

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. Guëll, Dr. Rahhal; Switzerland: Dr. Bianchetti, Dr. Spig, Dr. Thomann.

Study inclusion Criteria

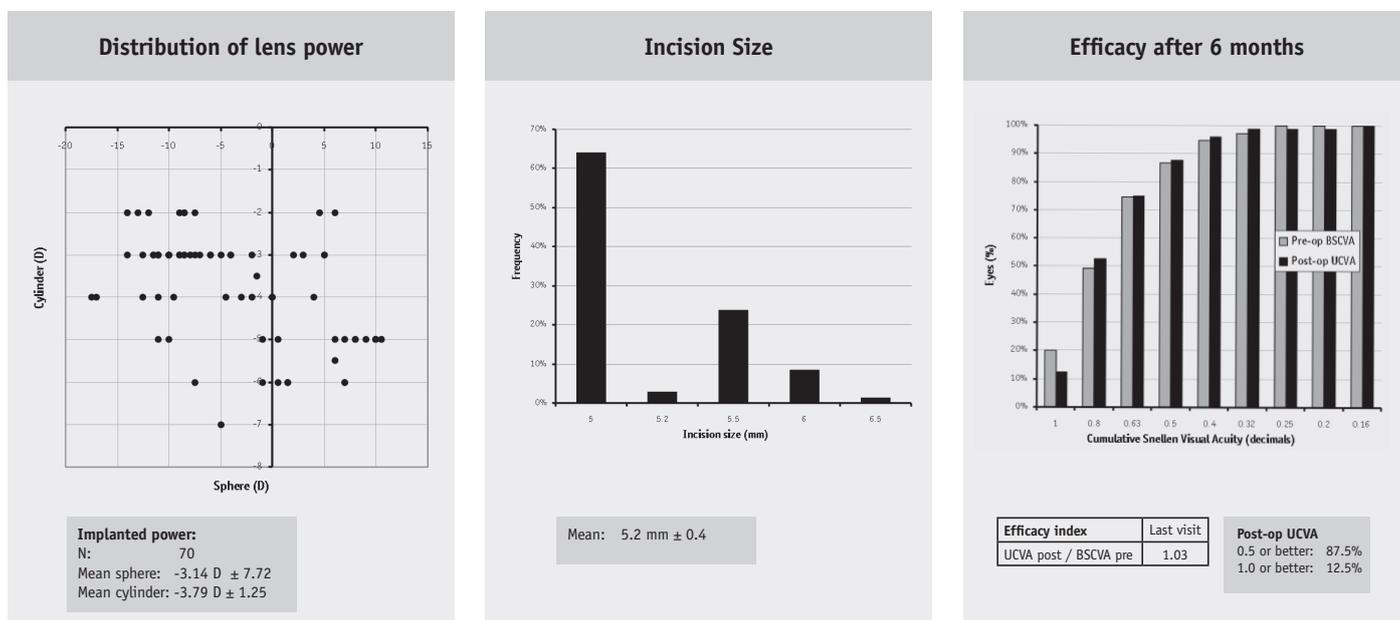
- Stabilized myopia or hyperopia in combination with astigmatism
- Preoperative endothelial cell count ≥ 2000 cells / mm²
- Anterior chamber depth ≥ 2.6 mm from epithelium

* Dick HB, Alio J, Bianchetti M, Budo C, Christiaans BJ, El-Danasoury MA, Guell JL, Krumeich J, Landesz M, Loureiro F, Luyten GP, Marinho A, Rahhal MS, Schwenn O, Spig R, Thomann U, Venter J. Toric phakic intraocular lens: European multicenter study *Ophthalmology* 2003; 110(1): 150-62.

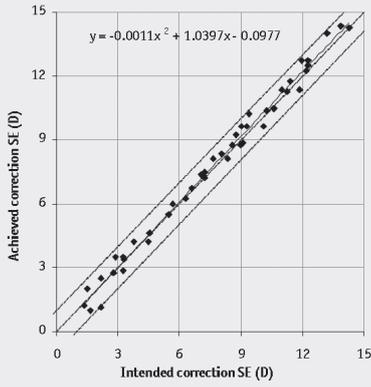
DEMOGRAPHICS

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

FIGURES

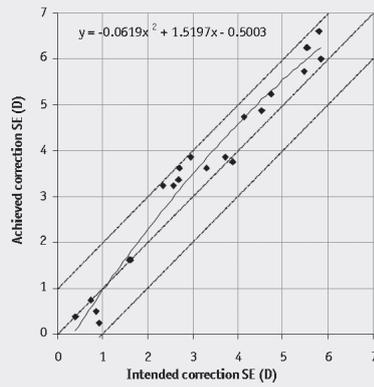


Intended vs achieved after 6 months



Myopic eyes (n=48)

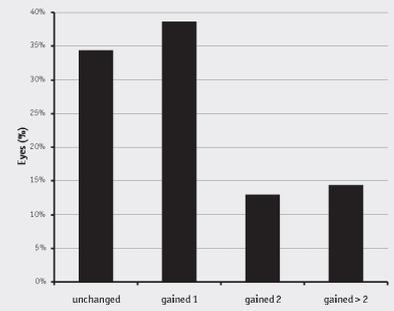
Deviation from target:
 ≤ 0.5 D: 83.3%
 ≤ 1.0 D: 100%



Hyperopic eyes (n=22)

Deviation from target:
 ≤ 0.5 D: 50.0%
 ≤ 1.0 D: 100%

Lines gained / lost (Safety) after 6 months

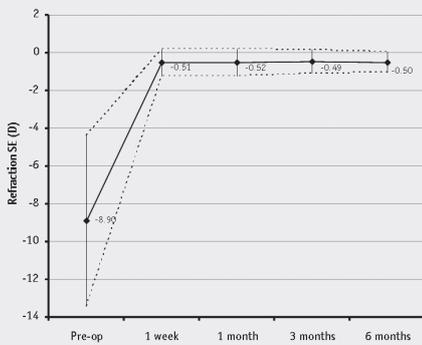


Safety index	Last visit
BSCVA post / BSCVA pre	1.25

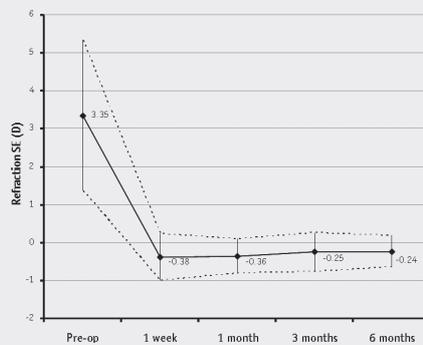
Unchanged or lines gain: 100%
 ≥ 2 lines gain: 27.1%

Post-op BSCVA:
 0.5 or better: 100%
 1.0 or better: 43.5%

Stability of refraction

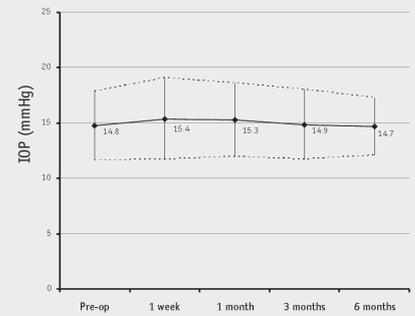


Myopic eyes (n=48)



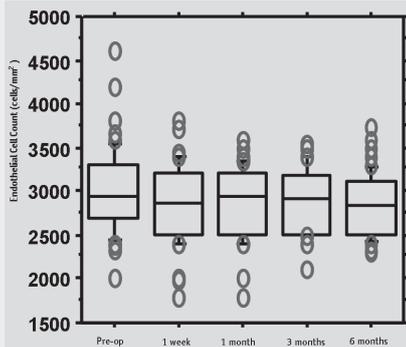
Hyperopic eyes (n=22)

Intraocular Pressure (IOP)



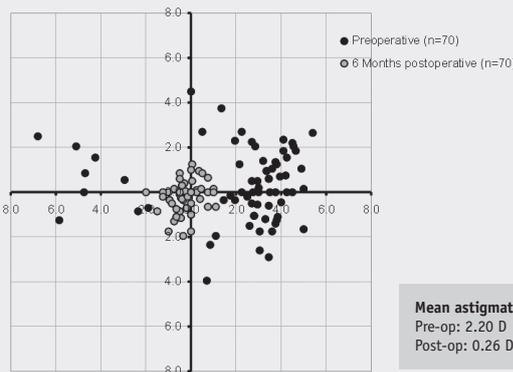
IOP after 6 months comparable to pre-op

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

Persistent 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%