

# Study on the effect of anterior cervical screw placement position difference on the stability of internal fixation system

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| <b>Submission date</b><br>10/11/2022   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>18/11/2022 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>14/11/2022       | <b>Condition category</b><br>Musculoskeletal Diseases | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input type="checkbox"/> Results                     |
|  |   | <input type="checkbox"/> Individual participant data |
|  |   | <input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Some scholars have conducted clinical experiments and biomechanical studies on the biomechanical differences between cross and parallel screw placement in anterior cervical discectomy and fusion surgery while treating cervical disc degeneration, and found that the uneven angle of screw placement did not affect the stability of the internal fixation system. However, the different screw placement angles on the stress transfer effect is not described in detail, the stress transfer effect determines the future system stability.

### Who can participate?

Healthy adult male volunteers.

### What does the study involve?

A CT scan of the spine in different positions.

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

None

### Where is the study run from?

Shanxi Bethune Hospital (China)

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

August 2022 to October 2022

### Who is funding the study?

Investigator initiated and funded

### Who is the main contact?

Dr Zejun Xing, 18735130965@163.com

## Contact information

**Type(s)**

Public

**Contact name**

Dr Zejun Xing

**Contact details**

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**Additional identifiers****Clinical Trials Information System (CTIS)**

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

Nil known

**Study information****Scientific Title**

Study on the effect of anterior cervical screw placement position difference on the stability of internal fixation system

**Study objectives**

Some scholars have conducted clinical experiments and biomechanical studies on the biomechanical differences between cross and parallel screw placement in anterior cervical discectomy and fusion surgery while treating cervical disc degeneration, and found that the uneven angle of screw placement did not affect the stability of the internal fixation system. However, the different screw placement angles on the stress transfer effect is not described in detail, the stress transfer effect determines the future system stability.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 08/11/2022, Medical Ethics Committee of Shanxi Bethune Hospital (No.99, Longcheng Street, Taiyuan, Shanxi Province, 030000, China; +86 351-8379145; dyyyc@163.com), ref:YXLL-2022-140

**Study design**

Machine learning case series

**Primary study design**

Observational

**Study type(s)**

Prevention

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

Cervical disc degeneration

**Interventions**

The CT data of the lower cervical spine of volunteers were obtained by 128-row spiral CT scanner. The image data were imported into Mimics software in the format of Dicom to perform threshold division of the data, cavity filling and other operations to generate a complete three-dimensional model of the lower cervical spine including C1-C7 segments, and imported into Geomagic Studio 2016 software in stl format for further denoising, smoothing, and fitting surface processing of the model to form a solid model.

**Intervention Type**

Procedure/Surgery

**Primary outcome(s)**

The stress, displacement and stress transfer of the intervertebral disc with different screw placement angles were observed under left bending, upright and anteflexion conditions obtained by 128-row spiral CT scanner at a single time point.

**Key secondary outcome(s)**

There are no secondary outcome measures.

**Completion date**

01/10/2022

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

1. Healthy male volunteers
2. No history of trauma surgery, osteoporosis, bone hyperplasia and other pathological conditions
3. Routine imaging examination to exclude cervical spondylosis disease history
4. Cervical activity in the normal range

**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Male

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

01/08/2022

**Date of final enrolment**

01/08/2022

## Locations

**Countries of recruitment**

China

**Study participating centre**

**Shanxi Bethune Hospital**

No.99 Longcheng Street

Taiyuan

China

030000

## Sponsor information

**Organisation**

Shanxi Bethune Hospital

## Funder(s)

**Funder type**

Other

**Funder Name**

Investigator initiated and funded

## Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Zejun Xing, 18735130965@163.com

**IPD sharing plan summary**

Available on request