2 eyes (7.7%) developed...
Table 3. Refractive and visual preoperative and postoperative outcomes in 21 eyes that developed cataract.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Pre-pIOL</th>
<th>pIOL Pre-Cataract</th>
<th>pIOL Pre-IOL</th>
<th>Post-IOL</th>
</tr>
</thead>
<tbody>
<tr>
<td>UDVA (logMAR)</td>
<td>0.96 ± 0.18</td>
<td>0.19 ± 0.24</td>
<td>0.35 ± 0.30</td>
<td>0.13 ± 0.10</td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>0.15 ± 1.0</td>
<td>0.0 ± 1.0</td>
<td>0.0 ± 1.0</td>
<td>0.0 ± 1.0</td>
</tr>
<tr>
<td>Range</td>
<td>20.00, -1.50</td>
<td>-1.50, +1.50</td>
<td>-1.50, +10.0</td>
<td>-1.00, +1.00</td>
</tr>
<tr>
<td>Sphere (D)</td>
<td>-1.16 ± 5.31</td>
<td>-0.06 ± 0.52</td>
<td>-0.39 ± 0.59</td>
<td>-0.02 ± 0.41</td>
</tr>
<tr>
<td>Cylinder (D)</td>
<td>-1.95 ± 1.34</td>
<td>-0.30 ± 0.55</td>
<td>-0.26 ± 0.62</td>
<td>-0.17 ± 0.30</td>
</tr>
<tr>
<td>CDVA (logMAR)</td>
<td>0.16 ± 0.13</td>
<td>0.10 ± 0.11</td>
<td>0.25 ± 0.24</td>
<td>0.06 ± 0.06</td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>0.0 ± 0.4</td>
<td>0.0 ± 0.4</td>
<td>0.0 ± 1.0</td>
<td>0.0 ± 0.15</td>
</tr>
<tr>
<td>Range</td>
<td></td>
<td></td>
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</tbody>
</table>

CDVA = corrected distance visual acuity; pIOL = phakic intraocular lens; IOL = intraocular lens; UDVA = uncorrected distance visual acuity

Recent studies\(^{19,20}\) have evaluated the V4c model. No patient with this model developed secondary cataract over a 6-month follow-up. Alfonso et al.\(^{21}\) assessed 35 eyes with the V4b toric pIOL at a 12-month follow-up. No eye required pIOL explantation, and no eye had lens opacities. These outcomes agree with those in the present study, in which 21 eyes (0.61%) developed cataract after pIOL implantation. All eyes that developed cataract had implantation of the previous model (V4). No eyes with the V4b or V4c model developed a cataract. The prevalence of cataract with the V4 model (1531 eyes) was 1.37%. Of the eyes that required pIOL explantation and phacoemulsification with posterior IOL implantation, 47% were of patients younger than 40 years and 53% were of patients 40 years or older. Of these eyes, 14% had less than -10.50 D of myopia, 19% had between -10.50 D and -13.50 D, and 67% had more than -13.50 D. Some differences between our outcomes and those in previous studies could be attributed to the differences in the age of the patients, the pIOL models implanted, the follow-up period, and the patients' preoperative refractive error.

The relationship between vaulting and cataract formation has been extensively studied.\(^{12-16}\) Lindland et al.\(^{13}\) studied the relationship between vaulting and lens opacities during accommodation. They did not find statistical differences in vault distance at baseline and during accommodation. The vaulting at baseline was significantly less in older patients. Anterior subcapsular opacities developed in 9 patients, and the Implantable Collamer Lens pIOL touched the crystalline lens in 5 eyes. The association between the crystalline lens-pIOL contact and cataract formation was significant. Govers et al.\(^{14}\) found that central vaulting greater than 90 µm appears to protect the crystalline lens from anterior subcapsular opacities, and no eye developed clinically significant cataract after pIOL implantation. In contrast, in Group 2, 38 eyes of 22 patients older than 45 years had implantation of the V3 model; 47.7% of eyes and 26.3% of eyes developed anterior subcapsular opacities or clinically significant cataract, respectively. The authors concluded that the incidence of lens opacities and cataract development was higher with previous pIOL models and in older patients. Sanders\(^{11}\) found that 6% to 7% of eyes developed anterior subcapsular opacities 7 years after Implantable Collamer Lens pIOL implantation, although only 1% to 2% progressed to clinically significant cataract, particularly older patients and those with very high myopia.
Figure 2. Changes in CDVA in 21 eyes that developed cataracts after pIOL implantation (CDVA = corrected distance visual acuity; IOL = intraocular lens; pIOL = phakic intraocular lens).

cataract formation. However, higher central vaulting (approximately 150 μm) is recommended to avoid contact between the pIOL and the crystalline lens because vault distance showed a slight decrease over time. They also found that cataracts developed more commonly in older patients than in younger patients. Schmidinger et al.15 studied long-term changes in Implantable Collamer Lens pIOL vaulting in myopic patients. They concluded that the minimum central vaulting to ensure total vaulting of the pIOL is 230 μm because there is a reduction in central vaulting over a 10-year period as well as clear evidence that insufficient pIOL vaulting is responsible for the development of anterior subcapsular cataract. Alfonso et al.16 found that the eyes that developed anterior subcapsular cataract were older, had a tendency to vault 2 (approximately 350 to 600 μm) or lower postoperatively, had a shallower ACD, and had a smaller pIOL. In our study, we also found a direct relationship between low vaulting and the incidence of cataract formation. All eyes that developed cataract had very low vaulting (70% <100 μm). With high refractive power pIOLs, peripheral vaulting becomes more critical in developing a cataract; thus, surgeons must consider this in patients with high myopia.

We must take into account that the follow-up periods for the 3 pIOL models were different. For the V4 model, the mean follow-up was 6 ± 2 years and more than 50% of patients who developed cataract had cataract surgery between the third and fourth year. In contrast, the mean follow-up for the V4b and V4c models was 2.0 ± 0.5 years and 6 ± 4 months, respectively. Further long-term study with the latest models is necessary to clarify this aspect. In addition to the follow-up and the pIOL model, other factors could affect cataract development, such as age, preoperative values, and the time of the surgery.

In conclusion, implantation of the Implantable Collamer Lens pIOL led to a very low incidence of cataract formation. The prevalence of cataract was higher in patients who were older, had high refractive errors, and had older pIOL models.

Figure 3. Vault distance values before cataract surgery in 21 eyes that developed cataracts after pIOL implantation.

WHAT WAS KNOWN

- The prevalence of cataract has been studied with previous pIOL models, showing a relationship between vaulting and cataract formation.

WHAT THIS PAPER ADDS

- The incidence of cataract formation was lower with the newest pIOL model than with previous models. Furthermore, results show the importance of peripheral vaulting in patients with high myopia.

REFERENCES

7. Sanders DR, Yukich JA; for the ICL in Treatment of Myopia (ITM) Study Group. Incidence of lens opacities and clinically significant