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avansee™ preload1P
TORIC

An innovative toric IOL with progressive axial correction (PAC) technology

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Introduction to the Avansee™ range of intraocular lenses

Kowa has been making pioneering contributions to ophthalmology for more than 70 years, and the company has been bringing this same spirit of innovative development to the field of intraocular lenses (IOLs) since it introduced the first Avansee IOL in 2007.[1]

- 2007: Avansee three-piece (3P) spherical models (AN6K, AU6K and AN6MK) launched in Japan
- 2010: Fully preloaded in a single-use injector system, spherical IOL, AvanseePreset (PN6 and PU6) launched in Japan
- 2013–15: Aspheric 3P counterparts (AN6KA, AU6KA, AN6MA, PN6A, PU6A, PN6AS, and PU6AS) launched in Japan and Europe
- 2016–18: One-piece (1P) version of Avansee (Avansee Preload1P: YP2.2, CP2.2, YP2.2R and CP2.2R), for insertion through a smaller 2.2 to 2.4 mm incision launched in Japan and Europe
- 2020: Avansee Preload1P Toric (CP-Tx) – the first toric IOL with progressive axial correction (PAC) technology launched in Europe

Avansee (Kowa Co. Ltd.) is an aspheric, hydrophobic acrylic, posterior chamber IOL designed for small incision cataract surgery.[2-5] Both the 1P and the 3P designs (Figure 1) are fully preloaded into a lightweight, syringe-type injector, which enables preparation in three simple steps and IOL insertion with just one hand.[2-7] No lens handling is required, ensuring sterility and reducing the risk of infection.[6-8] The injector requires low delivery force, minimising the risk of lens damage,[9,10] while the soft and flexible IOL material, together with the indented 1P haptic surface, ensures smooth lens opening after release.[11]

With a view to enhancing optic transparency for prolonged periods, all IOLs have been manufactured to have uniform and optimal density of cross-linkage which provides glistening-free, soft and flexible lenses. As a result, there have been no reported cases of glistening with Avansee since its launch in 2007.[2,7,12]

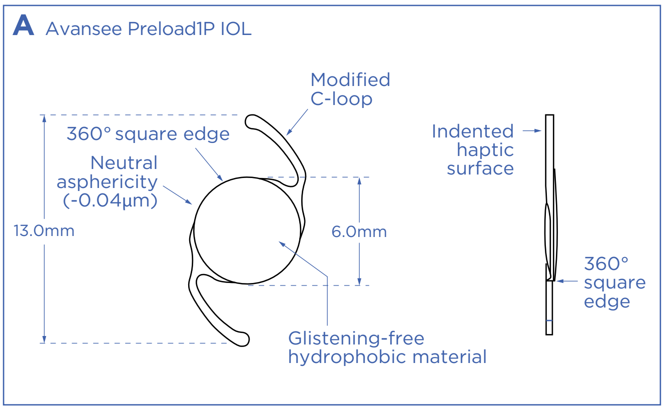
Similarly, the sharp 360° square edge seen on both 1P and 3P lenses reduces the risk of posterior chamber opacification (PCO).[13-16]

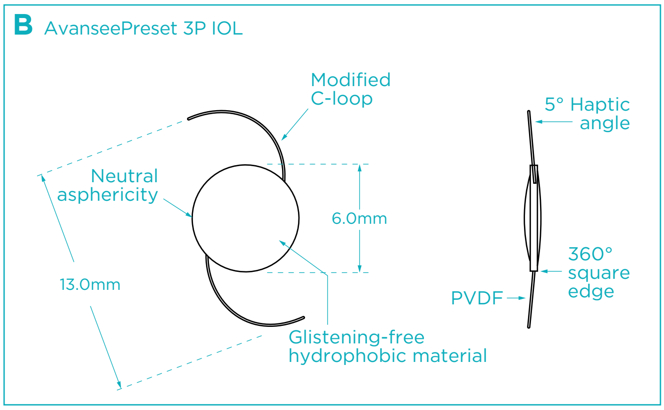
In terms of asphericity, Avansee IOLs are designed to retain the spherical aberration of the eye and therefore tend to be tolerant of decentration, tilt and astigmatism.[17,18]

Over 1 million Avansee lenses have been sold since their launch in 2007, with very low incidences of adverse effects (0.009%) and serious adverse events (0.0009%).[2,3,19]

When the company set about developing a toric IOL to join the Avansee family, Kowa was committed to build on the standards of excellence that characterise the range. Studies in both young and elderly eyes have shown that, in most cases, astigmatism is not uniform across the cornea but tends to decrease from the centre towards the periphery.[20-21] Since the cylinder power of conventional toric IOLs is uniform across the cornea, it is possible that they deliver excessive correction at the periphery and this may reduce visual performance, particularly under low light conditions. Avansee Preload1P Toric is the first IOL designed with PAC technology. By delivering greater cylinder power at the corneal centre, PAC technology means that the astigmatism correction delivered by the Avansee Preload1P Toric IOL more closely reflects the natural pattern of the corneal astigmatism.[20]

This supplement reviews laboratory and clinical experience with Avansee IOLs and provides a particular focus on the Avansee Preload1P Toric IOL – the first toric IOL designed with PAC technology.[4,22]





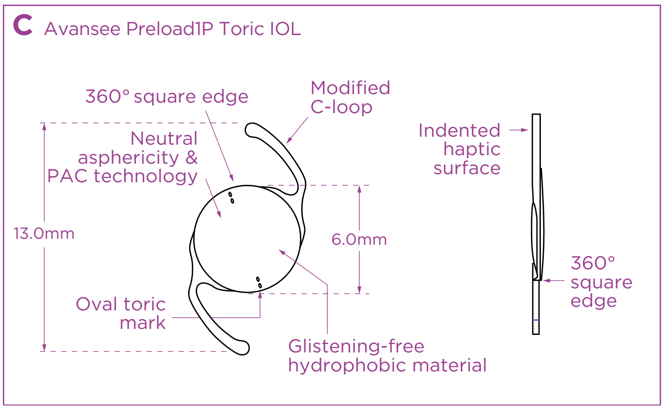


Figure 1. Avansee™ Preload lenses
A. One-piece (1P) IOL,[3]
B. Three-piece (3P) IOL,[2]
C. 1P Toric IOL[4]

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Central and peripheral patterns of corneal astigmatism: Implications for toric IOLs

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The development of the toric intraocular lens (IOL) by Shimizu in 1994[1] was a significant breakthrough in efforts to achieve effective control of postoperative astigmatism in patients undergoing cataract surgery. Since that time, considerable attention has been focused on means of ensuring that we select the optimal toric IOL for our patients and this, in turn, requires a clear understanding not only of the magnitude, but also the pattern of astigmatism. When assessing the extent of astigmatism, it is well known that both anterior and posterior corneal surfaces contribute to total corneal astigmatism (TCA) and that ignoring the posterior cornea may lead to errors in assessment and correction.[2] Posterior corneal astigmatism may decrease TCA in cases of with the rule (WTR) astigmatism and may increase TCA in patients with against the rule (ATR) astigmatism. Ignoring the astigmatic contribution of the posterior cornea may have the effect of overestimating the extent of WTR astigmatism and underestimating the extent of ATR astigmatism.[2,3]

Progressive axial astigmatism

The pattern of astigmatism across the corneal axis also has important implications for assessment and for selection of the appropriate toric IOL. The selection of lens power is based on astigmatism measurements taken in the central cornea across a diameter of approximately 3 mm. However, if the degree of astigmatism varies between the central and peripheral portions of the cornea, this would have the potential to affect visual performance, particularly during mesopic and scotopic conditions when the pupil is large.[4]

Over the past few years, increasing evidence has emerged to show that astigmatism is not uniform across the diameter of the cornea. Read *et al* studied corneal topography at diameters of 6 mm and 10 mm in 100 young adults and reported that the peripheral cornea becomes significantly flatter and is slightly less astigmatic than the central cornea.[5]

From the point of view of cataract surgery and IOL implantation, it has been important to confirm these observations in elderly patients and to this end the group at Kitasato University School of Medicine investigated corneal shape in 76 elderly subjects (aged 60–79 years, mean 72.6 ± 3.0 years) who had astigmatism of at least 1D. Mean values of corneal astigmatism (including ATR and WTR) decreased significantly from 2.16D at the centre (2 mm diameter) to 1.44D at the periphery (6 mm diameter) – a difference of 0.72D ($p<0.01$) (Figure 2). This study also found that the degree of axial variation (difference between mean values for central and peripheral astigmatism) was significantly related to the severity of astigmatism; the larger the corneal astigmatism, the greater was the difference between central and peripheral values.[4]

Similar results were found in a study conducted at Heidelberg University Eye Clinic which compared the degree of astigmatism at 3 mm and 6 mm concentric radii in 717 eyes aged 60 years or older with at least 1D of astigmatism.[6] In this sample, mean corneal astigmatism decreased from 1.82 ± 0.88D in the centre to 1.64 ± 0.98D at the periphery – a difference of 0.18D ($p<0.001$) (Figure 3). As with the data from the Japanese patients, this magnitude of the difference in astigmatism from centre to periphery increased with the degree of astigmatism, ranging from 0.13 ± 0.37D with astigmatism of <2.0D to 0.59D in cases with astigmatism of >4.0D.

Both of these studies in elderly eyes confirm that mean corneal astigmatism is greater at the centre than the periphery and that this axial difference is greater in patients with more pronounced degrees of astigmatism. It is therefore proposed that, for toric IOLs to provide more accurate correction of corneal astigmatism, their cylinder power should not be uniform, but should be decreased at the periphery of the lens.[6]

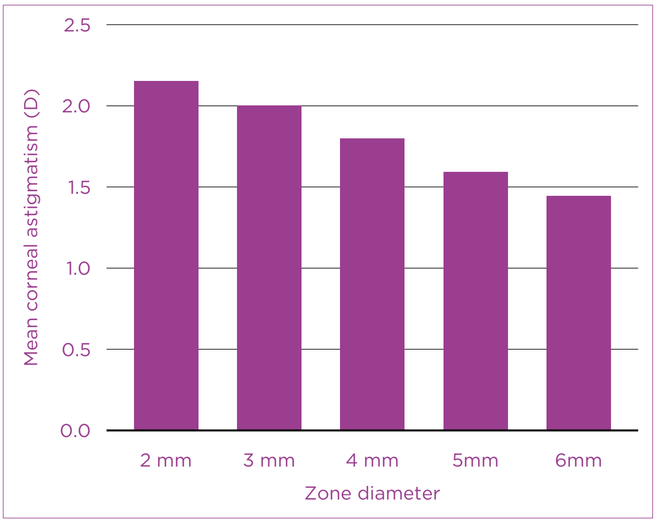

Figure 2. Variation in the magnitude of astigmatism across the corneal zones. Mean level of astigmatism decreased from 2.16D at 2 mm diameter to 1.44D at 6 mm diameter.[1]

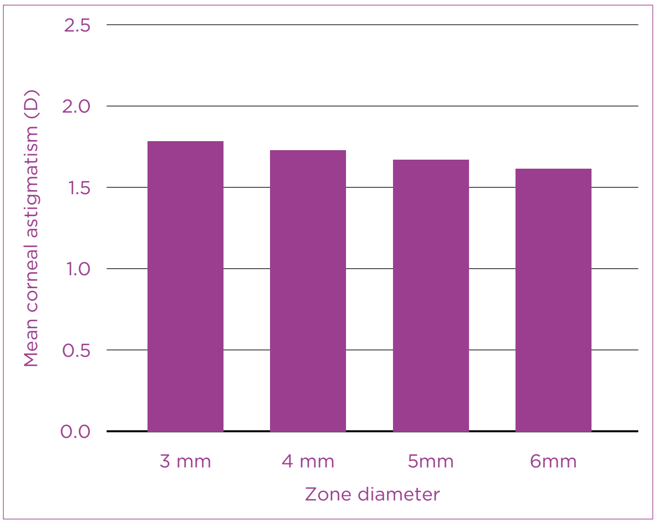

Figure 3. Variation in the magnitude of astigmatism across the corneal zones. Mean level of astigmatism decreased from 1.82D at 3 mm diameter to 1.64D at 6 mm diameter.[6]

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PAC technology: A new innovation in toric IOL design

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The studies by Kawamorita *et al*[1] and by our group in Heidelberg[2] have confirmed that the magnitude of corneal astigmatism is generally greater in the centre of the cornea than at the periphery. These studies also showed that the magnitude of axial variation in astigmatism (difference between astigmatism measured at 3 mm and 6 mm corneal diameters) increases with the extent of astigmatism. A standard toric intraocular lens (IOL), has uniform cylinder power and is thus unable to account for those differences across the corneal axis. In an attempt to address this, and to provide more accurate correction of astigmatism, a new design of IOL – Kowa's Avansee™ Preload1P Toric (Avansee Toric) – has been developed that delivers progressively-changing cylinder power across the axis. This concept, progressive axial correction (PAC), provides greater cylinder power at the centre of the cornea and less at the periphery, reflecting the patterns of astigmatism discovered in elderly eyes. In this study, we aimed to assess and compare the image quality metrics after correction of corneal astigmatism using IOL models with and without PAC in a personalised eye model.

Corneal topography data formed the basis of a customised physiological model eye which was used to assess outcomes following simulated implantation of a toric IOL.[3] Elevation maps of the anterior and posterior corneal surfaces were fitted with Zernike functions, and Zernike modes were calculated over a 6 mm circular area (Figure 4). The computed coefficients representing both corneal surfaces were applied in ray-tracing simulations. Optical quality (Strehl ratio) and residual astigmatism were investigated using both a 3 mm and 5 mm pupil for a toric IOL with PAC technology (Avansee™ Toric, Kowa) and for a lens with identical design parameters but with uniform cylinder power.

The study population included 52 patients with mean age 68.5 ± 5.0 years and corneal astigmatism ranging from 0.8 to 3.8D (mean 1.76 ± 0.76D). At 3 mm pupil, slightly lower residual astigmatism was obtained with the IOL with PAC technology (0.02 ± 0.07D; p=0.14), but the Strehl ratio was identical in both cases (0.51 ± 0.15; p=0.88). However, at 5 mm pupil, the Avansee Toric IOL yielded significantly lower residual astigmatism compared with the conventional IOL (0.10 ± 0.2D; p<0.01). The Strehl ratios were 0.30 ± 0.08 and 0.29 ± 0.08 with the Avansee Toric and the standard lens, respectively (p=0.001). High-order aberrations (HOAs) were computed and similar results were found in the primary, secondary, and tertiary order astigmatism (Figure 5). In addition, the degree of the primary and secondary spherical aberrations were significantly lower for the Avansee Toric compared with the standard toric IOL with a pupil diameter of 5 mm (0.17 vs 0.19 µm; p<0.001)

Although the optical performance of the two IOL types was comparable at 3 mm, when studied with a larger corneal diameter of 5 mm, Avansee Toric's PAC design was more effective in correcting corneal astigmatism than using a standard approach. In addition, the optical quality was slightly better in the progressive toric lens group.[3]

Kowa's Avansee Preload1P Toric is the first IOL with PAC technology, which provides greater correction of astigmatism at the centre and proportionately less at the periphery. PAC technology therefore has the potential to provide more accurate correction of corneal astigmatism for both photopic and scotopic conditions.

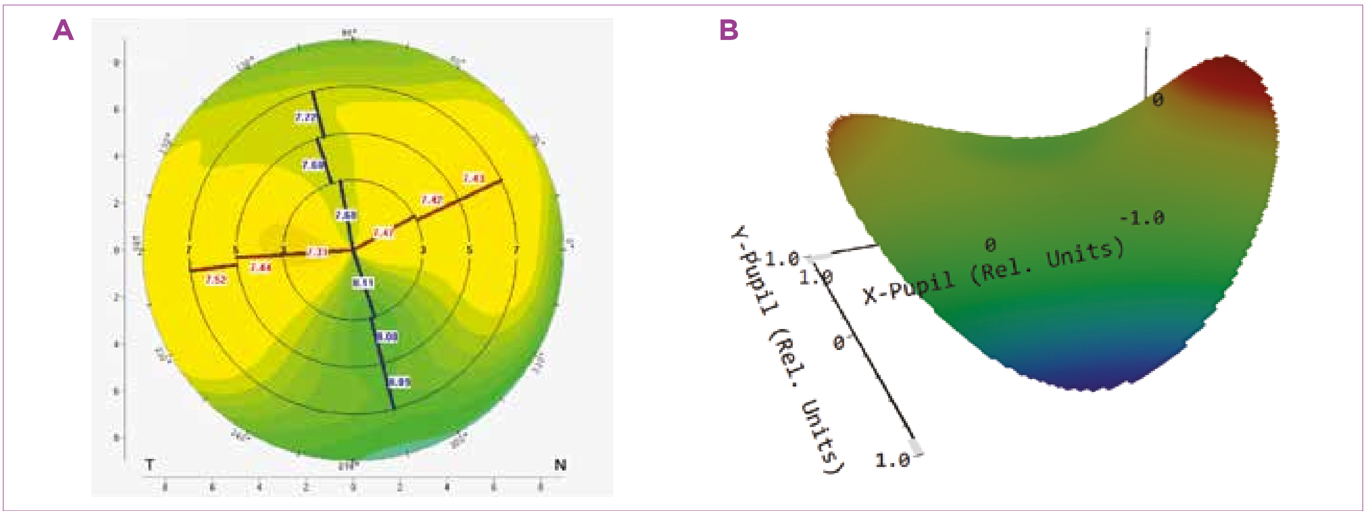
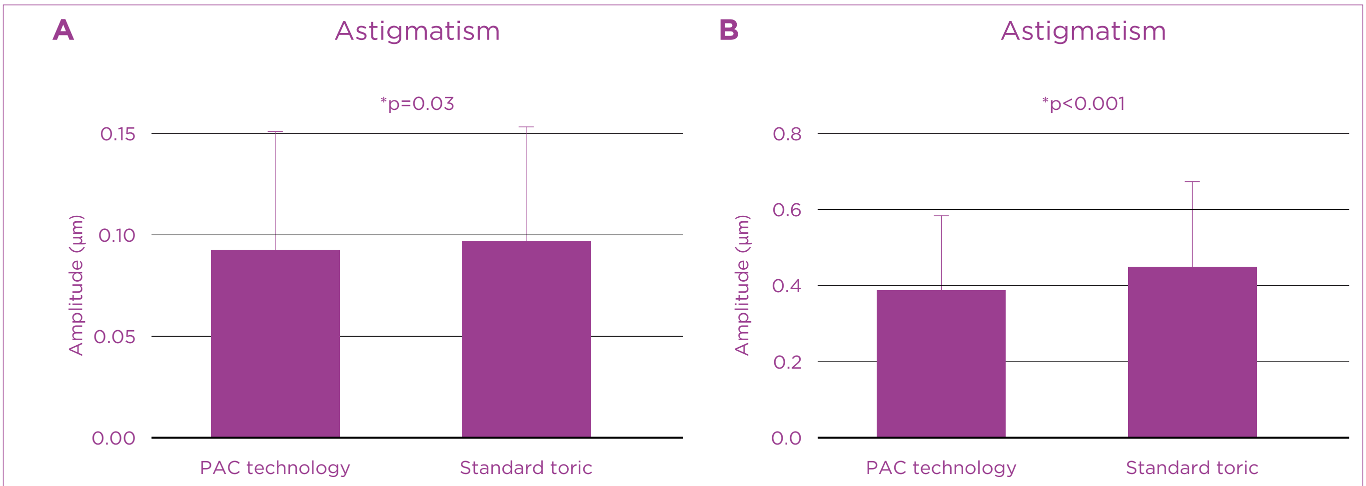


Figure 4. Example of corneal topography data of an astigmatic eye (A) with a corresponding wavefront map (B).



**Statistically significant differences (paired t-test; p<0.05); error bars = standard deviation.*

Figure 5. The comparison of the amplitude of the primary, secondary, and tertiary order astigmatism in case of (A) 3 mm pupil (B) 5 mm pupil.[3]

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Unique asphericity provides a longer depth of focus

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The Avansee™ Preload1P toric IOL is the first IOL designed with progressive axial correction (PAC) technology which gives it the ability to account for the decreased astigmatism at the periphery of the cornea.[1-3] In addition, as a member of the Avansee family, it also has a unique asphericity which is designed to provide a longer depth of focus in comparison with other aspheric IOLs.

Unique asphericity

Spherical aberration (SA) occurs when light waves that are parallel to the optic axis but at different distances from the optic axis fail to converge at the same point producing a circular blurred image.[4] The normal human cornea has a slight positive spherical aberration (+0.27 µm) which, in younger eyes, is partially offset by a negative SA of the lens (-0.2 µm) leaving a slight positive aberration. With advancing age, however, the negative SA of the lens tends to decrease, so that it loses the ability to compensate for corneal SA and the total ocular SA becomes increasingly positive with the potential to cause blurred vision and reduced contrast sensitivity. During cataract surgery, replacement of the crystalline lens with an IOL provides an opportunity to modify the SA of the eye and to improve visual function.[4]

A number of studies have reported that aspheric IOLs provide better contrast sensitivity than spherical IOLs (especially under low-light conditions)[5] and that they have the potential to enhance the visual quality. However, these aspheric IOLs function best when perfectly aligned with the visual axis and they are poorly tolerant of decentration and tilt which can lower visual performance. The Avansee IOL aims to mimic the natural variation in asphericity of the eye and is designed to provide an optimal combination of visual performance and tolerance to misalignment.

Fujikado and colleagues examined the effect of decentration (0.5 mm) and tilt (5.0°) on retinal image quality using one spherical and three aspheric 3P acrylic IOLs with different degrees of SA: -0.27 µm (corneal aberration fully corrected on average); -0.17 µm (whole eye aberration similar to that found in young subjects); and -0.04 µm (equivalent to the SA of the Avansee IOL).[4]

Landolt ring simulations showed that depth of focus increased when SA correction provided by the IOL was zero or small. In the absence of misalignment, coma aberration was small irrespective of the degree of SA, but for misaligned lenses it increased with the spherical corrective power of the IOL. Landolt ring simulations also confirmed that the plane of focus was sharpest for the IOLs with a high degree of SA correction, but these images degraded with defocus and misalignment. In contrast, IOLs with little or no corrective power produced an image that was slightly blurred at the plane of focus but was hardly affected by defocus or misalignment. The authors concluded that the quality of vision could potentially improve by reducing the risk of coma aberration due to IOL misalignment, through using IOLs that retain or have little effect on the SA of the eye.[4]

A similar study by Lawu and colleagues assess the effects of decentration and tilt on a model eye for six IOLs with varying degrees of asphericity (Table 1).[5]

Their results confirmed that the effect of decentration and tilt on astigmatism, coma and higher order aberrations was greater for IOLs with increasing amounts of SA corrective power

(Figure 6). They concluded that, while aspheric IOLs which correct SA may provide better optical performance than spherical IOL if alignment is perfect, the optical degradation caused by IOL misalignment has a greater effect with a higher degree of negative SA correction. In line with this general finding, the effect of misalignment due to decentration or tilt, was reduced with the Avansee IOL (SA -0.04).[5] In other words, Avansee works well even when there is some residual astigmatism, defocus, misalignment or tilt.

IOL model	Type	Design	Reduced SA (µm)
Sensar AR40e	3P	Spherical	NA
Avansee Natural AN6K	**3P**	**Aspheric**	**-0.04**
Nex-Acri AA NS-60YG	1P	Aspheric	-0.13
Eternity Natural Uni W-60	1P	Aspheric	-0.13
Vivinex iSert XY1	1P	Aspheric	-0.18
AcrySof IQ SN60WF	1P	Aspheric	-0.20
Tecnis OptiBlue ZCB00V	1P	Aspheric	-0.27

Table 1. Properties of studied IOLs. Refractive power was 20D for all.

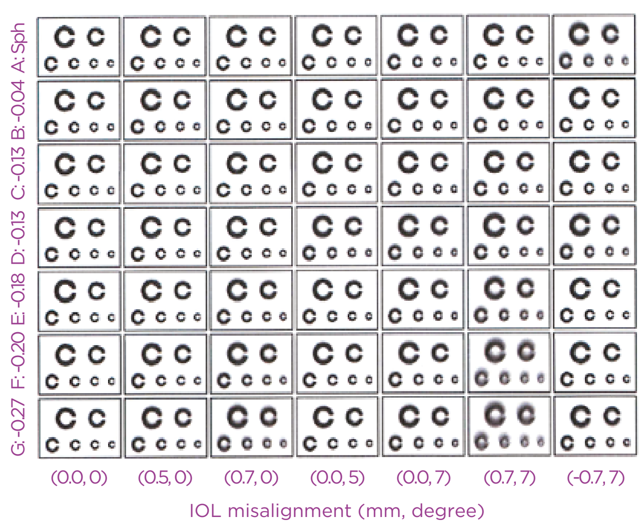

Figure 6. Measurement results of Landolt ring retinal imaging based on the higher-order aberrations generated by the wavefront aberrometer.[5]

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Avansee™ PreloadIP Toric: High quality material and manufacture deliver favourable practical experience and positive patient outcomes

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In common with all members of the Avansee family, the Avansee 1P toric lens is developed with the highest quality materials and standards of manufacture. It is composed of high-quality glistening-free material, has a 360° square-edged design and, for ease of use, it is preloaded in the original Avansee Preload injector. This ease of use, together with good rotational stability, has been clearly demonstrated in our clinical practice with this novel, innovative IOL.

Zero glistenings

After implantation, there is potential for the optical purity of IOL optics to deteriorate due to glistening. Typically, glistening is observed within a few months of surgery and appears as small bright spots across the optic. Physically, glistenings represent fluid-filled light-reflecting vacuoles (1-20 µm diameter) formed by the absorption and subsequent condensation of water within the matrix of the optic material. The impact of glistening on visual function is controversial, but some studies report significant increases in light scatter and decreases in contrast sensitivity. The formation of glistening can be influenced by manufacturing technique, IOL packaging, postoperative inflammation, ocular diseases, ocular medications and the duration of IOL use.[1]

The risk of glistening is reduced by increasing the density of cross-linkages in the optic. In general, a low density of cross-linkages can provide a soft, flexible lens but may increase the likelihood of glistenings. In contrast, a high density of cross-linkages reduces the risk of glistenings but may produce a hard lens. The density of cross-linkages in the Avansee™ lens is optimal allowing for a flexible lens without glistening. Avansee's cast-moulded optics are made from a stable, uniform and highly cross-linked polymer in combination with strictly controlled manufacturing process, which prevents water molecules gathering in the microvoids of the material, thereby reducing the risk of glistening.[2] This is reflected in experience from clinical practice – there have been no reports of glistening with Avansee since its launch in Japan in 2007[3] – and is also confirmed by the European bench study.[4]

Low risk of PCO

Posterior capsule opacification (PCO) is caused by hyperplasia and migration of lens epithelial cells from the anterior capsule to the posterior capsule following IOL implantation, leading to a thickening, opacification and clouding of the posterior lens capsule.[5] All Avansee IOLs – including 1P, 3P and toric lenses, have a 360° square-edged design (even at the toric optic-haptic junction) in order to reduce the risk of PCO[5-9] (Figure 7). The well-designed square edge runs around the optic without clear bends (almost circular) which theoretically fits well with the posterior capsule.

Smooth injection and lens opening

The Avansee Preload1P injector was designed specifically for the Avansee 1P IOL, which requires very low delivery force during implantation.[10] In addition, the indented haptic surface prevents optic haptic 'kissing' and which, together with the flexible material, achieves very smooth lens unfolding (Figure 8). This helps to ensure the lens fixes the position in the eye promptly after implantation avoiding the need to prolong surgery unnecessarily.

Rotational stability

The rotational stability of the Avansee Preload1P IOL, was assessed by comparing IOL alignment immediately post implantation with the position measured at 1 day and 3 months postoperatively.[11] Mean and median values for rotation at 3 months postoperatively were 2.12 ± 1.86° and 1.54° (0.04–7.68), respectively (n=26) (Table 2). The data at 1-day post-op show very little movement, suggesting that Avansee lenses become stable just after implantation in part due to the smooth lens unfolding.[12]

This excellent rotational stability has also been confirmed in our clinical experience with the Avansee Preload1P Toric IOL in our clinic in Heidelberg. The lens performs as designed by Kowa, unfolds very smoothly in the eye and stabilises itself soon after positioning. The table below summarises experience with a series of 10 patients and shows that lens rotation at 7 days post-operatively was less than 2 degrees in all patients (Table 3).[13]

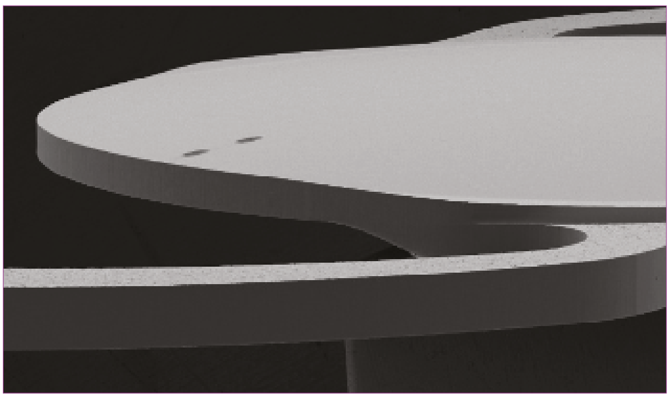

Figure 7. Photograph of Avansee Preload1P Toric showing 360° square edge.

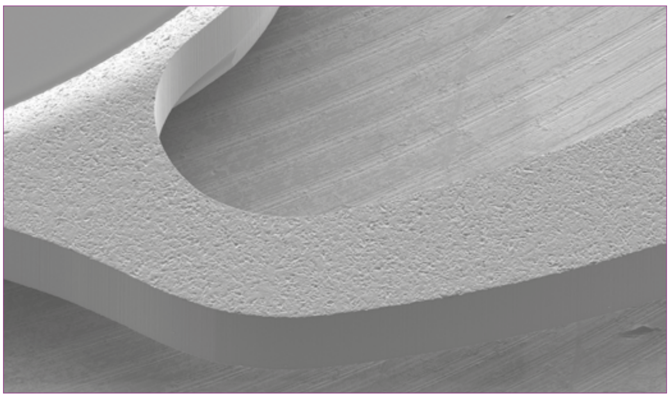

Figure 8. Photograph of haptic surface.

Parameter	Comparison		
	1 day post-op vs post implant	3 months post-op vs post implant	3 months post-op vs 1 day post-op
Eyes with large enough pupil to measure the central point of rotation of the IOL	N=63	N=58	N=66
Eyes with large enough pupil and good visibility of blood vessels to have a reference line for evaluation of the lens rotation excluding the impact of cycloduction	N=24	N=26	N=16
Variation in IOL alignment:			
Mean ± SD rotation (°)	1.44 ± 1.29	2.12 ± 1.86	1.54 ± 0.98
Median (max, min) rotation (°)	0.90 (0.09–5.39)	1.54 (0.04–7.68)	1.58 (0.06–4.04)
Eyes with <5° rotation (%)	95.8	92.3	100

Table 2. Rotational stability of Avansee™ Preload1P IOL.

Patient	Spherical power (D)	Placement lens angle (°)	Post-op lens angle (°)	Lens rotation (°)
1	+17	78	80	2
2	+17	79	78	-1
3	+18.5	77	78	1
4	+21	8	8	0
5	+21	174	175	1
6	+18.5	78	78	0
7	+17.5	98	100	2
8	+20.5	81	80	-1
9	+19	127	127	0
10	+22.5	0	0	0

Table 3. Rotational stability confirmed in clinical experience at post-operative day 7 (N=10) (Heidelberg University eye clinic).

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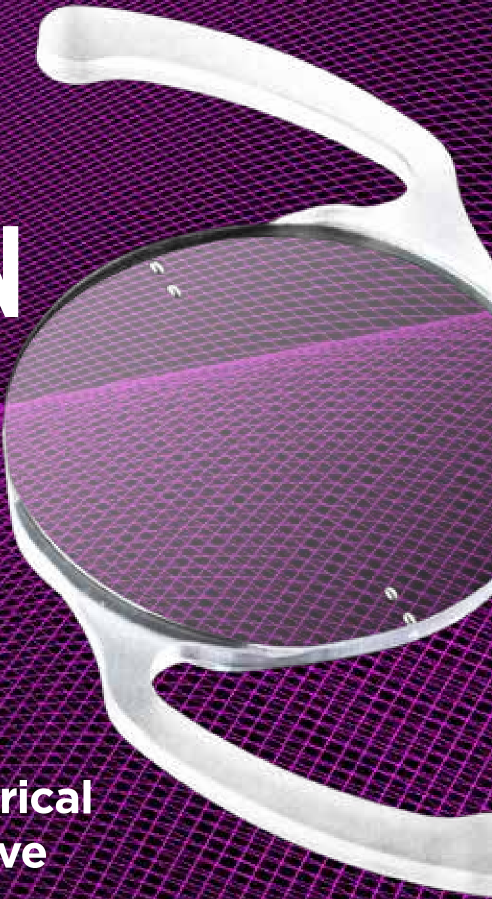
TORIC



THE NEXT GENERATION TORIC INTRAOCULAR LENS (IOL)

Avansee Preload1P Toric retains the spherical aberation of the eye and offers progressive axial correction (PAC) technology.

The degree of astigmatism is not uniform across the cornea.[1]

The unique PAC technology delivers greater cylinder power at the centre of the cornea, where the astigmatism is more pronounced, and less cylinder power at the periphery where the astigmatism is lower.[2]

Avansee Preload1P Toric corrects astigmatism where necessary and minimises overcorrection.[2]

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