Laser in situ keratomileusis flap complications and complication rates using mechanical microkeratomes versus femtosecond laser: Retrospective review

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ABSTRACT

Purpose: To compare the frequency and types of flap complications when a femtosecond laser versus a microkeratome is used in flap creation for laser in situ keratomileusis (LASIK).

Methods: Retrospective review of private and published results of intraoperative and postoperative complications seen with mechanical microkeratomes and the femtosecond laser. The data from 13,721 consecutive mechanical microkeratome created flaps and 10,348 consecutive femtosecond laser created flaps for LASIK performed by one surgeon (KS) were analyzed for this study.

Results: A lower rate of intraoperative complications (incomplete flap, buttonhole, free cap, thin/irregular flap) was seen in the femtosecond created flaps (0.019%) compared to the microkeratome created flaps in this study (0.095%, $p<0.001$) and large published studies (0.80%, $p<0.001$). Less postoperative complications (epithelial ingrowth, keratectasia) were also seen in the femtosecond group (0.03%) compared to the microkeratome group (0.14%, $p=0.01$). There were several complications seen that were unique to the femtosecond laser, including transient light sensitivity, anterior chamber bubbles and vertical gas breakthrough.

Conclusions: Intraoperative and postoperative flap complications were significantly higher with mechanical microkeratomes compared to the femtosecond laser. Femtosecond laser flap creation resulted in some complications that were unique to this modality.

Key Words: LASIK, Flap Complications, Microkeratome, Intralase, Femtosecond Laser

1.0 INTRODUCTION

The creation of the corneal flap is considered a crucial step in laser in situ keratomileusis (LASIK). The corneal flap has traditionally been created using a mechanical microkeratome. Over the past several years the femtosecond laser has been replacing the microkeratome as a method of flap creation. The current United States trends in refractive surgery survey as reported by Drs Duffey and Leaming showed a 57% use of the femtosecond laser as a method of flap creation.[1]

The creation of the corneal flap has been associated with both intraoperative and postoperative complications, with total reported complication rates ranging from 0.3% to 15.2% depending on the method of flap creation and types of complications reported.[2-3]

Complication rates related to flap creation are frequently cited by proponents of advanced surface ablation techniques as a reason to avoid LASIK. However, the majority of the literature regarding corneal flap complications describes microkeratome created flaps. Relatively little has been reported regarding femtosecond created flap complications and rates, although initial reports describe low rates of complications.[4-6]

To characterize and compare complications from femtosecond and microkeratome created flaps, we conducted a retrospective review of 24,069 LASIK surgeries (13,721 microkeratome created flaps and 10,348 femtosecond laser created flaps). We believe that this is the largest series to date to compare flap-related complications between the two devices.

2.0 MATERIALS AND METHODS

This was a retrospective review of all LASIK surgeries performed between 1997 and 2010 by one surgeon (KS). Spherical equivalent treatments ranged from -12 to +6 D with up to 6 D cylinder. At the cut off point, there were 13,721 consecutive mechanical microkeratome flaps included for analysis and 10,348 consecutive femtosecond laser flaps.

2.1 Microkeratome Flap Creation

All flaps were created using a Hansatome or Moria microkeratome and either a superior or nasal hinge location. Excimer treatments were performed with a VISX (AMO, Abbott), Autonomous (Alcon), or Wavelight Allegretto platform (Alcon).

2.2 Laser Flap Creation

Over the course of this study, three different speeds of the same laser (IntraLase FS Laser, Advanced Medical Optics, Santa Ana, CA) were used: 15 kHz, 30 kHz and 60 kHz. The flaps were created with a diameter between 8.5 mm and 9.3 mm, a thickness of 100 to 130 µm, a hinge angle of 45 degrees, and a side-cut angle of 70 degrees. Stromal ablation was then performed using one of the aforementioned excimer laser platforms.

2.3 Analysis

The results of all surgeries were compiled on an on-going basis using Refractive Surgery Consultant Elite Software (Refractive Consulting Group, Inc.),Evernote, (Evernote, Redwood City, CA) and Palm Pilot (Palm, Inc; US Robotics) software with a search for the following flap-related complications: epithelial in-growth requiring removal, epithelial defects, keratoectasia, incomplete pass, thin flap, free cap, buttonhole, and torn flap. Data sets were analyzed using the previously mentioned software and Microsoft® Excel using standard statistical methods. The results of this analysis were then compared to previously published rates of microkeratome flap complications.

3.0 RESULTS

A significantly lower intraoperative complication rate (incomplete flap, buttonhole, free cap, thin/irregular flap) was seen in the femtosecond flaps (0.019%) compared to the microkeratome created flaps in this study (0.095%, $p<0.001$) and in published studies of microkeratome complications (0.80%, $p<0.001$). Less epithelial defects were seen in the femtosecond group (0.02%) versus the microkeratome group (0.45%, $p<0.001$) in this study. Less postoperative complications (epithelial ingrowth, keratectasia) were also seen in the femtosecond group (0.03%) compared to the microkeratome group (0.14%, $p=0.01$) in this study (Table 1).

Table 1. Prevalence of intraoperative and postoperative flap complications using a mechanical and femtosecond laser from this study.

	Mechanical Keratome	Femtosecond Laser
Incomplete Flap	0.19% (26)	0.01% (1)
Thin Flap	0.07% (10)	0.01% (1)
Free Cap	0.01% (1)	0.00%
Buttonhole	0.015% (2)	0.00%
Torn Flap	0.00%	0.02% (2)
Epithelial Defects	0.45% (62)	0.02% (2)
Epithelial Ingrowth†	0.12% (16)	0.03% (3)
Keratoectasia	0.02% (3)	0.00%
Total	**0.875%**	**0.09%**

†Epithelial Ingrowth requiring removal

3.1 Mechanical Microkeratome Flap Complications

In the review of personal results, the most frequently seen complications with mechanical microkeratomes were: epithelial defects (0.45%), incomplete pass (0.19%), epithelial ingrowth requiring removal (0.12%), and thin flap (0.07%). Other complications seen in this group included: keratoectasia (0.02%) free cap (0.01%), and buttonholes (0.015%). There were no torn flaps encountered in this group.

In the published literature, the reported frequencies of intraoperative complications from four large studies[1, 7-9] (192,504 total eyes) were compiled (Table 2). The mean rates of complications were: incomplete flap (0.17%), buttonhole (0.09%), free cap (0.33%), and thin/irregular flaps (0.21%). Only two of the four studies reported epithelial defects/abrasions with rates ranging from 0.05% to 0.94%[8-9]. Postoperative complications including rates of keratectasia and epithelial ingrowth were not reported. There were also no torn flaps reported in any of these published studies.

Table 2. Published prevalence rates of intraoperative microkeratome flap complications.

	Jacobs et al.[1]	Carrillo et al.[6]	Nakano et al.[7]	Albeda et al.[8]	**Total**
Number of Eyes	84,711	26,600	47, 094	34, 099	**192,504**
Incomplete Flap	0.10% (84)	0.05% (13)	0.23% (107)	0.37% (126)	**0.17% (330)**
Thin/Irregular Flap	0.09% (74)	0.02% (5)	0.08% (36)	0.83% (282)	**0.20% (397)**
Free Flap/Caps	0.01% (10)	0.09% (23)	0.08% (39)	1.67% (571)	**0.33% (643)**
Buttonhole	0.07% (59)	0.04% (11)	0.13% (61)	0.11% (39)	**0.09% (170)**

3.2 Femtosecond Laser Flap Complications

The most frequently seen complications with the femtosecond laser were: epithelial ingrowth requiring removal (0.03%), torn flap (0.02%), and epithelial defects (0.02%). One incomplete pass occurred which did not preclude treatment in this eye.

Stage 1 or 2 diffuse lamellar keratitis (DLK) occurred in 0.08% of the first 6,131- femtosecond laser flap cases. These were aggressively treated with topical corticosteroids and resolved without any postoperative complications. Pretreatment with topical antibiotics and topical corticosteroids helped to reduce the occurrence rate to 0.04% in subsequent femtosecond laser flaps. There were no cases of Stage 3 or 4 DLK seen in this series.

There were also a number of complications seen that were unique to the femtosecond laser including: transient light sensitivity syndrome (TLSS) (1.1%), anterior chamber bubbles (0.2%) and vertical gas breakthrough (1 eye).

3.21 Transient Light Sensitivity Syndrome. The frequency of TLSS was 1.1% in this series and has been reported to occur in up to 1.3% of cases.[10-11] TLSS typically presents at 6 to 12 weeks following surgery and is marked by delayed onset of photophobia. It resolves 2 to 3 weeks after onset with aggressive treatment with topical corticosteroids.

3.22 Anterior Chamber Bubbles. It is believed that these bubbles occur as a result of the photodisruption process of the femtosecond laser. The bubbles cause air to enter into Schlemm's canal and the anterior chamber. The bubbles may prevent certain excimer laser eyetracking systems from functioning properly but treatment can still be performed after waiting for resolution of the bubbles.

3.23 Vertical Gas Breakthrough. In this series, only 3 cases of vertical gas breakthrough occurred. As the name implies, during the photodisruption process, gas will break through and can be seen between the glass applanation cone and the epithelium. If vertical gas breakthrough does occur in the visual axis, it is necessary to stop the case and have the patient return at a later date. If the breakthrough occurs outside the ablation zone, as in these cases, treatment can be and was performed.

3.24 Opaque Bubble Layer (OBL). This is more of a nuisance than a complication seen with the femtosecond laser. Rates were not recorded for this study but have previously been reported at over 50%.[12] This term applies to the collection of gas bubbles in the interlamellar space above and below the planar flap. Subsequent improvements in femtosecond laser speed from 15kHz to 60 kHz have also reduced the incidence rate.[13]

4.0 DISCUSSION

The femtosecond laser has changed the way many refractive and corneal surgeons perform surgery due to its ability to customize a corneal flap or shape corneal tissue based on patient requirements.

A number of published studies have shown that there are quantifiable benefits seen when the corneal flap is created with a femtosecond laser, particularly related to a reduction of induced astigmatism and higher order aberrations.[14-15]

4.1 *Advancement in Femtosecond Laser Speeds*

The femtosecond laser that was commercially introduced in 2002 was a 15 kHz model that took approximately 2 minutes for flap creation with high levels of energy. Particularly with the 15 kHz, there was a tendency for inflammation associated with surgery. Over the next several years, the manufacturer of the IntraLase FS Laser increased the speed of the laser from 15 to 60 kHz. The introduction of the 30 kHz, followed by the introduction of the 60 kHz in 2006, have all but eliminated many of these issues.[32] With the 60 kHz, there is a greater ability to lower the energy level and use a tighter raster pattern in the interface to reduce inflammation. In 2008, the manufacturer increased the speed of the femtosecond laser again, this time to 150 kHz, enabling flap creation times of less than 10 seconds.

4.2 Complication Rates

In this study, a lower rate of intraoperative complications was found in the femtosecond group except for torn flaps (0.02%). Several other smaller series and studies have also demonstrated low rates of intraoperative complications related to flap creation using the femtosecond laser.[16-17]

In a series of 1,000 consecutive femtosecond laser created flaps reported by Binder, there were no cases of decentered or irregular flaps, epithelial defects or flap perforations.[4] In a series of 3,009 eyes with femtosecond laser-created flaps, Chang reported a complication rate of 0.63% with no cases of corneal buttonholes, short flaps, flap striae or wrinkles reported.

Intraoperative complications accounted for 0.33% and postoperative complications for 0.30%.[5] Haft et al, in a retrospective, noncomparative series, described intra- and postoperative complications of the IntraLase FS microkeratomein 4,772 eyes.[6] They reported a total complication rate of 0.92%. Intraoperative complications developed in 0.25%, premature breakthrough of gas through the epithelium within the flap margins was seen in 0.17%, incomplete flap due to suction loss was found in 0.06% and one eye had an irregular flap due to a previous scar.[32]

A more recent retrospective, comparative study of microkeratome and femtosecond created flaps found lower rates of epithelial defects and dislocated flaps in the femtosecond group.[3] There is a considerable range in the reported prevalence of epithelial defects following microkeratome flap creation with rates ranging from 0.05%[14] to 8.8%.[18] In this study, the prevalence of epithelial defects in the microkeratome group (0.45%) was over 20 times greater than the femtosecond group (0.02%) with all surgeries performed by the same surgeon.

4.3 *Contributing Factors*

Several features of the femtosecond laser created flaps may account for the lower rates of some complications observed in this and other studies. The femtosecond laser has been shown to produce less variation in flap thickness and diameter compared to mechanical microkeratomes which may decrease the risk for flap perforations.[19-21] The low incidence of buttonholes in the femtosecond group may be due to the uniformly planar flap configuration as opposed to the meniscus-shaped flap created by the microkeratomes.[22] The vertical edge profile of femtosecond LASIK flaps may lead to a lower incidence of epithelial ingrowth following retreatments.[23]

Not all complications are observed more with mechanical microkeratome flaps. According to several published reports, the incidence of diffuse lamellar keratitis (DLK) is greater in eyes where the LASIK flap was created with a femtosecond laser.[3, 5, 24, 25] Interestingly, data from a recent study did not find a difference in the rates of DLK between the 15, 30, and 60 kHz models.[26]

4.4 *Unique Femtosecond Complications*

Several complications unique to the femtosecond laser were seen, including TLSS, anterior chamber bubbles, and vertical gas breakthrough. These complications have all been previously described in case reports or series. Seider et al, published a report on 4 epithelial gas breakthroughs that occurred during flap creation, with one resulting in a flap tear. In 2 of the 4 cases, corneal scars were present prior to LASIK.[27] An additional case of epithelial gas breakthrough has also been published with uneventful outcomes with the patient achieving an uncorrected visual acuity of 20/20 in both eyes on the first postoperative day.[28]

Anterior chamber bubbles is probably the most frequently seen, as well as the most benign, of complications experienced with the femtosecond laser. The first published report documented a case in the right eye of a patient undergoing bilateral LASIK. The bubbles were reported to resolve after 30 minutes and the case was completed without complication.[29] Srinivasan and Rootman also reported a similar case.[30]

A consecutive case series that looked at rates of opaque bubble layer found that out of 149 eyes undergoing femtosecond laser flap creation, 84 (56.4%) developed OBL. The OBL pattern was diffuse in 32.2% of eyes and hard in 24.4% of eyes. The authors found a significant correlation between the corneal steep curvature and central corneal thickness and the area of OBL. They concluded that thicker corneas and smaller flaps increase the rate of OBL during flap creation.[12]

The rates of both anterior chamber bubbles and OBL have declined as the speed of the femtosecond laser has increased along with a reduction in the energy used for the raster and side cuts. This has also been the case with TLSS. In 2006, we were involved in the first report of the phenomenon that looked at TLSS rates among 3 surgeons at 3 different locations. Out of a total of 5,667 eyes, there were 63 cases of TLSS (incidence rate of 1.1%). Onset of symptoms occurred between 2 and 6 weeks after uneventful LASIK. All cases resolved following treatment with topical corticosteroids.[10] A prospective series of 765 eyes undergoing femtosecond laser flap creation with the 15kHz laser found a rate of 1.3% (10 eyes), with all eyes successfully treated with steroid drops.[11]

5.0 CONCLUSION

With the introduction of any new technology, there will be the development of new and unique complications. What is interesting about the complications unique to the femtosecond laser is that none is sight threatening. In addition, in the case of intraoperative complications, in most cases it is possible to continue with flap creation, flap lifting and excimer laser ablation. Furthermore, the rates of intraoperative complications seen with the femtosecond laser are significantly lower than what has been previously reported with mechanical microkeratomes. In the series presented here, there was a nearly ten-fold reduction in overall flap-related complications.

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