Anatomic ACL repair:

DB For all or for selected patients?

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- **Study Design:**

  An active-controlled randomized noninferiority study

- **The goal of this study:**

  The goal is to compare the two techniques: single bundle hamstrings versus double bundle hamstrings using the KOOS score Quality of life (QoL) as the primary outcome.

  As secondary outcomes clinical examinations and standing radiographs (Kellgren Lawrence method) after 1,2 and 5 years

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Questions to be answered

- Is there a difference between double-bundle and single-bundle technique in the KOOS score?

- Are there differences between hamstrings single bundle and double bundle technique when the Lachman test and the pivot shift test are being used?

- Is there a difference between hamstrings double-bundle technique and single-bundle technique in return to sports?

- Are there differences between double-bundle technique and single-bundle technique in functional tests (one-leg hop and tre leg side jump)?

- Is there a difference in the development of osteoarthritis between the two techniques?

Patients & Methods

Patients

- **150 patients age 18-40 with an ACL injury will be envelope- randomized in the OR after the injury has been established arthroscopically to either the "double-bundle" or the "single-bundle" technique i.e. 75 patients in each group. The patients will have had a rehabilitation period preoperatively for 4 months prior to inclusion**

Inclusion criteria

- Clinically verified ACL rupture (history, Lachman test 2+ or more with no endpoint; pos pivot shift and arthroscopically verifies), MRI pos.
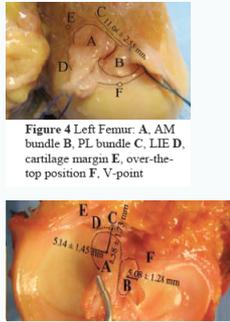
Exclusion criteria

- PCL injury,
- ACL injury to the contra lateral knee
- > 1+ medial or lateral-posterolateral ligament injury,
- previous ACL reconstruction,
- meniscal injury leaving < 50% of the meniscus intact
- established OA as judged by Kellgren 3-4
- Graft size < 6 mm

TABLE I Quantitative Relationships of the Centers of the ACL and the AM and PL Bundles to Landmarks on the Femur

Figure 4 Left Femur: **A**, AM bundle **B**, PL bundle **C**, LIE **D**, cartilage margin **E**, over-the-top position **F**, V-point

Slide 1

Radiographic Landmarks for Tunnel Positioning in Double-Bundle ACL Reconstructions

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Slide 2

A=tubercle of anterior horn of medial meniscus
B=attachment of anterior horn of medial menis
C=anterolateral fossa
D=anteromedial tubercle
E= anteromedial ridge
F= attachment of anterior horn of lateral menis
G= lateral tibial eminence
H=fibrous attachment to posterior horn of later
I=medial tibial eminence
J=attachment of posterior horn of lateral menis
K=retro-eminence ridge

TABLE II Quantitative Relationships of the Centers of the ACL and the AM and PL Bundles to Landmarks on the Tibia

Relationship	Distance* (mm)
Distance of the tibial ACL center to:	
Anteromedial tubercle	10.4 ± 1.9
Anteromedial ridge midpoint	10.5 ± 1.6
Anteromedial-most aspect of anterior horn of lateral meniscus attachment	10.2 ± 1.7
Posteromedial-most aspect of anterior horn of lateral meniscus attachment	8.5 ± 1.6
Posterior horn of lateral meniscus	15.7 ± 1.8
Posterior-most aspect of anterolateral fossa	10.2 ± 1.4
Lateral tibial eminence	11.0 ± 1.4
Retroeminence ridge	13.0 ± 1.4
Lateral plateau cartilage border	11.7 ± 1.6
Medial plateau cartilage border	7.9 ± 1.4
Anterior ACL border	10.9 ± 1.8
Posterior ACL border	9.9 ± 2.3
Distance of the tibial AM bundle center to:	
Anteromedial tubercle	7.1 ± 1.6
Anteromedial ridge midpoint	5.6 ± 1.3
Anteromedial-most aspect of anterior horn of lateral meniscus attachment	8.3 ± 1.9
Posterior-most aspect of anterolateral fossa	14.3 ± 2.0
Lateral tibial eminence	14.1 ± 1.8
Retroeminence ridge	17.8 ± 2.6
Lateral plateau cartilage border	13.6 ± 1.6
Medial plateau cartilage border	8.8 ± 1.5
Anterior ACL border	7.8 ± 1.5
Posterior ACL border	13.9 ± 2.4
PL bundle center	10.1 ± 1.3
ACL center	4.8 ± 1.1
Distance of the tibial PL bundle center to:	
Posteromedial-most aspect of anterior horn of lateral meniscus attachment	6.9 ± 1.7
Posterior horn of lateral meniscus	10.8 ± 2.2
Posterior-most aspect of anterolateral fossa	7.5 ± 1.6
Lateral tibial eminence	8.9 ± 1.3
Retro-eminence ridge	8.4 ± 2.1
Lateral plateau cartilage border	10.3 ± 2.1
Medial plateau cartilage border	8.5 ± 1.5

Slide 3

A=tubercle of anterior horn of medial meniscus.
B=anterolateral fossa
C=anteromedial tubercle
D= anteromedial ridge
E= attachment of anterior horn of lateral meniscus
F= lateral tibial eminence
G=medial tibial eminence
H=retro-eminence ridge

*The values are given as the mean and standard deviation. Anteromedial = AM; Posterolateral = PL

Lateral plateau cartilage border	10.3 ± 2.1
Medial plateau cartilage border	8.5 ± 1.5

Slide 4

Knee laxity:

- **Manual Lachman**, graded as: 0, + (< 5 mm), ++ (5-10 mm) or +++ (> 10 mm) compared to the normal knee

- **KT 1000** arthrometer, using 134 N anterior drawer as well as manual maximum test (MMT)

- **Pivot shift**, graded as: 0, +, ++ or +++ compared to the normal knee

   Range of motion (ROM) measured in flexion and extension using a goniometer

   RSA in a selected group (12) to measure rotations

Slide 5

- **Functional tests:**
  - One leg hop, best of 3 attempts and compared to the normal side
  - Zig-sag test from side to side along a 6 meter parallel line comparing injured and normal side
  - Knee walking test; 4-grade scale; OK, uncomfortable, painful very painful

- **Activity level:** is graded using the Tegner score, 0-4 representing activities in daily life and 5-10 sport at various levels

- **Subjective evaluation:**
  - KOOS score. Best result is 100 points
  - IKDC 2000 (International Knee Documentation Committee)

- **Radiographic follow up:**
  - These will be judges according to the Kellgren-Lawrence scale using a specific standing x-ray technique. The radiographs will be read by a blinded, experienced radiologist

  - MRI dGEMRIC in a subgroup of 12 patients pre and post

Slide 6

1. Sort out referred patients
2. Polyclinic: Inclusion criteria, X-ray, KT1000, consent form, questionnaire (KOOS, IKDC, Tegner-sco
3. 1-2 weeks, Physiotherapist: consent form, answer questions, receive questionnaire, tests
4. Operation: Envelope block randomize after arthroscopi; SB/DB, standardized operation description
5. 1. Year. physiotherapist (blinded): x-ray, tests, questionnarie, KT1000
6. 2. Year, physiotherapist (blinded): x-ray, tests, questionnaire, KT1000

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- **The patients will be followed by the PhD student and the study coordinator. The randomization will start approximately October 1st. The group sees approximately 300 ACL injuries per year, so the inclusion should last approximately 12 months.**

- **The patients will be followed for 12, 24 and 60 months.**

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Conclusion:

At this stage there is not enough evidence to establish firm selection criteria for DB ACL reconstruction