

Refractive outcomes of the implantable collamer lens for low to moderate myopia.

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Historically, the implantable collamer lens (ICL) has been used for the treatment of moderate to high myopia as the efficacy or suitability of laser in situ keratomileusis decreases. Theoretical comparisons of LASIK and ICL implantation for high refractive error indicate better optical and visual quality after ICL implantation.¹ Comparisons of LASIK and ICL implantation for high myopia indicate essentially equivalent refractive outcomes.² A recent comparison of wavefront guided LASIK and ICL implantation in high myopes indicated better visual performance in eyes that underwent ICL implantation.

However, low to moderate myopes may be candidates for ICL implantation due to pupil size, inadequate tissue volume for LASIK or they may have a personal preference for a reversible procedure (ICL implantation) versus a permanent procedure (LASIK). The Visian Implantable Collamer Lens (ICL) (STAAR Surgical Co., Monrovia, CA, USA) was granted approval by the United States Food and Drug Administration (FDA) in late 2005 for spherical myopia of -3.00 to

-20.00 D. In the current study, we investigated the refractive outcomes and complications of ICL implantation in low to moderate myopes.

METHODS

This retrospective chart review was performed of 56 patients (104 eyes) consecutive patients with low to moderate myopia who underwent ICL implantation by one surgeon (PJD). Inclusion criteria were age between 21 and 45 years old, myopia between -2.50 to -10.00 D (spherical equivalent), cylinder up to -5 D, no preexisting ocular pathology, no previous surgery, no systemic disease, contact lens intolerance, anterior chamber depth (ACD) of 2.80 mm or more (measured from the corneal endothelium to the anterior lens capsule), and endothelial cell count greater than 2000 cells/mm².

Comment [EE1]: Is this correct?

A thorough ophthalmic examination was performed included distance uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) using a Snellen chart, manifest and cycloplegic refractions, corneal topography, central pachymetry, applanation tonometry, horizontal corneal diameter (white-to-white), slit lamp biomicroscopy, anterior chamber depth (ACD), funduscopy and corneal endothelial cell count (cells/mm²). Examinations were performed preoperatively and postoperatively at 4 hours, 1 day and 1, 3, 6 months, 12 months and yearly thereafter. All eyes were targeted for emmetropia except for one patient who requested monovision and was targeted for -0.75 D in one eye.

Comment [EE2]: Correct? This is patient Chemei Fregoso on the excel spreadsheet. Did you remove this patient from analysis?

The ICL is a plate-haptic single-piece lens designed for implantation in the posterior chamber. It is made of collamer, a flexible, hydrophilic material derived from collagen that is a copolymer comprising hydrophilic collagen and HEMA. The lens has a central convex–concave optic zone with a diameter of 4.5 to 5.5 mm, depending on dioptric power. The ICL is 6.0 mm wide and comes in diameters of 11.0, 11.5, 12.0, 12.5, and 13.0 mm. In the current study, all patients underwent implantation of the ICM V3 model. Lens power calculations were performed based formulas supplied by the manufacturer.

Statistical Analysis

Data were collected on visual acuity, refractive outcomes and complication at any postoperative time period. Visual acuity data were converted to LogMAR values for statistical analysis. Data are presented for the preoperative visit and the last postoperative visit. The mean and standard deviation value are presented here. Statistical analysis was performed with Excel (Microsoft Corp., Redmond, WA, USA).

RESULTS

The preoperative spherical equivalent was -6.96 ± 1.60 D and the preoperative cylinder was -1.03 ± 0.88 D. The mean preoperative CDVA was 20/20 (range, 20/15 to 20/80). The last postoperative visit ranged from 2 months postoperatively to 50 months postoperatively (mean 13.12 ± 14.06 months).

At the last postoperative visit, the spherical equivalent was -0.08 ± 0.01 D and the cylinder was 0.29 ± 0.71 D (Figure 1). The mean postoperative CDVA was 20/20 (range, 20/15 to 20/80) (Figure 2). The refracting technician mistakenly neglected to record the CDVA of 1 patient (2 eyes).

Postoperative UDVA is presented in figure 3. Comparison of postoperative UDVA to preoperative CDVA indicated 27 eyes had better postoperative UDVA and 61 eyes had UDVA equivalent to the preoperative CDVA. Postoperatively, four eyes lost 1 line of CDVA and no eyes lost more than one line of CDVA (Figure 4).

Comment [EE3]: Were the rest worse than preop CDVA or UDVA was not recorded?

There were 32 eyes that gained at least 1 or more lines of CDVA and no eyes gained greater than 2 lines of CDVA (Figure 4).

There were no intraoperative complications. Postoperatively 3 patients (6 eyes) had dry eye, 2 with mild symptoms and 1 with moderate symptoms. All three patients were managed with topical lubricant therapy. One patient (2 eyes) reported unclear vision despite Snellen acuity of 20/20. One patient complained of halos at night in one eye only and was managed with pilocarpine as required.

DISCUSSION

The outcomes of this study of the ICL for low to moderate myopia indicate that the ICL is an effective treatment for correction in the range that is normally reserved for LASIK. The postoperative UDVA was better than preoperative BCVA in 30% (27 of 88) of eyes and equivalent in the remaining eyes. This outcome indicates excellent efficacy of ICL implantation. We found that fast

Comment [EE4]: Change based on PJD's answer to comment above.

visual recovery, usually within 5 days in most cases that remained stable over the postoperative period.

In the current study, 96% of eyes were within ± 0.50 D of emmetropia. This outcome better than the outcomes reported for the treatment of low myopia with the ICL and similar to recent studies of wavefront guided and wavefront optimized LASIK. For example Sanders and Vukich⁴ reported that 79% of eyes with preoperative spherical equivalent between -4 to -7.88 D were within ± 0.50 D after ICL implantation. Differing enrollment criteria or using data from multiple surgeons in the Sanders and Vukich⁴ study may explain the difference between studies. The outcomes of the current study are similar to. A recent study of aspheric LASIK reported 87% of eyes within ± 0.50 D.⁵ A meta-analysis of wavefront guided LASIK by Fares et al indicated 91.8% of eyes were within ± 0.50 D.⁶ The accuracy in our study indicates that ICL patients may not require enhancement with laser in situ keratomileusis or photorefractive keratectomy to achieve the targeted refraction.

Postoperative CDVA in the current study was well within the range reported for ICL and LASIK. A multisite FDA study of the toric ICL for myopic astigmatism reported 97% of eyes with 20/20 or better CDVA at 12 months postoperatively.⁷ This is similar to our result of 97% of eyes with CDVA of 20/20 or better at last visit. A recent comparison of aspheric, wavefront optimized or wavefront guided

LASIK with three excimer laser platforms reported mean CDVA ranging from approximately 20/40 to 20/20.⁸ Similarly we found mean CDVA of 20/20.

Data from the FDA trial of the ICL for moderate and high myopia reported improved CDVA with few complications.⁹ Loss and gain of CDVA is an index of the safety of the surgical procedure. We found very only 4% of eyes lost one line of CDVA and no eyes lost more than one line. This outcome indicates excellent safety profile for ICL implantation in the cohort of patients treated in this study. Additionally complications were rare and managed medically. No patients required explantation of ICL or other surgical procedures. Low complications rate have been previously reported with the ICL.^{9,10}

In summary the ICL implantation for low and moderate myopia up to -10 D was accurate, safe and efficacious. The results of this study were similar to previously published studies of wavefront guided and wavefront optimized LASIK. ICL implantation maybe an alternate to LASIK.

Comment [EE5]: RICH to do:
Need to add a comparison table for ICL for low myopia and LASIK studies
Also need to include a paragraph on the complications of ICLs cataract, endothelial cell loss etc
Drawback of the study

REFERENCES

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FIGURES

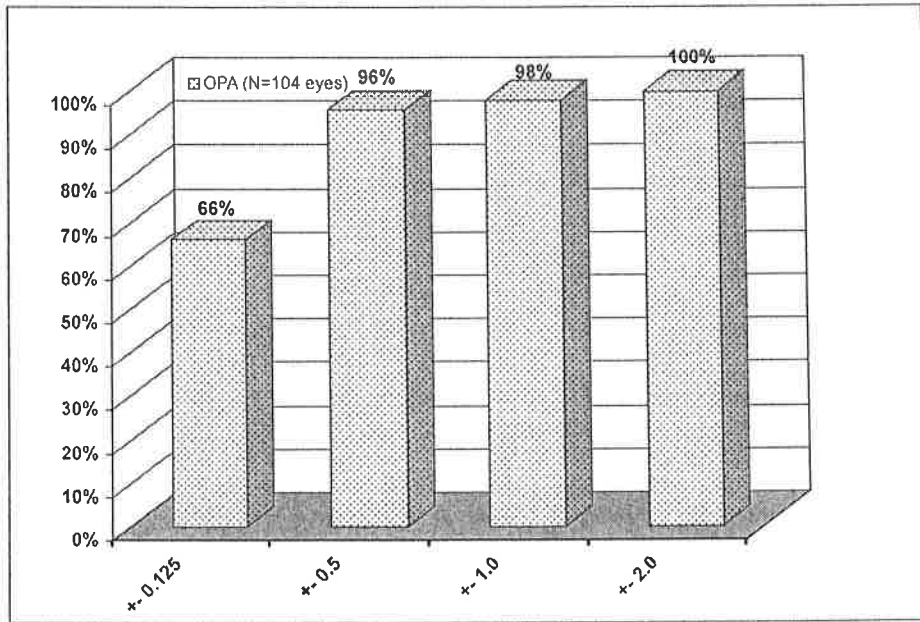


Figure 1. Refractive outcome percent within attempted at last postoperative visit of eyes with low to moderate myopia that underwent implantable collamer lens implantation.

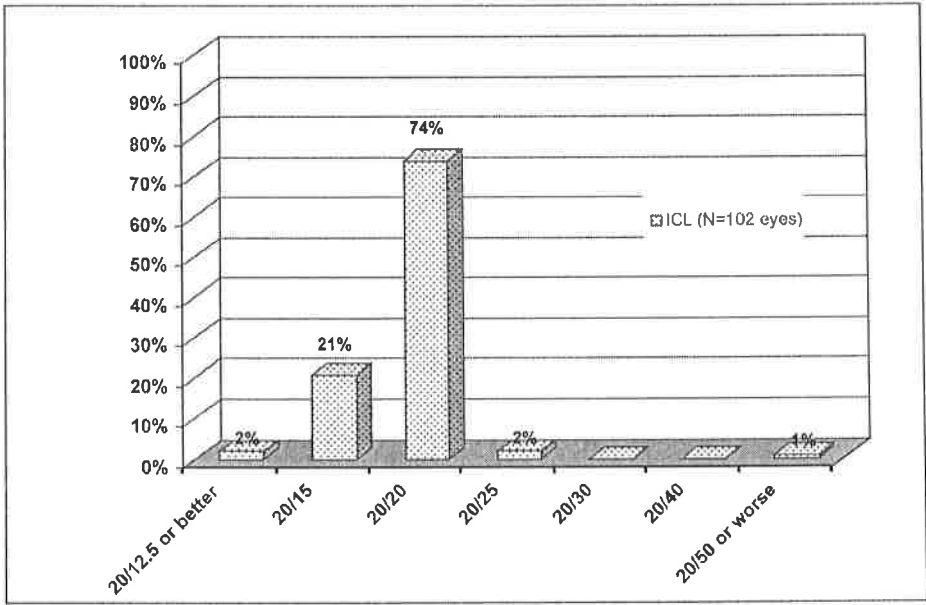


Figure 2. Corrected distance visual acuity at last visit of eyes with low to moderate myopia that underwent implantable collamer lens implantation.

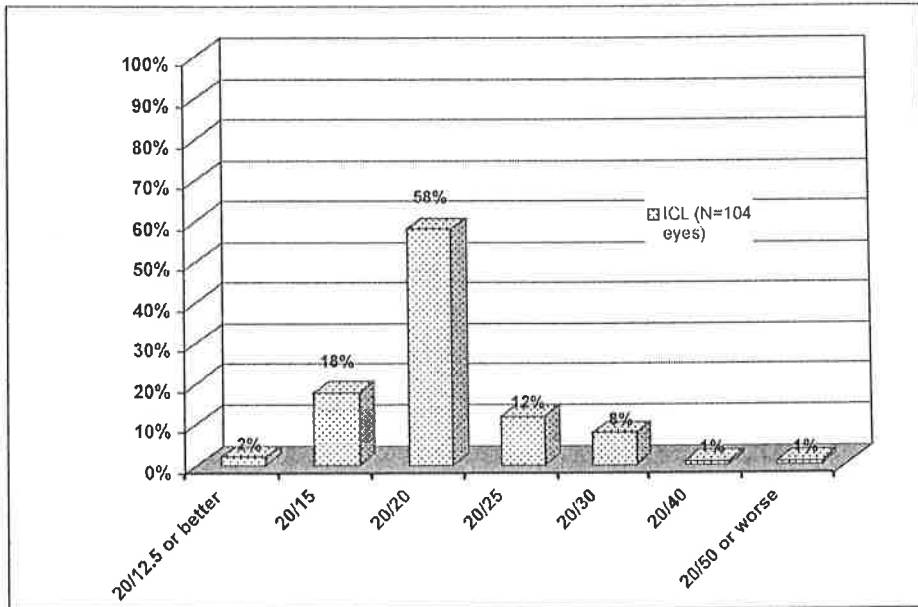


Figure 3. Uncorrected distance visual acuity at last visit of eyes with low to moderate myopia that underwent implantable collamer lens implantation.

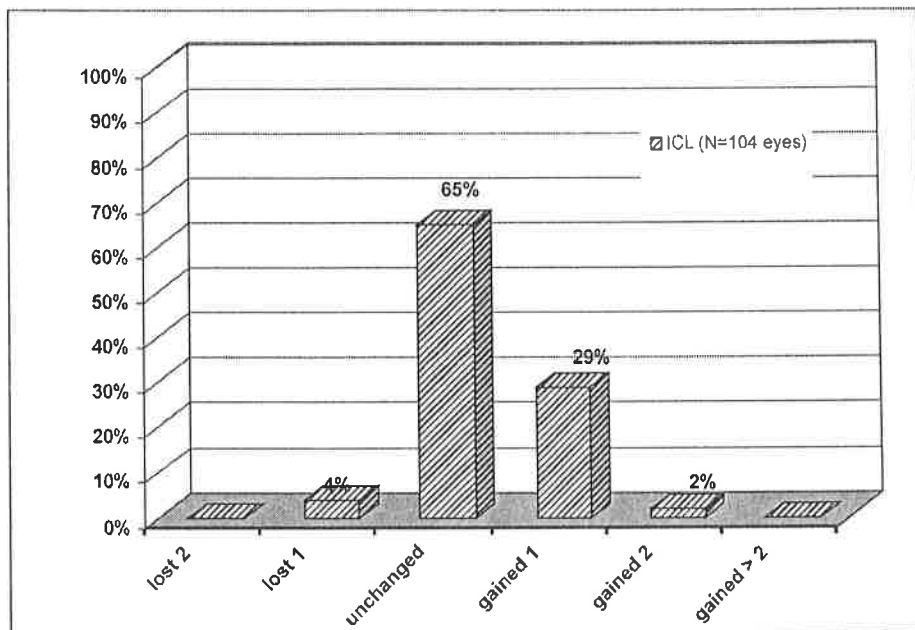


Figure 4. Change in corrected distance visual acuity at last postoperative visit of eyes with low to moderate myopia that underwent implantable collamer lens implantation.