# EFFECT OF SCLERAL LENS VAULT ON BEST POTENTIAL VISUAL ACUITY, CONTRAST SENSITIVITY, AND HIGHER ORDER ABERRATIONS

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## ABSTRACT

*Background:* There is great variance in what manufacturers recommend for acceptable central vault of scleral lenses. Results from a previous study conducted at the Michigan College of Optometry suggest that increasing central lens vault has a slight detriment on the subject's perceived visual acuity. This study will look at visual acuity, contrast sensitivity and higher order aberrations in subjects wearing scleral lenses with the same optical zone, but varying amounts of central vault.

*Methods:* Patients were fit with four pairs of scleral contact lenses according to the manufacturer fitting guide. The fit was then modified in the mid-peripheral portion to provide roughly 0-199, 200-399, 400-599, and 600-799 micrometers (μm) of central clearance after settling. All other lens parameters were held constant. The lenses were allowed to settle for at least 30 minutes, and the power was verified with an over-refraction prior to data collection. We then tested their visual acuity using a Snellen acuity chart, and contrast sensitivity using a Pelli-Robson chart. Aberrations were measured using the Nidek OPD-Scan III refractive power analyzer. Subjects were asked to fill out a short survey after completing data collection for each lens, as well as a final survey upon completion of all lenses in which they indicated lens preference.

*Results and Conclusions:* The data collected showed trends and patterns that one would expect clinically. As vault height increased, LogMAR visual acuity decreased. There were no changes in contrast sensitivity and higher order aberrations over time nor between vault categories. Lower order aberrations were shown to have increased between vault categories, and subject lens preference was towards the lower vault categories. As the overall ocular health is optimal with a lower vault clearance, it is fitting that the patients prefer these lenses.

Acknowledgments

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# CHAPTER 1: INTRODUCTION

Scleral lenses have been on the rise in recent years due to the advent of new lens materials and their versatility in managing a variety of anterior segment conditions.[1-3] The scleral lenses we are familiar with today have many similarities to the very first contact lenses developed over a hundred years ago.[2-3] These lenses originally fell out of favor because the materials at the time had little to no oxygen transmissibility (Dk/t), which resulted in hypoxic complications for the cornea.[2] The development of materials with improved oxygen transmissibility, and the ability to lathe-cut lenses for a more accurate fit, has resulted in many practitioners and manufacturers revisiting scleral lenses.[1-4]

The general concept of a scleral lens is that the lens is completely supported by the sclera, and vaults over the cornea and limbus to create a fluid reservoir between the cornea and the lens. [1,4] Recently many manufacturers have been developing their own lines of scleral lenses, however there is great variance in what manufacturers recommend for acceptable central vault.[3,5] As one may expect, lenses with a higher vault have a slight reduction in the oxygen transmissibility due to the increased amount of fluid in the reservoir.[3] In addition, results from a previous study conducted at the Michigan College of Optometry suggest that increasing central lens vault in scleral lenses has a slight detriment on the subject's perceived visual acuity.[6] This finding is in line with a similar study that stated that patients have often complained of "watery" and/or poor quality vision with steep fitting rigid gas-permeable lenses.[5] This study seeks to determine if there may be other consequences resulting from higher vaulting lenses. Visual acuity, contrast sensitivity, lower order aberrations, and higher order aberrations will be clinically measured in subjects wearing scleral lenses with the same optical zone (8.5mm) parameters while varying amounts of central vault.

# CHAPTER 2: METHODS

## *Subject Selection*

Participants in this study consisted of students and faculty from the Michigan College of Optometry. All involved were adults of at least 18 years of age or older, and exhibited no ocular abnormalities or pathology. A total of 9 subjects were selected, all willing to adhere to instructions throughout the study's length.

## *Instrumentation*

Visual acuity was measured utilizing a Snellen LCD acuity chart calibrated for a distance of 10 feet. Refractions/over-refractions were performed utilizing this same acuity chart. All visual acuities were converted to logarithm of the minimal angle of resolution (logMAR) for statistical analysis. Contrast sensitivity was measured via a Pelli-Robson chart with a test distance of 1 meter under bright room illumination. Aberrations were measured using the Nidek OPD-Scan III refractive power analyser. Scleral lens vault assessment was performed using Visante anterior segment optical coherence tomography (AS-OCT) during both the initial fittings as well as to verify vaults during data collection. The central spectral beam reflection was used as a landmark to position the eye appropriately to ensure accurate, repeatable scans between lenses. Figure 1 shows an example of the AS-OCT positioning.

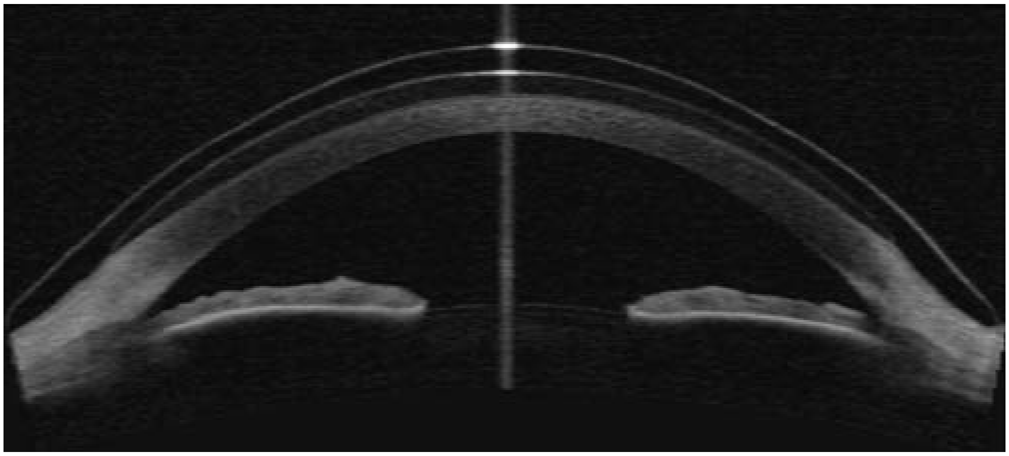

**Figure 1.** Visante AS-OCT anterior segment vault scan.

*Initial Visit*

Upon the first visit, subjects were asked to arrive wearing their glasses, and refraction was performed to achieve a best-corrected visual acuity (BCVA) of at least 20/20. An initial scleral lens was fit on each eye according to the manufacturers guide. After 30 minutes of settling, the lenses were verified for proper refractive error correction with a subjective over-refraction, and the AS-OCT was utilized to determine the central vault clearance. Since the desired vault categories were 0-199µm, 200-399µm, 400-599µm, and 600-799µm for each eye, the remaining 3 sets of lenses were ordered empirically by altering mid-peripheral parameters. These changes did not affect the optical zone of the lenses, and therefore any perceived differences between the lenses would be due to the increase/decrease in lens vault. Post-OCT scan, visual acuity was assessed monocularly via a Snellen chart, and contrast sensitivity via the Pelli-Robson chart. Aberrations were analyzed via the Nidek OPD-Scan III refractive power analyzer.

After 2 hours of settling had occurred, the lens were again verified with an over refraction, visual acuities, contrast sensitivity, aberrations, and vault clearance data were collected.  Throughout the study, the subject is unaware as of which category lens is on eye.  After data collection, each lens' vision quality was rated by the subject on a scale of 1-10; 1 being poor and 10 being excellent.  At the conclusion of the study, subjects were to choose their preferred overall lens based on the quality of vision experienced during wear.

### *Subsequent Visits*

At each subsequent visit, subjects would arrive for testing wearing their glasses, with the criteria that a scleral lens not be worn within the previous 12 hour period.  A lens for each eye from the same vault category (unknown to the subject) would be selected and placed on eye.  The lens would be allowed to settle for 30 minutes, where the subjective over-refraction, AS-OCT vault scan, Nidek aberrations scan, Snellen visual acuity, and contrast sensitivity data would be collected.  After the 1st round of data collection, the lens would be allowed to settle for another 90 minutes (for a total of 2 hours settling time), and data measurements would again be collected.

# CHAPTER 3: RESULTS

*Vault Clearance*

Table 1 shows the average vault clearance in micrometers (µm) after 30 and 120 minutes of settling.

| Table 1 | Vault Clearance Category (µm) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 0 - 199 µm | | 200 - 399 µm | | 400 - 599 µm | | 600 - 799 µm | |
| | Mean | Std Dev | Mean | Std Dev | Mean | Std Dev | Mean | Std Dev |
| **30 min** | 137.86 | 48.703 | 300.56 | 64.486 | 509.33 | 51.335 | 695.0 | 64.54 |
| **120 min** | 116.43 | 41.99 | 263.33 | 53.247 | 476.67 | 52.599 | 675.0 | 46.035 |
| **t{ }** | t(13) = 4.837 | | t(17) = 3.620 | | t(14) = 5.262 | | t(13) = 2.348 | |
| **p** | 0 | | 0.002 | | 0 | | 0.035 | |

**Table 1.** Average Vault Clearance After Lens Settling.

A paired-sample t-test was used to compare the differences between the average vault height within the same clearance category, for 30 and 120 minutes. When comparing the p-values, these statistics show that there are statistical differences between vault clearances at 30 and 120 minutes. This signifies that the lens did indeed settle down over time, and that the lens vault decreased over time.

*Contrast Sensitivity*

The Pelli-Robson contrast sensitivity chart was used to detect any differences in contrast sensitivity at the 30 minute and 120 minute settling mark within, and among, each vault category. Enforcing statistical analysis shows that there was no statistical difference between contrast sensitivity 30 and 120 minute in the same vault category. There also was no statistical difference in contrast sensitivity between vault categories at both the 30 and 120 minute. Figure 2 shows the average contrast sensitivity among vault categories.

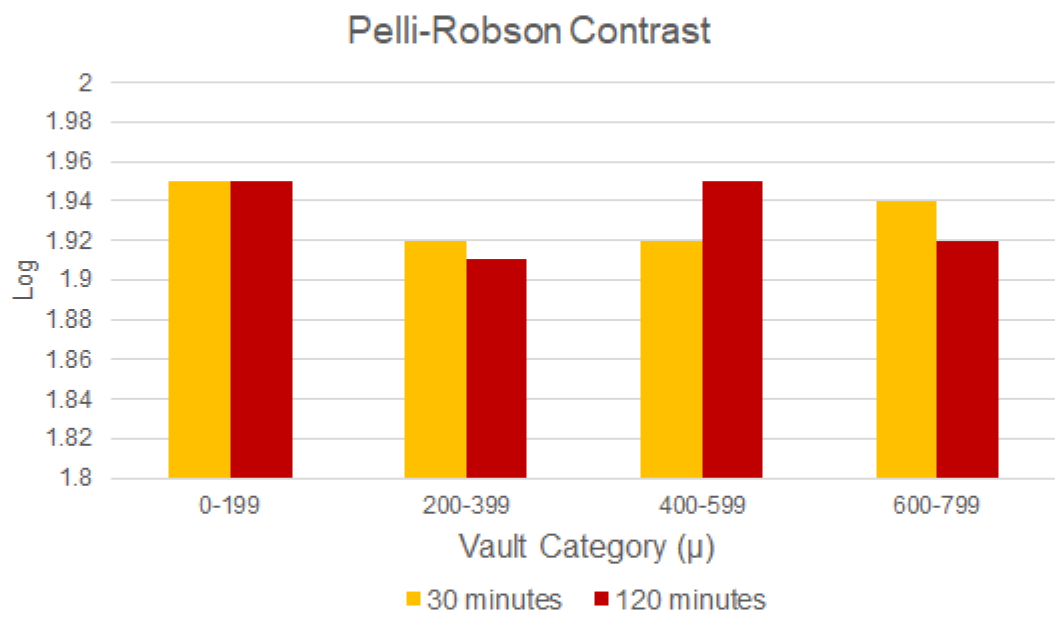


**Figure 2.** Average LogMAR Contrast Sensitivity Between Vault Categories.

*Aberrations*

Aberration data collected via the Nidek was measured with a 4.0mm pupil size. This simulated an average pupil size under both photopic and mesopic conditions, and allowed data to be compared amongst vault categories. Considering there are 14 types of aberrations, they can be split into two categories; lower and higher order. The lower order aberrations consist of piston, x-axis tilt, y-axis tilt, astigmatism, and defocus. The higher order aberrations consist of trefoil, vertical coma, horizontal coma, tetrafoil, secondary astigmatism, and spherical. It is important to note that trefoil and tetrafoil cannot be visually perceived.

Within vault categories, statistical analysis was performed to see if a decrease in vault clearance at 120 minutes from the 30 minute had an effect on aberrations. Paired-sample t-tests showed that vault clearance has a minimal effect on aberrations. Out of the numerous combinations of aberrations and vault heights, the only pair that showed a statistical difference in aberrations was horizontal coma at a 200-399 vault height.

| Table 2 | Horizontal Coma | |
|---|---|---|
| | **Mean** | **Standard Deviation** |
| **30 minutes** | -0.00873 | 0.0373 |
| **120 minutes** | -0.0146 | 0.037 |
| **t{17}** | 2.307 | |
| **p** | 0.034 | |

**Table 2.** Horizontal Coma Aberration T-test Within the Same Vault Category

The results of the paired-sample t tests suggest that both higher and lower aberrations do not change over time.

T-tests were also performed amongst vault categories to see if there is a statistical difference in aberrations with varying vault clearances. Table 3 reveals all the aberrations that were statistically significant between vault categories, accenting those vault categories that were statistically significant over time.

| **Table 3** | **Statistically Significant Vault Comparison** (P < 0.05) | |
|---|---|---|
| **Aberrations** | **30 minutes** | **120 minutes** |
| **piston (lower)** | 0-199 to 200-399 | 0-199 to 200-399 |
| | 0-199 to 400-599 | 0-199 to 400-599 |
| | 200-399 to 400-599 | 200-399 to 400-599 |
| **x-axis tilt (lower)** | 0-199 to 200-399 | no statistical difference |
| **defocus (lower)** | 0-199 to 200-399 | 0-199 to 200-399 |
| | 0-199 to 400-599 | 0-199 to 400-599 |
| | 200-399 to 400-599 | 200-399 to 400-599 |
| **vertical coma (higher)** | 0-199 to 200-399 | no statistical difference |
| **spherical (higher)** | 0-199 to 200-399 | no statistical difference |
| **tetrafoil (higher)** | no statistical difference | 0-199 to 200-399 |

**Table 3.** Statistically Significant Aberrations Between Vault Categories

While statistical analysis previously showed that aberrations do not change over time within a vault category, it was shown that lower order aberrations, specifically piston and defocus, do in fact increase as vault height increases. Data was not consistent enough to prove that there is a significant difference in higher order aberrations among vault categories.

*Subjective Vision Quality*

After data collection, subjects were asked to rate their quality of vision on a scale from 1 - 10; 1 being very poor and 10 being excellent. Figure 3 shows the average rating that each vault category received. Lower vault categories 0-199µm and 200-399µm received a larger rating versus the higher 400-599µm and 600-799µm categories. Figure 3 illustrates this data.

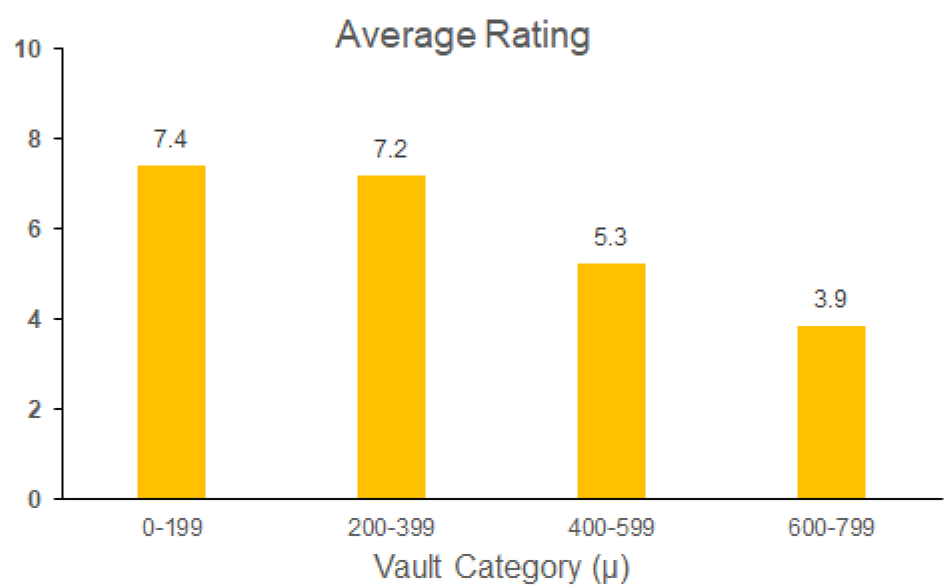


**Figure 3.** Average Rating of Visual Quality per Lens Category.

*Subjective Preferred Overall Lens*

Following conclusion of the study, subjects were asked to designate which lens they believed offered the highest visual quality. Subjects are unaware as to which vault height the lens corresponds to. As evident in Figure 4, 88% of the subjects preferred a vault size between 0 to 399µm, with only 12% preferring the 600-799µm clearance.

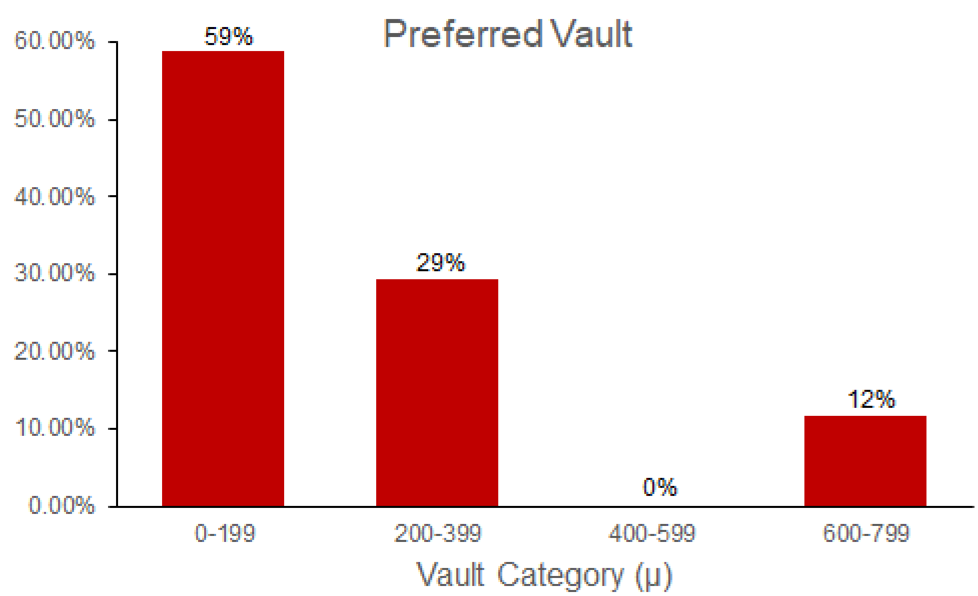


**Figure 4.** Post-Study Participant Preferred Lens Vault Category

*Visual Acuity*

Statistical analysis was also performed on the LogMAR visual acuity data to see if there is a significant difference in acuity over time within the same vault category, as well as different vault categories. What was shown is that there are no significant differences in visual acuity between the 30 minute and 120 minute mark within the same vault category. Table 4 exhibits those vault category comparisons that had statistically significant visual acuity differences, accenting the categories that were statistically different in each time category.

| **Table 4** | **Statistically Significant Differences in VA Vault Comparison** (P-value < 0.05) |
|---|---|
| **30 minutes** | 0-199 to 600-799 |
| | 0-199 to 400-599 |
| | 200-399 to 600-799 |
| **120 minutes** | 0-199 to 600-799 |
| | 0-199 to 400-599 |
| | 200-399 to 600-799 |
| | 400-599 to 600-799 |

**Table 4.** Statistically Significant Differences in VA Vault Comparison

As evident, LogMAR visual acuity is significantly different when comparing a lower vault to a higher vault.

# CHAPTER 4: DISCUSSION

When fitting a scleral lens, there are multiple factors to take into consideration that may have an effect on the overall vision quality perceived. This study was designed to isolate the scleral lens vault clearance element by keeping lens thickness, material (dk/t), and optical zone parameters constant between lenses. Data was gathered on visual acuity, contrast sensitivity, and aberrations to look for any differences or patterns between varying vault heights.

As noted previously, the Pelli-Robson contrast sensitivity chart showed no statistical difference between both the 30 minute and 120 minute mark, and different vault categories. While the test may have been performed under equal room illumination, the lack of even chart illumination may have had an influence on the results. It is also important to take into consideration that the Pelli-Robson chart measures contrast sensitivity in 0.08 log unit intervals. Utilizing a different chart, such as the MARS with 0.04 log unit intervals, may allow for increased sensitivity, and show a difference between vault categories.

Looking at optical aberrations within the study, it was found that lower order aberrations increased among increasing vault categories. Higher order aberrations were not statistically different both within and between vault categories. It is important to take into consideration that the Nidek instrument scanned for aberrations using a 4mm pupil size. Either increasing or decreasing pupil size may have a large effect on aberrations perceived. Knowing that higher order aberrations do not change with vault height while lower aberrations do is clinically relevant, as these aberrations can be minimized or corrected with a low vault clearance lens fit.

In regards to LogMAR visual acuity, the study revealed the inverse relationship that one would expect clinically; as vault clearance increases, visual acuity declines. This correlated with the participants subjective, post-study responses. When rating lenses individually, the lower vault categories received higher visual quality ratings than the greater clearance categories. When asked to choose their most preferred lens, 88% of the participants chose a lens with a 0-399 μm clearance, while 67% within that group chose the 0-199 μm lens.

Based on the results of this study, it's apparent that a lower lens vault clearance is the preferred fitting choice for a clinician. The lower vault height minimizes aberrations and maximizes visual acuity without impacting contrast sensitivity. Considering that a lower vault clearance is better for the overall ocular health (oxygen transmissibility), there is the added benefit that the data supports a lower clearance as the patient's preference.

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