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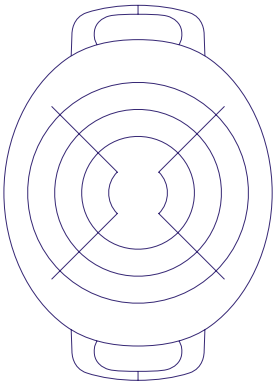

Artiplus

Clinical evidence

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Introduction

Artiplus is an innovative iris-fixated phakic intraocular lens unique in its class, born from the successful combination of the already proven safety and effectiveness of Ophtec's Artiflex platform and its patented CTF technology for presbyopia correction.

Artiplus has undergone a multicenter international clinical trial for CE Mark, involving nine sites from Europe and South Korea. A series of forty-two patients (eighty-four eyes) have been recruited for the study with excellent visual and safety outcomes.

This paper summarizes the clinical results and user experience of this series of patients bilaterally implanted with the Artiplus IOL and followed-up for 6 months.

In addition to exploring this paper, we encourage you to visit Ophtec's website (ophtec.com) to learn more about Ophtec's solution for presbyopia with our patented Continuous Transitional Focus (CTF) technology for both phakic and aphakic patients with the Artiplus and Precizon Presbyopic platforms respectively.

Prospective multicenter clinical trial with the Artiplus, an iris-fixated multifocal intraocular lens for the correction of presbyopia in phakic eyes.

Güell, JL; Cezón, J; Durán de la Colina, JA; Royo, M; Casado, D; Nuijts, R; Chung, SH; Choi, JH; Koh, IH
Clinical trial results. January, 2024

OVERVIEW

Study Design
Open-label, prospective, non-controlled multicenter clinical trial to evaluate the safety and efficacy of the Artiplus IOL, an iris-fixated intraocular lens for the correction of presbyopia in phakic eyes.

Study Sites
Nine sites in Europe and South Korea.

Patients
Forty-two (42) presbyopic adult subjects bilaterally implanted with the Artiplus iris-fixated phakic intraocular lens.

Methodology
Preoperative examination and evaluation of outcomes at 1 day, 1 week, 1, 3 & 6 months postoperatively

IOL Type
Artiplus, model 470 (Ophtec BV)

Key Endpoints
6 months postoperatively: corrected and uncorrected distance, near and intermediate visual acuity (UDVA, UNVA, UIVA, CDVA, DCIVA, DCNVA); manifest spherical equivalent; contrast sensitivity; defocus curve; endothelial cell count; IOP. Validated questionnaire was used to evaluate subjective quality of vision and patient satisfaction.

ANALYSIS AND CONCLUSIONS

Clinical results demonstrate that Artiplus is a safe and effective iris-fixated multifocal intraocular lens that provides excellent visual outcomes at all distances for presbyopic phakic eyes.

The Artiplus IOL based on CTF technology provides a continuous range of vision from distance to near with very high levels of satisfaction. 98% of the patients reported that they were quite to very satisfied with the outcome of the procedure.

STUDY RESULTS

VISUAL, REFRACTIVE AND SAFETY OUTCOMES (6 MONTHS)

- Mean monocular UDVA, UIVA and UNVA were 0.01 ± 0.08, 0.03 ± 0.08, and 0.07 ± 0.09 LogMAR respectively.
- Mean binocular UDVA, UIVA and UNVA were -0.06 ± 0.08, -0.01 ± 0.07, and 0.02 ± 0.08 LogMAR respectively.
- Mean monocular MRSE was -0.38 ± 0.30 D.
- Binocular defocus curve showed a VA ≤ 0.10 LogMAR between defocus levels of +0.50 to -3.00 D ***(Figure 1)***.
- 54% of patients gained between 1 and 3 lines of best corrected vision.
- Mean ECC loss was -0.30 ± 5.1%, in range with the annually expected levels of loss.
- Levels of contrast sensitivity were good with no statistically significant differences (P>0.05) comparing pre- and post-operative.

PATIENT SATISFACTION

- 92% and 93% of the patients "never" or "only occasionally" observed photic phenomena as glare and halos respectively.
- 98% of patients were quite to very satisfied with the overall outcome of the procedure and with their current uncorrected vision ***(Figure 2)***. 100% of patients were quite to very satisfied with their distance vision, 100% with their intermediate vision and 90% with their near vision.

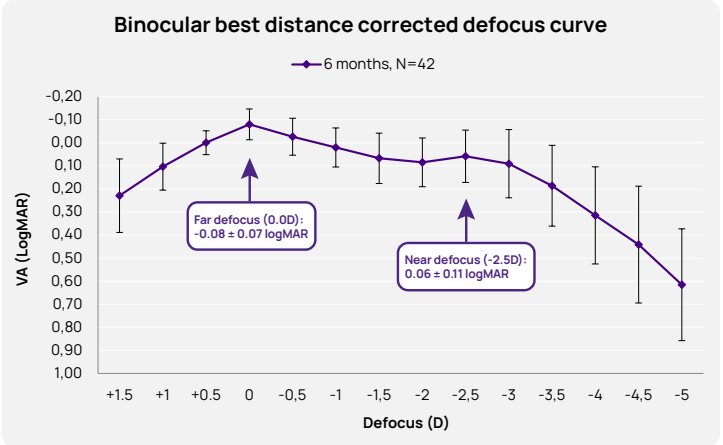
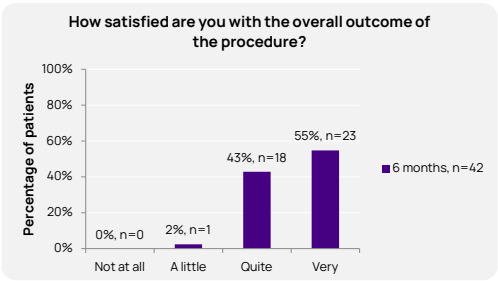


Figure 1. Binocular best distance corrected defocus curve.



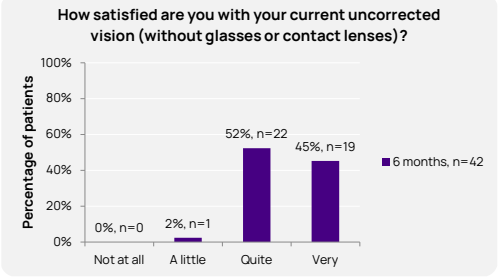


Figure 2. Patient satisfaction with the overall outcome of the procedure and with their current uncorrected vision following Artiplus pIOL implantation at postoperative 6 months.

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