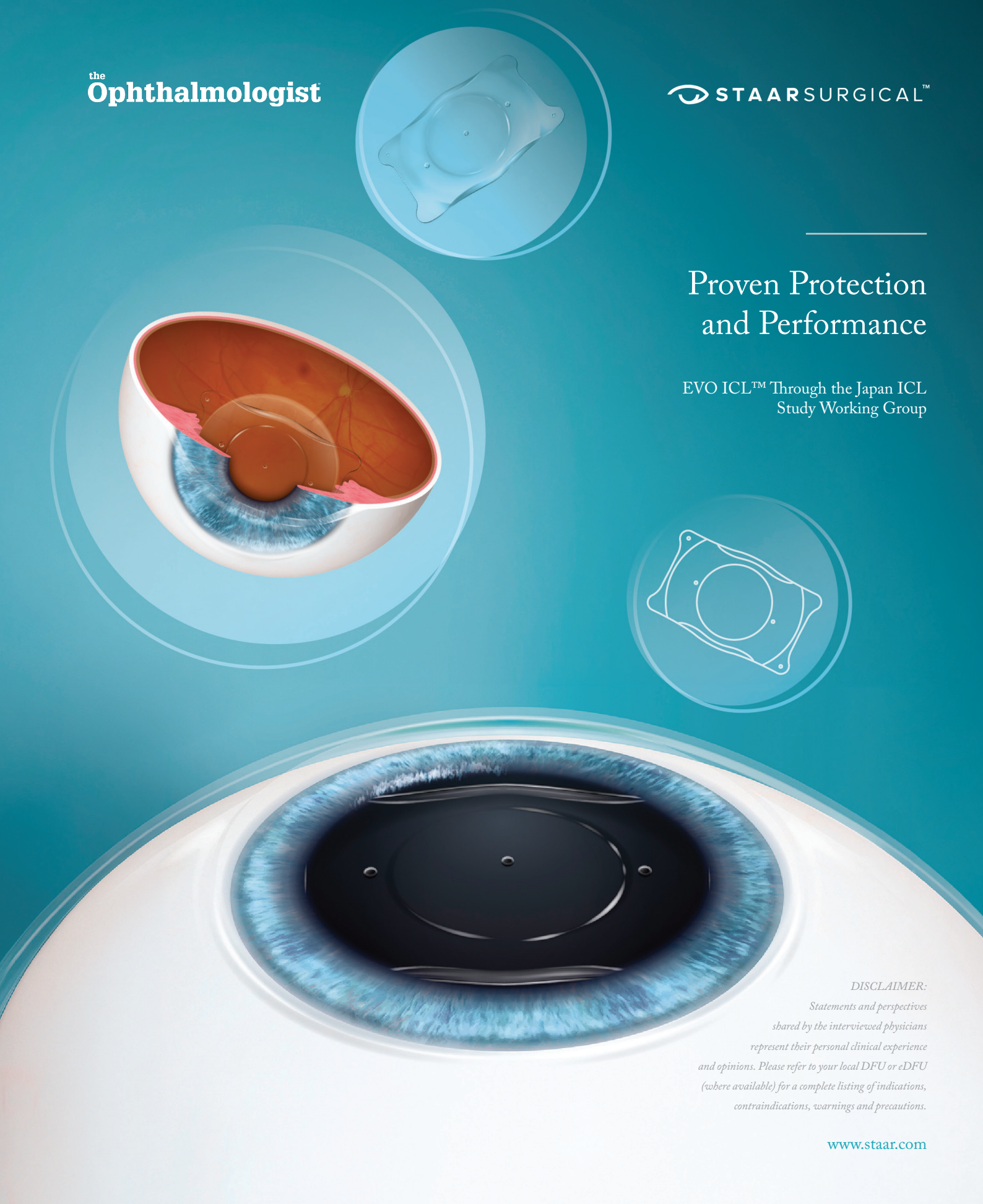


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EVO ICL™ Through the Japan ICL
Study Working Group



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Proven Protection and Performance

*EVO ICL™ Through the Japan
ICL Study Working Group*

Since its introduction more than 30 years ago, Implantable Collamer® Lens (ICL) surgery has grown to reflect the increasing global preference for lens-based solutions in refractive vision correction, as patients and surgeons opt for safe, effective, and minimally invasive options that preserve corneal integrity. By February 2026, sales of STAAR Surgical™'s EVO ICL™ – the only implantable lenses made with Collamer, a proprietary, biocompatible

material supporting long-term safety outcomes – surpassed four million.

Over the past two decades, Japan has played a pivotal role in shaping the trajectory of ICL technology. Nowhere is this more evident than in the work of the Japan ICL Study Working Group, guided by Professor Kimiya Shimizu, Director General, Department of Eye Center (Ophthalmology), Sanno Hospital; Professor, International University of Health and Welfare, Tokyo.

Formally established in 2009, the Group brings together more than 200 certified surgeons united by a single mission: to support and elevate high-quality ICL surgery. A growing network of instructors and a structured educational framework ensure consistent standards while nurturing the next generation of refractive specialists.

The research output speaks for itself – over 75 English-language papers, more than 50 Japanese articles, numerous multicenter studies, and several foundational texts. Together, these contributions have advanced understanding of EVO ICL performance across diverse patient populations, refined surgical norms, and helped expand the recognized indications for phakic IOLs globally.

But the Group's influence goes beyond publications and credentials. It is the collaborative culture – open, rigorous, and candid – that distinguishes the Japanese experience as EVO ICL adoption accelerates worldwide.

In the pages that follow, leading surgeons share the history, philosophy, research, and clinical innovation that have shaped Japan's unique relationship with EVO ICL.

Raising the Standard in Refractive Surgery

*Professor Kimiya Shimizu,
Director General,
Department of Eye
Center (Ophthalmology),
Sanno Hospital; Professor,
International University of
Health and Welfare, Tokyo*

My interest in phakic IOL technology was sparked by a single frustration: despite being superior to corneal refractive surgery in many respects, phakic IOLs required an iridotomy or iridectomy. That one drawback was enough to limit wider adoption – and eliminating it became the driving force behind much of my subsequent work.

In the early days, LASIK and PRK were sometimes promoted aggressively and, in certain cases, performed by non-board-certified ophthalmologists – an environment that inevitably produced complications. To



prevent ICL from going down the same path, we established the Japan ICL Study Working Group, focused on high-quality surgical practice and education. Its value lies in open, candid discussion. No surgery is complication-free, but honest debate at study meetings goes a long way toward reducing them.

My conviction that ICL should be the first-choice procedure for myopia crystallized during the clinical trial of the ICL with a central port, when we were simultaneously running LASIK studies. In some cases, we performed ICL in one eye and LASIK in the other; without exception, the ICL eye delivered better visual quality. That was the moment I knew.

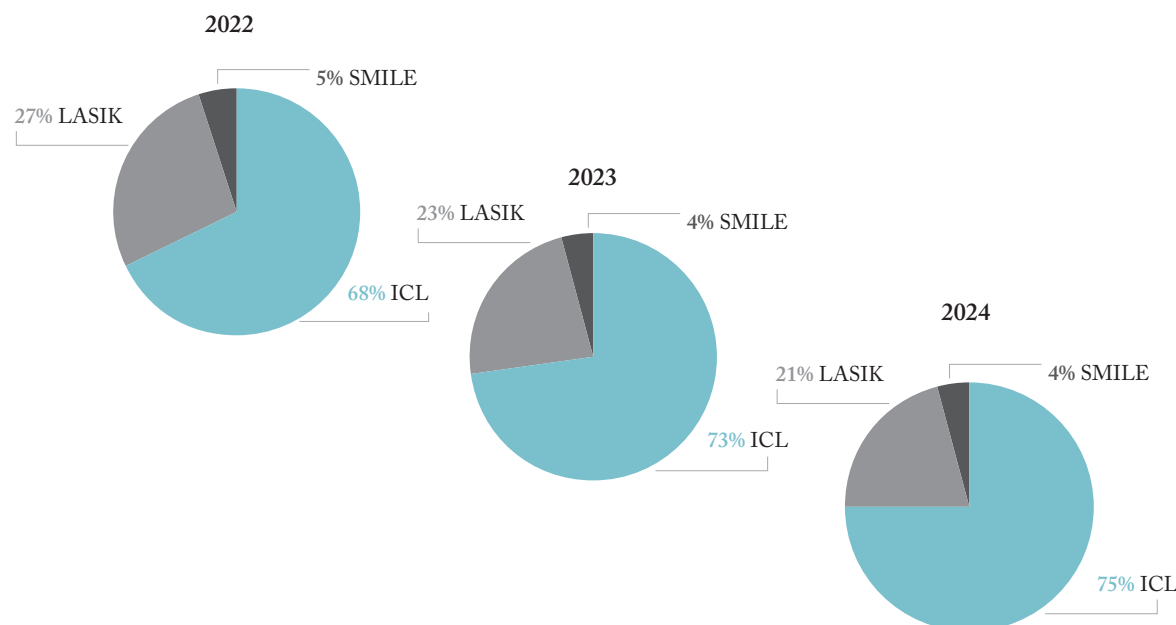
We now have nearly 10 years of long-term data for both LASIK and ICL, and both have shown consistent results. But I believe ICL is currently the safest and most precise refractive option available. In my own practice, we have discontinued LASIK and SMILE entirely – ICL is now the only refractive procedure we offer. After 29 years with ICL and long experience with PRK, LASIK, and SMILE, I am confident the ICL offers the best outcomes, particularly for moderate to high myopia.

Looking ahead, I believe the next major frontier for ICL will be presbyopia – particularly in patients aged 46 to 55. Beyond that, as the technology continues to advance rapidly, the possibilities are wide open, perhaps including better options for hyperopia and even pediatric amblyopia.



Professor Kimiya Shimizu is one of Japan's most influential refractive surgeons and a leading global authority on ICL surgery, having published the first articles describing the central opening in the ICL which has led the way to the remarkable safety profile of what is now known as the EVO ICL. As a founding force behind the Japan ICL Study Working Group, Professor Shimizu has championed collaborative research, rigorous education, and safety-focused clinical standards that have elevated refractive practice across Japan and beyond.

Market Share of Refractive Surgery in Japan
ICL has become the primary option for refractive surgery



*Data from STAAR Japan

*“In surgery,
simplicity is often
an advantage.
There’s a saying
that ‘the enemy
of good is better,’
and I think that’s
very relevant
in the OR.”*

The Japanese ICL Model: Collaboration, Evidence, and the New Era of Refractive Surgery

Japan's foremost experts discuss how the Japan ICL Study Working Group has shaped national practice and global confidence in phakic IOL technology

To examine the evolution of ICL surgery and its future direction, Professor Kimiya Shimizu moderated a discussion with several of Japan's most respected refractive surgeons. Together, they offer decades of experience across cataract, corneal, and refractive surgery, as well as leadership in clinical research, surgeon training, and technological advancement. Their discussion highlights the shared principles underpinning Japan's success: surgeon-led education, open exchange of clinical challenges, and growing confidence in the EVO ICL as a first-choice option across a wide spectrum of myopia.

Professor Shimizu: What role has the Japan ICL Study Working Group played in building trust in ICL technology among patients and surgeons?

Dr. Kitazawa: The Japan ICL Study Working Group introduced a licensing system for ICL surgery, limiting eligibility to ophthalmologists (certified by the Japanese Ophthalmological Society) who routinely perform cataract surgery. The licensing process is rigorous, requiring an instructor to be present during surgery to evaluate and determine pass or fail. As a result, ICL has become widely recognized as a safe and reliable procedure, distinctly different from LASIK. Today, it is regarded by the public in Japan as the safest and most dependable refractive surgery, and in 2024, approximately 70% of all domestic refractive surgeries were ICL procedures (1).

Dr. Fujimoto: Regarding new phakic intraocular lens surgery, the Study Group believes that its own surgeons discussing and exploring various questions and issues among

themselves play a crucial role in achieving safe and favorable outcomes.

Dr. Kojima: The Group holds regular academic meetings to provide educational updates. We also host discussions where ICL surgeons can obtain prompt responses to inquiries and where the environment increases surgeon confidence in performing ICL procedures.

Dr. Ouchi: Dr. Shimizu's initial publications regarding the central port, have provided substantial benefits to refractive surgery patients worldwide, should be regarded as one of the strongest achievements of the Japan ICL Study Group. I believe it should also be recognized as a singular and significant contribution on a global scale.

How many ICL implantations have you personally performed? How has your

technique changed over time? How has patient selection evolved over time?

Dr. Kitazawa: The number of ICL surgeries in Japan has already exceeded 200,000; I have performed more than 30,000 procedures. In the early 2000s, the number of ICL cases did not increase significantly, but they surged dramatically following the Ministry of Health, Labor and Welfare's approval of the EVO ICL in 2014.

Previously, ICL surgery was indicated only for patients with high to extreme myopia who were not candidates for LASIK, but the development of the EVO ICL made it possible for patients eligible for LASIK to also choose ICL. Furthermore, the Japanese Ophthalmological Society's refractive surgery guidelines expanded the

indication beyond high myopia to include moderate myopia (−3.0D to −6.0D), which had a major impact.

Dr. Ichikawa: I have performed over 2,000 procedures. Regarding insertion techniques, I am conservative and meticulous, with an eye toward long-term safety; perhaps because of this, cataract cases remain low – even long-term – in my own cases. However, because the results are so good across many ranges, I have started doing more lower diopter cases, the age of my target patients is increasing, and, although not standard teaching, I have started to experiment with different fixation locations other than horizontal.

Dr. Kamiya: I have performed numerous surgeries to date, but since most ICL patients have astigmatism, I

The Panel



Dr. Kahoko Fujimoto,
Chief Director, Fujimoto Eye Clinic
Dr. Fujimoto served as an ophthalmologist at Kansai Medical University Hospital and as Chief Ophthalmologist at Arisawa General Hospital, before establishing Fujimoto Eye Clinic in 1993. She was ahead of the curve in Japan in introducing same-day cataract surgery and is a pioneer in refractive correction fields including LASIK, ICL, and multifocal lens surgery.

Dr. Masayuki Ouchi,
Director, Masayuki Ouchi Eye Clinic; Specially Appointed Professor, Tokyo Medical and Dental University
After graduating from Tokyo Jikei University School of Medicine, Dr. Ouchi joined the Department of Ophthalmology at Kyoto Prefectural University of Medicine. After serving as Chief Ophthalmologist at Nantan Municipal Hospital and Visiting Lecturer at Kyoto Prefectural University of Medicine, he established Masayuki Ouchi Eye Clinic in 2018.



Dr. Kazutaka Kamiya, *Professor, Faculty of Health Sciences and Graduate School of Health Sciences (Department of Visual Function), Showa Medical University*
Dr. Kamiya is engaged in cutting-edge research activities on the development and clinical evaluation of next-generation ICLs and he is one of the top surgeons with the highest number of academic publications on ICLs. He is one of the few certified ICL expert doctors in Japan and has provided surgical training for ICL licensing at dozens of facilities. He was selected as one of the Best Doctors in Japan for six consecutive years starting in 2020.

Dr. Kazuo Ichikawa,
Director, Chukyo Eye Institute for Visual Science; Primary Surgeon, Grand Central Tower Tokyo Eye Clinic
Dr. Ichikawa's academic positions include Visiting Professor at Dalian Medical University in China and Part-Time Lecturer at Kitasato University School of Medicine. Recognized as a leading authority in cataract and refractive surgery, Dr. Ichikawa previously served as President of the Japanese Society of Cataract and Refractive Surgery.



Dr. Takashi Kojima,
Director, Nagoya Eye Clinic
“Qualifying as an MD at the Keio University School of Medicine, Dr. Kojima is a certified ophthalmologist, EVO ICL expert, and trabectome surgery instructor. After pursuing corneal research at Harvard University and the University of Illinois, he has performed over 10,000 cataract surgeries, over 1,500 pterygium surgeries, over 500 corneal transplants, and over 500 corneal cross-linking procedures. He also serves as Representative of the Safe Myopia Treatment Network and has trained numerous ICL-certified surgeons across Japan.”

Dr. Yoshihiro Kitazawa,
Group Chief Director, Eye Clinic Tokyo Group
Dr. Kitazawa gained clinical experience at Kawaguchi Medical Center and Shiraoka Central General Hospital before earning a PhD in Medicine from Tokyo Medical and Dental University. In 2023 he was appointed Director of Eye Clinic Tokyo Sapia Tower and currently serves as Group Chief Director of Eye Clinic Tokyo Group, overseeing all clinical operations.



Moderator
Professor Kimiya Shimizu

Current Status of Low-Diopter EVO ICL Use in Japan

At the 4th STAAR Surgical EVO ICL APAC Experts Summit (April 24–26, 2026), Dr. Kamiya reviewed the evolving landscape of low-diopter EVO Visian ICL™ surgery in Japan and presented findings from multicentre studies conducted by the Japan ICL Study Group.

Dr. Kamiya showed that the average ICL diopter power used in Japan has

steadily decreased over recent years, while the proportion of procedures performed for low-to-moderate myopia (≤6D) has risen significantly, reaching approximately 18%, notably higher than rates seen in Europe. Clinical studies demonstrated that EVO ICL implantation for low-to-moderate myopia achieved visual and safety outcomes comparable to, or slightly better than, those observed in high myopia cases (Figure 2). Compared with wavefront-guided LASIK, EVO ICL also produced fewer higher-order aberrations and improved contrast sensitivity.

Dr. Kamiya concluded that the excellent clinical outcomes and high patient satisfaction associated with EVO ICL (8) are likely to support continued expansion of low-to-moderate myopia indications in Japan.

Low to Moderate Myopia N=109*

Condition	
Iritis	0%
Infection	0%
Glare & Halo (main symptom)	4.6%
Significant Toric ICL Rotation	0%
Pigment Dispersion Syndrome	0%
Cataract (Symptomatic/Asymptomatic)	0%
Significant IOP Rise	0%
ICL Exchange:	0.9%
Reason: Incorrect Initial Size	XL
Additional Enhancement Surgery	0%

High Myopia N=589*

Condition	
Iritis	0%
Infection	0%
Glare & Halo (main symptom)	2.2%
Significant Toric ICL Rotation	0.3%
Pigment Dispersion Syndrome	0.2%
Cataract (Symptomatic/Asymptomatic)	0%
Significant IOP Rise	0%
ICL Exchange:	0.8%
Reason: Incorrect Initial Size	X2
Reason: Incorrect Initial Power	X2
Additional Enhancement Surgery	0.3%

No vision-threatening complications occurred in any case

*Unpublished data

Figure 2. 2024 APAC User Meeting_Current Situation Low Diopter in Japan

have recently had many opportunities to perform superior incisions and consider fixation locations other than vertical.

Dr. Kojima: Over 2,000 procedures. The major change in my personal surgical technique recently is that toric ICLs are not always fixed horizontally. Patient selection has also shifted toward performing surgery on patients with milder degrees of myopia.

Dr. Ouchi: I have performed approximately 2,000 ICL cases. Over the years, my surgical technique has undergone significant refinement, incorporating numerous small improvements such as precise cartridge loading, secure adjustment at the incision site, strategies to minimize inversion risk during insertion, smooth placement beneath the iris, and controlled lens rotation within the eye. As mentioned, patient selection criteria have also evolved. Currently, I advance confidently with myopic cases ranging from –3.0D to –6.0D, provided other indications are met. For patients aged 45 and older, thorough preoperative discussions regarding near vision have led to excellent postoperative satisfaction.

EVO ICL has become the first-choice refractive surgery for many surgeons in Japan. What key outcomes or patient experiences convinced you to prioritize EVO ICL over LASIK, SMILE, or other alternatives? What is your level of comfort using EVO™ in lower diopter patients (less than –6.0D)?

Dr. Fujimoto: A key advantage is that refractive correction is possible without altering the corneal shape, eliminating aberrations caused by corneal deformation.

Dr. Ichikawa: Importantly, EVO does not induce dry eye, which is one of its strongest points of appeal in comparison with laser-based procedures. The removable nature of the EVO ICL allows for postoperative adjustments even though they are rarely needed. We have

“Importantly, EVO ICL does not induce dry eye, which is one of its strongest points of appeal in comparison with laser-based procedures.”

encountered patients referred from other clinics who were concerned about delayed visual recovery after LASIK due to off-center laser application or SMILE.

Dr. Kamiya: For patients with mild to moderate myopia, ICL surgery demonstrates significantly lower increases in higher-order aberrations (particularly spherical aberration) (2) compared to LASIK, while also significantly improving contrast sensitivity. Consequently, the number of patients opting for ICL surgery is increasing.

Dr. Kitazawa: The surgical outcomes of ICL are equal to or better than those of LASIK (3–6). Moreover, as LASIK procedures increased, issues such as postoperative dry eye, halos, and glare affecting night vision, and regression of myopia became significant problems. ICL can compensate for these shortcomings (7). Patients also report high level of satisfaction after ICL surgery (8).

SMILE accounts for less than 5% of refractive surgeries in Japan and remains relatively unknown. According to the Japanese Ophthalmological Society’s refractive surgery guidelines, ICL is indicated for –3.0D and above, not –6.0D, and many patients with moderate myopia prefer ICL surgery over LASIK in Japan

(9). I have performed more than 50,000 LASIK procedures in the past, but today even my patients with moderate or mild myopia achieve greater satisfaction with ICL surgery than with LASIK. I am 100% confident in recommending ICL surgery.

Dr. Kojima: First and foremost, I believe ICL surgery was highly compatible for Japanese cataract surgeons in many ways. Many patients appreciate that ICL surgery is reversible and this is a significant advantage for their “peace of mind.”

Dr. Ouchi: I am a specialist in intraocular lenses and began my refractive surgery career with ICL. For cases around –3D or slightly less, I have observed a tendency toward mild undercorrection, and patients in this range are often less tolerant of residual myopia. Therefore, I now aim for slightly stronger correction and proceed confidently with surgery. Even for patients under –6.0D, I have never considered –3.0D or above to be problematic.

From your experience, how do Collamer’s material properties translate into clinical advantages for patients and surgeons?

Dr. Fujimoto: Collamer is softer than acrylic resin, making it less likely to cause damage even when it comes into contact with the corneal endothelium or lens epithelium. Its ease of removal and long-term stability are considered advantages.

Dr. Kamiya: The extremely soft material facilitates surgical manipulation, and its high biocompatibility reduces the risk of postoperative complications (10, 11). It also allows for ICL removal without causing adhesions. These factors contribute to enhanced safety during ICL removal and cataract surgery.

Dr. Kitazawa: I have been implanting ICLs for nearly 20 years, and I have never encountered a case where the lens had to be removed due to issues such as opacification. In contrast, hydrophilic acrylic IOLs used in cataract surgery are known to require removal because of opacification such as glistening (12).

Recently, posterior chamber phakic intraocular lenses made of hydrophilic acrylic have appeared, but their history is still short, and their long-term safety remains uncertain. In this respect, Collamer has a history of nearly 30 years and can be considered a proven safe material.

Dr. Ouchi: The material properties of Collamer provide significant clinical reassurance. The fact that postoperative ICL patients – despite possible contact with the posterior iris – do not experience pigment dispersion suggests excellent biocompatibility (10). Furthermore, its consistent behavior during insertion, from the optic zone to the haptics, offers surgeons a high level of confidence in handling.

Dr. Kojima: I believe patients still don’t fully appreciate its benefits. For surgeons, those with experience removing lenses that have been implanted for many years likely recognize their high stability leading to such safe longevity in the eye.

What are the most compelling long-term safety and stability findings from Japan’s large ICL datasets or multicenter studies that you believe set EVO ICL apart from competing technologies?

Dr. Ouchi: Extremely low explantation rates despite many millions of implantations. I am not aware of any reported cases of cataract formation due to lens touch during insertion and certainly the cataract incidence of EVO is exponentially lower than the already low incidence of the previous versions.

Dr. Kojima: Low incidence of long-term complications, such as cataracts.

Dr. Ichikawa: Maintaining improved vision and demonstrating fewer complications.

Dr. Fujimoto: The 30-year track record has been great, but, specifically since the European approval of the EVO ICL in 2011, safety and stability have further increased even further. There is no need

for a peripheral iridotomy/iridectomy, and the incidence of cataract complications has almost disappeared. With millions of procedures performed, long-term outcomes have also been confirmed.

Dr. Kamiya: Corneal endothelial damage, which was a common issue with anterior chamber lenses, is now rarely observed. Postoperative complications such as cataract associated with posterior chamber lenses have been significantly reduced. It has also become clear that postoperative regression of myopia is minimal.

Dr. Kitazawa: The ICL Study Group has published numerous papers based on multicenter study results in ophthalmology journals. These include many world-leading studies demonstrating excellent uncorrected visual acuity, high refractive accuracy, long-term stability, low complication rates, and applications such as mild myopia. In fact, in 2023, Japanese papers accounted for the highest number of citations on ICL (13) in global ophthalmology journals, contributing to the worldwide increase in ICL cases (14). Furthermore, among these are comparative studies with WFG LASIK, which have reported that ICL is superior to LASIK (10).

EVO ICL's central port design eliminated the need for preoperative iridotomy and improved aqueous flow. How has this innovation affected your surgical workflow and patient recovery?

Dr. Kitazawa: In the era before ICLs had a central port, preoperative or postoperative iridotomy or iridectomy was required, and many patients hesitated to undergo these procedures. However, with the development of the EVO ICL, an iridectomy became unnecessary, leading to a rapid increase in cases. The introduction of the central port also significantly reduced postoperative complications such as cataract and glaucoma. In fact, ICL surgery can now be performed under topical anesthesia, just like LASIK, with both eyes treated on the same day, and

patients are able to go home shortly after resting post-surgery.

Dr. Fujimoto: The elimination of preoperative treatment has reduced the burden on both patients and surgeons. Furthermore, the low rates of complications such as endothelial cell loss or cataract formation represent a significant breakthrough.

Dr. Ichikawa: The burden of monitoring multiple vault heights has eased, and the number of long-term examinations has decreased.

*“THE EVO ICL
is forgiving by
design and surgeons
express less concern
about vault
outcomes when
using the Collamer-
based EVO.”
– Scott Barnes,
MD, Chief Medical
Officer, STAAR
Surgical*

Dr. Kojima: The central port brought about a dramatic change. Until then, LI (laser iridotomy) had been a much more demanding procedure than surgery for both the practitioner and the patient.

Dr. Ouchi: I have exclusively used the central port model. In fact, its introduction was the reason I began performing ICL surgery.

How have innovations in phakic IOL technology enhanced its accuracy and widened the range of patients eligible for ICL implantation?

Dr. Ouchi: As a specialist in intraocular lenses who does not perform LASIK, my comparison has traditionally been with RLE (refractive lens exchange). For patients over 50 with high myopia seeking spectacle independence, many ophthalmologists recommend RLE due to presbyopia, and I shared that view until a few years ago. However, even without accommodative ability, the natural crystalline lens possesses unique optical properties – such as subtle aberration control – that cannot be replicated by monofocal IOLs. Removing it prematurely should not be taken lightly.

Advances in phakic IOL technology have introduced a critical alternative: using ICL as an intermediate solution rather than resorting immediately to irreversible RLE. This innovation has fundamentally changed my approach, making ICL my first choice for refractive correction in middle-aged patients without cataract.

Dr. Kamiya: The development of EVO ICL has significantly reduced the risk of complications such as pupillary block and cataracts.

Dr. Kitazawa: Since the 1990s, phakic IOL has been an excellent procedure for correcting high to extreme myopia in patients who are not candidates for LASIK. But anterior chamber phakic IOLs later became problematic due to a major complication – loss of corneal endothelial cells – which led to a global decline in cases. In contrast, the posterior chamber phakic IOL is a procedure that can be safely recommended to patients because of its low rate of endothelial cell loss and its very favorable long-term outcomes (15). ICL's indications have expanded beyond high myopia to include moderate and even mild myopia. In fact, about 20% of patients undergoing ICL surgery at our clinic have mild myopia.

What role does the ICL Study Group play in educating and training new surgeons?

Dr. Kitazawa: The ICL Study Group not only supervises certification surgeries for new surgeons seeking a license but also provides advice on cases involving indications or postoperative progress even after licensing, thereby helping improve surgeons' knowledge. The Group also organizes meetings that are open to all.

Dr. Ouchi: The Group plays a critical role in providing a high-quality educational environment for new surgeons. For those who sincerely wish to learn refractive surgery, it offers structured training and knowledge-sharing opportunities that enhance clinical standards. This open group opportunity helps to provide accountability for all surgeons as they share current and proposed practices with each other.

Dr. Fujimoto: The education and training of surgeons include instruction courses at ophthalmology conferences and STAAR Surgical's e-learning programs. After becoming a certified doctor, participating in ICL Study Group allows access to diverse perspectives from many doctors when encountering difficult or unusual cases. This system is highly effective for resolving such challenges.

Of all the findings collected by the ICL Study Group, which do you believe best reflects the long-term reliability and “forgiving” nature of EVO ICL technology?

Dr. Kitazawa: It's been more than 17 years since the ICL Study Group was established in Japan, and what is most remarkable is that, to date, we have not experienced the kind of collapse that occurred with LASIK. This reflects the daily efforts of the Group members and their commitment to promoting ICL safely and correctly in Japan.

Dr. Ouchi: The most remarkable

What One Explanted Lens Tells Us About ICL Longevity

Presenting at the 4th STAAR Surgical EVO ICL APAC Experts Summit (April 24–26, 2026), Dr. Ichikawa shared a remarkable clinical encounter: a phakic intraocular lens that had been sitting quietly inside a patient's eye for 29 years.

The case came to light during cataract surgery in Mongolia. The patient – a 51-year-old male – had undergone phakic IOL implantation in Russia nearly three decades earlier. When Dr. Ichikawa explanted the lens, what he found was striking: no deformation, no clouding, no iris inflammation. The lens was, in every meaningful sense, intact.

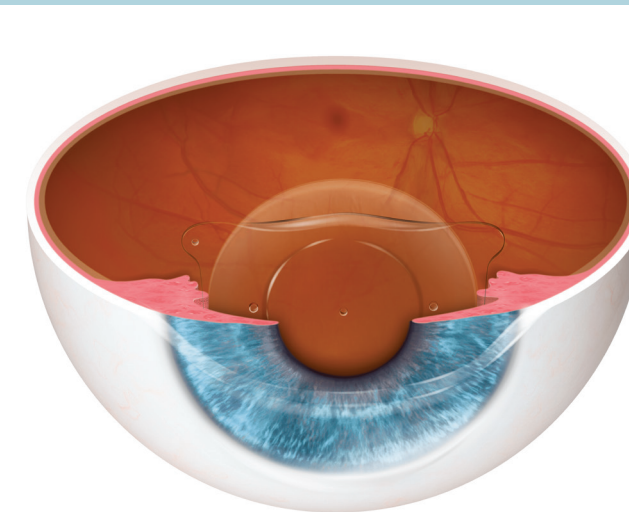
What explains that kind of longevity? Dr. Ichikawa's answer lies primarily in the material. Dr. Ichikawa noted that

Collamer is significantly more flexible than other lens materials. It is better able to absorb compressive forces within the eye over time, reducing the mechanical stress that can degrade other materials (16)

Lens geometry plays a role too. The ICL's smoother haptic-optic junction helps maintain consistent distance from the crystalline lens, appearing to mitigate the effects of transverse compression load – an important factor in long-term in-eye performance.

Further, Dr. Ichikawa investigated fibronectin adhesion. Fibronectin – a glycoprotein involved in tissue adhesion – accumulated more on ICL surfaces than on implantable phakic contact lenses, forming a membranous layer on the haptics and iris contact areas. He added that this fibronectin coating may reduce foreign body reaction, increasing the biocompatibility with the surrounding ocular tissue over time.

Taken together – material flexibility, favorable geometry, and fibronectin-mediated biocompatibility – these factors offer a compelling explanation for nearly three decades of stable in-eye performance.



“Collamer has a history of nearly 30 years and can be considered a proven safe material.”

findings from the Study Group are the consistently excellent postoperative uncorrected visual acuity and the extremely low incidence of patient dissatisfaction. Also, the ability to treat mild keratoconus cases represents a significant advantage over corneal ablative procedures such as LASIK.

Dr. Fujimoto: All participating facilities can approach daily treatment more safely by proactively learning, asking questions, and sharing information whenever complications arise.

Dr. Ichikawa: It was demonstrated that postoperative astigmatism lens rotation is not correlated with vault (16).

What areas of future research do you see as most critical for continuing the global expansion and credibility of EVO ICL?

Dr. Kitazawa: Currently, there are many published studies reporting long-term outcomes of ICL exceeding 10 years, but we look forward to even longer-term clinical follow-up being reported in the future. Another challenge is the distance between the lens and the crystalline lens, known as the vault. I believe that improvements in lens size selection methods, AI-based size recommendations, and possibly an increase in the number of lens sizes could further enhance safety.

Dr. Fujimoto: The three points are important: 1) the stability of long-term outcomes; 2) the incidence of complications; 3) future solutions for



patients with presbyopia.

Dr. Kojima: Long-term outcomes of vault and its effects on the anterior chamber angle (including pigment deposition).

Dr. Ouchi: I believe we should collect data on patient satisfaction and immediate postoperative feedback, even if only through survey-based methods.

Conclusion

The discussion here shows how EVO ICL combines strong visual performance, long-term protection of ocular structures, and a clinically proven safety profile. Across nearly two decades of clinical

experience, EVO ICL has shown consistently high patient satisfaction (8), stable long-term outcomes, and reversibility, while preserving corneal tissue and avoiding many of the postoperative concerns associated with corneal refractive procedures.

The discussion also highlights the unique role of Collamer, STAAR Surgical’s proprietary biocompatible material, which underpins EVO ICL’s long-term safety profile and contributes to the procedure’s reputation for visual quality beyond 20/20. For many surgeons in Japan, the combination of corneal preservation, optical performance,

rotational stability, and sustained patient satisfaction has reinforced the reputation of EVO ICL as a refractive procedure.

Japan’s extensive multicenter data sets provide compelling global evidence of durability, low complication rates, and sustained visual performance. Moreover, the Japan ICL Study Working Group has succeeded in building a foundation of trust in ICL at a time when confidence in refractive surgery had been shaken by LASIK-related complications – further establishing EVO ICL as a global leader in phakic IOLs.

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Important Safety Information for the EVO Visian ICL Product Family (US)

The EVO Visian ICL is indicated for phakic patients 21–60 years of age to correct/reduce myopia with up to 4.00 D of astigmatism with a spherical equivalent ranging from –3.00 to –20.0 D and with an anterior chamber depth (ACD) 3.0 mm or greater.

The EVO Visian ICL is contraindicated in patients with a true ACD of <3.00mm; with anterior chamber angle less than Grade III; who have moderate to severe glaucoma, who are pregnant or nursing; less than 21 years of age; and who do not meet the minimum endothelial

cell density (ECD) listed in the Directions For Use (DFU).

A summary of the relevant warnings, precautions and side effects: Endothelial cell loss, corneal edema, cataract, narrowing of the anterior chamber angle, pupillary block, increased intraocular pressure, glaucoma, secondary surgery to reposition, replace or remove the ICL, loss of BSCVA, increase in refractive astigmatism, glare and/or halos, pigment dispersion, iris transillumination defects, endophthalmitis, hypopyon, corneal endothelial damage, ICL dislocation, cystoid macular edema, iritis, retinal detachment, vitritis, and iris prolapse.

Please review the DFU available at <https://edfu.staar.com/edfu/> for complete safety and other information before performing the clinical procedure.

Important Safety Information for EVO/EVO+ ICL (EU)

The EVO/EVO+ ICL is indicated for phakic patients 21–60 years of age and pseudophakic patients 21 years and older to correct/reduce myopia up to –20.0 D with up to 6.0 D of astigmatism. Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/ benefit ratio before implanting a lens in a patient with any of the conditions described in the DFU. Prior to surgery, physicians should inform prospective patients of possible risks and benefits associated with the EVO/EVO+ ICL. Reference the EVO/ EVO+ ICL DFU available at <https://edfu.staar.com/edfu/> for a complete listing of indications, contraindications, warnings and precautions.

EU-EVO ICL-26-0046

