

THE ACUVUE DEFINE DESIGN: IS YOUR VISION REFINED OR DECLINED?

by

Joshua Halm and Brittany Hoolsema

This paper is submitted in partial fulfillment of the
requirements for the degree of

Doctor of Optometry

Ferris State University
Michigan College of Optometry
May 2017

THE ACUVUE DEFINE DESIGN: IS YOUR VISION REFINED OR DECLINED?

by

Joshua Halm and Brittany Hoolsema

Has been approved

31 May, 2017

APPROVED:



Faculty advisor

ACCEPTED:



Faculty Course Supervisor

Ferris State University
Doctor of Optometry Senior Paper
Library Approval and Release

THE ACUVUE DEFINE DESIGN: IS YOUR VISION REFINED OR DECLINED?

We, Brittany Hoolsema and Joshua Halm, hereby release this paper as described above to Ferris State University with the understanding that it will be accessible to the general public. This release is required under the provisions of the Federal Privacy Act.

Do

Doctoral Candidate

____3/28/17____
Date

ABSTRACT

Background: To investigate the influence of limbal ring-design 1-Day Acuvue® Define® decorative lenses on ocular wavefront aberrations and visual performance.

Methods: In 68 eyes of 34 subjects, LogMAR visual acuity, contrast sensitivity, and higher-order aberrations (HOAs) were evaluated before and during decorative disposable contact lens wear (1-day Acuvue® Define®; Vistakon, Jacksonville, FL). Corneal HOAs across a 4mm and 6mm pupil were measured for tilt, coma, trefoil, spherical, and total aberrations.

Results: There were no significant differences in the measured visual performance or HOAs between the 1-Day Acuvue® Define® and the 1-Day Acuvue® Moist®.

Conclusions: The limbal ring-design 1-Day Acuvue® Define® soft contact lenses were not found to induce HOAs and negatively affect visual performance in comparison to the clear 1-Day Acuvue® Moist®. In our study, we found the decorative lenses were often decentered, resulting in poor cosmetic appearance. Further investigation is needed to evaluate subjective visual and cosmetic performance of this lens design.

Keywords: Decorative lenses, Higher-order aberrations, Visual performance

ACKNOWLEDGEMENTS

We would like to thank Amy Dinardo, OD, FAAO for acting as our advisor for this project and guiding our research. We would also like to thank Minji Sohn, Ph.D. for running the statistical analysis and student Allegra Babiarz for data collection.

TABLE OF CONTENTS

	Page
LIST OF TABLES.....	vi
LIST OF FIGURES.....	vii
 CHAPTER	
1 INTRODUCTION.....	1
2 METHODS.....	3
3 RESULTS.....	5
4 DISCUSSION.....	11
 APPENDIX	
A. IRB APPROVAL LETTER.....	16

LIST OF TABLES

Table		Page
1	Effects of Lens Wear on Pupil Size.....	5
2	Effects of Lens Wear on Optical Quality.....	6
3	Effects of Lens Wear on Various Measures of Contrast.....	9

LIST OF FIGURES

Figure		Page
1	Corneal Aberrations Present in a Photopic Pupil: Baseline vs. Acuvue® Moist®.....	7
2	Corneal Aberrations Present in a Mesopic Pupil: Baseline vs. Acuvue® Moist®.....	8
3	Corneal Aberrations Present in a Photopic Pupil: Acuvue® Moist® vs. Acuvue® Define®.....	10
4	Corneal Aberrations Present in a Mesopic Pupil: Acuvue® Moist® vs. Acuvue® Define®.....	11

INTRODUCTION

The main use of cosmetic soft contact lenses (SCLs) is to change the appearance of the eyes, either by enhancing or by modifying the color of the underlying iris. The 1-Day Acuvue® Define® brand disposable contact lenses have a central clear zone and a tinted periphery that contains a pigmented area of color additives that alter or enhance the appearance of the natural iris at the limbus.

Higher-order aberrations (HOAs) are errors of the optical system of the eye which can deteriorate the quality of the retinal image. These optical irregularities result in halos, glare, loss of contrast sensitivity, decreased visual acuity, and night vision disturbances [1]. Takabayashi *et al* investigated wavefront aberrations between 1-Day Acuvue® Define® daily disposable lenses and clear 1-Day Acuvue® Moist®. Their study found that not only is there an increase in HOAs wearing the 1-Day Acuvue® Define®, but the total HOAs of decorative lenses which fit poorly were approximately 1.5-fold larger than those fit properly [2].

Schafer *et al* investigated the performance characteristics of two cosmetically tinted contact lenses; 1-day Acuvue® Define® and Bausch + Lomb® Naturelle™. Their study found that the Acuvue® Define® lenses were significantly less likely to be fully

centered and significantly more likely to have incomplete corneal coverage and/or edge lift compared with the Bausch + Lomb® Naturelle™ lens [3].

The purpose of this study is to investigate the influence of the limbal ring-design 1-Day Acuvue® Define® decorative lenses on corneal wavefront aberrations and visual performance.

METHODS

The study included non-presbyopic candidates with a refractive error between one diopter of hypermetropia and seven diopters of myopia, with astigmatism less than three quarters of a diopter. Exclusion criteria included not having a comprehensive eye examination within two years, best-corrected visual acuity (BCVA) less than 20/20, and the presence of ocular pathology.

The 1-Day Acuvue® Define® lenses (Vistakon, Jacksonville, FL) are decorative SCLs made of etafilcon A material available in spherical powers. The lens is colored with one or more of the following color additives: iron oxides, titanium dioxide, phthalocyaninato (2-) copper, phthalocyanine green, and Reactive Blue Dye #4. The total diameter is 14.2mm with a base curve of 8.6mm. The Dk/t is 25.5×10^{-9} with a water content of 58%. Although the lens is available in multiple variants including NATURAL SPARKLE®, NATURAL SHIMMER®, NATURAL SHINE®, ACCENT STYLE, and VIVID STYLE; only NATURAL SPARKLE® and NATURAL SHINE® were included in this investigation [4].

To evaluate visual performance of the decorative lenses, the following measurements were taken: 100% contrast logMAR acuity, 50% contrast logMAR acuity,

Pelli-Robson contrast sensitivity, pupil size (photopic & mesopic) and corneal HOAs before and during wear of the tinted SCLs. Each lens was worn for 5 minutes before measurements were taken. Corneal HOAs and wavefront analysis were performed across a 4.0 mm (photopic) and 6.0 mm (mesopic) pupil using a NIDEK OPD-Scan III, aberrometer/corneal topographer. These measurements were performed with the contact lens in place without the use of dilating drops. The fit of the lenses was assessed using a slit lamp examination and the Medmont E300 Corneal Topography. Contrast sensitivity was measured using a Pelli-Robson chart.

The methods described were repeated using the non-decorative 1-Day Acuvue® Moist® (Vistakon, Jacksonville, FL), which has similar physical and optical properties as the 1-Day Acuvue® Define®. The vision performance of the 1-Day Acuvue® Moist® was evaluated in both eyes and was compared to that of the NATURAL SPARKLE® (right eye, OD) and NATURAL SHINE® (left eye, OS). Statistical analyses were also performed to compare the results of pupil size, optical quality and corneal HOAs of 1-Day Acuvue® Moist® SCLs to no contact lens wear, hereafter referred to as baseline.

CHAPTER 3

RESULTS

Thirty-four subjects (68 eyes) met the study criteria (10 men, 24 women). Patients ranged in age from 21 to 28 with an average age of 24 and the mean spherical equivalent refractive error was -2.50 DS both OD and OS with a range of -7.00 DS to +0.50 DS. All patients were able to achieve 20/20 visual acuity or better with habitual correction. For all statistics, comparisons were made between differing conditions within the same eye; at no point was OD compared to OS.

The subject's data at baseline and wearing the control 1-Day Acuvue® Moist®

	OD Mean ± SD	OS Mean ± SD
Photopic Pupil		
Baseline	5.178 ± 0.867	4.776 ± 0.955
Acuvue® Moist®	4.597 ± 0.846*	4.400 ± 0.813 ⁺
Acuvue® Define®	4.322 ± 0.851 ⁺	4.115 ± 0.839 ⁺
Mesopic Pupil		
Baseline	6.918 ± 0.795	6.666 ± 0.837
Acuvue® Moist®	6.578 ± 0.837*	6.271 ± 0.837*
Acuvue® Define®	6.393 ± 0.846	5.771 ± 0.805 ⁺

Table 1. Mean pupil size (*mm*) in bright illumination (photopic pupil) and dim illumination (mesopic pupil) at baseline (no SCL wear), and wearing the Acuvue® Moist®, and the Acuvue® Define® SCLs (NATURAL SPARKLE® OD; NATURAL SHINE® OS). The Acuvue® Moist® was compared to baseline and Acuvue® Define® to Acuvue® Moist®. *SD* Standard Deviation, ⁺*P*<0.05, **P*<0.01, paired *t*-test.

Table 2. Strehl Ratio and RMS at baseline (no SCL wear), wearing the Acuvue® Moist®, and wearing the Acuvue® Define® (NATURAL SPARKLE® OD; NATURAL SHINE® OS). The Acuvue® Moist® was compared to

	OD	OS
	Mean ± SD	Mean ± SD
Strehl Ratio		
Baseline	0.044 ± 0.102	0.033 ± 0.075
Acuvue® Moist®	0.153 ± 0.147*	0.119 ± 0.060
Acuvue® Define®	0.094 ± 0.050 ⁺	0.113 ± 0.086
RMS Value		
Baseline	0.178 ± 0.081	0.200 ± 0.129
Acuvue® Moist®	0.199 ± 0.080	0.204 ± 0.114
Acuvue® Define®	0.207 ± 0.075	0.227 ± 0.113

baseline and Acuvue® Define® to Acuvue® Moist®. *SD* Standard Deviation. +P<0.05, *P<0.01, paired *t*-test.

SCL are summarized in Tables 1-2. Pupil size when wearing the

Acuvue® Moist® SCL was significantly smaller than at baseline in both photopic (P<0.01 OD, P<0.05 OS, paired *t*-test) and mesopic (P<0.01 both eyes,OU) conditions (Table 1). The Strehl ratio was significantly higher when wearing the lens in either eye (0.153 OD, 0.119 OS) than at baseline (0.045 OD, 0.033 OS; P<0.01 OU (Table 2)).

There was no significant difference in the RMS value between these two conditions.

Wear of this SCL also resulted in an increase in certain corneal aberrations. Under photopic conditions, tilt and coma aberrations were found to be increased OD from 0.115 ± 0.093 to 0.279 ± 0.253 (P<0.01) and from 0.061 ± 0.037 to 0.080 ± 0.055 (P<0.05), respectively (Figure 1).

Total aberration in the left eye was measured to be 0.604 ± 0.352 (P<0.05) compared to 0.479 ± 0.152 at baseline. Spherical aberration was found to be significantly decreased in the right eye when wearing the 1-Day Acuvue® Moist® SCL to 0.040 ± 0.018 from

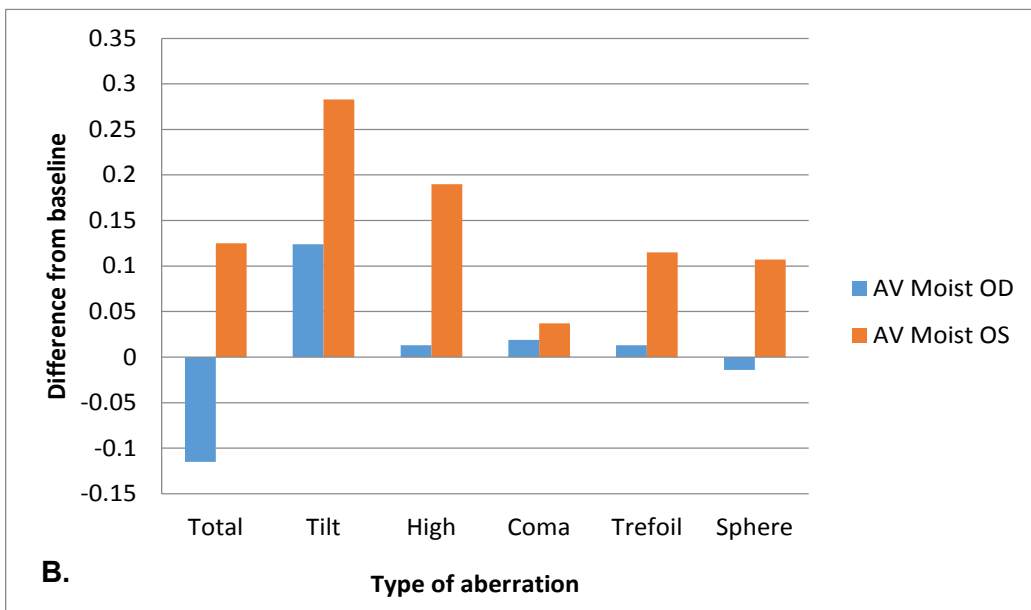
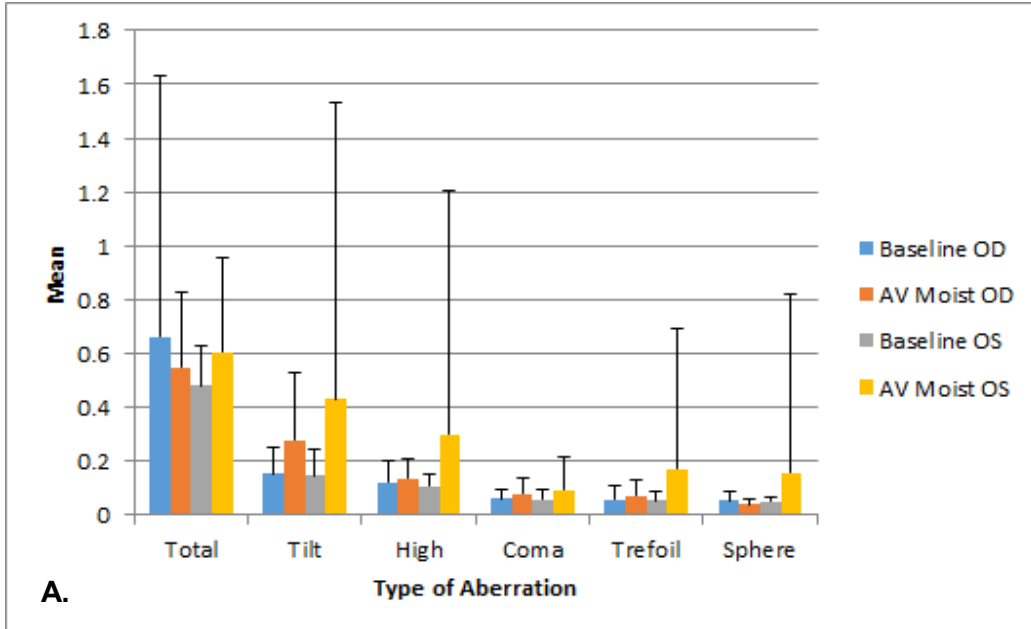


Figure 1. A. Corneal aberrations present at baseline (no SCL wear) and wearing the Acuvue® Moist® (AV Moist) OD and OS with a photopic (4mm) pupil. Total and Coma aberrations were significant OS and OD, respectively, at $P < 0.05$, paired t -test. Tilt and Spherical aberrations were significant OD at $P < 0.01$, paired t -test. Graph is expressed as the Mean \pm Standard Deviation. **B.** Demonstrates corneal aberrations induced by wear of the AV Moist lens compared to those already present at baseline.

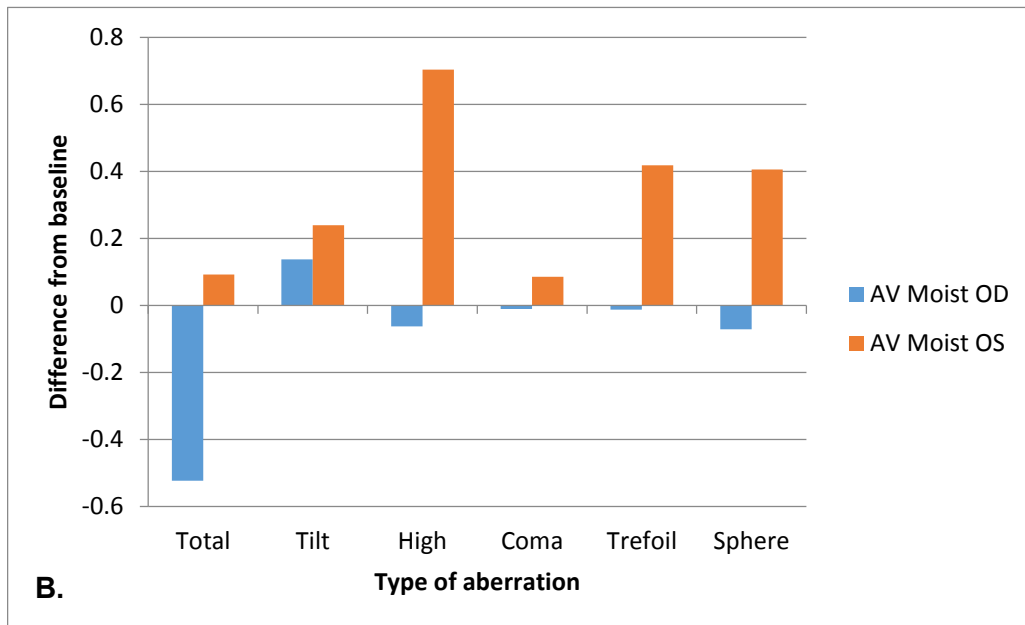
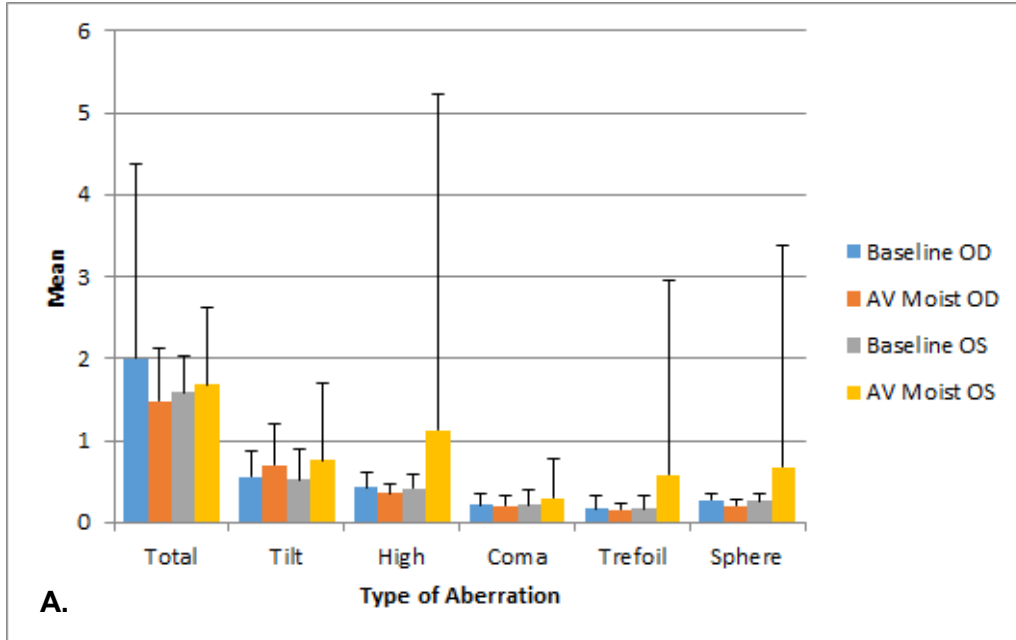


Figure 2. A. Corneal aberrations present at baseline (no SCL wear) and wearing the Acuvue® Moist® (AV Moist) OD and OS with a mesopic (6mm) pupil. Tilt aberrations were significant OD at $P < 0.05$, paired t -test. High and spherical aberrations were significant OD at $P < 0.01$, paired t -test. Graph is expressed as the Mean \pm Standard Deviation. **B.** Demonstrates corneal aberrations induced by wear of the AV Moist lens compared to those already present at baseline.

0.054 ± 0.032 at baseline (P<0.01). Under mesopic conditions, tilt aberration in the right eye was again significantly increased from 0.561 ± 0.322 to 0.698 ± 0.514 (P<0.05; Figure 2). Both spherical and high aberrations in the right eye were significantly decreased when wearing the Acuvue® Moist® SCL to 0.203 ± 0.088 from 0.274 ± 0.079 at baseline (P<0.01) and to 0.361 ± 0.114 from 0.424 ± 0.187 (P<0.01), respectively.

The subject's data comparing wear of the control 1-Day Acuvue® Moist® SCL and the study 1-Day Acuvue® Define® SCL's are summarized in Tables 1-3. Pupil size was significantly decreased in photopic conditions for both the NATURAL SPARKLE® and NATURAL SHINE® 1-Day Acuvue® Define® SCL's from 4.597 ± 0.846 to 4.322 ± 0.851 and from 4.400 ± 0.813 to 4.115 ± 0.839, respectively (P<0.05). Under mesopic conditions, wear of the NATURAL SHINE® SCL resulted in a significantly reduced pupil size from 6.271 ± 0.837 to 5.771 ± 0.805 (P<0.05). There were no significant

	OD Mean ± SD	OS Mean ± SD
High Contrast Acuity		
Acuvue® Moist®	-0.096 ± 0.099	-0.134 ± 0.113
Acuvue® Define®	-0.089 ± 0.086	-0.115 ± 0.078
Low Contrast Acuity		
Acuvue® Moist®	0.274 ± 0.169	0.265 ± 0.148
Acuvue® Define®	0.303 ± 0.131	0.290 ± 0.150
Contrast Sensitivity		
Acuvue® Moist®	1.905 ± 0.018	1.905 ± 0.018
Acuvue® Define®	1.932 ± 0.013	1.932 ± 0.013

Table 3. High and Low Contrast Visual Acuity and Contrast sensitivity wearing the Acuvue® Moist® and the Acuvue® Define® (NATURAL SPARKLE® OD; NATURAL SHINE® OS). There were no statistically significant differences between the Acuvue® Moist® and the Acuvue® Define® SCLs for any of these measurements (P<0.05, paired *t*-test). *SD* Standard Deviation.

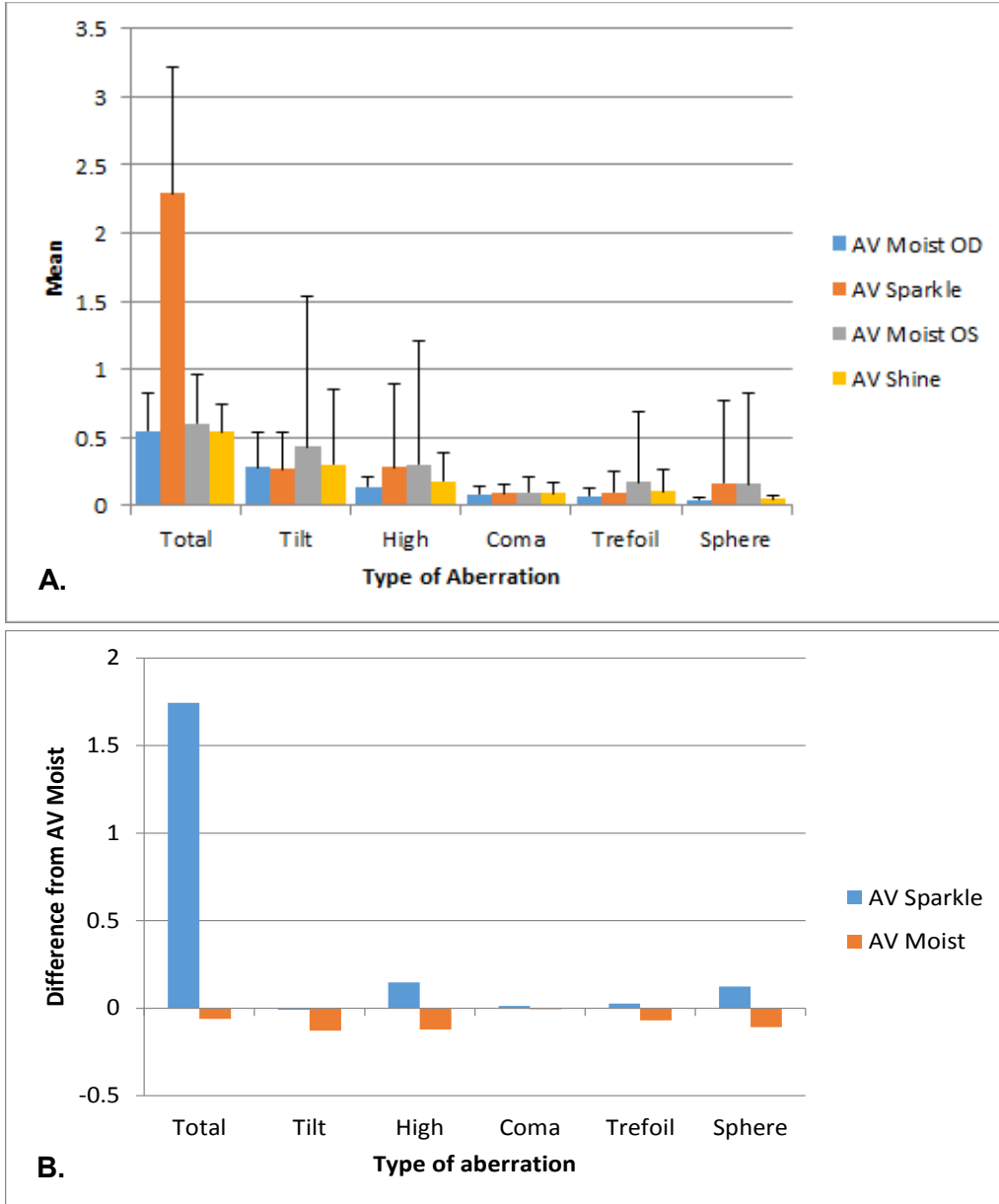


Figure 3. A. Corneal aberrations induced wearing the Acuvue® Moist® (AV Moist) OD and OS, and wearing the Acuvue® Define® (NATURAL SPARKLE® OD (AV Sparkle); NATURAL SHINE® OS (AV Shine)) with a photopic (4mm) pupil. There were no statistically significant differences ($P < 0.05$, paired t -test) in the aberrations between either of the Acuvue® Define® lenses and the Acuvue® Moist® lens. Graph is expressed as the Mean \pm Standard Deviation. **B.** Demonstrates the aberrations induced by wear of the Acuvue® Define® lens compared to those present when wearing the control Acuvue® Moist® lens.

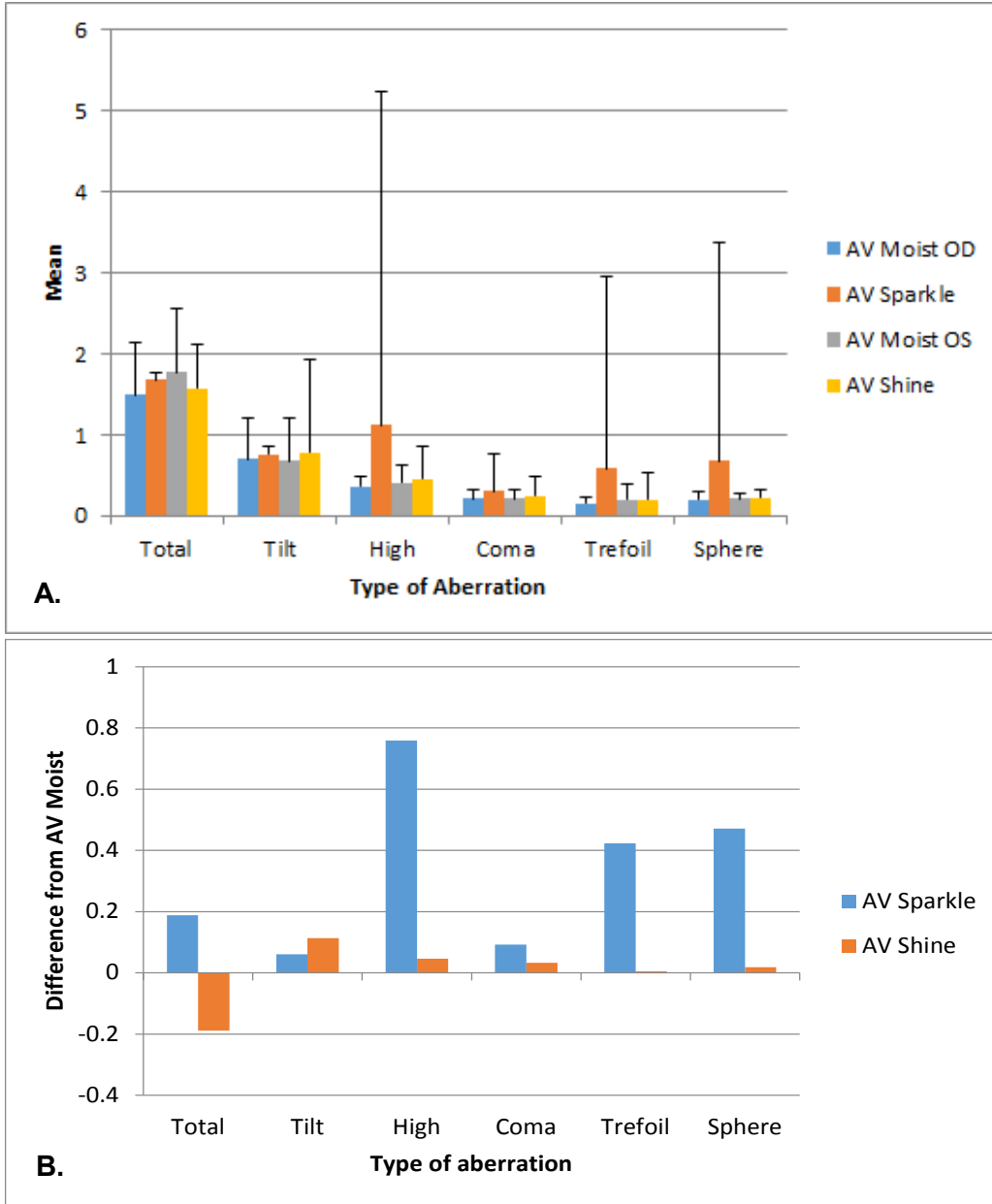


Figure 4. A. Corneal aberrations induced wearing the Acuvue® Moist® (AV Moist) OD and OS, and wearing the Acuvue® Define® (NATURAL SPARKLE® OD (AV Sparkle); NATURAL SHINE® OS (AV Shine)) with a mesopic (6mm) pupil. There were no statistically significant differences ($P < 0.05$, paired t -test) in the aberrations between either of the Acuvue® Define® lenses and the Acuvue® Moist® lens. Graph is expressed as the Mean \pm Standard Deviation. **B.** Demonstrates the aberrations induced by wear of the Acuvue® Define® lens compared to those present when wearing the control Acuvue® Moist® lens.

differences between the corneal HOAs of the 1-Day Acuvue® Define® and the 1-Day Acuvue® Moist® SCL's (all P-values > 0.05) under either photopic (Figure 3) or mesopic (Figure 4) conditions.

CHAPTER 4

DISCUSSION

Cosmetic soft contact lenses have been reported to have adverse effects on functional vision performance, including decreased contrast sensitivity and mesopic visual disturbances [2,3,5,6]. Our study results showed that wearing the NATURAL SPARKLE®/NATURAL SHINE® variants of the decorative 1-Day Acuvue® Define® lenses did not significantly alter corneal HOAs in a 4mm or 6mm pupil compared to the clear 1-Day Acuvue® Moist®. LogMAR BCVA and contrast sensitivity were also not significantly different while wearing the decorative lens.

Other publications have found increased HOAs while wearing both clear and decorative SCLs. However, aberration measurement can be influenced by multiple factors that our study did not address such as alternative contact lens physical properties (i.e. water content percentage, base curve, clear vs decorative area), lens fit, tear film instability, and wear time. Our study design had subjects wear the lenses for five minutes before data collection began, a shorter duration of lens settling time compared to similar study designs. Tinted lenses have been found to have a higher incidence of corneal swelling in comparison to clear lenses, leading to irregular corneal astigmatism [6]. Therefore the smaller duration lens wear time could have influenced our measurements.

Additional studies are needed to determine if the tinted limbal periphery results in increased corneal edema compared to clear SCL and if that leads to higher HOAs after prolonged wear.

The 1-Day Acuvue® Moist® caused significant disparity in Strehl Ratio but not root mean square (RMS) compared to no SCL wear. The overall level of optical aberrations can be characterized in many ways to assess the quality of an image. RMS provides an average level of wavefront deviation, or phase error, from perfect reference sphere across the pupil. In other words, RMS is an expression of the physical shape of an aberration-altered wavefront. A Strehl Ratio is the ratio of the peak intensity of a measured point spread function (PSF) to the peak intensity of a perfect diffraction-limited PSF for the same optical system.

Monochromatic aberrations can be divided into types such as tilt, high, coma, trefoil, and sphere. Comparing the clear and tinted lenses, none of these corneal aberrations differed. In comparison to no SCL wear, the 1-Day Acuvue® Moist® induced higher image degradation in a 6mm and 4mm pupil. However, for each “significantly” higher aberration induced, the other eye never showed the same significant difference. Therefore, no constructive conclusions can be drawn from this group of results.

Interestingly, both lenses showed a tendency to decrease mesopic and photopic pupil size when compared to wearing no contact lenses. To the best of the authors’

knowledge, pupil constriction secondary to soft contact lens wear is not found in any scientific literature.

In conclusion, both the limbal ring-design 1-Day Acuvue® Define® and clear 1-Day Acuvue® Moist® soft contact lenses did not diminish visual performance in our study. In retrospect, the following study design modifications to improve the credibility of our results include: larger sample size, repeat measurements, patient subjective survey, and longer lens settling time. Although not addressed in our study, we observed the decorative lens often did not have full corneal coverage and moved excessively while blinking. This resulted in poor cosmetic appearance and may have affected our measurements with the aberrometer. HOAs are increased by poor SCL fitting performance [3]. Future studies can investigate the quality of fit of the 1-Day Acuvue® Define® and how it influences the subjective vision and the cosmetic performance.

REFERENCES

1. Ortiz, C., & Jiménez, R. (2014). Optical Quality and Vision with Iris-Coloring Soft Contact Lenses. *Optometry and Vision Science*,91(5), 564-569.
2. Takabayashi, N., Hiraoka, T., Kiuchi, T., & Oshika, T. (2013). Influence of decorative lenses on higher-order wavefront aberrations. *Japanese Journal of Ophthalmology*,57(4), 335-340.
3. Rah, M., Schafer, J., Reindel, W., Chan, O., & Zhang, L. (2014). Differences in daily disposable circle lens performance characteristics. *Clinical Optometry*, 37.
4. 1-DAY ACUVUE® DEFINE® Package Insert and Fitting Guide. Jacksonville: Johnson & Johnson Vision Inc. 2014.
5. Watanabe, K., Kaido, M., Ishida, R., Dogru, M., Negishi, K., & Tsubota, K. (2014). The effect of tinted soft contact lens wear on functional visual acuity and higher-order aberrations. *Contact Lens and Anterior Eye*,37(3), 203-208.
6. Hunt L (2000) Annular tinted contact lenses caused irregular corneal astigmatism. *Insight* 25:16–17.

APPENDIX A

IRB APPROVAL LETTER