Biomechanical Corneal Changes Post LASIK with Mechanical Microkeratome Flap versus Femtosecond Flap
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ABSTRACT
Background: The biomechanical impact of flap creation may be important in explaining changes in the curvature of the residual stroma after flap creation which plays a critical role in the development of ectasia.

OBJECTIVE: To evaluate the impact of the creation of corneal flaps with mechanical microkeratome versus femtosecond laser on the biomechanical properties of the corneas.

METHOD: This study included 100 eyes of 50 patients (Microkeratome Group) Compared with 100 eyes of 52 patients (Femtosecond Group) with myopia with or without astigmatism. Corneal hysteresis (CH) and corneal resistance factor (CRF) were measured with Ocular Response Analyzer before and 1, 3, 6, and 12 months after surgery. We also investigated the relationship between these biomechanical changes and the amount of myopic correction.

RESULTS: Corneal resistance factor and hysteresis was changed significantly after flap creation in both groups. In Moria2 group, they decreased significantly from 11.55 ± 1.29 mm Hg and 11.68±1.40 mm Hg to 9.47 ± 1.29 mm Hg and 8.49 ± 1.54 mm Hg, respectively (P <.0001). In femtosecond group, they decreased from11.51 ± 1.25 mm Hg and 11.66±1.41 mm Hg to 9.49 ± 1.30 mm Hg and 8.5 ± 1.53 mm Hg, respectively (P <.0001). The ablation depth (P=0.650), residual corneal thickness (P=0.442), and postoperative corneal curvature (P=0.354) were not significantly different between femtosecond group and Moria2 group after surgery.

CONCLUSION: Both femtosecond LASIK and Moria2 LASIK can affect the biomechanical strength of the cornea depending on the amount of myopic correction. The amount of biomechanical changes is larger after LASIK with mechanical microkeratome than after femtosecond from a biomechanical viewpoint.

Keywords: LASIK, Femtosecond, Microkeratome, Flaps.

INTRODUCTION
Refractive surgery alters the biomechanical properties of the cornea, which may play an important role in affecting treatment outcome in terms of postsurgical complications(1,2). Advances in techniques and instruments have reduced the incidence and severity of flap abnormalities and other potentially severe complications(3). During LASIK, an immediate near-circumferential severing of corneal lamellae results in a redistribution of stress and unprogrammed biomechanical shape changes (4,5). Although some changes in the shape of the residual stroma during and after surgery may be precursors of an ectatic condition, others may represent non-progressive changes associated with the establishment of a new postoperative structural state (6).

The biomechanical impact of flap creation on the residual stroma likely plays a critical role in the development of ectasia. Biomechanical effects may also be important in explaining changes in the curvature of the residual stroma after flap creation and photoablation that do not represent ectasia but nonetheless affect refractive outcome. It is known that flap thickness can vary significantly with some mechanical microkeratomes, with standard deviations of 30 μm having been reported depending on the microkeratome used(7). The predictability of this process has a potential for compromising corneal stability in the long term as thicker flaps could more significantly modify the biomechanical integrity of the cornea (8).

In this study, we used the femtosecond laser to create flaps at same depths of microkeratome Moria2 and measured the impact of programmed flap thickness on the biomechanical properties of the underlying residual stroma.

PATIENTS AND METHODS
This study included 100 eyes of 50 patients (Moria2 Group) Compared with 100 eyes of 52 patients (Femtosecond Group) with myopia with or without astigmatism. Inclusion criteria were no symptoms or signs of dry eye before LASIK, no previous eye surgery, no topical ocular medications before surgery, and no other ocular conditions, such as ocular rosacea or chronic blepharitis. The preoperative evaluation consisted of a complete ophthalmic examination comprising uncorrected distance visual acuity (UDVA),
corrected distance visual acuity (CDVA), manifest and cycloplegic refractions, topographic analysis, wavefront analysis, fundus examination, Goldman applanation tonometry, ultrasound pachymetry, and slitlamp biomicroscopy. The Ocular Response Analyzer was used to measure corneal hysteresis (CH), corneal resistance factor (CRF), Goldmann-correlated intraocular pressure (IOPg), and corneal-compensated IOP (IOPcc). OCT optical coherence tomography (Visante OCT; Carl Zeiss Meditec, Jena, Germany) to measure corneal pachymetry and flap thickness; and surface wave velocity to estimate corneal stiffness before and 3 months after LASIK.

**Surgical Procedure**

After instillation of topical anesthetic and a sterile preparation of the lids. In femtosecond group the flaps were created with a iFS 150 IntraLase (Abbott Medical Optics Inc., Santa Ana, California) Femtosecond flap settings were a diameter of 9.0 and a standard 55-degree hinge and 70-degree side-cut angle. The lamellar cut and side cuts were performed with an energy of 9 mJ with the iFS150 laser. The attempted flap thickness was 110 mm The hinges in all eyes were superior.

In microkeratome group the flaps were created with mechanical microkeratome the Moria2 microkeratome with plastic head use 110 head to create 8.5-9.0 mm corneal flaps with superior hinge.

Stromal tissue ablation was performed with the Visx Star S4 IR (Abbott Medical Optics, Inc.) for both groups. Eyes were treated with moxifloxacin hydrochloride ophthalmic solution 0.5% and prednisolone acetate 1% ophthalmic suspension USP 4 times daily for 1 week. In addition, nonpreserved artificial tears (Systane or Refresh Plus) were used 4 to 8 times a day for 1 month as needed. Scheduled postoperative follow-up visits were at 1 day, 1 week, and 1, 3, and 6 months.

Data were expressed as mean ± standard deviation (SD) and analyzed with SPSS 17.0 software (SPSS Inc, Chicago, Illinois, USA). For independent-samples t-test was used to compare the mean values of each parameter between the two groups. Multiple linear step wise regression was used to evaluate influencing factors of corneal biomechanics. *P*<0.05 was considered statistically significant.

**RESULTS**

There were no statistically significant differences between the femtosecond group and the microkeratome group in age, sex distribution, or central corneal thickness. The following table (1) showed the patients’ demographic data and preoperative characteristics (Table 1).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Femtosecond (n = 100)</th>
<th>Microkeratome (n = 100)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>44</td>
<td>45</td>
<td>.8</td>
</tr>
<tr>
<td>Range</td>
<td>20-52</td>
<td>20-53</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>55%</td>
<td>53%</td>
<td>.9</td>
</tr>
<tr>
<td>Male</td>
<td>45%</td>
<td>47%</td>
<td></td>
</tr>
<tr>
<td>Mean CCT± SD</td>
<td>529 ± 30</td>
<td>531± 34</td>
<td>.6</td>
</tr>
<tr>
<td>Mean SE</td>
<td>-4.55 D</td>
<td>-3.87 D</td>
<td>.04</td>
</tr>
</tbody>
</table>

**Table (1): showed the patients’ demographic data and preoperative characteristics.** There were no statistically significant differences between the femtosecond group and the microkeratome group in age, sex distribution, or central corneal thickness.

Mean flap thicknesses ±SD were 128.8±13.5 µm for microkeratome group and 115.5±5.9 in femtosecond group (*p*<0.001). Corneal pachymetry did not show statistical difference between the groups Therefore, flaps for femtosecond group and microkeratome group represented 12.8% and 21.6% of the total pachymetry respectively.
Table (2): Ablation depth, residual corneal thickness, corneal flap thickness and Residual stromal bed thickness.

<table>
<thead>
<tr>
<th></th>
<th>Moria2 Group</th>
<th>Femtoescond Group</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ablation depth (µm)</td>
<td>73.8±22.9</td>
<td>73.5±20.3</td>
<td>0.690</td>
</tr>
<tr>
<td>Residual corneal thickness (µm)</td>
<td>462.4±21.5</td>
<td>469.6±32.8</td>
<td>0.450</td>
</tr>
<tr>
<td>Corneal flap thickness (µm)</td>
<td>128.8±13.5</td>
<td>115.9±5.9</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Residual stromal bed thickness (µm)</td>
<td>338.5±26.2</td>
<td>365.7±24.8</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

Table (2): showed ablation depth, residual corneal thickness, corneal flap thickness and Residual stromal bed thickness in both groups. The corneal flap thickness was significantly decreased in the femtosecond group, while the residual bed thickness was greater in moria 2 group.

In microkeratome group the preoperative mean± SD of corneal hysterisis was (11.55 ± 1.29 mm Hg and mean± SD corneal resistant factor was 11.68±1.40 mm Hg were significantly higher than postoperative values (9.47 ± 1.29 mm Hg and 8.49 ± 1.54 mm Hg, respectively) (P <.0001). A higher attempted correction was correlated with a larger delta corneal hysteresis and Delta Corneal resistant factor was (AD, r = 0.48 and r = 0.67, respectively; delta MRSE, r = 0.53 and r = 0.67, respectively). No correlation was found between delta corneal hysteresis, delta corneal resistant factor was, and preoperative CCT.

In femtosecond group the preoperative mean± SD of corneal hysterisis was11.51 ± 1.25 mm Hg and mean± SD corneal resistant factor was 11.66±1.41 mm Hg were significantly higher than postoperative values (9.49 ± 1.30 mm Hg and 8.5 ± 1.53 mm Hg, respectively) (P <.0001). A higher attempted correction was correlated with a larger delta corneal hysteresis and delta corneal resistant factor was (AD, r = 0.48 and r = 0.67, respectively; delta MRSE, r = 0.53 and r = 0.67, respectively). No correlation was found between delta corneal hysteresis, delta corneal resistant factor was, and preoperative CCT as shown in table (3)

Table (3): Preoperative and postoperative biomechanical parameters.

<table>
<thead>
<tr>
<th></th>
<th>Moria2 Group</th>
<th>Femtoescond Group</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corneal resistance factor CRF</td>
<td>11.68±1.40</td>
<td>11.66±1.41</td>
<td>0.097</td>
</tr>
<tr>
<td>Corneal hysteresis CH</td>
<td>11.55 ± 1.29</td>
<td>11.51 ± 1.25</td>
<td>0.218</td>
</tr>
<tr>
<td>Postoperative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corneal resistance factor CRF</td>
<td>8.49 ± 1.54</td>
<td>8.5 ± 1.53</td>
<td>0.097</td>
</tr>
<tr>
<td>Corneal hysteresis CH</td>
<td>9.47 ± 1.29</td>
<td>9.49 ± 1.30</td>
<td>0.218</td>
</tr>
</tbody>
</table>

Simulated keratometry was comparable between the groups (p=0.41). Simulated keratometry values changed in the microkeratome group (from 44.11±1.3 D to 40.3±1.1 D, p=0.003 after flap creation) as shown in figure (1) and in femtosecond group (from 44.4±1.2 to D 42.6±0.9 D to, p=0.55).

Figure (1): SimK of preoperative and 12 months after lasik in microkeratome group.

Preoperatively, Corneal Hysteresis and Corneal resistant factor showed similar results between the groups (p=0.05), but postoperatively was statistically different with higher values for the microkeratome group (, p=0.01) as shown in Figure (2).
DISCUSSION
The biomechanical impact of flap thickness on CH and CRF may be important in better understanding the pathophysiology of ectasia, one of the most vision-threatening complications encountered after refractive surgery. CH is thought to be a measure of viscous damping in the corneal tissue, or the energy absorption capability of the cornea, whereas CRF is a measure of the combined viscous damping and elastic resistance behaviors of the cornea (9-10). LASIK is the mainstream surgery to correct the refraction errors nowadays, which is proved to be safe, effective and well predictable. The critical step of LASIK is to make a thin and uniform lamellar cornea flap (11). Femtosecond laser flaps showed uniform thickness and planar-shape, however some microkeratome created flaps, which were not uniform but meniscus-shaped. The flaps made by femtosecond laser were proved to be more precise, more even, and better predictable than the flaps made by microkeratome (12-13).

After 12 months follow-up, CH or CRF were significantly different between the two groups. The femtosecond group provided thinner corneal flaps compared to the Moria 2 group. Therefore better performance of corneal biomechanics was gained in the femtosecond group. Based on the studies of Franco and Lira (14) and Kamiya et al. (15), sufficient Residual corneal thickness (RCT) was the guarantee of the post-operational corneal biomechanics. This outcome indicated that with the premise of the same RCT, the different way of flap formation had notable influence on the cornea biomechanical parameters including CRF and CH one year after surgery. This study was coincided with the previous two researches.

In this study there was significant decrease of CRF from 6 to 12months in the Moria 2 group. This outcome meant that femtosecond group had better long-term effect on cornea biomechanics than the Moria 2 group. Although iatrogenic post-LASIK ectasia is reported in the patients whose residual
cornea were less than 250 µm, reserving enough RCT was still the most important way to avoid post-LASIK ectasia (16–17). Furthermore, the greater inflammatory response and biomechanical stability of the femtosecond flap was reported by Dawson et al. (18) and Netto et al. (19) and proved by Kim et al. (20) that femtosecond flaps were more strong and unlikely to shift or have a crease. There was growing evidence that it was different in the wound-healing response and biomechanical effects on the cornea depending on whether a flap was created by a microkeratome or femtosecond laser (18,20).

It is noticeable that CRF and CH value increased with the increasing of CCT and the curvature of the cornea, while CH value decreased with the increasing of IOPcc. Cornea thickness was the main effective factor of cornea biomechanics. We found that cornea curvature had some influence on the CH value, which was proved by Lim et al. (21). The relationship between the cornea curvature and the biomechanical parameters indicated that cornea with high refractive power might need more strength to gain applanation. Therefore the IOP would be higher than actual. Hence, when the myopic eyes were taken the IOP test, not only the cornea thickness but also the cornea curvature should be taken into account.

Also in current study we found that CRF increased with the increasing of RCT, pre-LASIK CRF and RSBT, while CH increased with the increasing of RCT or pre-LASIK CRF and decreased with the increasing of pre-LASIK IOP or CFT. This result indicated that post-LASIK cornea biomechanical parameters (CRF and CH) correlate not only with the RCT but also with the inherited physical and physiological characters of the operated eyes. The femtosecond group got better corneal biomechanical performance one year after surgery than the Moria 2 group in this study. The femtosecond laser provide thinner and better cornea flaps. Thicker flaps induced a steepening that might be related to the more pronounced structural effect of a deeper lamellar insult. Thin flaps caused less acute changes in corneal shape and biomechanical properties and might, in general, be less prone to unexpectedly affecting postoperative refractive outcome or contributing to the generation or exacerbation of ectasia (22).

Femtosecond laser is able to create a customized corneal flap of between 90 and 110 µm with a diameter based on the requirements of the individual patient and the type of excimer laser with high precision, thus saving corneal tissue. The diameter could be precisely controlled by the surgeon (23) and is not dependent on corneal anatomy. Moreover, the decrease in hysteresis seems to be more predictable after LASIK with the femtosecond laser compared with a mechanical microkeratome (24).

CONCLUSION

Both femtosecond LASIK and Moria2 LASIK can affect the biomechanical strength of the cornea depending on the amount of myopic correction. The amount of biomechanical changes is larger after LASIK with mechanical microkeratome than after femtosecond from a biomechanical viewpoint.

REFERENCES