

ARTISAN® Toric PIOL | European Multicenter Study

Toric Phakic Intraocular Lens

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Abstract

Purpose: To evaluate safety, efficacy, predictability, stability, complications, and patient satisfaction after implantation of ARTISAN® PTIOLs for the correction of myopia or hyperopia with astigmatism.

Design: Prospective, nonrandomized, comparative (self-controlled) multicenter trial. Participants: Seventy eyes of 53 patients (mean, 35 years; range 22-59 years) with preoperative spherical equivalent between +6.50 and -21.35 D and cylinder between 1.50 and 7.25 D. Methods: Seventy eyes underwent implantation of a PTIOL with an optical zone of 5.0 mm (ARTISAN®, Ophtec, Groningen, the Netherlands). The dioptric power of the IOL was calculated by considering refraction, keratometry, and anterior chamber depth. The follow-up was 6 months in all cases. Lenses were available in powers ranging from +12.0 D to -23.5 D (spherical equivalent) in 0.5 D increments, with additional cylinder from 1.0 D to 7.0 D, also in 0.5 D increments. Main Outcome Measures: The main parameters assessed were best spectacle-corrected visual acuity (BSCVA), uncorrected visual acuity (UCVA), refraction, endothelial cell count (ECC), intraocular pressure, slitlamp biomicroscopy, indirect ophthalmoscopy, subjective complaints, and patient satisfaction.

Results: Eyes were divided in group A, myopia (n=48), with an average preoperative spherical equivalent of -8.90 ± 4.52 D, and group B, hyperopia (n=22), with an average preoperative spherical equivalent of $+3.25 \pm 1.98$ D. No eyes in either group experienced a loss in BSCVA, and 46 eyes gained 1 or more lines of their preoperative BSCVA. In 62 eyes (88.6%), UCVA was 20/40 or better. There was a significant reduction in spherical errors and astigmatism in all cases after surgery. All eyes of both groups were within ± 1.00 D of target refraction, and 51 eyes (72.9%) were within ± 0.50 D of target refraction. There was a 4.5% mean total loss of ECC during the first 6 months. No serious complications were observed. Overall patient satisfaction was very high. Conclusions: Six-month clinical trial results demonstrate that implantation of the ARTISAN® PTIOL safely, predictably, and effectively reduced or eliminated high ametropia and astigmatism with one procedure. The refractive effect was stable at 6 months after surgery. *Ophthalmology* 2003;110:150-162 © 2003 by the American Academy of Ophthalmology