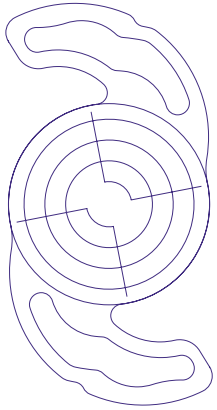


ophtec



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.

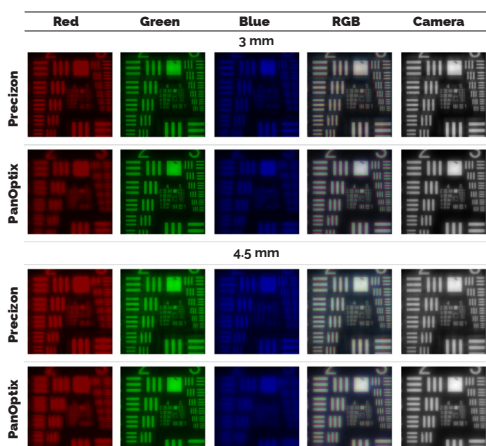


Figure 1. 1951 USAF resolution target photographs taken through the studied IOLs. A simulation of an RGB image and a direct Camera recording of an unprocessed (polychromatic) test chart are presented for comparison.

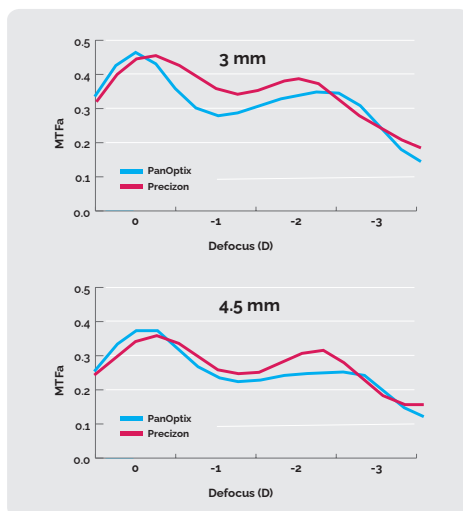


Figure 2. The MTFa curves of the two IOLs models measured at the defocus range from $+0.5$ D to -3.5 D at the spectacle plane. Each line represents the average of two samples for each IOL model.

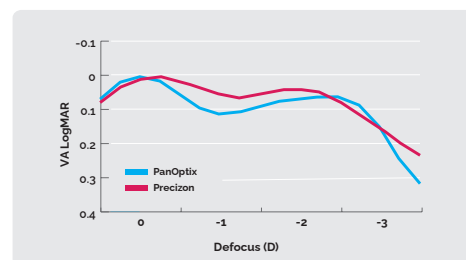


Figure 3. The logMAR VA of the two studied models measured at the defocus range from $+0.5$ D to -3.5 D (spectacle plane). Each line represents the average of two samples for each IOL model.



Bilateral Implantation of a New Refractive Multi-Segmented Multifocal Intraocular Lens in Cataract or Refractive Lens Exchange Patients

Mike P Holzer, Rudy MMA Nuijts, Soraya MR Jonker, Erik LJG Mertens, Asim Bozkurt Sener, Jorge AO Casal, Antoni Salvador Playa, Ramon Ruiz Mesa, Bettina C Thomas. *Clinical ophthalmology* 2021; 15 2117–2126.

OVERVIEW



Study Design

Prospective, open-label, single-arm, multicenter clinical trial to evaluate the safety and efficacy of the multi-segmented Precizon Presbyopic IOL.



Study Sites

Six sites in Europe.



Patients

Sixty-three (63) presbyopic subjects bilaterally implanted with the Precizon Presbyopic NVA A0 after phacoemulsification and refractive lens exchange.



Methodology

Preoperative examination and evaluation of outcomes at 1 day, 1 week, 1 & 3 months postoperatively. A validated Rasch-adjusted QoV questionnaire was used to evaluate subjective quality of vision.



IOL Type

Precizon Presbyopic, model 570 A0 (Ophtec BV).



Key Endpoints

3 months postoperatively: uncorrected distance, near and intermediate visual acuity (UDVA, UNVA, UIVA); contrast sensitivity; defocus curve; quality of vision; spectacle independence & patient satisfaction.

ANALYSIS AND CONCLUSIONS

Precizon Presbyopia IOL implantation is a safe and effective method to provide good visual outcomes at all distances following cataract extraction or refractive lens exchange.

Visual acuities found in the study were compared to literature-reported corresponding mean values of other refractive or diffractive MIOLs and were found to be either equivalent or better at all distances.

STUDY RESULTS

VISUAL OUTCOMES

- Mean binocular UDVA, UIVA and UNVA was 0.03 ± 0.12 logMAR, 0.06 ± 0.11 logMAR & 0.14 ± 0.12 logMAR, respectively at 3 months.
- Precizon Presbyopic IOL demonstrated visual acuity ≤ 0.1 logMAR from distance to -2.5 D on the binocular defocus curve.

PATIENT REPORTED OUTCOMES

- 98.4% patients reported that they “never” or “only occasionally” used spectacles (**Figure 1**).
- 93% of patients reported that they were quite or very satisfied with the outcomes of the procedure (**Figure 2**).
- Nearly 90% and 80% of the patients either “never” or “only occasionally” observed photic phenomena as glare and halos respectively.

Overall spectacle independence

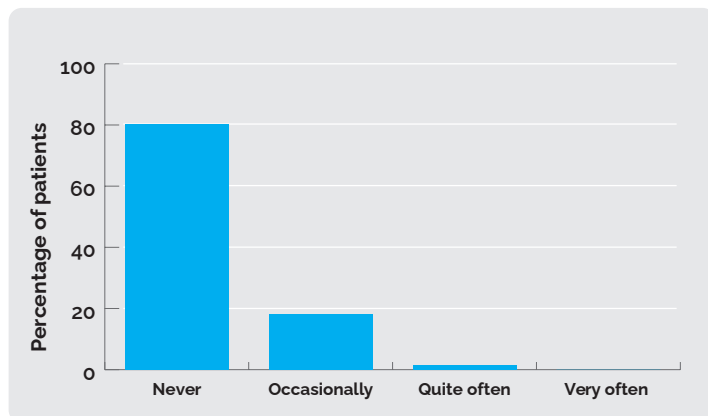


Figure 1. Overall spectacle independence following Precizon Presbyopic implantation in cataract and refractive lens exchange subjects at postoperative 3 months by means of a validated Rasch-adjusted QoV questionnaire (how often do you wear spectacles?).

Patient satisfaction

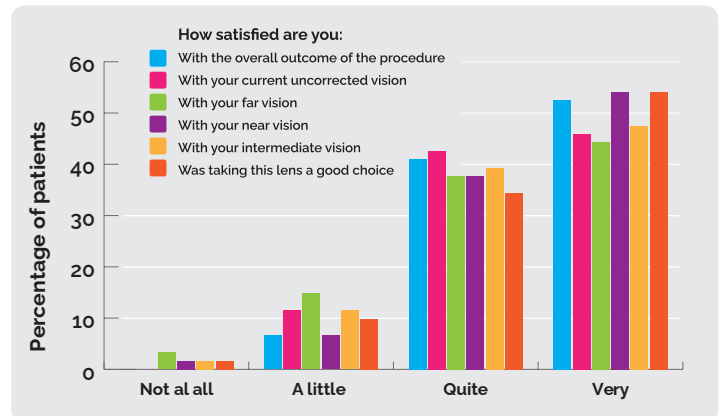


Figure 2. Patient satisfaction outcomes following Precizon Presbyopia IOL implantation – Percentage of patients reporting different levels of satisfaction in response to a directed questionnaire on different aspects of vision, procedure and IOL. Answers to questions with options, “not at all”, “a little”, “quite” and “very”.



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 Italy.



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 $+0.08 \pm 0.27$ 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 REPORTED OUTCOMES

- 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 ($P = .73$).

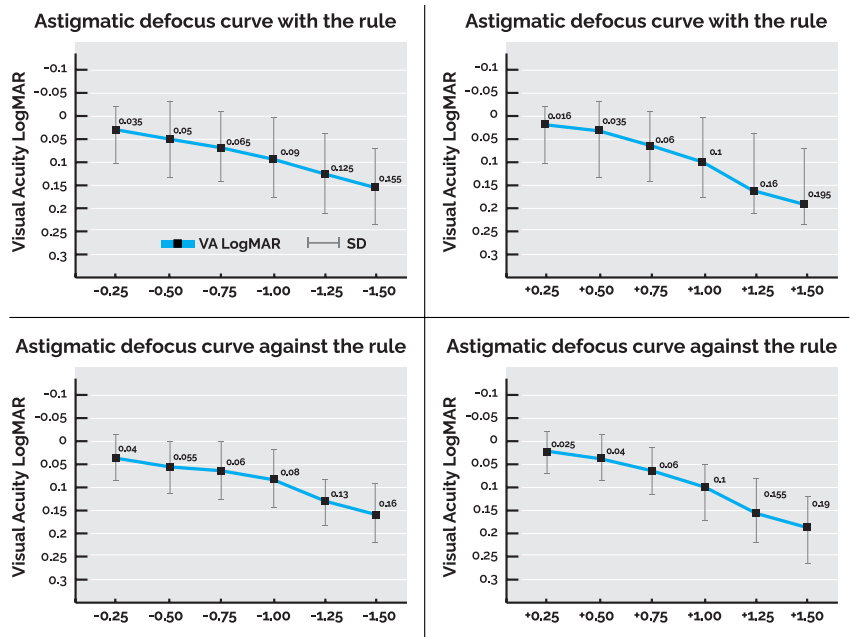


Figure 1. Mean binocular astigmatic defocus curves with confidence interval in the continuous transitional focus Precizon Presbyopic intraocular lens (Ophtec BV).

*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 20/25 (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 Spain.



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).

PATIENT REPORTED OUTCOMES

- 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.

Defocus curve

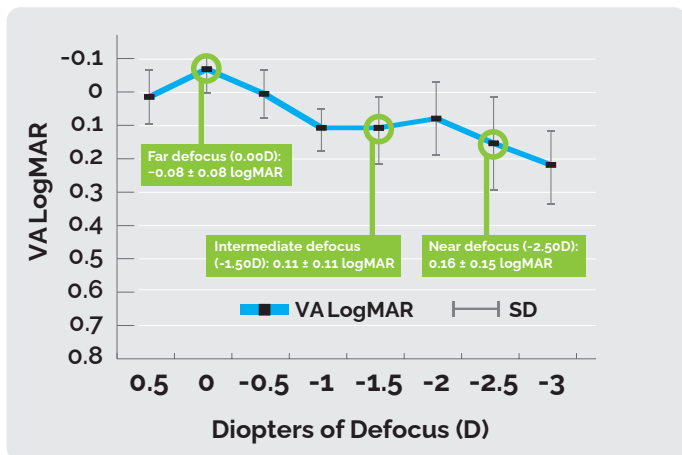
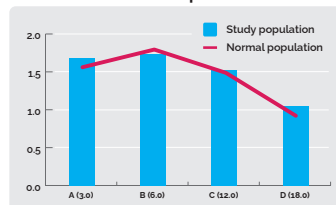
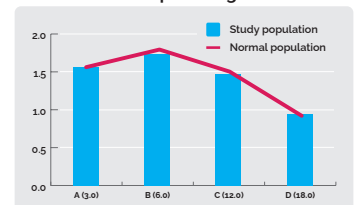


Figure 1. Binocular defocus curve 12 months postoperatively. The outcomes show good values of VA for far, intermediate and near vision defocus.

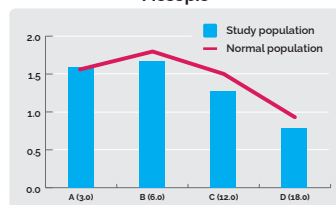
Photopic



Photopic with glare



Mesopic



Mesopic with glare

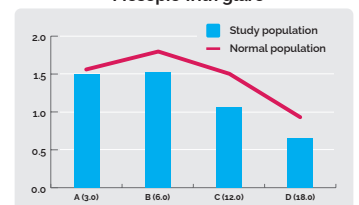


Figure 2. Contrast sensitivity outcomes (in log units) 12 months postoperatively, in photopic and mesopic conditions with and without glare. Red line shows the population norms for an age group between 50 and 75 years of age.



Clinical outcomes of cataract surgery with implantation of a continuous transitional focus intraocular lens

Mariano Royo, Angel Jimenez, David P. Piñero. *J Cataract Refract Surgery* 2020; 46(4):567-572.

OVERVIEW



Study Design
Nonrandomized prospective case series to evaluate clinical outcomes after cataract or crystalline lens surgery with implantation of a new continuous transitional focus intraocular lens (IOL).



Study Site
One site in Spain.



Patients
Sixty-two (62) eyes from thirty-one (31) patients with uncomplicated phacoemulsification cataract surgery with bilateral implantation of the continuous transitional focus IOL Precizon Presbyopic 570.



Methodology
Preoperative examination and evaluation of outcomes during a six month period follow-up.



IOL Type
Precizon Presbyopic, model 570 A0 (Ophtec BV)



Key Endpoints
6 months postoperatively: binocular uncorrected distance, near and intermediate visual acuity (UDVA, UNVA, UIVA); contrast sensitivity; defocus curve; incidence of postoperative disturbing photic phenomena.

ANALYSIS AND CONCLUSIONS

The Precizon Presbyopic CTF provides excellent levels of visual quality, and generates a continuous range of functional vision from distance to near with minimal levels of photic phenomena associated.

Visual acuities for all distances were better or clearly superior than those reported with other types of presbyopia correcting IOLs including EDOF or trifocal diffractive lenses.

Limited cases of photic phenomena were reported, with a similar incidence to that reported with EDOF IOLs, and clearly inferior to that reported for different types of bifocal and trifocal IOLs.

STUDY RESULTS

VISUAL AND PATIENT REPORTED OUTCOMES

- At 6 months, mean binocular UDVA, UIVA and UNVA were 0.01 ± 0.03 , 0.17 ± 0.04 , and 0.02 ± 0.04 logMAR respectively.
- At 6 months, a 100% (31/31) and 96.8% (30/31) of patients achieved a value of UDVA and UNVA of 20/25 or better, respectively. All patients (31/31, 100%) achieved 20/30 UIVA or better (Figure 1).
- The mean defocus curve showed a continuous range of functional vision from 0 to -3D of defocus.
- Only 9.7% (3/31) and 6.5% (2/31) of patients reported disturbing halos and glare respectively at 6 months. The perception of starbursts was not reported by any patient.
- Excellent distant contrast sensitivity outcomes were observed under dim ambient light conditions at 6 months (log contrast sensitivity was 1.22 ± 0.18 and 0.75 ± 0.10 for 12 and 18 cycles per degree, respectively).
- The values of dim light contrast sensitivity obtained were closer to those reported for monofocal and EDOF IOLs.

Visual acuity



Figure 1. Postoperative distribution of binocular UDVA, UIVA, and UNVA 6 months postoperatively.

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.

PATIENT REPORTED OUTCOMES

- 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

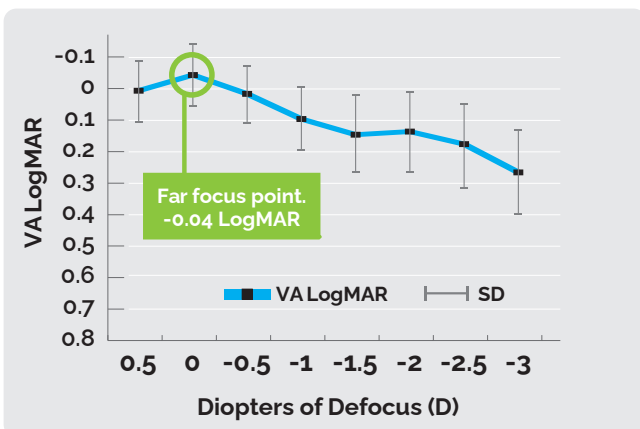


Figure 1. The best corrected binocular defocus curve taken at 6 months post-operative.

Glare



Halos

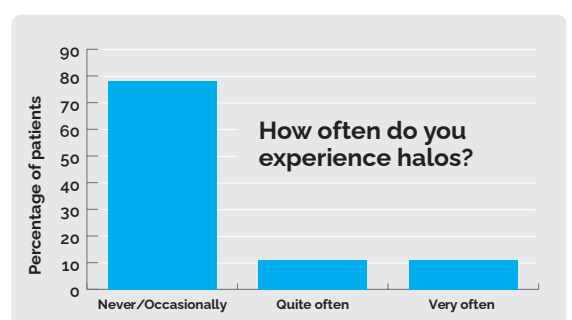


Figure 2. Results from McAlinden QoV questionnaire (validated, Rasch-adjusted).

Precizon Presbyopic NVA. Results and patient satisfaction

J. Mendicute del Barrio, L. Jeldes Saba, A. Churrua 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 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.

PATIENT REPORTED OUTCOMES

- 100% of the patients never observed glare. 100% of the patients "never" or "only occasionally" observed halos or starburst (Figure 1).
- 100% of patients were "very" satisfied with their distance vision. 100% and 80% of patients were "very" or "quite" satisfied with their intermediate 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.

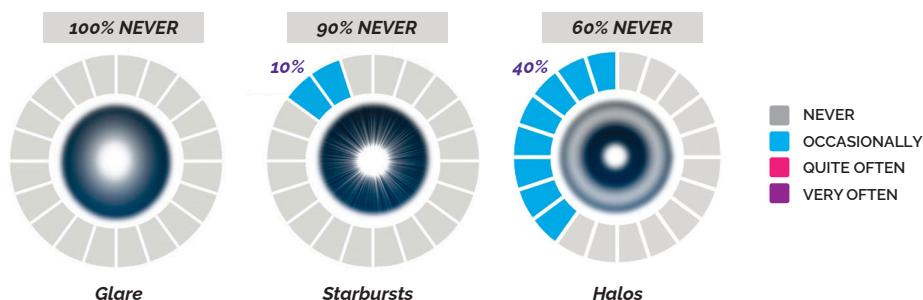


Figure 1. Patient-reported dysphotopsia experience at six months post Precizon Presbyopic IOL implantation, assessed using the Quality of Vision (QoV) questionnaire.

Patient Satisfaction

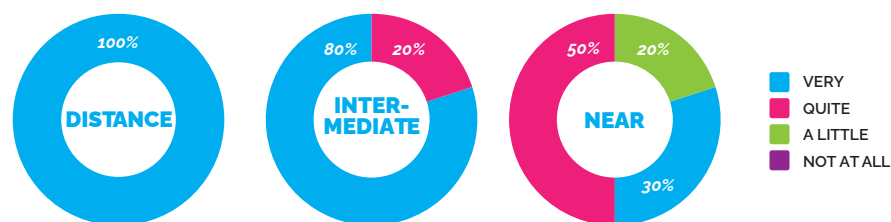


Figure 2. Patient-reported satisfaction with their vision at distance, intermediate and near vision at six months post Precizon Presbyopic IOL implantation, assessed using the Quality of Vision (QoV) questionnaire.



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 & Joeeunun 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 autorefractometry 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 autorefractometry, 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 autorefractometry. Autorefractometry 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

- Autorefractometry 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 × 1°	1.05 ± 0.81 × 96°
Manifest refraction	0.14 ± 0.44 × 171°	0.46 ± 0.40 × 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

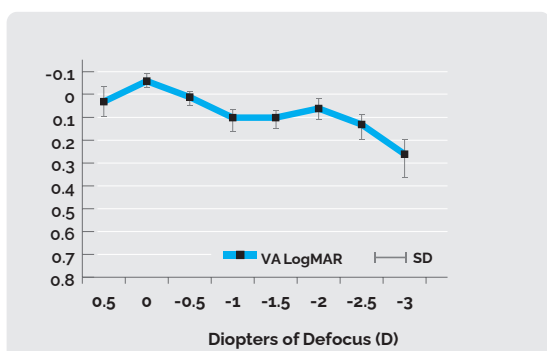


Figure 1. Mean binocular distance-corrected defocus curves measured 4 to 8 weeks after cataract surgery.

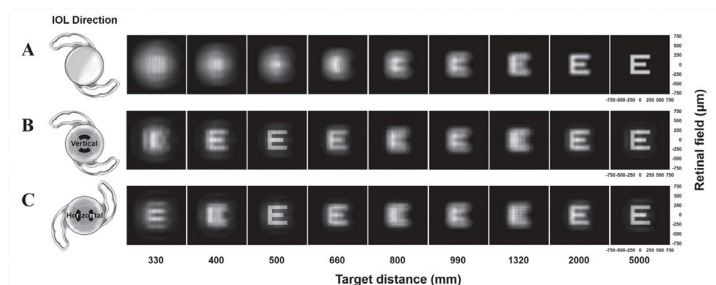


Figure 2. Retinal images of pseudophakic eyes using monofocal or Precizon Presbyopic IOL in integrated ray-tracing simulations (using Lambertian source E targets with various target distances and two IOL implantation directions). (A) Monofocal IOL. (B) Precizon Presbyopic IOL vertically oriented. (C)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

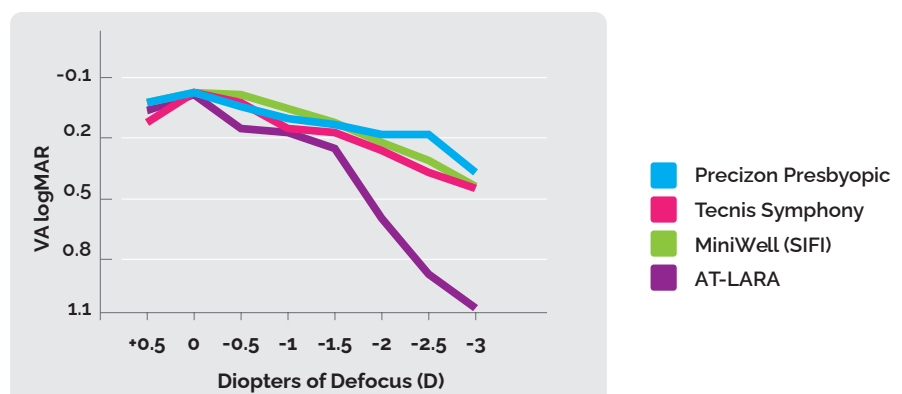


Figure 1. Comparison of the four defocus curves of the study lenses.



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 3.0 and 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).

