Sulcoflex® Platform:
A journey through supplementary IOLs and 12 years of clinical history

M. Amon

Head: Academic Teaching Hospital of St. John
Chair: Sigmund Freud University; Vienna

Financial disclosure:

Alcon

Bausch & Lomb

Geuder

Johnson & Johnson

Morcher

Rayner: Inventor of Sulcoflex

Zeiss Meditec

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Material and Design

Surgery

Results

Conclusion

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Material and Design:
The History of Sulcoflex®

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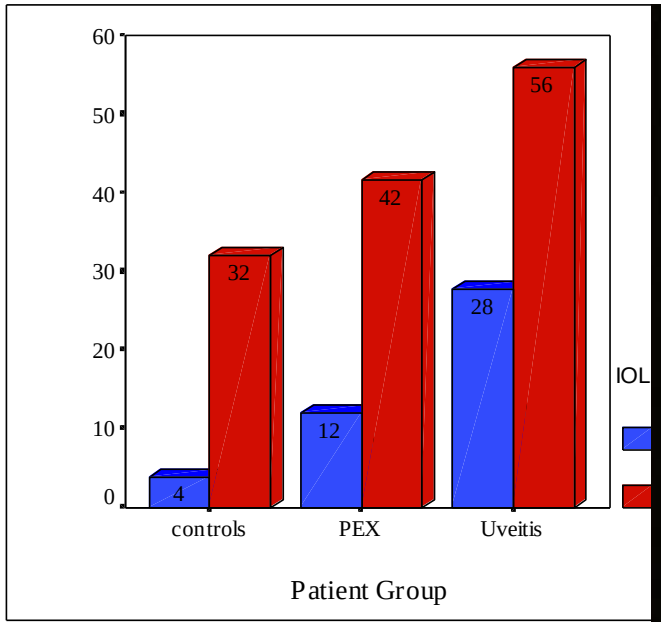
Uveal and Capsular Biocompatibility of Intraocular Implants

Hydrophilic Rayacryl:
HEMA-MMA copolymer
long term experience (>20 a)

Superb uveal biocompatibility



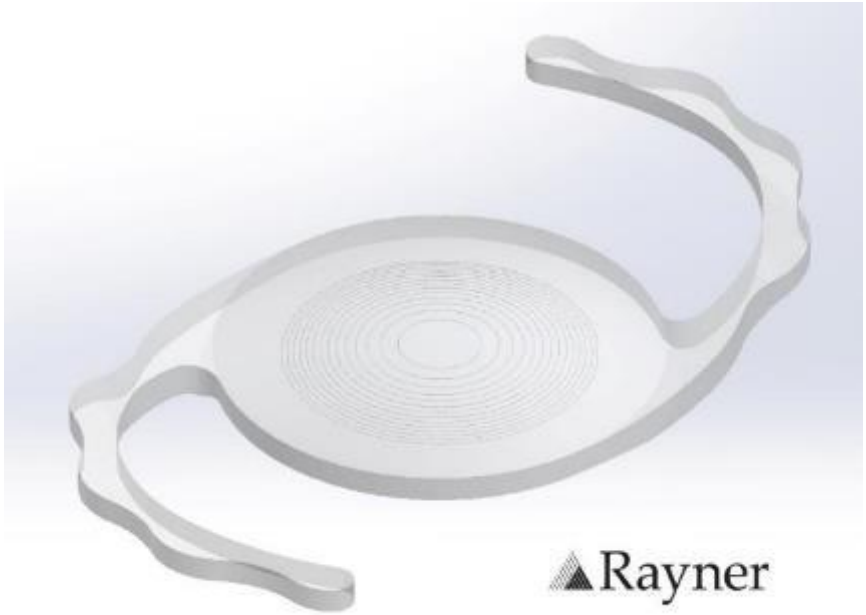
C. Abela, M. Amon, et al. Uveal and capsular biocompatibility after implantation of hydrophilic-acrylic, hydrophobic-acrylic and silicone intraocular lenses *J Cataract Refract Surg 2002* 28/1; 50-61

S. Richter-Müksch, G. Kahraman, M. Amon, et al. Uveal and capsular biocompatibility after implantation of sharp-edged hydrophilic acrylic, hydrophobic acrylic and silicone IOLs in eyes with PEX-syndrome J Cat Refract Surg 2007 33; 1414-1418

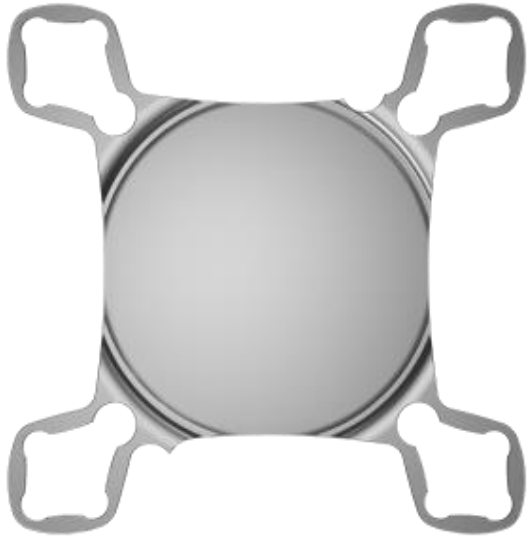
Additive IOLs available

Cristalens Reverso ®

Rayner Sulcoflex ®



1st Q ®



„Exotic“ IOLs:

Morcher: Extended depth of focus-IOLs
iOLAMD Eyemax®: Magnification x 1.3 (hyperaspheric optic)
1st Q ® SML

“off label” IOLs

production stopped: HumanOptics MS 714 PB®

“off label” ICL
anterior vaulting

Correction of residual refractive error in pseudophakic eyes with the use of a secondary piggyback toric implantable collamer lens; J.Cat.Refract.Surg. 26/19; 766-769; 2010

The History of Sulcoflex®

- 1991 first publication on uveal and capsular biocompatibility
- 1998 idea and invention of a single-piece hydrophilic add-on IOL
- 2000 contact and cooperation with Rayner to design Sulcoflex
- 2004 first prototype
- 2007 worlds first implantation of Sulcoflex
- 2007 first presentation at ESCRS
- 2008 toric, multifocal and multifocal/toric (bifocal, refractive) IOLs
- 2018 worlds first implantation of the new trifocal Sulcoflex

Cellular invasion on hydrogel- and poly(methyl methacrylate) implants. An in vivo study
M. Amon, et al. Journal of Cataract and Refractive Surgery, Vol. 17: 774-779. 1991
Uveal and capsular Biocompatibility of Intraocular Implants
M. Amon. J. Cat. Refract. Surg. 27/2; 178-179: 2001
Sulcoflex: a new IOL concept for the pseuophakic eye
M. Amon. Ophthalmology Times, 2007

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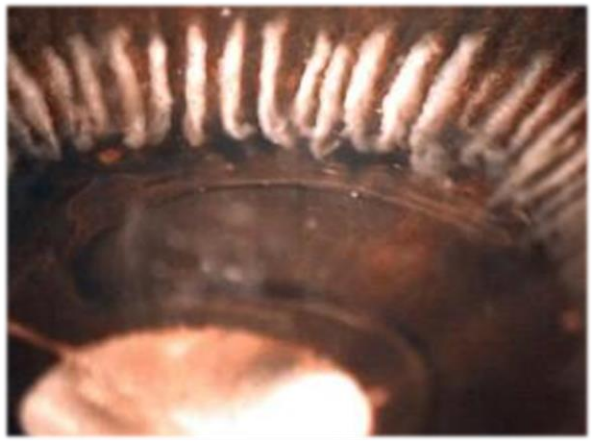
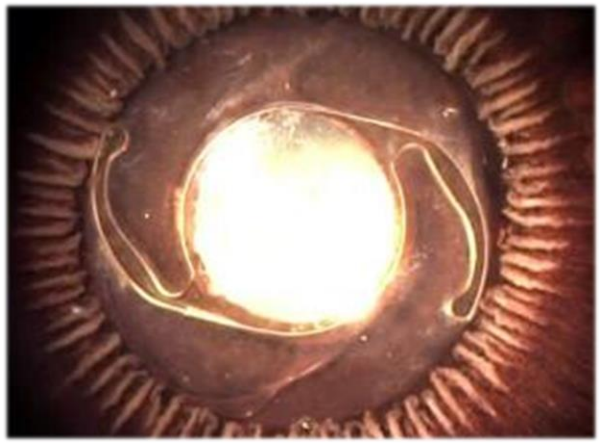
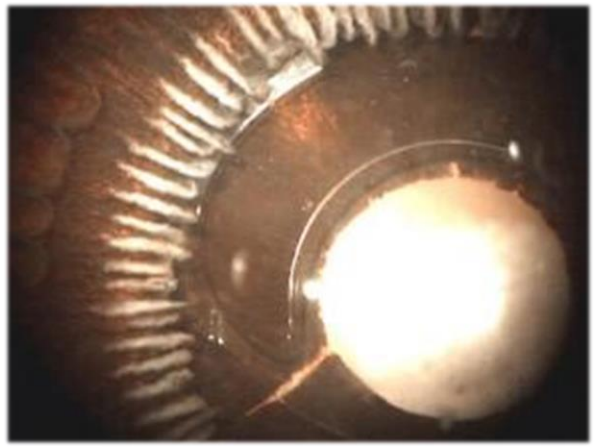
Cadaver Eye Study:

- appropriate sulcus fixation
- appropriate centration
- minimal interaction with uveal tissue
- minimal interaction with in-the-bag IOL

Werner L., ESCRS 2011 Istanbul

Optical bench study:

- same reflections from additional interfaces
- two IOLs similar optical quality to single IOL
- additional lightloss less than 1%

Effect of interface refelection in pseuophakic eyes with an additional refractive intraocular lens
Jens Schrecker, Katja Zoric, Arthur Messner, Timo Eppig
J Cat Refract Surg; 38/8; 1650-1656

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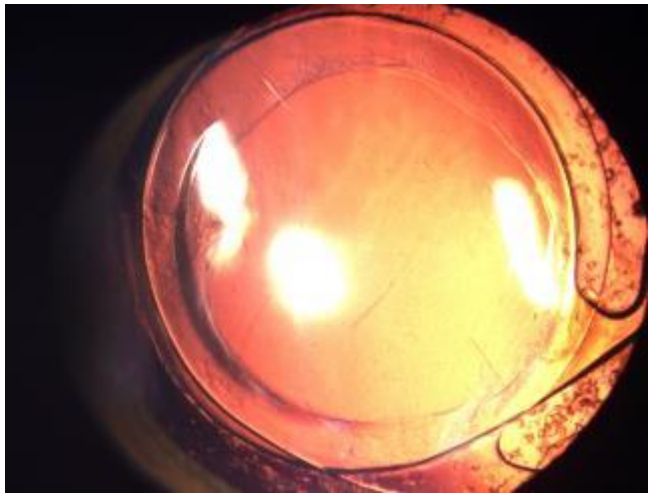
Results: Rayner Sulcoflex®

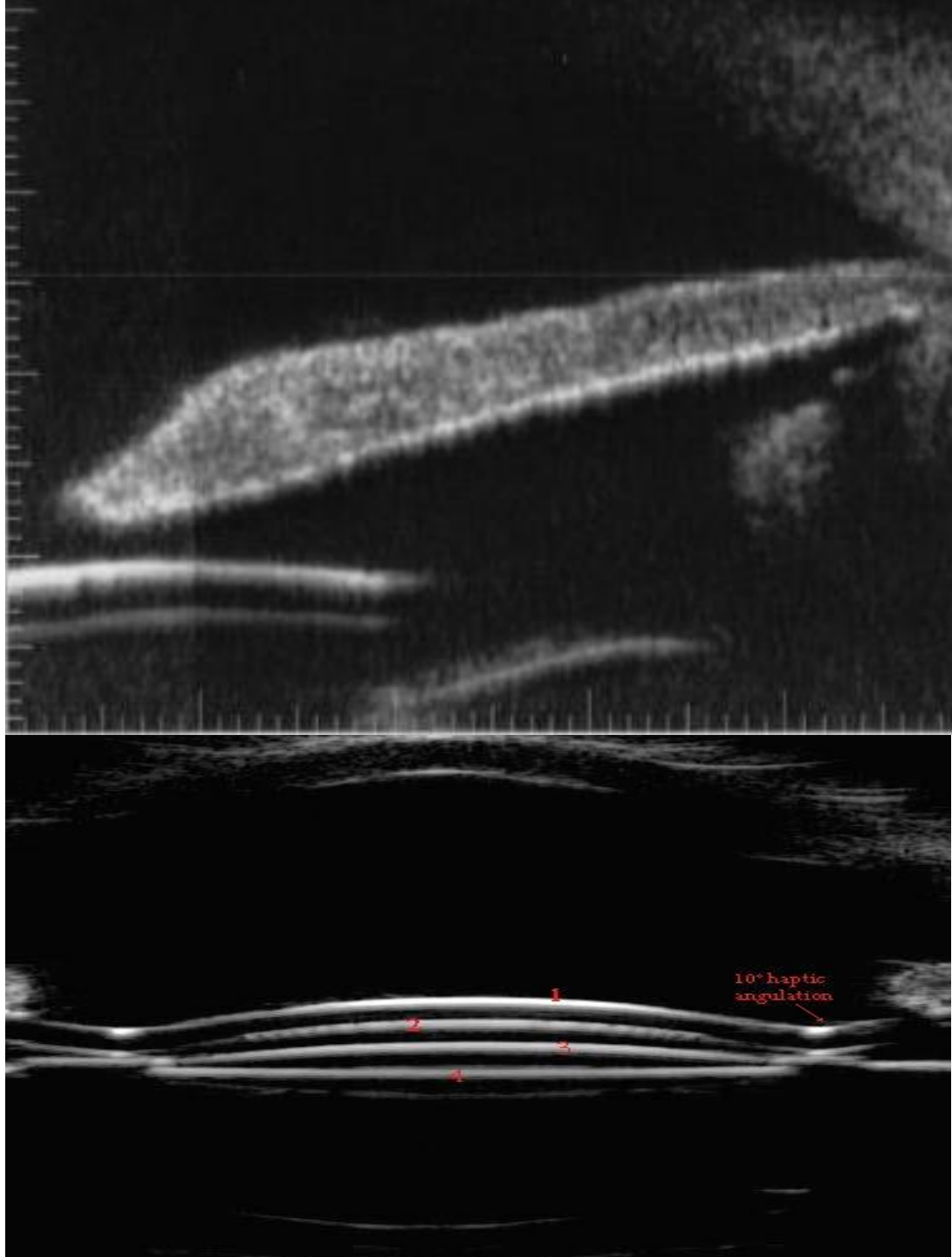
- n: 200 eyes/ 12 years follow-up
- refr. mf, toric, mf/t, monofocal
- LFCM: < than after phaco
- Iris trauma: 0
- Pigment dispersion syndrome: 0
- Interlenticular opacification: 0



Kahraman G, Amon M "Sulcoflex: A new supplementary intraocular lens for pseudophakic refractive errors
J. Cat. Refract. Surg. 2009

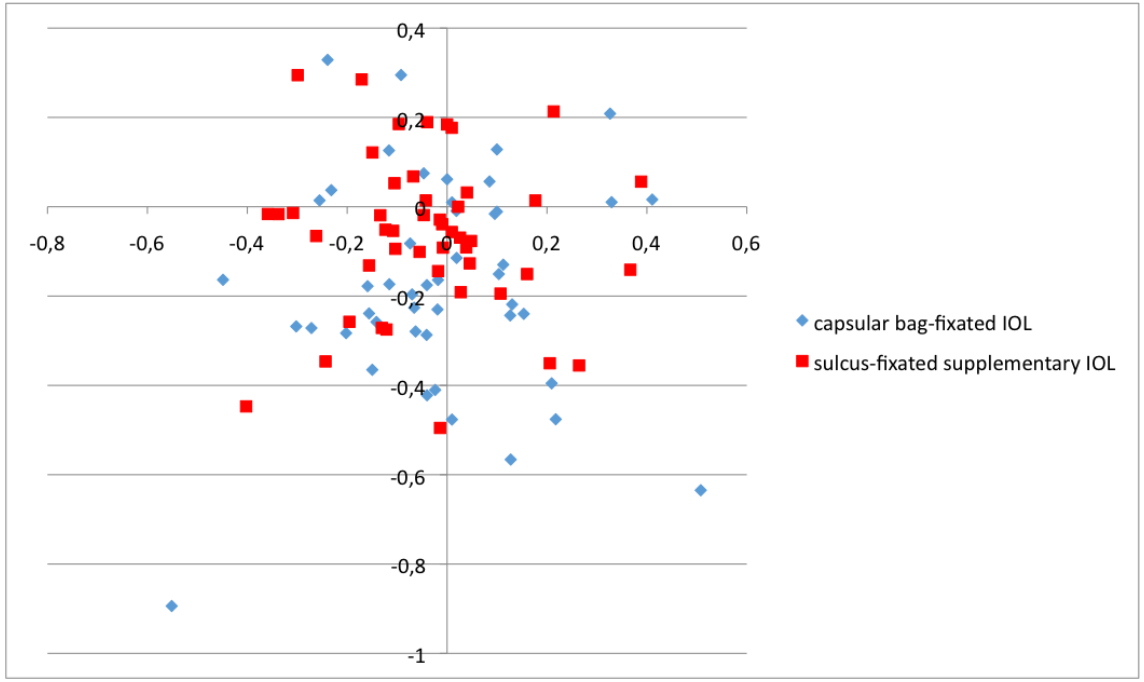
Results: Rayner Sulcoflex®

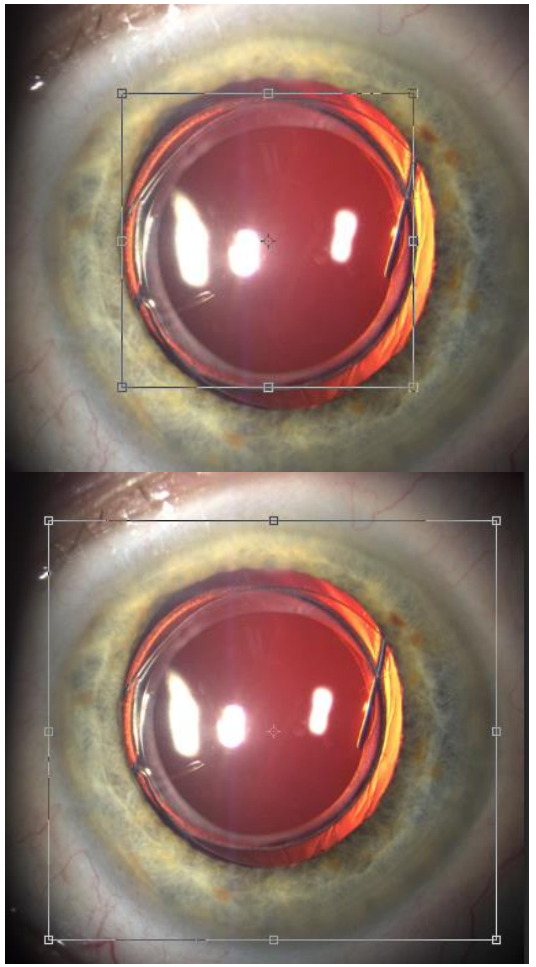
- positive iris-distance: 100%
- positive central optic-distance: 100%
- optic capture: 0
- pupil ovalisation: 0
- UCVA: 0.9
- refraction: +/- 0.25dpt



Kahraman G, Amon M "Sulcoflex: A new supplementary intraocular lens for pseudophakic refractive errors
J. Cat. Refract. Surg. 2009

Centration Study: Rayner Sulcoflex®





Decentration compared to the **center of the pupil** in mm
max. decentration capsular bag: 1,05 mm
max. decentration sulcus: 0,6 mm
Statistically significant better centration of ciliary sulcus fixated IOLs

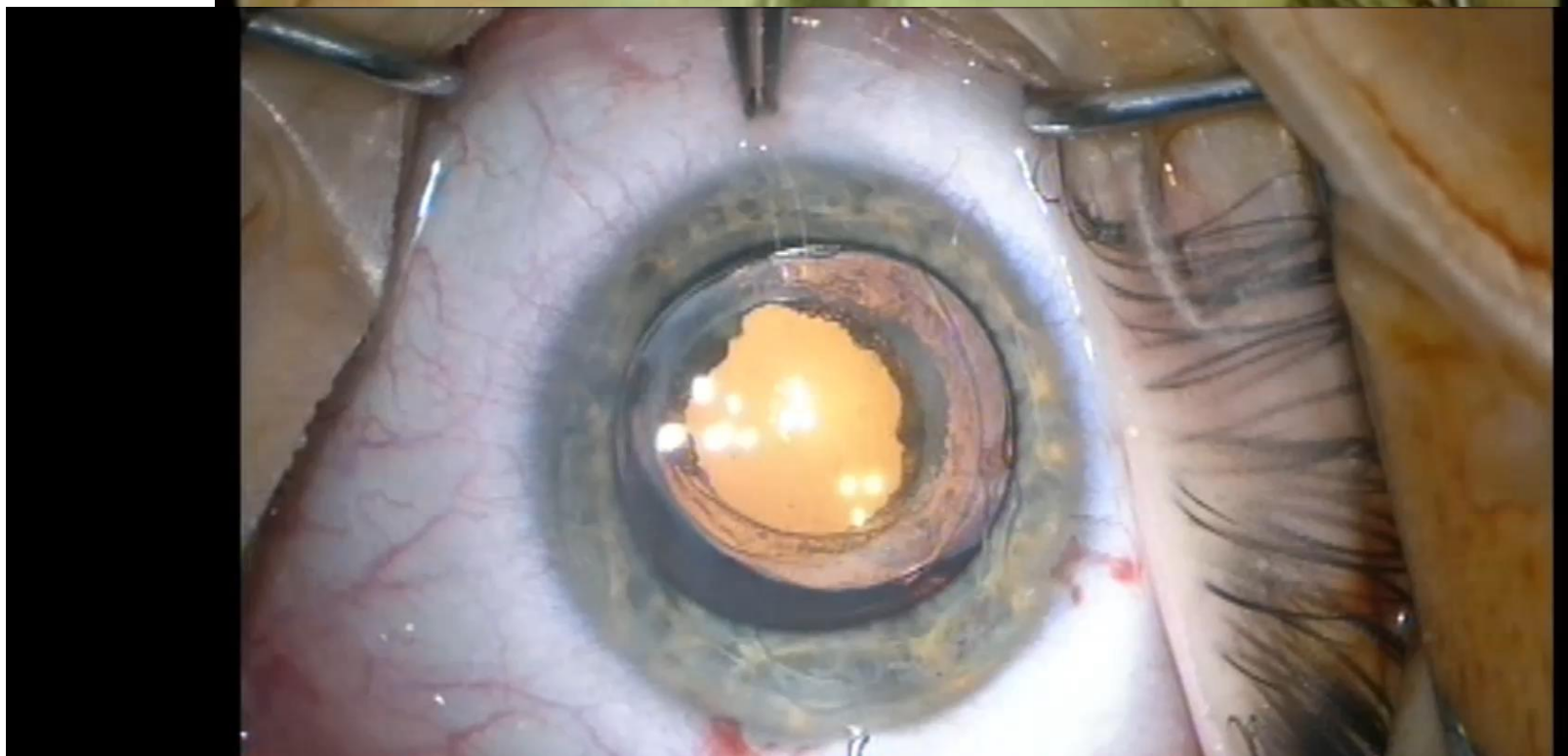
Prager F, Kahraman G, Wiesinger J, Wetzel B, Amon M. J. Cat. Refract. Surg. 2017

Specific indications
“Dynamic refraction”

- pediatric cataract

(refractive exchange of supplementaty implant RESI)

- silicone oil
- corneal/scleral alteration



Conclusion after 12 years

Supplementary IOLs are effective for secondary enhancement of the surgical result
and for primary “Duet implantation”

They represent a reversible or exchangeable technology for the future

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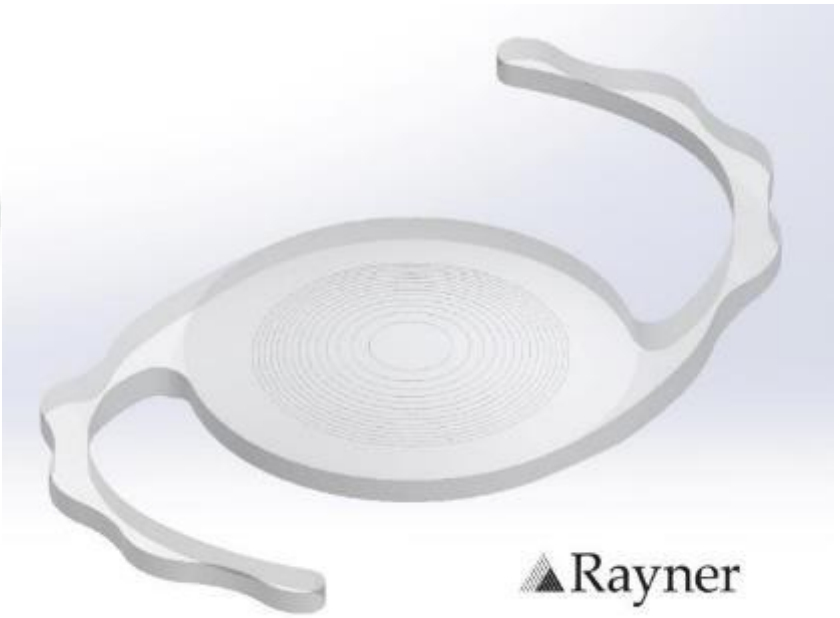
Next step: create first diffractive trifocal add-on IOL

RayOne® Trifocal has fewer rings on the IOL optic surface
for **reduced potential visual disturbances and improved night vision.**

Features:
- 16 diffractive steps / rings
- 4.5 mm diffractive zone
- > 4.5 mm monofocal, distance

Benefits:
- Reduces visual disturbances
- Developed to be less dependent on pupil size or lighting conditions
- Improves distance vision in mesopic condition



Surgery

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IOL calculation for secondary implantation

- R-vergence formula:

  sph. equivalent of ametropia, K-values, ACD

- postop ametropia within +/- 7 D:

  hyperopia:

  sph. equivalent x 1.5

  myopia:

  sph. equivalent x 1.2

IOL calculation for Duet-procedure

- in the bag IOL: monofocal, toric/monofocal
  any IOL-type (IOL neutral aspheric)
  emmetropia (“closest minus”)

- Sulcoflex: distance 0 dpt

- routine biometry, no change of any constant

150
180
30
60
90
120
150
0

Results

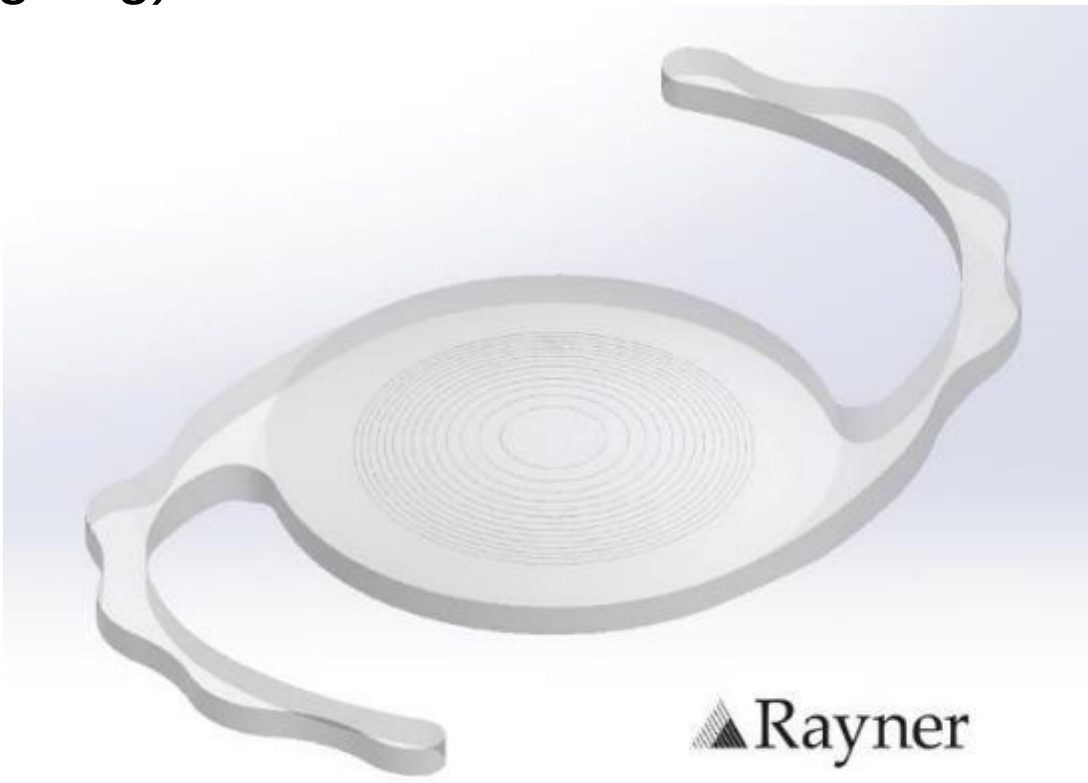
Initial Trial: Duet-implantation

Worlds first implantation:
30. 7. 2018

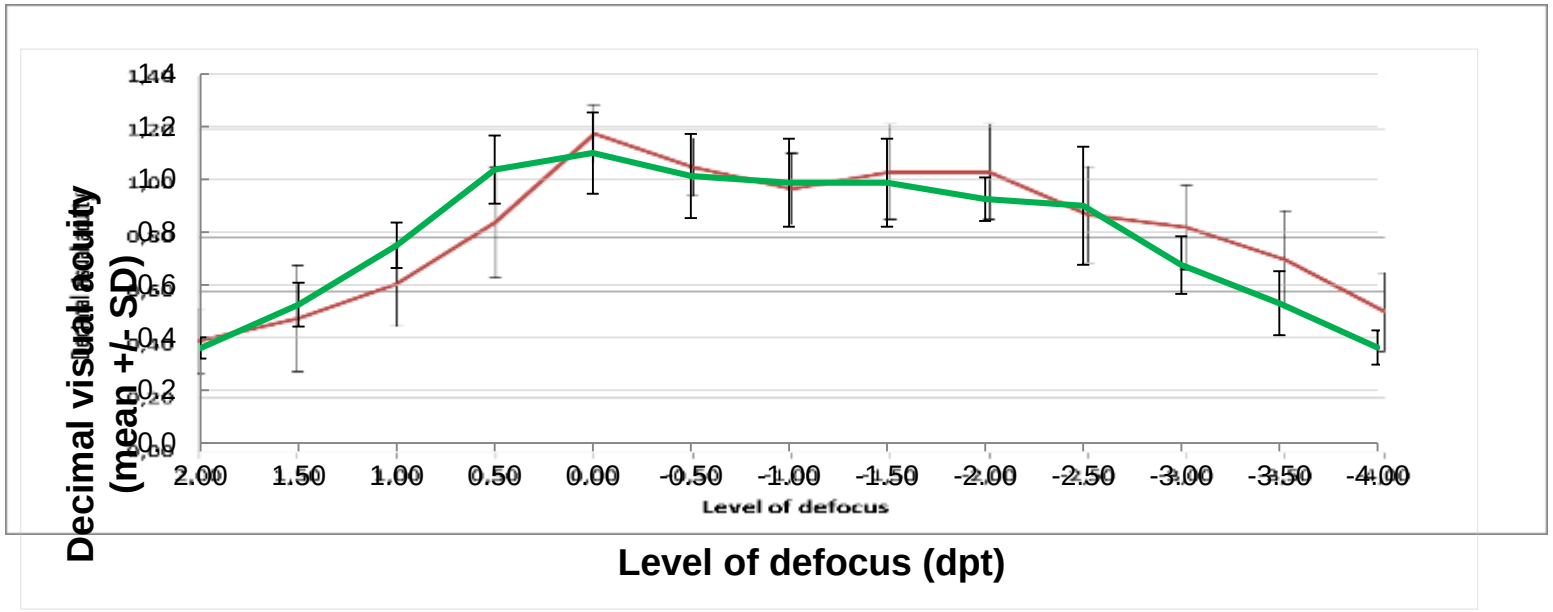
Duet-implantation: 40 eyes
implantation in pseudophakic eye: 40 eyes (ongoing)

bilateral surgery
follow-up: 6 months
single surgeon
postop refraction: 0

EU Trial: 68 eyes



Binocular defocus curve



RayOne tri

Sulcoflex tri

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Conclusion

- Excellent visual acuity results across all distances
- All patients were satisfied with their distance, intermediate and near vision
- No surgical and postop-complications
- Preliminary data of EU-studie support our data
- Results are comparable to trifocal “in the bag“ IOLs at least

But:

- Supplementary IOLs offer an adaptive option

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Secondary enhancement

Option of “finetuning“ with 0.25 dpt steps
All patient should get detailed information about potential dysphotopsia

Conclusion

Option of finetuning (0.25 dpt steps)

Option of specific IOL-combination:

asphericity, torus, material for bag-IOL,…

Need of uturefixation:

in case of toric IOL rotation

Option of exchange for future IOL-solutions

Early explantation: photopic phenomena, fine-tuning

Late explantation: AMD, DME,…

Conclusion

Main indications today:

In phakic patients: Multifocal Duet-implantation

In pseudophakic patients: Multifocal enhancement

Biometrical surprise

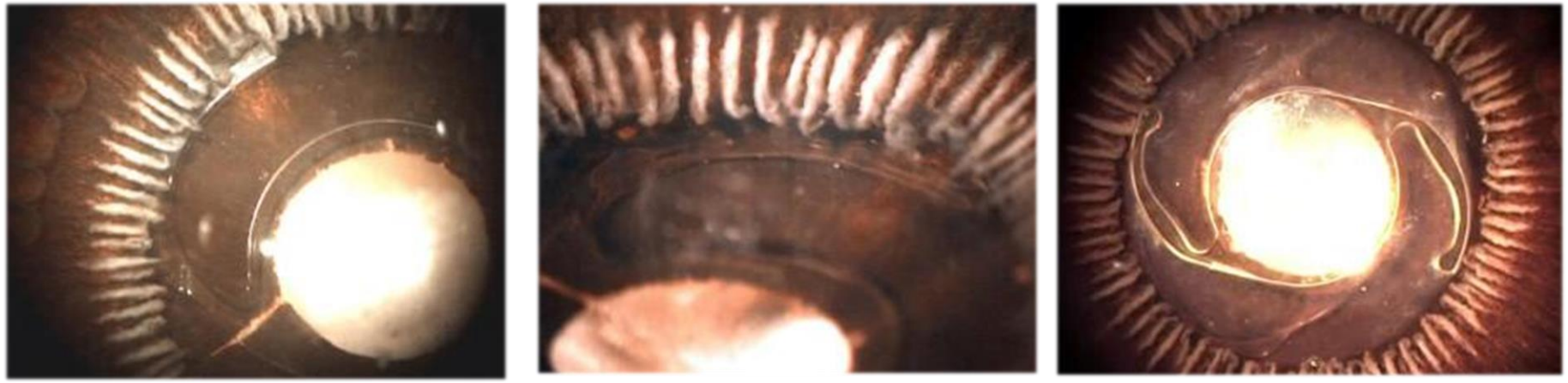
Sophisticated

Adjustable

Flexible

Effective

Cadaver Eye Study:



Werner L., ESCRS 2011 Istanbul
Effect of interface refelection in pseuophakic eyes with an additional refractive intraocular lens

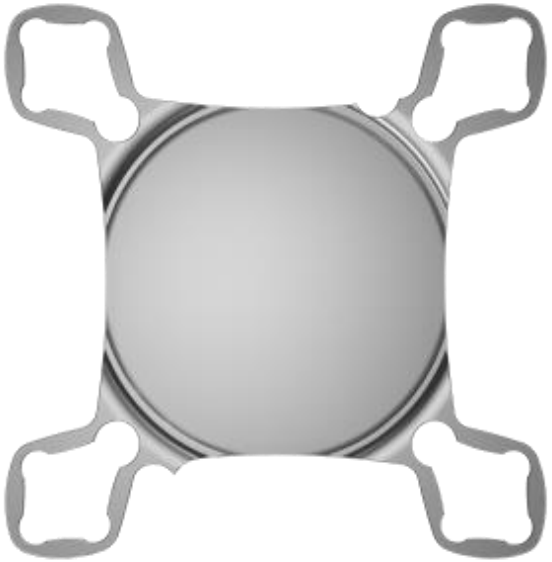
- Viable method to correct residual refractive error after primary IOL implantation

Toric Study: 1st Q A4W ®

- 90% residual error below 0.5dpt

- No intra- and postoperative complication

- Retrospective study



A REVIEW OF RESULTS AFTER IMPLANTATION OF A SECONDARY INTRAOCULAR LENS TO CORRECT RESIDUAL REFRACTIVE ERROR AFTER CATARACT SURGERY: K. GUNDERSEN ET AL.; CLINICAL OPHTHALMOLOGY; 11, 1791-1796; 2017

Centration Study: Rayner Sulcoflex®

Decentration compared to the **center of the pupil**
max. decentration capsular bag: 1,05 mm
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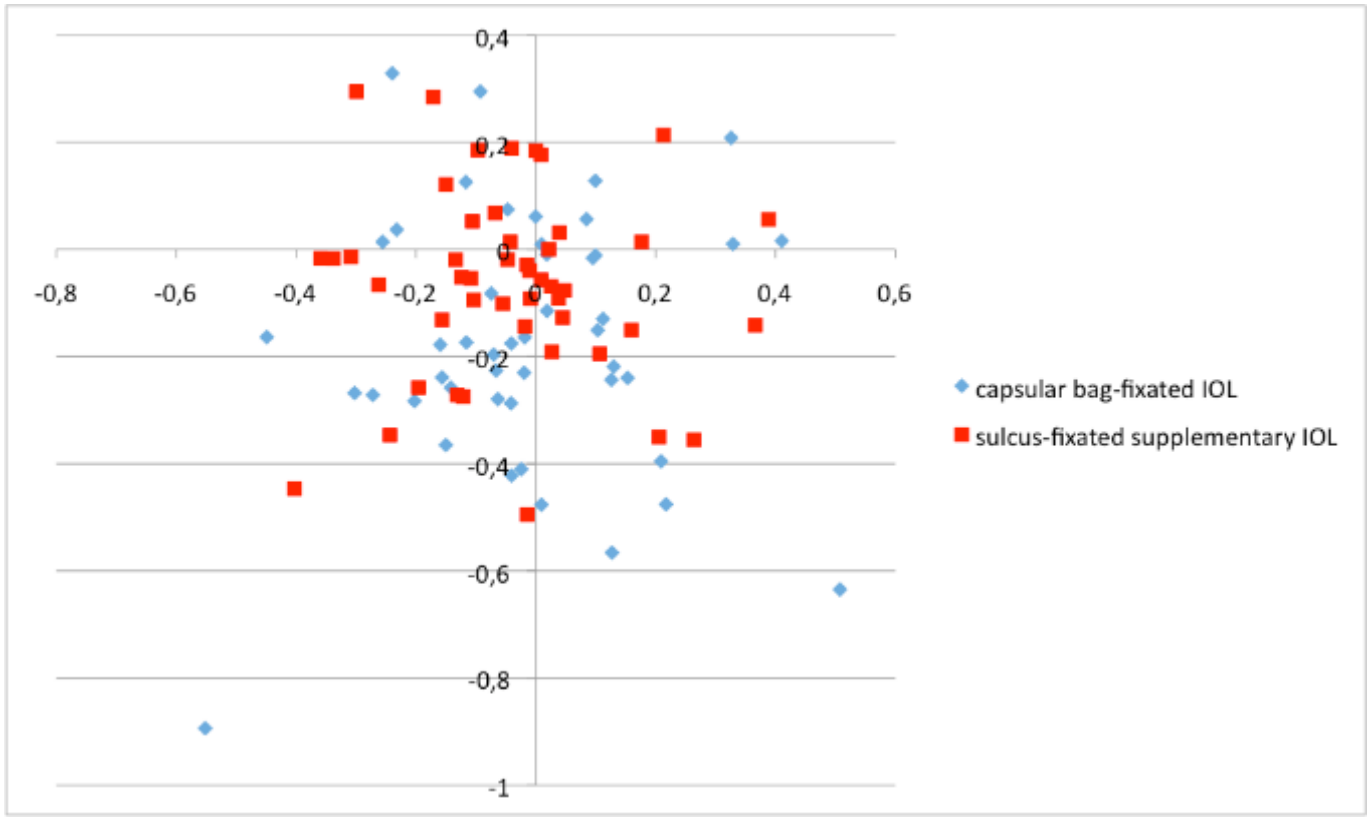
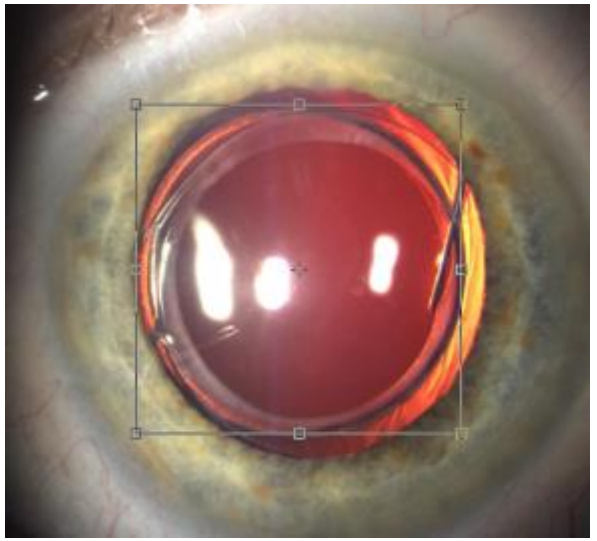
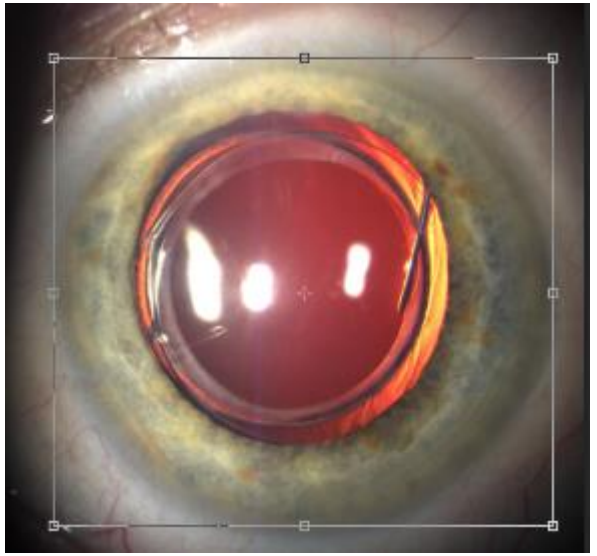
Statistically significant better centration of ciliary sulcus fixated IOLs







Prager F, Kahraman G, Wiesinger J, Wetzel B, Amon M. J. Cat. Refract. Surg. 2017

Comparison of optical performance and patient satisfaction with an Extended Range of Vision IOL and a trifocal IOL: A randomized prospective study

Guenal Kahraman
Franz Prager
Barbara Wetzel
Clemens Bernhart
Michael Amon

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Dept. of Ophthalmology Academic Teaching Hospital of St. John
Sigmund Freud Private University
Vienna, Austria

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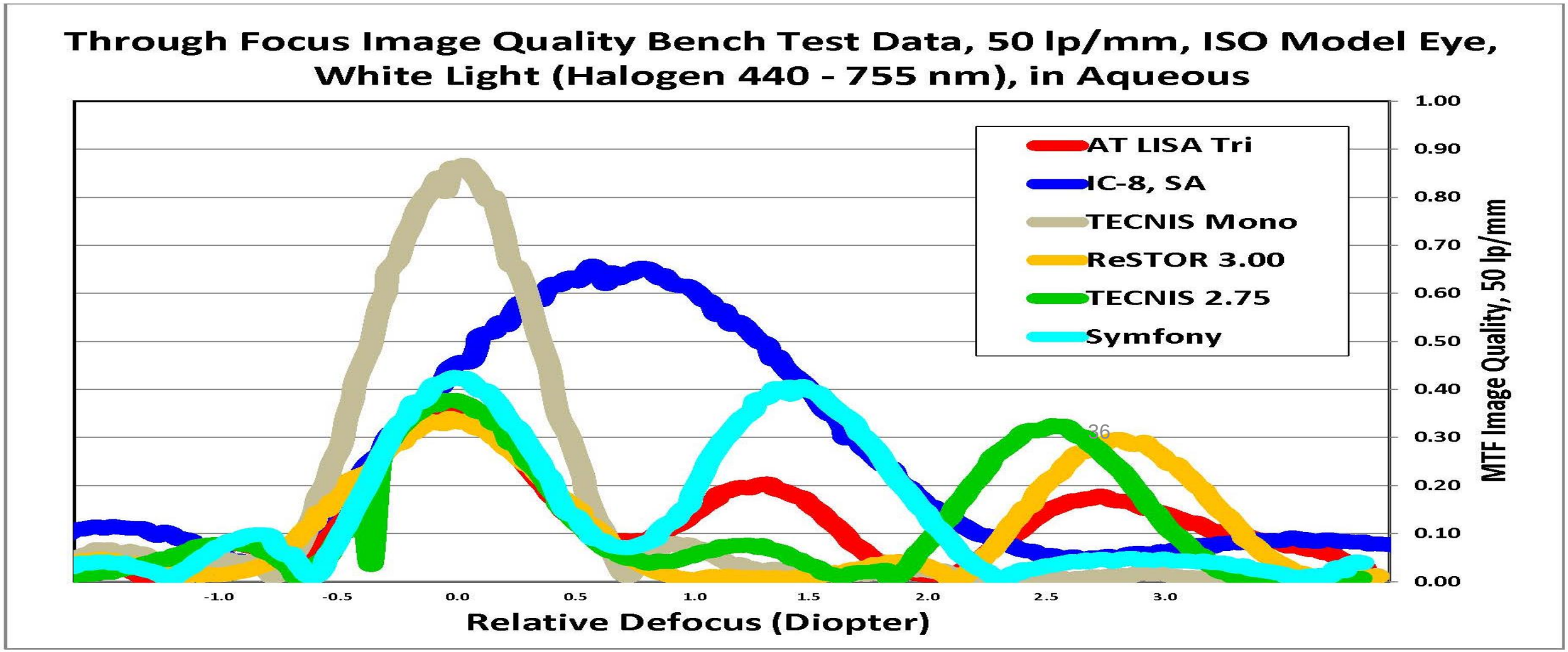
Distinct Single Focus

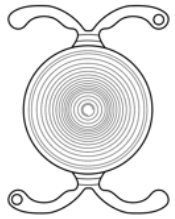
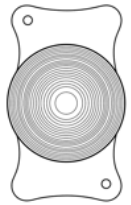
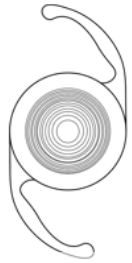
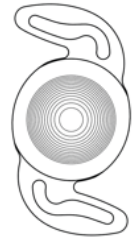
Two Distinct Foci

Elongated Focus

Image Quality of 6 different IOLs

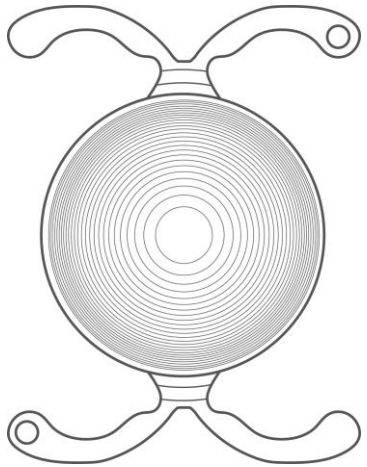


Comparison of Trifocal Technology

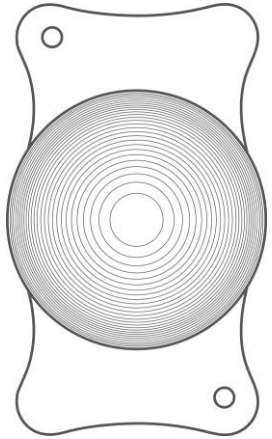
	PhysIOL FineVision	Zeiss AT LISA Tri	Alcon PanOptix	Rayner Trifocal
				
Diffractive Technology	Diffractive Apodized Trifocal across full optic surface	Diffractive Trifocal up to 4.34 mm thereafter bifocal	Diffractive Trifocal up to 4.5 mm thereafter monofocal	Diffractive Trifocal up to 4.5 mm thereafter monofocal
Diffractive Steps	26 diffractive steps	29 diffractive steps 0.0 D	15 diffractive steps	16 diffractive steps
Diffractive Orders	0, 1, 2	0, 1, 2	0, 2, 3 (non-sequential)	-1, 0, 1
Light Loss 3.0 mm pupil	14%	14.3% (Ave.)	12%	11%
Light Energy Split 3.0 mm pupil	49% D / 18% I / 34% N	50% D / 20% I / 30% N	42% D / 24% I / 22% N (includes 12% light loss)	52% D / 22% I / 26% N
Optic Add Powers	+3.50 D Near add +1.75 D Intermediate add	+3.33 D Near add +1.66 D Intermediate add	+3.25 D Near add +2.17 D Intermediate add	+3.50 D Near add +1.75 D Intermediate add
Reading Distance	37.5 cm 75.0 cm	40.0 cm 80.0 cm	42.0 cm 60.0 cm	37.5 cm 75.0 cm

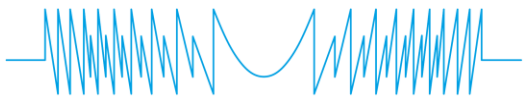
Comparison of Trifocal Technology

PhysIOL FineVision

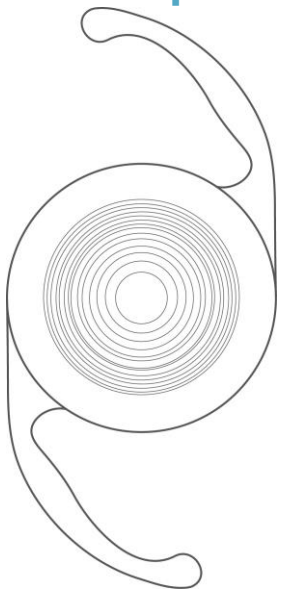


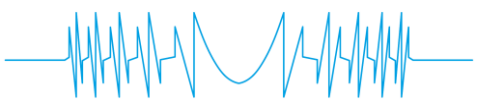
Zeiss AT LISA Tri



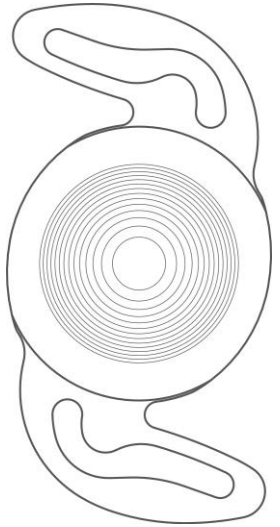


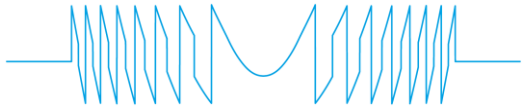
Alcon PanOptix



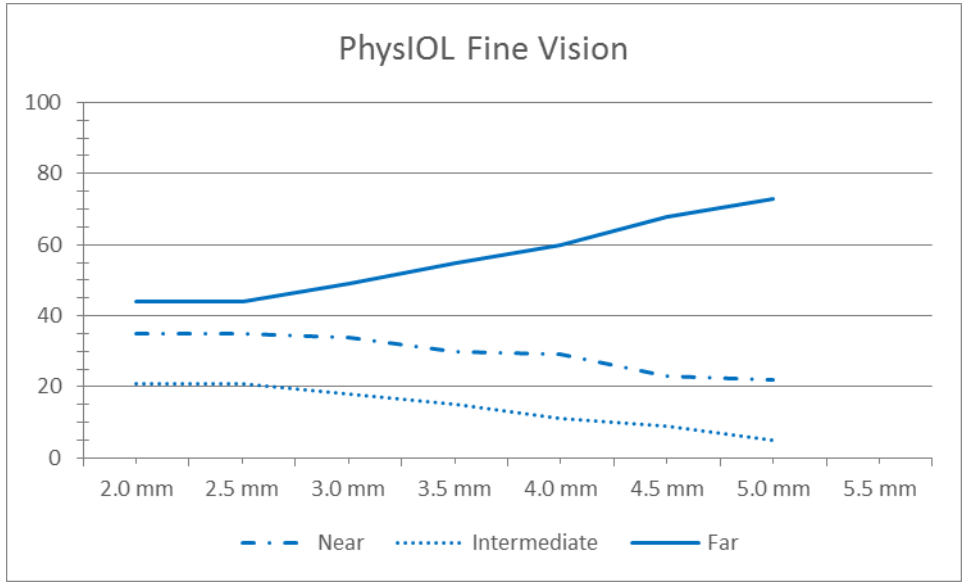


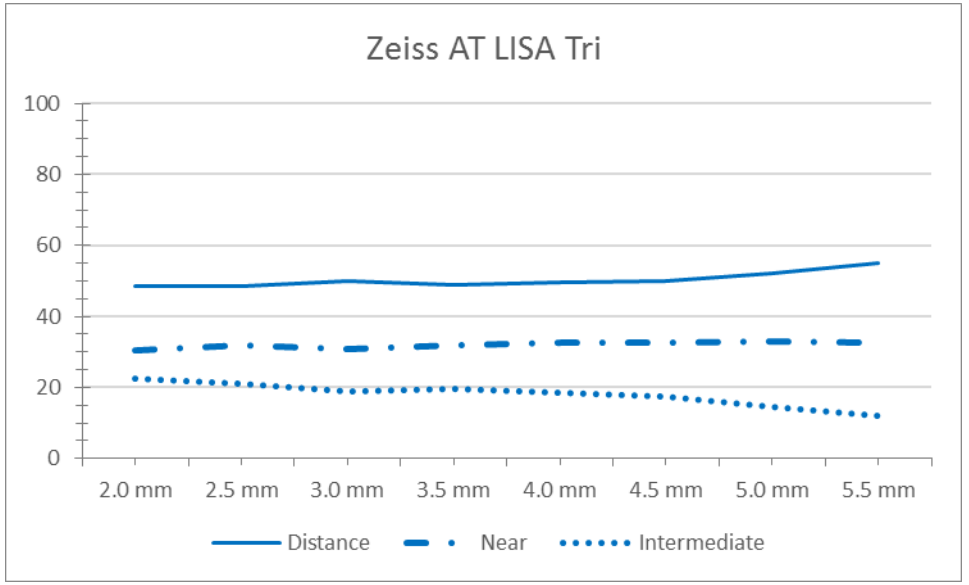
Rayner RayOne Trifocal

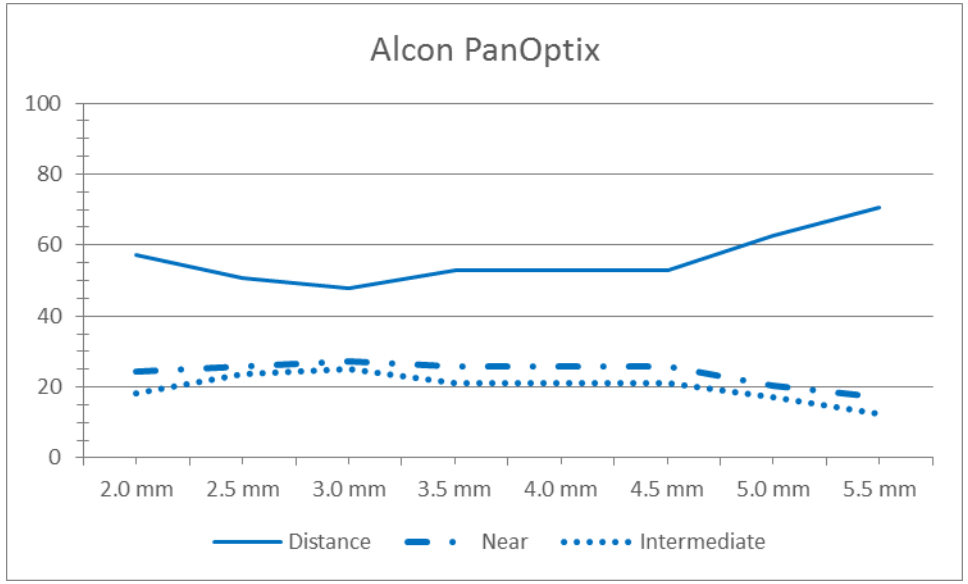


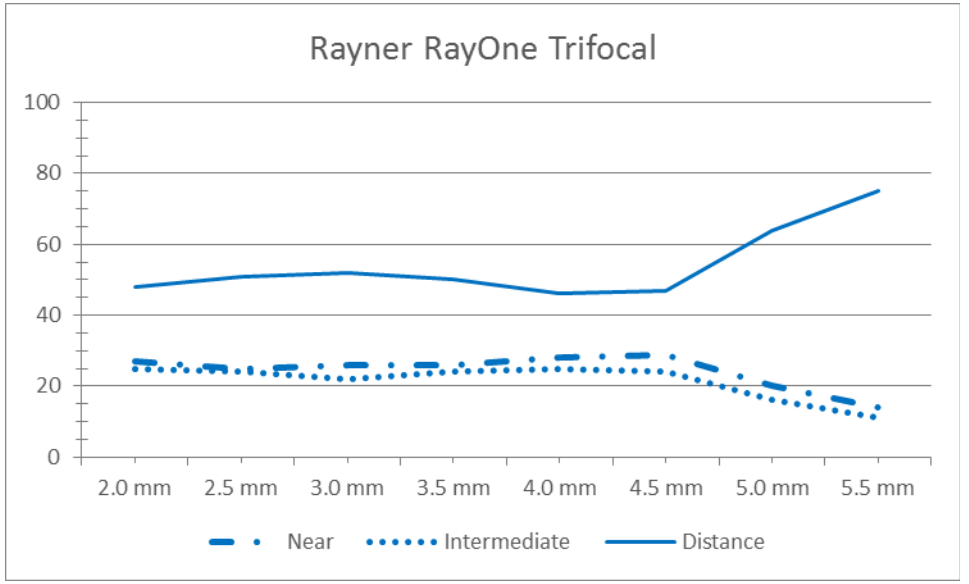


Competitor Source: Respective owners published marketing materials, graphical representations only of lenses and diffractive patterns



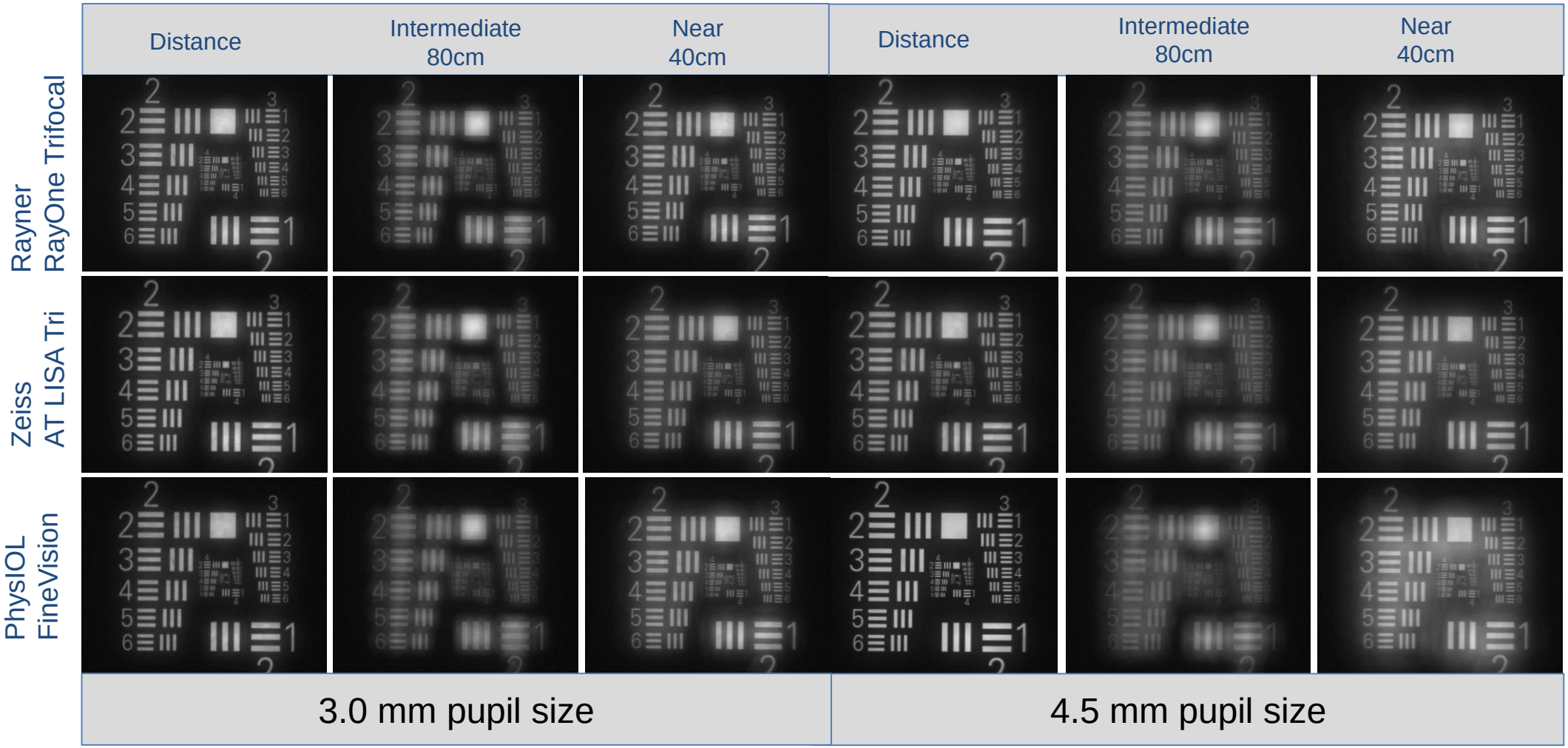




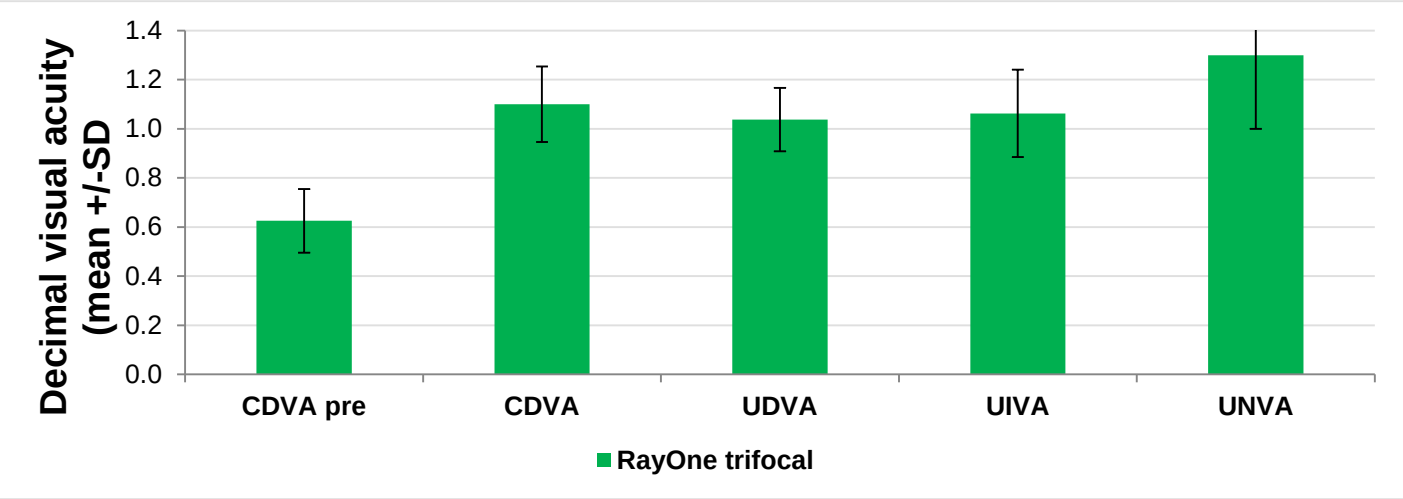


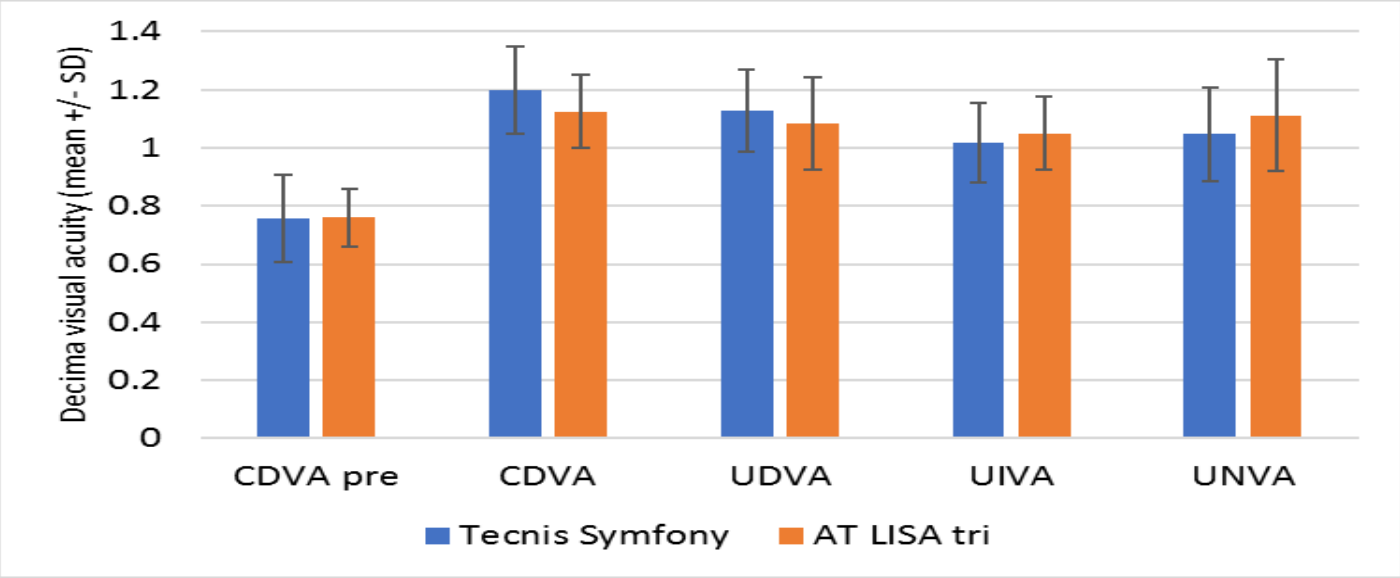
Competitor Source: Respective owners published marketing materials, Rayner test data held on file

USAF 1951 target charts



Visual Acuity





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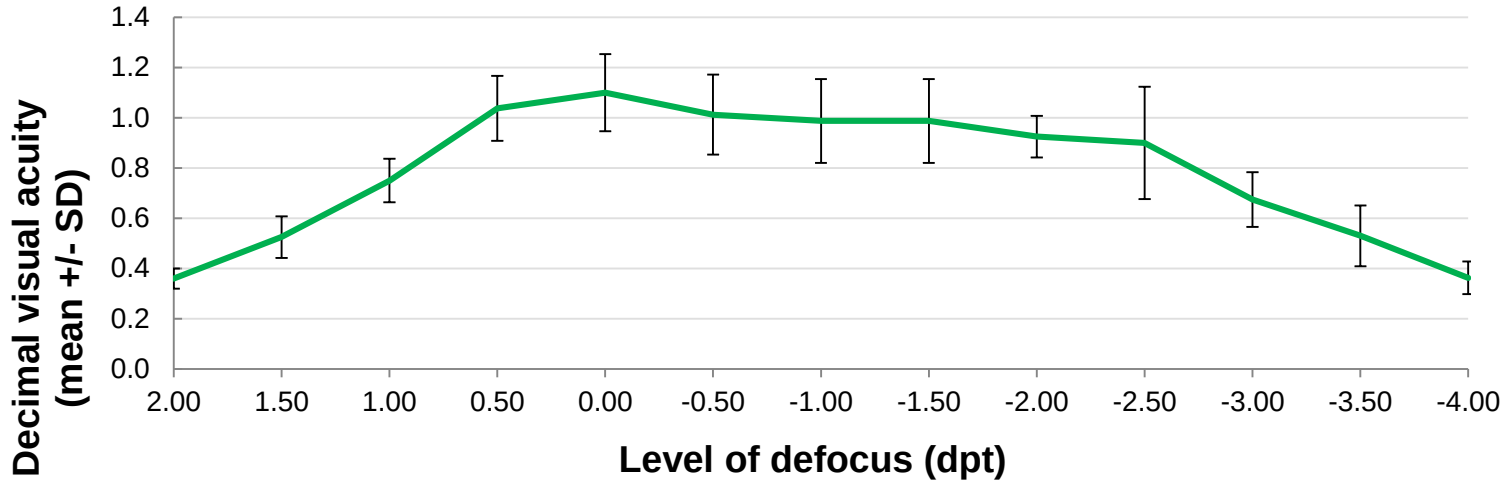
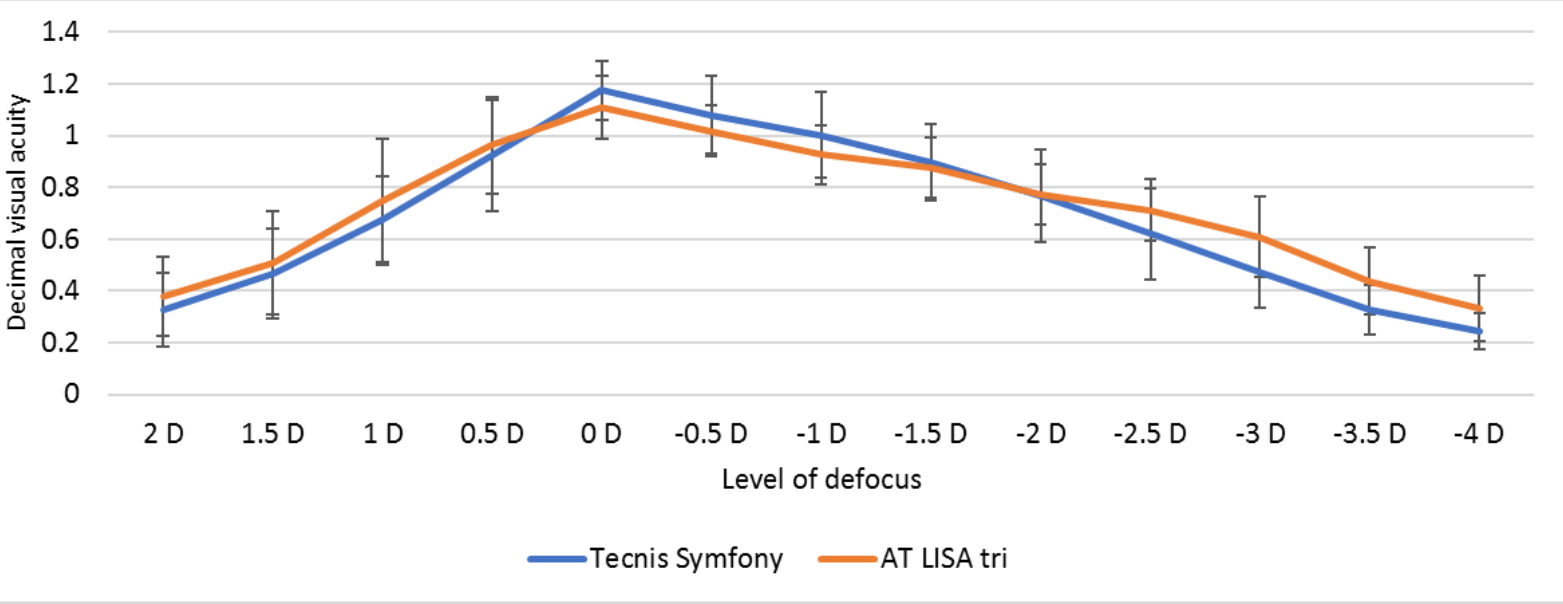
Binocular Defocus Curve





Medizinische Fakultät der Sigmund Freud Privatuniversität

BARMHERZIGE BRÜDER
KRANKENHAUS WIEN

EU TRIAL: CLINICAL RESULTS - SULCOFLEX TRIFOCAL

Multicentre evaluation assessing Visual acuity, contrast, defocus and patient satisfaction in pseudophakic patients with bilaterally implanted supplementary Sulcoflex Trifocal intraocular lenses

Prospective pilot study in pseudophakic patients

- Multicentre, 7 sites in Europe
- Multi-surgeon 7 surgeons
- Total of 68 eyes (34 patients)

FIRST RESULTS AND VISUAL PERFORMANCE

68 eyes (34 patients) underwent bilateral Sulcoflex Trifocal implantation

End Measures:

- Post operatative Subjective Refraction (SE, Sph, Cyl)

Monocular and Binocular VA (LogMar):

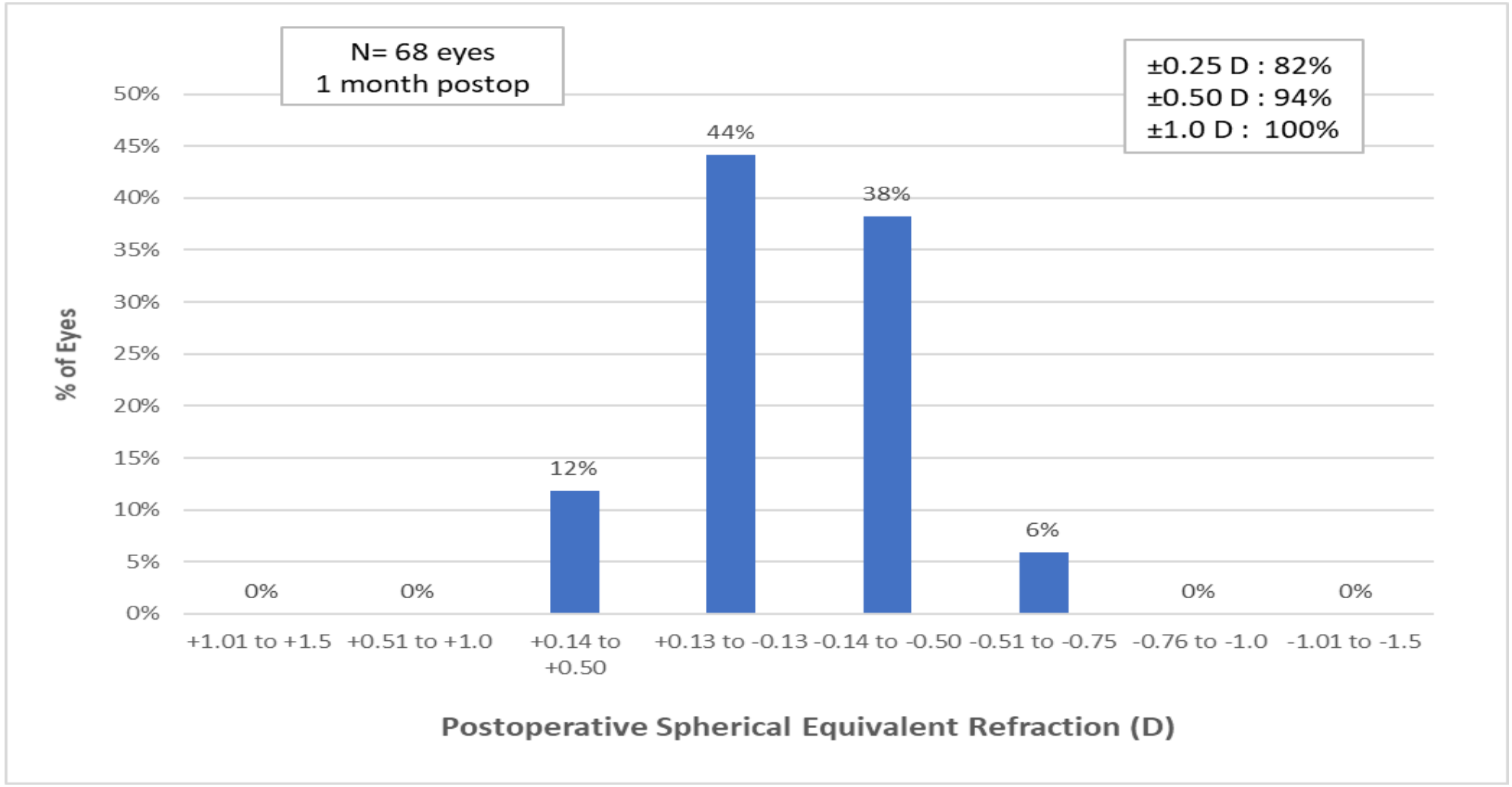
- Uncorrected Distance (UCVA) and Best Corrected Distance Visual Acuity (CDVA)
- Uncorrected Near (UNVA) and Distance Corrected Near Visual Acuity (DNVA)
- Uncorrected Intermediate (UIVA) and Distance Corrected Intermediate Visual Acuity (DNVA)
- Contrast sensitivity with F.A.C.T charts
- Defocus curve from -4.00 D to +2.00 D
- Patient satisfaction with a self-administered questionnaire (Likert Scale)
- Complications/AE

EXCLUSION CRITERIA:

- Previous ocular surgery
- Regular corneal astigmatism greater than 0.75 D
- Irregular astigmatism and corneal opacities
- Glaucoma with impairment of GCL and RNFL
- Macular diseases

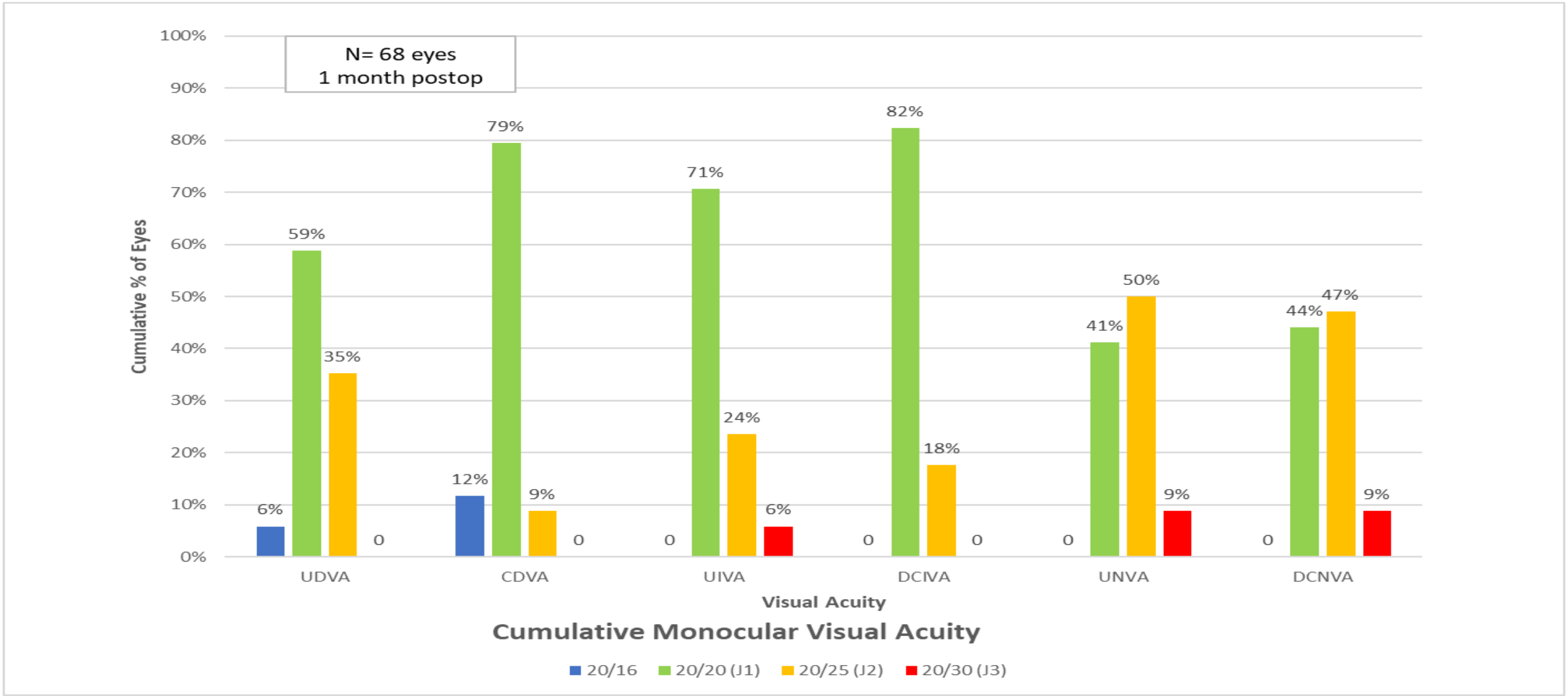
RESULTS – SUBJECTIVE REFRACTION

- All eyes were within ±1.00 D of emmetropia and 94% of eyes were within ±0.50 D



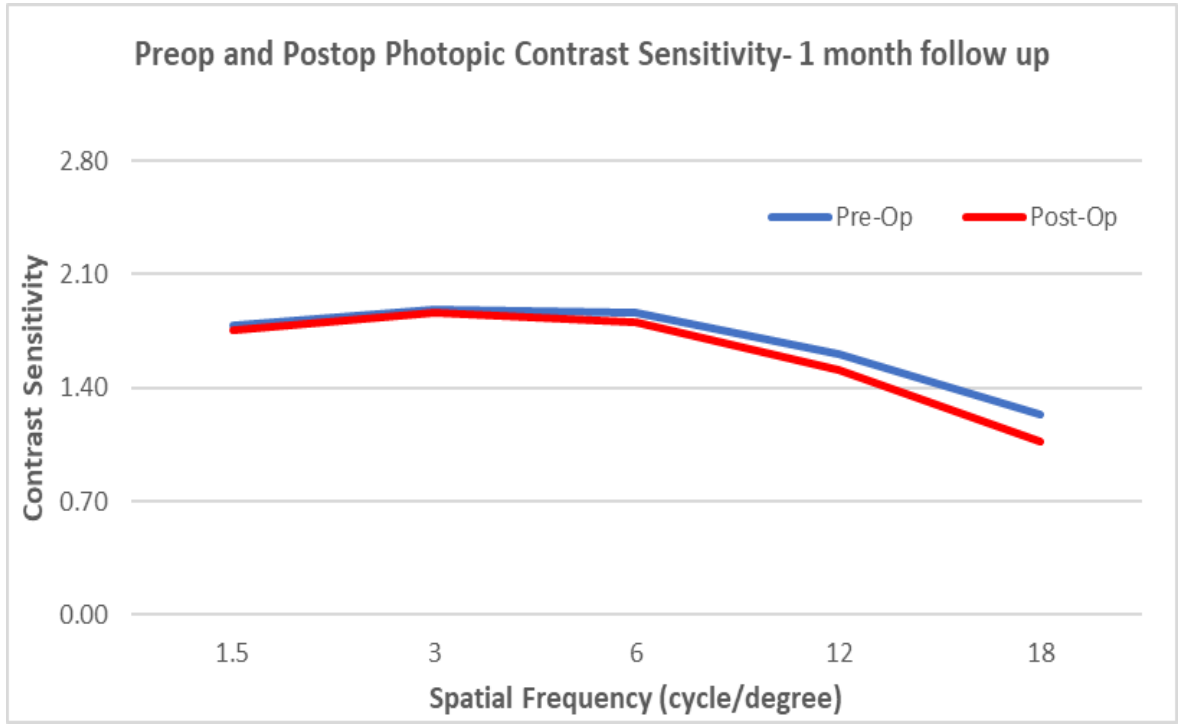
RESULTS – VISUAL ACUITY

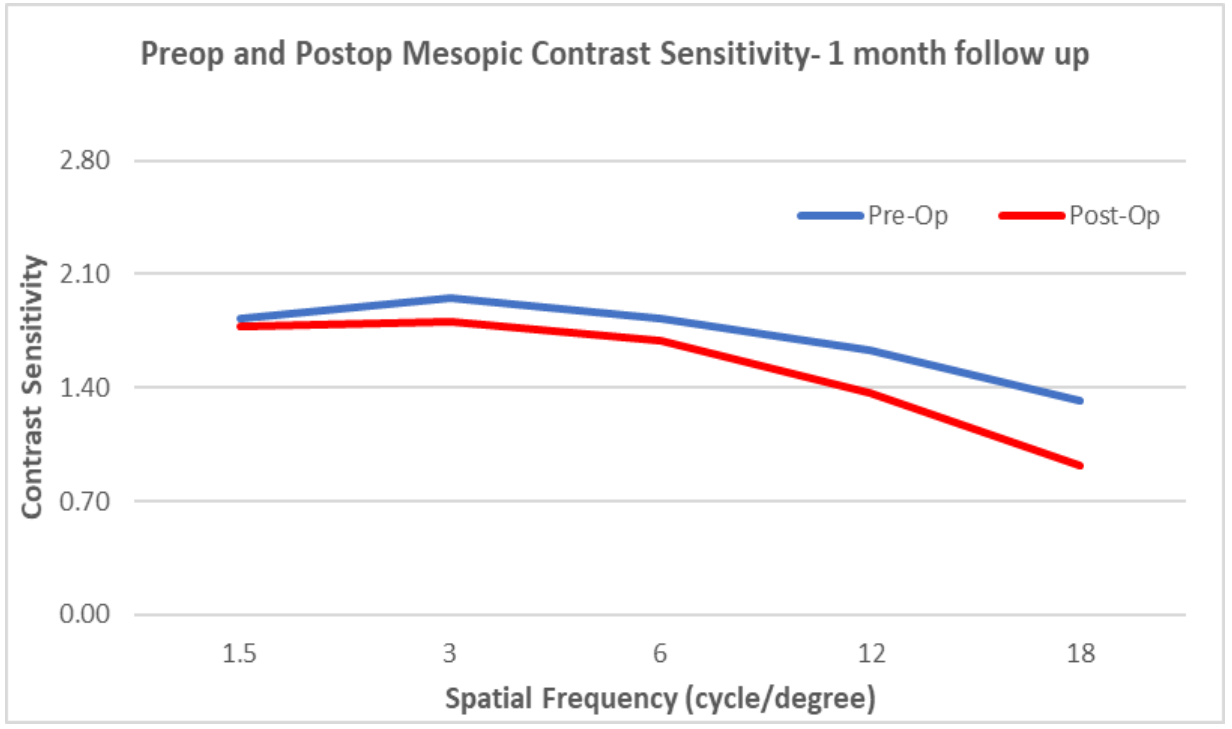
- All patients achieved Monocular UDVA of 0.1 LogMAR or better,
- 94% of patients acheived Monocular UIVA (70cm) of 0.1 LogMAR or better.
- 91% of patients achieved Monocular UNVA (40cm) of 0.1 LogMAR or better.



RESULTS – CONTRAST SENSITIVITY

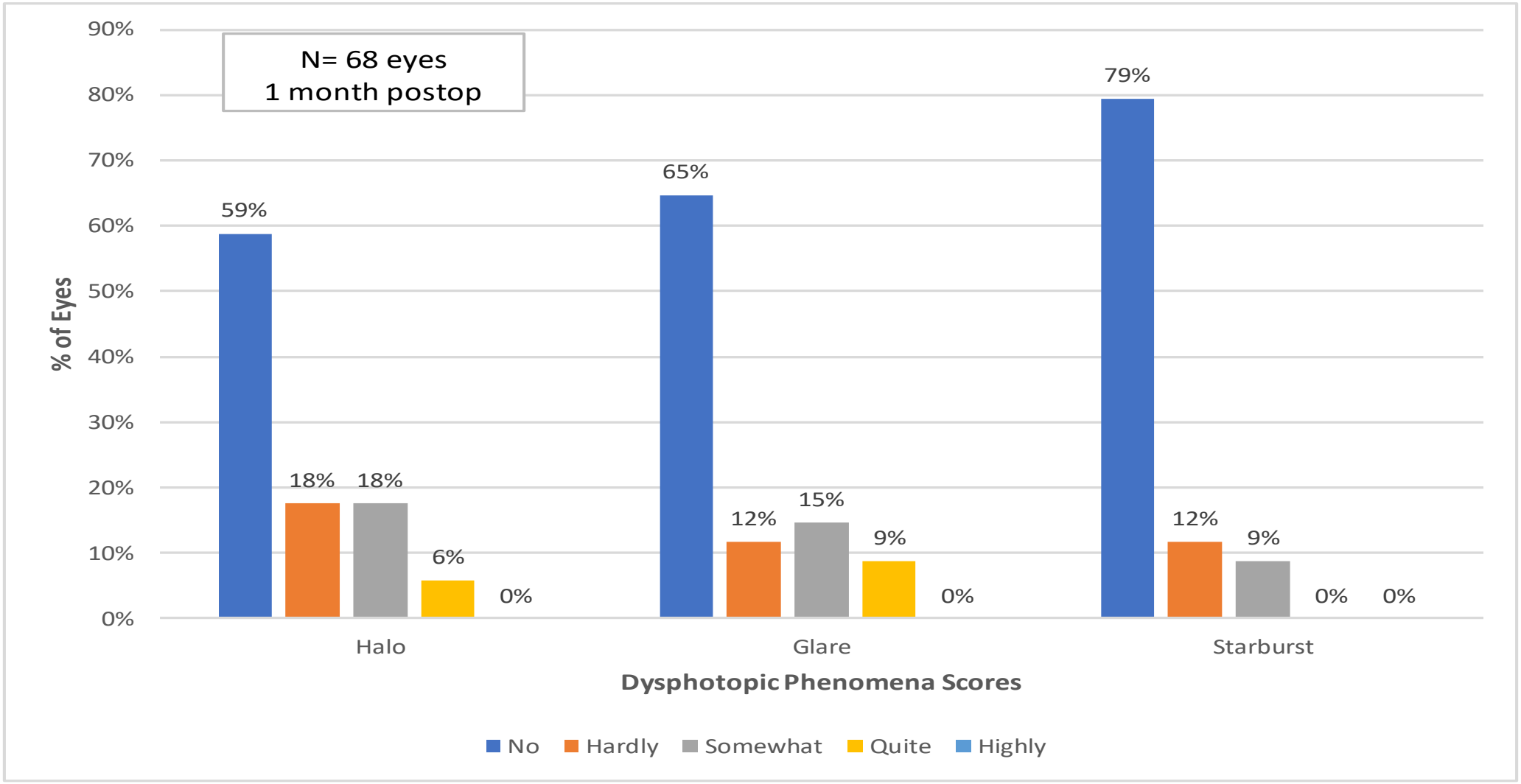
- Post-op photopic contrast sensitivity was similar compared to pre-op in pseudophakic eyes
- Post-op mesopic contrast sensitivity was lower compared to pre-op in pseudophakic eyes at higher spatial frequency (> 6 cycle/degree)





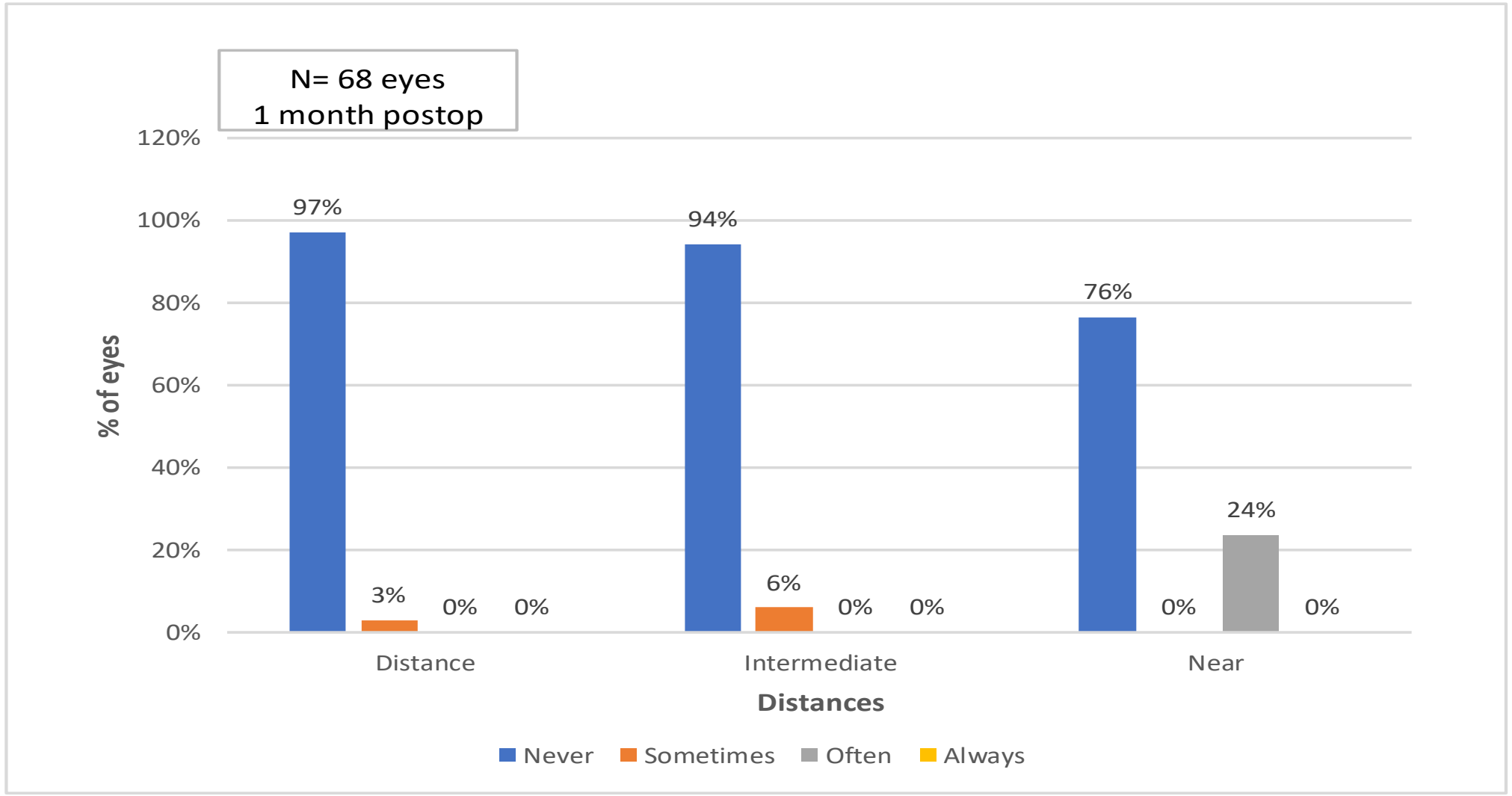
RESULTS – PATIENT SATISFACTION

Do you find the following phenomena disturbing and troublesome? (Likert Scale Scoring 0 to 4)



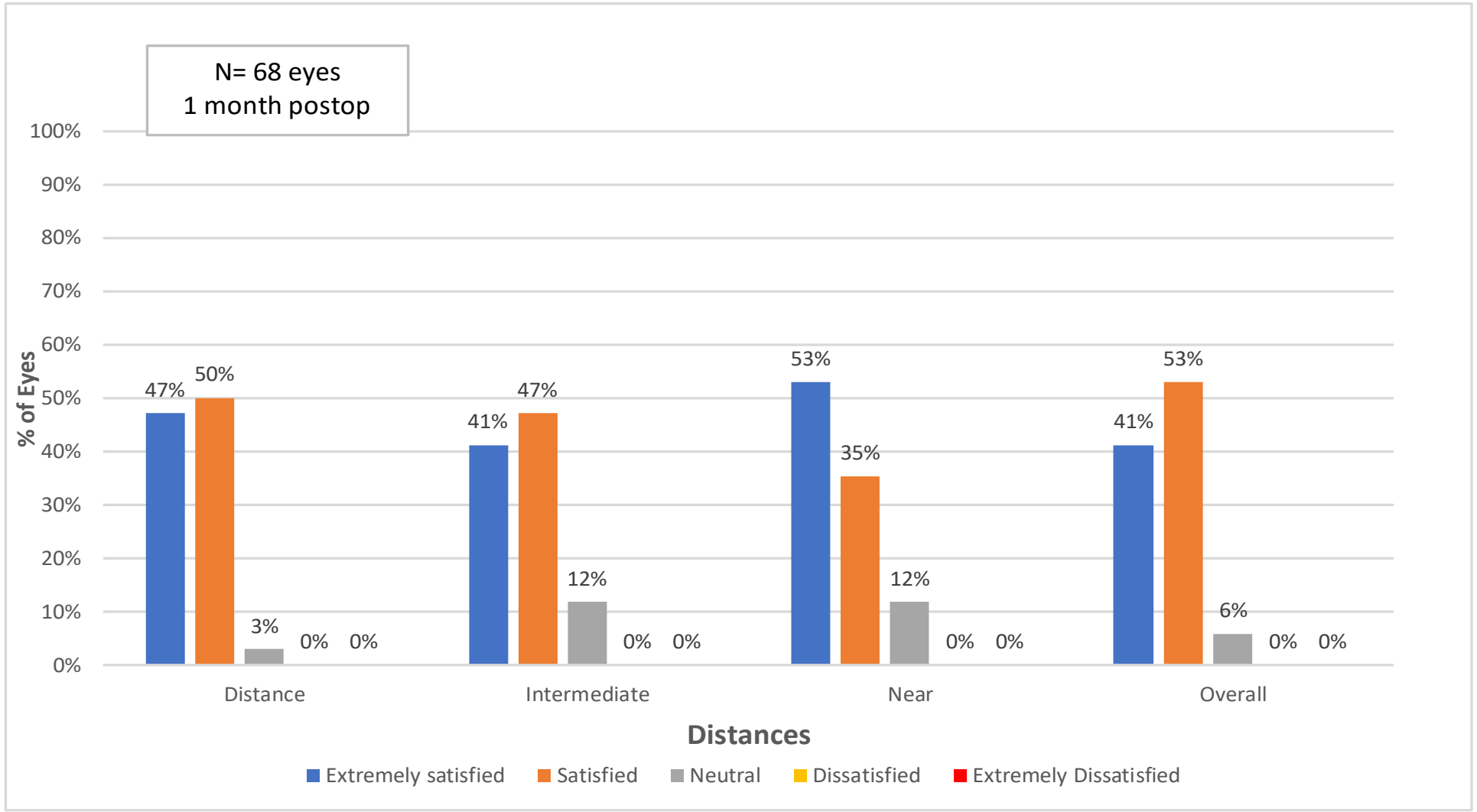
RESULTS – PATIENT SATISFACTION

Spectacle Independence- Do you wear spectacles for distance/intermediate/ near vision?



RESULTS – PATIENT SATISFACTION

How satisfied are you with your near/intermediate/distance and overall vision? (Likert Scale Scoring)



Female: U. P.; 72a

Oktober 2015: uneventful IOL implantation both eyes

September 2018: uneventful, bilateral secondary enhancement

VA right eye: 0.7 (secondary cataract);
Jg 1; YAG capsulotomy scheduled

VA left eye: 1.0; Jg 1