GENERAL STUDY INFORMATION AND INFORMED CONSENT

UNIVERSITY CEU CARDENAL HERRERA

Principal investigator: Dr. Sergio Montero Navarro

TITLE: Textural Analysis and Effect of ROI Size on Infrared Thermography in Athletes With Patellar Tendinopathy. A Cross-sectional Study

Research and Ethics Committee of University Católica San Antonio, Number: CE111803

NCT ID:

DATE: 07-23-2025

GENERAL STUDY INFORMATION

TITLE: **Textural Analysis and Effect of ROI Size on Infrared Thermography in Athletes With Patellar Tendinopathy. A Cross-sectional Study**

Mr. Sergio Montero Navarro, Physiotherapist, principal investigator and researcher reports that:

The tests performed are simple and in no case involve difficulty, fatigue, danger, injury, pain or adverse reaction.

They will be carried out by collegiate physiotherapists in the School of Physiotherapists of the Valencian Community.

The general data of the subject will be collected (name, age, sex, physical variables and clinical history). The article must be sent with comfortable clothes The day that sea cited by the researcher, previous notice. Personal data is recognized in this study.

The personal data are confidential, apply to the protection of personal data (Organic Law 15/1999, December 13) and any other thing that may be applicable.

This study was approved by the Research and Ethics Committee of University Católica San Antonio (CE111803).

INFORMED CONSENT

Mr/Mrs..... with Number identification .... freely and voluntarily, I DECLARE:

That I have read the information contained in this document about the general information of the study.

I have been informed that all tests are simple to perform and do not produce harmful effects on health. They will be carried out in appropriate facilities and will be carried out by qualified and specialized personnel.

I have also been informed that, the data collected in this study will be treated confidentially, applying the current legislation on protection of personal data (Organic Law 15/1999, of December 13) and any other applicable.

Therefore, I give my consent and I authorize Mr. Sergio Montero Navarro, to carry out the detailed study in this document with the help of the necessary personnel with the appropriate qualification and specialization.

In Elche, to ..... of ..... of 202

SIGNED:

STUDY PROTOCOL PLAN AND STADISTICAL ANALYSIS PLAN (SAP)

UNIVERSITY CEU CARDENAL HERRERA

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STUDY PROTOCOL PLAN

Objectives:

The objectives of our study have been the following:

The objectives of this study were: (1) to evaluate differences in thermal and GLCM-based textural features between athletes with PT and healthy controls; (2) to compare the diagnostic performance of IT and GLCM features applied to thermographic images; and (3) to identify the most appropriate ROI size for optimal characterization of PT using both thermal and textural analysis.

Volunteers who want to participate in the study will read the general information of the study and sign the informed consent to participate in the study.

Once the informed consent has been read and delivered, the evaluator will check that they meet the inclusion criteria.

Participants will be divided into two groups: (1) athletes with unilateral PT, diagnosed using a combination of clinical criteria, specific functional tests, and ultrasound evaluation. Additional inclusion criteria for this group included a symptom duration of more than 3 months, a VISA-P score of less than 80, and a differential diagnosis to rule out other possible causes of anterior knee pain; (2) healthy volunteer athletes, recruited under the inclusion criteria of no previous history of PT and a VISA-P score of 100.

Participants with any other lower limb pathology, nerve or vascular disorder, or skin lesion in the knee area that could alter the thermal information of the patellar tendon region will be excluded from both groups.

All participants were instructed not to engage in physical exercise; not to drink alcohol, coffee or energy drinks 12 hours before the measurements; not to smoke in the previous 6 hours; not to apply creams or lotions to their legs to avoid altering skin emissivity; to report any medication or treatments they were taking; and to try to avoid altering their rest and meal habits. These requirements minimise the influence of individual extrinsic factors on the IT results.

Recorded variables

Demographic and clinical characteristics (gender, age, BMI, and duration of evolution) will be recorded. The severity of patellar tendinopathy will be measured using the widely accepted and valid Victorian Institute of Sport Assessment-Patella (VISA-P) questionnaire. All thermal image recordings were performed by the same researcher.

Determination of sample size

The sample size will be calculated using G*Power v.3.1.9.7 software (Heinrich-Heine University) for a logistic regression design to evaluate the diagnostic accuracy of IT in distinguishing between patients with PT and healthy controls, taking into account the possible inclusion of covariates. The parameters are set as follows: odds ratio = 5, alpha error probability $\alpha = 0.05$, power $1-\beta = 0.80$, R^2 for other covariates = 0.1, binomial distribution with a proportion $\pi = 0.5$.

Image acquisition protocol

TI images will be recorded with an OPTRIS PI 450 IRT camera coupled to Optris PI Connect software (Germany). The IRT camera has a noise equivalent temperature difference <40 mK with a field of view of 38° x 29°, a wide temperature range of −20 °C to +100 °C, a spectral range of 7.5-13 µm, a focal plane array sensor size of 382 × 288 pixels, an emissivity set to 0.98, and a measurement uncertainty of ± 2% of the global temperature reading. The capture frame size was 55.4 × 40.63 cm (1.5 mm/px).

The participant will acclimatise in an isolated room (3.86 x 3.47 m2), without temperature sources, at an average temperature of (23.7 ± 0.9 ºC) and relative humidity of (49 ± 5 %) for 15 minutes without clothing on the lower extremities. The participant will sit on a hydraulic stretcher with their feet on a step to isolate contact with the floor, and the camera will be positioned perpendicular to the subjects for a more accurate reading. Two rectangular ROIs will be selected on each knee using a previously described method by superimposing ROIs on thermal images using markers on the skin. a) an ROI of the patellar tendon (tendon ROI); b) an ROI of the anterior part of the knee (knee ROI) using the anatomical references of the upper pole of the patella, anterior tibial tuberosity, and lateral contour of the knee.


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Statistical Analysis Plan (SAP)

The data will be analysed using IBM SPSS Statistics for Windows v.25.0 (IBM Company, 2017). The normality and homoscedasticity of the variables will be checked. The data will be summarised using absolute and relative frequencies for categorical variables, and means ± standard deviations (SD) and 95% confidence intervals for continuous variables.

Independent sample t-tests will be used to compare continuous variables, and a chi-square test will be used to compare categorical variables at baseline between PT patients and controls.

One-way analysis of covariance will be used to analyse the thermal difference and textural characteristics between PT patients and healthy controls, controlling for the effects of clinical and demographic covariates. Cohen's d statistic will be calculated to assess the effect size ($d > 0.1$ small, around 0.3 medium, and >0.5 large).

To calculate the diagnostic accuracy of the thermal difference and textural characteristics based on first- and second-order statistical analysis, simple logistic regression will be performed for age, sex, and BMI by group, including them in subsequent models if $p < 0.20$. Sensitivity (Se), specificity (Sp) and Youden's index (expressed as $Se + Sp - 1$) will be investigated, as well as the positive and negative likelihood ratios (LRp and LRn) of thermal difference, textural characteristics and their combinations. The thermal difference and textural characteristics will be introduced one by one and in all possible combinations (255 models) in the logistic regression analyses, including a maximum combination model containing all characteristics.

Receiver operating characteristic (ROC) curves will be used and the Hosmer-Lemeshow goodness-of-fit test will be performed by comparing the observed and expected frequencies of the outcome variable ($p > 0.05$ indicates a good fit). The Brier score will be calculated to evaluate the accuracy of the probabilistic predictions, where lower scores indicate better model performance. An area under the curve (AUC) value close to 90% and sensitivity and specificity values above 80% are considered acceptable.