Femtosecond Laser versus Mechanical Microkeratome for LASIK

A Randomized Controlled Study

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Purpose: To compare corneal haze (backscattered light) and visual outcomes between fellow eyes randomized to LASIK with the flap created by a femtosecond laser (bladeless) or with the flap created by a mechanical microkeratome.

Design: Randomized, controlled, paired-eye study.

Participants: Twenty-one patients (42 eyes) received LASIK for myopia or myopic astigmatism.

Methods: One eye of each patient was randomized to flap creation with a femtosecond laser (IntraLase FS, IntraLase Corp., Irvine, CA) with intended thickness of 120 μm, and the fellow eye to flap creation with a mechanical microkeratome (Hansatome, Bausch & Lomb, Rochester, NY) with intended thickness of 180 μm. Patients were examined before and at 1, 3, and 6 months after LASIK.

Main Outcome Measures: Corneal backscatter, high-contrast visual acuity, manifest refractive error, contrast sensitivity, and intraocular forward light scatter were measured at each examination. Flap thickness was measured by confocal microscopy at 1 month, and patients were asked if they preferred the vision in either eye at 3 months.

Results: Corneal backscatter was 6% higher after bladeless LASIK than after LASIK with the mechanical microkeratome at 1 month (P = 0.007), but not at 3 or 6 months. High-contrast visual acuity, contrast sensitivity, and forward light scatter did not differ between treatments at any examination. Flap thicknesses at 1 month were 143 ± 16 μm (bladeless, mean ± standard deviation) and 138 ± 22 μm (mechanical microkeratome), with no statistical difference in variances. At 3 months, 5 patients preferred the bladeless eye, 7 patients preferred the microkeratome eye, and 9 patients had no preference.

Conclusions: The method of flap creation did not affect visual outcomes during the first 6 months after LASIK. Although corneal backscatter was greater early after bladeless LASIK than LASIK with the mechanical microkeratome, patients did not perceive a difference in vision. Ophthalmology 2007;114:1482–1490 © 2007 by the American Academy of Ophthalmology.

Excimer laser refractive surgery is currently the most common surgical procedure performed on the central cornea. LASIK involves photoablation of corneal stroma deep to an anterior corneal flap. Flaps have traditionally been created with mechanical microkeratomes, but more recently, femtosecond laser technology has emerged as an alternative for flap creation.1 Femtosecond lasers are ultrafast lasers that precisely photodisrupt tissue by using very short duration energy pulses. The low amount of energy imparted to the tissue minimizes collateral tissue damage in theory.2,3 The precision of femtosecond lasers may make this technology safer than mechanical microkeratomes with more predictable flap parameters.1

Corneal haze after refractive surgery is typically associated with surface photoablation4 and rarely with LASIK.5 Our clinical and confocal microscopy6 observations suggest that corneas treated with the femtosecond laser may exhibit more haze after LASIK compared with corneas treated with mechanical microkeratomes. Haze, or increased corneal backscatter, may result from the greater inflammatory response associated with femtosecond laser flap creation,7,8 and can be measured objectively and noninvasively.9 Previous studies comparing the 2 methods of flap creation have reported similar visual acuity outcomes in the short-term after LASIK, and emphasize more predictable flap param-
acter with the femtosecond laser. In the present study, which was not sponsored by any manufacturer, 1 eye of each patient was randomized to LASIK with the flap created by a femtosecond laser (“bladeless LASIK”), and the fellow eye received LASIK with the flap created by a mechanical microkeratome. We objectively measured changes in corneal backscatter, visual function, and variability of flap thickness, and we report the results from the first 6 months of this paired-eye study.

Materials and Methods

Subjects

Twenty-one subjects were recruited from patients attending the refractive surgery service at Mayo Clinic College of Medicine. All patients had myopia or myopic astigmatism, were ≥21 years old, and were determined to be suitable candidates for LASIK after a rigorous screening examination. Subjects were excluded if they had any corneal abnormalities; a history of ocular disease, trauma, or surgery; diabetes mellitus or other systemic disease known to affect the eye; or if they used ocular medications. Systemic medications were permitted unless they were known to affect the cornea or anterior segment. Mean subject age at surgery was 38±10 years (mean ± standard deviation; range, 22–54 years). This study complied with the Health Insurance Portability and Accountability Act and was approved by our Institutional Review Board. Informed consent was obtained from all subjects after explanation of the nature and possible consequences of the study.

Randomization

Patients were stratified by ocular dominance and then 1 eye of each patient was randomized to LASIK with the flap created by a femtosecond laser, and the other eye to LASIK with the flap created by a mechanical microkeratome. Ocular dominance was tested by asking patients to use both hands to frame a distant target while an observer determined with which eye the target was aligned.

LASIK Procedure

Bladeless flaps were created with a 15-kHz femtosecond laser (IntraLase FS, IntraLase Corp., Irvine, CA). All flaps had a superior hinge and intended thickness of 120 μm. Raster line and spot separation were 9 and 11 μm, respectively; raster energy was 2.3 μJ, and side-cut energy was 2.5 μJ. Flaps created by the mechanical microkeratome (Hansatome, Bausch & Lomb, Rochester, NY) had a superior hinge with intended thickness of 180 μm. Ablation of the stromal bed was performed with a VISX Star S4 excimer laser (VISX, Santa Ana, CA) with radiant exposure of 160 mJ/cm². Emmetropia was attempted in all cases by using an ablation zone that ranged from 6.5×6.5 mm for spherical corrections to 6.5×5.0 mm for astigmatic corrections.

Both eyes of each patient were treated by 1 of the study ophthalmologists (SVP, LJM, or WMB) on the same day. All procedures followed a standard protocol: the bladeless flap was created first on the eye randomized to the femtosecond laser; the fellow eye then received a full LASIK procedure with the flap created by the mechanical microkeratome; finally, LASIK was completed on the first eye by separating and lifting the flap created by the femtosecond laser and ablating the stroma. It was not possible to mask patients as to which treatment was received in each eye. Postoperative topical medication regimens were identical for each eye and consisted of ciprofloxacin ophthalmic solution 4 times per day for 5 days, and fluorometholone 0.1% 4 to 8 times daily with a taper over 3 weeks.

Outcome Measures

Patients were examined before LASIK and at 1, 3, and 6 months after surgery. At each examination, high-contrast visual acuity, manifest refraction, contrast sensitivity, intraocular forward light scatter, and corneal backscatter were measured by observers masked as to which treatment was received in each eye. Corneas were also examined by confocal microscopy in vivo.

High-contrast visual acuity was measured by using the electronic Early Treatment of Diabetic Retinopathy Study testing protocol. Uncorrected visual acuity (UCVA) and best-spectacle corrected visual acuity (BSCVA) were recorded as letter scores, which were converted to logarithm of the minimum angle of resolution (logMAR).

Contrast sensitivity was examined by using the Functional Acuity Contrast Test (Stereo Optical, Inc., Chicago, IL) with best-spectacle correction in place. Patients were asked the orientation of lines of decreasing contrast for 5 spatial frequencies (1.5, 3, 6, 12, and 18 cycles/degree) under mesopic illumination (6 cd/m²). Intraocular forward light scatter was measured with a stray light meter, which used the direct compensation method to measure retinal stray light. This instrument measured the effect on central vision of light scattered within the eye from incident light sources at angles of 3.5, 10, and 28 degrees from the visual axis. A “stray light parameter” was defined as log(ϕ/E), where ϕ was the angle between the optical axis and the ring of modulated lights, L was the luminance of the compensating light at the center of the field, and E was the illuminance on the subject’s eye caused by the ring of lights. The stray light parameter was affected by scatter from all optical components of the eye, including all aberrations that degrade the point-spread function. Forward light scatter was proportional to the stray light parameter.

Central corneal backscatter (haze) was measured by using a custom scatterometer. Briefly, a modified slit-lamp was used to acquire high-magnification images of a narrow slit-beam through the cornea. Backscattered light from the anterior, middle, and posterior thirds of the cornea was measured from the intensity across the digitized image of the cornea. All measurements were standardized to a reference and expressed in scatter units. Although corneal haze consists of backscatter and reflectance, we will use the term backscatter broadly to include reflectance.

Confocal microscopy in vivo was performed with the Confoscan 3 or Confoscan 4 confocal microscopes (Nidek Technologies, Greensboro, NC), and with the Tandem Scanning confocal microscope (Tandem Scanning Corporation, Reston, VA). Images were acquired by continuous through-focusing as described in detail previously. Qualitative assessments of keratocytes were made from images acquired by the Confoscan confocal microscopes. Flap thickness at 1 month was calculated from the Tandem Scanning confocal microscope images by measuring the distance between the surface epithelium and the interface peak or image.

Data Analysis

The study was powered to detect a difference of 1 standard deviation in corneal haze between eyes (i.e., treatments), and this required a minimum of 13 subjects. Differences between treatments at each examination, and differences between preoperative and postoperative examinations for each treatment, were assessed by using 2-tailed paired t tests if the data were distributed normally and Wilcoxon signed-rank tests if they were not. Differences
between treatments at the 4 examinations were adjusted for 4 comparisons, and differences between the 3 postoperative examinations compared to preoperative within each treatment were adjusted for 3 comparisons. \( P < 0.05 \) was considered statistically significant. All statistical analyses were performed with Statistical Analysis System Version 9.1.3 (SAS Institute Inc., Cary, NC).

Minimum detectable differences were calculated for non-significant differences assuming that there were 21 independent observations (\( \alpha = 0.05/3 \) or 0.05/4 depending on the comparison, \( \beta = 0.20 \)). Correlations were assessed by using Pearson’s correlation coefficient if the data were distributed normally and Spearman’s test if they were not.

At the 3-month study visit, subjects were asked if they preferred the vision in one eye or the other, or whether they had no preference. We selected the 3-month visit because visual acuity and manifest refraction should have been stable with minimal influence from ocular surface pathology.

**Results**

**Corneal Backscatter**

Before LASIK, peak corneal backscatter originated from the anterior corneal surface, and a smaller peak was usually associated with the posterior surface (Fig 1). There were no differences in backscatter from the anterior, middle, or posterior thirds of the cornea between fellow eyes before surgery (Fig 1, Table 1).

Backscatter from the middle third of the cornea was higher 1 month after bladeless LASIK compared with LASIK with the mechanical microkeratome (\( P = 0.007 \)). No differences in backscatter were detected at 3 or 6 months (Fig 1, Table 1). Backscatter was higher in the anterior and middle thirds of the cornea at 1 and 3 months after bladeless LASIK compared with before surgery (\( P \leq 0.001 \)), and was higher in the anterior third of the cornea at 1 month after LASIK with the microkeratome compared to before surgery (\( P = 0.04 \)).

Confocal microscopy qualitatively showed more activated kerocytes in images centered at the interface early after bladeless LASIK than after LASIK with the microkeratome (Fig 2).

**High-Contrast Visual Acuity and Refractive Error**

No differences were detected in high-contrast UCVA and BSCVA between eyes that received a bladeless flap or eyes that received a microkeratome flap at any examination through 6 months after LASIK (Table 2). The minimum detectable differences in postoperative UCVA and BSCVA were \( \leq 0.11 \) logMAR and \( \leq 0.07 \) logMAR, respectively, during the first 6 months after surgery. Best-spectacle corrected visual acuity did not change at any ex-
amination after surgery compared with before surgery for either
treatment (Table 2). At 6 months after bladeless LASIK, BSCVA
increased by \(0.1\) logMAR in 1 eye and decreased by \(0.1\)
logMAR in 4 eyes. At 6 months after LASIK with the microker-
atome, BSCVA did not increase by \(0.1\) logMAR in any eye, and
decreased by \(0.1\) logMAR in 4 eyes. No eye lost
0.2 logMAR after either treatment.

For both treatments at all postoperative examinations, there was
no correlation between BSCVA and corneal backscatter. Manifest
refractive error did not differ between treatments before or after
LASIK (Tables 3, 4).

**Contrast Sensitivity**

Contrast sensitivity did not differ between treatments preopera-
tively or at any postoperative examination for any spatial fre-
quency (Fig 3). At the highest spatial frequency (18 cycles/
degree), contrast sensitivity increased at 3 months after LASIK.

<table>
<thead>
<tr>
<th>Table 1. Corneal Backscatter</th>
<th>Depth of Cornea</th>
<th>Treatment</th>
<th>Preoperative</th>
<th>1 Month</th>
<th>3 Months</th>
<th>6 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior third</td>
<td></td>
<td>Femtosecond laser</td>
<td>451±38</td>
<td>506±65*</td>
<td>499±76†</td>
<td>464±56</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mechanical microkeratome</td>
<td>457±35</td>
<td>496±64‡</td>
<td>481±58</td>
<td>463±45</td>
</tr>
<tr>
<td></td>
<td></td>
<td>P (MDD)</td>
<td>0.70 (18)</td>
<td>&gt;0.99 (37)</td>
<td>0.25 (33)</td>
<td>&gt;0.99 (28)</td>
</tr>
<tr>
<td>Middle third</td>
<td></td>
<td>Femtosecond laser</td>
<td>275±27</td>
<td>304±33‡</td>
<td>302±31*</td>
<td>288±28</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mechanical microkeratome</td>
<td>277±27</td>
<td>287±24</td>
<td>292±29</td>
<td>291±43</td>
</tr>
<tr>
<td></td>
<td></td>
<td>P (MDD)</td>
<td>&gt;0.99 (14)</td>
<td>0.007</td>
<td>0.07 (15)</td>
<td>&gt;0.99 (26)</td>
</tr>
<tr>
<td>Posterior third</td>
<td></td>
<td>Femtosecond laser</td>
<td>242±23</td>
<td>241±24</td>
<td>246±20</td>
<td>242±22</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mechanical microkeratome</td>
<td>246±28</td>
<td>243±24</td>
<td>246±16</td>
<td>245±23</td>
</tr>
<tr>
<td></td>
<td></td>
<td>P (MDD)</td>
<td>&gt;0.99 (17)</td>
<td>&gt;0.99 (12)</td>
<td>&gt;0.99 (12)</td>
<td>&gt;0.99 (10)</td>
</tr>
</tbody>
</table>

MDD = minimum detectable difference (paired data, \(\alpha = 0.05/4\), \(\beta = 0.20\), \(n = 21\)).

Data are presented as mean values ± standard deviation. \(P\) values comparing treatments were adjusted for 4
comparisons by the Bonferroni technique.

\(*P < 0.001; †P = 0.001; ‡P = 0.04\) versus preoperative (after adjusting for 3 comparisons by the Bonferroni technique).

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Figure 2. Confocal microscopy images (ConfoScan, Nidek Technologies) of both corneas of 1 subject before and after LASIK. The right eye was
randomized to bladeless LASIK, and the left eye to LASIK with the mechanical microkeratome. Preoperative images are from a depth equivalent to the
postoperative interface and show normal keratocyte nuclei. Postoperative images are centered at the interface and qualitatively show more keratocyte
activation, manifest as visible cell bodies and processes, with bladeless LASIK at 1 month. At 3 months, keratocyte activation appears to diminish in this
patient and is similar between treatments. Uncorrected Snellen visual acuity was 20/15 in each eye at both 1 and 3 months.
(bladeless, \(P = 0.02\); mechanical microkeratome, \(P < 0.001\)), but no difference was detected at 6 months for either treatment.

### Intraocular Forward Light Scatter

Forward light scatter within the whole eye did not differ between treatments at any examination (Table 5). Forward light scatter from stray light incident at 10 degrees was higher than preoperative at 6 months after LASIK with the mechanical microkeratome (\(P = 0.04\)) but not after bladeless LASIK (minimum detectable difference = 0.17, \(\alpha = 0.05/3, \beta = 0.20\)).

For both treatments at all postoperative examinations, there were no significant correlations between intraocular forward light scatter and corneal backscatter or between intraocular forward light scatter and contrast sensitivity.

### Flap Thickness

One month after bladeless LASIK, flap thickness was 143±16 \(\mu m\) (range, 110–172 \(\mu m\)), thicker than the intended 120 \(\mu m\) (\(P < 0.001\)). One month after LASIK with the mechanical microkeratome, flap thickness was 138±22 \(\mu m\) (range, 96–181 \(\mu m\)), thinner than the intended 180 \(\mu m\) (\(P < 0.001\)). The ratio of variances was 1.86 (\(P = 0.18\), Pitman test for paired data), and the minimum detectable ratio of variances was 3.44 (\(\alpha = 0.05, \beta = 0.20\), \(n = 21\)).

### Patient Preference

At 3 months after LASIK, 5 patients preferred the vision in the eye that received the bladeless flap, 7 patients preferred the vision in the eye that received the mechanical microkeratome flap, and 9 patients expressed no preference. For the 12 patients who did express a preference, the preferred eye was the dominant eye in 5 cases, and was the eye with better UCVA (\(\geq 0.1\) logMAR) in 4 cases.

### Discussion

This prospective study, in which fellow eyes were randomized to LASIK with flaps created by a femtosecond laser and by a mechanical microkeratome, showed no clinical or statistical differences in high-contrast visual acuity, manifest refractive error, contrast sensitivity, or intraocular forward light scatter through 6 months after surgery. Corneal backscatter increased with both treatments during the first month after LASIK, but was 6% higher in the corneas treated with the femtosecond laser than in corneas treated with the mechanical microkeratome. Increased backscatter with bladeless LASIK may be the result of increased inflammation compared with LASIK with mechanical microkeratome.

### Table 2. Visual Acuity (VA)

<table>
<thead>
<tr>
<th>Treatment</th>
<th>VA (logMAR), (n = 21) (Snellen Equivalent)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Preoperative</td>
</tr>
<tr>
<td>Uncorrected VA</td>
<td></td>
</tr>
<tr>
<td>Femtosecond laser</td>
<td>0.93±0.33 (20/160)</td>
</tr>
<tr>
<td>Mechanical microkeratome</td>
<td>0.98±0.35 (20/200)</td>
</tr>
<tr>
<td>(P) (MDD)</td>
<td>0.45 (0.10)</td>
</tr>
<tr>
<td>Best spectacle corrected VA</td>
<td></td>
</tr>
<tr>
<td>Femtosecond laser</td>
<td>−0.07±0.07 (20/15)</td>
</tr>
<tr>
<td>Mechanical microkeratome</td>
<td>−0.08±0.05 (20/15)</td>
</tr>
<tr>
<td>(P) (MDD)</td>
<td>0.67 (0.04)</td>
</tr>
</tbody>
</table>

MDD = minimum detectable difference (paired data, \(\alpha = 0.05/4, \beta = 0.20, n = 21\)).

Data are presented as mean values ± standard deviation. \(P\) values comparing treatments were adjusted for 4 comparisons by the Bonferroni technique.

### Table 3. Manifest Refractive Error

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Refractive Error (D), (n = 21)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Preoperative</td>
</tr>
<tr>
<td>Manifest sphere</td>
<td></td>
</tr>
<tr>
<td>Femtosecond laser</td>
<td>−4.02±1.61</td>
</tr>
<tr>
<td>Mechanical microkeratome</td>
<td>−4.15±1.62</td>
</tr>
<tr>
<td>(P) (MDD)</td>
<td>&gt;0.99 (0.35)</td>
</tr>
<tr>
<td>Manifest cylinder</td>
<td></td>
</tr>
<tr>
<td>Femtosecond laser</td>
<td>0.70±0.82</td>
</tr>
<tr>
<td>Mechanical microkeratome</td>
<td>0.77±0.88</td>
</tr>
<tr>
<td>(P) (MDD)</td>
<td>&gt;0.99 (0.27)</td>
</tr>
</tbody>
</table>

MDD = minimum detectable difference (paired data, \(\alpha = 0.05/4, \beta = 0.20, n = 21\)).

Data are presented as mean values ± standard deviation. \(P\) values comparing treatments were adjusted for 4 comparisons by the Bonferroni technique.
Inflammatory cell infiltration increases with higher side-cut energies (Invest Ophthalmol Vis Sci 2006;47:2733) because of epithelial disruption and release of proinflammatory cytokines. Although inflammatory cell infiltration was not observed by confocal microscopy in our study, eyes were not examined until 1 month after surgery, and an early transient inflammatory cell response may not have been detected. Higher energy levels are also associated with increased keratocyte death (Invest Ophthalmol Vis Sci 2006;47:2733; Invest Ophthalmol Vis Sci 2006; 47:2731), which triggers a greater wound healing response, sometimes resulting in haze. In our study, keratocyte activation was qualitatively more apparent after bladeless LASIK compared with LASIK with the mechanical microkeratome in some subjects, and appeared to diminish in parallel with haze. Further study is needed to correlate keratocyte activation after bladeless LASIK to corneal backscatter. Increased backscatter could have been the result of traumatic flap lifts, which occur for most surgeons early in their experience with the femtosecond laser. However, all surgeons in the present study had adequate experience with bladeless flap lifts before enrolling patients.

Table 4. Postoperative Manifest Sphere and Cylinder, n (%)

<table>
<thead>
<tr>
<th>Difference from Emmetropia</th>
<th>1 Month FL</th>
<th>MM</th>
<th>3 Months FL</th>
<th>MM</th>
<th>6 Months FL</th>
<th>MM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manifest sphere</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;0.5D</td>
<td>20 (95)</td>
<td>18 (86)</td>
<td>19 (90)</td>
<td>17 (81)</td>
<td>19 (90)</td>
<td>19 (90)</td>
</tr>
<tr>
<td>≥0.5D</td>
<td>1 (5)</td>
<td>3 (14)</td>
<td>2 (10)</td>
<td>4 (19)</td>
<td>2 (10)</td>
<td>2 (10)</td>
</tr>
<tr>
<td>Manifest cylinder</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;0.5D</td>
<td>20 (95)</td>
<td>20 (95)</td>
<td>20 (95)</td>
<td>19 (90)</td>
<td>19 (90)</td>
<td>20 (95)</td>
</tr>
<tr>
<td>≥0.5D</td>
<td>1 (5)</td>
<td>1 (5)</td>
<td>1 (5)</td>
<td>2 (10)</td>
<td>2 (10)</td>
<td>1 (5)</td>
</tr>
</tbody>
</table>

D = diopters; FL = femtosecond laser; MM = mechanical microkeratome.

Although corneal backscatter after bladeless LASIK was higher than after LASIK with the mechanical microkeratome, the differences were small and not visually significant. Corneal haze consists of reflected and backscattered light, neither of which directly affect the image formed on the retina. Forward light scatter does degrade the retinal image, and although a relationship between corneal backscatter and the other outcomes was not found, it is possible that haze may have caused some of the differences observed in this study.

Figure 3. Mesopic contrast sensitivity before and after LASIK (black line = bladeless; gray line = mechanical microkeratome). No differences were found between treatments preoperatively or postoperatively for any spatial frequency. Mesopic contrast sensitivity at 18 cycles/degree increased at 3 months after LASIK (bladeless, P = 0.02; mechanical microkeratome, P<0.001), but not at 6 months. The dotted line in the postoperative graphs represents preoperative mesopic contrast sensitivity for comparison.
scatter and forward scatter is often inferred, the relationship is complex. Nevertheless, increased corneal backscatter after photorefractive keratectomy has been correlated with whole eye forward light scatter and low-contrast visual acuity. In our study, Lim et al. and visual acuity did not differ between treatments at any examination except for differences in manifest postoperative astigmatism. Despite our small sample, the minimum detectable statistical differences for uncorrected and best-corrected visual acuities were approximately 0.1 logMAR or less (Table 2) at all postoperative examinations. Our study therefore had sufficient power to detect clinically significant differences in visual acuity between the 2 treatments. Contrary to Kezirian and Stonecipher, we were unable to detect statistical or clinical differences in residual refractive error or variance of astigmatism.

Changes in contrast sensitivity after LASIK are variable. Decreased contrast sensitivity has been reported at low through high spatial frequencies during the first 3 to 6 months after LASIK, with recovery to preoperative levels thereafter. Mutyala et al. found little change in contrast sensitivity after LASIK, and Lim et al. found an increase in mesopic contrast sensitivity at higher spatial frequencies 3 months after bladeless LASIK but not after LASIK with a mechanical microkeratome. Although optical magnification, which occurs after myopic LASIK, may account for some of the increase in contrast sensitivity at higher spatial frequencies compared with spectacle correction, controlled for optical magnification in a large retrospective analysis, and still found increased contrast sensitivity at all spatial frequencies after wavefront-guided LASIK. None of the eyes in our study received wavefront-guided ablations, and yet we found a small increase in mesopic contrast sensitivity at the highest spatial frequency at 3 months, but not at 6 months, with both methods of flap creation. Our results show that contrast sensitivity can be preserved during the first 6 months after conventional (non–wavefront-guided) LASIK, regardless of the method of flap creation.

Bladeless flaps were thicker than intended and mechanical microkeratome flaps were thinner than intended in our study, with the result that the achieved mean flap thicknesses were similar for both treatments. However, for an intended bladeless flap thickness of 120 μm, Binder measured 122±12 μm, and for an intended bladeless flap thickness of 130 μm, Kezirian and Stonecipher measured...
structures, including the surface epithelium and interface,19,21 cal microscopy enables direct visualization of corneal
ative and intraoperative ultrasonic pachometry measurements and Kezirian and Stonecipher11 derived flap thickness from preop-
erative and intraoperative ultrasonic pachometry measure-
ments, whereas we used confocal microscopy in vivo. Confo-
cal microscopy enables direct visualization of corneal
lower than we reported in a previous study with the same
mechanical microkeratome in the present study appears
is routinely calculated. Of note, flap thickness with the
femtosecond laser can create much thicker than intended
surgeons. However, similar to mechanical microkeratomes,
bladeless flap thickness was within 1 μm for individual
patients previously, uncorrected Snellen visual acuity was
immediately replaced and excimer ablation was not per-
formed on either eye at that time. Four months later, the
patient received photorefractive keratectomy to the eye with
the button-hole, and did well postoperatively with uncor-
rected Snellen visual acuity of 20/15 with > 1 year of
follow-up. After completion of bladeless LASIK in the
fellow eye by separating and lifting the flap created 4
months previously, uncorrected Snellen visual acuity was
20/20 1 year after surgery.6 Because our study was designed
to examine the long-term changes in keratocyte density and

effects on corneal haze and vision after LASIK, we ex-
cluded this patient from our study. Given the good outcome
in both eyes for this patient, we doubt that an intent-to-treat
analysis would have altered the conclusions of our study
with respect to visual outcomes. Although 1 significant flap
creation complication occurred with the mechanical micro-
eratome, our study was not designed to assess the safety of
the methods of flap creation. The incidence of button-hole
flaps with the Hansatome microkeratome has been esti-
ated to be <0.3%,40 and thus, determining differences in
safety between the femtosecond laser and the mechanical
microkeratome would require a very large prospective study
or a metaanalysis.

The lack of clinically significant differences in vision in
our study during the first 6 months after LASIK suggests
that either method of flap creation is acceptable. Predict-
ability of flap thickness may be better with the femtosecond
laser than with mechanical microkeratomes, but large devi-
ations from intended thickness are possible with both meth-
ods. Differences in safety and corneal biomechanics may
exist, but have yet to be demonstrated.

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