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ORIGINAL ARTICLE

Repeatability of Corneal Topography Measurement in Keratoconus with the TMS-1

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ABSTRACT: *Purpose.* The purpose of this study was to report the test–retest variability of simulated indices derived from the TMS-1 topography instrument (Tomey Technology, Waltham, MA) in keratoconus subjects enrolled in the Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Study. *Methods.* Four images were taken at an initial visit and at a repeat visit several weeks later. From these images, 17 indices were simulated from published formulas. Mixed-model analysis was used on test–retest data from the TMS-1 videokeratography instrument during the baseline year. This analysis yields estimates of within- and between-visit variability. *Results.* Repeatability analysis revealed that within-visit standard errors were 1.0 to 5.9 times greater in keratoconus eyes than in normal controls when two images were analyzed from each visit. These values changed only slightly when more images were used. The ratio of between-visit standard errors of the indices were nearly equally greater than normal controls for (0.9–4.6 and 0.9–4.3) two images per eye and all images per eye, respectively. *Conclusions.* These results suggest that the repeatability of simulated indices derived from TMS-1 topography in keratoconus subjects is poorer than in normal controls. (Optom Vis Sci 2005;82:405–415)

Key Words: corneal topography, videokeratography, keratoconus, keratometry, CLEK Study, test–retest repeatability, topographic indices, TMS-1

Keratoconus is a noninflammatory disorder characterized by progressive thinning and steepening of the central and paracentral cornea.[1, 2] As corneal curvature increases, there is an associated decrease in visual performance that ranges from mild to severe, depending on the degree of disease severity.[3–5]

The Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Study is an observational study of 1209 keratoconus subjects at 16 clinical centers in the United States. Its goals are to characterize the progression of keratoconus, to determine risk factors associated with its progression, and to assess its impact on vision-specific quality of life.[6] Patients were recruited and enrolled between June 1, 1995, and June 29, 1996.

Videokeratography data were collected on all study subjects. Approximately half of the subjects' baseline topography data was collected using the TMS-1 instrument (Tomey Technology, Waltham, MA). The remaining subjects had their baseline corneal topography measured using one of three other instruments: the EyeSys Corneal Analyzer (model II or System 2000; Houston, TX), the Alcon EH290 (Ft. Worth, TX), or the Humphrey Mastervue (San Leandro, CA). Of the four instruments, the TMS-1 was used on the largest number of subjects. This article reports only the analysis of data collected using the TMS-1 instrument.

Other clinical measures assessed in subjects with keratoconus have demonstrated poorer test–retest variability when compared with normal subjects.[7, 8] Of particular note, both keratometry and manifest refraction are more variable under retest conditions than the same measurements taken from normal subjects. It is reasonable to assume that reflection-based videokeratography would suf-

fer the same reduction in repeatability in eyes with keratoconus as these other tests.

It is the intent of the investigators to look at a variety of features of corneal topography, including several indices to characterize the disease, and the correlation of these findings with other clinical variables. For topographic data to be of quantitative value to the overall study goals, an accurate sense of the repeatability within visits and between visits of these measurements in keratoconus subjects with a wide range of disease severity is needed. The purpose of this study is to evaluate the intravisit and intervisit repeatability of topography measurements made from the TMS-1 in keratoconus and compare these with a normal subject group.

PATIENTS AND METHODS

Patients

To exclude patients with irregular corneal astigmatism resulting from other, nonkeratoconic causes, a strict definition of keratoconus was used in the CLEK Study. At the time of enrollment, subjects had to be 1) aged ≥12 years; 2) have an irregular cornea, determined by distortion of keratometric mires and/or the retinoscopic reflex and/or the "red" reflex on direct ophthalmoscopy; 3) have at least one of the following biomicroscopic signs of keratoconus: Vogt's striae, Fleischer's ring of ≥2 mm arc, or corneal scarring characteristic of keratoconus; and 4) anticipate remaining in the area for 3 or more years. Patients with corneal transplants, cataracts, intraocular lenses, macular disease, or optic nerve disease (other than mild glaucoma) in both eyes were not eligible. All enrolled patients provided informed consent according to the protocol of their clinic's Institutional Review Board.

During the recruitment period, patients were randomly selected for inclusion in a retest study by using their CLEK Study patient identification numbers. The coordinating center notified each clinic which patients to recall for a repeat visit after their baseline visit. This method of subject identification was used to avoid bias in the collection of repeatability data. If a patient declined a repeat visit, additional subjects were chosen by the coordinating center until each clinic completed repeat visit examinations on approximately 10% of their local sample.

All examination procedures were performed by clinicians, technicians, or both who had completed training and certification before examining study patients. The protocol allowed any certified examiner, whether the same or different from the baseline examiner, to perform repeat visit measurements to represent realistic clinical testing. Examiners performing the repeat visit were masked to the data collected at the baseline visit.

One hundred thirty-four subjects were randomly chosen to have repeat examinations performed, of which 73 were examined with the TMS-1 topography instrument. Of these, 11 subjects were excluded for the analyses because they did not have either baseline or retest corneal topography data collected with the TMS-1. Any eye that had undergone penetrating keratoplasty was excluded from the sample. No eyes within the sample had experienced corneal hydrops within the past year. Seven subjects whose contact lens base curve had changed by 0.1 mm or more between baseline and retest visits were excluded from analyses, because corneal molding from a change in the lens could impact the topography repeatability. Including such subjects would worsen the estimate of the repeatability of corneal topography measurements. These exclusions reduced the sample to 55 patients. The demographics of the entire CLEK sample have been described in detail elsewhere.[6, 7, 9]

Controls

Twenty-eight normal, noncontact lens-wearing adult subjects were used for a comparison group. These subjects have been described previously.[10, 11]

Data Collection

At each visit to the eight participating clinics using TMS-1, four images for each eye were to be acquired using this videokeratography instrument (software version 1.61). Instrument calibration was checked weekly following the manufacturer's instructions. Before each image was taken, the instrument was manually refocused. The focusing process followed the manufacturer's recommendations. All investigators taking TMS-1 images were trained and certified on the use of this device. The detailed nature of these instructions can be found in the CLEK Operations Manual.[9] If the examiner determined that the image quality was poor, the image was retaken until the four best images were acquired. The unprocessed video images and instrument-specific calibration files were mailed on floppy disks to the CLEK Topography Reading Center (CTRC) at the Department of Ophthalmology & Visual Sciences, University of Illinois at Chicago.

At the CTRC, the images were manually processed by trained staff to yield the usual set of TMS-1 files (.DIO, .RAD, and so on). Simulated indices were calculated for TMS statistics,[12–15] Rabinowitz indices,[16] and Maloney indices.[17] Additionally, the dioptric magnitude of a 1-mm area encompassing the steepest portion of the cone, part of a new index, the CLMI, was included.[18] Table 1 defines the simulated indices and statistics used in this study.

TABLE 1.
Indices and statistics used[12, 13, 15–17, 43]

Index Label	Name
sKVAL_a	Keratometry Value Average central corneal curvature in diopters
sSIMKS_a	Simulated keratometry-steep meridian
sSIMKF_a	Simulated keratometry-flat meridian
sCYL_a	Cylinder
sISVAL_a	Inferior-superior value
sACP_a	Average corneal power
sSDP_a	Standard deviation of corneal power
sDSI_a	Differential sector index
sOSI_a	Opposite sector index
sSAI_a	Surface asymmetry index
sIAI_a	Irregular astigmatism index
sSRI_a	Surface regularity index
sTI_a	Total irregularity
sBFS_a	Best fit sphere
sBFC_a	Best fit cylinder
Mag_t	Magnitude of power (magnitude component of CLMI)

s, simulated; _a, index calculated from axial curvature data; _t, index calculated from tangential curvature (meridional) data.

TABLE 2.
Test-retest variability for the first two images for one randomly selected non-grafted keratoconic eye and right eyes of normal controls.

Variable	Group	Within visit SE	Between visit			
			Est. diff.	SE	95% CI of diff.	
					Lower	Upper
sKVAL_a	Keratoconus	1.0578	−0.0622	0.1466	−0.3509	0.2266
	Normal	0.2065	0.0229	0.0390	−0.0540	0.0998
sSIMKS_a	Keratoconus	0.8083	0.1731	0.1120	−0.0476	0.3938
	Normal	0.3348	0.0629	0.0633	−0.0617	0.1876
sSIMKF_a	Keratoconus	1.2178	−0.1092	0.1686	−0.4414	0.2230
	Normal	0.2060	−0.0109	0.0389	−0.0875	0.0658
sCYL_a	Keratoconus	1.0596	0.2925	0.1467	0.0035	0.5816
	Normal	0.2636	0.0738	0.0498	−0.0243	0.1719
sISVAL_a	Keratoconus	1.5951	−0.3603	0.2263	−0.8062	0.0857
	Normal	0.5256	−0.2375	0.1005	−0.4355	−0.0395
sACP_a	Keratoconus	0.9322	−0.0603	0.1292	−0.3148	0.1942
	Normal	0.2374	0.0261	0.0449	−0.0623	0.1145
sSDP_a	Keratoconus	0.3990	−0.0343	0.0553	−0.1431	0.0746
	Normal	0.1154	0.0087	0.0218	−0.0342	0.0517
sDSI_a	Keratoconus	1.3089	−0.1621	0.1811	−0.5190	0.1947
	Normal	0.2540	0.0790	0.0480	−0.0155	0.1736
sOSI_a	Keratoconus	1.4224	−0.3535	0.1968	−0.7412	0.0342
	Normal	0.2731	0.0215	0.0516	−0.0802	0.1231
sCSI_a	Keratoconus	0.7009	−0.1577	0.0970	−0.3488	0.0334
	Normal	0.1338	−0.0107	0.0253	−0.0606	0.0391
sSAI_a	Keratoconus	0.3420	−0.0870	0.0473	−0.1803	0.0062
	Normal	0.0579	0.0084	0.0109	−0.0132	0.0300
sIAI_a	Keratoconus	0.0390	0.0016	0.0054	−0.0090	0.0123
	Normal	0.0132	0.0000	0.0025	−0.0049	0.0049
sSRI_a	Keratoconus	0.2160	−0.0594	0.0299	−0.1183	−0.0006
	Normal	0.1888	0.0090	0.0357	−0.0613	0.0793
sTI_a	Keratoconus	0.4142	−0.0406	0.0574	−0.1536	0.0724
	Normal	0.1802	0.0528	0.0341	−0.0143	0.1199
sBFS_a	Keratoconus	0.9013	0.0083	0.1249	−0.2377	0.2544
	Normal	0.2565	0.0442	0.0485	−0.0512	0.1397
sBFC_a	Keratoconus	1.0624	0.3401	0.1472	0.0502	0.6300
	Normal	0.2251	0.0644	0.0425	−0.0194	0.1482
MAG_t	Keratoconus	1.6506	−0.3242	0.2284	−0.7740	0.1257
	Normal	0.4652	0.0440	0.0879	−0.1292	0.2172

Data Editing

With the normal processing procedure, topography maps are subject to a variety of artifacts, including improper ring detection, ring crossover, and unusual gaps, leading to large changes in dioptric power over very small intervals. These are caused by eyelash and lid artifacts, an irregular tear film, and/or corneal scarring. The commitment to a robust analysis of TMS-1 repeatability provides for two alternatives: either discard all maps with suspect regions or attempt to remove aberrant data from those regions. In a clinical study setting, the scientific cost of eliminating maps is relatively high, in that one would risk the introduction of sampling bias through a reduction of the data pool. Furthermore, it is likely that maps from more severely diseased eyes would have a higher chance of being discarded for artifact reasons, thus biasing the sample. Selective removal of artifacts would permit some problematic maps to be maintained within the dataset. The TMS-1 does not contain any internal editing features, so a custom-designed method for selective data removal was needed. Zadnik and colleagues developed a method for doing this that we have modified and improved on.[11] A detailed description of the process and the rationale for the data-editing protocol used in this analysis, and the quality grading scheme used to determine which maps were included in the analysis can be found in the Appendix.

Test–Retest Analysis

Mixed-model analysis was used for the analysis of this test–retest data to account for the correlation of index values obtained within a visit from an eye and for the correlation of mean index values obtained at two different visits on a single eye.

Pilot work, not presented here, suggested that within-visit variances would be larger than between-visit variances, prompting re-

TABLE 3.
Test-retest variability for all images from one randomly selected non-grafted keratoconic eye and right eyes of normal controls.

Variable	Group	Within visit SE	Between visit			
			Est. diff.	SE	95% CI of diff.	
					Lower	Upper
sKVAL_a	Keratoconus	0.9181	−0.0940	0.0936	−0.2778	0.0898
	Normal	0.1985	0.0298	0.0265	−0.0223	0.0820
sSIMKS_a	Keratoconus	0.7851	0.0306	0.0800	−0.1266	0.1878
	Normal	0.2756	0.0532	0.0368	−0.0192	0.1255
sSIMKF_a	Keratoconus	1.0076	−0.1377	0.1026	−0.3394	0.0639
	Normal	0.2029	0.0080	0.0271	−0.0453	0.0613
sCYL_a	Keratoconus	0.9528	0.1729	0.0971	−0.0177	0.3636
	Normal	0.1929	0.0452	0.0258	−0.0054	0.0958
sISVAL_a	Keratoconus	1.3919	−0.0812	0.1435	−0.3632	0.2008
	Normal	0.4259	−0.1419	0.0572	−0.2543	−0.0296
sACP_a	Keratoconus	0.8073	−0.0987	0.0823	−0.2603	0.0629
	Normal	0.2170	0.0385	0.0290	−0.0185	0.0954
sSDP_a	Keratoconus	0.3604	−0.0379	0.0367	−0.1100	0.0343
	Normal	0.0969	0.0018	0.0130	−0.0236	0.0272
sDSI_a	Keratoconus	1.1050	−0.0986	0.1125	−0.3197	0.1225
	Normal	0.2092	0.0539	0.0280	−0.0010	0.1088
sOSI_a	Keratoconus	1.1878	−0.2436	0.1210	−0.4812	−0.0060
	Normal	0.2393	0.0069	0.0320	−0.0559	0.0697
sCSI_a	Keratoconus	0.5923	−0.1284	0.0603	−0.2469	−0.0099
	Normal	0.1280	−0.0117	0.0171	−0.0453	0.0219
sSAI_a	Keratoconus	0.3062	−0.0604	0.0312	−0.1217	0.0008
	Normal	0.0503	0.0044	0.0067	−0.0088	0.0176
sIAI_a	Keratoconus	0.0380	0.0048	0.0039	−0.0028	0.0124
	Normal	0.0112	−0.0005	0.0015	−0.0035	0.0024
sSRI_a	Keratoconus	0.1923	−0.0481	0.0196	−0.0866	−0.0096
	Normal	0.1704	0.0435	0.0228	−0.0012	0.0883
sTI_a	Keratoconus	0.3985	−0.0262	0.0406	−0.1060	0.0535
	Normal	0.1411	0.0302	0.0189	−0.0068	0.0672
sBFS_a	Keratoconus	0.8210	−0.0794	0.0837	−0.2438	0.0849
	Normal	0.2285	0.0464	0.0305	−0.0136	0.1064
sBFC_a	Keratoconus	0.9996	0.2224	0.1018	0.0223	0.4224
	Normal	0.1728	0.0291	0.0231	−0.0162	0.0745
MAG_t	Keratoconus	1.4404	−0.2107	0.1467	−0.4988	0.0774
	Normal	0.3825	0.0180	0.0511	−0.0825	0.1184

test analyses based on varied numbers of maps collected from each subject. Two parallel analyses were performed to explore the performance of using only two images per visit per eye (the "two images" protocol) versus using up to four images per visit per eye (the "all available images" protocol). The intent was to explore the benefit of increasing the number of images collected for the purposes of obtaining more stable estimates of visit-specific indices.

RESULTS

The interval between baseline and repeated visits for keratoconus subjects was 91.5 ± 53.4 d (mean ± standard deviation), with a median of 73 d. The recommended interval was 6 weeks for keratoconus subjects; however, emphasis was placed on examining the randomly selected subjects even if their 6-week time interval had elapsed. The interval between visits for normal subjects was 7.11 ± 0.83 d, with a median of 7 days. The recommended interval for the referenced historical normal group was 7 days.

Test–Retest Analysis

The within-visit variability is the residual standard error of the visit mean, computed for each treatment group as the square root of the group-specific residual variance component from the mixed-model analysis. The between-visit variability is the standard error of the difference in the visit means computed with the mixed-model methods. Table 2 displays those standard errors, the estimated mean difference (first visit–second visit), and 95% confidence intervals for the 17 indices calculated for one randomly selected eye of nongrafted keratoconus subjects and the right eyes of normal subjects for the first two images taken with the TMS-1. The within-visit standard errors typically were two to five times

TABLE 4.
Ratio of keratoconus to normal standard errors.

Variable	Ratio, Keratoconus/Normal			
	Within SE		Between SE	
	All	Two	All	Two
sKVAL_a	4.6	5.1	3.5	3.8
sSIMKS_a	2.8	2.4	2.2	1.8
sSIMKF_a	5.0	5.9	3.8	4.3
sCYL_a	4.9	4.0	3.8	2.9
sISVAL_a	3.3	3.0	2.5	2.3
sACP_a	3.7	3.9	2.8	2.9
sSDP_a	3.7	3.5	2.8	2.5
sDSI_a	5.3	5.2	4.0	3.8
sOSI_a	5.0	5.2	3.8	3.8
sCSI_a	4.6	5.2	3.5	3.8
sSAI_a	6.1	5.9	4.6	4.3
sIAI_a	3.4	3.0	2.6	2.2
sSRI_a	1.1	1.1	0.9	0.8
sTI_a	2.8	2.3	2.2	1.7
sBFS_a	3.6	3.5	2.7	2.6
sBFC_a	5.8	4.7	4.4	3.5
MAG_t	3.8	3.5	2.9	2.6
Mean	3.1	4.7	1.9	2.8

those of the normal corneas. Table 3 displays the same information as Table 2 but for all images of acceptable grade collected at a particular visit. We note that the within-visit standard error is consistently larger in keratoconus eyes, as is the case with the standard error of the between-visit difference for all variables except sSRI_a. Table 4 displays these relationships as ratios of values from keratoconus subjects to values from the normal controls. These ratios vary from 1.0–5.9 for two images and 1.1-6.1 for all images for the within-visit measurements and 0.9–4.6 and 0.9–4.3 for two eyes and all eyes for the between-visit measurements, respectively. The mean ratios in Table 4 for the within-visit standard errors are 3.1 and 4.7 for all images and two images, respectively. For between-visit ratios, the corresponding mean ratios are 1.9 and 2.8, respectively. These both represent a 33% reduction in the difference in the variability between keratoconus eyes and normal eyes when all images are used. As previously mentioned, the within-visit variability is noticeably larger than the between-visit variability. Although this is troubling, to some degree it is expected, because the between-visit variability refers to variability between means rather than among individual values. As an example, if one examines a commonly understood index, sSIMKS_a (simulated keratometry reading for the steep meridian), based on the "two images" protocol, the between-visit variance for keratoconus eyes is 0.112 D and for normal eyes it is 0.063 D. The 95% confidence intervals suggest that between-visit decreases larger than 0.048 D or increases larger than 0.394 D would be deemed statistically significant for keratoconus eyes; the corresponding values for normal eyes are -0.062 D and 0.188 D. If the "all available images" protocol is used in the same comparison for the sSIMKS_a, the comparable 95% confidence limits are -0.127 D and 0.188 D for keratoconus patients, whereas for normals, the 95% confidence limits are -0.019 D and 0.126 D. Although these differences are small, the upper bounds for detecting a change in keratometry drops from a change of 0.394 D to 0.188 D.

DISCUSSION

Disease severity and progression in keratoconus are typically measured by keratometry or videokeratography.[6, 7, 14, 16, 19–23] There are numerous reports on the repeatability of corneal topography measurements by videokeratography and keratometry for calibrated shapes and in normal eyes.[11, 24–33] The results vary considerably depending on the methodology used and the type of analyses performed.[11] Repeatability of Placido disk-based videokeratography has been reported to be within 0.50 D in the central cornea in normal eyes.[11, 28, 31, 33, 34] The repeatability for keratometry in normal corneas varies from 0.12 D to 0.75 D depending on the location and analysis technique used.[35, 36] In a previous report of CLEK Study eyes with keratoconus, the mean intervisit test–retest differences for flat and steep keratometry readings (95% confidence interval) were 0.29 D (±3.28 D) and 0.16 D (±3.50 D), respectively.[7] Although the intraclass correlation coefficients of 0.955 and 0.964 for flat and steep keratometric measurements, respectively, were very high, the large 95% confidence intervals suggest a substantially lower level of repeatability in keratoconus subjects.[7] There was also a clear indication of decreasing repeatability with more severe disease. In a recent report, McMahon and colleagues demonstrated that the short-term repeatability for several topography instruments in keratoconus subjects was generally larger than that reported for normal eyes. Depending on location and instrument, the variability per location within the central 6 mm ranged from 0.58 D to 3.31 D for axial curvature maps and from 0.79 D to 6.82 D for tangential curvature maps.[37]

Videokeratography has been reported to be superior to keratometry as a measure of corneal topography as a result of the greater number of data points sampled and videokeratography's capacity to more accurately reconstruct the contour of the cornea.[14, 38–42] Placido-based videokeratography is, like keratometry, a reflection-based technique, and it is therefore likely to suffer from a similar decrease in repeatability with increased corneal steepness, irregularity, and scarring. Artifacts and generally poor-quality maps are familiar findings in subjects with keratoconus. Controlling for these occurrences through selective editing and purging of poor-quality maps preserves the integrity of our historical dataset for analyses.

Figure 1 displays a difference plot for four indices representing curvature (sACP_a), asymmetry (sSAI_a), irregularity (sTI_a), and regular astigmatism (sBFC_a) as a function of simulated steep keratometry using the mean of two maps. As can be seen, for all measures displayed, the variability is greater in keratoconus eyes than in control eyes. Except for the occasional outlier, there does not appear to be an increase in the variability with increasing disease severity (as defined as increasing corneal steepening by central keratometry).

These results demonstrate that an automated method for editing and grading of data quality can be used in the building of a corneal topographic database. Additionally, these results show that topography-derived indices are less repeatable in keratoconus eyes than in normal eyes. Importantly, editing and quality controls appear to reduce the test–retest variability of TMS-1-derived indices in ker-

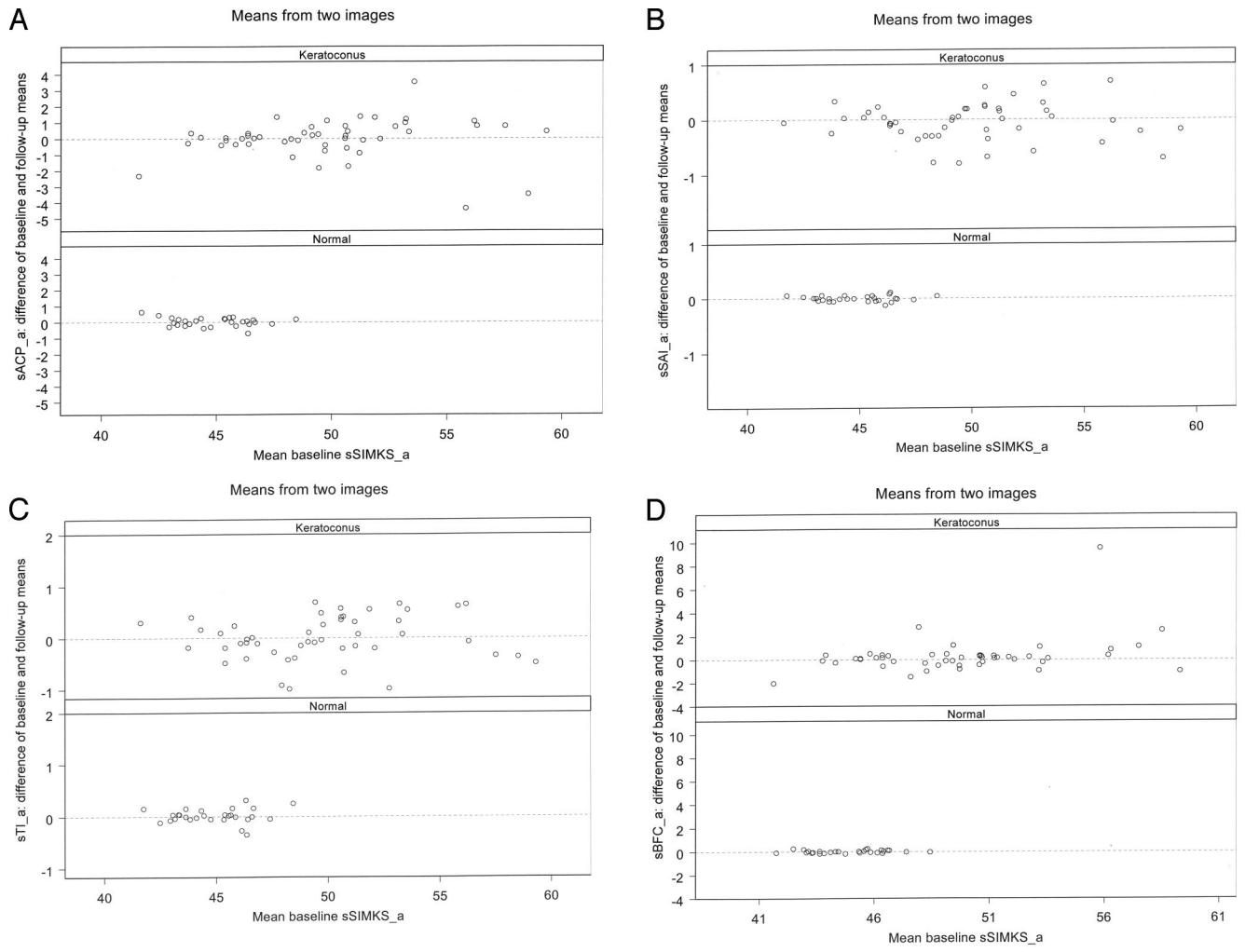


FIGURE 1.
Difference plots of the between-visit variability for a measure of curvature (A) (sACP_a), (B) asymmetry (sSAI_a), (C) irregularity (sTI_a), and (D) astigmatism (sBFC_a) as a function of disease severity (sSIMKS_a). Two images were used to compute the means at each visit.

atoconus. Lastly, in the paradigm described here, it would appear that the test–retest repeatability of these indices does not appreciably worsen with increasing disease severity.

SUMMARY

The results of the data editing analysis suggest that the CAP3 algorithm would be most useful, screening out the most artifacts while retaining the greatest number of maps in the dataset. Therefore, this algorithm was used.

Quality grades 2 and higher were determined to be appropriate for inclusion in the dataset. The grade level was determined by visual inspection as defined previously.

APPENDIX

In an effort to eliminate artifacts within a given map while trying to preserve the remaining map so that it could be included in the greater CLEK Study data analysis, a series of steps were developed and tested for suitability for use. The first was a data-editing protocol to remove artifact. The second was a grading system to analyze whether an edited map had enough viable data to be useful to the study analysis. In this Appendix, the development and testing of both of these steps are described.

Data Editing

As indicated in the body of the manuscript, 12 data-editing algorithms were developed and explored to remove selected artifacts from TMS-1 maps. These editing algorithms represent two fundamentally different approaches: 1) compare with two averages (*C2AX*) and 2) compare adjacent points (*CAPX*). The C2AX algorithms analyze the validity of a data point by comparing it with its neighbors both along a semimeridian and along the Placido ring. This is accomplished by taking the average of the two neighboring points along the semimeridian and the ring. If either average varies

by a specified dioptric amount (*X*), the data point is invalidated and removed. Using this model, the dioptric threshold X varied from 1 D to 6 D. Data points within the central 3-mm radius were deemed to be most important (and in the TMS-1, most likely to be erroneous). Outside of the central 3 mm, the dioptric interval was expanded to two times the distance from the center. The CAPX algorithm varied from C2AX in that adjacent points along the semimeridian and the ring were individually compared with the test data point. The dioptric threshold varied from 1 to 6 D as with C2AX. Outside the central 3 mm, the threshold varied by the distance from center like with C2AX. Twelve algorithms were tested.

Quality Grading

The editing process works by identifying and selectively removing suspect data from the .DIO data file, which is used to construct the maps and from which the corneal indices are produced. Although the aforementioned editing algorithms provide for the elimination of artifacts, in some cases, this leaves very limited information for some maps. There comes a point when there are so little remaining data that prudence suggests discarding the entire map. Because the editing process is incapable of doing this, a strategy was needed that would consistently identify maps that should, in the end, be discarded. An obvious choice would be to set a threshold for the minimum number of data points judged to be sufficient. Although in many circumstances, this would be adequate, central and paracentral data locations carry extra importance, because the vast majority of the calculated indices use these areas, and the peripheral points are less important. Thus, we needed a more sophisticated exclusion/inclusion process that weights the effects of artifacts based on region rather than simply using a minimum number of overall data points.

To do this, each map is divided into 30° polar coordinate wedges segmented by annular rings set at 1-mm, 2-mm, and 3-mm radii (Appendix Fig. 1). This divides the central and paracentral map into 36 parcels. The central wedges are smaller in area, encompassing roughly equal numbers of data points as the peripheral wedges. The central region is more prone to artifacts, so the criterion algorithm was designed to be very critical of grouped artifacts within a region. After the editing process, the percent area of data fill is calculated for each wedge or box. Following the algorithm used subsequently, the number of "filled" boxes is used to construct a score of 0 to 4, with 4 being best and 0 worst. For each grade, there are several types of losses that can place the map within a grade level.

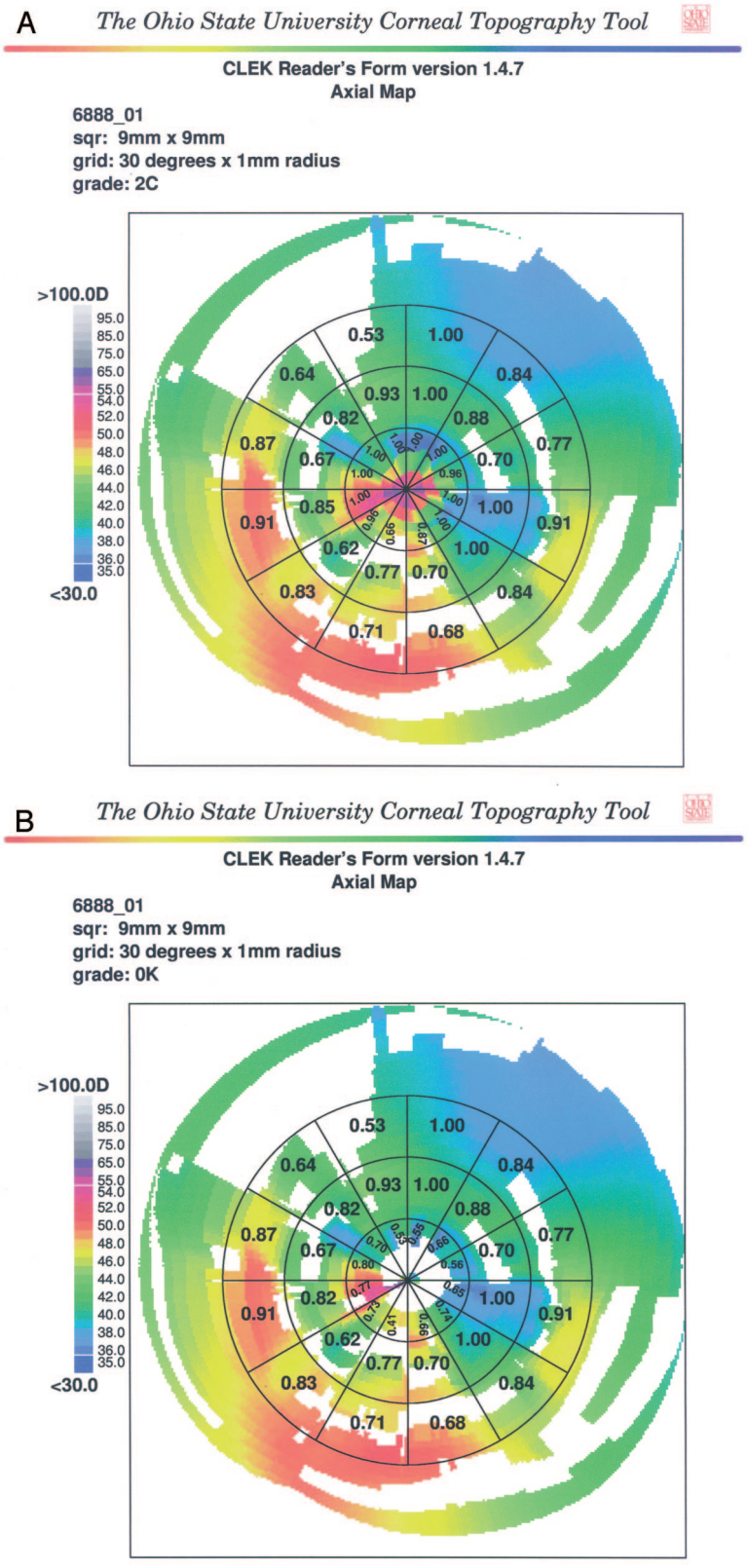
To establish a cutoff value for rejecting a map, we used a set of 12 right eyes from 12 keratoconic subjects selected from the CLEK Study data pool of subjects who had been evaluated with the TMS-1 but who were not in the retest group. Three images (after editing) from each grade level (0–4) were selected for analysis. There were 12 variants of the editing algorithms tested (C2A1-6 and CAP1-6). These were tested on three groups of keratoconus subjects (n = 60 maps) not included in the retest analysis, 20 maps each with unedited quality grades of 4, 3, and 2. The final arbiter for inclusion or exclusion in the CLEK topography database is the "quality grade." In a post hoc scenario, a balance must be struck between removing aberrant data and maintaining as much data in the database as possible. Toward this end, the editing algorithm variants tested were assessed on the number and "appropriateness" of maps moved to a score of 1 or 0 through the editing process. The algorithm(s) that removed the most visually evident artifacts with the least number of exclusionary grading scores would be used as the study-editing algorithm.

Results of the Editing Analysis

For both the C2AX and the CAPX algorithms, the dioptric intervals of 4 through 6 did not meaningfully remove artifact and were rejected and are not discussed further. C2A3, in which 3 indicates the dioptric threshold value, and C2A2 resulted in only one rejected map. C2A1 boosted the rejected count to five maps. Visual inspection of the edited maps indicated that the C2A3 and C2A2 algorithms had minimal impact on artifacts present. At the C2A1 interval, the effect was marked and the number of rejected maps resulting from a resultant grade jumped to 25% of the grade 2 unedited maps. CAP3 had a similar effect as C2A1 but with a slightly lower number of rejections. CAP2 and CAP1 demonstrated marked increases in map rejections. The vast majority of the artifactual points were located near the videokeratographic axis in this example. This tendency for greater variability between neighboring points and poorer repeatability in the most central regions has been previously described for the TMS-1.[11] In the 28 normal corneal maps, the different algorithms had relatively little effect with no data points being removed until C2A1 and CAP2 or CAP1 were used. Based on the observation that the CAP3 algorithm was most effective in removing local artifact with the least number of exclusions, it was adopted to serve as the study-editing algorithm. The results comparing an unedited map and a CAP3-edited map for a single representative eye can be found in Appendix Figure 2.

Results of the Quality Grading Analysis

For the normal eyes tested, no changes in the quality grades were found in the unedited versus edited conditions. Appendix Table 1 displays the combined effect of the CAP3 editing algorithm and selective elimination of maps on the standard error for one index, the surface asymmetry index (SAI), for right eyes of keratoconic and normal subjects. SAI is defined as "the centrally weighted summation of corneal power differences between corresponding points 180° apart on the mires, over 128 equally spaced meridians."[15] It is evident from inspection of this table that the standard error *decreases* for remaining maps as artifact is removed and poorer-quality maps from keratoconus subjects are removed from the dataset. On the other hand, the standard error is not affected for normal subjects by either the editing algorithms or the quality grading paradigms.



APPENDIX FIGURE 1.

The Ohio State University Corneal Topography Tool maps of a single keratoconic eye displaying the polar coordinate grid used in the quality grading scheme. The values in each wedge of the grid represent the percentage of the area filled, with 1.0 = 100%. The effect of the editing algorithm is compared with an unedited map shown for detecting artifact: (A) unedited, (B) CAP3.

APPENDIX TABLE 1.
Editing algorithm.

Grades	Unedited	CAP3
Keratoconus subjects		
0–4+	0.4402	0.4202
1–4+	0.3578	0.3321
2–4+	0.3006	0.2716
Normal subjects		
0–4+	0.0474	0.0474
1–4+	0.0474	0.0474
2–4+	0.0474	0.0474

Displays the combined effect of the CAP3 editing algorithm and selective elimination of maps on the standard error of the means, for between-visit measurements, for one index, SAI (Surface Asymmetry Index) for right eyes of keratoconic and normal subjects. Quality grades 0–4 includes all maps, grades 1–4 eliminates map with quality scores of zero, grade 2–4 eliminates maps with quality scores of zero and one.

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