ARTISAN® Myopia PIOL | European Multicenter Study

The European Clinical Investigation of the ARTISAN® Myopia Lens began in September 1991. A total of nine investigational sites have participated in the study, completing the protocol enrollment of 600 study subjects in 1997. All subjects have been monitored for a minimum of three years to determine the safety and efficacy of the Artisan® PIOL. A final report of the European Clinical Investigation was published in 2000.* The results of the 518 eyes that met with the inclusion criteria are presented here.

Study Group
Netherlands: Prof. Dr. Worst, Dr. Luyten; Belgium: Dr. Budo, Dr. Tassignon, Dr. Termote; France: Dr. Hessloehl; Slovakia: Dr. Izak; Spain: Dr. Menezo; Turkey: Dr. Sener.

Study Inclusion Criteria
- Stable myopia between -5.0 D and -20.0 D
- Anterior chamber depth ≥ 3.0 mm from epithelium
- Preoperative endothelial cell count ≥ 2000 cells / mm^2
- Preoperative intraocular pressure ≤ 21 mmHg
- Fixed Pupil Size < 4.5 mm

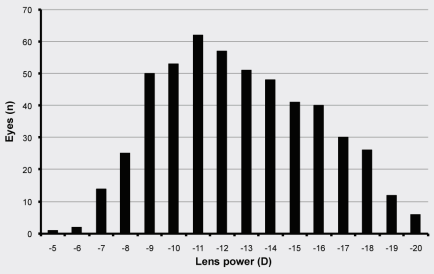
* *Camille Budo, MD, Jean C. Hessloehl, MD, Milan Izak, MD, Gregorius P.M. Luyten, MD, Jose L. Menezo, MD, Bozkurt A. Sener, MD, Marie José Tassignon, MD, Herve Termote, MD, Jan G.F. Worst, MD. Multicenter study of the ARTISAN® Phakic Intraocular Lens. J Cataract Refract Surg 2000; 26:1163-1171.*

DEMOGRAPHICS

Eyes (N)	518
Age @ OP	36.4 (range 18 to 65)
Gender	59.5 % female 40.5 % male
ACD	3.38 mm ± 0.71
Spherical equivalent	-12.95 D ± 4.35 (range -5.0 to -20.0)
Cylinder	1.23 D ± 1.13 (range 0 to 6.0)

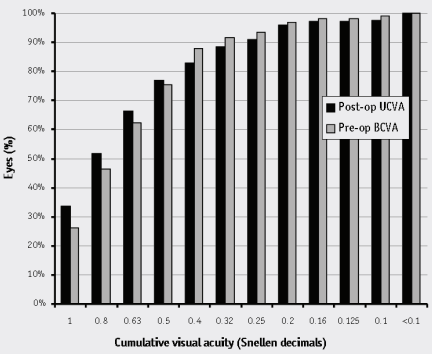
FIGURES

Distribution of lens power



Implanted power:
N 518
Mean -12.7 D
Std 3.19

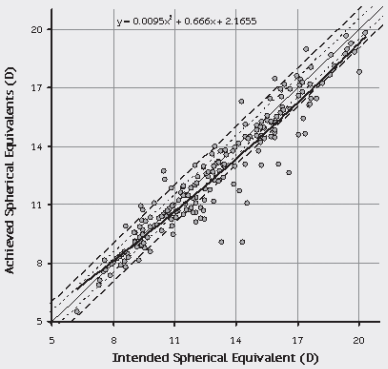
Efficacy after 3 years



Efficacy index	6 months	1 year	2 years	3 years
UCVA post / BSCVA pre	1.05	1.06	1.05	1.03

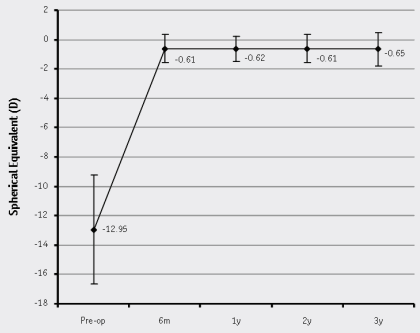
Post-op UCVA:
0.5 or better: 76.8%
1.0 or better: 33.7%

Intended vs achieved after 3 years



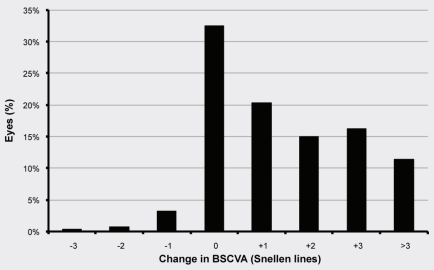
Deviation from target:
≤0.5 D: 57.1%
≤1.0 D: 78.8%

Stability of refraction



Refraction stable from 1 day to 3 years post-op.

Lines gained / lost (Safety) after 3 years

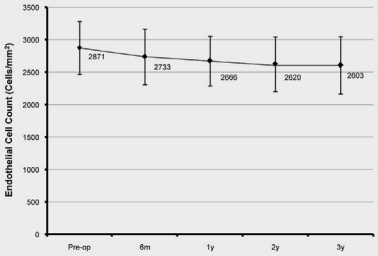


Safety index	6 months	1 year	2 years	3 years
Safety index BSCVA post / BSCVA pre	1,29	1,31	1,31	1,31

≥ 2 lines gain: 42.7%
≥ 2 lines lost: 1.2%

Post-op BCVA:
0.5 or better: 93.9%
1.0 or better: 61.8%

Endothelial Cell Count



Endothelial cell change per interval, paired analysis

preop - 3 years	-8.67%
6 months - 3 years	-4.14%
preop - 6 months	-4.38%
6 months- 1 year	-1.79%
1 year - 2 years	-1.36%
2 years - 3 years	-0.35%

Persistant complications after 3 years:

Glare	4.8%
Halo's	8.8%
Age related cataract formation	2.4%
Corneal Oedema	0.8%
Iris Atrophy	0.4%
Other	4.0%

Cumulative complications during study:

IOL removal*	2.8% (n=7)
Lens replacement	3.2% (n=8)
Lens repositioning	2.0% (n=5)
Repositioning Iris Hernia	0.4% (n=1)
Correcting Astigmatism with PRK	0.4% (n=1)
Pupillary Block	0.8% (n=2)
Retinal Detachment	0.8% (n=2)
Hyphema	1.6% (n=4)
IOL not well centered at surgery	8.8% (n=22)

* Wide Pupil Diameter (1)
Critical Endothelial Cell Count (1)
Trauma (punch on the eye), leading to a loosening of the claws (2)
Posterior Capsule Opacification followed by cataract formation (3)