QUALITATIVE ASSESSMENT OF SCLERAL SHAPE PATTERNS USING A NEW WIDE FIELD OCULAR SURFACE ELEVATION TOPOGRAPHER: THE SSSG STUDY

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Abstract

Background and Objectives

Objective was to examine new findings regarding conjunctival/scleral shape mapped with a novel wide field elevation topography device and software, to propose a new classification system for scleral shape.

Methods

The Scleral Shape Study Group (SSSG) collaborated on this research. Data were collected from 152 eyes of prospective scleral lens patients utilizing a new topography device and software specifically designed to measure and map the sclera out to as much as 22 mm. Circumferential scleral plots of sagittal height versus meridian at a 16-mm diameter from the corneal center was generated for each eye. Scleral shape patterns were reviewed in all cases and classified according to recurring characteristics.

Results

Twelve eyes were excluded from the analysis due to incomplete data. Of the remaining 140 eyes, 8 (5.7%), of the plots were primarily spherical (Group 1) and 40 (28.6%) were primarily regularly toric, largely conforming to a toric (Sin^2) curve with approximately 180° periodicity or interval between high point to high point or low point to low point (Group 2). Fifty-seven cases (40.7%) had asymmetric high points (or elevations) or asymmetric low points (or depressions) which were classified as Group 3. The remaining 35 cases (26%) had a recognizable toric pattern with elevations and depressions but they were irregularly spaced or did not have the customary 180° periodicity (Group 4).

Conclusion

A new classification of conjunctival/scleral shape is presented based upon data now available through wide field elevation topography, which could be helpful in scleral lens fitting and potentially soft lens fitting as the landing zone of these lenses are beyond the corneal borders.

Scleral contact lenses are more and more considered as a valid first option to be fitted on patients where it is needed to restore visual acuity or as part of a corneal eye disease treatment.[1] More recently, scleral lenses are also considered to be fitted in non-compromised eyes, where other modalities failed to provide adequate comfort or stable visual acuity.[2]

As it is the case for any emerging technologies, issues related to the increased usage of scleral contact lenses were raised by eye care practitioners and scientists in the field. As a proof of this huge increase in research in the scleral contact lens field, 43% of all peer reviewed publications through mid-2014 (184) were published since 2010.[3]

One of the elements that is of a prime importance, and for which little is known, is the landing of the lens on the conjunctival tissue and its underlying scleral shape (referred to as conjunctival/scleral shape throughout). Several factors can influence the way scleral lenses land on the ocular surface. Among them, the conjunctival/scleral shape profile, the corneo-conjunctival transition angle, the lens diameter and the relative support coming from the tear fluid layer under the lens should be considered. If the lens does not land properly, adverse reactions may develop. Conjunctival blanching, conjunctival prolapse, and staining of the ocular surface represent day-to-day challenges met by practitioners fitting scleral contact lenses.[4] There are no definitive answers to fix these issues, but most of the experts in the field consider that customizing to align the lens back surface to the ocular surface profile may help to alleviate these adverse events.

Early findings suggested that the conjunctival/scleral shape can be considered as a non-rotational asymmetrical surface.[5] It is also known that shape profile varies substantially from patient to patient[6] and even from eye to eye, and quadrant to quadrant. In order to customize lens design, it is of prime importance to rely on valuable assessment of the conjunctival/scleral shape profile.

Until recently, knowledge of patterns of the conjunctival/scleral shape has been very limited because commercially available technology like anterior segment optical coherence tomography (OCT) historically only provided information at one meridian at a time over the scleral range. Furthermore, studies[7,8] have demonstrated a poor correlation of scleral shape with the orientation and magnitude of corneal toricity. With the advent of new combined corneal and scleral elevation topographers,[9,10] it is now possible to get a more global view of the scleral surface. This paper describes the Scleral Lens Study Group's initial experience with such an instrument in observing and attempting to categorize patterns of conjunctival/scleral shape in scleral lens patients.

MATERIALS AND METHODS

This study was performed in compliance with the Declaration of Helsinki, IRB approval was obtained, and patient anonymity was protected. In this retrospective study, topographic data from 152 eyes of 116 patients (36 bilateral cases) were examined with the sMap3D corneo-scleral topographer. All presented for scleral lens fitting between September 2015 and April 2017. There were 78 right eyes and 74 left eyes.

The same examination technique was used as previously described.[10] A drop of fluorescein sodium 0.25% and benoxinate hydrochloride 0.4% ophthalmic solution (Bausch and Lomb, Tampa, FL.) was placed in the eye, the lids were retracted, and the patient was instructed to look at the fixation light in the straight-gaze, and, after focusing, the button on the slit lamp joystick was depressed to take the first exam. The patient was then instructed to look at the fixation light which was now in down-gaze. The examiner lifted the upper lid, to take the down-gaze image and again the button on the joystick was depressed.

The process was repeated again with the fixation light now in up-gaze, and the examiner holding the lower lid down. The reasons for and strategies to minimize missing data have been previously reported.[10]

Stitching of the up, straight and down-gaze images into a single wide field scleral surface was performed (Figure 1). A circumferential scleral shape plot for each case was created (Figure 2), which had an X-axis of meridian in degrees and a Y-axis of sagittal height value in millimeters. The sagittal height was graphed so the values were largest at the bottom of the scale and represented depressions or low areas on the ocular surface and elevations were at the top of the scale and demonstrated high areas. The software allows measurement at any diameter; all plots were taken at a 16-mm diameter.

This paper represents our attempt to qualitatively classify the observed conjunctival/scleral surfaces based upon the patterns observed and to provide an estimate of the frequency of these patterns in an unselected sample of scleral lens patients. The first goal was to identify those cases that represented a spherical shape which we defined as a graph that had 300 microns or less difference in sagittal height from the highest to lowest points on the graph (Group 1). This amount of deviation was considered to be a threshold that can affect the scleral lens to sclera fitting relationship. The cutoff point of 300 microns was chosen as a clinically significant difference in scleral shape since it is within the range of average bulbar conjunctival thickness (240–393 microns) reported with OCT[11,12] and somewhat higher than conjunctival settling of slightly under 200 microns with scleral lens wear.[13] Also, in reviewing manufacturing data, 300 microns of sagittal height difference between steep and flat axes at 16 mm was the most common posterior haptic toricity applied (Visionary Optics, unpublished data).

We then identified cases with uniform scleral toricity such as the case in Figure 2. A regular toric lens surface measured at a fixed diameter from the center of the surface graphed on a scleral shape plot such as Figure 2 is described by a Sin squared curve with a symmetric repeating pattern (periodicity) every 180°.
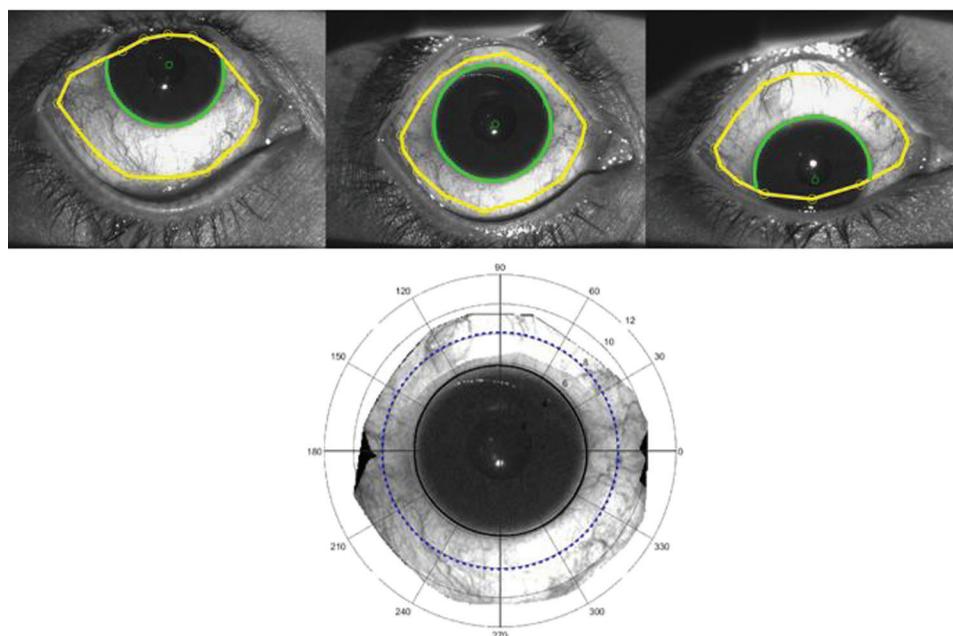

FIG. 1 The up, straight and down-gaze images (top) are obtained. Yellow lines demarcate the measurable conjunctival scleral surface and the green lines demarcate the limbus. The image on the bottom demonstrates the extent of ocular surface coverage obtained by stitching these 3 images above on a background of standard polar axis coordinates. The blue dotted line represents a 16-mm diameter through the center of the cornea.

To qualify in this group (Group 2), the cases had to have >300 microns in sagittal height from the highest to lowest points on the graph and they also had to have no more than 300 microns difference in sagittal height between the 2 lowest points or the 2 highest points as well as having to conform to a periodicity of 180° on visual inspection. Cases with >300 microns difference in sagittal height between the 2 lowest points or between the 2 highest points (Group 3) or cases that did not conform to a periodicity of 180° on visual inspection (Group 4) were considered abnormal.
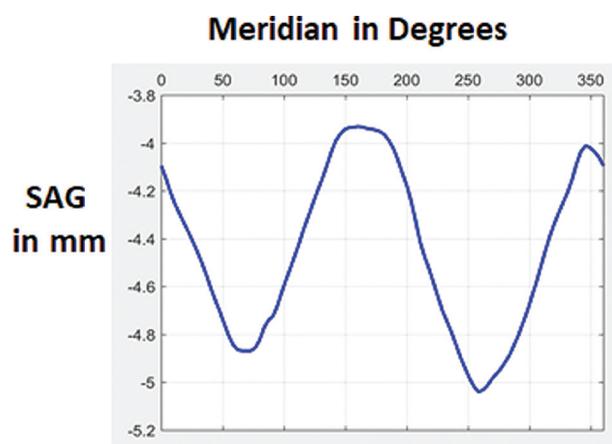

FIG. 2 Example of a circumferential scleral shape plot. This demonstrates a case with fairly uniform scleral toricity with the ocular surface approximating a Sin^2 curve with a periodicity of 180° (Group 2 case). Note that in this example each Y-axis tick mark is in 0.2 mm (200μ) steps and the distance from highest to lowest points of the graph is >1.0 mm (>1000μ).

RESULTS

Of the 152 cases collected, 12 cases were excluded from the analysis because data was missing at the 16mm diameter (8mm radius from the center of the cornea) which was necessary to exactly measure the sagittal height values at one of the low or high areas (Figure 3).

Of the remaining 140 eyes, 8 (5.7%) were predominantly spherical with low amplitude deviations within 300 microns from highest point to lowest point (Group 1, Figure 4). Forty cases (28.6%) were predominantly toric surfaces conforming to a regular toric curve and sagittal height values within 300 microns from elevation to elevation and depression to depression (Group 2, Figures 2 and 5). To define significant or substantial asymmetry in the irregular cases, >300-micron differences were used per definition. Fifty-seven cases (40,7%) had asymmetric depressions or elevations (Group 3). These included those that had a largely toric pattern but had asymmetric depressions (Figure 6) or asymmetric elevations (Figure 7). Others eyes did not have a recognizable toric pattern but showed a single large elevation (Figure 8) or depression (Figure 9). The remaining 35 cases (26%) had a recognizable toric pattern of elevations and depressions but the number and repeating pattern or periodicity was not that of a regular toric surface (Group 4, Figure 10). The classification and frequencies of the patterns of conjunctival/scleral shape seen in this series are summarized in Table 1.
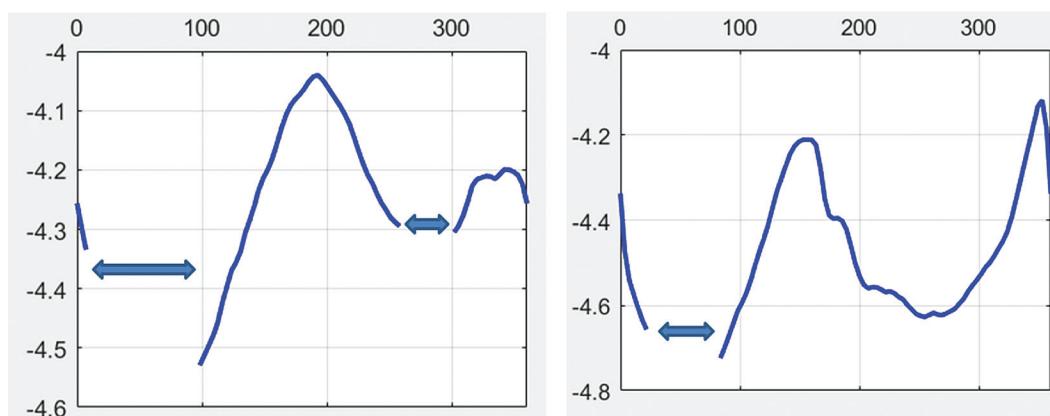

FIG. 3 Circumferential scleral shape plots of two cases where one or more of the surface elevations or depressions could not be measured on the surface line at 16mm due to a localized area of poor coverage (arrows).
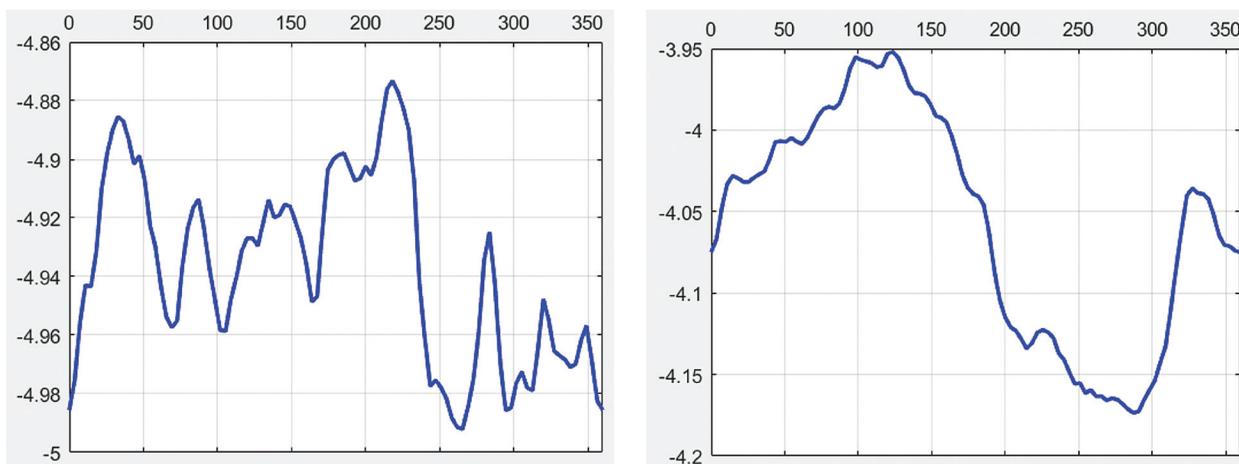
FIG. 4 Group 1 cases. Circumferential scleral shape plots of two cases classified as spherical scleral surfaces with low amplitude changes in sagittal height values over the entire measured 360°. Note that in the example on the left, each Y-axis tick mark is in 0.02 mm (20μ) steps and the distance from highest to lowest points of the graph is 0.125 mm (125μ); on the example on the right, each Y-axis tick mark is in 0.05 mm (50μ) steps and the distance from highest to lowest points of the graph is 0.220 mm (220μ).
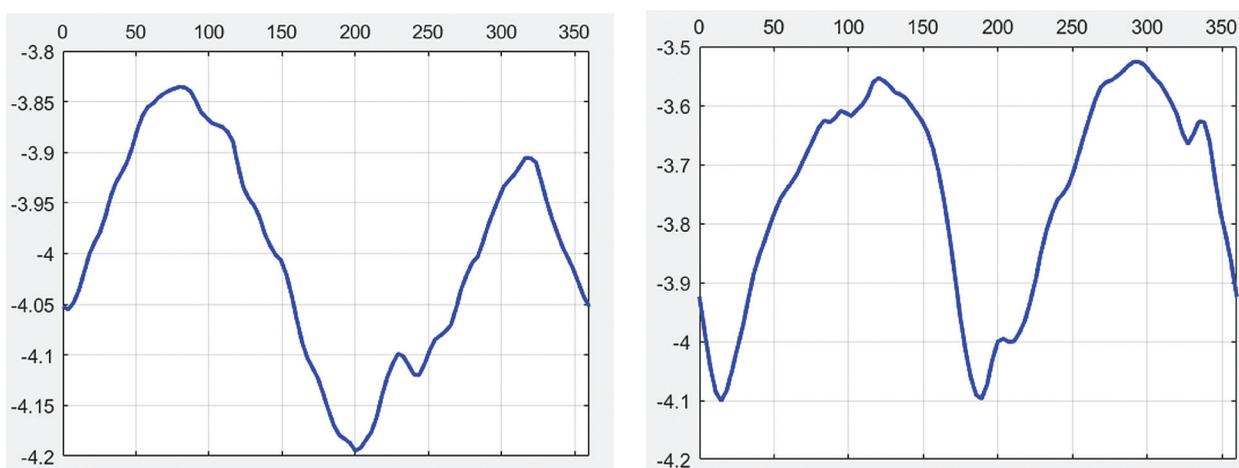

FIG. 5 Group 2 cases. Circumferential scleral shape plots of two cases with uniform scleral toricity with the ocular surface approximating a Sin^2 curve with a periodicity of 180°.

TABLE 1 Scleral Surface Patterns Observed in 140 Scleral Lens Patients

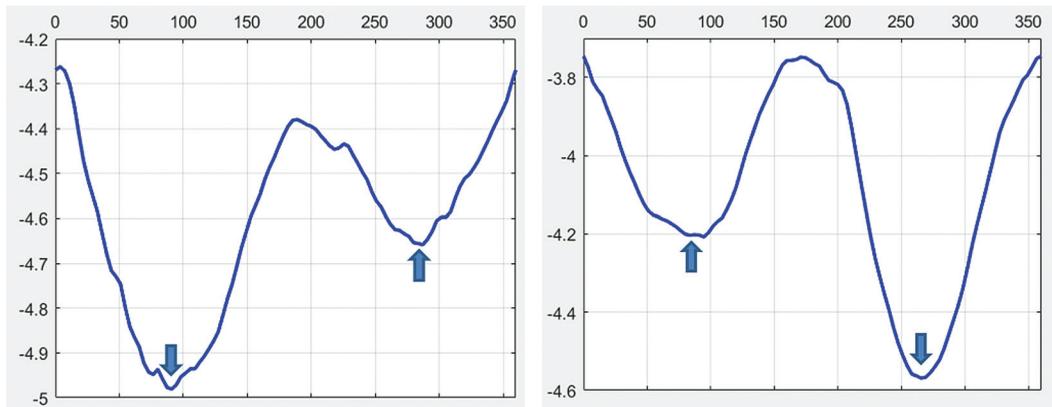| Group	Pattern Description	*N*(%)
1	Spherical	8 (5.7%)
2	Toric-Regular	40 (28.6%)
3	Asymmetric High or Low Points	57 (40.7%)
4	Periodicity different from 180°	35(25%)

FIG. 6 Group 3 cases. Circumferential scleral shape plots of two cases where the depressions or low points were of substantially different depths (arrows).
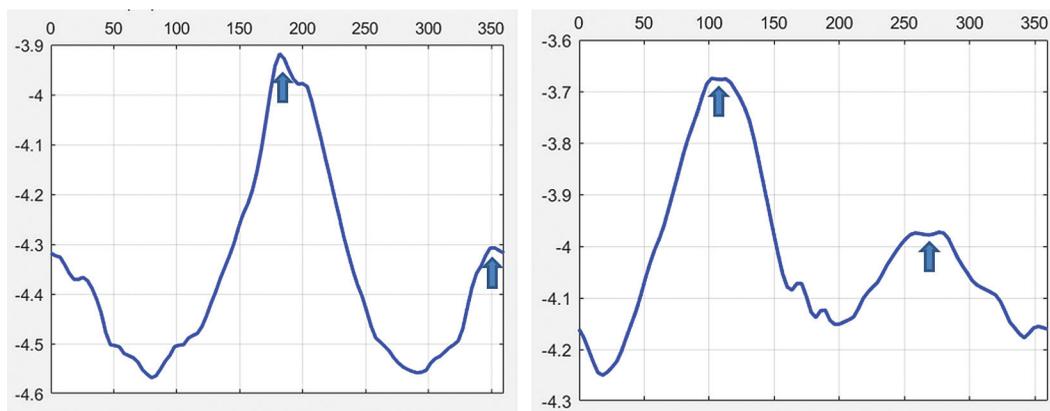

FIG. 7 Group 3 cases. Circumferential scleral shape plots of two cases where the elevations or high points are of substantially different heights (arrows).
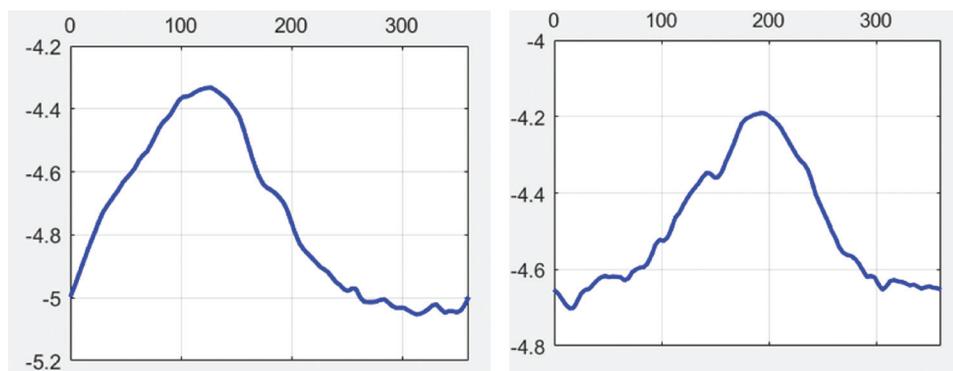

FIG. 8 Group 3 cases. Circumferential scleral shape plots of two cases with a single large elevation.
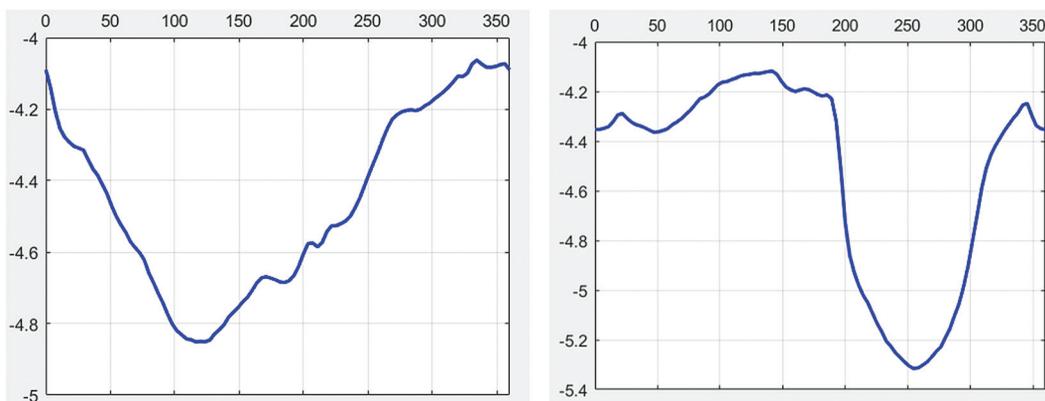
FIG 9. Group 3 cases. Circumferential scleral shape plots of two cases with a single deep depression. Note that the interval of the Y-axis tick marks (sagittal height value) for the plot on the right l is 200μ, so the depression is over 1,000μ from baseline.
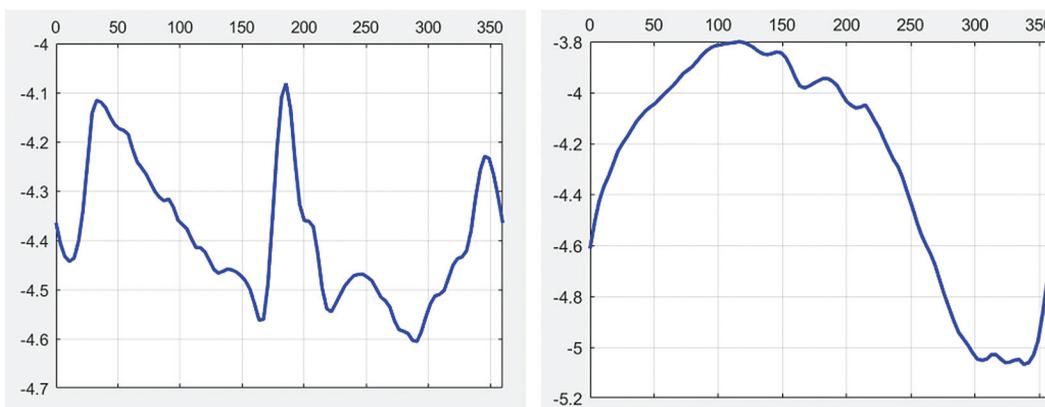

FIG 10. Group 4 cases. Circumferential scleral shape plots with the graph on the left demonstrating multiple elevations and depressions over 360°. In the figure on the right there is only 1 elevation and 1 depression over 360° thus the periodicity is twice that seen in a regular toric (Sin^2) curve (360° vs. 180°).

DISCUSSION

The goal of this retrospective analysis was simply to describe the patterns of conjunctival/scleral shape as assessed on a standard clinical population. To the best of our knowledge, this type of information has not been previously reported.

The classification system described looked at 3 basic characteristics of the scleral shape plots. Firstly, the amplitude of the deviation between the highest point and the lowest point on the graph; if this was 300μ or less, it was considered spherical (Group 1) and if not, it was one of the other 3 groups. The other 2 characteristics were the symmetry and periodicity (recurrence of pattern) of the deviation. If there was symmetry between the 2 highest points and the 2 lowest points (300μ or less difference in sagittal height) and periodicity of the pattern was approximately 180°, then the scleral surface was considered regular toric (Group 2). Asymmetry of the high points or the low points placed the case in Group 3. A periodicity other than 180° in the presence of >300μ between the highest point and the lowest point on the graph placed the case in Group 4.

The results of the analysis show that only 5.7% of conjunctival/scleral shapes were spherical in nature, while 28.6% were predominantly regular toric. Asymmetric depressions or elevations were seen in 40.7% of cases, while the remaining 26% had a recognizable

toric pattern with elevations and depressions but the repeating pattern or periodicity was not that of a regular toric surface. In other words, for a clinical perspective, roughly 1/3 of eyes had a rotationally symmetrical shape, which could in theory be fit with a spherical or toric scleral lens. But 2/3 showed an irregular pattern: either with asymmetric depressions and elevations in a circumferential scleral shape plot, or with periodicities different from 180 degrees.

Although speculative in nature, we observed a relative high incidence of asymmetric depression inferiorly not seen 180° away (right images, Figures 6, 9, and 10). This finding may contribute to inferior decentration frequently seen with scleral lenses.

We used a 300-micron cutoff point for clinically significant difference in scleral shape. Based upon clinical experience it is assumed that the eye can tolerate some asymmetry and that smaller changes would not result in relevant shape patterns that would affect scleral lens fit. Surprisingly, even with this conservative approach to clinical significance, almost two thirds of the cases studied were considered to have an irregular pattern in some way. Clearly more work needs to be done to determine which of these patterns can and which cannot be treated with standard spherical or toric posterior haptics.

In this series, only 12 of 152 cases (8%) were missing crucial information at the 16mm diameter necessary to include the data in this classification study. We ascribed this relatively low number to the use of stitching to obtain data from areas difficult to obtain with a single straight gaze image. In a recent study of amount of coverage at a 16-mm diameter circle,[10] 93% of the circumference of the circle contained data using a stitched image while only 39% of the circumference of the circle contained data using a straight gaze image. Typically, the area with missing data was superiorly of inferiorly where conjunctival/ scleral surface exposure can be more difficult. This limitation with a single gaze image was also pointed out with another scleral topography unit.[14]

No attempt was made to collect patient demographic or diagnostic information in these patients in this initial report, although the investigators do recognize the need to correlate that information with scleral shape patterns; this correlation will be the topic of a future report.

The current understanding of conjunctival/scleral shape may be only slightly less limited now than the understanding of corneal shape was before the advent and routine use of corneal topography instruments. In both cases only limited information was known and was used to characterize entire surfaces; 4-point keratometry data vs. localized averaged sagittal height data[15] or averaged corneal scleral angle data from OCT[16] in 8 meridians. Similarly, even though the importance of back toric scleral lenses has been known for a long time,[17–19] the only measurement tool used for this value has been meridional OCT.[20] The ability to measure scleral surfaces only in sagittal meridians has been limiting.

The Pacific University Scleral Shape Study[16] used angle measurements rather than using curves to investigate the shape of the corneo-scleral junction and the anterior scleral shape. The corneo-scleral tangential angle between 10.0 mm and 15.0 mm (defined in that study as the limbal angle) as well as the angle from 15.0 mm to 20.0 mm (the scleral angle) was established in 96 eyes of 48 normal subjects using anterior segment OCT to develop an eye model for the normal eye. Roughly, the limbal angles were in the same range and were not found to be statistically significantly different from each other. But for the scleral angle, there were significant differences especially between the nasal region (shallower angle) and the temporal-inferior section (steeper angle). While more variability was observed in scleral angles, no information on patterns of shape in individual cases was reported. The data in this current study is unique and cannot be readily compared this previous work since the goal of the current study was to demonstrate individual patterns of scleral shape and not averaged outcomes.

Scleral lenses have for many years been largely empirically fit with diagnostic fitting set lenses. The most likely reason for this has been the difficulty in obtaining conjunctival/scleral shape information in individual cases. For the first time, scleral surface data is readily available circumferentially for 360° allowing for identification of conjunctival/scleral shape patterns.

While the purpose of this study was to qualitatively assess the different patterns of scleral shape, the use of the circumferential scleral shape plots appears to be a bridge to the quantitative analysis necessary to design and accurately predict scleral lens central and limbal clearances, quantitate haptic toricity and, if necessary, produce an individualized customized posterior scleral haptic for patients. While the scleral toricity plots presented only showed the scleral shape at 16 mm,
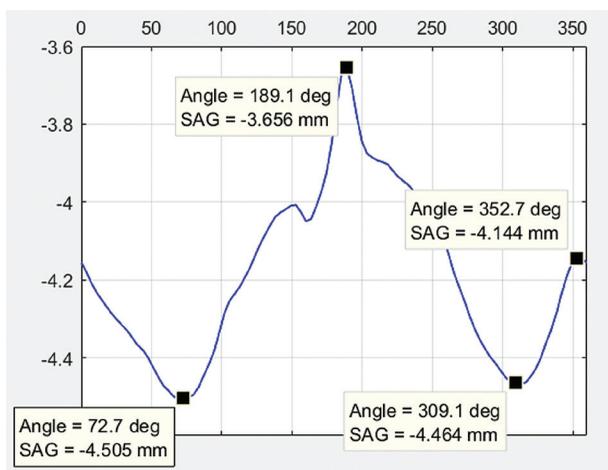

FIG. 11 Circumferential scleral shape plot of a case where 4 elevation and depression sagittal height (SAG) values and meridian data points are displayed on the graph.

these circumferential shape lines can be obtained for any diameter where data is present. Furthermore, any point on these surface plots can be identified and quantitated with regard to sagittal height and meridian (Figure 11). These plots can also be correlated to other ways the topography instruments can visualize the ocular surface such as 3-D imaging (Figure 12).

The authors recognize that the findings presented here are applicable only to the clinical population studied and, considering the high intra-subject and inter-subject variability, other studies may not duplicate our findings. Other bias includes the way data were collected (one or multiple technician), and the time of the day when data were collected. One way to alleviate such bias is to rely on a single operator for data collection, and at least 2 masked observers to analyze them. There is also the potential for inaccuracy of each individual gaze-direction acquisition, as well as inaccuracy due to suboptimal alignment (stitching) of multiple acquisitions into one combined surface.

Eye molding may be another way to assess the true conjunctival shape, however extracting data from a mold can also present optical and computer induced artifacts. While not reported here, we have used these circumferential scleral shape plots to successfully produce scleral lenses with highly customized designs. Cases with scleral obstacles such as pincueculae and
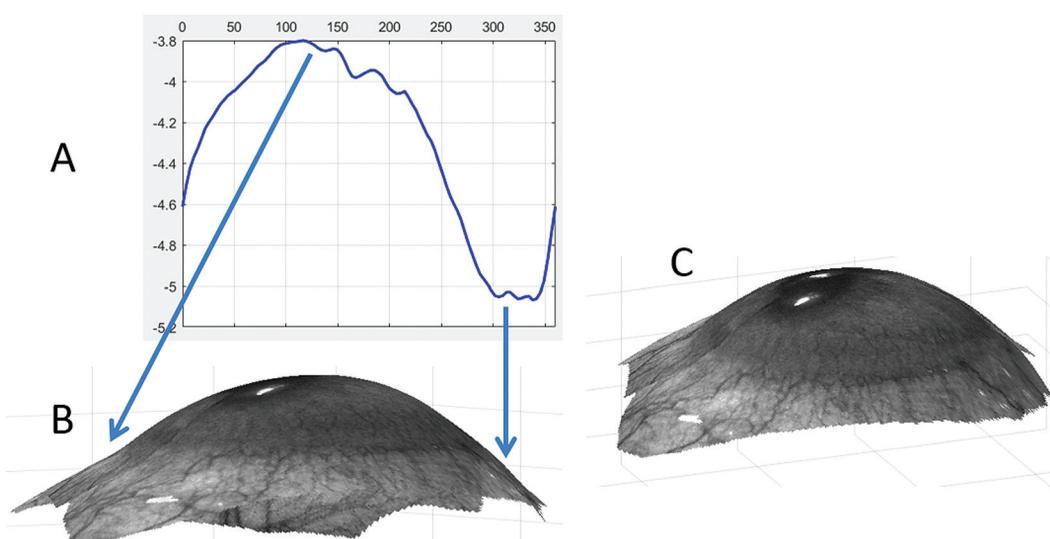

FIG. 12 Figure demonstrating correlation between Circumferential scleral shape plot (A) and 3-D imaging sagittal view (B). 13 (C) shows slightly oblique view of the 3-D imaging.

filtering blebs have been fit with notched lenses and with precision lifts (microvaults). In addition, cases with scleral depressions both with a toric pattern (Figure 6) and without (Figure 9) were fit with multi-meridian designs. The success of these cases argues against a significant error component in these measurements. Furthermore, sagittal height measurements using this corneo-scleral topography system has been well correlated with OCT[18] and sagittal height and scleral toricity were highly repeatable.[21]

The limited sample size also may not be sufficient for a definitive classification system, but this is a first attempt for such a classification. Future studies with larger sample sizes could further define and refine this.

The vast majority of scleral lenses are currently fit using diagnostic lens fitting sets without any measurement of the scleral surface. Errors in subjective judgment and accurately relaying fitting characteristics of fit scleral lenses to the manufacturer result in high remake rates. This is costly, in regards to time and expense, for both the patient and practitioner. Qualitative categorization is necessary to translate scleral shape measurements to lens design. Corneo-scleral topography provides accurate measurement and shape analysis that allows practitioners to efficiently select the appropriate lens design to successfully fit an individual eye. Measurement of the sclera transitions the philosophy of fitting scleral lenses from art to science.

CONCLUSION

It was possible to use a corneo-scleral topographer to map and describe the conjunctival/scleral shape on a clinical population. Results indicate that majority of the subjects present some sort of asymmetry but at least one third of them show a spherical or regular sinusoidal pattern. These results may influence the way scleral lenses are designed and fitted to alleviate adverse events and to improve lens comfort.

DISCLOSURE

Drs. DeNaeyer and Sanders are shareholders in Precision Ocular Metrology, the manufacturer of the sMap3D instrument. Dr. Sanders is a shareholder of Visionary Optics and Dr. DeNaeyer is a consultant to Visionary Optics. Visionary Optics distributes the sMap3D. None of the other authors have a financial interest in this subject Visionary Optics helped Fund this research.

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