Comparison of Flap Adhesion Strength Using the Amadeus Microkeratome and the IntraLase iFS Femtosecond Laser in Rabbits

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ABSTRACT

PURPOSE: To compare adhesion strength of flaps created with a mechanical microkeratome and the IntraLase femtosecond laser as well as to analyze the effect of different side-cut configurations.

METHODS: A flap was created in four groups of New Zealand white rabbits—microkeratome group (Amadeus II microkeratome, Ziemer Group AG [5 eyes; 9-mm suction ring and 140-μm head]), and three IntraLase groups (IntraLase iFS 150 kHz femtosecond laser, AMO Inc [9-mm diameter and 120-μm flap each]): normal energy side-cut (4 eyes; side-cut angle 70°, side-cut energy 0.8 μJ); high energy side-cut (4 eyes; side-cut angle 70°, side-cut energy 1.6 μJ); and inverted side-cut (4 eyes; side-cut angle 140°, side-cut energy 0.8 μJ). Flap adhesion strength was measured 75 days after surgery using a tension meter to dehisce the flaps.

RESULTS: In the microkeratome group, mean force was 210±89 *g* (range: 151 to 360 *g*); 492±46 *g* (range: 439 to 540 *g*) in the normal energy side-cut group; 444±13 *g* (range: 426 to 455 *g*) in the high energy side-cut group; and 687±105 *g* (range: 552 to 797 *g*) in the inverted side-cut group. Differences between the microkeratome and all IntraLase groups were highly significant (P=.001), and differences between the inverted side-cut group and the standard 70° side-cut groups were statistically significant (P=.01).

CONCLUSIONS: Flap adhesion is significantly stronger with the IntraLase femtosecond laser than with the Amadeus mechanical microkeratome, and an inverted side-cut increases flap adhesion significantly compared with a standard side-cut. [*J Refract Surg*. 2008;24:875-878.]

Femtosecond lasers were initially introduced to create corneal flaps, intracorneal tunnels, and intrastromal ablations.[1] Visual results after femtosecond LASIK were at least as good as after microkeratome LASIK.[2] The corneal stromal bed was shown to be smoother after a femtosecond laser cut than after a microkeratome cut.[3] Flap-induced optical aberrations were less in femtosecond LASIK than in microkeratome LASIK,[4-7] suggesting less biomechanical effect to the cornea. Comparing LASIK to surface ablation, the cutting of a flap with a mechanical microkeratome weakens the cornea and the flap may be dislodged or torn off as a result of ocular trauma.[8] Laurent et al[9] investigated the stability of LASIK flaps created with a mechanical microkeratome and found that air pressure of >600 lbs/sq inch was required to dislodge the flaps as early as day 1. Kim et al[10] compared adhesion strength 1 and 3 months after flap creation with a mechanical microkeratome and a femtosecond laser in rabbits. They found that the force required to lift the flap was significantly higher in the femtosecond laser groups. Our aim, therefore, was to validate their results with a new femtosecond laser. In addition, we were interested in studying the effect of side-cut design and energy on flap adhesion in a rabbit model.

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MATERIALS AND METHODS

This study was conducted at the Biological Test Center, Irvine, Calif (Protocol No. NP071015). It complied with all Biological Test Center animal welfare policies and was approved by the Institutional Animal Care and Use Committee.

A total of 14 female New Zealand white rabbits (28 eyes) were used. All surgeries were performed by one surgeon (M.C.K.). Of the 28 eyes operated, slipped flaps were observed on day 1 in 9 eyes, possibly because we did not amputate the nictitating membrane during surgery and/or did not orient the hinge nasally on all flaps. The slipped flaps were amputated on day 1 and the eyes left to epithelialize. One eye developed epithelial ingrowths, which extended under the whole flap, and one eye showed a partial slip. The remaining 17 eyes were divided into 4 groups:

Microkeratome Group (5 eyes). A corneal flap with nasal hinge was created with the Amadeus II microkeratome (Ziemer Group AG, Port, Switzerland) using a 9-mm suction ring and a 140-µm head.

IntraLase Normal Energy Side-cut Group (4 eyes). The IntraLase iFS femtosecond laser (AMO Inc, Irvine, Calif) with a repetition rate of 150 kHz was used to create a 120-µm flap with 9-mm diameter. Bed energy was 0.8 µJ, spot and line separation 7 µm, hinge 45°, side-cut angle 70°, and side-cut energy 0.8 µJ.

IntraLase High Energy Side-cut Group (4 eyes). The IntraLase femtosecond laser with repetition rate of 150 kHz was used to create a 120-µm flap with 9-mm diameter. Bed energy was 0.8 µJ, spot and line separation 7 µm, hinge 45°, side-cut angle 70°, and side-cut energy 1.6 µJ.

IntraLase Inverted Side-cut Group (4 eyes). The IntraLase femtosecond laser with repetition rate of 150 kHz was used to create a 120-µm flap with 9-mm diameter. Bed energy was 0.8 µJ, spot and line separation 7 µm, hinge 45°, side-cut angle 140°, and side-cut energy 0.8 µJ.

All eyes were examined with a slit lamp on day 1, 2, 6, 8, 30, 60, and 75. Topical treatment was performed for 15 days with gentamicin sulfate 0.3% ophthalmic solution and dexamethasone 1 mg/mL ophthalmic solution (Maxidex; Alcon Laboratories Inc, Ft Worth, Tex) three times daily. Rabbits were sacrificed on day 75. The corneal epithelium was carefully removed with a hockey knife (No. 375701; BD Medical, Franklin Lakes, NJ). A plano-concave acrylic lens with 10-mm radius of curvature (Edmund Industrial Optics, Barrington, NJ) was attached to a customized aluminum holder (Fig 1). The holder and acrylic lens were custom-made by AMO Inc. The acrylic lens was glued to the flap after epithelial removal using cynoacrylate ester (Loctite 411; Loctite Corp, Rocky Hill, Conn) (Fig 2). Care was taken to apply the glue to the flap only without extending onto the surrounding stroma. After applying the glue, the aluminum holder with acrylic lens was put in place with moderate pressure by hand, and was held there for 6 minutes, maintaining pressure, to allow the glue to harden. Adhesion strength was then measured with a tension meter (Digital Force Gauge, Model 475040; Extech Instruments, Waltham, Mass). The meter was attached to a rope at the end of the aluminum holder and the flap was pulled slowly until it dehisced (see Fig 2). The direction of the pull was not angled 90° but slightly tilted towards the hinge (about 60° angle between the cornea and direction of the pull) to avoid an over-effect by pulling directly at the hinge. The paired *t* test was used for statistical evaluation. Adhesion strength (*g*) was the only parameter tested, and a *P* value of <.05 was considered statistically significant.

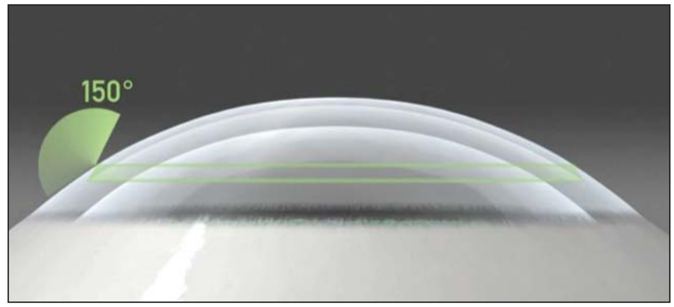

Figure 1. Schematic of inverted side-cut. The side-cut angle is 150°; the peripheral anterior cornea overlaps the edge of the LASIK flap.

RESULTS

All corneas with normal flaps were clear by day 6 and remained clear until day 75. Corneas with amputated flaps developed haze, most of which cleared by day 75.

In the Amadeus microkeratome group, the mean force to dehisce the flap was 210±89 *g* (range: 151 to 360 *g*) (Table). In the IntraLase normal energy side-cut group, the force was 492±46 *g* (range: 439 to 540 *g*), 444±13 *g* (range: 426 to 455 *g*) in the IntraLase high energy side-cut group, and 687±105 *g* (range: 552 to 797 *g*) in the IntraLase inverted side-cut group. Differences among the microkeratome group and all IntraLase groups were highly significant (*P*=.001). In addition, differences among the IntraLase inverted side-cut group and the IntraLase normal energy and high energy 70° side-cut groups were statistically significant (*P*=.01).

DISCUSSION

Flap adhesion after LASIK is important to minimize the risk of trauma, such as inadvertent flap disloca-

TABLE

Characteristics of Flaps Created With the IntraLase Femtosecond Laser and Amadeus Mechanical Microkeratome in Rabbit Eyes

	Flap Lift (*g*)			
Rabbit No./Eye	Amadeus Microkeratome	IntraLase Laser 70°, 0.8 μJ	IntraLase Laser 70°, 1.6 μJ	IntraLase Laser 150°, 0.8 μJ
1/OD			Flap slipped	
OS	154			
2/OD			Flap slipped	
OS	151			
3/OD			Flap slipped	
OS	Epithelial ingrowth			
4/OD			455	
OS	163			
5/OD			426	
OS	220			
6/OD			446	
OS	360			
7/OD		Partial slip		
OS			449	
8/OD		Flap slipped		
OS			Flap slipped	
9/OD		Histology, no lift		
OS				Histology, no lift
10/OD		439		
OS				736
11/OD		Flap slipped		
OS				552
12/OD		517		
OS				664
13/OD		470		
OS				Flap slipped
14/OD		540		
OS				797
Mean±Standard deviation	210±89	492±46	444±13	687±105

OD = right eye, OS = left eye

tion,[8] and to possibly decrease the risk of corneal ectasia. Anecdotally, in our clinical routine we observed that IntraLase flaps were more difficult to lift during retreatments than microkeratome flaps. We were, therefore, interested in investigating the flap adhesion strength after flap creation with the IntraLase femtosecond laser and a mechanical microkeratome. Our results in rabbits show that flap adhesion strength is more than twice as high with the IntraLase laser as with the Amadeus microkeratome (492 *g* compared to 210 *g*). These results compare qualitatively to those reported by Kim et al.[10] However, unlike that study we did not undermine one edge of the flap first but glued the tension meter to the flap. This method allowed us to measure the full force required to lift a flap. This force contained both the adhesion between the flap and corneal

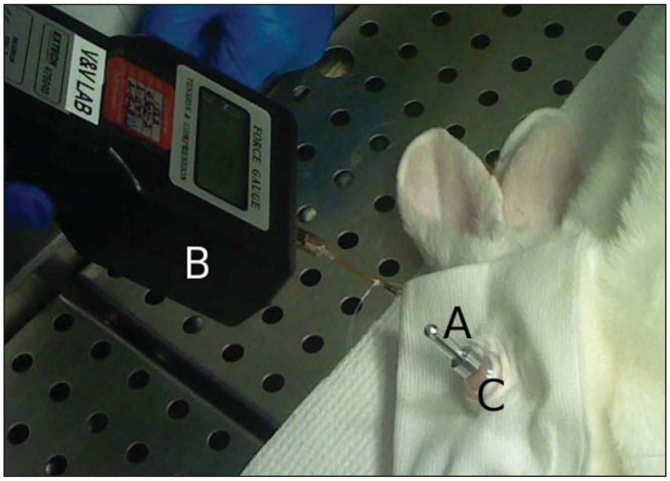

Figure 2. Flap adhesion strength measurement. A plano-concave acrylic lens with 10-mm radius of curvature (not visible), attached to a customized aluminum holder (A), was glued to the flap after removal of the epithelium and pulled with a tension meter (B). The peripheral cornea and sclera are visible (C) next to the aluminum holder (A).

bed and the adhesion at the edge of the flap, whereas Kim et al[10] could measure the flap edge adhesion in part only. This explains why the force measured in our study was much higher. At 75 days, we measured 210 *g* in the Amadeus microkeratome group and 492 *g* in the IntraLase normal energy side-cut group. Kim et al,[10] at 90 days, measured 128 *g* in the microkeratome group and 191 *g* in the IntraLase group (comparable to our normal energy side-cut group).

We also compared the effect of different side-cut energy levels. A higher energy is more likely to induce inflammation, which could create a stronger scar. We compared a "normal" energy level (0.8 µJ) with a "high" energy level (1.6 µJ). We did not find a significant difference of adhesion strength between these two groups (492 *g* in the IntraLase normal energy side-cut group versus 444 *g* in the IntraLase high energy side-cut group).

Finally, we compared a "standard" side-cut angle of 70° with an inverted side-cut of 140°. We found that the inverted side-cut caused a much stronger flap adhesion (687 *g* in the IntraLase inverted side-cut group compared with 492 *g* in the IntraLase normal energy side-cut group and 444 *g* in the IntraLase high energy side-cut group). This finding suggests that side-cut geometry is a far more significant factor in flap adhesion than side-cut energy. Therefore, if maximum flap adhesion is desired, an inverted side-cut should be used.

Possible limitations of our study were no unoperated controls to establish the strength of the normal uncut cornea for delamination and the small number of eyes in each group. However, there was little scatter and the differences among groups were highly significant. In addition, our results were confirmed by the findings of Kim et al.[10]

Our results indicate that flap adhesion is stronger in a femtosecond laser flap than in a flap created with a mechanical microkeratome and that the strongest adhesion is achieved with an inverted side-cut.

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