

Predictability of Corneal Flap Thickness in LASIK Using the WaveLight FS200 Femtosecond Laser

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ABSTRACT (250 of 250 words)

Purpose: To compare the intended versus resultant thickness of laser in situ keratomileusis (LASIK) flaps created with a new femtosecond laser (WaveLight FS200 Femtosecond Laser, WaveLight GmbH, Alcon Laboratories) and to report refractive outcomes at 3 months post-treatment.

Setting: Wellington Eye Clinic, Dublin, Ireland

Design: Retrospective consecutive case series

Methods: A consecutive series of eyes having LASIK flaps created using the WaveLight FS200 Femtosecond laser were included in this analysis. Eyes with preoperative spherical equivalent (SE) myopic refractive errors up to -12.00 diopters (D), hyperopic refractive errors up to +5.50D, and astigmatism up to 6.00D received primary LASIK surgery. Outcomes assessed included post-treatment flap thickness and 3 month post-treatment refractive outcomes.

Results: Outcomes of 431 eyes of 258 patients with LASIK flaps made using the same femtosecond laser were assessed. With an intended flap thickness of 120 microns (μm), the average post-LASIK flap thickness \pm standard deviation achieved was $120.23 \pm 13.94 \mu\text{m}$. In 349 of the 813 eyes, the EX500 optical pachymetry measurements were compared to Scheimpflug pachymetry readings. The mean corneal thickness was $553.52 \pm 29.81 \mu\text{m}$ with EX500 pachymetry and $553.39 \pm 29.12 \mu\text{m}$ with Pentacam. In 162 eyes flap thickness was measured with OCT and found to be $121.94 \pm 10.52 \mu\text{m}$. Achieved flap dimensions were as intended.

Conclusions: This study provides evidence of the predictability and lower variability of LASIK flaps created using the WaveLight FS200 Femtosecond Laser. Consecutive patients undergoing LASIK were found to have good, predictable, and stable outcomes at the 3 month mark.

INTRODUCTION

The predictability of corneal flap thickness is critical both in planning and producing successful laser in situ keratomileusis (LASIK) outcomes.¹ Avoiding well-documented risks associated with flaps that have been made too thin or too thick can contribute to the safety of the procedure.^{2 3 4 5 6} The femtosecond laser has rapidly evolved to become a widely adopted technology for surgeons performing LASIK surgery.⁷ Advances in femtosecond technology including higher laser repetition rates have resulted in a reduction in the time taken to create the cut and in the energy requirements. Because of the lower energy requirements, the cavitation bubble size is reduced, less tissue inflammation is observed, and the lifting of the flap is made easier.⁸ Faster repetition rates also enable the leading edge of treatment to stay ahead of the spreading opaque bubble layer (OBL).

Using optical coherence tomography (OCT), the uniformity and accuracy of LASIK flaps created with a femtosecond laser versus a mechanical microkeratome has previously been studied.⁹ At 1 month post-treatment, flap ranges in the microkeratome group were significantly greater than those found in the femtosecond laser group. The maximum deviation from the intended flap thicknesses was 7 microns (μm) in the femtosecond laser group compared to 26 μm in the microkeratome group. A difference in flap uniformity of $>20 \mu\text{m}$ was observed in 0.42% of eyes in the femtosecond laser group and in 15% of eyes in the microkeratome group.

A new 200 kilohertz (kHz) femtosecond laser (WaveLight FS200 Femtosecond Laser, WaveLight GmbH, Alcon Laboratories, Fort Worth, Texas) has been developed to create lamellar flaps in a very short period of time (6 to 7 seconds depending on the flap size). The femtosecond laser has been fully integrated with a 500 hertz (Hz) excimer laser, which incorporates non-contact pachymetry to allow surgeons to monitor flap and corneal thickness before, during, and after the ablation using the EX500 Excimer Laser's online optical pachymeter (WaveLight GmbH, Alcon Laboratories). In a pilot study of 20 eyes, Winkler von Mohrenfels et al¹⁰ reported the first clinical results using this femtosecond laser and reported high levels of safety, stability, and efficacy. This retrospective study assesses the intended and achieved corneal flap thickness using this new femtosecond laser in a consecutive series of patients and reports 3 month post-treatment refractive outcomes.

MATERIALS AND METHODS

This retrospective review included patients who had LASIK for myopia, hyperopia, and mixed astigmatism between June 24, 2010 to November 17, 2011. Data were collected on a consecutive series of patients treated by two surgeons at the Wellington Eye Clinic, Dublin, Ireland. Written informed consent was obtained from all patients. All eyes that underwent LASIK surgery as an initial refractive procedure and had flaps created using the WaveLight FS200 Femtosecond Laser were included in this analysis. Although there were no other specific eligibility criteria for inclusion in this study, patients met general eligibility criteria for LASIK surgery. Patients were at least 18 years of age with a stable refractive error (<0.50 diopter (D) change in the preceding year). Excluded ophthalmic conditions included anterior or posterior

segment abnormalities; clinically significant dry eyes; forme fruste keratoconus or keratoconus; and clinically significant abnormalities on topography and tomography. Eyes included in this study had preoperative spherical equivalent (SE) myopic refractive errors up to -12.00 D, SE hyperopic refractive errors up to +5.50 D, and up to 6.00 D of astigmatism. Eyes had to have preoperative central corneal thickness readings of at least 480 μm with an estimated post-procedure residual corneal bed of greater than 270 μm . The corneal thickness and predicted stromal bed depth were based on preoperative records and on pre-procedure pachymetry readings.

Preoperative evaluations of patients included uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA), manifest and cycloplegic refractions, scotopic pupil size (Procyon P3000, Haag-Streit UK), topography (Allegro Topolyzer, WaveLight GmbH, Alcon Laboratories), tomography (Allegro Oculyzer, WaveLight GmbH), wavefront (Allegro Analyzer, WaveLight GmbH), and pachymetry (Allegro Oculyzer, WaveLight GmbH). The distance UCVA and BCVA were evaluated under photopic conditions with a luminance level of 80 to 320 $\text{candela}/\text{m}^2$. Manifest refractions were obtained using plus-to-blur and fogging techniques to confirm the spherical endpoint. A complete anterior segment examination and a dilated fundus examination were performed. Postoperatively, UCVA, BCVA, and manifest refraction were evaluated at 6 weeks and 3 months.

Validation of the WaveLight Refractive Suite Online Pachymeter

The FS200 femtosecond laser combines with the EX500 Excimer Laser comprising the WaveLight Refractive Suite. The excimer laser has an inbuilt non-touch optical pachymeter that

can measure the total corneal thickness before and after flap creation. Flap thickness was calculated by subtraction technique as the difference between the preoperative central corneal thickness and the residual unmoistened corneal bed stroma, measured after flap lifting. Both measurements were performed by the same online pachymeter while at least three consecutive measurements were collected and compared to ensure low intrasession variability of measurements. Repeated measurements were applied when central corneal thickness variation was greater than 5 μm .

The pachymetry measurement occurs at the apex of the cornea. The distance diodes of the laser need to be centered manually by the surgeon on the corneal apex. The 2 red He-Ne distance diodes have to merge with the green blinking fixation diode on the cornea or first Purkinje reflex. A pachymetry measurement can only be recorded and stored in the system if 10 single measurements are equal. This process happens automatically and after activating the pachymeter. Once a pachymetry reading is displayed, it is a compilation of 10 automatic pachymetry measurements.

To validate the accuracy of flap thickness measurements, readings were obtained in 813 eyes using the inbuilt EX500 optical pachymeter. With a mean intended target flap thickness \pm standard deviation of $119.44 \pm 3.44 \mu\text{m}$, the mean flap thickness achieved was $120.22 \pm 13.94 \mu\text{m}$. In 349 of the 813 eyes, the EX500 optical pachymetry measurements were compared to Scheimpflug pachymetry readings (Pentacam, OCULUS Optikgeräte GmbH, Wetzlar, Germany). The mean corneal thickness obtained was $553.52 \pm 29.81 \mu\text{m}$ with EX500 pachymetry and was $553.39 \pm 29.12 \mu\text{m}$ with the Pentacam. Figure 1 shows that there was minimal deviation from the mean. In addition, the measurements correlated whether the cornea

was thick or thin. There was no statistical difference between EX500 and Pentacam pachymetry measurements with regard to total corneal thickness.

Flap thickness was measured at day 1 or week 6 postoperatively in 162 of the 813 eyes with the OCT anterior segment module of the Topcon 3D OCT (3D OCT-2000, Topcon, Rotterdam, Netherlands). These OCT measurements were compared to the intraoperative flap measurements that were obtained with the online pachymeter of the EX500 excimer laser. The mean flap thickness measurement with EX500 pachymetry was $120.85 \pm 12.45 \mu\text{m}$ as compared to $121.94 \pm 10.52 \mu\text{m}$ using OCT. The OCT measurements were performed using the zoom function on the OCT software to magnify the corneal image and the contrast function to highlight the flap interface resulting in a tighter standard deviation than was found using the EX500 pachymeter. Comparing measurements obtained on the same eye, the mean difference, which was compared to zero using the 1-sample student t-test, was $1.09 \mu\text{m}$ ($p = 0.180$), which was not statistically significant. Since there were two outliers, the Wilcoxon signed rank test was also performed, which found a significant difference ($p = 0.047$). However, a difference of $1.09 \mu\text{m}$ may not be of practical significance.

Flap dimension uniformity was studied in 30 of the 813 eyes by measuring the central flap thickness in addition to 2 sites located right and left of center at the 6 mm optic zone diameter using OCT. With mixed model techniques by the F-test, there was no significant difference between the means in the right, left, and center positions ($p = 0.510$). The standard deviation of repeated measures relating to the difference between measurements on the same eye was $4.37 \mu\text{m}$. The mean right measurement was $121.02 \pm 6.92 \mu\text{m}$, the mean central measurement was

123.06 ± 9.76 μm, and the mean left measurement was 120.95 ± 5.66 μm. The flap was quite planar in architecture (Figure 2). The standard deviation of 4.37 was lower than the other standard deviations cited because it represented variability of measurement differences in same the same eye (i.e. fixed patient effects were cancelled).

Treatment Planning and Procedure

To plan the treatments, topographical maps including posterior corneal surface readings using Scheimpflug principles were taken to ensure suitability of the patient for the planned procedure. For all myopic eyes, flaps required a diameter of 8.5 mm or greater depending on the degree of astigmatism present. A 6.5 mm diameter optical zone and a 1.0 mm transition zone were used for the ablation. For hyperopic eyes, flaps required a diameter greater than 8.5 mm with a 6.5 mm diameter optical zone and a 2.4 mm transition zone used for the ablation. The planned flap thickness in the majority of eyes (789 eyes) was 120 μm. Thinner flaps of 100 or 110 μm were planned in 1 eye or in 23 eyes, respectively, due to preoperative thin corneas or higher corrections. The femtosecond laser was programmed to the appropriate flap thickness and diameter with a 70-degree angled side cut. All flaps had a superior hinge and a 55-degree hinge angle. Raster line and spot separation were 8 and 8 μm, respectively; raster energy was 0.8 μJ and side-cut energy was 0.8 μJ.

Flaps in all primary cases were created using the WaveLight FS200 Femtosecond Laser (WaveLight GmbH, Alcon Laboratories). After applying the suction ring to the eye and turning on the suction, the laser system with the appplanation cone is lowered into the suction ring. A second automatic suction is activated that encourages a precise fit of the cone into the suction

ring. The cornea is flattened after the second vacuum between the suction ring and the applanation cone is applied. This connection creates a stable position of the eye. The suction ring can be decentered slightly superiorly so that more limbus is exposed at the 12:00 position. This provides space for the channel to vent the exhaust gas that may have otherwise collected and potentially contributed to an OBL. By smoothing the surface of the cornea with a LASIK irrigating cannula (Visitec, St. Charles, Illinois), more gas can be expressed. Due to reduced OBL, the physician does not have to wait for the bubbles to dissipate in order to perform the ablation. A standard flap is created in approximately 6 to 7 seconds. The edge of the flap is located and lifted by pressing downwards with a LASIK spatula at an approximate 70 degree angle. Fine adhesions can be dissected, the flap is folded back on itself, and the interface is cleared.

The procedure can be monitored through the laser microscope or on the monitor of the femtosecond laser, which allows the surgeon to see precisely where the ablation is planned to create the corneal flap appropriately. The applanated area can be controlled while using the monitor of the laser to center the ablation profile from the excimer laser on the cornea. After performing non-touch pachymetry to assess the residual stromal bed, the surgeon is ready to proceed with the ablation. All procedures were performed using the WaveLight EX500 Excimer Laser. The wavefront-optimized profile was used for the great majority of cases and the treatment was based on manifest refraction. A plano prescription was attempted in the majority of cases. Residual myopia of -1.00 DS was targeted for cases of mini-monovision and a correction of -1.75 DS was targeted for full monovision.

Statistical Methods

Summary statistics were computed for each variable. Measurements on the same eye were compared and differences were checked for outliers and normality. A one-sample student t-test was used to determine if the mean difference was zero. In the case of outliers or if the normality assumption was not satisfied, a non-parametric test (Wilcoxon signed rank test) was used. An evaluation was also performed to determine whether the mean value of a variable was equal to some hypothetical value. To compare variances of measurements, the F-test was used. An analysis of repeated measurements of a variable was carried out by fitting a random effects model (i.e. mixed model, with random effect patient) and estimating the variability of the measurement error. Effect with a p-value less than 0.05 was regarded as statistically significant. Analyses were carried out using SAS 9.2, version 9 (SAS Institute Inc., Cary, North Carolina, USA).

RESULTS

Demographic data for all treated eyes are presented in Table 1. This was a retrospective review of patients with at least 3 months of follow-up.

Central Flap Thickness and Dimensions

With an intended flap thickness of 120 microns (μm), the average post-LASIK flap thickness \pm standard deviation achieved was $120.23 \pm 13.94 \mu\text{m}$ (range: 73 to 176 μm). While flaps in eyes with preoperative myopia had a standard deviation of 13.97 μm , flaps in eyes with preoperative hyperopia had a standard deviation of 13.36 μm . An analysis of the last 200 flaps created

showed a slight improvement in accuracy with flaps produced having a standard deviation of 12.58 μm . When comparing right eyes to left eyes the mean flap thickness was 120.49 ± 13.89 and 120.03 ± 13.98 microns respectively and this difference was not statistically significant ($p = 0.503$) nor was it clinically significant. As far as flap dimensions are concerned, the initial 30 eyes were studied to determine flap size achieved versus flap size intended. In all cases, the flap size achieved was exactly what had been intended and this aspect of the study was deemed to be complete. No procedure was delayed or aborted due to suction loss or OBL. With hyperopic LASIK, some limbal and hinge hemorrhages were observed when large (9.5 mm) flaps were created; the blood was simply swabbed with a Weck-cell sponge and the procedures were completed without difficulty. There were no flap-related postoperative complications including epithelial ingrowth, corneal haze, or diffuse lamellar keratitis.

Outcomes of Primary LASIK in Patients with Preoperative Myopia or Myopic Astigmatism

With regards to efficacy of LASIK at 3 months post-treatment, the UCVA results of patients with preoperative myopia show that 91.4% of eyes achieved a Snellen UCVA of $\geq 20/25$, 83.4% had a UCVA of $\geq 20/20$, 69.5% had a UCVA of $\geq 20/16$, and 10.7% had a UCVA of $\geq 20/12.5$. At 3 months post-LASIK, BCVA results show that 93.9% of eyes with preoperative myopia achieved BCVA $\geq 20/20$, 88.4% had BCVA $\geq 20/16$, and 13.8% had BCVA $\geq 20/12.5$. Figure 3, which compares the preoperative BCVA results to the 3 month postoperative UCVA results in patients with preoperative myopia shows that postoperative UCVA values are approaching the preoperative BCVA levels; however the percentage of eyes achieving a UCVA of 20/12.5 or better (10.8%) at 3 months post-treatment was higher than the percentage having a preoperative BCVA of better or equal to 20/12.5 (5.9%). Safety outcomes in this group are shown in Figure

4. At 3 months, the change in UCVA ($p < 0.001$) and BCVA ($p = 0.0041$) compared to baseline was statistically significant by the t-test.

Figure 5 shows the post-treatment SE refraction at 3 months post-LASIK. The predictability analysis shows that 91% of eyes were within ± 0.50 D of the intended SE refraction; 2% were overcorrected and 7% were undercorrected. At 3 months post-LASIK, 72.0% of eyes had postoperative refractive astigmatism ≤ 0.25 D and 16.9% were ≤ 0.50 D. Mean residual astigmatism calculated by vectoral analysis was 0.28 ± 0.31 D. In regards to stability, LASIK eyes had preoperative SE myopia of -4.03 ± 2.29 D decreasing to -0.14 D at 6 weeks and -0.20 D at 3 months. No intraoperative or postoperative adverse events occurred in this cohort of patients.

Outcomes of Primary LASIK in Patients with Preoperative Hyperopia or Hyperopic Astigmatism

At 3 months post-LASIK, the UCVA results of eyes with preoperative hyperopia show that 57.1% of eyes achieved a UCVA $\geq 20/25$, 46.4% of eyes had a UCVA $\geq 20/20$, 39.3% had a UCVA $\geq 20/16$, and 3.6% had a UCVA $\geq 20/12.5$. At 3 months post-procedure, BCVA results show that 94.3% of eyes had $\geq 20/25$ vision, 81.1% had $\geq 20/20$ vision, and 52.8% had BCVA $\geq 20/16$. Figure 6 compares the preoperative BCVA results to the 3 month postoperative UCVA results in patients with preoperative hyperopia. Safety outcomes in this group are shown in Figure 7. At 3 months, the change in UCVA ($p < 0.001$) compared to baseline was statistically significant by the t-test while the change in BCVA was not statistically significant ($p = 0.1057$).

Figure 8 shows the post-treatment SE refraction at 3 months post-LASIK. The predictability analysis shows that 71% of eyes were within ± 0.50 D of the target refraction with 18% overcorrected and 12% undercorrected. At 3 months post-LASIK, 54.9% of eyes had postoperative refractive astigmatism ≤ 0.25 D and 19.6% were ≤ 0.50 D. Mean residual astigmatism calculated by vectoral analysis was 0.49 ± 0.51 D. In regards to stability, eyes had preoperative SE hyperopia of $+2.20 \pm 1.23$ D decreasing to -0.40 D at 6 weeks and -0.33 D at 3 months. No intraoperative or postoperative complications occurred in patients undergoing hyperopic LASIK.

DISCUSSION

The use of femtosecond technology for the creation of the LASIK flap has gained widespread use due to its improved safety, precision, and reproducibility.¹¹ With advances in femtosecond lasers, clinical safety and outcomes with their use have improved.^{12 13} Current mechanical microkeratomes create LASIK flaps with a standard deviation of approximately 22 to 26 microns.^{14[22] 15[22.8] 16[26] 17[23.5-25.5]} In this study, flap thickness was found to have excellent predictability with a lower standard deviation ($13.9 \mu\text{m}$) relating to flap thickness variability as compared to that generally achieved by mechanical microkeratomes. In addition, consecutive patients who underwent LASIK surgery for myopia, hyperopia, and mixed astigmatism with flaps made using this new femtosecond laser were found to have good, predictable, and stable outcomes.

Flap cutting with this femtosecond laser initially involves the placement of an automated suction ring onto the corneal surface in order to immobilize the eye. A computer-controlled applanation cone is then docked into the suction ring. For higher precision and consistency, a balanced beam control check calibrates each individual applanation cone to help eliminate the variance in length of each individual applanation cone and temperature shifts in the machine's components as well as the environment. With this femtosecond device, the centration of the flap can be repositioned within a 10 mm diameter area, even after the suction ring has been applied. Via a computer network, the ablation profile is fed to the femtosecond laser where it can be superimposed on the cornea to adjust the flap profile to fit the ablation. By shifting the placement grid, the surgeon can customize flap placement to best fit the planned ablation. The femtosecond laser releases infrared laser pulses in a raster pattern onto the cornea, resulting in the formation of small cavitation bubbles within the tissue. The creation of thousands of such cavitation bubbles in a lamellar pattern leads to the creation of a cleavage plane within the cornea. Subsequently, laser pulses are fired in a peripheral circular pattern onto the corneal stroma in order to create a vertical side cut and a hinge. This laser is capable of making large diameter corneal applanation zones, up to 13 mm, allowing comfortable margins when performing hyperopic LASIK. It automatically cuts a square tunnel through the flap's hinge that allows the cavitation gas to escape to minimize the development of an OBL. In addition, the beam target, size, and spacing are optimized to minimize the OBL, allowing the surgeon to perform an excimer laser treatment immediately after flap creation.

Corneal flaps created with the femtosecond laser have been shown to be more predictable in depth and have a more desirable planar morphology.^{18 19} The FS200 laser has a 10 mm

homogeneous beam that allows the user to vary the spot size, depth, and energy delivery of the femtosecond beam. The benefit of being able to adjust the laser's settings is customization. The laser can make stromal cuts as shallow as 30 μm away from Descemet's membrane and as deep as 1200 μm . The size, shape, angle, location, and depth of corneal cuts can be tailored according to the ablation profile, corneal thickness, or other surgical considerations. The laser can make round or elliptical cuts for corneal flaps as well as side cuts and reverse cuts for corneal segments and keratoplasties. It provides the ability to treat an array of corneal shapes and sizes. Relating to flap hinge location, this laser offers presets for superior, nasal, and temporal hinges. For example, when planning a LASIK treatment for hyperopes or an ablation in the upper nasal area, the surgeon can place the flap's hinge in the lower temporal quadrant. The surgeon can also adjust the size, angle and location of the hinge to preserve corneal nerves.

Mrochen et al²⁰ reported that the technical features of the FS200, such as optical design, pulse energy, and scanning algorithms at a high repetition rate, allow high reproducibility for tissue cutting with a standard deviation of <10 μm in depth and 0.1 mm laterally. These investigators found that intraocular pressure increases up to 150 mmHg during applanation. Due to the relatively short suction-on to suction-off time with this laser, there is a potential reduction in peak intraocular pressure duration. The patient can typically see when the vacuum is applied initially and the vision only blacks out completely for the 6 to 7 seconds when the 2nd vacuum is activated.

Previously, Winkler von Mohrenfels and colleagues²¹ evaluated the FS200 femtosecond laser in a laboratory setting on 20 porcine and 3 human cadaver eyes. Light microscopy, transmission

electron microscopy, and scanning electron microscopy were used to assess the surface of the cornea and the structure and ultrastructure of the corneal cells and stroma. Light microscopy and transmission electron microscopy revealed no side effects on the structure and ultrastructure of the corneal cells and stroma due to the laser application. Area around the flap cut was only minimally affected. Keratocytes and collagen fibers showed no to very little alteration due to laser treatment. In all cases, scanning electron microscopy revealed smooth surfaces and precise side cuts. In their pilot study involving 20 eyes of 11 patients, no structural or thermal side effects to corneal epithelium, stroma, or endothelium were observed.²² In addition, none of the flaps showed any signs of inflammation during the entire 12 month follow-up period.

Laser-assisted in situ keratomileusis (LASIK) requires precise corneal flap cutting. Improved predictability has led surgeons to explore the possibility of thin flap LASIK. Thin flap LASIK, also referred to as sub-Bowman's keratomileusis, has the advantage of preserving more stroma and potentially reducing the incidence of corneal ectasia but seems to be associated with an increased incidence of interface haze.^{23 24} In this study, there were no intraoperative or postoperative complications related to flap creation.

In this case series, LASIK outcomes in eyes having flaps created with this femtosecond laser showed good safety, efficacy, predictability, and stability. Postoperatively, 91% of eyes with preoperative myopia were within ± 0.50 diopter of the intended SE refraction, 69.5% had a UCVA $\geq 20/16$ (-0.1 logMAR), and 24.4% gained 1 or more lines of BCVA at 3 months post-treatment. In eyes with preoperative hyperopia, 71% of eyes were within ± 0.50 diopter of the intended SE refraction at 3 months post-treatment, 39.3% had a UCVA $\geq 20/16$, and 18.9% gained 1 or more lines of BCVA.

This study was designed to assess all-comers to reflect a population of patients seen in a typical refractive surgery practice. The femtosecond laser yielded precise and reproducible lamellar flap thickness with a narrow standard deviation. The creation of all flaps was easily performed without any intraoperative or postoperative complications. Suction loss occurred in 4 of the 831 eyes prior to commencing flap creation and once the suction ring was reapplied, a flap was created without any problems. The findings in this series also show that LASIK is a safe and efficacious treatment modality with flaps created with this laser and provides predictable refractive outcomes.

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Cover letter for Predictability of Corneal Flap Thickness in LASIK Using the WaveLight

FS200 Femtosecond Laser

What was known before: In a pilot study of 20 eyes, Winkler von Mohrenfels et al¹ reported the first clinical results using this femtosecond laser and reported high levels of safety, stability, and efficacy.

What this study adds: This paper reports the average post-LASIK flap thickness and standard deviation achieved in a large case series using the WaveLight FS200 Femtosecond Laser. In addition, post-treatment outcomes of the LASIK procedures are reported. As far as the authors are aware, this is the first report of a large series of eyes that were treated with the WaveLight FS200 femtosecond laser for the purpose of making LASIK flaps. This is also the first report of using the WaveLight EX500 excimer laser's online pachymeter during surgery to determine flap thickness.

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FIGURE LEGENDS

Figure 1. Graph of mean central corneal thickness showing a narrow standard deviation and no correlation with corneal thickness.

Figure 2. Optical coherence tomography image showing the planar morphology of the flap.

Figure 3. Graph of efficacy data for primary LASIK treatments in eyes with preoperative myopia. This graph compares the preoperative best-corrected visual acuity (BCVA) results to the 3 month postoperative uncorrected visual acuity (UCVA) results. The red bars show preoperative BCVA and the blue bars show postoperative UCVA. The actual percentage of eyes represented by the bars is shown at the top of each bar. At 3 months post-procedure, postoperative UCVA is approaching the preoperative BCVA in this group.

Figure 4. Graph of safety outcomes in eyes with preoperative myopia having primary LASIK showing lines of BCVA lost, remaining unchanged, or gained. The actual percentage of eyes represented by the bars is shown at the top of each bar.

Figure 5. Graph of spherical equivalent refractive error in eyes with preoperative myopia having primary LASIK. The actual percentage of eyes represented by the bars is shown at the top of each bar.

Figure 6. Graph of efficacy data for primary LASIK treatments in eyes with preoperative hyperopia. This graph compares the preoperative best-corrected visual acuity (BCVA) results to the 3 month postoperative uncorrected visual acuity (UCVA) results. The red bars show preoperative BCVA and the blue bars show postoperative UCVA. The actual percentage of eyes represented by the bars is shown at the top of each bar.

Figure 7. Graph of safety outcomes in eyes with preoperative hyperopia having primary LASIK showing lines of BCVA lost, remaining unchanged, or gained. The actual percentage of eyes represented by the bars is shown at the top of each bar.

Figure 8. Graph of spherical equivalent refractive error in eyes with preoperative hyperopia undergoing primary LASIK. The actual percentage of eyes represented by the bars is shown at the top of each bar.