

FDA Clinical Trial of the MEL 80*



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Dr. Steinert is a Professor of Ophthalmology, Professor of Biomedical Engineering, Director of Cornea, Refractive and Cataract Surgery, and Vice Chair of Clinical Ophthalmology at the University of California at Irvine

(UCI). From 2005 to 2006, Dr. Steinert served as President of the American Society of Cataract and Refractive Surgeons (ASCRS). Dr. Steinert was an original investigator of the excimer laser in 1983 and is currently the Medical Monitor for the U.S. clinical trials of the Carl Zeiss MEL 80 excimer laser.

Dr. Steinert presented results from the MEL 80 clinical trials for FDA approval. The trials started in 2004 with an investigation of myopia and hyperopia including astigmatism. While the hyperopia branch of the study is still ongoing, the myopia branch has been completed with excellent clinical outcomes. In particular, Dr. Steinert pointed out the efficacy numbers, with more than 90% of eyes achieving 20/20 uncorrected visual acuity at the 6-month follow-up visit.

This excerpt of my presentation at the Carl Zeiss Innovation Symposium gives you an update on the current status of the MEL 80 Excimer Laser FDA trials for myopia and hyperopia. As you will know, in the US we have to go through the exercise of a very strict approval process.

The study is designed to evaluate the safety and effectiveness for the correction of myopia with a sphere below -10 D and astigmatism below -3.5 D and hyperopia with a sphere below +6 D and astigmatism below +3.5 D.

This is a prospective multi-center trial in which 360 eyes have to be enrolled for both, myopia and hyperopia. The follow-up period is 6 months for myopia and 24 months for hyperopia.

This is the list of distinguished investigators:

Steven Dell, M.D.; Jon Dishler, M.D.; John Doane, M.D.; Howard Fine, M.D.; Richard Hoffman, M.D.; Mark Packer, M.D.; Roger Steinert, M.D. (Medical Monitor); Steve Schallhorn, M.D.; David Tanzer, M.D.; John Vukich, M.D.

While hyperopia clinicals are still ongoing because of lower patient volume and longer follow-up, myopia clinicals and follow-up have been completed and thus the final results for the myopia cohort are shown in the figures.

The first figure shows the scatter of all data (attempted vs. achieved) at the 6-month follow-up. You see an excellent clustering except for a very few outliers.

Figure 2 demonstrates the excellent refractive outcome with around 80% of eyes being in +/-0.5 D. The distribution of this chart shows a slight tendency to over-corrections which might allow small regressions during following years.

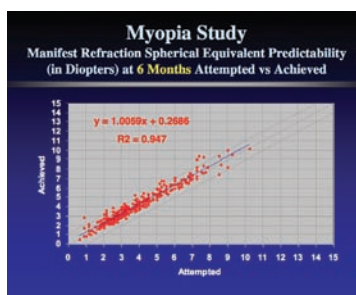


Fig. 1

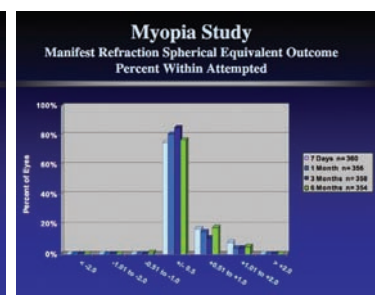


Fig. 2

If you look at the UCVA result shown in figure 3 you will realize why this laser has impressed everyone involved in this study. Even at week 1 more than 80% of patients came up with an uncorrected visual acuity of 20/20 or better and at 6 months well over 90% of patients see uncorrected 20/20 or better. These numbers are outstanding both in terms of fast visual recovery and final outcomes.

Fig. 4 shows the safety data with gain and loss of lines in BSCVA. Most patients are unchanged or gaining visual acuity with 40% gaining one line and some even two lines. The investigators found this very impressive and the patients are very aware of that.

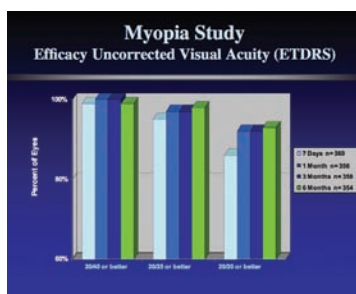


Fig. 3

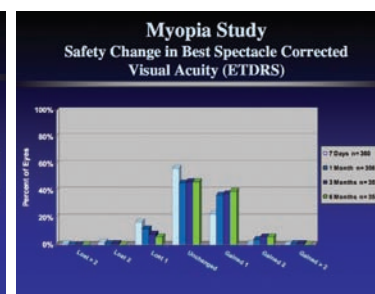


Fig. 4

Thus we can conclude as follows:

- Outcomes at the scheduled post-operative visits are very good
- Fast visual recovery noted
- No unanticipated adverse events to date

* CAUTION—Investigational device. Limited by Federal (or United States) law to investigational use.