ISRCTN13309889 https://doi.org/10.1186/ISRCTN13309889

Measuring the effectiveness of a novel treatment of chronic tennis elbow: the ArmLock sleeve

Submission date
04/04/2025

Recruitment status
No longer recruiting

Registration date
09/04/2025

Overall study status
Completed

Last Edited
09/04/2025

Condition category
Musculoskeletal Diseases

[ ] 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
Tennis elbow, or lateral epicondylitis (LE), is a condition that causes pain in the elbow, especially during wrist and hand movements. This pain can interfere with daily activities like dressing, lifting, or typing. The purpose of this study was to test a new device called the ArmLock Sleeve, which gently stretches the muscles that contribute to tennis elbow. The study aimed to find out if using this sleeve could reduce pain and improve arm function.

Who can participate?
Patients aged 18 years and over diagnosed with tennis elbow who met the study's inclusion criteria were invited to participate.

What does the study involve?
Participants wore the ArmLock Sleeve at home for 30 minutes each day over a 12-week period. They visited the lab three times at the beginning, at week 6, and at the end of the study to complete assessments of pain, grip strength, and arm mobility.

What are the possible benefits and risks of participating?
Some participants experienced reduced pain and improved arm function. The study also helps researchers learn more about non-surgical treatments for tennis elbow. However, there were some risks. Participants may have experienced temporary pain or discomfort during testing or from wearing the sleeve. The research team was prepared to stop any procedure if the participant felt too much discomfort.

Where is the study run from?
All in-person assessments took place at Lab 1-45 in Corbett Hall at the University of Alberta (Canada). Participants used the ArmLock Sleeve at home.

When is the study starting and how long is it expected to run for?
February 2020 to April 2023

Who is funding the study?
The study was funded by the Mathematics of Information Technology and Complex Systems (Mitacs) Accelerate Program (Canada)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
RES0046927

Study information

Scientific Title
Measuring the effectiveness of a novel treatment of chronic lateral epicondylitis: the ArmLock sleeve

Study objectives
Primary Hypothesis:
Wearing the ArmLock Sleeve for 30 minutes daily over a 12-week period will significantly reduce pain and functional disability in individuals with lateral epicondylitis.

Secondary Hypothesis:
The sustained positioning provided by the ArmLock Sleeve will significantly improve the extensibility of wrist and finger extensor muscles and increase pain-free grip strength in individuals with lateral epicondylitis.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/02/2020, Health Research Ethics Board - Health Panel (308 Campus Tower 8625 112 Street NW, Edmonton, T6G 1K8, Canada; +1 (0)780 492 0459; ethics@ualberta.ca), ref: Pro00095330

Study design
Multimethod design: a one-way repeated measures design over time was used to address research objective one and a qualitative description design and descriptive study design were used to address research objective two

Primary study design
Interventional

Secondary study design
Within-subjects repeated measures design

Study setting(s)
Community, University/medical school/dental school

Study type(s)
Efficacy

Participant information sheet
Not applicable

Health condition(s) or problem(s) studied
Lateral epicondylitis

Interventions
ArmLock sleeve. Participants were instructed to wear the device for 30 minutes daily over a 12-week period as an intervention to treat lateral epicondylitis.

Intervention Type
Other

Primary outcome measure
Pain-free grip strength (PFG), defined as the maximum force a person can apply during a gripping action without experiencing pain. This objective measure was recorded in pounds (lb) using a hydraulic dynamometer. It was measured at baseline, weeks 6, and 12.

Secondary outcome measures
1. Composite extensibility of wrist and finger extensor muscles: this measure reflects the overall flexibility of the wrist and finger extensor muscles. It is an objective indicator of muscle tightness, recorded in degrees using a goniometer. It was measured at baseline, weeks 6, and 12.
2. Pressure pain threshold (PPT): the pressure pain threshold refers to the minimum amount of pressure needed to produce pain. It is an objective measure assessed with a digital algometer and recorded in pounds (lb). It was measured at baseline, weeks 6, and 12.
3. Pain during resisted wrist extension (2 lb test): this subjective outcome captures the level of pain experienced while lifting a 2 lb weight during a resisted wrist extension. Participants rated their pain on a Numerical Rating Scale (NRS) from 0 (no pain) to 10 (worst possible pain). It was measured at baseline, weeks 6, and 12.
4. Self-Reported pain and functional disability: pain and functional limitations were assessed using the Patient-Rated Tennis Elbow Evaluation (PRTEE), a 15-item self-report questionnaire consisting of two subscales: one for pain (5 items) and one for functional disability (10 items). The functional section includes items on specific daily tasks and general activities. Each subscale is scored from 0 to 100, with higher scores indicating greater symptom severity. The pain subscale, functional subscale, and total score were used as outcome variables. These were measured at baseline, weeks 6, and 12.

Overall study start date
11/02/2020

Completion date
30/04/2023

Eligibility

Key inclusion criteria
1. 18 years or older
2. Able to communicate in English
3. Self-reported diagnosis of LE accompanied by the following symptoms:
3.1. Pain on the lateral side of the elbow elicited by resisted wrist extension
3.2. Tenderness at the lateral epicondyle
3.3. Measurable loss in composite muscle flexibility (extensibility)
3.4. Symptoms persisting for at least 12 weeks

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
33

Total final enrolment
19

Key exclusion criteria
1. Had a steroid injection for LE within the past three months: Steroid injections are a treatment for LE and could confound the study results.
2. Had undergone previous surgery for LE: Approximately 10% of post-surgical cases remain symptomatic, suggesting severe LE or underlying conditions unrelated to this study.
3. Had been diagnosed with elbow, wrist, or finger arthritis.
4. Sensory and/or motor changes distal to the elbow, such as carpal tunnel syndrome or elbow joint instability.
5. Pain associated with radiculopathy, cervical nerve compression or thoracic outlet syndrome.
6. Practice high-velocity racquet sports, such as tennis or badminton.
7. Exhibited a difference of less than 15 degrees in the range of motion (ROM) of wrist flexion with fingers extended compared to fingers flexed: Such cases indicate limited capacity for further mechanical stretching using the ArmLock Sleeve.
8. Experienced pain during ligament stress tests at the elbow: This pain may indicate ligament instability, precluding safe use of the device.
9. Had a wound or scarring in the area where the ArmLock Sleeve would be applied: These conditions could prevent proper application and pose risks to healing.

Date of first enrolment
23/03/2020

Date of final enrolment
18/01/2023

Locations

Countries of recruitment
Canada

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Funder(s)

Funder type
Not defined

Funder Name
Mitacs

Alternative Name(s)
Mathematics of Information Technology and Complex Systems, Mitacs Canada

Funding Body Type

Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Canada

Results and Publications

Publication and dissemination plan
The authors plan to submit the study to the journal Disability and Rehabilitation

Intention to publish date
11/04/2025

Individual participant data (IPD) sharing plan
The dataset generated during and analysed during the current study are not expected to be available due to ethics approval restrictions

IPD sharing plan summary
Not expected to be made available