**RESEARCH STUDY PROTOCOL**

# RESEARCH STUDY DETAILS

TITLE: Proximal Hamstring Avulsion Rehabilitation Regimes: Longitudinal versus Accelerated Protocol (PHARRLAP Study)

Protocol version: v1.0 – 2nd February 2021

Universal Trial Number: TBC

ANZCTR Number: TBC

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**Research Study Summary**

This is a prospective randomised controlled trial (RCT) comparing the outcomes for patients undergoing proximal hamstring tendon avulsion repair with two different post-operative rehabilitation regimes. The first regime includes a period of brace immobilisation and limited weight-bearing with a gradual progression of physiotherapy. The second regime allows immediate full-weight bearing with an accelerated rehabilitation program of physiotherapy.

Patient outcomes will be collected and compared between the two rehabilitation regime cohorts over a 24-month post-operative period. This will include validated Patient Reported Outcome Measures (PROMs) investigating pain, symptoms and patient satisfaction, and objective measures of hip range of motion (ROM), muscle girth, peak isokinetic knee flexor (hamstrings) and extensor (quadriceps) strength. Overall satisfaction and assessment of complications will be assessed throughout.

# BRIEF STUDY BACKGROUND

Proximal hamstring tendon avulsions are a significant traumatic injury, with surgical treatment increasing since early case reports in 2005 (1). Recent systematic reviews have demonstrated the benefit of surgical repair over non-surgical treatment (2–4). Despite an increasing number of published studies on the topic, there is no consensus on post-operative rehabilitation regimes following such injuries (5).

Accelerated rehabilitation is well established for multiple orthopaedic interventions such as lower limb arthroplasty (6), ankle sprains (7), Achilles tendon ruptures (8), surgical stabilisation of the shoulder (9) and ligamentous injuries of the knee (10). Advantages of accelerated rehabilitation include improved blood flow to accelerate biological healing, early longitudinal strain inducing organised collagen in healing tendons/ligaments, prevention of muscle atrophy, early return of neuromuscular control and psychosocial benefits. These philosophies are now being applied to rehabilitation following surgical repair of proximal hamstring avulsions (11,12). Today, both traditionally conservative and more accelerated rehabilitation regimes are employed, with many centres still reporting the use of knee braces (13–15), hip braces (16–18) or hip-knee-ankle orthosis in the post-operative care of these patients.

To date, no RCT has been conducted comparing a traditionally conservative versus more accelerated rehabilitation intervention in patients following repair of proximal hamstring tendon avulsions.

# RESEARCH STUDY AIMS AND HYPOTHESES

The primary outcome of this prospective RCT will be to:

1. Investigate post-operative function at 6 months following repair of proximal hamstring tendon avulsions between a traditionally conservative versus an accelerated rehabilitation regimen.

The secondary outcomes of this prospective RCT will be to:

1. Investigate the post-operative improvement in commonly employed patient-reported outcome measures (PROMs) up to 24 months after surgery, in patients undergoing a traditionally conservative versus an accelerated rehabilitation regimen following repair of their proximal hamstring tendon avulsion.
2. Investigate the level of patient satisfaction up to 24 months after surgery, in patients undergoing a traditionally conservative versus an accelerated rehabilitation regimen following repair of their proximal hamstring tendon avulsion.
3. Investigate the re-tear and re-operation rate, incidence of post-operative hamstring strain and the incidence of other pertinent surgical complications, throughout the post-operative timeline up to 24 months after surgery, in patients undergoing a traditionally conservative versus an accelerated rehabilitation regimen following repair of their proximal hamstring tendon avulsion.
4. Investigate the degree of post-operative hip range of motion (ROM) up to 24 months after surgery, in patients undergoing a traditionally conservative versus an accelerated rehabilitation regimen following repair of their proximal hamstring tendon avulsion.
5. Investigate the post-operative recovery of peak isokinetic knee strength (hamstrings and quadriceps), in patients undergoing a traditionally conservative versus an accelerated rehabilitation regimen following repair of their proximal hamstring tendon avulsion.
6. Investigate the post-operative recovery of single limb functional hop symmetry, in patients undergoing a traditionally conservative versus an accelerated rehabilitation regimen following repair of their proximal hamstring tendon avulsion.
7. Investigate the post-operative return to function and sport, in patients undergoing a traditionally conservative versus an accelerated rehabilitation regimen following repair of their proximal hamstring tendon avulsion.

Primary Hypothesis:

1. The accelerated rehabilitation protocol (versus the traditionally conservative regimen) will demonstrate superior limb symmetry index for peak isokinetic hamstring torque at 6 months following surgical repair, without any increase in re-rupture or complication rate.

# RESEARCH STUDY DESIGN

This study has been designed as a prospective RCT, investigating clinical outcomes to 24 months post-operatively in patients undergoing either a traditionally conservative versus an accelerated rehabilitation regimen following repair of their proximal hamstring tendon avulsion (Figure 1).

**Patient Consent and Recruitment**

All patients who are undergoing surgery with Dr Peter D’Alessandro, Dr Brendan Ricciardo & Dr Peter Annear, will be invited to participate in this trial. Participants will be invited to be part of the study after consultation with their surgeon, having confirmed proximal hamstring tendon avulsion by clinical examination and magnetic resonance imaging (MRI), and being scheduled for surgery. Initial contact and recruitment will be conducted by a member of the research team.

Following consent for surgery, the patient will be provided with the Participant Information Form for the study that includes the contact details of Dr Jay Ebert. Therefore, should participants be interested in the study they can contact Dr Ebert to discuss further, and the nature of the prospective research follow up will be outlined and presented to the participant. This will include a verbal discussion initially, and it will also be made clear to the potential participant that they are free to withdraw from the research at any time without prejudice or altered post-operative care. Should interest be sought, an appropriate time will be made to visit Dr Ebert for further study discussion, study consent and clinical review. Potential participants will be further provided the opportunity after face-to-face discussion with Dr Ebert to take the study information away if required and read in more detail, digest and then discuss with others including friends, family, colleagues and their own Health or General Practitioner. A subsequent time will be made for the participant to return should they wish to participate after speaking with others. Should they be willing to be involved in the research component, final consent from the participant will be obtained. It is acknowledged that while the orthopaedic surgeon is the best medical professional involved in the patient’s team to assess surgical (and therefore study) suitability, the decision to participate may be influenced by a potential unequal relationship between the surgeon and patient. Therefore, before participant consent, the aforementioned steps (i.e. surgeon not involved in recruitment, participant’s ability to take the information away to speak with others, before another clinical review time is made) should ensure the patient is well informed and not biased or coerced toward study participation due to this potential unequal relationship.

**Figure 1.** Study flow chart demonstrating patient assessment throughout the 24-month post-operative evaluation period.

Presentation for Orthopaedic Review,

Assessed for Surgical and Study Eligibility

Patient Study Consent and Pre-operative Study Review

Study Randomisation

Group 2 (Accelerated)

Group 1 (Conventional)

Proximal Hamstring Tendon Repair Surgery

Clinical Assessment (n=29)

Clinical Assessment (n=29)

Clinical Assessment (n=29)

Clinical Assessment (n=29)

Clinical Assessment (n=29)

Assessment

Days 1-14

Clinical Assessment (n=29)

Clinical Assessment (n=29)

Assessment

3 months

Clinical Assessment (n=29)

Assessment

6 months

Clinical Assessment (n=29)

Assessment

12 months

Clinical Assessment (n=29)

Assessment

24 months

## *Study Inclusion Criteria*

* Age 18-65 years.
* Presenting to the surgeon and operated on within 42 days of their injury.
* Physical examination supporting the diagnosis; positive hip extension test, palpable defect and/or local tenderness and haematoma.
* MRI showing complete acute avulsion of at least two of three tendons from the footprint at the ischial tuberosity.
* Patients able to give written informed consent.
* The individual is not currently being treated for a psychiatric disorder, senile dementia, Alzheimer’s disease, presence of alcohol/substance abuse.

## *Study Exclusion Criteria*

* The individual is unable or unwilling to sign the Patient Informed Consent, specific to this study, and approved by the Institutional Ethics Review Board.
* The individual is unable or unwilling to follow the designated rehabilitation protocol.
* The individual is classified as morbidly obese (>40 BMI).
* The individual is skeletally immature.
* Revision procedures.
* Isolated semimembranosus ruptures.
* Ruptures > 4cm away from the ischial tuberosity.

The randomization schedule and concealed envelopes will be created and provided by a separate member of the research team, who will not be involved with patients or patient assessment. It will not be possible to blind the patient, rehabilitation therapist or surgeon to the rehabilitation regimes assigned. However, the clinical assessor will be blinded.

## Study Sample Size

This prospective RCT seeks to compare outcomes in patients undergoing proximal hamstring tendon avulsion repair with two different post-operative rehabilitation regimes: 1) a program that includes brace immobilisation and limited weight-bearing with a slower progression of rehabilitation, or 2) a program that permits immediate full-weight bearing and accelerated rehabilitation.

A *priori* sample size power calculation has been determined based on the recommendations of Cohen, using G-Power (Dusseldorf, Germany). Pilot data already collected in patients after proximal hamstring repair has highlighted the significant side-to-side limb asymmetry observed at 6 months post-surgery in peak isokinetic hamstring torque/strength. Therefore, based on this pilot data and given the proposed role of an accelerated rehabilitation regimen in restoring these strength deficits at a faster rate, for an anticipated large effect size (d=0.80) in the primary outcome variable (limb symmetry index for peak isokinetic hamstring torque at 6 months post-surgery), a total of 26 patients are required in each group to reveal differences at alpha 0.05 with 80% power. We aim to recruit and clinically evaluate 58 patients (i.e. an additional 10% in each group) to allow for attrition over the 24-month assessment period.

## Surgical Technique

Apart from the post-operative rehabilitation regime, all other aspects of the surgery will be standardised. Patients will undergo proximal hamstring tendon repair under a general anaesthetic in a prone position. Strict aseptic precautions will be taken including pre-surgical hair removal, pre-wash and placement of a betadine-soaked gauze into the perineal area. Pre-operative antibiotics will be given and, following skin preparation and draping, the surgical field will be sealed with an ioband.

Transverse skin incision will be used within the gluteal fold. Standard sub-gluteal dissection down to the ischium will be performed with careful visualisation, mobilisation and protection of the sciatic nerve throughout the procedure.

Tendon mobilisation will be performed to ensure adequate reduction under minimal tension. The lateral wall of the ischium will be prepared. Repair will be performed using a minimum of three anchors in a double-row configuration. One of the paired sutures will be locked into the tendon using a Krackow technique. The second suture is passed once through the tendon and used to reduce the tendon down to the lateral wall of the ischium. A second row of anchors are placed into the lateral wall to complete the double-row. If excessive tension is required to maintain a comfortable reduction of the tendon then the surgeon may choose to apply a brace and then withdraw the patient from the study.

The surgical field is washed with lavage and sciatic nerve inspected. The wounds are then closed in layers, haemostasis ensured and absorbable subcuticular wound closure employed. Water proof dressings will be applied.

## Post-operative Rehabilitation

Patients will be randomised into Group 1 (traditionally conservative rehabilitation) or Group 2 (accelerated rehabilitation). The regimes are highlighted in Table 1 and 2, respectively.

**Table 1: Standard surgical repair + Conventional Rehabilitation (Group 1)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Phase** | **Weeks** | **Weight bearing (WB) status** | **Orthosis** | **Movement/Rehabilitation Overview** |
| *Protective* | 0-2 | Toe Touch | Knee brace applied with knee fixed in 30° flexion  (at all times) | Isometric quadriceps/gluteal exercises; minimal mobilisation with crutches only. |
| 3-4 | Partial | Knee brace applied with knee fixed in 30° flexion  (for mobilising) |
| 5-6 | Nil | Minimal walking with crutches only; short stride length. |
| *Early* | 7-8 | Full | Single leg standing; isometric hamstring exercises permitted; squat to 30° knee flexion. |
| 9-12 | As above; add standing knee curls and standing knee lifts. |
| 13-16 | Stationary bike once comfortable and hip flexion to 70° combined with knee flexion to 90° is achieved. |
| *Progressive* | 17-20 | Focus on flexibility, single leg balance, neuromuscular control; isometric hamstring exercises in prone; squat to 90°. |
| *Strength* | 21-24 | Stationary jogging; single leg bridges; eccentric hamstring training permitted; progressive closed chain exercises once limb control returns and pain is minimal. |
| *Sport Specific* | 24+ | No limitations. Return to sport assessment needed prior to returning to contact sport. |

**Table 2: Standard surgical repair + Accelerated Rehabilitation (Group 2)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Phase** | **Weeks** | **Weight bearing (WB) status** | **Orthosis** | **Movement/Rehabilitation Overview** |
| *Protective* | 0-1 | Full as pain allows | Nil | Isometric quadriceps/gluteal exercises; minimal mobilisation with crutches to prevent falls. |
| *Early* | 2 | Single leg standing; isometric hamstring exercises permitted; squat to 30° knee flexion. |
| 3 | As above; add standing knee curls and standing knee lifts. |
| 4 | Full | As above; walking in swimming pool/AlterG. |
| 5-6 | Stationary bike once comfortable and hip flexion to 70° combined with knee flexion to 90° is achieved. |
| *Progressive* | 7-8 | Focus on flexibility, single leg balance, neuromuscular control; isometric hamstring exercises in prone; squat to 90°. |
| *Strength* | 9-12 | Stationary jogging; single leg bridges; eccentric hamstring training permitted; progressive closed chain exercises once limb control returns and pain is minimal. |
| *Sport Specific* | 13+ | No limitations. Return to sport assessment needed prior to returning to contact sport. |

## Clinical Evaluation

While clinical reviews within the first 3 months will be undertaken in the private rooms of Coastal Orthopaedics and Perth Orthopaedic & Sports Medicine Centre for patient ease and given these assessment measures do not require any sophisticated equipment, clinical reviews at 6, 12 and 24 months will be undertaken at the HFRC Rehabilitation Clinic (Table 3).

Firstly, a thorough patient history will be taken to collect patient demographics (age, height, weight, body mass index), limb dominance, activity history (work and sports) and information on the injury mechanism (if known).

A number of PROMs will be undertaken pre-surgery and at 3, 6, 12 and 24 months post-surgery. These will include:

1. Pain diary – this will involve daily pain scores and analgesia usage for the first 6 weeks.
2. Visual Analogue Pain Scale (VAS) – this will be used to assess the frequency (VAS-F) and severity (VAS-S) of patients’ pain levels, on a whole number rating scale from 0 (no pain) to 10 (worst pain).
3. Perth Hamstring Assessment Tool (PHAT) (19) – this will be used to evaluate patient-perceived symptoms, physical function and sporting activity, scored from 0-100 with higher scores indicating a better score.
4. Lower Extremity Functional Score – this will be used to evaluate overall lower limb function.
5. Tegner Score – this will be used to evaluate the level of activity and sports participation.
6. 12-item Short Form Health Survey (SF-12) – this will be used to assess the patient’s overall level of health and well-being
7. Global Rating of Change (GRC) Scale – this is employed to evaluate the patient’s perceived status compared to before their surgery.
8. Patient Satisfaction – this will be used to evaluate the patient’s level of satisfaction with their surgery overall, as well as their satisfaction with surgery to relieve their pain, improve their ability to perform normal daily and work activities, improve their ability to return to recreational activities (e.g. walking, dancing, golf) and improve their ability to participate in sporting activities (e.g. running, tennis, surfing, soccer). A categorical tool will be employed: 1 = very satisfied; 2 = somewhat satisfied; 3 = somewhat dissatisfied; 4 = very dissatisfied.

A number of objective clinical assessments will also be undertaken throughout the post-operative period (Table 3).

Initially, the thigh girth of both limbs will be measured using a tape measure, marked 10cm above the superior pole of the patella whilst the patient is in an upright standing position.

Secondly, the active knee extension (AKE) test will be measured and documented (20). Passive straight leg raise to discomfort will also be assessed.

Thirdly, all patients will undertake a 4-hop test battery in the following order after a warm-up (5 min sub-maximal ride on a stationary bicycle followed by an optional stretching session): 1) the single hop for distance, 2) the 6 m timed hop, 3) the triple hop for distance, and 4) the triple crossover hop for distance. Patients will be provided verbal descriptions of each test and will be permitted 2-3 warm-up hops on each limb prior to initiating the hop battery. Each of the four hop tests are initiated on the unaffected limb, and then alternated between the unaffected and operated limbs until the required number of valid test trials is obtained. A total of four, two, three and three valid test trials will be collected for the single, 6 m timed, triple and triple crossover hop test, respectively. To avoid fatigue, patients will be given as much time as required between trials; though this time will not be standardized and will be based on the individual patient’s readiness to proceed.

Finally, following the four hop tests the maximal isokinetic strength of the quadriceps and hamstring muscle groups will be assessed via isokinetic dynamometry (Isosport International, Gepps Cross, South Australia). Peak concentric knee extension and flexion strength will be measured through a range of 0-90 ̊ of knee flexion, at a single isokinetic angular velocity of 90°/s. Patients will be informed that each trial will consist of four repetitions on the same leg: three low intensity repetitions of knee extension and flexion, immediately followed by one maximal test effort which is recorded. Standardized verbal encouragement will be provided across all trials. Each test will be initiated on the unaffected leg, and then alternated between the unaffected and operated limb until three valid trials on each limb are completed. Patients will again be given adequate rest in between trials to minimize fatigue.

**Table 3:** Timeline of patient evaluation throughout the study.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Measure | Pre-surgery | Days  1-14 | 6 weeks | 3 months | 6 months | 12 months | 24 months |
| Pain Diary | x | x | x |  |  |  |  |
| Recovery Checklist |  |  |  |  | x |  |  |
| Analgesia Usage | x | x | x | x | x |  |  |
| VAS (Pain) |  |  | x | x | x | x | x |
| PHAT | x |  |  | x | x | x | x |
| LEFS | x |  |  | x | x | x | x |
| SF-12 | x |  |  | x | x | x | x |
| Tegner | x |  |  |  | x | x | x |
| GRC |  |  |  |  | x | x | x |
| Satisfaction |  |  |  |  | x | x | x |
| Hip ROM |  |  |  |  | x | x | x |
| Thigh Girth |  |  |  |  | x | x | x |
| Hop Capacity |  |  |  |  | x | x | x |
| Strength |  |  |  |  | x | x | x |
| Complications |  | x | x | x | x | x | x |

**Planned Data and Statistical Analysis**

Firstly, the mean (SD, range) of all subjective and objective measures collected will be presented for the designated pre- and post-operative time-points. Furthermore, limb symmetry indices (LSIs) will be calculated for the single limb hop and strength tests by dividing the peak values on the operated limb by that recorded on the unaffected limb. The mean LSIs for each of the aforementioned hop tests will be presented, and further categorized by the number and percentage of patients with LSIs <90% and ≥90% (as per clinical recommendations of unsatisfactory and satisfactory performance, respectively). Repeated measures Analysis of Variance (ANOVA) will be employed to evaluate change over the pre- and post-operative timeline in all PROMs, as well as post-operative change in objective measures including thigh girth, ROM, hop capacity and strength measures, for both groups. ANOVA will also be employed to evaluate differences between the operated and non-operated limbs in all tests, as well as between the two surgical cohorts in all tests over time.

The number (and type) of surgical complications, post-operative adverse events and re-injuries will be presented. Associations between demographic, injury history and clinical measures with PROMs will be assessed using Pearson’s or Spearman’s correlation coefficient where appropriate. Where appropriate, statistical analysis will be performed using SPSS software (SPSS, Version 23.0, SPSS Inc., USA), while statistical significance will be determined at *p*<0.05.

## Adverse Events

Follow-up of any adverse event will be by the treating surgeons in accordance with best surgical practice. For this study, an adverse event has been defined as a clinical sign, symptom or condition that is causally related to the surgery and/or subsequent rehabilitation. Irrespective of the severity of adverse event, all events will be documented accordingly, along with relevant treatment(s), within the individual’s patient file and within the study database. Information on adverse events will be collected at each post-operative visit. Specific information will be solicited from participants at each study visit and via physical examination to capture adverse events associated with study treatment.

Adverse events will be graded as follows:

* Mild (Grade 1): Transient or mild discomfort; no limitation in activity; no intervention or therapy required.
* Moderate (Grade 2): Mild to moderate limitation in activity; some assistance may be needed; no or minimal medical intervention/therapy required.
* Severe (Grade 3): Marked limitation in activity; some assistance usually required; medical intervention/therapy required; hospitalisation possible.
* Extreme (Grade 4): Extreme limitation in activity; significant assistance required; significant medical intervention/therapy required; hospitalization or hospice care probable; potentially life-threatening. This will include re-rupture.

All adverse events deemed to be severe or extreme will be reported accordingly to the relevant ethics board, and treated accordingly.

# DATA MANAGEMENT AND RECORD KEEPING

Firstly, data collected from patients throughout the duration of this prospective follow up will include subjective information in the form of questionnaires, as well as clinical tests including the measurement of strength and functional hop capacity. The storage and disposal of data will comply with the guidelines set forth by the University of Western Australia, in accordance with the Western Australian University Sector Disposal Authority. All paper records will be kept under lock and key in a metal filling cabinet at Coastal Orthopaedics or the HFRC Rehabilitation Clinic (place of clinical and research work of Dr Jay Ebert). The HFRC Rehabilitation Clinic is also the location in which the latter assessments will take place. Data will be entered into a password protected electronic spreadsheet (which will also permit later data analysis) to be held at the HFRC Rehabilitation Clinic, in “re-identifiable” (coded) format. The research-specific database will be coded to protect the anonymity of the participant. The research-specific database will only be accessible to Dr Jay Ebert, and again once entered this data will be de-identified (coded). Dr Jay Ebert will also be responsible for entering research data and participant de-identification. If required clinically, the patient’s consulting surgeon will have access to hand written and standard clinical reporting records. As per the Western Australian University Sector Disposal Authority, in maintaining this randomised controlled trial retention of data will extend to 25 years of age for all participants. Data will then be securely erased as per the procedures adopted by the University of Western Australia in accordance with the Western Australian University Sector Disposal Authority. There will be no patient interviews undertaken and/or recorded specifically for this study, while no intellectual property will be created with the outcomes of this project.

# PUBLICATION AND RESULTS DISSEMINATION

It is anticipated that the results of this research study will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that the participant cannot be identified. Only mean (pooled) results will be disseminated, rather than individual results. Upon completion of the study, and the ethical dissemination of results (through published scientific means of data release), the pooled results in this published format can be provided to participants. It is important to note that this study does not involved the collection of genomic data, and the evaluations undertaken are routinely undertaken in these patients as part of standard care.

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