The European clinical investigation of the ARTIFLEX® design Myopia began in January 2003. Twenty-three investigator sites have participated in the prospective nonrandomized study. The enrollment phase continued until September 2006, after which 1000 ARTIFLEX® lenses were implanted. All study subjects were monitored for a period of two years to determine the safety and efficacy of the device. The data of the first 350 implantations meeting the inclusion criteria are published in Ophthalmology*, and presented here.

**Study Group**

**Study Inclusion Criteria**
- Axial myopia requiring correction from –2.0 D to –12.0 D
- Preoperative endothelial cell count ≥ 2000 cells / mm²
- Anterior chamber depth ≥ 3.2 mm from epithelium
- Scotopic pupil size ≤ 7.0 mm
- Preoperative cylinder ≤ 2.0 D (subjective refraction)
- Preoperative intraocular pressure ≤ 21 mmHg
- Age between 18 and 60 at the time of the surgery


**DEMOGRAPHICS**

<table>
<thead>
<tr>
<th>Eyes (N)</th>
<th>348</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>35.43 (range 19 to 57)</td>
</tr>
<tr>
<td>Gender</td>
<td>60.1% female, 39.9% male</td>
</tr>
<tr>
<td>Eye</td>
<td>50.9% left, 49.1% right</td>
</tr>
<tr>
<td>ACD</td>
<td>3.66 mm (range 3.20 to 4.79)</td>
</tr>
<tr>
<td>Axial length</td>
<td>25.88 mm ± 1.46 (range 21.74 to 31.33)</td>
</tr>
<tr>
<td>Pupil size (scotopic)</td>
<td>5.67 mm ± 0.91 (range 2.10 to 7.00)</td>
</tr>
<tr>
<td>Spherical equivalent</td>
<td>-7.23 D ± 2.65 (range -1.50 to -12.63)</td>
</tr>
<tr>
<td>Cylinder</td>
<td>-0.66 D ± 0.51 (range 0 to -2.0)</td>
</tr>
<tr>
<td>Incision size</td>
<td>3.20 mm ± 0.17 (range 3.0 to 4.0)</td>
</tr>
</tbody>
</table>

**FIGURES**

- Distribution of lens power
- Incision Size
- Efficacy after 2 years

**Efficacy after 2 years**
- UCVA post / BSCVA pre: 1.00 / 1.01 / 1.01
- Post-op UCVA: 0.5 or better: 97.3%, 1.0 or better: 68.9%
Intended vs achieved after 2 years

| Deviation from target: | ≤0.5 D: 77.5% | ≤1.0 D: 95.0% |

Stability of refraction

Refraction stable from 1 day to 2 years post-op

Lines gained / lost (Safety) after 2 years

<table>
<thead>
<tr>
<th>Safety index</th>
<th>6 months</th>
<th>1 year</th>
<th>2 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>BSCVA post / BSCVA pre</td>
<td>1.09</td>
<td>1.11</td>
<td>1.10</td>
</tr>
</tbody>
</table>

Persistant complications after 2 years:
- Glare: 3.2%
- Halo’s: 2.5%
- Pigment deposits: 4.4%
- Non pigment deposits: 1.3%
- Synechia: 1.0%

Cumulative complications during study:
- Lens replacement: 0.3% (n=1)
- Lens repositioning: 1.4% (n=5)
- Laser redo: 0.9% (n=3)
- Claw through iris: 0.3% (n=1)
- Urrets-Zavalia syndrome: 0.3% (n=1)