Short term changes in corneal stress-strain index and other corneal biomechanical parameters post-laser in situ keratomileusis

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Purpose: To report the short-term changes in a corneal stress-strain index (SSI) and other corneal biomechanical parameters post-laser in situ keratomileusis (LASIK) surgery. Methods: A retrospective study was conducted at a tertiary eye care center wherein patients who had undergone LASIK (microkeratome blade and femtosecond bladeless LASIK) between July and December 2019 were enrolled. Patients of age group 20-40 years, best-corrected visual acuity of 20/20, intraocular pressure (IOP) <22 mmHg, pre-LASIK pachymetry >500 microns, and corneal astigmatism ≤3.00 D were included. Subjects with a prior history of refractive surgery, any other ocular or systemic disease, poor-quality scans, intraoperative complications, and missing data were excluded. Corneal biomechanical properties including SSI were analyzed using Corvis ST and compared using the Paired T-test for each group separately at pre-LASIK, and 1-month post-operatively. Results: Overall, 202 eyes were reviewed, and 79 eyes fulfilled the inclusion criteria. Forty-three and 36 eyes had undergone Microkeratome Blade LASIK (Group I) and Femto LASIK (Group II), respectively. Overall, 29 and 26 corneal biomechanical parameters out of 33 changed significantly post-Microkeratome Blade LASIK and Femto LASIK, respectively. Statistically significant changes were noted in all the parameters at A1, maximum and VinCIguerra screening parameters (P<0.001), however, no changes were noted in SSI in both the groups when compared with the pre-surgery data. Conclusion: Though the reduction in SSI was not statistically significant, other biomechanical parameters showed significant biomechanical changes pre- and post-LASIK surgeries in both the groups. However, a long-term study with a larger sample size would be required to understand the changes and stability in SSI post-refractive surgery.

Key words: Corneal biomechanics, Corneal stress-strain index (SSI), LASIK

Laser in situ keratomileusis (LASIK) is one of the most commonly performed refractive surgeries in the world today as it reduces spectacle dependence and has a positive impact on an individual’s quality of life.[1,2] Although LASIK has proven to be safe, effective, and predictable, complications could still occur[3] and ectasia has been reported as a serious complication post-refractive surgery.[4] In the early stages, corneal ectasia can be managed with corneal collagen cross-linking, intrastromal corneal rings, and specialty contact lenses such as Rose K scleral lenses, however, the advanced cases require lamellar or partial thickness keratoplasty.[5] Thus, a better refractive screening strategy is warranted to prevent the occurrence of ectasia and the further implication of ectasia.

With refractive surgeries, alteration in corneal biomechanical parameters is unavoidable, hence, corneal biomechanical assessment has become a potential tool in screening post-refractive surgical ectasia. With the advancement in technology, the in vivo corneal biomechanical assessment in a clinical setting is possible. Previous studies have hypothesized that corneal biomechanical parameters precede tomographical and topographical changes.[7] Thus, it is important to study corneal biomechanical parameters to predict ectasia. The recently designed Corneal Visualization Scheimpflug Technology (Corvis ST) (Oculus Optikgeräte GmbH, Wetzlar, Germany) has shown to have good repeatability and reproducibility in measuring dynamic corneal responses[8] and metrics of Corvis ST such as Corvis Biomechanical Index (CBI) and tomographical biomechanical index (TBI) have a better diagnostic ability to separate ectatic eye from the normal eye.[9,10] CBI has been developed for keratoconus screening and includes various dynamic corneal response parameters such as deformation amplitude ratio at 1 and 2 mm, amplanation 1 velocity, the standard deviation of deformation amplitude at the highest concavity (HC), Ambrósio’s Relational Thickness to the horizontal profile, and stiffness parameter.[10] On the other hand, the TBI uses combined data from Pentacam HR and Corvis ST to screen ectatic corneal diseases.

The newly introduced metric such as corneal stress-strain index (SSI) describes the whole SSI curve of the corneal...
tissue. The SSI measures in vivo the material stiffness, and thus, helps facilitate the optimization of several corneal refractive treatments and management procedures, especially enhancement procedures. The SSI algorithm predicts the corneal behavior using the least square method and finite element models which simulate the effects of IOP and the Corvis ST air puff.[13] This algorithm has been validated previously in normal eyes;[13] however, it can be useful for clinical documentation of corneal biomechanical changes post-C3R.[13] In addition, it can also be used to screen the patients who are at high risk or are susceptible to developing/progression of post-refractive surgical ectasia such as LASIK. The previous studies have reported changes in the conventional corneal biomechanical parameters post-refractive surgeries.[14] However, no studies have reported post-refractive surgery changes in novel and more promising metrics of corneal biomechanics such as SSI. Hence, our aim is to report short-term changes in corneal SSI and other corneal biomechanical parameters post-LASIK surgeries (Microkeratome Blade and Femtosecond Bladeless LASIK).

**Methods**

This was a retrospective study conducted at a tertiary eye care center wherein subjects who have undergone refractive surgery (LASIK) between July 2019 and December 2020 were enrolled. The subjects were further divided into two groups depending on the technique used to create the flap.

1. Microkeratome Blade LASIK (Blade LASIK)
2. Femtosecond Bladeless LASIK (Femto bladeless LASIK).

The study was reviewed and approved by the Institutional Ethics Committee (EC reg. details: ECR/1088/Inst/MH/2018; EC approval ref. no. 2020/01: 15th Nov 2020) and was conducted in accordance with the tenets of the Declaration of Helsinki. The medical records of these patients were reviewed and analyzed. Patients between the age group of 20 and 40 years, best-corrected visual acuity of 20/20, IOP <22 mmHg, pre-LASIK pachymetry >500 microns, corneal astigmatism ≤3.00 D were enrolled. Corneal astigmatism >3.0 D is uncommon, acquired, and generally associated with ocular comorbidity. Thus, in order to make the research participants’ group coherent, corneal astigmatism equal to or less than 3.0 D was included. Subjects with a previous history of refractive surgery, any ocular or systemic disease, corneal astigmatism >3.00 D, poor-quality scans, intraoperative complications, and any missing data were excluded.

**Surgical procedure**

Both Microkeratome Blade and Femtosecond Laser-Assisted Bladeless LASIK surgery were performed by a single surgeon (VK).

**Blade LASIK**

Blade LASIK was done using Nidek EC 5000 CXII using Optimized Aspheric Treatments (OATz). All flaps were created using the Sub-Bowman Keratomileusis (SBK) automated disposable microkeratome with a 90 µm head (Moria, Antony, France).

**Femto Bladeless LASIK**

Femto LASIK was done using the Ziemer classic (Ziemer Ophthalmic Systems). The flap was created with the Zeimer Femtosecond Laser (Ziemer Ophthalmic Systems), targeting a flap thickness of 90 microns.

**Outcome variables**

**Demographics**

Parameters such as age, gender, types of refractive surgery, and scan quality were noted. Also, refractive and ocular parameters such as Best corrected visual acuity (BCVA), refraction, IOP, pachymetry, and keratometry before LASIK were noted.

**Corneal biomechanics parameter assessment**

The corneal biomechanical properties were analyzed using Corvis ST (OCULUS Optikgeräte GmbH; Wetzlar, Germany). Corvis® ST records the reaction of the cornea to a defined air pulse using a high-speed Scheimpflug camera. The camera takes over 4,300 images per second and 576 points per image. The IOP and corneal thickness can be measured with great precision on the basis of the Scheimpflug images. We noted corneal biomechanical parameters including SSI that were assessed using Corvis ST at pre-LASIK and 1-month post-operatively. Table 1 describes corneal biomechanical parameters in detail.

**Statistical analysis**

The data were entered into the Microsoft Excel spreadsheet (Microsoft Corporation). Further, Minitab 17 statistical software (Minitab LLC, State University, PA, USA) was used for statistical analysis. Pre- and post-surgery corneal biomechanical metrics were compared using the Paired T-test (Two-tailed, α<0.05) for each group separately.

**Results**

Out of the 202 eyes of 101 patients who had undergone LASIK refractive surgery, 119 eyes were excluded due to missing data whereas 2 eyes had LASIK enhancement and 2 eyes had astigmatism >3.00 D and were excluded. Finally, 79 eyes were included out of which 43 eyes had undergone Blade LASIK (Group I) whereas 36 eyes had undergone Femto LASIK (Group II). The pre-surgery mean ± SD age, spherical equivalent refractive error, IOP, keratometry, and pachymetry of Groups I and II have been described in Table 2.

**Corneal biomechanical parameters and SSI**

Out of 33, 29, and 26 corneal biomechanical parameters changed significantly post-Blade LASIK and Femto Bladeless LASIK, respectively.

**At applanation 1**

A1 time, A1 deformation amplitude, A1 deflection length, A1 deflection amplitude, and A1 deflection area were reduced significantly post-LASIK in both Blade (P<0.001) and Femto bladeless groups (P<0.001) whereas the A velocity and A delta arc length increased significantly post-LASIK in both the groups (P<0.001).

**At Applanation 2**

In the blade group, post-LASIK significant changes were noted in A2 time, A2 velocity, A2 deflection amplitude, A2 deflection area, A2 delta arc length (P<0.001) whereas A2 deformation amplitude and A2 deflection length remained unchanged. On the other hand, in the Femto bladeless group, significant changes were noted in A2 time (P = 0.003), A2 deflection length (P = 0.04), and A2 delta arc length (P<0.001).
post-surgery, however, the other parameters at A2 applanation remained unchanged.

At the highest concavity
Radius, HC deformation amplitude, HC deflection amplitude, peak distance, HC deflection area, and HC delta arc length significantly changed post-LASIK in both the groups ($P < 0.001$), however, no changes were noted in HC time in Blade LASIK ($P = 0.32$) and Femto groups ($P = 0.15$). Also, HC deflection length was significantly increased in the blade group ($P = 0.003$) whereas a non-significant increase was noted in the Femto group ($P = 0.18$).

Maximum parameters
Maximum deformation, maximum deflection, maximum delta arc length, and maximum inverse radius were found to be significantly increased in post-LASIK in both groups ($P < 0.001$).

| Parameters                          | Abbreviation | Description                                                      |
|-------------------------------------|--------------|------------------------------------------------------------------|
| First Applanation A1                | A1           | Moment at the first applanation of the cornea during the air puff |
| A1 time (ms)                        | A1T          | Time from start to A1                                            |
| A1 Velocity (m/s)                   | A1V          | Velocity of corneal apex at A1                                   |
| A1 Deformation amplitude            | A1DA         | Moving distance of the corneal apex from the initial position to that at the A1 time |
| A1 deflection length                | A1DL         | Length of the flattened cornea at A1                             |
| A1 deflection amplitude             | A1DeflA      | Similar to A1DA without whole eye movement                       |
| A1 delta Arc length                 | A1dArclength | Change in arc length from the initial state to A1, in a defined 7-mm zone |
| Second Applanation A2               | A2           | Moment at the first applanation of the cornea during the air puff |
| A2 time (ms)                        | A2T          | Time from start to A2                                            |
| A2 Velocity (m/s)                   | A2V          | Velocity of corneal apex at A2                                   |
| A2 Deformation amplitude            | A2DA         | Moving distance of the corneal apex from the initial position to that at A2 time |
| A2 deflection length                | A2DL         | Length of the flattened cornea at A2                             |
| A2 deflection amplitude             | A2DeflA      | Similar to A2DA without whole eye movement                       |
| A2 delta Arc length                 | A2dArclength | Change in arc length from the initial state to A2, in a defined 7-mm zone |
| Highest Concavity                   | HC           | Moment that the cornea assumes its maximum concavity during the air puff |
| HC time                             | HCT          | Time to reach the maximum deformation                             |
| Radius (mm)                         | Rad          | Central curvature radius at the highest concavity                 |
| HC Deformation amplitude            | HCDA         | Distance of the corneal apex movement from the initiation of the deformation to the highest concavity |
| HC deflection length                | HCDL         | Length of the flattened cornea at the highest concavity           |
| HC deflection amplitude             | HCDeflA      | Similar to HCDA without whole eye movement                       |
| Peak Distance                       | PD           | Distance between the two surrounding peaks of the cornea at the highest concavity |
| HC delta Arc length                 | HCdArclength | Change in arc length during the highest concavity moment from the initial state, in a defined 7-mm zone |
| Maximum                             | Max          | Similar as HC                                                    |
| Max Deformation Amplitude           | Max DA       | Distance of the corneal apex movement from the initiation of the deformation to the highest concavity |
| Max Deflection Amplitude            | Max DeflA    | Similar to HCDeflA                                               |
| Max Delta Arc Length                | MaxdArclength| Change in arc length during the highest concavity moment from the initial state, in a defined 7-mm zone |
| Vinciguerra Screening Parameters    |              |                                                                  |
| Deformation Amplitude ratio max (2 mm) | DA ratio max | Ratio between the deformation amplitude at the apex and the average deformation amplitude measured at 2 mm from the center |
| Ambrósio’s Relational Thickness to the horizontal profile | ARTh | Describes thickness profile in the temporal-nasal direction and defined as corneal thickness thinnest to the pachymetric progression |
| Integrated radius                   | INR          | Area under the inverse concave radius vs. time curve             |
| Stiffness Parameter at A1           | SP A1        | Describes corneal stiffness as defined by resultant pressure (Pr) divided by deflection amplitude at A1 |
| Corvis Biomechanical Index          | CBI          | Overall biomechanical index for keratoconus detection            |
| Biomechanically corrected Intraocular Pressure | biIOP | Derived by finite element simulations that take into account the influence of central corneal thickness, age, and DCR parameters |
| Stress-Strain Index                 | SSI          | Curve describes the stress-strain index of corneal tissue compared to a 50-year-old normal cornea |
Table 2: Describes pre-surgery mean±SD age, spherical equivalent refractive error, IOP, keratometry and pachymetry of Groups I and II

| Demographics and Ocular Parameters | Group I (Blade LASIK) | Group II (Femto bladeless LASIK) |
|-----------------------------------|----------------------|----------------------------------|
| Age                               | 28.76±5.84           | 23.43±3.57                       |
| Spherical equivalent refraction    | -4.07±1.52           | -5.34±3.05                       |
| IOP                               | 18.31±2.06           | 17.75±2.34                       |
| Keratometry                       | K1: 43.97±1.35       | K1: 43.70±1.50                   |
|                                    | K2: 44.75±1.52       | K2: 45.09±1.47                   |
| Pachymetry                         | 540.12±32.42         | 539.69±26.25                     |

Discussion

The alteration in the corneal biomechanical parameters post-ocular surgeries such as cataracts and various types of refractive surgeries have been well-described and reported in the literature previously. Various instruments such as ORA Corvis ST, supersonic shear imaging, and optical coherence tomography have been used to assess the corneal biomechanical changes. Instruments such as Corvis ST are still evolving and also record new metric that is SSI. In the present study, we have reported short-term changes in SSI along with corneal biomechanical parameters post-refractive surgery such as Blade LASIK and Femto Bladeless LASIK. We noted changes in various corneal biomechanical parameters at the first applanation at the highest concavity and in the Vinciguerra screening parameters, however, there was no statistically significant change in the SSI.

In the present study, the parameters at the second applanation such as A2 velocity, deflection amplitude, and deflection areas were affected post-surgery in the blade group, however, no difference was noted in the Femto LASIK group. Previous studies have also reported significant changes in the corneal biomechanical parameters post-refractive surgeries such as Blade LASIK, Femto LASIK, and SMILE. New Corvis ST parameters such as stiffness parameter at first applanation (SPA1), DA ratio max at 2 mm, Ambrósio’s relational thickness horizontal (ARTh), integrated radius, and CBI are significantly different in LASIK patients as compared to normal subjects. In the present study, we noted a reduction in the stiffness parameter at A1 post-LASIK surgeries in both groups. In the blade group, the stiffness parameter reduced to 92.52 from 118.08 units whereas, in the bladeless group, it reduced to 87.29 from 114.30 units. Also, the DA ratio Max at 2 mm was found to be significantly increased post-surgery in both groups. The DA ratio describes the corneal resistance to deformation where a higher value is associated with lower resistance to deformation. Thus, the increase in the DA ratio values post-refractive surgery suggests that the cornea becomes softer post-refractive surgery, however, in the present study the increase in the DA ratio was similar in both groups. The DA ratio was found to increase by 0.7 and 0.8 units in post-Blade LASIK and Femto bladeless LASIK groups, respectively.

CBI is a composite biomechanical metric that distinguishes a normal cornea from an abnormal cornea and helps predict ectasia. CBI up to 0.2 is considered as normal, from 0.21 to 0.49 is subnormal, and >0.5 is considered as abnormal. Previous studies have reported an increase in CBI in eyes with ectasia. However, the newer software allows an automatic assessment of the biomechanical stability post-laser vision correction using a new metric called CBI- Laser Vision Correction (LVC). CBI-LVC estimates the risk for ectasia after laser vision correction. This information helps to make a clinical decision about the re-treatment or further laser touchups. A recent study has shown that the CBI-LVC is highly sensitive and specific in distinguishing stable from ectatic post-LVC eyes. The mean ± SD pre-LASIK CBI was 0.29 ± 0.22 and 0.31 ± 0.17 in the Blade and Femto group, respectively, whereas the mean ± SD post-LVC-CBI was 0.07 ± 0.19 and 0.09 ± 0.23 in the Blade and Femto group, respectively, which are within normal ranges suggesting stable corneal biomechanics post-LVC, and thus, no further requirement of treatment. Since both CBI and LVC-CBI follow a different scale, we did not compare pre-op CBI and post-LVC-CBI.

The corneal deformation parameters in vivo are affected by IOP and Central corneal thickness (CCT), however, SSI is independent of CCT and IOP and positively associated with age. Using the bIOP algorithm, tangent modulus, which is a measure of material stiffness, can be determined under any IOP. Also, the stiffness parameter at HC (SP-HC) is more strongly associated with corneal stiffness than IOP, and thus, is used in the algorithm to estimate the SSI. In the present study, despite the changes in the other corneal deformation parameters, we did not find any significant changes in post-LASIK SSI which is a better predictor of strengthening. Previous research by Lopes et al. has reported a significant increase in SSI to 0.87 post-Corneal cross-linking (CXL) from 0.78 pre-CXL. SSI values >1.0 suggest a stiffer cornea and <1.0 suggest a softer cornea. To the best of our knowledge, this is the first study which describes the SSI post-Blade and Femto Bladeless LASIK. In the Blade group, the SSI decreased from 0.86 to 0.84 and in the Femto group, it reduced from 0.80 to 0.79. Though the reduction in the SSI was not statistically significant, other individual biomechanical parameters showed significant biomechanical changes pre- and post-refractive surgeries.

The strain is dependent on various factors such as refractive procedure (LASIK vs. PRK), preoperative refractive correction, flap thickness, and corneal geometries. In the present...
study, we did not find any association between preoperative refractive corrections with SSI (Pearson Correlation Blade LASIK: \( r = 0.25, P = 0.09 \); Femto LASIK: \( r = 0.07, P = 0.67 \)). SSI algorithm is suitable for corneas with normal topography. It is noteworthy that all patients enrolled in the study had normal corneal geometries. Also, the strain-stress relation of the cornea is non-linear\(^{28,29}\) which means that the tissue has tangent modulus and it increases with stress or pressure. This suggests that the weakening in the corneal biomechanics is not changing linearly with the laser ablation or percentage of tissue alteration. Thus, it is important to evaluate factors such as the affection of the corneal collagen fibers arrangement during refractive surgeries that are directly responsible for corneal strengthening.

Previous studies have reported that various corneal biomechanical parameters such as Corneal hysteresis (CH) and corneal resistance factor (CRF) by ORA and deformation parameters by Corvis ST were based on geometrical effects and IOP and did not provide a measure of material behavior. On the other hand, SSI describes intrinsic material stiffness. The SSI numerical model includes the effect of the ciliary muscle in simulating the corneal biomechanical response to IOP and air puff whereas the iris, lens, and retina effects are not accounted for due to their much lower stiffness relative to the cornea.
Corneal biomechanical weakening increases with an increase in the flap thickness and ablation depth. A thin flap (SBK) allows a thicker residual stromal bed, less damage to the nerves, and induces less biomechanical weakening of the cornea. Thus, it is more relevant to have a LASIK procedure which is tissue saving and inducing the least amount of corneal weakening. Thus, the present study evaluated the corneal biomechanical changes with the thinnest flap (90 microns). Although it has been reported that microkeratome tends to over-cut the flap by 10–15 microns on average, With this consideration, the present study could be useful to extrapolate biomechanical changes in the eyes with the 110-microns flap surgeries. Also, with the advent of Femtosecond procedures opting for thinner flaps and caps being a trend, the results of the present study would be applicable to clinical practice.

The refractive error range is not similar in both the groups (the mean ± SD spherical equivalent refractive error for Blade and Femto LASIK group is −4.07 ± 1.52 and −5.34 ± 3.05 years, respectively). The primary aim of the paper is to compare the LASIK-induced changes in SSI which are independent of the refractive error. Also, the other biomechanical parameter depends on the amount of refractive error treated and laser refractive correction decreases the biomechanical strength. However, the present study compares the pre-versus post-biomechanical changes in each group separately and not making any head-to-head comparison of biomechanical changes between post-Blade LASIK versus post-Femto LASIK.

Biomechanical changes post-LASIK over different timelines have been studies previously. Understanding the earliest time-point for post-LASIK biomechanical changes would help us to know the impact of weakening due to the procedure before the major reparative process sets in. Immediate 1-month changes were studied to understand the biomechanical changes and to understand each biomechanical parameter individually. This would help us to enhance our understanding of the behavior of the newer parameter (SSI) as well as other biomechanical parameters in response to LASIK. It has been reported that corneal biomechanical changes occur as early as 1 week to 10 days post-surgery. Here, we report short-term results at 1-month follow-up as studied previously. Nevertheless, the ultra-structural healing after LASIK takes at least 3 months, however, due to retrospective design. A Smaller sample size is the limitation of our study.

Conclusion
To conclude, the reduction in SSI was not statistically significant. Other biomechanical parameters showed significant changes post-LASIK surgeries in both groups. However, a long-term study with a larger sample size would be required to understand the changes and stability in SSI and other corneal biomechanical parameters post-refractive surgery.

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Conflicts of interest
There are no conflicts of interest.

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