

# Comparison of walking quality between incomplete spinal cord injury patients and healthy subjects using a Footscan plantar pressure system

<b>Submission date</b> 10/08/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 22/08/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 12/12/2018	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

In the majority of spinal cord injury (SCI) patients who retain some walking ability, movement is often limited to the confines of their homes or short distances, and patients are often dependent upon the assistance of devices or their caregivers. Therefore, one of the main focuses of rehabilitation for these patients is the recovery of the ability to walk well. Good walking quality includes walking fast and walking symmetrically. It is possible to obtain quantitative data about the walking ability of these patients, which can be used to help with recognition of the underlying causes and development of pathological gaits (walking abnormalities). This study aims to use a device called the Footscan plantar pressure system to collect this walking data to determine the differences in walking quality between SCI patients and healthy subjects.

### Who can participate?

Healthy adults with a spinal cord injury

### What does the study involve?

Participants will be asked to walk in bare feet upon the Footscan platform at a comfortable speed for at least 2 times to familiarise themselves with the device and then 3 times to test their walking quality after resting.

### What are the possible benefits and risks of participating?

The benefit of participating in this trial is that patients will receive a report about their walking quality (plantar pressure and gait). There are no known risks to participants taking part in this study.

### Where is the study run from?

Rehabilitation Department of Shengjing Hospital of China Medical University. (China)

When is the study starting and how long is it expected to run for?  
October 2013 to March 2017

Who is funding the study?  
Shengjing Hospital of China Medical University (China)

Who is the main contact?  
Dr Xiangnan Yuan  
yuanxn@sj-hospital.org

## Contact information

**Type(s)**  
Public

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
1.0

## Study information

**Scientific Title**  
The effects of the Footscan plantar pressure plate system on walking quality variables between spinal cord injury patients and healthy subjects

**Study objectives**  
Compared with healthy subjects, there will be a difference in variables of gait and an asymmetry of gait quality in spinal cord injury patients, including step length and the variables of plantar pressure.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Clinical Research Ethics Committee of Shengjing Hospital of China Medical University, 13/08 /2015, No. 2015PS54J

**Study design**

Observational prospective cross-sectional study

**Primary study design**

Observational

**Study type(s)**

Other

**Health condition(s) or problem(s) studied**

Spinal cord injury

**Interventions**

The subjects were asked to walk in bare feet upon the footscan platform at their comfortable speed. Each subject undertook at least 2 practice walks along the plate walkway in order to familiarize themselves with, and hence feel at ease with, the experimental process. Following an adequate recuperation period, each subject was asked to walk in bare feet upon the footscan platform at their comfortable speed for at least 3 successful trials. Subjects reporting fatigue were permitted to rest for a minimum of 2 minutes between trials.

**Intervention Type**

Behavioural

**Primary outcome(s)**

Walking speed, measured through participants walking on the the Footscan platform at their comfortable speed for at least 3 successful trials on the day of participation.

**Key secondary outcome(s)**

The following were measured on the day of participation by participants walking on the the Footscan platform at their comfortable speed for at least 3 successful trials:

1. Stride time in seconds
2. Stride length in metres
3. Stance time in seconds
4. Step length in metres
5. Peak plantar pressure in Newtons per cm<sup>2</sup>
6. Impulse in Newtons per second
7. Maximum force in Newtons
8. Contact area percentage

**Completion date**

01/03/2017

**Eligibility****Key inclusion criteria**

Spinal cord injury group:

1. Complete spinal cord injury (SCI) according to American Spinal Cord Injury Association (ASIA) Impairment Scale (AIS)
2. Capacity for independent walking, with or without mechanical support, for a minimum of 15 minutes

Healthy subjects:

1. None of the aforementioned conditions
2. Matching age ( $\pm$  5 years) and sex to participants in SCI group

**Participant type(s)**

Mixed

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

Spinal cord injury group:

1. Severe spasticity of the lower extremity muscles, rated as greater than or equal to 2 on the Modified Ashworth Scale (MAS)
2. Muscle or joint pain with an intensity rating of greater than 5 out of 10 on a numerical scale
3. Presence of cognitive or behavioural disorders
4. Spinal or lower extremity deformities, such as scoliosis, kyphosis or equinovarus
5. Clinical instability

Healthy subjects:

1. Muscle or joint pain of low extremities or spine
2. Presence of cognitive disorders
3. Flat foot
4. Cavus foot
5. Abnormal gait

**Date of first enrolment**

01/08/2015

**Date of final enrolment**

01/08/2016

**Locations**

**Countries of recruitment**

China

**Study participating centre**

**Shengjing Hospital of China Medical University**

No.36, Sanhao Street, Heping District

Shenyang

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# Sponsor information

## Organisation

Shengjing Hospital of China Medical University

## ROR

<https://ror.org/0202bj006>

# Funder(s)

## Funder type

Not defined

## Funder Name

the New Technique Project of Shengjing Hospital of China Medical University, China, No. 117

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Xiangnan Yuan (e-mail is [yuanxn@sj-hospital.org](mailto:yuanxn@sj-hospital.org)). Plantar pressure data will become available after the study results are published and will be available for 1 year.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/02/2019		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes