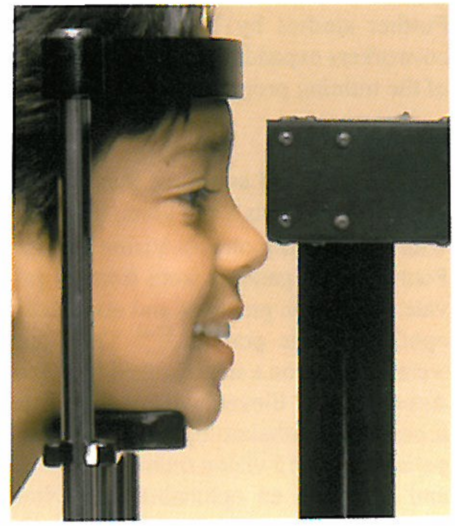
MYOPIA REDUCTION WITH BIOFEEDBACK TRAINING OF ACCOMMODATION



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ABSTRACT

We present data on 1,334 patients who received vision training using a regimen based in the biofeedback control of accommodation for myopia reduction. These patients were treated in 21 private optometric practices, one private ophthalmological practice, one hospital ophthalmology clinic, 15 vision training centers, and one ophthalmologic clinic center. Patients ranged in age from 7 to 62 years with an average age of 24 years, and were from the United States, Singapore, Israel, and Italy. Each patient received a clinical treatment program, whereby reductions in myopia were occasioned with 0.5 Diopter reductions in the habitual spectacle correction. The results showed a median 1.00 Diopter reduction in myopia after an average of 19 training sessions, with an average improvement in uncorrected visual acuity from 20/170 and 20/32. Accommodative relaxation appears to be related to the Alpha wave component of the electroencephalogram. Future research into myopia treatment should investigate further the relationship between myopia and brain function in general, and accommodative function and the Alpha brain wave, more specifically.

Key Words

myopia, accommodation, biofeedback, vision training

Biofeedback can be defined as supplying individuals with information about a bodily process or function of which they are normally not aware. Data of 1,334 patients collected from 1984 to 1993 are presented. All patients received training with the Accommotrac® Vision Trainer (AVT), a clinical device that trains voluntary control of accommodation by biofeedback. Basically, the technique applies auditory and visual biofeedback of accommodation, converting very small changes (0.05) in accommodation into greater than just noticeable difference (JND) changes in auditory feedback. Additionally, all patients received out-of-instrument in-office and home training based on their ability to voluntarily control accommodation as developed and determined by the AVT.

We are aware of and have previously reported on changes in aspects of vision and other physiological functions as the result of biofeedback training of accommodation, and these are listed in Table 1. However, we only report on changes in visual acuity and diopters of myopia.

Table 1
Visual and Other Physiological Changes Reported with Biofeedback Training to Relax Accommodation

> Contrast Sensitivity Function[1]
> Intraocular Pressure[2]
> Color Discrimination[1]
> Visual Field and Reaction Time[3]
> Emotions[4,5]
> Peripheral Blood Flow[6]
> General Muscular Relaxation[1]
> Alpha Brain Wave[1,6,7,8]

Literature Review

The best-known study of vision training to reduce myopia is the Baltimore Myopia Project.[9,10] A recent in-depth analysis reviewing the results found that there was a significant improvement in unaided visual acuity as a result of the training; but because of problems with the quality of the refractive error data, no conclusion could be reached concerning the measurement of myopia.[11]

A detailed historical review of myopia treatment has been previously reported,[12] as has a review of the bio- feedback treatment of myopia;[13] therefore, only a brief summary will be given here. The first reported reduction of myopia via biofeedback training of accommodation was by Randle in 1970.[14] The subjects were pilots, who had developed empty-field myopia during prolonged flights. Trachtman et al.[12,15] demonstrated small amounts of myopic reduction in four subjects utilizing a carefully controlled experimental paradigm. Trachtman et al.'s results were replicated in a number of independent studies by Barton and Young,[16] Berman et al.,[17] Ferri,[18] Franzblau,[19] Gallagher,[20] Giardina and Antoni,[21] Magun,[22] Randle,[23] and Richter[24] and most recently summarized by Ong and Ciuffreda.[25] Only two reports with small sample sizes failed to find similar findings[26,27] and the methodological problems with these reports have been explicitly described.[28,29]

Further studies by Trachtman and his co-workers expanded the range and scope of the training program.[1]

Patients

One thousand and three hundred and thirty-four patients were given treatment with the Accommotrac® Vision Trainer. Four hundred patients were from 21 private optometric practices and one private ophthalmologic practice.[30,31] Their data were reported on a standardized form (see Appendix A). Eleven patients were from a hospital ophthalmology clinic,[32,d] 712 patients from 15 vision training centers,[33] and 211 from an ophthalmologic clinic center.[34] The patients were from the United States of America, Singapore, Israel, and Italy respectively.

The patients ranged in age from 7 to 62 years with an average age of 24 years. To simplify data collection, gender and demographic information were not recorded.

Instrumentation

The Accommotrac® Vision Trainer (AVT) is a clinical biofeedback instrument that measures accommodation 40 times per second and provides the patient with immediate auditory feedback in the form of a change in frequency of a tone and/or a change in rate. Details of the instrument and its operation are fully described elsewhere as are the protocols that follow.[28]

Clinical Procedures

An overall and general outline of the training program follows. It is most important to keep in mind that the training program typically is customized. Factors related to customizing the program include: the patient's age, amount of myopia (measured with most plus for 20/20), occupation, avocation, general stress level (measured by either galvanic skin response (GSR) or peripheral body temperature, (i.e., finger), general health, binocular vision considerations, and the length of time that the patient has been wearing eyeglasses or contact lenses.

a. In-instrument Training

The main goal of training with the AVT is to teach the patient voluntary control of accommodation. In the case of myopia reduction, negative accommodation is trained. The training consists of various phases ranging from a darkened room with no visual stimuli to a fully illuminated room with accommodative stimuli. The patient is told to be aware of what the eye feels like when the sound is being driven properly. Any description such as a stretching, tightening, dilating, opening, or widening allows the patient to associate a physical feeling with proper muscle control. While there is a fully-described formal training protocol,[28] the training program is customized to meet the uniqueness of each patient.

b. In-office Out-of-instrument Training

The goal of the in-office out-of- instrument training is to teach the patient to generalize the voluntary control of accommodation from the AVT to the everyday world situation. The most popular method employs the following visualization process:

1. The patient sits comfortably in a chair and views an eye chart with several different sized optotypes.
2. The patient closes his eyes, and strives to mentally hear the sound change in tone and/or speed (as in the In-Instrument Phase) and "feel the stretching or relaxing of the eyes." When he feels the stretching or relaxing, he opens his eyes and reads the chart. The patient concentrates on the feeling inside his eyes but gradually becomes aware of the chart and then reads the letters. A tape recording of the changing sound and/or speed may be helpful. The sound should become a conditioned stimulus enabling the patient to relax accommodation. If this does not happen, there is something blocking this very basic nervous system reflex. Some usual causes include the patient exerting too much effort, becoming stimulus-bound by the blur of the letters, fatigue or any combination of these factors.

Home Training

The major component of the home training is for the patient to generalize what he has mastered in the previous phases to the real world. Consequently, the procedures outlined in Section b, above, are performed at home for at least 30 minutes per day. The practice should be performed for about five minutes to avoid fatigue. Also, by repeating the procedure many times during the day, the generalization will occur more efficiently. The tape recording can also be used. Additionally, the patient practices maximally clearing distant objects as much as possible during everyday tasks, such as walking, eating a meal, or watching television.

Ergonomic Considerations

These considerations include: posture and visual hygiene, which are important components of the patient's habitual behavior that is related to the myopia. Patients must be counseled that they must maintain a good distance from reading and/or writing material, i.e., the Harmon distance (the distance from the elbow to the first knuckle--this distance is typically 14 to 16 inches). Take rest periods when doing close work. They should take a break and stretch and relax the muscles in the neck, shoulders, upper back, and arms during these breaks.

Optical Considerations

There are several important considerations concerning the patient's corrections during the training program:

1. Patients are advised to wear their distance glasses only when necessary, e.g., driving a car or in order to see the blackboard. Some eyeglass wearing is more habit than related to vision function.
2. Weaker lenses should be prescribed as indicated — usually to give the patient 20/30+ binocular visual acuity. The exception to this is that the full minus correction should be prescribed for driving, especially at night. The patient will typically tell you when he would like his driving prescription reduced.
3. A near vision prescription may be given as determined by dynamic retinoscopy. The glasses should be full field and not bifocals. They may be worn at home and when watching television for at least a half-hour per day. This is especially helpful in improving children's unaided visual acuity to better than 20/30. Children can usually function well with 20/30 and wearing plus lenses at home will act as passive training to motivate them to see more clearly.
4. Even if reduction in prescription is measured, the Rx should not be reduced more than 0.50 Diopter. If it is, there will be too much adaptation required by

the patient. It is suspected that the problems in this area arise from the non-visual aspects of the myopia, such as muscle memory in the back, neck, shoulders, and arms, as well as the psychological aspects of being myopic. (This is especially important for those with initial prescriptions greater than -3.00 Diopters.)

This completes the training program. Table 2 outlines the patient's achievements and needs at the end of the training program.

Table 2
Patient's Achievements and Needs

Achievements
1. Voluntary control of accommodation
2. Reduction in ciliary spasm
3. 1.00 to 2.00 D reduction in myopia

Needs
1. Driving prescription, especially at night
2. Plus near prescription as indicated
3. A firm understanding of his focusing system
4. An understanding that some occasional blur is normal
5. A sensitivity about his vision to know when to return for "refresher" training.

Results of the Training

Data from 1,334 patients were received from 21 optometric private practices, 15 vision training centers, one ophthalmologic private practice, one ophthalmologic clinic center, and one hospital ophthalmology clinic. The basic data recorded for each patient were: Pre- and Post-Unaided Distance Visual Acuity O.D., O.S., and O.U.; Pre- and Post-Rx, O.D. and O.S.; the Patient's Age; and the Number of Training Sessions. See Appendix A.

For each category, the range and mean have been calculated. See Tables 3 and 5. However, for statistical reasons the mean of the Rx data was not calculated.[35] The basic reason is that a behavioral scale for myopia has not been established. Consequently, it cannot be stated that a 2.00 Diopter myope behaves twice as myopic as a 1.00 myope, and half as myopic as a 4.00 Diopter myope.[36] Here, the median value is given. See Table 4.

Table 3
Patient Summary Data Results of Treatment with the Accommotrac® Vision Trainer
N = 1,334

Visual Acuity (Snellen)	Range	Mean
Pre-TX OD	20/2000 to 20/20	20/170
Post-TX OD	20/500 to 20/10	20/58
Pre-TX OS	20/2000 to 20/15	20/170
Post-TX OS	20/500 to 20/10	20/55
Pre-TX OU	20/2000 to 20/10	20/170
Post-TX OU	20/500 to 20/10	20/32

Table 4
Patient Summary Data Results of Treatment with the Accommotrac® Vision Trainer
N = 1,334
Myopia (in Diopters)

	Range	Median
Pre-TX RX OD	-13.75 to +0.50	-2.75
Post-TX RX OD	-11.00 to +0.75	-1.75
Change OD	+7.50 to -0.50	+1.00*
Pre-TX RX OS	-13.25 to +0.50	-2.75
Post-TX RX OS	-11.00 to +0.50	-1.75
Change OS	+7.50 to -0.25	+1.00* *

For CHANGE a "+" sign indicates a reduction in myopia, and a "-" sign indicates an increase in myopia.

Table 5
Patient Summary Data Results of Treatment with the Accommotrac® Vision Trainer
N = 1,334
Number of Training Sessions and Age (years)

	Range	Mean
Number of TX Sessions	1 TO 140	19
Age (years)	7 TO 62	24

In summary, for an average of 19 training sessions there was an average improvement in unaided distance visual acuity of from O.U. 20/170 to 20/32, and a median reduction in myopia of 1.00 Diopter for each right and left eyes.

The range of myopia reduction was from 7.50 Diopter to a 0.25 Diopter increase for right eyes, and 7.50 Diopter reduction to a 0.50 Diopter increase for left eyes. All but one patient showed an improvement in unaided distance visual acuity. The average age of the patients was 24 years.

The patient with the 7.50 Diopter reduction requires some individual explanation. On Figures 1 and 2, the data points for this patient can be noted to be separate from the main trend of the other data, and are seen in the upper left side of the graphs. The patient is a female, who was 54 years old at the end of the training. She had 140 training sessions, spanning three years, with one session per week. The patient was employed as a part-time dispatcher for a trucking company. She had no particular avocation. Her general health was good. She was neither very verbal about her experience(s) with the training nor did she report any insights. The obvious question is: why was this patient so different from the other patients? Perhaps the answer was her motivation. When faced with being laid off from her job, she was asked if she wanted to continue the training? Her answer: "If I have to, I will scrub floors to continue with the training."

Discussion

A compilation of 1,334 cases of myopia successfully treated by biofeedback of accommodation training has been reported.

A question may be raised that the results are biased because the people making the reports have some financial,

FIGURE 1
PRE- VERSUS POST-TRAINING MYOPIA:O.D.

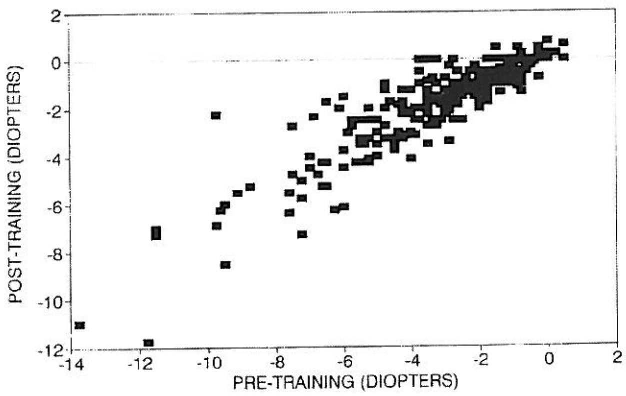


FIGURE 2
PRE- VERSUS POST-TRAINING MYOPIA:O.S.

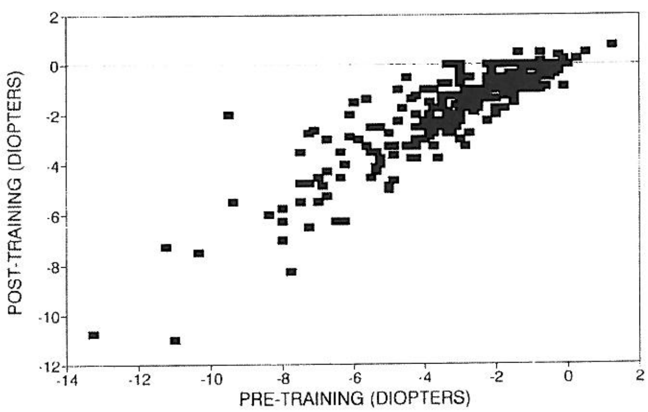
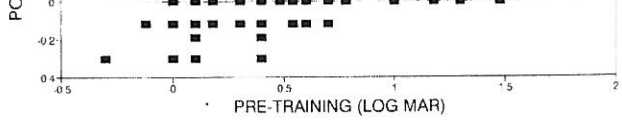


FIGURE 3
PRE- VERSUS POST-TRAINING VA:O.U.



commercial or other interest in the training procedure. Because of the large number of patients, 1,334, from 42 different eye care practitioners, both optometrists and ophthalmologists, from the United States of America, Israel, Italy, and Singapore, any bias will tend to be averaged and minimized. For example, in an earlier report of 400 patients[30] from 22 practitioners in the United States, the averages are very similar to the larger number of 1,334 cases. The 400 patients had a median 1.00 Diopter reduction in myopia after 17 vision training sessions; with the 1,334 patients there was a median 1.00 Diopter reduction after 19 vision training sessions. According to Hays' authoritative statistics text,[37] a large sample normalizes measurement error.

Another source of possible error is the amount of myopia reduction. As has been reported, there was a median 1.00 Diopter reduction for the 1,334 cases, this amount exceeds the clinical error measurement of 0.50 Diopter.[38]

Comparing the mean Post-Treatment Visual Acuity, 20/32 (Table 3) with the median Post-Treatment Myopia, -1.75 Diopters (Table 4), a question may arise that the visual acuity is disproportionately good compared to the myopia. Several hypotheses can be presented to explain this relationship. Utilizing Hirsch's[39] report on visual acuity and myopia as a guide, the present pre- training data for 2.75 Diopters of myopia with a monocular visual acuity of 20/200 would be expected. For the post- training data, for 1.75 Diopters of myopia, a monocular visual acuity of approximately 20/100 would be expected. The actual pre-training visual acuity was 20/170, and the actual post-training visual acuity was approximately 20/60. By making this comparison it is noted that the actual pre- and post-training visual acuities, were better than expected from Hirsch's average data. However when compared with Hirsch's complete data range, the actual data are within the range for 2.75 Diopters of myopia, and approximately equal to the limit of the range for 1.75 Diopters of myopia.

The coefficient of correlation between unaided distance visual acuity and diopters of myopia has been found to be 0.69.[1] To estimate the amount of variance accounted for by the relationship, the coefficient of determination is calculated by squaring the coefficient of correlation or $(0.69)^2$ which equals 0.48.[37] This means that 52% of the variance of the data is not accounted for by their empirical relationship. For example, factors other than diopters of blur[1] are involved in visual acuity, such as pupil size, retinal grain, perception, and the integrity of the vision system.[40] As mentioned earlier and will be discussed in more detail below, relaxation of accommodation is associated with improvement of other physiological functions, i.e., improvement of contrast sensitivity function in the higher spatial frequencies. Such an improvement could easily allow the actual data to fall in the middle of the data reported by Hirsch.

The physiological index that appears to be most related to myopia reduction and vision improvement is the EEG and most importantly, the Alpha brain wave.[1,6,7,8] Interestingly, the Translid Binocular Interaction Trainer (TBI), developed by Allen,[41] flashes at the rate of nine cycles per second, which photically drives people into a dominant Alpha pattern. Allen[42] more recently reported that suppression can be removed by the nine cycles per second flashing. He proposed reprogramming of neural pathways as the mechanism.

While Allen externally stimulated the Alpha rhythm, the biofeedback training teaches the patient to regulate it internally. In addition to decreasing suppression of vision, a dominant Alpha brain wave state is related to finger warming, general muscular relaxation, an increase in the size of the visual field, a decrease in reaction time, and improved accommodative function (see Table 1).

While Allen attributes the removal of suppression to stimulation of the visual pathway, the biofeedback mechanism can be attributed to a more general sympathetic nervous system effect via the hypothalamus. Among its many functions as the head ganglion of the sympathetic nervous system,[43] the hypothalamus regulates the symmetry of the EEG[44] as well as accommodation,[45] retinal functions,[46] the emotions,[43,47] the immune system,[48] and neurotransmitters in the brain.[41,49]

It could, therefore, be stated that understanding the global mechanism involved in the EEG,[50] and more specifically the Alpha Wave, helps explain many of the concepts of behavioral optometry, i.e., that the vision process is pervasive throughout the brain and body, even to the point of impacting nutrition.[51]

The topic of binocular vision and associated findings have not been dealt with in the present report. Preliminary data indicate that as a result of the biofeedback of accommodation training, vision findings tend to be normalized toward expecteds, with both fusional and accommodative ranges becoming markedly expanded.

Other possible mechanisms that may be involved in non-vision changes from vision training can be attributed to neuropolypeptides,[52] and cytokines[53] - both regulated by the hypothalamus.[48] In the future, as clinical tests for these neurotransmitters become simpler, the nature of the relationship between vision and these chemicals can become further explored.

As understanding of brain function increases, so will the understanding of the vision process, and within the above context, the treatment of myopia.

Long-term results have not been presented in the current report; but, in general, we have found that they vary from patient to patient. The main factors involved in the maintenance of a long-term improvement include the awareness of focusing correctly, posture, work and/or study habits, and stress. A systematic report of long-term results is in the planning stage.

According to Kuhn's classic work on the philosophy of science,[54] it is concerned with the collection, by experiments and/or observations, of facts, theories, and methods to understand phenomena. Regarding the collection of observable data, Webb, et al.,[55] stress that observations should be accurate and reliable. Because the measurements that have been reported have been shown to be repeatable across a very large patient base, the requirements for accurate and reliable measurements have been fulfilled. It has been previously mentioned that the measurements were well within an established and acceptable standard of the clinical accuracy of refraction of 0.50 D.[38]

An additional question may be raised regarding the lack of a control group and the scientific validity of the present report. This question can be answered in a variety of ways. The general use of single case experimental designs has been recognized as a valid scientific method since the 1960s.[56] For an excellent treatment of the topic see Hersen and Barlow.[57] More specifically, using the subject as his own control has been in use in regard to myopia reduction since 1978.[12,58] In point of fact, the most accepted study on myopia reduction training (with 103 subjects), The Baltimore Myopia Project.[59,60] did not have a control group — it was understood that the patient was his own control! More recently, there appeared a report on voluntary control of accommodation using only one subject as his own control.[61]

Alternately, to control for all the factors involved in the internal validity of a true experiment, Campbell and Stanley[62] cite "The Pre-Test Post-Test Control Group Design." Using the current clinical data, for each patient there was a pre-test, a treatment and a post-test for the treatment group. Concerning a control group, one can be obtained by randomly selecting 1,334 cases from the literature. It is well known (see for example, Goss and Rainey[63]) that myopia tends to increase at a rate of between approximately 0.4 D and 0.7 D per year in school children. Since approximately 50% of the reported cases were of school age, a lenient assumption would be that during the average 19 weeks of training there was no change in the amount of myopia. Assuming more stringently, it could be stated that during the 19 weeks, an increase of 0.2 D would be expected in the school age population. This would only increase the positive effects of the reported biofeedback treatment.

The large sample size would stand against any criticism in the external validity of the report.

The Null Hypothesis can be stated as: Biofeedback training of accommodation has no effect on myopia. After evaluating both the internal and external validity of the current report, the Null Hypothesis is clearly rejected. Future investigations will be concerned with the dynamics of the training paradigm with particular regard to intra- and inter-personal factors such as occupation, avocation, general stress level, and binocular vision status.

In summary, an efficacious method of myopia reduction of 1,334 cases is reported using biofeedback of accommodation vision training. A clinical protocol is described that incorporates a combination of in-office instrument, in-office and out-of-office non-instrument training. The importance of the relationship between accommodation with the Alpha brain wave is discussed within the context of both vision and non-vision changes as a result of the training protocol.

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APPENDIX A

PATIENT DATA FORM

Patient Data:
Occupation:____________________

Patient Initials:__________ Avocation:__________

Sex:_____ DOB:__________

Dr. First Name: __________ Dr. Last Name:__________

Pre-Training Data:
Pre-VA-OD: __________ Pre-VA-OS:__________

Pre-VA-OU:__________

Pre-RX-OD:__________ Pre-RX-OS:__________

Post-Training Data:
Post-VA-OD: __________ Post-VA-OS:__________

Post-VA-OU:__________

Post-RX-OD:__________ Post-RX-OS:__________

Training Data:
Number of Sessions:_____

Beginning Date: __________ Finish Date:_____

Comments:____________________

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EDITORIAL continued

well set a national precedent. However, beyond insurance coverage there lies the at least equally important issue of the more global implications the report has for optometry.

Keep in mind that most of the conditions that Hayes investigated regarding the efficacy of VT received a "C" rating, with the others receiving a "D." The report states that:

> *Much of the literature addressing the efficacy of vision therapy has been based more on author opinion than on quality scientific evidence. Most of the studies were found in professional journals published by the American Academy of Optometry and the American Optometric Association, organizations that advocate the use of vision therapy and may be biased toward publishing articles that support its efficacy.*

This statement puts the editorial policies, review processes and scholarliness of the two most recognized optometric journals and the integrity of their sponsoring organization in serious doubt. *But does anyone care?* And the issue of bias is also raised. In this regard can Hayes Inc., whose major clients are managed care entities and health care insurers, be likewise suspected of bias? Further, the report recognizes...

> *that in many states, the legal definition of optometry includes specific mention of vision training and orthoptics. A significant portion of the professional school training of an optometrist involves preparation to offer orthoptic therapy.*

The Hayes Report also brings in the National Board (of Optometry) examination. Thus, by its "C" and "D" ratings it strongly implies that many state legislatures, the Association of Schools and Colleges of Optometry and the National Board of Examiners in Optometry are endorsing interventions that are at best investigational and/or experimental with inconclusive supporting research. *But does anyone care?*

As would be expected, the Hayes Report has been read most carefully and commented upon most vociferously by those optometrists with interest and expertise in VT. However, several colleagues have told me that they had the same experience as I, after showing the report to some optometrists not practicing VT. The most frequent responses were a shrug of the shoulders and an "O.K., too bad" attitude. These individuals cared a little but were not too concerned. However, they're really missing the point. If the profession, and particularly the American Optometric Association, the American Academy of Optometry and the Association of Schools and Colleges of Optometry do not take strong and concerted action, we eventually stand to lose an area that has long been an integral part of our profession. It is one of the few areas that has been ours almost exclusively in terms of clinical care and meaningful research. In this instance, a lack of response is the same as condoning the report. And, there are others waiting in the wings to pick up what we will lose. It is no secret that vision therapy, in one form or another, is being increasingly practiced by non-optometrists.

But... does anyone care?

Footnotes

a. Joseph N. Trachtman, O.D., Ph.D. is the President of Biofeedtrac Inc., the manufacturer of Accommotrac ® Vision Trainer.

b. Scott Pelcyger is a former member of the Board of Directors of Biofeedtrac, Inc.

c. Catherine M. Venezia is a Certified Neurotherapist at the Institute for Advanced Vision Therapy[SM].

d. Copies of these unpublished reports are available from the corresponding author.

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