INPLASY PROTOCOL

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Conflicts of interest:
None.

A systematic review of the methodology to estimate stiffness of lower limb muscles using shear-wave elastography

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Review question / Objective: **To establish what parameters of the shear-wave elastography methodology must be included when conducting and reporting studies in order to determine an optimal methodology to use within elite sports.**
Condition being studied: **The purpose of the systematic review is to assess the variation in methods used to measure the shear modulus of the lower limb muscles using shear-wave elastography in order to estimate muscle stiffness. A secondary aim will be assessing the measurement properties of these measures to establish the reliability of the methodology. The current literature emphasises an inconsistency in the methods used to estimate muscle stiffness with shear-wave elastography in the lower limb muscles, with irregularities in key variables such as scanning procedure, number of repetitions, scans per repetition, type of contraction during the scan, joint angle, participant position, region of interest and the image processing. By performing this review, we aim to highlight the key variables which are consistent throughout the literature, and underline which aspects of the methodology have more variation. From this information, we aim to establish an optimal protocol, based on current knowledge, to estimate muscle stiffness with shear-wave elastography, and to develop a methodology that is suitable for research within an elite practical setting by identifying which aspects of the procedures and protocols are essential.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 January 2021 and was last updated on 15 January 2021 (registration number INPLASY202110053).

INTRODUCTION

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METHODS

Participant or population: Inclusion criteria - Only human participants will be included in the review (animal studies and studies with cadaveric specimens will be excluded). Exclusion criteria - Studies assessing participants with an illness/injury (Cerebral Palsy/Inflammatory Myopathesis/ Duchenne Muscular Dystrophy) will be excluded from the review as the aim of the study is to limit the range of participants to normal, healthy individuals and athletes, as the aim is to and to develop a methodology that is suitable for research within an elite practical setting.

Intervention: Inclusion criteria • Studies using shear-wave elastography to estimate stiffness of the lower-limb muscles on either the dominant or non-dominant limb (see exclusion criteria for excluded muscles). For example: o Rectus Femoris o Vastus Lateralis o Vastus Medialis o Biceps Femoris o Semitendinosus o Semimembranosus o Gastrocnemius (Medial and Lateral) o Soleus o Triceps Surae o Tibialis Anterior o Tibialis Posterior o Gluteus Maximus o Adductor Magnus o Peroneus Longus o Peroneus Brevis Exclusion criteria • Studies using other types of elastography (such as Magnetic Resonance Elastography, Supersonic Shear Imaging, Transient Ultrasound Shearwave Elastography, Acoustic Radiation Force Impulse Imaging, Contrast Enhanced Ultrasound) will be excluded from the review. • Studies assessing tendon stiffness will be excluded from the study unless there are also measurements on muscle). • Studies assessing nerves will be excluded from the study unless there are also measurements on muscle. • Studies assessing blood flow and assessing stiffness of arteries will be excluded from the study unless there are also measurements on muscle. • Studies using other devices (such as MyotonPro) to estimate muscle stiffness. • Studies only examining non-lower limb musculature (such as the torso or upper body).

Comparator: There will be no comparator or control group within this systematic review, as there is not yet an evidence-based protocol of shear-wave elastography which is used throughout the literature.

Study designs to be included: All types of observational studies using quantitative methods will be eligible for inclusion (including cohort, case-control, cross-sectional studies, case series and case reports).

Eligibility criteria: The major restrictions will be limiting the search to human participants. There will not be any restrictions on study cohort. However, in the study selection process, only full-text scientific papers, written in English, with original data will be included. Inclusion and Exclusion criteria has been stated in Question 12 (Participant or Population) and Question 13 (Intervention).

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Information sources: The following electronic bibliographic databases will be searched: PubMed; MEDLINE (OVID interface); Web Of Science; Scopus; SportDiscus. In addition to electronic bibliographic database searching, as the Methodological Expectations of Cochrane Intervention Reviews (MECIR) standards suggest, the reference lists of the included studies will be hand-searched for additional relevant studies that have been missed with the search. Any relevant in-progress work that has not been published yet, will be also identified by contacting relevant authors in the field. To minimise the risk of publication bias, grey literature will be included too, and it will be accessed via the British national bibliography for report literature (BNBRL), OpenGrey database, ProQuest Dissertations & Theses Global and EThOs. If deemed necessary, the authors of potentially eligible studies will be contacted to check/confirm whether they had published their study or not. Previous systematic reviews on the same topic will be searched too if applicable. However, to our knowledge no previous systematic review exists on this topic.

Main outcome(s): We aim to determine the key variables of the shear-wave elastography methodology which are consistent throughout the literature, and underline which aspects of the methodology have more variation. From this information, we aim to establish an evidence-based protocol to estimate lower body muscle stiffness with shear-wave elastography, and to develop a methodology that is suitable for research within an elite practical setting by identifying which aspects of the procedures and protocols are essential. We will establish an evidence-based protocol by: (1) Establishing the variability in reporting of methodological choices, (2) Identifying what methodological choices should be reported when conducting shear-wave elastography for measures of muscle stiffness, and (3) Establishing which methodological choices lead to reliable measures.

Data management: The titles and/or abstracts of studies retrieved using the search strategy and those from additional sources will be screened independently by two review authors (Jordan Slack (JS) and Ignacio Contreras (IC)) to identify studies that potentially meet the inclusion criteria outlined above. This will include citations and abstracts of potentially eligible studies identified and it will allow the identification and removal of any duplicates, before the start of the screening process. The full texts of these potentially eligible studies will then be retrieved and independently assessed for eligibility by JS and IC. Any disagreements between them over the eligibility of particular studies will be resolved through discussion with a third independent reviewer (Eduardo Martinez-Valdes (EMV)). A standardised, pre-piloted form will be used to extract data from the included studies for the assessment of study quality and for evidence synthesis. The screening forms will be pilot tested first by both reviewers on a small number of articles, to ensure their effectiveness. The screening process will begin with the screening of the titles/abstracts of the identified studies against the inclusion/exclusion criteria by the two reviewers (JS and IC) independently. If further information is required to support the screening process, the authors of the study will be contacted. Extracted information will include: • Study Population • Participant Demographics • Baseline Characteristics • Methodological Details for the Assessment of Shear-Wave Elastography - Examiner Experience - Anatomical Location Scanned - Identification of Where to Scan - Participant Position - Joint Angle - Scanning Procedure - Scanning Condition (Passive Condition or Contraction) - Number of Scans Per Repetition - Ultrasound System Used - Probe Size - Probe Orientation - Region of Interest (ROI) - Depth of ROI - Image Processing - Data Analysis - Sampling Frequency - Reliability Measure • Study Eligibility • Recruitment Details.

Quality assessment / Risk of bias analysis: Two reviewers (Jordan Slack (JS), Ignacio Contreras (IC)) will independently appraise

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the included studies for risk of bias (ROB) using the Newcastle-Ottawa scale (NOS). The NOS scale is the most commonly used tool to assess risk of bias in observational studies. Using the NOS scale, studies are rated in three main domains by using 8 items overall: selection (4 items), comparability (1 item) and exposure (3 items). One star can be given for the first and third categories, while up to two stars can be awarded for comparability. Therefore, the NOS scores range from 0 to 9 with the latter representing the highest quality. Depending on the number of stars that have been assigned to each study, then its quality will be converted to "Good", "Fair" and "Poor" in accordance with the Agency for Healthcare Research and Quality standards (AHQR). If the two reviewers disagree for the ROB rating of particular studies, this will be resolved with discussion. If they do not reach to an agreement, a third reviewer (EMV) will be approached in order to reach consensus.

Strategy of data synthesis: A narrative synthesis will be used for the systematic review, as a meta-analysis is not feasible without homogenous data. The narrative synthesis approach will adopt a textual approach to tell a story based on the findings of the studies included, which can also involve a degree of statistical data manipulation. Narrative synthesis is usually used in every systematic review to a greater or lesser extent and it can provide the first step to look at the data in a systematic way and organise them. The narrative synthesis approach consists of the following 4 key elements: (1) developing a theory of how the intervention/exposure works, why and for whom (2) developing a preliminary synthesis of findings of included studies, (3) exploring relationships in the data within and between studies and finally (4) assessing the robustness of the synthesis. During the second step and third step, the included studies are usually grouped in smaller groups (subgrouping) based on similarities, so that homogeneity is increased. This makes the narrative synthesis process more manageable and allow appropriate comparisons to be made or to specific questions to be answered.

Subgroup analysis: The included studies will be organised in smaller groups if possible, to make the process of narrative synthesis more manageable, increase the homogeneity and answer specific questions. Based on scoping searches, it is most likely that the studies will be organised based on the lower-limb muscle being measured. These subgroups may be categorised by: • Quadricep Muscles: Rectus Femoris, Vastus Lateralis, Vastus Medialis; • Hamstring Muscles: Biceps Femoris, Semitendinosus, Semimembranosus; • Calf Muscles: Medial/ Lateral Gastrocnemius, Soleus.

Sensibility analysis: N/A.

Language: English.

Country(ies) involved: United Kingdom.

Keywords: Shear wave Elastography; Elastography; Ultrasound; Shear Wave Ultrasound Elastography; Shear wave Velocity; Shear Modulus.

Contributions of each author:
Author 1 - Jordan Slack - The author drafted the protocol, and will act as first reviewer of the Systematic Review. Author 1 will be responsible for the final write-up.
Author 2 - Ignacio Contreras-Hernandez - The author will act as second reviewer, and helped contribute towards the protocol.
Author 3 - Dr. Eduardo Martinez-Valdes - The author is head of the Supervisory team, and will be third reviewer is JS and IC fail to reach a consensus.
Author 4 - Prof. Barry Drust - The author will act as part of the Supervisory team.
Author 5 - Prof. Deborah Falla - The author will act as part of the Supervisory team.

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