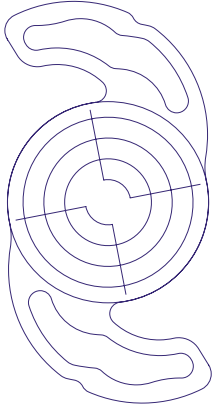# ophtec

CTF Technology & Precizon Presbyopic

Clinical science compendium

ophtec.com

Introduction

At Ophtec we believe that high quality scientific research and evidence is 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 provides a consolidated view of bench studies, scientific papers and presentations from international ophthalmology journals and congresses, involving the Precizon Presbyopic IOL and its patented Continuous Transitional Focus (CTF) technology. All this scientific data is the result of research studies conducted to evaluate the performance of the Precizon Presbyopic IOL, and/or the outcomes in patients receiving surgical implantation of the IOL.

A total of ten (10) studies are included: 8 scientific papers from international ophthalmology journals and 2 congress abstracts / presentations reporting clinical data.

In addition to exploring this compendium, 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 and the Precizon Presbyopic IOL.

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Spectral Effects and Range of Focus in a Multizonal-Refractive Intraocular Lens Compared with a Standard Trifocal Diffractive Design

Weijia Yan, Gerd U Auffarth, Ramin Khoramnia, Grzegorz Łabuz. Ophthalmol Ther. 2023 Mar 8

OVERVIEW

Study Design
In vitro laboratory study to comprehensively evaluate the performance of the Precizon Presbyopic IOL and test it against an established trifocal-lens model through various optical and visual quality metrics including longitudinal chromatic aberration (LCA).

Study Site(s)
Bench testing at David J Apple Center for Vision Research (Heidelberg, Germany).

Patients
N/A

Methodology
Effective focal length (EFL) was measured in monochromatic (546 nm) light to calculate the optical power measurement and the LCA. Optical quality parameters were assessed for an aperture size of 3.00 mm and 4.5 mm to calculate the area under the MTF (MTFa) and the predicted postoperative logMAR visual acuity (VA). Polychromatic image quality was simulated using the three monochromatic filters (480 nm, 546 nm, and 644 nm, resp blue, green and red light) at an optimal 546-nm far focus.

IOL Type(s)
Precizon Presbyopic NVA, model 570 A1 (Ophtec BV) & PanOptix (Alcon Inc.). 20D for both IOLs.

Key Endpoints
LCA, MTF, MTFa, predicted postoperative logMAR VA, polychromatic image quality.

ANALYSIS AND CONCLUSIONS

This study demonstrates that the Precizon can be used to extend the visual range of pseudophakic patients, which according to the MTF analysis, does not fall short of the established trifocal IOL.

Although both models' performance was affected by LCA, the HEMA/EOEMA material (Precizon) had a lower LCA level than AcrySof (PanOptix). The chromatic effects were low in the Precizon lens showing a nearly comparable performance in monochromatic and polychromatic light.

The MTFa and the predicted logMAR VA curves measured at a complete defocus range demonstrates that Precizon lens outperformed PanOptix in all the intermediate region maintaining a more continuous curve.

STUDY RESULTS

- For a 3mm pupil aperture, LCA was 0.41 ± 0.01 D and 0.91 ± 0.01 D for Precizon and PanOptix respectively. The aperture enlargement to 4.5 mm had virtually no impact on LCA (0.38 ± 0.03 D for Precizon and 0.95 ± 0.04 D for PanOptix).

- On the polychromatic image quality simulation, chromatic effects were less pronounced for the Precizon (especially in the red and blue light), confirming a lower LCA level of its material *(Figure 1)*.

- The MTFa curves at 3mm demonstrates that Precizon lens outperformed PanOptix at approximately -0.25 D to -2.25 D, which was reversed at -2.5 D to -3.0 D with a slight advantage of the PanOptix. The MTFa-curve trend between the IOLs was maintained at 4.5 mm, although with noticeable differences between the two models in the intermediate region *(Figure 2)*.

- The PanOptix and the Precizon yielded comparable predicted VA at far focus (0.00 logMAR). The Precizon's VA prediction at the secondary peak was minimally better than PanOptix (0.03 logMAR and 0.06 logMAR respectively). Between the two peaks Precizon shows a more continuous curve and a lower drop of VA *(Figure 3)*.

- The resolution-test images, in general, agreed with the MTFa results.
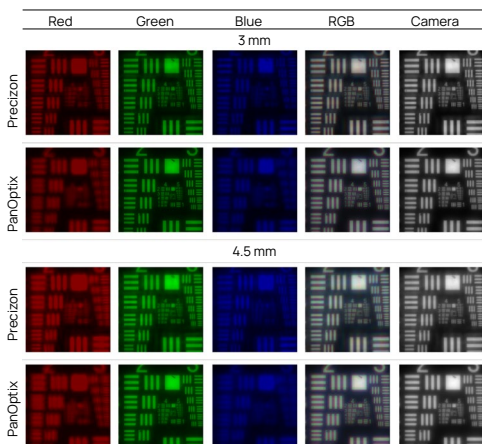
Figure 1. *1951 USAF resolution target photographs taken through the studied IOLs. A simulation of an RGB image and a direct Camera recording of an unprocessed (polychromatic) test chart are presented for comparison.*
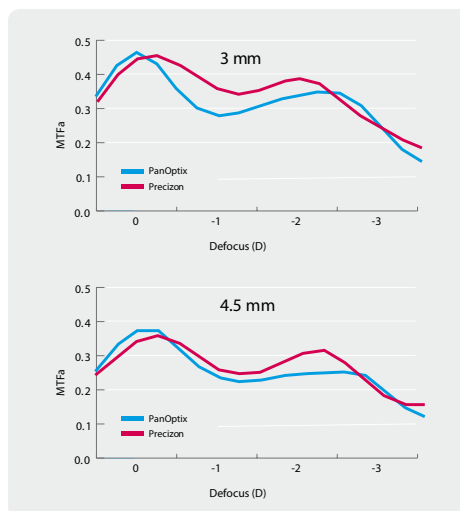
Figure 2. *The MTFa curves of the two IOLs models measured at the defocus range from +0.5 D to -3.5 D at the spectacle plane. Each line represents the average of two samples for each IOL model.*
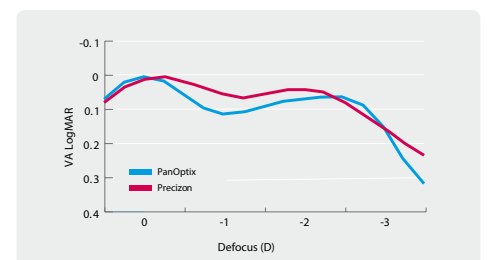
Figure 3. *The logMAR VA of the two studied models measured at the defocus range from +0.5 D to -3.5 D (spectacle plane). Each line represents the average of two samples for each IOL model.*

Visual and patient reported outcomes provided by a refractive multifocal intraocular lens based on continuous transitional focus

Jorge L. Alio, Antonio Martinez-Abad, Ramon Ruiz-Mesa, Hyo Myung Kim, Javier Mendicute, Filomena J. Ribeiro, Mike P. Holzer and Mario Canto-Cerdan. Eye Vis (Lond). 2024 Oct 14;11(1):4.

OVERVIEW

Study Design
Prospective multicenter study to analyze the quality of vision of patients implanted bilaterally with the multifocal Precizon Presbyopic intraocular lens (IOL), as well as to evaluate the visual performance provided by the lens.

Study Sites
Six sites in Europe and South Korea.

Patients
One hundred and twelve (112) eyes from fifty-six (56) patients bilaterally implanted with Precizon Presbyopic IOL after cataract or clear lens extraction surgery.

Methodology
Preoperative examination and evaluation of outcomes at 6 months postoperatively. Patient reported outcomes (PROMs) were evaluated with the QoV questionnaire.

IOL Type
Precizon Presbyopic NVA, model 570 A1 (Ophtec BV).

Key Endpoints
6 months postoperatively: corrected and uncorrected distance and near visual acuity (CDVA, UDVA, DCNVA and UNVA); subjective refraction; contrast sensitivity; binocular defocus curve; quality of vision (QoV).

ANALYSIS AND CONCLUSIONS

The Precizon Presbyopic NVA IOL provides a suitable quality of vision with a low rate of disturbance photic phenomena induction, as well as an excellent visual performance at main distances of sight accomplishing the visual demands of the majority of patients.

The outcomes of this study confirm the low rate of disturbance photic phenomena encountered with the CTF (Continuous Transitional Focus) IOL.

STUDY RESULTS

VISUAL OUTCOMES
At 6 months:
- Mean binocular UDVA and UNVA were 0.00 ± 0.09 and 0.20 ± 0.13 logMAR, respectively.

- Mean spherical equivalent was 0.29 ± 0.45 D.

- Efficacy and safety indices were 1.26 and 1.42, respectively.

- Binocular defocus curve shows a VA ≤ 0.20 LogMAR between defocus levels of +1.50 to -2.50 D.

QUALITY OF VISION
- 95% of patients reported that they "never" or "only occasionally" had seen glare or haloes. 0% of patients had severe glare or haloes.

- *Table 1* shows the mean QoV score for which each item was rated from 0 to 3 depending on the frequency and/or severity of each dysphotopic symptom.

- Compared to findings from studies on other multifocal IOLs, the current study shows that:
  ◦ The QoV scores indicate lower levels of glare and haloes with the studied design than with other refractive asymmetric multifocal designs (*Table 2*).

  ◦ Precizon Presbyopic NVA reveals better rates of glare and haloes than diffractive multifocal designs (*Table 3*).

Symptom	How often do you experience it?	How severe is it?	How bothersome is it?
Glare	0.55 ± 0.87	0.57 ± 0.89	0.30 ± 0.57
Haloes	0.66 ± 0.88	0.61 ± 0.78	0.38 ± 0.59
Starbursts	1.02 ± 1.10	0.96 ± 1.01	0.63 ± 0.82
Hazy vision	0.32 ± 0.64	0.30 ± 0.63	0.20 ± 0.48
Blurred vision	0.30 ± 0.60	0.32 ± 0.66	0.21 ± 0.49
Distortion	0.21 ± 0.65	0.21 ± 0.65	0.20 ± 0.64
Double vision	0.20 ± 0.70	0.21 ± 0.73	0.13 ± 0.51
Fluctuation In vision	0.39 ± 0.76	0.46 ± 0.89	0.39 ± 0.85
Focusing difficulties	0.52 ± 0.74	0.52 ± 0.76	0.38 ± 0.65
Difficulty judging distance or depth perception	0.18 ± 0.58	0.20 ± 0.64	0.16 ± 0.50

Grading scale: 0 = never or not all; 1 = occasionally or mild; 2 = quite often or moderate; 3 = very often or severe

Table 1. *Mean quality of vision (QoV) scoring corresponding to each dysphotopic symptom at 6 months for 56 eyes.*

	Glare	Haloes	Starbusts
Precizon Presbyopic NVA (Ophtec)	0.30	0.38	0.63
SBL-3 IOL (Lenstec, Inc.)	0.58	0.43	0.63
Lentis MPlus LS-312 MF 30 (Oculentis GmbH)	0.50	0.43	0.75

Table 2. *QoV overall scoring obtained with the studied design compared to findings from studies on other refractive asymmetric multifocal designs.*[1]

	% of patients completely absent of glare	% of patients completely absent of haloes	% of patients with very disturbing haloes and glare
Precizon Presbyopic NVA (Ophtec)	75%	68%	0%
AT Lisa 809 M (Carl Zeiss Meditec)	75%	56%	6%
Rayone (Rayner)	60%	60%	-
FineVision (PhysIOL)	33.3%	46.7%	-

Table 3. *Rates of glare and haloes obtained with the studied design compared to findings from studies on other diffractive multifocal designs.*[2,3,4]

Analysis of the visual function with the continuous transitional focus intraocular lens Precizon Presbyopic

Luis León-Ibáñez, David P Piñero. Eur J Ophthalmol. 2024 Nov 3.

OVERVIEW

Study Design
Retrospective consecutive case series study to evaluate the clinical outcomes of a refractive multi-segmented continuous transitional focus intraocular lens (IOL), analyzing the potential influence of patient pupil dynamics on these outcomes.

Study Sites
One sites in Europe.

Patients
Forty (40) eyes from twenty (20) patients bilaterally implanted with Precizon Presbyopic IOL after cataract or clear lens extraction surgery.

Methodology
Preoperative examination and evaluation of outcomes during a mean follow-up of 12 months.

IOL Type
Precizon Presbyopic NVA, model 570 A1 (Ophtec BV).

Key Endpoints
12 months postoperatively: corrected & uncorrected distance VA (CDVA, UDVA), distance-corrected intermediate & near VA (DCIVA, DCNVA); manifest refraction; photopic & mesopic contrast sensitivity (CS); defocus curve; perception of disturbing visual symptoms with a validated questionnaire.

ANALYSIS AND CONCLUSIONS

The Precizon Presbyopic NVA IOL provides an effective visual restoration at various distances, characterized by high levels of visual quality and minimal dependence on pupil dynamics.

The pupil independence of the refractive multi-segmented IOL contrasts with other presbyopia-correcting or EDOF IOLs that clearly show higher pupil-dependence of the visual outcomes compared to the Precizon Presbyopic IOL.

Autorefraction should not be taken into consideration in eyes implanted with Precizon Presbyopic IOL to avoid incorrect decisions in terms of management of the potential residual refraction.

STUDY RESULTS

VISUAL OUTCOMES
At 12 months:
- Mean binocular UDVA, DCIVA, UNVA and DCNVA were −0.09 ±0.07, 0.04 ±0.05, 0.17 ±0.12, and 0.15 ± 0.10 logMAR, respectively.

- Binocular defocus curve shows a mean CDVA over 0.20 logMAR for defocus levels from +1.50 to −3.00 D, and over 0.10 logMAR for defocus levels from +0.50 to −2.00 D (*Figure 1*).

- No significant correlations of photopic pupil diameter with postoperative outcomes were found. A weak correlation was found between mesopic pupil diameter and postoperative binocular UNVA.

- The difference between subjective sphere (0.28±0.45 D) and that obtained by autorefraction (−0.07±0.38 D) was statistically significant.

- The difference between the subjective cylinder (−0.33±0.41 D) and that obtained by autorefraction (−1.08±0.71 D) was also statistically significant.

QUALITY OF VISION & PATIENT SATISFACTION
- No significant differences were found between mesopic and photopic CS for the spatial frequencies of 1.5, 3, 6 and 18 cycles degree. (*Figure 2*).

- 95% and 85% of patients reported that they "never" or "only occasionally" had seen glares or halos, respectively. 0% of patients had severe glare or haloes.

- 90% of patients referred full spectacle independence for only 4 patients referred need of glasses for some near visual activities.

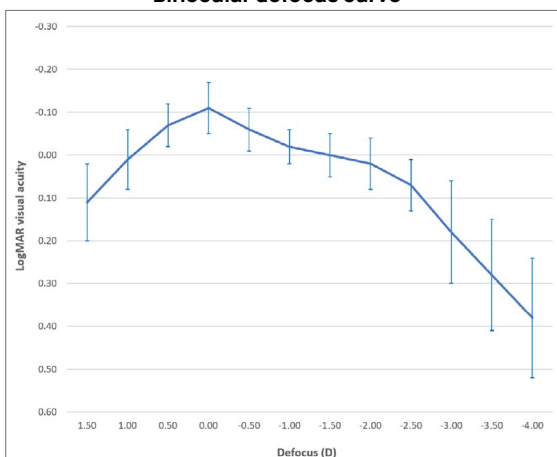### Binocular defocus curve

Figure 1. *Mean binocular defocus curve.*
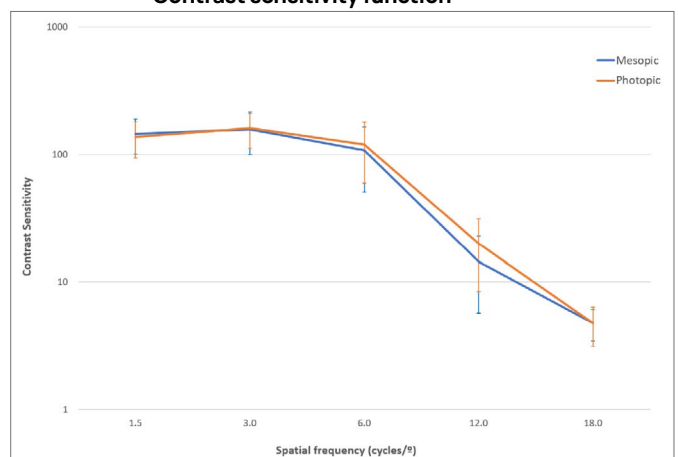
Contrast sensitivity function

Figure 2. *The mean binocular contrast sensitivity function measured under photopic (orange line) and mesopic (blue line) conditions.*

Astigmatism Tolerance and Visual Outcomes After Bilateral Implantation of a Hybrid Continuous Transitional Focus IOL

Emilio Pedrotti, MD, Erika Bonacci, MD; Jorge L. Alió del Barrio, MD; Rosa Longo, MD; Camilla Pagnacco, MD; Giorgio Marchini, MD. J Refract Surg 2023 Jan;39(1):33-39

OVERVIEW

Study Design
Prospective observational clinical study to evaluate the astigmatism tolerance and the visual outcomes after implantation of a premium IOL with a continuous transitional focus (CTF) in pseudophakic presbyopia correction.

Study Sites
One site in Europe.

Patients
Forty (40) eyes from twenty (20) patients bilaterally implanted with Precizon Presbyopic IOL after phacoemulsification.

Methodology
Preoperative examination and evaluation of outcomes at 3 months postoperatively. The NEI RQL-42 questionnaire was used to evaluate subjective quality of life and visual recovery.

IOL Type
Precizon Presbyopic NVA, model 570 A1 (Ophtec BV)

Key Endpoints
3 months postoperatively: corrected and uncorrected distance, near and intermediate at 80 & 67cm visual acuity (CDVA, UDVA, DCI80VA, UI80VA, DCI67VA, UI67VA, DCNVA, and UNVA); contrast sensitivity; astigmatic defocus curve; optical aberrations, objective halometry & quality of vision.

ANALYSIS AND CONCLUSIONS

The Precizon Presbiopic IOL shows an excellent range of astigmatism tolerance allowing for notable objective visual outcomes and high levels of subjective patient satisfaction.

The Precizon Presbyopic IOL has shown a better astigmatism tolerance when compared to bifocal or trifocal IOLs analyzed in recent studies. In terms of vision quality the Precizon Presbyopic IOL showed better performance than other premium IOLs

STUDY RESULTS

VISUAL & REFRACTIVE OUTCOMES

• Mean binocular UDVA, UI67VA and UNVA were 0.03 ± 0.08, 0.18 ± 0.11 and 0.14 ± 0.09 logMAR respectively.

• The mean postoperative SE and refractive cylinder were +0.08 ± 0.27 D and 0.17 ± 0.35 D respectively.

• Astigmatic defocus curves revealed an excellent astigmatism tolerance*: up to -1.00 and +0.75 D, and up to -1.00 and +1.00 D, for WTR & ATR astigmatism respectively *(Figure 1)*.

• In terms of vision quality, comparable results to age-matched control populations were obtained. MTF cut-off point, mean Strehl ratio and HOA RMS were 20.03 ± 4.86 cpd/deg, 0.11 ± 0.07 and 0.28 ± 0.09 respectively.

• Contrast sensitivity was within the normal range for all tested light conditions.

PATIENT SATISFACTION

• NEI RQL-42 questionnaire evidenced high subjective satisfaction. Mean results were not significantly different than the best possible response of 100 especially for far vision (P = .33), activity limitations (P = .15), dependence on correction (P = .09), suboptimal correction (P = .12), appearance (P = .84), and satisfaction with correction (P = .73).
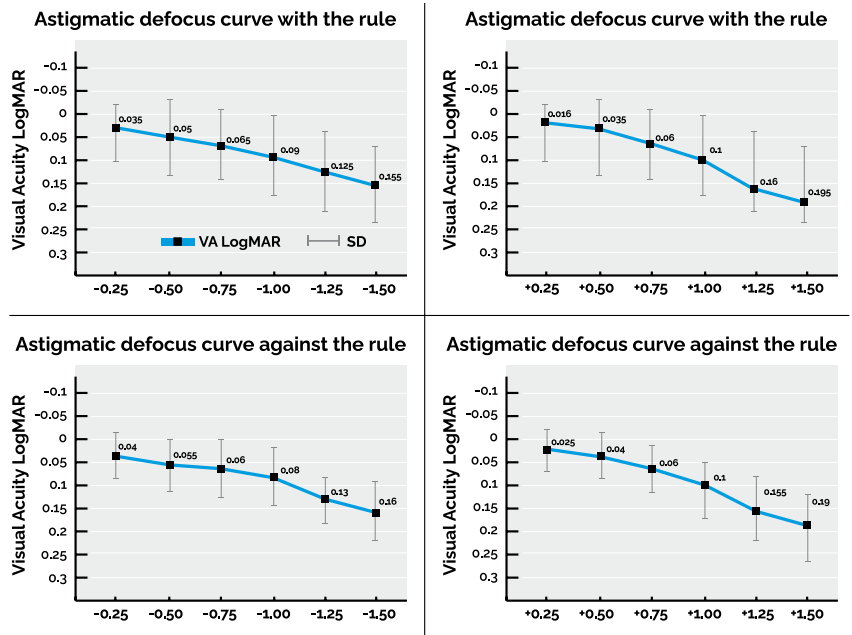
Figure 1. *Mean binocular astigmatic defocus curves with confidence interval in the continuous transitional focus Precizon Presbyopic intraocular lens (Ophtec BV).*

*The astigmatism tolerance was tested adding 0.25-D toric lens steps to CDVA at 4 m from +1.50 to -1.50 D at 90 and 180 degrees. The astigmatism tolerance was defined as higher astigmatism magnitude, which both allows visual acuity not worse than 20I 25 (0.1 logMAR) and does not significantly affect (P > .05) the visual acuity.

Clinical outcomes with a new design in multifocal intraocular lens: a pilot study

Jorge L. Alió, Pilar Yébana, Mario Cantó, Ana B. Plaza, Alfredo Vega, Jorge L. Alió del Barrio & Francisco Lugo. Eye and Vision 2020; 7:38.

OVERVIEW

Study Design
Pilot prospective consecutive non-comparative case series to evaluate the clinical and visual outcomes, quality of vision and patient satisfaction in patients bilaterally implanted with the Precizon Presbyopic IOL.

Study Site
One site in Europe.

Patients
Twenty (20) eyes from ten (10) patients bilaterally implanted with a Precizon Presbyopic IOL.

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

IOL Type
Precizon Presbyopic NVA, model 570 A1 (Ophtec BV).

Key Endpoints
12 months postoperatively: uncorrected distance, near and intermediate visual acuity (UDVA, UNVA, UIVA); contrast sensitivity; binocular defocus curve; quality of vision and satisfaction questionnaire.

ANALYSIS AND CONCLUSIONS

The Precizon Presbyopic NVA IOL provides a high percentage of spectacle independence with a full range of vision and good VA at far, intermediate and near distances.

High patient satisfaction was observed in quality of vision and satisfaction questionnaires with a low percentage of patients manifesting photic phenomena.

STUDY RESULTS

VISUAL OUTCOMES

- UDVA and UNVA at 12 months were – 0.01 ± 0.05 logMAR and 0.13 ± 0.12 logMAR, respectively. UIVA at 3 months was 0.16 ± 0.11 logMAR.

- Defocus curve showed a VA ≤ 0.16 LogMAR between defocus levels of + 1.00 to – 2.50D, with a maximum value of – 0.08 ± 0.08 logMAR at the far defocus (0.00 D) *(Figure 1)*.

- Contrast sensitivity outcomes were similar to normal population in photopic conditions and slightly reduced in mesopic conditions of lighting *(Figure 2)*.

QUALITY OF VISION & PATIENT SATISFACTION

- 100% and 80% of patients reported that they "never" or "only occasionally" had seen glares or halos, respectively.

- 90% of patients were satisfied with their visual results.

- 80% of patients had "never" or "only occasionally" required the use of glasses for near vision after surgery.

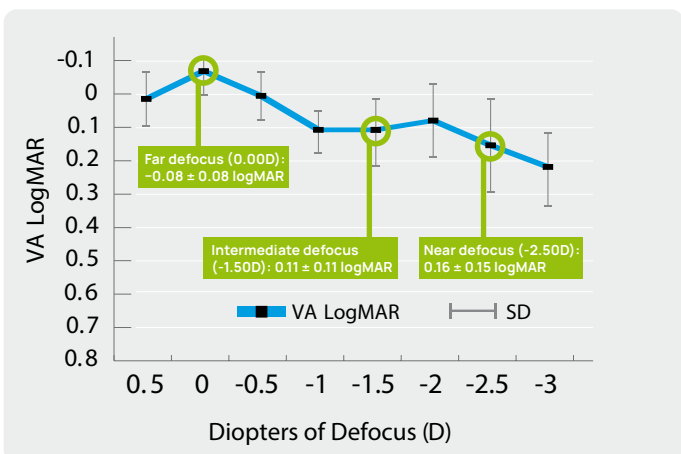**Figure 1.** *Binocular defocus curve 12 months postoperatively. The outcomes show good values of VA for far, intermediate and near vision defocus.*
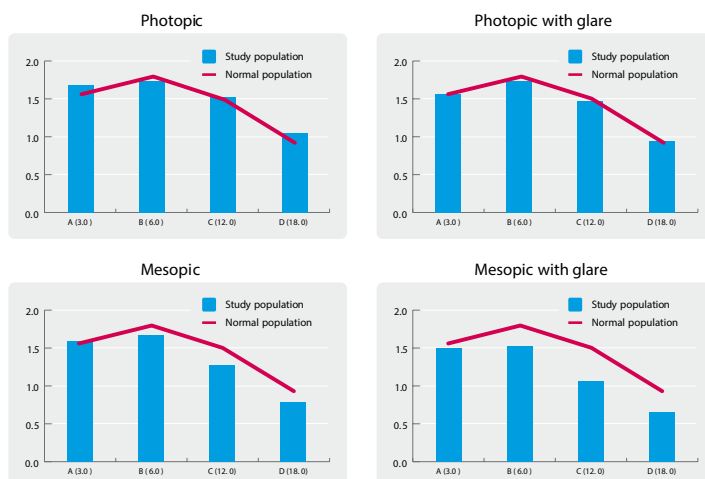

Figure 2. *Contrast sensitivity outcomes (in log units) 12 months postoperatively, in photopic and mesopic conditions with and without glare. Red line shows the population norms for an age group between 50 and 75 years of age.*

Functional Outcomes of a New Multisegmental Presbyopia Correcting Intraocular Lens PRECIZON CTF Technology

Mike P. Holzer. Presented at the Congress of the American Society of Cataract & Refractive Surgeons (ASCRS); April 22-26, 2022; Washington DC, USA.

OVERVIEW

Study Design
Prospective, open label, single-arm, multicenter clinical trial to evaluate the ability of the multisegmental Precizon Presbyopic NVA - CTF Technology Multifocal Intraocular Lens to provide near, intermediate and distance vision.

Study Sites
Six sites in Europe and South Korea.

Patients
One-hundred-and-eighteen (118) eyes from fifty-nine (59) patients bilaterally implanted with the Precizon Presbyopic NVA after cataract or clear lens extraction.

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

IOL Type
Precizon Presbyopic NVA, model 570 A1 (Ophtec BV)

Key Endpoints
6 months postoperatively: corrected and uncorrected distance, near and intermediate visual acuity (4m, 80cm & 40cm); manifest refraction spherical equivalent (MRSE); defocus curve; quality of vision (QoV).

ANALYSIS AND CONCLUSIONS

CTF technology provides excellent visual acuity at distance & intermediate distances, and good functional near vision. It also provides good quality of vision with very small percentage of halos and glare.

The study showed a slight hyperopic shift that led to an A constant optimization.

STUDY RESULTS

VISUAL & REFRACTIVE OUTCOMES

- At 6 months, mean binocular UDVA and UNVA was 0.00 ± 0.09 and 0.19 ± 0.13 LogMAR respectively. At 3 months, mean binocular UIVA was 0.14 ± 0.10 LogMAR.

- Mean MRSE at 6 month post-op was 0.14 ± 0.39 D.

- The defocus curve shows excellent VA at far & intermediate distance, and good functional near vision *(Figure 1)*. The best case reported presented a far VA of -0,13 LogMAR.

QUALITY OF VISION

- 90% and near 80% of patients reported that they "never" or "only occasionally" had seen glare or halos, respectively *(Figure 2)*. 80-86% of the patients that experienced glare or halos reported that they were "never"/"only occasionally" severe or bothersome respectively.
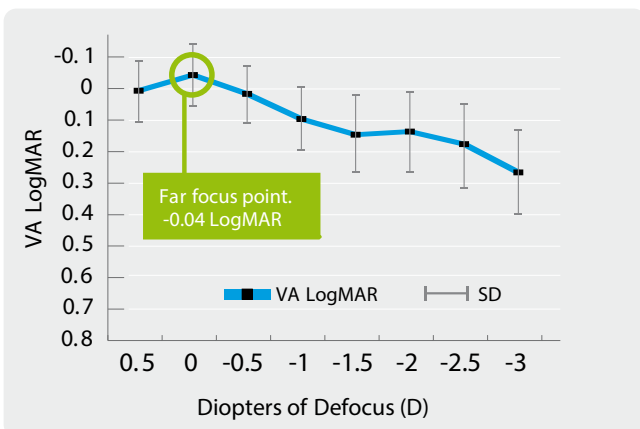
Defocus curve

Figure 1. *The best corrected binocular defocus curve taken at 6 months post-operative.*
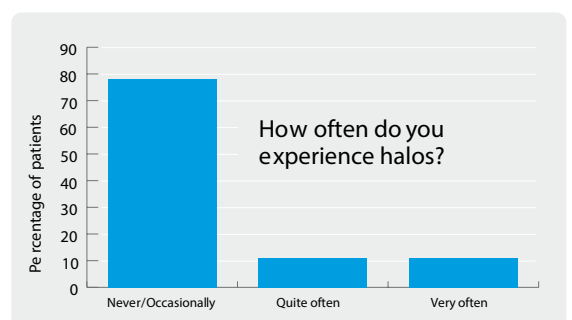

Figure 2. *Results from McAlinden QoV questionnaire (validated, Rasch-adjusted).*

Precizon Presbyopic NVA.
Results and patient satisfaction

J. Mendicute del Barrio, L. Jeldes Saba, A. Churruca Irazola, A. Acera Osa. Presented at the 34th Congress of the Spanish Society of Implant-Refractive Ocular Surgery (SECOIR); May 22-25, 2019. Presented at the 23rd Congress of FacoElche; June 17-19, 2021.

OVERVIEW

Study Design
Prospective, non-randomized, open-label and single-arm clinical study to evaluate visual performance of the Precizon Presbyopic IOL.

Study Site
One site in Spain.

Patients
Twenty (20) eyes from ten (10) patients bilaterally implanted with the Precizon Presbyopic NVA A1 after cataract or clear lens extraction (CLE).

Methodology
Preoperative examination and evaluation of post-operative outcomes at 1 day and 1, 2 & 3 months.

IOL Type
Precizon Presbyopic NVA, model 570 A1 (Ophtec BV).

Key Endpoints
6 month postoperatively: binocular UDVA, UNVA, UIVA; defocus curve; spherical equivalent (SE); quality of vision (QoV) and patient satisfaction.

ANALYSIS AND CONCLUSIONS

Precizon Presbyopic offers a very high degree of overall satisfaction, 90% of spectacle independence and non-existing or irrelevant photic phenomena.

Precizon Presbyopic offers an excellent uncorrected vision at far and intermediate distances, and a functional vision at near.

STUDY RESULTS

VISUAL & REFRACTIVE OUTCOMES
- At 6 months, mean binocular UDVA, UIVA and UNVA were 0.01 & 0.2 logMAR respectively. At 3 months, mean binocular UIVA was 0.12 logMAR.

- Mean SE was in emmetropic values and stable over time: +0.01D, +0.01D & 0.00D at 1, 3 and 6 months respectively.

QUALITY OF VISION & PATIENT SATISFACTION
- 100% of the patients never observed glare. 100% of the patients "never" or "only occasionally" observed halos or starbust *(Figure 1)*.

- 100% of patients were "very" satisfied with their distance vision. 100% and 80% of patients were "very" or "quite" satisfied with their inter mediate and near vision *(Figure 2)*.

- 90% of the patients were "very" satisfied with the general result. The remaining 10% were "quite" satisfied

- 90% patients reported that they "never" or "only occasionally" required spectacles for near vision.

100% NEVER — Glare
90% NEVER — 10% — Starbursts
60% NEVER — 40% — Halos

NEVER
OCCASIONALLY
QUITE OFTEN
VERY OFTEN
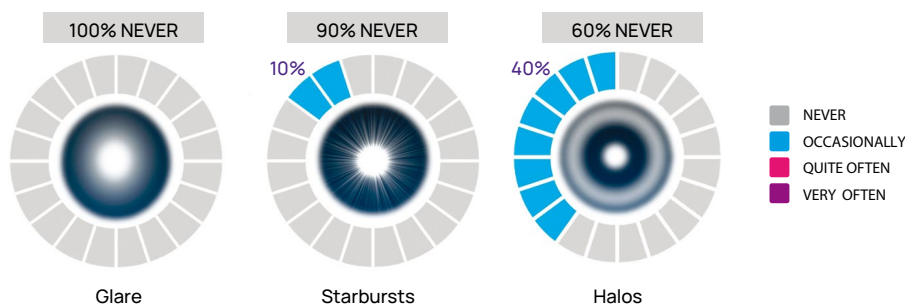
Figure 1. *Patient-reported disphotopsia experience at six months post Precizon Presbyopic IOL implantation, assessed using the Quality of Vision (QoV) questionnaire.*

Patient Satisfaction

100% — DISTANCE
80% — 20% — INTER-MEDIATE
50% — 20% — 30% — NEAR

VERY
QUITE
A LITTLE
NOT AT ALL

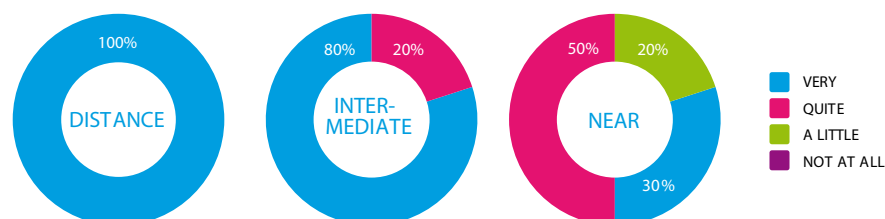**Figure 2.** *Patient-reported satisfaction with their vision at distance, intermediate and near vision at six months post Precizon Presbyopic IOL implantation, assessed using the Quality of Vision (QoV) questionnaire.*

Multizonal Design Multifocal Intraocular Lens–Induced Astigmatism According to Orientation

Youngsub Eom, MD, PhD; Seul Ki Yang, MS; Eun Gyu Yoon, MD; Ji Nyeong Choi, BS; Dongok Ryu, PhD; Dae Wook Kim, PhD; Jun-Heon Kim, MD; Jong Suk Song, MD, PhD; Sug-Whan Kim, PhD; Hyo Myung Kim, MD, PhD. J Refract Surg. 2020; 36(11): 740-748.

OVERVIEW

Study Design
Retrospective case-control and experimental ray-tracing simulation study to evaluate the induced astigmatism of the Precizon Presbyopic 570 A1 (Ophtec BV) IOL depending on the lens orientation (vertical vs horizontal). Visual outcomes and optical performance were also analyzed.

Study Sites
Korea University Ansan Hospital & Joeunnun Vision Clinic (South Korea).

Patients
Eighty (80) eyes from forty (40) patients with cataracts who underwent Precizon Presbyopic IOL implantation.

Methodology
Residual astigmatism (measured by autorefraction and manifest refraction) was investigated using vector analysis of eyes implanted with vertical and horizontal orientations of the first near segment of the IOL. Visual performance was also evaluated. Pseudophakic eyes with a Precizon Presbyopic IOL were modeled for the ray-tracing simulation study.

IOL Type
Precizon Presbyopic NVA, model 570 A1 (Ophtec BV).

Key Endpoints
IOL-induced astigmatism measured by autorefraction, manifest refraction and ray-tracing simulations; uncorrected distance visual acuity (UDVA) and uncorrected near visual acuity (UNVA); defocus curves.

ANALYSIS AND CONCLUSIONS

Combining the clinical and ray-tracing simulation results, Precizon Presbyopic induced astigmatism is clinically insignificant both with horizontal and vertical IOL implantations.

The manifest refraction and ray-tracing results of induced astigmatism were much smaller than those observed by autorefraction. Autorefraction should not be used to evaluate astigmatism in eyes implanted with the Precizon Presbyopic IOL.

The Precizon Presbyopic IOL has been shown to provide excellent visual performance from far to near distances.

STUDY RESULTS

VISUAL & REFRACTIVE OUTCOMES

- Autorefraction and manifest refraction measurements demonstrated that vertical and horizontal implantation of Precizon Presbyopic IOL induced WTR and ATR astigmatism respectively. However, manifest refraction measurements were much smaller.

	Vertical Orientation	Horizontal Orientation
Auto-refraction	0.68 ± 0.58 x 1°	1.05 ± 0.81 x 96°
Manifest refraction	0.14 ± 0.44 x 171°	0.46 ± 0.40 x 95°

- No significant difference was found between vertical and horizontal IOL orientation cases in the mean UDVA (0.01 ± 0.08 and 0.03 ± 0.08 logMAR, respectively) and UNVA (0.17 ± 0.13 and 0.14 ± 0.12 logMAR, respectively).

- Precizon Presbyopic IOL demonstrated excellent visual performance from far to near distances: visual acuity ≤ 0.2 logMAR from far to near (40 cm) in binocular defocus curve: -0.07 logMAR at 0.00 D; 0.05 logMAR at -2.00 D; < 0.2 logMAR at -2.50 D *(Figure 1)*.

BENCH PERFORMANCE

- In ray-tracing simulations, the Precizon Presbyopic IOL provided sharp images at both far & near distances *(Figure 2)*. The sharpest images were observed at 500 and 5,000 mm in both orientations. These results are in good agreement with the defocus curves collected in the clinical study.

- Ray-tracing simulations demonstrated Precizon Presbyopic IOL does not induce significant astigmatism neither with vertical nor horizontal implantation.

Defocus curve
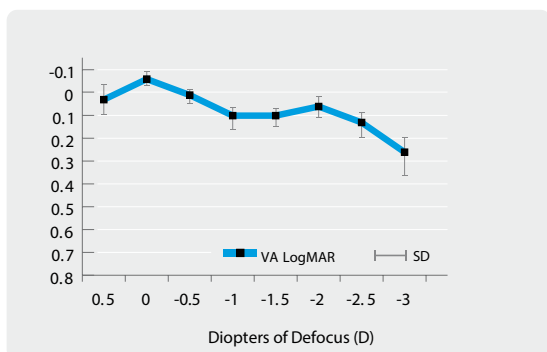
Figure 1. *Mean binocular distance–corrected defocus curves measured 4 to 8 weeks after cataract surgery.*
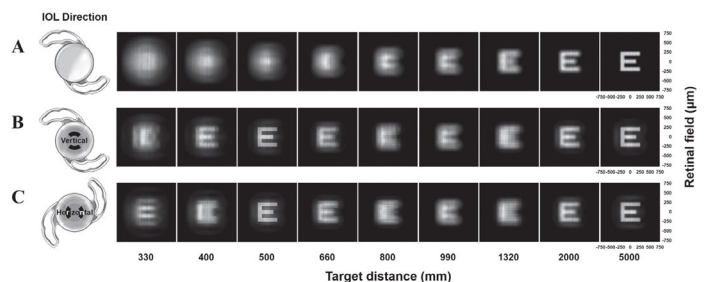

Figure 2. *Retinal images of pseudophakic eyes using monofocal or Precizon Presbyopic IOL in integrated ray-tracing simulations (using Lambertian source E targets with various target distances and two IOL implantation directions). (A) Monofocal IOL. (B) Precizon Presbyopic IOL vertically oriented. (C) Precizon Presbyopic IOL horizontally oriented.*

Comparison of visual results after implantation of extended focus intraocular lenses (EDOF) in cataract surgery

Francisco Pérez Cañete, Rafael Barañano Alcaide, Rafael Pérez Cambrodí, Belén Giménez Alcántara, Dr. Miguel Giménez De La Linde. Saera 2022.

OVERVIEW

Study Design
Prospective, randomized, comparative, double masked study to compare postoperative visual outcomes and patient satisfaction after the implantation of four different presbyopia correcting IOLs.

Study Site
One site in Spain.

Patients
Twenty (20) eyes from twenty (20) patients that underwent uncomplicated cataract surgery with unilateral implantation of an extended range of vision IOL. Five (5) patients were implanted with each IOL model compared in the study.

Methodology
Preoperative examination and evaluation of postoperative outcomes at 1 day and 1 month.

IOL Type(s)
Precizon Presbyopic, model 570 A0 (Ophtec BV), MiniWell (SIFI), Symfony (Johnson & Johnson) & AT-LARA (Carl Zeiss Meditec AG).

Key Endpoints
1 month postoperatively: monocular UDVA, UNVA, UIVA; monocular defocus curve; patient satisfaction.

ANALYSIS AND CONCLUSIONS

CTF Precizon Presbyopic showed to be the best solution for cataract surgery offering a good vision at distance, and a higher performance at intermediate and near vision compared to the other designs analyzed in the study. It provides the patient with a better natural and comfortable vision.

It is important to point out the patient's lack of complaints of halos and dysphotopsias reported with the Precizon Presbyopic CTF design. Patients described their vision as "very natural".

Patients implanted with Precizon Presbyopic IOL reported total independence from spectacles, and showed a continuous focus from far to near distances.

STUDY RESULTS

VISUAL OUTCOMES

• CTF Precizon Presbyopic IOLs achieved better postoperative mean VA results at all distances as shown in *Table 1*.

	FAR VA ± SD	INTERMEDIATE VA ± SD	NEAR VA ± SD
PRECIZON (n=5)	0.03 ± 0.06	0.15 ± 0.06	0.22 ± 0.06
SYMFONY (n=5)	0.07 ± 0.09	0.19 ± 0.05	0.35 ± 0.07
MINIWELL (n=5)	0.03 ± 0.04	0.12 ± 0.05	0.30 ± 0.08
AT-LARA (n=5)	0.06 ± 0.05	0.20 ± 0.10	0.63 ± 0.37
TOTAL (n=20)	0.05 ± 0.02	0.17 ± 0.04	0.38 ± 0.18

Table 1. *Mean VA for far, intermediate and near distance (logMAR). Far VA: mean VA in the 0 to +0.50 D range; Intermediate VA: mean VA in the -1.00 to -1.50 D range; Near VA: mean VA in the -2.00 to -2.50 D range.*

• As shown in *Figure 1*, the defocus curves show an overperformance of the Precizon Presbyopic IOL compared to the other studied lenses, specifically between the range of -1.50D and -2.50D (from intermediate to near focus points). Distance focus is similar for all studied IOLs.

• The shape & slope of the defocus curve reinforces the statement of Precizon Presbyopic being a continuous transitional focus IOL.

• Calculated area under the curve of defocus was wider for Precizon Presbyopic IOL, as showed in *Table 2*.

AREA UNDER THE CURVE	
PRECIZON PRESBYOPIC (OPHTEC)	3.51
SYMFONY (J&J)	2.93
MINIWELL (SIFI)	3.44
AT-LARA (ZEISS)	2.59

Table 2. *Calculation of the area under the curve by polynomial interpolation extracting the polynomial of tenth degree and integrating it between intervals +1.5 and -3.5D.*

PATIENT REPORTED OUTCOMES

An internal not validated subjective questionnaire was used to test level of satisfaction and presence of dysphotopsias with the following remarkable results from patients implanted with Precizon Presbyopic IOL:

• 100% of patients presented lack of complaints of halos and dysphotopsias.

• When asked for their vision, patients' described it as **very natural** and showed a high degree of subjective satisfaction.

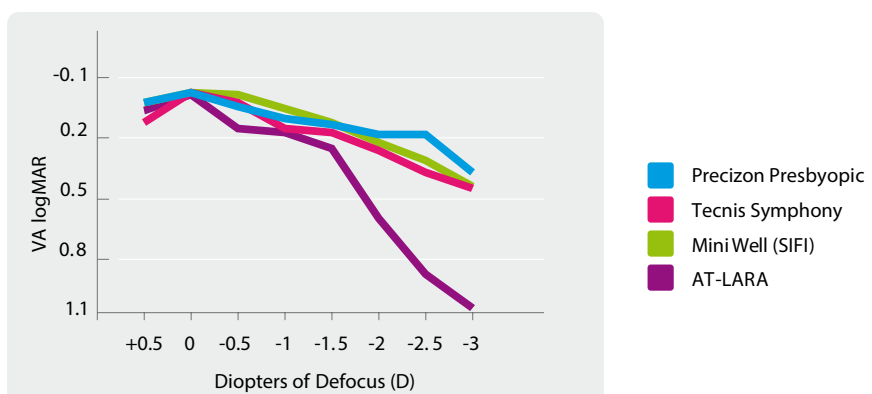• Patients reported total independence from spectacles.

Defocus curves

Figure 1. *Comparison of the four defocus curves of the study lenses.*

Retinal image quality with multifocal, EDoF, and accommodative intraocular lenses as studied by pyramidal aberrometry

Jorge L. Alio, Francesco D'Oria, Francesca Toto, Joan Balgos, Antonio Palazon, Francesco Versaci and Jorge L. Alio del Barrio.
Eye and Vision 2021, 8(1):37.

OVERVIEW

Study Design
Prospective, consecutive, comparative, case series study to evaluate the clinical optical quality of the retinal image with different types of IOLs in vivo by studying the PSF Strehl ratio in the far distance image with a model of pyramidal wavefront sensor (PWS) based aberrometer.

Study Site
One site in Spain.

Methodology
Preoperative examination and evaluation of post-operative outcomes at 3 months.

Patients
One-hundred-and-ninety-four (194) eyes of one-hundred-and-twenty (120) patients bilaterally implanted with one out of nine different IOL implants included in the study after uncomplicated cataract or refractive lens exchange surgery.

IOL Type(s)
Monofocal spherical AcrySof SA60AT as control group (Alcon, Inc.). One EDoF: Miniwell (SIFI). Three multifocal refractive: LENTIS Mplus LS-313 MF30 (Oculentis GmbH), LENTIS Mplus LS-313 MF15 (Oculentis GmbH) & Precizon Presbyopic (Ophtec BV).
One accommodative: AkkoLens Lumina (AkkoLens Clinical B.V.).
Two multifocal diffractive: AT LISA Tri 839 MP (Carl Zeiss Meditec) & AcrySof IQ PanOptix Trifocal (Alcon, Inc.).
One new aspheric monofocal: Tecnic Eyhance (Johnson & Johnson Vision, Inc.)

Key Endpoints
3 month postoperatively: uncorrected distance and near visual acuity (UDVA & UNVA); manifest refraction; evaluation of the optical quality of the far retinal image at a pupil diameter of 3 & 4mm: PSF Strehl ratio; PSF Strehl ratio excluding second-order aberrations (PSFw2); total root mean square (RMS); low-order aberration (LOA) and high-order aberration (HOA) RMS.

ANALYSIS AND CONCLUSIONS

AT LISA Tri, SA60AT and PanOptix showed the highest values of far distance retinal image quality, while the lowest PSFw2 Strehl ratios were displayed by Miniwell, Mplus MF30 and Precizon Presbyopic. However, PSFw2 values do not correlate with subjective distance uncorrected and corrected visual acuities results where AT LISA Tri & Precizon Presbyopic showed the best outcomes.

Influence of residual ametropia cannot fully be removed by eliminating the second-order aberrations. This might explain the lack of correlation between the PSFw2 Strehl ratios and the distance visual acuity results (note that Precizon Presbyopic showed the highest postoperative refractive sphere). Future prospective studies would be required to elucidate the relationship between far distance retinal image quality (PSFw2 Strehl ratios), visual outcomes and quality of vision perceived by the patient.

As an additional limitation of the study, the Osiris aberrometer used in the study is only able to simulate the main PSF of a diffractive lens, but not the others.

STUDY RESULTS

VISUAL OUTCOMES
- All treated groups had an improvement in UDVA, with AT LISA Tri & Precizon Presbyopic showing the highest values (0.03 ± 0.12 & 0.08 ± 0.16 logMAR respectively).

- All treated groups had an improvement in CDVA, with AT LISA Tri & Precizon Presbyopic showing the highest values (-0.01 ± 0.08 & 0.01 ± 0.13 logMAR respectively).

OPTICAL QUALITY OUTCOMES (DISTANCE)
- Precizon Presbyopic presented significant lower levels of retinal image quality measured with PSFw2 Strehl ratio (0.27 ± 0.07 and 0.17 ± 0.04 at 3.0and 4.00 mm, respectively) than the monofocal control group.

- When looking to the mean postoperative value of retinal image, AT LISA Tri had the highest significant PSFw2 Strehl ratio at both 3.0 and 4.0 mm pupil sizes (0.52 ± 0.14 and 0.31 ± 0.1), followed by the monofocal control group AcrySof SA60AT (0.41 ± 0.11 and 0.28 ± 0.07) and PanOptix (0.4 ± 0.07 and 0.26 ± 0.04).

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