CREATE A FOMULA TO EXTRAPOLATE THE CORNEAL SAGITTAL HEIGHT TO FIT SCLERAL CONTACT LENSES BY USING THE MEDMONT E300 CORNEAL TOPOGRAPHER WITHOUT THE NEED OF THE VISTANE OCULAR COHERENCE TOMOGRAPHY

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ABSTRACT

Background: This study predicts a modified equation for calculating sagittal depth for a desired scleral lens diameter without the need of an anterior segment Vistane Ocular Coherence Tomography (OCT). This will allow eye care practitioners to fit scleral lenses more effectively. Scleral lenses are mostly used in a specialty contact lens setting. These include- but are not limited to- vision improvement with irregular corneas, corneal protection, cosmetics and sports. *Methods:* Thirty eight subjects, totaling 76 eyes, volunteered to be a part of this study. The data collected through Medmont E300 and Vistane OCT was then statistically analyzed to create an equation to predict a sagittal height for fitting various diameter scleral contact lenses. *Results:* An excel program was used along with a statistical analysis software (SPSS) program which showed that the collected data followed quadratic relationship. This relationship showed $P \ll 0.05$. *Conclusion:* The eye care practitioner enters the desired scleral lens diameter and the Medmont topography sagittal height value at a 10.0mm chord length into the equation to obtain the sagittal height parameters for a trial lens. It is critical for optometrists, especially those serving the specialty contact lens field, to be able to provide the most appropriate contact lens option to the patient.

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INTRODUCTION

The concept of correcting corneal refractive error was initially proposed by Leonardo da Vinci in 1508 through the development of a liquid reservoir[1]. Scleral contact lenses made from blown glass, originally called “shells”, were first used in the late 1800s[2]. The popularity of these scleral contact lenses was soon decreased due to the high complication rate of corneal hypoxia, the lens suction and the inability to duplicate the lens parameters. Advancements in molding techniques in 1936 allowed for a more accurate fitting, which eventually led to the discovery of polymethyl methacrylate (PMMA) in 1940s[1]. The very first scleral contact lens made with oxygen permeable material was used by Don Ezekiel, O.D. in 1983. In 1994, the Food and Drug Administration (FDA) approved the use of scleral contact lenses for irregular corneas[2].

Today, scleral lenses are mostly used in a specialty contact lens setting. These include- but are not limited to- vision improvement with irregular corneas, corneal protection, cosmetics and sports. In conditions such as keratoconus, keratoglobus, pellucid marginal degeneration, post-refractive complications, traumas and corneal transplants, scleral lenses have shown to improve vision when standard gas permeable and soft lenses have failed. Scleral lenses are also used to protect the cornea in cases of exposure keratitis, Sjögern’s dieases, Stevens-Johnson syndrome, ocular cicatricial pemphigoid and graft versus host disease[2]. A study by Romero et al revealed improvements in comfort with scleral contact lenses in 92% of patients with ocular surface disorders, and 53% of the patients showed improvement in vision by two snellen lines or more[2]. Scleral contact lenses are occasionally used for cosmetic purposes. For instance, in cases of aniridia and ocular albinism, the lenses are painted to disguise the abnormality and to decrease glare. Another example includes unilateral or bilateral ptosis, in which scleral lenses can be made to lift the upper eyelid away from the visual axis and to match it to the other eye[2]. Lastly, scleral contact lenses are sometimes used in water sports and other sports-related activities due to lens stability, corneal hydration and good vision. Furthermore, they are utilized in dry and dusty environments.

It is not uncommon for patients with progressive corneal conditions to be referred to an optometrist for specialty contact lens fittings to avoid or postpone corneal transplant surgery. A study by Smiddy et al in 1988 demonstrated that 69% of the patients undergoing keratoplasty could have avoided the surgery and would have improved vision with scleral contact lenses. However 15-20% of the keratoconus patients will eventually go through keratoplasty with transplant survival rate being 74% after 5 years, 64% after 10 years, 27% after 20 years and 2% after 30 years[1]. Therefore, keratoplasty should be the last resort due to potential complications.

The purpose of our research is to predict a modified equation for calculating sagittal depth for a desired scleral lens diameter without the need of an anterior segment Vistane Ocular Coherence Tomography (OCT). This will allow eye care practitioners to fit scleral lenses more effectively.

METHODS

Thirty eight subjects, totaling 76 eyes, volunteered to be a part of this study. They were mostly first, second and third year optometry students along with some family members. The majority of the subjects' age range included 21-55 years of age, with most being of Caucasian descent and only a few minorities. The data was collected using noninvasive procedures using a Medmont E300 topographer and a Visante anterior segment OCT. The subjects were asked to sign an informed consent form before undergoing the imaging procedures. Once the informed consent forms were collected, a topography of the cornea of both eyes was obtained, followed by an anterior segment OCT. Exclusions from the study are current orthokeratology patients, patients with a corneal disease or ectasia, and patients who have undergone any sort of corneal surgery in the past.

The Medmont E300 topographer shows a topographical map of the cornea on a set chord length of 10.00mm. We were able to obtain the sagittal height of each eye for that specific chord length simply by using the analysis feature of the software that outlines the details of the cornea. The topographer could not provide us with an accurate measurement of sagittal depth for chord lengths greater than 10.00mm. Two images of each eye were saved based on the quality of the image. All of the images chosen had a quality score of 92 percent or above, with the majority being 98 percent or 99 percent. These values are based on focus and movement. Medmont E300 defines a good score as 75 or above[3]. Additionally, the images chosen were based on satisfactory patient fixation, eyelid position and central ring clarity.

The Visante anterior segment OCT presents a transverse section of the cornea to help us visualize and measure the sagittal depth of the cornea. The transverse section of anterior segment was attempted at the visual axis with good alignment, minimizing tilt of the iris in order to accurately determine the sagittal depth. Once all the data was collected, the caliper feature of the OCT was used to measure sagittal depth for chord lengths of 10mm, 11mm, 12mm, 13mm, 14mm, 15.00mm and 15.90mm. A caliper length of 15.90mm was used instead of 16.00mm due to the horizontal limit created by the Visante OCT. Otherwise, measurements at 16.00mm would have to be extrapolated. The measurement of the various chord lengths were made by placing the caliper ends on the outside edge of the cornea parallel to the iris as best as possible. The sagittal depth for various chord lengths was then measured using a different caliper from the anterior most aspect of the cornea perpendicular to the chord length. The data for each chord length was then recorded in a Microsoft excel spread sheet.

Finally, an excel program was used along with a statistical analysis software (SPSS) program to create a formula to fit different diameter scleral contact lenses. Initially, the interest was to find out whether the sagittal depth at different chord lengths fit more of a linear configuration versus a quadratic configuration. The configuration that best fit the data was, then, used to develop an equation for each chord length to predict its sagittal height. Therefore, for each of the seven regression equations, the slope in-between two chord lengths was calculated in 0.1mm increments starting from 10.0mm, 10.1mm, 10.2mm…15.9mm, essentially allowing the dots to be connected. Using the slope-intercept analysis, the intercept and slope for each point were calculated. Similarly, a linear versus a quadratic configuration needed to be distinguished to best fit the data of both the slope and the intercept. Then, the equation was created based off the linear model or the quadratic model. A P-value of less than 0.05 is considered statistically significant in this study.

RESULTS

To predict the sagittal depth of an initial scleral contact lens, the following equation was found:

$$SAG\ HT = (5254.11808056313 - 913.68871622977 * VisanteCL + 43.0391949577472 * VisanteCL^2) + (-4.52726314766971 + 0.789892744122091 * VisanteCL - 0.0261090863516937 * VisanteCL^2) * Medmont10$$

(Vistane CL= diameter of scleral lens)

The sagittal depth at the 10.0mm, 11.0mm, 12.0mm, 13.0mm, 14.0mm, 15.0mm, and 15.9mm chord lengths were obtained from the Visante OCT and the Medmont E300 Topographer. A Microsoft Excel software and SPSS program were then used to analyze the data. First, a comparison was made to determine whether a linear equation versus a quadratic equation would best fit each individual set of data, as shown in Figures 1 through 7.

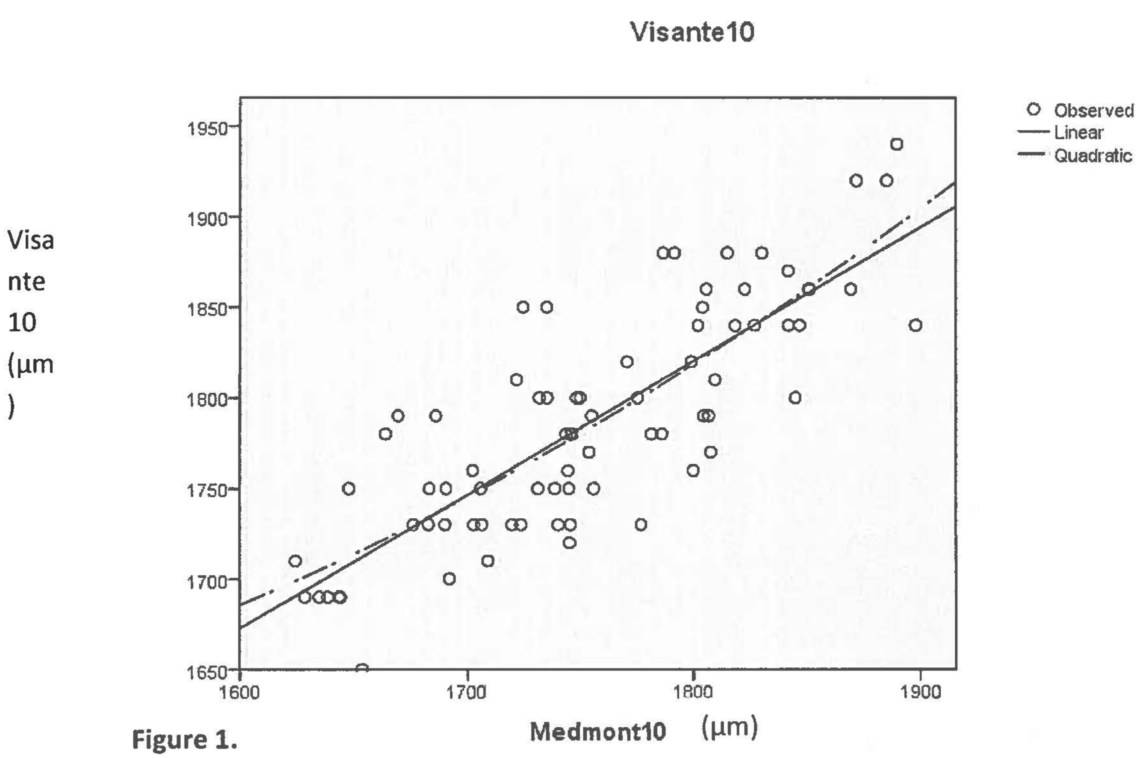
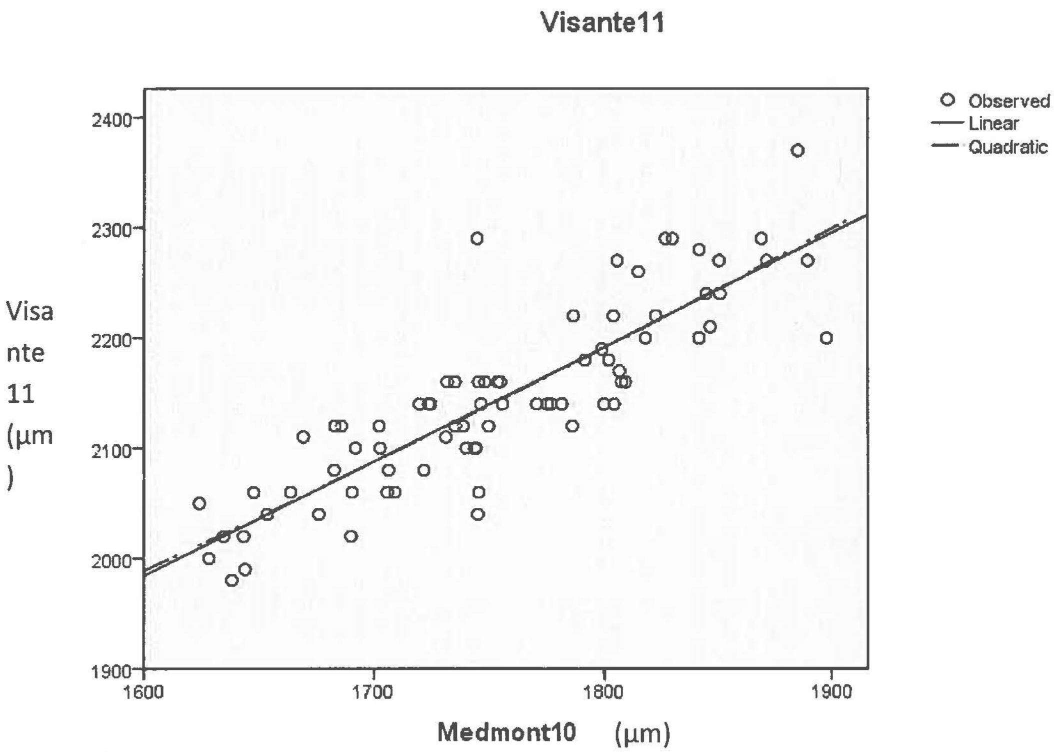


Figure 1.



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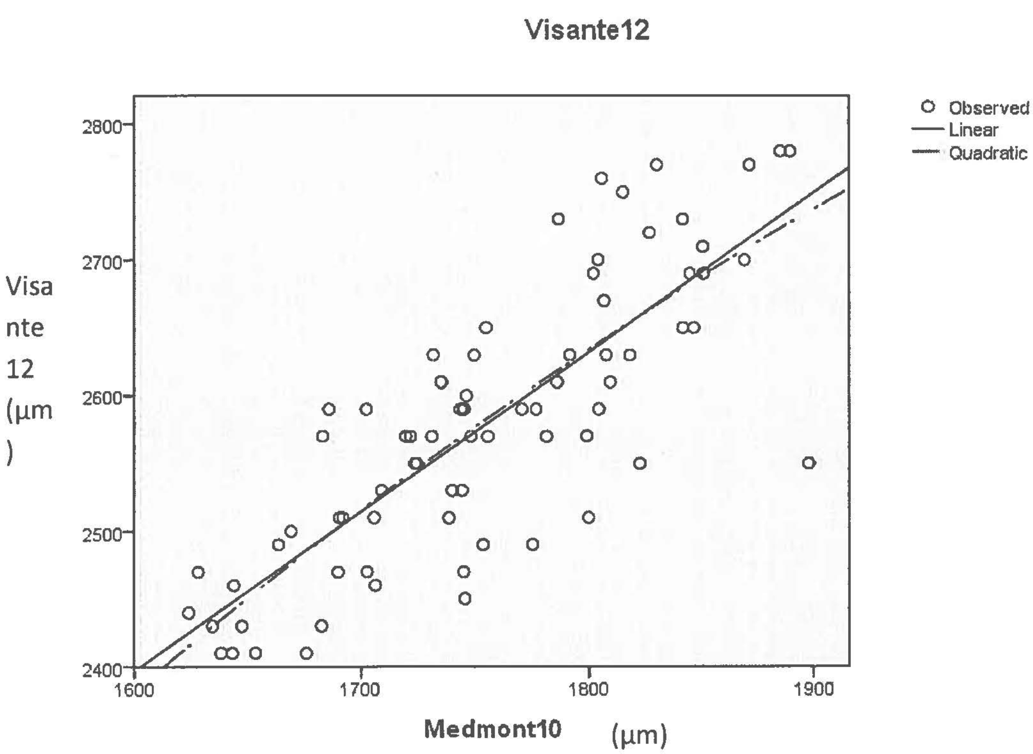

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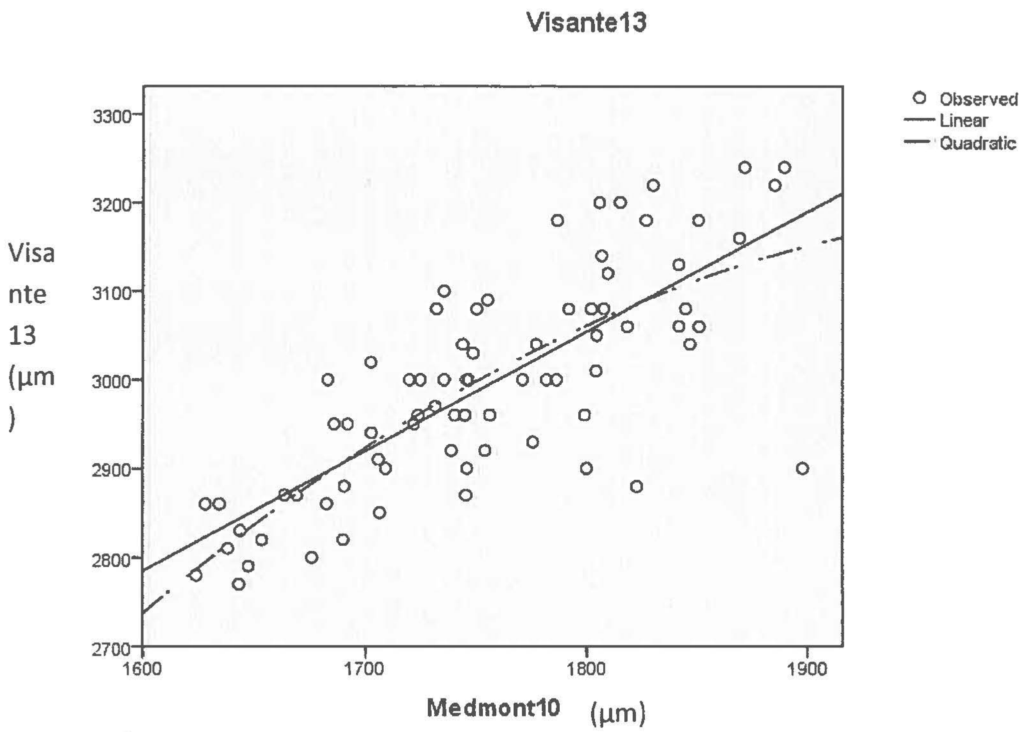

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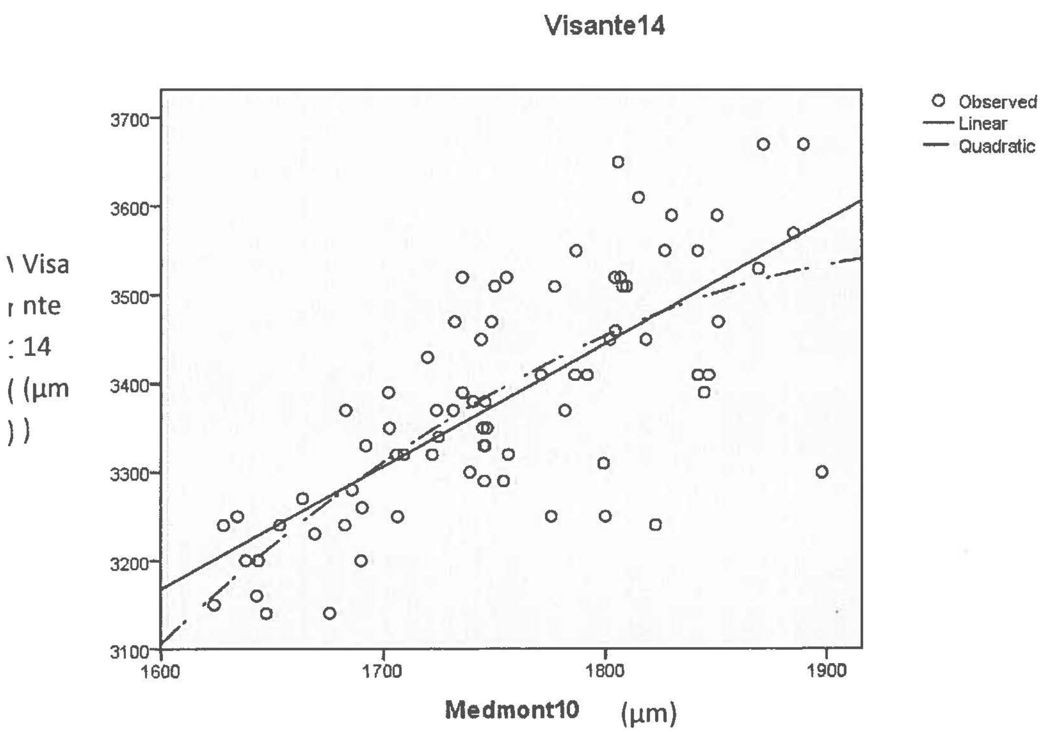

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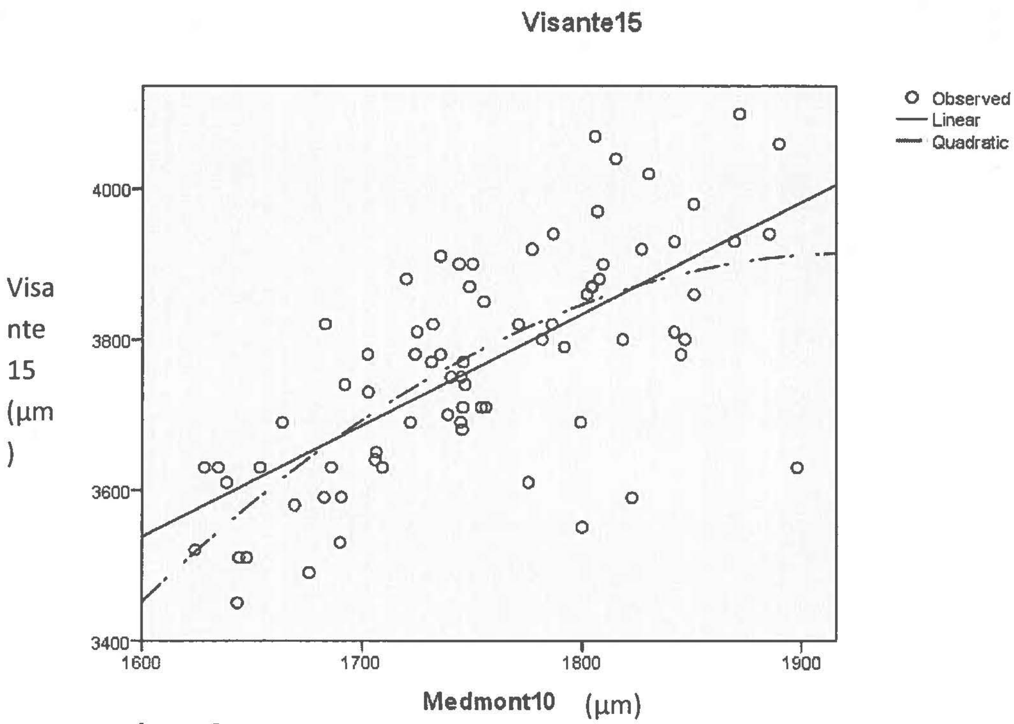

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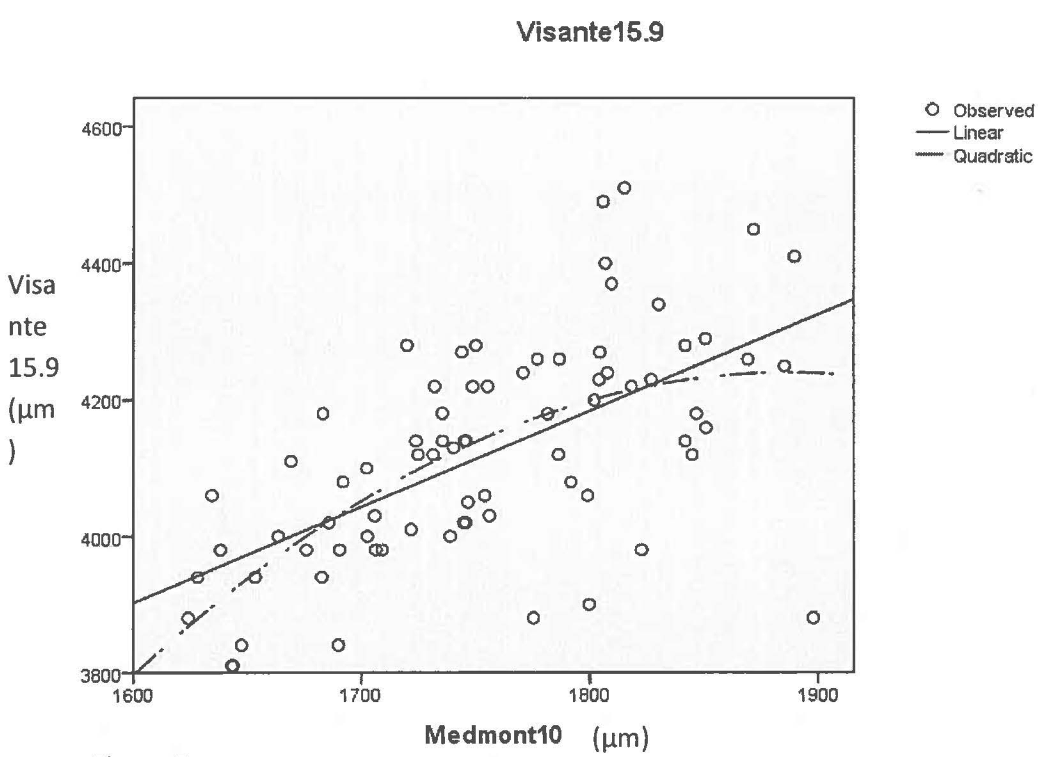

Figure 7.

Figures 1-7: These graphs show a comparison of a linear equation to a quadratic equation for each Visante chord length with the constant Medmont chord length of 10mm.

Then, a linear regression analysis was performed. The statistical significance values for each chord length are shown in Table 1.

Table 1: The statistical significance is shown here for the linear regression analysis.

Visante Chord Length (mm)	Linear Regression Statistical Significance (P-Value)
10.0	$4.166X10^{-19}$
11.0	$9.452X10^{-24}$
12.0	$1.243X10^{-18}$
13.0	$3.866x10^{-16}$
14.0	$6.419x10^{-14}$
15.0	$1.022x10^{-11}$
15.9	$5.191x10^{-9}$

The linear regression analysis was performed using the SPSS software for each of the Visante chord lengths. The Visante coefficients are as shown in Table 2.

Table 2: Coefficients of each Vistane chord length.

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B (Y intercept)	Std. Error	Beta		
Visante10	(Constant)	492.266	107.613		4.574	.000
	Medmont10	.738	.061	.814	12.040	.000
Visante11	(Constant)	326.177	123.292		2.646	.010
	Medmont10	1.036	.070	.864	14.761	.000
Visante12	(Constant)	515.356	175.381		2.938	.004
	Medmont10	1.176	.100	.807	11.775	.000
Visante13	(Constant)	628.009	227.481		2.761	.007
	Medmont10	1.348	.130	.771	10.407	.000
Visante14	(Constant)	941.160	265.056		3.551	.001
	Medmont10	1.392	.151	.731	9.219	.000
Visante15	(Constant)	1168.480	322.884		3.619	.001
	Medmont10	1.481	.184	.683	8.054	.000
Visante15.9	(Constant)	1645.144	374.784		4.390	.000
	Medmont10	1.411	.213	.609	6.610	.000

Using these coefficients, an equation for each of the chord lengths were predicted, as shown below.

Visante10.0	492.266 + 0.738 X Medmont10
Visante11.0	326.177 + 1.036 X Medmont10
Visante12.0	515.356 + 1.176 X Medmont10
Visante13.0	628.009 + 1.348 X Medmont10
Visante14.0	941.160 + 1.392 X Medmont10
Visante15.0	1168.480 + 1.481 X Medmont10
Visante15.9	1645.144 + 1.411 X Medmont10

In an attempt to combine all seven regression equations, the slope in-between two chord lengths was calculated in 0.1mm increments starting from 10.0mm, 10.1mm, 10.2mm…15.9mm. Using the slope-intercept analysis, the intercept and slope for each point were calculated. To determine which type of equation can predict the intercept and the slope best, a comparison was made between the quadratic and linear analysis as shown in Figure 8 and Figure 9, respectively.

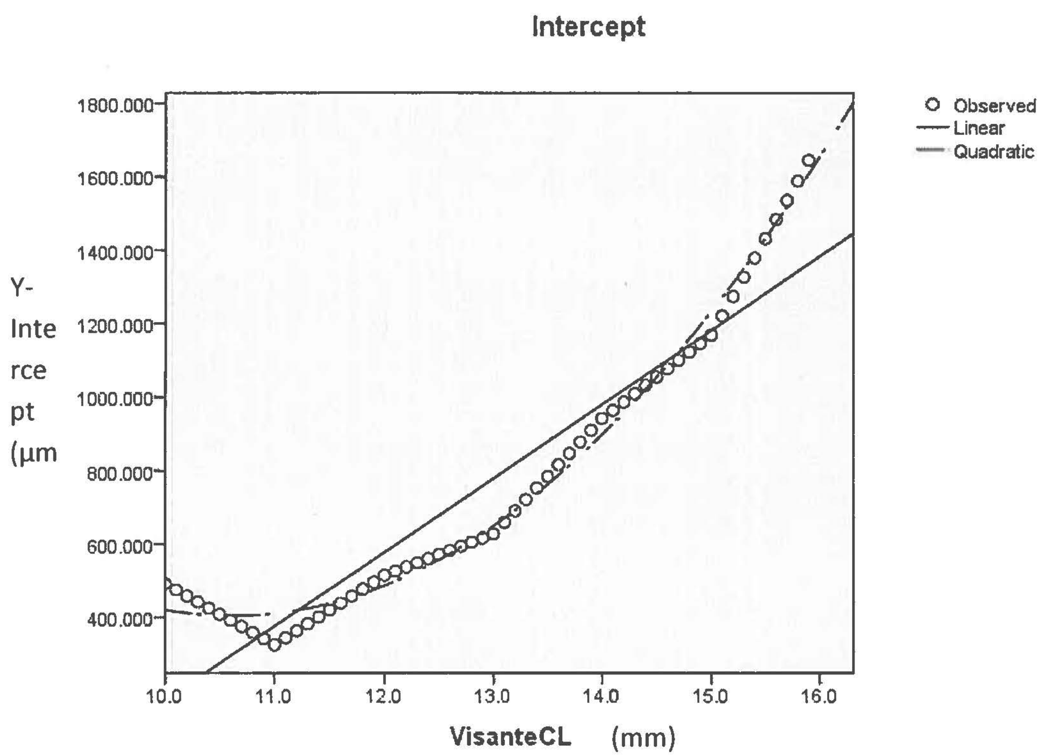

Figure 8: The graph shows a comparison of the quadratic versus the linear formula for each intercept.

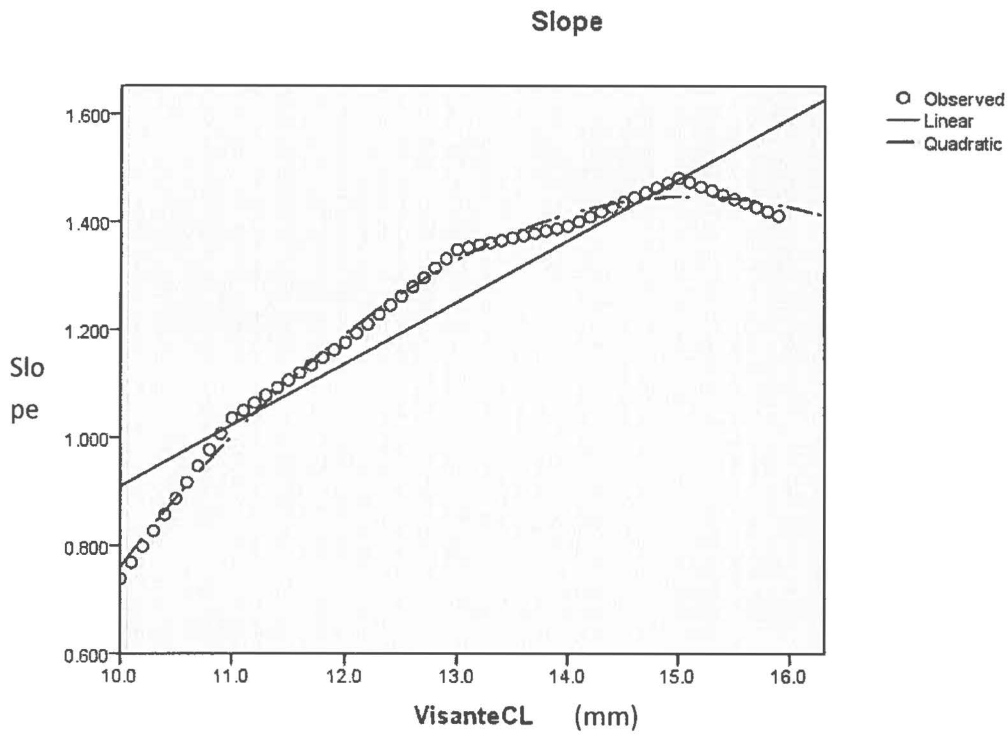

Figure 9: The graph shows a comparison of the quadratic versus the linear formula for each slope.

A summary of the correlation values for the intercept and slope showing the linear versus quadratic equations is given in Table 3.

Table 3: R-value (Correlation Coefficient)

		R	R Square	Adjusted R Square	Std. Error of the Estimate
Intercept	Linear	.945	.893	.892	122.285
	Quadratic	.996	.992	.991	34.589
Slope	Linear	.940	.883	.881	.073
	Quadratic	.997	.995	.995	.016

The chord length was predicted using the quadratic formula and the differences between the actual numbers and the predicted numbers are given in Table 4, along with the linear formula for direct comparison.

Table 4: Difference between predicted and actual Sag HT for each chord length.

Vistane Chord Length (mm)	Quadratic: Average difference between predicted and actual Sag HT ± standard deviation (μm)	Linear: Average difference between predicted and actual Sag HT ± standard deviation (μm)
10.0	30.892 ± 36.568	15.062 ± 38.425
11.0	-25.429 ± 41.922	-27.658 ± 41.866
12.0	0.117 ± 59.550	5.937 ± 59.601
13.0	11.873 ± 77.238	20.190 ± 77.521
14.0	3.784 ± 89.996	9.049 ± 90.003
15.0	-3.885 ± 109.641	-7.224 ± 109.615
15.9	1.723 ± 127.242	-14.107 ± 127.776

DISCUSSION

The popularity of scleral contact lenses have increased in the past few years due to the many advantages they can provide to a specialty population. Since they have not been on the forefront until recently, many practitioners are not comfortable or knowledgeable with the fitting of these lenses. Limiting factors to practitioners fitting these lenses include the time, skill, lack of an anterior segment OCT, and associated expenses such as a trial lens set. Therefore, the goal of this research is to simplify the fitting of scleral lenses to maximize vision and comfort for all patients.

The scleral lens design consists of three components: the optical zone, the transition zone, and the landing zone[4]. The optical zone contains the optical correction, and the base curve is along the back surface of the lens[1]. Like gas permeable (GP) lenses, a change in 0.10mm of the base curve equates to a 0.5 diopter change in power of scleral lenses[1]. The transition zone controls the sagittal height, and it is independent of the optical zone and the landing zone[1,4]. This zone has a larger influence on corneo-scleral lens designs than larger diameter designs due the mechanical pressure it may produce and the absence of limbal clearance[4]. The landing zone, also referred to as the haptic zone, is where the lens aligns with the sclera[4].

There are several factors that need to be considered in the fitting of these lenses such as diameter, clearance, landing zone assessment, lens edge, over-refraction, and movement. The sagittal height of the lens is multifactorial. It is dependent on the lens diameter, radius of curvature, asphericity of the cornea, and the shape of the anterior sclera. The diameter of the lens is directly correlated with the sagittal height of the lens. With an increase in diameter, there is an increase in sagittal height. However, it is important to note that the sagittal height can be altered independent of the lens diameter. Similarly, the base curve also alters the sagittal height. A steeper base curve leads to a larger sagittal height. An increase in sagittal height creates an increase in the clearance within the fit of the lens. Clearance describes the extent of the tear reservoir between the scleral lens and the cornea. It is viewed as the largest advantage of scleral lenses over standard GP lenses. The optimal amount of lens clearance stated in literature is approximately 200-300 microns. Too little clearance causes the lens to bear onto the cornea creating discomfort and instability. Too much clearance introduces bubbles between the scleral contact lens and the cornea which dries the cornea and may harbor microorganisms. Also, excessive clearance interferes with the quality of vision. Therefore, it is advised to maintain minimal vaulting of the cornea to best enhance the visual acuity, especially in cases of irregular corneas. Additionally, an excessive clearance creates a suction of the lens onto the eye making the lens difficult and uncomfortable to remove. The landing zone assessment is also critical to the fitting of scleral lenses. This is the area where all of the pressure from the contact lens is exerted onto the sclera. It is essential for patient comfort and ocular health that this fit is neither too loose nor too excessive. Currently, the only way to assess the corneo-scleral profile is to view it either via a slit exam examination or via an OCT. Finally, the lens edge is closely related to the landing zone, and this is important for patient comfort and lens stability.

The focus of the formula produced in the results section is to quickly and accurately determine which sagittal depth is optimal simply by taking a topography of the patient's cornea. As mentioned earlier the sagittal depth is directly related to the clearance of the lens fit. Therefore, the goal is to obtain optimal clearance (200-300 microns) by minimizing the number of trial lenses used. Figures 1-7 show that the sagittal depth at different chord lengths fit more of a linear configuration versus a quadratic configuration. Using the SPSS data analysis, the linear regression predicted a sagittal height at each chord length. The comparison of the predicted versus the actual data showed a statistical significance ($P<<0.05$) as evident in Table 1. This helped to formulate an equation to predict the sagittal height for each chord length. In order to combine these equations, the slope and the intercept in-between two chord lengths was calculated in 0.1mm increments starting from 10.0mm, 10.1mm, 10.2mm...15.9mm. The SPSS software showed that overall the quadratic regression fits both the y-intercept and the slope versus the linear regression as illustrated in Figure 8 and Figure 9, respectively.

Limitations of this study include: 1) the image of some corneas exceeded 15.9mm on the OCT, therefore this data was eliminated from the study, giving a smaller sample size and 2) subjective differences between three people in measuring the sagittal height and/or chord length using the caliper function of the Visante OCT.

The main benefit of this new equation is to simplify complicated lens fittings and to create a more efficient fitting experience for the specialty contact lens practitioner. Moreover, the goal is to make scleral lenses more available to patients in need by allowing practitioners to provide them as an option. The practitioner simply performs a Medmont E300 corneal topography to obtain the sagittal height at a constant chord length of 10.0mm. The eye care practitioner will, then, be able to predict the sagittal height at the desired scleral lens diameter using the provided equation. This offers advantages such as: 1) decreased chair time, 2) more accurate initial trial fit, 3) eliminates the need to purchase a Visante anterior segment OCT, 4) eliminates the need for a diagnostic trial lens set, and 5) it simplifies the fitting process overall.

CONCLUSION

In all, scleral contact lenses have a history within optometry. Not until recently have they been reconsidered for a niche population. Thousands of people with advanced keratoconus, pellucid marginal degeneration, unsuccessful corneal refractive surgeries, and corneal traumas can benefit from the vaulting property the lens boasts. The objective of this research was to develop an equation to predict a sagittal height eliminating the need for a Visante anterior segment OCT. With the use of a Microsoft excel spreadsheet and SPSS software analysis, the data from 76 eyes was converted to a quadratic regression equation that showed impressive statistical significance in the actual versus the predicted sagittal height value. Therefore, a corneal topography can be obtained and simply the eye care practitioner enters the desired scleral lens diameter and the Medmont sagittal height value at a 10.0mm chord length into the equation to obtain the sagittal height parameters for a trial lens. It is critical for optometrists, especially those serving the specialty contact lens field, to be able to provide the most appropriate contact lens option to the patient.

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