Informed consent

Scheme Name: Application of 3-Dimensional printing guide template and pointed lotus-style regulator in percutaneous pedicle screw fixation for thoracolumbar fractures

Research institutions: The Afiliated Huai'an Hospital of Xuzhou Medical University

You will be invited to a clinical study. This informed consent provides you with information to help you decide whether to participate in this clinical study. Please read carefully and if you have any questions, please ask the researcher responsible for the study. You are willing to participate in this study. This study has passed the review of our Ethical Committee. If you have any questions about the subjects' own rights and interests, please contact the Ethical Committee of The Afiliated Huai'an Hospital of Xuzhou Medical University at 0517-80871603. email :haeyllwyh@126.com

Objective: This study aims to analysis the application of the 3D printing percutaneous guide template in combination with the pointed lotus-style regulator in percutaneous pedicle screw fixation.

Research process: Inclusion criteria： ①It meets the clinical standards for thoracolumbar vertebral compression fracture, and the injury time is less than 7 days;②Vertebral fracture site is located in T11-L2 and CT scan indicates that bilateral pedicles are intact and vertebral fracture blocks are not turned over;③No clinical neurological symptoms and signs;④The patient has complete preoperative X-ray, CT, MRI and other imaging data.If you agree to participate in this study, we will number each subject and establish medical records. According to your group, your relevant pedicles will be inserted by 3D printing percutaneous guide template ,3D printing percutaneous guide template in combination with the Pointed lotus root regulator or Flat ended lotus root regulator in percutaneous pedicle screw fixation. Your case report will be published on global websites and journals. The printed and online versions will be available to doctors, media and the public.

Risk and discomfort: It may cause skin allergies and damage to important blood vessels and nerves due to deviation during puncture.

Benefits: It can improve your postoperative comfort and shorten your hospital stay through the study of your case.

As a research subject, you have the following responsibilities: provide true information about your own medical history and current physical condition; tell the doctors about any discomfort you have experienced during this study: don't take restricted drugs, food, etc; tell the doctors whether he has recently participated in other studies or is currently participating in other studies.

Privacy issues: if you decide to participate in this study, your personal data in the trial are confidential. Your tissue specimen will be identified by the number of your study number instead of your name. We will not disclose the information that identifies you to members outside the research group unless you have permission. All study members and study sponsors are required to keep your identity confidential. Your files will be kept in a locked file cabinet only for researchers' reference. In order to ensure that the research is carried out in accordance with the regulations, members of the government administration or the Ethical Committee may access your personal data in the research unit as required. When the research results are published, personal information of you will not be disclosed without your permission; if it is necessary to disclose your photos or any personal information, the doctors will sign another informed consent to use the photos and personal information with your consent.

If you are injured as a result of your participation in this study, you can receive free treatment and corresponding compensation.

You may choose not to participate in the study or inform the researcher to withdraw from the study at any time. Your data will not be included in the study results. Your medical treatment and rights will not be affected.

If you need additional treatment, or if you do not comply with the study plan, or if there is a study-related injury or there is no other reason, the doctors may terminate your continued participation in the study.

You can keep abreast of the information and research progress related to this study. If you have any problems related to this study, or if you have any discomfort or injury during the research, or have questions about the rights and interests of the participants in this study, you can contact Zhou Quan by Tel: 15861789806, email: wuque1@126.com,

Informed consent

I have read this informed consent form.

I have had the opportunity to ask questions and all have been answered.

I understand that participation in this study is voluntary.

I can choose not to participate in this study, or withdraw after notifying the researcher at any time without being discriminated against or retaliated against. My medical treatment and rights will not be affected.

If I need other treatment, or if I do not comply with the study plan, or if there is any injury related to the study, or for any other reason, the doctors may terminate my participation in this study.

I will receive a signed copy of the informed consent form.

Subject signature: Kai Wang relationship with subjects: self

Date: June 12, 2018

I have informed the subject accurately of this document, who has read the informed consent and has demonstrated that the subject has the opportunity to raise questions. I have proved that he / she has agreed voluntarily.

Researcher signature: Quan Zhou

Date: June 12, 2018

(Notes: If the subject is illiterate, the witness's signature is required; if the subject is incapacitated, the proxy signature is required)