

Summary Clinical Investigation data

PRECIZON Presbyopic Toric

Model: 575

Basic UDI-DI: 8717819Precizon575/6X

Indications for use:

The PRECIZON Presbyopic Toric is a multifocal lens intended for implantation in the capsular bag, indicated for optical correction of aphakia for adults in whom the crystalline lens has been removed and who desire presbyopia and corneal astigmatism correction.

Post Market Clinical Follow-up (PMCF) study with the PRECIZON Presbyopic Toric multifocal IOL

The PRECIZON Presbyopic Toric intraocular lens (IOL) was investigated in a prospective, open-label, single-armed, multicenter study. The primary objective of this study was to evaluate the ability of the PRECIZON Presbyopic Toric IOL to provide uncorrected near, intermediate and distance vision in patients undergoing cataract extraction or clear lens extraction (CLE), and intraocular lens implantation. The endpoints were:

- improvement in uncorrected near, intermediate, and distance visual acuity.
- stability of manifest refraction spherical equivalent (MRSE).
- spectacle dependency.
- contrast sensitivity.
- defocus curve.
- astigmatism correction.
- patient satisfaction and quality of vision.
- rates of adverse events and complications.

Twenty-four subjects with bilateral implantation were studied for six months, the results are below.

Summary of results

The mean visual acuity scores at six months follow-up are as following:

| Visual acuity | UDVA (LogMAR) | UIVA (LogMAR) | UNVA (LogMAR) |
|------------------|------------------|-----------------|-----------------|
| Monocular | -0.01 ± 0.15 | 0.09 ± 0.10 | 0.15 ± 0.11 |
| Binocular | -0.07 ± 0.12 | 0.04 ± 0.06 | 0.10 ± 0.09 |

UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA = uncorrected near visual acuity.

The mean MRSE was 0.05 ± 0.29 D at 6 months. The vector analysis for astigmatism correction showed a correction index, which is defined as the ratio 'achieved correction' versus 'intended correction', of 0.91 ± 0.16 . The defocus curve is shown in Figure 1.

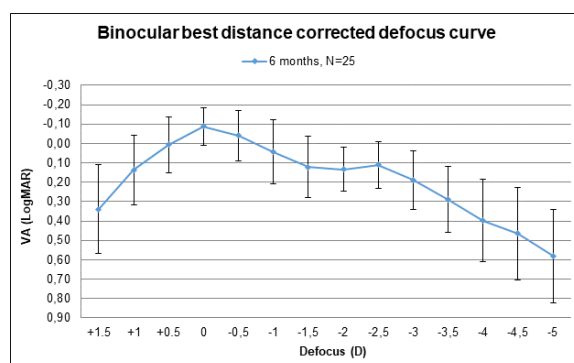


Figure 1 – PRECIZON Presbyopic Toric binocular best distance corrected defocus curve

No serious adverse events related to PRECIZON Presbyopic Toric were reported during the course of the study. Ninety-six % of the patients were quite or very satisfied with the outcome of the procedure.

Overall it can be concluded that PRECIZON Presbyopic Toric IOL implantation is a safe and effective way to correct aphakia, presbyopia and corneal astigmatism and provide patients with satisfactory levels of near, intermediate and far vision.