Effect of suction on the posterior segment after LASIK using Femtosecond Laser vs Microkeratome

H.M.El- Feky, A.M.Saeed and A.S.Abdel Aziz
Ophthalmology Dept., Faculty of Medicine, Benha Univ., Benha, Egypt
E-mail: Ahmed_said90@hotmail.com

Abstract

Background: Creating a successful corneal flap is the first critical step during LASIK surgery. Two techniques are used to produce corneal flaps during LASIK surgery: a microkeratome or a femtosecond laser. Femtosecond laser has a significant impact on refractive surgery by enabling non-mechanical creation of corneal flaps during laser in situ keratomileusis (LASIK). During LASIK flap creation, intraocular pressure (IOP) increases to levels exceeding 65 mm Hg. Femtosecond laser flap creation exerts less extreme IOP fluctuations but requires more procedural time than when using a microkeratome. This study was conducted upon 60 eyes of 38 patients to evaluate the effect of applied suction during LASIK procedures on the posterior segment of myopic eyes, whether the flap was created by Microkeratome or Femtosecond laser. The study subjects were equally divided into 2 groups: group F (30 eyes of 20 patients) underwent femtosecond laser-assisted LASIK surgery and group M (30 eyes of 18 patients) underwent microkeratome-assisted LASIK surgery using Moria M2 for the treatment of myopia. It was found that the central macular thickness and RNFL thickness were not changed significantly in both groups when measured 1 week after surgery. Regarding the incidence of PVD, there was a higher incidence in group F, it was detected in 8 eyes (26.7%) compared to group M, it was detected in 1 eye (3.3%). Conclusion: Slight localized changes of macular thickness and reduction of the RNFL thickness were caused by LASIK using the two major forms of flap creation, namely a microkeratome or a femtosecond laser. Regarding the incidence of PVD, it was found that femtosecond laser-assisted LASIK using Visumax femtosecond laser had a higher incidence than that after microkeratome-assisted LASIK with the Moria M2. So the surgery of LASIK is safe and efficient, but surgeons should choose effective and safe suction mode, shorten the suction time and exclude potential retinopathy and pre-existing glaucoma before surgery to improve the safety and efficacy of LASIK.

Keywords: Femtosecond Laser, LASIK, Microkeratome.

1. Introduction

Laser in situ keratomileusis (LASIK) is the commonest ophthalmic surgical procedure used to correct refractive error. Due to decreased time of recovery and post-procedure complications, this surgery quickly became popular. LASIK is among the most studied surgical procedures to have gone through FDA inspection since its introduction in clinical practice. [1]

Creating a successful corneal flap is the first critical procedure during LASIK surgery. Two techniques are used to produce corneal flaps during LASIK surgery: a microkeratome or a femtosecond laser.

Femtosecond laser has a significant influence on refractive surgery by enabling non-mechanical creation of corneal flaps during laser in situ keratomileusis (LASIK). The femtosecond laser offers advantages over microkeratomes. These include increased precision, a reduced incidence of flap complications, and the ability to cut thinner flaps without the risk of button-hole formation. [2]

Intraocular pressure (IOP) increases to high levels exceeding 65 mm Hg during LASIK flap creation. Femtosecond laser flap creation exerts less IOP fluctuations but requires more time than when using a microkeratome. The sudden spike in IOP, which can damage the eye, has been noted during LASIK. [3]

One hypothesis is that the axial length of the eye changes during suction ring application (lengthening or shortening), resulting in vitreoretinal traction at the vulnerable macula and vitreous base, which may result in various posterior segment effects ranging from PVD to rhegmatogenous RD. The incidence of posterior segment complications should theoretically decrease with the recent introduction of the femtosecond laser in refractive surgery because of the lower vacuum required during the suction phase, which should result in less vitreoretinal traction. [4]

2. Aim of the work

To assess and compare the posterior segment changes as incidence of PVD, macular and peri-papillary retinal nerve fibre layer thickness changes after femtosecond laser vs microkeratome assisted LASIK.

3. Patients and methods

This prospective, non-randomized comparative clinical trial was conducted upon 60 eyes of 38 patients. The study subjects were equally divided into 2 groups: group F (30 eyes of 20 patients) underwent femtosecond laser-assisted LASIK surgery and group M (30 eyes of 18 patients) underwent microkeratome assisted LASIK surgery for the treatment of myopia.

The two groups were chosen from the refractive clinic of Benha University Hospital and were planned to undergo the LASIK procedure.

Patients were enrolled in the study according to the following inclusion criteria: age range between 18 years and 35 years, having moderate degree of myopia from (3.0) to (-6.0) diopeters (D) and all patients fulfilled all the criteria for safe and successful LASIK procedure. While the exclusion criteria were: Preoperative PVD (partial or total) detected clinically or by optical coherence tomography, evidence of glaucomatous optic nerve damage, cup-disc ratio >0.4, diabetes, steroid
responder or other systemic diseases known to affect
the eye were excluded, disc anomalies as tilted disc
were also excluded, prolonged suction time due to
uncooperative patients or failed suction during the
procedure were excluded and patients who had previous
ocular or refractive surgeries was be excluded, as well
as patients who have peripapillary atrophy upon fundus
examination.

All patients underwent a complete preoperative
examination including: Uncorrected visual acuity
(UCVA), best corrected visual acuity (BCVA), manifest
and cycloplegic refraction, anterior segment assessment
including: Slit lamp examination, applanation
tonometry and pentacam, posterior segment assessment
including: slit lamp biomicroscopy and indirect
ophthalmoscopy to exclude the presence and any
associated retinal pathology, Macular and the
peripapillary RNFL thickness measurements and
assessment of PVD using optical coherence
tomography.

3.1. Intra-operative assessment

The eye was fixated by a suction ring using
negative pressure that was gradually built. A corneal
flap was created using Femtosecond laser in 30 eyes,
while the remaining 30 eyes had a flap created by
microkeratome. The time of suction applied to the eye
from “Suction ON” to “Suction OFF” was documented
in each group, also any intraoperative complication.

3.2. Surgical procedure

Eye preparation and Anaesthesia: An eyelid
speculum was inserted in the operative eye, which had
been anesthetized topically, and the fellow eye was
covered. The cornea was marked to aid postoperative
flap alignment. The patient was instructed to look at the
fixation light. A suction ring was applied to the globe.

Flap creation: Femtosecond laser or the
microkeratome were used to create a hinged corneal
flap. The flap hinge may be superior, nasal, or oblique
depending on the microkeratome used. Depending on
total corneal thickness, the flap thickness was chosen
between 90 and 110 microns.

Laser remodelling: After lifting the flap, ablations
were performed using the MEL 90 Zeiss Excimer laser
and/or Visumax femtosecond laser.

Repositioning of the flap: Following ablation, the
flap was repositioned with irrigation of the interface
bed. Once flap alignment is verified and the peripheral
gutters are inspected and found to be minimal and
symmetric, the flap was allowed sufficient time to
adhere. The eyelid speculum is carefully removed
without disturbing the flap. The eye then examined at a
slit-lamp biomicroscope 5 to 30 minutes later to verify
flap alignment. Postoperative assessment

The same preoperative examinations was repeated
1 week post-operative

3.3. Optical Coherence Tomography (OCT)

Assessment of PVD and measurements of the
macular and peripapillary retinal nerve fibre layer was
measured using Topcon 3D OCT-2000 Series of
Spectral Domain.

4. Statistical Analysis

Data were collected, revised, coded and entered to
the Statistical Package for Social Science (IBM SPSS)
version 23. The quantitative data were presented as
mean, standard deviations and ranges when their
distribution found parametric and median with inter-
quarterile range (IQR) when their distribution found non
parametric. Also qualitative variables were presented as
number and percentages. The comparison between
groups with qualitative data were done by using Chi-
square test and Fisher exact test instead of the Chi-
square only when the expected count in any cell found
less than 5. The comparison between two groups with
quantitative data and parametric distribution were done
by using Independent t-test. The comparison between
two groups with quantitative data and parametric
distribution were done by using Paired t-test. The
confidence interval was set to 95% and the margin of
error accepted was set to 5%.

5. Results

30 eyes of 20 patients (group F) underwent
femtosecond laser-assisted LASIK and 30 eyes of 18
patients (group M) underwent microkeratome-assisted
LASIK. There was no statistically significant difference
between the 2 groups regarding age, sex and spherical
equivalent. There was a statistically significant
difference in the suction time between the 2 groups.

The average preoperative RNFL thickness was
(103.00 ± 13.21 µm) in the FS group and (93.59 ± 8.61
µm) in the MMK group. No statistically significant
difference was found between both groups with regards
to these parameters.

The mean “Suction ON” to “Suction OFF” time was
(22 ± 1.2 seconds) in the MMK group compared to
(32.97 ± 1.19 seconds) in the FS group. The LASIK
procedure was uneventful in all patients.

One week after surgery, PVD (partial or complete)
was detected in 8 eyes (26.7%) in group F and 1 eye
(3.3%) in group M. The remaining study subjects
showed no OCT evidence of PVD, neither partial nor
total. The demographic data of both groups and the
incidence of postoperative PVD and their significance
(P value) are demonstrated in Table 1-3.

Table (1) Shows demographic data of both groups and their related p values.

<table>
<thead>
<tr>
<th></th>
<th>Group M No. = 18</th>
<th>Group F No. = 20</th>
<th>Test value</th>
<th>P-value</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age Mean ± SD</td>
<td>26.11 ± 4.48</td>
<td>28.20 ± 3.98</td>
<td>-1.521•</td>
<td>0.137</td>
<td>NS</td>
</tr>
<tr>
<td>Range</td>
<td>21 – 35</td>
<td>21 – 35</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td>10 (55.6%)</td>
<td>8 (40.0%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>8 (44.4%)</td>
<td>12 (60.0%)</td>
<td>0.920*</td>
<td>0.338</td>
<td>NS</td>
</tr>
</tbody>
</table>

Table (2) Shows the mean spherical equivalent and suction time of both groups.

<table>
<thead>
<tr>
<th></th>
<th>Group M No. = 30</th>
<th>Group F No. = 30</th>
<th>Test value</th>
<th>P-value</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spherical equivalent Mean ± SD</td>
<td>-4.43 ± 0.85</td>
<td>-4.60 ± 0.86</td>
<td>0.793•</td>
<td>0.431</td>
<td>NS</td>
</tr>
<tr>
<td>Range</td>
<td>-6 – -3</td>
<td>-6 – -3.25</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suction time</td>
<td>20.03 ± 1.22</td>
<td>32.97 ± 1.19</td>
<td>-41.639•</td>
<td>0.000</td>
<td>HS</td>
</tr>
<tr>
<td>Range</td>
<td>18 – 22</td>
<td>31 – 35</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

P-value > 0.05: Non significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant •: Independent t-test.

Table (3) Shows the macular thickness, RNFL thickness and the incidence of PVD in group M pre and post-operative.

<table>
<thead>
<tr>
<th></th>
<th>Group M Pre-operative</th>
<th>Group M Post-operative</th>
<th>Test value</th>
<th>P-value</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Macular thickness Mean ± SD</td>
<td>221.67 ± 19.93</td>
<td>221.30 ± 21.17</td>
<td>0.455•</td>
<td>0.652</td>
<td>NS</td>
</tr>
<tr>
<td>Range</td>
<td>187 – 257</td>
<td>182 – 257</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RNFL thickness  Mean ± SD</td>
<td>93.59 ± 9.61</td>
<td>92.83 ± 10.27</td>
<td>1.317*</td>
<td>0.198</td>
<td>NS</td>
</tr>
<tr>
<td>Range</td>
<td>77.41 – 110</td>
<td>71.33 – 112</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PVD No</td>
<td>30 (100.0%)</td>
<td>29 (96.7%)</td>
<td>1.017*</td>
<td>0.313</td>
<td>NS</td>
</tr>
<tr>
<td>PVD Yes</td>
<td>0 (0.0%)</td>
<td>1 (3.3%)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(P-value > 0.05: Non significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant *, Chi-square test; •: Independent t-test).

Table (4) Shows the macular thickness, RNFL thickness and the incidence of PVD in group F pre and post-operative.

<table>
<thead>
<tr>
<th></th>
<th>Femtolasik group Pre-operative</th>
<th>Femtolasik group Post-operative</th>
<th>Test value</th>
<th>P-value</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Macular thickness Mean ± SD</td>
<td>241.27 ± 16.26</td>
<td>240.30 ± 16.00</td>
<td>1.469</td>
<td>0.153</td>
<td>NS</td>
</tr>
<tr>
<td>Range</td>
<td>217 – 265</td>
<td>213 – 265</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RNFL           Mean ± SD</td>
<td>103.00 ± 13.21</td>
<td>102.37 ± 12.63</td>
<td>1.472</td>
<td>0.152</td>
<td>NS</td>
</tr>
<tr>
<td>Range</td>
<td>84 – 126</td>
<td>81 – 121</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PVD No</td>
<td>30 (100.0%)</td>
<td>22 (73.3%)</td>
<td>9.231</td>
<td>0.002</td>
<td>HS</td>
</tr>
<tr>
<td>PVD Yes</td>
<td>0 (0.0%)</td>
<td>8 (26.7%)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table (5) Shows the difference in macular and RNFL thicknesses pre and post-operative in both groups.

<table>
<thead>
<tr>
<th>Difference</th>
<th>Lasik group No. = 30</th>
<th>Femtolasik group No. = 30</th>
<th>Test value</th>
<th>P-value</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Macular thickness</td>
<td>-0.37 ± 4.41</td>
<td>-0.97 ± 3.61</td>
<td>-0.577•</td>
<td>0.566</td>
<td>NS</td>
</tr>
<tr>
<td>RNFL thickness</td>
<td>-0.76 ± 3.16</td>
<td>-0.63 ± 2.36</td>
<td>0.181•</td>
<td>0.857</td>
<td>NS</td>
</tr>
</tbody>
</table>

(P-value > 0.05: Non significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant). •: Independent t-test.

6. Discussion
In our study, a new generation of SD-OCT was used to evaluate the effect of applied suction during LASIK procedures on macular and RNFL thickness on 60 myopic eyes, whether the flap was created by microkeratome or Femtosecond laser. LASIK-induced corneal alterations do not affect OCT imaging, making the latter more reliable in the
evaluation of RNFL thickness in treated eyes than using other devices as Scanning Laser Polarimetry.

It was found in our study that the central macular thicknesses were not changed significantly in both groups when measured 1 week after surgery. Also, the RNFL thickness changes were found not to be of significance and is unlikely to have clinical consequences.

A study conducted by Özülken and Dıhan on randomly selected eye of 114 consecutive eligible patients was analyzed. Inclusion criteria were myopia up to -6.00 diopters and astigmatism up to -2.00 diopters. As clinically indicated, 50 patients underwent LASEK and 64 underwent FS-LASIK. The RNFL thickness was determined for each subject using OCT, the fovea, and the macula. The authors found that the changes present in the RNFL thickness measurements were due to corneal and scleral alterations. In accordance with our study, Hosny et al. (2013) used SD-OCT to evaluate the effect of applied suction during LASIK procedures on RNFL thickness in 40 myopic eyes, whether the flap was created by microkeratome or FS laser. The transient rise of IOP during suction was found to have no significant effect on RNFL thickness in both groups. [7]

Gürses-Özden et al. (2000) as well as Tsai and Lin (2000) reported that RNFL thickness may decrease after uncomplicated LASIK procedures when measured by conventional scanning laser polarimetry (SLP) with a fixed corneal compensator. [8], [9] Yet in 2001, Gürses-Özden et al. (2001) came to the conclusion that LASIK does not affect the RNFL thickness, as measured by OCT, SLP, and scanning laser tomography. The authors found that the changes present in the SLP thickness measurements were due to corneal alterations. Zangwill et al. (2005) confirmed these previous findings, and stated that the post-LASIK thinning of RNFL measured using SLP with a fixed corneal compensator can occur due to altered corneal birefringence, and may not actually be present. [10]

Regarding the incidence of PVD, in our study, 60 eyes of 38 patients were examined preoperatively by OCT to exclude existing preoperative PVD. We used OCT because it is known to be more useful in the evaluation of the vitreoretinal interface and more easily detects a flat and shallow posterior hyaloid detachment more than US.

Cases with double application of suction due to suction loss or inadequate centration in the first application were excluded. This could explain the relatively small sample size compared with other studies.

The mean “Suction ON” to “Suction OFF” time was (32.97 ± 1.19 seconds) in group F compared to (22 ± 1.2 seconds) in group M. We calculated the suction time in group F from the moment vacuum was applied until vacuum was released (not only the duration of femtosecond laser application), and in group M from the start of application of the suction ring until suction was switched off. This explains the significantly longer duration of suction application in the femtosecond laser group. One week after surgery, PVD (partial or complete) was detected in 8 eyes (26.7%) in group F and 1 eye (3.3%) in group M.

A study similar to ours was conducted by Wang et al. (2013) comparing the incidence of PVD in microkeratome-assisted-LASIK and femtosecond-assisted LASIK. [8] This study included 2 groups involving 80 eyes (40 cases in each group). One group underwent femtosecond laser-assisted (IntraLase FS-150; Abbott Medical Optics, American) LASIK surgery, and the other group underwent microkerateome-assisted (Amadeus II, Ziener, Switzerland) LASIK surgery. B-scan ultrasonography and optical coherence tomography were performed preoperatively and 1 week, 1, 3, and 6 months postoperatively to detect the presence of PVD. This study showed 27.5% incidence of postoperative PVD in the femtosecond laserassisted LASIK group and 20% incidence of PVD in the microkeratome-assisted LASIK group. Thus, there was no statistically significant difference between the 2 studied groups (x² = 2.257, P = 0.133).

The incidence of PVD after femtosecond laser-assisted LASIK agreed with that found in the study done by Wang et al., whereas the incidence of PVD after microkeratome-assisted LASIK (20%) strongly disagreed with that resulting from our study (3.3%). However, it should be noted that cases with double application of suction due to suction loss or inadequate centration in the first application were excluded from the study as well as cases with preoperative partial PVD and this may explain the decreased incidence of PVD in our study.

A study conducted by Osman et al. found that the incidence of PVD 1 month after femtosecond laser-assisted LASIK with the IntraLase FS-150 (85%) was higher than that after microkeratome-assisted LASIK with the Moria M2 (20%). The mean suction time was 18.6 ± 2 seconds in group M and 63.6 ±4 seconds in group F. [4]

However in our study the mean suction time was 32.97 ± 1.19 seconds in the FS group. Another difference is that The Visumax has a low-suction curved interface, and no suction ring is applied to the eye. Visumax generates suction on the cornea via a curved contact glass, in contrast to Intralase, which applies suction on the conjunctiva and sclera via a suction ring. This leads to less IOP elevation when using Visumax compared to IntraLase FS-150. [11]
The above-mentioned facts could explain the lower incidence of PVD after femtosecond laser-assisted LASIK (27.5%) found in our study compared with the incidence found in the study conducted by study conducted by Osman et al. [4]

7. Conclusion
Slight localized changes of macular thickness and reduction of the RNFL thickness were caused by LASIK using the two major forms of flap creation, namely a femtosecond laser or a microkeratome. So the surgery of LASIK is safe and efficient, but surgeons should choose effective and safe suction mode, shorten the suction time and exclude potential retinopathy and pre-existing glaucoma before surgery to improve the safety and efficacy of LASIK. Regarding the incidence of PVD, it was found that femtosecond laser-assisted LASIK using Visumax femtosecond laser had a higher incidence than that after microkeratome-assisted LASIK. This may be due to the longer duration of suction during femtosecond LASIK, although the suction pressure is lower during the femtosecond laser procedure. This could trigger screening of patients who have previously undergone LASIK surgery, especially femtosecond laser-assisted LASIK, for posterior segment complications, which would enable their early management.

References