Mini- and Micro-incision Cataract Surgery – A Critical Review of Current Technologies

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Abstract

Modern cataract surgery is striving for smaller and smaller incisions with the aim of making clear corneal incisions that are as safe and topographically stable as possible. Recent innovations in both phacoemulsification (phaco) and intraocular lens (IOL) technology have made micro-incision cataract surgery, defined as <2mm incision, safe and effective. Bi-axial sleeveless micro-phaco has recently been joined by sleeve-armed micro-co-axial micro-phaco, made possible by the development of slim-shaft strong-bevel phaco needles armed with micro-sleeves that run flush with an enlarged needle head. Such tip technology allows for a highly efficient and safe high-flow, high-vacuum phaco through incisions as small as 1.4mm by providing high influx and suppressing surge while avoiding mechanical and thermal tissue damage. Two tips have so far been made available for mini- (2.2–2.4mm) and micro-incision cataract surgery (MICS) (1.4–1.6mm, depending on the incision architecture used). With the micro-tip supplemented by additional flow through an infusion spatula ('infusion-assisted' or 'hybrid' phaco), excessive flow and vacuum rates may be used, resulting in a two-fold efficiency as mirrored by the reduced phaco power required. IOL technology is lagging behind phaco technology. The challenge is to avoid trade-offs with regard to implant stability and after-cataract formation, as well as optical performance. Current MICS-IOLs are mostly hydrophilic acrylic one-piece constructions with insufficiently sharp posterior optic edges and broad haptic–optic junctions, both of which features compromise the optic-edge barrier effect. Recently, a hydrophobic three-piece IOL has been made available, which features a slim haptic junction and an exquisitely sharp optic edge and also allows for optional optic entrapment into a posterior capsulorhexis for lasting eradication of after-cataracts.

Keywords

Micro-incision cataract surgery (MICS), micro-co-axial microphacoemulsification, high-flow high-vacuum phaco, surge suppression, mechanical and thermal tissue damage, MICS lenses, optic-edge barrier effect, sharp posterior optic edge, slim haptic–optic junction, posterior optic 'button-holing'

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Recent developments in cataract surgery have been dominated by efforts to further down-size the incision for phaco-emulsification (phaco) and intraocular lens (IOL) implantation. This article demonstrates and discusses the benefits and downsides of further down-sizing the cataract incision, the requirements regarding phaco and IOL technology, the pros and cons of the co-axial and bi-axial approaches and the currently available state-of-the-art co-axial instrumentation and implants.

Is There a Need for Further Down-sizing of the Cataract Incision?

Cataract incisions must fulfil two requirements:

- Deformation resistance (wound stability): to be safe, an incision must not open when manipulated. In practice, a patient may rub the eye with a finger tip. Temporally located incisions are particularly exposed to such deformation and must be designed accordingly. Deformation resistance depends on the size and construction of the incision; it increases as it gets smaller and longer and when it incorporates a scleral portion.
- Topographic neutrality (corneal stability): incisions must not induce corneal shape changes. Smaller incisions cause asymmetrical changes, which are properly picked up only with corneal topography. Topographical stability may be considered relevant within a pupillary zone of 5mm.

We have demonstrated that temporally located tunnel incisions with a scleral portion (temporal sclero-corneal incisions [SCIs]) are the best option to provide both adequate deformation resistance[1] against digital massage and topographical neutrality within a 5mm zone.[2] This is true for incision sizes up to 4mm.[3]

If temporally located sclero-corneal incisions up to a size of 4mm fulfil the requirements, why then should we struggle to further minimise the cataract incision? The answer is that the aforementioned is true only for sclero-corneal incisions. We have also demonstrated that 3mm-wide clear corneal incisions (CCIs) are not safe enough and induce asymmetrical corneal flattening adjacent to the incision that encroaches on the 5mm optical zone.[4] With temporal-superiorly or superiorly located incisions, this sectorial flattening effect increases significantly.[5] While SCIs, due to conjunctival healing, allow for permanent sealing within one week, CCIs take months to do so, thereby exposing the patient to a risk of endophthalmitis for an extended time. However, corneal incisions have become very popular since they are easy and fast to create, exclude intra-operative ballooning of the conjunctiva and are cosmetically appealing while avoiding patient disturbances due to conjunctival bleeding or foreign body sensations. However, to be safe and astigmatically neutral CCIs must be further down-sized.

How small must a safe CCI be? Deformation resistance of a CCI depends on the width and length of the incision. The smaller the incision, the shorter the incision can be while providing for the same amount of resistance against digital massage. Practically, a 2x1.5mm incision should fulfil these requirements. Smaller incisions further optimise safety, as long as they are not over-stressed during phaco and IOL insertion. Topographical impact on the central corneal zone has been shown to be negligible with a CCI size of 2.0mm or smaller.[6]

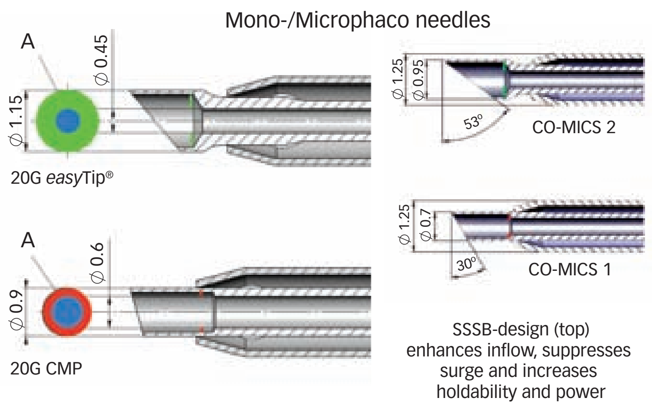
What are the requirements for phaco and IOL technology? Phaco should provide maximum safety and efficiency. Safety means minimal incisional trauma and maximum chamber stability. Efficiency means minimal phaco time and energy consumption. This should be achieved through the smallest incision possible. IOLs should provide easy and atraumatic insertion, auto-centration and stable fixation within the bag, circumferential barrier function against lens epithelial cell (LEC) immigration and optimum optical performance. Implanting IOLs through smaller than appropriate incisions may cause permanent tissue trauma, and compromises the self-sealing properties.[7]

What incision sizes should be aimed for? Incision sizes are dictated by the IOLs to be inserted. Current IOLs may be divided into two subgroups: mini-incision IOLs, which fit through a 2.2–2.4mm incision, and micro-incision IOLs, which fit through incisions smaller than 2mm. In conjunction with appropriate phaco equipment, the latter allow for what has been termed 'sub-2mm' or 'micro-incision' cataract surgery (MICS).

MICS through 2.2–2.4mm incisions is achieved with current co-axial phaco and IOL technology. However, this is a trade-off. Simply reducing the size of a standard phaco needle reduces holdability and energy output. Therefore, innovative phaco needle technology is mandatory (see *Figure 1*). When reducing the shaft diameter, higher vacuum and flow settings may be used, at the same time suppressing post-occlusion surge. By increasing the bevel angle of the needle, holdability – a function of the area of the opening – is augmented. The transition between the broad needle-head and the slim shaft increases the frontal projection area, which is proportional to the energy output. The slim shaft allows for a sleeve that runs almost flush with the needle-head, which further reduces the incision size required, and and avoids anteriorly directed infusion inflow, which tends to push particles away from the front opening of the needle. Together, this slim-shaft–strong-bevel (SSSB) needle design fits into a concept that optimises followability, holdability, energy transfer and surge suppression (see *Figure 2*).

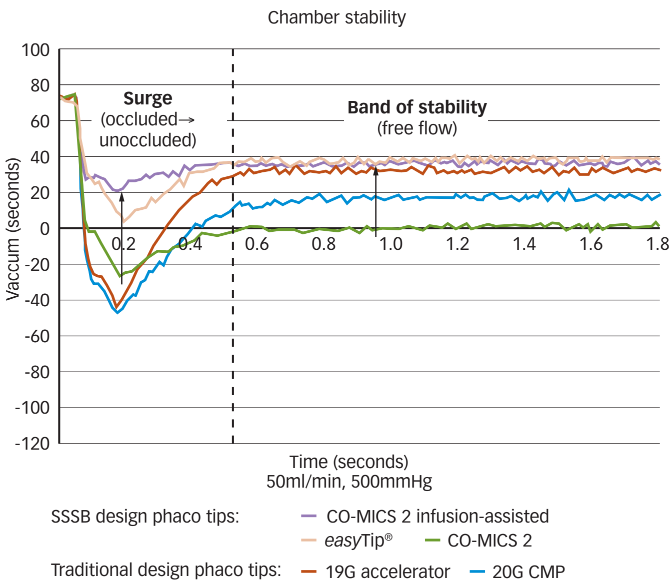
Such a needle has recently been released by the Oertli® Company: the *easy*Tip®2.2mm (see *Figure 1*, left). A significant decrease in phaco time and energy consumption in clinical tests has corroborated the

Figure 1: Design Characteristics of Slim-shaft Strong-bevel Phaco Needles for Co-axial Mini- and Micro-phacoemulsification (*easy*Tip®2.2mm, *easy*Tip®CO-MICS)



Source: Oertli Instruments Inc.

Figure 2: Post-occlusion Surge and Band of Steady-state Stability with Different Phaco Tips Including Infusion Assistance



theoretical advantage of this concept (Menapace et al., data on file). Of the IOLs on the market, several fit through a 2.2–2.4mm incision. However, most of these (e.g. Alcon Acrysof SN60WF, Zeiss-Acri.Tec AcriLyc 47LC) are one-piece acrylic IOLs with broad haptic–optic junctions with the injector tip docked to, and not inserted into, the incision. Broad junctions inherently interfere with capsular bending and thus compromise the barrier function against immigrating LECs, giving way to earlier and more pronounced after-cataract formation.[8] A singular exception is the HOYA AF-1 pre-loaded three-piece IOL, which has recently been fitted with an exquisitely sharp posterior optic edge and allows injection through a 2.4mm incision, if properly designed. Due to its slim junction design, the HOYA IOL may also be used in conjunction with posterior optic button-holing for permanent eradication of any form of after-cataract formation.[9] With this three-piece IOL the injector tip must be inserted into the tunnel; by contrast, it can be docked to the tunnel entrance with one-piece IOLs. While requiring a somewhat smaller incision width, docked injection is less controlled and exposes the incision to distending and shearing forces. Parallel-walled incisions are therefore not recommended. A

Figure 3: Infusion-assisted 'Hybrid Phaco' with the *easy*Tip®CO-MICS Micro-co-axial Phaco Tip and a Tight-fit Low-resistance Infusion Spatula (Geuder, Germany)

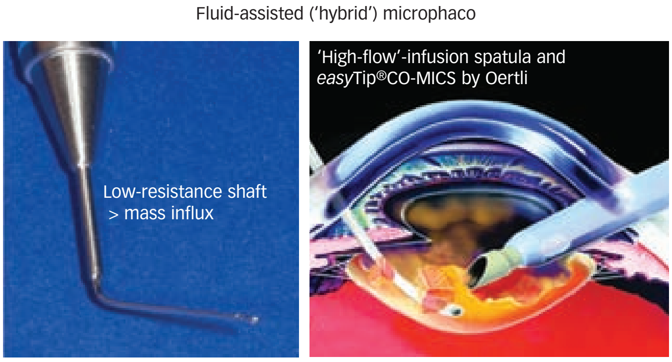


Figure 4: Modified 'Divide and Conquer' Technique for *easy*Tip®CO-MICS Micro-co-axial Phaco Tip with or without Infusion Assistance

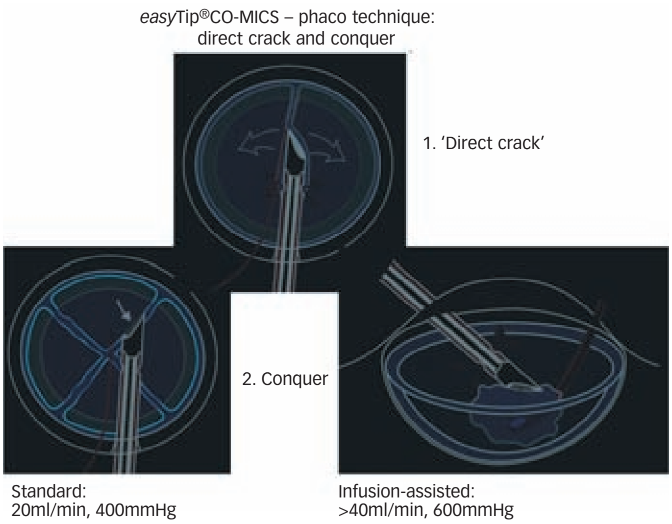
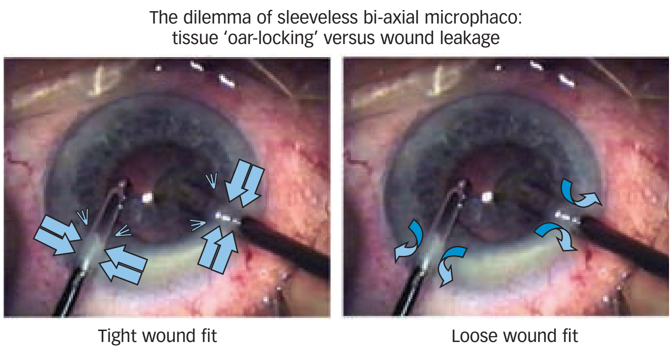


Figure 5: The Dilemma of Sleeveless Bi-axial Micro-phaco



funnel-shaped incision alleviates docking for insertion. However, the unfolding IOL exerts considerable stress on Descemet's membrane, which may compromise the self-sealing properties of the corneal lip. A trumpet-shaped incision makes appropriate docking more demanding, but minimises the stress on the corneal lip. Therefore, the latter is definitely preferable for the experienced surgeon. Alternatively, pre-loaded IOL injection systems have been made available that allow implantation of a continuous-edge three-piece IOL through a 2.4mm incision: the HOYA iSert hydrophobic acrylic and the Bausch & Lomb SofPort silicone. Recent long-term studies suggest that after-cataract and yttrium–aluminium–garnet (YAG) rates, due to the particular material and design properties, will be significantly lower with the three-piece silicone IOL compared with the one-piece acrylic models.[10]

Micro-incision Cataract Surgery Through Sub-2mm Incisions

Phaco Instrumentation

MICS requires new technologies and surgical techniques if the efficacy and safety of phaco are to be preserved. For phaco, a micro-co-axial or a bi-axial approach can been chosen. For several years, the bi-axial approach has been the only choice for real micro-incision phaco through incisions smaller than 2mm. Recent improvements in phaco needle manufacturing technology have allowed implementation of the SSSB design into a co-axial micro-tip – *easy*Tip®CO-MICS by Oertli (see *Figure 1*, right). This needle allows co-axial micro-phaco (MPE) through incisions as small as 1.4mm when used with trumpet-shaped incisions. Clinical studies have demonstrated its efficacy and safety. However, inflow remains the limiting factor for high-fluidic settings. To compensate for this, infusion-assisted or hybrid phaco[11] has been introduced and evaluated by the author. In place of a phaco spatula, a special infusion spatula is inserted through the side-port, which supplements the infusion inflow and allows for the manipulation of the cataractous lens during work-up and aspiration (see *Figures 3* and *4*). The additional fluid supply allows the use of excessive vacuum and flow settings for maximum phaco efficiency while at the same time preserving a 'rock-solid' chamber. The safety limits were elaborated in an experimental setting. Vacuum limits of 600mmHg and flow rates of up to 50mmHg have been demonstrated to be safe. In a clinical study comparing the *easy*Tip®CO-MICS tip standard and hybrid techniques, less than half the phaco energy was required when infusion assistance was used. While allowing for phaco through incisions as small as those used with bi-axial MPEs, co-axial MPE with SSSB tips offers the following advantages, especially when infusion-assisted: no incision leakage, which optimises chamber stability; no tissue damage by the oscillating needle, which preserves the self-sealing ability of the incision; abundant infusion supply, allowing for work with excessive flow, which optimises followability and needle occlusion; and usage of SSSB tip technology, which optimises holdability and energy output while suppressing post-occlusion surge. Thus, maximum efficiency and safety are provided while optimally preserving the tissue integrity and valve function of the incision.

Sleeve-armed Co-axial or Sleeveless Bi-axial Microphaco – Which Way to Go?

Proponents of sleeveless bi-axial phaco argue that it requires a smaller incision and improves the flow characteristics in the anterior chamber. Although bi-axial MPE is feasible, there are a number of downsides: in order to maintain a deep and stable chamber while using high fluidics, incision leak must be minimised. Sleeveless phaco needles tend to 'oar-lock' a tight CCI, or allow for continuous collateral wound leak with a wider CCI, which varies according to the changing angle of the instrument approach (see *Figure 5*). There is no way of designing and sizing a CCI that seals the wound and spares tissue at the same time. Histological studies have demonstrated that both the stromal tunnel and the corneal valve are compromised in their morphology and function.[12,13] A soft-silicone sleeve snugly adapts to the slit incision and guarantees both atraumatic tight sealing and a greater infusion throughput. The new SSSB design optimises phaco efficiency and safety by further increasing influx while running flush with the swollen


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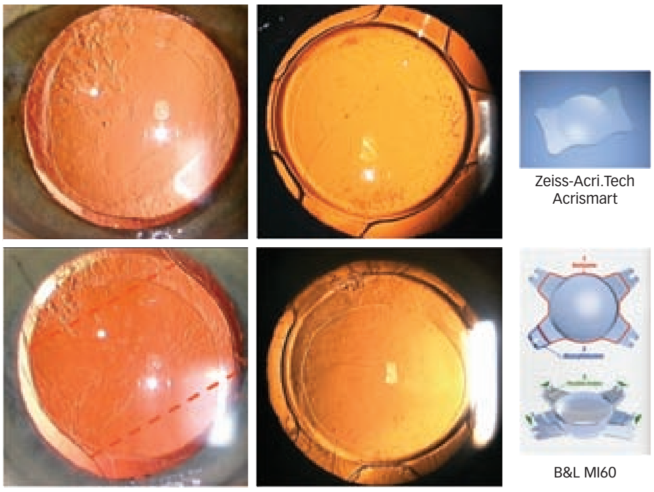
Figure 6: Early Primary Barrier Failure Along the Broad Optic–Haptic Junction of Hydrophilic Micro-incision Cataract Surgery Intraocular Lenses

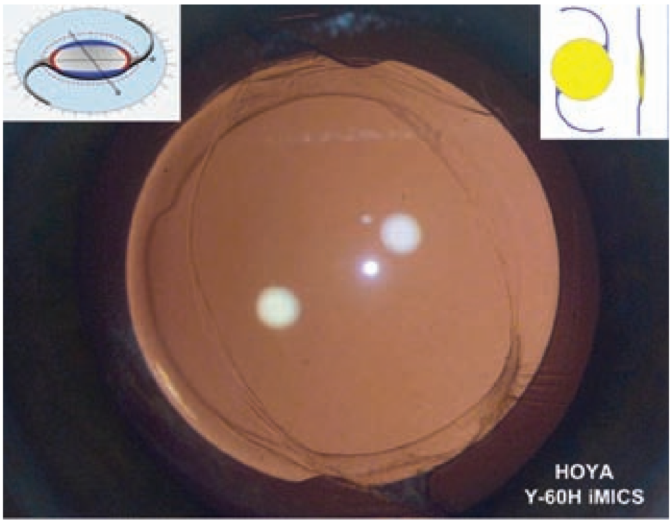
Barrier failure at one year post-operatively



Source: M Möglich. *Source: T Amzallag.*

Figure 7: Hydrophobic HOYA iMICS Three-piece Intraocular Lens – Optic Entrapment in Posterior Capsulorhexis Opening ('Posterior Optic Button-holing') Excludes Retro-optical Opacification

Posterior optic button-holing



needle head, which counteracts forward-directed flow. The infusion enters the chamber through the lateral openings of the sleeves and is re-attracted by the frontal opening of the phaco needle. The high fluidics allowed with this particular needle design and the incisional tightness provided by the sleeve minimise uncontrolled turbulences in the chamber by confining the fluid stream between the sleeve and needle openings to the tip of the handpiece. With infusion and aspiration separated, the fluid stream changes according to the relative positioning of the instrument openings and is superimposed by turbulences caused by the wound leak, which varies as the instruments manipulate the corneal wound. Also, the advantages of a slim-shaft needle cannot be fully exploited, since the outer wall of a needle used with sleeveless phaco must run flush with the head for proper wound sealing. In order to be efficient, needles for sleeveless phaco must be thicker, or they will be less efficient if down-sized in diameter for use in micro-incisions. Apart from the familiarity with the co-axial phaco techniques, these limitations are the main reason why sleeveless bi-axial phaco has not gained widespread usage.

Micro-incision Cataract Surgery Intraocular Lenses

A critical issue is IOL technology for micro-incisions. Currently, several IOL designs are available that may be inserted through incisions between 1.5 and 2.0mm. The MI60 IOL by Bausch & Lomb is a one-piece acrylic IOL with four solid flanges and an 'enhanced' edge that runs beneath the broad junctions to provide a barrier effect. A strong angulation will press the optic posteriorly in order to minimise the optic–capsule interspace for LEC immigration and pearl formation. The Micro AY by PhysIOL is another one-piece acrylic with four fenestrated haptics. Both lenses are designed to fit through a 1.8mm CCI with the injector tip docked to it. The Acri.Smart IOL by Zeiss-Acri.Tec is a one-piece IOL with two broad solid flanges similar to earlier plate lens styles. In addition to aspherical optics, it is also available with toric and bi-focal optics, or a combination of both. An incision size of only 1.5mm is claimed to be sufficient for implantation. All three MICS IOLs are made of hydrophilic acrylics, allowing the lens to be compressed and, thus, to pass through a micro-cartridge, and all are delivered by docking the injector tip to the incision entrance. By contrast, the Y-60H iMICS IOL by HOYA features a three-piece design with polymethylmethacrylate loops bonded to an optic made of hydrophobic acrylic. The optic features an exquisitely sharp posterior optic edge, which is also functional beneath the slim optic–haptic junctions. The IOL comes with a special micro-cartridge to allow implantation with the tip inserted through incisions as small as 1.8mm if designed accordingly.

In principle, IOLs with a broad haptic–optic junction suffer from deficiencies in the barrier effect against migrating LECs. Although attempts have been made to counterbalance this by implementing a so-called enhanced edge running beneath the flange haptics, thus bridging the posterior optic sharp edges outside the haptic junctions, this concept has been shown to be ineffective. This is not surprising as it is not the sharp edge *per se* but rather the capsular bend that blocks LEC migration. In the course of capsular-bag closure, the posterior capsule is pulled around and up to the anterior capsule to be finally sealed to the latter through collagen depletion by transforming anterior LECs.[8] Simply implementing a ridge beneath a broad haptic does not allow for bending of the posterior capsule, which is made impossible by a peripherally extending flange haptic, even if fenestrated. In addition, the edges of these hydrophilic IOLs are not as sharp as claimed and the barrier effect is therefore limited.[14] It is not surprising that as early as one year post-operatively, a significant percentage of eyes implanted with hydrophilic flange-haptic MICS-IOLs exhibit signs of primary barrier failure (see *Figure 6*).[8] The HOYA iMICS IOL complies with the standard of a slim haptic design and exhibits the sharpest posterior optic edge of all hydrophobic acrylic IOLs on the market,[15] thereby allowing optimum circumferential capsular bending. Since the injector tip is inserted into the incision, unfolding and delivering into the capsular bag is perfectly controlled. The HOYA iMICS three-piece IOL may also be used in conjunction with posterior optic button-holing for permanent eradication of any form of after-cataract formation (see *Figure 7*).[9] Considering the high rate of barrier failures, even with hydrophobic acrylic IOLs, this IOL feature may gain increasing importance in the future. In consideration of the market trend towards one-piece IOLs, which are most easily handled and inserted, HOYA is currently developing a single-piece IOL with a similar design to the Acrysof SX60 platform, but with sharper edges and a glistening-free hydrophobic acrylic optic.

Summary

In summary, recent developments in phaco and IOL technology have allowed for the reduction of incision sizes to around 2mm. Mini-incisions of 2.2–2.4mm allow for highly efficient high-flow, high-vacuum co-axial phaco-emulsification with SSSB-tip technology alone (*easy*Tip®2.2mm), followed by the implantation of one of the popular hydrophilic and hydrophobic single-piece IOLs or, alternatively, the pre-loaded IOL injector systems by HOYA and Bausch & Lomb for continuous-edge three-piece hydrophobic acrylic or silicone IOLs. With a down-sized SSSB-needle (*easy*Tip®CO-MICS), efficient and safe co-axial phaco can be performed through 1.4–1.6mm micro-incisions depending on the incision architecture used, but both efficiency and safety are tremendously boosted when fluid-assistance is added (hybrid phaco). Hydrophilic acrylic MICS lenses can be inserted through 1.5–1.8mm incisions by wound-assisted injection, but the particular monobloc design causes barrier deficiencies, which will lead to significantly higher YAG rates. The HOYA iMICS slim-loop design, with its exquisitely sharp posterior optic edge, optimises posterior capsular opacification prevention, and also allows for posterior optic entrapment into a posterior capsulorhexis for the full eradication of after-cataracts. ■

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