# ARTISAN® Hyperopia PIOL | US Phase III Clinical Investigation

In April 2000, the U.S. Clinical Investigation of the Artisan® Hyperopia Lens began. Since then, a total of nine investigation sites have participated Phase III of the study, nearly completing the protocol enrollment. 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 hyperopia from +3.0 D to +12.0 D
- Preoperative endothelial cell count ≥ 2000 c/mm² diameter
- Subject age ranges from 20 to 50 years.
- Anterior chamber depth ≥ 3.2 mm
- Mesopic pupil size ≤ IOL Optic
- Preoperative cylinder ≤ 2.5 D.

**PREOP**

### Preoperative Observations

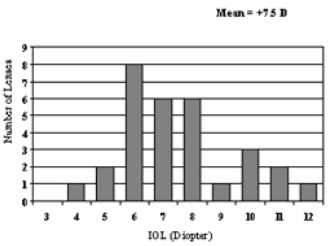
**N=30**

| Parameter | Mean | Range |
|---|---|---|
| Pupil diameter (mm) | 4.3 | 3.0 - 5.0 |
| ACD (mm) | 3.3 | 3.2 - 3.6 |
| Axial length (mm) | 21.77 | 19.4 - 22.8 |
| Corneal curvature (K1+K2)/2 (D) | 42.63 | 40.8 - 47.3 |
| Intraocular pressure (mmHg) | 11.8 | 10 -19 |
| Endothelial cell count (c/mm²) | 2276 | 2000 - 3607 |

### Operative Information

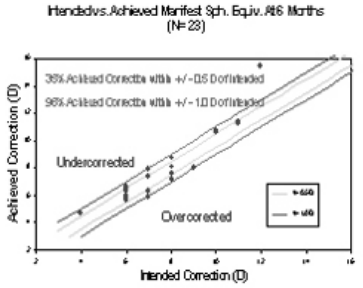
| Anesthesia | % | Surgical App. | % |
|---|---|---|---|
| - Peribulbar | 53.1 | - Superior | 62.5 |
| - Retrobulbar | 43.7 | - Temporal | 37.5 |
| - Topical | 3.1 | | |
| **Incision Loc.** | **%** | **Incision size** | **%** |
| - Corneal | 31.2 | - 5.0 | 9.4 |
| - Limbal | 28.1 | - 5.2 | 59.4 |
| - Scleral | 40.6 | - 5.5 | 18.7 |
| | | - 5.7 - 6.0 | 12.5 |

### IOL Power Distribution

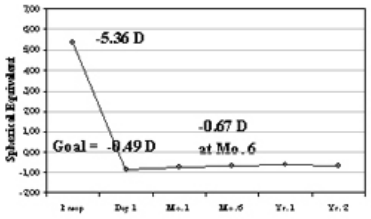



**POSTOP**

### Accuracy / Predictability Manifest Refraction (6 months)

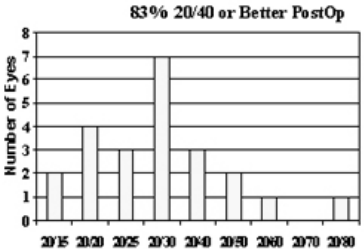



### Stability Spherical Equivalents

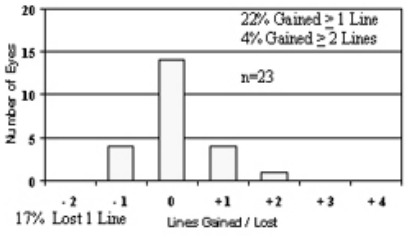



N=60 n=29 n=22 n=23 n=17 n=8

### Post-Op UCVA (6 months)




### Lines of BSCVA Gained / Lost (6 months)

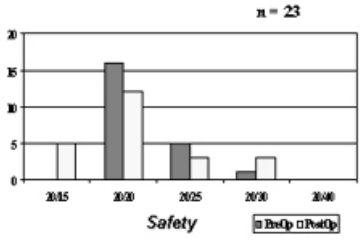



### Endothelial Cell Loss / Gain Pre-op vs 6 months

| | Pre-op | 6 Mo. |
|---|---|---|
| **Mean** | 2332 | 2467 |
| **Std. dev.** | 284 | 381 |
| **Cumulative %** | | +5.8% |

N = 23 (same patient data)

### Preop BSCVA vs Postop BSCVA




### Complications

2 subjects were observed to have pigment on the natural lens postoperatively. These subjects developed posterior synechiae inferiorly and were treated. Both cases resolved without sequelae. The prognosis is excellent. The cause was determined to be excessive iris touch. The patient selection criteria has been modified to exclude subjects with abnormal or protruding bulging irises.