# Translation of Eye Movement Reading Training to Clinical Practice

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**RESEARCH PROTOCOL NARRATIVE**
**Project Title: Translation of Eye Movement Reading Training to Clinical Practice**

**Problem Statement:**
Currently, AMD is among the top three leading causes of vision loss in veterans (Chomsky et al., 1995; Quillen & Henry, 2000). A recent survey found that 67% percent of individuals enrolled in low-vision rehabilitation programs had AMD (Owsley et al., 2009). Vision losses associated with this disease increase with age, and its impact on veterans' health care will dramatically increase as the number of older individuals is expected to double in the next ten years. In the United States, cases of early AMD are expected to double from 9.1 million to 17.8 million by 2050 (Rein et al., 2009).

The deficits in visual function as a result of diseases affecting the central retina, including AMD, are debilitating, as individuals lose their ability to carry out many of their daily activities that require resolving fine spatial details (Szlyk et al., 1997; 1998a; 2001a; 2001b; Ardickas et al., 2002; Stelmack et al., 2002). Often, individuals with poor central vision lose self-esteem and are subject to depression due to their inability to function normally in everyday life (Szlyk et al., 1998b; 2000a; Brody et al., 2001; Grant, Seiple & Szlyk, 2011).

As central visual acuity becomes progressively worse, a parafoveal locus for fixation, or preferred retinal locus (PRL), may be chosen because it provides better vision than the diseased fovea (Timberlake et al., 1986, 2006; Fletcher et al., 1999; Crossland et al., 2005;). Although reading speeds using a PRL are typically slower than with foveal vision, there are reports that the visual function of patients with macular disease can benefit from rehabilitation training (Watson & Jose, 1976; Nilsson & Nilsson, 1986; Nilsson, 1990; Frennesson et al., 1995; Hall & Ciuffreda, 2001). Many of the vision rehabilitation programs for these patients focus on eccentric viewing training and the use of optical magnifying devices (Goodrich & Quillman, 1977; Quillman, 1980; Maplesden, 1984; Nilsson & Nilsson, 1986; Nilsson, 1990; Frennesson et al., 1995; Nilsson et al., 1998, 2003). Such programs have individual exercises that explicitly and implicitly train visual skills with the goal of improving reading performance. Many of the published studies have reported increases in reading speeds as a result of training with low-vision devices, as well as maintenance of these skills and continued device usage following training (Watson et al., 1997). A different approach to reading rehabilitation emphasizes the training of oculomotor control relative to a new extrafoveal fixation locus (Solan et al., 1995; Hall & Ciuffreda, 2001; Contestabile et al., 2002; Seiple, Szlyk et al., 2005, 2011).

Our previous studies have shown that training with oculomotor control exercises results in significantly faster reading speeds in patients with AMD. All of our past work was conducted under controlled laboratory conditions**. In the proposed study, we will examine whether these training exercises are effective when practiced at home.** Because of the extensive cost of clinical resources required for vision rehabilitation and the significant number of veterans in need of services, it is critical to determine whether the training program can be made less expensive, but as effective when the program is self-trained.

**Key Questions:**
The key question of this proposed research project is whether a series of eye movement training exercises that we have validated in our laboratory environment can be translated into a home-based training system.

The primary question that this research is designed to answer is: Can a home-based eye movement training program be as effective as a clinically administered program? In order to answer this question, we will assess whether the opportunity for increased practice afforded by having the program available at home results in improved reading performance.

**Methods of Procedure:**
Our previous laboratory studies have demonstrated that eye movement control training significantly improves reading performance. In the proposed study, we will translate our methods into clinical practice with a large sample of patients with central vision loss.

In Phase 1, we will develop a standardized, user-friendly, computer-based platform that will allow patients to easily self-administer training exercises. The software platform will be designed to automatically choose the appropriate exercises based on a patient's previous performance, run the training exercise, and collect performance data into a universal patient data file. In Phase 2, the platform will be tested in two settings: in standard clinical rehabilitation practice and in the patient's home. Reading outcomes in the two settings will be compared.

**Phase 1 – Development and Testing of the Platform for Administration of Eye Movement Control Training (PAECT)**
The PAECT will be developed to allow patients to easily self-administer the exercises. We will design the interface to be accessible to users with low vision. Large icons, touch-sensitive displays, and/or voice controls will be used. The interface will be built, tested, and improved over the first year of the project.

**Phase 2 – Clinic-Based Versus Home-Based Training**
In this phase, we will compare reading outcomes from training with PAECT in a low-vision clinic setting and with feedback on performance given by a rehabilitation therapist to training with the PAECT by the patients in their own homes. We have previously demonstrated in our laboratory experiments that eye movement training exercises increase reading speed, but we wish to know whether these findings can be extrapolated to clinical practice. The results of this study will allow us to quantify the role of direct support and feedback from the therapist during each session versus any advantages that may result from more frequent practice on the exercises afforded by having the equipment at home.

**Procedure**
On Day 1 of the study, all patients will undergo clinical assessments to measure change in reading speed (MNREAD). Near refraction will be measured and, based on this, a pair of single vision spectacles will be made for each subject for testing purposes. On Day 2, all patients will return to the clinic for baseline assessments detailed instructions on running the PAECT platform and training on Module 1 of the platform. For those patients assigned to the clinical arm of the study, appointments will be made to

return at weekly intervals for two-hour PAECT training sessions. During these sessions, the subjects will run the PAECT program in the clinic, with feedback and encouragement given by the therapist.

There will be a total of *eight training sessions*. For those patients assigned to the At-home arm, arrangements will be made to deliver and set up a computer in their home. These subjects will be instructed to practice with the PAECT program as often as possible, but at least two hours per week. Patients will receive weekly from calls from the Program Coordinator, who will answer technical questions and encourage frequent use of the program, but no feedback about performance will be given. All patients in both arms will return to the clinic after one month, and two months to undergo assessments of reading performance. *Each subject will participate in the study for 12 weeks: 1 screening visit, 1 baseline testing visit, 4 weeks of training, Month 1 assessment visit, 4 weeks of additional training, and a final assessment visit.*

**Patient Recruitment**

Veteran patients will be recruited from the eye clinics of the Jesse Brown VAMC, Veteran and Non-Veteran patients from the University of Illinois at Chicago (UIC) Department of Ophthalmology and Visual Sciences, and Captain James A. Lovell Federal Health Care Center in North Chicago. We have ongoing collaborations with these sites and have successfully recruited from these centers for past studies. All potential patients will undergo a standard clinical examination at the recruitment sites to determine eligibility for the study.

Both Veterans and Non-Veterans will be recruited for this study, with priority given to eligible Veterans. The strict inclusion criteria will require additional subjects (non-veterans) to also be included in recruitment. This will allow us to meet recruitment levels specified by our VA Merit Review Grant. Non-veterans will not have medical records at the VA but their data will be stored and protected in an approved off-site VA laboratory. All data will be stored in a locked cabinet in a locked room with only research personnel access.

**Inclusion Criteria**

Patients with a diagnosis of retinal disease affecting the central visual field (e.g., non-exudative “dry” AMD) and a central scotoma, with visual acuity of less than or equal to 20/70 and greater than or equal to 20/400 (in the test eye) will be included in the study. The presence of a central scotoma and eccentric viewing will be confirmed using an Opko OCT/SLO Microperimeter. Our intent is to include subjects based upon their functional characteristics (e.g., eccentric viewing).

**Exclusion Criteria**

Patients will be screened to exclude those with other major ophthalmologic or neurologic disease, choroidal neovascularization (“wet” AMD), moderate to severe media opacities, and cognitive impairment. Patients’ disease status will be monitored throughout the study.

**Research Design and Statistical Analysis Plan**

We will recruit eligible patients per year for each of the three years for Phase 2 of the study to be assigned randomly to the Laboratory Group, while others will be assigned to an At-home Training Group. Three assessments will be taken for each subject: at

baseline, and after 1 and 2 months. To analyze the assessment data, we will utilize a two-way (group by time) repeated measures design. A major advantage of this design is subject homogeneity; that is, subject effects are reduced.