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A study protocol for objectively measuring knee recovery after anterior cruciate ligament reconstruction surgery: a biomechanical assessment technique

Submission date
19/04/2025

Recruitment status
No longer recruiting

Registration date
29/04/2025

Overall study status
Completed

Last Edited
28/04/2025

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Background and study aims
Knee function assessment plays a pivotal role in the management and rehabilitation of patients with anterior cruciate ligament (ACL) injuries, but knee function assessment primarily relies on clinical rating scales, and their reliability is often compromised by inter-individual variability, assessor subjectivity, and dependence on clinical experience. This study protocol aims to explore the application of mechanical quantitative techniques in the postoperative rehabilitation assessment following anterior cruciate ligament reconstruction (ACLR).

Who can participate?
Adult patients with unilateral leg ACL injury, arthroscopic autologous hamstring or patellar tendon ACL reconstruction surgery, with no other ligamentous injuries involved

What does the study involve?
This study involves an objective mechanical quantitative technology evaluation of knee muscle tension in patients after ACLR surgery.

What are the possible benefits and risks of participating?
Objective and quantitative evaluation results of the knee joint can be obtained by participating in this study, and since there are no other intervention means, it is believed that there is no potential risk in this study.

Where is the study run from?
Hunan Provincial Rehabilitation Hospital, China

When is the study starting and how long is it expected to run for?
October 2024 to April 2025

Who is funding the study?
The Research Project of the Hunan Provincial Sports Bureau, China

Who is the main contact?
Dr Zhichun Zhu, lagged@126.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
Research Project of Hunan Provincial Sports Bureau: 2024KT0188

Study information

Scientific Title
Application of mechanical quantitative techniques in postoperative rehabilitation assessment of anterior cruciate ligament reconstruction: a study protocol

Study objectives
This study protocol aims to explore the application of mechanical quantitative techniques in the postoperative rehabilitation assessment following anterior cruciate ligament reconstruction (ACLR). ACL injuries are prevalent among athletes and pose a considerable threat to their careers. While ACLR remains the primary therapeutic intervention for such injuries, the assessment of postoperative rehabilitation still encounters significant challenges. Traditional assessment methods are limited by subjectivity and the absence of quantitative data. Mechanical quantitative techniques present a novel approach, offering objective and precise quantitative metrics for knee functional rehabilitation through the analysis of soft tissue mechanical properties.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 10/10/2024, Ethics Committee of Hunan Provincial Rehabilitation Hospital (No. 31, Yuhua lane, Yuhua District, Changsha City, Hunan Province, 410021, China; -; 524352104@qq.com), ref: -

Study design
Cross-sectional study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Quantitative assessment for muscle tension of the knee after ACLR

Interventions
BRIEF NAME: Mechanical Quantitative Techniques.

WHY: This study protocol aims to explore the application of mechanical quantitative techniques in the postoperative rehabilitation assessment following anterior cruciate ligament reconstruction (ACLR) and provide a scientific measurement tool for muscle tension.

WHAT: Use of a musculoskeletal mechanical quantitative detector (M5) to measure the mechanical quantitative characteristics (shear modulus G) of the subject's rectus femoris and hamstring muscles. And the information about the materials can be found at:https://mp.weixin.qq.com/s/rJmYn8Yu-IFONFiqFXOIfQ.

PROCEDURES: Firstly, clinical data will be collected from patients with anterior cruciate ligament injury to ensure sample diversity and representativeness. Secondly, quantitative measuring equipment is used to measure the knee joint and obtain relevant parameters. Strictly follow the operating procedures to ensure accurate and reliable data. Then, traditional rehabilitation assessment is conducted. Combining biomechanical methods, conducting in-depth data analysis to reveal the quantitative correlation between the degree of knee joint functional recovery and rehabilitation assessment results. Finally, a new clinical evaluation method is proposed and validated through evaluation.

WHO PROVIDED:
a. Doctors: Major in rehabilitation medicine, with more than 10 years of working experience, and received training in medical statistics and ultrasonic testing.
b. physiotherapist: Major in rehabilitation therapy technology, with more than 5 years' working experience, and received relevant training on knee joint function, sports injury rehabilitation.

HOW: The invention is supposed to be delivered face-to-face and will be provided individually.

WHERE: The inventions will occur at the hospital

WHEN AND HOW MUCH: For this research, all participants will be assessed 2 times, and the interval between the two assessments is supposed to be 12- 14 weeks.

TAILORING: This research is an observational study with no tailoring or modifications.

Intervention Type
Not Specified

Primary outcome(s)
Shear modulus of the knee muscle measured using Mechanical Quantitative Techniques at the beginning of the study (t2) and 12- 14 weeks after t2 (t4)

Key secondary outcome(s))
The range of knee motion, knee muscle strength, and knee function measured using traditional assessment methods and theLysholm Knee Scoring Scale at the beginning of the study (t2) and 12- 14 weeks after t2 (t4)

Completion date
05/04/2026

Eligibility

Key inclusion criteria
1. Unilateral leg ACL injury, arthroscopic autologous hamstring or patellar tendon ACL reconstruction surgery, with no other ligamentous injuries involved
2. Swelling of the affected knee joint is grade 0 or 1+
3. Time from injury to surgery is less than 2 months
4. Ages between 18 and 60 years
5. Sign an informed consent form for rehabilitation treatment and actively cooperate with the treatment
6. The treatment plan is approved by the Ethics Committee of the Hunan Provincial Rehabilitation Hospital

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Total final enrolment
72

Key exclusion criteria
1. Concurrent posterior cruciate ligament rupture or meniscal repair
2. Concurrent postoperative complications affecting limb exercise
3. Patients with a history of hip joint trauma
4. Individuals with hypertension, diabetes, or other chronic diseases of organs
5. Individuals with concurrent severe diseases of the heart, brain, kidneys, and hematopoietic system, and patients with mental illnesses
6. Concurrent with any conditions that are detrimental to patient recovery or continuation of the trial

Date of first enrolment
05/04/2025

Date of final enrolment
05/10/2025

Locations

Countries of recruitment
China

Study participating centre
Hunan Provincial Rehabilitation Hospital
No. 31, Yuhua lane, Yuhua District
Changsha City, Hunan Province
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410021

Sponsor information

Organisation
Hunan Sports Bureau

ROR
https://ror.org/01351nn19

Funder(s)

Funder type
Research organisation

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol (other)		08/04/2025	22/04/2025	No	No
Statistical Analysis Plan			28/04/2025	No	No