Anterior Cruciate Ligament Reconstruction With or Without Lateral Extra-articular Tenodesis: Functional Outcomes from the ISAKOS Sponsored STABILITY Study

R. McCormack\textsuperscript{4,5}, A. Getgood\textsuperscript{1,2}, C. Hewison\textsuperscript{6}, A. Firth\textsuperscript{1}, D. Bryant\textsuperscript{3}, R. Litchfield\textsuperscript{1,2}, M. Heard\textsuperscript{7}, P. MacDonald\textsuperscript{8,9}, T. Spalding\textsuperscript{10}, P. Verdonk\textsuperscript{11,12}, D. Peterson\textsuperscript{13}, D. Bardana\textsuperscript{14}, A. Rezansoff\textsuperscript{6}, STABILITY Study Group

\textsuperscript{1}Fowler Kennedy Sport Medicine Clinic; \textsuperscript{2}Department of Surgery, Schulich School of Medicine and Dentistry, Western University; \textsuperscript{3}School of Physical Therapy, Western University; \textsuperscript{4}Department of Orthopedics, University of British Columbia; \textsuperscript{5}New West Orthopaedic & Sports Medicine Centre; \textsuperscript{6}Department of Surgery, University of Calgary; \textsuperscript{7}Banff Sport Medicine; \textsuperscript{8}Department of Surgery, University of Manitoba; \textsuperscript{9}Pan Am Clinic; \textsuperscript{10}University Hospital Coventry and Warwickshire NHS Trust; \textsuperscript{11}Department of Physical Medicine and Orthopedics, Ghent University; \textsuperscript{12}Antwerp Orthopedic Center; \textsuperscript{13}Department of Surgery, McMaster University; \textsuperscript{14}Department of Surgery, Queen’s University; \textsuperscript{15}Department of Surgery, University of Calgary; \textsuperscript{16}University of Calgary Sport Medicine Centre.
Disclosures

• **Research Support**
  - Canadian Institute for Health Research (CIHR)
  - Canadian Foundation for Innovation (CFI)
  - ISAKOS/OREF
  - American Orthopedic Society for Sports Medicine (AOSSM)
  - Musculoskeletal Transplant Foundation
  - Arthritis Society
  - Ontario Research Fund
  - Smith & Nephew Inc.
  - Arthrex Inc.
  - Conmed Inc.
  - Depuy Synthes Inc.
  - Eupraxia Inc.
  - SBM Inc.

• **Editorial Board**
  - AJSM Social Media
  - Knee Surgery Sports Traumatology Arthroscopy

• **Consultant**
  - Smith & Nephew Inc.
  - Ossur Inc.
  - Collagen Solutions
  - Joint Restoration Foundation
  - Graymont Equipment Distribution
  - Olympus
Introduction

• Background
  – Anterior cruciate ligament reconstruction (ACLR) is complicated by high failure rates in young, active individuals
  – The addition of a lateral extra-articular tenodesis (LET) to ACLR has been proposed to improve rotational stability and reduce failure rates
  – It is not clear how the addition of a LET to ACLR affects functional recovery

• Purpose
  – To evaluate the effect of single-bundle hamstring tendon ACLR with LET on functional outcomes in young, active individuals at a high risk of re-injury

• Hypothesis
  – ACLR+LET results in better functional outcomes and reduces the risk of persistent rotational laxity compared to single-bundle ACLR alone in patients who are deemed as being at high risk of graft failure
Methods

• **Stability study**
  – A multicenter, randomized controlled trial
  – Conducted from January 2015 to April 2019
  – Young, active patients were randomly assigned to undergo either:

• **Inclusion criteria**
  – ACL deficient knee
  – Skeletally mature but ≤25 years of age
  – ≥2 of the following:
    • Competitive pivoting sport
    • Pivot shift ≥grade 2
    • Generalized ligamentous laxity (Beighton score ≥4)

• **Randomization**
  – Computer-generated in permuted blocks of 2 and 4
  – Web-based in the OR after confirming eligibility with arthroscopy
  – Stratified by surgeon, sex, and presence/absence of a meniscal repair changing rehab
  – Randomly assigned to ACLR alone or ACLR + LET in a 1:1 ratio
Primary outcome measure
- Limb Symmetry Index (LSI)
  - Calculation based on the average of four hop tests (single leg hop, 6m timed hop, triple hop, and crossover hop)

Secondary outcome measures
- Quadriceps Index (QI) and Hamstring Index (HTI)
  - Measured using a computerized isokinetic dynamometer
  - Alternating knee flexion and extension repetitions (3 each) using maximal concentric muscle actions at an angular velocity of 90°/s
- Lower Extremity Functional Scale (LEFS)
  - 20 questions assessing function on a 5-point Likert type scale
  - Overall score ranges from 0 (worst function) to 80 (best function)

Outcome assessment
- Baseline (preoperative) and 6, 12 and 24 months postoperative
Statistical Analysis

- **Sample size calculation**
  - Two-sided, type 1 error rate 5%
  - 80% power to detect a moderate effect size of half a standard deviation
  - Expected approximately 15% attrition
  - A total of 146 patients (72 patients/group) required

- **Statistical tests**
  - LSI
    - Independent t test
  - Isokinetic strength indices (QI and HTI)
    - ANCOVA, baseline strength measurement of uninvolved (non-operative) knee included as a covariate
  - LEFS scores
    - ANCOVA, baseline LEFS score included as a covariate
CONSORT Flow Diagram

Assessed for eligibility (n = 1033)

Excluded (n = 409)
- Declined to participate (n = 48)
- Deemed ineligible at screening (n = 301) or at surgery (n = 51)
- Study recruitment ended prior to surgery (n = 9)

Randomized (n = 624)

Participating in functional assessments (n = 356)

Allocated to ACLR alone (n = 180)

Analysed (n = 173)
- Excluded from analysis (n = 7)
  - Missed assessment (n = 2)
  - Unable to complete strength and hop testing (n = 5)

Analysed (n = 164)
- Excluded from analysis (n = 9)
  - Incomplete LEFS (n = 3)
  - Unable to complete strength and hop testing (n = 6)

Analysed (n = 151)
- Excluded from analysis (n = 13)
  - Unable to complete strength and hop testing (n = 10)
  - Incomplete LEFS (n = 1)
  - Overdue assessment (n = 2)

Allocated to ACLR + LET (n = 176)

Analysed (n = 172)
- Excluded from analysis (n = 4)
  - Missed assessment (n = 1)
  - Unable to complete strength and hop testing (n = 3)

Analysed (n = 164)
- Excluded from analysis (n = 8)
  - Incomplete LEFS (n = 3)
  - Unable to complete strength and hop testing (n = 5)

Analysed (n = 149)
- Excluded from analysis (n = 15)
  - Unable to complete strength and hop testing (n = 7)
  - Incomplete LEFS (n = 4)
  - Overdue assessment (n = 3)
## Results – Patient Demographics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>ACLR alone</th>
<th>ACLR + LET</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex, ( n ) males (%)</td>
<td>79 (45.9)</td>
<td>75 (44.4)</td>
<td>0.77</td>
</tr>
<tr>
<td>Age, years (mean ± SD)</td>
<td>18.7 ± 3.2</td>
<td>19.0 ± 3.1</td>
<td>0.35</td>
</tr>
<tr>
<td>Height, cm (mean ± SD)</td>
<td>167.1 ± 33.1</td>
<td>170.1 ± 20.7</td>
<td>0.33</td>
</tr>
<tr>
<td>Weight, kg (mean ± SD)</td>
<td>71.9 ± 15.4</td>
<td>71.8 ± 14.7</td>
<td>0.98</td>
</tr>
<tr>
<td>BMI, kg/m² (mean ± S)</td>
<td>22.9 ± 5.7</td>
<td>23.8 ± 4.7</td>
<td>0.10</td>
</tr>
<tr>
<td>Beighton score, 0–9 (mean ± SD)</td>
<td>3.2 ± 2.6</td>
<td>3.0 ± 2.8</td>
<td>0.57</td>
</tr>
<tr>
<td>Time from injury to surgery, months (mean ± SD)</td>
<td>7.9 ± 18.8</td>
<td>9.2 ± 16.7</td>
<td>0.38</td>
</tr>
<tr>
<td>Operative limb, ( n ) dominant (%)</td>
<td>95 (55.2)</td>
<td>81 (47.9)</td>
<td>0.18</td>
</tr>
<tr>
<td>Mechanism of injury, ( n ) contact (%)</td>
<td>22 (17.6)</td>
<td>24 (19.8)</td>
<td>0.65</td>
</tr>
<tr>
<td>Sport played at time of injury, ( n ) (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Soccer</td>
<td>47 (28.1)</td>
<td>78 (47.6)</td>
<td></td>
</tr>
<tr>
<td>Football</td>
<td>12 (7.2)</td>
<td>17 (10.4)</td>
<td></td>
</tr>
<tr>
<td>Gymnastics</td>
<td>34 (20.4)</td>
<td>17 (10.4)</td>
<td></td>
</tr>
<tr>
<td>Squash</td>
<td>14 (8.4)</td>
<td>12 (7.3)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>60 (35.9)</td>
<td>40 (24.4)</td>
<td></td>
</tr>
<tr>
<td>Smoking status, ( n ) (%)</td>
<td></td>
<td></td>
<td>0.57</td>
</tr>
<tr>
<td>Current smoker</td>
<td>4 (2.3)</td>
<td>2 (1.2)</td>
<td></td>
</tr>
<tr>
<td>Ex-smoker</td>
<td>11 (6.4)</td>
<td>8 (4.7)</td>
<td></td>
</tr>
<tr>
<td>Non-smoker</td>
<td>157 (91.3)</td>
<td>159 (94.1)</td>
<td></td>
</tr>
<tr>
<td>Graft source, ( n ) (%)</td>
<td></td>
<td></td>
<td>0.54</td>
</tr>
<tr>
<td>Semi-tendinosis and gracilis</td>
<td>166 (96.5)</td>
<td>165 (97.6)</td>
<td></td>
</tr>
<tr>
<td>Semi-tendinosis</td>
<td>6 (3.5)</td>
<td>4 (2.4)</td>
<td></td>
</tr>
<tr>
<td>Graft diameter, mm (mean ± SD)</td>
<td>7.9 ± 0.7</td>
<td>7.8 ± 0.7</td>
<td>0.39</td>
</tr>
<tr>
<td>Meniscal pathology, ( n ) (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medial</td>
<td>76 (44.2)</td>
<td>86 (50.9)</td>
<td>0.22</td>
</tr>
<tr>
<td>Lateral</td>
<td>82 (47.7)</td>
<td>72 (42.6)</td>
<td>0.35</td>
</tr>
<tr>
<td>Both</td>
<td>33 (19.2)</td>
<td>39 (23.1)</td>
<td>0.38</td>
</tr>
<tr>
<td>Change in rehab due to meniscus repair, ( n ) (%)</td>
<td>14 (18.4)</td>
<td>19 (22.1)</td>
<td>0.84</td>
</tr>
<tr>
<td>Chondral defect, ( n ) (%)</td>
<td>30 (17.4)</td>
<td>24 (14.2)</td>
<td>0.41</td>
</tr>
</tbody>
</table>
Results – *LSI*

- No significant differences between groups at 6, 12 or 24 months

<table>
<thead>
<tr>
<th>Time</th>
<th>ACLR alone (mean ± SE)</th>
<th>n</th>
<th>ACLR + LET (mean ± SE)</th>
<th>n</th>
<th>Mean difference (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months</td>
<td>91.0 ± 2.0</td>
<td>129</td>
<td>89.3 ± 2.1</td>
<td>126</td>
<td>1.7 (-4.0 to 7.4)</td>
<td>0.55</td>
</tr>
<tr>
<td>12 months</td>
<td>97.0 ± 0.4</td>
<td>134</td>
<td>96.2 ± 10.8</td>
<td>131</td>
<td>0.8 (-1.3 to 2.8)</td>
<td>0.45</td>
</tr>
<tr>
<td>24 months</td>
<td>98.7 ± 0.7</td>
<td>132</td>
<td>99.3 ± 0.4</td>
<td>131</td>
<td>-0.5 (-2.2 to 1.0)</td>
<td>0.48</td>
</tr>
</tbody>
</table>
Results – *Isokinetic Strength*

- Significant differences in QI peak torque and average power at 6 months favoring ACLR alone → *Potential disruption to vastus lateralis during LET procedure?*
- No differences between groups at subsequent time points

<table>
<thead>
<tr>
<th>Strength measure (%)</th>
<th>ACLR alone (mean ± SE)</th>
<th>ACLR + LET (mean ± SE)</th>
<th>Mean difference* (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>QI peak torque</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>74.9 ± 2.2</td>
<td>75.2 ± 1.8</td>
<td>-0.3 (-5.8 to 5.3)</td>
<td>0.93</td>
</tr>
<tr>
<td>6 months</td>
<td>79.4 ± 1.6</td>
<td>74.3 ± 1.4</td>
<td>5.1 (0.5 to 9.6)</td>
<td><em>0.03</em></td>
</tr>
<tr>
<td>12 months</td>
<td>90.2 ± 1.4</td>
<td>86.9 ± 1.4</td>
<td>3.3 (-0.7 to 7.4)</td>
<td>0.11</td>
</tr>
<tr>
<td>24 months</td>
<td>90.5 ± 1.6</td>
<td>90.9 ± 1.5</td>
<td>-0.4 (-4.8 to 4.0)</td>
<td>0.87</td>
</tr>
<tr>
<td><strong>QI average power</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>76.9 ± 1.8</td>
<td>77.1 ± 1.9</td>
<td>-0.2 (-6.3 to 5.8)</td>
<td>0.94</td>
</tr>
<tr>
<td>6 months</td>
<td>81.0 ± 1.5</td>
<td>75.6 ± 1.5</td>
<td>5.4 (1.2 to 9.6)</td>
<td><em>0.01</em></td>
</tr>
<tr>
<td>12 months</td>
<td>89.9 ± 1.4</td>
<td>87.9 ± 1.4</td>
<td>2.0 (-2.0 to 6.0)</td>
<td>0.32</td>
</tr>
<tr>
<td>24 months</td>
<td>91.0 ± 1.6</td>
<td>90.1 ± 1.6</td>
<td>0.9 (-3.5 to 5.4)</td>
<td>0.60</td>
</tr>
<tr>
<td><strong>HTI peak torque</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>85.6 ± 2.1</td>
<td>82.9 ± 2.1</td>
<td>2.6 (-6.1 to 11.4)</td>
<td>0.55</td>
</tr>
<tr>
<td>6 months</td>
<td>85.2 ± 1.7</td>
<td>82.5 ± 1.7</td>
<td>3.2 (-1.4 to 7.9)</td>
<td>0.17</td>
</tr>
<tr>
<td>12 months</td>
<td>88.1 ± 1.6</td>
<td>86.8 ± 1.6</td>
<td>1.3 (-3.3 to 5.8)</td>
<td>0.59</td>
</tr>
<tr>
<td>24 months</td>
<td>92.0 ± 1.6</td>
<td>90.0 ± 1.5</td>
<td>2.1 (-2.3 to 6.5)</td>
<td>0.35</td>
</tr>
<tr>
<td><strong>HTI average power</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>88.4 ± 7.9</td>
<td>81.3 ± 2.3</td>
<td>7.1 (-9.1 to 23.3)</td>
<td>0.39</td>
</tr>
<tr>
<td>6 months</td>
<td>78.9 ± 1.6</td>
<td>74.4 ± 1.6</td>
<td>4.5 (0.1 to 9.0)</td>
<td>0.05</td>
</tr>
<tr>
<td>12 months</td>
<td>82.5 ± 1.5</td>
<td>81.6 ± 1.5</td>
<td>0.9 (-3.3 to 5.1)</td>
<td>0.68</td>
</tr>
<tr>
<td>24 months</td>
<td>86.8 ± 1.6</td>
<td>85.1 ± 1.6</td>
<td>1.7 (-2.8 to 6.2)</td>
<td>0.45</td>
</tr>
<tr>
<td><strong>HTI/QI ratio (involved)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>56.8 ± 2.0</td>
<td>55.7 ± 1.2</td>
<td>1.2 (-3.4 to 5.8)</td>
<td>0.62</td>
</tr>
<tr>
<td>6 months</td>
<td>55.6 ± 1.4</td>
<td>56.9 ± 1.4</td>
<td>-1.3 (-5.3 to 2.7)</td>
<td>0.53</td>
</tr>
<tr>
<td>12 months</td>
<td>51.1 ± 1.2</td>
<td>53.2 ± 1.2</td>
<td>-2.1 (-5.5 to 1.3)</td>
<td>0.22</td>
</tr>
<tr>
<td>24 months</td>
<td>52.2 ± 1.2</td>
<td>52.0 ± 1.2</td>
<td>0.2 (-3.1 to 3.6)</td>
<td>0.90</td>
</tr>
</tbody>
</table>

*Adjusted for baseline uninvolved limb strength measurement

ACLR, anterior cruciate ligament reconstruction; CI, confidence interval; HTI, hamstring index; QI, quadriceps index; SE, standard error
Results – LEFS Scores

• Significant difference at 6 months favoring ACLR alone
  – Reduced lower limb function at 6 months after ACLR+LET
  – Not a clinically significant difference

• No difference between groups at 12 or 24 months

<table>
<thead>
<tr>
<th>Time</th>
<th>ACLR alone (mean ± SE)</th>
<th>n</th>
<th>ACLR + LET (mean ± SE)</th>
<th>n</th>
<th>Mean difference* (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-op</td>
<td>54.2 ± 1.0</td>
<td>173</td>
<td>54.1 ± 1.0</td>
<td>172</td>
<td>0.08 (-2.7 to 2.8)</td>
<td>0.95</td>
</tr>
<tr>
<td>6 months</td>
<td>70.0 ± 0.8</td>
<td>173</td>
<td>67.6 ± 0.8</td>
<td>172</td>
<td>2.3 (0.2 to 4.5)</td>
<td>0.03</td>
</tr>
<tr>
<td>12 months</td>
<td>72.5 ± 0.9</td>
<td>164</td>
<td>73.3 ± 0.9</td>
<td>164</td>
<td>-0.8 (-3.1 to 1.6)</td>
<td>0.53</td>
</tr>
<tr>
<td>24 months</td>
<td>76.0 ± 0.5</td>
<td>151</td>
<td>75.7 ± 0.5</td>
<td>149</td>
<td>0.3 (-1.2 to 1.8)</td>
<td>0.70</td>
</tr>
</tbody>
</table>

*Adjusted for baseline LEFS score

ACLR, anterior cruciate ligament reconstruction; CI, confidence interval; HTI, hamstring index; QI, quadriceps index; SE, standard error
Conclusion

• Statistically significant differences between the two groups were found at 6 months for QI peak torque and average power as well as the subjective functional score in favor of ACLR alone, all of which normalized by 12 months
  – Unlikely to be clinically significant

• The addition of LET to ACLR suggests a slower rate of lower limb functional recovery with no differences from 12 months onward.

• There were no differences in LSI between the two groups at any time point.

• Indications have to be further defined.
Acknowledgments

Funded by: International Society of Arthroscopy, Knee Surgery and Orthopaedic Sports Medicine (ISAKOS)

FKSMC:
Dr. Alan Getgood
Dr. Robert Litchfield
Dr. Kevin Willits
Dr. Dianne Bryant
RA – Chris Hewison
RA – Nicole Kaniki
RA – Alliya Remtulla
RA – Stacey Wanlin
RA – Andrew Firth
RA – Ryan Pinto
RA – Ashley Martindale
Research Student – Lindsey O’Neill
Research Student – Morgan Jennings
Research Student – Michal Daniluk

Antwerp:
Dr. Peter Verdonk
Dr. Geert Declerq
RA – Kristien Vuylsteke
RA – Mieke Van Haver

Calgary:
Dr. Alex Rezansoff
Dr. Nick Mohtadi
RA – Rhamona Barber
RA – Denise Chan
RA – Caitlin Campbell
RA – Alexandra Garven
RA – Karen Pulsifer
RA – Michelle Mayer

Coventry:
Mr. Tim Spalding
Mr. Pete Thompson
Mr. Andrew Metcalfe
RA – Debra Dunne
RA – Laura Asplin
R&D Director - Ceri Jones
RA – Alisen Dube
RA – Louise Clarkson
RA – Jaclyn Brown
RA – Alison Bolsover
RA – Sarah Verdugo
RA – Kerri McGowan

McMaster:
Dr. Devin Peterson
RA – Nicole Simunovic
RA – Andrew Duong
RA – Ajaykumar Shanmugaraj

Pan Am:
Dr. Peter MacDonald
Dr. Greg Stranges
RA – Sheila Mcrae
RA – LeeAnne Gullett
RA – Holly Brown

Queen’s:
Dr. Davide Bardana
RA – Fiona Howells
PT – Murray Tough
PT - Gurupaul Dutta

FHA:
Dr. Dory Boyer
Dr. Bob McCormack
RA – Mauri Zomar
RA – Karyn Moon

FHA Cont’d:
RA – Raely Moon
RA – Brenda Fan
RA – Bindu Mohan
RA - Kyrsten Payne

Banff:
Dr. Mark Heard
Dr. Greg Buchko
Dr. Laurie Hiemstra
RA – Sarah Kerslake
RA – Jeremy Tynedal