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Original article

Comparison of microkeratome assisted sub-Bowman keratomileusis with photorefractive keratectomy

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Abstract

Purpose: To compare the outcomes of photorefractive keratectomy (PRK) and thin-flap Laser-Assisted in Situ Keratomileusis/sub-Bowman keratomileusis (SBK) with intended flap thicknesses of 100 μm using the One Use-Plus SBK microkeratome.
Methods: Ninety-eight eyes of 52 subjects with myopic manifest refraction spherical equivalent (MRSE) of up to −5 diopters (D), a stable refraction for 1 year and a corrected distance visual acuity (CDVA) of at least 20/20 in each eye which had undergone SBK or PRK were reviewed retrospectively. Primary outcome measures were MRSE, uncorrected distance visual acuity (UDVA), CDVA, pachymetry and higher order aberrations (HOA). All patients were seen at 1 and 3 days, 1 week, and 1, 3, and 6 months after surgery.
Results: Both MRSE and UDVA showed a statistically significant improvement at postoperative 1, 3 and 6 months from baseline in both SBK and PRK groups. At postoperative 6 months, 100% of eyes were within ±0.50 D of attempted correction in both groups. However, SBK group demonstrated better outcomes with 81% of eyes within ±0.13 D, compared to 70% eyes in the PRK group. Both SBK and PRK group demonstrated similar refractive astigmatism accuracy at postoperative 6 months, with 88% of eyes having cylindrical error ⩽0.25 D. None of eyes lost any lines of CDVA in the PRK, and 2% eyes lost one line of CDVA in SBK group at postoperative 6 months.
Conclusion: The visual and refractive outcomes after both PRK and microkeratome assisted SBK are comparable, albeit with a higher complication rate in the SBK group.

Keywords: Thin-flap LASIK, Sub-Bowman keratomileusis, SBK, Microkeratome assisted thin-flap LASIK

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Introduction

The excimer laser refractive correction procedures may be performed by surface or stromal ablation techniques. Surface ablation procedures [photorefractive keratectomy (PRK), Laser epithelial keratomileusis (LASEK) and Epi-Laser-Assisted in Situ Keratomileusis (Epi-LASIK)] are known to have better biomechanical outcomes when compared with thick flap-based stromal procedures [Laser-Assisted in Situ Keratomileusis (LASIK)].[1] However, surface ablation procedures are typically associated with greater postoperative discomfort, increased risk of haze and delayed recovery of visual acuity; therefore, LASIK with its rapid improvement in vision and lack of postoperative pain became the preferred option with patients.[2–4]

Creating a thinner flap provides a thicker residual stroma, resulting in a biomechanically more stable cornea and potentially lower incidence of ectasia.[5,6] Recent studies reveal that thin flap LASIK (intended flap thickness of ⩽100 μm) is safe and might have better outcomes than thick flap LASIK.[7–9] Eleftheriadis et al. reported that thinner flaps of 70–100 μm are associated with faster visual recovery [Uncorrected visual acuity (UCVA) at 1 week and 1 month] and less residual spherical equivalent (SE) at 1 month.[7] Similarly, Prandi et al. found that thin flaps of ⩽100 μm had better UCVA at 1 month and better residual SE at 6 months.[8] In addition, Cobo-Soriano

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et al. showed that thin flaps of <100 μm attained better contrast sensitivity and lower rate of enhancements.[9] These preliminary studies lead to an increasing interest in Sub-Bowman keratomileusis (SBK) or thin flap LASIK (<100 μm) which aims to combine the faster visual recovery of LASIK with the biomechanical benefits of surface ablation.[10–12]

Flaps for excimer laser stromal ablation can be created either by mechanical microkeratome or by femtosecond laser technique. While each method has advantages and disadvantages,[13] clinical experience over the past decade and previously published literature on LASIK indicates that there is no statistically significant difference in clinical outcomes between these two methods.[14–17] However, more research is needed to better understand the outcomes of these two methods for thin flap LASIK (SBK). Recent studies evaluating the outcomes of femtosecond assisted thin flap LASIK vs. PRK by Slade et al. (intended flap thickness of 100 μm) and Hatch et al. (intended flap thickness of 90 μm) have documented comparable results.[18,19] Since mechanical microkeratome is more commonly used in majority of the developing countries due to its cost-effectiveness, there is a need to evaluate the outcomes of PRK and microkeratome assisted SBK. Review of the current literature reveals that there is no study comparing PRK and microkeratome assisted SBK. Therefore, the present study aims to compare the outcomes of PRK and thin-flap LASIK (SBK) with intended flap thicknesses of 100 μm using the One Use-Plus SBK microkeratome (Moria, Antony, France).

Methods

The study involved a retrospective review of 98 eyes of 52 subjects (16 females and 36 males), with a mean age of 25.8 ± 5.4 years (range 18–40 years), who had undergone SBK or PRK at Tadawi Surgical Center, Taif, Saudi Arabia, by a single surgeon (T.A.) between February 2011 and June 2012. All patients were explained about the advantages, disadvantages and risks of both the procedures. The procedure to be carried out in each patient was based on the patients' preference. Prior to surgery, each eye underwent a complete eye examination, including manifest refraction spherical equivalent (MRSE), uncorrected (UDVA) and corrected distance visual acuity (CDVA), pachymetry (iPac® Pachymeter, Reichert Technologies, Reichert, Inc. Depew, NY, USA), corneal tomography (Pentacam; Oculus, Inc, Wetzlar, Germany) and higher order aberrations (HOA) (OPD scan 2, Nidek, Gamagori, Japan). Informed consent was obtained from all patients. Institutional review board approval for the study was obtained. All eyes underwent wave front-guided laser ablation treatment using a Nidek EC 5000 excimer laser (Nidek Co. Ltd, Aichi, Japan) following the manufacturer's operational instructions. Nomogram was adjusted so as to correct 95% of sphere and 111% of cylinder in the patients. The goal of all ablations was emmetropia.

Inclusion criteria were myopic MRSE of up to −5 diopters (D) (mathematically ⩾ −5 D), a stable refraction for 1 year (not fluctuating more than 0.5 D) and a CDVA of at least 20/20 in each eye. Soft contact lens wearers were required to discontinue lens use for 10 days prior to laser screening, whereas rigid contact lens wearers were required to discontinue use 3 weeks prior to laser screening and until the refractive error was stable.

The patients were screened for keratoconus or subclinical keratoconus on Pentacam. The Pentacam descriptors analyzed were keratometry (steep, flat and mean), pachymetry (central, thinnest and apex), corneal thickness progression indices, anterior and posterior elevation maps, anterior surface topometric indices, normalized deviation indices and overall deviation of normality [Belin/Ambrosio Enhanced Ectasia Display-Final D index (BAD-D)]. The patients showing abnormal values (⩾1.6) in the final D index[20–22] were excluded. Additional exclusion criteria included estimated residual stromal bed thickness (based on ultrasound pachymetry measurements) less than 350 μm and severe dry eye.

Surgical technique

Sub-Bowman's keratomileusis

For the SBK eyes, flaps were created using a One Use-Plus SBK microkeratome (Moria, Antony, France) with a planned flap diameter of 8.5 mm and an attempted flap thickness of 100 μm. The flap was lifted and excimer laser ablation of the stromal bed was performed. The flap was repositioned on the stromal bed. Corneal thickness was measured intraoperatively before and after flap creation with contact ultrasound pachymetry.

The average of 3 central measurements was recorded as corneal pachymetry. Achieved flap thickness was calculated by subtraction method [corneal pachymetry before flap creation minus stromal bed thickness after raising flap (before initiating excimer laser ablation)].

Photorefractive keratectomy

For the PRK eyes, an 8.5-mm diameter trephine was placed on the eye followed by the application of 20% ethanol for 35 s. The epithelium was then removed mechanically using a sponge. Wave front-guided ablation was performed using the Nidek EC 5000 excimer laser machine (Nidek Co. Ltd, Aichi, Japan) with a central optical zone of 6 mm and transition zone of 7.5 mm. All eyes received proparacaine 0.5% and tetracaine 0.5% drops pre- and intra-operatively. Antimetabolite, mitomycin C 0.4 mg/ml was used for 25 s in eyes with refractive error of more than 4 D. The corneal surface and the entire conjunctiva were then irrigated thoroughly with chilled balanced salt solution. A bandage contact lens (Bausch & Lomb SofLens 66; Bausch & Lomb, Rochester, NY) was placed on each PRK eye after treatment and left in place until the cornea reepithelialized.

All patients were instructed to use artificial eye drops (Refresh Plus®, Allergan, Inc., Irvine, CA, USA) every 2 h while awake, and moxifloxacin 0.5% (VIGAMOX® Alcon Laboratories, Inc., Fort Worth, TX, USA) 6 hourly. SBK eyes received prednisolone acetate 1% (PRED FORTE® Allergan, Inc., Irvine, CA, USA) every 6 h for 2 weeks, following which all medications were stopped except artificial tears, which were continued according to the individual patient's need. Instead of prednisolone acetate, PRK eyes received rimexolone 10 mg/ml (1%) (VEXOL®, Alcon Laboratories, Inc., Fort Worth, TX, USA) tapered over 2 months.

Statistical analysis

Primary outcome measures were MRSE, UDVA and CDVA (measured using Snellen chart). Ocular HOAs (RMS 6 mm)

were secondary outcome measures. Snellen's visual acuity measurements were converted into logMAR for statistical analysis. Refractive error, visual acuity (logMAR), and HOAs were treated as continuous variables and between the groups comparison was done by independent *t*-tests. Within a group, improvement over different time points was assessed by repeated measures ANOVA with Bonferroni post hoc tests for multiple time points or by paired *t*-test for 2 time points. In all tests, P values < 0.05 were considered statistically significant. Data analysis was done using SPSS software.

Results

Fifty-six eyes of 28 subjects underwent PRK and 42 eyes of 24 subjects underwent SBK. No patient lost to follow-up at postoperative 1, 3 or 6 months. Both groups were statistically comparable with regard to preoperative refraction, UDVA and CDVA. Preoperatively, mean MRSE was -2.36 ± 1.14 D and -2.33 ± 0.89 D in the SBK and PRK group respectively ($P = 0.864$) (Fig. 1A). Similarly, mean UDVA was 0.84 ± 0.32 logMAR and 0.90 ± 0.25 logMAR ($P = 0.260$, independent *t*-test), and mean CDVA was 0.00 ± 0.00 logMAR and 0.00 ± 0.00 logMAR (as all eyes were 20/20 preoperatively) in the SBK and PRK group respectively ($P > 0.05$) (Fig. 1B and C).

Both MRSE and UDVA showed a statistically significant improvement at postoperative 1, 3 and 6 months from baseline in both SBK and PRK groups ($P < 0.05$, repeated measures ANOVA with Bonferroni post hoc corrections). Fig. 1A and B demonstrates the improvement of mean MRSE and mean UDVA in both groups. It is apparent from the figures that the MRSE and UDVA in both groups improved significantly at postoperative one month and the improvement was maintained at postoperative 3 and 6 months.

Although a significant decrease in CDVA was observed in both SBK and PRK groups at postoperative 1 month (from baseline, $P < 0.05$, repeated measures ANOVA with Bonferroni post hoc corrections), it significantly improved at postoperative 3 months ($P = 0.001$, repeated measures ANOVA with Bonferroni post hoc corrections from postoperative 1–3 months), and reached preoperative values at postoperative 6 months in both SBK and PRK groups (Fig. 1C).

Fig. 2A describes the MRSE refractive accuracy in both groups at last follow-up. At postoperative 6 months, 100% of eyes were within ±0.50 D of attempted correction in both groups. However, SBK group demonstrated better outcomes with 81% of eyes within ±0.13 D, compared to 70% eyes in the PRK group. Both SBK and PRK groups demonstrated similar refractive astigmatism accuracy at postoperative 6 months, with 88% of eyes having cylindrical error $\leqslant 0.25$ D (Fig. 2B). The predictability scatter gram showing attempted versus achieved refractive correction at 6 months also demonstrates better predictability in the SBK group than the PRK group (Fig. 3).

Fig. 4 compares the efficacy of the SBK and PRK procedures. PRK demonstrates marginally better outcomes with 100% of the eyes being better than or equal to 20/20 compared to 98% in SBK group and similar proportion of eyes being 20/25 or better and 20/32 or better.

Both techniques demonstrated almost similar safety profiles, albeit marginally better for PRK group. While none of

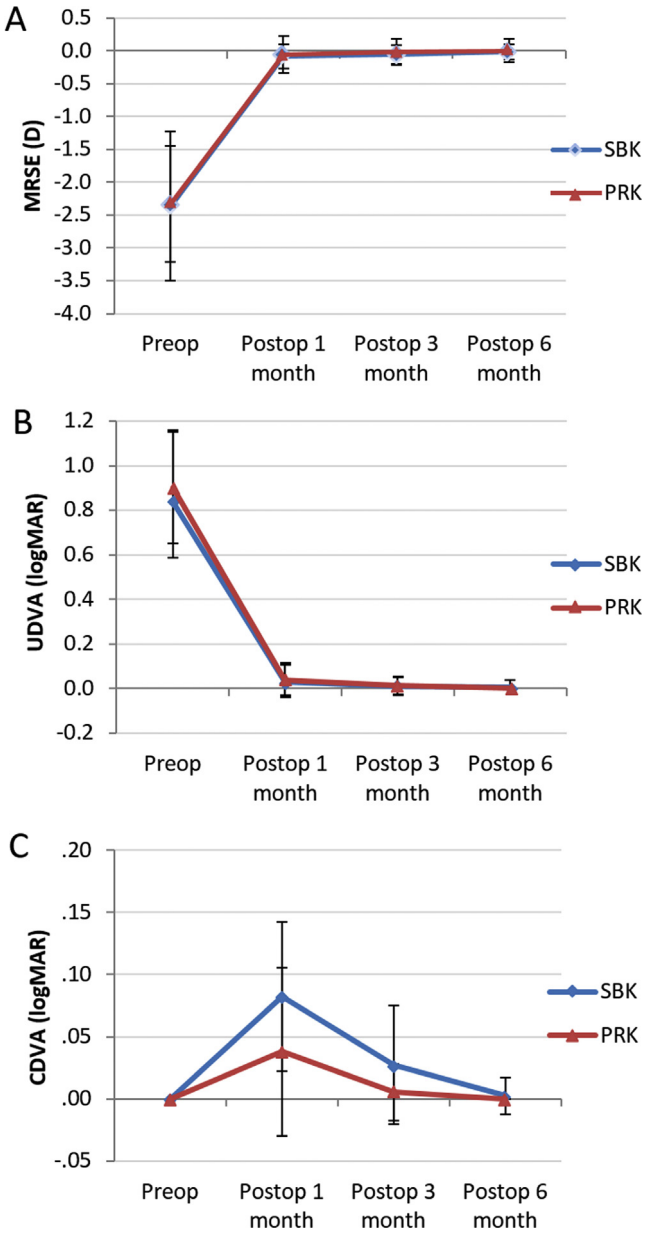

Fig. 1. Preoperative and postoperative 1, 3, and 6 months comparison of mean (A) MRSE; (B) UDVA and (C) CDVA in the SBK and PRK groups.

eyes lost any lines of CDVA in the PRK, one eye (2%) lost one line of CDVA in SBK group at postoperative 6 months (Fig. 5). Five eyes experienced complications in the SBK group (2 de-centered flaps, 2 flap striae and 1 free flap) compared to one eye (postoperative corneal infection) in the PRK group. Most of the complications resolved without visual sequelae. In the SBK group, two eyes developed central microstriae with resultant blurring of vision and were managed with conventional approach. Both eyes responded to treatment, while microstriae resolved completely in one eye, minimally persisting microstriae in the other eye which caused that eye to lose one line of CDVA (last recorded at 6 months visit). One eye developed epithelial haze of unclear etiology; however, it responded well to topical steroid therapy. One eye developed free flap; however, ablation was successfully completed in the same sitting followed by

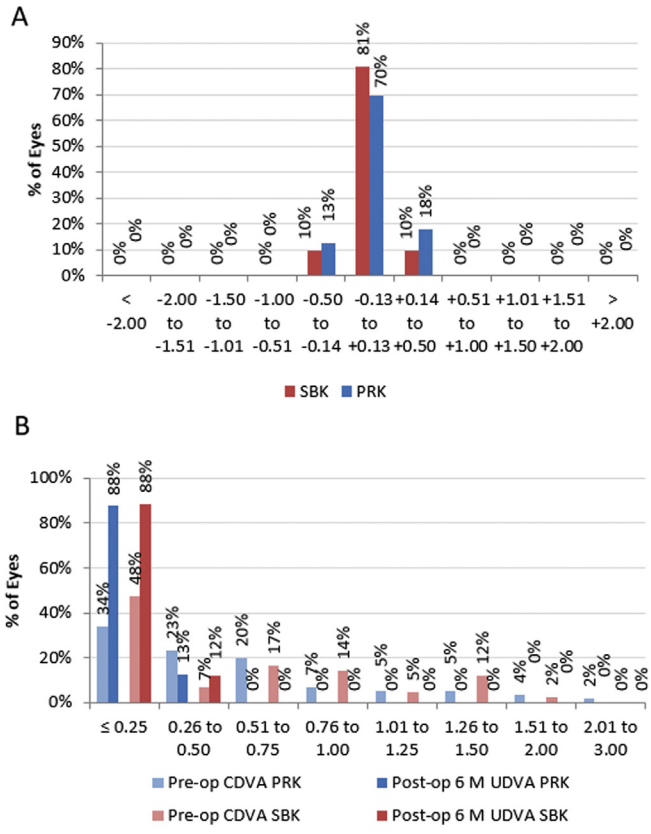

Fig. 2. Histograms demonstrating (A) spherical equivalent and (B) refractive astigmatism accuracy in SBK and PRK groups.

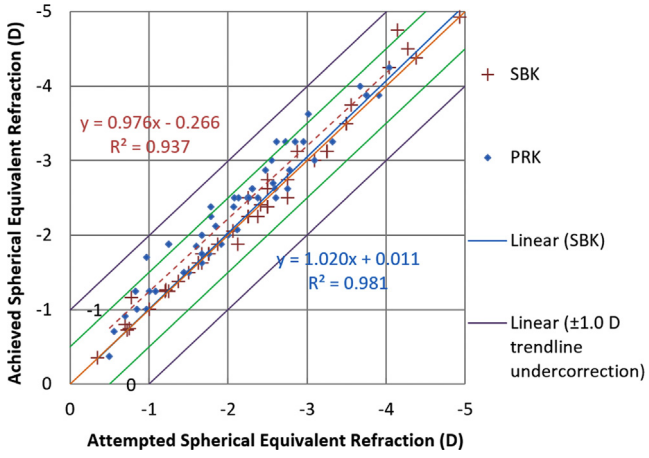

Fig. 3. Attempted vs. achieved spherical equivalent refraction in SBK and PRK group.

replacement of the free flap and bandage contact lens application for 2 days. In the PRK group, one eye developed keratitis but responded well to treatment with no residual sequelae.

An increase in total ocular HOAs (RMS 6 mm) was observed in both groups at 6 months, with mean values of 0.28 ± 0.11 μm and 0.32 ± 0.13 μm preoperatively to 0.35 ± 0.26 μm and 0.33 ± 0.22 μm at postoperative 6 months in the SBK group and PRK groups respectively; however, the change was not statistically significant in either group ($p > 0.05$, paired *t*-test). Increase in HOAs (postoperative HOA-preoperative HOA) in the PRK group was less than that in the SBK group, the difference being statistically not significant ($P > 0.05$, independent *t*-test).

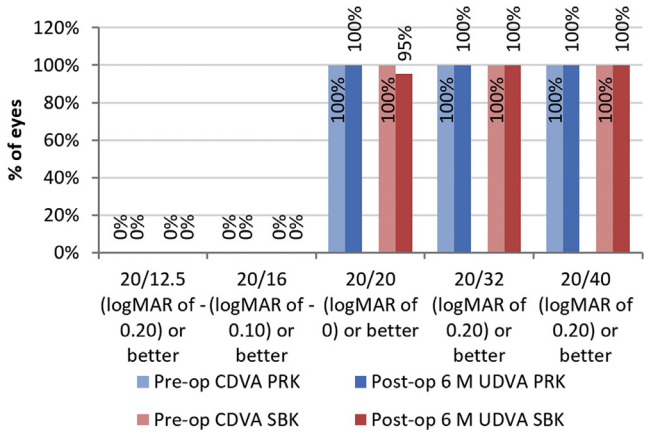

Fig. 4. Histogram showing comparison of preoperative CDVA and postoperative 6 months UDVA in both SBK and PRK groups.

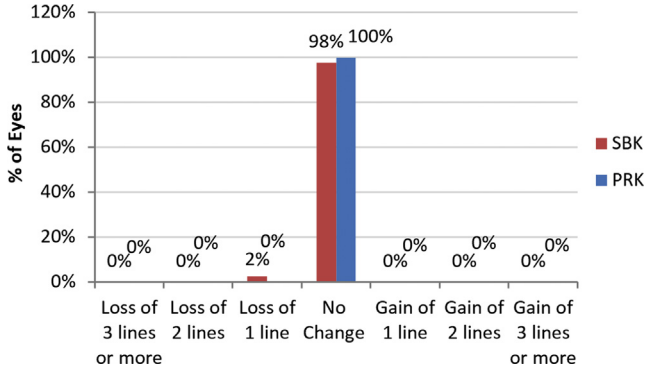

Fig. 5. Change in lines of CDVA at postoperative 6 months in SBK and PRK group.

Discussion

LASIK and PRK are the two most commonly performed refractive surgeries for the correction of myopia with both having their respective pros and cons.[23–26] PRK is associated with postoperative pain, corneal haze, and myopic regression but relatively little risk of developing ectasia.[27,28] To the contrary, LASIK offers rapid visual improvement and almost no postoperative pain, thereby becoming the preferred procedure for excimer laser refractive corrections.[29] However, due to the increased risk of corneal ectasia and other flap related complications, some surgeons prefer to opt for PRK.[30]

Sub-Bowman keratomileusis (SBK) is a hybrid approach with advantages of both LASIK and PRK; that is, it combines the faster visual recovery of LASIK with the biomechanical benefits of a surface ablation.[9,15] SBK is essentially a modification of LASIK procedure in which the flap is thinner than the conventional LASIK and several studies have documented the safety and efficacy of the procedure.[7–9,12] It is, therefore, worthwhile to compare the outcomes of PRK with SBK. Previous studies by Slade et al. and Hatch et al. focused on comparing the femtosecond laser assisted SBK with PRK.[18,19]

Even though femtosecond laser may create better and more uniform corneal flaps,[31–33] mechanical microkeratome still forms the preferred choice for a substantial majority of the surgeons. Therefore, there is a need to compare the outcomes of PRK and SBK using mechanical microkeratomes.

This study compared the refractive and visual outcomes between mechanical microkeratome assisted SBK and PRK for the correction of low to moderate myopia and found the two procedures to be clinically equivalent. Refractive predictability (Fig. 2A) was marginally better in SBK group and efficacy (Fig. 4) was marginally better in PRK group; however, there were no statistically significant differences in the outcomes of MRSE and UDVA, between the two groups, at postoperative 1, 3 or 6 months. Comparison of induced HOAs at 6 months also revealed the difference to be statistically not significant.

In contrast to the similar improvements for MRSE and UDVA in both the study groups, CDVA was found to worsen at Month 1, with more worsening in the SBK group. Although the worsening of CDVA in PRK group at postoperative 1 month was expected (due to development of corneal haze), it was unpredicted in SBK group. Possibly, the formation of flap striae in the initial postoperative period after SBK led to the worsening of CDVA. CDVA improved in both the groups at postoperative 3 months and reached preoperative levels at postoperative 6 months ($p > 0.05$). HOAs were studied preoperatively and postoperative at 6 months; within the group analysis for induction of HOAs revealed that there was postoperative increase in HOA in both groups; however, the change was not statistically significant compared to preoperative values.

Our results are in concordance with the previous literature in terms of achieving similar outcomes in both PRK and SBK at postoperative 6 months. Slade et al. studied differences in the visual and refractive parameters, in eyes undergoing either PRK or femtosecond assisted SBK at 1, 3, and 6 months after surgery and found no statistically significant difference between the 2 groups at 6 months.[10] Similarly, Hatch et al. also found that PRK and femtosecond assisted thin-flap LASIK achieved similar results in visual acuity, contrast sensitivity, and induction of HOAs at 6 months.[19] Additionally, similar to Hatch et al.'s finding of a higher complication rate in SBK group (35% of eyes in the thin-flap LASIK group vs. 7.7% in the PRK), we found that 5 eyes (11.9%) experienced complications in the SBK group, compared to one eye (1.8%) in the PRK group.

In contrast to the relatively better visual outcomes at 1 and 3 months in the SBK group reported by Slade et al. and Hatch et al., we did not notice a similar trend in our series. Although we did not assess the pain and discomfort in the current study, we expect that patients who had undergone PRK would have experienced more pain than the ones who underwent SBK. PRK patients also needed medications for a longer duration (2 months vs. 2 weeks) compared to SBK.

Limitations of our study included retrospective design, relatively small sample size and the absence of data evaluating patients' responses regarding pain and discomfort experienced after surgery and overall satisfaction rate. Longer studies are needed to evaluate whether the differences in biomechanical strength between the post-PRK and post-SBK eyes will translate into the lower risk for developing ectasia.

The results of this study indicate that the short-term visual and refractive outcomes of both PRK and mechanical microkeratome assisted SBK are comparable, albeit with a higher complication rate in the SBK group.

Conflicts of interest

The authors declared that there is no conflict of interest.

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