

1-month results

Correction yields 'excellent' outcomes

With advanced LASIK procedure, patients were 'very satisfied' with their enhanced vision, study finds

By Ron Rajecki

Reviewed by Stephen C. Coleman, MD

Albuquerque, NM—An advanced LASIK procedure (CustomVue iLASIK, Abbott Medical Optics [AMO]), which is performed using a proprietary excimer laser (STAR S4 IR) and femtosecond laser (IntraLase), provides excellent refractive outcomes, achieving 20/20 or better uncorrected visual acuity (UCVA) in 94.7% of the patients enrolled in a multicenter clinical trial, according to Stephen C. Coleman, MD. He is a private practitioner at Coleman Vision, Albuquerque, NM.

Dr. Coleman is conducting an open-label, multicenter, prospective, non-comparative evaluation of 20 patients scheduled to undergo primary LASIK with the excimer and femtosecond lasers. The goal of the study is to evaluate the efficacy, safety, and predictability of the advanced procedure.

"The excimer laser and femtosecond laser platform resulted in accurate treatment of postoperative sphere and cylinder," he said. "At the 1-month postoperative follow-up, all of the patients (100%) had UCVA of 20/30 or better. More than 97% of the patients (97.4%) had UCVA of 20/25 or better, 94.7% had UCVA of 20/20 or better, and 55.6% had UCVA of 20/16 or better (Figure 1).

"In addition, all of the patients in this study achieved low contrast acuity of 20/40 or better," Dr. Coleman added.

Advanced procedure

According to AMO, its proprietary LASIK procedure enables the broadest range of wavefront-guided approvals, with a high level of precision and accuracy. The procedure leverages iris registration, Fourier algorithms, and proprietary scanning (VSS [variable spot scanning] Refractive) and repetition rate (VRR [variable repetition rate]) technologies to ensure precise ablation, the company said.

According to AMO, the excimer laser system minimizes the thermal effects of LASIK on the cornea. In addition, the procedure conserves tissue, minimizes additional time for wavefront-guided custom treatment over conventional treatment, and eliminates the need for dilation by tracking on the natural pupil, they said.

"The 'glue' between the iris registration cap-

Take-Home Message

An advanced LASIK procedure (CustomVue iLASIK, Abbott Medical Optics) that uses an excimer laser and femtosecond laser is safe and effective, and it provides excellent refractive outcomes, based on 1-month results of an ongoing, multicenter, prospective, non-comparative evaluation of 20 patients.

ture and the Fourier algorithms is the [proprietary spot scanning technology]," Dr. Coleman said. "This feature allows maximum efficiency and accuracy when placing a profile on a cornea that has been constructed and described at the wavefront system in such a complex manner."

Study population

In his study, 20 patients (40 eyes) had the excimer laser and femtosecond laser procedure performed.

The mean patient age was 29.0 years (range, 23 to 35 years). Thirteen of the patients were male, and 11 were Caucasian.

To be included, the patients' myopia had to be within -0.5 to -6.0 D, cylinder up to -3 D, and mean refractive spherical equivalent of up to -6 D.

Follow-up was at 1 and 3 months, at which time pre- and postoperative refraction, wave-scan, UCVA, best corrected visual acuity (BCVA), and pupillometry were evaluated. In addition, all re-treatment information is being recorded and compared against historical rates.

'All 20 patients ...**felt that their vision****was significantly improved.'**

Stephen C. Coleman, MD

The target manifest spherocylindrical refractive error (MSRE) was 0.237. At 1 month postoperatively, mean MSRE in the 20 patients was 0.178. Target cylinder was 0 D; at 1 month, mean cylinder in these patients was -0.306 D.

In addition to the excellent UCVA results, low contrast visual acuity at 1 month was 20/40 or better in 100% of the patients, 20/30 or better in 52.4%, 20/25 or better in 47.6%, and 20/20 or better in 7.1% (Figure 2).

All of the patients (100%) reported being "very satisfied" with their vision during the day without contact lenses or glasses; 72% said they were "very satisfied" with their vision at night without corrective lenses, and 28% said they were "satisfied," Dr. Coleman said (Figure 3).

In addition, all of the patients (100%) said their vision was significantly improved after surgery without glasses compared with before surgery with glasses, and 100% said they were able to return to their normal daily activities the day after the LASIK procedure, he added.

No enhancement procedures were performed. "Patients were very satisfied with their visual



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Refractive

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Figure 1 Uncorrected visual acuity (UCVA) 1-month postoperative follow-up

Figure 1 More than 97% of the patients in the study (97.4%) had UCVA of 20/25 or better, 94.7% had UCVA of 20/20 or better, and 55.6% had UCVA of 20/16 or better.

Figure 2 Low contrast visual acuity (postoperative)

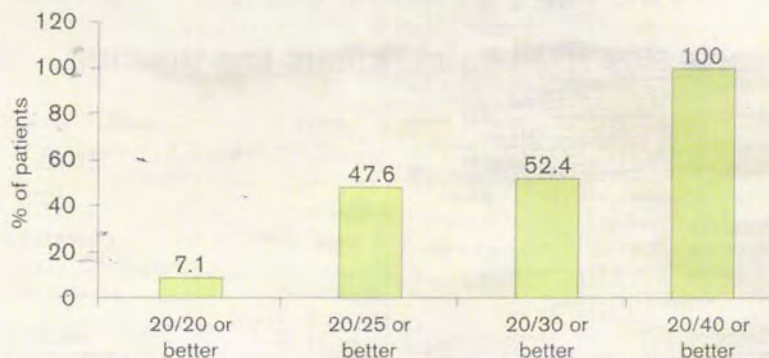


Figure 2 Low contrast visual acuity at 1 month was 20/40 or better in 100% of the patients, 20/30 or better in 52.4%, 20/25 or better in 47.6%, and 20/20 or better in 7.1%.

Figure 3 Patients satisfied with their vision without lenses/glasses

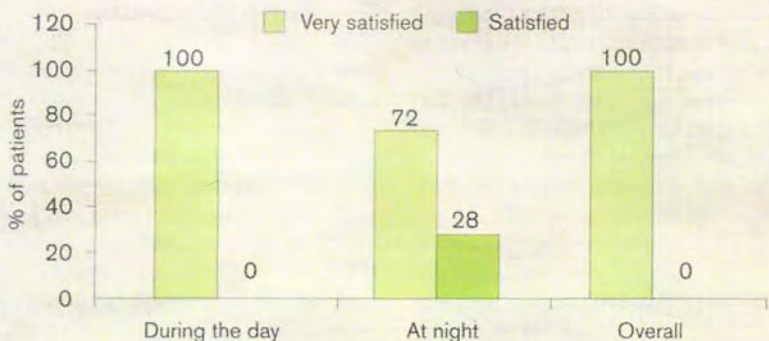


Figure 3 All of the patients (100%) reported being "very satisfied" with their vision during the day without contact lenses or glasses; 72% said they were "very satisfied" with their vision at night without corrective lenses, and 28% said they were "satisfied." (Figures courtesy of Stephen C. Coleman, MD)

outcomes at 1 month after the excimer laser and femtosecond laser procedure," Dr. Coleman said. "All 20 patients were satisfied with their vision at mesopic and photopic conditions, and all 20 felt that their vision was significantly improved."

Current trend

He said this study has implications that bode well for the trend of younger patients choosing to undergo LASIK rather than wear corrective lenses.

"The greatest trend currently in laser vision correction is that the average age and pre-op prescription of our typical patient have both decreased dramatically," Dr. Coleman said. "This is much different from 10 years ago, for instance, when prescriptions tended to be quite

high. I really consider 'X' and 'Y' generation patients with reasonable prescriptions to be the ideal candidates now. As this study demonstrates, it is unusual to have an outcome that is not 20/20 or better in this population group, and they are uniformly very satisfied with their new vision." **OT**



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Dr. Coleman is a clinical investigator for Abbott Medical Optics but receives no compensation from the company.

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