A prospective multicenter study has been conducted to evaluate efficacy and safety of the ARTIFLEX® Toric PIOL. Between September 2007 and April 2009, 132 eyes were enrolled in the study at 7 investigation sites. The results of the 115 eyes that met with the inclusion criteria will be published, and are presented here.

Study Group

Study Inclusion Criteria
• Stable myopia with astigmatism
• Preoperative endothelial cell count stratified by age:
  21 to 25 years of age: 2800 cells/mm²;
  26 to 30 years of age: 2650 cells/mm²;
  31 to 35 years of age: 2400 cells/mm²;
  36 to 45 years of age: 2200 cells/mm²;
  > 45 years of age: 2000 cells/mm².
• Anterior chamber depth ≥ 3.2 mm from epithelium
• Scotopic pupil size ≤ 7.0 mm
• Preoperative intraocular pressure ≤ 21 mmHg
• Age between 18 and 60 at the time of the surgery

DEMOGRAPHICS

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Eyes (N)</td>
<td>115</td>
</tr>
<tr>
<td>Age @ OP</td>
<td>37.7 years ± 8.0 (range 20 to 54)</td>
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<tr>
<td>Gender</td>
<td>67.1% female, 32.9% male</td>
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<tr>
<td>Eye</td>
<td>52.2% right, 47.8% left</td>
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<tr>
<td>ACD</td>
<td>3.65 mm ± 0.25 (range 3.20 to 4.28)</td>
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<tr>
<td>Axial length</td>
<td>26.20 mm ± 1.24 (range 23.53 to 29.32)</td>
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<tr>
<td>Pupil size (scotopic)</td>
<td>5.70 mm ± 0.97 (range 3.13 to 7.00)</td>
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<tr>
<td>Spherical equivalent</td>
<td>-7.53 D ± 2.70 (range -1.88 to -14.00)</td>
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<tr>
<td>Cylinder</td>
<td>2.18 D ± 0.79 (range 0.75 to 4.50)</td>
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<tr>
<td>Incision size</td>
<td>3.24 mm ± 0.09 (range 3.0 to 3.4)</td>
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FIGURES
Intended vs achieved after 6 months

Deviation from target:
- ≤0.5 D: 81.8%
- ≤1.0 D: 99.0%

Stability of refraction

Refraction stable from 1 day to 6 months post-op

Lines gained / lost (Safety) after 6 months

Safety index

Post-op BSCVA:
- 0.5 or better: 100%
- 1.0 or better: 83.3%

Unchanged or lines gain: 92.2%
≥2 lines gain: 16.7%

Intraocular Pressure (IOP)

IOP after 6 months comparable to pre-op

Endothelial Cell Count

Endothelial cell change, paired analysis:
- pre-op - 6 months: -4.3%

Astigmatism Correction

Contrast Sensitivity

Persistant complications after 6 months:
- n: 109
- glare: 7.3%
- halos: 4.6%
- pigment: 15.6%
- non-pigment: 12.8%
- synechia (cumulative): 4.3%
- oval pupil: 2.8%
- raised IOP: 0%
- SSI: 0%
- other: 1.8%