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 prospective nonrandomized study. The enrollment phase continued till 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
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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

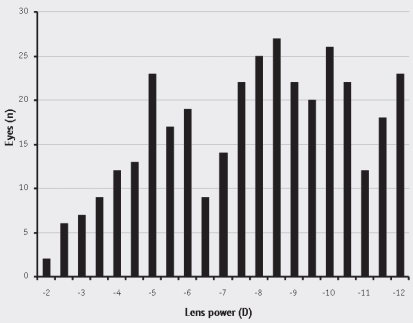
* *Dick HB, Budo C, Malecaze F, Güell JL, Marinho AA, Nuijts RM, Luyten GP, Menezo JL, Kohnen T. Foldable Artiflex phakic intraocular lens for the correction of myopia: two-year follow-up results of a prospective European multicenter study Ophthalmology 2009; 116(4):671-7.*

DEMOGRAPHICS

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

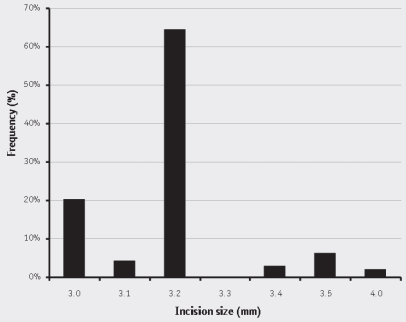
FIGURES

Distribution of lens power



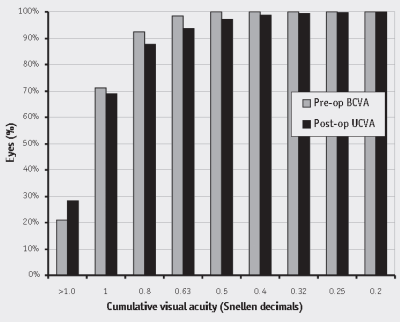
Implanted power:
N : 348
Mean : -7.9 D
Std : 2.6

Incision Size



Mean: 3.2 mm ± 0.17

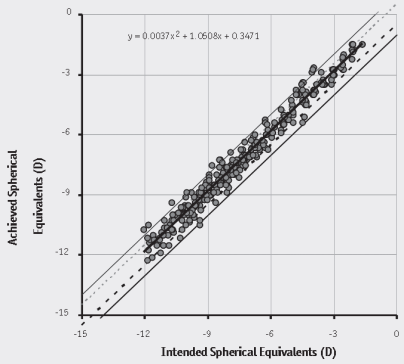
Efficacy after 2 years



Efficacy index	6 months	1 year	2 years
UCVA post / BSCVA pre	1.00	1.01	1.01

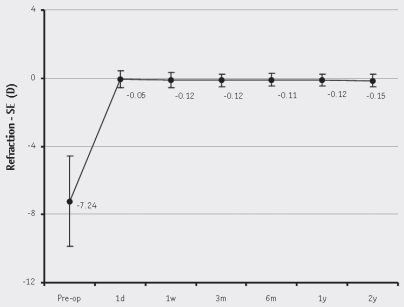
Post-op UCVA:
0.5 or better: 97.3%
1.0 or better: 68.9%

Intended vs achieved after 2 years



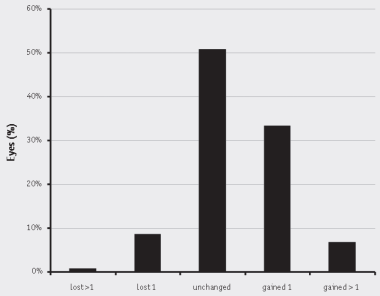
Deviation from target:
≤0.5 D: 77.5%
≤1.0 D: 95.0%

Stability of refraction



Refraction stable from 1 day to 2 years post-op

Lines gained / lost (Safety) after 2 years

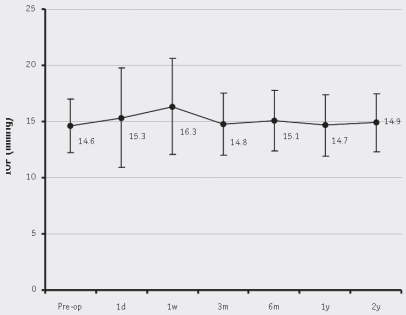


Safety index	6 months	1 year	2 years
BSCVA post / BSCVA pre	1.09	1.11	1.10

Post-op BSCVA:
0.5 or better: 100%
1.0 or better: 86.7%

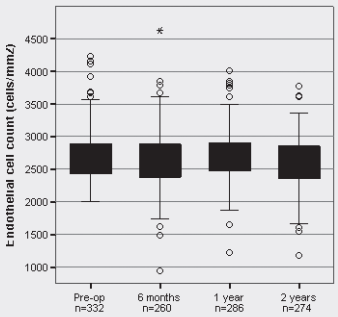
Unchanged or lines gain: 90.8%

Intraocular Pressure



IOP after 2 years comparable to pre-op

Endothelial Cell Count



Endothelial cell change, paired analysis:

pre-op - 6 months	-0.50%
pre-op - 1 year	1.64%
pre-op - 2 years	-0.50%

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)