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PEDRO BAINY FRANZ

Entorses Laterais Agudas de Tornozelo Comprometem Função e Força sem Comprometer Rigidez Muscular ou Tendínea: Um Estudo Observacional Controlado

DISSERTAÇÃO DE MESTRADO

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Orientador: Prof. Dr. João Luiz Quagliotti Durigan

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PROGRAMA DE PÓS-GRADUAÇÃO EM CIÊNCIAS DA REABILITAÇÃO

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Aos (trinta e um) dias do mês de (março) do ano de dois mil (e vinte e cinco), instalou-se a banca examinadora de Dissertação de Mestrado do(a) aluno(a) (PEDRO BAINY FRANZ), matrícula (222101159). A banca examinadora foi composta pelos professores Dr(a). (RODRIGO SCATTONE DA SILVA/Externo à Instituição/UFRN), Dr(a). (GRACIELLE VIEIRA RAMOS/Externa à Instituição/UNIP), Dr(a). (FELIPE AUGUSTO DOS SANTOS MENDES/Externo ao Programa/UnB) (Suplente) e Dr(a). (JOAO LUIZ QUAGLIOTI DURIGAN/Presidente/UnB), orientador(a)/presidente. O(A) discente apresentou o trabalho intitulado (Entorses Laterais Agudas de Tornozelo Comprometem Função e Força sem Comprometer Rigidez Muscular ou Tendínea: Um Estudo Observacional Controlado).

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PRESENTATION

The decision to present this work in English, despite the graduate program being based in Brazil and delivered in Portuguese, reflects a broader commitment to internationalization. By adopting English as the language of this dissertation, we aim to facilitate collaborations with institutions abroad, and contribute to the global dissemination of high-quality scientific knowledge. This choice also underscores the relevance of the topic beyond local or regional contexts, aligning with the worldwide interest in understanding the mechanical and functional consequences of musculoskeletal injuries.

Ankle sprains are among the most common musculoskeletal injuries in physically active individuals and the general population alike. Lateral ankle sprain, in particular, accounts for the majority of all ankle injuries and frequently leads to persistent symptoms, impaired function, and long-term complications such as chronic ankle instability. Despite its high incidence and substantial individual and societal burden, lateral ankle sprain is often underappreciated in clinical practice, especially in terms of its potential impact on muscle function, joint mechanics, and rehabilitation outcomes.

Over the past decade, research in sports and rehabilitation sciences has expanded its focus from purely clinical outcomes to more detailed biomechanical and tissue-level assessments. This shift has been enabled, in part, by technological advances in imaging techniques—such as shear wave elastography—which allow for the noninvasive quantification of tissue stiffness. These methods offer promising insights into the mechanical properties of muscles and tendons, both in healthy individuals and in those with musculoskeletal injuries. However, the interpretation of these parameters, particularly in acute stages of injury, remains a matter of scientific debate.

Although several studies have investigated tendon and muscle stiffness under chronic pathological conditions, the immediate effects of acute injuries such as LAS on the mechanical behavior of surrounding tissues are still poorly understood. A deeper understanding of these changes could improve clinical reasoning regarding early management strategies, prognosis, and the design of individualized rehabilitation protocols.

In light of these considerations, it becomes evident that further investigation into the mechanical and functional alterations associated with acute lateral ankle sprains is both timely and necessary. The present dissertation builds upon this perspective by exploring these alterations through a multidimensional approach, combining clinical, functional, and elastographic assessments.The following introduction presents the theoretical background, rationale, and specific objectives that guided the development of this study.

DEDICATION

I dedicate this work to my beloved son, who came into my life to break every imaginable boundary of love and taught me a new and beautiful meaning of life. To my dearly loved wife, who reveals to me each day a new reason to admire her even more, and who was the solid foundation that made the completion of this work possible. To my cornerstone, examples of love, respect, safety, and trust: my mother and my brother. And also to my dear father, who left us with the legacy of resilience and the view of science as a social commitment.

“We do not describe the world we see. We see the world we can describe” (René Descartes)

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First and foremost, I thank the participants of this study, who, in a moment of pain and uncertainty, contributed out of a sense of commitment to science and to the advancement of society.

To my wife and my son, my pillars—not only the foundation that enabled me to carry out this work, but also an endless source of inspiration and motivation.

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To Professor Jeam Geremia, from the Federal University of Rio Grande do Sul, who did not hesitate to share his knowledge and demonstrated a genuine spirit of collaboration.

Last but not least, to the entire team at Kale Espaço Saúde, with whom I have grown personally and professionally over the years. You are my dearest friends, my supporters—without whom I would never have been able to sustain the dedication required to complete this work.

LIST OF TABLES

LIST OF ABBREVIATIONS

AT – Achilles Tendon

BMI – Body Mass Index

FAOS – Foot and Ankle Outcome Score

FOV – Field of View

ICC – Intraclass Correlation Coefficient

ICC (95%) – Intraclass Correlation Coefficient with 95% Confidence Interval

IC (95%) – Confidence Interval (95%)

kPa – Kilopascal

LAS – Lateral Ankle Sprain

LG – Lateral Gastrocnemius

MG – Medial Gastrocnemius

MD – Mean Difference

MVIC – Maximal Voluntary Isometric Contraction

n.m – Newton-meter (Torque)

P – Probability Value

ROIs – Regions of Interest

SWE – Shear Wave Elastography

SO – Soleus

TL – Tibial Length

VAS – Visual Analog Scale

RESUMO

Objetivo: Investigar os efeitos da entorse lateral aguda de tornozelo (LAS) nas propriedades mecânicas dos músculos da panturrilha e do tendão de Aquiles (AT), juntamente com a função do tornozelo, dor, edema e força, em comparação com um grupo controle pareado ao longo de um período de seis semanas. **Métodos:** Catorze participantes com LAS aguda (≤72 horas pós-lesão) e 14 controles saudáveis foram avaliados no início do estudo e novamente após seis semanas. A rigidez do tríceps sural e do AT foi avaliada por meio de elastografia por onda de cisalhamento (SWE). A função do tornozelo, dor e edema foram avaliados, respectivamente, pelo *Foot and Ankle Outcome Score*, pela Escala Visual Analógica e pelo método da figura de oito. A força de flexão plantar foi medida com um dinamômetro isométrico. **Resultados:** Não foram encontradas diferenças significativas na rigidez muscular da panturrilha ou do AT entre ou dentro dos grupos. No entanto, um efeito do tempo indicou um aumento geral na rigidez do AT ao longo do tempo. No início do estudo, o grupo LAS apresentou escores significativamente mais baixos de função do tornozelo e níveis mais elevados de dor e edema em comparação aos controles. As análises dentro do grupo mostraram melhorias significativas na função do tornozelo, dor e edema na avaliação de seis semanas; no entanto, a função do tornozelo permaneceu significativamente inferior no grupo LAS em comparação aos controles. Nenhuma interação significativa grupo × tempo foi observada para o torque de pico, mas um efeito de grupo indicou menor torque de pico no grupo LAS, enquanto um efeito de tempo demonstrou aumentos gerais no torque de pico ao longo do tempo. **Conclusão:** A LAS reduz significativamente a função do tornozelo e causa dor e edema, mas não parece induzir alterações notáveis na rigidez dos músculos da panturrilha ou do AT dentro de seis semanas. Os profissionais de saúde devem considerar o grau da lesão, o tempo desde a entorse e as condições de carga durante a reabilitação, pois esses fatores afetam os músculos da panturrilha e o AT.

Palavras-chave: Desempenho funcional, Elastografia, Entorse de tornozelo, Força muscular, Tendão de aquiles.

ABSTRACT

Objective: To investigate the effects of acute lateral ankle sprain (LAS) on the mechanical properties of the calf muscles and the Achilles tendon (AT) in conjunction with ankle function, pain, edema, and strength compared to a paired control group over a six-week period. **Methods**: Fourteen participants with acute LAS (≤72 hours post-injury) and 14 healthy controls were evaluated at baseline and again after six weeks. Triceps surae and AT stiffness were assessed using shear wave elastography (SWE), ankle function, pain and edema were respectively assessed via the Foot and Ankle Outcome Score, the Visual Analog Scale and the figure-of-eight method. Plantar flexion strength was measured using an isometric dynamometer. **Results**: No significant differences were found in calf muscle or AT stiffness between or within groups. However, a time effect indicated an overall increase in AT stiffness over time. At baseline, the LAS group showed significantly lower ankle function scores and higher pain and edema levels compared to controls. Within-group analyses showed significant improvements in ankle function, pain, and edema at the six-week assessment, however ankle function remained significantly lower in the LAS group compared to controls. No significant group × time interactions were observed for peak torque, but a group effect indicated lower peak torque in the LAS group, while a time effect demonstrated overall increases in peak torque over time. **Conclusion**: LAS significantly reduces ankle function and leads to pain and edema but does not appear to induce notable changes in calf muscle or AT stiffness within six weeks. Clinicians should consider injury grade, time since sprain, and loading conditions during rehabilitation, as these factors affect the calf muscles and AT.

Key-words: Achilles tendon, Ankle sprains, Elastography, Functional performance, Muscle strength

SUMMARY

INTRODUCTION

Lateral ankle sprain (LAS) is one of the most common musculoskeletal injuries worldwide and is among the main orthopedic reasons for medical consultation involving the ankle-foot complex[1–4]. Although LAS is often managed conservatively and expected to heal within a few weeks[7], many individuals continue to experience symptoms and functional limitations for months or even years[7–12]. Persistent issues such as joint laxity, pain, and reduced performance can compromise recovery and quality of life[7–9].

One of the key concerns following LAS is the period of disuse caused by pain and swelling, which often leads to muscle weakness and atrophy[5–7]. Importantly, disuse can also affect deeper characteristics of the musculotendinous system, such as its mechanical properties[18–20]. Tendon stiffness, for example, plays an important role in joint stability and tissue health[21–23], and evidence suggests that changes in stiffness can occur early during periods of inactivity[24–25].

In addition to local symptoms, impairments in postural control are frequently observed after ankle sprains[5,26]. Since calf muscles and the Achilles tendon contribute to ankle stability and joint behavior[27–31], changes in their mechanical properties may influence how the joint responds after injury[27–34]. However, there is limited understanding of how these structures respond in the early stages following LAS[33–34].

Ultrasound shear wave elastography (SWE) has emerged as a reliable and non-invasive tool to evaluate tissue stiffness[21,35–39]. Unlike other methods that require muscle contraction[43–44], SWE can be used even when active movement is not possible, which is ideal for patients in pain or in the early stages of recovery[41–42]. Investigating muscle and tendon stiffness with SWE after LAS may help us better understand the effects of injury and disuse, and guide more effective rehabilitation approaches.

LITERATURE REVIEW

Lateral ankle sprain (LAS) is one of the most prevalent acute musculoskeletal injuries worldwide[1, 2] and ranks among the leading orthopedic injuries of the ankle-foot complex requiring medical attention[3, 4]. An immediate consequence of LAS is disuse due to pain, joint edema, and reduced weight-bearing, leading to muscle atrophy, weakness, and impaired function[5, 6] Although conservative treatment protocols for LAS typically last 4 to 6 weeks[7] (Mansur et al., 2022), significant reductions in the cross-sectional volumes of ankle muscles and tendons have been reported at this time point[7]. Persistent joint laxity[8], low function, and reduced muscle and tendon thickness can endure for years following LAS[7, 9-

[12]. While ligaments may heal within six weeks after mild or moderate LAS[13], most patients require longer periods to regain pre-injury function[7, 14-16].

Muscle disuse, such as that following a lateral LAS, leads to significant neuromuscular consequences. Notably, muscle strength declines more rapidly than muscle thickness during disuse, with strength losses occurring disproportionately early after the onset of disuse[16, 17]. Disuse affects not only the contractile components of musculotendinous structures but also their mechanical and material properties[18, 19]. Previous studies have demonstrated reductions of up to 30% in tendon stiffness and increased hysteresis in knee extensor tendons after 20 days of disuse[18, 20]. Stiffness reflects muscle and tendon mechanics[21] and aids in assessments of tissue health and injury recovery[22, 23]. Importantly, decreased tendon stiffness due to disuse occurs independently of morphological alterations, such as changes in tendon cross-sectional area[24] and may emerge within as little as 14 days of limb suspension[25].

Additionally, impaired postural control is a well-documented consequence of both acute and chronic ankle sprains[5, 26]. Understanding whether acute LAS leads to measurable changes in the mechanical properties of calf muscles and the Achilles tendon is essential, since these tissues may play a relevant role in joint stability and postural control[27-30]. The passive stiffness of the calf muscle–tendon complex contributes significantly to ankle joint impedance, especially in conditions requiring postural control and rapid torque production[27-29, 31]. Loram and colleagues[27, 32] highlighted the importance of Achilles tendon stiffness for ankle joint stiffness and stability but noted that its series elastic contribution is limited, with passive calf muscle stiffness playing a relevant role as well. Other studies support the link between tendon and muscle mechanical properties and joint behavior, showing positive associations between medial gastrocnemius and Achilles tendon stiffness and passive ankle joint stiffness[31]. Similarly, changes in the mechanical stiffness of soft tissues around the ankle can alter joint kinematics and contribute to symptoms following lateral ankle sprain, potentially leading to chronic ankle instability[33,34]. These findings suggest that alterations in tendon properties may significantly influence joint behavior and stability following injury. However, research on the immediate effects of LAS on tendon and muscle stiffness, as well as their recovery over time, remains scarce.

Changes in muscle and tendon stiffness can be reliably analyzed using ultrasound shear wave elastography (SWE), which offers a non-invasive method for assessing tissue stiffness without requiring muscle contractions[21, 35-39]. This technique offers the advantage of assessing stiffness in various tendon[38, 40] and muscle positions making it particularly useful for individuals with impairments or those unable to contract their muscle[41, 42]. In contrast, methods like Young's modulus rely on physical effort[43], limiting their feasibility for individuals with impairments or those unable to contract their muscles[44]. Given the lack of studies on calf muscles and Achilles tendon (AT) stiffness after LAS, investigating these potential changes over time may help advance our understanding of the impact of LAS on tendon and muscle function, and provide indirect but valuable insights into disuse-related changes in the assessed muscles and tendons.

JUSTIFICATION

There is still no consensus about which variables would help distinguish those with good and poor recovery after LAS. The development of CAI may involve mechanical and functional changes that appear very early. Identifying these changes may contribute to more effective rehabilitation strategies and help prevent long-term disability. However, the evidence on mechanical properties of muscles and tendons after LAS remains limited and inconclusive, reinforcing the need for further investigation.

OBJECTIVES

The current study aimed to investigate the effects of acute LAS on the mechanical properties of the calf muscles and AT in conjunction with ankle function, pain, edema, and strength compared to a paired control group over a six-week period.

HYPOTHESIS

We hypothesized that the time since LAS would affect calf muscles and AT mechanical properties, with the six-week period leading to increased calf muscle stiffness[45-48] and decreased AT stiffness[19, 22].

METHODS

Study Design

This is a Level 3 longitudinal and observational study with a six-week follow-up. The study was approved by the Institutional Review Board at the University of Brasília (number 68997923.2.0000.8093). Informed consent was obtained in accordance with the Helsinki Declaration and local resolution.

Participants

Patients with LAS and healthy controls were selected. The inclusion criteria for the LAS patients were: (I) Age between 18 and 60 years and; (II) history of grade I or II lateral ankle sprain (LAS) within 72 hours prior to evaluation. Grade I represents mild stretching without instability; Grade II (moderate) involves a partial rupture with mild instability; Grade III (severe) is characterized by a complete rupture with significant instability[49, 50]. Participants were excluded if they presented at least one of the following: chronic ankle instability, another ankle sprain in the past year, a grade III injury (diagnosed via clinical tests or imaging), bone injury confirmed by imaging, or, if no imaging had been taken, an indication for imaging based on the Ottawa Ankle Rules[51], lower limb injuries, or prior ankle surgeries. Healthy controls with no history of ankle sprains, severe lower limb injuries, or ankle, foot, or AT pain in the previous six months were included. Control group participants were matched according to sex, age, height, body mass, and body mass index. Both groups underwent identical evaluations twice, six weeks apart.

Outcomes

The primary outcome was the mechanical properties of the calf muscles and AT. Secondary outcomes included ankle function (measured by the Foot and Ankle Outcome Score – FAOS), pain, edema, and muscle strength of the plantar flexors, providing clinical context to clarify the extent of disuse in participants with acute LAS. These measures complemented the mechanical assessments, offering a broader understanding of post-injury impairments.

Experiment Outline

The study was conducted at the Laboratory of Muscle and Tendon Plasticity (LaPlasT) at the University of Brasilia. Participant recruitment and data collection occurred between August 2023 and January 2025. At the beginning of the experimental session, the body mass and height of the participants were recorded. Next, injury history, ankle function, pain, and edema were assessed. The translated and validated FAOS questionnaire was used to assess ankle function52 across five subscales: pain, symptoms, sports/recreation, daily activities, and quality of life. Participants rated their symptoms on a 0–4 scale, with scores normalized from 0 (extreme) to 100 (none). Pain intensity was measured using the Visual Analog Scale (VAS) as used by Terrier et al.53, on a 10 cm horizontal line ranging from 0 ("no pain") to 10 ("severe pain"). Participants were instructed to mark their perceived pain level at the time of assessment. Edema was quantified using the figure-of-eight method, adapted from Devoogdt et al.[54], with the zero point at the distal edge of the medial malleolus. Seated participants kept their foot relaxed. The tape followed a path from the medial malleolus, crossing laterally over the ankle to the fifth metatarsal, looping under the arch to the first metatarsal, passing over the lateral malleolus, wrapping around the Achilles tendon, and returning to the start.

Following these clinical assessments, anatomical landmarks to measure tibia length were identified and marked on the participant's skin using a dermographic pencil to ensure consistency in the SWE measurements. The variables measured were the mechanical properties of the soleus (SO), medial gastrocnemius (MG), lateral gastrocnemius (LG), and Achilles tendon (AT).

Lastly, plantar flexion strength was measured using an isometric dynamometer (IsoSystem 2.0, Cefise, SP, Brazil). Participants were seated with their assessed foot secured to the footplate. The hip was positioned at approximately 120°, the knee was fully extended and the ankle was positioned at approximately 90°. Testing began with a familiarization consisting of three maximal voluntary isometric contractions (5 seconds each), with a 2-minute rest between contractions. Following familiarization, three maximal voluntary isometric contractions (MVICs) were recorded using the same protocol. The average peak torque from these trials was used for data analysis. The details of the mechanical property assessments are provided below.

Testing protocol for muscle and tendon mechanical properties

The mechanical properties of the calf muscles AT were evaluated through stiffness measurements using SWE. Muscle stiffness in the SO, MG, LG, and AT was measured with the ACUSON Redwood Ultrasound System (Siemens Healthineers, Erlangen, Germany) and a linear probe (10 – L4 MHz). Musculoskeletal and tendon presets were applied with a 0-10 m/s (0–300 kPa) scale. For muscle assessments, settings included a smoothing level of 3, gain of 9 dB, and persistence of 3. Tendon measurements used the same settings, except for a gain of -3 dB. SWE measurements were obtained with participants lying prone, knee fully extended, and ankle relaxed and hanging off the table in a neutral position55. The ultrasound transducer was covered with water-soluble gel. A large rectangular field of view (FOV) captured the entire target tissue in the B-mode image56, with 3 mm circular regions of interest (ROIs) used for shear wave speed measurements. To account for tissue anisotropy, the probe was positioned perpendicular to the target56. Assessments were conducted in a climate-controlled room (23–25ºC) to prevent temperature-related stiffness changes57. For muscle assessment, the probe was placed longitudinally along the muscle fibers and perpendicular to the skin at 25% (LG and MG) and 70% (SO) of the tibial length, measured proximally to distally55. The tibia length was defined as the distance from the medial tibial plateau to the distal medial malleolus55.

SWE scans were performed at the thickest muscle region, identified using a transverse B-mode image. The probe was then aligned parallel to the orientation of the muscle fascicles, ensuring that multiple fascicles were continuously visible58. Thirty ROIs were manually distributed among the superficial, intermediate, and deep layers of the evaluated muscle, ensuring that no ROI contacted the superficial or deep aponeuroses to minimize their influence as artifacts on the measurements. For tendon assessment, the AT was evaluated using a probe positioned on the tendon, aligned parallel to its orientation in the free tendon area22. To reduce the influence of bone tissue on SWE data59, measurements were taken where the AT overlies Kager's fat pad. Nine regions of interest (ROIs) were selected along the tendon length, avoiding the area overlapping with the calcaneus. Probe orientation was verified by ensuring homogeneous visibility of the tendon and peritendon structures in the B-mode ultrasound image. A gel pad (Hill Laboratories®) was used to ensure acoustic coupling without applying additional pressure. To blind the assessor from qualitative information about tissue stiffness before distributing the ROIs, the SWE color elastogram was removed from the image before execution and reapplied after data acquisition for both muscle and tendon SWE. SWE velocity was used instead of shear wave modulus to minimize inaccuracies in Young’s modulus estimation, as the latter can be influenced by assumptions about tissue density and equipment limitations60. Each tissue was evaluated three times. For each analysis, the shear wave speed for a participant was calculated as the mean of 30 regions of interest (ROIs) for muscles and 9 ROIs for the AT. The overall tissue stiffness was determined as the average of the three analyses.

Reliability assessment

SWE was conducted by two physical therapist researchers, both trained in musculoskeletal ultrasound imaging and standardized SWE assessment protocols. To assess the reliability of the SWE measurements, intra- and inter-rater reliability were evaluated in the same session in a selected subset of healthy participants (n = 12). For intra-rater reliability, the same rater performed three SWE measurements on each participant. For inter-rater reliability, a second rater, blinded to the first rater’s results, performed three further independent SWE assessments 10 minutes after the first rater had completed their evaluation. To eliminate bias, all skin markings were erased between measurements, and the rater remeasured tibial length (TL) and reidentified anatomical landmarks to ensure an independent reassessment.

Sample size

A post hoc sample size calculation was conducted using the partial eta-square value (η^2) of the group-by-time interaction for shear-wave velocity of the Achilles tendon ($\eta^2 = 0.121$) obtained after data collection from 28 subjects. In G*Power software, we performed repeated-measures ANOVA (within-between interaction) with the following parameters: effect size f = 0.37 (obtained using $\eta^2 = 0.121$); level of significance $\alpha = 0.05$; power = 95%; number of groups = 2 (LAS vs. control); number of measurements = 2 (baseline vs. six-weeks). The G*Power software used the effect size index (f) for this analysis. The effect size f was directly calculated from the η^2 through the following formula: $f = p\ \eta^2/(1-\eta^2)$. The analysis indicated that a sample size of 26 participants would be sufficient for the study.

Data analysis

Data were analyzed using SPSS (Statistical Package for the Social Sciences) version 26.0. Descriptive statistics consisted of means and standard deviations for continuous variables and frequencies and percentages for categorical variables. Data normality was tested using the Shapiro-Wilk test, while homogeneity of variances was tested using the Levene's test. Missing data were imputed for both groups using the maximization method. Independent t tests were used to compare the general participants characteristics (age, body mass, height and body mass index) across study groups. A chi-square test was used to compare the proportion of male and female participants across the study groups. Group x time interactions for the primary and secondary outcomes were calculated using Two-way ANOVAs (group × time). Group (acute lateral ankle sprain × control) was used as the independent factor, time (baseline × six-weeks) as the repeated factor, and the primary (clinical aspects) and secondary outcomes (shear-way velocity and peak torque) as dependent variables. The Bonferroni's post hoc test was applied for pairwise comparisons. In the absence of a group x time interaction, the group and time effects were presented. A significance level of $p < 0.05$ was used for all analyses. Effect sizes were determined using partial eta-squared (η^2), where values of $\eta^2 > 0.01$ were defined as small, $\eta^2 > 0.06$ as medium, and $\eta^2 > 0.14$ as large[53] (Cohen, 1988). Cohen's d (d) was used for the pairwise comparisons. Values of d = 0.2 were defined as small, d = 0.5 as medium, and d = 0.8 as large[53] (Cohen, 1988). The reliability of shear-wave velocity measurements for the calf muscles and Achilles tendon was assessed using the Intraclass Correlation Coefficient (ICC). A mixed two-way model with absolute agreement was applied. Intra-rater reliability was determined based on three repeated measurements (k = 3), while inter-rater reliability was calculated by comparing the average of three measurements from each of the two raters (k = 2). ICC values were interpreted as follows: <0.50, poor reliability; 0.51–0.75, moderate reliability; 0.76–0.90, good reliability; and >0.91, excellent reliability[54].

RESULTS

General characteristics

The study included 28 participants (18 females, 10 males), divided into two groups: (I) Acute lateral ankle sprain (LAS) (n=14) and (II) healthy controls (n=14). Participants had a mean age of 29.03 ± 8.07 years, body mass of 73.25 ± 19.30 kg, height of 1.69 ± 0.09 m, and BMI of 25.26 ± 5.07 kg/m². No significant between-group differences were found (all P > 0.05) (Table 1).

Table 1. General characteristics of the participants (n=28)

	LAS (n=14)	Healthy (n=14)	MD (IC 95%)	P Value
Sex				
Female	10 (71.4%)	8 (57.1%)	-	0.430
Male	4 (28.6%)	6 (42.9%)		
Age, years	29.57 ± 10.16	28.50 ± 5.61	-5.30 – 7.44	0.366
Body Mass, kg	71.71 ± 20.11	74.78 ± 19.07	-18.30 – 12.16	0.267
Height, m	1.68 ± 0.09	1.70 ± 0.10	-0.09 – 0.05	0.341
BMI, kg/m^2	25.09 ± 5.52	25.42 ± 4.77	-4.34 – 4.68	0.434

Data presented as count and percentage or mean ± standard deviation. BMI, Body Mass Index; MD, mean difference; CI 95%, Confidence Intervals of 95%. *Group effect – p<0.05.

Muscle and Tendon Mechanical Properties

Intra-rater reliability of shear-wave velocity measurements demonstrated results varying from good (0.76-9.90) to excellent (>0.91) for both examiner 1 (E1) and examiner 2 (E2) for the SO (E1 ICC = 0.827; E2 ICC = 0.954), MG (E1 ICC = 0.945; E2 ICC = 0.929), LG (E1 ICC = 0.888; E2 ICC = 0.947), and AT (E1 ICC = 0.846; E2 ICC = 0.926). Inter-rater reliability was good for the soleus (ICC = 0.807), medial gastrocnemius (ICC = 0.905), lateral gastrocnemius (ICC = 0.867), and Achilles tendon (ICC = 0.880). No significant group x time interactions were found for shear-wave velocity of the calf muscles and Achilles tendon (all P > 0.05) (Table 2). However, a time effect for the shear-wave velocity of the

Achilles tendon was found (P = 0.005, $\eta^2 = 0.269$). Higher stiffness was found at the six-week assessment (MD = -0.72, -1.21 to -0.24, P = 0.05, d = 2.86).

Table 2. Differences in muscle and tendon stiffness, pain, edema, ankle function, and peak torque (n=28)

Muscle/Tendon	Groups	Baseline	Six-weeks	P Value	η2
Soleus (m/s)	LAS	2.14 ± 0.37	2.05 ± 0.25	0.932	<0.001
	Healthy	2.35 ± 0.48	2.27 ± 0.40		
Medial Gastrocnemius (m/s)	LAS	2.10 ± 0.19	2.06 ± 0.23	0.760	0.004
	Healthy	2.21 ± 0.31	2.21 ± 0.36		
Lateral Gastrocnemius (m/s)	LAS	1.92 ± 0.22	1.94 ± 0.21	0.800	0.003
	Healthy	2.06 ± 0.20	2.06 ± 0.29		
Achilles Tendon (m/s)	LAS	8.71 ± 1.01	9.00 ± 0.63	0.070	0.121
	Healthy	8.26 ± 1.94	9.43 ± 1.43		
Pain, 0-10 (cm)	LAS	3.42 ± 2.21† ‡	0.76 ± 1.84†	0.003*	0.298
	Healthy	0.00 ± 0.00‡	0.15 ± 0.06		
Edema (cm)	LAS	1.87 ± 1.5†	0.79 ± 0.55†	0.017*	0.199
	Healthy	-0.01 ± 0.28‡	0.38 ± 1.55		
FAOS (0-100)	LAS	47.49 ± 20.22† ‡	84.53 ± 11.06† ‡	<0.001*	0.625
	Healthy	98.76 ± 1.43‡	98.71 ± 1.82‡		
Peak Torque (N.m)	LAS	58.91 ± 30.98	78.60 ± 39.06	0.745	0.004
	Healthy	91.91 ± 26.93	109.71 ± 31.10		

Data presented as mean ± standard deviation. LAS (n-=14) and Healthy (Control) (n=14) groups; Group x time interaction – P < 0.05; Foot and Ankle Outcome Score (FAOS). † Within-group differences; ‡ Between-group differences

Clinical outcomes

Significant group x time interactions were found for pain (P = 0.003, $\eta^2 = 0.298$), edema (P = 0.017, $\eta^2 = 0.199$), and ankle function (P < 0.001, $\eta^2 = 0.625$) (Table 2). At baseline, the LAS group presented significantly greater levels of pain (MD = 3.43, 2.21 to 4.64, P < 0.001, d = 2.20) and edema

(MD = 1.88, 1.03 to 2.72, P < 0.001, d = 1.86), and worse ankle function (MD = -51.27, -62.41 to -40.13, P < 0.001, d = -3.58) compared to the control group. At the six-week assessment, only ankle function remained significantly different between groups, with lower levels persisting in the LAS group (MD = -14.17, -20.33 to -8.02, P < 0.001, d = -1.79).

Also, the LAS group experienced significant improvements in pain (MD = 2.66, 1.49 to 3.84, P < 0.001, d = -1.31) edema MD = 1.07, 0.23 to 1.91, P = 0.014, d = -0.95), and ankle function (MD = -37.04, -45.24 to -28.84, P < 0.001, d = 2.27) at the six-week assessment compared to baseline.

Peak torque

No significant group x time interaction was found for the peak torque of the calf muscles (p > 0.05) (Table 2). However, time ($p < 0.001$, $\eta^2 = 0.622$) and group effects ($p = 0.012$, $\eta^2 = 0.219$) were found for this outcome. Higher peak torque was found at the six-week assessment (MD = -18.74, -24.63 to -12.856, P < 0.001, d = 3.07). In addition, higher peak torque was found in the control group (MD = -32.05, -56.47 to -7.64, P = 0.012, d = -3.82).

DISCUSSION

To our knowledge, this is the first study to comprehensively investigate the impact of acute LAS on the mechanical properties of calf muscles and the AT, along with evaluations of ankle function, strength, and pain. Contrary to our hypothesis, we found no significant differences in calf muscle or AT stiffness between individuals with acute LAS and controls. This unexpected finding suggests that the functional deficits observed in the LAS group may not be primarily attributable to alterations in tissue stiffness. Our results suggest that muscle and tendon tissues may adapt to injury by maintaining mechanical properties that can support function despite damage due to LAS. Clinicians should consider injury grade, time since sprain, and loading conditions during rehabilitation, as these factors affect the calf muscles and AT. Rehabilitation strategies emphasizing balanced ankle loading and even strain distribution may optimize recovery, even in the absence of immediate tissue stiffness changes detected by SWE.

Tendons and muscles typically exhibit distinct responses to disuse and injury[18, 19]. Muscle stiffness can increase due to a relative rise in extracellular matrix content following muscle atrophy[38-41], while tendon's stiffness may decrease due to reduced loading[19, 22]. However, despite the presence of functional deficits following acute LAS, our findings did not reveal notable changes in calf muscle or

AT stiffness within the study period. Several factors could explain this dissociation. First, neuromuscular and sensorimotor impairments, such as altered muscle activation patterns and decreased proprioception, are known consequences of LAS[11, 14, 55]. These impairments can significantly contribute to functional limitations, even in the absence of detectable changes in tissue stiffness. Second, pain itself can inhibit muscle function and alter movement patterns[56]. The observed pain in the LAS group, even at the six-week follow-up, could contribute to functional deficits, independent of tissue stiffness. Finally, psychological factors, such as fear-avoidance beliefs, can play a role in recovery after LAS[16]. These factors can influence an individual's willingness to engage in activities and, consequently, their functional outcomes. Therefore, rehabilitation programs for lateral ankle sprains should address these multifaceted influences, including neuromuscular retraining, pain management, and psychological support, in addition to addressing any potential structural adaptations.

One possible explanation for our findings is that the severity of the injury plays a critical role in the extent of tissue adaptations. Participants with grade I and II injuries typically maintain some degree of functional activity and loading[5, 13] while grade III injuries, often demand prolonged immobilization and more restrictive rehabilitation protocols, conditions that are more likely to induce measurable changes in muscle and tendon stiffness due to extended periods of disuse and altered loading[5]. Accordingly, Mansur et al.[7] found significant reductions in the cross-sectional area and volumes of ankle muscles and tendons after 6 weeks of grade II and III acute LAS. This suggests that substantial structural adaptations may require more severe injury conditions than those in our study population. Consequently, the exclusion of participants with grade III LAS may have limited our ability to detect stiffness changes using SWE.

Since changes in muscle stiffness due to disuse are closely linked to changes in muscle mass[41], our baseline assessment, conducted within 72 hours post-injury, aimed to measure stiffness when small to no morphological alterations could have occurred[17, 57], This early evaluation established a baseline level for tracking changes over time. Short-term studies suggest muscle mass loss may occur within 2 to 4 days of limb disuse[17, 57], but measures of human muscle have described increased muscle stiffness following 60 days of bed rest[41]. In the same direction, tendons exhibit a high degree of plasticity in response to mechanical loading, unloading, and injury[19]. Prolonged unloading, such as complete limb suspension or bed rest from 14 to 23 days has been shown to reduce tendon stiffness, likely due to decreased collagen synthesis and altered matrix organization[18, 25]. However, partial loading may mitigate these effects, as even minimal mechanical stimuli seem sufficient to maintain tendon homeostasis[58, 59].

Christensen et al.[58] examined how calf muscle, AT cross-sectional area and tendon collagen synthesis responded to two weeks of leg suspension followed by a two-week rehabilitation period. The authors reported no changes in tendon cross-sectional area at any time point, a reduction in muscle cross-sectional area after suspension, and full muscle cross-sectional area recovery after rehabilitation. In the current study, while 72h may not have been enough for the onset of stiffness changes in our studied population, the following 6 weeks of disuse or partial loading experienced by our participants may have allowed for compensatory mechanisms that helped maintain tissue properties within normal ranges.

Despite the growing research on SWE for assessing muscle and tendon conditions, no previous studies were found that examined the effects of LAS. Previous studies on muscle and tendon stiffness have shown varying results depending on the disuse condition. Zhang et al.[60] and Yoshida et al.[61] observed increased stiffness in some muscles in individuals with medial tibial stress syndrome and MG injuries, respectively. In contrast, Wang et al.[62] found reduced stiffness in sarcopenia. For AT injuries, studies by Chen et al.[63] and Frankewycz et al.[64] reported lower stiffness in ruptured ATs and post-repair tendons. Additionally, Zhang et al.[65] and Busilacchi et al.[66] found a positive correlation between (SWE and functional outcomes, while lower AT stiffness has been consistently noted in tendinopathy studies[67-71].

Given the lack of SWE studies on calf muscles and the Achilles tendon following LAS, our results offer indirect yet valuable insights into disuse-related changes in these muscles and tendons. This is particularly relevant when comparing our findings to those of Kawai et al.[72] and McPherson et al.[70], both of whom found no differences in passive muscle stiffness at rest between injured and control groups post-surgery. On the other hand, McPherson et al.[73] observed higher vastus lateralis stiffness at 12 months post-ACL surgery, suggesting that time and injury type may influence muscle stiffness recovery. Our results are consistent with the findings of Kawai et al.[72] and McPherson et al.,[73] who reported no differences in passive stiffness between groups, despite some methodological differences in muscle and skeletal muscle lesion assessments. This comparison underscores the significance of considering both passive and active tissue properties when interpreting SWE data in musculoskeletal injuries. Factors like ankle positioning and muscle contraction significantly influence AT and calf muscle stiffness measurements[74]. This limitation is particularly relevant in acute injuries, such as LAS, where assessments were conducted within 72 hours post-injury. Pain, swelling, and functional limitations during this phase restrict the feasibility of performing measurements under varying joint positions or loading conditions.

Taken together, our data suggest the need to establish normative SWE values following LAS, enabling future comparisons with healthy individuals, elite athletes, and different muscle injuries.

Limitations and Future Prospects

Our study has limitations, including the inability to perform SWE measurements during active muscle contractions and the exclusion of participants with grade III LAS. Another factor influencing our results is the heterogeneity in managing participants with LAS, particularly regarding injury severity (grades I and II), professional care, early rehabilitation, and immobilization strategies. Individuals with grade II LAS are more likely to experience prolonged immobilization and greater functional limitations compared to those with grade I injuries[5], potentially leading to more pronounced tissue alterations. However, variability in rehabilitation protocols, ranging from early mobilization and functional exercises to rigid immobilization, may have introduced inconsistent mechanical stimuli, affecting tissue adaptation[19]. Additionally, our SWE equipment has a maximum measurement limit of 300 kPa (10 m/s), and multiple tendon measurements reached this upper threshold. Although injured AT typically exhibits SWE values below this limit[64, 68], it could be suggested that the actual tendon stiffness values may have exceeded 10 m/s but were not able to be distinguished within the device's range. This limitation has been previously described in the literature[52, 75,, 76], and potential confounding factors that may influence tendon strain should be considered in future studies.

CONCLUSION

LAS significantly reduces ankle function and leads to pain and edema but does not appear to induce notable changes in calf muscle or Achilles tendon stiffness within six weeks. Future research should investigate the dynamic mechanical properties of these tissues during activity, explore the influence of standardized rehabilitation protocols, and examine long-term adaptations following LAS.

PRACTICAL IMPLICATIONS OF THE FINDINGS FOR SOCIETY

The findings of this study have important implications for clinical practice and rehabilitation strategies following acute lateral ankle sprain (LAS).

Shear wave elastography (SWE) is not yet widely used in clinical practice but may serve as a promising tool for assessing the progress of rehabilitation. Since active evaluations of muscle and tendon stiffness are often unfeasible due to pain and initial functional impairment, elastography can provide an objective and non-invasive method to monitor tissue changes during recovery. The integration of this technology into clinical practice may enable a more precise assessment of injury progression and assist in decision-making regarding return to activity, particularly in cases where traditional functional tests are limited by pain.

From a rehabilitation perspective, the results of this study reinforce the need for early functional rehabilitation rather than prolonged rest or passive treatments, which are still widely used. Since stiffness changes were not the primary limiting factor, interventions should prioritize neuromuscular retraining, strength recovery, and progressive loading strategies to efficiently restore function.

Lastly, from a public health perspective, LAS is one of the most common musculoskeletal injuries, and its effective management can help reduce long-term disability and healthcare costs. By emphasizing early mobilization and functional rehabilitation, it is possible to prevent chronic instability and recurrent injuries, promoting better long-term outcomes and reducing the economic burden on healthcare systems.

These findings position the study within an international scope, as the results contribute to a globally relevant discussion in musculoskeletal rehabilitation. While the applicability of the findings is moderate, given that the use of SWE is still limited in clinical settings, the study provides valuable insights that can be replicated in different environments with appropriate resources. The complexity of the research is also moderate, as it integrates biomechanical, physiological, and rehabilitative knowledge but remains within a single disciplinary domain without requiring extensive cross-sector collaboration beyond participants recruitment. Lastly, the study presents a moderate level of innovation by combining established rehabilitation principles with a relatively recent technological approach, elastography, to assess tissue mechanics in LAS recovery. Although it does not introduce entirely new concepts, it advances current knowledge by applying SWE in a rehabilitation context where its use is not yet widespread, highlighting its potential as an objective assessment tool in clinical practice.

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ANEXO I – Comprovante de aprovação pelo Comitê de Ética em Pesquisa

FACULDADE DE CEILÂNDIA
DA UNIVERSIDADE DE
BRASÍLIA - UNB

Plataforma Brasil

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Avaliação da arquitetura muscular, propriedades tendíneas, extração de oxigênio dos músculos periarticulares do tornozelo, função física e funcionalidade, percepção de dor e edema em indivíduos com entorses laterais agudas de tornozelo.

Pesquisador: Pedro Bainy Franz
Área Temática:
Versão: 3
CAAE: 68997923.2.0000.8093
Instituição Proponente: FUNDACAO UNIVERSIDADE DE BRASILIA
Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 6.192.515

Apresentação do Projeto:
RESUMO: "Introdução: A entorse de tornozelo é a lesão ortopédica mais comum no complexo tornozelo-pé que leva indivíduos a buscar cuidados médicos. O desuso provocado pela entorse lateral aguda de tornozelo leva a uma situação de atrofia muscular e perda de funcionalidade. A maior parte da atrofia muscular causada por desuso ocorre durante os primeiros dias e semanas após a diminuição do uso do segmento corporal em comparação a
estágios mais tardios, tanto em indivíduos saudáveis quanto após fratura de tornozelo. Também é claro o efeito deletério do desuso nas propriedades tendíneas em experimentos animais. No entanto, não foram encontrados artigos avaliando a atrofia muscular após entorse lateral aguda de tornozelo e como esta lesão pode afetar as propriedades tendíneas em humanos. Objetivo: Avaliar a arquitetura muscular do gastrocnêmio medial (GM), gastrocnêmio lateral (GL) sóleo (SO), tibial anterior (TA), fibular longo e fibular curto (FLC), propriedades tendíneas, extração de oxigênio dos músculos periarticulares do tornozelo, função física e funcionalidade, percepção de dor e edema em indivíduos que apresentem
entorse lateral aguda do tornozelo de graus I e II. Métodos: Trata-se de um estudo observacional de delineamento transversal, com amostra de participantes de pesquisa diagnosticados com entorse lateral aguda de tornozelo. Participantes de ambos os sexos, com idade entre 18 e 60

anos, apresentando entorse lateral de tornozelo nas 72 horas prévias à avaliação. Os participantes serão encaminhados para a avaliação 01 em até 72 horas após consulta com médico ortopédico, e após 6 semanas será realizada a avaliação 02. Os participantes com diagnóstico de entorse lateral aguda de tornozelo serão comparados ao grupo controle (indivíduos saudáveis) quanto a arquitetura muscular (espessura muscular, ângulo de penação, comprimento do fascículo, ecogenicidade do músculo, avaliação do torque, ativação elétrica muscular e massa muscular), propriedades tendíneas (comprimento do tendão, área de secção transversa, força, stress e strain, rigidez, alongamento e deslocamento do tendão, módulo de elástico e ecogenicidade), extração de oxigênio dos músculos periarticulares do tornozelo, função física e funcionalidade, percepção da dor e edema. Os participantes com entorse lateral aguda de tornozelo serão comparados a um grupo de indivíduos saudáveis (grupo controle) que passará pelas mesmas avaliações em um intervalo de 6 semanas. Resultados esperados: Espera-se que os participantes com entorse lateral aguda do tornozelo de graus I e II possuam redução da espessura muscular, com aumento do ângulo de penação e redução do comprimento fascicular, modificações prejudiciais na mecânica tendínea e redução da manipulação e consumo de oxigênio nos músculos periarticulares. Acreditamos que esses resultados se tornem semelhantes entre os grupos na avaliação 02. Esse projeto fornecerá a base para o entendimento da mecânica muscular e tendínea após lesão lateral aguda do tornozelo, em especial para gerar hipóteses sobre as instabilidades crônicas de tornozelo comumente observadas na prática clínica."

Hipótese:
"A hipótese deste estudo é de que os participantes com entorse lateral aguda do tornozelo de graus I e II possuam redução da espessura muscular, com aumento do ângulo de penação e redução do comprimento fascicular, modificações prejudiciais na mecânica tendínea, redução da manipulação e consumo de oxigênio nos músculos periarticulares, perda de funcionalidade, edema e exacerbação de dor. Acredita-se que em 06 semanas esses parâmetros se assemelhem ao grupo controle."

Critério de Inclusão:
"Serão recrutados participantes de ambos os sexos, com idade entre 18 e 60 anos, que tenham sofrido entorse lateral de tornozelo nas 72 horas prévias à avaliação."

Critério de Exclusão:

"Serão excluídos do estudo aqueles que apresentarem uma das seguintes características:História de instabilidade crônica de tornozelo ou outra entorse de tornozelo nos últimos 12 meses, seja no mesmo membro ou no membro contralateral;Sinais de ruptura completa do ligamento talofibular anterior (lesão grau 3), diagnosticados pelo teste gaveta anterior, estresse por inversão ou exame de imagem;Lesão óssea em tornozelo,
diagnosticada por exame de imagem;Outras lesões em membros inferiores concomitantes à lesão do tornozelo, sejam lesões em outras articulações, em tecidos moles ou lesões ósseas;Cirurgias prévias no tornozelo lesionado;Contraindicação para realização de testes de força máxima (por exemplo, doenças cardiovasculares, respiratórias ou neurológicas);Ter dificuldade para compreender e/ou executar os testes no dinamômetro".

Objetivo da Pesquisa:

"Avaliar a arquitetura muscular do gastrocnêmio medial (GM), gastrocnêmio lateral (GL) sóleo (SO), tibial anterior (TA), fibular longo e fibular curto (FLC), propriedades tendíneas, extração de oxigênio dos músculos periarticulares do tornozelo, função física e funcionalidade, percepção de dor e edema em indivíduos que apresentem entorse lateral aguda do tornozelo de graus I e II e compará-los a um grupo controle."

Avaliação dos Riscos e Benefícios:

RISCOS: "Para a avaliação do torque os participantes deverão executar contrações musculares isométricas máximas. Durante esta avaliação, é possível que o participante sinta fadiga muscular e desconforto ou dor na região da lesão do tornozelo. Os participantes serão orientados que, caso não queiram dar continuidade, a avaliação poderá ser interrompida a qualquer momento sem qualquer prejuízo a eles, bastando que eles informem o desejo de
interrupção. Os pacientes serão monitorados durante todas as avaliações quanto a dores ou desconfortos. Caso quaisquer alterações fora dos padrões de normalidade sejam observadas, as avaliações serão interrompidas imediatamente e todas as medidas de cuidados para a saúde dos participantes serão providenciadas. Todos os participantes serão orientados a realizar crioterapia (aplicação de gelo) em casa por 20 minutos no caso de dor ou desconforto de início tardio causados pela avaliação física, e poderão entrar em contato com os pesquisadores por telefone para melhores orientações e suporte. A crioterapia também será oferecida no local da realização das avaliações ao término da coleta de dados. Durante as avaliações que envolvem preenchimento dos questionários, os participantes poderão sentir cansaço, desconforto pelo tempo gasto no preenchimento do questionário e possibilidade de um algum desconforto ou constrangimento por

relatar as limitações físicas a que está sujeito em sua vida por causa da lesão. Os participantes serão orientados que o preenchimento dos questionários poderá ser interrompido a qualquer momento sem qualquer tipo de prejuízo pessoal a eles.Caso qualquer sintoma físico ou desconforto pessoal se exacerba, os pesquisadores se responsabilizarão por providenciar toda assistência necessária de forma integral, sem custos ao participante. Se houver algum dano decorrente da presente pesquisa, o participante terá direito a recorrer a indenização, como dispõem o Código Civil, o Código de Processo Civil, a Resolução nº 466/2012 e a Resolução nº 510/2016 do Conselho Nacional de Saúde. Para minimizar os riscos de quebra de privacidade e confidencialidade dos dados dos participantes, os resultados deste estudo serão utilizados única e exclusivamente para fins de pesquisa, e os dados obtidos durante este estudo serão mantidos sob a posse do pesquisador, de forma codificada, por 5 anos após o término da pesquisa. Somente a equipe de pesquisa terá acesso aos dados obtidos, de forma anônima (codificada), e somente o pesquisador responsável terá acesso aos dados de codificação e identificação dos participantes."

BENEFÍCIOS:
"O estudo possibilitará o aumento dos conhecimentos a respeito das alterações morfológicas e fisiológicas que ocorrem nos músculos e tendões da perna em pacientes que sofreram entorses laterais agudas de tornozelo. Esse conhecimento permitirá novos questionamentos sobre melhores formas de reabilitar e mitigar as possíveis sequelas que estes indivíduos costumam apresentar após a lesão.Além disso, os participantes terão acesso a avaliações de alta complexidade sobre sua condição de saúde, que não são comumente oferecidas em ambiente ambulatorial ou hospitalar para estes casos. Todos os dados coletados serão disponibilizados aos respectivos participantes."

Comentários e Considerações sobre a Pesquisa:
Pesquisa ligada ao PPG em Ciências da Reabilitação, da UnB Ceilândia, nível mestrado. Outros pesquisadores vão auxiliar na pesquisa, mas não é identificado quem será o orientador.
Sobre a amostra, os pesquisadores escrevem que: "Foi realizado um cálculo amostral a priori usando o software G*Power (Kiel University, Germany) que estimou número mínimo de 20 participantes por grupo considerando os desfechos de arquitetura muscular e tendínea (effect size = 0.30; nível de significância = 0.05; poder = 0.80) (BARONI et a.l, 2013; MANSUR et al., 2022). Os pesquisadores irão confirmar o cálculo a posteriori (com 10 participantes por grupo) para determinar o tamanho de efeito real para a amostra baseado nos mesmos desfechos. "Caso o

tamanho de efeito real seja menor do que o calculado a priori, será solicitado emenda ao CEP/FCE para aumento do número total de participantes do presente estudo."

Considerações sobre os Termos de apresentação obrigatória:

O TCLE está adequado quanto à linguagem, vocabulário e apresentação dos riscos e das formas como minimizá-los.

Recomendações:

Não há.

Conclusões ou Pendências e Lista de Inadequações:

Todas as pendências foram atendidas.

Considerações Finais a critério do CEP:

Diante do exposto, o Comitê de Ética em Pesquisa – CEP, de acordo com as atribuições definidas na Resolução CNS n.º 466, de 2012, e na Norma Operacional n.º 001, de 2013, do CNS, manifesta-se pela aprovação do protocolo de pesquisa.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_2063049.pdf	07/07/2023 10:20:59		Aceito
Outros	Franz_carta_resposta.pdf	07/07/2023 10:19:39	Pedro Bainy Franz	Aceito
Cronograma	cronograma_franz_atualizado.docx	07/07/2023 10:17:55	Pedro Bainy Franz	Aceito
Projeto Detalhado / Brochura Investigador	Projeto_Franz.docx	13/06/2023 13:58:08	Pedro Bainy Franz	Aceito
Declaração de Pesquisadores	Termo_de_responsabilidade.pdf	20/04/2023 16:01:12	Pedro Bainy Franz	Aceito
Orçamento	Orcamento_Franz.docx	20/04/2023 16:01:03	Pedro Bainy Franz	Aceito
Folha de Rosto	Folha_de_rosto.pdf	20/04/2023 16:00:41	Pedro Bainy Franz	Aceito
Outros	Lattes_Lima.pdf	07/03/2023 17:23:47	Pedro Bainy Franz	Aceito
Outros	Lattes_Mansur.pdf	07/03/2023 17:23:27	Pedro Bainy Franz	Aceito
Outros	Lattes_Durigan.pdf	07/03/2023	Pedro Bainy Franz	Aceito

Outros	Lattes_Durigan.pdf	17:23:11	Pedro Bainy Franz	Aceito
Outros	Lattes_Franz.pdf	07/03/2023 17:23:00	Pedro Bainy Franz	Aceito
Outros	Lattes_Marqueti.pdf	07/03/2023 17:22:48	Pedro Bainy Franz	Aceito
Outros	Encaminhamento.pdf	07/03/2023 17:18:42	Pedro Bainy Franz	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.docx	07/03/2023 15:12:45	Pedro Bainy Franz	Aceito
Declaração de concordância	Termo_de_concordancia_proponente.pdf	07/03/2023 15:11:07	Pedro Bainy Franz	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

BRASILIA, 20 de Julho de 2023

Assinado por:
MARIANA SODARIO CRUZ
(Coordenador(a))

Comprovante de produção científica

Manuscript submitted to Orthopaedic Surgery Caixa de entrada ×

Orthopaedic Surgery <no-reply@atyponrex.com>
para mim

20:16 (há 1 hora)

Dear Pedro Bainy Franz,

Your manuscript "Acute Lateral Ankle Sprain Impairs Function and Strength without Altering Muscle or Tendon Stiffness: A Controlled Observational Study" has been successfully submitted and is being delivered to the Editorial Office of *Orthopaedic Surgery* for consideration.

You will receive a follow-up email with further instructions from the journal editorial office, typically within one business day. That message will confirm that the editorial office has received your submission and will provide your manuscript ID.

Thank you for submitting your manuscript to *Orthopaedic Surgery*.

Sincerely,
The Editorial Staff at Orthopaedic Surgery

Comprovante de um resumo publicado em anais de evento internacional

Verifique o código de autenticidade **28823512.0280593.138345.8.882765232836175787068** em https://www.even3.com.br/documentos

Certificado de Participação

Certificamos que o trabalho intitulado **EFEITOS DA CRIOTERAPIA EM PACIENTES COM ENTORSE LATERAL AGUDA DE TORNOZELO - UM PROTOCOLO DE ENSAIO CLÍNICO RANDOMIZADO** de autoria de Pedro Bainy Franz, Hortência Cordeiro de Lima, RITA DE CASSIA MARQUETI DURIGAN e JOAO LUIZ QUAGLIOTI DURIGAN, foi apresentado no **XIV Simpósio em Neuromecânica Aplicada**, realizado em 23/10/2024 a 26/10/2024.

Florianópolis, 26 de outubro.

Heiliane de Brito Fontana
Data: 27/10/2024
CPF: ***.801.929-**

PRESIDENTE DO XIV SNA

Realização BSiM | Apoio UFSC UDESC Cefid | Patrocínio fapesc CAPES CNPq DELSYS | Promoção SBB Sociedade Brasileira de Biomecânica

Comprovante de um resumo publicado em anais de evento internacional (continuação)

EFEITOS DA CRIOTERAPIA EM PACIENTES COM ENTORSE LATERAL AGUDA DE TORNOZELO - UM PROTOCOLO DE ENSAIO CLÍNICO RANDOMIZADO

Pedro Franz [1], Hortência Lima [1], Rita de Cássia Marqueti[1] e João Luiz Durigan [1*]
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Introdução

A crioterapia tem sido repetidamente recomendada pelas diferentes diretrizes de tratamento de entorse lateral aguda de tornozelo (ELAT)[1,2], e parece oferecer um efeito importante na redução da dor nas primeiras semanas de tratamento[3]. No entanto, as evidências quanto ao seu efeito sobre desfechos diferentes da dor ainda não são claras[4].

As recomendações para uso da crioterapia como intervenção eficaz para a reabilitação de ELAT são baseadas em pesquisas que não foram conduzidas com o método adequado para avaliar o efeito da crioterapia nesta população[4]. Uma revisão sistemática sobre a crioterapia como intervenção em ELAT[3] não foi capaz de incluir mais do que dois ensaios clínicos randomizados (ECR) comparando grupos que trataram o ELAT com e sem crioterapia, e tiveram um baixo escore, igual a 3 pontos, na escala PEDro de risco de viés.

Considerando o raciocínio controverso[5] e a insuficiência de ensaios clínicos bem desenhados para a recomendação do uso clínico da crioterapia nas ELAT, propõe-se um ECR visando compreender seus efeitos sobre a função física, dor, edema, amplitude de movimento articular, taxa de reincidência, força e extração de oxigênio pelos músculos periarticulares do tornozelo em indivíduos com ELAT.

Métodos

Este é um protocolo de ensaio clínico controlado, aleatorizado e cego (avaliador), reportado de acordo com a ferramenta CONSORT (Consolidated Standards of Reporting Trials).

Um total de 96 participantes com ELAT serão aleatoriamente alocados em dois grupos: Grupo Crioterapia, submetido a 6 semanas de tratamento fisioterapêutico juntamente à crioterapia; Grupo Controle, submetido ao mesmo tratamento, porém, sem crioterapia.

Serão realizadas 9 avaliações (Figura 1), que acontecerão nos seguintes momentos: uma completa até 72h após a lesão, uma avaliação parcial ao final de cada semana de intervenção (5 avaliações), além de outras 3 completas: logo após o final da intervenção, 6 meses após a lesão e 12 meses após a lesão. Nas avaliações parciais, não serão realizados os testes de força e extração periférica de oxigênio. O fisioterapeuta responsável pela avaliação será cego quanto a alocação dos participantes.

A função física será avaliada pela Escala Funcional de Extremidade Inferior (LEFS) – desfecho primário – e pelo questionário *Foot and Ankle Outcome Score* (FAOS); a dor pela Escala Visual Analógica de Dor; o edema pela perimetria figura 8; a amplitude de movimento pelo *Lunge Test*; a força muscular por dinamometria isométrica; a extração periférica de oxigênio pela espectroscopia por raios quase infravermelhos (NIRS) e a taxa de reincidência pelo levantamento de novos episódios de entorse baseado nas recomendações do *International Ankle Consortium*.

A crioterapia será administrada ao final de cada sessão de fisioterapia, por 20 minutos, em sacos plásticos preenchidos por gelo triturado. Este será fixado sobre o ligamento talofibular anterior com uma atadura elástica, de forma a gerar uma leve compressão. O grupo controle será submetido a uma intervenção utilizando um saco de areia com peso, duração e compressão similares à crioterapia.

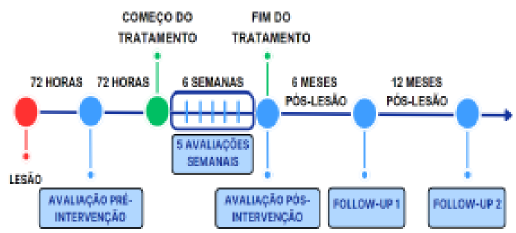

Figura 1. Fluxo de avaliações do estudo: Uma linha do tempo representa todas as 9 avaliações a serem realizadas seus respectivos pontos no tempo. Os momentos de avaliação estão destacados em círculos e linhas azuis. A força muscular e a extração de periférica de oxigênio (NIRS) serão avaliadas na linha de base, ao final do tratamento e nos acompanhamentos de 6 meses e 12 meses. A taxa de reincidência será avaliada apenas nos acompanhamentos de 6 meses e 12 meses.

Resultados e Discussão

Alguns estudos clínicos que abordaram a crioterapia aplicada no tratamento de ELAT compararam apenas diferentes métodos de crioterapia, sem grupo controle e avaliando apenas o desfecho dor[4].

Este ensaio clínico propõe avaliações semanais de diferentes desfechos durante um tratamento de 6 semanas, além de dois acompanhamentos. Isso permitirá não apenas compreender se a crioterapia desempenha um papel importante no processo de reabilitação, mas também permitirá uma análise abrangente sobre como cada desfecho progride durante e após o tratamento.

Significância

Este estudo ampliará a discussão sobre quão relevante a crioterapia pode ser para diferentes desfechos além da dor em indivíduos com ELAT.

Mensurar a evolução de cada desfecho ao longo das semanas de tratamento permitirá a compreensão da relevância da crioterapia nas diferentes fases existentes no processo de reabilitação, e o acompanhamento por 12 meses poderá elucidar questões sobre as características daqueles indivíduos que desenvolvem instabilidade crônica de tornozelo (cerca de 40%).

Referências

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Relatório de comprovação de um produto com impacto educacional, científico, sociocultural ou tecnológico/econômico

1. **Identificação do tipo de impacto do produto desenvolvido durante o mestrado**:

(x)	Impacto Educacional	**Definição** atividades/produtos que evidenciam a contribuição do PPG para a formação educacional. **Exemplos:** cursos de educação continuada, atividade na educação básica, cursos, minicursos, treinamentos de equipes, etc.
( )	Impacto Científico	**Definição:** atividades/produtos que evidenciam a contribuição do PPG na formação e divulgação científica. **Exemplos:** organização/participação de eventos, promoção de intercâmbio de discentes e docentes, participação conjunta de docentes e discentes em eventos, palestras, mesas redondas, cursos.
( )	Impacto Sociocultural	**Definição:** atividades/produtos que evidenciam contribuição do PPG para a cultura e sociedade. **Exemplos:** realização de atividades de assistência à comunidade (projetos de extensão vinculados à linha de pesquisa do docente do PPGCR), divulgação de conhecimento para a sociedade, etc.
( )	Impacto Tecnológico/econômico	**Definição:** atividades/produtos que evidenciam contribuição do PPG para o desenvolvimento tecnológico e econômico do país. **Exemplos:** desenvolvimento de técnicas, produtos, políticas públicas, etc.

2. **Informações complementares do produto com impacto:**
   a. **Título:** “I Visitação de Estudantes do Ensino Médio ao LaPlast”
   b. **Detalhamento do tipo de produto/atividade:** No dia 23/11/2023 foi realizada uma visita guiada ao LaPlast para os alunos do ensino médio do Centro de Ensino Médio 02, de Ceilândia, da Secretaria de Educação do Distrito Federal. Foram feitas explicações sobre o mundo acadêmico, a importância dos cientistas para a sociedade com foco na área de saúde, as possibilidades de carreira, como ingressar e as perspectivas de futuro. Foi dada grande ênfase ao fato de que a universidade pública torna a carreira acadêmica fortalecida de acessível para todos, independentemente de sua classe socioeconômica. Posteriormente foram realizadas demonstrações das atividades do laboratório. Por conduzir pesquisas com ultrassonografia e testes de força, fiquei responsável por demonstrar aos alunos as atividades de pesquisa realizadas e explicar como isso pode ajudar no futuro dos tratamentos fisioterapêuticos das pessoas com entorse de tornozelo (objeto da minha pesquisa). O intuito foi fazer com que os

alunos pudessem compreender que as atividades realizadas dentro do laboratório podem gerar bons impactos na sociedade, especialmente no âmbito de qualidade nos cuidados de saúde.

c. **Data ou período:** 23/11/2023
d. **Docente do PPGCR envolvido:** João Luiz Quagliotti Durigan

LaPlasT

CERTIFICADO

de participação

certificamos que

Pedro Bainy Franz

Participou como PALESTRANTE da "I visitação de estudantes do ensino médio ao LaPlast" com carga horária de 8 horas

Rita de Cássia Marqueti
Coordenadora do
LAM

João Luiz Q. Durigan
Coordenador do
LaPlast

Regina Recalde da Fonseca Cotrim
Professora
Responsável