A Prospective, Multi-center and Non-inferiority Clinical Study Evaluating Trochanteric Fixation Nail Advanced (TFNA) in Chinese Patient Population

Statistical Analysis Plan

V1.3

Statistical institution:	**Medical Research & Biometrics Center, National Center for Cardiovascular Diseases**
Sponsor:	**Johnson & Johnson Medical (Shanghai) Ltd.**
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Signature Page

Study title:	A Prospective, Multi-center and Non-inferiority Clinical Study Evaluating Trochanteric Fixation Nail Advanced (TFNA) in Chinese Patient Population	
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Table of Contents

Chapter Page

List of Abbreviations and Definitions of Terms

Abbreviation	Definition
GCP	Good Clinical Practice
CRF	Case Report Form
SF-12	12-Item Short Form Health Survey
IRB	Institutional Review Board
EC	Ethics Committee
ERB	Ethical Review Board
BMI	Body Mass Index
AE	Adverse Event
SAE	Serious Adverse Event
UADE	Unanticipated Adverse Device Effect
ICH-GCP	International Conference on Harmonization - Good Clinical Practice
HHS	Harris Hip Score
EQ5D	EuroQol-5D

1. Introduction

This document provides the specific contents of the statistical analysis plan for a prospective, multi-center and non-inferiority clinical study on the safety and effectiveness of Trochanteric Fixation Nail Advanced (TFNA) manufactured by Johnson & Johnson Medical (Shanghai) Ltd. After all subjects are included and use the implant, the postoperative 24-week (±4 weeks) follow-up is completed or the trial is terminated in advance and the database is forcibly locked, the statistical analysis report for preoperative preparation and postoperative 24-week (±4 weeks) follow-up will be issued for registration application. Refer to the relevant tables, lists and graphs in the statistical analysis plan for the detailed specific analysis.

2. Clinical Study

2.1 Study objective

The primary objective of this study is to evaluate whether fracture union rate, evaluated 24 weeks after proximal femur fracture, for the investigational TFNA intramedullary nail is non-inferior to that for currently available control product PFNA-II in patients with proximal femur fractures.

2.2 Study design

The Trochanteric Fixation Nail Advanced (TFNA) is an implant designed to treat

proximal femur fractures and is currently in use in several regions worldwide (e.g., US, Europe). TFNA is manufactured using a titanium-molybdenum alloy (TiMo) that has not been used for a similar clinical application within China. The study is a prospective, multi-center, controlled, two-arm, randomized, non-inferiority study comparing the 24-week fracture union rate for proximal femur fractures treated with intramedullary nails using investigational devices (TFNA) compared to control devices (Proximal Femoral Nail Antirotation, PFNA-II), under a 10% non-inferiority margin.

2.3 Primary endpoint

The primary endpoint is the fracture union rate 24 weeks after surgery. Fracture union success is a composite endpoint; in order for an individual subject's surgery implanted with TFNA or PFNA-II to be considered successful he/she must satisfy all of the following criteria:

1. No focal tenderness or lengthwise percussion pain, or abnormal movement
2. The frontal/lateral X-ray examination shows the vague or no fracture gap, or the continuous callus passing across the fracture line
3. No deformation or breakage is found in the investigational product

2.4 Secondary endpoints

Secondary endpoints include the safety and effectiveness results, imaging outcomes and adverse events.

- Adverse events (type and frequency) for all adverse events will be compared for the study and control groups
- 24-week revision rate where revision is defined as removal of any component for any reason
- 24-week reoperation rate is defined as secondary surgery at the fracture site(s) for any reason
- Clinical Outcomes
  - SF-12
  - Harris Hip Score
  - EQ-5D
- Radiographs: incidence of complications such as loosening or cut-out that require reoperation or revision.

3. Investigational Device

3.1 Investigational device

TFNA as the investigational product for this study, including:

- Short nails available in various diameters (Ø9, Ø10, Ø 11, Ø12 mm), lengths (170, 200, or 235 mm) and CCD angle (125°, 130° and 135°). The 235 mm short nail is available for left and right sides.
- Long nails available in various diameters (Ø9, Ø10, Ø 11, Ø12, Ø14mm), lengths (260-480mm in 20mm increments) and CCD angle (125°, 130° and 135°). All long nails are available for left and right sides.
- Head elements are available in blade and screw (both are 70-130 mm in length, available in 5mm increments)
- Locking screws (4.2mm diameter and available in lengths from 26-80mm (2mm increments) or 80-100mm (5mm increments)
- End caps available in 0, 5, 10 and 15mm lengths

3.2 Control device

PFNA-II as control product for this study, including:

- Short nails available in various diameters (Ø9, Ø10, Ø 11, Ø12 mm), lengths (170, 200, or 240 mm) and CCD angle (125° and 130°). The 240 mm short nail is available for left and right sides.
- Long nails available in various diameters (Ø9 and Ø10mm), lengths (260-340mm in 20mm increments and 340-420mm in 40mm increments) and CCD angle (125° and 130°). All long nails are available for left and right sides.
- Head elements are available in blade (70-120 mm in length, available in 5mm increments)
- Locking screws (4mm diameter and available in lengths from 16-60mm (2mm increments), 60-80mm (4mm increments) or 80-100mm (5mm increments)
- End caps available in 0, 5, 10 and 15mm lengths

4. Intended Use and Indications of the Product

The intended use for TFNA is the following:

Intended Use: intended for the treatment of proximal femur and combinations of proximal and shaft fractures of the femur

The indications of the TFNA are:

- Short Nails (lengths 170 mm, 200 mm, 235 mm)
- Pertrochanteric fractures (31-A1 and 31-A2)
- Intertrochanteric fractures (31-A3)
- 235 mm nails are additionally indicated for high subtrochanteric fractures

- Long Nails (lengths 260 mm - 480 mm)

- Pertrochanteric fractures (31-A1 and 31-A2)
- Intertrochanteric fractures (31-A3)
- Fractures of the trochanteric area (31-A1/A2/A3) with diaphyseal extension
- Combined fractures of the trochanteric area (31-A1/A2/A3) and the femoral shaft (32-A/B/C)
- Pathological fractures, including prophylactic use
- Malunion
- Nonunion

5. Inclusion and Exclusion Criteria of Subjects

5.1 Inclusion criteria

Subjects who meet all of the following inclusion criteria will be eligible for participation in the study:

1) Age ≥18 years
2) Patients with unilateral proximal femur fractures that will be treated with intramedullary nail internal fixation
3) According to AO fracture classification, subjects with following fracture type:

a. Pertrochanteric (31-A1 and 31-A2)
b. Intertrochanteric (31-A3)
c. Trochanteric area (31-A1/A2/A3) with diaphyseal extension

4) Subject must be comfortable with speaking and understanding questions and responses in an available translated language for patient reported outcomes (PROs)

5.2 Exclusion criteria

Subjects who meet any of the following criteria will be excluded from the study:

1) Subject does not provide voluntary consent to participate in the study.
2) The subject is a woman who is pregnant or lactating
3) Fractures where the operative treatment will occur more than three weeks after the primary injury
4) Patients with femoral head fractures and femoral neck fractures (AO classification 31-B and 31-C)

5) Pathological fracture (e.g., primary or metastatic tumor)
6) Serious soft tissue injury, judged by the investigator, will impact the union of the fracture, combined vascular injury, and combined osteofascial compartment syndrome.
7) Multiple systemic injuries judged by researchers not suitable for enrollment, or orthopaedic fractures in other bones at three or more sites
8) Revision surgeries (for example, due to malunion, nonunion or infection)
9) Concurrent medical conditions judged by researchers not suitable for enrollment, such as: diabetes, metabolic bone disease, post-polio syndrome, poor bone quality, prior history of poor fracture healing, etc.
10) Patients with anaesthetic and surgical contraindications
11) Patents known to be allergic to implant components
12) Patients who are currently using chemotherapeutics or accepting radiotherapy, use systematically corticosteroid hormone or growth factor, or long-term use sedative hypnotics (continuous use over 3 months) or non-steroidal anti-inflammatory drugs (continuous use over 3 months)
13) Intemperance judged by researchers not suitable for enrollment (e.g., excessive daily drinking or smoking, drug abuse);
14) Patients participated into other clinical trial in the previous 3 months;
15) Patients with bad compliance judged by researchers and cannot complete the trial according to the study plan, such as schizophrenia and dementia.

6. General Statistical Considerations

6.1 Study hypothesis

The primary endpoint analysis will be to demonstrate that the investigational device (TFNA) is non-inferior to the control device (PFNA-II) based on the fracture union rates at the 24 week follow-up visit. Non-inferiority test will be conducted based on a one-sided 97.5% confidence interval for the difference in the fracture union rate at 24 weeks between the study group and the control group.

The primary hypothesis is that, at 24 weeks after surgery, the investigational device (TFNA) is non-inferior to the control device (PFNA-II) based on the individual patient fracture union rate. Non-inferiority is defined by a test with a two sided 5% type I error and a 10% “margin of non-inferiority”.

The study’s null and alternative hypotheses are as follows:

$$H_o : P_{PFNA\text{-}II} - P_{TFNA} \geq 10\%$$
$$H_a : P_{PFNA\text{-}II} - P_{TFNA} < 10\%$$

Where, $P_{PFNA\text{-}II}$ represents the fracture union rate among those receiving PFNA-II implant and P_{TFNA} denotes the fracture union rate among the recipients of TFNA.

Decision Criterion: The decision will be made to reject the null hypothesis H_0 and conclude the alternative hypothesis H_a if the one-sided 97.5% confidence interval for the difference in the fracture union rates between the control group and the study group is less than the margin of non-inferiority, 10%.

6.2 Sample size calculation

The sample size calculation is determined based on the primary endpoint using PROC POWER in SAS software version 9.3. It assumes that the fracture union rate at 24 weeks after surgery in the TFNA group would be equivalent to that of the PFNA-II group, and a common fracture union rate is approximately 95% or greater based on the literature review. With a non-inferiority margin of 0.10 and a power of 80%, this implies a sample size of 75 for the TFNA and of 75 for PFNA-II surgery groups, respectively. The sample size will be increased to 188 (94 per group) to accommodate potential 20% attrition.

The sample size applies to patients enrolled, randomized, and actually treated. Some patients who enroll in a study and are randomized may not be ultimately treated for various reasons. Patient enrollment and randomization will continue until the proposed sample size for treated patients is complete.

6.3 Analysis population

Full Analysis Set (FAS): The set of subjects determined following the intent-to-treat (ITT) principle refers to the data set constituted by all subjects who participate in the randomized study and receive the investigational product (implant) (i.e., ITT population defined in the protocol).

Per Protocol Set (PPS): Refers to the subgroup of treatment population who completes the trial and excluded the population that seriously violates the protocol (which means that study subjects violating the inclusion criteria or meeting exclusion criteria, loss to follow-up during the trial, cross enrollment, out-of-specification use of investigational products, out-of-window time, etc.).

Safety Set (SS): Set of all subjects who participate in the study and use the investigational products and undergo at least one safety evaluation after baseline. (The definitions of SS and FAS are the same. Therefore, SS is not defined separately).

Actual Treatment Set (ATS): All patients who participate in the randomized grouping, complete the trial, actually receive the scheduled treatment in the study (not necessarily consistent with the results of randomized grouping) and do not seriously violates the protocol. On the basis of PPS, only cross-enrolled patients are included, but they are then grouped and analyzed according to their actual treatment, i.e., the actual treatment set is formed.

The primary efficacy analysis will be based on FAS, PPS and ATS (if applicable). All baseline demographic data and secondary efficacy indicator analysis will be performed on the basis of FAS, and the safety evaluation will be performed on the basis of FAS.

6.4 Detailed rules for determination of analysis population set and flow chart

(1) No investigational device is implanted: Subjects obtain random numbers but do not use any study-related treatment (implantation study group, control group or third party products);

(2) Violation of inclusion and exclusion criteria: The subjects do not meet the inclusion criteria or meet the exclusion criteria set in the study protocol, and the violation of this protocol will seriously affect the results of primary efficacy endpoints; the sponsor, investigators and statisticians will jointly determine through a blind review meeting whether the protocol violation will seriously affect the results of primary efficacy endpoints;

(3) Loss to follow-up during the trial: Subjects are unable to obtain the fracture union rate 24 weeks after the primary endpoint surgery;

(4) Cross enrollment: Subjects randomly assigned to the study group receive the control products, while subjects randomly assigned to the control group receive the investigational products;

(5) Out-of-window time: The difference between the follow-up date at 24 weeks after primary endpoint surgery and the surgery date do not fall within the range of [140, 196], and the violation of this protocol may seriously affect the results of primary efficacy endpoints; the sponsor, investigators and statisticians will jointly determine through a blind review meeting whether the protocol violation will seriously affect the results of primary efficacy endpoints;

(6) Out-of-specification use of investigational products: The specifications of the device implanted in the subject are not within the specification range specified in the study protocol;

(7) Use of third party products: The subjects randomly assigned to the study group or the control group use third party products;

(8) FAS = Number of subjects enrolled in the trial - Number of subjects not implanted with any investigational device;

PPS = FAS - Number of subjects who seriously violate the study protocol;

ATS = PPS + Number of cross-enrolled subjects alone; ATS will be displayed if subjects are cross-enrolled in the trial, while ATS will not be displayed if no cross-enrollment occurs.

Number of subjects who seriously violate the study protocol = Violation of inclusion and exclusion criteria + Loss to follow-up during the trial + Cross enrollment + Out-of-window time + Out-of-specification use of investigational products + Use of third party products;

The priority of serious violations from study protocol: Loss to follow-up during the trial, cross enrollment, use of third party products, violation of inclusion and exclusion criteria, out-of-specification use of investigational products, out-of-window time; if the subjects meets the above two or more serious violations, the violations will be classified by priority;

Serious violations from study protocol in the statistical table can be listed according to the actual situation of the data. If the number of subjects who exceed the time window in both the study group and the control group is 0, then such information may not be shown in the table. Meanwhile, the list of subjects who are not implanted with any investigational device or have serious violations from study protocol will be provided, including site number, random number, gender, age, type, reason, FAS, PPS and ATS.

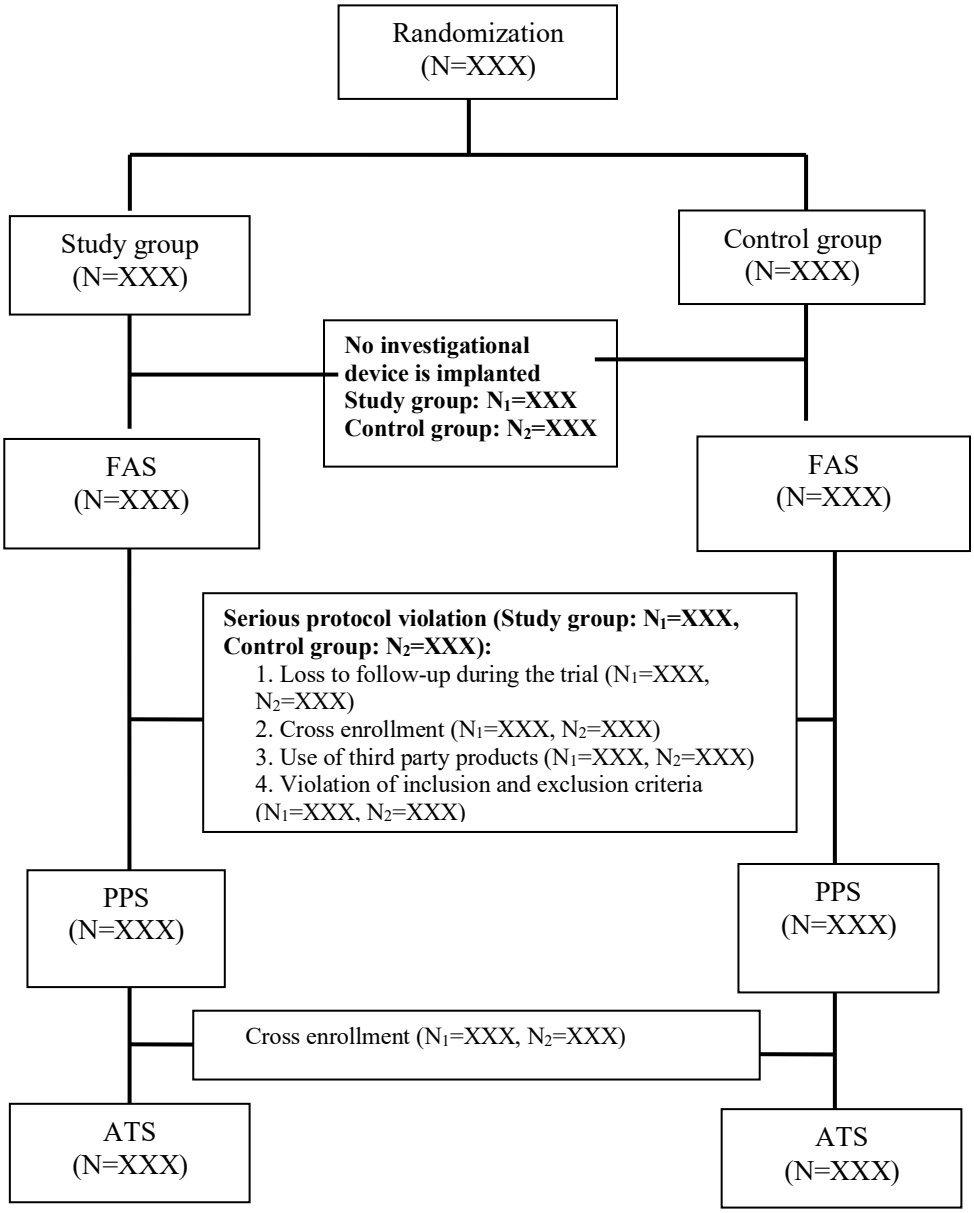

Figure 1 Flow chart for determination of analysis population data sets

6.5 Missing values, abnormal values and outlying values

For possible missing data in the study process, the missing of primary efficacy endpoints will be carried forward only in principle during the analysis. LOCF (Last Observation Carry Forward) was used as sensitivity analysis for the missing of primary efficacy endpoints. That is, the last observed value is used to replace the missing value. In the sensitivity analysis of the LOCF, the last observed value is " Nonunion of fracture " unless the fracture union is definitive. Other missing indicators will not be carried forward and will be directly analyzed based on the actually observed data.

Error and unreasonable data will be processed in the data cleaning process before statistical analysis. For withdrawal of subjects, this part of patient information will still be included in the final statistical analysis. Specific reasons for discontinuation or withdrawal of all patients will be explained in detail in the statistical report, and the missing primary endpoint due to early withdrawal will be analyzed according to the above strategy for processing missing values.

If the date (MMDDYYYY) of collection (non-CEC review data) during the trial is filled in with "UK" or "NA", no treatment will be done.

6.6 Significant level and statistical analysis software

For the primary endpoint, statistical analysis will be performed at the one-sided 0.025 significance level (corresponding to the one-sided confidence limit of the 95% confidence interval). For other endpoints, all statistical analysis will be performed at the two-sided 0.05 significance level (except for special instructions). SAS® 9.4 statistical software will be used for statistical analysis.

6.7 Site merging principle

This trial is to be conducted simultaneously in multiple clinical trial institutions, and the actual number of subjects successfully included in each site will vary. In order to avoid the influence of too few actual number of subjects successfully enrolled in the site on the stability and reliability of the primary endpoint analysis results, the sites with the actual number of subjects successfully enrolled less than 10 will be merged. According to previous experience and reference, site merging generally adopts the following two methods:

(1) Sort the sites with the number of subjects actually enrolled less than 10 according to the site number, and merge the sites directly until the number of subjects in the sites is ≥10 after merging;

(2) Merge the sites according to the principle of geographical proximity, and the number of subjects in the sites should be ≥10 after merging;

The site merging principle adopted in the statistical analysis will be further determined by the sponsor, the investigator and the statistician through a blind review meeting.

7. Statistical Analysis Indicators and Statistical Analysis Methods

7.1 Demographic indicators and other baseline indicators

Demographic data include gender, age, height, weight and BMI; other baseline indicators include the subject's medical history, SF-12v2 questionnaire, EQ-5D questionnaire and preoperative fracture status.

Where:

Age = (Date of informed consent - Date of birth)/365.25;

BMI = Body weight (kg)/(Height (m))^2.

The indicators in this part are mainly descriptive. Enumeration data are described by frequency and composition ratio, while measurement data are described by mean, standard deviation, median, quartile, maximum and minimum. The likelihood ratio Chi-square test will be used to compare the enumeration data between groups. Fisher's exact probability test will be used when the theoretical frequency in the fourfold table is less than 5.

7.2 Intraoperative information

The intraoperative information includes the subject's operation time, blood loss volume, blood transfusion volume, investigational device use, intraoperative fracture, etc.

The indicators in this part are mainly descriptive. Statistical analysis methods are the same as those in 7.1.

7.3 Primary endpoint

The primary endpoint is the fracture union rate 24 weeks after surgery.

Fracture union success is a composite endpoint; in order for an individual subject's surgery implanted with TFNA or PFNA-II to be considered successful he/she must satisfy all of the following criteria:

1. No focal tenderness or lengthwise percussion pain, or abnormal movement
2. The frontal/lateral X-ray examination shows the vague or no fracture gap, or the continuous callus passing across the fracture line
3. No deformation or breakage is found in the investigational product

Calculation principle: Based on the postoperative 24-week follow-up of the fracture status and the X-ray examination results of the fracture site, the calculation principle is as follows:

①. It is determined as 'Yes' when the focal tenderness, lengthwise percussion pain and abnormal activity at the postoperative 24-week follow-up of the fracture are filled as 'NA', 'NA' and 'No', respectively;

②. It is determined as 'Yes' when the X-ray examination at the fracture site 24 weeks after surgery shows that the fracture line is 'vague' or 'disappeared'; or that the frontal/lateral X-ray examination shows the continuous callus passing across the fracture line is filled as 'Yes';

③. It is determined as 'Yes' when the X-ray examination at the fracture site 24 weeks after surgery shows that the implant is filled as 'good';

If ①, ② and ③ are determined as 'Yes', then the successful fracture union 24 weeks after surgery is determined as 'Yes'; if one of them is missing, it is determined as missing, that is, 'loss to follow-up during the trial'; others are determined as 'No';

For the primary endpoint, the analysis bases on the actual data (except missing data). LOCF (Last Observation Carry Forward) was used as sensitivity analysis for the missing of primary efficacy endpoints. The below 2 analysis tests will be used for the above analysis, and estimates of the differences in efficacy between the groups and bilateral two-sided 95% confidence interval will be given:

(1) CMH chi-square test with adjusted central effects;

Calculation method for non – inferiority P value：

Se=(Rate difference 95% upper limit of confidence interval - Rate difference 95% low limit of confidence interval)/2/ probit (1-0.05/2)；

Z=(Investigational group-control group of difference in fracture union rates- non-inferiority margin)/Se；

P value=1-probnorm(Z)；

(2) Continuous correction Newcombe-Wilson for non-adjusted central;

The result from test (1) will used for the primary analysis result, the result from test (2) will be used as sensitivity analysis result. If the lower limit of the bilateral two-sided 95% confidence interval on differences in efficacy between the study group and the control group (equal to the lower limit of unilateral 95% confidence interval) is greater than -10%, it can be considered that the investigational product is not inferior to the control product

If the actual study results show that other baseline variables (such as age and gender) are significantly different between the study group and the control group, it will be fully communicated to the investigator in the data analysis stage. Based on the results of univariate analysis for baseline variables and primary endpoint, previous literature references and the clinical expert experience, the indicators affecting the primary endpoint to cause imbalance between groups, i.e., confounding factors, will be further specified. These indicators will be considered into the generalized linear model for correction and included into the sensitivity analysis of the primary endpoint analysis.

7.4 Secondary endpoints

Secondary endpoints include the safety and effectiveness results, imaging outcomes and adverse events.

(1) Adverse events (type and frequency) for all adverse events will be compared for the study and control groups

Calculation principle: Based on the collected adverse events in the CRF, if the subject has had at least one adverse event, it will be regarded as 'Yes'; otherwise, it will be 'No'.

The indicators in this part are mainly descriptive. Statistical analysis methods are the same as those in 7.1.

(2) 24-week revision rate, where revision is defined as any component removal for any reason.

Calculation principle: Based on the collected adverse events in the CRF, if the measure taken for the implant is filled as "Revision" and the difference between the date of occurrence of the event and the date of the operation is ≤196 days, the revision is determined as "Yes"; if postoperative 24-week follow-up is failed, it is determined as "Missing"; others are determined as 'No';

The indicators in this part are mainly descriptive. Statistical analysis methods are the same as those in 7.1.

(3) 24-week re-operation rate, where re-operation is defined as secondary operation of the fracture site for any reason.

Calculation principle: According to the AEs in CRF. If AE "re-operation" site collected in the CRF and occurrence of the event and the date of the operation is ≤196 days, it is determined as 'Yes'; if postoperative 24-week follow-up is failed, it is determined as 'Missing'; others are determined as 'No'.

The indicators in this part are mainly descriptive. Statistical analysis methods are the same as those in 7.1.

(4) Clinical outcomes

- SF-12
- Harris Hip Score
- EQ-5D

Calculation principle for SF-12 Score:

SF-12 v2 Questionnaire (each item consists of 8 parts: body functions, physical conditions, body pain, general health, mental health, emotional conditions, social functions and vitality) and general physical and mental health assessment.

Calculation principle: SF-12 scores will be calculated by special software, and statistical analysis will be performed using "_NBS" variable.

The indicators in this part are mainly descriptive. The descriptive analysis results of the SF-12 score and the change from baseline at each follow-up will be given. The statistical analysis method is the same as 7.1. At the same time, the 95% confidence interval of the mean value of change value from each group, the

difference between groups and its 95% confidence interval are also provided.

Calculation principle for Harris hip score:

Total Harris hip score: It can be calculated by adding the scores of each sub-item.

(I) Regarding the complaint pain score (44 points in total), the specific points are as follows:

None, or ignores it (44 points)

Slight, occasional, no compromise in activities (40 points)

Mild pain, no effect on average activities (30 points)

Moderate pain, tolerable (20 points)

Marked pain, serious limitation of activities (10 points)

Totally disabled, crippled, pain in bed, bedridden (0 point)

(II) Function score (47 points in total): Gait score (33 points) + daily life score (14 points), the specific points are as follows:

Gait score (33):

① Support: None (11 points); Cane for long walks (7 points); Cane most of time (5 points); One crutch (3 points); Two canes (2 points); Two crutches or not able to walk (0 point)

② Distance Walked: Unlimited (11 points); Six blocks (30 minutes) (8 points); Two or three blocks (10 or 15 minutes) (5 points); Indoors only (2 points); Bed and chair only (0 point)

③ Limp: None (11 points); Slight (8 points); Moderate (5 points); Severe or unable to walk (0 point)

Daily life score (14 points):

① Put on Shoes and Socks: With ease (4 points); With difficulty (2 points); Unable (0 point)

② Stairs: Normally without using a railing (4 points); Normally using a railing (2 points); In any manner (1 point); Unable to do stairs (0 point)

③ Enter public transportation: Yes (bus) (1 point); No (bus) (0 point)

④ Sitting: Comfortably in ordinary chair for one hour (5 points); On a high chair for 30 minutes (3 points); Unable to sit comfortably in any chair (0 point)

(III) Physical sign score (4 points in total), the specific points are as follows:

Whether all of the following conditions exist: (Less than 30° fixed flexion contracture; Less than 10° fixed internal rotation in extension; Less than 10° fixed

abduction; Limb length discrepancy less than 3.2 cm (1.5 inches);)

Yes (4 points), No (0 point)

(IV) Physical examination score: Score result ＝ The sum of A, B, C and D divided by 20; the specific points are as follows (refer to computation rule for Harris Hip Score in http://www.orthopaedicscores.com, which was approved by the Journal of Bone & Joint Surgery):

A. Total flexion: None (0 point), 0 >8 (0.4 points), 8 >16 (0.8 points), 16 >24 (1.2 points), 24 >32 (1.6 points), 32 >40 (2 points), 40 >45 (2.25 points), 45 >55 (2.55 points), 55 >65 (2.85 points), 65 >70 (3 points), 70 >75 (3.15 points), 75 >80 (3.3 points), 80 >90 (3.6 points), 90 >100 (3.75 points), 100 >110 (3.9 points);

B. Total abduction: None (0 point), 0 >5 (0.2 points), 5 >10 (0.4 points), 10 >15 (0.6 points), 15 >20 (0.65 points);

C. Total external rotation: None (0 point), 0 >5 (0.1 point), 5 >10 (0.2 points), 10 >15 (0.3 points);

Total internal rotation: None (0 point), 0 >5 (0.05 points), 5 >10 (0.1 points), 10 >15 (0.15 points);

Total Harris hip score: It can be calculated by adding the scores of the above four sub-items.

- If a sub-score is missing then the total score cannot be calculated
- If total score exceeds 100 then it should be forced to be 100

The indicators in this part are mainly descriptive. The descriptive analysis results of Harris hip score at each follow-up will be given. The statistical analysis method is the same as 7.1.

EQ-5D questionnaire:

Based on the EQ-5D questionnaire collected in the CRF, the analysis results of subjects' health status and health index are given. The analysis results 12 and 24 weeks after surgery are given, respectively.

Calculation principle:

Health status is measured in five dimensions (activity level, self-care, daily activities, pain/discomfort, anxiety/depression). Each dimension contains five levels: no difficulty, mild difficulty, moderate difficulty, severe difficulty, and extreme difficulty (marked 1-5). The health status of each subject is determined by arranging the five dimensions of each subject.

Health index is calculated by 《EQ-5D-5L_Crosswalk_Index_Value_Calculator.v2.xls》.

The indicators in this part are mainly descriptive. A descriptive analysis of each follow-up health index and changes relative to baseline will be presented. Statistical analysis methods are the same as those in 7.1.

(5) Radiographs: incidence of complications such as loosening or cut-out that require reoperation or revision.

Calculation principle: Based on the adverse events collected in the CRF. If the measure taken for the implant is filled as “Revision” or AE “re-operation” collected in the CRF, it is determined as ‘Missing’; otherwise are determined as ‘No’

The indicators in this part are mainly descriptive. Statistical analysis methods are the same as those in 7.1.

7.5 Follow-up data

The follow-up data include the frontal/lateral X-ray examination of fracture sites 1 week, 6 weeks, 12 weeks and 24 weeks after surgery, SF-12v2 health assessment scale, EQ5D and Harris hip score.

For indicators related to follow-up data, descriptive analysis is mainly performed. Statistical analysis methods are the same as those in 7.1.

7.6 Laboratory examinations

Laboratory test indicators include complete blood count and blood biochemical test. Blood test includes white blood cell (WBC), neutrophil percentage, red blood cell (RBC), hemoglobin, platelet, international normalized ratio (INR) and activated partial thromboplastin time (APTT); blood biochemical test includes alanine aminotransferase (ALT), aspartate aminotransferase (AST), albumin (ALB), cholesterol (CHOL), triglyceride (TRIG), creatinine (CREA), blood urea nitrogen (BUN), urea (UREA), uric acid (UA), low density lipoprotein (LDL-C), high-density lipoprotein (HDL-C), blood glucose (GLU), C-reactive protein (CRP) and hypersensitive CRP.

As for the laboratory examination indicators, the outcomes immediately after surgery relative to the preoperative conditions will be given. There are mainly five cases listed, including "Normal → Abnormal (with clinical significance)", "Normal → Abnormal (without clinical significance)", “Normal → Normal”, “Abnormal → Abnormal”; the descriptive analysis method is mainly adopted. Statistical analysis methods are the same as those in 7.1. Meanwhile, the list of subjects presenting “Normal → Abnormal (with clinical significance)” will be given, including laboratory examination indicators, site number, random number, group, age, gender, and laboratory indicator test values before surgery and immediately after surgery.

7.7 Concomitant medication, adverse events (AEs) or serious adverse events

(SAEs)

For concomitant medication, the subject's concomitant medication is provided in the form of a list.

The AEs and investigational device-related AEs in subjects will be tabulated and summarized, respectively. The list of subjects reported with AEs/ investigational device-related AEs includes site number, random number, group, age, gender, name of AE (SOC code), name of AE (PT code), time of postoperative occurrence (day), remission time (day), severity, measures taken, outcome, correlation with surgery, correlation with investigational device, withdrawal from the trial due to AEs, whether it is unanticipated adverse device effect (UADE), device failure or SAE.

Investigational device-related AEs refer to those “definitely related”, “probably related” and “possibly related” with the investigational device;

Time of postoperative occurrence (day) = Date of occurrence of AE - Date of surgery,

Remission time (day) = End date of AE - Date of occurrence of AE.

The summary form will list the total number of cases of AEs/investigational device-related AEs, the total number of subjects suffering from AEs/investigational device-related AEs.

Wherein, the total case of AEs refers to the number of subjects suffering from AEs, and the AEs occur in the subject at least one time, which is considered as "Yes";

Statistical analysis of the severity of adverse events, the relationship with the study device and the relationship with the surgery was performed. If multiple adverse events occurred in a patient, the analysis was performed with the most severe or highest correlation.

The SAEs and investigational device-related SAEs in subjects will be tabulated and summarized, respectively; such data will be presented in the same form as AEs. The list of subjects reported with SAEs/investigational device-related SAEs includes site number, random number, group, age, gender, name of SAE (SOC code), name of SAE (PT code), time of postoperative occurrence (day), remission time (day), severity, outcome, correlation with surgery, correlation with investigational device and SAE.

The list and summary of UADEs in subjects will be presented respectively in the same form as AEs.

The calculation method of the time of postoperative occurrence (day) and remission time (day), the presentation of the summary form and the statistical principle are the same as those for AEs.

8. Generation of Statistical Graphs, Tables and Lists

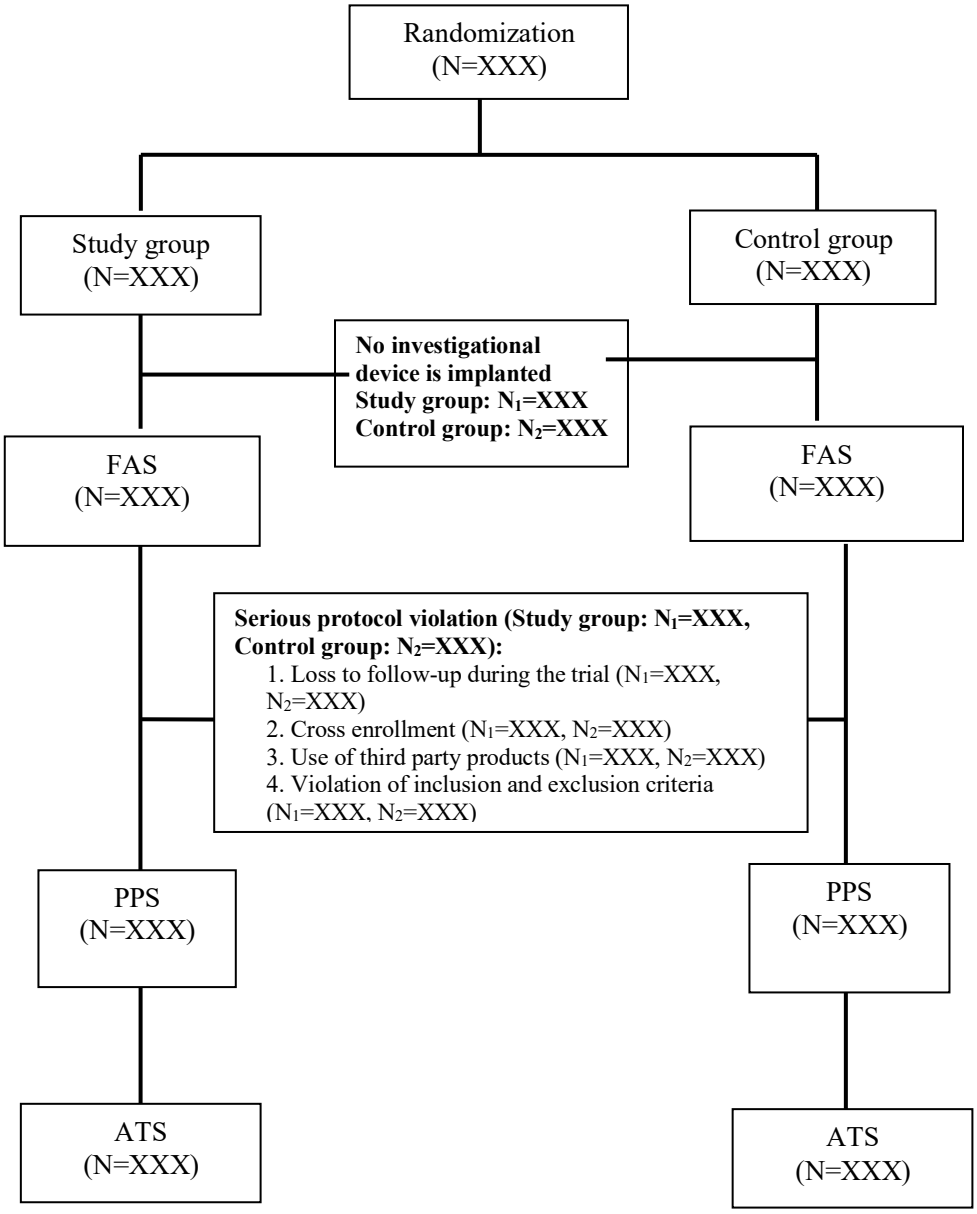

Figure 1 Flow chart for determination of analysis population data sets

Table 1 Determination of analysis population

Indicator	Study group	Control group
Randomization	XXX (XX.X%)	XXX (XX.X%)
No investigational device is implanted	XXX (XX.X%)	XXX (XX.X%)
Serious protocol violation		
Violation of inclusion and exclusion criteria	XXX (XX.X%)	XXX (XX.X%)
Loss to follow-up during the trial	XXX (XX.X%)	XXX (XX.X%)
Cross enrollment	XXX (XX.X%)	XXX (XX.X%)
Use of third party products	XXX (XX.X%)	XXX (XX.X%)
Out-of-specification use of investigational products	XXX (XX.X%)	XXX (XX.X%)
Out-of-window time	XXX (XX.X%)	XXX (XX.X%)
FAS	XXX (XX.X%)	XXX (XX.X%)
PPS	XXX (XX.X%)	XXX (XX.X%)
ATS	XXX (XX.X%)	XXX (XX.X%)

Notes: 1. FAS = Number of subjects enrolled randomly - Number of subjects not implanted with any investigational device;

2. Number of subjects who seriously violate the protocol = Violation of inclusion and exclusion criteria + Loss to follow-up during the trial + Cross enrollment + Use of third party products + Out-of-specification use of investigational products + Out-of-window time;

3. PPS = FAS - Number of subjects who seriously violate the protocol; ATS = PPS + Number of cross-enrolled subjects alone;

4. No investigational device is implanted means that the subject has been given a random number but has not received any study-related treatment;

Loss to follow-up during the trial refers to the situation in which the fracture union rate 24 weeks after the primary endpoint surgery is not available;

Cross enrollment refers to the situation in which subjects randomly assigned to the study group receive the control products, while subjects randomly assigned to the control group receive the investigational products;

Out-of-specification use of investigational products refers to the situation in which the specification of the device implanted in the subject is not within the specification range specified in the study protocol;

Use of third party products refers to the situation in which the subjects randomly assigned to the study group or the control group use third party products;

Out-of-window time refers to the situation in which the difference between the follow-up date at 24 weeks after subjects have received the primary endpoint surgery and the surgery date do not fall within the range of [140, 196], and this protocol violation may seriously affect the results of primary efficacy endpoints;

5: Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 2 List of subjects who withdrawal the informed consent or seriously violate the protocol

Site No.	Random No.	Group	Gender	Age	Type	Reason	FAS	PPS	ATS
XXX	XXX	XXX	XXX	XXX	……	……	……	……	……
XXX	XXX	XXX	XXX	XXX	……	……	……	……	……

Note: If the subject is included in FAS, PPS and ATS, mark with "√"; if the subject is not included in FAS, PPS and ATS, mark with "×".

Table 3 List of subjects who violate the protocol (CRF collection)

Site No.	Random No.	Group	Gender	Age	Type	AE/SAE related or not	Withdrawal of subjects from the trial or not
XXX	XXX	XXX	XXX	XXX	……	……	……
XXX	XXX	XXX	XXX	XXX	……	……	……

Table 4 Determination of analysis population in Beijing Jishuitan Hospital

Indicator	Study group	Control group
Randomization	XXX (XX.X%)	XXX (XX.X%)
No investigational device is implanted	XXX (XX.X%)	XXX (XX.X%)
Serious protocol violation		
Violation of inclusion and exclusion criteria	XXX (XX.X%)	XXX (XX.X%)
Loss to follow-up during the trial	XXX (XX.X%)	XXX (XX.X%)
Cross enrollment	XXX (XX.X%)	XXX (XX.X%)
Use of third party products	XXX (XX.X%)	XXX (XX.X%)
Out-of-specification use of investigational products	XXX (XX.X%)	XXX (XX.X%)
Out-of-window time	XXX (XX.X%)	XXX (XX.X%)
FAS	XXX (XX.X%)	XXX (XX.X%)
PPS	XXX (XX.X%)	XXX (XX.X%)
ATS	XXX (XX.X%)	XXX (XX.X%)

Notes: 1. FAS = Number of subjects enrolled randomly - Number of subjects not implanted with any investigational device;

2. Number of subjects who seriously violate the protocol = Violation of inclusion and exclusion criteria + Loss to follow-up during the trial + Cross enrollment + Use of third party products + Out-of-specification use of investigational products + Out-of-window time;

3. PPS = FAS - Number of subjects who seriously violate the protocol; ATS = PPS + Number of cross-enrolled subjects alone;

4. No investigational device is implanted means that the subject has been given a random number but has not received any study-related treatment;

Loss to follow-up during the trial refers to the situation in which the fracture union rate 24 weeks after the primary endpoint surgery is not available;

Cross enrollment refers to the situation in which subjects randomly assigned to the study group receive the control products, while subjects randomly assigned to the control group receive the investigational products;

Out-of-specification use of investigational products refers to the situation in which the specification of the device implanted in the subject is not within the specification range specified in the study protocol;

Use of third party products refers to the situation in which the subjects randomly assigned to the study group or the control group use third party products;

Out-of-window time refers to the situation in which the difference between the follow-up date at 24 weeks after subjects have received the primary endpoint surgery and the surgery date do not fall within the range of [140, 196], and this protocol violation may seriously affect the results of primary efficacy endpoints;

5: Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 5 Determination of analysis population in Peking University Third Hospital

Indicator	Study group	Control group
Randomization	XXX (XX.X%)	XXX (XX.X%)
No investigational device is implanted	XXX (XX.X%)	XXX (XX.X%)
Serious protocol violation		
Violation of inclusion and exclusion criteria	XXX (XX.X%)	XXX (XX.X%)
Loss to follow-up during the trial	XXX (XX.X%)	XXX (XX.X%)
Cross enrollment	XXX (XX.X%)	XXX (XX.X%)
Use of third party products	XXX (XX.X%)	XXX (XX.X%)
Out-of-specification use of investigational products	XXX (XX.X%)	XXX (XX.X%)
Out-of-window time	XXX (XX.X%)	XXX (XX.X%)
FAS	XXX (XX.X%)	XXX (XX.X%)
PPS	XXX (XX.X%)	XXX (XX.X%)
ATS	XXX (XX.X%)	XXX (XX.X%)

Notes: 1. FAS = Number of subjects enrolled randomly - Number of subjects not implanted with any investigational device;

2: Number of subjects who seriously violate the protocol = Violation of inclusion and exclusion criteria + Loss to follow-up during the trial + Cross enrollment + Use of third party products + Out-of-specification use of investigational products + Out-of-window time;

3. PPS = FAS - Number of subjects who seriously violate the protocol; ATS = PPS + Number of cross-enrolled subjects alone;

4. No investigational device is implanted means that the subject has been given a random number but has not received any study-related treatment;

Loss to follow-up during the trial refers to the situation in which the fracture union rate 24 weeks after the primary endpoint surgery is not available;

Cross enrollment refers to the situation in which subjects randomly assigned to the study group receive the control products, while subjects randomly assigned to the control group receive the investigational products;

Out-of-specification use of investigational products refers to the situation in which the specification of the device implanted in the subject is not within the specification range specified in the study protocol;

Use of third party products refers to the situation in which the subjects randomly assigned to the study group or the control group use third party products;

Out-of-window time refers to the situation in which the difference between the follow-up date at 24 weeks after subjects have received the primary endpoint surgery and the surgery date do not fall within the range of [140, 196], and this protocol violation may seriously affect the results of primary efficacy endpoints;

5: Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 6 Determination of analysis population in Chinese PLA General Hospital

Indicator	Study group	Control group
Randomization	XXX (XX.X%)	XXX (XX.X%)
No investigational device is implanted	XXX (XX.X%)	XXX (XX.X%)
Serious protocol violation		
Violation of inclusion and exclusion criteria	XXX (XX.X%)	XXX (XX.X%)
Loss to follow-up during the trial	XXX (XX.X%)	XXX (XX.X%)
Cross enrollment	XXX (XX.X%)	XXX (XX.X%)
Use of third party products	XXX (XX.X%)	XXX (XX.X%)
Out-of-specification use of investigational products	XXX (XX.X%)	XXX (XX.X%)
Out-of-window time	XXX (XX.X%)	XXX (XX.X%)
FAS	XXX (XX.X%)	XXX (XX.X%)
PPS	XXX (XX.X%)	XXX (XX.X%)
ATS	XXX (XX.X%)	XXX (XX.X%)

Notes: 1. FAS = Number of subjects enrolled randomly - Number of subjects not implanted with any investigational device;

2: Number of subjects who seriously violate the protocol = Violation of inclusion and exclusion criteria + Loss to follow-up during the trial + Cross enrollment + Use of third party products + Out-of-specification use of investigational products + Out-of-window time;

3. PPS = FAS - Number of subjects who seriously violate the protocol; ATS = PPS + Number of cross-enrolled subjects alone;

4. No investigational device is implanted means that the subject has been given a random number but has not received any study-related treatment;

Loss to follow-up during the trial refers to the situation in which the fracture union rate 24 weeks after the primary endpoint surgery is not available;

Cross enrollment refers to the situation in which subjects randomly assigned to the study group receive the control products, while subjects randomly assigned to the control group receive the investigational products;

Out-of-specification use of investigational products refers to the situation in which the specification of the device implanted in the subject is not within the specification range specified in the study protocol;

Use of third party products refers to the situation in which the subjects randomly assigned to the study group or the control group use third party products;

Out-of-window time refers to the situation in which the difference between the follow-up date at 24 weeks after subjects have received the primary endpoint surgery and the surgery date do not fall within the range of [140, 196], and this protocol violation may seriously affect the results of primary efficacy endpoints;

5: Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 7 Determination of analysis population in the Second Affiliated Hospital of Zhejiang University School of Medicine

Indicator	Study group	Control group
Randomization	XXX (XX.X%)	XXX (XX.X%)
No investigational device is implanted	XXX (XX.X%)	XXX (XX.X%)
Serious protocol violation		
Violation of inclusion and exclusion criteria	XXX (XX.X%)	XXX (XX.X%)
Loss to follow-up during the trial	XXX (XX.X%)	XXX (XX.X%)
Cross enrollment	XXX (XX.X%)	XXX (XX.X%)
Use of third party products	XXX (XX.X%)	XXX (XX.X%)
Out-of-specification use of investigational products	XXX (XX.X%)	XXX (XX.X%)
Out-of-window time	XXX (XX.X%)	XXX (XX.X%)
FAS	XXX (XX.X%)	XXX (XX.X%)
PPS	XXX (XX.X%)	XXX (XX.X%)
ATS	XXX (XX.X%)	XXX (XX.X%)

Notes: 1. FAS = Number of subjects enrolled randomly - Number of subjects not implanted with any investigational device;

2: Number of subjects who seriously violate the protocol = Violation of inclusion and exclusion criteria + Loss to follow-up during the trial + Cross enrollment + Use of third party products + Out-of-specification use of investigational products + Out-of-window time;

3. PPS = FAS - Number of subjects who seriously violate the protocol; ATS = PPS + Number of cross-enrolled subjects alone;

4. No investigational device is implanted means that the subject has been given a random number but has not received any study-related treatment;

Loss to follow-up during the trial refers to the situation in which the fracture union rate 24 weeks after the primary endpoint surgery is not available;

Cross enrollment refers to the situation in which subjects randomly assigned to the study group receive the control products, while subjects randomly assigned to the control group receive the investigational products;

Out-of-specification use of investigational products refers to the situation in which the specification of the device implanted in the subject is not within the specification range specified in the study protocol;

Use of third party products refers to the situation in which the subjects randomly assigned to the study group or the control group use third party products;

Out-of-window time refers to the situation in which the difference between the follow-up date at 24 weeks after subjects have received the primary endpoint surgery and the surgery date do not fall within the range of [140, 196], and this protocol violation may seriously affect the results of primary efficacy endpoints;

5: Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 8 Determination of analysis population in Shanghai General Hospital

Indicator	Study group	Control group
Randomization	XXX (XX.X%)	XXX (XX.X%)
No investigational device is implanted	XXX (XX.X%)	XXX (XX.X%)
Serious protocol violation		
Violation of inclusion and exclusion criteria	XXX (XX.X%)	XXX (XX.X%)
Loss to follow-up during the trial	XXX (XX.X%)	XXX (XX.X%)
Cross enrollment	XXX (XX.X%)	XXX (XX.X%)
Use of third party products	XXX (XX.X%)	XXX (XX.X%)
Out-of-specification use of investigational products	XXX (XX.X%)	XXX (XX.X%)
Out-of-window time	XXX (XX.X%)	XXX (XX.X%)
FAS	XXX (XX.X%)	XXX (XX.X%)
PPS	XXX (XX.X%)	XXX (XX.X%)
ATS	XXX (XX.X%)	XXX (XX.X%)

Notes: 1. FAS = Number of subjects enrolled randomly - Number of subjects not implanted with any investigational device;

2: Number of subjects who seriously violate the protocol = Violation of inclusion and exclusion criteria + Loss to follow-up during the trial + Cross enrollment + Use of third party products + Out-of-specification use of investigational products + Out-of-window time;

3. PPS = FAS - Number of subjects who seriously violate the protocol; ATS = PPS + Number of cross-enrolled subjects alone;

4. No investigational device is implanted means that the subject has been given a random number but has not received any study-related treatment;

Loss to follow-up during the trial refers to the situation in which the fracture union rate 24 weeks after the primary endpoint surgery is not available;

Cross enrollment refers to the situation in which subjects randomly assigned to the study group receive the control products, while subjects randomly assigned to the control group receive the investigational products;

Out-of-specification use of investigational products refers to the situation in which the specification of the device implanted in the subject is not within the specification range specified in the study protocol;

Use of third party products refers to the situation in which the subjects randomly assigned to the study group or the control group use third party products;

Out-of-window time refers to the situation in which the difference between the follow-up date at 24 weeks after subjects have received the primary endpoint surgery and the surgery date do not fall within the range of [140, 196], and this protocol violation may seriously affect the results of primary efficacy endpoints;

5: Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 9 Determination of analysis population in Nanfang Hospital Of Southern Medical University

Indicator	Study group	Control group
Randomization	XXX (XX.X%)	XXX (XX.X%)
No investigational device is implanted	XXX (XX.X%)	XXX (XX.X%)
Serious protocol violation		
Violation of inclusion and exclusion criteria	XXX (XX.X%)	XXX (XX.X%)
Loss to follow-up during the trial	XXX (XX.X%)	XXX (XX.X%)
Cross enrollment	XXX (XX.X%)	XXX (XX.X%)
Use of third party products	XXX (XX.X%)	XXX (XX.X%)
Out-of-specification use of investigational products	XXX (XX.X%)	XXX (XX.X%)
Out-of-window time	XXX (XX.X%)	XXX (XX.X%)
FAS	XXX (XX.X%)	XXX (XX.X%)
PPS	XXX (XX.X%)	XXX (XX.X%)
ATS	XXX (XX.X%)	XXX (XX.X%)

Notes: 1. FAS = Number of subjects enrolled randomly - Number of subjects not implanted with any investigational device;

2: Number of subjects who seriously violate the protocol = Violation of inclusion and exclusion criteria + Loss to follow-up during the trial + Cross enrollment + Use of third party products + Out-of-specification use of investigational products + Out-of-window time;

3. PPS = FAS - Number of subjects who seriously violate the protocol; ATS = PPS + Number of cross-enrolled subjects alone;

4. No investigational device is implanted means that the subject has been given a random number but has not received any study-related treatment;

Loss to follow-up during the trial refers to the situation in which the fracture union rate 24 weeks after the primary endpoint surgery is not available;

Cross enrollment refers to the situation in which subjects randomly assigned to the study group receive the control products, while subjects randomly assigned to the control group receive the investigational products;

Out-of-specification use of investigational products refers to the situation in which the specification of the device implanted in the subject is not within the specification range specified in the study protocol;

Use of third party products refers to the situation in which the subjects randomly assigned to the study group or the control group use third party products;

Out-of-window time refers to the situation in which the difference between the follow-up date at 24 weeks after subjects have received the primary endpoint surgery and the surgery date do not fall within the range of [140, 196], and this protocol violation may seriously affect the results of primary efficacy endpoints;

5: Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 10 Determination of analysis population in Affiliated Hospital of Nantong University

Indicator	Study group	Control group
Randomization	XXX (XX.X%)	XXX (XX.X%)
No investigational device is implanted	XXX (XX.X%)	XXX (XX.X%)
Serious protocol violation		
Violation of inclusion and exclusion criteria	XXX (XX.X%)	XXX (XX.X%)
Loss to follow-up during the trial	XXX (XX.X%)	XXX (XX.X%)
Cross enrollment	XXX (XX.X%)	XXX (XX.X%)
Use of third party products	XXX (XX.X%)	XXX (XX.X%)
Out-of-specification use of investigational products	XXX (XX.X%)	XXX (XX.X%)
Out-of-window time	XXX (XX.X%)	XXX (XX.X%)
FAS	XXX (XX.X%)	XXX (XX.X%)
PPS	XXX (XX.X%)	XXX (XX.X%)
ATS	XXX (XX.X%)	XXX (XX.X%)

Notes: 1. FAS = Number of subjects enrolled randomly - Number of subjects not implanted with any investigational device;

2: Number of subjects who seriously violate the protocol = Violation of inclusion and exclusion criteria + Loss to follow-up during the trial + Cross enrollment + Use of third party products + Out-of-specification use of investigational products + Out-of-window time;

3. PPS = FAS - Number of subjects who seriously violate the protocol; ATS = PPS + Number of cross-enrolled subjects alone;

4. No investigational device is implanted means that the subject has been given a random number but has not received any study-related treatment;

Loss to follow-up during the trial refers to the situation in which the fracture union rate 24 weeks after the primary endpoint surgery is not available;

Cross enrollment refers to the situation in which subjects randomly assigned to the study group receive the control products, while subjects randomly assigned to the control group receive the investigational products;

Out-of-specification use of investigational products refers to the situation in which the specification of the device implanted in the subject is not within the specification range specified in the study protocol;

Use of third party products refers to the situation in which the subjects randomly assigned to the study group or the control group use third party products;

Out-of-window time refers to the situation in which the difference between the follow-up date at 24 weeks after subjects have received the primary endpoint surgery and the surgery date do not fall within the range of [140, 196], and this protocol violation may seriously affect the results of primary efficacy endpoints;

5: Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 11 Determination of analysis population in West China Hospital, Sichuan University

Indicator	Study group	Control group
Randomization	XXX (XX.X%)	XXX (XX.X%)
No investigational device is implanted	XXX (XX.X%)	XXX (XX.X%)
Serious protocol violation		
Violation of inclusion and exclusion criteria	XXX (XX.X%)	XXX (XX.X%)
Loss to follow-up during the trial	XXX (XX.X%)	XXX (XX.X%)
Cross enrollment	XXX (XX.X%)	XXX (XX.X%)
Use of third party products	XXX (XX.X%)	XXX (XX.X%)
Out-of-specification use of investigational products	XXX (XX.X%)	XXX (XX.X%)
Out-of-window time	XXX (XX.X%)	XXX (XX.X%)
FAS	XXX (XX.X%)	XXX (XX.X%)
PPS	XXX (XX.X%)	XXX (XX.X%)
ATS	XXX (XX.X%)	XXX (XX.X%)

Notes: 1. FAS = Number of subjects enrolled randomly - Number of subjects not implanted with any investigational device;

2: Number of subjects who seriously violate the protocol = Violation of inclusion and exclusion criteria + Loss to follow-up during the trial + Cross enrollment + Use of third party products + Out-of-specification use of investigational products + Out-of-window time;

3. PPS = FAS - Number of subjects who seriously violate the protocol; ATS = PPS + Number of cross-enrolled subjects alone;

4. No investigational device is implanted means that the subject has been given a random number but has not received any study-related treatment;

Loss to follow-up during the trial refers to the situation in which the fracture union rate 24 weeks after the primary endpoint surgery is not available;

Cross enrollment refers to the situation in which subjects randomly assigned to the study group receive the control products, while subjects randomly assigned to the control group receive the investigational products;

Out-of-specification use of investigational products refers to the situation in which the specification of the device implanted in the subject is not within the specification range specified in the study protocol;

Use of third party products refers to the situation in which the subjects randomly assigned to the study group or the control group use third party products;

Out-of-window time refers to the situation in which the difference between the follow-up date at 24 weeks after subjects have received the primary endpoint surgery and the surgery date do not fall within the range of [140, 196], and this protocol violation may seriously affect the results of primary efficacy endpoints;

5: Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 12 Determination of analysis population in the First Affiliated Hospital of Guangzhou University of Chinese Medicine

Indicator	Study group	Control group
Randomization	XXX (XX.X%)	XXX (XX.X%)
No investigational device is implanted	XXX (XX.X%)	XXX (XX.X%)
Serious protocol violation		
Violation of inclusion and exclusion criteria	XXX (XX.X%)	XXX (XX.X%)
Loss to follow-up during the trial	XXX (XX.X%)	XXX (XX.X%)
Cross enrollment	XXX (XX.X%)	XXX (XX.X%)
Use of third party products	XXX (XX.X%)	XXX (XX.X%)
Out-of-specification use of investigational products	XXX (XX.X%)	XXX (XX.X%)
Out-of-window time	XXX (XX.X%)	XXX (XX.X%)
FAS	XXX (XX.X%)	XXX (XX.X%)
PPS	XXX (XX.X%)	XXX (XX.X%)
ATS	XXX (XX.X%)	XXX (XX.X%)

Notes: 1. FAS = Number of subjects enrolled randomly - Number of subjects not implanted with any investigational device;

2: Number of subjects who seriously violate the protocol = Violation of inclusion and exclusion criteria + Loss to follow-up during the trial + Cross enrollment + Use of third party products + Out-of-specification use of investigational products + Out-of-window time;

3. PPS = FAS - Number of subjects who seriously violate the protocol; ATS = PPS + Number of cross-enrolled subjects alone;

4. No investigational device is implanted means that the subject has been given a random number but has not received any study-related treatment;

Loss to follow-up during the trial refers to the situation in which the fracture union rate 24 weeks after the primary endpoint surgery is not available;

Cross enrollment refers to the situation in which subjects randomly assigned to the study group receive the control products, while subjects randomly assigned to the control group receive the investigational products;

Out-of-specification use of investigational products refers to the situation in which the specification of the device implanted in the subject is not within the specification range specified in the study protocol;

Use of third party products refers to the situation in which the subjects randomly assigned to the study group or the control group use third party products;

Out-of-window time refers to the situation in which the difference between the follow-up date at 24 weeks after subjects have received the primary endpoint surgery and the surgery date do not fall within the range of [140, 196], and this protocol violation may seriously affect the results of primary efficacy endpoints;

5: Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 13 Determination of analysis population in the University of Hong Kong - Shenzhen Hospital

Indicator Study group	Control group	
Randomization	XXX (XX.X%)	XXX (XX.X%)
No investigational device is implanted	XXX (XX.X%)	XXX (XX.X%)
Serious protocol violation		
Violation of inclusion and exclusion criteria	XXX (XX.X%)	XXX (XX.X%)
Loss to follow-up during the trial	XXX (XX.X%)	XXX (XX.X%)
Cross enrollment	XXX (XX.X%)	XXX (XX.X%)
Use of third party products	XXX (XX.X%)	XXX (XX.X%)
Out-of-specification use of investigational products	XXX (XX.X%)	XXX (XX.X%)
Out-of-window time	XXX (XX.X%)	XXX (XX.X%)
FAS	XXX (XX.X%)	XXX (XX.X%)
PPS	XXX (XX.X%)	XXX (XX.X%)
ATS	XXX (XX.X%)	XXX (XX.X%)

Notes: 1. FAS = Number of subjects enrolled randomly - Number of subjects not implanted with any investigational device;

2: Number of subjects who seriously violate the protocol = Violation of inclusion and exclusion criteria + Loss to follow-up during the trial + Cross enrollment + Use of third party products + Out-of-specification use of investigational products + Out-of-window time;

3. PPS = FAS - Number of subjects who seriously violate the protocol; ATS = PPS + Number of cross-enrolled subjects alone;

4. No investigational device is implanted means that the subject has been given a random number but has not received any study-related treatment;

Loss to follow-up during the trial refers to the situation in which the fracture union rate 24 weeks after the primary endpoint surgery is not available;

Cross enrollment refers to the situation in which subjects randomly assigned to the study group receive the control products, while subjects randomly assigned to the control group receive the investigational products;

Out-of-specification use of investigational products refers to the situation in which the specification of the device implanted in the subject is not within the specification range specified in the study protocol;

Use of third party products refers to the situation in which the subjects randomly assigned to the study group or the control group use third party products;

Out-of-window time refers to the situation in which the difference between the follow-up date at 24 weeks after subjects have received the primary endpoint surgery and the surgery date do not fall within the range of [140, 196], and this protocol violation may seriously affect the results of primary efficacy endpoints;

5: Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 14 Statistical analysis results of subjects' demographic data

Indicator	Study group	Control group	Statistics	P value
Age (years)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Gender				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Male	XXX (XX.X%)	XXX (XX.X%)		
Female	XXX (XX.X%)	XXX (XX.X%)		
Marital status				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Married	XXX (XX.X%)	XXX (XX.X%)		
Unmarried	XXX (XX.X%)	XXX (XX.X%)		
Nationality				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Han nationality	XXX (XX.X%)	XXX (XX.X%)		
Others	XXX (XX.X%)	XXX (XX.X%)		
Job nature				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Manual worker	XXX (XX.X%)	XXX (XX.X%)		
Non-manual worker	XXX (XX.X%)	XXX (XX.X%)		
Retired	XXX (XX.X%)	XXX (XX.X%)		
Unemployed	XXX (XX.X%)	XXX (XX.X%)		
Incompetent	XXX (XX.X%)	XXX (XX.X%)		
Others	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

3. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

4. Age = (Date of informed consent - Date of birth)/365.25;

5. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 15 Statistical analysis results of subjects' height and body weight

Indicator	Study group	Control group	Statistics	P value
Body weight (kg)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)X.XXXX	X.XXXX	
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Height (cm)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
BMI(kg/m^2)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		

Notes: 1. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

2. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

3. BMI= Body weight (kg)/Height (m)2;

4. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 16 Statistical analysis results of subjects' previous and current medical history

Indicator	Study group	Control group	Statistics	P value
Osteoporosis				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Still persist				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Malnutrition				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
None	XXX (XX.X%)	XXX (XX.X%)		
Ca	XXX (XX.X%)	XXX (XX.X%)		
P	XXX (XX.X%)	XXX (XX.X%)		
Protein	XXX (XX.X%)	XXX (XX.X%)		
Fe	XXX (XX.X%)	XXX (XX.X%)		
Others	XXX (XX.X%)	XXX (XX.X%)		
Still persist				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Anemia				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Still persist				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Hormone deficiency				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
None	XXX (XX.X%)	XXX (XX.X%)		

Growth hormone	XXX (XX.X%)	XXX (XX.X%)		
Parathyroid hormone	XXX (XX.X%)	XXX (XX.X%)		
Others	XXX (XX.X%)	XXX (XX.X%)		
Still persist				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 16 Statistical analysis results of subjects' previous and current medical history (continued 1)

Indicator	Study group	Control group	Statistics	P value
Diabetes mellitus				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes (satisfactory control)	XXX (XX.X%)	XXX (XX.X%)		
Yes (unsatisfactory control)	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Allergic history				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Other complications				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Still persist				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Smoke within one year or not				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Number of cigarettes/day				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Still persist				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Drink within one year or not				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

3. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

4. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 16 Statistical analysis results of subjects' previous and current medical history (continued 2)

Indicator	Study group	Control group	Statistics	P value
ml/day				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Still persist				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Surgical history				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

3. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

4. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 17 Statistical analysis results of subjects' preoperative SF-12v2 questionnaire

Indicator	Study group	Control group	Statistics	P value
SF-12 score (body functions)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
SF-12 score (physical conditions)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
SF-12 score (body pain)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
SF-12 score (general health)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
SF-12 score (vitality)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
SF-12 score (social functions)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		

Notes: 1. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

2. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 17 Statistical analysis results of subjects' preoperative SF-12v2 questionnaire (continued)

Indicator	Study group	Control group	Statistics	P value
SF-12 score (emotional conditions)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
SF-12 score (mental health)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
SF-12 score (total physical health score)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
SF-12 score (total mental health score)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		

Notes: 1. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

2. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 18 Statistical analysis results of subjects' preoperative EQ-5D questionnaire

Indicator	Study group	Control group	Statistics	P value
Activity level				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Walk easily	XXX (XX.X%)	XXX (XX.X%)		
Slightly difficult in walking	XXX (XX.X%)	XXX (XX.X%)		
Difficult in walking	XXX (XX.X%)	XXX (XX.X%)		
Very difficult in walking	XXX (XX.X%)	XXX (XX.X%)		
Completely unable to walk	XXX (XX.X%)	XXX (XX.X%)		
Self-care				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Easy to wash or dress independently	XXX (XX.X%)	XXX (XX.X%)		
Slightly difficult in washing or dressing independently	XXX (XX.X%)	XXX (XX.X%)		
Difficult in washing or dressing independently	XXX (XX.X%)	XXX (XX.X%)		
Very difficult in washing or dressing independently	XXX (XX.X%)	XXX (XX.X%)		
Completely unable to wash or dress independently	XXX (XX.X%)	XXX (XX.X%)		
Daily activities (such as work, study, housework, family or entertainment)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Easy to perform daily activities	XXX (XX.X%)	XXX (XX.X%)		
Slightly difficult in performing daily activities	XXX (XX.X%)	XXX (XX.X%)		
Difficult in performing daily activities	XXX (XX.X%)	XXX (XX.X%)		
Very difficult in performing daily activities	XXX (XX.X%)	XXX (XX.X%)		
Completely unable to perform daily activities	XXX (XX.X%)	XXX (XX.X%)		
Pain/discomfort				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No pain/discomfort	XXX (XX.X%)	XXX (XX.X%)		
Mild pain/discomfort	XXX (XX.X%)	XXX (XX.X%)		
Moderate pain/discomfort	XXX (XX.X%)	XXX (XX.X%)		
Severe pain/discomfort	XXX (XX.X%)	XXX (XX.X%)		
Very severe pain/discomfort	XXX (XX.X%)	XXX (XX.X%)		
Anxiety/depression				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No anxiety/depression	XXX (XX.X%)	XXX (XX.X%)		
Mild anxiety/depression	XXX (XX.X%)	XXX (XX.X%)		
Moderate anxiety/depression	XXX (XX.X%)	XXX (XX.X%)		
Severe anxiety/depression	XXX (XX.X%)	XXX (XX.X%)		
Very severe anxiety/depression	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

3. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.
4. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 18 Statistical analysis results of subjects' preoperative EQ-5D questionnaire (continued)

Indicator	Study group	Control group	Statistics	P value
Health index				
Number of subjects (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

3. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.
4. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 19 Statistical analysis results of subjects' preoperative fractures

Indicator	Study group	Control group	Statistics	P value
Limb malformation				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Flexion	XXX (XX.X%)	XXX (XX.X%)		
Shortening	XXX (XX.X%)	XXX (XX.X%)		
Limb malformation and external rotation				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
External rotation＜30°	XXX (XX.X%)	XXX (XX.X%)		
30°＜External rotation＜60°	XXX (XX.X%)	XXX (XX.X%)		
External rotation≥60°	XXX (XX.X%)	XXX (XX.X%)		
Closed fracture				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
C 0	XXX (XX.X%)	XXX (XX.X%)		
C I	XXX (XX.X%)	XXX (XX.X%)		
C II	XXX (XX.X%)	XXX (XX.X%)		
C III	XXX (XX.X%)	XXX (XX.X%)		
Open fracture				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
O	I	XXX (XX.X%)	XXX (XX.X%)	
O II	XXX (XX.X%)	XXX (XX.X%)		
O III	XXX (XX.X%)	XXX (XX.X%)		
O IV	XXX (XX.X%)	XXX (XX.X%)		
Degree of limb swelling				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mild	XXX (XX.X%)	XXX (XX.X%)		
Moderate	XXX (XX.X%)	XXX (XX.X%)		
Severe	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 20 Statistical analysis results of subjects' x-ray examination before surgery

Indicator	Study group	Control group	Statistics	P value
Fracture site - Lower limbs				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Left	XXX (XX.X%)	XXX (XX.X%)		
Right	XXX (XX.X%)	XXX (XX.X%)		
Type of trochanteric fracture				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Simple pertrochanteric fracture (31-A1)	XXX (XX.X%)	XXX (XX.X%)		
Comminuted pertrochanteric fracture (31-A2)	XXX (XX.X%)	XXX (XX.X%)		
Intertrochanteric fracture (31-A3)	XXX (XX.X%)	XXX (XX.X%)		
Type of fracture				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Open	XXX (XX.X%)	XXX (XX.X%)		
Closed	XXX (XX.X%)	XXX (XX.X%)		
Reason for fracture				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
High energy damage (such as, MVA)	XXX (XX.X%)	XXX (XX.X%)		
Low energy damage (such as, a fall in a standing position)	XXX (XX.X%)	XXX (XX.X%)		
Others	XXX (XX.X%)	XXX (XX.X%)		
Whether there are other fractures or not				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 21 Statistical analysis results of subjects' use of investigational devices

Indicator	Study group	Control group	Statistics	P value
Intramedullary nails - Product No.				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
XXXXX	XXX (XX.X%)	XXX (XX.X%)		
XXXXX	XXX (XX.X%)	XXX (XX.X%)		
XXXXX	XXX (XX.X%)	XXX (XX.X%)		
┆				
Head elements - Product No.				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
XXXXX	XXX (XX.X%)	XXX (XX.X%)		
XXXXX	XXX (XX.X%)	XXX (XX.X%)		
XXXXX	XXX (XX.X%)	XXX (XX.X%)		
┆				
Whether to implant distal locking screws				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Distal locking screws - Product No.				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
XXXXX	XXX (XX.X%)	XXX (XX.X%)		
XXXXX	XXX (XX.X%)	XXX (XX.X%)		
XXXXX	XXX (XX.X%)	XXX (XX.X%)		
┆				
Whether to implant proximal locking screws				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Proximal locking screws - Product No.				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
XXXXX	XXX (XX.X%)	XXX (XX.X%)		
XXXXX	XXX (XX.X%)	XXX (XX.X%)		
XXXXX	XXX (XX.X%)	XXX (XX.X%)		
┆				
Whether to implant intermediate locking screws				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 21 Statistical analysis results of subjects' use of investigational devices (continued)

Indicator	Study group	Control group	Statistics	P value
Intermediate locking screws - Product No.				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
XXXXX	XXX (XX.X%)	XXX (XX.X%)		
XXXXX	XXX (XX.X%)	XXX (XX.X%)		
XXXXX	XXX (XX.X%)	XXX (XX.X%)		
⋮				
End caps - Product No.				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
XXXXX	XXX (XX.X%)	XXX (XX.X%)		
XXXXX	XXX (XX.X%)	XXX (XX.X%)		
XXXXX	XXX (XX.X%)	XXX (XX.X%)		
⋮				

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 22 Statistical analysis results of subjects' use of other devices

Indicator	Study group	Control group	Statistics	P value
Any other internal or external fixation is used at the same time				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Site of application				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Femur	XXX (XX.X%)	XXX (XX.X%)		
Tibia and fibula	XXX (XX.X%)	XXX (XX.X%)		
Ulna and radius	XXX (XX.X%)	XXX (XX.X%)		
Humerus	XXX (XX.X%)	XXX (XX.X%)		
Others	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 23 Statistical analysis results of subjects' surgical details

Indicator	Study group	Control group	Statistics	P value
Surgery time (hour)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Intraoperative blood loss volume (mL)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Intraoperative blood transfusion volume (mL)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Specific components of intraoperative blood transfusion				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Concentrated red blood cell	XXX (XX.X%)	XXX (XX.X%)		
Whole blood	XXX (XX.X%)	XXX (XX.X%)		
Platelet	XXX (XX.X%)	XXX (XX.X%)		
Fresh frozen plasma (FFR)	XXX (XX.X%)	XXX (XX.X%)		
Others	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

3. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

4. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 24 Statistical analysis results of subjects' intraoperative fractures

Indicator	Study group	Control group	Statistics	P value
Closed fracture				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
C 0	XXX (XX.X%)	XXX (XX.X%)		
C I	XXX (XX.X%)	XXX (XX.X%)		
C II	XXX (XX.X%)	XXX (XX.X%)		
C III	XXX (XX.X%)	XXX (XX.X%)		
Open fracture				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
O I		XXX (XX.X%)	XXX (XX.X%)	
O II	XXX (XX.X%)	XXX (XX.X%)		
O III	XXX (XX.X%)	XXX (XX.X%)		
O IV	XXX (XX.X%)	XXX (XX.X%)		
Degree of limb swelling				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mild	XXX (XX.X%)	XXX (XX.X%)		
Moderate	XXX (XX.X%)	XXX (XX.X%)		
Severe	XXX (XX.X%)	XXX (XX.X%)		
Whether there is vascular injury?				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Whether there is nerve injury?				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Volume of drainage 24 hours after surgery (mL)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Method for reduction of fracture				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Closed reduction	XXX (XX.X%)	XXX (XX.X%)		
Open reduction	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

3. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

4. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 24 Statistical analysis results of subjects' intraoperative fractures (continued)

Indicator	Study group	Control group	Statistics	P value
Reaming				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Not reamed	XXX (XX.X%)	XXX (XX.X%)		
Reamed	XXX (XX.X%)	XXX (XX.X%)		
Diameter after reaming (mm)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Incision closure				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Tension-free suture	XXX (XX.X%)	XXX (XX.X%)		
Tension suture	XXX (XX.X%)	XXX (XX.X%)		
Non-direct closure	XXX (XX.X%)	XXX (XX.X%)		
Whether there is device-related event				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

3. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

4. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 25 Statistical analysis results of subjects' evaluation on product operability and tools during the surgery

Indicator	Study group	Control group	Statistics	P value
Difficulty level of determining the nail application position				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Good	XXX (XX.X%)	XXX (XX.X%)		
Average	XXX (XX.X%)	XXX (XX.X%)		
Poor	XXX (XX.X%)	XXX (XX.X%)		
Difficulty level of inserting an intramedullary nail				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Good	XXX (XX.X%)	XXX (XX.X%)		
Average	XXX (XX.X%)	XXX (XX.X%)		
Poor	XXX (XX.X%)	XXX (XX.X%)		
Difficulty level of proximal locking				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Good	XXX (XX.X%)	XXX (XX.X%)		
Average	XXX (XX.X%)	XXX (XX.X%)		
Poor	XXX (XX.X%)	XXX (XX.X%)		
Difficulty level of distal locking				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Good	XXX (XX.X%)	XXX (XX.X%)		
Average	XXX (XX.X%)	XXX (XX.X%)		
Poor	XXX (XX.X%)	XXX (XX.X%)		
Difficulty level of placing end caps				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Good	XXX (XX.X%)	XXX (XX.X%)		
Average	XXX (XX.X%)	XXX (XX.X%)		
Poor	XXX (XX.X%)	XXX (XX.X%)		
Whether the placement of intramedullary nails has an impact on restoration				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No impact	XXX (XX.X%)	XXX (XX.X%)		
Better than before	XXX (XX.X%)	XXX (XX.X%)		
Worse than before	XXX (XX.X%)	XXX (XX.X%)		
Instrument and its quantity				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Good	XXX (XX.X%)	XXX (XX.X%)		
Average	XXX (XX.X%)	XXX (XX.X%)		
Poor	XXX (XX.X%)	XXX (XX.X%)		
Tools in the toolbox				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Good	XXX (XX.X%)	XXX (XX.X%)		
Average	XXX (XX.X%)	XXX (XX.X%)		
Poor	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;
2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 26 Statistical analysis results of subjects' intraoperative AEs

Indicator	Study group	Control group	Statistics	P value
Whether there are adverse events or complications in the subjects during the surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 27 Statistical analysis results of subjects' intraoperative medication records

Indicator	Study group	Control group	Statistics	P value
Whether new drugs are added to the concomitant medication or whether the original concomitant medication is changed				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 28 Statistical analysis results of subjects' intraoperative combination therapy

Indicator	Study group	Control group	Statistics	P value
Whether new types of combination therapy are added				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 29 (FAS) Primary endpoint - statistical analysis results of fracture union rate of subjects at each site 24 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Site 01 Beijing Jishuitan Hospital - Successful fracture union 24 weeks after surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Site 02 Peking University Third Hospital - Successful fracture union 24 weeks after surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Site 03 Chinese PLA General Hospital - Successful fracture union 24 weeks after surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Site 04 The Second Affiliated Hospital of Zhejiang University School of Medicine - Successful fracture union 24 weeks after surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Site 05 Shanghai General Hospital - Successful fracture union 24 weeks after surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Site 05 Nanfang Hospital of Southern Medical University - Successful fracture union 24 weeks after surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Site 07 The First Affiliated Hospital of Nantong University - Successful fracture union 24 weeks after surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Site 08 West China Hospital, Sichuan University - Successful fracture union 24 weeks after surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Site 09 The First Affiliated Hospital of Guangzhou University of Chinese Medicine - Successful fracture union 24 weeks after surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Site 10 University of Hong Kong - Shenzhen Hospital - Successful fracture union 24 weeks after surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Table 29 (FAS) Primary endpoint - statistical analysis results of fracture union rate of subjects at each site 24 weeks after surgery (continued)

Indicator	Study group	Control group	Statistics	P value
#1 merged site- Successful fracture union 24 weeks after surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
…				
…				

Notes: 1. #1: hospital XXX, hospital XXX and hospital XXX merged;

2. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 30 (FAS) Primary endpoint - Statistical analysis results of subjects' fracture union rate 24 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Successful fracture union 24 weeks after surgery[#1]				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Difference in success rate (study group - control group) and 95% CI		XX.X% [XX.X%; XX.X%]		
P value in non-inferiority test #3		X.XXXX		
Difference in success rate (study group - control group) and 95% CI		XX.X% [XX.X%; XX.X%]		
P value in non-inferiority test #4		X.XXXX		
Successful fracture union 24 weeks after surgery[#2]				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Difference in success rate (study group - control group) and 95% CI		XX.X% [XX.X%; XX.X%]		
P value in non-inferiority test #3		X.XXXX		
Difference in success rate (study group - control group) and 95% CI		XX.X% [XX.X%; XX.X%]		
P value in non-inferiority test #4		X.XXXX		

Notes: 1. #3 is analyzed by CMH chi-square test with adjusted sites, estimate the difference in success rate and non-inferiority test the P value;

#4 is analyzed by Continuous correction Newcombe-Wilson for non-adjusted central, estimate the difference in success rate and non-inferiority test the P value;

2. #1: The primary efficacy indicators of the subjects lost to follow-up during the trial were not processed;

#2: The primary efficacy indicators of the subjects lost to follow-up during the trial were carried forward by LOCF;

3. If the lower limit of 95% CI of the difference in the rates of the study group and the control group is greater than the non-inferiority margin of -10%, then the investigational product is considered non-inferior to the control product, i.e., the non-inferiority conclusion is established in this trial.

4. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 31 (PPS) Primary endpoint - statistical analysis results of fracture union rate of subjects at each site 24 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Site 01 Beijing Jishuitan Hospital - Successful fracture union 24 weeks after surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Site 02 Peking University Third Hospital - Successful fracture union 24 weeks after surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Site 03 Chinese PLA General Hospital - Successful fracture union 24 weeks after surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Site 04 The Second Affiliated Hospital of Zhejiang University School of Medicine - Successful fracture union 24 weeks after surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Site 05 Shanghai General Hospital - Successful fracture union 24 weeks after surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Site 05 Nanfang Hospital of Southern Medical University - Successful fracture union 24 weeks after surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Site 07 The First Affiliated Hospital of Nantong University - Successful fracture union 24 weeks after surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Site 08 West China Hospital, Sichuan University - Successful fracture union 24 weeks after surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Site 09 The First Affiliated Hospital of Guangzhou University of Chinese Medicine - Successful fracture union 24 weeks after surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Site 10 University of Hong Kong - Shenzhen Hospital - Successful fracture union 24 weeks after surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Table 31 (PPS) Primary endpoint - statistical analysis results of fracture union rate of subjects at each site 24 weeks after surgery (continued)

Indicator	Study group	Control group	Statistics	P value
#1 merged site- Successful fracture union 24 weeks after surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
…				
…				

Notes: 1. #1: hospital XXX, hospital XXX and hospital XXX merged;

2. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 32 (PPS) Primary endpoint - Statistical analysis results of subjects' fracture union rate 24 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Successful fracture union 24 weeks after surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Difference in success rate (study group - control group) and 95% CI		XX.X% [XX.X%; XX.X%]		
P value in non-inferiority test #1		X.XXXX		
Difference in success rate (study group - control group) and 95% CI		XX.X% [XX.X%; XX.X%]		
P value in non-inferiority test #2		X.XXXX		

Notes: 1. #1 is analyzed by CMH chi-square test with adjusted sites, estimate the difference in success rate and non-inferiority test the P value;

#2 is analyzed by Continuous correction Newcombe-Wilson for non-adjusted central, estimate the difference in success rate and non-inferiority test the P value;

2. If the lower limit of 95% CI of the difference in the rates of the study group and the control group is greater than the non-inferiority margin of -10%, then the investigational product is considered non-inferior to the control product, i.e., the non-inferiority conclusion is established in this trial.

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 33 (ATS) Primary endpoint - Statistical analysis results of subjects' fracture union rate 24 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Successful fracture union 24 weeks after surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Difference in success rate (study group - control group) and 95% CI		XX.X% [XX.X%; XX.X%]		
P value in non-inferiority test #1		X.XXXX		
Difference in success rate (study group - control group) and 95% CI		XX.X% [XX.X%; XX.X%]		
P value in non-inferiority test #2		X.XXXX		

Notes: 1. #1 is analyzed by CMH chi-square test with adjusted sites, estimate the difference in success rate and non-inferiority test the P value;

#2 is analyzed by Continuous correction Newcombe-Wilson for non-adjusted central, estimate the difference in success rate and non-inferiority test the P value;

2. ATS = PPS + The number of subjects with cross enrollment but without other serious violations of the study protocol.

3. If the lower limit of 95% CI of the difference in the rates of the study group and the control group is greater than the non-inferiority margin of -10%, then the investigational product is considered non-inferior to the control product, i.e., the non-inferiority conclusion is established in this trial.

4. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 34 (FAS) Secondary endpoint - Statistical analysis results of adverse events of subjects

Indicator	Study group	Control group	Statistics	P value
Total number of AEs				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The total number of AEs refers to the number of subjects suffering from AEs, and the AEs occur in the subject at least one time, which is considered as "Yes".

2. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 35 (FAS) Secondary endpoint - Statistical analysis results of subjects' revision rate 24 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Whether revision is required 24 weeks after surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 36 (FAS) Secondary endpoint - Statistical analysis results of subjects' re-operation rate 24 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Whether re-operation is required 24 weeks after surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 37 (FAS) Secondary endpoint - Statistical analysis results of subjects' Harris hip score 12 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Total Harris hip score				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		

Notes: 1. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

2. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 38 (FAS) Secondary endpoint - Statistical analysis results of subjects' Harris hip score 24 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Total Harris hip score				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		

Notes: 1. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

2. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 39 (FAS) Secondary endpoint - Statistical analysis results of subjects' SF-12v2 questionnaire 12 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
SF-12 score (body functions)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (body functions) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			
SF-12 score (physical conditions)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (physical conditions) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			
SF-12 score (body pain)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		

Notes: 1. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

2. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 39 (FAS) Secondary endpoint - Statistical analysis results of subjects' SF-12v2 questionnaire 12 weeks after surgery (continued 1)

Indicator	Study group	Control group	Statistics	P value
SF-12 score (general health)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (general health) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			
SF-12 score (vitality)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (vitality) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			

SF-12 score (social functions)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (social functions) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			

Notes: 1. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

2. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 39 (FAS) Secondary endpoint - Statistical analysis results of subjects' SF-12v2 questionnaire 12 weeks after surgery (continued 2)

Indicator	Study group	Control group	Statistics	P value
SF-12 score (emotional conditions)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (emotional conditions) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			
SF-12 score (mental health)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (mental health) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			
SF-12 score (total physical health score)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		

Change in SF-12 score (total physical health score) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			

Notes: 1. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

2. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 39 (FAS) Secondary endpoint - Statistical analysis results of subjects' SF-12v2 questionnaire 12 weeks after surgery (continued 3)

Indicator	Study group	Control group	Statistics	P value
SF-12 score (total mental health score)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (total mental health score) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			

Notes: 1. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

2. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 40 (FAS) Secondary endpoint - Statistical analysis results of subjects' SF-12v2 questionnaire 24 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
SF-12 score (body functions)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (body functions) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			
SF-12 score (physical conditions)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (physical conditions) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			
SF-12 score (body pain)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		

Change in SF-12 score (body pain) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			

Notes: 1. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

2. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 40 (FAS) Secondary endpoint - Statistical analysis results of subjects' SF-12v2 questionnaire 24 weeks after surgery (continued 1)

Indicator	Study group	Control group	Statistics	P value
SF-12 score (general health)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (general health) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			
SF-12 score (vitality)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		

Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (vitality) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			
SF-12 score (social functions)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (social functions) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			

Notes: 1. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

2. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 40 (FAS) Secondary endpoint - Statistical analysis results of subjects' SF-12v2 questionnaire 24 weeks after surgery (continued 2)

Indicator	Study group	Control group	Statistics	P value
SF-12 score (emotional conditions)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (emotional conditions) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			
SF-12 score (mental health)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
z Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (mental health) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			
SF-12 score (total physical health score)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (total physical health score) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		

Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)	

Notes: 1. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

2. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 40 (FAS) Secondary endpoint - Statistical analysis results of subjects' SF-12v2 questionnaire 24 weeks after surgery (continued 3)

Indicator	Study group	Control group	Statistics	P value
SF-12 score (total mental health score)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (total mental health score) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			

Notes: 1. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

2. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 41 (FAS) Secondary endpoint - Statistical analysis results of subjects' EQ-5D questionnaire 12 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Activity level				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Walk easily	XXX (XX.X%)	XXX (XX.X%)		
Slightly difficult in walking	XXX (XX.X%)	XXX (XX.X%)		
Difficult in walking	XXX (XX.X%)	XXX (XX.X%)		
Very difficult in walking	XXX (XX.X%)	XXX (XX.X%)		
Completely unable to walk	XXX (XX.X%)	XXX (XX.X%)		
Self-care				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Easy to wash or dress independently	XXX (XX.X%)	XXX (XX.X%)		
Slightly difficult in washing or dressing independently	XXX (XX.X%)	XXX (XX.X%)		
Difficult in washing or dressing independently	XXX (XX.X%)	XXX (XX.X%)		
Very difficult in washing or dressing independently	XXX (XX.X%)	XXX (XX.X%)		
Completely unable to wash or dress independently	XXX (XX.X%)	XXX (XX.X%)		
Daily activities (such as work, study, housework, family or entertainment)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Easy to perform daily activities	XXX (XX.X%)	XXX (XX.X%)		
Slightly difficult in performing daily activities	XXX (XX.X%)	XXX (XX.X%)		
Difficult in performing daily activities	XXX (XX.X%)	XXX (XX.X%)		
Very difficult in performing daily activities	XXX (XX.X%)	XXX (XX.X%)		
Completely unable to perform daily activities	XXX (XX.X%)	XXX (XX.X%)		
Pain/discomfort				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No pain/discomfort	XXX (XX.X%)	XXX (XX.X%)		
Mild pain/discomfort	XXX (XX.X%)	XXX (XX.X%)		
Moderate pain/discomfort	XXX (XX.X%)	XXX (XX.X%)		
Severe pain/discomfort	XXX (XX.X%)	XXX (XX.X%)		
Very severe pain/discomfort	XXX (XX.X%)	XXX (XX.X%)		
Anxiety/depression				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No anxiety/depression	XXX (XX.X%)	XXX (XX.X%)		
Mild anxiety/depression	XXX (XX.X%)	XXX (XX.X%)		
Moderate anxiety/depression	XXX (XX.X%)	XXX (XX.X%)		
Severe anxiety/depression	XXX (XX.X%)	XXX (XX.X%)		
Very severe anxiety/depression	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the

intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 41 (FAS) Secondary endpoint - Statistical analysis results of subjects' EQ-5D questionnaire 12 weeks after surgery(continue)

Indicator	Study group	Control group	Statistics	P value
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in health index relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			

Notes: 1. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

2. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

3. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

4. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 42 (FAS) Secondary endpoint - Statistical analysis results of subjects' EQ-5D questionnaire 24 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Activity level				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Walk easily	XXX (XX.X%)	XXX (XX.X%)		
Slightly difficult in walking	XXX (XX.X%)	XXX (XX.X%)		
Difficult in walking	XXX (XX.X%)	XXX (XX.X%)		
Very difficult in walking	XXX (XX.X%)	XXX (XX.X%)		
Completely unable to walk	XXX (XX.X%)	XXX (XX.X%)		
Self-care				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Easy to wash or dress independently	XXX (XX.X%)	XXX (XX.X%)		
Slightly difficult in washing or dressing independently	XXX (XX.X%)	XXX (XX.X%)		
Difficult in washing or dressing independently	XXX (XX.X%)	XXX (XX.X%)		
Very difficult in washing or dressing independently	XXX (XX.X%)	XXX (XX.X%)		
Completely unable to wash or dress independently	XXX (XX.X%)	XXX (XX.X%)		
Daily activities (such as work, study, housework, family or entertainment)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Easy to perform daily activities	XXX (XX.X%)	XXX (XX.X%)		
Slightly difficult in performing daily activities	XXX (XX.X%)	XXX (XX.X%)		
Difficult in performing daily activities	XXX (XX.X%)	XXX (XX.X%)		
Very difficult in performing daily activities	XXX (XX.X%)	XXX (XX.X%)		
Completely unable to perform daily activities	XXX (XX.X%)	XXX (XX.X%)		
Pain/discomfort				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No pain/discomfort	XXX (XX.X%)	XXX (XX.X%)		
Mild pain/discomfort	XXX (XX.X%)	XXX (XX.X%)		
Moderate pain/discomfort	XXX (XX.X%)	XXX (XX.X%)		
Severe pain/discomfort	XXX (XX.X%)	XXX (XX.X%)		
Very severe pain/discomfort	XXX (XX.X%)	XXX (XX.X%)		
Anxiety/depression				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No anxiety/depression	XXX (XX.X%)	XXX (XX.X%)		
Mild anxiety/depression	XXX (XX.X%)	XXX (XX.X%)		
Moderate anxiety/depression	XXX (XX.X%)	XXX (XX.X%)		
Severe anxiety/depression	XXX (XX.X%)	XXX (XX.X%)		
Very severe anxiety/depression	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the

intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 42 (FAS) Secondary endpoint - Statistical analysis results of subjects' EQ-5D questionnaire 24 weeks after surgery(continue)

Indicator	Study group	Control group	Statistics	P value
Health index				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in health index relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			

Notes: 1. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

2. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

3. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

4. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 43 (FAS) Secondary endpoint - Statistical analysis results of subjects' incidence rate of complications requiring re-operation or revision

Indicator	Study group	Control group	Statistics	P value
Complications requiring re-operation or revision				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 44 (PPS) Secondary endpoint - Statistical analysis results of subjects' AE

Indicator	Study group	Control group	Statistics	P value
Total No.				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Total No.: the number of subjects who occurred AE, if at least once, will be determined as 'Y'

2. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 45 (PPS) Secondary endpoint - Statistical analysis results of subjects' revision rate 24 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Revision 24 weeks after surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 46 (PPS) Secondary endpoint - Statistical analysis results of subjects' re-operation rate 24 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Re-operation 24 weeks after surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 47 (PPS) Secondary endpoint - Statistical analysis results of subjects' Harris hip score 12 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Total Harris hip score				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		

Notes: 1. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

2. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 48 (PPS) Secondary endpoint - Statistical analysis results of subjects' Harris hip score 24 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Total Harris hip score				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		

Notes: 1. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

2. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 49 (FAS) Secondary endpoint - Statistical analysis results of subjects' SF-12v2 questionnaire 12 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
SF-12 score (body functions)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (body functions) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			
SF-12 score (physical conditions)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (physical conditions) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			
SF-12 score (body pain)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		

Notes: 1. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

2. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 49 (PPS) Secondary endpoint - Statistical analysis results of subjects' SF-12v2 questionnaire 12 weeks after surgery (continued 1)

Indicator	Study group	Control group	Statistics	P value
SF-12 score (general health)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (general health) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			
SF-12 score (vitality)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (vitality) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			

SF-12 score (social functions)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (social functions) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			

Notes: 1. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

2. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 49 (PPS) Secondary endpoint - Statistical analysis results of subjects' SF-12v2 questionnaire 12 weeks after surgery (continued 2)

Indicator	Study group	Control group	Statistics	P value
SF-12 score (emotional conditions)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (emotional conditions) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			
SF-12 score (mental health)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (mental health) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			
SF-12 score (total physical health score)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		

Change in SF-12 score (total physical health score) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			

Notes: 1. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

2. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 49 (PPS) Secondary endpoint - Statistical analysis results of subjects' SF-12v2 questionnaire 12 weeks after surgery (continued 3)

Indicator	Study group	Control group	Statistics	P value
SF-12 score (total mental health score)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (total mental health score) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			

Notes: 1. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

2. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 50 (PPS) Secondary endpoint - Statistical analysis results of subjects' SF-12v2 questionnaire 24 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
SF-12 score (body functions)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (body functions) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			
SF-12 score (physical conditions)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (physical conditions) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			
SF-12 score (body pain)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		

Change in SF-12 score (body pain) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			

Notes: 1. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

2. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 50 (PPS) Secondary endpoint - Statistical analysis results of subjects' SF-12v2 questionnaire 24 weeks after surgery (continued 1)

Indicator	Study group	Control group	Statistics	P value
SF-12 score (general health)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (general health) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			
SF-12 score (vitality)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		

Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (vitality) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			
SF-12 score (social functions)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (social functions) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			

Notes: 1. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

2. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 50 (PPS) Secondary endpoint - Statistical analysis results of subjects' SF-12v2 questionnaire 24 weeks after surgery (continued 2)

Indicator	Study group	Control group	Statistics	P value
SF-12 score (emotional conditions)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (emotional conditions) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			
SF-12 score (mental health)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
z Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (mental health) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			
SF-12 score (total physical health score)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (total physical health score) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1;Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		

Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)	

Notes: 1. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

2. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 50 (PPS) Secondary endpoint - Statistical analysis results of subjects' SF-12v2 questionnaire 24 weeks after surgery (continued 3)

Indicator	Study group	Control group	Statistics	P value
SF-12 score (total mental health score)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in SF-12 score (total mental health score) relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			

Notes: 1. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

2. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 51 (PPS) Secondary endpoint - Statistical analysis results of subjects' EQ-5D questionnaire 12 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Activity level				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Walk easily	XXX (XX.X%)	XXX (XX.X%)		
Slightly difficult in walking	XXX (XX.X%)	XXX (XX.X%)		
Difficult in walking	XXX (XX.X%)	XXX (XX.X%)		
Very difficult in walking	XXX (XX.X%)	XXX (XX.X%)		
Completely unable to walk	XXX (XX.X%)	XXX (XX.X%)		
Self-care				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Easy to wash or dress independently	XXX (XX.X%)	XXX (XX.X%)		
Slightly difficult in washing or dressing independently	XXX (XX.X%)	XXX (XX.X%)		
Difficult in washing or dressing independently	XXX (XX.X%)	XXX (XX.X%)		
Very difficult in washing or dressing independently	XXX (XX.X%)	XXX (XX.X%)		
Completely unable to wash or dress independently	XXX (XX.X%)	XXX (XX.X%)		
Daily activities (such as work, study, housework, family or entertainment)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Easy to perform daily activities	XXX (XX.X%)	XXX (XX.X%)		
Slightly difficult in performing daily activities	XXX (XX.X%)	XXX (XX.X%)		
Difficult in performing daily activities	XXX (XX.X%)	XXX (XX.X%)		
Very difficult in performing daily activities	XXX (XX.X%)	XXX (XX.X%)		
Completely unable to perform daily activities	XXX (XX.X%)	XXX (XX.X%)		
Pain/discomfort				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No pain/discomfort	XXX (XX.X%)	XXX (XX.X%)		
Mild pain/discomfort	XXX (XX.X%)	XXX (XX.X%)		
Moderate pain/discomfort	XXX (XX.X%)	XXX (XX.X%)		
Severe pain/discomfort	XXX (XX.X%)	XXX (XX.X%)		
Very severe pain/discomfort	XXX (XX.X%)	XXX (XX.X%)		
Anxiety/depression				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No anxiety/depression	XXX (XX.X%)	XXX (XX.X%)		
Mild anxiety/depression	XXX (XX.X%)	XXX (XX.X%)		
Moderate anxiety/depression	XXX (XX.X%)	XXX (XX.X%)		
Severe anxiety/depression	XXX (XX.X%)	XXX (XX.X%)		
Very severe anxiety/depression	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the

intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 51 (PPS) Secondary endpoint - Statistical analysis results of subjects' EQ-5D questionnaire 12 weeks after surgery(continue)

Indicator	Study group	Control group	Statistics	P value
Health index				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in health index relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			

Notes: 1. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

2. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

3. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

4. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 52 (PPS) Secondary endpoint - Statistical analysis results of subjects' EQ-5D questionnaire 24 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Activity level				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Walk easily	XXX (XX.X%)	XXX (XX.X%)		
Slightly difficult in walking	XXX (XX.X%)	XXX (XX.X%)		
Difficult in walking	XXX (XX.X%)	XXX (XX.X%)		
Very difficult in walking	XXX (XX.X%)	XXX (XX.X%)		
Completely unable to walk	XXX (XX.X%)	XXX (XX.X%)		
Self-care				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Easy to wash or dress independently	XXX (XX.X%)	XXX (XX.X%)		
Slightly difficult in washing or dressing independently	XXX (XX.X%)	XXX (XX.X%)		
Difficult in washing or dressing independently	XXX (XX.X%)	XXX (XX.X%)		
Very difficult in washing or dressing independently	XXX (XX.X%)	XXX (XX.X%)		
Completely unable to wash or dress independently	XXX (XX.X%)	XXX (XX.X%)		
Daily activities (such as work, study, housework, family or entertainment)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Easy to perform daily activities	XXX (XX.X%)	XXX (XX.X%)		
Slightly difficult in performing daily activities	XXX (XX.X%)	XXX (XX.X%)		
Difficult in performing daily activities	XXX (XX.X%)	XXX (XX.X%)		
Very difficult in performing daily activities	XXX (XX.X%)	XXX (XX.X%)		
Completely unable to perform daily activities	XXX (XX.X%)	XXX (XX.X%)		
Pain/discomfort				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No pain/discomfort	XXX (XX.X%)	XXX (XX.X%)		
Mild pain/discomfort	XXX (XX.X%)	XXX (XX.X%)		
Moderate pain/discomfort	XXX (XX.X%)	XXX (XX.X%)		
Severe pain/discomfort	XXX (XX.X%)	XXX (XX.X%)		
Very severe pain/discomfort	XXX (XX.X%)	XXX (XX.X%)		
Anxiety/depression				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No anxiety/depression	XXX (XX.X%)	XXX (XX.X%)		
Mild anxiety/depression	XXX (XX.X%)	XXX (XX.X%)		
Moderate anxiety/depression	XXX (XX.X%)	XXX (XX.X%)		
Severe anxiety/depression	XXX (XX.X%)	XXX (XX.X%)		
Very severe anxiety/depression	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the

intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);;

Table 52 (PPS) Secondary endpoint - Statistical analysis results of subjects' EQ-5D questionnaire 24 weeks after surgery(continue)

Indicator	Study group	Control group	Statistics	P value
Health index				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
Change in health index relative to before surgery				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ±XX.XX	XX.XX ±XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX ;XX.XX	XX.XX ;XX.XX		
Minimum; maximum	XX.XX ;XX.XX	XX.XX ;XX.XX		
95% confidence interval	(XX.XX ,XX.XX)	(XX.XX ,XX.XX)		
The difference and 95% confidence interval	XX.XX(XX.XX ,XX.XX)			

Notes: 1. Group t-test or Wilcoxon rank-sum test is used to analyze the intergroup comparison of quantitative indicators.

2. In quantitative indicators, Q1: 25th quantile, Q3: 75th percentile.

3. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

4. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 53 (PPS) Secondary endpoint - Statistical analysis results of subjects' incidence rate of complications requiring re-operation or revision

Indicator	Study group	Control group	Statistics	P value
Complications requiring re-operation or revision				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 54 Statistical analysis results of subjects' AE evaluation 1 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Whether there are adverse events or complications in the subjects after the last follow-up				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 55 Statistical analysis results of subjects' medication records 1 week after surgery

Indicator	Study group	Control group	Statistics	P value
Whether new drugs are added to the concomitant medication or whether the original concomitant medication is changed				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 56 Statistical analysis results of subjects' combination therapy 1 week after surgery

Indicator	Study group	Control group	Statistics	P value
Whether new types of combination therapy are added				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 57 Statistical analysis results of subjects' fractures 1 week after surgery

Indicator	Study group	Control group	Statistics	P value
Wound healing - healing grade				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A	XXX (XX.X%)	XXX (XX.X%)		
B	XXX (XX.X%)	XXX (XX.X%)		
C	XXX (XX.X%)	XXX (XX.X%)		
Wound healing - incision category				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Class I	XXX (XX.X%)	XXX (XX.X%)		
Class II	XXX (XX.X%)	XXX (XX.X%)		
Physical sign - Focal tenderness				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
NA	XXX (XX.X%)	XXX (XX.X%)		
Mild	XXX (XX.X%)	XXX (XX.X%)		
Severe	XXX (XX.X%)	XXX (XX.X%)		
Physical sign - Lengthwise percussion pain				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
NA	XXX (XX.X%)	XXX (XX.X%)		
Mild	XXX (XX.X%)	XXX (XX.X%)		
Severe	XXX (XX.X%)	XXX (XX.X%)		
Physical sign - Abnormal activity				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Evaluate postoperative weight-bearing				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No weight-bearing	XXX (XX.X%)	XXX (XX.X%)		
Lower degree of weight-bearing (support with two crutches)	XXX (XX.X%)	XXX (XX.X%)		
Higher degree of weight-bearing (support with one crutch)	XXX (XX.X%)	XXX (XX.X%)		
Fully weight-bearing (support without crutch)	XXX (XX.X%)	XXX (XX.X%)		
After the investigational device is implanted, whether external fixation is required to enhance the stability of the fracture site				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 58 Statistical analysis results of subjects' x-ray examination at the fracture site 1 week after surgery

Indicator	Study group	Control group	Statistics	P value
Reduction				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Stable	XXX (XX.X%)	XXX (XX.X%)		
Loss of reduction	XXX (XX.X%)	XXX (XX.X%)		
Is the re-operation required				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Implant				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Good	XXX (XX.X%)	XXX (XX.X%)		
Rupture of screw/bolt	XXX (XX.X%)	XXX (XX.X%)		
Rupture of intramedullary nail	XXX (XX.X%)	XXX (XX.X%)		
Displacement of screw/bolt	XXX (XX.X%)	XXX (XX.X%)		
Displacement of intramedullary nail	XXX (XX.X%)	XXX (XX.X%)		
Fracture line				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Clear	XXX (XX.X%)	XXX (XX.X%)		
Vague	XXX (XX.X%)	XXX (XX.X%)		
Disappeared	XXX (XX.X%)	XXX (XX.X%)		
Callus				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
NA	XXX (XX.X%)	XXX (XX.X%)		
Intermittent	XXX (XX.X%)	XXX (XX.X%)		
Continuous	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 59 Statistical analysis results of subjects' AE evaluation 6 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Whether there are adverse events or complications in the subjects after the last follow-up				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 60 Statistical analysis results of subjects' medication records 6 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Whether new drugs are added to the concomitant medication or whether the original concomitant medication is changed				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 61 Statistical analysis results of subjects' combination therapy 6 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Whether new types of combination therapy are added				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 62 Statistical analysis results of subjects' fractures 6 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Wound healing - healing grade				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A	XXX (XX.X%)	XXX (XX.X%)		
B	XXX (XX.X%)	XXX (XX.X%)		
C	XXX (XX.X%)	XXX (XX.X%)		
Wound healing - incision category				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Class I	XXX (XX.X%)	XXX (XX.X%)		
Class II	XXX (XX.X%)	XXX (XX.X%)		
Physical sign - Focal tenderness				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
NA	XXX (XX.X%)	XXX (XX.X%)		
Mild	XXX (XX.X%)	XXX (XX.X%)		
Severe	XXX (XX.X%)	XXX (XX.X%)		
Physical sign - Lengthwise percussion pain				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
NA	XXX (XX.X%)	XXX (XX.X%)		
Mild	XXX (XX.X%)	XXX (XX.X%)		
Severe	XXX (XX.X%)	XXX (XX.X%)		
Physical sign - Abnormal activity				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Evaluate postoperative weight-bearing				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No weight-bearing	XXX (XX.X%)	XXX (XX.X%)		
Lower degree of weight-bearing (support with two crutches)	XXX (XX.X%)	XXX (XX.X%)		
Higher degree of weight-bearing (support with one crutch)	XXX (XX.X%)	XXX (XX.X%)		
Fully weight-bearing (support without crutch)	XXX (XX.X%)	XXX (XX.X%)		
After the investigational device is implanted, whether external fixation is required to enhance the stability of the fracture site				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 63 Statistical analysis results of subjects' X-ray examination at the fracture site 6 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Reduction				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Stable	XXX (XX.X%)	XXX (XX.X%)		
Loss of reduction	XXX (XX.X%)	XXX (XX.X%)		
Is the re-operation required				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Implant				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Good	XXX (XX.X%)	XXX (XX.X%)		
Rupture of screw/bolt	XXX (XX.X%)	XXX (XX.X%)		
Rupture of intramedullary nail	XXX (XX.X%)	XXX (XX.X%)		
Displacement of screw/bolt	XXX (XX.X%)	XXX (XX.X%)		
Displacement of intramedullary nail	XXX (XX.X%)	XXX (XX.X%)		
Fracture line				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Clear	XXX (XX.X%)	XXX (XX.X%)		
Vague	XXX (XX.X%)	XXX (XX.X%)		
Disappeared	XXX (XX.X%)	XXX (XX.X%)		
Callus				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
NA	XXX (XX.X%)	XXX (XX.X%)		
Intermittent	XXX (XX.X%)	XXX (XX.X%)		
Continuous	XXX (XX.X%)	XXX (XX.X%)		
The frontal/lateral X-ray examination shows the continuous callus passing across the fracture line				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Determine the fracture union condition				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No union	XXX (XX.X%)	XXX (XX.X%)		
Union	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 64 Statistical analysis results of subjects' AE evaluation 12 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Whether there are adverse events or complications in the subjects after the last follow-up				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 65 Statistical analysis results of subjects' medication records 12 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Whether new drugs are added to the concomitant medication or whether the original concomitant medication is changed				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 66 Statistical analysis results of subjects' combination therapy 12 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Whether new types of combination therapy are added				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 67 Statistical analysis results of subjects' fractures 12 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Wound healing - healing grade				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A	XXX (XX.X%)	XXX (XX.X%)		
B	XXX (XX.X%)	XXX (XX.X%)		
C	XXX (XX.X%)	XXX (XX.X%)		
Wound healing - incision category				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Class I	XXX (XX.X%)	XXX (XX.X%)		
Class II	XXX (XX.X%)	XXX (XX.X%)		
Physical sign - Focal tenderness				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
NA	XXX (XX.X%)	XXX (XX.X%)		
Mild	XXX (XX.X%)	XXX (XX.X%)		
Severe	XXX (XX.X%)	XXX (XX.X%)		
Physical sign - Lengthwise percussion pain				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
NA	XXX (XX.X%)	XXX (XX.X%)		
Mild	XXX (XX.X%)	XXX (XX.X%)		
Severe	XXX (XX.X%)	XXX (XX.X%)		
Physical sign - Abnormal activity				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Evaluate postoperative weight-bearing				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No weight-bearing	XXX (XX.X%)	XXX (XX.X%)		
Lower degree of weight-bearing (support with two crutches)	XXX (XX.X%)	XXX (XX.X%)		
Higher degree of weight-bearing (support with one crutch)	XXX (XX.X%)	XXX (XX.X%)		
Fully weight-bearing (support without crutch)	XXX (XX.X%)	XXX (XX.X%)		
After the investigational device is implanted, whether external fixation is required to enhance the stability of the fracture site				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 68 Statistical analysis results of subjects' X-ray examination at the fracture site 12 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Reduction				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Stable	XXX (XX.X%)	XXX (XX.X%)		
Loss of reduction	XXX (XX.X%)	XXX (XX.X%)		
Is the re-operation required				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Implant				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Good	XXX (XX.X%)	XXX (XX.X%)		
Rupture of screw/bolt	XXX (XX.X%)	XXX (XX.X%)		
Rupture of intramedullary nail	XXX (XX.X%)	XXX (XX.X%)		
Displacement of screw/bolt	XXX (XX.X%)	XXX (XX.X%)		
Displacement of intramedullary nail	XXX (XX.X%)	XXX (XX.X%)		
Fracture line				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Clear	XXX (XX.X%)	XXX (XX.X%)		
Vague	XXX (XX.X%)	XXX (XX.X%)		
Disappeared	XXX (XX.X%)	XXX (XX.X%)		
Callus				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
NA	XXX (XX.X%)	XXX (XX.X%)		
Intermittent	XXX (XX.X%)	XXX (XX.X%)		
Continuous	XXX (XX.X%)	XXX (XX.X%)		
The frontal/lateral X-ray examination shows the continuous callus passing across the fracture line				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Determine the fracture union condition				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No union	XXX (XX.X%)	XXX (XX.X%)		
Union	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 69 Statistical analysis results of subjects' AE evaluation 24 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Whether there are adverse events or complications in the subjects after the last follow-up				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 70 Statistical analysis results of subjects' medication records 24 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Whether new drugs are added to the concomitant medication or whether the original concomitant medication is changed				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 71 Statistical analysis results of subjects' combination therapy 24 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Whether new types of combination therapy are added				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 72 Statistical analysis results of subjects' fractures 24 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Wound healing - healing grade				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A	XXX (XX.X%)	XXX (XX.X%)		
B	XXX (XX.X%)	XXX (XX.X%)		
C	XXX (XX.X%)	XXX (XX.X%)		
Wound healing - incision category				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Class I	XXX (XX.X%)	XXX (XX.X%)		
Class II	XXX (XX.X%)	XXX (XX.X%)		
Physical sign - Focal tenderness				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
NA	XXX (XX.X%)	XXX (XX.X%)		
Mild	XXX (XX.X%)	XXX (XX.X%)		
Severe	XXX (XX.X%)	XXX (XX.X%)		
Physical sign - Lengthwise percussion pain				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
NA	XXX (XX.X%)	XXX (XX.X%)		
Mild	XXX (XX.X%)	XXX (XX.X%)		
Severe	XXX (XX.X%)	XXX (XX.X%)		
Physical sign - Abnormal activity				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Evaluate postoperative weight-bearing				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No weight-bearing	XXX (XX.X%)	XXX (XX.X%)		
Lower degree of weight-bearing (support with two crutches)	XXX (XX.X%)	XXX (XX.X%)		
Higher degree of weight-bearing (support with one crutch)	XXX (XX.X%)	XXX (XX.X%)		
Fully weight-bearing (support without crutch)	XXX (XX.X%)	XXX (XX.X%)		
After the investigational device is implanted, whether external fixation is required to enhance the				

stability of the fracture site				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 73 Statistical analysis results of subjects' x-ray examination at the fracture site 24 weeks after surgery

Indicator	Study group	Control group	Statistics	P value
Reduction				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Stable	XXX (XX.X%)	XXX (XX.X%)		
Loss of reduction	XXX (XX.X%)	XXX (XX.X%)		
Is the re-operation required				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Implant				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Good	XXX (XX.X%)	XXX (XX.X%)		
Rupture of screw/bolt	XXX (XX.X%)	XXX (XX.X%)		
Rupture of intramedullary nail	XXX (XX.X%)	XXX (XX.X%)		
Displacement of screw/bolt	XXX (XX.X%)	XXX (XX.X%)		
Displacement of intramedullary nail	XXX (XX.X%)	XXX (XX.X%)		
Fracture line				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Clear	XXX (XX.X%)	XXX (XX.X%)		
Vague	XXX (XX.X%)	XXX (XX.X%)		
Disappeared	XXX (XX.X%)	XXX (XX.X%)		
Callus				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
NA	XXX (XX.X%)	XXX (XX.X%)		
Intermittent	XXX (XX.X%)	XXX (XX.X%)		
Continuous	XXX (XX.X%)	XXX (XX.X%)		
The frontal/lateral X-ray examination shows the continuous callus passing across the fracture line				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Determine the fracture union condition				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No union	XXX (XX.X%)	XXX (XX.X%)		
Union	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 74 Statistical analysis results of outcomes of subjects' complete blood count before and after surgery (before surgery → immediately after surgery)

Indicator	Study group	Control group	Statistics	P value
White blood cell (WBC)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Normal → Abnormal (with clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Abnormal (without clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Abnormal	XXX (XX.X%)	XXX (XX.X%)		
NE				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Normal → Abnormal (with clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Abnormal (without clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Abnormal	XXX (XX.X%)	XXX (XX.X%)		
Red blood cell (RBC)				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Normal → Abnormal (with clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Abnormal (without clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Abnormal	XXX (XX.X%)	XXX (XX.X%)		
HGB				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Normal → Abnormal (with clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Abnormal (without clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Abnormal	XXX (XX.X%)	XXX (XX.X%)		
Platelet				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Normal → Abnormal (with clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Abnormal (without clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Abnormal	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 74 Statistical analysis results of outcomes of subjects' complete blood count before and after surgery (before surgery → immediately after surgery) (continued)

Indicator	Study group	Control group	Statistics	P value
INR				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Normal → Abnormal (with clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Abnormal (without clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Abnormal	XXX (XX.X%)	XXX (XX.X%)		
APTT				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Normal → Abnormal (with clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Abnormal (without clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Abnormal	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 75 List of subjects with abnormal complete blood count with clinical significance after surgery changed from normal indicators before surgery (before surgery → immediately after surgery)

Indicator	Site No.	Random No.	Group	Age	Gender	Before surgery	Immediately after surgery
XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXXX
XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXXX
……	……	……	……	……	……	……	……
……	……	……	……	……	……	……	……

Table 76 Statistical analysis results of outcomes of subjects' blood biochemical test before and after surgery (before surgery → immediately after surgery)

Indicator	Study group	Control group	Statistics	P value
AST				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Normal → Abnormal (with clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Abnormal (without clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Abnormal	XXX (XX.X%)	XXX (XX.X%)		
ALT				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Normal → Abnormal (with clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Abnormal (without clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Abnormal	XXX (XX.X%)	XXX (XX.X%)		
ALB				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Normal → Abnormal (with clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Abnormal (without clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Abnormal	XXX (XX.X%)	XXX (XX.X%)		
CHOL				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Normal → Abnormal (with clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Abnormal (without clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Abnormal	XXX (XX.X%)	XXX (XX.X%)		
TRIG				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Normal → Abnormal (with clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Abnormal (without clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Abnormal	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 76 Statistical analysis results of outcomes of subjects' blood biochemical test before and after surgery (before surgery → immediately after surgery) (continued 1)

Indicator	Study group	Control group	Statistics	P value
CREA				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Normal → Abnormal (with clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Abnormal (without clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Abnormal	XXX (XX.X%)	XXX (XX.X%)		
BUN				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Normal → Abnormal (with clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Abnormal (without clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Abnormal	XXX (XX.X%)	XXX (XX.X%)		
UREA				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Normal → Abnormal (with clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Abnormal (without clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Abnormal	XXX (XX.X%)	XXX (XX.X%)		
UA				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Normal → Abnormal (with clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Abnormal (without clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Abnormal	XXX (XX.X%)	XXX (XX.X%)		
LDL-C				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Normal → Abnormal (with clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Abnormal (without clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Abnormal	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 76 Statistical analysis results of outcomes of subjects' blood biochemical test before and after surgery (before surgery → immediately after surgery) (continued 2)

Indicator	Study group	Control group	Statistics	P value
HDL-C				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Normal → Abnormal (with clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Abnormal (without clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Abnormal	XXX (XX.X%)	XXX (XX.X%)		
GLU				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Normal → Abnormal (with clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Abnormal (without clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Abnormal	XXX (XX.X%)	XXX (XX.X%)		
CRP				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Normal → Abnormal (with clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Abnormal (without clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Abnormal	XXX (XX.X%)	XXX (XX.X%)		
Hypersensitive CRP				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Normal → Abnormal (with clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Abnormal (without clinical significance)	XXX (XX.X%)	XXX (XX.X%)		
Normal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal → Abnormal	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 77 List of subjects with abnormal blood biochemical test indicators with clinical significance after surgery changed from normal indicators before surgery (before surgery → immediately after surgery)

Indicator	Site No.	Random No.	Group	Age	Gender	Before surgery	Immediately after surgery
XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXXX
XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXXX
……	……	……	……	……	……	……	……
……	……	……	……	……	……	……	……

Table 78 List of concomitant medication of subjects

Site No.	Random No.	Group	Age	Gender	Drug name	Indication or reason for medication	For treating AE	Single dose	Unit	Frequency of administration per day	Route of administration	Start date of administration	End date of administration	Still use after completion of the trial
XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXXX	XXX	XXX	XXX	XXX	XXX	XXX
……	……	……	……	……	……	……	……	……						
……	……	……	……	……	……	……	……	……						
……	……	……	……	……	……	……	……	……						
……	……	……	……	……	……	……	……	……						

Table 79 Specific description on subjects with AEs

Site No.	Random No.	Group	Age	Gender	Name of AE (SOC code)	Name of AE (PT code)	Time of postoperative occurrence (day)	Remission time (day)	Severity	Measures taken	Outcome	Correlation with the surgery	Correlation with the investigational device	Withdrawal from the trial due to AEs	Whether it is UADE	Whether it is device failure	Whether it is SAE
XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
……																	
……																	

Notes: 1. Time of postoperative occurrence (day) = Date of occurrence of AE - Date of surgery; Remission time (day) = End date of AE - Date of occurrence of AE.

Table 80 Summary of AEs

Adverse event	Study group		Control group	
	Number of events	Number of subjects (N=XXX)	Number of events	Number of subjects (N=XXX)
Name of AE (SOC code)	XXX	XXX(XX.XX%[#])	XXX	XXX(XX.XX%)
Name of AE (PT code)	XXX	XXX(XX.XX%)	XXX	XXX(XX.XX%)
Name of AE (PT code)				
Name of AE (SOC code)	XXX	XXX(XX.XX%)	XXX	XXX(XX.XX%)
Name of AE (PT code)	XXX	XXX(XX.XX%)	XXX	XXX(XX.XX%)
Name of AE (PT code)				
……				
……				

Notes: 1. #: Percentage of AEs = Number of subjects suffering from AEs/Total number of subjects in the study group or the control group;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 80 Summary of AEs (continued 1)

Adverse event	Study group	Control group	Statistics	P value
Total number of AEs				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Event rate difference (study group-control group) and 95%CI		XX.X [XX.X; XX.X]		

Notes: 1. The total number of AEs refers to the number of subjects suffering from AEs, and the AEs occur in the subject at least one time, which is considered as "Yes".

2. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

3. The difference of event rate and 95% confidence interval were analyzed by Wald test with continuous correction;

4. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 81 Specific description on subjects with investigational device-related AEs

Site No.	Random No.	Group	Age	Gender	Name of AE (SOC code)	Name of AE (PT code)	Time of postoperative occurrence (day)	Remission time (day)	Severity	Measures taken	Outcome	Correlation with the surgery	Correlation with the investigational device	Withdrawal from the trial due to AEs	Whether it is UADE	Whether it is device failure	Whether it is SAE
XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
……																	
……																	

Notes: 1. Time of postoperative occurrence (day) = Date of occurrence of AE - Date of surgery; Remission time (day) = End date of AE - Date of occurrence of AE.

Table 82 Summary of investigational device-related AEs

Investigational device-related AE	Study group		Control group	
	Number of events	Number of subjects (N=XXX)	Number of events	Number of subjects (N=XXX)
Name of AE (SOC code)	XXX	XXX(XX.XX%[#])	XXX	XXX(XX.XX%)
Name of AE (PT code)	XXX	XXX(XX.XX%)	XXX	XXX(XX.XX%)
Name of AE (PT code)				
Name of AE (SOC code)	XXX	XXX(XX.XX%)	XXX	XXX(XX.XX%)
Name of AE (PT code)	XXX	XXX(XX.XX%)	XXX	XXX(XX.XX%)
Name of AE (PT code)				
……				
……				

Notes: 1. #: Percentage of investigational device-related AEs = Number of subjects suffering from investigational device-related AEs/Total number of subjects in the study group or the control group;

2: Investigational device-related AEs refer to those “definitely related”, “probably related” and “possibly related” with the investigational device;

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 82 Summary of investigational device-related AEs (continued)

Investigational device-related AE	Study group	Control group	Statistics	P value
Total number of investigational device-related AEs				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Event rate difference (study group-control group) and 95%CI	XX.X [XX.X; XX.X]			

Notes: 1. The total number of investigational device-related AEs refers to the number of subjects suffering from investigational device-related AEs and the investigational device-related AEs occur in the subject at least one time, which is considered as "Yes".

2: Investigational device-related AEs refer to those “definitely related”, “probably related” and “possibly related” with the investigational device;

3. The likelihood ratio Chi-square test or Fisher’s exact probability test is used to analyze the intergroup comparison of qualitative indicators;

4. The difference of event rate and 95% confidence interval were analyzed by Wald test with continuous correction;

5. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 83 Summary of AEs (Number of events per subject)

Indicator	Study group（N= XXX [#1]）	control group（N= XXX [#1]）	P
Total number of adverse events			
	XXX [#2](XX.X [3])	XXX [#2] (XX.X [#3])	X.XXXX
	Event difference (study group-control group) and 95%C		XX.X [XX.X; XX.X]
Total number of device related adverse events			
	XXX [#2](XX.X [3])	XXX [#2] (XX.X [#3])	X.XXXX
	Event rate difference (study group-control group) and 95%CI		XX.X [XX.X; XX.X]
Total number of surgery related adverse events			
	XXX [#2](XX.X [3])	XXX [#2] (XX.X [#3])	X.XXXX
	Event rate difference (study group-control group) and 95%CI		XX.X [XX.X; XX.X]

Notes： 1. Devices related adverse events are the adverse events that are "probably related" or "possible related" or "definitely related" to the study devices;

2. Surgery related adverse events are the adverse events that are "probably related" or "possible related" or "definitely related" to surgery;

3.#1：Total number of subjects；#2：Total number of events；

#3：Total number of events/total number of patients: the average number of events per subject；

4. Group t-test is used to analyze Event rate difference (study group-control group) and 95%CI

5. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 84 Statistical analysis results of the severity and the device related AEs (According subject)

Indicator	Study group	control group	statistic	P
Severity				
NO. (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
mild	XXX (XX.X%)	XXX (XX.X%)		
moderate	XXX (XX.X%)	XXX (XX.X%)		
severe	XXX (XX.X%)	XXX (XX.X%)		
Device related				
NO. (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Not related	XXX (XX.X%)	XXX (XX.X%)		
Unlikely related	XXX (XX.X%)	XXX (XX.X%)		
Possible related	XXX (XX.X%)	XXX (XX.X%)		
probably related	XXX (XX.X%)	XXX (XX.X%)		
definitely related	XXX (XX.X%)	XXX (XX.X%)		
Surgery related				
NO. (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Not related	XXX (XX.X%)	XXX (XX.X%)		
Unlikely related	XXX (XX.X%)	XXX (XX.X%)		
possible related	XXX (XX.X%)	XXX (XX.X%)		
probably related	XXX (XX.X%)	XXX (XX.X%)		
definitely related	XXX (XX.X%)	XXX (XX.X%)		

Notes：1. If more than one adverse event occurred in a subject, the analysis was performed with the highest severity or correlation;

2. The likelihood ratio Chi-square test or Fisher’s exact probability test is used to analyze the intergroup comparison of qualitative indicators;

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II)；

Table 85 Statistical analysis results of the severity and the device related AEs (Number of events per subject)

Indicator	Study group（N=XXX#1）	control group（N=XXX#1）	total（N=XXX#1）
Severity			
mild	XXX#2 (XX.X%#3)	XXX (XX.X%)	XXX (XX.X%)
moderate	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
severe	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
Device related			
Not related	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
Unlikely related	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
Possible related	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
probably related	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
definitely related	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
Surgery related			
Not related	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
Unlikely related	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
possible related	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
probably related	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
definitely related	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)

Notes：1.#1：Total number of subjects；#2：Total number of events；
2.#3：Total number of events/total number of subjects: the average number of events per subject；
3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II)

Table 86 Specific description on subjects with SAEs

Site No.	Random No.	Group	Age	Gender	Name of SAE (SOC code)	Name of SAE (PT code)	Time of postoperative occurrence (day)	Remission time (day)	Severity	Outcome	Correlation with the surgery	Correlation with the investigational device	SAE condition
XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX

Notes: 1. Time of postoperative occurrence (day) = Date of occurrence of SAE - Date of surgery; Remission time (day) = End date of SAE - Date of occurrence of SAE.

Table 87 Summary of SAEs

SAE	Study group		Control group	
	Number of events	Number of subjects (N=XXX)	Number of events	Number of subjects (N=XXX)
Name of SAE (SOC code)	XXX	XXX(XX.XX%[#])	XXX	XXX(XX.XX%)
Name of SAE (PT code)	XXX	XXX(XX.XX%)	XXX	XXX(XX.XX%)
Name of SAE (PT code)				
Name of SAE (SOC code)	XXX	XXX(XX.XX%)	XXX	XXX(XX.XX%)
Name of SAE (PT code)	XXX	XXX(XX.XX%)	XXX	XXX(XX.XX%)
Name of SAE (PT code)				
……				
……				

Notes: 1. #: Percentage of SAEs = Number of subjects suffering from SAEs/Total number of subjects in the study group or the control group;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 87 Summary of SAEs (continued)

SAE	Study group	Control group	Statistics	P value
Total number of SAEs				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Event rate difference (investigation group-control group) and 95%CI		XX.X [XX.X; XX.X]		

Notes: 1. The total number of SAEs refers to the number of subjects suffering from SAEs and the SAEs occur in the subject at least one time, which is considered as "Yes".

2. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

3. The difference of event rate and 95% confidence interval were analyzed by Wald test with continuous correction;

4. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 88 Specific description on subjects with investigational device-related SAEs

Site No.	Random No.	Group	Age	Gender	Name of SAE (SOC code)	Name of SAE (PT code)	Time of postoperative occurrence (day)	Remission time (day)	Severity	Outcome	Correlation with the surgery	Correlation with the investigational device	SAE condition
XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
…													

Notes: 1. Time of postoperative occurrence (day) = Date of occurrence of SAE - Date of surgery; Remission time (day) = End date of SAE - Date of occurrence of SAE.

Table 89 Summary of investigational device-related SAEs

Investigational device-related SAE	Study group		Control group	
	Number of events	Number of subjects (N=XXX)	Number of events	Number of subjects (N=XXX)
Name of SAE (SOC code)	XXX	XXX(XX.XX%[#])	XXX	XXX(XX.XX%)
Name of SAE (PT code)	XXX	XXX(XX.XX%)	XXX	XXX(XX.XX%)
Name of SAE (PT code)				
Name of SAE (SOC code)	XXX	XXX(XX.XX%)	XXX	XXX(XX.XX%)
Name of SAE (PT code)	XXX	XXX(XX.XX%)	XXX	XXX(XX.XX%)
Name of SAE (PT code)				
……				
……				

Notes: 1. #: Percentage of investigational device-related SAEs = Number of subjects suffering from investigational device-related SAEs/Total number of subjects in the study group or the control group;

2: Investigational device-related SAEs refer to those “definitely related”, “probably related” and “possibly related” with the investigational device;

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 89 Summary of investigational device-related SAEs (continued)

Investigational device-related SAE	Study group	Control group	Statistics	P value
Total number of investigational device-related SAEs				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Event rate difference (investigation group-control group) and 95%CI			XX.X [XX.X; XX.X]	

Notes: 1. The total number of investigational device-related SAEs refers to the number of subjects suffering from investigational device-related SAEs and the investigational device-related SAEs occur in the subject at least one time, which is considered as "Yes".

2: Investigational device-related SAEs refer to those “definitely related”, “probably related” and “possibly related” with the investigational device;

3. The likelihood ratio Chi-square test or Fisher’s exact probability test is used to analyze the intergroup comparison of qualitative indicators;

4. The difference of event rate and 95% confidence interval were analyzed by Wald test with continuous correction;

5. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 90 Summary of SAEs (Number of events per subject)

Indicator	Study group（N= XXX[#1]）	control group（N= XXX[#1]）	P
Total number of adverse events	XXX[#2](XX.X[3])	XXX[#2] (XX.X[#3])	X.XXXX
Event difference (study group-control group) and 95%C			XX.X [XX.X; XX.X]
Total number of device related adverse events	XXX[#2](XX.X[3])	XXX[#2] (XX.X[#3])	X.XXXX
Event rate difference (study group-control group) and 95%CI			XX.X [XX.X; XX.X]
Total number of surgery related adverse events	XXX[#2](XX.X[3])	XXX[#2] (XX.X[#3])	X.XXXX
Event rate difference (study group-control group) and 95%CI			XX.X [XX.X; XX.X]

Notes： 1. Devices related adverse events are the adverse events that are "probably related" or "possible related" or "definitely related" to the study devices;

2. Surgery related adverse events are the adverse events that are "probably related" or "possible related" or "definitely related" to surgery;

3.#1：Total number of subjects；#2：Total number of events；

#3：Total number of events/total number of patients: the average number of events per subject；

4. Group t-test is used to analyze Event rate difference (study group-control group) and 95%CI

5. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 91 Statistical analysis results of the severity and the device related SAEs (According subject)

Indicator	Study group	control group	statistic	P
Severity				
NO. (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
mild	XXX (XX.X%)	XXX (XX.X%)		
moderate	XXX (XX.X%)	XXX (XX.X%)		
severe	XXX (XX.X%)	XXX (XX.X%)		
Device related				
NO. (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Not related	XXX (XX.X%)	XXX (XX.X%)		
Unlikely related	XXX (XX.X%)	XXX (XX.X%)		
Possible related	XXX (XX.X%)	XXX (XX.X%)		
probably related	XXX (XX.X%)	XXX (XX.X%)		
definitely related	XXX (XX.X%)	XXX (XX.X%)		
Surgery related				
NO. (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Not related	XXX (XX.X%)	XXX (XX.X%)		
Unlikely related	XXX (XX.X%)	XXX (XX.X%)		
possible related	XXX (XX.X%)	XXX (XX.X%)		
probably related	XXX (XX.X%)	XXX (XX.X%)		
definitely related	XXX (XX.X%)	XXX (XX.X%)		

Notes：1. If more than one adverse event occurred in a subject, the analysis was performed with the highest severity or correlation;

2. The likelihood ratio Chi-square test or Fisher’s exact probability test is used to analyze the intergroup comparison of qualitative indicators;

3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II)；

Table 92 Statistical analysis results of the severity and the device related SAEs (Number of events per subject)

Indicator	Study group（N=XXX#1）	control group（N=XXX#1）	total（N=XXX#1）
Severity			
mild	XXX#2 (XX.X%#3)	XXX (XX.X%)	XXX (XX.X%)
moderate	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
severe	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
Device related			
Not related	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
Unlikely related	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
Possible related	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
probably related	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
definitely related	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
Surgery related			
Not related	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
Unlikely related	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
possible related	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
probably related	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
definitely related	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)

Notes：1.#1：Total number of subjects；#2：Total number of events；
2.#3：Total number of events/total number of subjects: the average number of events per subject；
3. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II)

Table 93 Specific description on subjects with UADEs

Site No.	Random No.	Group	Age	Gender	Name of AE (SOC code)	Name of AE (PT code)	Time of postoperative occurrence (day)	Remission time (day)	Severity	Measures taken	Outcome	Correlation with the surgery	Correlation with the investigational device	Withdrawal from the trial due to AEs	Whether it is device failure	Whether it is SAE
XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
……																
……																

Notes: 1. Time of postoperative occurrence (day) = Date of occurrence of AE - Date of surgery; Remission time (day) = End date of AE - Date of occurrence of AE.

Table 94 Summary of UADEs

UADE	Study group		Control group	
	Number of events	Number of subjects (N=XXX)	Number of events	Number of subjects (N=XXX)
Name of adverse reaction (SOC code)	XXX	XXX(XX.XX%#)	XXX	XXX(XX.XX%)
Name of adverse reaction (PT code)	XXX	XXX(XX.XX%)	XXX	XXX(XX.XX%)
Name of adverse reaction (PT code)				
Name of adverse reaction (SOC code)	XXX	XXX(XX.XX%#)	XXX	XXX(XX.XX%)
Name of adverse reaction (PT code)	XXX	XXX(XX.XX%)	XXX	XXX(XX.XX%)
Name of adverse reaction (PT code)				
……				
……				

Notes: 1. #: Percentage of adverse reactions = Number of subjects suffering from adverse reactions/Total number of subjects in the study group or the control group;

2. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II);

Table 94 Summary of UADEs (continued)

UADE	Study group	Control group	Statistics	P value
Total number of UADEs				
Number of subjects (N miss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Event rate difference (investigation group-control group) and 95%CI			XX.X [XX.X; XX.X]	

Notes: 1. The total number of UADEs refers to the number of subjects suffering from UADE, and the UADE occur in the subject at least one time, which is considered as "Yes".

2. The likelihood ratio Chi-square test or Fisher's exact probability test is used to analyze the intergroup comparison of qualitative indicators;

3. The difference of event rate and 95% confidence interval were analyzed by Wald test with continuous correction;

4. Investigational device: Trochanteric Fixation Nail Advanced (TFNA); control device: Proximal Femoral Nail Antirotation (PFNA-II)