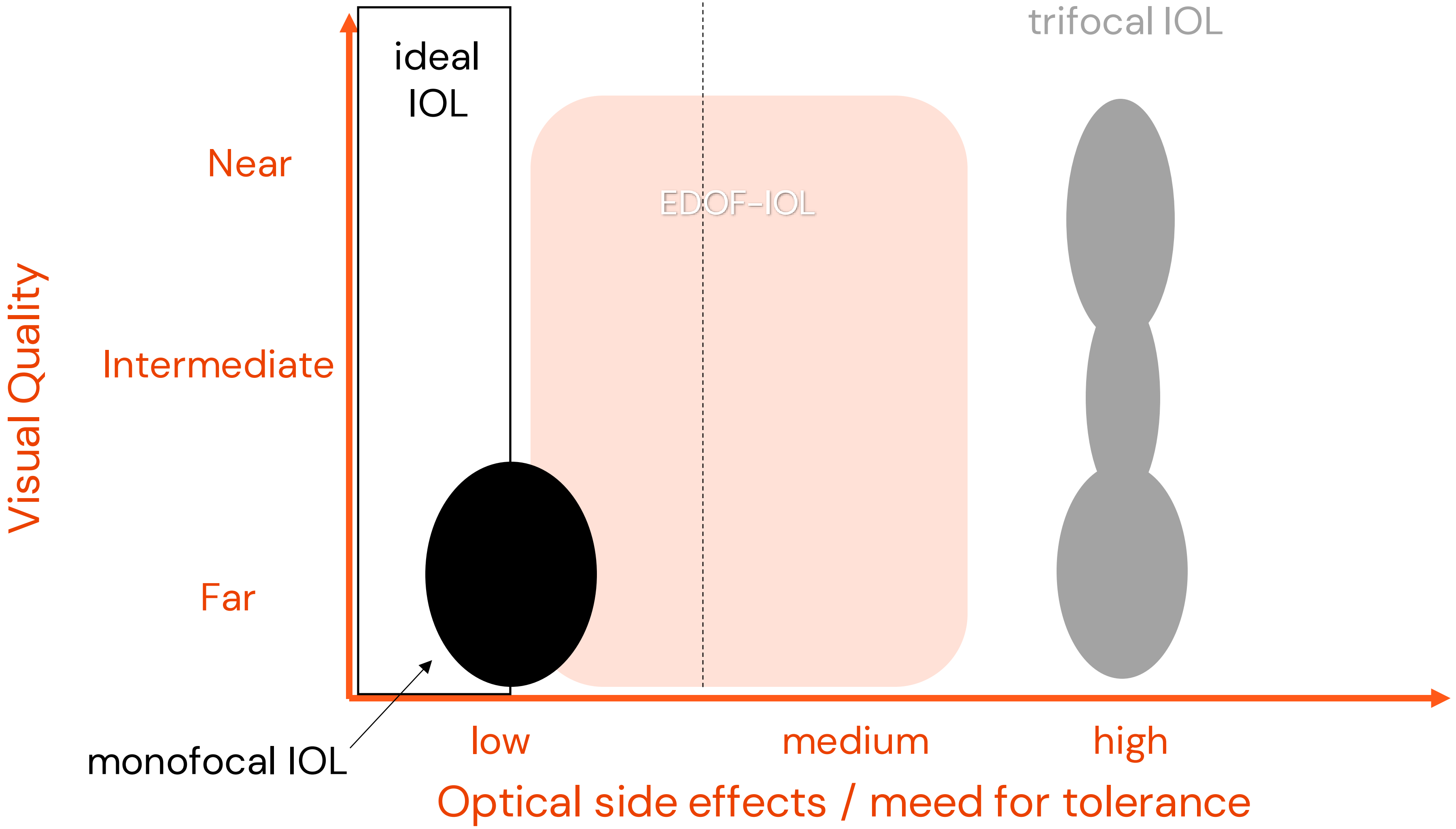
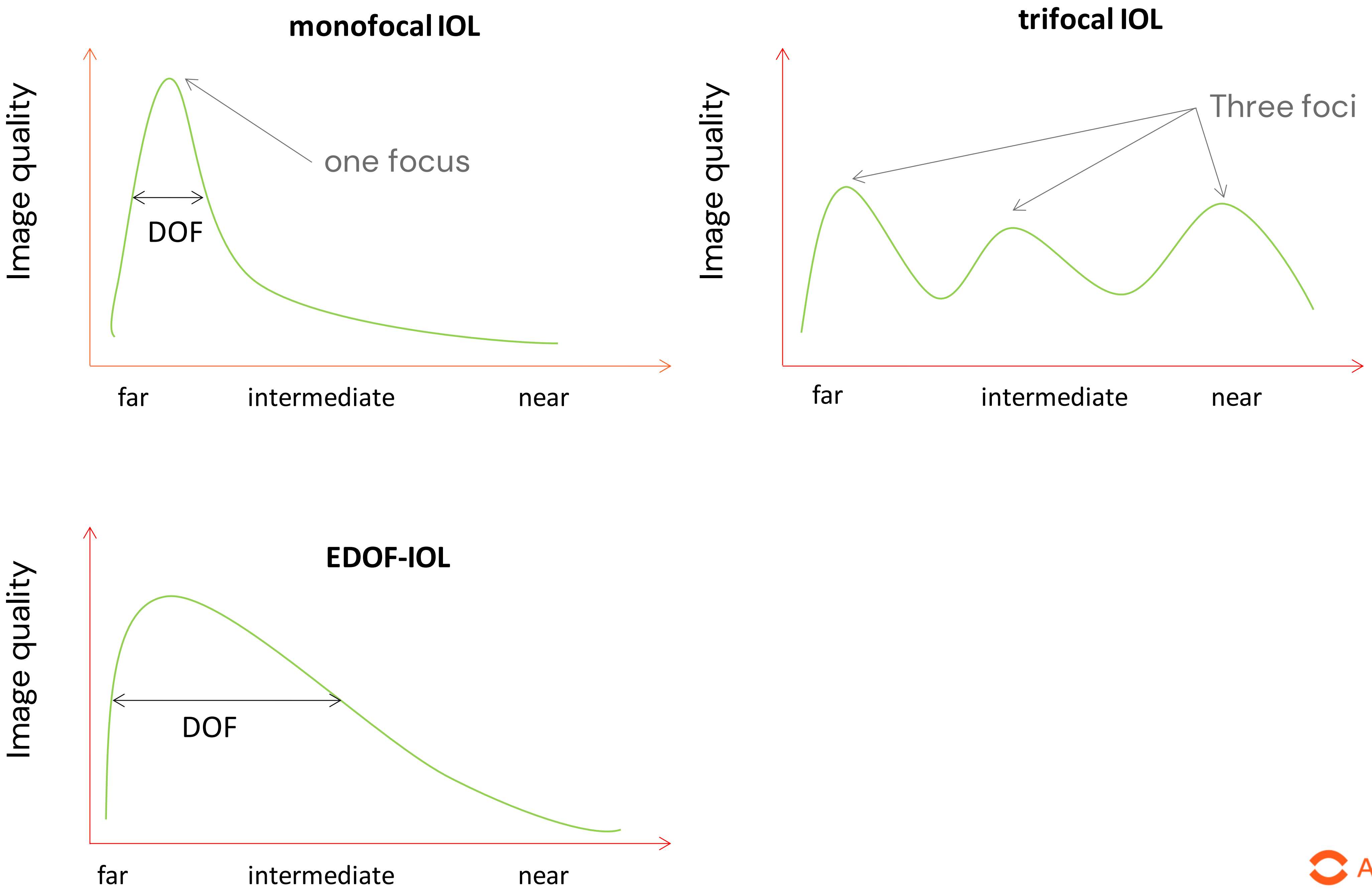
Why EDOF-IOL?

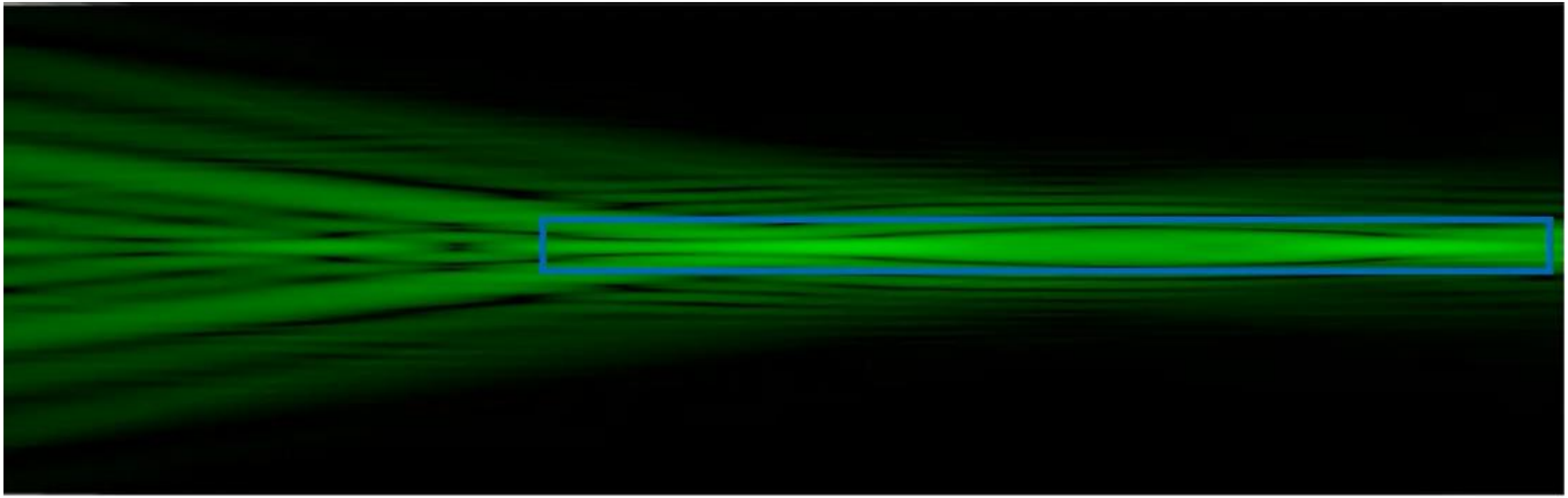


AddVision


monofocal IOL
Image quality
one focus
DOF
far
intermediate
near
trifocal IOL
Image quality
Three foci
far
intermediate
near
EDOF-IOL
Image quality
DOF
far
intermediate
near

Wavefront manipulating EDOF lens

„The wafefront linking EDOF technology creates an elongtaed focus through far and intermediate distances by utilyzing carefully chosen wavefront forming elements.“



AddVision

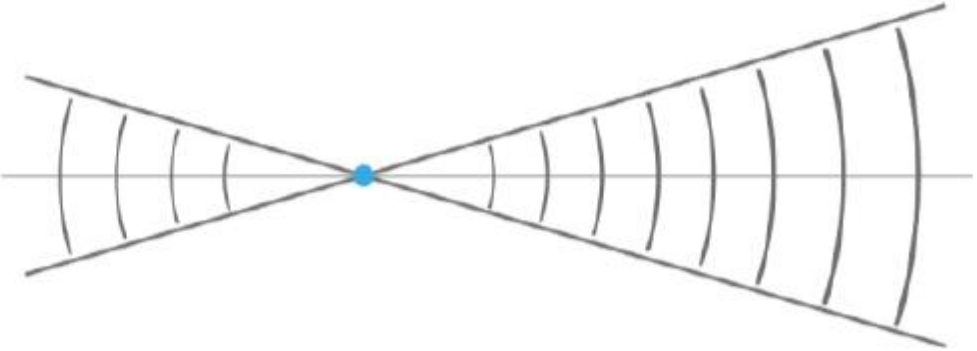
Wavefront manipulating EDOF lens

We are familiar with the optical principles of **refraction**, **diffraction** and **aberration**. However, there are many other optical principles that are used frequently and in many fields outside optometry and ophthalmology. These include the generation of an pseudo-non-diffractive beams (PNDB) by wavefront shaping. A pseudo-non-diffractive beam is characterised by an almost constant light intensity along a limited propagation distance. The intensity distribution is like that of a lightsabre.

These optical principles have many common applications, for example in materials processing. Also OCTs and excimer lasers use these technologies.

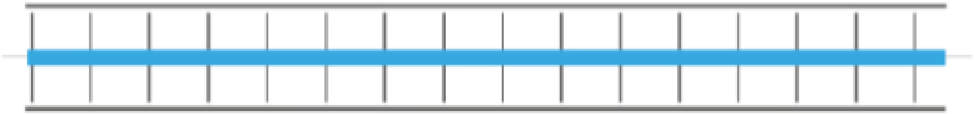
PNDB

refracted or
diffracted beam



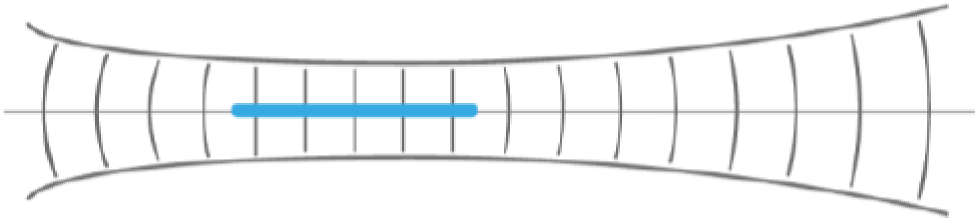
Focal point

Non-diffractive beam



Infinite focus line
(theoretical concept)

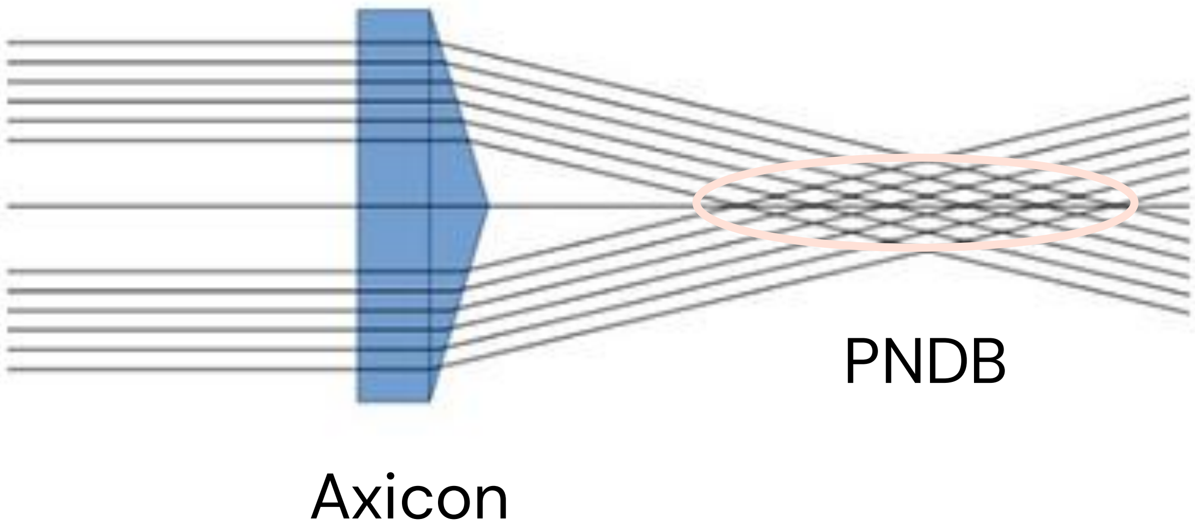
pseudo-non diffractive
beam (PNDB).

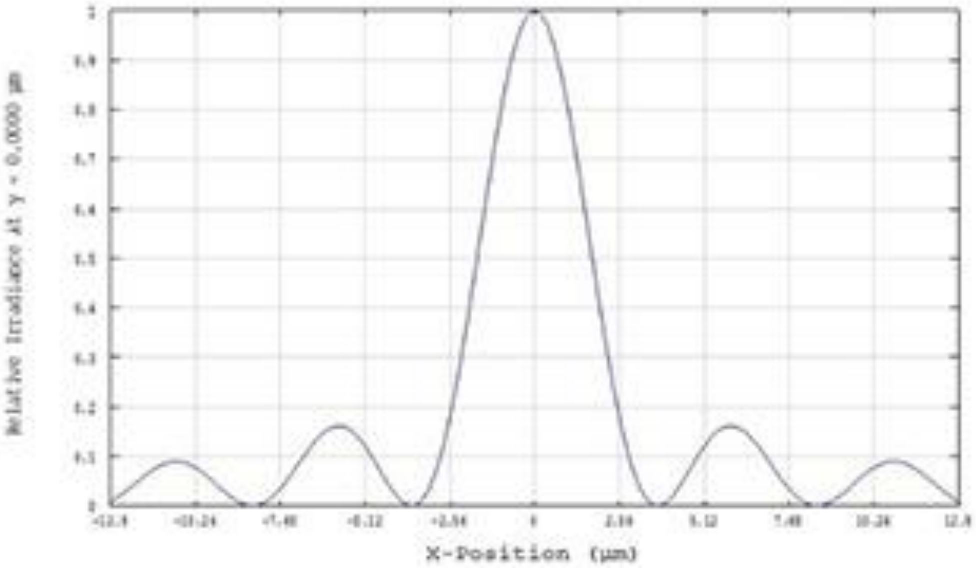


limited focus line
(continuous intensity
over a certain distance)

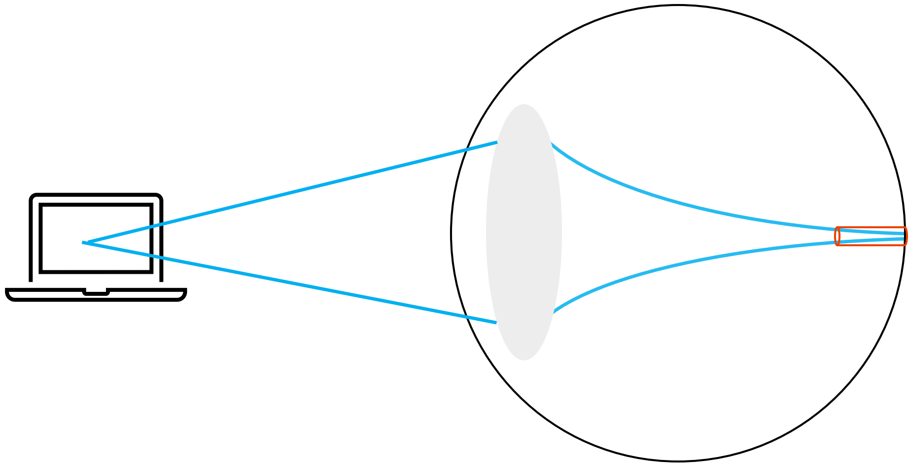
PNDB

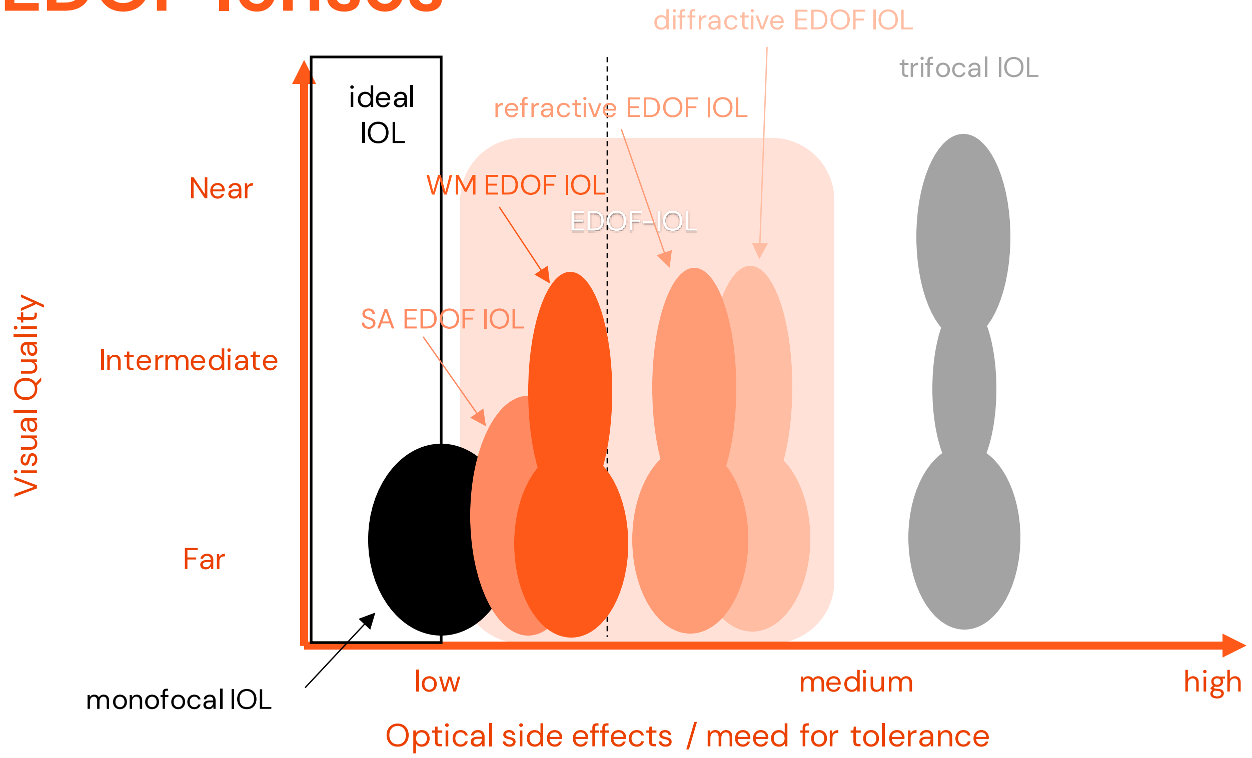
There are several methods to create a PNDB. From the point of view of geometrical optics, for example, an axicon produces such a sword beam. An axicon is a special, conically ground lens





Wavefront manipulating (WM) EDOF lenses





Pro
- High depth of focus
- Low optical side effects

Con
- Complex manufacturing
- Lower image quality compared to aspherical monofocal

Wavefront manipulating EDOF lenses

1stQ
Basis Z EDOF

Alcon
IQ Vivity

Medicontur
ELON

SAV-IOL
LUCIDIS
EDEN

Manufacturer	1stQ	Alcon AcrySof	Medicontur	SAV-IOL	SAV-IOL
Modell	Baisis Z EDOF	IQ Vivity	ELON	LUCIDIS	EDEN
Category 0	EDOF	EDOF	EDOF	EDOF	EDOF
Category 1	mono-EDOF	mono-EDOF	mono-EDOF	mono-EDOF	EDOF
Category 2	Hybrid MF/EDOF	Hybrid MF/EDOF	Hybrid MF/EDOF	Hybrid MF/EDOF	Hybrid MF/EDOF
Category 3	refractive/EDOF	refractive/EDOF	refractive/EDOF	refractive/EDOF	refractive-diffrctive/EDOF
Concept	refractive	refractive	refraktiv	refractive	diffractive
Optic	Wavefront Linking-Technologie	Aspherical anterior surface with wave-forming technology	Wavefront Linking-Technologie	„Instant Focus". Central zone for near and intermediate	„Instant Focus". Central zone for near and intermediate + diffractive arrey
Addition	-	2.0 D	-	3.0 D	3.0 D
Material	hydrophobic	hydrophobic	hydrophobic	hydrophilic	hydrophilic
Blulight filter	yes	yes (/401 nm)	yes	no (/370 nm)	no (/370 nm)
Haptic design	Z loop	C loop		closed C loop	closed C loop
Angulation	0°	0°	0°	0°	0°
Optic size	6.0 mm	6.0 mm	6.0 mm	6.0 mm	6.0 mm
overall diameter	13.0 mm	13.0 mm	13.0 mm	10.8 / 12.4 mm	10.8 / 12.4 mm
refract. Indiex	1.47	1.55	1.47	1.457	1.457
ABBE number	58	37	58	49	49
preloaded	yes	no	yes	no	no
incision size	2.2 mm	2.2 mm	2.2 mm	2.2 mm	2.2 mm
standard range	10-30 D (0.5)	15-25D (0.5)	8-30 D (0.5)	5-30 D (0.5)	5-30 D (0.5)
extended range	31-35 D (1.0)		31-35 D (1.0)		
toric available	no	yes	no	yes	yes

BASIS Z EDOF

1stQ

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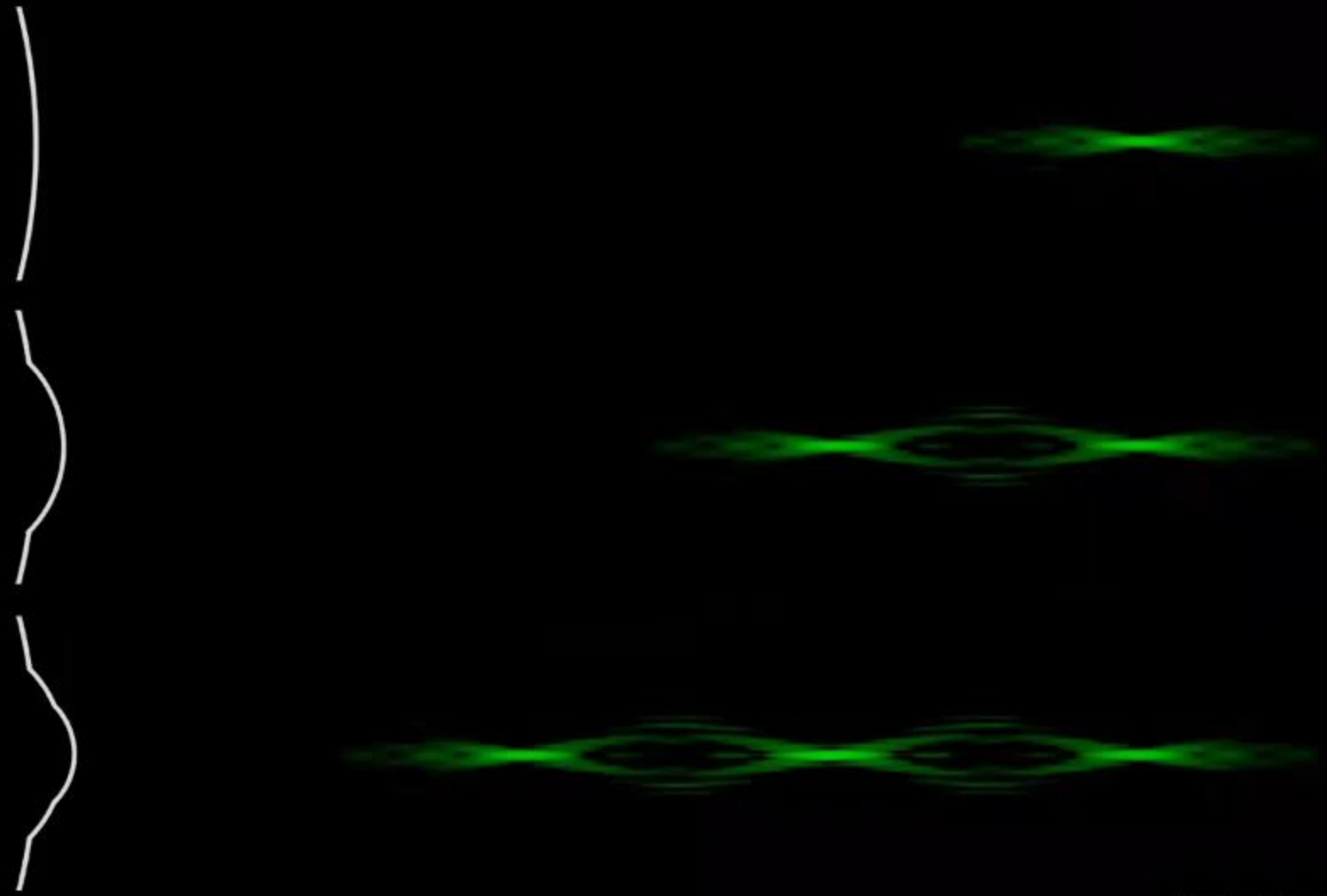
MEDICONTUR TECHNOLOGY – WAVEFRONT LINKING

Base radius

Base radius
+ 1 refractive zone

Base radius
+ 2 refractive zones



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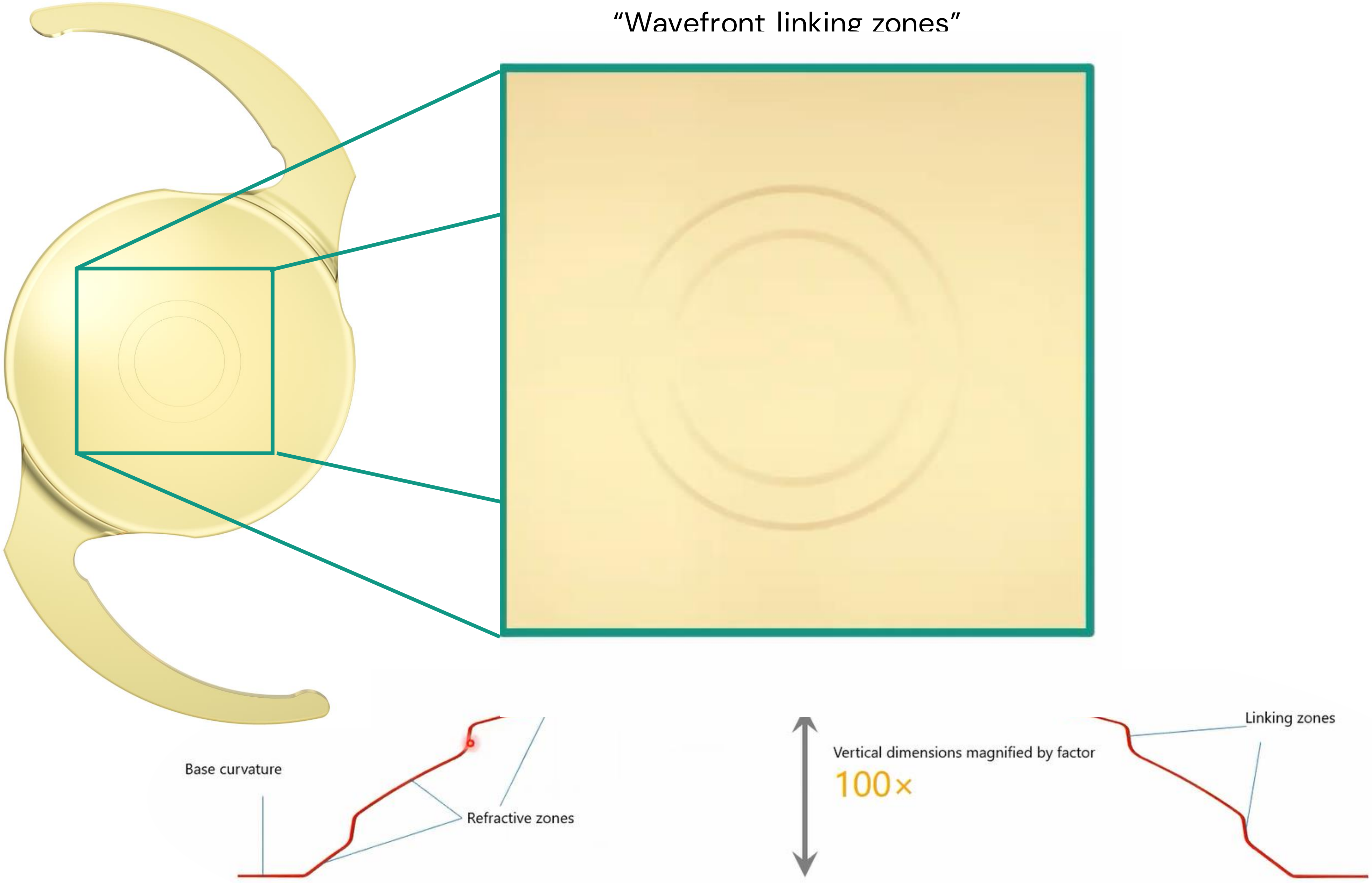
BASIS Z EDOF

1stQ



STUDY SETUP

Ethic
No.:


Date: 07-07-2021

INVESTIGATORS

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Petz Aladár Central County Hosiptal; Győr

DESIGN

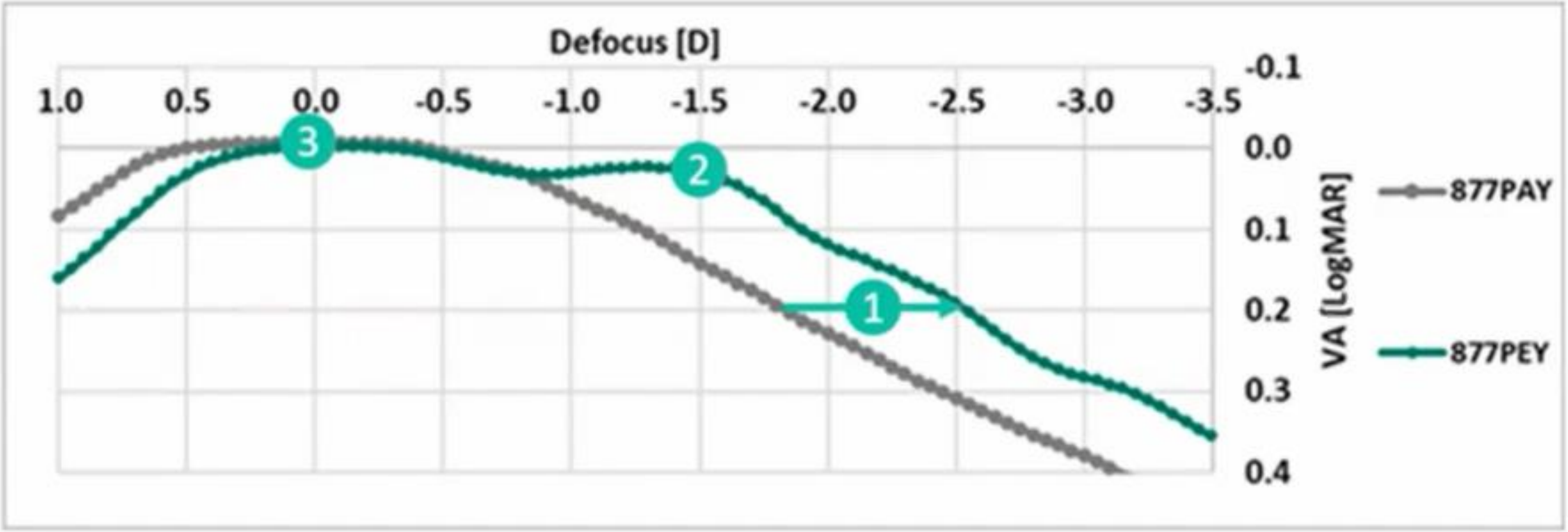
- Multicentric
- Prospective
- Comparative (877PEY vs. 877PAY)
- Randomized
- Planned duration: August 2020– December 2022

- 100 patients / 200 eyes (50 patients / 100 eyes / group)
- Cataract patients
- Preop corneal Cyl <1.0 D
- Binocular implantation with the same IOL model
- Follow-up: 12 months

Presbyopia correcting IOL - EDoF

THE NATURAL AGING OF THE CRYSTALLINE LENS

ANSI criteria to define EDoF IOLs	
Depth of focus	≥ 0.5 D greater than monofocal (1)
DCIVA (at 66 cm)	Superior to a monofocal (2)
DCIVA	≥ 0.2 logMAR (0.63 decimal) in 50% of eyes
CDVA	Non-inferior to a monofocal (0.1 logMAR) (3)
No criteria regarding visual disturbances for EDoF IOLs	



MONTH 1

elon 877PEY (EDoF)	Mean	Min - Max	877PAY (Mono)	Mean	Min - Max	p=*
UDVA (logMAR)	0.06	0.52 ; -0.20	UDVA (logMAR)	-0.01	0.10 ; -0.08	0.4219
CDVA (logMAR)	0.06	0.30 ; -0.08	CDVA (logMAR)	-0.02	0.00 ; -0.08	0.1518
UIVA (logMAR)	**0.07**	0.22 ; -0.08	**UIVA (logMAR)**	**0.41**	0.82 ; -0.08	**0.0008**
UNVA (logMAR)	**0.23**	0.49 ; 0.00	**UNVA (logMAR)**	**0.58**	1.00 ; 0.20	**0.0018**

MONTH 3

elon 877PEY (EDoF)	Mean	Min - Max	877PAY (Mono)	Mean	Min - Max	p=
UDVA (logMAR)	0.01	0.15 ; -0.08	UDVA (logMAR)	0.04	.22 ; -0.08	0.8670
CDVA (logMAR)	0.00	0.12 ; -0.08	CDVA (logMAR)	0.00	0.00 ; 0.00	>0.9999
UIVA (logMAR)	**0.11**	0.52 ; -0.08	**UIVA (logMAR)**	**0.36**	0.82 ; 0.02	**0.0353**
UNVA (logMAR)	**0.27**	0.70 ; 0.00	**UNVA (logMAR)**	**0.64**	1.00 ; 0.20	**0.0330**

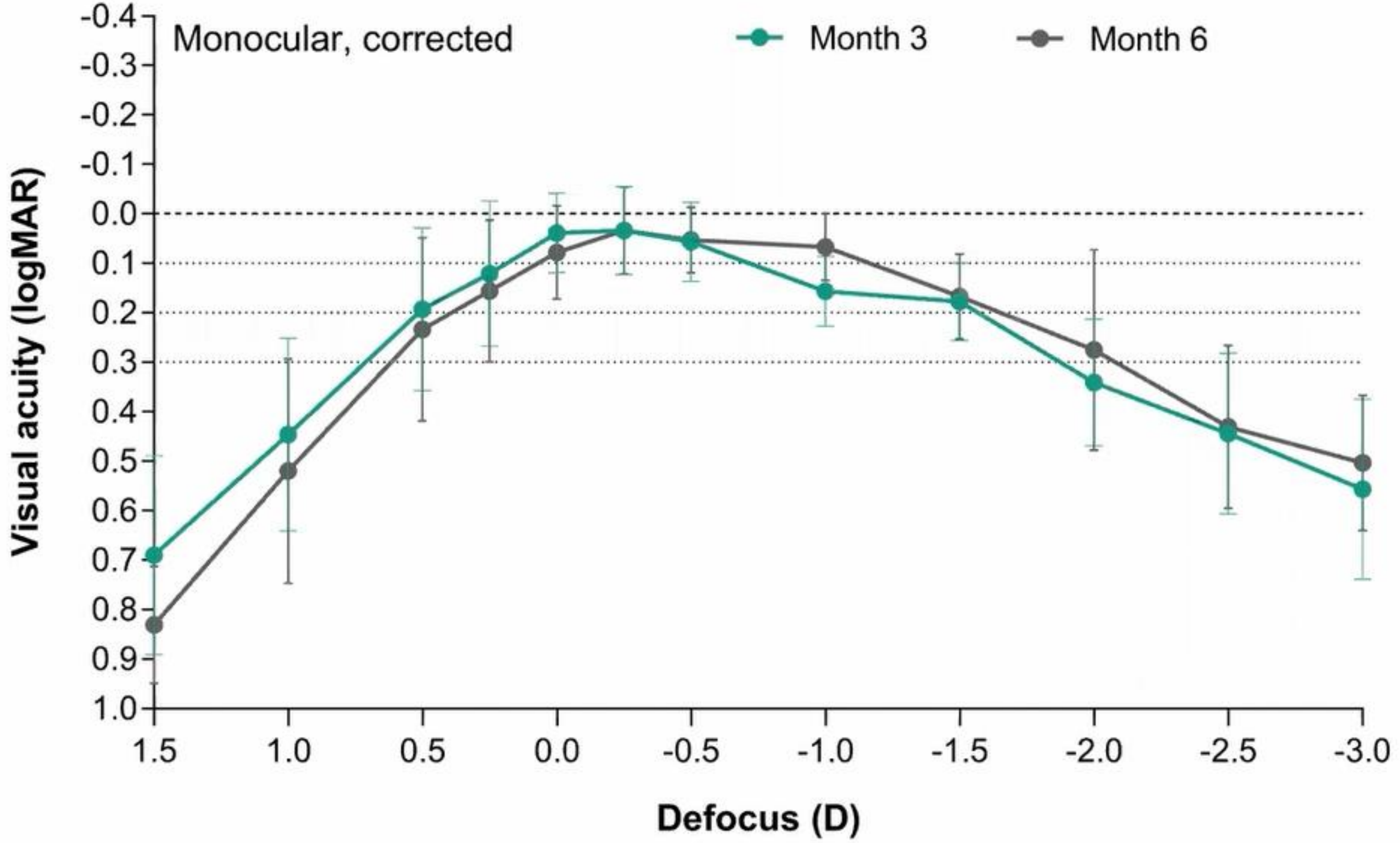
BINOCULAR VISUAL ACUITY – MONTH 3

Boglark

877PEY (EDoF)	Mean	Min - Max	877PAY (Mono)	Mean	Min - Max	p=
UDVA (Month 3)	-0.08	-0.08 ; -0.08	UDVA (Month 3)	-0.04	0.00 ; -0.08	0.0659
UIVA (Month 3)	**0.02**	0.22 ; -0.08	**UIVA (Month 3)**	**0.32**	0.52 ; 0.12	**0.0270**
UNVA (Month 3)	**0.18**	0.40 ; 0.00	**UNVA (Month 3)**	**0.50**	0.70 ; 0.30	**0.0190**

** Non-parametric Mann-Whitney test*

VISUAL ACUITY DEFOCUS CURVE (monocular)



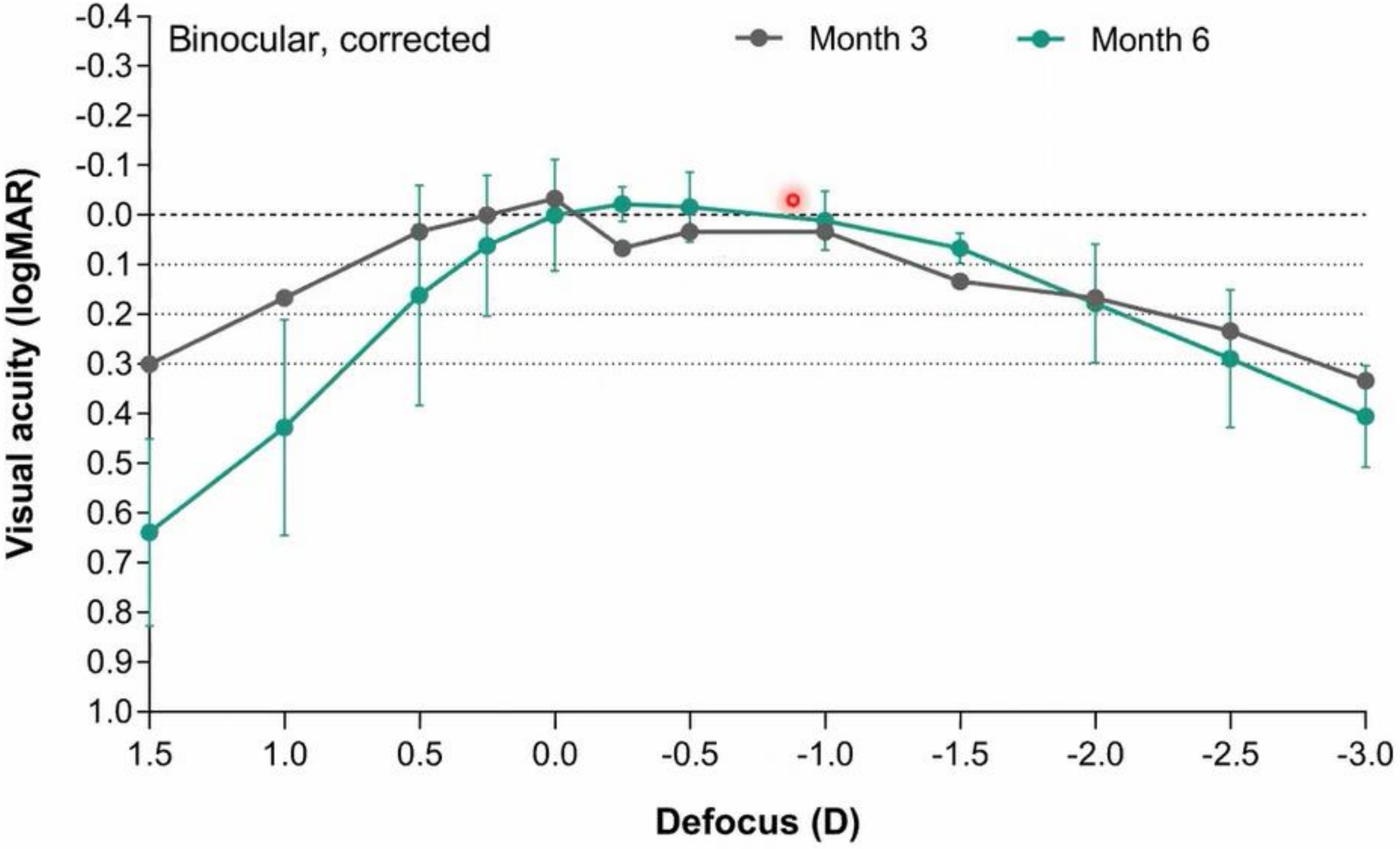
Corrected; Photopic

Month 3 n= 13 eyes

Month 6 n= 12 eyes

VISUAL ACUITY DEFOCUS CURVE (binocular)

Boglarka Sandor



Corrected; Photopic

Month 3 n= 1 patient

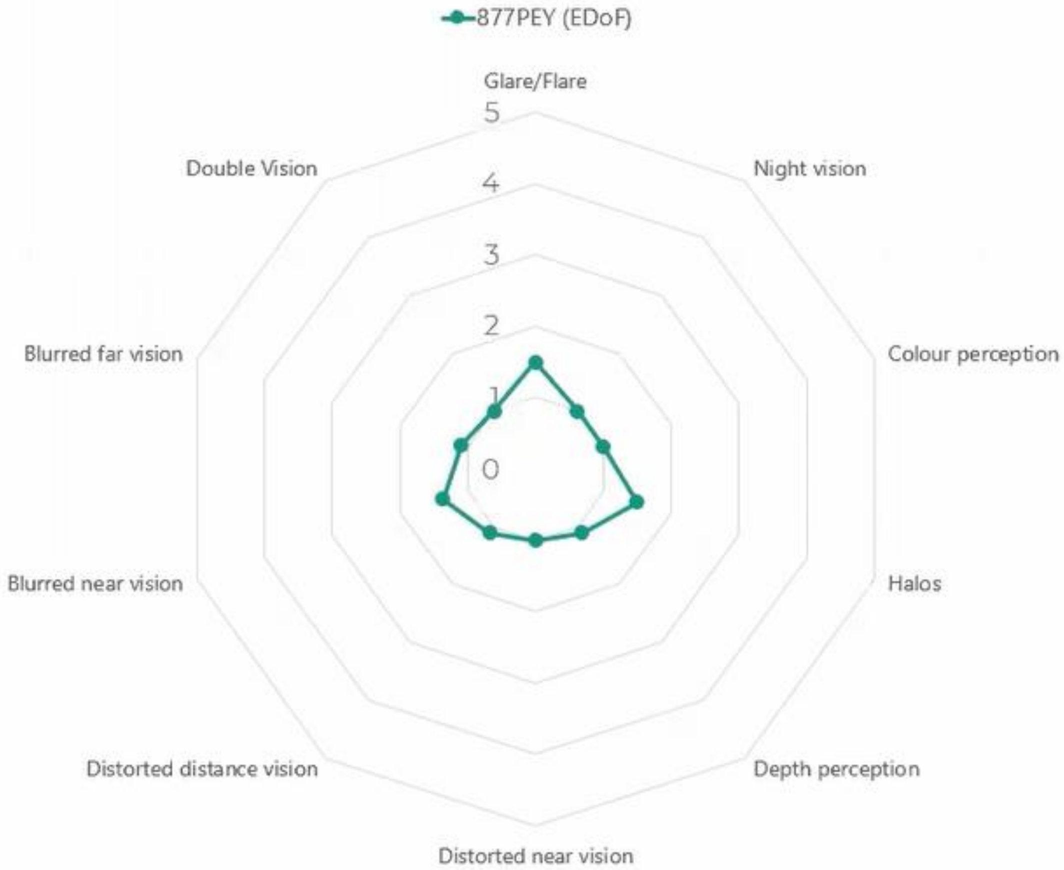
Month 6 n= 6 patients

VISUAL FUNCTIONS, DIFFICULTIES

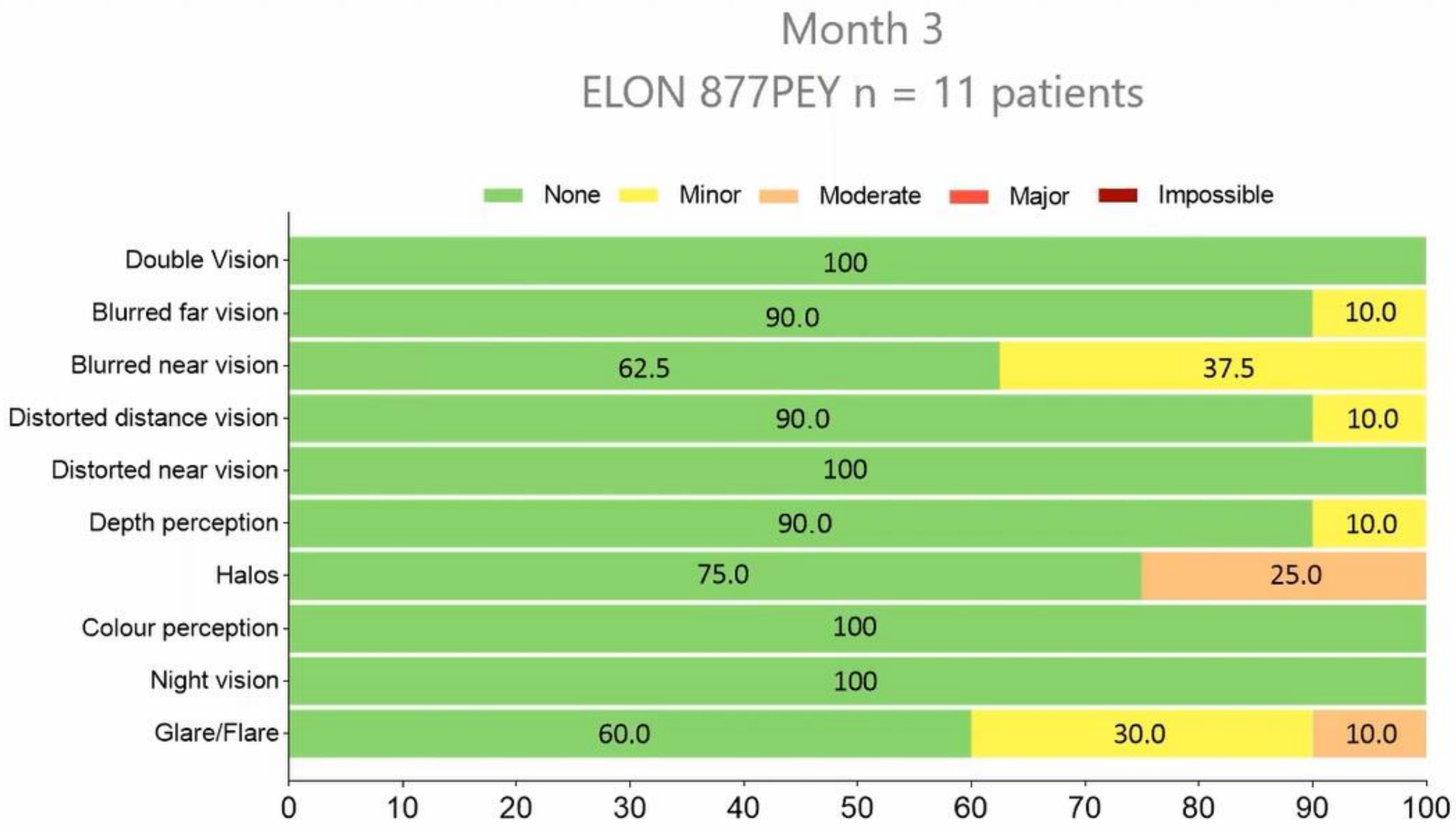
Boglarka Sandor

Month 3

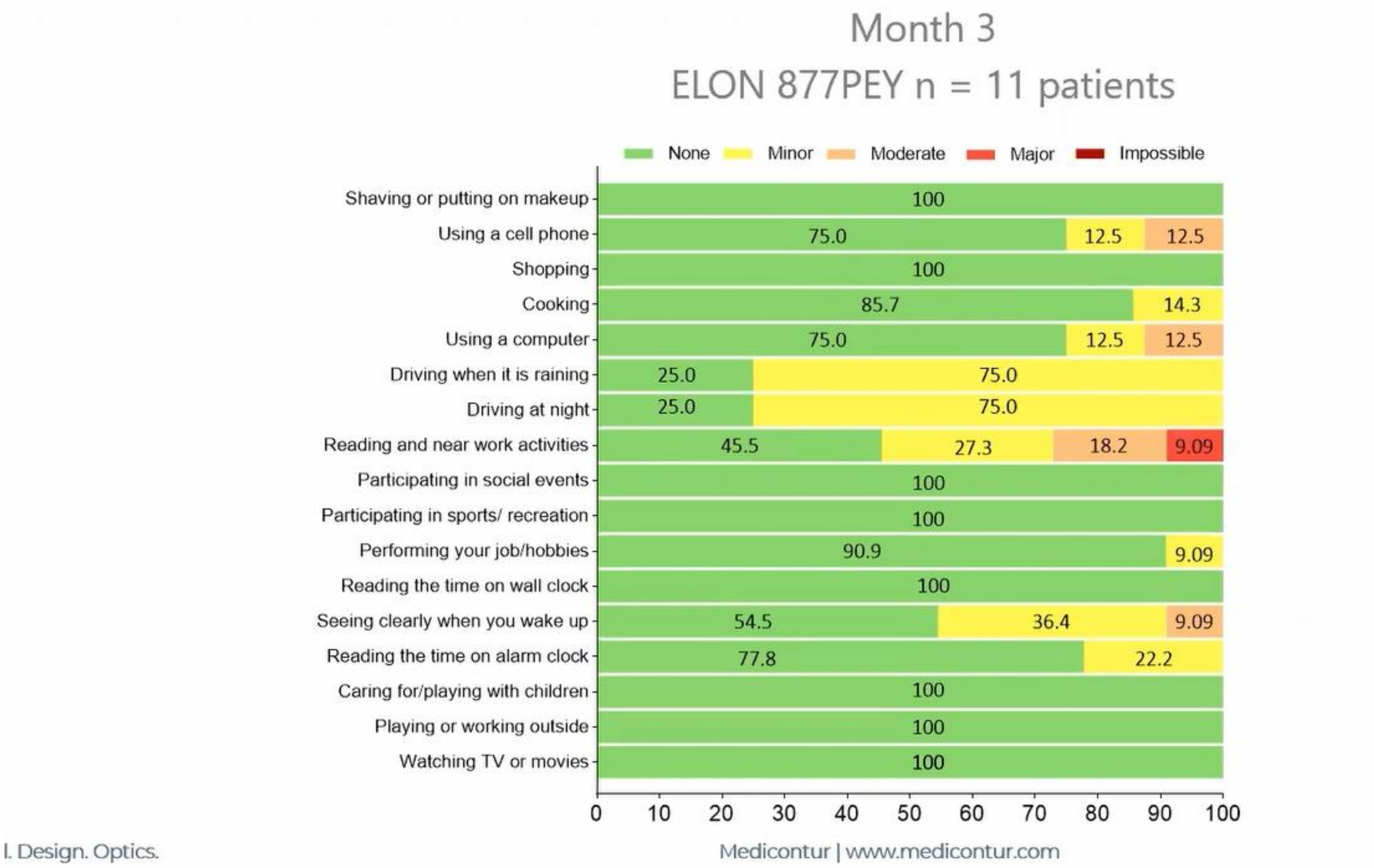
ELON 877PEY n = 11 patients



VISUAL FUNCTIONS, DIFFICULTIES



VISUAL FUNCTIONS, DIFFICULTIES



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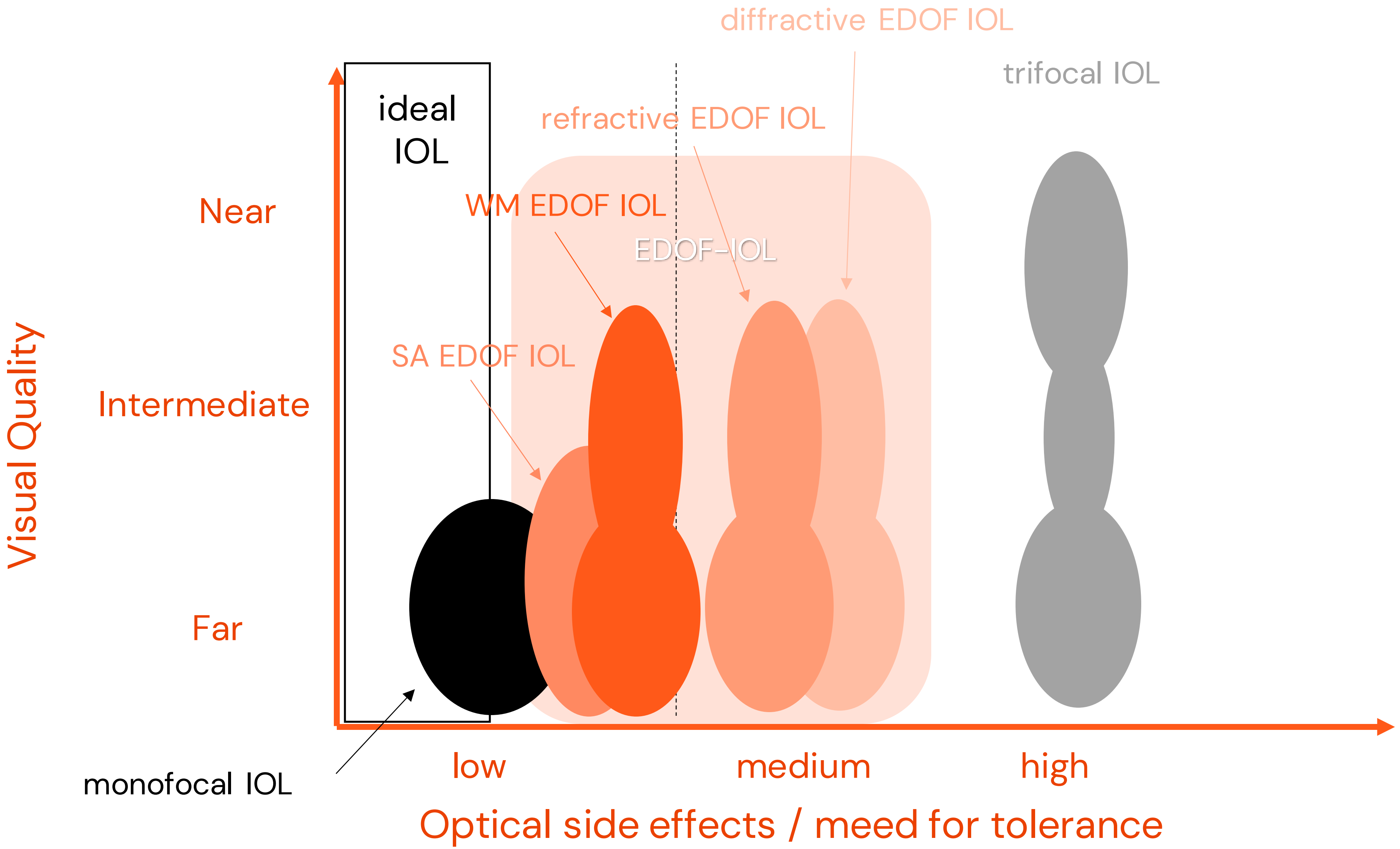
EDOF
Market overview

AddVision

EDOF lenses



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EDOF-IOL

Summary

Pinhole

AcuFocus
IC-8

Morcher
XtraFocus

Diffractive

J&J
Tecnis Symfony

Santen
Xact ME4

Zeiss
AT LARA

Refractive

Segment

Teleon
Acunex Vario

Teleon
Lentis Comfort

Teleon
Femtis Comfort

Spherical aberration

B+L
Lux Smart

PhysIOL
IsoPure 123

Cutting Edge
Synthesis +

Rayner
RayOne EMV

Ophthalmo Pro
ZOE

Sifi
Mini Well Ready

Hoya
Vivinex Impress

WM (Wavefront manipilating)

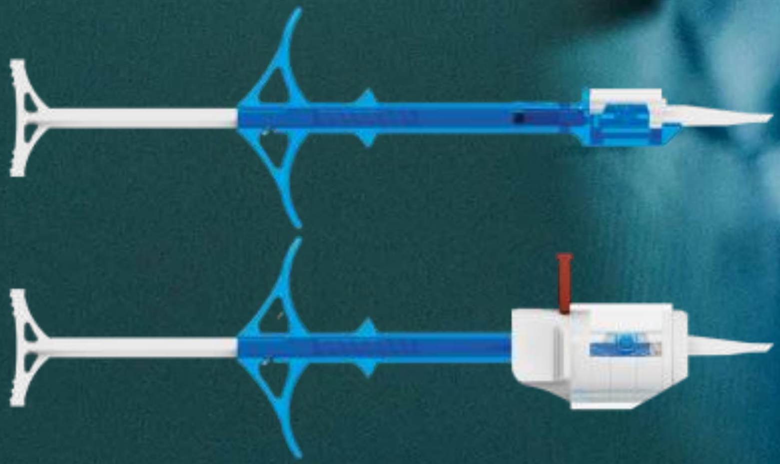
1stQ
Bais Z EDOF

Alcon
IQ Vivity

Medicontur
ELON

SAV-IOL
Lucidis

AddVision



Z-Felx POB-MA

hydrophobe, vorgeladene IOL

1st Q (Medicontur)

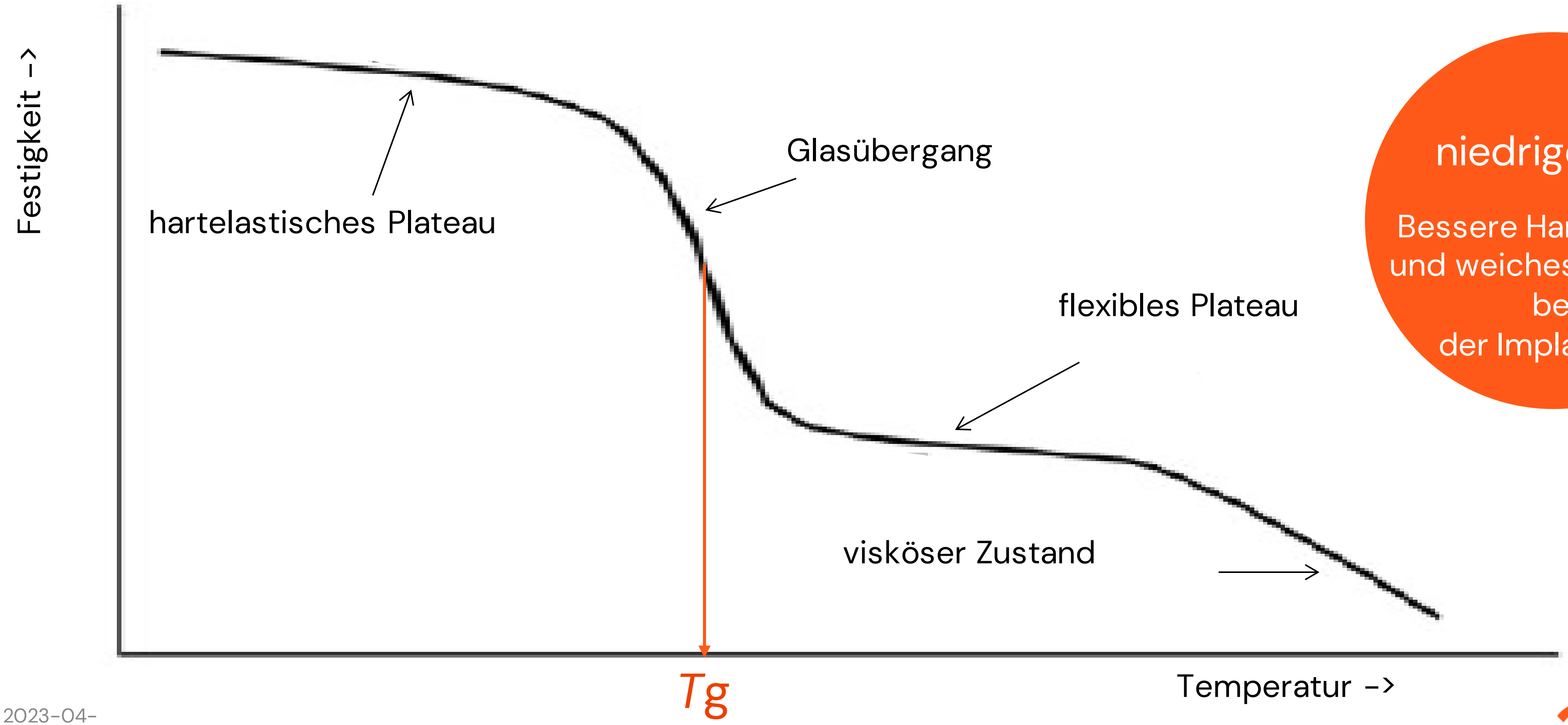
Z-Flex HB-Material: SEMTE

hydrophobes Material von Medicontur

- Eigenes Material von Medicontur
- Mehr als 10 Jahre klinische Erfahrung
- Rund 1 Mio. Implantationen
- Kein Glistening
- Hervorragende Materialeigenschaften

Glasübergangstemperatur *Tg*

Die Glasübergangstemperatur Tg (engl. glass transition temperature) ist die Temperatur, bei der ein Polymer vom hartelastischen, spröden Zustand in den flexiblen Zustand übergeht. Jeder Kunststoff wird durch seine spezifische Tg charakterisiert.



niedrige Tg =

Bessere Handhabung und weiches Entfalten bei der Implantation

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SEMTE – Glasübergangstemperatur *Tg*

Tg-Werte bei IOL-Materialien:

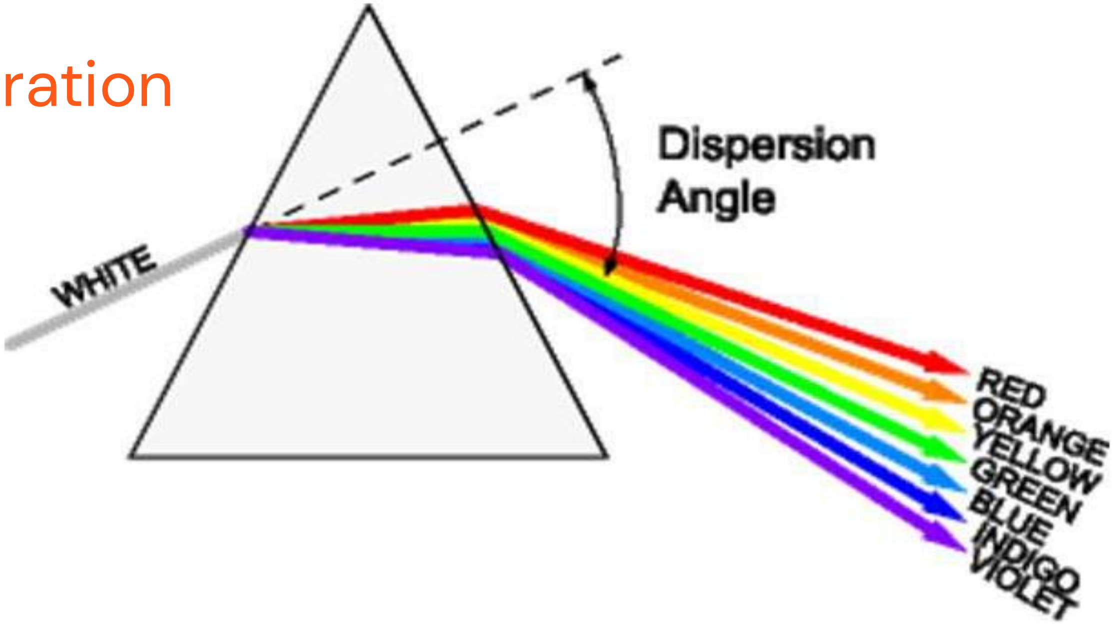
- SEMTE von Medicontur Tg = 4°C
- andere hydrophobe IOL: Tg = 11,0 bis 12,21°C
- PMMA: Tg = 105°C

Je weiter die Temperatur bei der Implantation von der Tg des IOL-Materials entfernt ist, desto flexibler und weniger rigide verhält sich die Linse.
Bei relativ niedrigen Temperatoren im OP kann es daher bei Linsenmaterialen mit hoher Tg zu Problemen beim Falten/Implantieren und Entfalten kommen.

niedrige Tg (4°C)

Bessere Handhabung und weiches Entfalten bei der Implantation

Chromatische Aberration

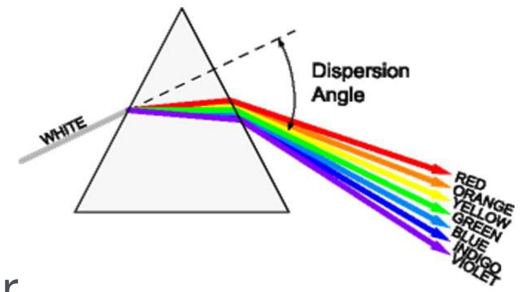


hohe chromatische Aberration
(Niedrige ABBE-Zahl, hoher RI)

geringe chromatische Aberration
(Hohe ABBE-Zahl, geringer RI)

SEMTE – ABBE-Zahl

Die Abbe-Zahl, auch Abbesche Zahl, ist eine dimensionslose Größe, die die optisch-dispersiven Eigenschaften eines Materials charakterisiert. Sie gibt an, wie stark sich der refraktive Index (RI) mit der Wellenlänge ändert, also wie hoch die chromatische Aberration ist. Je größer die ABBE-Zahl, desto geringer ist die chromatische Aberration



Niedrige ABBE-Zahl, hoher RI
hohe chromatische Aberration

Hohe ABBE-Zahl, geringer RI
geringe chromatische Aberration

ABBE-Zahlen im Vergleich

- **SEMTE von Medicontur: ABBE = 58**
- **andere hydrophobe IOL: ABBE = 37 bis 55**

hohe ABBE-Zahl (58)

Geringere chromatische Aberration – bessere Bildqualität

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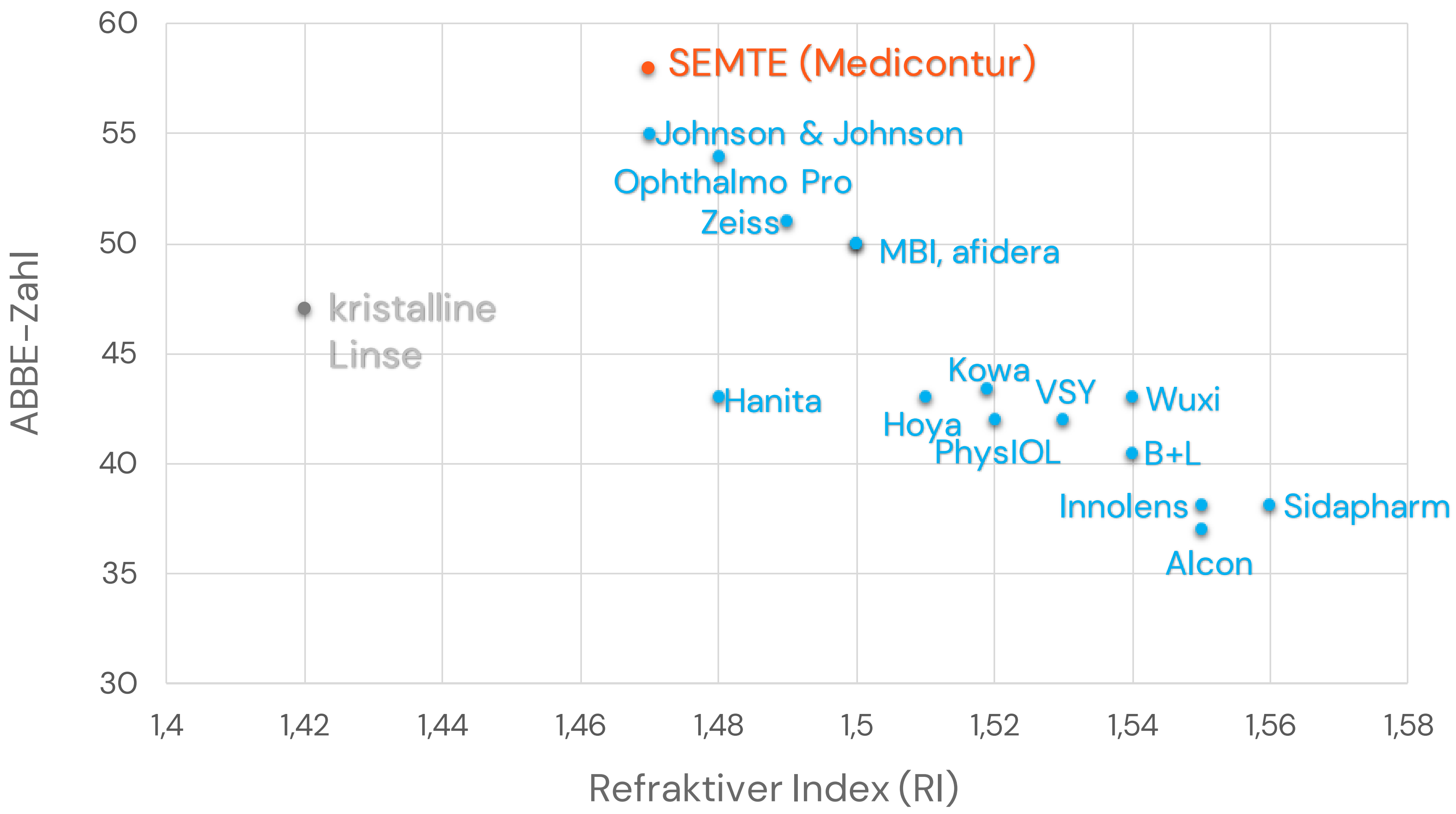
SEMTE – ABBE-Zahl und RI



SEMTE – Nutzen

Eigenschaft		Nutzen
Tg	4°C	weiche Entfaltung, auch bei geringeren Temperaturen, bessere Handhabung
ABBE-Zahl	58	überlegene optische Qualität durch geringere chromatische Aberration
Refraktiver Index	1,47	nahe dem der kristallinen Linse (1,43) kein Glistening, hohe Abbildungsqualität
Asphärizität	neutral	universell einsetzbar kein Verlust von Tiefenschärfe
Scharfe Kante	360°, 10 µm	Nachstarprophylaxe

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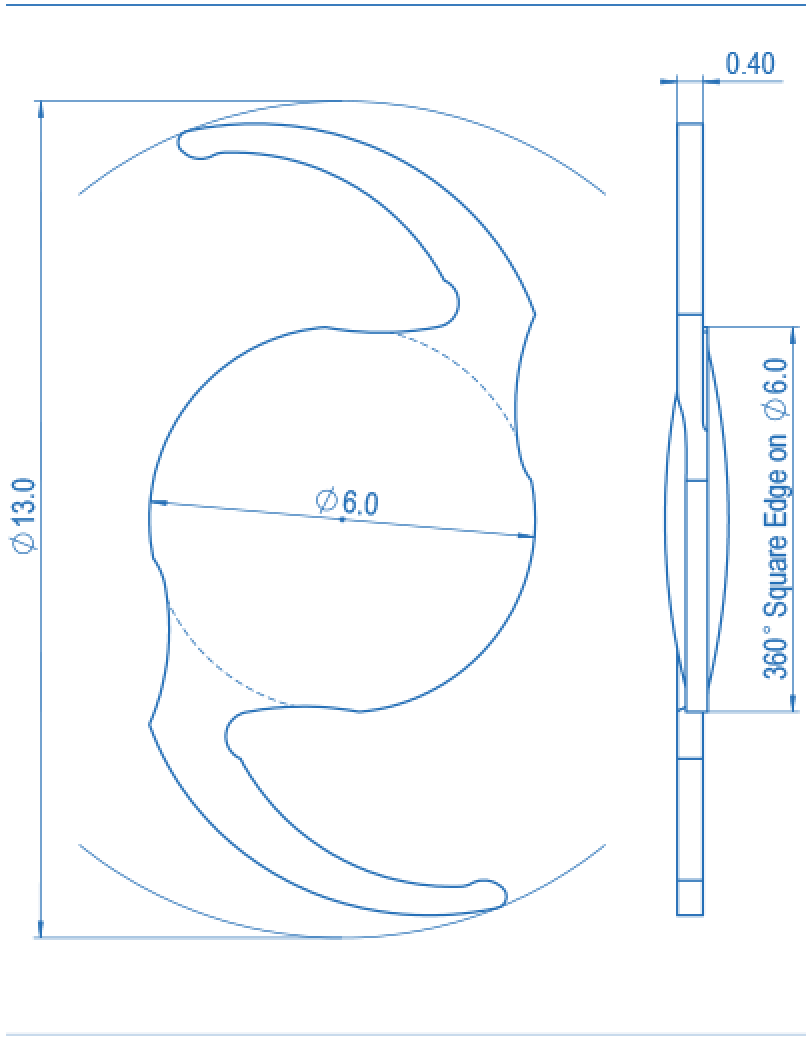
SEMTE – Marktvergleich

Hersteller	Herstellung	Kontaktwinkel Wasser	Wasserhegalt	Tg	RI	ABBE
Medicontur	**Drehen (Kälte)**	**87°**	**0,4%**	**4°**	**1,47**	**58**
Alcon	Spritzguss	88°	< 0,5%	14,0-15,5°C	1,55	37
Bausch + Lomb	Drehen (Raumtemperatur)	76°	4,0 %	15-20°C	1,54	40,5
Cristalens	Drehen (Kälte)	?	< 1,0%	11°C	1,545	?
Hanita	Drehen (Kälte)	?	< 2,0%	10°C	1,48	43 (49)
HOYA	Drehen	85°	< 0,3%	11°C	1,52	42
J&J	Drehen (Kälte)	88°	< 0,5%	12,2°C	1,47	55
KOWA	?	?	?	?	1,519	43,3
MBI	?	?	?	?	1,5	50
Nidek	?	?	?	?	1,52	?
PhysIOL	?	?	?	?	1,52	42
Wuxi	drehen und fräsen	?	< 0,5%	11°C	1,54	43
Zeiss	?	88°	0,3 %	?	1,49	50

Z-Felx - Design

- **Angenehme Handhabung durch**
  - ➢ Spontanes und symmetrisches Entfalten

- **Exzellente Ergebnisse durch**
  - ➢ Reproduzierbare Zentrierung
  - ➢ 180° Kontaktwinkel zwischen Haptiken und Kapselsack
    - ✓ Exzellente Stabilität
    - ✓ Optimales Aufspannen des Kapselsackes
    - ✓ 360° scharfe Kante > Nachstraprophylaxe



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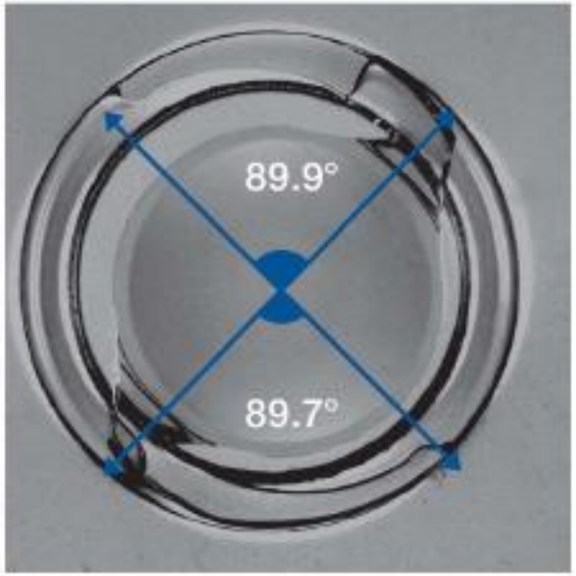
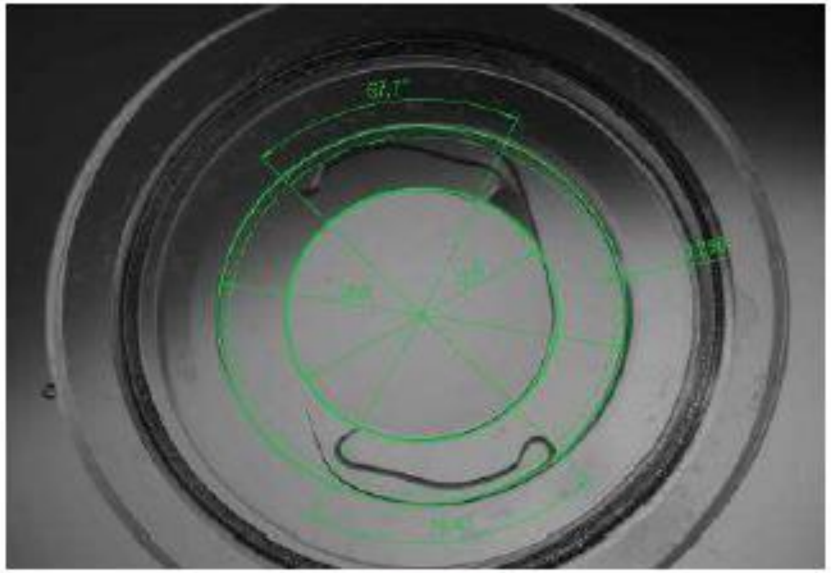
Z-Flex - Design

Kontaktwinkel mit dem Kapselsack

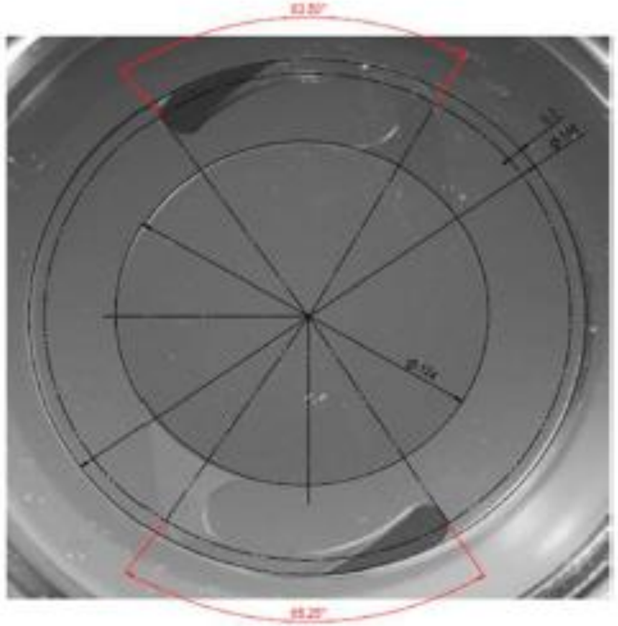
Experimental simulator with a diameter of **9 mm**



1stQ Basis Z
Average contact angle: 88.8°



Competitor 1
Average contact angle: 69°



Competitor 2
Average contact angle: 64.4°

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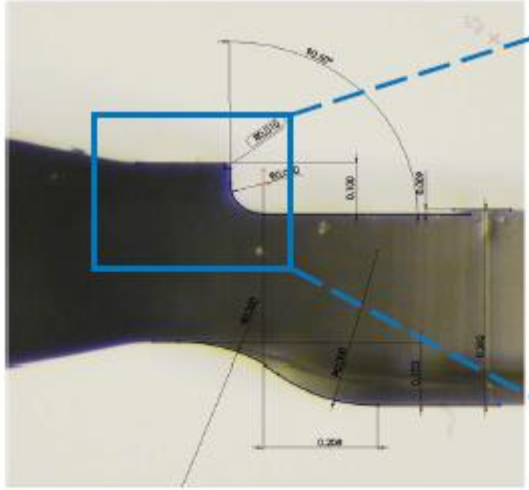
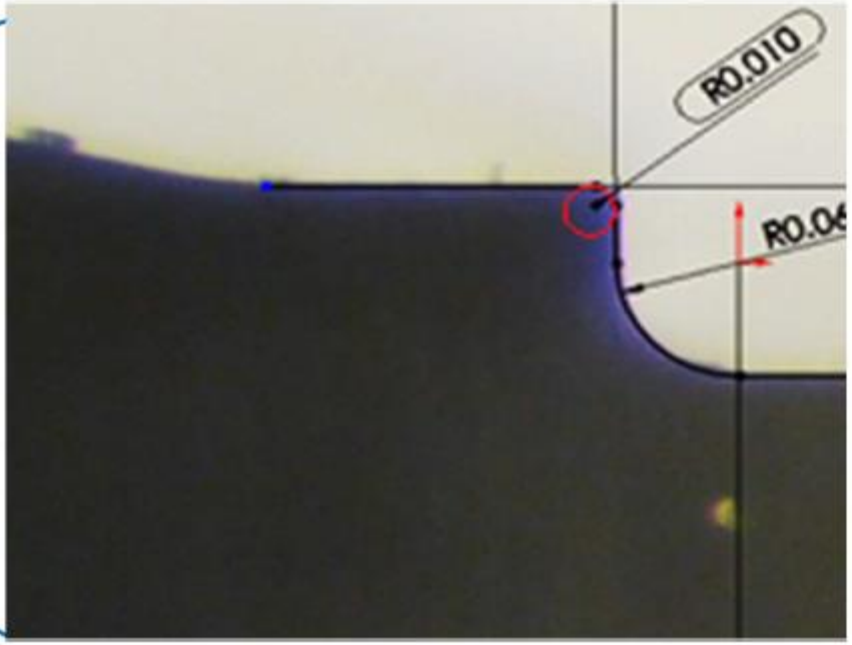
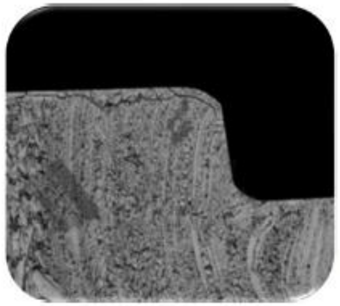
Z-Flex

360° scharfe Kante

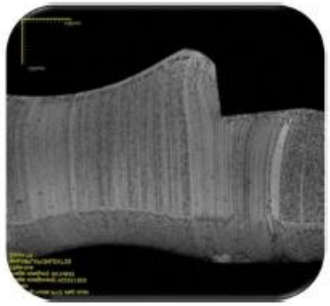




Basis Platforms
10 microns

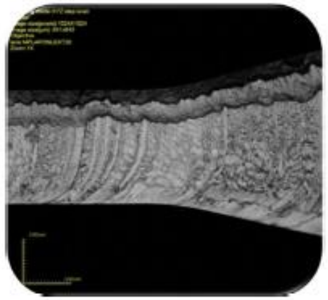


Comp 1
35 microns (B)

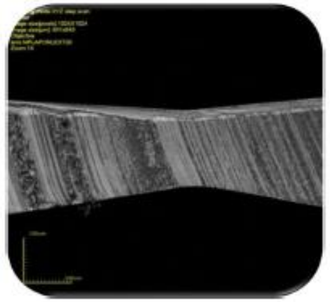


Comp 2
60 microns (P)

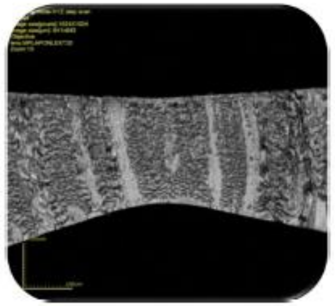
Comp 3
25 microns (R)



Comp 4

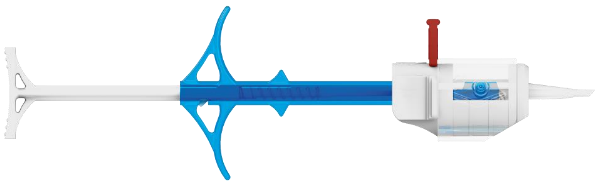


Comp 5



Comp 6

Eigenschaften



Z-FLEX HB POB-MA PRELOADED: 860PA / 860PAY

Vorgeladenes Injektions-System für die hydrophobe Z-Flex-IOL zur einfachen, sicheren und vorhersagbaren Implantation in den Kapselsack.

Linsentyp:	einteilige, asphärische hydrophobe Acryl-IOL
Durchmesser:	6,00 mm Optik / 13,00 mm Gesamtdurchmesser
Material:	hydrophobes Acryl mit UV-Filter
Asphäre:	Aberrationsneutral
Blaulichtfilter:	optional („Natural Yellow“)
Haptik:	0° Anwinkelung
Lieferbereich:	Standard: **0,0 D bis +9,0 D** (1,0 D-Stufen) und **+10,0 bis +30,0 D** (0,5D-Stufen) Extrem: **-10,00 D bis -1,0 D** und **+31,0 D bis +35,0 D** (1,0 D-Stufen)
PCO-Schutz:	360° scharfe Kante

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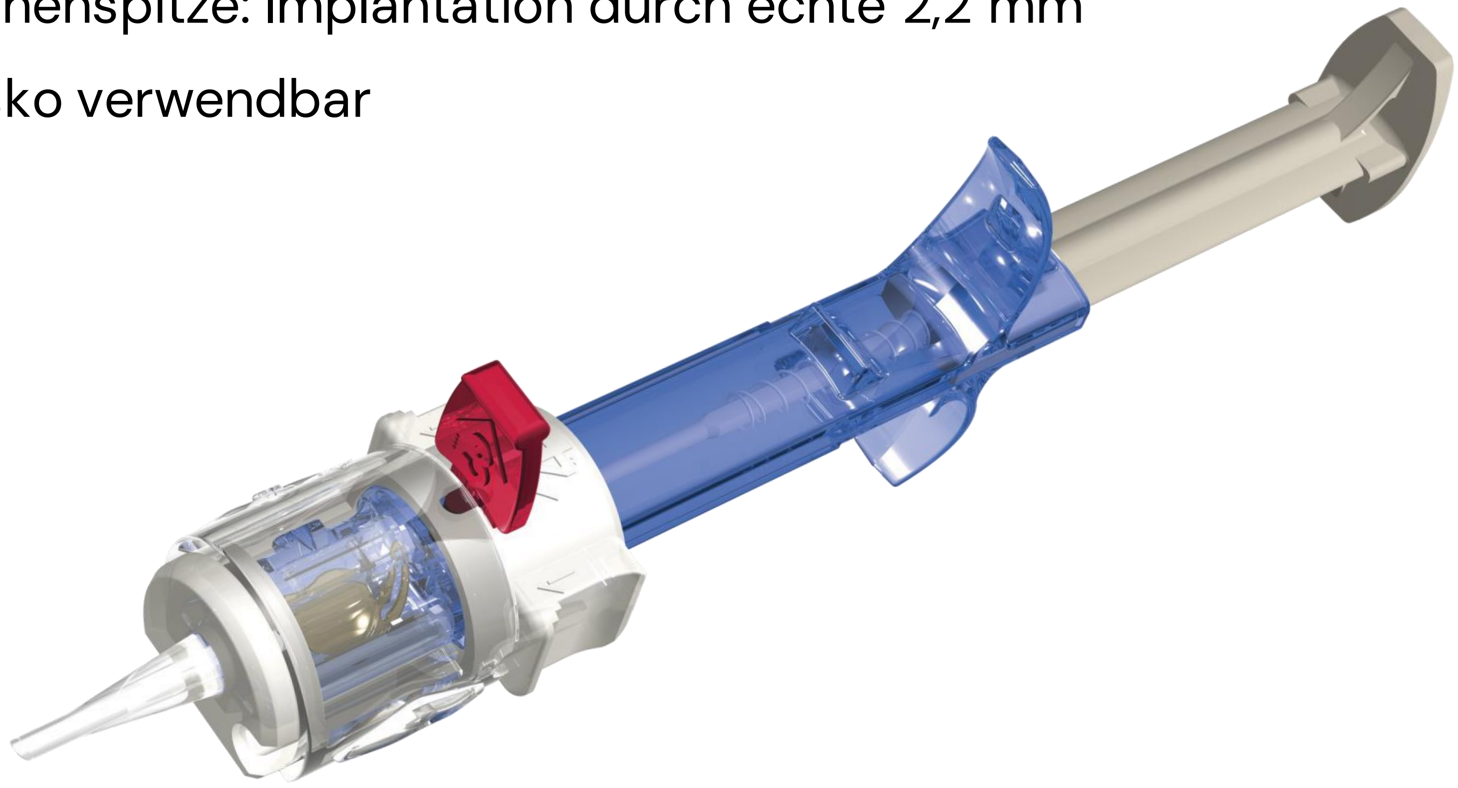
POB-MA: Injektor und Handhabung

Version P2

- Neue, kleinere Kartuschenspitze: Implantation durch echte 2,2 mm
- Mit allen Arten von Visko verwendbar



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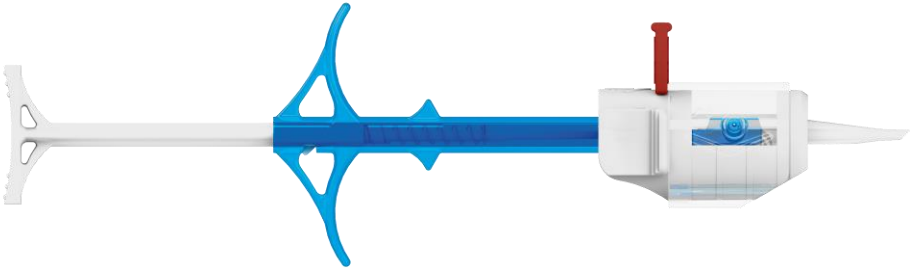
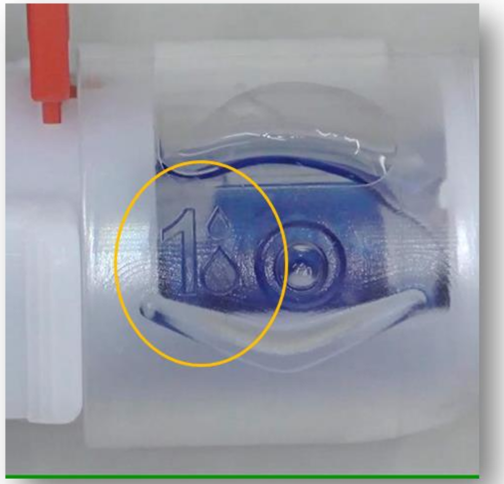
Handhabung POB-MA (P2)





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Handhabung POB-MA (P2)

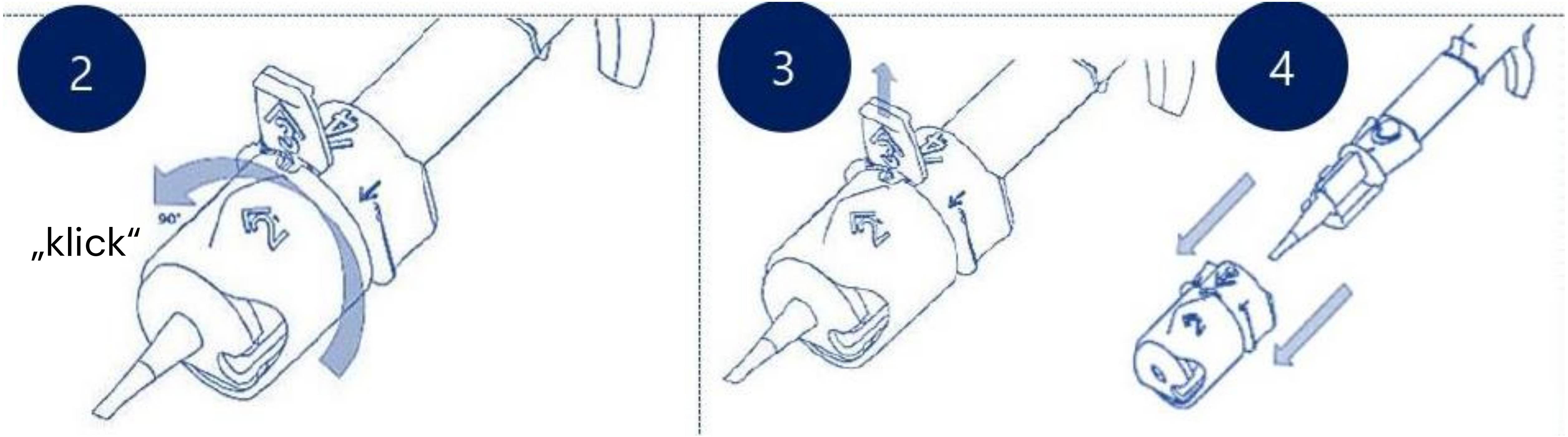
Einfüllen des Viskos

1

Die Viskokanüle bis zum „Anschlag“ einführen

Handhabung POB-MA (P2)

Falten der IOL

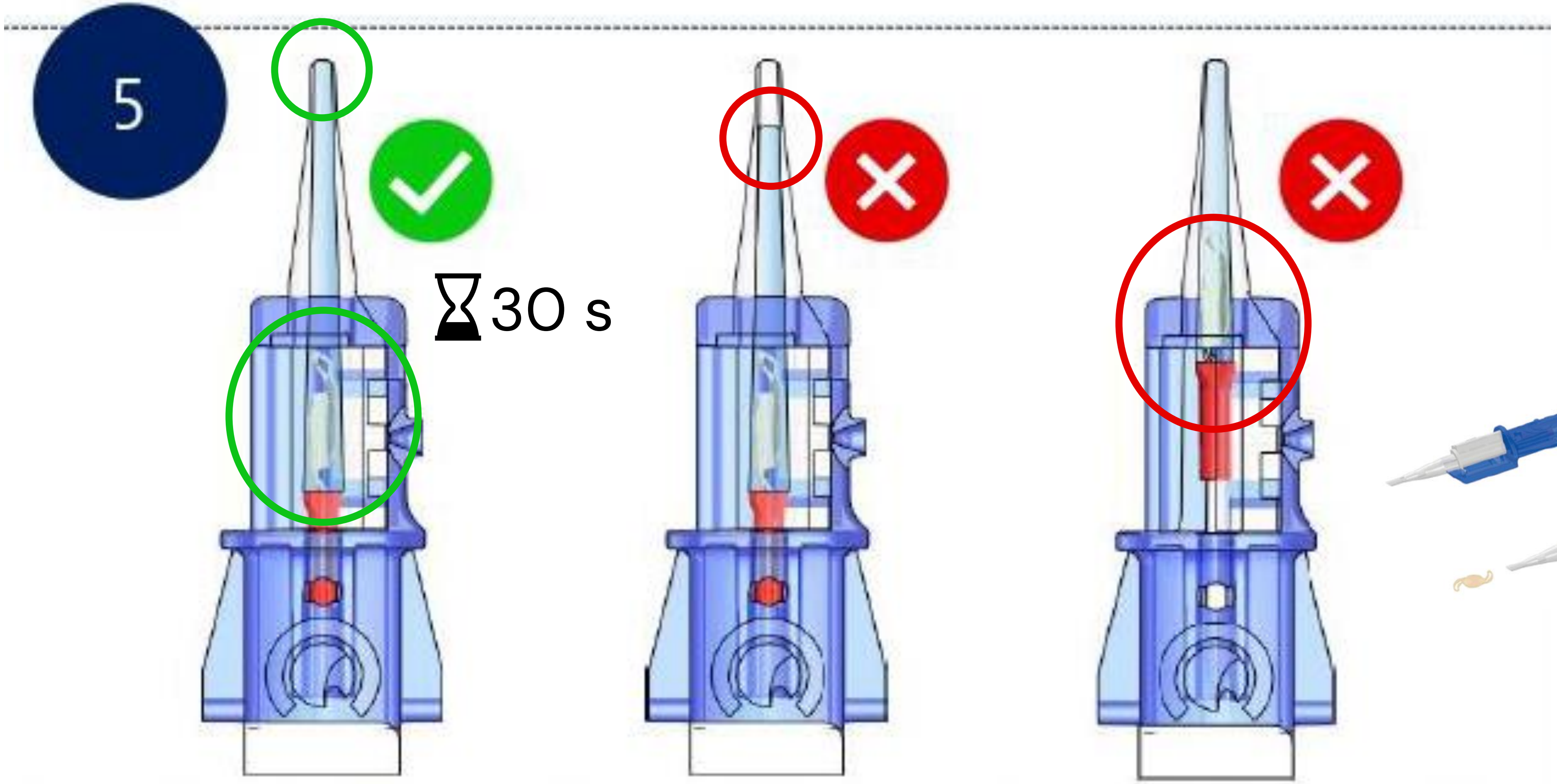


2: „Trommel“ um 90° bis zum „klick“ drehen

3: Roten Sicherungsstift herausziehen und 4: Trommel abziehen

Handhabung POB-MA (P2)

Aktivieren des Gleitfilmes



Stempel nach vorne schieben, bis das Visko die Kartuschenspitze erreicht hat. In dieser Position für ca. 30s belassen. Die IOL sollte sich dabei noch in der Ladekammer befinden.

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