Supplement to

November/December 2012

Cataract & Refractive Surgery TODAY

Sponsored by Alcon Laboratories, Inc.

The WaveLight Refractive Suite:

CLINICAL DATA 2012

The latest research on the WaveLight EX500 excimer laser and the FS200 femtosecond laser.

The WaveLight Refractive Suite:

CLINICAL DATA 2012

An overview of the latest research on the WaveLight EX500 excimer laser and the WaveLight FS200 femtosecond laser.

Laser refractive technologies continue to evolve and raise the standards for corneal surgery. This monograph features the latest data from clinical studies involving the WaveLight Refractive Suite, which encompasses the WaveLight EX500 excimer laser, the WaveLight FS200 femtosecond laser, and several WaveLight diagnostic instruments. These studies show that excimer ablations and femtosecond flap cuts made with these lasers are highly accurate and yield excellent results. Among these studies are also interesting findings on patients' visual recovery time after LASIK with the ALLEGRETTO WAVE Eye-Q Excimer laser and the biomechanics of flaps created with the WaveLight FS200 femtosecond laser versus a microkeratome. In short, these technologies continue to impress.

Contents

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Experience With the WaveLight Refractive Suite

Six-month data after LASIK and advanced surface ablations.

BY ARTHUR B. CUMMINGS, MD, AND GABRIELLE E. KELLY, PHD

Innovations in laser vision correction have included the development of faster excimer lasers, the use of femtosecond lasers to create more precise lamellar flaps, and advancements in laser platforms. A new laser refractive platform, the WaveLight Refractive Suite (Alcon Laboratories, Inc.), comprises a 500-Hz excimer laser (the EX500) and a 200-kHz femtosecond laser (the FS200) and multiple diagnostic instruments. We performed a retrospective analysis of consecutive patients who underwent primary LASIK or enhancement surgery for myopia, hyperopia, and mixed astigmatism using the WaveLight Refractive Suite. Overall, the study eyes demonstrated good, predictable, and stable outcomes with this new laser refractive platform.

MATERIALS AND METHODS

The study included eyes of patients with preoperative spherical equivalent (SE) myopic refractive errors of up to -12.00 D, SE hyperopic refractive errors of up to +5.50 D, and up to 6.00 D of astigmatism. These eyes underwent LASIK as an initial or secondary refractive procedure. Preoperative central corneal thickness readings had to measure at least 480 µm with an estimated postprocedure residual corneal bed of greater than 270 µm.

We excluded eyes with abnormalities in the anterior or posterior segment, clinically significant dry eye diseases, forme fruste keratoconus or keratoconus, and clinically significant abnormalities on topography and tomography.

We measured patients' UCVA, BCVA, manifest and cycloplegic refractions, scotopic pupil size, topography, tomography, wavefront, and pachymetry at baseline and again at 1, 3, and 6 months postoperatively. We evaluated corneal topography at 6 months postoperatively.

Treatment Planning and Procedure

The two lasers in this platform are linked mechanically by a single bed that swings between them at an angle of 30º or 45,° depending on the surgeon's preference. All patients underwent topographical mapping; we included posterior corneal surface readings using Scheimpflug principles and the Wavefront-Optimized profile for the majority of these cases with the treatment based on manifest refraction. We made no changes to the Wellington nomogram we used previously on the 400-Hz ALLEGRETTO WAVE Eye-Q excimer laser (Alcon Laboratories, Inc.). We also performed additional diagnostic testing for eyes undergoing wavefront- or topography-guided procedures.

The WaveLight Refractive Suite incorporates noncontact pachymetry, which enables the surgeon to monitor flap and corneal thickness before, during, and after the ablation. In all primary cases, we created the flaps using the FS200 femtosecond laser and performed all ablations using the EX500 excimer laser. The planned refractive outcome was a plano prescription in 94.4% of eyes where distance vision was being targeted, an undercorrection of 1.00 D in 2.3% of eyes, and an undercorrection of -1.75 D in 3.2% of eyes. Secondary treatments were also included in this analysis. If the previous LASIK surgery took place more than 3 years earlier, then other treatment options were discussed with the patient, because the incidence of epithelial ingrowth increases with flap-lift retreatment performed 3 or more years after primary LASIK.[1]

SAFETY

Overall, the safety outcomes in all groups were positive. At 3 months posttreatment in eyes having secondary treatments and at 6 months posttreatment in eyes having primary treatments of myopia, hyperopia, and astigmatism, the results exceeded FDA safety criteria that required less than a 5% rate of loss of two or more lines of BCVA. In preoperative myopes who underwent primary LASIK, the safety analysis at 6 months after surgery demonstrates a very safe procedure with this new treatment tool.

EFFICACY

Patients assessed in this study were all-comers to reflect a population of patients seen in a typical refractive surgery practice. Baseline characteristics are presented in Table 1. The mean change from baseline in UCVA at 3 and 6 months was significant and clinically meaningful in all treatment groups. In the myopic LASIK group at the 3- and 6-month interval, there was a clinically and statistically significant improvement in BCVA (Table 2). The findings in this large case series show that LASIK performed with this laser platform is an efficacious treatment modality and can

TABLE 1. DEMOGRAPHIC DATA AT BASELINE

	LASIK			
	Primary LASIK		LASIK Enhancements	
	Preoperative Myopia	Preoperative Hyperopia	Preoperative Myopia	Preoperative Hyperopia
Eyes (n =)	354	53	25	9
Patients (n =)	212	33	20	8
Eyes: Right, n (%) Left, n (%)	 181 (51.1%) 173 (48.9%)	 26 (49.1%) 27 (50.9%)	 16 (64%) 9 (36%)	 6 (66.7%) 3 (33.3%)
Gender: Males, n (%) Females, n (%)	148 (41.8%) 206 (58.2%)	27 (50.9%) 26 (49.1%)	7 (28%) 18 (72%)	7 (77.8%) 1 (11.1%)
Age in years: Mean ± SD Range	33.0 ± 8.5 19 to 65	45.2 ± 12.9 19 to 68	40.2 ± 11.7 27 to 67	50.6 ± 10.2 28 to 67
Mean logMAR UCVA ± SD Range Snellan range	 1.00 ± 0.92 -0.20 to 1.30 20/15 to 20/400	 0.49 ± 0.51 -0.20 to 1.0 20/15 to 20/200	 0.33 ± 0.55 -0.10 to 1.30 20/16 to 20/400	 0.28 ± 0.68 0.10 to 0.60 20/25 to 20/80
Mean SE refraction ± SD in diopters Range	 -4.01 ± 2.30 0 to -12.00	 +2.20 ± 1.23 0 to +4.88	 -0.96 ± 0.43 0 to -2.25	 +1.10 ± 0.58 0 to +2.63
Mean cylinder ± SD in diopters Range	 0.79 ± 0.92 0 to 6.00	 0.26 ± 2.03 0 to 5.25	 0.21 ± 0.95 1.75 to 2.50	 0.47 ± 0.76 0.75 to 1.75

Abbreviations: SD = standard deviation; n = sample size; SE = spherical equivalent; logMAR = logarithm of minimum angle of resolution.

provide predictable and stable refractive outcomes over time with a low risk of complications.

The postoperative refractions in preoperative myopes undergoing primary LASIK were stable over time. In regards to stability, LASIK eyes had a mean preoperative SE myopia of -4.01 ± 2.30 D, which decreased to -0.20 D at 3 months and -0.17 D at 6 months. Approximately 90% of LASIK eyes were within ±0.50 D of the target refraction at 6 months postoperatively.

We also analyzed outcomes for other groups, including LASIK enhancement in eyes with preoperative residual myopia and LASIK enhancement in eyes with preoperative residual hyperopia. With regard to both of these groups with preoperative residual myopia, the change in UCVA at 3 months compared with baseline was statistically significant, but the change in BCVA was not. In the group that underwent LASIK enhancement for preoperative residual hyperopia, the change in UCVA and BCVA was not statistically significant at 3 months (Table 3).

Similarly, our clinic recently reported outcomes of a large series of eyes that underwent LASIK with the 200-Hz ALLEGRETTO WAVE laser, the 400-Hz ALLEGRETTO WAVE Eye-Q laser, and the WaveLight EX500 excimer laser.[2] With each faster laser, fewer patients lost lines, and more patients gained lines of vision. Without adjusting our nomogram, we saw a greater percentage of patients achieve within 0.50 D of their intended correction, and more patients achieved better uncorrected and best-corrected acuities compared to those rates with the slower lasers (Figure 1).

PARA-METER	LASER	6/4	6/5	6/6	6/7.5	6/12
UCVA	200	1.3	43	63.5	77.5	87.5
	400	3.3	49.2	68.2	78.8	87.9
	500	6	50	72	88	93
BCVA	200	2.2	70	89.6	97.1	99.5
	400	3.8	75.1	91	97.1	99.3
	500	15	87	92	94	97

PREDICTABILITY	200 Hz	400 Hz	500 Hz
± 0.50	85%	83%	88%

(Courtesy of Arthur B. Cummings, MB, ChB)

Figure 1. Without adjusting the nomogram, Dr. Cummings and his team found better UCVAs, BCVAs, and predictability using faster lasers.

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TABLE 2. PRIMARY LASIK IN PATIENTS WITH PREOPERATIVE MYOPIA

	UCVA					BCVA				
	≥ 20/25	≥ 20/20	≥ 20/16	≥ 20/12.5	*P* Value	≥ 20/25	≥ 20/20	≥ 20/16	≥ 20/12.5	*P* Value
3 months posttreatment	91.4%	83.4%	69.5%	10.7%	*P*<.0001	98.3%	93.9%	88.4%	13.8%	*P*=.0041
6 months post-treatment (n=354)	91.1%	84.3%	69.4%	11.1%	*P*<.0001	97.9%	94.7%	90.2%	11.6%	*P*=.00176

TABLE 3. PRIMARY LASIK IN PATIENTS WITH PREOPERATIVE HYPEROPIA

	UCVA				BCVA			
	≥ 20/25	≥ 20/20	≥ 20/16	≥ 20/12.5	≥ 20/25	≥ 20/20	≥ 20/16	≥ 20/12.5
3 months posttreatment	57.1%	46.4%	39.3%	3.6%	94.3%	81.1%	52.8%	–
6 months posttreatment (n=53)	68.6%	54.3%	42.9%	2.9%	97.1%	85.7%	62.9%	2.9%

PLATFORM FEATURES AND DISCUSSION

LASIK is typically the preferred corneal laser surgery option, because it is more comfortable and has a faster recovery than alternative surface treatment options.[3,4]

The EX500 excimer laser, which operates at speeds of approximately 1.4 s per diopter of treatment at a 6.0-mm optical zone and 1.9 s per diopter at a 6.5-mm optical zone, has a 1050-Hz eye tracker synchronized at 500 Hz with a latency time of 2 ms (data on file). The femtosecond laser can complete flaps in approximately 6 to 10 s, depending on the selected spot and line separations and the size of the flap (data on file). The speed of these lasers has the potential to improve patient safety, because faster treatment times may result in less patient fatigue and anxiety and a reduced risk of ablation errors due to loss of fixation. In the case of the femtosecond laser, there may be a potential reduction in peak IOP resulting from decreased suction duration.[5]

With the faster repetition rates of new-generation excimer lasers, there has been some concern about possible side effects relating to corneal cell and tissue damage. A study has shown that the collagen in the cornea undergoes thermal denaturation and molecular damage when the temperature is elevated to 40°C or more.[6] The EX500 excimer laser has been designed so that only one in five pulses overlap to allow the treated area to cool before receiving additional laser pulses, thus potentially reducing thermal effects. A study comparing the influence of different ablation frequencies (50, 200, and 500 Hz) on endothelial cell density and structural and ultrastructural distribution of collagen fibers and keratocytes found no specific side effects that could be attributed to higher repetition rates.[7] In addition, other studies investigating this excimer laser[8] or a laser with an even faster repetition rate (1,000 Hz) demonstrated no thermal damage to the cornea.[9]

It is feasible that the faster ablation possible with this platform had a positive effect on corneal hydration, which in turn can affect the ablation rate and refractive profile. Corneal hydration is a large variable in laser vision correction and is relative to the humidity, temperature, technique, and length of treatment time. Uniform corneal hydration is an important consideration in order to achieve a more even ablation.[10] With the rapid treatment time, there may be less dehydration of the corneal bed with reduced flap shrinkage, a reduction in the incidence of striae, and an improved refractive predictability. Improved flap hydration can also facilitate healing. ■

ACKNOWLEDGEMENTS

The authors would like to acknowledge Dr. Richard Corkin, whose outstanding surgical skills were instrumental in achieving the excellent outcomes described in this article. The authors also thank Alcon Laboratories, Inc., for its financial support of this study.

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Testing the Reproducibility of a Femtosecond Laser

A single-center evaluation of flap thickness produced by the WaveLight FS200 femtosecond laser.

BY DANIEL S. DURRIE, MD

One of the expected benefits associated with using a femtosecond laser instead of a mechanical microkeratome blade to create a corneal flap is greater predictability in the targeted versus achieved flap thickness. Surgeons need to be able to accurately predict the thickness of a LASIK flap because of the effect a flap has on visual outcomes, the thickness of the stromal bed, and in challenging eyes such as high myopes and those with thin corneas prior to surgery. In order to test our own surgical accuracy, my staff and I recently conducted a prospective evaluation of the postoperative thickness of LASIK flaps created with the WaveLight FS200 femtosecond laser (Alcon Laboratories, Inc.).

STUDY METHOD

We used the Visante OCT (Carl Zeiss Meditec, Inc.) as well as the RTVue OCT (OptoVue, Inc.) to measure the thickness of flaps created with the WaveLight FS200 femtosecond laser in 30 myopic patients who were planned for bilateral, Wavefront-Optimized LASIK surgery (58 eyes total) with the ALLEGRETTO WAVE Eye-Q excimer laser (Alcon Laboratories, Inc.) (Table 1).

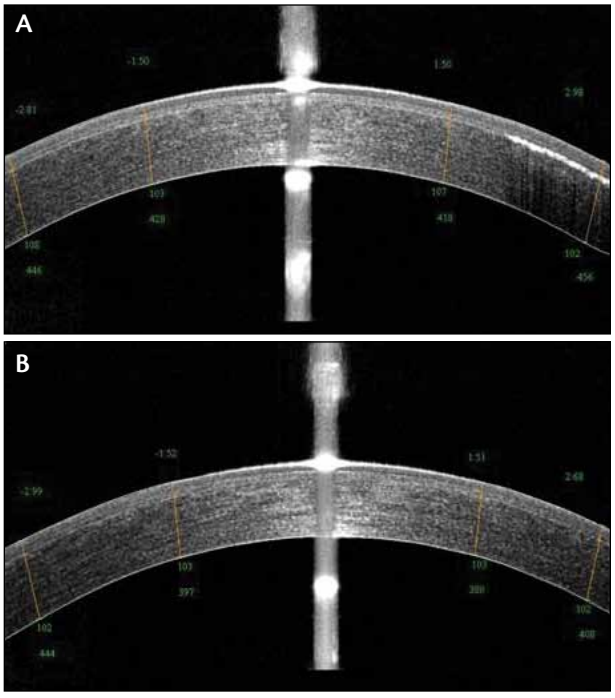

Figure 1. RTVue images of a flap made with the WaveLight FS200 femtosecond laser on surgery day, before being lifted (A), and the same flap 1 week postoperatively (B).

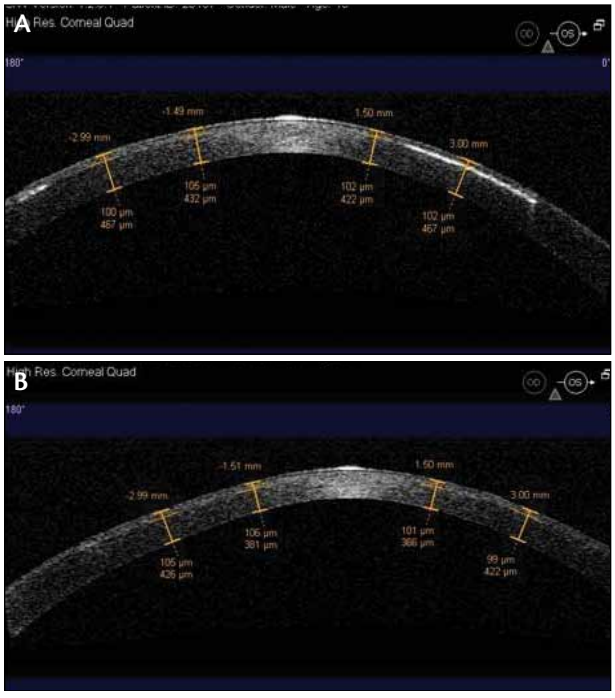

Figure 2. Visante OCT images of the same flap made with the WaveLight FS200 femtosecond laser, prior to lifting the flap (A) and 1 week postoperatively (B).

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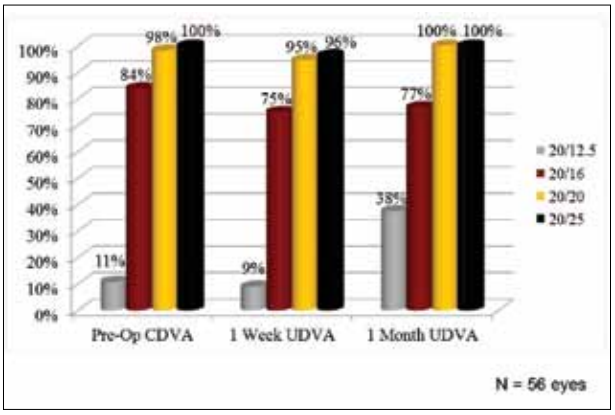

Figure 3. Monocular distance UCVA versus preoperative acuity.

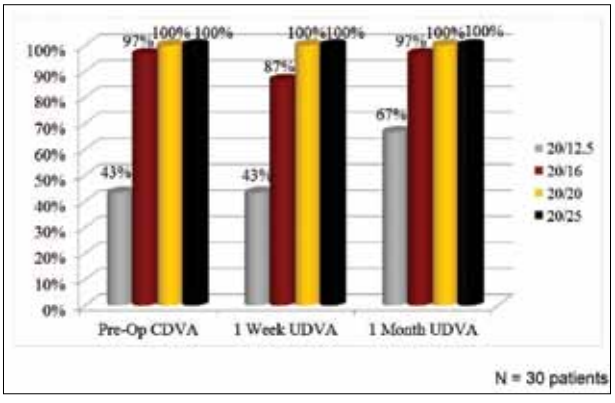

Figure 4. Binocular distance UCVA versus preoperative acuity.

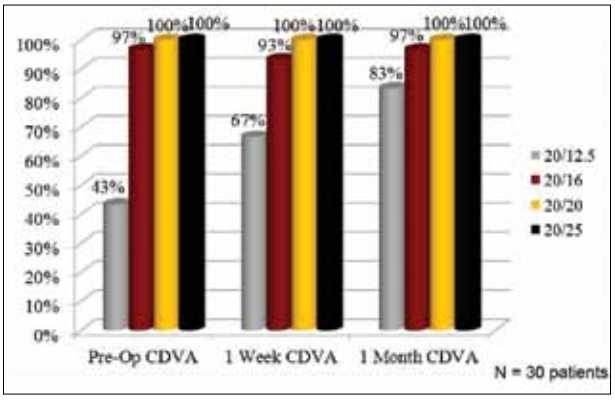

Figure 5. Binocular corrected distance visual acuity, preoperatively versus 1 month postoperatively.

We only included patients in whom both eyes had a preoperative manifest refractive error of -1.00 to -7.00 D and refractive astigmatism of less than or equal to 3.00 D. Both eyes also had to have a BCVA of 20/25 or better.

We created all the flaps at a 60° hinge angle and with a superior hinge. We targeted each flap for 8.5 mm in diameter and 100 µm thick, and created them with a 120° side cut that included a canal for gas to escape. We standardized the FS200 laser's energy for the planar and side cuts as well as the postoperative treatment regimen for each eye.

TABLE 1. PATIENT DEMOGRAPHICS	
Number	30 patients (58 eyes)
Age	18 to 46 years (29.57 ±6.84)
Gender	15 male, 15 female
Preop Spherical Equivalent	-1.25 to -7.00 D (-3.59 ±1.61)
Preop Astigmatism	0 to -1.75 D (-0.57 ±0.49)

We performed the OCT imaging of the flap before lifting it and at 1 week postoperatively, and we measured the subjects' distance UCVA immediately postoperatively as well as at 1 day, 1 week, and 1 month. We also asked the patients to complete a subjective questionnaire about their visual performance and symptoms both preoperatively and at each postoperative visit.

RESULTS

We found the mean flap thickness (before lifting) to be 104 ±5.0 µm per the RTVue OCT and 100 ±6.1 µm per the Visante OCT (Figures 1 and 2). At 1 week postoperatively, the flaps measured 108 ±4.6 µm on the RTVue OCT and 105 ±3.6 µm on the Visante OCT.

We tested patients' distance UCVA both monocularly and binocularly. Monocular results were as follows: 20/20 or better in 95% of eyes at 1 day, 20/16 or better in 75% of eyes at 1 week, and 20/12.5 or better in 38% of eyes at 1 month (Figure 3). Binocular distance UCVA results were 20/20 or better in 87% of eyes at 1 day, 20/16 or better in 87% by 1 week, and 20/12.5 or better in 67% of subjects at 1 month (Figure 4). None of the eyes lost two or more lines of distance BCVA (Figure 5).

CONCLUSIONS

We concluded that the WaveLight FS200 femtosecond laser creates planar corneal flaps safely and with a reproducible thickness. Although the flaps were slightly thinner than what we anticipated preoperatively, we believe we can compensate for this effect in the future by programming the laser 5 to 10 µm thicker than the desired correction. We felt that these anterior-segment OCT devices were a fast and noninvasive way to measure the thickness of corneal flaps. ■

ACKNOWLEDGEMENT

The author thanks Alcon Laboratories, Inc., for its financial support of this study.

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New Imaging Devices Show Novel Details About the Biomechanics of Corneal Flaps

Gaining insights into the quality of femtosecond versus microkeratome lasers.

BY ROHIT SHETTY, FRCS

Since the advent of femtosecond lasers for creating corneal flaps, many interesting studies have been conducted comparing the quality of the cuts between these lasers and manual microkeratomes. I am particularly interested in the architecture and biomechanics of flaps made with these two devices. Thus, my colleagues and I have a three-stage study underway. This article describes the study and our findings thus far.

Most studies of corneal flap architecture to date have been based on imaging and measurements taken after the excimer laser ablation, or, if taken prior to the ablation procedure, then the patient has had to sit up and move to another device for imaging. For the first part of this study, my colleagues and I wanted to image the corneal flap immediately after cutting it with either the femtosecond laser or the mechanical microkeratome, before lifting the flap to perform the excimer ablation. We used the hand-held Envisu Spectral Domain Ophthalmic Imaging System (Bioptigen, Inc.), which received FDA approval earlier this year. The Envisu has a small, sterile probe for taking corneal images. Because of the mobility of this device, we were able to image and measure patients' corneal flaps while the patients were still lying on the OR table, before lifting the flaps. Thus, we minimized dehydration and any biomechanical disturbances to the flap and stroma other than those caused by the femtosecond laser or microkeratome.

METHODOLOGY AND FINDINGS

Part 1: Post-Cut Biomechanics and Architecture

My colleagues and I enrolled 35 patients in the study for bilateral LASIK surgery. We randomized the eyes of each patient to receive a corneal flap with either a mechanical microkeratome (Hansatome; Bausch + Lomb) or the WaveLight FS200 femtosecond laser (Alcon Laboratories, Inc.).

> "The thin, planar flaps made with the WaveLight FS200 femtosecond laser had a precise depth, diameter, and centration."

We found that the flaps created with the microkeratome altered the lamellar structure of the cornea; these flaps were deeper in the periphery and showed variations in centration and diameter. The thin, planar flaps made with the WaveLight FS200 femtosecond laser had a precise depth, diameter, and centration. These showed minimal variability in central thickness as well as regionally within the flaps (Figure 1). These findings

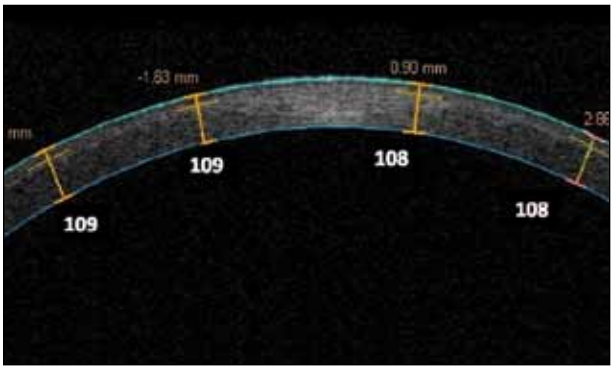

Figure 1. Flaps made with the FS200 femtosecond laser showed minimal variability in central thickness as well as regionally within the flaps. These findings confirm previous studies performed with regional subtraction pachymetry and histology.

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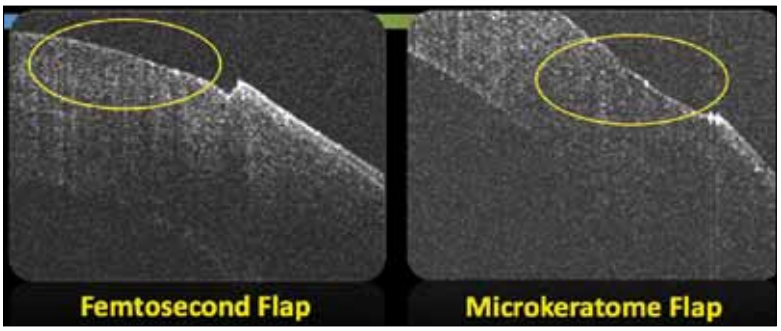

Figure 2. The femtosecond flap shows a clean, vertical edge compared to the irregular edge of the microkeratome flap.

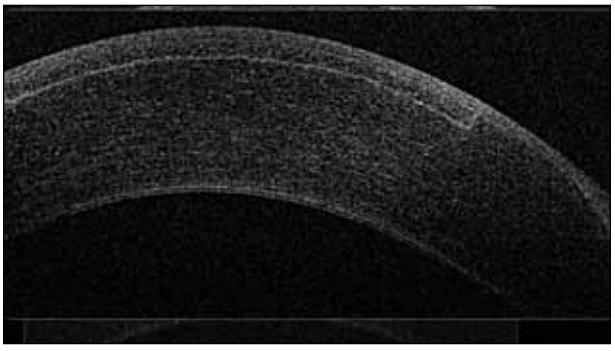

Figure 3. An intraoperative image of the WaveLight FS200 femtosecond laser-made flap.

correlated with those of earlier studies performed with regional subtraction pachymetry and histology.

Part 2: Post-Laser Evaluation

For the second phase of the study, my colleagues and I lifted the patients' flaps to measure the stromal bed and the angle of the side cuts that each instrument made. The OCT images showed an irregular, sloping flap edge created by the microkeratome versus a clean, vertical edge from the FS200 femtosecond laser (Figure 2). We believe that the vertical edge of the FS200 femtosecond laser's cut gives the cornea stronger biomechanical structure compared with a microkeratome flap.

We also measured the targeted versus the achieved flap thickness (in both the center and periphery) in three categories: thin (90 µm) and regular-thickness flaps (110 µm) made with the femtosecond laser, and regular-thickness flaps made with the microkeratome (120 µm). Again, the WaveLight FS200 femtosecond laser outperformed the manual microkeratome (Figure 3). The femtosecond-created flaps had a very low standard deviation: approximately 2 µm centrally and 5 µm peripherally for both thin and regularly sized flaps. In comparison, the standard deviation for the mechanically made flaps was approximately 10 µm in the center and 25 µm in the periphery.

Part 3: Quality of Vision After LASIK

Next, my colleagues and I evaluated the subjects' quality of vision after the LASIK procedure. We did not find a significant difference in postoperative UCVA between the eyes cut with a microkeratome versus the femtosecond laser, unless an eye had a high refractive error that necessitated extreme keratometric values that produced microstraie in the cut.

We also performed further biomechanical testing on these post-LASIK flaps using the Corvis ST noncontact tonometer from Oculus, Inc. This device offers a high-speed Scheimpflug camera (4,330 frames/sec) that can record the cornea's movements and then play them back in slow motion on a built-in control panel. This part of the study is ongoing to evaluate the deformation amplitude of these corneas. However, our preliminary findings suggest that corneas with femtosecond-made flaps are slightly stronger.

DISCUSSION

Because I want to give my refractive patients the best surgery possible, the results of this study give me even greater confidence to use the WaveLight FS200 femtosecond laser instead of a manual microkeratome. I prefer the predictability of the small standard of deviation for the femtosecond-created flaps, especially with thin or otherwise compromised corneas. Considering the precision of the laser, I am not surprised to find that the femtosecond-created flaps are biomechanically stronger than those made with a microkeratome, which are thinner in the center and thicker in the periphery. Also, microstriae and opaque bubble layers are minimized in flaps made with the FS200 femtosecond laser.

I also like that I can use images from the Envisu OCT device to show patients the difference in the smoothness and uniformity of the femtosecond flaps versus those made with a microkeratome, and thus the quality of the femtosecond cuts becomes its own counseling tool.

I am encouraged by these findings to continue using the WaveLight FS200 femtosecond laser for my patients. I expect the full results of this study to be published in November 2012 in a supplement to the *Journal of Refractive Surgery*. ■

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Flap Thickness and Predictability With the FS200 Femtosecond Laser

A report on the largest series of eyes to date treated with this laser.

BY ARTHUR B. CUMMINGS, MD

A critical component of successful LASIK outcomes is the predictability of the corneal flap's thickness.[1] Flaps that are too thin or too thick can compromise the safety of the LASIK surgery.[2-6] Femtosecond lasers with a high repetition rate (200 kHz) are able to create corneal flaps with less time and energy than older, slower systems (ie, 60 kHz). This lower energy requirement is expected to translate to less tissue inflammation, smaller cavitation bubbles, and an easier separation of the flap from the corneal bed.[7] A faster femtosecond repetition rate also keeps the leading edge of the treatment in front of the spreading bubble layer.

WaveLight GmbH, Alcon Laboratories, Inc., has developed a new, 200-kHz femtosecond laser (the WaveLight FS200 femtosecond laser) to create lamellar flaps in 6 to 7 seconds, depending on the size of the flap. This femtosecond laser is integrated with the WaveLight EX500 500-Hz excimer laser and several diagnostic tools to form the WaveLight Refractive Suite. This article describes 3-month results of a study conducted at the Wellington Eye Clinic in Dublin, Ireland, to evaluate the predictability of flaps made with the WaveLight FS200 femtosecond laser.

SUPPORTING DATA

In 2009, Soong et al[8] studied the uniformity and accuracy of LASIK flaps created with a femtosecond laser versus a mechanical microkeratome via optical coherence tomography (OCT). The 1-month results showed that the flaps made with a microkeratome had a significantly greater range than those made with the femtosecond laser (maximum deviation from the intended flap thicknesses: 7 µm in the femtosecond group compared to 26 µm in the microkeratome group). The investigators also found that flap uniformity differed by >20 µm in 0.42% of eyes in the femtosecond laser group versus 15% of eyes in the microkeratome group.

In a 2011 pilot study of 20 eyes, von Mohrenfels et al[9] reported the first clinical results using the WaveLight FS200 femtosecond laser. Preoperatively, the subjects' mean manifest refractive spherical equivalent was 4.22 D (SD ± 61.22 D), and at 12 months postoperatively, the mean postoperative spherical equivalent refraction was -0.15 D (SD ± 60.16 D).

METHOD

My colleagues and I conducted a retrospective study of 431 eyes of 258 LASIK patients to assess the intended versus achieved thickness of flaps made with the WaveLight FS200 femtosecond laser. We used a nontouch optical pachymeter that is built into the WaveLight EX500 excimer laser to measure the total corneal thickness prior to and after flap creation. To validate the pachymetric readings, we evaluated the total corneal thickness and standard deviation of 813 eyes measured with the EX500 pachymeter and compared the results to readings taken with the Pentacam (Oculus Optikgeräte GmbH). There was no statistical difference between the two pachymetric devices with regard to the preoperative total corneal pachymetry.

The myopic eyes required flaps that were 8.5 mm or greater in diameter, depending on the amount of astigmatism present. We used a 6.5-mm-diameter optical zone and a 1.0-mm transition zone for the ablation. The hyperopic eyes needed flaps that were 9.0 mm or greater in diameter with a 6.5-mm diameter optical zone and a 2.4-mm transition zone for the ablation. The planned flap thickness in the majority of eyes (789 eyes) was 120 µm. My coinvestigators and I planned thinner flaps of 100 µm (one eye) or 110 µm (23 eyes) to accommodate thin preoperative corneas or higher corrections. We programmed the FS200 laser to create the appropriate flap thickness and diameter with a 70° angled side cut, a superior hinge, and a 55° hinge angle.

SURGICAL TECHNIQUES

One feature of the FS200 laser that I appreciate is that the suction ring can be decentered slightly superiorly to expose

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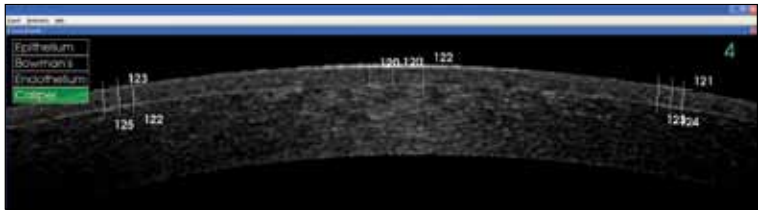

Figure 1. Flaps made with a femtosecond laser have a cleaner planar morphology compared with those made by a microkeratome.

more limbus at the 12 o'clock position, thereby making space for the channel to vent the exhaust gas that may otherwise collect and potentially contribute to an OBL. I have also found that I can express additional gas by smoothing the surface of the cornea with a LASIK irrigating cannula (Beaver-Visitec International, Inc.). Because the FS200 laser reduces OBL, the surgeon does not have to wait for the bubbles to dissipate in order to perform the ablation.

Again, the FS200 femtosecond laser creates a flap in approximately 6 to 7 seconds. To locate the edge of the flap, I press downward with a LASIK spatula at an approximate 70º angle. I use the spatula to dissect fine tissue adhesions as I lift the flap.

RESULTS

Our intended flap thickness for this study was 120 µm. The average flap thickness after LASIK treatment was 120.23 ±13.94 µm (range, 73 – 176 µm). Flaps in myopic eyes had a standard deviation of 13.97 µm versus 13.36 µm in the hyperopic eyes. My colleagues and I concluded that we achieved the intended flap size in all cases.

We did not have to delay or abort any procedure due to suction loss or OBL, and there were no flap-related postoperative complications, including epithelial in-growth, corneal haze, or diffuse lamellar keratitis. The full results of this study have been accepted for publication by the *Journal of Cataract and Refractive Surgery*.

CONCLUSIONS

Recent advancements in femtosecond laser technology have improved these lasers' clinical safety and outcomes.[10,11] The standard deviation of flaps made with current mechanical microkeratomes is approximately 22 to 26 µm;[12-15] my coinvestigators and I found excellent predictability of flap thickness with a lower standard deviation (13.9 µm). Furthermore, consecutive patients from this study who underwent LASIK for myopia, hyperopia, and mixed astigmatism after the flap creation had good, predictable, and stable outcomes.

Likewise, Mrochen et al[16] showed that the FS200 laser provides high reproducibility for tissue cutting, with a standard deviation of less than 10 µm in depth and 0.1 mm laterally.

Studies have shown that corneal flaps made with the femtosecond laser have a more predictable thickness and have a more desirable planar morphology (Figure 1) than flaps created with standard microkeratomes.[17,18] The FS200 laser has a 10-mm homogeneous beam that enables surgeons to vary the spot size, depth, and energy delivery of the laser's beam, giving them a high level of customization. The WaveLight FS200 laser can make stromal cuts as shallow as 30 µm away from Descemet's membrane and as deep as 1,200 µm. Users may also tailor the size, shape, angle, location, and depth of the LASIK flap according to the ablation profile, corneal thickness, or other surgical considerations as needed. Other cuts within the laser's capability are round or elliptical cuts for corneal flaps and side cuts and reverse cuts for corneal segments and keratoplasties. Thus, the FS200 femtosecond laser can treat an array of corneal shapes and sizes. Surgeons may also customize the location of the flap's hinge using presets for superior, nasal, and temporal hinges. Again, the surgeon may also choose the size, angle, and location of the hinge to preserve corneal nerves. ■

ACKNOWLEDGEMENT

The author thanks Alcon Laboratories, Inc., for its financial support of this study.

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Rapid Recovery Beyond 20/20

Seeking faster postoperative healing via a thin-flap technique.

BY DANIEL S. DURRIE, MD

One distinct advantage of thin-flap keratomileusis (thin-flap LASIK) is the speed with which patients regain their vision postoperatively. As refractive surgeons, we have become accustomed to seeing recipients of thin-flap LASIK achieve a distance UCVA of 20/20 or better on the first postoperative day. However, we have not yet quantified the rate at which patients begin to regain specific visual milestones or resume daily activities.

To that end, my colleagues and I devised a study to establish and measure patients' speed of visual recovery following myopic Wavefront-Optimized thin-flap LASIK with a femtosecond laser. Establishing a specific timeline for visual recovery is important, not only for understanding the potential of today's surgical techniques, but also in looking toward a future in which refractive patients might be able to resume driving and return to work within a few hours after surgery. My colleagues and I anticipate that with steady innovations in laser technologies and surgical techniques, the goal of "lunch-break LASIK" may indeed be attainable.

STUDY ENDPOINTS

My staff and I conducted this prospective study at Durrie Vision in Overland Park, Kansas. We evaluated 44 eyes of 22 patients who underwent simultaneous thin-flap LASIK in both eyes (Table 1). The primary endpoints of our study were postoperative UCVA and the deviation of the manifest refraction from the intended correction. We defined monocular and binocular distance UCVA and monocular mesopic contrast sensitivity as continuous variables.

SURGICAL TECHNIQUE

For the surgery, we used the WaveLight FS200 femtosecond laser (Alcon Laboratories, Inc.) to create a superior-hinge flap set at a 60° angle. All the flaps were circular, 8.5 mm in diameter, and had an intended thickness of 110 µm. We created the flaps using a 120° side cut (this included the creation of a canal for gas to escape). We also standardized the energy delivery for the planar cut and the side cut.

Next, we performed the ablations with the ALLEGRETTO WAVE Eye-Q excimer laser (Alcon Laboratories, Inc.). We used a Wavefront-Optimized ablation profile with a 6.5-mm optical zone and a 9.0-mm ablation zone, except in five eyes that did not have astigmatism. These eyes instead received a spherical treatment with a 7.1-mm ablation zone. All subjects received proparacaine 0.5%, tetracaine 0.5%, brimonidine 0.025% (Alphagan P; Allergan, Inc.), and gatifloxacin 0.5% (Zymaxid; Allergan, Inc.) intraoperatively. Postoperatively, we treated all eyes with gatifloxacin 0.5% and prednisolone acetate 1% (Pred Forte, Allergan, Inc.). For the first week after surgery, all patients received gatifloxacin 0.5% and prednisolone acetate 1% four times daily, as well as preservative-free tears six to eight times daily.

SUBJECTIVE AND OBJECTIVE MEASUREMENTS

We evaluated the patients' binocular and monocular distance UCVA prior to surgery and also at the following time points: immediately after surgery and 30 minutes, 1 hour, 2 hours, 4 hours, 1 day, and 1 month postoperatively.

We tested the subjects for monocular contrast sensitivity and asked them questions about their visual function at each of these time points. The patients also filled out a subjective questionnaire pertaining to their visual symptoms before surgery and also 1 month after surgery. We asked them questions such as, "Would you feel comfortable driving at this point?" and "Would you be able to text or use your cell phone at this point?" Also at 1 month, we collected wavefront and postoperative manifest refraction data.

VISUAL ACUITY RESULTS

In terms of monocular distance UCVA, all of the eyes in our study achieved 20/40 at 4 hours after surgery, and 98% saw 20/20 or better by day 1 (Figure 1). For binocular distance UCVA, 91% of the patients attained 20/40 at 1 hour,

TABLE 1. PATIENT DEMOGRAPHICS

Number	22 patients (44 eyes)
Age	24 to 40 years old (31.2 ±4.88)
Gender	9 male, 13 female
Preop Spherical Equivalent	-1.00 to -6.00 D (-3.32 ±1.47 D)
Preop Astigmatism	0 to -3.00 D (-0.65 ±0.64 D)

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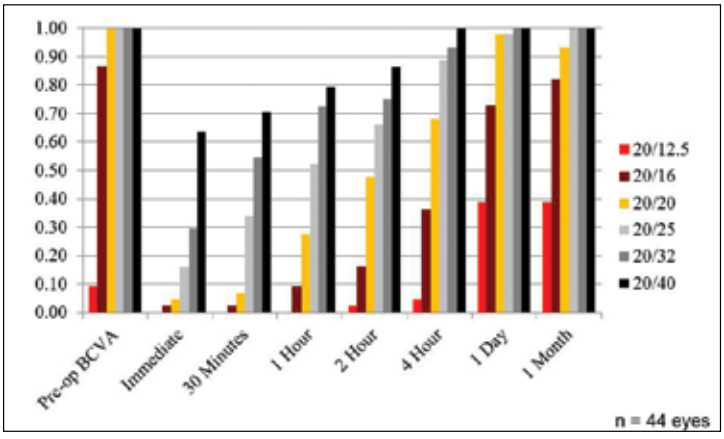

Figure 1. Monocular recovery of visual acuity at various time periods.

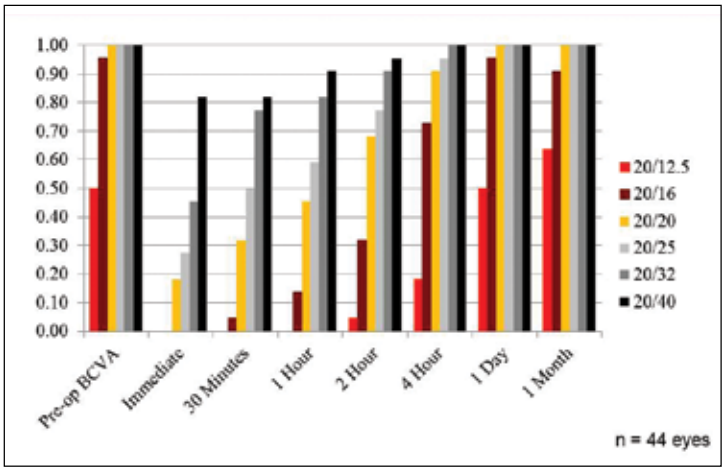

Figure 2. Binocular recovery of visual acuity at various time periods.

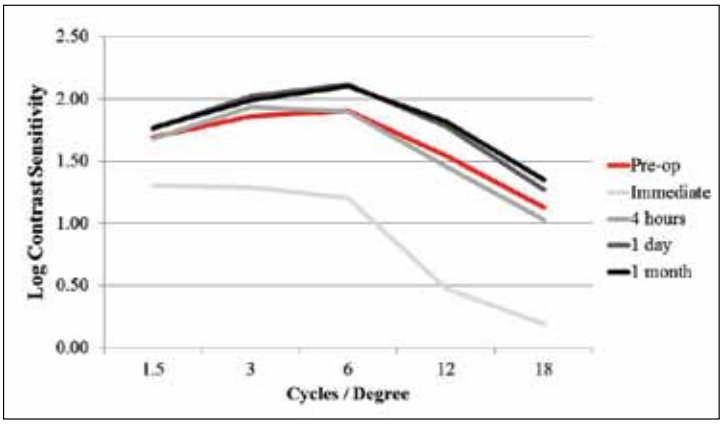

Figure 3. Mesopic contrast sensitivity up to 1 month postoperatively.

91% saw 20/20 at 4 hours, and 100% reached 20/20 or better by day 1 (Figure 2).

Previous studies have noted a decrease in contrast sensitivity linked to increased higher-order aberrations after thin-flap LASIK.[1-6] One study found that patients recovered contrast sensitivity function between 6 and 9 months after surgery.[6] The subjects in our study regained contrast sensitivity function much more quickly and ultimately improved.

In the immediate postoperative period, we found that low-frequency (1.5 cycles per degree [cpd]) monocular contrast sensitivity was decreased (1.69 cpd preoperatively vs 1.30 cpd immediately postoperatively: *P*<.01), but was restored to preoperative baseline by 4 hours (preoperative value vs 1.30 cpd at 4 hours [*P*=.63]) (Figure 3). By 1 day, low-frequency monocular contrast sensitivity showed a statistically significant improvement over baseline (preoperative value vs 1.76 cpd at day 1: *P*<.01) that was maintained at the 1-month visit (1.77 cpd at 1 month postoperatively).

High-frequency monocular contrast sensitivity (18 cpd) was also diminished in the immediate postoperative period (1.13 cpd preoperatively vs 0.19 cpd immediately postoperatively: *P*<.01), but returned to the preoperative baseline by 4 hours (preoperative value vs 1.03 cpd at 4 hours: *P*=.24) and showed a statistically significant improvement over preoperative baseline at 1 day (preoperative value vs 1.27 cpd at day 1: *P*<.01) that continued to improve at the 1-month visit (1.35 cpd at the first postoperative month).

SUBJECTIVE RESULTS

At 30 minutes after surgery, 45% of the patients who filled out the subjective questionnaire (n=22) said they would feel comfortable driving, and at 4 hours after surgery, all patients felt they were able to drive (Figure 4). At the 30-minute time point, 91% of patients reported that they felt able to send or read text messages on a mobile phone, and by 2 hours after surgery, all subjects felt comfortable doing so. At the 1-month visit, there was a statistically significant improvement (*P*<.01) over baseline in struggles with daily activities (from 1.19 to 0.41 on a scale of 0 to 9). There was no statistically significant difference between baseline and the 1-month visit in terms of visual disturbances such as glare, halos, double vision, ghost images, or vision fluctuations. We also did not find any significant difference in dry eye at 1 month after surgery, although there was a statistically significant increase in the use of artificial tears (from 0 to 3.5 on a scale of 0 to 9; *P*<0.01) at this time point (Figure 5).

ACUITY AND FUNCTIONAL VISION

Patients in this study attained excellent monocular and binocular visual acuities within hours of undergoing myopic thin-flap LASIK with the WaveLight FS200 femtosecond

TABLE 2. BINOCULAR UNCORRECTED VISUAL ACTIVITY							
	0 Minutes	30 Minutes	1 Hour	2 Hours	4 Hours	1 Day	1 Month
20/12.5 or better	0%	0%	0%	5%	18%	50%	64%
20/16 or better	0%	5%	14%	32%	73%	93%	91%
20/20 or better	18%	32%	45%	68%	91%	100%	100%
20/25 or better	27%	50%	59%	77%	95%	100%	100%
20/32 or better	45%	77%	82%	91%	100%	100%	100%
20/40 or better	82%	82%	91%	95%	100%	100%	100%

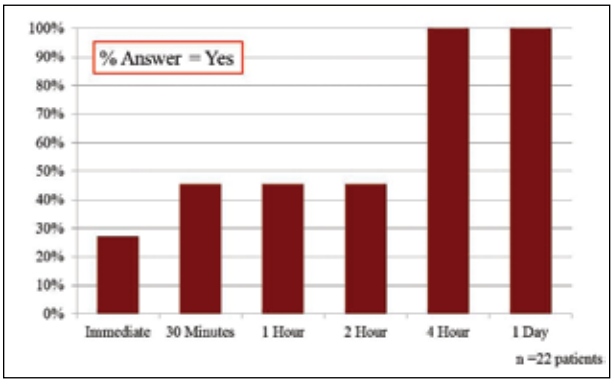

Figure 4. Patient questionnaire: Would you be comfortable to drive at this point?

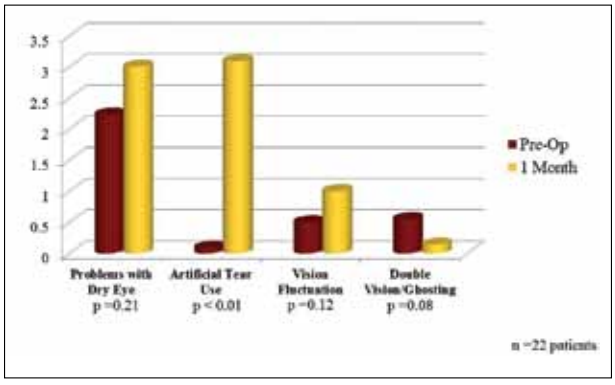

Figure 5. Subjective questionnaire responses about visual symptoms (scale = 0 to 9).

laser. Our visual acuity data from the first postoperative day compare favorably with previously published data at the same time point.[7,8]

Although functional vision also recovered quickly, there was a gap of several hours between subjects' recovery of visual acuity and functional vision. Although 91% of patients had achieved sufficient binocular distance UCVA (20/40 or better) to legally drive a car within 1 hour of surgery, only 45% of patients felt comfortable driving at that time point. By the 4-hour time point, at which 100% of patients had reached binocular distance UCVA of 20/32 or better, all patients said they would be comfortable driving. A total of 64% of the patients in the cohort demonstrated the ability to read the distance EDTRS 20/12.5 line at the 1-month visit, and three of the 22 patients had binocular distance UCVA of 20/10. These findings show that vision continued to improve up to this point (Table 2).

AN ACHIEVABLE GOAL

Given the rate of improvement and innovation in modern lasers and refractive surgical techniques, there is reason to think that "lunch-break LASIK" may be an obtainable goal with constantly changing technology. Studies indicate that the smoothness of the optical interface created by the WaveLight FS200 femtosecond laser during the thin-flap LASIK procedure allows for exceptional visual recovery. Although we are not yet able to allow patients to drive home or to work after laser vision correction, this could possibly be the rule rather than the exception. This study, to our knowledge, is the first to evaluate and quantify the speed of visual acuity and contrast sensitivity recovery immediately after thin-flap surgery. Although further study with a larger sample of eyes is required to corroborate these findings, we are encouraged by their implications. Rapid visual recovery that continues to improve beyond 20/20 represents the promise of a "wow" factor for a new generation of refractive surgery patients. ■

ACKNOWLEDGEMENT

The author thanks Alcon Laboratories, Inc., for its financial support of this study.

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Important Product Information About the WaveLight® ALLEGRETTO WAVE® / ALLEGRETTO WAVE® Eye-Q Excimer Laser System

Caution: Federal (USA) law restricts this device to sale by, or on the order of, a physician.

Statements regarding the potential benefits of wavefront-guided and Wavefront Optimized® laser-assisted in-situ keratomileusis (LASIK) are based upon the results of clinical trials. These results are indicative of not only the WaveLight® ALLEGRETTO WAVE® / ALLEGRETTO WAVE® Eye-Q Excimer Laser System treatment but also the care of the clinical physicians, the control of the surgical environment by those physicians, the clinical trials' treatment parameters and the clinical trials' patient inclusion and exclusion criteria. Although many clinical trial patients after the wavefront-guided and Wavefront Optimized® procedure saw 20/20 or better and/or had or reported having better vision during the day and at night, compared to their vision with glasses or contact lenses before the procedure, individual results may vary. You can find information about the clinical trials below and in the Procedure Manuals for the WaveLight® ALLEGRETTO WAVE® / ALLEGRETTO WAVE® Eye-Q Excimer Laser System.

As with any surgical procedure, there are risks associated with the wavefront-guided and Wavefront Optimized® treatment. Before treating patients with these procedures, you should carefully review the Procedure Manuals, complete the Physician WaveLight® System Certification Course, provide your patients with the Patient Information Booklet, and discuss the risks associated with this procedure and questions about the procedure with your patients.

Indications: The WaveLight® ALLEGRETTO WAVE® / ALLEGRETTO WAVE® Eye-Q Excimer Laser System is indicated to perform LASIK treatments in patients with documented evidence of a stable manifest refraction defined as less than or equal to 0.50 diopters (D) of preoperative spherical equivalent shift over one year prior to surgery, exclusive of changes due to unmasking latent hyperopia in patients 18 years of age or older: for the reduction or elimination of myopic refractive errors up to -12.0 D of sphere with and without astigmatic refractive errors up to -6.0 D; for the reduction or elimination of hyperopic refractive errors up to +6.0 D of sphere with and without astigmatic refractive errors up to 5.0 D at the spectacle plane, with a maximum manifest refraction spherical equivalent (MRSE) of +6.0 D; in conjunction with the WaveLight® ALLEGRO Analyzer® device for the reduction or elimination of up to -7.0 D of spherical equivalent myopia or myopia with astigmatism, with up to -7.0 D of spherical component and up to 3.0 D of astigmatic component at the spectacle plane; and in patients 21 years of age or older for the reduction or elimination of naturally occurring mixed astigmatism of up to 6.0 D at the spectacle plane.

LASIK is an elective procedure with the alternatives including but not limited to eyeglasses, contact lenses, photorefractive keratectomy (PRK), and other refractive surgeries. Only practitioners who are experienced in the medical management and surgical treatment of the cornea, who have been trained in laser refractive surgery including laser system calibration and operation, may use the device as approved. Prospective patients, as soon as they express an interest in an indicated LASIK procedure and prior to undergoing surgery, must be given the WaveLight® System Patient Information Booklet and must be informed of the alternatives for refractive correction including eyeglasses, contact lenses, PRK, and other refractive surgeries.

Clinical Data Myopia: The WaveLight® ALLEGRETTO WAVE® / ALLEGRETTO WAVE® Eye-Q Excimer Laser System was studied in clinical trials in the United States with 901 eyes treated, of which 813 of 866 eligible eyes were followed for 12 months. Accountability at 3 months was 93.8%, at 6 months was 91.9%, and at 12 months was 93.9%.

The studies found that of the 844 eyes eligible for the uncorrected visual acuity (UCVA) analysis of effectiveness at the 3-month stability time point, 98.0% were corrected to 20/40 or better, and 84.4% were corrected to 20/20 or better without spectacles or contact lenses.

The clinical trials showed that the following subjective patient adverse events were reported as moderate to severe at a level at least 1% higher than baseline of the subjects at 3 months post-treatment: visual fluctuations (12.8% at baseline versus 28.6% at 3 months). Long term risks of LASIK for myopia with and without astigmatism beyond 12 months have not been studied.

Clinical Data Hyperopia: The WaveLight® ALLEGRETTO WAVE® / ALLEGRETTO WAVE® Eye-Q Excimer Laser System has been studied in clinical trials in the United States with 290 eyes treated, of which 100 of 290 eligible eyes were followed for 12 months. Accountability at 3 months was 95.2%, at 6 months was 93.9%, and at 12 months was 69.9%.

The studies found that of the 212 eyes eligible for the UCVA analysis of effectiveness at the 6-month stability time point, 95.3% were corrected to 20/40 or better, and 67.5% were corrected to 20/20 or better without spectacles or contact lenses.

The study showed that the following subjective patient adverse events were reported as much worse by at least 1% of the subjects (in order of increasing frequency) at 6 months post final treatment: glare from bright lights (3.0%); night driving glare (4.2%); light sensitivity (4.9%); visual fluctuations (6.1%); and halos (6.4%). Long term risks of LASIK for hyperopia with and without astigmatism beyond 12 months have not been studied.

Clinical Data Mixed Astigmatism: The WaveLight® ALLEGRETTO WAVE®/ ALLEGRETTO WAVE® Eye-Q Excimer Laser System has been studied in clinical trials in the United States with 162 eyes treated, of which 111 were eligible to be followed at 6 months. Accountability at 1 month was 99.4%, at 3 months was 96.0%, and at 6 months was 100.0%.

The studies found that of the 142 eyes eligible for the UCVA analysis of effectiveness at the 3-month stability time point, 95.8% achieved acuity of 20/40 or better, and 67.6% achieved acuity of 20/20 or better without spectacles or contact lenses.

The clinical trials showed that the following subjective patient adverse events were reported as moderate to severe at a level at least 1% higher than baseline of the subjects at 3 months post-treatment: sensitivity to light (43.3% at baseline versus 52.9% at 3 months); visual fluctuations (32.1% at baseline versus 43.0% at 3 months); and halos (37.0% at baseline versus 42.3% at 3 months). Long term risks of LASIK for mixed astigmatism beyond 6 months have not been studied.

Clinical Data Wavefront-guided Treatment of Myopia: The WaveLight® ALLEGRETTO WAVE® / ALLEGRETTO WAVE® Eye-Q Excimer Laser System used in conjuction with the WaveLight ALLEGRETTO device was studied in a randomized clinical trial in the United States with 374 eyes treated; 188 with wavefront-guided LASIK (Study Cohort) and 186 with Wavefront Optimized® LASIK (Control Cohort). 178 of the Study Cohort and 180 of the Control Cohort were eligible to be followed at 6 months. In the Study Cohort, accountability at 1 month was 96.8%, at 3 months was 96.8%, and at 6 months was 93.3%. In the Control Cohort, accountability at 1 month was 94.6%, at 3 months was 94.6%, and at 6 months was 92.2%.

The studies found that of the 180 eyes eligible for the UCVA analysis of effectiveness at the 6-month stability time point in the Study Cohort, 99.4% were corrected to 20/40 or better, and 93.4% were corrected to 20/20 or better without spectacles or contact lenses. In the Control Cohort, of the 176 eyes eligible for the UCVA analysis of effectiveness at the 6-month stability time point, 99.4% were corrected to 20/40 or better, and 92.8% were corrected to 20/20 or better without spectacles or contact lenses.

The clinical trials showed that the following subjective patient adverse events were reported as moderate to severe at a level at least 1% higher than baseline of the subjects at 3 months post-treatment in the Study Cohort: light sensitivity (37.2% at baseline versus 47.8% at 3 months); and visual fluctuations (13.8% at baseline versus 20.0% at 3 months). In the Control Cohort: halos (36.6% at baseline versus 45.4% at 3 months); and visual fluctuations (18.3% at baseline versus 21.9% at 3 months). Long term risks of wavefront-guided LASIK for myopia with and without astigmatism beyond 6 months have not been studied.

Contraindications: LASIK treatments using the WaveLight® ALLEGRETTO WAVE® / ALLEGRETTO WAVE® Eye-Q Excimer Laser System are contraindicated if any of the following conditions exist. Potential contraindications are not limited to those included in this list: pregnant or nursing women; patients with a diagnosed collagen vascular, autoimmune or immunodeficiency disease; patients with diagnosed keratoconus or any clinical pictures suggestive of keratoconus; and patients who are taking one or both of the following medications: isotretinoin (Accutane®1), amiodarone hydrochloride (Cordarone®2).

Warnings: Any LASIK treatment with the WaveLight® ALLEGRETTO WAVE® / ALLEGRETTO WAVE® Eye-Q Excimer Laser System is not recommended in patients who have: systemic diseases likely to affect wound healing, such as connective tissue disease, insulin dependent diabetes, severe atopic disease or an immunocompromised status; a history of Herpes simplex or Herpes zoster keratitis; significant dry eye that is unresponsive to treatment; severe allergies; and unreliable preoperative wavefront examination that precludes wavefront-guided treatment. The wavefront-guided LASIK procedure requires accurate and reliable data from the wavefront examination. Every step of every wavefront measurement that may be used as the basis for a wavefront-guided LASIK procedure must be validated by the user. Inaccurate or unreliable data from the wavefront examination will lead to an inaccurate treatment.

Precautions: Safety and effectiveness of the WaveLight® ALLEGRETTO WAVE® / ALLEGRETTO WAVE® Eye-Q Excimer Laser System have not been established for patients with: progressive myopia, hyperopia, astigmatism and/or mixed astigmatism; ocular disease; previous corneal or intraocular surgery, or trauma in the ablation zone; corneal abnormalities including, but not limited to, scars, irregular astigmatism and corneal warpage; residual corneal thickness after ablation of less than 250 microns increasing the risk for corneal ectasia; pupil size below 7.0 mm after mydriatics where applied for wavefront-guided ablation planning; history of glaucoma or ocular hypertension of > 23 mmHg; taking the medication sumatriptan succinate (Imitrex®3); under 18 years (21 years for mixed astigmatism) of age; over the long term (more than 12 months after surgery); corneal, lens and/or vitreous opacities including, but not limited to, cataract; iris problems including, but not limited to, coloboma and previous iris surgery compromising proper eyetracking; taking medications likely to affect wound healing including, but not limited to, antimetabolites; treatments with an optical zone below 6.0 mm or above 6.5 mm in diameter; treatment targets different from emmetropia (plano) in which the wavefront-calculated defocus (spherical term) has been adjusted; myopia greater than – 12.0 D or astigmatism greater than 6 D; hyperopia greater than + 6.0 D or astigmatism greater than 5.0 D; mixed astigmatism greater than + 6.0 D; and in cylinder amounts > 4.0 to < 6.0 D.

Due to the lack of large numbers of patients in the general population, there are few subjects with cylinder amounts in this range to be studied. Not all complications, adverse events, and levels of effectiveness may have been determined.

Pupil sizes should be evaluated under mesopic illumination conditions. Effects of treatment on vision under poor illumination cannot be predicted prior to surgery. Some patients may find it more difficult to see in such conditions as very dim light, rain, fog, snow and glare from bright lights. This has been shown to occur more frequently in the presence of residual refractive error and perhaps in patients with pupil sizes larger than the optical zone size.

The refraction is determined in the spectacle plane, but treated in the corneal plane. In order to determine the right treatment program to achieve the right correction, assessment of the vertex distance during refraction testing is recommended. Preoperative evaluation for dry eyes should be performed. Patients should be advised of the potential for dry eyes post LASIK and post wavefront-guided LASIK surgery. This treatment can only be provided by a licensed healthcare professional.

Adverse Events and Complications for Myopia: Certain adverse events and complications occurred after the LASIK surgery. Two adverse events occurred during the postoperative period of the clinical study: 0.2% (2/876) had a lost, misplaced, or misaligned flap reported at the 1 month examination.

The following adverse events did NOT occur: corneal infiltrate or ulcer requiring treatment, corneal edema at 1 month or later visible in the slit lamp exam; any complication leading to intraocular surgery; melting of the flap of >1 mm2; epithelium of >1 mm2 in the interface with loss of 2 lines or more of BSCVA; uncontrolled IOP rise with increase of >5 mmHg or any reading above 25 mmHg; retinal detachment or retinal vascular accident; and decrease in BSCVA of >10 letters not due to irregular astigmatism as shown by hard contact lens refraction.

The following complications occurred 3 months after LASIK during this clinical trial: 0.8% (7/844) of eyes had a corneal epithelial defect; 0.1% (1/844) had any epithelium in the interface; 0.1% (1/844) had foreign body sensation; 0.2% (2/844) had pain; and 0.7% (6/844) had ghosting or double images in the operative eye.

The following complications did NOT occur 3 months following LASIK in this clinical trial: corneal edema and need for lifting and/or reseating the flap/cap.

Adverse Events and Complications for Hyperopia: Certain adverse events and complications occurred after the LASIK surgery. Only one adverse event occurred during the clinical study: one eye (0.4%) had a retinal detachment or retinal vascular accident reported at the 3 month examination.

The following adverse events did NOT occur: corneal infiltrate or ulcer requiring treatment; lost, misplaced, or misaligned flap, or any flap/cap problems requiring surgical intervention beyond 1 month; corneal edema at 1 month or later visible in the slit lamp exam; any complication leading to intraocular surgery; melting of the flap of > 1 mm2; epithelium of > 1 mm2 in the interface with loss of 2 lines or more of BSCVA; uncontrolled IOP rise with increase of > 5 mmHg or any reading above 25 mmHg and decrease in BSCVA of > 10 letters not due to irregular astigmatism as shown by hard contact lens refraction.

The following complications occurred 6 months after LASIK during this clinical trial: 0.8% (2/262) of eyes had a corneal epithelial defect and 0.8% (2/262) had any epithelium in the interface.

The following complications did NOT occur 6 months following LASIK in this clinical trial: corneal edema; foreign body sensation; pain, ghosting or double images; and need for lifting and/or reseating of the flap/cap.

Adverse Events and Complications for Mixed Astigmatism: Certain adverse events and complications occurred after the LASIK surgery. No protocol defined adverse events occurred during the clinical study. However, two events occurred which were reported to the FDA as Adverse Events.

The first event involved a patient who postoperatively was subject to blunt trauma to the treatment eye 6 days after surgery. The patient was found to have an intact globe with no rupture, inflammation or any dislodgement of the flap. The second event involved the treatment of an incorrect axis of astigmatism which required retreatment.

The following adverse events did NOT occur: corneal infiltrate or ulcer requiring treatment; corneal epithelial defect involving the keratectomy at 1 month or later; corneal edema at 1 month or later visible in the slit lamp exam; epithelium of > 1 mm2 in the interface with loss of 2 lines or more of BSCVA; lost, misplaced, or misaligned flap, or any flap/cap problems requiring surgical intervention beyond 1 month; decrease in BSCVA of > 10 letters not due to irregular astigmatism as shown by hard contact lens refraction; any complication leading to intraocular surgery; melting of the flap of > 1 mm2; uncontrolled IOP rise and retinal detachment or retinal vascular accident.

None of the following complications occurred at 3 months after LASIK during this clinical trial: corneal edema; corneal epithelial defect; any epithelium in the interface; foreign body sensation, pain, ghosting or double images; and need for lifting and/or reseating of the flap/cap.

Subjects were asked to complete a patient questionnaire preoperatively and at 3-months, 6-months, and 1-year postoperatively.

Adverse Events and Complications for Wavefront - guided Myopia: Certain adverse events and complications occurred after the wavefront-guided LASIK surgery. No adverse event occurred during wavefront-guided treatments during this clinical study.

The following adverse events did NOT occur: corneal infiltrate or ulcer requiring treatment; lost, misplaced or misaligned flap or any flap/cap problems requiring surgical intervention beyond 1 month; corneal edema at 1 month or later visible in the slit lamp exam; any complication leading to intraocular surgery; melting of the flap of > 1 mm2; epithelium of > 1 mm² in the interface with loss of 2 lines or more of BSCVA; uncontrolled IOP rise with increase of > 5 mmHg or any reading above 25 mmHg; and decrease in BSCVA of > 10 letters not due to irregular astigmatism as shown by hard contact lens refraction.

The following complications occurred 3 months after wavefront-guided LASIK during this clinical trial: corneal epithelial defect (0.6%); foreign body sensation (0.6%); and pain (0.6%).

The following complications did NOT occur 3 months following wavefront-guided LASIK in this clinical trial: corneal edema; any epithelium in the interface; ghosting or double images; and need for lifting and/or reseating of the flap/cap.

ATTENTION: The safety and effectiveness of LASIK surgery has ONLY been established with an optical zone of 6.0 – 6.5 mm and an ablation zone of 9.0 mm.

Reference the Directions for Use labeling for a complete listing of indications, warnings and precautions.

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