
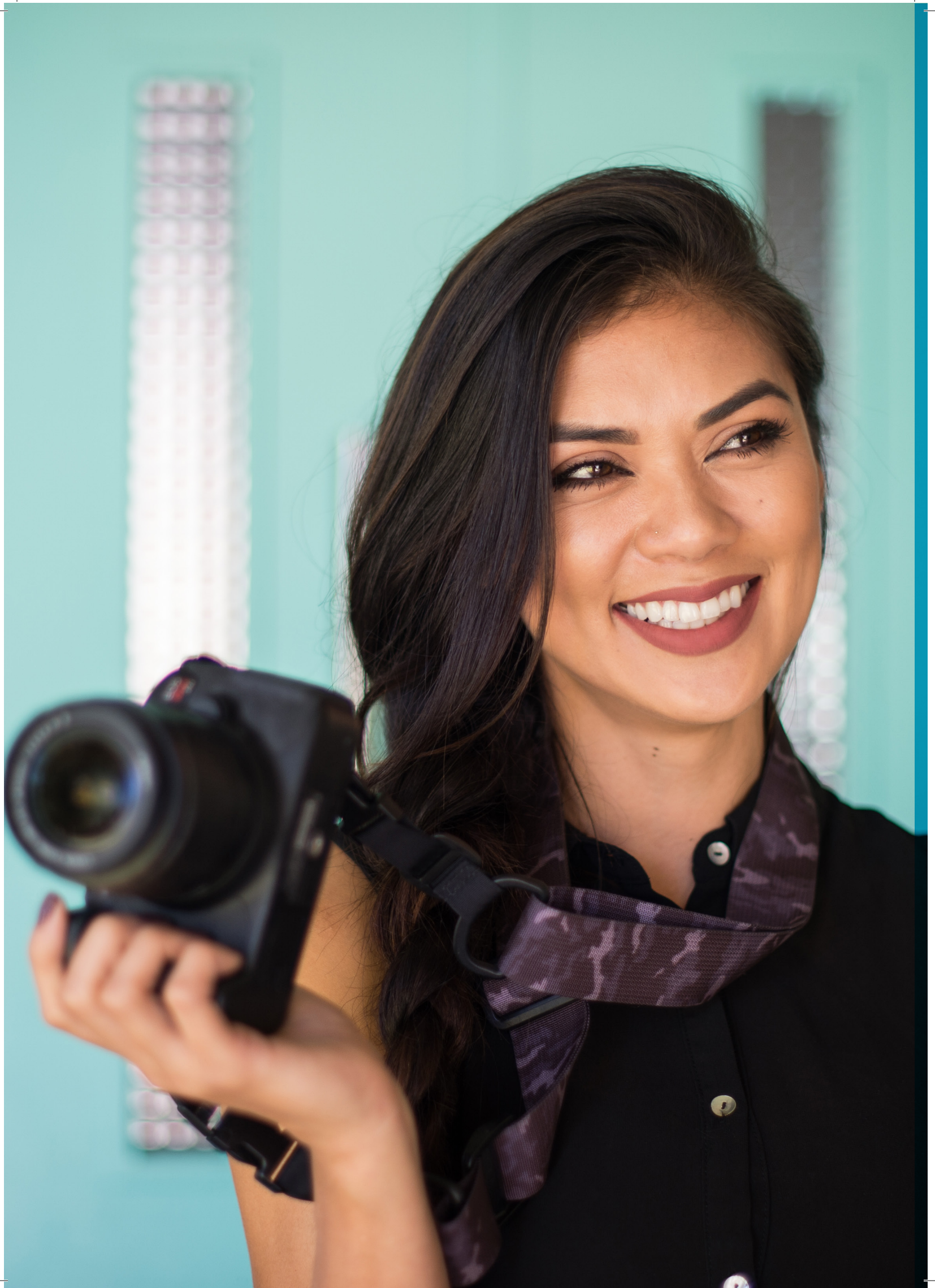



EVO+

Visian ICL[®]

Evolution in Visual Freedom.[™]

 STAAR SURGICAL[™]





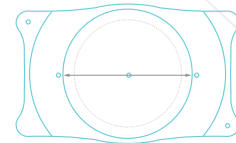
The EVO+ Visian ICL is an evolution in vision correction developed for patients with larger pupils including younger patients. Based on the proven EVO Visian ICL platform (formerly CentraFLOW™ V4c), EVO+ Visian ICL features an expanded optic (5.0 mm - 6.1 mm). EVO+ Visian ICL is designed to achieve a higher level of vision performance.¹



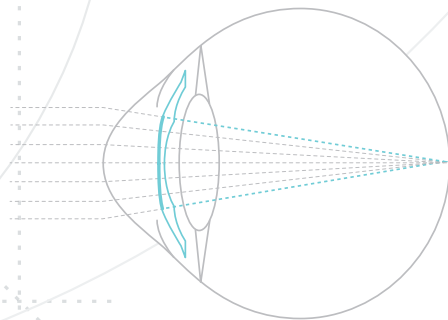
EVO+ Visian ICL[®] Optics

The new EVO+ Visian ICL[®] Expanded Optical Zone
Optic is an evolution in vision correction.

Expanded Optical Zone Optic Larger True Optical Zone



- EVO+'s larger optical zone may provide benefit to patients with expanded pupils (such as night driving)¹

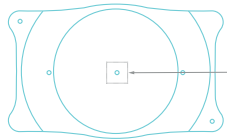


- May reduce risk of halos and glare¹
- Available from -0.5 D to -14.0 D



Aqueous Flow Through Central Port

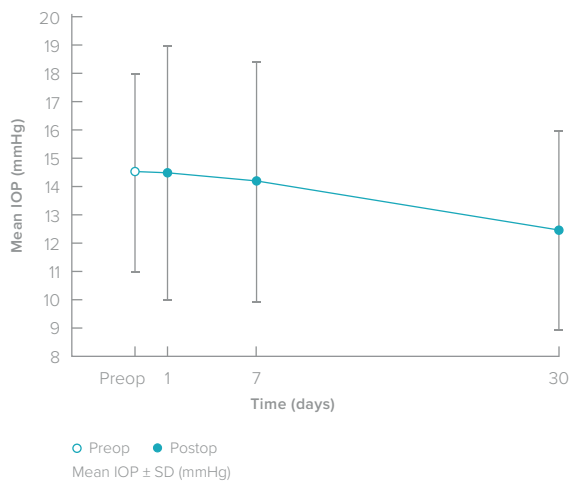
Eliminates PIs and restores a more natural aqueous flow²



- Eliminates the need for PIs; increasing the efficiency for both the surgeon and patient²
- Enhanced convenience and comfort for the patient
- Restores a more natural aqueous flow²
- Facilitates OVD removal
- Superb quality of vision³

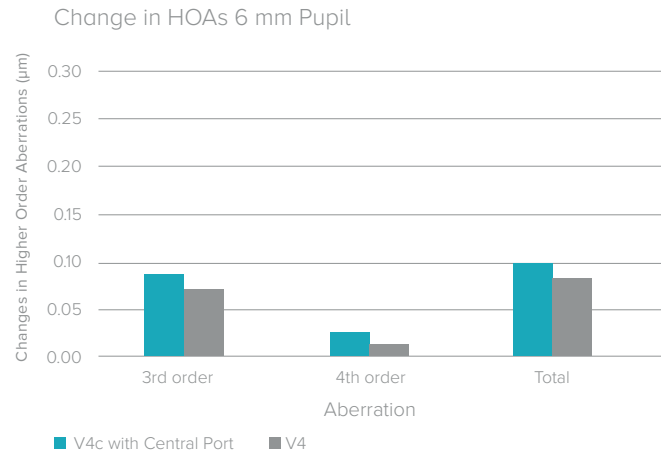
IOP Stability³

No significant changes in IOP overtime were detected after implantation

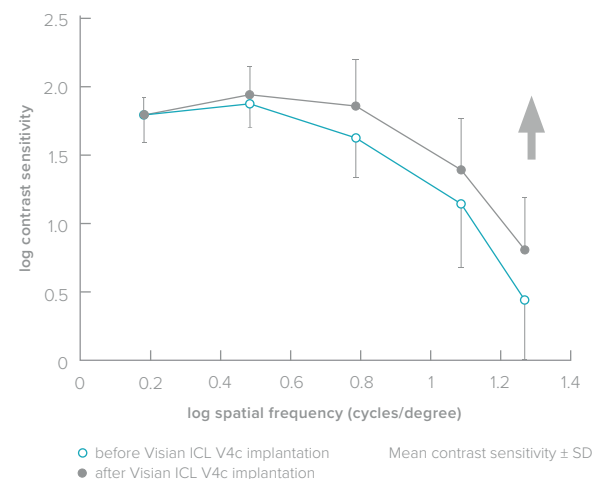
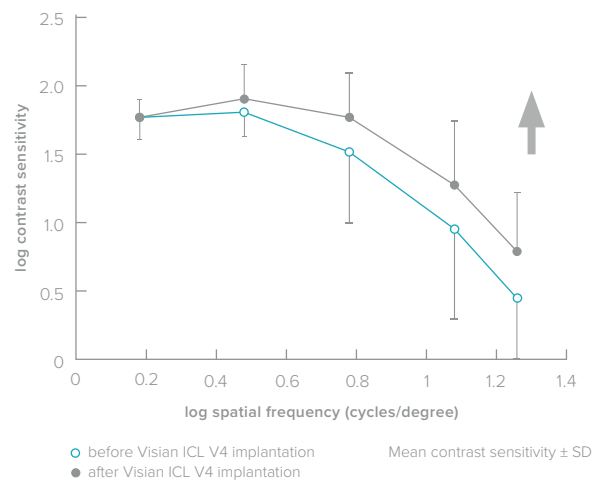


Superb Quality of Vision⁴

Very low induction of higher order aberrations⁴



Significant increase in contrast sensitivity with the Visian ICL and Visian ICL V4c with Central Port⁴



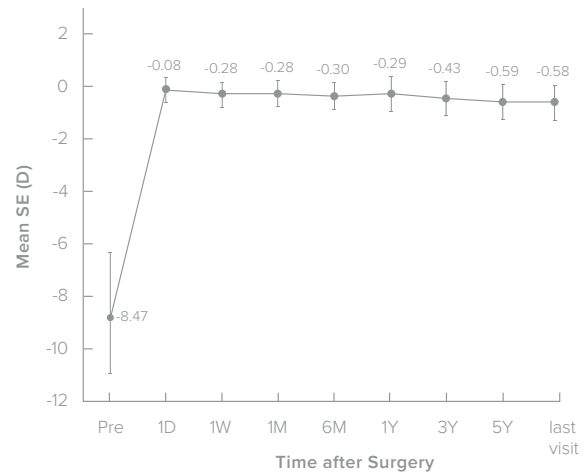


Proven Long Term Results

For more than 20 years, the Visian ICL family has continued to provide exceptional vision with more than 550,000 lenses implanted worldwide.*

Stability

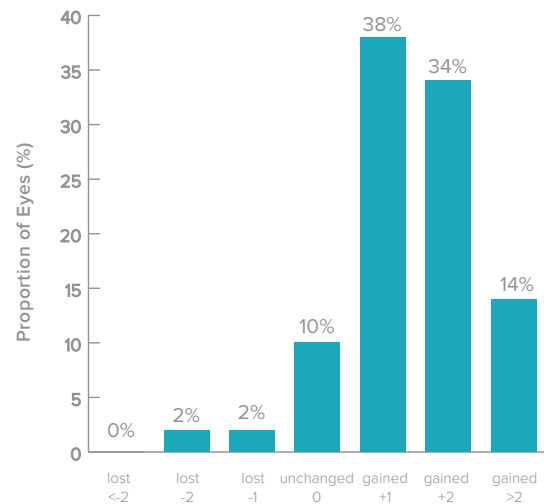
Time course of spherical equivalent up to 9 years postop Visian ICL⁵



- High levels of predictability were achieved early after surgery and maintained nine years postop

Safety

Change in CDVA (lines) 5 Years Post-op with the Visian ICL⁶



- 96% of eyes achieved the same or better UDVA as their preoperative CDVA

* Data as of December 2015

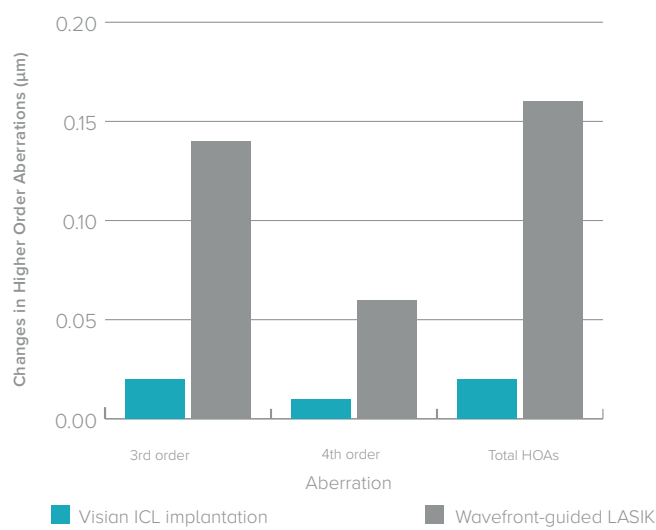


Exceptional Vision Quality

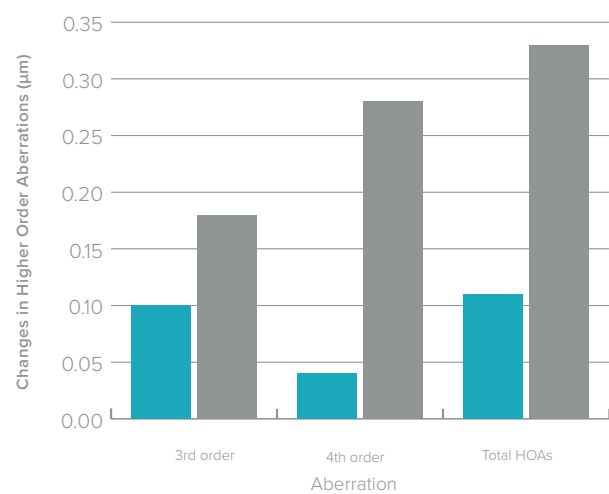
Visian ICL advanced lens technology with a unique lens material provides a superior vision performance.⁷

Visual Performance of the Visian ICL versus Wavefront-Guided LASIK for Low to Moderate Myopia⁷

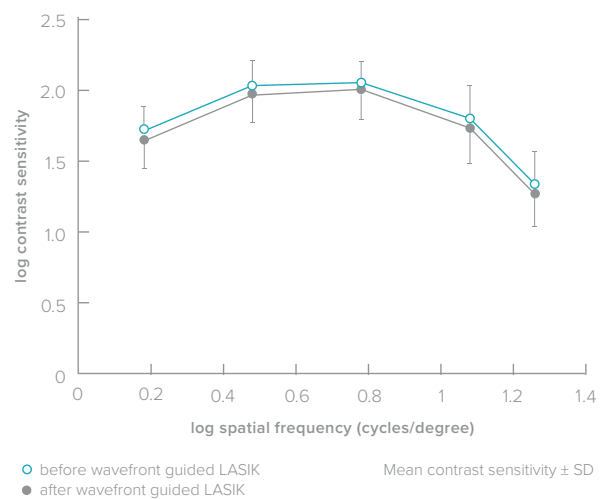
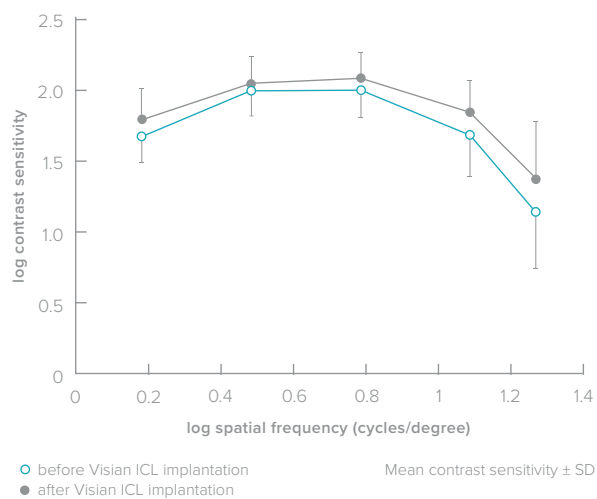
Change in HOAs 4 mm Pupil



Change in HOAs 6 mm Pupil



Visian ICL induces significantly fewer higher order aberrations than wavefront-guided LASIK⁷



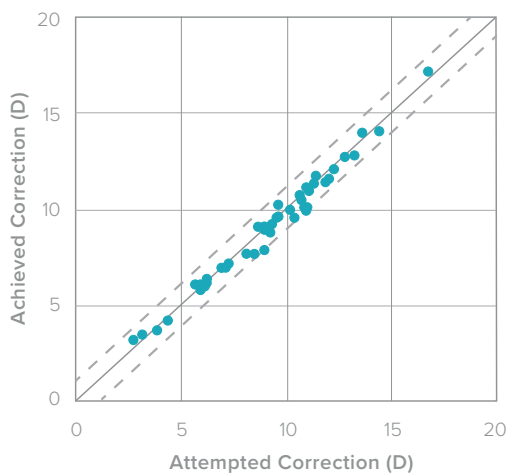
Visian ICL outperforms wavefront-guided LASIK delivering improved contrast sensitivity⁷



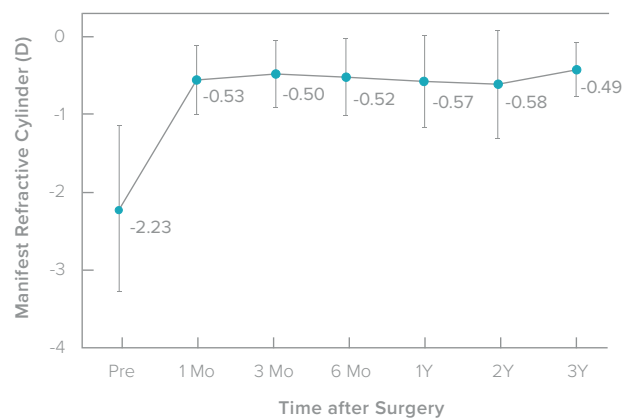
Proven Predictability and Stability of the Visian Toric ICL

Clinical studies have shown the Visian Toric ICL has excellent predictability and stability for the correction of moderate to high myopic astigmatism⁸

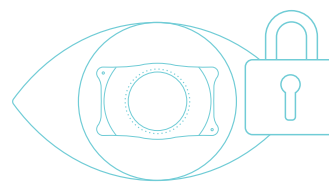
Predictability – Manifest refraction spherical equivalent (MRSE) attempted versus achieved correction with the Visian Toric ICL⁸



Stability – Time course of manifest refractive cylinder after Visian Toric ICL implantation⁸



- 82% of eyes were within 0.5 D of expected MRSE
- 98% of eyes were within 1.0 D of expected MRSE (indicated)



Excellent Rotational Stability for Precise Astigmatism Correction

- 92% of eyes implanted with the Visian Toric ICL had a change in axis of $\leq 10^\circ$ ⁹
- 87% of eyes implanted with the Visian Toric ICL had a change in axis of $\leq 5^\circ$ ⁹
- Only one eye (0.47%) needed to be repositioned due to misalignment⁹





Designed to Satisfy Patients

Preserving the integrity of the cornea provides advantages today and for the future.

Treatment options for the future

- The Visian ICL is an additive procedure that can easily be removed. There is no permanent removal of corneal tissue
- More accurate biometry may be achieved because the Visian ICL does not remove corneal tissue. This may result in more predictable future IOL calculations which may potentially avoid refractive surprises¹⁰
- The Visian ICL refractive procedure allows for future surgical interventions including corneal based treatments

Placement is safe and discreet

- The lens is positioned for stability in the sulcus, behind the iris and in front of the crystalline lens
- The placement of the Visian ICL provides a safe distance between the corneal endothelium and the lens

Exceptional patient satisfaction rate that's over 99%¹¹

- Short procedure time in an outpatient setting, small incision and sutureless surgery, a "WOW" factor of vision, no induction of dry eye¹² and quick patient recovery create an exceptional patient experience
- High patient satisfaction leads to a high patient referral potential. New patient referrals are the number one practice building method

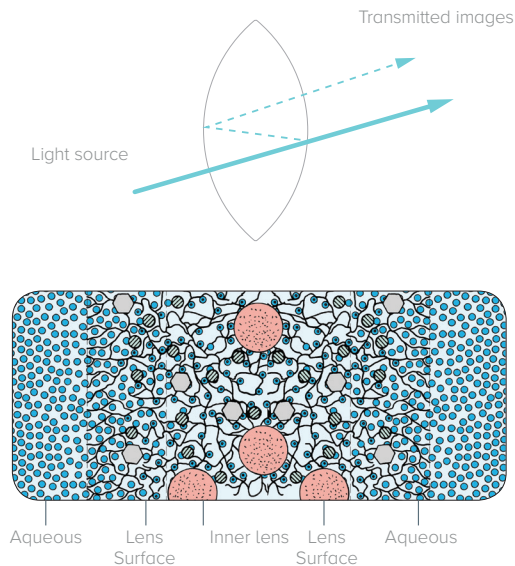
Higher Satisfaction Rates for Phakic IOLs versus LASIK¹³

- In a recent study comparing excimer laser refractive surgery versus phakic intraocular lenses, phakic IOLs scored more highly on the patient satisfaction preference questionnaire¹³



A Proven Visual Performance^{14,15}

A proprietary lens material composition of collagen and co-polymer—setting a new standard in IOLs.

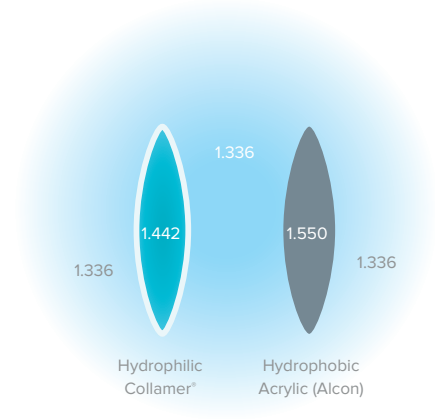


Hydrophilic Collamer® Features Anti-Reflectance Properties¹⁸

- The risk of dysphotopsia due to internal reflections increases as light passes through materials with more greatly differing refractive indexes (RI)^{19,20}
- The hydrophilic nature of Collamer® promotes a high water content (40%) in the lens minimizing the difference in RI between the lens and aqueous of the eye
- The RI of Collamer® minimizes reflections and may contribute to a lower potential for dysphotopsia

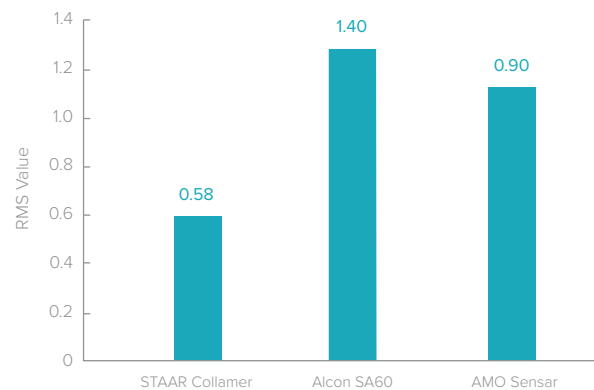
Hydrophilic Collamer® Water Concentration

| | % Water Content | Refractive Index | Difference in Refractive Index Len vs Aqueous |
|--|-----------------|---------------------|---|
| Hydrophobic Acrylic AcrySof® IOL (Alcon) | 0% | 1.55 ²¹ | 0.214 |
| Collamer® | 40% | 1.442 ¹⁴ | 0.106 |
| Aqueous | >99% | 1.336 | - |



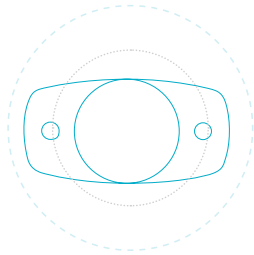
- Competitive lenses were associated with higher order aberrations between 110% and 140% greater than the Collamer® lens at both one week and one month postoperatively¹⁶

Postoperative Total Higher Order Aberrations¹⁶



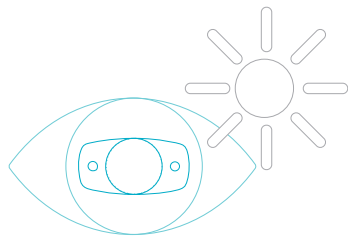


Collamer® Provides a “Quiet Eye,” UV Light Protection, and Years of Proven Experience



Highly Biocompatible Collamer® Inhibits Inflammatory Responses to Achieve a Postop Quiet Eye ^{15,17}

- The unique properties of Collamer® minimize inflammation, flare and cellular reaction^{15,17}



Offers UV Protection

- The Collamer® material is bonded with UV absorbing chromophore into a poly-HEMA based copolymer that offers UV protection¹⁵

A Proven Performance

- Collamer® is exclusive to STAAR. It has a proven history for over 20 years with more than 1 million lens implants worldwide

Indications

- The EVO Visian ICL is indicated for use in phakic eye treatment in adults 21- 45 years of age for:
- The correction/reduction of myopia in adults ranging from -0.5 D to -20.0 D at the spectacle plane
- With an anterior chamber depth (ACD) equal to or greater than 3.0 mm, as measured from the corneal endothelium to the anterior lens capsule



Spherical Lenses

| Diopter | Current Optical Diameter (mm) | EVO+ Optical Diameter (mm) | Approximate Equivalent OZ at Corneal Plane ^{22,23} (mm) |
|----------------|-------------------------------|----------------------------|--|
| -0.5 to -9.0 | 5.8 | 6.1 | 7.6 |
| -9.5 to -10.0 | 5.5 | 5.9 - 6.1 | 7.4 - 7.6 |
| -10.5 to -12.5 | 5.3 | 5.3 - 5.8 | 6.6 - 7.3 |
| -13.0 to -14.0 | 4.9 | 5.0 - 5.2 | 6.3 - 6.5 |
| -14.5 to -18.0 | 4.9 | N/A | 6.1 |
| +0.5 to +10.0* | 5.8 | N/A | 7.3 |

Available in 0.25 D increments from -0.5 D to -3.0 D and 0.5 D increments from -3.0 D to -18.0 D

*The Hyperopic Model is not EVO and has no central port in the optic. Data in this brochure relates to the myopic and toric myopic versions. For information on the hyperopic range, please contact STAAR Surgical

Lens lengths: **11.6 mm / 12.1 mm / 12.6 mm / 13.2 mm / ***13.7 mm
 ** Available only in the Hyperopic Model
 *** Available only in the Myopic Model

Toric Lenses

| Diopter | Cylinder | Current Optical Diameter (mm) | EVO+ Optical Diameter (mm) | Approximate Equivalent OZ at Corneal Plane ^{22,23} (mm) |
|----------------|--------------|-------------------------------|----------------------------|--|
| -0.5 to -9.0 | +0.5 to +6.0 | 5.8 | 6.1 | 7.6 |
| -9.5 to -10.0 | +0.5 to +6.0 | 5.5 | 5.9 - 6.1 | 7.4 - 7.6 |
| -10.5 to -12.5 | +0.5 to +6.0 | 5.3 | 5.3 - 5.8 | 6.6 - 7.3 |
| -13.0 to -14.0 | +0.5 to +6.0 | 4.9 | 5.0 - 5.2 | 6.3 - 6.5 |
| -14.5 to -18.0 | +0.5 to +6.0 | 4.9 | N/A | 6.1 |
| +0.0 to 10.0* | +0.5 to +6.0 | 5.8 | N/A | 7.3 |

Available in 0.5 D increments

*The Hyperopic Model is not EVO and has no central port in the optic. Data in this brochure relates to the myopic and toric myopic versions. For information on the hyperopic range, please contact STAAR Surgical

Lens lengths: **11.6 mm / 12.1 mm / 12.6 mm / 13.2 mm / ***13.7 mm
 ** Available only in the Hyperopic Model
 *** Available only in the Myopic Model

References

- Domínguez-Vicent A, Esteve-Taboada J, Ferrer-Blasco T, Montes-Mico R, Perez-Vives C. Optical quality comparison between 2 collagen copolymer posterior chamber phakic intraocular lens designs. *J Cataract Refract Surg* 2015; 41:1268-1278
- Alfonso JF, Lisa C, Fernández-Vega Cueto L, Belda-Salmerón L, Madrid-Costa D, Montés-Micó R. Clinical outcomes after implantation of a posterior chamber collagen copolymer phakic intraocular lens with a central hole for myopic correction. *J Cataract Refract Surg*. 2013 Jun;39(6):915-21
- Intraocular Pressure during the Early Postoperative Period after 100 Consecutive Implantations of Posterior Chamber Phakic Intraocular Lenses with a Central Hole By F. González-Lopez et al. *J Cataract Refract Surg* 2013 Dec;39(12):1859-63
- Intraocular Comparison Of Visual Performance After Posterior Chamber Phakic Intraocular Lens With And Without A Central Hole Implantation For Moderate To High Myopia By K.Shimizu, K.Kamiya, A. Igarashi, K.Shimizu, and T.Shiratori. *Am J Ophthalmol* 2012.Sep;154(3):486-494.e1.
- Long-term clinical results of posterior chamber phakic intraocular lens implantation to correct myopia. J.S. Lee, *Clin Experiment Ophthalmol*. 2015 Dec 12. doi: 10.1111/ceo.12691.
- Alfonso J, Baamonde B, Fernandez-Vega L, Fernandes P, Gonzalez-Mejome J, Montes-Mico R. Posterior Chamber Collagen Copolymer Phakic Intraocular Lenses to Correct Myopia: Five Year Follow-Up. *J Cataract Refract Surg* 2011;37:873-880.
- Kamiya K, Igarashi A, Shimizu K, Matsumura K, Komatsu M. Visual Performance After Posterior Chamber Phakic Intraocular Lens Implantation and Wavefront-Guided Laser In Situ Keratomileusis for Low to Moderate Myopia. *Am J Ophthalmol*. 2012;153:1178-1186.
- Kamiya K, Shimizu K, Igarashi A, Komatsu M. Three-year follow-up of posterior chamber toric phakic intraocular lens implantation for moderate to high myopic astigmatism. *PLoS One* 2013;8(2):e56453.
- D.R.Sanders et al. Toric Implantable Collamer Lens for moderate to High Myopic Astigmatism. *Ophthalmology* 2007;114:54-61
- Ravi H. Patel, MD; Carol L. Karp, MD; Sonia H. Yoo, MD; Guillermo Amescua, MD; Anat Galor, MD, MSPH, *Cataract Surgery After Refractive Surgery*. *Int Ophthalmol Clin*. 2016;56(2):171-182.
- UV-absorbing collamer implantable contact lens (ICL) for the correction of myopia. PMA# P030016. Presentation to the Ophthalmic Devices Advisory Panel. October 2003.
- Naves, J.S. Carracedo, G. Cacho-Babillo, I. Diadenosine Nucleotid Measurements as Dry-Eye Score in Patients After LASIK and ICL Surgery. Presented at American Society of Cataract and Refractive Surgery (ASCRS) 2012.
- Barsam A. Excimer laser refractive surgery versus phakic intraocular lenses for the correction of moderate to high myopia (Review). *The Cochrane Collaboration* 2012;10.
- Collamer Ultraviolet-Absorbing Posterior Chamber Single-Piece Foldable Intraocular Lens (Directions for use) STAAR Surgical.
- Brown DC1, Ziemba SL; Collamer IOL FDA Study Group. Collamer intraocular lens: clinical results from the US FDA core study. *J Cataract Refract Surg*. 2001 Jun;27(6):833-40.
- Martin R, Sanders D. A comparison of higher order aberrations following implantation of four foldable intraocular lens designs. *J Refract Surg*. 2005; 21(6):716-21.
- Schild G, Amon M, Abela-Formanek C, et al. Uveal and capsular biocompatibility of a single-piece, sharp-edged hydrophilic acrylic intraocular lens with collagen (Collamer): 1-year results. *J Cataract Refract Surg*. 2004 Jun;30(6):1254-8.
- N. A. Peppas. *Hydrogels in Medicine and Pharmacy Volume 1: Fundamentals*. Boca Raton, Florida. CRC Press Inc. 1986.
- Radford S, BM, BCh, Carlsson A, MD, FRCS, Barrett G, FRACS, FRACO. Comparison of pseudophakic dysphotopsia with Akreos Adapt and SN60-AT intraocular lenses. *J Cataract Refract Surg*. 2007;33(1):88-93.
- Tester R, Pace NI, Samore M, et al. Dysphotopsia in phakic and pseudophakic patients: Incidence in relation to intraocular lens type. *J Cataract Refract Surg*. 2000;26:810-816.
- AcrySof® IQ IOL Directions for Use. Alcon.
- Allió JL, Perez-Santonja JJ. *Refractive Surgery with Phakic IOLs: Fundamentals and Clinical Practice*. New Delhi, India. Jaypee Brothers Medical Publishers Ltd. 2013.
- Lovisolio CF, Pesando PM. *The Implantable Contact Lens (ICL) and Other Phakic IOLs*. Canelli, Italy:Fabione Editore s.r.l. 1999.

ATTENTION: Reference the EVO and EVO+ Visian ICL Product Information for a complete listing of indications, warnings and precautions.

For more information, please visit www.staar.com or contact STAAR Customer Service at customerservice@staarag.ch



©2016 STAAR Surgical Company
10000965 Rev A

STAAR Surgical AG
Hauptstrasse 104
CH - 2560 Nidau / Switzerland

www.staar.com
www.DiscoverEVO.com

