ARTISAN® Toric PIOL | European Multicenter Study

From 1998 to 2001, the European clinical investigation of the ARTISAN® Toric PIOLs was conducted. The PIOL for correction of myopia or hyperopia with astigmatism was evaluated for safety, efficacy, predictability, stability, complications, and patient satisfaction. Seventy eyes of 53 patients were implanted by 16 investigators, follow-up was 6 months. The results are published* and presented here. Some results are presented in 2 groups: spherical equivalent < 0 D and spherical equivalent > 0 D.

Study Group
Netherlands: Dr. Christiaans, Dr. Luyten, Dr. Landesz; Belgium: Dr. Budo; Germany: Dr. Dick, Dr. Krumeich; Portugal: Dr. Loureiro, Prof. Dr. Marinho; Saudi Arabia: Dr. El Danasoury; South Africa: Dr. Venter; Spain: Prof. Dr. Alió y Sanz, Dr. Guell, Dr. Rahhal; Switzerland: Dr. Bianchetti, Dr Spirig, Dr. Thomann.

Study inclusion Criteria
- Stabilized myopia or hyperopia in combination with astigmatism
- Preoperative endothelial cell count ≥ 2000 cells / mm²
- Anterior chamber depth ≥ 2.6 mm from epithelium


DEMOGRAPHICS

<table>
<thead>
<tr>
<th></th>
<th>Myopic eyes (SE &lt; 0)</th>
<th>Hyperopic eyes (SE &gt; 0)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eyes (N)</td>
<td>48</td>
<td>22</td>
</tr>
<tr>
<td>Age @ OP</td>
<td>35 years (range 22 to 59)</td>
<td>35 years (range 26 to 50)</td>
</tr>
<tr>
<td>Gender</td>
<td>Female: 60.4%</td>
<td>Female: 63.6%</td>
</tr>
<tr>
<td></td>
<td>Male: 39.6%</td>
<td>Male: 36.4%</td>
</tr>
<tr>
<td>Eye</td>
<td>Right: 27</td>
<td>Right: 10</td>
</tr>
<tr>
<td></td>
<td>Left: 21</td>
<td>Left: 12</td>
</tr>
<tr>
<td>ACD</td>
<td>3.57 mm ± 0.26 (range 3.2 to 4.1)</td>
<td>3.36 mm ± 0.28 (range 2.95 to 3.84)</td>
</tr>
<tr>
<td>Axial length</td>
<td>26.84 mm ± 1.87 (range 23.15 to 30.25)</td>
<td>21.99 mm ± 0.72 (range 20.69 to 22.80)</td>
</tr>
<tr>
<td>Pupil size (scotopic)</td>
<td>6.3 mm ± 1.30 (range 4.4 to 8.0)</td>
<td>6.5 mm ± 1.23 (range 4.0 to 8.0)</td>
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<tr>
<td>Spherical equivalent</td>
<td>-8.9 D ± 4.52 (range -21.25 to -1.25)</td>
<td>3.35 D ± 1.98 (range 0 to 6.5)</td>
</tr>
<tr>
<td>Sphere</td>
<td>-7.03 D ± 4.65 (range -19.0 to -1.75)</td>
<td>5.2 D ± 1.93 (range +2.0 to +8.0)</td>
</tr>
<tr>
<td>Cylinder</td>
<td>3.74 D ± 1.09 (range 1.75 to 7.25)</td>
<td>3.7 D ± 1.05 (range 1.5 to 6.0)</td>
</tr>
<tr>
<td>K-values</td>
<td>44.11 D ± 3.2</td>
<td>43.11 D ± 2.57</td>
</tr>
</tbody>
</table>

FIGURES
Intended vs achieved after 6 months

Myopic eyes (n=48)
Deviation from target:
- ≤ 0.5 D: 83.3%
- ≤ 1.0 D: 100%

Hyperopic eyes (n=22)
Deviation from target:
- ≤ 0.5 D: 50.0%
- ≤ 1.0 D: 100%

Stability of refraction

Lines gained / lost (Safety) after 6 months

Safety index
Last visit
BSCVA post / BSCVA pre: 1.25

Unchanged or lines gain: 100%
≥ 2 lines gain: 27.1%

Post-op BSCVA:
0.5 or better: 100%
1.0 or better: 43.3%

Intraocular Pressure (IOP)

IOP after 6 months comparable to pre-op

Persistant complications after 6 months:
SSI (surgery related)
- closing suture: 1.43%
- repositioning lens: 1.43%
Iris pigment precipitates on PIOL: 1.43%
Photopic phenomena (mild): 4.30%
Glare (moderate): 1.43%
Pupillary block: 0%
Endophthalmitis: 0%
Cataract: 0%
Retinal detachment: 0%
PIOL explantation: 0%

Endothelial Cell Count

ECC: 4.5% surgery related loss

Astigmatism Correction after 6 months

Mean astigmatism:
Pre-op: 2.20 D
Post-op: 0.26 D