Functional performance testing and return to sport criteria in patients after anterior cruciate ligament injury 12-18 months after index surgery: A cross-sectional observational study

Iris Leister, MSc. 1; Stefan Tino Kulnik, PhD. 2,3; Dr. Harald Kindermann 4; Reinhold Ortmaier, MD 5,6; Jürgen Barthofer, MD 7; Imre Vasvary, MD 8; Klaus Katzensteiner, MD 7; Georg Mattiassich, MD 9,10

1 Institute of Molecular Regenerative Medicine, Spinal Cord Injury and Tissue Regeneration Center Salzburg, Paracelsus Medical University Salzburg, Austria; 2 Department of Health Sciences, FH Campus Wien - University of Applied Sciences, Vienna, Austria; 3 Faculty of Health, Social Care and Education, Kingston University and St George’s, University of London, London, United Kingdom; 4 Department of Marketing and Electronic Business, University of Applied Sciences Upper Austria, Steyr, Austria; 5 Department of Orthopaedic Surgery, Ordensklinikum Linz Barmherzige Schwestern - Teaching Hospital of the Paracelsus Medical University Salzburg, Linz, Austria; 6 Research Unit of Orthopedic Sports Medicine and Injury Prevention, Institute for Sports Medicine, Alpine Medicine and Health Tourism (ISAG), UMIT, Hall in Tirol, Austria; 7 Traumacenter Linz, Teaching Hospital of the Paracelsus Medical University Salzburg, Linz, Austria; 8
Department of Radiology, Paracelsus Medical University, Salzburg, Austria; Ludwig-Boltzmann Institute for Experimental and Clinical Traumatology, Vienna, Austria; Traumacenter Graz, Teaching Hospital of the Medical University Graz, Graz, Austria

Correspondence and reprints requests:
Iris Leister, MSc
Institute of Molecular Regenerative Medicine
Spinal Cord Injury and Tissue Regeneration Center Salzburg
Paracelsus Medical University
Strubergasse 22
5020 Salzburg
Austria
phone: +43 660 4043329

E-mail:
Iris Leister, MSc – iris.leister.pt@gmail.com;
Stefan Tino Kulnik, PhD MRes PT - S.T.Kulnik@sgul.kingston.ac.uk
Dr. Harald Kindermann - harald.kindermann@fh-steyr.at;
Reinhold Ortmaier, MD - r.ortmaier@gmail.com;
Jürgen Barthofer, MD - ordination@barthofer.at;
Imre Vasvary, MD - vasvary@gmx.at;
Klaus Katzensteiner, MD - klaus.katzensteiner@auva.at;
Georg Mattiassich, MD – georg.mattiassich@gmail.com;
Functional performance testing and return to sport criteria in patients after anterior cruciate ligament injury 12-18 months after index surgery: A cross-sectional observational study
Abstract

Objectives: Objective return to sport (RTS) criteria after anterior cruciate ligament (ACL) injury are lacking. Study purposes were (1) to report Limb Symmetry Index (LSI) values achieved in a test battery, (2) to detect how many subjects meet RTS criteria 12-18 months post-operative and (3) to identify whether patient-administered scores predict RTS criteria.

Design: Observer-blinded, cross-sectional observational study.

Setting: Traumacenter Linz, Austria.

Participants: Eighty-eight subjects (48 females; mean(SD) age: 34.73(10.8) years); Twenty-five had undergone ACL repair (IB), 21 ACL reconstruction (AI). Forty-two healthy subjects served as control.

Main Outcome Measures: Participants were evaluated using a single-leg hop test battery. The variable of interest was meeting the RTS criteria by reaching defined cut-off values. Logistic regression was used to investigate the relationship between subjective scores (IKDC, WOMAC, KOOS, Lysholm) and fulfillment of RTS criteria. Additionally, subjective physical activity and anterior knee translation were assessed.
**Results:** Thirty-six percent of IB patients and 28.6% of AI patients met RTS criteria. None of the included scores produced significant odds to predict RTS.

**Conclusions:** Subjective scores, clinical examinations and fulfillment of RTS criteria did not differ significantly between groups. Maximum anterior translation revealed a significant difference ($p=0.009$) in favor of the AI group.
Keywords: Limb Symmetry Index; single-leg hop; return to sport; anterior cruciate ligament injuries
Introduction

Anterior cruciate ligament (ACL) rupture is a common ligamentous injury of the knee joint.\(^1\)\(^-\)\(^3\) ACL reconstruction with either hamstring, quadriceps or patella tendon graft is regarded as the gold standard operative therapy.\(^4\) Although numerous studies demonstrate good outcome after ACL reconstruction \(^5\), a meta-analysis by Biau et al. reported that only 33-41% of patients gain full functional recovery, and only 67-76% return to their pre-injury activity level.\(^6\)

Since the native ACL is considered to be an important factor for proprioceptive sensation \(^7\)\(^-\)\(^9\), its removal during reconstruction might have an influence on muscular stabilization and functional performance. Primary repair of the native ACL could present a treatment option for an appropriately selected subset of patients.\(^10\)

For proximal tears of the anterior cruciate ligament near the femoral attachment the InternalBrace® (IB) method can be performed arthroscopically with the aim to reattach the avulsed femoral end of the ACL to the insertion point using a non-absorbable polyethylene FiberTape® (Arthrex, Naples, FL, USA). Promising results have been presented recently in a study by Eggli et al. using a comparable method, which showed a high rate of return to pre-injury sports level.\(^4\) In another recent study, the FiberTape® served as an internal brace within an allograft, and it has been suggested that the internal brace protects the graft during the revascularization and remodeling process.\(^11\)
review, van Eck et al. concluded that ACL repair with an internal bracing may be a viable option in young patients with acute, proximal ACL tears. To the authors’ knowledge, ACL augmentation with FiberTape® has not been systematically evaluated with respect to functional performance in adults.

The diagnostic battery which is used in this study for testing of functional performance has been evaluated previously in a group of 42 healthy subjects with no history of knee trauma, and data from the healthy population were used to generate minimum reference values as return to sport (RTS) criteria. The integrated fatigue protocol is considered important, as testing in state of muscular fatigue may reveal higher informative value for the evaluation of functional performance. Changes in muscle activation due to fatigue result in higher impact accelerations and fatigue-induced modifications in lower-limb control may increase the risk of noncontact ACL injury. The test battery should facilitate clinical decision making considering RTS release in patients after ACL reconstructive surgery in order to prevent premature RTS which is associated with a high risk of re-injury. We hypothesized that the majority of patients is not ready to reach the healthy cut-off values in the test battery 12-18 months after surgery independent from surgical technique; and that subjective self-administered knee rating scores cannot predict fulfillment of the RTS criteria.
The purpose of this study was to evaluate the functional performance in patients after unilateral ACL injury, comparing a group of individuals after ACL primary repair with the InternalBrace® method (IB) against a group after ACL All-Inside (AI) reconstruction using a hamstring autograft.19,20

Study objectives were (a) to report the Limb Symmetry Index (LSI) values achieved in the functional performance test battery in patients 12-18 months after ACL primary repair or ACL reconstructive surgery; (b) to detect how many of the study subjects meet the RTS criteria according to the minimum reference values for the test battery; and (c) to identify whether subjective self-administered knee rating scores could predict the proposed RTS criteria.
Methods

Design

We conducted an observer-blinded, cross-sectional observational study on a sample of patients who sustained an isolated rupture of the ACL. Two groups of individuals participated in this study who underwent either ACL primary repair with the IB method, or ACL AI reconstructive surgery\textsuperscript{19,20} using a hamstring autograft. A description of the surgical techniques has been provided by Heitmann et al.\textsuperscript{21} A group of healthy subjects served as a control group. Results relating to the control group have been published elsewhere.\textsuperscript{13}

Participants

Inclusion Criteria for the two intervention groups were (1) female and male subjects, (2) age between 16 and 60 years, (3) an isolated tear of the ACL, confirmed on magnetic resonance imaging (MRI) scan, (4) surgical treatment of the IB group within the first three weeks after injury. Exclusion Criteria were (1) any kind of previous injury of hip, knee and ankle joints requiring operative treatment, (2) concomitant injuries such as fractures, articular cartilage lesions reaching subchondral bone or lesions of the collateral ligaments which required an additional surgical intervention (except for partial or complete meniscectomy and meniscal repair), (3) if a post-operative knee brace
was required, (4) if weight bearing was restricted post-operatively to non-weight bearing, (5) pregnant and nursing women, (6) concomitant medication or conditions that interfere with a person's ability to comply with study procedures, (7) existing contraindication against performing an MRI scan, and (8) circumstances that interfere with the participant’s ability to give informed consent.

Participants were recruited from the patient database of the traumacenter Linz. Eligible were all patients who had suffered an isolated unilateral ACL injury and undergone surgery 12-18 months prior. Operation theatre protocols were reviewed to confirm the type of surgery. Participant selection for this study took place after all standard clinical after-care examinations had been completed. None of the questionnaires and clinical tests included in this study had been used in the standard post-operative documentation of these patients. From a total of 72 eligible patients who had undergone IB surgery between July 2014 and August 2015 and were asked to participate in the study via telephone, 27 patients volunteered to participate in the study. Based on this IB group, 23 subjects with AI reconstruction were selected and matched according to sex and age.
Procedures

Clinical evaluation
Study procedures took place between December 2015 and August 2016. IB and AI patients participated in a clinical evaluation, which was prior to the functional performance testing and was conducted by the same physician (GM) for all participants. The clinical testing protocol included several clinical and subjective self-administered scores: the International Knee Documentation Committee (IKDC) Subjective Knee Form, the Western Ontario and McMaster Universities Arthritis Index (WOMAC), the Knee Osteoarthritis Outcome Score (KOOS) and the modified Lysholm-Score by Lysholm and Gillquist, all in their German language version.

An MRI scan of the affected knee included axial, coronal, and parasagittal scans with proton density-weighted sequences with and without fat saturation by a 1.5-Tesla MRI unit (Magnetom VISION; Siemens AG, Erlangen, Germany).

Subjective physical activity
The subjective physical activity level was assessed with the German version of the Tegner Activity Scale (TAS).
Anterior knee translation

The Anterior Drawer Test to measure anterior knee translation in millimeters was assessed with the KT-1000 Knee Ligament Arthrometer® (MEDmetric Corp., San Diego, CA, USA).\textsuperscript{37,38} A side-to-side difference in anterior-posterior translation of three or more millimeters is considered to be indicative of knee joint laxity.\textsuperscript{37–39} An anterior tibial translation of 13.5 millimeter or more is classified as pathologic laxity.\textsuperscript{40}

Limb dominance

For the determination of limb dominance, mode was adopted as an index of central tendency out of the three following tests: First, subjects were asked with which leg they preferred to kick a ball. Second, subjects were asked to step onto a 25cm high platform. Third, subjects were put off balance in standing and the leg used for reaction was observed.

Functional performance testing: Single-leg hop test battery

To assess functional performance, all subjects had to perform a test battery with an integrated fatigue element according to a standardized protocol.\textsuperscript{13} Briefly, this included the following sequence of components: a standardized warm-up (10min stationary cycling, 2x10 squats, 2x10 calf raises, 10 jumps on both legs, 5 unilateral jumps); an isometric strength test of the hamstrings in prone position
in 90 degree knee flexion using a portable dynamometer (Mecmesin Advanced
Force Gauge, Mecmesin, UK); a series of single-leg jump tests: (1) single-leg
hop for distance (SLHD), (2) single-leg 6m timed hop, (3) single-leg triple
crossover hop for distance and (4) side hop test; a fatigue protocol of alternating
squats lunges for the duration of two minutes continuously until maximum
voluntary exertion (i.e. for maximum two minutes, or until the person was unable
to perform further squat lunges); and a fatigued SLHD. A detailed description
including photos of the items of the test battery can be found in the
supplementary material to the authors’ previous publication.\textsuperscript{13}

\textbf{Return to sport criteria}

A subject meets the RTS criteria if he or she reaches the minimum reference
value in both, the LSI and the absolute jumping distances (in fatigued as well as
non-fatigued condition). The 5\textsuperscript{th} percentile of the values achieved by the healthy
control group is considered as the cut-off value. Cut-off values are categorized
by sex and subjective level of physical activity (TAS $\leq 5$ and TAS $>5$).\textsuperscript{13}

\textbf{Blinding and avoiding bias}

To avoid bias, the tests to assess the functional performance in the two
surgically treated groups were conducted observer-blinded. The test battery was
conducted by the same examiner (IL), who did not have access to patient data.
The subjects were asked not to disclose their treatment to the assessor. The KT-1000 measurement was conducted by the physician (GM) prior to the functional performance testing to assure blinding of the examiner (IL) during the functional performance testing.

Subjects were requested to attend the test appointment in long sports pants and sports shoes. Subjects who forgot to bring long pants were given an underwrap tube, which was fixed to the knee with elastic tape to ensure that the examiner (IL) would not be unblinded by noticing surgical scars.

The matched selection of AI patients took place on the basis of sex and age and we were not able to take physical activity into consideration which might represent a selection bias.

Statistical analysis

Sample size determination

The sample size was based on the number of patients treated with the new surgical IB method at the study site, and aiming for sex- and age-matched equal-sized groups. In 2015, 72 patients underwent IB surgery. The number of subjects who underwent AI reconstruction in the traumacenter Linz was 129 in 2015. A total of 92 subjects were enrolled in the study. The control group consisted of 42 healthy subjects with no history of knee trauma. Control participants were recruited to compile reference values for the test battery and to
assure safety of the test battery. Twenty-seven subjects who underwent primary ACL repair and 23 subjects who underwent reconstruction of the ACL were initially included.

**Statistical methods**

**Functional evaluation**

From the component tests of the functional performance battery, all scores were recorded as absolute distance (centimeters) or time (seconds). The LSI was calculated such that the score of the injured limb is expressed as a percentage of the score of the uninjured limb. In the control group, LSI was calculated such that the score of the non-dominant leg is expressed as a percentage of the score of the dominant leg.

LSI values were calculated for each subtest from the mean values of the valid trials (between one and three valid trials depending on the test). An overall LSI was calculated as an average percentage of all subtests. The non-fatigued LSI was calculated as an average of the subtests prior to the fatigue protocol. The non-fatigued LSI and the overall LSI are reported separately to assess whether limb symmetry changes due to muscular fatigue in the study groups. It was hypothesized that muscle fatigue accumulates during the hop testing and the subsequent fatigue protocol.\(^{15}\)
Return to sport criteria

To determine whether a subject met RTS criteria, we compared both LSI and absolute jumping distances with suggested minimum reference values from healthy subjects.\textsuperscript{13}

To identify whether scores from subjective self-administered questionnaires could predict readiness for RTS, a logistic regression model was used to investigate the relationship between different measures of knee function (IKDC, WOMAC, KOOS, KOOS Sport, Lysholm) and fulfillment of RTS criteria (yes/no).

Statistical analysis was performed with SPSS software (version 20.0, IBM). Descriptive statistics, including means and SDs for continuous variables (age, BMI, IKDC subjective score, WOMAC, KOOS, Lysholm, KT 1000, ISO force, LSI) and frequency counts for categorical variables (sex, IKDC pivot shift and IKDC objective score) were calculated. Depending on the variable, chi-square or independent t test were used to determine differences in the subjects’ characteristics for those undergoing ACL primary repair (IB) vs. ACL AI reconstructive surgery. The sample size resulted from the strict inclusion criteria in the IB group.
Results

From the initial 92 subjects that were enrolled in this study, a total of 88 subjects participated in the functional performance test battery. Twenty-seven subjects who underwent primary ACL repair with IB and 23 subjects who underwent AI reconstruction of the ACL were initially included in the study. After two participants dropped out in the IB group (one subject repeatedly did not show up for test appointments and one subject was enrolled by error because of an unknown ACL injury on the contralateral knee), the remaining 25 subjects participated in the functional performance test battery. In the AI group 21 subjects remained after two dropouts (one subject had a re-ruptured ACL according to MRI and one subject presented severe knee pain and the participation was therefore terminated).

Twenty-five subjects (16 females and 9 males) underwent ACL primary repair. Twenty-one subjects (10 females and 11 males) underwent AI reconstruction. Forty-two healthy subjects (22 females and 20 males) served as a control group. The time from injury to surgery ranged from one day to two months (mean=16.04 days, SD=15.1, median=13.55) and was significantly different between the two groups (p<0.001). There were no differences between subjects in the IB and AI group for important demographic variables (Table 1).
Subjective scores and clinical examination

The results of the follow-up examinations show that all measured subjective scores did not differ significantly between groups (Table 2). The same holds true for clinical examinations (Table 3).
Table 3: Clinical results of follow-up evaluation

<table>
<thead>
<tr>
<th>Clinical examination</th>
<th>IB (n=25)</th>
<th>AI (n=21)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IKDC objective score, n</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A=normal</td>
<td>14</td>
<td>13</td>
<td>0.896a</td>
</tr>
<tr>
<td>B=nearly normal</td>
<td>10</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>C=abnormal</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td><strong>IKDC pivot shift, n</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>tibia moves in smooth glide during reduction</td>
<td>13</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>tibia abruptly reduces</td>
<td>10</td>
<td>8</td>
<td>0.389a</td>
</tr>
<tr>
<td>tibia momentarily locks in a subluxed position</td>
<td>2</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

* variables expressed as mean (SD)

a t-test for independent samples
b Mann-Whitney U test

Anterior knee translation

Table 4 shows anterior tibial translation in millimeters. There were no significant differences for the healthy knee between subjects in the IB and AI group. For the injured knee the manual maximum test revealed a significant difference between the surgical groups (p=0.009; 95% CI 0.54-3.57), with mean anterior translation of 9.96mm (SD=2.82) and 7.90mm (SD=2.14) in the IB and AI groups, respectively. Eleven (44%) subjects from the IB group and six (28.6%) subjects from the AI group presented more than three millimeters side-to-side difference in the manual maximum test. Five (20%) subjects in the IB group exceeded the threshold of pathologic laxity of 13.5 millimeters.
Table 4: Results of instrument-based examination of anterior knee translation

<table>
<thead>
<tr>
<th></th>
<th>Healthy side [mm]</th>
<th>IB (n=25)</th>
<th>AI (n=21)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>KT 1000 Anterior Drawer</td>
<td>3.84 (1.80)</td>
<td>3.48 (1.75)</td>
<td>0.492 a</td>
<td></td>
</tr>
<tr>
<td>KT 1000 Compliance Index</td>
<td>5.48 (2.47)</td>
<td>5.00 (2.19)</td>
<td>0.493 a</td>
<td></td>
</tr>
<tr>
<td>KT 1000 Manual Maximum</td>
<td>6.32 (2.48)</td>
<td>6.33 (2.80)</td>
<td>0.986 a</td>
<td></td>
</tr>
<tr>
<td>Injured side [mm]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>KT 1000 Anterior Drawer</td>
<td>5.24 (2.19)</td>
<td>4.52 (1.83)</td>
<td>0.240 a</td>
<td></td>
</tr>
<tr>
<td>KT 1000 Compliance Index</td>
<td>7.32 (2.70)</td>
<td>6.19 (2.46)</td>
<td>0.149 a</td>
<td></td>
</tr>
<tr>
<td>KT 1000 Manual Maximum</td>
<td>9.96 (2.82)</td>
<td>7.90 (2.14)</td>
<td>0.009 a</td>
<td></td>
</tr>
</tbody>
</table>

All variables expressed in millimeters as mean (SD)

*a t-test for independent samples

Hamstring force measurement

Isometric hamstring force was assessed to ascertain to which extent post-operative donor morbidity in consequence of semitendinosus and gracilis tendon harvest affects hamstring force in subjects who underwent ACL reconstruction using a hamstring autograft (AI) when compared to subjects who underwent ACL primary repair (IB). There were no statistically significant differences for isometric hamstring force between the two surgical groups (Table 5), but there was a statistically significant difference for the LSI values of the isometric hamstring strength between the IB and AI group, with mean LSI values of 96.69 (SD=18.06) and 73.67 (SD=17.00), respectively (p<0.001; Table 6).

Table 5: Results of instrument-based examination of isometric hamstring force

<table>
<thead>
<tr>
<th>Isometric force [N]</th>
<th>IB (n=25)</th>
<th>AI (n=21)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy side</td>
<td>125.04 (55.75)</td>
<td>137.52 (56.32)</td>
<td>0.455 a</td>
</tr>
<tr>
<td>Injured side</td>
<td>118.60 (54.23)</td>
<td>99.95 (45.58)</td>
<td>0.219 a</td>
</tr>
</tbody>
</table>

Variables expressed as mean (SD)

*a t-test for independent samples
### Table 6: Results of functional evaluation

<table>
<thead>
<tr>
<th>LSI values [%]</th>
<th>IB (n=25)</th>
<th>AI (n=21)</th>
<th>Controls (n=42)</th>
<th>P (^a)</th>
</tr>
</thead>
<tbody>
<tr>
<td>overall</td>
<td>95.72 (9.60)</td>
<td>87.11 (14.53)</td>
<td>98.83 (4.63)</td>
<td>0.420 (b) (&lt;0.001) (c) (0.010) (d)</td>
</tr>
<tr>
<td>non-fatigued overall</td>
<td>93.09 (8.18)</td>
<td>88.03 (18.38)</td>
<td>97.65 (4.36)</td>
<td>0.226 (b) (0.004) (c) (0.263) (d)</td>
</tr>
<tr>
<td>isometric</td>
<td>96.69 (18.06)</td>
<td>73.67 (17.00)</td>
<td>96.74 (12.06)</td>
<td>1.000 (b) (&lt;0.001) (c) (&lt;0.001) (d)</td>
</tr>
<tr>
<td>SLHD</td>
<td>91.70 (11.05)</td>
<td>88.73 (20.14)</td>
<td>99.40 (5.07)</td>
<td>0.043 (b) (0.005) (c) (0.703) (d)</td>
</tr>
<tr>
<td>6m</td>
<td>99.01 (12.05)</td>
<td>91.20 (13.63)</td>
<td>95.84 (9.28)</td>
<td>0.546 (b) (0.308) (c) (0.072) (d)</td>
</tr>
<tr>
<td>tri</td>
<td>96.51 (12.52)</td>
<td>90.93 (14.01)</td>
<td>100.10 (9.70)</td>
<td>0.477 (b) (0.016) (c) (0.276) (d)</td>
</tr>
<tr>
<td>side hop</td>
<td>82.36 (14.97)</td>
<td>86.26 (19.39)</td>
<td>96.17 (13.66)</td>
<td>0.114 (b) (0.997) (c) (0.230) (d)</td>
</tr>
<tr>
<td>fatigue SLHD</td>
<td>95.67 (15.78)</td>
<td>91.04 (18.42)</td>
<td>102.06 (7.44)</td>
<td>0.176 (b) (0.010) (c) (0.509) (d)</td>
</tr>
</tbody>
</table>

Variables expressed as mean (SD)

\(^a\) ANOVA; Scheffé-Test was used to counteract the problem of multiple comparisons

\(^b\) p-values between IB and controls

\(^c\) p-values between AI and controls

\(^d\) p-values between IB and AI

Overall = mean overall combination of all LSI values in the subtests

Non-fatigued overall = mean LSI of the subtests prior to the fatigue protocol

Isometric = isometric hamstring strength

SLHD = Single-leg hop for distance

6m = Single-leg 6m timed hop

Tri = Single-leg triple crossover hop for distance

Side hop = 30 sec side hop test

Fatigue SLHD = Fatigued single-leg hop for distance

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**Functional performance testing**

The LSI scores are presented in Table 6. The overall LSI score from the diagnostic test battery revealed a significant difference between the two surgical groups (p=0.01) and between AI and the control group (p<0.001).

**Return-to-sport criteria**
Table 7 shows the cut-off values separately for male and female as well as less physically active (TAS ≤5) versus more active (TAS >5) participants.

<table>
<thead>
<tr>
<th></th>
<th>Male</th>
<th>female</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean non-fatigued</td>
<td>Mean fatigued</td>
</tr>
<tr>
<td></td>
<td>SLHD</td>
<td>SLHD</td>
</tr>
<tr>
<td>TAS ≤5</td>
<td>98.00 *</td>
<td>93.50 *</td>
</tr>
<tr>
<td>TAS &gt;5</td>
<td>145.50 *</td>
<td>129.50 *</td>
</tr>
</tbody>
</table>

* variables expressed in centimeters
b variables expressed in percent

Table 8 shows the number of patients per group who fulfilled the RTS criteria. There was no statistically significant difference between the surgical groups (p<0.05).

<table>
<thead>
<tr>
<th></th>
<th>IB</th>
<th>AI</th>
<th>P *</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men (n=20)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>yes</td>
<td>3</td>
<td>5</td>
<td>0.465</td>
</tr>
<tr>
<td>no</td>
<td>6</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Women (n=26)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>yes</td>
<td>6</td>
<td>1</td>
<td>0.139</td>
</tr>
<tr>
<td>no</td>
<td>10</td>
<td>9</td>
<td></td>
</tr>
</tbody>
</table>

* Chi-Square-test

**Relationship between subjective scores and functional knee evaluation**
Odds ratios for meeting the RTS criteria according to the different subjective measures of knee function are presented in Table 9, and these were not statistically significant.

Table 9: Results of logistic regression analyses

<table>
<thead>
<tr>
<th>Subjective measures of knee function</th>
<th>Odds ratio (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>IKDC</td>
<td>1.101 (0.980-1.236)</td>
<td>0.106</td>
</tr>
<tr>
<td>WOMAC</td>
<td>0.959 (0.835-1.101)</td>
<td>0.555</td>
</tr>
<tr>
<td>KOOS overall</td>
<td>1.075 (0.913-1.267)</td>
<td>0.384</td>
</tr>
<tr>
<td>KOOS Sport</td>
<td>0.977 (0.912-1.046)</td>
<td>0.507</td>
</tr>
<tr>
<td>Lysholm</td>
<td>0.931 (0.836-1.037)</td>
<td>0.193</td>
</tr>
</tbody>
</table>
Discussion

**Overall findings**

Among the patients in this study, 9 (36%) of IB patients and 6 (28.6%) of AI patients passed the RTS criteria 12-18 months after surgery. Altogether, only 33% of our study participants achieved the minimum reference values. Men had a slightly higher rate of passing the proposed RTS criteria (33.3% and 45.5% in IB and AI group, respectively) compared to women (37.5% and 10% in IB and AI group, respectively). These findings imply that most subjects in our study group were not eligible for a RTS attempt, despite satisfactory results in the subjective self-administered knee scores which supports our hypothesis. Our findings are consistent with a previous study by Augustsson et al. who concluded that patients are not fully rehabilitated eleven months after ACL reconstruction.\textsuperscript{14} The re-establishment of pre-injury gait patterns takes at least eight months \textsuperscript{41}, while a symmetrical gait is a prerequisite for the attempt to running and pivoting sports. In contrast to our findings, Di Stasi et al. reported 48% of patients passed RTS criteria as early as six months after ACL reconstruction and they concluded returning to sport within the first six months of surgery may place athletes at an increased risk of re-injury.\textsuperscript{42} A return to high demanding pivoting sports would likely be too early for the majority of patients in this study and probably associated with an increased re-injury risk although the surgery was at least 12 months prior.
The most commonly used criterion for RTS release in clinical practice is time from surgery, which is derived from biological healing time and ranges from a few months up to two years.\textsuperscript{43–45} In the literature, re-rupture rates between 5\% and 30\% have been reported after ACL reconstruction.\textsuperscript{18,46,47} A potential cause for such high re-injury rates is a premature RTS attempt.\textsuperscript{17} Grindem et al. reported, that the re-injury rate was significantly reduced by 51\% for each month RTS was delayed until 9 months after surgery and an estimated 84\% lower knee re-injury rate in patients who passed RTS criteria.\textsuperscript{48} A decision based on the post-operative time interval would likely lead to premature RTS release and an increased risk for re-injury.

One notable finding of the present study was that subjective patient-administered knee scores did not appropriately reflect or predict our proposed objective RTS criteria. None of the included knee scores (IKDC, WOMAC, KOOS, KOOS Sport, Lysholm) produced significant odds to predict the RTS criteria. Previous studies have found no or weak relationships between objective measures of knee function and patient-reported knee outcome measurements,\textsuperscript{49–51} and our study provides further evidence to support this. One explanation for this might be that patients overestimate their presumed ligamentous stability.\textsuperscript{51}
**Anterior knee translation**

Except for the manual maximum test, there were no significant differences in anterior knee translation on the surgically treated knee between the IB and AI groups. Although, subjects from the IB group generally present higher values of anterior translation and five subjects from the IB group exceeded the threshold of pathologic laxity of 13.5 millimeters. It should be further investigated which mechanism induces knee laxity in this group of surgically treated patients.

**Hamstring force measurement**

It is acknowledged that assessment of isometric hamstring force in supine position in a 90 degree knee flexion angle is a non-functional measurement. This sub-test was included to ascertain to which extent post-operative donor morbidity due to tendon harvest affects hamstring force. LSI values of the isometric strength test did differ significantly which is considered clinically relevant, as it indicates substantial donor-site morbidity in the AI group. Previous studies have found persisting deficits up to two years after tendon harvesting.52

**LSI (Limb symmetry index):**

The LSI is a frequently reported criterion for assessing whether functional performance is normal or abnormal. The rationale is to ensure that the injured leg reaches acceptable symmetry in order to minimize injury when returning to
sports or strenuous work. 53–58 LSI values between 80% and 95% are considered sufficient for return to pivoting sports after knee injury according to numerous studies,14,53,59–62 although there are some concerns regarding the use of the uninvolved limb as reference for the involved limb. A subject may demonstrate good limb symmetry and yet may not be ready for a return to demanding sports because both extremities are less trained than an average healthy individual’s. Wellsandt et al. stated that the LSI overestimates knee function six months after ACL reconstruction, which may be related to the risk of a secondary ACL injury.63

The overall LSI score from the test battery revealed a significant difference between the two surgical groups and between AI and reference values from a healthy control group. LSI values did not differ significantly between IB and AI in the subtests of the test battery, except for the isometric hamstring force measurement discussed above. The subtests alone were not consistently able to discriminate between healthy reference values and the surgically treated subjects. In accordance with previous studies it is therefore strongly suggested to use a battery of functional tests instead of single tests when it comes to the decision release a patient to unrestricted sports.14

**Study Limitations**

For the present study, it was not possible to ascertain how much physical rehabilitation and what type of rehabilitation subjects had undergone. In Austria,
there is no strictly prescribed clinical pathway following ACL surgery, and it is
difficult to ascertain in how far existing rehabilitation guidelines are used in
practice. Both study groups were similar in that they were given the same
opportunities to attend physiotherapy at the study site during the first weeks
after surgery. After that period, patients had to manage their rehabilitation on
their own. It is therefore acknowledged that the type and amount of prior
rehabilitation in this sample could vary considerably.

**Strengths and weaknesses in relation to other studies**

A specific standardized knee rehabilitation program for patients after ACL
surgery would be desirable. But since there is no clearly defined clinical
pathway, the authors decided not to manipulate the rehabilitation process. In this
respect, the sample in this study is representative of usual clinical practice at the
study site, and data reflect how the “normal” population after an ACL injury could
be expected to perform in these diagnostic test. An advantage of the test battery
employed in this study is that no special equipment is needed and it is therefore
an inexpensive assessment tool and convenient to perform in most outpatient
settings. We acknowledge that our results are not representative for professional
athletes, who are in superior physical condition and whose surgical and
therapeutic framework is not comparable to the average population. Our findings
therefore relate to patients post ACL surgery who are not engaged in
professional sports, and these represent the majority of patients with varying
levels of physical activity.

Conclusions

The majority of patients (67%) in our study did not meet the proposed RTS
criteria 12-18 months after surgery. Subjective knee scores, clinical
examinations and fulfillment of RTS criteria did not differ significantly between
surgical groups. The maximum anterior tibial translation revealed a significant
difference between the surgical groups (p=0.009) in favor for the AI group.
Subjective self-administered knee scores did not predict fulfillment of RTS
criteria in subjects who underwent either ACL reconstructive surgery or ACL
primary repair.
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Conflicts of interest

None declared.

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Clinical trial registration

The study was registered on the ClinicalTrials.gov database (unique identifier: NCT02760589).
Ethical Approval

All procedures performed in this study were in accordance with the ethical standards of the institutional and national research committee, and with the 1964 Helsinki declaration and its later amendments. All participants provided written, informed consent. The study was approved by the ethics committee of the Austrian social insurance for occupational risks (AUVA) (Vote No. 7/2015).
Highlights

A premature return-to-sport attempt might contribute to re-injury of the knee.

Knee scores did not produce significant odds to predict return-to-sport criteria.

Functional testing is recommended before return-to-sport.