

HOW DEEP IS YOUR VAULT? COMPARISON BETWEEN VAULT AND
CORNEAL EDEMA

by

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CORNEAL EDEMA

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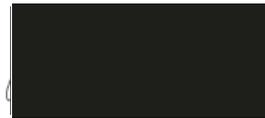


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ABSTRACT

Background: Scleral lenses are used to provide optimal vision for patients who have corneal pathology. Current practitioners are looking towards scleral lenses to fit healthy corneas for the comfort and vision they provide. Material Dk and lens thickness are adjusted when considering oxygen permeability, however, with the rigid nature of scleral lenses, post-settle vault thickness must also be observed. To determine how vault thickness relates to corneal edema, this study examines corneal pachymetry values before and after an eight hour day of wear. Four different vaults were assessed to determine if a pattern exists.

Methods: Participants in this study were optimally fit in a 15.8 mm diameter scleral lens that provided limbal clearance. The lens thickness (400 microns) and material Dk (100) remained the same for each pair. The limbal clearance zone was adjusted to provide post-settling vaults of 100, 300, 500, and 700 microns. Change in average corneal thickness before and after lens wear for each subject was assessed.

Results: There appears to be a direct relationship between vault depth and corneal swelling. As vault increased corneal swelling increases. Corneal swelling was less than clinically significant. Average corneal swelling ranged from 0.62-1.70%. *Conclusion:* For practitioners fitting scleral lenses on healthy corneas, there appears to be a range of vaults that induce less than significant corneal swelling. Clinically significant corneal edema of 6% was not reached when fit with a lens providing 600-799 microns of vault. Subjects measured higher visual acuity when wearing lenses that provided a post-settle

vault in the 0-199 micron range. Further research is needed to better understand the effects of wearing scleral lenses for longer than eight hours.

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CHAPTER 1

INTRODUCTION TO SCLERAL LENSES

Scleral contact lenses have been used for years to treat ocular surface disease and pathology.¹ With advancements in lathe and material technology, practitioners are beginning to fit scleral lenses on healthy corneas² for the comfort and quality of vision they provide. Expanding the use of scleral lenses to include more than disease state corneas brings up questions about what acceptable fitting parameters should allow. While there are many factors that go into the overall fit of a scleral contact lens, one of the constant concerns in the cornea-scleral-relationship is the oxygen available for the cornea after the introduction of the scleral lens. Maintaining oxygen presence at the level of the cornea in high enough concentrations is fundamental when discussing the safe use of contact lenses³, whether it is a gas permeable lens, soft lens, hybrid lens, or scleral lens. To address this, different materials have been used to create lenses that allow oxygen to move easily through them. The ease at which oxygen moves through lens material is referred to as the diffusion of oxygen constant or Dk. Due to the high metabolic need for oxygen by the cornea, this measurement of Dk is referenced when choosing the appropriate lens for daily, extended, or nocturnal lens wear⁴. Scleral contact lenses are currently being made with material that has a hyper Dk. That being the case, further investigation is required to fully understand whether or not Dk can be viewed by practitioners the same way as fitting a standard GP lens, or if there are other

considerations that need to be taken into account. Due to the rigid nature of scleral lenses, post-settle vault thickness must also be observed and accounted for. In order to more accurately determine how vault thickness relates to corneal edema, this study examines corneal pachymetry values before and after an eight hour day of scleral lens wear. Four different vaults were assessed to determine if a pattern exists between vault thickness and corneal edema in order to aid practitioners in fitting patients with healthy corneas in scleral lenses. By determining if there is a relationship between vault thickness and corneal edema, a practitioner will be able to more accurately assess what vault to choose for their patient.

CHAPTER 2

MATERIALS AND METHODS

Acuity Measurement

Participants were asked to present to clinic for baseline refraction; participants who were previous contact lens wearers were asked to wear their glasses for this exam. An optimal refraction was done and visual acuity was taken at a distance of 10 feet using a liquid crystal display (LCD) monitor calibrated for a room length of 20 ft. A Snellen chart was used on the LCD monitor for visual acuity measurements. All participants were best corrected to 20/20 with no known ocular pathology or binocular vision complications.

Pachymetry Measurement

Pachymetry measurements were obtained by using a Pachmate pachymeter by DGH technology. This pachymeter takes 25 measurements of corneal thickness at the point being tested and averages them. Before measurements were taken one drop of anesthetic was instilled into the eye being tested. Corneal integrity was inspected with slit lamp examination before and after each measurement. Corneal thickness values were then input into an excel spreadsheet for later analysis.

Anterior Segment Optical Coherence Tomography Measurements

A Visante anterior segment optical coherence tomography (AS-OCT) was used to obtain pre and post-settle lens vault, ensure adequate limbal clearance, and measure global pachymetry values before and after wear. The procedures involved with obtaining all

measurements required the participants to look into the AS-OCT at a target while placing their chin on a chin-rest and forehead on a forehead-rest. Different measurements were taken using the software on the Visante. Global pachymetry was measured before lens insertion and after lens removal; values from central, superior, inferior, nasal, and temporal cornea were recorded for each participant and input into an excel spreadsheet for later analysis. An enhanced AS-OCT was obtained 10 minutes after lens insertion and 10 minutes prior to lens removal to accurately measure vault depth. Vault depths for each participant before and after eight hours of wear was input into an excel spreadsheet for later analysis.

Participants in the Study

Participants who were involved in this study were adults (at least 18 years of age or older) selected from the Michigan College of Optometry student population. Each subject was willing and able to follow instructions and maintain the study appointment schedule. Participants with known corneal disease, ocular pathology, or binocular vision complications were excluded from the study along with anyone pregnant or underage.

Initial Visit

At the initial visit participants were optimally fit in a 15.8 mm diameter, toric periphery, scleral lens that provided limbal clearance while minimizing tear exchange. Four pairs of lenses were ordered for each participant. The lens thickness (400 microns) and material Dk (100) remained the same for each pair. The limbal clearance zone was adjusted to provide post-settling vaults consisting of 0-199, 200-399, 400-599, and 600-799 microns. After being awake for a minimum of one hour, participants were asked to arrive, wearing glasses if correction was necessary, for the first available morning appointment. Baseline

visual acuity, central corneal thickness, and global pachymetry measurements were obtained using Snellen visual acuity, Pachmate, and Visante AS-OCT respectively. A drop of 0.5% Tetracaine was used as an anesthetic during Pachmate testing. A pair of scleral lenses was then inserted with the proper insertion tool to be worn for eight hours. Scleral lenses were filled with sterile preservative-free saline. Following insertion of the scleral lenses, visual acuity was checked and an anterior segment OCT was performed to verify vault and limbal clearance.

After Wear Visit

Participants returned after eight hours of wear. Visual acuity was checked along with an additional anterior segment OCT scan to verify the post-settle vault. The lenses were then removed using a small suction removal device and global pachymetry was assessed with the Visante AS-OCT. A drop of 0.5% Tetracaine was instilled as an anesthetic for Pachmate testing of the central cornea. Corneal thickness measurements were accumulated in this manner for each eye of all four subjects for each vault being assessed. The data was analyzed by looking at the change in average corneal thickness before and after lens wear for each subject.

CHAPTER 3

RESULTS

Global Pachymetry Measurement

Figures 1 and 2 show the global pachymetry measurement function of the Visante AS-OCT before (Figure 1) and after (Figure 2) eight hours of scleral lens wear.

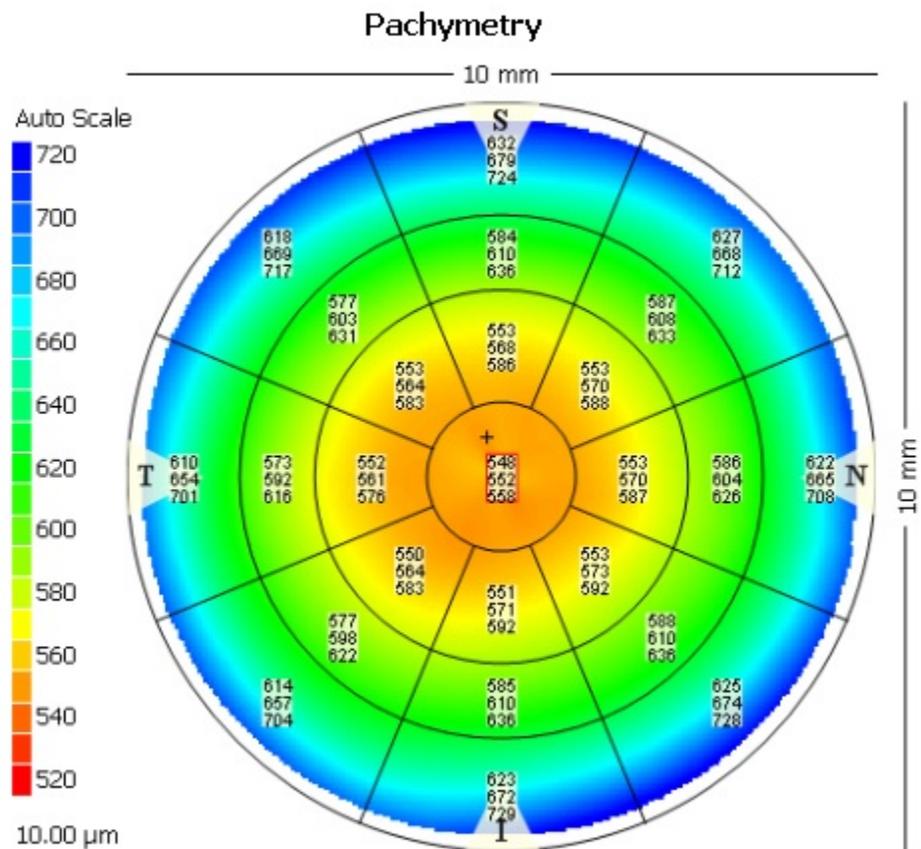


Figure 1. Visante AS-OCT global pachymetry measurement of subject prior to lens wear.

Measurements were taken from the central cornea and 2 mm out from central cornea in the superior, inferior, nasal, and temporal directions. At each location the Visante AS-

OCT recorded the minimum, average, and maximum value for the section of cornea being measured. Global pachymetry values analyzed were the average from each section of cornea measured by the Visante AS-OCT.

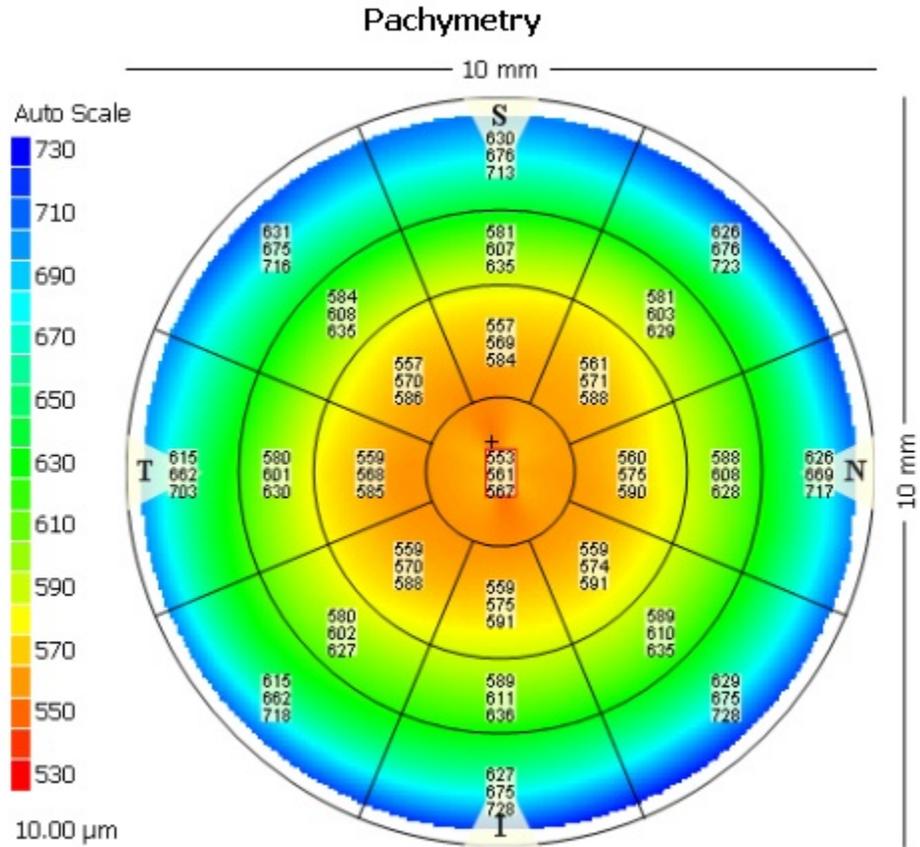


Figure 2. Visante AS-OCT global pachymetry measurement of subject after lens wear.

Values for each participant were analyzed by taking the difference of before and after scleral lens wear for each vault; a percentage of corneal edema was determined and organized in Table 1.

Vault	Pachmate		Central OCT		Nasal OCT		Temporal OCT		Average		Superior OCT		Inferior OCT	
	OD	OS	OD	OS	OD	OS	OD	OS	OD	OS	OD	OS	OD	OS
0-199	0.62	1.07	1.25	0.35	0.66	1.45	0.95	-0.40	0.86	0.67	0.63	0.95	1.06	0.61
200-399	0.79	1.30	0.80	1.21	0.41	0.01	2.16	1.58	1.24	1.13	3.05	1.27	0.24	1.38
400-599	0.74	1.44	0.97	0.81	1.78	0.90	1.27	1.38	1.29	1.52	1.32	3.38	1.67	1.19
600-799	1.00	1.70	1.06	0.64	1.51	1.64	2.05	0.67	1.67	1.17	2.04	1.32	2.35	1.02

Table 1. Percent of corneal swelling after eight hours of scleral lens wear based on accumulation of global pachymetry measurements categorized by location and eye.

Pachmate Pachymetry Measurement

Central corneal thickness (CCT) measurements for each eye were taken using a Pachmate pachymeter before and after scleral lens wear. The difference in CCT was calculated and a percentage of corneal edema was determined and organized based on vault and participant (Table 2).

Vault	Subject 1		Subject 2		Subject 3		Subject 4		Average %	
	OD	OS								
0-199	1.21	0.35	-1.35	1.02	0.85	1.51	1.78	1.41	0.62	1.07
200-399	2.10	2.46	0.34	0.34	-0.17	1.01	0.88	1.40	0.79	1.30
400-599	2.09	1.75	0.84	0.84	-0.68	0.67	0.70	2.49	0.74	1.44
600-799	1.75	1.05	3.75	3.03	-1.15	2.39	-0.35	0.35	1.00	1.70

Table 2. Pachmate measurements representing percent of corneal swelling after wearing a scleral lens for eight hours categorized by subject, eye, and vault.

Further analysis to determine average change in CCT for all participants can be seen in Figure 3.

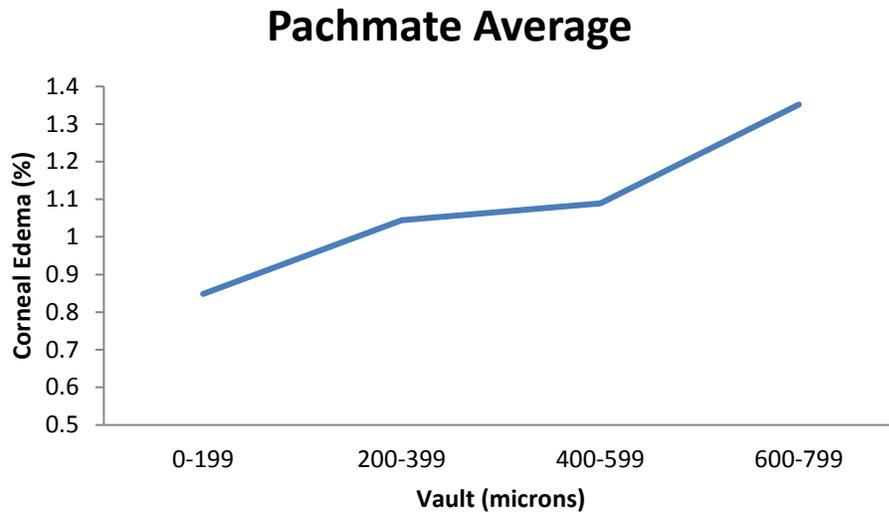


Figure 3. Pachmate measurements of average change in CCT represented as a percentage after eight hours of scleral lens wear.

Vault Depth and Limbal Clearance

Each participant's initial vault and end-of-day vault was measured to ensure parameters were maintained throughout the study. With the exception of four lenses, all pre and post-vaults were within pre-specified vault depths detailed by study protocol; the data collected for the four lenses that were outside study protocol were not included in data analysis. All lens fits provided adequate limbal clearance.

Corneal Edema

Analysis of the data shows a direct relationship between vault and corneal swelling. As vault increases corneal swelling appears to increase when measured by both Visante AS-OCT global pachymetry and Pachmate (Figure 4).

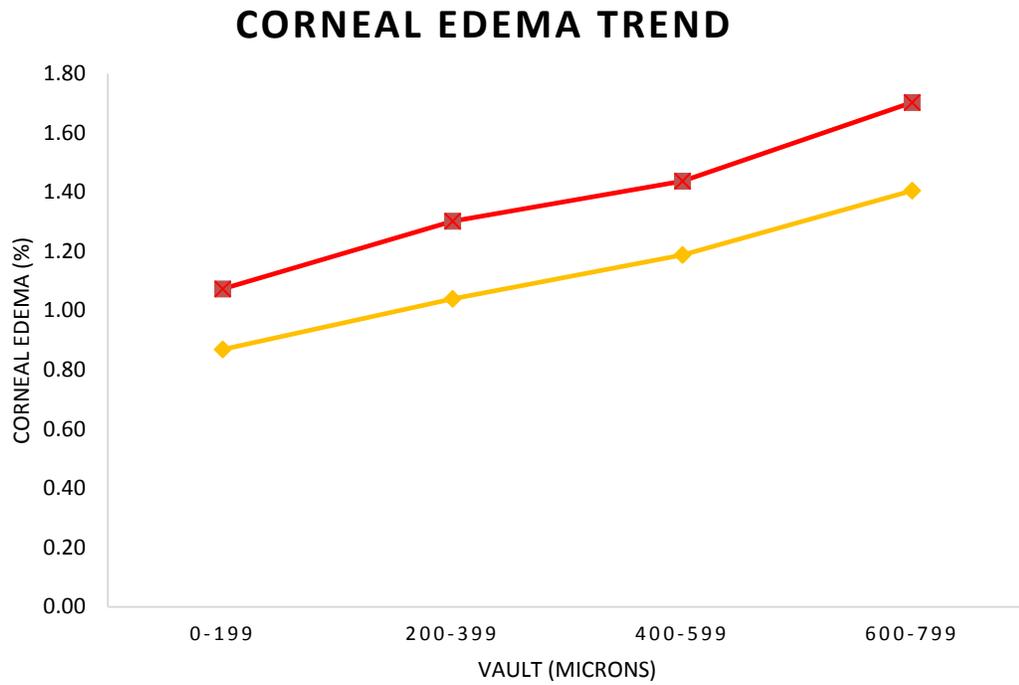


Figure 4. Comparison between OCT (diamond) and PachMate (square) measurements of change in corneal thickness represented as a percentage after eight hours of scleral lens wear.

On average the percent of corneal edema measured by the Pachmate was 0.25% higher than when measured with the Visante AS-OCT, however, both modes of measurement display a similar trend of increased corneal edema with higher amount of vault.

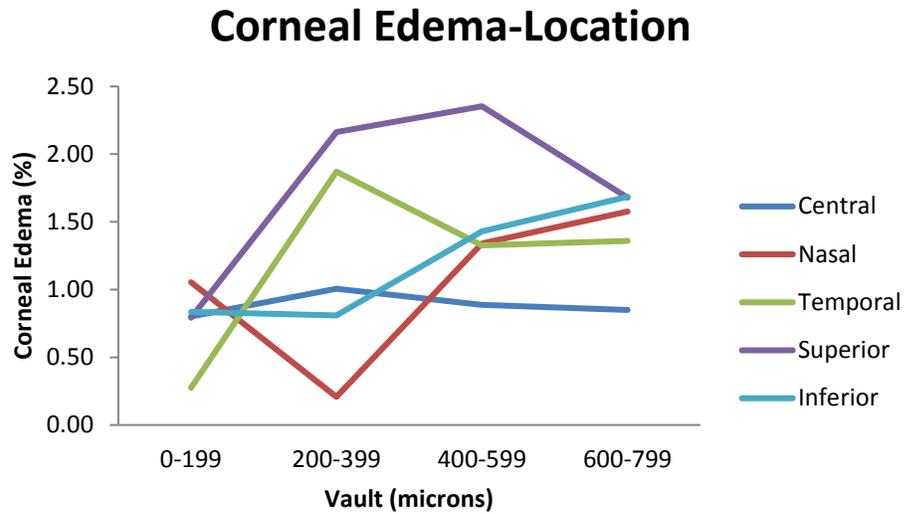


Figure 5. Comparison between vault and percent corneal edema based on location on the cornea.

When analyzing the superior, inferior, nasal, and temporal points, there appears to be a larger amount of corneal swelling taking place superiorly for all vault depths other than the 0-199 micron range (Figure 5). Higher vaults had a tendency to show slightly larger fluctuations in where swelling was occurring on the cornea and the 200-399 micron vault range showed the larger fluctuation in corneal edema, possibly suggesting a more stable fit with less movement throughout the day.

CHAPTER 4

DISCUSSION

There are a variety of parameters available for customization when fitting patients in scleral contact lenses. This study aimed to look specifically at post lens vault thickness. In this study the lens thickness (400 microns) and material Dk (100) remained constant. Other constants in the study were fits that provided limbal clearance as well as consistent peripheral curves of the toric scleral landing zone. There appears to be a direct relationship between post lens vault thickness and corneal edema. As post lens vault thickness increases so does corneal edema (Figure 4). Previous studies⁵ have shown when corneal edema reaches a clinically significant level of 6%, visual acuity begins to be affected. On average, participants in this study who were fit in a scleral lens that provides a tear lens vault of 600-799 microns, the most inappropriate scleral lens, corneal swelling was below 2% (Figure 4) contrary to what some theoretical models predict⁶.

While this study does show a direct relationship between post-lens tear vault thickness and corneal edema, even the thickest vault does not induce clinically significant corneal edema. For practitioners fitting scleral lenses on healthy corneas, there appears to be a range of vaults that induce less than significant corneal swelling. Careful consideration of physiological corneal requirements must be taken while determining the proper lens recommendation to patients. A cellular level of understanding is required to fully appreciate the importance of oxygen when discussing lens material as well as lens fit.

What is acceptable for one patient may not be acceptable for another. Regardless of the type of lens being fit, routine follow-ups are necessary to ensure patient health.

When making the decision to fit scleral contact lenses in a practice, Optometrists are required to have a deep level of understanding about complications that can arise and the physiological red flags to look for that are caused by these complications. With the proper level of education and comfort with the contact lens fitting process, practitioners are able to expand the use of lenses to maximize patient experience. Improvements in lens material and repeatability with precision lathes have provided fitters with the ability to fit some of the most optically clear and comfortable lenses available. With the proper comfort level, practitioners are able to build successful scleral lens practice and properly modify lenses to manage a variety of patient complaints. Having a proper balance to understanding the metabolic demands of the cornea and contact lens fitting procedures will provide the insight to accept and understand current unknowns as they are discovered throughout the upcoming years through research. Additional research is required to completely understand the differences in the cornea-lens relationship between traditional GP's and scleral lenses.

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APPENDIX A
IRB APPROVAL FORM