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The Computer Interface Device: Effects of Audio and Visual Biofeedback in Rehabilitation

Cassie Wulfekuhle

University of North Dakota

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THE COMPUTER INTERFACE DEVICE: EFFECTS OF AUDIO AND VISUAL BIOFEEDBACK IN REHABILITATION

by

Cassie Wulfekuhle
Bachelor of Science in Physical Therapy
University of North Dakota, 1999

An Independent Study
Submitted to the Graduate Faculty of the
Department of Physical Therapy
School of Medicine
University of North Dakota
in partial fulfillment of the requirements
for the degree of
Master of Physical Therapy

Grand Forks, North Dakota
May
2000
This Independent Study, submitted by Cassie R. Wulfekuhle is partial fulfillment of the requirements for the Degree of Master of Physical Therapy from the University of North Dakota, has been read by the Faculty Preceptor, Advisor, and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

(Faculty Preceptor)

(Graduate School Advisor)

(Chairperson, Physical Therapy)
## PERMISSION

<table>
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Signature [Signature]

Date 11-17-99

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ACKNOWLEDGEMENTS

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ABSTRACT

The purpose of this study was to see if a computer interface device was effective in improving quality of elbow joint motion in children by increasing motivation and attention span through the use of audio and visual biofeedback. Seventeen subjects between the ages of five and twelve were asked to participate in this study. The children were asked to complete ten repetitions of elbow flexion and extension while the tester manipulated the type of biofeedback given (1. audio and visual on, 2. audio on and visual off, 3. audio off and visual on, and 4. audio and visual off). These manipulations were features that the computer interface device provided and consisted of audio and visual biofeedback. After the children completed ten repetitions for each of the four conditions, a total quality score was calculated. A repeated measures analysis of variance was completed along with LSD Post Hoc comparison. Results showed that there was a significant difference in quality scores when biofeedback was provided as compared to when biofeedback was absent. The higher quality scores with biofeedback given may indicate that the computer interface device is an effective way to improve the quality of movement during rehabilitation with children.
CHAPTER I

INTRODUCTION

Have you ever found yourself frustrated with children in a rehabilitation setting due to lack of attention and cooperation? Often children associate rehabilitation with unwanted pain and boredom, creating negative reinforcement. The goal for us, as physical therapists, is to create an environment that is exciting for kids and which encourages them to enjoy exercise and to work towards a successful treatment session.

The computer interface device was constructed in hopes of providing positive biofeedback by incorporating audio and visual biofeedback into a rehabilitation activity. Discussed will be the purpose of biofeedback, augmented computer biofeedback, benefits of biofeedback, limitations of biofeedback, and the uses of audio and visual biofeedback in therapy.

As stated above, the computer interface device was designed in hopes of making exercise sessions more effective through the use of audio and visual biofeedback. A great deal of literature reports on the use of biofeedback in rehabilitation. Biofeedback has been used for head position training,1 gait training,2, 3 and other motor control issues in children who have cerebral palsy.4 In general, results from these studies indicate that biofeedback is an effective measure of treatment. A device such as a computer not only provides motivational feedback, but it can also collect objective data on patient performance.

This study is a pilot study and focuses on the effectiveness of the audio and visual biofeedback features of the computer interface device on normal subjects. Future studies should be done focusing on children with disabilities. The computer interface device also
has the feature of a joystick device that allows children to play video games as a reward for qualitative exercise therapy. This feature incorporates play therapy into rehabilitation and will be studied in the future.

**PROBLEM STATEMENT:** Because children have short attention spans, a clinical tool is needed to encourage motivation and compliance during an exercise session.

**PURPOSE OF STUDY:** The purpose of this study is to see if the computer interface device is effective in improving quality of elbow joint motion in children by increasing motivation and attention span through the use of audio and visual biofeedback.

**SIGNIFICANCE OF STUDY:** The results of this study may give clinicians an effective way to motivate and capture the attention of children so that time spent in an exercise session is more effective in attaining rehabilitation goals and compliance.

**RESEARCH QUESTIONS:**

1. Is using biofeedback more effective in obtaining qualitative results of exercise in children?
2. Is audio or visual biofeedback more effective?
3. Are children more motivated to participate during an exercise session with the use of audio/visual biofeedback?

**NULL HYPOTHESIS:** The computer interface device and the audio and visual biofeedback it provides will not improve attention, motivation, and compliance during an exercise program, as shown by decreased quality scores.

**ALTERNATE HYPOTHESIS:** The computer interface device and the audio and visual biofeedback it provides will improve attention, motivation, and compliance during an exercise program, as shown by increased quality scores.
CHAPTER II
REVIEW OF LITERATURE

PURPOSE OF BIOFEEDBACK. Biofeedback is defined as a technique using equipment (usually electronic) to reveal to human beings some of their internal physiological events, normal and abnormal, in the form of audio and visual signals. This allows them to manipulate unwanted or unfelt events through the displayed signals. Biofeedback training gives the patient the opportunity to do something for himself rather than being the passive recipient of a therapeutic procedure. Because human beings are goal orientated, they want to voluntarily improve performance to meet desired goals.

Biofeedback is useful because there is immediate reinforcement for the desired response. One of the advantages of biofeedback is that it allows small changes in the correct direction to be noticed and rewarded as success. These small changes gradually build up into larger changes. Eventually, patients learn to practice on their own without the instrument. This is especially effective with patients who may have the wrong perception as to what they are doing or with patients who can not perceive their initial small correct responses. Other advantages of the use of biofeedback is that it can encourage and motivate patients, relieve their sense of helplessness, and serve as a coping response to reducing symptoms of stress. Again, instead of just receiving treatment, the process aids in teaching the patient to be independent and active in the rehabilitation process. This process increases confidence and self-efficiency.

AUGMENTED COMPUTER BIOFEEDBACK. Augmented feedback is information provided from an external source, which is additional to the perception of the patients. This augmented feedback can be verbal or non-verbal, and can be provided while patients
are exercising, immediately following, or much later than the action. Biofeedback is a form of augmented feedback in which electrical instruments are used to amplify physical parameters, which are then fed back to patients.

Since augmented feedback is information provided from an external source, the computer would be considered a source to provide augmented feedback. Over the past years computers have become a common household item and are used in many physical therapy departments for visual and audio feedback. Studies show that manipulating the frequency of feedback and the time-delay between the action and the feedback is effective in improving patients learning and performance.

**BENEFITS OF BIOFEEDBACK.** The potential benefits of computer augmented feedback are precision, immediacy, and frequency. Computer software also gives the possibility of more interesting feedback (than the simple tones or lights that are often used) which could motivate practice. When the computer gives feedback to patients on the results of these measures, performance, motivation, and treatment effects may be enhanced.

Immediate and frequent feedback can be given by biofeedback aids without the use of computers. However, with children, the simple lights and noises used for feedback have only limited appeal and do not motivate children enough to practice for long periods of time. Since many people play computer games for long periods of time without any outside pressure of rewards, the joystick and controls of computer games could be converted to detect body movements and be used as powerful and motivating therapeutic aids. Since this is a pilot study, the application of a computer game as motivational enhancement is beyond the scope of this study.

**LIMITATIONS OF BIOFEEDBACK.** Although the benefits of computer feedback devices outweigh the limitations, there are still limitations to consider when incorporating the computer as a means of feedback into a rehabilitation setting. One of the most
important limitations is that children will try hard to achieve the highest level of what is being asked of them, and therefore, tend to use parts of their bodies and movement patterns that have the best coordination. Another limitation is that the equipment can be inflexible, costly, and may also malfunction. Most equipment is not readily portable, and the information has limited and specific applications, whereas human therapists who can give feedback on a range of aspects and on a variety of movements.

The main purposes of these computer aided devices are to enable physical therapists to incorporate computer-based assessment and practice in movement therapy with more flexibility and ease, and to have new ways to give patients immediate, precise, and interesting feedback on their movements during practice sessions. It is also important for physical therapists to fully understand computer devices being used and to develop optimum ways of using the equipment in the course of therapy. Augmented computer biofeedback has already been incorporated into rehabilitation, especially in children with cerebral palsy. A device such as a computer not only provides motivational feedback but can also collect objective data on patient performance.

USES OF AUDIO AND VISUAL BIOFEEDBACK IN THERAPY. Mackey investigated the use of computer-assisted feedback in a motor control task for children with cerebral palsy. Subjects were asked to push down with both arms onto a switchbox to activate the computer device. The feedback used in this study consisted of a visual target display, auditory tones, and a cassette player that was activated when subjects held the visual display on target. The children were tested in two phases. In phase A, the therapist gave verbal feedback to the subjects when accurate information was achieved. During phase B, in addition to the verbal feedback, subjects also received computer feedback. The results of this study indicated that computer-assisted feedback improved performance significantly (one-way analysis of variance test, p < 0.01) in all subjects and that it could be a useful adjunct to therapy.
Hartveld and Hegarty performed four single-cased experiments with children who have cerebral palsy (with only the legs affected). The purpose of this study was to examine the relationship between weight shift practice with feedback from a computer and standing balance. It was hypothesized that frequent weight shift practice with feedback from a computer would improve standing balance in children with cerebral palsy. Standing balance was tested twice weekly throughout the baseline and the treatment period. Graphic analysis of the data showed that there was an improving trend in the treatment period in comparison to the static trend of the baseline period. It was concluded that weight shift practice on the computer exercise board (Compex) was effective in bringing about an improvement in standing balance in some children with cerebral palsy in certain circumstances.

Two common forms of biofeedback, audio and visual may be used separately or together in a clinical setting. In the past 10 years, sensory feedback has been reported to be an effective way to treat impaired or delayed head control in adults and children with cerebral palsy. Studies have been done using both audio and visual biofeedback as well as separating the audio and visual biofeedback.

Malouin et al studied the effects of auditory feedback on head position training in young children with cerebral palsy. The purpose of this study was to compare the effects (short and long-term) of head position training with and without auditory feedback. Six children were divided into two groups. Two four week sessions of treatment were completed by the six children. Group 1 received the audio feedback (buzzer) during the second 4-week session of the study. The children in group 2 received the audio feedback in the first 4-week training session. The length of time children were able to hold their head at a pre-set angle (time in zone) was used to describe their performance and was measured during the study and up to one year following the study. The results of this study indicated stimuli other than auditory (but related to the group setting and the helmet
used) might be in part responsible for improved performance of children during head position training with auditory feedback. The authors stated that too much dependency on auditory feedback might interfere with carry-over effects and the generalization process. It was also noted that auditory feedback was more effective than non-auditory feedback, but head control could be improved during the non-auditory phase because of the stimuli related to the setting and helmet.

Flodmark assessed the usefulness of electronic biofeedback in gait training of children with cerebral palsy. Seven children were selected for the study with different types of cerebral palsy. A joint-position angle sensor was placed on the legs (knees) of the children as they trained with and without feedback. Auditory feedback was used during the training by a tone if the children exceeded the preset angle (negative feedback) or if the joint remained within the preset range of motion (positive feedback). Results showed that children with cerebral palsy who also displayed motor handicaps rapidly achieved good results and were able to walk with improved gait patterns. Children with additional difficulties such as short-attention span and athetoid movements did not do as well. Flodmark felt that the children’s intellectual capacity is also important in how the children respond and performs to the biofeedback.

Many studies have been done using computers as a source of augmented biofeedback. In general, there have been positive results with the use of audio and visual biofeedback, but one researchers feels that not all credit on performance improvements can be given to augmented biofeedback features alone. Some of the improvements may depend on intellectual level, severity of disorder, and other environmental factors. While limitations such as equipment inflexibility, cost, malfunctions, and the mis-use of computer feedback devices are present, the advantages still out weigh these potentials. Important advantages like precision, immediacy, frequency, and active participation in rehabilitation may be the keys for therapist to motivate patients, especially children.
CHAPTER III

MATERIALS AND METHODS

MATERIALS. The materials utilized in this study consist of a 4" long flexible strain gauge (Abrams gentile entertainment/patent #5,086,785) used as the angle and speed sensor, self-adhering tape, the computer interface device itself (constructed by North Dakota State University Electrical Engineering students), and a personal computer (PC) (Figure 1). Since this is a study on a new device, there is currently no literature on the reliability and validity of the computer interface device.

![Figure 1. Materials utilized in study.](image)

RESEARCH DESIGN. The computer interface device is an electronic device designed to allow the operator to provide both audio and visual feedback for a patient doing repetitive exercise. The sensor used was a 4" long flexible strain gauge that was
taped to the joint being exercised. This sensor is plugged into the side of the case, which then provides feedback for the range of motion of the joint, speed of the motion, and quality of the exercise (Figure 2).

![Diagram of computer interface device]

**Figure 2.** Layout for the computer interface device.

Visual biofeedback, in the form of light emitting diode's (LED), showed the range of motion between the two endpoints (set by the physical therapist). The auditory biofeedback for the range of motion was a chirp (internal piezo buzzer) that sounded when the children reached each endpoint. Visually for the speed, LED's displayed if the children were moving too fast or too slow. The auditory biofeedback for the speed of motion was also a chirp that sounded at the desired rate (similar to a metronome).

The quality of the exercises is shown from LED's. With this device, if all LED lights are displayed, it means "good" quality, while no lights displayed means "poor" quality. "Good" is defined as the child moves through the specified range of motion (i.e. moving beyond the targeted range of motion is penalized), and at the desired rate (i.e. moving too fast or too slow is penalized).
All audio and visual feedback was turned on or off by the following commands displayed on the computer interface device itself (LCD display). The serial port from this device is plugged into a serial port on a PC. The PC displayed the data on the screen as shown in Table 1.

<table>
<thead>
<tr>
<th>a</th>
<th>b</th>
<th>c</th>
<th>d</th>
<th>e</th>
<th>f</th>
<th>g</th>
<th>h*</th>
<th>i</th>
<th>j</th>
<th>k</th>
<th>l</th>
<th>m</th>
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<td>0</td>
<td>30</td>
<td>7</td>
<td>80</td>
<td>0.48</td>
<td>1</td>
<td>875</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>0.98</td>
<td>0</td>
<td>30</td>
<td>9</td>
<td>80</td>
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<td>80</td>
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<td>1</td>
<td>825</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
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<tr>
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<td>0</td>
<td>30</td>
<td>7</td>
<td>80</td>
<td>0.48</td>
<td>1</td>
<td>755</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

* Indicates column used to calculate a mean quality score of elbow movement.

The columns correspond to:

a) Time in seconds
b) The number of repetitions completed
c) The minimum angle to be traversed
d) The current angle
e) The maximum angle to be traversed
f) The time of the last half of a repetition
g) The desired time for half of a repetition
h) The quality score (from 0 to 1,000, 1,000 being best)
i) Angle LED's on (1) or off (0)
j) Angle buzzer on (1) or off (0)
k) Speed LED's on (1) or off (0)
l) Speed buzzer on (1) or off (0)
m) Quality LED's on (1) or off (0)

Data was saved for analysis by running a serial data collection program - HyperTerminal. This was located in Windows under the Start-Programs-Accessories-HyperTerminal. Once in the HyperTerminal, the terminal was set up as:
-Com Port 2
-9600 baud
-8 data bits
-Parity: None
-Stop Bits: 1
-Flow Control: Hardware

Transfer Capture Text was clicked on to save the data coming in.

**SUBJECTS.** Subjects from the community between the ages of 5 and 12 were asked to participate in this study. Participation was on a voluntary basis, but all children received a treat and/or toy for their time. The examiner, a student physical therapist, visually screened all children to see if they had full upper extremity range of motion and if they were able to fully understand verbal instructions. All participating children had no history of upper extremity orthopedic problems and were able to follow verbal commands. All subjects/parents signed informed consent forms prior to participation in this study. All children over the age of nine signed an assent form prior to participation in this study.

**PROCEDURE.** Following visual inspection, the children were asked their age and gender. This information was recorded under their given subject number. The children were asked to sit in a chair while the flexible strain gauge was attached to the posterior side of their arm (olecranon process). The center of the strain gauge was aligned with the center of the olecranon process. The strain gauge was secured to the arm with self-adhesive tape.

The children were asked to bend their elbow to ensure comfort and functional elbow range of motion. Both audio and visual biofeedback options were initially turned on. During the children’s three-minute trial period, each audio and visual display along
with the goals of each testing condition were explained to the children until they understood what was being asked of them.

Next, the following settings were set and remained the same for all four test conditions: 1) elbow range of motion set points, 2) the speed for one half of repetition was set for one second, and 3) thirty seconds was given for the children to complete ten repetitions of elbow flexion and extension. Once all the initial data was entered, the children began the four testing conditions in the following order. This order remained the same for all children allowing for a one-minute rest period between each test condition. The following describes the four test conditions and what type of biofeedback was given to the children in each test condition.

1. Audio and visual biofeedback ON for both range of motion and speed.
2. Audio biofeedback ON, and visual biofeedback OFF for range of motion and speed.
3. Audio biofeedback OFF, and visual biofeedback ON for range of motion and speed.
4. Audio and visual biofeedback OFF for both range of motion and speed.

When the four tests were completed, the children’s involvement was finished and they were allowed to choose a treat or toy.

DATA ANALYSIS. The data from the children were saved on a disk that was kept in a secure place that only the investigator had access to. The mean quality score for each test condition, gender, and age were recorded on the data collection form. (Appendix D) The quality score, as stated under research design, refers to the combined effort of children reaching the range of motion set points and maintaining the preset speed of motion. The results of each individual tests were compiled and analyzed statistically using a two-tailed repeated measures analysis of variance. The software program used to run the statistical analysis was SPSS 8.0 for windows.
CHAPTER IV

RESULTS

Data were obtained from 17 children (11 females, 6 males) ranging from 5 to 12 years of age (mean age = 8.24, S.D. = 2.16). The dependent variable in this study was the quality score obtained from the children's response to the four combinations of biofeedback manipulations as stated in the methods section. The quality scores were recorded in data sets. Complete data sets were collected for all 17 subjects (Table 2). This table also includes the subject’s age, the subject’s gender and the four test conditions that were given to the children during the study. Repeated measures analysis of variance was performed to see if using biofeedback was more effective in obtaining qualitative results in exercise with children and if audio or visual biofeedback is more effective according to the observed quality scores (Table 3). Table 3 consists of the analysis of variance data for individual subjects and also the total means and standard deviations for all subjects who participated in this study. Post Hoc test (LSD) was used to perform multiple comparisons of the four test conditions (Table 4). The alpha level was set a .05 level of confidence.

The above information is on the following pages, 14-16, in table format. A detailed discussion and importance of these tables are addressed in Chapter V (Discussion).
Table 2. Complete data sets for all subjects displaying the mean quality score for each of the four test condition, age, and gender.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Age</th>
<th>Gender</th>
<th>Test 1 (audio and visual on)</th>
<th>Test 2 (audio on &amp; visual off)</th>
<th>Test 3 (audio off &amp; visual on)</th>
<th>Test 4 (audio and visual off)</th>
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<td>1</td>
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<td>Female</td>
<td>755.32*</td>
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*Possible quality scores can range from 0-1000 (0 being no quality and 1000 being the best quality possible)
Table 3. Summary of analysis of variance for all subjects.

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Table 4. Post Hoc (LSD) Multiple Comparisons Based on Observed Means

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*Significant difference, p< .05 level.
** The conditions relate to the corresponding numbers throughout the chart.
CHAPTER V

DISCUSSION

The results of this study indicate that there is a significant difference (p< .05) in quality scores when biofeedback is given as compared to no biofeedback given. Specifically in comparing test four (no audio or visual biofeedback present) to test one (audio and visual biofeedback on), test two (audio on and visual biofeedback off), and test three (audio off and visual biofeedback on), there is a significant difference in quality scores: .001, .023, and .000 respectively (Table 5). These results indicate that the computer interface device is effective in improving quality of movement through the use of the audio and visual biofeedback. Mackey’s study on motor control tasks for children with cerebral palsy and Hartveld and Hegarty’s study on weight shift and balance on children with cerebral palsy indicated the results improved performance significantly and could be a useful adjunct to rehabilitation. Both studies agree with the findings in this study.

<table>
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Results also show that the type of biofeedback given (audio, visual, or both) did not significantly affect the quality scores. In this study the mean scores were higher for
visual biofeedback (mean = 648.05) as compared to audio biofeedback (mean = 595.35); however, the difference was not significant (p = .09).

Kellis and Baltzopoulos had conflicting thoughts and felt that one of the main factors affecting accuracy of isokinetic parameters during maximum activation efforts is visual biofeedback alone. The purpose of their study was to examine the effects of visual feedback on maximum moment measurements of the knee extensors and flexors during isokinetic eccentric activations. Twenty-five subjects performed maximal efforts at angular velocities of 30 degrees/second with and without visual feedback on a Biodex dynamometer. Their findings suggested that visual feedback can improve maximum eccentric output and should be provided during assessment of maximum eccentric strength on an isokinetic dynamometer.

The combined effort of audio and visual biofeedback with the computer interface device showed to be helpful in improving the children’s quality scores during an exercise session. Olney, Colborne and Martin completed a similar study combining computer assisted visual and auditory feedback in gait treatment of a patient with stroke secondary to hemiplegia. They also found that combining audio and visual biofeedback was helpful in achieving positive results with treatment. The computer hardware and software permitted immediate visual feedback of performance relative to the desired target with auditory reinforcement if the target was reached. The objective of the treatment in this study was to increase knee flexion during push-off and pull-off. After four weekly treatments, results showed an increase in gait velocity, stride lengths, energy conservation, and knee flexion.

One of the purposes of biofeedback is to motivate younger patients by using the feedback to provide a desirable response. The computer interface device did show promise in this respect as evident by the higher quality scores when given the various forms of biofeedback. By having biofeedback present in this study, the children were
allowed to actively participate in their own exercise session. The immediate feedback that they received for their efforts allowed the children to make changes, in speed of motion or in reaching the pre-set range of motion set points, in a positive direction. The key with the quality display on the device, monitored by the physical therapist, is to make sure the children are not making any substitutions for movement.

**LIMITATIONS.** As with any study, there are limitations present. Although all children were allowed a three minute trial period with the device prior to being tested, additional time and practice should have been allowed in order to familiarize themselves with the device and the audio and visual biofeedback features. It was noted that the limited time of practice hindered the quality scores. As with any other activity, practice aids in improving performance abilities. Another limitation was the placement of the strain gauge. Although careful attention was paid to the application and placement on the olecranon process, it was not possible to test the exact range of motion for all children. The use of a goniometer after placement of the strain gauge would have allowed for more consistently in the specified range of motion. Although this was not the main focus of the study, it would have allowed for greater consistency between children. Lastly, without manual stabilization by the investigator, the taping technique of the strain gauge on the posterior elbow was not sufficient enough to hold the strain gauge in place throughout all ten repetitions of elbow flexion and extension. Bulging of the strain gauge occurred over the olecranon process causing the children to have difficulty in reaching the pre-set range of motion limits. This limitation was eliminated with manual stabilization over the olecranon process.

**FUTURE STUDIES.** There is promise for utilizing this device in a clinical setting, but since this is a pilot study, there is still a need for future studies utilizing the computer interface device. This study focused more on the efficacy of the computer interface device, the biofeedback features it provides, and if those features can provide qualitative
data on children without any form of upper extremity disabilities or any other limiting factors. Future studies are needed to focus on the efficacy of this device on children with disabilities. Another feature of the computer interface device that was not tested was the use of a joystick and computer games. With incorporation of these devices, the children would be/could be given the opportunity to “build up energy” to operate a computer game by achieving “good” quality of movement. In return, the children could play computer games with the energy that they have accumulated. This aspect would focus more on incorporating play therapy into rehabilitation as a means of motivation.
CHAPTER VI

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS. The biofeedback technique is based on the fundamental learning principle that we learn to perform a particular response when we receive feedback or information about the consequences of that response and then make the appropriate compensatory behavioral adjustments. Literature supports the use of audio and visual biofeedback, in one form or another, as an effective way to increase the quality of rehabilitation. The way in which this biofeedback is presented is the key to motivating patients, especially children. The computer interface device takes a simple concept and creates an environment that would encourage the children to want to improve the quality of their movements. Results of this study indicate that the computer interface device was associated with increased performance, thereby achieving this goal.

However, in order to be successful, it is important to limit as many confounding variables as possible that may impact the results. For example, making sure that the atmosphere is optimal for learning, especially with children who have a decreased intellectual capacity and short attention spans. It may also be important to make sure that other sources of biofeedback do not interfere with what is being tested. For example, Malouin felt that the helmet used in his study on children who had CP was in part responsible for improvement in performance. Lastly, it is important not to let the children always depend on biofeedback as generalization may occur. Biofeedback should be used to let the children make changes in the correct direction, but more importantly, to encourage carryover and correction changes when biofeedback sources are removed.
CLINICAL IMPLICATIONS. By using this device in a clinical setting, the children are allowed to respond to the biofeedback presented, as well as being encouraged to make the appropriate corrections. This makes the children active participants in their own treatment sessions. The computer interface device is also small enough for the patients to take home and use on their own PC; however, this would not be done until the patients and guardians are proficient and comfortable with the use and purpose of the device.

Because physical therapists can not possibly watch and correct all aspects of movement, this device assists with treatment sessions allowing for more qualitative gains. These gains are in part responsible because of the immediate and precise feedback that the computer interface device provides. Due to the limited number of visits that health care is allowing, the computer interface device becomes a nice adjunct to physical therapy by providing more qualitative gains that carry over to home. The most important clinical implication of this device is the ability to capture the attention of children by making treatment sessions motivating and fun, which improves the quality of movements and allic.w is for quicker return to normal function.

RECOMMENDATIONS. As this study is repeated, I would like to make a few suggestions. First of all, something other than the strain gauge as a means of measuring range of motion and speed of motion should be used. A standard goniometer (with capabilities of being attached to the computer) attached to the lateral aspect of the joint being measured would provide more reliable data. In this study, biofeedback was in the form of a beep sound. For future studies, an audio voice (indicating slow, normal, or fast) would be less confusing to the children. I felt that there was a stimulus overload by hearing too many beeps at one time and making it necessary for the children to distinguish if the beep was due to the speed or indicating that they have reached the range of motion set points. Lastly, the children participating in the study should be tested more
than once (on different days). In addition, a form should be developed that is filled out each day they are tested that focuses on the motivational factor of this device.
INFORMATION AND CONSENT FORM


My name is Cassie Wulfekuhle, I am a physical therapy student at the University of North Dakota. I am conducting this study as part of my requirements for obtaining a Masters Degree in Physical Therapy at the University of North Dakota.

Your child is being invited to participate in a study to see if audio and visual biofeedback have a positive effect on rehabilitation. I hope to find positive results with biofeedback in order to increase motivation, attention span and compliance issues in pediatric rehabilitation. Only normal, healthy children between the ages of five and twelve will be asked to participate in this study.

Audio biofeedback for elbow range of motion and speed of motion will be in the form of a beep sound. Visual biofeedback for elbow range of motion and speed of motion will be in the form of a bar of lights (LED's).

Although the process of physical performance testing always involves some degree of risk, I feel that the risk of injury or discomfort is minimal. In order for us to record elbow range of motion, we will need to place a flexible strain gage on your child's arm that contains a sensor that will measure elbow range of motion and speed. This will be held in place with self-adhesive tape. Once the strain gauge is attached to your child's arm, your child will be given a three minute trial time to move their elbow and get used to how it feels and how the visual and audio biofeedback work.

Your child will be asked to perform a preset elbow movement (within normal limits) under the following conditions: 1) with both audio and visual biofeedback turned on, 2) audio biofeedback turned on while visual biofeedback is turned off, 3) visual biofeedback turned on while audio biofeedback is turned off, and 4) both audio and visual biofeedback turned off. Each experimental condition will be 30 seconds, and your child will be allowed a one minute rest period between trials.

The study will take approximately one half hour of your time. You and your child will be asked to report to the University of North Dakota Physical Therapy department in Grand Forks, ND or at North Dakota State University Engineering department in Fargo, ND at an assigned time in a short sleeve shirt for the experiment. We will first record your child's age, and gender. During the experiment, we will be recording elbow range of motion, speed, total time to complete 10 reps, and quality of elbow movement. The output data will be recorded on a computer program for further statistical analysis.

Your child's name will not be used in any reports of the results of this study. Any information that is obtained in connection with this study and that can be identified with your child will remain confidential and will be disclosed only with your permission. The data will be identified by a number known only by me. This data will be retained for
three years following study completion. At the end of three years, all forms will be shredded. I or your child may stop the experiment at any time if your child is experiencing discomfort, pain, fatigue, or any other symptoms that may be detrimental to his/her health. Your decision whether or not to let your child participate will not prejudice your future relationship with the Physical Therapy Department of the University of North Dakota or the Engineering department at North Dakota State University. If you decide to let your child participate, you and your child are free to discontinue participation at any time without prejudice.

I am available to answer any questions you have concerning this study. In addition, you are encouraged to ask any questions concerning this study that you may have in the future. Questions may be asked by calling Dr. Peggy Mohr at (701) 777-2831 or Cassie Wulfekuhle at (701) 372-3602. A copy of this consent form will be made available to you.

In the event that this research activity (which will be conducted at University of North Dakota Physical Therapy Dept. or at North Dakota State University Engineering Dept.) results in a physical injury, your child will be encouraged to receive prompt medical attention, as it is customary to a member of the general public in similar circumstances. Payment for any such treatment must be provided by you and your third party payer, if any.

ALL OF MY QUESTIONS HAVE BEEN ANSWERED AND I AM ENCOURAGED TO ASK ANY QUESTIONS THAT I MAY HAVE CONCERNING THIS STUDY IN THE FUTURE. MY SIGNATURE INDICATES THAT, HAVING READ THE ABOVE INFORMATION, I HAVE DECIDED TO LET MY CHILD PARTICIPATE IN THIS RESEARCH PROJECT.

I have read all of the above and I willingly agree to allow my child to participate in this study explained to me by Cassie Wulfekuhle.

____________________________
Parent or Legal Guardian Signature    Date

____________________________
Child's Assent    Date
REPORT OF ACTION: FULL BOARD REVIEW
University of North Dakota Institutional Review Board

DATE: June 21, 1999
PROJECT NUMBER: IRB-9906-265

NAME: Peggy Mohr, Jake Glower, Cassie Wulfekuhle
DEPARTMENT/COLLEGE: Physical Therapy

PROJECT TITLE: The Computer Interface Device: Effects of Audio and Visual Biofeedback in Rehabilitation

The above referenced project was reviewed by the Chair/Vice Chair/Designated Member of the University of North Dakota Institutional Review Board on June 23, 1999 and the following action was taken:

☐ Project approved. Next scheduled review is on June 2000
(See REMARKS SECTION for any special condition.)

☐ Project approved PENDING receipt of corrections/additions in ORPD. These corrections/additions should be submitted to ORPD for review and approval. This study may NOT be started UNTIL final IRB approval has been received. (See REMARKS SECTION for further information.)

☐ Project approval deferred. This study may not be started until final IRB approval has been received.
(See REMARKS SECTION for further information.)

☐ Project denied. (See REMARKS SECTION for further information.)

REMARKS: Any changes in protocol or adverse occurrences in the course of the research project must be reported immediately to the IRB Chairperson or ORPD.

PLEASE NOTE: Requested revisions for student proposals MUST include adviser’s signature.

cc: P. Mohr, Adviser
Dean, Medical School

Signature of Chairperson/Vice Chair/Designated Member
UND’s Institutional Review Board

6-23-99

If the proposed project (clinical medical) is to be part of a research activity funded by a Federal Agency, a special assurance statement or a completed 310 Form may be required. Contact ORPD to obtain the required documents.
The purpose of this study is to see if the computer interface device is effective in improving quality of elbow joint motion in children by increasing motivation and attention span through the use of audio and visual biofeedback. Difficulties in pediatric rehabilitation are decreased attention span, motivation, and compliance. The computer interface device has the capability to provide audio and visual biofeedback to the children while they perform a desired exercise. These features may encourage attention span, motivation, and compliance issues during a rehabilitation session. Performance will be measured by the resulting computerized data from the device. To test these features, human subjects are needed to provide accurate data that can be studied and further researched. Clinically, desired outcomes may help to improve rehabilitation with children by capturing their attention, providing motivation and improving future rehabilitation compliance.
PLEASE NOTE: Only information pertinent to your request to utilize human subjects in your project or activity should be included on this form. Where appropriate attach sections from your proposal (if seeking outside funding).

2. PROTOCOL: (Describe procedures to which humans will be subjected. Use additional pages if necessary.)

Introduction:
The computer interface device is an instrument that is attached to a computer that monitors data output. This device provides audio and visual biofeedback capabilities. These capabilities can be turned on and off at any given time. A strain gauge that measures elbow range of motion is attached to the elbow and sends the data to the computer. The target elbow range of motion is pre-determined, by adjusting two set points. Accuracy and speed in reaching these two set points will be evaluated. I hypothesize that the computer interface device and the audio and visual biofeedback it provides will improve attention, motivation, and compliance during an exercise program.

Subject Selection:
Children will meet the study requirements if they are healthy and between the ages of five and twelve. I will visually screen the children for full elbow range of motion and their ability to fully understand verbal instructions of what will be asked of them during the study. Children will be excluded from the study if they do not have full elbow range of motion or cannot understand the instructions.

Fifteen to twenty children between the ages of five and twelve will be obtained from friends, relatives, and by making inquiries in the community, and at UND via a letter asking for their participation. This letter will be in the form of an information/consent form. Participants will be asked to come to either the University of North Dakota Physical Therapy Department in Grand Forks, ND, or North Dakota State University Engineering Department in Fargo, ND. One-half hour will be needed to complete the test. Participants will have the right to withdraw without prejudice at any time during the course of the study up until the data has been collected. If this occurs, another subject will be selected to replace him/her. Parents are welcome to accompany their child to the testing area and to observe the testing process. This study will be done on a voluntary basis by the children.

Procedure:
Once the informed consent has been obtained (as described below), all children will be given a verbal set of instructions prior to the test. The children will be asked if he/she understands the instructions or would like them repeated. A strain gauge will be attached to the child's elbow, held on by self-adhesive tape. The strain gauge is a sensor that will measure elbow range of motion and speed of movement. The strain gauge is a standard piece of equipment that is used with human subjects. It is simply placed on the subject's skin. One end of the sensor has wires attached to it, but they will be covered with tape so that no injury will occur.

The child will be given a trial period of three minutes to bend the elbow back and forth to get a feel for the device and to understand the audio and visual output biofeedback features. Audio biofeedback for elbow range of motion and speed will be in the form of a beep sound. Visual biofeedback for elbow range of motion and speed will be in the form of a bar of lights (LED diagram). Elbow range of motion, which is within normal limits, will be set, prior to testing, by me.

The following tests will be done, in the same order for all children as shown below, by having the children complete 10 repetitions of elbow flexion and extension:
1. Both audio and visual biofeedback turned on
2. Audio biofeedback turned on, visual turned off
3. Visual biofeedback turned on, audio turned off
4. Both audio and visual turned off

Once the four tests have been completed, the children will be free to go. The children will be given a treat (candy or toy) if they want one. If a child withdraws from the study, as long as the consent form was signed, they will also receive a treat.
Statistical analysis of the data will be done to determine if there is a significant difference in performance speed and accuracy associated with the type of biofeedback being used and if there is a significant difference in performance with the biofeedback turned on as compared to biofeedback being turned off.

Attachment: Copy of instrument being used

Informed consent:
Informed consent will be obtained through an information and consent form (see attached form). This form will be explained to the parents and children. A copy will be left with the parent. Parents will provide consent and children age nine and up will be asked for their assent. The child’s name will not be used in any reports of the results of this study. Any information that is obtained in connection with the child will be coded to remain confidential. If the child decides not to participate, they are free to discontinue participation at any time without prejudice.

Compensation:
Children will receive treats (their choice of candy or a toy) for participating in this study. This treat will be given to all children who sign the consent form even if they withdrawal.

BENEFITS: (Describe the benefits to the individual or society.)
Rehabilitation exercises by nature are repetitive and often times boring, especially for children. By incorporating a device that would help to capture the attention of children and motivate them to continue exercise, it is felt that more effective rehabilitation session could be achieved. The individual can become more actively involved in their own process to recovery. By seeing immediate results, via feedback, the individual would be encouraged to keep making progress. Instead of just passively receiving treatment, this device assists in teaching individuals to do something for themselves, increases their confidence, and motivates them to continue. The benefits for society would be the possibility of more productive rehabilitation sessions with children, decreased amount of treatments, a more efficient means of working with children which may result in better quality of care.
Another benefit of the child’s participation in this study is that they will receive a treat (candy or toy). This treat will also be available to children who withdrawal form the study as long as they signed to consent form.

4. RISKS: (Describe the risks to the subject and precautions that will be taken to minimize them. The concept of risk goes beyond physical risk and includes risks to the subject's dignity and self-respect, as well as psycho-logical, emotional or behavioral risk. If data are collected which could prove harmful or embarrassing to the subject if associated with him or her, then describe the methods to be used to insure the confidentiality of data obtained, including plans for final disposition or destruction, debriefing procedures, etc.)

Since elbow range of motion is an exercise, there is some risk for personal injury. The child might move their elbow too fast and pull a muscle. Another risk that may arise is that the child might feel that they are not “passing the study”. The investigator believes the risk to be minimal, since all children selected are physically healthy and elbow range of motion is within normal limits. The child will be informed that this is not a test that they can fail.
I (Cassie Wulfekuhle) will monitor the testing sessions. I am a student physical therapist and a certified athletic trainer. If a child does have a personal injury during a testing session, they will be encouraged to receive prompt medical attention, as it is customary to a member of the general public in similar circumstances. Payment for such treatment will be provided by the child’s parents. In addition, the child will be informed they may stop the activity at any time.
Statistical analysis of the data will be done to determine if there is a significant difference in performance speed and accuracy associated with the type of biofeedback being used and if there is a significant difference in performance with the biofeedback turned on as compared to biofeedback being turned off.

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The children’s names will not be used in any reports of the result of this study. Any information obtained in connection with this study and that can be identified with the child will remain confidential. Data will be retained in a locked cabinet in the advisor’s office in the UND physical therapy department for three years following completion of this study. Only the investigator (Cassie Wulfekuhle), advisor (Peg Mohr) and NDSU’s engineering professor (Jake Glower) will have access to the information. At the end of the three year period, all data will be shredded.

CONSENT FORM: A copy of the CONSENT FORM to be signed by the subject (if applicable) and/or any statement to be read to the subject should be attached to this form. If no CONSENT FORM is to be used, document the procedures to be used to assure that infringement upon the subject’s rights will not occur.

Describe where signed consent forms will be kept and for what period of time.

A consent form will be sent to each child’s parents asking for participation, describing the study, and describing how it will be carried out. The child’s name will not be used in any reports of the results of this study. Any information that is obtained in connection with this study and that can be identified with the child, will remain confidential. The data will be identified by a number known only by the investigators. Signed consent forms will be stored in a locked cabinet in the advisor’s (Peg Mohr) office in the University of North Dakota Physical Therapy Department. They will be kept for three years following completion of this study. At the end of the three years, all forms will be shredded.

6. For FULL IRB REVIEW forward a signed original and thirteen (13) copies of this completed form, and where applicable, thirteen (13) copies of the proposed consent form, questionnaires, etc. and any supporting documentation to:

Office of Research & Program Development
University of North Dakota
Grand Forks, North Dakota 58202-7134

On campus, mail to: Office of Research & Program Development, Box 7134, or drop it off at Room 105 Twamley Hall.

For EXEMPT or EXPEDITED REVIEW forward a signed original and a copy of the consent form, questionnaires, etc. and any supporting documentation to one of the addresses above.

The policies and procedures on Use of Human Subjects of the University of North Dakota apply to all activities involving use of Human Subjects performed by personnel conducting such activities under the auspices of the University. No activities are to be initiated without prior review and approval as prescribed by the University’s policies and procedures governing the use of human subjects.

SIGNATURES:

Cassie Wulfekuhle  Date: 06-14-99
Principal Investigator

Peg Mohr  Date: 4-18-99
Project Director or Student Adviser

Training or Center Grant Director  Date: (Revised 3/1996)
STUDENT RESEARCHERS: As of June 4, 1997 (based on the recommendation of UNO Legal Counsel) the University of North Dakota IRB is unable to approve your project unless the following "Student Consent to Release of Educational Record" is signed and included with your "Human Subjects Review Form."

STUDENT CONSENT TO RELEASE OF EDUCATIONAL RECORD

Pursuant to the Family Educational Rights and Privacy Act of 1974, I hereby consent to the Institutional Review Board's access to those portions of my educational record which involve research that I wish to conduct under the Board's auspices. I understand that the Board may need to review my study data based on a question from a participant or under a random audit. The study to which this release pertains is *The Computer Interface Device: Effects of Audio and Visual Feedback in Rehabilitation*.

I understand that such information concerning my educational record will not be released except on the condition that the Institutional Review Board will not permit any other party to have access to such information without my written consent. I also understand that this policy will be explained to those persons requesting any educational information and that this release will be kept with the study documentation.

6-14-99 Cassie Wulfkolk
Date Signature of Student Researcher

1Consent required by 20 U.S.C. 1232g.
To: Dr. Peg Mohr  
UND School of Medicine  
PT Depart. Box 9037  
Grand Forks, ND 58202-9037

From: Dr. Jake Glower  

date: April 23, 1999  

Dear Mrs. Mohr,

I have had the opportunity to discuss the research proposal "The Computer Interface Device: Effects of Audio and Visual Biofeedback in Rehabilitation" with Cassie Wulfekuhle. As the supervisor for NDSU's senior design program in electrical engineering, I approve and fully support this research endeavor. Moreover, I hope this will lead to more joint projects between our departments in the near future. We look forward to working together with you.

Sincerely,

[Signature]

Jake Glower

cc.  
Otto Helweg, Dean of Engineering and Architecture, NDSU  
Orlando Baiocchi, Chair of Electrical and Computer Engineering, NDSU
APPENDIX D
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REFERENCES


9. Kellis E and Baltzopoulos V. Resistive eccentric exercise effects of visual feedback
