

HIGHER ORDER ABERRATIONS INDUCED BY DIFFERENT SOFT CONTACT
LENS BRANDS IN YOUNG ADULTS

by

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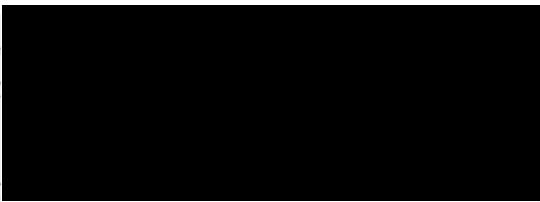
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ABSTRACT

Background: Few studies in the literature have compared wavefront aberrations between different hydrogel lens brands. Additionally, very few studies have examined differences in aberration characteristics in the natural eye in comparison to eyes wearing hydrogel lenses. The purpose of this study was twofold – i) Comparison of wavefront aberrations with lens on and off eye ii) To examine for differences in wavefront aberrations between various soft contact lens (SCL) brands. *Methodology:* A sample of students (N=30; 60 eyes) between the age range of 21-29 years were included. Subjects included were habitual SCL wearers. Information pertaining to the SCL brand and prescription were documented for each subject. For each subject we measured, i) total aberrations, ii) total higher order aberration (HOA), iii) total coma, iv) total trefoil, v) total spherical aberration. Measurements were made with the NIDEK OPD Scan III. *Results:* A single factor Analysis of Variance (ANOVA) was run on the Root Mean Squared (RMS) data to compare induced aberrations across the different brands of lenses. Overall, the results were statistically non-significant ($p > 0.05$). A paired, two-tailed t-test was done to compare RMS values for the lens ON and OFF eye conditions. There was a significant increase in the total HOA ($p < 0.001$); total spherical aberration, ($p < 0.042$), total trefoil, ($p < 0.003$) with the lens on eye. There was a significant decrease ($p < 0.0001$) in total aberrations (lower & higher) with the lens on eye. *Conclusion:* Our results indicate that soft contact lenses induce a significant increase in higher order aberrations on the eye. The amount of aberration induced does not seem to be significantly different when compared between different hydrogel brands. These results are partially consistent with the findings in the literature and require further research.

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CHAPTER 1

INTRODUCTION OF HIGHER ORDER ABERRATIONS INDUCED BY DIFFERENT SOFT CONTACT LENS BRANDS

The optical quality of the eye and our perceived vision is dependent upon a multitude of factors, including pupil size, defocus and wavefront aberrations. Optical aberrations can be classified as lower and higher order aberrations (HOA). Traditionally, eye care providers use spectacles, contact lenses and refractive surgery to correct for the lower order aberrations (sphere and cylinder). However, recent advances in technology mean that incorporating higher-order aberration elements into contact lens corrections is in prospect⁵. Wavefront aberrations data are often represented as Zernike polynomials. According to the Zernike model, different types of aberrations are represented as specific modes. The sum of these individual modes forms the polynomial, with orders of three and higher qualifying as higher orders⁵. Higher order aberrations which include vertical and horizontal Comas, Trefoil, and the Spherical aberration, impact the quality of vision experienced by the wearer. The extent to which the quality of vision is impacted by HOA depends upon a few factors including the type of aberration and the pupil size. Literature suggests that hydrogel lenses induce HOA in eyes with myopia⁴. That being said, to the best of our knowledge very few studies have addressed this question. Similarly, there is a relative deficit in the number of studies that have compared on-eye aberrations induced by the different soft contact lens brands. Therefore, the purpose of our study is twofold – i) To compare total HOA with and without SCL, and ii) To compare on eye HOA induced between the various SCL brands.

CHAPTER 2

METHODOLOGY OF MEASURING HIGHER ORDER ABERRATIONS INDUCED BY DIFFERENT SOFT CONTACT LENS BRANDS IN YOUNG ADULTS

Subjects – We initially recruited a sample of (N=30; 60 eyes) from the Michigan College of Optometry (MCO) student body to participate in our study. Measurements from six subjects were not used in the final data analysis since we did not have a complete data set from these participants. All subjects were habitual soft contact wearers and were in the age range of 21 to 29 years. The brands included in the study were Acuvue 1 Day Moist, Acuvue Oasys, Biofinity Toric, Cooper Biofinity, Cooper ClearSight Toric, and Proclear 1 Day. Subjects had a hyperopic, myopic, and or astigmatic refractive error. An email explaining the criterion for participation and the data collection process was distributed to the MCO student body. Students were urged to participate in the study if they were currently wearing soft contact lenses for refractive correction and if they were between 21 and 29 years of age. A consent form approved by the Ferris State University, Institutional Review Board (150101) was presented to the prospective subjects either prior to or upon the initial office visit. Subjects were required to sign the consent form prior to any data collection.

Wavefront Aberration Measurement & Instrumentation – We made the following measurements on our subjects using the Nidek OPD-Scan III – (1) Total aberrations (lower order + higher order), (2) Higher Order Aberrations (total HOA, total Coma, total Trefoil, total Spherical Aberration). The Nidek OPD is a multifunctional ophthalmic

device and one of many commercially available devices currently available that can be used to measure wavefront aberrations. The device produces a slit of light that scans the eye in various meridians. Photodetectors within the instrument then measure the time it takes for the light to reflect from the back of the retina. This information, along with the scan rate, is then used to construct the wavefront and thereby the aberrations. The machine was first prepared by cleaning the forehead and chinrest with alcohol swabs. Subjects were required to place their chin in the chinrest, rest their heads gently against the forehead bar and fixate on a target presented by the instrument while it takes the measurements. The height of the chinrest was adjusted so that the subjects' eyes were aligned with the eye alignment marker. OPD scans were first taken with the subjects' natural eyes (CL OFF condition). The second measurement was taken while the subjects were wearing their habitual soft contact lenses (CL ON condition). We also documented the specific brand of contact lens worn by each participating subject.

CHAPTER 3

RESULTS OF TOTAL HIGHER ORDER ABERRATIONS INCUCED BY DIFFERENT BRANDS OF SOFT CONTACT LENSES IN YOUNG ADULTS

Root Mean Squared (RMS) values were obtained for i) total aberrations, ii) total HOA, iii) total coma, iv) total trefoil, v) total spherical aberration for the CL on and off conditions. The RMS value is an index that is used as a measure of the magnitude or severity of aberrations present in the eye.

A single factor Analysis of Variance (ANOVA) was run on the RMS data for each of the aberrations described above. The total HOA measured across the different brands of lenses fell just short of statistical significance ($F(5,41) = 2.42$; $p = 0.054$). Similarly, total coma was also just outside the criterion of statistical significance ($F(5,41) = 2.45$; $p < 0.051$). The total aberrations (high + low) were not significantly different between the different SCL brands ($F(5,41) = 1.60$; $p < 0.18$). Likewise, differences in total spherical ($F(5, 41) = 1.30$; $p < 0.28$) and total trefoil ($F(5, 41) = 2.28$; $p < 0.06$) were also statistically non-significant across the different soft contact lens brands.

A single factor Analysis of Variance (ANOVA) was also run to compare wavefront aberrations for the lens ON and OFF eye conditions. For each aberration class, the RMS values under the different SCL brands were pooled for the ON-Eye condition. Post-hoc pairwise comparisons were made between CL on and off eye conditions for each aberration class using a paired two-tailed t-test. The results were as follows –

- i) The total higher order aberrations were significantly higher with soft contact lenses on the eye than without. $p < 0.001$
- ii) The total aberration (lower + higher) were significantly lower with soft contact lenses on the eye than without $p < 0.000$
- iii) The total Spherical Aberration was significantly higher with soft contact lenses on the eye than without $p < 0.042$.
- iv) The total Trefoil was significantly higher with soft contact lenses on the eye than without $p < 0.003$.

- v) Lastly, the total Coma was NOT significantly higher with soft contact lenses on the eye than without $p < 0.28$.

DATA ANALYSIS OF HIGHER ORDER ABERRATIONS INUCED BY DIFFERENT BRANDS OF SOFT CONTACT LENSES IN YOUNG ADULTS

Table 1 HOAs On Eye vs. Off Eye

HOA	Naked Eye	Eye with SCL
Average	0.109905	0.1585
Standard Deviation	0.032251	0.098142

P-Value =0.001185	HOA significantly higher with SCL
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Table 2 T. COMA On Eye vs. Off Eye

T. COMA	Naked Eye	Eye with SCL
Average	0.049619	0.055429
Standard Deviation	0.026025	0.040084

P-Value =0.280782	No significant difference in t. coma
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Table 3 TOTAL ABERRATION On Eye vs. Off Eye

TOTAL ABERRATION	Naked Eye	Eye with SCL
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Average	2.02269	0.45431
Standard Deviation	1.34462	0.252064

P-Value =1.01E-08 **Significant difference in total aberration**

Table 4 T-SPHERE On Eye vs. Off Eye

T-SPHERE	Naked Eye	Eye with SCL
Average	0.017357	0.028214
Standard Deviation	0.016603	0.028436

P-Value =0.042775 **Significant difference in spherical aberration**

Table 5 TREFOIL On Eye vs. Off Eye

TREFOIL	Naked Eye	Eye with SCL
Average	0.081929	0.115857
Standard Deviation	0.39837	0.083604

P-Value =0.003489 **Significant difference in trefoil**

Table 6: Comparing HOAs Between Different SCL Brands

COMA	(F 1.41) =2.45; p < 0.05)	Significantly different
TOTAL ABERRATION	(F (1.41) =1.60; p < 0.18)	Not significantly different

Conclusion: Significant difference in the total HOA between different SCL brands

(F (1.41) =2.42; p < 0.05)

CHAPTER 4

DISCUSSION OF PILOT STUDY: HIGHER ORDER ABERRATIONS INDUCED BY DIFFERENT BRANDS OF SOFT CONTACT LENSES IN YOUNG

In this pilot study we compared the wavefront aberrations including the total aberrations, total higher order aberrations, total coma, total trefoil and total spherical aberration for two conditions – i) with the natural eye (or the lens off condition) and ii) with the subject wearing the contact lens (or the lens on condition). We found a significant difference in total HOA between the two conditions, with soft lenses inducing a significant increase in total HOA on the eye. Similarly, we found that soft lenses induced a significant increase in the total spherical aberration and total trefoil. The total aberrations (high + low) were significantly higher for the natural eye. This is understandable because contact lenses correct for lower order aberrations including defocus (myopia, hyperopia) and astigmatism. Therefore, one can expect that the total aberrations (including higher and lower order) would be lower with the lenses on the eye. Coma was higher for the lens on-eye condition but the increase was not statistically significant. Our results are fairly consistent with those of Roberts et al.⁴ who also found that soft lenses induce a significant amount of HOA. However, unlike our study results, they did not find a statistically significant increase in total spherical aberration and trefoil

with hydrogel lenses on the eye. Theoretical calculations have also proven that HOA are higher with contact lens wear versus the naked eye³. Typical values of HOA like coma and trefoil are 0.1 μm (for a 5 mm pupil)¹. Eyes with pathology such as keratoconus and history of penetrating keratoplasty have larger amounts of these aberrations (1.2 μm)¹. In comparison, other recent studies have also shown that myopic patients specifically who wear contact lenses, have a larger amount of HOA when measured in comparison to the naked eye⁴. It has been suggested that factors such as lens material, shape and wettability could be attributed to increase in HOA with soft lenses.⁴ Additionally, soft contact lenses also create more distortion and optical aberration when measured in comparison to rigid gas permeable (RGP) lenses which have been shown to decrease overall aberration⁴. RGP lenses actually help reduce the eye's asymmetric (odd-order) aberrations and positive spherical aberrations which results in a decrease in HOA⁴.

A comparison of differences in wavefront aberrations between different soft contact lens brands was statistically non-significant. This implies that the various hydrogel brands included in our study induced roughly the same amount of aberrations on the eye. One could attribute any significant differences in aberrations between lens brands to the contact lens manufacturing process and lens design. For instance, Berntsen et al.¹ compared effect of spherical and toric contact lens design on higher order aberrations. They found that the toric contact lens included in their study that used a prism-ballast stabilization design induced a significant amount of vertical coma. Consistent with our results, they did not find any significant differences in total HOA between brands. It is possible that specific characteristics of a lens brand that makes it unique in comparison to the other brands have a bearing on the amount aberrations

induced by the lens on the eye. These include factors such as lens diameter, water content, specific material or optic zone diameter. Further research is required to determine if any of these lens characteristics induce an increase in HOA. Even if some of the aforementioned factors are controlled in an effort to decrease the amount of HOA induced by the specific soft lenses, unfortunately, there are some variables such as lateral movement with blinking, power of the lens, dehydration and flexure that will always induce some visual aberrations versus spectacle correction alone⁴. Current researchers are suggesting that a soft lens with an asymmetric front surface and spherical back surface to correct for some of the HOA⁴. We are hopeful that the results from our study will be a valuable addition to the existing knowledge base in this area and will serve as a precursor for future work to determine which lens factors, if any, can be modified to control for the increase in overall higher order aberrations induced by the soft lenses.

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Institutional Review Board for Human Subjects in Research

Office of Academic Research, 220 Ferris Drive, PHR 308 · Big Rapids, MI 49307

Date: January 14, 2015

To: Vandana Rajaram, Emelie Phillips and Rebecca Dewitt

From: Dr. Stephanie Thomson, IRB Chair

Re: IRB Application #150101 (*Higher Order Aberrations Induced by Different Soft Contact Lens Brands*)

The Ferris State University Institutional Review Board (IRB) has reviewed your application for using human subjects in the study, "*Higher Order Aberrations Induced by Different Soft Contact*

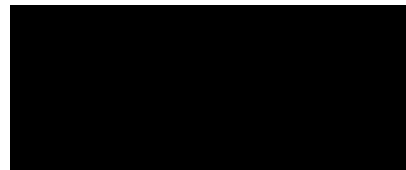
Lens Brands" (#150101) and has determined that it meets Federal Regulation category, Expedited –2D. This approval has an expiration date of one year from the date of this letter. **As such, you may collect data according to procedures in your application until January 14, 2016.** Your application has been assigned a project number (#150101), which you should refer to in future correspondence involving the same research procedure.

This approval applies only to the activities described in the protocol submission and does not apply should changes be made. Might any revisions need to be made, all materials must be approved by the IRB prior to initiation. In addition, the IRB must be made aware of any serious and unexpected and/or unanticipated adverse events in addition to complaints and non-compliance issues.

Understand that Informed Consent is a process beginning with a description of the study and assurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

We also wish to inform researchers that the IRB requires follow-up reports and/or annual reviews for all research protocols as mandated by Title 45 Code of Federal Regulations, Part 46 (45 CFR 46) for using human subjects in research. Thank you for your compliance with these guidelines and best wishes for a successful research endeavor. Please let us know if the IRB can be of any future assistance.

Regards,



Ferris State University Institutional Review Board
Office of Academic Research, Academic Affairs