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Custom air puff-derived biomechanical variables in a refractive surgery screening setting: Study from 2 centers

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Purpose: To assess the ability of air puff-derived biomechanical variables to predict surgeon-perceived candidacy for laser in situ keratomileusis (LASIK).

Setting: Cole Eye Institute, Cleveland Clinic, Cleveland, Ohio, and Emory Eye Institute, Emory University, Atlanta, Georgia, USA.

Design: Retrospective case series.

Methods: Data were collected from refractive surgery screening examinations by 2 surgeons at 2 centers. Disqualified cases (19 eyes and 28 eyes from each surgeon) were judged not to be candidates based on available data including standard variables from the Ocular Response Analyzer. Controls consisted of LASIK candidates (n = 26 and 23). Three custom biomechanical variables not available during screening were calculated and compared by group and surgeon.

Results: The hysteresis loop area was significantly different between disqualified cases and controls for both surgeons (Surgeon 1: controls, 121.50 ± 25.38 [SD], disqualified, 107.62 ± 18.50, $P = .04$; Surgeon 2: controls, 135.89 ± 22.47, disqualified, 106.11 ± 16.40, $P < .001$). The area under the curves of the receiver operating characteristics and the cutoff values were statistically significant for the concavity minimum and hysteresis loop area for Surgeon 1 and for all variables except concavity minimum for Surgeon 2. The hysteresis loop area had the highest odds ratio (Surgeon 1, 4.48, Surgeon 2, 20.00). Adjusted R^2 in best-subsets regressions were 40.2% for Surgeon 1 and 62.9% for Surgeon 2.

Conclusions: The hysteresis loop area was predictive of which patients were disqualified for LASIK at different sites. Certain measures of the corneal dynamic response to an air puff might serve as correlates to clinically perceived ectasia risk.

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Corneal topography and tomography are important clinical tools in the assessment of candidacy for corneal refractive surgery.[1,2] However, some patients still develop postoperative ectasia, even with apparently normal examinations at the initial evaluation.[3–5] Given the likelihood that abnormalities of corneal biomechanical strength are an early disease driver in keratoconus and a risk factor for development of post-refractive surgery ectasia,[6] research efforts are underway in the area of corneal biomechanical assessment with the clinical goal of enhancing the sensitivity and specificity of preoperative risk assessment using more direct biomechanical measures.

The Ocular Response Analyzer (Reichert Ophthalmic Instruments) is a dynamic bidirectional applanation device that indirectly measures corneal deformation while stressing it with an air puff. The current commercially available device reports 2 biomechanical variables: corneal hysteresis (CH) and corneal resistance factor (CRF). Both have shown relatively low sensitivity and specificity for detecting early or preclinical ectatic disease.[7–9] However, custom variables have been derived from alternative analyses of the deformation response that are not commercially available for the dynamic bidirectional applanation device.[10,11] Some of these variables have been shown to produce better

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predictive results when compared with the standard CH and CRF, especially for keratoconus diagnosis and severity classification,[12–14] although their performance in the setting of clinical decision making has not yet been investigated.

To address this gap in information about the relationship between custom dynamic bidirectional applanation device variables and screening decisions in the setting of clinical refractive surgery, the present study aimed to compare the objective dynamic bidirectional applanation device-derived custom variables with subjective surgeon-specific screening criteria between patients who were screened in for or disqualified from refractive surgery.

PATIENTS AND METHODS

Patients were retrospectively selected from the clinical practices of 2 surgeons: W.J.D. at the Cole Eye Institute, Cleveland Clinic, Cleveland, Ohio (Surgeon 1) and J.B.R. at the Emory Eye Center, Emory University, Atlanta, Georgia (Surgeon 2). Thus, 4 groups were formed after initial selection: disqualified patients and a control group for both centers. Candidates were seen between July 2013 and October 2015. The clinical data used in this study were acquired at the initial appointment as part of each surgeon's routine preoperative screening protocol. Institutional Review Board approvals at both Cleveland Clinic and Emory University were obtained for this retrospective chart review study.

Preoperative screening examinations included uncorrected (UDVA) and corrected (CDVA) distance visual acuities, manifest refraction, intraocular pressure measurement, slitlamp, and posterior segment evaluations, Placido topography (Atlas 9000, Carl Zeiss Meditec AG), Scheimpflug tomography (Pentacam, Oculus Optikgeräte GmbH), and dynamic bidirectional applanation device measurements. Patient age, sex, and manifest refraction spherical equivalent (MRSE) were also documented.

The disqualified group was comprised of patients advised not to have corneal refractive procedures after initial clinical evaluation because of a subjectively perceived higher risk for postoperative ectasia but without definitive clinical or tomographic signs of keratoconus. To minimize selection bias, the control group consisted of consecutive patients who were deemed suitable for myopic laser in situ keratomileusis (LASIK) after preoperative screening and had LASIK in 2015 with stable follow-up for at least 9 months. Figure 1 shows an example of a tomographic scan for each group. Exclusion criteria included any history of previous ocular surgery, corneal scars, and slitlamp and/or tomographic evidence of keratoconus. In general, the practice pattern of both investigators is to apply a decision about either eye of a refractive surgery candidate to both eyes and thus the patient's overall candidacy.

Standard Dynamic Bidirectional Applanation Device Variables

The method of operation of the dynamic bidirectional applanation device has been described in detail elsewhere.[15] Concisely, a puff of air causes an inward deformation of the cornea and results in a slight concavity. This is followed by a return to its preperturbation convex shape. During this process, the plenum pressure of the air jet chamber is measured and an infrared detector system monitors the intensity of the reflected infrared signal. This quantity is a function of specular reflection of photons from the anterior corneal surface and reaches its peak when the cornea is most planar. The difference between the inward (P_1) and outward (P_2) applanation pressures is reported as the CH and is interpreted as a measure of viscous damping, reflecting the capacity of cornea and other ocular structures to absorb and dissipate energy. The CRF is closely related to CH and is a linear combination of the applanation pressure values, $P_1 - (\kappa \times P_2)$, which biases the CRF toward the pressure associated with the ingoing applanation event. The coefficient κ used in the CRF calculation was empirically set to 0.7 by the manufacturer to maximize the dependence of the CRF on the central corneal thickness.

Custom Dynamic Bidirectional Applanation Device Variables

The infrared intensity, pressure, and time series data from the dynamic bidirectional applanation device were exported using the device's software and analyzed in custom code (Matlab, Mathworks, Inc.) that provides 15 custom variables as previously described by Hallahan et al.[10] From this set of variables, 3 were selected for the current analysis based on previous performance in differentiating normal and keratoconus eyes,[10] as well as surgical changes after refractive surgery[11] and corneal crosslinking[16]: hysteresis loop area, concavity minimum ($Concavity_{min}$), and concavity mean ($Concavity_{mean}$). Their definitions and interpretations are presented in Table 1.

Statistical Analysis

Based on significant intraclass correlation, only the right eye of each patient was included in this assessment. Statistical comparisons were performed only between control and disqualified groups within each surgeon's group and not between surgeons. Statistical analysis was performed using SPSS software (version 20.0, IBM Corp.), Medcalc (version 15.11.4, Medcalc Software bvba), and Minitab software (version 18, Minitab, Inc.). The normality of all data samples was checked with the Shapiro-Wilk test. Data were expressed as means ± SD. The means of all variables were evaluated separately for each group using the Student *t* test for independent samples.

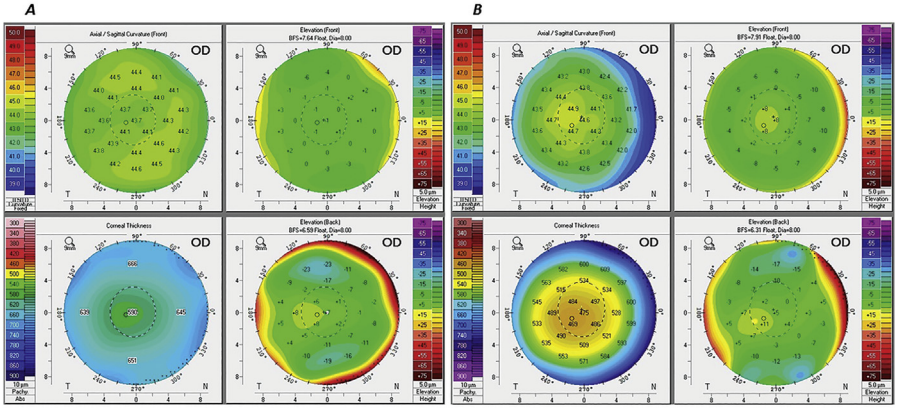

Figure 1. *A*: Example of tomography from a control group patient. The CDVA was 20/15 and MRSE error was −4.75 diopters (D). *B*: Example of tomography from a patient disqualified from LASIK. Note the decentered apex associated with a thin cornea (thinnest point = 468 μm) and anterior and posterior corneal elevation and steep features co-localizing with the thinnest point. The CDVA was 20/20 and MRSE error was −6.25 D (ABS = absolute scale; BFS = best fit sphere; CDVA = corrected distance visual acuity; LASIK = laser in situ keratomileusis; MRSE = manifest refraction spherical equivalent; Pachy = pachymetry).