ASSESSING THE QUALITY OF FUNCTIONAL VISION THROUGH ADSPECS

A thesis presented to the graduate faculty of New England College of Optometry in partial fulfillment of the requirements for the degree of Master of Science

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April, 2015

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ABSTRACT

Purpose: To determine if there are differences in quality of vision when wearing Adjustable Spectacles (AdSpecs) compared to habitual eye glasses, and more specifically to determine whether AdSpecs have any adverse effects on visual function.

Methods: 30 adults 21-41 years of age; 7 males and 23 females of various ethnic backgrounds were recruited from New England College of Optometry. Distance Visual Acuity (DVA), Near Visual Acuity (NVA) and Contrast Sensitivity (CS) were all measured monocularly and binocularly. DVA was measured using a Good-lite ETDRS chart (ESV3000) at 4 meters. NVA was measured using a Precision Vision ETDRS 2000 Series Chart near card at 40 cm. CS was measured using a Mars Test (mars perceptrix) at 50 cm with chart luminance of 90-100 cd/m^2. Lateral and Vertical Phorias were measured by Modified Thorington at 40 cm. All near tests were done in primary gaze and down gaze (45° from primary gaze) with both AdSpecs and Habitual Correction (HC). Convergence Insufficiency Symptoms Survey (CISS) scores between AdSpecs and HC were also compared. Inclusion criteria were: Hyperopia +1.50D to +4.50D, Myopia -0.75D to -6.00D,

Astigmatism ≤2.00D, Anisometropia <1.00D and entering corrected distance VA of 20/25 in each eye or better. Exclusion criteria were: Best corrected distance VA worse than 20/25, amblyopia, strabismus, history of ocular surgery, or current or previous eye disease other than resolved anterior segment inflammatory/infectious disease.

Results: DVA mean for the right eye (OD) was -0.230 ± 0.120 with HC and -0.150 ± 0.112 with AdSpecs (mean diff.: 0.080 ±0.111 p-value: 0.0004*). NVA mean for OD was -0.035 ± 0.060 with HC and +0.009 ± 0.090 with AdSpecs (mean diff.: 0.044±0.086, p-value: 0.009*). CS mean for OD was 1.761 ±0.07 with HC and 1.768 ±0.05 with AdSpecs (mean diff.: -0.007±0.073, p-value: 0.62). Lateral Phoria mean was -3.567pd (Exo) ±4.745pd with HC and -3.483pd (Exo) ±5.154pd with AdSpecs (mean diff.: 0.084±1.737 pd, p-value: 0.79). Vertical Phoria mean was +0.017pd (RHyper) ±0.425pd with HC and -0.083pd (RHypo) ±0.475pd with AdSpecs (mean diff.: -0.10±0.462pd, p-value: 0.25). CISS mean score was 13.633 ± 9.004 with HC and 11.667 ± 11.966 with AdSpecs (mean difference: -1.967± 9.00, p-value: 0.24).

Conclusion: This study investigated if AdSpecs have any adverse effects on visual function. Statistically significant reduction in DVA and NVA with AdSpecs compared to HC was found. This may not necessarily translate into a clinically significant reduction that can affect one's quality of life based on some studies. CS, Phoria and CISS score were not statistically different between AdSpecs and HC. Despite the statistical difference in VA that this study showed, AdSpecs appear to be a feasible way to measure and correct refractive error in the developing world where access to eye care is limited. However, there remain some unanswered questions with respect to the long term use of these adjustable glasses.

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GENERAL INTRODUCTION

Visual impairment is one of the most common and important preventable conditions in the world today. It is defined by the American Optometric Association as "a functional limitation of the eye(s) or visual system and can manifest as reduced visual acuity or contrast sensitivity, visual field loss, photophobia, diplopia, visual distortion, visual perceptual difficulties, or any combination of the above" and by the World Health Organization (WHO) as "best corrected visual acuity of 20/70 or worse in the better eye". In 1999 the topic of preventable visual impairments took center stage when a global initiative was launched to address it. Vision 2020: The Right to Sight is a partnership created between the WHO and the International Agency for the Prevention of Blindness (IAPB) (Ackland, 2012). Backed by Resolution WHA 59.25 and Resolution WHA 59.26, the global initiative aims to eliminate all worldwide avoidable blindness by the year 2020. In an effort to raise the profile of Uncorrected Refractive Error (URE), these resolutions have directly led to the development of over 100 Vision 2020 national plans throughout the world (IAPB website; advocacy). While there have been numerous success stories in this regard, it is also important to remind ourselves of the challenges that lay in store.

Perhaps one of the most pressing issues Vision 2020 attempts to address is the definition of blindness itself. Given that the current classification of visual impairment is based upon the ICD-10 1st and 2nd editions derived from a WHO study held in 1972 (Lalit and Rakhi, 2006). ICD is the 10th revision of the International Statistical Classification of Diseases and Related

Health Problems; a medical classification list by the WHO. It contains codes for diseases, signs and symptoms, abnormal findings, complaints, social circumstances, and external causes of injury or diseases. While Trachoma, Onchocerciasis, Xerophthalmia and Cataract were quite well covered at the time, there was no consideration of Refractive Error (RE) as an underlying cause of visual impairment (Lalit and Rakhi, 2006). Unfortunately, and in spite of its high prevalence and ease to treat, RE has been largely ignored by the organizations mentioned above. Consequently, URE remains the leading cause of visual impairment worldwide.

As with many other health impairments, URE is more prevalent in the developing world. Its prevalence seems closely related to the critical issue of health care provider access and availability. Other than the data made available through Vision 2020 not much research had been conducted in this regard on a broader global level. Nonetheless, there have been a number of country specific studies which focused on the prevalence of RE, especially in children.

A literature review had been conducted to shed light upon three critical aspects related to the research project at hand. First and in order to grasp the severity of the topic of URE, a global data and incidence perspective will be presented. Second, a broad reflection on topics of RE and relevant evidence available, as it relates to this study. Third, revisiting and highlighting a variety of literatures available on the topic of Adjustable Spectacles (AdSpecs).

GLOBAL DATA AND INCIDENCE OF UNCORRECTED REFRACTIVE ERROR

According to the latest data published by the WHO statistics, URE stands for approximately 42 percent of all recorded cases of visual impairment across the world (See figure 1). Two facts stand out when addressing the prevalence of URE. First and foremost is the fact that nearly 80% of all visual impairment can be prevented or cured. Second, data from 2007 shows that there are 703 million cases of visual impairment worldwide due to URE; this includes distance and near vision impairment (Fricke, Holden, Wilson, Schlenther, Naidoo, Resnikoff, and Frick, 2012).

Data over the last 20 years shows that there has been significant progress in preventing and curing visual impairment in many countries. Based upon early estimates from the 90s the incidence of visual impairment has continued to decrease worldwide. Unfortunately though, URE in children continues to be the leading cause of visual impairment in the world. Current worldwide data indicates that there are still about 19 million children who are visually impaired. Of these, 12 million children are visually impaired due to RE (WHO; Visual Impairment and blindness, 2014), a condition that could otherwise certainly and most easily be diagnosed and corrected. In addition, several studies have shown that the prevalence of RE and specifically myopia is projected to rise as the level of education increases. Studies conducted in Asia, Australia, Europe and the US have shown that near work intensity and the level of education are positively correlated with the prevalence of myopia (Mirshahi, Ponto, Hoehn, Zwiener, Zeller, Lackner, Beutel and Pfeiffer, 2014; French, Morgan, Mitchell and Rose, 2013; Gwiazda, Deng , Dias and Marsh-Tootle, 2011; Pi et al, 2011; Pi, Chen, Liu,

Ke, Fang, Zhang, Xiao, Ye, Xiong, Shi and Yin, 2010). Although, no studies in regards to this topic were conducted in Africa, the outcome is expected to be the same. As the level of education starts to increase in the developing world, there will be a major increase in the prevalence of myopia. This will in turn overwhelm an already limited eye care system in those underserved areas.

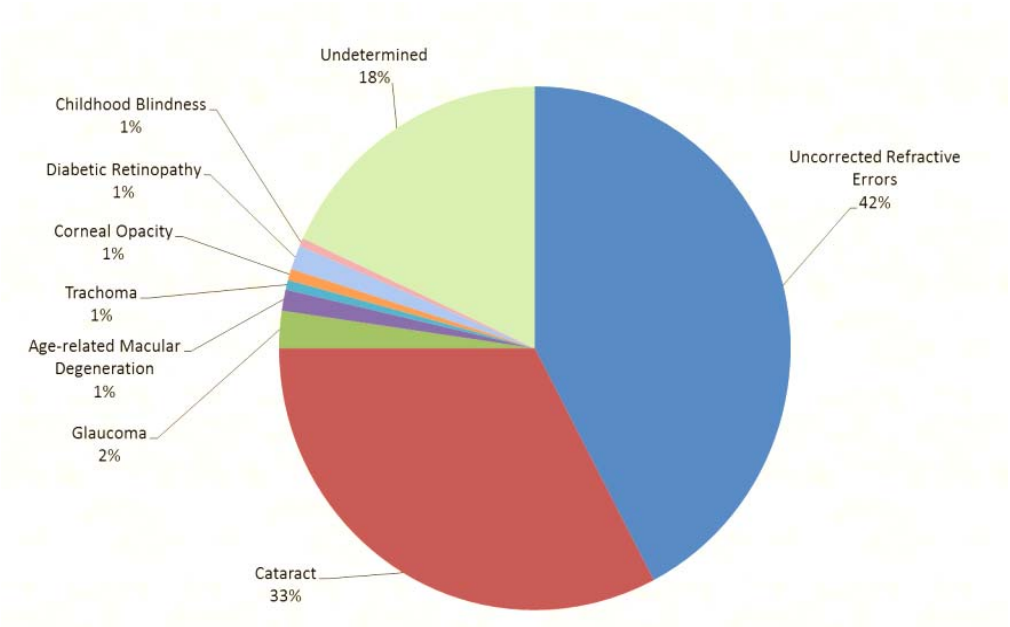


Figure 1: Global causes of visual impairment (including blindness).
(Pascolini & Mariotti, 2012)

PREVALENCE OF REFRACTIVE ERROR

Several country specific studies have been conducted to show the prevalence of RE. Refractive Error Study in Children (RESC) represents a series of surveys that began in 1998 and were carried out in several rural areas of the world; such as in Nepal, China, Chile, India and South Africa, and were done on children 5-15 years of age. RESC results from La Florida, Chile reported that RE was the cause in 56.3% of the 1,285 eyes examined with reduced vision (20/40 or worse in the better eye) (Maul, Barroso, Munoz, Sperduto and Ellwein, 2000). In addition, results from Shunyi District, China showed that RE was the cause in 89.5% of the 1,236 eyes tested with reduced vision (20/40 or worse in the better eye) (Zhao, Pan, Sui, Munoz, Sperduto and Ellwein, 2000). Also, results of the same study done in New Delhi, India showed that RE was the cause in 81.7% of eyes with vision impairment (VA of 20/40 or worse in the better eye) (Murthy, Gupta, Ellwein, Muñoz, Pokharel, Sanga and Bachani, 2002). Moreover, results from Nepal demonstrated that RE was the cause in 56% of 200 eyes with reduced uncorrected vision in their study (20/40 or worse in at least one eye), (Pokharel, Negrel, Muno and Ellwein, 1999).

In addition to the RESC data, a study conducted in Cape Coast, Ghana on 957 children aged between 5 and 19 years showed that 25.6% of the children had refractive errors. Respectively, 4.6% had hyperopia, 6.9% had myopia and 14.1% had astigmatism (Ovenseri-Ogbomo and Omuemu, 2010). Another study done in Southwest Singapore on 2639 children aged 6 to 72 months showed an overall myopia prevalence of 11.0% and the prevalence of 1.4%, 8.6%, and 0.6% for hyperopia, astigmatism, and anisometropia respectively (Dirani,

Chan, Gazzard, Hornbeak, Leo, Selvaraj, Zhou, Young, Mitchell, Varma, Wong and Saw, 2010).

The studies mentioned above are only a few of many studies which demonstrate that RE is common in children in different parts of the world. Access to eye care to correct RE in many areas of the developing world is overwhelmingly difficult due to cost and lack of eye care providers. Vision screening proves to be effective in identifying children benefiting from refractive correction. However, correcting the vision of children detected by screening is resource-intensive. Subjective refraction by a trained professional requires skilled practitioners who are locally available. Automated refraction by auto-refractors in itself requires access to expensive equipment, which need to be adequately-maintained and calibrated. Retinoscopy is a less expensive approach but it is a difficult technique which requires intense training. Self-refracting devices offer a new approach to RE correction in these underserved areas. Devices such as focometers and smart-phone based applications are only capable of measuring RE, as opposed to correcting it. However, self-refraction glasses not only measure RE but may also be worn as a corrective device. This eventually allows RE correction to occur independent of specialized eye care professionals. This approach will permit the limited number of professionals to focus their skills and time on more complex cases. In addition, self-refraction glasses can be utilized as a screening tool; where individuals who are unable to achieve improved vision with self-refraction may be identified as needing more specialized care. Ultimately, this will allow the limited number of eye care providers to work at their highest professional level. In addition, in the circumstances of the

anticipated myopia prevalence increase as mentioned earlier, self-refraction glasses can demonstrate an even greater contribution to the issue of URE.

There are different types of self-refraction glasses. The one that this thesis study will focus on is the fluid-filled type called Adjustable Spectacles (AdSpecs).

INTRODUCTION TO ADSPECS

AdSpecs are adjustable glasses based on the process of "self-refraction" which is the ability to correct one's own vision. They offer the user the ability to change the power of each lens independently to improve vision in each eye (Figure 2).

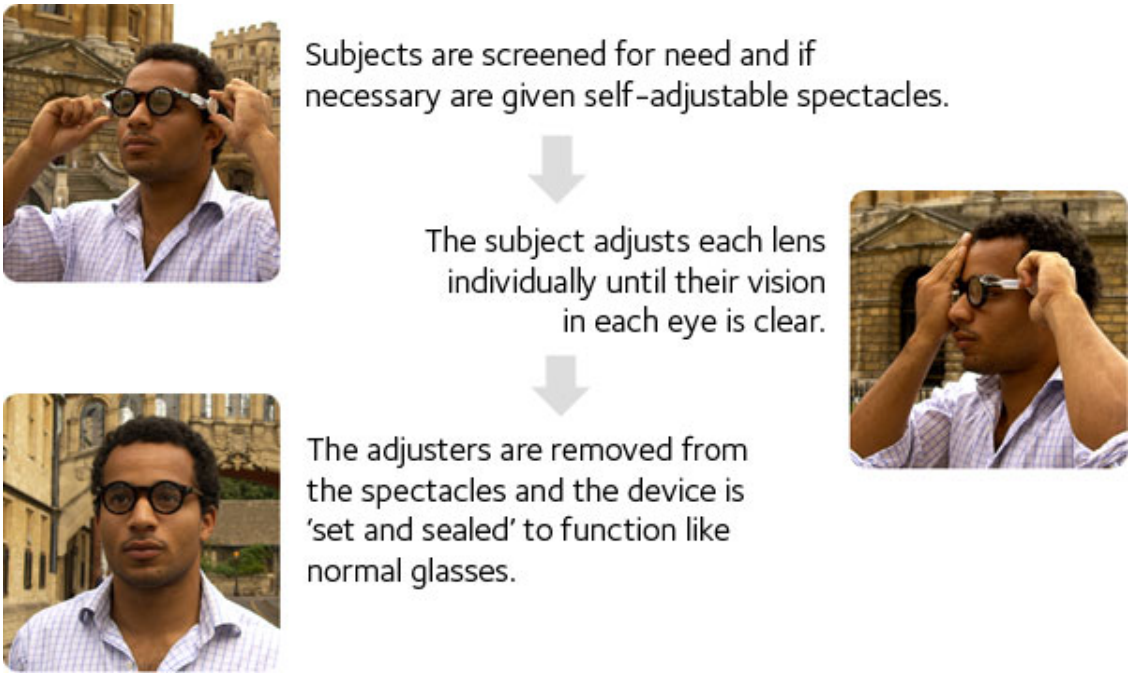


Figure 2: Demonstration of the Self-Refraction Process

Each lens contains two thin membranes, both of which are sealed and stretched at a circular perimeter of diameter 42 mm by a circular frame and the volume between them is filled with a silicone liquid of refractive index 1.579. The optical power of the resulting lens is determined by the curvature of its surfaces which in turn is controlled by varying the volume of liquid in the lens. When fluid is pumped in, the bladder carrying the fluid becomes fatter resulting in a convex lens shape and a more plus power system correcting for farsightedness (hyperopia). When fluid is removed, the bladder carrying the fluid becomes thinner resulting in a concave lens shape and a more minus power system correcting for nearsightedness (myopia) (Figure 3). Hard plastic membranes house the soft lens bladder on each side to provide a durable protective surface.

These self-refracting spectacles only provide spherical correcting lenses and have a useful power range of -7.00 D to +6.00 D.

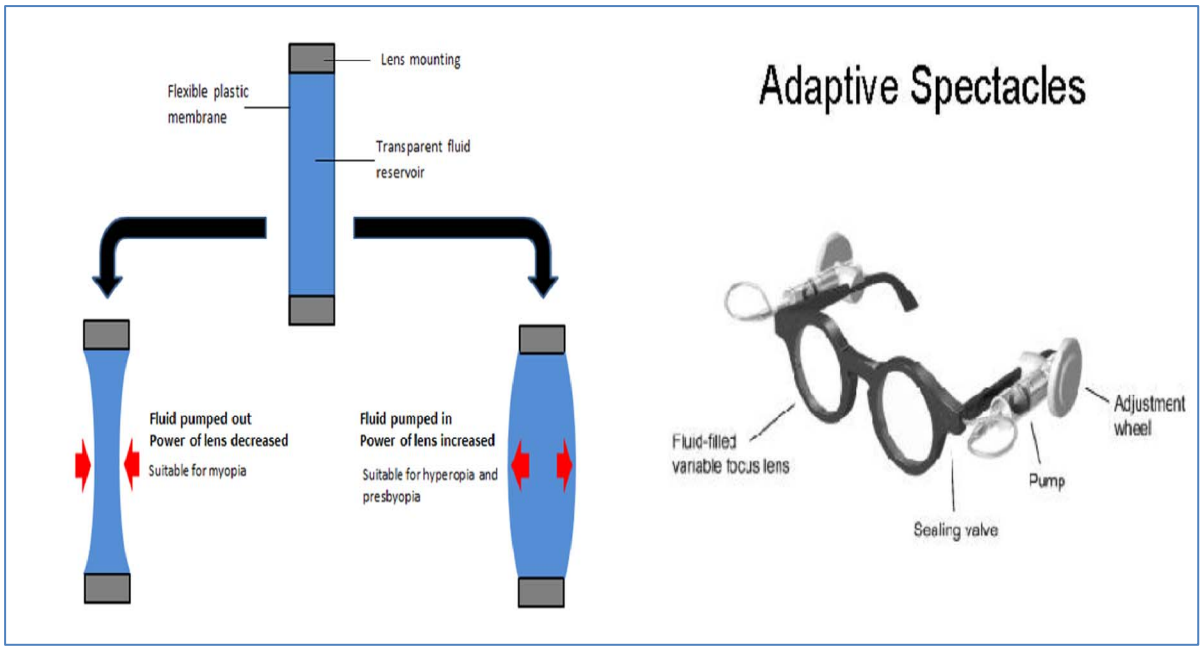


Figure 3: Demonstration of the AdSpecs fluid-filled system

AdSpecs are currently being used in a number of areas in the world for a variety of purposes, and by different organizations. Figure 4 shows a map demonstrating where AdSpecs are currently used in the world. These Adjustable glasses are convenient as they do not only measure RE but can also be used as a corrective device. However, there are a number of limitations to this technology. The most notable three being: 1) the inability to correct astigmatism, where it is unclear whether a self-refraction method would be able to provide this type of correction; 2) the range of the corrective power is limited; hence extreme cases of myopia or hyperopia cannot be corrected; 3) lastly, for individuals who are unfamiliar with vision correction, it may be difficult for them to understand the fitting and explanation of the concept.

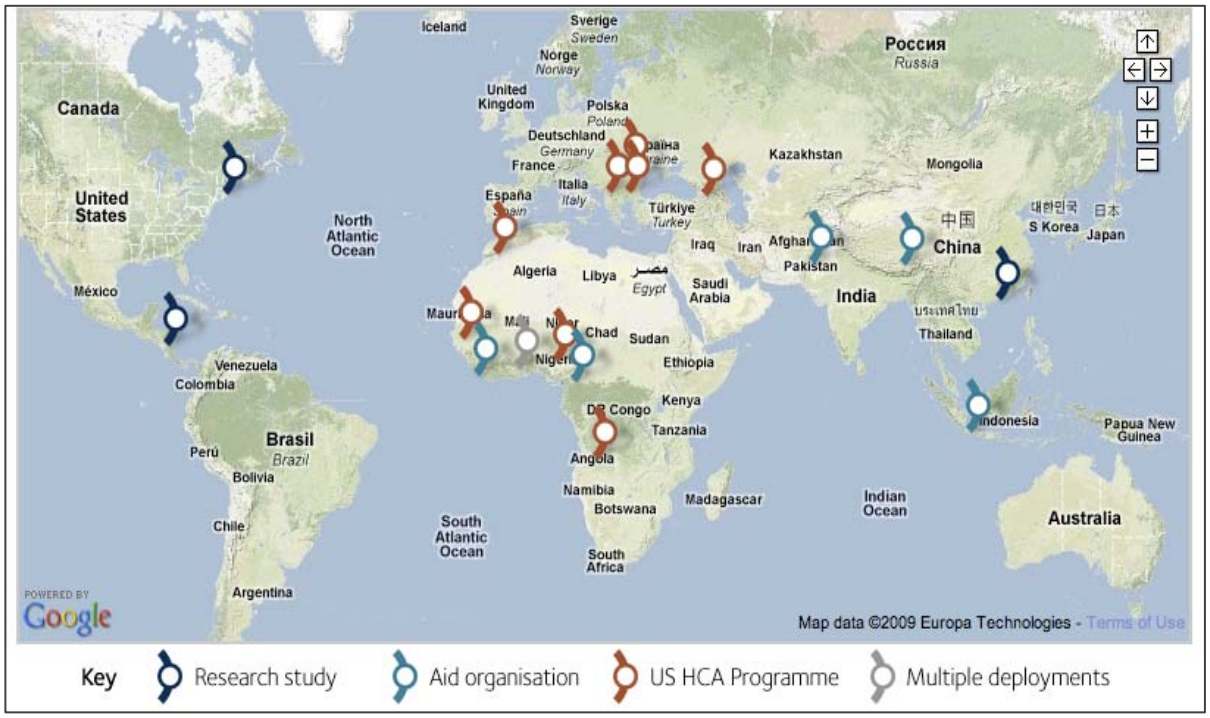


Figure 4: World map with markers showing where AdSpecs are used (US HCA=United States Health Care Administration)

Several studies have been conducted in the past which have shown that AdSpecs can successfully be used by school aged children and they can also provide good VA. The Child Self-Refraction Study (CSRS) conducted in Guangzhou, China compared visual and refractive outcomes between noncycloplegic self-refraction using AdSpecs, noncycloplegic and cycloplegic autorefraction, and cycloplegic subjective refraction in 554 Chinese children 12-17 years of age. The study found that the percentage of children with visual acuity better or equal to 6/7.5 (20/25 in Snellen notation) in the better eye to be 34.8% with habitual correction, 92.4% with self-refraction, 99.5% with noncycloplegic autorefraction, and 99.8% with cycloplegic subjective refraction. The mean difference between cycloplegic subjective refraction and noncycloplegic autorefraction (which was more myopic) was significant (–0.328D, $P<0.001$), whereas cycloplegic subjective refraction and self-refraction did not differ significantly (–0.009D, $P= 0.33$). The study concluded that a large number of their subjects (92.4%) was able to successfully complete self-refraction and had an acuity of at least 6/7.5 (20/25) or better with AdSpecs. They also found that self-refraction appeared to be less prone to accommodative inaccuracy when compared to noncycloplegic autorefraction - another modality appropriate for use in areas where access to eye care providers is limited. The study also found that greater cylindrical power is associated with less accurate results since the AdSpecs used in the study could not correct astigmatism (He, MD, Congdon, MacKenzie, Zeng, Silver and Ellwein, 2010).

A related study that took place in Guangdong, China had 648 participants 12-18 years of age. All participants successfully completed self-refraction with AdSpecs. The percentage of children with visual acuity of 6/7.5 (20/25) or better in the better eye was 30.2% with

currently-worn spectacles, 96.9% with self-refraction, 98.4% with automated refraction and 99.1% with subjective refraction. The study reported that failure to achieve maximum recorded visual acuity of 6/6 (20/20 in Snellen notation) with self-refraction was associated with higher absolute value of myopia/hyperopia and higher astigmatism, but not age, gender or previous glasses wear. Significant inaccuracies in power (> 1.00 Diopter) were less common with self-refraction than automated refraction (4.6% versus 10.8%, $P < 0.001$). The study concluded that visual acuity with self-refraction was excellent in the large majority of their subjects and inaccurate power was less common with self-refraction than automated refraction (Zhang M., Zhang R., He, Liang, Li, She, Yang, MacKenzie, Silver, Ellwein and Moore, 2010).

Moreover, The Boston Child Self-Refraction Study that took place in Boston, Massachusetts reported results similar to those in the two related studies mentioned above. They recruited 350_children 12-18 years of age. All subjects completed self-refraction with AdSpecs, and then had a cycloplegic refraction, autorefraction, and ocular health assessment. Self-refraction resulted in a mean spherical difference of -0.23D (standard deviation: 0.67D) compared to cycloplegic subjective refraction. 98.72% of 700 eyes achieved VA of 20/32 or better, 92.15% achieved VA of 20/25 or better through their self-refraction. Only 2 subjects (0.571%) could not obtain VA of 20/32 in their better eye, and only 9 eyes (1.28%) could not obtain VA of 20/32 or better. Of the 78 eyes having astigmatism between -1.25D and -2.25D along with their myopia, none of those eyes were unable to obtain a VA of 20/32 or better. The study concluded that refractive accuracy was a mean of less than 0.25D over-minused compared to cycloplegic refraction. The combination of excellent vision and accurate

spherical refraction derived from self-refraction provide encouragement for further investigation of this technique for myopic children in regions where access to refractive care is limited or absent (Moore, Johnson, Lyons, Quinn, Tattersall, Silver, Crosby, He, Elwein, MacKenzie and Congdon, 2011).

The above studies clearly show that self-refraction with AdSpecs is successfully achieved by children and that AdSpecs may have the potential to be used as a RE measuring and correcting device that provides clear vision in children. However, it is uncertain whether this complex lens system may adversely affect visual function. Therefore, this thesis study was conducted to assess visual function through AdSpecs and to determine if there are any side effects related to the use of these self-refracting spectacles.

PURPOSE

To determine if there are differences in quality of vision when wearing AdSpecs compared to habitual eye glasses, and more specifically to determine whether AdSpecs have any adverse effects on visual function.

METHODS

PARTICIPANTS

Thirty adults 21-41 years of age, average age of 24.7 ± 3.58 years, were randomly recruited from New England College of Optometry. Subjects included 7 males and 23 females of various ethnic backgrounds.

Subjects had to meet both inclusion and exclusion criteria to be eligible to participate. Inclusion criteria were: Hyperopia +1.50D to +4.50D, Myopia -0.75D to -6.00D, Astigmatism equal or less than 2.00D, Anisometropia of less than 1.00D and entering Distance Visual Acuity (DVA) of 20/25 or better in each eye. Exclusion criteria were: Best corrected DVA of less than 20/25, amblyopia, strabismus, history of ocular surgery, current or previous eye disease other than resolved anterior segment inflammatory/infectious disease. The subjects' habitual refractive error for the right eye based on their Habitual Correction (HC) had a range of -0.75D to -5.75D sphere and -0.25D to -1.50D cylinder with a mean spherical equivalent of -3.11D ± 1.60D. The subjects' Pupillary Distance (PD) measurement had a range of 50.0-72.0 mm for far with a mean of 61.47 ±4.47 mm and 47.0-68.0 for near with a mean of 58.07 ±4.37 mm.

STUDY DESIGN

Subjects were scheduled individually by appointments. On the day of study participation, subjects were required to wear their HC for at least an hour before arriving to the appointment to ensure that they were adapted to it. Upon arrival, the purpose of the study was reviewed with each subject by the examiner and a handout with additional information was also provided (see Figure 1 in Appendix). Subjects had a chance to ask questions and voluntarily withdraw from the study if they wished. Once subjects decided to proceed, DVA with HC was measured, cover-test was performed to exclude strabismus and power of HC was verified using Marco manual lensometer (Model 101). If habitual DVA was 20/25 or better in each eye and the subjects met the other inclusion criteria, they were eligible to participate in the study and were asked to sign an informed consent (see Figure 1D in Appendix). Interpupillary distance was measured with a PD ruler. Subjects then completed a Convergence Insufficiency Symptoms Survey (CISS) questionnaire (see Figure 2 in Appendix) regarding the quality and comfort of their near vision through their HC. Following that, habitual Near Visual Acuity (NVA), Contrast Sensitivity (CS), Lateral and Vertical Phorias were all measured. The subjects had to then adjust the Adjustable Spectacles (AdSpecs) to the correct refractive power monocularly by looking at a 20/30 line at 4 meters as their target. The AdSpecs were adjusted to a power of +4.00D in each lens by the examiner before given to subjects to self-refract. Subjects were asked to cover one eye and turn the dial backwards (more minus direction) on the opposite eye, then do the same with the fellow eye. Self-refraction was done twice, first run was considered practice and the

second one was the one recorded and the subject had to wear. Once adjusted, the power was verified using manual lensometry and the subjects were instructed to wear the AdSpecs for 60 minutes. The first 30 minutes required distance viewing, and the last 30 minutes required a light reading task using magazines that were provided to subjects by the lab. The same initial survey and tests were then repeated after 60 minutes of wear time through AdSpecs.

The study focused on 5 distinct variables: Distance Visual Acuity (DVA), Near Visual Acuity (NVA), Contrast Sensitivity (CS), Phoria and CISS score.

Distance Visual Acuity (DVA) Measurement: DVA was measured in primary gaze using a Good-lite ETDRS chart (ESV3000) at 4 meters (figure 5a). ETDRS chart was placed at 4 meters from the subject in a back-illuminated stand. The ETDRS chart was printed with high-contrast letters on a translucent white polystyrene panel lit from behind and displayed in a standard light box. A single chart was used that had 5 letters per line arranged in 0.1 LogMAR steps with each letter corresponding to 0.02 LogMAR. With the proper correction worn, the subject was asked to occlude the eye not being tested and to start reading from the last row where the subject can read all of the letters correctly, then to continue reading down until the subject reached a row where three letters or more could not be identified. 0.02 log units were subtracted for every letter that was correctly identified beyond the last row where all the letters were correctly identified. The same procedure was repeated on the fellow eye and then binocularly.

Near Visual Acuity (NVA) measurement: NVA was measured using a Precision Vision ETDRS 2000 Series Chart near card at 40 cm (figure 5b). The near card was placed on a music stand at an angle of 45 degrees and was maximally illuminated with an overhead lamp. With the proper correction worn, the subject was asked to occlude the eye not being tested and to start reading from the last row where the subject can read all of the letters correctly, then to continue reading down until the subject reached a row where three letters or more could not be identified. 0.02 log units were subtracted for every letter that was correctly identified beyond the last row where all the letters were correctly identified. The same procedure was repeated on the fellow eye and then binocularly. The music stand was then moved to an upright position and NVA was measured again in the same manner mentioned above but in primary gaze.

The near card used in the study had no printed LogMAR notation on it; therefore, NVA scores were recorded in Snellen notation then converted to LogMAR using the equation below:

LogMAR= - Log (Snellen Decimal Acuity)

Contrast Sensitivity (CS) measurement: CS was measured using a Mars Letter Contrast Sensitivity Test (Mars Perceptrix) at 50 cm with chart luminance of 90-100 cd/m2 (measured with Cal-LIGHT 400 lightmeter) (figure 5c). The Mars test is approximately 23x35.5 cm in size and is printed on rigid plastic with 3 different forms. Each form consists of 48 letters,

1.75 cm high, arranged in eight rows of six letters each. Letter contrast varies from 91.2% (0.04 log units) to 1.2% (1.92 log units) with the contrast of each letter decreasing by a constant factor of 0.04 log units. Each letter subtends 2 degrees at test distance of 50cm (equivalent to 20/480 in Snellen notation).

The Mars test was administered based on the manufacturer's instructions. The test was placed on a music stand at a 45 degrees angle. The 3 forms were alternated to control for memorization. With proper correction worn, subjects were instructed to occlude the eye not being tested and start reading from left to right starting with the highest contrast letters. Subjects were encouraged to guess until they missed two consecutive letters. At that point the testing was stopped and CS was scored. A special score recording sheet provided by the manufacture was used to track the performance of the subjects. The final CS score was the log of the last correct letter minus 0.04 for each letter missed before that. The same procedure was repeated on the fellow eye and then binocularly. The music stand was then moved to an upright position and CS was measured again in the same manner mentioned above but in primary gaze.

Phoria measurement: Lateral and Vertical Phorias were measured by Modified Thorington (MT) test at 40 cm (figure 5d). The MT card was held by the examiner at 40 cm at a 45 degree angle. A trans- illuminator was inserted in the opening on the back of the card so the light was shining through the small hole at the center. With the proper correction worn, the subject was instructed to hold a Maddox rod over their right eye. For lateral phoria, the Maddox rod was held so that the subject saw a vertical line. The subject was asked to look at

the white light in the center of the card and to report which diagonal letter or number the red line intersected. For vertical phoria, the Maddox rod was rotated 90 degrees so that the subject saw horizontal line. The subject was asked again to look at the white light in the center of the card and to report which diagonal letter or number the red line intersected. If the red line passed through the white light, the patient was considered orthophoric. If the vertical line went through a number (or to the right of the light) the subject was considered to have an esophoria and if it went through a letter (or to the left of the light) the subject was considered to have an exophoria. If the horizontal line went through a number (or above the light) the subject was considered to have a right hypophoria and if it went through a letter (or below the light) the subject was considered to have a right hyperphoria. Each number or letter away from the center represented one prism diopter and that's how the amount of phoria was determined. The MT card was then held upright and the procedure mentioned above was repeated in the same manner but in primary gaze.

CISS Questionnaire: this questionnaire was developed by the Convergence Insufficiency Treatment Trial (CITT) group. It is used in clinic to assess symptoms related to Convergence Insufficiency (CI). In the CITT studies, cut-off scores of 16 for children and 21 for adults were used. In their studies, individuals who scored the cut-off scores or higher were identified as symptomatic and need binocular vision evaluation. The cut-off scoring system was not used in this thesis study. The purpose of using the questionnaire in this study was only to obtain information about the quality and comfort of the subjects' near vision through AdSpecs and their HC, and to directly compare the scores obtained by each method.

The figure that follows demonstrates the equipment used for measuring each of the independent variables mentioned in the methods section.

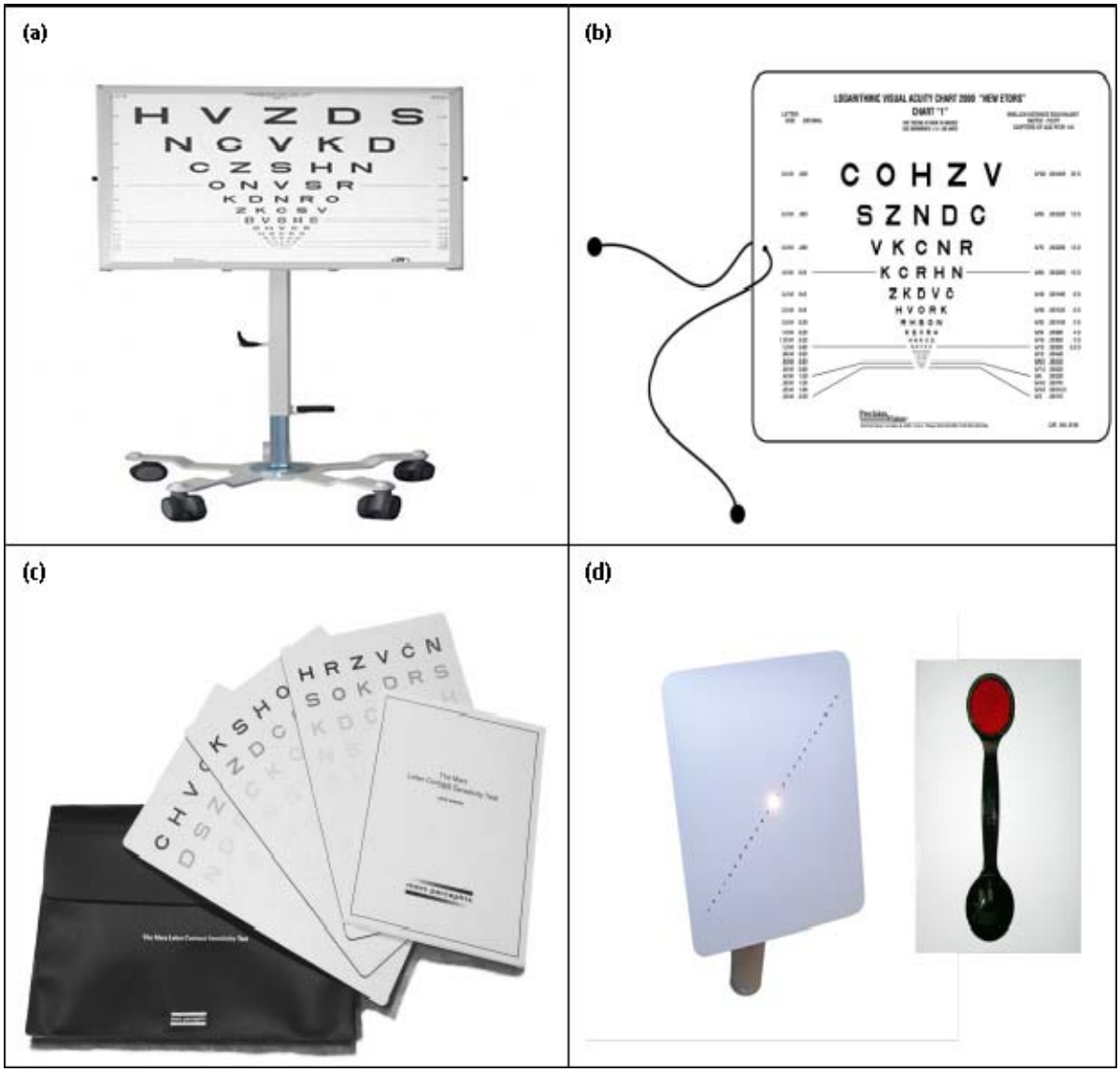


Figure 5: (a) Good-lite ETDRS Distance Chart used at 4 meters to measure DVA with both AdSpecs and HC (b) Precision ETDRS Near Chart used at 40 cm to measure NVA with both AdSpecs and HC (c) Mars (mars perceptrix) Contrast Sensitivity Test used at 50 cm to measure CS with both AdSpecs and HC (d) Modified Thorington Test with a transilluminator and a Maddox rod used at 40 cm to measure lateral and vertical phorias with both AdSpecs and HC.

After the completion of each participation appointment, a request for study compensation of $25 per subject was sent to New England College of Optometry's business office to be given to each subject who had successfully participated.

The study protocol was reviewed and approved by the Institutional Review Board of New England College of Optometry. The study protocol also met the guidelines of the World Medical Association Declaration of Helsinki-Ethical Principles for Medical Research Involving Human Subjects. All subjects signed an informed consent to participate in the study (see Figue 1D in Appendix).

DATA ANALYSIS

The measurements for each subject were written by hand on a data recording sheet for both AdSpecs and HC then manually entered into Microsoft Excel for analysis. Since the study had one sample of subjects, a paired sample t-test was used to analyze the data. This method of analysis is normally used to determine whether there is a significant difference between the mean values of the same measurement made under two different conditions, the two conditions in this study are AdSpecs and HC.

In addition, a Bland-Altman plot using 95% limits of agreement (±2SD) was graphed for DVA, NVA and CS analysis. Bland-Altman plot is a graphical method that compares the mean difference between two conditions plotted against the average of the two conditions

(Bland & Altman, 1986 and 1999). Values in this study were calculated and statistical significance was established as $p < 0.05$.

RESULTS

Data of the right eye (OD) was analyzed using a paired sample t-test with statistical significance p-value of < 0.05 for Distance Visual Acuity (DVA), Near Visual Acuity (NVA) in downgaze and Contrast Sensitivity (CS) in downgaze. There was no statistical significance between measurements made in downgaze and primary gaze for each NVA, CS and phoria. Therefore, downgaze results were chosen for analysis since this posture represents the natural head posture while reading and doing most near activities. Lateral Phoria, Vertical Phoria and CISS score were analyzed with the same method of analysis and p-value significance.

DISTANCE VISUAL ACUITY

Table 1 shows DVA values in LogMAR through Adjustable Spectacles (AdSpecs) and Habitual Correction (HC) with their average and the difference between them for each subject. DVA mean for OD was -0.230 ± 0.067 with HC and -0.149 ± 0.112 with AdSpecs (mean difference: 0.080±0.111, p-value: 0.0004) - (Figure 6).

Table 1: DVA values of OD through AdSpecs and HC with their average and the difference between them for each subject.

Subject ID	AdSpecs DVA OD(LogMAR)	Habitual DVA OD(LogMAR)	Average	Difference
1	0.02	-0.30	-0.14	0.32
2	-0.30	-0.30	-0.30	0.00
3	0.00	-0.04	-0.02	0.04
4	-0.06	-0.30	-0.18	0.24
5	-0.08	-0.26	-0.17	0.18
6	-0.26	-0.30	-0.28	0.04
7	-0.02	-0.26	-0.14	0.24
8	-0.22	-0.30	-0.26	0.08
9	-0.30	-0.30	-0.30	0.00
10	-0.30	-0.22	-0.26	-0.08
11	-0.10	-0.30	-0.20	0.20
12	-0.18	-0.20	-0.19	0.02
13	-0.22	-0.20	-0.21	-0.02
14	-0.10	-0.20	-0.15	0.10
15	-0.30	-0.30	-0.30	0.00
16	-0.28	-0.28	-0.28	0.00
17	-0.12	-0.08	-0.10	-0.04
18	-0.26	-0.30	-0.28	0.04
19	0.04	-0.22	-0.09	0.26
20	0.04	-0.14	-0.05	0.18
21	-0.24	-0.24	-0.24	0.00
22	-0.18	-0.18	-0.18	0.00
23	-0.08	-0.22	-0.15	0.14
24	-0.18	-0.20	-0.19	0.02
25	-0.12	-0.22	-0.17	0.10
26	-0.28	-0.22	-0.25	-0.06
27	-0.18	-0.18	-0.18	0.00
28	0.00	-0.28	-0.14	0.28
29	-0.06	-0.18	-0.12	0.12
30	-0.18	-0.18	-0.18	0.00

The table above demonstrates DVA values of the right eye for each subject with AdSpecs and HC. The average of the two DVA values for each subject is also presented along with the

difference between them. The average and difference values are used to graph a Bland-Altman plot (Figure 7).

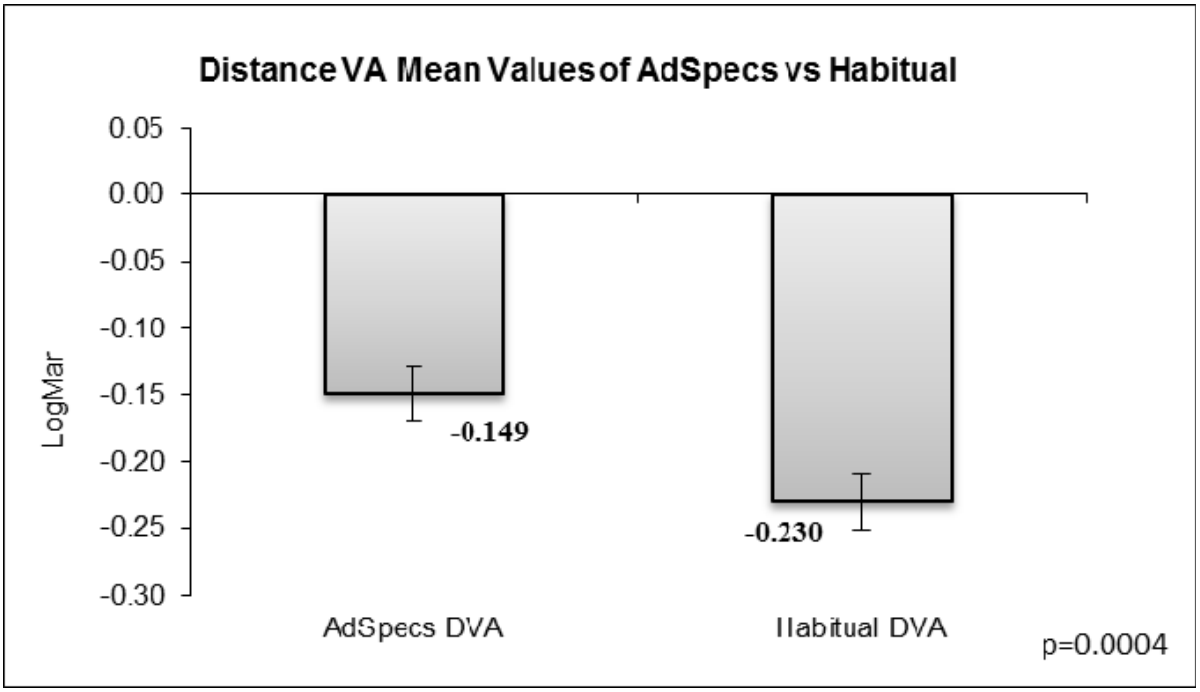


Figure 6: Graph showing mean values of the right eye for DVA through AdSpecs and HC.

A Bland-Altman plot was graphed to show the agreement between the measurements obtained with HC and AdSpecs. The difference between the two methods (y-axis) is plotted against the average of the two methods (x-axis) for each of the 30 subjects (each diamond represents a subject). The upper and the lower limits on the graph represent +/- 2 standard deviations from the mean (dashed line) (Figure 7).

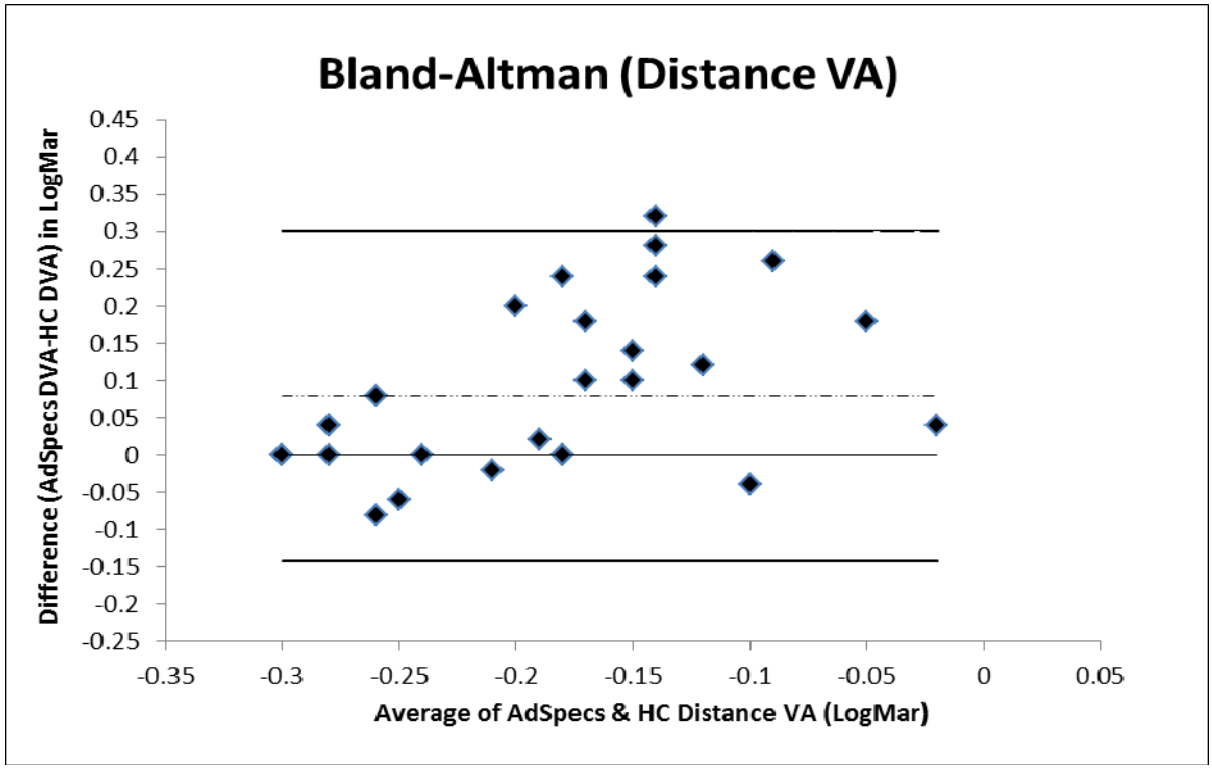


Figure 7: Bland-Altman plot showing the difference between DVA of AdSpecs and HC using 95% limits of agreement (+/- 2SD).

NEAR VISUAL ACUITY

Table 2 shows downgaze NVA values in LogMAR through AdSpecs and HC with their average and the difference between them for each subject. NVA mean for OD was -0.035 ± 0.060 with HC and +0.009 ± 0.090 with AdSpecs (mean difference: 0.044±0.086, p-value: 0.009) (Figure 8).

Table 2: NVA values in downgaze of the right eye through AdSpecs and HC with their average and the difference between them for each subject

Subject ID	AdSpecs NVA OD (LogMAR)	Habitual NVA OD (LogMAR)	Average	Difference
1	0.04	-0.02	0.01	0.06
2	0.04	0.02	0.03	0.02
3	0.00	0.02	0.01	-0.02
4	0.06	-0.08	-0.01	0.14
5	-0.04	-0.04	-0.04	0.00
6	-0.06	0.04	-0.01	-0.10
7	-0.06	-0.04	-0.05	-0.02
8	-0.08	-0.08	-0.08	0.00
9	-0.06	-0.06	-0.06	0.00
10	-0.08	-0.10	-0.09	0.02
11	0.20	0.00	0.10	0.20
12	0.10	-0.08	0.01	0.18
13	-0.08	-0.10	-0.09	0.02
14	-0.08	-0.10	-0.09	0.02
15	0.00	-0.10	-0.05	0.10
16	-0.10	-0.10	-0.10	0.00
17	-0.02	-0.08	-0.05	0.06
18	-0.04	0.00	-0.02	-0.04
19	0.20	-0.02	0.09	0.22
20	0.10	-0.06	0.02	0.16
21	0.02	0.06	0.04	-0.04
22	-0.04	0.00	-0.02	-0.04
23	0.00	-0.10	-0.05	0.10
24	-0.06	-0.02	-0.04	-0.04
25	0.04	0.02	0.03	0.02
26	-0.10	-0.16	-0.13	0.06
27	0.14	0.06	0.10	0.08
28	0.18	-0.04	0.07	0.22
29	0.10	0.10	0.10	0.00
30	-0.06	0.00	-0.03	-0.06

The table above demonstrates NVA values of the right eye for each subject with AdSpecs and HC. The average of the two NVA values for each subject is also presented along with the difference between them. The average and difference values are used to graph a Bland-Altman plot (Figure 9).

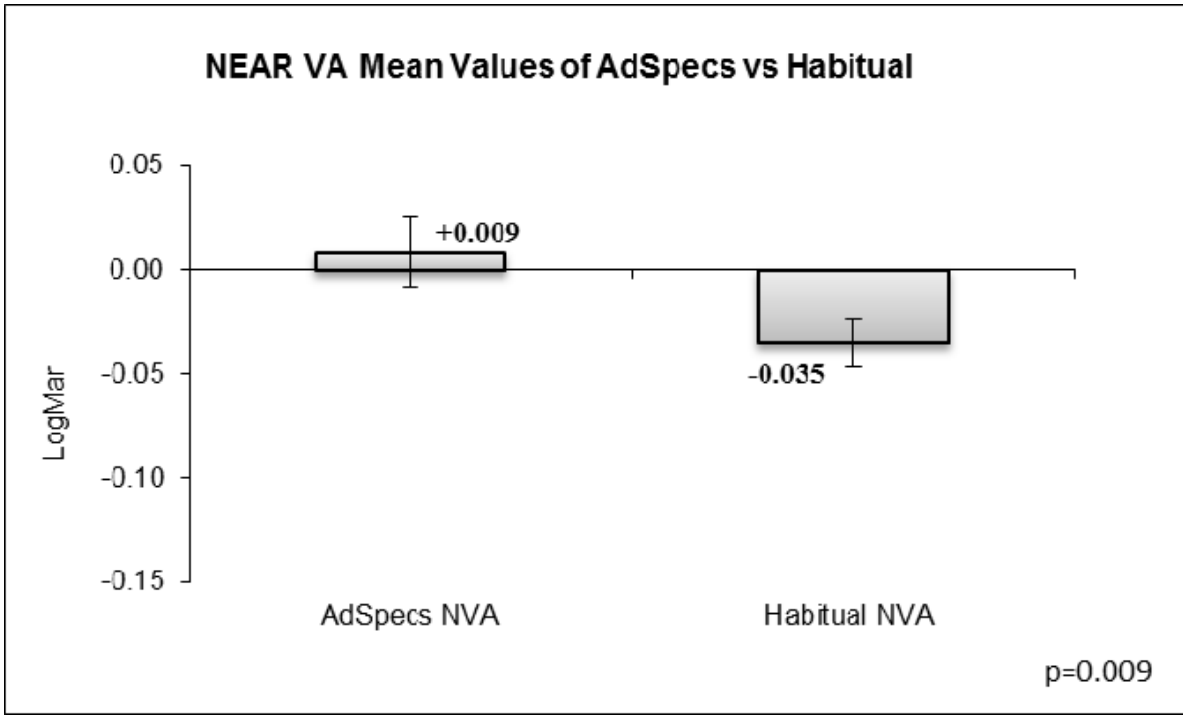


Figure 8: Graph showing mean values of the right eye for NVA through AdSpecs and HC.

A Bland-Altman plot was graphed for NVA to show the agreement between the measurements obtained with HC and with AdSpecs. The difference between the two methods (y-axis) is plotted against the average of the two methods (x-axis) for each of the 30 subjects (each diamond represents a subject). The upper and the lower limits on the graph represent +/- 2 standard deviations from the mean (dashed line) (Figure 9).

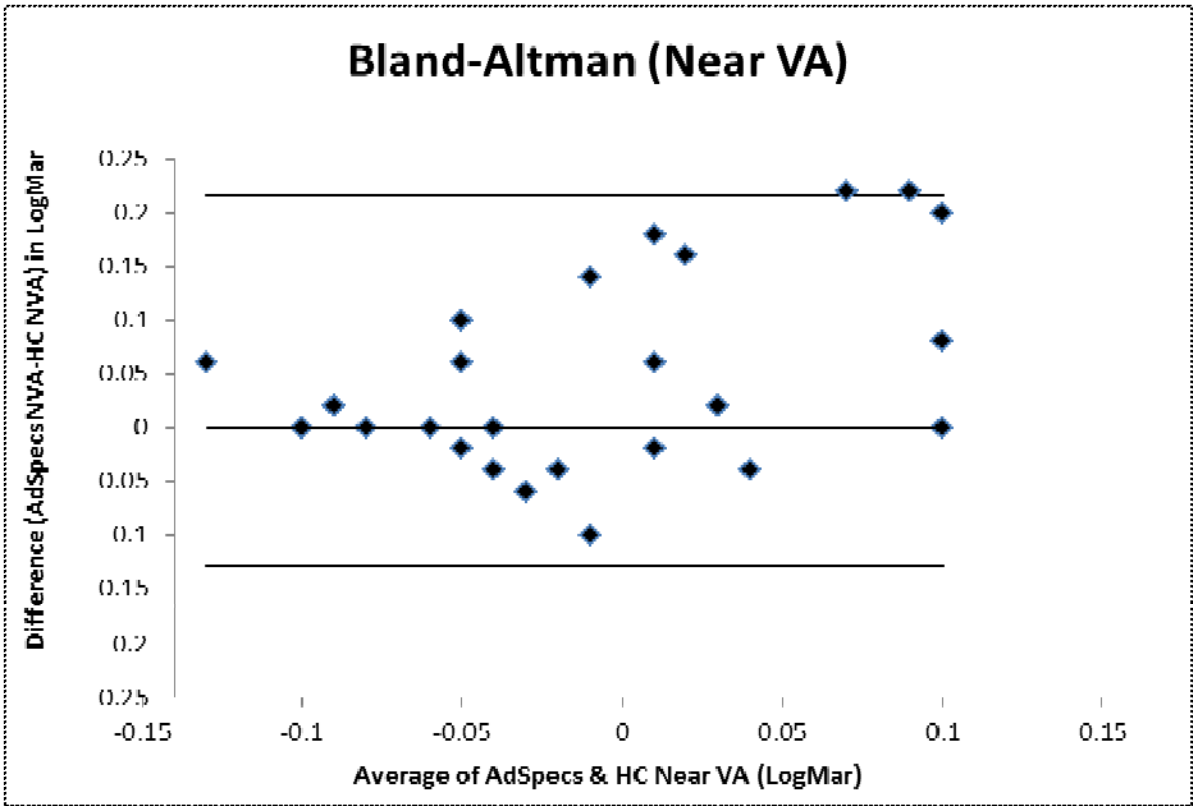


Figure 9: Bland-Altman plot showing the difference between NVA of AdSpecs and HC using 95% limits of agreement (+/- 2SD).

CONTRAST SENSITIVITY

Table 3 shows CS values through AdSpecs and HC with their average and difference between them for each subject. CS mean for OD was 1.761 ±0.068 with HC and 1.768 ±0.049 with AdSpecs (mean difference: 0.007±0.073, p-value: 0.62) (Figure 10).

Table 3: Contrast Sensitivity (CS) values in downgaze of the right eye through AdSpecs and HC with their average and the difference between them for each subject.

Subject ID	AdSpecs CS OD	Habitual CS OD	Average	Difference
1	1.68	1.76	1.72	-0.08
2	1.76	1.80	1.78	-0.04
3	1.80	1.76	1.78	0.04
4	1.76	1.72	1.74	0.04
5	1.84	1.80	1.82	0.04
6	1.80	1.76	1.78	0.04
7	1.80	1.88	1.84	-0.08
8	1.80	1.76	1.78	0.04
9	1.80	1.76	1.78	0.04
10	1.76	1.80	1.78	-0.04
11	1.80	1.68	1.74	0.12
12	1.76	1.88	1.82	-0.12
13	1.76	1.80	1.78	-0.04
14	1.80	1.84	1.82	-0.04
15	1.76	1.76	1.76	0.00
16	1.64	1.76	1.70	-0.12
17	1.80	1.80	1.80	0.00
18	1.76	1.80	1.78	-0.04
19	1.76	1.80	1.78	-0.04
20	1.72	1.72	1.72	0.00
21	1.68	1.68	1.68	0.00
22	1.80	1.72	1.76	0.08
23	1.72	1.52	1.62	0.20
24	1.76	1.68	1.72	0.08
25	1.80	1.72	1.76	0.08
26	1.84	1.76	1.8	0.08
27	1.72	1.80	1.76	-0.08
28	1.80	1.80	1.80	0.00
29	1.72	1.76	1.74	-0.04
30	1.84	1.76	1.80	0.08

The table above demonstrates CS values of the right eye for each subject with AdSpecs and HC. The average of the two CS values for each subject is also presented along with the difference between them. The average and difference values are used to graph a Bland-Altman plot (Figure 11).

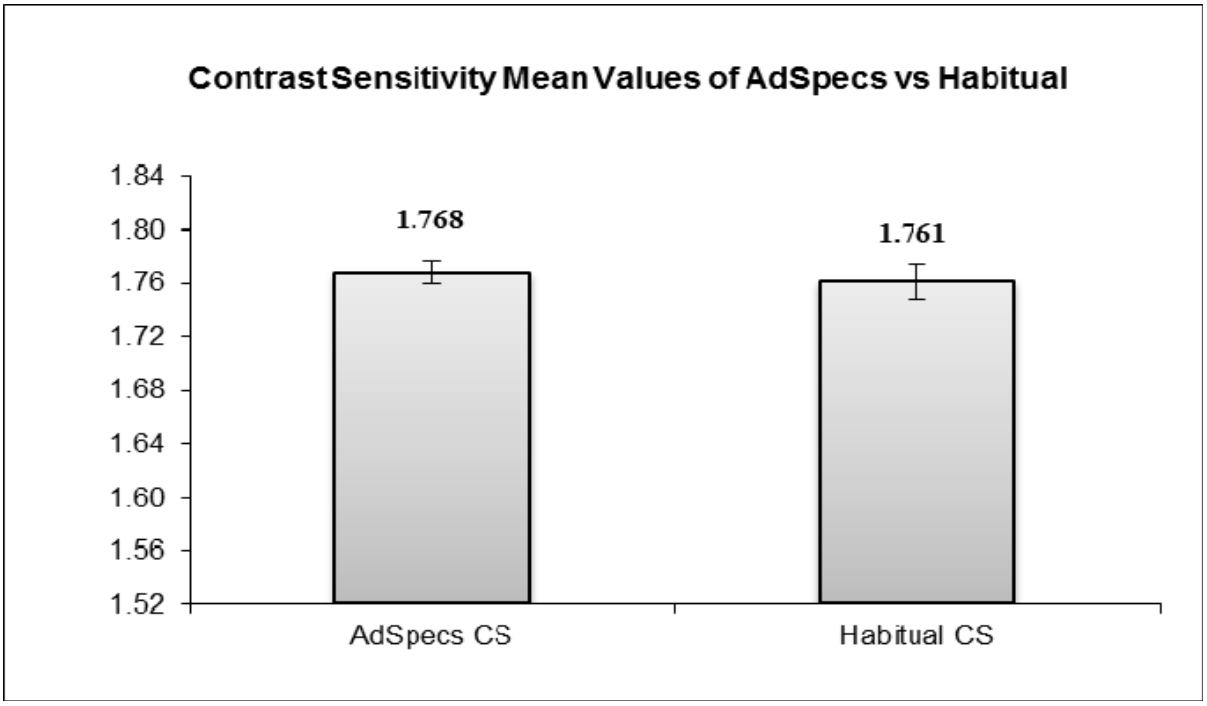


Figure 10: Graph showing mean values of the right eye for CS through AdSpecs and HC.

A Bland-Altman plot was graphed for CS to show the agreement between the measurements obtained with HC and with AdSpecs. The difference between the two methods (y-axis) is plotted against the average of the two methods (x-axis) for each of the 30 subjects (each diamond represents a subject). The upper and the lower limits on the graph represent +/- 2 standard deviations from the mean (dashed line) (Figure 11).

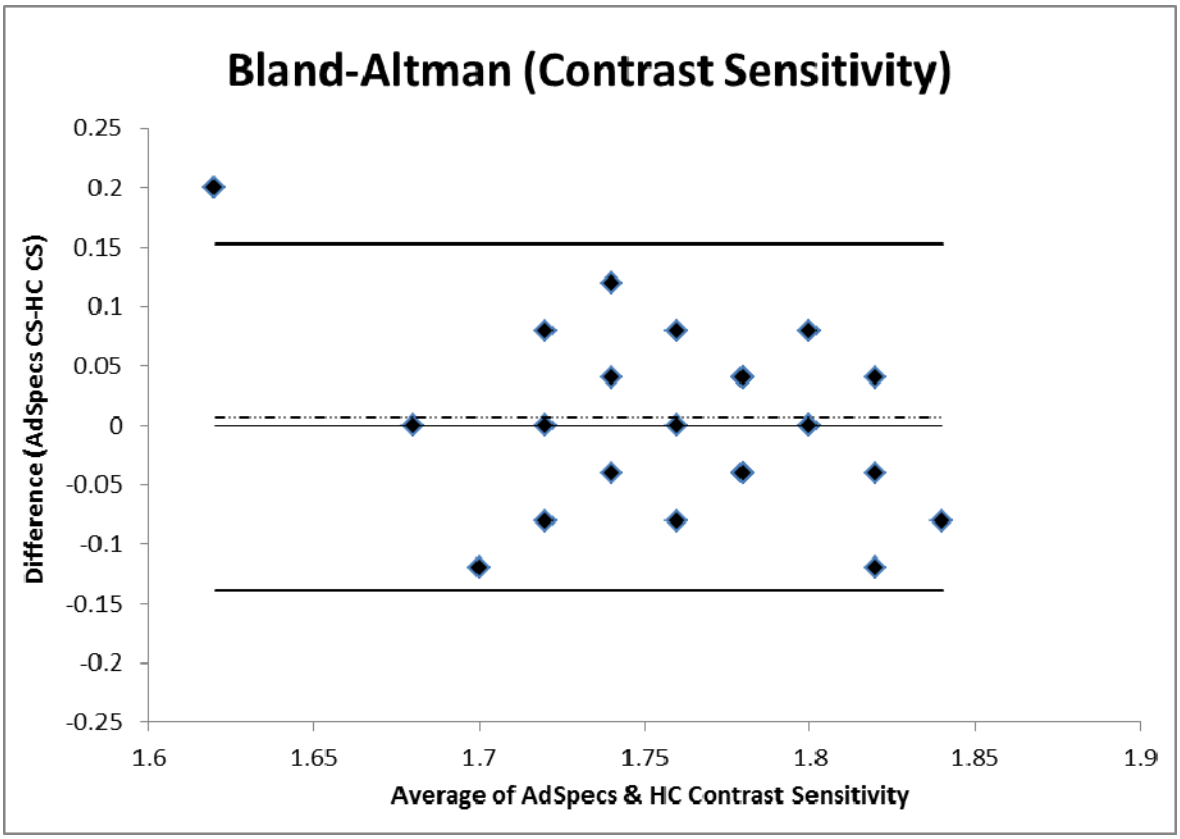


Figure 11: Bland Altman plot showing the difference between CS of AdSpecs and HC using 95% limits of agreement (+/- 2SD).

PHORIA

For lateral phoria, negative values indicate an Exo deviation and positive values indicate an Eso deviation. Lateral phoria mean was -3.567pd (Exo) ±4.745pd with HC and -3.483pd (Exo) ±5.154pd with AdSpecs (mean difference: 0.084±1.737 pd, p-value: 0.79) (Figure 12).

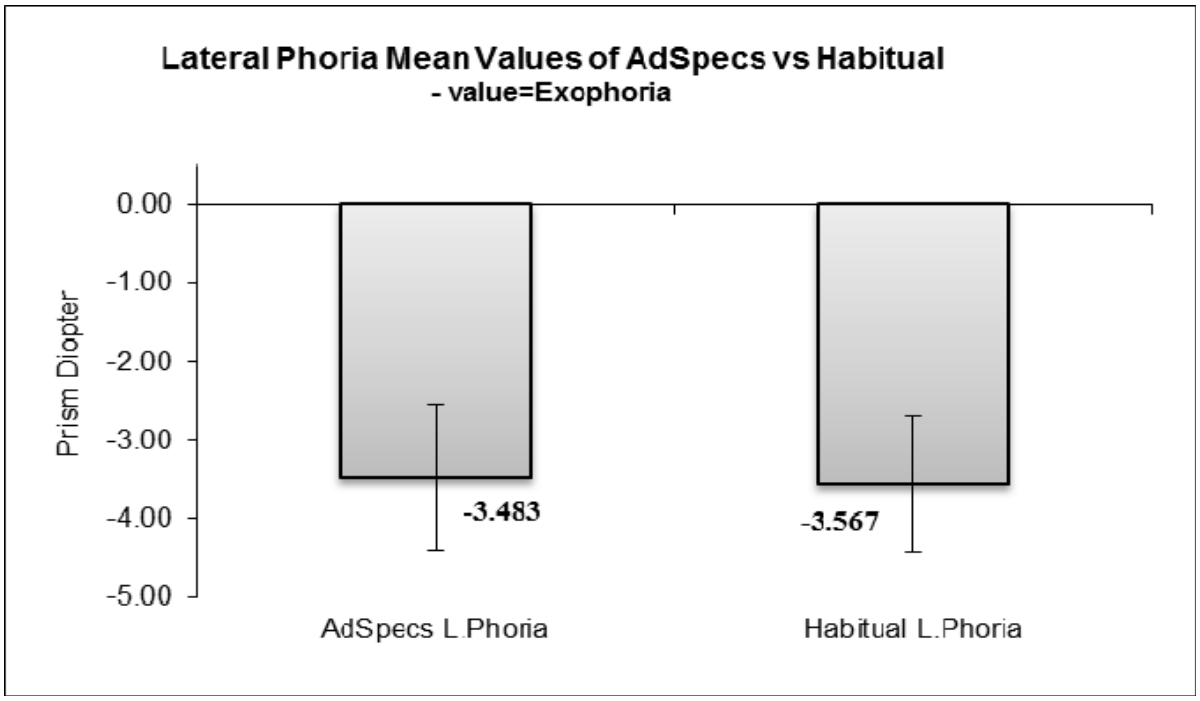


Figure 12: Graph showing the mean values of the Right eye for lateral phoria through AdSpecs and HC.

For vertical phoria, reference when recording was made to the right eye, negative values indicate Hypo deviation and positive values indicate Hyper deviation. Vertical phoria mean was +0.017pd (RHyper) ±0.425pd with HC and -0.083pd (RHypo) ±0.475pd with AdSpecs (mean difference: -0.10±0.462pd, p-value: 0.25) (Figure 13).

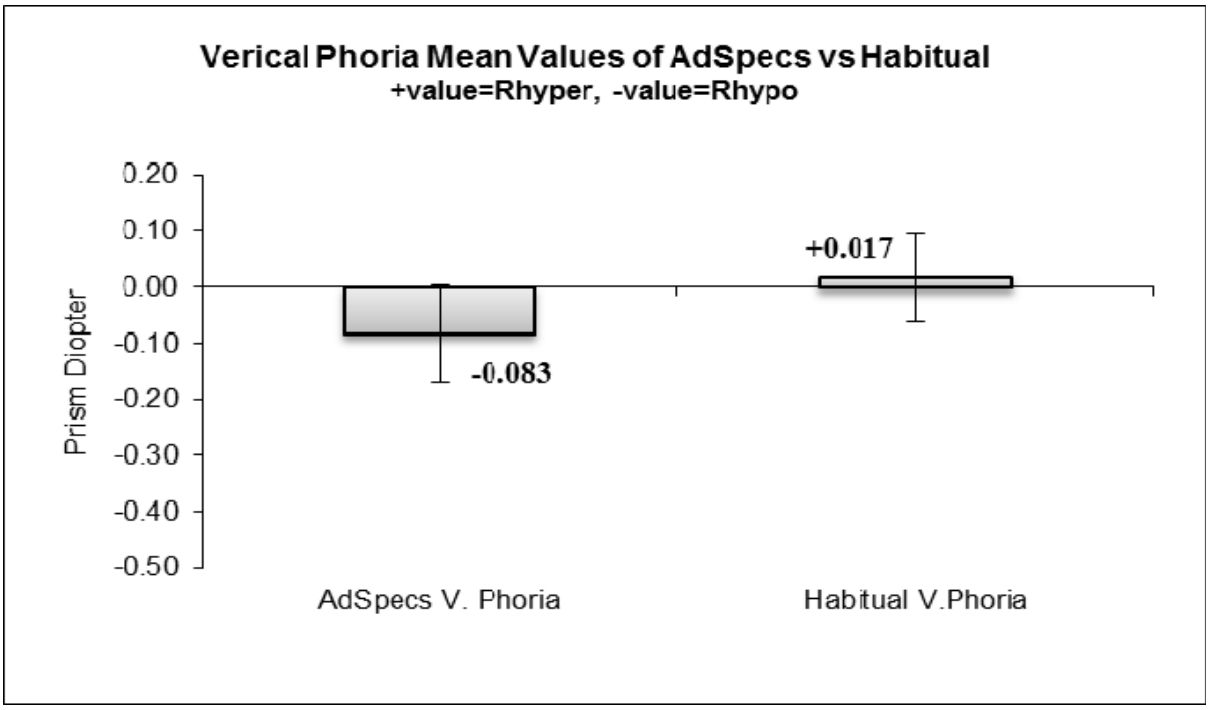


Figure 13: Graph showing mean values of the right eye for vertical phoria through AdSpecs and HC.

CISS SCORE

CISS mean scores were calculated for both AdSpecs and HC for the purpose of comparison between them. CISS mean score was 13.633 ± 9.004 with HC and 11.667 ± 11.966 with AdSpecs (mean difference: -1.967± 9.00, p-value: 0.24) (Figure 14).

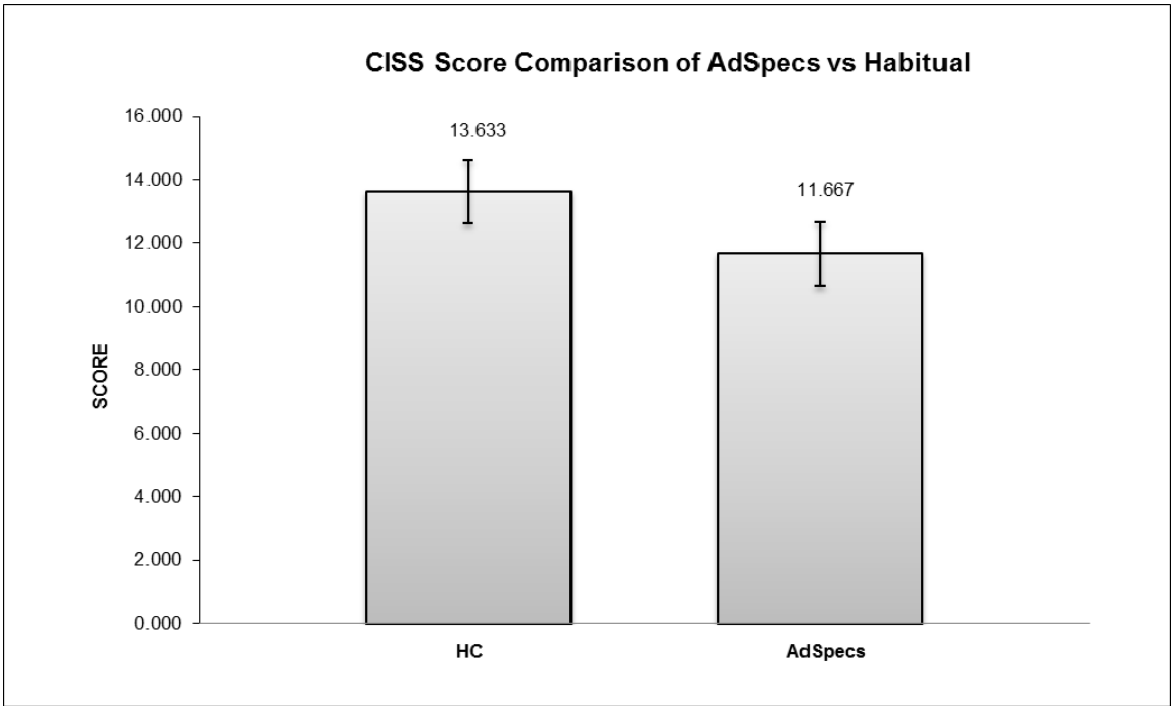


Figure 14: Graph showing mean values of the CISS score for AdSpecs and HC (CITT Questionnaire).

PUPILLARY DISTANCE (PD) MEASUREMENT

The AdSpecs used in this study had a Pupillary Distance (PD) measurement of 62.0 mm. The subjects' far PD had a mean of 61.47 ±4.47 mm and near PD had a mean of 58.07 ±4.37 mm. The mean difference between AdSpecs PD and HC mean far PD was 0.53 mm with a p-value of 0.519, and the mean difference between AdSpecs PD and HC mean near PD was 3.93 mm with a statistically significant p-value of 0.00003.

HC REFRACTIVE POWER COMPARED TO ADSPECS REFRACTIVE POWER

Habitual Sphere Power vs AdSpecs: The mean refractive power of AdSpecs for the right eye had value of -3.00D ±1.613D. The mean habitual sphere power for the right eye was -2.91D ± 1.568D with a mean difference of -0.087±0.507D and a p-value of 0.35 when compared to AdSpecs. 11 of the 30 subjects (36.7%) under-minused themselves with AdSpecs, 13 of the 30 subjects (43.3%) over-minused themselves with AdSpecs and 6 of the 30 subjects (20.0%) achieved the same power as their habitual sphere power with AdSpecs. Of the 13 subjects that over-minused themselves, only 6 subjects did by 0.50D or more (20% of total subjects). (See Figure 3 in Appendix)

Habitual Spherical Equivalent vs AdSpecs: The mean habitual spherical equivalent power for the right eye was -3.114 ± 1.604D with a mean difference of 0.115±0.480D and a p-value of 0.20 when compared to AdSpecs. 15 of the 30 subjects (50%) under-minused themselves with AdSpecs, 8 of the 30 subjects (26.7%) over-minused themselves with AdSpecs and 7 of the 30 subjects (23.3%) achieved the same power as their habitual spherical equivalent power with AdSpecs. Of the 8 subjects that over-minused themselves, only 3 subjects did by 0.50D or more (10% of total subjects). (See Figure 3 in Appendix)

DISCUSSION

Adjustable Spectacles (AdSpecs) are currently being used in several areas of the developing world. It has been shown in previous studies that individuals are able to perform the process of self-refraction and obtain good vision through them. However, no studies were performed to investigate whether these adjustable glasses have any adverse effects on visual function. Therefore, this study was conducted in order to determine if there are any differences in quality of vision when wearing AdSpecs compared to Habitual Correction (HC), and more specifically to check whether AdSpecs have any adverse effects on visual function.

A number of important variables that affect visual function were examined in this study. Visual Acuity (VA) is the most common measurement that gives information about the visual system. VA has been suggested to be an important indicator of an individual's performance in relation to certain daily activities involving visual tasking. In this study, the ETDRS chart was chosen for VA measuring as it is considered the “gold standard” in clinical research and for FDA registration trials in the United States (Kaiser, P. K., 2009). Moreover, the ETDRS charts provide letters of equal recognition difficulty and allow precise quantification of vision with reliable measures of vision change. Several studies have shown a lower test-retest variability score compared to Snellen. These charts have significant advantages over the old Snellen-type charts (Kaiser, P. K., 2009).

The results in this study showed a statistically significant reduction in Distance Visual Acuity (DVA) through AdSpecs with a mean -0.149 LogMAR (p-value: 0.0004) compared to HC, mean -0.23 LogMAR. When looking at the left side of the Bland-Altman plot (figures 7), we notice that there is a positive linear pattern. The subjects with better average DVA (more minus) show better agreement between the two methods and a smaller difference, with a few subjects demonstrating better DVA through AdSpecs. As we move to the right towards the more positive average DVA, we notice that the difference between the two methods increases showing subjects that obtained a better DVA results through their HC. A few points on the right side of the graph are scattered but only one of those points represents a slightly lower DVA with HC compared to AdSpecs. All points on the Bland-Altman plot fall within the 95% limits of agreement except for one subject that shows significantly better HC DVA compared to AdSpecs. The mean difference line shows a bias towards HC being the method demonstrating better DVA.

Near Visual Acuity (NVA) also showed a statistically significant reduction through AdSpecs with a mean of +0.009 logMAR (p-value: 0.009) compared to HC, mean -0.035 logMAR. The Bland-Altman plot shows a trumpet like pattern (figure 9). On the left side of the graph, subjects with better average NVA (more minus) show better agreement between the two methods and a smaller difference, with a few subjects demonstrating better NVA through AdSpecs. As we move to the right towards the more positive average NVA, we notice that the majority of subjects show a larger difference between the two methods and a better NVA results through their HC. All points on the Bland-Altman plot fall within the 95% limits of agreement except for 2 points that fall on the upper limit line. Those 2 points represent two

subjects that obtained a significantly better NVA with HC compared to AdSpecs. Similar to the case for DVA, the mean difference line for NVA shows a bias towards HC as being the method showing better NVA.

The reduction in VA may be due to a variety of factors. First, AdSpecs' complex lens design. Multiple lens surfaces result in reflection and reduced light transmission to the eye. Second, the lack of astigmatic correction with AdSpecs for subjects with higher amounts of astigmatism. This has been shown as the case in some of the CSRS studies (Zhang et al, 2010). Third, factors such as; fatigue and boredom since AdSpecs' VA measurement was obtained after the subjects have already been engaged in the study for at least 90 minutes.

Mean DVA was reduced by 0.080 logMAR with AdSpecs compared to HC. This translates to less than one line reduction on the ETDRS chart since each letter is 0.02 and there are 5 letters per line. Mean NVA was reduced by 0.044 logMARwith AdSpecs compared to HC. This translates to 2 letters reduction on the ETDRS chart as explained above. The question is: if this is a statistically significant difference, can one say it is also clinically significant? This is a difficult question to answer since there is not much research done in this area, and since the sensitivity to VA change varies for different individuals. However, some studies have already been conducted in the past and can help us arrive at an understanding of how much VA reduction may alter one's quality of life or can be recognized as clinically significant.

One of those studies was conducted in Los Angeles, California where the association between longitudinal changes in VA and Health Related Quality of Life (HRQOL) in a

population-based sample of adult Latinos was examined. The study used data from the Los Angeles Latino Eye Study (LALES) for 3,169 adult Latino participants. This data was used to assess HRQOL using the National Eye Institute Visual Function Questionnaire (NEI-VFQ-25). The study found approximately 5 point loss in the NEI-VFQ-25 composite score for participants with a 2 line loss in VA with the largest score changes found for the driving difficulties, vision related mental health, and vision related dependency. The researchers noted an approximate 5 point gain in the NEI-VFQ-25 composite score for participants with a 2 line improvement in VA with the largest change found for the driving difficulties subscale. The study concluded that clinically important, longitudinal changes in visual acuity (2 line changes or greater) were associated with significant changes in self-reported visual function and well-being. (McKean-Cowdin, Varma, Hays, Wu, Choudhury and Azen, 2010). Based on their conclusion, VA needs to be reduced by at least 2 lines in order for it to affect someone's quality of life.

Another significant study was conducted in London, the United Kingdom, where researchers looked at determining whether measured changes in ETDRS LogMAR VA reflect true clinical change or are attributable to measurement error alone using the sensitivity to change and specificity achieved by test–retest variability (TRV). They found that simulated acuity change of 0.2 LogMAR (two lines of letters) or greater can be reliably distinguished from no change (both sensitivity and specificity 95%) with the ETDRS chart, but a change of 0.1 logMAR or less cannot be distinguished (Rosser D.A, Cousens, Murdoch, Fitzke and Laidla, 2003).

In addition, a cross-sectional study that was conducted in Victoria, Australia looked at the variability of VA in a large busy eye clinic. The study compared measurements of VA obtained under normal clinical conditions (using different VA charts, examination rooms and examiners) to measurements obtained using standard clinical research protocols, and they found that in order to be confident that a real change in VA has occurred between measurements, a difference of at least 0.15 logMAR is required (Siderov and Tiu, 1999).

The above studies indicate that 0.08 logMAR reduction in mean DVA and 0.04 logMAR reduction in mean NVA found in this study are small and not necessarily considered to be clinically significant or affects one's quality of life.

Another significant variable that was measured in this study is Contrast Sensitivity (CS). CS is an important aspect of vision. Its measurement provides useful information about visual function, which may not be revealed by VA alone. A number of studies have shown a relationship between CS and driving performance, mobility, face recognition, reading speed, and ability to perform activities of daily living, not to mention its value in the detection and progression of ocular diseases.

The Mars Letter CS test was used in this study. Several studies have indicated that Mars letter CS test demonstrates good agreement with the commonly used Pelli-Robson test with similar test–retest repeatability and validity. A study found the Mars test mean test-retest difference for a normal control group to be 0.02 log units, indicating a trivial learning effect. (Haymes, Roberts, Cruess, Nicolela, LeBlanc, Ramsey, Chauhan, Artes, 2006). In addition,

Mars test uses finer contrast scales, in which each letter represents a smaller change in contrast. On the Mars test, each letter corresponds to 0.04 log units compared to the Pelli-Robson test that uses 0.15-log unit steps. CS tests with finer scales demonstrate less variability. (Dougherty, Flom and Bullimore, 2005). In addition to its validity and low variability, the Mars test is desirable to use for its small size, durability, and portability. The above reasons contributed to the decision of choosing this CS test in this study.

The results showed similar mean CS value between AdSpecs and HC, 1.768 and 1.761 respectively with no statistical significance (p-value: 0.62). The Bland-Altman plot (figure 11) shows a normal distribution with the mean difference line almost at zero indicating no bias. All points on the Bland-Altman plot fall within the 95% limits of agreement except for one outlier. This outlier possibly resulted due to issues related to instructions to the subject, or other factors that are not fully understood.

Another measured variable was phoria. This measurement was important in this study to obtain knowledge about the binocular system. Binocular fusional issues can contribute to reduced visual function by causing many symptoms such as; asthenopia, diplopia, blurry vision, inability to concentrate or pay attention and headaches (Westmana and Liinamaa, 2012). In this study, to obtain phoria measurements, Modified Thorington (MT) was used. MT is notable for its simplicity in administration. A number of articles showed that MT has a similar test-retest reliability to the gold standard method for measuring ocular deviation; Cover Test but better than Von Graefe. (Cebrian, Antona, Barrio, Gonzalez, Gutierrez and Sanchez, 2014; Schroeder, Rainey, Goss and Grosvenor, 1996). Lateral phoria mean values

were similar between AdSpecs and HC, -3.483pd (Exo) and -3.567pd (Exo) respectively with no statistical significance (p-value: 0.79). The small difference in lateral phoria is likely due to the pre-set pupillary distance on the AdSpecs, resulting in induced prismatic effect for some subjects which was exacerbated by the complex lens system. This is supported by the fact that the HC mean near PD was 3.93 mm smaller than AdSpecs PD of 62.0 mm.

Vertical phoria mean values were similar between AdSpecs and HC, -0.083pd (RHypo) and +0.017pd (RHyper) respectively with no statistical significance (p-value: 0.25). The small difference in vertical phoria may be due to the weight of the AdSpecs that caused them to slide down and fit lower on the face in some subjects and also possibly due to the optical center not falling at the visual axis in some subjects.

The CISS questionnaire was developed by the Convergence Insufficiency Treatment Trial (CITT) group. Previous studies have supported its reliability and validity (Borsting, Rouse, Mitchell, Scheiman, Cotter, Cooper, Kulp and London, 2003; Rouse, Borsting, Mitchell, Scheiman, Cotter, Cooper, Kulp, London and Wensveen, 2004). It is used in clinic to assess symptoms related to Convergence Insufficiency (CI). In the CITT studies, a cut-off scoring system was used to identify individuals as symptomatic and in need for binocular vision evaluation. The cut-off scores were not used in this study. Instead, the scores obtained with AdSpecs and HC were compared directly with the aim of obtaining information about the quality and comfort of the subjects' near vision through each method. The mean value of the CISS score was a slightly higher with HC but similar between AdSpecs and HC, 11.667 and 13.633 respectively with no statistical significance (p-value: 0.24). The lower score indicates that subjects were less symptomatic for ocular discomfort. The AdSpecs questionnaire was

given at the end of the study, it is uncertain but possible that the subjects were tired and therefore did not spend a great time or paid much attention while filling out that questionnaire which resulted in a lower score value.

The results of mean Refractive Error (RE) comparison between AdSpecs and HC were not as expected. It was anticipated that more subjects would over-minus themselves with AdSpecs but only 43.3% did when looking at sphere (SPH) and 26.7% when looking at spherical equivalent (SE). About 20% of the total subjects over-minused themselves by 0.50D or more when looking at SPH and 10% when looking at SE. The percentages mentioned are lower than anticipated. A similar outcome was also found in the CSRS studies done in China where they reported that cycloplegic subjective refraction and self-refraction with AdSpecs did not differ significantly (He et al, 2011; Zhang et al, 2011). Two factors may have contributed to this; first, setting the lenses to a high plus power before having the subjects self-refract may have helped in controlling accommodation. Second, having the subjects use a lower acuity line such as a 20/30 line as their target while self-refracting may have also played a role. The decision to use a 20/30 line as a target in this study was based on the protocols of the CSRS studies.

The difference in dioptric power between AdSpecs and HC was -0.09D when compared to habitual mean SPH with AdSpecs having a more minus power, and 0.115D when compared to habitual SE with AdSpecs having a less minus power. Both comparisons showed no statistical significance with p-value of 0.355 and 0.199 for SPH and SE, respectively. Although, the difference in refractive power showed no statistical significance, it was

important to investigate further and find out what is considered a clinically significant difference in RE. In a study conducted in Finland that examined the repeatability of RE measurement in clinical settings, it was found that the test-retest difference in SE in a group with logMAR VA of 0.15 or better to be ±0.51D (Leinonen, Laakkonen and Laatikainen, 2006). A similar study by the School of Optometry, University of California at Berkeley reported a subjective refraction repeatability for SE power of ± 0.63D (Zadnik, Mutti and Adams, 1992). Another study by the School of Optometry at State University of New York reported a better repeatability of subjective refraction in vision professional (teachers and students of optometry) of ±0.27D for SPH (Rosenfeld & Chiu, 1995). In addition, a literature review by the School of Optometry at Indiana University on the repeatability of refraction found that the intra-examiner reliability (same examiner) and inter-examiner reliability (different examiners) of subjective refraction for both SPH and SE powers to be close to 80% agreement within ± 0.25D and 95% agreement within ± 0.50D (Goss & Grosvenor, 1996). The studies mentioned indicate that the repeatability of RE measurement in clinical settings has a certain degree of variability and that RE difference of ±0.25 is negligible in clinical settings regardless of the population type at hand. Therefore, the small difference in RE found in this study between AdSpecs and HC can be considered trivial.

With respect to the comfort level experienced by the subjects while wearing AdSpecs, none of the subjects reported headaches or nausea, they did however report some expected discomfort mainly due to the AdSpecs weight and thick plastic material of the frame. This limitation directly influenced the decision to change the initial study design, where instead of requiring subjects to wear the AdSpecs for 6 hours they were instructed to wear them for

only an hour. It is noteworthy to mention that future designs with reduced lens thickness and weight have since been produced.

An interesting observation in this study was the level of high DVA that a large number of subjects achieved. 19 out of 30 subjects (63.3%) achieved a DVA of 20/15 or better with the AdSpecs, and 28 out of 30 subjects (93.3%) had a DVA of 20/15 or better with their HC. It is difficult to explain what factors may have contributed to the high level of VA besides that most of the subjects were young optometry students who were familiar with the VA measuring process and had healthy eyes. It is also noticed that this population works harder to obtain precise results; their answers are normally of higher quality compared to naïve observers. This is supported by one of the studies mentioned above that showed better subjective refraction repeatability in vision professionals (Rosenfeld & Chiu, 1995).

This study had several limitations. To begin with, none of the subjects in the study were hyperopic and that is due to difficulty finding hyperopes. The results reported were only on myopic and astigmatic subjects and may not exactly represent results for hyperopes. Also, different examiners were involved in the data collection process, which may have led to inconsistent results due to inter-examiner variability. Additionally, AdSpecs VA was always taken after habitual VA using the same VA charts. It is possible that subjects may have memorized the letters on the charts and that contributed to better VA values obtained with AdSpecs. And as mentioned earlier, AdSpecs have no astigmatic correction which may have resulted in poorer VA for those subjects with astigmatism.

Moreover, CS was measured using the Mars test, which provides variable contrast levels but with a single letter size. While uncertain, it is possible if a different CS test was used - one with variable spatial frequency letters (especially higher spatial frequency) - the results may have varied between the two methods since the contrast sensitivity threshold varies for different spatial frequencies.

Another limitation of this study is the small sample size. Also, all subjects came from similar educational and likely similar social backgrounds. It is unknown if the results of this study hold true for a larger population or a population with a different socioeconomic status.

In addition, there was no precise way of knowing if the prescription in the subject's habitual glasses reflected the subject's exact prescription. Subjects were asked to wear their most recent pair of spectacles to the study but the age of the spectacles varied for different subjects.

Lastly, this study only looked at the short term use of AdSpecs which by itself does not answer questions about the long term use of these adjustable spectacles.

CONCLUSIONS

This study was carried out with the aim to examine a self–refraction type of spectacles called AdSpecs. AdSpecs are currently being used in the developing world to help alleviate the burden of uncorrected refractive error in numerous underserved areas. This study investigated the possibility of whether or not AdSpecs might have adverse effects on visual function. A statistically significant reduction in Distance and Near Visual Acuities with AdSpecs was found when compared to Habitual Correction (HC). This may not necessarily translate into a clinically significant reduction that can affect one's quality of life according to some studies (McKean-Cowdin et al, 2010, Siderov et al, 1999, Rosser et al, 2003). Contrast Sensitivity, Phoria and CISS scores were not statistically different between AdSpecs and HC.

The results of this study indicate that AdSpecs may have the potential of contributing to efforts aimed at addressing a critical need in the developing world, where they could be used as a screening tool or to measure and correct refractive error with spherical lenses without causing harm. However, there remain some notable limitations to this technology, which include but are not limited to: the inability to correct astigmatism, the limited range of corrective power and potential difficulties for those who are unfamiliar with vision correction to understand and perform self-refraction. In addition, this study focused on the short term use of AdSpecs which by itself does not answer questions one may have about the long term use of these adjustable glasses. Future studies should be carried out to look at the effects of long term use of AdSpecs.

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APPENDIX:

Figure 1-A: Study information and informed consent handed to the subject upon arrival to participation appointment (Pg 1):

The New England College of Optometry
Boston, Massachusetts
Informed Consent
Quality of Adjustable Spectacles Study
Bruce Moore, O.D. Principal Investigator
Co-Investigators: Catherine Johnson, Stacy Lyons, Nicole Quinn, Nadine Solaka, Hilary Gaiser

This study is funded by The World Bank through the Imperial College in London UK, the Center for Vision in the Developing World in Oxford, UK, and internal research funding from NECO

PURPOSE:
Adjustable eyeglasses, such as the AdSpecs, have been shown to provide clear distance visual acuity when adjusted by adults and children with myopia and low to moderate levels of astigmatism and are being used to provide refractive correction in areas of the world where there is limited access to eye care. However, the quality of near point vision through AdSpecs has not been evaluated.

You are being asked to volunteer as a subject in a research study that will involve up to 30 students from the New England College of Optometry (NECO). The purpose of this study is to determine if there are differences in quality of near vision experienced when wearing AdSpecs compared to conventional eyeglasses.

PROCEDURES:
Testing will be done in Dr. Bruce Moore's Research Laboratory at the New England College of Optometry on the third floor of 418 Beacon Street.

The duration of the study is 90 minutes. During this visit your eligibility to participate in the study will be determined. If you decide to participate you will undergo testing while wearing your habitual correction. The testing procedures will be near visual acuity, Modified Thorington Phoria testing and Mars Contrast Sensitivity testing. Testing will occur while looking straight ahead and when looking down 45 degrees. All of these tests are commonly used in the clinical setting and are non-invasive. You will also be asked to complete a Convergence Insufficiency Symptom Survey Questionnaire (CISS) based on your experiences with your habitual correction. Following testing you will be asked to wear the AdSpecs for a continuous 60 minutes. During the last 30 minutes of wear time you will be asked to perform a reading task. After the 60 minutes of wear time has elapsed you will repeat the initial testing while wearing the AdSpecs and fill out the Convergence Insufficiency Symptom Survey based on your AdSpec experience.

BENEFITS:
There are no direct benefits to you from participating in this study. The main benefit of participating in this study is that the information from this research study may help to improve access to quality refractive correction to individuals in the developing world where eyecare is currently unavailable to most of the population. Participating in a research study also gives the subject knowledge in how the research process works and, therefore, may be of benefit to your education.

RISK AND DISCOMFORTS:
The project does not include any serious health risks, as each of the tests are routinely used in eye examinations. The tests are not invasive or threatening in any way. You may become tired or get temporary eyestrain during testing. If so, we will take a break of sufficient length for you to feel

Figure 1-B: Study information and informed consent handed to the subject upon arrival to participation appointment (Pg 2)

comfortable to continue with the testing. YOU MUST NOT DRIVE OR DO ANY OTHER POTENTIALLY HAZARDOUS ACTIVITIES WHILE WEARING THE ADSPECS.

You may contact Bruce Moore, OD at the New England College of Optometry at **(617) 587-5597** or cell phone number **(617) 921-5875** to discuss any side effects that are of concern to you. If the frequency or severity of the adverse reactions warrants, the Institutional Review Board (Human Protection Committee) may alter the study protocols, suspend, or terminate the study.

You will be made aware of any significant new findings that may influence your willingness to participate in this study.

CONFIDENTIALITY:
Your medical records will be kept as confidential as possible within limitations of state and federal law.

If you decide to be a subject in this study, both demographic and technical information will be collected. Demographic information will include, but not be limited to such things as name, date of birth, address, gender, ethnicity, etc. Technical information will include elements of your personal health history and results of all the tests and measurements related to the study. This information is collected in order to determine whether you are eligible to be a subject in the study: that is, to meet the inclusion/exclusion criteria and, if so, to allow the study investigators to gather the data that is necessary to support the study's purpose. The results from all of the subjects in the study can then be analyzed to develop the study's conclusion.

All study related information will remain confidential with the study investigators or administrative staff. However, any regulatory authority or the Institutional Review Board may inspect the investigator's records pertaining to your child as a subject. But they too should maintain confidentiality.

The results of the study may be used in health care education or in scientific publications. Neither your name nor any information that specifically could identify you will be used in such presentation or publication.

PERSONAL HEALTH INFORMATION:
Your personal health information (PHI), as related to this study, is described in the "Confidentiality" section above. If you sign this informed consent form, it grants permission to use your PHI as specifically discussed. This permission does not have an expiration date, but you can cancel at any time by writing to the principal investigator(s) at the address below.

If you cancel your permission to use your PHI after the study has started but before your study participation would normally be concluded, you will not be allowed to continue in the study and the investigators will stop collecting data. However, they retain the rights to use the information they have already collected to evaluate the study's results.

PRIVACY PRACTICES AND YOUR RIGHTS:
Health care providers are required by law to keep private any health information that identifies people. Federal Privacy Regulations require that you authorize the release of any health information that may reveal your identity. The persons and entities that you are authorizing to use or inspect all of the health

Figure 1-C: Study information and informed consent handed to the subject upon arrival to participation appointment (Pg 3):

information generated or collected about you during this study includes the study doctor's), the study staff, the Institution, any study sponsor (or authorized agents of the sponsor), the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) agencies and the Institutional Review Board. Because of the need to release information to these parties absolute confidentiality cannot be guaranteed. Once your personal health information is released it may be re-disclosed, at which point the health information may no longer be protected by federal privacy regulations.

You may ask the study investigators to see a copy of your PHI related to the study. You may also request the study investigator to correct any information that you feel is incorrect. However, you may have to wait until the end of the study to see your records so that the study can be organized and conducted scientifically.

You must be given notice of your investigators privacy polices. The Confidentiality, Personal Health Information, and Privacy Practices and Your Rights sections of this form fulfill this requirement.

Unless you authorize the use and disclosure of your Personal Health Information, you cannot participate in this research study. If you refuse to give your authorization, your medical care will not be affected.

VOLUNTARY PARTICIPATION OR WITHDRAWL:
Being part of this project is voluntary. Whether or not you chose to take part in the project will have no bearing on your education or participation in any program at The New England College of Optometry. You may take yourself out of this project at any time. Taking yourself out of the project will not affect your right to health care. The sponsor, Institutional Review Board, or the investigator may terminate your participation in the study (with or without your consent) if it believed to be in your best interest or if you fail to keep appointments or follow study instructions.

COMPENSATION: Subjects will be reimbursed $25 for their participation in the study. The subjects will receive their compensation at the completion of the study.

Adaptive Spectacles



Figure 1-D: Study information and informed consent handed to the subject upon arrival to participation appointment (Pg 4):

New England College of Optometry
Boston, Massachusetts
Informed Consent

If you have any questions about this project, you may contact Bruce Moore O.D. the Principal Investigator at the New England College of Optometry, 424 Beacon Street Boston, Massachusetts 02215 or by calling **(617) 587-5597**, or by email: mooreb@neco.edu. In case of an emergency, please call (617) 262-2020.

I have fully explained to _____
Subject

the nature and purpose of the above-described procedures and the risks involved in its performance. I have answered and will answer all questions to the best of my ability. I will inform the participant of any changes in the procedure of the risks and benefits if any should occur during or after the course of the study.

_____
Investigator's Signature (or Designee)

Consent: I have been satisfactorily informed of the above-described procedure with its possible risks and benefits. I give permission for my participation in this study. I know that Dr. Moore will be available to answer any questions that I may have and may be reached at **(617) 587-5597** or by cell phone at **(617) 921-5875**. If I feel that my questions have not been adequately answered I may request to speak to Dr. Paul White, Chairman of the New England College of Optometry Institutional Review Board, by calling **(617) 236-6247**. I understand that I am free to withdraw this consent and discontinue my participation in this project at any time, even after signing this form, and it will not affect my care or my standing as a NECO student. I have been given a copy of this form.

_____ _____
Date **Signature of Subject**

_____ _____
Date **Witness to Signatures**

This informed consent was approved by The New England College of Optometry Institutional review board.

_____ _____
Date **Signature of Chairman**

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Figure 2 - CISS used for HC and AdSpecs symptoms:

Convergence Insufficiency Symptom Survey

Name _____ DATE __/__/__

Clinician instructions: Read the following subject instructions and then each item exactly as written. If subject responds with "yes" - please qualify with frequency choices. **Do not give examples.**

Subject instructions: Please answer the following questions about how your eyes feel when reading or doing close work.

		Never	(not very often) Infrequently	Sometimes	Fairly often	Always
1.	Do your eyes feel tired when reading or doing close work?					
2.	Do your eyes feel uncomfortable when reading or doing close work?					
3.	Do you have headaches when reading or doing close work?					
4.	Do you feel sleepy when reading or doing close work?					
5.	Do you lose concentration when reading or doing close work?					
6.	Do you have trouble remembering what you have read?					
7.	Do you have double vision when reading or doing close work?					
8.	Do you see the words move, jump, swim or appear to float on the page when reading or doing close work?					
9.	Do you feel like you read slowly?					
10.	Do your eyes ever hurt when reading or doing close work?					
11.	Do your eyes ever feel sore when reading or doing close work?					
12.	Do you feel a "pulling" feeling around your eyes when reading or doing close work?					
13.	Do you notice the words blurring or coming in and out of focus when reading or doing close work?					
14.	Do you lose your place while reading or doing close work?					
15.	Do you have to re-read the same line of words when reading?					
		__x 0	__x 1	__x 2	__x 3	__x 4

TOTAL SCORE _____

Figure 3: Table with refractive power comparison between habitual correction sphere and spherical equivalent to AdSpecs.

HC SPH=habitual correction sphere power, HC CYL=habitual correction cylinder power, HC SE= habitual correction spherical equivalent power.

Subject ID	HC SPH (D)	HC CYL (D)	HC SE (D)	AdSpecs Power (D)	Difference (AdSpecs-HC SE) (D)	Difference (AdSpecs-HC SPH) (D)
1	-5.00	-1.25	-5.63	-5.25	0.38	-0.25
2	-5.25		-5.25	-5.00	0.25	0.25
3	-3.00	-0.50	-3.25	-4.00	-0.75	-1.00
4	-5.25	-0.75	-5.63	-5.00	0.63	0.25
5	-2.00	-1.00	-2.50	-1.25	1.25	0.75
6	-2.25	-0.50	-2.50	-2.00	0.50	0.25
7	-3.75		-3.75	-3.00	0.75	0.75
8	-0.75	-0.25	-0.88	-1.50	-0.63	-0.75
9	-2.25		-2.25	-2.12	0.13	0.13
10	-0.75		-0.75	-0.37	0.38	0.38
11	-2.00	-0.75	-2.38	-2.50	-0.13	-0.50
12	-4.50	-1.00	-5.00	-4.87	0.13	-0.37
13	-1.00	-0.50	-1.25	-1.25	0.00	-0.25
14	-5.50	-0.50	-5.75	-5.50	0.25	0.00
15	-0.75		-0.75	-0.50	0.25	0.25
16	-2.50		-2.50	-2.50	0.00	0.00
17	-3.25		-3.25	-3.25	0.00	0.00
18	-3.37		-3.37	-3.00	0.37	0.37
19	-4.25	-0.75	-4.63	-4.75	-0.13	-0.50
20	-1.50	-1.50	-2.25	-1.50	0.75	0.00
21	-4.75	-0.50	-5.00	-5.00	0.00	-0.25
22	-4.00		-4.00	-3.75	0.25	0.25
23	-2.00		-2.00	-1.25	0.75	0.75
24	-3.25		-3.25	-3.50	-0.25	-0.25
25	-4.00		-4.00	-4.00	0.00	0.00
26	-1.00	-0.50	-1.25	-1.50	-0.25	-0.50
27	-2.75	-0.75	-3.13	-4.25	-1.13	-1.50
28	-4.75	-0.50	-5.00	-5.00	0.00	-0.25
29	-1.50		-1.50	-1.50	0.00	0.00
30	-0.50	-0.62	-0.81	-1.12	-0.31	-0.62