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Avansee[™] Preset / Avansee[™] Preload1P: Personal experience with Kowa's preloaded three-piece (3P) and one-piece (1P) lens

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1. Introduction

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vansee[™] (Kowa Co. Ltd.) is an aspheric, hydrophobic acrylic, posterior chamber intraocular lens (IOL) designed for smallincision cataract surgery.^{1,2} Both the one-piece (1P) and the three-piece (3P) designs (Figure 1) are fully preloaded into a lightweight, syringe-type injector (Figure 2), which enables preparation in three simple steps and IOL insertion with just one hand.¹⁻⁴ After surgical insertion, the lens gently unfolds to restore the optical performance of the lens. Overall, the number of adverse effects reported for Avansee is low.^{1,2}

For some IOLs, optic transparency deteriorates after implantation due to glistening (small bright spots caused by fluid-filled vacuoles in the optic).⁵ If visual function is affected, the lens should be replaced with a new one. This is not a concern for Avansee, which uses a highly cross-linked, glistening-free material for the optics;⁶ no cases of glistening have been reported for Avansee since its launch in 2007.^{4,6} Another benefit for Avansee is its low risk of posterior capsule opacification (PCO).^{3,4} PCO is caused by hyperplasia and migration of lens epithelial cells (LECs) from the anterior capsule to the posterior capsule following IOL implantation, leading to a thickening, opacification and clouding of the posterior lens capsule.⁷ Avansee's cast-molded, 360° square-edged lens is designed to reduce the risk of PCO.⁸

Numerous 3P and 1P IOLs are currently available, each with slightly different designs and characteristics.^{3,4} The choice of IOL largely depends on the type of surgery, cost, patient characteristics, long-term performance, reliability, ease of use, and safety.^{3,4;9}

This Supplement reviews a number of clinicians expereinces with the Avansee lens. Whilst these examples are not within the formal indication for the lens they demonstrate the adaptability of the lens and suitability for a number of varied situations.

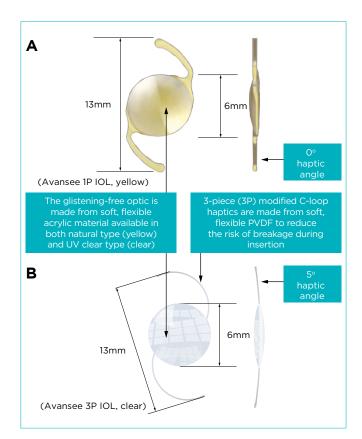


Figure 1 Avansee A. One-piece (1P) IOL,¹ B. Threepiece (3P) IOL²

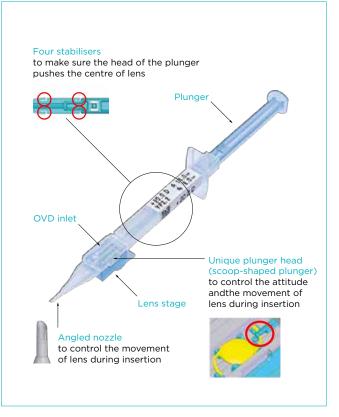


Figure 2 Fully preloaded, single-use Avansee Preload1P inserter¹

Combining the advantages of a one-piece (1P) and a threepiece (3P) lens: Personal experience with Avansee Preload1P

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he advanced-design, preloaded Avansee Preload1P injector system from Kowa allows reliable, sutureless cataract surgery with minimal postoperative complications, and a low risk of optic deterioration over time.¹ At the Ophthalmic Department of the University Hospital of Bari, we have performed surgery using Avansee Preload1P in 10 patients with cataracts, and no other ocular pathologies. The injector is contained in a box with double packaging to ensure sterility and to maintain the characteristics and integrity of the lens. After removing the injector from the sterile blister, it is ready for use in three simple steps: 1. Injection of viscoelastic solution, 2. Removal of the lens stage, and 3. Pushing the plunger until the IOL edges make contact with each other. In our experience, directions for preparing the IOL for insertion are easy to follow with no margin of error.

Avansee Preload1P and AvanseePreset (3P) IOLs are injected using the same procedure: leading haptic first, then the optic, and finally the trailing haptic.¹ Moreover, Avansee Preload1P has a number of additional features that were specifically designed for the 1P lens. For example, the plunger is designed to prevent overlapping (and possible sticking) of the trailing haptics with the optic disk when the lens is folded into the nozzle – a phenomenon that frequently occurs with other C-loop 1P lenses. We find that the injection procedure is naturally driven by the system itself and we particularly appreciate the unique "scoop shaped" plunger, which ensures full control of trailing haptics with no risk of unexpected events.

The injector includes an angled nozzle tip; we therefore find that the surgeon needs to rotate the injector approximately 30° counterclockwise to enter the corneal incision with the bevel down, followed by a 30° clockwise rotation once the injector is inside the anterior chamber. This procedure is easy to perform, resulting in perfect, smooth injection of the lens into the capsular bag. Importantly, we have not experienced any trouble with haptics or lens injection. We find that the 2.2 mm incision size is comfortable and that lens unfolding in the capsular bag is gentle and safe, with a similar unfolding time (and hence surgery time) to that observed with a 3P lens. After implantation, Avansee1P looks well centered and stable in the capsular bag, with no deformation.

Whereas other 1P IOLs have a reduced/square edge at the haptic junctions, Avansee's squareedge extends 360° around the lens, including the optic-haptic junction.^{1:8:40-41} Consequently, Avansee is associated with a low risk of posterior capsule opacification (PCO). Risk is further reduced by the smooth lens surface and the use of haptics that maintain space between the optic and haptic, aiding adhesion between the anterior and posterior capsule.

We believe that the Avansee Preload1P injector system combines all the advantages of a 1P and a 3P lens. Cataract surgery is quick and easy from the very beginning, and lens insertion can be performed using just one hand. Improved control of the trailing haptics during surgery ensures a fast, safe unfolding process, resulting in more stable IOL insertion than some other IOLs, but with no adverse events and a low risk of PCO. We believe that this new system will improve the reliability, reproducibility, and speed of IOL surgery.

The benefits of AvanseePreset: three-piece (3P) versus one-piece (1P) IOLs in complex cases of vitreoretinal surgery

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omplex cases of vitreoretinal surgery often require the removal of the crystalline lens, even when there is no evidence of cataract.¹⁵ Easy access to the extreme periphery is needed for various surgical manoeuvres, including complete or nearcomplete removal of the vitreous (Figure 1), peripheral retinotomy, peeling of fibrovascular membranes and peripheral treatment of the retina/ciliary body with laser or diathermy (Figure 2). These procedures carry a risk of iatrogenic damage to the posterior capsule of the lens (Figure 3) leading to rapid intraoperative opacification. If this happens, the lens should be removed before completing surgery on the posterior segment.

I believe that, in addition to lensectomy via pars plana, a vitreoretinal surgeon should master anterior segment techniques and in primus phacoemulsification. Removal of the lens through the anterior segment allows IOL implantation in the bag in most cases. In cases where phacoemulsification is required but not planned, the risk of lens luxation/subluxation into the vitreous chamber is increased due to the iatrogenic damage of the bag. In contrast, surgery is simple, clean and elegant if phacoemulsification is routinely planned and performed at the beginning of surgery.

Considering the sequence of surgical steps, I prefer to introduce the infusion line into the vitreous chamber through the sclerotomy before removing the cataract. This allows me to introduce the infusion line in a close globe with controlled, normal intraocular pressure. In fact, opening the sclerotomy by trocars insertion requires a great deal of pressure on the globe. At this point, the corneal wounds necessary for phacoemulsification might open with anterior chamber loss or iris incarceration. Other surgeons prefer to complete phacoemulsification before proceeding with trocars insertion or, more rarely (but still useful), proceed with opening 20 G sclerotomies. This last sequence is justified by the idea that the presence of the trocars might interfere with the handling of the instruments during phacoemulsification.

In complex vitreoretinal cases, a three-piece (3P) IOL is preferable to a one-piece (1P) IOL for a

number of reasons. Firstly, the risk of iatrogenic damage to the posterior capsule during vitrectomy leading to IOL luxation is high. Many surgeons (including myself) create a posterior capsulotomy every time to avoid the need for postoperative Yag laser — a difficult procedure to perform if the silicone oil fills the vitreous chamber. In these cases, it is possible to luxate the plate of the 3P lens in front of the anterior capsulorhexis, leaving both haptics in the bag. This fixes the IOL and avoids luxation in the vitreous chamber. Secondly, if the bag receives significant damage involving the anterior capsulorhexis, 3P IOL haptics can be used to fix the IOL either to the iris or to the sclera. Fixation to the iris can be carried out using a 10-0 Prolene suture and a sliding knot that preserves the integrity of the iris (Figure 4). Fixation to the sclera can be achieved with scleral tunnels 1 mm from the limbus, in which tips of the haptics are inserted with forceps. Thirdly, whereas 1P IOLs IOL might luxate into the anterior chamber due to fluidair exchanges, the stability of 3P IOLs in the bag during posterior manoeuvres is high.

In my opinion, AvanseePreset (3P) has a number of benefits compared to other 3P IOLs for complex cases of submacular surgery, proliferative vitreoretinopathy, proliferative diabetic retinopathy, and trauma. Insertion of Avansee 3P using the fully preloaded AvanseePreset inserter offers ease of use, good visualisation of the fundus, good stability, and a low risk of posterior capsule opacification (PCO). I have implanted roughly 50 Avansee 3P IOLs in the past year and I have learnt that I need to place the nozzle tip of the cartridge in the middle of the capsulorhexis, and slightly point the nozzle tip toward the capsulorhexis before injecting the IOL into the bag in one single step (Figure 5). This can be done without pushing the haptics, rotating the lens, or applying stress to the capsular bag. Importantly, I found that the lens remained stable even in cases requiring intraoperative posterior capsulotomy with the vitrectomy probe. Without intentional removal of the posterior capsule, I observed no significant opacification at one year, even if the surgical trauma had been significant.

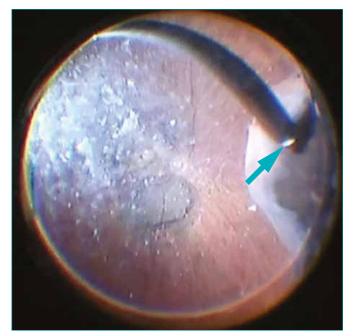


Figure 1. Perfect view of extremely peripheral vitrectomy through the Avansee 3P lens. The border of the lens is visible outside the visual field of the surgeon (arrow). (Triamcinolone vitreous staining).

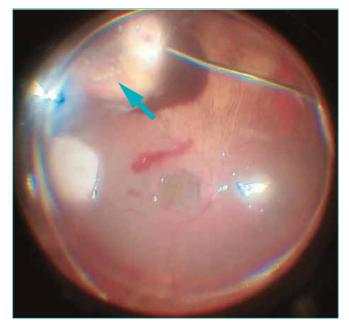


Figure 2. Panoramic view of the fundus through the Avansee 3P lens. The retina has been re-attached with perfluorocarbon liquid. Laser is applied to the peripheral retinotomy. The laser spots (arrow) are visible inside the edge of the IOL.

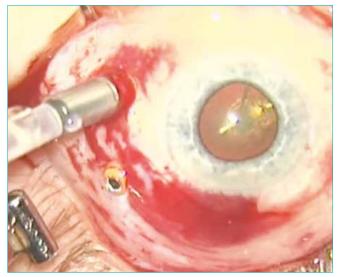


Figure 3. The crystalline lens has been iatrogenically damaged by a laser probe, which inadvertently touched the lens while the scleral depressor was rotating the eye.

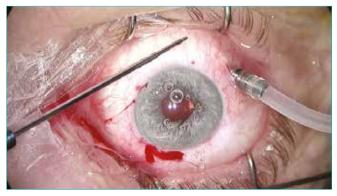


Figure 4. Luxation of a 3P IOL into the vitreous chamber. The capsular bag was compromised. The haptics of the 3P IOL could be sutured to the iris with 10-0 Prolene suture and a sliding knot.



Figure 5. Insertion steps for Avansee 3P. The cartridge is inserted in the anterior chamber, placing the nozzle tip in the middle of the capsulorhexis (A). The lens is gently inserted into the bag while turning the opening of the cartridge down with a vertical movement (B). The hook in the opposite hand might help stabilise the position of the IOL, but it is not mandatory. Finally, the second haptic is inserted into the bag and finds its way with a spontaneous movement (C).

The benefits of AvanseePreset (3P, Kowa) versus Acrysof (1P, Alcon) for combined vitreoretinal and cataract surgery

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ombined vitreoretinal and cataract surgery is a safe and effective treatment for cataracts associated with age-related vitreoretinal disease.¹⁶ Challenges associated with phacovitrectomy include the lack of vitreous support, unstable anterior chamber depth, intra-operative miosis, dense nuclear cataracts, recurrent macular edema, and/or re-opening of the macular hole.¹⁷ This can lead to complications such as refractive errors, intraocular lens (IOL) decentration or dislocation, and poor visualisation of the retina during subsequent post-vitrectomy checks due to posterior capsule opacification (PCO) and/or glistening.

Avansee 3P minimises refractive errors after vitrectomy

Refractive error after IOL implantation is defined as the difference between the expected postoperative refraction (based on preoperative calculations) and the actual refraction achieved after surgery.¹⁸ A negative refractive error (myopic shift) can be caused by a number of factors, including changes in effective lens position (ELP).^{19,20} This, in turn, depends on axial length, corneal height, lens thickness, and anterior chamber depth (ACD). After cataract surgery, the ACD increases and a posterior shift occurs in ELP.²¹ An even greater posterior shift in ELP occurs following vitrectomy in phakic,⁷ but not in pseudophakic, eyes.^{22,23}

The refractive effect of an IOL largely depends on the degree of IOL tilt and decentration, whether the IOL is inside or outside the capsular bag, and the IOL's axial movements.²⁵ In phacovitrectomy, the axial movement of the IOL is greater in 1P IOLs than in 3P IOLs.²⁶ Other features that determine the refractive effect include optic/ haptic material and design, and optic-haptic angulation.²⁷ In general, IOL stability increases as the angle of contact between the loop and the lens capsule gets larger. Compared to some IOLs, the angle of contact for Avansee 3P is relatively large.^{2;4} Moreover, whereas Acrysof 1P haptics are flaccid and do not self-centre the lens, Avansee 3P haptics are made from flexible polyvinylidene fluoride (PVDF), which reduces the risk of refractive instability as the capsule tightens with time. This suggests that Avansee 3P is likely to be associated with a smaller myopic shift after phacovitrectomy than Acrysof 1P.

Avansee 3P allows good retinal visability during and after phacovitrectomy

Intraoperative IOL decentration/dislocation due to surgical stress on the capsular bag and zonular fibres may impair the surgeon's view of the retina.¹⁶ Compared to other IOLs, Avansee 3P does not cause zonular stress or transformation of the capsular bag (Figure 1).⁴ Moreover, video analysis of AvanseePreset (3P) insertion into an eye model showed controlled capsular bag implantation with uncomplicated IOL unfolding, smooth haptic opening, no stickiness between the optic and the haptic, and only a minor interaction between the haptics and the capsular bag due to the large arc of contact between the loop and the lens capsule (Figure 2).⁴ Consequently, AvanseePreset (3P) is unlikely to be associated with misalignment and provides good retinal vision during vitreoretinic surgery.

Retinal visualisation post-vitrectomy can potentially be improved by using IOLs with a low risk of glistening and PCO. Unlike other hydrophobic acrylic IOLs, Avansee does not show glistening-like opacity (Figure 3).^{4;6;28} Moreover, cast-molded hydrophobic IOLs, such as AcrySof and Avansee, that are carved without grinding after polymerisation have squarer edges than IOLs that are manufactured using other techniques (Figure 4), and are therefore associated with a low risk of PCO.^{3,4;6} However, unlike 3P lenses, AcrySof 1P haptics extend directly from the posterior surface leaving a potential gap in the 360° truncated edge, which may increase PCO rates.¹

In our experience, Avansee 3P is associated with a low rate of complications after phacovitrectomy, and assumes a stable position in the eye without zonal stress or transformation of the capsular bag. Its low risk of PCO and glistening allows good visualisation of the retina after vitrectomy, offering advantages over other IOLs for vitreoretinal surgery.



Figure 1. Avansee is associated with a low risk of misalignment. Posterior Miyake apple views showing the effects of five different IOLs on the capsular bag⁴

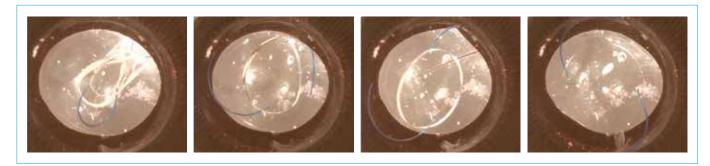


Figure 2. Sequence of events observed using video analysis of AvanseePreset PU6A insertion into a cadaver eye model using Miyake-Apple view attached to a high-speed camera⁴

	Optical Purity	Microvacuoles/ mm ²	Glistening severity grade
Alcon MA60AC		251	3
Hoya PC-60AD		883	3
Bausch & Lomb Envista		15	0
Avansee AU6KA	and the second	21	0

Figure 3. Avansee has a high level of optical purity in vitro.⁴ IOLs underwent severe accelerated deterioration tests.* Graded 0 to 3 using the method described by Miyate et al.

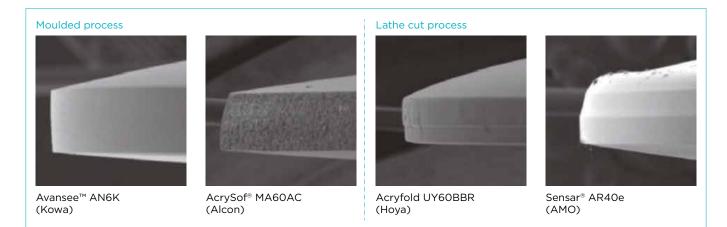


Figure 4. Avansee is carved without grinding to provide a squarer edge than other IOLs, thereby preventing lens epithelial cell migration and posterior capsule opacification (PCO) formation³

AvanseePreset (3P) is suitable for sutureless intra-scleral implantation in patients without capsular support

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cular trauma, congenital anomalies and/ or complications during cataract surgery are common indications for intraocular lens (IOL) implantation in the absence of capsule support.²⁹⁻³¹ In such cases, the IOL can be implanted in the anterior chamber (AC) at the front of the iris (open-loop AC-IOL or iris-claw IOL), or in the posterior chamber (PC), fixed either to the iris or to the sclera using suture.³²⁻³⁴ Whereas AC-IOLs are associated with a high risk of uveitis, glaucoma, hyphema, bullous keratopathy, and cystoid macular edema, fixed PC-IOLs are associated with suture erosion, knot exposure, and recurrent dislocation due to broken sutures. Several authors propose fixing the IOL haptics into the sclera in order to minimise inflammation and suture degradation, and to delay IOL dislocation. Intra-scleral IOL fixation offers several advantages compared to other techniques. For example, accurate placement of the haptics in the scleral tunnel can minimise IOL torsion and decentration, the small clearcornea incision prevents higher surgically-induced astigmatism, and the fibrin glue prevents wound leakage and post-operative hypotony.^{35,36} New techniques have been proposed for the intra-scleral fixation of PC-IOLs that might reduce the potential complications associated with these techniques.³⁷⁻³⁹

AvanseePreset (3P)-IOL intra-scleral implantation: Surgical technique

Anterior or complete 25-gauge vitrectomy is performed under peribulbar anaesthesia in patients with vitreous prolapse into the anterior chamber or luxated cataract in the vitreous cavity. Localised peritomy and bland cautery of the episcleral vessels are performed 180 degrees from each other, usually at 3 and 9 o'clock. Two partial thickness scleral flaps are created, approximately 2.5 mm x 2.5 mm and 300 microns in depth. A 23-gauge sclerotomy is performed approximately 1.5 mm posterior to the limbus under the flaps and AvanseePreset (3P) is injected through a 2.5 mm clear-cornea incision (Figure 1A). The distal haptic is grasped at the tip with end-gripping 25-gauge forceps and pulled through the sclerotomy (Figure 1B). The trailing haptic is then grasped with the same forceps and pulled through the second sclerotomy. A 25-gauge needle is used to obtain a scleral tunnel under the scleral flap at the point of externalisation of the haptic (Figure 1C), into which the haptic tips are inserted (Figure 1D). Finally, the scleral flaps and conjunctiva are closed with fibrin glue (Figures 1E and F).

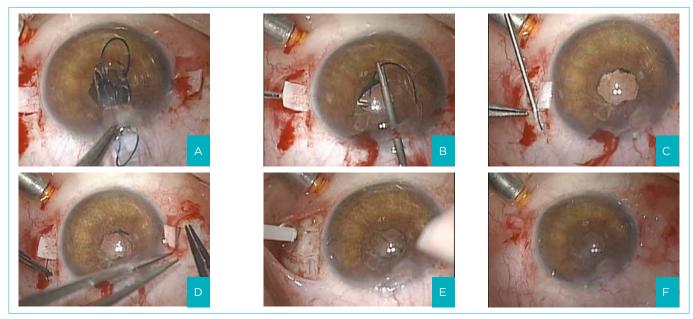


Figure 1. AvanseePreset (3P) intra-scleral fixation: A. AvanseePreset (3P) injection through a 2.5 mm clear corneal incision; B. The distal haptic is grasped at the tip with 25-gauge forceps; C. A scleral tunnel is created using a 25-gauge needle; D. The haptic tips are introduced and locked in the fashioned tunnel; E and F. Conjunctiva and scleral flap are closed with glue without requiring sutures.

AvanseePreset (3P, Kowa): My preferred intraocular lens (IOL) in congenital and paediatric cataract surgery

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hen deciding whether to implant intraocular lenses (IOLs) in congenital and paediatric cataract surgery, we need to consider which kind of IOL can be implanted and how. Most commercialised IOLs have a high degree of biocompatibility and are pre-loaded to minimise the risk of inflammatory reactions and/or endophtalmitis.¹⁰ When implanting IOLs in childrens' eyes we need to focus on reducing the risk of complications and avoiding additional intraocular surgeries in pseudophakic (as opposed to aphakic) eyes. Consequently, acrylic, hydrophobic, foldable IOLs (one-piece [1P] or three-piece [3P]), are the best choice.¹¹ Where possible, IOLs should be fully pre-loaded into an injection system ensuring sterility, reproducibility and safety, and have an overall IOL diameter <12.5 - 13 mm. A low risk of tissue damage and IOL deformation, good long-term optic performance, and IOL stability within the capsular bag/sulcus are also essential. In theory, children will benefit from long-term light protection to reduce the risk of age-related macular degeneration; consequently, IOLs that incorporate a blue light filter may be preferable.¹²

Based on the literature, I prefer to use posterior optic capture techniques for congenital and paediatric cataract surgery, thereby reducing the risk of posterior capsule opacification (PCO) and preventing the vitreous from extending anteriorly towards the IOL. This approach also ensures stability and long-term centration of the IOL. The cataract should be removed and anterior vitrectomy should be performed via limbal incision using a 23-gauge cutter, thereby allowing the IOL optic to be captured through the posterior capsulorhexis opening (Figure 1). Haptics with a total IOL diameter of 13 mm can be inserted into the sulcus providing excellent stability with very low rates of IOL decentration or dislocation.^{13,14}

AvanseePreset (3P) is my preferred IOL for congenital and paediatric cataract surgery. In my experience, this fully pre-loaded aspheric acrylic hydrophobic 3P IOL system delivers reliable, reproducible and controlled IOL insertion in few simple steps, through a main incision of only 2.4 mm.² The system provides a low, consistent and homogeneous delivery force with controlled IOL unfolding, ensuring good shape recovery and optical quality restoration. Moreover, the soft flexible lens can be positioned behind the posterior capsulorhexis opening, providing comfort and control during such a demanding surgical step.

The 3P foldable IOL is 13 mm in diameter, and is available with natural (yellow tinted) optics.² The polyvinylidene fluoride (PVDF) haptics can easily be inserted into the bag/sulcus, with very good stability and no sign of dislocation over the time in my young patients.⁴ To date, I have used AvanseePreset (3P) in eight patients aged from 45 days to three years over a period of 18 months. At the present time, none of my patients require additional surgery and their visual performance is good. No complications (e.g. IOL dislocation, PCO, postoperative glaucoma) have occurred.

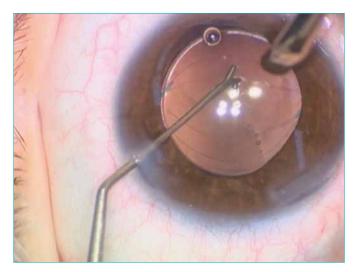


Figure 1 Posterior optic capture of the IOL through posterior capsulorhexis opening

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