EFFECTS OF PROGRESSIVE LENS EYEGLASSES ON GAIT PERFORMANCE FACTORS AMONG YOUNG AND MIDDLE-AGED GROUPS

by

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ABSTRACT
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The University of Wisconsin-Milwaukee, 2012
Under the Supervision of Roger O. Smith & Kurt Beschorner

Background: It is estimated that over 85% of adults over the age of 45 develop a condition called presbyopia (Holden et al., 2008). Multifocal lenses (MfLs) are used to functionally adapt to this condition to allow for convenient near and distance vision. However, this causes vision distortion in the lower part of the visual field at ground level while walking. Since safe ambulation relies on the lower visual field to detect obstacles (Marigold et al., 2008), and vision acts as a moderating factor for increased fall rates as individuals age (Heasley et al., 2005), there is a need to investigate the connection between MfLs, falls, and age.

Objective: This study hypothesized that when wearing MfLs, both young and middle-aged individuals would experience a significant decrease in functional gait performance when compared to wearing single lenses. In addition, non-experienced MfLs wearers would both show similar within group gait performance decrement.

Methods: Sixteen 18-35 year olds and seven 45-60 year old novice MfL wearers with no history of balance or gait impairments participated. A within-between subjects repeated measures ANOVA and t-tests evaluated the effects of MfLs and age on toe clearance, step force, and functional gait (the Dynamic Gait Index-Modified).

Results: A statistically significant difference in toe clearance and DGI-m scores were found for young and middle-aged individuals between lens conditions. Young group: increase in toe clearance (t=4.801, p=.000) and decrease in DGI-m scores (t=-3.9, p=.001); Middle-aged group: increase in toe clearance (t=3.230, p=.018) and decrease in DGI-m (t=3.092, p=.021). No significant difference between groups was found (DGI-m F=.020, p=.836, toe clearance F=.015, p=.905, and maximum force F=.463, p=.505). Due to the multiple t- tests performed, an adjustment of a .0125 alpha was used for a significance threshold.

Conclusion: MfLs appear to not only degrade visual performance, but also degrades key components of gait performance. The results of this study provided evidence that contributes to the validation of MfLs as a possible fall risk.

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PART I: THESIS OVERVIEW

Overview

This thesis is comprised of three parts: 1) the introduction to the thesis, 2) the research manuscript, and 3) the appendices. Part 1) that you are reading consists of the introduction to the thesis and provides an overview of the entire thesis and time line of the study. Part 2) includes the research manuscript that contains sections such as literature review and discussion of the results. The manuscript was written in a general manuscript format in order to accommodate for different journals. Part 3) contains nine appendix sections pertaining to the manuscript and overall thesis. These sections include research proposal, supporting data, IRB approval documents, and equivalent text descriptions. All writing is based on APA format.

Time Line of the Study

The following is a chronological summary of this study. Original documents were submitted to the Institutional Review Board (IRB) in September, 2010. The protocol was approved in October, 2010. After a pilot study, the research proposal was presented to the committee of advisors. Committee members approved the research design and hypotheses. Supplemental funding was provided through the Support of Undergraduate Research Fellows and College of Health Science Research Grant.

The additional funding allowed participants to receive compensation upon completing the study. Amendments were submitted to IRB due to changes in targeted populations on the research flier. IRB also approved a protocol continuation on October 2011 which lasts until October 2012.

Summary of Changes

The proposal was adjusted based on feedback provided by the committee of advisors. Research hypotheses were clarified and refined to increase understanding. Committee members discussed using t-test to increase understanding of the statistics. Changes were made after the data was collected. These include excluding the variable of heel to step edge and decrease in the number of participants. The variable of heel to step edge was excluded due to errors in data collection and processing. These errors made the data enabled use. The remaining variables included modified dynamic gait index, maximum force, and toe clearance. The number of participants included in the study was sixteen 18-35-year-olds and seven 45-60-year-olds. Initial proposed recruitment included twenty 18-35-year-olds and ten 45-60-year-olds. A smaller participant group was deemed proficient as it demanded less resulted time to recruit and avoided difficulties recruiting older individuals. All other protocol and procedures remained intact.

PART II: RESEARCH MANUSCRIPT

Abstract

Objective: The purpose of this study was to investigate the use of multifocal lenses (MfLs) on both young and middle-aged individuals and how it affects their functional gait.

Methods: Sixteen 18-35 year olds and seven 45-60 year old novice MfL wearers with no history of balance or gait impairments. A within-between subjects repeated measures design evaluated the effects of MfLs and age on toe clearance, step force, and functional gait (the Dynamic Gait Index-Modified).

Results: A statistically significant difference in toe clearance and DGI-m scores were found for young and middle-aged individuals when between lens conditions. Young group: increase in toe clearance (t=4.801, p=.000) and decrease in DGI-m scores (t=-3.9, p=.001); Middle-aged group: increase in toe clearance (t=3.230, p=.018) and decrease in DGI-m (t=3.092, p=.021). No significant difference was found between groups (DGI-m F=.020, p=.836, toe clearance F=.015, p=.905, and maximum force F=.463, p=.505).

Conclusion: The results of this study provided evidence that MfLs affect an individual's ability to perform normal gait patterns, and contributed to the validation that MfLs should be considered a possible fall risk. This evidence eliminated the variable of age as a factor in the changes in normal gait and provided more evidence that MfLs are affecting gait patterns.

Introduction

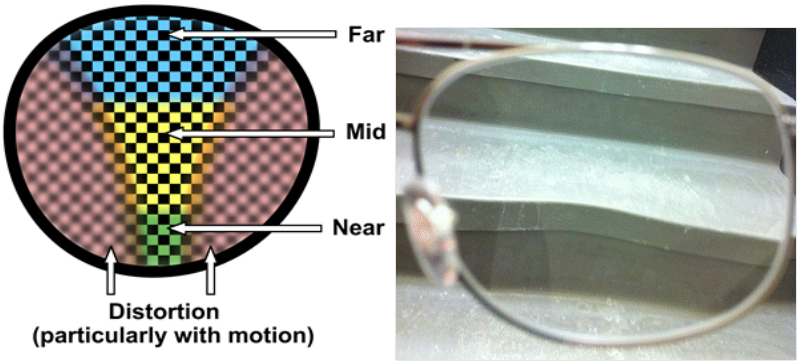
Background on Multifocal Lenses

It is estimated that over 85% of adults over the age of 45 develop a condition called presbyopia (Holden, Fricke, Ho, Wong, Schlenther, & Cronje, et al., 2008). This

condition occurs with age and results in a loss of near distance vision. Reading glasses are used as a functional adaptation for presbyopia. When an individual develops presbyopia and also has a far distance vision impairment (myopia), reading glasses are not sufficient to correct both impairments. Thus, many middle-aged and older adults wear multifocal lenses (MfLs). Types of MfLs include lined bifocals, trifocals, and unlined progressive lenses. MfLs are designed for both near and distance viewing. Progressive lenses, the type most commonly worn today, attempt to make the transition from the different lens fields smoother without having a bifocal line. This is achieved through grinding two lenses into one seamless lens.

On the other hand, MfLs also cause visual challenges. In addition to a distortion at the sides (Figure 1), MfLs, including progressive lenses, distort vision in the lower part of the visual field at ground level while walking. Since safe ambulation relies on the lower visual field to detect obstacles (Marigold & Patla, 2008), this distortion may lead to an increase in falls and near falls when walking.

Figure 1: a) Progressive lens regions and b) view through progressive lens.



Falls and Vision

Falls are a major health problem with many correlated factors, including poor vision. Falls result from intrinsic and extrinsic factors. Intrinsic factors include general factors such as age and gender, physiological or functional factors, medical risk factors

such as poor health, and the use of medications (Black & Wood, 2005). Extrinsic factors include environmental risk factors such as inappropriate footwear and poor lighting (Black & Wood, 2005). In 2008, 2.2 million nonfatal fall injuries among older adults were treated in the emergency room and more than 581,000 of the 2.2 million were hospitalized in the U.S. (Centers for Disease Control and Prevention, 2008).

Intrinsic factors that increase falls as individuals age include a decrease in balance, strength, and overall health (Lord, Tiedemann, Chapman, Munro, Murray, & Sherrington, 2005). As overall health decreases, there is an increase in the prevalence of visual impairments. Many decreases in visual function are associated with falls including: decreased contrast sensitivity, decreased visual acuity, impaired depth perception, and visual field impairments. These visual impairments approximately double the fall risk rate, making vision accountable for many falls (Lord, Smith, & Menant, 2010). Overall, fall risk increases as visual impairments become more severe (Hardwood, 2001).

Two significant aspects of vision that contribute to an increase in falls include contrast sensitivity and depth perception (Lord et al., 2010). Impairments in these are linked affect changes in ambulation such as gait speed and variability, standing balance, and toe clearance (Marigold & Patla, 2008; Black & Wood, 2005; Buckley, Harley, & Elliott, 2008; Elliot & Chapman, 2010). MfL glasses are found to impair depth perception and contrast sensitivity when detecting obstacles in the environment at critical distances (Lord, 2006; Lord, Dayhew, & Howland, 2002). The impaired depth perception and contrast sensitivity is caused by the lower reading portion of MfLs. Balance and stability is also negatively affected by the impairment of depth perception and contrast sensitivity (Lord, Sherrington, & Menz, 2000). Balance control is one of the main contributors to

falls among aging individuals (National Institute of Health: Senior Health, 2009; Black & Wood, 2005). Since adequate depth perception and contrast sensitivity are needed to maintain balance and to detect and avoid hazards in an environment, MfLs can be considered a potential fall risk (Lord & Dayhew, 2001; Menant, Smith, & Lord, 2008).

Falls and Multifocal Lenses

It is known that as individuals age they become increasingly prone to falls because of an overall decrease in health (Lord et al., 2000; Lord et al., 2005). Because of this fact, it is difficult to parse out how factors, such as MfLs, contribute to falls and near falls. Research has found that MfL glasses affect middle-aged and older adults similarly, except that the risk of falling is not as common in the middle-aged population. Middle-aged, first time wearers experience significant decreases in depth perception, contrast sensitivity, and functional mobility scores (Smith, Tomashek, Stalberger, & Rust, n.d.). More importantly, depth perception, contrast sensitivity, and functional mobility did not return to prior single lens levels of performance which indicates that adaptation may not occur even six months after initially wearing MfLs (Smith, et al., n.d.). Comparing the performance among different age groups will control for factors associated with age and isolate the true effects of MfL glasses. Vision impairments increase with age which makes vision a moderating role in increased fall rates (Heasley, Buckley, Scally, Twigg, & Elliott, 2004). The need to investigate the connection between MfLs glasses and falls is important for healthcare providers and fall prevention measures (Lord et al., 2002). Observing the effects of MfLs on differing age groups may provide more evidence to distinguish MfLs as a moderating variable between vision and gait impairment.

Hypotheses

MfLs have been linked to degraded vision and gait changes. Falls also have been connected to age and use of MfLs. However, no studies have examined age, MfLs, and gait. As result, this study addressed three specific research hypotheses: 1) young non-experienced MfL wearers decrease their functional gait performance when using MfL glasses compared to single lenses, 2) middle-aged non-experienced MfL wearers decrease their functional gait performance when using MfL glasses compared to single lenses, and 3) the decrease in gait performances in both groups will be similar. These results will show across three measures: toe clearance while walking up a step, force in stepping down, and in the modified Dymanic Gait Index (DGI-m).

Methods

Design

This study implemented an experimental mixed methods design and examined MfL performance within-subject groups and between-subject groups. Two lens conditions (single lenses and progressive MfLs) and two age groups (middle-aged and young) served as the independent variables. Primary dependent variables included maximum force on step down, toe clearance on step-up, and DGI-m scores. Maximum force and toe clearance were measured using motion analysis, and the DGI-m was scored by a trained rater.

Participants

Participants included sixteen 18-35 year olds and seven 45-60 year olds who did not wear MfL glasses at the time of the study. Individuals who had mobility impairments (such as slowness and poor balance), neurological diseases limiting daily activity, history of osteoarthritis and osteoporosis, impaired stereopsis, visual diseases such as cataracts, inner ear problems, history of vertigo or orthostasis, and individuals under the age of 18 years old were excluded from the study. Individuals with vision impairments that could not corrected with contact lenses were excluded from the study. The eligibility questionnaire included questions regarding age, gender, and physical condition (See Appendix B). Individuals that met all criteria were considered for the study. Table 1 presents participant demographic information.

Table 1: Mean and standard deviation demographic information for young and middle-aged groups.

	Young Group		Middle-Aged Group	
	mean	s.d.	mean	s.d.
Age	24.13	3.58	51.86	3.98
Gender (M/F)	(5/11)		(3/4)	
Weight (lb)	142.53	34.68	157.03	29.51
Height (cm)	167.75	7.70	163.13	12.66

Measurement Instruments

Two methods were used to collect data and evaluate functional gait and components of gait: 1) a motion analysis system, and 2) the DGI-m.

Motion analysis system. Ten Motion Analysis Raptor Cameras and three force plates (AMTI) were used. The computer software used was Cortex 2.0.0 Motion Analysis. This software was used to assess maximum force and toe clearance. Data collected through Cortex 2.0.0 was labeled using motion analysis software. Labeled data was then entered into MATLab and analyzed using coding. No filtering was performed on the data and the sampling rate was 100 Hz.

Biomechanical measurements. Two biomechanical measurements were used in this study. Toe clearance refers to the vertical height of the toe in relation to the step when stepping onto a raised platform. Heasley et al. (2004) found that visual impairments result in a higher toe clearance. Results from the Elliott & Chapman (2010) study indicated that positive diopter blur caused an increase in toe clearance and negative

diopter blur caused a decrease in toe clearance. In the current study, the progressive lenses all had the same positive diopter or reading lens. The objective was to determine if higher toe clearance was a physical result of the vision impairment caused by wearing progressive lenses. Maximum force, the second biomechanical measure used, refers to the maximum pressure when stepping down on a surface. Buckley, Heasley, Scally, & Elliott (2004) hypothesized an increase in force on the landing foot when stepping down in individuals that have a visual impairment. It was also found that participants used a cautious approach when stepping down, which leads to 'feeling' or searching to find the step (Buckley et al., 2004). This could have been the result of the participants being in an elderly population. The variable of force could be an indicator of a visual impairment.

Dynamic Gait Index-Modified

The DGI assess was created to assess an individual's ability to maintain balance while walking in the presence of stimuli. The Dynamic Gait Index (DGI) has well established reliability and validity for assessing functional mobility (Whitney, Hudak, & Marchetti, 2000; Whitney, Wrisley, & Furman, 2003; Herman, Inbar-Borovsku, Brozgol, Giladi, & Hausdorff, 2008; Jonsdottir & Cattaneo, 2007; McConvey & Bennett, 2005). The DGI has been tested and validated on a variety of populations with balance impairments; these impairments include vestibular disorders, multiple sclerosis, stroke, Parkinson's disease, and geriatrics (Rehabilitation Institute of Chicago, 2010). The eight tasks of the DGI include gait on even surfaces, gait with changing speeds, both horizontal and vertical head turns and gait, stepping over and around obstacles, gait with pivot turns, and ascending and descending stairs. Scores are based on a 4-point scale. The highest possible overall score is 24 points.

This study implemented the use of the modified Dynamic Gait Index (DGI-m) used by Smith et al. (n.d.). This contained an additional two tasks and a six point scale (0-5) to accommodate for ceiling effects in younger participants found in a previous thesis study (Brayton, 2006). A zero indicated the individual could not walk 20 feet without assistance and contained severe gait deviations or imbalance. A five indicated gait with a normal speed, no evidence of imbalance, and a normal pattern. The highest possible score was equivalent to 50, which indicated no gait impairments. The DGI-m consists of ten walking tasks. The two additional tasks involved: stepping over a diagonal long box and stepping on and off a platform. In this study the tenth task of the DGI-m was replaced with a step/ramp to accommodate for the motion analysis creating the DGI-m2. The highest possible score was equivalent to 45. Data collected from the rated DGI-m was entered into a Microsoft Excel spreadsheet, which was then transferred into SPSS for analysis.

Procedure

Institutional Review Board approval was obtained from the University of Wisconsin-Milwaukee (UWM) prior to start the study. Participants were recruited through fliers on the UWM campus and in the surrounding community. Interested participants emailed the primary researcher and received a brief description of the study and eligibility questions. After eligibility was confirmed, the researcher scheduled the participant to come to the Gait and Biomechanical Lab. Participants were asked to wear tight fitting clothes to ensure that markers stayed attached to skin or clothing.

Upon arrival at the lab, the participants, first read and signed the consent form. The participants were then fitted with a safety harness connected to a trolley system to

prevent injury if a fall were to occur. The researchers then applied 39 reflective markers based on the Cleveland Clinic modified marker set directly to the skin and onto clothing. Participants were attached to the harness pulley system and told to walk normally back and forth across the lab to get comfortable walking with the harness and markers. While the participant practiced, the researcher observed if their step down landed on the three force plates. All instructions given to participants were script-based to minimize bias. Also, the researcher did not instruct participants to step on the force plates so participants were not drawn to think about their steps as normal gait was targeted. The participants walked through 36 trials of a looped course that included 15 meters of walking in a straight line. During this walk, they encountered either a ramp/step, a step/ramp, or flat surface.

For the DGI-m tasks a trained rater scored participant's gait on the DGI-m walkway. Participants received specific instructions for each task. Following the instructions, participants ambulated down the grid runway and performed the task. At the end of the runway, participants walked to the ramp/step entry, forming a loop track. The nine DGI-m tasks were performed four times or 36 trials; two while wearing +2.75 strength progressive lenses and two wearing blank single lenses. The order of lenses and ramp/step was randomized. Additionally, a video camera was used to view the DGI-m task for future reference. The step heights also randomized varied between three inches and six inches. Single and progressive lens glasses were alternated every 18 trials. All biomechanical data from the motion capture markers were collected by lab assistants.

Data Analysis

SPSS Version 19.0 (SPSS, Inc., Chicago) was used to analyze data. Statistics were calculated to determine the differences between and within age groups and lens conditions.

Within subjects analyze was completed using a paired samples t-test to determine the significance of wearing the different lenses within each population. Rare scores were used when comparing the within data. Due to the multiple t- tests performed, an adjustment of a .0125 alpha was used for a significance threshold. The between subjects analysis was completed using a repeated measures Analysis of Variance (ANOVA). Between subjects analysis determined the difference between lens conditions within the populations and compared the difference among the two populations to determine if there is a significant difference in switching lenses between groups. This was performed for each dependent variable to investigate the change.

Results

The sample included 23 participants (16 in the young and seven in the middle-aged group). All participants completed the full trials and protocol. Overall, all participants were healthy and demonstrated normal functional gait patterns prior to the study.

Dynamic Gait Index-Modified

The first two research hypotheses pertained to the within subjects gait performance. As hypothesized within the young adult group, results demonstrated a significant decrease in DGI-m score (t=-3.900, p=.001) (p<.0125) between single to progressive lenses. Decrease in DGI-m indicated a decrement in gait. The mean for young adults when wearing progressive lenses was 43.1 and single lenses was 44.6. The within middle-aged adult group was found to be not significant (t=3.092, p=.021) between single to progressive lenses (Figure 2). The mean for middle-aged adults when wearing progressive lenses was 43.2 and single lenses was 44.8.

The final hypothesis pertained to between subject performance. As hypothesized, the difference between the within young and middle-aged groups revealed no significant difference when comparing groups (F=.044, p=.836) (Figure 3). Table 2 displays the results of the paired t-test among the two groups and lens conditions for DGI-m scores.

Table 2: Displays the DGI-m results of the paired t-test data for within subjects.

***= significant at .0125**

Group	*Mean (progressive lenses)*	*Mean (single lenses)*	*t-test*	*p-value*
Within-Subject				
Young Adult	43.1	44.6	-3.9	.001*
Middle-aged	43.2	44.8	3.1	.021

Figure 2: Bar graph depicting DGI-m means for single and MfLs within group.

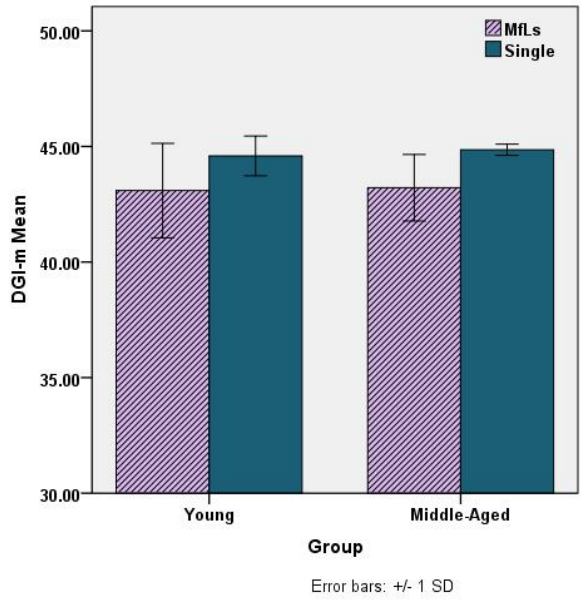
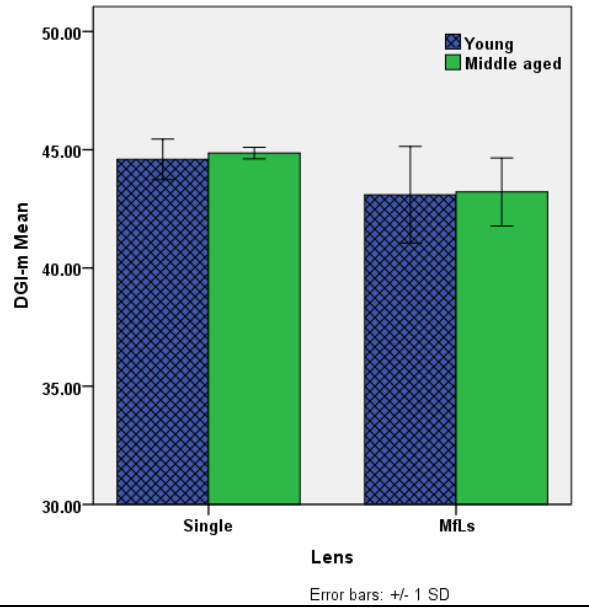


Figure 3: Bar graph depicting DGI-m means for single and MfLs between groups.



Step Up Toe Clearance

As hypothesized, within the young adult group, results showed a significant increase in toe clearance (t=4.801, p=.000) between single to progressive lenses. Within the middle-aged adult group, results demonstrated no significance (t=3.230, p=.018) between lenses (Figure 4). The mean for young adults when wearing progressive lenses was 122.2 and single lenses was 93.8. The mean for middle-aged adults when wearing progressive lenses was 138.5 and single lenses was 111.4. The difference between the within young and middle-aged groups while switching lenses revealed no significant difference when comparing groups (F=.015, p=.905) (Figure 5). Table 3 displays the results of the paired t-test among the two groups and lens conditions for toe clearance.

Table 3: Displays the toe clearance results of the paired t-test data for within subjects.

Group	*Mean (progressive lenses)*	*Mean (single lenses)*	*t-test*	*p-value*
Within-Subject				
Young Adult	122.2	93.8	4.801	.000*
Middle-aged	138.5	111.4	3.230	.018
	***= significant at .0125**			

Figure 4: Bar graph depicting toe clearance means for single and MfLs within groups.

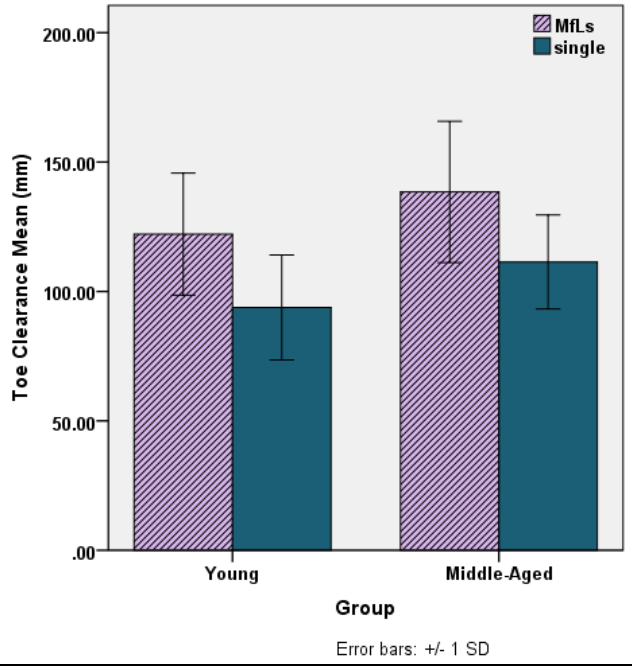
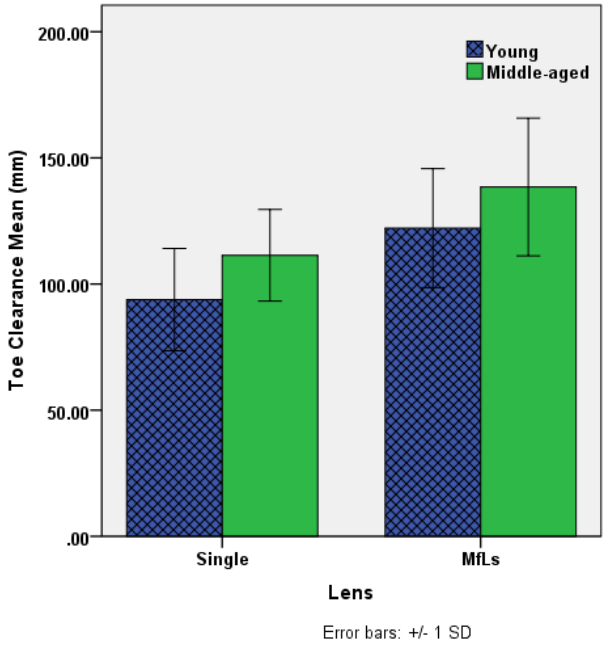


Figure 5: Bar graph depicting toe clearance means for single and MfLs between groups.



Step Down Maximum Force

Within the young adult group, force results were found to be not significant (t=1.645, p=.124) between single to progressive lenses. The within middle-aged adult group was found to be not significant (t=.336, p=.751) between lenses (Figure 6). The mean for young adults when wearing progressive lenses was 1.64 and single lenses was 1.57. The mean for middle-aged adults when wearing progressive lenses was 1.59 and single lenses was 1.57. The difference between the within young and middle-aged groups while switching lenses revealed no significant difference when comparing groups

(F=.463, p=.505) (Figure 7). Table 4 displays the results of the paired t-test among the two groups and lens conditions for force.

Table 4: Displays the force results of the paired t-test data for within subjects.

Group	*Mean (progressive lenses)*	*Mean (single lenses)*	*t-test*	*p-value*
Within-Subject				
Young Adult	1.64	1.57	1.645	.124
Middle-aged	1.59	1.57	.336	.751

Figure 6: Bar graph depicting force means for single and MfLs within groups.

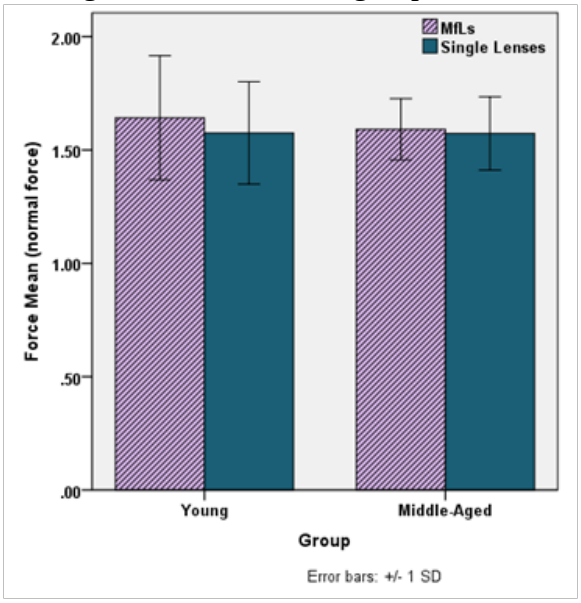
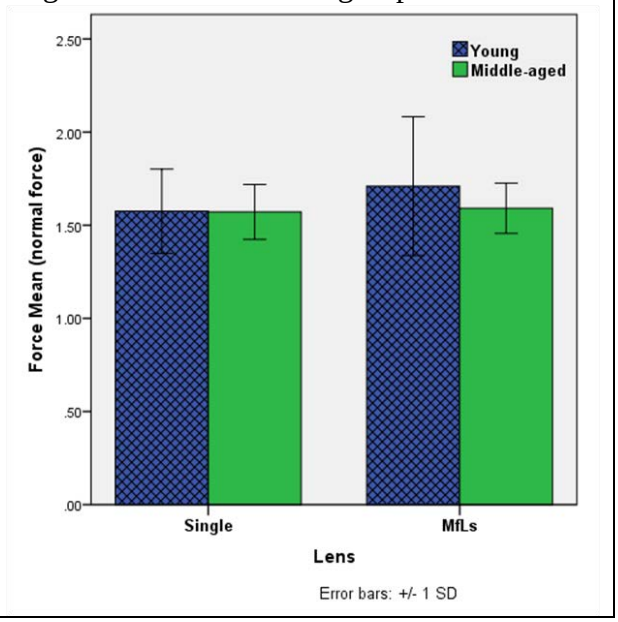


Figure 7: Bar graph depicting force means for single and MfLs between groups.



Discussion

There is a lack of clear understanding of how MfLs affect the gait of people of different ages. The purpose of this study was to test the negative effects of the use of MfLs among two age groups to determine if MfLs are a variable for fall risk. The results of this study provided evidence that MfLs affect an individual's ability to perform normal gait patterns and contributed to the validation of MfLs as a possible fall risk. Because a change in gait patterns was found in both age groups, it appears that MfLs are linked to a decrement in normal gait pattern, regardless of age. Significantly lower DGI-m and higher toe clearance scores suggested that the visual distortion in the lower visual field of the lenses produced these gait abnormalities. Data distributions were examined through histograms; see Appendix C.

Within Age Group Analysis

The significant difference between the single lens and MfLs trials for toe clearance and DGI-m scores showed participants actively changing their gait to accommodate for the distortion of their lower vision field. Data showed that individuals experienced an increase in toe clearance when stepping up and decrease in functional gait assessment scores. An increase in toe clearance indicated that, because of the distortion of the step, individuals used a compensatory technique to find the location of the step. Decrement in gait and compensatory actions changed the normal gait pattern of individuals when MfLs were worn. Normal gait patterns changed when wearing the MfLs. This changed gait pattern may result in an increased fall risk. The lack of a significant difference between single and MfL trials for force indicated that participants were not using a 'feeling' or protective method when detecting the floor upon stepping

down, which was found in a previous study (Buckley et al., 2004). Additionally, this outcome revealed that participants were not using increased force when stepping down. This lack of increased force exhibits that the individuals understood the location of the floor. The Buckley et al. (2004) study contained elderly participants with a mean age of 72.3 years. This difference in the age of participants may account for the increase in force. Additionally, the participants in Buckley et al. (2004) study stepped from a stationary position in comparison to the participants in this study performed a more natural continuous gait which may contribute to a normal step down force.

Between Group Analysis

The data provided evidence that MfLs affect young and middle-aged individuals similarly. This evidence eliminated the variable of age as a factor in the changes in normal gait and provided more evidence that MfLs are affecting gait patterns. Both groups showed the same overall change, but had different base scores for toe clearance and the DGI-m. Different base scores are expected for the two groups due to the decrease in health in the middle-aged group. Maximum force revealed the same overall change indicating that MfLs do not affect force in both groups.

Limitations

Five limitations of this study are discussed. First, it was difficult to recruit middle-aged individuals that did not wear distance lenses because of the limited population. Second, the participants' visual acuity had not been tested before performing the study and visual acuity is based on participant report. Third, there may be a learning effect of the DGI-m obstacles if the participants received the randomization of wearing the single lens glasses first. Fourth, participants had difficulty adjusting to a comfortable gait

pattern while wearing the harness and sensors. Some participants were concerned with accidently detaching the sensors, which may have caused them to change their gait. Fifth, the researcher, who was aware of the research hypotheses, preformed the rating of the DGI-m, which may have biased the study results. Biomechanical variables are measured using a computerized system which is free from bias. Protocol given to participants was script-based which minimized bias when providing verbal instruction.

Future Research

Future research is needed in the area of MfLs effect on functional activities. Further reliability and validity testing of the Dynamic Gait Index-modified in relation to biomechanical measurements is required in order to show the need for a stronger instrument for visual impairment detection. The relationship between MfLs and length-of-wear time needs investigation in order to further understand lens adaptation. Qualitative analysis of the comfort level of MfLs wearers would help researchers better understand tasks that caused wearers personal discomfort and decreased function. Continuing the research of MfLs and biomechanical variables will provide concrete instrumentation measurement of the effects of the lenses. Effects of Mfls should continue to be researched due to the large population of users.

Implications

The possible effects of MfLs has tremendous implications for a number of professions including occupational therapists. “Occupational therapy is a profession that specializes in reducing the impact of disabilities and promoting the highest level of independence and quality of life in children and adults with all types of functional

limitations" (AOTA, 2001). Occupational therapists show interest in the meaningful activities and occupations that contribute to the client's quality of life. Prevention methods and interventions play a key role in occupational therapy practice. Identifying possible risks, such as MfLs, will reduce the amount of injuries, and understanding the possible risks of MfLs can lead to possible interventions. Interventions can take place through patient education on the possible changes in gait and different strategies to use for daily activities.

"Occupational therapy practitioners adjust the task or environment for the individual's particular needs and provide training or assistive technology to assist the individual" (AOTA, 2001). Visual impairment ranks among the ten most prevalent causes of disability in the United States, making it a significant area of practice for occupational therapists (National Eye Institute, 2004). Occupational therapists need to have the correct information in order to identify possible fall risks associated with visual impairments related to MfLs. Increasing their knowledge of MfLs and how they affect functional activities will allow occupational therapists to better address risks connected with wearing MfLs.

Conclusion

This study found that MfLs led to an increase in toe clearance and a decrease in DGI-m score. This effect on functional gait could be found across all study populations. The MfLs, however, had no measurable effect on stepping force. As a result of this research a better understanding of MfLs and their usage among age ranges can be determined. More research is needed to further knowledge and provide MfL users with alternatives or interventions.

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PART III: APPENDICES

Appendix A: Research Proposal

Introduction and Literature Review

Summary of the Problem

Literature has shown a link between visual impairments and an increased risk of falling in older adults (Lord, 2002). Multifocal eyeglasses, which are designed for both distance viewing and correcting presbyopia, distort vision in the lower part of the visual field at ground level while walking. This distortion of vision may lead to an increase in falls and near falls when walking. This project aims to provide clarification on the relationship between multifocal eyeglasses (MfLs) and impairments to normal gait. Specifically, this continuation of a previous pilot study investigates the functional gait performance within and between groups of individuals while wearing multifocal and single lens glasses. Functional gait performance will be compared within each age group while wearing MfLs and single lens glasses. The within age group comparisons will allow investigation of the reaction to initial use of multifocal lens glasses on gait performance. The between groups analyses will allow investigation of age as variables that may affect gait performance in ways that are known to increase the risk rate of falls.

Significance of Study

Fall prevention is an important public health issue that needs to be addressed by all healthcare professionals because of the growing elderly population. Knowing specific fall risk factors can provide healthcare providers with the information needed to prevent falls. Investigating the use of MfLs and how they affect the gait of adults of all ages can help identify and confirm MfLs as a moderating variable between vision and gait impairment. Additionally, confirming evidence linking MfLs glasses and falls will lead to

the creation of better interventions. Gaining knowledge about possible risk factors for falls, such as MfLs use, will help occupational therapists who serve older populations and individuals improve individuals' vision and decrease fall risk.

Importance to Healthcare Professionals

Provision of the possible effects of MfLs has tremendous implications for a number of professions including occupational therapists. "Occupational therapy is a profession that specializes in reducing the impact of disabilities and promoting the highest level of independence and quality of like in children and adults with all types of functional limitations" (AOTA, 2012). Occupational therapists show interest in the meaningful activities and occupations that contribute to the client's quality of life. Prevention methods and interventions play a key role in occupational therapy practice. Identifying possible risks, such as MfLs, will reduce the amount of injuries and understanding the possible risks of MfLs can lead to possible interventions. Possible interventions can take place through patient education on the possible changes in gait and different strategies that to use for daily activities.

"Occupational therapy practitioners adjust the task or environment for the individual's particular needs and provide training or assistive technology to assist the individual" (AOTA, 2012). Visual impairment ranks among the ten most prevalent causes of disability in the United States, making it a significant area of practice for occupational therapist (National Eye Institute, 2004). Occupational therapists need to have the correct information in order to identify a possible fall risks associated with visual impairments related to MfLs. Increasing the knowledge of the role of MfLs and

how they affect functional activities will allow occupational therapists to better address risks connected with wearing MfLs.

Background

The following literature review describes the essentialness of mobility and the role vision plays in mobility. This includes an overview of fall, balance, and vision literature. Next, the implications of MfLs on mobility are discussed with a review of the available literature. Following this is a discussion about the moderating variable of age. Important definitions and a review of the literature ensues. Lastly is a discussion about the proposed paradigm for the present study.

Scope of Falls Research

Falls are caused by numerous factors, both intrinsic and extrinsic. Intrinsic factors include general factors such as age and gender, physiological or functional factors, medical risk factors such as poor health, and the use of medications (Black, 2005). Extrinsic factors include environmental risk factors such as inappropriate footwear and poor lighting (Black, 2005). In 2009, 2.2 million nonfatal fall injuries among older adults were treated in the emergency room and more than 581,000 of the 2.2 million were hospitalized. In all ages and populations, the overall nonfatal fall number in 2009 was 8,782,664 (Centers for Disease Control and Prevention, 2010). In 2000, medical costs for falls totaled $19 billion in the United States (Centers for Disease Control and Prevention, 2010). Unintentional falls have been the leading cause of nonfatal injuries treated in hospital emergency departments (Center for Disease Control and Prevention, 2008). Additionally, the risk rate for falls for individuals increases as they age. This is significant because of the projected increase of older individuals over the next few

decades (U.S. Census Bureau, 2010). As people age their sense of balance becomes less acute; balance is one of the main contributor to falls (National Institute of Health: Senior Health, 2009).

Link between Vision and Balance

Balance is primarily controlled by the inner ear (also known as the vestibular system), information from the proprioceptive system, and the visual sensory system (Redfern, 2001). Symptoms of balance disorders consist of dizziness, feeling of falling, lightheadedness, and blurred vision (National Institutes of Health). The visual system plays a vital role in maintaining balance when standing still and while moving (Wade, 1997). Because of this, visual impairments can greatly affect balance. The visual system provides a visual reference of where the body is in space and the location of obstacles in the environment surrounding the body. This information is then integrated with input from vestibular balance and proprioceptive or somatosensory systems. A deficit in any of these systems can cause an increased reliance on the other systems to remain balanced (Black, 2005). As individuals age, reliance on visual information to maintain balance increases (Pyykko, 1990). This has serious implications, as there is an increase in prevalence of visual impairments with age. Middle-aged and older individuals are also more dependent on vision than young individual for postural control (Harwood, 2001). Impaired vision reduces postural stability, especially when paired with a disruption in the vestibular and somatosensory systems, for young and older individuals (Lord, 1993; Anand, 2002 & 2003). In addition, contrast sensitivity, depth perception, and stereopsis are visual functions that are predictors of stability and reductions in these functions have been found to reduce postural stability (Lord, 2000). The action of stepping can also

account for a period of instability because of a narrow base support caused by a single limb supporting all bodyweight (Buckley, 2004). This period of instability additional factors that influence balance, such as vision, could cause a fall. Because age-related changes in the visual system and disruptions in the vestibular or somatosensory systems result in impaired balance control, impairment in balance control can lead to falls in older individuals (Black, 2005).

Link between Vision Impairments and Falls

Impaired vision is an important and independent risk factor for falls (Lord, 2010). Adequate depth perception and distant-edge contrast sensitivity are needed to maintain balance and to detect and avoid hazards in an environment (Lord, 2001). Several visual impairments are associated with falls; these include: contrast sensitivity, poor visual acuity, self-reported poor vision, impaired depth perception, and visual field impairments. These visual impairments approximately double the falls risk rate, making vision accountable for half of all falls (Lord, 2010). Falls risk increases as visual impairments become more severe (Hardwood, 2001). Because visual impairments increase with age, falls also increase with age thus, there is a strong correlation of visual impairments and falling as age increase (Heasley, 2005). Visual impairments such as poor visual acuity, contrast sensitivity, depth perception, and visual field impairments all effect gait (Marigold, 2008). Visual impairments have been linked to changes in gait speed and gait variability, standing balance, toe clearance, and foot distance approaching a step, all of which have been associated with an increase in the risk rate for falls (Black, 2005; Buckley, 2008; Elliot, 2010). Impairment in visual functions, such as visual acuity, contrast sensitivity, visual fields, and depth perception, are associated with falls or are

identified as risk factors for falling (Black, 2005). Visual impairments are a risk factor for falls in individuals of all ages, but especially aging and middle-aged adults. Lord and Dayhew (2001) found that fallers perform significantly worse on distance and near depth perception when compared to non-fallers. It is also reported that low contrast visual acuity nearly doubles the risk of falling (Lord, 2001). There are other factors that are associated with falls and balance such as lighting, flooring, distractions, fatigue, and loud noises that also need to be taken into consideration (Lord, 2000).

Contribution of Multifocal Lens Glasses

It is estimated that over 85% of all adults over the age of 45 will develop presbyopia (Holden, 2008). This condition develops with age and causes loss of near distance viewing. Reading glasses are used to correct presbyopia. When an individual develops presbyopia and has a far distance viewing impairment, also known as myopia, reading glasses are not sufficient to correct both impairments. Because of this dilemma, MfLs, which include lined bifocals, trifocals, and progressive lenses, are often prescribed. In lined bifocals, the lower lens corrects near distance vision and the upper lens acts as regular distance corrective lenses. These sections are clearly delineated, as the reading portion is “added” to the regular distance viewing lens. In an attempt to make the transitions from the different lens fields smoother without having a bifocal line, progressive lenses have distortion on the sides of the lens caused by grinding (Figure 1). Progressive lenses, which are common today, can potentially cause more problems because of the additional region for middle distance viewing vision (Figure 2). This distortion results in loss of visual acuity. Progressive lens users experience a warping effect when turning their head, which can lead to an experience of discomfort and

dizziness. MfLs glasses also impair depth perception and edge-contrast sensitivity at critical distances for detecting obstacles in the environment (Lord, 2006 & 2002). The impaired depth perception and edge-contrast sensitivity is caused by the lower portion of multifocal lenses. Safe ambulation relies on the lower visual field to detect obstacles (Marigold, 2008). Additionally, impairments in depth perception and edge-contrast sensitivity may cause negative changes in balance (Lord, 2000). Thus, the various effects of MfLs could be a factor that cause increased risk rates for falls among different ages.

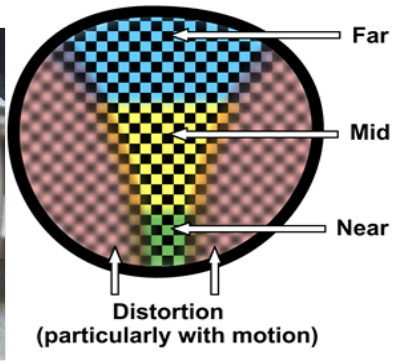

Figure 1: View through progressive lens Figure 2: Progressive lens regions

Multifocal lens glasses and older adults. Individuals over the age of 45 are at risk of developing presbyopia as they age (National Eye Institute, 2010). Because of this condition, many older adults wear MfLs glasses. In 2005, about 1.8 million individuals aged 65 and older were treated for nonfatal falls (Center for Disease Control and Prevention). The relationship between vision and falls has generally focused on older adults who have a decrease in corrective balance, limb sensation, strength, and overall health (Lord, 2005). Physical impairments caused by aging increases the possible risk factor of MfLs glasses. It is found in older adults that the near distance lens portion impairs distance contrast sensitivity and depth perception in the lower visual field (Lord,

2006). This impairment causes a decrease in the ability to detect ground level objects. The add region of MfLs glasses cause an increase in toe clearance variability (Elliott, 2010). The risk of falling when using stairs may be exacerbated due to inaccurate visual information regarding the exact location of the step caused by blurring (Johnson, 2007). Lord (2002), anecdotally states that it appears there is an increase risk of tripping or falling strongly associated with stairs.

Multifocal lens glasses and middle-aged adults. MfLs glasses have a similar effect on middle-aged adults as older adults, except the risk of falling is not as common in the middle-aged population. In a previous study it was found that participants who wore new MfLs for the first time experienced significantly decreased depth perception, contrast edge sensitivity, and functional mobility scores (Smith, R.O., Tomashek, D., Stalberger, K., & Rust, K.). Over 6 months, there was a gradual adaptation in depth perception and contrast edge sensitivity but results never reached initial single lens scores. It was found that functional mobility was effected with new MfLs when compared to single lenses and mobility did not significantly change in the first six months of wearing MfLs. Although falling is not common in this population, the impairments caused by MfLs are identified as risk factors for falling. Most importantly it was found that depth perception, contrast edge sensitivity, and functional mobility did not return to the levels of performance when wearing single lenses, which indicates that adaptation, may not happen as quickly as 6 months (Smith, R.O., Tomashek, D., Stalberger, K., & Rust, K.). The adaptation of MfLs needs further investigation to understand fully.

Investigating age. The reason for investigating age is to show the direct effect of MfLs on gait. Young individuals that wear MfLs will show that the lenses are the cause

of disturbances in gait, thus eliminating other factors associated with aging. As individuals age they become increasingly prone to falls (Lord, 2000). This is due to decrease in balance, strength, and overall health (Lord, 2005). Analyzing the performance between single and MfLs will show the effect of the lenses on gait in young and middle-aged groups. The analysis of age performance the researchers can then compare the performance between ages. Comparing the performance among ages will control for the factors associated with age and show the effect of MfLs glasses instead of showing the effect of the aging process.

Influence of experience. Experience refers to the length of time (approximately six months) an individual has been wearing MfLs glasses. It is thought that experienced multifocal lens wearers undergo an adaptation phase. This adaptation phase consists of adjusting the visual system and body to the distortion of the lower portion of the visual field. A common perception is individuals who have visual impairments adjust their movements to adapt for the visual distortion (Buckley, 2008). Also, literature hypothesizes that experienced individuals mentally normalize themselves to performing with a cautious gait. When an individual cannot see a step or obstacle, they adapt a more cautious gait pattern, which includes overcompensations, such as lifting their foot higher when negotiating a step, longer single lens stance, and greater head flexion. This type of gait has been found to be dangerous and may increase fall risk (Heasley, 2004; Buckley, 2008). Individuals that wear MfLs glasses for the first time exhibit the same cautious gait (Buckley, 2008). This type of gait may be an indication that experienced multifocal wearers never fully adapt to the glasses. Rather, they adapt a cautious gait style to compensate. Initial MfLs wearers show a significant decrease in depth perception,

contrast edge sensitivity, and functional mobility. Most importantly it was found that depth perception, contrast edge sensitivity, and functional mobility did not return to the levels of performance when wearing single lenses, which indicates that adaptation, may not happen as quickly as 6 months in middle-aged individuals (Smith, R.O., Tomashek, D., Stalberger, K., & Rust, K.).

Multifocal Overall Research Needs

Past research in the area of MfLs glasses points to five current needs for investigation of vision related falls. These include further reliability and validity testing of the Dynamic Gait Index-modified in relation to biomechanical measurements will show the need for a stronger instrument for visual impairment detection and investigating the relationship between middle-aged and young novice MfLs wearers to understand the role of age when wearing MfLs.

This proposed study targets the issue of age acting as a mediating variable for gait impairments in young and middle-aged novice MfLs wearers. Investigating age will control for the factors associated with age such as poor balance and decreased strength (Lord, 2005). This control will show the effect of the MfLs glasses rather than age effects.

Hypotheses

The research hypotheses are as follows:

1. Young non-experienced MfLs wearers will show a decreased functional gait performance when using MfLs glasses compared to single lenses.

2. Middle-aged non-experienced MfLs wearers will show a decreased functional gait performance when using MfLs glasses compared to single lenses.
3. Given groups of individuals (young non-experienced MfLs wearers and middle-aged non-experienced MfLs wearers) both will show the same within group gait performance difference when using MfLs glasses compared to single lenses when using two biomechanical instruments and the gait index. Between group gait performance will have different base scores but the same overall change.

    a) When walking up a step, young non-experienced MfLs wearers and middle-aged non-experienced MfLs wearers will show a similar within group increase toe clearance between single and MfLs glasses conditions.
    b) When stepping down, young non-experienced MfLs wearers and middle-aged non-experienced MfLs wearers will show a similar within group normal force increase between single and MfLs glasses conditions.
    c) When performing the DGI-m, young non-experienced MfLs wearers and middle-aged non-experienced MfLs wearers will show a similar within group gait performance score decrease between single and MfLs glasses conditions.

Research Design

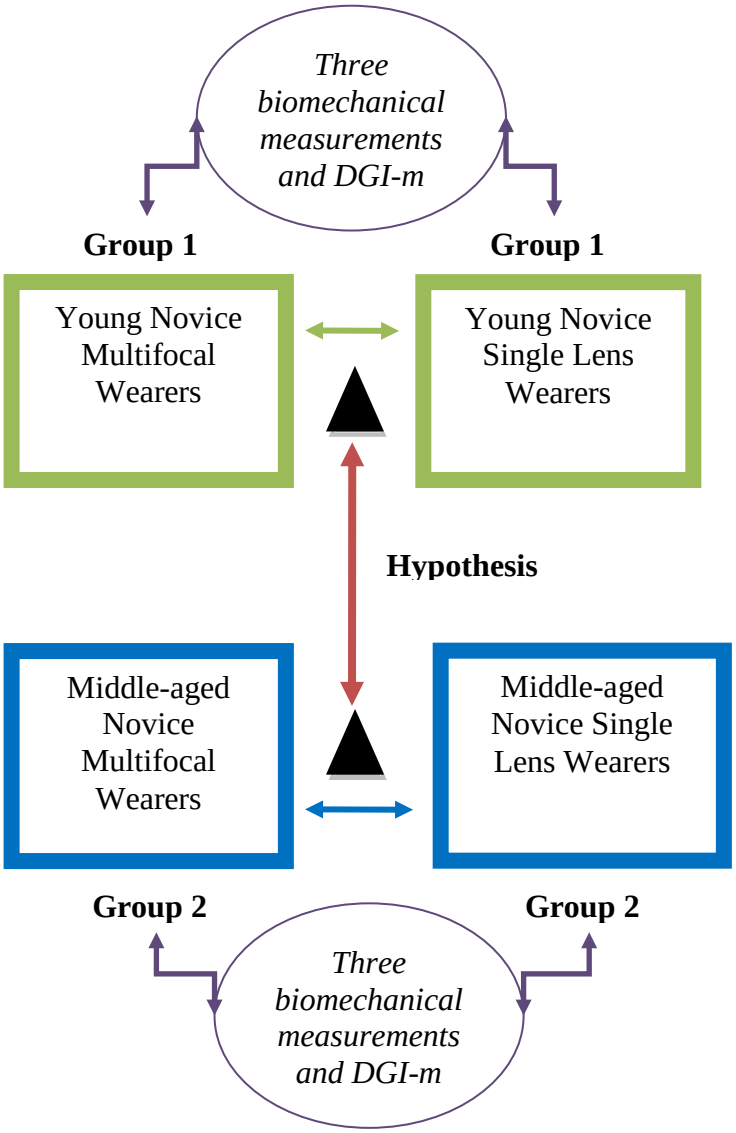

Figure 3: This figure represents the hypothesis as a within and between group analysis of middle-aged and young novice multifocal and single lens wearers. All participants will be measured using three biomechanical variables and the DGI-m.

Methods

Overall Design

This study implements an experimental simple mixed methods design. This design consists of both within-subjects and between-subjects variables. This design is being used because it allows the researcher to test different populations under different variables such as single and MfLs glasses. As this study examines two independent variables, it is considered a simple mixed design (Meyers, 2006). Figure 4 represents the different groups in the study and the characteristics of each group.

Group	Age	Experience	Glasses
One	Young	Novice	Multifocals/ Single
Two	Middle-aged	Novice	Multifocals/ Single

Figure 4: Table of participant group demographics.

Participants

The study is being conducted at the Gait and Biodynamics Laboratory at the University Services and Research (USR) building on the UWM campus. The study takes approximately 1.5 hours over the course of one day for each participant. Participants sign an informed consent document to participate in the study per the protocol approved by the University of Wisconsin–Milwaukee Institutional Review Board for human subject research. The recruitment process is being done through flyers around campus and in the surrounding community.

Thirty participants will be recruited to participate. They will divide into two groups. Group one will consist of 20 young individuals and Group 2 will consist of ten middle-aged individuals. This research expands on 6 young subjects recruited by the researcher for a previous pilot study. The 6 previous subjects will be included in this study.

Inclusion and exclusion criteria. Qualifying participants must be healthy individuals between the ages of 18-35 (Group One Younger) or 45-60 (Group Two Middle-aged). Individuals who have mobility impairments such as slowness and poor balance, neurological diseases limiting daily activity, history of osteoarthritis and osteoporosis, impaired stereopsis, visual diseases such as cataracts, inner ear problems, history of vertigo or orthostasis, and individuals under the age of 18 years old will be excluded from the study. Individuals who have vision impairments that are not corrected with contact lenses will be excluded from the study. The progressive lenses will be non-prescription on the top, and cannot be worn over other glasses, only those with vision corrected with contact lenses will be eligible.

Eligibility questionnaire includes:

1. What is your age?
2. Are you male or female?
3. Can you walk without any assistive devices?
4. Do you typically wear eye glasses?
    a. Do you wear bifocal or progressive lens glasses?
    b. Do you have contact lens glasses that you can wear during the testing session that correct your vision?

5. Are you currently recovering from or do you currently suffer from any musculoskeletal disorders that affect your ability to walk such as: broken bones, strains sprains or genetic disorders?
6. Are you currently pregnant, think you could be pregnant or trying to become pregnant?
7. Do you have osteoporosis or osteoarthritis?
8. Do you currently have any sensory disorders that affect your balance or are you taking any medications that might affect your balance?
9. Do you weigh over 300 pounds?

Independent and Dependent Variables

Independent variables. The independent variables consist of the two lens conditions; single lens glasses and MfLs glasses. The single lens glasses are blank non-prescription lenses which are worn by the young and middle-aged novice participants. The young and middle-aged novice participants wear progressive lenses with an add prescription of +2.75 for the multifocal lenses. Progressive lenses with +2.75 prescription are used because of popularity of the lenses and +2.75 is a moderate level prescription. Age is also an independent variable. The age of the young participants is 18-35 years old and the age of the middle-aged participants is 45-60 years old. The different ages of the participants will be analyzed in the results.

Dependent variables. The dependent variables include maximum normal force, heel to step edge, toe clearance, and DGI-m scores. Normal force refers to the maximum pressure when stepping down on the floor. This is measured by the foot stepping down onto a force plate. In an article by Buckley et al. (2004), it was hypothesized that there

will be an increase in bodyweight on the landing foot when stepping down in individuals that have a visual impairment. It was also found that participants were using a cautious approach when stepping down, which led to 'feeling' to find the step (Buckley, 2004). This could have been the result of the participants being an elderly population. Heel to step edge on the stair refers to the position of the first heel contact in relation to the edge of the step. Research has shown that individuals with visual impairments step closer to the edge of the step or slightly off the step (Elliott, 2010; Johnson, 2008). Toe clearance refers to the vertical height of the toe in relation to the step. Heasley et al 2004 found that visual impairments result in a higher toe clearance. Results from the Elliott et al 2010 study indicate that positive diopter blur causes an increase in toe clearance and negative diopter blur causes a decrease in toe clearance. The progressive lenses used in this study all have the same positive diopters. This variable will be measured to analysis which theory applies to multifocal wearers. DMI-m scores illustrate the gait performance of the participants.

		Variables	**18 Trials**	**18 Trials**
	Age	Independent Variables	Single Lens Glasses (randomized)	Multifocal Lens Glasses +2.75 (randomized)
Group 1: Young Novice Wearers	18-35	Dependent Variables	• Dynamic Gait Index Modified • Normal Force • Toe Clearance	• Dynamic Gait Index Modified • Normal Force • Toe Clearance
Group 2: Middle-aged Novice Wearers	45-60			

Instrumentation

Two data collection instruments will be used to observe the changes that may occur when wearing MfLs: 1) The modified version of the Dynamic Gait Index-modified (DGI-m) and 2) biomechanical variables recorded using a motion capture system as subjects move through a walking course.

Dynamic Gait Index-modified. The DGI has well established reliability and validity for testing functional mobility for many different populations (Whitney, S.L., 2000 & 2003; Herman, T., 2008; Jonsdottir, J., 2007; McConvey, J., 2005). This study will use the modified DGI version used by Stalberger (unpublished). This contains an additional two tasks and a six point scale to accommodate for ceiling effects in younger participants found in a previous thesis study (Brayton, unpublished). The DGI-m consists of nine walking tasks. These include: walking at normal speed, changing speeds, turning the head horizontally while walking, turning the head vertically, walking then pivoting, stepping over a shoebox and diagonal long box, stepping around cones, and stepping on and off a platform. Figure 5 illustrates the shoebox task. The original DGI contains a tenth task of a multiple up and down steps. This task is replaced with a step/ramp to accommodate for the motion analysis. All nine tasks are scored by a trained rater. Scoring is based on a zero through five scale. A zero indicates the individual could not walk 20 feet without assistance and contained severe gait deviations or imbalance. A five indicates gait was a good speed, no evidence of imbalance, and a normal pattern. A perfect score is equivalent to 45.

Figure 5: Participant performing Task 6 of the DGI; Stepping over an obstacle

Biomechanical measurements. Biomechanical variables will be collected using motion capture analysis (MCA) by applying 39 motion capture markers on participant's joint landmarks. The markers are placed in a Cleveland Clinic modified marker set. Motion capture markers are placed on the extremities, head, back, and pelvis (Figure 6). MCA measures participant's joint flexion and extension of the lower extremities to detect changes in gait. MCA will be analyzed using the Cortex 2.0.0 software. The biomechanical variables that are being collected consist of normal force, lead heel position on the stair, and toe clearance.

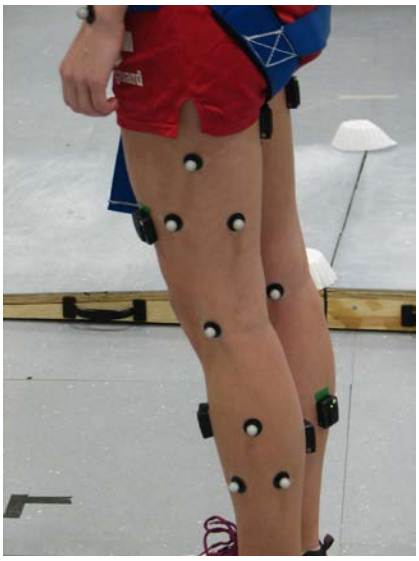

Figure 6: Picture of the motion capture sensors on the lower extremities.

Procedure

Participants are recruited through fliers on the UWM campus and in the surrounding community. Interested participants email the researcher and receive a brief description of the study and eligibility questions. After eligibility is confirmed, the researcher schedules the participant to come to the University Services and Research (USR) building. Participants are asked to wear tight fitting clothes to ensure markers stay attached to skin or clothing. Upon arrival at the lab, the participant first signs the consent form. The participant is then fitted with a safety harness connected to a trolley system that prevents a participant who falls from hitting the ground. The researchers then apply 36 reflective markers directly to the skin and onto clothing.

Participants are then attached to the harness pulley system and told to walk normally back and forth across the lab to get comfortable walking with the harness and markers. While the participant is practicing, the researcher observes if their step down lands on the force plates. After the appropriate amount of practice walks the participant is ready to begin the experiment. The participant walks through 36 trials of a looped course.

The loop course includes 15 meters of walking in a straight line. During this walk, they encounter a ramp/step, step/ramp, or flat surface. This is then followed by a DGI-m task (Figure 7).

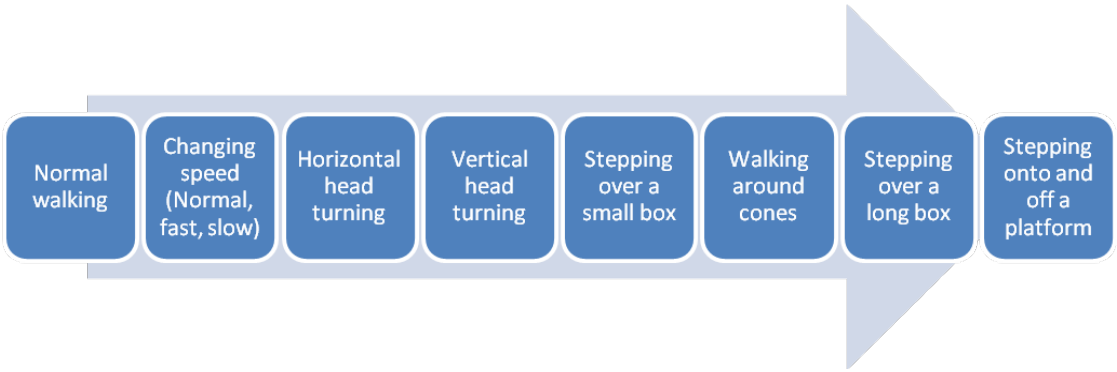

Figure 7: Order of the DGI-m tasks.

A trained rater scores the participant as they walk down the DGI-m walkway. Additionally, a video camera is used to view the DGI-m task for future reference. The order of the ramp and step is randomized. The step heights vary between 3 inches and 6 inches. Single and progressive lens glasses were alternated every 18 trials. The order of single and progressive lenses is randomized. All biomechanical data from the motion capture markers is collected by Gait and Biomechanical Lab researchers. After completion of the 36 loop trials, the participant is asked to remove all markers. Lastly, the participant fills out a subjective, Likert-like survey pertaining to comfort when wearing the multifocal lenses when completing tasks of the DGI-m. The researcher then obtains information regarding the participant receiving their compensation of a $30 check.

Data Analysis

This study implements an experimental simple mixed methods design. This method is being used to measure within differences when switching from single lens glasses to MfLs and differences between the two groups. Data collected through Cortex 2.0.0. will be labeled using motion analysis software. Labeled data will then be entered into MATLab and analyzed using coding. Data collected from the rated DGI-m will be entered into an Excel spreadsheet, which will then be transferred into SPSS for analysis.

A repeated measures multivariate ANOVA will be conducted for data analysis. A MANOVA will allow the researcher to perform a between and within comparison among the middle-aged and young participants. The independent variables include: The glasses conditions (i.e., MfLs glasses vs. single lenses), and age (young vs. old). The dependent variables include: normal force, lead heel position, toe clearance, and DGI-m scores. Within-subjects comparison means the subjects act as their own control. The change in the subjects' performance is compared to the subjects' initial base line (Portney, L.G., 2009). The within group variable is gait performance with MfLs versus single lens glasses. The difference in the performance of the individuals while wearing the different lenses will provide the amount of change in gait. Between-subjects comparison means the subjects are assigned to independent groups and the subjects in one group are compared to the other group (Portney, L.G., 2009). The between group variables for this study are middle-aged and young participants. The difference found between the different lens conditions within each group is then compared between age groups. The outcome measures will differ for the two groups because of age but the overall measurement will be the same.

	Within-Subjects	Between-Subjects
Variables	Single Lens ←→ MfLs	Middle-aged ←→ Young
DGI-m	X - X	M_1 - M_2
Toe Clearance	X - X	M_1 - M_2
Normal Force	X - X	M_1 - M_2

Figure 12: Represents within and between subjects difference.

Anticipated Results

Data is collected using Cortex 2.0.0 and interpreted into biomechanical variables through MATLab. The graphs below show the expected results when switching between single lens glasses and MfLs for middle-aged and young novice participants.

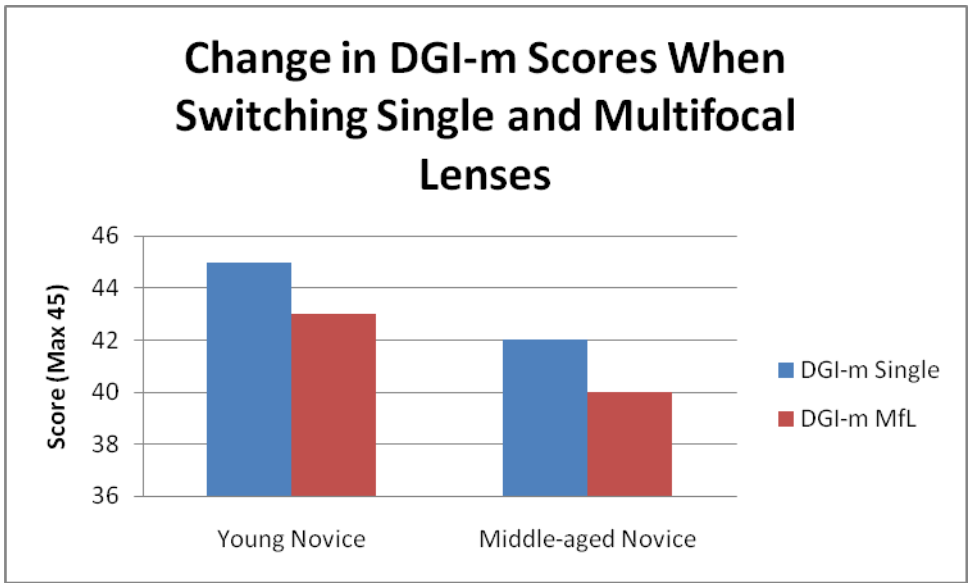

Figure 8: When performing the DGI-m young non-experienced MfLs wearers and middle-aged non-experienced MfLs wearers will show a similar within group gait performance score decrease between single and MfLs glasses conditions. Lower DGI-m score indicates gait impairment.

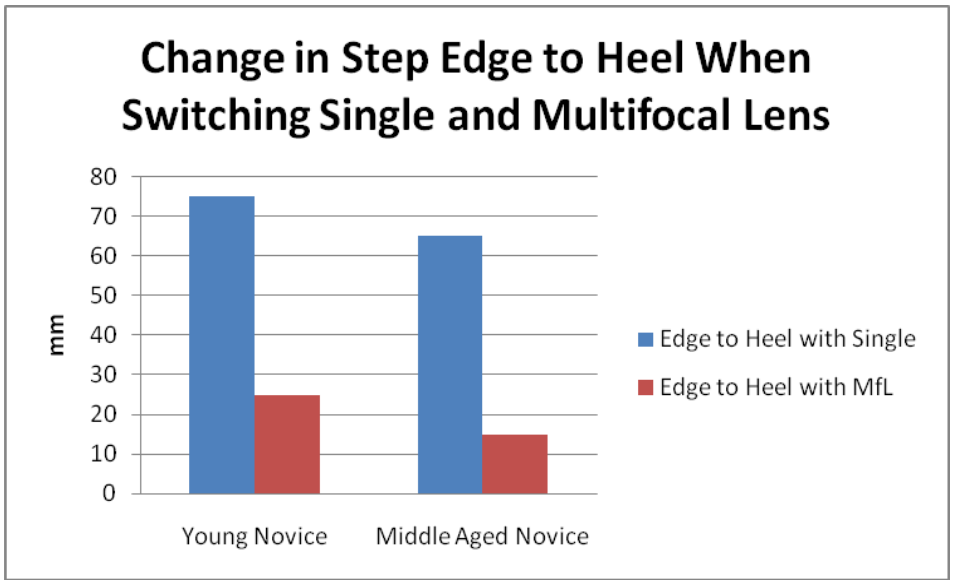

Figure 9: This figure represents walking up a step young non-experienced MfLs wearers and middle-aged non-experienced MfLs wearers will show a similar within group reduced step edge to heel placement length performance between single and MfLs glasses conditions. Lower edge to heel length indicates gait impairment.

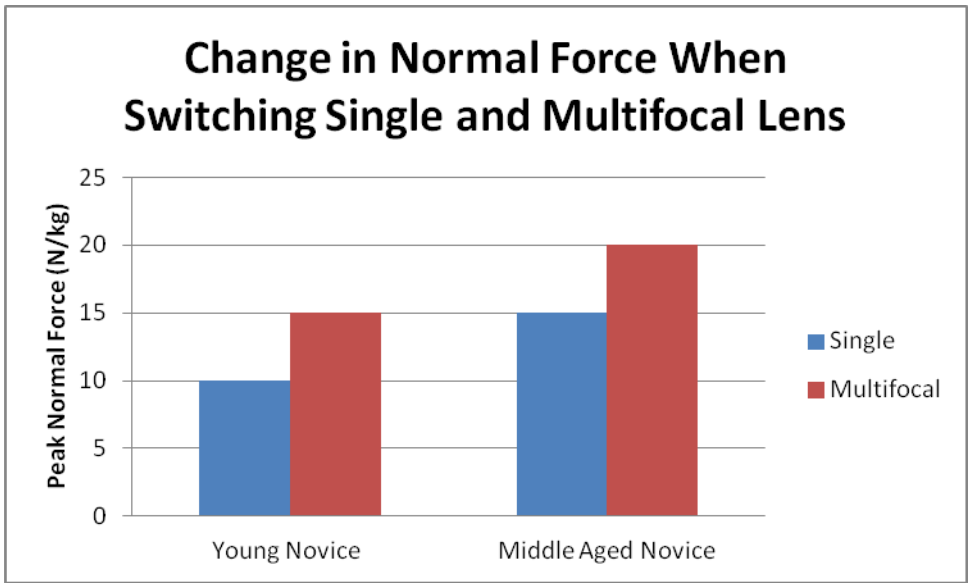

Figure 10: This figure represents stepping down young non-experienced MfLs wearers and middle-aged non-experienced MfLs wearers will show a similar within group normal force increase between single and MfLs glasses conditions. An increase in normal force indicates gait impairment.

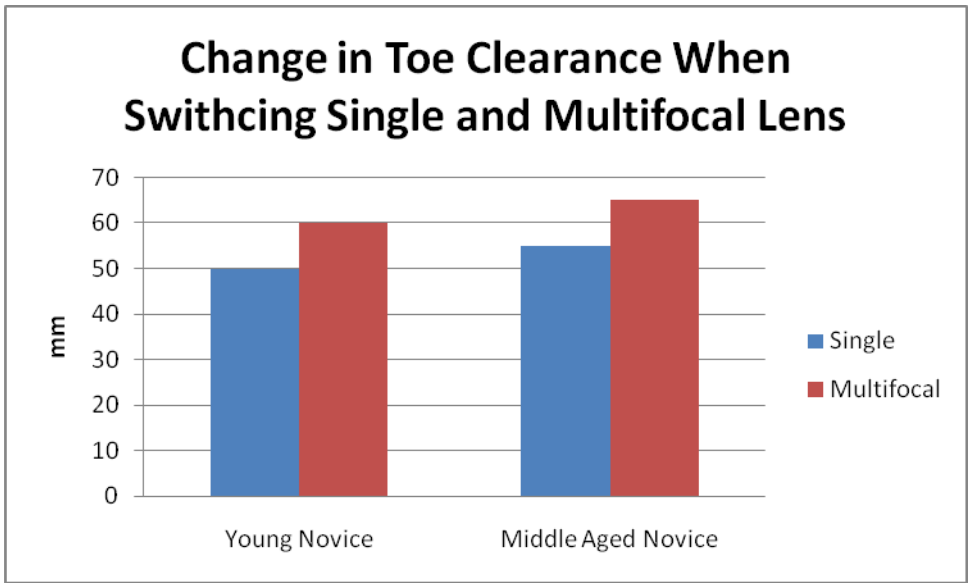

Figure 11: This figure represents walking up a step young non-experienced MfLs wearers and middle-aged non-experienced MfLs wearers will show a similar within group increase toe clearance between single and MfLs glasses conditions. Higher toe clearance indicates a cautious gait.

Discussion

Limitations

Five limitations of this study are discussed. First, it may be difficult to recruit middle-aged individuals that do not wear distance lenses because of the limited population. Second, researchers suggested recruiting ten middle-aged novice MfLs wearers, which may be underpowered. Third, the participant's visual acuity has not been tested before performing the study and visual acuity is based on participant report. Fourth, there may be a learning effect of the DGI-m obstacles if the participants receive the randomization of wearing the single lens glasses first then the MfLs glasses. Fifth, participants can have a difficult time adjusting to their comfortable gait while wearing the harness and sensors. Additionally, some participants are concerned in regards to accidently detaching the sensors, which may cause them to change their gait.

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Appendix B: Eligibility Questionnaire

Thank you for your interest. The purpose of this study is to determine the effects of bifocal glasses on walking balance. During this study, you will be asked to walk across a course that includes different tasks including: walking on ramps, and stepping up and down from stairs. While you are walking, we will record your motion, forces and muscle activity using several different sensors. In addition, we will video record you walking but you have the option to refuse the use of this videotaping without an effect on your eligibility. Testing will take 1.5 hours over 1 day. Testing will take place at the University Services Research Building on North 1st Street about 1.5 miles from the main University of Wisconsin-Milwaukee campus.

You will have to answer some questions to check eligibility. All answers will be kept confidential.

A) What is your age? Answer: _____

B) Are you male or female? Answer: _____

B) Can you walk without any assistive devices? Answer: _____

C1) Do you typically wear eye glasses? Reading or Distance? Answer: _____

C2) If answer is yes, then ask: Do you wear bifocal or progressive lens glasses? Answer: _____

C3) If answer to C2 is yes: Do you also have a set of single lens glasses? Answer: _____

C4) If answer to C2 is no, then ask: Do you have contact lens glasses that you can wear during the testing session that correct your vision?
Answer: _____

D) Are you currently recovering from or do you currently suffer from any musculoskeletal disorders that affect your ability to walk such as: broken bones, strains sprains or genetic disorders?
Answer: _____

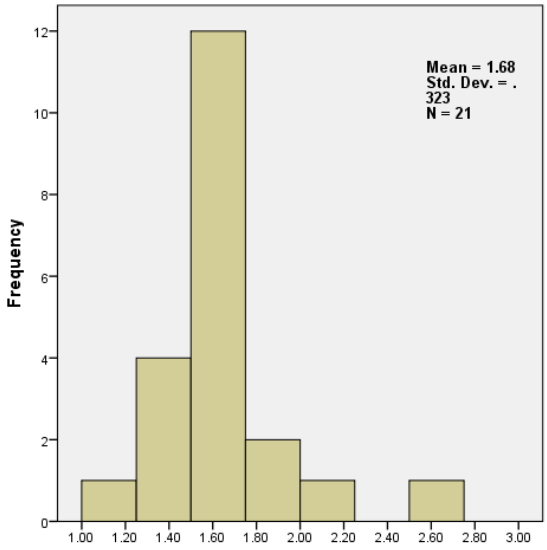
E) If subject is female: Are you currently pregnant, think you could be pregnant or trying to become pregnant? Answer: _____

F) Do you have osteoporosis or osteoarthritis? Answer: _____ (Modification for item 1)

G) Do you currently have any sensory disorders that affect your balance or are you taking any medications that might affect your balance? These include: bilateral vestibular disorder and peripheral neuropathy?
Answer: _____

H) Do you weigh over 300 pounds? Answer: _____

Appendix C: Supporting Data and Graphs



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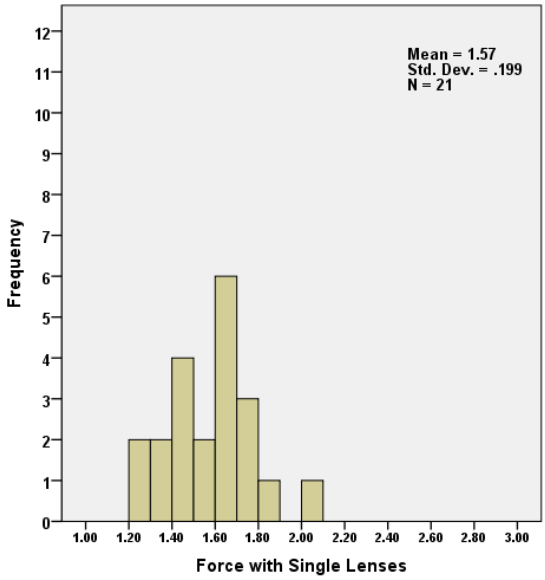

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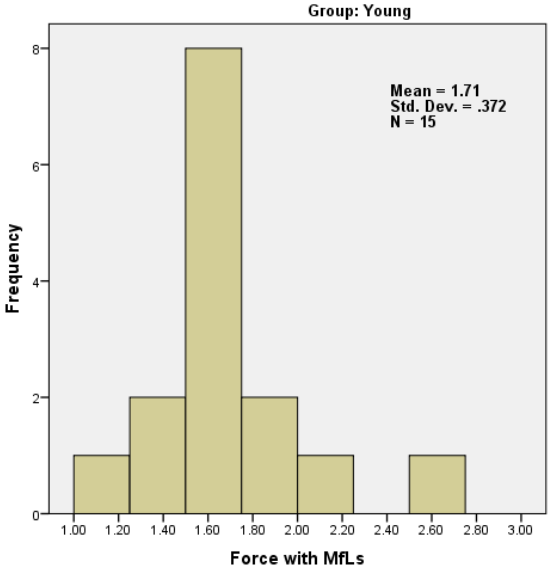

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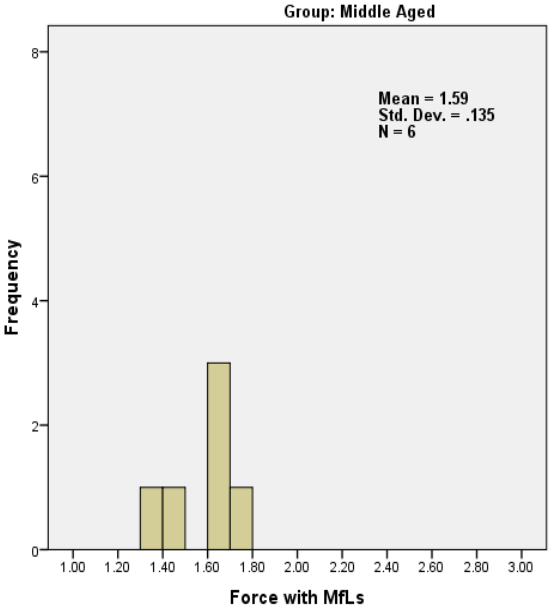

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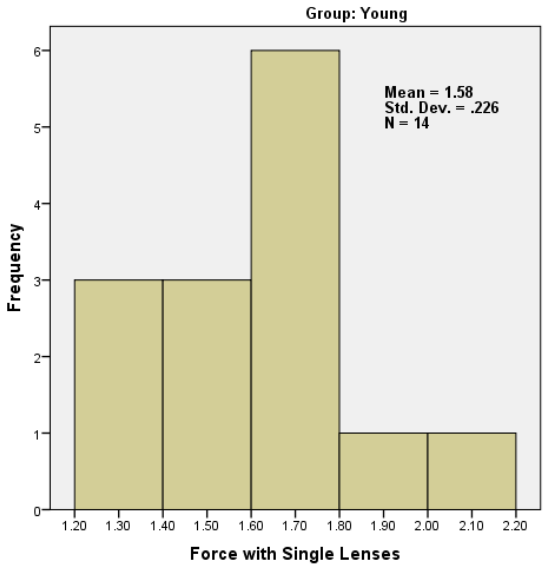

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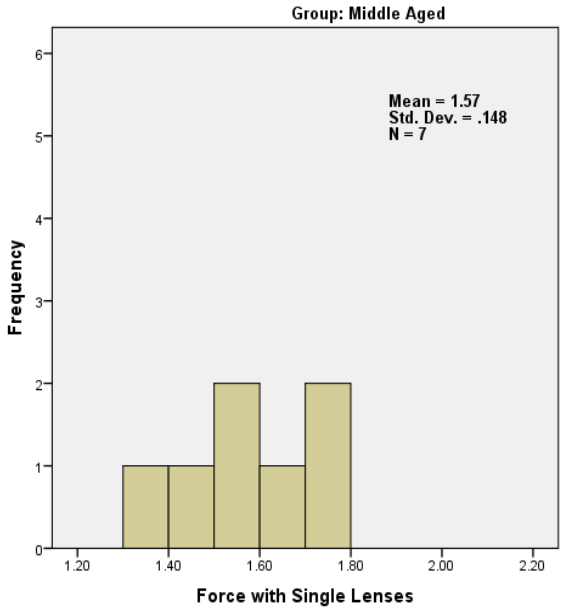

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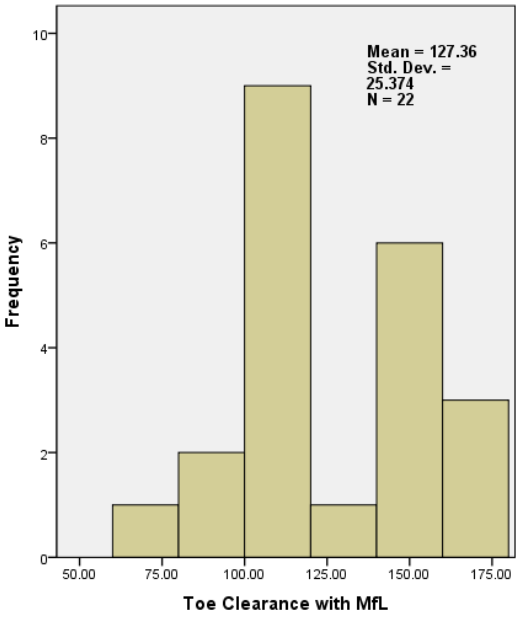

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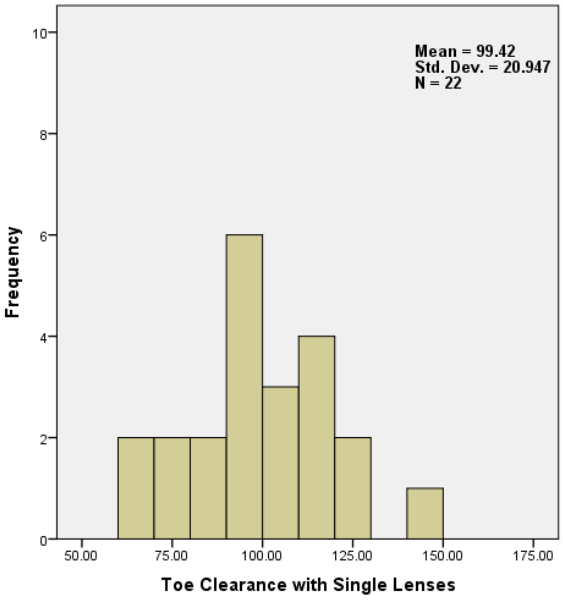

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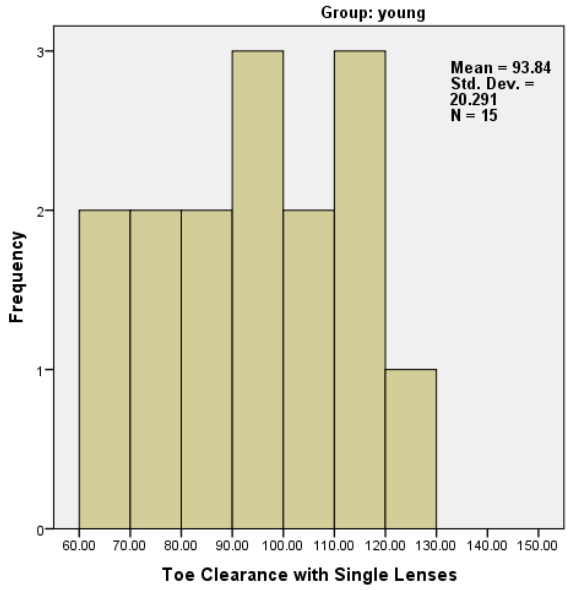

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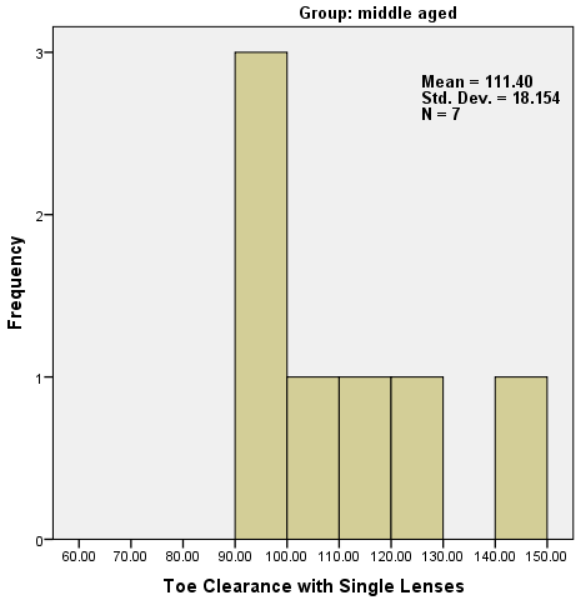

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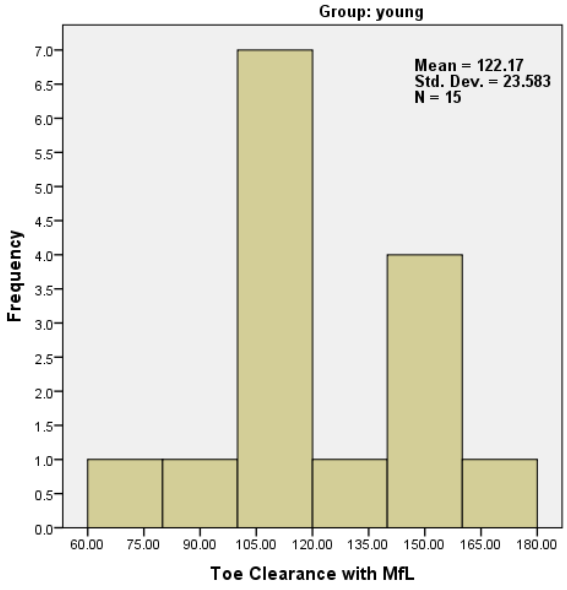

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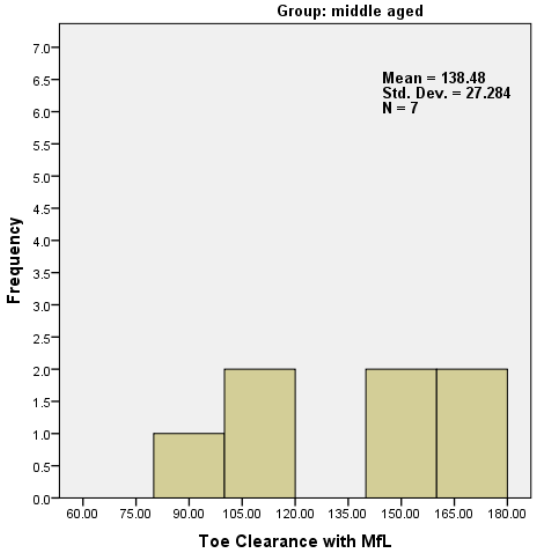

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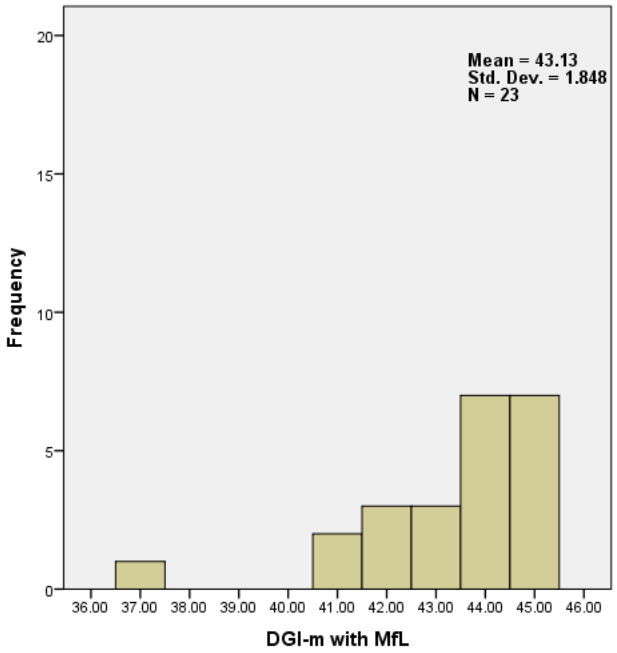


Figure 12

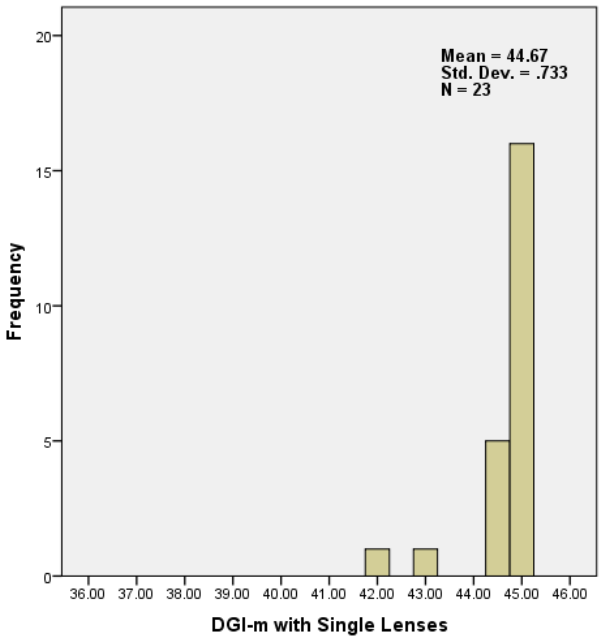
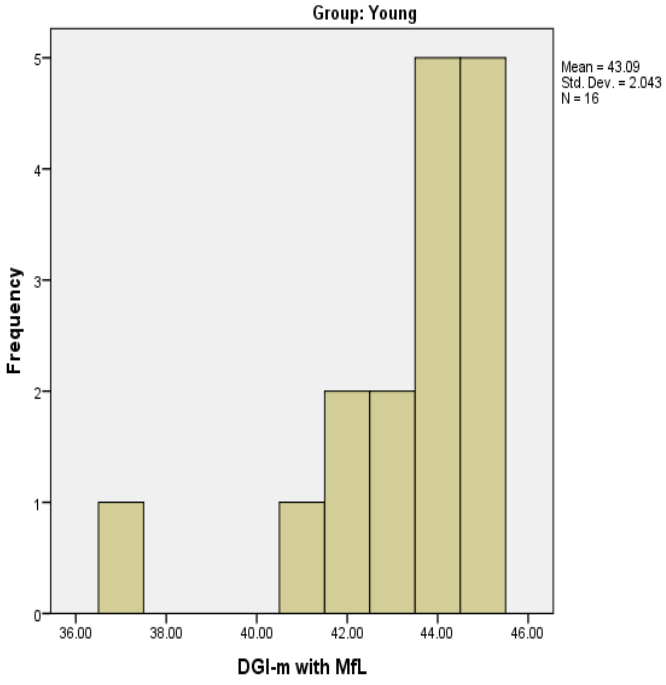


Figure 13



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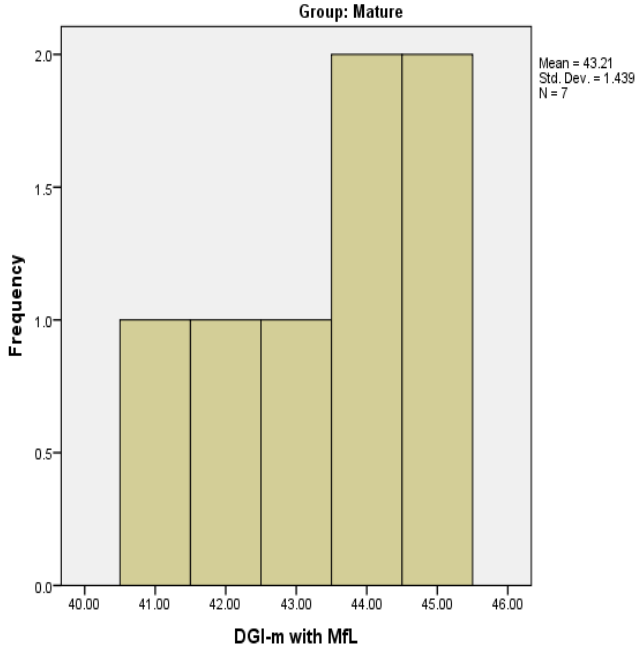

Figure 15

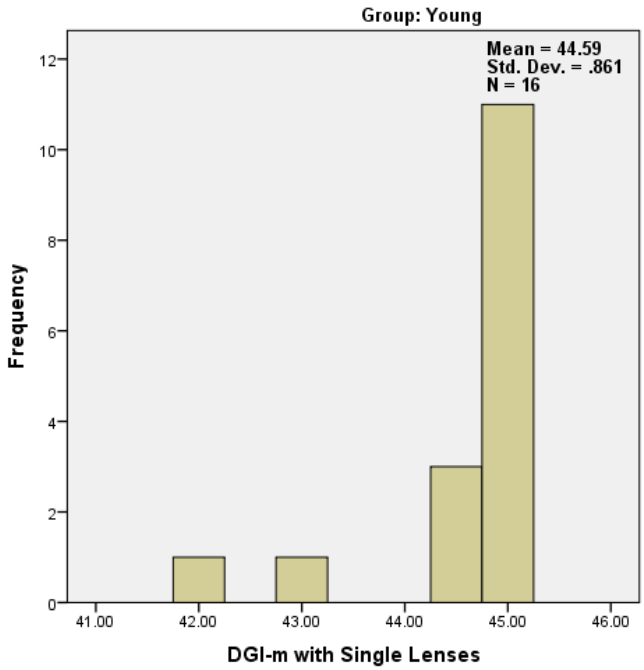

Figure 16

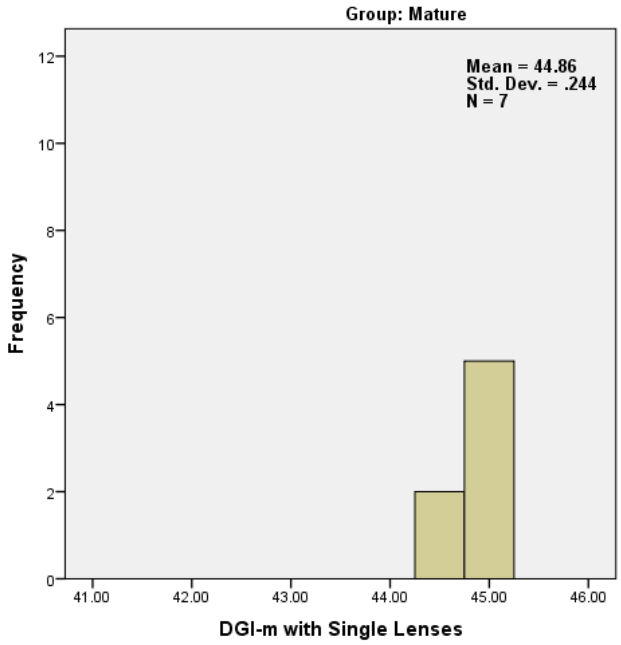

Figure 17

Appendix D: Study Flyer

IRB: 11.069

Subjects Needed

"Role of bifocal lens glasses on walking balance"

Primary Investigator: Kurt Beschorner, Ph.D.

Eligibility: 45-60 year old adults. We are seeking participants who do *not* wear glasses.

Participation: Eligible subjects will wear different kinds of eye glasses while their walking balance is measured. Motion capture technology will be used to measure motion and electromyography will be used to record muscle activity. Testing requires a single 1.5 hour testing session.

Location: Testing will occur at the Gait and Biodynamics Laboratory at the University Services Research Building on North 1st Street.

Contact: Autumn Milanowski

Compensation: $30 upon completion

"Bifocal Study" milanow2@uwm.edu

"Bifocal Study" milanow2@uwm.edu
"Bifocal Study" milanow2@uwm.edu
"Bifocal Study" milanow2@uwm.edu
"Bifocal Study" milanow2@uwm.edu
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"Bifocal Study" milanow2@uwm.edu
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Appendix E: Research Study Script

Role of Bifocal Lens Glasses on Walking Balance IRB 11.069 Directions Script

Welcome participants:
Make sure the participants have appropriate clothing and footwear; show them where the changing room is located.

Introduce the study:
"For this study we will be performing a number of walking trials. Each trial will consist of walking through a specific route. To begin, we will be attaching a safety harness, to protect you from any unexpected trips or falls. First, we will help you to put on the harness, which you will wear through the entire test. We will then attach sensors for our motion capture and EMG equipment. You will also have these on for the entire testing period."

"As we begin each trial, we will attach the harness to a hook, We will give you a brief set of instructions, then have you walk at your natural pace either up a step or ramp. When the experimenter says stop, stop and we will unhook the harness. You will then turn to your left and walk to the next testing area. The next test consists of you walking down a walkway. I will explain different tasks, such as turning your head, or walking at different speeds to perform while walking down the walkway. After finishing the walkway tasks, I will say OK, and you will turn left back to the starting point to be reharnessed. Any questions?"

(NOTE: We should probably go over the tasks of the DGI-m with the participants at this time, so that the directions are clear and quick when they do the actual task.)

Trial set-up:
Apply the EMG markers to the participant. (Explain that the experimenter will touch them to apply the markers and shave hair in EMG area so they stick better.)
Help the participant into the harness. Explain to them that the harness should be tight fitting but comfortable.

Apply the motion capture markers to the participant. (Explain that the experimenter will touch them to apply the markers and will come in close contact with them.)
Test the motion capture equipment. "*Now we are going to test the markers we've just placed on you. Stand facing the wall with your arms out to the side and feet hip width apart, like this* (demonstrate). *When I say go, start moving and bending your shoulders, then wrists, then elbows, then knees and ankles, and lastly hips." (*Demonstrate movement for participant) (Wait until experimenter at computer say go*) "Ok, start*." " *OK, stop."*

Trials:
Show the participant where to start (on the tape mark).

"When I say start, start walking. Always begin with your left foot (Point to which foot you would like them to start with). *Walk at your natural pace. When I say stop, stop walking. Do you have any questions?"*

"Let me know if you are having any problems, or feeling uncomfortable, and we will stop at anytime during the testing. We'll give you a break or two to drink water or use the facilities."

"Start."

Participant walks over ramp/step to the end.
"Stop."

Unhook the harness, and have the participant proceed to the DGI-m walkway. Explain the DGI task. (See DGI instructions).

Participant does the DGI task.
"Stop. OK, turn to the left, and we'll reharness you for the next trial."

Next trial:
"Ok, we're going to do the same task as before. Do you have any questions?"

Every 3-4 trials:
"Remember to start with your left foot, and to walk at your natural pace."

Appendix F: Dymanic Gait Index- modified Instructions

DGI-M Protocol and Directions

Introduction*:*

"I will be asking you to perform various tasks such as stepping over and walking around an object while walking on the mat. For each task you will walk to the other end of the grid. IF I say "OK", walk to the next part of the experiment. Please listen carefully to the instructions. There are 9 tasks total. These tasks include, walking at your normal speed, changing speeds, turning your head to the sides while walking, tilting your head up or down while walking, stopping and turning in the middle, and stepping over or around obstacles.

"I will give you detailed information before each set of tasks.

Do you have any questions?"

1. Gait level surface _____ next task: change speed

Instructions:

"When I tell you to begin, walk at your normal speed from here to the end of the grid."

[Therapist walks to side]

"Begin walking at your normal speed now."

Grading: Mark the lowest category that applies.

(5) Normal: Walks 20 feet: Good speed, no evidence of imbalance, normal gait pattern.

(4) Walks 20 feet: Good speed, ***either*** *slight* imbalance or steps out of gait pattern.

(3) Mild impairment: Walks 20 feet, normal gait pattern with *slower speed.*

(2) Moderate impairment: Walks 20 feet,

- *slow speed*, AND
- evidence of *mild imbalance* and/or *abnormal gait pattern*.

(1) Walks 20 feet,

- slow speed, AND
- *abnormal gait pattern*, evidence of *moderate imbalance*.

(0) Severe impairment: Cannot walk 20 feet without assistance, severe gait deviations, or imbalance.

2. Change in gait speed _____ next task:

Horizontal head turns

Instructions:

"When I tell you to begin, walk at your normal speed towards the end of the grid [for 5 feet]. When I say "quick", walk as fast as you can [for 5 feet] until I say "slow", then walk as slowly as you can [for 5 feet]."

[Therapist walks to side]

"Begin walking at your normal speed now … Quick … Slow … Normal speed."

Grading: Mark the lowest category that applies.

(5) Normal: Able to smoothly change walking speed without loss of balance or gait deviation. Shows a significant difference in walking speeds between normal, fast, and slow speeds.

(4) Able to change speed, but demonstrates *either slight* imbalance or *slight* step out of gait pattern.

(3) Mild impairment: Is able to change speed but demonstrates *mild gait deviations*, **or** no gait deviations but *unable to achieve a significant change in velocity*.

(2) Changes speed with a *moderate* loss of balance and is able to continue walking.

(1) Moderate impairment: Makes only *minor adjustments to walking speed*, **or** accomplishes a change in speed with *significant gait deviations*, **or** changes speed but demonstrates *significant* loss of balance.

(0) Severe impairment: Cannot change speeds, or loses balance and has to reach for wall or be caught.

3. Gait with horizontal head turns _____ next task: vertical head turns

Instructions:

"When I tell you to begin, walk at your normal speed from here to the end of the grid, following my instructions as you walk. When I tell you to look right [5 feet], keep walking straight but turn your head to the right. Keep your head turned to the right until I tell you, "look left" [5 feet], then keep walking straight and turn your head to the left. Keep your head to the left until I tell you, "look straight" [5 feet], then keep walking straight, but return your head to the center."

[Therapist walks to side]

"Begin walking at your normal speed now… Look right… Look left … Look straight."

Grading: Mark the lowest category that applies.

(5) Normal: Performs head turns smoothly with no change in gait.

(4) Normal speed, performs head turns smoothly with evidence of ***either*** *slight* imbalance or *slight* step out of gait pattern.

(3) Mild impairment: Performs head turns smoothly with *slight change in gait velocity*.

(2) Performs head turns smoothly with evidence of *moderate* loss of balance.

(1) Moderate impairment: Performs head turns with moderate change in gait velocity, slows down, staggers but recovers, can continue to walk.

(0) Severe impairment: Performs task with severe disruption of gait, i.e., staggers outside 15-inch path, loses balance, stops, reaches for wall.

4. Gait with vertical head turns _____ next task: Pivot turn

Instructions:

"When I tell you to begin, walk at your normal speed from here to the end of the grid, following my instructions as you walk. When I tell you to "look up," keep walking straight, but tip your head and look up towards the ceiling. Keep looking up until I tell you, "look down.". Keep looking down until I tell you, "look straight," then keep walking straight, but return your head to the center."

[Therapist walks to side]

"Begin walking at your normal speed now … Look up … Look down … Look straight."

Grading: Mark the lowest category that applies.

(5) Normal: Performs head turns with no change in gait.

(4) Performs head turns with evidence of ***either*** *slight* imbalance or *slight* step out of gait pattern.

(3) Mild impairment: Performs task with *slight change in gait velocity*

(2) Performs head turns with evidence of *moderate* loss of balance.

(1) Moderate impairment: Performs task with *moderate change in gait velocity*, slows down, staggers but recovers, can continue to walk.

(0) Severe impairment: Performs task with *severe disruption of gait*, i.e., staggers outside 15 inch path, loses balance, stops, reaches for wall.

5. Gait and pivot turn _____ next task: step over shoebox

Instructions:

"When I tell you to begin, begin walking at your normal speed towards the end of the grid. When I tell you, "half-turn and stop," turn half way around as quickly as you can to face the opposite direction and stop. I will then ask you to turn back to the original direction, and walk to the end."

[Therapist walks to side]

"Begin walking at your normal speed now … half-turn and stop, turn around again and continue walking to the end."

Grading: Mark the lowest category that applies.

(5) Normal: Pivot-turns safely within 3 seconds and stops quickly with no loss of balance.

(4) Pivot-turns safely within 3 seconds and stops quickly with a *slight* loss of balance.

(3) Mild impairment: Pivot-turns safely in *more than 3 seconds* and stops with no loss of balance.

(2) Pivot turns with a *moderate* loss of balance

(1) Moderate impairment: Turns slowly, requires verbal cueing, requires several small steps to catch balance following turn and stop.

(0) Severe impairment: Cannot turn safely; requires assistance to turn and stop.

6. Step over obstacle (shoebox) _____ next task: step around cones

Instructions:

"When I tell you to begin, walk at your normal speed from here to the end of the grid and stop. When you come to the shoebox, step over it, not around it, and keep walking."

[Therapist walks to side]

"Begin walking at your normal speed now by stepping over the shoebox, not around it."

Grading: Mark the lowest category that applies.

(5) Normal: Is able to step over box without changing gait speed; no evidence of imbalance.

(4) Steps over box with *slight* imbalance/step out of gait pattern or *unable to clear box* completely.

(3) Mild impairment: Is able to step over box but must *slow down and adjust steps* to clear box safely.

(2) Steps over box with *moderate* loss of balance.

(1) Moderate impairment: Is able to step over box, but must stop, then step over. May require verbal cueing.

(0) Severe impairment: Cannot perform without assistance.

7. Step around obstacles (cones) _____next task: diagonal long block obstacle

Instructions:

"When I tell you to begin walking down the grid. When you come to the first cone, walk on the outside of it and keep walking. When you reach the second cone, walk around the outside of it and keep walking."

[Therapist walks to side]

"Begin walking at your normal speed now by walking around the cones, not over them."

Grading: Mark the lowest category that applies.

(5) Normal: Is able to walk around cones safely without changing gait speed; no evidence of imbalance.

(4) Walks around cones with *slight* loss of balance or slight step out of gait pattern.

(3) Mild impairment: Is able to step around both cones but must *slow down and adjust steps* to clear cones.

(2) Walks around cones with *moderate* loss of balance.

(1) Moderate impairment: Is able to clear cones, but must *significantly slow speed* to accomplish task or requires verbal cueing.

(0) Severe impairment: Unable to clear cones, walks into one or both cones, or requires physical assistance.

8. Diagonal Obstacle (block) _____ next task: step on/off platform

Instructions:

"When I tell you to begin, walk at your normal speed from here to the end of the grid and stop. When you come to an obstacle, step over it, not around it, and keep walking."

[Therapist walks to side]

"Begin walking at your normal speed now by stepping over the obstacles, not around."

Grading: Mark the lowest category that applies.

(5) Normal: Is able to step over obstacle safely without changing gait speed; no evidence of imbalance.

(4) Steps over obstacle with ***either*** *slight* imbalance or *slight* step out of gait pattern.

(3) Mild impairment: Is able to step over obstacle but must *slow down and adjust steps* **or** makes contact with box

(2) Walks over obstacle with *moderate* loss of balance.

(1) Moderate impairment: Is able to step over box, but must stop, then step over. May require verbal cueing.

(0) Severe impairment: Cannot perform without assistance.

9. Step up/Step down (platform) _____

Instructions:

"When I tell you to begin, walk at your normal speed from here to the end of the grid and stop. When you come to the platform, step up and continue walking forward, step down and continue walking to the end of the grid."

[Therapist walks to side]

"Begin walking at your normal speed now by walking onto and off of the platform."

Grading: Mark the lowest category that applies.

(5) Normal: Is able to step up/down off platform without changing gait speed; no evidence of imbalance.

(4) Steps up/down off platform with *slight* imbalance **or** *slight* step out of gait pattern.

(3) Mild impairment: Is able to step up/down off platform but must *slow down and adjusts steps* for on/off platform.

(2) Steps up/down off platform with *moderate* loss of balance.

(1) Moderate impairment: Is able to step up/down off platform, but must stop. May require verbal cueing.

(0) Severe impairment: Cannot perform without assistance.

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Appendix G: Consent Form

UNIVERSITY OF WISCONSIN – MILWAUKEE
CONSENT TO PARTICIPATE IN RESEARCH

THIS CONSENT FORM HAS BEEN APPROVED BY THE IRB FOR A ONE YEAR PERIOD

1. General Information

Study title:
Role of Bifocal Lens Glasses on Walking Balance

Person in Charge of Study (Principal Investigator):
My name is Dr. Kurt Beschorner. I am an assistant professor in the Department of Industrial Engineering at University of Wisconsin-Milwaukee.

2. Study Description

You are being asked to participate in a research study. Your participation is completely voluntary. You do not have to participate if you do not want to.

Study description:
The purpose of this study is to learn more about the role of bifocal lens glasses on walking balance.

The long-term goal of this project is to develop interventions that reduce falling accidents in people who wear bifocal lens glasses. This study is meant to identify changes in walking balance that occur in subjects wearing bifocal glasses compared with those wearing single lens glasses.

The study is being conducted in the Gait and Biodynamics Laboratory at UWM. Twenty subjects will participate in the study. All subjects will be tested at the same site. Your participation will take approximately 1.5 hours over the course of 1 day.

3. Study Procedures

What will I be asked to do if I participate in the study?
Are you currently pregnant, think you could be pregnant, or trying to become pregnant?

If the answer is “YES” you will are disqualified from study enrollment for this protocol.
If the answer is “NO” you could be included, assuming you meet all other study inclusion criteria.

At the testing session, you will wear tight fitting clothing, be instrumented with different sensors and be asked to walk several times. Seventy-six (76) spherical sensors will be attached to your skin using double-sided tape. Sensors will be attached to your feet, legs, hips, arms, shoulders, head, neck and one will be placed on your chest just above the collarbone. Care will be taken during placement and removal of sensors and you should not expect any lasting discomfort related to placement or removal of sensors. Placement and removal of markers will feel similar to "placing and removing a band-aid". You will also have small sensors attached to different muscles on your legs and arms. These sensors measure muscle activity and are similar to ECG's, which measure heart activity.

You will be asked to walk several times (no more than 40 laps or half a mile) on a loop course. During this period, you will be performing two tasks. During the first task, you will be walking on flat terrain, ramps and steps. During the second task, you will be performing a functional balance test, which consists of 9 separate tasks walking tasks. These may include requiring you to turn your head while walking or step over objects. You will wear both standard non-prescription single lens glasses and non-prescription bifocal lens glasses during the testing. You will wear a safety harness, which will be attached to an overhead harness system during testing to protect you from hitting the ground in case of a fall.

Throughout the testing, your motion will be captured through a system that tracks the spherical sensors on your body. In addition, your muscle activity will also be recorded. We will also video record you, while you walk. The video-recordings are performed so that we can watch your movements, which is helpful in analyzing the data. You may choose to not be recorded without an effect on your eligibility. We will also use the video recordings to describe our experiments to colleagues and at scientific conferences. This data is necessary to determine what changes in walking balance due to the corrective lens glasses. This task will last approximately 1 hour.

4. Risks and Minimizing Risks

What risks will I face by participating in this study?

Physical: There are some physical risks from this study. There is a rare risk (<1%) that you might fall and experience an injury. You will wear a harness so that if you fall as you walk on the ramp or step surfaces, you will not hit the ground.

Social: There are no foreseeable social risks for participating in this research study.

Psychological: There are no foreseeable psychological risks for participating in this research study.

5. Benefits

Will I receive any benefit from my participation in this study?
You will receive $30.00 check for the 1.5 session. You *might* also benefit from your participation in this study by learning about how bifocal lens glasses affect your balance.

6. Study Costs and Compensation

Will I be charged anything for participating in this study?
You will not be responsible for any of the costs from taking part in this research study.

Are subjects paid or given anything for being in the study?
You will receive $30.00 check for the 1.5 hour session.

7. Confidentiality

What happens to the information collected?
All information collected about you during the course of this study will be kept confidential to the extent permitted by law. We may decide to present what we find to others, or publish our results in scientific journals or at scientific conferences. Information that identifies you personally will not be released without your written permission. Only the PI and Co-I will have access to the information. However, the Institutional Review Board at UW-Milwaukee or appropriate federal agencies like the Office for Human Research Protections may review this study's records.

You will be identified on your data files with a made-up initial and a number. Your name will not appear anywhere and no one will know about your answers, or see your data except the research team.

All data will be saved in the password protected files and computers in a secure room with access limited only to research team members. The laboratory is in building with keycard access afterhours on weekdays and on weekends. All of the information and data collected for this study will be stored in the files and portable hard drive in a locked file cabinet in the Gait Analysis and Biodynamics Laboratory at UWM for 5 years for future use.

8. Alternatives

Are there alternatives to participating in the study?
There are no known alternatives available to you other than not taking part in this study.

9. Voluntary Participation and Withdrawal

What happens if I decide not to be in this study?

Your participation in this study is entirely voluntary. You may choose not to take part in this study. If you decide to take part, you can change your mind later and withdraw from the study. You are free to not answer any questions or withdraw at any time. Your decision will not change any present or future relationships with the University of Wisconsin Milwaukee.

If you decide to withdraw or if you are withdrawn from the study before it ends, we will use the information we collected up to that point.

10. Questions

Who do I contact for questions about this study?
For more information about the study or the study procedures or treatments, or to withdraw from the study, contact:

Dr. Kurt Beschorner (PhD)
College of Engineering and Applied Science
Industrial and Manufacturing Engineering
University of Wisconsin-Milwaukee
USR Building, Room 201C
4090 N 1st St., Milwaukee, WI 53212
Phone: (414)229-6403

Who do I contact for questions about my rights or complaints towards my treatment as a research subject?
The Institutional Review Board may ask your name, but all complaints are kept in confidence.

Institutional Review Board
Human Research Protection Program
Department of University Safety and Assurances
University of Wisconsin – Milwaukee
P.O. Box 413
Milwaukee, WI 53201
(414) 229-3173

11. Signatures

Research Subject's Consent to Participate in Research:
To voluntarily agree to take part in this study, you must sign on the line below. If you choose to take part in this study, you may withdraw at any time. You are not giving up any of your legal rights by signing this form. Your signature below indicates that you have read or had read to you this entire consent form, including the risks and benefits, and have had all of your questions answered, and that you are 18 years of age or older.

_____
Printed Name of Subject/ Legally Authorized Representative

_____ _____
Signature of Subject/Legally Authorized Representative Date

Research Subject's Consent to Audio/Video/Photo Recording:

It is okay to videotape me while I am in this study and use my videotaped data in the research.

Please initial: ____Yes ____No

Principal Investigator (or Designee)
I have given this research subject information on the study that is accurate and sufficient for the subject to fully understand the nature, risks and benefits of the study.

_____ _____
Printed Name of Person Obtaining Consent Study Role

_____ _____
Signature of Person Obtaining Consent Date

Appendix H: IRB

Protocol Summary

Instructions: In order to review research involving human subjects, the UWM IRB requires the completion and submission of the New Study Application Form and a Protocol Summary. The following guidelines are designed to help researchers develop a comprehensive yet concise research protocol to facilitate timely review by the IRB. Please note, Capstone, thesis, dissertation, grant, and funding proposals cannot be submitted as, or in lieu of, this Protocol Summary as they do not contain all the required information (45CFR46).

Each Section must be completed unless directed otherwise. Incomplete forms will delay the IRB review process and may be returned to you. Enter your information in the **colored boxes**. The boxes will expand as you type.

SECTION A: Title and Date	
Note that the study title must be the same on all study documents (e.g., consents, advertisements, grants, etc.). If not, a reason must be given in the Protocol Summary Form Section I.	
A1. Project Title:	Role of Bifocal Lens Glasses on Walking Balance
A2. Today's Date:	9/23/2010

SECTION B: Project Purpose/ Research Question/ Objectives
In non-technical language, address the following: **1)** Area of the research **2)** Describe the purpose/objective **3)** Significance of the research is **4)** Any relevant literature pertaining to the proposed research study
1) Balance, vision 2) The long term goal of this project is to develop interventions that reduce the number of falling accidents in older adults wearing bifocal/multifocal lens glasses. The proposed research is needed to develop and validate a walking task that is sensitive to balance and gait changes that occur when subjects wear bifocal/multifocal lens glasses as opposed to single-lens glasses. 3) Falling accidents are a major cause of injuries, especially for older adults. Falling accidents often occur when a person is not able to adapt to changes in their environment. Adapting to changes in the environment requires proactive and reactive responses. Proactive responses include gait adjustments such as modifying step length, cadence, muscle activation patterns and foot trajectories in anticipation of an obstacle. Reactive patterns include generating a postural response to a perturbation through muscle

activations in the legs and arms in response to an unexpected perturbation. This study will examine the ability of young adults to proactively adapt to changes in their walking environment while either wearing bifocal lens glasses or single lens glasses. Developing and validating the measures and walking course is necessary to measuring the effectiveness of interventions on improving proactive feedback to environmental changes for bifocal/multifocal lens wearers.

4) Previous research has indicated that bifocal/multifocal lens glasses wearers have an increased risk of falling (Lord et al., 2002). Bifocal/multifocal lens glasses blur and/or distort vision in the bottom part of the field of view, which reduces a person's ability to identify ground-level obstacles and negotiate unexpected changes in ground level terrain. Johnson et al. has shown that persons wearing multifocal lens glasses have greater variability in toe clearance when ascending variable height steps compared with single lens glass wearers (Johnson et al., 2007). Incorrect perception of the height and angle of steps and ramps lead to increases in toe clearance variability (Johnson et al.), slower gait speed (Menant et al.) and increases in muscle activity (van der Linden et al., 2007). While the effect of bifocal/multifocal lens glasses on fall risk is well documented, few interventions have been shown to be successful. Testing interventions in a laboratory setting requires that a course be built and validated for its capability to test subjects' ability to perform functional activities while negotiating subtle changes in the flooring. This study aims at identifying these biomechanical changes by having subjects negotiate a course that includes a ramp and step, while wearing single lens glasses and multifocal lens glasses.

Lord, S., J. Dayhew, B. Sc, and A. Howland, *Multifocal Glasses Impair Edge-Contrast Sensitivity and Depth Perception and Increase the Risk of Falls in Older People.* Journal of the American Geriatrics Society, 2002. 50(11): p. 1760-1766.

Johnson, L., J. Buckley, A. Scally, and D. Elliott, *Multifocal spectacles increase variability in toe clearance and risk of tripping in the elderly.* Investigative ophthalmology & visual science, 2007. 48(4): p. 1466.

Menant, J.C., R.J.S. George, B. Sandery, R.C. Fitzpatrick, and S.R. Lord, Older People Contact More Obstacles When Wearing Multifocal Glasses and Performing a Secondary Visual Task. Journal of the American Geriatrics Society, 2009. 57(10): p. 1833-1838.

M. H. van der Linden, D. S. Marigold, F. Gabreëls, and J. Duysens, *Muscle Reflexes and Synergies Triggered by an Unexpected Support Surface Height During Walking.* J Neurophysiol, 2007. **97**: p. 3639-50.

SECTION C: Recruitment and Consent/Assent

Describe the following:

1) How the **recruitmen**t will take place. E.g., through flyers, beginning announcement for X class, referrals, random telephone sampling, etc.
2) **Inclusion** criteria. E.g., age, gender, health status/condition, ethnicity, location, English

speaking, etc.

3) **Exclusion** criteria. E.g., age, gender, health status/condition, ethnicity, location, English speaking, etc.
4) How **consent/assent** will take place. E.g., in person, online web survey, "request to waive consent" as this is secondary data analysis only, etc.
    a. If participants do not speak English as a first language or might have trouble comprehending the consent, describe the process for obtaining consent (e.g., translated consent, verbal consent, etc.).

1) Step A: Recruitment will take place through flyers place around campus and the surrounding community and through word-of-mouth. These flyers will include the phone number of our lab and the name of the study.

Step B: Subjects who call will be given additional information about the study will complete a questionnaire over the phone to determine eligibility. The subject will be asked to provide verbal consent to participate in the questionnaire. The phone conversation will be performed using a script although the researcher will be allowed to go off script to answer questions that the subject might have. If the subject appears to meet all of the eligibility requirements and is still interested in participation of the study, the researcher will then schedule a visit.

Step C: Subjects will review and complete the consent form prior to testing. Subjects will be provided as much time to review the consent as they need. The consent form will be verbally explained to the subjects to ensure that they are aware of the purpose, protocol and risks of the study. Once the subject is familiar with the consent, they will sign it in the presence of the researcher.

2) Healthy adults between the ages of 18 and 35 or 45 and 60 will be included in this study.

3) Children under the age of 18 years old will not be included in this study. Children do not typically wear bifocal/multifocal lens glasses and are therefore not at a high risk for fall injuries due to bifocal/multifocal lenses in the public sector. Therefore, we believe that this research would have a limited benefit to this group.

Pregnant women or women that think they could be pregnant will not be recruited for this study in order to protect an unborn child and a mother from the risks associated with falling into the harness during testing.

Subjects with osteoarthritis will be excluded from the study because joint pain might impede their ability to respond to the slipping perturbation.

Subjects with osteoporosis will be excluded from the study because they will be at increased risk of injury due to the fall.

Subjects with musculoskeletal disorders, sensory disorders or take medication that affect their ability to walk normally will be excluded as these are special populations that are not representative of the general population. ***(Modification for Item 1)***

Subjects who weigh over 300 pounds will not be included due to concerns with the harness system.

Non-bifocal wearing subjects who have vision impairments that are not corrected with contact lenses will be excluded from the study. The study requires that subjects wear non-prescription bifocal lens glasses, which cannot be placed over another set of glasses and so subjects must be able to see properly without glasses. Experienced bifocal wearing subjects that do not have both single lens and bifocal lens glasses will also be excluded.

Subjects who do not speak English will not be recruited.

4) The consent form will be administered by a PI or member of the research team who will be available to answer all of the individual's questions prior to their participation. PI and/or research team member will meet with those individuals who do not meet the exclusion criteria, explain the consent and study procedures. This consent form will outline the study, the risks and benefits to the individual participating, and inform the individual that they are free to withdraw from the study at any time. Once subject understands the scope and has no further questions, he/she will sign an informed consent, complete the questionnaire and be scheduled for their biomechanical testing session at Gait and Biodynamics Laboratory at UWM. All individuals participating in the study will be required to sign an informed consent approved by the University of Wisconsin Milwaukee's Institutional Review Board (IRB).

SECTION D: Data Collection and Design

In non-technical language, address the following:

1) Chronologically state the **study activities**. Describe both the activities conducted by the PI and the research participants. (E.g., screening, survey, taking a test, answering questions in an interview, completing a specific task, tasks on a computer, running on a treadmill, debriefing, etc.). If videotaping, photographs, or audiotaping will take place, explain for what and why.

2) Explain how the **data will be analyzed** or studied (i.e. quantitatively or qualitatively) and how the **data will be reported** (i.e. aggregated, anonymously, pseudonyms for participants, etc.).

1)

A. Specific Aims

A.1. Specific Aim #1: **Identify gait characteristics that occur between single lens glasses wearers and multifocal lens glasses wearers.** This specific aim will identify gait changes that occur while approaching a step/ramp ascending the step/ramp and descending a ramp/step between single lens glasses and bifocal lens glass wearers.

Hypothesis 1 (H1): There will be a significant difference in gait speed as the subject approaches the step between subjects wearing single lens and bifocal glasses.

Hypothesis 2 (H2): Toe clearance variability will increase for subjects wearing bifocal lens glasses compared with subjects wearing single lens glasses.

Hypothesis 3 (H3): Muscle activity will increase while negotiating the ramp and steps in subjects wearing multifocal lens glasses compared with subjects wearing single

lens glasses.

B. Approach

The proposed research will examine the effects of bifocal lens glasses on subjects' ability to negotiate ramps with variable pitch and steps of variable heights.

B.1. Apparatus for Specific Aims #1 and #2

Several different measures will be collected during data collection. Whole body motion will be collected based on a modified version of the Cleveland Clinic marker set. A 13 rigid body segment model will be applied to the marker data for the following segments: feet, shanks, thighs, pelvis, torso, upper arms, lower arms and head similar to Moyer et al (2006). Two force plates will record subjects' ground reaction forces prior to ascending the stair/ramp and while stepping off of the ramp/stair. An overhead harness system will support the subjects in the case of a fall or stumble. Lastly, an EMG system will record muscle activity of the rectus femoris, medial hamstring, tibialis anterior and medial gastrocnemius. These muscles will specifically be examined, as they are known to be part of the postural response during perturbations.

B.2. Specific Aim #1

B.2.1. Protocol: Twenty subjects will be recruited to participate in this part of the study.

Prior to data collection, subjects will be fitted with a set of reflective markers and electromyography sensors. Subjects will don a harness that will be connected to a trolley system that is attached to an I-beam to keep the subjects from hitting the ground in the event of an irrecoverable fall. In addition, subjects will be given tight-fitting clothing to minimize marker error due to skin artifact. Subjects will wear their own shoes. Subjects will have 76 markers placed on different anatomical landmarks of their feet, shanks, thighs, pelvis, torso, upper arms, lower arms and head ***(Modification from Item 5)***. Subjects will walk through a loop course (~200 feet long), which will consist of two tasks: 1) negotiating step/ramp task and 2) get-up-and-go task. Subjects will perform 18 laps around this course while wearing single lens glasses and 18 laps while wearing bifocal lens glasses. The bifocal lens glasses will not be prescription and will be worn both by subjects not requiring corrective lenses and by subjects wearing contact lens glasses. Subjects requiring corrective lenses will wear contact lenses in addition to the glasses during testing ***(Modification from Item 2)***. The order of glasses conditions will be randomized.

Step/Ramp Task: Subjects will perform 3 trials of each of 6 different ramp/step conditions for each glasses condition. For each trial, subjects will either walk up a ramp and then down a step (ramp-step) or walk up a step and then down a ramp (step-ramp). Three different conditions will be used for the height and pitch of the ramps and steps: 1) the ramp will be pitched at 1" rise per foot of run (this is a standard ramp pitch) and a 3" step; 2) the ramp will be pitched at 2" rise per foot of run and a 6" step; and 3) the ramp will be pitched at 2" rise per foot with two 3" steps.

The Dynamic Gait Index (DGI) is a well validated instrument that is often used to measure functional mobility in the older population and for specific populations of people with disabilities (Shumway-Cook & Woollacott, 2001; Chiu, et al., 2004).The DGI consists of a 20 foot walkway with the participant engaging in 9 tasks, such as

turning the head while walking, stepping over an obstacle, etc. The participant is rated on a 0-5 scale by a trained observer. Participants will complete each task 4 times, twice with single lens glasses, and twice with bifocal glasses to match the number of trials with the step/ramp. The primary purpose of including the DGI in this study is to Beta test the logistics of setting up the track, changing the obstacles, etc., in order to access the time and number of researchers needed to ensure optimal operation.

B.2.2. Data Analysis: To determine differences between the bifocal condition versus the single lens condition, toe clearance variability, gait speed and electromyography will be analyzed. Toe height variability will be analyzed for each subject during step-up, step-down, walking up the ramp and walking down the ramp conditions as the minimum height of a marker placed on the toe during 20 and 80% of swing. In addition, gait speed and gait speed variability will be measured by the whole body center of mass velocity during the 2 steps preceding the ramp up or step up condition. Lastly, EMG's will be filtered using a high-pass filter to eliminate motion artifact at 20Hz, full-wave rectified and then low-pass filtered, similar to Marigold et al. (2002). The peak muscle activity will be the primary variable analyzed. Additional data will be collected for further exploratory analyses including joint angles and ground reaction forces while approaching the ramp/step and while stepping off of the ramp/step.

Subjects will be scored by a trained rater on their proficiency for each DGI task on a scale of 0 (severe performance problems) to 5 (no performance problems). The scores for the 9 tasks are then combined to form a 0-45 point score.

Subjects' motion will be recorded using motion capture technology that records the motion of reflective markers placed on anatomical landmarks. In addition, subjects will be videotaped so that irregularities in testing can be identified post-hoc.

Moyer, B., *Slip and Fall Risks: Pre-Slip Gait Contributions and Post-Slip Response Effects*, in *Bioengineering*. 2006, University of Pittsburgh: Pittsburgh.

Marigold, D.S. and A.E. Patla, *Strategies for dynamic stability during locomotion on a slippery surface: effects of prior experience and knowledge.* J Neurophysiol, 2002. **88**(1): p. 339-53.

Shumway-Cook & woollacott, M.H. (2001). *Motor control: Theory and practical applications* (3rd ed.) Philadelphia: Lippincott Williams & Wilkins.

Chui, Y., Fritz, S.L., Light, K.E., & Velozo, C.A. (2006). *Use of item response analysis to investigate measurement properties and clinical validity of data for the Dynamic Gait Index.* Physical Therapy, 86(6), p. 778-787.

2) **Statistical Analyses:**

Data will be compared for each of the 6 ramp conditions across subjects using paired t-tests between the bifocal conditions and the single lens glass conditions. Seven variables will be analyzed for 6 different conditions. Because of the exploratory nature of this pilot study, no statistical adjustments will be made.

Data from the DGI trial analysed using paired t-tests between glasses conditions. The DGI data will also be correlated with the data from the 6 ramp conditions.

A subject number will be assigned to each subject and all subjects will be analyzed using this de-identified subject number.

SECTION E: Risks to Subjects

Research risk is the probability of harm occurring as a result of participation in research. In non-technical language, address the following:

1) The types of risks (e.g., physical, psychological, social, economic, legal, etc.) the subject may ***reasonably*** encounter.
2) Identify the **frequency/likelihood** of those risks.
3) Describe the **procedures/process** which will reduce or minimize risks:
    a. How the data will be safeguarded (e.g., data is anonymous, assigning pseudonyms, coded, etc.).
    b. Where data will be stored and who will have access to it.
    c. What will happen to the data after the study is complete.
    b. What happens if the participant gets hurt or upset? E.g., referred to Norris Health Center, PI will stop the interview, given telephone hotlines for abuse, etc.

1) Subjects will be exposed to minor risks from being exposed to the ramp/stair during the protocol. A harness system will be used to prevent subjects from hitting the ground in the case of an irrecoverable fall so this risk will be minimal.

There are no known psychological or social risks from this testing protocol.

The PI has worked extensively on projects using harness technologies to prevent falling accidents after subjects experience destabilizing perturbations. During the PI's dissertation work at the University of Pittsburgh, he extensively studied the biomechanics of slip and fall accidents. Across 3 different studies, over 100 subjects experienced a slip and approximately half of those subjects fell into the harness after the slip. These studies included both young and older adults. No injuries were ever experienced in any of those slips because the harness prevented the subjects from falling to the ground. We expect the risk will be less in the proposed study because: 1) all subjects will be young and healthy and 2) the subjects will not be perturbed with a slip or trip.

2) We expect the risks as being rare. The risk of injury from the induced fall is expected to be <1%.

3) All data will be kept confidential to the extent permitted by law. Research team members may decide to present what we find to others, or publish our results in scientific journals or at scientific conferences. Only the PI and research team personnel will have access to the information. On all data sheets and computer files, the subject will be identified by a number randomly assigned to the subject when admitted into the study. The only document linking the subject's name to the number will be the informed consent, which will be locked in a file cabinet with the PI and Co-I as the only person's with access.

All data will be saved in password protected files and computers in a secure room with access limited only to research team members. All of the information and data collected for this study will be stored in the files and portable hard drive in a locked file cabinet in Gait Analysis and Biodynamics Laboratory at UWM for 5 years for future use.

SECTION F: Benefits

1) **Describe any direct benefits** participants could potentially receive**.** If there are no direct benefits, explain.
2) **Explain how the risks compare to benefits.**
3) **If monetary or gift compensation will be given to subjects, explain:**
    d. In what form (i.e., cash, check, pens, etc.,).
    e. The amount or approximate value.
    f. When the participant will receive the item (e.g., $5 after completing each survey, subject will receive [item] even if they do not complete the procedure).
4) **If extra credit will be offered, explain:**
    a. If an alternative task that is not study related will be offered for the same extra credit.
    b. If the task is a class requirement/assignment that students would be required to complete even if the study was not being conducted.

1) The subjects may experience some benefit by learning how bifocal lens glasses affect their ability to negotiate changes in flooring. In addition, subjects may gain an understanding of biomechanics research topics. Subjects will receive compensation of $30.

2) We anticipate risks to the subject will be slight and will occur rarely. We expect that the subjects will be exposed to a minimal amount of risk and will receive a limited amount of benefit from the study. The research will be used to identify changes in walking patterns on ramps and steps while wearing bifocal lens glasses compared with single lens glasses, which is critical to developing intervention to improve balance of person's wearing bifocal glasses. Therefore, we anticipate that this study will result in a great amount of societal benefit.

3) Subjects will be paid $30 for their participation.

4) N/A

SECTION G: Deception/ Incomplete Disclosure (INSERT "NA" IF NOT APPLICABLE)

If you cannot adequately state the true purpose of the study to the subject in the informed consent, deception/ incomplete disclosure is involved.

1) Describe the deception/ incomplete disclosure of information to the subjects.
2) Explain why such deception/ incomplete disclosure is necessary.
3) Explain the debriefing process, or explain why there will not be a debriefing process.

1) N/A

2) N/A

3) N/A

SECTION H: Conflicts of Interest

When researchers are involved with commercial ventures, there is the potential for diverting from their primary mission of research and education. Conflicts of interest can arise when the interests of the commercial venture differ from the interests and primary obligations of the researcher, or when the

commercial venture consumes an undue share of employee time. Contact the Graduate School Research Services and Administration for more information.

Reminders:

1. Make sure all questions that are applicable have been answered on this form.
2. Responses should be consistent with other forms (e.g., New Study Submission Form, Consent Form, etc.).

New Study Form

Instructions: Each Section must be completed unless directed otherwise. Incomplete forms will delay the IRB review process and may be returned to you. Enter your information in the **colored boxes** or place an **"X"** in front of the appropriate response(s).

SECTION A: Title & Date
Section Notes… • Study title must be the same on all study documents (e.g., consents, advertisements, grants, etc.). If not, a reason must be given in the Protocol Summary Form. • Mismatched titles between what the IRB approves and what is on the grant application may delay funding.

A1. Study Title: Role of Bifocal Lens Glasses on Walking Balance

A2. Today's Date: 9/23/2010

SECTION B: Investigators & Study Personnel
Section Notes… • IRB correspondence (e.g., Approval Letters, IRB revisions, etc.) will be emailed to the email addresses listed under the PI and contact person (B1 and B2). • Only UWM faculty and staff may be listed as PI. However, students may be listed as a Student PI in B2.

B1. Principal Investigator (P.I.) (UWM faculty and staff only):

Name:	Kurt Beschorner, Ph.D.	**Degree(s):**	PhD
Title/Position:	Assistant Professor	**Department:**	Industrial Engineering
Telephone:	(414)229-6403	**Email:**	beschorn@uwm.edu

B2. Student Principal Investigator (S.P.I.) or Other Contact than PI:

Name:		**Degree(s):**	

Telephone:		**Email:**	

B3. Co-Investigators and Research Personnel and identify their role in the study (e.g., Co-PI, Research Assistant, Graduate Student, etc) (if applicable). Add additional rows or attach addendum if more personnel requires listing than space provided**:**

Name:	Roger Smith, Ph.D.	**Study Role:**	Co-PI
Name:	Dennis Tomashek	**Study Role:**	Researcher Specialist
Name:	Autumn Milanowski	**Study Role:**	Data Collection
Name:		**Study Role:**	

SECTION C: Review Type Requested

Section Notes…

- C1: "Minimal Risk" is when the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than the harm and discomfort ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.
- C3: The most common Exempt Category for a social science study is 2. To help determine if your study qualifies for Exempt Status, see the checklist the IRB Reviewer uses.
- C4: The most common Expedited Category for a social science study is 7.
- Upon review, the IRB office may change the requested type of review. Disqualifiers from exempt or expedited may include but not limited to: use of deception; studies involving minors, prisoners, pregnant women, impaired adults, or students; study of illegal activities like drug use; or study of private activities like sexual behavior.

C1. Are the human subjects at more than "minimal risk"? More than minimal risk will require Full Board Review. Place an "X" next to the appropriate response.

[__] Yes
[_x_] No

C2. Will the study involve deception or incomplete disclosure to human subjects? Place an "X" next to the appropriate response.

[__] Yes
[_x_] No

C3. I am requesting the following review by the IRB: (Select "a", "b", or "c". If "b" or "c" is selected, continue by selecting the appropriate category.) Place an "X" next to the appropriate response.

[__] a. Full Board Review (e.g., greater than minimal risk, the combination of a vulnerable population and sensitive information being collected, invasive procedures excluding blood draws); **OR**

[__] b. Exempt Review where there is no more than "minimal risk" under (select all that apply)**…**
OR
[__] Category 1 Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as **(i)** research on regular and special education instructional strategies, or **(ii)** research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

[__] **Category 2** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: **(i)** information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and **(ii)** any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

[__] **Category 3** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt if: **(i)** the human subjects are elected or appointed public officials or candidates for public office; or **(ii)** federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

[__] **Category 4** Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

[__] **Category 5** Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: **(i)** Public benefit or service programs; **(ii)** procedures for obtaining benefits or services under those programs; **(iii)** possible changes in or alternatives to those programs or procedures; or **(iv)** possible changes in methods or levels of payment for benefits or services under those programs.

[__] **Category 6** Taste and food quality evaluation and consumer acceptance studies.

[_x_] **c. Expedited Review under where there is no more than minimal risk and** (select all that apply)**…**

[__] **Category 1** Clinical studies of drugs and medical devices only when condition (a) or (b) is met. **(a)** Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) **(b)** Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

[__] **Category 2** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: **(a)** from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or **(b)** from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

[__] **Category 3** Prospective collection of biological specimens for research purposes by noninvasive means.
Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with

accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

[_x_] **Category 4** Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

[__] **Category 5** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

[__] **Category 6** Collection of data from voice, video, digital, or image recordings made for research purposes.

[__] **Category 7** Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

SECTION D: Study Funding
Section Notes…

- D1: Federally funded studies (e.g., NIH, CDC, etc.) requires IRBs to review the grant application for consistency in human protections. Submit 2 copies of the grant application.

D1. This study's funding source is or will be:

[__] a. Federally Funded (e.g., NIH, CDC, FDA, NIOSH, DOE, DOJ, etc.)

[__] b. Industry, Foundation, Commercial, or Private

[__] c. Internal – Research Growth Initiative

[__] d. Internal – **not** Research Growth Initiative (e.g., department)

[_x_] e. Not Funded (SKIP TO SECTION E)

D2. If "a," "b," "c," or "d" was selected in D1, complete this section:

a. Name of funding source(s):	
b. Address of funding source(s):	
c. UWM Proposal/ grant # (if applicable):	

D3. If "a" or "b" was selected in D1, and the sponsor requires notification directly from the IRB, complete this section. Provide the name and the method of transmission (address/ fax/ email) of the individual who requested the notification. A letter will be prepared and forwarded.

SECTION E: Study Locations

Section Notes…
Federal regulations require all institutions engaged in human subjects research that is not exempt from the regulations and has adopted the Common Rule be covered by an OHRP approved assurance of compliance. The Federalwide Assurance (FWA) is the only type of assurance accepted and approved by OHRP.

In general, an institution is considered to be engaged in human subjects research when its employees or agents: (1) obtain data about living individuals for research purposes through intervention or interaction with them, or (2) obtain individually identifiable private information for research purposes (45 CFR 46.102(d),(f)) http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102

Simply informing potential subjects about a research study is not considered engagement in research. Also, providing written information about a research study, including how to contact the investigators for information and enrollment, and seeking and obtaining prospective subjects' permission for investigators to contact them are not considered engagement in research. **However, seeking or obtaining informed consent from a research participant is considered engagement in research.**

1. The Principal Investigator must contact the collaborating performance site to determine whether the site has an active FWA. If they do not he/she should provide them with a copy of the IRB-appropriate template (see below) and the link to the OHRP website (http://www.hhs.gov/ohrp/assurances/assurances_index.html).
2. If a site does not have a registered IRB and the site requests to use UWM's IRB as the IRB of Record, the Principal Investigator is responsible for obtaining appropriate local authorization. **Contact the IRB office.**

E1. Describe the location(s) where the study will take place. The location should not be limited to interventions but also take into account recruitment, enrollment, data storage, and data analysis. For example: recruitment at nursing homes, chart reviews at Froedtert Hospital, data storage at UWM Engelmann Hall 270, etc.

All data collection will take place in the Center for Ergonomics at USR building, 2nd floor.

E2. List any other IRB, review committee, or institutional permission needed for this study and explain the status for each. Attach appropriate approval letters. For example, "This study has also been submitted to MATC's IRB and is awaiting approval. Milwaukee Public School's Research Committee has already approved. Dr. Smith, the professor of Pych 101 has given me her permission to survey her class (see email correspondence Appendix G)."

SECTION F: Study Duration

F1. What is the expected start date? *No study related activities (e.g., screening, recruitment, or enrollment) can begin until IRB approval has been granted. Format: January 25, 2007*

October 7, 2010

F2. What is the expected end date? *Expected end date should take into account data analysis, queries, and paper write-up. Format: July 1, 2009*

October 6, 2011

SECTION G: Subject Population

G1. Does the study involve direct human subject participation? Place an "X" next to the appropriate response.

[_x_] Yes
[___] No (e.g., secondary data analysis)

G2. State the subject group and total number to be enrolled for each group. For example, teachers-50, students-200, parents-25, parent's children-25, student control-30, student experimental-30, medical charts-500, dataset of 1500, etc. If this is a multi-center study, enter the total number of subjects to be enrolled for UWM. Total enrollment from all sites should be explained in the Protocol Summary Form.

Subject Group	**Number**
Adults (18-35 and 45-60)	40
TOTAL:	40

G3. This study involves (place an "X" next to all that apply)**…**

[___] a. Not Applicable (e.g., de-identified datasets)

OR

[___] b. Students of PI or study staff
[___] c. Students to be recruited in their educational setting, i.e. in class or at school.
[___] d. UWM Staff or Faculty
[___] e. Minors
[___] f. Prisoners
[___] g. Diagnosable Psychological Disorder
[___] h. Institutionalized
[___] i. Poor/uninsured

[__] j. Pregnant women
[__] k. Fetuses
[__] l. Nursing home residents recruited in the nursing home
[__] m. Cognitively impaired
[__] n. Psychiatrically impaired
[__] o. Limited or non-readers
[__] p. Wards of the state (e.g., foster children)
[__] q. Terminally ill
[__] r. Others vulnerable to coercion (Specify in the box below):

[_x_] s. Normal healthy subjects not requiring special protections
[__] t. Other (Specify in the box below):

SECTION H: Study Involvement

Section Notes…

- Internet Research is subject to additional guidelines. See IRB website.

H1. This study involves (place an "X" next to all that apply)**…**

[_x_] a. Datasets
[__] b. Interviews/Focus Groups
[_x_] c. Questionnaires/Surveys
[__] d. Observations
[_x_] e. Videotaping
[__] f. Audiotaping
[__] g. Photography
[__] h. Internet research
[__] i. Records Review (e.g., medical, educational tests/scores, etc.)
[__] j. Collection of Blood/ Blood Products
[__] k. Genetic Material
[__] l. Diagnostic imaging (e.g., MRI, fMRI, X-Rays, etc.) Ionizing radioactive materials or radiation producing devices located here on campus requires the review and approval from the Radiation Safety Program.
[__] m. Exposure to psychological stress
[__] n. Surgery
[__] o. Electrical Shock
[__] p. Chemical or Biological Agent (clinical)
[__] q. FDA for "off label" use
[__] r. Investigational New Device (clinical)
[__] s. Investigational Drug Exemption (clinical)
[__] t. Other invasive procedure (Specify in the box below):

SECTION I: Informed Consent Documents/ Assents

I1. How will the consenting of subjects take place? (place an "X" next to all that apply)**…**

[_x_] a. Written informed consent with the subject's or legal representative's signature. Use IRB Template and attach to IRB submission. **Go to Section M**
[__] b. Waiver to obtain informed consent. E.g., dataset or chart study. **Complete Section J**

[__] c. Waiver to alter the required elements of the informed consent document. E.g., survey conducted over the telephone, short form of the consent. **Complete Section J and Section K**.
[__] d. Waiver to document informed consent. E.g., informed consent process if done verbally. **Complete Section k**.
[__] e. Assent for minors. Use IRB Template. **Complete Section L**.

SECTION J: Request to Waive Informed Consent/ Request to Alter Informed Consent
Section Notes… • Complete this section if you are requesting a Waiver to Obtain Consent or requesting to Alter Informed Consent. • Skip this section if you are **not** requesting a Waiver to Obtain Consent or requesting to Alter Informed Consent. • Answer all A's **OR** all B's

J1. Answer A's OR B's

[__] **A1.** The research or demonstration project is to be conducted by, or subject to the approval of, state or local government officials, and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
Explain:

[__] **A2.** The research could not practicably be carried out without the waiver or alteration.
Explain:

[__] **B1.** The research involves no more than minimal risk to the subjects;
Explain:

[__] **B2.** The waiver or alteration will not adversely affect the rights and welfare of the subjects;
Explain:

[__] **B3.** The research could not practicably be carried out without the waiver or alteration; and
Explain:

[__] **B4.** Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Explain:

SECTION K: Request to Waive Documentation of Informed Consent

Section Notes…
• Complete this section if you are requesting a Waiver to Document Informed Consent.
  o I.E., the research participant is not signing the consent form.
• Skip this section if you are **not** requesting a Waiver to Document Informed Consent.
• Answer all A's **OR** all B's
  o If A1, A2, or A3 is marked "No", a request to waive documentation of informed consent cannot be granted.
  o If B1 or B2 is marked "Yes", a request to waive documentation of informed consent cannot be granted.

K1. Answer A's OR B's

A1. If consent was documented, would the only record linking the subject and the research be the informed consent form?

[__] Yes
[__] No

A2. If consent was documented, would the principal risk to the subject be the potential harm from a breach of confidentiality?

[__] Yes
[__] No

A3. Will each subject be asked whether he/she wants documentation linking the subject with the research, and the subjects wishes will govern?

[__] Yes
[__] No

B1. Does the research present more than minimal risk of harm to subjects?

[__] Yes
[__] No

B2. Are any procedures involved for which written consent is normally required outside of the research context?

[__] Yes
[__] No

SECTION L: Assent for Minors
Section Notes… • Permission (consent) of a parent or legally authorized representative must be obtained. Under certain limited conditions it may be possible for the minor to consent on her/his own behalf, without the need for parental permission. For example research concerning neglect and abuse.

L1. The assent will be for (select all that apply):

[__] a. Minors who are not wards of the state or other agency

[__] b. Minors who are wards of the state or other agency

SECTION M: Subject Incentives/ Compensations

Section Notes…

- If you intend to submit to the Travel Management Office for reimbursement purposes make sure you understand what each level of payment confidentiality means **(click here for additional information).**
  - **Level 1:**
    - The payee's name, address, and social security number and the amount paid must be recorded.
    - When Level 1 is selected, a formal notice is not issued by the IRB and the Travel Management Office assumes Level 1.
    - Level 1 payment information will be retained in the extramural account folder at UWM/Research Services and attached to the voucher in Accounts Payable. These are public documents, potentially open to public review.
  - **Level 2:**
    - A list of names, social security numbers, home addresses and amounts paid.
    - When Level 2 is selected, a formal notice will be issued by the IRB.
    - Level 2 payment information, including the names, are attached to the PIR and become part of the voucher in Accounts Payable. The records retained by Accounts Payable are not considered public record.
  - **Level 3:**
    - Payments are made to the research subjects by either personal check or cash.
    - Gift cards are considered cash.
    - If a cash payment is made, the PI must obtain signed receipts.
    - The PI shall maintain a record of the research subject's name and corresponding coded identification. This will be the only record of payee names, and it will stay in the control of the PI.

M1. Does this study involve incentives or compensation to the subjects? For example cash, class extra credit, gift cards, or items.

[_x_] Yes

[__] No

M1a. If applicable, select the appropriate confidentiality level for payments (see section notes):

[_x_] Level 1 indicates that confidentiality of the subjects is not a serious issue, e.g., providing a social security number or other identifying information for payment would not pose a serious risk to subjects.

[__] Level 2 indicates that confidentiality is an issue, but is not paramount to the study, e.g., the participant will be involved in a study researching sensitive, yet not illegal issues. For example, a study of individuals with contagious diseases would fall into this category.

[__] Level 3 indicates that confidentiality of the subjects must be guaranteed. In this category, identifying information such as a social security number would put a subject at increased risk. An example of this type of study would be any research involving illegal activity.

SECTION N: HIPAA and Protected Health Information (PHI)

What is it?

The Health Information Portability and Accountability Act (HIPAA) Privacy Rule is Federal legislation

which regulates the way certain health care groups, organizations, or businesses, handle the individually identifiable health information known as **protected health information (PHI)**. The Privacy Rule establishes the conditions under which covered entities can use or disclose PHI for many purposes, including for research. Researchers seeking to use PHI from a UWM Covered Department or an external covered entity as part of their research study must comply with HIPAA. Compliance typically requires either obtaining a HIPAA Authorization during the informed consent process or obtaining a Waiver of such Authorization from the IRB.

What is PHI?
Protected health information **(PHI)** includes information relating to an individual's past, present or future physical or mental health or condition, the provision of health care services or the past, present or future payment for such services. It only covers information that is individually identifiable. There are 18 identifiers under the Privacy Rule, some of which include: names, dates, geographic locations, telephone numbers, medical record numbers, account numbers, biometric identifiers, and other unique identifying number or code.

What are UWM's Covered Departments?
UWM is considered a "hybrid entity" under HIPAA because it has some departments and units that are covered by HIPAA and some that are not. All employees and volunteers in UWM's Covered Departments must comply with the Privacy and Security Rules, including in connection with research.

UWM's Covered Departments are currently comprised of the following entities:

A. Provider Units:
1. Athletics Trainers (Division of Student Affairs)
2. Hearing Evaluation Center (College of Health Science)
3. Norris Student Health Center (Division of Student Affairs)
4. Psychology Clinic (College of Letters and Sciences)
5. Speech and Language Clinic (College of Health Sciences)
6. Urban Health Partnerships (College of Nursing)

B. Administrative Units:
1. Bursar's Office (Division of Finance & Administrative Affairs)
2. IT Personnel in Business & Financial Services (Division of Academic Affairs)
3. Information and Media Technologies (I&MT) (Division of Academic Affairs)
4. Institutional Review Board Members and Administrative Staff (Division of Finance & Administrative Affairs)
5. Internal Audit (Division of Finance & Administrative Affairs)
6. Office of Legal Affairs (Division of Finance & Administrative Affairs)
7. Risk Management (Division of Finance & Administrative Affairs)
8. Privacy Officers

How do I know if I am using PHI as part of my research study and have to comply with HIPAA?

If you answer "yes" to any of the below questions, you are using PHI:

Are you accessing or using a participant's health information from a UWM Covered Department or an external covered entity (such as a hospital, clinic or other health care agency)?

Are you conducting research in connection or collaboration with an entity covered by HIPAA?

Are you using information from a database that was created using health care information obtained by a UWM Covered Department or external covered entity?

Note: If you are asking a participant to self-report his medical history outside a clinical/hospital setting

and do not wish to see his/her medical record, you do not need to obtain the required HIPAA Authorization or Waiver unless you answer "yes" to one of the above questions.

If you answered yes to any of the questions above, you must either obtain either an "Authorization Form for Research For the Use and Disclosure of Patient Health Information" from your Research Participants or IRB approval of an "Application for IRB Waiver of Authorization or Altered Authorization under the HIPAA Privacy Rule." You also must complete online HIPAA training at www.hipaa.uwm.edu.

Who do I contact to for more information on this?
Contact the UWM Office of Legal Affairs (https://www4.uwm.edu/legal/hipaa/)

SECTION O: Principal Investigator and Student Principal Investigator Assurances

As Principal and Student Principal Investigator, I certify the following:

- I have reviewed this protocol submission and acknowledge my responsibilities as Principal Investigator.
- The information in this submission accurately reflects the proposed research.
- I will not initiate this study until I receive written approval from the IRB.
- I will promptly report to the IRB any unanticipated problems and adverse events, as well as any findings during the course of the study that may affect the risks and benefits to the subjects.
- I will obtain prior written approval for modifications (amendments) to this protocol including, but not limited to, changes in procedures.
- I have completed the UWM Human Subjects Training Module.
- I have determined whether or not I am accessing protected health information as part of my proposed research, and if so, I accept responsibility for assuring adherence to HIPAA.
- If I am using PHI in my research, I have visited the UWM HIPAA Training website (www.hipaa.uwm.edu) and have completed all required training, and I am complying with HIPAA's requirements for researchers.
- I accept responsibility for assuring adherence to applicable Federal and State research regulations and UWM polices relative to the protection of the rights and welfare of the subjects enrolled in this study.
- I understand that the UWM IRB operates under a Federal Wide Assurance (FWA) from the Department of Health and Human Services.
- Unless given Exempt Status, I understand that this study is subject to continuing review and approval by the IRB.

Kurt Beschorner _____
Principal Investigator (PRINT NAME)

_____
DATE

_____
Student Principal Investigator (PRINT NAME)

_____
DATE

UNIVERSITY of WISCONSIN
UWMILWAUKEE

Department of University Safety & Assurances

NewStudy-NoticeofIRBExpedited Approval

Date: October 12, 2010
To: Kurt Beschorner, Ph.D.
Dept: Industrial Engineering
Cc: --------
IRB#: 11.069
Title: Role of Bifocal Lens Glasses on Walking Balance

Melissa Spadanuda IRB Administrator Institutional Review Board Engelmann 270
P. O. Box 413
Milwaukee, WI 53201-0413 (414) 229-3173 phone
(414) 229-6729 fax

http://www.irb.uwm.edu spadanud@uwm.edu

After review of your research protocol by the University of Wisconsin – Milwaukee Institutional
Review Board, your protocol has been approved as minimal risk Expedited under Category 4 and
7 as governed by 45 CFR 46.110.

This protocol has been approved on October 12, 2010 for one year. IRB approval will expire on October 11, 2011. If you plan to continue any research related activities (e.g., enrollment of subjects, study interventions, data analysis, etc.) past the date of IRB expiration, a continuation for IRB approval must be filed by the submission deadline. If the study is closed or completed before the IRB expiration date, please notify the IRB by completing and submitting the Continuing Review form found on the IRB website.

Unless specifically where the change is necessary to eliminate apparent immediate hazards to the subjects, any proposed changes to the protocol must be reviewed by the IRB before implementation. It is the principal investigator's responsibility to adhere to the policies and guidelines set forth by the UWM IRB and maintain proper documentation of its records and promptly report to the IRB any adverse events which require reporting.

It is the principal investigator's responsibility to adhere to UWM and UW System Policies, and any applicable state and federal laws governing activities the principal investigator may seek to employ (e.g., FERPA, Radiation Safety, UWM Data Security, UW System policy on Prizes, Awards and Gifts, state gambling laws, etc.) which are independent of IRB review/approval.

Contact the IRB office if you have any further questions. Thank you for your cooperation and best wishes for a successful project.

Respectfully,

Melissa C. Spadanuda
IRB Administrator

CC: Study File

Department of University Safety & Assurances

Modification/Amendment - IRB Expedited Approval

Benjamin J. Kennedy, MA IRB Manager
Institutional Review Board
Engelmann 270
P. O. Box 413
Milwaukee, WI
53201-0413
(414) 229-3182 phone (414) 229-6729 fax http://www.irb.uwm.edu
kennedbj@uwm.edu

Date: April 28, 2011

To: Kurt Beschorner, Ph.D.
Dept: Industrial Engineering

Cc: Autumn Milanowski, BS

IRB#: 11.069
Title: Role of Bifocal Lens Glasses on Walking Balance

After review of your research protocol by the University of Wisconsin – Milwaukee Institutional Review Board, your protocol has received modification/amendment approval for:

- Modify subject age range from 18-35 to 18-60 years of age and include experienced multifocal lens glasses wearers;
- Addition of $30.00 payment to subjects with a Level 2 Confidentiality for subjects.;
- Addition of exclusionary criteria for subjects taking medication that could affect their ability to walk or balance;
- Revised Protocol Summary;
- Revised recruitment flyer;
- Addition of payment sheet;
- Revised Consent; and
- Revised phone script.

IRB approval will expire on October 11, 2011. If you plan to continue any research related activities (e.g., enrollment of subjects, study interventions, data analysis, etc.) past the date of
IRB expiration, a Continuation for IRB Approval must be filed by the submission deadline. If the study is closed or completed before the IRB expiration date, please notify the IRB by completing and submitting the Continuing Review form found on the IRB website.

Unless specifically where the change is necessary to eliminate apparent immediate hazards to the subjects, any proposed changes to the protocol must be reviewed by the IRB before implementation. It is the principal investigator's responsibility to adhere to

the policies and guidelines set forth by the UWM IRB and maintain proper documentation of its records and promptly report to the IRB any adverse events which require reporting.

It is the principal investigator's responsibility to adhere to UWM and UW System Policies, and any applicable state and federal laws governing activities the principal investigator may seek to employ (e.g., FERPA, RadiationSafety, UWMDataSecurity, UWSystempolicyonPrizes, AwardsandGifts, State gaming laws, etc.) which are independent of IRB review/approval.

Contact the IRB office if you have any further questions. Thank you for your cooperation and best wishes for a successful project.

Respectfully,

Benjamin J. Kennedy
IRB Manager
CC: Study File

Modifications/ Amendment Form

Instructions: Each Section must be completed unless directed otherwise. Incomplete forms will delay the IRB review process and may be returned to you. Enter your information in the **colored boxes** or place an **"X"** in front of the appropriate response(s).

Amendment submissions with IRB# of 09.210 and higher (e.g., 09.215, 09.300, 10.010) may be submitted **electronically by email** to irbinfo@uwm.edu. Type "Amendment Submission" in the subject line. All other Amendment submissions with IRB# 09.209 and lower (e.g., 03.02.052, 05.02.200, 07.02.350, 08.325, 09.199) must **submit 3 collated copies in paper (2 copies + 1 signed original)**.

SECTION A: Title & Date

Section Notes…

- A1. Study title must be the same on all study documents (e.g., consents, advertisements, grants, etc.).

A1. Study Title: Role of Bifocal Lens Glasses on Walking Balance

A2. IRB#: 11.069

A2. Today's Date:

A3. Principal Investigator (P.I.):

Name:	Kurt Beschorner	**Degree(s):**	PhD
Title/Position:	Assistant Professor	**Department:**	Industrial Engineering
Telephone:	414-229-6403	**Email:**	beschorn@uwm.edu

A4. Student Principal Investigator (S.P.I.) or Other Contact than PI:

Name:	Autumn Milanowski	**Degree(s):**	BS
Telephone:		**Email:**	Milanow2@uwm.edu

SECTION B: Modification/ Amendment Type

Section Notes…

- Remember to update and submit any materials which may be affected by the proposed amendment. For instance, if the requested change is add additional study procedures, the Protocol Summary Form and Consent Form may need to be updated as well.
- If "Minor Amendment" was selected, submit 3 copies (2 showing track changes, 1 clean version

showing revisions).
- If "Major Amendment" was selected, submit 14 copies (13 showing track changes, 1 clean version showing revisions)

B1. What is the nature of the modification/ amendment request? *See "Section Notes" for required materials to submit.*

[_x_] a. A **Minor Amendment** which does **NOT** alter the risk to benefit ratio of the study and does **NOT significantly** change the study design/procedures. Examples include but are not limited to:

- changes in research personnel;
- administrative updates to protocol, consent, etc.;
- addition of recruitment materials
- increasing sample size; and
- small compensation to participants.

[__] b. A **Major Amendment** which **DOES** alter the risk to benefit ratio of the study and **DOES significantly** change the study design/procedures. Examples include but are not limited to:

- additional risks have been identified;
- a significant change to compensation; and
- length of participant involvement significantly increase.

SECTION C: Description of the Modification/ Amendment

Section Notes…
- If the modification/ amendment is for a change in PI or study coordinator, include their contact information (name, department, phone, fax, address, and email).

C1. Describe the requested modification/ amendment.

The modifications include changing the participant total to 40 and excluding ages 35-45.

SECTION D: Rationale for Modification/ Amendment

Section Notes…
- **D2.** If currently enrolled participants are unaffected by the modification/ amendment or consent is not obtained from subjects, explain below.

Example: *The amendment is for a change in co-investigator who does not interact with the subjects.*

Example: *The amendment is an administrative change and this study is an anonymous telephone survey.*

Example: *The amendment is to revise the study design to include an additional intervention. The subjects will be re-consented at the time of their next study visit using the revised consent form which is being submitted for IRB approval along with this amendment request.*

D1. Explain the rationale for the proposed modification/ amendment below.

The age range will exclude ages 35-45 because the researchers want to investigate a younger and older population. The total number of participants was increased to allow additional participants in each age group.

D2. Explain how the new information (modification/ amendment) will be communicated to currently enrolled subjects?

The additional exclusion criteria will be added to the recruitment materials.

SECTION E: Principal Investigator Signature

_____	_____
Principal Investigator (PRINT NAME)	Principal Investigator (SIGNATURE)
_____	_____
DATE	DATE
_____	_____
Student Principal Investigator (PRINT NAME) (SIGNATURE)	Student Principal Investigator
_____	_____
DATE	DATE

Reminders: Make sure all questions that are applicable have been answered on this form. To avoid automatic IRB termination of your study, request for Continuing Review should be submitted no later than one month before the date of IRB expiration.

Amendment submissions with IRB# of 09.210 and higher (e.g., 09.215, 09.300, 10.010) may be submitted **electronically by email** to irbinfo@uwm.edu. Type "Amendment Submission" in the subject line. All other Amendment submissions with IRB# 09.209 and lower (e.g., 03.02.052, 05.02.200, 07.02.350, 08.325, 09.199) must **submit 3 collated copies in paper (2 copies + 1 signed original)**.

Modifications/ Amendment Form

Instructions: Each Section must be completed unless directed otherwise. Incomplete forms will delay the IRB review process and may be returned to you. Enter your information in the **colored boxes** or place an **"X"** in front of the appropriate response(s).

Amendment submissions with IRB# of 09.210 and higher (e.g., 09.215, 09.300, 10.010) may be submitted **electronically by email** to irbinfo@uwm.edu. Type "Amendment Submission" in the subject line. All other

Amendment submissions with IRB# 09.209 and lower (e.g., 03.02.052, 05.02.200, 07.02.350, 08.325, 09.199) must **submit 3 collated copies in paper (2 copies + 1 signed original)**.

SECTION A: Title & Date
Section Notes… • A1. Study title must be the same on all study documents (e.g., consents, advertisements, grants, etc.).

A1. Study Title: Role of Bifocal Lens Glasses on Walking Balance

A2. IRB#: 11.069

A2. Today's Date:

A3. Principal Investigator (P.I.):

Name:	Kurt Beschorner	**Degree(s):**	PhD
Title/Position:	Assistant Professor	**Department:**	Industrial Engineering
Telephone:	414-229-6403	**Email:**	beschorn@uwm.edu

A4. Student Principal Investigator (S.P.I.) or Other Contact than PI:

Name:	Autumn Milanowski	**Degree(s):**	BS
Telephone:		**Email:**	Milanow2@uwm.edu

SECTION B: Modification/ Amendment Type
Section Notes… • Remember to update and submit any materials which may be affected by the proposed amendment. For instance, if the requested change is add additional study procedures, the Protocol Summary Form and Consent Form may need to be updated as well. • If "Minor Amendment" was selected, submit 3 copies (2 showing track changes, 1 clean version showing revisions). • If "Major Amendment" was selected, submit 14 copies (13 showing track changes, 1 clean version showing revisions)

B1. What is the nature of the modification/ amendment request? *See "Section Notes" for required materials to submit.*

[_x_] a. A **Minor Amendment** which does **NOT** alter the risk to benefit ratio of the study and does **NOT** **significantly** change the study design/procedures. Examples include but are not limited to:

- changes in research personnel;
- administrative updates to protocol, consent, etc.;
- addition of recruitment materials
- increasing sample size; and
- small compensation to participants.

[__] b. A **Major Amendment** which **DOES** alter the risk to benefit ratio of the study and **DOES** **significantly** change the study design/procedures. Examples include but are not limited to:

- additional risks have been identified;
- a significant change to compensation; and
- length of participant involvement significantly increase.

SECTION C: Description of the Modification/ Amendment
Section Notes… • If the modification/ amendment is for a change in PI or study coordinator, include their contact information (name, department, phone, fax, address, and email).

C1. Describe the requested modification/ amendment.

The modifications include changing the age range and eligibility on the recruitment flier.

SECTION D: Rationale for Modification/ Amendment
Section Notes… • **D2.** If currently enrolled participants are unaffected by the modification/ amendment or consent is not obtained from subjects, explain below. Example: *The amendment is for a change in co-investigator who does not interact with the subjects.* Example: *The amendment is an administrative change and this study is an anonymous telephone survey.* Example: *The amendment is to revise the study design to include an additional intervention. The subjects will be re-consented at the time of their next study visit using the revised consent form which is being submitted for IRB approval along with this amendment request.*

D1. Explain the rationale for the proposed modification/ amendment below.

The researchers are recruiting only ages 45-60 because all younger subjects have been recruited. The eligibility has been changed because bifocal wearers are not needed and participants can wear reading glasses or contacts.

D2. Explain how the new information (modification/ amendment) will be communicated to currently enrolled subjects?

Changes will be made to the recruitment materials.

SECTION E: Principal Investigator Signature

_____	_____
Principal Investigator (PRINT NAME)	Principal Investigator (SIGNATURE)
_____	_____
DATE	DATE
_____	_____
Student Principal Investigator (PRINT NAME) (SIGNATURE)	Student Principal Investigator
_____	_____
DATE	DATE

Reminders: Make sure all questions that are applicable have been answered on this form. To avoid automatic IRB termination of your study, request for Continuing Review should be submitted no later than one month before the date of IRB expiration.

Amendment submissions with IRB# of 09.210 and higher (e.g., 09.215, 09.300, 10.010) may be submitted **electronically by email** to irbinfo@uwm.edu. Type "Amendment Submission" in the subject line. All other Amendment submissions with IRB# 09.209 and lower (e.g., 03.02.052, 05.02.200, 07.02.350, 08.325, 09.199) must **submit 3 collated copies in paper (2 copies + 1 signed original)**.

Department of University Safety & Assurances

ContinuingReview-NoticeofIRBExpedited Approval

Benjamin J. Kennedy, MA IRB Manager
Institutional Review Board
Engelmann 270
P. O. Box 413
Milwaukee, WI
53201-0413
(414) 229-3182 phone (414) 229-6729 fax http://www.irb.uwm.edu
kennedbj@uwm.edu

UNIVERSITY of WISCONSIN
UWMILWAUKEE

Date: October 7, 2011

To: Kurt Beschorner, Ph.D.
Dept: Industrial Engineering

Cc: --------

IRB#: 11.069
Title: Role of Bifocal Lens Glasses on Walking Balance

After review of your research protocol by the University of Wisconsin – Milwaukee Institutional Review Board, your protocol has received continuing approval as minimal risk Expedited under category 4 & 7 as governed by 45 CFR 46.110.

This protocol has been approved on October 7, 2011 for one year. IRB approval will expire on October 6, 2012. If you plan to continue any research related activities (e.g., enrollment of subjects, study interventions, data analysis, etc.) past the date of IRB expiration, a Continuation for IRB Approval must be filed by the submission deadline. If the study is closed or completed before the IRB expiration date, please notify the IRB by completing and submitting the Continuing Review form found on the IRB website.

Unless specifically where the change is necessary to eliminate apparent immediate hazards to the subjects, any proposed changes to the protocol must be reviewed by the IRB before implementation. It is the principal investigator's responsibility to adhere to the policies and guidelines set forth by the UWM IRB and maintain proper documentation of its records and promptly report to the IRB any adverse events which require reporting.

It is the principal investigator's responsibility to adhere to UWM and UW System Policies, and any applicable state and federal laws governing activities the principal investigator may seek to employ (e.g., FERPA, RadiationSafety, UWMDataSecurity, UWSystempolicyonPrizes, AwardsandGifts, State gaming laws, etc.) which are independent of IRB review/approval.

Contact the IRB office if you have any further questions. Thank you for your cooperation and best wishes for a successful project.

Respectfully,

Benjamin J. Kennedy
IRB Manager
CC: Study File

Appendix I: Equivalent Text Descriptions

1. **Table 1 EqTD**

Table 1. Mean and standard deviation demographic information for young and middle-aged groups

Brief Description: Table showing the demographic information for both middle-aged and young participants.

Essential Description: The author included this table to provide the reader with specific information on the participants age, gender, weight, and height.

Detailed Description: The table consists of 5 columns and 6 rows. The first column lists gender, age, weight, and height. The first row lists both groups both middle-aged and young individuals. The second row contains the headings mean and standard deviation for both young and middle-aged groups. Columns 2-5 contains the means and standard deviations.

2. **Table 2 EqTD**

Table 2. Displays the DGI-m results of the paired t-test data for within subjects

Brief Description: Table showing the DGI-m mean and t-test results for young and middle-aged within subjects.

Essential Description: The author included this table to provide the reader with specific information on of the within group t-tests and means

Detailed Description: The table consists of 5 columns and 4 rows. The first column lists the within subjects and the groups young and middle-aged. The first row lists mean for progressive lens, mean for single lens, t-test, and p-value. Rows 2-4 list all the results of the within groups.

3. **Table 3 EqTD**

Table 3. Displays the toe clearance results of the paired t-test data for within subjects

Brief Description: Table showing the toe clearance mean and t-test results for young and middle-aged within subjects.

Essential Description: The author included this table to provide the reader with specific information on of the within group t-tests and means

Detailed Description: The table consists of 5 columns and 4 rows. The first column lists the within subjects and the groups young and middle-aged. The first row lists mean for progressive lens, mean for single lens, t-test, and p-value. Rows 2-4 list all the results of the within groups.

4. **Table 4 EqTD**

Table 4. Displays the force results of the paired t-test data for within subject

Brief Description: Table showing the force mean and t-test results for young and middle-aged within subjects.

Essential Description: The author included this table to provide the reader with specific information on of the within group t-tests and means

Detailed Description: The table consists of 5 columns and 4 rows. The first column lists the within subjects and the groups young and middle-aged. The first row lists mean for

progressive lens, mean for single lens, t-test, and p-value. Rows 2-4 list all the results of the within groups.

5. **Figure 1 EqTD**

Figure 1. a) Progressive lens regions and b) view through progressive lens
Brief Description: Picture a) shows the three regions of a progressive lens and b) shows the distorted view when looking through a progressive lens.
Essential Description: The author included these pictures to provide the reader with a visual of what is included in a progressive lens and how the distortion can affect vision.
Detailed Description: Picture a) shows the progressive lens with three regions. Top region is for far viewing, middle region is for mid viewing, and lower region is for reading viewing. The blurry regions of the sides represent the distortion caused by grinding the regions together to remove the lines. Picture b) is a looking through a progressive lens at a stair. The stair is distorted and curved due to the lens.

6. **Figure 2 EqTD**

Figure 2. Bar graph depicting DGI-m means for single and MfLs within group
Brief Description: This bar graph shows two bars per group (young and middle-aged) which illustrate the means of MfLs and single lenses.
Essential Description: The author included this bar graph to provide the reader with a visual of the difference between MfL and single lens means within each group. For DGI-m scores there is a decrease in score for MfLs in both groups.
Detailed Description: There are four bars. The pink bars represent MfLs and the blue bars represent single lenses. The x-axis contains young and middle-aged groups. Each group has a blue and pink bar to represent within group change. The MfLs bar is lower than the single lens bar representing higher DGI-m scores for MfLs in both groups. The highest number on the y-axis is 50.

7. **Figure 3 EqTD**

Figure 3. Bar graph depicting DGI-m means for single and MfLs between groups
Brief Description: This bar graph shows two bars per group (MfLs and single lenses) - which illustrate the differences between groups (middle-aged and young).
Essential Description: The author included this bar graph to provide the reader with a visual of the difference between MfL and single lens means between each group. For DGI-m scores there is no difference between group single and MfL scores.
Detailed Description: There are four bars. The green bars represent middle-aged and the blue bars represent young. The x-axis contains MfLs and single lenses. Each lens has a green and blue bar to represent between group change. Both green and blue bars are similar heights representing no difference between groups. The highest number on the y-axis is 50.

8. **Figure 4 EqTD**

Figure 4. Bar graph depicting toe clearance means for single and MfLs within groups
Brief Description: This bar graph shows two bars per group (young and middle-aged) which illustrate the means of MfLs and single lenses.

Essential Description: The author included this bar graph to provide the reader with a visual of the difference between MfL and single lens means within each group. For toe clearance scores there is a decrease in score for MfLs in both groups.
Detailed Description: There are four bars. The pink bars represent MfLs and the blue bars represent single lenses. The x-axis contains young and middle-aged groups. Each group has a blue and pink bar to represent within group change. The MfLs bar is higher than the single lens bar representing higher toe clearance scores for MfLs in both groups. The highest number on the y-axis is 200.

9. **Figure 5 EqTD**

Figure 5. Bar graph depicting toe clearance means for single and MfLs between groups
Brief Description: This bar graph shows two bars per group (MfLs and single lenses) - which illustrate the differences between groups (middle-aged and young).
Essential Description: The author included this bar graph to provide the reader with a visual of the difference between MfL and single lens means between each group. For toe clearance scores there is no difference between group single and MfL scores.
Detailed Description: There are four bars. The green bars represent middle-aged and the blue bars represent young. The x-axis contains MfLs and single lenses. Each lens has a green and blue bar to represent between group change. Both green and blue bars are similar heights representing no difference between groups. The highest number on the y-axis is 200.

10. **Figure 6 EqTD**

Figure 6. Bar graph depicting force means for single and MfLs within groups
Brief Description: This bar graph shows two bars per group (young and middle-aged) which illustrate the means of MfLs and single lenses.
Essential Description: The author included this bar graph to provide the reader with a visual of the difference between MfL and single lens means within each group. Force scores no change between bars.
Detailed Description: There are four bars. The pink bars represent MfLs and the blue bars represent single lenses. The x-axis contains young and middle-aged groups. Each group has a blue and pink bar to represent within group change. The MfLs bar is slightly higher than the single lens bar indicating no significant change in force when switching lenses. The highest number on the y-axis is 2.0.

11. **Figure 7 EqTD**

Figure 7. Bar graph depicting force means for single and MfLs between groups
Brief Description: This bar graph shows two bars per group (MfLs and single lenses) - which illustrate the differences between groups (middle-aged and young).
Essential Description: The author included this bar graph to provide the reader with a visual of the difference between MfL and single lens means between each group. For force scores there is no difference between group single and MfL scores.
Detailed Description: There are four bars. The green bars represent middle-aged and the blue bars represent young. The x-axis contains MfLs and single lenses. Each lens has a green and blue bar to represent between group change. Both green and blue bars are

similar heights representing no difference between groups. The highest number on the y-axis is 2.0.

12. Appendix A.1 EqTD

Figure 1. a) Progressive lens regions and b) view through progressive lens

Brief Description: Picture a) shows the three regions of a progressive lens and b) shows the distorted view when looking through a progressive lens.

Essential Description: The author included these pictures to provide the reader with a visual of what is included in a progressive lens and how the distortion can affect vision.

Detailed Description: Picture a) shows the progressive lens with three regions. Top region is for far viewing, middle region is for mid viewing, and lower region is for reading viewing. The blurry regions of the sides represent the distortion caused by grinding the regions together to remove the lines. Picture b) is a looking through a progressive lens at a stair. The stair is distorted and curved due to the lens.

13. Appendix A.2 EqTD

Research hypotheses design figure

Brief Description: Figure represents hypothesis one, two, and three through boxes and arrows.

Essential Description: The author included this figure to provide the reader with a visual to better understand the hypotheses.

Detailed Description: The top two boxes represent hypothesis one which is the switch between lenses in young novice wearers. The bottom two boxes represent hypothesis two which is the switch between lenses in middle-aged novice wearers. The arrow connecting the change between the switch of lenses represents hypothesis three which is the comparison between the two group changes when switching lenses. The circles represent the three biomechanical variables and the DGI-m.

14. Appendix A.3 EqTD

Table of participant group demographics

Brief Description: Table represents each group demographics. Shows that the two groups are middle-aged and young, both are novice wearers, and they both will be wearing single and MfL glasses.

Essential Description: The author included this figure to provide the reader with a visual to better understand the two groups.

Detailed Description: The table contains 3 rows and 4 columns. The first row contains group, age, experience, and glasses. The first column contains group one and two. The column under age includes young and middle-aged. The column under experience includes novice for both and the column under glasses contains MfL/single for both.

15. Appendix A.4 EqTD

Participant stepping over a shoebox as one of the DGI-m tasks.

Brief Description: Picture represents the shoebox task for the DGI-m.

Essential Description: The author included this figure to provide the reader with a visual of a participant performing one of the DGI-m tasks.

Detailed Description: The participant is in mid-step when walking down a gridded runway. The participant is stepping over a show box. The participant is wearing lenses and motion capture markers.

16. Appendix A.5 EqTD

Picture of a participant's lower body with motion capture markers
Brief Description: Picture represents participant with motion capture markers on their leg.
Essential Description: The author included this figure to provide the reader with a visual of where the markers are located on the participant's legs.
Detailed Description: There are 7 markers on the side of one leg. There are 3 markers on the side of the middle of the thigh, one marker on the lateral knee, and 3 markers on the side of the middle of the calf.

17. Appendix A.6 EqTD

Picture of the flow of DGI-m tasks.
Brief Description: Picture represents the order of DGI-m tasks.
Essential Description: The author included this figure to provide the reader with a visual the clearly order the DGI-m tasks.
Detailed Description: The DGI-m consists of nine walking tasks. These include: walking at normal speed, changing speeds, turning the head horizontally while walking, turning the head vertically, walking then pivoting, stepping over a shoebox and diagonal long box, stepping around cones, and stepping on and off a platform.

18. Appendix A.7 EqTD

Represents the within and between group analysis
Brief Description: Shows the data analysis for the variables DGI-m, toe clearance, and normal force. The raw scores are compared for the within group analysis and the difference between mean scores are compared for the between analysis.
Essential Description: The author included this figure to provide the reader with a visual that clearly represents the within and between data analysis for each variable. It also represents the raw scores and means needed for each test.
Detailed Description: **Brief Description:** Picture represents the order of DGI-m tasks.
Essential Description: The author included this figure to provide the reader with a visual the clearly order the DGI-m tasks.
Detailed Description: There are 5 rows and 3 columns. The first row contains within and between analysis. The second row contains the variable and the switch between single and MfL glasses for each within and between group analysis. Column one contains the variables of DGI-m, toe clearance, and normal force. The within group analysis compares raw scores and the between group analysis compares mean scores of each group.