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Faculteit Geneeskunde en Levenswetenschappen

master in de revalidatiewetenschappen en de kinesitherapie

Masterthesis

Quantitative, qualitative or a combined movement assessment during return to sport testing after anterior cruciate ligament reconstruction

Sofie Hawinkel
Tine Petré

Scriptie ingediend tot het behalen van de graad van master in de revalidatiewetenschappen en de kinesitherapie, afstudeerrichting revalidatiewetenschappen en kinesitherapie bij musculoskeletale aandoeningen

PROMOTOR :
dr. Bart DINGENEN

COPROMOTOR :
Prof. dr. Johan BELLEMANS

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www.uhasselt.be
Universiteit Hasselt
Campus Hasselt:
Martelarenlaan 42 | 3500 Hasselt
Campus Diepenbeek:
Agoralaan Gebouw D | 3590 Diepenbeek

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Holrakkerstraat 76 3510 Kermt, 30/05/2018 S.H.

Rode Kruisstraat 22, Herk-de-Stad, 30/05/2018 T.P.

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1. Context of master thesis

This master thesis fits in the research domain of musculoskeletal rehabilitation. An anterior cruciate ligament injury (ACLI) mostly occurs during sport participation [2]. Most athletes who wish to return to sport (RTS) after injury are recommended to undergo an anterior cruciate ligament reconstruction (ACLR) [7]. The surgery is followed by a rehabilitation period in which the athlete is prepared to RTS [3]. The rehabilitation period is an important period because biopsychosocial deficits have to be normalized before the patient can safely RTS [3]. This period of rehabilitation traditionally ends with RTS testing [3]. This is mostly done 6 months following surgery [1]. These tests are mainly based on quantitative outcome measures (e.g. distance covered during different hop tests) however recent studies also included qualitative outcome measures (e.g. knee valgus during landing) [3,4,9]. Furthermore patient reported outcome measures (PROMs) are also frequently assessed during RTS testing [3,5,6]. These self-reported questionnaires collect information on patients' physical and psychological functioning [3,5,6]. Hence the decision whether a patient is ready to RTS is multifactorial and the need for valid RTS criteria is high because re-injuries are common [8,10].

Quantity of movement, quality of movement and PROMs are associated with RTS testing, but the relationship between these outcomes has not been assessed at the moment of RTS. Therefore the main goal of this study was to assess the relationship (i.e. correlations) between quantity of movement and quality of movement in an ACLR group 6 months following surgery. The second goal of this study was to assess the relationship between: (1) PROMs and quantity of movement and (2) PROMs and quality of movement in an ACLR group 6 months following surgery. A third goal of this study was to assess the percentage of patients that would pass a well-defined RTS test battery 6 months following surgery.

This duo master thesis was part of a broader research project about optimization of clinical tests used to evaluate the possibility to RTS after ACLR. Consequently, there were more tests done than analysed in our master thesis part 2. Our master thesis only included the following outcomes: (1) quantitative outcomes of hop tests (2) movement qualitative outcomes of the drop vertical jump (DVJ), single leg drop vertical jump (SLDVJ) and the tuck jump and (3) PROMs. The following PROMs were completed: (1) Anterior Cruciate Ligament-Return to Sport after Injury (ACL-RSI), (2) Knee injury and Osteoarthritis Outcome Score (KOOS), (3) Knee Self-

Efficacy Scale (K-SES) and (4) International Knee Documentation Committee Subjective Knee Form (IKDC). These outcomes were assessed in an ACLR group 6 months following surgery. All measurements were done in Diepenbeek at the research centre REVAL of UHasselt. The research design (i.e. cross-sectional study) of master thesis part 2 was determined by our promotor dr. Bart Dingenen and the research method was developed in association with our promotor. The research question and outcomes included in our master thesis were determined after an appointment with our promotor. Our promotor performed all measurements. It took about 2 hours to test a patient. We assisted with: (1) placing material, (2) noting outcome measures and (3) capturing videos during the various tests. Subsequently our promotor delivered us the quantitative outcomes of the hop tests and the videos by which quality of movement was assessed afterwards. We renamed and analysed the videos. Some tests were analysed with scoring sheets and some tests were analysed with joint angles. PROMs were filled in at home by the patients. Data processing was done independently. Academic writing was done independently and afterwards it was checked by our promotor.

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2. Abstract

Background Currently the majority of patients do not pass well-defined criteria to safely RTS following ACLR. Valid clinical-oriented RTS criteria are necessary because re-injuries are common.

Objectives The main goal of this study was to assess the relationship between quantity and quality of movement in an ACLR group 6 months following surgery. The second goal of this study was to assess the relationship between: (1) PROMs and quantity of movement and (2) PROMs and quality of movement. A third goal of this study was to assess the percentage of patients that would pass a well-defined RTS test battery.

Participants Fourteen patients (i.e. 2 females and 12 males) with a mean age of 24.72 ± 5.28 years were examined 6 months following ACLR.

Measurements Correlations were calculated between: (1) quantitative and qualitative outcomes, (2) PROMs and quantitative outcomes and (3) PROMs and qualitative outcomes. The RTS criteria were: (1) a limb symmetry index (LSI) ≥ 90% on 4 hop tests, (2) Landing Error Scoring System (LESS) < 5 during the DVJ, (3) K-SES males > 7.2 and females > 6.8, (4) IKDC score within 15% of healthy gender–age-matched subjects and (5) ACL-RSI > 56.

Results No significant correlations were found between quantitative and qualitative outcomes. PROMS were high to very high statistically significant correlated with quantitative and qualitative outcomes. None of the patients passed the RTS test battery.

Conclusion There was no clear association between quantitative and qualitative outcomes. This highlights the importance of multifactorial RTS test batteries because both quantitative and qualitative outcomes have been associated with re-injuries in previous studies. Strong statistically significant correlations were found between PROMs and quantitative outcomes. No clear association was found between PROMs and qualitative outcomes.

3. Introduction

ACLIs usually occur during sport participation and most athletes who wish to RTS are recommended to undergo ACLR [12,50]. Although 81% of athletes return to some kind of sport participation, not all athletes return to competitive sport [3]. Only 55% of athletes return to competitive sport following ACLR [3]. The overall risk of re-injury is 20% and currently it is unknown which measures should be taken into account to predict a safe RTS (i.e. low risk of a second ACLI) [77,82]. Therefore valid RTS criteria are necessary [77].

The decision to RTS can be challenging, as it is a complex interaction of multiple factors [68,86]. The most commonly used criterion to assess readiness to RTS is time [5]. This varies from 12 weeks to more than 12 months postoperative but most studies used 6 months as criterion to RTS [5]. Grindem et al. (2016) found that RTS before 9 months increases the risk of knee re-injury with 51% [29]. There is no association between time from surgery and functional deficits and therefore Dingenen & Gokeler (2017) advised a multifactorial RTS approach [14,53]. Recent studies recommended the following RTS criteria: (1) time, (2) PROMs, (3) quantitative outcome measures (e.g. hop tests and strength tests), and (4) qualitative outcome measures (e.g. biomechanical alterations) [14,77].

Quantitative assessment of RTS after ACLR, such as hop tests are commonly described in literature [5,14,33]. There are many different hop tests but there is no agreement on which hop tests should be assessed during RTS testing [14]. Currently there is also no consensus about the LSI level the athlete has to reach before returning to sport [75,77]. A recent practice guideline recommended a LSI of ≥ 100% for pivoting and cutting sports although mostly a LSI of 90% is advised [5,77]. During the RTS decision-making process, hop tests traditionally focus on quantitative outcomes and do not assess qualitative outcomes [85].

In the past few years more attention has been paid to quality of movement following ACLR, although it is not yet widely implemented in RTS decision-making [5,8,33,64]. Examining quality of movement is frequently performed in athletic tasks such as a DVJ [6,20,25,27,45,58,64], SLDVJ [51,58] and tuck jump [20,54] in patients following ACLR. Paterno et al. (2010) identified 4 predictors of a second ALCI in a cohort of young athletes participating in level 1 or 2 sports: (1) contralateral hip internal rotation moment during the first 10% of landing, (2) side-to-side difference in knee moment at initial contact (i.e. knee internal

extensor moment of the unreconstructed leg and knee internal flexor moment of the reconstructed leg, (3) increased two-dimensional (2D) peak frontal plane knee valgus during the landing phase and (4) deficits in postural stability on the reconstructed leg, measured by a Biodex stability system [64]. Hence this study highlighted the importance of assessing quality of movement during RTS decision-making. Furthermore several studies highlighted assessment of PROMs following ACLR and RTS [14,46,48]. PROMs are self-reported questionnaires that capture information on patients' physical and psychological functioning [14,46,48].

Quantity of movement, quality of movement and PROMs are frequently assessed following ACLR and are associated with RTS decision-making but the relationship between commonly used clinical-oriented RTS outcomes has not been established at the moment of RTS [14,33,77]. Therefore the main goal of this study was to assess the relationship between commonly assessed clinical-oriented quantitative and qualitative RTS outcomes in an ACLR group 6 months following surgery. The second goal of this study was to assess the relationship between: (1) PROMs and quantity of movement and (2) PROMs and quality of movement in an ACLR group 6 months following surgery. The null hypotheses stated that there would be no significant correlations between: (1) quantity of movement and quality of movement, (2) PROMs and quantity of movement and (3) PROMs and quality of movement, which we expect to reject since all these factors are considered important to measure the construct of readiness to RTS [2,68]. A third goal of this study was to assess the percentage of patients that would pass a well-defined RTS test battery 6 months following surgery.

4. Methods

4.1. Participants

Patients with ACLR were recruited by two orthopedic surgeons (i.e. Prof. dr. J. Truijen and Prof. dr. J. Bellemans) of ziekenhuis Oost-Limburg (i.e. ZOL) at Genk. These surgeons referred suitable patients with ACLR to the research project of dr. Bart Dingenen. Participation was voluntary and testing could be discontinued whenever the patient wanted. All patients signed an informed consent form and the research protocol was approved by the ethical committee prior to the commencement of the study.

Inclusion criteria were:

(1) Unilateral ACLR with hamstrings autograft

(2) Age between 18 and 44 years

Exclusion criteria were:

(1) ACLR revision

(2) Meniscectomy (i.e. >1/3 meniscus) within the injured knee

(3) Traumatic cartilage injury as result of the ACLI

(4) History of a grade 3 posterior cruciate ligament injury within the injured knee

(5) History of a grade 3 collateral ligament injury (i.e. lateral or medial) within the injured knee

(6) History of a grade 3 posterolateral corner injury within the injured knee

(7) History of a grade 3 ACLI within the uninjured knee

(8) History of a grade 3 posterior cruciate ligament injury within the uninjured knee

(9) History of a collateral ligament injury (i.e. lateral or medial) within the uninjured knee

(10) History of a posterolateral corner injury within the uninjured knee

(11) History of a major trauma and/or major orthopaedic surgery at the lumbar spine, pelvis or lower extremity

(12) Neurological disorder

(13) Vestibular disorder and

(14) Pregnancy

Fourteen patients participated. Detailed demographics are presented in table 1. A non-contact injury was defined as an event where there was no direct or indirect contact between the injured knee and the opponent [49].

Table 1 | Participant characteristics

Sex, n (females/males)	2/12
Age, years (M ± SD)	24.72 ± 5.28
Length, cm (M ± SD)	177.11 ± 7.70
Weight, kg (M ± SD)	77.38 ± 12.29
BMI, kg/m^2 (M ± SD)	24.52 ± 2.52
Operated side (R/L)	7/7
Dominant side (R/L)	12/2
Injury mechanism (non-contact/contact)	11/3

Abbreviations: n; number of participants, M; mean, SD; standard deviation, BMI; body mass index, R; right, L; left.

4.2. Procedure

4.2.1. Preparation

Before the measurements could start, some preparations had to be made. First, a metal tape measure was placed on the ground so that the jump distances of the hop tests could be measured. Secondly, two iPads were placed in the frontal and sagittal plane. The iPads were placed on a tripod at a height of 60 cm and a distance of 3.50 m from the patients [15]. Thirdly, reflective markers (n=11) were placed at predetermined anatomic points (i.e. manubrium sterni, acromioclavicular joint, anterior superior iliac spine, trochanter major, lateral femoral epicondyle and lateral malleolus) [15]. Furthermore, patients had to wear their own athletic shoes and a short. During the quality of movement measurements, females had to wear a sports bra and males were tested bare-chested. During the remaining part, the patients wore a t-shirt. The warming-up consisted of bipedal squats (i.e. 2x8 repetitions) and bipedal maximal jumps (i.e. 2x5 repetitions) [72].

4.2.2. Measurement

4.2.2.1. Quantity of movement

Four hop tests were assessed: (1) single hop for distance (SHD) [30,47,56,65,75], (2) triple hop for distance (THD) [47,56,65], (3) side triple hop for distance (STHD) [32,44] and (4) rotational hop for distance (RHD). Hop tests were executed based on descriptions of previous studies [22,30,32,44,47,56,65,75]. Only the RHD is a newly developed hop test and therefore the

description was not based on previous studies. The patients performed 1 practice trial with each leg followed by 3 successful trials with each leg [22]. If the last jump was the longest jump, the patients performed additional hops until no further improvement was obtained [75]. The patients first used their non-operated leg followed by their operated leg [30,65,75]. Hop tests had to end with a successful landing. A successful landing consisted of: (1) maintenance of balance for 2 seconds, (2) not touching the ground with the upper extremity or contralateral leg and (3) no additional hops [30,65]. Arm swing was allowed during testing [65]. Distance was measured at the most anterior part of the foot [65]. The patients had to rest 30 seconds between trials and 2 minutes between different hop tests [22,65]. Hop tests were performed in a randomized order [44]. Figure 1 shows the different hop tests. During the SHD, the patients had to perform 1 maximal hop for distance [30,47,56,65]. The THD consisted of 3 consecutive forward hops [47,56,65]. The STHD consisted of 3 consecutive hops in medial direction of the stance leg [32,44]. The patients started and stopped with their feet placed perpendicular to the measuring tape [32,44]. During the RHD, the patients started with their foot placed perpendicular to the measuring tape and ended with their feet parallel to the measuring tape. Hence the patients turned 90 degrees during the hop test.

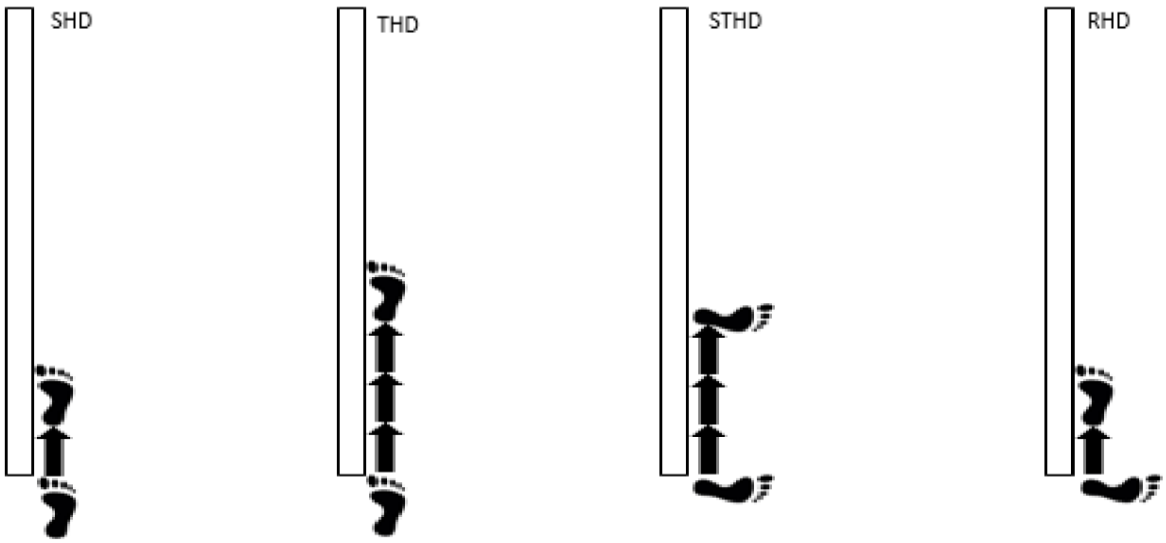

Fig. 1 | Graphical illustration of the hop tests. Abbreviations: SHD; single hop for distance, THD; triple hop for distance, STHD; side triple hop for distance and RHD; rotational hop for distance

4.2.2.2. Quality of movement

Movement qualitative tests were performed in the following order: (1) DVJ, (2) SLDVJ and (3) tuck jump. The DVJ is a bipedal jump-landing task [16]. The DVJ started with the patients standing on a box with a height of 30 cm [16]. The patients dropped off the box, landed on 2

feet and immediately performed a maximal jump for height [16]. During the vertical jump, the patients had to reach with both hands as high as possible [16]. A successful landing was defined as a landing at the same place [16]. Landing errors were: (1) reaching upward with only one hand, (2) loss of balance and (3) looking downwards instead of upwards [16]. The patients performed 2 practice trials followed by 3 successful trials [16].

The SLDVJ is a unipodal jump-landing task [15,17,72]. The SLDVJ started with the patients standing on a box with a height of 10 cm [17]. The patients dropped off the box, landed on 1 foot and immediately performed a maximal jump for height [17]. During the vertical jump, the patients had to reach with both hands as high as possible [15]. A successful landing was defined as a landing at the same place. Landing errors were: (1) reaching upward with only one hand, (2) loss of balance and (3) looking downwards instead of upwards [15]. The patients performed 2 practice trials followed by 3 successful trials with each leg.

The last movement qualitative test was the tuck jump [21]. During the tuck jump the patients had to bring their knees simultaneously towards their chest as many times as possible [21]. The patients had to perform repeated tuck jumps for 10 seconds [21]. They were instructed to land on the same footprint [21]. The patients were allowed to perform 2 practice trials followed by 1 successful trial [21].

4.2.2.3. PROMs

Patients were also asked to complete PROMs and particular questions at home. The following PROMs were assessed: (1) ACL-RSI, (2) KOOS, (3) K-SES and (4) IKDC. The ACL-RSI measures patients' emotions, confidence in performance and risk appraisal in relation to RTS after ACLR [70]. The questionnaire consists of 12 items with an 11-point numeric rating scale ranging from 0 to 100 [70].

The KOOS measures functional status and quality of life (QOL) of patients following ACLR [66]. The KOOS consists of 42 items and 5 dimensions: (1) pain (i.e. 9 items), (2) symptoms (i.e. 7 items), (3) activities of daily living (i.e. 17 items), (4) sport and recreational function (i.e. 5 items) and (5) knee-related QOL (i.e. 4 items) [13]. Each KOOS question should be rated on a scale from 0 to 4 [13].

The K-SES measures perceived self-efficacy in patients with an ACLR [31,74]. It consists of 22 items. The K-SES present consists of 18 items and the K-SES future consists of 4 items [74]. The 11-grade Likert scale ranges from 0 (i.e. not at all certain) to 10 (i.e. very certain) [74].

The IKDC subjective knee evaluation form measures symptoms, sport activity and function in patients with knee-related injuries such as ACLR [14,34,38,42]. The form is scored by summing the scores of the 10 questions [34].

4.2.3. Analysis of measurement

4.2.3.1. Quantitative outcome measure

Concerning the hop tests, distance was measured in centimetres and subsequently the LSI was calculated as quantitative outcome measure of hop tests. The LSI is the distance of the operated leg divided by the distance of the non-operated leg [65]. The LSI is traditionally expressed as a percentage hence the ratio was multiplied by 100 to obtain a percentage [65]. The best trial was used for data analysis [22,30,75].

4.2.3.2. Qualitative outcomes measures

Quality of movement was assessed with scoring sheets and joint angles. The DVJ was captured with the 2 iPads and the LESS scoring sheet was completed afterwards [15,60]. The LESS consists of 17 items [60]. The total LESS score is 17 and a lower score indicates a better jump-landing technique [7,60]. If patients scored an error in 2 of 3 trials, it was scored as an error on that specific LESS item [6].

The SLDVJ was processed with the SL-LESS (Single Leg-Landing Error Scoring System) scoring sheet and 2D video analysis [15,57]. The total SL-LESS score is 11 and a lower score indicates a better jump-landing technique [57]. Kinovea® (i.e. a software package) was used to examine well-defined angles (i.e. hip flexion and the sum of knee valgus with ipsilateral trunk lean) at the deepest landing point of the first landing. Knee valgus and ipsilateral trunk lean were drawn as previously described [17].

The knee valgus angle was defined as the angle between the following lines: (1) the line between the anterior superior iliac spine and the knee joint centre and (2) the line between the knee joint centre and the ankle joint centre [17]. Knee valgus angles lower than 180° represented higher knee valgus [17]. Trunk lean was defined as the angle between: (1) a vertical line that started at the ipsilateral anterior superior iliac spine and (2) the line formed by the ipsilateral anterior superior iliac spine and the manubrium sterni. Lower lateral trunk motion angles represented higher ipsilateral trunk lean (i.e. lateral trunk motion in the direction of the supporting leg) [17]. The angle was negative when the manubrium sterni was more lateral than the ipsilateral anterior superior iliac spine [17]. The sum of knee valgus and

lateral trunk motion was calculated and smaller values represented decreased quality of movement [17].

Hip flexion was measured as previously described [16]. Hip flexion was defined as the angle between: (1) the line formed by the acromioclavicular joint and the greater trochanter and (2) the line from the greater trochanter to the lateral femoral epicondyle [16]. Lower hip flexion angles represented more hip flexion [16]. The choice to correlate these specific angles with quantitative outcomes and PROMs was based on previous studies [9,16,17,37]. Landing with the trunk more erect (i.e. higher hip flexion angle) is suggested to be related to increased risk of ACLI [9,16]. Furthermore, the combination of increased ipsilateral trunk motion and knee valgus is also associated with an increased risk of ACLI [17,37].

The tuck jump was captured with the 2 iPads measuring at 120 frames per second and the tuck jump scoring sheet was completed afterwards [15,21]. The tuck jump assessment consists of 10 items [21]. Each item was scored with 0 (no error), 1 (i.e. small error) or 2 (i.e. large error) [21]. The total score is 20 and a lower score indicates a better performance [21]. An error (i.e. score 1 or 2) had to appear 2 or more times during the 10 second tuck jump assessment to be scored as an error [21].

4.2.3.3. PROMs

Concerning the PROMs, the ACL-RSI score ranged from 0 to 100 [70]. A higher ACL-RSI score indicates a better psychological response [70].

The KOOS score was a transformed score that ranged from 0 to 100 for each subscale [13]. A higher score indicates less problems [13]. Only the subscales: (1) sport and recreational function and (2) knee-related QOL were analysed [11,41].

The total K-SES and subscales scores (i.e. K-SES present and K-SES future) were analysed [31]. The total score and subscale scores ranged from 0 to 10 [31,74]. A higher score indicates higher perceived self-efficacy [74].

The IKDC score was calculated and converted into a score that ranged from 0 to 100 [13]. A higher score indicates: (1) lower levels of symptoms (e.g. pain), (2) higher levels of function and (3) higher levels of sport activity [42].

4.2.4. RTS test battery

The cut-off values of the RTS test battery were based on previous studies [1,14,27,31,47,60,73]. To pass these RTS criteria, patients had to meet all the criteria mentioned in table 2.

Table 2 | RTS criteria with cut-off values

LSI ≥ 90% on all hop tests: SHD, THD, STHD and RHD
LESS < 5 during the DVJ
K-SES: males > 7.2 and females > 6.8
IKDC score within 15th percentile of healthy gender–age-matched subjects
ACL-RSI scale > 56

Abbreviations: RTS; return to sport, LSI; limb symmetry index, SHD; single hop for distance, THD; triple hop for distance, STHD; side triple hop for distance, RHD; rotational hop for distance, LESS; Landing Error Scoring System, DVJ; drop vertical jump, K-SES: Knee Self-Efficacy Scale, IKDC; International Knee Documentation Committee Subjective Knee Form, ACL-RSI; Anterior Cruciate Ligament-Return to Sport after Injury.

4.3. Data analysis

All statistical analyses were performed with the statistical software package JMP (i.e. JMP pro 13.2). All outcome measures were first assessed for normality. Ordinal data (i.e. questionnaires and scoring sheets) were assessed with Spearman's Rho. Continuous data were assessed with Pearson's correlation coefficient if they were normally distributed. The significance level was set at $p < 0.05$ for all analyses. The magnitudes of the obtained correlations were considered as: very small (i.e. < 0.10), small (i.e. 0.10-0.30), moderate (i.e. 0.30-0.50), high (i.e. 0.50-0.70), very high (i.e. 0.70-0.90) and extremely high (0.90-1) [39]. Subsequently, descriptive statistics (i.e. percentages, means and standard deviations) were calculated to clarify the percentage of patients that passed the well-defined RTS criteria.

5. Results

Table 3 represents the correlations between quantitative and qualitative outcomes. There were no statistically significant correlations between these outcomes. Table 4 gives an overview of correlations between PROMs and quantitative outcomes. Table 5 summarizes correlations between PROMs and qualitative outcomes. High to very high statistically significant correlations were found between: (1) PROMs and quantitative outcomes and (2) PROMs and qualitative outcomes. Consequently, we could not reject all the null hypotheses because there were no statistically significant correlations between quantitative and qualitative outcomes. None of the 14 patients passed all criteria of the RTS test battery. The results of the RTS test battery are represented in table 6.

Table 3 | Correlations between quantitative outcomes and qualitative outcomes

	SHD	THD	STHD	RHD
Tuck Jump	0.17[a]	0.09[a]	-0.11[a]	-0.16
LESS DVJ	-0.13[a]	-0.15[a]	-0.33[a]	-0.06[a]
LESS SLDVJ-O	0.27[a]	0.20[a]	-0.26[a]	-0.03[a]
LESS SLDVJ-NO	0.07[a]	0.02[a]	-0.04[a]	-0.29[a]
KVLTM-O SLDVJ	-0.15[a]	-0.17[a]	-0.19[b]	0.21[b]
HF-O SLDVJ	-0.31[a]	-0.33[a]	-0.42[b]	-0.19[b]
KVLTM-NO SLDVJ	-0.51[a]	-0.31[a]	0.01[b]	0.20[b]
HF-NO SLDVJ	-0.29[a]	-0.34[a]	-0.27[b]	-0.10[b]

Abbreviations: LESS; Landing Error Scoring System, DVJ; drop vertical jump, SLDVJ; single leg drop vertical jump, O; operated knee, NO; non-operated, KVLTM; knee valgus lateral trunk motion, HF; hip flexion, SHD; single hop for distance, THD; triple hop for distance, STHD; side triple hop for distance and RHD; rotational hop for distance.
a Spearman's Rho.
b Pearson's correlation coefficient

Table 4 | Correlations between PROMs and quantitative outcomes

	SHD	THD	STHD	RHD
ACL-RSI	0.47	0.42	0.30	0.36
KOOS sport/recreation	0.51	0.41	0.17	**0.57***
KOOS QOL	0.35	0.24	0.10	-0.06
K-SES	**0.71***	**0.58***	**0.67***	**0.70***
K-SES present	**0.67***	**0.54***	**0.64***	**0.70***
K-SES future	**0.71***	**0.58***	0.53	0.43
IKDC	**0.76***	**0.61***	**0.55***	0.38

In **bold***: significant correlations. Abbreviations: ACL-RSI; Anterior Cruciate Ligament-Return to Sport after Injury, KOOS; Knee injury and Osteoarthritis Outcome Score, ADL; activities of daily living, QOL; quality of life, K-SES; Knee Self-Efficacy Scale, IKDC; International Knee Documentation Committee Subjective Knee Form, SHD; single hop for distance, THD; triple hop for distance, STHD; side triple hop for distance and RHD; rotational hop for distance.

Table 5 | Correlations between PROMs and qualitative outcomes

	Tuck jump	LESS DVJ	LESS SLDVJ-O	LESS SLDVJ-NO	KVLTM-O SLDVJ	HF-O SLDVJ	KVLTM-NO SLDVJ	HF-NO SLDVJ
ACL-RSI	0.07	**-0.56***	0.00	-0.32	-0.32	-0.25	-0.42	-0.39
KOOS sport/recreation	0.05	0.14	0.33	0.24	0.01	-0.02	-0.28	-0.01
KOOS QOL	**0.56***	-0.21	0.16	-0.14	**-0.55***	**-0.58***	**-0.64***	**-0.55***
K-SES	0.02	-0.33	-0.16	-0.08	-0.26	-0.42	-0.36	-0.33
K-SES present	-0.02	-0.31	-0.19	-0.07	-0.25	-0.38	-0.33	-0.28
K-SES future	0.05	**-0.55***	0.02	-0.06	-0.29	-0.38	**-0.57***	**-0.54***
IKDC	0.16	-0.31	0.15	0.13	-0.35	-0.49	**-0.78***	-0.48

In **bold***: significant correlations. Abbreviations: ACL-RSI; Anterior Cruciate Ligament-Return to Sport after Injury, KOOS; Knee injury and Osteoarthritis Outcome Score, ADL; activities of daily living, QOL; quality of life, K-SES; Knee Self-Efficacy Scale, IKDC; International Knee Documentation Committee Subjective Knee Form, LESS; Landing Error Scoring System, DVJ; drop vertical jump, SLDVJ; single leg drop vertical jump, O; operated knee NO; non-operated knee, KVLTM; knee valgus lateral trunk motion and HF; hip flexion.

Table 6 | RTS test battery

Pass criteria	Percentage of patients that passed the criterion	Mean ± SD
LSI ≥ 90% SHD, THD, STHD and RHD	21.43%	0.87 ± 0.11
LSI ≥ 90% SHD	64.29%	0.90 ± 0.11
LSI ≥ 90% THD	57.14%	0.88 ± 0.10
LSI ≥ 90% STHD	50.00%	0.86 ± 0.12
LSI ≥ 90% RHD	42.86%	0.86 ± 0.11
LESS < 5	0.00%	7.50 ± 1.30
K-SES males > 7.2	66.67%	7.66 ± 1.25
K-SES females > 6.8	50.00%	6.20 ± 1.00
IKDC score within 15 % of healthy gender–age-matched subjects	21.43%	79.47 ± 9.81
ACL-RSI > 56	42.86%	56.51 ± 19.53

Abbreviations: SD; standard deviation, LSI; limb symmetry index, SHD; single hop for distance, THD; triple hop for distance, STHD; side triple hop for distance, RHD; rotational hop for distance, LESS; ; Landing Error Scoring System, K-SES: Knee Self-Efficacy Scale, IKDC; International Knee Documentation Committee Subjective Knee Form, ACL-RSI; Anterior Cruciate Ligament-Return to Sport after Injury.

6. Discussion

6.1. The relationship between quantity of movement and quality of movement

The main goal of this study was to assess the relationship between commonly assessed clinical-oriented quantitative and qualitative RTS outcomes in an ACLR group 6 months following surgery. No statistically significant correlations were found between quantitative outcomes of hop tests and various qualitative outcomes. This is in line with previous studies where there was no association between the SHD and biomechanical asymmetries during landing in patients following ACLR [79,85]. Xergia, Pappas & Georgoulis (2015) did not found statistically significant correlations between the LSI of the SHD and well-defined biomechanical asymmetries (i.e. LSI peak hip flexion angle, LSI peak knee flexion angle, LSI peak ankle dorsiflexion angle, LSI peak hip flexion moment, LSI peak knee flexion moment and LSI peak ankle dorsiflexion moment) measured with three-dimensional motion analysis [85].

Further, a recent study of Welling et al. (2018) demonstrated only small statistically significant correlations between jumping distance and kinematic outcomes (i.e. knee flexion at initial contact, peak knee flexion, knee flexion ROM and knee valgus ROM) measured with 2D video analysis during the SHD [79]. Hence these 2 studies concluded that quantity of movement (i.e. jumping distance) and quality of movement (i.e. jumping technique) are not strongly related [79,85].

6.2. The relationship between PROMS and quantity of movement

Generally, PROMs were positively correlated with hop tests indicating that higher self-reported physical and psychological functioning is associated with more symmetric hop performance. Several high to very high statistically significant correlations were found between PROMs and quantity of movement. For example, all hop tests were statistically significant correlated with the K-SES. Hence patients who were more certain about carrying out different activities (i.e. higher K-SES score) demonstrated better jump performances (i.e. higher LSIs) during hop tests.

Interestingly, a recent study identified clinical factors that predict a second ACLI following ACLR and RTS [63]. Two high risk profiles were identified. The content of the first high-risk

profile was: (1) < 19 years old, (2) THD normalized to height (i.e. 1.34 - 1.90 times body height) and (3) THD < 98.50% LSI [63]. The content of the second high-risk profile was: (1) < 19 years old, (2) THD normalized to height (i.e. > 1.34 times body height), (3) THD > 98.50% LSI, (4) female sex and (5) high knee-related confidence [63]. This study shows that therapists also have to be careful with patients within a certain risk profile because high physical capacity and high knee-related confidence may result in greater willingness to RTS and higher intensity of play despite the fact that tissue healing and graft maturation has not yet entirely occurred [55,63].

6.3. The relationship between PROMs and quality of movement

Further, high to very high statistically significant correlations were found between PROMs and qualitative outcomes. However higher self-reported physical and psychological functioning was not always associated with a better jump-landing technique. On the one hand, patients who reported that they felt more certain about their knee function in the future (i.e. higher K-SES future score) demonstrated a better jump landing technique (i.e. lower LESS) during the DVJ. On the other hand, patients who reported that they felt more certain about their knee function in the future (i.e. higher K-SES future score) demonstrated more knee valgus lateral trunk motion of the non-operated leg (KVLTM-NO) during the SLDVJ. Hence despite the fact that self-efficacy is known to be beneficial during rehabilitation and RTS testing, therapist should be vigilant because re-injuries occur mostly contralateral and this less optimal movement pattern of the non-operated leg is considered as one of the risk factors of an ACLI [15,82,84].

In addition, the statistical method used in our study allows us to identify an association between landing technique and knee-related confidence, but it does not allow us to draw information about whether one variable moves in response to another because a statistically significant correlation does not imply causation [52].

Further, both hip flexion of the operated leg (HF-O) and hip flexion of the non-operated leg (HF-NO) were statistically significant negative correlated with the KOOS-QOL. Hence patients who: (1) were often reminded of their knee, (2) adjusted their life to spare their knee, (3) did not trust their knee and (4) experienced hindrance of their knee, demonstrated less hip flexion (i.e. stiffer landing) during the SLDVJ with their operated and non-operated leg. Despite the

fact that few studies assessed the relationship between quality of movement and PROMs, there are some studies with similar results. A previous study found that fear of re-injury was statistically significant correlated with a stiffer landing pattern (i.e. less hip flexion) [76]. Fear of re-injury at the moment of RTS was also associated with an increased risk of a second ipsilateral ACLI within 24 months of RTS following ACLR [62]. However fear of re-injury was not associated with contralateral second ACLI within 24 months of RTS following ACLR [62].

6.4. RTS test battery

The third purpose of this study was to assess the percentage of patients that would pass a well-defined RTS test battery 6 months following surgery. None of the patients passed the RTS test battery 6 months following ACLR. This is in line with previous studies which already demonstrated that patients do not pass well-defined RTS criteria to safely RTS 6 months following ACLR [27,80]. Nevertheless, the percentage of patients that passed a specific RTS criterion (e.g. LESS < 5) was low compared to previous studies [27,80]. None of the patients in this study had an acceptable LESS score while 67.90% and 51.60% passed this criterion in previous studies [27,80]. These lower success rates could be explained by the fact that a standardized rehabilitation protocol was used in these previous studies while rehabilitation was not controlled in this study.

Moreover, recent studies highlighted the importance of evidence-based rehabilitation because there is alarming underutilisation of rehabilitation (i.e. inadequate rehabilitation content or premature RTS) in athletes following ACLR [18,24,28,77]. This evidence-based rehabilitation consists of 1 pre-operative and 3 criterion-based post-operative phases [77]. A battery of: (1) strength tests, (2) hop tests, (3) quality of movement and (4) psychological tests are recommended to guide progression during rehabilitation [77]. In addition van Melick et al. (2016) recommend a postoperative rehabilitation period of 9-12 months. Consequently, it is not surprising that the patients in this study did not pass the RTS test battery because currently RTS 6 months following ACLR is discouraged [29].

6.5. Clinical implications

Some suggestions for further research were made. First, no statistically significant correlations were found between quantity and quality of movement. This highlights the importance of multifactorial RTS test batteries because both quantitative and qualitative outcomes have

been associated with re-injuries in previous studies [63,64]. Future research should investigate which combination of clinical-oriented RTS outcomes can predict a second ACLI with high sensitivity and specificity.

Second, PROMs were associated with quantitative and qualitative outcomes. Strong statistically significant correlations were found between PROMs and quantitative outcomes. However this clear association was not found between PROMs and quality of movement. Higher self-reported physical and psychological functioning resulted in more symmetric hop performance but it did not always result in a better jump-landing technique. Future studies should investigate these results, because both too little and too much self-reported physical and psychological functioning (e.g. too little and too much self-efficacy) may be disadvantageous during RTS testing. In addition, future studies should assess the association between patient-reported outcomes (e.g. fear of re-injury and self-efficacy) and the incidence of a second (i.e. ipsilateral or contralateral) ACLI.

6.6. Strengths of the study

This was the first study that gave an overview of the relationship between commonly assessed clinical-oriented RTS outcomes in an ACLR group 6 months following ACLR [5,14]. Furthermore, detailed descriptions of all tests and outcomes were given. Standardisation of methodology is important for the generalisability of findings [35].

6.7. Limitations of the study

Several limitations should be noted in this study. First, the sample size was small as only 14 patients were included in this study. This small amount of patients does not allow us to obtain low to moderate statistically significant correlations. According to Hulley et al (2013), 29 to 783 patients would be required to obtain significant results for moderate (i.e. 0.30-0.50) to low (i.e. 0.10-0.30) correlations [39,40].

Second, quantitative outcome measures of particular tests were correlated with qualitative outcome measures of different tests. It may be more interesting to correlate quantitative outcome measures (e.g. LSI values or absolute values of distance covered during a hop test) with qualitative outcome measures (e.g. knee valgus during a hop test) of the same test because in this way the demands of the task are similar. Hop tests are very often used during RTS testing but it is difficult to perform a qualitative analysis that is simple and clinical-

oriented, especially if multidirectional hop tests or hop tests that consist of multiple jumps are assessed [79].

Third**,** LSIs of hop tests were correlated with well-defined qualitative outcome measures. Some of these qualitative outcome measures were analysed unilaterally (e.g. KVLTM-O) while the LSI is a ratio obtained by measuring performance of the operated and the non-operated side. Recent studies questioned the use of the LSI as quantitative outcome measure of hop tests because LSIs may overestimate knee function following ACLR [26,81]. This can be explained by the fact that bilateral deficits are present following ACLR [26,81]. Therefore it may be interesting to correlate absolute values of hop tests with these unilaterally measured qualitative outcome measures (e.g. KVLM-O).

Fourth, rehabilitation was not controlled. The RTS decision-making process is a continuum which starts with pre-operative rehabilitation and end with RTS testing [77]. The rehabilitation period is a long and important period that strongly influences the results of RTS outcomes [18].

Fifth, in the past few years more and more studies payed attention to quality of movement following ACLR [64,79,85]. However currently it is unknown which cut-off scores should be used for scoring sheets (i.e. LESS, SL-LESS and tuck jump assessment) to predict a safe RTS (i.e. low risk of second ACLI). Regarding the joint angles, it is difficult to determine clinical cut-off scores. For example, a previous study of Paterno et al. (2010) demonstrated that patients who suffered a second ACLI had an average of 16.20° knee valgus during 3 DVJs measured with 2D motion analysis [64]. This result was obtained by doing planned DVJs in a controlled laboratory setting with patients in a non-fatigue condition. However quality of movement may be influenced by various factors such as: (1) the task (e.g. planned or unplanned) [10], (2) the environment (e.g. a closed laboratory environment or an open clinical environment) [14], (3) fatigue [25] and (4) the content of the rehabilitation protocol [23,78]. In conclusion, quality of movement is influenced by several factors and future studies should pay attention to all these factors when assessing readiness to RTS.

Finally, previous studies already identified several sex-related differences following ACLR [61,67,69]. Therefore, generalizability may be low because 12 of the 14 included patients in this study population were males.

7. Conclusion

First, there was no clear association between quantitative and qualitative outcomes. This highlights the importance of multifactorial RTS test batteries because both quantitative and qualitative outcomes have been associated with re-injuries in previous studies. Second, strong correlations were found between PROMs and quantitative outcomes. Generally, PROMs were high to very high statistically significant correlated with hop tests indicating that higher self-reported physical and psychological functioning was associated with more symmetric hop performance. Third, no clear association was found between PROMs and qualitative outcomes. Higher self-reported physical and psychological functioning was not always associated with a better jump-landing technique.

Furthermore, none of the patients passed the RTS test battery 6 months following ACLR. Therapists should keep in mind that the RTS decision-making process is a continuum which starts with evidence-based rehabilitation and ends with RTS testing more than 6 months following ACLR.

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9. Appendices

List of abbreviations	
2D	two-dimensional
ACLI	anterior cruciate ligament injury
ACLR	anterior cruciate ligament reconstruction
ACL-RSI	Anterior Cruciate Ligament- Return to Sport after Injury
ADL	activities of daily living
DVJ	drop vertical jump
HF-NO	hip flexion of the non-operated leg
HF-O	hip flexion of the operated leg
IKDC	International Knee Documentation Committee Subjective Knee Form
KOOS	Knee injury and Osteoarthritis Outcome Score
K-SES	Knee Self-Efficacy Scale
KVLTM-NO	knee valgus ipsilateral trunk motion of the non-operated leg
KVLTM-O	knee valgus lateral trunk motion of the operated leg
LESS	Landing Error Scoring System
LSI	limb symmetry index
PROMs	patient reported outcome measures
QOL	quality of life
RHD	rotational hop for distance
RTS	return to sport
SHD	single hop for distance
SLDVJ	single leg drop vertical jump
SL-LESS	Single Leg-Landing Error Scoring System
STHD	side triple hop for distance
THD	triple hop for distance

Informatiebrochure en toestemmingsformulier patiënten

Titel van de studie:
Onderzoek naar een optimalisatie van klinische testen ter evaluatie van de terugkeer tot sport na een voorste kruisband reconstructie

Opdrachtgever:
In opdracht van Universiteit Hasselt, Martelarenlaan 42, 3500 Hasselt

Onderzoeksinstelling:
REVAL – Studiecentrum voor revalidatieonderzoek, Agoralaan gebouw A, 3590 Diepenbeek
Ziekenhuis Oost-Limburg, Schiepse Bos 6, 3600 Genk

Ethisch comité:
Comité voor Medische Ethiek UHasselt

Plaatselijke artsen-onderzoekers:

dr. Bart Dingenen	REVAL, UHasselt
Prof. dr. Johan Bellemans	REVAL, UHasselt; Ziekenhuis Oost-Limburg, Genk
dr. ir. Stijn Quanten	Online Tools for Human Organizations - Othor ®
dr. Alli Gokeler	Universiteit Groningen
Prof. dr. Jan Truijen	Morfologie, UHasselt; Ziekenhuis Oost-Limburg, Genk

Geachte heer / mevrouw,

U wordt uitgenodigd om deel te nemen aan een observationele studie, die door de Universiteit Hasselt wordt uitgevoerd, in samenwerking met het Ziekenhuis Oost-Limburg (ZOL), Genk. Het betreft een studie naar de beslissing of iemand klaar is om terug te gaan sporten na een voorste kruisband reconstructie. Hiervoor worden een heel aantal metingen uitgevoerd, die ons in staat zullen stellen een beter beeld te vormen over het functioneren van personen na een voorste kruisband reconstructie. Het doel van deze studie is uiteindelijk de beslissing om terug te keren tot sport na een voorste kruisband reconstructie te verbeteren in de klinische praktijk.

Voordat u akkoord gaat om aan deze studie deel te nemen, vragen wij u om kennis te nemen van wat deze studie zal inhouden op het gebied van organisatie, zodat u een welbewuste beslissing kunt nemen. Dit wordt een “geïnformeerde toestemming” genoemd. Wij vragen u de volgende pagina’s met informatie aandachtig te lezen. Heeft u vragen, dan kan u terecht bij de arts-onderzoeker of zijn of haar vertegenwoordiger.

Dit document bestaat uit 3 delen: 1. de noodzakelijke informatie die u nodig heeft voor het nemen van uw beslissing of u wel of niet zal deelnemen, 2. uw schriftelijke toestemming en 3. aanvullende informatie waarin u meer details terugvindt over bepaalde onderdelen van de basisinformatie.

I. Noodzakelijke informatie voor uw beslissing om deel te nemen

Als u aan deze studie deelneemt, moet u weten dat:

- De behandeling die de arts-onderzoeker u in overeenstemming met de huidige aanbevelingen heeft voorgesteld niet zal veranderen door uw deelname aan deze studie.
- Deze klinische studie opgesteld is na evaluatie door één of meerdere ethische comités.
- Uw deelname is vrijwillig; er kan op geen enkele manier sprake zijn van dwang. Voor deelname is uw ondertekende toestemming nodig. Ook nadat u hebt getekend, kan u de arts-onderzoeker laten weten dat u uw deelname wilt stopzetten.
- De gegevens die in het kader van uw deelname worden verzameld, zijn vertrouwelijk. Bij de publicatie van de resultaten is uw anonimiteit verzekerd.
- Er is een verzekering afgesloten voor het geval dat u schade zou oplopen in het kader van uw deelname aan deze klinische studie.
- Indien u extra informatie wenst, kan u altijd contact opnemen met de arts-onderzoeker of een medewerker van zijn of haar team.

Aanvullende informatie over uw “Rechten als deelnemer aan een klinische studie” vindt u in bijlage XX.

Doelstellingen en verloop van de studie

Een voorste kruisband (VKB) ruptuur is een knieblessure die een langdurige revalidatie met zich meebrengt. De meeste patiënten ondergaan een VKB reconstructie na een VKB ruptuur. Wetenschappelijk gezien bestaan er de dag van vandaag nog veel vragen over de meest optimale criteria waaraan een sporter moet voldoen om veilig terug te keren tot sport (in het Engels return to sport). Dit kan minder optimale resultaten op lange termijn na een VKB reconstructie in de hand werken.

Het doel van deze studie is uiteindelijk de beslissing om terug te keren tot sport na een voorste kruisband reconstructie te verbeteren in de klinische praktijk. Om dit doel te bereiken, zal u gevraagd worden verschillende testen uit te voeren en vragenlijsten in te vullen. Deze metingen zullen 6 maanden en 12 maanden na de operatie gebeuren. Enkel de vragenlijsten en de neurocognitieve testen (zie later) zullen op 0, 3, 6, 9 en 12 maanden worden uitgevoerd. Deze testen nemen slechts een minimale tijd in beslag (20 minuten) en kunnen thuis online worden uitgevoerd op een computer. Na het verzamelen van de data wordt u 2 jaar opgevolgd naar sportparticipatie en blessures toe. Dit zal gebeuren door u terug te contacteren 1 en 2 jaar na de laatste metingen. Voor deze opvolging dient u enkel en alleen enkele vragenlijsten in te vullen, welke digitaal worden verstuurd via een online platform waarmee vragenlijsten in een beveiligde omgeving kunnen afgenomen worden (www.surveymonkey.com). De resultaten van dit onderzoek zouden ons toelaten te bestuderen of sommige testen meer of minder geschikt zullen zijn om te integreren binnen een return to sport beslissing. De doelstelling is dat de testen die in dit project gebruikt worden makkelijk toepasbaar zijn in de klinische praktijk. Op deze manier kan de return to sport beslissing in de toekomst met een bredere wetenschappelijk ondersteuning gebeuren. Verder kunnen de resultaten bijdragen tot een optimalisatie van preventieve maatregelen om de kans om een nieuwe VKB of andere blessure te krijgen in de toekomst te verkleinen.

Wij stellen u voor om aan deze studie deel te nemen omdat uw arts bij u een voorste kruisband reconstructie heeft uitgevoerd in het kader van uw klinische situatie.

Aan deze klinische studie zouden 50 patiënten moeten deelnemen waarvan ongeveer 50 patiënten in België, en 50 controle proefpersonen, waarvan 50 in België.

Om te toetsen of u kunt deelnemen aan deze studie, hebben wij enkele in- en exclusie criteria opgesteld, waaraan u moet voldoen voordat wij u kunnen toelaten in de studie.

Inclusiecriteria:

1. Aanwezigheid van een VKB reconstructie aan 1 knie, met een hamstrings autogreffe.
2. Leeftijd van de patiënt gelijk of groter dan 18 jaar en jonger dan 45 jaar.
3. Bereid zijn om het informed consent te tekenen.

Patiënten worden geëxcludeerd indien aan één of meer van de volgende criteria wordt voldaan:

1. Revisie VKB chirurgie (meer dan een 1-malige VKB reconstructie).
2. Meniscectomie die meer dan 1/3 van de meniscus behelzen in de knie met de VKB reconstructie.
3. Traumatische kraakbeenletsels ten gevolge van het VKB letsel.
4. Een voorgeschiedenis van een graad 3 letsel van de achterste kruisband of collaterale gewrichtsbanden, of letsel van de posterolaterale hoek, in de knie met de VKB reconstructie.
5. Een voorgeschiedenis van een graad 3 ligamentair letsel in de contralaterale knie (i.e. letsel van de VKB, achterste kruisband, lateraal collateraal ligament, mediaal collateraal ligament of posterolaterale hoek).
6. Voorgeschiedenis van een majeur trauma en/of majeure orthopedische chirurgie ter hoogte van de lumbale wervelkolom, bekken of het onderste lidmaat (buiten de VKB reconstructie).
7. Aanwezigheid van één van volgende aandoeningen of constituties: neurologische of vestibulaire stoornissen, zwangerschap.

De duur van uw deelname aan deze studie bestaat uit 7 meetmomenten (0, 3, 6, 9 en 12 maanden na de voorste kruisband reconstructie, en de online opvolging via de vragenlijsten op 1 en 2 jaar na de laatste meting, wat wil zeggen 24 en 36 maanden na de operatie). Tijdens deze studie zal uw arts-onderzoeker u vragen om alle voor de studie noodzakelijke gegevens en informatie te verzamelen - zoals uw demografische gegevens (leeftijd, gewicht, lengte, geslacht).

Uw arts-onderzoeker zal u ook vragen om verschillende vragenlijsten in te vullen die knie-specifieke symptomen, functie, sportactiviteiten, motivatie en tevredenheid evalueren.

Het invullen van deze vragenlijsten zal ongeveer 10 minuten van uw tijd in beslag nemen tijdens elk meetmoment.

Naast deze vragenlijsten, wordt er tijdens de metingen op 0, 3, 6, 9 en 12 maanden ook een set van neurocognitieve testen afgenomen. Dit zijn testen die verschillende soorten van reactietijden zullen evalueren. Deze testen worden uitgevoerd op een computer via een online platform, waarvoor u een login zal krijgen en deze testen thuis kan uitvoeren. Het uitvoeren van deze testen duurt ook slechts een 10-tal minuten. Op 6 maanden en 12 maanden na de voorste kruisband reconstructie zullen er ook verschillende andere testen uitgevoerd de volgende aspecten evalueren:

- Sprongafstand, spronghoogte (bewegingskwantitatieve testen)
- Snelheid van richtingsveranderingen (dynamische reactiesnelheid)

- De manier van bewegen wordt tijdens enkele functionele taken zoals het buigen door 1 been en het springen op 2 benen, het springen op 1 been en het evenwicht bewaren geëvalueerd (bewegingskwalitatieve testen)
- Kracht van de heup, knie en kuitspieren

Al deze metingen zijn niet-invasief en worden uitgevoerd in het Studiecentrum voor Revalidatieonderzoek REVAL aan de Universiteit Hasselt (Agoralaan, gebouw A, 3590 Diepenbeek). Deze metingen in het labo zullen ongeveer 2 uur in beslag nemen. In onderstaande tabel worden de metingen binnen dit onderzoeksproject schematisch en chronologisch weergegeven:

Tijdstip na de operatie	**Metingen**	**Locatie**
0 maanden	Vragenlijsten Fundamentele neurocognitieve testen	Thuis op pc
3 maanden	Vragenlijsten Fundamentele neurocognitieve testen	Thuis op pc
6 maanden	Vragenlijsten Fundamentele neurocognitieve testen Dynamische reactiesnelheid testen Bewegingskwantitatieve testen Bewegingskwalitatieve testen Krachttesten	Labo UHasselt
9 maanden	Vragenlijsten Fundamentele neurocognitieve testen	Thuis op pc
12 maanden	Vragenlijsten Fundamentele neurocognitieve testen Dynamische reactiesnelheid testen Bewegingskwantitatieve testen Bewegingskwalitatieve testen Krachttesten	Labo UHasselt
24 maanden	Vragenlijsten	Thuis op pc
36 maanden	Vragenlijsten	Thuis op pc

Wat moet ik meenemen naar het onderzoekslabo?

Wanneer u een afspraak heeft in het Studiecentrum voor Revalidatieonderzoek REVAL aan de Universiteit Hasselt (Agoralaan, gebouw A, 3590 Diepenbeek) om uw testen op 6 en 12 maanden uit te voeren, wordt gevraagd een short, nauw aansluitend T-shirt en sportschoenen mee te nemen.

Beschrijving van de risico's en van de voordelen

Er zijn geen bijkomende risico's verbonden aan de deelname aan bovengenoemde experimentele metingen ten opzichte van de standaardprocedure die gevolgd wordt bij een voorste kruisband ruptuur. Er wordt voldoende rust gelaten tussen de verschillende testen. Het onderzoeksteam zal al het mogelijke doen om een aangename sfeer te creëren tijdens het onderzoek. Het voordeel voor u is dat er tijdens de meetmomenten ook feedback kan geformuleerd worden, binnen de mate waarin dit wetenschappelijk op dit moment reeds kan. U moet begrijpen dat de resultaten van het onderzoek zullen bijdragen tot een verhoogd inzicht in de return to sport beslissing na een voorste kruisband reconstructie waardoor in de toekomst een meer optimale opvolging kan worden uitgewerkt. De deelname aan dit onderzoek brengt geen kosten voor u mee. Er wordt geen extra vergoeding voorzien voor de medewerking aan het onderzoek.

Intrekking van uw toestemming

U neemt vrijwillig deel aan deze studie en u hebt het recht om uw toestemming voor gelijk welke reden in te trekken. U hoeft hiervoor geen reden op te geven.

Als u uw toestemming intrekt, zullen de gegevens bewaard blijven die tot op het ogenblik van uw stopzetting werden verzameld. Dit om de geldigheid van de studie te garanderen. Er zal geen enkel nieuw gegeven aan de opdrachtgever worden gegeven.

De opdrachtgever/verantwoordelijke van de studie zou ook kunnen beslissen om de studie te stoppen indien:

- U zich niet houdt aan de instructies voor deelname aan de studie
- Verdere deelname aan de studie schadelijk blijkt te zijn voor u
- Er na inclusie wordt ontdekt dat u niet aan de studievoorwaarden voldoet
- De opdrachtgever de studie stop zet wegens andere (onbekende) redenen

Als u aan deze studie deelneemt, vragen wij om:

- Tenvolle mee te werken voor een correct verloop van de studie.
- Geen informatie over uw gezondheidstoestand of de symptomen die u ervaart te verzwijgen.
- Uw arts-onderzoeker op de hoogte te brengen als men u voorstelt om aan een andere studie deel te nemen zodat u met hem/haar kan bespreken of u aan deze studie kunt deelnemen en of uw deelname aan de huidige klinische studie moet worden stopgezet.

Contact

Als u bijkomende informatie wenst, maar ook ingeval van problemen of als u zich zorgen maakt, kan u contact opnemen met de arts-onderzoeker (dr. Bart Dingenen) via het e-mail adres bart.dingenen@uhasselt.be of het telefoonnummer +3211299203.

Als u vragen hebt met betrekking tot uw rechten als deelnemer aan de studie, kan u contact opnemen met de ombudsdienst in uw ziekenhuis op het telefoonnummer +3289321521. Indien nodig kan de ombudsdienst u in contact brengen met het Ethisch Comité.

Onderzoek naar een optimalisatie van klinische testen ter evaluatie van de terugkeer tot sport na een voorste kruisband reconstructie

II. Geïnformeerde toestemming

Deelnemer

- ✓ Ik verklaar dat ik geïnformeerd ben over de aard, het doel, de duur, de eventuele voordelen en risico's van de studie en dat ik weet wat van mij wordt verwacht.
- ✓ Ik heb kennis genomen van het informatiedocument en de bijlagen ervan.
- ✓ Ik heb voldoende tijd gehad om na te denken en met een door mij gekozen persoon, zoals mijn huisarts of een familielid, te praten.
- ✓ Ik heb alle vragen kunnen stellen die bij me opkwamen en ik heb een duidelijk antwoord gekregen op mijn vragen.
- ✓ Ik begrijp dat mijn deelname aan deze studie vrijwillig is en dat ik vrij ben mijn deelname aan deze studie stop te zetten zonder dat dit mijn relatie schaadt met het therapeutisch team dat instaat voor mijn gezondheid.
- ✓ Ik begrijp dat er tijdens mijn deelname aan deze studie gegevens over mij zullen worden verzameld en dat de arts-onderzoeker en de opdrachtgever de vertrouwelijkheid van deze gegevens verzekeren overeenkomstig de Belgische wetgeving ter zake.
- ✓ Ik stem in met de verwerking van mijn persoonlijke gegevens volgens de modaliteiten die zijn beschreven in de rubriek over het verzekeren van de vertrouwelijkheid (bijlage XX).
- ✓ Ik ga ermee akkoord dat de studiegegevens die voor de hier vermelde studie worden verzameld, later zullen worden verwerkt, op voorwaarde dat deze verwerking beperkt blijft tot de context van de hier vermelde studie voor een betere kennis van de ziekte en de behandeling ervan.
- ✓ Ik heb een exemplaar ontvangen van de informatie aan de deelnemer en de geïnformeerde toestemming.

Naam	Datum	Handtekening deelnemer
_____	_____	_____

Arts-Onderzoeker

- ✓ Ik verklaar de benodigde informatie inzake deze studie mondeling te hebben verstrekt evenals een exemplaar van het informatiedocument aan de deelnemer te hebben verstrekt.
- ✓ Ik bevestig dat geen enkele druk op de deelnemer is uitgeoefend om hem/haar te doen toestemmen met deelname aan de studie en ik ben bereid om op alle eventuele bijkomende vragen te antwoorden.
- ✓ Ik bevestig dat ik werk in overeenstemming met de ethische beginselen zoals vermeld in de "Verklaring van Helsinki", de "Goede klinische praktijk" en de Belgische wet van 7 mei 2004 inzake experimenten op de menselijke persoon.

Naam	Datum	Handtekening onderzoeker
_____	_____	_____

III. Geïnformeerde toestemming

Aanvullende informatie over de bescherming en de rechten van de deelnemer aan een klinische studie

Ethisch comité

Deze studie werd geëvalueerd door de onafhankelijke ethisch comités van het Ziekenhuis Oost-Limburg en de Universiteit Hasselt, die een gunstig advies hebben uitgebracht. Een ethische comité heeft de taak om personen die aan klinische studies deelnemen te beschermen. Ze controleren of uw rechten als patiënt en als deelnemer aan een studie gerespecteerd worden, of de studie wetenschappelijk relevant en ethisch verantwoord is.

Hierover brengen de ethische comités een advies uit in overeenstemming met de Belgische wet van 7 mei 2004. U dient het positief advies van de Ethische Comités in geen geval te beschouwen als een aansporing om deel te nemen aan deze studie.

Vrijwillige deelname

Aarzel niet om alle vragen te stellen die u nuttig vindt voordat u tekent. Neem de tijd om er met een vertrouwenspersoon over te praten, als u dit wenst. U heeft het recht om niet deel te nemen aan deze studie of met deze studie te stoppen zonder dat u hiervoor een reden hoeft te geven, zelfs al hebt u eerder toegestemd om aan deze studie deel te nemen.

Als u aanvaardt om aan deze studie deel te nemen, ondertekent u het toestemmingsformulier. De onderzoeker zal dit formulier ook ondertekenen en zal zo bevestigen dat hij u de noodzakelijke informatie voor deze studie heeft gegeven. U zult het voor u bestemde exemplaar ontvangen.

Kosten in verband met uw deelname

De opdrachtgever heeft voorzien om de universiteit te vergoeden voor de tijd die de onderzoeker en zijn team aan deze studie besteden. Uw deelname zal echter voor u geen bijkomende kosten met zich meebrengen. Een vergoeding voor de reiskosten zal worden voorzien.

Vertrouwelijkheidgarantie

Uw deelname aan de studie betekent dat u ermee akkoord gaat dat de onderzoeker gegevens over u verzamelt en dat de opdrachtgever van de studie die gebruikt voor onderzoek en in het kader van wetenschappelijke en medische publicaties.

U hebt het recht om aan de onderzoeker te vragen welke gegevens hij/zij over u heeft verzameld en waarvoor ze gebruikt worden in het kader van de studie. Deze gegevens hebben betrekking op uw huidige (klinische) situatie. U hebt het recht om deze gegevens in te kijken en om verbeteringen te laten aanbrengen indien ze foutief zouden zijn[1].

1 Deze rechten zijn bepaald door de wet van 8 december 1992 tot bescherming van de persoonlijke levenssfeer ten opzichte van de verwerking van persoonsgegevens en door de wet van 22 augustus 2002 betreffende de rechten van de patiënt.

De onderzoeker is verplicht om deze verzamelde gegevens vertrouwelijk te behandelen. Dit betekent dat hij zich ertoe verbindt om uw naam nooit bekend te maken in het kader van een publicatie of een conferentie en dat hij uw persoonlijke gegevens zal coderen (uw identiteit zal worden vervangen door een identificatiecode in de studie). De onderzoeker en zijn team zullen gedurende de volledige klinische studie de enige personen zijn die een verband kunnen leggen tussen de overgedragen gegevens en uw medisch dossier[2]. De overgedragen persoonlijke gegevens omvatten geen combinatie van elementen waarmee het mogelijk is u te identificeren [3].

Om de kwaliteit van de studie te controleren, kan uw medisch dossier worden ingekeken door personen die gebonden zijn aan het beroepsgeheim zoals vertegenwoordigers van de ethische comités, van de opdrachtgever van de studie of een extern auditbureau. Dit kan enkel gebeuren onder strikte voorwaarden, onder de verantwoordelijkheid van de onderzoeker en onder zijn/haar toezicht (of van één van zijn/haar onderzoeksmedewerkers).

De (gecodeerde) onderzoeksgegevens kunnen doorgegeven worden aan Belgische of andere regelgevende instanties, aan de ethische comités, aan andere artsen en/of instellingen die samenwerken met de opdrachtgever.

Uw toestemming om aan deze studie deel te nemen betekent dus ook dat u akkoord gaat dat uw gecodeerde medische gegevens gebruikt worden voor doeleinden die in dit informatieformulier staan beschreven en dat ze worden overgedragen aan bovenvermelde personen en/of instellingen. De opdrachtgever verbindt zich ertoe om de verzamelde gegevens enkel in het kader van deze studie te gebruiken.

Indien u uw toestemming tot deelname aan de studie intrekt, zullen de gecodeerde gegevens die al verzameld waren vóór uw terugtrekking, bewaard worden. Hierdoor wordt de geldigheid van de studie gegarandeerd. Er zal geen enkel nieuw gegeven aan de opdrachtgever worden doorgegeven.

Verzekering

In een observationele studie is het enige mogelijke risico een probleem met de maatregelen die werden genomen om de vertrouwelijkheid van uw persoonsgegevens te beschermen. De opdrachtgever is, ook indien er geen sprake is van fout, aansprakelijk voor de schade die u als deelnemer - of in geval van overlijden uw rechthebbenden - oplopen en die rechtstreeks of onrechtstreeks te wijten is aan de deelname aan deze studie. Hiervoor heeft de opdrachtgever een verzekeringscontract afgesloten[4].

Gegevens van de verzekeringsmaatschappij:

Ethias - Zetel voor Vlaanderen

Prins-Bisschopssingel 73

3500 Hasselt

Tel. 011 28 21 11

Polisnummer: wordt aangevraagd

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[2] De wet verplicht om voor klinische studies dit verband met uw dossier gedurende 20 jaar te bewaren.

3 De database met de resultaten van de studie zal dus geen elementen bevatten zoals uw initialen, uw geslacht en uw volledige geboortedatum (dd/mm/jjjj).

[4] Conform artikel 29 van de Belgische wetgeving inzake experimenten op de menselijke persoon (7 mei 2004)

+32 89 32 13 25
ec.submission@zol.be

+32 11 26 85 02
CME @uhasselt.be

+32 11 30 90 06
ethische.toetsingscommissie@jessazh.b

+32 11 80 92 33
sanne.strijbos@msreva.be

+32 475 34 28 17
ethische.commissie@sfz.be

+32 11 80 92 33
sanne.strijbos@msreva.be

+32 11 69 96 00
Jolanda.Verheezen@rzst.be

+32 12 39 61 11
CME@azvesalius.be

+32 89 50 99 52
c.goossens@zmk.be

+32 89 32 59 59
kpc@kpc-genk.be

Verklaring diensthoofd

Titel studie: Onderzoek naar een optimalisatie van klinische testen ter evaluatie van de terugkeer tot sport na een voorste kruisband reconstructie
Acroniem: ACLRTS2017
Indieningsdatum: 03/01/2017

Door ondertekening van dit document verklaar ik op de hoogte te zijn en akkoord te gaan met de indiening van bovengenoemde studie bij volgende comités medische ethiek:

- ● Ziekenhuis Oost-Limburg, Genk
- ● Universiteit Hasselt, Diepenbeek
- ○ Jessaziekenhuis, Hasselt
- ○ Ziekenhuis Maas en Kempen, Bree-Maaseik
- ○ Mariaziekenhuis, Overpelt
- ○ Vesaliusziekenhuis, Tongeren

O Sint-Franciscusziekenhuis, Heusden-Zolder

O St-Trudoziekenhuis, St-Truiden

Hoofd afdeling Orthopedie - ZOL
dr. Jan Oosterbosch

ZIEKENHUIS OOST-LIMBURG
ORTHOPEDIE
Dr. Jan OOSTERBOSCH
1/71929/52/480

Handtekening

www.uhasselt.be
Campus Hasselt | Martelarenlaan 42 | BE-3500 Hasselt
Campus Diepenbeek | Agoralaan gebouw D | BE-3590 Diepenbeek
T + 32|0|11 26 81 11 | E-mail: info@uhasselt.be

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VOORTGANGSFORMULIER WETENSCHAPPELIJKE STAGE DEEL 2

DATUM	INHOUD OVERLEG	HANDTEKENINGEN
16/11/2017	Overleg thesis: onderzoeksvraag, onderzoeksdesign en onderzoeksmethode bespreken	Promotor: Copromotor: Student(e): Student(e):
04/04/2018	Overleg thesis: bespreking resultaten en statistiek	Promotor: Copromotor: Student(e): Student(e):
		Promotor: Copromotor: Student(e): Student(e):
		Promotor: Copromotor: Student(e): Student(e):
		Promotor: Copromotor: Student(e): Student(e):
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		Promotor: Copromotor: Student(e): Student(e):
		Promotor: Copromotor: Student(e): Student(e):

Auteursrechtelijke overeenkomst

Ik/wij verlenen het wereldwijde auteursrecht voor de ingediende eindverhandeling:
Quantitative, qualitative or a combined movement assessment during return to sport testing after anterior cruciate ligament reconstruction

Richting: **master in de revalidatiewetenschappen en de kinesitherapie-revalidatiewetenschappen en kinesitherapie bij musculoskeletale aandoeningen**
Jaar: **2018**

in alle mogelijke mediaformaten, - bestaande en in de toekomst te ontwikkelen - , aan de Universiteit Hasselt.

Niet tegenstaand deze toekenning van het auteursrecht aan de Universiteit Hasselt behoud ik als auteur het recht om de eindverhandeling, - in zijn geheel of gedeeltelijk -, vrij te reproduceren, (her)publiceren of distribueren zonder de toelating te moeten verkrijgen van de Universiteit Hasselt.

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Ik verklaar tevens dat ik voor het materiaal in de eindverhandeling dat beschermd wordt door het auteursrecht, de nodige toelatingen heb verkregen zodat ik deze ook aan de Universiteit Hasselt kan overdragen en dat dit duidelijk in de tekst en inhoud van de eindverhandeling werd genotificeerd.

Universiteit Hasselt zal mij als auteur(s) van de eindverhandeling identificeren en zal geen wijzigingen aanbrengen aan de eindverhandeling, uitgezonderd deze toegelaten door deze overeenkomst.

Voor akkoord,

Hawinkel, Sofie **Petré, Tine**