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Flap complications in our learning curve of laser *in situ* keratomileusis using the Hansatome microkeratome

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PURPOSE. *To determine the incidence and the type of flap complications in our initial series of eyes undergoing laser* in situ *keratomileusis and the impact of microkeratome-related complications on best spectacle-corrected visual acuity.*

METHODS. *We reviewed the charts of the 630 consecutive eyes operated in the Refractive Surgery Department of Cerrahpasa Medical School, University of Istanbul, Turkey using the Hansatome microkeratome and the Summit, SVS Apex Plus excimer laser between March 1998 and November 1999. The mean follow-up was 12.6 months.*

RESULTS. *The incidence of total flap complications was 19.8 %. Flap folds (5%) were the most common complication. The incidence of epithelial ingrowth was 3.3%. Diffuse lamellar keratitis was encountered in 20 cases (3.17%). Displaced flaps were seen shortly after the procedure in 8 eyes (1.26%) and repositioned immediately. Improper keratectomy occurred in 14 eyes (2.2%) and incomplete keratectomy in four procedures (0.63%). The presence of interface debris and hemorrhage was each 1.9%. We observed one interface abscess, which was culture-negative and cured with fortified antibiotics, and one free flap.*

CONCLUSIONS. *Although the LASIK procedure with the Hansatome had an easy learning curve without any of the serious complications that frequently occur in this phase, we still observed flap related complications that affected visual outcome (Eur J Ophthalmol 2001; 11: 328-32)*

KEY WORDS. *LASIK, Microkeratome, Flap complication*

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INTRODUCTION

Preservation of the Bowman membrane and rapid visual rehabilitation make laser *in situ* keratomileusis (LASIK) the choice of most surgeons and patients (1-3). Most complications are related to the creation of a corneal flap or the newly created interface between the flap and the underlying stromal bed (2, 3). Although LASIK has significant advantages, there is a substantial learning curve before proficiency is attained (4-8). However, improvements in microkeratome design and modifications to the technique are reducing complications (9). The purpose of this retrospective study was to determine the incidence of flap complications in our series and the effect on visual outcome.

PATIENTS AND METHODS

This retrospective study included a consecutive series of 630 eyes of 348 patients who had LASIK between March 1998 and November 1999 for the treatment of myopia and/or myopic astigmatism in the Refractive Surgery Department of Cerrahpasa Medical School, University of Istanbul, Turkey. The patients' mean age was 30.31±6.62 (range 19-40 years) and mean baseline spherical equivalent refraction was –8.81 ± 4.51 diopters (D), range –2.00 to –13.25 D. The criteria for entering the study included no history or slit lamp evidence of ocular trauma, ocular surgery or ocular pathology; no use of systemic corticosteroids, antimetabolites or immunosuppressants, and dis-

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continuation of contact lens wear for at least two weeks. Clinical examinations included ocular history, slit lamp biomicroscopy, manifest refraction, and computerized videokeratography using TMS-1 system version 1.60 in all patients before laser treatment. Central corneal thickness was measured with an ultrasonic pachymeter (Mentor, Advent). The same surgeon, using the Summit Apex Plus excimer laser, performed all surgical procedures. Laser parameters included a repetition rate of 10 Hz and a fluence of 180 mj/cm^2. The flap was prepared with the Hansatome microkeratome (Chiron Vision; Claremont, California), assembled and tested preoperatively. The blade was changed for each procedure. The center of the pupil was marked with a Sinskey hook and the cornea with a Ruiz marker. The suction ring was centered on these marks and suction was applied with 25" Hg to create a superior hinged flap 9.5 mm in diameter). The 180-micron microkeratome plate was used in all procedures. The intraocular suction pressure was measured with Barraquer applanation tonometry and verified as being greater than 65 mm Hg. The flap was repositioned with a double cannula after the laser treatment, and the interface was irrigated with a balanced salt solution (BSS) to remove debris and epithelial cells. The flap was then centered for proper alignment. All patients were observed at least for an hour, and examined again by slit lamp biomicroscopy before discharge. Patients were instructed to avoid rubbing and squeezing their eyes for the first hours after surgery. Visual outcome, slit-lamp examination and corneal topography were repeated in all eyes 1 week, and 1, 3, and 6 months after surgery. Flap-related complications and their management, either intraoperative or postoperative, were recorded on the patients' charts. Any eyes in which there was a microkeratome cut, or the ablation was aborted, were also recorded.

RESULTS

Of the 630 eyes in the study, 113 (17.9%) had flap-related complications, and 12 (1.9%) had two complications together (Tab. I). At a mean follow-up of 12.6 months the postoperative uncorrected visual acuity (UCVA) ranged from 20/20 to 20/60. The best spectacle-corrected visual acuity (BSCVA) decreased by two lines in five of the latter, and one line in one patient at the end of the follow-up. Two of the eyes that had vertical flap folds and induced irregular astigmatism lost two lines of BSCVA. The other case that lost two lines had an irregular cut and epithelial ingrowth that induced stromal thinning and astigmatism. The only eye that had a free small cap also lost two lines of BSCVA although a non-eventful new cut was done three months later. BSCVA reduced two lines in one case and one line in another because of epithelial ingrowth that extended through the visual axis (Tab. II).

Fig. 1 - *Epithelial ingrowth associated with improper cut.*

Improper keratectomy occurred in 14 eyes (Tab. II), but ablation was not postponed in these procedures. The flaps were not circular and had irregular borders because of contraction of the edges in two eyes. The others were bisected flaps thinning towards the hinge. Neither button-hole nor doughnut-shape flaps were seen among the two-leveled cuts. Epithelial ingrowth was seen with the improper cut in two eyes (Fig. I). The flap was reopened and the interfaces were cleaned by scraping the epithelial cells mechanically 28 days after the initial procedure in one of these eyes. Although there were no complications after this enhancement procedure, this patient lost two lines of her BSCVA (13 months after the first procedure). In the other case the ingrowth was outside the visual axis and resolved with time.

Keratectomy was incomplete in four procedures (Tab. II) when the microkeratome stopped before completing the cut. As the pass stopped outside the planned ablation zone, laser was performed in two of them. The other two cases were treated by recutting the cornea six weeks after the initial procedure because the hinge of the flap was over the visual axis. There

was significant stromal edema in one case after the second cut, but it resolved in a week. Final visual acuity was not affected in any of these cases.

We had only one case of free cap (Tab. II) whose procedure was aborted and treated by recutting another flap after three months. This patient lost two lines of BSCVA and final BSCVA was 20/25 one year after the second cut. Displaced flaps were observed shortly after the procedure in 8 eyes (Tab. II) and repositioned immediately. The flap contracted inwards again in one case after the first replacement and was replaced once more after irrigating the interface with hypertonic solution. Epithelial ingrowth was noticed three weeks later at the same border where contraction was recorded. A month after the initial cut, melting of the flap was detected in the same part of the cornea where the flap contracted inwards. However, as the flap melting appeared on the far edge, visual acuity was not affected.

Flap folds were detected in 32 eyes (Tab. II) postoperatively. Most of them were detected as fine lattice lines on the first day after the procedure. Flap striae that extended through the visual axis induced irregular astigmatism in two eyes. Although flap-repositioning procedures were performed in both cases, they still had residual folds at the last examinations, at 8 and 12 months, and lost two lines of BSCVA. Diffuse lamellar keratitis occurred in 20 eyes, all stage II or I, and was treated with topical corticosteroids. Mild interface inflammation never extended to the posterior stromal bed and disappeared easily with topical steroid treatment in a few days.

Infectious keratitis occurred in one case. On the first postoperative day the cornea was clear but the patient came back with photophobia, conjunctival hyperemia and decreased visual acuity on the sixth day. A 1 mm round abscess with stromal infiltration was located beneath the corneal flap. The interface was opened and irrigated promptly with solution containing antibiotic and povidone iodine after taking a culture which was negative. The progression of infiltration and necrosis was controlled and visual complications were prevented as the infiltration was again at the inferior temporal region and outside the visual axis.

Epithelial ingrowth was one of the serious complications in our study (Tab. II), usually associated with another group of flap complications (7 of the 21 eyes) or with an epithelial defect (Tab. I). Cases with foreign body sensation, glare and blurred vision threatening the visual axis were treated by reopening the flap. The stromal bed and the back of the flap were scraped and the interface was irrigated with BSS in three cases. Uncorrected visual acuity (UCVA) had not changed in the eyes where epithelial ingrowth was outside the visual axis, but one eye lost two lines and another one lost one line of BSCVA, where epithelial ingrowth extended through the visual axis. Second removal of the epithelial cells was only required in one case.

In 12 eyes we observed interface debris (Tab. II). Most of them were talc particles and the others were sponge fibers. Except for two cases who also had diffuse lamellar keratitis (DLK) none of the eyes, were symptomatic.

Bleeding from perilimbal vessels occurred in 12 eyes

TABLE I - SOME COMPLICATIONS SEEN SIMULTANEOUSLY

Simultaneous complications (n=12)		
Epithelial ingrowth	Displaced flaps	3
Epithelial ingrowth	Improper keratectomy	2
Epithelial ingrowth	Flap folds	2
Diffuse lamellar keratitis	Flap folds	3
Diffuse lamellar keratitis	Interface debris	2

TABLE II - THE INCIDENCE OF COMPLICATIONS

Incidence of Hansatome complications (n=113)		
Complications	**Incidence**	**Loss in BSCVA**
Improper keratectomy*	14 (2.2%)	2 lines (1 case)
Incomplete keratectomy	4 (0.63%)	
Free flap	1 (0.15%)	2 lines (1 case)
Folds	32 (5.0%)	2 lines (2 cases)
Displaced flaps	8 (1.26%)	
Epithelial ingrowth*	21 (3.3%)	2 lines (1 case) 1 line (1 case)
Diffuse lamellar keratitis	20 (3.17%)	
Interface abscess	1 (0.15%)	
Interface debris	12 (1.90%)	
Bleeding	12 (1.90%)	

* Epithelial ingrowth and improper keratectomy were seen together in the eye that lost 2 lines of best spectacle-corrected visual acuity

(Tab. II). For focal bleeding, a Merocel sponge was soaked in phenylephrine and applied directly to the bleeding site during the procedure. None of the cases with the blood in the interface required relifting the flap and all resolved spontaneously at the end of the first week.

DISCUSSION

The primary disadvantage of LASIK over photo refractive keratectomy (PRK) is the risk of flap complications (4-8). Although flap-related complications are common, the incidence decreases as the surgeon gains experience with the microkeratome used (5,8). The actual microkeratome technology has advanced continuously since the development of LASIK to attain more user-friendly technology and better refractive results. The new-generation microkeratomes are designed to eliminate flap-related problems (9).

In this study we reviewed the incidence of flap complications in our series using the Hansatome microkeratome. The incidence of improper keratectomy was 2.2%, this figure being consistent with reports in the literature, which range from 0.7% to 6.6% (5).

A common cause of incomplete pass is interference with the advancement of the microkeratome by the lids, speculum, or drapes (4). Although the incidence of incomplete keratectomy was 0.63% in our series it was 1.2% in Lin and Maloney's study (5) where they used the Automated Corneal Shaper microkeratome (ACS). This may be related to the easier placement of the Hansatome compared with the ACS (10).

We had only one case of free cap that was treated by recutting another flap after waiting three months. The reported incidence of free flaps with other microkeratomes ranges from 0.7% to 5.9% (5), i.e. higher than our study. In a retrospective study Lin et Maloney reported a free cap incidence of 1.0% using the ACS (5). The incidence of free cap is also low in other studies using the Hansatome (9). We had no doughnut-shaped flaps or buttonholes, and never experienced a corneal perforation, which is a complication unique to the ACS and is caused by faulty assembly of the microkeratome (9).

Flap striae and folds were the most frequent complications in our series (5%). Different microkeratomes create different morphological features as they cut corneal tissue. Although the Hansatome reduces intraoperative flap complications (9), postoperative flap folds are more frequent (11). Using a similar technique, the incidence of flap folds and displacement was three times higher with the Hansatome than with the ACS in another study (11). This is theoretically related to a larger flap, which may mean the lid has more effect on the security of the flap. Flap folds and slippage might also increase with a thinner corneal flap (11, 12). Heng and Chan consistently found thinner flaps created with the Hansatome microkeratome with both the 160 µm and 180 µm plates (11). In a previous study we reported that the thickness of the flaps created with the Hansatome was not reproducible and they were usually thinner (13). Although not supported by the data in this study, a thinner flap created by the Hansatome may be another reason for the higher rate of folds.

Epithelial ingrowth was observed in 3.3% of eyes in our study and one third also had another flap complication. Epithelial ingrowth is not a rare condition after LASIK (2-8.8%) (5). Epithelial cells may reach the lamellar interface by several mechanisms. The risk of epithelial ingrowth increases with poorly adherent flaps, with epithelial basement membrane dystrophy (14) and with enhancement procedures (8). They usually appear with a fine demarcation line (5). In the majority of the cases epithelial cells either resolve in time or remain at a clinically insignificant level (8). Epithelial ingrowth is removed only for symptoms such as glare or blurred vision, induced astigmatism and progression threatening the visual axis (8). We performed enhancement treatment in three symptomatic eyes. Epithelial ingrowth may be associated with progressive keratolysis and melting of the flap, which we observed in one of our patients (15). We preferred to follow this case up as the demarcation line was distant from the pupil. At the end of one year there was no loss in visual acuity although a large peripheral portion of the flap was missing.

Diffuse lamellar keratitis was detected in 20 eyes, with multifocal interface inflammation, but no extension into the posterior stroma. The origin of this syndrome is still unknown, except that it is not infectious (16). An allergic or toxic reaction is the most commonly invoked hypothesis. The inflammation typically responds rapidly to topical corticosteroid therapy. In a retrospective study Lin and Maloney (5) report-

ed an incidence of 1.8%. Shah and co-authors noted that the presence of an epithelial defect after LASIK increases the relative risk of developing DLK 24 times (17). In our study we did not observe this association. However, two of the cases with DLK also had interface debris. None of the eyes with DLK lost their visual acuity.

Bleeding arose in 12 cases. As most of these patients were contact lens users and had superior or inferior pannus, this may be theoretically related to a larger flap (9) which may pass near this zone.

The LASIK procedure with the Hansatome had an easy learning curve, without any of the serious intraoperative complications that frequently occur in this phase. Even though most of these complications can be minimized with careful technique as the surgeon gains experience, there are some complications related to microkeratome technology that require further improvement to be prevented.

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