THE EFFECTIVENESS OF THE SEE CLEARLY METHOD

A Thesis

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the Degree Master of Science in the Graduate School of
The Ohio State University

By

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The purpose of this study is to determine the effectiveness of the See Clearly Method. The See Clearly Method is a program of eye exercises designed to naturally improve eyesight without traditional optical correction. The goals of this study are to quantify changes that occur after using the See Clearly Method for one month, specifically changes in visual acuity, refractive error and subjective quality of life.

Thirty subjects were randomized into two groups. The test group was given the See Clearly Method and was instructed to use the kit for one month, keeping track of progress in a daily journal. The control subjects did not use the See Clearly Method during the month. Uncorrected high contrast visual acuity, subjective refraction and autorefraction were measured at baseline and at one month and analyzed for change. Subjective quality of life was assessed using the National Eye Institute Refractive Error Quality of Life (NEI-RQL) instrument both at baseline and at one month.
No statistically significant changes were found for any of the outcomes analyzed, which indicates that in this study, the See Clearly Method did not change the patient's refractive error or uncorrected visual acuity, and it did not improve visual quality of life. Findings can be used to educate doctors and patients about this product.
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CHAPTER 1

INTRODUCTION

Traditionally, spectacle lenses have been used to correct refractive error. Today there are many alternative options for correcting all types of refractive error. Contact lenses can be use for myopia, hyperopia, astigmatism, and presbyopia. Surgical procedures are also becoming a more common choice for patients to reduce or eliminate refractive error. Aside from optical and surgical correction, there has been an increased interest in alternative forms of vision correction. Methods of alternative vision correction include vision training exercises, acupuncture, massage, biofeedback therapy and hypnosis. The See Clearly Method (Vision Institute of America) is a vision training product designed to naturally improve vision.

The See Clearly Method is a series of eye exercises and activities designed by a team of award-winning optometrists to address common vision problems such as myopia, hyperopia, astigmatism, presbyopia and asthenopia. The system includes exercises and activities designed to help strengthen and relax eye muscles.
The See Clearly Method was developed to help users see more clearly and comfortably without glasses or contact lenses, to reduce dependence on optical correction, and/or to stabilize changes in refractive error to prevent progression.

In a clinical test performed by the Vision Institute of America, subjects were trained to use the See Clearly Method (www.seeclarlymethod.com). The authors reported that most patients felt there was a moderate to significant improvement in their vision that occurred after using the kit for six weeks. The subjects also felt less dependent on their previous method of vision correction. However, this testing was not formal clinical research. The investigators did not randomize subjects to treatment groups and no quantifiable data were reported to support their claims.

The See Clearly Method is available to the general public and is advertised on the radio and television. It can be used without a doctor’s supervision. Many interested patients may hear the product claims and ask their eye care practitioner regarding the effectiveness of the program. This formal research will help doctors and patients by providing clinical information about the See Clearly Method. Our purpose is to test the efficacy of this program by gathering both clinical data and subjective quality of life information. The goals of this thesis are:

- to determine if using the See Clearly Method for one month improves the uncorrected visual acuity of subjects;
• to determine if the program is effective in reducing the amount of the subject's manifest refractive error; and
• to discover the effect the See Clearly Method has on vision-related quality of life of our subjects.
Refractive error is common today. Myopia is a leading cause of vision impairment, affecting up to 25% of adolescents in westernized countries (Gilmartin 2004). Hyperopia, though it causes less visual impairment for most people, affects about 50% of the adult population according to the Beaver Dam Eye Study (Wong, Klein et al. 2002). Presbyopia, a condition that occurs in all individuals over age 40 years requires the use of bifocals or reading glasses to see clearly at near. Conventional treatments include glasses, contact lenses and surgical procedures. Alternatives to all types of conventional medical treatment, including vision care, are prevalent in today’s society. It has been shown that 42% of the population in the United States has used at least one form of complementary or alternative medicine (Chou 2004).

2.1 The Bates Method

The idea that visual training can improve vision and reduce or eliminate the need for spectacles is not a new one. Ophthalmologist William H. Bates first published a book
in 1920 which outlines his solution to seeing without glasses (Bates 1920). The Bates Method, as his program was dubbed, has prevailed in spite of many attempts to refute it. Interestingly it still has a following.

The Bates Method operates on the idea that the crystalline lens has no effect on the accommodation of the eye (Bates 1920), though it has long been shown that accommodation is determined by the change in curvature of the crystalline lens (Pollack 1956). Bates theorized that changes to the shape of the eyeball that occur with accommodation are caused by the extraocular muscles (Bates 1920). He stated that increased, sustained tension in these muscles is what leads to a state of myopia.

Myopia has been described as a “pattern of pronounced tension in the forehead, jaw, neck, shoulders, upper arms, and lower back (Bambridge 2002).” It has also been linked to personality (Kelly 1962), with myopic patients being described as introverted and very controlled. The Bates Method and other visual training programs use relaxation of the eyes, as well as the body and mind, to improve vision.

The basic principles of the Bates Method are as follows:

**Palming:** This exercise includes cupping the hands over the closed eye and remembering total darkness or “seeing black.” This technique is the
complete relaxation of all of the senses including vision. The thinking is, when one can completely relax and picture perfect black, he or she will have perfect vision.

Shifting and Swinging: Shifting and swinging involves changing focus between two targets. The patient should use eccentric fixation to see the targets clearly because trying to look directly at the target or staring at it will increase tension. When the eyes are trained to move rapidly, vision would be improved.

Imagination: Imagining that one can see better will increase the ability to actually increase the number of letters read on a vision chart.

Sun-gazing or “sunning”: People with normal vision should be able to look at the sun without sustaining damage. After looking at the sun, patients will be able to see more clearly. If damage occurs, Bates believed that strain, not sunlight, was the cause for the damage.

Though the Bates Method has had many followers, it has not been without its share of critics. Marg (1952) investigated the phenomenon of “clear flashes” of vision that some patients seem to experience. Marg found that only one percent of subjects tested could exhibit such a flash of clear vision, and that it was not sustainable. He also tested subjects who were undergoing Bates training and found that they were able to improve
their visual acuity, but there was no significant change in refractive error. Marg said that
the Bates Method might “…have conceivable uses, but they are no substitute for helpful
optical correction of the eyes (Marg 1952).”

In a book published in 1956, Pollack points out the fallacies of the Bates Method in a
simple, easy to understand book written for the general public. He points out that the
research performed by Bates was at times unscientific and that it was impossible for the
extraocular muscles to control accommodation (Pollack 1956). Pollack stresses that the
vision training used in the Bates Method, and programs that have since arisen from its
influence, represent unorthodox vision training. Orthodox vision training includes such
things as orthoptic training for strabismus and training eye muscles to improve reading
levels. Orthodox vision training has always and should hold an important place in
optometric practice.

The Bates Method is based predominantly on the scientific studies he performed himself,
mainly on animal eyes. Consider the theory of accommodation. Bates was unable to
detect a change in the shape of the crystalline lens during accommodation; therefore, he
rejected the well-founded theory that the lens is responsible (Pollack 1956). He also cited
anecdotal cases (e.g. when atropine drops failed to eliminate accommodation or described
a patient who was able to read at near following cataract lens extraction) to support his
theory. He failed to realize that these patients were the exception rather than the rule.
There are also anecdotes in Bates's book (Bates 1920) that indicate that ocular disease such as glaucoma and cataracts can be cured by using the Bates Method. This theory was not well accepted at the time of original publication and definitely has not been since. These claims were also based on a few cases he observed. Subsequent publications of his book after his death in 1936 no longer make these claims (Pollack 1956). Sunning, or staring into the sun, was also removed from the book in further publications (Bates 1981), as it was clearly understood to cause damage to the eye.

The Bates research on human subjects is based making case by case conclusions and applying them universally. Case studies do have an appropriate place in practice. They can be used to influence treatments and can trigger investigational research projects, but one must be careful not to draw inappropriate conclusions. Bates’s use of them does not satisfy these useful criteria.

2.2 Visual Training Techniques

Many visual training and behavioral approaches have emerged under the influence of the Bates Method (Huxley 1942; Peppard 1959). These books are less controversial than Bates’s book and therefore are less well-known. The approaches also focus on the relaxation of the eye, especially the accommodative system, to rid the patient of his or her spectacle correction.
A different approach is offered by Dr. Edward Friedman. This training method is based on the concept of functional myopia, defined as "simple myopia of nongenetic origin (Friedman 1981)." The concepts of the program are based on the AC/A response style, the relationship between accommodation and convergence of the eye. When patients are straining, or trying "too hard" to see a distant object, they have a tendency to overaccommodate. This increased accommodation, when sustained, can lead to the development of myopia. Patients are taught to train accommodative control and to become less responsive to both prism and minus lens stimuli. Clinical results reported some stabilization of subjects under age 12 years and inconsistent results in the 12 to 16-year-old age group. The best stabilization and improvement occurred in those 20 years old and older, who developed myopia later in their lives (Friedman 1981). There are no data published to support or quantify these claims.

Friedman’s approach is described here because it differs from other visual training systems. It is based on true accommodative changes. Patients are guided through the program by in-office training, which is more specific to the individual patient’s needs. He recognizes the difficulty of conducting clinical research and separating vision training from other causes as the sole cause of refractive changes, and does not make any claims about his system. While he does not provide data from the patients or quantify the changes that occurred, there is information regarding which type of patients would be successful and which would not be helped. It is not designed to "cure" myopia, but by altering the AC/A response, it can be used to improve the myopic condition.
The AC/A response and its relationship to myopia is still being considered today. In a recent three-year study following children aged 6-18 years at study entry Gwiazda et al. (2005) found that children who went on to develop myopia had lower accommodative amplitudes and therefore lower AC/A ratios. This supports previous results by Mutti et al. (2000) from the Orinda Longitudinal Study of Myopia, which showed a strong association between the AC/A ratio and refractive error. The AC/A ratio was highest for myopes and lowest for hyperopes (Mutti 2000).

While most natural vision improvement programs are focused on the correction of myopia, vision training has also been used to treat functional astigmatism (Forrest 1984). Studies have shown that against-the-rule astigmatism is prevalent in young children, and is then eliminated or becomes with-the-rule astigmatism as children age. Later in life, a change occurs again toward against-the-rule astigmatism (Gudmundsdottir 2000). These changes are said to occur because of changes in lid tension or because of changes in accommodation or convergence (Birnbaum 1978). In a clinical study, Forrest tested the efficacy of using eye movement exercises to reduce astigmatism. The results indicated that a reduction in astigmatism occurred in both eyes of those patients who used the exercises.

In Gudmundsdottir's study, subjects were accepted from a population that was currently undergoing vision training. Those that performed the exercises as prescribed were considered the test group and those that did not complete the exercises were considered
control subjects. Another problem with the design of study was that the examiners were not masked. It is difficult to control for bias when randomization and masking are not used.

2.3 Optical Devices used in Myopia Reduction Therapy

The focus on natural vision correction has predominantly been for the treatment of myopia. Several products designed to help train the eyes for reducing myopia have been developed and are available today (www.myopia.org). Some of these products include pinhole glasses and the Myopter Viewer™. The concept of the pinhole glasses is well accepted in optometry for testing best attainable visual acuity in patients with reduced vision, but they are not corrective. They will not improve uncorrected visual acuity if the person is not wearing the pinhole glasses, thus patients are not less dependent on glasses. By reducing the light rays that enter the eye, they are also difficult to use in dim environments.

The Myopter Viewer™ was developed by Rehm in 1975. Rehm (1975) shared the view that acquired myopia developed in response to excessive near work. The increased demand at near stimulates an accommodative spasm which leads to myopia. The Myopter Viewer™ is worn on the head similar to a pair of glasses and is used instead of glasses for near work. Normally, light entering the eye from a near point stimulates both accommodation and convergence of the eye muscles. The Myopter Viewer™ uses beam splitters, mirrors and lenses to eliminate the eyes’ need to accommodate and to
converge by creating parallel rays entering both eyes. The idea behind the Myopter Viewer™ is that, by reducing the accommodative and convergence response, the user will not stimulate myopia development. There are no formal, clinical tests reported in the literature to either support or disprove this instrument. Both the Myopter Viewer™ and pinhole glasses can be purchased today (www.myopia.org/).

2.4 Suggestion and Improvement in Visual Acuity

Clinical accounts of improving visual acuity with relaxation and vision training exercises lead to investigating the use of hypnosis or positive suggestion to reduce myopia (Raz 2004). Hypnosis can be used to increase concentration and attention. There are several studies that have been completed to test the effect of hypnosis on myopia. Dr. Charles Kelly, a qualified Bates Method instructor, found that in combining the theories of the Bates Method and hypnosis, he was able to find improvements in visual acuity as well as decreases in myopia (Kelly 1962). Kelly’s subjects experienced the improvements in a cycloplegic state, thus, he concluded that changes occurred due to relaxation and not due to changes in accommodation. The baseline characterization of the subjects is not specified.

The early studies showing improvement in uncorrected visual acuity prompted Graham and Leibowitz to conduct a series of studies of the relationship between suggestion and myopia. They found that highly suggestible individuals could improve uncorrected visual acuity with and without hypnosis better than less suggestible people. They found
that the effects following hypnosis in a highly suggestible population were maintained to a lesser extent in an unhypnotized state (Graham and Leibowitz 1972). Using an infrared optometer, they were able to measure refractive error during testing and found no change in refractive error to explain the improved visual acuity. Improved visual acuity was found to be highest in the most highly myopic subjects.

Concern was raised over the sampling done by Graham and Leibowitz (Sheehan 1982; Raz 2004), suggesting that their subjects in the experiment were not matched for suggestibility. The trend of higher myopes getting the most change in visual acuity may have been subject to the “regression to the mean effect (Raz 2004).” Some of the higher myopes’ initial acuities were also reported as “count fingers,” which is not consistent between examiners and subjects and is not a truly quantifiable visual acuity. They also allowed the subjects to look at the charts between tests with full correction, giving the subjects a chance to memorize the letters.

Their results were further explored in 1982 by Sheehan et al. In an attempt to better control sampling differences that occurred with Graham and Leibowitz, Sheehan et al matched subjects in test and control groups by suggestibility scores found on the Barber Suggestibility Scale (BSS). Using listening to music as the control, they offered suggestion that vision could be improved. Their results confirmed that, while visual acuity could be improved, there was no accompanying change in refractive error. There was also no significant difference between those with higher scores and those with lower scores on the BSS. Their statistical analysis was questioned by Wagstaff,
indicating that their results were not significant (Wagstaff 1983). In a response publication, Shaheen et al. changed their statistical analysis and found no significant differences between groups (Smith 1983).

In summary, while most hypnosis studies show an improvement in visual acuity with positive suggestion, they do not show an accompanying change in refractive error. This implicates increased awareness and concentration as the agent for change. They have shown that if an individual is told (regardless of his or her suggestibility) that his or her vision can be improved, he or she will read more letters on an acuity chart, temporarily. These hypnosis studies are not without their critics as well, and they seem to draw conclusions from data that is not significant or that is nearly significant.

2.5 Behavioral Modification—Biofeedback
As previously discussed, accommodation has been implicated in the development of myopia. Studies have shown that accommodation, or changes in the shape of the crystalline lens, can be voluntarily controlled via the ciliary muscle (Rosen 1984). Many studies of biofeedback and the control of accommodation have been conducted, mainly using auditory tones as the feedback mechanism.

Comsweet and Crane developed an optometer device that was able to continuously measure accommodation (Comsweet and Crane 1973). The subject was able to control an auditory tone that he or she could change by turning a dial. Another tone was emitted
by the optometer, depending on the level of accommodation. The subjects were asked to vary the dialed tone and to try to match the output tone by changing their accommodative tonus (Rosen 1984). This study showed a learned ability to control accommodation.

The first reported improvement was published in 1978 (Trachtman 1978). Feedback training utilized the Accommodrec Vision Trainer (AVT) developed by Trachtman, which could measure accommodation every 32 msec and emit a tone corresponding to the accommodative level. Results for the three subjects saw a reduction in refractive error of up to 0.75 D of myopia. Visual acuity was also improved.

Collins et al demonstrated that feedback vision training is effective in increasing visual acuity. Subjects in each group were matched for visual acuity. Feedback involved verbal confirmation of correct answers with a positive statement (Collins 1981). Fading involved varying the stimulus distance from the subject until the minimum threshold of ten consecutive correct responses was found. Groups were also tested for fading without feedback, feedback without fading, a yoked group tied to what their matched subject did, and a control. Visual acuity improved most in the feedback-fading group and the fading group to a lesser degree. The authors concluded that fading was the most important aspect in the improvement of visual acuity.

An interesting observation was made by Balliet et al. After training myopes over a three-month period, they were able to show a general improvement in visual acuity for all subjects. Subjectively, the patients in the study reported improved vision during
everyday tasks. They found no changes in retinoscopy findings, no significant
improvements of blur interpretation, and no changes in corneal shape (Balliet 1982).
Balliet et al. did find that in 90% of subjects there was evidence of increased tear film.
The subjects were seen to have a uniform tear film during periods of poor visual acuity.
During periods of good vision, two types of changes were seen. In some patients, the
central tear film thickness was very thin causing breakup, and in others there was an
increased tear volume that showed thickness greater in the periphery than over the central
cornea. Decreased tear break-up times were noted in all subjects with increased tear
action, but it was not quantified. They theorized that the changes that occurred in the tear
film could be acting like a minus lens and correcting some degree of the subject's
myopia.

Though most treatments for feedback have only included myopia training, Rupolo et al
used hyperopes/emmetropes as controls in addition to untreated myopes as subjects in
their study (Rupolo 1997). Visual acuity was measured using a logMAR visual acuity
chart and a computer-based system that presents letters in a randomized order to prevent
memorization. The subjects underwent acoustic biofeedback accommodative training.

They found a significant improvement in visual acuity in the myopic trained group by the
optotype chart, but results were not confirmed by the computer-based visual acuity
testing. Conclusions included that auditory feedback training did not reduce the amount
of myopia, nor did it improve visual acuity, but it did improve the subjects' assessment of
symptoms over time.
Biofeedback training studies have similar problems as the suggestion and vision training studies—they do not give data to support their conclusions. Critics of biofeedback training site this, as well as problems in subject matching for the control and test groups. Gilmartin et al. point out that there has been no defined relationship between myopia and accommodation, which is the foundation of the biofeedback training concept (Gilmartin, Gray et al. 1991).

2.6 The See Clearly Method
The See Clearly Method was developed for the Vision Institute of America by a team of optometrists. It is designed to reduce dependency on spectacles not just for myopes, but for hyperopes, astigmats, and presbyopes. The See Clearly Method ascribes to the theory of near point stress. The near point stress model says that the extensive near work that is prevalent in today's society leads to modifications of the visual system to help the eyes cope with the stress (Birnbaum 1993). These coping mechanisms include development of refractive error, binocular vision problems, and problems with tear film function.

Each kit contains an instruction manual with a background on the mechanisms of the eye and an outline of the See Clearly Method program. There are four different weekly exercise routines that are described in the instruction manual or on video cassette, DVD or CD-ROM, which guides the user through each exercise. The exercise program takes about 30 minutes daily to perform and is best done without spectacle correction. If the...
patient’s refractive error is too high to perform the exercises without glasses, progressive undercorrection, or slowly prescribing weaker and weaker glasses, should give the best results.

In addition to the exercise sessions, “New Visual Habits” should be practiced throughout the day. These are the exercises from the sessions incorporated into everyday life. One of the See Clearly Method exercises should be practiced throughout the day, especially when completing extensive near work. This works to break up the near point stress.

To attain best results, it is suggested to track progress and to set goals. These are recorded in the daily progress journal included in the instruction manual. Exercises that should be emphasized depending on the user’s particular refractive problem are explained in detail, although all exercises in the sessions should be performed by all users. Depending on the type of refractive error, there is also advice on how to modify daily activities to speed results. Suggestions about nutrition and improving the condition of the eyes are also given.

The basic principles of the See Clearly Method fall into four categories including: focusing exercises, range of motion exercises, relaxation exercises and eye teaming exercises. Specific exercises can be seen to reflect some of the previously discussed methods such as the Bates Method, suggestion and improvement of visual acuity and vision training exercises.
Some of the exercises and their influences are listed below:

Pumping: Involves changing focus back and forth between near and distant objects. This is similar to the swinging and shifting outlined in the Bates Method (Bates 1981).

Clock Rotations: The patient will move eyes to an imagined clock dial, from the number back to the center, then to the next clock hour. In vision training for the reduction of astigmatism, a very similar exercise is used (Forrest 1984).

Acupressure: The user massages the acupressure points around the eyes in four different massage techniques. The roots of acupressure can be traced back to Chinese practice of acupressure, or “Qi Qong” facial exercises developed in the 1950s for the reduction of myopia (Saw 2002).

Palming and Light Therapy: The user sits about six inches from a 150-watt light bulb, and closes his or her eyes. In palming, both hands are placed over the eyes. In both of these techniques, the user is asked to relax and imagine the eyes getting healthier and stronger. This exercise is very similar to the Bates techniques of palming and the use of imagination (Bates 1981). There are also aspects of suggestion and the ability to see better if believing it to be so, even without being in a hypnotic state (Graham 1972).

There has been little formal clinical research performed on the See Clearly Method. Though there is limited research available concerning the different exercises in the program, there is scarce evidence regarding the efficacy of this program. The doctors that created The See Clearly Method conducted a clinical test of the product to support
the product's claims. The tests were conducted at the Vision Institute of America, the company that created the program. The 21 subjects were selected from a public seminar on the program.

Guidelines for inclusion into the clinical test performed were narrow. Those included were subjects with a low to moderate amount of eyestrain at a computer, low to moderate myopic patients with a spherical equivalent power less than -2.87 diopters (D) and beginning presbyopes who were using, or who were about to use, their first near correction. Those excluded from the test included moderate to high presbyopes, medium and high myopes and people with medium to high astigmatism. These strict criteria eliminated a lot of the population wearing corrective lenses. All people with binocularity problems such as strabismus and amblyopia and those with ocular or systemic diseases were also excluded.

The subjects were first given a comprehensive eye examination and were told to use The See Clearly Method for six weeks. Weekly training sessions were conducted for all of the subjects. A second comprehensive eye examination was then given following six weeks. The results of the 21 subjects are shown in Table 2.1.
<table>
<thead>
<tr>
<th>Reported Improvement on Outcomes Measured</th>
<th>Significant Improvement/ Eliminated Dependency</th>
<th>Moderate Improvement/ Reduced Dependency</th>
<th>Needed Weaker Prescription</th>
<th>No Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visual Acuity</td>
<td>9</td>
<td>11</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>Refractive Error</td>
<td>7</td>
<td>7</td>
<td>-</td>
<td>7</td>
</tr>
<tr>
<td>Dependence on Corrective Lenses</td>
<td>7</td>
<td>11</td>
<td>7</td>
<td>3</td>
</tr>
</tbody>
</table>

Table 2.1 Reported Outcomes from See Clearly Method Clinical Testing

There is no definition of “significant improvement”, “moderate improvement” or “reduced dependency on corrective lenses.” They do not quantify this improvement in lines of acuity gained or dioptic changes in refractive error. This needs to be quantified in a clinical study. They do not discuss how measurements were made, what charts were used to determine if changes in acuity occurred, nor how refractive error was determined.

The subjects that enrolled in this test were given one-hour training sessions on a weekly basis. When the product is purchased by an individual, he or she does not receive any training beyond what is included in the kit. In this clinical test, the effectiveness of the See Clearly Method was not truly being tested because the patients were not just using the kit. The patients did not have to rely on the instructional videos and were trained individually. The instructional sessions also acted as a reminder to keep the patients on track. They do not receive reminders to keep performing the exercises daily when the system is purchased independently by the patient.
The clinical tests done by the Vision Institute of America did not include a questionnaire, but the study reported that all but one subject expressed satisfaction with the product. They also stated that all patients who exhibited eyestrain noticed improvement after participating in the program. The reports are anecdotal and include statements like; “eyes feel stronger” and “colors seem brighter.” Without using a survey or questionnaire that is unbiased, there is no way to accurately quantify the subjective data. There is also no indication of what questions were asked and how they were worded, so it is a possibility that the questions used could lead subjects to give a favorable response. Without knowing all this information, there is no indication of control of investigator bias.

A formal study should be done to evaluate the See Clearly Method, because the product is universally available. The inclusion criteria should not be restrictive with respect to the amount of refractive error, as the See Clearly Method claims to help all users. It should be determined whether the See Clearly Method is able to improve uncorrected visual acuity, or reduce people’s dependence on correction by reducing refractive error. A formal survey should also be used to assess symptoms of eyestrain and improvements in vision related to quality of life. This would demonstrate if any subjective improvements can be attributed to the See Clearly Method. It is also important to randomize interested and motivated subjects into a test group and a control group for good statistical comparison.
CHAPTER 3

METHODS

3.1 Recruitment
Subjects were recruited through informational flyers posted on campus busses and publications at The Ohio State University. No patients were recruited from the students, staff or faculty at The Ohio State University College of Optometry. Interested subjects were accepted beginning November 2004. Recruitment continued through February 2005. Thirty patients were enrolled in this study.

3.2 Eligibility Criteria and Enrollment
Subjects in this study were provided with informed consent forms approved by The Ohio State University’s Biomedical Institutional Review Board. Patients were asked to review and sign this form before any testing was initiated. The subjects were then given a comprehensive vision examination to confirm study eligibility. All races and both genders were eligible for this study. Pregnant women were also able to participate, as the See Clearly Method poses no risk for the women or fetus.
Those enrolled must have met the following inclusion criteria:

- Must be at least 18 years of age
- Must currently wear glasses or contact lenses for either near or distance vision that provide at least 20/30 vision with both eyes at distance and at near
- Be able to see 20/20 or better in each eye with corrective lenses (best correction)
- Must have one of the following refractive conditions
  - myopia
  - hyperopia
  - astigmatism
  - presbyopia

Exclusion Criteria:

- Eye disease or condition that could affect vision (e.g. cataract, macular degeneration)
- History of strabismus
- History of general health problems causing any vision problems
- Optometry students, faculty, staff or their family members

3.3 Randomization

At the completion of the comprehensive examination, each subject was randomly assigned to the treatment group or the control group. A randomization table was generated, creating two groups of equal size. Randomization matched the study group with the subject number. Randomization tables were not opened until completion of the first study visit.
The test group in this study was asked to use the See Clearly Method for one month. They were asked to perform the activities exactly as described by the See Clearly Method instructional materials. Approximate time of participation was 30 minutes daily. Additionally, they were asked to keep a log of their compliance, marking in the daily journal each day the exercises were performed. No additional training on any of the methods described by the See Clearly Method was given. The patients were not contacted during the study to encourage participation.

The control group was not given the See Clearly Method for the duration of the study. They were not asked to do anything differently from their normal routine during the study period. At the completion of their one-month follow-up visit, each member of the control group was given the opportunity to take the See Clearly Method and use the kit for one month. They were not assessed again after using the See Clearly Method.

3.4 Design Overview
Subjects were asked to attend two examination visits. The first baseline visit included subject enrollment and a comprehensive eye examination. The follow-up visit was four weeks later and repeated some of the testing from the baseline visit. A list of procedures performed at the two study visits follows. A detailed description of the procedures is included in section 3.5.
Visit one: Baseline Examination Procedures:

- Informed consent
- Patient history
- Completion of the Refractive Error Quality of Life Instrument (NEI RQL-42) Questionnaire
- Manifest refraction
- Bailey-Lovie high contrast visual acuity measurement at distance and near
- Autorefraction
- Stereo vision testing
- Accommodative testing
- Vergence testing
- Slit lamp examination with non-contact microscope
- Dilated eye examination
- Randomization
- Dispensing of the See Clearly Method (if applicable)

Visit two: One-Month Visit

- Completion of the Refractive Error Quality of Life Instrument (NEI RQL-42) Questionnaire
- Manifest refraction
• Bailey-Lovie high contrast visual acuity measurement at distance and near
• Autorefraction
• Stereo vision testing
• Accommodative testing
• Vergence testing
• Slit lamp examination with non-contact microscope
• Collect the See Clearly Method materials including the daily journal
• Dispensing of the See Clearly Method (if applicable)

3.5 Specific Protocols for Measurements

3.5.1 Visual Acuity
Any changes in visual acuity measured from baseline to one month that occurred in the
test group were compared to changes in the control group from baseline to one month.
All visual acuity measurements were taken using Bailey-Lovie high contrast visual acuity
charts. Corrected and uncorrected measurements were taken at distance and at near for
the right eye, then the left eye, following the protocol established by the Collaborative
Longitudinal Evaluation of Keratoconus (CLEK) Study (Gordon, Schechtman et al.
1998). Patients were required to start with the first line on each chart and read each line
until three out of five letters were missed on a single line. Once a patient started a given
line, he or she had to attempt to identify all five letters on that line. All corrected distance
visual acuity measurements were taken at four meters. If the subject was unable to read
the first line of letters on the chart uncorrected, he or she was moved to 2 m, then 1 m
until he or she could accurately read the first five letters. Corrected acuity was also measured at 40 cm. If he or she was unable to read the near card at 40 cm, the card was moved to 30 cm or to 50 cm. The total number of letters correct and the distance tested were used to calculate logMAR visual acuity. All charts were read under photopic conditions, with illumination levels between 75-110 cd/m². Illumination levels were verified using a photometer. All visual acuity measurements were taken by masked examiners.

3.5.2 Manifest Refraction
All manifest refractions were performed utilizing standard clinical techniques. Manifest refraction was performed at both visits to determine if there was a change in the refractive error following use of the See Clearly Method. Endpoint for refraction was the most plus or least minus sphere power required to read the 20/20 line on the standard Snellen visual acuity chart. All refractive data were converted to vector notation (M, J₀, J₄⁵) for analysis.

3.5.3 Slit Lamp Examination
Slit lamp examination was performed at each visit to evaluate the health of the anterior segment of the eye. This was done to ensure that the ocular media were normal and would not cause any changes in visual function. Slit lamp examination findings were not used as an outcome in this study.
3.5.4 National Eye Institute Refractive Quality of Life Instrument 42

Subjects were asked to complete the questionnaire at both visits. The NEI RQL-42 instrument was developed to evaluate problems experienced by patients who wear glasses or contact lenses. The survey was used to determine if there were any subjective improvements in vision and daily lives attained by using the See Clearly Method. Subjects were encouraged to answer the questions to the best of their ability without assistance.

There are 13 subscales for the NEI-RQL-42 including: clarity of vision, expectations, near vision, far vision, diurnal fluctuations, dependence on correction, worry, suboptimal correction, appearance, and satisfaction with correction. Responses to the questions on the survey have values from 0-6, depending on the number of possible responses for the questions. Each of the values is later assigned a value from 0-100. A higher score indicates a better quality of life.

The questions are then grouped into the 13 subsets and averaged to generate scale scores. If a question is not answered on the NEI RQL-42, it is not used in the calculation of the scale score. Differences in the scale score between baseline and one month for the test group were compared to differences in the scale scores for the control group for the baseline and one-month visits.
3.5.5 Autorefraction using the Grand Seiko Autorefractor

The Grand Seiko Autorefractor used in this study was equipped with a Badal track that allows for measurement of refractive error with different accommodative stimuli. Measurements were first taken to determine distance refractive error. With no correction, the target was moved past the patient's blur point. The target was then moved toward the patient until he/she reported the letters first became clear. Distance refractive error was measured for the right and left eye. All measurements were taken without cycloplegia.

Habitual correction was worn by the subjects to measure the response to accommodation (accommodative lag). With correction in place, the patient was asked to keep the letters clear as the target was moved toward the eye. Measurements were taken at the plano position and at 0.50-diopter (D) intervals up to 4.0 D. During each measurement, the subject was instructed to try to keep the letters clear.

Five measurements were taken at each position. Measurements were taken beginning at the plano position until the average reading did not show more minus (less plus) power. As the study progressed, a computer program was used to divert all readings into a database. Subsequent subjects were measured at all positions from plano to 4.00 D. The five readings for each position were converted to vector notation and averaged for analysis.
3.6 Statistical Analysis

All statistical analyses were done using SPSS v11.5 software. Groups were tested at baseline with independent t-tests. The descriptive statistics were generated and the t-test results were used to determine if the two groups were equal at baseline.

The raw data were converted for statistical evaluation. For autorefraction and manifest refraction, the M value, or spherical equivalent was used. All visual acuity measures were transformed into logMAR for evaluation. For the See Clearly Method group, the number of days the subjects reported completing the exercises was calculated from the daily progress journal they were provided.

Analysis of covariance was used to test the null hypothesis of no difference between treatment and control at one month. Analysis of covariance was used because it controls for differences between groups at baseline. A dose response effect was tested within the See Clearly group by regressing 1 month findings with baseline findings and number of sessions recorded in the daily diary. This was performed on visual acuity, manifest refraction, and autorefraction.
CHAPTER 4

RESULTS

4.1 Study Population Demographics
Thirty patients were examined and enrolled in the study, but only 28 patients (14 in each group) completed the study. The remaining two patients failed to attend the one-month visit. Of the 28 patients who completed the study, 17 (60.7%) were male and 11 (39.3%) were female. Subjects ranged in age from 18 to 67 years of age (mean ± SD = 38.79 ± 14.4). The mean age (± SD) of subjects in the control group was 43.21 ± 10.96 years, and the mean age of subjects in the See Clearly Method group was 38.71 ± 16.35 years. There was no statistically significant difference in age between the two groups (p = 0.104). There was also no difference between the two groups with respect to the type of vision correction being used (p=0.136).

The refractive error of the subjects is listed for each subject in Table 4.1. Most subjects were myopic. The control group contained three hyperopes, while the See Clearly Method group only had one. All but four subjects in the control and three in the See Clearly Method group had astigmatism.
### Manifest Refraction

<table>
<thead>
<tr>
<th>OD</th>
<th>OS</th>
<th>OD</th>
<th>OS</th>
</tr>
</thead>
<tbody>
<tr>
<td>+1.50 DS</td>
<td>+1.75 DS</td>
<td>+4.25–1.25 x 160</td>
<td>+2.00–0.75 x 100</td>
</tr>
<tr>
<td>+2.00–5.00 x 170</td>
<td>+2.75–5.00 x 180</td>
<td>pl–0.75 x 085</td>
<td>-0.50–0.25 x 100</td>
</tr>
<tr>
<td>+0.50 DS</td>
<td>+0.50 DS</td>
<td>-0.50–0.50 x 010</td>
<td>-1.25–0.50 x 015</td>
</tr>
<tr>
<td>-0.25–0.75 x 095</td>
<td>-0.25–1.00 x 085</td>
<td>-1.25 DS</td>
<td>-1.25 DS</td>
</tr>
<tr>
<td>-0.50–0.50 x 165</td>
<td>plano</td>
<td>-2.00 DS</td>
<td>-2.75 DS</td>
</tr>
<tr>
<td>-0.50–0.75 x 040</td>
<td>-0.50–1.25 x 010</td>
<td>-2.50 DS</td>
<td>-2.75 DS</td>
</tr>
<tr>
<td>-0.75–0.75 x 073</td>
<td>-1.25–0.25 x 075</td>
<td>-2.50–1.75 x 100</td>
<td>-2.75–1.25 x 070</td>
</tr>
<tr>
<td>-2.75–0.50 x 105</td>
<td>-2.50–0.25 x 080</td>
<td>-2.50–2.25 x 100</td>
<td>-2.75–2.75 x 075</td>
</tr>
<tr>
<td>-3.00–0.75 x 067</td>
<td>-3.50–1.25 x 076</td>
<td>-3.00–0.50 x 075</td>
<td>-2.75 DS</td>
</tr>
<tr>
<td>-3.50 DS</td>
<td>-3.25 DS</td>
<td>-3.50–2.00 x 088</td>
<td>-4.50–0.25 x 110</td>
</tr>
<tr>
<td>-5.25–0.75 x 025</td>
<td>-4.25–0.50 x 110</td>
<td>-3.75–0.50 x 060</td>
<td>-4.25 DS</td>
</tr>
<tr>
<td>-5.50–2.50 x 085</td>
<td>-5.50–3.75 x 100</td>
<td>-5.75–0.50 x 045</td>
<td>-5.25–2.50 x 150</td>
</tr>
<tr>
<td>-6.50 DS</td>
<td>-7.50 DS</td>
<td>-5.75–1.50 x 015</td>
<td>-6.50–0.75 x 175</td>
</tr>
<tr>
<td>-6.75–0.50 x 005</td>
<td>-7.50–0.50 x 140</td>
<td>-8.50–1.00 x 030</td>
<td>-8.00–0.50 x 095</td>
</tr>
</tbody>
</table>

Table 4.1 Baseline Manifest Refractive Error for Subjects

### 4.2 Manifest Refraction

The spherical equivalent value, or M, of the manifest refraction was used in analysis. To control for inclusion of both myopes and hyperopes, the absolute value of the refractive error was used in the analyses. Descriptive statistics for the non-cycloplegic manifest refraction spherical equivalent are listed in Table 4.2. At baseline, there was no statistical significant difference between the two groups regarding spherical equivalent refractive error measured by subjective refraction for either the right eye (p = 0.851) or the left eye (p = 0.517).
An analysis of covariance (ANCOVA) computed the difference between the See Clearly Method and the control groups at 1 month, correcting for baseline. There was no significant difference between the two treatment groups regarding the subjective refraction of the right eye in the two groups ($p=0.851$). There was also no significant difference between the average subjective refraction of the left eye's subjective refraction in the two groups ($p=0.689$).

<table>
<thead>
<tr>
<th>Visit</th>
<th>Control</th>
<th></th>
<th></th>
<th></th>
<th>See Clearly Method</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>OD</td>
<td>OS</td>
<td>OD</td>
<td>OS</td>
<td>OD</td>
<td>OS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>2.97 ± 2.53</td>
<td>3.06 ± 2.79</td>
<td>3.63 ± 2.36</td>
<td>3.66 ± 2.28</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Month</td>
<td>3.00 ± 2.52</td>
<td>3.07 ± 2.69</td>
<td>3.63 ± 2.41</td>
<td>3.70 ± 2.25</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change</td>
<td>0.03 ± 0.20</td>
<td>0.01 ± 0.23</td>
<td>0.00 ± 0.32</td>
<td>0.04 ± 0.38</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 4.2 Descriptive Statistics for Manifest Refraction Spherical Equivalent

4.3 Baseline Autorefraction

The absolute value of the spherical equivalent of non-cycloplegic autorefraction measurement was used in the analysis. Descriptive statistics for the manifest refraction spherical equivalent are listed in Table 4.3. There was no statistically significant difference between either the right eye ($p = 0.540$) or the left eye ($p = 0.488$) for the two
groups’ spherical equivalent refractive error as measured by autorefraction at baseline. ANCOVA showed no significant difference for the two groups between baseline and one month for either the right (p=0.795) or left eyes (p=0.217).

<table>
<thead>
<tr>
<th>Autorefraction Spherical Equivalent (D)</th>
<th>Visit</th>
<th>Control</th>
<th>See Clearly Method</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OD</td>
<td>OS</td>
<td>OD</td>
</tr>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
</tr>
<tr>
<td>Baseline</td>
<td>2.59 ± 2.26</td>
<td>2.97 ± 2.45</td>
<td>3.54 ± 2.35</td>
</tr>
<tr>
<td>1 Month</td>
<td>2.82 ± 2.04</td>
<td>2.91 ± 2.35</td>
<td>3.76 ± 2.37</td>
</tr>
<tr>
<td>Change</td>
<td>0.23 ± 0.58</td>
<td>-0.06 ± 0.35</td>
<td>0.22 ± 0.70</td>
</tr>
</tbody>
</table>

Table 4.3: Autorefraction Spherical Equivalent at Baseline and One Month

4.4 Uncorrected Visual Acuity

The uncorrected baseline and one-month high contrast visual acuity measured in logMAR for both the right and left eye is listed in Table 4.4. There were no statistically significant differences between the control group and the See Clearly Method group at baseline (p>0.57).
ANCOVA was used to determine differences in visual acuity over time. There were no significant differences detected for a change in distance visual acuities in either the right eye (p=0.25) or the left eye (p=0.90). Near visual acuity also showed no significant changes from baseline to one month for the right (p=0.25) or left eye (p=0.95).

<table>
<thead>
<tr>
<th>Visit</th>
<th>Control</th>
<th></th>
<th>See Clearly Method</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OD</td>
<td>OS</td>
<td>OD</td>
<td>OS</td>
</tr>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
</tr>
<tr>
<td>Uncorrected Distance Visual Acuity</td>
<td>Baseline</td>
<td>0.61 ± 0.51</td>
<td>0.59 ± 0.56</td>
<td>0.61 ± 0.36</td>
</tr>
<tr>
<td></td>
<td>1 Month</td>
<td>0.60 ± 0.55</td>
<td>0.60 ± 0.55</td>
<td>0.57 ± 0.39</td>
</tr>
<tr>
<td></td>
<td>Change</td>
<td>0.01 ± 0.13</td>
<td>-0.01 ± 0.11</td>
<td>0.04 ± 0.13</td>
</tr>
<tr>
<td>Uncorrected Near Visual Acuity</td>
<td>Baseline</td>
<td>0.37 ± 0.39</td>
<td>0.32 ± 0.38</td>
<td>0.40 ± 0.36</td>
</tr>
<tr>
<td></td>
<td>1 Month</td>
<td>0.36 ± 0.40</td>
<td>0.28 ± 0.38</td>
<td>0.32 ± 0.36</td>
</tr>
<tr>
<td></td>
<td>Change</td>
<td>0.01 ± 0.17</td>
<td>0.04 ± 0.16</td>
<td>0.08 ± 0.14</td>
</tr>
</tbody>
</table>

Table 4.4 Uncorrected Visual Acuity Means at Baseline and One month

4.5 NEI-RQL-42

Multivariate ANOVA was used to test for differences of the NEI-RQL-42 at baseline. There were no differences between the subjects’ overall survey results at baseline (p=0.385). On the thirteen subscales, there was a difference at baseline for two of the
subscales; dependence on correction (p=0.034) and suboptimal correction (p=0.045). The descriptive statistics for baseline and one month are listed in Table 4.5.

<table>
<thead>
<tr>
<th>Subscale</th>
<th>Control</th>
<th>See Clearly Method</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>1 Month</td>
<td>Change</td>
<td>Baseline</td>
<td>1 Month</td>
<td>Change</td>
</tr>
<tr>
<td>Clarity</td>
<td>82.0 ± 18.9</td>
<td>86.5 ± 18.4</td>
<td>4.5 ± 10.6</td>
<td>77.1 ± 22</td>
<td>78.2 ± 24.4</td>
<td>1.1 ± 25.1</td>
</tr>
<tr>
<td>Expectations of vision</td>
<td>26.8 ± 25.0</td>
<td>34.0 ± 27.0</td>
<td>7.2 ± 15.2</td>
<td>14.3 ± 23.4</td>
<td>21.6 ± 23.6</td>
<td>7.3 ± 15.2</td>
</tr>
<tr>
<td>Near Vision</td>
<td>86.6 ± 14.5</td>
<td>87.1 ± 12.2</td>
<td>0.5 ± 7.2</td>
<td>82.9 ± 17.5</td>
<td>87.4 ± 9.8</td>
<td>4.5 ± 17.2</td>
</tr>
<tr>
<td>Far Vision</td>
<td>86.5 ± 11.5</td>
<td>89.3 ± 13.6</td>
<td>2.8 ± 7.8</td>
<td>82.5 ± 14.0</td>
<td>85.8 ± 11.9</td>
<td>3.3 ± 12.4</td>
</tr>
<tr>
<td>Diurnal Fluctuation</td>
<td>83.1 ± 17.3</td>
<td>88.4 ± 17.5</td>
<td>5.3 ± 16.5</td>
<td>75.0 ± 22.6</td>
<td>84.3 ± 19.4</td>
<td>9.3 ± 28.5</td>
</tr>
<tr>
<td>Limitation of Activity</td>
<td>83.5 ± 22.3</td>
<td>81.3 ± 28.5</td>
<td>-2.2 ± 11.7</td>
<td>82.6 ± 16.8</td>
<td>79.5 ± 19.1</td>
<td>-3.1 ± 18.5</td>
</tr>
<tr>
<td>Glare</td>
<td>84.8 ± 20.9</td>
<td>88.4 ± 17.3</td>
<td>3.7 ± 16.6</td>
<td>76.8 ± 24.9</td>
<td>76.8 ± 28.5</td>
<td>0 ± 13.9</td>
</tr>
<tr>
<td>Symptoms</td>
<td>84.7 ± 15.7</td>
<td>84.3 ± 15.4</td>
<td>-0.3 ± 14.5</td>
<td>74.2 ± 22.4</td>
<td>76.0 ± 19.3</td>
<td>1.8 ± 12.4</td>
</tr>
<tr>
<td>Dependence on Correction</td>
<td>37.5 ± 29.4</td>
<td>34.8 ± 27.8</td>
<td>-2.7 ± 7.2</td>
<td>17.9 ± 24.9</td>
<td>27.7 ± 26.0</td>
<td>9.8 ± 20.9</td>
</tr>
<tr>
<td>Worry</td>
<td>58.9 ± 19.9</td>
<td>61.6 ± 21.6</td>
<td>2.7 ± 25.6</td>
<td>44.6 ± 21.8</td>
<td>49.1 ± 23.7</td>
<td>4.5 ± 20.6</td>
</tr>
<tr>
<td>Suboptimal Correction</td>
<td>98.2 ± 6.7</td>
<td>96.4 ± 13.4</td>
<td>-1.8 ± 6.7</td>
<td>87.5 ± 19.6</td>
<td>94.6 ± 11.7</td>
<td>7.1 ± 16.0</td>
</tr>
<tr>
<td>Appearance</td>
<td>74.8 ± 25.2</td>
<td>73.3 ± 31.1</td>
<td>-1.5 ± 14.6</td>
<td>81.9 ± 17.6</td>
<td>74.3 ± 27.0</td>
<td>-7.6 ± 18.3</td>
</tr>
<tr>
<td>Satisfaction with Correction</td>
<td>78.6 ± 16.6</td>
<td>75.7 ± 22.4</td>
<td>-2.9 ± 19.0</td>
<td>78.6 ± 14.6</td>
<td>74.3 ± 12.2</td>
<td>-4.3 ± 8.5</td>
</tr>
</tbody>
</table>

Table 4.5 NEI-RQL Means at Baseline and One Month
Controlling for the difference at baseline, an ANOVA table was generated for each subscale on the NEI-RQL to compare baseline and one month findings. There was no statistically significant difference detected for any of the subscales. Table 4.6 lists the p-values associated with each subscale.

<table>
<thead>
<tr>
<th>Subscale</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clarity</td>
<td>0.537</td>
</tr>
<tr>
<td>Expectations of vision</td>
<td>0.766</td>
</tr>
<tr>
<td>Near Vision</td>
<td>0.612</td>
</tr>
<tr>
<td>Far Vision</td>
<td>0.767</td>
</tr>
<tr>
<td>Diurnal Fluctuation</td>
<td>0.765</td>
</tr>
<tr>
<td>Limitation of Activity</td>
<td>0.876</td>
</tr>
<tr>
<td>Glare</td>
<td>0.378</td>
</tr>
<tr>
<td>Symptoms</td>
<td>0.760</td>
</tr>
<tr>
<td>Dependence on correction</td>
<td>0.152</td>
</tr>
<tr>
<td>Worry</td>
<td>0.500</td>
</tr>
<tr>
<td>Suboptimal correction</td>
<td>0.375</td>
</tr>
<tr>
<td>Appearance</td>
<td>0.289</td>
</tr>
<tr>
<td>Satisfaction with correction</td>
<td>0.794</td>
</tr>
</tbody>
</table>

Table 4.6 ANCOVA findings for NEI-RQL Comparing Baseline and One Month
4.6 Regression Analysis

Regression analysis was used to determine if the number of days the See Clearly Method was used influenced changes from baseline to 1 month. Regression was performed on the non-cycloplegic manifest refraction spherical equivalent for each eye, visual acuity for each eye at distance and near, and for non-cycloplegic spherical equivalent measured by autorefraction. No significant associations were found. Table 4.7 summarizes the regression statistics.

<table>
<thead>
<tr>
<th>Test</th>
<th>Coefficient</th>
<th>p-values</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OD</td>
<td>OS</td>
</tr>
<tr>
<td>Manifest Refraction Spherical Equivalent</td>
<td>-0.002</td>
<td>+0.005</td>
</tr>
<tr>
<td>Visual Acuity (logMAR)</td>
<td>-0.003</td>
<td>0.000</td>
</tr>
<tr>
<td>Visual Acuity (logMAR)</td>
<td>-0.002</td>
<td>-0.901</td>
</tr>
<tr>
<td>Autorefraction Spherical Equivalent</td>
<td>-0.005</td>
<td>+0.015</td>
</tr>
</tbody>
</table>

Table 4.7 Regression Statistics for Number of Days by Tests Used
CHAPTER 5

DISCUSSION

Alternative forms of medicine, including in the area of vision care, have been gaining popularity. Different programs and ideas have been explored for more than 100 years. It has been, and still is, difficult to determine how effective these programs are without controlled clinical studies, as there are many confounding factors. Inevitably there are differences between subjects and their lifestyles which can be difficult to interpret. Previous studies of non-traditional vision correction methods have had varied results, recommendations and conclusions.

There has been no formal clinical research done to determine the efficacy of the See Clearly Method. The Vision Institute of America has been selling the See Clearly Method based on claims supported by their clinical trial. They used strict inclusion criteria, tightly controlled exercise sessions and revealed no quantifiable results.
The See Clearly Method is commercially available to all people. Patients learn to do the exercises in their own homes with no special training sessions. They will have to take it upon themselves to continue to use the product with consistency, there will be no reminders. The See Clearly Method should be tested in this real world environment.

5.1 Changes in Visual Acuity
Uncorrected high contrast visual acuity was tested at both distance and near. At baseline, there was no significant difference between the test and control group. After one month, there was again no significant improvement for either the control group or the See Clearly Method group and no difference between the groups. There was also no relationship between the number of days the subject reported using the kit and the final visual acuity at one month. No matter how many or how few days the subjects performed the exercises, there was no change in visual acuity. This was true for both distance and near visual acuity.

Many of the exercises in the See Clearly Method program use both eyes. There are exercises that work to improve binocularity, for example the fusion charts. Better binocular vision may relieve strain on the visual system and may show improved binocular visual acuity, especially at near. In this study binocular visual acuity was not assessed, but if it had been, it may have reflected an improvement that was not shown in monocular acuity testing.
Uncorrected visual acuity was also tested after corrected visual acuity for each eye. This could lead to memorization of the letters. This was consistent across all subjects at both visits; therefore this potential effect should have been minimized.

Another factor that could have affected the visual acuity outcome was the question of masking. The investigators were masked to the group the subject was assigned to, limiting investigator bias. There was no plausible way to mask the subjects, and this could have led to bias. Considering the subjects' initial interest in the See Clearly Method and the time and effort spent practicing the exercises, it may bias for the program. They may be trying harder to read letters they would have given up on previously.

5.2 Changes in Spherical Equivalent
Refractive error was measured two different ways in this study, both done without cycloplegia. The first was subjective manifest refraction and the second was an objective assessment from an autorefractor. There were no significant findings for either of the methods and no relationship was found between spherical equivalent and the number of days the exercises were performed.

The manifest refraction was performed by the same investigator for all subjects, eliminating inter-investigator bias. The investigator was not masked when performing the one month manifest refraction. Having an unmasked examiner measure refractive error could influence the final endpoints. To attempt to control for this bias an objective
measure of spherical equivalent, autorefraction was used. If the investigator was biased for or against the See Clearly Method, there should be a difference between the subjective and objective measurements, which was not evident.

5.3 Changes in the NEI-RQL-42
The NEI-Refractive Quality of Life Scale can be divided into 13 subscales that are compared individually. Comparing the groups at baseline there was no significant difference between the groups, though there were differences in two of the subscales. The two scales that differed were suboptimal vision and dependence on correction. The See Clearly Method group was lower on these two scales. This means that the See Clearly Method subjects were starting off less satisfied than the controls in both their dependence on correction and on suboptimal vision. To control for this difference, the ANOCOVA was used in analysis. At the one-month visit the two groups did not differ when controlling for the baseline NEI-RQL-42 results. This means that after using the See Clearly Method for one month the subjects reported no changes in their refractive error-specific quality of life.

No significant results were obtained in this study using the NEI-RQL-42, but it cannot be concluded that there are no changes. The sample size needed to find a significant effect with the NEI-RQL-42 is much larger than the 28 used in this study. To test for meaningful differences on this scale, a much larger sample size should be obtained.
5.4 Daily Progress Journals

To determine if the patients in the See Clearly Method group were completing the exercises each day, we relied on the progress journals they were dispensed at baseline. The patients were asked to designate each day that they performed the exercises with a checkmark. The average number of days the subjects performed the exercises was 20.1 days (±7.34 [SD]) out of 28, or about 5 days per week. One subject in the study did not perform the See Clearly Method at all during the one-month period and another used the kit for only two weeks. These subjects were analyzed in the test group, which may have had an effect on the one-month outcome measures. It is important to consider these patients in the analysis, as non-compliance could be an issue when considering the effectiveness of the program.

In this study, the patients were asked to keep track of their progress on their own. They were not reminded throughout the study to continue to use the kits. This was done to keep the study as close to the “real world” as possible. When the See Clearly Method is purchased, the patient will not be monitored or reminded to stay on task.

To truly test the effectiveness of the See Clearly Method, compliance should be tightly controlled. Subjects should be continually reminded to complete the daily exercises and a reporting system should be put in place to insure complete honesty. The See Clearly Method may produce results that support its claims if done in a more tightly controlled environment.
5.5 Future Studies

This study was done to test the effectiveness of the See Clearly Method for all people. The criteria for enrollment were less strict than previous tests, and an attempt was made to keep the environment as natural as possible. Quantifiable testing was done and results showed that there was no significant improvement in or worsening of a subject’s refractive error, visual acuity or quality of life in this sample.

Future testing should include separation of different refractive errors. This would provide more information about the effectiveness of the See Clearly Method for a more specific group. Subjects should be matched based on baseline refractive error when randomized. This would provide a better comparison between the two groups.

Age is an important factor that must be considered. Future studies would benefit from stratifying patients by age for comparison. This was not possible for this study, as the overall sample size tested was too small. There may be an age or age range that the See Clearly Method is more effective for. For example, it may be more efficacious for younger patients that are still able to accommodate. Stratifying by age would better show these differences.

The See Clearly Method kits included an Eyestrain Relief Program that was to be used on a daily basis. The subjects in this study did not use this part of the kit because it was not
universally accessible. Future testing should include the use of this program. The See Clearly Method instruction manual also puts emphasis on the nutritional habits of its users. Nutrition was not considered in this study.

Subjects in the See Clearly Method group reported satisfaction when asked about the program. Though none of the subjects returned for the one-month follow-up visit reporting an improvement in visual acuity, all but one reported enjoying the exercises. Thirteen of the 14 subjects stated that they would continue to practice these methods in some form or another. This outcome is interesting considering that no significant changes were detected by any of the testing. It is also interesting to note that the subjects that performed the See Clearly Method for the second month, the control subjects, responded to the program differently. Most of these patients felt that the program did not work well, and that the time spent was not worth the results. More investigation is necessary to determine a potential placebo effect.

In this study, no detectable changes could be found in either visual acuity or refractive error, which makes it difficult to explain the See Clearly Method and other program’s popularity. Advertisements for the See Clearly Method contain testimonials from users that their vision is clearer and more comfortable. There is a published case report on a subject who is able to function without glasses secondary to using the Bates Method (Bambridge 2004). The psychological factors of the See Clearly Method warrant further investigation.

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It has also been reported in myopic populations that prolonged exposure to uncorrected vision would lead to visual improvement. Studies have shown that this phenomenon is measurable and can be attributed to cortical changes and changes in spatial frequency sensitivities (Mon-Williams 1998; Webster 2002). This may explain the increased vision reported anecdotally by programs such as the See Clearly Method. It would be interesting if an improvement were found after using the program, to compare to a blur adapted visual acuity taken on the same subjects.
CHAPTER 6

CONCLUSION

This thesis describes a randomized controlled clinical trial with an observational control group to investigate the effectiveness of the See Clearly Method when used for one month. The main outcomes of this study were uncorrected visual acuity, refractive error and refractive error-specific quality of life. The data presented here can be summarized as follows:

- The See Clearly Method was not effective in improving uncorrected high contrast visual acuity for distance or for near.
- The See Clearly Method did not significantly change refractive error tested by subjective refraction or by objective autorefraction.
- No changes in refractive error-specific quality of life could be detected using the NEI-RQL questionnaire after 1-month of use.
- Larger sample sizes must be used in future studies to improve statistical power for assessment of the refractive error-specific quality of life.
REFERENCES


