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ORIGINAL ARTICLE

Flap protection during laser-assisted *in situ* keratomileusis improves refractive outcomes in high myopic astigmatism

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Abstract

Purpose: Subtle irregularities in the corneal flap may affect laser-assisted *in situ* keratomileusis (LASIK) outcomes. The aim of this study was to evaluate flap protection during ablation in myopic astigmatic patients.

Methods: Medical files and corneal topographies of consecutive patients with myopic astigmatism (>2.5 D) that underwent LASIK were retrospectively reviewed. The visual and refractive outcomes with and without flap protection during the procedure were compared. We calculated and compared safety index, efficacy index, index of success (Alpins vector analysis) and ratio between nasal and temporal ablation.

Results: We included 57 subjects that fulfilled inclusion criteria. Patients in the flap guarding group were similar to patients in the no-guarding group, in terms of pre-operative parameters and similar treatment zones were used in both groups. Post-operatively, the flap guarding group had a better efficacy index (1.08 ± 0.17 vs. 0.96 ± 0.24, $P = 0.04$) and index of success (0.16 ± 0.07 vs. 0.23 ± 0.17, $P = 0.04$). The proportion of subjects with more than double nasal over-ablation ratio (>200%) was significantly lower in the guarding group compared to the no-guarding group (04.2% [1/23] vs. 32.3% [11/34], $P = 0.02$). No significant differences were found between groups in terms of post-operative safety index, uncorrected visual acuity, best-corrected visual acuity, sphere, cylinder and keratometry.

Conclusion: Guarding the flap during high myopic astigmatic LASIK was associated with better visual and refractive outcomes.

Introduction

The objective of laser refractive surgery is to improve visual acuity and quality independently of external refractive accessories. Advances in technology such as corneal reshaping laser systems and eye tracking software have led to unprecedented successful results with more than 200 million surgeries performed worldwide.[1] Although, in most cases, Laser-assisted *in situ* keratomileusis (LASIK) provides safe, efficient, and predictable results, undesirable results, such as surgically induced astigmatism or corneal aberrations, may occur in some patients.[2] Post-operative residual or induced astigmatism may limit uncorrected visual acuity (UCVA) and cause starbursts and glare. Irregular astigmatism can also cause loss of best-corrected visual acuity (BCVA), monocular diplopia, and ghosting of images.[3]

It has been suggested that even subtle irregularities in the corneal flap can reduce visual acuity postoperatively and even regular normal flaps may induce optical aberrations.[4] Creating and handling the corneal flap are crucial steps in LASIK. The hinge should be created slightly eccentric by placing the suction ring slightly eccentric, both in superior and nasal hinges, in order to avoid ablation of the flap during the procedure, especially in the case of large ablation zone.

Following flap lifting and before ablation ensues attention may be given to the "protection" of the flap during the procedure.

This serves for both, protecting the flap from excessive dehydration, and for protecting it from laser ablation. Although protecting the flap during laser ablation is an accepted practice in some clinics, not all surgeons routinely protect the flap during LASIK and this procedure has yet to be validated. Therefore, the purpose of this study was to compare the visual, refractive and topographic outcomes obtained in myopic astigmatic patients with and without flap protection during laser ablation.

Patients and Methods

All data for the study were collected and analyzed in accordance with the policies and procedures of the Institutional Review Board of the Barzilai Medical Center and the tenets set forth in the declaration of Helsinki.

Study participants

This retrospective study included consecutive patients who underwent LASIK between January 2014 and December 2015 at the Care-Vision Laser Center, Tel-Aviv, Israel. Data were obtained through the computerized database registry, which includes patient demographic and clinical data variables, archived by a computerized electronic medical record.

Inclusion criteria

This study included patients with with-the-rule myopic astigmatism ≥ −2.5 D (axis 165–180° or 0–15°) as the ablation of these patients has the highest chance of encountering the nasal hinged flap created by the microkeratome.

Additional inclusion criteria were age over 18 years; a stable refraction for at least 12 months; IOP <21 mmHg; a period without wearing contact lenses (more than 2 weeks for rigid contact lenses and more than 4 days for soft contact lenses); and no history of autoimmune disease, diabetes, ocular surgery or other eye disease [Supplemental Figure 1].

Data collection

The medical files of all eligible patients were reviewed and the following demographic and pre-operative information were extracted: age, gender, systemic co-morbidities, pre-operative refractive error (sphere, spherical equivalence (SE) and cylinder), pre-operative keratometry values, pre-operative pachymetry and pre-operative scotopic pupil size. The following intraoperative information was extracted: flap protection during the operation, the involved eye (right or left), surgeon, treatment zone, ablation depth, room temperature, room humidity and complications during the procedure. Post-operative information included: refractive error, keratometry values, UCVA and BCVA.

Surgical technique

All patients underwent the following detailed LASIK procedure. One drop of a topical anesthetic (benoxinate hydrochloride 0.4%) was instilled in the conjunctival fornix of the eye prior to surgery, after which a lid speculum was inserted. The Moria SBK-90 (Moria, Antony, France) head was used to create nasal-hinge flaps. The flaps were fully lifted nasally and the stromal bed was ablated using the same excimer laser (Wavelight AG, Erlangen, Germany). A balanced salt solution was used for irrigation before the flap was reinstated. One of the surgeons, placed a wet Weck-Cel (Beaver-Visitec International, Inc., Waltham, MA, USA) over the flap making sure that the whole inner surface of the flap was shielded from the laser while the other surgeon, did not. This was based on personal preference as one surgeon believes that it is important to protect the flap while the other does not. Both used their preferred method in all of their cases.

Outcomes

Main outcome measures were safety index (post-operative BCVA divided by the pre-operative BCVA) and efficacy index (post-operative UCVA divided by the pre-operative BCVA).

Alpins vector analysis was applied for comparison of astigmatic outcomes.[5] The difference vector (DV) was calculated as the induced astigmatic change (by magnitude and axis) that would enable the initial surgery to achieve its intended target. Target induced astigmatism (TIA) vector was calculated as the astigmatic change (by magnitude and axis) the surgery was intended to induce. Index of success was calculated by dividing the DV by the TIA. The index of success is a relative measure of success and is preferably zero.

Keratometric power was obtained from corneal topographic maps (Sirius, CSO, Firenze, Italy): Nasal (paracentral) keratometric power (NKP) and temporal (paracentral) keratometric power (TKP) were measured at the 6 mm optical zone. The difference between pre-operative and post-operative keratometric powers was calculated (ΔNKP = pre-operative NKP – post-operative NKP and ΔTKP = pre-operative TKP – post-operative TKP). The nasal over-ablation ratio (NOAR) was calculated as the ratio between ΔNKP and ΔTKP. The NOAR is a measure of how much the nasal cornea was over-ablated (compared to the temporal cornea) due to laser ablation of the nasal inner side of the flap.

Statistical analysis

Data were analyzed with the Minitab Software, version 16 (Minitab Inc., State College, PA). Normality of the data was assessed by the Kolmogorov-Smirnov test. The Student *t*-test was used for normally distributed data and the Kruskal-Wallis test for non-normally distributed data. For the analysis of categorical variables, the Chi-square test was used. A $P < 0.05$ was considered statistically significant.

Results

A total of 57 myopic highly astigmatic eyes of 57 consecutive patients that underwent LASIK were included in this study. Mean age was 31.4 ± 9.3 years and 56% were of male gender. The flap protection technique was applied in 40.4% of the eyes ($n = 23/57$). Both groups were similar in terms of pre-operative parameters

(age, gender, pre-operative visual acuity, cylinder, keratometry, pachymetry, pupil size and treatment zone), except for sphere and SE that were both higher in the flap guarding group (mean difference in sphere of 0.84 ± 0.39 D, 95% confidence interval (CI): 0.05–1.63 D, P = 0.04; mean difference in spherical equivalent of 0.89 ± 0.41D, 95% CI: 0.07–1.72 D, P = 0.03) [Table 1]. Subsequently, subjects in the flap guarding group underwent higher ablation depth (mean difference 18.25 ± 5.342 μ, 95% CI: 7.024–6.95, P = 0.002) and larger treatment for the sphere (mean difference of 1.52 D ± 0.39 D, 95% CI: 0.72–2.31 D, $P \leq$ 0.001). The flap guarding group had a slightly better efficacy index (1.08 ± 0.17 vs. 0.96 ± 0.24, P = 0.04) and index of success (0.16

Table 1: Comparison of pre-operative variables and post-operative outcomes in the flap guarding group versus the no flap guarding group

Parameter	Flap guarding	No flap guarding	*P*-value
n	23	34	
Age	29.96±8.89	32.38±9.58	0.33
% Female	43.48	44.12	0.96
Pre-operative BCVA (LogMAR)	0.86±0.16	0.87±0.11	0.82
Pre-operative UCVA (LogMAR)	0.15±0.19	0.21±0.13	0.24
Pre-operative sphere (D)	−1.93±1.51	−1.09±1.41	0.04*
Pre-operative cylinder (D)	3.05±0.81	3.04±0.58	0.93
Pre-operative SEQ (D)	−3.45±1.49	−2.6±1.45	0.04*
Pre-operative K Min (D)	42.52±1.3	42.38±1.2	0.68
Pre-operative K Max (D)	45.4±1.5	45.3±1.6	0.84
Pre-operative mean K (D)	43.96±1.3	43.85±1.3	0.76
Pre-operative pachymetry (μm)	536.17±24.11	543.88±21.7	0.21
Scotopic pupil size (mm)	5.95±1.7	6.0±0.09	0.82
Optical zone (mm)	6.58±0.19	6.48±0.08	0.02*
Treatment zone (mm)	8.97±0.08	9.0±0.0	0.26
Max ablation depth (μm)	78.13±21.59	59.88±19.46	0.01*
Humidity (%)	37.96±8.32	37.85±6.18	0.16
Room temperature (°C)	23.40±1.12	23.07±1.30	0.33
Actual treatment sphere (D)	−2.56±1.55	−1.04±1.41	<0.001*
Actual treatment cylinder (D)	−2.58±0.66	−2.95±0.55	0.03*
Post-operative BCVA (LogMAR)	0.93±0.15	0.93±0.08	0.92
Post-operative UCVA (LogMAR)	0.90±0.15	0.83±0.19	0.11
Safety index	1.10±0.17	1.08±0.13	0.62
Post-operative K Min (D)	40.49±1.5	39.95±2.33	0.27
Post-operative K Max (D)	41.11±1.41	40.43±2.66	0.33
Post-operative mean K (D)	40.80±1.44	40.19±2.43	0.288
Post-operative sphere (D)	0.01±1.3	0.17±0.53	0.56
Post-operative cylinder (D)	−0.68±0.34	−0.89±0.31	0.10
Post-operative s equivalent (D)	−0.24	−0.29	0.8
Efficacy index	1.08±0.17	0.96±0.24	0.04
Index of success (Alpins analysis)	0.16±0.07	0.23±0.17	0.04
NOAR >125%	30.4%	52.95%	0.09
NOAR >150%	26.0%	44.1%	0.16
NOAR >175%	17.3%	41.14%	0.06
NOAR >200%	4.4%	32.4%	0.02*

UCVA: Uncorrected visual acuity, SEQ: Spherical equivalent, NOAR: Nasal over-ablation ratio. ,BCVA: Best-corrected visual acuity

± 0.07 vs. 0.23 ± 0.17, $P = 0.04$). No significant differences were found between groups in terms of safety index (1.10 ± 0.17 vs. 1.08 ± 0.13) nor in post-operative UCVA, BCVA, sphere, cylinder, SE and keratometry values [Table 1].

The proportion of subjects with various ratios between the amount of nasal ablation and temporal ablation is presented in Figure 1. The proportion of subjects with more than double (NOAR >200%) were significantly lower in the guarding group compared to no-guarding group (4.4% vs. 32.4%, $P = 0.02$). In addition, the no-guarding group had a 10.5 odds ratio ($P = 0.006$) of having a NOAR >200%.

Discussion

Previous studies have investigated flap creation techniques, using different microkeratomes and femtosecond laser, and non-validated recommendations regarding handling the flap during laser ablation and protecting it from accidental ablation have been previously suggested.[6] The purpose of flap guarding is to avoid inadvertent flap ablation and flap dehydration. Inadvertent flap ablation can cause ablation of both the stromal bed and the overlying stromal side of the flap leading to a double ablation effect. As described by Reinstein *et al*. this double ablation may cause over-flattening of the cornea in the hinge side and therefore cause irregular astigmatism [Supplemental Figure 2].[7]

Ghobashy and Shahin evaluated flap protection by using the "taco" method (flap folded into half) in hyperopic patients. In their study, 25% of non-protected eyes showed partial hinge ablation.[8] Our use of a simple Weck-Cel to protect the flap is a simple method that may reduce potential complications of the "taco" method such as post-operative corneal striae.[6]

We believe that protecting the flap to prevent double ablation also reduces the chances of ocular aberrations, a dreaded complication of LASIK.[4] Accidental flap ablation might induce irregular astigmatism, which can limit UCVA and cause subjective symptoms.[4] Reinstein *et al*. described a patient who complained of diplopia, halos and starbursts after hyperopic LASIK.[7] An Artemis very-high frequency ultrasound along with corneal topography helped diagnose double ablation of both the stromal surface and underneath the flap. A few case series describing the correction of decentered ablations report various symptoms such as halos, ghost images, or night driving difficulties. Similar symptoms might be caused by accidental flap ablation.[3,9,10]

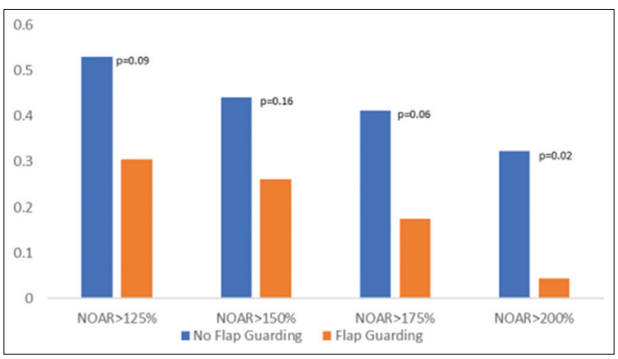

Figure 1: Proportion of patients with different nasal over-ablation ratios (NOARs). The NOAR signify over-ablated (compared to the temporal cornea) due to laser ablation of the nasal inner side of the flap. A NOAR >200% was significantly lower in the flap guarding group compared to no-guarding group

In the current study, a Weck-Cel sponge was used to shield the flap from the laser during ablation and was associated with a better efficacy index and index of success when compared with the no-guarding group. The NOAR was calculated using pre-operative and post-operative corneal topographies and a considerably high percentage of patients (32.4%) had a 200% or greater nasal over-ablation in the no-protection group, compared to the flap protection group (4.4%), $P = 0.02$. This implies that in the no-guarding group the nasal zone was double-ablated on both the nasal stromal bed and the stromal side of the flap. Moreover, the no guarding group had a 10.5 odds ratio ($P = 0.006$) of having a NOAR >200%.

One limitation of this study includes the fact that we compared between two surgeons. Although the microkeratome, laser machine and all other equipment were the same for both surgeons, slight variation in surgical technique may have affected the results. For example, placing the suction ring slightly differently by each surgeon may affect the final outcome and not the flap protection itself. In addition, this study has a retrospective design and a relatively small sample size. In order to minimize this bias, we analyzed all myopic LASIK cases conducted by the 2 surgeons ($n = 2346$) during the study periods. The comparison showed no clinical difference between the surgeons in terms of refractive outcome (efficacy: 1.06 ± 0.15 vs. 1.00 ± 0.13, p<0.001) [Supplemental Table 1]. Finally, we did not measure the arc length of the hinge and we did not perform corneal topography and thickness evaluation along the hinge meridian to confirm the double ablation in all cases.

Despite the aforementioned limitations, using a simple Weck-Cel to protect the flap during myopic astigmatic LASIK may prevent "double ablation" and lead to better refractive outcomes. Further randomized prospective single surgeon studies are needed to ascertain this hypothesis.

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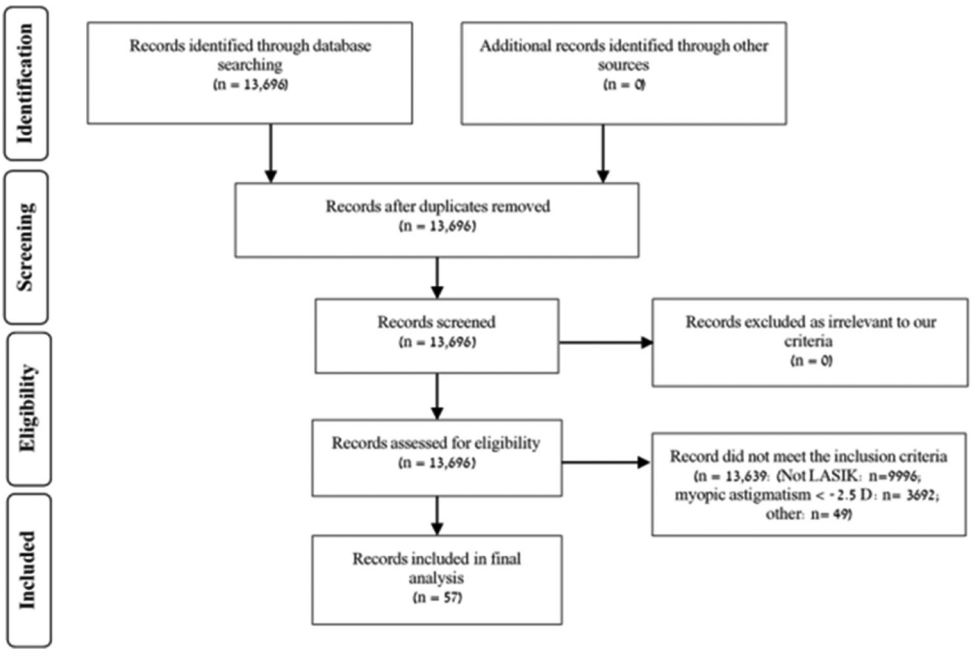
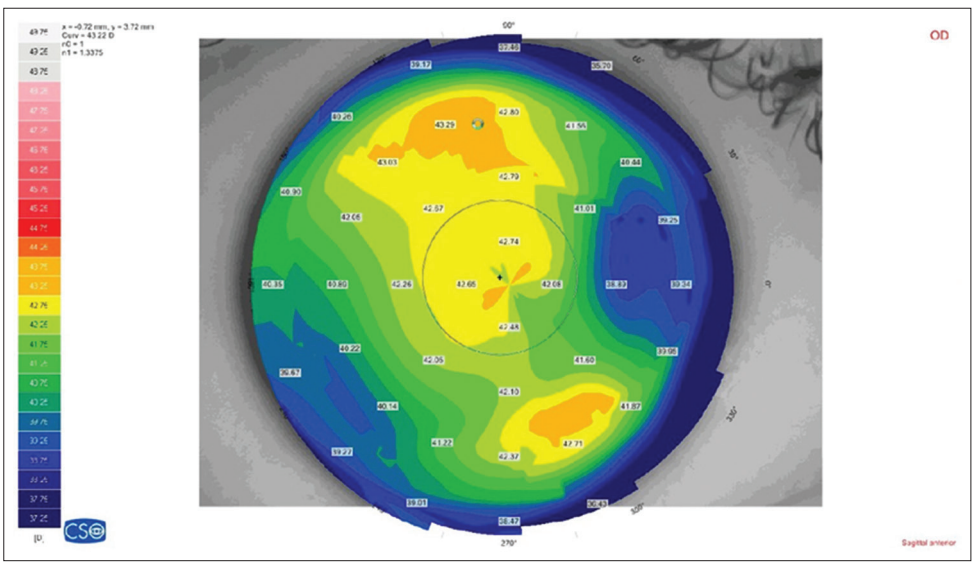
Supplementary



Supplemental Figure 1: Flowchart of the patients included in the analysis



Supplemental Figure 2: Corneal topography of the right eye of a patient from the no-protection group, which demonstrates corneal flattening on the nasal side (hinge area), demonstrating corneal flattening on the nasal side. Final UCVA was 1.0 and final refraction was −0.5 D with no cylinder

Supplemental Table 1: Comparison of pre-operative variables and post-operative outcomes in the laser-assisted *in situ* keratomileusis Patients by surgical methods (with flap guarding group versus without flap guarding group)

Parameter	Surgeon A. flap guarding	Surgeon B. without flap guarding	*P*-value
n	370	1976	
Age	26.26±5.5	27.96±5.6	<0.001
% Male	57.1	54.8	0.42
Pre-operative BCVA (LogMAR)	0.96±0.06	0.96±0.07	0.33
Pre-operative UCVA (LogMAR)	0.11±0.14	0.12±0.15	0.11
Pre-operative sphere (D)	−2.85±1.53	−2.63±1.85	0.03
Pre-operative cylinder (D)	−0.62±0.74	−0.75±0.71	0.01
Pre-operative SEQ (D)	−3.1±1.4	−3.0±1.7	0.16
Pre-operative mean K (D)	43.88±1.3	43.85±1.3	0.50
Pre-operative pachymetry (μm)	544.3±29.7	544.2±28.0	0.91
Scotopic pupil size (mm)	6.2±0.8	6.2±0.7	0.11
Optical zone (mm)	6.6±0.24	6.5±0.11	<0.001
Treatment zone (mm)	8.69±0.68	8.68±0.76	0.03
Max ablation depth (μm)	65.64±41.9	55.25±27.9	<0.001
Humidity (%)	37.8±6.7	37.2±6.98	0.10
Room temperature (°C)	23.60±1.31	2305±1.22	<0.001
Actual treatment sphere (D)	−3.43±1.41	−2.71±1.82	<0.001
Actual treatment cylinder (D)	−0.67±0.60	−0.93±0.65	<0.001
Post-operative BCVA (LogMAR)	0.99±0.10	0.97±0.22	<0.001
Post-operative UCVA (LogMAR)	1.02±0.15	0.96±0.12	<0.001
Safety index	1.06±0.15	1.00±0.13	<0.001
Post-operative mean K (D)	40.78±1.78	41.30±1.91	0.75
Postoperative sphere (D)	−0.08±0.84	−0.21±0.74	0.40
Post-operative cylinder (D)	−0.30±0.39	−0.40±0.44	0.17
Efficacy index	1.06±0.15	1.00±0.13	<0.001

UCVA: Uncorrected visual acuity, SEQ: Spherical equivalent, NOAR: Nasal over-ablation ratio, BCVA: Best-corrected visual acuity