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Common Factors in Multifocal Contact Lens Dissatisfaction

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COMMON FACTORS IN MULTIFOCAL CONTACT LENS DISSATISFACTION

by

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COMMON FACTORS IN MULTIFOCAL CONTACT LENS DISSATISFACTION

by

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Has been approved

31 May, 2017

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_______3/13/2017_______________________
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ABSTRACT

Background: This research project aims to better understand factors contributing to the dissatisfaction of soft multifocal contact lens wearers, leading to better patient outcomes for future lens selection. *Methods:* Patients were recruited based on a negative response to the question “Is/was your contact lens use meeting your expectations for success?”. A documented comprehensive eye exam within the last two years and previous fitting/use of a soft multifocal lens were also used as inclusion/exclusion criteria. Twelve study participants were analyzed for their wearing and lens care habits/time, style/design of lens, high and low contrast visual acuity, occupation, visual tasks while wearing their lenses, refractive and ocular measurements, allergies, systemic and ocular medications, personality traits, expectations, age, quality of life, previous lens wear and number of lenses necessary to be fit successfully. The collected data was then compared to values from a partner study of successful multifocal contact lens wearers. *Results:* No significant differences in distance acuity, habitual working distance, activities of daily living, or personality were found between the satisfied and dissatisfied study groups. Significant differences were found for objective and subjective measurements of near and intermediate vision between the two groups. The average coma for unsuccessful patients not wearing multifocal lenses was higher compared to successful patients while not wearing multifocal lenses (0.63 versus. 0.50). Although it was not statistically significant, it was very close ($p = 0.53$). Average pupil size differences were found also to be significantly larger (by an average of 0.5 mm) in unsuccessful patients. *Conclusions:* Complete fitting of candidates for multifocal contact lens correction should include average pupil testing to increase lens satisfaction. Further testing for induced aberrations should be conducted to determine significance in multifocal lens satisfaction. Future multifocal lens design could be further refined if pupil size and induced aberrations were considered.

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CHAPTER 1

INTRODUCTION

Although multifocal/bifocal contact lenses have been available for many years, the factors that contribute to true patient success have remained elusive. A minority of patients have been quite successful with their presbyopic lenses, often satisfying their visual demands comfortably for many years with excellent results. Many more patients have been unable to achieve the quality of vision they desire while others have difficulty with comfort and wearing time (Martin et al. 2003).

This raises the question "Is it possible to better predict who might be more successful presbyopic contact lens wearers?" By evaluating a series of "unsuccessful" lens wearers we hope to identify what visual, anatomical, environmental, and/or psychological factors are common among them. This may lead to improved selection methods for patients in this category who have expressed interest in contact lens wear.

Despite the emergence of an aging population, there is a lack of paralleled growth in multifocal contact lens wearers. Of the 40% of the population age 45 and older in the

United States, sources indicate that only 8-18% of all prescribed contact lenses fall into this presbyopic category (CL Spectrum, 2017). Many of the common causes for declining multifocal lens wear, such as shortcomings in vision or comfort, still remain despite advances in lens technology. This allows for the opportunity to question the growing gap between these two populations. Exploration of multifocal contact lens correction offers insight as to the choices that presbyopic patients have with lens selection.

Multifocal lenses offer the advantage of using multiple viewing distances within one lens, without the need for additional vision aids. Lens correction with the ability to view at multiple distances is also referred to as simultaneous vision. Different designs offer the same breadth of vision and are steadily growing in number and availability from manufacturers.

Figure 1 shows several current lens designs and where the refractive power lies within the optic zones of the lens. Aspheric multifocal lenses allow for gradual changes in refractive power, some providing correction for distance vision at the center while others the reverse with center-near vision correction. These sloping changes in eccentricity provide many different refractive power changes in the lens which give its simultaneous vision. Another type of lens follows a concentric ring design. As the name implies, alternating rings provide different refractive powers that focus at variable distances (Ruiz-Alcocer et al. 2012).

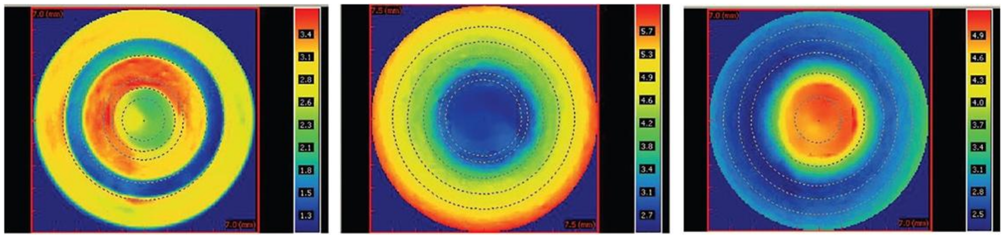

Figure 1: Power profiles of several multifocal lens designs

Figure 2 accompanies the above diagram, relating how the power of the lenses, measured in diopters, make either gradual or steep changes to allow for the multiple viewing distances in the lenses.

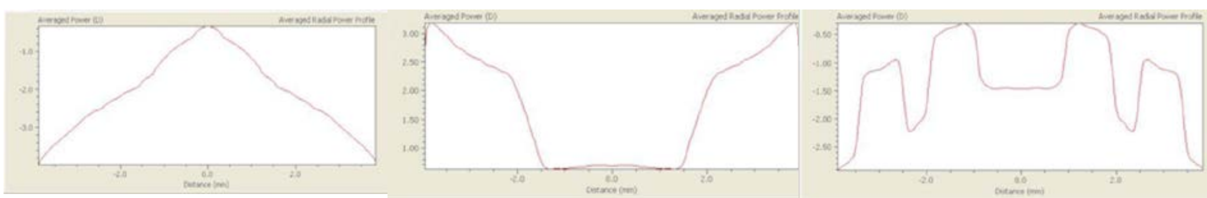

Figure 2: Corresponding dioptric powers for multifocal designs

Both Figure 1 and 2 demonstrate some of the many capabilities of the NIMO imaging camera. This technology allows for precise measurement of contact lens parameters, particularly power mapping. With this information available, it allows users to visually represent how the lenses bend light spatially within the multifocal lens. It should be noted that other/newer lens designs have been introduced to the optometric market since this study was conducted.

While this type of lens allows for multiple viewing distances, patients who wear multifocal lenses must adapt to the “transition” zones and actively ignore the blur caused by areas of refractive power that do not correlate to the working distance the patient is using. This idea of having 20/20 vision but lacking the overall quality of looking through lenses with one focal distance is another cause of dissatisfaction in unsuccessful multifocal patients (Kollbaum and Bradley, 2014).

Exploring which factors affect quality of vision, comfort, quality of life, and personality will help practitioners better fit these lenses for their future patients (Rueff et al. 2016). Comparisons between successful and unsuccessful multifocal wearers can also give insight into which objective and subjective measures affect the wearability and long-term use of lenses themselves.

CHAPTER 2

METHODS

Participants were recruited to take part in this study, based on their negative response to the question “Is/was your contact lens use meeting your expectations for success?”. Twelve patients were selected through a chart review at the Michigan College of Optometry at Ferris State University. The criteria for participation included a comprehensive eye exam and refraction within the last two years, a diagnosis of presbyopia, and previous use of multifocal lenses. All twelve patients met these criteria and were asked to come to the eye clinic at the College of Optometry for a single-visit evaluation that would encompass objective and subjective measurements of multifocal lens wear.

Selected subjects were between the ages of 45 and 68 with an average age of 56 years old. Participants wore a variety of soft multifocal lenses from several different contact lens manufacturers and spanned a range of refractive errors, including astigmatic and spherical error.

Study participants were analyzed for their wearing and lens care habits/time, style/design of lens, high and low contrast visual acuity, occupation, visual tasks while wearing lenses, refractive and ocular measurements, allergies, systemic and ocular medications, personality traits, expectations, age, quality of life, previous lens wear and number of lenses necessary to be fit successfully.

Prior to the start of the visit, subjects were mailed a survey for details on their previous or current multifocal contact lens wear. Information regarding wear time, comfort, lens care systems and use, occupation, and daily tasks were included in the inquiry.

An on-site clinical examination was done on each subject, with and without the multifocal contact lenses on the eye. Visual acuity was measured several ways including distance acuity, near, and via contrast sensitivity. An adjusted Snellen chart was projected on a computer screen across the length of the exam room. Near acuities were taken at 40 centimeters using an Ohio State Visual Acuity Card. Contrast sensitivity was collected using a Pelli-Robson chart at a standard distance. The power and curvature of the cornea, with and without the contact lenses, was measured using a Medmont 300 automated keratometer. This scan was also used to collect data on each subject's horizontal visible iris diameter (HVID) and pupil size in photopic and scotopic conditions. Also, Medmont mapping was used to measure decentration of the optic design from the central visual axis. A Nidek OPD-Scan III wavefront aberrometer was also utilized over the multifocal lenses and without lenses to gather information on induced aberration while wearing lenses on the eye. A Haag-Streit Photo Slit Lamp measured lid apposition in relation to the globe of the eye as well as assess tear film function when used in combination with different dye agents. The slit lamp was also used to assess general fitting parameters of the contact lenses.

Patients were also given subjective measures of multifocal lens wear. Two surveys were utilized to gain more information on lack of success with lenses. The Contact Lens Impact on Quality of Life (CLIQ) Questionnaire was used to quantitatively measure how contact lenses affect a subject's quality of life. 28 items are used to scale various aspects of contact lens wear such as perceived comfort, clarity, and ability to perform activities of daily living.

The NEO Five-Factor Inventory-3 (NEO-FFI-3) served as a quick and reliable way to measure the five large domains of personality: neuroticism, extraversion, openness, agreeableness, and conscientiousness. It contains 60 items that categorizes which domains of personality each subject characterizes. Both survey measurements were collected and graded during the on-site research visit.

CHAPTER 3

RESULTS/DISCUSSION

Analysis of the collected unsuccessful patient data resulted in several groupings. The pre-visit survey demonstrated individual lens wear preferences. The dropout rate from the individuals in the unsuccessful study accumulated to be around 19%, with 58.3% as the “success” population. These seven of the twelve (58.3%) subjects were still utilizing their multifocal lenses, albeit with aided vision corrected at near using over-the-counter reading glasses. Although the term “success” is applied, these patients were still considered to fit into the criteria of unsuccessful, as full autonomy from glasses was not achieved. Three of the subjects (25%) had discontinued multifocal contact lens wear in exchange for other types of contact lenses, ie. single vision lenses in combination with over-the-counter readers or monovision. Two subjects (16.7%) at the time of chart review were no longer wearing any type of contact lens correction and were only using glasses for vision correction.

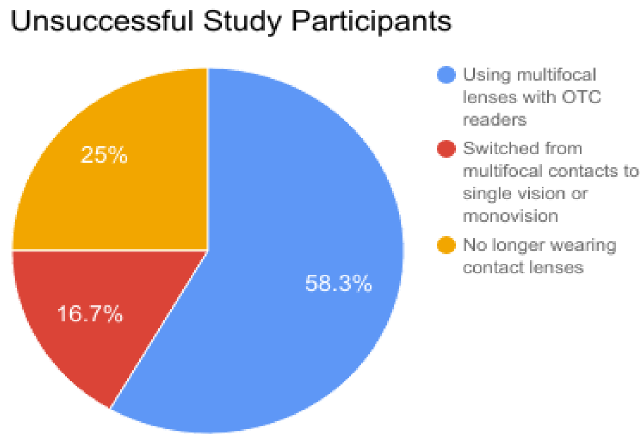

Figure 3. A breakdown of chosen refractive correction after unsuccessful multifocal use

A companion study previously done on successful multifocal patients provided a means of contrast between the data collected during unsuccessful patient research (Dinardo, 2016). Much of the data collected between the two groups did not vary enough to be statistically relevant. Distance visual acuity between the two studies did not vary as both groups read within one line of acuity letters; successful patients saw 20/18 (LogMAR -.03 +/- 0.06) at distance while unsuccessful saw 20/20 (LogMAR 0.2 +/- .12). Intermediate vision between groups followed the same pattern, while also not statistically significant.

Personality testing between the two groups did not show a significantly higher level of any of the five major personality groups, specifically neuroticism in regard to visual clarity standards. Similar activities of daily living, such as tasks around the home, leisure reading, and hobbies, and similar level of visual demand were seen between the two comparison groups. Between the two, unsuccessful and successful patients both wore the lenses an average amount of time per week, accumulating around 10.2 hours per day. Despite rating their vision in the multifocal lenses as below the criteria for success, many unsuccessful patients still wore the lenses as often as the successful patients: 5.56 +/- 1.7 days and 4.8 +/- 2.0 days for successful and unsuccessful, respectively.

5 point scale	Distance Vision Rating	**Intermediate Vision Rating (p=0.45)**	**Near Vision Rating (p=0.01)**	Daily Comfort (p=0.008)
Successful Study	4.3	**4.4**	**4.0**	4.5
Unsuccessful Study	3.5	**3.2**	**2.5**	3.5

Table 1: Scaled Subjective Ratings, Contact Lens Use Survey

While there were many similarities, differences were also apparent in the collected data. The scaled scores on the contact lens use survey ranged between 1 to 5, 1 being highly dissatisfied with 5 being extremely satisfied on the scale. The results are compared in Table 1 above. Distance vision subjective ratings in the unsuccessful contact lens survey averaged at 3.5 with successful patients averaged at 4.3. Daily comfort rating held a difference of 1 point on the scale. Neither of these subjective ratings, however, were statistically significant. Intermediate vision rating was given an average of 3.2 between the 12 unsuccessful while the successful subjective rating of intermediate vision rated at 4.4, giving it statistical significance. Subjective unsuccessful near vision ratings were significantly lower still at 2.5 compared to 4.0 for successful patients. Subjective results based on a Snellen scale, showed significant corresponding decreases in visual acuity, with unsuccessful near acuity at 40 cm being close to 20/40 while successful acuity was closer to 20/25. Table 2 below demonstrates the comparison between these measures.

	Distance Visual Acuity (LogMAR)	Near Acuity at Habitual Distance (p=0.12)	**Near Acuity at 40 cm (LogMAR) (p=0.001)**	Contrast Sensitivity (Pelli-Robson)
Successful Study	-0.0385 (20/18)	5.7 point print	**0.0975 (20/25)**	1.95
Unsuccessful Study	0.0233 (20/20)	8.3 point print	**0.290 (20/40)**	1.95

Table 2: Subjective Visual Acuity, Successful vs Unsuccessful

These numbers indicate that the subjective quality of near vision comprises the biggest difference between successful and unsuccessful patients. This demonstrates the fact that the near vision was not at a functional level for the unsuccessful patients. Those that fit this statistic the best were the 58.3% that still retained use of the multifocal lenses for distance but still required more help at near through the use of over-the-counter reading glasses.

The average coma for unsuccessful patients not wearing multifocal lenses was higher compared to successful patients while not wearing multifocal lenses (0.63 versus. 0.50). Although it was not statistically significant, it was very close (p = 0.53). Other higher order aberrations, such as spherical aberration, were not examined between the two studies.

A secondary study, however, was done to further understand the amount of aberration induced by multifocal contact lenses while interacting with a patient's natural spherical aberration. (Dinardo, 2016). Using data from the initial studies, pupil sizes in photopic and scotopic conditions were taken, as aperture size tended to influence the overall effect of aberration. This information combined with the spherical aberration changes with and without the contact lenses was examined.

	Successful Group	Unsuccessful Group
Photopic Pupil Size (mm)	OD: 3.5 +/- 0.5 OS: 3.4 +/- 0.4	OD: 4.0 +/- 0.5 OS: 3.8 +/- 0.6
Scotopic Pupil Size (mm)	OD: 5.0 +/- 0.7 OS: 4.9 +/- 0.6	OD: 5.5 +/- 0.4 OS: 5.3 +/- 0.7

Table 3. Average pupil sizes in scotopic and photopic conditions

With the average unsuccessful pupil size being around 0.5 mm larger than successful patients, the question of the effect on the optics of the multifocal center-near design was examined. Given differences in amount of spherical aberration, naturally occurring positive aberration and overall negative aberration within the design of the contact lens, there was the possibility of a canceling-effect taking place. With natural aberration being positive spherical aberration and placing an overlying multifocal center-near lens with negative spherical aberration on the eye, there would be an overall decrease in the amount of spherical aberration and minimize the effect of the multifocal lens at near. This was also correlated to the fact that unsuccessful patients had a significantly lower near visual acuity and near vision rating from the previous unsuccessful study. These lend to the fact that smaller pupil sizes, which allow less of the spherical aberration, lead to better visual outcomes in the case of soft multifocal contact lenses.

CHAPTER 4

CONCLUSION

With the conclusion of the unsuccessful multifocal wearer study, there were adjustments in the study that could have been made to further enhance the data that was collected. An example of this was the lack of variety of lens types. While a larger sample population have been preferred to enhance the research, only soft multifocal contact lens data was collected during the unsuccessful study. It would have been beneficial to incorporate more gas permeable lenses in the population study as they were present in the successful study. Data could be collected and judged based on level of presbyopia to see if there was an influence on the magnitude of near vision correction required. Another area of inquiry could be how other higher order aberrations interacted with the spherical aberrations present. In addition, having a way of controlling pupil sizes would have helped standardize what amount of interference was produced in the form of aberration. Comfort is also another factor that is common in multifocal dropout. Research specific to the gas permeable comfort compared to soft lens comfort would have been useful as well. Much of what has been studied thus far in multifocal lens research lends way for further studies to take place.

While multifocal contact lens wearers were not unsuccessful based on one factor alone, other areas of multifocal design have yet to be explored. While not significant in this study, it could be beneficial to practitioners who choose to fit these lenses to take into consideration pupil size in photopic and scotopic conditions when choosing a design. This could also carry over into other areas such as lens manufacturing and considering the decrease in pupil size as aging continues (Bennett 2008) (Gispets et al. 2011).

Bridging the gap between the increasing presbyopic population and decreasing multifocal lens wear can be done with further inquiry into this line of research. Having the ability to better serve patients and their vision will be outcomes to look forward to in the future.

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APPENDIX A

IRB APPROVAL FORM

Ferris State University

Institutional Review Board (FSU - IRB)
Office of Academic Research
Ferris State University
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Big Rapids, MI 49307
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To: Dr. Amy Dinardo and Gabrielle Smiley
From: Dr. Stephanie Thomson, IRB Chair
Re: IRB Application #140602 (Title: *Common Factors in Multifocal Contact Lens Dissatisfaction*)
Date: July 14, 2014

The Ferris State University Institutional Review Board (IRB) has reviewed your application for using human subjects in the study, "*Common Factors in Multifocal Contact Lens Dissatisfaction*" (#140602) 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 July 14, 2015.** It is your obligation to inform the IRB of any changes in your research protocol that would substantially alter the methods and procedures reviewed and approved by the IRB in this application. Your application has been assigned a project number (#140602), which you should refer to in future correspondence involving the same research procedure.

We also wish to inform researchers that the IRB requires follow-up reports for all research protocols as mandated by Title 45 Code of Federal Regulations, Part 46 (45 CFR 46) for using human subjects in research. We will send a reminder to complete either the Final Report Form or the Extension Request Form to apply for a study continuation. Both forms are available on the IRB homepage. 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,

S. Thomson

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