

Comparison of the Toric Implantable Collamer Lens and Custom Ablation LASIK for Myopic Astigmatism

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ABSTRACT

PURPOSE: To compare the results of wavefront-guided custom LASIK and the Toric Implantable Collamer Lens (TICL) in the correction of myopic astigmatism.

METHODS: This observational, non-randomized study compared clinical efficacy results from the TICL's US Food and Drug Administration Clinical Trial and published Summaries of Safety and Effectiveness of two wavefront-guided lasers: STAR S4 CustomVue excimer laser system (VISX Inc) and LADARVision4000 Custom-Cornea excimer laser system (Alcon Laboratories Inc). Preoperative myopic refractive error was divided into two groups: -3.00 to -7.00 diopters (D) and -7.00 to -11.00 D.

RESULTS: The percentage of eyes with uncorrected visual acuity (UCVA) of 20/20 and 20/40 and predictability of manifest refraction spherical equivalent within ± 0.50 and ± 1.00 D in the three groups was similar with only one statistically significant difference (TICL versus Alcon within ± 1.00 D: 97% versus 82%, $P = .008$). The TICL had significantly better postoperative best spectacle-corrected visual acuity (BSCVA) compared to preoperative BSCVA than both the VISX CustomVue and Alcon CustomCornea ($P < .001$). The TICL postoperative UCVA outcomes compared to preoperative BSCVA were significantly better than Alcon CustomCornea outcomes ($P < .001$). Additionally, almost half (48%) of the TICL cases had improvement in postoperative UCVA compared to preoperative BSCVA, whereas only 23% of the Alcon CustomCornea eyes showed improvement.

CONCLUSIONS: Although comparable in clinical efficacy outcomes, the TICL had a significantly better postoperative improvement in BSCVA and significantly better postoperative UCVA than preoperative BSCVA. The TICL can be considered as an alternative to LASIK through the full range of use. [*J Refract Surg.* 2008;24:773-778.]

Wavefront-guided LASIK is considered superior to conventional LASIK¹⁻³ and is generally regarded as the refractive procedure of choice within its approved range. The Visian Implantable Collamer Lens (ICL; STAAR Surgical, Monrovia, Calif) was granted approval by the United States Food and Drug Administration (FDA) in December 2005 for commercial use in the United States for spherical myopia of 3.00 to 20.00 diopters (D). The Toric Implantable Collamer Lens (TICL) represents an expansion of the earlier Visian ICL study and is currently awaiting approval in the United States.

A number of studies have compared outcomes among the Visian ICL and LASIK or PRK,⁴⁻⁷ which demonstrated clear superiority of the ICL for various refractive ranges; however, these comparisons were done before the availability of wavefront-guided custom ablation. We compare the efficacy results from the FDA clinical trial of the TICL and the FDA trial results of two approved custom LASIK clinical trials for the treatment of myopic astigmatism.

PATIENTS AND METHODS

The TICL group for this analysis consisted of 210 eyes of 124 patients with 2.38 to 19.50 D of myopia (spherical equivalent) and 1.00 to 4.00 D of astigmatism followed for 1 year from the US FDA multicenter clinical trial of the TICL.⁸ For a majority of the analyses, 141 of 210 study eyes with -3.00 to -11.00 D of preoperative myopia were used for comparison.

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The STAR S4 CustomVue excimer laser system (VISX Inc, Santa Clara, Calif) and the LADARVision4000 CustomCornea excimer laser system (Alcon Laboratories Inc, Ft Worth, Tex) were used in this comparison of wavefront-guided LASIK procedures and the TICL. All LASIK data were derived from the published Safety and Effectiveness Summaries of the approved Premarket Approval Applications made available from the FDA through the Freedom of Information Act.⁹⁻¹¹ To compare the desired range of myopia (3.00 to 11.00 D), we used two different STAR S4 CustomVue Summaries of Safety and Effectiveness due to their division of low and high myopia.^{9,10}

OUTCOME MEASURES

The US FDA clinical study of the TICL was intended to evaluate the efficacy of the ICL for treatment of moderate to high myopic astigmatism as the safety of the phakic IOL was based mainly on the larger study of the spherical version of the ICL.^{6,12} The spherical ICL study was otherwise identical to the TICL study with the exception of the incorporation of a toric optic. Therefore, the outcomes compared and analyzed were those of efficacy: uncorrected visual acuity (UCVA) and manifest refraction spherical equivalent predictability of ± 0.50 to ± 1.00 D.¹³ We collected the UCVA data using traditional FDA-guideline reporting criteria of the percentage of eyes that are 20/20 and 20/40 or better. Due to the FDA requirement that all Summaries of Safety and Effectiveness have particular data stratified into one-diopter steps, we were able to accurately divide these efficacy outcomes in two refractive groups that depicted moderate to high myopia: 3.00 to 7.00 D and 7.00 to 11.00 D. The integer was in the higher category of Alcon's Summary of Safety and Effectiveness (-3.00 to -6.99 D and -7.00 to -10.99 D) and in the lower category of VISX's Summary of Safety and Effectiveness (-3.01 to -7.00 D and -7.01 to -11.00 D). The TICL clinical data was portrayed in the same manner as the method used by VISX (integer in lower category). For further efficacy analysis, we also compared change in pre- to postoperative best spectacle-corrected visual acuity (BSCVA) and preoperative BSCVA to postoperative UCVA. All data compared had an endpoint of 6 months except for VISX's low myopia (≤ 6.00 D) Summary of Safety and Effectiveness⁹ data that were published with an endpoint of 3 months.

Due to the limitations of data available in the FDA Summaries of Safety and Effectiveness, which are not designed to be all-inclusive, we were only able to perform efficacy data comparisons that were readily available in those documents or in the published literature. For data that did not allow direct comparison of iden-

tical information, it was aligned as accurately as possible to allow equivalent populations to be analyzed against one another.

The data used for change in BSCVA comparison was composed of all eyes from the TICL FDA Clinical Trial Data (N=210) and the Alcon CustomCornea System's Safety and Effectiveness data (N=331). No VISX data were reported on this specific variable. Fortunately, a STAR S4 CustomVue excimer laser published data series of 277 eyes¹⁴ reported this variable from 3.00 to 6.00 D and consequently was used in this comparison. All eyes from Alcon's study cohort (spherical and astigmatic) were used for this comparison, as this variable was not reported in the Summary of Safety and Effectiveness for the subset of astigmatic eyes only.

The preoperative BSCVA versus postoperative UCVA comparison also used all eyes from the TICL FDA Clinical Trial Data (N=210) and all eyes from the Alcon CustomCornea's Safety and Effectiveness data (N=331). VISX data for this comparison were not reported in their Summary of Safety and Effectiveness and could not be found in the literature.

STATISTICAL METHODS

The following statistical analyses were used to compare the custom LASIK and TICL series: for dichotomous variables (eg, UCVA percentage of 20/20 and 20/40 or better and manifest refraction spherical equivalent predictability of ± 0.50 or ± 1.00 D), the Fisher exact test was performed; and for ordered categories (eg, line changes in UCVA and BSCVA), Mann-Whitney U tests were performed. Software Stat Exact 2.0 for Windows (Cytel Software, Cambridge, Mass) was used for all tabulations of data and statistics.

RESULTS

Table 1 provides a comparison of demographics and preoperative BSCVA and cylinder for the VISX CustomVue, Alcon CustomCornea, and TICL groups. Table 2 provides an overall comparison of the efficacy outcomes between the three populations. The columns labeled "P value" contain values that were dichotomous variables representing results of Fisher exact tests.

UNCORRECTED VISUAL ACUITY

In the moderate refractive group of 3.00 to 7.00 D, 94% of the toric lens patients had UCVA of 20/20 or better compared to 80% of VISX CustomVue and 81% of Alcon CustomCornea. Ninety-seven percent of TICL, 94% of VISX CustomVue, and 97% of Alcon CustomCornea patients had UCVA of 20/40 or better.

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TABLE 1

Population Comparison of the STAAR Toric Implantable Collamer Lens (TICL) and VISX CustomVue and Alcon CustomCornea Laser Systems

	TICL	VISX CustomVue ^{9,10}	Alcon CustomCornea ¹¹
Gender (%)			
Male	44.4	55.1	59.2
Female	55.6	44.9	40.8
Race (Caucasian) (%)	82.3	83.0	94.6
Age (mean ± standard deviation) (y)	36.42 ± 7.37	35.85 ± 7.85	37.00 ± 9.00
Preoperative BSCVA	20/40 or better	20/20 or better	20/25 or better
Preoperative cylinder (D)	1.94	1.30*	1.58*

BSCVA = best spectacle-corrected visual acuity

*Preoperative cylinder values were estimated from Premarket Approval Application Summary of Safety and Effectiveness data.

TABLE 2

Comparison of the STAAR Toric Implantable Collamer Lens (TICL) and FDA Custom Ablation LASIK Outcomes

Variable	TICL (%)	VISX CustomVue ^{9,10} (%)	P Value (TICL vs VISX)	Alcon CustomCornea ¹¹ (%)	P Value (TICL vs Alcon)
UCVA 20/20 or better					
3.00 to 7.00 D	30/32 (94)	105/132 (80)	.071	100/123 (81)	.109
7.00 to 11.00 D	91/109 (84)	55/77 (71)	.069	23/28 (82)	1.000
UCVA 20/40 or better					
3.00 to 7.00 D	31/32 (97)	124/132 (94)	1.000	119/123 (97)	1.000
7.00 to 11.00 D	106/109 (97)	75/77 (97)	1.000	28/28 (100)	1.000
MRSE Predictability within ±0.50 D					
3.00 to 7.00 D	26/32 (81)	102/132 (77)	.812	98/123 (80)	1.000
7.00 to 11.00 D	85/112 (76)	55/77 (71)	.504	18/28 (64)	.235
MRSE Predictability within ±1.00 D					
3.00 to 7.00 D	32/32 (100)	124/132 (94)	.357	111/123 (90)	.129
7.00 to 11.00 D	109/112 (97)	70/77 (91)	.094	23/28 (82)	.008

UCVA = uncorrected visual acuity, MRSE = manifest refraction spherical equivalent

Although the proportion of patients seeing 20/20 or better was numerically higher in the TICL group, none were significantly better.

For the higher refractive group of 7.00 to 11.00 D, 84% of TICL patients saw 20/20 or better compared to 71% and 82% of VISX CustomVue and Alcon CustomCornea, respectively. The proportion of patients seeing 20/40 or better was very high, with 97% of patients in both the TICL and VISX CustomVue groups and 100%

of the Alcon CustomCornea group. No results were significantly better.

PREDICTABILITY

In the moderate refractive group of 3.00 to 7.00 D, 81% of TICL, 77% of VISX CustomVue, and 80% of Alcon CustomCornea patients were within ±0.50 D. At ±1.00 D, the TICL group was slightly, though not significantly, more accurate at 100% compared to

TICL Compared to Custom LASIK/Sanders & Sanders

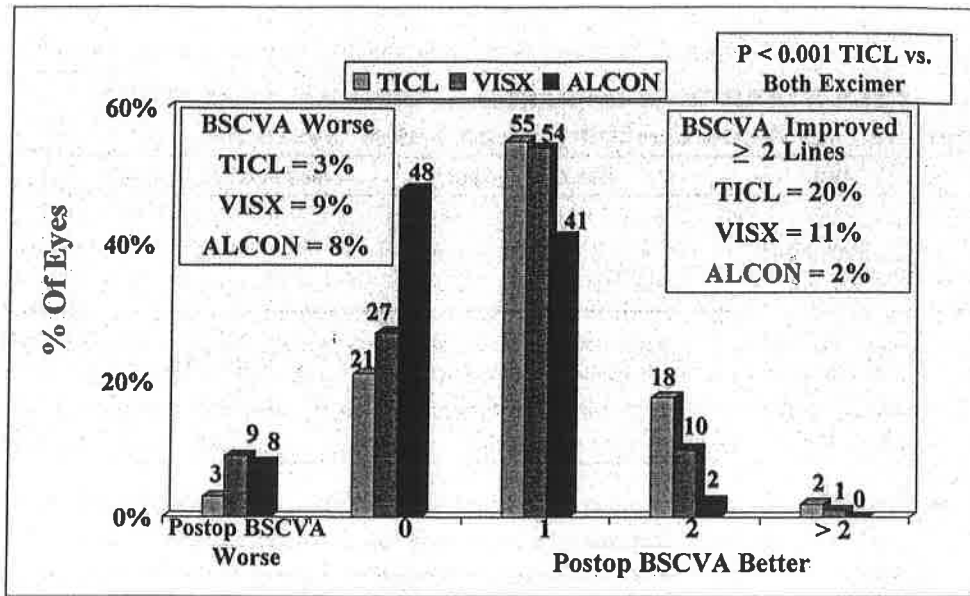


Figure 1. Preoperative versus postoperative best spectacle-corrected visual acuity (BSCVA) for Toric Implantable Collamer Lens (TICL) versus custom ablation (all eyes). (Note: VISX data from previous study.¹⁴) TICL N=210; VISX N=277; Alcon N=331; Postop BSCVA Worse = 1 line lost

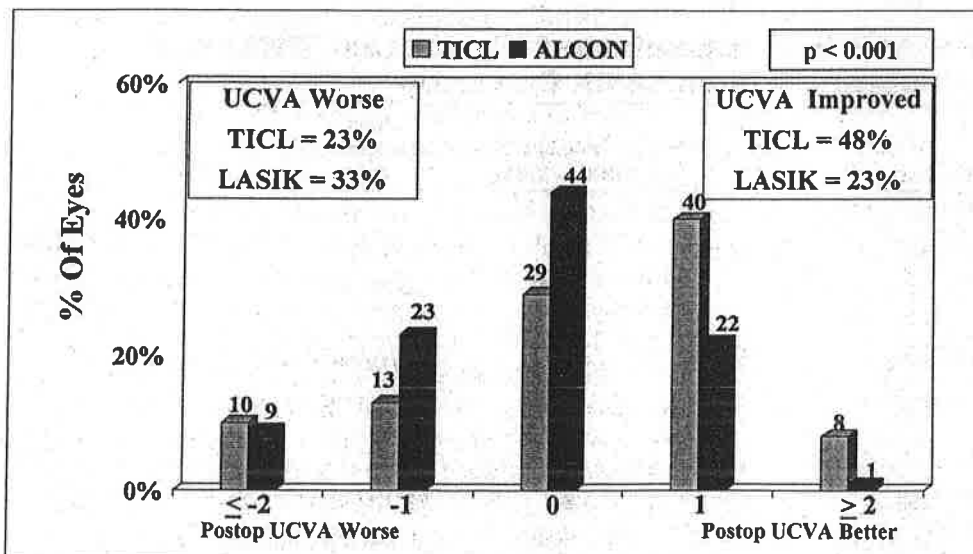


Figure 2. Preoperative versus postoperative uncorrected visual acuity (UCVA) for Toric Implantable Collamer Lens (TICL) versus custom ablation (all eyes). TICL N=210; Alcon N=337

94% for the VISX CustomVue and 90% for the Alcon CustomCornea groups.

In the higher refractive group, 76% of TICL, 71% of VISX CustomVue, and 64% of Alcon CustomCornea patients were within ± 0.50 D. At ± 1.00 D, the TICL group was numerically higher in accuracy at 97% compared to 91% for the VISX CustomVue group and significantly higher in accuracy compared to 82% for the Alcon CustomCornea group ($P=.003$).

CHANGE IN BEST SPECTACLE-CORRECTED VISUAL ACUITY

The TICL group had significantly better postoperative BSCVA compared to preoperative BSCVA than both the VISX CustomVue and Alcon CustomCornea ($P<.001$) (Fig 1). The BSCVA was worse than preoperatively in 3% of TICL patients, 9% of VISX

CustomVue patients, and 8% of Alcon CustomCornea patients. Twenty percent of the TICL cases gained >2 lines of visual acuity compared to 11% and 2% for the VISX CustomVue and Alcon CustomCornea, respectively.

POSTOPERATIVE UNCORRECTED VISUAL ACUITY VERSUS PREOPERATIVE BEST SPECTACLE-CORRECTED VISUAL ACUITY

The TICL postoperative UCVA outcomes compared to preoperative BSCVA were significantly better than the Alcon CustomCornea outcomes ($P<.001$) (Fig 2). Postoperative UCVA was worse in 23% of TICL patients compared to 33% of Alcon CustomCornea patients. Additionally, almost half (48%) of the TICL patients had an improvement in UCVA compared to preoperative

BSCVA whereas only 23% of Alcon CustomCornea eyes showed improvement.

DISCUSSION

In the past, there has been an underlying assumption that cutting or reshaping the cornea is better and safer than even a minimally invasive intraocular procedure. This assumption has been confronted with the use of a phakic implant that involved an intraocular procedure, unlike alternative refractive procedures such as custom or conventional LASIK. The use of phakic intraocular lenses (IOLs) offers the predictability and efficacy of IOL technology yet is less invasive as the crystalline lens is left intact.

A dramatic improvement in UCVA and BSCVA in the TICL group relative to custom LASIK procedures was seen. It can be assumed that this improvement is not due to retinal image magnification as LASIK treatments and the TICL have the same image magnification effects for equivalent amounts of myopia.⁷ Although the baseline efficacy variables were comparable between the two wavefront LASIK procedures and the TICL, the change in BSCVA was substantially better in the TICL study. The inclusion criteria found in both excimer laser studies' Summaries of Safety and Effectiveness indicated that the VISX CustomVue study cohort was required to have a BSCVA of 20/20 or better and the Alcon CustomCornea study cohort was required to have a BSCVA of 20/25 or better. The TICL FDA Clinical Trial Study, however, required that potential study eyes have a BSCVA of only 20/40 or better. Preoperatively, 83% of eyes in the TICL clinical trial had 20/20 or better BSCVA and 93% had 20/25 or better, only 7% of eyes had 20/30 to 20/40. Although the VISX and Alcon study cohorts included eyes only with BSCVA 20/20 or better and 20/25 or better, respectively, the TICL performed better than the two wavefront lasers with not only a greater proportion of cases at these levels, but a numerically higher amount of patients having an improvement in BSCVA from preoperative measurements. These differences in BSCVA and UCVA between the TICL and LASIK procedures may be due to the increases in higher order aberrations following LASIK relative to the ICL.⁷ Increases in higher order aberrations are seen with both conventional and custom LASIK procedures.¹⁵

The TICL allowed more patients to not only have the convenience of not wearing spectacles or contact lenses, but it also gave them the ability to see better than with traditional optical devices. Almost half of the TICL study cohort had UCVA better than the preoperative BSCVA compared to less than one-fourth of Alcon's study cohort.

Because implantation of the TICL is an intraocular procedure, the potential for complications, especially in the later follow-up periods, is a concern. Although the TICL study was a short-term study, the spherical ICL has been followed for 3 years as part of an FDA clinical trial.⁶ Three (0.6%) retinal detachments, two (0.4%) clinically significant anterior subcapsular cataracts, and five (1.0%) nuclear cataracts (thought to be unrelated to the ICL surgery) occurred within the 3-year follow-up. Three (0.6%) of the cataracts described above required cataract extraction and IOL implantation with no loss of BSCVA from before ICL implantation. Incidence of patient symptoms, glare, halos, double vision, night vision problems, and night driving difficulties decreased or remained unchanged after ICL surgery. Thus, it appears that the long-term safety profile of the ICL is quite good.

Although the wavefront-guided lasers and the TICL both gave patients consistent postoperative UCVA and accuracy, when factoring in the worse overall BSCVA of the preoperative cohort in the TICL group and focusing on the change in BSCVA and the amount of postoperative visual improvement, the TICL performed superiorly to the custom LASIK procedures. When the TICL is approved for commercial use in the United States, it should be considered as an alternative to wavefront-guided custom LASIK procedures throughout its full range of approved spherical and astigmatic correction.

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