

QUALITY OF LIFE COMPARISON BETWEEN PATIENTS WEARING  
MULTIFOCAL CONTACT LENSES AND PATIENTS WEARING MULTIFOCAL  
SPECTACLES

by

Tom Lavern Hall II & Christina Renee McCarrell

Has been approved

May 15, 2013

APPROVED:



\_\_\_\_\_, Faculty Advisor

ACCEPTED:



\_\_\_\_\_  
Faculty Course Supervisor



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MULTIFOCAL CONTACT LENSES AND PATIENTS WEARING MULTIFOCAL  
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Tom Lavern Hall II & Christina Renee McCarrell

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, 2013

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Ferris State University  
Doctor of Optometry Senior Paper  
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## ABSTRACT

Background: Presbyopia is an inevitable condition, which involves the loss of accommodation, near vision blur, and increasing difficulty with near vision tasks over time. Luckily, today's presbyopic patients have more options than ever before in terms of optical correction. These options include different types of spectacles, contact lenses, or even intraocular lens implants. When prescribing optical correction for presbyopes, the modern eye care practitioner must consider many factors, including lifestyle and activities of daily living. This study will aim to reveal the difference in the quality of life in presbyopes corrected with multifocal contact lenses and those corrected with spectacles. Methods: Prior to enrollment in the study, informed consent was obtained for each participant. Participants were given two surveys to complete. The first survey was a short questionnaire regarding the type of optical correction the patient is currently using. The National Eye Institute Refractive Error Quality of Life Instrument-42 (NEI RQL-42) was also used to highlight the impact of different types of visual correction on the participants' quality of life. Subjects were given the opportunity to complete the surveys either on paper or online. Results: Of the 13 subscales that make up the NEI-RQL-42 survey, only two subscales showed a statistically significant difference between the two groups. Group 2 scored better than Group 1 in the appearance ( $p = 0.029$ ) and the satisfaction with correction ( $p = 0.005$ ) subscales. Group 3 also scored better than Group 1 in the appearance ( $p = 0.037$ ) and satisfaction with correction ( $p = 0.025$ ) subscales. Conclusion. There is little difference in quality of life between contact lens wearing

presbyopes and those wearing multifocal spectacles. Overall, contact lens wearers were happier with their appearance and more satisfied with their correction than spectacle wearers.

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## CHAPTER 1

### INTRODUCTION TO OPTICAL CORRECTION OF PRESBYOPIA

For the first four decades of life, the human eye has the ability to focus at a large range of distances. The eye's accommodative system works, through the use of the ciliary muscle and lens zonules, to change the shape of the lens and maintain a focused image on the retina. No matter how close or far away an object is moved, its image remains clear. However, by the age of 40, changes have begun to occur and the lens is no longer able to focus objects that are held in close proximity to the eye. This loss of amplitude of accommodation is known as presbyopia.<sup>1,2</sup>

It is easy to adapt to the early stages of presbyopia by simply moving the object farther from the eye. As this becomes uncomfortable while reading or the distance needed to see clearly is longer than an arm's length away, the need for addition lenses becomes apparent. By the age of 52, most eyes have lost all of their accommodative amplitude and require a full addition correction.<sup>3</sup> In order to be able to perform all daily activities efficiently, presbyopes must be corrected for both distance and near vision.

Spectacles are the most popular choice of correction for presbyopes. Many prefer single vision reading glasses that are only worn when confronted with a near demand.

Those who choose this method of near correction are only able to see at one distance

when wearing the reading glasses. They also must remember to carry the spectacles with them wherever they go. Other options such as bifocals, trifocals, and progressive lenses allow the patient to leave the spectacles on throughout the day and have easy access to clear vision at more than one distance. Bifocals are engineered to correct for distance and near vision, but not vision at intermediate distances. Trifocals correct for distance, near, and intermediate vision, but they do not allow a smooth transition between all distances. Therefore, it is easy to see why progressive lenses are gaining popularity. They have the ability to correct a range of vision from distance to near, meeting most of the wearer's needs.<sup>3</sup>

Despite the many advantages of bifocal and progressive spectacles, they have their disadvantages as well. Because the spectacle lenses do not move with the eye, the eye's position determines which distance correction is being used. As a result, the head may need to tilt or turn to achieve optimal correction, often causing the wearer discomfort. Additionally, bifocal wearers may experience a phenomenon known as image jump when moving down into the near portion of the lens. If the image jump is large enough, it may be bothersome to the wearer. Likewise, progressive wearers may experience distortion in the periphery of the lens that may make simple activities like walking or climbing stairs difficult.<sup>3</sup>

In addition to spectacle lens correction, advancing contact lens technology provides a number of different options for presbyopic patients. Monovision is commonly used as an option for contact lens correction of presbyopia. This option involves correcting one eye, most commonly the dominant eye, for distance and the other eye for near.<sup>3</sup> Depending on the distance of the object being viewed, the brain chooses which eye

to use to focus a clear image, suppressing the eye with a blurred image.<sup>3,4</sup> However, as the add increases, the difference in power between eyes also increases and may result in the loss of stereoacuity.<sup>3,4,5</sup> A decrease in stereoacuity can lead to poor driving performance and an increase in the number of falls the wearer may experience.<sup>4,6</sup>

A safer option for presbyopes wishing to wear contact lenses would be to consider multifocal contact lenses. Multifocal contact lenses work by employing simultaneous vision or alternating technology. Simultaneous vision lenses contain multiple powers within the pupil area. As light passes through the pupil, rays traveling from distance and near objects are imaged on the retina and the brain chooses to suppress the most defocused image. The image with the most blur will be from the object that is not located at the same distance as the task at hand, allowing the wearer to see clearly at his or her desired working distance. There are two types of simultaneous vision designs: aspheric and concentric. Aspheric multifocal lens designs gradually flatten in the periphery, creating an increase in plus power that is equal to the addition correction. A center-near aspheric lens can also be made where the center of the lens contains the highest plus power and the power then decreases in the periphery. Concentric multifocal lens designs are created with a small, central, circular zone, which houses the distance power. This annular area is surrounded by rings that contain the near power. A center-near design is also available for this type of lens.<sup>4</sup>

Alternating or translating multifocal contact lenses are another option for presbyopes. These lenses are made with a distance power in the top of the lens and a near power in the bottom. When the wearer looks in primary gaze, he or she will see distant objects clearly. The eye must then rotate down into the bottom portion of the contact lens

to view near objects. In order for this translation to occur, the lens must be supported by the wearer's lower eyelid so that it does not move down with the eye upon rotation. Prism or lens truncation is often used to stabilize the lens and provide optimal lens positioning. The main challenge with this type of correction is getting enough rotation of the eye into the near power of the lens. If adequate rotation does not occur, the image may be degraded by images from the distance power.<sup>3</sup>

Studies have been conducted to compare the visual acuity through multifocal spectacles to visual acuity through multifocal contact lenses.<sup>4</sup> Fisher, Bauman, and Schwallie found that visual acuity at both distance and near was slightly better with spectacles than with the concentric or aspheric multifocal contact lens designs.<sup>7</sup> However, Jumenez, Durban, and Anera<sup>8</sup> and Woods et al<sup>9</sup> found no difference in distance and near visual acuities between subjects wearing spectacles and those wearing contact lenses. Even though these studies found little difference in acuity between spectacle and contact lens correction for presbyopia, other aspects of life may be negatively affected depending on the type of correction worn.

#### The National Eye Institute Refractive Error Correction Quality of Life

Questionnaire is a 42 question survey that was created to investigate how different optical corrections affect daily life. Information gained from studies using this questionnaire have assisted both practitioners and patients in understanding the strengths and weaknesses of different optical corrections. Richdale et al compared multifocal and monovision soft contact lens corrections in low-astigmatic presbiopic patients. Although there was no statistical significance, this study found that overall, patients wearing multifocal contact lenses were more satisfied with their correction than those fit in

monovision contact lenses. This difference may be attributed to the loss of stereoacuity that patients can experience with monovision. After comparing monovision and multifocal contact lenses in succession, patients preferred multifocal lenses three to one over monovision.<sup>10</sup>

The NEI-RQL-42 questionnaire has also been used to compare optical corrections in non-presbyopic patients. Queiros et al compared the quality of life of myopes corrected with Laser-assisted in situ keratomileusis (LASIK), spectacles, contact lenses, and orthokeratology. In this study, a global score was calculated by averaging all 13 subscales of the questionnaire. This score revealed that overall, LASIK corrected myopes present with a globally higher quality of life than myopes corrected with contact lenses or spectacles.<sup>11</sup> Both of these studies provided valuable information regarding different options of visual correction and their affect on quality of life. The goal of this study is to use the NEI-RQL-42 questionnaire to determine if there is a difference in quality of life between those wearing multifocal spectacles and those wearing multifocal contact lenses.

## CHAPTER 2

### MATERIALS & METHODS

#### **NEI-RQL-42 Questionnaire**

The National Eye Institute Refractive Error Correction Quality of Life Questionnaire (NEI-RQL-42) consists of questions that are aimed at determining the level of satisfaction with the subject's current visual correction. Unlike other surveys that detect the influence of chronic eye diseases on the patient's quality of life, the NEI-RQL-42 can be used to identify issues in patients with 20/30 or better visual acuity. As a result, the questionnaire is useful in comparing the affect of different types of refractive correction on a patient's quality of life.<sup>12</sup> In this study, the NEI-RQL-42 was used to compare the quality of life between those wearing multifocal spectacles and those wearing multifocal contact lenses.

The NEI-RQL-42 questionnaire is composed of 42 multiple-choice questions that are broken up into 13 subscales.<sup>11</sup> These subscales include clarity of vision, expectations, near vision, far vision, diurnal fluctuations, activity limitations, glare, symptoms, dependence on correction, worry, suboptimal correction, appearance, and satisfaction with correction.<sup>11,13</sup> To score the survey, each multiple-choice answer for a given question is assigned a point value from 0 to 100. Answers that correlate to a better quality of life are given a higher score and those indicating a lower quality of life are given a

score closer to zero. Within each of the 13 subscales, scores for each question are averaged to give the scale score for that subscale.<sup>14</sup>

### **Use of Optical Correction Questionnaire**

In addition to the NEI-RQL-42, a Use of Optical Correction questionnaire was added to this study. This survey consisted of 9 questions pertaining to the subjects' choice of visual correction and the way they choose to use it on a daily basis. Answers to these questions allowed researchers to categorize each subject based on their specific type of visual correction and gave information regarding how long the subjects had been wearing a particular correction.

### **Subjects and Inclusion Criterion**

Participants were recruited from an optometry school database. Those who met the inclusion criteria listed below were contacted by phone and asked if they were willing to participate in the study. Depending on their access to a computer, the willing participants were either mailed a consent form and paper copy of the questionnaire or emailed a link to the online consent form and questionnaire. Paper surveys were returned to the lead investigator to be added to the data compilation.

If any eligible subjects presented to the eye clinic for an examination, they were asked at the time of their exam if they would be willing to participate in the study. Those who agreed were educated about the study, given a consent form, and left in a private room to complete the online survey.



In order to participate in this study, all subjects had to be between the ages of 40 and 60 and have presbyopia that has been corrected for at least six months with either multifocal contact lenses or multifocal spectacles. Participants were required to have a binocular acuity of no less than 20/30 and wear their visual correction at least 8 hours per day for 5 days a week. Subjects must also have had a comprehensive eye exam, including a dilated fundus exam, within the past 12 months and be free of ocular disease or any condition that may negatively impact visual acuity.

### **Statistical Analysis**

For the purpose of statistical analysis, the subjects were broken into 3 groups: Glasses (Group 1) – those who exclusively wear multifocal glasses (7 subjects), Contact Lenses (Group 2) – those who wear multifocal contact lenses (7 subjects), and Contact Lenses > Glasses (Group 3) – those who wear multifocal contact lenses more than multifocal glasses (6 subjects).

Averaged scaled scores for each subscale were compared using independent two-sample t-tests to determine statistical significance between the groups. Two-tailed t-tests were used. Group 1 was compared with Group 2 and Group 3 independently. Group 2 was not compared directly to Group 3. Since Group 1 and Group 3 had unequal numbers of subjects, a t-test for unequal sample sizes with equal variance was used. The results of the t-tests were used to calculate p values using 12 degrees of freedom for comparing Group 1 and Group 2. When comparing Group 1 and Group 3, 11 degrees of freedom were used. P values less than 0.05 were considered statistically significant.

## CHAPTER 3

### RESULTS

The demographics of the 14 subjects determined by the Use of Optical Correction questionnaire are represented in Table 1. This study was comprised of 14 subjects: 7 (50%) who wore multifocal spectacles exclusively and 7 (50%) who wore multifocal contact lenses. Of the subjects wearing multifocal contact lenses, 6 subjects (42.9% of total subjects) answered that they wore contact lenses more often than spectacles.

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Demographic	Number of participants	Percent (%) of participants
Number of participants	14	
Number wearing glasses		
Bifocals	12	85.7
Trifocals	5	35.7
PAL	1	7.1
Readers	5	35.7
Readers	1	7.1
Length of time wearing multifocal glasses		
<1 year	2	14.3
1-5 years	2	14.3
5-10 years	3	21.4
>10 years	5	35.7
On average, how many days per week wearing glasses		
7 days	7	50
3 days	2	14.3

5 days	2	14.3
1 day	1	7.1
Number wearing multifocal contact lenses Those wearing contact lenses more often than glasses	7	50
Length of time wearing contact lenses		
<1 year	6	42.9
1-5 years	1	7.1
5-10 years	2	14.3
>10 years	3	21.4
Type of multifocal contact lens worn		
Cooper Biofinity MF	1	7.1
Cooper Proclear MF	3	21.4

On average, how many days per week wearing contact lenses		
2 days	1	7.1
4 days	1	7.1
7 days	5	35.7

**Table 1.** Demographics of subjects as determined by the Use of Optical Correction questionnaire

The results of the NEI-RQL-42 survey are located in Table 2. Of the 13 subscales that make up the NEI-RQL-42 survey, only two subscales showed a statistically significant difference between the two groups. Group 2 scored better than Group 1 in the appearance (p = 0.029) and the satisfaction with correction (p = 0.005) subscales. Group 3 also scored better than Group 1 in the appearance (p = 0.037) and satisfaction with correction (p = 0.025) subscales.

**Table 2.** Results of the NEI-RQL-42 survey broken up into 13 subscales. Mean scaled score<sup>a</sup>, standard deviation, floor, and ceiling are listed for each study group. P values are listed for each subscale, representing statistically significant differences between responses from the Glasses group and the other two groups, respectively.

	Mean $\pm$ SD		P value	
	<i>floor – ceiling (%)<sup>b</sup></i>			
	Glasses (1)	Multifocal Contact Lenses (2)	Multifocal Contact Lenses > Glasses (3)	(1) vs (2) (1) vs (3)
Clarity of vision	87.2 $\pm$ 24.9 <i>0 – 75.0</i>	80.4 $\pm$ 26.4 <i>0 – 60.7</i>	82.6 $\pm$ 26.6 <i>0 – 66.6</i>	0.49 0.76
Expectations	50.0 $\pm$ 28.9 <i>14.3 – 14.3</i>	42.9 $\pm$ 34.5 <i>28.6 – 14.3</i>	41.7 $\pm$ 37.6 <i>33.3 – 16.7</i>	0.56 0.66
Near vision	74.7 $\pm$ 29.1 <i>0 – 50</i>	81.8 $\pm$ 20.7 <i>0 – 46.4</i>	86.8 $\pm$ 16.8 <i>0 – 54.2</i>	0.47 0.39
Far vision	90.2 $\pm$ 16.1 <i>0 – 68.6</i>	92.1 $\pm$ 12.8 <i>0 – 71.5</i>	91.9 $\pm$ 12.7 <i>0 – 70</i>	0.73 0.84
Diurnal fluctuations	82.1 $\pm$ 27.9 <i>0 – 42.9</i>	82.7 $\pm$ 16.7 <i>0 – 28.6</i>	79.9 $\pm$ 16.5 <i>0 – 25</i>	0.95 0.86
Activity limitations	99.1 $\pm$ 4.7 <i>0 – 96.4</i>	99.1 $\pm$ 4.7 <i>0 – 96.4</i>	100 $\pm$ 0 <i>0 – 100</i>	1.00 0.65
Glare	85.7 $\pm$ 27.2 <i>0 – 71.4</i>	66.1 $\pm$ 30.4 <i>7.1 – 35.7</i>	64.6 $\pm$ 31.0 <i>8.3 – 33.3</i>	0.097 0.22
Symptoms	85.7 $\pm$ 22.2 <i>0 – 63.3</i>	85.2 $\pm$ 20.5 <i>0 – 55.1</i>	85.1 $\pm$ 20.7 <i>0 – 57.2</i>	0.96 0.96
Dependence on correction	44.0 $\pm$ 45.2 <i>42.9 – 35.7</i>	33.3 $\pm$ 31.1 <i>32.1 – 10.7</i>	34.0 $\pm$ 32.8 <i>33.3 – 12.5</i>	0.48 0.66
Worry	64.3 $\pm$ 25.4 <i>0 – 21.4</i>	66.1 $\pm$ 27.0 <i>0 – 28.6</i>	68.8 $\pm$ 28.5 <i>0 – 33.3</i>	0.86 0.77
Suboptimal correction	100 $\pm$ 0 <i>0 – 100</i>	96.4 $\pm$ 8.5 <i>0 – 85.7</i>	97.9 $\pm$ 7.2 <i>0 – 91.7</i>	0.14 0.47
Appearance	28.7 $\pm$ 41.2 <i>23.8 – 47.6</i>	66.7 $\pm$ 40.0 <i>19.0 – 71.4</i>	78.1 $\pm$ 32.3 <i>11.1 – 83.3</i>	0.029 0.037
Satisfaction with correction	74.3 $\pm$ 15.1 <i>0 – 14.3</i>	91.4 $\pm$ 10.7 <i>0 – 57.1</i>	93.3 $\pm$ 10.3 <i>0 – 66.7</i>	0.005 0.025

<sup>a</sup>Scores were scaled using the NEI-RQL-42 manual for use and scoring.  
<sup>b</sup>Floor percentage value represents percent of subjects who scored a scaled score of 0 and ceiling percentage value represents percent of subjects who scored a scaled score of 100

## CHAPTER 4

### DISCUSSION

The information gained from quality of life surveys can educate practitioners and patients on the benefits and disadvantages of different forms of treatment and the affect they will have on daily life. There are patients with a visual acuity of 20/20, a full visual field, and 20 seconds of stereoacuity with a particular optical correction, who still experience problems with their vision and are not completely happy.<sup>12</sup> The NEI-RQL-42 questionnaire analyzes how subjects perceive their vision with a given form of optical correction without looking solely at the examination data. The results of these studies aid practitioners in understanding the causes of patient dissatisfaction with a given correction. With this added knowledge, eye care professionals can adequately inform their patients of possible drawbacks when they are making a decision regarding what is best for their particular visual needs.

The onset of presbyopia is associated with a decline in quality of life.<sup>15</sup> The goal of multifocal optical correction is to bring the patient as close to their pre-presbyopic vision as possible without compromising comfort, appearance, mobility, or ability to perform tasks. This study found that overall, there is little difference between the quality of life of those wearing multifocal contact lenses and those wearing multifocal spectacles.

The appearance and satisfaction with correction subscales were the only areas that showed a statistically significant difference in quality of life between the two groups.

The clarity of vision reported by those wearing multifocal spectacles nearly matched that of multifocal contact lens wearers. Most reported good vision, free of distortion and intolerable blur. However, when asked about blur in general, contact lens wearers were more inclined to report that they experienced a small amount of blur while performing daily activities. On the other hand, multifocal spectacle wearers reported slightly worse near vision than contact lens wearers. These results are similar to the visual acuity comparison studies previously mentioned.<sup>7,8,9</sup>

When asked how life would change if no vision correction was required to see clearly, both spectacle and contact lens wearing subjects responded that life would improve. Although there was not a statistically significant difference, contact lens wearing presbyopes anticipated a slightly larger increase in happiness without a need for correction. This small difference may be due to the extra care and maintenance required of contact lens wearers.

It may be expected that spectacles would restrict athletic performance. However, the results of this study showed that the type of correction worn did not hinder subjects from participating in activities that they enjoyed. Both categories of subjects reported that they were able to perform high-energy activities without difficulty. Likewise, both groups reported little to no difficulty with daily fluctuations in vision, which results in less problems when performing activities of daily living.

Although the results were not statistically significant, issues with glare were reported more often by multifocal contact lens wearers than by those wearing multifocal

spectacles. More specifically, contact lens wearers reported more incidences of starbursts and halos around lights at night. Previous studies have shown that glare is a common problem among contact lens wearing presbyopes due to the design's dependence on pupil size. In dim light, the pupil increases in size, resulting in more light scatter.<sup>16</sup> Multifocal spectacle correction is not subject to the same dependence on pupil size and therefore, is not as susceptible to glare. Despite historical findings, there are other more recent studies that found no significant increase in glare symptoms with multifocal contact lenses compared to other forms of correction.<sup>15,10</sup>

Overall, this study found no significant difference between symptoms reported by contact lens wearers compared to spectacle lens wearers. This is somewhat surprising, considering the increased risk of infection and incidence of dryness in contact lens wearers in general. Dryness is a common problem for many contact lens wearers and often leads to discontinuation of wear. This problem is more evident in soft contact lens wearers than those in hard lenses.<sup>17,18,19</sup> For the majority of patients, lens dryness is worse towards the end of the day, after the lenses have been worn for several hours.<sup>17</sup> Giant papillary conjunctivitis is also a common condition found in contact lens wearers. Itching may occur after the contact lenses have been removed and is often accompanied by increased lens awareness and movement.<sup>20</sup>

Contact lens and spectacle wearing presbyopes agreed on the importance of vision and expressed a similar amount of worry about their vision. As would be expected, both groups of subjects also reported an equally high dependence on their optical correction.

The need for correction is especially high when attempting activities that require good



near vision. For this reason, almost all presbyopes in this study stated that they wore their correction despite its possible negative affects on their appearance.

As was mentioned previously, the appearance subscale was one of two areas that showed a significant difference in responses. This study found that contact lens wearing presbyopes were much happier with their appearance than those presbyopes wearing spectacles. The negative effect of spectacles on comesis has also been found in other studies that involve a quality of life comparison between spectacles and contact lenses.<sup>10</sup>

It is interesting to note that multifocal contact lens wearers were significantly more satisfied with their current form of optical correction than multifocal spectacle wearers. The NEI-RQL-42 questionnaire did not ask detailed questions about why the subject is or is not satisfied with his or her optical correction. Since there is not a considerable difference between the two groups when comparing other subscales, it seems that appearance plays a major role in the subjects' satisfaction.

Due to the restrictions placed on the methods for gathering data for this study, the number of participants was lacking. While the university database is full of presbyopic patients, only a few in the desired age range were free of disease and willing to participate. This proved to be the biggest limitation of the study. With access to a larger population of eligible subjects, this study would provide information that would be useful to optometrists and presbyopic patients who are choosing their personal form of vision correction.

Since this study was based on results from the NEI-RQL-42 questionnaire, it was subject to a few limitations that should be considered if research is continued on this topic. Future studies comparing quality of life between multifocal spectacle wearers and

multifocal contact lens wearers should also make note of the exam data pertaining to each subject. It may be useful to compare actual visual acuity and stereo acuity to that which is perceived by the subject. Additionally, this study only assessed the quality of life of subjects while wearing their preferred visual correction. It may be advantageous to study how the subjects' perceived quality of life changes when wearing the opposite correction. Every subject has a different set of criteria for judging the effectiveness of their visual correction. Some are stricter than others. Comparing the data between spectacle correction and contact lens correction for the same subject may provide some valuable data that can further help interpret the study's data.

This pilot study provides some important information for both patients and practitioners who are contemplating the use of multifocal contact lenses. Many eye care professionals are reluctant to suggest multifocal contact lenses to their presbyopic patients because they do not believe the visual outcome is worth the time and money spent on fitting the lenses. The results of this study show that the quality of life of multifocal contact lens wearers was not any worse than that of multifocal spectacle wearers. Contact lens wearers did not feel that fluctuating vision, aberrations, or decreased comfort limited their ability to complete daily tasks. In fact, overall, multifocal contact lens wearers proved more satisfied with their vision and appearance than spectacle wearers.

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APPENDIX A

IRB APPROVAL LETTER

Office of Academic Research  
Ferris State University  
1201 S. State Street-CSS 310 H  
Big Rapids, MI 49307  
(231) 591-2553  
IRB@ferris.edu

To: Dr. Amy Dinardo, Ms. Christina Becker and Mr. Tom Hall II  
From: Dr. John Pole, Interim IRB Chair  
Re: IRB Application #130501 (Title: *Quality of Life Comparison between Patients Wearing Multifocal Contact Lenses and Patients Wearing Multifocal Spectacles*)  
Date: May 15, 2013

The Ferris State University Institutional Review Board (IRB) has reviewed your application for using human subjects in the study, “*Quality of Life Comparison between Patients Wearing Multifocal Contact Lenses and Patients Wearing Multifocal Spectacles*” (#130501) and determined that it is *exempt-1C* from full committee review. This approval has an expiration date of three years from the date of this letter. As such, you may collect data according to procedures in your application until *May 15, 2016*. 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 protocol has been assigned a project number (#130501) which you should refer to in future applications 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 one-year reminder to complete the final report or note the continuation of this study. The final-report form is 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.