The Identification of Geometric Center of Soft Contact Lenses in Relation to the Visual Axis

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Visual Axis

Abstract

Purpose: This study aimed to investigate the geometric center position of soft contact lenses and the influence of the scleral shape on lens position.

Methods: In this study, the geometric center of soft contact lenses were marked with a white cross image. The lenses had an overall diameter 14.5 (mm), and were prism ballasted. The lenses were applied to 60 healthy eyes of 30 subjects (16 male, and 14 female). The mean ± SD age of the subjects was 25.5 ± 3.03 years, and spherical equivalent was (-1.91±1.82 (D)). Vertical and horizontal lens position was measured from the visual axis to the optical center of the lens with the Medmont E300 Corneal Topographer. Scleral sagittal height at a chord of 14.50 mm was measured in eight meridians with Precision Ocular Metrology, LLC sMap3D.

Results: The horizontal contact lens mean decentration was 0.81± 0.35 (mm) temporally in the right eye and 0.67 ± 0.31(mm) temporally in the left eye. The vertical decentration mean was 0.59 ± 0.38 (mm) superiorly in the right eye, and 0.56 ± 0.35 (mm) superiorly in the left eye. The contact lens decentered temporally in both eyes for all 30 subjects. Vertically, the lenses decentered superiorly in 55 eyes and stayed centered in 5 eyes. The lens decentration was not statistically significantly different between the right and left eyes (F= 3.308, P=.079, ES= 0.471). The scleral sagittal height varied between the eight primary segments of the sclera (90°, 45°, 0°, 235°,270°, 315°,180°,135°), and there was a statistically significant difference between the right and left eyes (F= 4.230, P

Conclusions: Soft contact lenses were frequently decentered temporally and superiorly in the primary gaze. The scleral shape was asymmetrical and was not associated with lens decentration in this study.

Keywords: Soft contact lenses, decentration, sagittal height (SAG), scleral shape

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THE IDENTIFICATION OF GEOMETRIC CENTER OF SOFT CONTACT LENSES IN RELATION TO THE VISUAL AXIS

by

AMANE ABDULLAH ALSHAMRANI

A THESIS

Submitted to the Graduate Faculty of Pacific University Vision Science Graduate Program, in partial fulfillment of the requirements for the degree of
Master of Science
in
Vision Science

PACIFIC UNIVERSITY
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This thesis of Amane Abdullah Alshamrani, titled “The Identification of Geometric Center of Soft Contact Lenses in Relation to The Visual Axis”, is approved for acceptance in partial fulfillment of the requirements of the degree of Master of Science.

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THE IDENTIFICATION OF GEOMETRIC CENTER OF SOFT CONTACT LENSES IN RELATION TO THE VISUAL AXIS

AMANE ABDULLAH ALSHAMRANI

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ABSTRACT

**Purpose:** This study aimed to investigate the geometric center position of soft contact lenses and the influence of the scleral shape on lens position.

**Methods:** In this study, the geometric center of soft contact lenses were marked with a white cross image. The lenses had an overall diameter 14.5 (mm), and were prism ballasted. The lenses were applied to 60 healthy eyes of 30 subjects (16 male, and 14 female). The mean ± SD age of the subjects was 25.5 ± 3.03 years, and spherical equivalent was (-1.91±1.82 (D)).

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The scleral sagittal height varied between the eight primary segments of the sclera (90°, 45°, 0°, 235°,270°, 315°,180°,135°), and there was a statistically significant difference between the right and left eyes ($F= 4.230, P <0.001$). The difference between the temporal and nasal scleral
quadrants was not correlated to the horizontal decentration (R²= .020, P=.457) for the right eyes and (R²= .025, P =.401) for the left eyes. Also, the difference between the superior and inferior quadrants was not correlated to the vertical decentration (R²= .003, P=.768) for the right eyes and (R²= .018, P =.480) for the left eyes. The palpebral fissure and the horizontal iris diameter were not correlated to the lens decentration.

Conclusions: Soft contact lenses were frequently decentered temporally and superiorly in the primary gaze. The scleral shape was asymmetrical and was not associated with lens decentration in this study.

Keywords: Soft contact lenses, decentration, sagittal height (SAG), scleral shape
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LIST OF ABBREVIATIONS

CL: contact lens.
HVID: horizontal visible iris diameter.
SAG: scleral sagittal height.
BC: base curve.
I: inferior.
S: superior.
T: temporal.
N: nasal.
V: vertical axis.
H: horizontal axis.
1. INTRODUCTION

1.1. Background:

Contact lenses play a vital role in eye care and have been prescribed for vision correction, therapeutic, or cosmetic purposes.\(^1\) They vary based on the material of the lens, the design, and the optical properties.\(^1\) The material of the contact lens determines its rigidity.\(^2\) Depending on the purpose of the treatment and the patient’s condition, the prescribed contact lens is either soft or rigid contact lens. Among the different types, soft contact lenses are most commonly prescribed, which represents about 90% of the market.\(^3\) Suboptimal contact lens fitting can lead to poor vision, discomfort, and finally contact lens discontinuation\(^4\). The accurate contact lens fitting process and the proper lens design will provide satisfactory vision for patients.\(^5\)

Besides the ideal materials that promote comfort, and ideal fitting process (e.g., surface wettability and oxygen permeability), the optical parameters need to be determined for high-quality soft contact lens fitting. For instance, the overall diameter of the contact lens, the base curve, the lens thicknesses, back vertex power, and contact lens edge design are essential to achieve optimal visual quality.\(^6\) Also, determining the scleral shape will be useful to avoid contact lens discomfort, and to improve the lens design that enhances the contact lens fitting.\(^7\)

The optical center of the lens is another essential contact lens parameter that has been neglected and needs to be considered by the contact lens manufacturer and eyecare practitioner. The optical zone (the part of the lens that corrects the refractive error) of the soft contact lenses are placed in the geometric center of the lens. Indeed, contact lens manufactures assume that the central corrective power of the contact lens is lining up with the visual axis, and it covers the patient’s pupil. Also, they assume that contact lenses center ideally on the patient’s cornea, so they manufacture the lenses based on these two hypotheses. As a matter of fact, the visual axis is nasal
to the center of the pupil\textsuperscript{8}, and the pupil is slightly nasal and inferior from the center of the iris.\textsuperscript{9}

For more clarification, the optical axis is a line passing from the center of the refractive system (e.g., Contact lens) passing the center of the cornea, aqueous humor, crystalline lens, and vitreous humor.\textsuperscript{10} In contrast, the visual axis is the center line of vision that connects the center of the field of vision by the center of the macula.\textsuperscript{10} For these facts, the optical center of the contact lenses needs to be manufactured based on the correct position of the visual axis of the eye (which is mostly nasal to the center of the pupil) to obtain a clear vision.

1.2. Soft Contact Lens Decentration:

Soft contact lenses are not usually centered over the cornea. The anterior ocular surface and the anatomical shape of the eye contributes in contact lens position in addition to other factors. The most crucial factor is the conjunctiva/sclera shape since the soft contact lenses land on the scleral surface. The sclera is not always symmetrical in all meridians, or spherical as well as asymmetrical elevations and depressions causes irregular toricity.\textsuperscript{29} Also, the extraocular muscles are not inserted at an equal distance from the center of the cornea. The insertion of medial rectus muscle is the closest to the limbus, then the inferior muscle, then the temporal muscle, and finally the superior muscle which is the farthest muscle from the limbus (Figure.1).\textsuperscript{9} Consequently, the on eye soft lens tend to land on the position based on the scleral shape and the sagittal height of the sclera.
Figure 1: The four extraocular muscles image demonstrates unequal distances between the limbus and the muscles insertion. “Adapted from ‘Clinical Anatomy and Physiology of the Visual System (P 187).’”

Understanding the scleral shape explains where soft contact lenses tend to be decentered horizontally and vertically. To be more specific, the sagittal height of the sclera is the perpendicular distance from the apex of the cornea to a particular chord in cross section of the anterior segment that demonstrate the shape of sclera (Figure.2).\textsuperscript{11} From this point, defining the actual position of the soft contact lenses on the eye are essential for most soft contact lens fitting processes. For instance, multifocal contact lenses; which are designed to provide a good vision in different distances, have shown vision improvement at a distance and near versus single vision distance, only contact lens in those patients with presbyopia.\textsuperscript{12} Previous studies have indicated that multifocal contact lenses have the ability to slow myopia progression in children.\textsuperscript{13,14} Because of these significant implications, determining the position of on eye contact lenses will play a vital role in the multifocal contact lenses fitting process.
Figure 2. Measuring the sagittal height from the highest point of the cornea (apex) to a point at a chord of 14.50 (mm).

Furthermore, the palpebral fissure size could be a factor that may impact contact lens stabilization. The forces and the position of the eyelid may cause the soft contact lens to decenter inferiorly. Also, the horizontal visible iris diameter could influence the contact lens fitting and the centration. Undoubtedly, when the optical center of a contact lens coincides with the visual axis of the eye, the vision should be improved. Therefore, knowing the distance between the optical center of the decentered soft contact lens and the visual axis of the patient will enhance the optical design of the lenses in a way that increases the vision performance for the patient.

Zheng et al. (2015) found the impact of decentered multifocal contact lenses on visual performance, and their results showed that the visual acuity and clarity decrease as the distance between the visual axis and the contact lens optical zone increases. A study in centration and decenteration of soft contact lenses was conducted to determine the amount of contact lens decenteration in multifocal contact lenses and spherical contact lenses (El-Nimri & Walline, 2017).
They found that multifocal contact lenses were significantly decentered temporally by amount 0.09 mm in the primary gaze, and superiorly by amount 0.02 mm. Also, their results showed no significant decentration with habitual spherical contact lenses in the temporal quadrant (0.02 mm) but decentered significantly superiorly by the distance of 0.29 mm.  

Fedtke et al. (2016) showed the effect of multifocal soft contact lenses decentration on the visual performance in presbyopic and non-presbyopic groups. They used multifocal contact lenses as a test lens and a single vision lens as a control group. Fedtke et al. (2016) reported the lens decentration horizontally and vertically, and they found that all lenses decentered temporally and inferiorly (X = 0.36 ± 0.29 mm, y = -0.28 ± 0.28 mm). Also, they concluded that the multifocal contact lenses decentration varied from one to another design and fitting process.

Furthermore, Vincent and Collins (2019) conducted a study in measuring scleral contact lens decentration by a topographical method. They measured vertical and horizontal decentration for the lens with a total diameter of 16.50 mm. They found that the decentration mean was 0.91 ± 0.33 mm inferiorly, and 0.62 ± 0.18 mm temporally by measuring the distance from the front optic zone relative to the pupil center. Hickson-Curran et al. (2016) conducted a study in Chinese and Caucasian groups to evaluate the ocular topography on the soft contact lenses. They used spherical contact lenses with two base curves (8.50 mm and 9.00 mm), and toric soft contact lenses with accelerated stabilization design. Their results showed a significant difference in the decentration between the two groups with the spherical and toric contact lenses.

Based on the anatomical shape of the sclera, contact lenses assumed to be decentered temporally. DeNaeyer et al. (2017) has done a retrospective study and investigated the conjunctival/scleral shape at 16 mm in diameter. A 78 right eyes and 74 left eyes were examined with the sMap3D corneoscleral topographer. They found that 40.7% of the eyes had asymmetric
scleral shape, and 26% had irregular patterns with elevations and depressions. Moreover, an analysis of the anterior scleral shape study was conducted by Ritzmann et al. (2018). Their primary purpose was investigating the scleral shape by measuring the sagittal height corneoscleral angle in the eight segments. They reported the sagittal height at 10.0 mm, at 12.8 mm, and at 15.0 mm chords by (Zeiss Visante AS-OCT) for each eye. They found that the scleral shape at 10.0 mm was symmetric, and at chord 12.0 mm the sclera was nearly asymmetric, and at 15.0 mm the sclera became significantly more asymmetric. Also, Ritzmann et al. (2018) found the greatest value of the sagittal height for right eyes was in the inferior temporal segment, and the lowest value was in the inferior nasal segment at 15.0 mm diameter. For left eyes, the greatest sagittal height was in the temporal segment, and the lowest value was in the nasal segment.

Thus, the scleral shape could impact contact lens fitting which makes the relationship between scleral shape and contact lens position on the eye is essential to discover. The hypothesis is when the temporal sagittal height of the scleral is greater than the nasal side, the lens would land on the nasal segment first and then decenter to the temporal side.
1.3. Purposes:

Our goals are as follows: (1) to know the exact location of the contact lens on the eye and compare the location between right and left eyes, (2) to determine the offset distance between the visual axis and the optical center vertically and horizontally of the contact lens in right and left eyes which will be helpful in lens manufacture modification, (3) to investigate the scleral shape in the right and the left eyes and demonstrate the relationship between the scleral sagittal height and the location of the contact lens position, (4) to examine the other possible factor (palpebral fissure size and horizontal iris diameter) on contact lens decentration.

Knowing the relationship between the scleral height and the location of the position of the contact lens on the eye will enable us to provide a rationale in how much to offset the contact lens optics and in which direction they should be offset. It will enable contact lens manufacturers to consider the optimal placement of the optical contact lens and adjusting the contact lens’ optical position, which will enhance the patient’s visual performance.
2. METHODS

2.1. Subjects:

This study was performed after Institutional Review Board Approval, and the subject's privacy was protected. In this subject case series study, a total of thirty subjects (16 male, 14 Female), were recruited from Pacific University and included former research participants, health professions students, faculty members, and their families. The inclusion criteria involved the age ranged from (18 to 60 years old), and refractive error within the range from +5:00D to -5:00D. Right and left eyes were examined for each subject (60 eyes). There were no preferences for gender and ethnicity/race in the current study. Subjects with normal medical and ocular health, and with astigmatism less than 2.00 Diop ters were included in this study. Participants with ocular diseases affecting contact lens fitting, history of ocular surgeries, history of contact lenses intolerance, high irregular astigmatism, and the use of high-risk medications were excluded from this study. Also, subjects who were known to have allergies to dye and extreme sensitivity to the light were not included in this study.

2.2. Materials:

Orion soft contact lenses that incorporated a white cross in the geometric center of the lens were used in this study. The contact lens parameters were 14.50 mm overall diameter with three different base curves (8.3 mm, 8.6 mm, and 8.9mm). All the lenses were Plano in power and were manufactured in Methafilcon 55% material, and were prism ballasted with 1.50 PD base down prism. The geometrical center of the contact lens was marked with a white cross to detect the amount of on eye decentration more easily. The contact lenses were tested with Rotlex Contest Plus system (a contact lens analyzer) to validate that the white cross was at the exact geometrical center of the lens.
Also, ophthalmic sodium fluorescein dye was used for image capture purpose with the sMap 3D. The contact lens was disinfected with Lens Fresh cleaner, and stored in Biotrue Multi-Purpose contact lens solution as recommended by the manufacture.

2.2.1. Apparatus:

2.2.1.1. Nidek ARK-510A Auto-ref/keratometer

The Nidek ARK-510A Auto-ref/keratometer is a medical appliance that contains both refractometer and keratometer in one unit. The refractometer performs measurements of the eye's refractive error including sphere, cylinder, and axis for the lenses to correct the patient's vision. The keratometer gives the corneal radius of curvature, principal meridians, and corneal cylindrical power, which helps in the contact lens fitting. The Nidek ARK-510A Auto-ref/keratometer was used to measure the refractive error, and the average corneal curvature for the participant objectively.

2.2.1.2. Keeler slit lamp

The Keeler slit lamp is a biomicroscopic slit lamp that includes a light source and magnification, and it is intended for the examination of the anterior segment and the posterior segment of the eye. It provides a magnified view of the eyelid, sclera, cornea, conjunctiva, iris, and crystalline lens. Attached is a camera to capture an image of the contact lens on the eye. Keeler slit lamp was used to evaluate the corneal integrity, and to assure the subject's eyes were healthy and did not have any infection or problem that might affect the contact lens fitting. Also, it was used to evaluate the contact lens fitting for each subject.

2.2.1.3. Medmont E300 Corneal Topographer

The Medmont E300 Corneal Topographer is a computerized video-keratometer which images the subject's corneal surface by projecting Placido rings on to the cornea. It interprets the
eye in terms of corneal elevation, curvature, refractive power, corneal height, and can simulate contact lens fluorescein patterns based on the individual corneal map taken. In this study, the axial power map was utilized, and the built-in ruler annotation was used to accurately measure the distance between the visual axis and the optical center of the contact lens. The visual axis of the eye is coincident with the smallest centered circle of the Placido rings, and the geometric center of the contact lens was marked with a white cross.

2.2.1.4. Precision Ocular Metrology - sMap3D

The sMap 3D is an eye surface topographer that uses light illumination projected on the anterior eye surface. A birefringent pattern is projected on to the surface of the eye and is used to interpret the corneoscleral topography. The device is designed mainly for customized scleral lens fitting and provides a corneal/scleral shape profile. The sMap3D was used to compare the sagittal height of the sclera in different segments at a chord of 14.50 mm from scleral elevation map. It defined the sagittal height of the scleral surface in different meridians (90°, 45°, 0°, 235°, 270°, 315°, 180°, 135°).

2.3. Procedure:

2.3.1 Recruitment:

All participants were recruited via email that explained the study's intent, inclusion, and exclusion criteria. The recruitment email was sent to all students and faculty in the college of optometry at Pacific University, and an excel sign-up sheet was attached to schedule the day and the time of the appointment. The study required only one visit of approximately one hour.
2.3.2 Consenting and Screening:

Each participant read and signed the consent form, and was given a brief questionnaire regarding their ocular history. Next, the participants' refractive error and corneal curvature were measured by using Nidek ARK-510A Auto-ref/keratometer. The average (K) reading, the sphere and the cylinder powers were recorded for the right and the left eye. Then, the participant's eyes were checked with a Keeler slit lamp to evaluate the ocular integrity and to ensure they did not have any active ocular diseases that would affect the contact lens fitting or exclude them from participation.

2.3.3 Soft Contact Lens Examination:

An eligible participant was screened the Medmont E300 corneal topographer to measure the horizontal visible iris diameter and the palpebral fissure size. The palpebral aperture size was measured from the center of the upper eyelid to the center of the lower eyelid while the subject typically fixated at the topographer fixation light. Based on the subject’s corneal diameter, a base curve of the contact lens was selected and fitted. The lenses were given a time of 10 minutes to settle before they were evaluated by slit lamp.

After making sure that the contact lenses were stable, the Medmont E300 corneal topographer was used to capture images for both eyes to visualize the contact lens position (Figure. 3). Also, it was utilized to measure the geometric position of the marked soft contact lens. The subject was asked to fixate straight at the fixation light within the instrument to get an image at the primary gaze. The clearest image captured was chosen, and Placido rings in the axial power map was used to measure the distance between the geometric center of the contact lens and the visual axis of the subject. Horizontal and vertical position of the contact lens was measured (in mm) by corneal topography ruler (Figure. 4). Moreover, the angle of the decentered
contact lens was determined by movable displayed axes showing the position of the lens on the eye (Figure. 5).

Figure 3. The Medmont E300 corneal topographer took a clear image for the right eye. The contact lens decentered to the temporal side of the eye.

Figure 4. The Medmont E300 corneal topographer showed the distance vertically (A) and horizontally (B) between the visual axis (smallest green circle) and the optical center (white cross) of the soft contact lens.
Once the contact lenses were worn and evaluated, they were removed from the participant's eyes. Next, the scleral height was measured with sMap3D Eye Surface Topographer, which interpreted the conjunctival/scleral shape. After applying ophthalmic sodium fluorescein dye (a diagnostic dye that is required by the instrument manufacturer for image capture) to the subject's eye, the subject was instructed to focus on the fixation light. The examination technique required the subjects to look at the fixation light in three different gazes. First, the straight primary-gaze image was taken while both lids were retracted; the lower lid was retracted by the subject and the upper lid by the examiner per sMap3D user manual. Second, the down-gaze image was taken, and the upper lid was lifted by the examiner. Third, the up-gaze image was taken while the subject retracted their lower lid. Images of the up, straight, and down-gaze were stitched and combined into a single image that mapped the entire anterior surface of the eye up to 22 mm in diameter (Figure. 6). In this study, the sagittal height was measured at a chord 14.50 mm (similar to the contact lenses diameter) (Figure. 7). The sagittal height of the
sclera was compared in the primary eight segments as it relates to on eye contact lens position as measures by the Medmont E300 (Figure.8).

**Figure 6.** The up, straight, and down-gaze images were stitched and combined into a single image.

**Figure 7.** An elevation map demonstrates the sagittal height value at 14.50 mm diameter in the temporal segment of the right eye.
2.4. Data Analysis:

SPSS software (Version 26, IBM Inc.) was used for data analysis. The mixed model design was used to find the geometric position of the soft contact lenses for both eyes. Also, it was conducted to compare the amount of decentration between the right and the left eyes. Besides, the relationship between the contact lenses decentration and the sagittal height of the sclera was determined by Bivariate correlation analysis.
3. RESULTS

3.1. Subject characteristics and optical features:

A total of 30 qualified subjects, 16 subjects were male, and 14 subjects were female. One subject was excluded from the analysis because of incomplete data at 14.5mm diameter for the sMap3D. The mean ± SD age was 25.5 ± 3.03 years. The mean ± SD of spherical equivalent was -1.91±1.82 (D), ranged from +0.50 diopters(D) to -6.00 diopters (D), and the mean average ± SD K was 42.77± 1.19 diopters. The base curve of the soft contact lens was chosen based on the subject’s horizontal visible iris diameter and based on a quick contact lens evaluation; 10 subjects wore 8.3 base curve contact lens, 18 subjects wore 8.6 base curve contact lens, and only two subjects wore 8.9 base curve contact lens. The horizontal visible iris diameter mean ± SD was 11.79 ± 0.38 (mm), and the vertical palpebral aperture mean ± SD was 9.77 ± 1.20 (mm). A summary data of 30 subjects for the right and left eyes are presented in Table 1.

Table 1. Summary of subject’s age, K readings, spherical equivalent, palpebral fissure size, and iris diameter.
3.2. Vertical and Horizontal Decentration:

For the decentration analysis, a Mixed model was performed to determine the amount of decentration for both eyes and to compare between the right and the left eyes. The contact lenses decentration measurements of both the right and left eyes were taken vertically and horizontally in (mm) and the total decentration were computed by trigonometric formula (the square root of the sum of the squares of vertical and horizontal decentration distances), and were confirmed with E300 corneal topography (Medmont) tools. The horizontal contact lens decentration mean ± SD was 0.81 ± 0.35 (mm) in the right eye; it was 0.67 ± 0.31 (mm) in the left eye. The contact lens frequently decentered toward the temporal quadrant for all 30 subjects for both eyes. On the other hand, the vertical decentration mean was 0.59 ± 0.38 (mm) in the right eye, and it was 0.56 ± 0.35 (mm) in the left eye. The contact lenses decentered superiorly in 28 right eyes and 27 left eyes; whereas the contact lens stayed centered along with vertical axis in two right eyes and three left eyes (Table 3). The total decentration was measured directly from the visual axis to the optical center of the contact lens, and the mean ± SD was 1.07 ± 0.36 (mm) in the right eye, and 0.94 ± 0.29 (mm) in the left eye (Table 2).

The angle of the contact lens position on the eye (where the optical center of the contact lens locates) was determined for both eyes. The angle mean ± SD for the right eye was 145.33 ± 31.95 and for the left eye was 53.6 ± 37.46 (in degrees). Thus, the mean of the angle indicated that the position of the contact lens on the eye was superior temporal for the right and the left eyes.

The mixed model results demonstrated that the horizontal decentration was not statistically significantly different between the right and left eyes ($F = 3.308, P = .079$). The effect
size was calculated (ES= 0.471) and indicated that the horizontal decentration between the right and left eyes was moderately different. Also, the vertical decentration was not statistically different between the right and the left eyes ($F = .277, P = .603, ES = 0.137$), and the effect size showed no clinical relevance. Furthermore, the total decentration was not statistically significant between the right and the left eyes ($F = 2.151, P = .153, ES = 0.235$) and was not clinically relevant.

Table 2. Horizontal, vertical, and total decentration mean and standard deviation of the soft contact lens in the left and the right eyes.

<table>
<thead>
<tr>
<th>Contact Lens Position (mm)</th>
<th>Right Eye</th>
<th></th>
<th></th>
<th></th>
<th>Left Eye</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Minimum</td>
<td>Maximum</td>
<td>Mean</td>
<td>Std. Deviation</td>
<td>Minimum</td>
<td>Maximum</td>
<td>Mean</td>
</tr>
<tr>
<td>Horizontal</td>
<td>30</td>
<td>0.16</td>
<td>1.81</td>
<td>0.809</td>
<td>0.354</td>
<td>0.11</td>
<td>1.25</td>
<td>0.672</td>
</tr>
<tr>
<td>Vertical</td>
<td>30</td>
<td>0</td>
<td>1.65</td>
<td>0.587</td>
<td>0.37635</td>
<td>0</td>
<td>1.27</td>
<td>0.555</td>
</tr>
<tr>
<td>Total Decentration</td>
<td>30</td>
<td>0.505</td>
<td>2.016</td>
<td>1.065</td>
<td>0.358</td>
<td>0.424</td>
<td>1.504</td>
<td>0.940</td>
</tr>
</tbody>
</table>

Table 3. Horizontal, vertical, and total decentration frequency in the right and left eyes.

<table>
<thead>
<tr>
<th>Contact Lens Position</th>
<th>Right Eye</th>
<th></th>
<th></th>
<th></th>
<th>Left Eye</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Frequency</td>
<td>Percent</td>
<td>Valid Percent</td>
<td>Cumulative Percent</td>
<td>Frequency</td>
<td>Percent</td>
<td>Valid Percent</td>
<td>Cumulative Percent</td>
</tr>
<tr>
<td>Centered (Vertically)</td>
<td>2</td>
<td>6.7</td>
<td>6.7</td>
<td>6.7</td>
<td>3</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Superior (Vertically)</td>
<td>28</td>
<td>93.3</td>
<td>93.3</td>
<td>100</td>
<td>27</td>
<td>90</td>
<td>90</td>
<td>100</td>
</tr>
<tr>
<td>Temporal (Horizontally)</td>
<td>30</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>30</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>
3.3. Scleral sagittal height:

The sagittal height at 14.50 mm diameter was measured in 8 segments of the sclera (superior, superior nasal, nasal, inferior nasal, inferior, inferior temporal, temporal, and superior temporal) for both eyes. The sagittal height mean was 3.321± 0.031 (mm) in the right eye, and it was 3.376± 0.031 (mm) in the left eye. The sagittal height for each segment for both eyes is presented in Table 4.

The mixed model analysis was performed to demonstrate the sagittal height differences in 8 segments of the sclera between the right and the left eyes. The sagittal height was greatest in the inferior nasal segment for the right eye (SAG=3.441 mm) while it was greatest in the inferior temporal segment for the left eye (SAG=3.422 mm). Furthermore, the lowest sagittal height was the superior and the superior temporal for the right eye (SAG= 3.271 mm), and superior for the left eye (SAG=3.191 mm). The interaction between the eye and sagittal height segments was statistically significant ($F= 4.230, P <0.001$), and the effect size was calculated for each segment (Table 5). Also, the results showed that the sagittal height varied between segments, and the bar chart demonstrated the differences in the sagittal height in each segment for each eye (Figure.9). The variation in the sagittal heights indicated the asymmetrical shape of the eye.
Table 4. The sagittal height means for each segment for right and left eyes.

<table>
<thead>
<tr>
<th>Eye</th>
<th>Sagittal Height</th>
<th>Mean</th>
<th>Std. Error</th>
<th>df</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right</td>
<td>I</td>
<td>3.419</td>
<td>0.04</td>
<td>93.302</td>
</tr>
<tr>
<td></td>
<td>IN</td>
<td>3.441</td>
<td>0.04</td>
<td>93.302</td>
</tr>
<tr>
<td></td>
<td>IT</td>
<td>3.381</td>
<td>0.04</td>
<td>93.302</td>
</tr>
<tr>
<td></td>
<td>N</td>
<td>3.404</td>
<td>0.04</td>
<td>93.302</td>
</tr>
<tr>
<td></td>
<td>S</td>
<td>3.271</td>
<td>0.04</td>
<td>93.302</td>
</tr>
<tr>
<td></td>
<td>SN</td>
<td>3.385</td>
<td>0.04</td>
<td>93.302</td>
</tr>
<tr>
<td></td>
<td>ST</td>
<td>3.271</td>
<td>0.04</td>
<td>93.302</td>
</tr>
<tr>
<td></td>
<td>T</td>
<td>3.364</td>
<td>0.04</td>
<td>93.302</td>
</tr>
<tr>
<td>Left</td>
<td>I</td>
<td>3.41</td>
<td>0.04</td>
<td>93.302</td>
</tr>
<tr>
<td></td>
<td>IN</td>
<td>3.306</td>
<td>0.04</td>
<td>93.302</td>
</tr>
<tr>
<td></td>
<td>IT</td>
<td>3.422</td>
<td>0.04</td>
<td>93.302</td>
</tr>
<tr>
<td></td>
<td>N</td>
<td>3.298</td>
<td>0.04</td>
<td>93.302</td>
</tr>
<tr>
<td></td>
<td>S</td>
<td>3.191</td>
<td>0.04</td>
<td>93.302</td>
</tr>
<tr>
<td></td>
<td>SN</td>
<td>3.212</td>
<td>0.04</td>
<td>93.302</td>
</tr>
<tr>
<td></td>
<td>ST</td>
<td>3.279</td>
<td>0.04</td>
<td>93.302</td>
</tr>
<tr>
<td></td>
<td>T</td>
<td>3.39</td>
<td>0.04</td>
<td>93.302</td>
</tr>
</tbody>
</table>

Table 5. The sagittal height effect size values in the eight segments.

<table>
<thead>
<tr>
<th>Segment</th>
<th>I</th>
<th>IN</th>
<th>IT</th>
<th>N</th>
<th>S</th>
<th>SN</th>
<th>ST</th>
<th>T</th>
</tr>
</thead>
<tbody>
<tr>
<td>ES=</td>
<td>-0.059</td>
<td>-0.887</td>
<td>0.270</td>
<td>-0.697</td>
<td>-0.526</td>
<td>-1.137</td>
<td>0.053</td>
<td>0.171</td>
</tr>
</tbody>
</table>
3.4. Contact lens decentration and scleral sagittal height:

A Bivariate correlation analysis was conducted to investigate if the sagittal height of the sclera related to the contact lens decentration position on the eye. The sagittal height in the superior temporal (where most of the contact lenses decentered to) was not statistically significant in its relationship to total decentration ($R^2 = 0.010, P = 0.868$) for the right eye and ($R^2 < 0.001, P = 0.737$) for the left eye (Figure 10).

To obtain an accurate analysis, the difference between sagittal height in the superior temporal segment and the inferior nasal segment were computed, and it was not correlated to the contact lens total decentration ($R^2 < 0.001, P = 0.934$) for the right eye and ($R^2 = 0.005, P = 0.708$) for the left eye (Figure 11). Likewise, the difference between the temporal and nasal sagittal heights was not correlated to the horizontal decentration ($R^2 = 0.020, P = 0.457$) for the right eye and ($R^2 = 0.020, P = 0.457$) for the right eye and ($R^2 =
.025, P = .401) for the left eye (Figur. 12). Also, the difference between the superior and inferior was computed and was not correlated to the vertical decentration ($R^2 = .003$, $P = .768$) for the right eye and ($R^2 = .018$, $P = .480$) for the left eye (Figur. 13).

**Figure 10.** The total decentration and the superior temporal scleral sagittal height.
Figure 11. The correlation between the decentration and the superior temporal sagittal height minus the inferior nasal sagittal height of the sclera.

Figure 12. The correlation between contact lens horizontal decentration to the difference between nasal and temporal scleral sagittal height segments.
Figure 13. The correlation between contact lens vertical decentration to the difference between superior and inferior scleral sagittal height segments.

3.5. Palpebral fissure and horizontal iris diameter:

The correlation analysis showed that the palpebral fissure was not statistically related to vertical decentration \( (R^2 = .007, P = .666) \) for the right eye and \( (R^2 < 0.001, P = .916) \) for the left eye (Figure. 14). Also, the horizontal iris diameter did not correlate to the contact lens horizontal decentration \( (R^2 = .024, P = .414) \) for the right eye and \( (R^2 = .037, P = .312) \) for the left eye (Figure. 15).
Figure 14. The correlation between contact lens vertical decentration and palpebral fissure size.

Figure 15. The correlation between contact lens horizontal decentration and the horizontal visible iris diameter.
4. DISCUSSION

Soft contact lens decentration has become an interesting topic to investigate and to study the factors that impact on the contact lens position. Eye care practitioners and manufacturers often neglect the contact lens decentration and the visual axis position that are essential factors for better vision. The main goal of this study was investigating the location of the contact lens on the eye and determining the distance between the contact lens optical center and the eye's visual axis. The current study results showed that in all cases, the contact lenses were decentered temporally along with the horizontal axis (100%) by average 0.74 mm. Along with vertical axis, 91% of the cases the contact lenses decentered superiorly by average 0.57 mm. The amount of the decentration was not significantly different between both eyes, which indicated the consistency in the amount and location in both eyes.

El-Nimri & Walline (2017) study showed similar results for contact lens position even though the average horizontal decentration was about 0.02 mm and vertical decentration was 0.29 mm. These differences might be due to measuring the decentration distance from the contact lens edge to the limbus with a slit lamp reticle magnifier. Our precise procedure to define the decentration distance has not been previously used. The marked contact lenses gave an accurate measurement with Medmont E300 Corneal Topographer. Moreover, El-Nimri & Walline (2017) indicated that the different lens designs gave different measurements in lens decentration which explained the differences between the results.

Other studies contradict our results in the vertical contact lens decentration. Fedtke et al. (2016) reported that the contact lenses decentered temporally (0.36 mm) and inferiorly (0.28 mm). Their decentration measurements were based on the distance from the contact lens edge
to the pupil center, which might be a reason for giving different values from our study. Furthermore, the material of the contact lenses and the design may explain the inferior decentration. In Fedtke et al. (2016) study, contact lenses were made of different materials, water content, designs, parameters and powers. They included high power contact lenses ranged from +6:00D to -10:00 D, which might be contributed in the opposite vertical decentration results.

Interestingly, in the current study the prism did not bring the contact lens inferiorly, and this is an unexplained situation. The prism should have some force on the lower lid that hold the contact lens in its position. However, contact lens parameters and materials could have some effect on the superior decentration. Zheng et al. (2015) findings supported our results; the lenses consistently decentered superiorly and temporally.\textsuperscript{17} They used a prism ballasted contact lenses, which were similar to prism ballasted lenses that were used in our study. Also, their contact lenses material was Hioxifilicon D 54% water content, which advocated that the water content and prism ballasted could be a cause of superior decentration.

Another study showed that an inferior decentration result was found by Vincent and Collins (2019).\textsuperscript{20} They discovered that temporal decentration distance was 0.62 mm, which is close to our temporal findings. However, their contact lenses were decentered 0.91 mm inferiorly. The irregular scleral design and the diameter of the lenses (16.50 mm) in their study were possible reasons for inferior decentration.

A 55-year-old subject was excluded from this study because of incomplete sMap3d data. This subject showed a different decentration result; the contact lenses were decentered inferiorly and temporally in both eyes. The anterior segment of the eye, including corneal curvature, and eyelid structures change with aging; which may have effects on the contact lens
position.\textsuperscript{27,28} Also, the amount and direction of decentration could be affected by ethnicity; which is an essential factor that needs to consider in future contact lens decentration studies. A previous Chinese and Caucasian study has done by Hickson-Curran et al. (2016) showed that there was an influence of ethnicity and the anatomy difference on the contact lens decentration.\textsuperscript{16}

Additionally, the current study showed that the scleral sagittal height in eight segments was significantly different. Previous studies findings showed a variation in the scleral elevations and depressions which advocated the differences in the scleral sagittal height at different meridians.\textsuperscript{29,21}

Surprisingly, our study outcomes showed a significant sagittal height difference between right and left eyes. Left eyes showed predictable results, temporal SAG greater than nasal SAG, based on the extraocular muscle insertion what causes this normal scleral asymmetry. However, 17 right eyes showed an unexpected result, nasal SAG greater than the temporal SAG. The sMap3D that was used in the current study did not show consistent measurements. For more clarification, two subjects in this study were screened with the sMap3D in two different visits. In the first visit, the sagittal height for the subject (A) showed that the temporal SAG greater than the nasal SAG for the right eye. Then, the sagittal height was reversed in the second visit; the nasal SAG was greater than the temporal (Figure.16). Subject (B) showed that the temporal SAG was greater than nasal in first visit, but the measurements were extremely different in the second visit (the difference was about 87 μm nasally and 309 μm temporally) (Figure.17). An important consideration for testing sMap3D repeatability within-subject for each measurement.
Ritzmann et al. (2018) result demonstrated that the temporal SAG greater than the nasal SAG in both eyes with Zeiss Visante AS-OCT instrument. Different results may be due to the various devices that measured the sagittal height of the sclera. OCT measures the sagittal height based on manual stitching, which may result in different readings. It has been noted that different instruments or mechanism gives different interpretations, even though they work for the same purpose. An early study compared between three instruments for measuring scleral sagittal height. Harkness et al. (2015) indicated that SAG measurements were significantly different based on different methods.
Besides, our results exhibit that the contact lenses decentration was not correlated to the sagittal height of the sclera in this study. Many studies indicated the location of the soft contact lens on the eye could be related to the scleral shape.\textsuperscript{7,17,29} However, due to inconsistent sagittal height measurements, the contact lens decentration did not reveal any correlation. Investigating the relationship between the sclera and the soft contact lens decentration has not been reported before. Further studies with different sclera instruments should be conducted to discover the causes of contact lens decentration.

Other possible factors that may contribute to the lens decentration were tested in the present study. El-Nimri & Walline (2017) expected the interaction between the lower lid and contact lens edge helped in the superior decentration. However, our findings showed neither the palpebral fissure nor the HVID was associated with lens decentration. The ethnic factor could be the confounding variable that had an influence on the correlation results.

In general, there were some methodological limitations and challenging during this study. It was too challenging to conduct sMap3D and obtain complete data, especially in the superior part of the sclera. Future studies need to consider the repeatability for each instrument and each measurement. Also, a prospective investigation needs to determine the amount of decentration in different materials, parameters, and designs. Ethnicity, gender, and age may be considered in further contact lens decentration studies.
5. CONCLUSIONS

In this study soft contact lenses consistently decenter to the superior temporal quadrant of both right and left eyes in primary gaze. The average amount of decentration was 0.74 mm temporally and 0.057 superiorly and were not significantly different between right and left eyes. Scleral shape was different between the right and left eyes and showed no correlation to the contact lens decentration.
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