

Randomized prospective comparison of visian toric implantable collamer lens and conventional photorefractive keratectomy for moderate to high myopic astigmatism.

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Abstract

PURPOSE: To compare the Visian Toric Implantable Collamer Lens (TICL), a toric phakic intraocular lens (IOL), and photorefractive keratectomy (PRK) in the correction of moderate to high myopic astigmatism.

METHODS: This prospective, randomized study consisted of 43 eyes implanted with the TICL (20 bilateral cases) and 45 eyes receiving PRK with mitomycin C (22 bilateral cases) with moderate to high myopia (-6.00 to -20.00 diopters [D] sphere) measured at the spectacle plane and 1.00 to 4.00 D of astigmatism. All patient treatment and follow-up occurred at the Naval Medical Center San Diego. Study follow-up was 1 day, 1 week, 1, 3, 6, and 12 months postoperative.

RESULTS: Mean best spectacle-corrected visual acuity (BSCVA), change in BSCVA, proportion of cases with improvement of 1 or more lines of BSCVA, proportion of cases with BSCVA and uncorrected visual acuity (UCVA) 20/12.5 or better, proportion of cases with BSCVA and UCVA 20/16 or better (6 months, 88% vs 54%, $P=.002$), and predictability ± 1.00 D (6 months, 100% vs 67%, $P<.001$) were all significantly better in the TICL group than the PRK group at all time periods studied postoperatively. Similarly, contrast sensitivity, tested at both the 5% photopic level and the 25% mesopic level, was significantly better at all postoperative time points in the TICL group. Mean spherical equivalent refraction was closer to emmetropia (0.28 ± 0.41 vs 0.76 ± 0.86 , $P=.005$), and predictability ± 0.50 D and stability of manifest refraction (± 0.50 D and ± 1.00 D) were significantly better in the TICL group at all postoperative visits through 6 months. Mean astigmatism correction at 6 months was not significantly different between the two groups (0.52 ± 0.33 vs 0.46 ± 0.35 , $P=.450$).

CONCLUSIONS: The TICL performed better than PRK in all measures of safety (BSCVA), efficacy (UCVA), predictability, and stability in this comparison, supporting the TICL as a viable alternative to existing refractive surgical treatments

Night driving simulation outcome favors ICL Visian toric ICL **Source: STAAR Surgical**

The Visian toric ICL (implantable contact lens, STAAR Surgical, Monrovia, Calif.) outperformed conventional PRK in night driving simulator testing in a recent study published in the May 2010 issue of the Journal of Refractive Surgery. Results from the study indicated that for identification tasks during night driving simulation, the toric ICL performed better than conventional PRK, according to Capt. (Ret.) Steven C. Schallhorn, M.D., San Diego, and medical director, Optical Express, London. "There is a subset of patients who would not meet the indications for LASIK and for whom we would be faced with the options of either implanting a phakic intraocular lens or possibly considering a surface procedure," Dr. Schallhorn said. Investigators hoped that this study would help to clarify which procedure would be preferable here.

Night driving simulation

In this prospective, randomized study involving patients with moderate to high myopic astigmatism, the toric ICL was implanted in 43 eyes while another 45 eyes underwent conventional PRK with application of mitomycin C. As a sub study, 27 of the toric ICL patients and 21 of the PRK patients were tested using a night driving simulator. "The night driving simulator is a very unique device because it measures the visual essence of night driving—the ability to detect and identify targets like pedestrian hazards, road signs, and business signs," Dr. Schallhorn said. "That's a lot of the essence of the vision requirements of night driving." While the simulator measures these elements, it does not require the skills of night driving, he stressed. Investigators felt that testing driving was an excellent way to discern visual performance. "We chose night driving because patients who have quality-of-vision problems after surgery often complain of night driving issues such as glare and halos," Dr. Schallhorn said. "Also, night driving is a very strenuous task because it involves low light but high intensity potential glare sources, it requires skill, and it's commonly performed by people."

During the simulation, patients sat in a car with a road scene image projected in front of them. Investigators then noted how many feet away they could detect hazards or road signs and at what point they could actually identify them. Dr. Schallhorn sees the way the training took place as very sophisticated. "We would have a training period where the subjects were trained in what they were looking for and how they were supposed to respond," he said. "Then we tested their detection and identification ability repeatedly." Investigators then looked at the learning curve and identified the point at which the patients' performance peaked; it was these results that were included in the study.

Detecting driving hazards

Results from the night driving simulator indicated that the ICL performed better than the conventional PRK. While there was no difference in the distances needed to detect signs or hazards, identification tasks were another story. With such tasks, patients would be asked to determine, for example, whether a pedestrian was walking into or away from the road. With such identification tasks, those in the toric ICL group performed significantly better than their PRK counterparts. Investigators found that both with and without glare, ICL patients were better able to identify pedestrian hazards as well as business and road signs.

Dr. Schallhorn theorized that the difference was in the aberrations that were likely induced by PRK during the conventional treatment. Despite the fact that the optics favored the ICL, Dr. Schallhorn was a little surprised at how well the lens fared overall. "I think that the most surprising thing was that the ICL performed better," he said. "The levels of P values were really significant for the identification tasks, but across the board the ICL performance was quite superior."

He hopes that others come away from the study with a better understanding of the quality of vision the lens can offer patients compared to a conventional laser approach. "The visual quality of this phakic intraocular lens is superior and should be considered for the high visual quality as compared to conventional excimer laser," Dr. Schallhorn said. "I think that it compares very favorably to a conventional excimer laser procedure." Overall, Dr. Schallhorn thinks that the biggest strength of the study is that a real task was performed here. "This is significant because it has intrinsic meaning," he said. "We tested night driving, so that adds an element of importance to this type of work—this is task-based analysis and that is very rarely done in ophthalmology."