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ORIGINAL ARTICLE

# Intraoperative flap complications in laser in situ keratomileusis with two types of microkeratomes ☆

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**Abstract** *Purpose:* To determine the incidence and types of intraoperative flap complications in laser in situ keratomileusis (LASIK) encountered with the Hansatome microkeratome and the Moria microkeratome.

*Methods:* In this retrospective case series, all patients with intraoperative flap complications who were treated between June 1999 and July 2008 at the Eye Consultants Center in Riyadh, Saudi Arabia, were identified and reviewed.

*Results:* Of the 4352 subjects who underwent bilateral primary LASIK procedure, intraoperative microkeratome complications were detected in 89 eyes of 83 patients. The overall incidence of flap complications was 89/8704 (1.00%): incomplete flaps occurred in 53 eyes (0.60%), followed by buttonhole flaps in 17 eyes (0.19%), free complete flaps in 10 eyes (0.11%), free partial flaps in 6 eyes (0.07%), sluffed epithelium in 2 eyes (0.023%), and a splitted flap (vertical flap cut) in 1 eye (0.01%). The incidence rates of intraoperative flap complications with the Hansatome microkeratome and the Moria microkeratome were 1.21% (41/3378) and 0.90% (48/5326), respectively ($P = 0.19$). There was a statistically significant difference between the two microkeratomes with

☆ The study was performed as per the tenets on the Declaration of Helsinki.

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regard to the incidence of buttonhole flaps: 0.33% (11/3378) for the Hansatome microkeratome versus 0.11% (6/5326) for the Moria microkeratome ($P = 0.04$).

*Conclusion:* Generally, the incidence rates of intraoperative flap complications with the Hansatome microkeratome and the Moria microkeratome were similar. However, buttonhole flaps occurred more often with the Hansatome microkeratome (a type of microkeratome that produces larger flaps). The commonest complication encountered was the incomplete flap, followed by the buttonhole flap and free flap.



## 1. Introduction

Laser in situ keratomileusis (LASIK) is a popular method for the surgical correction of refractive errors (Esquenazi and Mendoza, 1999; Knorz et al., 1996). Creating a corneal flap is one of the most critical steps for successful LASIK. Poor keratectomy may be the most worrisome intraoperative complication facing refractive surgeons. However, flap complications such as buttonhole flaps, free flaps, incomplete flaps, and lacerated flaps are considered to some extend avoidable. In extreme cases, corneal perforation can result in damage to the iris and the lens (Pallikaris and Siganos, 1997).

An ideal microkeratome should be reliable, highly predictable, and easy to use so as to create a good quality flap. In this study, we determined the incidence and nature of poor keratectomy in primary LASIK with two different types of microkeratomes.

## 2. Patients and methods

In this retrospective study, we identified all cases that developed significant microkeratome complications as a result of poor keratectomy between June 1999 and July 2008 at the Eye Consultants Center in Riyadh, Saudi Arabia. During the study period, a total of 4352 subjects underwent bilateral primary LASIK procedure by eight refractive surgeons. All patients were 18 years or older and had a stable refraction for at least 1 year. Subjects who were pregnant, had a history of ocular pathology (e.g., dry eye, glaucoma, or retinal disease), a history of corneal disease (e.g., subclinical or clinical keratoconus), had previously undergone ocular surgery (including refractive corneal surgery), or had worn contact lenses for the past 2 weeks were excluded from the study.

Because of the relatively large number of surgeons involved, no uniform surgical technique was used. However, the standard LASIK technique was generally commenced. Simultaneous bilateral surgeries were performed, with the right eye always receiving the initial treatment. All LASIK flaps were created with either the Hansatome microkeratome (Bausch & Lomb, Rochester, NY) or the Moria LSK2 Carriazo-Barraquer manual microkeratome (Moria SA, Anthony, France). For the Hansatome microkeratome, a superiorly placed hinge flap was created with a 160- or 180-μm gap head and either an 8.5- or 9.5-mm suction ring. For the Moria microkeratome, a 9.0-mm superiorly placed hinged flap was created with a 130-μm plate. A −1 ring was used for corneas with a mean keratometry of 41 diopters (D), a 0 ring was used for a mean keratometry of 41–43 D, a +1 ring was used for a mean keratometry of 43–46 D, and a +1 or +2 ring was used if the mean keratometry was more than 46 D. Microkeratome assembly followed by the inspection of the suction ring and the microkeratome blade under a microscope was performed by the surgeon before commencing the procedure. The same blade was used for microkeratome translation in both eyes of the same patient. The microkeratomes were serviced regularly in accordance with company recommendations or whenever difficulties or abnormalities with the microkeratomes were noted. Laser ablations were performed with the NIDEK EC-5000 Excimer Laser (Nidek, Gamagori, Japan).

Data collected from the files included patient's age, gender, preoperative refraction, and mean keratometry and pachymetry values. Flap complications were classified as incomplete flaps, buttonhole flaps, free (complete or partial) flaps, and others. The association between two categorical variables was investigated using the Fisher exact test. A $P$ value less than 0.05 was considered statistically significant. The study conforms to the tenets of the Declaration of Helsinki.

## 3. Results

Between June 1999 and July 2008, 4352 subjects (8704 eyes) had primary LASIK. Of these, 89 eyes of 86 patients with intraoperative microkeratome complications were identified. Among the 83 affected patients in the study, 53 (61.6%) were men and 33(38.4%) were women. The mean patient age was 26.6 ± 8 years (range: 18–53 years). The mean preoperative spherical equivalent (SE) was −3.1 ± 2.8 D (range: +4.25 to −14.75 D), the mean keratometry value was 43.2 ± 1.64 D (range: 38–47 D), and the mean pachymetry value was 546.8 ± 36.3 μm (range: 461–646 μm).

The overall incidence of flap complications was 89/8704 (1.00%): Incomplete flaps occurred in 53 eyes (0.60%), followed by buttonhole flaps in 17 eyes (0.19%), free complete flaps in 10 eyes (0.11%), free partial flaps in 6 eyes (0.07%), sluffed epithelium in 2 eyes (0.023%), and a splitted flap (vertical flap cut) in 1 eye (0.01%).

Of the complications, 42 (0.97%) occurred in the right eye, and 47 (1.03%) in the left eye. Of these, 3 patients developed flap complications in both eyes (one with incomplete pass, one with free flap, and one patient with sluffed epithelium). There was no statistically significant difference between right and left eyes for all types of flap complications (Table 1). For the eight surgeons combined, the overall rate of microkeratome complications were 1 in 87 (1.15%) in the first 2176 cases, decreasing to 1 in 111.6 (0.90%) in the last 2176 cases ($P = 0.28$, Fisher exact test).

Intraoperative flap complications occurred with the Moria microkeratome in 48 eyes (54%), whereas it occurred with the Hansatome microkeratome in 41 eyes (46%). The LASIK procedure was performed with the Hansatome microkeratome

**Table 1** Comparison between right and left eye intraoperative microkeratome complications.

| Complication | Right eye | | Left eye | | *P* value |
|---|---|---|---|---|---|
| | *n* | Incidence (%) | *n* | Incidence (%) | |
| Incomplete pass | 26 | 0.30 | 27 | 0.31 | 0.99 |
| Buttonhole flap | 6 | 0.07 | 11 | 0.13 | 0.33 |
| Free complete flap | 6 | 0.07 | 4 | 0.05 | 0.75 |
| Free partial flap | 2 | 0.023 | 4 | 0.05 | 0.70 |
| Sluffed epithelium | 1 | 0.01 | 1 | 0.01 | 0.99 |
| Splitted flap | 1 | 0.01 | – | – | – |
| Total | 42 | 0.49 | 49 | 0.55 | 0.53 |

**Table 2** Comparison of intraoperative flap complications between Hansatome and Moria microkeratomes.

| Complication | Hansatome | | Moria | | *P* value |
|---|---|---|---|---|---|
| | *n* | Incidence (%) | *n* | Incidence (%) | |
| Incomplete pass | 24 | 0.71 | 29 | 0.55 | 0.4 |
| Buttonhole flap | 11 | 0.33 | 6 | 0.12 | 0.04* |
| Free complete flap | 3 | 0.09 | 7 | 0.13 | 0.75 |
| Free partial flap | 3 | 0.09 | 3 | 0.06 | 0.68 |
| Sluffed epithelium | – | – | 2 | 0.04 | – |
| Splitted flap | – | – | 1 | 0.02 | – |
| Total | 41 | 1.21 | 48 | 0.90 | 0.19 |

in 3378 eyes (38.8%), whereas it was performed with the Moria microkeratome in 5326 eyes (61.2%), thus indicating that the overall incidence rates of intraoperative flap complications with the Hansatome microkeratome and the Moria microkeratome were 1.21% (41/3378) and 0.90% (48/5326), respectively ($P = 0.19$, Fisher exact test). With regard to incomplete or free flaps, no statistically significant differences were detected between the two microkeratomes. However, a statistically significant difference between the two microkeratomes was found with regard to buttonhole flaps: 0.33% (11/3378) for the Hansatome microkeratome versus 0.11% (6/5326) for the Moria microkeratome ($P = 0.04$, Fisher exact test) Table 2.

## 4. Discussion

Although LASIK has some advantages over surface ablation (Wang et al., 1997; Helmy et al., 1996), its primary disadvantage is that flap-related complications can occur. The cumulative percentage of keratome-related complications published in various series is reported to be 17% (Farah et al., 1998), ranging from 0.3% (Walker and Wilson, 2000) to 20% (Pallikaris and Siganos, 1997). We found an overall incidence of 1.00% for intraoperative microkeratome complications, which compares favorably with those found by other authors.

The etiopathogenesis of poor keratectomy has been postulated to be multifactorial. Mechanical microkeratome obstructions in the speculum, drape, lid, and lashes have been suggested as a cause of incomplete flaps (Lin and Maloney, 1999). In addition, a damaged blade, balanced salt solution deposits on the blade during the second eye cut, and surgeon inexperience have been postulated as contributory factors to the occurrence of incomplete flaps (Jacobs and Taravella, 2002). Buttonhole LASIK flaps occur when the microkeratome blade exits through the epithelium during the mid-incision and then reenters to complete the flap. Research suggests that the etiology of buttonhole flaps includes steep corneas, small corneal diameters, deep eye sockets, loss of suction ring pressure, and conjunctival incarceration in the suction port, which can lead to loss of suction during flap creation (Farah et al., 1998). In addition, the more friable epithelium in the second eye as a result of longer anesthetic action (Pulaski, 2000) and aspects (e.g., blunted blades, microflaws of blades, and poor oscillation) related to the microkeratome (Leung et al., 2000) have been suggested as predisposing factors for buttonholes. Free flaps (partial or complete) may occur because of a loss of suction during the microkeratome pass that causes shallow engagement of the keratome on the corneal surface, which allows the blade to skim across the top of the cornea and produce a free cap (Stulting et al., 1999).

In this study, we found that the incidence rates of complications with the Hansatome microkeratome and the Moria microkeratome were 1.21% and 0.90%, respectively. These incidence rates are in agreement with the reported studies where it was found that the incidence of flap complication with the Hansatome microkeratome and the Moria microkeratome were 0.16–1.22% (Walker and Wilson, 2000; Jacobs and Taravella, 2002; Nakano et al., 2004; Ito et al., 2004) and 0.77% (Ito et al., 2004), respectively.

Although Hansatome microkeratomes have the advantage of performing a large flap diameter that may reduce flap complications such as postoperative flap displacements, our study demonstrated that buttonhole flaps were statistically more prevalent with the Hansatome microkeratome compared to the Moria microkeratome ($P < 0.05$). Our finding is in agreement with those of two previous studies (Tham and Maloney, 2000; Al-Mezaine et al., 2009). As suggested by Tham and Maloney (2000), microkeratomes that produce large flaps, such as the Hansatome, may flatten a greater area of the corneal surface and, in the presence of inadequate intraocular pressure, may produce dimpling centrally, thus resulting in the formation of a buttonhole flap.

The incidence of an intraoperative flap complication profile in this series is comparable to what has been reported in other studies: an incidence rate of 0.60% for incomplete flaps in this study versus a range of 0.7–6.6% in the literature (Knorz et al., 1996; Lyle and Jin, 1996; Manche and Maloney, 1996), an incidence rate of 0.19% for buttonhole flaps in this study versus a range of 0.04–2.60% in the literature (Farah et al., 1998; Lin and Maloney, 1999; Stulting et al., 1999; Al-Mezaine et al., 2009; Carrillo et al., 2005; Gimbel et al., 1998; Waring et al., 1999; Harissi-Dagher et al., 2008), and an incidence rate of 0.18% for free flaps in this study versus a range of 0.7–5.9% in the literature (Knorz et al., 1996; Helmy et al., 1996; Lyle and Jin, 1996; Manche and Maloney, 1996; Price et al., 1996; Pérez-Santonja et al., 1997).

The femtosecond laser is the first alternative to a mechanical microkeratome in creating LASIK flaps. Researchers have reported on the safety of this technique and its improved uniformity and better predictability of flap dimension (Nordan et al., 2003; Binder, 2006). However, incomplete flaps can occur as a result of suction loss (Binder, 2004; Lim et al., 2006). In addition, Srinivasan and Herzig (2007) and Seider et al. (2008) have reported buttonhole flaps secondary to subepithelial gas breakthrough during the femtosecond laser flap creation for LASIK.

In this study, no statistical significant correlation was detected between the laterality of the eye and the incidence of intraoperative flap complications. However, our study showed that in the unilateral buttonhole cases (13 eyes), 9 eyes (69.2% of cases) had buttonholes in the left eye in same-session consecutively treated eyes. Research shows that corneal flaps are thinner in the second eye when the same microkeratome blade is used on both eyes of a patient having bilateral same-session LASIK (Wallerstein, 2001; Reinstein, 2000; Behrens et al., 2000a; Behrens et al., 2000b; Shemesh et al., 2002). Lichter et al. (2007) reported on five patients with buttonhole flaps; in all cases, the buttonhole flaps occurred in the second of two consecutively treated eyes of the same patient. We agree with the recommendation put forth by Lichter et al. (2007) that the microkeratome blade should be changed whenever a thin flap is noticed in the first eye of bilateral same-session consecutively treated eyes of the same patient.

Three cases in our series had bilateral flap complications. Although a microkeratome malfunction or blade defect might be blamed, intrinsic corneal factors in these cases cannot be ruled out. We agree with the proponents of same-session bilateral simultaneous LASIK who argue that the risk-benefit ratio is favorable (Gimbel et al., 1999). However, it cannot be overemphasized that the surgery on the second eye should be canceled or postponed if a substantial complication occurs in the first eye.

Although the rate of incidence of flap complications decreases with increased surgeon experience, flap complications do not disappear completely. Thus, factors other than surgeon experience must play a role. Something intrinsic to the corneal anatomy or texture might be involved. Moreover, Tham and Maloney (2000) demonstrated a 12.5% complication rate at repeat LASIK compared with 0.66% in primary cases; therefore, an eye with poor keratectomy initially was substantially more likely to have a complication at repeat keratectomy.

Like any retrospective study, ours has limitations. We cannot exclude a bias on the part of surgeons who choose a microkeratome according to predisposing factors for intraoperative complications such as steep or flat keratometry, nor a bias related to differences among surgeons when identifying and classifying flap complications. In addition, a multiple surgeon setting can be questioned on the basis of the varying levels of surgical experience.

In conclusion, the incidence rates of intraoperative flap complications with the Hansatome microkeratome and the Moria microkeratome were generally comparable. However, buttonhole flaps occurred more often with microkeratomes that produce larger flaps, such as the Hansatome microkeratome. The commonest type of complication was the incomplete flap, followed by the buttonhole flap and the free flap.

## 5. Conflicts of interest statement

The authors have no conflict of interest or proprietary interest with any of the material presented in the manuscript.

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