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Effectiveness of Pressure Biofeedback in Activation of Transversus Abdominis during the Abdominal Draw-In Maneuver

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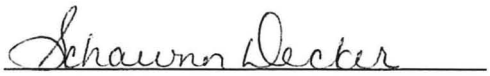
This Scholarly Project, submitted by Jenni Freie, Jan Kruse, Amanda Kvien, and Kimberly Rzeszutko in partial fulfillment of the requirements of the Degree of Doctor of Physical Therapy from the University of North Dakota, has been read by the Advisor and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.



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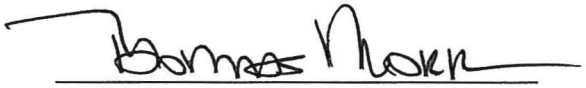

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Title	**Effectiveness of Pressure Biofeedback in Activation of Transversus Abdominis during the Abdominal Draw-In Maneuver**
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Degree	**Doctor of Physical Therapy**

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Signature Jenni Freie

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Date 12-15-05

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES AND GRAPHS

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We would also like to give a special thanks to our parents, family, and friends for supporting us through our educational experiences. Without their love and support, we would not be where we are today.

ABSTRACT

Effectiveness of pressure biofeedback in activation of transverse abdominis during abdominal draw-in maneuver.

Study Design: Repeated Measures Design.

Objectives: To compare the recruitment of the transversus abdominis and internal oblique during the performance of the supine abdominal draw-in maneuver with the use of pressure biofeedback and without the use of pressure biofeedback. Muscle recruitment will be measured through the use of surface electromyography (EMG).

Background: Surface EMG reliability and validity is reported for transversus abdominis.

Methods: Thirty-nine healthy subjects of the ages 18 to 54 were tested. The subjects were instructed and performed practice trails of the supine draw-in maneuver with and without pressure biofeedback prior to data collection. EMG muscle activity was recorded during a 30 second hold of the supine draw-in maneuver.

Results: Data was analyzed on 32 subjects. There was no significant difference in the EMG activity of the transversus abdominis during the performance of the supine

CHAPTER I

INTRODUCTION

"Low back pain is a symptom that affects 80% of the general United States population at some point in life with sufficient severity to cause absence from work. It is the second most common reason for visits to primary care doctors, and is estimated to cost the American economy $75 billion every year."[1] Although there are many lumbar core stabilization exercises available, not all of them activate the internal oblique and transversus abdominis which are the muscle that provide primary stability to the lumbar spine. Core stabilization exercises, including the supine draw-in maneuver, have been well researched and have been shown to be effective in strengthening abdominal muscles.[2,3,4] Physical therapists are constantly trying to find more effective ways to teach patients the correct technique in performing core stabilization exercises. One possible technique that has not been well researched is the pressure biofeedback bladder with regard to instruction for core stabilization exercises.

Problem Statement

There has been multiple research studies done of core stabilization exercises for the treatment of low back pain, however there has been minimal scientific research completed for the instruction of exercises with the pressure biofeedback unit.

Purpose of the study

The purpose of this study is to show that the pressure biofeedback bladder increases recruitment of the internal oblique and transversus abdominis, to establish an objective measure to ensure the subject is doing the exercise correctly. A simple pressure biofeedback bladder would be useful to ensure the subject is recruiting the correct muscles.

Significance

There has been little scientific research done on the use of the pressure biofeedback bladder in the instruction of core stabilization exercises. The goal of completing this study is to provide physical therapists and other health practitioners with research of the use of pressure biofeedback in the instruction of core stabilization exercises.

Research Question

Does the use of a pressure biofeedback device increase electromyography (EMG) activity of the transversus abdominis/internal oblique during the supine draw-in maneuver compared to without the pressure biofeedback unit?

Null Hypothesis

There is no significant difference between the use of pressure biofeedback versus no biofeedback during the supine draw-in maneuver in measuring EMG activity of the transversus abdominis/internal oblique.

Alternative Hypothesis

There is a significant difference between the use of pressure biofeedback versus no biofeedback during the supine draw-in maneuver in measuring EMG activity of the transversus abdominis/internal oblique.

CHAPTER II

LITERATURE REVIEW

Lumbar Stability Exercises and the Muscles they Activate

Muscles that are categorized as core stabilizers or intersegmetal stabilizers are the internal oblique, transversus abdominis, and multifidus because of their intervertebral attachments to the spine. Erector spinae and rectus abdominis are longer trunk muscles devoted to generating movement; therefore, they are not optimal trunk stabilizers.[2] The internal oblique muscle is attached dorsally and ventrally, it generates forces onto the pelvis and spine through the attachment to the lumbodorsal fascia. The lumbodorsal fascia is the strongest lumbar supportive structure; the only two abdominal muscles attached to it are the internal oblique and transversus abdominis from the anterior trunk to the lumbar spine. Internal oblique and transversus abdominis muscles are active during intra-abdominal pressure activities such as core stabilization and provide rotational and lateral stability to the spine.[3,4] These two muscles, in conjunction with the lumbar multifidus, are considered to enhance dynamic stability of the lumbar spine by providing rigidity.[3]

There are many lumbar or core stabilization exercises available, but not all have proven to activate the muscles that provide primary lumbar spine stability. The abdominal drawing in maneuver or abdominal hollowing maneuver is recognized as an

exercise that activates the internal oblique and transversus abdominis muscles for stabilization with little recruitment of the rectus abdominis muscle in the healthy population.[3] The supine abdominal maneuver is also an exercise commonly found in a Pilates program. The Pilates program is a group of exercises that designed to target the core stabilizing muscles.[5]

The supine abdominal drawing maneuver is shown to activate the transversus abdominis in patients with low back pain. Activation was found through the use of ultrasound imaging.[6] O'Sullivan, Twomey, and Allison's[3] study found a significant increase ($F=-7.35$, $p=.013$) in internal oblique recruitment in the abdominal drawing in maneuver exercise group after they were instructed in the exercise. To show that as the internal oblique activity increased with the abdominal drawing in maneuver and the rectus abdominis activation decreased, a ratio of activation was calculated. A significant difference ($F=19.7$, $p=.0002$) was seen in the exercise group, where no significant difference was seen in the control group. The result of this study supported the view that the abdominal drawing in maneuver does increase activation of the deep abdominal muscles such as internal oblique and transversus abdominis without increasing activity of rectus abdominis in people who suffer from chronic lumbar back pain. A major limitation of this study was analysis of the exercises that were non-normalized showed significant findings, but analysis of the exercises that were amplitude normalized did not have significant findings.

One study stated, if deficits are seen in stabilizing muscles, there is incorrect recruitment from movement muscles such as erector spinae and rectus abdominis which can increase chances of re-injury because of the incorrect muscle coordination patterns on

the spine.[2] There has to be a way to ensure correct recruitment of lumbar stabilizing muscles during the stabilization exercises. The clinical measure used to ensure activation of the transversus abdominis muscle in Koumantakis, Watson, and Oldham's[2] study was to observe the abdominal wall just below the umbilicus and look for contraction or a drawing in of that area. This measure is subjective, there was no way of verifying that the transversus abdominis muscles were being recruited.

This study is designed to prove the pressure biofeedback bladder increases recruitment of the internal oblique and transversus abdominis muscles, so there is an objective measure to ensure the subject is doing the exercise correctly. A simple pressure biofeedback bladder would be useful to ensure the subject is recruiting the correct muscles. There are other devices such as electromyographic biofeedback units or real-time ultrasound scanners to ensure the correct muscles are being recruited, but these devices are not currently used in the clinical setting.[2]

Electromyography and Transversus Abdominis

Electromyography is a technique that requires the use of electrodes to measure the muscles' electrical activity during contraction. Two types of electrodes that are currently used are surface and fine wire. Due to the deep anatomical location of the transversus abdominis, fine-wire EMG has been used in the past. This invasive technique involves the use of needle electrodes to be inserted into the prospective muscle under the guidance of ultrasound imaging. As a non-invasive and cost-effective technique, surface electrodes were used in this study. Surface electrodes have been used in several studies to investigate the muscle activity of the abdominal muscles.[3,4,7,8,9,10]

Direct and distinct electrical activity with the use of surface electrodes has been questionable, because the transervsus abdominis is located deep to the internal oblique. Anatomically, these two muscles are combined and have similar attachments at the iliac crest and the thoracolumbar fascia. The transervsus abdominis origin is on the 7th through 12th ribs, the thoracolumbar fascia, crest of the ilium, and the inguinal ligament. The muscle fibers then proceed towards midline to insert on the pubic crest and linea alba. The origin of the internal oblique consists of the thoracolumbar fascia, anterior proportion of the iliac crest, and lateral half of the inguinal ligament. The fibers of the internal oblique run medially and superiorly to insert on the anterior and inferior aspect of the 10th through 12th ribs via abdominal aponeurosis into the rectus sheath, and pectineal line of the pubic bone.[11]

McGill[8] demonstrated that the placement of surface electrodes superior to the inguinal ligament represents the combined muscle activity of the transversus abdominis and internal oblique. The muscle activity with the use of surface electrodes represented 10 to 15 percent of recorded fine wire muscle activity for the transervsus abdominis. To further investigate the validity and reliability of surface electrodes, Marshall et al,[7] evaluated the crosstalk of the transversus abdominis/internal oblique EMG activity to adjacent muscles and found this signal to be separate and distinct from rectus abdominis for the draw-in maneuver and supine rapid arm movements. At this electrode placement site the transversus abdominis and internal oblique are the only muscles directly under the electrodes.

Pressure Bio-feedback

This study used the STABAILIZER™ pressure bio-feedback unit manufactured by Chattanooga group. This unit was designed by physical therapists, and is a simple device that shows the changes in pressure that are exerted on the air-filled bladder. The unit was designed to monitor and provide feedback on body movement during exercise.[12]

According to the "Journal of Nursing," bio-feedback helps people learn how to exert conscious control over various autonomic functions by using physiologic feedback from a device.[13] The information provided by the bio-feedback device allows the person to observe fluctuations of a particular body function. By observation of the fluctuations in body function, the person can eventually learn how to alter their autonomic response. Some common uses of bio-feedback include: headaches, hypertension, temporomandibular joint syndrome, insomnia, as well as other stress-related disorders. Equipment needed for bio-feedback varies depending on which physiologic function is targeted. Although devices may vary, in order to provide proper bio-feedback to the body and specific function, a bio-feedback device is required. It is recommended that while practicing bio-feedback techniques, distractions should be minimized to achieve optimal results.[12]

Studies have shown that other forms of bio-feedback, such as the use of electromyography are successful in increasing the recruitment of targeted muscles.[13] However, the use of pressure bio-feedback for exercises that require recruitment of the transversus abdominis/internal oblique, as well as the other abdominal muscles, is not well published. One study was found by Allison et al,[14] which utilized the pressure biofeedback bladder to determine the role of the diaphragm during abdominal hollowing

exercises. O'Sullivan et al[3] also utilized the same pressure bio-feedback unit in their study which investigated altered abdominal muscle recruitment in patients with chronic back pain following exercise. Both studies used the pressure bio-feedback bladder according to manufacturer's guidelines for the purpose of operationally defining the motor control tasks involved in the studies, not to measure any effect the pressure bio-feedback bladder may have had on muscle recruitment.[3,15]

Low Back Pain

Low back pain occurs in 70-85% of individuals, and it is a common diagnosis seen by medical professionals. Furthermore, 80% of these individuals will report recurrent episodes of back pain.[16] There has been evidence of a direct relationship between trunk muscle dysfunction and individuals with low back pain. Hodges and Richardson[17] studied the effects of contraction time of trunk musculature with arm movements in patients with low back pain. They showed that there was significant delay in the contraction of transversus abdominis with shoulder flexion, extension, and abduction. These results also showed the lack of motor control with movements and the subsequent decreased trunk muscular stabilization.

Liddle, Baxter, and Gracey[16] conducted a systematic review on the treatments for low back pain patients. They concluded that chronic low back pain patients will have positive effects from an exercise program and patients will also be able to maintain the results for follow-up. Fritz, Whitman and Childs[18] found that patients with hypermobile segments of the trunk will benefit greatly from a lumbar stabilization program in the treatment of low back pain. Performing exercises which promote strengthening of the

horizontal fibers of the transversus abdominis provides the trunk with an internal corset. The added stability can be a benefit for the treatment for patients with low back pain.

CHAPTER III

METHODOLOGY

Subjects:

Thirty-nine participants volunteered for this study. Fifteen males and twenty-four females between the ages of 18-54 (mean age=26) completed the study, however 6 subjects were excluded. Five participants were excluded due to interference of the electrical activity of the heart in the EMG data. The other subject was excluded due to increased EMG readings as a result of lower extremity movement. This left 33 subjects (female=22, male=11) remaining for data analysis.

All subjects completed a pre-screening questionnaire prior to participation. Subjects were screened for history of low back pain, current pregnancy, high blood pressure, cardiac conditions, skeletal or postural abnormalities, and/or previous or current neurological conditions; however, no subjects were excluded for these reasons. Subjects also read and signed an IRB approved consent form (Appendix B) and received a copy of this form. All study activities took place at the University of North Dakota in the Physical Therapy Department with paper consent under the supervision of the Physical Therapy faculty.

Instruments:

Testing Devices:

The STABILIZER™ Pressure Bio-Feedback (Chattanooga Group, Austin, Texas) was used during the core stabilization exercises, both during practice and test trials.[12] This equipment was made available by the UND Physical Therapy Department. Calibration of this device was done by setting the needle of the gauge at 40 mmHG as per Chattanooga protocol. (Figure 1)

Electromyography (EMG):

EMG activity of the transversus abdominis/internal oblique was collected using a TeleMyo 900 telemetry unit (Noraxon USA, Scottsdale, AZ). Surfaces electrodes used were pre-gelled, self-adhesive Ag/Ag (Model #M-00-S, Blue Sensor, Ambu; Rugmarken, Denmark). These electrodes had an inter-electrode distance of 3.3 cm and were placed over the transversus abdominis/internal oblique according to the electrode placement charts.[19] The muscle activity was read by the electrodes and the telemetry transmitter and transmitted to the TeleMyo 900 receiver . The EMG data was viewed, processed, and analyzed using the Myoresearch XP software program (Noraxon, USA) and a laptop computer (HP Pavilion ZV5000, Pentium 4 2.80 GHz Processor).

Exercises:

Supine Draw-in Maneuver:

The supine draw-in maneuver required a contraction of the transversus abdominis to draw in the naval towards the spine. The subject was in the supine position with hips and knees flexed and feet flat on the mat.[3] Each subject was required to hold the supine

draw-in maneuver position for 30 seconds. The subjects were given verbal instruction prior to practice trails and trial performance. (Appendix C and D) To ensure standardization, the instructions were given to subjects by the same investigator. (Figure 2)

Maximum Voluntary Contraction:

The Maximum Voluntary Contraction (MVC) was performed in the supine position with hips and knees bent and the subject's feet flat on the mat. Subjects were instructed to lift upper body up until both scapulas cleared the mat. The purpose of the MVC is to establish a baseline of EMG activity of the supine draw-in maneuver in order to normalize the data during data analysis.[20] The MVC was performed after the practice trials, but before the supine draw-in maneuver. (Refer to Appendix D) (Figure 3)

Procedure:

Prior to the beginning of the study, the EMG equipment was set-up and tested for proper signal transmission and reception. All subjects were tested independently at the University of North Dakota Physical Therapy Department in Grand Forks, ND.

Upon arrival subjects were given the written consent form (Appendix B), pre-screening questionnaire (Appendix E), and a verbal description of the procedure and physical requirements. Prior to data collection, the subjects were instructed in practice trials of the supine draw-in maneuver with and without pressure biofeedback. Participants were allowed to complete 3 trials without pressure biofeedback and three trials with pressure biofeedback. The pressure biofeedback unit was placed above the level of the Posterior Superior Iliac Spine (PSIS) in all trials, and the pressure was set a 40 mmHg prior to performance.[3,11,14] The subjects were instructed to maintain a pressure

reading as close to 40 mmHg or within a range of 35-45 mmHg. If participants were unable to maintain the pressure reading within this range, they were allowed 2 additional practice trials. Subjects were excluded if they were unable to maintain the range after 5 practice trials, however all subjects were able to complete this requirement.

Electrode Placement:

Electrode placement occurred after the completion of practice trials. The subject's skin was cleaned with alcohol and shaved if necessary. Six electrodes were used; four were placed over the transversus abdominis/internal oblique bilaterally according to reference charts.[19] Electrode placement was located inferior and lateral to the naval.[9] Two reference electrodes were also placed on the subject's olecranon and the ASIS.[19] The olecranon electrode was used as a reference, however if there was too much feedback preventing accurate readings, the ASIS reference electrode was used. All electrodes were applied with the subject in the supine position. To ensure standardization and accuracy, the same investigator applied electrodes to all participants. The placement of the electrodes is shown in Figures 4-6.

Data Collection:

Each participant's electrodes were attached to the EMG data collection unit. Data was collected for the participant's baseline Maximum Voluntary Contraction (MVC), one recording of the supine draw-in maneuver with pressure biofeedback, and one without pressure biofeedback; for a total of 3 measurements recorded. EMG was recorded 3 seconds before and after the participant's contractions, and the middle 10 seconds were used for data analysis.

Data Analysis:

In order to normalize the data to the normal population for the statistical analysis, over 30 subjects were recruited (n=39). The independent variable for this study was the use of the STABILIZER™ Pressure Bio-Feedback bladder for the first or second trail during the abdominal drawing-in maneuver. The dependent variable was EMG measurements of the internal oblique muscle activity during the abdominal drawing-in maneuver. The statistical analysis was done using a two-tailed, related samples T-test with an alpha level of .05.

All data was imputed into Statistical Package for Social Sciences (SPSS) 10.0 software program which analyzed the data using two-tailed Paired T-tests with a 95% Confidence Interval (CI) to compare 10 seconds to 30 seconds of EMG data. The two-way repeated measures ANOVA using SPSS was used to analyze and compare the following: biofeedback vs. no-biofeedback, right vs. left, and the interaction between biofeedback variable and muscle variable.

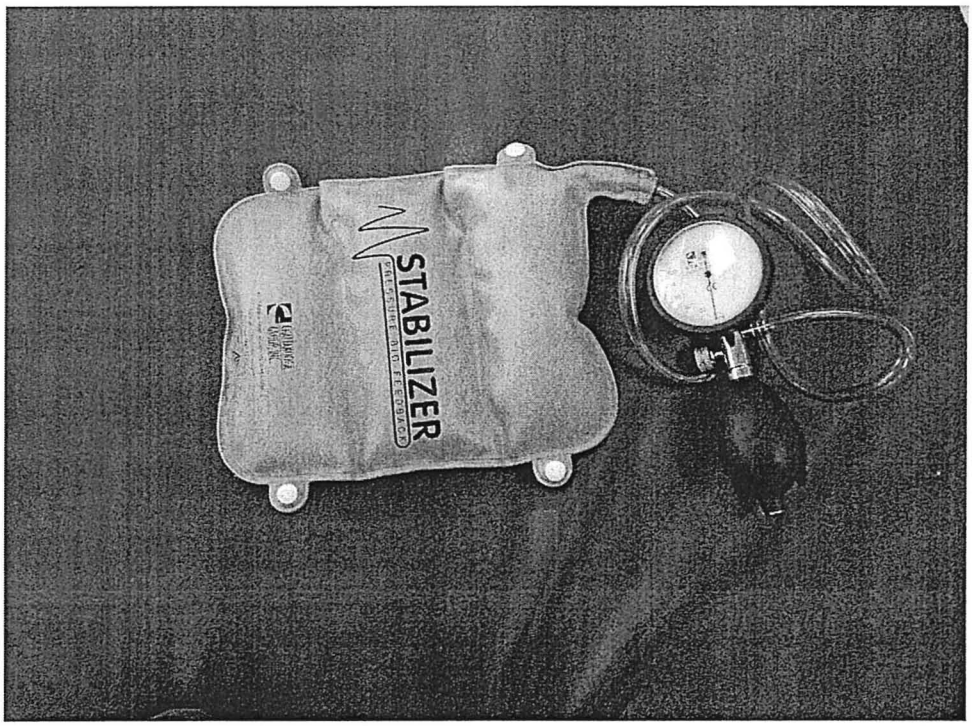


Figure 1: STABILIZER™ Pressure Biofeedback Bladder

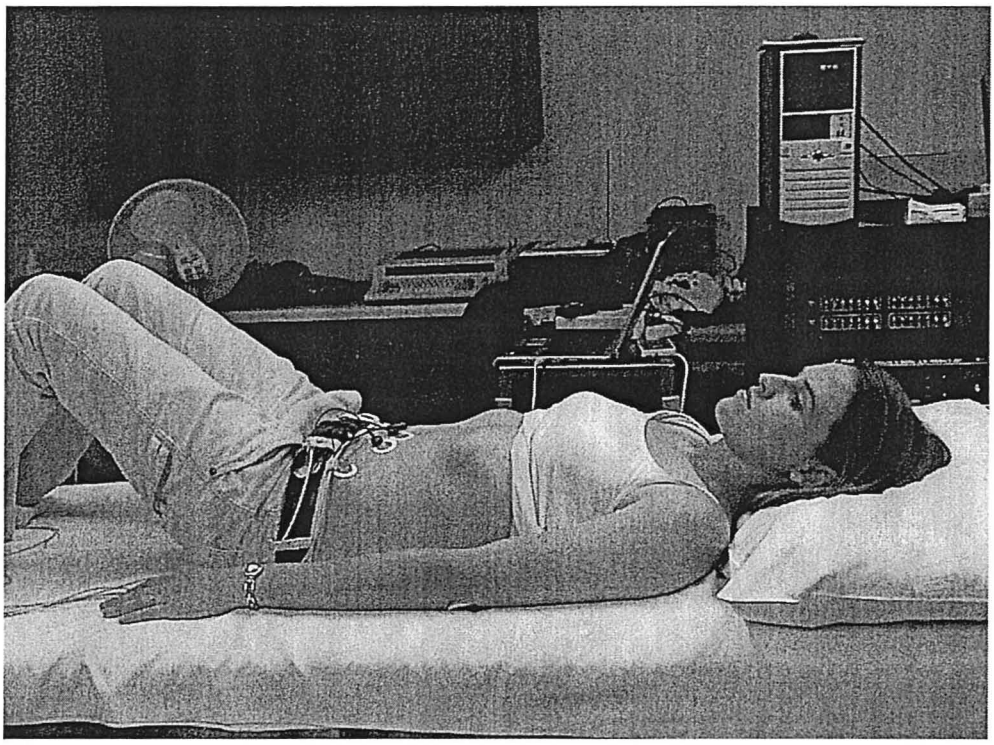


Figure 2: Supine Draw-in Maneuver

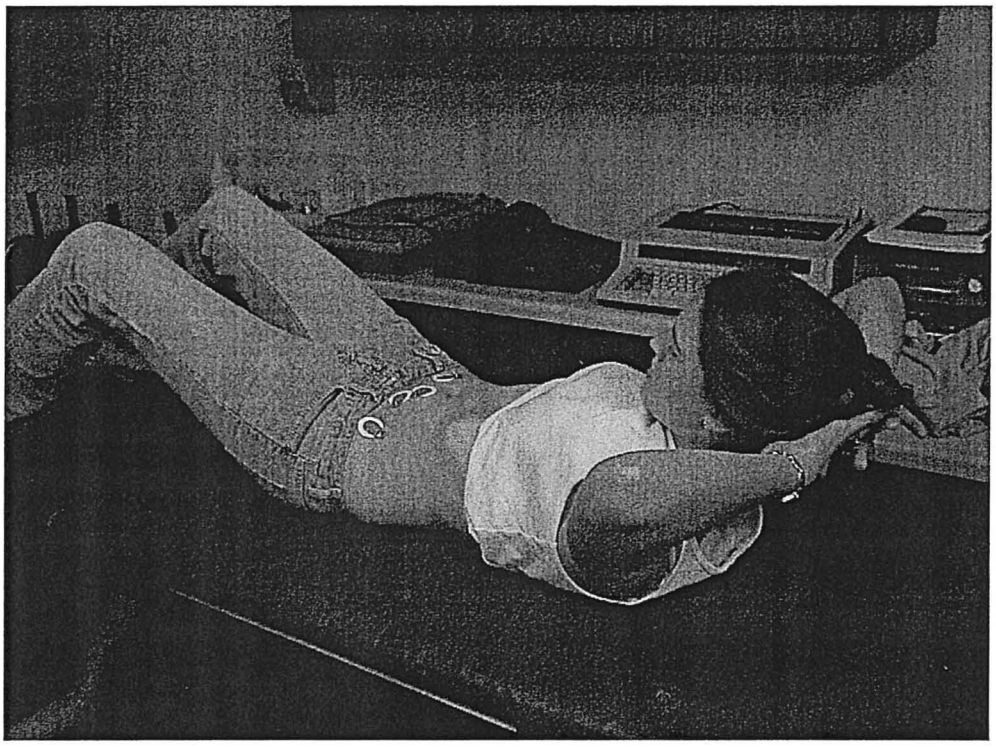


Figure 3: Maximal Voluntary Contraction

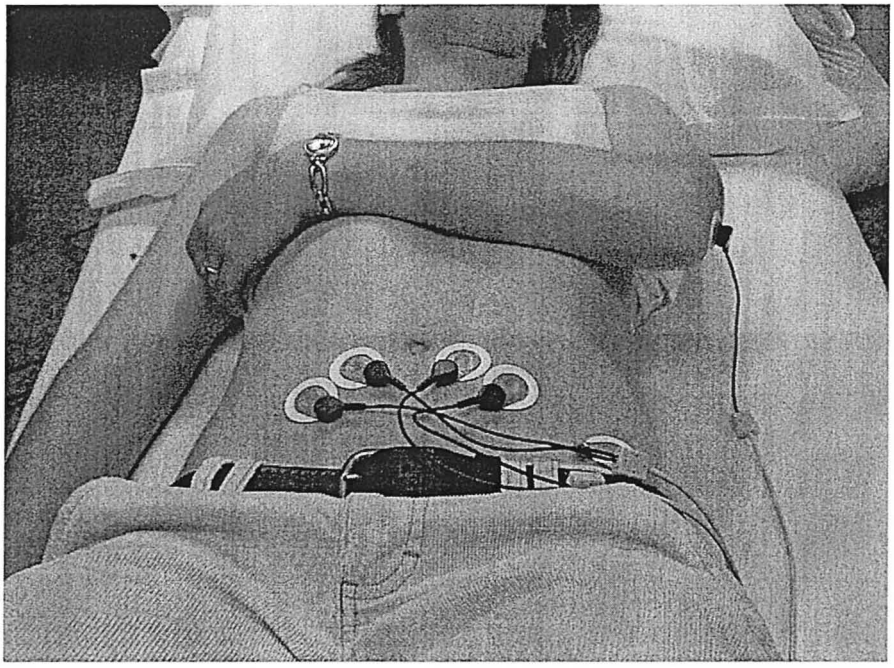


Figure 4: Electrode Placement for internal oblique

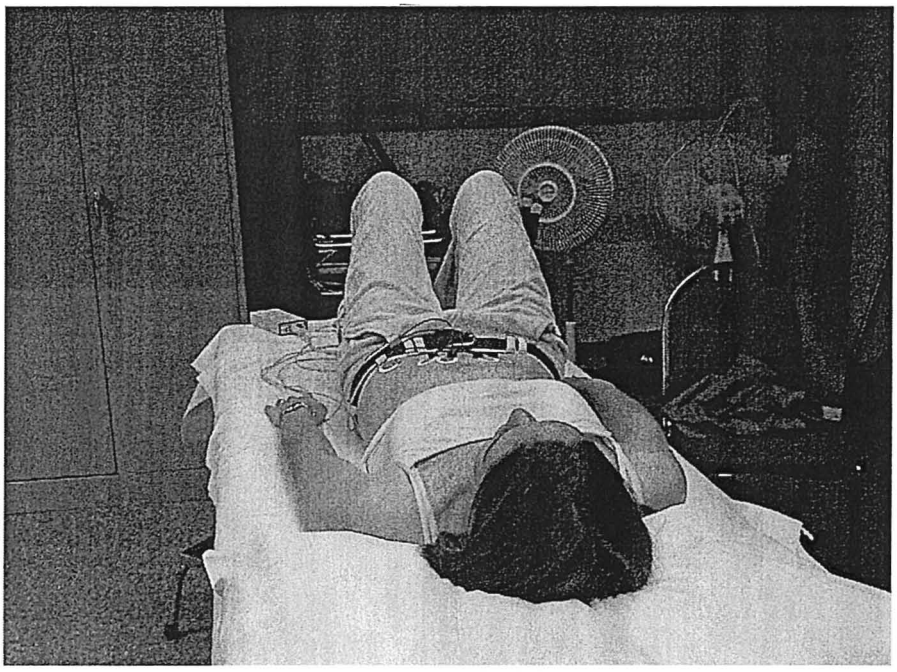


Figure 5: Experimental Setup

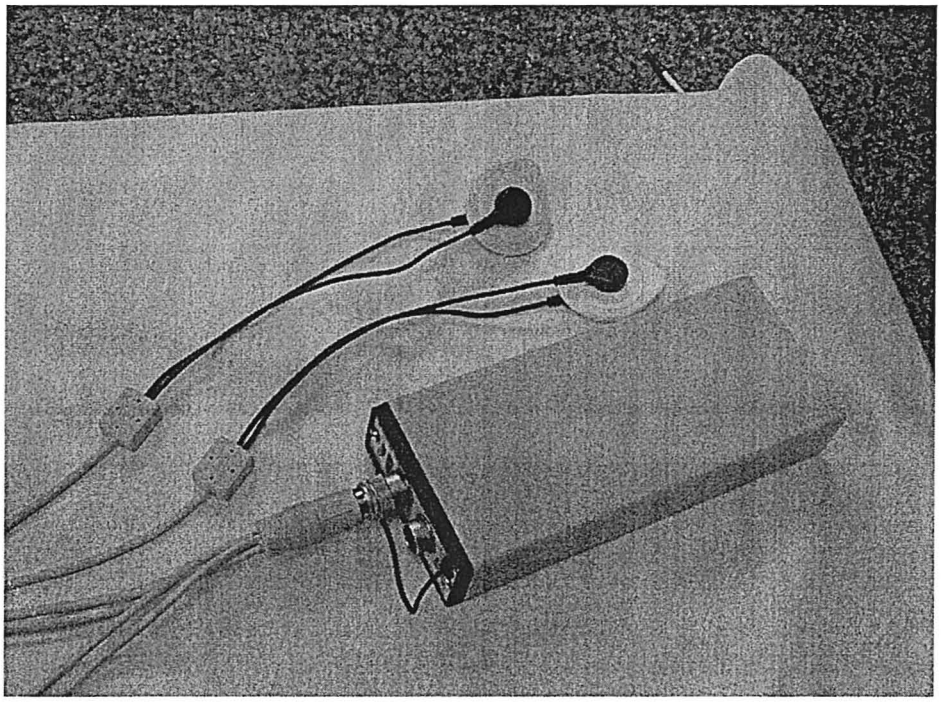


Figure 6: EMG transmitter and Lead 3 & 4 placement to reduce electrode noise

CHAPTER IV

RESULTS

Statistical Analysis:

The results were computed comparing the middle 10 seconds of data collection versus the whole 30 seconds of data collection, pressure biofeedback versus no pressure biofeedback, and right transversus abdominis/ internal oblique versus the left transversus abdominis/ internal oblique. The results showed no significant difference between biofeedback versus no biofeedback, and 10 seconds versus 30 seconds. A significant difference was found between right versus left transversus abdominis/internal oblique.

Demographics:

A frequency distribution table was constructed from the study information to display participant's demographics. Thirty-nine subjects were recruited for the study, however 6 subjects were excluded, as noted previously.

Thirty-three subjects were included in the final analysis of the data. The majority of the subjects were female (n=22), with range of 22-52 years and a mean of 2. The minority of subjects were male (n=11), with a range of 18-54 years and a mean of 28 years. The overall mean for both male and female was 26 years old. Most participants were not previously involved in a Pilates program. (Table 1.)

10 second vs. 30 second:

The Paired T-Test analysis showed there was no significant difference (t(-.442 ± .249,p =.659) between the data collected in the mid 10 seconds of the abdominal draw-in maneuver and the entire 30 second contraction of the internal oblique during the abdominal draw-in maneuver. It was originally intended to use the mid 10 seconds of data for statistical analysis due to the idea that it would have the greatest and more accurate EMG activity of muscle recruitment. However, once data was analyzed there was no difference between the whole 30 seconds and the mid 10 seconds.

Biofeedback vs. No-Biofeedback:

This study failed to demonstrate a significant difference between the used of pressure bio-feedback and using no pressure bio-feedback. There was no significant difference [F(1, 160) =.091, p=.763 power=.060] between the mean of the right and left internal oblique EMG activity with biofeedback and without bio-feedback. (Table 2 and Table 3 for means.)

Right vs. Left:

There was a significant difference between right and left transversus abdominis/internal oblique, regardless of the biofeedback variable (yes, no) using a Two-way ANOVA design, [F(2, 160) = 52.219; p<.001, eta^2=.395; power = 1.0]. (Table 4) The right transversus abdominis/internal oblique showed an increase in EMG recruitment compared to the left. This difference is postulated to be related to equipment malfunction or other interference and error.

Interactions between biofeedback variable and muscle variable:

The interaction was analyzed between the biofeedback variable (yes, no) and the muscle variable (right, left, mean right and left internal oblique). There was no significant difference in the interaction between these variables. [$F(2, 160) = .031$, $p = .969$, power = .55]. (Graph 1)

Table 1: Demographics of subjects included in study

	N	Percent	Mean +/- SD	Range
Gender				
Males	11	33		
Females	22	67		
Previous Pilates Participation				
Yes	5	15		
No	28	85		
Age				
Males			28 +/- 9.7	18-54
Females			26 +/- 7	22-52
Total			26 +/- 8	18-54

Table 2: EMG means without the use of pressure biofeedback

Means, No Biofeedback				
			95% Confidence Interval	
	Mean	**Std Error**	**Lower Bound**	**Upper Bound**
Left	26.945	1.062	24.848	29.043
Right	16.358	1.062	14.26	18.455
Mean	21.653	1.062	19.556	23.573

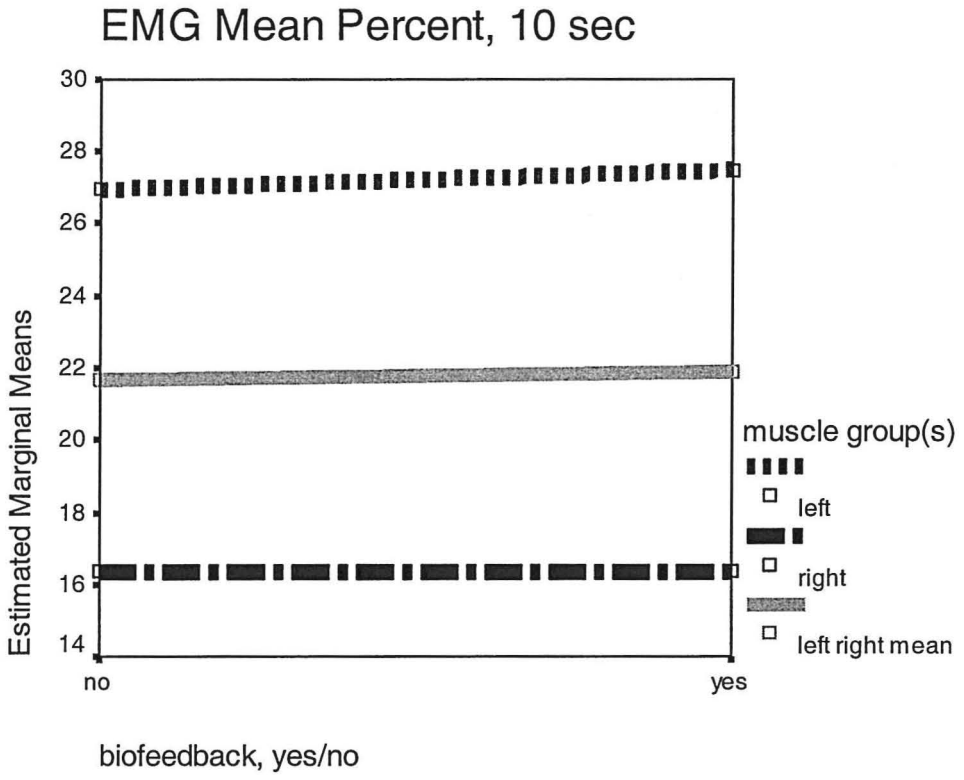
Table 3: EMG means with the use of pressure biofeedback

Means, Biofeedback				
			95% Confidence Interval	
	Mean	Std Error	Lower Bound	Upper Bound
Left	27.476	1.062	25.378	29.573
Right	16.358	1.062	14.26	18.455
Mean	21.909	1.062	19.812	24.006

Table 4: EMG means with and without pressure biofeedback

Means, Computed					
				95% Confidence Interval	
	Mean	SD	Std Error	Lower Bound	Upper Bound
Left	26.945	13.087	1.062	24.848	29.043
Right	16.358	8.437	1.062	14.26	18.455
Mean	21.653	8.925	1.062	19.556	23.573

Graph 1: Interactions



CHAPTER V

DISCUSSION

Our study demonstrated there was no significant difference between the use bio-feedback and no bio-feedback for the transversus abdominis EMG activity. There was a significant difference between the right and left internal oblique/transversus abdominis EMG activity. Since there was a consistent increase in the right internal oblique/transversus abdominis EMG activity, we further analyzed the data. Results displayed that the right side EMG activity was skewed and kurtosed, however the left side had no skewness or kurtosis. Based on this information, we ran a nonparametric statistical analysis on the left EMG data. Results from the nonparametric analysis of the left side internal oblique/transversus abdominis showed there still was no significant difference between the biofeedback variable. The nonparametric statistical results were the same as the parametric results; therefore the parametric results were used to explain the data.

There could be many explanations for the significant difference between the right and left EMG activity. Possibilities include equipment malfunctions with the lead or transmitter on the right side and experimenter error through testing set up.[21] An effort was made to locate a malfunctioning lead or transmitter, but the attempt was unsuccessful

as a result of duplicates of equipment and other studies being conducted in the research area.

Limitations and Recommendations:

The exercise chosen for this study was relatively simple and easy to perform. Further studies may want to incorporate a more complex stabilization exercise, such as adding upper and/or lower extremity movements. It has been shown that shoulder flexion activated the transversus abdominis before the prime mover muscle (anterior portion of the deltoid) and the rectus abdominis.[18] Therefore, shoulder flexion would be beneficial to include in the stabilization exercises in order to recruit more muscle activity of the transversus abdominis.

A maximum voluntary contraction was used in this study to normalize the data. It has been recommended in core stabilization articles with participants who have low back pain to use a submaximal contraction such as a double leg raise exercise.[3,16] It has been shown that maximal contractions have been unreliable in subjects with low back pain; therefore a submaximal contraction has been used.[3,16]

This study also had up to 8 practice trails immediately prior to data collection which may have led to carryover of the learned task. It is recommended that subjects come in on separate days for practice trials and data collection to prevent a learning curve.

It is shown that EMG activity is more accurate with the ectomorphic and mesomorphic populations.[9] Skin folds standards may be set in future studies and incorporated into the exclusion criteria in order to reduce impedance of adipose tissue and subcutaneous tissue overlying the musculature. Further impedance with the use of

surface EMG was likely to occur due to the deep anatomical location of the transversus abdominis/internal oblique musculature.[9]

If equipment and training were available, ultrasonography would have been more accurate in recording transversus abdominis activity. Ferreira et al[22] studied ultrasound compared to needle EMG of the transversus abdominsis in patients with low back pain and a control group. They found ultrasonography was correlated with needle EMG data. The validity and reliability of ultrasonography has been established in a previous study.

The EMG equipment may have been the cause of the skewed and kurtosed data. Frequent inspections of equipment may be necessary to ensure proper functioning of EMG leads and transmitters.

Future studies may want to look at the possibility of having a control group with no instruction while performing the supine draw-in maneuver exercise and another group with instruction on how to perform the exercise and pressure biofeedback unit to analyze whether a learning curve has an effect on the results of the study.

Clinical Relevance:

The supine draw-in maneuver is effective in recruiting the internal oblique/transversus abdominis for core stabilization. This exercise could be used in the treatment and prevention in patients with low back pain through the activation of the internal oblique/transversus abdominis. The activation of these muscle has been found to significantly decrease pain and patients have a significantly fewer episodes of low back pain.[3,23]

This study found instruction alone for the supine draw-in maneuver was sufficient to produce the desired muscle contraction. Pressure biofeedback does not provide a

significant advantage in instruction of this exercise. The results showed that there is no significant difference in EMG activity with and without pressure biofeedback.

Conclusion:

The aim of this study was to test the reliability and validity of the STABILIZER™ Pressure Bio-Feedback unit specifically for core stabilization exercises. There has not been much research completed on this device used for core stabilization exercises. This study failed to demonstrate clinical significance in the use of pressure biofeedback. Although, there was a significant difference between the right and left internal obliques/transversus abdominis; there was no significant difference with the use of pressure biofeedback versus without it.

Differences between the right and left may be due to the experiment setup, experimental error, and equipment malfunction. Instruction alone for the supine draw-in maneuver was sufficient to produce the desired muscle contraction. This study provided evidence that pressure biofeedback does not show a significant advantage in instruction of this exercise. However, this study was performed on a normal population; if it was performed on a patient population with low back pain, this device may show a significant difference in muscle recruitment. Further research needs to be performed to confirm our results before utilizing the pressure bio-feedback device in clinical use.

APPENDIX

Appendix A

University of North Dakota Human Subjects Review Form

All research with human participants conducted by faculty, staff, and students associated with the University of North Dakota, must be reviewed and approved as prescribed by the University's policies and procedures governing the use of human subjects. It is the intent of the University of North Dakota (UND), through the Institutional Review Board (IRB) and Research Development and Compliance (RD&C), to assist investigators engaged in human subject research to conduct their research along ethical guidelines reflecting professional as well as community standards. The University has an obligation to ensure that all research involving human subjects meets regulations established by the United States Code of Federal Regulations (CFR). When completing the Human Subjects Review Form, use the "IRB Checklist" for additional guidance.

Please provide the information requested below:

Principal Investigator: Schawnn Decker, Kimberly Rzeszutko, Jan Kruse, Jenni Freie, Amanda Kvien

Telephone: (701) 777-2831 E-mail Address: sdecker@medicine.nodak.edu

Complete Mailing Address: Schawnn Decker
Dept. of Physical Therapy
UND School of Medicine & Health Sciences
PO Box 9037
Grand Forks, ND 58202-9037

School/College: University of North Dakota Department: Physical Therapy

Student Adviser (if applicable): Tom Mohr

Telephone: (701) 777-2831 E-mail Address: tommohr@medicine.nodak.edu

Address or Box #: PO Box 9037, Grand Forks, ND 58202-9037

School/College: University of North Dakota Department: Physcial Therapy

Project Title: Effectiveness of pressure biofeedback in activation of transverse abdominis during abdominal draw-in maneuver.

Proposed Project Dates: Beginning Date: May 23, 2005 Completion Date: May 13, 2006
(Including data analysi

Funding agencies supporting this research: Private Funding

(A copy of the funding proposal for each agency identified above MUST be attached to this proposal when submitted.)

___ YES or _X_ NO Does the Principal Investigator or any researcher associated with this project have a financial inte in the results of this project? If yes, please submit, on a separate piece of paper, an additional explanation of the financial interest (other than receipt of a grant)

If your project has been or will be submitted to other IRBs, list those Boards below, along with the status of each proposal.

_____ Date submitted: _____ Status: ___ Approved ___ Penc

_____ Date submitted: _____ Status: ___ Approved ___ Penc

Type of Project: Check "Yes" or "No" for each of the following.

X	YES or ___ NO	New Project	___	YES or X NO	Dissertation/Thesis
___	YES or X NO	Continuation/Renewal	X	YES or ___ NO	Student Research Project

___ YES or X NO Is this a Protocol Change for previously approved project? If yes, submit a signed copy of this form with the changes bolded or highlighted.

___ YES or X NO Does your project involve medical record information? If yes, complete the HIPAA Compliance Application and submit it with this form.

___ YES or X NO Does your project include Genetic Research? If yes, refer to Chapter 3 of the Researcher Handbook for additional guidelines regarding your topic.

___ YES or X NO Does your project include Internet Research? If yes, refer to Chapter 3 of the Researcher Handbook for additional guidelines regarding your topic.

___ YES or X NO Will subjects or data be provided by Altru Health Systems? If yes, submit two copies of the proposal. A copy of the proposal will be provided to Altru.

___ YES or X NO Will research subjects be recruited at another organization (e.g., hospitals, schools, YMCA) or v assistance with the data collection be obtained from another organization?

If yes, list all institutions: _____

Letters from each organization must accompany this proposal. Each letter must illustrate that the organization understands their involvement in that study, and agrees to participate in the study. Letters must include the name and title of the individual signing the letter and, if possible, should be printed on letterhead.

Subject Classification: This study will involve subjects who are in the following special populations: Check all that apply.

___	Minors (< 18 years)	X	UND Students
___	Prisoners	___	Pregnant Women/Fetuses
___	Persons with impaired ability to understand their involvement and/or consequences of participation in this res		
x	Other Participants age 18-55 from the local community		

For information about protections for each of the special populations, refer to Chapter 5 of the Researcher Handbook.

This study will involve: Check all that apply.

___	Deception	___	Stem Cells
___	Radiation	___	Discarded Tissue
___	New Drugs (IND)	___	Fetal Tissue
___	Non-approved Use of Drug(s)	___	Human Blood or Fluids
___	Recombinant DNA		Other
X	None of the above will be involved in this study		_____

I. Project Overview

Please provide a brief explanation (limit to 200 words or less) of the rationale and purpose of the study, introduction of any sponsor(s) of the study, and justification for use of human subjects and/or special populations (e.g., vulnerable populations such as minors, prisoners, pregnant women/fetuses).

Low back pain is frequently seen in the physical therapy clinic. Core stabilization is a common component in the plan of care for the treatment of these patients. Pressure biofeedback can be a teaching method for increasing patient awareness of transverses abdominis/trunk control. Pressure biofeedback is a safe device that monitors the

positioning of the low back and provides feedback to ensure quality movements during exercises. However, currently there is minimal research available on its application and effectiveness.

The purpose of this research project is to evaluate and analyze the activity in the transverse abdominis and internal oblique during the supine abdominal draw-in maneuver while using pressure biofeedback. Electromyography (EMG) will be used to measure muscle activity. Surface electrodes will be placed over the internal oblique/transverse abdominis. This will allow us to report the clinical effectiveness of pressure biofeedback use for core stabilization exercises.

We will compare EMG muscle activity of the transversus abdominis/internal oblique during a core stabilization exercise with pressure biofeedback reading and without pressure biofeedback reading. We anticipate that with the use of the pressure biofeedback during the core stabilization exercise there will be increased EMG muscle activity in the transversus abdominis/internal oblique muscles compared to without. We predict this information will beneficial to the field of Physical Therapy in instruction of exercise programs for patients with low back pain.

II. Protocol Description

Please provide a succinct description of the procedures to be used by addressing the instructions under each of the following categories. Individuals conducting clinical research please refer to the "Guidelines for Clinical-Research Protocols" on the Research and Program Development website.

1. Subject Selection.

a) Describe recruitment procedures (i.e., how subjects will be recruited, who will recruit them, where and when they will be
recruited and for how long) and include copies of any advertisements, fliers, etc., that will be used to recruit subjects. If incentive payments will be made to anyone for enrolling participants, describe the incentive package.

Subjects will be recruited through advertisement in the Grand Forks local Herald, along with flyers around the University of North Dakota campus. Our recruitment will be completed by the researchers. Participants will be recruited to the Physical Therapy department for approximately one hour on one day. An incentive program will include a home exercise program handout and instruction session on core stabilization exercises. See addendum for example of flyer.

b) Describe your subject selection procedures and criteria, paying special attention to the rationale for including subjects from any of the categories listed in the "Subject Classification" section above.

Our subjects will include healthy males and females between the ages of 18 to 55 years old from the UND campus and surrounding community. The subjects will participate voluntarily. The subjects will be selected because of their age and health status. The UND students were included in our participant population because they are easily accessible.

c) Describe your exclusionary criteria and provide a rationale for excluding subject categories.

Subjects will complete a written screening questionnaire to exclude any of the participants with history of low back pain within the past 12 months, or any participant that is currently pregnant. Screening questionnaires will also gather information regarding other conditions such as history of cardiac conditions, abnormal blood pressure, skeletal/postural abnormalities of the spine, pregnancy, and history of neurological disorders or diseases. Any of these conditions may potentially bias our outcome, or pose risk to the patient (ie. Pregnancy and abnormal blood pressure) Participants will also be excluded if unable to maintain pressure of 40 mmHg on the pressure biofeedback bladder after practice trials of the supine abdominal drawing maneuver. See addendum for screening questionnaire.

d) Describe the estimated number of subjects that will participate and the rationale for using that number of subjects.

We are expecting to recruit approximately 35 volunteers for our research study. For statistical purposes, any sample size less that 30 does not adequately represent the population. To ensure over 30 final participants, we chose 35 potential subjects to account for participant dropout.

e) Specify the potential for valid results. If you have used a power analysis to determine the number of subjects, describe
your method.

We chose 35 subjects to decrease the chance of sample error. Adhering to accurate testing procedures and computer analysis will ensure valid results.

2. Description of Methodology.

a) Describe the procedures used to obtain informed consent.

Informed consent by the subjects will be obtained through independent and voluntary signature of an information and consent form. See attached form.

b) Describe where the research will be conducted. Document the resources and facilities to be used to carry out the proposed research. Please note staffing, funding, and space available to conduct this research.

The research will be conducted at the Physical Therapy department at the University of North Dakota. Address is as follows: 501 North Columbia Road, P.O. Box 9037, Grand Forks, ND 58202-9037. Within the Physical Therapy department, space is available for setting up the EMG and biofeedback devices that are available for the research project.. We will be under the supervision of Tom Mohr, and Schawnn Decker.

c) Indicate who will carry out the research procedures.

Kimberly Rzeszutko, Jenni Freie, Jan Kruse, Amanda Kvien, Schawnn Decker and Tom Mohr.

d) Briefly describe the procedures and techniques to be used and the amount of time that is required by the subjects to complete them.

During our study, muscle activity of our subjects will be recorded by surface electromyography (EMG). The skin will be cleansed with alcohol and shaved if needed prior to EMG electrode placement. Placement of electrodes over the transverse abdominis/internal oblique will be determined according to standard electrode placement charts. A baseline maximal voluntary contraction (MVC) of the transervse abdominis/internal oblique of each subject will be recorded prior to research to normalize data. The EMG data during MVC will be utilized to compare the muscle activity during the supine draw-in maneuver. The subject will perform the supine draw-in maneuver with a 30 second hold with pressure biofeedback reading for 2 repetitions and without pressure biofeedback reading for 2 repetitions. During the pressure biofeedback reading trial subjects will be instructed to maintain pressure at 40mmHg. Prior to these repetitions, subjects will be allowed up to 5 practice trials. If unable to maintain pressure of 40 mmHg on the pressure biofeedback bladder after practice trials, subject will be excluded from the study. The pressure biofeedback bladder will be placed directly above the posterior superior iliac spine (PSIS.) There will be a 1-minute rest between all trials. The EMG computer software will then process the data. The order of pressure biofeedback reading or no pressure biofeedback reading assignments will be random. The subjects will perform up to 12 abdominal repetitions and the study will require approximately one hour of their time.

e) Describe audio/visual procedures and proper disposal of tapes.

There will be no audio/visual recordings of participants in this study.

f) Describe the qualifications of the individuals conducting all procedures used in the study.

Kimberly Rzeszutko, Jenni Freie, Jan Kruse, and Amanda Kvien are all currently in the Doctoral program for Physcial Therapy at UND. The student researchers will be under the supervision of Schawnn Decker, DPT, and Tom Mohr, PT, PhD. All study investigators have attended an EMG instrumentation course.

g) Describe compensation procedures (payment or class credit for the subjects, etc.).
Attachments Necessary: Copies of all instruments (such as survey/interview questions, data collection forms completed by subjects, etc.) must be attached to this proposal.

Subjects will be offered an instruction and demonstration session on a core stabilization home exercise program along with handouts. See addendum for home exercise program.

3. Risk Identification.

a) Clearly describe the anticipated risks to the subject/others including any physical, emotional, and financial risks that might result from this study.

The abdominal draw-in exercise is a minimal risk exercise that is commonly included in core stabilization exercise protocol. Any risks will be minimized through proper instruction of exercise and direct supervision. Any participants who are pregnant or have current low back pain/injury will be excluded from this study.

Participants will be personally responsible for any medical expenses, should an injury occur.

b) Indicate whether there will be a way to link subject responses and/or data sheets to consent forms, and if so, what the justification is for having that link.

The participants will be randomly assigned a number to link them to their demographic information taken on the screening questions, but they will not be linked back to their consent form. Therefore all information will be confidential and blinded to the researcher.

4. Subject Protection.

a) Describe precautions you will take to minimize potential risks to the subjects (e.g., sterile conditions, informing subjects that some individuals may have strong emotional reactions to the procedures, debriefing, etc.).

Risks will be minimized through proper instruction and supervision of participants. Study investigator will ensure proper sterilization of equipment (i.e. mats, electrode skin preparation, and study personnel). Also participants will be informed that they are free to withdraw from the study at anytime.

b) Describe procedures you will implement to protect confidentiality (such as coding subject data, removing identifying information, reporting data in aggregate form, etc.).

The participants will be randomly assigned a number to link them to their demographic information taken on the screening questions, but they will not be linked back to their consent form. Therefore all information will be confidential.

c) Indicate that the subject will be provided with a copy of the consent form and how this will be done.

Prior to participation, subjects will be asked to sign a copy of the consent for our records, and an extra copy of the experimental consent form will be provided to all subjects.

d) Describe the protocol regarding record retention. Please indicate that research data from this study and consent forms will both be retained in separate locked locations for a minimum of three years following the completion of the study.

Describe: 1) the storage location of the research data (separate from consent forms and subject personal data)
2) who will have access to the data
3) how the data will be destroyed
4) the storage location of consent forms and personal data (separate from research data)
5) how the consent forms will be destroyed

Subject information will be kept completely confidential. Participant's names will not be disclosed at any time. Access to this information is limited to people who audit IRB procedures and the study investigators. All study results will be reported in aggregate form. All information obtained throughout this study will be kept in a locked office in the Physical Therapy Department at the University of North Dakota. The consent forms and personal information of our participants will be stored separately from the research results. Once the study is complete, all

participant information will be shredded and destroyed after three years, unless it is of further use for future studies.

e) Describe procedures to deal with adverse reactions (referrals to helping agencies, procedures for dealing with trauma, etc.).

In case of an incident or emergency, all study investigators are CPR certified. If medical care is required, emergency transportation will be arranged to the nearest hospital, and participants will receive the care required.

f) Include an explanation of medical treatment available if injury or adverse reaction occurs and responsibility for costs involved.

In case of an incident or emergency, subjects will be prompted to seek medical care. All medical expenses will be the participant's responsibility.

III. Benefits of the Study

Clearly describe the benefits to the subject and to society resulting from this study (such as learning experiences, services received, etc.). **Please note:** payment is not a benefit and should be listed in the Protocol Description section under Methodology.

This study will benefit the medical community by furthering the information available on trunk stabilization. The results will help the development of teaching methods for home exercise programs for patients with low back pain. The results will also help direct future investigators in their research efforts. Our goal of our study is to show increased abdominal exercise performance with the use of pressure biofeedback. Participants will benefit from the education and training in core stabilization exercise which may have a positive effect on their general health and wellbeing.

IV. Consent Form

A copy of the consent form must be attached to this proposal. If no consent form is to be used, document the procedures to be used to protect human subjects. Refer to the RD&C website for further information regarding consent form regulations.

Please note: Regulations require that all consent forms, and all pages of the consent forms, be kept for a minimum of 3 years after the completion of the study, even if the subject does not continue participation. The consent form must be written in language that can easily be read by the subject population and any use of jargon or technical language should be avoided. It is recommended that the consent form be written in the third person (please see the examples on the RD&C website), and at no higher than an 8th grade reading level. A two inch by two inch blank space must be left on the bottom of each page of the consent form for the IRB approval stamp. The consent form must include the following elements:

See addendum for consent form.

a) An introduction of the principal investigator

b) An explanation of the purposes of the research

c) The expected duration of subject participation

d) A brief summary of the project procedures

e) A description of the benefits to the subject/others anticipated from this study

f) A paragraph describing any reasonably foreseeable risks or discomforts to the subject

g) Disclosure of any alternative procedures/treatments that are advantageous to the subject

h) An explanation of compensation/medical treatment available if injury occurs.

i) A description of how confidentiality of subjects and data will be maintained. Indicate that the data and consent forms will be stored separately for at least three years following the completion of the study. Indicate where, in general, the data and consent documents will be stored and who will have access. The following statement must be included in all consent forms and informational letters: "Only the researcher, the adviser, [if applicable] and people who audit IRB procedures will have access to the data." Please make appropriate additions to the persons that may have access to your research data. Indicate how the data will be disposed of. Be sure to list any mandatory reporting requirements that may require breaking confidentiality.

l) If applicable: an explanation of financial interest must be included.

m) Regarding participation in the study:

1) An indication that participation is voluntary and that no penalties or loss of benefits will result from refusal to participate.

2) An indication that the subject may discontinue participation at any time without penalty, with an explanation of how they can discontinue participation.

3) An explanation of circumstances which may result in the termination of a subject's participation in the study.

4) A description of any anticipated costs to the subject.

5) A statement indicating whether the subject will be informed of the findings of the study.

6) A statement indicating that the subject will receive a copy of the consent form.

By signing below, you are verifying that the information provided in the Human Subjects Review Form and attachedinformation is accurate and that the project will be completed as indicated.

Signatures:

(Principal Investigator) Date:

(Student Adviser) Date:

Requirements for submitting proposals:
Additional information can be found on the IRB web site at
www.und.nodak.edu/dept/orpd/regucomm/IRB/index.html.

Original Proposals and all attachments should be submitted to Research Development and Compliance, P.O. Box 7134, Grand Forks, ND 58202-7134, or brought to Room 105, Twamley Hall.

Prior to receiving IRB approval, researchers must complete the required IRB human subjects' education. Please go to http://www.und.nodak.edu/dept/orpd/regucomm/IRB/IRBEducation.htm for more information.

The criteria for determining what category your proposal will be reviewed under is listed on page 3 of the IRB Checklist. Your reviewer will assign a review category to your proposal. Should your protocol require full Board review, you will need to provide additional copies. Further information can be found on the RD&C website regarding required copies and IRB review categories, or you may call the RD&C office at 701 777-4279.

In cases where the proposed work is part of a proposal to a potential funding source, one copy of the completed proposal to the funding agency (agreement/contract if there is no proposal) must be attached to the completed Human Subjects Review Form if the proposal is non-clinical; 7 copies if the proposal is clinical-medical. If the proposed work is being conducted for a pharmaceutical company, 7 copies of the company's protocol must be provided.

Please Note: Student Researchers must complete the "Student Consent to Release of Educational Record".

Revised 6/7/04

INVESTIGATOR LETTER OF ASSURANCE OF COMPLIANCE WITH ALL APPLICABLE FEDERAL REGULATIONS FOR THE PROTECTION OF THE RIGHTS OF HUMAN SUBJECTS

I _____
(Name of Investigator)

agree that, in conducting research under the approval of the University of North Dakota Institutional Review Board, I will fully comply and assume responsibility for the enforcement of compliance with all applicable federal regulations and University policies for the protection of the rights of human subjects engaged in research. Specific regulations include the Federal Common Rule for Protection of the Rights of Human Subjects 45 CFR 46. I will also assure compliance to the ethical principles set forth in the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research document, The Belmont Report.

I understand the University's policies concerning research involving human subjects and agree to the following:

1. Should I wish to make changes in the approved protocol for this project, I will submit them for review PRIOR to initiating the changes.

2. If any problems involving human subjects occur, I will immediately notify the Chair of the IRB, or the IRB Coordinator.

3. I will cooperate with the UND IRB by submitting Research Project Review and Progress Reports in a timely manner.

I understand the failure to do so may result in the suspension or termination of proposed research and possible reporting to federal agencies.

_____ _____
Investigator Signature Date

STUDENT RESEARCHERS: As of June 4, 1997 (based on the recommendation of UND 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[1]

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

_____

_____

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.

304030-5
326181-6
340126-0
357217-0

_____ _____

NAID # Printed Name

May 5, 2005 _____ _____

Appendix B

Information and Consent Form

An EMG analysis of the supine draw-in maneuver with the use of pressure biofeedback

Principal investigators: Schwann Decker, Jenni Freie, Jan Kruse, Amanda Kvien, & Kim Rzeszutko

You are being recruited to be a subject in our study using pressure biofeedback during an abdominal muscle exercises. Electromyography will be used to record the muscle activity of your transverses abdominals/internal oblique during this exercise. The purpose of the study is to determine whether the pressure biofeedback device recruits more muscle activity during this exercises compare to without its use. Our goal is to provide information to physical therapists on the effectiveness of this simple clinical device to aide in targeting core muscles in patients.

You were chosen because of you're: 1.) age (18-55 y/o) 2.) deficiency of current low back pain and pregnancy. Failure of a subject to complete all exercises will be excluded from this study.

As a participant of our study we will ask you to arrive 10 minutes prior to your appointed time at the Physical Therapy department at the University of North Dakota. Address is as follows: 501 North Columbia Road, P.O. Box 9037, Grand Forks, ND 58202-9037. For this study you will be required to fill out a screening questionnaire of past and current medical conditions, age, and gender. You will be required to lift up your shirt to approximately 2 inches above your navel. Then your skin will be cleansed with alcohol and shaved if needed. The surface EMG electrodes will be placed in the proper positions over the transversus abdominis/internal oblique. You will perform a sit-up prior to test exercises for a baseline muscle contraction; which will then be compared to the muscle activity during the supine draw-in maneuver. For the testing exercise you will perform the supine draw-in maneuver with a 30 second hold using pressure biofeedback for 2 repetitions and without pressure biofeedback for 2 repetitions. Prior to research you will be given verbal instructions on proper performance of the supine draw-in maneuver with or without pressure biofeedback. You will be allowed 1 practice trail. The pressure biofeedback bladder will be placed under the curve of your low back. You will be a 1-minute rest between all trials. This study will require you to perform a total of 7 abdominal repetitions and will take approximately one hour of your time.

There is a low risk to you as a participant in this study, but there always could be some degree of risk while performing physical testing. Performance of the exercises may result in mild muscle soreness. We feel because of the decreased risk factors and our close supervision the risk of injury is minimal. If injury should occur, we will direct you to the proper medical facilities and you or your third party payer will be responsible for all charges.

All information will be confidential; your name will not be associated with any results of this study. There will be no audio/visual recordings of participants in this study. The screening questionnaire will be assigned a number and will not be associated with this consent form. Both forms will be stored separately in locked files and will not be released without your consent.

You or the researchers have the right to stop or discontinue your participation in this study at any time. You will not be subjected to any prejudice due to your discontinuation.

The researchers are available for your questions or concerns about this study. Contact:

Schwann Decker
(701)-777-6389
501 North Columbia Road P.O. Box 9037
Grand Forks, ND 58202-9037
sdecker@medicine.nodak.edu

For further questions, please contact the Research Development and Compliance at (701)-777-4279. You can request a duplicate of this form and this study's results.

I have read the above information completely. I understand all information presented by_____ to me and agree to participate in this study. If I have any further questions about this study, I will contact the above persons.

_____ _____

Subject's signature Date

University of North Dakota
Institutional Review Board
Approved on JUN 8 2005
Expires on JUN 7 2006

Appendix C

Practice Trial Script:
Give the subject the Screening Form:

Give the subject the Consent Form:

- We are studying the EMG activity of the transversus abdominis during the supine draw-in maneuver with the use of pressure biofeedback and without pressure biofeedback.
- Prior to data collection I am going to have you perform 6 to 8 practice trials. (3 without pressure biofeedback readings and 3-5 using of pressure biofeedback readings.) You will need to perform 4 additional trials during data collection.
- The pressure biofeedback device is a safe device that monitors the positioning of the low back and provides feedback to ensure quality movements during exercises. The pressure biofeedback unit will be set at 40mmHg. We will require you to keep the reading at 40mmHg.
- All information will remain confidential
  - Sign and date
  - Here is copy of the consent form
  - You are free to withdraw at anytime

Practice Trials:

- I will have you lay down on your back with your knees bent and feet flat on the mat.
- I will place the pressure biofeedback bladder under your low back. (Directly above PSISs). Please lift your low back and butt off the matt and I will feel for your PSISs.
- I will instruct you in the performance of the supine draw-in maneuver without the use of pressure biofeedback readings for 3 trials each with a 1-minute rest between trials.
- When I say go contract or tighten your abdominal muscles to drawn in your belly button towards your spine and hold for 30 seconds while maintaining the normal arch in you low back. Do not hold your breath or talk during the trial.
  1. Ready, Set, Go.... Stop.
  2. Ready, Set, Go.... Stop.
  3. Ready, Set, Go.... Stop.
- Now I will instruct you in the performance of the supine drain maneuver with the use of pressure biofeedback for three trials with a 1-minute rest between trials.
- I will set the pressure at 40 mmHg and I will require you to keep the reading as close as possible to 40 mmHg or the orange bar during the maneuver.
- When I say go contract or tighten you abdominal muscles to draw in your belly button towards your spine and hold for 30 sec while maintaining the normal arch in your low back. Do not hold your breath or talk during the trial.
  1. Ready, Set, Go.... Stop.
  2. Ready, Set, Go.... Stop.
  3. Ready, Set, Go.... Stop.

Appendix D

Test Trial Script:

MVC:

- You are free to withdraw at anytime
- Hello, my name is Amanda and this is Kim/Jan. We are going to take EMG readings of your internal oblique which an abdominal muscle. I am going to put these EMG leads onto the electrodes which Jenni placed on your skin. (Record lead noise, tell subject to relax.
- The first exercise you will be doing is an abdominal crunch.
- Please bend your knees and cross your arms on your chest.
- When we say go, you will contract your abdominal muscle and bring upper body off the table until your shoulder blades clear the table. I will let you know when you have cleared your shoulder blades from the table and then you can relax and lower your upper body back onto the table. (Do this 2 times for 5 secs, first time to see if computer is working.)
- You will have one minute to rest between exercises. Remain breathing during the exercise. Do you have any questions?

Ready, Set, Go.
Relax

Draw in- feedback:

- Next, I am going to place a biofeedback air bladder under your lower back (directly above PSISs)
- Keep your legs bent and lay flat on your back.
- I am going to pump the pressure on this gauge up to 40 mmHg. I am going to let you look at this gauge, and I want you to maintain the needle as close to 40 mmHg which is the orange bar.
- Contract or tighten your abdominal muscles and draw in your belly button towards your spine while maintaining the normal arch in your low back. Hold this contraction for 30 seconds, I will tell you when you can relax. Maintain the needle as close to the orange bar as you can.

Ready, Set, go.
Relax.

Draw in- no feedback:

- I will have you lay down on your back with your knees bent and feet flat on the mat.
- I will place the pressure biofeedback bladder under your low back. (directly above PSISs)
- I will instruct you in the performance of the supine draw-in maneuver without the use of pressure biofeedback readings

- When I say go contract or tighten your abdominal muscles to drawn in your belly button towards your spine and hold for 30 sec. while maintaining the normal arch in your low back.
- Ready, Set, go……stop.

Appendix E

Screening Information

Participant's Number:

Please fill out the following information to the best of your knowledge:

Age: _____

Sex: _____

Past Physical Traumatic Event:

History of Low Back Pain? Yes: ____ No: ____

If yes, when was the last episode? _____

Are you pregnant? Yes: ____ No: ____

Please list any past medical conditions: Check if applicable

_____High or low blood pressure
Please list: _____

_____Cardiac Conditions
Please list: _____

_____Skeletal or postural abnormalities of the spine
Please list: _____

_____History of Neurological disorders
Please list: _____

Are you currently involved in any core stabilization or Pilates exercises? Yes ___ No ___

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