ARTIFLEX® Toric PIOL | European Multicenter Study

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
Netherlands: B. Christiaans, M. Luger, R. Nuijts; Belgium: C. Budo; Germany: H. B. Dick; Portugal: A. Marinho; Spain: J. L. Güell.

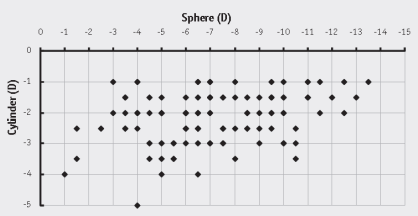
Study Inclusion Criteria
- Stable myopia with astigmatism
- Preoperative endothelial cell count stratified by age:
  21 to 25 years of age 2800 cells/mm²;
  26 to 30 years of age 2650 cells/mm²;
  31 to 35 years of age 2400 cells/mm²;
  36 to 45 years of age 2200 cells/mm²;
  > 45 years of age 2000 cells/mm².
- 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

Eyes (N)	115
Age @ OP	37.7 years ± 8.0 (range 20 to 54)
Gender	67.1% female 32.9% male
Eye	52.2% right 47.8% left
ACD	3.65 mm ± 0.25 (range 3.20 to 4.28)
Axial length	26.20 mm ± 1.24 (range 23.53 to 29.32)
Pupil size (scotopic)	5.70 mm ± 0.97 (range 3.13 to 7.00)
Spherical equivalent	-7.53 D ± 2.70 (range -1.88 to -14.00)
Cylinder	2.18 D ± 0.79 (range 0.75 to 4.50)
Incision size	3.24 mm ± 0.09 (range 3.0 to 3.4)

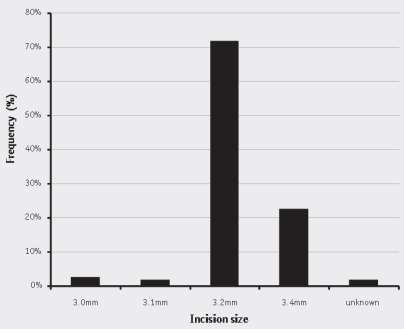
FIGURES

Distribution of lens power



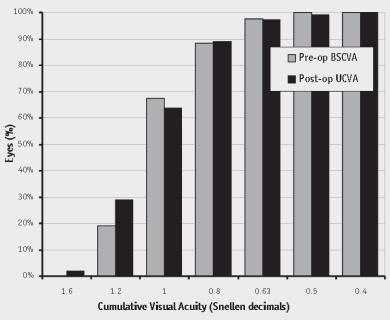
Implanted power:
N: 115
Mean sphere: -7.10 ± 2.70
Mean cylinder: -2.14 ± 0.80

Incision Size



Mean: 3.24 mm ± 0.09

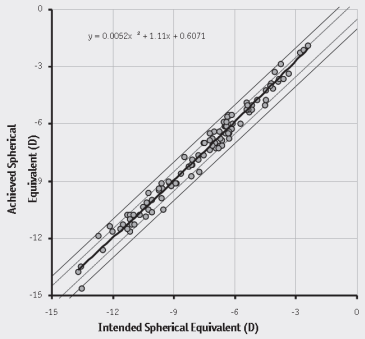
Efficacy after 6 months



Efficacy index	1 month	3 months	6 months
UCVA post / BSCVA pre	0.99	1.02	1.04

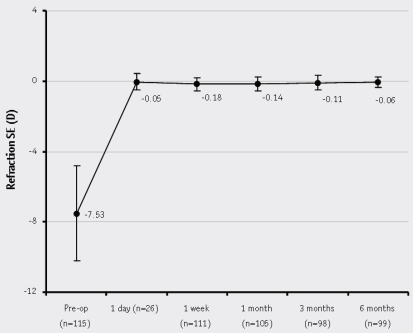
Post-op UCVA
0.5 or better: 99.0%
1.0 or better: 65.7%

Intended vs achieved after 6 months



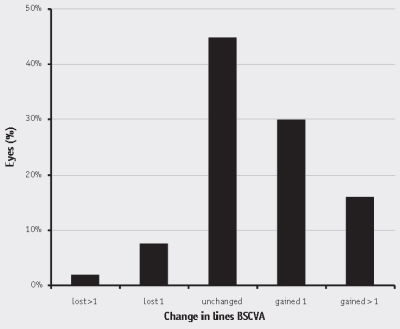
Deviation from target:
≤0.5 D: 81.8%
≤1.0 D: 99.0%

Stability of refraction



Refraction stable from 1 day to 6 months post-op

Lines gained / lost (Safety) after 6 months

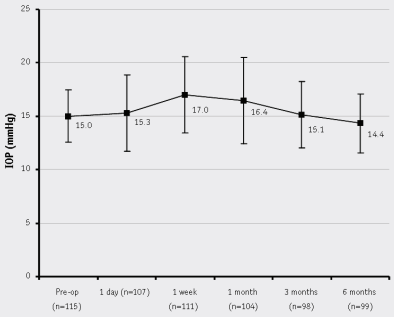


Safety index	1 month	3 months	6 months
BSCVA post / BSCVA pre	1.12	1.13	1.13

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

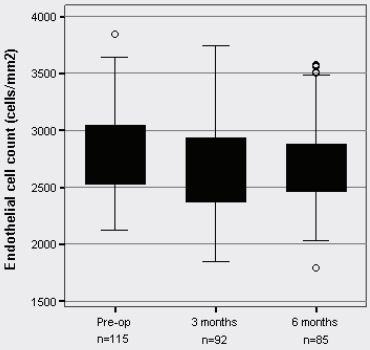
Unchanged or lines gain: 92.2%
≥ 2 lines gain: 16.7%

Intraocular Pressure (IOP)



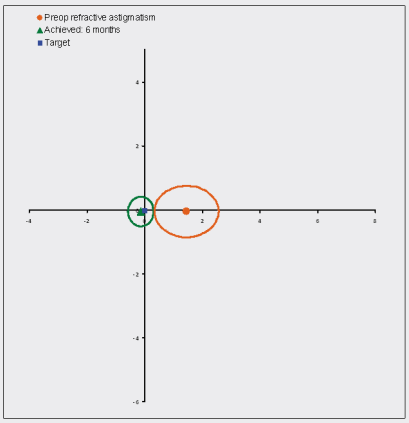
IOP after 6 months comparable to pre-op

Endothelial Cell Count

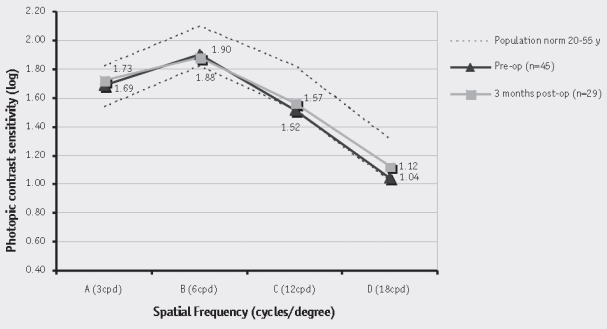


Endothelial cell change, paired analysis:
pre-op - 6 months: -4.3%

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%