ZEISS VisuMax® FEMTOSECOND SYSTEM IN COMBINATION WITH THE MEL 80™ EXCIMER LASER

A prospective study related to clinical outcome and ergonomic aspects for femtosecond vs. conventional flap generation applying MEL 80™ LASIK corrections.

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Purpose: To evaluate the clinical performance and workflow efficiency of the Carl Zeiss Meditec refractive laser workstation in a high-volume clinic setting by a comparative study on femtosecond versus conventional LASIK.
Methods: In this prospective study, 41 eyes underwent a LASIK treatment, where all flaps were created with the VisuMax® femtosecond system followed by a refractive treatment with the MEL 80™ excimer laser. Manifest refraction, BSCVA and UCVA at 1 day, 1 week and 1 month were analyzed and compared with retrospective data from LASIK treatments with a mechanical microkeratome (MK). Furthermore, the general workflow efficiency and patient comfort was evaluated.
Results: Safety and efficacy outcomes were comparable or better than the results obtained with the MEL 80™ in conventional LASIK treatments (VisuMax®: 1 month, no lines lost, 91% gained one or two lines, MK: 1 month, 6% lost one line, 62% gained one or two lines). Flap quality and handling of the femtosecond laser flaps were excellent and unsurpassed. Patients are able to continuously view the fixation target during and after contact glass docking. Mild corneal suction with curved applanation avoids significant changes in IOP and was experienced by the patients to be less unpleasant than conventional MK application. Due to small bubble generation, refractive treatments could be performed immediately after the flap lift without affecting the MEL 80™ eyetracker.
Conclusion: The Carl Zeiss Meditec refractive workstation showed excellent performance in terms of clinical outcomes and ergonomic aspects. The optimized workflow and the gentle femtosecond laser procedure allowed for a very fast patient throughput with high patient confidence and satisfaction.

INTRODUCTION

Femtosecond laser systems are starting to outstrip the competition with mechanical microkeratomes for LASIK flap cutting. While mechanical microkeratomes of the third generation are already available for LASIK, the usage of femtosecond lasers for flap cutting is a relatively new technology for perforation of the stroma by light. Besides the Carl Zeiss Meditec VisuMax®, three other systems are now commercially available: the Intralase FS60[3], Intralase Corporation, Irvine, USA, the Femtec system[1], 20/10 Perfect Vision, Heidelberg, Germany, and the Femto LDV[2], Ziemer Ophthalmic Systems AG, Port, Switzerland.
The principle behind femtosecond lasers is a nonlinear interaction of the light with the stromal tissue realized through a laser beam focused intensively into the stroma. Due to the strong temporal compression of the laser pulses (pulse length in the order of femtoseconds, 1 femtosecond equals 10^{-15} seconds), very low light intensity is required for cutting, i.e. to disrupt the tissue, and as a result, the surrounding tissue is only minimally damaged. Microscopically small gas bubbles are subsequently formed, which further break up the tissue. The scanned flap area appears as a separating surface created by the densely arranged micro bubbles.

We were interested in establishing how the workflow efficacy and patient comfort and especially the clinical performance of the new Carl Zeiss Meditec VisuMax® femtosecond laser system compare to conventional LASIK in a high-volume clinical environment. To answer this question, we performed a prospective study with a limited small cohort of consecutive patients treated with the VisuMax® (VisuMax® group) and utilized our own retrospective results of a similar LASIK group with mechanical microkertome flaps as a comparison.

METHODS

PATIENTS

For the VisuMax® LASIK study group, spherocylindrical myopic patients seeking refractive correction at the SMILE EYES Augenklinik Airport Munich, Germany were enrolled. In addition, they had to fulfil our standard criteria for LASIK, with no other particular selection criteria being applied. General exclusion criteria for us were pregnancy, severe dry eye, keratoconus or other ocular diseases with a certain history. The required residual stromal thickness limit was 300 µm as an individual preference of the surgeon. The gender distribution of the VisuMax® group was slightly unequal, with 22 % male and 78 % female. Further details of the subject demographics for the VisuMax® group of 41 eyes included are summarized in Table 1 below.

	Mean	Range
Age	34 y	23 y – 54 y
K-Values	(7.84 ± 0.20) mm	(7.52 to 8.33) mm
Sphere	(–3.48 ± 1.94) D	(–0.50 to -7.50) D
Cylinder	(–0.91 ± 0.75) D	up to -3.00 D
MRSE	(–3.93 ± 1.96) D	(–0.88 to -7.75) D

Table 1: VisuMax® group subject demographics, 41 eyes

For the mechanical microkeratome comparison group, we selected patients from our patient data base who were treated contemporarily before the start of the VisuMax® study. Moreover, cases were selected to provide subject demographics similar to the VisuMax® group with 36 % male and 64 % female. Details of the subject demographics for the microkeratome group of the 52 eyes included are summarized in Table 2.

	Mean	Range
Age	35 y	22 y – 58 y
K-Values	(7.81 ± 0.20) mm	(7.43 to 8.25) mm
Sphere	(–4.79 ± 1.61) D	(–0.25 to -7.25) D
Cylinder	(–0.75 ± 0.69) D	up to -2.50 D
MRSE	(–5.16 ± 1.56) D	(–1.13 to -7.75) D

Table 2: Microkeratome group subject demographics, 52 eyes.

VisuMax® – MEL 80™ REFRACTIVE WORKSTATION

The VisuMax® patient group was treated with the Carl Zeiss Meditec refractive workstation consisting of the VisuMax® femtosecond laser system used for flap cutting and the MEL 80™ excimer laser system for the refractive treatment. A pivoting patient bed combines the two laser systems into one unit to become an integrated set-up. Therefore, the entire surgical procedure, i.e. flap cutting plus refractive treatment, can be carried out without having to move the patient between these steps and without delay times between femtosecond flap cut and excimer laser ablation. The Carl Zeiss Meditec workstation as set-up in our facilities in Munich is shown in Picture 1.

Picture 1: Carl Zeiss Meditec workstation set-up in Munich. VisuMax® is seen in the front and MEL 80™ in the rear. As shown, the patient bed is pivoted 180° from the VisuMax® position into the MEL 80™ position for the refractive procedure with the MEL 80™.

Through gentle applanation of the eye to the spherical curved contact glass during the docking procedure, the eye is immobilized when suction is applied. Contact glasses were selected following the manufacturer recommendation out of three types (small (S), medium (M), and large (L)). The sole selection criterion is the white-to-white distance (limbus diameter). This is required due to the fact that the corneal suction must leave the sclera untouched. Docking and alignment is performed pursuant to patient cooperation through patient fixation on the blinking green fixation light during the docking procedure. By means of adjustment of the internal optics of the VisuMax®, the patient's eye refraction can be compensated for and the fixation light is always seen as a sharp point during the whole procedure. The curved applanation accompanied by only a low increase in intraocular pressure means that this important property is fulfilled during the whole docking procedure and after the initiation of the suction (Carl Zeiss Meditec's 'gentle corneal interface concept')!

Spherocylindrical refractive corrections have been done with the Carl Zeiss Meditec MEL 80™ excimer laser system. It is a high-speed, flying spot scanning excimer laser with 0.7 mm Gaussian beam (FWHM), 250 Hz repetition rate and eye registration and eye tracking capabilities. Further information on the MEL 80™ excimer laser can be found elsewhere. Active eye tracking was enabled and implemented for all treatments, and standard nomograms for sphere and cylinder corrections were used. The target refraction was selected to make the eyes plano in all cases. All treatments were performed using the ASA (advanced surface ablation) profiles that aim at aspheric corrections.

SURGICAL PROCEDURE

All patients of the VisuMax® and the microkeratome group were treated by the same surgeon (R. Wiltfang). The VisuMax® and microkeratome treatments with subsequent MEL 80™ refractive correction were performed to correct spherocylindrical errors as given in Table 1 and Table 2. Pre-operative evaluation of the patients and indications were the same for both groups. For the VisuMax® group, flap diameter settings were 8.0 mm except for one case with 7.5 mm diameter, flap thickness was typically set to 120 µm, and flap side-cut angle to 110° (where 90° side-cut angle would be perpendicular to the corneal surface at side-cut position). Hinge position was either superior or nasal depending on the refractive cylinder axis. Hinge width was set to 3.5 mm in all cases. Except for certain cases where S-type contact glasses seemed to be better adapted due to the white-to-white diameter, M-type contact glasses were normally used. Patients were asked to fixate the green blinking fixation light during the docking procedure.

Docking is performed by adjusting the patient bed in order to optimally align the patient with the contact glass. This alignment procedure and the applanation procedure are observed through the operating microscope. When applanation takes place, the applanation zone size can easily be inspected by mediation of the fluid meniscus seen through the contact glass. This meniscus starts to cover the whole inner zone during increased applanation of the contact glass and it disappears if applanation is sufficient. The contact glass was centered with the pupil center during the docking procedure to create the flap centered with the pupil. Following the flap creation, the patient bed with the patient in a lying position was rotated 180° under the MEL 80™ for the refractive procedure. Rotation can be done in seconds without any mechanical obstacles. Only slight residual bubbles generated during the VisuMax® flap cut were present after alignment of the patient under the MEL 80™. Hence, no further waiting time or flap bed massage was necessary and instant eye tracker operation was possible in all cases. Flaps were lifted under the MEL 80™ using our standard equipment.

The microkeratome group was a retrospective group bundled from our existing treated patient database to widely match the subject demographics of the VisuMax® group for a reasonable comparison. In all cases, the flaps were generated with the Carriazo-Pendular microkeratome[7]. It is a "third generation" microkeratome providing a reliable and well approved system for flap cutting. The flap diameter was 9.5 mm in all cases. Until now, we have used the Carriazo-Pendular microkeratome in our daily business for flap generation due to the good experience and stable outcomes gained.

PATIENT FOLLOW-UP

Postoperative follow-up visits after one day, one week and one month included determination of manifest refraction, best and uncorrected visual acuity (BSCVA, UCVA), WASCA™ (Carl Zeiss Meditec) ocular wavefront, and ATLAS™ (Carl Zeiss Meditec) topography measurement. Patients had to additionally complete a questionnaire.

RESULTS

In addition to refractive outcome and adverse events and complications, we were especially interested in assessing the overall workflow efficacy and patient and surgeon comfort during the overall treatment within the interplay of the VisuMax® – MEL 80™ workstation compared to the microkeratome usage in conjunction with the MEL 80™. Evaluation of the latter aspects was based on "softer" criteria which, however, were of key interest for us.

REFRACTIVE OUTCOME

Refractive outcome was evaluated with respect to predictability, refractive outcome for spherical equivalent (SEQ), efficacy measured through uncorrected visual acuity (UCVA), safety measured through best spectacle corrected visual acuity (BSCVA), and stability of the correction over time. Data analysis was performed using Microsoft EXCEL[4] and Datagraph[5] software. Moreover, adverse events and complications were defined and classified in advance and evaluated for both groups.

Predictability Refraction achieved vs. attempted

Manifest refraction spherical equivalent (MRSE) correction was found to be widely comparable between the VisuMax® and the microkeratome groups. Results for the 41 eyes of the VisuMax® group and the 51 eyes of the microkeratome group are contrasted in Figure 1 on the left and right, respectively. In both groups, the refractive results in the scattergram of achieved vs. the attempted refraction was mostly in the ± 0.5 D corridor with only a very few eyes outside.

In conjunction with this finding, the mean SEQ changed from −3.93 D ± 1.96 D preoperatively to −0.04 D ± 0.35 D postoperatively in the VisuMax group after 1 month and from −5.16 D ± 1.65 D preoperatively to −0.01 D ± 0.46 D postoperatively in the microkeratome group. Due to the small number of eyes and the minor differences in the subject demographics, this result is not statistically reliable and may undergo slight variances, but is sufficient for a rational evaluation of our opinion.

Refractive outcome – SEQ percent within attempted

Our subjective impression – while questioning the patients and doing the post-surgery follow-up examination – that the VisuMax® group has better refractive outcomes was confirmed by the detailed analysis. This analysis is shown in Figure 2. On the left, the results of the VisuMax® group and on the right, the respective microkeratome group results are given. 93 % of the eyes from the VisuMax® group are found between ± 0.5 D around the attempted target refraction.

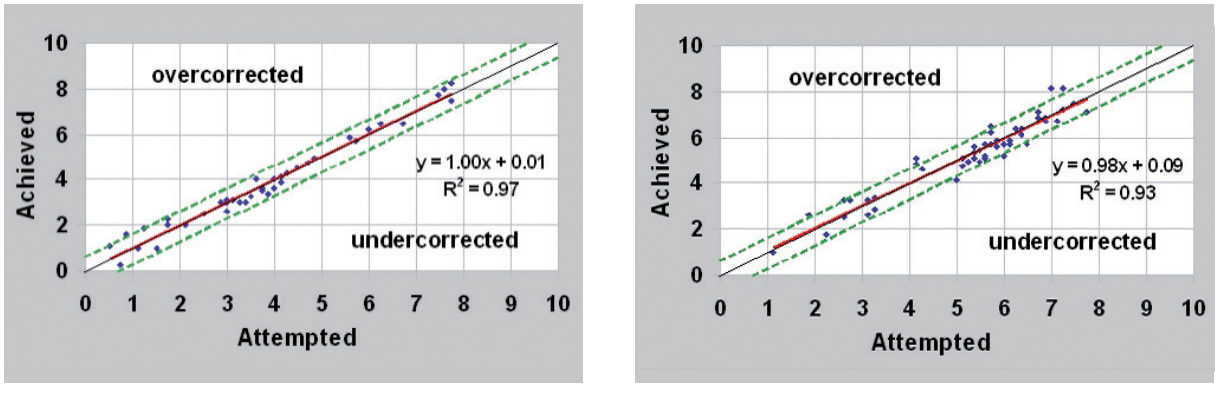

Figure 1: Predictability SEQ. Predictability mean spherical equivalent achieved vs. attempted of the VisuMax® group (41 eyes, left) and the microkeratome group (52 eyes, right).

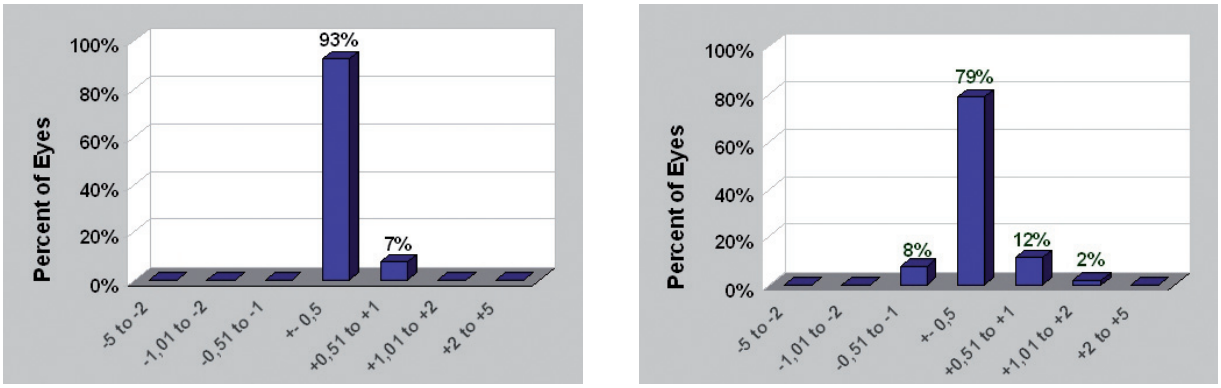

Figure 2: Refractive outcome for SEQ at one month. Percentage of the eyes within the attempted SEQ sectioned in the intervals as given on the abscissa; VisuMax® group (41 eyes, left) and the microkeratome group (52 eyes, right).

Cumulative 100 % are within – 0.5 D to 1.0 D with a marginal trend towards overcorrection. This result is better than the results within the microkeratome group where only 79 % of the eyes are within ± 0.5 D around the attempted target refraction and cumulatively nearly 100 % are within ± 1 D. One eye was more than 1 D off the target refraction.

Efficacy – UCVA at one month

Findings for the uncorrected visual acuity (UCVA) at one month for the two groups are summarized in Figure 3. A very pronounced trend can be seen from the given analysis. 10 % of the eyes in the VisuMax® group are already 20/15 at one month and 75 % are 20/20 or better. In contrast, none of the eyes from the microkeratome group is better than 20/20 and only 54 % are 20/20 after one month post-surgery. We were astonished at this result. At first glance, we discussed the possibility that either visual recovery is faster or visual acuity better in general for the VisuMax® group.

As this is an ongoing study where we have part of the three-month data available for the VisuMax® group, we found only slight further improvements with respect to uncorrected visual acuity after three months compared to the one-month data in this group. As we moreover know that the microkeratome-treated eyes tend to improve to some extent beyond one month in UCVA, we are now considering the possibility that a faster visual recovery of the VisuMax®-treated eyes was mainly responsible for the excellent one-month results.

To what extent generally better VisuMax® efficacy in the long term already contributes to the one-month data compared to the microkeratome group can only be speculated for the time being. We, however, expect to find better efficacy for the VisuMax® group when assessing our first three-month data.

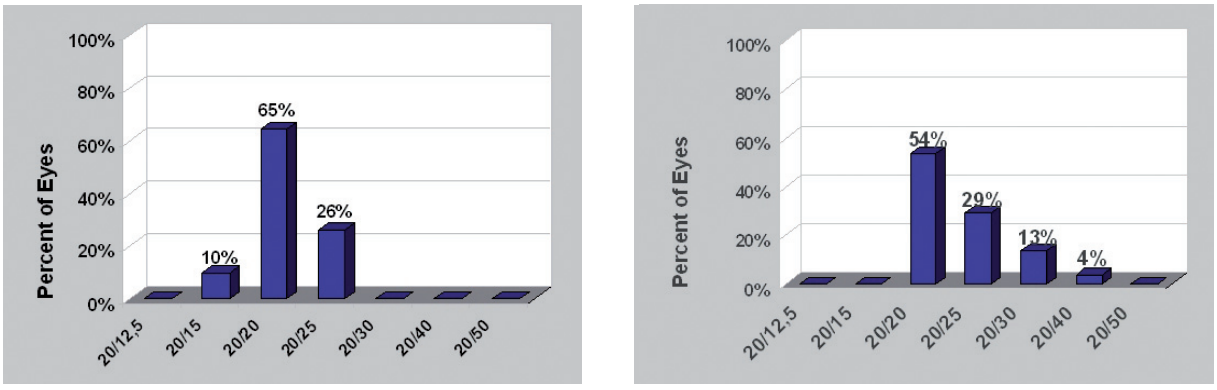

Figure 3: Efficacy at one month. Percentage of eyes with uncorrected visual acuity in the intervals given on the abscissa; VisuMax® group (41 eyes, left) and the microkeratome group (52 eyes, right).

Safety – Change in best corrected visual acuity

Best spectacle corrected visual acuity (BSCVA) changes pre- to post-surgery (see Figure 4) correlate with the finding in UCVA. In the VisuMax® group, most eyes, i.e. 90 % gained one or two lines and 10 % were unchanged post-surgery. No eye lost a line. In the microkeratome group, 3 eyes lost one line and one third remained unchanged. 60 % gained one line and one eye lost a line. Also, safety is definitely in favor of the VisuMax® group after one month.

For the VisuMax® group, we found very stable refraction comparable to the microkeratome group at one week to one month. At day one, we were off the target refraction by less than a quarter of a diopter with very little scatter around the average (not shown).

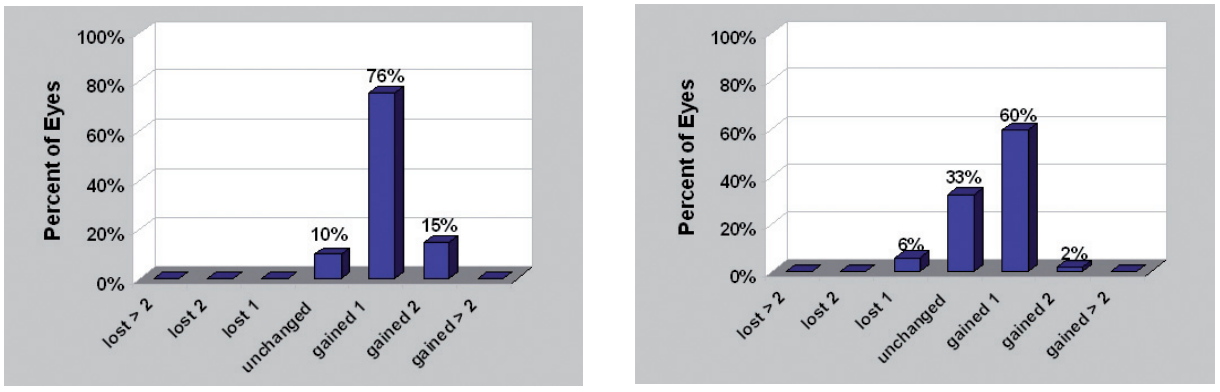

Figure 4: Safety at one month. Percentage of eyes change in best spectacle corrected visual acuity in the intervals given on the abscissa; VisuMax® group (41 eyes, left) and the microkeratome group (52 eyes, right).

Stability – Refraction (MRSE)

Stability (see Figure 5) over the course of time for the microkeratome group reproduces our experience to a high degree. Usually, refraction is already quite good (i.e. near the intended target refraction) after one week and decreases from a very slight overcorrection to match the target refraction after about one month.

ADVERSE EVENTS AND COMPLICATIONS IN THE VisuMax® GROUP

We had 7 eyes with mild sicca in the VisuMax® group (see Table 3). This number is absolutely comparable to our experience with microkeratome flap generation and confirmed our expectations in this respect. It can hardly be expected that a measurable difference in dry

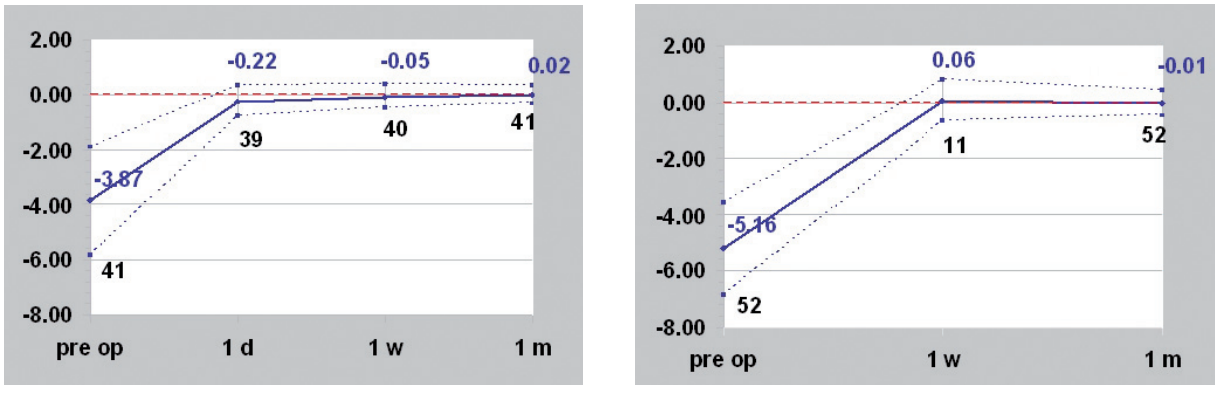

Figure 5: Stability after one month. MRSE changed from pre-surgery to 1 day (1 d), one week (1 w) and one month (1 m) post-surgery; VisuMax® group (41 eyes, left) and the microkeratome group (52 eyes, right). Note: for the microkeratome group no refraction at day one is available

eye syndrome between eyes treated with the VisuMax® and a mechanical microkeratome will appear as there is no reason related to the origin of sicca discussed so far today.

In two cases microstria formation was observed – a finding that is not exceptional compared to the microkeratome flap group and that, in our opinion, does not require any further consideration for this small number of eyes. One patient touched the eye after the surgery and as a consequence, the flap was displaced. It was repositioned on day one after surgery without subsequent complications. We had no adverse events.

Adverse Events / Complications	Quantity
Dry eye	7
Epithelium in the interface	0
Eye irritated	0
VA blurry, (interface) Haze, other complaints	0
DLK / corneal infiltrate or ulcer?	0
Microstriae	2
Opening of flap / flap lift / flap repositioning	1
Corneal epithelial defect involving the keratectomy	0
Flap complications (lost, incomplete, too thin, other)	0
TLSS	0

Table 3: Summary table of adverse events or complications related to the VisuMax® group

WORKFLOW EFFICIENCY, PATIENT COMFORT AND OTHER ASPECTS

Astonishingly, we experienced the handling of the VisuMax® to be less demanding than a mechanical microkeratome although the device itself appeared to be very impressive to us during the first application training. This is due to the clear and safe control concept and the straightforward application approaches implemented into the system. Key parameters related to the patient and the flap parameters are always present on one screen and the software control elements on another. Both displays are ergonomically arranged to the left and right of the operation microscope.

The patient bed control is extremely precise and can be conveniently manipulated while looking through the microscope. Once the contact glass is adapted to the eye, only the press of a single button is needed for initiation of the treatment. In fact, the VisuMax® learning curve is very short.

Carl Zeiss implemented a very effective, safe, and easy contact glass interface with the 'gentle corneal interface' concept. Unlike most other femtolaser systems[2, 3], the VisuMax® creates a spherical contact interface with the corneal surface due to the fact that a curved contact glass design avoids excessive applanation deformation of the cornea. The patient's eye is brought directly to the contact glass that is clamped (pre-positioned) at the VisuMax® optical aperture. Suction is applied and the flap cutting procedures can be started. This reduces effective suction time (see below) to about the treatment time for flap cutting itself because there is no additional adaptation process and additional suction time necessary as with other systems[1, 3].

We found the short suction time very convenient for the patient. Moreover, the unique corneal suction approach guarantees very low suction pressure and, hence, keeps the IOP increase mediated through suction very low. This is very important for the surgeon and very comfortable for the patient. All our patients could clearly see the fixation target during the docking procedure and after initiation of the suction. This allows docking and alignment pursuant to patient cooperation, a prerequisite for good flap centration –

we had no case of decentration after docking. Some of our patients compared the docking procedure to applying a contact lens. No patient experienced anxiety or complained about the procedure afterwards. Net flap creation time that is also about the suction time for the procedure lies between 30 to 50 seconds – compared to about 20 seconds overall suction time for the Carriazo-Pendular usage – depending on the flap diameter selected. Immediately after flap creation, suction is released by the VisuMax®.

Flap lift was easy and comparable to a flap relift after about two to three months. Flaps created are different to microkeratome flaps because they have a step side-cut angle of 110° and do not run out smoothly at the flap edges like for a mechanical microkeratome. Therefore, we found that flap repositioning is more precise as the flap inserts naturally into its bed. We could not find any evidence of a changed microstria generation (see also Table 3) for the number of eyes investigated. Our impression was that flaps are more stable and behave more practically. We associate this with the more constant flap thickness that is found in to be published soon[6]. Flap beds were smooth with a fine-structured stromal bed surface.

Due to the pivoting patient bed combining the two laser systems into one unit, the entire surgical procedure, i.e. flap cutting plus refractive treatment, can be carried out without having to move the patient between these steps and without delay times between femtosecond flap cut and excimer laser ablation. As a consequence, increased patient and surgeon comfort result. Flap lift was done by the MEL 80™ and by this time, the bubble layer had already disappeared fully or was insignificant and negligible. Neither stromal bed massage nor additional waiting time was necessary and the MEL 80™ eye tracker was instantly operational.

CONCLUSION

The Carl Zeiss Meditec workstation provides safe, predictable, stable, and high-quality refractive outcomes at least at the same high or a higher level obtained in the standard LASIK microkeratome. Visual recovery is similar but seems to be faster than for the LASIK microkeratome using the Carriazo-Pendular microkeratome. No adverse events appeared and complications like microstria and dry eyes in the VisuMax® group are comparable to the mechanical microkeratome group. We experienced the learning curve for the VisuMax® usage to be shorter than for a mechanical microkeratome. The workstation concept is safe and effective in daily practice with a very ergonomic and straightforward application approach. At the same time, flap centration and patient comfort is guaranteed through the 'gentle corneal interface concept' of low corneal suction plus short suction times.

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