Comparison of microkeratome assisted sub-Bowman keratomileusis with photorefractive keratectomy

Talal A. Althomali

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

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)]. 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. Creating a thinner flap provides a thicker residual stroma, resulting in a biomechanically more stable cornea and potentially lower incidence of ectasia. Recent studies reveal that thin flap LASIK (intended flap thickness of ≤100 µm) is safe and might have better outcomes than thick flap LASIK. 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. Similarly, Prandi et al. found that thin flaps of ≤100 µm had better UCVA at 1 month and better residual SE at 6 months. In addition, Cobo-Soriano

Received 24 January 2016; received in revised form 17 January 2017; accepted 18 January 2017; available online 29 January 2017.

Taif University, PO Box 795, Taif 21944, Saudi Arabia
e-mail address: tthomali@hotmail.com
et al. showed that thin flaps of <100 μm attained better contrast sensitivity and lower rate of enhancements. 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.

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, 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. 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. 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) with a central optical zone of 6 mm and transition zone of 7.5 mm. All eyes received preoperative (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, Irvine, CA, USA) every 2 h 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 preoperative 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 \(-2.36 \pm 1.14\) D and \(-2.33 \pm 0.89\) D in the SBK and PRK group respectively (\(P = 0.864\) (Fig. 1A). Similarly, mean UDVA was \(0.84 \pm 0.32\) logMAR and \(0.90 \pm 0.25\) logMAR (\(P = 0.260\), independent t-test), and mean CDVA was \(0.00 \pm 0.00\) logMAR and \(0.00 \pm 0.00\) 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 \(\pm 0.50\) D of attempted correction in both groups. However, SBK group demonstrated better outcomes with 81% of eyes within \(\pm 0.13\) 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 \(\leq 0.25\) 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. 1C).

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.](image-url)
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 $0.28 \pm 0.11 \mu m$ and $0.32 \pm 0.13 \mu m$ preoperatively to $0.35 \pm 0.26 \mu m$ and $0.33 \pm 0.22 \mu m$ 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).

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. 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.9,15 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

![Histogram demonstrating (A) spherical equivalent and (B) refractive astigmatism accuracy in SBK and PRK groups.](image)

![Attempted vs. achieved spherical equivalent refraction in SBK and PRK group.](image)

![Histogram showing comparison of preoperative CDVA and postoperative 6 months UDVA in both SBK and PRK groups.](image)

![Change in lines of CDVA at postoperative 6 months in SBK and PRK group.](image)
Even though femtosecond laser may create better and more uniform corneal flaps,\textsuperscript{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 post-operative 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.\textsuperscript{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.\textsuperscript{15} 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.

Acknowledgment

Writing, editing and statistics assistance were provided by IrisARC - Analytics, Research & Consulting (Chandigarh, India).

References

1. Kamiya K, Shimizu K, Ohmoto F. Comparison of the changes in corneal biomechanical properties after photorefractive keratectomy and laser in situ keratomileusis. Cornea 2009; 28:765–9.
2. Moller-Pedersen T, Cavanagh HD, Petrrelli WM, Jester JV. Stromal wound healing explains refractive instability and haze development after photorefractive keratectomy: a 1-year confocal microscopic study. Ophthalmology 2000;107:1235–45.
3. Carr JD, Patel R, Hersh PS. Management of late corneal haze following photorefractive keratectomy. J Refract Surg 1995;11: S309–13.
4. Shortt AJ, Bunce C, Allan BD. Evidence for superior efficacy and safety of LASIK over photorefractive keratectomy for correction of myopia. Ophthalmology 2006;113:1897–908.
5. Reynolds A, Moore JE, Naroo SA, Moore CB, Shah S. Excimer laser surface ablation – a review. Clin Experiment Ophthalmol 2010;38:168–82.
6. Randleman JB. Post-laser in-situ keratomileusis ectasia: current understanding and future directions. Curr Opin Ophthalmol 2006;17:406–12.
7. Eleftheriadis H, Prandi B, Díaz-Rato A, Morcillo M, Sabater JB. The effect of flap thickness on the visual and refractive outcome of myopic laser in situ keratomileusis. Eye (Lond) 2005;19:1290–6.
8. Prandi B, Baviera J, Morcillo M. Influence of flap thickness on results of laser in situ keratomileusis for myopia. J Refract Surg 2004;20:790–6.
9. Cobo-Soriano R, Calvo MA, Beltran J, Llovet FL, Baviera J. Thin flap laser in situ keratomileusis: analysis of contrast sensitivity, visual, and refractive outcomes. J Cataract Refract Surg 2005;31:1357–65.
10. Slade SG. Thin-flap laser-assisted in situ keratomileusis. Curr Opin Ophthalmol 2008;19:325–9.
11. Durrie DS, Slade SG, Marshall J. Wavefront-guided excimer laser ablation using photorefractive keratectomy and sub-Bowman’s keratomileusis: a contralateral eye study. J Refract Surg 2008;24: S77–84.
12. Azar DT, Ghanem RC, de la Cruz J, Hallak KA, Kojima T, Al-Tobaigy FM, et al. Thin-flap (sub-Bowman keratomileusis) versus thick-flap laser in situ keratomileusis for moderate to high myopia: case-control analysis. J Cataract Refract Surg 2008;34:2073–8.
13. Sun Y, Deng YP, Wang L, Huang YZ, Qiu LM. Comparisons of morphologic characteristics between thin-flap LASIK and SBK. Int J Ophthalmol 2012;5:338–42.
14. Li H, Sun T, Wang M, Zhao J. Safety and effectiveness of thin-flap LASIK using a femtosecond laser and microkeratome in the correction of high myopia in Chinese patients. J Refract Surg 2010;26:99–106.
15. Prakash G, Agarwal A, Kumar DA, Chari M, Agarwal A, Jacob S, et al. Femtosecond sub-bowman keratomileusis: a prospective, long-term, intereye comparison of safety and outcomes of 90- versus 100- \( \mu \)m flaps. Am J Ophthalmol 2011;152:582–590.e2.
16. Zhang ZH, Jin HY, Suo Y, Patel SV, Montes-Mico R, Manche EE, et al. Femtosecond laser versus mechanical microkeratome laser in situ keratomileusis for myopia: metaanalysis of randomized controlled trials. J Cataract Refract Surg 2011;37:2151–9.
17. Chen S, Feng Y, Stojanovic A, Jankov 2nd MR, Wang Q. IntraLase femtosecond laser vs mechanical microkeratomes in LASIK for myopia: a systematic review and meta-analysis. J Refract Surg 2012;28:15–24.

18. Slade SG, Durrie DS, Binder PS. A prospective, contralateral eye study comparing thin-flap LASIK (sub-Bowman keratomileusis) with photorefractive keratectomy. Ophthalmology 2009;116:1075–82.

19. Hatch BB, Moshirfar M, Ollerton AJ, Sikder S, Mifflin MD. A prospective, contralateral comparison of photorefractive keratectomy (PRK) versus thin-flap LASIK: assessment of visual function. Clin Ophthalmol 2011;5:451–7.

20. Ambrosio Jr R, Nogueira LP, Caldas DL, Fontes BM, Luz A, Cazal JO, et al. Evaluation of corneal shape and biomechanics before LASIK. Int Ophthalmol Clin 2011;51:11–38.

21. Belin MW, Steinmueller M. The brains behind the BAD. Ophthalmol Times Europe 2009.

22. Manual PU. Wetzlar, Germany: Oculus Optikgerate GmbBH; 2008.

23. Bower KS, Weichel ED, Kim TJ. Overview of refractive surgery. Am Fam Physician 2001;64:1183–90.

24. Huang SC, Chen HC. Overview of laser refractive surgery. Chang Gung Med J 2008;31:237–52.

25. Kaminski S, Lukas J. Refractive laser surgery of the cornea. Wien Med Wochenschr 1997;147:302–7.

26. Kohnen T, Strenger A, Klaproth OK. Basic knowledge of refractive surgery: correction of refractive errors using modern surgical procedures. Dtsch Arztebl Int 2008;105:163–70, quiz 70-2.

27. Rajan MS, Jaycock P, O’Brart D, Nystrom HH, Marshall J. A long-term study of photorefractive keratometry: 12-year follow-up. Ophthalmology 2004;111:1813–24.

28. Bricola G, Scotto R, Mete M, Cerruti S, Traverso CE. A 14-year follow-up of photorefractive keratectomy. J Refract Surg 2009;25:545–52.

29. Duffey RJ, Leaming D. US trends in refractive surgery: 2002 ISRS survey. J Refract Surg 2003;19:357–63.

30. Moisseiev E, Sela T, Minkev L, Varsano D. Increased preference of surface ablation over laser in situ keratomileusis between 2008–2011 is correlated to risk of ectasia. Clin Ophthalmol 2013;7:93–8.

31. Zhai CB, Tian L, Zhou YH, Zhang QW, Zhang J. Comparison of the flaps made by femtosecond laser and automated keratomes for sub-bowman keratomileusis. Chin Med J (Engl) 2013;126:2440–4.

32. Zhou Y, Tian L, Wang N, Dougherty PJ. Anterior segment optical coherence tomography measurement of LASIK flaps: femtosecond laser vs microkeratome. J Refract Surg 2011;27:408–16.

33. Zhou Y, Zhang J, Tian L, Zhai C. Comparison of the Ziemer FEMTO LDV femtosecond laser and Moria M2 mechanical microkeratome. J Refract Surg 2012;28:189–94.