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Application of 3D-printed osteotomy guide in total hip arthroplasty via direct anterior approach

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Registration date 15/06/2026	**Overall study status** Ongoing	
Last Edited 22/06/2026	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
Total Hip Arthroplasty (THA) is the gold standard treatment for end-stage hip diseases such as osteonecrosis of the femoral head and hip osteoarthritis, which can relieve joint pain, restore hip mobility and improve quality of life. The Direct Anterior Approach (DAA) is a minimally invasive technique with advantages of less intraoperative blood loss, faster postoperative recovery and low dislocation rate. However, limited by the small surgical incision and lack of anatomical landmarks for intraoperative reference, femoral neck osteotomy highly rely on surgeons' personal experience, leading to inaccurate osteotomy height, high incidence of leg length discrepancy, and increased risks of prosthesis loosening and periprosthetic fracture.3D printing technology enable patient-specific osteotomy guides designed based on individual femoral proximal CT data, which can precisely locate the osteotomy plane. This prospective controlled study aims to evaluate the clinical value of 3D printed patient-specific osteotomy guides in DAA THA. The primary objective is to verify whether the guide can improve femoral osteotomy accuracy, optimize femoral prosthesis placement and reduce complications. The secondary objective is to compare surgical indicators, postoperative functional recovery and adverse events between guide-assisted surgery and traditional empirical DAA THA, so as to provide clinical evidence for precise minimally invasive DAA total hip arthroplasty.

Who can participate?
Patients aged 18 to 70 years old, diagnosed with ARCO IIIB–IV osteonecrosis of femoral head or hip osteoarthritis, who need primary unilateral DAA total hip arthroplasty. Participants must have no severe dysfunction of heart, lung, liver, kidney or other vital organs to tolerate surgery, with normal mental and cognitive function to complete follow-up examinations and scale assessments voluntarily.
Exclusion criteria include participants with active infection in joints or other body parts, inflammatory arthritis such as rheumatoid arthritis and ankylosing spondylitis, severe osteoporosis or bone tumors, previous ipsilateral hip surgery, neurological diseases causing lower limb motor dysfunction, refusal of 3D printing technology or DAA surgery, as well as pregnant and lactating women.

What does the study involve?
This single center study is carried out at Luoyang Orthopedic-Traumatological Hospital of Henan Province (Henan Provincial Orthopedic Hospital) from June 2026 to June 2027, with a total of 100 eligible participants randomly allocated into two groups at a 1:1 ratio (50 patients in each group).
Before surgery: All enrolled participants will receive routine preoperative examinations including pelvic radiograph, hip axial film, bilateral hip CT, blood routine, liver and kidney function, coagulation function and electrocardiogram. Internal medicine and anesthesiology consultations will be arranged to evaluate physical conditions and adjust underlying diseases. Participants will receive standardized preoperative health education.
Intervention group: Bilateral hip CT DICOM data will be imported into Mimics19 software for 3D reconstruction of proximal femur. A semi-open osteotomy guide with 1.5mm Kirschner wire fixing holes will be customized with the osteotomy plane set 10–15mm above the lesser trochanter. 3D printed femoral model and osteotomy guide will be produced, and in vitro pre-operation simulation will be conducted to adjust the guide before low-temperature plasma sterilization.
Control group: No customized 3D printed osteotomy guide will be produced; femoral osteotomy will rely on surgeons' clinical experience intraoperatively.
All participants will sign written informed consent before random grouping via sealed opaque envelopes generated by independent researchers. Evaluators responsible for imaging and functional scoring will remain blind to group allocation.
Surgery and hospital stay
All operations are performed by the same chief surgeon with standard DAA technique and unified hip prostheses for both groups. Acetabular component implantation follows the same standard (45° abduction, 25° anteversion).
Intervention group: The customized osteotomy guide is fully attached to the proximal femur and fixed with Kirschner wires, and osteotomy is conducted along the guide slot; subsequent femoral canal preparation and prosthesis implantation follow standard procedures.
Control group: Surgeons judge osteotomy position by finger measurement based on intertrochanteric line and femoral neck saddle without guide assistance.
No drainage tube will be placed postoperatively. Prophylactic antibiotics will be used for 48 hours, and low molecular weight heparin combined with venous pump will be applied for venous thrombosis prevention. Standardized staged rehabilitation training will be guided starting 24 hours after surgery, and patients will get out of bed on postoperative day 2 if radiograph shows satisfactory prosthesis position. Analgesics will be used to relieve postoperative pain as needed. Intraoperative blood loss and operation duration will be recorded as core surgical indicators.
After surgery
All participants will attend scheduled follow-up visits with standardized imaging scans and functional assessments up to 9 months postoperatively:
Imaging examinations: Pelvic radiograph and hip axial film at postoperative 1 week, 3 months, 6 months; bilateral hip CT at postoperative 1 week. Researchers will measure osteotomy height difference between actual and preoperative design, leg length discrepancy (LLD) and femoral stem-medullary canal matching grade.
Functional questionnaires and scales: VAS pain score at postoperative day 1 and week 1; Harris hip score and SF-36 quality of life score at baseline, postoperative 1 week, 3 months and 9 months, completed by blind assessors.
Safety monitoring: Vital signs, incision healing, limb neurovascular function, laboratory tests (blood routine, liver and kidney function, coagulation function) and all adverse events (including surgical complications, drug-related reactions) will be fully recorded throughout the whole study period. Serious adverse events will be reported to the institutional ethics committee within 24

hours.
The whole follow-up period will last until 9 months after surgery. All data will be double-entered into electronic database, verified and locked after blind data review for statistical analysis.

What are the possible benefits and risks of participating?
Potential benefits
All participants receive standardized DAA total hip arthroplasty performed by experienced orthopedic surgeons, unified postoperative anti-infection, anticoagulation and rehabilitation protocols, and regular professional follow-up without extra charge for study-related imaging and functional evaluation.
Participants in the intervention group receive free customized 3D printed osteotomy guide, which may achieve more accurate femoral neck osteotomy, reduce leg length discrepancy, improve prosthesis matching and lower long-term complication risks such as prosthesis loosening, thus gaining faster hip functional recovery and better long-term hip function.
Participants' clinical data will provide high-quality evidence for optimizing DAA THA osteotomy technique and popularizing 3D printed personalized surgical guides, which can benefit more hip disease patients in the future.
Participants have the right to withdraw from the study at any time without penalty, and will receive standardized clinical treatment regardless of group allocation.

Potential risks
General surgical and anesthetic risks: All patients receive conventional hip replacement surgery, with inherent risks including anesthetic allergy, intraoperative hemorrhage, surgical site infection, deep vein thrombosis, pulmonary embolism, nerve and vascular injury, prosthesis dislocation, periprosthetic fracture, aseptic loosening, and even rare life-threatening adverse events. Medical staff will strictly follow standardized prevention and treatment procedures to monitor and manage all complications timely.
3D printed osteotomy guide-related risks (intervention group only): Possible poor anatomical fitting, intraoperative guide displacement or manufacturing precision error leading to osteotomy deviation. Preoperative in vitro simulation and intraoperative repeated position verification will be performed to minimize such risks; surgeons will adjust osteotomy plane immediately if guide failure occurs.
Radiation risk from imaging examinations: X-ray and CT scans involve low-dose ionizing radiation within the safe medical exposure range. Lead protective equipment will be provided during scanning to reduce radiation exposure.
Adverse reactions to routine postoperative drugs: Antibiotics, analgesics and anticoagulants may cause gastrointestinal discomfort, skin allergy or transient abnormal laboratory indicators, which will be monitored and intervened timely by clinicians.

Where is the study run from?
Luoyang Orthopedic-Traumatological Hospital of Henan Province (Henan Provincial Orthopedic Hospital), Luoyang, Henan, China

When is the study starting and how long is it expected to run for?
June 2026 to December 2027

Who is funding the study?
Luoyang Guiding Scientific Research Project (Grant No. 2501161B)

Who is the main contact?
Guo Chaowei, Department of Intelligent Orthopedics, Luoyang Orthopedic-Traumatological Hospital of Henan Province,gcwlyzg@126.com

Contact information

Type(s)
Principal investigator

Contact name
Dr Chaowei Guo

Contact details
No. 82 Qiming South Road
Luoyang, Henan Province
China
471000
+86 15237990910
gcwlyzg@126.com

Type(s)
Scientific, Public

Contact name
Prof Yanfeng Tang

Contact details
No. 82 Qiming South Road
Luoyang, Henan Province
China
471000
+86 18939008728
tyflyzg@126.com

Additional identifiers

Study information

Scientific Title
Application of 3D-printed osteotomy guide-assisted femoral osteotomy in total hip arthroplasty via direct anterior approach

Study objectives
To evaluate the clinical efficacy of 3D-printed osteotomy guide-assisted precise femoral osteotomy in direct anterior approach (DAA) total hip arthroplasty (THA), specifically in improving osteotomy accuracy, optimizing femoral prosthesis placement, and reducing the incidence of complications such as postoperative leg length discrepancy.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 12/05/2026, Henan Luoyang Orthopedic-Traumatological Hospital (No. 82 Qiming South Road, Luoyang, Luoyang, Henan Province, 471000, China; +86 037963546811; 13752523307@163.com), ref: 11

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Total hip arthroplasty in patients with osteonecrosis of the femoral head

Interventions
Patients were randomly assigned to either the research group or the control group using a computer-generated randomization sequence to ensure unbiased allocation. The detailed surgical interventions for the two groups are described as follows:

- Experimental Group (DAA approach combined with 3D-printed osteotomy guide plate)
CT scans of the patient’s bilateral hips are performed to obtain DICOM data. Mimics 19 software is used for image processing and three-dimensional reconstruction of the proximal femur. Based on the anterior anatomical contour of the femoral head and neck, the osteotomy plane is determined at 1.0 cm above the lesser trochanter, and an osteotomy guide plate with 1.5 mm Kirschner wire fixation holes is designed. The femoral model and the customized osteotomy guide plate model are manufactured via 3D printing. In vitro preoperative simulated surgery is conducted to evaluate the accuracy and strength of the guide plate. After necessary modifications, the guide plate is sterilized by low-temperature plasma for application.
Surgical procedure: A standard direct anterior approach (DAA) is adopted to establish the surgical access and perform acetabular management. For the femoral side, sufficient release and exposure of the intertrochanteric line of the femoral head and neck are performed. The customized 3D-printed osteotomy guide plate is fully fitted to the osteotomy area of the proximal femur and temporarily fixed with Kirschner wires. The oscillating saw is guided through the groove of the guide plate to perform a precise femoral neck osteotomy. Subsequently, standard procedures including proximal femoral medullary cavity opening and reaming are completed, followed by implantation of appropriately sized femoral stem and femoral head prostheses.

- Control Group (simple DAA approach)
All surgical operations are completed via a standard DAA approach. The acetabular management procedure is identical to that in the experimental group. For femoral neck osteotomy, the surgeon determines the osteotomy position based on clinical experience. The subsequent procedures of femoral prosthesis implantation and joint reduction are consistent with those in the experimental group.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Consistency of femoral osteotomy height, defined as the absolute difference between the actual osteotomy level, measured using postoperative computed tomography (CT) at postoperative day 3 (POD 3)

Key secondary outcome(s)
1. Leg length discrepancy (LLD) measured using digital radiography (DR) at postoperative day 3 (POD 3)

2. Pain measured using a Visual Analog Scale (VAS) pain score at postoperative day 1 (POD 1) and 3 (POD 3)

3. Assessment of the results of total hip arthroplasty (THA) measured using the Harris Hip Score (HHS) at Postoperative day 7 (POD 7) and postoperative 3 months

Completion date
30/06/2028

Eligibility

Key inclusion criteria
1. The diagnostic criteria for osteonecrosis of the femoral head (ARCO stage IIIB-IV) or hip osteoarthritis, requiring primary unilateral total hip arthroplasty
2. No severe functional impairment of vital organs such as the heart, lungs, liver or kidneys, and able to tolerate surgery
3. Normal mental status and good cognitive function, able to cooperate with follow-up and related examinations
4. Voluntarily participate in the study and able to cooperate with follow-up

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
100

Key exclusion criteria
1. Presence of active infection in the joint or other body sites
2. Concomitant inflammatory joint diseases such as rheumatoid arthritis or ankylosing spondylitis
3. Concomitant other severe joint diseases, bone tumors, or severe osteoporosis
4. Previous surgical history of the ipsilateral hip joint
5. Lower limb muscle strength or mobility impairment caused by neurological diseases

Date of first enrolment
01/07/2026

Date of final enrolment
30/06/2027

Locations

Countries of recruitment
China

Sponsor information

Organisation
Luoyang Orthopedic-Traumatological Hospital of Henan Province

ROR
https://ror.org/05br7cm44

Funder(s)

Funder type

Funder Name
Henan Luoyang Orthopedic-Traumatological Hospital

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available