

**Body Structure and Capacity Evaluation of Adults With Scoliosis**

UALBERTA Health research ethics board ID: Pro00089305

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**Purpose :**

**To describe the deficits affecting adults with scoliosis in comparison to healthy controls that could be targeted by future physical therapy treatments.**

**Obj I: To determine differences between adults with idiopathic scoliosis, adults with de novo scoliosis and healthy controls matched for age, height and weight for the primary outcome function / quality of life assessed by the SRS-22r.**

**Obj II: To determine differences between adults with idiopathic scoliosis, adults with de novo scoliosis and healthy controls matched for age, height and weight for the secondary outcomes introduced in the method section below.**

**Obj III: To determine the number of patients who can fit in each category of the treatment-based classification proposed by Fritz et al. for each scoliosis group?**

**Obj IV: Determine the number of patients who can fit in each of Petersen's pathoanatomical classification categories.**

**Methods :**

**-Study type : A cross sectional study.**

**-Participants :**

**Inclusion criteria for the idiopathic scoliosis group: Diagnosis of idiopathic scoliosis, age  $\geq 18$  years old, curve severity over  $10^\circ$ , and fluent in English.**

**Inclusion criteria for the degenerative scoliosis group: Diagnosis of degenerative (De novo) scoliosis, age  $\geq 45$  years old, curve severity over  $10^\circ$ , and fluent in English.**

**Exclusion criteria for the scoliosis groups: History of spine surgery or history of diseases affecting the torso or lower extremity function, surgery or trauma, secondary scoliosis, unable to fill out the questionnaires or attend physical examination, pregnant or gave birth within the last two years.**

**Recruitment locations and procedures for the scoliosis groups: Eligible patients from Dr Mahood's and Dr Huang's clinics will be invited to participate until 27 participants in each group have been recruited. Patient eligibility will be screened by the surgeons who will solicit permission to contact. Then, the physiotherapist research assistant will contact participants to explain the study and schedule the baseline exam where informed consent will be reviewed and signed.**

**Inclusion criteria for the healthy groups:**

**Age  $\geq$  18 years,**

matched for age/height/weight (+/-5 years; +/- 10 lbs; +/- 10cm) to a scoliosis participant, and fluent in English.

**Exclusion criteria for the healthy groups:**

**Serious systemic pathology,**

spine deformity,

spine surgery,

pregnant or gave birth between 0 and 2 years ago.

fluent in English

Received treatments for the spine/the lower limbs within the last year.

**Recruitment locations and procedures for the healthy groups: Healthy participants will be recruited using a database of healthy volunteers (bethecure.com), by asking patients with scoliosis to refer people they know and poster ads on campus.**

**Sample size justification: We expect a 0.8 point difference between the expected score in the healthy groups (of 4.5) and the score in the scoliosis groups (expected scores of 3.7) on the SRS 22 with an expected SD of 1 in each group. We considered  $\alpha=0.0167$  (corrected**

for multiple comparisons) and  $\beta=0.8$  using an unilateral test. So we expect to recruit 27 patients per group based on G\*power 3.1.9.2 for a paired t test analysis. So we need 108 patients in total (27 per scoliosis group and 27 for each of the control groups)

**-Procedures summary:**

Each participant will do the following tasks consistently in the order presented:

- read and review the information letter with the assistant
- sign a consent
- complete a battery of questionnaires to fill out at home or during their lab visit.
- a physiotherapist research assistant will perform the physical exam

**-Assessment methodology:**

We will obtain from the scoliosis patient's file: The most recent spine radiograph will be retrieved in order to measure the Cobb angle, vertebral rotation, apical vertebra deviations (1). The measurements needed to obtain the Schwab adult scoliosis type classification will also be extracted (2).

**Questionnaires :** Questionnaires will be administered using Redcap survey with the participant invited to complete the questionnaires at home or face to face.

A general patient characteristics questionnaire will collect: age, gender, height and weight. The following questions about work ability will be administered using branching logic to minimize the number of unnecessary questions: 1) Are you presently working? 2) Why are you not working? 3) Are you working at the same physical work levels as before your injury/condition or are you performing modified duties because of your back? 4) Have you decreased your daily number of work hours due to Low Back Pain? 5) Please answer the following question in relation to your work prior to your injury/condition whether working for the same employer, same job or not.

Questions about the clinical history will also be computer administered (3,4): Have you ever been diagnosed from a spinal stenosis (Imaging evidence of lumbar spinal stenosis). When did the spinal pain begin ? Does frequency of the pain episodes increase? Painful location will be reported by selecting codes using a pain drawing tool. Do you have more pain in the leg than in the back? If you have pain while walking, is that better with a lumbar flexion (for example when you go uphill). How many prior episode of torso pain did you have? When was your first episode? Participants will also be asked what treatments they have previously received and their effect.

A pain score on a numerical pain rating scale (NRS) [\(5\)](#) will be collected for thoracic pain, lumbar pain and leg pain at the best, worse and current levels over the last 24 hours.

According to the Mechanical Diagnosis and Therapy (MDT) approach described by McKenzie [\(6\)](#) Participants will report if the following positions / actions make them always better, sometimes better, have no effect, sometimes worse or always worse: bending, sitting, rising, standing, walking, lying, during the am, as the day progresses, during the pm, when still, or on the move. This helps identify directional preference. Participants will also report their typical sleeping posture (Prone, supine, side R or L). They will report the course of their symptoms since onset as Improving, getting worse or unchanged.

The following validated outcome and prognostic questionnaires will also be administered using REDCAP.

Scoliosis Research Society -22r SRS 22r [\(2\)](#) The SRS-22r consists of 22 questions assessing 5 quality of life domains: Function, Pain, Self-Image, Mental health (5 questions), satisfaction (2 questions) and a total.

Spinal Appearance Questionnaire SAQ [\(7,8\)](#) The SAQ consists of 11 pictogram questions and 12 multiple choice questions and an open question to assess the perceived appearance.

Fear Avoidance Belief FABQ [\(9\)](#) The FABQ was developed on the basis of the assumption that fear-avoidance beliefs play a major role in LBP-related disability. It comprises 16 items scored by the patient and includes sub-scores for fear-avoidance beliefs regarding work and physical activity.

Oswestry Disability Index [\(9\)](#) The ODI uses 10 questions with 5 answer options to assess the degree of disability associated with spinal disorders.

Örebro Musculoskeletal Screening Questionnaire 12-Item Short Form (ÖMSQ-12) [\(10\)](#). For each item, a 0 to 10 scale is used to answer the questions. It assess pain, feelings, expectations and physical abilities.

Work Ability Index (WAI) [\(11\)](#). It is a five items questionnaire which assess the worker's ability to work perception and expectations,

International physical activity questionnaire (IPAQ) short form [\(12\)](#). It is a 7 items questionnaire which assess the vigorous/moderate/low physical activity and sedentary time spent each week. Participants have to declare an average time for each type of activity.

**Physical Exam :** A detailed physical therapy physical exam will then be completed by a research physical therapist. This exam will be filmed using a Panasonic lumix DMC ZS3 digital camera (model) placed on a tripod, and video saved on password protected research drive to allow a second physical therapist to review the captured responses to symptom provocation and relieving tests.

**Standing :**

Posture photographs of the front and back and side profile of the participants will be collected to later extract the Posterior and Anterior Trunk Symmetry Indices (POTSI and ATSI) as well as clinical photographic posture assessment tool measurements (13,14).

Visible frontal plane deviation of the shoulders relative to the pelvis (4) will be recorded as a lateral shift with direction based on shoulder position. Coronal balance will be recorded as a lateral deviation of C7 relative to a plumb line aligned with the natal cleft will be recorded to the nearest mm.

Adam bending test with a scoliometer (1) The patient will be asked to slowly bend forward while the examiner puts the scoliometer on his back in order to measure the most important lateral tilt at the level of the main curvature and the compensatory curves. The difference between the most rotation read on either side will be noted.

Myotome S1 (3): To access the S1 myotome, the strength of the triceps surae will be tested. The patient, on one feet will be asked to raise the heel from the floor to go on the toes. A pressure on the shoulder can be added.

Intervertebral slip (3): The examiner will assess if there is any slip, a depth difference between the spinous processes of adjacent levels, by inspection/palpation

A flexicurve, moldable ruler, will be aligned over the spine to illustrate the sagittal profile from C0 to L5S1. The Kyphotic and lordosis index will be extracted with a method showing high reliability and good validity. A photography of the flexicurve will be taken on a quadrille background. Occiput, C7, D12, maximal lumbar lordosis, l5/s1 position in the sagittal plan will be expressed in relation to the most prominent kyphosis point after the exam.

**Lumbar ranges of motion:** Lumbar flexion, extension and lateral flexion ranges will be tested with two inclinometer (9). One inclinometer will be placed on the thoracolumbar junction and one on the sacrum in the sagittal plane. Both inclinometers will then zeroed in natural standing position. The patient will then be asked to bend forward. The flexion range of motion is the difference between the two inclinometers measurements. Then the patient will be asked to bend backward. The extension range of motion is the difference

between the two inclinometers' measurements. The same method is used for the lateral flexions with inclinometers placed flat against the back in the frontal plane.

“Instability catch” or aberrant movements will be recorded during lumbar flexion/extension ROM (3) We consider the following as aberrant movements: painful arc with flexion or return from flexion, instability catch, Gower sign, and reversal of lumbopelvic rhythm. A painful arc with flexion or return from flexion is determined as follows: the patient is asked to bend forward and return to the initial position. We consider the test positive if the patient feels/increases pain during the procedure except if it is at the end of the movement (maximum flexion). The instability catch is determined by asking the patient to bend forward and backward. The test is considered as positive if the patient does not stay in the sagittal plane during the whole movement. The Gower sign is considered as positive if the patient uses his hands on his thighs to help the return from a flexion movement. Reversal of lumbopelvic rhythm is considered positive if the patient uses hip flexion rather than spine motion to achieve forward flexion range of motion.

Joint laxity (Beighton score )(1) The examiner will note if the patient is actively able to do a lumbar flexion with the knee extended and put the palms of their hands on the floor.

A repeated movement exam according to MDT(6) will be completed to note centralisation, peripheralization, and detect directional preference. The patient will be asked to perform 10 repeated movements in a direction determined based on whether the participant reported symptoms became more proximal (centralisation), more distal (peripheralization) or if he had no change after attempting the flexion, and extension ROM tests. We will consider that the patient has a directional preference if his pain and ROM increase after repeated movement in one direction and his symptoms improve in the opposite direction. The repeated movements tested will be flexion, extension, right side glide, left side glide. Up to ten repeated movements in each direction will be attempted.

Thomas' test (15): The participant will stand at the end of the table and be helped in lying supine position by the therapist while holding one knee to the chest. One leg will be maximally flexed (hip and knee) and manually held by the patient, while the other hip is extended. The examiner will make sure that long portion of the quadriceps is relaxed by holding the tibia. The measurement will be done between the horizontal (table) and the femoral axis using an inclinometer placed at the distal end of the thigh.

**Sitting:**

Lumbar rotation ROM (16) will be tested with the BROM device positioned on the patient with the compass on the T12 process and the magnet on S1. The patient will be asked to rotate and the examiner will read the measure.

Thoracic flexion, extension, lateral flexion and rotations ROM will be tested with two inclinometers (expect for the rotation, where a goniometer will be used(17)). The same process as in the lumbar spine will be replicated for the thoracic region with an inclinometer on the cervicothoracic junction and another on the thoracolumbar junction. During movement testing the arms will be crossed with the hands of the patient resting on their opposite shoulders.

Respiratory capacity (1). The Spiro pro from Jaeger will be used to obtain a flow volume curve and extract the following parameters (vital capacity, Forced expiratory vital capacity, Forced expiratory volume after 1 second, FEV1 in % of maximal vital capacity, Maximal expiratory flow, Maximal expiratory flow at 25% of the vital capacity, Maximal expiratory flow at 50% of the vital capacity, Maximal expiratory flow at 75% of the vital capacity, mean maximal expiratory flow between 25% and 75% of FVC, Maximal inspiratory flow). Participants, with a nose clip, will be asked to breath normally, then to inhale as deep and fast as possible, then expire as fast and as much as possible. Procedures will be repeated two additional times. We will use the American Thoracic Society program to derive measurements and follow the standardisation of spirometry guidelines (Miller. standardisation of spirometry. EurRespir J 2005; 26: 319-338). The part of the device put in the mouth will be clean as described in the user manual after each usage.

Patellar reflexes(3): To assess S1 root function, the patellofemoral tendon will hit by a reflex hammer.

Achilles reflexes(3): The tendon will be hit by a reflex hammer. The reflexes is judged as normal, hyperreactive, hyporeactive.

Myotomes motor function(3): The psoas, quadriceps, tibialis anterior; peroneals, extensor hallucis longus, triceps surae will be tested. The muscles will be rated as normal (5/5=heavy manual resistance equal to the opposite side. Exception: the triceps is rated 5/5 only if the patient can walk on his toes) or abnormal (4/5=resistance inferior compared to the opposite side, 3/5=mouvement against the gravity, 2/5=mouvement without gravity, 1/5=contraction palpable, 0/5= no contraction). In addition, the strength will be measured with a hand held dynamometer by capturing 2 maximal efforts for each muscle.

Lying supine :

Joint laxity (Beighton score )(1) The examiner will assess if the patient is passively able to hyper extends the fifth metacarpophalangeal joint beyond 90°, bring the thumb to the forearm, and to hyperextend the elbow and the knee.

Neurological tension exam (3,9) the Straight leg raise (SLR)and crossed SLR will be tested. The examiner will passively raise the patient's leg (hip flexion with an extended knee). This test will be performed on both sides. We will measure the range of motion (the movement will be stopped if the patient experiences pain) and we will record if the patient has a



radiating pain (positive test) on the homolateral side (SLR) or contralateral side (crossed SLR).

**Sensory testing:** With the eyes closed the patient will have to tell if he feel a pin touch (filament) or a light touch (tissue) while the examiner uses a disposable pin prick or a touch tool to test the area. The following areas are tested: the front side of the hip and of the thigh, the medial side of the knee, the medial malleolus, the top of the hallux, the heel; and behind the knee. Filament will be cleaned after each usage and a new tissue will be used.

**Repeated movement testing MDT (centralisation, peripheralization, directional preference)(6).** The patient will be asked to perform 10 repeated flexion movements (knees to chest) and report symptoms as described above.

**Measurement of lower limb length discrepancy (1).** The measurement will be taken for each lower extremity between the ASIS and the medial malleolus.

**Hip abduction ROM(15):** The examiner will passively abduct the patient's hip (knee extended) until a firm stop or a pelvis movement. The first goniometer's arm will be placed on the line between the right and the left anterior superior iliac spines. The second will be directed along the thigh axis.

**FABER test (15):** The patient's heel will be positioned on the opposite knee. The patient's hip will be abducted, flexed and externally rotated with a stabilisation on the pelvic with one hand on the opposite ASIS. The other hand will overpressure the hip movement. The test is considered positive if it reproduces the patient's symptoms. The ROM is measured with an inclinometer placed on the proximal medial side of the tibia.

**Distraction test (3):** The examiner will apply an anterior-posterior force on the two ASISs. The test is considered positive if it reproduces the patient's symptoms.

**Thigh thrust (3):** The examiner will flex the patient's hip until 90° (knee flexed), then he will put one hand under the patient's sacrum. The other hand will apply a downward force on the femur in its axis. The test is considered positive if it reproduces the patient's symptoms.

**Gaenslen's test (3)** The examiner will flex the patient's hip until the end of the movement (knee flexed). One hand will be used to maintain one hip in flexion while the other therapist's hand will be used to apply a downward force on the other femur in order to maintain a hip extension. The test will be considered positive if it reproduces the patient's symptoms.

**Lying on the side:**

**Compression test (3)** The examiner will apply a latero-medial force on the ASIS. The test will be considered positive if it reproduces the patient's symptoms.

**Lying prone:**

**Prone Knee Bending (PKB) test and crossed PKB (18):** The examiner will flex the patient's knee. We will record the range of motion (the movement is stopped if the patient experiences pain) and if the patient has radiating pain (positive test) on the homolateral side (PKB) or contralateral (crossed PKB)

**Hip internal rotation (15):** The examiner will passively flex the patient's knee. A stabilisation of the pelvis is done by applying the examiner's hand on it and a stabilisation of the hip is done with the examiner's hand on the tibiofemoral joint. The internal rotation is done until the end of the passive motion (the examiner feels that a pelvis movement would be needed to continue the movement). Then an inclinometer is placed on the shaft of the tibia (proximally to the medial malleolus). The measure is done between the vertical plane and the tibia.

**Repeated movement testing MDT (centralisation, peripheralization (6), directional preference** The patient will be asked to hold a prone position supported on elbow for 30 second and then to perform 10 repeated movements of prone press-up to extended arms. For each of those, participants will be asked about symptoms as described above.

**Posterior-anterior mobility test/segmental mobility assessment (9).**The clinician will apply force on each thoracic and lumbar spinous process with the hypothenar eminence of one of his hand. The other hand will be positioned directly on the first hand and with the elbows extended. The movement will be generated by body oscillations from the therapist. The examiner will judge if there is a hyper/normal/hypo-mobility.

**Sacral thrust (3)** The examiner will apply a posterior-anterior force on the patient's sacrum. The test is considered positive if it reproduces the patient's symptoms.

**Passive lumbar extension test (3)** The examiner will passively raise the two legs until 30° with soft traction. The test is considered positive if it reproduces the patient's symptoms.

**Prone instability test (9)** The patient will be positioned with his trunk on the table and his feet on the floor. The examiner will perform a postero-anterior pressure on the patient's lower back and record if the patient has any pain. The same process will then be repeated with the patient's legs actively held off the floor (all the body of the patient is straight). The test is considered positive if there is pain during the first procedure and not during the second.

**-Analysis :**

**We will describe the population with averages and standard deviations for the continuous data and frequencies with confidence intervals for the categorical.**

**Comparisons between groups: We will compare the continuous data among the 3 groups with an ANOVA using Bonferroni post hoc comparison. Categorical data will be compared between groups with a Chi2 test (2 by 2).**

## **References**

- [1. Methodology of evaluation of morphology of the spine and the trunk in idiopathic scoliosis and other spinal deformities - 6th SOSORT consensus paper | Scoliosis and Spinal Disorders | Full Text \[Internet\]. \[cité 20 févr 2019\]. Disponible sur: https://scoliosisjournal.biomedcentral.com/articles/10.1186/1748-7161-4-26](https://scoliosisjournal.biomedcentral.com/articles/10.1186/1748-7161-4-26)
- [2. Negrini S, Donzelli S, Aulisa AG, Czaprowski D, Schreiber S, de Mauroy JC, et al. 2016 SOSORT guidelines: orthopaedic and rehabilitation treatment of idiopathic scoliosis during growth. Scoliosis Spinal Disord. 2018;13:3.](#)
- [3. Petersen T, Laslett M, Juhl C. Clinical classification in low back pain: best-evidence diagnostic rules based on systematic reviews. BMC Musculoskelet Disord. 12 2017;18\(1\):188.](#)
- [4. Fritz JM, Cleland JA, Childs JD. Subgrouping patients with low back pain: evolution of a classification approach to physical therapy. J Orthop Sports Phys Ther. juin 2007;37\(6\):290-302.](#)
- [5. Kaiser U, Neustadt K, Kopkow C, Schmitt J, Sabatowski R. Core Outcome Sets and Multidimensional Assessment Tools for Harmonizing Outcome Measure in Chronic Pain and Back Pain. Healthcare \[Internet\]. 29 août 2016 \[cité 21 févr 2019\];4\(3\). Disponible sur: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5041064/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5041064/)
- [6. McKenzie R, May S. The Lumbar Spine: Mechanical Diagnosis and Therapy. Spinal Publications; 2003. 372 p.](#)

- [7. Carreon LY, Sanders JO, Polly DW, Sucato DJ, Parent S, Roy-Beaudry M, et al. Spinal appearance questionnaire: factor analysis, scoring, reliability, and validity testing. Spine. 15 août 2011;36\(18\):E1240-1244.](#)
- [8. Sanders JO, Harrast JJ, Kuklo TR, Polly DW, Bridwell KH, Diab M, et al. The Spinal Appearance Questionnaire: results of reliability, validity, and responsiveness testing in patients with idiopathic scoliosis. Spine. 15 nov 2007;32\(24\):2719-22.](#)
- [9. Delitto A, George SZ, Van Dillen L, Whitman JM, Sowa G, Shekelle P, et al. Low Back Pain. J Orthop Sports Phys Ther. 1 avr 2012;42\(4\):A1-57.](#)
- [10. Gabel CP, Burkett B, Melloh M. The shortened Örebro Musculoskeletal Screening Questionnaire: evaluation in a work-injured population. Man Ther. oct 2013;18\(5\):378-85.](#)
- [11. Schouten LS, Joling CI, van der Gulden JWJ, Heymans MW, Bültmann U, Roelen CAM. Screening manual and office workers for risk of long-term sickness absence: cut-off points for the Work Ability Index. Scand J Work Environ Health. janv 2015;41\(1\):36-42.](#)
- [12. Lee PH, Macfarlane DJ, Lam T, Stewart SM. Validity of the international physical activity questionnaire short form \(IPAQ-SF\): A systematic review. Int J Behav Nutr Phys Act. 21 oct 2011;8:115.](#)
- [13. Stolinski L, Kozinoga M, Czaprowski D, Tyrakowski M, Cerny P, Suzuki N, et al. Two-dimensional digital photography for child body posture evaluation: standardized technique, reliable parameters and normative data for age 7-10 years. Scoliosis Spinal Disord \[Internet\]. 19 déc 2017 \[cité 27 févr 2019\];12. Disponible sur: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5738151/>](#)
- [14. Negrini S, Donzelli S, Aulisa AG, Czaprowski D, Schreiber S, de Mauroy JC, et al. 2016 SOSORT guidelines: orthopaedic and rehabilitation treatment of idiopathic scoliosis during growth. Scoliosis Spinal Disord. 10 janv 2018;13\(1\):3.](#)
- [15. Hip Pain and Mobility Deficits—Hip Osteoarthritis: Revision 2017 | Journal of Orthopaedic & Sports Physical Therapy \[Internet\]. \[cité 25 févr 2019\]. Disponible sur: <https://www.jospt.org/doi/10.2519/jospt.2017.0301>](#)
- [16. Madson TJ, Youdas JW, Suman VJ. Reproducibility of lumbar spine range of motion measurements using the back range of motion device. J Orthop Sports Phys Ther. août 1999;29\(8\):470-7.](#)
- [17. Johnson KD, Kim K-M, Yu B-K, Saliba SA, Grindstaff TL. Reliability of Thoracic Spine Rotation Range-of-Motion Measurements in Healthy Adults. J Athl Train. 2012;47\(1\):52-60.](#)

**18. Suri P, Rainville J, Katz JN, Jouve C, Hartigan C, Limke J, et al. The Accuracy of the Physical Examination for the Diagnosis of Midlumbar and Low Lumbar Nerve Root Impingement. Spine. 1 janv 2011;36(1):63-73.**