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Multivariate model of refractive shift in Descemet-stripping automated endothelial keratoplasty

William J. Dupps Jr, MD, PhD, Ying Qian, MD, and David M. Meisler, MD

Cole Eye Institute (Dupps, Qian, Meisler) and Department of Biomedical Engineering (Dupps), Lerner Research Institute, Cleveland Clinic, Cleveland, Ohio, USA

Abstract

Purpose—To relate in situ graft shape in Descemet-stripping automated endothelial keratoplasty (DSAEK) to surgically induced refractive error.

Setting—Academic eye institute.

Methods—High frequency arc-scanning ultrasound was performed in 7 patients enrolled in a prospective of microkeratome-assisted endothelial keratoplasty approved by the Investigative Review Board. A region of interest spanning the horizontal meridian was defined for analysis of epithelial, host, graft, and total corneal thicknesses. Graft thickness profiles were fit by quadratic polynomials where the 2nd-order coefficients represent the posterior corneal curvature contributed by the graft. The curvature coefficient and central graft thickness were analyzed as predictors of induced refractive error.

Results—At final follow-up (mean 5.9 months $\pm$ 3.2 [SD]), 3 patients had a hyperopic shift (+2.50 diopters [D] each), 3 had insignificant (< 0.50 D) refractive shifts, and 1 had a myopic shift. In the group with hyperopic shift, a negative lens effect was predicted by positive curvature coefficients, representing grafts that were thinner centrally than peripherally (mean $+22.72 \mu\text{m}/\text{mm}^2$; range $+4.95$ to $+45.17 \mu\text{m}/\text{mm}^2$). In the group with minimal refractive shift, coefficients were less positive (mean $+7.28 \mu\text{m}/\text{mm}^2$; range $+2.01$ to $+13.82 \mu\text{m}/\text{mm}^2$). The patient with a myopic shift (-1.00 D) had the only negative curvature coefficient ($-0.64 \mu\text{m}/\text{mm}^2$). In a 2-predictor model of refractive shift, central graft thickness and the curvature coefficient together accounted for 86% of the variance in the refractive response to DSAEK ($P = .025$).

Conclusion—Nonuniform thickness profiles and variable central graft thicknesses contribute to refractive shift after DSAEK.

Descemet-stripping automated endothelial keratoplasty (DSAEK) with microkeratome-assisted procurement of the donor lenticule¹ has emerged as an important alternative to penetrating keratoplasty (PKP) in the treatment of corneal endothelial disease. Important advantages of DSAEK over PKP include rapid visual recovery, minimal induced spherical and astigmatic refractive error,² and avoidance of the mechanical instability of a 360-degree full-thickness corneal wound. Ongoing challenges in endothelial transplantation include graft

Corresponding author: William J. Dupps Jr, MD, PhD, Cole Eye Institute, Cleveland Clinic, 9500 Euclid Avenue/i-32, Cleveland, Ohio 44195, USA. E-mail: bjdupps@sbcglobal.net.

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dislocation³ and multifactorial endothelial cell loss⁴ that may be associated with trauma during donor preparation and insertion.

Although the reduced influence of DSAEK on refractive error is one of its primary advantages over PKP,² even small refractive shifts are important for purposes of patient counseling and intraocular lens selection in combined or staged cataract surgery and DSAEK.⁵ In DSAEK, a microkeratome is used to create a donor disk comprised of posterior stroma, Descemet membrane, and endothelium. The use of a microkeratome for graft preparation is expected to yield more consistent donor thicknesses and smoother interfaces than free-handed techniques.⁶ Nevertheless, donor lenticles prepared using a microkeratome are often visibly thicker in the periphery on slitlamp examination. In addition, most patients experience a hyperopic shift after DSAEK, a shift that has been anecdotally attributed to a differential graft-thickness pattern.^{1,2,4}

Commercially available tools capable of resolving lamellar corneal thicknesses have only recently become available. One such technique using very high-frequency arc-scanning ultrasound (US) of the anterior segment was introduced by Reinstein et al.⁷ and has been used to obtain high-precision measurements of epithelial, flap, and residual stromal thickness maps after laser in situ keratomileusis. We subsequently reported the use of high-frequency US to visualize and measure host and donor cornea thicknesses after DSAEK (Meisler DM, et al. IOVS 2006; 47:ARVO E-abstract 1355). The purpose of this study was to use very high-frequency US arc-scan imaging to characterize corneal host, epithelial, and donor thicknesses after DSAEK and to relate elements of graft shape to surgically induced refractive error.

Patients and Methods

A prospective interventional study of DSAEK was initiated at the Cole Eye Institute in March 2005 after approval by the Cleveland Clinic Institutional Review Board. All patients in the series were pseudophakic with endothelial dysfunction attributed to Fuchs endothelial corneal dystrophy and/or pseudophakic bullous keratopathy (PBK) except patient 2, who was referred with a chronic Descemet membrane detachment after phacoemulsification.

The donor lenticule for DSAEK was prepared as previously described^{1,4} by placing the donor cornea on an artificial anterior chamber pressurized with air from a 10 cc syringe, and passing a 300 µm LSK (n = 4) or 300 µm CB microkeratome (n = 3) (both Moria) under irrigation to remove the anterior cornea. The donor tissue was removed from the artificial anterior chamber, inverted in a Barron disposable corneal punch (Katena), trephined to 8.5 mm diameter, and then folded and inserted into the anterior chamber using a Utrata forceps. Positioning and unfolding of the graft was achieved with a bent 30-gauge needle on a 3 cc air-filled syringe.⁸

The best spectacle corrected visual acuity, central corneal thickness by US pachymetry, and manifest refraction were performed at all analyzed visits. Corneal topography (Humphrey Atlas CTS, Carl Zeiss Meditec, Inc.) was attempted in all patients preoperatively and at each follow-up visit reported in the Results section. Endothelial cell density measurements were obtained during the same visit as Artemis scans (Noncon Robo SP6000, Konan Medical Corp.) and were reported with clinical data not directly pertinent to the current analyses in a previously published clinical series.⁴

Very high-frequency corneal US imaging (Artemis, UltraLink LLC) was performed in 7 patients at 9 postoperative visits spanning from 2 weeks to 12 months using a dedicated lithium niobate corneal transducer housed in a water bath. All available US examinations were included in the study. Only the latest examination for each of the 7 patients was used in the regression model described below. Each examination consisted of 6 meridional arc scans separated by 30 degrees of rotation. Five to 10 scans of each meridian were obtained with the pupil centered

as completely as possible on the video reticule; 1 scan from each set was selected for the composite map based on adequate centration and a high-contrast interface. Graft–host interfaces were manually seeded through the ArtPro v1.50 software interface (UltraLink LLC) by the same investigator (W.J.D.) to enhance edge detection and facilitate accurate automated interface digitization. The same software was used to construct color maps of total corneal, epithelial, host, and donor thickness profiles using proprietary interpolant algorithms. Numerical thickness arrays for the grafts were exported to Excel (version 10, Microsoft Corp.) with a coordinate system centered ($x = 0$, $y = 0$) on the pupil. A central rectangular region of interest 2.0 mm in height and spanning 40 0.1 mm intervals along the horizontal meridian (4.0 mm total) was defined for each graft-thickness profile analysis. This horizontal region was thought to most reliably represent the optically significant portion of the cornea in these patients, whose narrow vertical interpalpebral fissures frequently interfered with the acquisition of peripheral vertical meridian data.

Central graft thickness was taken from the value at the central point of the coordinate system. Then, each horizontal thickness profile was fit by a quadratic regression equation using Minitab (v. 14.2, Minitab Inc.). The coefficient of the 2nd-order polynomial was extracted to characterize the spatial rate of change in graft thickness in $\mu\text{m}/(\text{horizontal distance from the center of the Artemis image in mm}^2)$, which relates to the posterior corneal curvature contributed by the lenticule due to its nonuniform thickness. This coefficient, along with central total corneal thickness and central donor thickness, were investigated in best-subsets regressions as predictors of DSAEK-induced refractive shift. Preoperative and postoperative spherical equivalent (SE) refractive errors obtained by manifest refraction was calculated for the horizontal meridian in each patient using optical cross transformations to ensure correspondence with the horizontal rectangular region of interest analyzed by VHF US.

Results

Ultrasound images showed the anterior and posterior corneal borders and clearly demarcated the graft–host and epithelial–stromal interfaces. Figure 1 shows an example of a single geometrically corrected meridian scan with the associated anterior segment slitlamp photograph. The mean follow-up time was $5.9 \text{ months} \pm 3.0 \text{ (SD)}$ (range 2 to 12 months). Figure 2 shows the thickness data displayed on color maps; the values at the center of each scan are shown in Table 1. Across the central $4.0 \text{ mm} \times 2.0 \text{ mm}$ region of interest (shown in Figure 2), donor lenticules were thicker in the periphery in 5 of 7 patients. Across 7 examinations in 7 patients obtained 2 or more months after DSAEK, the mean donor lenticule thickness was $173 \pm 24 \mu\text{m}$; the mean host corneal thickness, $530 \pm 63 \mu\text{m}$; and the mean epithelial thickness, $44 \pm 7 \mu\text{m}$. Graft and host thicknesses decreased markedly after the 2-week examination in 2 patients for whom serial measurements were available. Mean central graft thicknesses derived from Artemis images across all postoperative visits ranged from 137 to $407 \mu\text{m}$; the thickest grafts were measured at the 2-week visits. Total central corneal thickness by Artemis showed a high correlation with 8 available same-visit US pachymetry values averaged from 3 replicate measures ($R^2 = 90.2\%$, $P < .001$) (Figure 3).

The mean SE refractive error shifted toward hyperopia (mean $+1.13 \pm 1.89$ diopters [D], range -1.00 to $+3.88$ D) after DSAEK (Table 2). Refractive shifts in the horizontal meridian ranged from -1.00 to $+2.50$ D. Patients were divided into 3 groups based on surgically induced refractive change: hyperopic, neutral, and myopic. In the group with the largest hyperopic shift ($+2.50$ D; $n = 3$ at 6 months), a negative lens effect was predicted by the 2nd-order curvature coefficient (mean $+22.72 \mu\text{m}/\text{mm}^2$; range $+4.95$ to $+45.17 \mu\text{m}/\text{mm}^2$) and unequivocal U-shaped thickness plots (Figure 4). In the neutral group with minimal refractive shifts ($+0.50$ to -0.50 D; $n = 3$), the coefficients were less positive on average (mean $+7.28 \mu\text{m}/\text{mm}^2$; range

+2.01 to +13.82 $\mu\text{m}/\text{mm}^2$). The lone patient who experienced a myopic shift (-1.00 D) had the only negative (myopically biased) curvature coefficient ($-0.643 \mu\text{m}/\text{mm}^2$).

In a single-predictor model of DSAEK-induced refractive shift, the graft curvature coefficient from lenticule thickness profiles explained 41% of the variance but was not significant by analysis of variance (ANOVA) ($R^2 = 41\%$, $P = .12$). Adding total central corneal thickness to the model did not improve its performance. Graft central thickness and total central corneal thickness performed poorly as lone predictors of refractive shift ($R^2 = 12\%$ and $P = .46$ and $R^2 = 0.02\%$ and $P = .92$, respectively). A 2-predictor model containing the curvature coefficient for the graft-thickness profile and the graft central thickness was significant in all coefficients ($P < .025$, ANOVA) and explained 86% of the variance in refractive shift in this series of patients. A plot of actual refractive shift versus refractive shift predicted by the model is shown in Figure 5. The regression equation for refractive change in the horizontal meridian is

$$\text{Refractive shift (D)} = -8.62 + (0.095 \times \text{curvature coefficient}) + (0.048 \times \text{graft central thickness})$$

where P values for each term were 0.025, 0.01, and 0.023, respectively. Variance inflation factors of 1.2 for each predictor suggest that each explains non-redundant aspects of the refractive behavior observed in this series (ie, graft central thickness and the graft curvature coefficient are not collinear).

An analysis of the sensitivity of refractive shift to the model predictors was performed by alternately fixing 1 variable in the regression equation above and varying the other throughout the range of values encountered in this series. Variation in the curvature coefficient from its minimum of $-0.64 \mu\text{m}/\text{mm}^2$ to its maximum of $+45.17 \mu\text{m}/\text{mm}^2$ resulted in a potential difference in induced refractive error shift of 4.25 D. The model was slightly less sensitive to graft central thickness across the range of 144 to 221 μm , which resulted in a 3.70 D range of refractive influence. Corneal topography was measurable preoperatively in only 4 of 7 patients. The mean simulated K value in these patients was 43.45 ± 1.84 D preoperatively and 44.72 ± 1.19 D at the last analyzed follow-up (at least 6 weeks after suture removal), with an insignificant trend toward increased keratometric power after DSAEK (mean 1.27 ± 0.99 D) ($P = .08$). All measurements were obtained at least 6 weeks after suture removal.

Discussion

Descemet-stripping automated endothelial keratoplasty is gaining prominence as a surgical approach to treating corneal endothelial diseases such as Fuchs endothelial dystrophy and pseudophakic or aphakic bullous keratopathy. Patients typically enjoy more rapid visual rehabilitation than historically achieved with PKP with less profound ametropic and astigmatic effects.^{2,9} In this study, we confirm a tendency toward hyperopic shift after DSAEK that, although mild compared to refractive instability after PKP, remains an important consideration, particularly in combined or staged management of endothelial disease and cataract.

Our primary objective was to use arc-scanning US to analyze donor and recipient corneal thicknesses after DSAEK and test the hypothesis that elements of the in situ donor lenticule shape contribute directly to DSAEK-induced refractive shift. Donor lenticules produced with the LSK and CB microkeratomes favored nonuniform thickness profiles that tended to be thinner centrally than peripherally. This shape, when added to the posterior host corneal surface, reduces the radius of curvature of the posterior corneal surface, increases the negative power of this surface (F_2), and reduces the effective corneal power (F_E) according to the thick-lens equation¹⁰

$$F_E = F_1 + F_2 - \frac{t}{n_c} F_1 F_2$$

where F_1 is the power of the anterior cornea in diopters, t is the thickness of the total cornea at its vertex (epithelium, host stroma, and graft thickness) in meters, and n_c is the refractive index of the cornea. The net effect would be a reduction in effective power or a clinical shift toward hyperopia if all other variables remained constant.

The effect of graft-thickness profile on posterior corneal surface power F_2 was approximated by fitting the graft-thickness profile to a quadratic polynomial and extracting the 2nd-order polynomial from the equation, as shown in Figure 4. This coefficient has dimensions of microns of graft thickness per millimeter squared of graft breadth and captures information about the rate of change of graft thickness as a function of the horizontal graft coordinate. In other words, this coefficient characterizes the parabolic shape of the graft and quantifies the curvature added to the posterior cornea as a result of the graft's shape. This presumption is supported by the segregation of high positive, low positive, and negative graft curvature coefficients into clinical groups exhibiting hyperopic, neutral, and myopic responses to surgery, respectively.

Linear regression analyses to identify the major mechanisms of DSAEK-induced refractive shift pointed to the graft curvature coefficient and the central graft thickness as 2 key variables in explaining this phenomenon. Jointly, these predictors accounted for all but 14% of the refractive response across all analyzed visits. An explanation of these effects is outlined in Figure 6. The relationship between graft curvature and refractive shift was consistent with effects predicted by the thick-lens equation: Hyperopia is favored when the graft thickens toward the periphery because the radius of curvature of the posterior surface is reduced (Figure 6, A).

The relationship between refractive shift and central graft thickness was particularly interesting. A thick central graft favored hyperopic shift in this series despite predictions by a thick-lens model that thicker central grafts should favor slight myopic shifts (see Appendix). A thicker graft, even if uniform in thickness, will tend to decrease the posterior radius of curvature once in position, as shown in Figure 6, B. This occurs because the graft assumes a curved configuration on the host-stromal surface relative to paraxial light rays and because the best-fit sphere of this new surface must be smaller than that of the preoperative posterior surface. Central rays encounter the graft at a point where curvature is negligible and also traverse the shortest path length through the graft tissue. As distance increases from the central axis, parallel rays of light encounter the graft at increasingly oblique angles of incidence, and because the graft is curved, they encounter a longer path length through the graft. Therefore, even a graft with uniform thickness as measured in situ with an arc-scanning technique will act as a negative lens.

We suspect this phenomenon explains the apparent contradiction between the multivariate model and the thick-lens equation. The thick-lens equation predicts a myopic shift due to the increased path length of light in the cornea and treats thickness, t , as independent of posterior curvature. In practice, however, graft thickness produces simultaneous changes in posterior curvature according to the mechanism in Figure 6, B, even in the absence of a differential graft-thickness profile. The multivariate model captures these independent effects statistically. The magnitude of the effect shown in Figure 6, B, was similar to that of graft-thickness profile based on a sensitivity analysis of the multivariate model, at least over the range of values encountered in this small series. The curvature coefficient consistently explained a greater portion of the refractive response in single-predictor models. The relative insensitivity of a thick-lens corneal model to the total central corneal thickness, t , is consistent with our finding

that total central corneal thickness, a variable with little optical leverage in the thick-lens equation, was also of little empirical value in predicting refractive shift apart from the specific morphological features of the donor lenticule.

It is likely that the shape of the graft in situ is not only influenced by surgical preparation but also by its response to the intraocular environment after insertion. Post hoc analyses of endothelial cell counts obtained with a Konan specular microscope, as previously described,⁴ at the time of each Artemis measurement showed no correlation between cell counts and graft central thickness ($r = 0.42$, $P = .35$) or between cell count and curvature coefficient ($r = -0.21$, $P = .65$). Accordingly, we have no evidence that endothelial cell function directly influences either variable in a way that affects refractive error. However, it is possible that differential peripheral thickening of the graft results from direct, continuous exposure of the hydrophilic peripheral stromal matrix to aqueous and that this relative peripheral hydration would augment the hyperopic effect of the lenticule.

Even though the model showed excellent performance and explained the most of the refractive response, additional variables that can influence refractive outcomes after DSAEK should be considered. Although preoperative keratometry and topography can be unreliable in patients with advanced endothelial disease and associated epithelial changes, anterior corneal shape could contribute to refractive shift if altered significantly by DSAEK. Topographic changes were insignificant in larger series presented previously.^{2,4} In this series, topography slightly favored myopic changes that certainly cannot account for the strong net tendency toward hyperopic shift. It is also possible that postoperative resolution of the disproportionate central corneal edema present in some Fuchs and PBK patients favor a decrease in radius of curvature of the host posterior surface that adds to the minus lens effect of the donor lenticule.

In summary, we used arc-scanning high-frequency US and multivariate regression to show a strong relationship between refractive shift in DSAEK and graft geometry. By improving our understanding of these relationships, we may begin to optimize graft geometry through technique modification, microkeratome selection or redesign, or customized femtosecond laser specification of graft shape. We observed with serial pachymetry that the corneal tissue on the Moria artificial anterior chamber can thin rapidly under high chamber pressures (unpublished data). Modifications of DSAEK technique, such as rigorously controlling the pressure of the artificial anterior chamber during the microkeratome pass or measuring the central thickness of the mounted donor cornea, may help reduce the variability of graft thickness and shape by standardizing stromal compressive forces and allowing more informed selection of microkeratome heads with appropriate cutting depths. As an example of this approach, the 2-predictor model presented in this study predicts that a 180- μ m graft of uniform thickness in situ would have best favored refractive neutrality of DSAEK. Alternatively, a graft with a profile that thins toward the periphery could be used to conserve posterior radius of curvature and offset a tendency toward hyperopic shift, but this would add complexity to the tissue preparation and would not eliminate uncertainty introduced by the postoperative changes in the host and donor lenticule outlined above. While the primary goal of DSAEK remains restoration of an optically clear cornea, advances in femtosecond laser delivery coupled with insight into the refractive effects of graft geometry could potentially be combined in efforts to minimize induced refractive error or to target a desired refractive result.

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Appendix

Following is the thick-lens equation with the Gullstrand schematic eye¹⁰ applied to thinnest and thickest central graft dimensions to explore the theoretical optical influence of increasing central graft thickness on equivalent corneal power, F_E , with no change in posterior surface curvature:

$$F_E = F_1 + F_2 - \frac{t}{n_c} F_1 F_2$$

$$\text{where } F_1 = \frac{n_c - 1}{r_1} \text{ and } F_2 = \frac{n_{aq} - n_c}{r_2}$$

and r_1 is the radius of curvature of anterior cornea (7.8 mm), r_2 is the radius of curvature of posterior cornea (6.8 mm), n_c is the refractive index of cornea (1.375), n_{aq} is the refractive index of aqueous (1.335), and t is the vertex thickness of the cornea (0.0005 m).

Case of thinnest graft: $48.08 + (-5.88) - [(0.000550 + 0.000144)/1.375](48.08)(-5.88) = 42.34$ D

Case of thickest graft: $48.08 + (-5.88) - [(0.000550 + 0.000221)/1.375](48.08)(-5.88) = 42.36$ D

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Biography

Figure 1.
Appearance of host cornea and donor lenticule by (A) slitlamp biomicroscopy and (B) very high frequency arc-scanning US with the Artemis system.

Figure 2.

ArtPro software representations of corneal thicknesses obtained by 6-meridian Artemis scans of patient 1 6 months after DSAEK. Unit of color scale at right is μm . At the far periphery of each scan, there is an abrupt increase in thickness in total corneal thickness, epithelial thickness, and donor thickness and a sharp decrease in host thickness, attributed to software artifact in recognizing the lateral termination of the graft. Within the central and paracentral zones, subtle transitions to warmer colors toward the periphery represent increases in thickness. The lower right map shows donor thickness with the $4.0\text{ mm} \times 2.0\text{ mm}$ region of interest from which horizontal graft profiles were measured.

Figure 3.
Correlation between central US pachymetry and total central corneal thickness by Artemis image analysis on same-day examinations.

Figure 4.

The DSAEK graft thickness (μm) averaged vertically across a 2.0 mm high rectangular region of interest spanning 4.0 mm of the horizontal meridian in patient 1. The graft is clearly thicker in the periphery. The quadratic regression equation fit to the profile is shown in the figure. The constant ($173.7 \mu\text{m}$) represents the minimum of the function, and the 1st-order term characterizes the very weak linear portion of the function. (Note the small coefficient magnitude.) The positive 2nd-order polynomial coefficient ($+18.03$) reflects the parabolic shape of the graft and reflects negative optical power the graft contributes at the posterior corneal surface. This patient had a 2.50 D hyperopic shift.

Figure 5. Correlation of actual DSAEK-induced refractive shift and refractive shift predicted by a 2-predictor model incorporating (1) the 2nd-order coefficient representing graft curvature and (2) central graft thickness ($R^2 = 86\%$, $P = .02$).

Figure 6. Schematic illustration of the hyperopic contributions of (A) a nonuniform graft-thickness profile and (B) the absolute thickness of the graft irrespective of uniformity. In both cases, graft morphology results in a smaller posterior radius of curvature after surgery ($r_{\text{postop}} < r_{\text{preop}}$).

Central corneal point thicknesses measured with very-high-frequency are-scanning US after DSAEK. Patients are grouped by surgically induced refractive shift. Host stromal thicknesses are in the range of those in normal corneas, while total corneal thicknesses reflect the added thickness of the transplanted tissue.

Table 1

Refractive Group	Microkeratome	Postop Visit	Thickness (µm)			Total	
			Epithelium	Host	Donor		
Hyperopic shift	Patient 1	LSK	2 wk	41	556	192	738
	Patient 1	LSK	6 mo	34	533	176	707
	Patient 2	CB	6 mo	54	563	221	755
	Patient 3	LSK	6 mo	41	510	144	649
Neutral	Patient 4	LSK	2 wk	42	527	275	805
	Patient 4	LSK	1 y	40	462	177	643
	Patient 5	CB	2 mo	44	608	170	771
	Patient 6	CB	3 mo	49	448	159	605
Myopic shift	Patient 7	LSK	6 mo	48	607	161	768

Table 2

Change induced by DSAEK in the manifest refractive error in the horizontal meridian in categorized by refractive shift. The 2nd-order curvature coefficient is derived from least-squares fit of donor thickness profiles and reflects the bulk curvature of the profile attributable to the donor tissue thickness profile. A positive value indicates increased posterior corneal curvature (decreased radius of curvature) and favors hyperopic shift. R^2 values indicate the goodness of fit for the regression model from which the 2nd-order coefficient was derived.

Refractive Group	Microkeratome	Preop MRx @ 180° (D)	Postop MRx @ 180° (D)	Preop MRx @ 180° (D) (Exam)	Curvature Coefficient	R^2 of Fit (%)
Hyperopic shift						
Patient 1	LSK	-2.00	+0.50	+2.50 (6 mo)	+18.03	89
Patient 2	CB	-1.75	+0.75	+2.50 (6 mo)	+4.95	59
Patient 3	LSK	-1.00	+1.50	+2.50 (6 mo)	+45.17	53
Neutral						
Patient 4	LSK	-0.50	-0.25	+0.25 (1 yr)	+13.82	65
Patient 5	CB	+1.00	+1.25	-0.25 (2 mo)	+6.00	85
Patient 6	CB	+0.50	+0.08	-0.42 (3 mo)	+2.01	70
Myopic shift						
Patient 7	LSK	+1.25	+0.25	-1.00 (6 mo)	-0.64	12

MRx = manifest refractive error