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The LASIK Nomogram Validation of the MEL 80

F. Goes (Antwerp), S. Gierek-Ciaciura, E. Mrukwa-Kominek, D. Wygledowska-Promienska (Katowice), Z. Smecka (Zlin)

Introduction

The MEL 80 from Carl Zeiss Meditec is a new Excimer Laser for refractive corneal surgery, which is working with the most actual parameters for modern state of the art flying spot devices: it is using a tiny spot with a real Gaussian beam profile, diameter 0.7 mm (FWHM). The laser acts at 250 Hz with a video based active eye tracking working with just the same frequency of 250 Hz. There is a forced air flow at corneal level to achieve regular ablation characteristics undisturbed by plume effects.

The ablation profiles were designed considering the strongly curved cornea as a target: thus different angles of incidence have different fluence values and reflection losses.
The shape of the ablated tissue lens is not spherical but aspherical with an asphericity of q = -0.25.

Methods

All eyes were treated with the MEL 80 following a clinical protocol with these key issues: Full correction for Myopia –1 to –9 D, Astigmatism 0 to –3.50 D, preop BSCVA ≥ 0.8; treatment diameter 6 – 7 mm.; LASIK cut with residual stromal thickness > 250 µm.
The patients were recruited and surgery was performed at three centers: Antwerp (Belgium), Katowice (Poland), Zlin (Czech Republic).
The Antwerp center used a Hansatome and contributed 48 eyes, the Katowice Center used a SKBM and contributed 68 eyes, Zlin used a Moria LSK and contributed 58 cases.

The results were gathered after the one-month-visits and have been analyzed with the Datagraph software (1) and using graphs recommended by George O. Waring III (2).

Visual results

The refractive outcomes are best presented by a scattergram of the attempted versus the achieved refractive change for each eye (Figure 1). Whereas figure 1 is giving an impression of the spread of cases over the whole correction range is figure 2 giving relevant numbers:
99 % of eyes being in the so called happiness zone of ± 1 D and 93 % of eyes being in the range ± 0.5 D, which is the new gold standard for refractive outcomes today.

Figure 3 summarizes the ***Predictability*** numbers in a cumulative graph for the postop defocus equivalent refraction.

Figure 4 is an acuity bar graph presenting the ***Efficacy***, it consists of two components: component 1 is the spectacle corrected visual acuity at base line (BSCVA); component 2 is a cumulative bar graph of uncorrected visual acuities after surgery (UCVA). Impressive is that 83 % have 20/20 uncorrected postop from this cohort with 84 % 20/20 best corrected preop.

The ***Safety*** issue is shown in Figure 5. This bar graph depicts the change in spectacle-corrected visual acuity from baseline to the postoperative examination in terms of the number of Snellen lines changed. Because a change of 1 Snellen line is within the accepted range of normal biological variability, the relevant number is, which percentage of eyes have 2 or more lines lost, here we have 1 % or two eyes, which lost 2 lines, but 11 % who gained 2 or more lines.

The ***Stability*** of refraction graph is presented in Figure 6. The timeline depicts the mean spherical equivalent with error bars showing the standard deviation.

Aberrometric results

The MEL 80 produces aspheric ablation profiles as mentioned above. These profiles should help to avoid the strong increase of aberrations after refractive laser surgery, especially of the spherical aberrations (Zernike polynomial Z(4,0)).
It is well known that standard LASIK increases these aberrations by factors of several 100 % (3).To evaluate the usefulness of the MEL 80 profiles a subgroup of eyes from F. Goes (Antwerp) have been measured preop and 1 month postop with the aberrometer WASCA from Carl Zeiss Meditec. The analysis of Zernike Polynomials of 3rd and 4th order show, that the increase/change is not high (RMS HighOrder from 0.20 to 0.28); especially the spherical aberration (Z(4,0)) is only increasing by 18 %.

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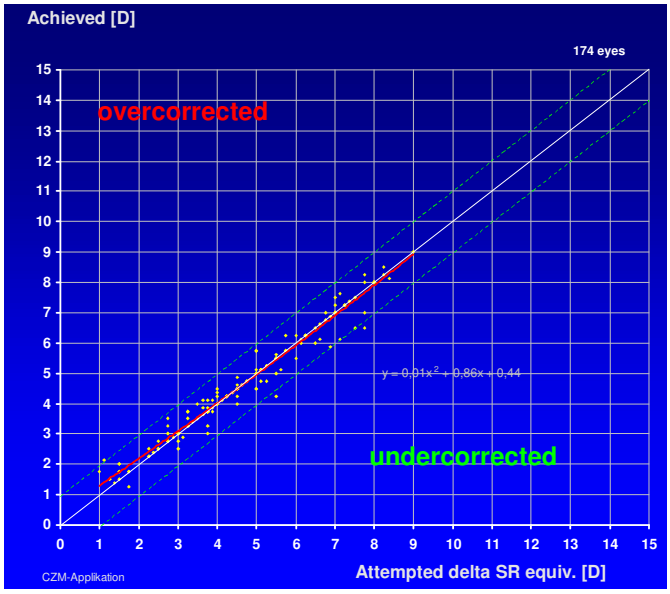


Fig. 1: Scattergram of attempted vs. achieved refraction

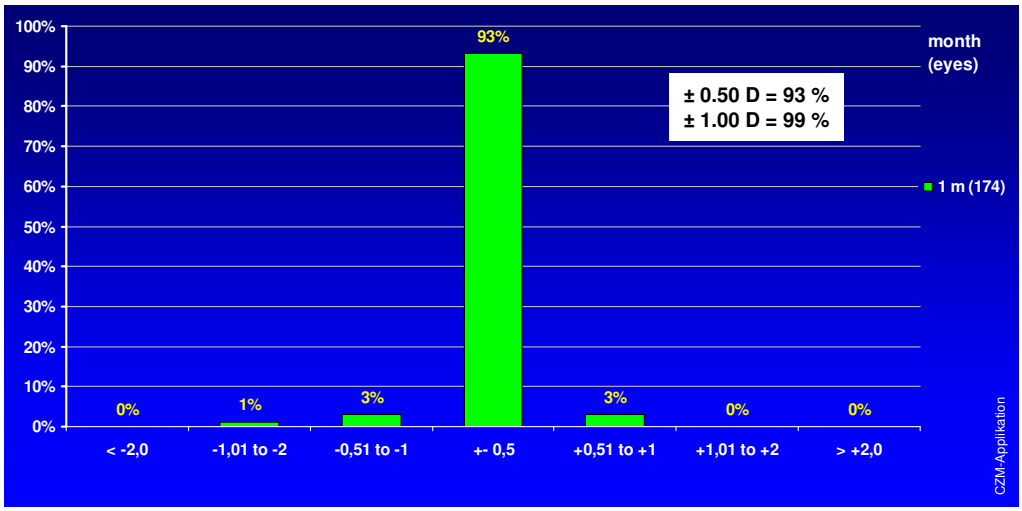


Fig. 2: Spherical equivalent refractive outcome bar graph

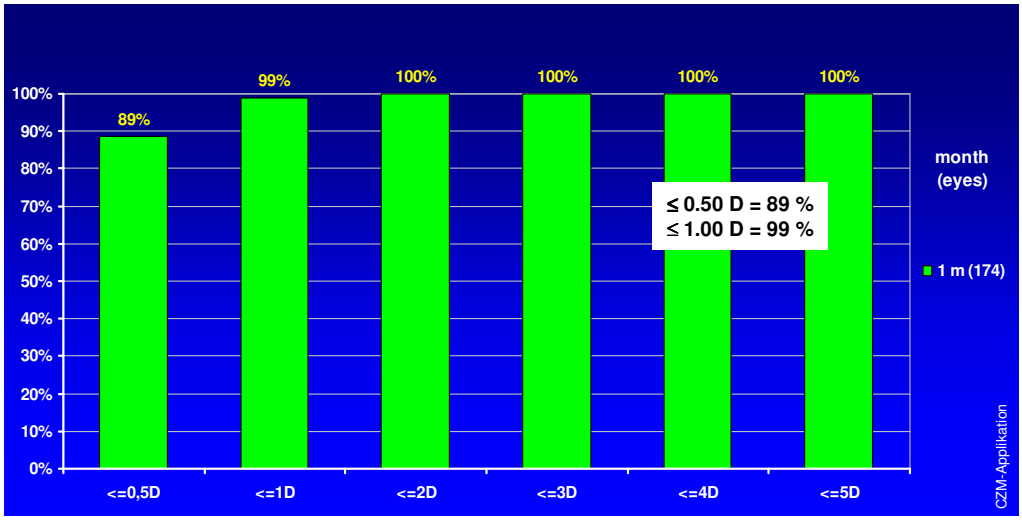


Fig. 3: Defocus equivalent bar graph

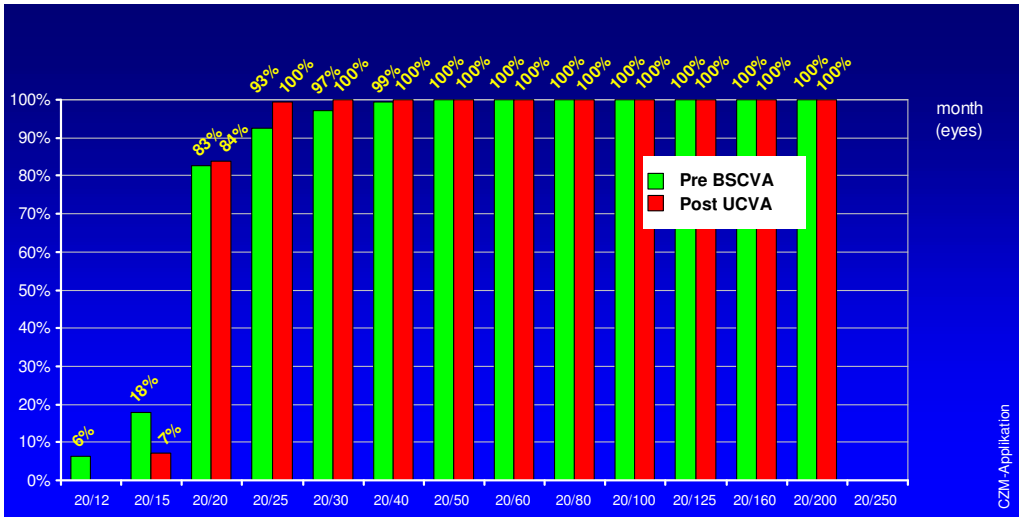


Fig. 4: Cumulative Snellen Visual Acuity (20/-)

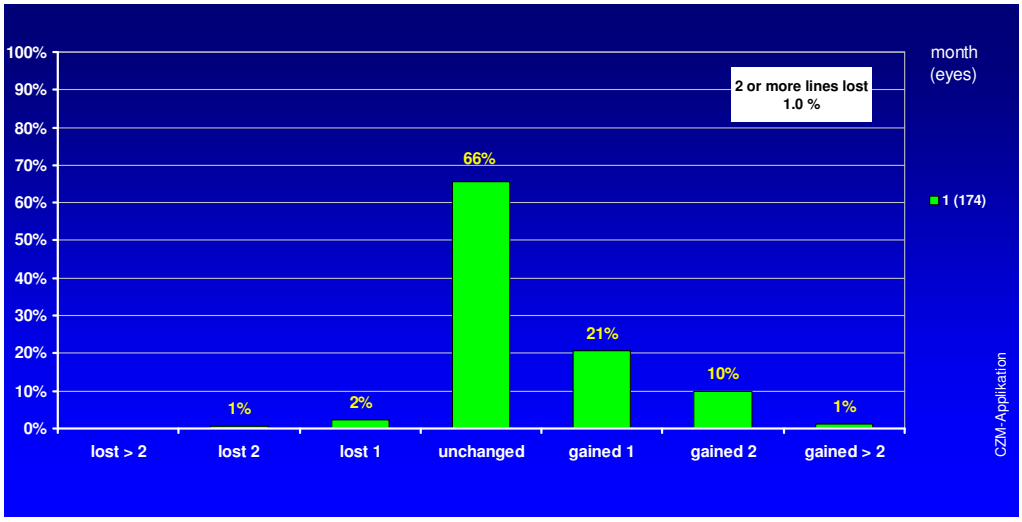


Fig. 5: Change in spectacle-corrected visual acuity bar graph

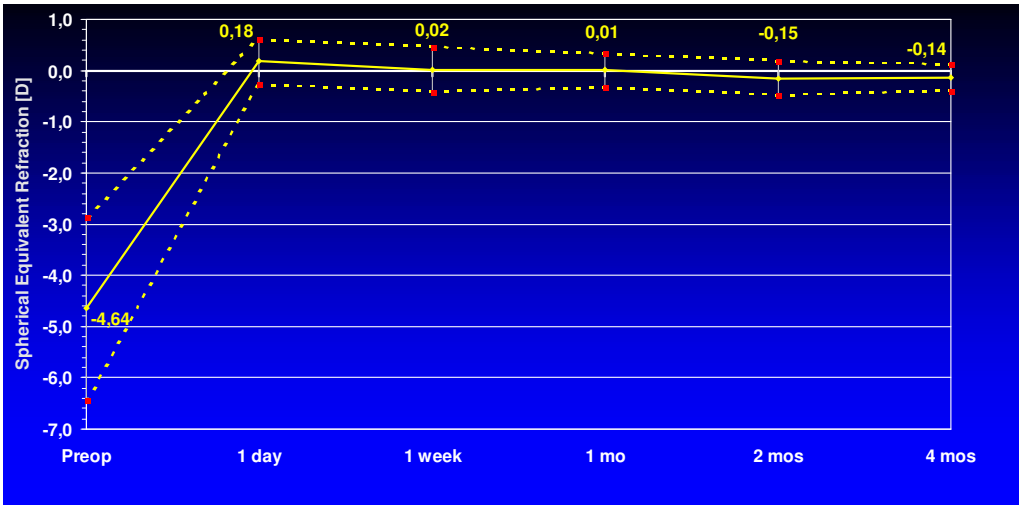
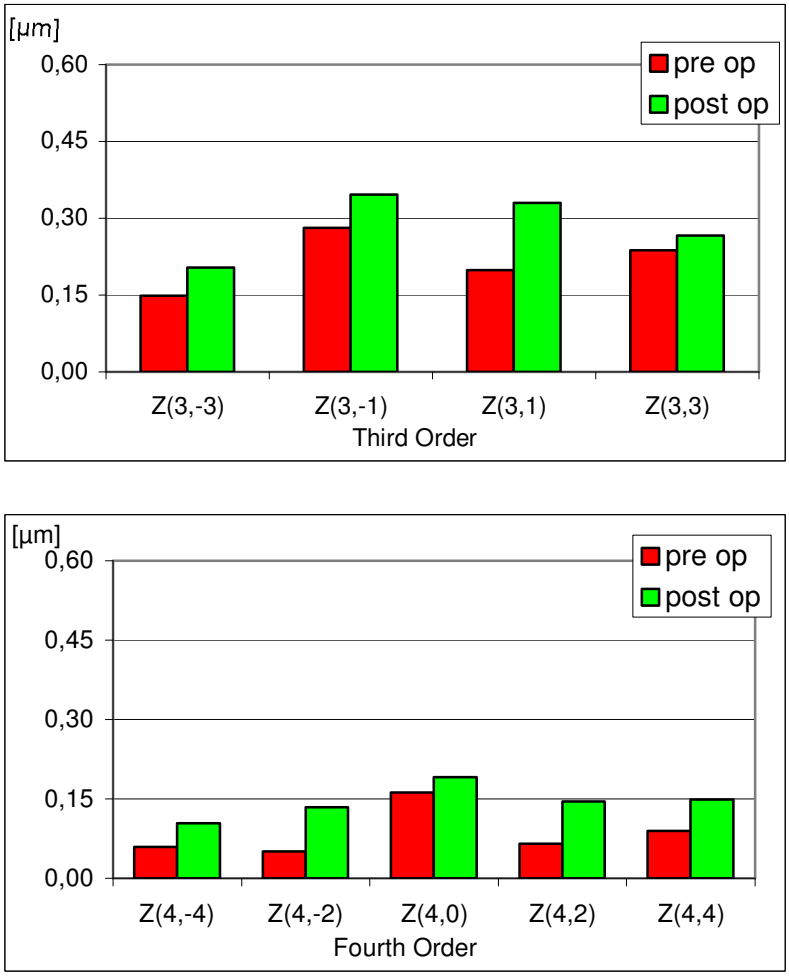


Fig. 6: Stability of refraction graph



RMS HighOrder:	**pre 0.20**	**post 0.28**
Spherical Aberration Z(4,0):	**pre 0.16**	**post 0.19**

Fig. 7: Mean values of Zernike Polynomials

References:

(1) Datagraph med (Medical Data Analysis Software)
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(2) Waring G. Standard Graphs for Reporting Refractive Surgery.
J Refract Surg 2000; 16: 459-466

(3) Seiler T, Kaemmerer M, Mierdel P, Krinke H-E. Ocular optical aberrations after photorefractive keratectomy for myopia and myopic astigmatism.
Arch Ophthalmol 2000; 118: 17-21

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Carl Zeiss Meditec AG
D - 07740 Jena
Germany

Telephone: +49 (0) 36 41/2 20-0
Fax: +49 (0) 36 41/2 20-1 12
e-mail: info@meditec.zeiss.com
Internet: http://www.meditec.zeiss.com