Comparison of Sagittal Height Measurement Methods in Scleral Contact Lens Fitting

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Comparison of Sagittal Height Measurement Methods in Scleral Contact Lens Fitting

Abstract

Purpose: This study compared 3 methods of measuring sagittal height of the eye (Zeiss Visante anterior segment OCT, Eaglet Eye Surface Profiler (ESP), and Medmont E300 Corneal Topographer Estimated Sagittal Height (ESH) software) and evaluated the ability of each to predict central clearance of a scleral contact lens.

Methods: Sagittal height at a chord of 15mm was measured on 52 normal eyes with each of 3 methods. Visante OCT corneal sections were measured with calipers, Eaglet software analyzed ESP corneal sclera maps, and Medmont ESH software utilized composite corneal topography for calculations. A random subset of 30 eyes was selected to wear an ICD 16.5 (Valley Contax) 4400µm lens, and central clearance was measured on Visante OCT scans taken within 5 minutes of lens insertion.

Results: Sagittal height measurements differed by method [F(2,102)=8.12, p<0.001]. Eaglet ESP values were significantly lower than Zeiss OCT and significantly lower than Medmont ESH (p'sp 0.29).

Conclusions: Medmont ESH module sagittal height measurements do not significantly differ from Visante OCT, a highly specialized imaging instrument. Eaglet ESP sagittal height measurements were significantly lower than both Medmont ESH and Visante OCT. As Placido ring topographers are common in clinical practice, the addition of software such as the Medmont ESH may empower more clinicians to make precise measurements to aid the process of scleral lens fitting.
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COMPARISON OF SAGITTAL HEIGHT MEASUREMENT METHODS IN SCLERAL CONTACT LENS FITTING

by

BROOKE MORRIS HARKNESS
BS, OD and MS Candidate

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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ABSTRACT

**Purpose:** This study compared 3 methods of measuring sagittal height of the eye (Zeiss Visante anterior segment OCT, Eaglet Eye Surface Profiler (ESP), and Medmont E300 Corneal Topographer Estimated Sagittal Height (ESH) software) and evaluated the ability of each to predict central clearance of a scleral contact lens.

**Methods:** Sagittal height at a chord of 15mm was measured on 52 normal eyes with each of 3 methods. Visante OCT corneal sections were measured with calipers, Eaglet software analyzed ESP corneal sclera maps, and Medmont ESH software utilized composite corneal topography for calculations. A random subset of 30 eyes was selected to wear an ICD 16.5 (Valley Contax) 4400µm lens, and central clearance was measured on Visante OCT scans taken within 5 minutes of lens insertion.

**Results:** Sagittal height measurements differed by method \([F(2,102)=8.12, p<0.001]\). Eaglet ESP values were significantly lower than Zeiss OCT and significantly lower than Medmont ESH \((p’s<0.005)\). Medmont ESH values did not
significantly differ from Visante OCT. All methods predicted greater clearance
($p<0.0005$) of an ICD 16.5 scleral lens compared to on-eye lens clearance as
measured by Visante OCT. Mean differences ($\pm1$ SD) in predicted versus
measured clearance were as follows: Visante OCT +101.67$\pm$84.45µm, Medmont
ESH +123.43$\pm$98.49µm, Eaglet ESP +150.00$\pm$87.53µm. Sagittal height of all
subject eyes by all methods was normally distributed ($n=52$, Visante OCT mean
3727.50$\pm$188.45µm, Eaglet ESP mean 3680.96$\pm$202.70µm, Medmont ESH mean
3732.48$\pm$159.14µm; Shapiro-Wilk $W=0.974-0.979$, $p$'s > 0.29).

**Conclusions:** Medmont ESH module sagittal height measurements do not
significantly differ from Visante OCT, a highly specialized imaging instrument.
Eaglet ESP sagittal height measurements were significantly lower than both
Medmont ESH and Visante OCT. As Placido ring topographers are common in
clinical practice, the addition of software such as the Medmont ESH may
empower more clinicians to make precise measurements to aid the process of
scleral lens fitting.

**Keywords:** sagittal height, scleral lens fitting, scleral shape, contact lens,
Medmont Estimated Sagittal Height (ESH), anterior segment optical coherence
tomography (OCT), Eaglet Eye Surface Profiler (ESP)

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Optometry meeting.
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“Nothing has such power to broaden the mind as the ability to investigate systematically and truly all that comes under thy observation in life.”

Marcus Aurelius
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LIST OF ABBREVIATIONS

Dk: oxygen permeability
Dk/t: oxygen transmissibility
ESH: Estimated Sagittal Height
ESP: Eye Surface Profiler
HVID: horizontal visible iris diameter
MK: microbial keratitis
OCT: optical coherence tomography
PK: penetrating keratoplasty
I. INTRODUCTION

Background

Scleral contact lenses have recently re-emerged at the forefront of care for patients whose needs are not met by conventional contact lenses. This is, in large part, due to modern gas-permeable materials, technological advances in lens design and manufacturing, and improved understanding of anterior ocular surface anatomy.¹

The first contact lenses, dating back to the 1800s and perhaps earlier, were made of blown glass and designed to rest on the sclera (more correctly, the conjunctiva). Although lens designs evolved to include optical correction and more precise apposition to the eye, these glass lenses effectively sealed the cornea off from oxygen supply. August Müller, a pioneer in contact lenses, recognized this limitation in his 1889 doctoral dissertation, documenting marked corneal edema after wearing glass scleral lenses of his own design.² The development of polymethylmethacrylate (PMMA) plastic in the early 1900s enhanced the efficiency of lens manufacturing, but its impermeability to oxygen led practitioners to abandon the scleral design in favor of smaller diameter corneal contact lenses, which allow for tear exchange upon normal movement of the lens. Gas permeable materials, developed in the mid 1970s, further improved the safety of contact lens wear by decreasing complications resulting from corneal hypoxia.³ Soft hydrogel contact lenses, also introduced in the 1970s, became widely prescribed due to their comfort and stability on the eye, allowing for ease of fit.⁴ Novel rigid gas permeable materials continued to attain higher
levels of oxygen permeability (Dk) in the 1980s and 1990s. Subsequently, practitioners began to revisit the scleral lens design in order to address challenges in ocular surface disease, complex optical needs, and irregular corneas.

**The Modern Scleral Lens**

The very design of scleral lenses, vaulting the cornea to make contact with the sclera, presents unique applications for eyes that are unsuccessful in other contact lens modalities. These indications may be divided into three general categories, as described by van der Worp et al: vision improvement via optical correction; protection of the ocular surface; and cosmetic, sports, and others. Irregular corneas may be the result of primary ectasic disorders (such as keratoconus, pellucid marginal degeneration, and keratoglobus), secondary (post-surgical) ectasia, post-penetrating keratoplasty, scarring, and other conditions. The ability of scleral lenses to protect the ocular surface is beneficial in a wide range of conditions in which the eye remains exposed, dehydrated, or injured. These include congenital lid malformation, Sjögren’s syndrome, graft versus host disease, persistent epithelial defects, neurotrophic corneal disease, Stevens-Johnson syndrome, and others. The third, “miscellaneous” category ranges from cosmetic indications such as aniridia and atrophy bulbi, to athletes in water sports or dusty environments. Experimental applications include medication delivery to the cornea, electronic health monitoring devices, and even augmented reality technology.
The diameter of scleral lenses ranges from 14.0mm to larger than 20.0mm. The Scleral Lens Education Society has recommended standardized nomenclature of these lenses based on the point of contact between the lens and ocular surface rather than on lens diameter. Full scleral lenses, by definition, rest entirely on the sclera. Full scleral lenses may be further classified as mini-scleral, which are up to 6mm larger than horizontal visible iris diameter (HVID), or large-scleral, which are more than 6mm larger than HVID. The same diameter lens then, by this nomenclature, may be classified differently on individual patients due to varying anatomy.

Current digitally-guided manufacturing techniques create lenses with complex, customizable designs for optimum fit, even in larger-diameter lenses. In order to achieve appropriate fit on irregularly shaped eyes, scleral lenses are designed with multiple geometric zones that may be manipulated independently. The names of these zones vary by manufacturer, but may be described as follows for a standard concentric symmetrical (non-toric) lens:

1. Central optical zone: provides spherical or front-aspheric optical correction using radii of curvature. The back surface of this zone may be steepened or flattened to best fit the contour of the central cornea.
2. Transition zone: connecting the central optics to the landing zone, the angle of the transition, or intermediate, zone determines the sagittal height of a scleral lens.
3. Landing zone: the region of contact between lens and eye. This zone should closely align with scleral shape to ensure even distribution of lens
pressure without impinging on conjunctival vessels. The angle of this zone is typically tangential, consistent with findings of Pacific University of corneo-scleral shape.  

**Lens Fitting**

A properly fit scleral lens provides exceptional comfort, optical correction, and ocular surface protection by closely mirroring the shape of the anterior eye and acting, in essence, as a prosthetic ocular surface. Standard gas-permeable materials used for scleral lenses are available with Dk over 100, allowing a high amount of oxygen to pass through the lens. Dk is a standard expression of oxygen permeability, encompassing the diffusion coefficient (D) and the oxygen solubility (k) of the material. However, the post-lens tear reservoir beneath the scleral lens presents a substantial barrier to oxygen diffusion and must be considered in the ultimate Dk of the system. Consequently, characteristics of appropriate scleral lens fit include a finite range of desired post-lens tear thickness, or clearance. This space, measured in microns, is defined as the distance between the anterior ocular surface and the posterior lens surface. It is occupied by fluid, typically non-preserved sterile saline, which is used to fill the “bowl” of the scleral lens before insertion. No definitive guideline currently exists for optimal clearance, and the range of acceptable clearance may be dependent on the type of lens being fit. Lower limits of clearance prevent direct pressure on ocular tissues, while upper limits preserve optical quality, prevent excessive suction forces, and maintain adequate oxygen transmission through the total
resistance of the lens itself plus the fluid reservoir. Clearance over the limbus must also be considered in order to protect the stem cells, which are already fragile in the conditions that may benefit most from scleral lens wear. Recent studies by Michaud, Compañ, and Lotoczky support a target of 100-300µm of central corneal clearance and 50-100µm of limbal clearance.\textsuperscript{6,9,10}

Evaluating scleral lens fit requires observation of several points of lens-eye interaction, as well as subjective patient responses. Clinical assessment of scleral lens fit includes the following:

1. Post-lens tear thickness: measured behind the slit lamp with an optical section (with or without sodium fluorescein in the post-lens tear reservoir), or by anterior segment OCT (Fig. 1). A study by Yeung and Sorbara from the University of Waterloo found that even "expert" clinicians tend to overestimate clearance by approximately 50µm when measuring with slit lamp compared to anterior segment OCT.\textsuperscript{11} Clearances should be measured at various time points after lens insertion due to variable effects of lens settling into the conjunctiva. Studies by Caroline and Andre at Pacific University, Kauffman et al at University of Houston, and others have found that 100-200µm of settling may be expected over 8 hours of lens wear, most of which occurs within the first 2 to 4 hours.\textsuperscript{6,12,13}
2. Landing zone fit: effectively evaluated behind the slit lamp, with and without sodium fluorescein (Fig. 2). Ideal fit represents broad, equal bearing of the lens on the sclera. Blanching of conjunctival blood vessels at the lens edge indicates impingement by a landing zone angle that is too steep. Blanching in the circumlimbal area suggests a landing zone angle that is too flat.

Figure 1: Observation of post-lens tear thickness behind the slit lamp with sodium fluorescein in the lens reservoir. From the left, the first vertical band is the lens material, adjacent to a green band visualizing the post-lens tear thickness with sodium fluorescein, followed by the cross-section of the cornea. Estimation of post-lens tear thickness is best made in reference to the thickness of the lens, as specified by the manufacturer.

Figure 2: The landing zone and edge of a scleral lens demonstrating equal bearing without vessel impingement (A), and conjunctival vessel blanching (B) indicating a steep landing zone.
3. Edge lift: similar to corneal gas permeable lenses, inadequate or excessive lift of the lens edge is detrimental to comfortable, healthy scleral lens wear. Edge lift may be evaluated by slit lamp examination, and is closely related to landing zone fit. Not all lens designs allow for the independent manipulation of the lens edge, and the landing zone may therefore need to be modified.⁶

4. Visual acuity and over-refraction: performed after satisfactory lens fit has been achieved. Sphero-cylindrical over-refraction may be performed in or out of phoropter and then corrected appropriately for vertex distance.

Meeting all lens fit criteria may require adjustment of some or all lens parameters beyond a standard fitting set. In complex cases, lens design may include specialized components such as a toric peripheral back surfaces, quadrant-specific designs, edge notching, ballasting, fenestrations, and front-surface toric optical correction.¹⁴

While the fitting process nearly always involves multiple iterations of lens design before final dispensing, understanding the patient’s eye shape aids in the efficient selection of viable starting parameters. Sagittal height, the perpendicular distance from a given chord in cross section of the anterior eye to the corneal apex, is a primary consideration in the fitting of scleral lenses. Sagittal height may be dramatically higher in corneal ectasic disorders and post-penetrating keratoplasty.¹⁵,¹⁶ Sagittal height of the eye can be measured by various specialized instruments including anterior segment optical coherence
tomography (OCT), moiré infrared profilometry, ultrasonography, and Scheimpflug camera systems. However, the limited accessibility of these instruments presents a barrier to broader use within the optometric community.

II. PURPOSE

Appropriate clearance of the cornea and limbus with a scleral lens ensures the best optics, comfort, and ocular health for patients. Sagittal height of the eye is a major determinant of post-lens tear film thickness. However, this measurement is difficult to obtain without the use of highly specialized equipment. As the use of scleral lenses becomes more widespread, including by primary eye care clinicians, there is a need for accessible, accurate assessment of sagittal height. This pilot study compared 3 methods of measuring sagittal height at a chord of 15mm: Zeiss Visante anterior segment OCT, Eaglet Eye Surface Profiler (ESP), and Medmont E300 Corneal Topographer Estimated Sagittal Height (ESH) software. I hypothesized that sagittal height measurements by Medmont ESH would not differ significantly from those made using Visante OCT or Eaglet ESP. I additionally hypothesized that sagittal height measurements by all 3 methods would overestimate actual central clearance of a sagittal lens on the eye.
III. METHODS

26 normal subjects, 18 female and 8 male, between the ages of 22 and 30 participated in this study. Exclusion criteria included the presence of any corneal, scleral, or conjunctival pathology, as well as a history of any ocular surgeries, including refractive surgery. All subjects were recruited through Pacific University College of Optometry.

Measurement and calculation

52 eyes of 26 subjects were scanned with Zeiss Visante OCT (instrument details) in anterior segment cross-section mode in the 0-180 degree meridian. Each cross-section scan was measured for sagittal height at a 15mm chord using calipers on Visante software (Fig. 3).

Figure 3: Anterior segment cross-section scan in 0-180 degree meridian on Zeiss Visante OCT. Sagittal height was measured using software calipers at a 15mm chord.
Each eye was also imaged with the Eaglet Eye Surface Profiler. Sodium fluorescein dye was applied liberally to the ocular surface to allow for moiré infrared profilometry readings. Eaglet analysis software was used to measure sagittal height at 15mm in the 180-degree meridian (Fig. 4).

Figure 4: Eaglet Eye Surface Profiler (ESP) utilizes moiré infrared profilometry to image the anterior ocular surface to a 20.0mm diameter. Eaglet software was used to calculate sagittal height at a 15mm chord in the 0-180 meridian.

Composite corneal topography was taken on each subject eye with the Medmont E300 corneal topographer. In this imaging technique, the central map is supplemented with 4 additional, off-center, maps attained by having the subject fixate three rings up, down, left, and right on the concentric ring target. These 5 total maps of the ocular surface are digitally montaged by Medmont software to allow for greater than 12mm total diameter of corneal topographical data. The Medmont Estimated Sagittal Height software, set to a chord of 15mm,
produced calculations of sagittal height using the composite corneal topography for each subject eye (Fig. 5).

Figure 5: Composite corneal topography on the Medmont E300 corneal topographer creates a montage from four off-centered maps in addition to the central topography in order to effectively image the entire visible iris diameter.

**On-Eye Scleral Lens Clearance**

A random subset of 30 eyes (15 subjects) was selected for application of an ICD 16.5 (Valley Contax) with a sagittal height of 4400μm. This lens has a scleral landing zone diameter of 15mm. Lenses were applied following standard techniques, after filling with non-preserved sterile inhalation saline, 0.9%. Post-lens tear thickness over the central cornea was measured with manual calipers on high-resolution corneal scans taken with the Visante OCT within 5 minutes of lens application to avoid extensive lens settling effects (Fig. 6).
Figure 6: High-resolution corneal cross-section scan in the 0-180 degree meridian on Zeiss Visante OCT of an eye wearing the ICD 16.5 lens. Calipers were used to measure the post-lens tear thickness, or central clearance, from the anterior surface of the corneal apex to the posterior lens surface.

**Statistical Analysis**

Mixed model analysis of variance (ANOVA) was used to analyze within-subject variance of sagittal height data from subject eyes and measurement method (Visante OCT, Eaglet ESP, and Medmont ESH). Repeated measure ANOVA was also used to analyze within-subject variance of sagittal height data from measurement method. Significant main effects were examined using Neuman-Keuls test for *post hoc* mean comparisons when appropriate. Alpha level was set at 0.05. Statistical analyses were performed using Statistica 12 (StatSoft, Tulsa, OK). Bland-Altman difference plots were used to analyze agreement of sagittal height measurements between methods, and also agreement between on-eye measured lens clearance and predicted clearance by
each measurement method. For comparison of sagittal height measurement methods, limits of agreement were set at ±2 standard deviations (SD) of Eaglet ESP difference values, which were smaller than those of Medmont ESH. For analysis of measured clearance versus predicted clearance, limits of agreement were set at ±2 SD of Visante OCT values, which were the smallest. Bland-Altman plots were constructed using Numbers 3.5.3 (Apple, Cupertino, CA).

IV. RESULTS

Sagittal height measurements differed by measurement method, but not by eye (right vs. left within subject) when analyzed by mixed model ANOVA [F(2,100)=1.19, p>0.3]. Therefore eye was not included as a factor in further analyses.

Repeated measure ANOVA indicated that sagittal height measurements differed by method [F(2,102)=8.12, p<0.001]. Eaglet ESP values were significantly lower than both Zeiss OCT and Medmont ESH (p’s<0.005) (Fig. 7). Medmont ESH values did not significantly differ from Visante OCT. Average sagittal height at 15mm (±1 SD) for all 52 eyes was as follows for each measurement method: Visante OCT mean 3727.50±188.45µm, Eaglet ESP mean 3680.96±202.70µm, Medmont ESH mean 3732.48±159.14µm. Effect sizes (Cohen’s d) were as follows for sagittal height measurement method: Visante OCT versus Medmont ESH measurements: 0.029, Visante OCT versus Eaglet ESP: 0.238, Medmont ESH versus Eaglet ESP: 0.283. Sagittal height of all subject eyes by all methods was found to be normally distributed by a Shapiro-
Wilk test ($W=0.974-0.979$, $p's > 0.29$). A random subset of subject eyes fit with a scleral lens was also normally distributed for OCT and Eaglet ($W=0.977-0.981$, $p's > 0.73$), but was non-normal for the Medmont ESH ($W=0.911$, $p=0.016$).

Figure 7: Sagittal height measurements differed by method [$F(2,102)=8.12$, $p<0.001$]. Eaglet ESP values were significantly lower than Zeiss OCT and significantly lower than Medmont ESH ($p<0.005$). Medmont ESH values did not significantly differ from Visante OCT.

A Bland-Altman difference plot compared sagittal height measurements at 15mm by Eaglet ESP and Medmont ESH, corrected to Visante OCT (Fig. 8). This analysis illustrates the relative distributions of subject measurements by each method compared to Visante OCT, and may indicate greater precision of measurements collected by Eaglet ESP. However, Medmont ESH appears to
result in more accurate measurements relative to Visante OCT, though with more variability than Eaglet ESP.

Figure 8: Bland-Altman difference plot comparing sagittal height at a 15mm chord as measured by Visante OCT, Eaglet ESP, and Medmont ESH. X-axis is Visante OCT data set, y-axis is difference, in microns, of other methods from Visante measurement for each eye. Dashed lines indicate ±2 SD of Eaglet data.

“Predicted clearance” was defined as the difference between the known height of the ICD 16.5 lens (4400μm) and the sagittal height of the eye as measured by each method. There was a main effect of measurement method for ICD 16.5 scleral lens clearance \([F(3,87)=29.64, p<0.0001]\). All measurement methods predicted greater clearance of the ICD 16.5 scleral lens compared to on-eye post-lens tear thickness as measured by Visante OCT \((p<0.0005)\) (Fig. 9). Medmont ESH predicted clearance did not significantly differ from Eaglet ESP or Visante OCT predicted clearance. Mean predicted lens clearance values \(±1\)
SD) were as follows for each method (n=30): Visante OCT 629.67±183.91 µm, Medmont ESH 651.43±153.86µm, Eaglet ESP 678.00±181.67µm. Mean differences (±1 SD) between predicted clearance and measured post-lens tear thickness were as follows (n=30): Visante OCT +101.67±84.45µm, Medmont ESH +123.43±98.49µm, Eaglet ESP +150.00±87.53µm. Effect sizes for predicted clearance between methods were similar to effect sizes for sagittal height measurement, and were as follows: Visante OCT versus Medmont ESH: 0.128, Visante OCT versus Eaglet ESP: 0.264, Medmont ESH versus Eaglet ESP: 0.158. Given similar effect sizes, discrepancies between p values when comparing sagittal height (all subjects) to predicted clearance (the subset selected to wear an ICD 16.5 lens) are likely due to differences in sample size.

8 eyes of 4 subjects demonstrated excessive decentration of the ICD lens by visual examination. These lenses were manually centered for the purpose of measuring central post lens tear thickness on Visante OCT.
Figure 9: There was a main effect of measurement method for ICD 16.5 scleral lens clearance \( F(3,87)=29.64, \ p<0.0001 \). All measurement methods predicted greater clearance of the ICD 16.5 scleral lens compared to on-eye post-lens tear thickness as measured by Visante OCT \( (p<0.0005) \). Medmont ESH predicted clearance did not significantly differ from Eaglet ESP or Visante OCT predicted clearance.

Central lens clearance of an ICD 16.5, 4400μm scleral lens as predicted by Visante OCT, Eaglet ESP, and Medmont ESH is illustrated in a Bland-Altman difference plot (Fig. 10). Differences in clearance, corrected to actual on-eye measurement by Visante OCT, are represented for each method. Relative precision and accuracy does not appear to differ significantly between predictive measurement method, and all methods overestimated clearance in comparison to on-eye measurements.
V. DISCUSSION

Increased interest in and availability of scleral lenses has expanded their use beyond specialty practices and into the realm of the average contact lens practitioner. Current literature reveals a myriad of successful case studies and clinical research data supporting the therapeutic value of scleral contact lenses, yet a standardized protocol for fitting remains to be established. Many practitioners rely on the application of a series of diagnostic lenses rather than empirical fitting, by which lenses are ordered based solely on eye parameter measurements. Final selection of a dispensible scleral lens typically involves...
multiple office visits and modifications of lens parameters based on both initial fit and settling effects on the eye after several hours of wear. The details of this process necessarily vary with the nature of lens being fit; a 15mm mini-scleral lens for the optical correction of corneal ectasia will likely require fewer revisions than a 21mm large-scleral lens indicated for advanced ocular surface disease. Accurate and complete characterization of anterior eye shape is advantageous to fitting any design of scleral contact lens, as more efficient fitting benefits both the clinician and patient. Even with simplified diagnostic lens sets designed for the average contact lens practice, there is a steep learning curve in fitting scleral lenses. Availability of accurate instruments for anterior ocular surface measurement benefits the fitting process, and improves accessibility of scleral lenses for practitioners and patients.

In this thesis, I demonstrated that Medmont ESH software is capable of producing sagittal height measurements at 15mm that do not significantly differ from the Visante OCT for normal eyes. The mean horizontal sagittal height measured by Visante OCT (3727.50±188.45µm) and Medmont ESH (3732.48±159.14µm) for this subject population were closely matched and in agreement with previous OCT studies of normal anterior segment anatomy. Hall et al reported a mean horizontal sagittal height at 15mm of 3700±170µm in 202 eyes, and Sorbara et al reported a mean of 3740±190µm in 40 eyes.\textsuperscript{15,16} Sagittal height at a chord equal to lens diameter is a key factor in the ultimate lens fit achieved, as full scleral lenses vault the cornea entirely.\textsuperscript{1} However, the variable overestimation of central lens clearance by all three measurements as
compared to on-eye fit in this study exhibits the complex interaction of the scleral lens and ocular surface.

Recent insights on scleral shape have informed the initiation and troubleshooting of scleral lens fitting. A study at Pacific University characterized standard values for limbal angle (the corneo-scleral junction between 10.0mm and 15.0mm) and anterior scleral angle (from 15.0mm to 20.0mm). The authors report a trend in the normal subject population that the nasal sclera is flatter than temporal sclera. Furthermore, this asymmetry is greater at the scleral angle, i.e. larger diameter from the cornea. These angles, in combination with central corneal radius of curvature, corneal diameter, and corneal eccentricity, determine sagittal height of the eye. This study also found that the greater sagittal depth of eyes with keratoconus is a product of changes within the central 10mm chord of the cornea, with the limbal and scleral angles remaining fairly constant.⁸
Figure 11: Effect of limbal (10-15mm) and scleral (15-20mm) angles on sagittal height. Smaller angles (A) at limbal and scleral zones as compared to larger angles (B) result in smaller sagittal depth measured at 15mm. Reproduced with permission from Pacific University Contact Lens Department slide archive.

The observation of increasing asymmetry at larger diameters is supported elsewhere in the literature, and by the relative clinical difficulty fitting large-diameter scleral lenses.\textsuperscript{14,20} Asymmetry and toricity of the sclera manifest clinically as lens decentration and uneven lens bearing, respectively. Lens manufacturers are now able to produce lenses with toric, quadrant-specific, or even up to 8 meridian-specific curves. These lenses provide better alignment with the ocular surface, improved centration, less movement, and decreased debris accumulation- all of which contribute to increased comfort and long-term success of scleral lens wearers.\textsuperscript{14,21}
Complete characterization of the anterior eye intended to allow more empirical design of such precise lenses would describe the following:

1. Elevation profile, diameter, and eccentricity of the cornea
2. Sagittal height in each of 4 primary meridians (0-180 degrees, 45-225 degrees, 90-270 degrees, and 135-315 degrees) to a chord equal to lens landing zone diameter
3. Conjunctival irregularities such as pingueculae, filtering blebs, or scarring.

These data comprise what approaches a virtual topographical map of the entire ocular surface beneath a scleral lens. Alternatively, some practitioners advocate the use of actual impression-mold lens fitting. This process has been used for many years, but was previously only available in the manufacture of PMMA lenses due to the material used for molding. New polymers for molding and digitization of the cast now allow the resulting lens to be lathe cut in high-Dk gas permeable materials. The impression process is reported to be relatively fast to perform and comfortable for the patient.

With procedural modification, anterior segment OCT is capable of imaging up to a 20mm diameter of the anterior ocular surface. This technique is similar to the composite corneal topography with the Medmont E300 as described previously. The validity of OCT measurements of anterior segment structures is well established, and this instrument is favored by many clinicians fitting scleral lenses of different types, from mini-sclerals to large diameter scleral shells such as the Prosthetic Replacement of the Ocular Surface Ecosystem (PROSE)
device developed by Boston Foundation for Sight. At this time, use of the OCT has primarily been studied in the assessment of lens fit rather than data collection for empirical fitting. Gemoules described a method for scleral lens fitting based on conoid formula calculations from corneal curvature, eccentricity, and sagitta. This data set was measured on the steepest and flattest meridians according to corneal toricity. He reported success with this method, reducing the number of diagnostic lenses required before final selection.

The Medmont E300 corneal topographer with Medmont ESH software produced statistically similar sagittal height measurements to Visante OCT in the 0-180 degree meridian of normal eyes. Computation of sagittal height in the remaining 3 principle meridians (45-225 degrees, 90-270 degrees, and 135-315 degrees) with this software would likely add useful data on scleral shape. It should be noted that determination of flat and steep meridians by corneal toricity is not adequate, as the Pacific scleral shape study found that scleral toricity does not necessarily occur in the same meridians.

Scleral lenses present an opportunity to drastically improve quality of life for patients who have exhausted all other lens modalities. However, the list of fitting challenges and limitations, in addition to lens wear complications that are not fully understood, warrants caution in prescribing scleral lenses when other modalities may be feasible. In an extensive review of scleral lens complications and challenges, Walker and colleagues describe that while serious infectious events are reported rarely in scleral lens wear, such incidents have increased with more widespread use of the lenses. Various studies reporting cases of
microbial keratitis (MK) in scleral lens wearers note other pre-existing risk factors for MK such as ocular surface disease and epithelial compromise.\textsuperscript{5,25} Other complications include inflammatory events, corneal epithelial “bogging”, conjunctival prolapse, midday fogging, excessive suction forces, limbal bearing, and hypoxia-related complications.\textsuperscript{3} Due to the recent re-emergence of scleral lenses into common clinical practice, the long-term sequelae of these complications have yet to be fully described.

The patients who arguably have the most to gain from scleral lens wear may also be the most vulnerable to these effects, as ocular tissues compromised by injury, ectasia, surgery, or disease are less resilient.\textsuperscript{10} However, cases such as extreme ocular surface disease or post-penetrating keratoplasty (PK), especially with bulging grafts, scleral lenses provide outcomes unmatched by other modalities. Severinsky et al performed a retrospective study of patients fit in scleral lenses for visual rehabilitation after PK, with a follow up range of 6 months to 9 years. All study subjects had previously failed with spectacles and other contact lenses, and further surgical treatment was contraindicated or undesirable. The authors reported 2 incidents of MK, and a total failure rate of 19.4%. Overall, subjects were visually successful, and had a graft rejection rate similar to post-PK patients who did not wear scleral lenses.\textsuperscript{26}

The decision to fit any patient with scleral lenses must involve a cost-benefit analysis, as well as careful attention to all aspects of lens fitting. Post-lens tear thickness is a key consideration due to the potential for mechanical and hypoxic stress if clearance is inappropriate. Michaud et al developed a theoretical
model for calculating oxygen transmissibility (Dk/t) across scleral lenses and the post-lens tear reservoir. The authors concluded that, in order to meet the previously established minimum Dk/t of 24 centrally and 35 peripherally to avoid hypoxic stress to the cornea, a 250μm-thick lens of 150 Dk material could have a maximum central clearance of 100μm. A 250μm-thick lens of 100 Dk material, could not satisfy both central and peripheral minimum Dk/t values, and could have a maximum central clearance of 100μm to satisfy only the central Dk/t minimum.9 Compañ et al later conducted similar theoretical calculations in combination with a clinical trial measuring partial pressure of oxygen at the ocular surface after lens wear with varying clearance. These results similarly showed that lenses up to 300μm thick with Dk over 75 should be fit with approximately 100μm of clearance to provide the cornea with adequate oxygen.10

There is debate surrounding the clinical significance and long-term effects of low-level corneal hypoxia potentially induced by scleral lens wear. In an editorial regarding theoretical versus clinically observed hypoxia, Bergmanson et al discuss the discrepancy between oxygen availability models discussed previously and the lack of clinical reports of hypoxia-related complications. The authors cite factors missing from the theoretical models, including tear mixing and gas exchange along the perimeter of the lens that may be delivering additional oxygen to the ocular surface.27

Despite the challenges and unknowns, clinicians around the world are turning to scleral lenses when other treatments fail to meet the visual, ocular surface protection, and other ophthalmic needs of their patients. As we have
seen with other contact lens modalities, scleral lens technology and protocols will continue to improve with better understanding of their benefits and risks.

Much of the difficulty faced in fitting scleral lenses is due to their large diameter and the limited understanding of eye shape beyond the limbus. This study explored measurement of sagittal height, a key component of eye shape relevant to scleral lens design. One consideration of the present study is the inclusion of only non-diseased eyes. While serving as a relatively homogenous sample, this is not the demographic most often being fit in scleral lenses. Further study is warranted on the use of Medmont ESH software to measure sagittal height on eyes with more varied and irregular profiles. An additional consideration is the lack of demonstrated within-subject repeatability for each measurement method. However, it is of note that OCT sagittal height data in this study agree closely with published studies of normal populations, as described previously. Future investigation may also include the potential for Medmont ESH software to measure sagittal height in multiple meridians, giving a more complete assessment of the anterior ocular surface.
VI. CONCLUSIONS

Medmont ESH sagittal height measurements do not significantly differ from Visante OCT, a highly specialized imaging instrument. Eaglet ESP sagittal height measurements were significantly lower than both Medmont ESH and Visante OCT. As Placido ring topographers are common in clinical practice, the addition of software such as the Medmont ESH may empower more clinicians to make precise measurements to aid the process of scleral lens fitting.
VII. REFERENCES


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Comparison of Sagittal Height Measurement Methods

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Introduction

Methods

Practical Application

Results

Summary

Conclusion

Visante OCT mean 3,727.50 ± 188.45 μm
Eaglet ESP mean 3,680.96 ± 202.70 μm
Medmont ESH mean 3,732.48 ± 159.14 μm

The lower the corneal angle the less the height.
The higher the angle the greater the height.