# Soft-Tissue Quadriceps Autograft Anterior Cruciate Ligament Reconstruction in the Skeletally-Immature vs Hamstrings (SQuASH): Feasibility of a Randomized Controlled Trial

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## Introduction

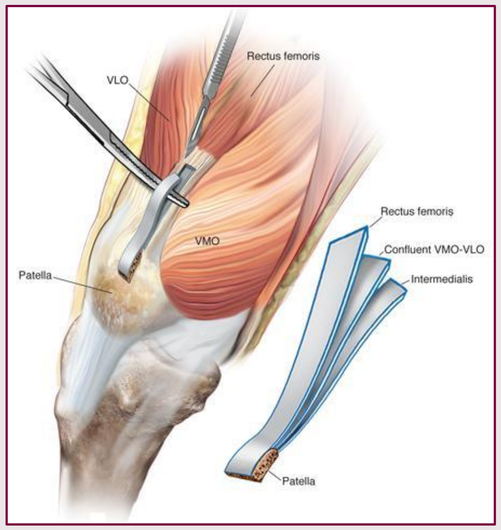
Pediatric anterior cruciate ligament reconstruction (ACLR) is increasing in incidence[1]

Common graft choices for general ACLR include hamstring tendon (HT) and bone-patellar tendon-bone (BPTB) autografts[2]

The International Quadriceps Tendon Interest Group has advocated for the use of the quadriceps tendon (QT) autograft in ACLR[2]

QT autografts have shown low failure rates in the pediatric population as per recent meta-analyses (2.7%), however there is a low level of evidence amongst included studies[3]

This suggests the need for a randomized controlled trial (RCT) investigating this graft choice in the pediatric group




## Purpose

1) This study aims to demonstrate the feasibility of a global randomized controlled clinical trial evaluating the efficacy of soft-tissue quadriceps versus hamstring autograft tendons on re-operation, return-to-sport, and knee function among skeletally-immature, paediatric patients undergoing primary ACL reconstruction.

## Methods

A total 100 patients, aged 10-18 years inclusive, who are skeletally-immature at the time of their injury, and undergoing arthroscopic-assisted, single-bundle primary ACL reconstruction was randomized into two autograft treatment arms: 1) soft-tissue quadriceps or 2) hamstring tendon.

The primary outcome of interest is the rate of re-operation within the first two years post-operatively.

### Site Status Update

| Site Name | Participants Enrolled to Date | Participants Withdrawn | Total Active/Completed Participants | Current Follow-Up Rate |
|---|---|---|---|---|
| Hamilton Health Sciences, Canada | 35 | 1 | 34 | **97%** |
| Shriners Hospital for Children, Canada | 16 | 5 | 11 | **69%** |
| Kobe University, Japan | 15 | 0 | 15 | **100%** |
| CHEO, University of Ottawa, Canada | 14 | 3 | 11 | **79%** |
| Michael Garron Hospital, Canada | 13 | 1 | 12 | **92%** |
| CHU Sainte-Justine, Canada | 7 | 2 | 5 | **71%** |
| **TOTAL:** | 100 | 12 | 88 | **88%** |

| Demographic Results (data based on 97 patients) | |
|---|---|
| **Total Number of Patients** | 97 |
| **Female Sex, N (%)** | 36 (37.1) |
| **Mean (SD) Age** | 14.5 (1.4) |
| **Affected Knee, N (%)** | 44 (45.4) |
| **Playing Sports at Time of Injury?, N (%)** | 87 (89.7) |
| **Mechanism of Injury, N (%)** | |
| Non-traumatic | 13 (13.4) |
| Traumatic, Non-contact | 63 (64.9) |
| Traumatic, Contact | 21 (21.6) |
| **Mean Body Mass Index (BMI), N (%)** | |
| Under Weight < 18.5 | 19 (19.6) |
| Normal weight 18.5 to <25 | 53 (54.6) |
| Overweight 25 to <30 | 14 (14.4) |
| Obese 30 to <40 | 9 (9.3) |
| Morbidly obese >= 40 | 0 (0) |

## Results

| | Total | |
|---|---|---|
| | N | % |
| **Total Enrolled** | **100** | |
| **Active** | 53 | 53.0 |
| **Lost to Follow-up** | 4 | 4.0 |
| **Withdrawn** | **8** | **8.0** |
| Improperly Randomized* | *2* | *2.0* |
| Surgeon revised procedure | *1* | *1.0* |
| Patient declined surgery | *2* | *2.0* |
| Patient declined continuing with the study | *1* | *1.0* |
| Surgery performed at another hospital | *2* | *2.0* |
| **Completed 1-year Follow-up** | 29 | 29.0 |
| **Completed 2-year Follow-up** | 36 | 36.0 |
| **Number of Missed Visits** | 15 | 15.0 |

## Discussion and Conclusion

SQuASH has reached completion of the pilot feasibility trial in terms of recruitment, with an 88% follow-up rate

SQuASH represents one of the largest, international RCTs in the realm of pediatric ACLR, and the first investigating the QT autograft for pediatric patients

SQuASH has demonstrated feasibility as well as safety, justifying the expansion to a definitive trial of 352 patients

SQuASH STUDY

# Disclosures

Darren de SA:
-Pendopharm Speakers Bureau
-International Quadriceps Tendon Interest Group Member
-Magellan Society Member
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