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ORIGINAL PAPER

Z-LASIK and Trans-PRK for correction of high-grade myopia: safety, efficacy, predictability and clinical outcomes

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Abstract

Purpose The aim of the study was to examine the outcomes of transepithelial photorefractive keratectomy (Trans-PRK) and Femtosecond Laser-assisted in situ keratomileusis (Z-LASIK) for the correction of high myopia.

Methods A retrospective cohort study design was used. The study group included 792 eyes with high-grade myopia (− 6.0 diopters or higher) or high-grade myopia with astigmatism that were treated with Z-LASIK or Trans-PRK in 2013 through 2014 in an optical outpatient clinic of a large private medical service. The Trans-PRK group comprised of 674 eyes with a spherical equivalent (SE) of − 7.87 ± 1.46 and the Z-LASIK group comprised of 118 eyes with a SE of − 7.19 ± 0.81 ($P < 0.001$).

Results The mean postoperative SE in the Trans-PRK group was − 0.06 and − 0.02 in the Z-LASIK group ($P = 0.545$). Efficacy index values were 0.92 in the Trans-PRK group and 0.95 in the Z-LASIK group ($P = 0.083$), and corresponding safety index values were 0.95 and 0.97 ($P = 0.056$). An UCVA of 20/40 or better was achieved in 94.20% of eyes in the Trans-PRK group, and 98.31% in the Z-LASIK group ($P = 0.063$). The majority of eyes in both the Trans-PRK and Z-LASIK groups were within ± 0.5D of attempted correction: 59.35 and 64.71%, respectively ($P = 0.271$).

Conclusions Both Trans-PRK and Z-LASIK demonstrated excellent efficacy, safety and predictability profiles, with results comparable and in some cases superior to the current literature. Results of Z-LASIK were slightly better than those of Trans-PRK, though the preoperative SE of the latter was higher.

Keywords High myopia · FS-LASIK · Trans-PRK · Refractive surgery · Efficacy · Safety · Predictability

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Introduction

Myopia, which is the most common refractive error of the eye, has become more prevalent in recent years. Traditionally, it is divided according to the level of myopia to mild, moderate and high, the latter of which is used by the American Academy of Ophthalmology

to describe myopia which is above 6.0 diopters (D). The presence of high-grade myopia is one of the leading reasons for not performing refractive surgery [1, 2].

In the 1990s, photorefractive keratectomy (PRK) was the most performed surgical procedure to correct low to moderate myopia. Even though it is considered safe and effective, the side effects include postoperative pain, slow visual rehabilitation, glare or halos and the risk of iatrogenic corneal haze and poor predictability, especially in high myopia [3, 4].

Transepithelial PRK (Trans-PRK) refers to the Schwind Amaris platform (Schwind eye-tech-solutions GmbH, Kleinostheim, Germany) which uses an excimer laser to ablate the epithelium and then reshape the cornea in order to correct the refractive error. This platform can obviate the need of alcohol epithelial debridement or mechanical removal of the epithelium during PRK but has the potential to interfere with the final refractive outcomes of the procedure. Trans-PRK has been shown to be faster to perform, less painful and stressful, inducing less postoperative haze and faster healing time than alcohol-based PRK [5–7].

The other procedure which evolved over the years alongside PRK is the Laser In Situ Keratomileusis (LASIK) which nowadays is the most popular procedure for the surgical correction of refractive error. It provides faster visual recovery, minimal postoperative pain, less regression and the ability to correct high degrees of myopia with little postoperative corneal haze [8]. Shortt et al. [9] compared LASIK with PRK and concluded that the former had superior efficacy and safety than the latter.

Nevertheless, one should be aware of LASIKs' complications profile: flap- and interface-related complications, flap-related corneal biomechanical instability, and iatrogenic keratectasia, which is more of a concern in high myopia [10–18]. The technological evolution of flap creation enabled the creation of a more precise and reproducible flap with the femtosecond laser in general, and with the Ziemer-Laser In Situ Keratomileusis (Z-LASIK) procedure in particular [19–25]. In their research from 2011, Alio et al. [26] concluded that LASIK for high myopia with the Amaris Excimer laser and a femtosecond platform for flap creation is safe, effective and predictable. A recent publication which compared FS-LASIK with alcohol-assisted PRK for the treatment of a wide range of refractive errors found superior visual outcomes in the FS-LASIK group [27].

The purpose of the current study was to examine the safety, efficacy, predictability and clinical outcomes of Trans-PRK and Z-LASIK for the correction of high-grade 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 792 eyes with high-grade myopia (− 6.0D or higher) or high-grade myopia with astigmatism that were treated with Z-LASIK or Trans-PRK at the optical outpatient clinic of the largest private medical service in Israel from January 2013 through December 2014. All procedures were performed by one of 7 experienced staff surgeons.

Patients were included in the study if they were 18 years or older, had a myopic spherical equivalent (SE) of − 6.0D or higher, underwent Z-LASIK or Trans-PRK and had a complete medical record. Exclusion criteria were age lower than 18 years, change of more than 0.5D in refraction during the year prior to 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, myopic spherical equivalent (SE) lower than − 6.0D, hyperopia, intended monovision, pregnancy and incomplete medical records.

Preoperative evaluation

The preoperative 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 Z-LASIK or Trans-PRK was left to the discretion of the operating physician.

In the Trans-PRK group, all treatments were aspheric aberration-neutral non-wavefront-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 5.7–7.0 mm optical zone. Mitomycin C (MMC 0.02%) was immediately applied for 50 s using a damp Merocel sponge, then copiously irrigated with BSS (balanced normal saline solution), and dried. One drop of ofloxacin (0.3%) was subsequently instilled, and a bandage contact lens (purevision, Bausch&Lomb) was inserted. After surgery, all eyes received topical ofloxacin (0.3%) qid until removal of the contact lens, dexamethasone (0.1%) drops qid with a slow tapering down over 12 weeks, and artificial teardrops qid for 3 months.

In the Z-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 5.7–7.5 mm optical zone and 0.5 mm transition 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 ofloxacin (0.3%) qid for 1 week, dexamethasone (0.1%) drops qid for 2 weeks, and artificial tears qid for 3 months.

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

Study procedure

Patients who met the study criteria were divided into those who underwent Z-LASIK surgery and those who underwent Trans-PRK.

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, and postoperative complications. Efficacy was calculated as the ratio of mean postoperative UCVA to mean preoperative BCVA (efficacy index). Safety was calculated as the ratio of mean postoperative BCVA to mean preoperative BCVA (safety index). Findings were compared between the Z-LASIK and Trans-PRK groups.

Postoperative haze was defined as clinically apparent haze and was noted even if it was visible in only one follow-up appointment and did not affect the patients' vision considerably.

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. Student's t test was used for variable comparisons between both groups when normal distribution could be assumed, whereas the Kruskal–Wallis test was used for non-normally distributed data. For the analysis of categorical variables, Chi-square or Fisher exact test was used. A P value of less than 0.05 was considered statistically significant.

Results

Subject demographics

After an exclusion of patients who were lost to follow-up (24.60% in the Trans-PRK group and 29.88% in the Z-LASIK group), the Trans-PRK group comprised 674 eyes and the Z-LASIK group of 118 eyes. While in the former group there was a male predominance of 54.01%, in the latter there was a female one of 68.64%. Mean age was higher in the Z-LASIK group. As Z-LASIK was not performed on corneas thinner than 500 microns, the mean corneal thickness of the Trans-PRK group was lower than that of the Z-LASIK group. The preoperative spherical equivalent (SE) was higher in the Trans-PRK group (Table 1).

Efficacy

The efficacy index was 0.92 in the Trans-PRK group and 0.95 in the Z-LASIK group ($P = 0.08$) (Table 2).

Table 1 Patient's demographics and preoperative data

Parameter	Trans-PRK ($n = 674$)	Z-LASIK ($n = 118$)	P
Male	54.01%	31.36%	< 0.001
Age (year)	26.08 ± 7.52	28.39 ± 6.52	0.001
Corneal thickness (μm)	533.4 ± 31.1	549.0 ± 26.0	< 0.001
Spherical equivalence (D)	− 7.87 ± 1.46	− 7.19 ± 0.81	< 0.001
Sphere (D)	− 7.45 ± 1.50	− 6.73 ± 1.01	< 0.001
Cylinder (D)	− 0.83 ± 0.79	− 0.92 ± 0.98	0.38

Values are mean ± SD unless otherwise indicated

Table 2 Postoperative outcomes

Parameter	Trans-PRK ($n = 674$)	Z-LASIK ($n = 118$)	P
Follow-up time (months)	4.57 ± 3.39	3.55 ± 3.33	0.003
Spherical equivalence (D)	− 0.06 ± 0.91	− 0.02 ± 0.65	0.55
Sphere (D)	0.24 ± 0.89	0.28 ± 0.67	0.51
Cylinder (D)	− 0.59 ± 0.44	− 0.60 ± 0.41	0.81
Efficacy index	0.92 ± 0.22	0.95 ± 0.16	0.08
UCVA	0.84 ± 0.19	0.88 ± 0.14	0.001
Safety index	0.95 ± 0.20	0.97 ± 0.14	0.06
20/20 or better	29.46%	29.66%	0.97
20/25 or better	62.20%	69.49%	0.13
20/30 or better	85.27%	94.07%	0.01
20/40 or better	94.20%	98.31%	0.06
20/50 or worse	5.36%	1.69%	0.09
BCVA	0.86 ± 0.17	0.90 ± 0.12	0.002
Distance from target (D)	0.64 ± 0.66	0.50 ± 0.42	0.004
% Within ± 0.50 D	59.35%	64.71%	0.27

Values are mean ± SD or percent of eyes

UCVA uncorrected visual acuity, *BCVA* best-corrected visual acuity

An UCVA of 20/40 or better was achieved in 94.20% of eyes in the Trans-PRK group and 98.31% in the Z-LASIK group ($P = 0.06$). Rates for UCVA 20/25 or better were 62.20 and 69.49%, respectively ($P = 0.13$) (Fig. 1).

Predictability

Both Z-LASIK and Trans-PRK proved efficient at achieving the attempted correction, and the postoperative SE was comparable between the two groups (Table 2, Fig. 2). The mean postoperative SE in the Trans-PRK group was − 0.06 and − 0.02 in the Z-LASIK group ($P = 0.55$) (Table 2). The distance from target was marginally but significantly more accurate with the Z-LASIK group. The majority of eyes in both the Trans-PRK and Z-LASIK groups were within ± 0.5D of attempted correction: 59.35 and 64.71%, respectively ($P = 0.271$) (Table 2). Figure 3 shows the SE refractive accuracy in the two groups, and Figs. 4 and 5 show the preoperative and postoperative differences in refractive astigmatism between the groups.

Safety

The safety index was marginally, but not significantly, higher in the Z-LASIK group (Table 2). Two lines or more of BCVA were lost in 47 out 674 (7%) in the Trans-PRK group, while only 1 eye out of 118 (0.8%) lost 2 lines or more in the Z-LASIK group (Fig. 6).

Complications

The types and rates of postoperative complications are shown in Table 3. Haze was identified in 55 out of 674 eyes (8.16%) that underwent Trans-PRK and was associated with a BCVA loss of 1 line or more in 25 patients (3.71%). A grading of the postoperative corneal haze alongside its respective mean

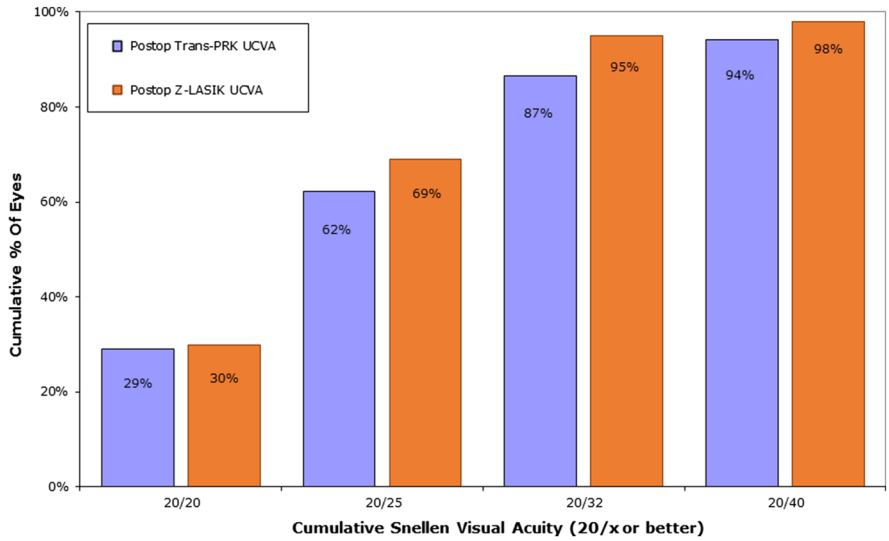

Fig. 1 Uncorrected distance visual acuity achieved

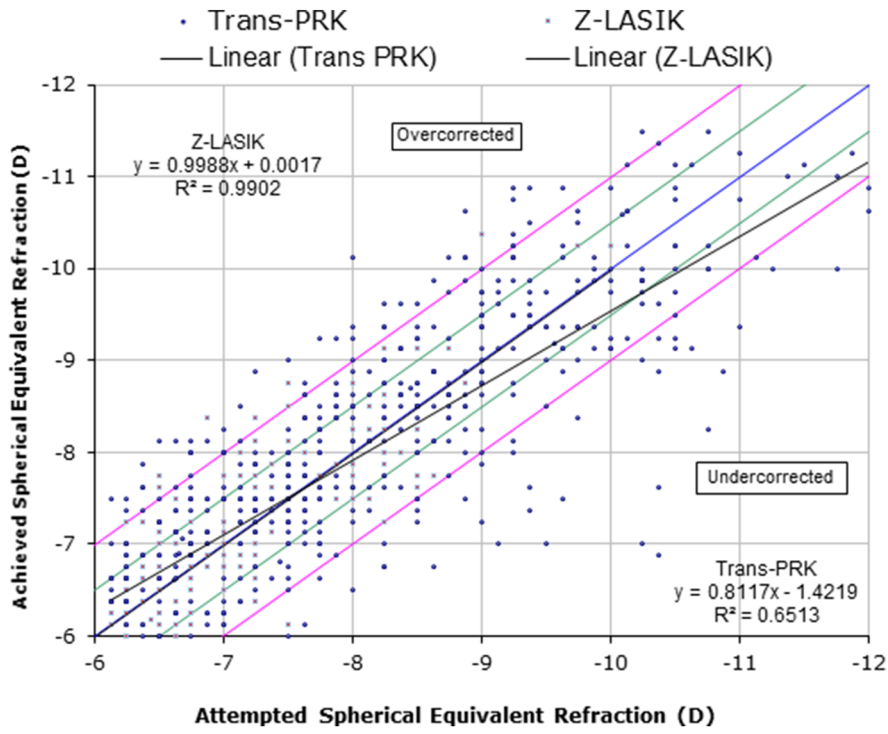

Fig. 2 Spherical equivalent attempted versus achieved

preoperative SE is described in Table 4 and Fig. 7. A Pearson's correlation was conducted as well and exhibited a statistically significant negative linear correlation between the patient's preoperative SE and the postoperative grade of corneal haze ($r = -0.20$, $P < 0.001$). Elevated intraocular pressure (IOP) was measured in only 6 eyes out 792 eyes in the study (0.76%) with no statistical difference between the 2 groups. Diffuse Lamellar Keratitis (DLK) was not diagnosed in any patient. Flap-related complications,

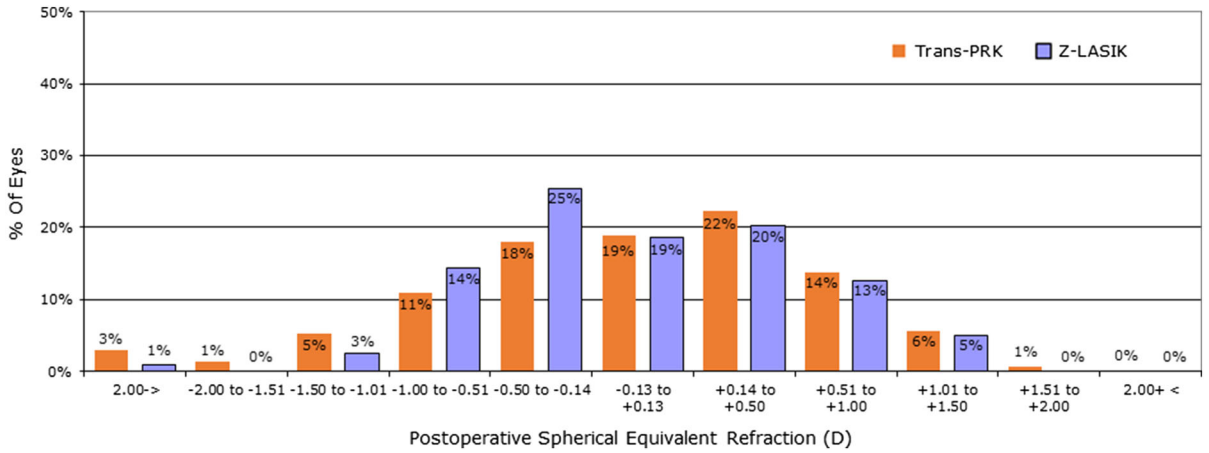

Fig. 3 Postoperative spherical equivalent refractive accuracy

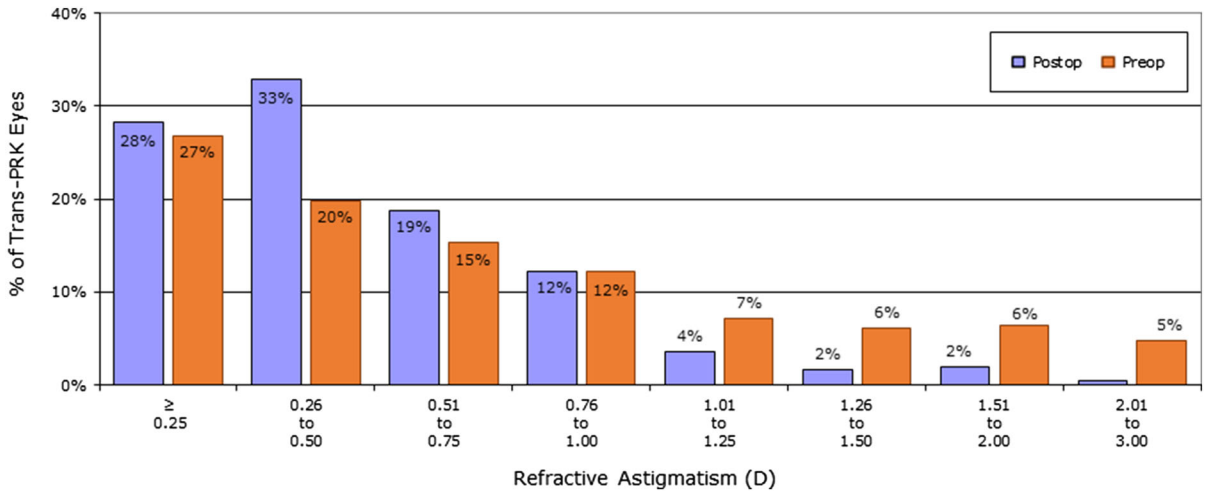

Fig. 4 Refractive astigmatism in Trans-PRK group

including nonvisual compromising microstria, occurred in 5 eyes out of 118 in the Z-LASIK group (4.24%).

Discussion

The adequate treatment for patients with high myopia has been a topic of controversy for many years in the field of refractive surgery. Two emerging technologies, the Z-LASIK and the Trans-PRK presume to give a safe and effective solution for these patients. The current study compared these two bladeless approaches in the correction of eyes with high myopia, and found that both Z-LASIK and Trans-PRK showed excellent safety, efficacy and predictability. To the best of our knowledge, this is the first report comparing Z-LASIK with Trans-PRK for the treatment of high myopia.

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 and with the percentage of eyes achieving an UCVA of 20/40 or better, which is the mandatory minimum requirement for driving without spectacles in the USA. In the contemporary literature, Trans-PRK for the treatment of high myopia achieved rates of UCVA of 20/40 or better between 95.4 and 100% [28, 29]. Efficacy index values for the treatment

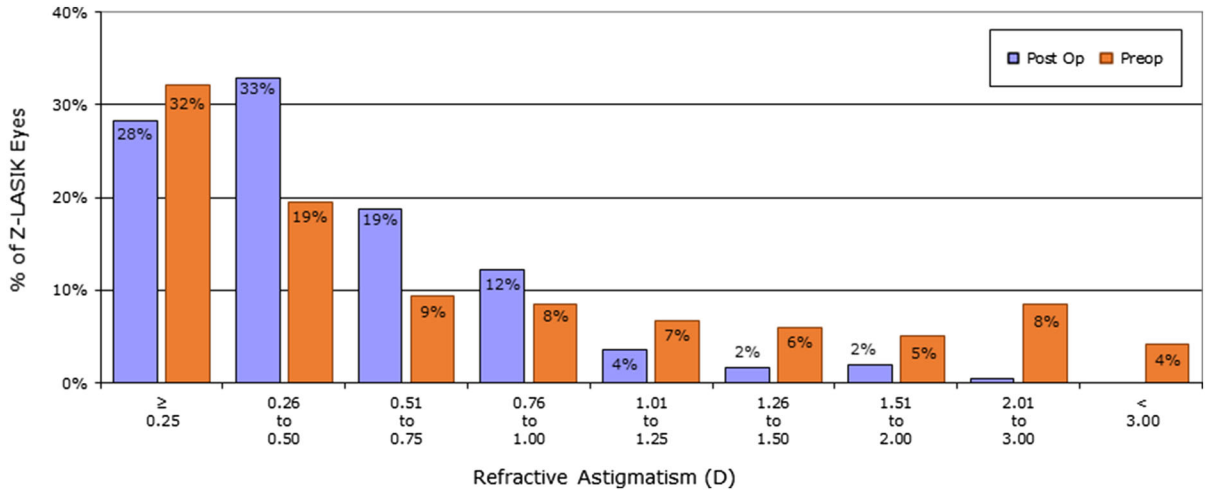

Fig. 5 Refractive astigmatism in Z-LASIK group

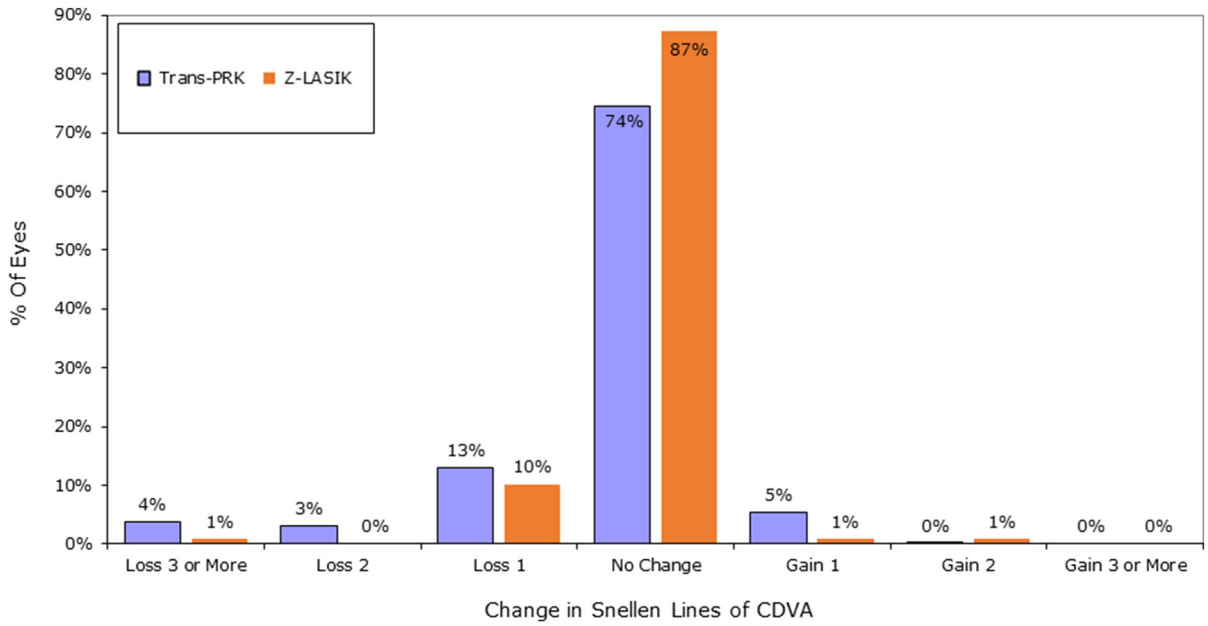

Fig. 6 Change in corrected distance visual acuity

Table 3 Complications

Parameter	Trans-PRK ($n = 674$)	Z-LASIK ($n = 118$)	P
Haze	8.16%	N/A	N/A
Elevated IOP	0.59%	1.69%	0.221
DLK	N/A	0.00%	N/A
Flap-related complications	N/A	4.24%	N/A
Regression	1.93%	0.00%	0.235
Overcorrection	0.00%	1.69%	0.022

Values represent percent of eyes

IOP intraocular pressure, *DLK* diffuse lamellar keratitis

Table 4 Postoperative corneal haze grading and its respective preoperative SE

Postoperative haze grade	Preoperative SE (D)
Grade 0 (619 eyes)	− 7.79 ± 1.40
Grade 1 (43 eyes)	− 8.42 ± 1.47
Grade 2 or more (12 eyes)	− 10.03 ± 2.35

Values are mean ± SD

ANOVA: $P < 0.001$

Pearson's correlation: $r = -0.20$ ($P < 0.001$)

of high myopia with FS-LASIK range between 0.91 and 0.97 [21–23, 26], and rates of UCVA 20/40 or better, between 88.2 and 99% [21, 23–26].

In our study, the efficacy of both procedures was comparable and in some cases even superior to previous studies describing treatment for high myopia. With an efficacy index of 0.95 and with 98.31% of eyes achieving an UCVA of 20/40 or better, the results of the Z-LASIK group were marginally better than those of the Trans-PRK group which had an efficacy index of 0.92 and 94.20% of eyes achieving an UCVA of 20/40 or better, though the advantage was not statistically significant. As a rule, due to the fact that we did not exclude patients with an impaired BCVA preoperative (numerous studies included only eyes with a BCVA of 20/25 or better preoperatively and some even of 20/20 or better), our percentage of eyes achieving an UCVA of 20/20 or better was lower than reported in some studies. This does not mean that the reported operations were not successful, as can be seen in our very high efficacy index which takes into account the preoperative BCVA.

In terms of predictability, the literature suggests that the percentage of eyes treated for high myopia that were within ± 0.5D of intended correction ranged between 17 and 71.6% for LASIK [28, 30, 31], 91.4 and 95.4% for Trans-PRK [28, 29], and 56 and 100% for FS-LASIK [20, 21, 23–26].

All of the patients in both our groups were targeted for emmetropia. In the Trans-PRK group 59.35% of the patients and 64.71% in the Z-LASIK group were within +/0.50D of the intended correction, a margin which was not statistically significant. For predictability, our Trans-PRK results were lower than those reported in the previous studies [28, 29], but one study excluded patients with myopia higher than − 10.0D and above − 4.0D astigmatism, and one study was conducted on only 35 eyes and patients with over − 3.5D astigmatism were excluded as well.

Until recently, a relatively high percentage of the patients undergoing refractive surgery for the correction of high myopia would lose 2 lines or more of BCVA postoperatively. In the book "refractive surgery outcomes and complications" from 2008 [32], the authors advised that an acceptable percentage of loss of 2 or more lines of BCVA at 6 months of follow-up must be between 1 and 5%.

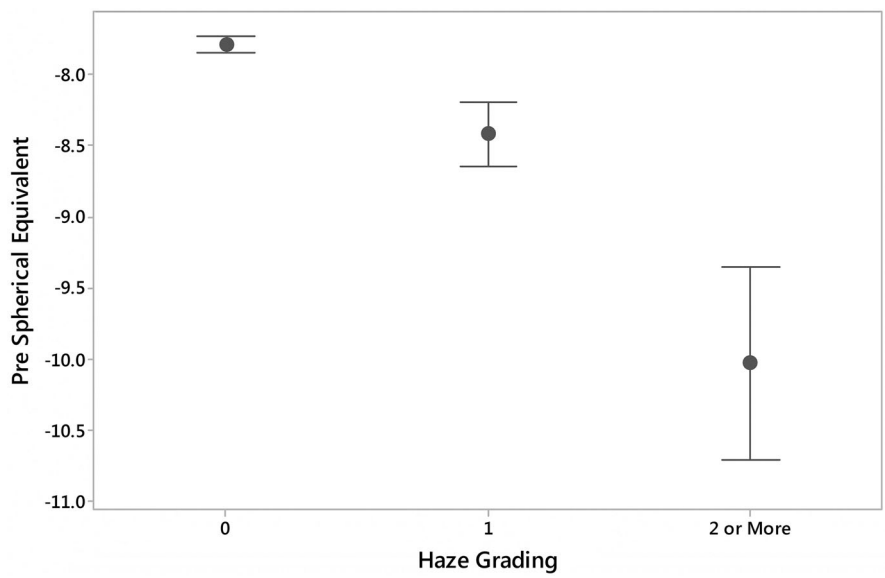

Fig. 7 Interval plot of preoperative spherical equivalent and postoperative corneal haze grading

The percentage of eyes with high myopia that lost 2 of more lines of BCVA postoperatively in similar studies ranged between 0.6 and 27% for LASIK [24, 28, 30, 33, 34], 0% for Trans-PRK [28, 29], and 0 to 2.3% for FS-LASIK [20, 22, 23]. In our study, 47 out 674 (7%) in the Trans-PRK group lost 2 or more lines—a higher percentage than advised in the aforecited book, though we have a negative bias in our group as will be explained further on. This rather high percentage might also be explained by the large rate of clinically apparent postoperative haze in our Trans-PRK group (8.16%), which indeed needs to be further evaluated. Only 1 eye out of 118 (0.8%) lost 2 lines or more in the Z-LASIK group (Fig. 6) which is extremely low, especially when considering the large amount of eyes examined.

In our study, the safety index in the Trans-PRK group and in the Z-LASIK group was 0.95 and 0.97, respectively, which is acceptable with regard to the safety index reported in the literature for high myopia [21–23, 30].

The complications of Trans-PRK and FS-LASIK are not vastly reported in the literature with regards to high myopia. The total incidence of all intraoperative LASIK flap complications that have been published in studies of $\geq$ 1000 eyes ranges from 0.3 to 5.7% [11]. Kulkamthorn et al. [23] reported on 5 eyes out of 43 that had stria postoperatively. Kojima et al. [24] found one DLK case, one flap-related complication and one epithelial ingrowth out of 320 eyes. There were other publications which did not mention having any complications [20, 22, 25, 26]. In our study, flap-related complications occurred in 5 eyes out of 118 (4.24%), 3 of which were nonvisual compromising microstria, and there was no DLK present in any eye.

Aslanides et al. [29] reported on up to 37% of eyes with clinically apparent haze 3 months postoperatively which reduced to about 2% 12 months postoperatively, while in our study the incidence of haze was 8.16%. This relatively high incidence of haze can be attributed to differences in the diagnosis and grading of haze, which can be variable among different observers. Another possible explanation is that the higher the preoperative SE is, so is the increased cumulative ablation energy which is employed in order to correct it, a reasoning which also explains the correlation we discovered between the preoperative SE and the grade of postoperative haze, which was further validated by a Pearson's correlation. Further studies are needed to investigate whether the Trans-PRK platform causes more haze than the PRK one, or is it merely a coincidence.

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, because we do not practice alcohol deepithelization in our clinic, and we rarely practice mechanical deepithelization, we were unable to perform a comparison between the above-mentioned and Trans-PRK—a comparison which would have added valuable knowledge regarding complications, haze level and reepithelization timing. Third, patients undergoing surgery at our clinic are not obliged to attend follow-up appointments. Therefore, those with a very good UCVA in the early postoperative examinations tended not to adhere to the full 12-month follow-up, whereas those with worse early outcomes were motivated to appear for reexamination. The consequent high attrition rate probably caused a negative bias in terms of efficacy in both groups. Fourth, there was also a potential negative bias in terms of the safety index/loss of BCVA because we do not routinely examine BCVA in patients with a good postoperative UCVA; instead, we use the postoperative UCVA value for both parameters. This may have lowered the expected safety index and increased the number of eyes that lost lines of BCVA postoperatively, in both groups. Another bias between both procedures consists of the fact that eyes with a degree of myopia higher than 10D were rarely operated with the Z-LASIK approach—thus creating a bias against the Trans-PRK group. In addition, when a patient underwent another operation to correct the remaining myopic error we only related to the results of the first operation in the analysis, thus lowering our cumulative results. The last negative bias acting against our results is that we did not exclude patients with a very high myopia which were excluded in some other studies, thus, again, lowering the eyes achieving an UCVA of 20/20 or better.

In conclusion, in this single-center retrospective study, we found both procedures to have excellent efficacy, safety and predictability profiles, with results comparable and in some cases superior to the current literature. The results of the Z-LASIK operation were slightly better than those of the Trans-PRK one, though the preoperative SE of the latter was significantly higher than that of the former. The findings

should be confirmed in prospective trials with longer follow-up.

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