Original Article

The Changes of Tear Status after Conventional and Wavefront-Guided IntraLASIK

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Abstract

Background: **IntraLASIK is a LASIK surgery that involved IntraLase femtosecond laser for the corneal flap creating. The objective of this research was to investigate and compare the changes in tear status at 1 and 3 months after undergoing conventional IntraLASIK with Bausch & Lomb PlanoScan (PS) algorithm, Bausch & Lomb Zyoptix Tissue Saving (ZTS) algorithm, and wavefront-guided (WG) IntraLASIK with VISX CustomVue.**

Methods: **Tear status of 36 patients who were divided into 3 groups depending on the type of IntraLASIK they underwent (PS, n = 13; ZTS, n = 9; WG, n = 14) was evaluated. Tear status was determined by classifying the category of the thickness of pre-corneal tear lipid layer, non-invasive tear break-up time, and tear meniscus height. Repeated measures analysis of variance (ANOVA) and one way ANOVA were used for the statistical analyses.**

Results**: The category of the thickness of tear lipid layer, non-invasive tear break up time and tear meniscus height were neither significantly changed after IntraLASIK for all groups nor showed significant difference among groups at 1 and 3 months post-IntraLASIK ($P > 0.05$). Blinking rate and palpebral aperture also had no significant changed after IntraLASIK.**

Conclusion**: Both conventional (PS and ZTS) and WG IntraLASIK did not affect tear status up to 3 months post-IntraLASIK. WG IntraLASIK did not show superiority in preserving tear status 1 and 3 months post-surgery compared with conventional IntraLASIK.**

Keywords: *laser, LASIK, ophthalmology, refractive surgery, side effects, tear*

Introduction

Laser in situ keratomileusis (LASIK) has provided patients with fast and relatively painless recovery of vision, lower probability of regression of refractive correction, and absence of subepithelial haze (1). However, LASIK has been shown to affect the health of the ocular surface by decreasing corneal sensation (2), tear secretion, tear quality, corneal and conjunctival epithelial integrity, and conjunctival goblet cell density (3). As a consequence, these alterations decrease tear film stability (4), which may lead to dry eye symptom during the first 6 months post-surgery (1,2,5,6). Asians have been reported to be more prone to having dry eyes after LASIK surgery compared with Caucasians (7). The prevalence of myopia is much higher in Asians than in Caucasians (8,9) and appears to be increasing in urbanised Asian communities (10). Presently, LASIK continues to be the dominant refractive surgery procedure for myopia (11), and therefore it is likely that an increasing number of myopic Asians will opt for LASIK for refractive correction. Advancement of the technology in refractive surgery, such as the improvements in machine features and the introduction of IntraLase femtosecond laser and wavefront-guided LASIK, can minimise the risk of having dry eye symptom after LASIK surgery.

Wavefront-guided (WG) LASIK uses customized laser ablation with the help of aberrometer to treat visual problems, including higher-order aberrations. This method provides better vision quality than conventional LASIK (12,13). With the availability of various ablation sizes, WG laser is able to save more corneal tissue compared with several conventional LASIK procedures. Both Bausch & Lomb PlanoScan (PS) algorithm and Zyoptix Tissue Saving (ZTS) algorithm are examples of conventional LASIK procedures, which treat defocus and astigmatism measured from subjective refraction method. ZTS have been shown to reduced ablation depth (14) with availability of smaller ablation size and truncated Gaussian laser beam compared with PS. The lower ablation depth minimized the injury to the corneal layer during the surgery and reduced the risk of post-LASIK dry eye.

As such, a study was conducted in Vista Laser Eye Center, Petaling Jaya, Malaysia, where the demand of the LASIK surgery is increasing in recent years. In this study, the tear characteristics before and after LASIK surgery in which IntraLase femtosecond laser was used to create the corneal flap (IntraLASIK) was assessed. The aim of this study was to investigate the changes of tear status and compare the tear status among 3 IntraLASIK procedures at 1 and 3 months post-IntraLASIK. The study also aimed to find out whether the improvement of the methods or techniques could minimize the complications caused by LASIK.

Subjects and Methods

A total of 36 patients who gave written informed consent were recruited in this prospective, longitudinal, and non-randomized study. The study was approved by Universiti Kebangsaan Malaysia (UKM) Research Ethics Committee (UKM 1.5.3.5/244/SPP2, 24 July 2006) and was conducted according to the tenets of Declaration of Helsinki.

The eligibility criteria were as follows:

- age between 20 and 35 years;
- no autoimmune, metabolic, or uncontrolled systemic disease;
- no active disease of the external eye or adnexae;
- no intraocular disease;
- no degenerative or neurotrophic corneal disease;
- no pre- or post-operative use of topical medications other than those prescribed;
- no previous ocular surgery or trauma;
- not pregnant, expecting to become pregnant within 6 months following the LASIK procedure, or breastfeeding;
- stable refraction for at least 12 months within ± 0.50 D prior to LASIK;
- refractive error within -1.00 DS and -12.00 DS and maximum astigmatism of -4.00 D;
- stable keratometry and pachymetry following cessation of contact lens wear;
- no lenticular opacities identified before or after surgery that were deemed to have a significant effect on the refractive outcome; and
- compliant with prescribed tear film and ocular surface management before and after surgery.

Patients who failed to attend all the visits and undergo all the clinical examinations required were excluded from this study.

All LASIK procedures were performed by two ophthalmologists in Vista Eye Laser Center, and the clinical examinations were performed by an optometrist who was blinded to what type of LASIK surgery patients underwent. The patients were divided into 3 groups depending on the type of LASIK surgery they underwent: conventional LASIK with PS or ZTS, and WG LASIK with VISX CustomVue. IntraLase femtosecond laser (FS30) was used to create the corneal flap for all the patients. The decision on the type of IntraLASIK to be performed on each subject was based on the ophthalmologist's recommendation, which depended on subject's refractive error, corneal layer thickness, pupil size, and subject's individual expectation of the surgery outcome. If the subject was eligible for all 3 procedures, the decision would depend on subject's preference and the procedure's affordability.

The excimer laser platform used for PS and ZTS was Bausch & Lomb Technolas 217z; for WG, VISX STAR S4™. A 6.0-, 6.5-, or 7.0-mm ablation zone was selected based on the available corneal stroma thickness and pupil size. Corneal flap with 100- or 110-µm thickness and 90° superior hinge was created by IntraLase femtosecond laser. After surgery, all patients were given dexamethasone (0.1%) every 2 hours on the first day and 2 times daily for a week, moxifloxacin hydrochloride (5.45 mg) every 4 hours on the first day and 4 times daily for a week, and artificial tear every hour on the first day and 4 times or more daily for a month. All subjects had finished their medication with a minimum of 1 day before their 1-month post-IntraLASIK visit.

The tear status of the patients was assessed 1 week pre-surgery (baseline) as well as 1 and 3 months post-surgery. The clinical examination of tear status included classifying the category of thickness of pre-corneal tear lipid layer, non-invasive tear break-up time (NITBUT), and tear meniscus height (TMH). Blinking rate and palpebral aperture of patients were also measured at every visit.

Keeler Tearscope Plus was used to determine the category of the thickness of the pre-corneal tear lipid layer. The thickness of the tear lipid layer was divided into 5 categories based on the overall interference pattern on the tear lipid layer: (1) no lipid layer, (2) open/closed meshwork (up to 50 nm), (3) wave/flow (50 to 80 nm), (4) amorphous (80 to 90 nm), and (5) colour fringes (more than 90 nm). NITBUT was also measured by using Keeler Tearscope plus by observing the grid image on patient's eye. NITBUT was recorded as the interval between the last complete blink and the first appearance of a distortion on the grid image. Three readings were recorded; each new reading was taken after the patients had closed their eyes for 1 minute. TMH was measured using slit lamp biomicroscope; 25 times magnification and 0.3 mm slit height were used to guide the measurement. Only 1 reading was taken for each eye as the light from the slit lamp can cause tear stimulation, which will affect the study result. Blinking rate was taken while the patient was reading a distance chart for 1 minute, and palpebral aperture was measured using a ruler.

Statistical analyses were performed with SPSS 12.0 (SPSS Inc., Chicago, IL). Distributions of the data was determined first by using Shapiro–Wilk test and the skewness of the data; repeated measures analysis of variance (ANOVA) was used on the results with normally distributed data while Friedman test was used on non-normally distributed data or results with categorical variables to determine the significance of the changes in tear status after IntraLASIK. In order to determine the significance of the differences among the 3 groups, one way ANOVA was used for normally distributed data while Kruskal–Wallis test was used for non-normally distributed data.

Results

All 36 patients underwent bilateral IntraLASIK: 13 patients underwent conventional LASIK with PS, 9 patients underwent conventional LASIK with ZTS, and 14 patients underwent WG LASIK with VISX CustomVue. Only the result for the right eye was taken for this study. There were no intra- or post-operative complications up to 3 months of examination in this series of 36 eyes. The means of age and spherical equivalent for each group are shown in Table 1. There was no significant age difference among the 3 groups ($F (2, 33) = 0.345$, $P = 0.711$), but the PS group had significantly lower spherical equivalent refraction before LASIK compared with the other 2 groups (one-way ANOVA, $P = 0.045$). All patients attended their 1- and 3-month post-IntraLASIK visits.

There were no statistically significant differences among all 3 visits for all the parameters measured for the PS group, as shown in Table 2. NITBUT showed some increment at 1 and 3 months post-IntraLASIK, but the difference is not statistically significant. Blinking rate and palpebral aperture also did not change significantly at 1 and 3 months post-IntraLASIK. The ZTS group and WG group also showed no statistically significant changes at 1 and 3 months post-IntraLASIK in NITBUT, TMH, category of the thickness of tear lipid layer, blinking rate, and palpebral aperture, as shown in Table 3 and 4.

A comparison among the 3 groups at 1 month post-IntraLASIK shows no statistically significant differences for all the tear-related parameters measured, as shown in Table 5. All groups also showed no statistically significant differences at 3 months post-IntraLASIK (shown in Table 5), although PS group had significantly lower spherical equivalent refraction before surgery compared with the other 2 groups.

There were no differences among the medians of the lipid thickness category of all groups at 1 and 3 months post-IntraLASIK. However, based on the distribution of tear lipid layer thickness categories, there were increments in the subject number in thinner categories (less than 50 nm) for PS group (at 1 and 3 months post-IntraLASIK) and ZTS group (at 3 months post-IntraLASIK), as shown in Figure 1; such increment was not seen in WG group. On the other hand, WG group had an increment in the subject number in thicker categories (more than 80 nm) after IntraLASIK, and such increment was not seen in PS and ZTS groups.

Table 1: Means of age and spherical equivalent of subjects

Type of LASIK	*n*	Age (year)		Spherical Equivalent (D)		Range	
		Mean (SD)	Range	Mean (SD)	Range	Sphere (D)	Cylinder (-)(D)
PS	13	27.6 (3.9)	22–35	-4.43 (2.36)	-10.38 to -1.88	-8.75 to -1.75	0.00 to 3.25
ZTS	9	27.7 (4.7)	22–35	-6.24 (1.93)	-9.38 to -4.25	-9.00 to -4.00	0.00 to 2.00
WG	14	28.9 (4.4)	21– 35	-6.73 (3.13)	-12.50 to -2.75	-11.50 to -2.50	0.00 to 2.00
P value*		0.711		0.045			

* One-way ANOVA
Abbreviations: PS = PlanoScan algorithm, ZTS = Zyoptix Tissue Saving algorithm, WG = wavefront-guided.

Table 2: Tear status outcomes for PlanoScan (PS) group at baseline, 1 month, and 3 months post-IntraLASIK

Type of test	*n*	Baseline		Post-IntraLASIK				*P* value
				1 month		3 months		
NITBUT (s)	13	14.55	(9.05)	17.99	(5.84)	22.59	(13.38)	0.152 [b]
TMH (mm)	13	0.22	(0.06)	0.20	(0.06)	0.20	(0.06)	0.679 [b]
Lipid thickness (category)[a]	13	3	(2 to 5)	3	(2 to 4)	3	(2 to 5)	0.446 [c]
Blinking rate (no./ min)	13	12.85	(9.53)	14.46	(10.71)	15.69	(11.39)	0.511 [b]
Palpebral aperture (mm)	13	10.00	(0.65)	9.69	(0.95)	9.73	(1.15)	0.455 [b]

Data are expressed in mean (SD) with exception of [a] lipid thickness, in median (range). [b] Repeated measures ANOVA and [c] Friedman test were conducted.

Table 3: Tear status outcomes for Zyoptix Tissue Saving (ZTS) group at baseline, 1 month, and 3 months post-IntraLASIK

Type of test	*n*	Baseline		Post-IntraLASIK				*P* value
				1 month		3 months		
NITBUT (s)	9	14.82	(5.22)	12.87	(8.40)	15.44	(9.18)	0.781 [b]
TMH (mm)	9	0.19	(0.07)	0.15	(0.03)	0.18	(0.04)	0.189 [b]
Lipid thickness (category)[a]	9	3	(2 to 4)	3	(2 to 3)	3	(2 to 3)	0.472 [c]
Blinking rate (no./ min)	9	15.33	(8.70)	14.22	(8.23)	18.56	(8.76)	0.283 [b]
Palpebral aperture (mm)	9	10.17	(0.71)	9.56	(0.58)	9.56	(0.68)	0.054 [b]

Data are expressed in mean (SD) with exception of [a] lipid thickness, in median (range). [b] Repeated measures ANOVA and [c] Friedman test were conducted.

Table 4: Tear status outcomes for wavefront-guided (WG) group at baseline, 1 month, and 3 months post-IntraLASIK

Type of test	*n*	Baseline		Post-IntraLASIK				*P* value
				1 month		3 months		
NITBUT (s)	14	17.46	(9.19)	16.43	(11.84)	15.00	(10.21)	0.622 [b]
TMH (mm)	14	0.26	(0.22)	0.20	(0.09)	0.20	(0.08)	0.195 [b]
Lipid thickness (category)[a]	14	3	(2 to 5)	3	(2 to 5)	3	(2 to 5)	0.846 [c]
Blinking rate (no./ min)	14	15.93	(8.94)	14.86	(8.16)	16.71	(6.43)	0.565 [b]
Palpebral aperture (mm)	14	10.14	(1.31)	9.96	(1.39)	10.25	(1.45)	0.404 [b]

Data are expressed in mean (SD) with exception of [a] lipid thickness, in median (range). [b] Repeated measures ANOVA and [c] Friedman test were conducted.

Table 5: *P* values in the comparison of tear status assessments among PS, ZTS, and WG groups at baseline, 1 month, and 3 months post-IntraLASIK

Type of test	Baseline	Post-IntraLASIK	
		1 month	3 months
NITBUT (s)	0.620 [a]	0.442 [a]	0.180 [a]
TMH (mm)	0.575 [a]	0.167 [a]	0.726 [a]
Lipid thickness (category)	0.203 [b]	0.478 [b]	0.430 [b]
Blinking rate (no./ min))	0.661 [a]	0.986 [a]	0.767 [a]
Palpebral aperture (mm)	0.902 [a]	0.651 [a]	0.342 [a]

[a] One-way ANOVA and [b] Kruskal–Wallis test were conducted.

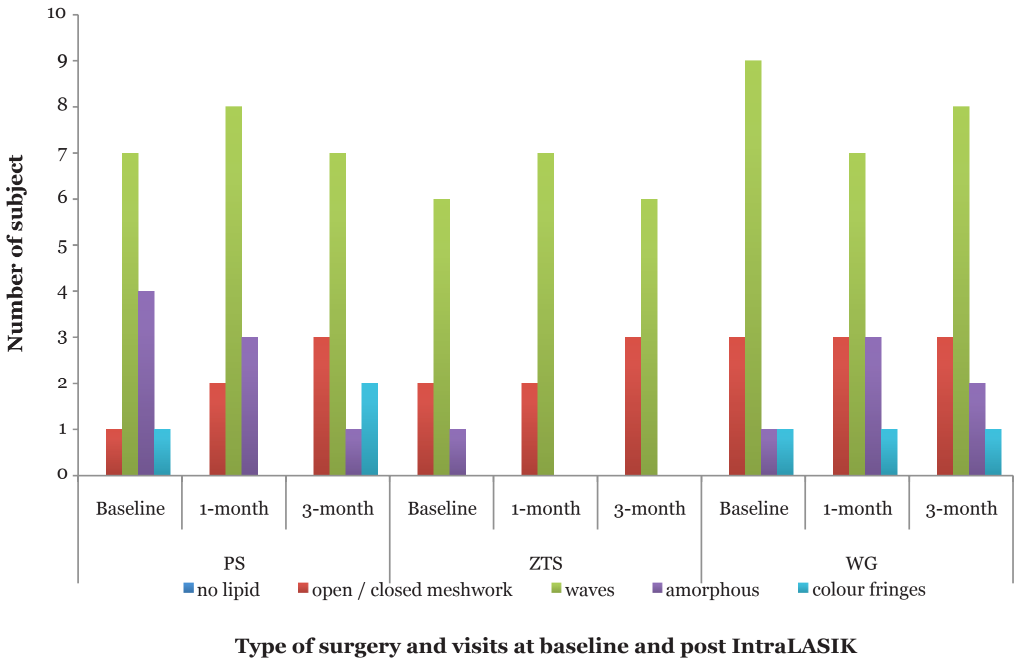

Figure 1: Frequency distribution of tear lipid layer thickness categories

Discussion

All assessments involved in this research were non-invasive as the cornea layer needs minimal disruption during its healing process. NITBUT and tear lipid layer thickness were used to check the tear quality and stability, and TMH was used to monitor the tear quantity. This study assessed the tear parameters at 3 visits (i.e., 1 week pre-IntraLASIK, 1 and 3 months post-IntraLASIK) to determine the effects of the IntraLASIK on patients' tear status.

Subjects who underwent conventional LASIK with PS showed no significant changes 1 and 3 months post-LASIK in TMH, NITBUT, and category of tear lipid layer thickness. There was a study that reported subjects having dry eye 1 month post-LASIK surgery (1), but the research used more invasive test, such as fluorescein tear break-up time and Schirmer test. Yu et al. (15) also showed lower tear break-up time after LASIK that was caused by operative trauma on cornea epithelium. In LASIK, the major corneal nerve trunks are severed by the microkeratome, and the anterior stromal nerves are disrupted by photoablation (16). Both processes damage the corneal innervation. The reduction in corneal neuronal feedback to the brain stem reduces brain stem innervation of the lacrimal glands, thus diminishing tear production. Corneal nerves regenerates post-operatively and corneal sensation returns to normal level within 3 to 6 months (1,17–19). However, another study reported that both sub-basal and stromal corneal nerves in LASIK flaps recovered slowly and did not return to pre-operative densities by 3 years post-LASIK (20). Kato et al. (21) also reported that the corneal recovery process took up to 9 months, while Benitez-del-Castillo et al. (22) reported that the tear secretion took up to 9 months for recovery after surgery.

All these studies were conducted before 2007, and technology in LASIK surgery has improved since then. One of the new technologies introduced in the recent years is the IntraLase femtosecond laser. Femtosecond laser is said to reduce the intra-operative risk in LASIK surgery and minimize damage to the corneal layer (23). This was seen in the present study as there was no significant changes in tear status after IntraLASIK for PS group. The IntraLase femtosecond laser may play an important role in maintaining the tear status after LASIK surgery.

Although the mean spherical equivalent before surgery for PS group was lower than the other 2 groups and thus less laser ablation was needed, there was no significant difference among the groups in terms of their tear quality and quantity.

ZTS group also showed no significant changes in NITBUT and TMH after surgery. This group had higher pre-operative mean spherical equivalent compared with PS group; however, with the introduction of IntraLase and availability of smaller laser beam size, the damage caused by more laser ablation on cornea could be minimized.

Based on data from Yu et al. (15), 59.4% of subjects who underwent LASIK surgery had dry eye symptoms 1 month post-surgery. The reasons given were injury to corneal epithelium caused by the surgery, toxicity from prescribed eye-drop, inflamatory responses to the surgery with the release of cytokines and immune mediator, reduction of corneal sensation that caused lower blinking rate, and the changes of corneal contour where flatter central corneal surface affects the distribution of the tear. However, in the current study, the blinking rates were not reduced after IntraLASIK in all groups. In fact, there was an increment in blinking rate 3 months post-IntraLASIK for all 3 groups; this could be a reaction to reduce the dryness of the eyes.

IntraLase femtosecond laser was used in this study for creating the corneal flap. A consistent and thinner corneal flap was created with IntraLase (24). The damage to the corneal layer could be reduced using this technology. IntraLase femtosecond laser also uses disposable suction ring, which causes less damages to the conjunctiva compared with microkeratome. This may reduce the possibility of the changes to the mucin layer in tear film, which is produced by conjuctival goblet cells. Salomao et al. (25) showed that eyes with femtosecond flaps had a lower incidence of LASIK-associated dry eye and required less treatment for the disorder compared with microkeratome.

WG group had the highest mean pre-operative spherical equivalent compared with the other 2 groups. With the advancement of the technology and improvement of the features, WG LASIK with VISX CustomVue uses variable laser spot size, which could minimize the damage to corneal layer caused by laser ablation. This can help to preserve the tear quality and quantity. From this study, WG group showed no significant changes in NITBUT, TMH, and category of tear lipid layer thickness, but they also showed no difference compared with PS group and ZTS group 1 and 3 months post-IntraLASIK. The advantage of wavefront-guided LASIK in preserving tear quality and quantity could not be shown in this study.

In a study by Patel et al. (26), it was seen that the tear lipid layer thickness was reduced after LASIK surgery. Although a similar method of evaluation of tear lipid layer thickness was used in this study, no significant change in categories of tear lipid layer thickness after IntraLASIK was seen in any group. PS and ZTS group, which used conventional LASIK as Patel's research, showed some increments in the number of subject under the categories of less than 50 nm tear lipid layer thickness after surgery, but not the WG group. On the contrary, WG group showed an increment in thicker categories, and the increment was not seen in PS and ZTS groups. The flatter corneal contour after surgery could affect the distribution of the tear lipid layer; however, this was not evident in this study. Combination IntraLase and improved technology could minimize the damage in the corneal layer; this could be the reason the results of this study are different from the results of Patel et al.'s (26). However, Durrie et al. (27) did show that there was no difference in corneal sensation recovery between IntraLase and microkeratome.

Conclusion

Tear status of the subjects who underwent IntraLASIK were not affected at 1 and 3 months post-IntraLASIK. Conventional and WG IntraLASIK did not show differences in preserving tear quality and quantity after surgery. Therefore, this study showed that the tear stability and tear quantity were maintained 1 and 3 months post-IntraLASIK.

Authors' Contributions

Conception and design: SKF, SK, AJL
Obtaining of funding: SK, FAM, AJL
Provision of study materials or patients: AJL
Collection and assembly of the data: SKF
Analysis and interpretation of the data, drafting of the article: SKF, SK
Criticle revision of the article, final approval of the article: SK, FAM

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