

MEL 80 Clinical Results Key to FDA Clearance for Myopia and Hyperopia



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A specialist in refractive surgery, Dr. Dishler has personally performed approximately 40,000 LASIK procedures during the last 10 years.

He participated in the original development of the excimer laser within the framework of the FDA approval studies, and, from the very beginning, contributed to the development of the femtosecond laser. Currently, he is active in the area of refractive surgery as a clinical adviser for product improvement for various companies.

Dr. Dishler has been awarded several patents for inventions in his area of specialty.

At this year's AAO annual meeting in Las Vegas, Dr. Dishler held a lecture at the Carl Zeiss exhibit booth.

Ladies and Gentlemen, in the following article that summarizes my presentation at AAO, I would like to introduce to you the outstanding clinical results that led to the FDA approval of the MEL 80 for myopia and astigmatism in the US. In addition, I would like to inform you about the current results from the hyperopia study.

I can report to you that in the meantime, all necessary hyperopic eyes have also been treated. In these cases, the follow-up still needs to be completed.

However, I want to say at the outset that it is not my intention to bore you with statements about another excimer laser, but rather to inform you about the best in class.

The MEL 80 is simple to operate and extremely fast. A feature that I particularly liked is the simple method of calibration.

However, the most important clinical statement is that, after correction of myopia, 93% of the eyes achieved a visual acuity of 20/20 or better. Over 40% of the eyes achieved a visual acuity of 20/12 or better, which up until now had not been achieved in studies with wavefront correction.

The aim of the study was the evaluation of the safety and efficacy of the correction of myopia up to -10 diopters, and astigmatism up to -3.5 diopters, as well as hyperopia ranging to +6 diopters and astigmatism to +3.5 diopters.

This was a prospective multi-center study with 360 myopic and hyperopic eyes. The follow-up period is 6 months for myopia and 24 months for hyperopia.

The following study physicians played a substantial role: Steven Dell, MD; Jon Dishler, MD; John Doane, MD; Howard Fine, MD; Richard Hoffman, MD; Mark Packer, MD; Roger Steinert, MD (Medical Monitor); Steve Schallhorn, MD; David Tanzer, MD; and John Vukich, MD.

The final results of the myopia cohort are shown in Illustrations 1-4.

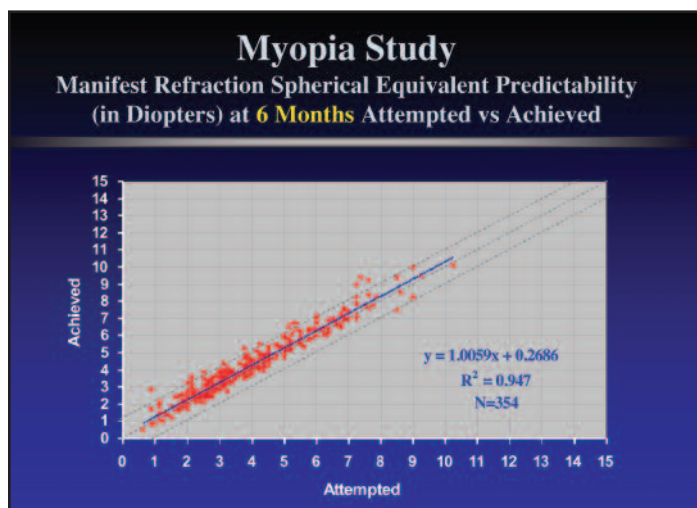


Illustration 1

The first graph shows the distribution of all data (target vs. achieved correction) at the follow-up after 6 months. Aside from a few outliers, you see an excellent, small scatter.

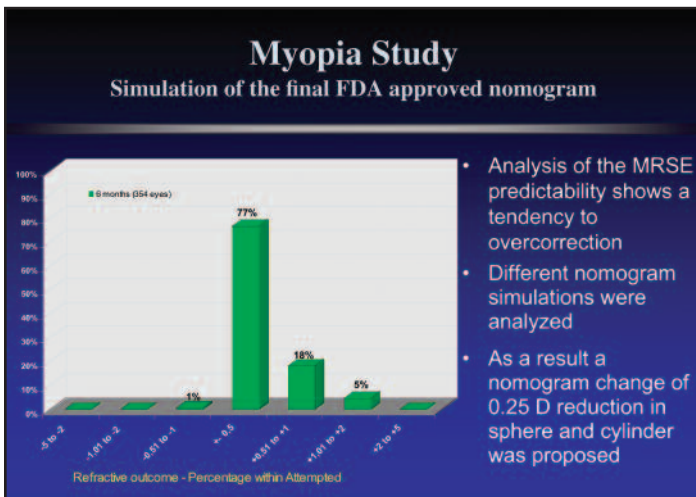


Illustration 2a

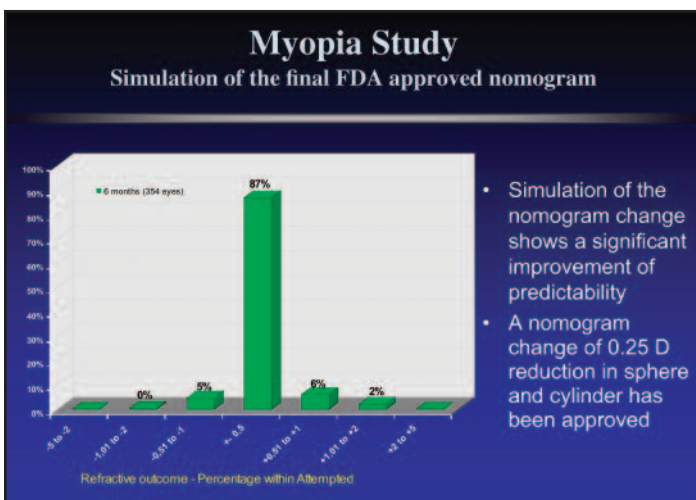


Illustration 2b

Illustration 2a shows the refractive result after 6 months, wherein 77% of the eyes lie in the range between ± 0.5 diopters. In this graph, the distribution shows a slight tendency towards over correction. At the conclusion of the myopia study, a nomogram change of 0.25 diopters, both in sphere and cylinder, was recommended to the FDA. The FDA accepted this recommendation. An outcome distribution that takes this approved nomogram change into account can be seen in Illustration 2b. As a result, 87% of the eyes could now be found in the range of ± 0.5 diopters-- an outstanding value.

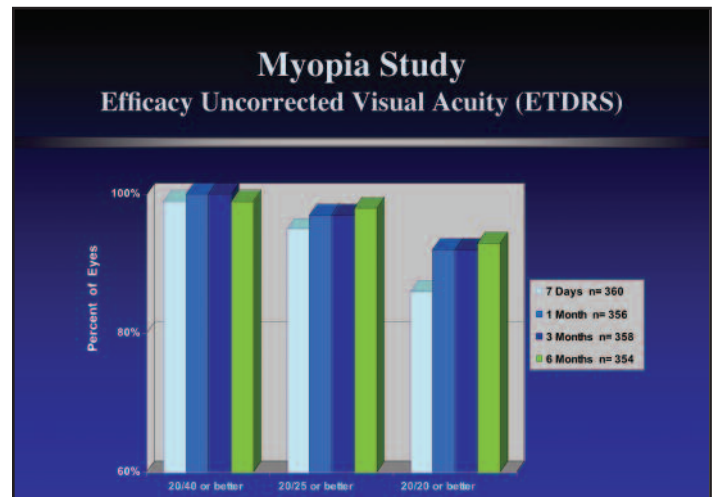


Illustration 3

However, the result with respect to uncorrected vision is much more impressive, as shown in Illustration 3. As early as the first week after the operation, 80% of the patients exhibited an uncorrected visual acuity of 20/20 (1.0) or better, which documents an extremely rapid visual recovery.

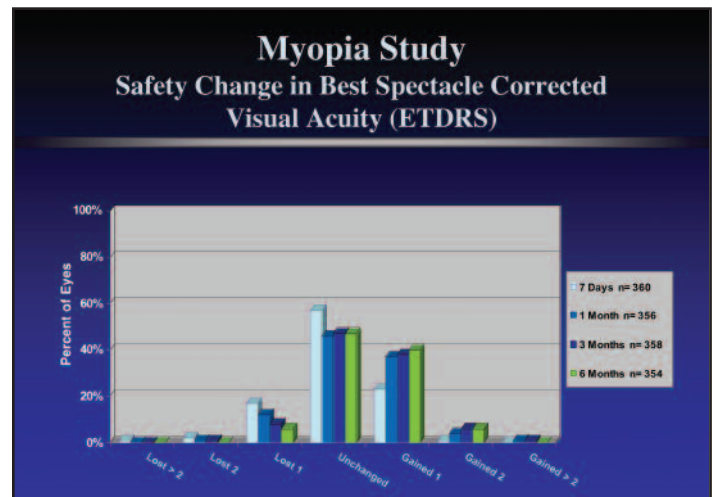


Illustration 4

Illustration 4 shows the results regarding the safety of the treatment, with gain and loss from the best-corrected vision. Most patients remained unchanged; 40% were able to improve by one line, and some, in fact, by two lines.

Physicians found this study very impressive, and the results were confirmed by the subjective impression of the patients.

On August 11, 2006, the MEL 80 was approved in the US for correction of myopia up to -7 diopters and astigmatism up to -3 diopters, with a spherical equivalent of up to -7 diopters.

Surgical Insights

For the correction of both myopia and hyperopia, it was noted that, through the aspheric shaping of the ablation profile, many patients who were older than 40 not only had very good distant vision, but also good near vision.

A 53-year-old female patient, for example, now sees 20/15 in the distance and J2 at close range.

Let's now look at the results from the Hyperopia study.*

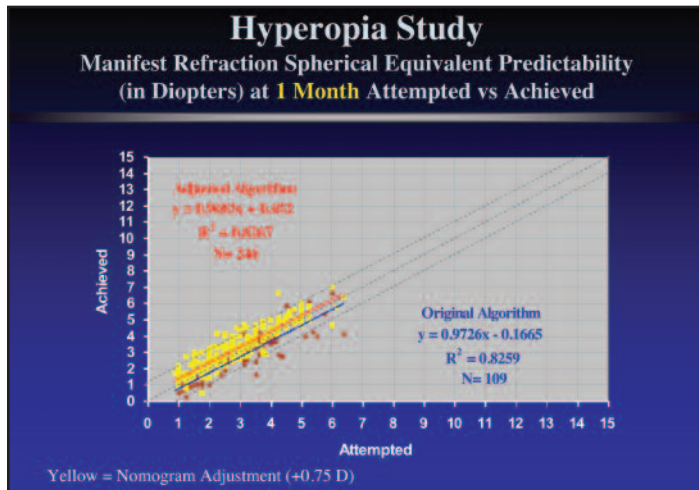


Illustration 5

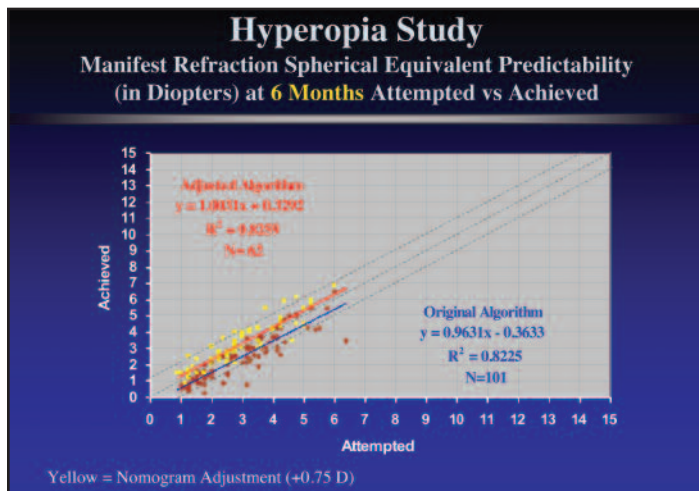


Illustration 6

Illustration 5 shows the scatter without (brown dots) and with nomogram correction of 0.75 (yellow dots) after one month. After 6 months, the compensation curve lies parallel to the reference curve with a slight over correction of approximately 0.3 diopters which permits absorption of the expected slight regression (Illustration 6).

* MEL 80 not approved for this use in the U.S.

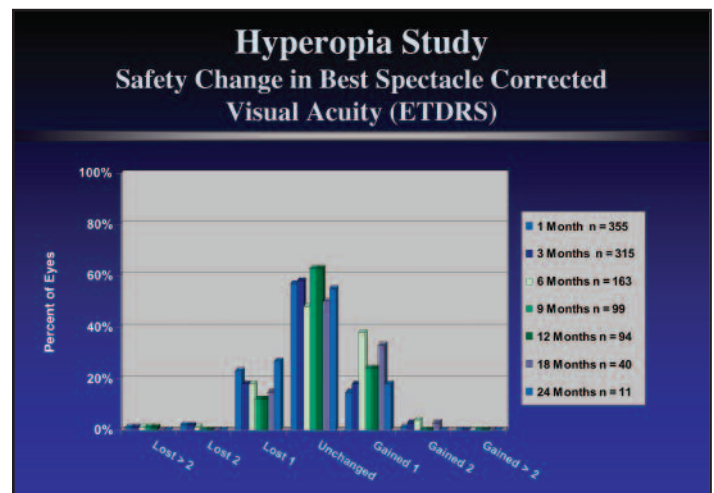


Illustration 7

From Illustration 7, one can see that significantly more eyes gained visual acuity than lost it, which, for a hyperopia study, is very good.

Thus, we can summarize as follows:

- The results of the scheduled postoperative examinations are very good.
- A rapid recovery of vision was noted.
- To date there have been no unanticipated, negative side effects.

I would like to share some impressions from my staff's perspective during the study. The personnel found it simple to handle the laser, particularly in terms of calibration. The processing of patients was very rapid. The Eyetracker followed both the pupils as well as the margins, and functioned without problems throughout the entire study.

From my point of view, the MEL 80 is simple to operate, extremely fast and no doubt, the best in class for exceptional results.

Note: Due to the limited number of cases in the higher diopters range, the approved range is limited to -7 D. However, the first graph shows that even the high corrections showed good predictability results.