Non-invasive assessment of the tear film after LASIK

E.C. YESILKAYA¹, Z. BURKE², M.T. OKSAR², I. IRITAS³, C. TANRIVERDI², Y. KARACA², A. KILIC²

Abstract. – **OBJECTIVE:** The aim of the study was to compare the assessment of the ocular surface using classic methods with the newly developed keratoscopy-based MYAH (Topcon EU, Visia Imaging, Japan) device after femtosecond laser-assisted *in situ* keratomileusis (LASIK).

PATIENTS AND METHODS: This cross-sectional and observational study analyzed 80 eyes of 40 patients. Tear film and ocular surface evaluation were performed at baseline, postoperative week 1, and month 1. Measurements obtained using the Schirmer I test and invasive tear-film breakup time (I-TBT) were compared with non-invasive evaluation of the tear break-up time (NI-TBT), tear meniscus height (TMH) and blink analysis obtained using the MYAH device. Findings were correlated with the Ocular Surface Disease Index (OSDI) questionnaire in all subjects.

RESULTS: The study included 80 eyes of 40 consecutive patients (21 males and 19 females) with a mean age of 26.6±5.9 years (18-40 years) and a mean spherical equivalent value of -3.64 D (-9.63 to -0.25 D). There was a significant decrease in Schirmer I test (19.21 ±8.4 vs. 16.61 ±9.1 vs. 14.69 \pm 9.86, p= 0.02, respectively) and I-TBT values (8.59±3.4 vs. 7.4±3.25 vs. 6.17±3.01, p=0.03 respectively). OSDI values showed a significant increase after LASIK (11.56 ± 6.3 vs. 17.24 ± 7.5 vs. 14.71 \pm 9.6, p=0.03, respectively). 5% level NI-TBT was significantly lower at 1 week 6.75 and 1 month 7.45 than baseline 13.2 at follow-up (p=0.037). Ocular protection index (6.6 vs. 2.3 vs. 2.6, p=0.009, respectively) and blink/minutes (18 vs. 17 vs. 15, p=0.002, respectively) values showed a statistically significant decrease. Our data detected a weak correlation between I-TBT and noninvasive first TBT, 5% level TBT parameters at month 1 follow-up. This study also found no correlation between contact lens use, older age, female gender, and pre-operative refractive error with the noninvasive MYAH dry eye parameters.

CONCLUSIONS: This study demonstrated the ability of the new keratoscopy-based MYAH device to detect changes in the short term after LASIK surgery.

Key Words:
Dry eye, STODS, LASIK, MYAH, Keratoscopy.

Introduction

The laser-assisted *in situ* keratomileusis (LASIK) surgery can affect the normal function of the ocular surface through several underlying mechanisms, including reduced corneal sensitivity, the creation of an unstable tear film, decreased production of aqueous tears, and the induction of corneal inflammation. Despite reporting excellent visual results, several studies^{1,2} have demonstrated that patients who undergo LASIK surgery often experience temporary ocular discomfort due to ocular surface complaints, which can present a challenge to postoperative management.

It has been shown that markers, such as (matrix metalloproteinase-9), which typically increase dry eye, do not change in tear film analysis after LASIK. Consequently, some researchers3 have proposed that the condition is more accurately defined as surgical temporary ocular discomfort syndrome (STODS), rather than classic dry eye disease. In clinical practice, traditional examination techniques, such as fluorescein tear break-up time (F-TBT), the Schirmer test, and the Ocular Surface Disease Index (OSDI) questionnaire, are still widely used to evaluate the tear film quality and patient symptoms after refractive surgery⁴. However, these tests are prone to subjective assessment error and have poor to moderate repeatability.

In recent years, the noninvasive evaluation of dry eye findings using keratoscopy-based devices has yielded reliable and reproducible results^{5,6}. The newly developed MYAH device (Topcon EU,

¹Department of Ophthalmology, Health Sciences University, Şişli Hamidiye Etfal Research and Training Hospital, Istanbul, Turkey

²Department of Ophthalmology, Istanbul Medipol University, Istanbul, Turkey

³ Department of Ophthalmology, Pendik State Hospital, Istanbul, Turkey

Visia Imaging, Japan) is designed to evaluate tearfilm assessment, corneal curvature, pupillometry measurements with Placido disc topography, and axial length measurement with optical low coherence interferometry in a noninvasive manner. It provides noninvasive tear break-up time (NI-TBT), tear meniscus height (TMH), and blink analysis for measuring dry eye parameters.

This study aims to assess noninvasive tear film measurements during the early postoperative period of LASIK using the keratoscopy-based MYAH device and to compare the results with those obtained using conventional methods.

Patients and Methods

Study Design and Participants

This cross-sectional, single-center, and observational study was conducted in accordance with the tenets of the Declaration of Helsinki and performed between September 2022 and February 2023. The study protocol was approved by the Istanbul Medipol University Medical Ethics Committee (No. 676). Written informed consent was obtained from all the study participants.

80 eyes of 40 consecutive patients who underwent bilateral primary LASIK were included in this study. Inclusion criteria included: being 18 years or older, a stable refraction for 12 months, intraocular pressure less than 21 mm Hg, not wearing contact lenses for at least 2 weeks, and no history of clinically significant dry eye disease.

Exclusion criteria included: a history of previous intraocular surgery or trauma, chronic use of topical eye drops, any intraocular or systemic disease, and central corneal thickness <500 µm and ablation leaving <300 µm residual stromal bed (RSB).

Preoperative Assessment

Each participant underwent a comprehensive preoperative ophthalmological examination, including auto kerato-refractometry, measurement of best-corrected visual acuity with a Snellen chart, slit-lamp biomicroscopy, measurement of intraocular pressure, cycloplegic refraction, and dilated fundus examination. Corneal topography was obtained using the Scheimpflug camera system Pentacam HR (Oculus Optikgeräte, Wetzlar, Germany). All study procedures were performed both preoperatively and at week 1 and month 1 postoperatively.

Tear film assessment was performed both preoperatively and postoperatively, using both conventional methods and the MYAH device, as described below.

Surgical Procedure

One experienced ophthalmic surgeon (AK) performed all the surgeries. The iFS 150kH Intralase femtosecond laser platform (Abbott Medical Optics Inc., CA, USA) was used to create the LASIK flap with a planned diameter of 8.0 mm and thickness of 110 µm. The hinge was positioned at 90 degrees (superior), and the side cut angle was set at 110 degrees. Stromal laser ablation was performed using the WaveLight EX500 (Alcon Laboratories, Inc., Fort Worth, TX, USA) using a wavefront-optimized treatment. LASIK parameters, including optical zone, transition zone, ablation zone, and RSB values, were recorded.

In adherence to a postoperative standard treatment regimen, patients were instructed to administer topical moxifloxacin 0.5% (Vigamox; Alcon Laboratories, Inc., Fort Worth, TX, USA) and dexamethasone 0.1% (Dexa-sine SE; Alcon Pharmaceuticals Ltd, TX, USA) eye drops four times daily for two weeks, followed by a gradual tapering to one drop per week over four weeks. Additionally, patients were advised to utilize non-preservative, single-dose sodium hyaluronate eye drops (Eyestil; SIFI SpA, Catania, Italy) artificial tears four times a day for a period of three months.

Conventional Tear Film Measurements

For the Schirmer I test, anesthesia was applied, and test strips were placed at the lateral and middle thirds of the bottom lid margin for five minutes. After five minutes, the strips were removed, and the wetness was measured in millimeters. Wetness levels of less than 5 mm were categorized as "severe symptomatic", while levels between 10-15 mm were classified as "moderate symptomatic", and levels greater than 15 mm were categorized as "normal" as per previous literature.

To calculate the invasive tear-film breakup time (I-TBT), 1% fluorescent dye was used to identify the amount of time from the last full blink to the appearance of the first corneal black spot on the stained tear film. The test was repeated three times, and the measurements were averaged. A label of "severe symptomatic" was assigned to I-TBT <5 seconds, "moderate symptomatic" for I-TBT between 5 and 10 seconds, and "normal" for I-TBT >10 seconds⁸.

The OSDI questionnaire was created to measure the precise effect of dry eye disease on health-related quality of life with a focus on vision. OSDI scores range from 0 to 100; while 100 is described as severe dry eye disease and 0 asymptomatic, with higher OSDI scores in this context indicating more severe symptoms. OSDI scores between 0-12 are considered as "normal", 13-22 as "mild symptomatic", 23-32 as "moderate symptomatic", and >33 as "severe symptomatic".

Tear Film Assessment Using MYAH Device

Before conducting other ophthalmic examinations, all subjects underwent imaging with the MYAH device. They were instructed to keep their eyes open as long as possible after three blinks during the imaging, which was performed in a dark room by the same technician. The device utilizes 24 Placido rings reflected from the anterior corneal curvature for topographic assessment. In addition to noninvasively measuring ocular surface parameters, the device also provided a video recording and color-coded map of local dry areas, allowing for a visualization of tear film instability as irregularities in the reflected image.

Values for NI-TBT and blink analysis were recorded by the device's software. Total TBT duration, first TBT, 5% level TBT, interblink interval (IBI), and ocular protection index (OPI) were the parameters measured for NI-TBT. IBI represented the mean time between two blinks, while OPI represented the mean breakup time divided by the IBI. Blink acquisition time and blink/minute values were recorded for blink analysis (Figure 1).

The TMH measurements were taken three times at the 6 o'clock position of the cornea on the TMH screen of the device, as this height varies along the length of the lower eyelid, and the average of these measurements was recorded (Figure 2). A TMH value >0.2 mm suggested a normal tear film, while a TMH value <0.2 mm indicated an abnormal tear film¹⁰.

Statistical Analysis

Descriptive statistics of the collected data were presented using mean and standard deviation for numerical variables, while frequency and percentage were utilized for categorical variables. The normal distribution conformity of the measurements was assessed using the Shapiro-Wilk test. For variables conforming to a normal distri-

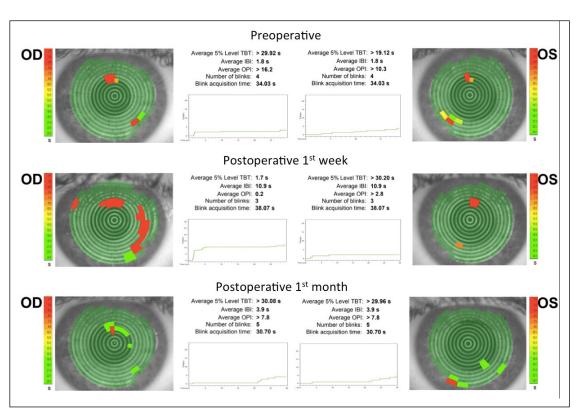


Figure 1. An example of Placido disk non-invasive tear breakup time (NI-TBT) assessment.

0.36mm 0.63mm Postoperative 1st month 0.27mm

Figure 2. An example of tear meniscus height measurement.

bution, repeated measures variance analysis was used to compare the measurements at different time points. In contrast, Wilcoxon and Friedman tests were employed for variables that did not conform to normal distribution. For multiple comparisons of measurements obtained at different time points, the LSD test was utilized for variables conforming to normal distribution, and the Dunn-Bonferroni test for variables that did not conform to normal distribution. The statistical analyses were performed using SPSS 22.0 (IBM Corp., Armonk, NY, USA). Significance was set at p < 0.05.

Preoperative

Postoperative 1st week

Results

The study included 80 eyes of 40 consecutive patients (21 males and 19 females) with a mean age of 26.6 ± 5.9 years (18-40 years) and a mean spherical equivalent value of -3.64 D (-9.63 to -0.25D). The demographic and preoperative characteristics of the study population are detailed in Table I. No significant differences were observed

between postoperative week 1 and postoperative month 1 regarding Spherical equivalent, corrected distance visual acuity (CDVA) logMAR, and K_{mean} (Table II).

There was a significant decrease in Schirmer I test between the preoperative and week 1 and month 1 postoperative examinations $(19.21 \pm 8.4 \text{ vs. } 16.61 \pm 9.1 \text{ vs. } 14.69 \pm 9.86, p = 0.02,$ respectively). The results also revealed that there was a significant decrease between the preoperative and week 1 and month 1 postoperative examinations on I-TBT values $(8.59 \pm 3.4 \text{ vs.})$ 7.4 ± 3.25 vs. 6.17 ± 3.01 , p = 0.03, respectively). OSDI values showed a significantly increase in week 1 and month 1 after LASIK, compared with the baseline $(11.56 \pm 6.3 \text{ vs. } 17.24 \pm 7.5 \text{ vs.})$ 14.71 ± 9.6 , p = 0.03, respectively). Changes in Schirmer I, I-TBT, and OSDI test scores are given in Figure 3.

Significant reductions were seen in 5% NI-TBT at week 1 and month 1 from baseline. However, the total TBT duration and first TBT were not statistically different at all follow-up times. OPI decreased significantly at week 1 (p=0.009)

Table I. Baseline demographic and preoperative characteristics of the study patients.

Demographic parameters			
Age	26.6 ± 5.9		
Gender			
Female (n,%)	19 (47.5)		
Male	21 (52.5)		
Kmean	43.47 ± 1.69		
Spher	-2.99 ± 2.09		
Cylinder	-1.32 ± 1.25		
Spherical equivalent (D)	-3.64 ± 1.94		
CDVA logMAR	0.02 ± 0.06		
Soft contact less usage			
n, %	34 (42.5)		
years	7.76 ± 4.82		
Cornea thickness	558.65 ± 29.68		
Surgical parameters			
Optical zone	6.5 ± 0		
Transition zone	1.14 ± 0.3		
Ablation zone	8.69 ± 1.04		
Flap thickness	110 ± 0		
Residual stroma	388.8 ± 41.17		
Ablation depth	60.6 ± 24.65		

All data (ex. gender) were presented as mean ± standard deviation; N, number; D, diopters;

and month 1 (p<0.004). Similarly, blink/minutes values showed a statistically significant decrease at postoperative week 1 and this trend contin-

ued at month 1 compared to baseline and week 1. However, no significant difference in the IBI score was detectable between the baseline and week 1 and month 1 (p = 0.124). Although TMH increased non-significantly at week 1, the value was lower at month 1 compared to baseline ($0.2 \pm 0.05 \ vs. \ 0.21 \pm 0.05 \ vs. \ 0.18 \pm 0.08, p = 0.04$, respectively). Table II shows the detailed MYAH device measurements.

Discussion

Ocular surface complaints are common after LASIK¹¹. Prior studies³ have shown that the biomarkers found in patients with ocular surface complaints after LASIK are distinct from those found in patients with dry eyes, leading to the recommendation to not refer to ocular surface complaints after LASIK as "dry eyes", but rather as STODS.

In both dry eyes and STODS, the evaluation of the ocular surface is often performed using classic tests such as Schirmer test, I-TBT, tear film osmolarity, ocular surface fluorescein staining, and meibomian gland secretion scoring^{4,12}. Most of these tests are prone to user-dependent errors of analysis and interpretation, and the use of dyes and Schirmer's strips may alter findings. This study showed that the objective non-invasive measurements of

Table II. Visual and MYAH device measurements of study population.

	Pre-OP	1 Week Post-OP	1 Month Post-OP	
Visual parameters				
Spherical equivalent (D)	-3.64 (-5.752.88) ^a	-0.25 (-0.50.13) ^b	-0.5 (-0.69-0) ^c	$0.001*^{\dagger}$
CDVA logMAR	0.02 (0.00-0.40)	0.01 (0.00-0.40)	0.00 (0.00-0.10)	0.150‡
Kmean	43.47 (42.39-44.97)	40.21 (38.98-41.7)	40.25 (39.38-41.5)	0.001* ^Ψ
MYAH device parameters				
NI-TBT duration	24.94 (10.52-29.92)	29.58 (20.2-29.88)	28.16 (14.44-29.84)	0.651‡
First TBT	1.8 (1.4-4.2)	1.6 (1.3-2.8)	1.6 (1.2-4.4)	0.116 [‡]
5% Level TBT	13.2 (3.6-29.76)	6.75 (2-24.6)	7.45 (2.4-16.72)	0.037‡
Tear meniscus height (central)	0.2 (0.17-0.25) ^a	0.21 (0.15-0.26) ^{ab}	0.18 (0.15-0.25) ^b	0.040*‡
IBI	3.3 (2.5-3.5)	3.45 (2.35-6.4)	3.95 (3.45-4.4)	0.124 [‡]
IBI, SD	1.2 (0.4-1.4) ^a	1.2 (0.5-1.9) ^{ab}	1.6 (0.7-2.5) ^b	0.038*‡
Blink acquisition time	31.1 (31-33.1)	31.1 (30.8-31.5)	31 (30.7-34.5)	0.870‡
Blink/minute	18 (14-26) ^a	17 (8-26) ^b	15 (10-17) ^b	0.002*‡
OPI	6.6 (1.6-9.4) ^a	2.3 (0.7-6.9) ^b	2.6 (0.8-4.4) ^b	0.009*‡

All data were presented as mean± (Q1-Q3); NI-TBT, non-invasive tear-film breakup time; TBT, tear-film breakup time; IBI, interblink interval; SD, standard deviation; OPI, Ocular Protection Index. †: Repeated measures variance analysis; *:Friedman testi; **Wilcoxon testi; *a, b, c: Different letters represent the difference between groups (LSD test or Dunn-Bonferroni test).

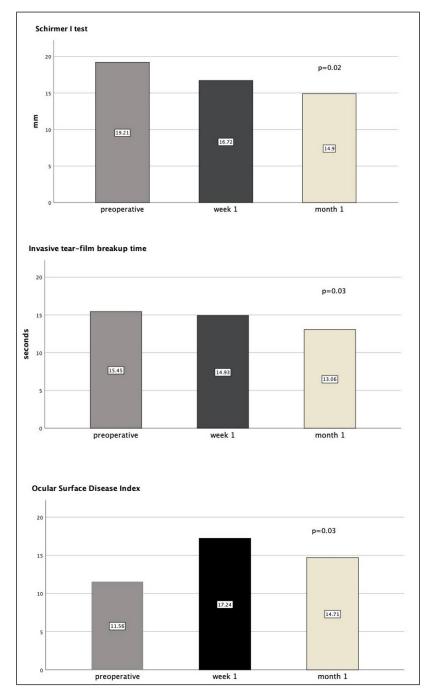


Figure 3. Comparison of preoperative and postoperative Schirmer I (top), invasive tear breakup time (I-TBT) (central) and OSDI (bottom) tests.

ocular surface metrics using the newly developed keratoscopy-based MYAH device provided useful, objective, and non-invasive data about the ocular surface after LASIK, though not all the measurements correlated with the class tests.

NI-TBT was developed to overcome the potential shortcomings of I-TBT. NI-TBT has the advantage of avoiding the ocular surface contact and tear

film disruption that occurs with the classic Schirmer's test. The findings of this study showed a significant decrease in I-TBT after surgery at 1-week and 1-month after LASIK, suggesting tear dysfunction. Similar trends were detected at the 5% Level NI-TBT but not in the NI-TBT duration and First NI-TBT in noninvasive assessment. In prior studies^{10,13}, the optimal NI-TBT cut-off varies between

2.7 seconds and about 10 seconds, depending on the algorithms and observation techniques used. In our study, 5% Level NI-TBT was significantly lower at 1 week 6.75 (2-24.6) and 1 month 7.45 (2.4-16.72) than baseline 13.2 (3.6 -29.76) at follow-up. Our data also detected a weak correlation between I-TBT and NI-TBT duration, first NI-TBT, 5% level NI-TBT parameters at month 1 follow-up (r=0.318 p=0.016 vs. r=0.290 p = 0.03 and r= 0.475 p=0.01, respectively). Therefore, we conclude that a direct comparison between NI-TBT and I-TBT cannot be made in a meaningful way due to the poor correlation between them.

Invasive assessment of TMH is challenging due to its limitations. Moreover, it has been reported that its results are affected by drug stimulation, time periods, rapid blinking, moisture, and warmth¹⁰. Conversely, noninvasive TMH has been shown to have highly reliable and accurate tear meniscus volume measurements¹⁴. In a previous study¹⁵, the TMH cutoff values were identified to be 204.96 µm with high sensitivity and specificity. Accordingly, the results of the TMH performed in our study also support the finding that LASIK increases the incidence of ocular surface disruption. In our analysis, the mean noninvasive TMH preoperatively was 0.2 mm (0.17-0.25). It increased nonsignificant to 0.21 mm (0.15-0.26) at week 1, while at month 1 it decreased significantly to 0.18 mm (0.15-0.25).

Incomplete blinking may contribute to both dry eyes and STODS. To our knowledge, there is no standardized method to assess incomplete blinking. The OPI, which predicts the risk of corneal exposure and potential associated ocular surface inflammation, is of particular interest¹⁶. In our study, a statistically significant change was observed in OPI measurements, which decreased from 6.6 (baseline) to 2.3 (week 1) and 2.6 (month 1). In addition to the OPI, we measured the IBI, blink acquisition time, and blink/ minute parameters for eyelid dynamics and blinking pattern. Although there was a non-significant increase in IBI from preoperative to 1st follow-up at week 1 and to 2nd follow-up at month 1, a significant decrease was found in the prevalence of tear dysfunction with blinks/minute at week 1 and month 1. These results may indicate an increased risk or worsening of the patient's dry eye signs and symptoms.

A survey of the literature indicates that contact lens wearers have a higher risk of developing STODS following LASIK^{17,18}. Female gender and older age as demographic factors have

also been reported to be associated with an increased risk of STODS^{19,20}. This study found no such link between contact lenses, older age, female gender, and noninvasive MYAH tear film metrics.

A higher level of preoperative refractive error has also been associated with an increased risk of STODS after LASIK surgery^{18,21}. Contrary to these previous studies, no direct relationship was found between high refractive error and noninvasive MYAH parameters in our data. This may be due to differences in the depth of stromal ablation used in the studies, as well as the use of different diagnostic modalities. It has been known that flap thickness and size are also associated with STODS in LASIK patients, but since a single type of standard flap (diameter was 8.0 mm, thickness was 110 μ m) was used in our study, such an analysis could not be performed.

Limitations

There are a number of limitations to this study that are worth noting. One of them is that the follow-up period is limited to two postoperative time points for the study. The findings of this study can only be applied to the early postoperative setting and should not be extrapolated to findings over time. Secondly, the study was limited to LASIK and does not consider other corneal laser refractive surgeries, such as lenticular extraction procedures or photorefractive keratectomy (PRK). Another limitation is the lack of well-defined cutoff values for noninvasive parameters to make a definitive diagnosis for normal and abnormal findings.

Notwithstanding these limitations, to our knowledge, this study is the first to assess the STODS following LASIK using the keratoscopy-based MYAH device, and the authors hope that it will be a pioneer for further studies.

Conclusions

New non-invasive methods that do not require anesthesia, the instillation of dyes, or the use of Schirmer strips have been gaining popularity and may be ideal for use in refractive surgery. This study demonstrated the ability of the new keratoscopy-based MYAH to describe short-term post-LASIK changes objectively. The findings of this study demonstrate that the MYAH device can detect disruption of the ocular surface and tear film from 1-week to 1-month after surgery.

Ethics Approval

The study protocol was approved by Istanbul Medipol University Medical Ethics Committee (No. 676).

Informed Consent

Written informed consent was provided from all study participants.

Availability of Data and Materials

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Conflict of Interest

The authors have no conflicts of interest to declare.

Funding

This study has no financial assistance.

Authors' Contributions

Concept – ECY, ZB, CT, AK; Design – ECY, MTO, YK, AK, Supervision – ECY, AK, Funding – ECY, MTO, II, YK. Materials – ZB, MTO, CT, YK, AK, Data Collection and/or processing – ECY, II, YK Analysis &/or interpretation – ECY, ZB, MTO, Literature search – ECY, II, CT, YK Writing – ECY, ZB, CT; Critical review – ECY, ZB, MTO, II, CT, YK, AK.

ORCID ID

Elif Ceren Yesilkaya: 0000-0003-3613-808X

Ziya Burke: 0000-0003-3161-9095

Muhammed Taha Okşar: 0000-0001-5444-5804

İlter İritaş: 0000-0003-1789-4787 Cafer Tanriverdi: 0000-0003-2445-6339 Yiğit Karaca: 0000-0003-2090-6072 Aylın Kılıç: 0000-0001-8880-0026

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