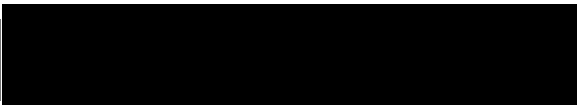


Ferris State University  
Doctor of Optometry Senior Paper  
Library Approval and Release

The relationship between contrast sensitivity loss and falls in a low vision population

I/We, Taylor Oie and Margaret Baumgartner, 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.



\_\_\_\_\_  
Signatures : Doctoral Candidate(s)

05/02/2016

Date

**THE CORRELATION BETWEEN CONTRAST SENSITIVITY LOSS AND  
FALLS IN A LOW VISION POPULATION**

by

Taylor Oie and Margaret Baumgartner

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 CORRELATION BETWEEN CONTRAST SENSITIVITY LOSS AND  
FALLS IN A LOW VISION POPULATION**

by

Taylor Oie and Margaret Baumgartner

Has been approved

31 May, 2017

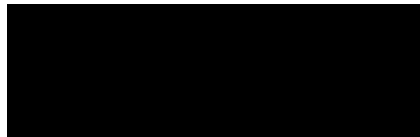
APPROVED:



---

Faculty Advisor:

ACC



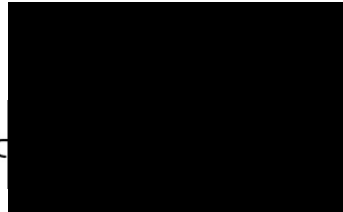
---

Faculty Course Supervisor

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

**THE CORRELATION BETWEEN CONTRAST SENSITIVITY LOSS AND  
FALLS IN A LOW VISION POPULATION**

I/We, Taylor Oie and Margaret Baumgartner, 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.



---

Doctoral Candidate(s)

03-13-17

---

Date

## ABSTRACT

**Background:** Contrast sensitivity loss has a profound effect on vision. With decreased contrast sensitivity, spatial localization can be negatively affected. Spatial localization is one of the key elements needed to accurately and efficiently navigate one's environment. The aim of this study was to quantify the magnitude of contrast sensitivity loss that predisposes patients to falls. **Methods:** This study was a retrospective review of electronic health record data gathered at the Ferris State University Eye Center. Thirty-six patient records were reviewed. Only records obtained in the Vision Rehabilitation Service were reviewed. These records were used to associate the incidence of falls with contrast sensitivity loss. Data collected included age, ocular diagnoses, fall history, any difficulties with orientation and mobility, and contrast sensitivity values. This data was inputted into a spreadsheet with all patient identifying information removed. **Results:** We expected there to be a positive correlation between contrast sensitivity loss and a history of falls. A statistical analyzation of the data gathered was completed to uncover the link between contrast sensitivity and falls. This information was studied and analyzed to determine the range of contrast sensitivity loss which leads to a higher probability of future falls. Through our analysis, we discovered that there was a weak correlation between contrast sensitivity loss and a history of falls. A stronger correlation was discovered between contrast sensitivity loss and orientation and mobility deficits. The

strongest correlation made was between increasing age and orientation and mobility deficits. **Conclusions:** The results of this study will advance the field of optometry, specifically in the field of low vision, by allowing practitioners to better predict the risk of falls in the low vision population as it relates to loss of contrast sensitivity. This will allow practitioners to better prepare and equip their patients so falls may be avoided in the future. With the information gathered in this study, optometrists can provide the appropriate devices and make the appropriate referrals to better assist this population.

## TABLE OF CONTENTS

	Page
LIST OF TABLES.....	vi
CHAPTER	
1 INTRODUCTION.....	1
2 METHODS.....	4
3 RESULTS.....	7
4 DISCUSSION.....	10
5 REFERENCES.....	14
APPENDIX	
A. IRB APPROVAL LETTER.....	21

## LIST OF TABLES AND FIGURES

Figures		Page
1	Normal Values for Log Contrast Sensitivity.....	16
2	Proportion of sample population by contrast sensitivity loss.....	16
3	Data Table.....	17
4	Contrast Sensitivity Loss Compared to a History of Fall.....	18
5	Contrast Sensitivity Loss as a Function of Age Graph 1.....	19
6	Contrast Sensitivity Loss as a Function of Age Graph 2.....	20



## CHAPTER 1

### INTRODUCTION

It is common for those in the elderly population to fall. Unfortunately, the incidence of falls among the elderly is one-third each year, and this increases for those living in any type of care facility.<sup>1</sup> Falls in any population significantly contribute to health care costs and place a financial burden on the economy. In 2013, \$34 billion were spent on direct medical costs for individuals older than 65 that experienced falls; studies have shown that vision is a contributing factor to the incidence of falls.<sup>2,3,4</sup> Hospital patients tend to have a higher rate of falls; through research it has been discovered that vision loss is also higher among hospital patients, suggesting a link between vision loss and falling.<sup>4</sup>

It is well known that vision often decreases with increasing age, due to an increased prevalence of ocular conditions such as macular degeneration, cataracts, glaucoma, and diabetic retinopathy. Ocular conditions such as these often lead to visual impairment and low vision. According to the American Optometric Association, low vision is a term used for anyone who has reduced vision despite best optical correction.<sup>5</sup> These individuals are also considered visually impaired and are classified by the World Health Organization based on certain classifications of visual acuity and visual field loss. According to the World Health Organization, 285 million people are visually impaired in the world.<sup>6</sup> Of these, 2.8 million older adults have severe vision impairment.<sup>2</sup> For individuals between the ages of 70-74, 2.6% have some type of visual impairment; for

those between ages of 75-80, the prevalence increases to 4.8%.<sup>1</sup> With visual impairment, there is typically a loss of functional vision as well. According to Dhital et.al, functional vision loss is a better predictive factor for the risk of falls than solely visual acuity loss.<sup>7</sup> Functional vision relates to visual skills needed to perform activities of daily living. These skills affect one's ability to maneuver his environment and live independently. In order to appropriately assess functional vision, other factors should be considered such as contrast sensitivity, depth perception and peripheral vision.<sup>1</sup>

Currently available studies typically use measurements of visual acuity to predict the risk of falls. Many studies focus solely on the elderly population. One study focusing on elderly patients with age-related macular degeneration (AMD) showed a correlation between decreased contrast sensitivity, typically associated with AMD, and risk of falls and injuries. This same study also demonstrated that visual acuity alone was only associated with falls and not with injuries.<sup>3</sup> Of the individuals living with blindness, 82% are aged 50 and above. Not only are many older individuals suffering from visual impairment, but there are 1.4 million people under age 15 that are blind.<sup>6</sup> Individuals who are visually impaired are at a higher risk for experiencing falls, and one study found that more than 40% of low vision patients fell each year.<sup>8</sup> The goal of this study was to examine the link between falls in the low vision population and a decrease in contrast sensitivity. A primary objective was to expand the subject population to include a variety of patient ages, focusing on those who are established as members of the low vision patient population.

Many studies have attempted to show a link between decreased visual function and an increased risk of falls. Such studies have predominantly focused on visual acuity

while also including contrast sensitivity, depth perception, and visual field loss as risk factors. As an important part of assessing functional vision, contrast sensitivity can have a profound effect on overall visual function and spatial localization. A study published by Lord et. al demonstrated a link between falls in the elderly population and an impaired contrast sensitivity and depth perception associated with the use of multifocal glasses. They positively identified falls involving tripping and a decrease in perceived obstacles due to impaired depth perception and specifically decreased edge-contrast sensitivity.<sup>9</sup> This study attempted to assess a similar correlation between contrast sensitivity and the risk of falls in the low vision population.

While vision is a large factor that contributes to an increased risk for falls, the presence of physical and mental comorbidities should also be explored. According to a study by Court et. al, visually impaired patients aged 65 years and older are more likely to have more physical and mental health comorbidities as compared to individuals of the same age without visual impairment.<sup>10</sup> This is important to remember when coordinating care of the patient. Optometrists may be the first ones to diagnose the patients with vision loss. As such, they need to be aware of the importance of having these patients evaluated thoroughly to uncover any existing physical and mental comorbidities in order to prevent future falls and mobility issues.

## CHAPTER 2

### METHODS

The sample population gathered included thirty-six men and women ages 19 to 94. All individuals in the sample population were members of the low vision community. The data was gathered from electronic health records at the University Eye Center at the Michigan College of Optometry. Subjects of the study did not participate in a survey; charts were retrospectively reviewed. All information gathered was de-identified and placed in a spreadsheet for review. The information gathered included patient age, ocular diagnoses, a history of falls, a history of orientation and mobility issues, contrast sensitivity findings, the date of their examination, and the random identification number assigned to each patient.

Of the population collected, 10 individuals (27.8%) had a primary diagnosis of nonexudative macular degeneration as a cause of their vision loss, 4 (11.1%) had exudative macular degeneration, 7 (19.4%) had optic atrophy, 1 (2.8%) had diabetes mellitus with ocular complications, 4 (11.1%) had visual field loss, 2 (5.6%) had glaucoma, 3 (8.3%) had ocular albinism, 5 (13.9%) had retinal dystrophies, and 4 (11.1%) had other ocular diseases. These other ocular diseases included optic nerve head drusen, macular scars, microphthalmos, and aniridia.

Collection of data regarding a history of falls was completed through the use of a patient questionnaire completed at the time of the examination. This verbal survey was

given to all entering low vision patients at each examination and included questions regarding a history of falls and difficulty with orientation and mobility.

Contrast sensitivity testing was performed using the MARS Letter Contrast Sensitivity Test during the examinations. The test chart includes 48 letters which are arranged in 8 rows. It is intended to be tested at a distance of 50 cm, and each letter subtends 2 degrees at the given test distance. Each letter from left to right decreases in contrast by a factor of 0.04 log units and continues to do so moving down each row.<sup>11</sup> Patients are asked to read the letters from left to right and continue down the chart until they are no longer able to do so. Size of the letters remains consistent while each set of three letters decreases in contrast. The MARS Letter Contrast Sensitivity Test is accompanied by a scoring sheet which identifies different levels of contrast sensitivity loss into the following categories: normal for middle/young adults, normal for individuals greater than age 60, moderate, severe, and profound.

The test is administered at a distance of 50 cm from the patient but may be moved up to 25 cm depending on the severity of the patient's visual deficits. The test is performed while the patient is undilated, and patients should wear their preferred optical correction for comfortable viewing at the test distance. The chart should be viewed in a room with full illumination, which includes the use of the standard ophthalmic equipment stand lamp and uniform illumination.<sup>11</sup>

Results of the MARS Letter Contrast Sensitivity Test are recorded in logarithmic values. These values are collected using the logarithmic value prior to two consecutive misidentified letters. The number of misidentified letters prior to this last correct letter is multiplied by 0.04. This "scoring correction" is subtracted from the logarithmic contrast

sensitivity value at the final correct letter to achieve the true contrast sensitivity measure. The true contrast sensitivity value can then be sorted into one of 5 categories of loss (as shown in Figure 1).<sup>11</sup>

## CHAPTER 3

### RESULTS

Of the 36 members of this study, 22 (61.1%) reported having difficulty with orientation and mobility. Of those with difficulty, 8 (22.2%) answered yes to having a history of falls. A history of falls without other orientation and mobility issues was reported in 3 (37.5%) individuals. The highest percentage of contrast sensitivity loss in the population studied was moderate (39%) followed by severe (33%), profound (11%), normal for individuals over 60 (11%), and normal for young/middle-aged adults (6%) (see Figure 2). There were 5 (13.89%) total individuals who had a normal contrast sensitivity level based on their age while all others were reduced (see Figures 2 and 3).

While the trend lines on Figures 4 and 5 seemed to suggest an association between decreased contrast sensitivity and a higher risk for falling, the percentages of our sample population who reported a history of falls did not support this conclusion. Of those that responded positively to a history of falls, 87.5% had contrast sensitivity findings of moderate loss or worse. This initially seemed to suggest a strong link between falls and decreased contrast sensitivity. However, upon further extrapolation of the data, 85.7% of those that responded negatively to a history of falls also had a contrast sensitivity of moderate loss or worse. These two percentages are very similar and demonstrate that contrast sensitivity loss most likely does not predispose an individual to an increased risk of falls. Of the total number of subjects who had decreased contrast

sensitivity relative to their age group, 96.4% did not have a history of falls. This further supports that contrast sensitivity loss may not lead to a higher probability of falls. Upon further analysis of the data, a probability of correlation or p-value was determined for those patients with decreased contrast sensitivity and a history of falls. The p-value calculated was 0.0001 which suggests that there was strong evidence to support the initial hypothesis that contrast sensitivity loss is linked to a history of falls. Even though the p-value was strong, this value was based on a small sample size and data that was weakly correlated.

Despite a lack of evidentiary support for a link between contrast sensitivity loss and falls, the data does suggest a weak relationship between contrast sensitivity loss and general orientation and mobility deficits. Of those that responded positively to orientation and mobility problems, 86.4% also had a contrast sensitivity of moderate loss or worse. When compared to those that responded negatively to orientation and mobility problems, only 64.3% had a contrast sensitivity of moderate loss or worse. This suggested that decreased contrast sensitivity places an individual at increased risk for difficulties with orientation and mobility. The trend lines shown in Figure 6 suggest a negative correlation between orientation and mobility problems and contrast sensitivity loss. However, the coefficient of determination shows a weak correlation for both trend lines represented on the figure. Using the coefficient of determination, a p-value was approximated. The p-value for patients with contrast sensitivity loss and a positive history of orientation and mobility deficits was 0.1907. This value suggests that there is not enough evidence that patients with contrast sensitivity loss will respond positively to having a history of falls. However, it also means that there is not enough evidence that



patients with contrast sensitivity loss will not respond positively to having a history of falls.

Orientation and mobility issues are positively correlated to increasing age (see Figure 6). There were a total of 15 individuals over age 65 that participated in our study. Of those individuals, 100% reported orientation and mobility problems. The p-value for individuals greater than age 65 with a history of orientation and mobility deficits was 0.00001 which is very strong. This means that there is strong evidence to support the theory that individuals aged 65 and older will respond positively to a history of falls. Those individuals below age 65 were much less likely to report falls and other orientation and mobility difficulties. Increasing age also shows a mild-moderate relationship to decreasing contrast sensitivity (see Figure 2). Of those greater than age 65, 92.3% had contrast sensitivity loss of moderate or worse.

## CHAPTER 4

### DISCUSSION

The results of this study were different than anticipated when the decision was made to research the link between contrast sensitivity and increased prevalence of falling. It was interesting to find that while there was a weak correlation between contrast sensitivity loss and falling, there was a stronger correlation between orientation and mobility deficits and contrast sensitivity loss. The correlations drawn from this study may be weak, but there were some limitations to the study which brought about unforeseen flaws.

One major flaw with this study was the small sample size used. It is challenging to draw meaningful conclusions from the data of only 36 individuals. This 36-person sample size represents only a small fraction of the low vision population as a whole. This study was limited by the number of low vision patients seen at the University Eye Center with documented contrast sensitivity measurements and fall history. While a goal of our study was to focus on a variety of ages rather than just the elderly population, the low vision community is comprised predominantly of individuals greater than age 65 solely due to the higher prevalence of ocular conditions found among these individuals. This is represented in the study with the mean age of the participants being 61.08 years, and 41.67% of the total individuals studied being over the age of 65.

Another flaw was that the only visual impairment factor studied was contrast sensitivity. Visual impairment can occur in not only contrast sensitivity loss, but in a variety of other visual measures such as visual acuity, depth perception, and visual field loss. A study performed by Lord et. al showed that decreased contrast sensitivity and depth perception were the most influential factors for falls. This study exhibited that the most relevant predictor of multiple falls was depth perception with decreased low-contrast visual acuity following.<sup>12</sup> This suggests a correlation between decreased contrast and incidence of falls. However, other factors may have had significant influence over the patient's ability to navigate their environment and may have more positive association to fall risk in this population.

The last flaw with this study was the reliance on subjective input supplied by the patients. The questionnaire given to all patients in the Vision Rehabilitation Service asked if the patient had any history of falls. It did not define for the patient what was constituted a fall. It also did not ask when the patient had fallen or how many times. This allowed for the patient's own interpretation of what it meant to fall or have difficulty with a certain task, such as walking, bumping into things, or using the stairs. The perception of the patient on their ability to navigate their environment was likely to be influenced by other factors such as age, physical limitations, onset of their visual impairment, etc.

One significant finding from the study was the correlation between orientation and mobility problems with decreased contrast sensitivity and increased age. Through the research conducted in this study, there was a correlation shown between increasing age and decreasing contrast sensitivity. It is well proven that increasing age is related to orientation and mobility difficulties.<sup>1,9</sup> There are confounding factors to be considered

such as an increase in health problems, physical limitations and systemic diseases in the elderly population that contribute to risks of falls and injuries. Unfortunately it is impossible to distinguish which factors are responsible; there is a high likelihood that multiple factors are at fault. In order to isolate decreased contrast sensitivity as a risk factor for falls, it would be necessary to exclude individuals with an increased incidence of falls due to age and health conditions that put them at a higher risk for falling. A study performed on older adults with AMD revealed that of all the elements considered, contrast sensitivity was the strongest prognostic factor for fall risk.<sup>3</sup> The parallel between decreased contrast sensitivity and falls was corroborated by other studies on the general population. These studies indicate a stronger connection between contrast sensitivity and falls than those found between age and falls, as in our study.<sup>13,14</sup>

The results of this study affect the way eye care providers should practice in regard to patients ages 65 and older. Any individual over 65 is at increased risk of having orientation and mobility deficits which also puts them at a higher risk for falls. Practitioners should be aware of this and educate their patients on preventative strategies, as falling has not only implications on the health of patients, but large financial consequences as well. One important fall prevention strategy for optometrists to discuss with their patients relates to the optical correction options best for the patients. According to a study by Lord et. al, older patients wearing multifocal glasses such as progressive addition lenses have impaired edge contrast sensitivity.<sup>9</sup> This can lead to a loss of depth perception, which makes safe ambulation difficult. It would be wise to counsel patients, especially those with a history of visual impairment, regarding this risk and may be advantageous to recommend separate distance and near glasses to avoid future issues.

Another important consideration for eye care providers would be to establish a relationship with an orientation and mobility specialist. While maximizing a patient's visual potential would help to decrease the risk of future falls, this does not entirely eliminate the risk. Referring patients to an orientation and mobility specialist may help them to learn strategies for preventing future falls.

## REFERENCES

1. Källstrand-Eriksson, J., Baigi, A., Buer, N., & Hildingh, C. (2012). Perceived vision-related quality of life and risk of falling among community living elderly people. *Scandinavian Journal of Caring Sciences*, 27(2), 433-439.
2. Crews JE, Chou C, Stevens JA, Saaddine JB. Falls Among Persons Aged  $\geq 65$  Years With and Without Severe Vision Impairment — United States, 2014. *MMWR Morb Mortal Wkly Rep* 2016;65:433–437. DOI:
3. Joanne M. Wood, Philippe Lacherez, Alex A. Black, Michael H. Cole, Mei Ying Boon, Graham K. Kerr; Risk of Falls, Injurious Falls, and Other Injuries Resulting from Visual Impairment among Older Adults with Age-Related Macular Degeneration. *Invest. Ophthalmol. Vis. Sci.* 2011;52(8):5088-5092.
4. Keeling A, et al. Vision loss and falls among hospital inpatients: A case-control study. Presented at: American Academy of Optometry annual meeting; Anaheim, Calif.; Nov. 8-13, 2016.
5. Low Vision. (n.d.). Retrieved January 29, 2017, from <http://www.aoa.org/patients-and-public/caring-for-your-vision/low-vision?sso=y>
6. Visual impairment and blindness. (n.d.). Retrieved January 29, 2017, from <http://www.who.int/mediacentre/factsheets/fs282/en/>
7. Dhital, A., Pey, T., & Stanford, M. R. (2010). Visual loss and falls: a review. *Eye*, 24(9), 1437-1446.

8. Lamoureux, E., Gadgil, S., Pesudovs, K., Keeffe, J., Fenwick, E., Dirani, M., . . . Rees, G. (2010). The relationship between visual function, duration and main causes of vision loss and falls in older people with low vision. *Graefe's Archive for Clinical and Experimental Ophthalmology*, 248(4), 527-533.
9. Lord, S. R., Dayhew, J., Sc, B. A. and Howland, A. (2002), Multifocal Glasses Impair Edge-Contrast Sensitivity and Depth Perception and Increase the Risk of Falls in Older People. *Journal of the American Geriatrics Society*, 50: 1760–1766.
10. Court, H., Mclean, G., Guthrie, B., Mercer, S. W., & Smith, D. J. (2014). Visual impairment is associated with physical and mental comorbidities in older adults: a cross-sectional study. *BMC Medicine*, 12(1).
11. *The MARS Numeral Contrast Sensitivity Test User Manual* [Pamphlet]. (2003-2010). Chappaqua, NY: The MARS Perceptrix Corporation.
12. Lord, S. R., & Dayhew, J. (2006). Visual risk factors for falls in older people. *Age and Ageing*, 35(Supplement 2), Ii42-Ii45.
13. Boer, M. R., Pluijm, S. M., Lips, P., Moll, A. C., Völker-Dieben, H. J., Deeg, D. J., & Rens, G. H. (2004). Different Aspects of Visual Impairment as Risk Factors for Falls and Fractures in Older Men and Women. *Journal of Bone and Mineral Research*, 19(9), 1539-1547.
14. Cummings, S. R., Nevitt, M. C., Browner, W. S. (1995). Risk factors for hip fracture in white women. Study of Osteoporotic Fractures Research Group. *New England Journal of Medicine*, 332, 767–773.

### Normal Values for Log Contrast Sensitivity

Chart Row	Chart Column					
	1	2	3	4	5	6
1	0.04	0.08	0.12	0.16	0.20	0.24
2	0.28	0.32	0.36	0.40	0.44	0.48
3	0.52	0.56	0.60	0.64	0.68	0.72
4	0.76	0.80	0.84	0.88	0.92	0.96
5	1.00	1.04	1.08	1.12	1.16	1.20
6	1.24	1.28	1.32	1.36	1.40	1.44
7	1.48	1.52	1.56	1.60	1.64	1.68
8	1.72	1.76	1.80	1.84	1.88	1.92

Key		
■		Profound (<0.48)
■		Severe (0.52 – 1.00)
■		Moderate (1.04 – 1.48)
■	and	Normal > Age 60 (1.52 – 1.76)
■	and	Normal Middle/Young Adult (1.72 – 1.92)

*The MARS Numeral Contrast Sensitivity Test User Manual [Pamphlet]. (2003-2010). Chappaqua, NY: The MARS Perceptrix Corporation.*

Figure 1

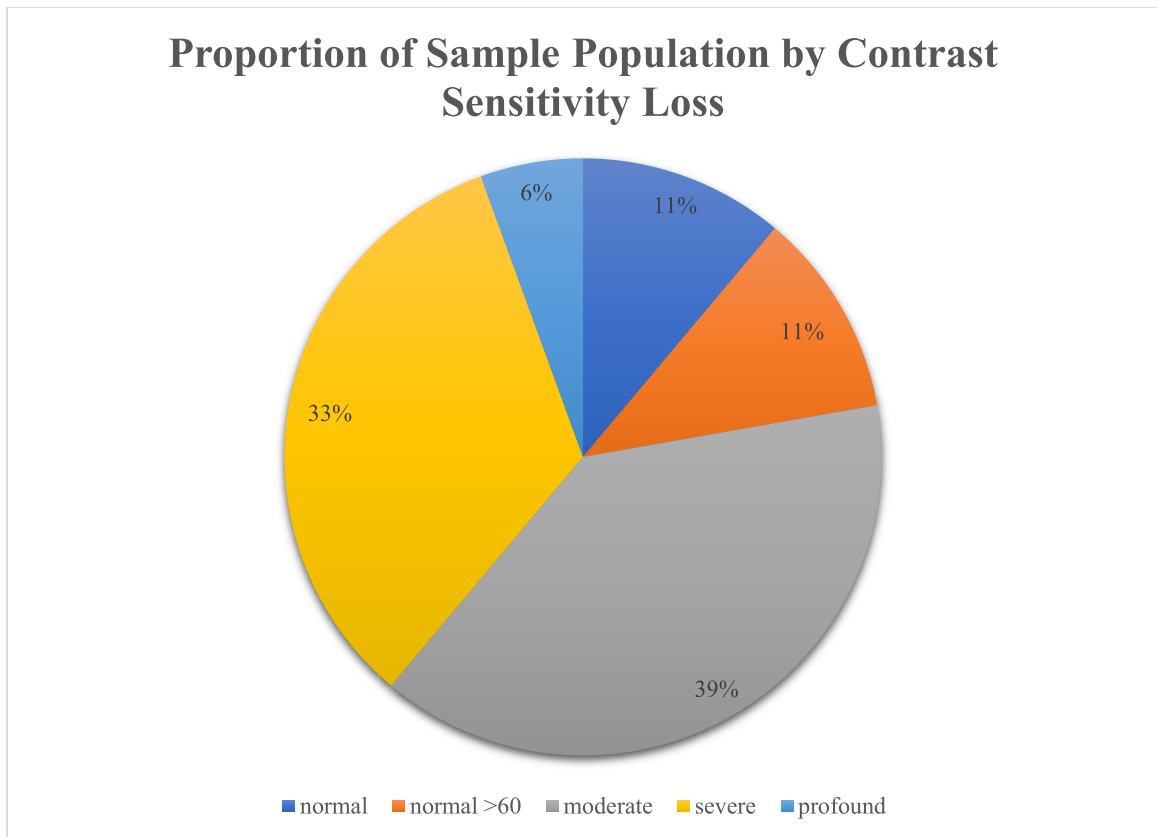


Figure 2



Age	Contrast sensitivity	General orientation and mobility deficits	Falls	Difficulty with walking, stairs, and bumping into objects
24	normal	No	No	No
46	normal	Yes	Yes	Yes
53	normal	Yes	No	Yes
68	normal	No	No	No
35	normal >60	Yes	No	Yes
34	normal >60	Yes	No	Yes
31	normal >60	Yes	No	Yes
61	normal >60	No	No	No
19	moderate	No	No	No
35	moderate	No	No	No
49	moderate	No	No	No
53	moderate	No	No	No
55	moderate	Yes	No	Yes
61	moderate	No	No	No
73	moderate	Yes	No	Yes
82	moderate	Yes	Yes	No
84	moderate	Yes	No	Yes
88	moderate	No	No	No
89	moderate	No	No	No
90	moderate	Yes	No	Yes
90	moderate	Yes	No	Yes
94	moderate	Yes	No	Yes
33	severe	Yes	Yes	Yes
35	severe	Yes	No	Yes
41	severe	Yes	No	Yes

54	severe	No	No	No
56	severe	Yes	Yes	No
63	severe	Yes	No	Yes
74	severe	Yes	Yes	Yes
75	severe	Yes	Yes	No
84	severe	Yes	No	Yes
84	severe	No	No	No
85	severe	Yes	Yes	Yes
90	severe	Yes	No	Yes
52	profound	Yes	Yes	Yes
59	profound	Yes	No	Yes
Total Yes		24	8	21

Figure 3

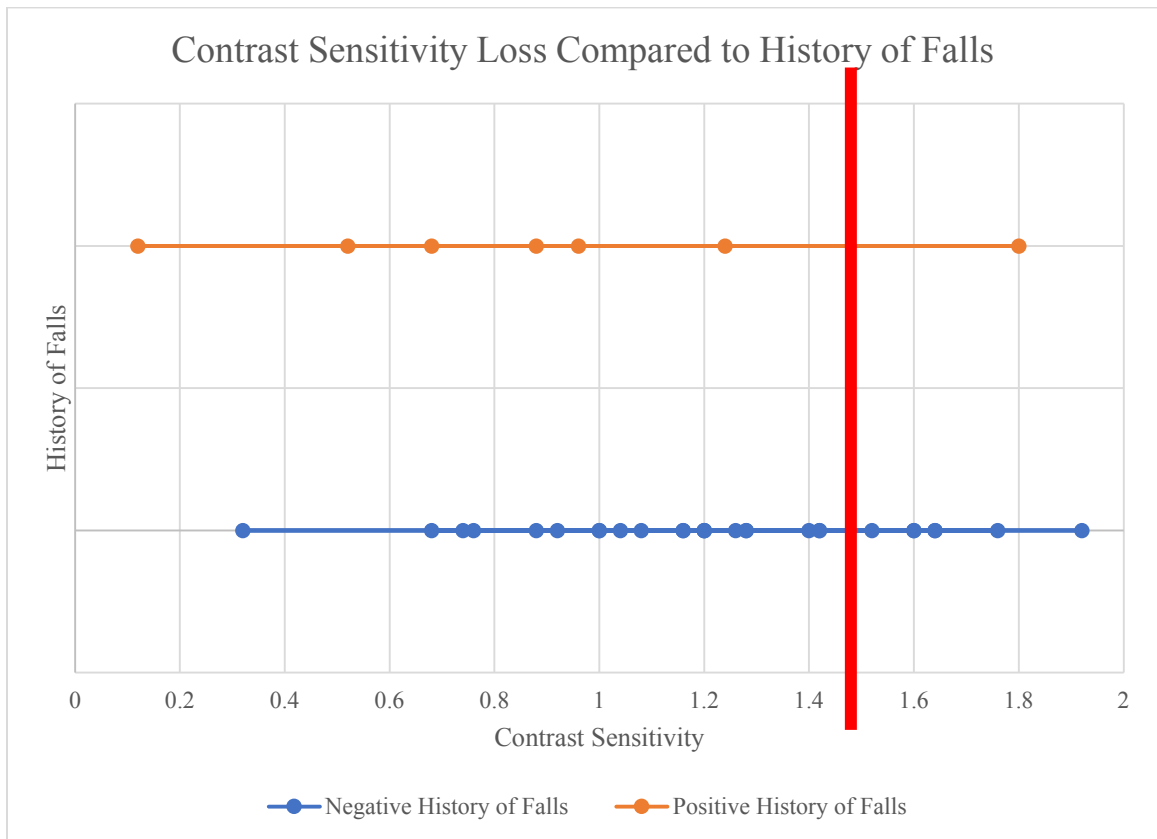


Figure 4

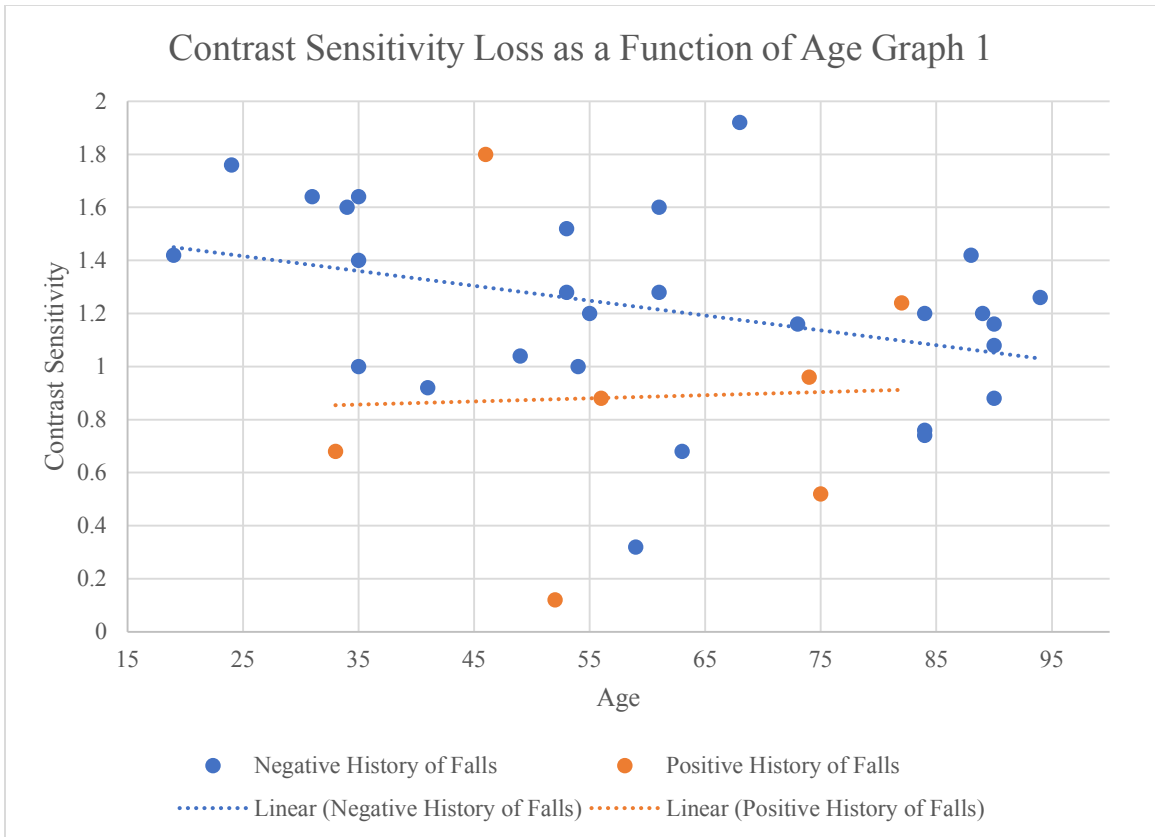


Figure 5

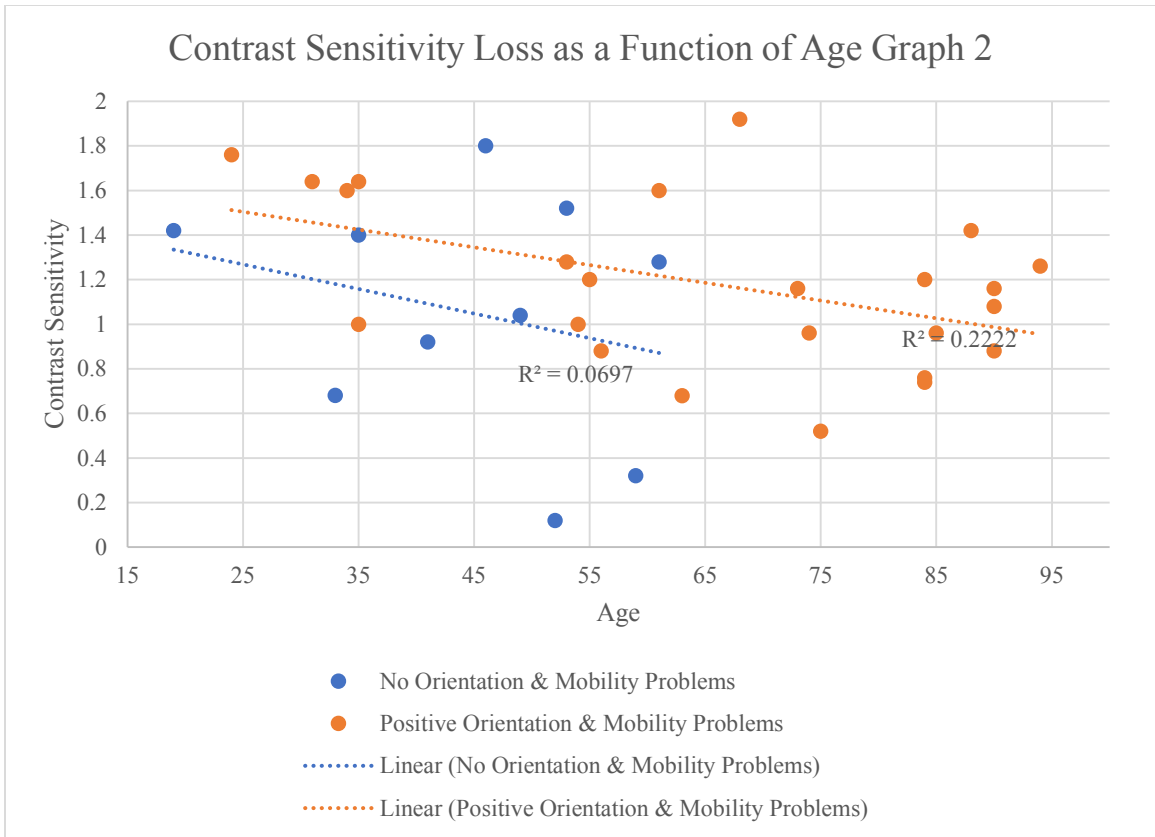


Figure 6

APPENDIX A

SAMPLE IRB APPROVAL FORM

**Institutional Review Board for Human Subjects in Research**

Office of Research & Sponsored Programs, 220 Ferris Drive, PHR 308 · Big Rapids, MI 49307 Date: May 4, 2016

To: Dr. Sarah Hinkley, Taylor Oie and Margaret Baumgartner

From: Dr. Gregory Wellman, IRB Chair

Re: IRB Application #160410 (*The relationship between contrast sensitivity loss and falls in a low vision population*)

The Ferris State University Institutional Review Board (IRB) has reviewed your application for using human subjects in the study, "*The relationship between contrast sensitivity loss and falls in a low vision population*" (#160410) and determined that it meets Federal Regulations Exempt-category 1E. This approval has an expiration date of three years from the date of this letter. **As such, you may collect data according to the procedures outlined in your application until May 4, 2019.** Should additional time be needed to conduct your approved study, a request for extension must be submitted to the IRB a month prior to its expiration.

Your protocol has been assigned project number (#160410), which you should refer to in future correspondence involving this same research procedure. Approval mandates that you follow all University policy and procedures, in addition to applicable governmental regulations. Approval applies only to the activities described in the protocol submission; should 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 as well as complaints and noncompliance issues.

This project has been granted a waiver of consent documentation; signatures of participants need not be collected.

As mandated by Title 45 Code of Federal Regulations, Part 46 (45 CFR 46) the IRB requires submission of annual reviews during the life of the research project and a Final Report Form upon study completion. 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 Research and Sponsored Programs