ophtec

Summary Clinical Investigation data

ARTIPLUS

Model: 470
Basic UDI-DI: 8717819Artiplus470/7P

Indications for use:

The Artiplus phakic intraocular lens (pIOL) is indicated for the correction of presbyopia and ametropia in phakic presbyopic adults.

Global multicenter clinical trial with the Artiplus multifocal pIOL

The Artiplus multifocal pIOL is currently being investigated in a global multicenter clinical investigation. The study is prospective, non-controlled, and open-label, with a follow-up of three years. The objective of the study is to investigate the effectiveness, safety, and patient satisfaction after implantation of the Artiplus pIOL. Endpoints are:

- change in uncorrected near, intermediate, and distance visual acuity (UNVA, UIVA, and UDVA, respectively).
- defocus curve.
- predictability and stability of manifest refraction spherical equivalent (MRSE).
- spectacle dependency.
- contrast sensitivity.
- subject quality of vision and satisfaction.
- endothelial cell density.
- adverse event rates.

A total of 49 subjects are enrolled to achieve 30 subjects at three years follow-up. The interim results at 12 months postoperative (47 subjects, 94 eyes) are below.

Performance results

The mean visual acuity scores at 12 months follow-up are as following:

Visual acuity	UDVA (LogMAR)	UIVA (LogMAR)	UNVA (LogMAR)
Monocular	0.0 ± 0.09	0.04 ± 0.11	0.05 ± 0.09
Binocular	-0.06 ± 0.07	0.01 ± 0.10	0.01 ± 0.06

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

The mean MRSE was -0.34 ± 0.28 D. The binocular defocus curve (measured at six months) showed a mean score of at least 0.1 logMAR or better from +0.50 to -3.0 D. Ninety-four (94)% of eyes either gained lines of vision or remained the same.

Safety results

One patient complained about dry eyes (2.1%). A drop of two lines of corrected distance visual acuity (CDVA) occurred in one eye (1.0%) that had a preoperative CDVA of -0.2 LogMAR, which was reduced to 0.0 LogMAR at one year postoperatively.
The endothelial cell count did not statistically change over time; an average reduction of 0.51% was observed at 12 months post-op.

Patient satisfaction

All patients (100%) reported that they were quite to very satisfied with the outcome of the procedure. Complete spectacle independence was achieved in 91% of the subjects after 12 months; 9% of the patients occasionally needs to wear spectacles.

Overall it can be concluded that implantation with Artiplus pIOL is a safe and effective way to correct ametropia and presbyopia, and can provide patients with satisfactory levels of near, intermediate, and distance vision.

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