

Summary Clinical Investigation data

PRECIZON Presbyopic NVA

Model: 570

Basic UDI-DI: 8717819Precizon570/6G

Indications for use:

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

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

The PRECIZON Presbyopic NVA intraocular lens (IOL) was investigated in a prospective, open-label, single-armed, multicenter study. The objective of the study was to evaluate the effectiveness and patient satisfaction of the PRECIZON Presbyopic NVA IOL. The endpoints were:

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

Fifty-nine subjects with bilateral implantation were studied for six months.

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	0.06 ± 0.12	0.14 ± 0.10	0.28 ± 0.16
Binocular	0.00 ± 0.09	-	0.20 ± 0.13

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

The mean MRSE was 0.14 ± 0.39 D at 6 months. The defocus curve is shown in Figure 1.

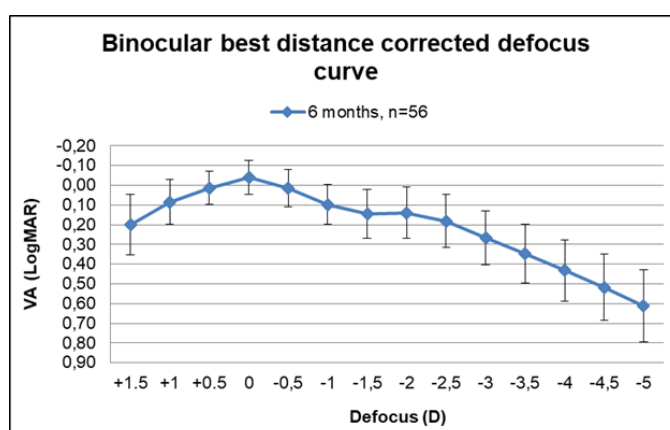


Figure 1 – PRECIZON Presbyopic NVA binocular best distance corrected defocus curve

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

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