Effect of a Suction Device for Femtosecond Laser on Anterior Chamber Depth and Crystalline Lens Position Measured by OCT

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ABSTRACT

PURPOSE: To investigate the position and stability of the crystalline lens after application of a suction device containing a contact lens and a vacuum unit for the treatment of presbyopia using a femtosecond laser.

METHODS: Twenty presbyopic (44.4 ± 4.3 years) and 5 pre-presbyopic patients (31.6 ± 3.8 years) were included. The anterior chamber depth, along with the position of the lens, was investigated before and after application of the suction device with optical coherence tomography (Visante OCT; Carl Zeiss Meditec AG). The type of suction device is routinely used for femtosecond LASIK with the VisuMax laser (Carl Zeiss Meditec AG).

RESULTS: In both groups, there was a reduction in anterior chamber depth of approximately 700 µm due to the suction device, and the anterior chamber depth achieved was stable. The maximum variation was 160 µm. At the periphery of the crystalline lens, there were movements up to 310 µm axially and 470 µm laterally.

CONCLUSIONS: The study proves that once the suction device has been applied, the crystalline lens is stable enough to undergo presbyopic laser therapy. However, the reduction in anterior chamber depth induced by the suction device showed significant individual variation. The exact position of the lens should therefore be measured immediately before laser surgery. [J Refract Surg. 2009;25:1005-1011]
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The use of a femtosecond laser1 for cutting corneal flaps and subsequent refractive correction with an excimer laser is common in refractive surgery, and the use of the femtosecond laser system for refractive correction is the subject of an ongoing clinical study by Carl Zeiss Meditec AG (Jena, Germany).2 In both procedures, the patient’s eye is fixed in place with a suction device using a contact lens and vacuum unit (Fig 1).

As in refractive surgery, in the treatment of presbyopia with the femtosecond laser, ultra-short laser pulses are focused on the tissue. In contrast to refractive surgery, in presbyopia treatment, the laser pulses should be applied to the lens to improve its elasticity and thus increase its accommodation. Initial research using human cadaver lenses and animal models demonstrates the fundamental feasibility of this method.3,5 Whereas the corneal target tissue is fixed in place by the suction device in refractive surgery, the crystalline lens remains possibly partially mobile during presbyopia treatment. However, a prerequisite for making targeted incisions in the lens and preventing incisions in the capsular sac is that the position of the lens be stable during treatment.

An investigation into the change in lens position after the application of a suction device and the stability of the lens position in equilibrium are the subject of this clinical study.
PATIENTS AND METHODS

STUDY DESIGN
The clinical trial was conducted as a single-center, prospective clinical feasibility study at the Helios Klinikum Erfurt in compliance with the Declaration of Helsinki. The study was approved by the Ethics Committee of the Thuringian Regional Medical Council (‘Landesärztekammer Thüringen’), and informed consent was obtained from all patients.

PATIENTS
In a preliminary phase of the study, five patients were tested to ensure that evaluation of the anterior chamber and lens data produces meaningful results. This group consisted of relatively young, non-presbyopic individuals. This was followed by the testing of 20 presbyopic patients at different stages of presbyopia with the main focus on early stages. The age distribution also made it possible to draw comparisons between the pre-presbyopic group (31.6±3.8 years, range: 27 to 36 years) and the presbyopic group (44.4±4.3 years, range: 38 to 59 years). All patients had healthy eyes.

The study was designed to determine anterior chamber depth and anterior lens radii before and after the application of a suction device.

MEASUREMENT TECHNIQUE
To simulate the test setup for subsequent laser therapy, a suction device was used (see Fig 1), consisting of a contact lens, filter, water trap, and hose, as used routinely for cutting flaps and lenticules with the VisuMax refractive laser (Carl Zeiss Meditec AG). The cornea was drawn by a defined suction (pressure: 20 kPa) onto the spherical glass surface (curvature radius: 20 mm).

The study did not include laser therapy but the system was connected to an anterior chamber optical coherence tomography (OCT) scanner (Visante OCT, Carl Zeiss Meditec AG) to visualize the anterior segment of the eye. A special holder (Fig 3) was made for using the suction device on the Visante OCT. To protect the eye, there was also a built-in spring that was designed to reduce the increased pressure on the eyeball.

The docking process with the suction device was conducted after cycloplegia (Zyklolat-EDO eye drops 3 times every 10 min; Dr Mann Pharma, Berlin, Germany) because this is where the lens can be visualized best and subsequent treatment with the femtosecond laser will also be conducted after mydriasis or cycloplegia. The patient was seated in front of the Visante OCT with his/her head fixed on the head rest. Centering of the eye was more difficult due to the suction lens as the patient could not use the internal target. Instead, the examiner centered on the pupil center through the suction lens using the live video image of the eyeball provided by the OCT.

After application of the suction lens to the anesthetized eye (Proparacain-POS 0.5%, Ursapharm, Saarbrücken, Germany), a vacuum was created with a defined suction pressure (p = 20 kPa) for fixation of the eye to the suction test and a follow-up examination approximately 1 hour after completion of the test.
lens. The vacuum was maintained for 90 seconds. Suction pressure was controlled continuously with a standard pressure monitor to detect detachment of the eye from the suction unit. In the event of a loss of pressure, e.g., due to detachment of the patient’s eye, the examination was stopped immediately. The OCT frame was videotaped during the entire docking process including application and centering of the suction lens as well as the vacuum time.

**DATA ANALYSIS**

Analysis of the images with the suction device was conducted using a specially developed image analysis module based on the LABVIEW program (National Instruments Inc, Austin, Tex). The software was based on ray-tracing algorithms and corrected the measured OCT data with regard to the influence of the curved contact glass in the beam path. This software was verified with defined test objects. All measurements were taken by an examiner three times and then averaged.

Data analysis was performed with the program WinSTAT for Excel Version 2005.1 (Robert K. Fitch Inc, Bad Krozingen, Germany). Demographic data and the Visante OCT data were first described with descriptive statistics. Differences before and after suction were investigated with the aid of parameter-free tests such as the Mann-Whitney U test/Wilcoxon rank sum test or the Wilcoxon signed rank test for paired samples. These tests are particularly suitable for relatively small sample sizes and when the underlying distribution is unclear.

The various side effects were recorded individually. For each group of side effects, the absolute number of side effects and the percentage of the total population were stated.

**RESULTS**

**GENERAL DATA**

Table 1 shows the general patient data. The pre-presbyopic patients (group 1) and presbyopic patients (group 2) showed demographic data as expected. There was good correlation between age and accommodation range, demonstrating a reduction in accommodation slope. Pupils of the presbyopic patients dilated less than in younger patients after application of the cycloplegic drug. The intraocular pressure measured before and 1 hour after suction showed no significant change.

Best spectacle-corrected visual acuity (BSCVA) after the suction test showed a slight but statistically significant change ($P<.05$) due to the applied device. In particular, this causes hyperopic refraction (Table 1) due to slight flattening of the cornea. This change is only temporary and disappears after approximately 1 to 2 hours.

**SIDE EFFECTS**

In comparison with the preliminary examination, there were mild cases of conjunctival hyperemia (pre-presbyopic group, 6/10 eyes; presbyopic group, 22/38 eyes), petechiae (presbyopic group, 1/38 eyes), and superficial punctate keratitis (pre-presbyopic group, 3/10 eyes; presbyopic group, 7/38 eyes). In addition, there was one case of orthostatic dysregulation due to low arterial pressure that soon normalized in the recumbent position with the legs raised. The side effects observed correlated with the experiences of another study with the suction device and can be regarded as safe. In routine ophthalmological practice, orthostatic dysregulation is a potential side effect of examinations after cycloplegia or contact lens applications.

**EXAMINATION OF ANTERIOR CHAMBER DEPTH FOLLOWING APPLICATION OF THE SUCTION DEVICE**

It was always the anatomical anterior chamber depth that was measured, i.e., not including corneal thickness. Table 2 shows the determination of anterior chamber depth in the study population in a stable state before and after application of the suction device.

For both groups, the anterior chamber depth with a suction device showed a significant difference from the anterior chamber depth without a suction lens. In both groups, there was a decrease in anterior chamber depth amounting to approximately 700 µm. This deformation of the anterior chamber occurred immediately after application of the vacuum.

Anterior chamber depth without a suction device was significantly less in presbyopic patients than in pre-presbyopic patients. Anterior chamber depth with a suction lens, on the other hand, showed no significant difference between the two groups.
tion of the Suction Device. To investigate the kinetics of the anterior chamber depth change after flattening of the anterior chamber due to the suction unit, the anterior chamber depth was examined relative to time after suction. However, due to the evaluation procedure it was not always possible to determine and average the anterior chamber depth at exactly identical times. This was because the video signal was disturbed for short time intervals during the measurement when a picture was saved for control purposes. To improve the analysis of time response, the range of the individual data was therefore analyzed (Table 3).

With regard to the temporal change in anterior chamber depth after application of the suction device, the two groups of patients showed no significant differences. Anterior chamber depth decreased slightly over time after suction. The changes observed (pre-presbyopic group, 70 µm; presbyopic group, 70 µm) were in the precision range of the method amounting to approximately 60 µm. The maximum range was 160 µm.

Visualization with the OCT device showed that a stable ultimate state was achieved immediately after application of the suction device.

Examination of the Anterior Lens Radius After Application of the Suction Device. Table 4 shows the measurements of the anterior lens radius in the study population before and after application of the suction device. There was no difference in lens radius without a suction device between the two groups. However, with a suction lens, the radius was significantly smaller in the presbyopic group.

Kinetics of Lens Periphery After Application of the Suction Device. Presbyopia treatment requires not only anterior chamber stability but also secure positioning/stability of the lens and lens margin. Figure 2 illustrates the parameters ACDp,z and ACDp,x, which characterize the variations in lens margin.

Table 5 presents the edge parameter data. The lens periphery showed variations that are greater than the variation in central anterior chamber depth. There were

### Table 1

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Group 1 (Pre-presbyopic)</th>
<th>Group 2 (Presbyopic)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (range) (y)</td>
<td>31.6±3.8 (27 to 36)</td>
<td>44.4±4.3 (38 to 59)</td>
</tr>
<tr>
<td>Mean pupil diameter after cycloplegia (range) (mm)</td>
<td>8.1±0.7 (7.0 to 9.0)</td>
<td>5.2±1.0 (3.0 to 7.0)</td>
</tr>
<tr>
<td>Sex (male/female [n, %])</td>
<td>3/2 (60/40)</td>
<td>10/10 (50/50)</td>
</tr>
<tr>
<td>Mean BSCVA (range)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>20/15.4 (20/15.4 to 20/13.3)</td>
<td>20/16.7 (20/25 to 20/10)</td>
</tr>
<tr>
<td>Postoperative</td>
<td>20/18.2 (20/20 to 20/15.4)</td>
<td>20/18.2 (20/25 to 20/12.5)</td>
</tr>
<tr>
<td>Mean SEQ (range) (D)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>±0.50 (−0.80 to 0.80)</td>
<td>0.10±1.60 (−4.50 to 4.60)</td>
</tr>
<tr>
<td>Postoperative</td>
<td>0.40±0.30 (−0.10 to 1.00)</td>
<td>0.50±1.90 (−9.40 to 5.10)</td>
</tr>
<tr>
<td>Mean intraocular pressure (mmHg)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>13.9±2.7 (10 to 17)</td>
<td>15.2±2.7 (10 to 19)</td>
</tr>
<tr>
<td>Postoperative</td>
<td>12.5±2.8 (8 to 15)</td>
<td>14.3±3.4 (9 to 24)</td>
</tr>
</tbody>
</table>

BSCVA = best spectacle-corrected visual acuity, SEQ = spherical equivalent, NS = not significant
*Mann-Whitney U test.
†Wilcoxon signed rank test.
no differences between the presbyopic group and pre-presbyopic group. During the 90-second phase of suction, maximum movements of the peripheral lens surface were found to be 310 µm axially and 470 µm laterally.

To visualize the movement of the periphery of the lens, an image sequence is shown in Figure 4 (maximum observed lens movement).

**DISCUSSION**

To the best of our knowledge, there are no published reference data available for this study, so the interpretation of the data is subject to certain limitations.

The demographic data of the population of patients in the presbyopic study group correlated with the target group for presbyopia treatment. Data documented the expected senile miosis resulting in a decreased ability of the pupil to dilate with age.7 The age dependence of accommodation correlated with published data.7,8

As expected, there were no serious adverse side effects due to application of the suction device.

The side effects observed, such as conjunctival hyperemia, petechiae, and superficial punctate keratitis, are generally known side effects of the use of contact lenses or suction devices in ophthalmology. In terms of severity, all cases were mild. After the administration of tear substitutes recovery was rapid. Petechiae were only observed in one patient caused by difficulties with suction of the device with initial decentering and application of the lens unit in the area of the conjunctiva.

Regarding anterior chamber depth, it must be mentioned that analysis of the images was conducted with LABVIEW software that had been verified on test objects (see Patients and Methods). The underlying algorithms were the same as the algorithms in the commercial Visante OCT software but nevertheless it is possible that this causes a systematic error. However, because the figures observed are comparable to published data,7,9,10 the bias may be regarded as minimal. In addition, anterior chamber depth with and without a suction device was measured with the same software so the figures may be regarded as comparable.

It became evident that the anterior chamber depth without a suction device was significantly smaller in the presbyopic group than in the pre-presbyopic group. This was to be expected because it is known that anterior chamber depth decreases with age due to an increase in lens thickness.11

A decrease in anterior chamber depth after application of the suction device was also to be expected because the radius of curvature of the suction lens, which is larger than the corneal radius, causes corneal...
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It was possible to quantify the movement of the lens after application of the suction unit. The variation in anterior chamber depth observed was 70 µm on average. This is within the range of precision of the method used herein. In isolated cases, a maximum of 160 µm was measured. These variations must be taken into account when conducting any future laser surgery on the lens and appropriate safety distances from the capsular sac must be maintained.

The results indicated that the anterior lens radius was significantly reduced in the presbyopic group after application of the suction device. This observed reduction is non-critical for the development of the laser method, although it was unexpected.

Based on the present level of knowledge one would assume that application of the suction device causes the ciliary muscle to extend, thus increasing the lens radius. The findings observed, on the other hand, suggest that the presbyopic lens partially retains its elasticity. However, this can also be caused by a systematic error due to imprecise measurement at the apex of the lens when determining lens radius after application of the suction device. A deviation of the plane of measurement from the apex would have a bigger influence on presbyopic patients because of the smaller radius of the lens. Furthermore, for this group the radius of curvature could be determined only with a slightly reduced precision because the pupils are narrower and the visible lens section was therefore reduced. Further investigations should be conducted to clarify these findings because this observation may be important for the understanding of presbyopia.

The more pronounced variation observed in the lens margin is of vital importance for the treatment of the lens with femtosecond laser. Acceptable variations between 90 and 140 µm on average were observed. However, in isolated cases, there were variations of 310 µm (axially) and 470 µm (laterally). These observed movements of the

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**TABLE 4**

<table>
<thead>
<tr>
<th>Anterior Eye Lens Radius Before and After Application of the Treatment Pack</th>
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<tbody>
<tr>
<td><strong>Lens Radius (mm)</strong></td>
</tr>
<tr>
<td><strong>Without Treatment Pack</strong></td>
</tr>
<tr>
<td>Group 1 (Pre-presbyopic)</td>
</tr>
<tr>
<td>Average±SD</td>
</tr>
<tr>
<td>Range</td>
</tr>
<tr>
<td>95% CI</td>
</tr>
<tr>
<td>Significance* groups 1 and 2</td>
</tr>
<tr>
<td>Significance† group 1 with/without TP</td>
</tr>
<tr>
<td>Significance† group 2 with/without TP</td>
</tr>
</tbody>
</table>

Cl = confidence interval, NS = not significant, TP = treatment pack
*Mann-Whitney U test.
†Wilcoxon signed rank test.

**TABLE 5**

<table>
<thead>
<tr>
<th>Change in the Lens Margin Parameters With Treatment Pack Applied</th>
</tr>
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<tbody>
<tr>
<td><strong>ACD (µm)</strong></td>
</tr>
<tr>
<td><strong>Group 1</strong> (Pre-presbyopic)</td>
</tr>
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</tr>
<tr>
<td>95% CI</td>
</tr>
<tr>
<td>Significance U test</td>
</tr>
</tbody>
</table>

ACD = anterior chamber depth, CI = confidence interval, NS = not significant
lens were not sudden but took place slowly over several seconds. Possible corrective movements on the part of the patients for example may be the cause of these relatively pronounced variations. Because examination with the OCT scanner was performed in the seated position, slight turns of the head were possible, even though the head was fixed on the head rest. In addition, no vision guidance in the sense of a fixation target was possible. However, in future laser therapy, the patient will be positioned on a table with a shaped head rest, which is intended to provide greater stability. Therefore, similar testing will need to be done to ensure the lens stability is the same in the supine position.

In any case, for presbyopic lens surgery using femtosecond laser, the variation in the lens margin area means that a scan of the individual lens is required during the operation, directly before the incisions are made, to quantify this lateral movement and allow for a safe distance from the capsular sac during laser surgery.

In summary, the study indicates that after application of the suction device the crystalline lens is basically stable enough to allow laser therapy. However, because it is not possible to predict exactly where the lens will be located after suction, its position should be determined after application of the suction device. This can either be done by online monitoring during the entire procedure or by a single scan immediately after application of the suction unit. In the latter case, a residual drift of 160 µm of the lens has to be taken into account to keep proper distance of the aimed laser spots from the capsular sac to prevent damage of the lens capsule. In addition, suitable precautions should be taken to reduce tilting of the margin (eg, fixation of the patient’s head).

**AUTHOR CONTRIBUTIONS**

Study concept and design (K.S.K., M.B., M.R., M.D., C.R.); data collection (K.S.K., M.R., C.R.); interpretation and analysis of data (K.S.K., M.B., M.R., C.R.); drafting of the manuscript (K.S.K., M.R.); critical revision of the manuscript (M.B., M.D., C.R.); statistical expertise (C.R.); obtained funding (M.D.); administrative, technical, or material support (K.S.K.); supervision (M.D.)

**REFERENCES**