Development and Validation of the Thoracic-Lumbar Control Scale to Measure Strength and Coordination of Trunk Muscles

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Specific aims

1) Define a set of muscle tests and clinical maneuvers that most efficiently measure and provide maximal discrimination of motor ability for muscles innervating the thoracic and lumbar regions of the spinal cord

2) Determine the measurement properties and measurement efficiency of the individual muscle tests, clinical maneuvers and the entire scale

3) Conduct a multi site reliability study for the trunk scale.

4) Conduct a construct validity investigation of the scale

5) Determine the predictive value of the newly defined sets of muscle tests

Background

The proposed research module presented by TMSCIS is designed to develop a clinical scale for measuring the strength of trunk musculature. There are currently no scales designed to measure the strength of the muscles of the trunk. The most commonly used clinical measures have largely ignored the trunk and focused on the four extremities[12-14]. However, with advances in restorative, regenerative as well as activity based therapies, there is a need for scales that can measure the restoration of function in the trunk muscles. Interventions intended to restore spinal cord function or repair spinal

cord injury will most likely be tested in patients with thoracic injuries, and the effects will most likely be only detectable for a few spinal segments[3]. Therefore the need for standardized scales that can measure changes in spinal cord function in the thoracic regions is great. A scale so developed would have an impact on clinical trials or activity based therapy outcomes measurement. This scale development project will employ both item response theories and classical reliability and validity. These validating studies will utilize samples from both collaborating Model Systems centers and NeuroRecovery Network centers to assess wide applicability of the scale.

The International Standards for Neurological Classification of Spinal Cord Injury were developed by the American Spinal Injury Association (ASIA) to provide a standardized physical examination and categorization procedures to facilitate communication concerning the level and extent of spinal cord injuries[14] (SCI). The key muscles designated in the ASIA motor score (AMS) component of the standards were chosen to facilitate the logical deduction level of the spinal injury. Most muscles have multiple root innervations. The key muscles designated in the AMS were chosen partly because the pattern of root innervations and manual muscle testing results would help the examiner locate the precise level of the SCI. The level of SCI in the thoracic and lumbar spine is determined by the use of the sensory ratings from the ASIA examination. There are no key muscles defined between the levels T-01 and L-02 because the muscles of the trunk are innervated by many spinal nerve roots thus making the determination of a level of injury with these tests impractical.

The AMS is the only clinical scale of motor function to become widely accepted of motor function to be and to be used as an index of recovery following spinal cord

injury (SCI)[3, 15-18] and as an outcome measure for clinical trials[19, 20]. However, the AMS was developed and validated as a classification device, not an outcome measure. Evidence has been published that the twelve level gap between the upper extremity key muscles and lower extremity key muscles presents several measurement problems that cause the AMS to be insensitive to change, unable to distinguish motor ability in large portions of the SCI population[21] and invalid for use in clinical trials as a single total score[13]. In distributions of motor scores as much as 30% of the scores will have the same score value of 50[21]. The AMS consistently shows this large concentration of observations at the single score of 50. This condition demonstrates that the AMS is insensitive as well as incapable of distinguishing between levels of motor ability for a large group of patients. Both factor analysis and item response theory (IRT) investigations suggest that the AMS total score is invalid for use as a single score. Factor analysis show an orthogonal two factor solution with simple structure[21]. When the AMS is analyzed with IRT, the sum of the information functions from the separate upper and lower extremity scales exceeds the function for the single scale[22-25] demonstrating that a single motor scale violates the unidimensionality assumption, and thereby introduces measurement error.

	R^2	
Predictor	**Self Care**	**Mobility**
Single AMS		
ASIA Motor Score Total	.235	.357
Separate Upper and Lower		
Upper Extremities	.328	.099
Lower Extremities	.057	.342
Separate Upper and Lower plus Sensory Scale		
Upper Extremities	.219	.062
Sensory Variable	.226	.201
Lower Extremities	.087	.206

Table 2. Demonstration of the incremental gain in predictive value of the ASIA Motor Score when broken into its component parts and with sensory scale augmentation.

Evidence suggests that sensory measures from the trunk region increases the predictive value of the AMS analyzed as a single score or as separate upper and lower motor scores[26]. A weighted linear composite of the light touch and pinprick sensory ratings (n = 448) between T-02 and L-01 increased the total proportion of variance accounted for in FIM self care ***change scores*** (from admission to discharge) from 23% to 53% and mobility change scores from 35% to 46%[26]. See Table 2. This pattern demonstrates that measurements of spinal cord function from the thoracic and lumbar region of the spine do add power to the prediction of functional recovery that can not be obtained from the upper and lower extremities alone. However, using sensory ratings as an indirect measure of muscle strength may not be optimal[3].

The musculature of the thoracic and lumbar regions was excluded from the ASIA motor score because of the innervation from multiple nerve roots made determination of a distinct level of injury impractical. However, the muscles innervated by the thoracic and lumbar spine play key roles in body positioning and posture which are very important in conducting functional activities such as ambulation, reaching and activities of daily living (ADL)[4]. This study proposes to develop a clinical scale that will measure the motor ability in the thoracic and lumbar regions.

Methods

Participants: Participants for this investigation will consist of 500 medically stable patients with spinal cord injury. Four hundred patients will be necessary to provide adequate stability of the item parameters in the scale calibration phase. The

remaining 100 patients will provide adequate statistical power to test the construct validity of the resulting scale.

The patient recruitment schedule depends on the number of centers participating in this project. Table 3 lists several scenarios showing the project is feasible with as few as four centers collecting 30 records per center per year. The multi-center reliability study will require no fewer than four centers to provide adequate generalizability of the results.

Number of Centers	Records per year	Duration of the study in years	Estimated Cost per center Calibration Phase	Estimated Cost per center Validation Phase
4	20	6.25	$6,750	$2,156
	30	4.25		
5	20	5.00	$5,400	$1,725
	30	3.50		
6	20	4.25	$4,500	$1,438
	30	2.75		
7	20	3.50	$3,860	$1,233
	30	2.50		
8	20	3.25	$3,375	$1,078
	30	2.25		

Table 3. Estimate of the study duration and cost by the number of centers involved and the number of cases per year per center.

Inclusion criteria:

1) Medically stable and afibrile
2) Spinal stability without external immobilizing devices (spinal orthoses)
3) Cervical motor incomplete injury or injury in thoracic, lumbar or sacral regions.
4) receiving treatment in Model SCI System.
5) Cognitively able to comprehend and follow instructions.

Exclusion criteria:

1) cervical complete SCI with no sparing extending beyond key muscles at T01

2) spinal instability

3) Any medical complication that would prevent full participation (e g decubitus ulcers)

Data

The data collection for this investigation will consist of two phases, a scale development phase (first 400 cases) and a scale validation phase (last 100). During both phases data on the eleven new items, four manual muscle tests rated bilaterally and three clinical ratings of supine to sit, sit to supine and sitting posture will be collected. These elements will need to be collected on all 500 subjects. Table 3 provides the details for the new data elements. The manual muscle tests will be performed and scored in compliance with the procedures outlined in Daniels and Worthingham's Muscle testing 7th Ed.[27] (precise scoring criteria are found in the Appendix). The clinical ratings will be rated on the well known levels of assistance (min, mod and max). The evaluation of unassisted sitting will have the rating scale defined in Table 3. The rating scale was developed for this investigation. Data used to calibrate the items will not be included in the validation phase.

Procedures

Patients will be rated on the MMT and clinical maneuvers as close to discharge from initial rehabilitation as possible or in the outpatient setting. The patient can be evaluated in an outpatient setting if necessary. During the scale development phase of this investigation (the first 400 patients), only the eleven new data elements need to be

recorded. The ratings must be within one week of the full ASIA examination during the scale validation phase (last 100 patients). In the validation phase the patients will also be rated on additional data for evaluation (i.e., Balance, functional reach Etc.).

<table>
<tr><th colspan="4">Manual Muscle Tests</th></tr>
<tr><th>Maneuver</th><th>Muscles</th><th>Root segment</th><th>Rating scale</th></tr>
<tr><td>Trunk extension</td><td>Iliocostalis Thoracis;
Iliocostalis Lumborum;
Longissimus thoracis;
Spinalis thoracis;</td><td>T-01 to L-05</td><td>0-5*</td></tr>
<tr><td>Elevation of the hip</td><td>Quadratus Lumborum</td><td>T-12 to L-03</td><td>0-5*</td></tr>
<tr><td>Trunk Flexion</td><td>Rectus abdominis</td><td>T-07 to T-12</td><td>0-5*</td></tr>
<tr><td>Trunk rotation</td><td>Obliquus externus Abdominis
Obliquus internus Abdominis</td><td>T-07 to L-01
T-07 to T-12</td><td>0-5*

*MMT rating scale:
As defined in Daniels and Worthington</td></tr>
<tr><th colspan="4">Clinical Ratings</th></tr>
<tr><th>Maneuver</th><th colspan="3">Rating Scale</th></tr>
<tr><td>Supine to sit and Sit to supine</td><td colspan="3">0 = Dependent to max assist;
1 = Mod assist;
2 = Min assist;
3 = No assist</td></tr>
<tr><td>Beevor"s Sign</td><td colspan="3">0 = Negative
1 = Positive</td></tr>
<tr><td>Sitting Balance
Standing Balance</td><td colspan="3">0 = Max assist to dependent to maintain Balance
1 = Moderate assist to dependent to maintain Balance
2 = Minimal assist to dependent to maintain Balance
3 = Maintains independently unable to perform excursions
4 = Maintains with Minimal excursions of trunk
5 = Maintains with moderate excursions of trunk at edge of base of support
6 = Maintains with Maximal excursions of trunk outside the base of support
7 = Maintains in all functional activities</td></tr>
<tr><td>Unassisted Sitting</td><td colspan="3">0 = Unable to sit up;
1 = Able to raise to 45° angle but not 90°;
2 = Sit at 90° with shoulders slumped;
3 = Sit at 90° and head up;
4 =Head up and shoulders back hold for < 1min;
5 = Head up and shoulders back hold for 1 to 5 min;
6 = head up and shoulders back hold > 5min</td></tr>
<tr><td colspan="4">Table 4. Description of the individual scale items and the rating scale that will be used.</td></tr>
</table>

Reliability study: The reliability study will be completed within the first six months of the investigation. The reliability study will be completed in conjunction with the Annual Meeting of the NeuroRecovery Network. A minimum of two clinical personnel from four centers will be present to observe and rate four different patients on two consecutive days. This study design will provide intra-rater reliability as well as inter-rater reliability coefficients. This will provide the opportunity to estimate the error sources related to variability in the patient, as well as variability in the raters. Intraclass correlation coefficients and standard error will be computed for the MMT and clinical maneuvers separately.

Objective	Year 1				Year 2				Year 3				Year 4				Year 5			
Enlist participating centers	■																			
Reliability Study			■	■																
Prepare reliability Publication				■	■															
Phase I data collection	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■				
Calibrate New scale Items																■	■			
Prepare calibration Publications																■	■	■	■	
Phase II data collection																■	■	■	■	
Validation study																		■	■	
Prepare validation publications																			■	■

Item calibrations: The data from the first 400 cases will be analyzed using item response theory measurement models. It will be essential to determine if the MMT and clinical scales are measuring one construct. The dimensionality of the data will be analyzed using factor analysis. Unidimensional data is necessary for analysis with the Graded Response Model (GRM)[28, 29]. The response frequencies for each item will be examined to determine if the response scale fits the ability range of the participants. If there are response categories with few or no responses, these items may need revision.

The item discrimination and threshold parameters will be examined for fit to the model. The elevation of the scale information function will also be examined. If one or more scales are successfully defined in this manner, it will be possible to accurately determine the amount of motor ability even if not all of the items are assessed.

Construct validity study: In the scale validation phase (last 100 cases) additional data elements will be collected. These data should be routinely available within model systems. These elements are: AMS upper and lower extremity key muscle ratings; light-touch and pin perception sensory ratings between T01 and L02; FIM; other items from the national database that are routinely collected. These data elements will not require calibration since other data sources have provided sufficient samples to develop stable parameter estimates.

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May 07, 2007

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H-21087 - DEVELOPMENT AND VALIDATION OF THE THORACIC-LUMBAR CONTROL SCALE TO MEASURE STRENGTH AND COORDINATION OF TRUNK MUSCLES

APPROVAL VALID FROM 5/7/2007 TO 4/16/2008

Dear Dr. GRAVES

The Institutional Review Board for Human Subject Research for Baylor College of Medicine and Affiliated Hospitals (BCM IRB) is pleased to inform you that the research protocol and consent form(s) named above were approved.

The study may not continue after the approval period without additional IRB review and approval for continuation. You will receive an email renewal reminder notice prior to study expiration; however, it is your responsibility to assure that this study is not conducted beyond the expiration date.

Please be aware that only IRB-approved informed consent forms may be used when written informed consent is required.

Any changes in study or informed consent procedure must receive review and approval prior to implementation unless the change is necessary for the safety of subjects. In addition, you must inform the IRB of adverse events encountered during the study or of any new and significant information that may impact a research participants' safety or willingness to continue in your study.

The BCM IRB is organized and operated according to guidelines of the International Council on Harmonization , the United States Office for Human Research Protections and the United States Code of Federal Regulations and operates under Federal Wide Assurance No. 00000286, issued April 30, 2001. Affiliated hospitals include: the Michael E. Debakey Veterans Affairs Medical Center, St. Luke's Episcopal Hospital, The Methodist Hospital, Texas Childrens Hospital, Texas Institute for Rehabilitation and Research, and the Harris County Hospital District.

Sincerely yours,

JULIE PAMELA KATKIN, M.D.

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Protocol Number: H-21087
Status: Approved
Initial Submit Date: 4/3/2007
Approval Period: 5/7/2007 - 4/16/2008

Section Aa: Title & PI

A1. Protocol Title

DEVELOPMENT AND VALIDATION OF THE THORACIC-LUMBAR CONTROL SCALE TO MEASURE STRENGTH AND COORDINATION OF TRUNK MUSCLES

A2. Principal Investigator

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A3b. Cooperative Agreement

Is this a cooperative agreement protocol?
No

Which institution is theIRB of record?
BCM: Baylor College of Medicine

Section Ab: General Information

A4. Co-Investigators

None

A5. Funding Source:

Other: NIDRR

A6a. Institutions where work will be performed:

TIRR: The Institute for Rehabilitation and Research

A6b. Research will be conducted outside of the United States:

Country:
Facility/Institution:
Contact/Investigator:
Phone Number:

If documentation of assurances has not been sent to the Office of Research, please explain:

A7. Research Category:

Section B: Review Path Determination

B1. Full Board or Expedited Review

Is this an compassionate/emergency use situation?
No

If this is a drug study, is an investigational new drug (IND) application required?
N/A

If this is a device study, is an investigational device exemption (IDE) application required?
N/A

If the research involves ONLY blood collection, are subjects healthy, non-pregnant adults whose weight is at least 110 pounds, with amount drawn less than 550 ml in an 8 week period, and with collection not occurring more frequently than 2 times per week?
N/A

If the research involves ONLY blood collection for other adults and children, considering age, weight and health of subjects, is the amount drawn in an 8 week period less than 50ml or 3 ml per kg, and with collection not occurring more frequently than 2 times per week?
N/A

Does the research involve ONLY the collection of biological specimens for research purposes by noninvasive means? (e.g. Hair; extracted teeth; excreta, sputum and external secretions; placenta removed at delivery; mucosal and skin cells collected by scraping or swab)
N/A

Does the research involve ONLY the collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves? (e.g. EKG, ECHO, EEG, Ultrasound, MRI)
Yes

Does the research involve ONLY materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis)?
N/A

Does the research involve ONLY the collection of data from voice, video, digital, or image recordings made for research purposes?
N/A

Does the research involve ONLY individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies?
N/A

Does the research involve pedigree studies, collection and/or storage of specimens for DNA analysis or gene transfer?

No

B2. Exempt From IRB Review

Not Applicable

B3. Waiver of Subject Authorization

Not Applicable

Section C: Background

The proposed research module is designed to develop a clinical scale for measuring the strength of trunk musculature. There are currently no scales designed to measure the strength of the muscles of the trunk. The most commonly used clinical measures have largely ignored the trunk and focused on the four extremities. However, with advances in restorative, regenerative as well as activity based therapies, there is a great need for scales that can measure the restoration of function in the trunk muscles. Interventions intended to restore spinal cord function or repair spinal cord injury will most likely be tested in patients with thoracic injuries, and the effects will most likely be only detectable for a few spinal segments. Therefore the need for standardized scales that can measure changes in spinal cord function in the thoracic regions is great. A scale so developed would have an impact clinical trials or activity based therapy outcomes measurement. This scale development project will employ both item response theories and classical reliability and validity. These validating studies will utilize samples from both collaborating Model Systems centers and NeuroRecovery centers to assess wide applicability of the scale. The International Standards for Neurological Classification of Spinal Cord Injury were developed by the American Spinal Injury Association (ASIA) to provide a standardized physical examination and categorization procedures to facilitate communication concerning the level and extent of spinal cord injuries(SCI). The key muscles designated in the ASIA motor score (AMS) component of the standards were chosen to facilitate the logical deduction level of the spinal injury. Most muscles have multiple root innervations. The key muscles designated in the AMS were chosen partly because the pattern of root innervations and manual muscle testing results would help the examiner locate the precise level of the SCI. The level of SCI in the thoracic and lumbar spine is determined by the use of the sensory ratings from the ASIA examination. There are no key muscles defined between the levels T-01 and L-02 because the muscles of the trunk are innervated by many spinal nerve roots thus making the determination of a level of injury with these tests impractical.

The AMS is the only clinical scale to become widely accepted of motor function to be and to be used as an index of recovery following spinal cord injury (SCI) and as an outcome measure for clinical trials. However, the Motor score was developed and validated as a classification device, not an outcome measure. Evidence has been published that the twelve level gap between the upper extremity key muscles and lower extremity key muscles presents several measurement problems that cause the ASIA motor score to be insensitive to change, unable to distinguish motor ability in large portions of the SCI population21 and invalid for use in clinical trials as a single total score. In distributions of motor scores as much as 30% of the scores will have the same score value of 50. The AMS consistently shows this large concentration of observations at the single score of 50. This condition demonstrates that the AMS is insensitive as well as incapable of distinguishing between levels of motor ability for a large group of patients. Both factor analysis and item response theory (IRT) investigations suggest that the AMS total score is invalid for use as a single score. Factor analysis show an orthogonal two factor solution with simple structure. When the ASM is analyzed with IRT, the sum of the information functions from the separate upper and lower extremity scales exceeds the function for the single scale demonstrating that a single motor scale violates the unidimensionality assumption, and thereby introduces measurement error. Evidence suggests that sensory measures from the trunk region increases the predictive value of the AMS analyzed as a single score or as separate upper and lower motor scores. A weighted linear composite of the light touch and pinprick sensory ratings (n = 448) between T-02 and L-01 increased the total proportion of variance accounted for in FIM self care change scores (from admission to discharge) from 23% to 53% and mobility change scores from 35% to 46%. See Table 1. This pattern demonstrates that measurements of spinal cord function from the thoracic and lumbar region of the spine do add power to the prediction of functional recovery that can not be obtained from the upper and lower extremities alone. However, using sensory ratings as an indirect measure of muscle strength may not be optimal. The musculature of the thoracic and lumbar regions was excluded from the ASIA motor score because of the innervation from multiple nerve roots made determination of a distinct level of injury impractical. However, the muscles innervated by the thoracic and lumbar spine play key roles in body positioning and posture which are very important in conducting functional activities such as ambulation, reaching and Activities of daily living (ADL)4.

Section D: Purpose and Objectives

1.Define a set of muscle tests that most efficiently measure and provide maximal discrimination of motor ability for muscles innervated the thoracic and lumbar regions of the spinal cord that when combined comprise a clinical scale of thoracic and lumbar control of posture and stability. 2.Determine the measurement properties and measurement efficiency of the individual muscle tests and the entire scale 3.Conduct a multi site reliability study for the trunk scale. 4.Determine the relation between the trunk muscle items and the upper and lower extremity motor items defined in the ASIA standards 5.Determine the predictive value of the newly defined sets of muscles

Section E: Protocol Risks/Subjects

E1. Risk Category

(45 CFR 46.404) Category 1: Research not involving greater than minimum risk.

E2. Subjects

Gender:
Both

Age:
Adolescent (13-17 yrs), Adult (18-64 yrs), Geriatric (65+ yrs)

Ethnicity:
All Ethnicities

Primary Language:
English, Spanish

Groups to be recruited will include:
Patients

Vulnerable populations to be recruited as subjects:

Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?

Section F: Design/Procedure

F1. Design

Select one category that most adequately describes your research:
Other

Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.

The data collection for this investigation will consist of two phases, a scale development phase (first 400 cases) and a scale validation phase (last 100). During both phases data on the eleven new items, four manual muscle tests rated bilaterally and three clinical ratings of supine to sit, sit to supine and sitting posture. These elements will need to be collected on all 500 subjects. The manual muscle tests will be preformed and scored in compliance with the procedures outlined in Daniels and Worthingham's Muscle testing 7th Ed. The clinical ratings will be rated on the well known levels of assistance (min, mod and max). The The rating scale was developed for this investigation. Data used to calibrate the items will not be included in the validation phase.

Inclusion Criteria:

1) medically stable and afibrile 2) spinal stability without external protections (body jackets) 3) cervical incomplete injury or injury in thoracic, lumbar or sacral regions. 4) receiving treatment in Model SCI System. 5) Cognitively able to comprehend and follow instructions.

Exclusion Criteria:

1) cervical complete SCI with no sparing extending beyond key muscles at T01 2) spinal instability

F2. Procedure

Patients will be rated on the MMT and clinical maneuvers as close to discharge from initial rehabilitation as possible or in the outpatient setting. The patient can be evaluated in an outpatient setting if necessary. During the scale development phase of this investigation (the first 400 patients), only the eleven new data elements needs to be recorded. The ratings must be within one week of the full ASIA examination during the scale validation phase (last 100 patients). In the validation phase the patients will also be rated on additional data for evaluation (i.e., Balance, functional reach Etc.). Reliability study: the reliability study will be completed within the first six months of the investigation. The reliability study will be completed in conjunction with the Annual Meeting of the NeuroRecovery Network. A minimum of two clinical personnel from four centers will be present to observe and rate four different patients on two consecutive days. This study design will provide intra-rater reliability as well as inter-rater reliability coefficients. This will provide the opportunity to estimate the error sources related to variability in the patient, as well as variability in the raters. Intraclass correlation coefficients and standard error will be computed for the MMT and clinical maneuvers separately. Item calibrations: the data from the first 400 cases will be analyzed using item response theory measurement models. It will be essential to determine if the MMT and clinical scales are measuring the same construct. The dimensionality of the data will be analyzed using factor analysis. Unidimensional data is necessary for analysis with the Graded Response Model28, 29. The response frequencies for each item will be examined to determine if the response scale fits the ability range of the participants. If there are response categories with few or no responses, these items may need revision. The item discrimination and threshold parameters will be examined for fit to the model. The elevation of the scale Information function will also be examined. If one or more scales are successfully defined in this manner, it will be possible to accurately determine the amount of motor ability even if not all of the items are assessed. Validation study: In the scale validation phase (last 100 cases) additional data elements will need to be collected. These data should be routinely available within model systems. These elements are: AMS upper and lower extremity key muscle ratings; light-touch and pin perception sensory ratings between T01 and L02; FIM; other items from the national database that are routinely collected. These data elements will not require calibration since other data sources have provided sufficient samples to develop stable parameter estimates. In addition to validation against other clinical ratings we will seek to validate this set of items using electrophysiological recordings of the muscle activity.

F3. Subject Access to Research Related Health Information

Subject may never be able to obtain limited research health information.

Provide an explanation:

All colected data will be de-identified.

Section G: Sample Size/Data Analysis

G1. Sample Size

How many subjects (or specimens, or charts) will be used in this study?

Local: 50 Worldwide: 500

Please indicate why you chose the sample size proposed:

Participants for this investigation will consist of 500 medically stable patients with spinal cord injury. This number of participants is necessary to provide adequate stability of the item parameters in the scale calibration phase and adequate statistical power to test the validity of the resulting scale. Four hundred patients will be necessary to provide 10 replicates for each parameter calculated in the item calibration phase. The remaining 100 patients will provide adequate statistical power for the initial construct validity investigations.

G2. Data Analysis

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study?

the data from the first 400 cases will be analyzed using item response theory measurement models. It will be essential to determine if the MMT and clinical scales are measuring the same construct. The dimensionality of the data will be analyzed using factor analysis. Unidimensional data is necessary for analysis with the Graded Response Model. The response frequencies for each item will be examined to determine if the response scale fits the ability range of the participants. If there are response categories with few or no responses, these items may need revision. The item discrimination and threshold parameters will be examined for fit to the model. The elevation of the scale Information function will also be examined. If one or more scales are successfully defined in this manner, it will be possible to accurately determine the amount of motor ability even if not all of the items are assessed.

Section H: Potential Risks/Discomforts

there are very few risks involved with participation in this study. all patients will be evaluated during a preliminary evaluation for participation in an outpatient treatment clinic. All muscle tests will be completed and rated by licensed PT.

Section I: Potential Benefits

Describe potential benefits to be gained by the individual subject as a result of participating in the planned work.

the patient will receive no direct benefit from participating in this study.

Describe potential benefits to society of the planned work.

there is currently no scale that measures the trunk control of persons with spinal cord injury. such a scale will provide valuable information concerning the recovery from spinal cord injury with the new treatment modalities that are becoming available.

Do anticipated benefits outweigh potential risks? Discuss the risk-to-benefit ratio.

the risk benefit ratio is favorable for this low risk project.

Section J: Consent Procedures

J1. Consent Procedures

Who will recruit subjects for this study?

PI
PI's staff

Describe how research population will be identified, recruitment procedures, and consent procedures in detail.

Patients will be identified by either physicians or PT's while evaluating patients for placement in outpatient therapy program. these patients will be informed of the study purpose and provided an opportunity to participate.

J2. Primary Physician's Consent

Not Applicable

J3. Waiver of Consent

Will this research require a waiver of consent and authorization?

No

Section K: Confidentiality

Will research data include health information by which subjects can be identified?

Yes

Where will research data be kept? How will such data be secured?

All research data will be compiled on a computer on the PI's office. All data forms for this investigation will be preprinted with a random study ID number printed on the form. Once an informed consent is obtained the study coordinator will provide a data form. The completed data form will have no link to the patient. During the validation phase, a temporary spreadsheet will be maintained connecting the participant to the data form until the data from the therapist and physician can be combined. Once the data form is completed this link will be destroyed. All data forms will be scanned and once data is verified the form will be shredded. The data, form image and backup data will remain on the TIRR server in a secured folder accessible only by the PI and study coordinator..

Who, besides the PI, the study staff, the IRB and the sponsor, will have access to identifiable research data?

no PHI will be released to any entity at any time.

Will you obtain a Certificate of Confidentiality for this study?

No

Please further discuss any potential confidentiality issues related to this study.

Section L: Cost/Payment

Delineate clinical procedures from research procedures. Will subject's insurance (or subject) be responsible for research related costs? If so state for which items subject's insurance (or subject) will be responsible (surgery, device, drugs, etc). If appropriate, discuss the availability of financial counseling.

there will be not extra charges involved in this research.

If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid upon completion, etc) of the payment.

Dollar Amount:

0

Distribution Plan:

Section M: Genetics

How would you classify your genetic study?

Discuss the potential for psychological, social, and/or physical harm subsequent to participation in this research. Please discuss, considering the following areas: risks to privacy, confidentiality, insurability, employability, immigration status, paternity status, educational opportunities, or social stigma.

Will subjects be offered any type of genetic education or counseling, and if so, who will provide the education or counseling and under what conditions will it be provided? If there is the possibility that a family's pedigree will be presented or published, please describe how you will protect family member's confidentiality?

Section N: Sample Collection

None

Section O. Drug Studies

Is this study placebo-controlled?
No

IND Number:

Section P. Device Studies

Does this study need an IDE?
No

Regarding your device study, could potential harm to subjects be life-threatening?
No

Regarding your device study, could potential harm to subjects result in permanent impairment of a body function?
No

Regarding your device study, could potential harm to subjects result in permanent damage to a body structure?
No

Section Q. Consent Form(s)

Trunk Scale

Section R: Advertisements

None

CONSENT FORM

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Trunk Scale

H-21087- DEVELOPMENT AND VALIDATION OF THE THORACIC-LUMBAR CONTROL SCALE TO MEASURE STRENGTH AND COORDINATION OF TRUNK MUSCLES

Background

This research project is designed to develop a measurement scale to measure the function of trunk muscles. these are the muscles that help up balance and hold your body in good posture. There are currently no scales designed to measure the strength of the muscles of the trunk. The most commonly used clinical measures have focused on the arms and legs. With new treatments like activity based therapy, there is a great need for scales that can measure the restoration of function in the trunk muscles. The need for standardized scales that can measure changes in spinal cord function in the thoracic regions is great.

This research study is sponsored by NIDRR.

Purpose

the purpose of this project is to collect data from many persons with Spial cord injury to determine the measurement properties of the trunk muscles. when this is complete the muscle tests with the best measurement properties will be put together into a new scale and tested to determine how well it works.

Procedures

A total of 500 subjects at 5 institutions will be asked to participate in this study. You will be one of approximately 100 subjects to be asked to participate at this location.

The research will be conducted at the following location(s): Baylor College of Medicine, TIRR: The Institute for Rehabilitation and Research.

If you agree to participate in this project, a therapist will ask you to preform a few muscle tests and other maneuvers like lying down and sitting up on a mat. the therapist will rate your preformance according to establishe guidelines. once these activities are copmplete your participation is complete. we will collect other information from your medical record.

Your research doctor may never be able to provide you with your research related health information.

Potential Risks and Discomforts

there are always risks invloved in research projects. the risks are minimized for this project. your therapist will determine if you are capable of preformaing the required tests safely before the evaluation begins. risks of loss of confidentiality are minimized by storing all dataunder a code number. no data will be kept linking you to the data.

Potential Benefits

You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand the recovery of function in trunk muscles and thier role in the recovery from spinal cord injury.

Alternatives

You may choose to not participate in this study.

Subject Costs and Payments
There are no costs to you subsequent to your participation in this research study. You will not be paid to participate in this research study.

Subject's Rights
Your signature on this consent form means that you have received the information about this study and that you agree to be a part of the study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

The investigator or sponsor may decide to stop you from taking part in this study at any time. You could be removed from the study for reasons related only to you (for example, if you move to another city, if you do not take your study medication, or if you have a serious reaction to your study medication) or because the entire study is stopped. The sponsor may stop the study at any time.

There may be unknown risks/discomforts involved. Study staff will update you in a timely way on any new information that may affect your health, welfare, or decision to stay in this study.

If you are injured because of this study, you will receive medical care that you or your insurance will have to pay for just like any other medical care. You will not be paid for the injury.

Your Health Information

We may be collecting health information that could be linked to you (protected health information). This protected health information might have your name, address, social security number or something else that identifies you attached to it. Federal law wants us to get your permission to use your protected health information for this study. Your signature on this form means that you give us permission to use your protected health information for this research study.

If you decide to take part in the study, your protected health information will not be given out except as allowed by law or as described in this form. Everyone working with your protected health information will work to keep this information private. The results of the data from the study may be published. However, you will not be identified by name.

People who give medical care and ensure quality from the institutions where the research is being done, the sponsor(s) listed in the sections above, representatives of the sponsor, and regulatory agencies such as the U.S. Department of Health and Human Services will be allowed to look at sections of your medical and research records related to this study. Because of the need for the investigator and study staff to release information to these parties, complete privacy cannot be guaranteed.

The people listed above will be able to access your information for as long as they need to, even after the study is completed.

If you decide to stop taking part in the study or if you are removed from the study, you may decide that you no longer allow protected health information that identifies you to be used in this research study. Contact the study staff to tell them of this decision, and they will give you an address so that you can inform the investigator in writing. The investigator will honor your decision unless not being able to use your identifiable health information would affect the safety or quality of the research study.

The investigator, DANIEL E GRAVES, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: DANIEL E GRAVES at 713-799-5023 during the day and MIchelle Feltz at (713.797.5981) after hours.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970.

If your child is the one asked to take part in this study you are signing to give your permission. Each child may agree to take part in a study at his or her own level of understanding. When you sign this, you also note that your child understands and agrees to take part in this study according to his or her understanding.

Please print your child's name here ___________________________

CONSENT FORM

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Trunk Scale

H-21087- DEVELOPMENT AND VALIDATION OF THE THORACIC-LUMBAR CONTROL SCALE TO MEASURE STRENGTH AND COORDINATION OF TRUNK MUSCLES

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Subject	Date	
Legally Authorized Representative	Date	Relationship to Subject
Investigator or Designee Obtaining Consent	Date	
Witness (if applicable)	Date	
Translator (if applicable)	Date	