Liverpool University Hospitals
NHS Foundation Trust

Style Definition: Central Title

Study Title: A prospective cross-sectional study to determine the reliability and validity of inline 'pull' dynamometry for measuring peak knee extensor torque in patients following anterior cruciate ligament (ACL) reconstruction.

Internal Reference No: R&D SP0558

Ethics Ref: Insert

EUDAMED (AVAILABLE FROM Dec 2020): Insert

UDI (available from May 2021): Insert

Date and Version No: 19 May 2021, version 1.1

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the **Liverpool University Hospitals NHS Foundation Trust** SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of Liverpool University Hospitals NHS Foundation Trust

Signature:

.....

Date:
...../...../.....

Name (please print):

.....

Position:

.....

Chief Investigator:

Date:
01/02/2021

Signature:

Name: Paul Carter

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Joint-sponsor(s)/co-sponsor(s)	N/A
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Confidentiality Statement

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, host(s), regulatory authorities, and members of the Research Ethics Committee.

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1. AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made
1	1.1	19/05/21	Richard Norris	Change of device

2. SYNOPSIS

Measurement of peak knee extensor torque is important following anterior cruciate ligament (ACL) reconstruction. Isometric electromechanical dynamometry (Iso-ED) is the gold standard method of measuring peak knee extensor torque, but access to this equipment is limited due to the associated expense and lack of portability. Inline 'pull-type' dynamometry is an alternative measure that is more affordable, portable and less time consuming, but this device has not been adequately investigated for reliability or validity. This study will investigate the reliability and validity of an inline 'pull-type' dynamometer for measuring peak knee extensor torque in patients following ACL reconstruction. For the reliability study, healthy volunteers will be assessed by two assessors (inter-rater) at the index testing session, with testing repeated by one assessor one week later (test-retest). Validity will be investigated against Iso-ED as the gold standard. The results of this study will help to determine whether inline dynamometry can be recommended as a reliable and valid means of measuring knee extensor torque in clinical practice.

Study Title	Reliability and validity of inline 'pull-type' dynamometry for measuring peak knee extensor torque in patients following anterior cruciate ligament (ACL) reconstruction.
Internal ref. no.	R&D SP0558
Type of study	Clinical investigation of a medical device
Trial Design	Prospective, cross sectional study using a within-participant, repeated measures design.
Trial Participants	Healthy participants recruited from staff at LUH for reliability study Patients who have had ACL reconstruction at LUH for validity study
Planned Sample Size	20 participants for reliability study 44 participants for validity study
Follow-up duration	One week for reliability study No follow up required for validity study
Planned Trial Period	6 months
Primary Objective	To determine the reliability and validity of inline 'pull-type' dynamometry for measuring peak knee extensor torque
Secondary Objectives	To determine comfort levels when testing using different devices
Primary Endpoint	Peak knee extensor torque, recorded in Newton-metres, measured with inline dynamometry and isometric electromechanical dynamometry
Secondary Endpoints	Pain during testing measured with a numerical rating scale
Device Name	KForce Link Cybex HUMAC Norm (CSMI Medical Solutions, Stoughton, MA, USA) dynamometer, using software version Humac 2009.
Manufacturer Name	K-invent
Principle intended use	Force measurement
Length of time use the device has been in use.	Inline dynamometer: 3 years

3. ABBREVIATIONS

AE	Adverse event
ADE	Adverse Device Effect
CI	Chief Investigator
CRF	Case Report Form
CRO	Contract Research Organisation
CT	Clinical Trials
CTA	Clinical Trials Authorisation
GCP	Good Clinical Practice
GP	General Practitioner
ICF	Informed Consent Form
ICH	International Conference of Harmonisation
LUHft	Liverpool University Hospitals NHS Foundation Trust
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health Service
NRES	National Research Ethics Service (previously known as COREC)
PI	Principal Investigator
PIL	Participant/ Patient Information Leaflet
R&I	R&I Department
REC	Research Ethics Committee
SAE	Serious Adverse Event
SADE	Serious Adverse Device Effect
SIL	Subject Information Leaflet (see PIL)
SOP	Standard Operating Procedure
TMF	Trial Master File
UADE	Unanticipated Adverse Device Effect

4. BACKGROUND AND RATIONALE

Lower limb strength testing is utilised in various settings including surveillance of uninjured athletes (1), patient monitoring during rehabilitation and determining readiness to return-to-play (RTP) following anterior cruciate ligament reconstruction (ACLR) (2). Knee extensor muscle weakness is associated with an increased risk of re-injury and reduced functional performance following ACLR (3-5) and is a modifiable risk factor for knee osteoarthritis (6). Knee extensor strength deficits may be present in those that pass functional RTP tests (e.g., hop for distance) (5, 7, 8), highlighting the importance of quantifying knee extensor strength specifically.

Isometric electromechanical dynamometry (Iso-ED) is the gold standard method for quantifying knee extensor strength (indicated by peak isometric torque) (9), with hand-held dynamometry (HHD) considered an alternative measure that is more affordable, portable and less time consuming (10). 'Push-type' HHD requires belt stabilisation for stronger subjects (10-13) and demonstrates similar peak isometric torque generating capacity to Iso-ED when performed at approximately 90° knee flexion in healthy volunteers (14). However, peak knee extensor torque occurs at 60-70° knee flexion (15), which is difficult to measure using belt-stabilised 'push-type' HHD due to slippage of the device or a non-perpendicular force being applied to the gauge (16). When compared directly, 'push-type' HHD performed at approximately 90° knee flexion overestimated limb symmetry in subjects with various knee joint impairments and could not be recommended as a direct substitute for Iso-ED at 60° knee flexion (16).

To date, only one study has investigated the reliability and validity of HHD for measuring peak knee extensor torque in patients following ACLR (17). 'Push-type' HHD performed isometrically at 90° knee flexion was shown to have excellent test-retest reliability (ICC: 0.98) and 100% specificity for detecting a limb symmetry index (LSI) >10%, but only moderate to good validity (r=0.62) versus isokinetic dynamometry. Although LSI is recommended as an objective, criterion-based guideline for return to running (18) or RTP (2) following ACLR, leg dominance or dysfunction of the reference limb may overestimate the capacity of the side being measured, potentially leading to a premature return to high-risk activities and subsequent re-injury (19). Peak isometric knee extensor torque normalised to body weight is an alternative means of determining whether an individual has achieved target values associated with positive knee-joint function following ACLR (≥3.0-3.1 Nm/kg) (20, 21). Mean peak torque values in the aforementioned study were 1.67 (±7.4) Nm/kg and 2.03 (±7.9) Nm/kg for isometric HHD and isokinetic testing respectively, indicating a lower force generating capacity for 'push-type' HHD. In addition, since the reference values were

obtained isokinetically (60º/sec), it is likely that the validity of 'push-type' HHD would be lower if Iso-ED was used as the reference standard.

Inline dynamometers allow isometric knee extensor torque to be measured at peak angles (i.e., 60-70°), but the reliability and validity of this 'pull-type' dynamometry has not been adequately evaluated (10, 22). The objective of this study therefore is to determine the reliability and validity of inline 'pull-type' dynamometry for measuring peak isometric knee extensor torque in patients following ACLR. We hypothesise that inline dynamometry is a reliable and valid measure of peak isometric knee extensor torque when performed at 60-70° knee flexion, using Iso-ED as the gold-standard reference.

5. OBJECTIVES

5.1 Primary Objective

To determine the reliability (inter and test-retest) and validity of the KForce Link inline dynamometer for measuring peak isometric knee extensor torque in patients following ACLR.

5.2 Secondary Objectives

To determine comfort levels for each device during testing, as measured with a numerical rating scale of pain (0-10).

6. TRIAL DESIGN

6.1 Summary of Trial Design

This is a prospective, cross sectional study using a within-participant, repeated measures design.

Reliability:

A convenience sample of 20 healthy subjects (10 legs) will be recruited from Liverpool University Hospital to determine the inter- and test-retest reliability of the inline dynamometer. The testing procedure will be standardised between assessors. Subjects and assessors will be blinded to the results until all testing is completed.

Subjects will be tested by assessors A and B at the first assessment to determine inter-rater reliability. Assessor A is a physiotherapy knee specialist with 17 years clinical experience and three years clinical experience using HHD. Assessor B is a specialist physiotherapist with 8 years clinical experience but no previous experience using HHD. The order of testing will be randomised to account for fatigue and learning effect using the random.org website (https://www.random.org/).

To determine test-retest reliability, measurements will be repeated by assessor A seven days after the index testing. All tests will be performed at the same time of the day, with subjects encouraged to continue their usual weekly exercise between testing sessions, but to avoid significant changes in training loads, which may affect fatigue levels and their ability to generate force.

Validity:

A convenience sample of 44 patients that have undergone ACL reconstruction will be recruited from Liverpool University Hospitals NHS Foundation Trust to determine the validity of the inline dynamometer versus Iso-ED. Inline dynamometry will be performed by Assessor A and Iso-ED performed by Assessor C (15 years' experience). The order of testing will be randomised to account for fatigue and learning effect. Subjects and assessors will be blinded to the results until all testing is completed.

6.2 Primary and Secondary Endpoints/Outcome Measures

The peak torque for each leg (Force [Newtons] x lever length [metres]) recorded at 60° knee flexion will be used as the primary outcome measure. Pain during testing on a numerical rating scale (NRS) will be used as a secondary outcome measure.

6.3 Trial Participants

6.3.1 Overall Description of Trial Participants

Reliability study: healthy subjects, as defined by the inclusion criteria below, recruited from NHS staff at Liverpool University Hospitals NHS Foundation Trust.

Validity study: patients that have undergone ACL reconstruction surgery, with or without meniscal surgery, at Liverpool University Hospitals NHS Foundation Trust.

6.3.2 Inclusion Criteria

- Participant is willing and able to give informed consent for participation in the study.
- Male or Female, aged 18 years or above.
- No contraindications to maximal force testing (see exclusion criteria).
- For the ACL reconstruction participant cohort: diagnosed with ACL injury that was managed with ACL reconstruction surgery, with or without additional meniscal surgery. If medicated, stable dose of current regular medication for at least 4 weeks prior to study entry.
- For the healthy control participant cohort: no current or previous history of significant lower limb injury, or a history of previous minor injury that is symptomatic at the time

of recruitment. No previous lower limb surgery. No course of medication, whether prescribed or over the counter, other than vitamins and mineral supplements or, for females, oral contraceptives.

6.3.3 Exclusion Criteria

The participant may not enter the study if they are unable to provide written consent to study participation, or there are contraindications to maximal force testing, including the following:

- History of chronic disease or disorder that may put the participants at risk because of participation in the study including non-united fractures, epilepsy, cardiac insufficiency, severe peripheral vascular disease, aneurysms, anticoagulant therapy, recent (<3 months) radiotherapy or chemotherapy, long term steroid use (>3 months), pregnancy, neurological disorders (e.g., Parkinson's disease), skin conditions at point of force testing, severe osteoporosis, malignancy, rheumatoid arthritis.
- Conditions or symptoms that may influence the result of the study, or the participant's ability to participate in the study including pain, limited range of motion, knee effusion, or anaemia.

6.4 Study Procedures

Before testing, all subjects will complete a 10-minute warm up on a stationary bike followed by three trials (50%, 75% and 100% maximal effort) to familiarise themselves with each device and to screen for pain. If pain during testing is deemed intolerable by the subject, no further testing will be performed, and the subject will be excluded from the study. A 10-minute recovery period will be used between testing on devices to avoid fatigue.

Inline dynamometer – KForce Link (capacity 300kg):

The subject will be sat on the end of a sturdy plinth with a small foam pad placed under the distal thigh for comfort. Ankle straps with double D-rings (Vorcool) will be securely attached directly above the malleoli, with one end of the dynamometer connected to the D-rings via a snap hook. Using a goniometer, the knee will be positioned in 60° knee flexion and the inline dynamometer aligned perpendicular to the leg by adjusting the height of the plinth and the inelastic strap, which anchors the dynamometer to the plinth. The subject will be instructed to maintain the trunk in an upright position, using their hands on the side of the plinth for stability. The dynamometer will be 'zeroed' with the knees relaxed at right angles before each trial. Lever length will be recorded in metres with a tape measure, using the lateral epicondyle of the femur and middle of the ankle strap as reference points.

Cybex isokinetic dynamometer:

The testing procedure will be conducted at 60° knee flexion in accordance with the device instructions. Humantrak software will be used to determine peak knee extensor torque.

For both devices, three maximal efforts will be performed on each leg with verbal encouragement to 'push as hard as possible' for five seconds, which is sufficient time to generate peak torque. Subjects will rest for 60-seconds between attempts, monitored with a timer (18). The highest value from the three efforts for each device will be used as the primary outcome for each subject.

6.4.1 Informed Consent

Informed consent will be gained by the principal investigator (Richard Norris) and co-investigators (Malcolm Peoples and Huw Williams), as authorised by the Chief Investigator and Principal Investigator.

The participant must personally sign and date the latest approved version of the informed consent form before any study specific procedures are performed. Written and verbal versions of the participant information and informed consent will be presented to the participants detailing no less than:

- the exact nature of the study
- the implications and constraints of the protocol
- the potential side effects and any risks involved in taking part.

It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice or impact on future care, and with no obligation to give the reason for withdrawal. The participant will be allowed as much time as required to consider the information, and the opportunity to question the Investigator, their GP or other independent parties to decide whether they will participate in the study.

Written informed consent will then be obtained by means of participant dated signature and dated signature of the person who presented and obtained the informed consent. The person who obtained the consent must be suitably qualified and experienced and have been authorised to do so by the Chief/Principal Investigator. A copy of the signed Informed Consent will be given to the participants. The original signed form will be retained at the study site.

6.4.2 Screening and Eligibility Assessment

Hospital staff and patients (18 years or older) will be recruited by direct invitation or word of mouth. Patients that have undergone ACL reconstruction, who are already scheduled for force testing on the isokinetic dynamometer will be invited to have additional testing using inline dynamometry. Potential participants will be initially screened via telephone or face to face interview to confirm eligibility. Once signed consent is obtained, participants will be invited to attend testing sessions in a physiotherapy department at Liverpool University Hospitals.

6.4.3 Baseline Assessments

The following demographics will be recorded routinely at baseline:

Gender, age, weight, height, leg dominance, Tegner activity score (TAS).

Pain at rest, measured by a 0-10 numerical rating scale (NRS), will be recorded before initiation of testing. Lever length and force measurements will be recorded during testing.

6.4.4 Randomisation and Codebreaking

For both the reliability and validity studies, the order of testing will be randomised to account for fatigue and learning effect using the random.org website (https://www.random.org/). Subject numbers will be assigned sequentially as each subject enters the study. Subjects and assessors will be blinded to the force measurement results until testing is complete on each device. Lever length will be measured and recorded by each individual assessor.

6.4.5 Subsequent assessments

Torque measurements for the participants in the test-retest reliability study will be repeated one week after index testing. At each visit, an eligibility check will be conducted (i.e., change to circumstances).

6.5 Definition of End of Trial

The end of trial is defined as the point when all subject data has been collected for the reliability and validity studies and analysis of this data has been completed.

6.6 Discontinuation/ Withdrawal of Participants from Study Treatment

Each participant has the right to withdraw from the study at any time. In addition, the investigator may discontinue a participant from the study at any time if it is considered necessary for any reason including:

- The subject becomes pregnant
- Ineligibility (either arising during the study or retrospectively having been overlooked at screening)
- Significant protocol deviation
- Significant non-compliance with study requirements
- An adverse event which requires discontinuation of the testing procedure or results in an inability to continue to comply with study procedures
- Disease progression which requires discontinuation of the study device or results in inability to continue to comply with study procedures
- Consent withdrawn
- Lost to follow up

Withdrawal from the study will result in exclusion of the data for that participant from analysis. In the healthy participant cohort, withdrawn participants will be replaced unless the withdrawal was due to an adverse event that was directly associated with the testing procedure. The reason for withdrawal will be recorded in the CRF.

If the participant is withdrawn due to an adverse event, the investigator will arrange for follow-up visits or telephone calls until the adverse event has resolved or stabilised.

6.7 Source Data

Source documents are original documents, data, and records from which participants' CRF data are obtained. These include, but are not limited to, hospital records containing medical history and surgical information. All documents will be stored safely in confidential conditions. On all study-specific documents, other than the signed consent, the participant will be referred to by their personal identification number (PIN), not by name.

7. TREATMENT OF TRIAL PARTICIPANTS

7.1 Description of Study Intervention(s)

For the reliability study, healthy subjects will be tested by two assessors at the index testing session, with three trials performed per assessor per leg. Testing will be repeated by one examiner, one week after index testing.

For the validity study, ACL subjects will be tested by two assessors with the two different devices, with three trials performed per assessor per leg. The highest score from the three trials per device will be used for analysis.

7.2 Maintenance and storage of device

The inline dynamometer and accessories will be stored in a customised, protective case. Between testing sessions, this device will be stored in a locked room, accessible only to the Principal Investigator. The Cybex isokinetic dynamometer is a fixed device and remains in the physiotherapy department at Broadgreen hospital.

8. SAFETY REPORTING

8.1 Reporting of AE

All AE's occurring during the study observed by the investigator or reported by the participant, whether or not attributed to the device under investigation will be recorded on the CRF, as specified in the protocol. All ADE's will be recorded in the CRF.

The following information will be recorded: description, date of onset and end date, severity, assessment of relatedness to device and action taken. Follow-up information will be provided as necessary.

The relationship of AEs to the device will be assessed by a medically qualified investigator or the sponsor/manufacturer and will be followed up until resolution or the event is considered stable.

All ADEs that result in a participant's withdrawal from the study or are present at the end of the study, will be followed up until a satisfactory resolution occurs.

Where relevant, any pregnancy occurring during the clinical study and the outcome of the pregnancy, will be recorded and followed up for congenital abnormality or birth defect.

8.2 Reporting Procedures for All SAEs/ SADEs/ UADEs

As the devices are CE marked, all SAE/SADE/UADEs will be reported to the sponsor/legal representative and manufacture and LUHFT R&D **within one working day** of the investigator team becoming aware of them.

Reports of related and unexpected SAEs will be submitted to ethics within 15 days of the Chief Investigator becoming aware of the event, using the SAE report form for non-CTIMPs published on the NRES website.

All reporting to LUHFT R&D will be signed by the PI or Co-investigator.

8.3 Annual Reports

In addition to the above reporting the Chief Investigator will submit once a year, throughout the trial, or on request a progress/safety report to the REC and R&D.

9. STATISTICS

9.1 Description of Statistical Methods

Inter and test-retest reliability will be calculated using intra-class correlation coefficients (ICC) with 95% confidence intervals (CI) and illustrated using a Bland & Altman plot. Standard error of measurement (SEM = [SD√(1-ICC)]) and the minimal detectable change (MDC) (1.96 x √2 x SEM) will be calculated to verify the absolute error of the instrument and the smallest change considered significant respectively.

ICC values will be considered as follows: < 0.69: weak reliability, 0.70–0.79 reasonable reliability, 0.80–0.89 good reliability, and 0.90–1.0 excellent reliability

Validity will be calculated using ICC (95% CI), Pearson product moment correlation (Pearson-r) and illustrated using Bland & Altman plot.

Pearson values of coefficients will be established as follows: < 0.5 indicated weak validity, 0.5–0.75 indicated moderate to good validity, and > 0.75 indicated excellent validity.

9.2 The Number of Participants

Since this is a study looking at criterion validity using two repeated measures, the following formula is recommended: √3(SDdiff/*N*). Values from a similar study (Deones et al., 1994) were used to calculate an effect size of 0.506. After running a power calculation using G*Power, the sample size required for statistical significance was 40 subjects. A 10% larger sample size (n=44) will negate the attrition rate whilst maintaining statistical significance.

9.3 The Level of Statistical Significance

An alpha level of $P < 0.05$ was considered statistically significant for all analyses

9.4 Criteria for the Termination of the Trial.

The trial will be terminated after all data for the reliability and validity studies have been collected and the data analysed, as described in section 9.1.

9.5 Procedure for Accounting for Missing, Unused, and Spurious Data.

It is unlikely that we will not be able to collect data because of the single measures taken using a non-invasive orthopaedic device that is already in clinical use.

All data, including instances where data was not able to be collected or the data was spurious, will be presented in the final report and acknowledged in published work with raw data included as supplementary material.

9.6 Procedures for Reporting any Deviation(s) from the Original Statistical Plan

Power calculations have been performed using preliminary data and therefore we do not anticipate that we will deviate from the statistical plan.

Any deviations will be described and justified in the final report,

9.7 Inclusion in Analysis

Data included in the analysis is described in section 6.6

10. DIRECT ACCESS TO SOURCE DATA/DOCUMENTS

Direct access will be granted to authorised representatives from the sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections.

11. QUALITY CONTROL AND QUALITY ASSURANCE PROCEDURES

The study will be conducted in accordance with the current approved protocol, ICH GCP, relevant regulations and standard operating procedures.

Regular monitoring will be performed according to ICH GCP. Data will be evaluated for compliance with the protocol and accuracy in relation to source documents. Following written standard operating procedures, the monitors will verify that the clinical trial is conducted and data are generated, documented and reported in compliance with the protocol, GCP and the applicable regulatory requirements.

12. ETHICS

12.1 Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

12.2 ICH Guidelines for Good Clinical Practice

The Investigator will ensure that this study is conducted in full conformity with relevant regulations and with the ICH Guidelines for Good Clinical Practice R2

12.3 Approvals

The protocol, informed consent form, participant information sheet and any proposed advertising material will be submitted to an appropriate Research Ethics Committee (REC), regulatory authorities (MHRA in the UK), Health Research Authority and host institution(s) for written approval.
The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

12.4 Participant Confidentiality

The trial staff will ensure that the participants' anonymity is maintained. The participants will be identified only by initials and a PIN on the CRF and any electronic database. All documents will be stored securely and only accessible by trial staff and authorised personnel. The study will comply with the Data Protection Act 2018 which requires data to be anonymised as soon as it is practical to do so.

12.5 Other Ethical Considerations

None identified

13. DATA HANDLING AND RECORD KEEPING

All study data will be stored on a password protected Microsoft Excel spreadsheet and entered on SPSS for data analysis. The participants will be identified by a study specific participants number and/or code in any database. The name and any other identifying detail will NOT be included in any study data electronic file.

14. FINANCING AND INSURANCE

NHS bodies are legally liable for the negligent acts and omissions of their employees. If you are harmed whilst taking part in a clinical trial as a result of negligence on the part of a member of the study team this liability cover would apply.

Non-negligent harm is not covered by the NHS indemnity scheme. The LUHFTt , therefore, cannot agree in advance to pay compensation in these circumstances. In exceptional circumstances an ex-gratia payment may be offered.

15. END OF STUDY DEFINITION

End of study is defined as the point when all data has been collected for the reliability and validity studies and this data has been analysed.

16. PUBLICATION POLICY

The end of study is defined as the point when all data sets for the reliability and validity studies have been collected and the data has been analysed.

17. ARCHIVING

Archiving for Device studies will be 15 years.

18. REFERENCES

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