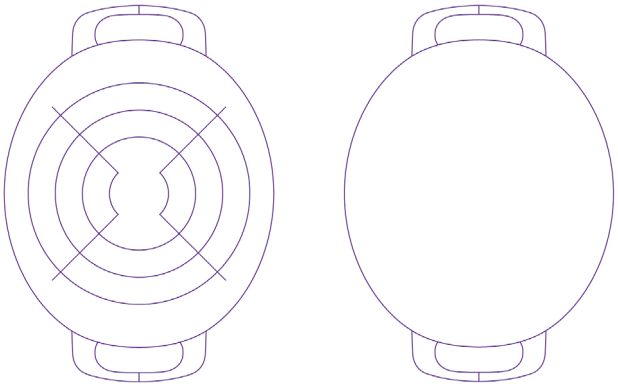
ophtec



Artiplus
Artiflex

Clinical science compendium

ophtec.com

Introduction

At Ophtec, we believe that high-quality scientific research and evidence are essential to provide the health care community with trustworthy knowledge and experience regarding new technology. In this sense, we are committed to generating and communicating high-quality scientific facts to the eye care professional community.

This clinical science compendium offers a comprehensive overview of clinical trials and scientific papers published in international ophthalmology journals involving the Artiflex and Artiplus phakic foldable intraocular lenses (pIOLs). All this scientific data is the result of research studies conducted to evaluate the performance of Artiflex and Artiplus, as well as the outcomes in patients receiving surgical implantation of these pIOLs.

The compendium features a total of ten (10) studies: nine peer-reviewed papers on the Artiflex platform and one multicenter clinical trial dedicated to Artiplus.

In addition to exploring this compendium, we invite you to visit our website (ophtec.com) to learn more about the Artilens Family, a comprehensive range of iris-fixated pIOLs for correcting refractive errors, including presbyopia with our latest addition: Artiplus.

Artiplus,
the new phakic IOL for presbyopic correction

Artiplus is an innovative iris-fixated phakic intraocular lens (pIOL) unique in its class. It merges the proven safety and efficacy of the already existing Ophtec's Artiflex platform with the patented CTF technology, delivering a unique solution for presbyopia correction in phakic patients.

Artiplus has undergone a multicenter international clinical trial for CE Mark approval, conducted at nine sites across Europe and South Korea. A series of 49 patients (98 eyes) who underwent bilateral implantation with Artiplus have been recruited for the study.

This clinical science compendium summarizes the one-year clinical results of this series of patients. It also provides a comprehensive review of the latest scientific publications on Artiflex, analyzing safety outcomes in the short, medium, and long-term.

The scientific evidence presented in this compendium shows excellent visual and safety outcomes of the Artiplus pIOL. More importantly, it features the long-term safety of its predecessor platform, particularly in terms of endothelial health. Multiple studies have consistently reported a low rate of endothelial cell density (ECD) loss with the Artiflex platform. In expert-conducted studies, with patients meeting current anterior chamber depth (ACD) selection criteria, the average annual ECD loss ranged from 0.98% to 1.2%. This rate is only marginally higher than the physiological age-related loss of 0.6% per year[1], and it is comparable to that of posterior phakic IOLs[2,3,4,5].

In conclusion, the clinical results confirm that Artiplus provides a safe and effective solution for presbyopia correction in phakic patients, supported by long-term safety evidence from its platform.

Table of Contents

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; Choi, JH; Koh, IH; Wanten, JC; Choe, CM; Park, CS; Bauer, NJC
Clinical trial results. October, 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-nine (49) 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 & 12 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 (1 YEAR)

- Mean monocular UDVA, UIVA and UNVA were 0.00 ± 0.09, 0.04 ± 0.11, and 0.05 ± 0.09 LogMAR respectively.
- Mean binocular UDVA, UIVA and UNVA were -0.06 ± 0.07, 0.01 ± 0.10, and 0.01 ± 0.06 LogMAR respectively.
- Mean monocular MRSE was -0.34 ± 0.28 D.
- Binocular defocus curve showed a VA ≤ 0.10 LogMAR between defocus levels of +1.00 to -3.00 D ***(Figure 1)***.
- 56% of patients gained between 1 and 3 lines of best corrected vision.
- Mean ECC loss was -0.51 ± 5.8%, in range with the annually expected levels of physiologic loss.
- Levels of contrast sensitivity were good with no statistically significant differences (P>0.05) comparing pre- and post-operative.

PATIENT SATISFACTION

- 98% of the patients "never" or "only occasionally" observed photic phenomena as glare and halos.
- 100% of patients were quite to very satisfied with the overall outcome of the procedure and with their current uncorrected vision. 100% of patients were quite to very satisfied with their distance vision, 98% with their intermediate vision and 96% with their near vision.
- Perceived bothersome of visual disturbances decreased postoperatively for most of the categories compared to preoperative patient perception ***(Figure 2)***.

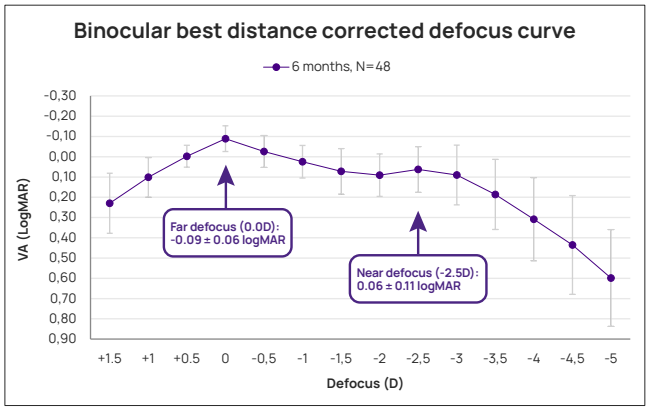


Figure 1. Binocular best distance corrected defocus curve.

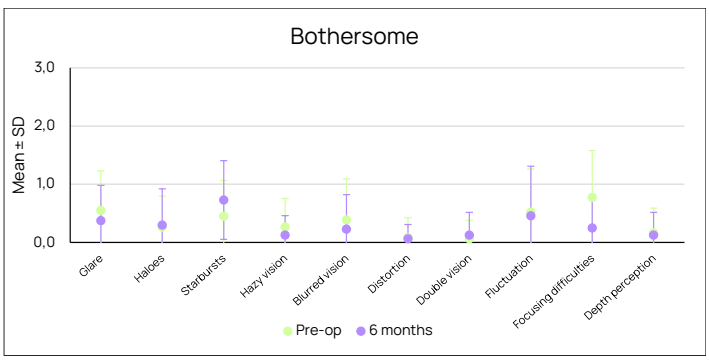


Figure 2. Perceived bothersome of visual disturbances 12 months postoperatively vs preoperatively.

Paired-eye comparison of corneal endothelial cell counts after unilateral iris-claw phakic intraocular lens implantation.

Morral M., Güell J.L., El Husseiny M.A., Elies D., Gris O., Manero F. J Cataract Refract Surgery 2016; 42(1):117-26

OVERVIEW

Study Design
Retrospective interventional nonrandomized paired-eye comparison study to compare the corneal endothelial cell density (ECD) after unilateral iris-claw phakic intraocular lens (pIOL) implantation in 1 eye and corneal refractive surgery (CRS) or no surgery in the fellow eye.

Study Sites
One site in Europe.

Patients
Fifty-eight (58) patients divided into 2 groups: Group 1 (n=29) had pIOL implantation in 1 eye and corneal refractive surgery; Group 2 (n=29) had pIOL implantation in 1 eye and no surgery in the fellow eye.

Methodology
Preoperative examination and evaluation of outcomes at 1, 5 & 10 years postoperatively.

IOL Type
Artiflex Myopia & Artisan Myopia (Ophtec BV).

Key Endpoints
Central corneal ECD, percentage of corneal endothelial cell loss, uncorrected & corrected distance visual acuity (UDVA, CDVA), manifest refraction, and complications.

ANALYSIS AND CONCLUSIONS

Iris-claw pIOL implantation does not produce significant corneal endothelial cell loss up to 10 years after surgery compared with corneal refractive surgery and unoperated eyes as long as inclusion criteria are met.

According to the study results, iris-claw pIOLs and corneal refractive surgery do not differ in corneal endothelial safety during the first 10 years after surgery.

STUDY RESULTS

SAFETY OUTCOMES

- At 10 years, the mean endothelial cell loss was 6.41% ± 8.02% (Group 1, pIOLs), 5.59% ± 5.98% (Group 1, CRS), 7.84% ± 6.83% (Group 2, pIOLs), and 6.74% ± 3.97% (Group 2, no surgery).
- No statistically significant differences were found between preoperative and postoperative ECD values in either group (P > .05).
- No significant endothelial cell loss was observed after pIOL implantation or corneal refractive surgery at any timepoint (P > .05 ***(Figure 1)***.
- No significant differences were observed in the percentage of endothelial cell loss between the groups (P > .05).
- None of the pIOLs had to be explanted because of unacceptable endothelial cell loss.

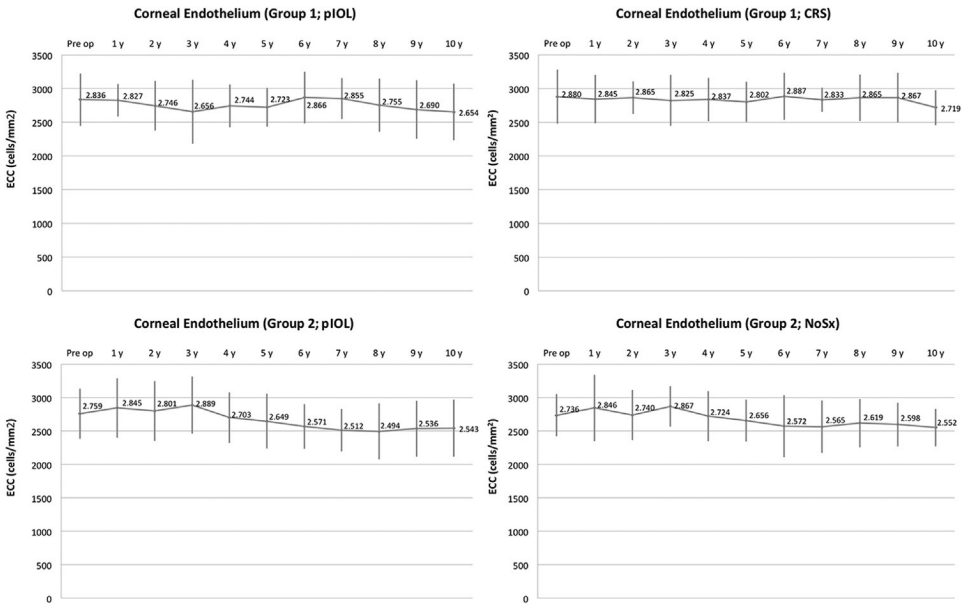


Figure 1. Corneal central ECC in each group at each follow-up point. Error bars indicate mean ± SD. Group 1 (pIOL and CRS) & Group 2 (pIOL and unoperated eyes) are depicted (CRS = corneal refractive surgery; ECC = endothelial cell count; NoSX = no surgery; pIOL = phakic intraocular lens).

Long-term safety and efficacy of a foldable iris-fixated phakic intraocular lens for the correction of myopia.

Mariano Royo, Ángel Jiménez, David P. Piñero. Int Ophthalmol. 2023 Dec;43(12):4491-4502

OVERVIEW

Study Design
Retrospective analysis of the long-term outcomes in terms of efficacy and safety of eyes implanted with the spherical version of the Artiflex phakic intraocular lens (pIOL) for the correction of myopia.

Study Sites
One site in Europe.

Patients
Fifty-six (56) eyes of thirty-two (32) patients implanted with an Artiflex Myopia pIOL.

Methodology
Preoperative examination and evaluation of outcomes at 4 & 6 months, and 1, 2, 7, 10 and 12 years postoperatively.

IOL Type
Artiflex Myopia (Ophtec BV).

Key Endpoints
Uncorrected & corrected distance visual acuity (UDVA, CDVA), manifest refraction, intraocular pressure (IOP), biometry and endothelial cell density (ECD).

ANALYSIS AND CONCLUSIONS

Myopia correction with the Artiflex Myopia pIOL is an effective and safe procedure in the long term, with minimal anatomical changes that could be mainly attributed to age-related processes, and a stable position within the anterior chamber not leading to complications.

Artiflex Myopia pIOL allows an effective refractive correction leading to complete spectacle independence.

STUDY RESULTS

VISUAL & REFRACTIVE OUTCOMES

- A significant reduction of manifest sphere and SE, along with a significant improvement of UDVA, was found at 4 weeks postoperatively (all $p < 0.001$).
- High stability with no significant changes in sphere, SE and UDVA ($p \geq 0.072$) was found during the whole follow-up period.
- 83% of the eyes were within ± 1.00 D of the intended SE correction during the whole follow up period.

SAFETY OUTCOMES

- A non-significant trend to IOP increase was observed at 4 weeks postoperatively ($p = 0.530$), with a significant reduction at 1 year after ($p = 0.039$) and no significant changes during the rest of follow-up ($p = 0.180$). ***(Figure 1)***
- There was a significant reduction of ACD at 4 weeks after surgery ($p < 0.001$), with no significant changes during the following 9 years of follow-up ($p = 0.118$). An additional significant decrease of this parameter was observed between 10 and 13 years after surgery ($p = 0.027$) (***Figure 2***). This variation is consistent with age-related physiological ACD changes due to the thickening of the crystalline lens.
- Mean ECD loss went from 2.01 ± 4.49% at 4 weeks after surgery to 9.11 ± 2.24% at the end of the follow-up. Considering that in the healthy eye the physiological cell loss rate is around 0.6% per year, an ECD loss of around 8% could be expected during a period of 13 years only due to age-related changes

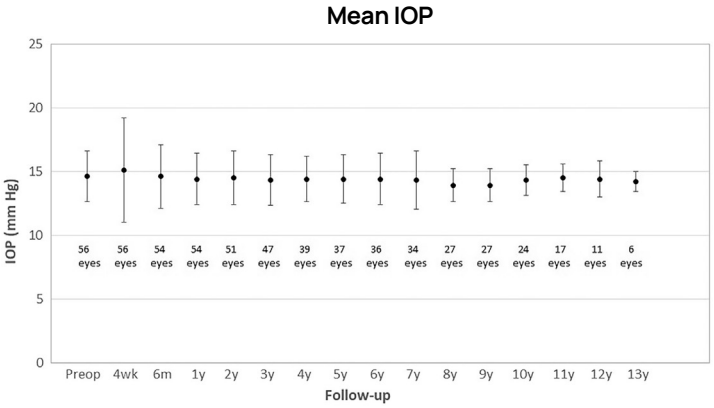


Figure 1. Changes in intraocular pressure (IOP) during the follow-up.

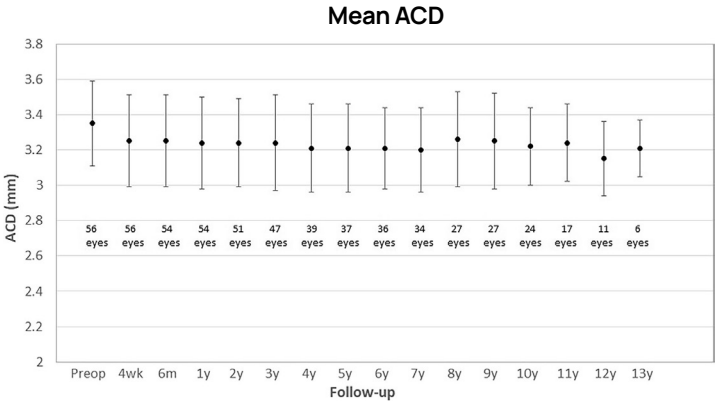


Figure 2. Changes in anterior chamber depth (ACD) during the follow-up.

Long-term efficacy and safety profiles of iris-fixated foldable anterior chamber phakic intraocular lens implantation in eyes with more than 10 years of follow-up.

Mario R Papa-Vettorazzi, Nuno Moura-Coelho, Felicidad Manero, José B Cruz-Rodriguez, Daniel Elies, José L Güell. J Cataract Refract Surg. 2022 Sep 1;48(9):987-992

OVERVIEW

Study Design
Retrospective review of consecutive patients to evaluate the long-term efficacy, safety, predictability and stability of Artiflex plOL in eyes with more than 10 years of follow-up.

Study Sites
One site in Europe.

Patients
Seventy-six (76) eyes from forty (40) patients who underwent an Artiflex plOL implantation.

Methodology
Preoperative examination and evaluation of outcomes at 1 month and 1, 5 & 10 years postoperatively.

IOL Type
Artiflex Myopia & Artiflex Toric (Ophtec BV).

Key Endpoints
10 years postoperatively: uncorrected & corrected distance visual acuity (UDVA & CDVA), manifest refraction, endothelial cell count (ECC) and intraocular pressure (IOP).

ANALYSIS AND CONCLUSIONS

Long-term results demonstrated that Artiflex plOL implantation was effective, predictable, stable, and safe for the correction of high myopia and myopic astigmatism in eyes with more than 10 years of follow-up.

STUDY RESULTS

VISUAL & REFRACTIVE OUTCOMES

At 10 years:

- 76% eyes had a postoperative UDVA of ≥20/40, 42% of ≥20/20, and 3% of ≥20/16 (***Figure 1***).
- 39% eyes gained 1 or 2 lines of CDVA, 57% were stable and only 4% lost 1 line (***Figure 2***).
- 61% and 76% eyes were within ±0.50 D and ± 1.00 D of attempted SE correction, respectively.
- A myopic progression of -0.56 ± 0.83 D was observed.

SAFETY & EFFICACY OUTCOMES

- Efficacy and safety indices were 0.82 and 1.11 respectively at 10 years.
- Mean ECC loss was 2.96 ± 11.9% (P = .02) at 1 year.
- Total cell loss (from 1 to 10 years) was 8.78% ± 11.9%, corresponding to a 0.98% loss per year (P < .01).*
- IOP remained stable, with mean IOP of 14.3 ± 3.1 mm Hg preoperatively and 15.8 ± 4.2 mm Hg at 10 years.

Uncorrected Distance Visual Acuity

76 eyes (plano target) › 10 years postop

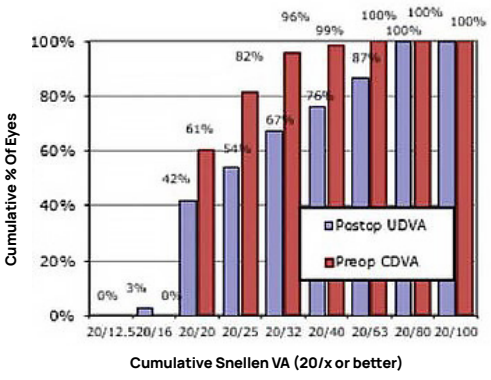


Figure 1. Cumulative percentages of preoperative CDVA and postoperative UDVA to measure efficacy **at more than 10 years**.

Change in Corrected Distance Visual Acuity

76 eyes › 10 years postop

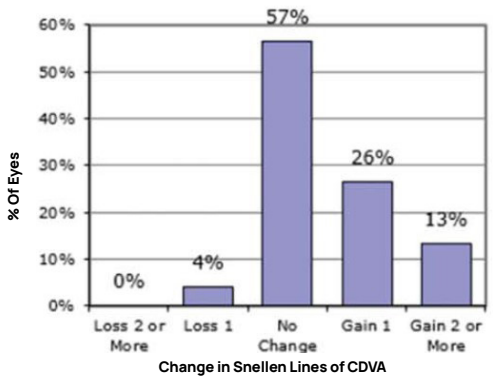


Figure 2. Change in corrected distance visual acuity **after more than 10 years**.

** Note: physiological cell loss is around 0.6% per year[1].*

Long-term efficacy and safety results after iris-fixated foldable phakic intraocular lens for myopia and astigmatism: 6-year follow-up.

Tiago Monteiro, Fernando Faria Correia, Nuno Franqueira, José Carlos Mendes, Christophe Pinto, Fernando Vaz.
J Cataract Refract Surg 2021 Feb 1;47(2):211-220

OVERVIEW

Study Design
Retrospective cohort study to evaluate the long-term efficacy and safety of iris-fixated foldable phakic IOLs for the management of myopia and astigmatism after 6-year follow-up.

Study Sites
One site in Europe.

Patients
Hundred seventy-seven (177) eyes of ninety-eight (98) patients who underwent iris-fixated foldable Artiflex IOL implantation.

Methodology
Preoperative examination and yearly evaluation of outcomes up to 6 years.

IOL Type
Artiflex Myopia (Ophtec BV).

Key Endpoints
Uncorrected and corrected distance visual acuity (UDVA & CDVA), manifest refraction, endothelial cell density (ECD) and anterior chamber depth (ACD).

ANALYSIS AND CONCLUSIONS

The iris-fixated foldable Artiflex pIOL implantation is a safe and effective surgical option for the long-term management of moderate to high myopia, with stable and predictable outcomes.

In our study we observed a low mean ECD loss after six years of follow-up. From the results obtained, it is possible to advise: 1) the preoperative value of ACD used as an inclusion criterion should always be measured to the corneal endothelium; 2) a minimum ACD value of 3.00 mm (to the endothelium) appears to be a safer indication for the iris-fixated pIOL.

STUDY RESULTS

VISUAL & REFRACTIVE OUTCOMES

- Mean UDVA was 0.09 ± 0.01 and 0.12 ± 0.02 logMAR at 1 and 6 years, respectively.
- Mean CDVA was 0.03 ± 0.01 and 0.04 ± 0.02 logMAR at 1 and 6 years respectively, remaining stable throughout the study period.
- At six years, 51% of eyes gained one or more lines of CDVA, 28% remained unchanged and only 5.7% lost one or more lines ***(Figure 1)***.
- 90.96% and 89.51% of patients achieved CDVA of 20/25 or better at 1 and 6 years, respectively ***(Figure 2)***.
- Mean SE was reduced from -9.51 ± 2.93 D preoperatively to -0.24 ± 0.42 D and -0.41 ± 0.45 D at 1 and 6 years postoperatively.

SAFETY & EFFICACY OUTCOMES

- At 6 years, efficacy and safety indexes were 0.94 and 1.15, respectively.
- Annual mean ECD loss was 31.77 cells/mm^2 (1.19%).*
- The overall mean ECD loss after correction for the physiological loss was 3.02% after 6 years.
- No significant difference ($p > 0.05$) was observed between the preoperative and the 1-year and 6-year follow-up visits regarding the percentage of hexagonal endothelial cells.

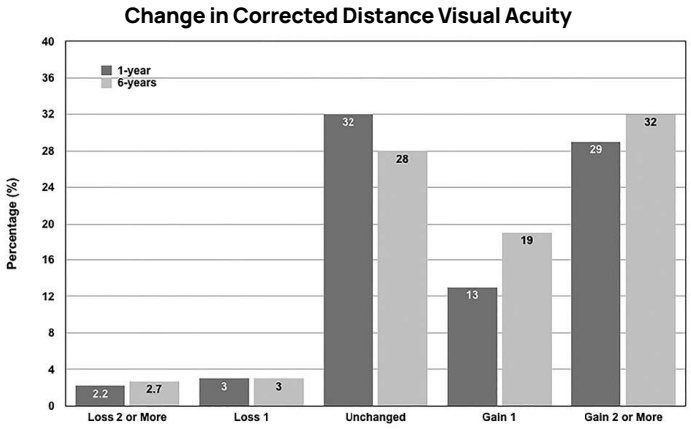


Figure 1. Changes in CDVA outcomes 6 years postoperatively. Almost 80% gained one or more lines or remained unchanged.

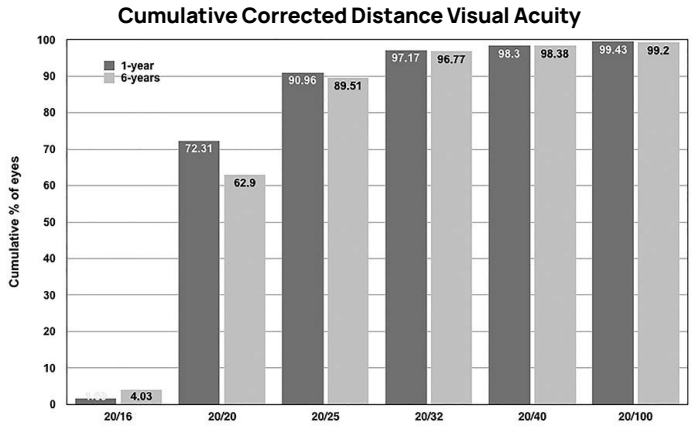


Figure 2. Cumulative CDVA after 1 and 6 years postoperatively.

** Note: physiological cell loss is around 0.6% per year[1].*

Long-term results in patients with iris-fixated foldable phakic intraocular lenses for myopia and astigmatism.

Marta A, Leite J, Abreu AC, Monteiro S, Pinto C. J Cataract Refract Surg. 2022 Sep 1;48(9):993-998

OVERVIEW

Study Design
Prospective cohort study to evaluate the long-term results of iris-fixated foldable phakic intraocular lens (pIOL) implantation for the management of myopia and astigmatism.

Study Sites
One site in Europe.

Patients
One hundred and ninety-nine (199) eyes who underwent an Artiflex implantation were evaluated at 5 years. 187 eyes were evaluated at 10 years, and 43 eyes at 15 years.

Methodology
Preoperative examination and evaluation of outcomes at 5, 10 & 15 years postoperatively.

IOL Type
Artiflex Myopia & Artiflex Toric (Ophtec BV).

Key Endpoints
Spherical equivalent, uncorrected and corrected distance visual acuity (UDVA & CDVA), safety and efficacy indices, intraocular pressure (IOP), and endothelial cell density (ECD).

ANALYSIS AND CONCLUSIONS

Long-term results demonstrated that the implantation of Artiflex pIOLs was a stable, predictable, and effective procedure at 5 years, 10 years, and 15 years of follow-up.

ACD is a key feature within the selection of patients. ACD lower than 3.00 should be an exclusion criterion for Artiflex pIOL implantation.

STUDY RESULTS

VISUAL & REFRACTIVE OUTCOMES

At 5, 10 and 15 years after surgery:

- Mean logMAR UDVA was 0.03 ± 0.06, 0.05 ± 0.08, and 0.07 ± 0.09 respectively (***Figure 1***).
- Mean logMAR CDVA was 0.03 ± 0.06, 0.04 ± 0.11, and 0.06 ± 0.11 respectively (***Figure 1***).
- Mean spherical equivalent was -0.11 ± 0.31 D, -0.33 ± 0.62 D, and -0.80 ± 1.32 D respectively ***(Figure 2)***.

SAFETY & EFFICACY OUTCOMES

- At 5, 10 and 15 years after surgery, safety and efficacy indexes showed stable values of 1.07 and 1.06, 1.04 and 0.99, and 1.05 and 1.00 respectively.
- Mean ECD loss per year was 1.0%, 1.7%, and 1.2% until the 5th, 10th, and 15th year of follow up, respectively.*

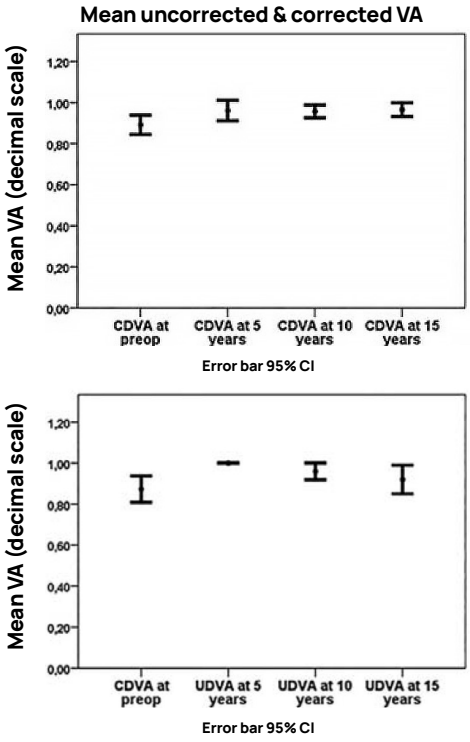


Figure 1. Stability of corrected (A) and uncorrected (C) visual acuity after Artiflex pIOL implantation for the correction of myopia and astigmatism.

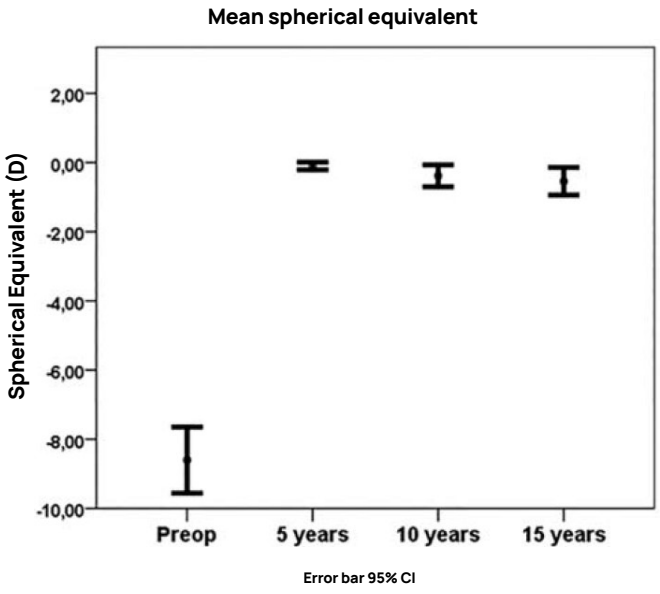


Figure 2. Postoperative spherical equivalent after Artiflex pIOL implantation for the correction of myopia and astigmatism.

** Note: physiological cell loss is around 0.6% per year[1].*

Eight-year follow-up of Artiflex and Artiflex Toric phakic intraocular lens.

Royo M, Jiménez Á, Martínez-Alberquilla I, Alfonso JF. Eur J Ophthalmol. 2022 Jul;32(4):2051-2058

OVERVIEW

Study Design
Retrospective and observational cohort study to analyze long-term efficacy, safety, visual and refractive stability and physiological changes of Artiflex Myopia and Artiflex Toric phakic intraocular lenses (pIOL) throughout an 8-year follow-up.

Study Sites
One site in Europe.

Patients
Sixty-seven (67) eyes of thirty-seven (37) patients who underwent Artiflex Myopia (47 eyes) or Artiflex Toric (20 eyes) pIOL implantation for correcting myopia and/or astigmatism.

Methodology
Preoperative examination and evaluation of outcomes at 1, 3, 5 & 8 years postoperatively.

IOL Type
Artiflex Myopia & Artiflex Toric (Ophtec BV).

Key Endpoints
Uncorrected and corrected distance visual acuity (UDVA &CDVA), manifest refraction, spherical equivalent (SE), efficacy and safety indexes, endothelial cell density (ECD) and intraocular pressure (IOP).

ANALYSIS AND CONCLUSIONS

Artiflex Myopia and Toric pIOLs showed excellent safety, efficacy, predictability and refractive stability 8 years after pIOL implantation.

Artiflex Toric showed outstanding rotation stability, probably provided by the iris-claw fixation.

STUDY RESULTS

VISUAL & REFRACTIVE OUTCOMES

- UDVA remained stable over the 8 years, with 0.12 ± 0.13 logMAR for Artiflex Myopia and 0.08 ± 0.13 for Artiflex Toric.
- For Artiflex Myopia, 88.2%, 82.4% and 70.6% of eyes were within ±1.00 D, ±0.50 D and ±0.25 D of emmetropia, respectively. For Artiflex Toric, 100%, 95% and 85% were within ±1.00 D, ±0.50 D and ±0.25 of emmetropia, respectively.
- SE significantly improved after surgery and remained stable with no significant differences between visits, confirming excellent stability over 8 years ***(Figure 1)***.
- J0 & J45* components showed no significant changes between postoperative visits confirming outstanding rotation stability for Artiflex Toric ***(Figure 2)***.

SAFETY & EFFICACY OUTCOMES

- At 8 years, efficacy and safety indexes were 0.94 ± 0.16 and 1.07 ± 0.18 for Artiflex Myopia and 1.00 ± 0.11 and 1.10 ± 0.15 for Artiflex Toric, respectively.
- At 8 years, total ECD loss was 4.8% and 10.4% for Artiflex Myopia & Toric, respectively. ***Figure 3*** shows the mean endothelial cell density throughout the 8-year follow-up.

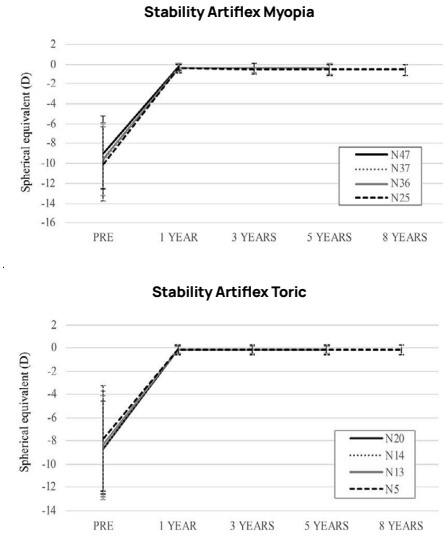


Figure 1. Stability of Artiflex Myopia (top) and Artiflex Toric (bottom) over the 8-year follow-up. Spherical equivalent before and after surgery. N=number of eyes.

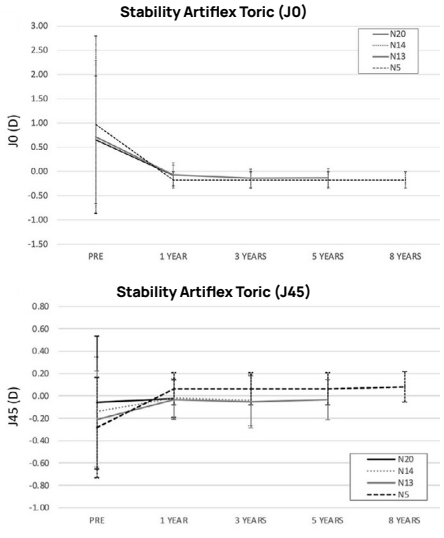


Figure 2. Stability of J0 (top) and J45 (bottom) vectors for Artiflex Toric over 8 years. N=number of eyes.

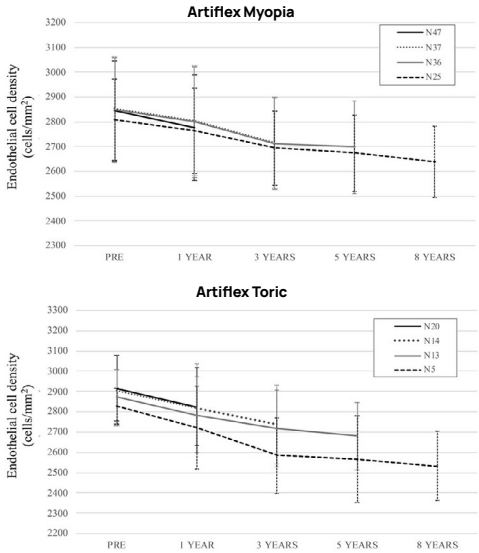


Figure 3. Endothelial cell density (ECD) of Artiflex Myopia and Artiflex Toric before implantation and after 8 years of follow-up. N=number of eyes.

**J0 and J45 are mathematical components used to represent the orientation and magnitude of astigmatism. This approach is useful for analyzing astigmatism quantitatively and comparing refractive outcomes. J0 represents the horizontal and vertical components of astigmatism at 0º and 90º, and J45 represents the oblique components of astigmatism at 45º and 135º.*

Artiflex foldable lens for myopia correction results of 10 years of follow-up.

Gracia Castro de Luna, Darío Ramos-López, Ana Belén Castaño Fernández, Diego Cuevas Santamaría. Eye (Lond) 2019 Oct;33(10):1564-1569

OVERVIEW

Study Design
Retrospective study of an observational case series to evaluate the long-term efficacy and safety of the Artiflex lens implant and to follow the evolution of the number of corneal endothelial cells over time.

Study Sites
One site in Europe.

Patients
Fifty-three (53) eyes from thirty (30) patients who underwent an Artiflex pIOL implant for the correction of stable myopia from −4 to −14D.

Methodology
Preoperative examination and evaluation of outcomes at 4 & 6 months, and 1, 2, 5 & 10 years postoperatively.

IOL Type
Artiflex Myopia (Ophtec BV).

Key Endpoints
Uncorrected & corrected distance visual acuity (UDVA, CDVA), spherical equivalent (SE), endothelial cell count (ECC), efficacy index & safety index.

ANALYSIS AND CONCLUSIONS

The Artiflex phakic IOL could be a safe and effective long-term alternative for myopic patients in whom laser surgery was contraindicated.

Patients operated with an Artiflex phakic IOL implant maintained their BCDVA and UCDVA over time.

STUDY RESULTS

VISUAL OUTCOMES

- UDVA showed statistically significant improvement from month 1 to year 2, with no statistically significant change and therefore stability at 5 & 10 years (***Figure 1***).
- At 10 years, UDVA was ≥20/25 in 100% and ≥20/20 in 80% of the eyes.

SAFETY & EFFICACY OUTCOMES

- The efficacy index increased from 1.01 ± 0.43 at 1 month to 1.1 ± 0.30 after 10 years.
- The safety index increased from 1.04 ± 0.27 at 1 month to 1.06 ±0.2 after 10 years.
- At 10 years, loss of corneal endothelial cells was 12% ***(Figure 2)***.*

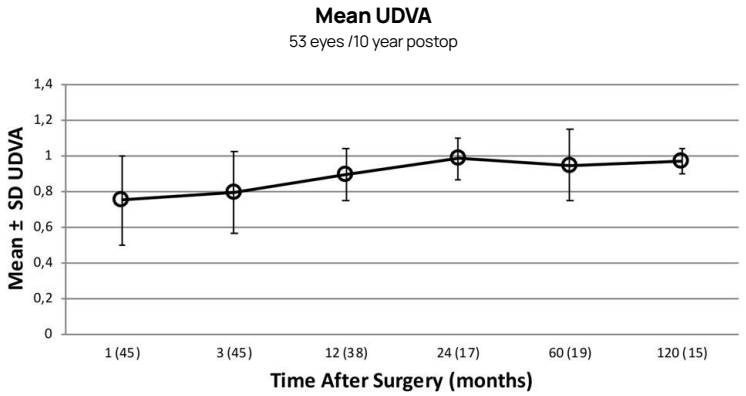


Figure 1. Uncorrected distance visual acuity (UDVA) time after surgery (months).

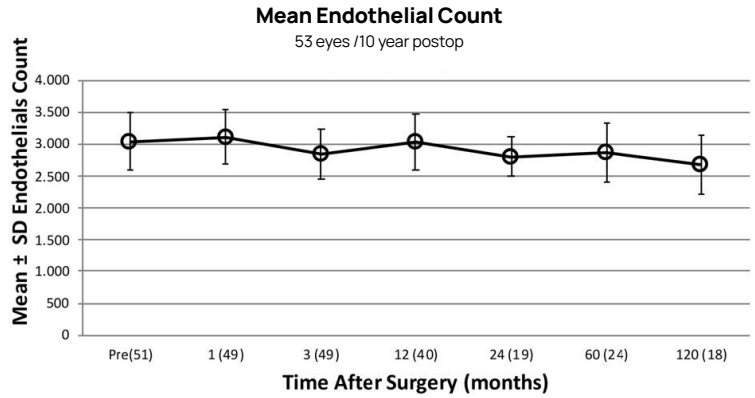


Figure 2. Endothelial cell count time after surgery (months).

** Note: physiological cell loss is around 0.6% per year[1].*

Iris-fixated toric phakic intraocular lens for myopic astigmatism.

Gonzalo Muñoz, Antoni Cardoner, César Albarrán-Diego, Teresa Ferrer-Blasco, Lurdes Belda-Salmerón.
J Cataract Refract Surgery 2012; 38:1166–1175

OVERVIEW

Study Design
Prospective nonrandomized interventional clinical study to evaluate the efficacy, predictability, safety and stability of the Artiflex toric iris-fixated phakic intraocular lens (pIOL) for myopic astigmatism.

Study Sites
One site in Europe.

Patients
Forty-two (42) eyes of twenty-five (25) patients who underwent an Artiflex Toric pIOL implantation for the correction of myopic astigmatism.

Methodology
Preoperative examination and evaluation of outcomes at 1 day, 1 week, and 1, 3, 6 & 12 months.

IOL Type
Artiflex Toric (Ophtec BV).

Key Endpoints
At 12 months: uncorrected and corrected distance visual acuity (UDVA & CDVA), refraction, pIOL misalignment and endothelial cell count (ECC). Indices of success and misalignment were calculated using vector analysis.

ANALYSIS AND CONCLUSIONS

Implantation of Artiflex Toric pIOL is effective, predictable, safe, and stable for the correction of myopic astigmatism.

The Artiflex toric pIOL provides excellent rotational stability, probably due to the nature of fixation of the IOL to the iris. This could be a main advantage of the iris-fixated toric pIOL design.

STUDY RESULTS

VISUAL OUTCOMES & REFRACTIVE OUTCOMES

At 12 months:

- Mean SE decreased from -8.85 ± 2.71 D to -0.37 ± 0.46 D.
- Astigmatism correction was excellent, with the mean manifest refractive cylinder decreasing from -2.90 D at baseline to -0.39 D postoperatively.
- UDVA was ≥ 20/40 in 100% of eyes and ≥ 20/25 in almost 80% of eyes.
- Almost 70% of eyes gained 1 line or more lines of CDVA; no eye lost 1 or more lines of CDVA.
- Postoperative refractive errors after vector conversion shows good stability with no statistically significant differences between each pair of visits up to 12 months, except for J0 that was higher at 1 month than during the rest of the follow-up ***(Figure 1)***.
- Safety index was 1.11.

MISALIGNMENT AND INDICES OF SUCCESS

- Alignment of the toric pIOLs calculated from vector analysis showed a mean angle of error of 1.8 ± 2.7 degrees.
- Vector analysis showed excellent mean indices of success for overall (0.94 ± 0.04), spherical (0.96 ± 0.05), and astigmatic (0.95 ± 0.16) corrections.

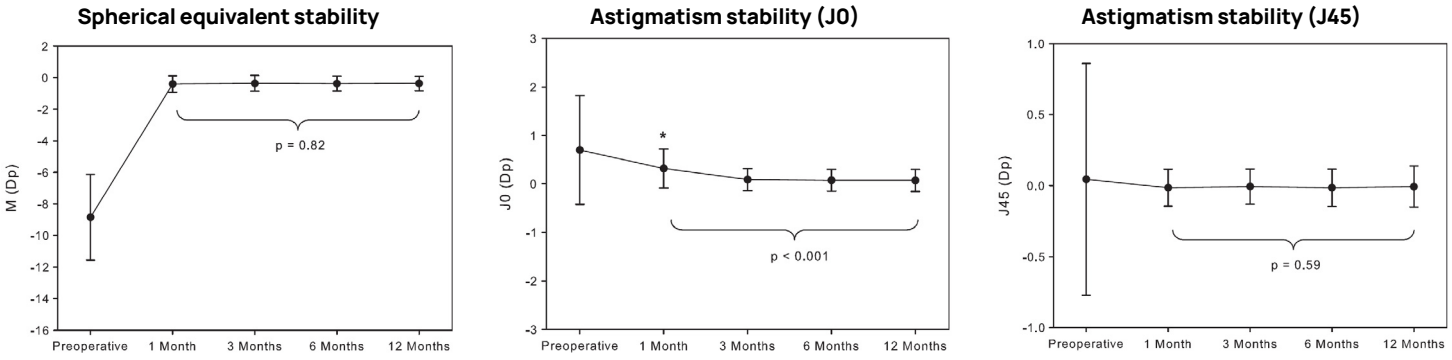


Figure 1. Spherical equivalent (left) and astigmatism (middle and right) stability. An asterisk represents statistically significant difference with the rest of the follow-up visits (J0 and J45 Z astigmatic components of refraction in vectorial notation; M Z spherical equivalent).

Correction of myopic astigmatism with a foldable iris-claw toric phakic intraocular lens: Short-term follow-up.

Josef Ruckhofer, Orang Seyeddain, Alois K Dexl, Günther Grabner, Josef Stoiber. J Cataract Refract Surgery 2012; Apr;38(4):582-8

OVERVIEW

Study Design
Retrospective nonrandomized observational case series to evaluate the efficacy, predictability, stability, and complications after implantation of a foldable iris-fixated toric phakic intraocular lens (pIOL) to correct myopic astigmatism.

Study Sites
One site in Europe.

Patients
Forty-two (42) eyes of twenty-four (24) patients who underwent an Artiflex Toric pIOL implantation with spherical power ranging from -1.0 to -13.5 D and additional cylinder from -1.0 to -5.0 D.

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

IOL Type
Artiflex Toric (Ophtec BV).

Key Endpoints
At 6 months: Uncorrected and corrected distance visual acuity (UDVA & CDVA), manifest refraction stability, intraocular pressure (IOP) and central endothelial cell count (ECC).

ANALYSIS AND CONCLUSIONS

Artiflex Toric pIOL implantation is effective, predictable, stable, and safe for the correction of myopic astigmatism.

The postoperative visual outcomes in our study were significantly enhanced and a fast visual recovery was observed in all eyes.

STUDY RESULTS

VISUAL & REFRACTIVE OUTCOMES

At 6 months:

- 98% eyes had a postoperative UDVA of ≥20/25, and 90% of ≥20/20.
- 52% of eyes had gained 1 line and 5% had gained 2 lines; no eye lost a line of CDVA ***(Figure 1)***.
- Mean SE and refractive astigmatism were -0.05 ± 0.20 D and -0.18 ± 0.30 D, respectively.
- 100% and 86% of eyes were within ±0.50 D and ±0.25 D of the intended SE correction, respectively (***Figure 2)***.
- 90% of eyes were within ±0.50 D of attempted cylinder correction ***(Figure 3)***.

SAFETY & EFFICACY OUTCOMES

- Efficacy and safety indices were 1.07 and 1.14 respectively.
- At 6 months, a slight ECC loss of -0.72% was observed.
- There were no serious complications.

Change in Snellen Lines of CDVA

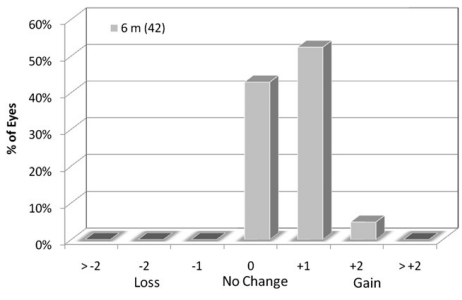


Figure 1. Safety (CDVA= corrected distance visual acuity).

Postoperative Spherical Equivalent (D)

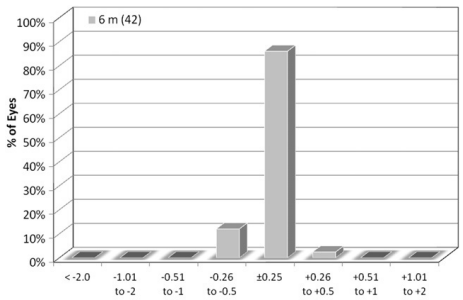


Figure 2. Predictability.

Refractive Astigmatism (D)

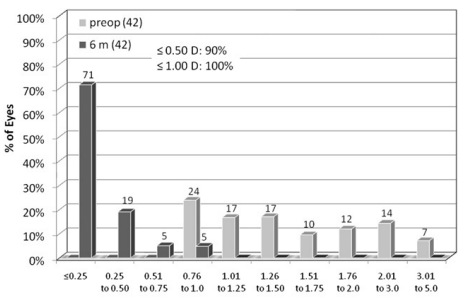


Figure 3. Distribution of refractive astigmatism preoperatively and 6 months postoperatively.

Bibliography

1. *Bourne WM, Nelson LIL, Hodge DO (*1997) Central corneal endothelial cell changes over a ten-year period. Invest Ophthalmol Vis Sci 38:779–782.

2. *Papa-Vettorazzi MR, Güell JL, Cruz-Rodriguez JB, Moura-Coelho N, Elies D.* Long-term efficacy and safety profiles after posterior chamber phakic intraocular lens implantation in eyes with more than 10 years of follow-up. J Cataract Refract Surg. 2022 Jul 1;48(7):813-818.

3. *Lwowski C, Van Keer K, Ruscher T, Van Keer L, Shajari M, Kohnen T.* Five-year follow-up of a posterior chamber phakic intraocular lens with a central hole for correction of myopia. Int Ophthalmol. 2023 Dec;43(12):4933-4943.

4. *Kırgız A, Yalçınkaya Çakır G, Çakır İ, Yıldırım Y, Ağca A.* Seven-Year clinical outcomes after implantation of Eyecryl posterior chamber phakic intraocular lenses for high myopia. Eur J Ophthalmol. 2024 Sep;34(5):1424-1431.

5. *Cakir I, Sonmez O, Pehlivanoglu S, Cakir GY, Yildiz BK, Yildirim Y, Agca A.* Long-term results of a new posterior chamber phakic intraocular lens in patients with high myopia: 5-year results. J Cataract Refract Surg. 2023 Apr 1;49(4):409-415.

ophtec

ophtec.com