

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

Submission date 10/11/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 18/11/2022	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/11/2022	Condition category 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

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Contact details

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

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