

The assessment of the stiffness of the trunk by the Scolibed

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		<input type="checkbox"/> Protocol
Registration date 06/05/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 14/08/2020	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Scoliosis is a progressive condition where the spine twists and curves in an abnormal way over time. Symptoms include a curved spine, prominent ribcage and one shoulder being higher than the other. It can cause back pain, particularly in adults, emotional problems (associated with body image and self-esteem) and, in some more severe cases, lung and heart problems as the ribcage can be pushed against these organs. In some cases, again particularly in adults, the bones in the spine can compress nerves which can lead to a number of problems including back and leg pain, numbness in the legs, incontinence and (in men) erectile dysfunction. One possible treatment is surgery, where the spine is moved to a more normal position using metal rods, plates and screws before finally being fused into place with bone grafts. This results in a completely stiff spine. A new system has been developed which corrects the spine which fusion, keeping it flexible. Since the spine is connected to the trunk (torso), this is corrected as well. To assess the new scoliosis correction device it is necessary to determine the individual stiffness of the patient's trunk. To determine the stiffness of the trunk, a device named "Scolibed" has been developed. It is a bed-shaped mechanical system, divided into two parts, connected by an axis. It is unknown whether the device can measure the stiffness in a reproducible way and whether there is a large individual variation. From a scientific point of view it is interesting to know if the stiffness of a scoliotic spine is different from a healthy one, since it may provide information about the underlying mechanisms of scoliosis, which are not currently known. Here, we aim to the reproducibility of the device to observe and compare the variation in stiffness found among healthy subjects and scoliotic patients. The results of this work will be used as the basis for a bigger study assessing truncal stiffness in healthy subjects and patients.

Who can participate?

Healthy volunteers, between 12 and 14 years old and scoliotic patients, between 12 and 14 years old.

What does the study involve?

The participants are positioned on a vacuum mattress that is fixed to the "Scolibed" and strapped to the bed with Velcro® straps that are passed over the subject's body (two straps over the upper part and three straps over the legs). Then the upper part is rotated relative to the lower part.

The burden for the subjects is the tightness of the straps, and the unnatural feeling of being bent. The maximum time for a measurement session is limited to 60 minutes and will be done after a regular appointment with the orthopedic surgeon in case of patient subjects. Four measurement sessions have to be performed, three in the same day and one with a time difference of minimum 5 days and maximum 20 days. In this way, we hope to determine the repeatability of the "Scolibed" results, variation in stiffness for healthy individuals and variation in stiffness for scoliotic patients. We will also compare the results of healthy individuals and scoliotic patients.

What are the possible benefits and risks of participating?

The main risk of taking part in the study is that the participant is bent too much and experience pain. But since this being is done manually an immediate stop and movement back is possible. There is also a risk of device breaking or malfunctioning, causing the participant to fall on the ground. The design has been tested with volunteers and passed without any signs of failure. Finally, it is possible that the participants will receive an electric shock from the device. This risk is very low, however, since the patient is lying on a plastic vacuum mattress and a wooden bed frame and the sensors are running on low voltage.

Where is the study run from?

Department of Orthopaedic Surgery, Groningen University Medical Centre (Netherlands)

When is the study starting and how long is it expected to run for?

April 2015 to May 2015

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Professor Bart Verkerke

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Study information

Scientific Title

The assessment of the stiffness of the trunk by the Scolibed: a pilot study

Study objectives

1. The expectation of the first phase is that the device will be reproducible.
2. The expectation of the second phase is that the range of truncal stiffness of healthy individuals and scoliotic patients measured by the device will be small.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Nit provided at time of registration

Study design

Interventional study. First phase directed to determine if the device is reliable and accurate. Second phase is going to be performed to assess the difference in truncal stiffness between healthy subjects and scoliotic patients.

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Scoliosis

Interventions

The subjects are positioned on a vacuum mattress that is fixed to the "Scolibed" and strapped to the bed with Velcro® straps that are passed over the subject's body (two straps over the upper part and three straps over the legs). Then the upper part is rotated relative to the lower part.

Intervention Type

Device

Primary outcome(s)

1. Our first goal is to determine the device's reproducibility. To assess the influence of time variation and operator variation and also to determine the repeatability, each subject must undergo four series of measurements, three in one day (day one) and one after minimum five days and maximum 20 days (day two).
2. After organizing the results a simple analysis regarding the difference among the intra-subject results will be performed using the statistics software SPSS. With the outcome of this analysis, each subject will have a number (referent to the difference found among the results). We will call this number "Variation Coefficient", shortly "VC", and like in the table above, we will work with "S1VC", "S2VC", and so on. It is determined by calculating the ratio of the standard deviation to the mean value of the intra-subject results. The same statistical method is going to be used to analyse the inter-subject results.

Key secondary outcome(s)

Range of truncal stiffness of healthy individuals and scoliotic patients measured by "Scolibed". We intend to perform statistical analysis of variation to determine if the difference on the stiffness found between our control and study group is statistically significant. After ensuring

that the difference found is not “by accident” we want to add some variants (such as gender and severeness of the curve) and compare the results and the likelihood of some statements according to the data collected (e.g. How likely it is that truncal stiffness is larger/ lower in scoliotic patients than in healthy subjects.).

Completion date

01/06/2015

Eligibility

Key inclusion criteria

Control group:

1. Age between 12 and 14 years
2. Individuals able to walk and perform all trunk movements
3. Weight < 120 kg

Study group:

1. Idiopathic or congenital scoliosis
2. Age between 12 and 14 years
3. Under treatment at the scoliosis clinic in the UMCG
4. Capability to stand up normally without any supporting devices
5. Cobb angle: between 20° and 60 °
6. Weight < 120 kg

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Child

Lower age limit

12 years

Upper age limit

14 years

Sex

All

Key exclusion criteria

Control group:

1. Pregnancy
2. Already underwent spinal surgery
3. Recent surgery in trunk or abdomen. Use of implants or prosthesis in trunk or abdomen which limits body motion.
4. Back pain
5. Neurological disorder

6. Any spinal disease
7. Body malformation with effects on body motion
8. History of spinal injury and/or ribcage injury
9. History of handicap
10. Use of strong painkillers or opioids

Study group:

1. Pregnancy
2. Already underwent spinal surgery
3. Back pain
4. Neurological disorder
5. Spinal disease not related to scoliosis
6. Body deformation unrelated to scoliosis
7. Scoliosis with Cobb's Angle $<20^{\circ}$ or $>60^{\circ}$
8. Use of strong painkillers or opioids

Date of first enrolment

07/04/2015

Date of final enrolment

01/05/2015

Locations

Countries of recruitment

Netherlands

Study participating centre

Department of Orthopaedic Surgery, Groningen University Medical Centre (Universitair Medisch Centrum)

Netherlands

9700 RB

Sponsor information

Organisation

Faculty of Medical Sciences / UMCG, Orthopedics (Faculteit Medische Wetenschappen/UMCG, Orthopedie)

ROR

<https://ror.org/012p63287>

Funder(s)

Funder type

Not defined

Funder Name

Investigator initiated and funded

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Available on request