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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

Registration date
18/11/2022

Overall study status
Completed

Last Edited
14/11/2022

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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; dyyywc@163.com), ref:YXLL-2022-140

Study design
Machine learning case series

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

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 measure
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.

Secondary outcome measures
There are no secondary outcome measures.

Overall study start date
01/08/2022

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

Age group
Adult

Sex
Male

Target number of participants
1

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

Sponsor details

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/11/2023

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