

Project name:

Arthroscopic Assisted Balloon Tibioplasty for the Treatment of Schatzker II-IV
Tibial Plateau Fractures
Clinical trial protocol

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Responsible unit:

Second Affiliated Hospital of Wenzhou Medical University

Clinical researcher: You-ming Zhao

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Version number 1.1

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Signature of the Sponsor: I've read and confirmed this Project (Project number : SAH_oWMU-CR2017-08-105 ; Version number: 1.1 ; Version date: 2017.09.01).I agree to perform relevant duties in accordance with Chinese law, the Helsinki declaration, China's GCP and the research program.

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Project name:Arthroscopic Assisted Balloon Tibioplasty for the Treatment of Schatzker II-IV Tibial Plateau Fractures

Version number 1.1

Project signature page

Signature of researcher: I've read and confirmed this Project (Project number : SAHoWMU-CR2017-08-105 ; Version number: 1.1 ; Version date: 2017.09.01). And agree that this project is scientific and ethical. We will perform related duties in accordance with the law, the Helsinki declaration, Chinese China GCP and the research program, and only in the bid after the notice to amend, approved by the ethics committee before implementation, unless for the protection of the safety of subjects, rights and interests and must take measures.

We will keep the research plan confidential.

Researcher: trauma department of orthopedics Second Affiliated Hospital of Wenzhou Medical University

Researcher (Printed matter)

Researcher (autograph)

Signature date (year / month / day)

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Abbreviation

ALT	Glutamate aminotransferase
APTT	Activated partial thromboplastin time
AST	Aspartate aminotransferase
BLD	Urine red blood cell
BP	blood pressure
BUN	Urea nitrogen
Cr	creatinine
CRF	Case report form
FBG	Fasting plasma glucose
FIB	Fibrinogen
GCP	Specification for quality management of drug clinical trials
Hb	hemoglobin
HCT	Hematocrit
HR	heart rate
INR	International normalized value
LEU	The number of white blood cell
NEUT	Neutrophils
PLT	Platelet
PRO	Urine protein
PT	prothrombin time
RBC	Red blood cell
TT	Thrombin time
UA	uric acid
U-GLU	urine sugar
Urea	urea
VAS	Visual analogue score
WBC	white blood cell

Project abstract

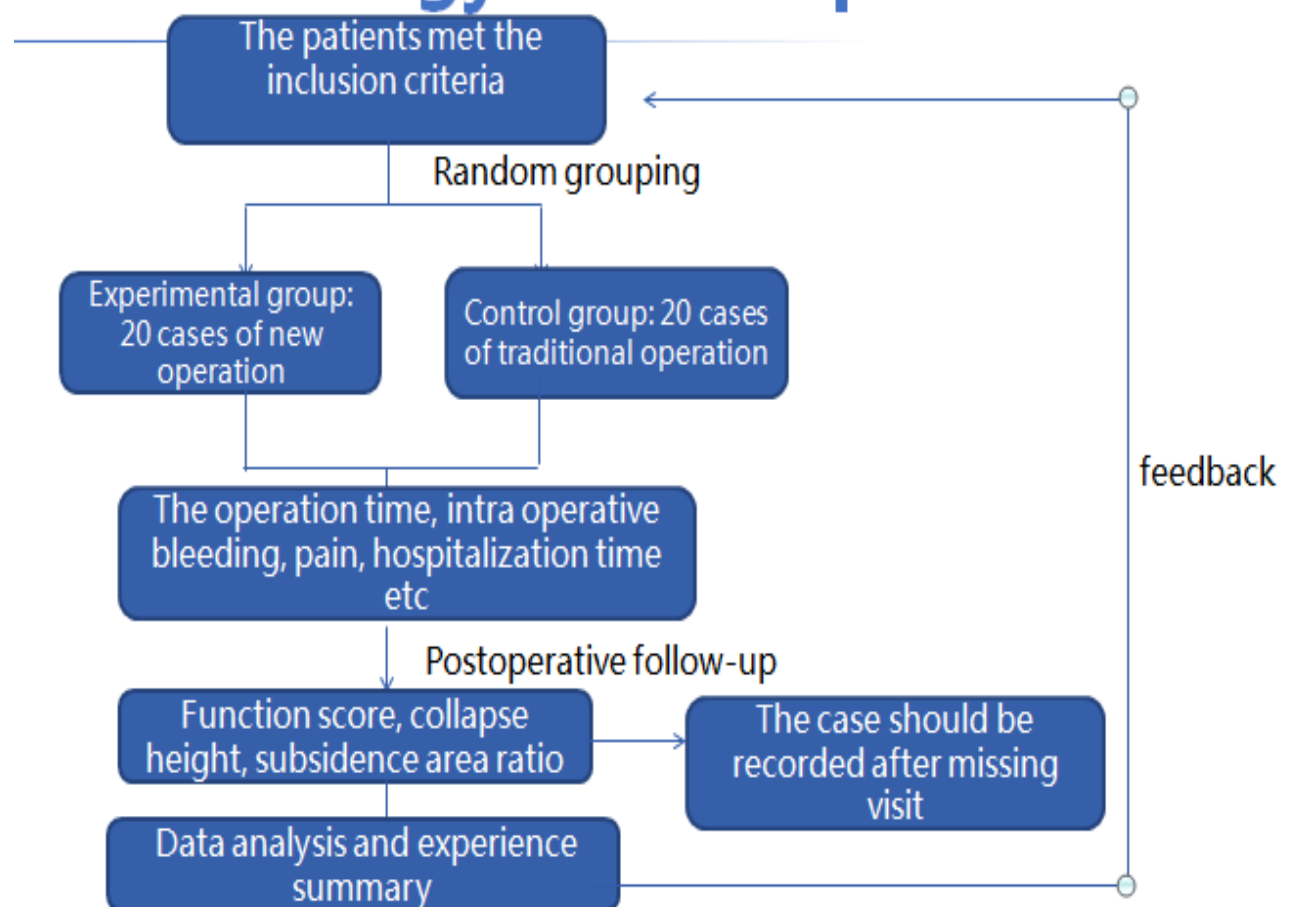
Research topics	Arthroscopic Assisted Balloon Tibioplasty for the Treatment of Schatzker II-IV Tibial Plateau Fractures
purpose	Objective to compare the clinical diagnosis and treatment of open reduction and internal fixation with Schatzker II-IV tibial plateau fracture or arthroscopic assisted balloon tibioplasty of tibial plateau fractures.
overall design	This study used a randomized controlled trial design research.
diagnostic criteria	At least 2 fixed researchers by X-ray or CT examination to determine fracture type
Screening criteria	<p>Inclusion criteria: <u>The following criteria must be according with.</u></p> <ul style="list-style-type: none">(1) fresh closed fracture, X-ray and CT examination diagnosed Schatzker type II-IV tibial plateau fracture patients(2) sign the informed consent form(3) age from 18 to 80 years <p>Exclusion criteria:</p> <ul style="list-style-type: none">(1) exclude open fractures, pathological fractures, immunodeficiency, hematological diseases and severe hepatorenal disorders(2) refuse to sign informed consent form

Methods	<p>Experimental group: patients were randomly divided into the experimental group and underwent Arthroscopic Assisted Balloon Tibioplasty.</p> <p>Control group: patients were randomly divided into control group and underwent Open Reduction and Internal Fixation(ORIF).</p>
<p>Curative effect observation index</p>	<p>Primary Outcome Measure:</p> <p>1.Rasmussen scores change after surgery the knee joint Rasmussen scores change after surgery [Time Frame: 1、 2、 3、 4、 6、 12mouth Rasmussen scores change after surgery]</p> <p>Secondary Outcome Measures:</p> <p>1.Intraoperative blood loss blood loss in surgery [Time Frame: Operation day]</p> <p>2.Postoperative pain score Postoperative pain score(Visual Analogue score, range of scores from 0 to 10,the score is designed to measure the level of the pain and the higher score is,the more painful the patient is) [Time Frame: from operation day to leave hospital day(up to 2 weeks)]</p> <p>3.Fracture healing time Fracture healing time [Time Frame: from leave hospital day to healing time(up to 1 year)]</p> <p>4.The percentage of joint area recovered after operation was</p>

	<p>satisfactory</p> <p>The percentage of joint area recovered after operation was satisfactory</p> <p>[Time Frame: 1、 2、 3、 4、 6、 12 month after surgery]</p> <p>5.operation time</p> <p>Duration of surgery</p> <p>[Time Frame: Operation day]</p> <p>6.the postoperative hospital stay days</p> <p>the total hospital stay days after surgery</p> <p>[Time Frame: from operation day to Leave hospital day(up to 4 weeks)]</p>
Safety observation index	Intraoperative vital signs, Intraoperative C arm examination, postoperative examination etc.
Visiting point	<p>Screening / baseline: admission to the preoperative / postoperative day from the first day to the day of discharge.</p> <p>1、 2、 3、 4、 6、 12 months after the operation.</p>
statistical analysis	<p>Spss22.0 software was used for statistical analysis.</p> <p>The measurement data in SX, using t test, count data expressed as a percentage, using X - test, $P < 0.05$, the difference has statistical significance, and draw the relevant charts with RevMan software. Case characteristics and efficacy analysis were analyzed by complete analysis set (FAS) and compliance program set (PPS), and safety evaluation was analyzed by safety set (SS).</p>
sample size	A total of 40 patients were included this project, the experimental group 20 cases and the control group 20 cases.
Research cycle	<u>July 2017 ~ June 2020</u>

Technology Roadmap

Technology Roadmap



Project text

1. Research topics

Arthroscopic Assisted Balloon Tibioplasty for the Treatment of Schatzker II-IV Tibial Plateau Fractures

2. Research background

Tibial plateau fractures account for 1-2% of all fractures, including 8% of the elderly. In recent years, the incidence of accidents such as traffic accidents and high falls has increased the incidence of tibial plateau fractures. The traditional internal fixation treatment has a series of demerits such as too much damage, the limited explosion of articular cavity, the insufficient diagnosis and treatment for the internal joint injury and the postoperative complications such as the infection of incisional wound and joint degeneration. In recent years, with the development of technology, the treatment concept of tibial plateau fractures has developed from original mechanical fixation to present biomechanical fixation and minimally invasive surgical direction, namely developed from the absolute anatomic reduction and fixation, fracture mechanics healing fixed to minimally invasive operation, indirect reduction and elastic fixation, indirect fracture healing (callus healing). Such as MIPPO technology represented by the LISS system, arthroscopic assisted reduction and internal fixation technology, as well as recently suggested balloon dilation tibioplasty (Balloon Tibioplasty) and other surgical techniques. The key of the Schatzker II-IV type of tibial plateau fracture treatment is to the medial and lateral tibial plateau collapse of the articular surface reduction, arthroscopically assisted balloon distension tibial plasty as an emerging technology, which aims to arthroscopy assisted by the ball Capsule expansion tibial angioplasty, reduction of the collapse of the articular surface, and according to the patient's specific injury to be plate fixation, the technology has shown its initial collapse of the articular surface reduction accuracy, and its surgical trauma is small, postoperative better functional recovery of the joint and early functional exercise of the patient. However, the short occurrence time, the high cost of operation, the unripe surgical technique and the lack of clinical promotion have also been reported in the literature both at home and abroad. Postoperative leakage of bone cement and fractures lost patients reset, the lack of long-term follow-up, and no large number of case data, the clinical treatment remains to be further observed and studied.

3. Test purpose and design basis

3.1 Purpose

Based on the current data of arthroscopically assisted balloon expansion tibial angioplasty, we designed the subject. 1. For the patients who met the inclusion criteria, we randomly performed Open Reduction and Internal Fixation or Arthroscopically assisted balloon expansion tibia. Surgical follow-up, statistical evaluation of the two techniques after surgery for the tibial plateau joint resection and joint function recovery clinical efficacy difference. 2. Through the clinical practice and experience summary, found that the new technology in the operation of the deficiencies in order to improve the technology. 3 through the results of feedback and analysis to guide the clinical diagnosis and treatment.

3.2 Research overall design

The use of existing resources in our hospital to carry out this new technology for patients who meet the inclusion criteria, randomized performed traditional Open Reduction and Internal Fixation or Arthroscopically assisted balloon distension tibial angioplasty, access to a certain period of time the corresponding patient raw data, through professional statistics and epidemiological analysis of comparative data, analysis and discussion based on the analysis results and experience. Concluded the postoperative tibial plateau joint surface resection and joint function recovery clinical efficacy difference between the Balloon Tibioplasty and traditional Open Reduction and Internal Fixation, and the results of feedback to guide the clinical diagnosis and treatment. .

3.3 Sample size

A total of 40 patients were included this project, the experimental group 20 cases and the control group 20 cases.

3.4 Study patients

Outpatient and emergency patients in trauma department of orthopedics of our hospital.

4. Research subjects

4.1 inclusion criteria

- (1) fresh closed fracture X-ray and CT examination diagnosed Schatzker type II-IV tibial plateau fracture patients
- (2) sign the informed consent form

- (3) age from 18 to 80 years

4.2 Exclusion criteria

(1) excluding open fractures, pathological fractures, immunodeficiency, hematological diseases and severe hepatorenal disorders

- (2) refusing to sign informed consent form

4.3 Exit criteria

The patients were lost, half-way to quit and other unpredictable problems

5. Project design

5.1 Project process

A randomized controlled trial design study using the research methods:

1) After signed the informed consent, a complete medical history, vital signs and detailed physical examination were performed, and patients who met the inclusion criteria who did not meet the exclusion criteria were randomly assigned to study.

2) Patients were enrolled and randomized into groups. The arthroscopically assisted balloon expandable tibial plateau in the experimental group and the control group were treated by traditional Open Reduction and Internal Fixation.

3) Experiment group: preoperative preparation: patients with continuous epidural anesthesia, supine, conventional arthroscopic approach to the patient's joint cavity to carefully check the articular cavity hemorrhage removed, explored the meniscus and before and after cruciate ligament and collateral ligament. If there is damage, try to repair first. Step 1: If there is splitting of the tibial plateau, then make an incision in the appropriate part of the proximal tibia according to the fracture type and make a small knee transverse incision in the proximal end of the incision. The first use of minimally invasive surgical techniques in the surgical incision site to place the appropriate specifications of the locking support plate, the bottom of the plate screw holes pre-placed in a temporary cortical bone screw plate can be used in the expansion of the balloon as the outer cortex support structure, prevention of cortical rupture. The temporary fixation of cortical bone screws allow the latter to adjust the height of the plate as needed, and place two Kirschner wires on the anterior and posterior sides of the lower part of the collapsed platform to obstruct preparation for subsequent surgical procedures. Step 2: C arm fluoroscopy positioning and placement of 3 Kirschner wires, the plane formation was located at the center of the platform collapse position below the support point, as

balloon dilatation, select the appropriate balloon needle angle, guided by fluoroscopy, placed in the center of the balloon platform collapse, so that it is in the best position, filling device of bone cement injected with bone cement after expansion, at the same time the use of arthroscopy intervention on the articular surface, prevent the reduction of the articular surface is not complete, not smooth or excessive. Then Insert the other screws, suture the incision. If the tibial plateau does not splitting, the procedure should be carried out directly, and the collapsed articular surface of the tibial plateau can be restored directly.(step 2). A detailed record of 20 case of the operation time (min), the amount of bleeding(ml), postoperative pain score (visual analogue score (VAS)), the postoperative knee joint space width (mm), hospitalization time after operation (d), fracture healing time after operation (m), postoperative maximum articular surface collapse height (mm), the percentage of the restoration of joint collapse area (%),the knee joint Rasmussen scores change after surgery (Rasmussen score), failure rate and complications.

4) Control group: under the condition of random grouping, the patients in the control group were treated with traditional Open Reduction and Internal Fixation of the tibial plateau fracture. A detailed record of 20 case of the operation time (min), the amount of bleeding(ml), postoperative pain score (visual analogue score (VAS)), the postoperative knee joint space width (mm), hospitalization time after operation (d), fracture healing time after operation (m), postoperative maximum articular surface collapse height (mm), the percentage of the restoration of joint collapse area (%),the knee joint Rasmussen scores change after surgery (Rasmussen score), failure rate and complications.

5.2 Screening period (from admission to day before surgery)

- 1) come to our hospital after injury, meet the inclusion criteria.
- 2) at least 2 permanent investigators confirm the type of fracture by X-ray or CT examination.
- 3) after signed the informed consent form, according to random table method, the patients were randomly divided into experimental group or control group for corresponding treatment.

5.3 During the study period (from the day of surgery to 1 years after surgery)

- 1) the day of surgery recorded in detail the surgical procedures, operation time, intraoperative blood loss were recorded.
- 2) from operation day to leave hospital day(up to 2 weeks),the postoperative pain score, postoperative knee gap width, postoperative hospital stay days were recorded.
- 3) the patients were followed up after leave hospital: make a detailed record of the knee joint Rasmussen scores change after surgery (Rasmussen score) (1,2,3,4,6,12 months after surgery), The

percentage of joint area recovered after operation where was satisfactory, postoperative fracture healing time, maximal postoperative articular surface collapse height, postoperative failure rate and related complications.

5.4 The end of the study period (the end of the follow-up to the project end)

1. sort the appropriate information, through epidemiological or statistical experts guidance, experimental group and control group data analysis, using SPSS 22.0 statistical software analysis, measurement data to t test, counting data Percentage, using χ^2 test, $P < 0.05$ for the difference was statistically significant, and use RevMan software to draw the relevant charts.
2. based on the data and charts after treatment, organize clinical discussions and experience of relevant personnel: 1.the actual operation of the new technology found in all aspects of the existing shortcomings and explore ways to improve the arthroscopic balloon dilatation tibial angioplasty, and improve the clinical diagnosis and treatment of fractures related to our hospital level. 2 through get the follow-up data under this new technology to enrich our hospital clinical data resources.
- 3 According to the results of the comparison, comparative analysis of Arthroscopic Assisted Balloon Tibioplasty and traditional Open Reduction and Internal Fixation for reduction of articular surface of tibial plateau and joint function recovery clinical curative effect, to guide the clinical work, and output clinical practical guidance and industry recognized research results for clinical decision-making and diagnosis and treatment guidelines provide a scientific basis.

6. Efficacy evaluation index

6.1The main efficacy indicators

Operation time (min)

Postoperative hospital stay (d) (first day after surgery to discharge day, up to 4 weeks)

Postoperative knee function Rasmussen score changes (1, 2, 3, 4, 6, 12 mouths)

6.2 secondary efficacy indicators

Intraoperative bleeding (ml)

Postoperative pain score (visual analogue scale (VAS)) (first postoperative day to discharge day, maximum 2 weeks)

Postoperative fracture healing time (m) (discharged to fracture healing, maximum 1 year)

Postoperative knee gap width (mm)

Postoperative articular surface maximum collapse height (mm)

Height of well-resumed postoperative articular area as a percentage of collapse area (%)

7. Safety evaluation

7.1 Adverse event definition

Since the patients signed informed consent to the completion of all visits, the patients to report or research physician observed any adverse medical events, regardless of whether there is a causal relationship with the test drugs, were convicted of adverse events. Adverse events included general adverse events, adverse events and serious adverse events.

7.2 Ways of getting information about adverse events

All the adverse events report in directly medical terminology report.

7.3 Record of adverse events

Record the occurrence of adverse events, severity, duration, and outcome measures. Adverse events should be recorded in the specified CRF adverse event reporting table.

When the adverse events appear, the researcher should immediately report to the responsible party and determine the necessary diagnosis and treatment according to the condition of the patient to decide whether to stop the clinical trial. All adverse events should be followed up, and the treatment process and results should be carefully recorded until the proper solution or the condition is stable, and the correlation between the method and the test method is determined. If associated with surgery, should be tracked to return to preoperative levels. Follow up visits can be done according to the severity of adverse events such as hospitalization, outpatient visits, home visits, telephone calls, communication, etc..

7.4 Criteria for severity of adverse events

When completing the CRF adverse event table, the researchers referred to the CTCAE4.0 criteria to describe the intensity of adverse events using mild, moderate, severe, life-threatening, and fatal events. For a unified standard, classification of event intensity of light moderate and severe criteria are as follows:

Mild: does not affect the normal function of patients;

Moderate: to a certain extent affect the normal function of patients;

Severe: normal function of affected patients.

Pay attention to the difference of adverse events and severity of strength. Used to describe the severe intensity, not necessarily SAE. For example, headache may be severe in intensity, but not in SAE unless it meets SAE criteria.

7.5 The judgment standard of adverse events and test operation relations

Evaluation according to the following interpretation.

It was confirmed that the adverse events were accorded with the reasonable time after the trial operation, and the reaction accorded with the type of reaction known in the test operation;

It is likely that the adverse events are accorded with the reasonable time after the trial operation, that the response conforms to the type of reaction known to the test operation, and that there is unlikely to be additional explanation, such as concomitant medication or concomitant disease;

It may be related to the occurrence of adverse events that are consistent with the time order of the trial operation, the response to the type of reaction known to the test operation, and the patient's clinical status or other treatment modalities may also reaction of operation;

It may be irrelevant: adverse events do not conform to the reasonable time sequence after the trial operation, and the reaction is not in line with the known type of reaction in the test operation; it is more likely to be related to other factors;

Certainly nothing: the reaction does not comply with the time sequence test operation after reasonable, a type of reaction with non test operation known reaction; the patient's clinical status or other treatment may cause the reaction, improve the disease state or stop the elimination reaction of other treatments, the repeated use of other treatment response.

Certainly, adverse reactions may be associated and may be related to all adverse events.

7.6 Important adverse events

Serious adverse events (SAE) that required hospitalization, prolonged hospitalization, disability, affecting work ability, endanger life or death, resulting in congenital malformation occurred during the clinical trial.

7.7 Plans to deal with cases of serious adverse events

When serious adverse events occur, we should do our best to save them and take all kinds of measures to avoid permanent damage. From the beginning of project to any SAE appear in the observation period, the researchers shall immediately notify the person in charge of project in our hospital, clinical trial management, ethics committee, fill out the "serious adverse events", 24h in a written report to the applicant, our hospital clinical trial management

departments, the ethics Committee and relevant drug management department. Serious adverse events in the end of treatment, the patients should be submitted to the follow-up report

Contacts for serious adverse events

unit	linkman	contact way
Project Leader	You-ming Zhao	13806691852 ymzhao710@163.com
The Second Affiliated Hospital of Wenzhou Medical University	Medical ethics committee	0577-88002560 feykjkcy@126.com
The Second Affiliated Hospital of Wenzhou Medical University	The clinical research center for drug clinical trial institution Office	0577-88002664、 88002738 ywlcsy409@163.com

8. Statistical analysis

8.1 Data selection for statistical analysis

Totally analyzed data sets (FAS): all randomized, grouped, and postoperative studies were performed with a complete analysis set. For the therapeutic data that failed to be observed in all treatments, the final measured efficacy data was used as end point data for analysis.

PPS (PPS): contained in the FAS, met the inclusion criteria, does not meet the exclusion criteria, no major protocol violations, and has completed the treatment period of efficacy evaluation, good compliance cases, this study constitutes with the scheme set.

Safety analysis data set (SS): all patients who were randomized to receive research methods and had postoperative safety evaluation data constituted the safety analysis data set of this study.

8.2 Statistical analysis plan

There was no significant difference in age, gender, fracture type and other aspects between the two groups ($P>0.05$). Through epidemiological or statistical expert guidance, the experimental group and the control group data were analyzed using SPSS 22 statistical software, the measurement data in SX, using t test, count data expressed as a percentage, using X - test, $P < 0.05$, the difference has statistical significance, and draw the relevant charts with RevMan software.

9. Data management and statistical analysis

9.1 Filling and transferring of case report form

The case report form (CRF) was filled out by the researchers. The data in CRF were derived from original records and physical and chemical examination reports and other original documents and should be consistent with the original documents. Any observation and examination result in the test should be completed in time, correctly, completely, clearly, standard and truly in CRF, and should not be changed at will. All the items in the CRF are required to fill in, not empty or missed. If necessary, CRF data correction, fill in the data modification

9.2 Data input and modification

Data entry and management by the responsible investigators. Using EDC data entry system to establish a dedicated database for data entry and management, in order to ensure the accuracy of data, by two data managers independently double input and proofreading. The data entry process any data modification system are recorded.

The existence of the case report form questions, the data administrator will produce FAQ table (DRQ), and the issue of asking researchers by CRA, researchers should answer as soon as possible and return data, modify, and confirm the administrator for data entry on the answer, when necessary, can be re issued DRQ.

9.3 Data locking

By the principal investigators, sponsors, statistical analysis of data locking. The locked data file is no longer changed. The data after the database lock should be saved for reference, and the database will be sent to statistical experts for statistical analysis.

10. Amendment of project

Any necessary changes in the project must be carried out in the form of a revised project, which should be signed by the principal investigator and submitted to the Ethics Committee for approval or filing.

11. GCP principle - the rights and safety of subjects

1. the plan must be approved by the Second Affiliated Hospital of Wenzhou medical university ethics committee.
2. all patients should understand the purpose, method, function and advantages and disadvantages of the test method, voluntarily participate in the test and sign the written informed consent.
3. patients had the right of informed consent, and they could quit the experiment according to their wishes without affecting their normal medical treatment.

4. patients had adverse events related to trials during the trial, and the team was responsible for providing treatment costs or corresponding compensation for adverse events related to the trial.
5. the responsible party should ensure the normal operation of the medical monitoring system, the patients can contact with the research doctor at any time needed to obtain timely medical treatment, and if necessary, they can be hospitalized for diagnosis and treatment.
6. emphasize the responsibility of the medical staff at all levels, close observation to ensure patient's safety.
7. if the adverse events occurred, the patients should be treated in timely, and the patients were followed up until the adverse events were cured and the outcome was stable. The researchers thought that it was no longer clinically significant or that the subjects were lost to follow-up.
8. if serious adverse events occur, the necessary measures should be taken to ensure the safety and rights of the patients, and they shall be reported to the ethics committee and clinical research center of the Second Affiliated Hospital of Wenzhou Medical University within 24 hours.
9. the informed consent accords with the latest revised version of the Helsinki declaration, as well as any applicable provisions and policies. Each participant or his legal representative must have a comprehensive understanding of the test and sign his name and date on the informed consent to express his consent.

12. The responsibilities of researchers

The main investigator and participant should carry out the test according to the clinical research plan and abide by the Helsinki declaration, the relevant laws and regulations of China and the current GCP principle.

13. Project schedule

2017.7-2019.6: corresponding operation was performed on the experimental group and the control group. The patients were followed up for 1,2,3,4,6,12 months after the operation. The X-ray and CT examination of the corresponding parts was performed, and the corresponding data were collected.

2019.7-2019.12: according to the existing problems in the operation, the improvement program was put forward, and the relevant feedback data were implemented after improvement.

2020.1-2020.6: statistical analysis, experience summary and the relevant papers published.

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15. Appendix I Clinical trial flow chart

content	Screening period ¹ (1 days before surgery)	Operati on day	Visiting V1							Visiting v2
			至出院 ²	1m	2m	3m	4m	6m	12m	Until the end of the study
informed consent	√									
Inclusion / exclusion criteria	√									
Vital signs	√	√	√							
physical examination	√	√								
Fracture classification	√									
random	√									
Combined treatment and diseases	√	√	√	√	√	√	√	√	√	√
Routine blood test	√		√							
Urine routine	√									
Blood biochemistry	√		√							
Coagulation function	√									
Routine electrocardiogram	√									
pulmonary function	√									
Operative time and intraoperative bleeding		√								
VAS score(rest, movement) ³			√	√	√	√	√	√	√	√
X-ray and CT after operation ⁴			√	√	√	√	√	√	√	√
HSS scores			√	√	√	√	√	√	√	√
Adverse events monitoring and recording		√	√	√	√	√	√	√	√	√

Explain:

- 1. Within 14 days before randomization, the same organization completed the test and inspection report of the same project, which can be used as the baseline result of screening period.**
- 2.The daily morning measurement of vital signs after the operation until the leaving day, the first day of blood routine and biochemical routine after surgery and every three days thereafter retest, routine postoperative analgesia for 3 days, as the subjects of analgesic requirements, the method of analgesia, determined by the doctor in charge, and do the record.**
- 3.VAS were assessed on the first postoperative days to discharge day before the daily infusion.**
- 4. Routine X-ray and CT examination were performed second days after operation, and were followed up regularly in 1, 2, 3, 4, 6 and 12mouths after operation.**
- 5. Routine blood test: red blood cell (RBC), white blood cell (WBC), neutrophil (NEUT), hemoglobin (Hb), platelet (PLT), hematocrit (HCT), C reactive protein (CRP), erythrocyte sedimentation rate (ESR).**
- 6.Routine urine test with urine (U-GLU), urine protein (PRO), urine red blood cell (BLD), white blood cell (LEU).**
- 7.Blood biochemical detection: containing aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (ALP), total bilirubin (TBIL), urea nitrogen or urea (BUN or Urea), creatinine (sCr or Cr), uric acid (UA), fasting blood glucose (FBG).**
- 8.Coagulation function: including prothrombin time (PT), activated partial thromboplastin time (APTT), international normalized ratio (INR), thrombin time (TT), fibrinogen (FIB).**