

FIRST EXPERIENCE WITH THE ZEISS FEMTOSECOND SYSTEM IN CONJUNCTION WITH THE MEL 80™ IN THE US

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INTRODUCTION AND STUDY OBJECTIVES

This article summarizes the first US experience with the FDA-approved MEL 80™ and the 510(k) cleared VisuMax® femtosecond laser system as presented at the ASCRS 2007 during the Carl Zeiss Meditec Innovation Symposium.

The general objective of this study was to determine the surgical outcomes of patients undergoing myopic LASIK using both the VisuMax® laser keratome to create corneal flaps and the MEL 80™ excimer laser to perform the refractive correction, within the FDA-approved range, as part of an integral LASIK procedure. It is also very important to analyze how accurately the system is able to create the flaps. Hence it was an objective of this study to determine corneal flap thickness using the Visante™ OCT.

Especially flap thickness issues are widely discussed to be of major interest due to safety considerations. Thinner flaps weaken the cornea less during the LASIK procedure. Therefore, thinner flaps are safer for patients because of the decreased risk of postoperative ectasia. Moreover, the greater the residual bed thickness due to thin flaps, the better is the chance that if a patient does need retreatment it can be accomplished. Another objective is to report possible adverse events and complications associated with the combined use of the VisuMax® laser keratome and the MEL 80™ excimer laser system in the myopic LASIK procedure.

STUDY DESIGN AND SUBJECT DEMOGRAPHICS

All treatments have been performed at one clinical site, the Dishler Laser Institute, Denver, Colorado, USA and were completed during March 2007. One surgeon (Jon Dishler) operated on 62 eyes of 32 consecutive patients undergoing initial myopic LASIK. The approved myopic LASIK treatment range was up to -7.00 D sphere, -3.00 D cylinder and -8.00 D manifest refraction spherical equivalent (MRSE). The VisuMax® femtosecond laser keratome LASIK flaps created were of 100 µm, 110 µm, or 120 µm planned flap thickness. Initially, a 120 micron depth flap was cut, then 110 µm and 100 µm flaps were created. Visante™ scans were performed preoperatively and postoperatively to determine corneal flap thickness.

Study end points were defined to cover the base parameters required for primary evaluation, i.e. predictability, safety and effectiveness. The following safety and effectiveness parameters were applied. The percentage of eyes with uncorrected visual acuity (UCVA) of 20/20 or better and 20/40 or better was analyzed to account for the effectiveness of the procedure and the number of eyes within ± 0.50 D and ± 1.00 D of the intended correction ranges for predictability. For safety, the number of eyes with a loss of more than 2 lines of best spectacle corrected visual acuity (BSCVA) and the number of eyes with more than 2.0 D of induced manifest refractive astigmatism were counted. Mean corneal flap thickness as measured by the Visante™ OCT compared to the intended flap



thickness for the VisuMax® treatment is also a very important evaluation criterion for safety. Patients were screened for corneal pathologies by complete ocular examinations. Patients with ocular pathologies like severe dry eye, keratoconus, corneal scars, corneal dystrophies, other ocular diseases with a certain history, and previous ocular surgery were excluded. With 14 (44 %) male and 18 (56 %) female patients, the gender distribution of the recruited patients was uniformly distributed. Further details of the subject demographics of the 62 eyes are summarized in Table 1.

Pre-OP	Mean	Range
Age	38 y	24 y – 55 y
Sphere	-2.92 D	(-0.25 to -5.75) D
Cylinder	-0.85 D	(0.00 to -2.75) D
MRSE	-3.33 D	(-0.88 to -6.13) D

Table 1: Pre operative subject demographic for the Zeiss VisuMax® – MEL 80™ LASIK study, 62 eyes

When programming the VisuMax® laser to create a 100 µm flap, the mean measured thickness (13 eyes) was 97.6 µm at seven days. Note the small range of measurements observed from 95 to 101 µm. Data gathered at one month on seven eyes was virtually the same, with a mean flap thickness of 98.9 µm. Similar good results were found for programmed flap thicknesses of 110 µm and 120 µm, where 22 patients and 9 patients were measured, respectively, after 7 days. For the investigated flap thicknesses, very good accuracy of the mean post-surgery flap thickness was

Keratome	N	Mean	SD	Range
Intralase 110 µm	20	125.9	15.2	106–160
Hansatome 200 µm	9	171.3	9.5	146–188
Moria 130 µm	4	187.2	16.4	168–210

Table 3: Flap thickness results measured 7 days after LASIK surgery using the Intralase femtosecond flap cutter, the Hansatome and Moria microkeratomes measured with Visante™ OCT

RESULTS AND FINDINGS

Flap Thickness

Initially, the focus was on the flap thickness as one of the most important clinical aspects related to flap parameters. We anticipated improved accuracy of the flap thickness for femtosecond flaps made with the VisuMax® laser keratome. The findings at 7 days and 1 month postoperatively are summarized in Table 2. The flap thickness results shown were determined by averaging three Visante™ measurements for each flap measured.

noted with just a few microns below the programmed thickness. Concerning the range of flap thicknesses, we did not find flaps that were off more than 6 µm for 120 µm. It should be noted that the accuracy of the Visante™ OCT to measure corneal flap thickness is on the order of 10 µm.

The data from this study was compared with data gathered during the first Visante™ pachymetry and flap thickness study that was submitted to the FDA for premarket clearance. The FDA 510(k) Visante™ study involved three investigators who each used a different

Programmed Thickness	7 days post-operatively			1 month post-operatively		
	N	Mean	Range	N	Mean	Range
100 microns	13	97.6	95–101	7	98.9	97–102
110 microns	22	108.0	104–113	9	110.0	108–112
120 microns	9	117.8	114–122	8	112.8	104–119

Table 2: Flap thickness results measured 7 days and 1 month after myopic LASIK surgery using the VisuMax® laser for flap cutting and the MEL 80™ for the refractive correction measured with Visante™ OCT

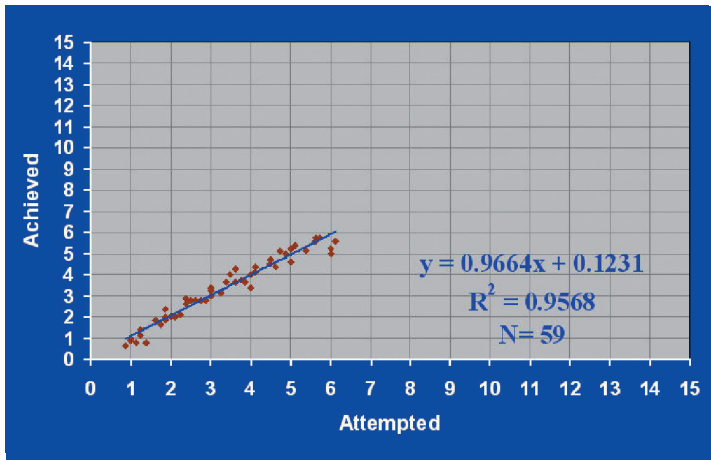


Figure 1: Predictability of VisuMax® – MEL 80™ combined treatments after 7 days post-surgery. Achieved manifest refraction spherical equivalent (MRSE) versus attempted MRSE is shown for 59 eyes.

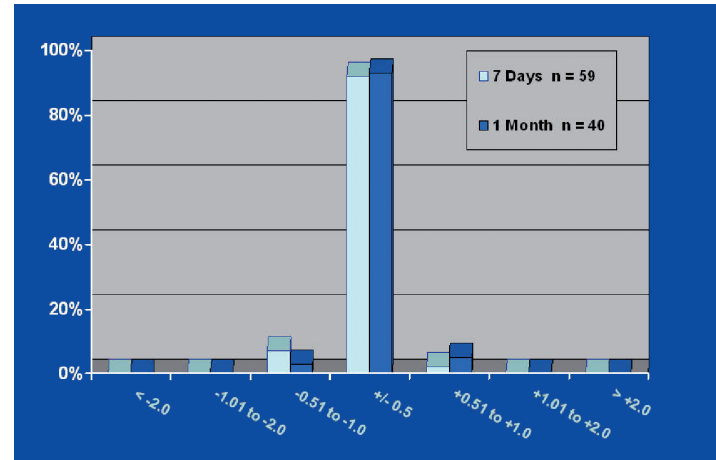


Figure 2: Refractive outcome of VisuMax® – MEL 80™ combined treatments after 7 days and 1 month post-surgery. Percentage of the eyes within the attempted manifest refraction spherical equivalent sectioned in the intervals as given on the abscissa for 59 eyes after 7 days and 40 eyes 1 month post-surgery.

keratome (one used IntraLase, one used Hansatome, and one used Moria). The flap thickness observed during the first study at 7 days is provided in Table 3 below. Note that mean flap thickness for these three keratomes was not as close to the target flap thickness as the VisuMax® findings noted above.

The mean flap thickness for 20 eyes was 125.9 for the IntraLase femtosecond laser system when a flap thickness of 110 μm was targeted. Note the wide range of measurements from 106 to 160 μm . For the Hansatome microkeratome, mean flap thickness was 171.3 μm for nine eyes at 7 days when the targeted thickness was 200 μm , with a range of 146 to 188 μm . For the Moria microkeratome, mean flap thickness was 187.2 μm for 4 eyes at 7 days when the targeted thickness was 130 μm , with a range of 168 to 210 μm . As can be seen from these data, the range of values obtained is much greater for the IntraLase, Hansatome, and Moria keratomes than the VisuMax® femtosecond laser. We noted a large range of findings for measured flap thickness during the IntraLase measurements. Although there seems to be a reasonable lower limit (106 μm) for measured flap thicknesses below the programmed ones (110 μm), a much extended upper range of measured flaps (160 μm) above the programmed thickness appeared. This higher measurement potentially could increase

the risk of surgical complications such as ectasia. Our data is more consistent with findings reported in the literature, see (4) for IntraLase studies or (1, 2, 3) for Hansatome and Moria microkeratome studies respectively.

In conclusion, the VisuMax® system generates more accurate flaps compared to the IntraLase femtosecond laser and Hansatome and Moria mechanical microkeratome. The small range of measured flap thickness for the VisuMax® system (104 μm to 113 μm for 110 μm programmed flap thickness) compared to the IntraLase system (106 μm to 160 μm for 110 μm programmed flap thickness) appears to be an important finding for increased safety in daily clinical practice. Moreover, we on average gain residual corneal thickness as the VisuMax® provides flap thickness upper limits well below the IntraLase system. This is very important in case of potential retreatments and reduces the risk of ectasia.

The increased accuracy is in part due to the calibration of each disposable contact glass immediately before the procedure, and this is unique to the Zeiss femtosecond laser system. It might also be due in part to the curved contact glass, which allows for flap cuts in the cornea in a more anatomically correct manner than other microkeratomes, whether blade- or laser-based.

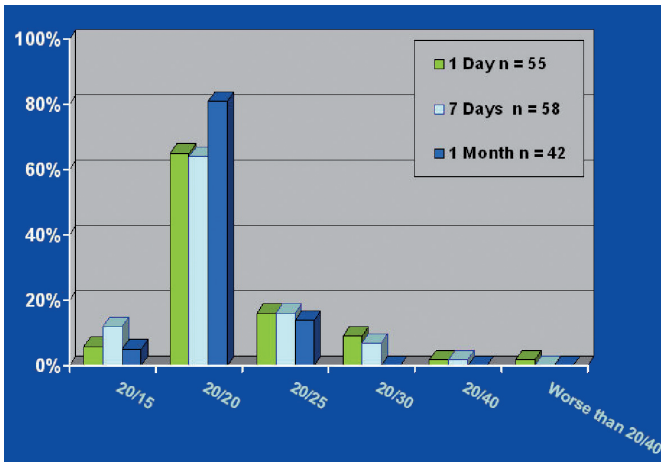


Figure 3: Efficacy of VisuMax® – MEL 80™ combined treatments at day one and after 7 days and 1 month post-surgery. Percentage of the eyes with uncorrected (Snellen) visual acuity for 55 eyes at day 1, 58 eyes after 7 days and 42 eyes after 1 month.

Refractive outcome

In general, we found accurate refractive outcomes reproducing the excellent results of the FDA clinical trial that led to approval of the MEL 80™ for myopia. The predictability in particular is very high for treatments using the VisuMax® for flap cutting followed by MEL 80™ refractive corrections. This is shown in Figure 1 where the achieved manifest refraction spherical equivalent (MRSE) versus the attempted MRSE at 7 days post-surgery is provided. All eyes are very tightly clustered around “ideal” attempted versus achieved line without outliers beyond the ± 1 diopter interval. Although not shown here, changes from 7 days to 1 month postoperatively were minor, demonstrating the rapid stability of results of LASIK procedures with VisuMax® femtosecond flap creation combined with the MEL 80™.

Figure 2 shows the accuracy of refractive outcome for VisuMax® – MEL 80™ combined treatments after 7 days and 1 month post-surgery. Over 90 % of the eyes are within plus or minus half a diopter within the attempted manifest refraction spherical equivalent 7 days post-surgery (92 %) and 1 month post-surgery (93 %). Virtually all patients are within the one-diopter interval. Efficacy for VisuMax® – MEL 80™ combined treatments at day 1 and after 7 days and 1 month post-surgery is shown in Figure 3. Given

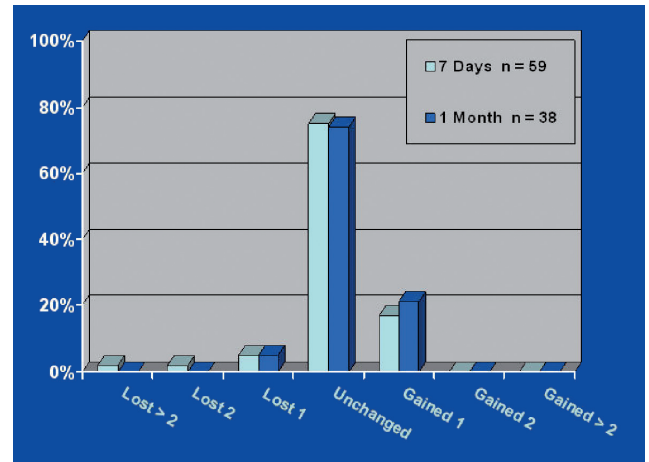


Figure 4: Safety of VisuMax® – MEL 80™ combined treatments after 7 days and 1 month post-surgery. Percentage of the eyes with change in (Snellen) best spectacle corrected visual acuity for 59 eyes after 7 days and 38 eyes after 1 month.

is the percentage of eyes with uncorrected Snellen visual acuity from visual acuity 20/15 down to 20/40 or worse for 55 eyes at day 1, 58 eyes after 7 days and 42 eyes after 1 month. Patients were not challenged during their examination to read at 20/15 or better vision because we intended to get realistic data comparable to what we found in other studies. Nevertheless, cumulatively 100 % of eyes were 20/25 or better 1 month post-surgery and about 85 % or 36 of 42 eyes were 20/20 or better. This is a very good result.

Best spectacle corrected visual acuity (BSCVA) changes pre- to post-surgery (see Figure 4) demonstrate the high level of safety when using the VisuMax® for flap cutting followed by the MEL 80™ refractive correction approach. 95 % of all eyes were unchanged or gained one line after 1 month post-surgery. Only 5 % of or two eyes lost one line but no eye lost two or more lines after 1 month follow-up.

Surgical and postoperative complications and other aspects

Femtosecond flap cutting using VisuMax® was a new approach for us. Of importance were findings related to adverse events and surgical or postoperative complications. Not very much can be reported in this respect. The only surgical complications at all out of 62 eyes treated related to suction loss in two cases. One suction loss appeared in the very beginning of the procedure. We simply placed the suction back on, and finished treatment without any further complication. In the other case, the patient moved after most of the cut was made but before the sidecut had been completed. Following the company recommendations, we simply replaced the contact glass, and did the sidecut only. That flap lifted up perfectly and the case was uneventful. In the course of MEL 80™ refractive correction, following the flap cut with VisuMax®, we had no surgical complication and excellent visual result. This points out the added safety of femtosecond flap creation. In case of a suction loss that can occur with any microkeratome, what might be a significant complication, became an insignificant event for the VisuMax®.

In Table 4, we summarized our findings related to postoperative complications. We had virtually no significant complications except 2 dry eyes out of 60 eyes. Two cases of corneal edema between one week and one month resolved subsequently and one patient complained about temporary light sensitivity.

Postoperative complications, 60 eyes	Quantity
Corneal edema between one week and one month after the procedure	2
Increase IOP	4
Permanent plug for significant SPK	2
Transient light sensitivity syndrome	1
D L K	0

Table 4: Summary table of postoperative complications related to VisuMax® – MEL 80™ combined treatments.

CONCLUSION

The Carl Zeiss Meditec VisuMax® laser keratome and MEL 80™ excimer laser system as part of the LASIK procedure provide safe, predictable, stable, and highest quality refractive outcomes, with a fast visual recovery. Surgical and postoperative complication rate was extremely low and no adverse events appeared during this study. Flap quality was excellent with the highest accuracy ever observed so far by us when compared to another femtosecond laser system and other conventional mechanical microkeratomes. Initial clinical results were excellent with rapid stabilization of excellent visual acuity and no significant complications were experienced.

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