

**Objective:** To study the effect of varying four parameters on the refractive change induced by the LASIK flap.

**Methods:** Using a variety of patient-specific data such as topography, pachymetry, and axial length, a finite element model is built. The model is used in a non-linear finite element analysis to determine the response and change in optical power of the cornea as a function of a material property of the cornea (corneal elasticity), flap diameter and thickness, and intraocular pressure.

**Results:** The central flattening or hyperopic shift occurred atop the flap in all four of the simulated eyes tested with the creation of the LASIK flap. Of the four parameters tested, modulus of elasticity (Young’s modulus) had the most profound effect on the results of hyperopic shift, varying from \(0.5\) diopters (D) in the least elastic (stiffest) cornea to \(2.0\) D of hyperopic shift in the most elastic cornea. The depth of the lenticular cut was the second-most significant parameter tested varying from \(0.24\) D at 100 microns to \(1.25\) D at 275 microns of depth. Varying intraocular pressure demonstrated less difference, and varying corneal flap diameter demonstrated the least difference in induced refractive change on the model. The hyperopic shift was noted to be greater in hyperopic than in myopic eyes (simulated) tested.

**Conclusions:** Three-dimensional finite element analysis modeling of actual patient data could lead to a better understanding of the biomechanical response of corneal tissue to the lenticular flap creation and potentially for ablation patterns produced by the excimer laser. Understanding these biomechanical responses may lead to greater predictability and improvement of visual outcomes. 

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Over recent years LASIK has become a popular surgical alternative for the correction of refractive errors such as myopia, hyperopia, and astigmatism. In this technique, a hinged flap is created and folded back, and the exposed stroma is photoablated using an excimer laser so that the curvature of the central cornea is reshaped, to improve uncorrected vision.

Due to the inherent asymmetry of the corneal geometry, a quantitative study of the topography is complex. Analytical studies have been carried out using simulated picosecond laser keratomileusis involving two mathematical models. One was with a shape-subtraction paradigm, based on the assumption that the biomechanical response of the cornea is negligible. Another was a finite element method that took the cornea’s biomechanical response into account. Both of these models overpredicted the curvature change, but the average overprediction for the finite element model was by a much smaller margin. The models used by Bryant et al look at very high myopic corrections produced by the removal of an intrastromal lenticule of tissue. The comparative results support the view that final corneal refractive changes cannot be determined by the shape of the ablated tissue alone. In another study, Djotyan et al constructed an analytically solvable elastic shell model for biomechanical response of the cornea to refractive surgery. The cornea was represented as an axisymmetric shell with position-dependent thickness and an estimated modulus of elasticity. First, the shape-sub-
trication paradigm provided the postoperative geometric parameters of the cornea. The postoperative values of the corneal modulus of elasticity, its range of variation, and its dependence on the geometric parameters of the removed corneal tissue were determined by best fitting (the fitting parameter is the modulus of elasticity of the cornea) of predictions of the elastic shell model with LASIK nomograms from commercially available Bausch & Lomb (Rochester, NY) and VISX (Santa Clara, Calif) software for two different values of the ablation zone diameter. The elastic shell model then considered the action of intraocular pressure (IOP) on the deformation of the anterior corneal surface and calculated the resulting principal curvatures of the cornea.

Dupps and Roberts proposed a biomechanical model of the intraoperative phototherapeutic keratectomy-induced central flattening. The peripheral stromal thickness was considered a feature of the biomechanical model and the acute postoperative flattening of the central cornea, i.e., the hyperopic shift induced by the procedure, was shown to rely on changes in peripheral stromal thickness rather than on the ablation pattern.

Roberts also presented a conceptual model that took into account the corneal biomechanical response to ablative surgery. The proposed model suggested that the corneal shape change induced by the surgery is contingent on structural modification along with ablation profile and that it cannot be predicted with wavefront analysis alone. In LASIK (flap creation) without tissue removal, central flattening and peripheral steepening were shown to occur.

Traditionally, the surgical outcome has been analyzed based on the solid material assumption. Katsube et al proposed a model that treated the cornea as a fluid-filled porous material. The solid and fluid constituents of the cornea were modeled separately and the internal subatmospheric fluid pressure was deemed an important component of the mechanical loading, in addition to IOP. This model demonstrated higher amounts of unintended flattening (hyperopic shift) compared to models based on solid material assumption.

Most biomechanical models of the cornea have been simplified geometric models of sphere or an ellipsoid or an axisymmetric model. They have not been based on actual patient data. Overall, the material properties have been assumed to be isotropic. The cornea has numerous layers, each layer with different geometrical thickness parameters, exhibiting different material behavior, all adding up to a complex material. Hence, a biomechanically plausible computer model of the cornea will likely require an actual determination of each cornea’s material properties.

The principal aim of any refractive treatment regardless of the surgical technique is to attain a level of reliability and predictability. One of the more promising approaches is to combine the current technology of wavefront analysis with a biomechanical model. The latter provides a methodology that can be used to predict exactly how the components of the eye, especially the cornea, react to the surgical plan on a patient-specific basis. One of the cornerstones of this biomechanical approach to improve visual outcome is the finite element method.

The primary objective of our study was to scrutinize and identify the relative importance that different parameters might have on the refractive change induced by a LASIK flap. First understanding these potential changes could be vital to predict a final visual outcome after the stromal ablation has occurred.

The specific objectives of this study were:
1. develop a methodology for creating a patient-specific finite element model of the eye using topography data, pachymetry, axial length, and corneal dimensions;
2. develop a methodology for modeling the LASIK flap-creation surgery using the information from (1) in the form of a finite element model with elements, nodes, boundary conditions, loads, and material behavior all defined; 
3. develop a methodology for computing the power (or curvature) at various points on the anterior surface of the cornea for both the pre- and postoperative eye; 
4. implement the developed methodologies in the form of computer programs; and 
5. study the sensitivity of refractive changes induced by the LASIK flap by varying the different parameters used in the finite element model while using actual patient data.

PATIENTS AND METHODS

The three-dimensional corneal topography data are used to construct the geometric model of a patient’s eye. The geometric model established a reference configuration of the cornea against which the response of the structural change from the LASIK flap can be juxtaposed to evaluate the resultant refractive change. Construction of the geometric model is accomplished by a combination of curve and surface fitting procedures.

In this study, a commercially available corneal topographer (Humphrey Atlas Eclipse Corneal Topography System Model 995) is used in the form of 25 rings, each divided into 180 evenly spaced data points. The data are transformed into spatial Cartesian (X, Y, Z) coordinates. A typical topography map is shown in Figure 1. There is some amount of missing data usually in the superior area of the cornea due to the shadow of the upper lid and lashes.

Along each ray, a cubic polynomial is represented as
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\[ z = g(r) \]

with \( r \) as the independent variable. The cubic spline interpolation was used to estimate the values of \( z \) for the missing data points. In addition, the points describing the sclera are mapped by extrapolating beyond the last corneal point on each ray. The transition from the cornea to the sclera has been modeled biomechanically with a change in elasticity at the transition, but it also involves a change in curvature at the limbus, which is unaccounted for in the current model. Thus the extrapolation of the scleral geometry points might potentially introduce an error. The scleral model was constructed for only half of the entire axial length of the eye, as the posterior half has little or no influence on the corneal model. Examples of completed points used in constructing the finite element model are shown in Figure 2.

The finite element nodes are generated to be coincident with the topographic data points. The structure is modeled with two layers of elements across the thickness. The nodes for the second layer of elements are generated by projecting the nodes on the anterior surface. The thickness of the cornea is obtained clinically from ultrasonic pachymetry data at 33 points on the cornea, with the thickness at the remaining points estimated by linear interpolation. The cornea has a substantially higher grid density than the sclera (Fig 3). The higher mesh density used in the cornea is required to reach a good quantitative match to the experimental data. The finite element mesh (see Fig 3) of the model has 26,402 nodes (79,206 degrees-of-freedom) and 16,200 elements, of which 9000 are used to model the cornea. All of the degrees-of-freedom are assumed to be fixed for the nodes at the periphery of the finite element model. Linear triangular prism and hexahedral elements are used to mesh the cornea, and linear hexahedral elements are used to mesh the sclera.

The hinged flap is modeled as a crack on the anterior surface of the cornea (Fig 4). The flap starts from a specified angle, extending counterclockwise to the specified angle at a specified radius along the surface (see Fig 2 for coordinate system). The arc length of the hinge used is 4 mm in each eye. Note that the strain lessens within the lenticule of the lamellar flap, which has been cut (see Fig 4). Note that Figure 4 shows strain in units of...
Duplicate nodes are introduced for all nodes present along the surface crack and beneath the flap. The interaction between the two layers, resulting from the flap, is simulated using spring elements that span the two nodes and have the same location in space before the incisions are made. The stiffness of each spring is computed using the following equation:

$$k = \frac{E_{11}A}{n}$$ (1)

where $E_{11}$ is the elastic modulus of the cornea in the direction perpendicular to the corneal plane, $A$ is the area of the posterior surface of the hinged flap, and $n$ is the number of spring elements that are in parallel. The area $A$ of the posterior surface of the flap is computed as

$$A = 2\pi r^2 \Delta \theta$$ (2)

where $r$ is the radius of the cornea and $\theta$ is the angle described between the center of the cornea and the last corneal point on a ray. The purpose of these springs is to keep the two surfaces from physically penetrating each other.

The cornea is assumed to be orthotropic.$^6,7$ The modulus of elasticity in the direction perpendicular to the corneal plane, $E_{11}$, is assumed to be 0.125% of the in-plane elastic modulus—$E_{22}$ or $E_{33}$. The in-plane moduli values are assumed to be equal, $E_{22} = E_{33}$. The corneal stiffness is primarily in-planar and the stiffness in the direction perpendicular to the corneal plane is negligible. The in-plane Poisson’s ratio, $\nu_{23}$, is assumed to be 0.49 (nearly incompressible). The other two Poisson’s ratios, $\nu_{12}$ and $\nu_{13}$, are each assigned a value of 0.01. The shear moduli are assumed to be small relative to the in-plane modulus of elasticity. The (low) values of the material constants are selected so that there are no numerical problems in the finite element analyses. The sclera is assumed to be linear isotropic and the ratio of the modulus of elasticity of the sclera to the in-plane modulus of elasticity of the cornea is assumed to be 2.5 throughout the study.

The model is subjected to a nonlinear static structural analysis using the commercial finite element program ABAQUS (ABAQUS Inc, Providence, RI). The response of the structure at each node is used to update the coordinates of the reference configuration and thereby map the postoperative topography. The postoperative ($X$, $Y$, $Z$) locations of the nodes on the anterior surface of the cornea are computed as the sum of the reference configuration and the nodal displacements ($\Delta X$, $\Delta Y$, $\Delta Z$). The computation of curvature of the corneal first surface at finite element nodes is accomplished by a method based on the least squares approach. In this method, the curvature is obtained by fitting a sphere through a set of representative data points lying around the point in question. Because only the central 3 mm of the cornea (optical zone) are evaluated...
in this fashion, the model does not attempt to measure the effect of the flap on the peripheral cornea, either anatomically or refractively.

The least squares method is used and the problem is posed as follows:

Find \( (R, a, b, c) \) to minimize \( f_g = \sum_{i=1}^{n} \left[ R^2 - \left( \frac{x_i - a}{b} \right)^2 - \left( \frac{y_i - b}{c} \right)^2 \right] \)

where \( R \) is the radius of the fitted sphere, \( a, b, \) and \( c \) are the coordinates of the center of the fitted sphere, and \( n \) is the number of representative data points. Once \( R \) is obtained, the power, \( D \), expressed in terms of diopters, is evaluated as

\[
D = \frac{376}{R}
\]

where the constant, 376, is a factor based on the difference between the refractive indices of the air and the cornea.

The parameters that are selected for the study are as follows (Fig 5). Two clinical and one exaggerated thickness were selected for consideration.

- a) The in-planar modulus of elasticity of the cornea—varying from 2 MPa to 12 MPa.
- b) Diameter of the flap—varying from 8 to 10 mm.
- c) Flap thickness—varying from 100 to 275 \( \mu \)m (ie, 100 \( \mu \)m, 160 \( \mu \)m, 275 \( \mu \)m).
- d) Intraocular pressure—varying from 15 to 25 mmHg.

The Table summarizes the parameters examined.

The refractive change was derived from the average change of corneal power in the central 3-mm optical zone. Two patients (four eyes) were selected for the study with the following manifest spherical equivalent refractions: Patient 1: right eye +1.75 sphere, left eye +1.75 sphere and Patient 2: right eye −5.25 sphere, left eye −5.00 +0.25 × 170.

**RESULTS**

In all four modeled eyes, a hyperopic shift occurred with the creation of a LASIK flap. The amount of hyperopic shift noted in each modeled eye increased in relation to increased elasticity, flap thickness, and IOP. It did not change appreciably in relation to flap diameter. From this model, it is not possible to determine whether the hyperopic shifts occurred as a result of relative thickening of the peripheral cornea, changes in the stress/strain relationship of the corneal collagen fibrils, or some combination of both. However, the model does show the relative sensitivity of refractive
changes to each of these four variables. The clinical correlation of these sensitivities needs to be validated.

**EFFECT OF MODULUS OF ELASTICITY**

A series of finite element simulations is carried out with a variety of corneal elasticity from very high ($E_{11} = E_{22} = 2 \text{ MPa}$), gradually changing to a relatively stiffer cornea (low elasticity) ($E_{11} = E_{22} = 12 \text{ MPa}$), holding the other parameters to constant values as reported in the Table. Peripheral steepening and central flattening are observed from the flap formation in each case (hyperopic shift). The amount of corneal deformation, or hyperopic shift, is proportional to elasticity and decreases as stiffness increases. The variation of the postoperative change in curvature with the modulus of elasticity of the cornea is observed to be approximately linear in each of the four simulated eyes that were examined (Fig 6). The effect the corneal elasticity has on the postoperative elevation maps is depicted in Figures 7 and 8 for a myopic and hyperopic eye. The resultant refractive change varied from less than 0.5 D in the stiffest cornea ($E_{11} = E_{22} = 12 \text{ MPa}$) to more than 2.25 D in the most elastic cornea ($E_{11} = E_{22} = 2 \text{ MPa}$). However, for the same elasticity, more hyperopic shift occurred on the hyperopic simulated eyes than the myopic simulated eyes.

**EFFECT OF FLAP DIAMETER**

The flap diameter varied from 8 to 10 mm. Using a moderately elastic cornea ($E_{11} = E_{22} = 8 \text{ MPa}$), the change in flap diameter appears to exert no influence on the postoperative refractive change (see Fig 6).

**EFFECT OF FLAP THICKNESS**

The central portion of the optical zone steepens as the thickness of the 9-mm diameter flap increases from 100 to 275 µm. However, the peripheral cornea steepens to an even larger extent with the deep lamellar cut, creating a relative flattening of the central cornea (hyperopic shift). This hyperopic shift increases from +0.24 D at 100 µm depth to +1.25 D at 275 µm depth (see Fig 6). Figure 9 shows the more marked elevation of the postoperative cornea in the 275 µm flap when compared to the 100 µm flap in the myopic eye. Comparison of the circumferential strain distribution on the posterior corneal surface on a myopic eye shows a deeper lamellar cut, which also creates a higher strain within the remaining stromal bed.

**EFFECT OF INTRAOCULAR PRESSURE**

The magnitudes of the peripheral corneal steepening increase as the pressures increase from 15 to 25 mmHg. The central hyperopic shift increases from +0.75 D at 15 mmHg to +1.25 D at 25 mmHg (see Fig 6).

**DISCUSSION**

From our results of four simulated eyes studied in the finite element analysis model presented, the parameter that had the most effect on the refractive...
change in power distribution was the modulus of elasticity. Patient eyes (simulated) with a highly elastic cornea (modulus of elasticity = 2 MPa) could undergo as much as \( \geq 2.0 \) D hyperopic shift with just the introduction of the flap.

The second most sensitive parameter was the depth of the cut. However, within the clinical range of depth used for LASIK flaps, the hyperopic shift was \(<1.0\) D.

Higher IOP induced a greater hyperopic shift than lower IOP. The diameter of the LASIK flap appeared to have little effect on the induced hyperopic shift. A hyperopic eye with the same corneal stiffness as the myopic eye experienced a greater hyperopic shift with the introduction of the flap.

Pallikaris et al.\(^8\) have shown that the flap cut changes the eye’s higher order aberrations and the present study may explain that observation. In addition, there is a growing body of evidence that the combination of wavefront technology and corneal topography provides the surgeon with the optimal information on the vision characteristics of the eye.\(^4\) The effectiveness of this combination in predicting better visual outcomes and reducing higher ocular aberration may be increased by tying these to the finite element simulation of the LASIK procedure. A better understanding of the corneal biomechanical response to LASIK may be essential to achieving optimal visual performance.

REFERENCES
