

The Eye M.D. Association

COMPLEMENTARY THERAPY ASSESSMENT VISUAL TRAINING FOR REFRACTIVE ERRORS October 2004

SUMMARY

DESCRIPTION OF VISUAL TRAINING

Visual training programs to improve vision include eye exercises, muscle relaxation techniques, biofeedback, eye patches, or eye massages alone or in combinations and may also recommend using undercorrected prescription lenses and nutritional supplements.

BENEFITS

One randomized controlled trial of biofeedback training for control of accommodation for myopia reported no statistically significant benefits from training (level I evidence). In other studies undertaken over the last 60 years, an improvement in subjective visual acuity in myopes with no corresponding improvement in objective visual acuity has been reported (level II/III evidence).

RISKS

The only risk attributable to visual training is financial, as most health insurers do not cover these programs.

CONCLUSIONS

There is level I evidence that visual training for control of accommodation has no effect on myopia. In other studies (level II/III evidence), an improvement in subjective visual acuity for patients with myopia who have undertaken visual training has been shown but no corresponding physiological cause for the improvement has been demonstrated. The improvements in myopic patients noted in these studies have been postulated to be due to improvements in interpreting blurred images, changes in mood or motivation, creation of an artificial contact lens by tear film changes, or a pinhole effect from miosis of the pupil.

No evidence was found that visual training has any effect on the progression of myopia. No evidence was found that visual training improves visual function for patients with hyperopia or astigmatism. No evidence was found that visual training improves vision lost through disease processes such as age-related macular degeneration, glaucoma, or diabetic retinopathy.

<u>REPORT</u>

DESCRIPTION OF VISUAL TRAINING

Self-directed eye exercise programs to improve vision have been promoted since at least 1912¹ and have had fluctuating levels of interest since.^{2, 3} The programs advocate eye exercises, muscle relaxation techniques, biofeedback, eye patches, or eye massages alone or in combinations and may also recommend using undercorrected prescription lenses and nutritional supplements. There is a large market for programs such as these since it is estimated that 150 million U.S. residents currently use some form of eyewear to correct refractive error.⁴

FDA STATUS/LEGAL STATUS

There are no legal or Federal Drug Administration controls or restraints on visual training programs. The Federal Trade Commission, which oversees advertising, will take enforcement actions against companies whose advertisements contain false and misleading information.

SUMMARY OF EVIDENCE

Search Methods and Study Selection

On July 22, 2004 the PubMed database was searched with combinations of the text words see clearly, vision therapy, eye exercises, vision exercises, visual training, and exercise therapy. The search was limited to English language and human studies; 198 citations were retrieved. From these abstracts, 10 articles were obtained and reviewed as being of relevance to the assessment. The reference lists of these articles were consulted and yielded 2 additional articles.

Statistical Issues and Study Design

Studies reviewed were conducted in a variety of age groups and levels of myopia, with varied training methods and in subjects with varied degrees of motivation. Case series of visual training techniques were first reported in the 1940s.⁵⁻⁷ One controlled trial without randomization was reported in 1957; examiners also were not masked as to whether a patient was in the control or intervention group.⁸ One randomized trial did not specify if examiners were masked as to whether patients were in the therapy or control group.⁹ In 1991, a randomized controlled trial of a visual training method for control of accommodation was reported.¹⁰ There have been case series and controlled studies of accommodation biofeedback training and myopia,¹¹⁻¹⁴ and the effects of exercise on vision.¹⁵ Reports of controlled trials of biofeedback visual training and the effects of exercise on vision do not specify if examiners were masked as to whether a patient was in the control or intervention group.

Specification of Level of Evidence

The randomized controlled trial for visual training for control of accommodation is rated as level I evidence. The other evidence that currently exists in the peer-reviewed literature reviewed for this assessment is graded as Level II to Level III, with most studies graded as Level III. Because of the different methods of visual training in the papers reviewed, all levels of evidence are discussed in this assessment.

Properly conducted, well-designed randomized clinical trials are rated as Level I evidence. Level II evidence is that obtained from well-designed controlled trials without randomization; well-designed cohort or case-control analytic studies, preferably from more than one center; and, multiple time series with or without the intervention. Level III evidence consists of evidence obtained from descriptive studies, case reports, and reports of expert committees or organizations.

BENEFITS

In 1946, Woods⁵ reported results of an optometric training technique in 103 myopic patients, of whom 30 (29%) showed a small improvement in VA, 31 (30%) showed inconsistent improvements in VA, 32 (31%) had no change, and 10 (9%) had a decrease in VA. Seventeen of the 61 patients who demonstrated improved VA returned for an examination 5 months after the training was completed. Two of these patients had maintained the improvement in VA; the other 15 patients had not maintained the improvement. Of the 103 patients, 67 received noncycloplegic refraction after the training was completed; no change in refraction was noted.

Hildreth et al⁶ studied 54 patients with myopia of –0.5D to –3.00D and found 12 (22%) improved one to two lines in Snellen acuity, 30 (55%) showed no change in VA, and 12 (22%) showed a questionable improvement of one line or less in Snellen acuity. There were no changes in retinoscopic refraction. Eleven patients who showed definite improvement returned for evaluation at 15 to 22 months after the training. Five of these patients retained their improved VA following training, and 2 retained a partial improvement. Compared with the pretraining VA, one had worsened acuity and three had reverted back to the original VA. The authors compared their patients with a normative database¹⁶ and concluded that patients whose VA was not as good as would be expected for their amount of myopia benefited the most from the training. In this group, 73% showed some improvement in VA.

Another case series of 8 patients published in 1948 reported no improvements in VA and no change in retinoscopic refraction after 12 group sessions of visual training.⁷

A review article published in 1957 proposed that VA improvement after visual training was due to perceptual learning,¹⁷ based on the Marx¹⁸ grouping of vision into four phases of processes: optic, receptive or retinal, conductive, and perceptive. Perceptual learning will increase the individual's ability to interpret blurred images.

Berens et al⁸ studied visual training in 80 patients with low myopia; the control group consisted of 60 patients. The investigators reported that 74 of 80 (92.5%) patients improved in terms of subjective VA as measured on VA charts while 59 of 60 (98%) patients in the control group lost VA; this difference was statistically significant (P<0.001). Patients in the treatment group improved VA on average from 20/98 to 20/63 (uncorrected) and 20/21 to 20/19 (corrected). Patients in the control group changed on average from 20/97 to 20/131 (uncorrected) and 20/21 to 20/19 (corrected). The average elapsed time between the first assessment upon entry to the trial and the post-

trial assessment differed between the two groups. It was 12 weeks for the treatment group and 16 weeks for the control group. Examiners were not masked as to whether the patients were in the control or treatment group. There was a statistically significant difference in refraction as measured by cycloplegic retinoscopy in the intervention group, but as it was approximately one-quarter diopter, this could have been due to measurement error. Berens et al constituted one-third of their control group from those who did not attend visual training sessions regularly in the first two weeks, thus introducing a possible bias towards less motivated patients in the control group compared to the intervention group.

In 1982, Balliet et al¹¹ reported a series of 17 patients with myopia from –1.5D to –7.25D and no more than –3.0D of astigmatism undergoing computer-based visual training incorporating biofeedback for an average of 35 sessions. All patients increased their VA, with the average acuity change for all subjects about 3.4 lines (2.12D); no refractive changes were found. The authors proposed that an artificial contact lens created by tear film changes could be the cause of the improvement in VA, based on increased tear action observed in 15 of 17 (90%) patients and low-tear break-up time during follow-up examinations. Balliet et al noted that a learned perceptual processing mechanism could also explain the improvement. Shih et al¹⁴ investigated the effect of Qi-Qong ocular exercise training on accommodation and demonstrated a slight improvement in amplitude; they conclude that the improvement in visual function noted may be the result of a pinhole effect by miosis of the pupil.

In 1984, Rosen et al⁹ studied the effect of visual training in 29 patients. Ten patients received training and feedback, 10 received training without feedback, and nine patients constituted the control group. The training period lasted 6 weeks and all groups were evaluated then and again after 2 months. The method of randomization was not stated and it was not stated in the report if examiners were masked as to treatment group. Acuity was measured with a Bausch and Lomb (Rochester, NY) vision tester; refractive error was assessed by subjective refraction. Change in refraction for both treatment groups was not statistically significant. Visual acuity results improved in both treatment groups (P<0.05); the control group was unchanged for VA and refractive error.

A review article from 1991 discussed the effect on myopia of accommodation biofeedback and concluded that reported results of a positive effect should be confirmed by more comprehensive clinical trials with pre-and post-training cycloplegic refraction in addition to subjective VA measurements.¹⁹ Koslowe et al¹⁰ conducted a randomized double-masked study (level I evidence) of a visual training method for control of accommodation with negative results. There were no statistically significant differences in VA, retinoscopy, or subjective refraction between the control (n=15) and treatment groups (n=15).

In a controlled trial of biofeedback visual training conducted in 1996, Angi et al¹² reported that VA measured by subjective refraction in the treated group improved significantly compared to the untreated group but was unchanged when measured by a computer-generated optotype. A 1997 trial reported similar results;¹³ in both trials, measures of psychological distress showed improvement in the treated groups.

An investigation into the effect of mood or motivation on the outcomes of visual training or exercise concluded that the improvement in visual function demonstrated may be attributable to "a change in decision criterion (i.e. an increased willingness to say 'yes')" rather than to a physiological change in the visual system.¹⁵ The investigators note that many of the studies of visual training and visual function lack the ability to discriminate between improvements from physiological change in the visual system and changes in mood.

RISKS

Most of the costs of a visual training program are not covered by health insurance although cost of prescription eyeglasses may be covered by a vision insurance plan.

CONCLUSIONS

There is level I evidence that visual training for control of accommodation has no effect on myopia. In other studies (level II/III evidence), an improvement in subjective visual acuity for patients with myopia who have undertaken visual training has been shown but no corresponding physiological cause for the improvement has been demonstrated. The improvements in myopic patients noted in these studies have been postulated to be due to improvements in interpreting blurred images, changes in mood or motivation, creation of an artificial contact lens by tear film changes, or a pinhole effect from miosis of the pupil.

It is not clear if patients purchasing these programs for use at home outside of the controlled environment of a research study will have any improvement in their vision.

No evidence was found that visual training has any effect on the progression of myopia. No evidence was found that visual training improves visual function for patients with hyperopia or astigmatism. No evidence was found that visual training improves vision lost through disease processes such as age-related macular degeneration, glaucoma, or diabetic retinopathy.

The only risk attributable to visual training is financial.

DEVELOPMENT OF COMPLEMENTARY THERAPY ASSESSMENTS

Complementary, or alternative therapies are a growing part of health care in America. Americans spend an estimated \$14 billion a year on alternative treatments. Mainstream medicine is recognizing a need to learn more about alternative therapies and determine their true value. Most medical schools in the United States offer courses in alternative therapies. The editors of the *Journal of the American Medical Association* announced that publishing research on alternative therapies will be one of its priorities. The National Institutes of Health National Center for Complementary and Alternative Medicine has broadly defined complementary and alternative medicine as those treatments and health care practices not taught widely in medical schools, not generally used in hospitals, and not usually reimbursed by medical insurance companies. More scrutiny and scientific objectivity is being applied to determine whether evidence supporting their effectiveness exists.

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In the fall of 1998, the Board of Trustees appointed a Task Force on Complementary Therapy to evaluate complementary therapies in eye care and develop an opinion on their safety and effectiveness, based on available scientific evidence, in order to inform ophthalmologists and their patients. A scientifically grounded analysis of the data will help ophthalmologists and patients evaluate the research and thus make more rational decisions on appropriate treatment choices.

The Academy believes that complementary therapies should be evaluated similarly to traditional medicine: evidence of safety, efficacy, and effectiveness should be demonstrated.²⁰⁻²² Many therapies used in conventional medical practice also have not been as rigorously tested as they should be. Given the large numbers of patients affected and the health care expenditures involved it is important that data and scientific information be used to base all treatment recommendations. In this way, we can encourage high-quality, rigorous research on complementary therapies.^{23, 24}

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