

ARTISAN® Myopia 5/8.5 | European Clinical Investigation

The European Clinical Investigation of the ARTISAN™ Myopia Lens began in September 1991. Since then, a total of eighteen investigational sites have participated in the study, completing the protocol enrollment of 600 cohort study subjects in 1997. All study subjects have been monitored for a minimum of three years to determine the safety and efficacy of the device. A final report of the European Clinical Investigation was published in 2000.

Multicenter study of the ARTISAN® Phakic Intraocular Lens

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Abstract

Purpose: To assess the ARTISAN® Intraocular Lens to correct myopia in phakic eyes

Methods: In this prospective multicenter clinical study, the ARTISAN® lens was implanted in 518 eyes between September 1991 and October 1999. The power of the lenses ranged from -5.0 to -20.0 diopters (D). Follow-up examinations were performed at 6 months and 1, 2, and 3 years. Follow-up ranged from 6 months (n = 454) to 3 years (n = 249). The preoperative uncorrected visual acuity (UCVA) was not recorded but was estimated to be worse than 0.1. The preoperative mean best spectacle-corrected visual acuity (BSCVA) was 0.67 ± 0.26 (SD). Endothelial cell counts were done at 6 months and 1, 2, and 3 years in a subgroup of 129 eyes.

Results: A UCVA of 20/40 or better was observed in 76.8% of eyes regardless of the postoperative goal. A BSCVA of 20/40 or better was observed in 93.9% of eyes and remained stable throughout the follow-up. Of the eyes with extremely high myopia ($>-15.0D$), 63.3% gained 2 or more lines. The mean endothelial cell density change was 4.8% at 6 months, 2.4% at 1 year, 1.7% at 2 years, and 0.7% at 3 years. The incidence of persistent adverse events at 3 years was relatively low. Secondary surgical interventions included repositioning of the lens because of poor initial placement and lens exchange because of preoperative power calculation errors. Glare and hal effects during night driving were noted and were related to large pupils in young patients.

Conclusion: The ARTISAN® lens is a safe, stable, efficacious and predictable method to correct -5.0 to -20.0 D of myopia. This study suggests that the corneal endothelial cell loss is stabilized to the physiologically normal level after 3 years.

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