

EVALUATION OF THE *COMFORT SL* SCLERAL CONTACT LENS DESIGN

by

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Has been approved

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EVALUATION OF THE *COMFORT SL* SCLERAL CONTACT LENS DESIGN

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## ABSTRACT

*Background* : This research study aimed to investigate and evaluate the *COMFORT SL* scleral contact lens design in its correction of ametropia. Assessment focused on clarity of vision, comfort level, corneal health, fit, maximum wear time, and overall patient acceptance of this design. *Methods* : 10 subjects were recruited for this study and all participants wore contact lenses of the aforementioned design for a minimum of 2 months that were ordered empirically based on comprehensive baseline data. Patients were evaluated at dispense, 1 week, 1 month, and 2 months, and various exam elements were conducted over this time period, including history, visual acuity, over-refraction, subjective responses and symptoms, slit lamp examination, objective evaluation, etc.. This data was recorded and evaluated at the conclusion of the study. *Results* : By the end of the study, 8 of the 10 subjects had worn the *COMFORT SL* scleral contact lens successfully as a daily wear modality for the entire research period. Most felt that these lenses provided the same or better vision and comfort than their previous soft spherical or toric contact lenses, and the majority said they would wear these lenses in the future on at least a part-time basis. *Conclusion* : Scleral contact lens designs, such as the *COMFORT SL* by Acculens, permit adjustment of the sagittal depth, which can allow the entire cornea to be vaulted and thus a constant reservoir of fluid to be present. Other benefits include improved lens centration and stability, an increase in best corrected visual acuity, and better overall patient comfort, all of which illustrate why this particular design has been and should continue to be so successful in the clinical setting.

## TABLE OF CONTENTS

	Page
BACKGROUND.....	vii
METHODS.....	x
RESULTS.....	xii
DISCUSSION.....	xxiii
CONCLUSION.....	xxix
REFERENCES.....	xxx

## LIST OF FIGURES

Figure		Page
1	<i>COMFORT SL</i> Study Form – Initial Visit / Fitting / Order Form .....	xxxii
2	<i>COMFORT SL</i> Study Form – Dispense, 1 Week, 1 Month, 2 Months .....	xxxiii
3	Visante Anterior Segment Ocular Coherence Tomography (OCT) Illustrating Ideal Corneal Vault .....	xxxvi
4	Anterior Segment Photography Illustrating Overall Fluorescein Pattern With Lens .....	xxxvii
5	Anterior Segment Photography Illustrating Tear Film Assessment and Ideal Corneal Vault .....	xxxviii

## BACKGROUND

Scleral contact lenses were first described by Adolf Eugen Fick in the late 1880s and are considered to be one of the first contact lens designs utilized in the clinical setting<sup>1</sup>. These early scleral lenses were ultimately unsuccessful, with failure mainly contributed to poor cornea-lens fitting relationships and hypoxia issues secondary to the glass material they were composed of. Such initial obstacles have been overcome throughout the past century as scleral lens designs have continued to improve and evolve to address these concerns. Hypoxia has been greatly reduced due to innovations in lens material, from glass to polymethylmethacrylate (PMMA), and then later to gas permeable (GP), which has increased oxygen transmission remarkably<sup>2</sup>. Fitting relationships between the cornea and lens have also increased in success drastically due to the development of improved fitting techniques, multiple advances in the manufacturing process, and an expansion in the designs and types of scleral contact lenses available.

Modern scleral contact lenses are currently defined as those greater than 18mm in diameter, however mini-scleral, semi-scleral, and corneo-scleral GP lenses are also accessible and effective, and begin at just 14.5mm. Scleral contact lenses are fit to rest upon the scleral conjunctiva and align centrally and without much movement in order to completely vault the corneal surface. The amount of vault that is created is determined by the difference in sagittal depth between the cornea and contact lens, and this space allows for a healthy reservoir of fluid to be maintained between these structures<sup>3</sup>. The number of these lenses fit by practitioners has risen considerably over the past few years, with the main reason being due to the success that this particular design has had for patients with mild to severe forms of corneal irregularities and disease. Some benefits

noted for such patients include protection of the corneal surface from a variety of factors, corneal surface hydration, masking of various types of distortion, and improved optical correction and resultant visual acuity due to the decreased prevalence of flexure and warpage<sup>2</sup>. This has led to improved vision, symptom relief, better comfort, and a more acceptable overall fit for patients that suffer from various ocular diseases.

Due to the many advantages and benefits that scleral contact lenses provide for patients with distorted and irregular corneas, many clinicians are looking toward this method of optical correction for those without corneal abnormalities. An example of such a lens is the *COMFORT SL* design by Acculens. The *COMFORT SL* lens is a semi-scleral design that is intended for patients with non-distorted, ametropic corneas. It incorporates a proprietary multiple posterior curve system that provides optimal corneal alignment and allows wearers to obtain excellent comfort and visual clarity<sup>4</sup>. The fitting process is extremely straightforward, with the practitioner needing only to provide the manifest refraction, keratometric measurements, and corneal diameter. Once accurate data is obtained, Acculens consultants take these items and design a lens of the appropriate diameter, base curve, sagittal depth, power, and center thickness in order to achieve proper fit, centration, and acuity for the patient.

The *COMFORT SL* scleral contact lens design has shown exceptional promise for the correction of non-distorted corneas with ametropia. Due to the potential of this contact lens modality, research and a comprehensive evaluation of this particular lens was warranted. The purpose of this particular study was to investigate the *COMFORT SL* scleral contact lens design in its correction of general refractive error. Assessment focused on clarity of vision, comfort level, corneal health, fit, maximum wear time, and



overall patient acceptance of this design, with the ultimate goal being an accurate and complete assessment of how successful the *COMFORT SL* lens would be when designed from the required examination elements.

## METHODS

An investigator fit each of the 10 subjects that participated in this study with the new *COMFORT SL* scleral contact lens design empirically based on comprehensive baseline data. After the subjects were successfully fit in these lenses, they were asked to wear them for a minimum of 2 months as a daily wear modality. Throughout this investigatory period, patients were asked to remain cognizant and evaluate various aspects of these lenses, including vision, comfort, maximum wear time, etc.

The following examination elements were performed and recorded at the initial visit and utilized for the empirical design process:

- Detailed Explanation of Project
- Completion of Informed Consent
- Patient History
- Manifest Refraction
- Distance Visual Acuity
- Corneal Topography
  - Keratometric Measurements
  - Corneal Diameter
- Slit Lamp Examination

At the dispense, 1 week, 1 month, and 2 months visits, the subsequent tests were completed and documented :

- Patient History
- Visual Acuity
  - Distance

- Near
- Over-Refraktion
  - Distance Visual Acuity
- Subjective Quote, Responses, and Symptoms
- Slit Lamp Examination
- Fitting Characteristic Evaluation

Following evaluation of the initial pair of the *COMFORT SL* contact lens, modification (by reordering) of the lens parameters was performed if necessary to improve fitting characteristics and/or visual acuity.

In addition to the aforementioned data that was collected, Visante Ocular Coherence Tomography (OCT) of the anterior segment was executed at this visit to visually capture the cross-sectional corneal profile and to quantify the amount of corneal vault present. Anterior segment photography was also performed at the 1 month visit to document the overall fluorescein pattern appearance with the lens and to assess the tear film and amount of corneal vault on all subjects by utilizing the Marco idoc camera system mounted to the slit lamp.

All of the data collected from this study was recorded on exam forms specific to this study and kept in patient folders created for this research project. All information will be retained solely at the Michigan College of Optometry.

## RESULTS

At the initial visit, all 10 subjects were first given a detailed explanation of the research project and asked to read and complete an informed consent document. Next, a history was obtained regarding applicable details about ocular health, past refractive correction, success with such products, etc. This revealed that half of the subjects had worn soft spherical contact lenses successfully, but with 1 having suffered from solution sensitivities and ocular allergies, and another of whom had a history of dry eye and wore these lenses only for sports and outdoor activities. The other half of the participants had a history of wearing soft toric contact lenses, only 1 of whom reported consistently good overall comfort and vision. The other 4 had some vision fluctuation and compromised comfort with this type of lens. Manifest refraction and an anterior slit lamp examination were then done on all of the subjects for baseline data. Finally, an average of 3 corneal topography measurements were used to determine simulated keratometric values and corneal diameter. This information was then used to order *COMFORT SL* scleral contact lenses empirically for all 10 subjects.

At the dispense visit, one of the investigators inserted the lenses into the subjects' eyes (with fluorescein added to aid in sagittal depth and tear film assessment) and measured distance visual acuity. Of the 20 eyes involved, 16 were in the 20/20 range, 2 were in the 20/25 range, 1 was in the 20/30 range, and 1 was in the 20/40 range. Next, an over-refraction was performed, which yielded 20/20 vision for all 20 eyes. The participants were then asked to give a subjective quote about the new lenses. Most discussed either the comfort of the lens (4 addressed some awareness and slight irritation) or vision (4 reported vision that was a little blurry) that they experienced. Next, all

subjects were asked to rate certain items subjectively for both the right and left eye based on a scale from 1 to 10, with 1 being extremely poor and 10 being extremely good. The mean and mode responses are noted below:

	Mean	Mode
OD Vision	7.8	8
OS Vision	7.5	8
OD Comfort	7.9	8
OS Comfort	7.9	9
OD Overall Opinion	7.9	9
OS Overall Opinion	7.6	8

Next, they were asked to rate subjective symptoms on a scale from 0 to 4, with 0 being absent and 4 being severe. The mean and mode of these responses are noted below:

	Mean	Mode
OD Irritation	0.7	1
OS Irritation	0.6	1
OD Awareness	1.2	1
OS Awareness	1.1	1
Cloudy/Variable OD Vision	0.8	0
Cloudy/Variable OS Vision	0.6	0

Finally at the dispense visit, a slit lamp examination was performed and the lens fit was evaluated. Centration was evaluated objectively on a scale from -2 to +2, with -2 = extreme temporal decentration (clinically unacceptable), -1 = temporal decentration (clinically acceptable), 0 = optimal centration, +1 = nasal decentration (clinically acceptable), and +2 = extreme nasal decentration (clinically acceptable). Sagittal depth was evaluated on a similar scale, with -2 = central bearing and/or limbal bubbles (clinically unacceptable), -1 = light bearing (clinically acceptable), 0 = alignment, +1 = slightly steep (clinically acceptable), and +2 = deep pooling and/or central bubbles (clinically unacceptable). The periphery was also estimated on a scale in which -2 = excessive lift off sclera (clinically unacceptable), -1 = slight lift off sclera (clinically acceptable), 0 = ideal scleral fit, +1 = slightly steep without blanching (clinically acceptable), and +2 = excessive impingement (clinically unacceptable). The mean and mode results are noted below:

	Mean	Mode
OD Centration	0	0
OS Centration	0	0
OD Sagittal Depth	-0.4	0
OS Sagittal Depth	-0.4	0
OD Periphery	-0.1	0
OS Periphery	-0.1	0

Finally, tear film assessment was performed to estimate the amount of corneal vault in microns. The mean and mode in both the right and left eyes were 100 microns.

Based on the results of the dispense visit, lenses needed to be reordered for 4 of the subjects. 1 due to poor vision, 1 as a result of poor fit, and 2 secondary to a combination of both decreased vision and excessive corneal touch. At the second dispense visit for these subjects, all had acceptable vision, fit, and improved subjective responses.

A follow-up was conducted 1 week post-dispense following a similar examination sequence to the dispense visit. Distance visual acuity of the 20 eyes yielded 18 in the 20/20 range and 2 in the 20/25 range (over-refraction, again, brought all to 20/20 vision). Subjective quotes about the lenses were again focused on comfort and vision, with 2 noticing some lens awareness and 2 observing somewhat blurry and/or fluctuating vision. Next, all subjects were asked to rate certain items subjectively for both the right and left eye based on a scale from 1 to 10, with 1 being extremely poor and 10 being extremely good. The mean and mode responses are noted below:

	Mean	Mode
OD Vision	8.7	10
OS Vision	7.7	10
OD Comfort	8.5	7 & 10
OS Comfort	8.4	7 & 9
OD Maximum Wear Time	8.4	7 & 9
OS Maximum Wear Time	8.4	7 & 9
OD Overall Opinion	8.4	8 & 10
OS Overall Opinion	8.5	8

Next, they were asked to rate subjective symptoms on a scale from 0 to 4, with 0 being absent and 4 being severe. The mean and mode of these responses are noted below:

	Mean	Mode
OD Irritation	1.2	1 & 2
OS Irritation	1.2	1 & 2
OD Awareness	1	1
OS Awareness	1.1	1
OD Redness	1.1	0
OS Redness	1.3	1
Cloudy/Variable OD Vision	1.3	1
Cloudy/Variable OS Vision	1.2	1
OD Light Sensitivity	0.2	0
OS Light Sensitivity	0.2	0

At this visit, the investigator also rated examination findings objectively on a scale from 0 to 4, with 0 being absent and 4 being severe. The mean and mode of these responses are noted below:

	Mean	Mode
OD Injection	0.7	0
OS Injection	0.7	0
OD Central Staining	0	0
OS Central Staining	0	0



OD Peripheral Staining	0.5	0
OS Peripheral Staining	0.8	0, 1
OD Corneal Edema	0	0
OS Corneal Edema	0	0

Centration and peripheral fit were the last items evaluated at this visit based on the -2 to +2 scale as outlined at the dispense visit. The mean and mode results are noted below:

	Mean	Mode
OD Centration	0	0
OS Centration	0	0
OD Periphery	+0.1	0
OS Periphery	+0.1	0

The 1 month follow-up examination was conducted in the same manner. Distance visual acuity of the 20 eyes yielded 17 in the 20/20 range, 2 in the 20/25 range, and 1 in the 20/30 range (over-refraction yielded 20/20 vision for all). Subjective quotes included mainly positive comments, with 2 noting slightly blurry vision. Next, all subjects were asked to rate certain items subjectively for both the right and left eye based on a scale from 1 to 10, with 1 being extremely poor and 10 being extremely good. The mean and mode responses are noted below:

	Mean	Mode
OD Vision	8.8	9
OS Vision	8.4	10
OD Comfort	8.7	9
OS Comfort	8.8	9
OD Maximum Wear Time	8.5	9
OS Maximum Wear Time	8.5	9
OD Overall Opinion	8.4	9
OS Overall Opinion	8.4	9

Next, they were asked to rate subjective symptoms on a scale from 0 to 4, with 0 being absent and 4 being severe. The mean and mode of these responses are noted below:

	Mean	Mode
OD Irritation	0.7	1
OS Irritation	0.8	1
OD Awareness	0.9	1
OS Awareness	1	1
OD Redness	0.2	0
OS Redness	0.2	0
Cloudy/Variable OD Vision	0.8	0
Cloudy/Variable OS Vision	0.7	0
OD Light Sensitivity	0	0

OS Light Sensitivity	0	0
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At this visit, the investigator also rated examination findings objectively on a scale from 0 to 4, with 0 being absent and 4 being severe. The mean and mode of these responses are noted below:

	Mean	Mode
OD Injection	0.2	0
OS Injection	0.2	0
OD Central Staining	0	0
OS Central Staining	0	0
OD Peripheral Staining	0.2	0
OS Peripheral Staining	0.5	0 & 1
OD Corneal Edema	0	0
OS Corneal Edema	0	0

Centration, sagittal depth, and peripheral fit were the last items evaluated at this visit based on the -2 to +2 scale as outlined at the dispense visit. The mean and mode for all three parameters was 0.

At this 1 month visit, anterior segment photography and Visante OCT of the anterior segment were also performed. Examples of these can be found in the figures section and demonstrate an ideal fluorescein pattern, tear film assessment, and amount of corneal vault as noted by the majority of our subjects.

The subjects in this study were evaluated one last time at 2 months post-dispense. 2 of the subjects had reported not wearing the lenses over the past month secondary to ocular allergy and comfort issues and that they had been wearing primarily spectacles during this time. Of the 16 eyes remaining, all 16 had 20/20 range vision. Of the 8 participants that were evaluated at this follow-up, all had positive subjective quotes. They were asked to rate certain items subjectively for both the right and left eye based on a scale from 1 to 10, with 1 being extremely poor and 10 being extremely good. The mean and mode responses are noted below:

	Mean	Mode
OD Vision	9.5	9 & 10
OS Vision	9.13	9
OD Comfort	9	9
OS Comfort	8.88	8 & 9
OD Maximum Wear Time	8.63	9
OS Maximum Wear Time	8.63	9
OD Overall Opinion	8.63	9
OS Overall Opinion	8.38	9

Next, they were asked to rate subjective symptoms on a scale from 0 to 4, with 0 being absent and 4 being severe. The mean and mode of these responses are noted below:

	Mean	Mode
OD Irritation	0.5	0 & 1

OS Irritation	0.5	0 & 1
OD Awareness	0.5	0 & 1
OS Awareness	0.5	0 & 1
OD Redness	0.88	1
OS Redness	0.88	1
Cloudy/Variable OD Vision	1	1
Cloudy/Variable OS Vision	0.88	1
OD Light Sensitivity	0	0
OS Light Sensitivity	0	0

At this visit, the investigator also rated examination findings objectively on a scale from 0 to 4, with 0 being absent and 4 being severe. The mean and mode of these responses are noted below:

	Mean	Mode
OD Injection	0.38	0
OS Injection	0.38	0
OD Central Staining	0	0
OS Central Staining	0	0
OD Peripheral Staining	0.75	0
OS Peripheral Staining	0.75	0
OD Corneal Edema	0	0
OS Corneal Edema	0	0

Centration, sagittal depth, and peripheral fit were the last items evaluated at this visit based on the -2 to +2 scale as outlined at the dispense visit. The mean and mode for all three parameters was 0.

At the conclusion of the study, 8 of the 10 subjects had successfully worn the *COMFORT SL* scleral contact lens as a daily wear modality for 2 months. Most felt that these lenses provided the same or better vision and comfort than they were used to with their soft spherical or toric contact lenses, and the majority said they would wear these lenses in the future on at least a part-time basis.

## DISCUSSION

The *COMFORT SL* scleral contact lens from Acculens is a semi-scleral design that is intended for patients with general ametropia and who lack corneal irregularities. It consists of a proprietary multiple posterior curve system that allows it to align properly on the cornea and provide superior comfort and vision for its wearers<sup>4</sup>. Acculens consultants design these lenses by taking into account three examination elements: manifest refraction, keratometric measurements, and corneal diameter. Based on these data points, the proper material, diameter, base curve (BC), sagittal depth (SAG), power, and center thickness can be selected to provide the best overall fit and visual acuity.

Lens material must be designated, and those with a higher oxygen transmission (DK) are often preferred since there is minimal movement and tear exchange with this particular design. High DK materials offer a greater chance of better overall ocular health when compared to lower DK materials, since the eye is receiving more oxygen with the former<sup>5</sup>. The most frequently used material for this design is Boston XO2, which has a DK of 141 and both good wettability and stability<sup>6</sup>. Next, the diameter of the lens must be selected. The most common size of the *COMFORT SL* is 16.2mm, but it can be manufactured larger or smaller based on the diameter of the patient's cornea. Both the BC and SAG are determined by taking into account the overall corneal shape and amount of astigmatism, and are set by the consultants. The ideal SAG will completely vault the cornea by approximately one-hundred microns. Final power of the lens is also designated by the consultants and is determined by utilizing the flat keratometric value and the manifest spectacle refraction. Finally, the center thickness is

based on the other parameters of the lens and is calculated by the laboratory during the development process<sup>4</sup>.

In order to determine whether an appropriate fit has been obtained, evaluation with fluorescein dye must be conducted. This is best done by instilling the dye into the sterile saline solution that fills the concave lens surface at the time of insertion. A full, even fluorescein pattern should be noted when evaluating with a wide, blue beam; this denotes complete vaulting of the cornea. A yellow Wratten filter can aid in this evaluation and should be used on all scleral lens fits<sup>7</sup>. Next, the amount of corneal vault should be determined, which can be done by using a thin parallelepiped beam under white illumination. By placing the beam to the side and comparing the thickness of the fluorescein fluid reservoir to the thickness of the cornea, a relatively accurate estimation of corneal vault can be made<sup>8</sup>. Since one-hundred microns of vault is ideal, the fluorescein reservoir should be roughly one-fifth the breadth of the cornea. If there is any bearing, the SAG should be increased by 0.1mm for every 1mm of touch in order to obtain the best possible fit. Conversely, if there is excessive vault, flatter lenses can be selected in succession until one is found that provides the ideal SAG<sup>8</sup>.

The edge of the lens is meant to rest upon the scleral conjunctiva without impinging or excessively lifting off of it. If it is impinging, it will cause blanching of the fine conjunctival vessels under the lens and could lead to discomfort, redness, and/or corneal edema. If the lens lifts off of the sclera in excess, it can lead to lens awareness and possible discomfort. If either of these problems are noted, the peripheral curves can be modified to provide a more appropriate edge relationship<sup>4</sup>.



If all of the aforementioned elements are correct, an ideal fit will be attained. This would mostly likely translate to excellent comfort and best corrected visual acuity for the patient.

Insertion and removal is one of the most important aspects of scleral contact lens wear, and potentially the most challenging. It is essential for the patient to know how to perform these techniques correctly and to understand why proper methods are necessary. A large diameter plunger is best utilized throughout both the insertion and removal process. For insertion, the lens should be placed convex side down on the plunger. Next, the concave surface should be filled completely to almost overflowing with a non-preserved sterile saline. This helps maintain a full and even fluid reservoir between the cornea and lens and also helps to reduce the risk and likelihood of insertion bubbles, which can potentially cause some discomfort and decreased visual acuity for the patient. The patient should then place their head directly parallel to the ground and insert the lens straight onto the cornea. After insertion, the lens should be allowed to settle for approximately 20 minutes before final visual acuity, over-refraction, and fit is performed to obtain the most accurate data. To remove the lens, a rewetting drop or saline irrigation should be utilized to loosen the lens, since it tends to settle and tighten somewhat over the course of wear time. The patient should look up slightly and place the plunger on the lower third of the lens to create some suction. The lens can then be removed with the aid of the plunger<sup>4</sup>.

Occasionally, some ocular concerns arise secondary to scleral contact lens wear. These may include corneal edema, excessive edge lift, superficial punctate keratitis (SPK), decreased visual acuity, and redness<sup>4</sup>. Corneal edema can occur if there is too

much vault present or if the edge of the lens is impinging onto the scleral conjunctiva. This can be resolved by either decreasing the sagittal depth in the case of the former, or by flattening the peripheral curves to decrease a tight edge fit. Excessive edge lift has the potential to occur if the SAG is too low or if the peripheral curves are too flat. These issues can be corrected by either increasing the sagittal depth or by steepening the peripheral curves of the lens. SPK can potentially develop if the lens is filled with a non-preservative free solution or if there is bearing on the cornea. Solutions to these problems would be to utilize a preservative free solution or to increase the SAG value. Decreased acuity can frequently occur if debris and deposits collect along the visual axis of the lens. By encouraging the patient to properly clean the lenses with an abrasive cleaner, especially on the inner concave surface, or by possibly changing to a hydrogen peroxide based system, this can be resolved. Finally, redness of the conjunctival sclera can occur if the SAG is too deep or the peripheral curves are overly tight. Solutions include decreasing the SAG or flattening the peripheral curves<sup>4</sup>. Again, the aforementioned concerns are not extremely common, but knowing how to address such issues if they arise can be extremely important throughout the evaluation process.

There are a few different cleaning systems that can be used with the *COMFORT SL* lens. Two of the most frequently prescribed are Boston Advance and Clear Care. Boston Advance, a 2-step system with an abrasive cleaner and a cushioning conditioning solution, and Clear Care, a preservative-free hydrogen peroxide system, are effective at cleaning, disinfecting, and storing these lenses.

A major benefit of the *COMFORT SL* scleral contact lens is the ability to incorporate a sphero-cylindrical over-refraction by utilizing a front-toric design. This is

denoted by either a dot marking or prism ballast that should be inserted to sit at the 6 o'clock position. Since this particular design provides such exceptional centration and has little to no movement, the front toric is able to lock into place to improve visual acuity. This capability can be extremely beneficial for patients, and is often able to provide better and more stable vision than soft toric contact lenses.

Until recently, the best way to fit scleral contact lenses was through a diagnostic approach in which various trial lenses were inserted and a bracketing technique was utilized to determine the best overall fit. This method proved to be a rather lengthy and tedious process, and one that was affected by subjective influence<sup>9</sup>. Of late, use of various imaging instruments, such as the Visante OCT, has proven to be an effective alternative to the previous protocol. The Visante OCT is a non-contact device that can generate cross-sectional views of the anterior segment and corneal profile, producing up to a 16mm wide image<sup>9</sup>. It has the capability to measure various structures by using a built-in caliper function, such as the amount of vault between the cornea and lens, which was performed on all of our subjects in this study at the 1 month visit. Research is constantly emerging regarding new ways to utilize this equipment to streamline the fitting process for scleral contact lenses. This could in turn make it a much more objective and standardized evaluation. Such anterior segment imaging is proving to be a valuable addition to traditional corneal topography and diagnostic fitting techniques by providing more accurate data about the peripheral cornea and sclera<sup>9,10</sup>.

At the conclusion of this study, a few potential limitations were noted. Firstly, all of the subjects that participated in this research project were optometry students. Since they have a broad background in how these lenses function, their expectations can be

quite high and they can be over-critical about overall performance. Another potential limitation, and one that may have prolonged the fitting process for some of the subjects, was that we utilized the ruler function on the Medmont Corneal Topographer to determine the corneal diameter. This method seemed to underestimate the actual corneal size, which led to a few improper initial fits. If this is used in the future, we have found that by adding 0.5mm to the corneal diameter as measured by the ruler function, a more appropriate corneal diameter, and thus initial fit, would be obtained. Finally, although the Visante anterior segment OCT was an excellent resource and may have the potential to streamline scleral contact lens fitting in the future, the high cost of this instrument is a definite constraint for the average practitioner.

## CONCLUSION

Fitting a scleral contact lens design on a patient with an irregular cornea, especially if an advanced disease process or severe distortion is present, can be extremely beneficial. The same holds true for patients with general ametropia who lack such irregularities. Like other contact lenses in this category, the *COMFORT SL* design permits adjustment of the sagittal depth, which can allow the entire cornea to be vaulted and thus a constant reservoir of fluid to be present. Other benefits include improved lens centration and stability, an increase in best corrected visual acuity, and better overall patient comfort, all of which illustrate why this particular design has been and should continue to be so successful in the clinical setting.

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FIGURE 1: *COMFORT SL* Study Form – Initial Visit / Fitting / Order Form

**COMFORT SL Study Form**

**Initial Visit / Fitting / Order Form**

**Subject Name:** \_\_\_\_\_ **Date of Birth:** \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**Investigator:** \_\_\_\_\_

**Date:** \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**Project Explanation and Informed Consent Completed:**      YES      NO

**History:** \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**Manifest Refraction:**

OD: \_\_\_\_\_ VA: \_\_\_\_\_  
 OS: \_\_\_\_\_ VA: \_\_\_\_\_

**Corneal Topography Performed:**      YES      NO

**Keratometry:**

OD: \_\_\_\_\_ @ \_\_\_\_\_ ; \_\_\_\_\_ @ \_\_\_\_\_  
 OS: \_\_\_\_\_ @ \_\_\_\_\_ ; \_\_\_\_\_ @ \_\_\_\_\_

**Corneal Diameter:**

OD: \_\_\_\_\_  
 OS: \_\_\_\_\_

**Slit Lamp Examination:**

	<b>OD</b>	<b>OS</b>
<b>Ocular Adnexa</b>		
<b>Tear Film</b>		
<b>Conjunctiva</b>		
<b>Cornea</b>		
<b>Anterior Chamber</b>		
<b>Iris</b>		

**Comfort SL Contact Lens Parameters**

OD: BC \_\_\_\_\_ Power \_\_\_\_\_ Diameter \_\_\_\_\_ SAG \_\_\_\_\_  
 OS: BC \_\_\_\_\_ Power \_\_\_\_\_ Diameter \_\_\_\_\_ SAG \_\_\_\_\_



FIGURE 2: *COMFORT SL* Study Form – Dispense, 1 Week, 1 Month, 2 Months

**COMFORT SL Study Form**

**Visit Type (circle one):      Dispense      1 Week      1 Month      2 Months**

**Subject Name:** \_\_\_\_\_ **Date of Birth:** \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**Investigator:** \_\_\_\_\_

**Date:** \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**History:** \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**Visual Acuity:**

	Distance	Near
OD		
OS		

**Over-Refraction:**

	Distance
OD	
OS	

**Subjective Quote:**

\_\_\_\_\_  
 \_\_\_\_\_

**Subjective Responses:**

*\* Ask the subject to rate the following items based on the scales as shown and circle the appropriate response (0=extremely poor; 10=extremely good)*

**Vision:**

OD -    1    2    3    4    5    6    7    8    9    10  
 OS -    1    2    3    4    5    6    7    8    9    10

**Comfort:**

OD -    1    2    3    4    5    6    7    8    9    10  
 OS -    1    2    3    4    5    6    7    8    9    10

**Maximum Wear Time:**

OD -    1    2    3    4    5    6    7    8    9    10  
 OS -    1    2    3    4    5    6    7    8    9    10

**Overall Opinion:**

OD -    1    2    3    4    5    6    7    8    9    10  
 OS -    1    2    3    4    5    6    7    8    9    10

**Subjective Symptoms:**

\* Ask the subject to rate the presence/severity of the following symptoms and then write in the appropriate response for each eye on the line provided

**Irritation (i.e. dryness, burning, scratching, grittiness, stinging, itching)**

- 0 = absence
- 1 = minimal      **OD** \_\_\_\_\_
- 2 = mild
- 3 = moderate    **OS** \_\_\_\_\_
- 4 = severe

**Awareness**

- 0 = absence
- 1 = minimal      **OD** \_\_\_\_\_
- 2 = mild
- 3 = moderate    **OS** \_\_\_\_\_
- 4 = severe

**Redness**

- 0 = absence
- 1 = minimal      **OD** \_\_\_\_\_
- 2 = mild
- 3 = moderate    **OS** \_\_\_\_\_
- 4 = severe

**Cloudy/Variable VA**

- 0 = absence
- 1 = minimal      **OD** \_\_\_\_\_
- 2 = mild
- 3 = moderate    **OS** \_\_\_\_\_
- 4 = severe

**Light Sensitivity/Halos**

- 0 = absence
- 1 = minimal      **OD** \_\_\_\_\_
- 2 = mild
- 3 = moderate    **OS** \_\_\_\_\_
- 4 = severe

**Slit Lamp Examination:**

	<b>OD</b>	<b>OS</b>
<b>Ocular Adnexa</b>		
<b>Tear Film</b>		
<b>Conjunctiva</b>		
<b>Cornea</b>		
<b>Anterior Chamber</b>		
<b>Iris</b>		

**Injection**

- 0 = absence of signs
- 1 = minimal amount      **OD** \_\_\_\_\_
- 2 = mild amount
- 3 = moderate amount    **OS** \_\_\_\_\_
- 4 = severe amount

**Central Staining**

- 0 = absence of signs
- 1 = minimal amount      **OD** \_\_\_\_\_
- 2 = mild amount
- 3 = moderate amount    **OS** \_\_\_\_\_
- 4 = severe amount

**Peripheral Staining**

0 = absence of signs  
1 = minimal amount      **OD** \_\_\_\_\_  
2 = mild amount  
3 = moderate amount      **OS** \_\_\_\_\_  
4 = severe amount

**Corneal Edema**

0 = absence of signs  
1 = minimal amount      **OD** \_\_\_\_\_  
2 = mild amount  
3 = moderate amount      **OS** \_\_\_\_\_  
4 = severe amount

**Other** \_\_\_\_\_

0 = absence of signs  
1 = minimal amount      **OD** \_\_\_\_\_  
2 = mild amount  
3 = moderate amount      **OS** \_\_\_\_\_  
4 = severe amount

**Other** \_\_\_\_\_

0 = absence of signs  
1 = minimal amount      **OD** \_\_\_\_\_  
2 = mild amount  
3 = moderate amount      **OS** \_\_\_\_\_  
4 = severe amount

**Lens Fitting Rating Scales:**

**Centration**

-2 = extreme temporal decentration, clinically unacceptable  
-1 = temporal decentration, clinically acceptable      **OD** \_\_\_\_\_  
0 = optimal centration  
+1 = nasal decentration, clinically acceptable      **OS** \_\_\_\_\_  
+2 = extreme nasal decentration, clinically unacceptable

**Fluorescein Pattern Interpretation/Sagittal Depth**

-2 = central bearing and/or limbal bubbles, clinically unacceptable  
-1 = light bearing, clinically acceptable      **OD** \_\_\_\_\_  
0 = alignment  
+1 = slightly steep, clinically acceptable      **OS** \_\_\_\_\_  
+2 = deep pooling and/or central bubbles, clinically unacceptable

**Edge/Periphery**

-2 = excessive lift off sclera, clinically unacceptable  
-1 = slight lift off sclera, clinically acceptable      **OD** \_\_\_\_\_  
0 = ideal scleral fit  
+1 = slightly steep (no blanching), clinically acceptable      **OS** \_\_\_\_\_  
+2 = excessive impingement, clinically unacceptable

**Tear Film Assessment**

**OD** \_\_\_\_\_ microns  
**OS** \_\_\_\_\_ microns

FIGURE 3: Visante Anterior Segment Ocular Coherence Tomography (OCT) Illustrating Ideal Corneal Vault

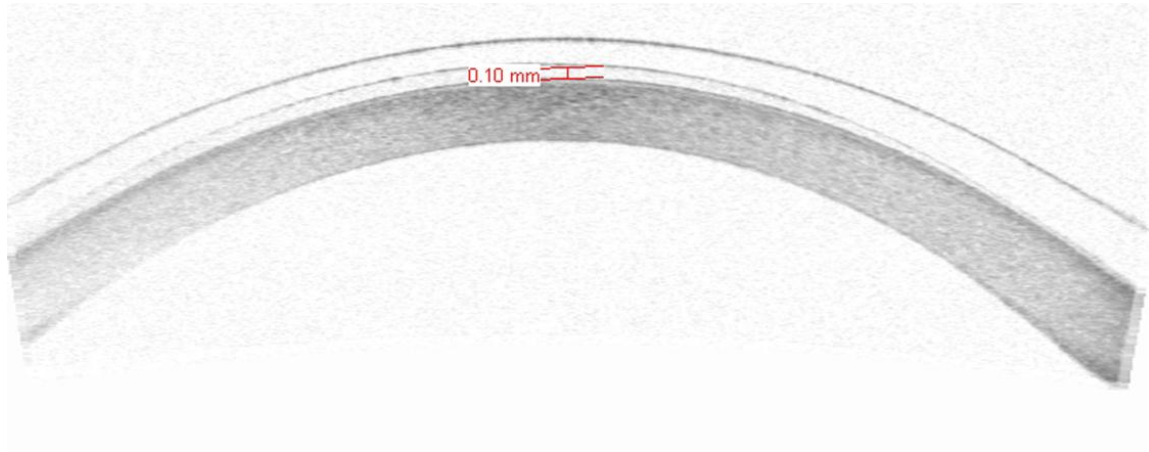


FIGURE 4: Anterior Segment Photography Illustrating Overall Fluorescein Pattern With Lens

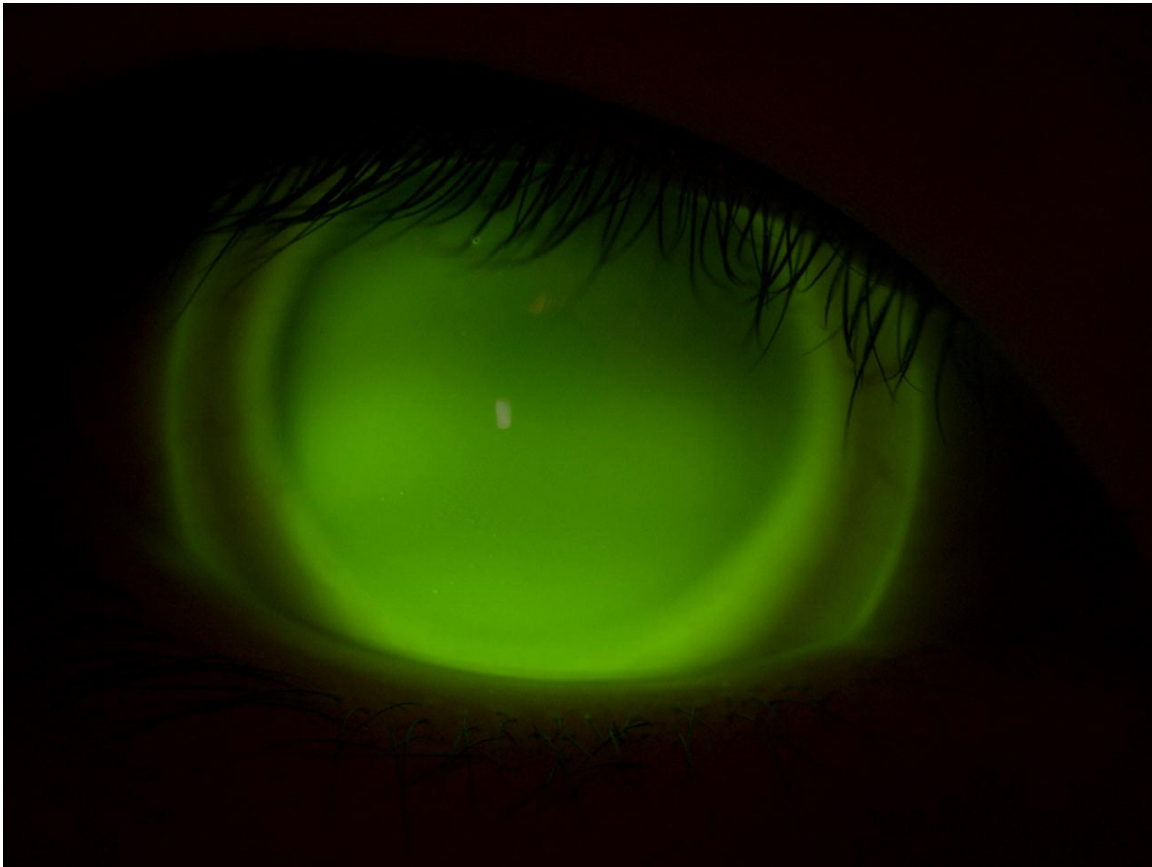


FIGURE 5: Anterior Segment Photography Illustrating Tear Film Assessment and Ideal Corneal Vault

