FIELD MEASURES OF REFRACTIVE ERROR

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

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ABSTRACT: FIELD MEASURES OF REFRACTIVE ERROR
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Refractive error is a common and treatable cause of visual disability. In the developing world, the measurement of refractive error is often hindered by a lack of eye care professionals. Different methods of measuring refractive error designed to be used by lay technicians, referred to as "field measures," have been developed to overcome this problem. This study compares three field measures of refraction performed by a lay technician to a subjective refraction performed by trained eye care professionals in both a controlled clinical setting as well as a field trial conducted in Central America.

Fifty subjects were recruited from the New England College of Optometry (NECO), in Boston, MA and 50 subjects were recruited from Rivas Province, Nicaragua. Field measures included: (1) AdSpecs, adjustable focus fluid filled lenses; (2) Focometer, a self adjusted focusable telescope; and (3) Predetermined Lens Refraction (PLR), a pre-scripted series of spherical lens choices. All techniques were conducted in a randomized order and examiners were masked to each others' findings. Student's t-test was used to compare mean refractive error determined by each method with a confidence interval of 95%.

The mean (SD) age for subjects recruited from NECO was 24.3 years (1.5). Mean refractive error determined by subjective refraction was -2.50D (3.2). Mean (SD)

refractive error for AdSpecs, Focometer and PLR was -2.42D (2.68), -2.80D (2.816), -1.79D (1.76) respectively. Mean PLR refractive error had the greatest absolute deviation from the gold standard, 0.77D (p=0.004). Visual acuity was corrected to 20/20 by subjective refraction, AdSpecs, Focometer and PLR in 98%, 88%, 84%, and 66% of subjects respectively.

The mean (SD) age for subjects recruited in Rivas Province, Nicaragua was 40 years (14). Mean (SD) refractive error determined by subjective error was 0.51D (0.71). Mean (SD) refractive error for AdSpecs, Focometer and PLR was 0.68D (0.83), 0.42D (1.13), and 0.27D (0.79) respectively. Mean PLR refractive error had the greatest absolute deviation from the gold standard by 0.24D (p=0.002). Visual acuity was corrected to 20/20 by subjective refraction, AdSpecs, Focometer and PLR in 78%, 66%, 66%, and 88% of subjects respectively.

In the field trial, all three techniques demonstrated potential and were able to determine similar refractive error (within 0.25D) when compared to the gold standard subjective refraction. However, in the clinical trial, the Focometer and the AdSpecs held a statistically and clinically significant advantage over the PLR in determining refractive error. In the field trial, all field measures of refractive error were able to achieve a visual acuity similar to that of the subjective refraction. In the clinical trial, the AdSpecs and Focometer also held an advantage over the PLR in their ability to achieve 20/20 visual acuity. The inadequate performance by the PLR in the clinical trial is most likely due to

the limited range of the PLR method and could likely be eliminated if the range of refractive error correctable by the PLR was expanded.

In both the field and clinical trials, all three techniques showed potential. Their performances, particularly the PLR method, could perhaps be enhanced if they were modified to better correct the refractive error profile of the target population.

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CHAPTER1: INTRODUCTION

1.1 The problem at hand

Recent estimates from the World Health Organization suggest that there are 161 million visually impaired persons with 37 million people blind (BCVA worse than 3/60 in the better seeing eye) and 124 million people visually impaired (BCVA 6/18-3/60 in the better seeing eye) (Pascolini, Mariotti, Pokharel, Pararajasegaram, Etya'ale, Négrel and Resnikoff 2004; Resnikoff, Pascolini, Etya'ale, Pararajasegaram, Ppkharel and Mariotti 2004). Since these estimates are based on best corrected visual acuity, they neglect the significant number of individuals with uncorrected refractive error, who do not have access to eye care and/or spectacles. This can be seen with major classification systems including the International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) which ignores uncorrected refractive error as a cause of visual impairment or blindness (WHO 1992).

In March 2006, Dandona and Dandona published a review of all population based visual impairment surveys from 1996 onward and estimated that if presenting visual acuity were used, the number of visually impaired individuals would be closer to 259 million. This approximation is 61% more than the commonly quoted WHO estimate, thus making refractive error one of the most common causes of visual impairment worldwide (Dandona and Dandona 2006).

The role of refractive error in visual impairment was highlighted by Vision 2020: the Right to Sight, a joint initiative between the World Health Organization and the International Agency for Prevention of Blindness. The mission of VISION 2020 is to eliminate the main causes of avoidable blindness. In particular, five eye diseases were identified as preventable and treatable causes of blindness: cataract, trachoma, onchocerciasis (also known as River Blindness), Vitamin A deficiency and refractive error (2005). This is the first major initiative to recognize refractive error as a major cause of avoidable blindness and it is only recently that refractive error has become a major focus.

1.2 Prevalence of refractive error visual impairment

There are currently no sources, including the WHO, of prevalence data describing large multinational populations. Because of the inconsistencies in collecting data on prevalence of visually significant refractive error including (1) different techniques in measuring refractive error and (2) different amounts used to define refractive error, it is difficult to draw conclusions about prevalence patterns.

An exception to this challenge is the Refractive Error in School Children (RESC) studies. The RESC studies are a series of studies conducted throughout China, India, Nepal, Chile, South Africa and Malaysia that have implemented a common protocol with standardized methods to collect data concerning refractive error and associated visual impairment. The studies, although criticized by some for over representing urban areas, provide very useful information. While type and prevalence varied between geographic

areas, refractive error was the overriding cause of visual impairment (Maul 2000; Negrel 2000; Pokharel 2000; Zhao 2000). Many children who were correctible to near normal vision in at least one eye were often without glasses, up to 45% in urban China and 93% in rural Nepal (Pokharel 2000; Zhao 2000). The RESC studies, even though they are not targeted to the adult world population, show the need for refractive correction world wide. Further studies in other geographical locations and different types of populations are necessary to determine the true prevalence of refractive error blindness and visual impairment.

It has been shown that large populations tend to display a normal distribution of refractive error however there are variations associated with gender, geographical and ethnic differences (Borish 1975; Baldwin 1981). Higher prevalence rates of specific refractive errors have been shown to be associated with certain populations. For example, high prevalence rates of myopia have been found in areas including China and Taiwan(Lin, Shih, Tsai, Chen, Lee, Hung and Hou 1999; Zhao 2000). Similarly, a high prevalence of astigmatism has been found in ethic groups including Native Americans (Pensyl, Harrison, Simpson and Waterbor 1997; Harvey, Dobson and Miller 2006). Groups such as these are likely to benefit from refractive error correction.

1.3 Quality of Life Implications

Just as the magnitude of refractive error visual impairment has not accurately been assessed, the impact of uncorrected refractive error on quality of life has not been definitively identified. Some studies have shown uncorrected refractive error to have a

significant impact on quality of life. Broman et al. (2002) investigated the impact of visual impairment in a Mexican-American population. After adjustment for demographic variables including age, gender, level of acculturation, income level, education level, location and self report of having medical insurance, subjects with visual impairment were found to have a decrement on all measured domains of self reported, vision related quality of life. They state that patients with uncorrected refractive error reported decrements in quality of life that were comparable to those reported by patients with cataracts (Broman, Munoz, Rodriguez, Sanchez, Quigley, Klein, Snyder and West 2002). Nirmalan et al. (2005) also found a relationship between decreased presenting visual acuity and decreased quality of life (Nirmalan, Tielsch, Katz, Thulasiraj, Krishnadas, Ramakrishnan and Robin 2005). Nutheti et al. (2007) did not find an association between refractive error and visual function but also noted that subjects in the study with refractive error had better mean presenting visual acuity than subjects presenting with decreased acuity due to other causes (Nutheti, Keeffe, Shamanna, Nirmalan, Krishnaian and Thomas 2007). West et al. (1997) report that subjects with binocular visual acuity worse than 20/40 showed a decrement in all self-report measures of functional status, but do not specifically mention the effects of refractive error alone (West, Munoz, Rubin, Schein, Bandeen-Roche, Zeger, German and Fried 1997).

Owsley et al. (2007) examined the effect of treating uncorrected refractive error with spectacles in nursing home residents. After two months, residents who had immediate refractive correction had higher scores on several subscales of the Nursing Home Vision-Targeted Health-Related Quality of Life Questionnaire than residents whose correction

was delayed. These subscales include: general vision, reading, psychological distress, activities and hobbies and social interaction. They also had fewer depressive symptoms on the Geriatric Depression Scale (Yesavage, Brink, Rose, Lum, Huang, Adey and Leirer 1982-1983; Kørner, Lauritzen, Abelskov, Gulmann, Marie Brodersen, Wedervang-Jensen and Marie Kjeldgaard 2006). The investigators concluded that correcting the refractive error of nursing home residents improves quality of life and decreases symptoms of depression (Owsley, McGwin, Scilley, Meek, Seker and Dyer 2007).

In addition to the adult population, children are also significantly affected by uncorrected refractive error. Some studies examining the effect of uncorrected refractive error on elementary school children found associations between hyperopia (1.25 to 3.00D) and lower academic achievement scores (Eames 1955; Stewart-Brown, Haslum and Butler 1985; Rosner and Rosner 1987; Rosner and Rosner 1997; Simons and Gassler 1998; Williams, Latif, Hannington and Watkins 2005); one study however, found no associations (Helveston, Weber, Miller, Robertson, Hohberger, Estes, Ellis, Pick and Helveston 1985). A mild decrease in scores on the Movement Assessment Battery for children (a test of visual-motor integration) was shown in children between 9 months and 5.5 years, with hyperopia greater than 3.50D in one meridian (Atkinson, Anker, Nardini, Braddick, Hughes, Rae, Wattam-Bell and Atkinson 2002; Atkinson, Nardini, Anker, Braddick, Hughes and Rae 2005).

Roch-Leveq et al. (2008) showed that low income children with uncorrected refractive error had significantly reduced scores on the Beery-Biktenica Test of Visual Motor

Integration (Beery 1997) (VMI) and the Wechsler Preschool and Primary Scale of Intelligence (Wechsler 1989)(WPPSI-R). Subjects with uncorrected refractive error in this study had bilateral hyperopia of 4.00 D or more in children aged 3 to 5 years, astigmatism of 2.00 D or more in children aged 3 years and 1.50 D or more in children aged 4 to 5 years. Emmetropes had bilateral refractive error of 2.00 sphere diopters or less and 1.00 cylinder diopter or less in both eyes. After wearing glasses for 6 weeks , the ametropic group improved to equal levels compared to the emmetropic group with the VMI and showed improvement with the WPPSI – R, although the change was not statistically significant (Roch-Levecq, Brody, Thomas and Brown 2008).

Further compounding the problem, refractive error is likely to occur early in life, as opposed to age related eye diseases such as cataracts. Thus the number of years visually impaired and the socioeconomic impact of such visual impairment is immense (Dandona, Dandona, Srinivas, Giridhar, Vilas, Prasad, John, McCarty and Rao 2001) with a decrease in quality of life secondary to refractive error being present over a much longer period of time.

1.4 Barriers to care

Among the five major causes of preventable blindness identified by the WHO, refractive error is often singled out as the easiest to correct (Holden and Resnikoff 2002; 2005; WHO 2006). However, the correction of refractive error is not a one time event. Instead, it requires continuous support and periodic assessment to ensure that a patient maintains acceptable visual acuity over time. This is perhaps best illustrated by the correction of

myopia or presbyopia (Hunter and Shipp 1997 Mar; Gwiazda, Hyman, Norton, Hussein, Marsh-Tootle, Manny, Wang and Everett 2004; Hyman, Gwiazda, Hussein, Norton, Wang, Marsh-Tootle and Everett 2005). Both of these refractive conditions are likely to "progress" over time and would require periodic updating to maintain a reasonable functional acuity. In the case of myopia, the progression is due to an elongation of the axial length of the eye (González Blanco, Sanz Ferńandez and Muńoz Sanz 2008), while in the case of presbyopia it is due to a decrease in the accommodative ability of the ocular lens (Strenk, Strenk and Koretz 2005).

The provision of refractive error correction is further complicated by cultural barriers that may exist to spectacle wear including mis-conceptions that spectacles make the eyes weak or are socially unacceptable. Holguin et Al. (2006) demonstrated a low compliance rate (13%) of spectacle wear in school aged Mexican children. Children in both rural and urban areas were more likely to be non compliant with spectacle wear because of concerns about appearance and likeliness of being teased (Holguin, Congdon, Patel, Ratcliffe, Esteso, Flores, Gilbert, Rito and Munoz 2006).

The lack of affordable and accessible spectacles in the developing world is prohibitive. In Central America, where access to care and spectacle correction is limited, the 2004 Gross Domestic Product (GDP) per capita ranges from $970 in Honduras to $4159 in Costa Rica (2004) (Ruis, Guisasola, Stobart, Grasas and Rius 2005) which is diminutive when compared to that of the United States at $41,800 (2005)(CIA 2007). According to the UNESCO Report on Visual Health in Central America 2004, the average price of frames,

including ophthalmic lenses, in Central America ranges from US$20 to US$60; in Nicaragua this is about 60% of the monthly GDP per capita (Ruis et al. 2005). This obstacle is compounded by the fact that spectacles are often lost, broken or scratched and need to be replaced. Furthermore, it is not enough that the spectacles accurately correct a patient's refractive error; they must also be aesthetically pleasing to the wearer if we are to expect reasonable compliance.

Perhaps the greatest obstacle to overcome in providing refractive care is the limited supply of eye care professionals; this is especially true in the developing world. In these areas the number and distribution of professionally trained refractionists are not adequate to meet the estimated need (WHO 2006) and the already limited workforce is clustered in urban areas, therefore amplifying the problem in rural areas(WHO 2006).

In Central America it is difficult to determine the exact number of eye care professionals per person due to the large number of people providing eye care who have no specialized training. The UNESCO Report on Visual Health, Central America (2004) attempted to quantify the number of eye care professionals in each Central American country by drawing from preexisting databases and by conducting fieldwork based on interviews and surveys. They estimate that in Nicaragua, whose population is close to 5.4 million inhabitants, there are 115 untrained and trained opticians and optometrists as well as 55 university trained ophthalmologists. From this report it is clear that there is a lack of trained personnel in the provision eye care in Central America (Ruis et al. 2005).

1.5 Overcoming a Primary Obstacle in Providing Refractive Care

One method that is often implemented by optometric and ophthalmic organizations is the provision of direct clinical care to individual patients in developing countries by means of short term "parachute" missions. These missions are advantageous in that they provide immediate and high quality care for a large number of individuals, but are increasingly being disparaged by the international eye care community (Holden et al. 2002). Most of these missions, often executed by foreign volunteers, do not facilitate the creation of sustainable local services and render the people they are trying to help dependent on foreign aid (Vincent, Pearce, Leasher, Mladenovich and Patel 2007). These missions may also serve as competition for groups working toward a sustainable solution in the same region.

Not without controversy, another method that is gaining popularity is the use of non-eye care professionals in the provision of eye care. The use of lay individuals to determine refractive correction has been proposed and is being tested or used in several different regions, but currently the literature in this area is limited (Faal, Minassian, Dolin, Mohamed, Ajewole and Johnson 2000; Weissberg, Quinn, Travison and Chan 2005; WHO 2005; Vincent 2006).

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Vincent (2006) published data on a program implementing trained lay people for the provision of refractive and basic ocular healthcare in refugee camps along the Thailand-Burma border. Lay people recruited from the community underwent a two week course in basic refraction and these lay people were able to provide eye care through specific

clinics that were held one half day per week. These clinics provided a total of 7219 eyeglasses with 84% of lenses prescribed for presbyopia, 10% for myopia, and 6% for hyperopia. The author concluded that the training of refugee health workers allowed for the provision of sustainable, low cost eye to a disadvantaged population (Vincent 2006). Weissberg et al. (2005) demonstrated that lay community workers can be trained to perform simple spherical refractions with high success in Northern Nicaragua (Weissberg et al. 2005). Programs such as the National Eye care Programme in the Gambia and LV Prasad Eye Institute in Andhra Pradesh, India have also reported the utilization of trained lay people in the provision of eye care (Faal et al. 2000; WHO 2005).

The use of trained lay people is a potentially viable and sustainable solution, but there is a need for the development and implementation of training programs and technology that is easy to use, reliable, affordable and durable. Although many tools specifically developed for use by lay individuals are currently being used, there is a paucity of literature on the validation and comparison of these techniques.

Consequently, there lacks universal agreement on the best approach to overcoming the obstacles to providing refractive eye care in the developing world. Although there is no universal consensus on how refractive services should be delivered, there is general agreement that the solution must be sustainable. Sustainability has been a huge obstacle in the history of public health. All manner of public health projects can fail without input from a third party. One of the best ways to maintain an intervention may be to draw from the local population for manpower and other resources. The concept of community

empowerment has been used in several other fields including farming and education (The World Bank 2005; Arrien 2006).

1.6 Current Techniques in Refractive Care

Currently, the standard of care in providing refractive correction is the subjective refraction when employed by a trained professional. This is not always possible as in many areas of the world access to eye care professionals are limited. This has lead to the development of techniques that can be used by non eye care professionals. These techniques include the AdSpecs, Focometer and the Predetermined Lens Refraction (PLR).

1.6.1 AdSpecs

The AdSpecs are a pair of plastic frames whose lenses are made of two thin mylar films filled with silicon oil (**Figure 1.1**). The amount of fluid within the lenses can be altered by the wearer to change the power of the lenses.



Figure 1.1 The AdSpecs

The power achievable by the lenses of the AdSpecs is spherical. Two syringes mounted on either side of the frame control the amount of fluid in the lenses and thereby alter the power. A lensometer can be used to determine the power of the lenses. The AdSpecs have previously been investigated and have been shown to be a good method of determining and correcting spherical refractive error (Afenyo and Silver 2001; Douali and Silver 2004). In practical use, the amount of fluid pushed into the lenses by the wearer is locked in to place by two flat head screws on either side of the frame. The tubes connecting the syringes to the lenses are cut and the syringes can then be removed. The glasses therefore do not need to be manufactured; the lenses created by the patient are ready to wear. The AdSpecs are the only tool that provides both a means of measuring refractive error as well as a tool to correct it.

Douali and Silver (2006) tested the AdSpecs with 213 subjects in several different areas including South Africa, Ghana, Malawi and Nepal. They showed that, when the fogging

protocol is used, the refractive error measured by the AdSpecs correlates well (r=0.84) with the spherical equivalent of the refractive error determined by an optometrist's refraction (Douali et al. 2004). Subjects in this study were shown to have a slight tendency to 'over-minus' the AdSpecs refractive error measure.

1.6.2 The Focometer

Developed and distributed by InFOCUS (Interprofessional Fostering of Ophthalmic Care for Underserved Sectors), the Focometer is an optometer intended to measure refractive error (**Figure 1.2**). This tool was designed to be used in populations that are lacking in refractive care whether due to inability to afford care or diminished access to care.



Figure 1.2 The Focometer

The Focometer is a two lens system with a magnification of 1x used to produce a real unmagnified image to the viewer. Within the system is a Pechan prism used to erect the image presented to the user. By turning the focus collar, the distance between the two lenses of the Focometer can be altered thereby changing the focal length of the optical

system. The spherical power capabilities of the Focometer range from +12.00 to -7.00 (Berger, Spitzberg, Nnadozie, Bailey, Feaster, Kuether, Tran and Swann 1993). The Focometer is patented and registered with the F.D.A.

In order to use the Focometer, patients must view a real target through the device and adjust the focusing collar until the best possible focus is achieved. The refractive error measured by the Focometer has been shown to be comparable to the spherical equivalent found by other methods of subjective refraction (Du Toit, Soong, Garry, Franzco and Ramke 2006). DuToit et al. (2006) measured the refractive status in one eye of 80 subjects with an autorefractor. The same eye was subsequently measured three separate times with the Focometer. The Focometer found the spherical equivalent to be 0.25D more positive than that measured with the autorefractor; however, 84% of measurements were within 0.75D of the autorefractor measurement. This study showed a significant learning effect with repeated measurement and suggested that only the third measure of refractive error be used to identify a patient's refractive error. While the Focometer is advertised as having the capability of measuring astigmatic refractive error, Du Toit et al. (2006) showed that the Focometer was unable to show a consistent and accurate measurement of this type of refractive error.

The Focometer holds an advantage over traditional methods of refractive care in that it does not require a complicated protocol, is relatively inexpensive, requires no electricity and can be used by non professionals in areas where there are few or no eye care professionals. The Focometer also requires little maintenance, has few small moving

parts and its small size allows it to be easily transported. It is important to remember that once the prescription has been determined by the Focometer, spectacles must then be provided to the patient.

1.6.3 The Predetermined Lens Refraction

The PLR is a scripted series of simple steps involving the use of flipper lenses in one diopter increments held in front of the eye to provide a diagnosis of refractive error. A ±0.50 D lens is incorporated into the end of the protocol to refine the refraction. After the prescription has been determined, a plano placebo lens is placed in front of the subject's naked eye and the visual acuity is measured again. This process allows for the identification of malingering or the prescription of spectacles where none are indicated. Although this technology has been presented at public meetings, published data on its performance is missing. Weissberg et al. (2005) used a variation of the PLR and showed that lay community workers can be trained to perform simple spherical refractions with high success in Northern Nicaragua during a Volunteer Optometric Services to Humanity (VOSH) trip (Weissberg et al. 2005). Two local healthcare workers underwent training in the use of the protocol by means of a two hour tutorial conducted by an experienced optometrist, and the practical examination of about 15 patients supervised by the optometrist. The lay community health workers prescribed spherical lenses ranging +3 to -3 for distance for both the right and left eyes. The same subjects were also refracted using the same technique by the experienced optometrist. Eighty five subjects (170 eyes), age 30 to 80, were randomly chosen from patients examined during the VOSH clinic. The lay community worker was able to prescribe an equal prescription to that of the

optometrist for nearly 89% of eyes. An additional 10% of eyes were within 1.00D of the refractive error determined by the optometrist.

The PLR is a simple and inexpensive procedure that can be taught to multiple members in a community. This procedure has the benefit of drawing from the resources of the community thus making it a sustainable method in the diagnosis of refractive error. As with other techniques, spectacles will have to be provided after refractive error has been identified.

1.7 Gaps in Our Current Knowledge

In order to address the present deficiencies in providing eye care we must first compare the potential solutions to the problem. Both the PLR and Focometer have been tested for accuracy. The accuracy of the AdSpecs has previously been examined, however the reliability of this tool has not yet been determined (Douali et al. 2004). We therefore designed an experiment to test the following: (1) the ability of each tool or method to achieve a measure of refractive error similar to that of a subjective refraction in a clinically controlled setting, (2) the ability of each tool or method to achieve a visual acuity end point similar to that obtained by means of a subjective refraction in a clinically controlled setting, (3) the ability of each tool or method to achieve a measure of refractive error similar to that of a subjective refraction in a field trial (4) the ability of each tool or method to achieve a visual acuity end point similar to that obtained by means of a subjective refraction in a field trial.

1.8 Goals of the Study

In order to investigate the potential of these field measures of refraction we conducted a clinical randomized epidemiological study comparing the ability of each technology to correct refractive error in a healthy population. A similar experiment was conducted within a high risk population in a third world country. The repeatability of the AdSpecs, one field measure of refractive error that had not yet been determined was assessed concurrently.

CHAPTER 2: METHODS

2.1 Brief Overview

This study was conducted in three parts, Parts I, II and III. Part I was a controlled clinical experiment whose subjects were recruited from the New England College of Optometry in Boston, MA. All subjects were refracted with each of the different tools for refraction. Part II of the study was a duplication of Part I with another, very different population from Rivas Province, Nicaragua. Part III tested the repeatability of refractive error and visual acuity obtained with the AdSpecs. The techniques were conducted in a randomized order in order to prevent fatigue and learning effects. All study activities were approved by the Institutional Review Board at the New England College of Optometry.

2.2 Population under study

Students from the New England College of Optometry in Boston, MA were recruited for Parts I and III of the study. Students were between the ages of 18 and 65 with at least a college degree.

Residents from the communities surrounding San Juan del Sur Nicaragua were recruited for Part II of the study. Subjects in Part II of the study were between the ages of 18 and 65.

2.3 Specific Aims

The specific aims of this study are as follows:

1. To examine each of the field measures of refraction (the AdSpecs, the Focometer, and the PLR) and compare them to a standard subjective refraction.
2. To determine and compare the best corrected visual acuity achievable by each of these methods.
3. To determine the reliability of AdSpecs measurements.
4. To determine the impact of specific instructions on the final prescription determined by the AdSpecs.

2.4 Instruments for measuring outcomes

The three tools of refraction described above were studied and compared to a subjective refraction performed by an experienced optometrist. These tools include the AdSpecs, the Focometer and the Predetermined Lens Refraction (PLR).

A gold standard subjective refraction was conducted as performed in routine clinical practice. The process of subjective refraction determines the refractive status of the eye using the patient's subjective responses. The refractive prescription is refined by asking the patient to judge the clarity of an image viewed through a series of lenses. The process of refining the sphere and cylinder and binocular balance is performed as in routine clinical practice. The spherical refraction was done first and included an initial fogging, to find the most plus to maximize visual acuity (MPMVA) and Binocular Balance and then the cylinder was refined as is consistent with standard clinical practice.

2.5 Outcome Measures

Throughout the study, the two outcome measures of interest were the amount of refractive error as well as the best corrected visual acuity determined by the measure in question.

In Parts I and II, refractive error was determined by each method and was then compared to that which was found by subjective refraction. The best corrected visual acuity determined by each of the refractive tools was also compared to the acuity determined by the subjective refraction.

In Part III, refractive error was determined by manipulation of the AdSpecs three times. The refractive error determined by each measurement was compared to the two others and the visual acuity found by each measurement was also compared.

2.6 Analytic Goals

The Specific Aim 1 of Part I of the study concerned the comparison of field measures of refractive error to that obtained by an optometrist. Estimates of the mean population difference in refractive error between the field methods and subjective refraction was compared. Our hypothesis was that field methods of refraction are not inferior to subjective refraction. Specific Aim 2 concerned estimation of the proportion of subjects who achieved BCVA of 20/20 or better using field refraction. We hypothesized that there would be no difference in the ability to achieve BCVA of 20/20 when using field measures versus subjective refraction. Specific Aim 3 of Part I of the study concerned the

impact of instruction on the use of the AdSpecs. We compared (1) deviation from subjective refraction in measuring refractive error, AdSpecs with instruction versus AdSpecs without instruction. Because use of instruction would contaminate a subsequent non-instructed use of AdSpecs, the first use of the device was always without instruction. If no evidence of learning was detected, the difference between the first and second uses of AdSpecs would be associated with the introduction of instruction.

The Specific Aims of Part II of the study included Specific Aims 1, 2 and 3 of Part I of the study. Specific Aim 4 concerned evaluation of the loss of precision of each of the field measurement tools when they are used in a target population. We conducted qualitative comparisons of the performance of each of the methods in Part I versus Part II of the study. The intention was to simulate a public health intervention implemented in a target population.

The specific aim of Part III of the study concerned the reliability of the AdSpecs measurements of visual acuity. Reliability was measured by having a group of subjects repeat the measurement of refractive error three times with the same eye at the same starting point.

2.7 Data Collection

Parts I and III of the study occurred in the Preclinic of the New England College of Optometry in Boston MA. Data collection occurred during weekday hours primarily Mondays and Fridays during the months of March through July of 2007. Subjects

completed the consent form and questionnaire before entering the study and completed the study within one of two lanes of the preclinic.

Part II of the study occurred in the areas surrounding the town of San Juan del Sur in Nicaragua over the course of three days. During Days 1 and 2, collection occurred in class rooms of the local school during daylight hours. During Day 3, data collection occurred on the deck of the community center building, also during daylight hours.

2.8 Experimental protocol

Before the experiment began, the equipment was cleaned and set up for the subject. The AdSpecs were set to +6.00D with the aid of a lensometer. The Focometer was set to a power of +10.00.

At the start of the experiment, the study procedures were described to the subject. The subject was then given a copy of the recruitment letter, a consent form (**Appendix A**) and the questionnaire (**Appendix B**). The completed consent form and questionnaire were placed in a folder with the subject's identification number.

If the subject recorded in the questionnaire that he or she had non-diseased eyes and had consented to the experiment he or she received preliminary eligibility. Any subject that was preliminarily eligible for the study received compensation for his or her participation. Final eligibility was determined once the subject had undergone the subjective refraction. The subject was included in the study if they met all of the

inclusion criteria and had a best corrected visual acuity of 20/20 or better as determined by the subjective refraction.

In a random order, the subject was then brought to the optometrist performing the subjective refraction or the trained layperson conducting the field measures of refraction. If the subject was randomly assigned to the layperson first, the subject performed each of the field refraction measured in a randomized order. If the subject was seen by the optometrist first, the optometrist would perform a spherical subjective refraction followed by a sphere-cylindrical subjective refraction. The order in which the field measures of refraction were performed was determined by the randomization table (**Appendix C**). Part III of the study involved the repetition of the standardized AdSpecs protocol an additional three times.

2.8.1 AdSpecs Protocol

The AdSpecs, which had previously been adjusted to a randomized starting point (**Appendix C**), was given to the subject and the subject was told that the frames contain lenses whose power can be changed by turning the knobs on the sides of the frame. The subject was then asked to adjust the glasses by turning the knobs on the side of the frame until he could see out the window as clearly as possible and inform the examiner when that point had been reached. The subject's monocular acuity, OD and OS, was then tested with a logMAR chart at a distance of 10 feet through the AdSpecs which had just been adjusted by the patient. The power determined by the AdSpecs was measured via a

lensometer and both the lens power and visual acuity obtained by the subject was recorded on the subject's chart.

2.8.2 Standardized AdSpecs Protocol

The AdSpecs were set to a power of +6.00 diopters using the handheld lensometer to determine the power of the lenses. The AdSpecs were placed on the subjects face and the subject was asked to occlude his left eye. The layperson then decreased the power in the lens by turning the knob backwards until the chart came into clear focus and the subject was told to ask the layperson to stop turning the knob when no additional change in clarity was noted. The layperson then turned the knob in the opposite direction until a small amount of blur was achieved. The layperson then reversed direction again and was told by the subject to stop when the chart once again appears as clear as possible. The LogMAR acuity through the final lens was measured and the lens was neutralized with a lensometer. The standardized refraction using the AdSpecs was repeated for the left eye.

2.8.3 Focometer Protocol

The subject was seated facing the distance visual acuity chart. The subject was given the Focometer which had previously been set to a power of +10.00, as determined by the Focometer manual. The left eye of the subject was occluded and the right eye was tested. The subject was told, "This device, the Focometer, will allow us to determine your prescription. We will ask you to look at the chart in front of you and turn the knob on the Focometer to make the chart as clear as possible. Let me know when you feel that the chart is clear." The subject then turned the focus collar until the chart appeared as clear as

possible and no additional clarity could be achieved with further turning. The subject was then instructed to turn the focus collar in the opposite direction until the clarity just achieved became blurry. The subject was instructed to turn the collar in the opposite direction once again and stop when the chart is as clear as possible and no additional clarity could be achieved. The LogMAR visual acuity for the eye was measured through the Focometer with the final setting in place. The power determined by the subject was recorded off the side of the Focometer. The right eye was then occluded and the Focometer procedure was repeated for the left eye.

2.8.4 Predetermined Lens Refraction Protocol

In order to determine the monocular visual acuity of the right eye without correction, the subject was asked to read the lowest line on the LogMAR chart as possible without any correction in front of the unoccluded eye. The left eye was occluded with a solid paddle occluder while the right eye was tested. Once acuity had been measured lenses were placed in front of the unoccluded eye in one diopter increments beginning with a +3.00 lens. Through each lens, the subject was asked to read the lowest line he was able to. The lenses were continually placed in front of the eye in decreasing amounts until visual acuity no longer improved. The most plus powered lens resulting in the best corrected visual acuity was identified and held before the subject's eye. A +0.50/-0.50 flipper lens was placed in front of the most plus lens and the subject was asked if +0.50 or -0.50 made things clearer. If the subject chose the +0.50 or -0.50 the subjects acuity was re-checked through the new resultant lens. The final prescription was determined to be the most plus powered lens that resulted in the best corrected visual acuity. A plano placebo lens was

then placed before the naked eye and the best corrected visual acuity achieved with the placebo lens was compared to the final prescription. The subject was then asked which set of lenses allowed them to see most clearly. If the best corrected visual acuity was the same through the placebo lens as the PLR lens, then the final prescription was determined to be plano, unless the subject preferred the lens determined by the PLR. If the final prescription results in better acuity than the placebo, then that lens was the final prescription. The procedure was then repeated for the other eye. Best corrected monocular visual acuity with the LogMAR chart was well as the prescription determined by the PLR for each eye was recorded.

2.8.5 Subjective Refraction Protocol

The subject was seated facing the distance visual acuity chart. The subject was asked to look at a 20/400 E or other non-accommodative target. The retinoscope, held at the examiner's customary working distance was used to locate the two major meridians and a lens rack was used to neutralize each meridian of right eye. The spherical gross retinoscopy findings were then placed in front of the right eye in the trial frame. The retinoscope was then used to neutralize the two major meridians of the left eye and the spherical gross findings were then placed in front of the left eye in the trial frame. Neutrality for both the right and left eye were rechecked. The spherical equivalent of the net retinoscopy findings were placed in front of the right and left eyes in the trial frame and the left eye was occluded. An initial most plus to maximize visual acuity (MPMVA) was performed on the right eye leaving subject over-minused by 0.25D. The sphere in the trial frame was modified to reflect the results of the MPMVA. The right eye was then

occluded and an initial MPMVA was performed on the left eye leaving the subject over-minused by 0.25D. The sphere in the trial frame was modified to reflect the results of the MPMVA. Both eyes were then fogged with +0.75D and the subject's visual acuity was measured. The subject was instructed to focus on single line of letters one line above the subject's VA. The occluder was moved between the left and right eye and the subject was asked to judge which line of letters appears clearer. Binocular balance was conducted as described below: +0.25D was then added to the better seeing eye until the two eyes are equally clear or most closely clear. -0.25D lenses were then introduced binocularly until the 20/20 line could be read or additional lenses did not result in improved acuity. A final -0.25 was then added to both eyes and the subject was asked if the additional lenses improves acuity, makes no difference, or letters appear "smaller and darker." The additional -0.25D was given only if subject reports "improved acuity." The final monocular LogMAR visual acuity and refractive error for both the right and left eyes was then recorded. Once the spherical refraction was completed the sphero-cylindrical refraction was then conducted. The gross retinoscopy findings were placed in front of the right and left eye in the trial frame and the left eye was occluded. An initial MPMVA was performed on the right eye leaving subject over-minused by 0.25D. The sphere in the trial frame was modified to reflect the results of the MPMVA. Next, the Jackson Cross Cylinder test was performed using a hand held Jackson Crossed Cylinder (JCC). The cylinder axis was refined by flipping the JCC in front of the trial frame with the axis of the cross cylinders 45 degrees away from the correcting cylinder axis. The lens cell of the trial frame was rotated to change the cylinder axis. Then the cylinder power was refined using the JCC. The subject was fogged again by adding +0.75D or until the 20/40 line

could just be read. Lenses were introduced in -0.25D steps until the 20/20 line could be read or additional lenses did not result in improved acuity. An additional -0.25 was added and the subject was asked if the additional power improves acuity, makes no difference, or makes the letters appear "smaller and darker." The additional -0.25D was only given if subject reported "improved acuity." The right eye was then occluded and the refraction was repeated for the left eye. If the BCVA of both eyes was the same a binocular balance was conducted. Binocular balance was conducted as previously described. The final monocular LogMAR visual acuity and refractive error were recorded for each eye.

2.9 Differences in experimental protocol

Every effort was made to keep the protocol of Part I and II the same however due to the circumstances surrounding the study, certain compromises needed to be made. Due to the nature of Part II of the experiment, recruitment and communication with subjects was more difficult than that of Parts I and III. In Part II, the experiment occurred simultaneously with eye care provided to the communities surrounding San Juan del Sur, Nicaragua. Residents of the communities surrounding San Juan del Sur, Nicaragua, were informed that several US optometrists would be conducting vision clinics on a predetermined day in their villages and they were encouraged to come to the clinic for a comprehensive visual exam. Subjects who arrived at the clinic were asked to participate in the study. The study procedures were described by means of a translator to the subject and the subject's name, age and gender was recorded. Once verbal consent had been given by the subject he or she was recruited into the study. Subjects in all parts of the

study were screened for obvious ocular disease detected on gross appearance. Other differences between Part I and II of the experiment are described in **Appendix D**.

CHAPTER 3: RESULTS

3.1 Overview

As stated previously, this study was conducted in three parts. In Part I of the study, we used each of the three refractive tools described above to measure the refractive error and visual acuity of subjects in a controlled clinical setting. Part II involved the implementation of these same tools in a field trial. In Part III of this study, we repeated several measurements of refractive error and visual acuity using the AdSpecs. The acuity and refractive error measures below are for the right eye only of all subjects unless stated otherwise.

3.2 Descriptive Statistics

Descriptive statistics are provided in **Table 3.1**.We observe that the Boston population has a mean (SD) age of 24.3 (1.5) years. The fifty subjects recruited from San Juan del Sur had an mean (SD) age of 40 (13.7) years. There were slightly more women in Part I of the study than in Part II, with 78% of subjects female in Part I and 74% of subjects female in Part II subjects.

Table 3.1 Study sample characteristics

	Part I[a](n=50)	Part II[b] (n=50)	Part III[c] (n=21)
Population			
Age	24.3y (1.5)	40.0y (13.7)	24.9y (1.6)
Gender			
Female	39 (78%)	37 (74%)	13 (62%)
Male	11 (22%)	13 (26%)	9(38%)
Mean Refractive Error (SD)	-2.56D (3.20)	0.51D (0.72)	-1.46 (2.63)
Emmetropes	3 (6%)	6 (12%)	2 (10%)
Hyperopes (>0.25D)	10 (20%)	37 (74%)	7 (33%)
Myopes (<-0.25D)	37 (74 %)	7 (14 %)	12(57%)

[a] Part I represents subjects recruited from The New England College of Optometry.

[b]Part II represents subjects recruited from Rivas Provice, Nicaragua.

[c]Part III represents subjects randomly selected from Part 1 of the study.

Subjects recruited from Boston were also more myopic than subjects recruited from Nicaragua. Mean (SD) refractive error as determined by subjective refraction was -2.56 (±3.2) and 0.51D (±0.72) for Boston and Nicaragua subjects respectively. Of the Boston subjects ten (20%) subjects were hyperopic (>0.25 D), three (6%) were emmetropic, and 37 (74%) were myopic (>-0.25D). Of the Nicaragua subjects, 37 (74%) subjects were hyperopic, six (12%) were emmetropic, and seven (14%) were myopic.

A random group of 21 Boston subjects were recruited for Part III of the study. These subjects had a mean (SD) age of 24.9 (1.61) and a mean refractive error of -1.46 (2.63). Subjects consisted of 2 (10%) emmetropes, 7 (33%) hyperopes and 12 (57%) myopes.

Table 3.2 Uncorrected visual acuity

Part I: Boston		Part II: Nicaragua	
Snellen Acuity	n	Snellen Acuity	n
20/20	14	20/20	25
20/25	2	20/25	8
20/30	4	20/30	1
20/40	2	20/40	2
20/50	2	20/50	5
20/60	1	20/70	7
20/100	3	20/80	1
20/160	5	>20/100	1
20/200	5		
>20/200	12		
Total	50	Total	50

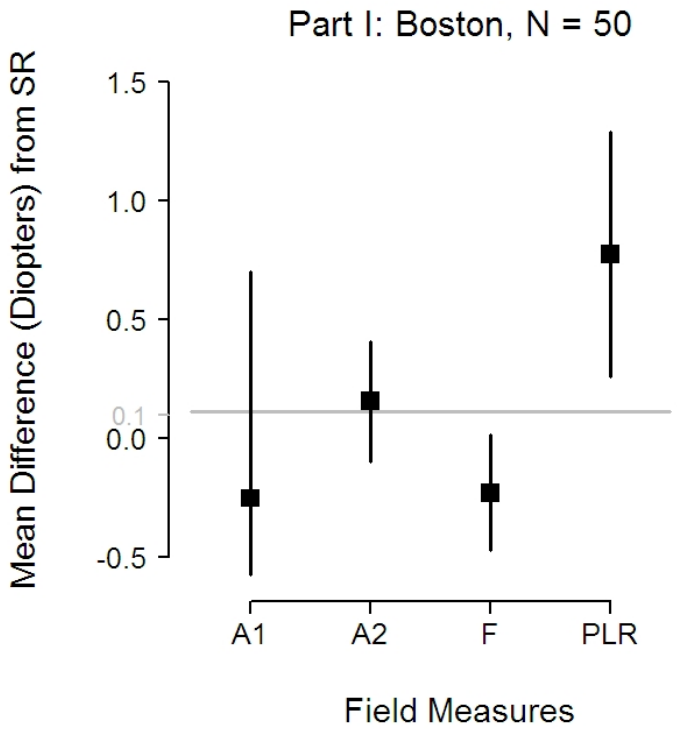
Uncorrected visual acuity is shown in **Table 3.2.** In Boston, 30 (60%) of subjects had an uncorrected acuity of 20/40 or worse. In Nicaragua, 16 (32%) of subjects had an uncorrected acuity of 20/40 or worse.

3.3 Basic Results

In Boston, mean (SD) refractive error for AdSpecs without Instruction, AdSpecs with Instruction, Focometer and PLR was -2.818 (2.659), -2.42 (2.68), -2.80 (2.816), and -1.79 (1.76) respectively (**Table 3.3**). Mean PLR refractive error had the greatest absolute deviation from the gold standard by 0.77D (p=.004) (**Figure 3.1a**). In Nicaragua, subjects had an average refractive error of -0.07 (1.189), 0.68 (0.83), 0.42 (0.16), and 0.27 (0.79) when measured with the AdSpecs without Instruction, AdSpecs with Instruction, Focometer, and PLR respectively (**Table 3.3**). AdSpecs with Instruction indicated more hyperopia than the other techniques, however the difference was not statistically significant (p=0.06) (**Figure 3.1b**). A statistically significant difference was found

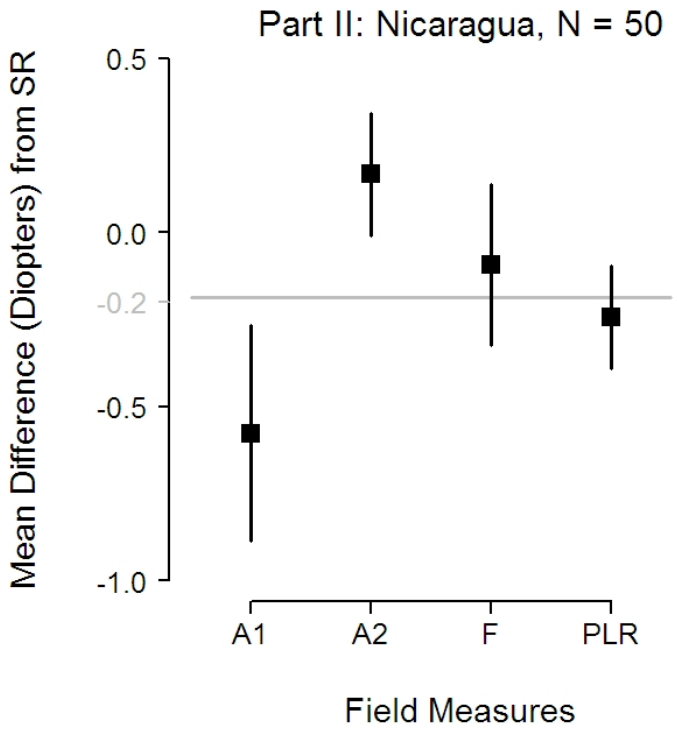
between the refractive error measured by the AdSpecs without instruction and subjective refraction (p= 0.0005) and the PLR and the subjective refraction (p=0.0017). Please note that in **Figures 3.1a** and **3.1b** the scales used in each figure are different for the convenience of showing the data more concisely.

Figure 3.1a Average difference from mean refractive error determined by gold standard subjective refraction in Boston subjects



A1 = AdSpecs with Instruction
A2 = AdSpecs without Instruction
F = Focometer
PLR = Predetermined Lens refraction
SR = Subjective Refraction

Figure 3.1b Average difference from mean refractive error determined by gold standard subjective refraction in Nicaragua subjects



A1 = AdSpecs with Instruction
A2 = AdSpecs without Instruction
F = Focometer
PLR = Predetermined Lens refraction
SR = Subjective Refraction

Table 3.3 Average refractive error and distribution of refractive error type as determined by each method of refraction.

		Part I: Boston	Part II: Nicaragua
Subjective Refraction			
	Mean Refractive Error	-2.56 (3.179)	0.5125 (0.718)
	Myopes[a] n (%)	37 (74 %)	7 (14 %)
	Emmetropes[b] n (%)	3 (6%)	6 (12%)
	Hyperopes[c] n (%)	10 (20%)	37 (74%)
AdSpecs without Instruction			
	Mean Refractive Error	-2.818 (2.659)	-0.07 (1.189)
	Myopes n (%)	41 (82%)	25 (50%)
	Emmetropes n (%)	3 (6%)	4 (8%)
	Hyperopes n (%)	6 (12%)	21 (42%)
AdSpecs with Instruction			
	Mean Refractive Error	-2.41 (2.687)	0.68 (0.835)
	Myopes n (%)	38 (76%)	8 (16%)
	Emmetropes n (%)	2 (4%)	3 (6%)
	Hyperopes n (%)	10 (20%)	39 (78%)
Focometer			
	Mean Refractive Error	-2.70 (2.817)	0.42 (0.160)
	Myopes n (%)	40 (80%)	15 (30%)
	Emmetropes n (%)	2 (4%)	13 (26%)
	Hyperopes n (%)	8 (16%)	22 (44%)
PLR			
	Mean Refractive Error	-1.79 (1.756)	0.27 (0.7903)
	Myopes n (%)	37 (74%)	11 (22%)
	Emmetropes n (%)	9 (18%)	21 (42%)
	Hyperopes n (%)	4 (8%)	18 (36%)

[a] Myopes are subjects with refractive error less than or equal to -0.25D

[b]Emmetropes are subjects with refrative error less than 0.25 and greater than -0.25.

[c]Hyperopes are subjects with greater than 0.25D of refractive error

Forty nine (98%) of the Boston subjects were able to achieve 20/20 BCVA with subjective refraction. 40 (80%) of subjects were able to achieve 20/20 visual acuity with AdSpecs without instruction, 44 (88%) of subjects were able to achieve 20/20 with the AdSpecs with Instruction, 42 (84%) with the Focometer and 33 (66%) with the PLR (**Table 3.4**). The greatest percentage of subjects were correctable to 20/20 by the

subjective refraction followed by the AdSpecs with Instruction, Focometer, AdSpecs without Instruction and PLR. 30 (60%) of subjects had an uncorrected acuity of 20/40 or worse and after subjective refraction none of the subjects were worse than 20/25.

Thirty nine (78%) of the Nicaraguan subjects were able to achieve 20/20 BCVA with subjective refraction. Twenty nine (58%) of subjects were able to achieve 20/20 with the AdSpecs without Instruction, 33 (66%) of subjects were able to achieve 20/20 with the AdSpecs with Instruction, 33 (66%) with the Focometer and 44 (88%) with the PLR. The greatest percentage of subjects were correctable to 20/20 by the PLR, followed by the subjective refraction, then the AdSpecs with Instruction, Focometer and the AdSpecs without Instruction (**Table 3.4**). The PLR was more effective in attaining 20/20 BCVA when compared with both the AdSpecs with Instruction and Focometer (P=0.0001 and P=0.0010 respectively). The PLR did not hold a statistically significant advantage over subjective refraction in achieving 20/20 BCVA (p=0.1147). 14 (28%) of subjects had an uncorrected acuity of 20/40 or worse and after subjective refraction only 1 (2%) was worse than 20/40.

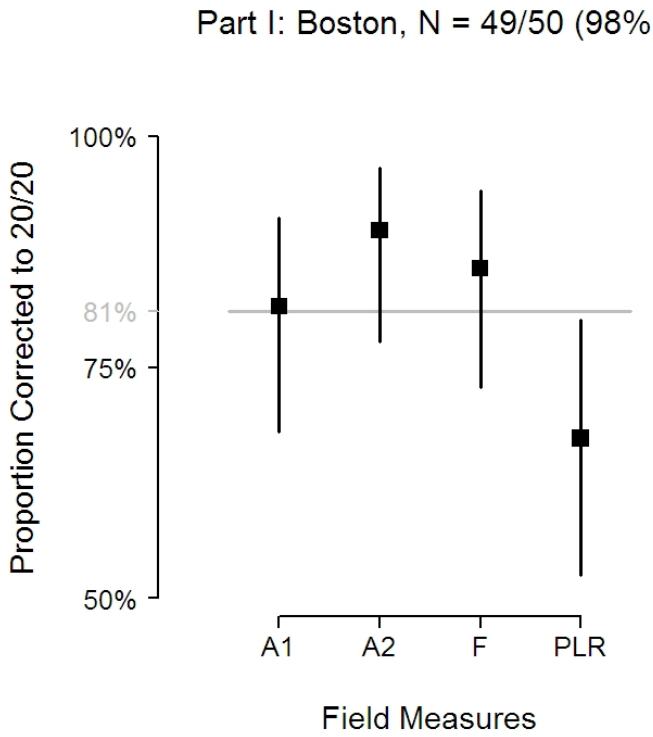
Table 3.4 Number and percent of subjects able to achieve 20/20 visual acuity with each mesure of refractive error

	Boston	Nicaragua
Subjective Refraction	49 (98%)	39 (78%)
AdSpecs without Instruction	40 (80%)	29 (58%)
AdSpecs with Instruction	44 (88%)	33 (66%)
Focometer	42 (84%)	33 (66%)
PLR	33 (66%)	44 (88%)

When looking at the 49 subjects in Boston able to achieve 20/20 acuity by subjective refraction 40 (82%), 44 (90%), 42 (86%), and 33 (67%) were able to achieve 20/20 acuity with the AdSpecs without instruction, AdSpecs with Instruction, Focometer and PLR respectively (**Figure 3.2a**).

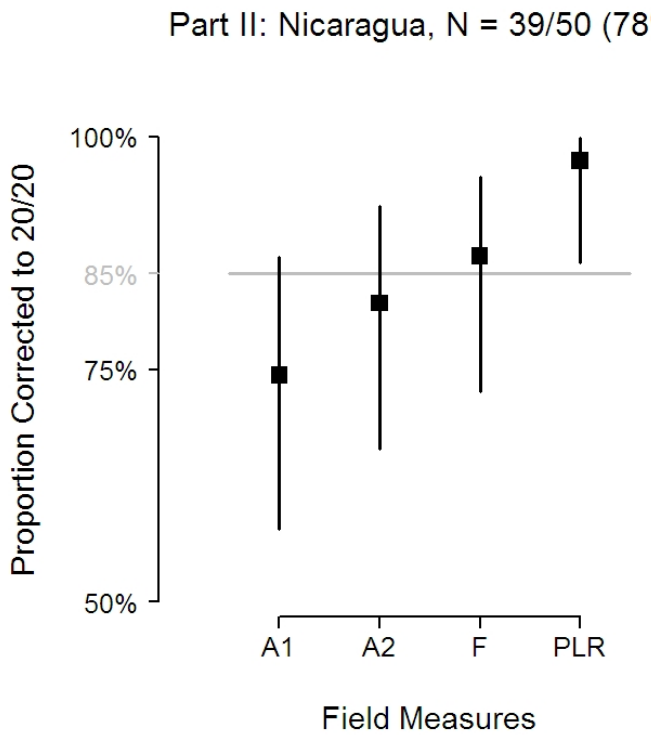
When looking at the 39 subjects in Nicaragua able to achieve 20/20 acuity by subjective refraction 24 (62%), 26 (67%), 29 (74%) and 36 (92%) were able to achieve 20/20 acuity with the AdSpecs without instruction, AdSpecs with Instruction, Focometer and PLR respectively (**Figure 3.2b**).

Figure 3.2a Percent of subjects able to achieve 20/20 visual acuity with each measure of refractive error in Boston subjects



A1 = AdSpecs with Instruction
A2 = AdSpecs without Instruction
F = Focometer
PLR = Predetermined Lens refraction
SR = Subjective Refraction

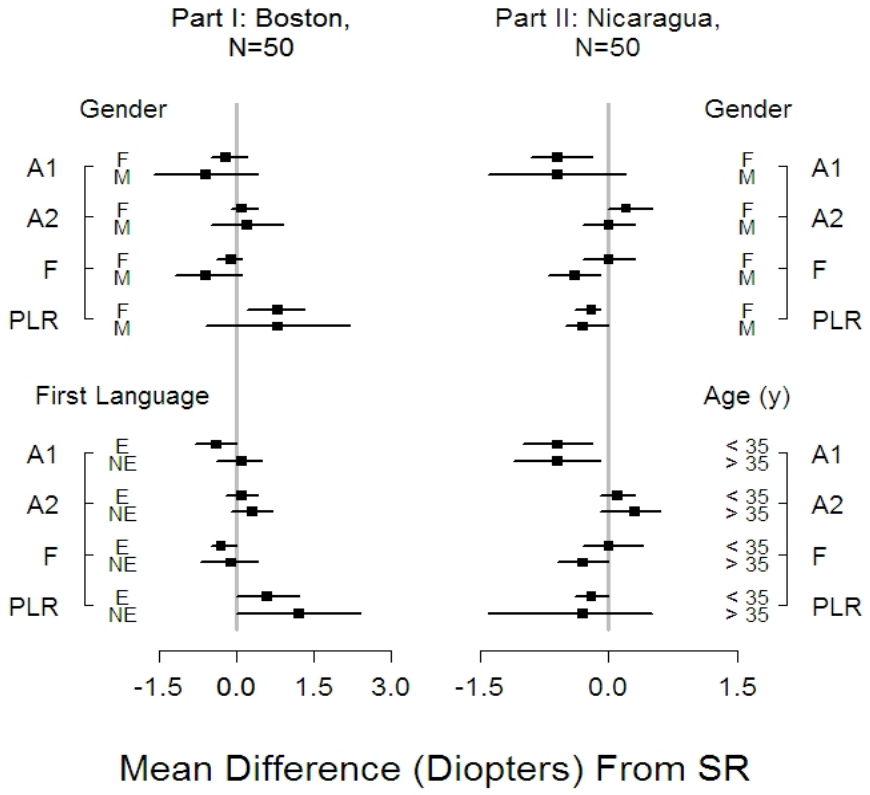
Figure 3.2b Percent of subjects able to achieve 20/20 visual acuity with each measure of refractive error in Nicaragua subjects



A1 = AdSpecs with Instruction
A2 = AdSpecs without Instruction
F = Focometer
PLR = Predetermined Lens refraction
SR = Subjective Refraction

The effect of English as a subject's native language was examined in the Boston population and age effects were looked at in the Nicaragua population. **Figure 3.3** shows that there are no significant differences in refractive error determined by each of the measurements when you consider gender, native language and age.

Figure 3.3 Correlation between measures of refractive error and subject characteristics



F = Female
E = English is the subject's native language
<35 = Subject is younger than 35
A1 = AdSpecs without instruction
F = Focometer

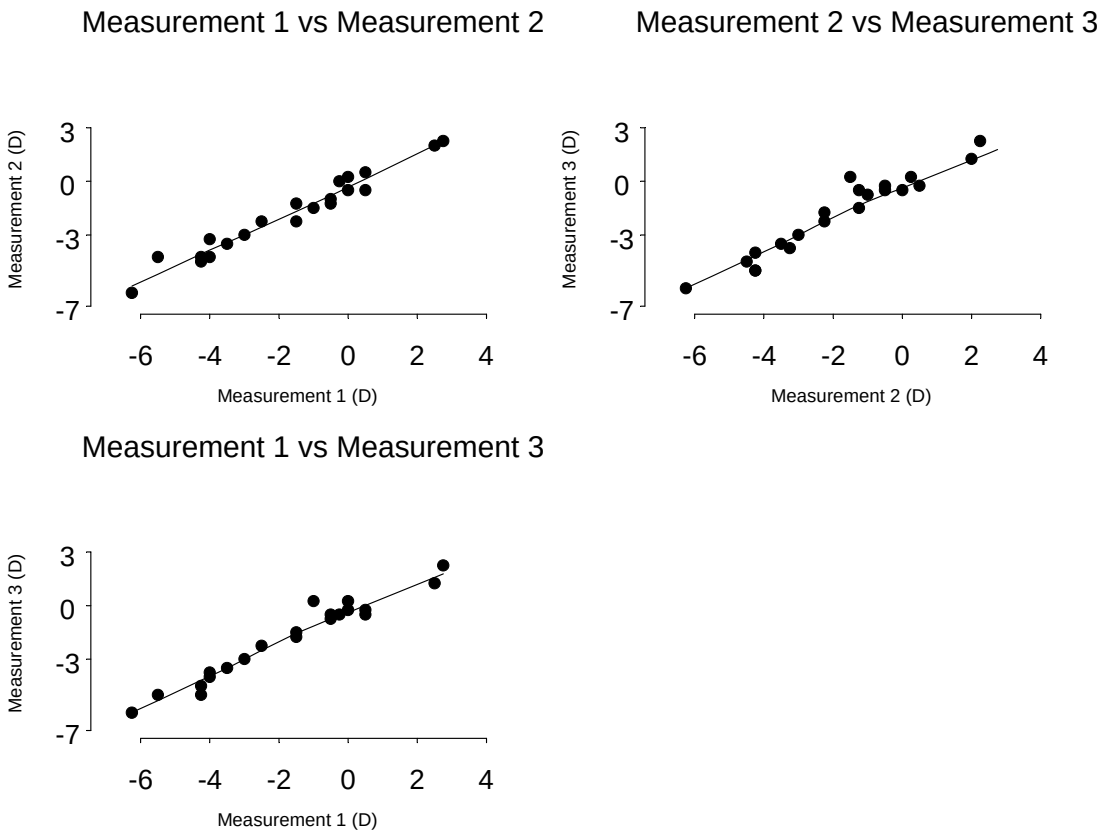
M = Male
NE = English is not the subject's native language
> 35 = Subject is 35 or older
A2 = AdSpecs with instruction
PLR = Predetermined Lens Refraction

Part III showed that multiple measurements with the AdSpecs were highly correlated with each other. Each measure of refractive error was correlated with the other (**Table 3.5 & Figure 3.4**).

Table 3.5 Correlation between each AdSpecs measurement of refractive error

	Measure 1	Measure 2	Measure 3
Measure 1	1	0	0
Measure 2	0.98 ($p<0.0001$)	1	0
Measure 3	0.98 ($p<0.0001$)	0.97 ($p<0.0001$)	1

Figure 3.4 Correlation between each AdSpecs measurement of refractive error



In **Table 3.6** the measures of visual acuity through each measurement of refractive error were also highly correlated.

Table 3.6 Comparison of Visual Acuity Across AdSpecs Measurements

		Visual Acuity After Second AdSpecs Measurement (p=0.000)			
		20/20	20/25	>20/25	Total
Visual Acuity after First AdSpecs Measurement	20/20	13	0	0	13
	20/25	1	5	0	6
	>20/25	0	0	2	2
	Total	14	5	2	21

		Visual Acuity After Third AdSpecs Measurement (p=0.000)			
		20/20	20/25	>20/25	Total
Visual Acuity after Second AdSpecs Measurement	20/20	13	1	0	14
	20/25	1	4	0	5
	>20/25	0	0	2	2
	Total	14	5	2	21

		Visual Acuity After Third AdSpecs Measurement (p=0.000)			
		20/20	20/25	>20/25	Total
Visual Acuity after First AdSpecs Measurement	20/20	12	1	0	13
	20/25	2	4	0	6
	>20/25	0	0	2	2
	Total	14	5	2	21

CHAPTER 4: DISCUSSION

4.1 General Discussion

In Part I of the study both the AdSpecs with Instruction and the Focometer demonstrated potential and were able to determine similar refractive error (within 0.30D) when compared to the gold standard subjective refraction. The Focometer and AdSpecs with Instruction held a statistically significant advantage over the PLR in determining refractive error. The advantage was also seen in their ability to achieve 20/20 visual acuity compared to the PLR. From this we can conclude that in a population which is predominately myopic such as this one, the AdSpecs with Instruction and Focometer are at least comparable to a subjective refraction and are more practical than the PLR when determining spherical refractive error. The differences between technologies did not appear to vary by age or native language

Among the subjects who had refractive error within the range of the PLR (+3.50 to -3.50 versus about +6.00 to -6.00 for other techniques), the difference in refractive error found between the subjective refraction and the PLR method was insignificant. It is feasible that the PLR could be modified to deal with a wider range of refractive error and it would be a reasonable assumption that the observed measurement difference would disappear.

In Part II of the study, the AdSpecs with Instruction, the Focometer and the PLR performed well. There were no clinically significant differences between these techniques with all three techniques measuring within 0.25D as compared to the gold standard subjective refraction. The AdSpecs without Instruction and the PLR had a statistically

significant difference from the subjective refraction. The difference between the PLR and the subjective refraction was less than 0.25D; however the difference between the AdSpecs without Instruction and the subjective refraction was 0.50D.

While all the tools in Part II were comparable in BCVA to the subjective refraction, the PLR achieved a statistically significant advantage in the final BCVA over both the AdSpecs with Instruction and the Focometer. It would appear that the PLR achieved a better BCVA compared to the subjective refraction, but it is important to point out that this was not a statistically significant difference. It is difficult to know exactly why the PLR was more successful than the other techniques, perhaps because this technique incorporated a placebo lens test whereas the others did not. The placebo lens step in the PLR method may have provided an added opportunity to read the 20/20 line.

The AdSpecs performed well with instructions but poorly without them. Without instructions subjects tended to overminus themselves and were not able to achieve the same level of best corrected visual acuity as they could with instruction.

It has been suggested that these tools could be used as a referral device in patients who are suspected of having a more complicated ocular condition than refractive error. Weissberg et al. (2005) referred subjects who were not able to achieve 20/20 acuity with one or both eyes to a referral center which was staffed with more experienced eye care professionals, including optometrists. A protocol could be designed with one or more of

these tools that included referral to a facility where a higher level of eye care could provided, including a sphero-cylindrical refraction for astigmats.

Although the AdSpecs with Instruction has been reported to have comparable optical quality to a standard lens, this is the first report we are aware of that applied the device multiple times as a refraction tool as compared to a one time procedure. The AdSpecs proved to be durable as a refraction device being used approximately 120 times during this study. With the exception of the formation of a few air pockets within the periphery of the lenses, upon observation, the AdSpecs were intact and functioning at the termination of the study. This finding coupled with the versatility of the AdSpecs and the tool's ability to serve as refractive correction for a patient gives them an advantage over the other methods of refraction tested.

The AdSpecs with Instruction measurement of refractive error and visual acuity measurements were repeated three times on 21 randomly selected Boston subjects. The refractive error measurements and resulting visual acuity through the lenses were shown to be highly correlated with the others. There were no statistically significant differences between refractive error measurements 1, 2 and 3 nor were there any statistically significant differences between visual acuity measurements 1, 2 and 3.

The repeatability of these measurements show that the ability of AdSpecs with Instruction to determine refractive error and provided the best possible visual acuity is not dependent on learning. There were no differences between the first and third

measurements so repeated measurement does not change the outcome BCVA and refractive error. This is very different from the Focometer. Du Toit et al (2006) showed that the third measurement made with the Focometer by a patient gives the most accurate measure of refractive error (Du Toit et al. 2006). Unfortunately, this information was not available during the data collection phase of this study and refractive error as determined by the Focometer was measured only once per patient. The Focometer, which performed well in this evaluation may have provided an even closer measure of refraction had we re-measured refractive error three times and used the final measurement as the true refractive error.

4.2 Strengths and limitations of analysis

One strength of the study is that each aspect of the study was tightly controlled. A step by step protocol described above was predetermined for each arm of the study and was performed by the study staff. The same lay person, although limited by language barriers, performed the field measures on every subject.

Randomization was extremely important in this study as the ability of the study to provide an accurate assessment of visual acuity was dependent upon the number of eye charts available. The measures of refractive error were performed in a randomized order to eliminate the effects of memorization and fatigue.

Blinding methods were also used to prevent experimenter bias. The lay person was masked to the results of the gold standard subjective refraction and the reciprocal is true for the optometrists conducting the subjective refractions.

The subjects recruited in this study are likely representative of their respective populations (Wingert 1994). Because the two populations are so different, we are able to see how these tools perform under completely different circumstances in patients with very difference refractive error profiles.

The power of the study was predetermined before recruitment so sample sizes were set to establish statistically significant results. This study, however, is limited by its small sample size. Funding, time and population pool limited our ability to recruit subjects for this study; further research with a larger sample should be done to validate our results.

This study is cross sectional and not longitudinal so we are unable to draw any conclusions about a subject's performance with a tool from one point to another and therefore cannot assess the effect time has on the implementation of these tools.

The comparisons made between the two populations in this study are limited by the fact that no elders were recruited in the Boston arm of the study. Young subjects were chosen because of the decreased likelihood of ocular disease or opacification of the ocular media. In order to assess, each of these tools ability to achieve the best correction possible, young healthy eyes were chosen.

The recruitment of young healthy subjects in Boston results in a much lower risk for significant comorbidities in the study sample, not only because of their ages but also because of their access to healthcare. Data was not collected on the comorbidities of subjects in Nicaragua.

The study was potentially limited by the lack of adequate translation for the field trial of the study. None of the subjects recruited in Nicaragua spoke English, but every subject recruited in Boston, regardless of native language spoke English fluently.

Two optometrists performed the subjective refractions in Nicaragua, while a third and different optometrist performed the subjective refractions in the Boston arm of the study. This may introduce systematic error to the results between Boston and Nicaragua.

In this study, a non-cycloplegic subjective refraction was identified as the gold standard as the role of these tools is to provide clear and comfortable vision and not necessarily identify the absolute amount of refractive error present. These tools are designed to identify the amount of refractive error manifest in a patient's daily life. Since the population studied was between the age of 18 and 65, the risk of overlooking treatable amblyopia was less critical than it would be in younger populations. Further research with cycloplegics maybe useful, however they were not possible in this study because of limited time and resources.

4.3 Future work

Further work is necessary to replicate, validate and expand on the data that has been compiled. With a larger sample population, the conclusions drawn in this study can be further supported. These tools also need to be compared in more varied populations.

Since eyes without gross ocular disease or amblyopia were used in this experiment, further research would be necessary to see how these tools perform in patients who have vision loss secondary to causes other than refractive error. In practical use, this is likely to be a common occurrence and would improve the external generalizability of the results.

Only adult subjects were included in both phases of this study. Further research is necessary to determine whether or not these tools are useful in the pediatric population. The pediatric population presents a new set of challenges as many of the techniques rely on subjective report and one cannot assume that the findings of this study would apply. Additionally, in the pediatric population, the risk of amblyopia is present and it is important to identify and treat causes of amblyopia as early as possible. These tools may not provide an accurate assessment of refractive status of a pediatric patient and therefore may not make sense for practical use in younger patients. Further research is necessary.

Although the distribution of refractive error in the samples are representative of refractive error found in each population additional testing with a larger sample size would be

required to assess the use of these tools in areas where other types of refractive errors are prevalent.

It is important to remember that these tools were tested in correcting spherical refractive error only, although they do hold the possibility of being adapted to target astigmatism as well. Additional studies may need to focus on the increased application of these tools in order to serve a wider range of patients or specifically areas with a high prevalence of significant astigmatism.

An automated measure such as an autorefractor, was not included in this investigation, however could be an additional viable solution to the problem of uncorrected refractive error. Automated refractions have been shown to be extremely repeatable, even when compared with subjective refractions (Rosenfield and Chiu 1995; Bullimore, Fusaro and Adams 1998). One barrier to the use of automated refraction is the cost of such a tool, however if a low cost autorefractor were available, it could be a more promising alternative to a subjective refraction.

CHAPTER 5: CONCLUSIONS

Although there were statistically significant differences between the different refractive methods, from a clinical standpoint, the tools were all nearly equally successful in correcting spherical refractive error. Further research is necessary to evaluate how these tools would perform in different populations.

This is the first and promising report of the AdSpecs being used as a refractive tool. All things being equal, the AdSpecs may have advantages due to versatility of design – they can be used as a refractive tool as well as provide continuous refractive correction in certain situations.

This study is one of the first steps in determining the best way to measure refractive error in areas where no eye care professionals are available. Very little research has been done in this area and it is clear that there is much more to be done.

BIBLIOGRAPHY

Afenyo, G. & Silver, J. (2001). Vision Correction with Adaptive Spectacles. World Blindness and its Prevention, Hyderabad, India.

Arrien, J. (2006). Background paper prepared for the Education for All Global Monitoring Report 2006 Literacy for Life: Literacy in Nicaragua, United Nations Educational, Scientific and Cultural Organization**:** 1-27.

Atkinson, J., Anker, S., Nardini, M., Braddick, O., Hughes, C., Rae, S., Wattam-Bell, J. & Atkinson, S. (2002). Infant vision screening predicts failures on motor and cognitive tests up to school age. *Strabismus* **10**(3): 187-198.

Atkinson, J., Nardini, M., Anker, A., Braddick, O., Hughes, C. & Rae, S. (2005). Refractive errors in infancy predict reduced performance on the Movement Assessment Battery for Children at 3½ and 5½ years. *Developmental Medicine & Child Neurology* **47**(4): 243-251.

Baldwin, W. (1981). A review of statistical studies of relations between myopia and ethnic, behavioral and physiological characteristics. *American Journal of Optometry & Physiological Optics* **58**: 515-527.

Beery, K. (1997). The Beery-Buktenica Developmental Test of Visual-Motor Integration: VMI With Supplemental Developmental Tests of Visual Perception and Motor Coordination: Administration, Scoring and Teaching Manual. Parsippany, NJ, Modern Curriculum Press.

Berger, I., Spitzberg, L., Nnadozie, J., Bailey, N., Feaster, J., Kuether, C., Tran, M. & Swann, S. (1993). Testing the FOCOMETER-a new refractometer. *Optometry and Vision Science* **70**: 332-8.

Borish, I. (1975). The refractive status of the eye - distribution and influences. Chicago, IL, Professional Press, Inc.

Broman, A., Munoz, B., Rodriguez, J., Sanchez, R., Quigley, H., Klein, R., Snyder, R. & West, S. (2002). The impact of visual impairment and eye disease on vision-related

quality of life in a Mexican-American population: Proyecto VER. *Investigative Ophthalmology & Visual Science* **43**(11): 3393-3398.

Bullimore, M., Fusaro, R. & Adams, C. (1998). The repeatability of automated and clinician refraction. *Optometry and Vision Science* **75**(8): 617-22.

CIA (2007). The World Fact Book, Central Intelligence Agency.

Dandona, L. & Dandona, R. (2006). What is the global burden of visual impairment? *BMC Medicine* **4**(6).

Dandona, L., Dandona, R., Srinivas, M., Giridhar, P., Vilas, K., Prasad, M., John, R., McCarty, C. & Rao, G. (2001). Blindness in the Indian state of Andhra Pradesh. *Investigative Ophthalmology & Visual Science* **42**(5): 908-16.

Douali, M. & Silver, J. (2004). Self-optimised vision correction with adaptive spectacle lenses in developing countries. *Ophthalmic and Physiological Optics* **24**(3): 234-241.

Du Toit, R., Soong, K., Garry, B., Franzco & Ramke, J. (2006). Quantification of Refractive Error: Comparison of Autorefractor and Focometer. *Optometry & Vision Science* **83**(8): 582-588.

Eames, T. (1955). The influence of hypermetropia and myopia on reading achievement. *American Journal of Ophthalmology* **39**(3): 375-377.

Faal, H., Minassian, D.C., Dolin, P.J., Mohamed, A.A., Ajewole, J. & Johnson, G.J. (2000). Evaluation of a national eye care programme: re-survey after 10 years. *British Journal of Ophthalmology* **84**(9): 948-951.

González Blanco, F., Sanz Ferńandez, J. & Muńoz Sanz, M. (2008). Axial length, corneal radius, and age of myopia onset. *Optometry & Vision Science* **85**(2): 89-96.

Gwiazda, J., Hyman, L., Norton, T., Hussein, M., Marsh-Tootle, W., Manny, R., Wang, Y. & Everett, D. (2004). Accommodation and related risk factors associated with myopia progression and their interaction with treatment in COMET children. *Investigative Ophthalmology & Visual Science* **45**: 2143-2151.

Harvey, E., Dobson, V. & Miller, J. (2006). Prevalence of high astigmatism, eyeglass wear, and poor visual acuity among Native American grade school children. *Optometry & Vision Science* **83**(4): 206-12.

Helveston, E., Weber, J., Miller, K., Robertson, K., Hohberger, G., Estes, R., Ellis, F., Pick, N. & Helveston, B. (1985). Visual function and academic performance. *American Journal of Ophthalmology* **99**(3): 346-355.

Holden, B. & Resnikoff, S. (2002). The role of optometry in vision 2020. *Community Eye Health* **15**(43).

Holguin, A., Congdon, N., Patel, N., Ratcliffe, A., Esteso, P., Flores, S., Gilbert, D., Rito, M. & Munoz, B. (2006). Factors Associated with Spectacle-Wear Compliance in School-Aged Mexican Children. *Investigative Ophthalmology & Visual Science* **47**(3): 925-928.

Hunter, H. & Shipp, M. (1997 Mar). A study of racial differences in age at onset and progression of presbyopia. *Journal of the American Optometric Association* **68**(3): 171-7.

Hyman, L., Gwiazda, J., Hussein, M., Norton, T., Wang, Y., Marsh-Tootle, W. & Everett, D. (2005). Relationship of age, sex, and ethnicity with myopia progression and axial elongation in the correction of myopia evaluation trial. *Archives of Ophthalmology* **123**: 977-987.

Kørner, A., Lauritzen, L., Abelskov, K., Gulmann, N., Marie Brodersen, A., Wedervang-Jensen, T. & Marie Kjeldgaard, K. (2006). The Geriatric Depression Scale and the Cornell Scale for Depression in Dementia. A validity study. *Nordic Journal of Psychiatry* **60**(5): 360-4.

Lin, L., Shih, Y., Tsai, C., Chen, C., Lee, L., Hung, P. & Hou, P. (1999). Epidemiologic study of ocular refraction among schoolchildren in Taiwan in 1995. *Optometry & Vision Science* **76**(5): 275-81.

Maul, E. (2000). Refractive error study in children: results from La Florida, Chile. *American Journal of Ophthalmology* **129**(4): 445-54.

Negrel, A. (2000). Refractive Error study in children: sampling and measurement methods for a multi country survey. *American Journal of Ophthalmology* **129**(4): 421-6.

Nirmalan, P., Tielsch, J., Katz, J., Thulasiraj, R., Krishnadas, R., Ramakrishnan, R. & Robin, A. (2005). Relationship between vision impairment and eye disease to vision specific quality of life and function in Rural India: The Aravind Comprehensive Eye Survey. *Investigative Ophthalmology & Visual Science* **46**(7): 2308-2312.

Nutheti, R., Keeffe, J., Shamanna, B., Nirmalan, P., Krishnaian, S. & Thomas, R. (2007). Relationship between visual impairment and eye diseases and visual function in Andhra Pradesh. *Ophthalmology* **114**: 1552-1557.

Owsley, C., McGwin, G., Scilley, K., Meek, G., Seker, D. & Dyer, A. (2007). Effect of refractive error correction on health-related quality of life and depression in older nursing home residents. *Archives of Ophthalmology* **125**(11): 1471-7.

Pascolini, D., Mariotti, S., Pokharel, G., Pararajasegaram, R., Etya'ale, D., Négrel, A. & Resnikoff, S. (2004). 2002 global update of available data on visual impairment: a compilation of population-based prevalence studies. *Ophthalmic Epidemiology* **11**(2): 67-115.

Pensyl, C., Harrison, R., Simpson, P. & Waterbor, J. (1997). Distribution of astigmatism among Sioux Indians in South Dakota. *Journal of the American Optometric Association* **68**(7): 425-31.

Pokharel, G. (2000). Refractive error study in children: results from Mechi Zone, Nepal. *American Journal of Ophthalmology* **129**(4): 436-44.

Resnikoff, S., Pascolini, D., Etya'ale, K., Pararajasegaram, R., Ppkharel, G. & Mariotti, S. (2004). Global data on visual impairment in the year 2002. *Bulletin of the World Health Organization* **82**(11): 844-851.

Roch-Levecq, A., Brody, B., Thomas, R. & Brown, S. (2008). Ametropia, Preschoolers' Cognitive Abilities, and Effects of Spectacle Correction. *Archives of Ophthalmology* **126**(2): 252-8.

Rosenfield, M. & Chiu, N. (1995). Repeatability of subjective and objective refraction. *Optometry & Vision Science* **72**(8): 577-579.

Rosner, J. & Rosner, J. (1987). Comparison of visual characteristics in children with and without learning difficulties. *American Journal of Optometry & Physiological Optics* **64**(7): 531-533.

Rosner, J. & Rosner, J. (1997). The relationship between moderate hyperopia and academic achievement: how much plus is enough? *Journal of the American Optometric Association* **68**(10): 648-650.

Ruis, A., Guisasola, L., Stobart, Grasas, R. & Rius, Q. (2005). Report on Visual Health in Central America 2004. Chair in Visual Health and Development UNESCO. Catalonia, University Politecnica de Catalonia.

Simons, H. & Gassler, P. (1998). Vision anomalies and reading skill: a meta-analysis of the literature. *American Journal of Optometry & Physiological Optics* **65**(11): 893-904.

Stewart-Brown, S., Haslum, M. & Butler, N. (1985). Educational attainment of 10-year-old children with treated and untreated visual defects. *Developmental Medicine & Child Neurology* **27**(4): 504-513.

Strenk, S., Strenk, L. & Koretz, J. (2005). The mechanism of presbyopia. *Progress in Retinal & Eye Research* **24**(3): 379-93.

The World Bank (2005). Implementation completion report on a credit in the amount of US$23.6 million to the Republic of Nicaragua for a agricultural technology project, The World Bank**:** 1-64.

Vincent, J. (2006). Simple Spectacles for Adult Refugees on the Thailand-Burma Border. *Optometry & Vision Science* **83**(11): 803-810.

Vincent, J., Pearce, M., Leasher, J., Mladenovich, D. & Patel, N. (2007). The rationale for shifting from a voluntary clinical approach to a public health approach in addressing refractive errors. *Clinical and Experimental Optometry* **90**(6): 429-433.

Wechsler , D. (1989). Wechsler Preschool and Primary Scale of Intelligence-Revised Manual. San Antonio, TX, Harcourt Brace & Co.

Weissberg, E., Quinn, N., Travison, T. & Chan, K. (2005). Validation of a refraction protocol to enhance the delivery of eye care to underserved populations. San Diego, CA, American Academy of Optometry.

West, S., Munoz, B., Rubin, G., Schein, O., Bandeen-Roche, K., Zeger, S., German, S. & Fried, L. (1997). Function and visual impairment in a population-based study of older adults. The SEE project. Salisbury Eye Evaluation. *Investigative Ophthalmology & Visual Science* **38**(1): 72-82.

WHO (1992). International Statistical Classification of Diseases and Related Health Problems, 10th Revision. Geneva, World Health Organization**:** 456-457.

WHO (2005). State of the world's sight vision 2020 : the right to sight 1999 - 2005. Geneva, WHO.

WHO (2006). WHO Monitoring Committee for the Elimination of Avoidable Blindness VISION 2020-The Right to Sight: The Global Initiative for the Elimination of Avoidable Blindness Report of the First Meeting.

WHO (2006). The World Health Report 2006 - working together for health. Geneva, World Health Organization.

Williams, W., Latif, A., Hannington, L. & Watkins, D. (2005). Hyperopia and educational attainment in a primary school cohort. *Archives of Disease in Childhood* **90**(2): 150-153.

Wingert, T.A. (1994). Prevalence of refractive errors on a VOSH mission to Nicaragua. *Journal of the American Optometric Association* **65**(2): 129-32.

Yesavage, J., Brink, T., Rose, T., Lum, O., Huang, V., Adey, M. & Leirer, V. (1982-1983). Development and validation of a geriatric depression screening scale: a preliminary report. *Journal of Psychiatric Research* **17**(1): 37-49.

Zhao, J. (2000). Refractive error study in children: results from Shunyi District, China. *American Journal of Ophthalmology* **129**(4): 427-35.

APPENDIX A

Consent Form

New England College of Optometry
Boston, Massachusetts
Informed Consent

Project Title: Field Measures of Refractive Error: A Comparative Study

Principal Investigator: Erik Weissberg, OD
Co-Investigators: Kimberley Chan, OD
Thomas Travison, PhD
Kyla Smith, BA

Participant's Name: _____

PURPOSE:
Refractive error occurs when your eye cannot focus an image on your retina (the back of your eye) and without a clear image your vision is blurry. Because refractive error causes blurred vision, it is important to measure refractive error so that it can be corrected and vision can be improved. However, due to expense and lack of services, providing refractive error correction to individuals in some parts of the world is quite challenging.

In this study we will compare several methods of measuring and correcting refractive error. These methods may be most useful when it is difficult for a patient to see an eye doctor on a regular basis. The goal of the study is to understand which methods are best and easiest to use. This information will assist us in recommending the best strategy for correcting refractive error when a doctor is not available.

One of the new methods, a device called AdSpecs, is a pair of eyeglasses that have adjustable lenses whose power can be changed to make vision less blurry. Patient can then wear the AdSpecs that they have adjusted to correct their refractive error. Another method is a device called the Focometer. The Focometer consists of lenses aligned in a tube that a patient can adjust to make his or her vision clearer. A third method, the Predetermined Lens Refraction (PLR), uses a series of pre-selected lenses to show a patient how he or she would be able to see with different types of lenses in front of his or her eyes. With this method, the patient's amount of refractive error would be determined after a several steps of supervised instructions. With these steps already described, a trained layperson could carry out a PLR if an eye care professional were not available. The AdSpecs, Focometer, and PLR method are referred to as field measures because they are used primarily outside of the optometrists' offices in areas where traditional equipment might not be available.

In addition to testing these new methods, we will be providing each study participant with a subjective refraction that includes a spherical component all of which is performed by an optometrist. The field methods of refraction will then be compared to the standard subjective refraction from each subject. The results of the optometrist's evaluation will be made available to you at the end of your visit.

There will be about 52 subjects in this research study; most of whom will come from the New England College of Optometry (NECO) student body. There will be one session for each subject and it will last approximately two hours.

INCLUSION /EXCLUSION CRITERIA:
You may be included in the study if you are physically and psychologically capable of having your eyes refracted and if you have non-diseased eyes. The presence of ocular pathology (eye disease) and/or amblyopia, resulting in vision that cannot be completely corrected in one or both eyes, would lead to exclusion from the experiment. You will be excluded from participating in the study if you are not capable of having a refraction performed, if you have any diseases of the eye, or if you are physically unable to perform the tasks necessary for the study.

PROCEDURE:
The six different measurements involved in the study will occur during the same visit and will all be performed by an optometrist. You will determine your refraction and your best visual acuity using the AdSpecs, first without instruction and then with instruction. You will use the Focometer to determine your refraction and best visual acuity. You will undergo a subjective refraction by an optometrist utilizing the Predetermined Lens Refraction (PLR) and another optometrist will perform a standard subjective refraction. The subjective refraction will include a spherical refraction as well as a sphero-cylindrical refraction. These procedures will be explained verbally to you in more detail during the study. We will ask you several questions about your age, gender, ethnicity and eye status in order to develop background correlations. The entire procedure will take up to two hours and you will receive monetary compensation in the amount of ten dollars from the New England College of Optometry for your time.

POTENTIAL BENEFITS:
The study offers no immediate benefit to you as a participant; however the results of your standard subjective refraction will be provided to you. The information generated from this study will help determine how the various procedures compare to one another and to a standard subjective refraction and will increase scientific knowledge.

RISKS AND DISCOMFORTS:
The study poses minimal risk to you as shown by the previous use of these procedures.

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

If you decide to be a subject in this study, you will fill out a questionnaire which asks about both demographic and technical information. Demographic information will include, but will not be limited to such things as, your 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 from you 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 you as a subject. Even so, 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 could specifically identify you will be used in any 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 it at any time by writing to the principal investigator(s) at the address below.

If you cancel your permission to use your PHI after you have started the study 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 right 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 information generated or collected about you during this study includes the study doctor(s), the study staff, the Institution, any study Sponsor (or the 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 redisclosed, at which point your health information may no longer be protected by federal privacy regulations.

You may ask the study investigator 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 investigator's privacy policies. The Confidentiality, Personal Health Information, and Privacy 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 WITHDRAWAL:
Being part of this project is voluntary. Whether or not you choose to take part in the project will have no bearing on any care you may be receiving or your academic standing at the New England College of Optometry. The Institutional Review Board or the investigator may terminate your participation in the study (with or without your consent) if it is believed to be in your best interest.

COMPENSATION:
There is no cost to you and you will be financially compensated for your time in the amount of ten dollars. Upon your completion of your role on the study, you will be asked to fill out a check request form that will be submitted to the business office of the New England College of Optometry. You will then receive a check from the College within two to three weeks from the date of submission. The entire procedure should take no more than two hours. Although highly unlikely to occur, if you have any reaction directly related to the study, treatment will be provided at no cost to you by the New England Eye Institute. Any other treatment is your responsibility and the responsibility of your health insurance.

If you have any questions about this project, you may contact the Principal Investigator:

Erik Weissberg, OD, FAAO
Telephone: (617) 369-0157

or in writing at:

The New England College of Optometry
424 Beacon Street
Boston, MA 02115

I have fully explained to _____

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.

_____

Doctor's Signature

Consent: I have been satisfactorily informed of the above-described procedures with their possible risks and benefits. I give permission for my participation in this study. I know that Dr. Weissberg or his associates will be available to answer any questions that I may have and may be reached a**t (617) 369-0157**. 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 study at any time, even after signing this form, and it will not affect my care or standing at the New England College of Optometry. I have been given a copy of this form. Although unlikely, if I have an adverse reaction related to the study I will call Dr. Weissberg. If he is unavailable, I will call the emergency phone **(617-262-2020)** at the New England Eye Institute.

_____ _____

Date **Subject's Signature**

_____ _____

Date **Witness to Signatures**

This informed consent was approved by the New England College of Optometry Institutional Review Board.

_____ _____

Date **Signature of Chairman**

APPENDIX B

Subject Questionnaire

Field Measures of Refractive Error: A Comparative Study

Clinical Data Questionnaire

Principal Investigator:
Erik Weissberg, OD

Co-investigators: Kimberley Chan, OD
Thomas G. Travison, PhD
Kyla Smith, BA

The New England College of Optometry
424 Beacon St.
Boston, MA 02115

Note: The information contained in this document is confidential. If this document has been misplaced, please return with care to Erik Weissberg, OD at the above address. Thank you.

Staff use only:

Patient Number:
_____

Staff Use Only:			
Evaluation Date:			
	Day	Month	Year
Evaluation Time:			
	Hour	Minute	AM/PM
Examiner Names			
	First	Last	MI
	First	Last	MI

To the study subject: Please complete pages iii, iv, v, and vi of the following questionnaire as completely and accurately as you can. Instructions for each item are marked "Instructions" and with the relevant item number; please record your responses in the fields marked "Data Entry." Your responses will be kept confidential in accordance with the provisions of the informed consent document you have received. Any items to which you do not wish to respond can be left blank. Please direct any questions to the study staff.

Thank you!

Table I – Demographic Information

This information will assist in describing the broad social characteristics of the study population, and to assess variation in study outcomes across socioeconomic categories.

No personally identifying information will be used in any analysis.

Instructions	Data Entry
I.1 Full Name. Please enter your name in the following format: Firstname MI Lastname.	I.1 _____
I.2 Date of Birth. Please enter your date of birth in the following format: mm/dd/yyyy. For instance, a subject born on May 2nd, 1967 would enter 05/02/1967.	I.2 _____
I.3 Gender. Please specify your gender, male or female.	I.3 _____
1.4 Ethnicity. **I.4a** Please select the category that you believe best describes your ancestral ethnic heritage, among the following: 1 American Indian/Alaska Native 2 Asian 3 Black or African-American 4 Native Hawaiian or Pacific Islander 5 White/Caucasian 6 Other **I.4b** Are you of Hispanic or Latino descent (Yes/No)? **I.4c** If you selected "Other" above, how would you describe your ethnic background?	I.4a _____ I.4b _____ I.4c _____
I.5a Is English your native language (Yes/No)? **1.5b** If English is not your native language, please specify which language you would consider your native language.	I.5a_____ I.5b_____
1.6a Please select the category that you	I.6a_____

believe best describes your level of education, among the following: 1 Less than a High School Degree 2 High School Degree or GED 3 College Degree 4 Graduate Degree 5 Other **I.6b** If you selected “Other” above, how would you describe your level of education?	I.6b_____

Table II – Clinical Background

This information will assist in describing the clinical and medical characteristics of the study population, and permit exploration of the relationship between these characteristics and outcome measures.

No personally identifying information will be used in any analysis.

Instructions	Data Entry
II.1 General Health Status.	
II.1a Have you ever suffered a serious injury or illness? If so, please specify the approximate date(s) and nature of the incident(s).	**II.1a** _____
	_____
II.1b Please specify any medication that you are currently taking.	**II.1b** _____
II.2 Ophthalmic History.	
II.2a Do you use corrective eyeware such as glasses or contact lenses (Yes/No)?	**II.2a** _____
II.2b Do you wear contact lenses (Yes/No)?	**II.2b** _____
II.2c CRT. Have you ever had Corneal Refractive Therapy (CRT) or Orthokeratology?	**II.2c** _____
II.2c1 If so, please specify the year(s) that you underwent CRT.	**II.2c1** _____
II.2d LASIK. Have you had Laser Assisted In Situ Keratomileusis (LASIK), Photorefractive Keratectomy (PRK), or Conductive Keratoplasty (CK)?	**II.2d** _____
II.2d1 If so, in what year was the surgery performed?	**II.2d1** _____
II.2e Injury. Have you ever sustained injury to either eye?	**II.2e** _____
II.2e1 If so, for each injury please specify which eye and the nature and date of the injury.	**II.2e1** _____
	_____
	_____

II.3 Additional notes. Are there additional considerations of which you think we should be aware? If so, please specify as succinctly as you can.	**II.3** _____ _____ _____ _____ _____ _____ _____ _____ _____ _____

Staff use only **CLINICAL OUTCOMES MEASURES**	
OD Measurement	**OS Measurement**
OD VA (sc)_____	OS VA (sc) _____
AdSpecs Unstandardized	
OD VA _____	OS VA _____
OD Rx _____	OS Rx _____
AdSpecs Standardized	
OD VA _____	OS VA _____
OD Rx _____	OS Rx _____
Focometer	
OD VA _____	OS VA _____
OD Rx _____	OS Rx _____
Flipper Method	
OD VA _____	OS VA _____
OD Rx _____	OS Rx _____
Spherical Subjective Refraction	
OD VA _____	OS VA _____
OD Rx _____	OS Rx _____
Subjective Refraction	
OD VA _____	OS VA _____
OD Rx _____	OS Rx _____

APPENDIX C

Randomization Schedule

FMORE RANDOMIZATION TABLE (10.05.05)		Experimental Procedures			
Subject	**Starting Adspecs Position**	**1st**	**2nd**	**3rd**	**4th**
1	-5	PLR	Focometer	Adspecs	Subj. Opto. Refr.
2	6	PLR	Adspecs	Focometer	Subj. Opto. Refr.
3	2	Adspecs	Focometer	Subj. Opto. Refr.	PLR
4	-3	PLR	Adspecs	Focometer	Subj. Opto. Refr.
5	1	Adspecs	Focometer	PLR	Subj. Opto. Refr.
6	0	Subj. Opto. Refr.	Focometer	PLR	Adspecs
7	-1	Adspecs	Focometer	Subj. Opto. Refr.	PLR
8	-4	Subj. Opto. Refr.	PLR	Focometer	Adspecs
9	4	Adspecs	PLR	Subj. Opto. Refr.	Focometer
10	-6	Subj. Opto. Refr.	PLR	Focometer	Adspecs
11	3	Subj. Opto. Refr.	Focometer	Adspecs	PLR
12	-2	Adspecs	Subj. Opto. Refr.	Focometer	PLR
13	5	Subj. Opto. Refr.	Adspecs	PLR	Focometer
14	3	Subj. Opto. Refr.	Focometer	PLR	Adspecs
15	2	Adspecs	Focometer	PLR	Subj. Opto. Refr.
16	-3	PLR	Subj. Opto. Refr.	Focometer	Adspecs
17	-1	Subj. Opto. Refr.	Adspecs	PLR	Focometer
18	-2	Adspecs	Subj. Opto. Refr.	Focometer	PLR
19	-6	Subj. Opto. Refr.	Focometer	Adspecs	PLR
20	1	Subj. Opto. Refr.	Adspecs	PLR	Focometer
21	5	PLR	Subj. Opto. Refr.	Adspecs	Focometer
22	6	Focometer	PLR	Subj. Opto. Refr.	Adspecs
23	0	Subj. Opto. Refr.	Adspecs	PLR	Focometer
24	-4	PLR	Subj. Opto. Refr.	Focometer	Adspecs
25	-5	Focometer	Subj. Opto. Refr.	Adspecs	PLR
26	4	Subj. Opto. Refr.	Focometer	PLR	Adspecs
27	6	Subj. Opto. Refr.	PLR	Focometer	Adspecs
28	-5	PLR	Focometer	Subj. Opto. Refr.	Adspecs
29	-4	Adspecs	Focometer	Subj. Opto. Refr.	PLR
30	-2	Focometer	PLR	Subj. Opto. Refr.	Adspecs
31	1	PLR	Adspecs	Focometer	Subj. Opto. Refr.
32	2	PLR	Adspecs	Subj. Opto. Refr.	Focometer
33	4	Adspecs	PLR	Subj. Opto. Refr.	Focometer
34	-3	Adspecs	Subj. Opto. Refr.	PLR	Focometer
35	-6	Subj. Opto. Refr.	Adspecs	Focometer	PLR
36	3	Subj. Opto. Refr.	PLR	Adspecs	Focometer
37	5	Focometer	PLR	Adspecs	Subj. Opto. Refr.
38	0	Subj. Opto. Refr.	PLR	Adspecs	Focometer
39	-1	Focometer	Subj. Opto. Refr.	Adspecs	PLR
40	-1	PLR	Adspecs	Subj. Opto. Refr.	Focometer
41	0	Subj. Opto. Refr.	PLR	Focometer	Adspecs
42	-4	Focometer	Subj. Opto. Refr.	PLR	Adspecs
43	-5	Subj. Opto. Refr.	Focometer	Adspecs	PLR
44	-6	Subj. Opto. Refr.	Focometer	PLR	Adspecs
45	-3	Focometer	Subj. Opto. Refr.	Adspecs	PLR
46	2	Subj. Opto. Refr.	PLR	Adspecs	Focometer
47	4	Subj. Opto. Refr.	Focometer	PLR	Adspecs
48	6	Subj. Opto. Refr.	PLR	Focometer	Adspecs
49	1	Adspecs	PLR	Focometer	Subj. Opto. Refr.
50	3	PLR	Subj. Opto. Refr.	Adspecs	Focometer
51	-2	Subj. Opto. Refr.	Focometer	PLR	Adspecs
52	5	Focometer	Adspecs	Subj. Opto. Refr.	PLR
53	-1	Focometer	Subj. Opto. Refr.	PLR	Adspecs
54	-4	Focometer	Subj. Opto. Refr.	PLR	Adspecs
55	2	Adspecs	Focometer	PLR	Subj. Opto. Refr.
56	0	PLR	Subj. Opto. Refr.	Adspecs	Focometer
57	1	PLR	Subj. Opto. Refr.	Adspecs	Focometer
58	3	PLR	Adspecs	Focometer	Subj. Opto. Refr.
59	4	Subj. Opto. Refr.	PLR	Focometer	Adspecs
60	-5	Subj. Opto. Refr.	Focometer	Adspecs	PLR
61	-2	Subj. Opto. Refr.	Adspecs	PLR	Focometer
62	-6	Subj. Opto. Refr.	PLR	Adspecs	Focometer
63	6	Focometer	Adspecs	PLR	Subj. Opto. Refr.
64	-3	Focometer	PLR	Adspecs	Subj. Opto. Refr.
65	5	PLR	Subj. Opto. Refr.	Adspecs	Focometer
66	-3	Adspecs	Subj. Opto. Refr.	PLR	Focometer
67	6	Subj. Opto. Refr.	Adspecs	Focometer	PLR
68	-6	Subj. Opto. Refr.	Adspecs	PLR	Focometer
69	-2	Adspecs	PLR	Subj. Opto. Refr.	Focometer
70	-5	Focometer	Adspecs	Subj. Opto. Refr.	PLR

APPENDIX D

Appendix D: Differences in Experimental Protocol

Parts I and III: Boston, MA	Part II: San Juan del Sur, Nicaragua
One optometrist performed all subjective refractions.	Two optometrists performed subjective refractions.
Same optotypes were used by both optometrist and lay person.	Two different charts were used by the optometrists and lay person.
Both eyes were refracted by each method of refraction.	Only the right eye of each patient was refracted with the field measures of refraction.
Two refractions were performed with the AdSpecs: one without formal instruction and one without.	Only one AdSpecs refraction was performed with a starting point of +6.00 and with instruction.
A standard lensometer was used to determine the power of the AdSpecs throughout all parts of the study.	A handheld lensometer was used to determine the power of the AdSpecs.
Both a spherical and sphero-cylindrical refraction was performed by the optometrist	Only a sphero-cylindrical refraction was conducted by the optometrists.