Quadriceps tendon grafts does not cause patients to have inferior subjective outcome after anterior cruciate ligament (ACL) reconstruction than do hamstring grafts: a 2-year prospective randomised controlled trial

Martin Lind, Torsten Grønbech Nielsen, Ole Gade Soerensen, Bjarne Mygind-Klavsen, Peter Faunø

ABSTRACT
Objective We performed a randomised controlled trial (RCT) in patients undergoing ACL reconstruction (ACLR) using either quadriceps tendon graft (QT) or semitendinosus/gracilis hamstring (STG) graft. We compared subjective outcome (primary outcome) and knee stability, donor site morbidity and function (secondary outcomes).

Methods From 2013 to 2015, we included 99 adults with isolated ACL injuries in the RCT. Fifty patients were randomised to QT grafts and 49 to STG grafts and followed for 2 years. Patient evaluated outcomes were performed by subjective International Knee Documentation Committee, Knee Injury and Osteoarthritis Outcome Score, Kujala and Tegner activity scores. Knee laxity was measured with a KT-1000 arthrometer. Donor site morbidity was evaluated by the ‘donor site-related functional problems following ACLR score’. One-leg hop test tested limp strength symmetry.

Results At 2-year follow-up, there was no difference between the two graft groups regarding subjective patient outcome, knee stability and reoperations. Also, at 2 years, donor site symptoms were present in 27% of patients in the QT group and 50% of patients in the STG group. The donor site morbidity score was 14 and 22 for the QT and STG, respectively. Hop test demonstrated lower limp symmetry for QT graft than STG graft of 91% and 97% respectively.

Conclusion QT graft for ACLR did not result in inferior subjective outcome compared with STG graft. However, QT graft was associated with lower donor site morbidity than STG grafts but resulted in more quadriceps muscle strength deficiency than hamstring grafts. Both graft types had similar knee stability outcome.

Trial registration number NCT02173483.

OBJECTIVES
ACLR reconstruction (ACLR) is one of the most commonly performed procedures in orthopaedic sports medicine; however, there are still challenges including donor site morbidity, suboptimal post-operative objective knee stability, unsatisfactory subjective clinical outcomes and osteoarthritis development.1–3 The ACL is primarily reconstructed using one of two autografts: the patellar tendon (PT) or the hamstring tendon (STG). The choice between these two graft types typically depends on physician preference, with an overall predominance of STG autografts in Denmark and Sweden but not in Norway.4–6 The STG predominance is mainly caused by the ease of STG harvest and that PT autograft is associated with anterior knee pain.7,8 The current graft choice paradigm is presently being challenged due to large volume registry studies reporting a higher revision rate with STG autografts than with PT autografts.9,10 Donor site morbidity is associated with both PT and STG autografts. The most common complication of PT autograft harvesting is anterior knee pain and kneeling discomfort, which has been reported in up to 28%–53% of patients compared with 11%–20% for STG graft usage.7,8 However, minimal invasive surgical techniques can reduce donor site morbidity after PT autograft harvest.11 The most common complications of STG autograft harvesting are sensory deficits related to injury to the infrapatellar branches of the saphenous nerve.12 Sensory nerve injury can also cause anterior knee pain.

There has been increased interest in the quadriceps tendon (QT) as an alternative autologous graft source for ACLR.13 The QT graft has a long track record in ACL revision and posterior cruciate ligament (PCL) reconstruction surgery. Good outcome profiles for these indications combined with favourable anatomical and biomechanical properties of greater tendon thickness and strength compared with PT and STG grafts have increased the interest in QT graft usage in primary ACLR surgery. Furthermore, harvesting the hamstring tendons lead to muscular weakening, which could be a cause of ACL graft failure as hamstring function protects against anterior tibial translation, especially during sports activities. Also, a recent RCT demonstrated that ACLR performed with QT autografts had lower donor site morbidity and equivalent clinical outcomes scores compared with ACLR with PT autografts after 2 years follow-up.14 This finding has been supported by a retrospective study by Geib et al reporting no difference in clinical outcomes between PT and QT autografts after intermediate follow-up.15 The present literature on QT autografts for ACLR is limited by small series studies and only one comparative level one study.
No level one study has compared clinical outcome after QT and STG autograft ACLR.

The purpose of the present study was to compare subjective clinical outcomes, donor site morbidity objective knee stability and knee function and after ACLR with QT and STG autografts. We hypothesised that QT autografts would not result in inferior subjective clinical outcomes than STG graft.

**METHODS**

**Study design and approvals**

A prospective randomised controlled clinical trial was conducted at the Division of Sportstrauma, Orthopedic Surgery, Aarhus University Hospital. The study compared clinical outcome after ACLR with either quadriceps graft or hamstring graft with 50 patients randomised to each graft type.

The study was registered at www.clinicaltrials.org and all participants provided written consent.

**Study population**

All patients scheduled for simple isolated ACLR in the period May 2014–January 2016 (Division of Sportstrauma, Orthopedic Surgery, Aarhus University Hospital) were invited to join the study. Inclusion criteria was MRI documented ACL lesion with subjective instability symptoms. Exclusion criteria were: active malignant disease, other knee ligament instability, rheumatoid arthritis, Morbus Bechterew, body mass index >30, current treatment with glucocorticoid drugs or growth hormone and expected inability to complete the standard rehabilitation programme. All ACLR patients followed a standard rehabilitation regiment. The patient randomisation according to Consolidated Standards of Reporting Trials is presented in figure 1.

**Randomisation**

The participants were randomised using concealed numbered envelopes containing either QT or STG-marked pieces of paper. The surgeon opened the envelope just prior to surgery, and informed the patient about graft type after the surgery.

**Surgery**

All surgeries were performed arthroscopically by four experienced ACLR surgeons. Femoral drilling was performed visually by anteromedial portal viewing and drilling. The centre of the drill hole was placed in the anteromedial bundle fibre remnants of the ACL femoral insertion. Tibial drilling was performed by drillguide visually centred in ACL tibial remnant using the lateral meniscus anterior horn as landmark in the sagittal plane.

STG ACLR was performed with four-strand gracilis and semitendinosus graft fixed at the femur with Endobutton CL (Smith&Nephew, Andover, USA) and in the tibia with a 30 mm PEEK interference screw (Smith&Nephew) with a diameter of the four-strand graft.

![Figure 1: Randomisation and patient follow-up characteristics according to Consolidated Standards of Reporting Trials.](http://bjsm.bmj.com/)

Enrollment

Assessed for eligibility n=153

Excluded (n=53)

- Died before participation (n=6)
- Other ligament injury (n=2)
- BMI>30 (n=1)
- Other reasons (n=2)

Randomized (n=100)

Allocated to Hamstring graft (n=50)

- Received allocated intervention (n=49)
- Small patella (n=1)

Allocated to Quadriceps tendon graft (n=50)

- Received allocated intervention (n=50)

Follow-Up 1 year

Lost to follow-up (n=1)

- New ACL injury (n=1)

Follow-Up 2 year

Lost to follow-up (n=1)

- Not appear for FU (n=3)
- New ACL injury (n=1)

Lost to follow-up (n=3)

- Not appear for FU (n=2)
QTG ACLR was performed with 5 mm partial thickness grafts with 70 mm soft tissue graft length and 10 mm width using a special knife-based method (Minimally Invasive Quadriceps Tendon Harvesting System, Karl Storz, Tuttlingen, Germany) and a 20 mm length patella bone block.16 Drillholes were of 9 mm diameter. Femoral fixation was performed with a 25×7 mm titanium interference screw (Arthrex, Naples, USA) and in the tibia with a 30×9 mm PEEK interference screw (Smith & Nephew).

Postoperative rehabilitation
The knee was allowed free range of motion from day 1, followed by isometric quadriceps and passive flexion exercises. Patients were allowed full weight bearing as tolerated by pain and effusion using crutches for first two postoperative weeks. Stationary bike exercises were used from fourth postoperative week and progressive quadriceps strength exercises from sixth week. Running was allowed at 3 months postoperatively, followed by return to cutting actions and contact sports at 12 months postoperatively or later. Rehabilitation was physiotherapist supervised for 3 months and used criterion-based activity progression.

Outcome evaluation
Midpoint assessment was performed 1 year after surgery (objective and subjective outcomes) and the primary outcome was evaluated at 2 years (subjective outcomes only). An independent physiotherapist performed objective knee examinations. Our primary end point was patient-reported subjective clinical outcome using the subjective International Knee Documentation Committee (IKDC) score.17

Secondary end points were the following. Objective knee stability evaluated as maximal sagittal knee translation measured by KT-1000 arthrometer (MEDmetric, San Diego, California, USA), pivot shift test with presentation of patients without a positive pivot shift test postoperatively. Donor site morbidity was evaluated by the ‘donor site-related functional problems following ACLR’ score.19 The score has 16 questions related to donor site morbidity weighted from 0 to 6 with 0 being no morbidity. The 16 scores are aggregated and normalised to 100 so that a score of 0 represents no donor site issues and 100 represents worst response to all questions. As the score was initially validated for PT and STG donor site morbidity, we modified the questions so that PT questions were changed to QT questions. Also, a simple questionnaire addressing whether the patients experience any present hamstring or quadriceps tendon donor site symptoms at 2-year follow-up was used.

The subjective outcome scores were further evaluated by Knee Injury and Osteoarthritis Outcome Score (KOOS)20 and Kujala score.21 Sports-related knee function was evaluated by Tegner activity scale.21 Muscle function was evaluated by one-leg hop test and performance compared with the normal non-operated leg.21

Statistics
The initial sample size calculation was based on non-inferiority power analysis for a continuous parameter. Our primary end point was subjective IKDC score. Our analysis was based on the following assumptions. Based on the literature, IKDC score after ACLR is approximately 80 points with a SD of 12 points. We decided that a more than seven-point lower IKDC score would represent a clinically significant inferior outcome. Based on these assumptions, 37 patients per group would be needed to provide 80% statistical power to detect equality between groups.

### Table 1

<table>
<thead>
<tr>
<th>Patient characteristics of the two graft groups</th>
<th>QT (SD)</th>
<th>STG (SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients (N)</td>
<td>50</td>
<td>49</td>
<td></td>
</tr>
<tr>
<td>Age (mean)</td>
<td>27.2 (6.4)</td>
<td>27.1 (6.1)</td>
<td>0.89</td>
</tr>
<tr>
<td>Male/female (N)</td>
<td>29/21</td>
<td>25/24</td>
<td>0.49</td>
</tr>
<tr>
<td>BMI</td>
<td>24.3 (3.4)</td>
<td>23.8 (2.8)</td>
<td>0.46</td>
</tr>
<tr>
<td>Cause of ACL injury</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sport (N)</td>
<td>43</td>
<td>42</td>
<td>0.97</td>
</tr>
<tr>
<td>Time injury to surgery (months)</td>
<td>14 (19)</td>
<td>12 (14)</td>
<td>0.41</td>
</tr>
<tr>
<td>Meniscus injury (N)</td>
<td>16</td>
<td>18</td>
<td>0.73</td>
</tr>
<tr>
<td>Cartilage injury ICRS &gt;2 (N)</td>
<td>3</td>
<td>1</td>
<td>0.36</td>
</tr>
</tbody>
</table>

BMI, body mass index; ICRS, International Cartilage Repair Society Classification System; QT, quadriceps tendon; STG, hamstring tendon.

An inclusion number of 2×50 patients were decided to account for patient dropouts.

KOOS subscale scores, IKDC score values and Kujala score were compared with Student’s t-test. Donor site morbidity score were not normally distributed and group data were compared with Mann-Whitney U test. Proportions of gender, cause of injury, concomitant injuries were compared with χ² test. P values <0.05 were considered to be statistically significant.

### RESULTS

#### Patient characteristics

Patient characteristics regarding epidemiology and concomitant meniscus and cartilage injuries are presented in table 1. No significant differences between the two groups were found.

#### Subjective and functional clinical outcome

Subjective IKDC, KOOS subscores and Kujala score improved significantly from preoperatively to 1-year and 2-year follow-up in both study groups. No significant differences were found for the QT and STG groups at either 1-year or 2-year follow-up (tables 2 and 3). Regarding functional outcome evaluated by Tegner activity scale, similar findings of significant improvements from preoperatively to 1-year and 2-year follow-up and no significant differences at follow-up time points were found for the QT and STG groups. The Tegner activity scale levels at

<table>
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<tr>
<th>Table 2</th>
<th>Objective and patient-reported outcome at 1-year follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-year follow-up</td>
<td>QT (SD)</td>
</tr>
<tr>
<td>Subjective outcome</td>
<td></td>
</tr>
<tr>
<td>IKDC score, mean (SD)</td>
<td>75 (17)</td>
</tr>
<tr>
<td>KOOS mean (SD)</td>
<td></td>
</tr>
<tr>
<td>Symptoms</td>
<td>82 (16)</td>
</tr>
<tr>
<td>Pain</td>
<td>87 (12)</td>
</tr>
<tr>
<td>ADL</td>
<td>91 (11)</td>
</tr>
<tr>
<td>Sport and recreation</td>
<td>70 (23)</td>
</tr>
<tr>
<td>QOL</td>
<td>60 (18)</td>
</tr>
<tr>
<td>Tegner activity score, mean (SD)</td>
<td>5.5 (1.5)</td>
</tr>
<tr>
<td>Kujala score, mean (SD)</td>
<td>83 (13)</td>
</tr>
<tr>
<td>Donor site morbidity score mean (SD)</td>
<td>18 (17)</td>
</tr>
<tr>
<td>Objective outcome</td>
<td></td>
</tr>
<tr>
<td>Pre-op KT-1000 (mm), mean (SD)</td>
<td>4.9 (2.0)</td>
</tr>
<tr>
<td>KT-1000 (mm), mean (SD)</td>
<td>1.8 (1.0)</td>
</tr>
<tr>
<td>Negative pivot shift test (%)</td>
<td>83</td>
</tr>
<tr>
<td>One-leg hop test % of normal side</td>
<td>91 (13)</td>
</tr>
</tbody>
</table>

ADL, activities of daily living; IKDC, International Knee Documentation Committee; KOOS, Knee Injury and Osteoarthritis Outcome Score; QOL, quality of life.
2-year follow-up were 6.0 and 5.9 for the QT and STG groups, respectively. Knee function and strength symmetry evaluated by one-leg hop test revealed that at 1-year follow-up the QT graft-operated patients had a poorer strength symmetry of 91% hop length compared with normal knee with STG graft-operated patient had a symmetry of 97% (p=0.02) (tables 2 and 3).

Knee stability
No significant differences in knee stability or proportion of negative pivot shift test were found between graft groups. KT-1000 measurements at 1-year follow-up demonstrated a mean side-to-side difference of 1.8 (1.0) mm and 1.9 (1.6) mm in the QT and STG groups, respectively (p=0.67). A negative pivot shift at 1-year follow-up was seen in 83% and 77% of patients in the QT and STG groups, respectively (p=0.34).

Donor site morbidity
At 2-year follow-up, 27% experienced donor site morbidity in the QT group vs 50% in STG group (p<0.04). There was also significantly lower ACL donor site morbidity score for QT graft compared with STG grafts at both 1-year and 2-year follow-up (tables 2 and 3).

Complications and reoperations
One patient in each group had ACL revision within the first 2-year follow-up. For the patient in the QT group, the cause was a new trauma in contact sport 12 months postoperatively resulting in ACL graft lesion and medial collateral ligament (MCL) injury. The patient was revised 17 months after primary surgery with allograft ACL revision and hamstring MCL reconstruction. For the patient in the STG group, the cause was a new trauma in contact sports 11 months postoperatively resulting in ACL graft lesion. The patient was revised 13 months after primary surgery with QT autograft ACL revision.

Both ACL revision patients recovered well after their revision surgery.

Of other reoperations, four patients in QT group had arthroscopic synovectomy due to cyclops scar tissue formation. In the STG group, five patients were reoperated. Three due to cyclops scar tissue formation, one due to new meniscus lesion that was managed by repair and one due to protruding tibial screw that was removed.

DISCUSSION
The primary finding of the present study was, for our primary end point of subjective outcome based on IKDC score, that the QT graft did not have inferior outcome compared with STG graft as IKDC scores were almost similar to 2-year follow-up scores of 82 and 78 for QT and STG grafts, respectively.

Subjective outcome
The finding of similar subjective outcome has been demonstrated in a previous non-randomised study that compared Lysholm and pain scores between QT and STG cohorts and found no differences in these subjective outcomes.24 Lee et al found similar IKDC and Lysholm score when retrospectively comparing QT and double-bundle STG grafts.25 A study comparing QT and patella tendon graft also found similar equal subjective outcomes. The finding of similar clinical outcome in relation to knee stability is similar to a retrospective study by Geib et al who reported no difference in clinical outcomes between PT and QT autografts after intermediate follow-up.26,27 So, the present study and other studies indicate that patient-perceived outcome with QT graft are similar to other autograft types.

Donor site morbidity
For the donor site morbidity, 27% patient in QT graft described any donor site complaint compared with 50% in the STG group. A similar difference of almost 50% lower donor site morbidity score was demonstrated. The high rate of donor site morbidity for STG of 50% is likely caused by the fact that the global score represents any minor as well major complaint for the donor site, whereas previous studies demonstrating 20% donor site morbidity for STG grafts has a higher threshold for which symptoms are considered donor site morbidity.28,29 The finding of a 27% donor site symptoms for QT graft is similar to another RCT of QT graft usage, which reported 34% donor site symptoms.30 Also early postoperative morbidity has been shown to be lower for QT compared with STG grafts.26

There are limited validated instruments for evaluation of donor site morbidity after ACLR. We choose the ‘donor site-related functional problems following ACLR’ score,31 which was validated for STG and patellatendon graft types. The questionnaire was then modified so that questions were corrected towards the QT donor site instead of the patella tendon donor site. Thus, our instrument for this outcome has not been validated. Also, a simple questionnaire asking if there were any symptom from the donor site area was used.

Knee stability and functional outcome
In the present study, a 5 mm partial thickness QT graft was harvested by a novel minimally invasive technique.16 It could the speculated that a partial thickness QT graft could result in inferior ACL stability due to the lower amount of collagen compared with a full-thickness QT graft. We found similar knee stability between the partial thickness QT graft and the four-strand STG grafts indicating that a partial QT graft can result in acceptable knee stability. We found a KT-1000 side-to-side knee stability of 1.8 mm for QT graft. When comparing these stability data with the other randomised QT graft study using full-thickness QT grafts, which found a side-to-side difference of 0.8 mm,14 then this difference in stability could indicate that full-thickness QT grafts results in better knee stability. But a recent review comparing partial with full-thickness QT graft for ACLR have concluded no difference in clinical outcome.27

We found equal improvement in functional outcome from preoperatively to follow-up with Tegner activity score levels reaching around 6.0 at 2-year follow-up for both graft types. However, we did find significant lower 1-year strength symmetry
for the QT group based on one-leg hop test where QT patient has 91% of normal sided strength compared with 97% in STG patients. This finding is to some degree expected, as a QT harvest will have a greater impact on quadriceps muscle function and strength compared with an STG ACLR where the extensor mechanism is left unaffected. This effect has been found in previous biomechanical studies demonstrating a 10% reduction in extensor strength after QT graft ACLR. 28

Regarding complications, we found only one failure in each graft group defined as ACL revision surgery. This corresponds to a 2-year overall revision rate of 2%. These findings correspond well with high patient volume registry data, which also have found 2-year revision rates in the range of 20%. 29 So we did not see an ACL revision failure issue within the study patient cohort.

There are anatomical and biomechanical differences between the QT, PT and STG, which could impact the clinical outcome with QT graft usage. The fibres of the PT and STG are parallel, while the QT is composed of several layers. Most studies describe the QT as a trilaminar structure with the rectus femoris (RF) tendon as the most superficial layer, the vastus medialis oblique (VMO) and vastus lateralis (VL) tendons constituting the middle layer and the vastus intermedius (VI) tendon serving as the deep layer. 30-32 The RF and VL tendons have straight fibres directed towards the patella, whereas the VMO and VL tendons have oblique or crossing fibres. Therefore, the VMO and VL tendons may add volume, but may lack the strength of the straight fibres. However, a biomechanical study Shani et al reporting strength of the QT, PT and STG grafts found a higher strength of the QT compared with both the PT and STG and also that the QT had a cross-sectional area two times greater than that of the PT. 33

The QT graft might be a better graft choice for ACLR than hamstring graft due to its excellent donor site morbidity and otherwise similar knee stability and clinical outcome profiles as shown in the present and previous studies. Further studies are needed with higher patient numbers to establish the revision rates for QT graft usage with different patient profiles such as high-level athletes and young patients which have known higher risk of graft failures.

Strength and limitations
The most important strength of this study is the randomised and controlled study design of which only one previous study investigating QT grafts for ACLR exists. There are limitations of this study. The patients were not blinded to the type of graft used since the incisions revealed the type of graft harvest. Four surgeons performed the ACLR, which could permit subtle variation in the surgical technique despite the surgeons’ efforts to perform identical surgeries. The study is only powered to investigate subjective outcome and knee stability. Other important outcomes such as failure rates (ACLR revision rate) cannot be estimated in the present study due to the low incidence of this complication during the 2-year study period. Future studies with higher patient number such as clinical registry studies are needed to investigate failure risk with QT graft for ACLR.

CONCLUSION
QT graft for ACLR did not result in inferior subjective outcome compared with STG graft. However, QT graft was associated with lower donor site morbidity than STG grafts but resulted in more quadriceps muscle weakness than hamstring grafts. Both graft types had similar knee stability outcome. The QT graft could be a better graft choice for ACLR than ST grafts.

Contributors ML has designed study, operated patients, analysed data and written paper. TGN has included patients, analysed data and written paper. OGS has operated patients and written paper. BM-K has operated patients and written paper. PF has operated patients and written paper.

Funding The study received financial support from Smith and Nephew Inc.

Competing interests ML has performed previous research on QT graft for ACL reconstruction which might bias the presentation of data.

Patient consent for publication Not required.

Ethics approval The study was approved by the Region Midtjylland Scientific Ethical Committee (approval no. 1-10-72-85-14) and by the Danish Data Protection Agency, and was conducted in accordance with the Declaration of Helsinki.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on request.

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