

ARTIFLEX® Myopia PIOL | European Multicenter Study

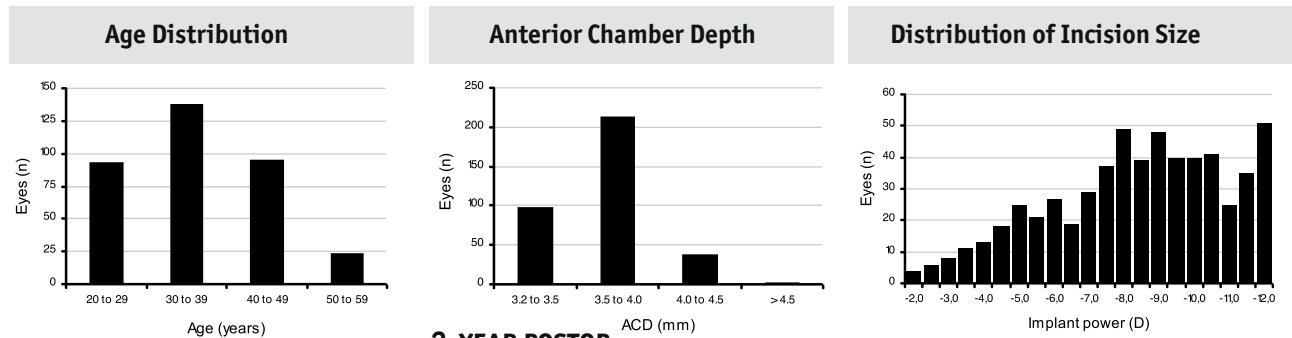
The European clinical investigation of the ARTIFLEX® design Myopia began in January 2003. Twenty-three investigator sites have participated in the study. The enrollment phase continued till September 2006, after which 1000 ARTIFLEX® lenses were implanted. All study subjects will be monitored for a period of two years to determine the safety and efficacy of the device.

At the time of this writing, 263 eyes have reached 2 years follow-up. The preoperative data of the first 350 implantations and the post-operative data of the group that reached 2 years follow-up are presented here.

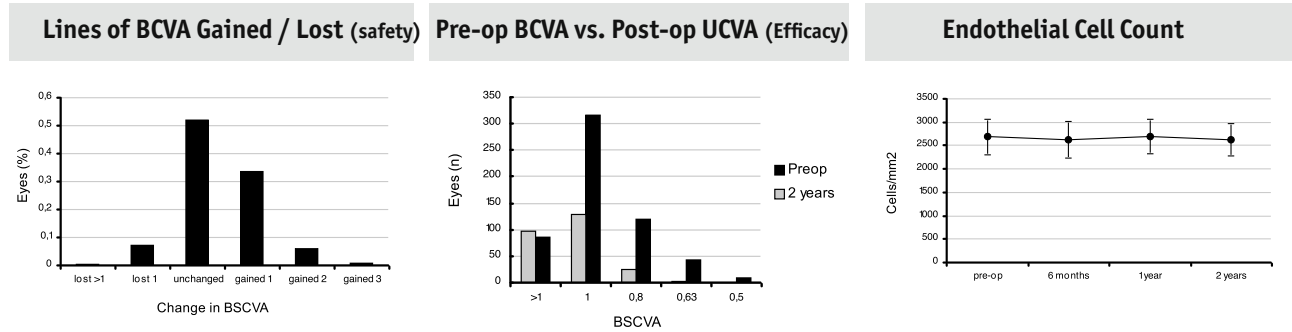
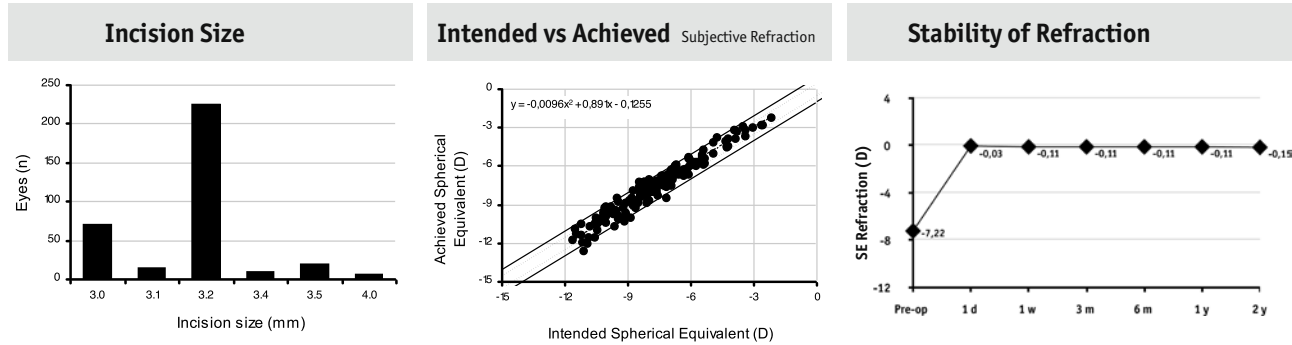
Study Inclusion Criteria

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

PREOP



2-YEAR POSTOP



Adverse Events reported at 2 year post-op

Description	n	% of N
Mild glare	8	2.9 %
Mild halos	7	2.6 %
Iris pigment precipitates	16	5.8 %
Non pigment precipitates	2	0.7 %
Synechia	3	1.1 %
IOL replacement*	1	0.4 %
Claw through iris	1	0.4 %

* Because of an incorrect lens power