ARTISAN® Myopia PIOL | US Phase III Clinical Investigation

In October 1997, the U.S. Clinical Investigation of the Artisan® Myopia Lens began, with Maurice John, M.D. performing the first implant at the John-Kenyon Eye Center in Jeffersonville, IN. Since then, a total of twenty-two investigational sites have participated in the first three phases of the study, nearly completing the protocol enrollment of 550 cohort study subjects. All study subjects will be monitored for a minimum of two years to determine the safety and efficacy of the device.

Study Inclusion Criteria

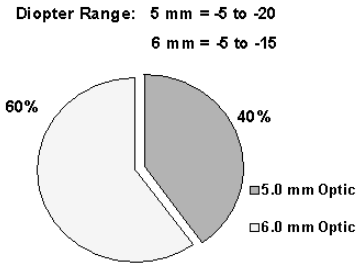
- Correction of axial myopia from –5.0 D to –20.0 D
- Preoperative endothelial cell count ≥ 2000 c/mm² diameter
- Subject age ranges from 21 to 54 years.
- Anterior chamber depth ≥ 3.2 mm
- Mesopic pupil size ≤ IOL Optic
- Preoperative cylinder ≤ 2.5 D.

Age / Gender / Race Distribution

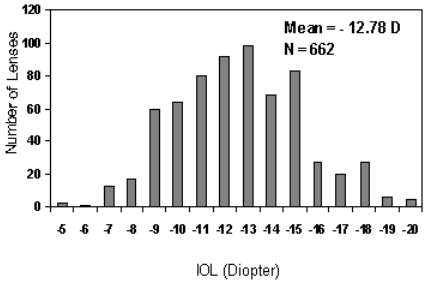
N = 662

Mean age	39.6 yrs (±7.8)
Range	21 - 58 yrs
Female	64%
Male	36%
Caucasian	85%
Asian	6%
Black	3%
Other	6%

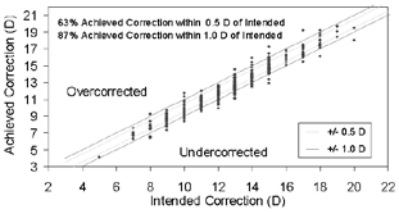
ARTISAN® Myopia Lens Model (Optic Size) Distribution



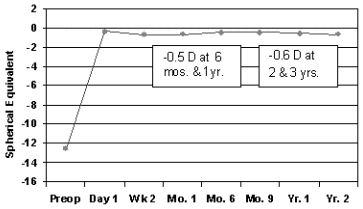
PIOL Power Distribution



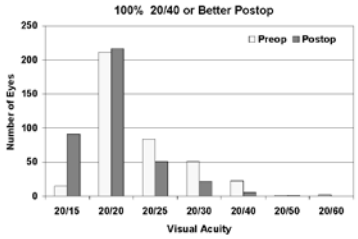
Accuracy / Predictability Manifest Refraction (6 months)



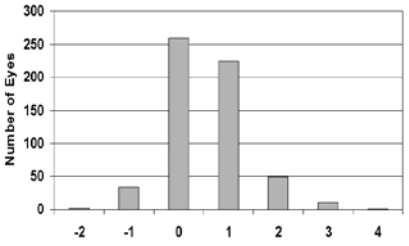
Stability Spherical Equivalents



Pre-Op vs Post-Op BSCVA (6 months)



Lines of BSCVA Gained / Lost (6 months)

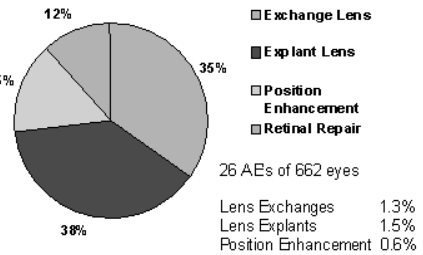


* 2 subjects 20/15 Preop - 20/20 Postop
1 subject 20/20 Preop - 20/25 Postop

Endothelial Cell Loss / Gain Pre-Op vs 6 months & 1 year

	PreOp	1 Year	3 Years
Mean	2594	2558	2570
Std. Dev.	454	465	510
Cumulative % +/-		-1.8%	-1.3%

Adverse Events Reported



26 AEs of 662 eyes

Lens Exchanges	1.3%
Lens Explants	1.5%
Position Enhancement	0.6%
Retinal Repair	0.4%

Adverse Events Reported

Description	n	% of N
Corneal	12	2.1 %
Natural Lens	13	2.2 %
Cell & Flare	8	1.4 %
Corneal Edema	2	0.3 %
Glare	45	7.7 %
Halos	31	5.3 %
Iris Pigment Precipitates	42	7.2 %
Pupil	20	3.4 %
Other	31	5.3 %