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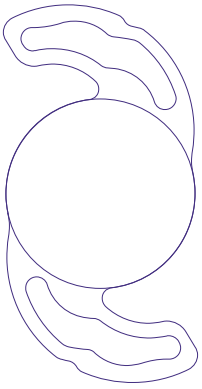

Precizon Go

Clinical science compendium

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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.

Precizon Go is an innovative enhanced intermediate vision intraocular lens unique in its class. This paper summarizes the initial results on the performance of the lens as a result of research studies conducted to evaluate its optical quality and clinical patient outcomes.

In addition to exploring this compendium, we encourage you to visit Ophtec's website (ophtec.com) to learn more about Ophtec´s Precizon Family and the complete range of solutions we offer for any cataract challenge.

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Comparative optical-quality assessment of the Precizon Go intraocular lens with the standard monofocal Precizon Monofocal

David J Apple Center for Vision Research, University of Heidelberg, Germany. Data in file 2023.

OVERVIEW

Study Design
In vitro laboratory study to comprehensively evaluate the performance of the Precizon Go IOL and test it against the Precizon Monofocal IOL through various optical and visual quality metrics.

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

Patients
N/A

Methodology
Optical quality parameters such as modulation transfer function (MTF), phase transfer function (PTF) and optical transfer function (OTF) were assessed for an aperture size of 3.0 mm and 4.5 mm, using a cornea lens with 0.28 µm of spherical aberration at 5.15 mm. The weighted optical transfer function (wOTF) was also calculated, and from there postoperative logMAR visual acuity (VA) was predicted. IOL's tolerance to defocus was tested within a +1.0 D to -2.0 D range. A polychromatic point spread function (PSF) was used to assess the size of halos projected by the IOLs at a 4.5-mm aperture.

IOL Type(s)
Precizon Go, model 580 (Ophtec BV) & Precizon Monofocal, model 560 (Ophtec BV).

Key Endpoints
MTF, through-focus MTF, PTF, OTF, wOTF, predicted postoperative logMAR VA, tolerance to defocus and predicted size of halos.

ANALYSIS AND CONCLUSIONS

This study provides the first evidence that Precizon Go IOL can improve the patient's visual function at the intermediate range while ensuring high-quality distance vision.

This study demonstrates that Precizon Go provides good optical performance. The measured optical-quality parameters proved reproducible, confirming the high-manufacturing standards of the lens.

The halo pattern observed during the study predicts that Precizon Go has a low potential to induce significant photopic phenomena.

STUDY RESULTS

- The MTF curves at 4.5 mm show a partial overlap demonstrating a close optical quality between Precizon Go and Precizon Monofocal IOLs (0.19 ±0.01 vs 0.22 ±0.01) ***(Figure 1)***.
- The through-focus (TF) MTF curves at 50 lp/mm demonstrate a more extended TF area of Precizon Go compared to Precizon Monofocal, with a more extended peak width and a secondary peak at about -1.5D ***(Figure 2)***.
- LogMAR VA simulations demonstrate similar results for both IOLs at the far focus, with a peak close to -0.1logMAR. Moreover, a clear advantage of the Precizon Go IOL is shown within the defocus range of -0.50 D to -2 D. At -1.5D Precizon Go shows a predicted improvement of VA close to one-line (0.08 logMAR) over the Precizon Monofocal ***(Figure 3)***.

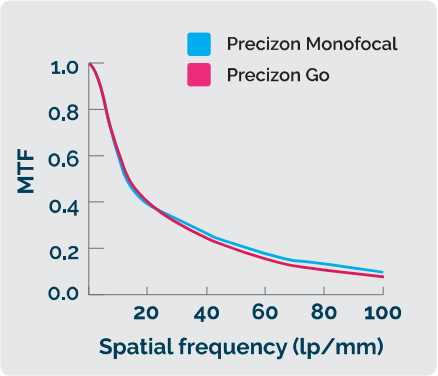

Figure 1. *MTF levels of the studied IOLs at the best focus for a 4.5-mm aperture.*

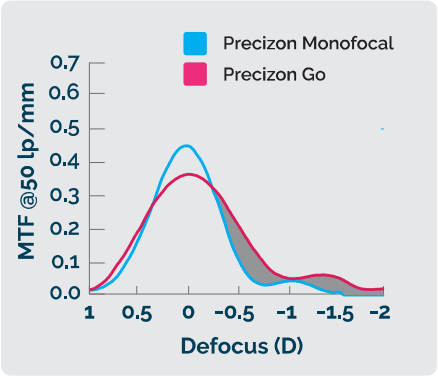

Figure 2. *Through-focus MTFs at 50 lp/mm assessed at 3 mm.*

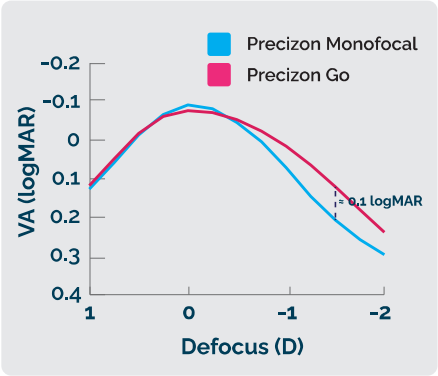

Figure 3. *LogMAR VA simulations as a function of spectacle defocus.*

Clinical outcomes after bilateral implantation of a new enhanced intermediate vision intraocular lens in cataract surgery

Multicenter study in Germany, Spain and South Korea. Data in file 2023.

OVERVIEW

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

Study Sites
Seven Multicenter studies in Germany, Spain and South Korea.

Patients
Fifty-two (52) eyes from twenty-six (26) patients bilaterally implanted with a Precizon Go IOL.

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

IOL Type
Precizon Go, model 580 (Ophtec BV)

Key Endpoints
1 month postoperatively: uncorrected and corrected distance visual acuity (UDVA, CDVA); best corrected distance intermediate visual acuity at 80 and 66 cm (DCIVA80, DCIVA66); manifest refraction spherical equivalent (MRSE); patient satisfaction and photic phenomena.

ANALYSIS AND CONCLUSIONS

Precizon Go implantation is a safe and effective method to provide cataract surgery patients with enhanced intermediate vision while maintaining excellent vision at distance.

Excellent patient satisfaction was observed with very low rate of photic phenomena.

STUDY RESULTS

VISUAL & REFRACTIVE OUTCOMES

- Mean monocular UDVA and CDVA were 0.92 ± 0.11 snellen and 1.00 ± 0.13 snellen, respectively ***(Chart 1)***.
- Mean monocular DCIVA at 80 and 66cm was 0.75 ± 0.14 snellen and 0.63 ± 0.11 snellen, respectively ***(Chart 1)***.
- 85% of eyes achieved a value of DCIVA of 20/25 snellen (0.1 LogMAR) or better at 80 cm and 92% achieved 20/32 snellen (0.2 LogMAR) or better at 66cm.
- Mean MRSE at 1 month post-op was -0.15 ± 0.29 D ***(Chart 2)***.

PATIENT REPORTED OUTCOMES

- 100% and 96% of patients reported that they were very satisfied or satisfied with their far and intermediate vision respectively
- 85% of patients reported that they "never" experienced halos or glare.

Parameter	Preop (N=52)	1 month post-op (N=52)
UDVA		
Mean ± SD	0,47 ± 0,17	0,92 ± 0,11
Range	0,10 , 1,00	0,63 , 1,00
CDVA		
Mean ± SD		1,00 ± 0,13
Range		0,80 , 1,25
DCIVA@66		
Mean ± SD		0,63 ± 0,11
Range		0,40 , 1,00
DCIVA@80		
Mean ± SD		0,75 ± 0,14
Range		0,32 , 1,00

Chart 1. *Postoperative monocular visual acuity (snellen) results at 1 month*

Parameter	Preop (N=52)	1 month post-op (N=52)
Sphere (D)		
Mean ± SD	0,77 ± 1,68	0,04 ± 0,31
Range	-4,0, +3,25	-0,75, 1,00
Refractive cylinder (D)		
Mean ± SD	-0,66 ± 0,48	-0,38 ± 0,36
Range	-2,00, 0,00	-1,50, 0,00
SE (D)		
Mean ± SD	0,44 ± 1,74	-0,15 ± 0,29
Range	-4,75, +3,13	-0,88, 0,50

Chart 2. *Monocular refractive and visual acuity results at pre-operative and 1 month*

Decimal	LogMAR	Snellen (Feet)	Snellen (Meters)
1.25	-0.1	20/16	6/4.8
1.0	0.0	20/20	6/6
0.8	0.1	20/25	6/7.5
0.63	0.2	20/32	6/9.5

Chart 3. *Visual acuity conversion chart*

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