Clinical Results of the US T-CAT Study

US approval of the platform is expected within a year.

BY DANIEL S. DURRIE, MD

US surgeons first began performing corneal laser surgery in 1987. At that time, the phoropter was the primary technological tool used to predict the proper laser treatment. Data to enable the creation of regression nomograms did not exist, so surgeons were forced to make assumptions and create a treatment plan based on theoretical algorithms. In 1999, nomograms were used in laser refractive surgery. By then, it was well accepted that incorporating information about individual eyes and physician-created nomograms into laser surgery enhanced patients' outcomes. The next major advance, wavefront-guided technology, was approved in the United States in 2002. Surgeons then added this feature to the phoropter and nomograms.

It was subsequently determined that significant spherical aberrations were being induced with some laser platforms. WaveLight AG (Erlangen, Germany) was the first company to investigate the application of regression analyses—a sort of super nomogram—to determine if these aberrations could be systematically eliminated. When the WaveLight laser was in US clinical trials, the investigators sought to optimize the midperipheral ablation zone. Procedures using this technology are known as *wavefront optimized*.

The most recent addition along the continuum of technological developments for laser corneal surgery is the use of topography. Outside the United States, surgeons can now incorporate patients' corneal topography into the laser treatment plan. It is a very reproducible technology, and it offers many advantages, because all of the correctable visual distortions occur in the cornea. This extra information has the potential to take laser refractive surgery to the next level.

Figure 1. Refractive outcomes within the intended target.

TOPOGRAPHY-GUIDED ABLATIONS

Phase 3 Study

My fellow investigators and I undertook a clinical study of topography-guided customized ablation treatments (T-CAT) to determine whether this technology represented an improvement over what is already in use. T-CAT has been performed internationally since 2003, so we were able to consult large patient databases to help guide the study.

Primary LASIK was performed on healthy eyes with myopia or hyperopia, with or without astigmatism, using the Allegretto Wave Eye-Q 400-Hz laser system (Alcon Laboratories, Inc., Fort Worth, TX). There were 10 investigational sites in the United States included in this prospective nonrandomized study. Each patient's refractive correction was based on his or her preoperative manifest refraction, and the correction of higher-order aberrations and the adjustment of asphericity were based on corneal topography.

There were two cohorts, one myopic (up to -9.00 D sphere, -6.00 D cylinder, -9.00 D manifest refraction

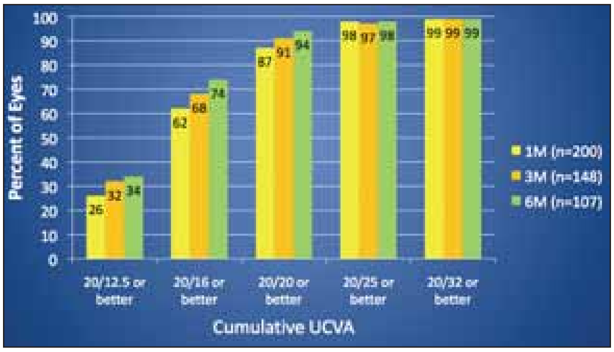

Figure 2. Visual outcomes: cumulative UCVA.

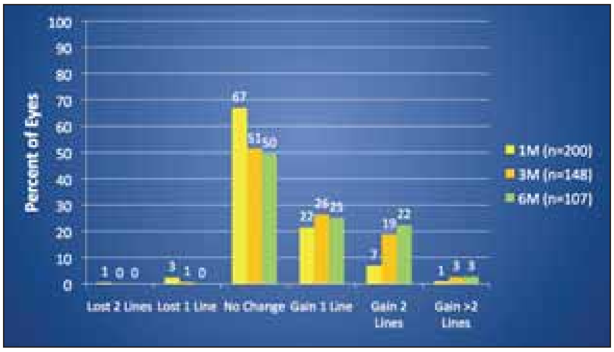

Figure 3. Change in BCVA.

Question	None - Moderate		Marked - Severe		Difference in Marked - Severe	p-value
	Baseline	3M	Baseline	3M		
Light Sensitivity	92.03%	99.07%	7.97%	0.93%	-7.04	0.0113
Difficulty Driving at Night	91.30%	97.20%	8.70%	2.80%	-5.89	0.0620
Reading Difficulty	89.86%	98.13%	10.14%	1.87%	-8.28	0.0097
Double Vision	99.28%	99.07%	0.72%	0.93%	0.21	0.8656
Fluctuation in Vision	98.55%	99.07%	1.45%	0.93%	-0.51	0.7286
Glare	92.75%	100.0%	7.25%	0.00%	-7.25	0.0038
Halos	94.93%	99.07%	5.07%	0.93%	-4.14	0.0740
Starbursts	97.10%	98.13%	2.90%	1.87%	-1.03	0.6214
Dryness	94.93%	96.26%	5.07%	3.74%	-1.33	0.6342
Pain	99.28%	100.0%	0.72%	0.00%	-0.72	0.3768
FBS	100.0%	99.07%	0.00%	0.93%	0.93	0.3150

Figure 4. Improvement in visual symptoms.

spherical equivalent) and one hyperopic (up to +6.00 D sphere, +5.00 D cylinder, +6.00 D manifest refraction spherical equivalent). Here are the interim 6-month results from the 222 myopic patients.

Results

The results were extremely good. They showed excellent refractive predictability, which was to be expected with a mature platform, good nomograms, and excellent clinical investigators. At 6 months, 94.4% of eyes were within ±0.50 D of the intended target, and 99.1% were within ±1.00 D (Figure 1). Topography-guided technology still takes into account the information gathered with the phoropter and nomograms, so it is not 100% new. The use of topographic information can add an element of customization that allows the laser to more effectively correct corneal asymmetries.

Uncorrected visual acuity was excellent, with 94% of patients seeing 20/20 or better and 74% seeing 20/16 or better (Figure 2). I believe these data are as good as any that have been published. Importantly, no lines of BCVA were lost, and all patients either preserved or gained lines of visual acuity (Figure 3). This allows surgeons to say to patients that, not only is this procedure safe and effective, there is a very high likelihood that they will see better than they ever did with glasses or contact lenses.

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Quality of Vision

We also took into consideration the importance of patients' visual symptoms and their quality of vision. We found a statistically significant improvement in almost all of the subjective categories of visual symptoms such as halo, glare, night vision, and dryness (Figure 4). These valuable data appear to confirm that the incorporation of this technological advance is moving patients' visual outcomes in the right direction.

CONCLUSION

The T-CAT study's results underscored the importance of accurate corneal topography to refractive outcomes. In the past, topography was primarily used as a screening tool to determine a patient's candidacy for a refractive procedure. Now, it is being used to calculate the laser's shot pattern.

The future of refractive surgery will include the use of the phoropter, wavefront data, and topography. Surgeons will go to the OR with more data on their patients' eyes than ever before as well as 20 years of experience with laser vision correction and 20 million procedures performed. Topography-guided ablations are a part of an ongoing process. Results from the T-CAT study show that there is still a frontier of even better vision that surgeons can achieve for their patients. ■

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