Learning curve in FS-LASIK with curved cone

[Original Article]

The impact of learning curve on flap thickness outcome in femtosecond laser assisted LASIK performed with new LenSx dual platform

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Abstract

Background: To evaluate the effect of learning curve on flap thickness outcome in femtosecond (FS) laser assisted LASIK operation for myopia performed with recently introduced LenSx dual platform using curved applanation cone.

Methods: Seventy eyes of 36 patients with myopia or myopic astigmatism operated with FS laser-assisted LASIK with recently introduced LenSx dual platform were evaluated in this retrospective study. Operations were divided into two groups including first-20 operations (20 eyes of 10 patients) and next-50 operations (50 eyes of 26 patients). Data on patient demographics, preoperative and postoperative keratometric and aberrometric parameters and flap thickness related outcome including mean central flap thickness (MCFT), mean total flap thickness (MTFT), intra-FT range and flap thickness homogeneity (FTH) were compared in study groups.

Results: Except for significantly lower preoperative steepest keratometry (K2) values in the next-50 operations vs. first-20 operations (p=0.033), no significant difference was noted between study groups in terms of preoperative and postoperative parameters. When compared to first-20 operations, next-50 operations were associated with significantly higher values for MCFT (median 123 vs. 114 µm, p=0.007) and MTFT (median 123 vs. 113 µm, p=0.015), whereas significantly lower intra-FT range (median 4.0 vs. 4.5 µm, p=0.003).

Conclusions: In conclusion, our findings related to FS laser assisted LASIK surgery for myopia with new LenSx dual platform using curved applanation cone revealed significant impact of learning curve on the corneal flap thickness outcome in terms of closer flap thickness to the intended value and lower intra-flap range.

Keywords: flap thickness, LASIK, learning curve; LenSx
Introduction
Laser in situ keratomileusis (LASIK) remains to be the most commonly used technique in refractive surgery for correction of ametropia.\cite{1-3} LASIK flap creation, obtaining a flap of predictable thickness and morphology with minimum alteration in corneal biomechanics, is considered the most critical step of LASIK in terms of postoperative visual outcome of the whole procedure.\cite{3-5}

Thus, the technological evolution of flap creation has emerged from manually guided mechanical microkeratomes to automated microkeratomes, single-use microkeratomes, and most recently to femtosecond (FS) laser technology.\cite{3,6,7}

In 2015, a new software program was installed to the original software of the LenSx FS laser to perform LASIK flaps via the same FS laser previously used for cataract surgery. Thus, new FS laser platforms that are able to perform both corneal LASIK flaps and FS laser–assisted cataract surgery with a “one-for-all” approach have been developed. Some of these new “dual” FS lasers use a curved patient interface in the applanation cone. This theoretically allows for better approximation of the contour of the cornea, enabling an easier docking process while requiring less suction and minimizing corneal compression and distortion with less elevation in intraocular pressure (IOP), and it is therefore easier for the patient to maintain fixation while the suction ring is seated.\cite{5,8}

Although the perceived benefits are promising in terms of good visual outcomes and acceptable flap thickness predictability, there is limited published evidence regarding the corneal flap morphology outcome of the dual LenSx FS laser (Alcon Laboratories, Inc, Aliso Viejo, CA) device using curved applanation cone.\cite{5,6} Indeed, the learning curve of surgeons, and the lack of sufficient data on safety profiles of FS laser technology overall, not only for the new LenSx dual platform, are considered amongst the major barriers in use of FS lasers for LASIK in real-life clinical practice.\cite{10}

Notably, moistness status of the contact surface is of critical importance in using the curved applanation cone. If the cornea is too wet, there is a risk of thinner flap than planned since excess fluid at the interface can go up to suction loss. Therefore, it is required to remove excess fluid from the sclera before docking. However, in case of insufficient moisturization epithelial wrinkles may occur, which negatively impacts the focus of laser
Learning curve in FS-LASIK with curved cone beams and flap quality.\cite{5,11} Hence, although the transition is easy for existing FS laser-assisted LASIK surgeons, there is a short learning curve for optimization of the contact surface. We aimed to evaluate the effect of this learning curve on flap thickness using the anterior segment optical coherence tomography (AS-OCT), considered a reliable method for assessing flap thickness parameters in LASIK for the cornea.\cite{12,13} This study was therefore designed to evaluate the effect of learning curve on flap thickness outcome in FS laser assisted LASIK operation for myopia performed with recently introduced LenSx dual platform (LenSx; software version 2.31, Alcon Laboratories, Inc., Aliso Viejo, CA) using curved applanation cone.

**Methods**

**Study population**

Seventy eyes of 36 patients with myopia or myopic astigmatism who underwent FS laser-assisted LASIK between January 2019 and August 2019 in xx Hospital were evaluated in this retrospective study. Operations were divided into two groups based on the time of operation including first-20 operations (the first 20 eyes of 10 patients) and next-50 operations (50 eyes of 26 patients). The surgery of first 20 eyes of 10 patients were performed under supervision during education to be eligible to perform FS laser-assisted LASIK surgery with curve applanation. That is why we divided the first 20 eyes of 10 patients as first cases which were performed under supervision. Patients with myopia (up to 7.75 D), with or without astigmatism (up to 4.00 D), with a preoperative corrected distance visual acuity (CDVA) of at least 0.63 (decimal notation) were included in the study. Presence of unstable refraction, previous refractive or other type of ocular surgery, topographic suspicion of keratoconus, and any ocular or systemic disease that could interfere with the wound-healing process were the exclusion criteria of the study.

Written informed consent was obtained from each subject following a detailed explanation of the objectives and protocol of the study which was conducted in accordance with the ethical principles stated in the “Declaration of Helsinki” and approved by the institutional ethics committee.

**Study parameters**
Data on patient demographics (age, gender), preoperative [manifest sphere diopter (D), cylinder (D), spherical equivalent (SE), flat (K1) and steep (K2) keratometry reading, mean keratometry, pachymetry (µm), planned flap thickness (µm), flap diameter (mm) and optic zone] and postoperative [manifest sphere diopter (D), cylinder (D), SE, K1, K2 and mean keratometry] keratometric and aberrometric parameters were recorded in each patient. Flap thickness related outcome was evaluated based on mean central flap thickness (MCFT), mean total flap thickness (MTFT), intra-FT range and flap thickness homogeneity (FTH).

**Keratometric and aberrometric analyses**

Scheimpflug imaging-based corneal tomography system (Oculus Pentacam, Oculus GmbH, Wetzlar, Germany) and placido-based corneal topography system (Allegro Topolyzer, WaveLight Technologie AG, Alcon Laboratories) were used to determine K1 (steep keratometric reading), K2 (flat keratometric reading), Q value (corneal asphericity coefficient) and corneal aberrations which analyzed included total aberrations, high order aberrations (HOA), vertical coma, horizontal coma and spherical aberrations.

**Surgery and imaging analysis**

All surgeries were performed by the same surgeon (BSA) who was experienced in FS lasers with planar applanation. The flap was created with the LenSx FS laser (LenSx; software version 2.31, Alcon Laboratories, Inc., Aliso Viejo, CA). No patient had suction loss. The FS laser was programmed to a flap thickness of 120 µm and a flap diameter of 9.0 mm to with a 70-degree angled side cut and a 50-degree hinge angle (Table I). In all cases, flaps were lifted with a parabolic shaped tip lifter (RHEIN 08-16172) and the stromal ablations were performed with the same WaveLight EX500 excimer laser (WaveLight Technologie AG, Alcon Laboratories), with an optical zone larger than or equal to the mesopic pupillary size, in all cases. For the hydration and to lay the flap back down, we use a multi-port irrigator.

Imaging and measurement of the LASIK flaps were performed by high-speed AS-OCT (Cirrus HD OCT 5000; Carl Zeiss-Meditec, Dublin, CA, USA). Flap thickness was measured at three points in each horizontal image (center, 2 mm nasal and temporal to the vertex) (Fig. 1). Flap thickness was measured at three points along the horizontal meridian passing through the corneal center. The corneal center was determined by the presence of high reflective artifacts while scanning for corneal apex. The flap was evaluated with a horizontal line scan measuring 20 degrees and flap thickness was measured at three points: center, 2 mm nasal and
The adjustments were done manually, and readings were calculated accordingly based on the measuring tool of the device. Flaps were visible in all OCT scans obtained 2 weeks postoperatively.

Flap thickness related outcome was evaluated based on MCFT, MTFT (defined as the mean thickness value of all 3 FT points measured in the horizontal meridian of each flap), intra-FT range (defined as the difference between the thickest and thinnest points in each flap) and FTH (defined as the thickness difference between the 2 measurement points located 2 mm nasally and temporally from the corneal apex).

Statistical analysis
Statistical analysis was performed using the MedCalc Statistical Software version 12.7.7 (MedCalc Software bvba, Ostend, Belgium; http://www.medcalc.org; 2013). The normality of continuous variables was investigated by Shapiro-Wilk’s test. Categorical variables were assessed with Chi-Square test and Fisher Exact test. For comparison of two normally distributed groups Student t test was used. Non-parametric statistical methods were used for values with skewed distribution. For comparison of two non-normally distributed groups Mann Whitney U test was used. The χ² test was used for categorical variables. Data were expressed as mean±standard deviation (SD), median (minimum-maximum) and n (%) where appropriate. p<0.05 was considered statistically significant.

Results
Patient demographics and preoperative and postoperative keratometric and aberrometric parameters
Overall, the mean±SD patient age was 26.7 ±7.5 years and females composed 50% of the study population. Patients in the first-20 and next-50 operations were homogenous in terms of age and gender (Table II). Except for significantly lower preoperative steepest keratometry (K2) values in the next-50 operations vs. first-20 operations (median (min-max) 43.9(42-47.8) vs. 45(40.5-49), p=0.033), no significant difference was noted between study groups in terms of preoperative and postoperative parameters (Table II).

Comparison of flap thickness related outcome in study groups
When compared to first-20 operations, next-50 operations were associated with significantly higher values for MCFT (median 123 vs. 114 μm, p=0.007) and MTFT (median 123 vs. 113 μm, p=0.015), whereas significantly lower intra-FT range (median 4.0 vs. 4.5 μm, p=0.003). No significant difference was noted between study groups in terms of FTH (Table III, Fig. 2).

In the first-20 operations, overall flap thickness was thinner than planned by -4.6 μm (minimum, 110.7 μm with a −9.3 μm average difference; maximum, 131.3 μm with a +11.3 μm difference) with an average thickness standard deviation of 10.8 μm. In the next-50 operations, overall flap thickness was thicker than planned by +3.0 μm (minimum, 109.0 μm with a −11.0 μm average difference; maximum, 133.7 μm with a +13.7 μm difference) with an average thickness standard deviation of 6.6 μm (Table II). Intra-FT range (FT variability) was also significantly lower within the next-50 operations compared to those for the first-20 operations (median 4.0, range 1-6 vs. median 4.5, range 3-16, p=0.003) (Table III).

Discussion

Our findings revealed significant impact of learning curve on flap thickness outcome during FS laser-assisted LASIK surgery with use of new curved applanation cone in terms of achievement of postoperative flap thickness which is closer to the intended thickness along with lower intra-flap range with increase in surgeon’s experience. Eventhough all surgeries were performed by the same surgeon (BSA) who was experienced in FS lasers with planar applanation and femtosecond laser assisted cataract surgery for six years, the patient interface for LenSx laser cataract surgery and LASIK is quiet different which requires experience. The aim of this study was to evaluate the impact of learning curve on flap thickness outcome in femtosecond laser assited LASIK performed with a new LenSx dual form and new patient interface.

In the current study, as compared with first-20 operations, next-50 operations enabled LenSx flaps that were closer to the intended flap thickness along with lower intra-flap range, suggesting an improving learning curve. This seems notable given that preoperative and postoperative keratometric and aberrometric parameters were homogenous in study groups. While preoperative K2 values were significantly lower in the next-50 eyes than first-20 eyes in our study, no significant association of preoperative keratometry or pachymetry with flap thickness has been previously reported in studies on the accuracy and precision of flap thickness using the FS laser assisted LASIK.\textsuperscript{[14,15]}
According to our experience, in the first-20 operations flaps were thinner than planned by -4.6 μm and SD of flap thickness was 10.8 μm (ranged −9.3 μm to +11.3 μm), whereas in the next-50 operations, flaps were thicker than planned by +3.0 μm and SD of flap thickness was 6.6 μm (ranged, −11.0 μm to +13.70 μm). Notably, in the first study to evaluate the visual outcomes and flap thickness accuracy of the LASIK performed with new LenSx multifunctional FS laser system (Alcon Laboratories, Fort Worth, TX) by Juhasz et al., the authors reported good visual results and a high flap thickness predictability with the LenSx device when they performed a targeted thick corneal flap of 140 μm in all cases.\textsuperscript{[9]} However, they also emphasized that after gaining an initial experience with the device, the flap thickness was set to the current depth of 110 μm for use in our everyday clinical practice.\textsuperscript{[9]}

The flap thickness predictability with the LenSx device in the current study seems in agreement with the lower SD of flaps created with FS laser (±5.6 μm to ±14.5μm) vs. microkeratome (ranged, ±20 to ±40μm) reported in the past studies.\textsuperscript{[16-19]} The advantage of the FS laser in terms of narrower range of achieved flap thickness vs. conventional microkeratomes is considered to translate into fewer thicker-than-expected flaps and very few thinner flaps, which lowers the risk for ectasia, and both the cap perforation and corneal striae, respectively.\textsuperscript{[15]}

Accordingly, our findings seems to suggest a higher precision in planar flap thickness creation and thus better aberrations profile and better mesopic and scotopic visual functions after the first 20 LASIK operations for myopia or myopic astigmatism performed with LenSx FS laser using the new curved applanation cone. This supports the presence of a short learning curve for optimization of the contact surface in LenSx FS laser assisted myopic LASIK surgery for novice surgeons. Notably, data from a past study among experienced and novice LASIK surgeons indicated a fellowship-training program based on a standardized surgical protocol to result in statistically comparable outcomes between an expert surgeon and a fellowship-trained surgeon when newly transitioned from mechanical microkeratome to a FS laser flap creation.\textsuperscript{[20]}

However, it should be noted that, while FS laser-created LASIK flap has been reported to be a uniform flap that may contribute to more predictable refractive and wavefront outcomes,\textsuperscript{[5,9,21]} the clinical relevance of FS laser is considered to remain controversial.\textsuperscript{[5,19]} In a past study comparing iFS 150-kHz vs. LenSx FS lasers in correction myopia, authors reported association of iFS 150 kHz with significantly lower intra-FT range at
every postoperative time point, thus suggesting that this device creates more predictable and more uniform flaps compared with LenSx.\[5\]

In fact, during flap creation using the LenSx platform with a low IOP system with a curved patient interface, the curved interface has been considered likely to make creation of a planar flap more challenging, along with additional potential disadvantages such as the likelihood of the degree of corneal compression to be not uniform depending on the corneal curvature and that of small inadvertent eye movements during suction with a system inducing low IOP elevation to affect FT homogeneity.\[5,11\] Likewise, use of Victus FS laser (Bausch & Lomb, Rochester, NY), a dual FS laser that similarly to the LenSx system also uses a curved interface and induces low IOP increase, is also considered likely to be not ideal for creation of perfectly planar flaps.\[11\]

However, it should be noted that higher success of FS laser technique in terms of flap thickness predictability has been suggested when set between 110 \(\mu\)m and 120 \(\mu\)m with an SD of 12 \(\mu\)m rather than set between 130 \(\mu\)m and 140 \(\mu\)m with an SD of 18.5 \(\mu\)m.\[22\] Hence, association of FS laser technique with achievement of a comparable flap thickness in thicker flaps (130 \(\mu\)m), whereas with a more predictable result in thinner flaps (100 to 110 \(\mu\)m) has also been noted.\[23\]

Certain limitations to this study should be considered. First, potential lack of generalizability due to relatively small sample size seems an important limitation. Second, short duration of the follow up period seems another limitation which otherwise would extend the knowledge achieved in the current study. Nonetheless, given the scarcity of available studies, providing data on the corneal flap outcome with newly introduced LenSx dual platform using curved applanation cone in FS-assisted LASIK surgery, our findings represent a valuable contribution to the literature.

In conclusion, our findings related to FS laser assisted LASIK surgery for myopia with new LenSx dual platform using curved applanation cone revealed significant impact of learning curve on the corneal flap thickness outcome in terms of closer flap thickness to the intended value and lower intra-flap range. Thus, our findings emphasize the likelihood of planning and producing more successful LASIK outcomes in terms of consistency and predictability of corneal flap thickness to be attained with increasing surgical experience.

The utility of LenSx dual platform with curved applanation cone needs to be further investigated in prospective larger scale long term studies to justify the its potential to improve safety and predictability of FS laser assisted LASIK surgery.
Conflicts of Interest: There is no conflict of interest to declare for all authors.

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References


LEGENDS TO THE FIGURES

Fig 1. Flap thickness measurement in 3 flap points through horizontal anterior segment OCT

Fig 2. Comparison of mean central flap thickness (MCFT), mean total flap thickness (MTFT) and intra-flap thickness range in study groups
<table>
<thead>
<tr>
<th>Flap parameters</th>
<th>Set at</th>
<th>Side Cut Parameters</th>
<th>Set at</th>
</tr>
</thead>
<tbody>
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<td>Diameter (mm)</td>
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<td>Hinge Position (dgrs)</td>
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<td>Thickness (µm)</td>
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<td>Hinge Angle (dgrs)</td>
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<td>Energy (µJ)</td>
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<td>Side Cut Angle (dgrs)</td>
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<td>Spot Separation (µm)</td>
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<td>Layer Separation (µm)</td>
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Table 2. Patient demographics and preoperative and postoperative keratometric and aberrometric parameters in study groups

<table>
<thead>
<tr>
<th>Patient demographics</th>
<th>First-20 operations (n=10)</th>
<th>Next-50 operations (n=26)</th>
<th>p value&lt;sup&gt;1&lt;/sup&gt;</th>
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<tbody>
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<td><strong>Age (year)</strong></td>
<td>Mean±SD</td>
<td>26.5±6.0</td>
<td>26.9±8.1</td>
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<td></td>
<td>Median (min-max)</td>
<td>24.5(21-40)</td>
<td>25(20-55)</td>
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<td><strong>Gender, n(%)</strong></td>
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<tr>
<td>Female</td>
<td>4(40.0)</td>
<td>14(53.8)</td>
<td>0.711&lt;sup&gt;2&lt;/sup&gt;</td>
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<td>Male</td>
<td>6(60.0)</td>
<td>12(46.2)</td>
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<td><strong>Preoperative parameters</strong></td>
<td>Mean±SD</td>
<td>Median (min-max)</td>
<td>Mean±SD</td>
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<td>Manifest sphere diopter (D)</td>
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<td>K1 (D)</td>
<td>43.4±1.9</td>
<td>43.1(39.8-46.8)</td>
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<td>K2 (D)</td>
<td>44.9±2.1</td>
<td>45(40.5-49)</td>
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<td>Mean keratometry (D)</td>
<td>44.2±1.9</td>
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<td>Pachymetry (µm)</td>
<td>561±28.5</td>
<td>554.5(524-615)</td>
<td>568.1±29.3</td>
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<td>Planned flap thickness (µm)</td>
<td>120±0.0</td>
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<td>Flap diameter (mm)</td>
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<td>9(8.8-9.1)</td>
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<td>Optic zone</td>
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<td><strong>Postoperative parameters</strong></td>
<td>Mean±SD</td>
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<td>Mean±SD</td>
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<td>Manifest sphere diopter (D)</td>
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<td>-0.02±0.3</td>
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<td>SE (D)</td>
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<td>K2 (D)</td>
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<td>40.7±1.8</td>
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<td>Mean keratometry (D)</td>
<td>41.1±2.6</td>
<td>41.2(36.6-45.9)</td>
<td>40.3±1.7</td>
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</tbody>
</table>

<sup>1</sup>Mann Whitney U test, <sup>2</sup>Fisher Exact test

D diopter; SE: Spherical equivalent; K1: flat keratometry reading; K2: steep keratometry reading
Table 3. Comparison of flap thickness parameters in study groups

<table>
<thead>
<tr>
<th>Flap outcome</th>
<th>First-20 operations (n=10)</th>
<th>Next-50 operations (n=26)</th>
<th>p value</th>
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<tr>
<td></td>
<td>Mean±SD</td>
<td>Median (min-max)</td>
<td>Mean±SD</td>
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<tr>
<td>MCFT (µm)</td>
<td>114.4±11.6</td>
<td>114(94-132)</td>
<td>122.5±6.6</td>
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<td>MTFT (µm)</td>
<td>115.4±10.8</td>
<td>113(100.7-131.3)</td>
<td>123.0±6.6</td>
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<td>Intra-FT range (µm)</td>
<td>6.1±3.6</td>
<td>4.5(3-16)</td>
<td>3.5±1.3</td>
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<td>FTH (µm)</td>
<td>-3.2±4.1</td>
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</tbody>
</table>

MCFT: mean central flap thickness; MTFT: mean total flap thickness; FTH: flap thickness homogeneity

1 Student t test, 2 Mann-Whitney U test