VOL. 30, NO. 8

Ophthalmology Times

All the Clinical News in Sight

APRIL 15, 2005

www.ophthalmologytimes.com

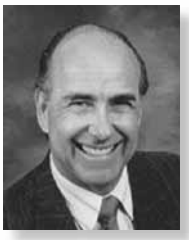
Good predictability

# Interim results of hyperopic LASIK trial highly favorable

By Cheryl Guttman

Reviewed by George O. Waring III, MD

Atlanta—Interim study analyses from a multicenter, North American trial indicate LASIK for treatment of hyperopia with or without astigmatism using the Nidek EC-5000 excimer laser is associated with consistently good safety and efficacy outcomes, reported George O. Waring III, MD, the medical monitor for the study.



Dr. Waring

The study is under way at seven clinical sites, Dr. Waring explained.

A total of 144 eyes with spherical hyperopia and 149 eyes with hyperopic astigmatism were entered into the trial, and 168 eyes have been examined at the 6-month visit.

"The 6-month data show that treatment with this excimer laser system yields efficacy, predictability, and safety outcomes that consistently meet or exceed FDA benchmarks for myopia. We are pleased that the outcomes are as good as or better than those achieved in FDA trials of other excimer lasers that have received approval for hyperopic LASIK," commented Dr. Waring, who is in private practice in Atlanta.

Patients enrolled in the EC-5000 study had to have normal topography, stable refraction over the past 12 months, and be a candidate for a bilateral procedure. The allowed ranges of refractive error were between 0.50 and 6 D for sphere and 0.50 to 3 D for cylinder. The actual MRSE range of treatment was 0.50 to 6.687 D with the cylinder values ranging from 0.50 to 2.375 D.

### Treated for distance

All eyes were treated for distance correction using a 6-mm optical ablation zone and 9-mm transition ablation zone. Operating parameters were fixed at each investigational site with no nomogram adjustments.

At the 6-month follow-up visit, 109 (64.9%) of the 168 eyes evaluated achieved an uncorrected visual acuity (UCVA) of 20/20 or better. Rates of UCVA of 20/25 or better were achieved by 86.3% and 20/40 or better by 98.8%.

"Although the FDA has no benchmarks for criteria for hyperopic LASIK, the FDA criteria for myopic LASIK require that 85% of eyes achieve UCVA of 20/40 or better; and the unofficial target for 20/20 is 50%. The results with the Nidek EC-5000 clearly surpass those benchmarks," Dr. Waring said.

The refractive predictability outcomes at 6 months also exceeded the FDA requirements for myopic LASIK: manifest spherical equivalent refraction (MRSE) was within 0.5 D of attempted in nearly three-quarters of eyes (120/169; 71%); 94.7% were within ±1 D, and in no eye was the MRSE ≥2 D of attempted. FDA criteria suggest that MRSE be within ±0.50 D in 50% of eyes and ±1 D in 75%.

The best spectacle-corrected visual acuity (BSCVA) analyses showed that only 3% (5/168) of the eyes lost 2 or more lines of BSCVA; the FDA benchmark is <5%. Among the 155 eyes seen at 6 months that had BSCVA 20/20 or better preoperatively, only one (0.7%) had BSCVA worse than 20/25 at 6 months. The FDA criterion is <1%.

Dr. Waring also compared the Nidek EC-5000 study data with results from the FDA trials for the Technolas laser (Bausch & Lomb), LADARVision (Alcon Laboratories), STAR (AMO/VISX), and Allegretto (WaveLight Laser Technologie AG) lasers using information taken from the FDA Web site. Although the composition of the various study populations varied with respect to treatment ranges for both sphere and cylinder and the Nidek study has fewer eyes, the results with the EC-5000 results were at least as good if not superior to those achieved with the other systems.

"Most notably, the 65% rate of UCVA of 20/20 or better achieved in this study was higher than that reported at 6 months postoperatively in the Technolas (61.4%), LADARVision (43.3%), and STAR (48.1%) clinical trials, and the Nidek study has the lowest rate of loss of ≥2 lines of BSCVA," Dr. Waring observed.

He noted that while Nidek may be a top-selling excimer laser globally, it has a lower market share in the United States.

"These outcome comparisons should dispel any speculation by American refractive surgeons that the lesser popularity of the Nidek system domestically has anything to do with its ability to achieve excellent results," Dr. Waring said.

Key features of the EC-5000 include its 200-Hz eye tracker and scanning slit delivery system that is able to achieve a very smooth blend zone.

Disclosing that he is a paid consultant for Nidek, Dr. Waring observed, "When considering the purchase of a luxury car, there are many who would pick a Japanese import over an American model because of the reliability issue. The Nidek EC-5000 excimer laser benefits from the same type of excellent, reliable Japanese engineering." OT

## Take-Home Message

Approximately 160 eyes have reached the 6-month examination in the multicenter North American clinical trial evaluating the Nidek EC-5000 excimer laser for the treatment of hyperopia and hyperopic astigmatism. Their results meet or exceed FDA target criteria for efficacy, safety, and predictability and are comparable to those achieved with other FDA-approved excimer laser systems.

FYI

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