BMJ Open

Criteria for Return to Sport after Anterior Cruciate Ligament reconstruction with lower reinjury risk (CR'STAL study): protocol for a prospective observational study in France

Alexandre J M Rambaud,[1,2] Bertrand Semay,[1,3] Pierre Samozino,[4] Jean-Benoît Morin,[5] Rodolphe Testa,[1] Rémi Philippot,[1,3] Jérémy Rossi,[1] Pascal Edouard[1,6]

CrossMark

For numbered affiliations see end of article.

Correspondence to
Alexandre J M Rambaud;
alexandre.rambaud.kine@gmail.
com

ABSTRACT

Introduction The decision regarding when to return to sport after an anterior cruciate ligament reconstruction (ACLR) is an important one. Using a variety of subjective and objective parameters, various attempts have been made to determine an optimal timeline for a return to sport after ACLR, but none have been validated. The aim of the present study is therefore to determine which criteria or combination of criteria could allow to return to sport with the lowest possible risk of reinjury.

Methods and analysis This study is a prospective cohort, single-centre study, with repeated assessments at 6, 9 and 12 months post-ACL surgical reconstruction and including a 3-year follow-up of patients' sporting activity and reinjuries. 275 patients will be included to test explanatory variables. Postural control analysis, knee laxity, questionnaires (International Knee Documentation Committee (IKDC), Tampa Scale of Kinesiophobia-11 (TSK-11), Anterior Cruciate Ligament—Return to Sport After Reinjury (ACL-RSI) and Single Assessment Numeric Evaluation (SANE)), modified Star Excursion Balance Test, running and sprinting biomechanics, Hop Tests and Isokinetic Tests will all be used. The primary outcome will be any reinjury during the follow-up period, defined as a graft rupture, a contralateral ACL rupture or any injury necessitating an interruption of training and requiring a medical consultation. Two groups will be constituted during the follow-up, separating reinjured from non-reinjured patients. In addition, classic analysis and data mining approaches will be used to build predictive models.

Ethics and dissemination The results of this study will be disseminated through peer-reviewed publications and scientific presentations. Ethical approval was obtained through the ethics committee of the University Hospital of Saint-Etienne (reference number IRBN522015/CHUSTE).

Strengths and limitations of this study

► This is the first study to associate the analysis of several parameters (both habitual and innovative, considered both singly and in combination) with an exploratory data analysis (data mining), to formulate the best decision-making model for determining the optimal time for a return to sport after anterior cruciate ligament reconstruction (ACLR).

► This study has been designed to include evaluations at 6, 9 and 12 months post-ACLR in order to include and analyse data from the usual time when athletes return to pivot-sport training (6–9 months) and the time when they can return to competition (generally 9–12 months).

► The study includes only young competitive athletes, which is the population with the highest risk of reinjury and with the highest chance to return to sport at the preinjury level. These findings would not necessarily be applicable to the general population.

► This screening protocol seeks to assess elements involved in the return to sport after ACLR with knee-specific and task-specific objective measurements associated with subjective assessment of knee function and psychometric capabilities.

► The design and objectives of this study will require a significant number of patients, but since this population is highly motivated to return to sport, we are convinced that this choice will limit dropouts.

INTRODUCTION

Anterior cruciate ligament (ACL) tears represent a public health challenge[1] with an incidence reported as 60–71 per 100 000 subjects.[2 3] ACL tears often give rise to problems like post-traumatic osteoarthritis, which could lead to middle-term and long-term problems for the patient, a potential increase in knee surgery in the future and consequently a significant cost to society. In this context, appropriate treatment of ACL tears

and secondary and tertiary prevention among young pivot-shift athletes represent very relevant challenges and a major orientation for orthopaedics and sports medicine research.[1]

After an injury, and especially ACL tear, one of the most frequent questions asked by the patient is: "when can I get back to my sport?". ACL reconstruction (ACLR) is the current clinical standard[4] for patients with an ACL tear and considered to be at a high risk of knee instability (young, high-level athletes in a pivoting and/or contact sport). After surgical reconstruction, a rehabilitation programme is set up to allow patients to return to a painless and fully functional daily life.[5–9] In patients aiming to return to sport (RTS), the rehabilitation programme must continue until this is possible.

To consider an ACLR successful,[10] the patient should be able to return to the same level of sporting activity as before the injury. Moreover, a recent patient satisfaction survey[11] confirms that a patient who can resume his sporting activity is more likely to be satisfied with the outcome of the ACLR. However, in their updated review, Ardern et al[12] had shown that on average 80% of patients returned to sport, while only 55% returned to competitive levels after ACLR. These mitigated results highlight the fact that the RTS represents an important challenge after ACLR and that current practices should be improved in this aim.

After ACLR, rehabilitation should be optimal to allow athletes RTS and the decision of when RTS is an important one for patient satisfaction and challenging in the context of secondary and tertiary prevention. Indeed, the more the delay in time to RTS, the poorer the patient motivation and their psychological readiness, decreasing as well their chance to RTS at the same level, but on the other hand, an early RTS exposes the patient to a high risk of reinjury.[13–17] RTS, especially with pivoting or contact sports, exposes the athlete to a risk of reinjury: Wiggins et al,[18] in a systematic review and meta-analysis, had found 15% of second ACL reinjury rate, with 7% for the ipsilateral ACL and 8% for the contralateral reinjury rate. Moreover, in the subgroup of younger patient who wanted to RTS, the secondary ACL injury rate was 23%. A new injury after an ACLR could nonetheless be another musculoskeletal injury,[19] as well it could affect the joint (rupture of the graft or contralateral ACL, chondral and/or meniscal lesion). Indeed, a history of an ACLR is a risk factor for developing a repeat hamstring strain,[20] hindering RTS and the future practice of sport. Thus, the decision of when RTS is a challenging decision, in order to optimise the chance to RTS at the preinjury level, and in a health protection perspective to minimise the risk of reinjury.

Many factors have been implicated in reinjury risk, including sex,[7 21 22] age,[7 23–25] activity level,[26 27] graft placement,[28–30] graft type,[31–35] time from surgery[32 34] and deficits in neuromuscular and biomechanical control of the lower limb.[36] Considering those risk factors, clinical studies used many techniques and criteria to determine the optimal

moment for a RTS after ACLR.[13 16 37–39] The most used is the postoperative timeline, either alone or with muscle strength, knee laxity, knee assessment form or functional tests. However, to the best of our knowledge, there are no clearly validated criteria for determining a safe RTS after ACLR. This decision is currently based on multiple criteria[13 37 38] mostly using the postoperative time frame needed for the biological integration of the graft.[40 41] It seems, according to a recent publication,[16] that a delayed RTS from 6 months after surgery to 9 months after surgery decreased the risk of reinjury by 51% each month RTS is delayed. However, time criteria alone was not sufficient in determining readiness for a safe RTS; Grindem et al thus recommended the uses of both time-based and functional RTS criteria.[16] Barber-Westin and Noyes,[13] in a systematic review, described how this decision is associated with subjective parameters ('satisfactory clinical examination', 'stable knee', 'normal joint function', self-reported knee function (subjective International Knee Documentation Committee (IKDC)[42]) and that only 10% of the included studies used objective criteria, such as, muscular strength, knee laxity, the Limb Symmetry Index (LSI) or functional tests (Hop Tests, Star Excursion Balance Test). Kyritsis et al[39] had also evaluated a set of objective criteria (muscle strength and functional tests) with 158 male professional athletes. Those who did not meet the criteria (quadriceps deficit <10% at 60°/s, LSI for each Hop Tests >90%, running t-test <11 s) had four times greater risk of graft reinjury, and hamstring to quadriceps ratio deficits were associated with an increased risk of ACL rerupture. Among the objective criteria, testing isokinetic muscular strength is a clear measure of strength recovery[16 39 43 44] and seems to be central in objective assessment of a readiness to RTS.[16 39] Moreover, contextual factors such as a positive attitude and fear of injury have not been assessed either in these studies or in the literature as predictors of reinjury although it is well known that these factors influence the capacity to RTS, especially at the same level of participation.[45 46]

In addition, evaluation of lower limb function, close to sport tasks, could also give important information to allow RTS.[47] Kyritsis et al[39] have recently associated classical functional tests and 'running t-test' to evaluate agility and performance, but analysis of running or sprinting pattern has not been performed. Mazet et al[48] have analysed running patterns in patients with ACLR and reported that biomechanical stiffness, calculated using time of flight and contact time, was significantly greater on the operated limb than on the healthy limb or in healthy patients. Using a non-motorised treadmill fitted with force sensors, Brown and Brughelli[49] evaluated the sprint of a rugby player after ACLR during the period of RTS (between the return to training and competition). An asymmetry of the ground reaction force (GRF) persisted (horizontal force, 13%; vertical force, 7%) while the isokinetic muscular strength testing result appeared normal. They concluded that an evaluation of sprint mechanics complemented the usual functional assessments. This analysis, in line
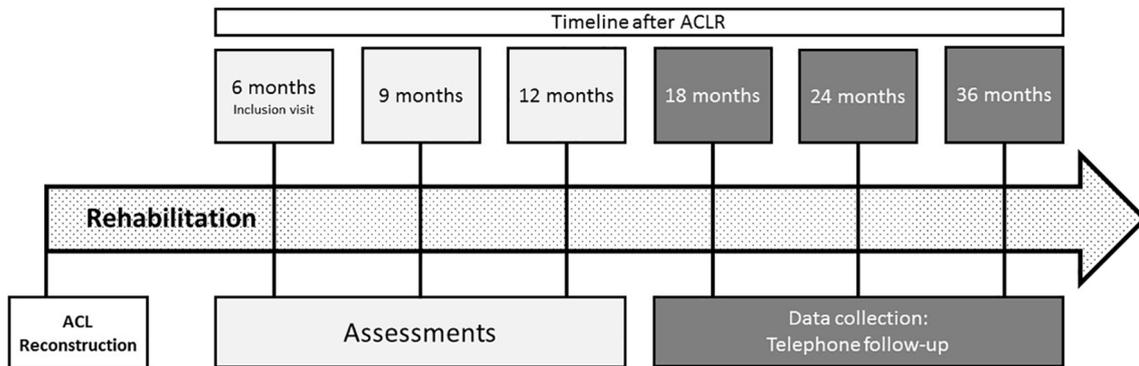
Figure 1 The study design. ACLR, anterior cruciate ligament reconstruction.

with sports reality,[50] could detect an asymmetry during the RTS phase (6–12 months). This sport-specific assessment seems very relevant to the decision to RTS; indeed, a good gait with efficient biomechanical performance in the sagittal plan is an essential step for a return to pivoting/cutting sports.

In this context, the determination of an association of criteria to help in the decision-making process regarding RTS with the lowest risk of reinjury or associated lesions (muscles or ligaments of the lower limbs) is of major interest in the management of patients with ACLR who want to return to a competitive pivoting sport. Thus, the aim of the present study is therefore to determine which criteria or combination of criteria could allow to RTS with the lowest possible risk of reinjury.

METHODS

The present study is a prospective cohort single-centre study, with repeated measures at 6, 9 and 12 months postoperatively after an ACLR and follow-up of the RTS and reinjury for 3 years after the ACLR. The research started in January 2015 and is due to be completed in December 2020. The study design is shown in figure 1.

Study patients

Potential patients will be drawn consecutively from along the patients of the sports medicine unit or the orthopaedic surgery and traumatology department of the local university hospital. Patients included in the study must meet the criteria for inclusion/exclusion shown in table 1. All study patients will undergo postsurgical rehabilitation in the same physiotherapy clinic using the protocol recommended in the literature[8 9 51] (for more information about the protocol, please see online supplementary appendix ACL Reconstruction Rehabilitation Protocol).

Assessment procedure

All tests will be performed in the same place, and all patients will be tested at the same time of day between 2 pm and 6 pm. Forty-eight hours before each evaluation session, patients will receive an email reminding them of the test procedure and asking them to complete a subjective questionnaire online (IKDC, Tampa Scale of Kinesiophobia-11 (TSK11), Anterior Cruciate Ligament-Return to Sport After Reinjury (ACL-RSI) and Single Assessment Numeric Evaluation (SANE)).

Table 1 Inclusion and exclusion criteria for patients	
Inclusion criteria	**Exclusion criteria**

► Participation in pivot and/or contact sports and with intensive sporting activity before the anterior cruciate ligament (ACL) tear:
► with a Marx Scale score above 11 before the injury
► with a Tegner score above 6 before the injury (competition training with more than three training sessions per week before the injury)
► Unilateral tear
	► Bilateral lower limb pathologies
	► Recurrence of ACL rupture (with a MRI diagnostic)
	   ► Contraindications for carrying out a test, that is : Postoperative time less than 6 months
	   ► Persistence of knee pain (score >3 at Numeric Pain Rating Scale)
	   ► Persistence of a joint effusion (positive patellar tap test)
	   ► Incomplete range of motion (range of motion <90% on contralateral side)
	   ► Abnormal walk (observable gait deviations during the walk)
	► Allografts
	► Skeletal immaturity
	► Older than 35 years

Informed consent will be obtained from all patients before testing begins and a standardised explanation of the assessment procedure given to the patients. Each test session will include, in the same order, a medical check-up, postural control analysis, knee laxity measurements, a modified Star Excursion Balance Test, biomechanical running and sprint analysis, Hop Tests and Isokinetic Tests, with a 5 min rest between each test. Before the biomechanical analysis begins, patients will warm up with 10 min of cycling to raise muscle temperature. A specific warm up activity will be included before each new activity. The isokinetic evaluation is at the end of the battery to avoid tiredness affecting the results of the other tests.

Evaluation of subjective parameters by questionnaires

The first questionnaire is the IKDC, an algofunctional questionnaire commonly used for ACLR follow-up.[52 53] An IKDC within the 15th percentile of healthy patients is considered as criteria for a RTS.[42 54 55] The patient will then complete the TSK11. This questionnaire, containing 11 questions (choice between five answers), is used to estimate a patient's fear of movement and reinjury giving a score from 11 to 55.[56–58] A score below 20 indicates low pain avoidance and could also allow a RTS.[59] The last questionnaire the patient is asked to complete is the ACL-RSI. This 12-item scale measures three specific psychological constructs—emotions, confidence in performance and risk appraisal—on a scale from 0 to 100. This scale is a predictive parameter for a successful RTS after ACLR.[55]

The patient will also be asked to estimate his knee recovery on a scale (from 0 to 100) with a SANE.[53 60]

Medical check-up

First, we will check if the online questionnaires have been done, and the presence of inclusion criteria and absence of exclusion criteria. The assessor will fill out the demographic information in the observation book (sex, age, weight, height, sport, training frequency and Marx's score before the ACL tear), a timeline for a return to running, sport-specific training and competitive play where possible, and finally, the ACLR surgeon and technique used. The clinical examination will follow the IKDC-2000 grid.[52]

Postural control analysis

A WinPosturo (Medicapteurs, Balma, France) stabilometry platform will be used with the WinPosture software (Medicapteurs, Balma, France) to determine variations in the centre of pressure (CoP). The force plate, which measures 530×460×35 mm has three pressure gauges (hysteresis <0.2%), with a sensitivity of 90 points per Newton. The sampling frequency will be fixed at 40 Hz with the platform recalibrated before each session. The assessment will be conducted in an isolated room, in a noise-free environment, with a hard, flat floor, following the recommendations of the American Academy of Neurology[61] and the study of Ruhe et al.[62] The standardised position of the feet will be oriented 15° laterally
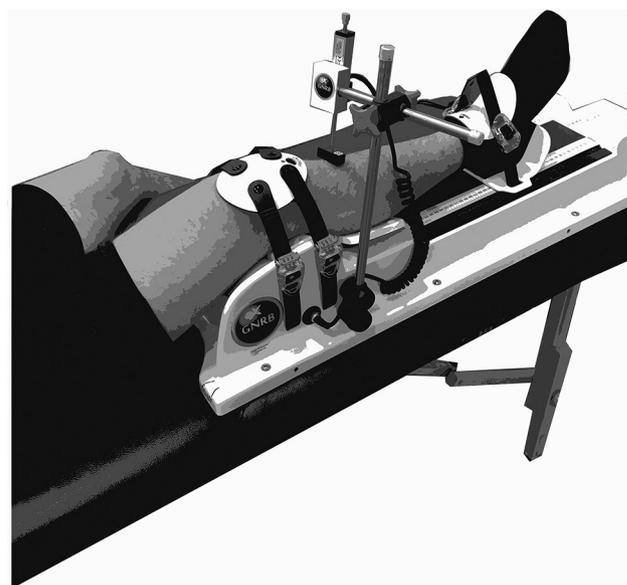

Figure 2 Knee laxity measurement position and the GNRB system.

to the sagittal plane. The patient will have to breathe normally and stare at a point 1.5 m in front him, at eye level, the arms relaxed along the body. The patient will be in sportswear and socks.

Four measurements, knees in extension, separated by 30 s of recovery in a sitting position, will be performed:
► Bipedal position, eyes open (60 s)
► Bipedal position, eyes closed (60 s)
► Single-leg squat followed by balancing on the healthy leg (30 s), eyes open[17]
► Single-leg squat followed by balancing on the operated leg, eyes open (30 s)[17]

The values of total CoP path (CoP in mm), CoP velocity (in mm/s), SD of CoP (SDx and SDY) and CoP sway area (in mm^2) will be recorded. Kouvelioti et al showed good or excellent reproducibility of all these variables using a similar assessment protocol (intraclass correlation coefficient (ICC) range from 0.68 to 0.91).[63]

Knee laxity measurements

The GNRB system (Genourob, Laval, France) is a non-invasive arthrometer that provides comparative bilateral measurements of knee laxity. This system is reliable and reproducible (ICC range from 0.77 to 0.91).[64–66] The patient will lie on a standard examination table in the supine position, with the knee at 20° flexion and 0° of rotation (figure 2). The lower limb is immobilised in a thermoformed shell, adaptable for different leg lengths, at the patella and the foot with a force of about 65±5 N controlled by a force sensor with a precision of 0.1 mm. The analysis will begin with the healthy leg, with a push to 134 N and three pushes to 250 N. The same procedure is then repeated on the operated limb. The displacement of the anterior tibial tubercle relative to the femur is measured. The drawer shift/pressure curve is determined by the displacement (with 0.1 mm precision) and

the slope of the curve (Slp in degree) which defines ligamentous laxity. The push to 250 N with the largest displacement (D_{ap} in mm) and Slp will be retained. The difference between the operated and healthy limb will be calculated for D_{ap} and Slp.

Modified Star Excursion Balance Test

The patient, shoeless, will be asked to stand on one leg, starting with the healthy limb, without lifting the heel and with hands on hips and perform the following exercise as described in the literature[67–69]: to reach maximally to touch a point as far as possible in three directions, along (1) an anteroposterior axis (2) the posterolateral axis and, finally, (3) the posteromedial axis, returning to the initial position between each movement. Two attempts and two measurements will be made for each direction. The longest distance (in cm) will be noted for each direction. The reliability is high with ICC from 0.83 to 0.96.[70]

Running and sprinting mechanics

Patients will choose either a cycle ergometer and/ or jogging for a 10–15 general warm-up, followed by a specific sprint warm-up including sprint drills and short sprints. On a motorised instrumented treadmill (ADAL3D-WR; Medical Development, HEF Tecmachine, Andrezieux-Boutheon, France), with four piezoelectric force transducers (KI 9077b, Kistler, Winterthur, Switzerland), on a hard, flat surface in a quiet room, the patient will then undergo the biomechanical evaluations first for running and then sprinting with a 1 min rest between them (figure 3). The reliability is high with ICC from 0.85 to 0.90.[71]

For the running biomechanical evaluation, each patient will run for 3 min at 3.33 m/s (12 km/h) and, without the patient being informed of the exact moment of data recording, 20 s of biomechanical parameters will be recorded. Mechanical data will be sampled at 1000 Hz. After appropriate filtering (Butterworth-type 30 Hz low-pass filter, second order), instantaneous data of vertical force will be averaged for each support phase (vertical force above 30 N) over the 20 s (FV_R) and expressed in Newtons (N) and body weight (BW). For each step, contact (t_c) and aerial (t_a) times will be calculated. Spring–mass parameters, like vertical stiffness
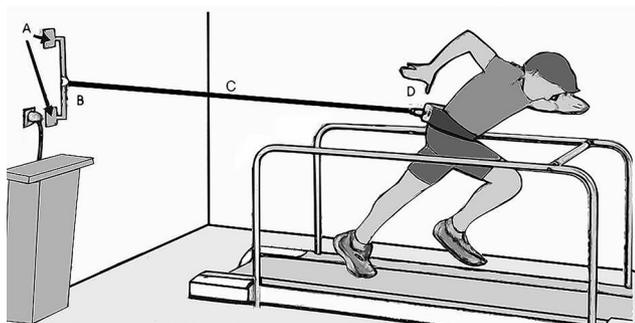

Figure 3 A runner fitted with a leather weightlifting belt (D) attached with a rigid tether (C) to the wall-mounting bracket (A and B) sprinting on a motorised treadmill.

(k_{vert} in kN/m) and leg stiffness (k_{leg} in kN/m), will be calculated using the computation method proposed by Morin *et al.*[72] The lower limb leg length will be the distance behind the great trochanter to ground distance in a standing position. The stride length (l_{stride} in m) will be calculated as: $l_{stride} = (t_c + t_a) \cdot v$.

For the sprint running biomechanical evaluation, each patient will first be familiarised with sprinting on a treadmill by three 6 s sprints separated by 1 min of rest. The patient is fitted with a leather weightlifting belt attached via a rigid tether (0.6 cm in diameter) to the wall (figure 3), as described by Morin *et al.*[72] The constant motor torque will be set to 160% of the default torque, ie, the motor torque necessary to overcome the friction on the treadmill belt due to the participant's BW. The default torque will be measured by making the participants stand still and by increasing the driving torque until a movement of the treadmill belt greater than 2 cm is observed over 5 s. Motor torque of 160% of the default value will be selected after several preliminary measurements comparing various torques, as this will allow participants to sprint in a comfortable manner and produce maximal effort without risking a loss of balance. Once the patient is correctly attached, he will be required to lean forward in a typical crouched sprint-start position with their preferred foot forward. This starting position will be used and standardised throughout the sprint series. After a 3 s countdown, the treadmill will be released, and the treadmill belt will begin to accelerate as participants apply a positive horizontal force. With patients strongly encouraged to produce their maximum intensity, two sprints will be recorded separated by a 1 min rest period. The data used for analysis will be: instantaneous data of vertical, net horizontal and total GRF averaged for each support phase (vertical force above 30 N) over 6 s sprints (FV_{sprint}, FH_{sprint}, $Ftot_{sprint}$, respectively), and expressed in Newtons (N) and BW. For each step, the ratio of forces applied on the ground (RF) will be calculated as the ratio of FH_{sprint} to $Ftot_{sprint}$ for one contact as follows: $RF = FH_{sprint} \cdot Ftot_{sprint}^{-1}$ (expressed in %).[73] Then, mean and maximal values of ratio forces for the 6 s sprint will be computed (RF-mean and RF-max, respectively). The index of force application technique (D_{RF}) representing the decrement in RF with increasing speed (S) will be computed as the slope of the linear RF-speed relationship calculated from the step-averaged values between the second step and the step at top speed.[50] Therefore, the higher the DRF (ie, a flat RF-speed relationship), the more RF will be maintained despite increasing velocity, and vice versa.[74] Lastly, for each 6 s sprint, performance will be described through mean and maximal running speeds (S and S-max, respectively).

Hop Tests

The patient will be asked to perform the following exercises, as described by Noyes *et al*[75] (figure 4):

▶ Single One-Leg Hop Test on the healthy limb and then the operated limb, with the arms crossed, hands
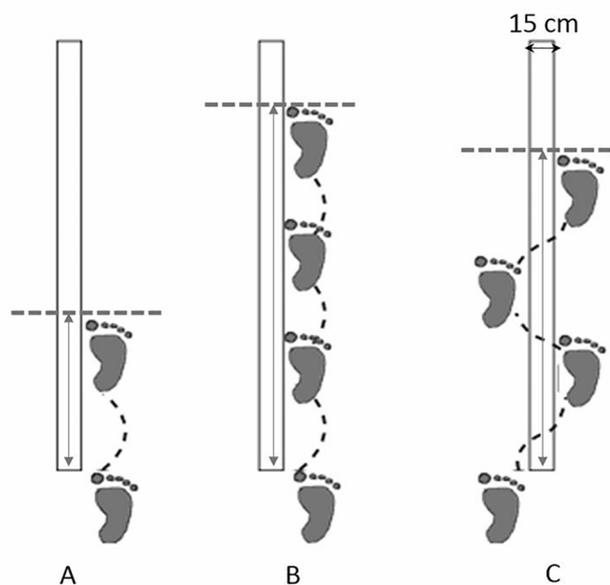
Figure 4 Hop Tests. (A) Single One-Leg Hop Test, (B) Triple One-Leg Hop Test and (C) Cross-over One-Leg Hop Test.

on shoulders. The patient will perform one hop, as far as possible, with a controlled, balanced landing (minimum 3 s). If the patient cannot maintain the landing position, makes extra hops, or does not keep his hands on his shoulders, then the Hop Test will be considered a failure.

► Triple One-Leg Hop Test on the healthy limb and then the operated limb with the arms in any position. The patient will perform three consecutive hops as far as possible. The last hop position must be maintained for a minimum of 3 s as with the Single One-Leg Hop Test.

► Cross-over One-Leg Hop Test on the healthy limb and then the operated limb with the arms in any position. The test is carried out on a 6.5 m strip of carpet with a central line 15 cm in width. The patient is asked to make three hops, the first laterally, crossing the line on each hop. Landing after the final hop must be as with the Single One-Leg Hop Test. The Cross-over One-Leg Hop Test allows assessment of the cutting

movement capabilities of the patient.[75] It imposes both predominant sagittal plane and rotation forces on the frontal plane of the knee. In addition, the test highlights any instability in the knee and tests muscle extensibility, muscle strength and power, proprioception, neuromuscular control, dynamic balance and agility.[76]

Patients start from single limb stance. Every attempt will include at least three jumps and will continue until the patient progresses. The best distance for each leg and each Hop Test will be recorded for analysis (in cm). In case of failure, the patient will have the opportunity to do the Hop Test again until it will be considered valid. The reliability is high with ICC from 0.84 to 0.92.[77]

Isokinetic assessment

As the resulting tiredness could affect the other tests if done earlier in the battery, the isokinetic quadriceps and hamstring muscle strength assessment will be performed last. They will be done on a Con-Trex Multi-Joint dynamometer (CMV AG, Dübendorf, Switzerland) and controlled by Con-Trex Software. The installation is described elsewhere in the literature.[78 79] The participants will be seated with the hip joint at about 85° and strapped in place at the chest, pelvis and mid-thigh to avoid postural compensation during the assessment. The contralateral limb will be fixed to a support at the ankle. The axis of the dynamometer will be perfectly aligned with the rotation axis (lateral femoral epicondyle) of the knee joint. Resistive support will be strapped to the leg, at 2–3 cm proximal to the ankle joint line. The range of knee motion will be set from 80° for a safe, comfortable, comparative assessment of quadriceps (extensor) and hamstring (flexors) muscles. The gravity correction will be used. Assessment will begin with the healthy knee, and then the operated knee, and each series of repetitions will be followed by 1 min of rest. The assessment is summarised in table 2.

The isokinetic assessment will be performed in this order, using gravity corrections, at a range of motion of 5°–85°, and measuring peak torque for each test session. A 1 min rest will be allowed between each session.

Table 2	Isokinetic assessment design		
		Repetitions	**Angular velocity and mode of contraction**
First specific warm-up	↓	Six submaximal	120°/s in concentric
Second specific warm-up	↓	Six submaximal	120°/s in concentric
Habituation session	↓	Three submaximal	60°/s in concentric
Maximal test session with encouragement	↓	Three maximal	60°/s in concentric
Maximal test session with encouragement	↓	Three maximal	120°/s in concentric
Habituation session	↓	Three submaximal	30°/s in eccentric
Maximal test session with encouragement	↓	Three maximal	30°/s in eccentric

Torque, position and angular velocity data will be recorded from the isokinetic dynamometer with a sampling rate of 100 Hz. After appropriate filtering, for concentric and eccentric strength trials, the software will calculate a large number of parameters, but we will retain only the absolute peak torque, the most reproducible parameter (ICC >0.96).[78]

The peak torque value normalised to the BW (Nm/kg) will be recorded for each mode and speed of contraction for the quadriceps (Q) and hamstring (H). The Q/H ratio will be calculated for each mode and speed of contraction on the operated side, with a ratio ≥60% considered to be physiologically sufficient to obtain joint control. A mixed functional ratio, associating the eccentric performance of the flexor (at 30°/s) and the concentric performance of the extensor (at 240°/s) will also be calculated, as reported by Croisier et al.[79]

Follow-up after ACL surgical reconstruction

Patient follow-up will continue until 36 months postoperatively. After the evaluation at 12 months postsurgery, patient follow-up will continue for a further 2 years. The researchers will attempt to follow-up all patients by phone interview every 6 months to determine the date of return to running, to pivoting sport-specific training and to pivoting sport competition, as well as the date and the nature of any reinjury that may occur. The reinjury is defined as rupture of the transplant, or the contralateral ACL, or any injury requiring the sporting activity to cease and necessitating a consultation and/or medical care. We will also collect the Tegner score at 3 years post-ACLR.

The decision for clearance to a RTS will be made by a sport physician, blinded to all the tests results except the isokinetics results. This decision will be taken after considering the time from surgery, clinical experience and the isokinetics results.

Primary outcome

The main criterion for assessment is the occurrence of reinjury during the 3-year follow-up. A reinjury is defined as a rupture of the transplant or the contralateral ACL or any injury requiring the sporting activity to cease and necessitating a consultation and/or medical care.

Method of accounting for missing, unused or invalid data

A patient's participation in the study will cease if significant complications appear when performing the tests and all data collected before that point will be analysed.

Power and sample size considerations

Based on the rate of ACL reinjury (rupture of the transplant or the contralateral ACL)[18] described in the literature for the subgroup of younger athletes who RTS, and considering the unknown rate of other possible injuries (any injury requiring the sporting activity to cease and necessitating a consultation and/or medical care) after an ACLR, a global rate of reinjury after ACLR could be assumed at 20%. Considering a 10% dropout rate, and that 10 cases (reinjury) are needed to test one explanatory variable, it is necessary to include 50 patients to test one explanatory variable for 95% power and a type-I error rate (alpha) of 0.05. Depending on the results of the data mining procedures (principal components analysis and hierarchical clustering on principal components) on the variables presented in table 3, we will choose a maximum of five variables to construct the model. We will therefore need to include 275 patients.

Statistical analyses

Exploratory data analysis will be performed, following five steps adapted from data mining processes[80 81]: (1) identification of study objectives, (2) data acquisition, (3) data evaluation and preparation, (4) data analysis and modelling and (5) results, interpretation and validation.

In step 3, we will analyse the data quality checking that there are no inconsistencies, errors, duplicates or 'aberrant' data. We will also verify the overall consistency of the data.

In step 4, classification and selection of variables reported in table 3 will define the explanatory variables required to build the models (with principal components analysis then hierarchical clustering on principal components). We will choose the best data analysis taking into account the characteristic of the model variables.

Lastly, in step 5, the model(s) will be analysed and compared in order to define as precisely as possible the explanatory variables and the most suitable model. The p value will be adjusted if necessary and other methods could be used (Akaike information criterion or Bayesian information criterion). The parameters of the model will then be analysed in order to define their clinical relevance.

The use of this exploratory data analysis will be based on by some of the work in medical research to use data mining.[80 82] However, this method does not exclude the classical statistical analyses for the creation of a model. Lastly, depending on our variables, we will use the appropriate statistical tests. After performing a correlation matrix and calculating collinearity using linear regression, we will calculate several generalised linear models if possible: linear regression, generalised estimating equations and generalised linear mixed model, depending on the characteristics of our variables.

Statistical analyses will be performed using R (http://www.R-project.org).

ETHICS AND DISSEMINATION

The present study has been approved by the local ethical committee (IRBN522015/CHUSTE) and will be recorded on ClinicalTrials.gov. Prior to enrolment in the study, all patients will be asked to give their informed consent. The patient can decide at any time to be released from the study, and they will be informed of this in the information leaflet. His/her data will then be deleted from the data collection file. Leaving the study will have no incidence on the normal monitoring protocol of patients postsurgery.

Table 3 Explanatory variables

Categories of criteria	Explanatory variables	Unit or range	Calculated data
	Marx preinjury	0–16	
	Tegner preinjury	0–10	
Self-reported measures	IKDC	0–100	
	TSK11	11–55	
	SANE	0–100	
	Centre of pressure (CoP)	mm	
	CoP velocity	mm/s	
Postural control analysis	CoP area	mm^2	
	GnRB slope	mm	
Knee laxity measurements	GnRB anteroposterior displacement	mm	
SEBT	Anterior distance	m	
	Posterolateral distance	m	
	Posterolateral distance	m	
	Composite SEBT score	%	X
Running and sprinting mechanics	LSI Leg stiffness	%	X
	LSI stride length	%	X
	LSI sprint vertical force	%	X
	LSI sprint horizontal force	%	X
	LSI sprint total force	%	X
	LSI sprint ratio of forces	%	X
	LSI sprint DRF	%	X
Hop Tests	LSI Single One-Leg Hop Test	%	X
	LSI Triple One-Leg Hop Test	%	X
	LSI Cross-over One-Leg Hop Test	%	X
Isokinetic assessment	Quadriceps peak torque at 60°/s BW	N/kg	
	Quadriceps peak torque at 240°/s BW	N/kg	
	Quadriceps peak torque at 30°/s BW	N/kg	
	Hamstring peak torque at 60°/s BW	N/kg	
	Hamstring peak torque at 240°/s BW	N/kg	
	Hamstring peak torque at 30°/s BW	N/kg	
	Mixed functional ratio	%	X
Follow-up	Marx 3 years postop	0–16	
	Tegner 3 years postop	0–10	
	SANE 3 years postop	0–100	

LSI=operated leg/healthy leg; Mixed functional ratio=IJ30/Q240 (with IJ30 the Hamstring peak torque at 30°/s of isokinetic assessment, and Q240 the Quadriceps peak torque at 240°/s of isokinetic assessment).

BW, body weight; IKDC, International Knee Documentation Committee; LSI, Limb Symmetry Index; postop, postoperative; SANE, Single Assessment Numeric Evaluation; SEBT, Star Excursion Balance Test; TSK11, Tampa Scale of Kinesiophobia-11.

The results of this study will be disseminated via presentation at local, national and international conferences and peer-reviewed journals.

Author affiliations
[1]Inter-university Laboratory of Human Movement Biology (LIBM EA 7424), University of Lyon, University Jean Monnet, Saint-Etienne, France
[2]Physiotherapy Clinic of the Sport Center, La Talaudière, France
[3]Department of Orthopaedic and Trauma Surgery, University Hospital Center of Saint-Etienne, Hôpital Nord, Saint-Etienne, France
[4]Université Savoie Mont Blanc, Laboratoire Interuniversitaire de Biologie de la Motricité (LIBM), EA 7424, F-73000 Chambéry, France
[5]Université Côte d'Azur, LAMHESS, Nice, France
[6]Department of Clinical and Exercise Physiology, Sports Medicine Unit, University Hospital of Saint-Etienne, Faculty of Medicine, Saint-Etienne, France

REFERENCES

1. Wilk KE. Anterior cruciate ligament injury prevention and rehabilitation: let's get it right. *J Orthop Sports Phys Ther* 2015;45:729–30.
2. Parkkari J, Pasanen K, Mattila VM, *et al*. The risk for a cruciate ligament injury of the knee in adolescents and young adults: a population-based cohort study of 46 500 people with a 9 year follow-up. *Br J Sports Med* 2008;42:422–6.
3. Nordenvall R, Bahmanyar S, Adami J, *et al*. A population-based nationwide study of cruciate ligament injury in Sweden, 2001-2009: incidence, treatment, and sex differences. *Am J Sports Med* 2012;40:1808–13.
4. Shea KG, Carey JL, Richmond J, *et al*. The American Academy of Orthopaedic Surgeons evidence-based guideline on management of anterior cruciate ligament injuries. *J Bone Joint Surg Am* 2015;97:672–4.
5. Kvist J. Rehabilitation following anterior cruciate ligament injury: current recommendations for sports participation. *Sports Med* 2004;34:269–80.
6. Paulos L, Noyes FR, Grood E, *et al*. Knee rehabilitation after anterior cruciate ligament reconstruction and repair. *Am J Sports Med* 1981;9:140–9.
7. Shelbourne KD, Gray T, Haro M. Incidence of subsequent injury to either knee within 5 years after anterior cruciate ligament reconstruction with patellar tendon autograft. *Am J Sports Med* 2009;37:246–51.
8. Kruse LM, Gray B, Wright RW. Rehabilitation after anterior cruciate ligament reconstruction: a systematic review. *J Bone Joint Surg Am* 2012;94:1737–48.
9. van Melick N, van Cingel RE, Brooijmans F, *et al*. Evidence-based clinical practice update: practice guidelines for anterior cruciate ligament rehabilitation based on a systematic review and multidisciplinary consensus. *Br J Sports Med* 2016;50:1506–15.
10. Lynch AD, Logerstedt DS, Grindem H, *et al*. Consensus criteria for defining 'successful outcome' after ACL injury and reconstruction: a Delaware-Oslo ACL cohort investigation. *Br J Sports Med* 2015;49:335–42.
11. Ardern CL, Österberg A, Sonesson S, *et al*. Satisfaction with knee function after Primary Anterior Cruciate Ligament Reconstruction is Associated with Self-Efficacy, Quality of Life, and returning to the Preinjury Physical Activity. *Arthroscopy* 2016;32:1631–8.
12. Ardern CL, Taylor NF, Feller JA, *et al*. Fifty-five per cent return to competitive sport following anterior cruciate ligament reconstruction surgery: an updated systematic review and meta-analysis including aspects of physical functioning and contextual factors. *Br J Sports Med* 2014;48:1543–52.
13. Barber-Westin SD, Noyes FR. Objective criteria for return to athletics after anterior cruciate ligament reconstruction and subsequent reinjury rates: a systematic review. *Phys Sportsmed* 2011;39:100–10.
14. Paterno MV, Rauh MJ, Schmitt LC, *et al*. Incidence of second ACL injuries 2 years after primary ACL reconstruction and return to Sport. *Am J Sports Med* 2014;42:1567–73.
15. Ardern CL. Anterior cruciate ligament reconstruction-not exactly a one-way ticket back to the preinjury level: a review of contextual factors affecting return to sport after surgery. *Sports Health* 2015;7:224–30.
16. Grindem H, Snyder-Mackler L, Moksnes H, *et al*. Simple decision rules can reduce reinjury risk by 84% after ACL reconstruction: the Delaware-Oslo ACL cohort study. *Br J Sports Med* 2016;50:804–8.
17. Culvenor AG, Alexander BC, Clark RA, *et al*. Dynamic single-leg postural control is impaired bilaterally following anterior cruciate ligament reconstruction: implications for reinjury risk. *J Orthop Sports Phys Ther* 2016;46:357–64.
18. Wiggins AJ, Grandhi RK, Schneider DK, *et al*. Risk of secondary injury in younger athletes after anterior cruciate ligament reconstruction: a systematic review and meta-analysis. *Am J Sports Med* 2016;44:1861–76.
19. de Visser HM, Reijman M, Heijboer MP, *et al*. Risk factors of recurrent hamstring injuries: a systematic review. *Br J Sports Med* 2012;46:124–30.
20. Koulouris G, Connell DA, Brukner P, *et al*. Magnetic resonance imaging parameters for assessing risk of recurrent hamstring injuries in elite athletes. *Am J Sports Med* 2007;35:1500–6.
21. Paterno MV, Rauh MJ, Schmitt LC, *et al*. Incidence of contralateral and ipsilateral anterior cruciate ligament (ACL) injury after primary ACL reconstruction and return to sport. *Clin J Sport Med* 2012;22:116–21.
22. Allen MM, Pareek A, Krych AJ, *et al*. Are female soccer players at an increased risk of second anterior cruciate ligament injury compared with their athletic peers? *Am J Sports Med* 2016;44:2492–8.
23. Kamien PM, Hydrick JM, Replogle WH, *et al*. Age, graft size, and Tegner activity level as predictors of failure in anterior cruciate ligament reconstruction with hamstring autograft. *Am J Sports Med* 2013;41:1808–12.
24. Magnussen RA, Lawrence JT, West RL, *et al*. Graft size and patient age are predictors of early revision after anterior cruciate ligament reconstruction with hamstring autograft. *Arthroscopy* 2012;28:526–31.
25. Webster KE, Feller JA, Leigh WB, *et al*. Younger patients are at increased risk for graft rupture and contralateral injury after anterior cruciate ligament reconstruction. *Am J Sports Med* 2014;42:641–7.
26. Borchers JR, Pedroza A, Kaeding C. Activity level and graft type as risk factors for anterior cruciate ligament graft failure: a case-control study. *Am J Sports Med* 2009;37:2362–7.
27. Salmon L, Russell V, Musgrove T, *et al*. Incidence and risk factors for graft rupture and contralateral rupture after anterior cruciate ligament reconstruction. *Arthroscopy* 2005;21:948–57.
28. Brophy RH, Selby RM, Altchek DW. Anterior cruciate ligament revision: double-bundle augmentation of primary vertical graft. *Arthroscopy* 2006;22:683.e1–683.e5.
29. Marchant BG, Noyes FR, Barber-Westin SD, *et al*. Prevalence of nonanatomical graft placement in a series of failed anterior cruciate ligament reconstructions. *Am J Sports Med* 2010;38:1987–96.
30. Hui C, Salmon LJ, Kok A, *et al*. Fifteen-year outcome of endoscopic anterior cruciate ligament reconstruction with patellar tendon autograft for "isolated" anterior cruciate ligament tear. *Am J Sports Med* 2011;39:89–98.
31. Gifstad T, Foss OA, Engebretsen L, *et al*. Lower risk of revision with patellar tendon autografts compared with hamstring autografts: a registry study based on 45,998 primary ACL reconstructions in Scandinavia. *Am J Sports Med* 2014;42:2319–28.
32. Laboute E, Savalli L, Puig P, *et al*. Analysis of return to competition and repeat rupture for 298 anterior cruciate ligament reconstructions with patellar or hamstring tendon autograft in sportspeople. *Ann Phys Rehabil Med* 2010;53:598–614.
33. Leys T, Salmon L, Waller A, *et al*. Clinical results and risk factors for reinjury 15 years after anterior cruciate ligament reconstruction: a prospective study of hamstring and patellar tendon grafts. *Am J Sports Med* 2012;40:595–605.
34. Maletis GB, Inacio MC, Desmond JL, *et al*. Reconstruction of the anterior cruciate ligament: association of graft choice with increased risk of early revision. *Bone Joint J* 2013;95-B:623–8.
35. Persson A, Fjeldsgaard K, Gjertsen JE, *et al*. Increased risk of revision with hamstring tendon grafts compared with patellar tendon grafts after anterior cruciate ligament reconstruction: a study of 12,643 patients from the Norwegian Cruciate Ligament Registry, 2004–2012. *Am J Sports Med* 2014;42:285–91.
36. Paterno MV, Schmitt LC, Ford KR, *et al*. Biomechanical measures during landing and postural stability predict second anterior cruciate ligament injury after anterior cruciate ligament reconstruction and return to sport. *Am J Sports Med* 2010;38:1968–78.

37. Czuppon S, Racette BA, Klein SE, et al. Variables associated with return to sport following anterior cruciate ligament reconstruction: a systematic review. *Br J Sports Med* 2014;48:356–64.

38. Ardern CL, Webster KE, Taylor NF, et al. Return to sport following anterior cruciate ligament reconstruction surgery: a systematic review and meta-analysis of the state of play. *Br J Sports Med* 2011;45:596–606.

39. Kyritsis P, Bahr R, Landreau P, et al. Likelihood of ACL graft rupture: not meeting six clinical discharge criteria before return to sport is associated with a four times greater risk of rupture. *Br J Sports Med* 2016;50:946–51.

40. Claes S, Verdonk P, Forsyth R, et al. The "ligamentization" process in anterior cruciate ligament reconstruction: what happens to the human graft? A systematic review of the literature. *Am J Sports Med* 2011;39:2476–83.

41. Kawamura S, Ying L, Kim HJ, et al. Macrophages accumulate in the early phase of tendon-bone healing. *J Orthop Res* 2005;23:1425–32.

42. Anderson AF, Irrgang JJ, Kocher MS, et al. The International Knee Documentation Committee subjective knee evaluation form: normative data. *Am J Sports Med* 2006;34:128–35.

43. Undheim MB, Cosgrave C, King E, et al. Isokinetic muscle strength and readiness to return to sport following anterior cruciate ligament reconstruction: is there an association? A systematic review and a protocol recommendation. *Br J Sports Med* 2015;49:1305–10.

44. Pua Y-H, Bryant AL, Steele JR, et al. Isokinetic dynamometry in anterior cruciate ligament injury and reconstruction. *Annals Academy of Medicine Singapore* 2008;37:330.

45. Langford JL, Webster KE, Feller JA. A prospective longitudinal study to assess psychological changes following anterior cruciate ligament reconstruction surgery. *Br J Sports Med* 2009;43:377–8.

46. Lai CC, Ardern CL, Feller JA, et al. Eighty-three per cent of elite Athletes return to preinjury sport after anterior cruciate ligament reconstruction: a systematic review with meta-analysis of return to sport rates, graft rupture rates and performance outcomes. *Br J Sports Med* 2017:bjsports-2016-096836 (Published Online First: 21 February 2017).

47. Ardern CL, Glasgow P, Schneiders A, et al. 2016 Consensus statement on return to sport from the First World Congress in Sports Physical therapy, Bern. *Br J Sports Med* 2016;50:853–64.

48. Mazet A, Morin JB, Semay B, et al. Changes in running mechanical pattern after an anterior cruciate ligament plasty. *Science & Sports* 2016;31:219–22.

49. Brown SR, Brughelli M. Determining return-to-sport status with a multi-component assessment strategy: a case study in rugby. *Phys Ther Sport* 2014;15:211–5.

50. Morin JB, Sève P. Sprint running performance: comparison between treadmill and field conditions. *Eur J Appl Physiol* 2011;111:1695–703.

51. Shelbourne KD, Nitz P. Accelerated rehabilitation after anterior cruciate ligament reconstruction. *Am J Sports Med* 1990;18:292–9.

52. Hefti F, Müller W, Jakob RP, et al. Evaluation of knee ligament injuries with the IKDC form. *Knee Surg Sports Traumatol Arthrosc* 1993;1:226–34.

53. Shelbourne KD, Barnes AF, Gray T. Correlation of a single assessment numeric evaluation (SANE) rating with modified Cincinnati knee rating system and IKDC subjective total scores for patients after ACL reconstruction or knee arthroscopy. *Am J Sports Med* 2012;40:2487–91.

54. Gokeler A, Welling W, Zaffagnini S, et al. Development of a test battery to enhance safe return to sports after anterior cruciate ligament reconstruction. *Knee Surg Sports Traumatol Arthrosc* 2017;25.

55. Logerstedt D, Di Stasi S, Grindem H, et al. Self-reported knee function can identify athletes who fail return-to-activity criteria up to 1 year after anterior cruciate ligament reconstruction: a Delaware-Oslo ACL cohort study. *J Orthop Sports Phys Ther* 2014;44:914–23.

56. Hapidou EG, O'Brien MA, Pierrynowski MR, et al. Fear and avoidance of movement in people with chronic pain: psychometric properties of the 11-Item Tampa Scale for Kinesiophobia (TSK-11). *Physiother Can* 2012;64:235–41.

57. Tkachuk GA, Harris CA. Psychometric properties of the Tampa Scale for Kinesiophobia-11 (TSK-11). *J Pain* 2012;13:970–7.

58. Woby SR, Roach NK, Urmston M, et al. Psychometric properties of the TSK-11: a shortened version of the Tampa Scale for Kinesiophobia. *Pain* 2005;117:137–44.

59. Lentz TA, Zeppieri G, Tillman SM, et al. Return to preinjury sports participation following anterior cruciate ligament reconstruction: contributions of demographic, knee impairment, and self-report measures. *J Orthop Sports Phys Ther* 2012;42:893–901.

60. Winterstein AP, McGuine TA, Carr KE, et al. Comparison of IKDC and SANE outcome measures following knee Injury in active female patients. *Sports Health* 2013;5:523–9.

61. American Academy of Neurology. Assessment: posturography. Report of the Therapeutics and technology assessment subcommittee of the American Academy of Neurology. *Neurology* 1993;43:1261.

62. Ruhe A, Fejer R, Walker B. The test-retest reliability of centre of pressure measures in bipedal static task conditions--a systematic review of the literature. *Gait Posture* 2010;32:436–45.

63. Kouvelioti V, Kellis E, Kofotolis N, et al. Reliability of Single-leg and Double-leg balance tests in subjects with Anterior Cruciate Ligament reconstruction and Controls. *Res Sports Med* 2015;23:151–66.

64. Vauhnik R, Morrissey MC, Perme MP, et al. Inter-rater reliability of the GNRB® knee arthrometer. *Knee* 2014;21:541–3.

65. Robert H, Nouveau S, Gageot S, et al. A new knee arthrometer, the GNRB: experience in ACL complete and partial tears. *Orthop Traumatol Surg Res* 2009;95:171–6.

66. Collette M, Courville J, Forton M, et al. Objective evaluation of anterior knee laxity; comparison of the KT-1000 and GNRB® arthrometers. *Knee Surg Sports Traumatol Arthrosc* 2012;20:2233–8.

67. Kinzey SJ, Armstrong CW. The reliability of the star-excursion test in assessing dynamic balance. *J Orthop Sports Phys Ther* 1998;27:356–60.

68. Herrington L, Hatcher J, Hatcher A, et al. A comparison of Star Excursion Balance Test reach distances between ACL deficient patients and asymptomatic controls. *Knee* 2009;16:149–52.

69. Gribble PA, Hertel J, Plisky P. Using the Star Excursion Balance Test to assess dynamic postural-control deficits and outcomes in lower extremity injury: a literature and systematic review. *J Athl Train* 2012;47:339–57.

70. Hyong IH, Kim JH. Test of intrarater and interrater reliability for the star excursion balance test. *J Phys Ther Sci* 2014;26:1139–41.

71. Morin JB, Samozino P, Bonnefoy R, et al. Direct measurement of power during one single sprint on treadmill. *J Biomech* 2010;43:1970–5.

72. Morin JB, Dalleau G, Kyröläinen H, et al. A simple method for measuring stiffness during running. *J Appl Biomech* 2005;21:167–80.

73. Morin JB, Edouard P, Samozino P. Technical ability of force application as a determinant factor of sprint performance. *Med Sci Sports Exerc* 2011;43:1680–8.

74. Morin JB, Bourdin M, Edouard P, et al. Mechanical determinants of 100-m sprint running performance. *Eur J Appl Physiol* 2012;112:3921–30.

75. Noyes FR, Barber SD, Mangine RE. Abnormal lower limb symmetry determined by function hop tests after anterior cruciate ligament rupture. *Am J Sports Med* 1991;19:513–8.

76. Clark NC. Functional performance testing following knee ligament injury. *Physical Therapy in Sport* 2001;2:91–105.

77. Reid A, Birmingham TB, Stratford PW, et al. Hop testing provides a reliable and valid outcome measure during rehabilitation after anterior cruciate ligament reconstruction. *Phys Ther* 2007;87:337–49.

78. Maffiuletti NA, Bizzini M, Desbrosses K, et al. Reliability of knee extension and flexion measurements using the Con-Trex isokinetic dynamometer. *Clin Physiol Funct Imaging* 2007;27:346–53.

79. Croisier JL, Ganteaume S, Binet J, et al. Strength imbalances and prevention of hamstring injury in professional soccer players: a prospective study. *Am J Sports Med* 2008;36:1469–75.

80. Esfandiari N, Babavalian MR, Moghadam A-ME, et al. Knowledge discovery in medicine: current issue and future trend. *Expert Syst Appl* 2014;41:4434–63.

81. Witten IH, Frank E, Hall MA. *Data mining: practical machine learning tools and techniques*. Third Edition. Burlington: Morgan Kaufmann, 2011.

82. Combes C, Azema J. Clustering using principal component analysis applied to autonomy–disability of elderly people. *Decis Support Syst* 2013;55:578–86.