

# 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 < 0D 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. Spirig, Dr. Thomann.

### Study inclusion Criteria

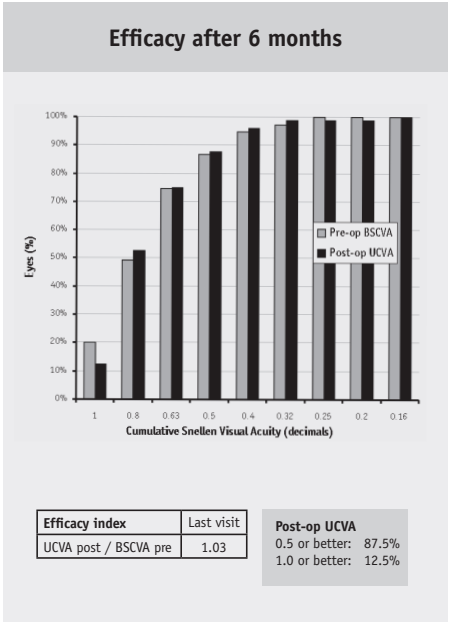
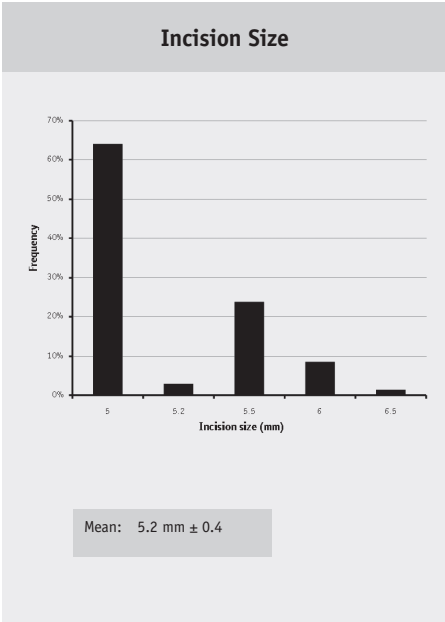
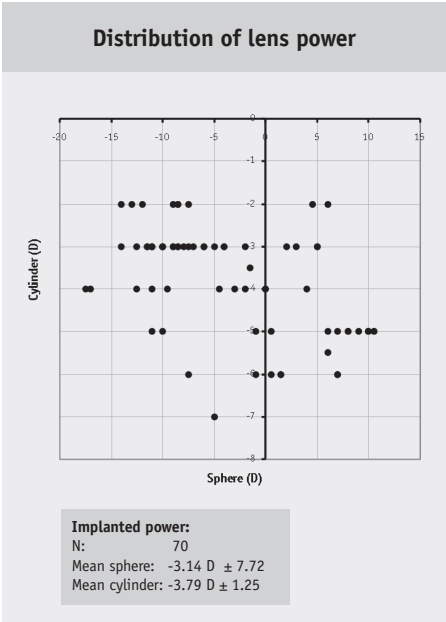
- Stabilized myopia or hyperopia in combination with astigmatism
- Preoperative endothelial cell count ≥ 2000 cells / mm²
- Anterior chamber depth ≥ 2.6 mm from epithelium

\* 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, Spirig R, Thomann U, Venter J. Toric phakic intraocular lens: European multicenter study Ophthalmology 2003; 110(1): 150-62.

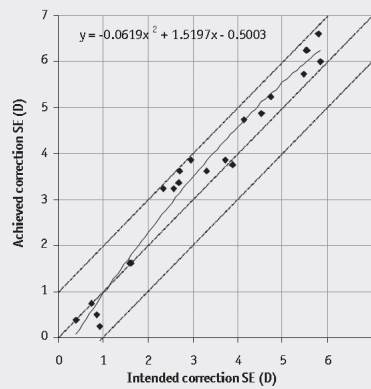
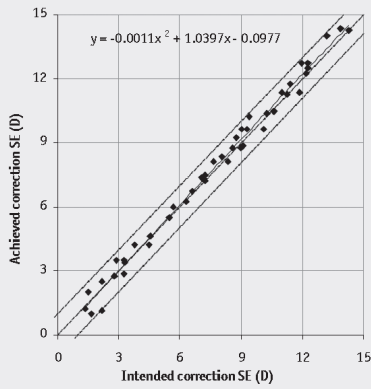
## DEMOGRAPHICS

	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 ± 0.26 (range 3.2 to 4.1)	3.36 mm ± 0.28 (range 2.95 to 3.84)
Axial length	26.84 mm ± 1.87 (range 23.15 to 30.25)	21.99 mm ± 0.72 (range 20.69 to 22.80)
Pupil size (scotopic)	6.3 mm ± 1.30 (range 4.4 to 8.0)	6.5 mm ± 1.23 (range 4.0 to 8.0)
Spherical equivalent	-8.9 D ± 4.52 (range -21.25 to -1.25)	3.35 D ± 1.98 (range 0 to 6.5)
Sphere	-7.03 D ± 4.65 (range -19.0 to -1.75)	5.2 D ± 1.93 (range +2.0 to +8.0)
Cylinder	3.74 D ± 1.09 (range 1.75 to 7.25)	3.7 D ± 1.05 (range 1.5 to 6.0)
K-values	44.11 D ± 3.2	43.11 D ± 2.57

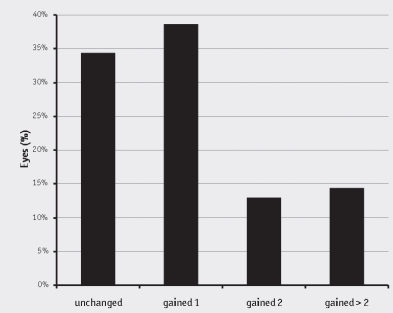
## FIGURES



### Intended vs achieved after 6 months



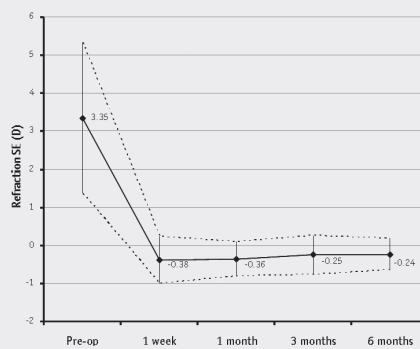
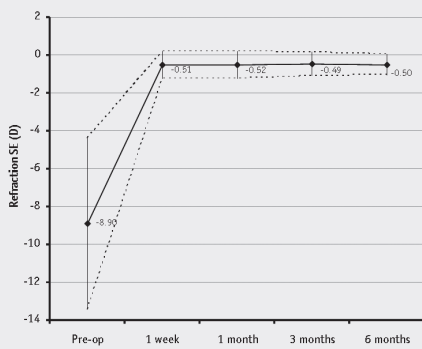
### Lines gained / lost (Safety) after 6 months



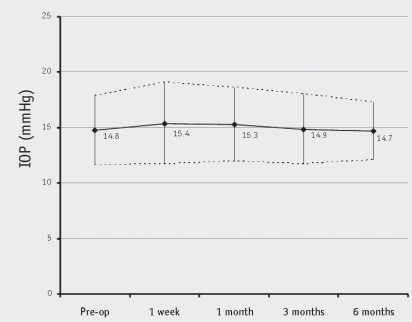
Unchanged or lines gain: 100%  
 $\geq 2$  lines gain: 27.1%

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

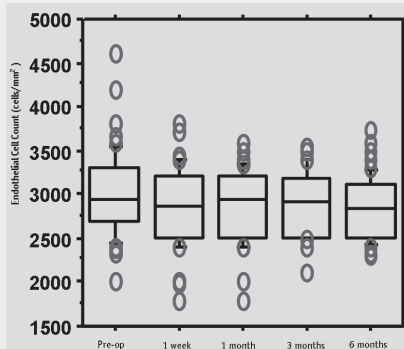
### Stability of refraction



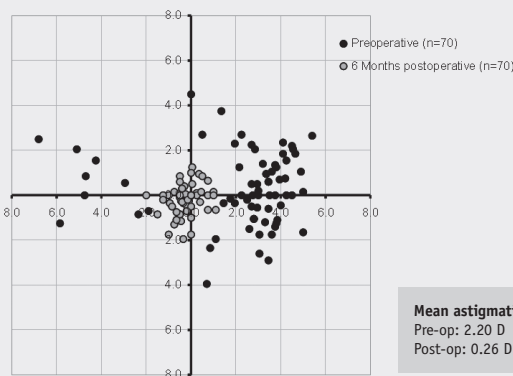
### Intraocular Pressure (IOP)



### Endothelial Cell Count



### Astigmatism Correction after 6 months



### 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%