

Corneal biomechanical measurements before and after laser in situ keratomileusis

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PURPOSE: To study the correlation between corneal biomechanical properties and surgical parameters in myopic patients before and after laser in situ keratomileusis (LASIK).

SETTING: UCLA Laser Refractive Center of the Jules Stein Eye Institute, Los Angeles, California, USA.

METHODS: In 43 eyes of 43 patients, the Ocular Response Analyzer was used to measure corneal hysteresis (CH), corneal resistance factor (CRF), Goldmann-correlated intraocular pressure (IOPg), and corneal-compensated IOP (IOPcc) before and 1 month after LASIK. Manifest refraction spherical equivalent (MRSE), preoperative central corneal thickness (CCT), flap thickness (FT), and ablation depth (AD) were also recorded. Changes in these parameters after LASIK were calculated and the correlations between the change in CH (Δ CH), change in CRF (Δ CRF) and the AD, change in MRSE (Δ MRSE), and CCT were examined. The relationship between Δ CRF and Δ MRSE was examined by linear regression analysis.

RESULTS: The preoperative mean CH and mean CRF ($11.52 \text{ mm Hg} \pm 1.28 \text{ [SD]}$) and $11.68 \pm 1.40 \text{ mm Hg}$, respectively) were significantly higher than postoperative values ($9.48 \pm 1.24 \text{ mm Hg}$ and $8.47 \pm 1.53 \text{ mm Hg}$, respectively) ($P < .0001$). A higher attempted correction was correlated with a larger Δ CH and Δ CRF (AD, $r = 0.47$ and $r = 0.65$, respectively; Δ MRSE, $r = 0.51$ and $r = 0.66$, respectively). No correlation was found between Δ CH, Δ CRF, and preoperative CCT.

CONCLUSIONS: Changes in CH and CRF after LASIK suggest alteration in corneal biomechanics correlating with attempted correction. The CRF parameter may be more useful than the CH parameter in assessing biomechanical changes resulting from LASIK.

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The Ocular Response Analyzer (ORA) (Reichert Ophthalmic Instruments) was originally developed to measure intraocular pressure (IOP) that is less influenced by corneal biomechanics and corneal thickness. In

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addition to providing a corneal-compensated IOP (IOPcc), another ORA feature measurement relevant to refractive surgery is its ability to quantify the viscoelastic properties of the cornea. The corneal biomechanical properties measured by the ORA are corneal hysteresis (CH) and corneal resistance factor (CRF). According to the manufacturer of the ORA, CH is a measure of viscous damping in the corneal tissue, or the energy absorption capability of the cornea. The CRF parameter is a measure of the cumulative effects of both the viscous damping and elastic resistance of the cornea. The CH and CRF parameters vary from person to person, providing distinct biomechanical information (Luce DA. IOVS 2007; 47:ARVO E-Abstract 2226).¹

Refractive surgery alters the biomechanical properties of the cornea,^{2,3} which are thought to play an important role in affecting treatment outcome.^{4–6} Thus, an in vivo method of measuring corneal biomechanics could be useful in identifying laser in situ keratomileusis (LASIK) candidates and in predicting treatment response.

The ORA device provides an efficient and repeatable in vivo method of providing biomechanical metrics of the cornea. A previous study using the ORA by Ortiz et al.⁷ found statistically significant decreases in CH and CRF after LASIK performed using femtosecond laser for flap creation. In this study, we examined the correlation between CH, CRF, and various parameters in myopic patients before and after LASIK using a microkeratome for flap creation.

Ultimately, by analyzing preoperative CH and CRF and understanding the effects of LASIK on these biomechanical properties, we may improve our ability to identify patients at high risk for post-LASIK ectasia, a visually debilitating complication of an elective refractive procedure.^{5,8-10}

PATIENTS AND METHODS

All files of patients who had myopic LASIK at the UCLA Laser Refractive Center of the Jules Stein Eye Institute from February to September 2006 were reviewed. The UCLA Institutional Review Board approved the study.

Patients who have LASIK at the UCLA Laser Refractive Center receive an extensive preoperative examination to determine candidacy for the procedure. This includes Orbscan (Bausch & Lomb) anterior segment analysis to exclude patients with topographic evidence of forme fruste keratoconus or thin/asymmetric pachymetric profile. As a result, the population in this study was rigorously selected to have "normal" corneas. Patients were excluded from the study if they did not have all requisite preoperative parameters measurements, did not have postoperative follow-up of at least 1 month with all parameters recorded, or had femtosecond laser flap creation. Unless the patient had LASIK in the left eye only, the right eye was used for statistical analysis in all cases.

The manifest refraction spherical equivalent (MRSE), CH, and CRF were measured before and after LASIK. Before and after LASIK, the IOPcc and the Goldmann-correlated IOP (IOPg) were recorded with the ORA device. A qualified technician experienced in study protocols obtained the ORA waveforms, all of which showed symmetric peak heights and similar widths. The preoperative central corneal thickness (CCT) and the bed thickness after flap lift (before excimer ablation) were measured by ultrasound pachymetry. Flap thickness (FT) was then calculated by subtracting these 2 measurements. Residual bed thickness (RBT) was calculated by subtracting the predicted ablation depth (AD) and the FT from the CCT. The AD measurement was provided by the excimer laser computer. An RBT index was calculated to account for preoperative CCT as follows: RBT index = RBT/preoperative CCT. An AD index was calculated to account for FT and the preoperative CCT as follows: AD index = (AD + FT)/preoperative CCT.

All LASIK procedures were wavefront guided using the myopic astigmatism algorithm on the LADARVision 4000 excimer laser with Custom Cornea (Alcon Laboratories). This algorithm uses a 6.50 mm optical zone with a 1.25 mm blend zone that cannot be altered. All flaps were created using the One Use Plus automated disposable microkeratome with a 130 μ m head (Moria Surgical). A new microkeratome blade was used in each eye. The postoperative

medication regimen consisted of topical steroid and antibiotic drops 4 times daily for 1 week.

Statistical analysis was performed using SAS software (version 9.1, SAS Institute, Inc.). The changes in CH and CRF (Δ CH and Δ CRF, respectively), defined as the differences between the preoperative and postoperative CH and CRF, were assessed using the 2-sided paired *t* test. The same test was used to assess the changes between the preoperative and postoperative IOPg and IOPcc; that is, the change in IOPg and in IOPcc (Δ IOPg and Δ IOPcc, respectively).

Pearson correlation coefficients were calculated to evaluate the relationship between Δ CH, Δ CRF and the following parameters: AD, AD index, Δ MRSE (difference between postoperative MRSE and preoperative MRSE), preoperative CCT, RBT, RBT index, Δ IOPg, and Δ IOPcc. In addition, Pearson correlation coefficients were calculated to evaluate the relationships between the preoperative CCT and (1) the preoperative CH and (2) the preoperative CRF. Linear regression analysis was performed to examine the relationship between Δ CRF and Δ MRSE. A *P* value less than 0.05 was considered statistically significant.

RESULTS

Forty-three eyes of 43 patients were included in the study (Table 1). The decrease in the mean CH and the mean CRF from preoperatively and postoperatively was statistically significant (both *P* < .0001) (Table 2 and Figure 1).

Positive correlations were found between Δ MRSE and Δ CH, Δ MRSE and Δ CRF, AD and Δ CH, and AD and Δ CRF (Table 3). Positive correlations were

Table 1. Characteristics of 43 eyes (43 patients) receiving LASIK.

Characteristic	Value
Age (y)	
Mean \pm SD	40.53 \pm 10.47
Range	22 to 62
Preop MRSE (D)	
Mean \pm SD	-4.04 \pm 2.00
Range	-9.12 to -0.25
Preop CCT (μ m)	
Mean \pm SD	549.87 \pm 29.53
Range	493 to 617
FT (μ m)	
Mean \pm SD	118.95 \pm 13.23
Range	92 to 148
AD (μ m)	
Mean \pm SD	72.14 \pm 28.79
Range	16.8 to 137.2
RBT (μ m)	
Mean \pm SD	358.84 \pm 38.62
Range	274.3 to 449.3

AD = ablation depth; CCT = central corneal thickness; FT = flap thickness; MRSE = manifest refraction spherical equivalent; RBT = residual bed thickness

Table 2. Parameters of 43 eyes of 43 patients before and after LASIK surgery

	Preoperative		Postoperative		Change		P Value
	Mean \pm SD	Range	Mean \pm SD	Range	Mean \pm SD	Range	
MRSE (D)	-4.04 ± 2.00	-9.12 to -0.25	-0.13 ± 0.46	-1.13 to 0.88	-3.91 ± 2.01	-9.12 to 0.00	<.0001
CH (mm Hg)	11.52 ± 1.28	9.25 to 14.30	9.48 ± 1.24	6.95 to 12.10	2.04 ± 1.00	0.35 to 5.10	<.0001
CRF (mm Hg)	11.68 ± 1.40	8.55 to 14.70	8.47 ± 1.53	5.80 to 11.70	3.21 ± 1.12	0.55 to 7.10	<.0001
IOPg (mm Hg)	16.31 ± 4.00	5.05 to 24.05	11.80 ± 2.76	6.20 to 19.40	4.51 ± 3.11	-7.55 to 9.30	<.0001
IOPcc (mm Hg)	16.00 ± 3.32	9.10 to 23.85	14.06 ± 2.44	6.20 to 19.40	1.94 ± 2.17	-2.10 to 6.40	<.0001

CH = corneal hysteresis; CRF = corneal resistance factor; IOPg = Goldmann-correlated IOP intraocular pressure; IOPcc = corneal-compensated intraocular pressure; MRSE = manifest refraction spherical equivalent

also found between the preoperative CCT and preoperative CH ($r = 0.37$; $p = 0.015$) and the preoperative CCT and preoperative CRF ($r = 0.39$; $p = 0.009$). The AD index did not correlate with Δ CH but did correlate with Δ CRF. The RBT index also did not correlate with Δ CH but did correlate with Δ CRF.

A linear regression model showed that every diopter (D) of myopic correction in MRSE resulted in an increase in Δ CRF of 0.37 mm Hg (95% confidence interval [CI], 0.24-0.50) ($r^2 = 0.44$, $P < .0001$) (Figure 2). That is, a larger myopic correction correlated with a larger decrease in CRF.

Although a significant difference was found between the preoperative and postoperative IOPg ($P < .0001$) and between the preoperative and postoperative IOPcc ($P < .0001$), the mean Δ IOPg (4.51 ± 3.11 mm Hg) was much greater with a larger standard deviation than the mean Δ IOPcc (1.94 ± 2.17 mm Hg) (Figure 1). In addition, although there was no statistically significant difference between the preoperative IOPg and the preoperative IOPcc ($P = .329$), the difference between postoperative IOPg and the postoperative IOPcc was statistically significant ($P < .0001$).

DISCUSSION

The cornea has been modeled as a viscoelastic material with quantifiable biomechanical properties.^{4,9,11,12} Until recently, however, no device provided a repeatable measurement of corneal biomechanics in vivo. The ORA device measures the biomechanical parameters CH and CRF, which characterize the viscoelastic properties of the cornea.

Consistent with previous studies,^{1,7,13,14} both the CH and CRF values in our study were significantly decreased after LASIK, suggesting that in LASIK, the flap creation, the ablation, or both significantly alter the ability of the cornea to absorb or dissipate energy (Luce DA. IOVS 2007; 47:ARVO E-Abstract 2226; M. Shimmyo, MD, et al., "Corneal Hysteresis and Corneal

Resistance Factor in Keratoconus, Fuch's Dystrophy and Before and After LASIK," poster presented at the ASCRS Symposium on Cataract, IOL and Refractive Surgery, San Diego, California, USA, April 2007).

Furthermore, consistent with previous reports by Ortiz et al.⁷ and Kirwan et al.,¹⁴ the significant positive correlations between AD and Δ CH, AD and Δ CRF, Δ MRSE and Δ CH, and Δ MRSE and Δ CRF suggest that a deeper ablation, typically corresponding with a higher attempted correction, has a more significant effect on corneal biomechanics than a shallower ablation or lower attempted correction.

Keratoconic corneas are known to have lower CH and CRF values¹ and a higher tendency to develop post-LASIK ectasia (M.H. Shabayek, MD, et al., "Changes in Corneal Biomechanics in Keratoconic and Post-LASIK Eyes," paper presented at the annual meeting of the American Academy of Ophthalmology,

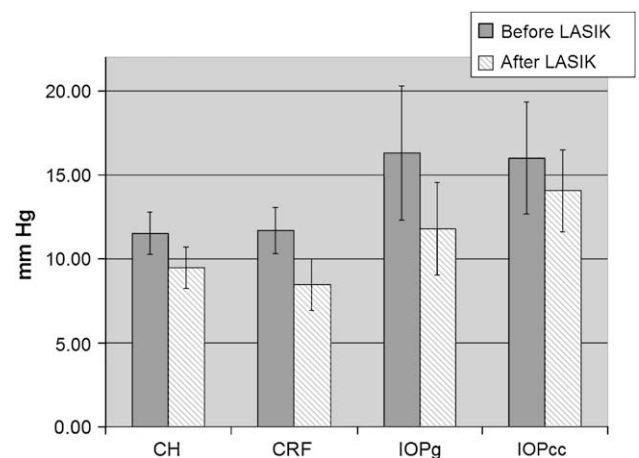


Figure 1. Mean CH, CRF, IOPg, and IOPcc before and after LASIK (43 eyes). The error bars represent 1 standard deviation above and below the mean values. All variables changed significantly from before to after LASIK ($P < .0001$) (CH = corneal hysteresis; CRF = corneal resistance factor; IOPg = Goldmann-correlated IOP intraocular pressure; IOPcc = corneal-compensated intraocular pressure; LASIK = laser in situ keratomileusis).

Table 3. Pearson correlation coefficients (N = 43 eyes).

Parameter	<i>r</i> Value (<i>P</i> Value)	
	Δ CH	Δ CRF
Δ MRSE	0.51 (.005)*	0.66 (<.0001)*
AD	0.47 (.002)*	0.65 (<.0001)*
AD index	0.24 (.126)	0.47 (.001)*
RBT	-0.10 (.519)	-0.28 (.066)
RBT index	-0.22 (.150)	-0.44 (.003)*
Δ IOPg	0.073 (.641)	0.58 (<.0001)*
Δ IOPcc	-0.29 (.058)	0.33 (.033)*
Preop CCT	0.14 (.369)	0.11 (.463)

AD = ablation depth; CCT = central corneal thickness; Δ CH = change in corneal hysteresis; Δ CRF = change in corneal resistance factor; Δ IOPg = change in Goldmann-correlated IOP intraocular pressure; Δ IOPcc = change in corneal-compensated intraocular pressure; Δ MRSE = change in manifest refraction spherical equivalent; RBT = residual bed thickness
*Statistically significant correlation

Las Vegas, Nevada, USA, November 2006).^{4,8,10} The literature also supports higher corrections as a risk factor for post-LASIK ectasia.¹⁵ Previous studies^{7,14} and the current study found that higher attempted corrections correlate with greater reductions in the CH and CRF parameters; therefore, further study is needed to determine whether low preoperative CH and CRF values are of value in estimating the risk for poor outcomes in a patient presenting for refractive surgery.

Recent studies testing the cohesive tensile strength of the cornea show that the anterior corneal stroma has the greatest cohesive tensile strength.^{16,17} Cohesive tensile strength is not uniform throughout the corneal stroma but is inversely correlated with stromal depth. With this in mind, the AD must be adjusted for each eye to take into account the relative depth at which tissue removal occurs. Accordingly, we created the AD index to adjust for variation in FT and CCT. In our study, the AD index correlated with the CRF parameter but not with the CH parameter. Furthermore, the CRF parameter had a higher correlation than the CH parameter with changes in ablation depth and manifest refraction. Although some previous studies^{1,14} focused on the CH parameter, the CRF parameter, a cumulative measure of both the viscous damping and elastic resistance of the cornea, may be more useful in assessing changes in corneal biomechanics after LASIK (Luce DA. IOVS 2007; 47:ARVO E-Abstract 2226).

The ORA device provides a corneal-compensated IOP measurement (IOPcc) that is theoretically independent of corneal thickness and that may prove useful in determining true IOP after LASIK. In this study, there was no significant difference between preoperative IOPg and IOPcc; however, there was a significant decrease in both parameters after LASIK, with IOPcc

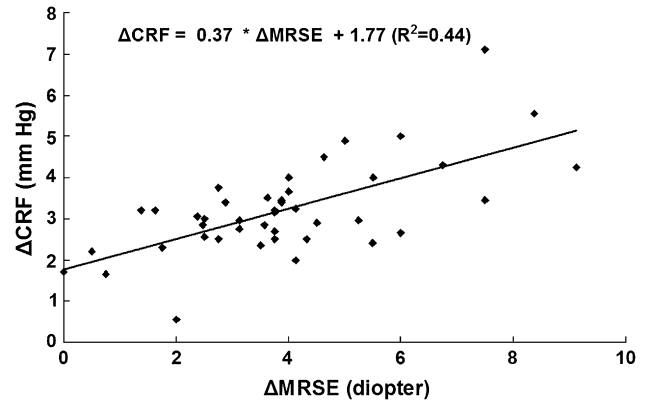


Figure 2. Linear regression model of the Δ MRSE versus the Δ CRF (43 eyes) ($P < .0001$) (Δ MRSE = change in manifest refraction spherical equivalent; Δ CRF = change in corneal resistance factor).

changing less than IOPg. These findings are consistent with those of Ortiz et al.⁷ and Pepose et al.¹³ The finding that IOPcc and IOPg decrease after LASIK but that IOPcc decreases less suggests that although the IOPcc parameter is a more accurate indicator of true IOP, the ORA device does not completely compensate for the biomechanical properties of the cornea when measuring IOP.

The myopia treated in this study ranged from -0.25 to -9.12 D, covering more than 95% of myopic patients treated at the UCLA Laser Refractive Center. Although this range does not reflect the full range of myopia that can be treated with LASIK,¹⁸ we believe it is indicative of the more conservative myopic range embraced by most contemporary refractive surgeons. All eyes in the study were from patients who passed the rigorous screening process at our center to determine candidacy for LASIK. As a result, the range of preoperative CCT values was much narrower than in ORA studies that were not specific to refractive surgery.¹⁹⁻²¹ Furthermore, as the biomechanical properties of a given patient's right eye and left eye may be correlated, only single eyes from a given patient were included in the current study to avoid statistical bias (Shimmyo ML, Luce D. IOVS 2004; 48:ARVO E-Abstract 5564).

The linear regression model for Δ CRF versus Δ MRSE yielded a y intercept of 1.77 mm Hg (95% CI, 1.19-2.34). Although this study had a relatively small sample size, one hypothesis for the meaning of this intercept is that it describes the corneal biomechanical effect of the flap creation alone in the absence of excimer laser ablation. A recent case report in the literature²² supports this hypothesis; flap creation without ablation resulted in an immediate decrease in CH and CRF that remained lower than preoperative values from 1 hour to 25 days. A larger series is needed to further elucidate the biomechanical effects of flap creation alone.

In this study, the flap creation technique was limited to the mechanical microkeratome. The range of FT achieved in the current study, 92 to 148 μm with a standard deviation of 13 μm , was tighter than many ranges reported in studies using mechanical systems^{23,24} and is similar to the range of FT achievable with femtosecond laser systems.^{25–27} Today, many surgeons use the femtosecond laser for flap creation. There is growing evidence that there are different effects on corneal biomechanics depending on the method of flap creation (R. Krueger, MD, “Flap Biomechanics: IntraLase Vs Microkeratome,” presented at the ASCRS Symposium on Cataract, IOL and Refractive Surgery, San Francisco, California, USA, March 2006).²⁸ Ortiz et al.⁷ report results in LASIK patients who had flap creation with a femtosecond laser; the preoperative to postoperative mean decrease in CH was from 10.44 ± 1.74 mm Hg to 9.3 ± 1.9 mm Hg and in CRF, from 10.07 ± 1.97 mm Hg to 8.1 ± 1.8 mm Hg. The decreases in both parameters after LASIK are less than the decreases reported in this current study, although the preoperative mean CH and CRF values reported by Ortiz et al. are also lower than the values reported in this study. Direct comparative studies are needed to investigate the differences in biomechanical effect secondary to method of flap creation.

The ORA waveforms may be affected by patient positioning, brow and lid anatomy, patient breathing, and Valsalva maneuvers. Although every effort was made in this study to obtain waveforms not corrupted by these factors and to include only waveforms with symmetric P1 and P2 peak heights, the clinical use of this technology is in its infancy and further refinement of acquisition techniques may improve the quality of the ORA waveforms.

During the surgical procedure, hydration changes in the cornea may affect the laser-calculated AD and may introduce variation in assessing FT and RBT. Every effort was made to minimize this variability by following routine protocol and using the same laser in all eyes. The hydration variability can be indirectly assessed through the mean and standard deviation of the postoperative spherical equivalent. In the current study, the mean postoperative MRSE was -0.13 ± 0.46 D. This range of postoperative outcomes for myopic astigmatic surgery is similar to those reported in the literature.²⁹

At present, corneal topography is the most widely used diagnostic tool for screening refractive surgery patients.³⁰ Further work is needed to determine whether the combination of topography with the new ORA metrics can assist the refractive surgeon in diagnosing subtle corneal abnormalities and ultimately allow improved exclusion criteria of patients at risk for postsurgical ectasia.

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