Avansee Preload1P Toric

avansee™ preload1P TORIC

UIN: IOL20 00023 Date of Prep: October 2020

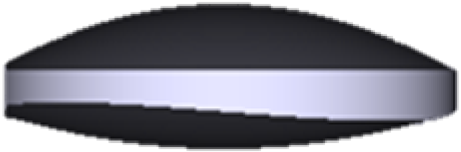
Avansee Preload1P Toric

Kowa

Lens design

Anterior surface

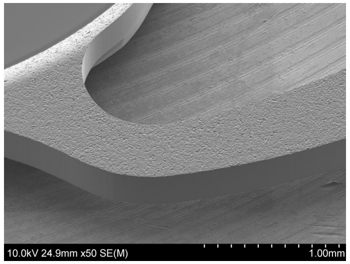
- Original aspheric design
  - i. Spherical aberration : -0.04µm



Posterior surface

- **Original Toric design**

Indented haptics



Toric mark

Avansee Preload1P Toric

Avansee Preload1P Toric Clear Model: CP-Tx

Dioptre range

Spherical power : from +6.0D to +26.0

Cylinder power : from +1.5D to +4.5D

Cylinder powers (D):

Model : YP-/CP-	T3	T4	T5	T6	T7
IOL plane (labeled)	1.50	2.25	3.00	3.75	4.50
Corneal plane	1.0	1.5	2.0	2.5	3.0

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Avansee Preload1P Toric

The USPs of Avansee Preload1P Toric

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Avansee Preload1P Toric

The USPs of Avansee Preload1P Toric

I. Progressive Axial Correction (PAC) Technology

II. Original Asphericity

III. Proven Rotational Stability

IV. Smooth Unfolding

V. Glistening-Free

VI. 360 Degree Square Edge

VII. Easy to Use

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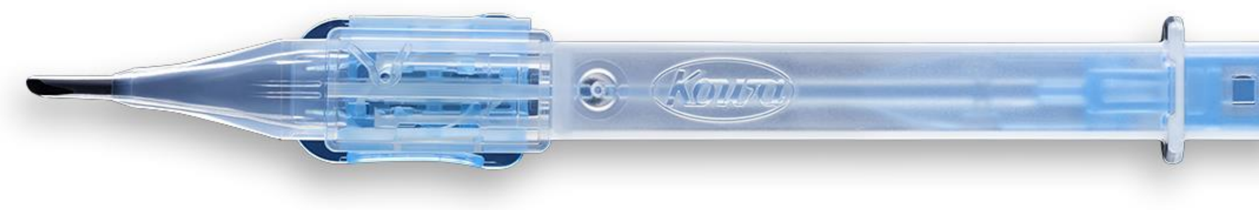
Progressive Axial Correction (PAC) Technology



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The relationship between central and peripheral corneal astigmatism in elderly patients

The magnitude of corneal astigmatism decreased with an increase in the diameter of the zone analysed, regardless of whether the astigmatism was WTR or ATR

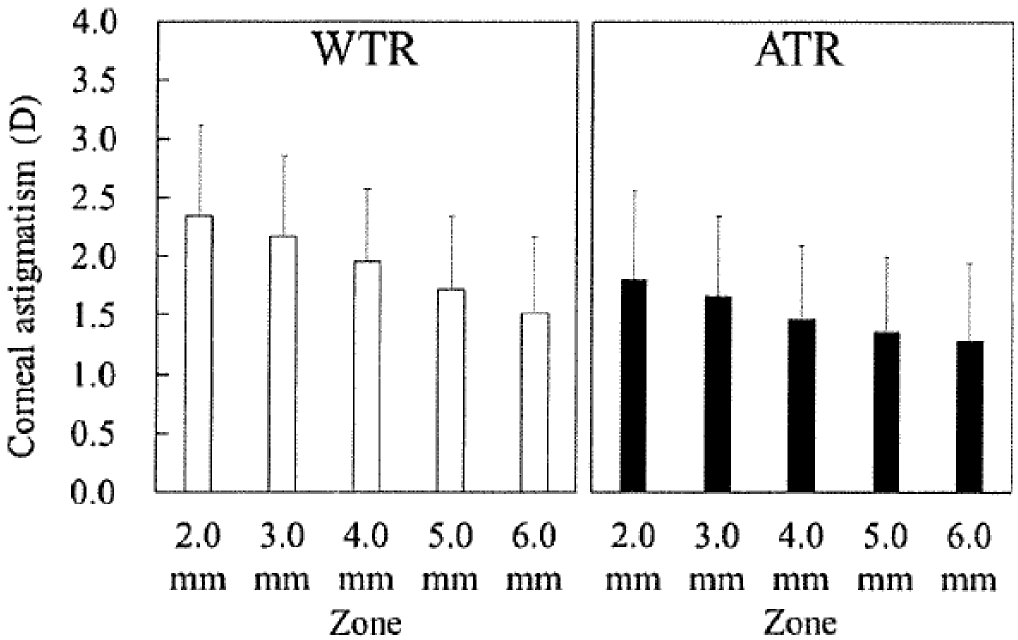

Fig. 1 Central and peripheral corneal astigmatism. Statistical analyses were performed using ANOVA ($p<0.01$). *WTR* with-the-rule, *ATR* against-the-rule

Optical Review, June 2018, Volume 25, Issue 3, pp 336–339 | Cite as
Relationship between central and peripheral corneal astigmatism in elderly patients
Takushi Kawamorita, Kimiya Shimizu, Rie Hoshikawa, Kazutaka Kamiya, Nobuyuki Shoji

The relationship between central and peripheral corneal astigmatism in elderly patients

The larger the corneal astigmatism, the greater is the difference between central and peripheral corneal astigmatism

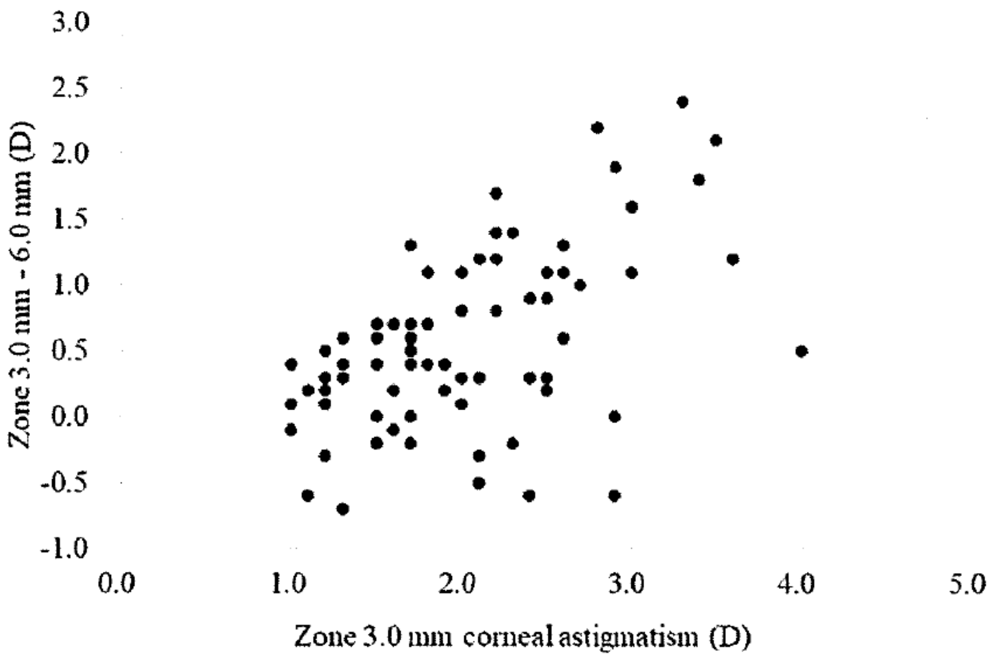

Fig. 2 Effect of corneal astigmatism magnitude. Statistical analyses were performed using a Spearman's rank-correlation coefficient test ($r = 0.51$, $p < 0.01$)

Optical Review, June 2018, Volume 25, Issue 3, pp 336–339 | Cite as
Relationship between central and peripheral corneal astigmatism in elderly patients
Takushi Kawamorita, Kimiya Shimizu, Rie Hoshikawa, Kazutaka Kamiya, Nobuyuki Shoji

Progressive Axial Correction (PAC) Technology

Presented by David J Apple Lab at ESCRS 2020 as the oral presentation #2553

Kowa

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UNIVERSITY EYE CLINIC 152 Years Since 1868

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Grzegorz.Labuz@med.uni-heidelberg.de | www.ivcrc.com | www.djapplelab.com

Assessment of central and peripheral corneal astigmatism in an elderly population: a retrospective analysis of topography results from 717 eyes

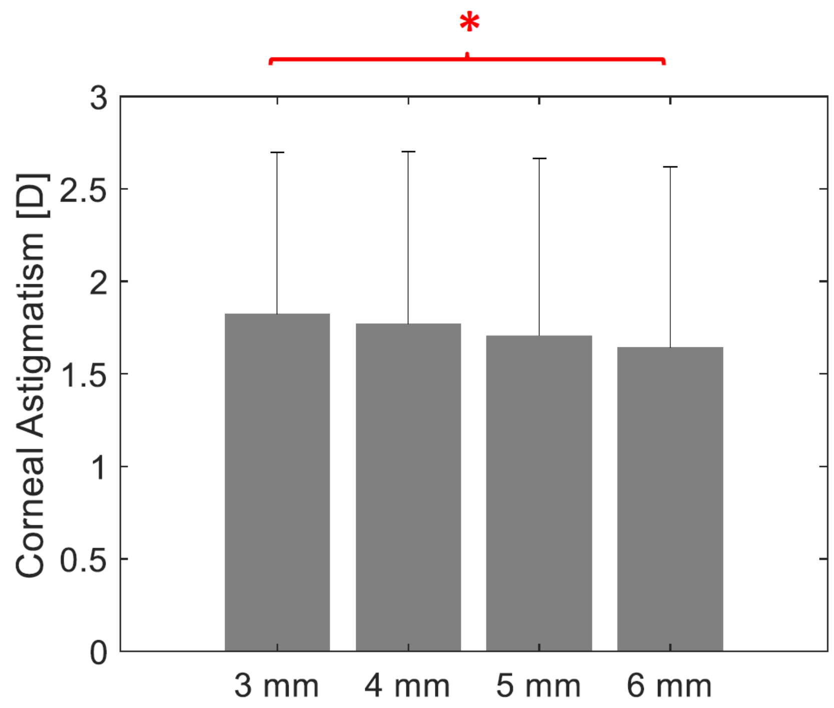
Grzegorz Łabuz, Dorottya Varadi, Ramin Khoramnia, Gerd U. Auffarth

International Vision Correction Research Centre (IVCRC),
The David J. Apple International Laboratory for Ocular Pathology
Department of Ophthalmology, Ruprecht-Karls-University of Heidelberg
Chairman: G. U. Auffarth, MD, PhD, FEBO

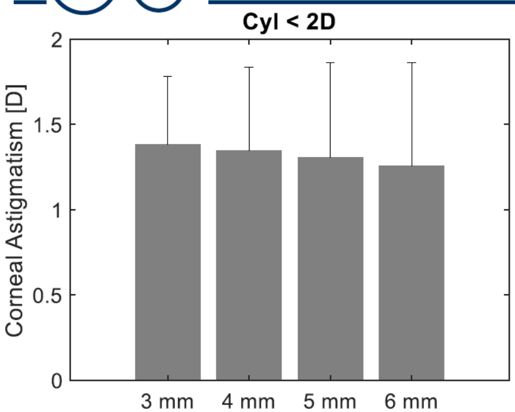
UK HD

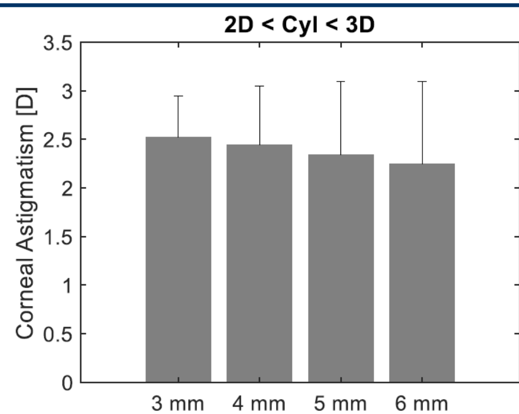
Results

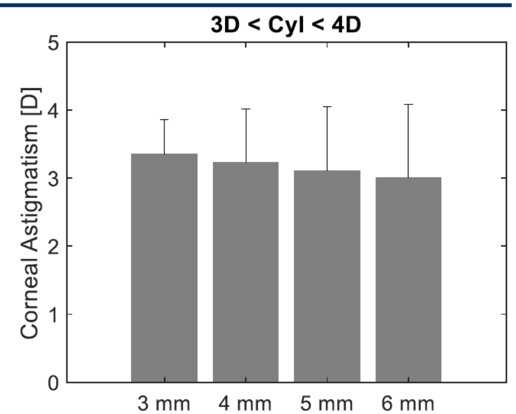
- Corneal astigmatism, on average, decreases from the center to the periphery.
- The mean difference in astigmatism measured in the 3- and 6-mm zone was 0.18 ±0.41D (paired t-test, P<.001).

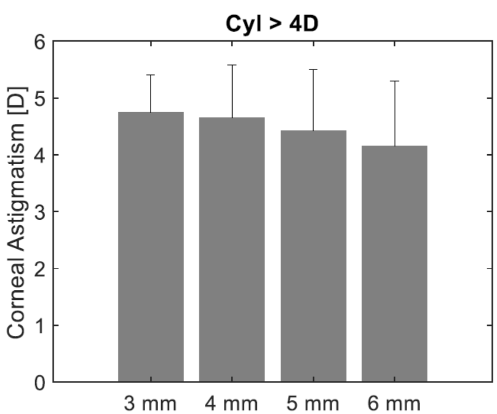


Results









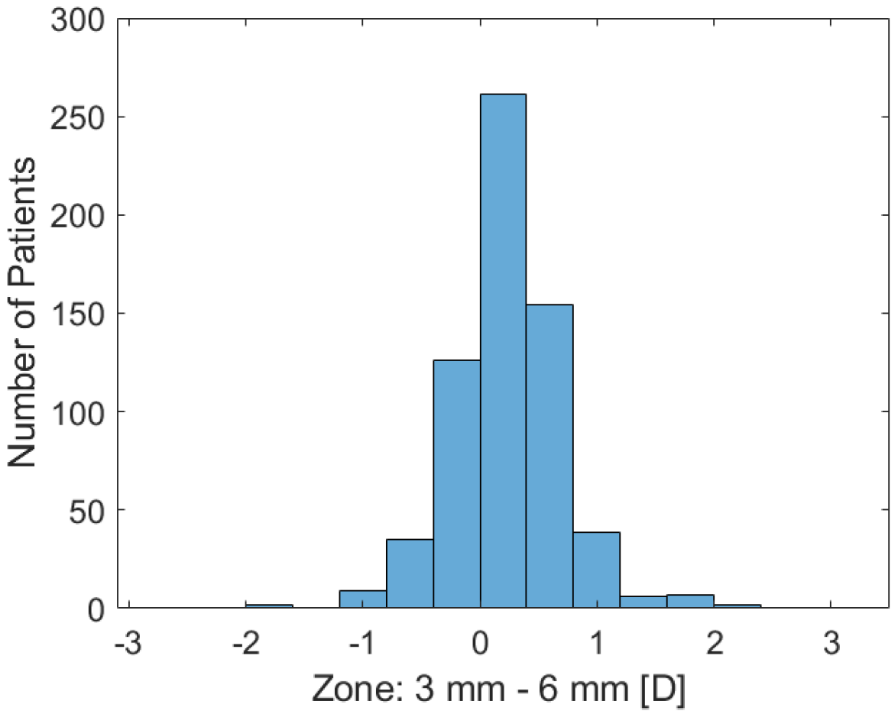
Zone: 3 mm – 6 mm

	Cyl <2D	2D < Cyl < 3D	3D < Cyl < 4D	Cyl > 4D
MD [D]	0.13	0.27	0.34	0.59
SD [D]	0.37	0.57	0.63	0.70

MD = mean difference; SD = standard deviation; Cyl = corneal cylinder

Results

- The majority of the study corneas demonstrated the decrease of corneal astigmatism with pupil size.
- Only 27% showed the opposite behavior, which mostly lay in the low range of the cylinder difference.



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Conclusions

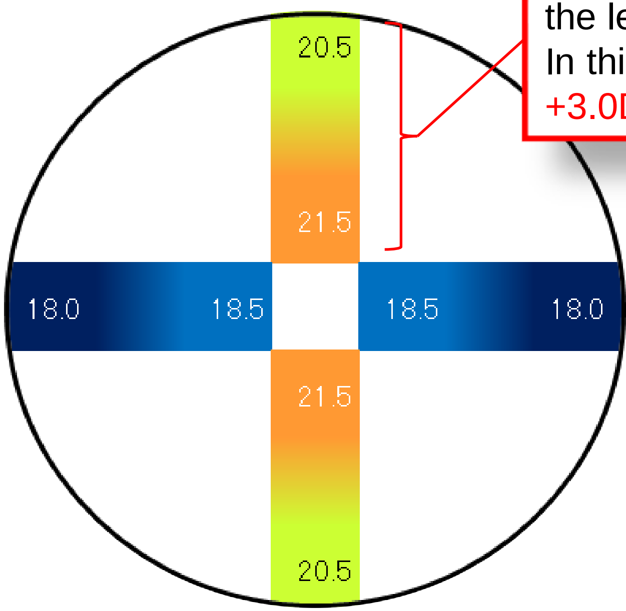
- Corneal astigmatism decreases from the center to the periphery.
- On average, the cylinder-power change is more substantial in cases with higher corneal astigmatism.
- The axis of astigmatism did not change with zone diameter.
- Toric IOLs can be improved by decreasing the cylinder power at the lens' periphery to account for these differences.

Avansee Preload1P Toric IOL with PAC (progressive axial correction) technology provides optimal correction for astigmatism from the centre to periphery

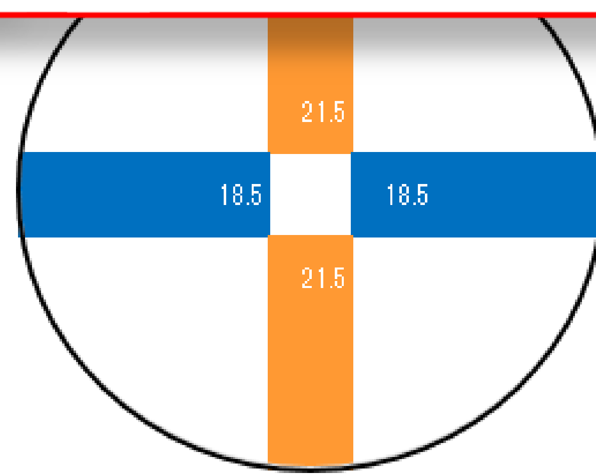
Example: spherical power:+20.0D and cylinder power:3.0D

- In Avansee Toric, the cylinder power in the centre portion of the lens is higher than in the peripheral portion of the lens.

The cylinder power gradually reduces from the centre portion of the lens to the peripheral portion of the lens.
In this case the cylinder power in the middle and peripheral are +3.0D and +2.5D.



Avansee Preload1P Toric



Conventional Toric

Progressive Axial Correction (PAC) Technology

Presented by David J Apple Lab at ESCRS 2020 as the ePoster #2015

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Grzegorz.Labuz@med.uni-heidelberg.de www.ivcrc.com www.djapplelab.com

A progressive-toric IOL design that accounts for the decrease of corneal astigmatism with pupil size: ray-tracing simulations using corneal topography data

Grzegorz Łabuz, Dorottya Varadi, Ramin Khoramnia, Gerd U. Auffarth

International Vision Correction Research Centre (IVCRC)
The David J. Apple International Laboratory for Ocular Pathology
Department of Ophthalmology, Ruprecht-Karls-University of Heidelberg
Chairman: G. U. Auffarth, MD, PhD, FEBO

FINANCIAL DISCLOSURE 2019/2020

Acufocus[1]
Alcon[1,2,3,4]
Alimera[1,2,3]
Johnson&Johnson[1,2,3,4]
Anew[1]
Biotech[1,3]
Carl Zeiss Meditec[1,2,3]
Physiol[1]
Rayner[1,2,3]
Rheacell[1]
Santen[1,2,3]
SIFI[1,2,3]
Ursapharm[1,2,3]

1 = Research Grants; 2 = Travel Expenses; 3 = Lecture Fees; 4 = Consulting

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Materials & Methods

- Pentacam (OCULUS Optikgeräte GmbH, Germany) Scheimpflug corneal topography data of 52 patients (mean age: 69.5 ±6.0 years) were obtained during routine patient examinations at the Heidelberg University Eye Clinic and fitted with Zernike functions using MATLAB (MathWorks, Inc, USA).

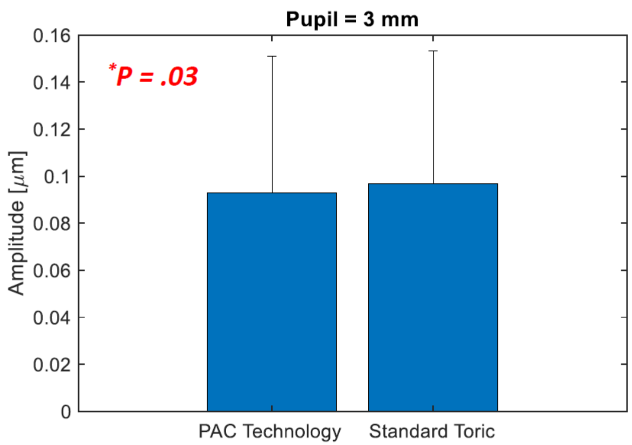
- A model eye was built in OpticStudio (Radiant Zemax LLC, USA) based on measured Scheimpflug topography. Corneal astigmatism (range: 0.8 to 3.8D) was corrected with an Avansee Toric (Kowa), which features Progressive Axial Correction (PAC) technology i.e., gradually decreasing cylinder power from the center to the periphery. Its performance was compared against a lens having identical design parameters but conventional astigmatism correction.

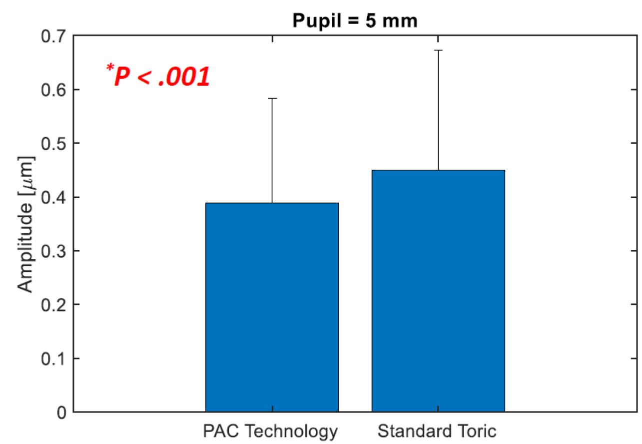
- Higher-order aberrations, residual astigmatism,[3] and the Strehl ratio of the two conditions were compared at 3- (photopic) and 5-mm (scotopic) pupils.

[3]*Thibos et al. JOSA A 2002*

Results

The primary, secondary and tertiary astigmatism of the new toric IOL was significantly lower than that of the standard toric, which resulted in reduced residual astigmatism.





Residual Astigmatism [D]

	PAC toric	Standard toric	*P value
Photopic	-0.36 ±0.26	-0.38 ±0.25	.06
Scotopic	-0.57 ±0.30	-0.67±0.33	<.001

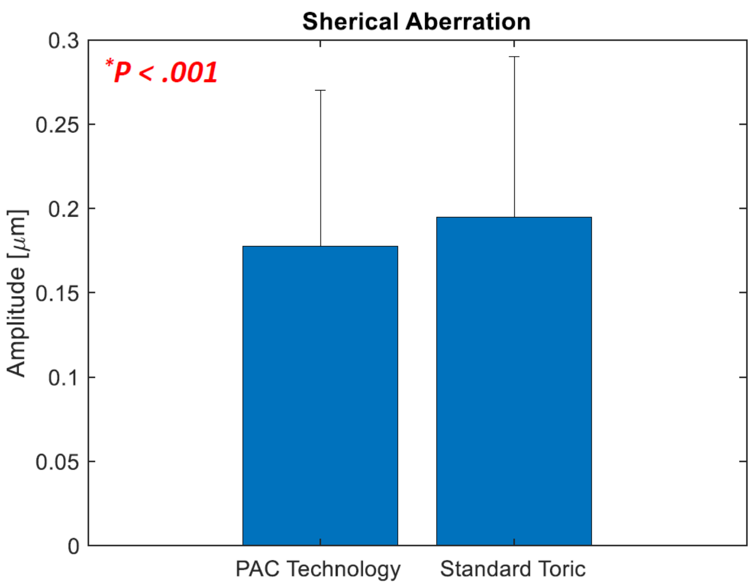
**Two-tailed paired t-test*

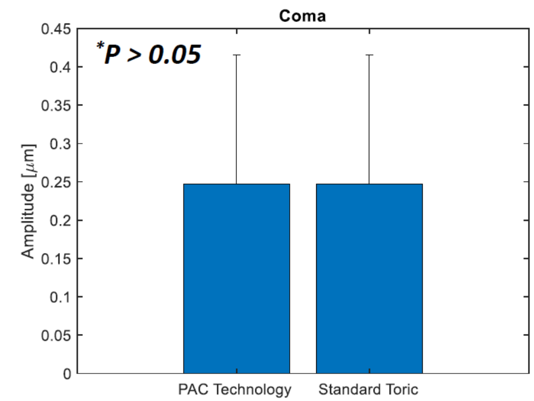
Progressive Axial Correction (PAC) Technology

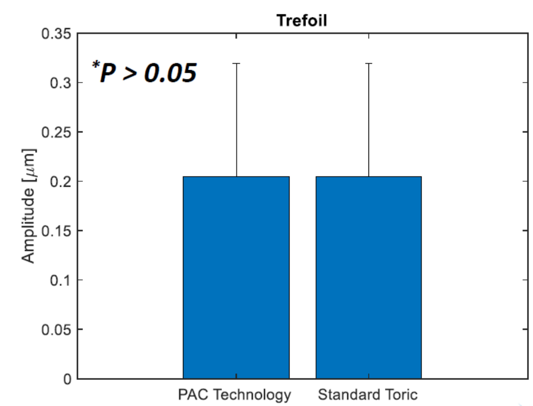
Presented by David J Apple Lab at ESCRS 2020 as the ePoster #2015

Results

The comparison of the other HOAs at 5 mm showed that the new toric design minimally, albeit statistically significantly, lowered primary and secondary Spherical Aberration, but Coma and Trefoil did not differ.





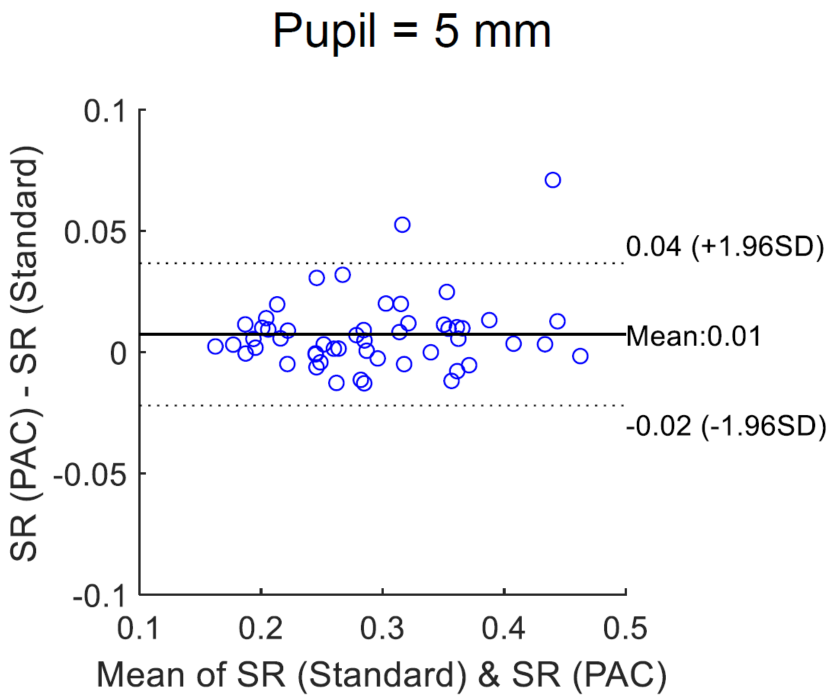


*Two-tailed paired t-test

Results

- The optical quality was comparable between the PAC and standard toric IOLs at 3 mm with the Strehl ratio (SR) of 0.53 ±0.15 for both conditions (*P=.94).

- At 5 mm, the Strehl ratio (SR) was 0.30 ±0.08 for the progressive and 0.29 ±0.08 for the standard lens (*P=.002).



*Two-tailed paired t-test

Conclusions

- The optical performance of the two IOL types was comparable at 3 mm.
- At 5 mm, the progressive toric design was more effective than using a standard toric IOL, and this resulted in lower residual astigmatism.
- The PAC technology enhances the Avansee IOL's -0.04µm asphericity - that in turn leads to further reduction of the spherical aberration.
- The optical quality was (minimally) better in the progressive-lens group; thus, this new technology may contribute to the continuous effort to improve the visual quality of toric-IOL patients.

Original Asphericity

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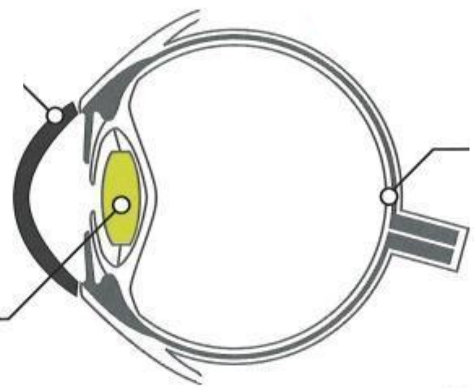
Avansee Preload1P Toric

Avansee's Original Asphericity

- **Provides long depth of focus** and is less affected by decentration or tilt than other IOLs with a greater spherical aberration corrective power

Corneal aberration
- spherical aberration = +0.27μm[1]
- (+ coma aberration)



Residual ocular spherical aberration
+0.23μm

Avansee's
asphericity
-0.04μm

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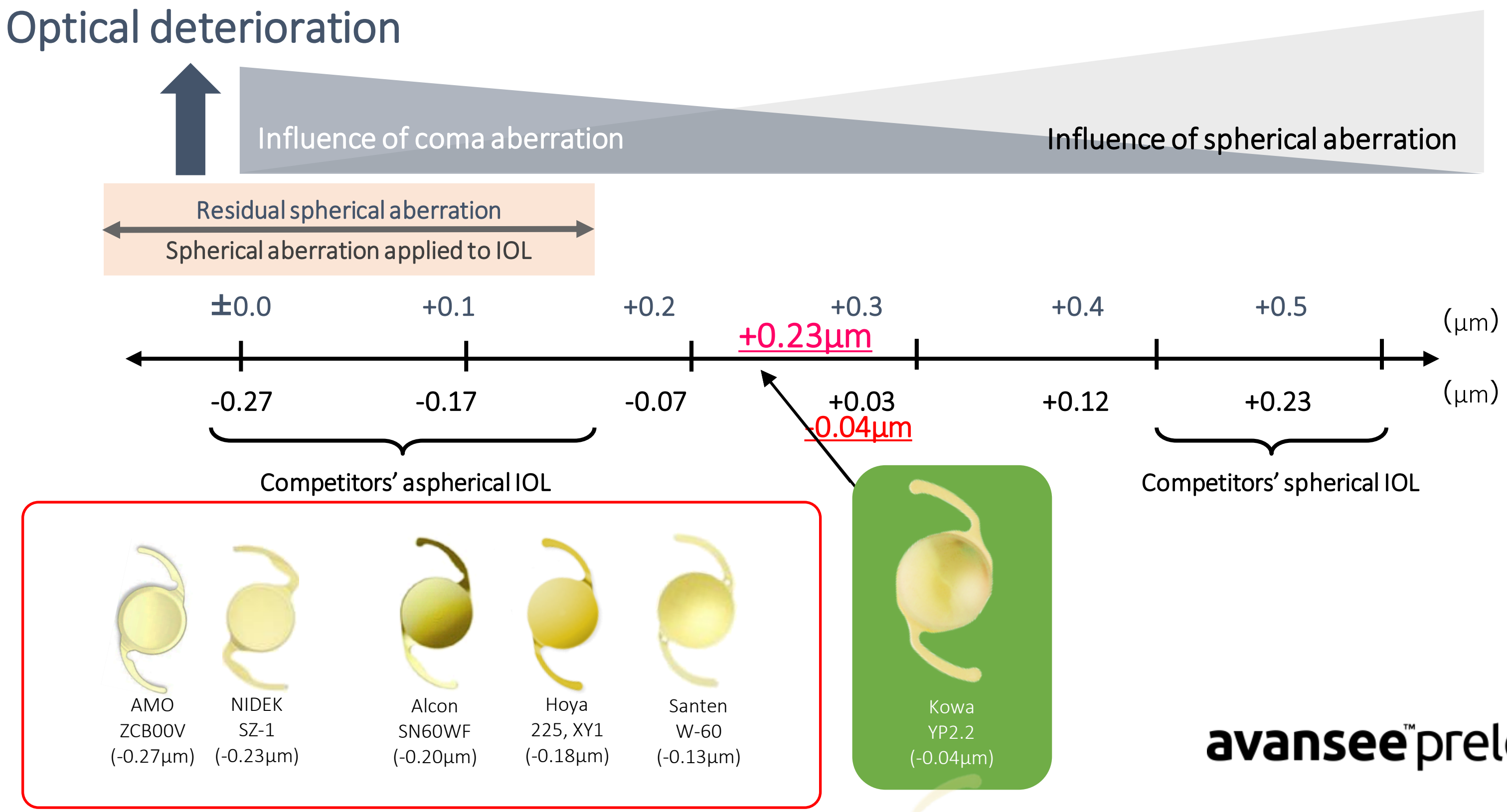
1. Wang L, et al. J Cataract Refract Surg. 2003 Aug;29(8):1514-21.
Average corneal aberration of 60 years old people (Pupil size : 6.0mm)

Avansee Preload1P Toric

Avansee's Original Asphericity

- **Provides long depth of focus** and is less affected by decentration or tilt than other IOLs with a greater spherical aberration corrective power



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Based on Rinsho Ganka, Junya Kisawa 70(1):16-23,2016

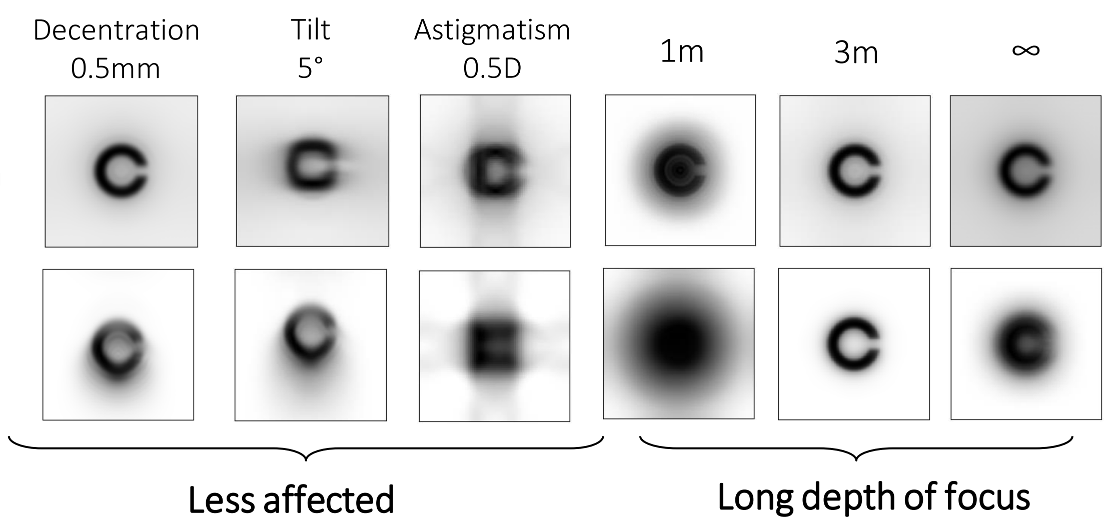
Avansee Preload1P Toric

Avansee's Original Asphericity

- **Provides long depth of focus** and is less affected by decentration or tilt than other IOLs with a greater spherical aberration corrective power

Avansee
Residual spherical aberration
+0.23μm

Reference
Residual spherical aberration
±0μm



→ Neutral asphericity concept provides long depth of focus and is less affected by decentration and tilt

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Fujikado T, et al. Clin Ophthalmol. 2014; 8: 2415–2423.
Evaluation of actual retinal images produced by misaligned aspheric intraocular lenses in a model eye

Original Asphericity

J Cataract Refract Surg. 2019 May;45(5):662-668. doi: 10.1016/j.jcrs.2018.10.049. Epub 2019 Mar 12.

Effects of decentration and tilt on the optical performance of 6 aspheric intraocular lens designs in a model eye.

Lawu T, Mukai K, Matsushima H, Senoo T.

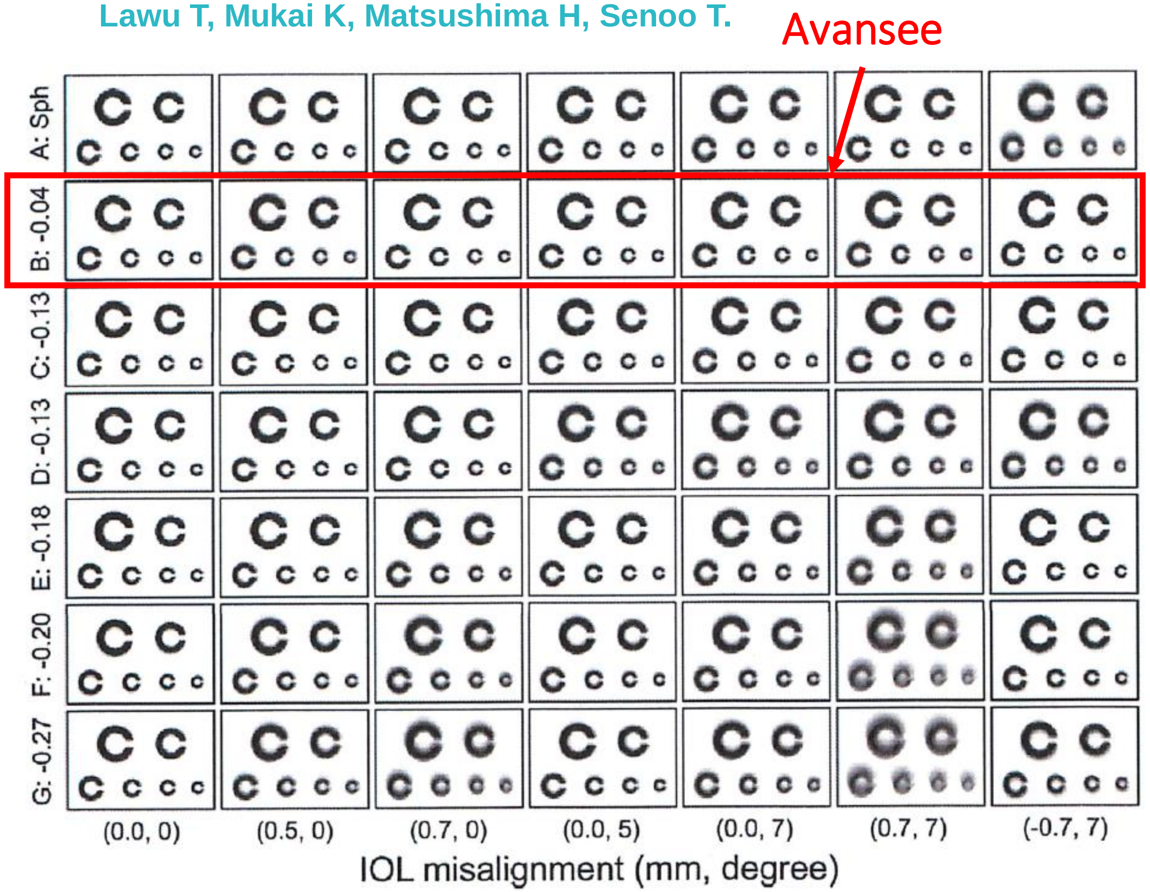
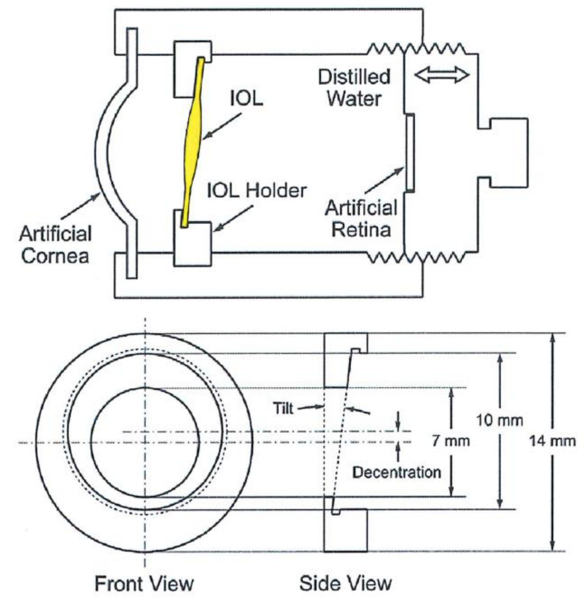
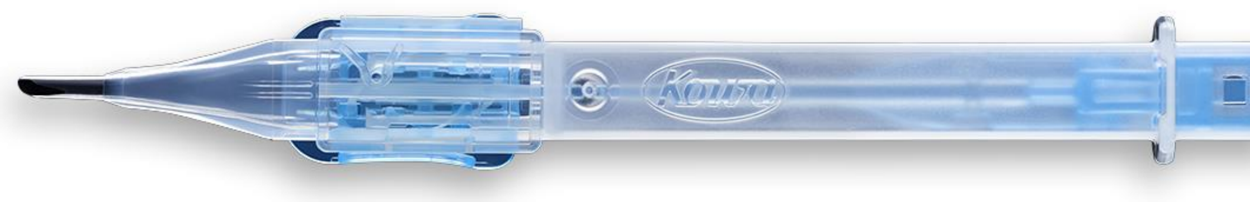


Figure 7. Measurement results of Landolt ring retinal imaging based on the higher-order aberrations generated by the wavefront aberrometer. The sizes of C-images were similar to those used in the theoretical evaluation (IOL = intraocular lens).



Proven Rotational Stability



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Evaluation of Rotational Stability of Avansee Preload1P

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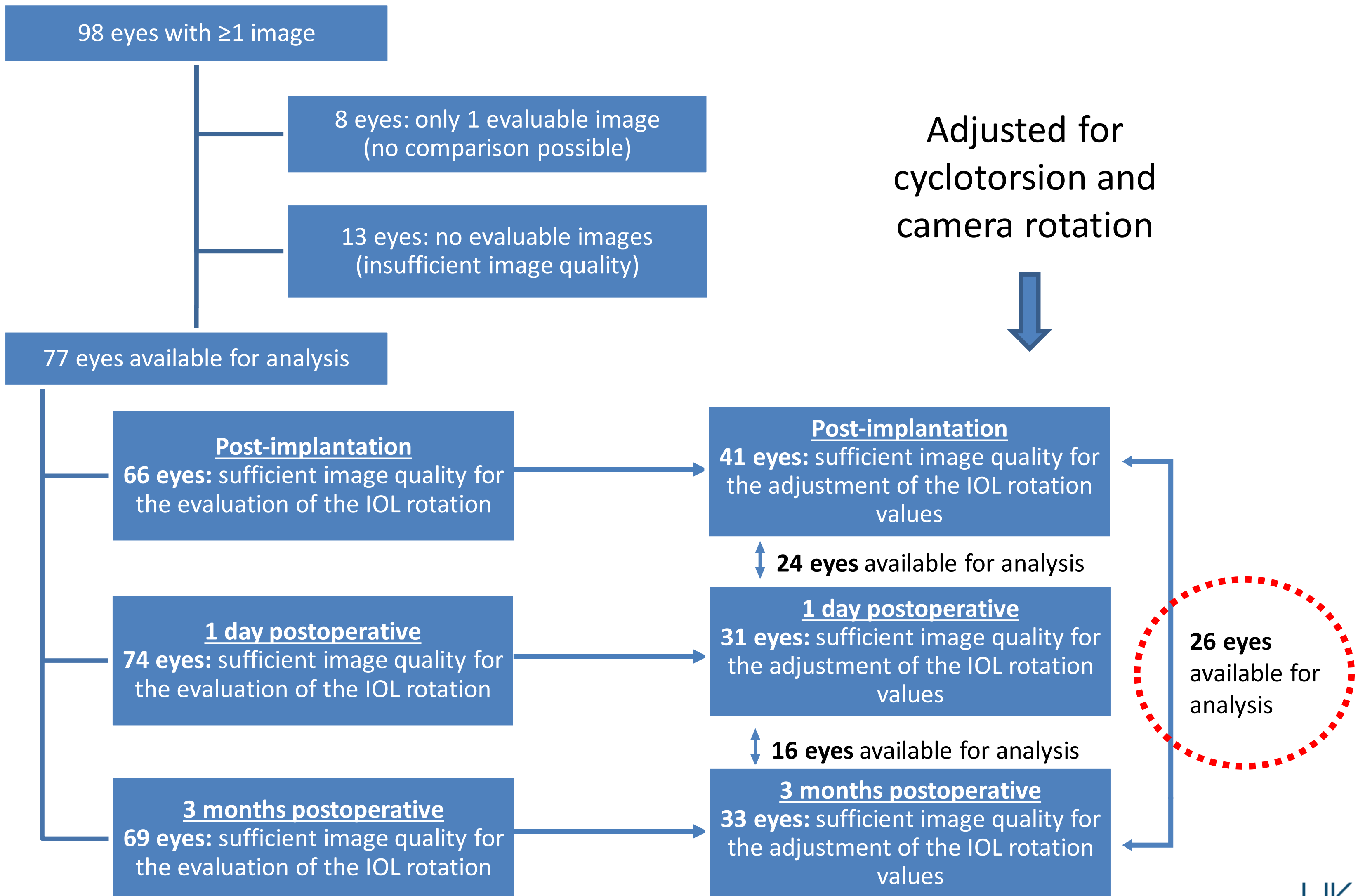
The David J. Apple International Laboratory for Ocular Pathology
Department of Ophthalmology, Ruprecht-Karls-University of Heidelberg
Chairman: G. U. Auffarth, MD, PhD, FEBO

UK HD

Rotational Stability: Data Analyzed



Rotational Stability: Mean and Median Values

	1 day postoperative - post-implantation, n=24	3 months postoperative - post-implantation, n=26	3 months postoperative - 1 day postoperative, n=16
Mean ± SD, degrees	1.44 ± 1.29	2.12 ± 1.86	1.54 ± 0.98
Median (min; max), degrees	0.90 (0.09; 5.39)	1.54 (0.04; 7.68)	1.58 (0.06; 4.04)

Avansee Preload1P Toric

Published in IOL&RS Vol. 34 No.3 Sep 2020 by Dr. Iida, Dr. Shimizu and Dr. Shoji

Kowa

Evaluation of Rotational Stability after Avansee®1P Implantations in the Capsule

Summary

Purpose: To evaluate the postoperative rotational stability of Avansee®1P (CN6).

Methods: Thirty-three eyes of 20 patients whose pupils were dilated enough during cataract surgery and were confirmed to show no evidence of weak Zinn's zonule for assuming the application of toric IOL were implanted with CN6. CCC status, axial length, IOL power, postoperative refractive error, and IOL fixation (rotational angles) were assessed.

Results: The mean absolute rotational angles of IOL from the end of surgery in all 33 eyes was 2.1 degrees ± 1.4 (SD) after postoperative rest, 2.2 ± 1.4 degrees 1 day postoperatively, 2.1 ± 1.4 degrees 1 week postoperatively, and 2.2 ± 1.4 degrees 3 months postoperatively, respectively.

Conclusion: CN6 was fixed satisfactorily in the capsule from the end of the surgery and was considered to be able to maintain stable intracapsular fixation as the basic shape of toric IOL. In addition, CN6 rotated maximally between the end of surgery and after postoperative rest, and IOL remained stable within 1 week after surgery. The postoperative refractive error was −0.03 ± 0.34D, and the A-constant (for optical biometry) of 118.8 was considered appropriate.

	Just after the operation	A day after the operation	A week after the operation	Three months after the operation
Rotational stability	2.1±1.4°	2.2±1.4°	2.1±1.4°	2.2±1.4°

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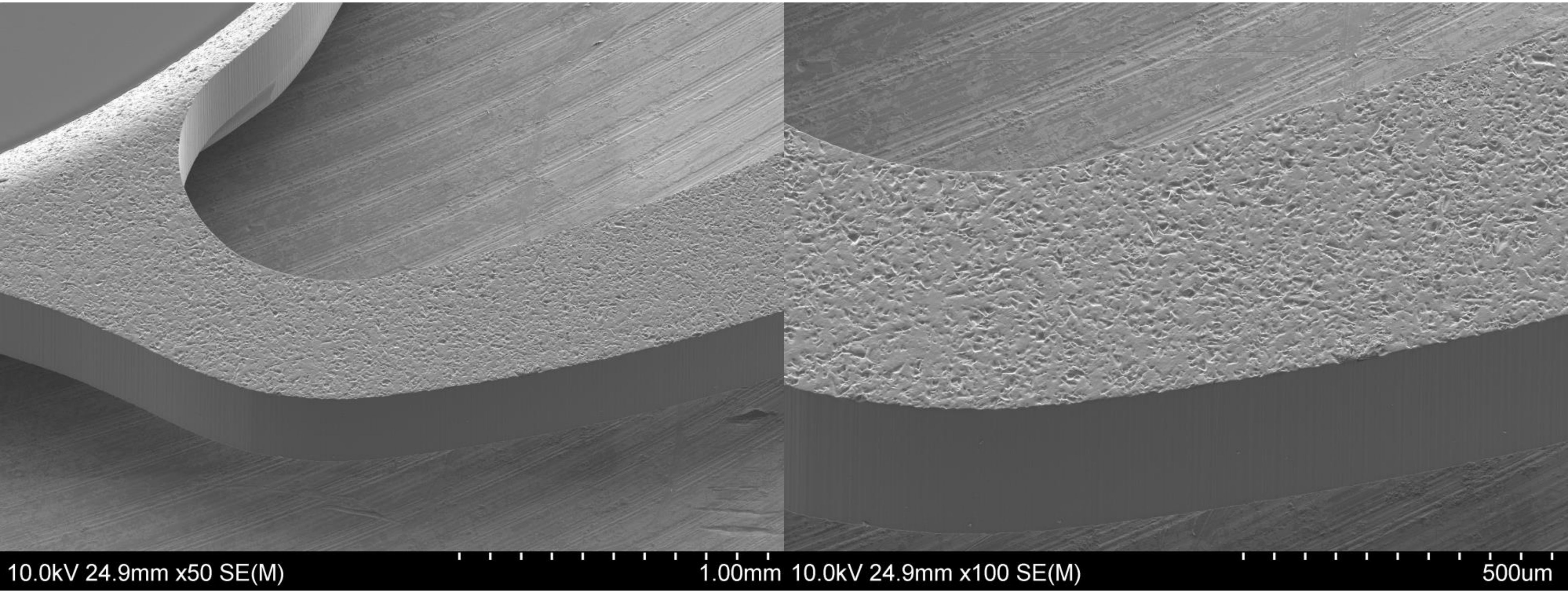
Avansee Preload1P Toric
Smooth Unfolding

Smooth lens unfolding because of…..

I. Lens material
II. Indented haptic surface



[Method] High-resolution scanning electron microscope with X-ray analysis function

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Avansee Preload1P Toric

Smooth Unfolding

Glistening-Free

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TORIC

Quality of Lens

Kowa

Am J Ophthalmol. 2018 Dec;196:112-120. doi: 10.1016/j.ajo.2018.08.032. Epub 2018 Sep 4.

Glistening Formation and Light Scattering in Six Hydrophobic-Acrylic Intraocular Lenses.

Łabuz G, Knebel D, Auffarth GU, Fang H, van den Berg TJ, Yildirim TM, Son HS, Khoramnia R.

1. Avansee is truly glistening free

2. Glistening causes the straylight

Given the absence of glistenings in the Avansee and an unorthodox distribution of glistenings in the Aktis, these IOLs were excluded from a comparison between the straylight parameters and the total number of glistenings.

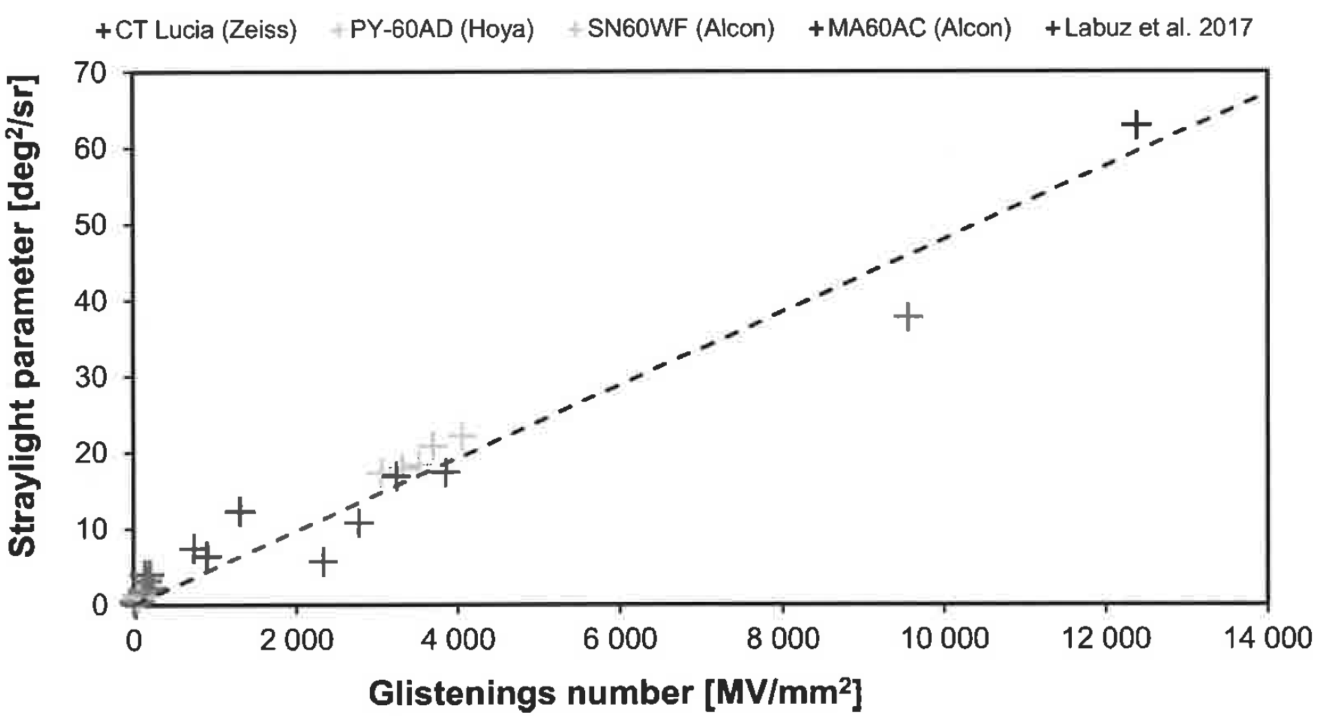

FIGURE 5. A proportional relationship between the straylight parameter and the glistening number in different lens models.

360° Degree Square Edge

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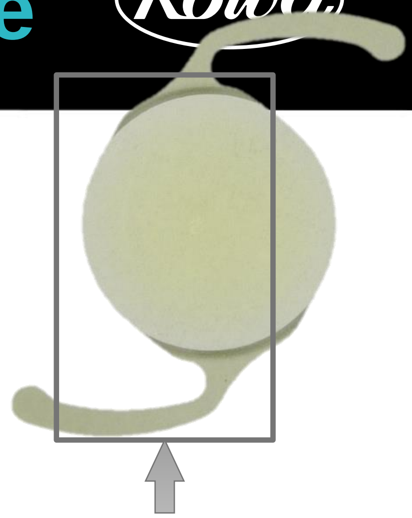
TORIC

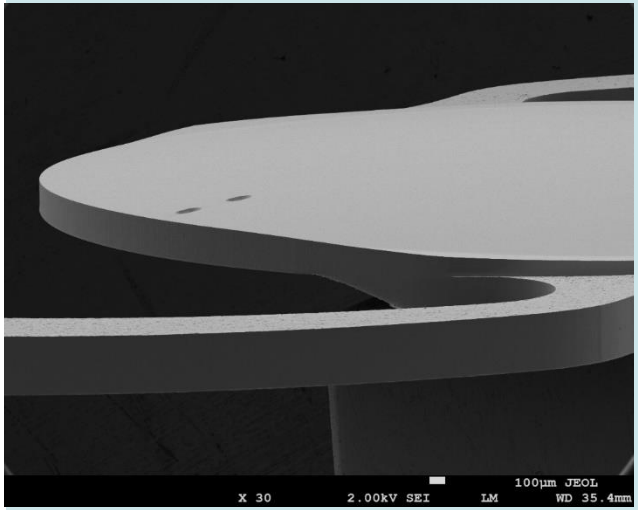
Avansee Preload1P Toric

360° Degree Square Edge

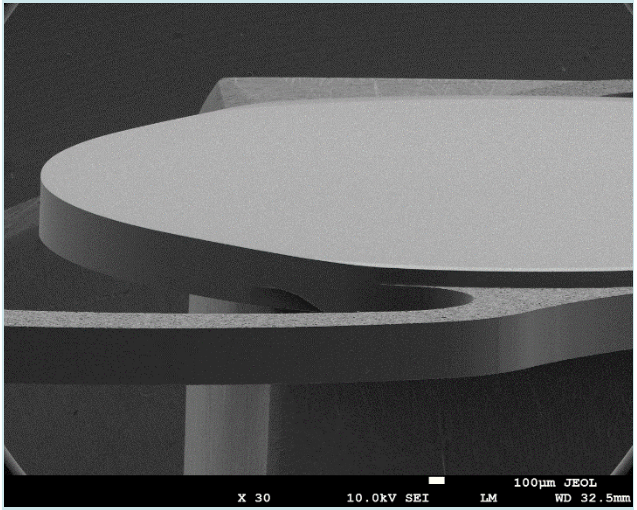
As with all Avansee lenses the Avansee Preload1P Toric has a 360° square edge – including the optic-haptic junction



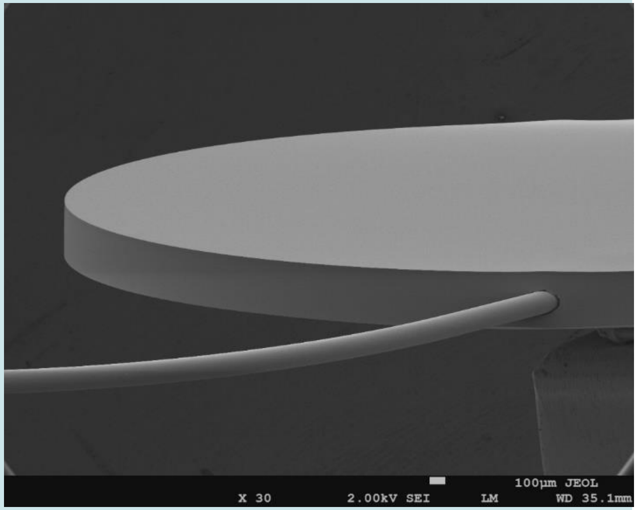
CP-T6



CP2.2R



AN6KA

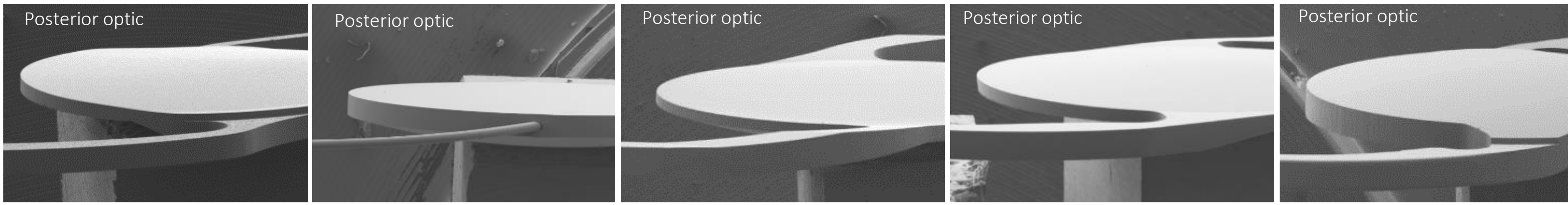


Avansee Preload1P Toric

360° Degree Square Edge

Kowa

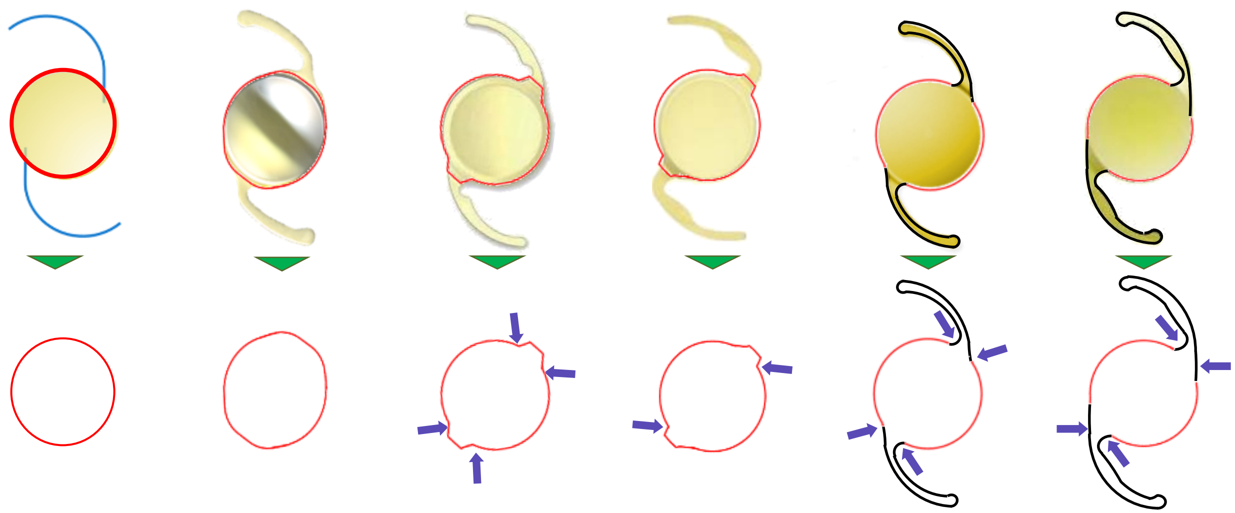
The 360° degree square edge is almost round allowing an ideal fit to the posterior capsule



Kowa YP2.2 (1P and Toric)	Kowa AN6KA	Hoya Micro255	Alcon SN60AT	AMO ZCB00V

[Method] High-resolution scanning electron microscope with X-ray analysis function

Kowa AN6KA	Kowa YP2.2	AMO ZCB00V	NIDEK SZ-1	Hoya XY1	Alcon SN60WF



Round shape	Almost round	Not round	Not round

1P
RIC

Ease of Use

avansee™ preload1P
TORIC

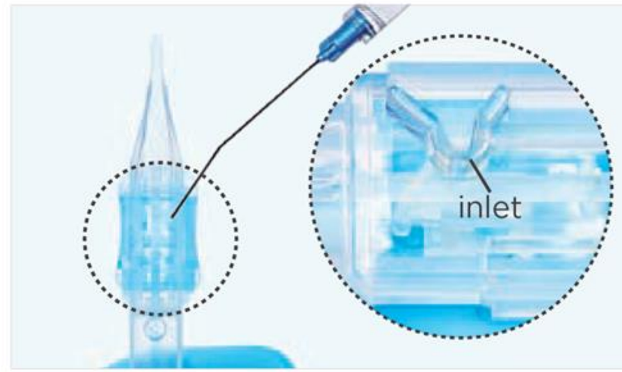
Avansee Preload1P Toric

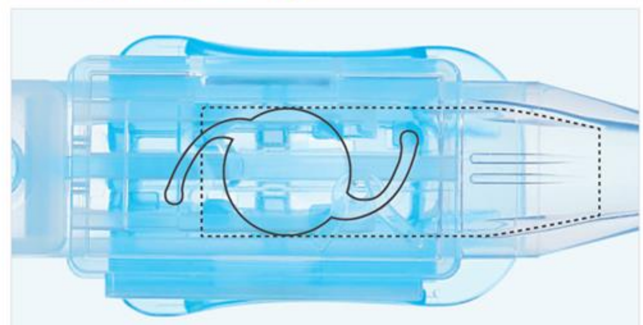
Ease of Use

1 Injecting the ophthalmic viscosurgical device (OVD)

Insert the OVD needle deeply, **only into the inlet**, and inject the OVD up to the dashed line as shown, filling the nozzle and covering the entire lens optic. Inject at least **0.17ml** of OVD, using an OVD needle with 25 gauge or greater. The OVD must be injected before removing the lens stage.

The OVD needle should be inserted through the inlet in a vertical fashion until the tip of the needle touches the bottom surface.





avansee™ preload1P TORIC

Ease of Use

Kowa

2 Removing the lens stage

Supporting the main injector body, slowly remove the lens stage, keeping it straight and without it twisting away from the injector body.

Ease of Use

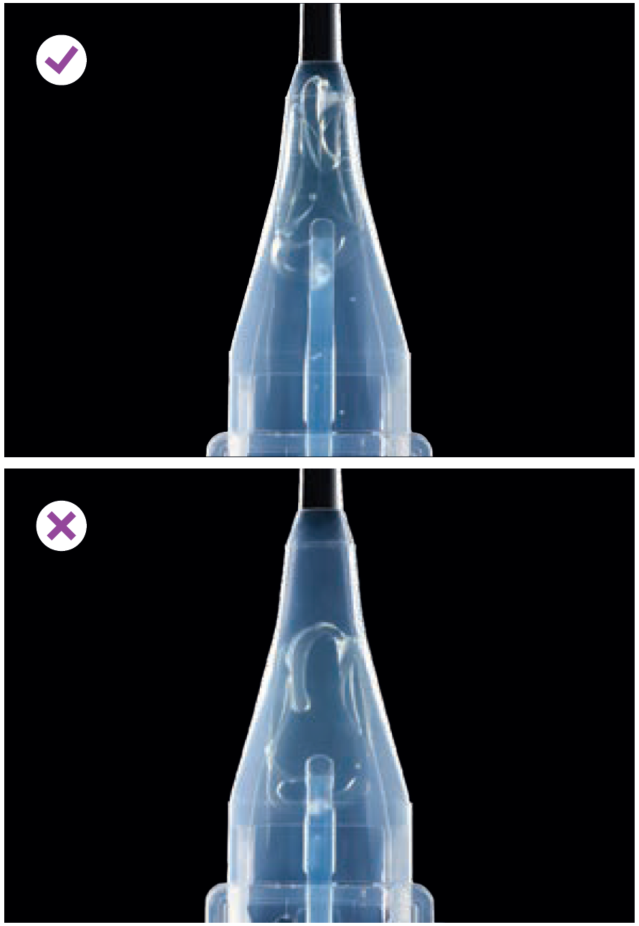
3 Positioning the lens for insertion

Push the plunger at a constant rate to move the IOL forward; stopping at the point when the IOL optic is rolled and its edges make secure contact. **Once the plunger is advanced, the IOL must be inserted into the eye within 20 seconds.**

Positioning of the lens is best completed smoothly, within 2 seconds and in a single action.

Failure to push the plunger until the edges of the lens make secure contact, will increase the likelihood of an unsuccessful lens injection.

For best results, all 3 preparation steps should flow continuously, without interruption.

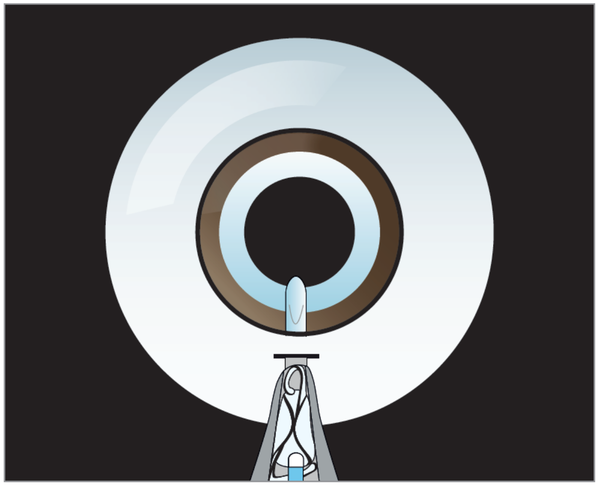


Avansee Preload1P Toric

Ease of Use

1 Insertion

Insert the nozzle tip until the bevel (opening part of the nozzle) completely penetrates the anterior chamber.



2 Release

Keeping the inlet (Kowa mark) upward, push the plunger ahead at a constant rate and release the IOL inside the capsular bag. Continue to push the plunger until the trailing haptic is completely released.

Avansee Preload1P Toric

Ease of Use

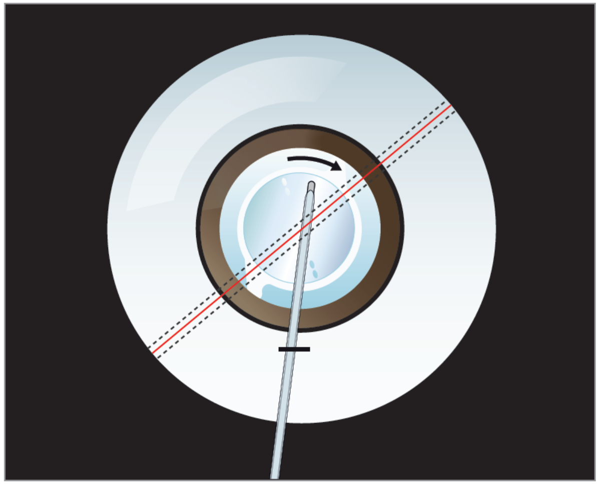
3 Removal of injector

Check the lens positioning and remove the nozzle from the eye.

The trailing haptic MUST be released into the eye before the removal of the nozzle.

4 Alignment

Rotate the IOL in a clockwise fashion until just before the intended axis. Remove the OVD from the eye and align the cylinder axis marks with the intended axis.



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122nd JOS The 122nd Annual Meeting of the Japanese Ophthalmological Society

Up to Date: Cataract Surgery in Europe

Gerd U. Auffarth

International Vision Correction Research Centre (IVCRC),
The David J. Apple International Laboratory for Ocular Pathology
Department of Ophthalmology, Ruprecht-Karls-University of Heidelberg
Chairman: G. U. Auffarth, MD, PhD, FEBO

UK HD

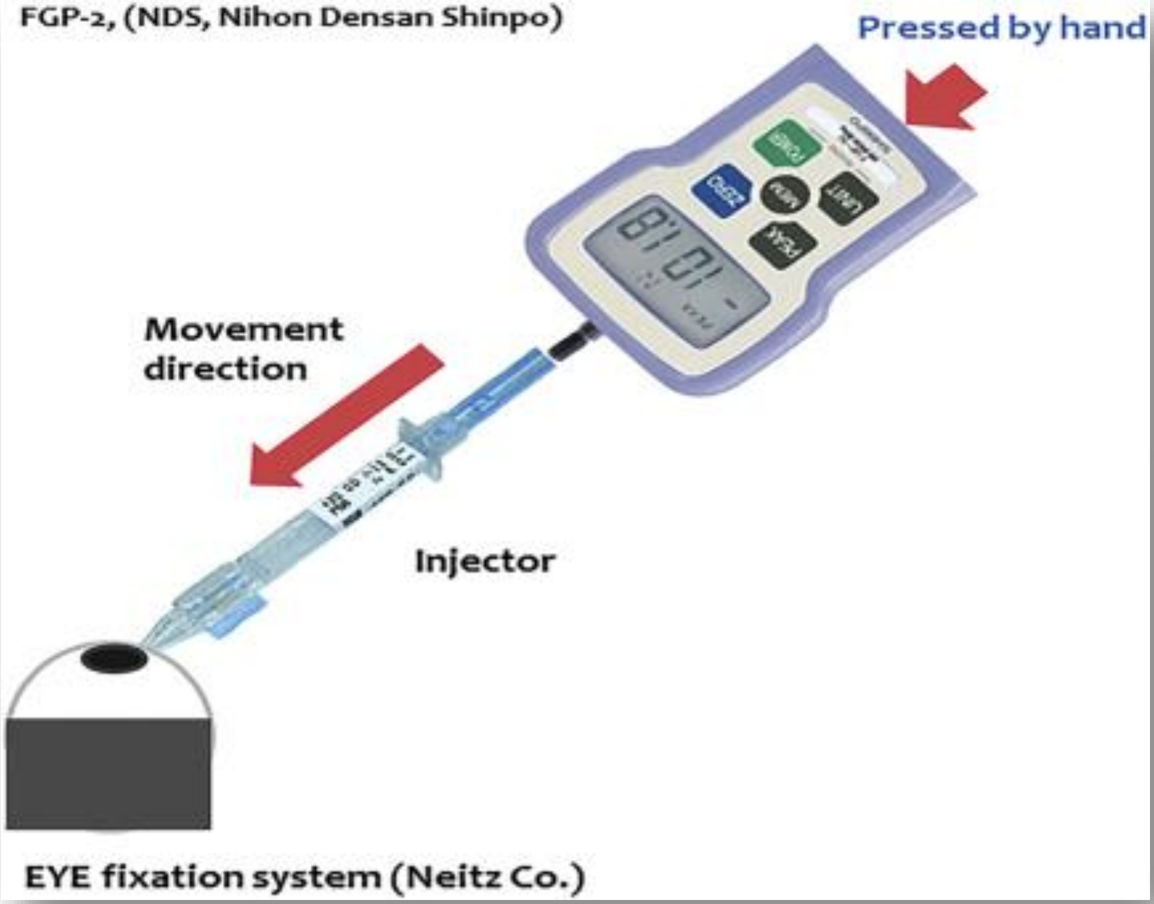
Heidelberg Study: Material and Methods*

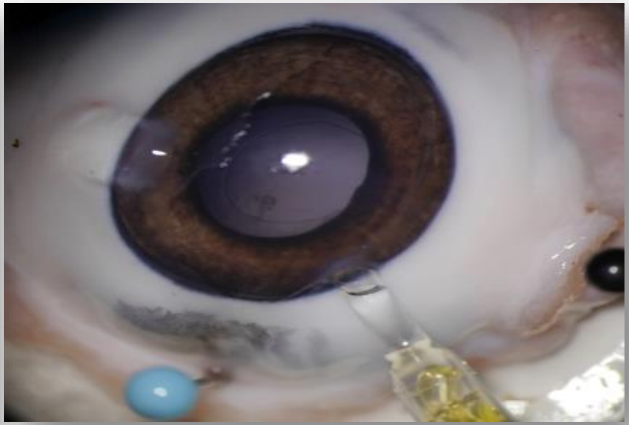
- IOLs: 6 different groups of 10 IOLs with +26.0 diopters and control group
- Pig eyes: 59 (implantation into pig eyes and to a plastic dish as control)
- OVD: 0.5 mL
- Incision size for 6 injection system: 1.8 - 2.5 mm
- Resistance force measurement: FGV-10XY, Shimpo instruments
- Shimpo Toriemon Force Gauge Software

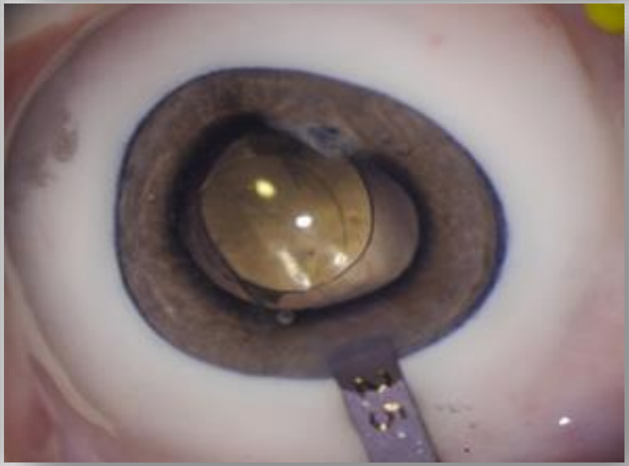
Manufacturer	IOL type	Injector model	IOL material	IOL loading	Incision size	OVD
Alcon Laboratories, Inc.	AcrySof® IQ AU00T0	UltraSert™	hydrophobic arcylate	preloaded	2.2	Viscoat®
Bausch & Lomb GmbH	enVista® MX60P	ACCUJECT™ 2.2	hydrophobic arcylate	manual	2.2	Amvisc®
Cristalens Industrie	ARTIS® PL E	ACCUJECT™ 1.8	hydrophobic arcylate	preloaded	1.8	Pe-Ha-Visco®
KOWA Company, Ltd	Avansee™Preset 1P	AvanseePreload	hydrophobic arcylate	preloaded	2.4	Pe-Ha-Luron® F
KOWA Company, Ltd	Avansee™Preset PU6	AvanseePreload	hydrophobic arcylate	preloaded	2.5	Pe-Ha-Luron® F
NIDEK CO.,LTD	Aktis SP (NS-60YG)	Nex-Load System SP SZ-1	hydrophobic arcylate	preloaded	2.2	POLYVISC®
Carl Zeiss Meditec AG	CT LUCIA® 601PY	ACCUJECT™ 2.2	hydrophobic arcylate	preloaded	2.2	Z-HYALIN®

*Data on file: David J Apple International Laboratory fir Ocular Pathology, University Eye Clinic Heidelberg

Material and Methods*







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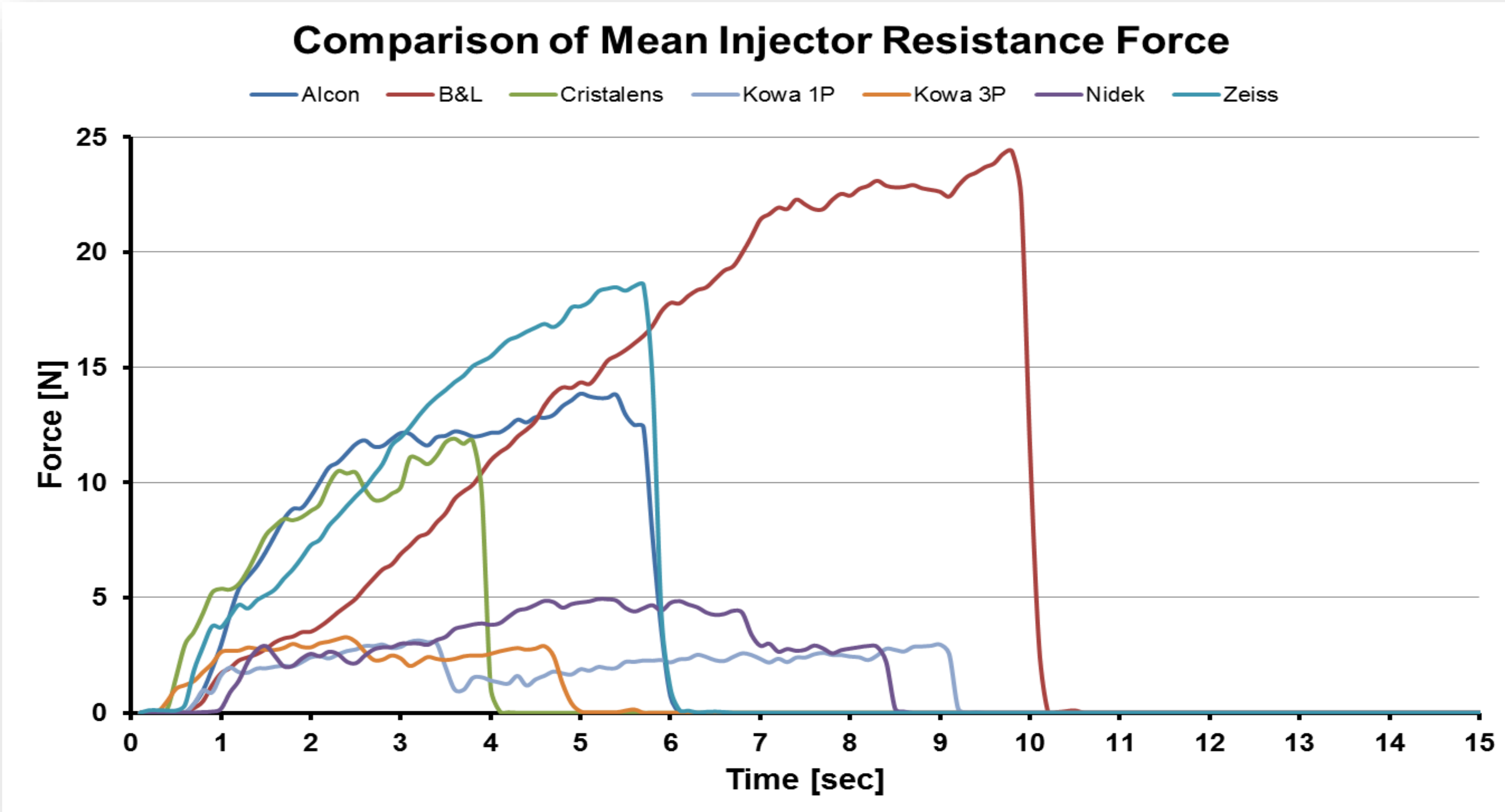
Results*



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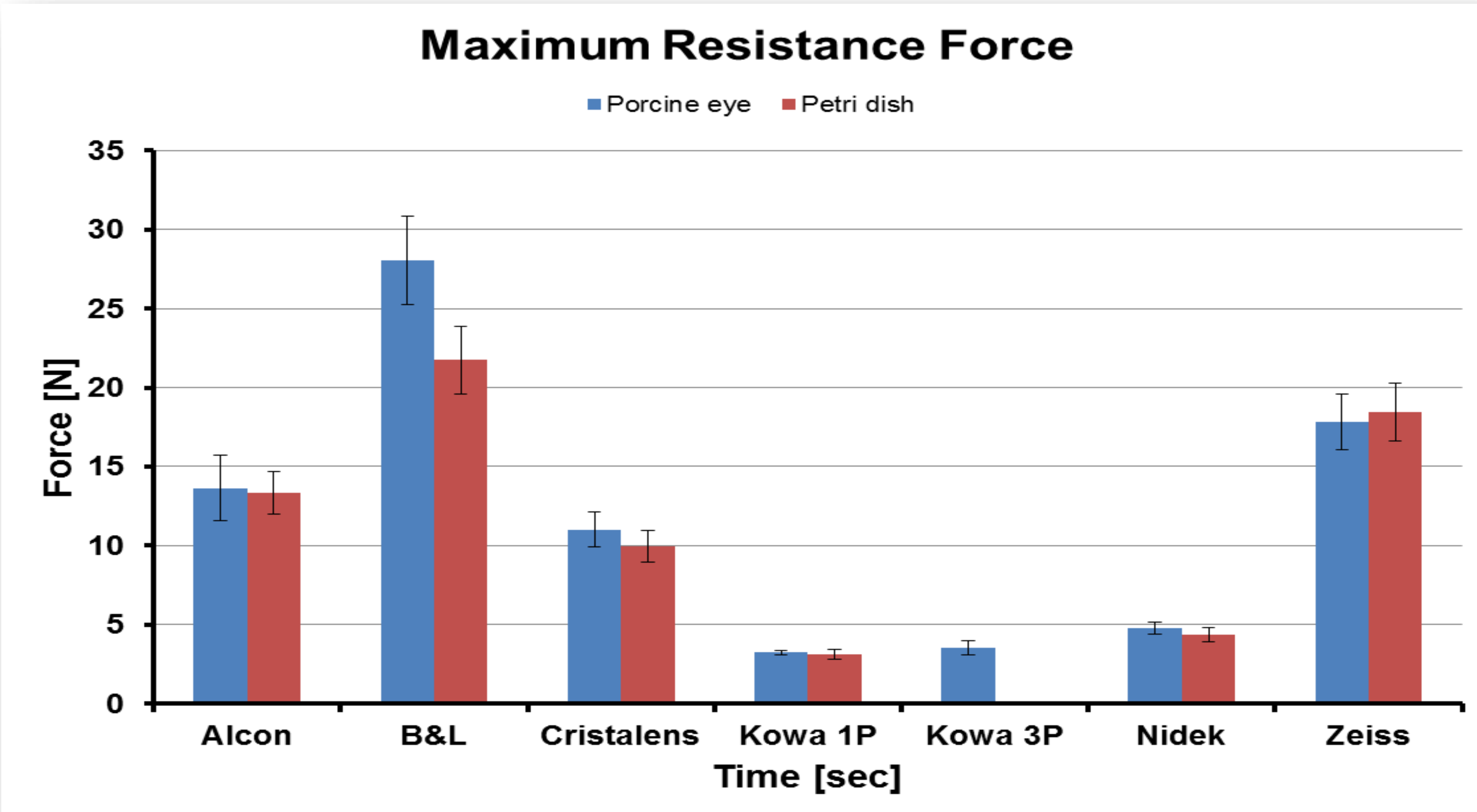
Results*



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Summary

I. **Progressive Axial Correction (PAC) Technology**

II. **Original Asphericity**

III. Proven Rotational Stability

IV. Smooth Unfolding

V. **Glistening-Free**

VI. 360 Degree Square Edge

VII. Ease of Use

(I–II) Unique design offers better outcome

(V–VI) Well controlled manufacturing process and precision design offer long term purity

Thank you very much for your attention!!!