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Studying how muscles, ligaments and connective tissues around the knee work in healthy people using vibration testing, body composition analysis and muscle activity sensors

Submission date
10/10/2025

Recruitment status
No longer recruiting

Registration date
06/03/2026

Overall study status
Completed

Last Edited
06/03/2026

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Understanding the biomechanical properties of myo-ligamentous-fascial structures is crucial in both the prevention and diagnosis of musculoskeletal disorders, as well as in optimizing therapy in physiotherapy and sports medicine. Increasing importance is being attributed to objective, quantitative methods for muscle assessment, which not only allow monitoring rehabilitation outcomes but also enable detection of subtle preclinical dysfunctions. The primary objective of this study is an interdisciplinary approach to the evaluation of muscles and fascial structures, integrating three independent diagnostic methods (myotonometry, sEMG, and BIA) within a unified research procedure.

Who can participate?
Healthy volunteers aged 20 to 24 years without musculoskeletal disorders or injuries, no implanted electronic devices such as pacemakers, and not pregnant in the case of female participants.

What does the study involve?
The study will be prospective, observational, and non-invasive. Each participant will undergo a single research session during which demographic data will be collected and non-invasive physiological, biomechanical, and bioelectrical measurements will be performed. The entire procedure will take approximately 20–25 minutes. The study will be conducted during one individual visit per participant and will include the following stages: interview and demographic-clinical data collection, body composition analysis (bioimpedance – Tanita), biomechanical properties assessment (myotonometry – MyotonPRO), and bioelectrical activity recording (sEMG).

What are the possible benefits and risks of participating?
The study does not provide direct therapeutic benefits and is of a cognitive and diagnostic-scientific nature. However, participants may gain indirect benefits such as receiving

individualized information about the biomechanical properties of soft tissues and body composition, increasing awareness of their musculoskeletal health, and utilizing this information for prevention, lifestyle, or physiotherapeutic/medical consultations. Participation does not pose significant burden or health risk; all procedures are safe, brief, painless, and do not cause tissue damage or adverse effects. The project meets criteria for low-risk research with a high level of safety.

Where is the study run from?
Wroclaw Medical University (Poland)

When is the study starting and how long is it expected to run for?
June 2025 to December 2025

Who is funding the study?
Wroclaw Medical University (Poland)

Who is the main contact?
Weronika Bajer, weronika.bajer@umw.edu.pl

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title
Assessment of the repeatability and agreement of myotonometry in measuring the biomechanical properties of myofascial–ligamentous structures: comparison with muscle bioelectrical activity and bioimpedance in the knee region – a prospective observational study (MYOFLEX)

Acronym
MYOFLEX

Study objectives
Primary specific objectives:
1. To assess the intra-rater reliability of biomechanical property measurements of selected myo-ligamentous-fascial structures around the knee joint using myotonometry.
2. To compare the values obtained from myotonometric measurements with the bioelectrical activity (sEMG) of the muscles studied.
3. To compare biomechanical property measurements of the structures obtained by myotonometry with the results of bioimpedance analysis of the corresponding tissues.

Secondary specific objectives:
1. To investigate the relationships between biomechanical properties, bioelectrical activity, and bioimpedance parameters within the myo-ligamentous-fascial tissues of the knee in healthy subjects.
2. To evaluate the influence of selected individual factors such as anthropometric characteristics (e.g., body mass, height, BMI), history of previous injuries, musculoskeletal disorders, and physical activity level assessed by the IPAQ questionnaire on the results of biomechanical property measurements of myo-ligamentous-fascial structures obtained by myotonometry.

Hypotheses:
H1: Myotonometry provides high reliability (ICC > 0.80) of biomechanical property measurements for all assessed structures within the knee, including muscles, ligaments, and fasciae.
H2: There is a significant correlation between myotonometry results and the level of bioelectrical activity (sEMG) in the quadriceps femoris, adductor, and tensor fasciae latae muscles.
H3: Biomechanical measurements obtained by myotonometry are significantly consistent with bioimpedance analysis results for periarticular soft tissues of the knee.
H4: Biomechanical properties assessed by myotonometry correlate with bioelectrical activity and bioimpedance parameters, enabling a comprehensive functional characterization of the myo-ligamentous-fascial structures.H5: The biomechanical parameters of myo-ligamentous-fascial structures assessed by myotonometry differ significantly depending on anthropometric characteristics, medical history, history of injuries, and the level of physical activity declared in the IPAQ questionnaire.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 11/06/2025, Komisja Bioetyki Uniwersytetu Medycznego we Wrocławiu (50-367 Wrocław, ul. J. Mikulicza-Radeckiego 4a, Wrocław, 50-367, Poland; +48 (0)71 784 10 14; bioetyka@umw.edu.pl), ref: KB 203/2025

Study design
Observational cross sectional study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Healthy volunteers

Interventions
The planned study is exploratory in nature and focuses on the non-invasive assessment of biomechanical, bioelectrical, and bioimpedance properties of myo-ligamentous-fascial structures in the region of the knee joint in young adults. The rationale for conducting this project stems from the need to expand knowledge regarding the reliability and utility of modern functional diagnostic methods (myotonometry), which remain insufficiently studied in terms of their concordance with other techniques such as surface electromyography (sEMG) and bioimpedance analysis (BIA). The innovative character of the study lies in the comprehensive and simultaneous application of three assessment methods — MyotonPRO, EMG, and BIA — allowing not only analysis of measurement repeatability but also determination of relationships between physiological parameters, bioelectrical activity, and mechanical properties of soft tissues. Scientific literature lacks studies integrating these three diagnostic methods in a single protocol, particularly in the context of a healthy young adult population.

The experiment is designed as a single-session, safe, short-duration, and non-invasive procedure. The required equipment and consumables are available at the University Center for Physiotherapy and Rehabilitation. The research team possesses appropriate experience and qualifications in deploying the methods used (myotonometry, sEMG, bioimpedance), ensuring the validity of procedural execution. The planned sample size (110 participants) is based on prior statistical analyses (G*Power) and data from systematic reviews concerning myotonometry.

In the study, the demographic and clinical interview, along with the assessment of physical activity level using the short form of the International Physical Activity Questionnaire (IPAQ), will be conducted after obtaining informed consent from each participant. Subsequently, body composition will be analyzed via bioimpedance using the Tanita method. The next step will be the evaluation of biomechanical properties of the myo-ligamentous-fascial structures around the knee using the MyotonPRO device. Lastly, the bioelectrical muscle activity will be recorded through surface electromyography (sEMG).

Intervention Type
Other

Primary outcome(s)
1. Body mass, fat mass (kg and %), muscle mass (kg), hydration status (%), other relevant indices measured using bioelectrical impedance with Tanita analyzer at a single measurement during the study visit (baseline)
2. Muscle tone (frequency, Hz), stiffness (N/m), elasticity (dimensionless index), relaxation time (ms), creep (deformation time ratio) measured using MyotonPRO at rest and during isometric contraction during a single study visit
3. Amplitude and pattern of bioelectrical muscle activity (μV), background sEMG, response to functional tension measured using surface electromyography (sEMG) with disposable EMG electrodes at rest and during isometric contraction during a single study visit.

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Age between 20 and 24 years
2. Informed and voluntary consent to participate confirmed by signing a consent form
3. No serious cardiovascular or respiratory diseases in acute phase
4. No implanted electrical devices such as pacemakers or defibrillators
5. No acute musculoskeletal injuries

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
20 years

Upper age limit
24 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Lack of consent to participate in the study
2. Age outside the range of 20–24 years
3. Severe musculoskeletal
4. Infections or exacerbation of chronic diseases
5. Recent muscle injury at measurement site
6. Implanted pacemaker or other active electronic device
7. Pregnancy in women
8. Extensive skin lesions preventing attachment of EMG electrodes
9. Inability to cooperate

Date of first enrolment
11/06/2025

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
Poland

Study participating centre
Wydział Fizjoterapii, Niezależne Laboratorium Edukacji Medycznej i Symulacji Fizjoterapii, Uniwersytet Medyczny Wrocławski
st .Chaulbinskiego 3, 50-368 Wrocław
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Sponsor information

Organisation
Wroclaw Medical University

ROR
https://ror.org/01qpw1b93

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Uniwersytet Medyczny im. Piastów Slaskich we Wroclawiu

Alternative Name(s)
Wroclaw Medical University

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Poland

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request from Dr Wojciech T Laber, Wroclaw Medical University, weronika.bajer@umw.edu.pl.
Type of data to be shared: De-identified individual participant data (IPD) including baseline demographics, gait parameters, functional assessment scores, and quality-of-life measures.
Timing of availability: Data will be available beginning 12 months after study completion and for at least 5 years thereafter.
Consent: Written informed consent for participation has been obtained from all participants. Additional consent for data sharing is included in the patient information sheet.
Data anonymization: All data will be fully de-identified prior to sharing; no names, dates of birth, or identifying information will be included.
Ethical or legal restrictions: Data will only be shared in anonymized form and in accordance with applicable data protection regulations (GDPR).
Additional comments: Access to data will be provided upon reasonable request to the corresponding author and after approval of a data-sharing agreement.

IPD sharing plan summary

Available on request