

Sulcoflex® trifocal: An adaptive solution towards DIVA (Distance Independent Visual Ability)

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**BARMHERZIGE BRÜDER
ÖSTERREICH**



Medizinische Fakultät der Sigmund Freud
Privatuniversität

Initial Trial

Worlds first implantation:

30. 7. 2018

Duet-implantation: 40 eyes

implantation in pseudophakic eye: 40 eyes (ongoing)

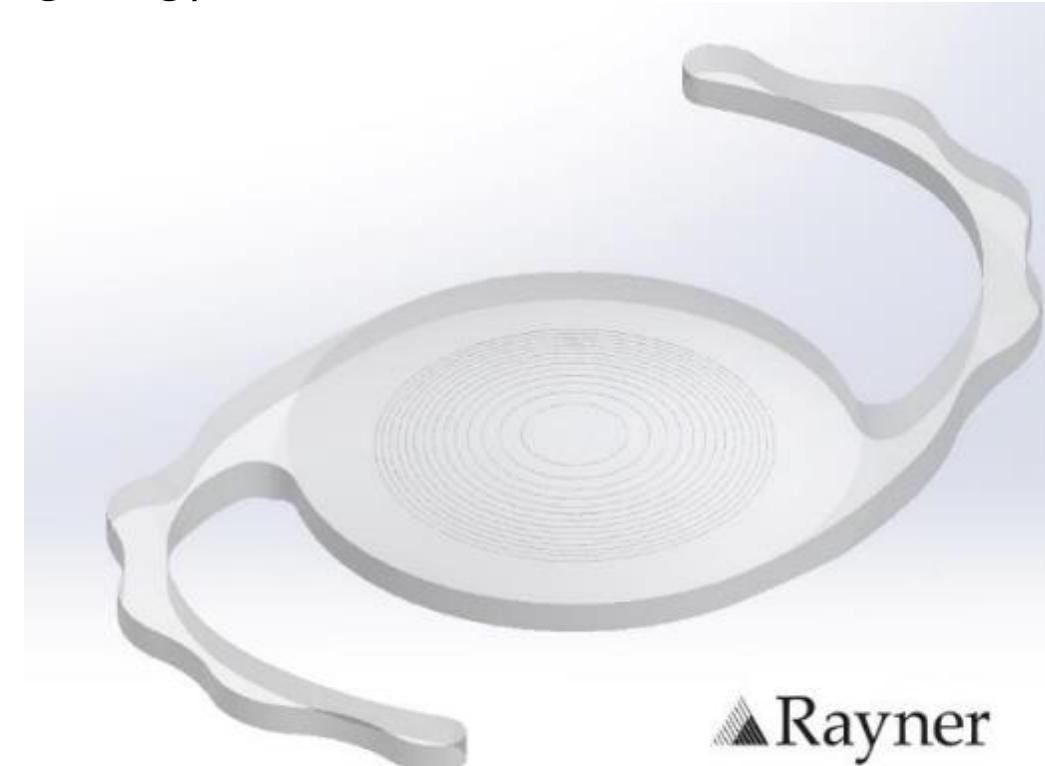
EU Trial: 68 eyes

bilateral surgery

follow-up: 6 months

single surgeon

postop refraction: 0



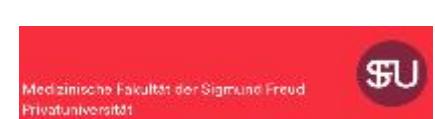
▲Rayner

Material and Design

Surgery

Results

Conclusion



Material and Design: The History of Sulcoflex®

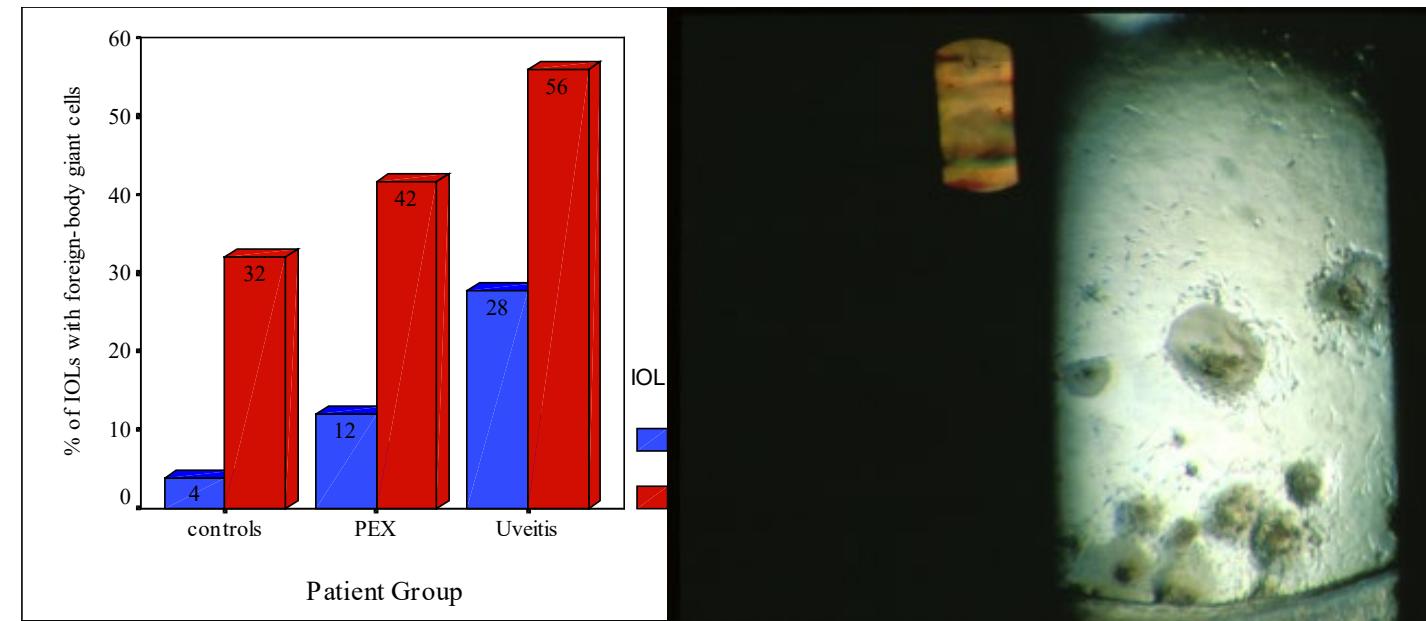


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Uveal and Capsular Biocompatibility of Intraocular Implants

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

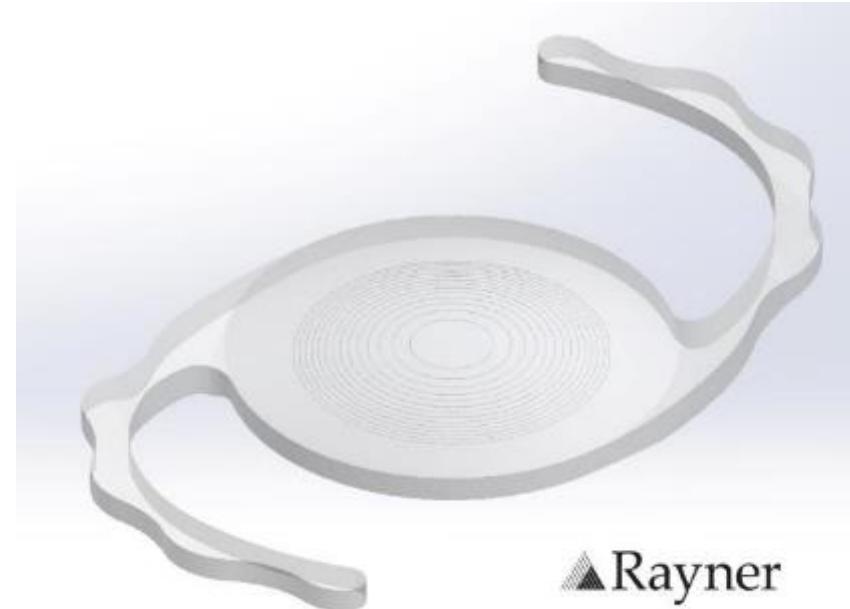
S. Richter-Müksch, G. Kahraman, M. Amon, et al. Uveal and capsular biocompatibility after implantation of sharp-edged hydrophilic acrylic, hydrophobic acrylic and silicone IOLs in eyes with PEX-syndrome *J Cat Refract Surg* 2007 33; 1414-1418

Additive IOLs available

Cristalens Reverso®

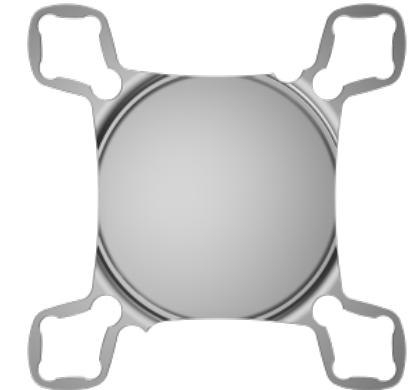


Rayner Sulcoflex®



▲Rayner

1st Q®



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 pseudophakic eye

M. Amon. Ophthalmology Times, 2007



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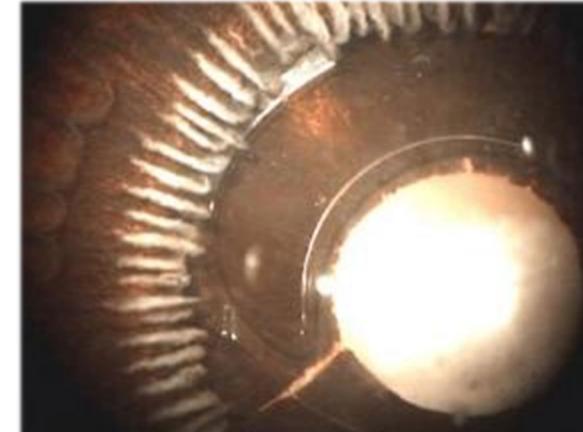


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Cadaver Eye Study:

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



Effect of interface refection in pseuophakic eyes with an additional refractive intraocular lens

Optical bench study:

- equal reflections from additional surfaces/interface
- similar optical quality of two IOLs as compared to single IOL
- additional lightloss less than 1%

Jens Schrecker, Katja Zoric, Arthur Messner, Timo Eppig

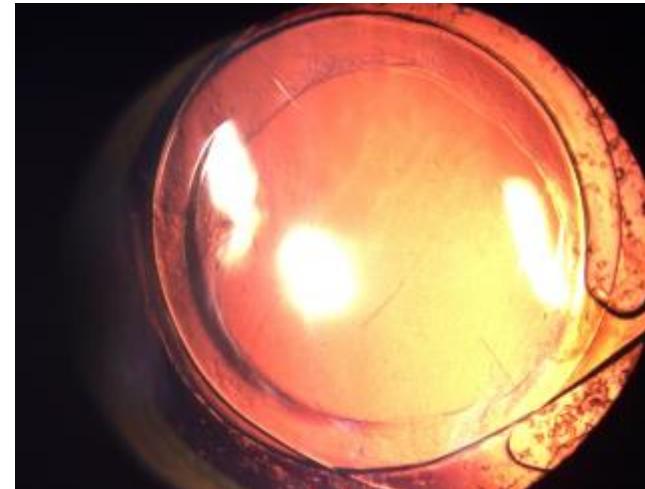
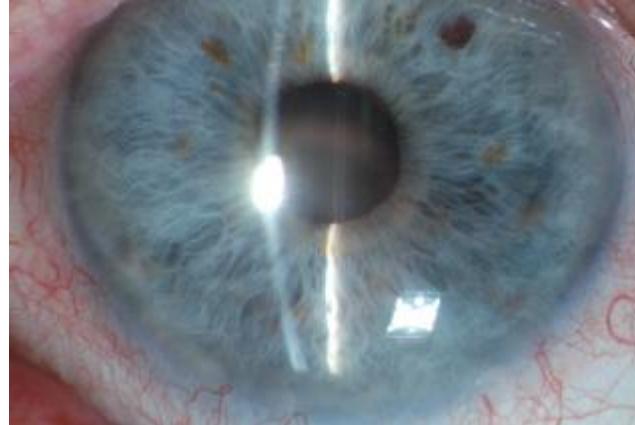
J Cat Refract Surg; 38/8; 1650-1656; 2011

Ramin Khoramnia et al.

ESCRS, Paris 2019

Results: Rayner Sulcoflex®

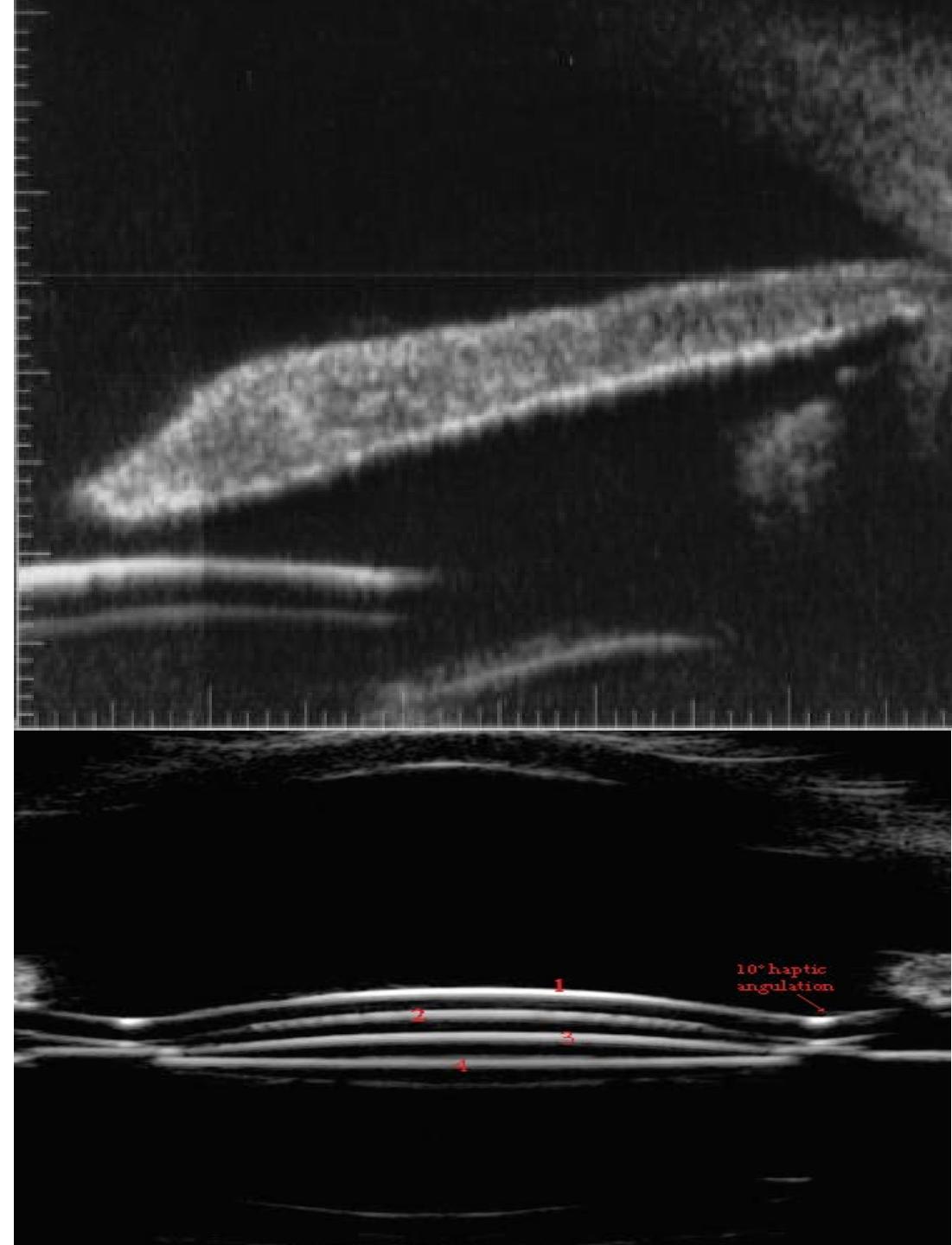
- n: 200 eyes/ 13 years follow-up
- refr. mf, toric, mf/t, monofocal
- LFCM: < than after phaco
- iristrauma: 0
- pigmentdispersion: 0
- interlenticular opacification: 0



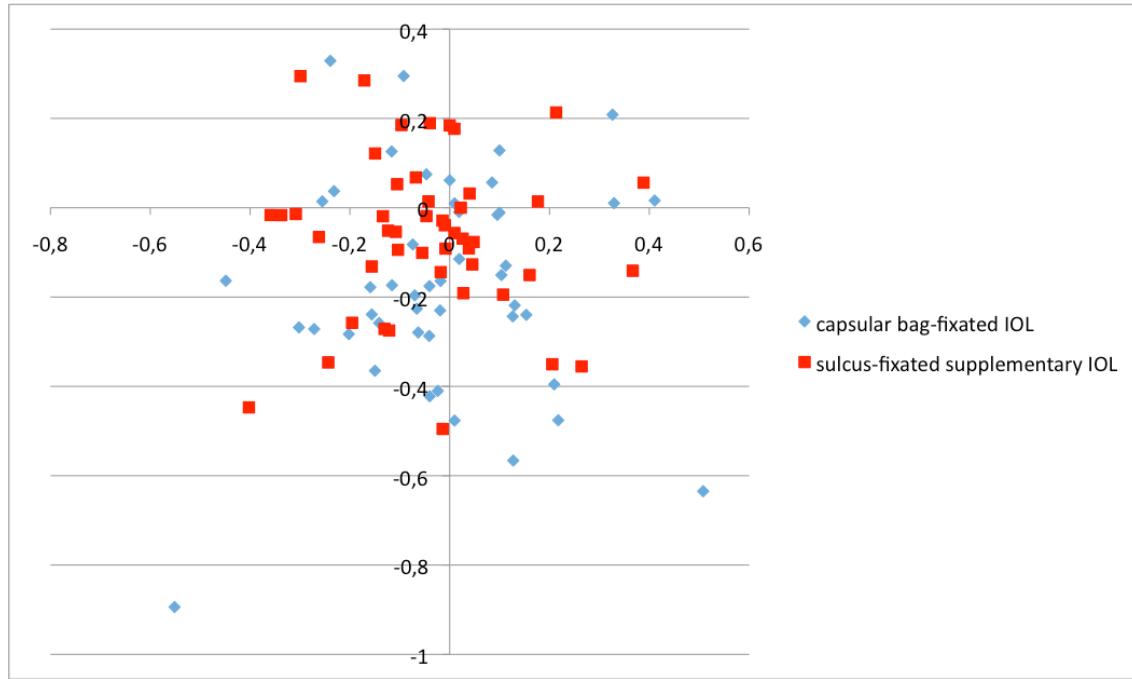
Kahraman G, Amon M "Sulcoflex: A new supplementary intraocular lens for pseudophakic refractive errors
J. Cat. Refract. Surg. 2009

Results: Rayner Sulcoflex®

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



Centration Study: Rayner Sulcoflex®

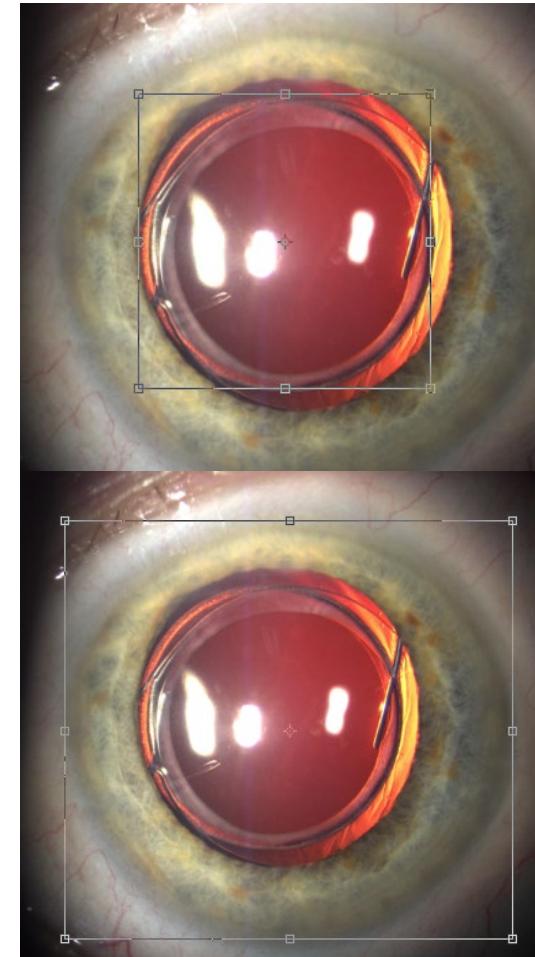


Decentration compared to the **center of the pupil** in mm

max. decentration capsular bag: 1,05 mm

max. decentration sulcus: 0,6 mm

Statistically significant better centration of ciliary sulcus fixated IOLs



Specific indications

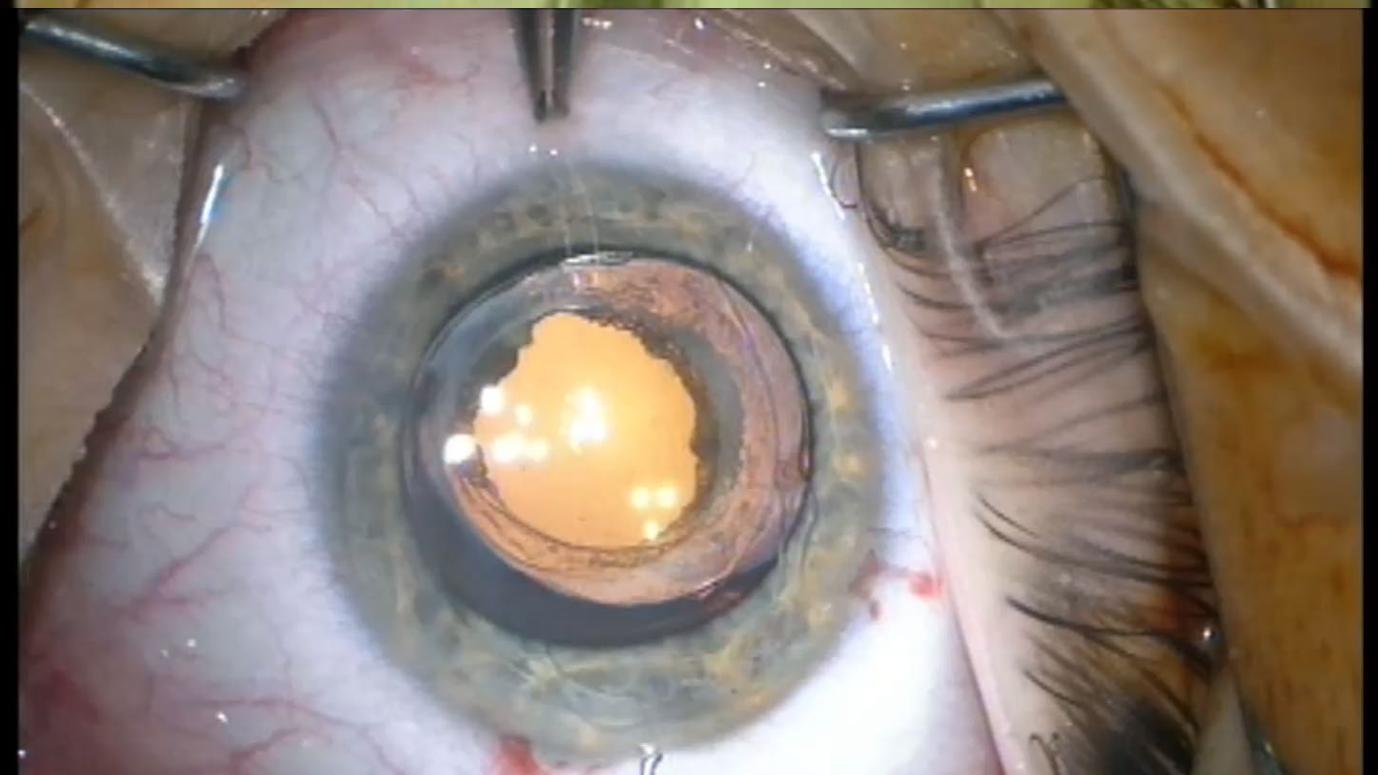
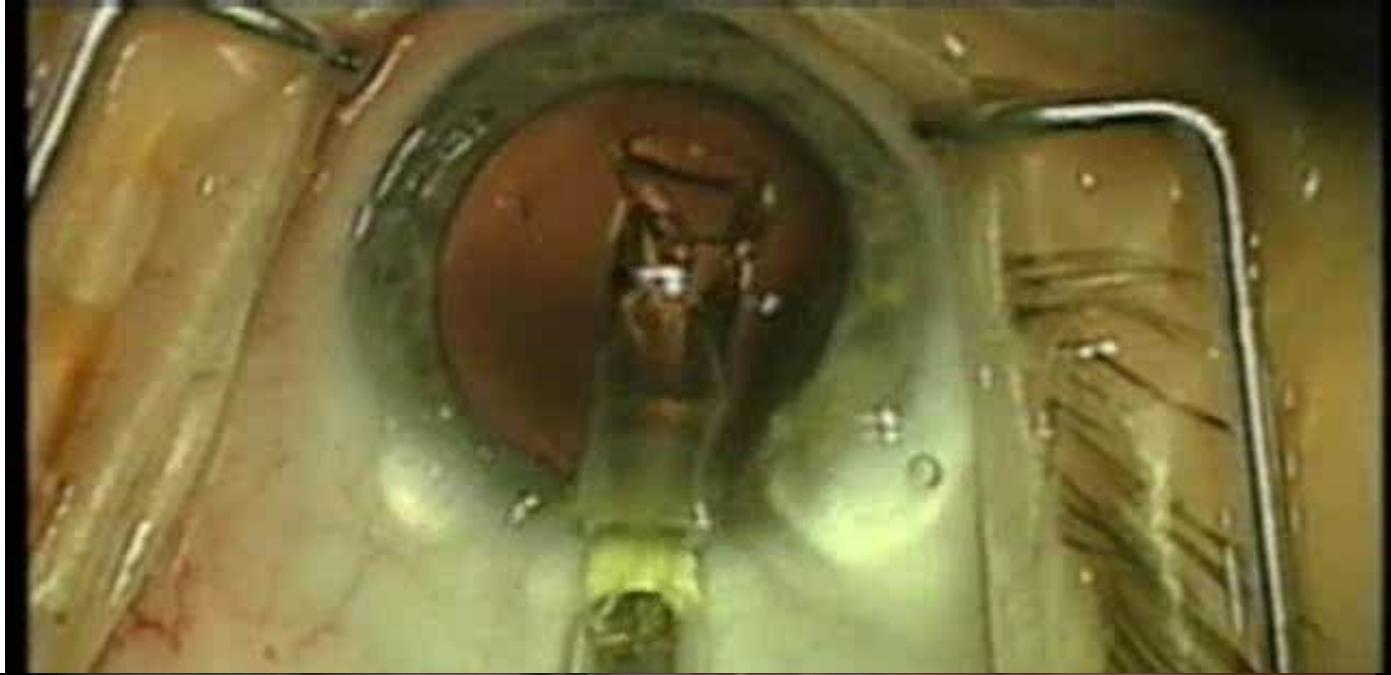
“Dynamic refraction”

- pediatric cataract

(refractive exchange of supplementary implant RESI)

- silicone oil

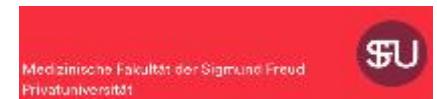
- corneal/scleral alteration



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



Next step: create first diffractive trifocal add-on IOL

RayOne® Trifocal has fewer rings on the IOL optic surface

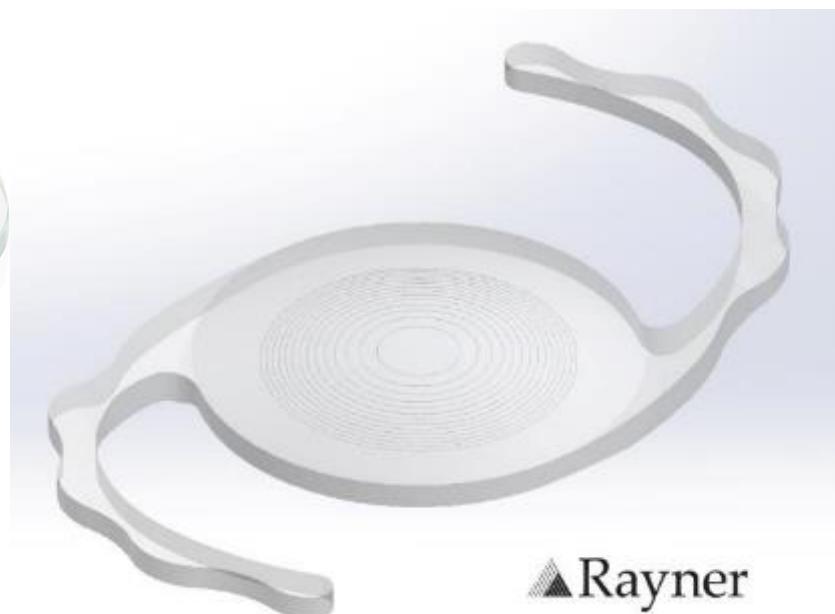
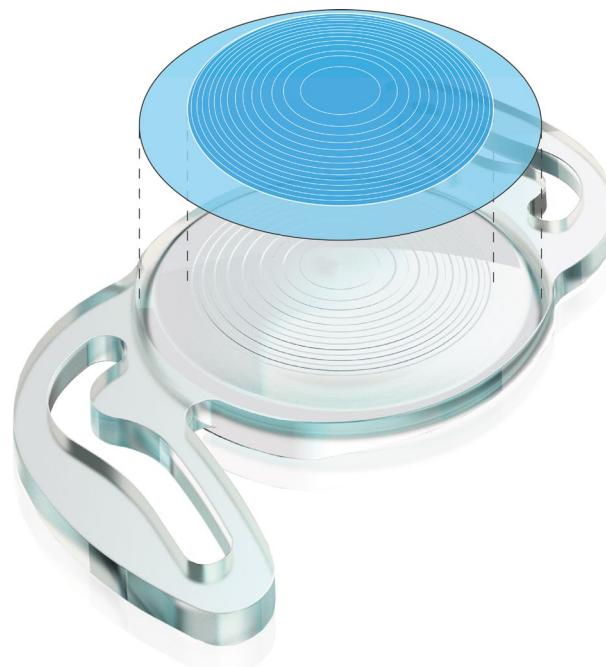
for **reduced potential visual disturbances and improved night vision.**

Features:

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

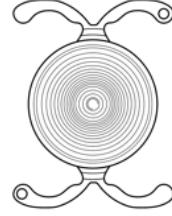
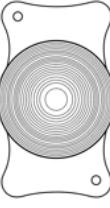
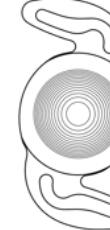
Benefits:

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



▲Rayner

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



▲Rayner

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

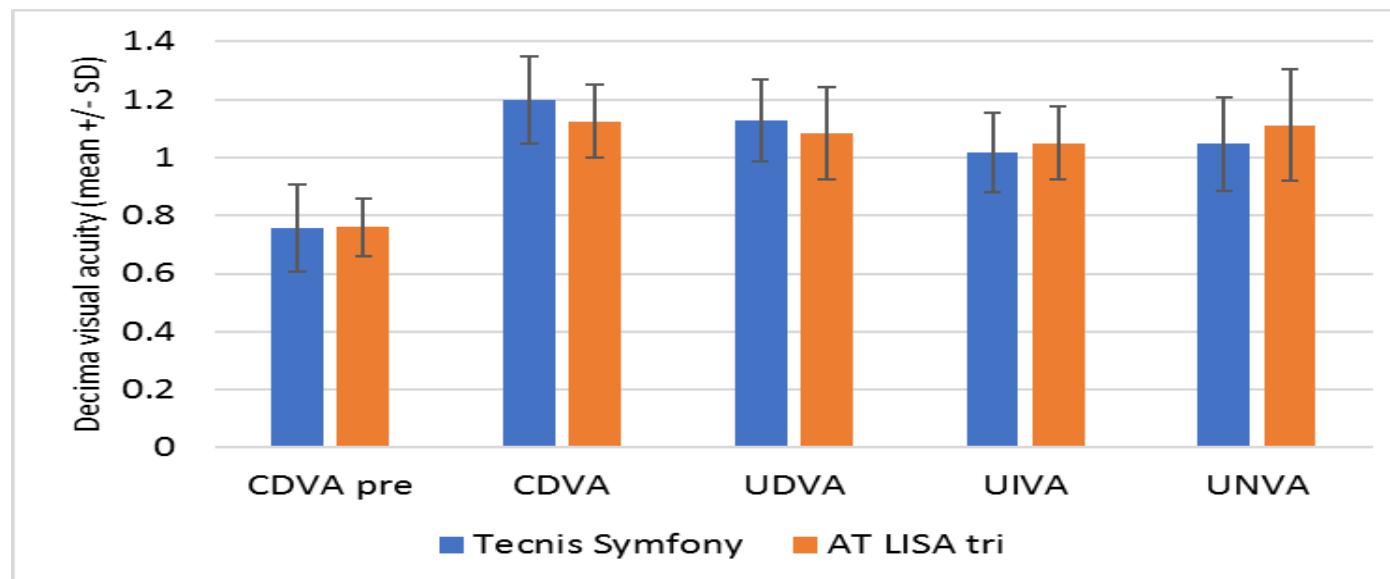
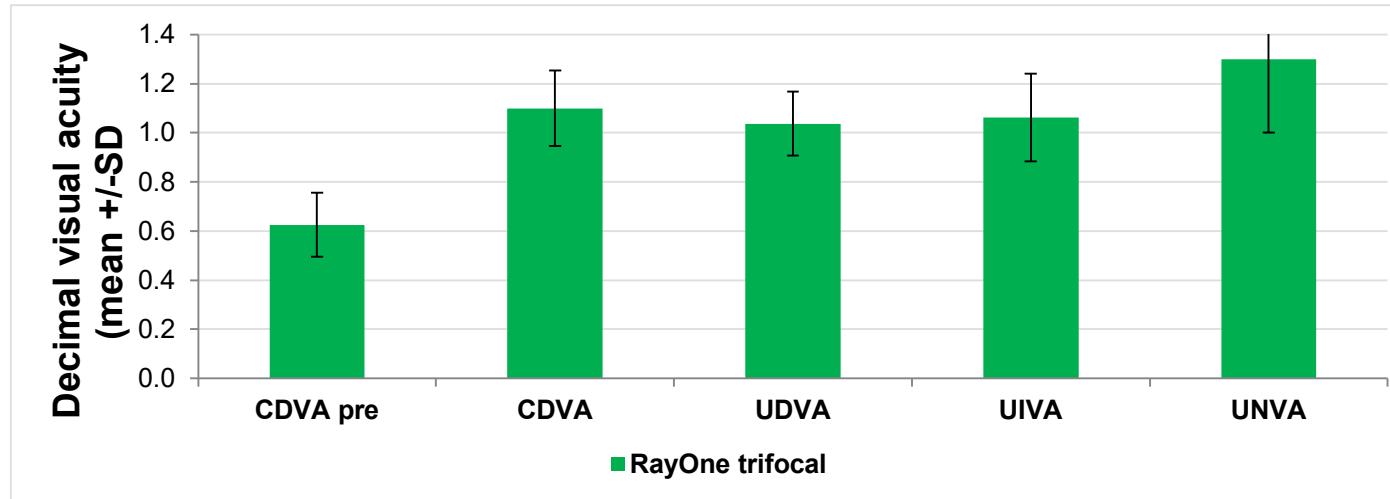


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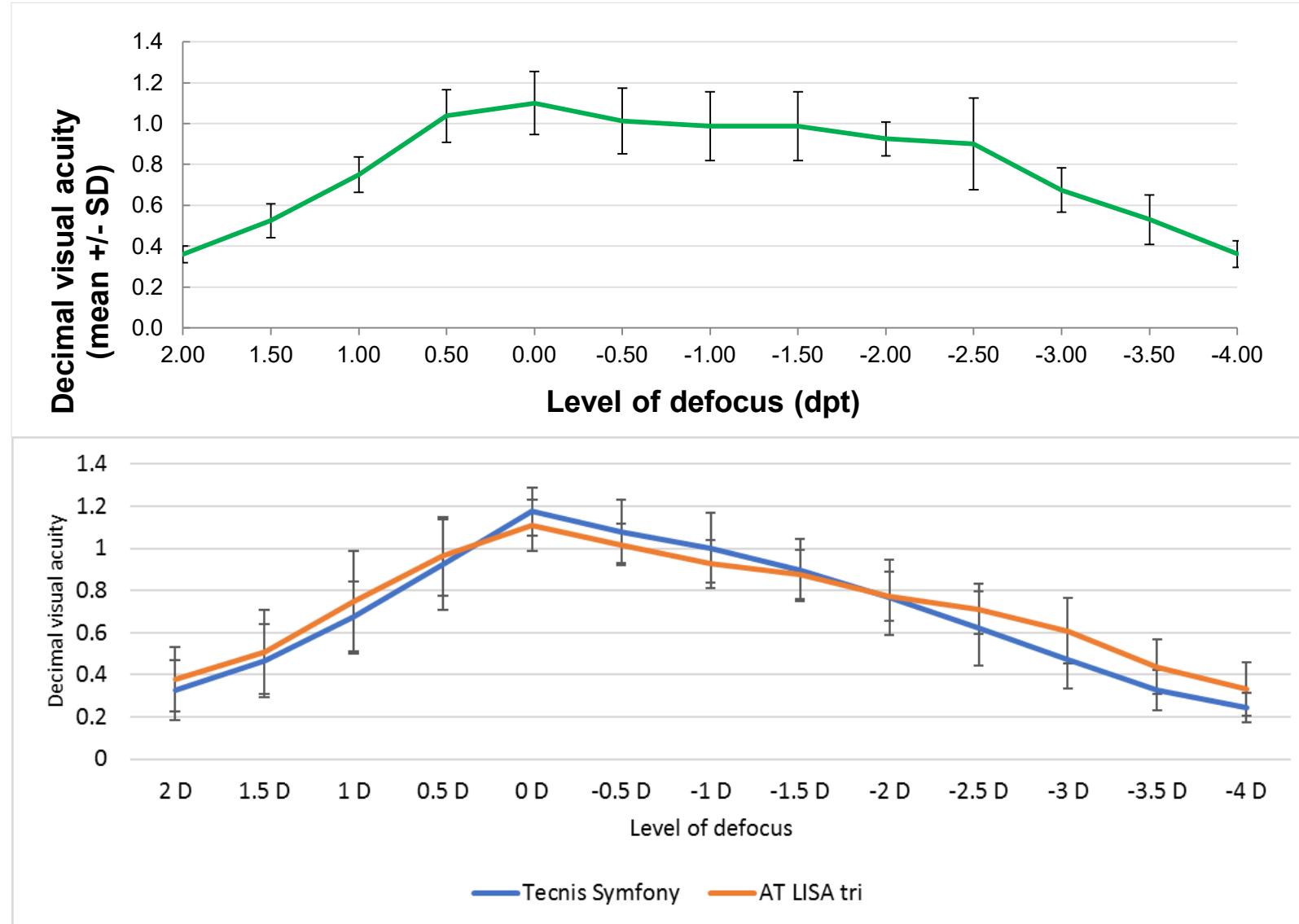
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Visual Acuity



Binocular Defocus Curve



Surgery



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IOL calculation for secondary implantation

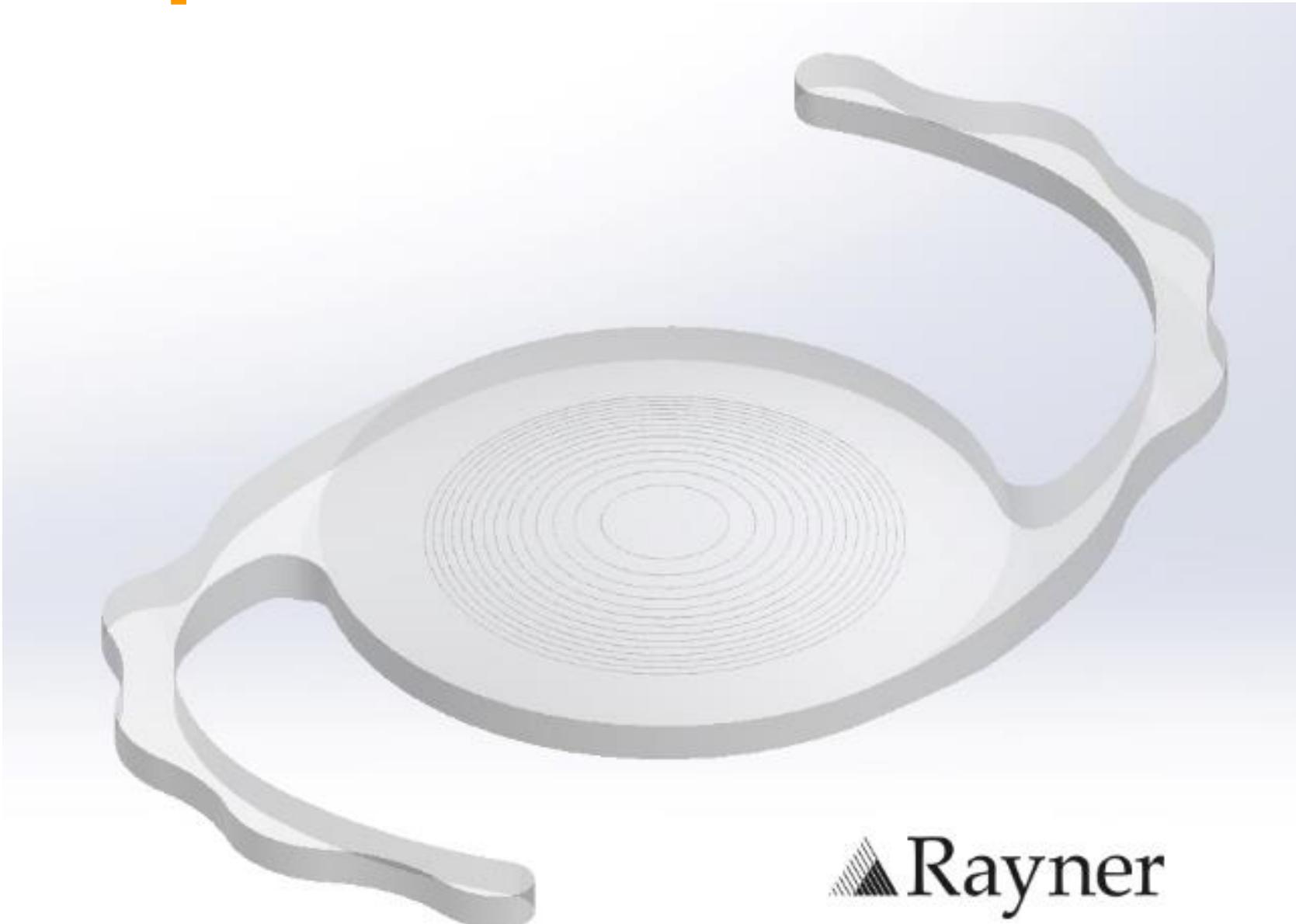
- R-vergence formula:
sph. equivalent of ametropia, K-values, ACD
- postop ametropia within +/- 7 D:
hyperopia:
sph. equivalent x 1.5
myopia:
sph. equivalent x 1.2

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

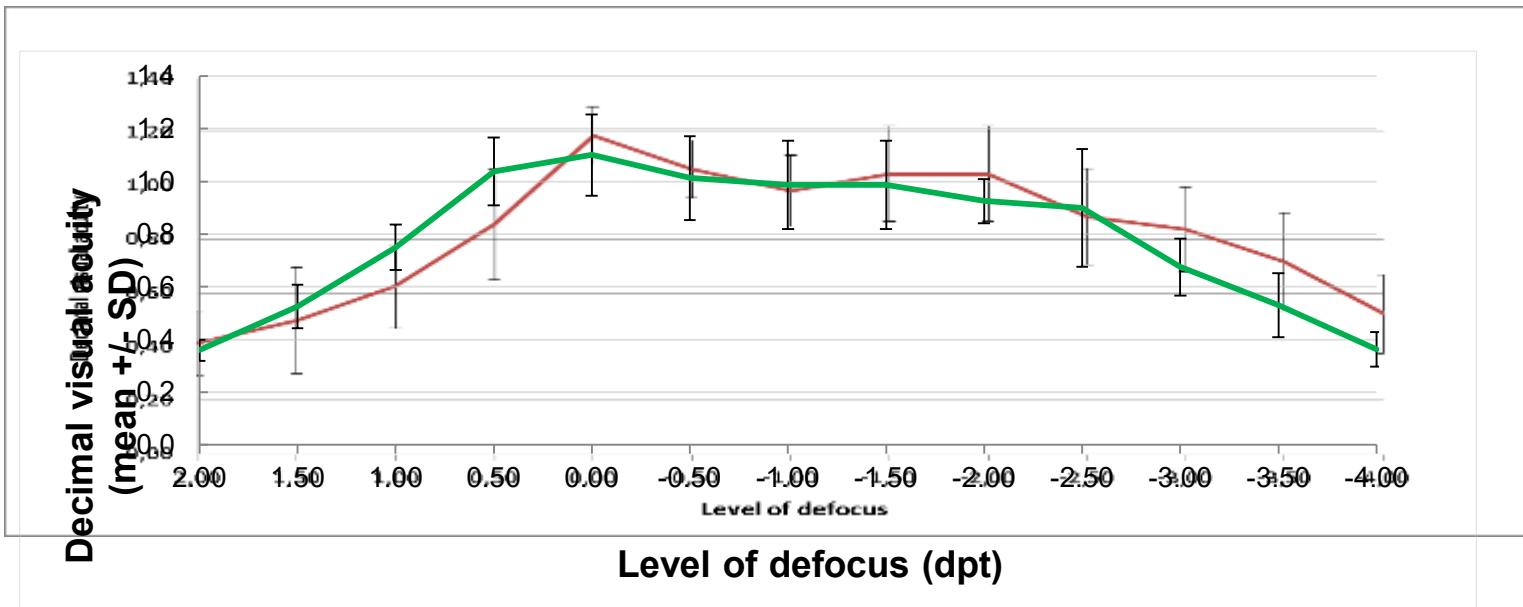
Results

Duet-implantation



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Binocular defocus curve



RayOne tri
Sulcoflex tri

Secondary enhancement



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Option of “finetuning” with 0.25 dpt steps

All patient should get detailed information about potential dysphotopsia

The case



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U. P.: whish of spectacle independance; female, 72a

1. visit (august 2018):

heterochromia, no uveitis, normal posterior segment

od: well centered IOL (Acrysof SA 60; 2015); secondary cataract

VA: +0.75sph +0.5cyl/140 0.8

os: cortical cataract

VA: +0.75sph 0.6

U. P.: whish of spectacle independance; female, 72a

surgery:

september 2018

os: uneventful Duet-procedure with Sulcoflex trifocal (0dpt plus trifocality)

U. P.: whish of spectacle independance; female, 72a

1 week later, september 2018

od: secondary enhancement with +1.5dpt Sulcoflex trifocal;
incision at steep axis: 140 degrees

YAG capsulotomy performed 4 weeks after Sulcoflex implantation

U. P.: whish of spectacle independance; female, 72a

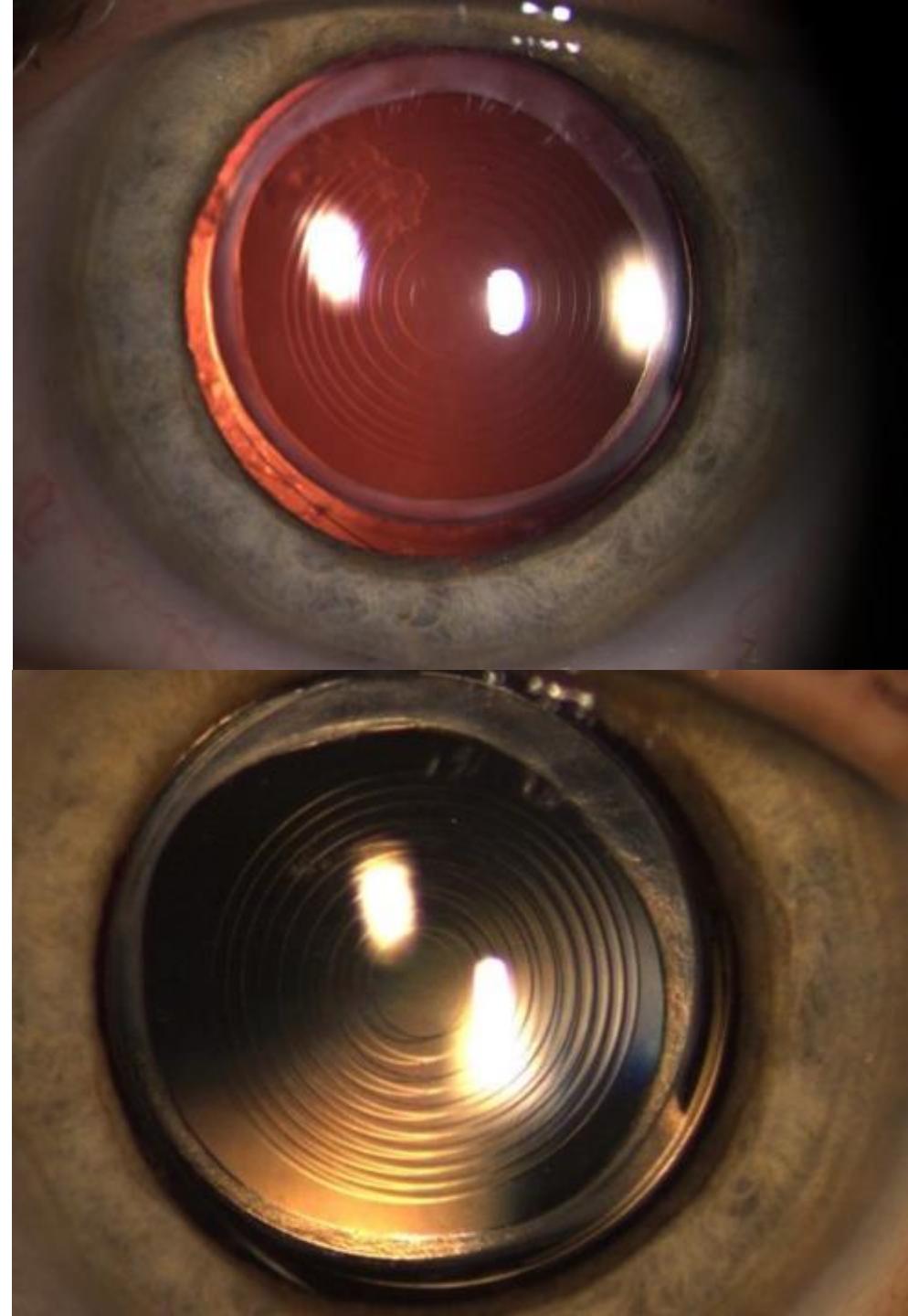
last visit (march 2019):

ou: well centered IOLs, no pigment dispersion, no interlenticular opacification, good iris/IOL clearance, no central IOL contact

VA: od: sc 1.25; Jg 1

VA: os: sc 1.25; Jg 1

spectacle independance, halos acceptable



Conclusion

- Excellent visual acuity results across all distances
- Results are comparable to trifocal “in the bag” IOLs at least

But:

- Supplementary IOLs offer an adaptive option

Conclusion

Option of finetuning (0.25 dpt)

Option of specific selection of IOL-combination (asphericity, torus, material for bag-IOL,...)

Option of exchange for future IOL-solutions

Reversibility, exchangeability: wider spectrum of indications

Increased explantation-rate due to different technology

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

