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• Rate of ASO/

cataract less than 2%

• 43% of eyes gain 1 line

or more of BCVA

5 year follow-up report of 335 eyes from the post approval study to the original PMA study for myopia<sup>2</sup>

Visian ICL Adverse Events

Clinically Significant Anterior Subcapsular Opacities (ASO)

Cataract Extraction

Glaucoma

**Retinal Detachment** 

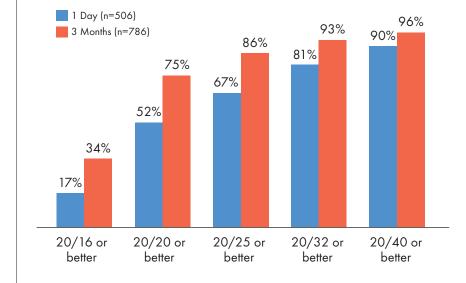
Remove or Replace

### 95% of Eyes with BCVA the Same or Better Than Pre-Op<sup>1</sup>

Change in BCVA (n=3,494)



WOW Vision at Day 1 That Improves at 3 Months<sup>1</sup> UCVA at 1 Day and 3 Months Percentage of cumulative eyes with pre-op sphere -3D to -15D with cylinder up to 0.75 D



## 74% Achieved Their Best Vision Ever<sup>1</sup> UCVA the same or better than pre-op BCVA (n= 2,164) Percentage of eyes with UCVA measured at 1, 2, 3 or 6 month Post-Op visit Average UCVA 20/25 • 78% with UCVA of 20/40 Better: 26% or better 26% Same: 48% Same/Better Worse

• 26% with UCVA better than pre-op BCVA

• 90% with UCVA 20/40

•75% with UCVA 20/20

• 34% with UCVA 20/16

at 1 day

at 3 months

at 3 months





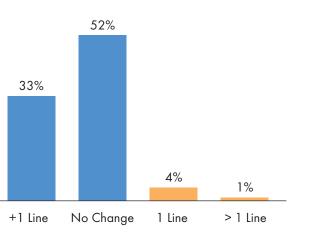
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### Very Consistent Low Incidence Rates

	Cumulative Incidence Rates	Comments
l Ir	1.52%	Vast majority first noted within 6 months of surgery-surgically induced
	2.09%	Higher than clinically significant ASO because 2 of the 8 were nuclear sclerotic
	1.33%	The incidence of glaucoma is two to three times higher for myopia. In a cohort aged 21 – 45 with myopia the expected average rate would be around 1.5% <sup>3</sup>
	0.57%	Estimates of retinal detachment risk in the un-operated highly myopic population vary from 0.4% to 0.68% <sup>4</sup>
		The incidence of retinal detachment in myopic eyes following clear lens extraction has been reported at over 8% after 7 years <sup>5</sup>
	1.71%	Rates of less than 1% seen in post market complaints <sup>6</sup>

Cumulative incidence rates calculated using a Kaplan-Meier methodology over 7+ years

All eyes with BCVA measured at 1, 2, 3 or 6 month Post-Op visit



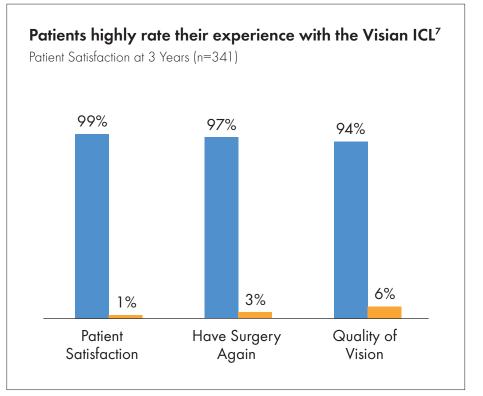
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# The Visian ICL provides unrivaled patient satisfaction

- 99% of patients were satisfied with their results
- 97% of patients would be willing to have the procedure again
- 94% of patients rate their quality of vision as excellent to good



References

- 1. Data on File. STAAR Surgical. Post-op Outcome Database.
- 2. Data on file. STAAR Surgical. 5 Year Follow-Up Report to the PMA Study for Myopia.
- Mitchell P, Hourihan F, Sandbach J, Wang JJ. The relationship between glaucoma and myopia: the Blue Mountains Eye Study. Ophthalmology 1999 Oct; 106(10):2010-5
- Burton TC. The influence of refractive error and lattice degeneration on the incidence of retinal detachment. Trans Am Ophthalmol Soc 1990;87:143-55
- Colin J. Retinal detachment after clear lens extraction for high myopia seven-year follow-up. Ophthalmology 2001 Feb; 108(2):239
- Data on file. STAAR Surgical. Post Market Surveillance Complaints Database. 2008 -2010.
- UV-absorbing collarmer implantable contact lens (ICL) for the correction of myopia. PMA# P030016. Presentation to the Ophthalmic Devices Advisory Panel. October 2003.

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