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A Clinical Trial of Two Devices in Altering the Facilitation of Accommodation and Progression of Myopia

Joseph CW Cho[1] and George C Woo[2]*

[1]General Eye and Low Vision Centre, The Hong Kong Society for the Blind, Sham Shui Po, Kowloon, Hong Kong SAR, China

[2]School of Optometry, The Hong Kong Polytechnic University, Kowloon, Hong Kong SAR, China; InnoHK, Centre for Eye and Vision Research, 17W Hong Kong Science Park, Hong Kong SAR, China

ABSTRACT

It has been suspected that accommodative hysteresis and the lag of accommodation caused by intensive near work can drive the development of myopia. Accommodation training has been found to be effective in improving accommodative facility and accommodative lag, and has been reported by some to be a useful means to control myopia progression. This study investigates whether two accommodation training devices requiring minimal clinical supervision and allowing home use to lower training cost can significantly increase accommodative facility and reduce myopia progression in myopic school children.

This study is a double-blind randomized clinical trial with two treatment groups, each using one of the two devices, and one control group. Primary school children with myopia progression were randomly assigned into the three groups, each with an equal number of male and female subjects. An optometrist assigned the subjects into the three groups and provided two weeks of training to subjects in the treatment groups. A second optometrist carried out the pre-, post-, and three follow-up examinations at 3-month intervals for all subjects. Measurements collected and analyzed included accommodative facility, axial length, and best corrected visual acuity.

Findings show that short-term use of the two devices does not result in a significant improvement in measurements of accommodative facility, and does not significantly reduce the progression of myopia.

***Corresponding author**

George C Woo, School of Optometry, The Hong Kong Polytechnic University, Kowloon, Hong Kong SAR, China; InnoHK, Centre for Eye and Vision Research, 17W Hong Kong Science Park, Hong Kong SAR, China.

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Introduction

Many environmental factors influence the onset and progression of myopia. Early and intense education and sustained near work activities at close distance are suspected to be some of the possible causes [1-6].

It has been found that intensive near work can increase ciliary body tonus and affect its relaxation to produce accommodative hysteresis and transient myopia [7].

Near work can also change the accommodative responses with a decrease in accommodative facility and an increase in accommodative lag [8,9]. Some have reported that myopes have higher accommodative lag than emmetropes and suggested that the retinal hyperopic defocus blur due to the lag can cause axial elongation and myopia progression [10-13].

There have been reports of accommodative accuracy improvement through increased accommodative facility and decreased accommodative lag by subjects who undertook Orthokeratology treatment and successfully slowed myopia progression [14-16]. This tends to support the idea of a possible link between accommodative lag and hyperopic defocus in the course of myopia progression [17,18].

Some clinical studies have shown that accommodation training can reduce accommodative lag, increase accommodative facility and improve the conditions of symptomatic subjects [19-23].

The above results have led to studies that try to reduce or slow myopia progression by using various accommodation training methods that can modify accommodation flexibility, such as biofeedback training, and fading and feedback training [24,25]. Trachtman and Randle reported success in the treatment of myopia with biofeedback training. They attributed the success to the modification of the subjects' volitional control over their accommodative response to extend their far point or range of negative accommodation [26,27]. However, Koslowe and Angi reported that no significant difference was found between the control and experimental subjects using biofeedback training. The contradictory findings indicate that using biofeedback training to modify the test subjects' accommodative flexibility can produce disparate results [28].

Bronskill et al. reported reduction in myopia and improvement in unaided visual acuity in 32 eyes after two weeks of training with the Optolax II, which exercised both positive and negative accommodation and promoted the extension of far point. According to them, training with the Optolax II relaxed ciliary muscle to reduce accommodative hysteresis, and reduced the extent of myopia with an improvement in unaided visual acuity, because the training had increased accommodative flexibility.

Compared to the methods used in biofeedback as well as fading and feedback training, the Optolax II required much more simple instrumentation and instructions, which minimized training costs and made home based training possible.

In view of such advantages offered by the Optolax II and its potential therapeutic value in the treatment of myopia, a more thorough investigation of its effectiveness in the improvement of accommodative facility, unaided visual acuity and reduction of myopia by using subjects of a narrower refractive error and age range is carried out for this study. The subjects are randomly placed into either treatment or control groups that each has an equal number of male and female subjects, and the examiner is masked to prevent any experimenter's bias. The treatment groups are given the same amount of training as in Bronskill et al.'s study.

The Optolax II has a lens design such that both defocus and size cues are available to elicit the correct accommodative response. A commercially available simple accommodation training device, the Visomed, is used in one of the treatment groups to find out whether size or defocus cues alone or together mediate the effect of training. The Visomed has a similar function as the Optolax II, but has a different optical design that produces no change in fixation target's image size as the image approaches the observer.

The randomized controlled clinical trial of the Optolax II and the Visomed is carried out using two treatment groups and one control group to find out whether:

- There is any difference in the rate of progression of myopia between the treatment and control groups over the 9-month period.
- The improvement, if any, is comparable to that reported by Bronskill et al.
- The two training devices produce different effects on accommodative facility and myopia progression.

Materials and Methods

The three groups of subjects were school students matched in age, refractive error, and the groups were matched in their numbers of male and female subjects. The subjects chosen were aged 6 to 12, and each had an increase of myopia of -0.50D or more over the 12 months before taking part in this study. The range of their refractive errors were from -0.50D to 2.75D with - 0.50D or less astigmatism in each eye. All the subjects had normal binocular vision and ocular health, with aided monocular visual acuity of each eye being 6/9 or better [29]. Goss reported earlier onset and higher final amount of myopia in female than in male subjects. In this experiment, the numbers of male and female subjects in each group was equal to avoid a larger number of female subjects in a particular group being the cause of greater increase in myopia in that group.

The potential subjects were identified by a nurse through patient record search. 220 invitation letters which described the purposes and procedures of this study were sent to the potential subjects. This was followed by telephone calls to answer queries and to make appointments for 25 males and 25 females to attend the preliminary examination.

The preliminary examination was carried out by an optometrist to confirm the suitability of the candidates. Details of the experimental procedures in writing and consent forms were given to the guardians with verbal explanations after the examination. Interested guardians were asked to sign and return the consent form.

After the preliminary examination 44 subjects were found suitable for the pre-training examination. All 44 subjects returned for the pre-training examination and each received an assigned number. A second optometrist in charge of training was given the number and sex of the subjects. He picked equal numbers of male and female subjects for the two treatment groups, which was 7 males to 7 females in each group. The remaining 16 subjects served as controls.

The first optometrist carried out measurements for the subjects in the days immediately before and after the two weeks of training, and then at 3-month intervals for 9 months. He was unaware of the group assignment of each subject. Group identities of the subjects were reviewed after the last follow-up for data analysis.

Clinical measurements included retinoscopy, subjective refraction, monocular unaided distance acuity and aided distance visual acuity. Cycloplegic refraction was not used because cycloplegia might affect the training result of voluntary control of accommodation. A Kowa accommodation meter was used to measure the speed of positive and negative accommodation to determine whether training induced improvement in the flexibility of accommodation, with an increase in the positive and negative accommodation reaction times. LogMAR chart was used in the visual acuity measurement. A Storz biometer of model name Omega was used to measure the change in axial length to find out whether change in myopia or visual acuity was related to the change in axial length. The axial length measurement for the A-scan mode of the Omega was found to be reliable and repeatable to ±0.25D [30].

Paired two-sided t-test was used to test the significance of the difference between any two of the five examinations in each group. The Analysis of Variance (ANOVA), which could take into account "within" group variation as well as "between" group variation, was used to assess the significance of difference in improvement between the treatment and control groups in refractive error and unaided visual acuity.

The two training devices used in this study were the Optolax II and the Visomed.

Subjects in the two treatment groups were given the same amount of training as in the Bronskill et al. study: 5 minutes for each eye (i.e. 10 minutes total) every day for 14 consecutive days.

The design of the Optolax II is shown in Figure 1. The eye in it views a slide, the target, which moves linearly in the system by means of a motor. The motor drives the slide rhythmically to and away from the eye in cycles of 12 seconds each. The range of the displacement of the target is set to produce an accommodation range from 0D to 10D for an emmetropic eye. A myope without their -2.00D correction has to accommodate between the range of 0D to 8D during training. Lenses L1 and L2 are achromatic, with focal lengths (f) 100mm. As the target moves, both the change in image size or the size cue, and the blur of the retinal image or defocus blur, serve as cues for correct accommodation.

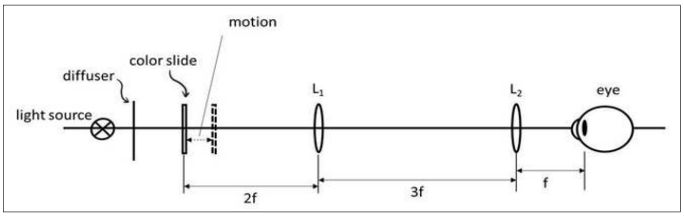

Figure 1: The Optics of Optolax II

The design of the Visomed is shown in Figure 2. The Visomed has a motor which drives the target slide towards and away from the eye. The range of accommodation it can exercise is 0D to 10D for an emmetrope. The time for one full cycle is approximately 22 seconds, which is longer than that of the Optolax II. The Visomed has a simpler optics design using the Badal lens system. This has the feature in which the retinal image does not change in size as the light from the object becomes more divergent when it approaches the eye. In this system, correct accommodation must be based entirely on the blur of the retinal image. The cue of increasing retinal image size which is observed in the Optolax II and natural situation is not available.

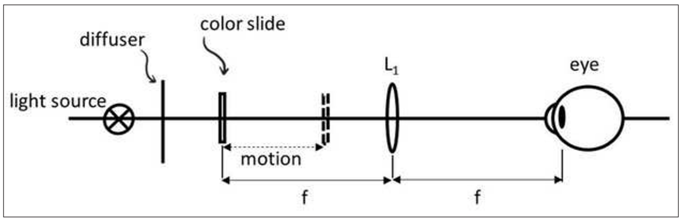

Figure 2: The Optics of Visomed

During their training with the Optolax II or the Visomed, each subject was asked to view an illuminated slide monocularly without refractive correction and to try to maintain clarity of the picture in the slide as it moved in the system. The other eye was occluded with an occluder. To ensure a subject was fixating on the moving slide throughout each training session, different slides with countable features such as buildings were used in each of the 14 days of training. The subjects were asked to count the number of windows in a building, the number of lights on a street, etc., that they could see in the slide.

Results

6 subjects dropped out before the post-training examination. Only 38 subjects successfully completed the pre-training and post-training examinations. 13 were in the group trained with the Visomed, 12 were in the group trained with the Optolax II, and 13 in the control group. One subject dropped out from the Visomed group after the first follow-up examination. A total of 37 subjects (12 in each of the training groups and 13 in the control group) remained until the final follow-up examination. Results from 36 subjects, 6 males and 6 females from each of the 3 groups, are considered in the analysis after the last female subject enrolled into the control group has been excluded.

The age range of the subjects was 6 to 12. The mean age of the subjects in the group trained with the Visomed was 9.0, 8.9 in the group trained with the Optolax II, and 8.9 in the control group. The initial mean amount of myopia in the group trained with the Visomed, the group trained with the Optolax II and the control group was 2.04D, 1.85D, 1.79D in the right eye and 2.04D, 1.89D, 1.88D in the left eye respectively. The difference between the maximum (2.04D) and minimum (1.79D) mean myopia was 0.25D.

The four parameters under investigation in the experiment were accommodative facility, change in refractive error, unaided visual acuity and axial length.

Accommodative Facility

F value and t value results after training showed that positive and negative accommodative facility were equally variable and had approximately the same mean result between the right eye and left eye in all groups. This was an indication of the consensuality between the right and left eye's accommodative facility.

A paired t-test was conducted to test the level of significance of improvement in positive and negative accommodative facility between the pre-training and post-training examinations in all three groups (Table 1). The degree of improvement in the two treatment groups' positive and negative accommodative facilities immediately after the training period was not statistically significant.

Table 1: Difference in Positive and Negative Accommodative Facility Before and After Training and at Follow-Up Examinations

Legends

VSM: The Group Trained with Visomed **OII:** The Group Trained with Optolax II **Control:** The Control Group
Pre: Pre-Training Examination **Post:** Post-Training Examination **R1:** First Follow-Up Examination **R2:** Second Follow-Up Examination **R3:** Third Follow-Up Examination **RE:** Right Eye **LE:** Left Eye **X:** Mean **SD:** Standard Deviation **P:** t-test Probability

Note

- Unit in mean is seconds per cycle
- Positive value indicates an increase in positive or negative accommodative facility
- Negative value indicates a decrease in positive or negative accommodative facility
- p values ≤0.05 are underlined

	Positive Accommodative Facility						Negative Accommodative Facility					
	RE			LE			RE			LE		
Pre vs Post	X	SD	P	X	SD	P	X	SD	P	X	SD	P
VSM	0.22	0.46	0.13	0.27	0.53	0.11	0.13	0.61	0.47	0.16	0.54	0.37
OII	0.17	0.28	0.06	0.14	0.27	0.10	0.04	0.29	0.62	0.06	0.32	0.54
Control	0.04	0.36	0.72	0.08	0.24	0.26	0.01	0.25	0.87	0.06	0.27	0.48
Post vs R1												
VSM	0.19	0.51	0.22	0.13	0.57	0.44	0.11	0.43	0.39	0.14	0.52	0.37
OII	-0.04	0.20	0.56	0.00	0.23	0.95	0.06	0.22	0.35	0.08	0.20	0.22
Control	0.08	0.41	0.51	0.13	0.36	0.25	0.05	0.47	0.72	0.11	0.31	0.24
R1 vs R2												
VSM	0.03	0.31	0.73	0.07	0.37	0.52	0.06	0.33	0.52	-0.03	0.31	0.77
OII	0.09	0.34	0.40	0.09	0.12	0.03	-0.02	0.29	0.83	-0.03	0.18	0.53
Control	0.13	0.20	0.05	0.16	0.21	0.03	0.16	0.29	0.07	0.08	0.15	0.10
R2 vs R3												
VSM	0.01	0.34	0.91	0.01	0.27	0.92	-0.14	0.26	0.10	-0.14	0.19	0.03
OII	-0.01	0.31	0.93	-0.05	0.32	0.57	0.01	0.41	0.91	0.03	0.43	0.81
Control	-0.01	0.11	0.77	-0.02	0.18	0.77	0.06	0.14	0.15	0.08	0.27	0.31
Pre vs R3												
VSM		0.95	0.12	0.48	0.93	0.10	0.17	0.57	0.32	0.13	0.57	0.44
OII		0.41	0.10	0.17	0.29	0.07	0.10	0.57	0.56	0.13	0.37	0.23
Control	0.24	0.24	0.01	0.35	0.26	0.00	0.29	0.39	0.03	0.33	0.38	0.01

Table 2: Difference in Subjective Equivalent Sphere Before and After Training and at Follow-Up Examinations

Legends

VSM: The Group Trained with Visomed **OII:** The Group Trained with Optolax II **Control:** The Control Group
Pre: Pre-Training Examination **Post:** Post-Training Examination **R1:** First Follow-Up Examination
R2: Second Follow-Up Examination **R3:** Third Follow-Up Examination **RE:** Right Eye **LE:** Left Eye
X = Mean **SD** = Standard Deviation **P** = t-test Probability

Note

- Unit in mean is dioptre
- Positive value indicates that myopia has decreased
- Negative value indicates that myopia has increased
- p values ≤0.05 are underlined

	Difference in Equivalent Sphere					
	RE			LE		
	X	SD	P	X	SD	P
Pre vs Post						
VSM	0.08	0.22	0.21	0.12	0.22	0.10
OII	0.08	0.18	0.15	0.09	0.21	0.15
Control	0.02	0.18	0.69	0.04	0.19	0.46
Post vs R1						
VSM	-0.21	0.26	0.02	-0.17	0.20	0.01
OII	-0.21	0.26	0.02	-0.23	0.27	0.01
Control	-0.23	0.19	0.00	-0.23	0.22	0.00
R1 vs R2						
VSM	-0.26	0.24	0.00	-0.23	0.21	0.00
OII	-0.19	0.16	0.00	-0.24	0.19	0.00
Control	-0.29	0.32	0.01	-0.25	0.21	0.00

R2 vs R3						
VSM	-0.18	0.21	0.01	-0.22	0.19	0.00
OII	-0.28	0.20	0.00	-0.20	0.15	0.00
Control	-0.26	0.21	0.00	-0.35	0.22	0.00
Pre vs R3						
VSM	-0.56	0.44	0.00	-0.50	0.43	0.00
OII	-0.60	0.35	0.00	-0.57	0.22	0.00
Control	-0.76	0.39	0.00	-0.79	0.46	0.00

All three groups showed some increase in positive and negative accommodative facilities from pre-training to the third follow-up examination. This was smallest in the group trained with the Optolax II, and higher in the group trained with the Visomed and the control group. The improvement, however, was statistically insignificant for the group trained with the Visomed. Both training devices were not effective in improving the accommodative facility of the test subjects.

Refractive Error

A two-sided t-test for objective and subjective refractions showed no significant differences in results between the two refraction methods. Thus, the refraction results were reliable, and either objective or subjective results could be used in the results analysis. Conventionally, the subjective refraction is a better indication of the final refractive error, and was used in the result analysis.

A decrease in myopia was found in all 3 groups at the post-training examination, with the greatest decrease in the group trained with the Visomed, followed by the group trained with the Optolax II, then the control group. The p values indicated that the decreases in myopia in the two treatment groups after two weeks of training were not statistically significant (Table 2). The ANOVA results showed that the relatively greater decrease in myopia in the treatment groups after two weeks of training was not statistically significant, and the training had not successfully reduced the subjects' myopia (Table 3-T3.1).

All 3 groups had an increase in myopia at the first follow-up examination, 3 months after the pre-training examination, and were more myopic at the first follow-up examination than at the pre-training examination. All three groups experienced very significant increases in myopia in each of the 3-month re-examination intervals, and myopia appeared to increase faster in the control group, which also had the greatest magnitude of myopia progression. ANOVA test was performed to test whether the above results were the effect of training which produced slower rates of myopia progression in the treatment groups, and found the rate of myopia progression in the control group was not significantly different from that of the two treatment groups over the 9-month period (Table 3-T3.2).

Table 3: Analysis of Variance Results. F value (F) and Probability (P) are Shown

Legends

VSM: The Group Trained with Visomed **OII:** The Group Trained with Optolax II **Control:** The Control Group **Pre:** Pre-Training Examination **Post:** Post-Training Examination **R3:** Third Follow-Up Examination **RE:** Right Eye **LE:** Left Eye

Table 3-T3.1: The Differences in Subjective Refraction between Pre and Post											
3 Groups (VSM, OII, Control)				**2 Groups (VSM, Control)**				**2 Groups (OII, Control)**			
RE (36 eyes)		LE (36 eyes)		RE (24 eyes)		LE (24 eyes)		RE (24 eyes)		LE (24 eyes)	
F	P	F	P	F	P	F	P	F	P	F	P
.411	.67	.398	.68	.607	.44	.754	.40	.685	.42	.417	.53

Remark. Between Pre and Post, there is no significant difference in subjective refraction changes among the 3 groups.

Table 3-T3.2: The Differences in Subjective Refraction between Pre and R3											
3 Groups (VSM, OII, Control)				**2 Groups (VSM, Control)**				**2 Groups (OII, Control)**			
RE (36 eyes)		LE (36 eyes)		RE (24 eyes)		LE (24 eyes)		RE (24 eyes)		LE (24 eyes)	
F	P	F	P	F	P	F	P	F	P	F	P
.870	.43	1.850	.17	1.379	.25	2.542	.13	1.179	.29	2.202	.15

Remark. Between Pre and R3, there is no significant difference in subjective refraction changes among the 3 groups.

Table 3-T3.3: The Differences in Unaided Visual Acuity between Pre and Post											
3 Groups (VSM, OII, Control)				2 Groups (VSM, Control)				2 Groups (OII, Control)			
RE (36 eyes)		LE (36 eyes)		RE (24 eyes)		LE (24 eyes)		RE (24 eyes)		LE (24 eyes)	
F	P	F	P	F	P	F	P	F	P	F	P
1.001	.38	1.214	.31	1.687	.21	2.395	.14	1.373	.25	1.196	.29

Remark. Between Pre and Post, there is no significant difference in unaided visual acuity changes among the 3 groups.

Table 3-T3.4: The Differences in Unaided Visual Acuity between Pre and R3											
3 Groups (VSM, OII, Control)				2 Groups (VSM, Control)				2 Groups (OII, Control)			
RE (36 eyes)		LE (36 eyes)		RE (24 eyes)		LE (24 eyes)		RE (24 eyes)		LE (24 eyes)	
F	P	F	P	F	P	F	P	F	P	F	P
2.987	.06	2.575	.09	4.552	.04	3.793	.06	1.422	.25	1.379	.25

Remark. Between Pre and R3, there is no significant difference in unaided visual acuity changes among the 3 groups.

Unaided Visual Acuity

All three groups' unaided visual acuities became better at the post-training examination after the two weeks of training. The improvement was significant in the two treatment groups, with p values being 0.05 and 0.03 in the right and left eye of the group treated with the Visomed, and 0.04 and 0.07 in the right and left eye of the group treated with the Optolax II (Table 4). ANOVA results showed that the difference in improvement of the three groups' unaided visual acuities before and after training were not statistically significant (Table 3-T3.3).

Over the 9-month period from pre-training examination to the third follow-up examination, there were very significant deteriorations in all the three groups' unaided visual acuities. ANOVA test results showed that the differences of the three groups' unaided visual acuities over the 9-month period were insignificant (Table 3-T3.4) and the smaller reduction in the treatment groups' unaided visual acuities did not appear to be the result of the training.

Table 4: Difference in Unaided Visual Acuity Before and After Training and at Follow-Up Examinations

Legends

VSM: The Group Trained with Visomed **OII:** The Group Trained with Optolax II **Control:** The Control Group
Pre: Pre-Training Examination **Post:** Post-Training Examination **R1:** First Follow-Up Examination
R2: Second Follow-Up Examination **R3:** Third Follow-Up Examination **RE:** Right Eye **LE:** Left Eye
X: Mean **SD:** Standard Deviation **P:** t-test Probability

Note

- Unit in mean is LogMAR scale
- Positive value indicates that unaided visual acuity has become better in the subsequent examination
- Negative value indicates that unaided visual acuity has become worse in the subsequent examination
- p values ≤0.05 are underlined

	Difference in Unaided Visual Acuity					
	RE			LE		
	X	SD	P	X	SD	P
Pre vs Post						
VSM	0.047	0.074	0.05	0.058	0.082	0.03
OII	0.040	0.061	0.04	0.043	0.075	0.07
Control	0.012	0.058	0.50	0.013	0.062	0.50
Post vs R1						
VSM	-0.035	0.102	0.26	-0.067	0.094	0.03
OII	-0.085	0.072	0.00	-0.087	0.095	0.01
Control	-0.132	0.103	0.00	-0.119	0.068	0.00
R1 vs R2						
VSM	-0.060	0.076	0.02	-0.052	0.143	0.24

OII	-0.057	0.045	0.00	-0.078	0.050	0.00
Control	-0.053	0.138	0.21	-0.059	0.141	0.18
R2 vs R3						
VSM	-0.047	0.089	0.10	-0.062	0.100	0.06
OII	-0.062	0.059	0.00	-0.050	0.050	0.01
Control	-0.067	0.071	0.01	-0.078	0.060	0.00
Pre vs R3						
VSM	-0.095	0.118	0.02	-0.122	0.085	0.00
OII	-0.163	0.089	0.00	-0.172	0.075	0.00
Control	-0.240	0.204	0.00	-0.244	0.200	0.00

Axial Length

The axial length changes in the first three months between the pre-training and post-training examinations, and between the post-training examination and the first follow-up examination, were not statistically significant in both the right eye and left eye of the three groups (Table 5). From the 4th to the 6th month and from the 7th to 9th month, there were increases in axial length for all groups. There were also highly significant axial length increases over the 9-month period from the pre-training examination to the third follow-up examination for all groups except the right eye of the group trained with the Visomed.

Average increase in axial length between the pre-training examination and the third follow-up examination was greatest in the control group, followed by the group trained with the Optolax II, and then the group trained with the Visomed. This order corresponded with the order of increase in their myopia (Table 2).

The increase in the 72 eyes' axial lengths over the 9-month period was found to have a strong positive correlation with their increase in myopia (Table 6).

Table 5: Difference in Axial Length Before and After Training and at Follow-Up Examinations

Legends

VSM: The Group Trained with Visomed **OII:** The Group Trained with Optolax II **Control:** The Control Group
Pre: Pre-Training Examination **Post:** Post-Training Examination **R1:** First Follow-Up Examination
R2: Second Follow-Up Examination **R3:** Third Follow-Up Examination **RE:** Right Eye **LE:** Left Eye **X:** Mean
SD: Standard Deviation **P:** t-test Probability

Note

- Unit in mean is mm
- Positive value indicates that axial length has decreased
- Negative value indicates that axial length has increased
- p values ≤0.05 are underlined

	Difference in Axial Length					
	RE			LE		
	X	SD	P	X	SD	P
Pre vs Post						
VSM	-0.01	0.39	0.91	-0.02	0.26	0.81
OII	-0.01	0.15	0.92	-0.01	0.11	0.84
Control	-0.06	0.19	0.33	-0.07	0.31	0.47
Post vs R1						
VSM	0.09	0.37	0.41	0.01	0.20	0.81
OII	0.05	0.11	0.11	0.06	0.24	0.39
Control	-0.06	0.17	0.30	0.11	0.24	0.14
R1 vs R2						
VSM	-0.17	0.18	0.01	-0.10	0.17	0.09
OII	-0.22	0.16	0.00	-0.16	0.22	0.03
Control	-0.10	0.31	0.30	-0.13	0.25	0.09
R2 vs R3						
VSM	-0.08	0.13	0.06	-0.11	0.11	0.01

OII	-0.05	0.11	0.13	-0.16	0.31	0.10
Control	-0.09	0.38	0.42	-0.11	0.15	0.02
Pre vs R3						
VSM	-0.18	0.36	0.12	-0.21	0.19	0.00
OII	-0.22	0.21	0.00	-0.26	0.28	0.01
Control	-0.30	0.23	0.00	-0.20	0.26	0.02

Table 6: Difference in Axial Length and Myopia from Pre-Training Examination to the Third Follow-Up Examination

Legends
VSM: The Group Trained with Visomed **OII:** The Group Trained with Optolax II **Control:** The Control Group
Pre: Pre-Training Examination **R3:** Third Follow-Up Examination **RE:** Right Eye **LE:** Left Eye

Table 6.1: Difference in Axial Length and Myopia				
		VSM	**OII**	**Control**
RE	Axial Length Changes	-0.18mm	-0.22mm	-0.30mm
	Myopia Changes	-0.56D	-0.60D	-0.76D
LE	Axial Length Changes	-0.21mm	-0.26mm	-0.20mm
	Myopia Changes	-0.50D	-0.57D	-0.79D

Table 6.2: Correlation Coefficient Values between Increase in Axial Length and Myopia from Pre to R3				
		VSM	**OII**	**Control**
	VSM (24 eyes)	OII (24 eyes)	Control (24 eyes)	All 3 Groups (72 eyes)
C. Coeff. (r)	0.597*	0.045	0.384	0.391*
	Myopia Changes	-0.50D	-0.57D	-0.79D
1-tailed significance. * P<.01				

Discussion

All three groups showed some increase in their accommodative facility from the pre-training examination to the third follow-up examination. However, these improvements were not statistically significant in the treatment groups, which indicated that it was likely to be a practice effect and the training had not produced any immediate and significant improvement in the test subjects' accommodative facility. Since there was no significant difference in the improvement of accommodative facility between the two treatment groups, providing the correct size cue during accommodation training did not result in a better training result and faster accommodation speed.

When the total change in refraction between the first and last examinations of the three groups were subjected to ANOVA test, no significant difference was found between the treatment and the control groups, which means that the training did not significantly retard the speed of myopia progression.

When the difference between the treatment and control groups' improvement in unaided visual acuity was subjected to ANOVA tests, the difference was no longer statistically significant. The training, according to the ANOVA results, has not produced a statistically significant improvement in the treatment groups' unaided visual acuity. A possible explanation for better unaided visual acuity in the treatment groups at post-training examination was the lack of placebo for the controls during the training period, with the result of expectation of improvement effect only in the treated subjects to promote a better score in unaided visual acuity.

The reduction of myopia and improvement in unaided visual acuity found in the treatment group of this study was not as significant as that reported by Bronskill et al. in their pilot study of treating myopia with the Optolax II, even though the amount of training received by subjects in both studies was the same. The difference could possibly be due to:

- The subjects in the Bronskill et al. study were asked to wear their glasses as little as possible and to avoid long periods of close work. All the subjects in this study continued to use glasses in their usual manner. No glasses and reduction of close work were behavioral techniques used to develop better interpretation of blur ability and to reduce accommodative demand and lag to slow the speed of myopia progression.
- Bronskill et al. had included some subjects up to 18 years of age who had passed their childhood myopia progression phase and were experiencing a time of relatively stable refraction in their young adulthood. Reversible transient myopia that might subside after training was more likely to develop in these young adults' eyes, which had a relatively rigid sclera and posterior pole than a child's eyes.

Koslowe et al. conducted a double-masked myopia treatment experiment, with one experimental and one control group, using the biofeedback training method and the Accommotrac Vision Trainer invented by Trachtman [26]. Koslowe et al. closely followed the training procedure prescribed by Trachtman and administrated by the agent of Accommotrac Vision Trainer, and found no significant difference between the treatment and control groups in their visual acuity, cycloplegic and noncycloplegic retinoscopy, subjective refraction, amplitude of accommodation, and flexibility of accommodation after the training. The results reported by Koslowe et al. and the present study suggest the possibility that number of myopes with myopia and accommodation functions that can be significantly improved by training probably constitute a minor fraction of the myopia population, and there might be more myopes with reversible myopia of an accommodative nature in the earlier studies by Bronskill et al. and Trachtman [31]. In his response to the treatment result of using Accommotrac Vision Trainer in Koslowe's study, suggested that Koslowe et al. had not included subjects with significant accommodative components to their myopia [32, 33].

Factors such as outdoor exposure under daylight and the intensity and frequency of breaks during near work are known to influence myopia progression [34,35]. Such should be taken into consideration in the future experimental designs of similar clinical trials which span over weeks or months, with these essential daily living activities being unavoidable.

Conclusion

The two accommodation training devices of different optical design did not significantly increase the accommodative facility, improve unaided visual acuity, and reduce myopia progression of the test subjects in this study, suggesting that the myopia and related accommodative function of the myopic primary school children are unlikely to be reversible or improved by two weeks of training with the devices.

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The study adhered to the tenets of the Declaration of Helsinki. Parents of the children were given written information of the study content and procedures, supplemented by verbal explanation. Signed consent forms were obtained from the parents before the participation of their children in the clinical examination and treatment.

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