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3D-printed vs thermoformed orthosis for trigger finger and hyperextension of the proximal interphalangeal joint

Submission date
08/11/2025

Recruitment status
Recruiting

Registration date
11/11/2025

Overall study status
Ongoing

Last Edited
11/11/2025

Condition category
Musculoskeletal Diseases

[X] 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
This study is exploring a new way to make orthoses (hand supports) using 3D printing technology. These supports are used to help people with a condition called trigger finger, which causes pain and stiffness in the fingers. Although 3D printing has many advantages over traditional methods, it's not yet commonly used in clinics. The aim of this study is to see how acceptable and useful 3D-printed orthoses are for patients and healthcare professionals.

Who can participate?
Adults aged 18 years and over who have trigger finger can take part in the study. Both men and women will be included, and participants will be recruited from different healthcare centres.

What does the study involve?
Participants will join online meetings using Microsoft Teams or Zoom. They will receive a custom-made 3D-printed orthosis to wear. They will also be asked to fill out questionnaires about their pain and hand function at five different times: before wearing the orthosis, and then 24 hours, 1 week, 1 month, and 2 months after starting to wear it. All questionnaires can be completed from home using a phone or computer.

What are the possible benefits and risks of participating?
Participants may benefit from reduced pain and improved finger movement thanks to the orthosis. However, wearing it might be uncomfortable and could cause skin irritation or pain due to limited finger movement. The study also requires some time commitment—about 30 minutes online and around 15 minutes to complete questionnaires at each of the five time points.

Where is the study run from?
The study is being run by Université du Québec à Trois-Rivières (UQTR) in Canada.

When is the study starting and how long is it expected to run for?
June 2025 to December 2026

Who is funding the study?
Projet 2024-2025 de la Planification stratégique institutionnelle de l'UQTR (Canada)

Who is the main contact?
The main contact for the study is Tokiko Hamasaki, an occupational therapist and PhD researcher at UQTR.
tokiko.hamasaki@uqtr.ca

Contact information

Type(s)
Principal investigator

Contact name
Ms Tokiko Hamasaki

ORCID ID
https://orcid.org/0000-0002-9514-0676

Contact details
555 Boulevard de l'Université, Bureau 2021
Drummondville
Canada
J2C 0R5
+1 819-478-5011, 2903
tokiko.hamasaki@uqtr.ca

Type(s)
Scientific

Contact name
Mr Stéphane Bedwani

ORCID ID
https://orcid.org/0000-0002-1057-9883

Contact details
1000 rue St-Denis, DS350-DS450
Montréal
Canada
H2X OC1
+1 514-890-8000, ext. 11126
stephane.bedwani.chum@ssss.gouv.qc.ca

Type(s)
Public

Contact name
Miss Emma Brown

Contact details
3351 Boulevard des Forges
Trois-Rivières
Canada
G8Z 4M3
+1 819-376-5064
emma.brown@uqtr.ca

Type(s)
Public

Contact name
Mr William Beauchemin

Contact details
850 Boulevard de Maisonneuve Est, 3e-4e étages
Montréal
Canada
H2L 4L8
+1 514-623-4531
william.beauchemin@umontreal.ca

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Comparison of 3D-printed and thermoformed orthosis fabrication methods for trigger finger and hyperextension of the proximal interphalangeal joint: a pilot study

Study objectives
This project aims to evaluate whether 3D-printed orthosis is acceptable in a clinical setting, both for professionals and for patients with trigger finger and hyperextension of the proximal interphalangeal joint. This technology, which is still rarely used in this field, could offer practical and clinical advantages over traditional methods.

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 14/10/2025, Comité d'éthique de la recherche du CIUSSS de la Mauricie-et-du-Centre-du-Québec (2700, boulevard des Forges, bureau 302, Trois-Rivières, G8Z 1V2, Canada; +1 819 372-3133, poste 32303; 04ethiqueciusssmcq@ssss.gouv.qc.ca), ref: MP-29-2026-895, 1025

Study design
Quasi-experimental crossover study with repeated measures

Primary study design
Interventional

Study type(s)
Quality of life, Treatment

Health condition(s) or problem(s) studied
Trigger finger and hyperextension of the proximal interphalangeal joint

Interventions
The study design is semi-experimental; thus, there is no randomization, and there is only one arm for which the treatment is a 3D-printed orthosis. Every participant will wear the 3D orthosis and the thermoformed orthosis (control). They will wear each orthosis for a total of 2 months. The participants will answer a questionnaire assessing their symptoms before wearing the orthosis and questionnaires about the orthosis 24 hours, 1 week, 1 month and 2 months after beginning to wear the orthosis. They will not wear the 3D orthosis and the thermoformed orthosis at the same time.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Pain and upper limb function measured using 0-10 rating scale for pain at the start of the study and after beginning to wear the orthosis at multiple intervals (24 hours, 1 week, 1 month, 2 months)
2. QuickDASH questionnaire for upper limb function at the start of the study and after beginning to wear the orthosis at multiple intervals (24 hours, 1 week, 1 month, 2 months)

Key secondary outcome(s))
User satisfaction measured using QUEST 2.0 questionnaire after beginning to wear the orthosis at multiple intervals (24 hours, 1 week, 1 month, 2 months)

Completion date
01/12/2026

Eligibility

Key inclusion criteria
1. The patient must be 18 years or older
2. The patient must have a trigger finger and hyperextension of the proximal interphalangeal

joint
3. The patient must be able to use Microsoft Teams or Zoom with their cell phone or computer
4. The patient must be able to read, write and answer the questionnaires

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. The patient is already wearing an orthosis
2. The patient received a cortisone injection in the last 4 months
3. The patient received surgery for this condition

Date of first enrolment
01/12/2025

Date of final enrolment
01/12/2026

Locations

Countries of recruitment
Canada

Study participating centre
CHUM
1000 Saint Denis St
Montreal
Canada
H2X 0C1

Study participating centre
Clinique Multidisciplinaire en Santé de l'UQTR
Pavillon de la Santé, Local 2827
Trois-Rivières
Canada
G9A 5H7

Study participating centre
CBI Santé - Trois-Rivières
1785 Bd du Carmel local 103
Trois-Rivières
Canada
G8Z 3R8

Study participating centre
Centre hospitalier affilié universitaire régional de Trois-Rivières
1991 Bd du Carmel
Trois-Rivières
Canada
G8Z 3R9

Sponsor information

Organisation
Centre Hospitalier de l'Université de Montréal

ROR
https://ror.org/0410a8y51

Organisation
Université du Québec à Trois-Rivières

Funder(s)

Funder type
University/education

Funder Name
Université du Québec à Trois-Rivières

Alternative Name(s)
Universidad de Quebec en Trois-Rivières, UQTR

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon request from Tokiko Hamasaki (tokiko.hamasaki@uqtr.ca)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes