CUHK Achilles Tendon Disorder Registry

Research Project Statement

The Achilles tendon is one of our body's most important structures, and the' Achilles heel' is a real clinical problem. The management of its pathologies—spanning acute ruptures to chronic tendinopathies—remains heterogeneous, with a critical absence of high-quality longitudinal data to compare treatments and guide personalized rehabilitation strategies. To address this evidence gap, we will establish a comprehensive prospective Achilles Tendon Disorder Registry.
The registry will integrate our team's expertise in Achilles tendon research, which encompasses standardized assessment tools, biomechanical studies, and treatment evaluation. By systematically collecting outcome data, it will enable us to: determine the effectiveness of different treatment methods, advance evidence-based knowledge, improve the quality of care, enhance patient safety, achieve better patient outcomes, and reduce healthcare costs. This longitudinal registry will monitor long term outcome of Achilles tendon problem, and track Achilles tendon treatment outcomes, thereby helping to inform precision rehabilitation strategies and reduce long-term disability in the future.

Research Questions

1. Does the baseline status (e.g., vascularity and elastography metrics) influence the prognosis?
2. Does pre-existing Achilles tendinopathy increase the risk of acute Achilles tendon rupture?
3. Which group of patients is more responsive to which treatment?

Hypothesis

1. Baseline status (e.g., vascularity and elastography metrics) significantly influences prognosis.
2. Pre-existing Achilles tendinopathy significantly increases the risk of acute Achilles tendon rupture.
3. Different patient groups respond differently to various treatment methods.

Research Methodology

Study setting

This prospective cohort study will be conducted at the Prince of Wales Hospital in Hong Kong. All self-reported, functional, and ultrasonographic outcomes will be assessed at baseline, 6 weeks, 3 months, 6 months, and 1 year. Following the initial 1-year follow-up, all self-reported outcomes will be assessed annually through online questionnaires at 2, 3, 4, and 5 years. All participants must provide written informed consent prior to enrolment. The investigator will obtain and document consent before any study procedures are performed. All eligible participants will be fully informed about the study and given ample time to consider participation; the research team will answer all participant questions. The trial will be conducted in accordance with the Declaration of Helsinki.

Eligibility

Inclusion:

- Adults (>18 years of age)

Exclusion:

- Any physical or psychological comorbidity that would impair the ability to complete study assessments (e.g., significant neurological deficits) or preclude the provision of informed consent.
- Concomitant diseases that severely affect lower limb function or assessment (e.g., severe osteoarthritis of the knee or hip, prior lower limb amputation, peripheral vascular disease, active rheumatoid arthritis, lower limb paralysis, etc.)

Outcome measures

Baseline demographic data will be collected, including age (date of birth), gender (biological sex), occupation, recreational activity (Pre-injury and current activity levels -Tegner score), diagnosis (types of Achilles tendon problem) , treatment modalities already tried.

Time frames for collection include 0 weeks (baseline), 6 weeks, 3 months, 6 months, 1 year. Following the initial 1-year follow-up, all self-reported outcomes will be assessed annually through online questionnaires at 2, 3, 4, and 5 years.

Primary Outcome: Victorian Institute of Sports Assessment (VISA-A) Questionnaire

The primary outcome measure will be the Victorian Institute of Sport Assessment (VISA-A) questionnaire, available in either the original English or validated Chinese version, depending on the participant's native language. This specific scoring system developed for the Achilles tendon is the most widely used score for clinical Achilles research. The VISA-A is scored on a scale of 0 to 100; lower scores indicate more severity of symptoms, while a score of 100 indicates a healthy and pain-free Achilles tendon.

Secondary Outcomes: Numeric Pain Rating Scale (NPRS); Foot and Ankle Outcome Scores (FAOS); Achilles tendon resting angle (ATRA); Royal London hospital test; Calf Muscle Strength; Heel raise test; Jump test; Foot pressure distribution; Ultrasonographic tendon thickness; Ultrasonographic tendon cross-sectional area; Ultrasonographic neovascularity; Ultrasonographic tendon elasticity; Ultrasonographic calf muscle quality; Photoacoustic imaging-derived tendon oxygenation and vascularity; Thermographic tendon temperature.

Numeric Pain Rating Scale (NPRS): The Numeric Pain Rating Scale (NPRS; 0–10, where 10 represents maximum pain) will be used to assess pain levels, as pain is the primary symptom of midportion Achilles tendinopathy. Participants will report their “Worst pain during sports in the past two weeks,” “Worst pain during daily activities in the past two weeks."

Foot and Ankle Outcome Scores (FAOS): The FAOS is a validated patient-reported scoring system used for general foot and ankle problems. It is split into five categories: symptoms, pain, daily activities, sporting function, and quality of life. Scores range from 0 to 100, with 0 being the lowest and 100 being the highest.

Achilles tendon resting angle (ATRA): The ATRA will measure participants' tendon length/tension. Participants should be positioned in a prone position with the knee flexed to 90 degrees. The assessor will use a dynamic joint goniometer to measure the angle at which the foot passively falls.

Royal London hospital test: The Royal London Hospital Test is used to help diagnose mid-portion Achilles tendinopathy. The patient lies prone with the foot relaxed, and the examiner

palpates the most tender spot on the Achilles tendon. The patient then moves the ankle through dorsiflexion and plantarflexion. A positive test occurs if tenderness decreases during dorsiflexion.

Calf Muscle Strength: The hand-held dynamometer will be used to quantify isometric muscle strength during ankle dorsiflexion and plantarflexion. Participants will maintain maximal isometric contraction for 3 seconds. Three trials will be recorded for each movement, with 30-second rest intervals between trials to prevent fatigue.

Heel raise test: Participants will be instructed to keep the knee straight and rise as high as possible on the toes each time until fatigue. Participants can place two fingertips per hand on the wall to maintain balance. The rhythm will be set at a frequency of 30 heel rises per minute by following a metronome. Total test duration (in seconds) will be recorded.

Jump test: Participants will perform three one-legged counter-movement jumps on a pressure mat (Tekscan, USA) with jump height (cm) calculated from flight time. After demonstration and submaximal practice jumps, the patient executed maximal jumps from a standing position by rapidly squatting (flexing knee/hip/ankle) before exploding upward. The highest jump was recorded, with NPRS-reported Achilles tendon pain immediately post-test.

Foot pressure distribution:

In foot pressure distribution examination, the scan (Tekscan, USA) will be masked and divided the foot into eight regions including both forefoot, midfoot and hindfoot: hallux, lesser toes, lateral and medial forefoot, lateral and medial midfoot, lateral and medial hindfoot. Peak pressure and impulse in each region will be calculated to see the before-and-after change. Additionally, the centre of pressure excursion index (CPEI) will also be calculated to which reflects the excursion of the centre of pressure. The first and last points of a centre of pressure curve will be connected to construct a line measured in the distal tertile of the foot and normalized by the foot's width.

Zebris Treadmill Gait and Stance Analysis: The Zebris is a treadmill equipped with advanced pressure sensors designed to analyze gait and stance. Subjects were instructed to walk barefoot on the treadmill at their comfortable pace while maintaining a natural walking pattern. During the test, the pressure distribution across the plantar surface of the feet was recorded, capturing dynamic data such as force, timing, and spatial parameters of each step, which ensures precise measurement of walking and stance characteristics, providing valuable insights into balance, weight distribution, and movement symmetry for clinical or research purposes.

Achilles Ultrasonography:

To ensure reproducibility, a standardised Achilles tendon ultrasound imaging protocol will be used to perform the assessment at all time points in the trials. Subjects will lie prone on the examination table with knees straight and ankles hanging in a relaxed position. The Achilles tendons will be imaged bilaterally using an ultrasound machine equipped with a 12 MHz linear transducer (Aixplorer, SuperSonic Imagine, Aix-En-Provence, France). All regions of interest (ROIs) will be measured at: (1) the maximum thickness point, and (2) standardized locations 2 cm, 4 cm, and 6 cm proximal to the insertion.

Tendon thickness: Using B-mode ultrasound scanning, the probe is moved from the medial to the lateral aspect of the Achilles tendon until a planar image of the Achilles tendon is clearly shown. The probe was adjusted straight perpendicular to the tendon fibres. A greyscale sonogram is acquired, and the tendon thickness is measured at the maximum thickness point and at 2, 4, 6 cm proximal to the insertion. Less than 5.3 mm was considered a healthy value for the Achilles tendon.

Tendon vascularity: Vascularity will be documented using the Ohberg score. Using the Doppler mode on the ultrasound machine, the transducer is placed vertically to obtain a sagittal view of the softest area of the Achilles tendon. Pressure on the skin from the

transducer should be kept to a minimum to prevent occlusion of blood vessels. The colour box is focused on the dorsal aspect of the tendon. The assessor will spend one minute exploring the blood flow over the tendon to find the area of maximum Doppler flow. After locating the area, sonograms are taken to determine the Öhberg score. The Öhberg score ranges from 0 to 3 points. In this scoring system, the score is defined as 0 (no neovascularisation, healthy), 1 (mild neovascularisation with a few single vessels), 2 (moderate neovascularisation with a moderate number of mostly transverse vessels), and 3 (multiple, mostly transverse vessels distributed throughout the depth of the tendon). Higher scores indicate more Doppler blood flow in the peritendinous and intratendinous tissues. Healthy tendons (Ohberg score of 0) have no blood vessels in the Achilles tendon.

Tendon elasticity :

Shear wave elastography (SWE) can be used to quantify soft tissue stiffness. Once the optimal scan plane of the tendon is determined, the SWE function is activated. It enters penetration mode and the measured stiffness range is normalized to 0-600 kPa. The SWE color card (H × W: 1.4 cm × 1.3 cm) is placed immediately above the upper edge of the calcaneus. After the color signal stabilized for five seconds, the elastogram was recorded and stored. Tendon stiffness was measured using a Q-box stiffness meter. Depending on the size of the tendon, the diameter of the circular measuring area (Q-box) is set to 2 mm, which covers the Achilles tendon and excludes other adjacent soft tissues. The Q-box is located in the center of the maximum thickness point and 2, 4, 6 cm proximal to the calcaneal insertion site. For each Q-box, the average tendon stiffness (in kPa) is measured.

Tendon oxygenation and vascularity: The pathological tendon's oxygenation and vascularity were quantified using a multiwavelength photoacoustic ultrasound (PAUS) system equipped with a 7Hz probe and dual-wavelength LED sources (850nm/750nm). The participant assumes a prone position with heels extended beyond the examination table. The probe is positioned on the target tendon, with mode-specific presets selected ("Deep PA" for vascularity at 850nm; "Deep Oxy" for oxygenation at 750nm). Each 20-second acquisition captures 200 frames, with two repeated scans per mode to ensure data reliability.

Thermographic tendon temperature: Participants will be advised to avoid physical exercise and hot baths before the procedure to ensure data reliability. Each participant will rest in a seated position for 10 minutes followed by 2 minutes without socks. The room will be maintained at 20-24°C. The infrared camera will be positioned one meter from the participant, using a ThermaCam FLIR-T8210. Images will be analyzed with ThermaCAM Researcher Pro 2.8 SR-1 software, and a rectangular area covering the Achilles tendon will be used for temperature assessment.

Sample size

As a prospective registry study, this study plans to consecutively enroll all eligible patients presenting to the Prince of Wales Hospital between 2025 and 2028. Based on the annual patient volume, a minimum of 500 participants is expected to be recruited, which is anticipated to provide sufficient statistical power for the planned multivariable analyses.

Recruitment

Participants will be recruited through multiple concurrent strategies. Our primary recruitment site is the Prince of Wales Hospital. We will also utilize our sports medicine network, which includes school sports teams, professional organizations (e.g., Kitchee Football Club), and an extensive alumni network of doctors and sports medicine professionals from our MSc program. Simultaneously, study advertisements will be distributed to all staff and students of The Chinese University of Hong Kong through the CUHK Mass Mail System to ensure comprehensive outreach.

Data collection and management

Plans to promote participant retention and complete follow-up: The schedule for all the outcome measure appointments will be provided from the beginning. For patients who have missed their scheduled appointments for follow-up assessments, additional hours will be extended to the evenings at the Sports Performance and Biomechanics laboratory at CUHK so that participants may come for assessment (e.g., after work, rescheduled due to illness, etc.).

Data management: Data collected will be securely stored in password-protected computers and archived for five years after publication. The Principal Investigator (PI) and research assistants will oversee data collection, entry, and analysis. To ensure accuracy, a double data entry method and range checks will be implemented. Data will be restored into an Excel files and then transferred to SPSS software for analysis.

Confidentiality: To ensure the highest level of privacy and security, the Sports Performance and Biomechanics Laboratory stores all personal information and consent forms in securely locked cabinets. Our online electronic database is protected by password-protected computers, ensuring the utmost confidentiality. Access to the collected data is strictly limited to trusted trial team members, with no access granted to participants. De-identified participant data may be shared with other researchers upon reasonable request and after execution of appropriate data sharing agreements, subject to approval by the ethics committee.

There is no plan for using biological specimens outside of this study plan.

Statistical methods for primary and secondary outcomes: Statistical analyses will be performed using SPSS (version 28.0), with a two-sided significance level of $\alpha = 0.05$. Continuous outcomes (e.g., VISA-A, NPRS, tendon thickness, dynamometry) will be summarized as mean ± standard deviation, assessed by Shapiro–Wilk test. Categorical variables will be presented as frequencies and percentages.

To address Q1 (prognostic influence of baseline status), multivariable linear or logistic regression models will be constructed to evaluate the association between baseline metrics (e.g., vascularity, elastography) and functional outcomes (e.g., VISA-A, heel raise capacity), adjusting for covariates such as age, sex, and symptom duration.

For Q2 (risk assessment), a Cox proportional hazards model or logistic regression will be used to examine whether pre-existing tendinopathy (dichotomized: yes/no) predicts subsequent acute rupture, with results reported as hazard ratios or odds ratios and 95% confidence intervals.

For Q3 (treatment responsiveness), interaction terms between patient subgroups (e.g., defined by baseline severity, structural metrics) and treatment types will be incorporated into regression models to identify effect modifiers. Should significant interactions be detected, stratified analyses will be performed.

Interim analyses: An interim analysis will be performed on the primary endpoint when 20% of participants completed the 1-year follow-up. The interim analysis ensures that no serious adverse event happened during the study period.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data: Missing data will be handled using multiple imputation under the missing-at-random assumption. Sensitivity analyses will include complete-case assessments. Model assumptions (e.g., linearity, proportionality) will be verified graphically and analytically.

Plans to give access to the full protocol, participant-level data, and statistical code: The protocol will be registered on clinicaltrials.gov. The participant-level data and statistical code can be provided upon request.

Oversight and monitoring: The principal investigator will monitor the progress of the study. The trial steering committee consists of research team members who will participate in participant recruitment, data collection, and management. The trial steering committee consists of orthopaedic surgeons and researchers (research assistants and biostatisticians). The orthopaedic surgeons and research assistants will participate in data collection and analysis. The biostatistician will monitor data collection and perform interim analysis. There is no independent data monitoring committee, as the ethics committee does not require this.
Adverse events reporting and harms: The procedure will be supervised by orthopaedic surgeons licensed under the Medical Council of Hong Kong. If a participant experiences a severe adverse reaction to the intervention, it will be reported to the trial steering committee immediately, and the participant will be removed from the trial.
Frequency and plans for auditing trial conduct: An independent auditor from the ethics committee will conduct the trial conduct annually. The principal investigator will complete a progress report form for the ethics committee to review conduct annually during the trial period.
Plans for communicating necessary protocol amendments to relevant parties: The investigators will seek protocol amendments from the ethics committee, which must approve them before implementation. Trial participants will be notified of any changes to the protocol. Furthermore, the protocol modifications will be publicly available in the Trial Register.

Funding and Sponsors:
There are no declared funding sources or sponsors at this stage.
Institutional Affiliations:
The study is conducted by the Department of Orthopaedics and Traumatology, Faculty of Medicine, The Chinese University of Hong Kong (CUHK).
Potential Conflicts of Interest:
All investigators involved in this study have declared no competing interests.
Incentives for Subjects:
No financial or material incentives are provided for participation.
Provisions for Harm:
Participants who experience adverse effects directly attributable to the study will receive appropriate medical care at the Prince of Wales Hospital, CUHK, at no additional cost. Compensation for research-related harm will follow institutional and ethical guidelines.