Visian® ICL™
Clinical Highlights from the ESCRs Congress

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Visual and refractive outcomes in amblyopic eyes with moderate myopia after implantation of a posterior chamber collamer phakic intraocular lens in comparison with corneal laser surgery........................................................................... 9
The purpose of this study was to assess the efficacy, predictability, safety and stability of the Visian ICL with centraFLOW technology for the correction of myopia over a 2 year follow-up.

- 179 eyes of 95 patients
- Mean sphere -8.17±2.87D (-17.50 to -2.25 D)
- Mean cylinder -1.07±1.08D (-2.00 to 0.00 D)

**Postoperative outcomes at 2 years**

<table>
<thead>
<tr>
<th></th>
<th>Mean UCVA</th>
<th>Mean BCVA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-op</td>
<td>-</td>
<td>0.93±0.2 (0.0 to 1.0)</td>
</tr>
<tr>
<td>2 years Post-op</td>
<td>0.94±0.1 (0.5 to 1.0)</td>
<td>0.99±0.05 (0.6 to 1.0)</td>
</tr>
</tbody>
</table>

**Predictability**
95.5% of eyes were within ±0.50D of the target refraction.
100% of eyes were within ±1.00D of the target refraction.

**Safety**
See fig.1

**Conclusion**
According to this study the authors found high predictability, stability, efficacy and safety outcomes at 2 years follow-up. The authors also considered the Visian ICL with CentraFLOW Technology to have good tolerance to high vault without inducing IOP complications.

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**Phakic intraocular lens Visian with CentraFLOW Technology: up to 2 years.**

**J. Fernández-Pérez (Spain) Free-paper**

The purpose of this study was to evaluate the efficacy, predictability, safety and stability of Visian ICL with CentraFLOW Technology to correct myopia after two years follow-up.

- 63 eyes (39 patients)
- Mean age was 31.8±7.05 years (19 to 46 years)

**Postoperative outcomes at 2-years**

- **Stability**: mean postoperative spherical equivalent was -0.12±0.22D at 6 months follow-up and remained stable for the rest of the study period.
- **Safety**: no eyes lost any lines of BCVA. 60% of eyes remained unchanged and 40% of eyes gained one or more lines of BCVA.
- No eyes had more than a 2mmHg increase in intraocular pressure over the entire follow-up.
- At 1 month, 55% of patients were aware of halos, but by 6 months, only 5% of patients perceived halos.

**Conclusion**
According to this study, the Visian ICL with centraFLOW technology was effective, predictable, safe and stable to correct moderate to high myopia and provided good IOP outcomes.
Visian Toric ICL™

V4B Toric Implantable Collamer Lens for Myopic Astigmatism: One Year Follow-up.
T. Ferrer-Blasco (Spain) Poster

The purpose of this study was to assess the predictability, stability, safety and efficacy of the V4B toric ICL to correct moderate and high astigmatism with a 1 year follow-up.

- 35 eyes (20 patients)
- Mean preoperative sphere -5.46±4.17D
- Mean preoperative cylinder -3.14±1.19D

**Postoperative outcomes at 1 year:**

**Predictability:** mean sphere was -0.04±0.16D
97% of the eyes within ±0.50D of the target spherical equivalent (SEQ).
Mean cylinder was -0.29±0.42D with 65% of the eyes with less than 0.25D of residual cylinder.

**Efficacy:** See Fig. 3. Mean UCVA was 0.89±0.16; more than 50% of eyes had UCVA of 20/20. The Efficacy Index at 1 year was 1.01.

**Safety:** mean BCVA was 0.95±0.12; 77% had BCVA of 20/20. No eyes lost any line of BCVA.

**Conclusion**

The outcomes of this study with a 1 year follow-up indicate that this toric ICL model was predictable, stable, safe and effective to correct astigmatism between 1.5D and 6D of astigmatism.
The purpose of this study was to evaluate the prevalence of cataract after Implantable Collamer Lens implantation (Visian V4, V4B and V4c ICL models) up to 7 years follow-up.

- 3420 eyes (1898 patients)
- 1531 eyes underwent Visian ICL V4
- 1108 eyes Visian ICL V4B
- 781 eyes Visian ICL V4c.

### Postoperative Outcomes

- 21 eyes (0.61%) of 15 patients had ICL explantation for cataract development.
- All ICLs explanted were Visian ICL V4 model.
- The mean time between the ICL implantation and cataract surgery was 4.2±1.8 years.
- The mean vault distance in eyes that developed cataracts was 103±69 µm; where 70% of these eyes had a vault distance less than 100 µm.
- The ICL explantation and cataract surgery were successful in all eyes. Mean BCVA was 0.87±0.13. Every eye remained without change or had improved BCVA of one or two lines after explantation. (See fig. 5)

### Prevalence of Cataract after Implantable Collamer Lens for High to Low Myopia.

**R. Montés-Micó (Spain)** Poster

<table>
<thead>
<tr>
<th>N=3420</th>
<th>Mean ±SD</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>31.2±6.4</td>
<td>18 to 50</td>
</tr>
<tr>
<td>Pre-op Sphere (D)</td>
<td>-7.27±5.24D</td>
<td>-26.50 to 5.50D</td>
</tr>
<tr>
<td>Pre-op Cylinder (D)</td>
<td>-1.58±1.23D</td>
<td>-7.25 to 0.00D</td>
</tr>
</tbody>
</table>

**ICL (V4) Spherical Power**

<table>
<thead>
<tr>
<th>Lower than -10.50D</th>
<th>-10.50D to -13.50D</th>
<th>Higher than -13.50D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incidence of Cataract</td>
<td>0.54%</td>
<td>0.99%</td>
</tr>
</tbody>
</table>

*Incidence of cataract by Visian ICL V4 power implanted.*

### Factors contributing to cataract development were:

- V4 Version
- Older age
- Higher myopic power
- Low vault

**Fig. 5 Snellen decimal UDVA and BCVA for 21 patients that developed cataracts after ICL (V4) implantation showing good efficacy and safety even after ICL and cataract**

### Conclusion

According to this long-term study with up to 7 years follow-up, the incidence of cataract is low with the Visian ICL V4 model and zero for the other ICL models evaluated: V4B and V4c with CentraFLOW Technology.

The authors concluded that the prevalence of cataract was higher for older patients and higher refractive errors in patients that had Visian ICL V4 model.
Visian ICL: Long-term Outcomes continued

Correction of moderate to high hyperopia with the implantable collamer lens (ICL): 3 to 6 year follow-up. F. Benda (Czech Republic) Free-paper

The purpose of the study was to evaluate the medium-term clinical results of Visian ICL (Version V3) implantation to correct moderate and high hyperopia.

- 28 eyes (15 patients) underwent implantation ICH V3.
- Mean age 28 years (range 18 to 36).
- Amblyopia was present in 15 eyes.
- Mean follow-up was 3.6 years (range 3 to 6 years).

Postoperative outcomes

Predictability results at 1 year follow-up
- 52% of eyes were within ±0.50D of target.
- 86% of eyes were within ±1.00D of target.

Stability
Mean refractive spherical equivalent (MRSE) differences between year 1 and final follow-up visit were not significant (P<0.255; Wilcoxon signed rank test).

Efficacy
See fig. 6
At 1 year postoperatively, 83% of eyes were 20/40 or better (53% of eyes were amblyopic).

Safety
67% gained 1 line of BCVA or remained unchanged. No eye lost more than 1 line of BCVA.

Other findings
- The mean endothelial cell loss from preoperative endothelial density until the last follow-up visit was 4.91%.
- Two clinically significant cortical opacities occurred in one patient.
- In 3 eyes with vault below 100µm during a 3-year follow-up, no development of cataract or anterior subcapsular opacities occurred.

Patient satisfaction survey
13 patients (87%) were satisfied with the outcomes. No patient was dissatisfied. 4 patients (27%) experienced a little disturbing halo and glare under scotopic conditions, (these patients had preoperative MRSE over +7.00D).

Conclusion
According to this study with follow-up of up to 6 years, implantation of ICL is a safe, effective, predictable and stable method for the correction of moderate and high hyperopia. In 3 eyes with low vault of less than 100µm, no cataract or anterior subcapsular opacity formation occurred during the study period.
Visian® ICL Optical Quality

Vision quality comparison after Visian ICL and femtosecond LASIK surgery for myopia.  Z. Jin (China) Free-paper

The purpose of this study was to assess and compare visual quality parameters 6 months after Visian ICL implantation (V4) and after femtosecond-LASIK. The following measures were considered important in determining optical quality:

Visual Acuity
Contrast Sensitivity
Wavefront Aberration
Corneal Aspherical Parameters

Results were produced with regard to:
- uncorrected visual acuity
- refractive diopter
- total high-order aberration (HOA)
- spherical aberration and coma aberration.

Postoperative Outcomes at 6 months:

<table>
<thead>
<tr>
<th></th>
<th>Visian ICL (n=75 eyes)</th>
<th>FemtoLASIK (n=114 eyes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample size</td>
<td>75 eyes (43 patients)</td>
<td>114 eyes (60 patients)</td>
</tr>
<tr>
<td>Mean SEQ</td>
<td>-11.20±7.13D</td>
<td>-8.00±1.35D</td>
</tr>
<tr>
<td>Mean Cylinder</td>
<td>-2.50±1.13D</td>
<td>≤ -2.0D</td>
</tr>
</tbody>
</table>

Compared with preoperative aberrations, total root mean square higher-order aberrations (total RMSh) and coma were not statistically significantly changed; but spherical aberration was significantly reduced after ICL implantation, whereas, in the femtoLASIK group, total RMSh, coma aberration and spherical aberration were significantly increased after treatment.

**Conclusion**

According to this study Visian ICL implantation induced less HOAs than femtosecond LASIK procedure for the correction of high myopia. ICL implantation provided better visual quality compared with LASIK treatment.
The changes of iris ciliary cyst after implantations of the Visian phakic implantable collamer lens.  

Q. Chen (China) Free-paper

The purpose of this study was to evaluate the changes of primary iris-ciliary cyst 1 year after implantations of the Visian ICL and the effects of the location of the implantable collamer lens.

**Visian ICL implantations: 145 patients (270 eyes)**

| Iris-ciliary cysts | Male: 29 cases (46 eyes) | Female: 27 cases (42 eyes) |

**Incidence rate of iris–ciliary cysts: 32.6%**

**Surgical Procedure and management:**

In cases of cysts larger than 0.8mm, either:

- If ICL, they were rotated to avoid contact between iris-ciliary cyst and lens haptics.
- If toric ICL, then axis of lens was customised to avoid contact of lens haptics and iris-ciliary cyst.

From a cohort of 80 eyes with cysts, a group of 17 eyes were followed up 1 year after Visian ICL implantation with UBM examinations to review location of Visian ICL and changes in the cysts.

**Postoperative Outcomes at 1 year:**

- 10 cases (17 eyes).
- 7 cases of binocular cysts.
- 3 cases of monocular cysts.
- Preoperative size range 0.2mm to 1.8mm.
- 12 eyes with cysts smaller than 0.8mm (70.1%).

<table>
<thead>
<tr>
<th>Appearance of cyst</th>
<th>Number of eyes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Became larger</td>
<td>0</td>
</tr>
<tr>
<td>No change</td>
<td>6 eyes (35.3%)</td>
</tr>
<tr>
<td>Became smaller</td>
<td>5 eyes (29.1%)</td>
</tr>
<tr>
<td>Disappeared</td>
<td>6 eyes (35.3%)</td>
</tr>
</tbody>
</table>

The largest cyst to have disappeared at 1 year post-op was 0.8mm in diameter prior to implantation. All ICL and toric ICLs remained stable up to 1 year follow-up.

**Conclusion**

According to the results of this study, the authors found, when reviewed at a 1 year follow-up, small primary iris-ciliary cysts can disappear or become smaller after the ICL implantation.

Most iris-ciliary cysts had no influence on the location of the ICLs. Primary iris-ciliary cysts that disappeared or became smaller were mainly located in the nasal and temporal regions. Cysts that remained unchanged were predominantly located superiorly or inferiorly.

The author suggested that contact between the ICL and the primary iris-ciliary cyst may oppress the cyst and cause shrinkage.
Visual and refractive outcomes in amblyopic eyes with moderate myopia after implantation of a posterior chamber collamer phakic intraocular lens in comparison with corneal laser surgery.  

F. González-López (Spain) Free-paper

This non-matched study was a comparison of results for amblyopic patients with refractions that ranged between –5.00D and –10.00D. Cylinder values were less than 2.00D. Preoperative best corrected visual acuity (BCVA) was less than or equal to a Snellen decimal value of 0.7 in these amblyopic eyes. Follow-up was between 1 month and 1 year and the age range was 18 to 47 years.

**LASIK Cohort**
- 1310 eyes
- Mean Spherical Equivalent (SEQ) –7.24D (range –5.00 to –10.00)
- Mean BCVA 0.62 (range 0.1 to 0.7)

**Visian ICL V4 Cohort**
- 94 eyes
- Mean Spherical Equivalent (SEQ) –8.68D (range –5.50 to –9.80)
- Mean BCVA 0.60 (range 0.2 to 0.7)

### Postoperative Outcomes

<table>
<thead>
<tr>
<th></th>
<th>LASIK</th>
<th>Visian ICL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean BCVA pre-op</td>
<td>0.62±0.11</td>
<td>0.60±0.10</td>
</tr>
<tr>
<td>(0.1 to 0.7)</td>
<td>(0.2 to 0.7)</td>
<td></td>
</tr>
<tr>
<td>Mean BCVA post-op</td>
<td>0.80±0.16</td>
<td>0.84±0.12</td>
</tr>
<tr>
<td>(0.1 to 1.0)</td>
<td>(0.58 to 1.0)</td>
<td></td>
</tr>
<tr>
<td>Mean UCVA post-op</td>
<td>0.76±0.18</td>
<td>0.77±0.15</td>
</tr>
<tr>
<td>(0.05 to 1.0)</td>
<td>(0.45 to 1.0)</td>
<td></td>
</tr>
<tr>
<td>Mean post-op SEQ</td>
<td>-0.30±0.42D</td>
<td>-0.19±0.38D</td>
</tr>
<tr>
<td>(-2.38 to +1.00)</td>
<td>(-1.37 to +0.75)</td>
<td></td>
</tr>
</tbody>
</table>

**Conclusion**

From this study with up to 1 year follow-up, the authors concluded that in this long series of moderately myopic eyes with sub-optimal vision, LASIK and Visian ICL implantation rendered a statistically significant visual gain compared to preoperative values. The authors' concluded that the Visian ICL group performed significantly better than the LASIK group in terms of safety and efficacy in this study.