Summary Clinical Investigation data

ARTISAN TORIC

Models: 1301W / 140**1W**
Basic UDI-DI: 8717819ArtisanToric/KY

Indications for use:

The ARTISAN Toric phakic intraocular lens (pIOL) is indicated for the correction of astigmatism, in patients aged 18 and older, when there are no compromising ocular pathology(ies).

European Multicenter Study with the ARTISAN Toric pIOL

The safety and efficacy of the ARTISAN Toric pIOL were investigated in a European multicenter clinical investigation. The study was prospective, non-randomized, comparative (self-controlled), with a follow-up of six months. The endpoints were refraction in terms of predictability and stability, visual acuity, endothelial cell count (ECC), and adverse events. Seventy eyes (53 subjects) were enrolled and divided into two groups: group A contained eyes with a preoperative SE <0.0 D (n=48) and group B contained eyes with a preoperative SE ≥0.0 D (n=22). The results after six months are shown below:

Performance results

The overall efficacy index was 1.03 after six months, and all eyes of both groups achieved a spherical equivalent (SE) within ± 1.0 D of the target refraction. The mean preoperative cylinder was reduced in all eyes from 3.7 D in average to 0.7 D at six months.
Preoperative, the uncorrected distance visual acuity (UDVA) was ≤20/60 (Snellen feet) in all cases. After six months, the UDVA was ≥20/40 (Snellen feet) in 85.4% of eyes in group A and in 95.5% of eyes in group B.

Safety results

The safety index was 1.3 at six months. The mean preoperative best corrected visual acuity (BCVA) for all eyes was 0.68 ± 0.23 Snellen decimals. After six months the mean BCVA was 0.85 ± 0.16 Snellen decimals for all eyes in both groups. A BCVA of ≥20/40 (Snellen feet) was reported in all eyes at six months. No serious complications were reported; three patients complained about photic phenomena and one patient was bothered with glare. No secondary surgical interventions were performed. There was a 4.5% mean total loss of ECC during the first six months.

The results of this study have been published in Ophthalmology, 2003 Jan;110(1):150-62 by Dick et al.
The conclusion was that implantation of the ARTISAN Toric pIOL was safe and predictable, and effectively reduced or eliminated high ametropia and astigmatism with one procedure, and that the refractive effect was stable after six months.

