Summary Clinical Investigation data

ARTIFLEX TORIC

Model: 4A0**SW / 4C0**SW
Basic UDI-DI: 8717819ArtiflexToric/U7

Indications for use:

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

European Multicenter Study with the ARTIFLEX Toric pIOL

The ARTIFLEX Toric pIOL was investigated in a European multicenter clinical investigation. The study in which 132 eyes were enrolled was prospective, non-randomized, and open-label, with a follow-up of six months. The objective was to study the performance of the ARTIFLEX Toric pIOL and establish the mechanical properties of the lens in the anterior chamber. The endpoints included:

- reduction of cylinder.
- lens axis misalignment (compared to intended position).
- mechanical stability (tilting, distortion, fixation of the lens).
- manifest refraction spherical equivalent (MRSE).
- best spectacle corrected and uncorrected distant visual acuity (BSCVA and UDVA).
- and safety (adverse events, endothelial cell count (ECC), IOP).

Performance results

The efficacy index was 1.04, and the mean UDVA was 0.98 at six months postoperative. 92.3% of the cases were within ± 0.5 D, and 100.0% of cases were within ± 1.0 D of the target refraction at six months postoperative. The mean postoperative subjective spherical equivalent was -0.05 D at one day postoperative and remained stable until six months postoperative (-0.06 D). The mean preoperative absolute subjective cylinder at spectacle plane was 2.20D. At six months postoperative, the mean subjective cylinder was reduced with 83.2% to 0.37 D. The remaining cylinder was 0.5 D or less in 75.8%, and 1.0 D or less in 96.0% of the cases.

Safety results

At six months postoperative, the safety index was 1.13, and the mean BSCVA was 1.04 Snellen decimals. Most frequently reported complications at six months postoperative were glare and haloes, pigment deposits, and non-pigment deposits. There were five reports of synechia, of which three resolved after lens explantation, one stabilized and one unknown. There was one secondary surgical intervention (SSI) reported (non IOL-related). The intraocular pressure measure was elevated at one week postoperative but was normal at six months.
There was no significant difference between preoperative, three, and six months ECC, indicating that the initial endothelial cell loss was surgery-related.
No tilting, optic distortion or other irregularities concerning mechanical stability were reported.

The results of this study have been published in Am J Ophthalmol, 2012; 154(4):730-739.e2 by Doors et al.
It was concluded that the implantation of ARTIFLEX Toric proved to be effective and a safe option for the correction of myopia and astigmatism in phakic eyes.

 Updated: 01-Apr-2025