

Rigorous statistical analyses prove upper limit for safe, successful hyperopic PRK

**Cheryl Guttman
in Paris**

THE limit for safe and successful hyperopic surface ablation performed using a scanning spot excimer laser with a Gaussian beam profile is between +3.45 D and +4.0 D, according to the results of a statistical analysis undertaken by surgeons from the Ophthalmologic Laser Clinic Dausch, Nürnberg, Germany.

Speaking at the XXII Congress of the European Society of Cataract and Refractive Surgeons, Sven Lee MD, PhD presented the results of a study that included 237 eyes of 183 patients treated with the MEL-70 laser (Carl Zeiss Meditec AG). Preoperative hyperopia for the 237 eyes ranged from +0.25 to +9.50 D and astigmatism ranged from -0.25 to -6.50 D and mean spherical equivalent was +2.79 (± 2.56 D).

Dr Lee and his associate Prof Dieter Dausch analysed a prospectively followed cohort of 678 eyes of 413 patients that underwent PRK for treatment of

hyperopia during the years 1997 to 2003. All eyes had complete follow-up data available from postoperative visits at one week and one, six and 12 months.

In an initial analysis, the eyes were divided into 18 groups representing increasing levels of preoperative refractive error. Group 1 included eyes with no more than +0.25 D of hyperopia, and each successive group represented higher levels of hyperopia in steps of +0.25 D (or +0.50 D, depending on the number of eyes available).

Beginning with group 1 and group 2 (between +0.25 and +0.50 D) and moving in order across all groups, pair-wise comparisons were made of safety, efficacy, stability, and predictability of outcomes. Statistical analyses were performed using the SPSS package, and the results showed the first statistically significant differences occurred between eyes with +3.45 D and +4.0 D of hyperopia. In further analyses, there were no statistically significant differences in any of the

successively paired groups with higher levels of hyperopia.

Based on those findings, the total cohort was divided into two groups – the first comprised of 146 eyes with preoperative hyperopia ranging from +0.25 D to +3.75 D and the second including the remaining 91 eyes with at least +4.00 D of hyperopia. Outcome comparisons for those two groups showed statistically significant differences in efficacy, predictability, and safety favouring the lower hyperopes.

Slower recovery and more regression in higher hyperopes

Mean preoperative spherical equivalent was +2.83 D for eyes with up to +3.75 D of hyperopia, and +6.85 D for those with higher levels of hyperopia. At one week postoperatively, the average spherical equivalent was near plano in both groups. However, spherical equivalence remained very stable during continued follow-up in the lower hyperopes, changing by only +0.02 D over the first year, while there was significantly more regression (+0.37 D) among the higher hyperopes.

The predictability analyses for the one-year outcomes showed that 81% of the lower hyperopes were within 0.5 D of their intended refraction, while only 54% of the higher hyperopes fell within that target range ($p < 0.05$). The efficacy results showed postoperative UCVA was 20/40 or better in a significantly higher proportion of lower hyperopes compared with higher hyperopes, 83% versus 69% ($p < 0.05$), respectively.

Mean BCVA was not statistically significantly different between the two groups preoperatively.

However, recovery of BCVA occurred significantly earlier, within one to four weeks, among the lower hyperopes. In contrast, visual recovery took one to six months for those with higher hyperopia. In addition, at one year, BCVA was the same or better than the preoperative level in a significantly higher proportion of lower hyperopes compared with higher hyperopes, 85% vs. 67%, respectively ($p < 0.05$).

While encouraging other refractive surgeons to undertake similar studies, Dr Lee emphasised that valid analyses require adequately sized study populations and use of proper statistical methods.

Treatment limit guidelines overdue

Dr Lee said that this type of statistical analysis to identify the limit for safe and successful treatment of hyperopia with surface ablation treatment was long overdue. Reviewing the literature on this issue, he noted that various authors have recommended thresholds for patient selection, but those suggestions were largely based on clinical experience and impressions without any rigorous analysis to provide scientific proof.

“As the number of patients undergoing refractive surgery continues to increase worldwide, more studies such as this are needed, particularly to analyse outcomes of LASIK, which is now the predominant procedure for refractive surgery,” Dr Lee said.

Dr Lee pointed out that their study had high statistical power; all tests were nonparametric, based on the Kolmogorov Smirnov Test. The Wilcoxon test was used for paired data, the



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Mann-Whitney-U test was used for unpaired data with two variables, and unpaired data with more than two variables were analysed with the Kruskal-Wallis test.

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“As we reviewed the literature, we found that incorrect use of statistical tests is a common error. For example, many authors will use the student’s t-test regardless of the number of data points or type of data,” he explained.

In addition, Dr Lee noted that refractive surgeons reading the literature should realise that the findings from a particular study may only be relevant to their own practice if they are using the same type of laser system.

“The findings from our study were based on treatment with the MEL-70, but they would be applicable for any spot scanning laser system with a Gaussian profile,” Dr Lee said.

For these laser systems the limit for safe and successful hyperopic surface ablation is between +3.75 and +4.0 D.

He noted that since the study was conducted he has switched to the MEL 80 from Zeiss Meditec. He said the MEL 80 laser is approximately five times faster than the MEL 70.

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