Femtosecond Laser Versus Mechanical Microkeratome: A Retrospective Comparison of Visual Outcomes at 3 Months

Mesha Tanna, BSc(Hons), MCOptom; Steven C. Schallhorn, MD; Keith A. Hettinger, MS, MBA

ABSTRACT

PURPOSE: To compare the visual outcomes of LASIK procedures in which flaps were created with a femtosecond laser (IntraLase FS 60Hz, Abbott Medical Optics [AMO]) to procedures in which flaps were created with a mechanical microkeratome (Moria Evo3 One Use-Plus, Moria SA).

METHODS: A retrospective analysis was performed on 2000 eyes treated in 2008 for low myopia and astigmatism (sphere <-3.00 diopters [D]; cylinder $\leqslant-0.75$ D). The first 1000 consecutive eyes that had LASIK flaps created with a femtosecond laser were compared with the first 1000 consecutive eyes that had flaps created with a mechanical microkeratome. All eyes received wavefront-guided LASIK treatments performed with a VISX S4 IR Advanced CustomVue excimer laser (AMO). Refractive predictability, change in mean spherical equivalent refraction, postoperative uncorrected visual acuity (UCVA), and loss of best spectacle-corrected visual acuity (BSCVA) were compared at 1 day, 1 week, 1 month, and 3 months following surgery.

RESULTS: The refractive accuracy was the same for both groups. At all time points measured, the percentage of eyes that achieved a postoperative UCVA of 20/20 or better was significantly higher in the femtosecond laser group than in the mechanical keratome group. Also, a higher percentage of eyes in the femtosecond laser group achieved a postoperative UCVA of 20/16 at 3 months. Finally, a lower percentage of eyes in the femtosecond laser group lost two or more lines of BSCVA at 1 week and 1 month postoperative.

CONCLUSIONS: Creating LASIK flaps with the femtosecond laser resulted in faster visual recovery and better UCVA. [*J Refract Surg*. 2009;25:S668-S671.]

doi:10.3928/1081597X-20090611-08

Compared to a flap created with a mechanical microkeratome, a femtosecond laser flap offers several potential advantages: more uniform flap thicknesses, customizable flap diameter and hinge position, smoother stromal beds, and lower rates of flap creation complications. However, mechanical keratomes have a long track record of safety, and they cost significantly less than a femtosecond laser.

A few published reports have compared these two competing techniques, but the results of these studies have been mixed.[1-4] Some studies have shown equivalency between the femtosecond laser and the mechanical keratome whereas other studies have reported improved visual results with the femtosecond laser.[1-4] The current study was designed to determine whether use of different flap creation techniques yields differences in visual outcomes and visual recovery.

PATIENTS AND METHODS

Data for this study were taken from patient records extracted from the Optical Express 2008 clinical database. For both the mechanical microkeratome and femtosecond laser groups, the first 1000 consecutive eyes that met the following conditions were included in the study: 1) preoperative myopia <-3.00 diopters (D), 2) preoperative cylinder $\leqslant-0.75$ D, 3) target refraction of emmetropia, 4) primary wavefront-guided ablation, and 5) 3-month examination data available.

The femtosecond laser flaps were created using an IntraLase FS-60 femtosecond laser (Abbott Medical Optics, Santa Ana, Calif), and the mechanical microkeratome flaps were created using the disposable Moria Evo3 One Use-Plus (Moria SA, Antony, France). The femtosecond laser flap diameter varied

From Optical Express, London, United Kingdom (Tanna) and San Diego, Calif (Schallhorn, Hettinger).

Ms Tanna and Mr Hettinger are employees of the Optical Express Group. Dr Schallhorn is the Chief Medical Director for Optical Express and a consultant to Abbott Medical Optics and AcuFocus.

Assistance in preparing this manuscript was provided by medical writer Kay Downer.

Correspondence: Mesha Tanna, BSc(Hons), MCOptom, Optical Express, 5 Deerdykes Rd, Westfield, Cumbernauld G68 9HF United Kingdom. Tel: 44 1236 723300; Fax: 44 1236 730300; E-mail: meshatanna@opticalexpress.com

TABLE 1

Demographic and Preoperative Parameters in Eyes That Underwent LASIK Flap Creation With a Femtosecond Laser or Mechanical Microkeratome

Parameter	Mean±Standard Deviation (Range) Femtosecond Laser (n=1000 eyes)	Mechanical Microkeratome (n=1000 eyes)	*P* Value*
Male/female (%)	31/69	28/72	.3796
Age (y)	37.3±10.8 (18 to 69)	35.6±10.0 (18 to 65)	.0019
Sphere (D)	−1.92±0.69 (−0.25 to −3.00)	−1.88±0.69 (−0.25 to −3.00)	.1748
Cylinder (D)	−0.38±0.25 (−0.75 to 0.00)	−0.37±0.26 (−0.75 to 0.00)	.4142
MSE (D)	−2.11±0.69 (−0.50 to −3.38)	−2.07±0.69 (−0.50 to −3.38)	.1332
Pupil size (mm)	6.3±1.1 (3.0 to 9.0)	6.3±1.0 (3.0 to 9.0)	.2095

MSE = mean spherical equivalent refraction
**For continuous variables, a two-sample* t *test was used to measure significance. For categorical variables, a chi-square test was used. All assumptions were met for these respective tests.*

from 8.4 to 9.2 mm, with a programmed ablation depth between 100 and 120 µm (median=110 µm). The 130-µm head was used for the mechanical microkeratome. Patients were educated about both methods of flap creation and selected the one they preferred for their procedure. The wavefront-guided treatments were performed using a VISX STAR S4 IR Advanced CustomVue excimer laser (AMO) with an optical zone of 6.0 mm and transition zone of 8.0 mm. Postoperative examinations were conducted by Optical Express optometrists who were unaware of the method of flap creation.

Demographic and other preoperative parameters were analyzed to ensure that the groups were well matched. Refractive predictability, change in mean spherical equivalent refraction, postoperative uncorrected visual acuity (UCVA), and loss of best spectacle-corrected visual acuity (BSCVA) were compared at 1-day, 1-week, 1-month, and 3-month follow-up. Visual acuity was measured at each visit using a projected eye chart.

Tabulations of data and statistics were performed with SAS 9.1 (SAS Institute Inc, Cary, NC) and Microsoft Office Excel 7.0 (Microsoft, Redmond, Wash).

RESULTS

The two groups were well matched in terms of gender, sphere, cylinder, mean spherical equivalent refraction, and pupil size (Table 1). The mean preoperative sphere was −1.92 D for the femtosecond laser group and −1.88 D for the mechanical microkeratome group; the mean cylinder was −0.38 D for the femtosecond laser group and −0.37 D for the mechanical microkeratome group. A small difference in mean age was noted between groups (femtosecond laser: 37.2 years; mechanical keratome: 35.6 years), but this difference was not deemed clinically relevant.

Both groups achieved similar refractive predictability results. The percentage of eyes with a postoperative mean spherical equivalent refraction within 0.50 D of the target was high in both groups and similar at all follow-up examinations (Fig 1). Both groups also achieved similar levels of refractive stability, with eyes in both groups remaining close to plano from the 1-day follow-up through the 3-month follow-up (Fig 2).

Although refractive results were similar, a significant difference was observed in the percentage of eyes that achieved a postoperative UCVA of 20/20 or better (Table 2). At 1-day follow-up, 88.6% of eyes in the femtosecond laser group achieved UCVA of 20/20, compared to 83.2% of eyes in the mechanical microkeratome group (P=.0005). Both groups showed improvement with continued follow-up, but a higher percentage of eyes in the femtosecond laser group achieved 20/20 UCVA at each time point (Fig 3).

In addition to achieving faster visual recovery immediately after surgery, eyes in the femtosecond laser group also achieved significantly better 3-month UCVA (one-way analysis of variance, P=.0058). At 3-month follow-up, 78% of eyes in the femtosecond laser group achieved UCVA of 20/16 or better, compared to 70% of eyes in the mechanical microkeratome group (Fig 4).

Fewer eyes in the femtosecond laser group experienced a loss of two or more lines of BSCVA in the early postoperative period. At 1-week postoperative, only 0.9% of eyes in the femtosecond laser group had lost two or more lines of BSCVA, compared to 2.8% in the mechanical microkeratome group (Fig 5). By 3 months postoperatively, however, both groups showed similar results.

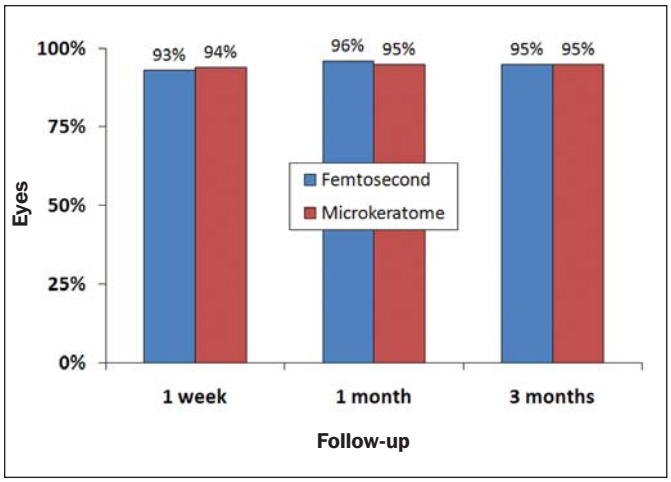

Figure 1. Efficacy. A high percentage of eyes achieved a mean spherical equivalent refraction within 0.50 D of the intended refraction at all time points following surgery.

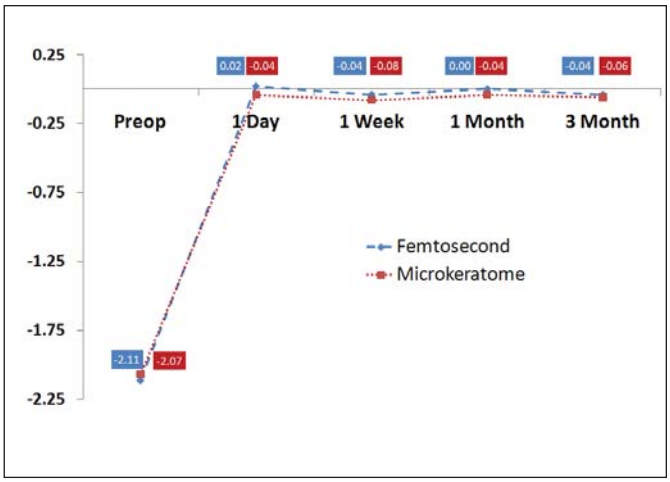

Figure 2. Refractive stability. Eyes in both the femtosecond laser group and mechanical microkeratome group achieved high levels of refractive stability from 1-day follow-up through 3-month follow-up.

TABLE 2

Percent of Eyes Achieving 20/20 Uncorrected Visual Acuity After LASIK With the Femtosecond Laser or Mechanical Microkeratome

	Percentage of Eyes			
Time point	Femtosecond Laser	Mechanical Microkeratome	Difference	*P* Value*
1 day	88.6	83.2	5.4	.0005
1 week	92.6	85.9	6.7	<.0001
1 month	95.5	93.0	2.5	.0166
3 months	96.0	93.5	2.5	.0098

**Chi-square test.*

DISCUSSION

As this study shows, the femtosecond laser significantly improves both the speed of visual recovery as well as UCVA through 3 months postoperative. This improvement occurred despite similar refractive predictability in both the femtosecond laser group and mechanical microkeratome group. Thus, the improved UCVA was not due to residual refractive error in the mechanical microkeratome group.

The percentage of eyes that experienced a loss of two or more lines of BSCVA at 1 week postoperative was three times higher in the mechanical microkeratome group compared to the femtosecond laser group. Although this difference disappeared by 3 months postoperative, the initial disparity further indicates a faster visual recovery when flaps are created with the femtosecond laser.

Given that most patients prefer LASIK over surface ablation in part because LASIK offers a more rapid improvement in vision, the enhanced speed of visual recovery after a femtosecond laser procedure represents a significant advantage. Speed of visual recovery also has implications for when patients can return to work after surgery, particularly for patients who have jobs that require excellent vision, such as aviators.

The results of previous studies comparing the outcomes of femtosecond laser LASIK with mechanical keratome procedures have been varied. A study by Patel et al[1] examined 21 patients who had a femtosecond laser flap created in one eye and a mechanical microkeratome flap created in the other eye, and they found that the method of flap creation did not affect visual outcomes. Similarly, Lim et al[2] (n=55 eyes) and Kezirian and Stonecipher[3] (n=375 eyes) concluded that use of a femtosecond laser failed to produce any statistically significant difference in postoperative UCVA at 3 months postoperative. In contrast, Durrie and Kezirian[4] (n=102 eyes) reported that the femtosecond laser–created flaps produced a statistically better UCVA. Several reasons for these different results are

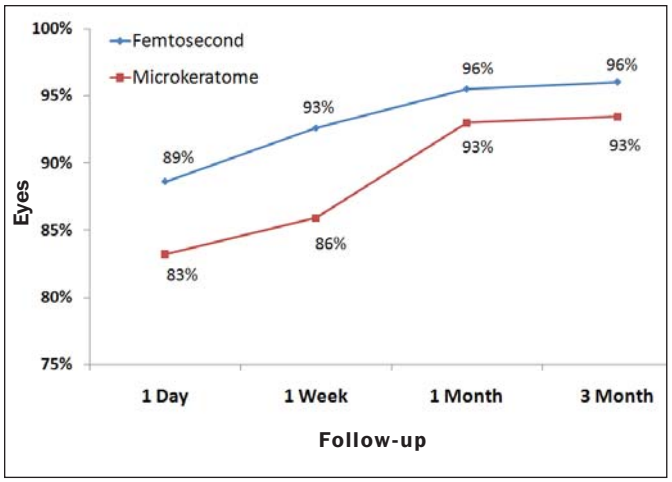

Figure 3. Percentage of eyes that achieved uncorrected visual acuity of 20/20 or better was higher for the femtosecond laser group at all time points.

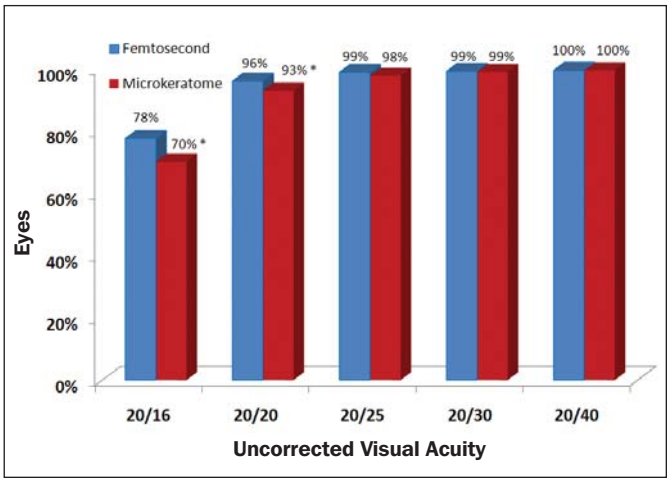

Figure 4. A higher percentage of eyes in the femtosecond laser group achieved uncorrected visual acuity of 20/16 at 3-month follow-up.

possible, including the relatively small sample sizes of these studies, which may be partially responsible for their lack of agreement.

Although the retrospective nature of the current study is a drawback, the study design also has several strengths. The large sample size (2000 well-matched eyes) allowed for statistically valid conclusions; limiting the study to consecutive treatments minimized selection bias. Also, the limits on preoperative myopia and cylinder reduced the confounding influence of unpredictable clinical results that can occur when treating higher levels of ametropia. In addition, all treatments were performed in 2008 using the latest technology and the same wavefront-guided ablation profile, therefore the study is representative of modern clinical practice.

Because this study was intentionally confined to eyes with low preoperative myopia and cylinder, it cannot predict results for hyperopia or high myopia treatment. Nonetheless, clinical reasoning suggests that similar results would be expected for a wide range of ametropia.

Although it is not readily apparent why the femtosecond laser improves visual outcomes, several possible explanations include the more predictable planar flap, more accurate repositioning of the flap at the end of the procedure, and/or improved smoothness of the stromal bed. Particularly for procedures that use complex ablation patterns, such as wavefront-guided treatments, minimizing stromal bed imperfections and maximizing the predictability of the flap dimensions may help in achieving optimal results.

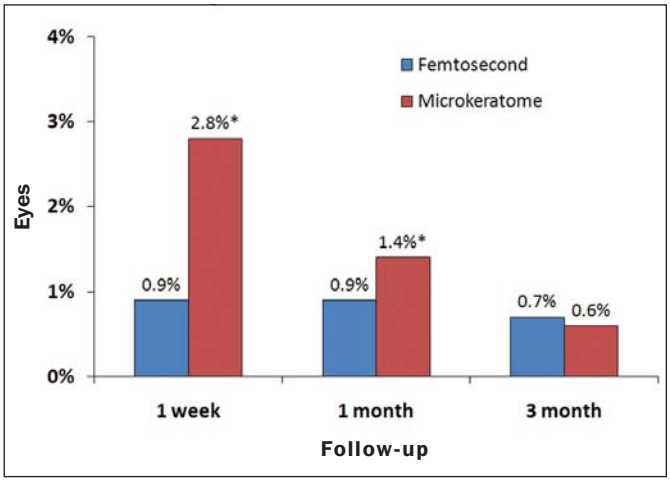

Figure 5. Loss of 2 or more lines of best spectacle-corrected visual acuity was greater in the mechanical microkeratome group at 1-week and 1-month follow-up.

AUTHOR CONTRIBUTIONS

Study concept and design (M.T., S.C.S.); data collection (S.C.S., K.A.H.); interpretation and analysis of data (S.C.S., K.A.H.); drafting of the manuscript (S.C.S.); critical revision of the manuscript (M.T., S.C.S., K.A.H.); statistical expertise (S.C.S., K.A.H.); administrative, technical, or material support (S.C.S.); supervision (S.C.S.)

REFERENCES

1. Patel SV, Maguire LJ, McLaren JW, Hodge DO, Bourne WM. Femtosecond laser versus mechanical microkeratome for LASIK: a randomized controlled study. *Ophthalmology*. 2007;114:1482-1490.
2. Lim T, Yang S, Kim M, Tchah H. Comparison of the IntraLase femtosecond laser and mechanical microkeratome for laser in situ keratomileusis. *Am J Ophthalmol*. 2006;141:833-839.
3. Kezirian GM, Stonecipher KG. Comparison of the IntraLase femtosecond laser and mechanical keratomes for laser in situ keratomileusis. *J Cataract Refract Surg*. 2004;30:804-811.
4. Durrie DS, Kezirian GM. Femtosecond laser versus mechanical keratome flaps in wavefront-guided laser in situ keratomileusis: prospective contralateral eye study. *J Cataract Refract Surg*. 2005;31:120-126.