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Moria One-Use Plus sub-Bowman’s keratomileusis head: a useful tool in the refractive surgeon’s armamentarium
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Introduction
Many characteristics of the cornea, including its physical strength, stability of shape, and transparency, are largely attributable to the anatomic and biochemical properties of the stroma. The stroma constitutes the largest portion (>90%) of the thickness of the cornea. Excimer laser ablation is carried out at the level of the stroma. To reach the corneal stroma, we have to both remove the corneal epithelium and perform a photorefractive keratectomy, or create a corneal flap using a mechanical microkeratome or a femtosecond laser and perform laser in situ keratomileusis (LASIK). The mechanical microkeratome uses an oscillating blade for sharp dissection, which passes across the corneal stroma in a rotational or translational approach. Sub-Bowman’s keratomileusis (SBK) is a LASIK procedure in which a special mechanical blade (SBK One-Use Plus blade) is used to create a thinner flap. The greatest advantage of creating a thin flap during SBK is that it leaves sufficient stromal tissue to allow safer excimer laser ablation, especially in patients with moderate or high myopia [1,2]. When the US Food and Drug Administration approved LASIK, it recommended that a minimum of 250 μm of residual stromal thickness should be left under the flap after LASIK surgery to avoid corneal ectasia. Currently, most LASIK surgeons prefer to leave 275–300 μm of residual stromal bed (RSB) for more safety. The thinner LASIK flap created with the SBK spares more stroma, increasing the available residual stromal thickness. Some reports [3–7] claim that the ideal flap thickness in LASIK should be 130 μm or more.

Patients and methods
A total of 500 eyes of 250 patients underwent laser in situ keratomileusis (LASIK) surgery using the One-Use Plus sub-Bowman’s keratomileusis head for the creation of an ultrathin LASIK flap. During the follow-up at 1, 6, 12, and 24 months, both uncorrected visual acuity (UCVA) and best-corrected visual acuity were recorded. A keratoconus screening corneal topography was carried out during the last follow-up visit.

Results
A total of 500 eyes of 250 myopic patients were included in this study. There were 115 male patients and 135 female patients. The mean age was 27.5 years (range: 18–44 years). The mean preoperative refractive error was −5.0 diopter sphere (DS) (range: −3 to −9 DS). The mean cylindrical error was −2.5 diopter cylinder (DC) (range: −0.75 to −4.5 DC). The mean UCVA was 0.07 (range: 0.01–0.3), and it improved to 1.0 (range: 0.8–1.25) on day 1 postoperatively. At the end of the follow-up, the mean UCVA was 1.0 and the mean best-corrected visual acuity was 1.0. The mean stromal residual bed thickness was 362 μm (range: 304–466 μm), and the mean central flap thickness was 102 μm (range: 82–120 μm). Complications were perilimbal bleeding in 15 eyes and fine irregular stromal edge cuts at the sides of the hinge in 10 eyes. There were no epithelial defects, no epithelial heaping or sliding, no irregular stromal bed surface cuts, no free caps or button holes, or incomplete flaps. Diffuse lamellar keratitis occurred in one eye of one patient, and no slipped flaps, macrostriae or microstriae, or epithelial downgrowth was seen during the follow-up period. At the end of the follow-up period none of our patients had topographic evidence of keratoconus.

Conclusion
The One-Use Plus sub-Bowman’s keratomileusis head is a safe and effective method for creating an ultrathin LASIK flap and allows the surgeon to treat higher errors of refraction while maintaining a higher safety margin by leaving more residual stromal tissue.

Keywords: cornea, laser in situ keratomileusis, Moria, One-Use Plus, sub-Bowman’s keratomileusis, sub-Bowman’s keratomileusis head

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because thin flaps may be associated with a higher frequency of potential complications such as flap folds, striae, epithelial ingrowth, and irregular astigmatism. Other studies evaluated the effect of intended thin flaps on the outcomes of LASIK surgery and proposed that intended thin flaps may be advantageous over thicker flaps for myopic LASIK [8–10]. Prandi et al. [8] showed that thin flaps were associated with better uncorrected visual acuity (UCVA) at 1 month and better residual spherical equivalent (SE) at 6 months. Eleftheriadis et al. [9] reported faster visual recovery (UCVA at 1 week and 1 month) and lower postoperative myopic spherical equivalent in eyes with thinner flaps. Cobo-Soriano et al. [10] found that patients with thin flaps achieved better contrast sensitivity and lower retreatment rates. These studies paved the way to SBK, which combines the advantages of LASIK and surface ablation [11]. The purpose of this study was to investigate the safety, efficacy, and advantages of the Moria One-Use Plus SBK head in the treatment of moderate and high myopia.

Patients and methods

Patients in this study were treated according to an approved protocol. All patients signed an informed consent form before each procedure.

A total of 500 eyes of 250 patients were included in this study. There were 115 male patients and 135 female patients. The mean age was 27.5 years (range: 18–48 years). All of the 250 patients were myopic. The plan was to leave an untouched RSB of 300 μm in all patients to increase safety. Creating a thinner flap using the SBK One–Use Plus blade increased the amount of myopic correction up to −8 diopters of sphere (DS) while keeping an RSB of 300 μm. Preoperatively, all patients underwent a slit lamp examination, including fundus biomicroscopy and applanation intraocular pressure measurement, corneal topography using the Allegretto Oculyzer (WaveLight, Alcon, A Novartis company), ultrasonic pachymetry using the DGH 55 Pachmate (DGPHachmate, DGHTechnology, Inc., 110 Summit Drive Suite B Exton, PA 19341, USA) hand-held pachymeter, scotopic pupil size evaluation, and both manifest and cycloplegic refraction. All acquired data recorded for each patient were entered into the Allegretto IQ 400 LASIK machine (WaveLight, Alcon, A Novartis company), and an assumed LASIK flap thickness of 100 μm was entered and the theoretical RSB was calculated accordingly. Only cases with an assumed RSB of more than 300 μm were included in the study.

Surgical procedure

All primary LASIK procedures were performed under topical anesthesia. The patient was positioned under the operating microscope of the Allegretto IQ 400 (WaveLight, Alcon, A Novartis company) excimer laser. Two drops of tetracaine 0.5% were instilled in the eye. The central corneal thickness was measured three times with the ultrasonic pachymeter and the mean recorded as the preflap thickness. A corneal marker was used to mark the cornea. The microkeratome suction ring was placed on the eye, and suction was applied. The microkeratome Moria SBK One-Use Plus was used to create the flap. The flap was retracted and the central corneal bed thickness was measured three times with the ultrasonic pachymeter; the mean was recorded as the postflap thickness. The ablation was completed in a routine manner and the flap repositioned into its primary position. A Merocel sponge was brushed across the cornea away from the hinge three or four times to remove excess fluid from the interface, and the flap edge was dried. The corneal markings were checked for proper alignment. The patients received a topical steroid antibiotic suspension (Tobradex) and antibiotic drops (Vigamox; Alcon, A Novartis Division) four times daily for 10 days. The postoperative course was uneventful in all cases.

Main outcome measures were as follows: preoperative visual acuity (VA) and refractive error and corneal thickness of the eyes of enrolled patients, RSB thickness, intraoperative central flap thickness, incidence of complications, postoperative VA on day 1 postoperatively, and final postoperative visual outcome at the end of the 2-year follow-up. Appendix 1 and 2 show the Moria SBK motor, blade and ring, assembly and SBK technique illustrated in photos.

Results

A total of 500 eyes of 250 patients were included in this study. There were 115 male patients and 135 female patients. The mean age was 27.5 years (range: 18–44 years). All of the 500 patients were myopic. The mean preoperative refractive error was −5.0 DS (range: −3 to −9 DS), and the mean cylindrical error was −2.5 diopter cylinder (DC) (range: −0.75 to −4.5). The mean UCVA was 0.07 (range: 0.01–0.3), and it improved to 1.0 (range: 0.8–1.25) on day 1 postoperatively. At the end of the follow-up, the mean UCVA was 1.0 and the mean best-corrected VA was 1.0. The mean stromal residual bed thickness was 362 μm (range: 304–466 μm), and the mean central flap thickness was 102 μm (range: 82–120 μm). Table 1 shows the results.
Complications
Intraoperative complications were minimal and confined to perilimbal bleeding in 15 eyes and fine irregular stromal edge cuts at the sides of the hinge in 10 eyes (Fig. 1).

There were no epithelial defects, no epithelial heaping or sliding, no irregular stromal bed surface cuts, no free caps, and no button holes or incomplete flaps.

Postoperative complications were limited to one case of diffuse lamellar keratitis in one eye of one patient; no slipped flaps, macrostriae or microstriae, or epithelial downgrowth was seen during the follow-up period. At the end of the follow-up period none of our patients had topographic evidence of keratoconus.

Table 2 shows encountered complications.

Discussion
The One-Use Plus SBK blade used in this study is assumed to produce a LASIK flap thickness of 100 μm. In this study, the blade was used on 500 eyes of 250 patients. The efficacy and safety of the blade was evaluated with regard to complications resulting from the blade cut and also by studying the final visual outcome and incidence of post–LASIK ectasia or keratoconus at the end of the 2-year follow-up period as well as speed of postoperative VA recovery.

Various studies evaluating the effect of corneal flap thickness published conflicting results. Yi and Joo [12] mentioned that thicker flaps of 165 μm and above resulted in slightly better visual outcomes when compared with flaps of 135 μm or less. Pisella et al. [13] found higher postoperative cellular activation in posterior stroma in patients in whom an unintended thin flap occurred using a mechanical microkeratome for creating a flap of 160 μm.

Durrie et al. [11] reported an early and better VA result when an SBK blade was used to intentionally create a LASIK flap of 100 μm or less. Cobo-Soriano et al. [10] found that thin flaps were associated with better contrast sensitivity and lower retreatment rates. Prandi et al. [8] showed that patients with flaps of 100 μm or less had better functional results at 1 month than those with thicker flaps.

Dimitri et al. [14] attributed worse visual acuities associated with thin flaps to unintentional complications during flap creation, resulting in irregular thin flaps, when using microkeratomes originally designed to create flaps of 160 μm or more.

Chen et al. [15] in a meta-analysis comparing IntraLase with mechanical microkeratomes found no difference in efficacy or safety.

In this study we found a fast VA recovery in all cases with an average VA of 1.0 on day 1 postoperatively. We did not encounter any flaps with folds, stria, loose epithelium, or button holes. We did not encounter loss of suction nor did we face difficulty in fixing the Moria SBK ring in any of the cases, even in eyes with a narrow palpebral fissure.

Perilimbal bleeding that occurred in 15 cases occurred in a lesser frequency as we went through our study and learned to use higher ring selections for small corneas and the highest ring selection possible for a certain steepest K reading as found in the SBK Moria ring.
selection nomogram, which resulted usually in a smaller flap size and less perilimbal bleeding.

Serrated irregular cuts occurring at the hinge sides tended to decrease in number as we became very careful in stopping the Moria motor as soon as it reached the endpoint. The serrated edges that occurred in the 10 eyes in our study, however, had no consequences and were all healed on the first postoperative day without any case of epithelial ingrowth throughout the study.

Post-Lasik ectasia and keratoconus were not found in any of our cases until the very end of the 2-year study. This could be partially attributed to the thicker RSB we could retain after LASIK ablation because of the thin flap created with the SBK microkeratome as well as other preoperative selection criteria, such as refractive error, preoperative corneal thickness, and pupil size.

The absence of a comparison group with thicker flaps to compare with our thin SBK flaps limits the results of our study. However, vast literature on different visual outcomes with different flap thickness could be found elsewhere, and our main purpose was not to compare thin with thick flaps but rather to evaluate the safety and efficacy of the Moria SBK blade.

Two other parameters could make our study even more valuable – namely, contrast sensitivity and corneal hysteresis study. However, they were not incorporated in this study as we used the UCVA as an indication of visual outcome after the procedure and the nil incidence of corneal postoperative topographic ectasia at the end of the follow-up period as an indication of corneal stability after the SBK LASIK flap creation.

Studies incorporating longer follow-up periods, corneal hysteresis, and comparing contrast sensitivity after SBK flaps with other methods of flap creation could be an addition to this study.

On the basis of the current literature and results of our study, we found that the One-Use Plus SBK head is a safe and effective method for the creation of an ultrathin LASIK flap and allows the surgeon to treat higher errors of refraction while maintaining a higher safety margin by leaving more residual stromal tissue.

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Conflicts of interest There are no conflicts of interest.

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