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One year LASIK experience treating Myopia with the Carl Zeiss Meditec MEL 80 LASER

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INTRODUCTION

Over the last 7 years LASIK has become the procedure of choice for the surgical correction of low to moderate myopia. Studies in the literature have shown that LASIK is effective and predictable in obtaining very good to excellent uncorrected visual acuity and that it is safe in terms of minimal loss of visual acuity (1). During the last years the laser technology switched from broad beam ablation to small flying spot scanning techniques. The trend on focusing on treating minor irregularities and/or high order aberrations with customized ablation techniques was introduced in Laser Refractive Surgery. However an interesting question, "How will this new generation of lasers perform in standard treatments", remained open. In order to answer this question we tested the MEL 80 in a small cohort of consecutive patients.

PATIENTS AND METHODS

PATIENTS

For this LASIK study in compound Myopia, patients were enrolled if they fulfilled the following criteria: 20 years or older, preoperative cycloplegic spherical refraction between -1 and -9 Myopia and up to -3 D of myopic astigmatism, a stable refraction (change of less than 0.5 D/year) for at least 1 year, preoperative BSCVA better or equal to 20/25, sufficient corneal thickness for full correction with residual stromal thickness of at least 280 µm remaining beneath the LASIK flap. Patients with a history of any ocular disease, keratoconus, keratoconus fruste, connective tissue disorder, pregnancy, and severe dry eye were excluded from the study.

Treatments were performed between July 2002 and November 2002 in the "Goes Eye Centre" in Antwerp Belgium; a private outpatient surgery centre.

LASER

The Laser used was the MEL 80 from Carl Zeiss Meditec (Jena, Germany). This is a high speed flying spot scanning laser with a Gaussian laser beam profile (0.8 mm FWHM). The laser is working at 250 Hz with a video based active eye tracking working with 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 profile was not calculated according to the Munnerlyn formula (2) as was done in former laser models (e.g. MEL 60, MEL 70). Here the profiles were designed considering the strongly curved cornea as a target. Doing this way different angles of incidence have different fluence values and reflection losses (3). The shape of the ablated tissue lens is not spherical but aspherical with an asphericity of q = -0.25 (4).

PREOPERATIVE ASSESSMENT

Patients were instructed to remove soft contact lenses 2 weeks and rigid gas permeable (Rgp) contact lenses 4 weeks before their preoperative examination as well as before their surgery.

The preoperative examination included assessment of uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), manifest and cycloplegic refraction, slit-lamp microscopy, mesopic pupillometry with the Colvard Pupillometer (Oasis Medical) specular microscopy, non-contact tonometry, eye length measurement with the IOL Master (Carl Zeiss, Jena, Germany), detailed fundus evaluation by both direct and indirect ophthalmoscopy, autokeratomety (Zeiss Humphrey), corneal topography (Tomey TMS2), Aberrometry (Wasca Analyzer Carl Zeiss Meditec) and Pachymetry (Corneogage Plus TM, Sonogage, Inc., 44128, Cleveland OH, USA).

Topographic maps were taken with the TMS 2 Topographer from Tomey using the TMS 3 software.

The aberrometric measurements were taken with the WASCA Analyzer from Carl Zeiss Meditec. This is a Shack-Hartman type sensor with an extremely high resolution; it takes 800 measuring points inside a 7mm pupil zone (5).

SURGICAL TECHNIQUE

A standard surgical treatment protocol was used. Treatment conditions were as follows; room temperature 21 °C ± 1 °C, Humidity 45% ± 5%. A laser fluence test was performed between each patient.

The microkeratome used was a Hansatome (Bausch and Lomb Surgical, Inc., Rochester, NY, USA); the intended flap thickness was 180 µm in all cases. In six eyes with borderline corneal thickness a 160 Micron plate was used.

The hinge position was superior. As a standard a 9.5 mm ring was used except in 3 eyes; one eye with a small corneal diameter (11mm) and two eyes with limbal neovascularisation caused by contact lens wear, where a 8.5 mm ring was used in order to avoid haemorrhages.

The patient's preparation before surgery was as follows: Diazepam (Valium®), 5mg, 1 hour before surgery, three drops of Ciloxan® (Ciprofloxacine hydrochloridum 0.3% Alcon), one drop every ten minutes, starting half an hour before surgery.

In the laser room, prior to the keratectomy, 2 drops of a non-preserved anaesthetic, Minims Benoxinate Hydrochloride® (Oxybuprocaine hydrochloride 0.4%, Chauvin, UK) were instilled in the eye, Betadine® (Povidone Iodine 5%) antisepsis was performed at the level of the eyelids and eyelid margins. A locked aspiration speculum was placed after supplementary anaesthesia of the bulbar and palpebral coniunctiva with a sponge soaked in non-preserved Xylocaine 1%. Prior to the keratectomy one supplementary drop of non-preserved 1% Xylocaine was instilled. The Hansatome microkeratome was placed, decentred slightly superiorly and the cut was made. The suction was released during the backpass of the microkeratome. The bed and the flap were inspected; the cone system swept in, the eye tracker engaged, the flap lifted and the excimer laser ablation was performed, centered on the pupil.

The bed was not dried before or during lasering except in two cases where, during the keratectomy, minor bleeding occurred from pericorneal vascularisation caused by previous contact lens wear. During the whole treatment attention was given that the eye remained in a horizontal position. At the end of the laser treatment the interface was cleaned with a sponge soaked in Deicol® (Dexamethasone 0.1%, Chloramphenicol 0.40%, Viatris) and the flap was repositioned. The interface was irrigated with 1 to 2cc of BSS and the flap was painted with three strokes of a wet sponge (BSS). Thereafter, the Johnston Applanator was delicately applied with soft pressure from superior to inferior for 1 to 2 seconds, and the flap was repainted again with three strokes of a wet sponge. After a 15 seconds waiting period, a drop of Ciloxan® (Ciprofloxacine 0.4% Alcon), Aculare® (Ketorolac acid 0.5%, Allergan) and Healon® (Pharmacia) was successively applied and the speculum was removed.

The patient was accompanied by the circulating nurse to the waiting area and was offered a soft drink or coffee.

After twenty minutes an external check was made and the patient was discharged.

All surgery and postoperative examinations were done by the same ophthalmologist (F.G.).

The mean preoperative pachymetry (average of three central readings) was 551 ± 26 micron; range 490 to 620 microns.

The average pupil diameter, measured in mesopic conditions was 6.310 ± 0.65; range 5 to 7 mm.

The average ablation zone was 6.69 ± 0.30 with a range of 6 to 7 mm.

POSTOPERATIVE TREATMENT PROTOCOL

Postoperative treatment consisted of, a shield at bedtime for two nights, Tobradex drops® (Tobramycine Dexamethasone Alcon) (QID) for one week and preservative free artificial tears, Oculotect Unidose® every hour at day one and two and later on 4 to 6x a day for a duration of 2 to 10 weeks depending on the dry eye symptoms. Patients were examined by the surgeon at 1 and 24 hours, 1 week, 1, 2, 4 and 12 months after surgery. Parameters evaluated at each control except the 1 hour postoperative control were uncorrected visual acuity (UCVA); best spectacle corrected visual acuity (BSCVA), residual refractive error, regression of correction, Topography, Aberrometry and presence of any complication.

REFRACTIVE RESULTS

One of the most difficult problems facing refractive surgeons is comparison of results along refractive procedures. That is why our results were analysed with the Datagraph Software (6) using graphs recommended by George O. Waring III (7) suggesting standard methods for reporting refractive surgical procedures.

A total of 70 eyes of 41 patients with myopia between -1 and -9 D and myopic astigmatism up to -3 D of were reviewed at one month after LASIK surgery done with the Mel 80 laser. There were 22 females and 19 males. The mean age of the treated patients was 32 years with a range of 18 to 55 years.

The mean preoperative BSCVA was 0.975 ± 0.141 with a range between 20/25 and 20/15.The mean BSCVA at one month was 1.13 ± 0.17 with a range between 0.9 and 1.3.

The average refractive error before LASIK was -4.41 ± 1.98 (extremes -1 and -9 sphere 0 and -3 cylinder). At one month the average refractive error was 0.14 ± 0.32 D.

PREDICTABILITY

The mean spherical equivalent refraction was reduced from -4.41 ± 1.98 D preoperatively to 0.14 ± 0.31 D at 1 month post-op, and 0.07 ± 0.35 D at 4 months post-op and 0.11 ± 0.30 D at 12 months post-op. The standard deviation was below 0.5 D during this whole period.

The best picture of the whole scatter of results is presented by Fig. 1: scattergram of attempted versus achieved refraction for each eye at the 1 month and the 12 months follow-up. Not a single eye was outside the ± 1 D range.

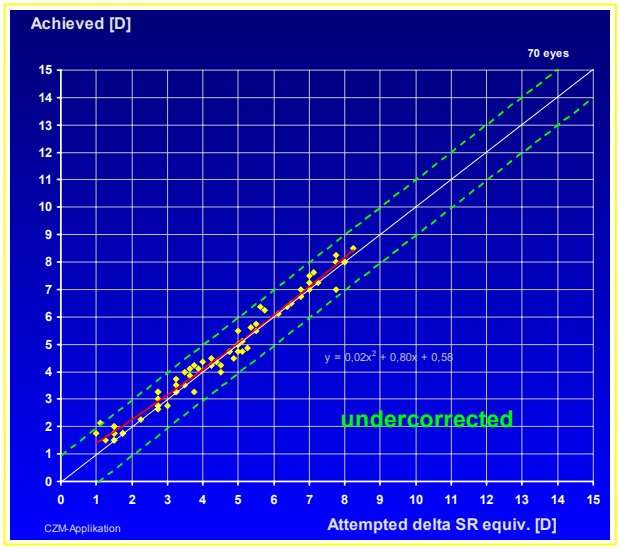

Fig. 1a: Attempted vs. achieved refraction (1 month)

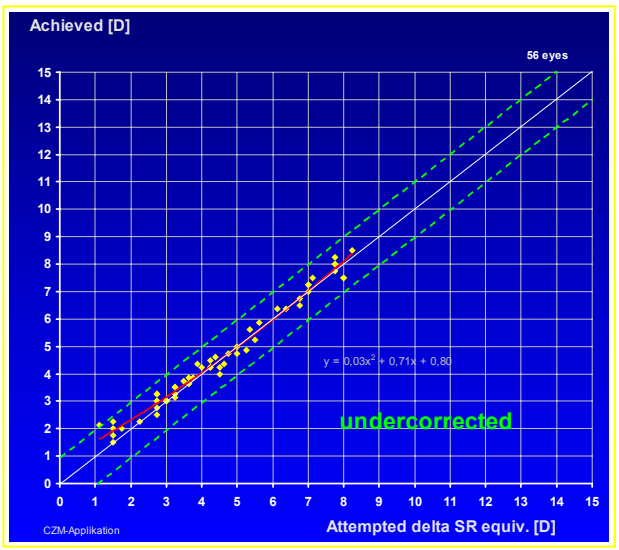

Fig. 1b: Attempted vs. achieved refraction (1 year)

Predictability numbers are given in Fig. 2: at the 1 month follow-up 100% of eyes were within ± 1 D and 94% of eyes were within ± 0.5 D of attempted correction, the so-called gold standard for refractive outcome.

Most impressive for me are the numbers within ± 0.25 D: 69% at 1 month and 79% at 1 year.

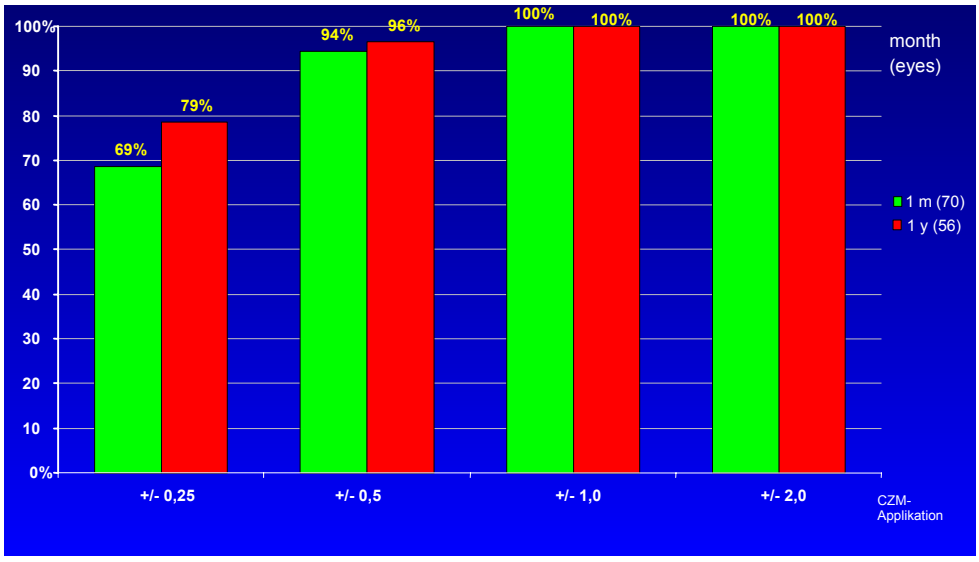

Fig. 2: Spherical equivalent refractive outcome bar graph

Fig. 3 summarizes the predictability in a cumulative graph for the defocus equivalent refraction. Defocus is a very severe notion. It is calculated by adding one-half of the cylinder, independent of sign, to the spheroequivalent (7, 8). For example, a -2 sph +4 cyl axis 180° gives a mean spherical equivalent error of ZERO but a defocus value of TWO. The defocus equivalent bar graph is presented as a cumulative graph, building in one direction and presenting the number of eyes with a given defocus equivalent value.

83% resp. 95% of eyes had a defocus equivalent refraction within ± 0.50 D at 1 month resp. at 1 year.

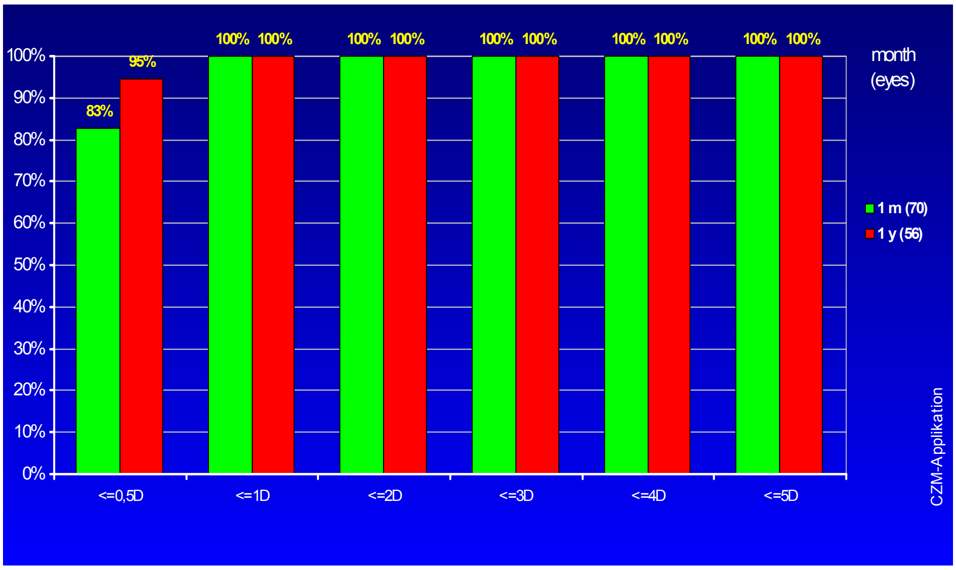

Fig. 3: Defocus equivalent bar graph at 1 month and 1 year

EFFICACY

The preop BSCVA of graph Fig. 4 takes into account the overall visual potential of the patients before treatment. 16% of eyes were refracted to 20/15, 79% of eyes to 20/20 and all eyes were refracted to 20/25 BSCVA. According to the protocol only patients with 20/25 or better acuity were admitted to the study.

The postop UCVA in Fig. 4 is a cumulative graph of uncorrected visual acuities after surgery. At 1 month 20/15 was achieved in 50% of eyes, 20/20 was achieved in 83% and 20/25 or better was achieved in 97% of treated eyes; after 1 year these numbers improved to 55% (20/15), 88% (20/20) and 100% (20/25).

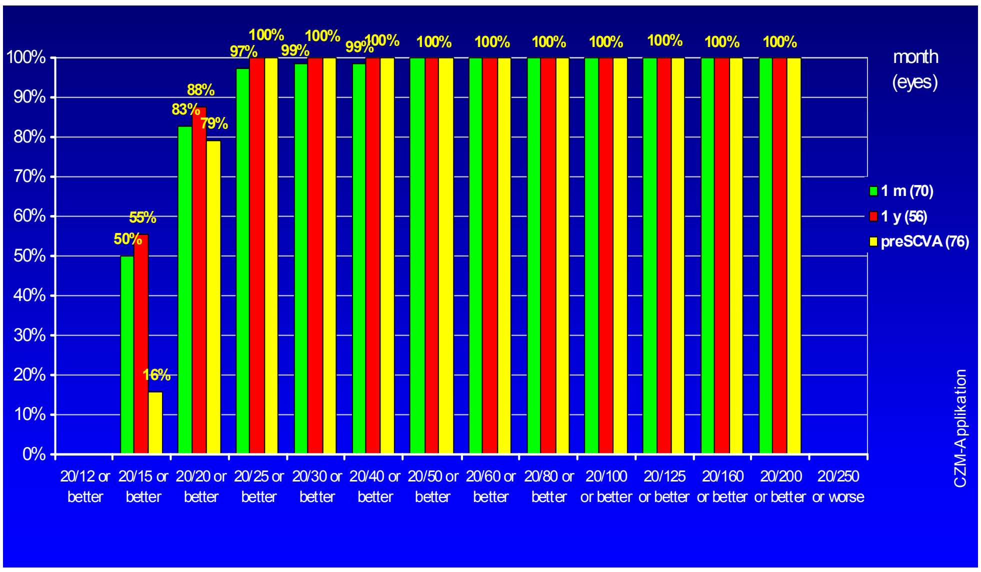

Fig. 4: Cumulative Snellen Visual Acuity

SAFETY

The safety issue is presented in Figure 5. This bar graph depicts the change in BSCVA - best spectacle-corrected visual acuity - from baseline to the postoperative examination in terms of the number of Snellen lines changed. A change of 1 Snellen line is, according to clinical standards, within the range of normal biological variability for repeated measures and therefore not a meaningful change. A change of 2 or more lines has been generally adopted as the standard of safety (7). Assessed 1 month after treatment no eye (0%) lost two lines of BSCVA. Only 1% lost one line but 49% gained one line and 17% of treated eyes gained two lines of Snellen visual acuity. This one eye with a loss had a severe form of dry eye with neurotrophic keratitis. At the 4 month control examination this eye had regained the best preoperative BSCVA.

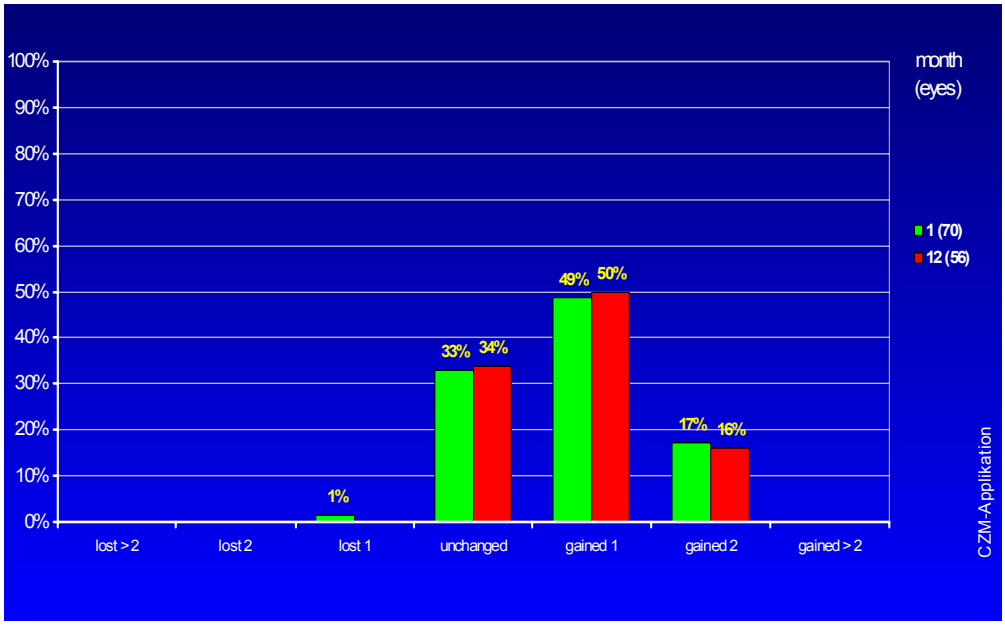

Fig. 5: Change in spectacle-corrected visual acuity bar graph

At the 1 year follow-up none eye had a loss of lines but 50% gained one line and 16% gained two lines.

STABILITY

The stability of refraction is presented in the graph in Figure 6. The timeline depicts the mean spherical equivalent refraction and one standard deviation depicted by the error bars at various intervals after surgery.

The mean preoperative refraction of -4.41 D decreased to 0.14 D at one month. At 4 months it was 0.07 D and at 12 months it was 0.11 D. According to FDA (Food and Drug Administration / USA) regulations, stability is defined as a 1 D or less variation in manifest spherical equivalent during an interval of 3 months. When we compared the eyes measured at 4 months and 12 months to the eyes measured at one month, 100% of eyes fulfilled the FDA stability criteria.

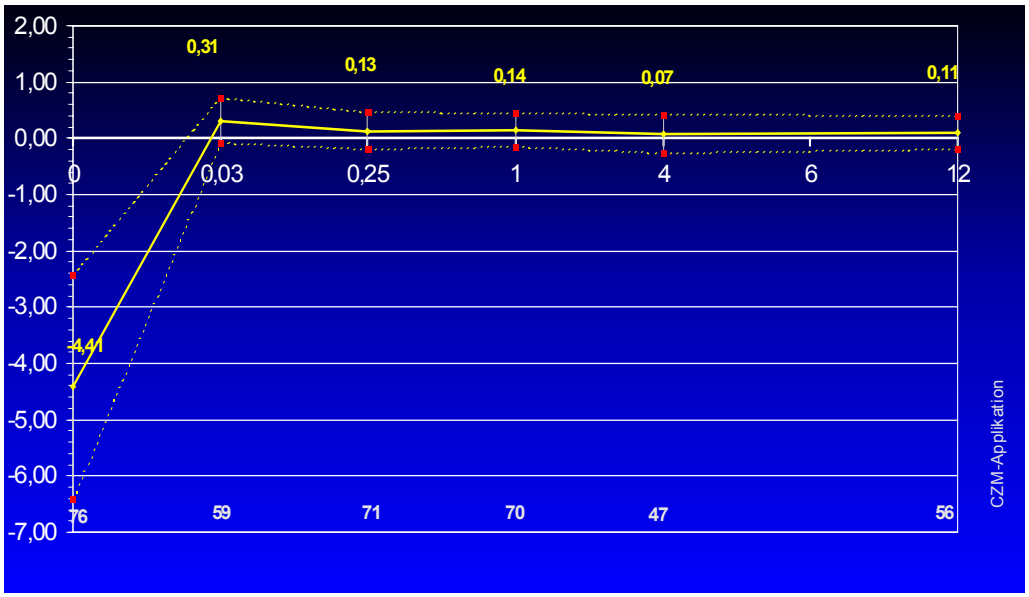

Fig. 6: Stability of refraction graph up to 1 year

RETREATMENTS

No eye underwent any retreatment during this 4 month follow up period.

RESULTS AT DAY ONE POSTOPERATIVE

In 51 eyes UCVA was recorded less than 24 hours after LASIK at the occasion of the day one postoperative visit. In 33% of eyes these measurements were carried out less than 18 hours after the treatment. The mean value of UCVA at day one was 0.90 ± 0.14 ranging from 0.8 to 1.2.

ADVERSORY EFFECTS

No major keratome or flap related complications or slitlamp abnormalities such as -subepithelial haze or DLK- were encountered.

Minor intraoperative bleeding from the flap edge was noted in three eyes (4%) of two patients who had a history of prolonged Rgp (gas permeable contact lens) wear; all these eyes had a flap diameter of 9.5 mm. One patient needed prolonged use of artificial tears (up to 4 month) because of important postoperative dry eye syndrome.

At the one month visit 6 eyes had minor dry eye syndromes and microstriae were detected in 5 other eyes. None of these patients had subjective complaints or had a loss of BSCVA. At the 4 month follow up visit these signs had disappeared.

No patient had specific complaints about glare, halos, and night time starbursts or had night driving problems.

CONCLUSION

We conclude that LASIK using the MEL 80 excimer laser for the treatment of myopia and myopic astigmatism is a safe, effective and predictable method in eyes with preoperative myopia up to -9 D and astigmatism up to -3 D. The outcomes with the MEL 80 laser seem to be better than published data.

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