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Controversies, consensuses and guidelines on posterior chamber phakic intraocular lens for the correction of myopia and myopic astigmatism in healthy phakic eyes by the Academy of Asia-Pacific Professors of Ophthalmology (AAPPO) and the Asia-Pacific Myopia Society (APMS)

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ABSTRACT

Phakic Intraocular Lens (pIOL) has been studied for correction of high myopia and myopic astigmatism long before the advent of laser refractive surgery. It offers excellent visual and refractive outcomes, but the inherited risk of intraocular surgery cannot be overlooked. The posterior chamber pIOL (PC-pIOL), designed to be placed in the ciliary sulcus, may offer additional advantages compared to its anterior chamber counterparts. Given the complexity of sulcus anatomy and individual variations, controversies exist regarding perioperative management, implant selection, and operative techniques, necessitating standardisation. Given the emergence of novel approaches and long-term clinical data, a panel comprising 19 international experts from 9 countries/territories was formed by the Academy of Asia-Pacific Professors of Ophthalmology (AAPPO) and the Asia-Pacific Myopia

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Society (APMS). The panel critically reviewed the subject and synthesised 58 consensus statements that aim to provide evidence-based, real-world practice recommendations for optimal outcomes in PC-pIOL surgery.

Introduction

Strampelli implanted the first minus-powered phakic intraocular lens (pIOL) in the anterior chamber for correction of high myopia in 1953,[1,2] shortly after the first successful intraocular lens implantation after cataract extraction by Sir Harold Ridley in 1949.[3] It is followed by Barraquer and Choyce,[4,5] all happened long before the first reported laser refractive surgery in 1983.[6] However, due to severe complications due to poor quality of lens and inappropriate length, a high proportion of earlier pIOL were explanted.[1,7] Further development of pIOL had been largely halted for decades due to skepticism towards potential risks. This also highlighted the concerns about long-term safety in pIOL procedures.

With improvement in materials, manufacturing process and techniques, there was a revival of interest in pIOL in the late 1980s, such as Baikoff's angle-supported anterior chamber pIOL,[8,9] Fechner's modification of Worst's iris fixated lobster claw IOL.[5] In 1986, Svyatoslav Fyodorov developed the first silicone posterior chamber phakic intraocular lens (PC-pIOL) in collar-button / mushroom configuration.[1,10,11] The material and design were revised to a proprietary collagen polymer named Collamer after further development with STAAR Surgical AG (Switzerland), which lead to the first Implantable Contact Lens (ICL).[12] After the first United States Food and Drug Administration (FDA) approved phase 1 implantation since 1998,[13] the design of ICL underwent several modifications for safety improvement. After the FDA clinical trial on the ICL of V4 lens design from 1998 to 2001,[14] the Visian ICL obtained the first FDA approval in 2005 and was the first FDA-approved PC-pIOL. It was followed by subsequent FDA approval of toric ICL (TICL) in 2018,[15] and EVO/EVO+ Visian ICL and TICL in 2022.[16] The ICL family is the only FDA approved PC-pIOL at the time of writing.

The direction for use (DFU) documents provided by the manufacturer (STAAR Surgical),[17] along with summary of safety and effectiveness data (SSED) from FDA, provided in-depth instructions regarding pre-operative assessment, operative technique and post-operative management. Clinical guidance is further supplemented by preferred practice patterns and guidelines from international ophthalmic societies.[18–22] Nevertheless, nuances in every aspect of management still significantly affect outcomes and are yet to be addressed. There was also exponential growth of new evidence, novel techniques and calculation algorithms that may offer new insights for better outcomes. With ongoing clinical experience, continual academic communications and thorough literature review, certain controversies were identified at different critical points of management. Further clarification and consensus are preferable to ensure safe and effective outcomes.

In light of the latest advancement, the Asia Pacific Myopic Society (APMS) and the Academy of Asia-Pacific Professors of Ophthalmology (AAPPO) felt the need for updated guidance and consensus statements for ICL implantation surgery. Two of the senior authors of this manuscript were appointed to coordinate this consensus project. This consensus statement aims to synthesize evidence-based real world practice recommendations from global leading experts to guide safe and effective clinical practice in ICL implantation surgery.

Methodology

Further to appointing the coordinators, the APMS and AAPPO formed an international expert panel comprising of 19 panelists from 9 countries/territories. A core group of 5 members (KHL, XYW, KHW, XZ, and DSCL) selected from the 19 panelists was then established to perform an extensive literature search and review on PC-pIOL and ICL, and prepare the first draft of the consensus statements with explanation and elaboration. These statements were organized into each area of controversy, covering patient selection, pre-operative planning, operative technique, and postoperative management.

Literature review aimed to include all articles related to ICL by STAAR Surgical (the only FDA-approved PC-PIOL at the time of writing). A PubMed search was done on 12 Feb 2025, using the following phrase:

"Implantable Collamer Lens$_*$" OR "Implantable contact lens$_*$" OR ("ICL" AND "EVO") OR "Visian" OR "Phakic Intraocular Lens$_*$" OR "Phakic IOL$_*$" OR "Phakic Posterior Chamber Intraocular Lens$_*$" OR "Phakic Posterior Chamber IOL$_*$"

The core group screened the title, abstract and content of all articles. All articles with Implantable Collamer Lens (including early models) by STAAR Surgical, being the surgical intervention or technology to be studied, alone or with other surgical or medical interventions, are included for analysis. The search resulted in a total of 1867 articles, with 757 articles being excluded for the following reasons:

- 134 articles not related to pIOL surgery
- 8 articles with unretrievable abstract or full-text
- 133 articles not published in English
- 513 articles related to pIOL that do not include ICL from STAAR Surgical

An additional 10 articles were discovered as relevant from cross-references. A total of 1133 articles were analysed according to the different aspects of the surgery, paying particular attention to several key types of literature:

- Authoritative guidelines
- Official DFU / Item Label / SSED
- FDA Trials reports
- Latest expert consensus
- Latest systematic reviews
- Latest long-term large-scale studies
- Establishment studies (Studies that establish currently accepted key concepts and guiding metrics)

After drafting the initial statements, each panel member independently and anonymously reviewed each statement and provided comments to the core group. The core group then reviewed, evaluated the feedback and comments, revised the document, and sent out the second draft for further opinions. The process was repeated until the statements were finalized. Subsequently, each panel member voted on each statement anonymously in the final draft using a five-point Likert scale, ranging from "strongly agree", "agree", "neutral", "disagree", to "strongly disagree". A consensus was reached when at least 75 % of the experts voted either "agree" or "strongly agree" for a statement.

Controversies and Key Questions Identified

1. Is ICL indicated in normal eyes of healthy young adults below 21 of age?
2. What is the safety and efficacy of ICL implantation in patients above 45 of age with presbyopia? What is the best strategy and refractive target?
3. Is ICL indicated in eyes with Anterior Chamber Depth (ACD) below 3 mm?
4. Is there any advantage regarding the long-term safety of ICL with central hole over non-hole models, in terms of risk of cataract, glaucoma and endothelial cell loss?

5. What is the minimal Endothelial Cell Density (ECD) requirement for ICL implantation?
6. What are the optimal measurement methods of parameters essential for ICL size selection vault prediction?
7. What are the advantages of Ultrasound Biomicroscopy (UBM) in the planning and management of ICL surgery?
8. What is the optimal method for vault prediction and the target vault?
9. What is the optimal strategy for low astigmatism (Within 1.0 Diopter Cylinder), toric ICL or non-toric ICL with modified corneal incision techniques?
10. Which is more preferable between Delay Sequential Bilateral ICL Surgery (DSBICLS) and Immediate Sequential Bilateral ICL Implantation Surgery (ISBICLS)?
11. Is there any difference in safety and efficacy regarding various implantation techniques, between the conventional method, the minimal Ophthalmic Viscosurgical Device (OVD) method, and the OVD-free method?
12. What is the indication for ICL replacement or removal?

Consensus statements

Section 1: Is ICL indicated in normal eyes of healthy young adults below 21 of age?

ICL implantation in patients aged 21–45 is approved by the FDA and is generally safe and effective when all the criteria set by the approved label are met.[15,16,23] The use of ICL in patients under 21 years of age is, however, off-label according to the DFU in both the US and non-US regions. The age of 18 is the minimum age allowed for standard clinical trials for pIOL according to American National Standards Institute (ANSI) Z80.13–2007 (R2022) standard.[19] Recommendations by the German Society of Ophthalmology also permit patients aged 18 or above.[21] Multiple post-market studies included patients aged 18 or above.[24–34] According to the Chinese expert consensus on PC-pIOL, ICL implantation in young adults aged 18 – 21 may be considered in patients with special occupational needs, high anisometropia and corneal diseases.[22] However, in a study specifically targeting younger population with healthy eyes (aged 17–21), although the safety and efficacy is comparable with older group (age >21), significantly higher degrees of myopic shift at 3 and 5 years postoperatively were noted in younger group.[35] Potential young candidates should be informed on this matter when considering ICL implantation.

***Consensus Statement: 1.1*:**

ICL implantation in a patient aged 21 – 45 in accordance with criteria set by FDA approved label, is generally safe and effective.

(Consensus score: 100.00 % [strongly agree: 70.59 %; agree: 29.41 %])

Consensus statement: 1.2:

ICL implantation in young adult aged 18 – 21 may be considered in patients with special occupational needs, high anisometropia and corneal diseases.

(Consensus score: 100.00 % [strongly agree: 58.82 %; agree: 41.18 %])

For the pediatric population, studies also reported ICL implantation in children with refractive or anisometropic amblyopia. The youngest age being reported is 1.8 years old (with non-holed ICL),[36,37] and 4 years old for holed ICL.[38] The mean follow-up period of most studies ranged from 8 months[39] to 2 years.[36] The short-term data showed comparable results with normal adult cases, but long-term safety and efficacy is yet to be established. As the anatomy, physiology, and perioperative management differ significantly from adult cases, ICL in pediatric patients requires collaboration between experienced ICL surgeons and pediatric ophthalmologists.

Consensus statement: 1.3:

ICL implantation in patients aged below 18 is mostly reserved for treatment of refractive or anisometropic amblyopia. It should be considered only by experienced ICL surgeons, in collaboration with specialists in pediatric ophthalmology.

(Consensus score: 88.24 % [strongly agree: 41.18 %; agree: 47.06 %])

Section 2:What is the safety and efficacy of ICL implantation in patients above 45 of age with presbyopia? What is the best strategy and refractive target?

ICL implantation is acceptable in patients aged 45–60, if a patient meets all the criteria set out in the DFU in European regions. Several studies on ICL included patients with healthy phakic eyes aged above 45 up to 59,[40–46] with one reported up to 65 of age.[47] However, special precautions should be taken regarding refractive targets tailored for presbyopic symptoms. Patients should also be informed that anatomical changes, such as increased crystalline lens rise (CLR), may increase the likelihood of postoperative complications or the need for ICL exchange. Safety is not determined for phakic eyes in patients aged over 60, with a paucity of relevant studies identified.

ICL implantation in pseudophakic eyes of patients aged 21 or above is also included as an indication in the DFU in European regions, in particular the latest ICL with aspheric optic.[48] It is reported in multiple studies with satisfactory results. Patients aged up to 85 have been reported.[49–55] However, patients should be informed that long-term safety and efficacy is not yet established.

Consensus statement: 2.1:

ICL implantation is acceptable in patients aged 45–60. However, special precautions should be taken regarding refractive targets tailored for presbyopic symptoms. Patient should also be informed that anatomical changes such as increased crystalline lens rise (CLR) may increase the likelihood of postoperative complications or the need for ICL exchange.

(Consensus score: 88.24 % [strongly agree: 41.18 %; agree: 47.06 %])

Consensus statement: 2.2:

Safety is not determined for phakic eye in patients aged over 60, with paucity of relevant study identified.

(Consensus score: 88.24 % [strongly agree: 47.06 %; agree: 41.18 %])

Consensus statement: 2.3:

ICL implantation in pseudophakic patients aged 21 or above, if a patient meets all criteria set out in DFU in European region, is reported in multiple studies with satisfactory results. However, patients should be informed that long-term safety and efficacy is not yet established.

(Consensus score: 94.12 % [strongly agree: 47.06 %; agree: 47.06 %])

Refractive target of spherical equivalent (SE) is usually aimed at closest to emmetropia in patients without presbyopia. In patients aged over 40 with presbyopic symptoms, modification of refractive target is commonly considered to improve visual performance in near distance. Different approaches have been described, namely bilateral planned under-correction, monovision, and extended depth-of-focus (EDOF) ICL (also known as ICL with aspheric optic by the manufacturer).

Bilateral planned under-correction, targeting around −0.5 to −1.0 Diopter (D) was reported with good satisfaction. Kamiya et al.[56] found significantly better visual performance than wavefront-guided laser in situ keratomileusis (wfg-LASIK) at myopic defocus levels of −1 and −2D. Takahashi et al.[57] intentionally selected under-correction of myopia in both eyes as target refraction (actual target −0.61 +/-0.28D), and achieved unaided distant visual acuity (UDVA) of −0.03 + /-0.20 logMAR postoperatively. The mean binocular visual acuity was 0.02 logMAR or better at all distances (5.0, 3.0, 2.0, 1.0, 0.7, 0.5, and 0.3 m). The postoperative satisfaction score was 8.2 ± 1.1 (range, 7–10).

Monovision strategy may also produce satisfactory results. Ye et al.[58] treated 32 patients aged 40–50 with presbyopic add power ≥ +0.5D, targeting 0 to −0.75D on dominant eye and −0.5 to −2.25D on non-dominant eye. In binocular uncorrected visual acuity testing, 68.75

% achieved 20/20 at the distance of 5.0 m, and 81.25 % achieved near visual acuity of 20/20 at the distance of 0.4 m. In the last follow-up (after 33–58 months), 81.25 % of patients were very satisfied or felt excellent with their near visual acuity, and 87.50 % were very satisfied or felt excellent with their distant visual acuity.

The latest EDOF ICL seeks to improve intermediate and near vision by intentionally increasing spherical aberrations, while aiming emmtropia as target. Toric version of the lens is not available at present. Several strategies have been described. EDOF ICL may be implanted bilaterally targeting emmetropia in both eyes. Packer et al.[40] reported the performance of EDOF ICL in presbyopic patients from 40 to 60 years of age who require reading add from + 1.00 to + 2.50D. Only patients exhibited ≤ 0.75D refractive astigmatism were included. Post-op binocular UDVA was 20/20 or better in 32.4 %, and 20/40 or better in 100 %. Binocular unaided near visual acuity (UNVA) was 20/20 or better in 61.8 %, and 20/40 or better in 100 %. 91.2 % of patients were satisfied with their vision. In the study by Alfonso et al.,[59] 77 % has UDVA 20/25 or better. At vergence of −2.5D (40 cm from eye), UNVA was 20/40 or better in 70 %. Another strategy termed "hybrid monovision" was described by Shimizu et al.[60] The team implanted EVO+ ICL (ICL V5) in the dominant eye, and EDOF ICL in the contralateral nondominant eye in patients aged 42–54 who had subjective near visual disturbance, targeting emmetropia in all eyes. The postoperative satisfaction score, which is a visual analog scale ranging from 0 (very dissatisfied) to 5 (very satisfied), was 3.9 ± 1.0. However, further studies are required to establish safety and efficacy.

Consensus statement: 2.4:

Refractive target of spherical equivalent (SE) is usually aimed at closest to emmetropia in patients without presbyopia. Target could be modified according to patient's specific requirements, after thorough trial in different distance and environment settings to ensure best visual experience.

(Consensus score: 94.12 % [strongly agree: 70.59 %; agree: 23.53 %])

Consensus statement: 2.5:

In patients aged over 40 with presbyopic symptoms, modification of refractive target is commonly considered to improve visual performance in near distance.

(Consensus score: 100.00 % [strongly agree: 64.71 %; agree: 35.29 %])

Consensus statement: 2.6:

Bilateral planned under-correction, targeting around −0.5 to −1.0D, may be considered in selected cases after thorough trial with spectacle or contact lenses with satisfactory performance.

(Consensus score: 100.00 % [strongly agree: 50.00 %; agree: 50.00 %])

Consensus statement: 2.7:

Monovision strategy targeting 0 to −0.75D on dominant eye, and −0.5 to −2.25D on non-dominant eye, may be considered in selected cases after thorough trial with spectacle or contact lenses with satisfactory performance.

(Consensus score: 100.00 % [strongly agree: 50.00 %; agree: 50.00 %])

Consensus statement: 2.8:

The EDOF ICL seeking to improve near visual performance while targeted at emmetropia remained investigational with limited published data to confirm effectiveness. Toric version of the lens is not available at present. Further studies are required to establish safety and efficacy.

(Consensus score: 82.35 % [strongly agree: 47.06 %; agree: 35.29 %])

Section 3: Is ICL indicated in eyes with anterior chamber depth (ACD) below 3 mm?

For ACD between 2.8 to < 3 mm, ICL is permissible by manufacturer's DFU in non-US region, well studied in multiple studies and shown good safety profile.[61,62]

For ACD from 2.6 to 2.8, studies by Yuan et al. (2024),[63] Huang et al. (2024)[64] and Qian et al. (2023)[65] reported satisfactory safety and efficacy over 1–2 years of follow-up. No increased incidence of IOP rise or severe complications were noted. Narrow of anterior chamber angle was noted especially in the nasal and temporal region. The angle-opening distance (AOD500) was significantly reduced on nasal and temporal sides by 50.2 % and 48.1 % respectively.[63] ICL implantation should be carefully considered in eyes with confirmed open angle.[63–65]

Consensus statement: 3.1:

For Anterior Chamber Depth (ACD) ≥ 3 mm, ICL is generally safe as recommended by FDA-approved label requirements

(Consensus score: 100.00 % [strongly agree: 88.24 %; agree: 11.76 %])

Consensus statement: 3.2:

For ACD between 2.8 to < 3 mm, ICL is permissible by manufacturer's DFU in non-US region, well studied in multiple studies and shown good safety profile

(Consensus score: 100.00 % [strongly agree: 70.59 %; agree: 29.41 %])

Consensus statement: 3.3:

For ACD between 2.6 to < 2.8 mm, off-labelled ICL implantation is reported by several studies with satisfactory outcomes. Long-term safety is not yet established. It should be considered cautiously with open angle confirmed on gonioscopy

(Consensus score: 88.24 % [strongly agree: 52.94 %; agree: 35.29 %])

Consensus statement: 3.4:

For ACD < 2.6 mm, safety of ICL is not established. It should only be considered in exceptional cases, under expert care with extreme caution.

(Consensus score: 83.33 % [strongly agree: 33.33 %; agree: 50.00 %])

Section 4: Is there any advantage regarding the long-term safety of ICL with central hole over non-hole models, in terms of risk of cataract, glaucoma and endothelial cell loss?

Cataract

The term cataract in the setting of ICL may refer to mild anterior subcapsular opacities (ASO) insignificant to vision, or significant cataract that affects vision and required cataract extraction operation. Review of long-term data showed a much lower incidence of lens opacities and cataract in eyes undergone holed ICL than non-holed ICL. Comparative studies with long-term follow-up may provide better insight on that matter. Chen et al. (2022)[66] followed-up 78 eyes with holed ICL and 78 eyes with non-holed ICL implanted in different patients for 5 years. In non-holed ICL group, 2.56 % developed cataract that required extraction, 1.28 % developed mild central ASO that only required observation. In holed ICL, 3.85 % developed ASO. No eye developed significant cataract that requires extraction. In another contralateral eye study by Shimizu et al. (2016)[67] involving 32 eyes with holed ICL and non-holed ICL in the contralateral eyes. After 5 years of follow-up, 3.1 % of eyes with non-holed ICL developed asymptomatic ASO and lost 1 line of corrected distant visual acuity (CDVA). No ASO or cataract developed in eyes with holed ICL. Other studies also reported a relatively low incidence of cataract formation after holed ICL implantation (0.17 %-1.7 %),[68–70] with some investigations reporting no instances.[67,70,71] In contrast, long-term studies of previous non-hole ICL (V4 ICL) reported a relatively high incidence of cataract formation (7–29 %).[72–75]

Consensus statement: 4.1:

Long-term data showed a much lower incidence of lens opacities and cataract in eyes undergone holed ICL than non-holed ICL.

(Consensus score: 100.00 % [strongly agree: 70.59 %; agree: 29.41 %])

Glaucoma

Glaucoma after ICL includes acute intraocular pressure (IOP) rise in the early postoperative period (pupillary block, retained OVD, inflammation related), or chronic IOP rise due to pigment dispersion, narrow angle and angle closure, or chronic inflammation.[76] Early IOP rise due to retained OVD, blocking of central hole, or topical steroids may still happen in holed ICL. However, long-term IOP elevation is much less common in holed ICL compared with non-holed ICL, as shown by studies with follow-up over 10 years.[66,67,69,71,76–79]

IOP rise requiring long-term glaucoma medication and surgery is exceedingly rare in holed ICL, but not uncommon in non-holed ICL (range from 0.9 % to 3.8 %).[72,74,76]

Consensus statement: 4.2:

Early IOP rise due to retained OVD, blocking of central hole, or topical steroids may still happen in holed ICL. However, long-term IOP elevation is much less common in holed ICL compared with non-holed ICL.

(Consensus score: 88.24 % [strongly agree: 58.82 %; agree: 29.41 %])

Endothelial Cell Loss

Both non-holed ICL and holed ICL exhibit an initial phase (3 months to 1 year) of more rapid ECD loss attributed to surgical trauma and corneal remodelling, which reduces and stabilizes afterwards at a lower rate. A comparative study by Goukon et al. included both holed ICL and non-holed ICL did not reveal significant difference in central ECD after 2 years of follow-up), except for increased ECD loss in superior region in non-holed ICL, possibly related to pre-operative laser iridotomies. There is also no significant change in endothelial morphology parameters such as coefficient of variation in cell size (CV) and the percentage of hexagonal cells (HEX) in both hole ICL-implanted eyes and non-hole ICL-implanted eyes.[80] In other comparative studies with 5 years of follow-up, the reported cumulative ECD loss was 1.2–2.7 % for non-holed ICL, and 0.5–2.5 % for holed ICL.[66,67] No significant difference in long-term ECD loss between non-holed ICL and holed ICL was demonstrated from previous comparative studies, meta-analysis and non-comparative long-term studies.

The reported annual rate of ECD loss in long-term range from lowest reported value of 0.45 %,[69] to 1.2 % based on longest follow-up data (10 years) of holed ICL at present,[79] up to 1.8 % from meta-analysis on long-term follow-up of non-holed ICL.[17] The reported natural age-related ECD loss was around 0.5–0.6 % per year.[81,82] These serve as a basis to rationalize the minimal ECD requirements for inclusion.

Consensus statement: 4.3:

Current data regarding the long-term ECD loss between non-holed ICL and holed ICL is still inconclusive. Further long-term comparative studies may provide better insight.

(Consensus score: 100.00 % [strongly agree: 50.00 %; agree: 50.00 %])

In summary, holed ICL alleviated the need for laser iridotomies before implantation, minimizing the associated risk of peripheral corneal endothelial injury. It results in much lower incidence of anterior subcapsular lens opacities or cataract, IOP rise and glaucoma in long-term. Short term IOP rise may still occur due to blocking of central hole by OVD or inflammatory debris, or induced by steroids. Chronic ECD loss was comparable in both holed and non-holed ICL, and long-term continual loss is within acceptable range as long as minimal ECD criteria are observed preoperatively. In summary, holed ICL should be preferred choice for myopia and myopic astigmatism in the suitable range.

Consensus statement: 4.4:

Holed ICL is the preferred choice over non-holed ICL for myopia and myopic astigmatism in the suitable range.

(Consensus score: 100.00 % [strongly agree: 94.12 %; agree: 5.88 %])

Consensus statement: 4.5:

Short-term IOP rise may still occur. Chronic ECD loss was comparable in both holed and non-holed ICL, and long-term continual loss is within acceptable range as long as minimal ECD criteria are observed preoperatively.

(Consensus score: 94.12 % [strongly agree: 47.06 %; agree: 47.06 %])

Section 5: What is the minimal Endothelial Cell Density (ECD) requirement for ICL implantation?

Endothelial cell loss represents the most important risk of all pIOL surgeries. The rationale of minimal ECD requirement is to ensure a safe level of ECD remains at a certain age that may require cataract surgery, acknowledging an initial acute ECD loss after surgery, and possibly accelerated continual loss in the long term. However, the exact figure of requirement remained controversial, with a large difference among different guidance documents. Thorough literature review and expert panel discussions seek to arrive at a consensus.

In early days of pIOL development, the American National Standards Institute (ANSI) defined an age-dependent minimal ECD requirement targeting clinical trials on pIOL in general:[19]

- 21–25:2800 cells/mm^2
- 26–30:2650 cells/mm^2
- 31–35:2400 cells/mm^2
- 36–45:2200 cells/mm^2
- ≥ 46:2000 cells/mm^2

Patients were also excluded if coefficient of variation of endothelial cell area of > 0.45, or percent hexagonality of endothelial cell shape ≤ 45 %. The requirement represents the average minimum ECD necessary to leave 1000 cells/mm2 at 72 years of age or older, assuming a 10 % surgical loss and a yearly rate of loss of 2 %.

mm^2

In the FDA premarket approval (PMA) study for Visian ICL (non-holed ICL), the 3-year data revealed a continual steady ECD loss of 2.2 % per year, which has not been established as safe. A much more stringent age-depending minimal ECD requirement was developed according to three different ACD ranges, aiming to result in ECD of at least 1000 cell/mm^2 at 75 years of age.[17,23] For instance, patients aged 21–25 with ACD ≥ 3.0 mm but < 3.2 mm would require a minimum ECD of 3875 cells/mm^2 to be eligible. The recommended values exceed most of the published normal range at the age suitable for ICL,[83,84] rendering most younger candidates unsuitable for surgery.

On the other hand, the non-US version of DFU included low/abnormal corneal ECD as contraindication, but without a definite ECD value.[62] To enable ICL implantation in wider range of patients without jeopardizing safety, an updated ECD requirement is to be sought. Two different approaches were attempted, one focused on published literature with safety results, another calculates with exponential decay model based on updated ECD loss data.

Approach 1: Literature review

A review of literature revealed that most studies on ICL with central hole (except the FDA PMA studies), as well as expert consensus from China[20,22] and recommendation from German Society of Ophthalmology (Kommission Refraktive Chirurgie, KRC)[21] adopt the cut-off of 2000 cells/mm^2 as minimal ECD requirements, irrespective of age and ACD.[24,26,27,29–31,43–45,70,79,85–91] Some included ECD as low as 1800 cells/mm^2,[69,92] while some used 2500 cells/mm^2 as cut-off.[93] This deviates significantly from the FDA age/ACD-dependent recommendations.

The actual included cases in the studies have ECD range from 2000 to over 3900, while the average of mean ECD lies around 2780 (average of all reported mean pre-op ECD) + /- 277 (average of all reported SD of pre-op ECD).[24,26,27,29–31,43–45,70,79,85–91] Based on (Mean − 2 ⁎ SD) rounded to nearest hundred, which presented the vast majority of eyes in published studies, a slightly higher cut-off value of 2200 cells/mm^2 is considered as minimal ECD requirement

Approach 2: Exponential decay model based on updated ECD loss data

The approach of ANSI standard was referred, assuming an initial 10 % in acute phase. The following revised table of age-dependent minimal ECD requirement was developed using a different annual loss from latest published data, targeting an ECD of at least 1000 cell/mm^2 at age of 75, rounded to nearest hundred. It should be noted that a small change in annual loss rate results in a large change in the minimal ECD requirements. The values generally exceed that of ANSI standard if 1.8 % annual loss was considered, and generally below literature reported inclusion requirement if 1.2 % annual loss was considered. This implies that the literature reported minimal ECD requirements is generally safe if minimal ECD loss is anticipated as of latest literature. It should be noted that a level of 2000 cell/mm^2 is not considered safe under the age of 26. If higher level of safety is warranted, such as in the early phase of ICL development with non-holed model, a minimal ECD slightly higher than ANSI standard is required. Furthermore, the measured ECD may vary by around 230 cells/mm^2 among different devices.[94] To further enhance safety, an additional 250 cells/mm^2 is added to the required number.

Age	Minimal ECD requirement (cells/mm^2) assuming 10 % acute loss followed by continual loss of		
	1.2 % from 10 years holed-ICL data[79]	1.8 % from[17]	1.5 % (Average of 2 values) + 250 cells/mm^2 measurement variation
21–25	2100	2900	2700
26–30	2000	2700	2500
31–35	1900	2500	2400
36–40	1800	2300	2200
41–45	1700	2000	2100
46 or above	1600	1900	2000

Consensus statement: 5.1:

A tiered approach of preferred minimal ECD according to the level of safety is proposed. For beginning surgeons in the early phase of training, a higher age-dependent ECD requirement (assuming 10 % acute loss followed by 1.5 % annual loss, considering 250 cells/mm^2 measurement variation) is preferable.

Preferred Minimal ECD (cells/mm^2) according to age:

21–25:2700

26–30:2500

31–35:2400

36–40:2200

41–45:2100

40 or above:2000

(Consensus score: 83.33 % [strongly agree: 50.00 %; agree: 33.33 %])

Consensus statement: 5.2:

For experienced surgeons with good track record of safety, a minimum of 2200 cells/mm^2 should be required for implantation at age 21, and 2000 cells/mm^2 from age 26 onwards. Any potential candidate with ECD lower than that should be meticulously considered by experts only.

(Consensus score: 88.24 % [strongly agree: 52.94 %; agree: 35.29 %])

Section 6: What are the optimal measurement methods of essential parameters for ICL size selection vault prediction?

The essential parameters to measures included 1) horizontal white-to-white distance (WTW), 2) internal ACD measurements from corneal endothelium to anterior surface of crystalline lens, 3) endothelial cell density (ECD), and 4) mesopic pupil size. Gonioscopy is also desirable for studying and documenting the angle status, as narrow angles may also occur in myopic eyes.

Horizontal White-to-White distance (WTW)

In measuring horizontal WTW distance, it is suggested to use Caliper / Pentacam / Orbscan (depends on availability) to be used with the manufacturer's Online Calculation and Ordering System (OCOS) nomogram, with automated measurements showing higher repeatability. It should be noted that WTW was regarded as indirect measure and does not correlate to sulcus-to-sulcus (STS) measurement.[17,95] Additional direct measure of ciliary sulcus is suggested by US-region DFU.[17] Manual measurement could be done with the tips of Castroviejo surgical caliper (range 0–20 mm in 1 mm step) placed on nasal and temporal limbus with patient under topical anesthesia, distance read from the scale. Limbus itself is a 1.5 mm to 2 mm gray zone, which introduces up to 4.0 mm of variability in WTW measurement, depending on whether inner or outer limbus is selected as starting point. For the best reproducibility, it should be measured from mid gray zone to mid gray zone. Other options of automated optical device for WTW measurement include: Slit-scanning corneal tomography (Orbscan II), IOLMaster 500 (anterior segment image), Scheimpflug camera (Pentacam HR and Pentacam AXL),[96,97] SS-OCT system (IOLMaster 700),[96] Lenstar LS 900 and Galilei G4,[98] CASIA2 anterior-segment optical coherence tomography (AS-OCT),[99] Anterion AS-OCT.[96] Automated measurements of WTW provide more precise results, with higher inter-observer agreement. However, the result among different devices may vary significantly due to difference in optical principles. They should not be used interchangeably.[100]

Internal Anterior Chamber Depth (ACD)

In measuring ACD, it should be measured from corneal endothelium to the anterior surface of the crystalline lens. ACD measured by Pentacam / IOLMaster / AS-OCT / UBM show good inter-device agreement.[20,101,102] Precautions should be taken in using ACD from IOLMaster that it includes the central corneal thickness, which must be subtracted before ICL size and power calculations.

Endothelial Cell Density (ECD)

For specular microscopy, American Academy of Ophthalmology (AAO) recommended a minimum of 6 scans with good images should be performed at pre-op visit, and 3 scans for each post-op visit.[103] Non-contact specular microscope should be used.[104] According to ANSI guideline of pIOL studies, a good image is indicated by: 1) distinct cells; 2) at least 100 identifiable (countable) cells as a minimum, 150 cells preferred; and 3) cells can be grouped in a uniform area[19]

Mesopic Pupil Size

Mesopic pupil size should be measured with infrared or light amplification pupillometer, under the background luminance of 3 cd/m^2 (equiv. to 3 lux) or less, with a precision of + /- 0.5 mm, only after sufficient time for dark adaptation (approx. 10 mins) according to ANSI standard.[19] Detailed protocol for improved repeatability had been described.[105] Mesopic pupil size greater than optic diameter of ICL lens may experience glare and/or halos, and patients should be advised.[17]

Vault

ICL vault, which is the distance between posterior ICL surface and central anterior surface of crystalline lens, can be estimated at the slit-lamp at 24 h postoperatively, as a percentage of central corneal thickness.[17,106] For more accurate and reproducible results, non-contact measurement can be done by rotating Scheimpflug camera (Pentacam; Oculus, Lynwood, WA),[107] or with AS-OCT.[76] UBM can also provide vault measurement with good correlation with clinical estimation with slit lamp.[106] It should be noted that pupil size and accommodation, affected by room lighting, can alter the apparent crystalline lens rise and vault in imaging. Standardizing lighting conditions during measurements and postoperative imaging is important for consistent evaluation.

Consensus statement: 6.1:

The essential parameters to measures included 1) Horizontal White-to-White distance (WTW), 2) internal Anterior Chamber Depth measurements (ACD) from corneal endothelium to anterior surface of crystalline lens, 3) Endothelial cell density (ECD), and 4) Mesopic pupil size.

(Consensus score: 82.35 % [strongly agree: 47.06 %; agree: 35.29 %])

Consensus statement: 6.2:

Horizontal WTW was shown to correlate poorly with sulcus anatomy. AS-OCT and UBM is increasingly important in vault prediction and modern nomogram development.

(Consensus score: 94.12 % [strongly agree: 47.06 %; agree: 47.06 %])

Consensus statement: 6.3:

In measuring horizontal White-to-white (WTW) distance, it is suggested to use Caliper / Pentacam / Orbscan (depends on availability) to be used with OCOS nomogram, with automated measurements showing higher repeatability.

(Consensus score: 82.35 % [strongly agree: 47.06 %; agree: 35.29 %])

Consensus statement: 6.4:

Manual measurement could be done with the tips of Castroviejo surgical caliper (range 0–20 mm in 1 mm step) placed on nasal and temporal limbus with patient under topical anesthesia, distance read from the scale. Limbus itself is a 1.5 mm to 2 mm gray zone, for the best reproducibility, it should be measured from mid gray zone to mid gray zone

(Consensus score: 94.12 % [strongly agree: 47.06 %; agree: 47.06 %])

Consensus statement: 6.5:

Automated measurements of WTW provide more precise results, with higher inter-observer agreement. Examples included Slit-scanning corneal tomography (Orbscan II), IOLMaster 500 (anterior segment image), Scheimpflug camera (Pentacam HR and Pentacam AXL), SS-OCT system (IOLMaster 700), Lenstar LS 900 and Galilei G4, CASIA2 AS-OCT, Anterion AS-OCT. The results among different devices may vary significantly and should not be used interchangeably. Measurement should ideally be done with the same type of device.

(Consensus score: 100.00 % [strongly agree: 58.82 %; agree: 41.18 %])

Consensus statement: 6.6:

ACD should be measured from corneal endothelium to the anterior surface of the crystalline lens, by Pentacam, IOLMaster, AS-OCT or UBM. Precautions should be taken in using ACD from IOLMaster that it includes the central corneal thickness, which must be subtracted before ICL size and power calculations

(Consensus score: 94.12 % [strongly agree: 41.18 %; agree: 52.94 %])

Consensus statement: 6.7:

For specular microscopy, an ideal of 6 scans with good images is preferable at pre-op visit, and 3 scans for each post-op visit. Non-contact specular microscope should be used, with good image indicated by: 1) distinct cells; 2) at least 100 identifiable (countable) cells as a minimum, 150 cells preferred; and 3) cells can be grouped in a uniform area

(Consensus score: 82.35 % [strongly agree: 41.18 %; agree: 41.18 %])

Consensus statement: 6.8:

Mesopic pupil size should be measured with infrared or light amplification pupillometer, under the background luminance of 3 cd/m^2 (equiv. to 3 lux) or less, with a precision of + /- 0.5 mm, only after sufficient time for dark adaptation (approx. 10 mins). Mesopic pupil size greater than optic diameter of ICL lens may experience glare and/or halos, and patients should be advised.

(Consensus score: 94.12 % [strongly agree: 47.06 %; agree: 47.06 %])

Consensus statement: 6.9:

ICL vault can be estimated at the slit-lamp at 24 h postoperatively, as a percentage of central corneal thickness. It is further measured by rotating Scheimpflug camera or AS-OCT.

(Consensus score: 83.33 % [strongly agree: 50.00 %; agree: 33.33 %])

Consensus statement: 6.10:

Pupil size and accommodation, affected by room lighting, can alter the apparent clear lens rise and vault in imaging. Standardizing lighting conditions during measurements and postoperative imaging is important for consistent evaluation.

(Consensus score: 100.00 % [strongly agree: 33.33 %; agree: 66.67 %])

Section 7: What are the advantages of ultrasound biomicroscopy (UBM) and anterior-segment optical coherence tomography (AS-OCT) in the planning and management of ICL surgery?

UBM allows direct measurement of ciliary sulcus by UBM (Sulcus-to-Sulcus, STS), which is recommended as alternative methods in the FDA-approved DFU.[17] If OCOS nomogram alone is used, there is a tendency of obtaining higher vault when STS is smaller than WTW, and lower vault when STS is larger than WTW.[108] Current high-frequency UBM with a wide scanning field enables direct measurement of the ciliary STS diameter.[95] UBM can also detect ciliary body cysts and other anatomical variations and abnormalities that may affect the ICL position, post-op vault and long-term safety.

AS-OCT can measure anterior segment parameters with very good Intra- and inter-examiner reproducibility.[95,109] Parameters measured included but not limited to horizontal angle-to-angle (ATA), distance between the angle recesses (junction between the cornea and iris) on the nasal and temporal sides,[109] crystalline lens rise (CLR), distance between the anterior crystalline lens surface and the angle recess-to-angle recess line, anterior chamber width (ACW), distance between the scleral spurs (the point where the curvature of the angle wall changes, often appearing as an inward protrusion of sclera) on the nasal and temporal sides.[109] Various devices were reported in literature for ICL size prediction and vault measurements. As with other devices for automated measurement, anatomic values cannot be used interchangeably[95]

Ciliary body cyst (CBC) is reported to be present asymptomatically in 26–35 % of ICL candidates.[110,111] Upon careful UBM examination, CBC appeared as an echo-free, round or oval fluid-filled lesion detected in the ciliary body or sulcus, with size reported from 0.5 mm to 1.5 mm.[111] ICL implantation may not be absolutely contraindicated,[110–112] but potential risk of acute IOP rise due to angle closure,[113] rotation of toric ICL, iris chafing due to forward rotation of footplate may occur.[111] Risk factors may include size of cyst above 1 mm, and location in horizontal meridian in the ciliary sulcus.[110,111]

There is conflicting evidence regarding the vault prediction accuracy and performance of achieving optimal vault of ICL size selection methods with or without inclusion of UBM parameters. There are concerns on the repeatability and reproducibility of UBM parameters, but several studies demonstrate that UBM parameters are most correlated with post-op vault. Most studies on prediction formulae relied on retrospective analysis of pre-operative parameters. With the advent of AS-OCT which is less operator dependent, there is increasing trend of developing formula using AS-OCT parameters, with or without adding UBM data. Some comparative studies demonstrate higher accuracy in vault prediction by AS-OCT derived formulae,[114] while others showed higher performance by formulae with UBM parameters.[115] However, many studies regarding UBM and AS-OCT derived formulae were based on highly myopic Asian population, and most of the included population has small eyes that minimal proportion used the largest ICL size of 13.7 mm. Caution should be taken when utilizing those formula especially in eyes with different demographics from those in the studies.

Addition of AS-OCT and UBM into routine pre-op assessment provides good insight into vault prediction and may supplement ICL size selection by the OCOS nomogram. They also provide valuable data to facilitate local nomogram construction and future research. Absent of those technologies, however, does not preclude safe ICL implantation with OCOS nomogram. Addition of ATA (by AS-OCT) and STS (by

UBM) is not universally applied in published large scale and long-term studies, including FDA trials. However, careful WTW measurement with multiple modalities should be employed, with periodic review of post-op vault for construction of custom nomogram.

Consensus statement: 7.1:

Current high-frequency UBM with a wide scanning field enables direct measurement of the ciliary STS diameter. UBM can also detect ciliary body cysts and other anatomical variations and abnormalities that may affect the ICL position, post-op vault and long-term safety.

(Consensus score: 94.12 % [strongly agree: 58.82 %; agree: 35.29 %])

Consensus statement: 7.2:

AS-OCT can measure anterior segment parameters with very good Intra- and inter-examiner reproducibility and facilitates ICL size prediction and vault measurements. Anatomic values cannot be used interchangeably among different devices.

(Consensus score: 94.12 % [strongly agree: 47.06 %; agree: 47.06 %])

Consensus statement: 7.3:

ICL implantation may not be absolutely contraindicated in presence of ciliary body cyst (CBC), but potential risk of acute IOP rise due to angle closure, rotation of toric ICL, iris chafing due to forward rotation of footplate should be observed. Risk factors include size of cyst above 1 mm, and location in horizontal meridian in the ciliary sulcus.

(Consensus score: 88.24 % [strongly agree: 41.18 %; agree: 47.06 %])

Consensus statement: 7.4:

Addition of AS-OCT and UBM into routine pre-op assessment provides good insight into vault prediction and may supplement ICL size selection by the OCOS nomogram. They also provide valuable data to facilitate local nomogram construction and future research. Absent of those technologies, however, does not preclude safe ICL implantation with OCOS nomogram. Careful WTW measurement with multiple modalities should be employed, with periodic review of post-op vault for construction of custom nomogram.

(Consensus score: 100.00 % [strongly agree: 58.82 %; agree: 41.18 %])

Section 8: What is the optimal method for vault prediction and the target vault?

Vault represents the distance between posterior ICL surface and central anterior surface of crystalline lens. Normal range of 250–750 microns was widely adopted in literature and research. It was first defined by Choi et al. (2007) and adopted in subsequent studies[116,117] The recent FDA-approved DFU recommended a high upper limit, while lower limited remained the same (250 – 900 microns).[17] The vault of 500 microns is commonly agreed as ideal vault. However, it should be noted that extremes of vault must be viewed as risk factors for adverse events, not as adverse events in and of themselves. In the absence of symptoms, lens vault outside of this range may not necessarily require exchange or removal.[76] Careful ICL size selection should aim to avoid excessively low or high vault.

Excessively low vault is regarded as risk factors for complications such as anterior subcapsular lens opacities (ASO), clinically significant anterior subcapsular cataract (ASC), or rotation of toric ICL (TICL), but not a complication by itself.[106,118–120] Additional risk factors for ASC development such as age older than 45, and ACD < 3.0 mm, which are outside the FDA limit, were identified.[107] Vault as low as 90 microns has been observed for long periods of time without any complication.[121,122] However, vault is observed to decrease consistently with time.[123–125] Risk of ASC development could possibly increase over time. Close surveillance is necessary. Threshold warranting ICL removal to be discussed in latter sector in this article (Section 12: Indication for ICL replacement or removal)

Excessively high vault may increase risk of glaucoma (due to angle crowding or closure, synechiae formation, iris chaffing and pigment dispersion) and corneal endothelial cell loss.[116,126,127] The ideal upper limit was defined as 750 microns,[116,126] which was later increased to 900 in subsequent literature and FDA-approved DFU.[16] Meta-analysis by Packer et al. placed the lower limited from 50 to 250 microns, and upper limit from 1000 microns upwards, as long as the anterior chamber angle structure and function remain normal.[118]

Consensus statement: 8.1:

Careful ICL size selection should aim to avoid excessively low or high vault.

(Consensus score: 100.00 % [strongly agree: 70.59 %; agree: 29.41 %])

Consensus statement: 8.2:

The vault of 250–750 microns was widely accepted as an ideal range. The upper range up to 900 microns is acceptable by the FDA-approved directions for use.

(Consensus score: 94.12 % [strongly agree: 58.82 %; agree: 35.29 %])

Consensus statement: 8.3:

Extremes of vault must be viewed as risk factors for adverse events, not as adverse events in and of themselves. In the absence of symptoms, lens vault outside of this range may not necessarily require exchange or removal.

(Consensus score: 94.12 % [strongly agree: 64.71 %; agree: 29.41 %])

Standard OCOS formula by manufacture was used in FDA studies but provided no vault prediction. It aims to maximize the chance of producing optimal vault. The major parameters are ACD (true ACD or internal ACD measured from apex of posterior corneal surface to apex of anterior crystalline lens surface[17]) and WTW. FDA trial for EVO/EVO + using the OCOS formula reported mean vault of 492 + /-227 microns at 6 months,[76] which correlated closely to the ideal range (250–750 microns) in previous literature.

Size selection based on OCOS formula alone may not completely prevent abnormally low or high vault. At least one supplemental formula for vault prediction is recommended. A number of formulas have been developed using parameters from UBM and AS-OCT and other parameters such as CLR, CSA and pupil size have been studied. Some may even combined multiple variables or utilize machine learning and artificial intelligence. There is no single formula or strategy that outperforms others significantly in vault prediction. What is more important is to identify risk factors for abnormal vault. Other non-measured factors play also affect the vault achieved, such as patient demographics or even surgical techniques.

The FDA-approved OCOS formula with WTW and ACD should be observed, but further with verification of one or more additional formula depending on ATA, STS or other anterior segment parameters is highly recommended, based on surgeon's expertise and availability of equipment. The surgeon should ensure consistent technique and review the vault achieved and incidence of complications from time to time to construct one's own nomogram, aiming to minimize vault related complications. In case of conflicting ICL size recommendations from different formulas, one could consider ordering multiple ICLs of adjacent sizes, enabling switching of ICL size during operation.

Consensus statement: 8.4:

The FDA-approved OCOS formula with WTW and ACD should be observed. Further verification with one or more additional formula depending on AS-OCT, UBM or other anterior segment parameters is highly recommended, depending on expertise and availability of equipment.

(Consensus score: 100.00 % [strongly agree: 64.71 %; agree: 35.29 %])

Consensus statement: 8.5:

No single formula or strategy outperforms others significantly in vault prediction. It is important to identify risk factors for abnormal vault, which may include patient demographics or surgical techniques.

(Consensus score: 94.12 % [strongly agree: 58.82 %; agree: 35.29 %])

Consensus statement: 8.6:

The ciliary sulcus is typically vertically elongated. The vault values may be lower when ICL is placed in non-horizontal orientations. This should be taken into account for both sizing and postoperative interpretation.

(Consensus score: 100.00 % [strongly agree: 58.82 %; agree: 41.18 %])

Consensus statement: 8.7:

The surgeon should ensure consistent technique and review the vault achieved and incidence of complications from time to time to construct one's own nomogram, aiming to minimize vault related complications.

(Consensus score: 88.24 % [strongly agree: 47.06 %; agree: 41.18 %])

Consensus statement: 8.8:

In cases of conflicting ICL size recommendations from different formulas, one could consider ordering multiple ICLs of adjacent sizes if resources allowed. This enables switching of ICL size during operation when obviously abnormal vault is detected.

(Consensus score: 83.33 % [strongly agree: 33.33 %; agree: 50.00 %])

Section 9: What is the optimal strategy for low astigmatism (Within 1.0 Diopter Cylinder), toric ICL or non-toric ICL with modified corneal incision techniques?

In most young healthy eyes, astigmatism < 0.5D did not degrade visual acuity. Report by Villegas et al.[128] suggested that correction of astigmatism of more than 0.5D, but not correction of lower astigmatism, would improve visual acuity. In non-US region, the manufacturer provides toric ICL with cylinder as low as + 0.5D. It does not provide meaningful correction of pre-existing lower astigmatism (e.g. 0.25D). It just flips the axis of astigmatism with similar resultant magnitude of astigmatism.

It should also be noted that standard temporal corneal incision may contribute less than 0.5D of with-the-rule (WTR) astigmatism to the net corneal toricity, as shown in the Vision TICL study.[15,17] It should be taken into account when considering the astigmatism correction strategy. For instance, 0.5D of against-the-rule (ATR) astigmatism can be corrected with temporal clear corneal incision without toric ICL, while 0.5D of WTR astigmatism may be aggravated by the same temporal incision such that toric ICL may produce better outcome.

Steep meridian incision have been shown to be effective in correcting astigmatism of 0.5–1.5D.[129] Other studies revealed better outcome for toric ICL compared to incision-based correction in astigmatism above 1.0D.[130,131]

Reported strategies to tackle astigmatism in ICL included

- Corneal incision-based strategies, e.g. placement of main incision according to meridian of astigmatism,[132] additional limbal relaxing incision,[131] paired opposite clear corneal incisions (reported in astigmatism of 0.5–3.0 DC),[133] femtosecond-assisted arcuate keratotomy (reported in astigmatism of 0.75–3.0 DC)[134]
- Toric ICL[17,135]
- Bioptics (combination of ICL with corneal refractive surgery)
- Combination of above

Consensus statement: 9.1:

Consider astigmatism correction with 0.5D or more pre-existing astigmatism

(Consensus score: 82.35 % [strongly agree: 41.18 %; agree: 41.18 %])

Consensus statement: 9.2:

Astigmatism of 0.5–1.0D can be corrected by either corneal incision-based method (e.g. steep meridian incision) or toric ICL

(Consensus score: 100.00 % [strongly agree: 52.94 %; agree: 47.06 %])

Consensus statement: 9.3:

Astigmatism of 1.0D or above is best corrected with toric ICL

(Consensus score: 94.12 % [strongly agree: 58.82 %; agree: 35.29 %])

Section 10: Which is more preferrable between delay sequential bilateral ICL surgery (DSBICLS) and immediate sequential bilateral ICL implantation surgery (ISBICLS)?

Delayed Sequential Bilateral ICL Implantation Surgery (DSBICLS), where the second eye is operated from 1 to 14 days after uneventful surgery in the first eye

In US FDA trial on EVO/EVO+ ICL, fellow eye implantation occurred between 7 days and 14 days after uneventful surgery in the first eye.[76] Immediate bilateral ICL implantation could have a low risk of bilateral complications but it involves a significant risk of binocular excessively high or low vault. Gonzalez-Lopez et al. (2018) recommended a minimum waiting period of 2–5 days after first eye implantation, to allow for amendment of ICL size of second eye according to the early post-operative vault of the first eye.[136] Martínez-Plaza et al. (2023) implant ICL in the dominant eye first, then non-dominant eye after 1 or 2 days.[137]

Immediate Sequential Bilateral ICL Implantation Surgery (ISBICLS)

In a survey among Chinese ophthalmologists who implant ICL, 68 % reported performing ISBICLS, while 32 % perform DSBICLS. For those performing ISBICLS, most (69.5 %) perform the second eye < 30 mins after the first eye surgery. For those performing DSBICLS, 85.1 % chose performing the second eye surgery 1 days after the first eye surgery.[138] Another survey by Russo et al. indicated that 72.73 % of surgeons favor immediate approach for sequential bilateral phakic surgery. It was suggested that the primary reservations against the immediate approach revolve around potential phakic lens sizing and power issues, infection and toxic anterior segment syndrome risks, and diminished compensation for the surgeon and ambulatory surgery center.[139]

In a comparative study of ISBICLS vs DSBICLS (where second eye operated < 7 days after first eye surgery), no significant difference in mean vault and vault distribution was found between 2 groups.[140] Study by Lorger et al. concluded that both the one- and two-stage approaches are equally effective, predictable and safe.[141]

Consensus statement: 10.1:

Delay Sequential Bilateral ICL Surgery (DSBICLS), and Immediate Sequential Bilateral ICL Implantation Surgery (ISBICLS) are equally safe and effective.

(Consensus score: 88.24 % [strongly agree: 64.71 %; agree: 23.53 %])

Section 11:is there any difference in safety and efficacy regarding various implantation techniques, between conventional method, minimal ophthalmic viscosurgical device (OVD) method, and OVD-free method?

Conventional Technique

In the conventional technique as recommended by DFU,[62] anterior chamber is filled with OVD before ICL insertion. Complete removal of OVD is imperative before closure. Incomplete OVD removal, especially behind the ICL in the posterior chamber, may lead to acute severe IOP rise in the early post-op period. Retained OVD may obstruct the trabecular meshwork or block the central hole of holed ICL causing pupillary block and severe IOP rise. Thus, variations of technique emerged which centered around the timing and techniques of OVD injection and removal (minimum OVD technique), or to eliminate the usage of OVD altogether (OVD free technique).

The manufacturer recommends a low molecular weight 2 % hydroxypropyl methylcellulose (HPMC) or dispersive, low viscosity OVD, and advised against using short chain sodium hyaluronate acids (e.g. Dis-

persive low-molecular weight OVD) due to increased risk of cataract formation related to trapped OVD.[17] Other clinical guidance suggested cohesive OVD for better anterior chamber formation, and easier removal.[22] In published studies on ICL implantation, most reported using 1–1.7 % sodium hyaluronate (HA) as OVD.[24,27,33,35,41,43,70,79,86,87,91,93,142–146] One study compared 2 % HPMC and 1 % HA in contralateral eyes of same patients, finding that 1 % HA significantly reduces total surgical time and incidence of acute IOP spike compared to 2 % HPMC. OVD removal is done by either direct irrigation and wash out by balanced salt solution,[24,27,31,33,35,41,44,46,69,86,91,92,142,145,147,148] or simultaneous irrigation and aspiration (coaxial or bimanual).[79,90,93,143,149]

Minimum OVD Technique

In minimum OVD technique, the ICL is inserted into the anterior chamber without any OVD and only a minimal amount of OVD is injected to adjust the ICL into the posterior chamber. This minimize the OVD retained in the posterior chamber and simplify the OVD removal.[150–153] Comparing with conventional technique, this technique was shown to result in significantly less IOP rise at 2–3 h postoperatively. Significantly less paracentesis is necessary. Significantly shorter operative time was observed. No difference in visual outcomes, refractive outcome, surgically-induced astigmatism, lens vault, aqueous depth, ECD at all time points.[150,151,153]

OVD Free Technique

In OVD free technique, ICL insertion and tucking of footplates are all done when anterior chamber is maintained by continuous infusion with BSS, usually through the side port.[154–158] Variation exists that use only one single self-closing incision for ICL insertion. The ICL is carefully implanted such that the footplates unfold and reach the ciliary sulcus directly.[159] Footplates that remained in anterior chamber are tucked into position after minimum OVD injection,[159,160] or manipulated by a syringe-coupled injection needle.[161] This technique inherits all the advantages of the minimal OVD technique over conventional technique.[154–158]

Both minimum OVD and OVD free technique are technically demanding, require precise control of lens insertion and unfolding. Supervision by experienced surgeons is recommended during the learning phase.

Consensus statement: 11.1:

The conventional method carries risk of IOP spike at 1–2 h postoperatively due to incomplete removal of OVD that may block the trabecular meshwork or central hole and got entrapped behind the ICL in the posterior chamber. Complete removal of OVD should be ensured.

(Consensus score: 100.00 % [strongly agree: 58.82 %; agree: 41.18 %])

Consensus statement: 11.2:

Apart from the manufacturer recommended 2 % HPMC, cohesive OVD such as 1–1.7 % sodium hyaluronate can be used, with good safety profile reported.

(Consensus score: 83.33 % [strongly agree: 50.00 %; agree: 33.33 %])

Consensus statement: 11.3:

Both minimum OVD method and OVD-free method are safe and effective and produce clinical outcomes similar to conventional method, results in significantly less acute IOP rise within 1–2 h and less surgical time. However, the methods are technically demanding, require precise control of lens insertion and unfolding. Supervision by experienced surgeons is recommended during the learning phase.

(Consensus score: 83.33 % [strongly agree: 50.00 %; agree: 33.33 %])

Section 12:what is the indication for ICL replacement or removal?

ICL removal / replacement is less common among pIOL implantation, compared to angle-supported or iris-fixated anterior chamber pIOL. Early removal are mostly due to abnormal vault (mostly high vault), and late removal are mostly due to cataract. ECD loss accounted for 5–14 % of ICL removal.[162,163] In published prospective studies with 5–10 years of follow-up, the culminative incidence of ICL replacement varies from 0 %[79] to 7.9 %.[71] With a few exceptions, most studies reported ICL replacement rate less than 2 %,[17,69,72,74,79,164] mostly due to high vault and angle closure. One study reported total of 7.9 % (10 eyes) required ICL replacement over 10 years of follow-up, 5 due to myopic progression, 4 replaced on day 1 due to high vault, and 1 due to toric ICL rotation.[71] Another study on non-holed ICL with at least 17 years of follow-up reported culminative ICL replacement rate of 4.3 % (3 eyes) due to high vault with risk of angle closure.

Low vault is a known risk factor of lens opacities, ASC or cataract, but may not necessitate ICL removal.[76] Visually significant cataract, however, may require simultaneous ICL removal, cataract extraction and intraocular lens implantation (bilensectomy). Reported incidence of bilensectomy in prospective studies with 5–10 years follow-up ranged from 0.5 % to 5.5 %.[17,71,72,164–166] With longer follow-up period over 10–17 years, 7.6–14.3 % of eyes had bilensectomy done.[74,167]

High vault is also regarded as a risk factor for angle closure, glaucoma and corneal endothelial cell loss, but may not necessitate ICL removal per se. Careful monitoring of IOP and angle status is important in such cases, and patients should be advised to return if related symptoms arise.

The accuracy of biometry, especially axial length measurements for IOL calculation was addressed in the FDA Post-Approval Study of Visian ICL (MICL).[17] Average difference Pre-op and Post-op measurements was 0.02 mm (correlated to 0.05D IOL power, well below measurement of IOL power manufacturers). There was negligible influence on axial length measurement. However, the accuracy of ultrasound-based measurement is unknown.

Consensus statement: 12.1:

ICL removal should be considered, but not limited to the following conditions:

- Insufficient vault associated with early anterior subcapsular cataract that affects vision
- Excessive vault causing narrowing of the anterior chamber angle and decreasing aqueous flow
- Abnormally progressive ECD loss, or when ECD dropped to a critical level

(Consensus score: 100.00 % [strongly agree: 70.59 %; agree: 29.41 %])

Consensus statement: 12.2:

Low vault is a known risk factor of lens opacities, ASC or cataract, but may not necessitate ICL removal. Visually significant cataract, however, may require simultaneous ICL removal, cataract extraction and intraocular lens implantation (bilensectomy).

(Consensus score: 94.12 % [strongly agree: 52.94 %; agree: 41.18 %])

Consensus statement: 12.3:

The accuracy of biometry for IOL calculation in presence of ICL was shown to be relatively unaffected. There was negligible influence on axial length measurement. However, the accuracy of ultrasound-based measurement is unknown.

(Consensus score: 82.35 % [strongly agree: 58.82 %; agree: 23.53 %])

Endothelial cell loss is a common concern in PC-pIOL. Early studies on iris-fixated pIOL suggested that if ECD reaches levels less than 1500 cells/mm^2 (the safety limit in most pIOL FDA trials), lens removal or bilensectomy should be performed.[168] In a more recent retrospective study on ICL removal cases by Yoon et al. (2024),[169] a cohort of 93 eyes with progressive decrease in ECD were observed for at least 9 months. ICL removal was considered as ECD decreased by 20 % or more from initial visit. The pre-op mean ECD was 1871 + /-537.4 (range

930–2488), vault 282.2 + /-182.9 (range 2–765), mean age 37.9 + /-6.21 (range 27–53). 70 % involves non-holed ICL, and 30 % were holed ICL. Significant risk factors of ECD loss (before ICL removal) included high vaulting, high vaulting/ACD, lower AC angle, high iris pigmentation on ICL surface. After ICL removal, 15.1 % eyes had decreased ECD (10.5 % loss), 51.0 % remained stationary ECD, 34.4 % had increased ECD (12.7 % gain).

Descemet Membrane Endothelial Keratoplasty (DMEK) after ICL was reported for pIOL-related corneal decompensation. Moura-Coelho et al. (2023)[170] reported 16 such cases, 2 of which (12.5 %) had ICL implanted. Most cases (75 %) underwent staged operation, with pIOL removal + /- refractive lens exchange, followed by DMEK within 4 months. Significant improvement in BCVA was observed in medium-long term (4 year follow-up) with good safety profile.

Consensus statement: 12.4:

ICL removal should also be considered when ECD reaches levels less than 1500 cells/mm^2, in presence of abnormal progressive ECD loss, with or without concurrent cataract surgery

(Consensus score: 100.00 % [strongly agree: 50.00 %; agree: 50.00 %])

Consensus statement: 12.5:

Abnormal progressive ECD loss, with documented loss of 20 % or more over 9 months, may raise suspicion and close monitoring is warranted. ICL removal may be considered if ECD decreases progressively and approach 1500 cells/mm^2.

(Consensus score: 100.00 % [strongly agree: 50.00 %; agree: 50.00 %])

Consensus statement: 12.6:

Most cases could achieve stable ECD after ICL removal, but some may exhibit persistent ECD loss 6 months after ICL removal. Risk factors included lower pre-ICL-removal ECD, higher vault and vault-to-ACD ratio, lower anterior chamber angle (ACA). Special precautions should be exercised in managing such cases.

(Consensus score: 100.00 % [strongly agree: 47.06 %; agree: 52.94 %])

Consensus statement: 12.7:

In established corneal decompensation after ICL, staged operation with ICL removal + /- refractive lens exchange, followed by endothelial keratoplasty, particularly Descemet's membrane endothelial keratoplasty (DMEK) offers good anatomical and functional outcomes.

(Consensus score: 94.12 % [strongly agree: 47.06 %; agree: 47.06 %])(Table 1).

Results of voting and discussion

Posterior chamber phakic intraocular lens, especially ICL, has emerged as a promising option for correcting high myopia and myopic astigmatism, particularly in eyes deemed unfit for corneal refractive surgeries. The safety and efficacy have been proven by the FDA clinical trials and other long-term studies. With the emergence of long-term data and modern anterior segment imaging techniques, more insights have been gained regarding ICL selection, operative techniques, and perioperative management. That results in various novel approaches that warrant critical review and further standardization.

Based on the voting results, a consensus was reached on all the above statements, providing new evidence-based recommendations to the current literature. Despite the relatively high level of agreement among the panelists, it is worth noting that the statements are not intended as strict guidance to be followed. The recommendations do not guarantee optimal outcomes; therefore, surgeons should exercise clinical judgment in evaluating each surgical candidate and formulate an individualized surgical plan based on the best available information. In developing the consensus, certain statements required in-depth discussion and repeated modifications before a final agreement was reached.

Table 1
Results of the voting of the consensus statements of ICL.

Section	Consensus Statement	**C Score**	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1. Is ICL indicated in normal eyes of healthy young adults below 21 of age?							
1.1	ICL implantation in a patient aged 21 – 45 in accordance with criteria set by FDA approved label, is generally safe and effective.	**100.00 %**	70.59 %	29.41 %	0.00 %	0.00 %	0.00 %
1.2	ICL implantation in young adult aged 18 – 21 may be considered in patients with special occupational needs, high anisometropia and corneal diseases.	**100.00 %**	58.82 %	41.18 %	0.00 %	0.00 %	0.00 %
1.3	ICL implantation in patients aged below 18 is mostly reserved for treatment of refractive or anisometropic amblyopia. It should be considered only by experienced ICL surgeons, in collaboration with specialists in pediatric ophthalmology.	**88.24 %**	41.18 %	47.06 %	11.76 %	0.00 %	0.00 %
2. What is the safety and efficacy of ICL implantation in patients above 45 of age with presbyopia? What is the best strategy and refractive target?							
2.1	ICL implantation is acceptable in patients aged 45–60. However, special precautions should be taken regarding refractive targets tailored for presbyopic symptoms. Patient should also be informed that anatomical changes such as increased crystalline lens rise (CLR) may increase the likelihood of postoperative complications or the need for ICL exchange.	**88.24 %**	41.18 %	47.06 %	5.88 %	5.88 %	0.00 %
2.2	Safety is not determined for phakic eye in patients aged over 60, with paucity of relevant study identified.	**88.24 %**	47.06 %	41.18 %	5.88 %	5.88 %	0.00 %

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Table 1 (*continued*)

Section	Consensus Statement	C Score	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
2.3	ICL implantation in pseudophakic patients aged 21 or above, if a patient meets all criteria set out in DFU in European region, is reported in multiple studies with satisfactory results. However, patients should be informed that long-term safety and efficacy is not yet established.	**94.12 %**	47.06 %	47.06 %	5.88 %	0.00 %	0.00 %
2.4	Refractive target of spherical equivalent (SE) is usually aimed at closest to emmetropia in patients without presbyopia. Target could be modified according to patient's specific requirements, after thorough trial in different distance and environment settings to ensure best visual experience.	**94.12 %**	70.59 %	23.53 %	0.00 %	5.88 %	0.00 %
2.5	In patients aged over 40 with presbyopic symptoms, modification of refractive target is commonly considered to improve visual performance in near distance.	**100.00 %**	64.71 %	35.29 %	0.00 %	0.00 %	0.00 %
2.6	Bilateral planned under-correction, targeting around −0.5 to −1.0D, may be considered in selected cases after thorough trial with spectacle or contact lenses with satisfactory performance.	**100.00 %**	50.00 %	50.00 %	0.00 %	0.00 %	0.00 %

Table 1 (*continued*)

Section	Consensus Statement	C Score	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
2.7	Monovision strategy targeting 0 to −0.75D on dominant eye, and −0.5 to −2.25D on non-dominant eye, may be considered in selected cases after thorough trial with spectacle or contact lenses with satisfactory performance.	**100.00 %**	50.00 %	50.00 %	0.00 %	0.00 %	0.00 %
2.8	The EDOF ICL seeking to improve near visual performance while targeted at emmetropia remained investigational with limited published data to confirm effectiveness. Toric version of the lens is not available at present. Further studies are required to establish safety and efficacy.	**82.35 %**	47.06 %	35.29 %	5.88 %	11.76 %	0.00 %
3. Is ICL indicated in eyes with Anterior Chamber Depth (ACD) below 3 mm?							
3.1	For Anterior Chamber Depth (ACD) ≥ 3 mm, ICL is generally safe as recommended by FDA-approved label requirements.	**100.00 %**	88.24 %	11.76 %	0.00 %	0.00 %	0.00 %
3.2	For ACD between 2.8 to < 3 mm, ICL is permissible by manufacturer's DFU in non-US region, well studied in multiple studies and shown good safety profile.	**100.00 %**	70.59 %	29.41 %	0.00 %	0.00 %	0.00 %

(*continued on next page*)

Table 1 (*continued*)

Section	Consensus Statement	C Score	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
3.3	For ACD between 2.6 to < 2.8 mm, off-labelled ICL implantation is reported by several studies with satisfactory outcomes. Long-term safety is not yet established. It should be considered cautiously with open angle confirmed on gonioscopy.	**88.24 %**	52.94 %	35.29 %	5.88 %	5.88 %	0.00 %
3.4	For ACD < 2.6 mm, safety of ICL is not established. It should only be considered in exceptional cases, under expert care with extreme caution.	**83.33 %**	33.33 %	50.00 %	16.67 %	0.00 %	0.00 %
4. Is there any advantage regarding the long-term safety of ICL with central hole over non-hole models, in terms of risk of cataract, glaucoma and endothelial cell loss?							
4.1	Long-term data showed a much lower incidence of lens opacities and cataract in eyes undergone holed ICL than non-holed ICL.	**100.00 %**	70.59 %	29.41 %	0.00 %	0.00 %	0.00 %
4.2	Early IOP rise due to retained OVD, blocking of central hole, or topical steroids may still happen in holed ICL. However, long-term IOP elevation is much less common in holed ICL compared with non-holed ICL.	**88.24 %**	58.82 %	29.41 %	5.88 %	5.88 %	0.00 %
4.3	Current data regarding the long-term ECD loss between non-holed ICL and holed ICL is still inconclusive. Further long-term comparative studies may provide better insight.	**100.00 %**	50.00 %	50.00 %	0.00 %	0.00 %	0.00 %
4.4	Holed ICL is the preferred choice over non-holed ICL for myopia and myopic astigmatism in the suitable range.	**100.00 %**	94.12 %	5.88 %	0.00 %	0.00 %	0.00 %
4.5	Short-term IOP rise may still occur. Chronic ECD loss was comparable in both holed and non-holed ICL, and long-term continual loss is within acceptable range as long as minimal ECD criteria are observed preoperatively.	**94.12 %**	47.06 %	47.06 %	5.88 %	0.00 %	0.00 %
5. What is the minimal Endothelial Cell Density (ECD) requirement for ICL implantation?							
5.1	A tiered approach of preferred minimal ECD according to the level of safety is proposed. For beginning surgeons in the early phase of training, a higher age-dependent ECD requirement (assuming 10 % acute loss followed by 1.5 % annual loss, considering 250 cell/mm^2 measurement variation) is preferable. Preferred Minimal ECD (cell/mm2) according to age: 21–25: 2700 26–30: 2500 31–35: 2400 36–40: 2200 41–45: 2100 40 or above: 2000	**83.33 %**	50.00 %	33.33 %	16.67 %	0.00 %	0.00 %
5.2	For experienced surgeons with good track record of safety, a minimum of 2200 cells/mm^2 should be required for implantation at age 21, and 2000 cells/mm^2 from age 26 onwards. Any potential candidate with ECD lower than that should be meticulously considered by experts only.	**88.24 %**	52.94 %	35.29 %	5.88 %	5.88 %	0.00 %
6. What are the optimal measurement methods of essential parameters for ICL size selection vault prediction?							

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Table 1 (*continued*)

Section	Consensus Statement	C Score	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
6.1	The essential parameters to measures included 1) Horizontal White-to-White distance (WTW), 2) internal Anterior Chamber Depth measurements (ACD) from corneal endothelium to anterior surface of crystalline lens, 3) Endothelial cell density (ECD), and 4) Mesopic pupil size.	**82.35 %**	47.06 %	35.29 %	5.88 %	11.76 %	0.00 %
6.2	Horizontal WTW was shown to correlate poorly with sulcus anatomy. AS-OCT and UBM is increasingly important in vault prediction and modern nomogram development.	**94.12 %**	47.06 %	47.06 %	5.88 %	0.00 %	0.00 %
6.3	In measuring horizontal White-to-white (WTW) distance, it is suggested to use Caliper / Pentacam / Orbscan (depends on availability) to be used with OCOS nomogram, with automated measurements showing higher repeatability.	**82.35 %**	47.06 %	35.29 %	11.76 %	5.88 %	0.00 %
6.4	Manual measurement could be done with the tips of Castroviejo surgical caliper (range 0–20 mm in 1 mm step) placed on nasal and temporal limbus with patient under topical anesthesia, distance read from the scale. Limbus itself is a 1.5 mm to 2 mm gray zone, for the best reproducibility, it should be measured from mid gray zone to mid gray zone.	**94.12 %**	47.06 %	47.06 %	5.88 %	0.00 %	0.00 %

Table 1 (*continued*)

Section	Consensus Statement	C Score	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
6.5	Automated measurements of WTW provide more precise results, with higher inter-observer agreement. Examples included Slit-scanning corneal tomography (Orbscan II), IOLMaster 500 (anterior segment image), Scheimpflug camera (Pentacam HR and Pentacam AXL), SS-OCT system (IOLMaster 700), Lenstar LS 900 and Galilei G4, CASIA2 AS-OCT, Anterion AS-OCT. The result among different devices may vary significantly and should not be used interchangeably. Measurement should ideally be done with the same type of device.	**100.00 %**	58.82 %	41.18 %	0.00 %	0.00 %	0.00 %
6.6	ACD should be measured from corneal endothelium to the anterior surface of the crystalline lens, by Pentacam, IOLMaster, AS-OCT or UBM. Precautions should be taken in using ACD from IOLMaster that it includes the central corneal thickness, which must be subtracted before ICL size and power calculations.	**94.12 %**	41.18 %	52.94 %	0.00 %	5.88 %	0.00 %

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Table 1 (*continued*)

Section	Consensus Statement	C Score	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
6.7	For specular microscopy, an ideal of 6 scans with good images is preferable at pre-op visit, and 3 scans for each post-op visit. Non-contact specular microscope should be used, with good image indicated by: 1) distinct cells; 2) at least 100 identifiable (countable) cells as a minimum, 150 cells preferred; and 3) cells can be grouped in a uniform area.	**82.35 %**	41.18 %	41.18 %	11.76 %	5.88 %	0.00 %
6.8	Mesopic pupil size should be measured with infrared or light amplification pupillometer, under the background luminance of 3 cd/m^2 (equiv. to 3 lux) or less, with a precision of + /- 0.5 mm, only after sufficient time for dark adaptation (approx. 10 mins). Mesopic pupil size greater than optic diameter of ICL lens may experience glare and/or halos, and patients should be advised.	**94.12 %**	47.06 %	47.06 %	5.88 %	0.00 %	0.00 %
6.9	ICL vault can be estimated at the slit-lamp at 24 h postoperatively, as a percentage of central corneal thickness. It is further measured by rotating Scheimpflug camera or AS-OCT.	**83.33 %**	50.00 %	33.33 %	16.67 %	0.00 %	0.00 %
6.10	Pupil size and accommodation, affected by room lighting, can alter the apparent clear lens rise and vault in imaging. Standardizing lighting conditions during measurements and postoperative imaging is important for consistent evaluation.	**100.00 %**	33.33 %	66.67 %	0.00 %	0.00 %	0.00 %
7. What are the advantages of Ultrasound Biomicroscopy (UBM) and Anterior-segment Optical Coherence Tomography (AS-OCT) in the planning and management of ICL surgery?							
7.1	Current high-frequency UBM with a wide scanning field enables direct measurement of the ciliary STS diameter. UBM can also detect ciliary body cysts and other anatomical variations and abnormalities that may affect the ICL position, post-op vault and long-term safety.	**94.12 %**	58.82 %	35.29 %	5.88 %	0.00 %	0.00 %
7.2	AS-OCT can measure anterior segment parameters with very good Intra- and inter-examiner reproducibility and facilitates ICL size prediction and vault measurements. Anatomic values cannot be used interchangeably among different devices.	**94.12 %**	47.06 %	47.06 %	5.88 %	0.00 %	0.00 %

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Table 1 (*continued*)

Section	Consensus Statement	C Score	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
7.3	ICL implantation may not be absolutely contraindicated in presence of ciliary body cyst (CBC), but potential risk of acute IOP rise due to angle closure, rotation of toric ICL, iris chafing due to forward rotation of footplate should be observed. Risk factors include size of cyst above 1 mm, and location in horizontal meridian in the ciliary sulcus.	**88.24 %**	41.18 %	47.06 %	11.76 %	0.00 %	0.00 %
7.4	Addition of AS-OCT and UBM into routine pre-op assessment provides good insight into vault prediction and may supplement ICL size selection by the OCOS nomogram. They also provide valuable data to facilitate local nomogram construction and future research. Absent of those technologies, however, does not preclude safe ICL implantation with OCOS nomogram. Careful WTW measurement with multiple modalities should be employed, with periodic review of post-op vault for construction of custom nomogram.	**100.00 %**	58.82 %	41.18 %	0.00 %	0.00 %	0.00 %
8. What is the optimal method for vault prediction and the target vault?							
8.1	Careful ICL size selection should aim to avoid excessively low or high vault.	**100.00 %**	70.59 %	29.41 %	0.00 %	0.00 %	0.00 %
8.2	The vault of 250–750 microns was widely accepted as an ideal range. The upper range up to 900 microns is acceptable by the FDA-approved directions for use.	**94.12 %**	58.82 %	35.29 %	5.88 %	0.00 %	0.00 %
8.3	Extremes of vault must be viewed as risk factors for adverse events, not as adverse events in and of themselves. In the absence of symptoms, lens vault outside of this range may not necessarily require exchange or removal.	**94.12 %**	64.71 %	29.41 %	5.88 %	0.00 %	0.00 %
8.4	The FDA-approved OCOS formula with WTW and ACD should be observed, with verification of one or more additional formula depending on AS-OCT, UBM or other anterior segment parameters based on surgeon's expertise and availability of equipment.	**100.00 %**	64.71 %	35.29 %	0.00 %	0.00 %	0.00 %
8.5	No single formula or strategy outperforms others significantly in vault prediction. It is important to identify risk factors for abnormal vault, which may include patient demographics or surgical techniques.	**94.12 %**	58.82 %	35.29 %	0.00 %	5.88 %	0.00 %
8.6	The ciliary sulcus is typically vertically elongated. The vault values may be lower when ICL is placed in non-horizontal orientations. This should be taken into account for both sizing and postoperative interpretation.	**100.00 %**	58.82 %	41.18 %	0.00 %	0.00 %	0.00 %

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Table 1 (*continued*)

Section	Consensus Statement	C Score	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
8.7	The surgeon should ensure consistent technique and review the vault achieved and incidence of complications from time to time to construct one's own nomogram, aiming to minimize vault related complications.	**88.24 %**	47.06 %	41.18 %	5.88 %	5.88 %	0.00 %
8.8	In cases of conflicting ICL size recommendations from different formulas, one could consider ordering multiple ICLs of adjacent sizes if resources allowed. This enables switching of ICL size during operation when obviously abnormal vault is detected.	**83.33 %**	33.33 %	50.00 %	16.67 %	0.00 %	0.00 %
9. What is the optimal strategy for low astigmatism (Within 1.0 Diopter Cylinder), toric ICL or non-toric ICL with modified corneal incision techniques?							
9.1	Consider astigmatism correction with 0.5D or more pre-existing astigmatism.	**82.35 %**	41.18 %	41.18 %	11.76 %	5.88 %	0.00 %
9.2	Astigmatism of 0.5–1.0D can be corrected by either corneal incision-based method (e.g. steep meridian incision) or toric ICL.	**100.00 %**	52.94 %	47.06 %	0.00 %	0.00 %	0.00 %
9.3	Astigmatism of 1.0D or above is best corrected with toric ICL.	**94.12 %**	58.82 %	35.29 %	0.00 %	5.88 %	0.00 %
10. Which is more preferrable between Delay Sequential Bilateral ICL Surgery (DSBICLS) and Immediate Sequential Bilateral ICL Implantation Surgery (ISBICLS)?							
10.1	Delay Sequential Bilateral ICL Surgery (DSBICLS), and Immediate Sequential Bilateral ICL Implantation Surgery (ISBICLS) are equally safe and effective.	**88.24 %**	64.71 %	23.53 %	5.88 %	5.88 %	0.00 %
11. Is there any difference in safety and efficacy regarding various implantation techniques, between conventional method, minimal Ophthalmic Viscosurgical Device (OVD) method, and OVD-free method?							
11.1	The conventional method carries risk of IOP spike at 1–2 h post-operatively due to incomplete removal of OVD that may block the trabecular meshwork or central hole and got entrapped behind the ICL in the posterior chamber. Complete removal of OVD should be ensured.	**100.00 %**	58.82 %	41.18 %	0.00 %	0.00 %	0.00 %
11.2	Apart from the manufacturer recommended 2 % HPMC, cohesive OVD such as 1–1.7 % sodium hyaluronate can be used, with good safety profile reported.	**83.33 %**	50.00 %	33.33 %	16.67 %	0.00 %	0.00 %
11.3	Both minimum OVD method and OVD-free method are safe and effective and produce clinical outcomes similar to conventional method, results in significantly less acute IOP rise within 1–2 h and less surgical time. However, the methods are technically demanding, require precise control of lens insertion and unfolding. Supervision by experienced surgeons is recommended during the learning phase.	**83.33 %**	50.00 %	33.33 %	16.67 %	0.00 %	0.00 %
12. What is the indication for ICL replacement or removal?							

(*continued on next page*)

Table 1 (*continued*)

Section	Consensus Statement	**C Score**	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
12.1	ICL removal should be considered, but not limited to the following conditions: - Insufficient vault associated with early anterior subcapsular cataract that affects vision. - Excessive vault causing narrowing of the anterior chamber angle and decreasing aqueous flow. - Abnormally progressive ECD loss, or when ECD dropped to a critical level.	**100.00 %**	70.59 %	29.41 %	0.00 %	0.00 %	0.00 %
12.2	Low vault is a known risk factor of lens opacities, ASC or cataract, but may not necessitate ICL removal. Visually significant cataract, however, may require simultaneous ICL removal, cataract extraction and intraocular lens implantation (bilensectomy).	**94.12 %**	52.94 %	41.18 %	0.00 %	5.88 %	0.00 %
12.3	The accuracy of biometry for IOL calculation in presence of ICL was shown to be relatively unaffected. There was negligible influence on axial length measurement. However, the accuracy of ultrasound-based measurement is unknown.	**82.35 %**	58.82 %	23.53 %	17.65 %	0.00 %	0.00 %
12.4	ICL removal should also be considered when ECD reaches levels less than 1500 cells/mm^2, in presence of abnormal progressive ECD loss, with or without concurrent cataract surgery.	**100.00 %**	50.00 %	50.00 %	0.00 %	0.00 %	0.00 %
12.5	Abnormal progressive ECD loss, with documented loss of 20 % or more over 9 months, may raise suspicion and close monitoring is warranted. ICL removal may be considered if ECD decreases progressively and approach 1500 cells/mm^2.	**100.00 %**	50.00 %	50.00 %	0.00 %	0.00 %	0.00 %
12.6	Most cases could achieve stable ECD after ICL removal, but some may exhibit persistent ECD loss 6 months after ICL removal. Risk factors included lower pre-ICL-removal ECD, higher vault and vault-to-ACD ratio, lower anterior chamber angle (ACA). Special precautions should be exercised in managing such cases.	**100.00 %**	47.06 %	52.94 %	0.00 %	0.00 %	0.00 %
12.7	In established corneal decompensation after ICL, staged operation with ICL removal + /- refractive lens exchange, followed by endothelial keratoplasty, particularly Descemet's membrane endothelial keratoplasty (DMEK) offers good anatomical and functional outcomes.	**94.12 %**	47.06 %	47.06 %	5.88 %	0.00 %	0.00 %

Consensus Score (C Score) was defined as the value of the summation of the 'strongly agree', and 'agree' percentages; C Score ≥ 75 % was considered 'consensus achieved' and C Score < 75 % was 'consensus not reached'. *No statement was 'consensut not acheieved'.*

ICL implantation in patients aged 45–60 with presbyopic symptoms poses a particular challenge. Patients may exhibit different refractive requirements, ocular anatomy, and expectations. Various approaches have been proposed, such as bilateral planned under-correction, monovision, and the use of EDOF ICL. Based on current evidence, no single approach has been shown to outperform the others. Thorough simulation with trials of spectacles and contact lenses should be performed, and decisions should be made after complete discussion with patients.

Endothelial cell density (ECD) loss has been the potential complication of greatest concern. With better experience, improved implantation techniques, and the availability of longer-term data, the current trend is to loosen the minimal preoperative ECD requirements. After the MICL study by the FDA, a stringent requirement of minimal preoperative ECD has been recommended, which was retained in the US version of DFU, but not in others. Subsequent long-term studies yielded more favorable results. A much looser requirement has been suggested, but concerns on long-term safety arise due to potential variability in automated ECD measurements, particularly when close to the minimal threshold values. A revised recommendation featuring a stepwise minimal ECD requirement, considering all the above factors, was proposed and reached a final agreement among the panelists.

ICL size selection, vault prediction and management of high or low vault remained the most active area of research. Numerous alternative strategies, apart from the original manufacturer's instructions, have emerged over the years. It is widely accepted that the anatomy of the ciliary sulcus is much more important than merely horizontal WTW and ACD in vault prediction. Other factors such as crystalline lens rise (CLR) and orientation of implant may also affect the vault, as the ciliary sulcus is typically vertically elongated. On the other hand, abnormally high or low vaults may not necessarily mandate ICL removal, but close monitoring for complications is needed. In both scenarios, anterior segment imaging such as AS-OCT and UBM plays a critical role and will soon become the standard of care.

This study and the consensus statements have certain limitations. The list of consensus is by no means comprehensive since it focuses only on selected controversial topics. It cannot replace official instructions and guidance from manufacturers and regulatory authorities, but can be viewed as supplementary information in areas otherwise not covered. In-depth analysis of each ICL sizing algorithm is lacking in this study, and further comparative studies are needed to determine the most accurate strategies. Meta-analysis involving the latest clinical studies may yield better insights. Finally, the consensus statements cannot replace careful clinical judgment, effective communication, and proficient surgical skills in optimizing outcomes in PC-pIOL surgery.

Consent for publication (please confirm your consent)

All authors confirm their consent for publication.

Ethics approval and consent to participate

Not applicable.

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Competing Interests

Barbara Leyssens: Staar consultancy agreement.

Julian Stevens: Previous Consultant to Staar Surgical R&D, patent assigned to Staar surgical WO2023060017A1 Ophthalmic implants for correcting vision with a tunable optic, and methods of manufacture and use.

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