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Combined surgical approach: simultaneous reconstruction of anterior cruciate ligament and anterolateral structures through a modified single femoral tunnel technique

Submission date
27/02/2024

Recruitment status
No longer recruiting

Registration date
06/05/2024

Overall study status
Completed

Last Edited
14/08/2025

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Anterior cruciate ligament (ACL) injury is a very common sports injury. It is reported that there are about 2 million cases of ACL injuries worldwide each year. ACL reconstruction (ACLR) is the main and standard surgery for ACL injury. Despite the development of techniques, grafts, and rehabilitation, 10-30% of patients still have rotational instability after isolated ACLR, increasing the risk of graft rupture, affecting patient movement and delaying patient recovery. The aim of this study is to explore the clinical outcomes of combining ACL reconstruction and anterolateral structure (ALS) reconstruction through a modified single femoral tunnel in patients with a high risk of clinical failure.

Who can participate?
Patients aged under 50 years undergoing ACLR combined with ALS reconstruction from December 2018 to August 2022

What does the study involve?
All procedures were performed by the same experienced surgeon. All patients received similar perioperative management programs. Measurements included function, stability and safety evaluations at different time points (preoperative, postoperative, 3 months, 6 months, 1 year, 2 years, 3 years and more).

What are the possible benefits and risks of participating?
Possible risks of the surgery include deep venous thrombosis, knee joint stiffness, and acute knee infection.

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

When is the study starting and how long is it expected to run for?
June 2017 to December 2022

Who is funding the study?
1. National Natural Science Foundation of China
2. Project of Science and Technology of Henan Province (China)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Meniscus surgical treatment demonstrated inferior clinical outcomes as no meniscus injury with simultaneous combined anterior cruciate ligament and anterolateral structure reconstruction: a case-controlled study

Study objectives
Patients without meniscus injury have superior clinical outcomes. Meniscus repair and partial meniscectomy with simultaneous anterior cruciate ligament (ACL) and anterolateral structure (ALS) reconstruction could result in equivalent clinical outcomes.

Ethics approval required

Ethics approval required

Ethics approval(s)
approved 10/10/2023, Luoyang Orthopedic Hospital of Henan Province (82 Qiming South Road, Luoyang, 621000, China; +86 (0)37963536160; smxwx@163.com), ref: 2023ZXKT005-01

Study design
Retrospective case controlled study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Combined anterior cruciate ligament and anterolateral structure reconstruction

Interventions
From December 2018 to August 2022, a total of 62 patients with ACL injury were enrolled in this study. All patients were associated with a high risk of clinical failure, meeting the indications of ALS augmentation, including 47 males and 15 females, aged 16-52 years with an average age of 29.3 ± 9.2 years. All patients accepted arthroscopic single-bundle ACL reconstruction and ALS reconstruction using hamstring autograft through a modified single femoral tunnel. Perioperative clinical outcome measurements comprised function, stability and safety evaluations at different time points (preoperative, postoperative 3 months, 6 months, 1 year, 2 years, 3 years and more). The functional evaluation included the Lysholm score, Tegner activity scale, and subjective and objective International Knee Documentation Committee (IKDC) score.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Knee-specific symptoms measured using the Lysholm score at preoperative, postoperative 3 months, 6 months, 1 year, 2 years, 3 years and more

Key secondary outcome(s))
1. Sports activity measured using the Tegner activity scale at preoperative, postoperative 3 months, 6 months, 1 year, 2 years, 3 years and more
2. Knee function measured using the subjective and objective International Knee Documentation Committee (IKDC) score at preoperative, postoperative 3 months, 6 months, 1 year, 2 years, 3 years and more

Completion date
30/12/2022

Eligibility

Key inclusion criteria

1. Patients with ACL and ALS reconstruction through single femoral tunnel
2. Aged 16-52 years
3. No history of previous ipsilateral knee injury and surgery

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Upper age limit
52 years

Sex
All

Total final enrolment
62

Key exclusion criteria
1. Multiple ligament injuries
2. ACL rupture associated with fracture
3. ACL revision
4. Significant degree of osteoarthritis (OA) or cartilage damage
5. Skeletally immature or incomplete medical records

Date of first enrolment
01/12/2018

Date of final enrolment
30/08/2022

Locations

Countries of recruitment
China

Study participating centre
Luoyang Orthopedic Hospital of Henan Province
82 Qiming South Road

Luoyang
China
471000

Sponsor information

Organisation
Luoyang Orthopedic-Traumatological Hospital of Henan Province

Funder(s)

Funder type
Government

Funder Name
National Natural Science Foundation of China (82104896)

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, , NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Funder Name
Project of Science and Technology of Henan Province

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Guorui Cao (13688172272@163.com)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/08/2025	14/08/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes