Optimised aspheric LASIK achieves good results in FDA trial

Steven Dell

Roibeard O'hEineachain in Lisbon

OPTIMISED aspheric LASIK ablations with the Carl Zeiss Meditec MEL 80™ laser provide an excellent level of safety and efficacy in the treatment of myopia, suggest preliminary data from an FDA clinical trial.

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The multicentre trial included 357 eyes of 181 patients with a mean age of 34 years, ranging from 21 to 60 years. The mean preoperative manifest refraction spherical equivalent was -3.87 D, ranging from -0.63 D to -10.25 D. Mean preoperative cylinder was –0.74 D, with a range of 0.0 D to -3.50 D. All underwent non-wavefront-driven optimised aspheric LASIK ablations with the MEL-80 excimer laser.

Visual recovery was very rapid in the study, Dr Dell noted. On the first postoperative day 77% of eyes were 20/20 or better without correction, as were 82% of eyes at one week. Among 59 eyes that had reached six months' follow-up, uncorrected visual acuity was 20/16 or better in 63%, 20/20 or better in 93%, and 20/40 or better in all but 3.0%.

Slight tendency for overcorrection

The refractive accuracy of the procedure was also very high, although there was slight tendency for overcorrection, Dr Dell said. At one month 80% had a MRSE within 0.5 D of attempted correction. At six months, 81% of eyes were within 0.5 D of attempted refraction and 90% were within 1.0 D. However, 8.0 % of eyes were overcorrected by +1.0 D or more. No eyes were undercorrected.

"The laser will require a little bit of a nomogram adjustment, but the vast majority of these patients are within a half a dioptre of attempted correction."

In terms of safety, all eyes had best-corrected acuity of 20/20 or better by the first postoperative month. At six months' follow-up, 7.0% of eyes had gained two lines, and 34% had gained one line. Some 6.0% of eyes had lost one line, with no eyes losing two or more lines, Dr Dell noted.

"For every eye that lost a line of best-corrected visual acuity there were six eyes that gained a line, and that is really quite extraordinary."

The only surgery-related adverse event in the trial was a case of epithelial ingrowth in one eye, he added

Fast and quiet, but still a bit smoky

Dr Dell said that in addition to the excellent visual outcomes that it can achieve, the Mel 80 laser system has several features that can increase its appeal to refractive surgeons and patients alike. The laser is very fast. It has a 0.7 mm flying spot firing at 250 Hz and the ablation time is less than 4.0 seconds per dioptre of correction. The laser is also very quiet, contributing to a more relaxed operating environment.

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The disadvantages of the laser system include its plume evacuation system, which, while very effective in getting the plume out of the way of the laser beam, is not very effective in removing it from the room, raising safety concerns.

In addition, intraoperative manipulations can be awkward with the system. They require the surgeon to manoeuvre a cluster of instrumentation away from the patient, which can interrupt the workflow. Furthermore, the working height of the laser is somewhat low, which can be a disadvantage to taller surgeons, he said.

He noted that the optimised aspheric ablation profile used in the FDA trial is designed to preserve the natural prolate asphericity of the cornea. He added that his impression has been that patients in the trial have had few night-vision complaints as a result.

Another trial is now underway in which patients will undergo wavefront-guided customised ablations with the MEL 80™, he said. The investigators will incorporate patients' wavefront and topography data into the ablation profiles using Carl Zeiss Meditec's CRS™ Master software.

"With 357 eyes treated to date the 20/20 UCVA results with an aspheric optimised profile have been similar to wavefront guided lasers and this seems to be holding at six months. Visual recovery has also been very fast and there have been no unanticipated adverse events to date. We eagerly await results of the Mel 80 wavefront customised LASIK trial."

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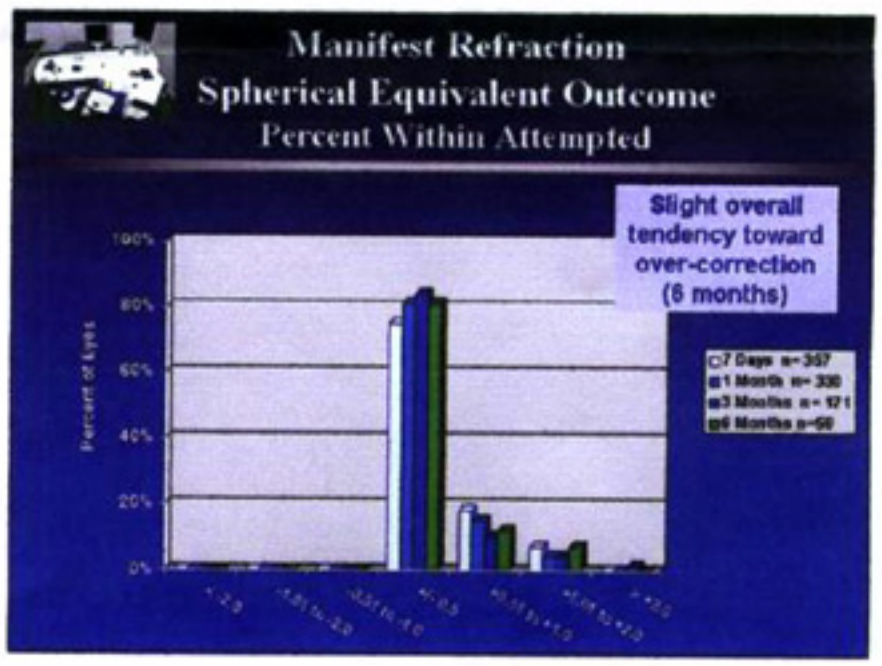

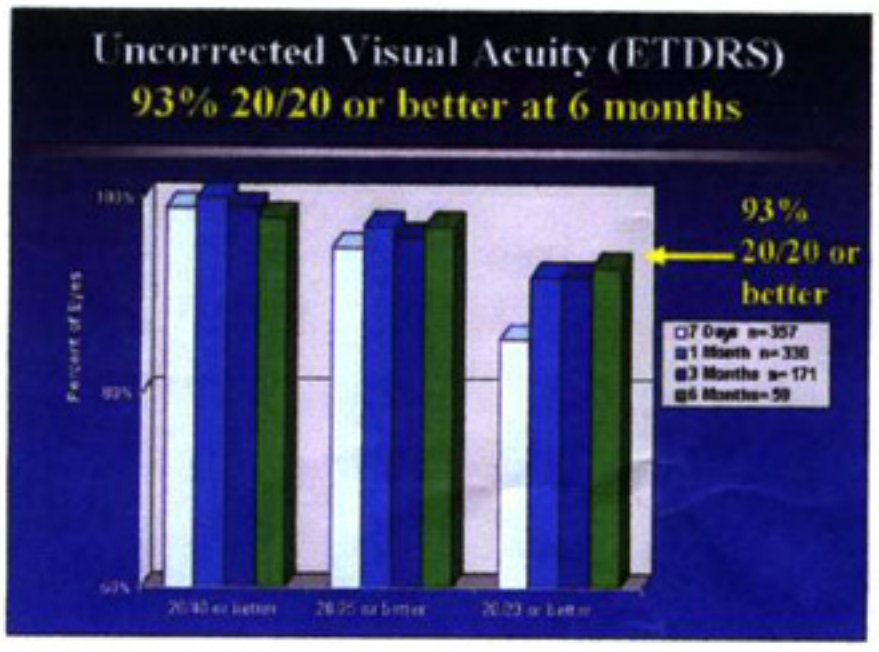

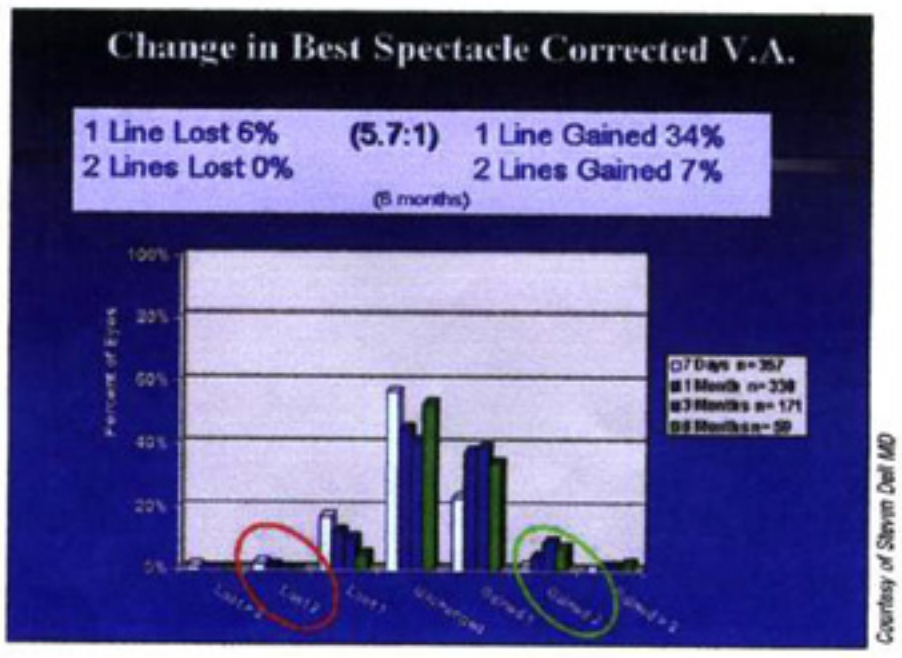

Courtesy of Steven Dell MD