Summary Clinical Investigation data

ARTIFLEX MYOPIA

Model: 40114SW
Basic UDI-DI: 8717819Artiflex401/TV

Indications for use:

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

European Multicenter Study with the ARTIFLEX Myopia pIOL

The ARTIFLEX Myopia pIOL was investigated in a European multicenter clinical investigation. The study was prospective and non-randomized, with a two years follow-up of. The objective of the study was to determine the safety and performance of the ARTIFLEX Myopia pIOL. The endpoints were near and distant visual acuity, mechanical properties in terms of stability, distortion and fixation of the lens, complications and adverse events, and identifying groups at high risk of developing complications. The data of 348 eyes were studied for two years.

Performance results

The efficacy index was 1.01 at two years postoperative, while mean uncorrected distance visual acuity (UDVA) was 0.97 Snellen decimals. At two years postoperative, 87.9% of the cases were within ± 0.5 D of emmetropia. The mean postoperative subjective spherical equivalent was -0.12 D at one week and remained stable at two years (-0.15 D). The mean induced astigmatism was 0.27 D @ 87.6° at two years postoperative.

Safety results

At the end of the second year, the safety index was 1.10, and the mean corrected distance visual acuity (CDVA) was 1.04. The most frequently reported complications were glare and haloes, and both pigment and non-pigment deposits. The need for a second surgical intervention (SSI) was reported in nine cases (repositioning n=5, lens-exchange n=1, additional laser treatment n=3). The intraocular pressure measure was elevated at one week postoperative but was normal at two years. No significant endothelial cell loss was found at two years postoperative (-0.5%). No tilting, optic distortion or other irregularities concerning mechanical stability were reported.

The results of the study have been published in Ophthalmology, 2009;116(4):671-677 by Dick et al.
It was concluded that the implantation of ARTIFLEX Myopia proved to be effective and predictable for the correction of myopia in phakic eyes.

Although the study showed a good performance of the ARTIFLEX Myopia pIOL, the occurrence of pigment dispersion was higher than expected. Hence, an IOL design improvement was implemented during the study. The performance of the new design was investigated in a limited substudy with 119 eyes, focusing on the occurrence of pigment precipitates.

Summary of results

The modified ARTIFLEX Myopia pIOL effectively corrected the refractive error, gave an excellent visual acuity outcome, and resulted in fewer complications compared to the first ARTIFLEX Myopia pIOL. The most frequently reported complications were glare and haloes, pigment deposits, and non-pigment deposits. The need for an SSI was reported in two cases (both additional laser treatment).
After two years follow-up, the occurrence of both iris pigment precipitates and non-pigment precipitates was lower in the study with the modified ARTIFLEX Myopia pIOL compared to the study with the first design.

The clinical trial with the first model of ARTIFLEX Myopia proved the safety and efficacy of the pIOL. Minor modifications to the design were made to reduce the occurrence of precipitates on the optic, this resulted in the current ARTIFLEX Myopia model 40114SW. The current ARTIFLEX Myopia effectively corrects the refractive error, gives an excellent visual acuity outcome, and less complication rates when compared to the first ARTIFLEX Myopia pIOL.

