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ORIGINAL ARTICLE

Effect of treatment zone diameter on the clinical results of femtosecond laser-assisted *in situ* keratomileusis and trans-photorefractive keratectomy for the correction of myopia

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Abstract

Aim: The aim of this study is to examine and compare the effect of treatment zone diameter on the results of femtosecond laser-assisted *in situ* keratomileusis (FS-LASIK) and trans- photorefractive keratectomy (PRK) procedures performed for the treatment of myopia.

Materials and Methods: This was a retrospective cohort study. The study reviewed medical files of patients who underwent trans-PRK (2630 eyes) and FS-LASIK (879 eyes) in which different treatment area diameters were used. For each type of surgery, the eyes were divided into three groups, based on the treatment zone diameter (6 mm, 6.5 mm. and 7 mm).

Results: In the FS-LASIK group, there was no difference in both the safety and efficacy indices or in the distance from the intended result between the groups (P = 0.79, P = 0.57, and P = 0.09, respectively). In myopic trans-PRK, a treatment area of 7 mm was associated with worse outcomes in terms of safety (P = 0.01) and efficacy (P < 0.01) in comparison with the other groups. In addition, a treatment zone of 7 mm was associated with a significantly larger distance from the refractive target (P < 0.001). There were no significant differences between the 6 mm and 6.5 mm groups in any outcome measure. These results recurred in a multivariate analysis, after correcting them for age, gender, pre-operative refractive error, and pachymetry.

Conclusions: Different treatment zone sizes gave similar results in FS-LASIK, while in trans-PRK, a 7 mm zone was associated with inferior outcomes in comparison to smaller treatment zones. Hence, in trans-PRK, we recommend choosing a treatment zone smaller than 7 mm while taking pupillometry into account and opting FS-LASIK whenever a very large treatment zone is required.

Introduction

The world of refractive surgery has seen many changing trends in the past three decades. The introduction of laser ablation for the correction of myopia has significantly increased both the safety and the efficacy of procedures compared to manual approaches.[1] Nowadays, laser refractive procedures can be divided into two main groups: Laser surface ablation procedures and laser-assisted *in situ* keratomileusis (LASIK).

Transepithelial photorefractive keratectomy (trans-PRK) uses an excimer laser to ablate the epithelium and then reshape the cornea to correct the refractive error. This platform obviates the need of alcohol epithelial debridement or mechanical removal of the epithelium during PRK.

Currently, LASIK is the most popular procedure for the surgical correction of refractive error.[2] The technological evolution of flap creation enabled the creation of a more precise and reproducible flap with the femtosecond laser.[3]

The anatomical area of the cornea which is ablated during the procedure is called the treatment zone, which is composed of the optical and transition zones. The transition zone is the passageway between the treated and untreated zones. According to Munnerlyn's formula,[4] as the size of the treatment zone increases, so does the volume of cornea tissue removed, and to avoid corneal ectasia, there might be a necessity to limit the treatment zone size for each individual patient.

In the 1st year of LASIK, small treatment zones of up to 5 mm were used; however, these resulted in a high frequency of regression and vision disturbances within scotopic conditions. Hence, the minimal treatment zone increased to 6 mm and more. Night vision disorders were reported even while using larger treatment areas, and it was recommended that the treatment area, including the transition zone, will be 0.5–1 mm larger than the size of the pupil at low illumination conditions.[5] Schallhorn *et al.*[6] demonstrated that, for a given treatment zone, there is an inverse correlation between pupil size and vision quality in the early post-operative period, but no such correlation was established after 6 months of surgery. Some patients with a mesopic pupil size larger than the treatment zone were asymptomatic, while others with a mesopic pupil size smaller than the treatment zone suffered from halos. The researchers concluded that there are other factors influencing patients' symptoms such as cortical adaptation mechanisms. In two studies, Bühren and Kohnen[7,8] demonstrated that, for patients with large pupils, there is a correlation between optical aberrations and the size of the treatment zone and that a correlation exists between the optical zone-to-pupil ratio and optical aberrations.

Literature about the treatment area's diameter and its effect on PRK results is scant in comparison to LASIK. Endl *et al.*[9] demonstrated an advantage in using an optical area of 5.5 mm with a transition area of 7 mm compared to a treatment area of 5 mm without a transition area. Rajan *et al.*[10] concluded that a 6.0 mm ablation zone in PRK was superior to ablation zones of 4.0 mm and 5.00 mm, with regard to refractive predictability, early hyperopic shift, regression, corneal transparency, and night haloes. In another study, Mohammadi *et al.*[11] concluded that an optical zone smaller than 6.00 mm leads to a higher prevalence of undercorrection and regression. We have found no studies comparing the effect of treatment zones diameter in LASIK versus PRK.

The purpose of the current study was to compare the effect of treatment zone diameter on the results of femtosecond LASIK (FS-LASIK) and trans-PRK procedures performed for the treatment of myopia.

Materials and Methods

A retrospective cohort study design was used. The study followed the tenets of the Declaration of Helsinki and was approved by the Institutional Review Board of Assuta Medical Center.

Study cohort

The study group consisted of consecutive patients treated with FS-LASIK or trans-PRK for myopia of various severities at the optical outpatient clinic of the largest private medical service in Israel from January 2013 to December 2014. Results of the trans-PRK and FS-LASIK groups were analyzed separately. In each group, patients were divided into subgroups according to the treatment zone diameter utilized during the surgery.

Inclusion criteria for the procedure were the age of 18 years or higher and a myopic spherical equivalent (SE). Exclusion criteria were the age lower than 18 years, change of more than 0.5D in refraction during the year before the initial consultation, abnormal or keratoconus topography, coexisting ocular pathology or previous surgery, inflammatory or infectious corneal disease, relevant systemic dermatologic or connective tissue disorders, hyperopia, mixed astigmatism, a follow-up period of under 3 months, pregnancy, intended monovision, and incomplete medical records.

Study procedure

The medical files of the patients were reviewed for demographics, operative data, length of follow-up, manifest refraction, uncorrected and best corrected visual acuity (UCVA and BCVA), corneal thickness, efficacy and safety indexes, refraction distance from intended target, and post-operative complications. Efficacy was calculated as the ratio of mean post-operative UCVA to mean pre-operative BCVA (efficacy index). Safety was calculated as the ratio of mean post-operative BCVA to mean pre-operative BCVA (safety index). Findings were compared between groups of patients treated with different treatment zone diameters in both the FS-LASIK and trans-PRK groups.

Pre-operative evaluation

The pre-operative evaluation included manifest and cycloplegic refraction, autorefraction, slit-lamp biomicroscopy, dilated fundoscopy, Goldmann tonometry, and mesopic pupil diameter measurement. Slit-scan corneal Scheimpflug tomography (Sirius, SCHWIND eye-tech-solutions GmbH, Kleinostheim, Germany) and total ocular wavefront measurement (Hartmann-Shack Aberrometer/ORK-Wavefront Analyzer; SCHWIND eye-tech-solutions) were carried out as well.

Surgical technique

Decision to perform FS-LASIK or Trans-PRK was left to the discretion of the operating physician. The common practice in our institution is not to perform LASIK when the central corneal thickness is <500 μm. The procedures were performed by one of seven experienced surgeons.

In the trans-PRK group, all treatments were aspheric aberration-neutral non-wave front-guided profiles, and excimer laser application was preceded by standardized wet sponge application. Single-step laser delivery with the Schwind Amaris 500E excimer laser (SCHWIND eye-tech-solutions GmbH, Kleinostheim, Germany) was carried out immediately afterward with a 6.0–7.0 mm treatment zone, and mitomycin C (MMC 0.02%) was immediately applied for up to 50 s (depending on the amount of ablation) using a damp Merocel sponge, then copiously

irrigated with balanced saline solution, and dried. One drop of ofloxacin (0.3%) was subsequently instilled, and a bandage contact lens (Purevision, Bausch and Lomb) was inserted. After surgery, all eyes received topical ofloxacin (0.3%) qid until removal of the contact lens, dexamethasone (0.1%) drop qid with a slow tapering down over 12 weeks, and artificial tear drop qid for 3 months.

In the FS-LASIK group, a minimum residual stromal bed of 300 microns was mandatory for the procedure. The corneal flaps were created under topical anesthesia using the Ziemer LDV Z6 femtosecond laser (Ziemer Ophthalmic Systems, Allmendstrasse, Switzerland). Nominal flap thickness was set at 110 μm and flap diameter, to 9.5 mm, with a 0.4 mm hinge placed superiorly. After the flap was lifted, ablations were performed using the Schwind Amaris 500E excimer laser with a 6.0–7.0 mm treatment zone. The corneal flap and stromal surface were irrigated with balanced salt solution, and the flap was repositioned. After surgery, patients were instructed to instill topical moxifloxacin qid for 1 week, dexamethasone (0.1%) drop qid for 2 weeks, and artificial tear qid for 3 months.

Patients were examined immediately after surgery and invited for follow-up visits at 1 day, 1 week, 1 month, 3 months, 6 months, and 1 year after surgery.

Statistical analysis

Data were analyzed with the Minitab Software, version 16 (Minitab Inc., State College, PA). For the analysis of categorical variables, Chi-square test was used. Comparisons between normal distribution variables were made using the ANOVA test with *post hoc* Tukey's test for multiple comparisons. A $P < 0.05$ was considered statistically significant. We also performed a stepwise multiple regression analysis when needed. Due to the lack of relevant results from past studies and since we analyzed data of thousands of patients, a power analysis was not completed. We expected to find statistical significant results for each difference found and to examine the importance of the results within their clinical significance.

Results

The FS-LASIK group was comprised of 879 eyes of 441 patients with a female predominance of 54.28% and a mean age of 29.10 ± 7.44 years [Table 1]. The trans-PRK group included 2630 eyes of 1315 patients, with a clear male predominance of 60.75%, and a younger mean age of 25.66 ± 6.92 years [Table 2]. For each type of surgery, the patients were divided into three subgroups, based on the treatment zone diameter (6 mm, 6.5 mm, and 7 mm). The pre-operative SE for FS-LASIK and trans-PRK was −3.7 ± 1.9 and −4.6 ± 2.3, respectively ($P < 0.0001$).

In the FS-LASIK group, no difference was found regarding the safety and efficacy indices or in the distance from the intended refractive result between all subgroups ($P = 0.79$, $P = 0.57$, and $P = 0.09$, respectively) [Table 1]. In myopic trans-PRK, a treatment area of 7 mm was associated with worse outcomes in terms of safety ($P = 0.01$) and efficacy ($P < 0.01$) in comparison with the other groups [Table 2]. Furthermore, a treatment zone of 7 mm was associated with a significantly larger distance from the refractive target in comparison to the other areas ($P < 0.001$). There were no significant differences between the 6 mm and 6.5 mm groups in any of the outcome measures. These results recurred in a multivariate analysis, after correcting them for age, gender, preoperative refractive error, and pachymetry [Tables 3-5].

Discussion

The adequate treatment zone selection for optimal outcomes and minimal adverse effects has been a topic of controversy for many years in the field of refractive surgery. While several studies tried to examine this subject with regard to the LASIK procedure,[5-8,12-16] literature about the treatment area diameter and its effect on PRK results is scant,[9-11] and as this procedure is gaining its popularity back,[2] this issue is of great importance. In a meticulous search through the relevant literature, we have found no papers comparing the effect of treatment zone diameter

Table 1: Treatment outcomes for different treatment zone sizes in FS-LASIK

Parameter	6.0 mm (*n*=179)	6.5 mm (*n*=668)	7.0 mm (*n*=32)	*P* value
Age (years)	30.01±7.98 (A)	28.54±7.05 (B)	35.63±8.82 (C)	<0.001
Gender (%male)	44.13% (A)	44.44% (A)	81.25% (B)	<0.001
Pre-operative SE (D)	−4.88±2.25 (A)	−3.52±1.67 (B)	−1.88±0.88(C)	<0.001
Pre-operative sphere (D)	−4.53±2.21 (A)	−3.18±1.69 (B)	−0.93±1.11 (C)	<0.001
Pre-operative cylinder (D)	−0.75±0.72 (A)	−0.74±0.89 (A)	−1.98±1.00 (B)	<0.001
Pre-operative UCVA (logMAR)	1.26±0.41 (A)	1.08±0.34 (B)	0.75±0.31 (C)	<0.001
Pre-operative BCVA (logMAR)	0.02±0.05 (A)	0.02±0.04 (A)	0.03±0.03 (A)	0.47
Pre-operative pachymetry (microns)	533.36±21.38 (A)	549.04±27.43 (A)	553.00±39.10 (B)	<0.001
Post-operative safety index	0.99±0.13 (A)	0.99±0.12 (A)	1.00±0.14 (A)	0.79
Post-operative efficacy index	0.97±0.16 (A)	0.98±0.13 (A)	0.97±0.20 (A)	0.57
Post-operative distance from target (D)	0.40±0.31 (A)	0.45±0.41 (A)	0.32±0.34 (A)	0.09

*Values that do not share a letter are significantly different. SE: Spherical equivalent, FS-LASIK: Femtosecond laser-assisted *in situ* keratomileusis

Table 2: Treatment outcomes for different treatment zone sizes in trans-PRK

Parameter	6.0 mm (n =519)	6.5 mm (n =1936)	7.0 mm (n =175)	P value
Age (years)	26.92±7.19 (A)	25.36±6.79 (B)	24.77±6.61 (B)	<0.001
Gender (%male)	55.49% (A)	60.64% (B)	77.14% (C)	<0.001
Pre-operative SE (D)	−6.42±2.68 (A)	−4.23±1.98 (B)	−3.26±1.75 (C)	<0.001
Pre-operative sphere (D)	−6.04±2.66 (A)	−3.91±1.94 (B)	−2.70±1.93 (C)	<0.001
Pre-operative cylinder (D)	−0.81±0.77 (A)	−0.70±0.70 (B)	−1.22±1.20 (C)	<0.001
Pre-operative UCVA (logMAR)	1.44±0.46 (A)	1.15±0.37 (B)	0.96±0.38 (C)	<0.001
Pre-operative BCVA (logMAR)	0.03±0.05 (A)	0.02±0.03 (B)	0.02±0.04 (B)	<0.001
Pre-operative pachymetry	520.59±32.76 (A)	533.16±37.22 (A)	536.18±37.14 (B)	<0.001
Post-operative safety index	0.95±0.18 (A)	0.96±0.14 (A)	0.91±0.18 (B)	0.001
Post-operative efficacy index	0.93±0.20 (A)	0.95±0.16 (B)	0.88±0.21 (C)	<0.001
Post-operative distance from target (D)	0.60±0.58 (A)	0.47±0.41 (A)	0.57±0.69 (B)	<0.001

*Values that do not share a letter are significantly different. SE: Spherical equivalent, PRK: Photorefractive keratectomy

Table 3: Safety index - multivariant analysis for different treatment zone sizes in trans-PRK

Difference of treatment zone groups levels	Difference of means	SE of difference	Simultaneous 95% CI	T-value	Adjusted P value
6.5–6.0	−0.0116	0.00838	(−0.03168, 0.00844)	−1.39	0.496
7.0–6.0	−0.0634	0.0144	(−0.0979, −0.0290)	−4.41	0
7.0–6.5	−0.0518	0.0123	(−0.0813, −0.0224)	−4.21	0

PRK: Photorefractive keratectomy

Table 4: Efficacy index - multivariant analysis for different treatment zone sizes in trans-PRK

Difference of treatment zone groups levels	Difference of means	SE of difference	Simultaneous 95% CI	T-value	Adjusted P value
6.5–6.0	0.0006	0.0091	(−0.0212, 0.0224)	0.07	1
7.0–6.0	−0.0725	0.0157	(−0.1102, −0.0348)	−4.6	0
7.0–6.5	−0.0731	0.0135	(−0.1055, −0.0406)	−5.4	0

PRK: Photorefractive keratectomy

Table 5: Distance from target - multivariant analysis for different treatment zone sizes in trans-PRK

Difference of treatment zone groups levels	Difference of means	SE of difference	Simultaneous 95% CI	T value	Adjusted P value
6.5–6.0	−0.0418	0.0245	(−0.1006, 0.0170)	−1.7	0.265
7.0–6.0	0.1012	0.0424	(−0.0005, 0.2028)	2.38	0.052
7.0–6.5	0.143	0.0366	(0.0554, 0.2307)	3.91	0

PRK: Photorefractive keratectomy

in LASIK versus PRK. In this study, we aimed to examine and compare the effect of treatment zone diameter on the results of FS-LASIK and trans-PRK procedures performed for the treatment of myopia.

In the 1st year of LASIK, small treatment zones were used which resulted in a high frequency of regression and vision disturbances within scotopic conditions, when the pupil is larger than the ablation zone.[7,17-19] Pop and Payette[20] showed a 2.5 times increase in night vision complaints for an optical zone of 6.00 mm or lower. Night vision disorders were reported even while using larger treatment areas, and it was recommended that the treatment area, including the transition zone, will be 0.5–1 mm larger than the size of the pupil at low illumination conditions.[5] In a recent study, Milivojevic *et al.*[12] concluded that diameter enlargement of the treated optical zone from 6.5 mm to 7.00 mm does not threaten the stability of the cornea structure and significantly improves outcomes for corneas in which larger ablation (resulting in deeper ablation and increased risk for ectasia)[21,22] can be safely done.

As mentioned before, the treatment area diameter and its effect on PRK results were explored to a lower magnitude. One study[9] demonstrated an advantage in using an optical area of 5.5 mm with a transition area of 7 mm compared to a treatment area of 5 mm without a transition area. Two other studies[10,11] concluded that a 6.0 mm ablation zone in PRK was superior to smaller ablation zones with regard to outcomes and adverse effects.

When discussing elective refractive procedures, one should be aware that the most critical factor to our patients is

eliminating their dependency on spectacles. This factor can be assessed most accurately with the efficacy index. In this study, we found no significant differences between the treatment zone diameters (6 mm, 6.5 mm, and 7 mm) in FS-LASIK with regard to the efficacy index, the safety index, and the distance from the refractive target [Table 1]. It is worthwhile to point out that the 7 mm group consisted of only 32 eyes. However, in trans-PRK, a 7 mm zone was associated with inferior outcomes in comparison to smaller treatment zones even though the pre-operative SE in this group was significantly lower than in the other two groups [Table 2]. This variance can stem from the fact that ablations of larger zones can lead to more high order aberrations. While the source of these aberrations in PRK is on the corneal surface, the area which most influences the refraction, in LASIK, these aberrations may be deducted to some degree by the flap or may be less influential as they lie deep within the stroma and not on the surface.

As described earlier, the pre-operative SE of the trans-PRK group was higher than that of the FS-LASIK group, although eyes with a high degree of myopia were rarely operated with the FS-LASIK approach. Even though the degree of myopia was taken into account in the multivariant analysis [Tables 3-5], this could have altered the results to some degrees. For instance, perhaps, some patients who were treated with trans-PRK for very high myopia and needed a larger treatment zone due to a large pupil received a suboptimal correction because of the restraints of the ablation depth which is proportional to the square of the diameter.

There are several limitations to this study. First, although the sample was large, we used a retrospective study design with a limited follow-up time of 12 months. Second, a bias exists since some patients with a very good UCVA in the early post-operative examinations tended not to adhere to the full 12-month follow-up, whereas those with worse early outcomes were motivated to appear for reexamination. Third, there was also a potential negative bias in terms of the safety index because we do not routinely examine BCVA in patients with a good post-operative UCVA; instead, we use the post-operative UCVA value for both parameters. This may have lowered the expected safety index postoperatively, in both procedures. Fourth, due to technical constraints, we did not adjust the results according to the mesopic pupil size, which is the main drawback of this study.

Conclusion

In this large-scale study, we found that different treatment zone sizes gave similar results in FS-LASIK, while in trans-PRK, a 7 mm zone was associated with inferior outcomes in comparison to smaller treatment zones. Hence, in PRK, we recommend using a treatment zone smaller than 7 mm when possible while taking pupillometry into account and opting FS-LASIK whenever a very large treatment zone is required.

Clinical Significance

This study shed some more light on a topic of much controversy in the field of refractive surgery and may help the ophthalmic surgeon to select the adequate treatment zone when correcting myopia with trans-PRK or FS-LASIK, to gain optimal outcomes and minimal adverse effects.

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