Protocol for validating the clinical effect of a knee brace

Presented to the Véritas IRB Research Ethics Committee

TOPMED

Version 02

Approved in French on May 8th 2024

Translated on August 6th 2025

NCT06655558

SCHEDULED START AND END DATES

December 2023 to December 2024

RESEARCH PROJECT DESCRIPTION

Issues

Knee orthoses are one form of treatment for patients suffering from gonarthrosis. The aim of this form of treatment is to compensate for certain biomechanical deficits in patients. A multitude of joint arrangements are available to target specific biomechanical deficits. A constant challenge for orthosis manufacturers is to transmit the biomechanical effect of the orthosis to the patient. The desired effect requires a change in the forces applied inside the knee, but the orthosis cannot directly transmit the forces to the patient's bones due to its external nature. Orthotic customization is essential to improve the transmission and tolerance of the biomechanical effect. O3D Inc. is keen to validate the effectiveness of its new custom orthosis in treating symptoms.

State of knowledge and project relevance

The changing demographics of the Canadian population are playing an important role in the growing need for orthopaedic devices. The aging population is constantly on the rise, partly due to increasing life expectancy [1-3]. At the same time, chronic diseases of the musculoskeletal system (e.g. osteoarthritis), whose prevalence increases with age, are limiting the daily activities of sufferers, affecting more and more people [4]. Osteoarthritis is the most common form of these diseases worldwide [5]. According to the Institut de la statistique du Québec, nearly one in two Quebecers aged 15 and over suffers from a chronic health problem [6-8]. Furthermore, Statistics Canada informs us that “in 2016, 20.6% of Canadians aged 15 and over reported having been diagnosed with arthritis by a health professional" [9]. The knee is one of the critical joints in the practice of activities of daily living (ADLs). Knee orthoses are way of helping people with gonarthrosis to carry out their daily activities.

The effectiveness of orthotic treatment can be measured by a reduction in gonarthrosis symptoms or medication intake, and potentially an increase in the patient's ability to perform problematic movements. As the orthoses will be custom-made, we wish to explore the relationship between orthotic efficacy and patient anthropometry. The Western Ontario and McMaster Universities Osteoarthritis Index Questionnaire (WOMAC) is a scientifically validated tool for measuring pain, stiffness and ability to perform tasks of daily living in gonarthrosis. This tool is used regularly with this type of patient to measure the evolution of their symptoms during various types of intervention.

Research objectives

The aim of this research is to validate the clinical effect of a custom-made orthosis.

With this research, we seek to answer the following questions:

- Does this new orthosis help control the symptoms of gonarthrosis?
- Does the participants' anthropometry influence the control of gonarthrosis symptoms?

Our hypotheses are that treatment with the new orthosis will reduce patients' symptoms. We have no hypotheses regarding a potential relationship between anthropometry and treatment efficacy.

Financing

The project was funded by NSERC's *Strengthening College and Community Innovation* program in partnership with O3D Inc.

Partner company

O3D Inc.

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RESEARCH METHODOLOGY

Research location

On TOPMED's premises at Collège Mérici, 755 Grande-Allée Ouest, Quebec City.

Type of test

Measurements will be taken using a single-group repeated measures methodology: before and after an 8-week intervention.

Measurement, assessment and data collection tools

Questionnaires :

A questionnaire containing general information: age, gender, height, weight and brace-wearing history. This questionnaire will only be completed prior to the start of treatment.

A Quebec version of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) questionnaire will be used to quantify the evolution of the participant's symptoms and their effects on quality of life. This questionnaire will be completed twice (before and after the treatment phase).

Anthropometric measurements :

The anthropometric measurements used by O3D to make the participant's orthosis will be transmitted to the research team. These data will be used in analyses to explore relationships with treatment efficacy.

Estimated duration of participants' activities

Questionnaire

Two questionnaires must be completed before starting treatment with the custom-made orthosis (total duration approx. 18 minutes). **Participants who have already begun treatment will no longer be eligible for the study.** After 8 weeks of treatment, a questionnaire will have to be completed again (duration approx. 15 minutes). For each questionnaire, a link will be sent to the participant by e-mail so that he or she can access it on the Lime Survey platform (accessible on the Internet).

INVOLVEMENT OF LIVE HUMAN, ANIMAL OR MATERIAL PARTICIPANTS

50 adult participants will be recruited. Participants must have gonarthrosis. Only participants who receive a regular model of the O3D orthosis will be able to take part.

Participant inclusion criteria:

- Medial gonarthrosis;
- Be between the ages of 18 and 75 inclusively;
- Receive a regular model of the O3D orthosis

Participant exclusion criteria:

- Tri-compartmental gonarthrosis
- Have completed the delivery meeting for your O3D orthosis

SCIENTIFIC JUSTIFICATION FOR USING LIVE SUBJECTS

The participation of human participants representative of the clientele is essential for validating the efficacy of treatment with the custom-made orthosis. The evolution of the participants' symptoms will give us essential information on the efficacy of the orthosis, and relationships can be explored between it and their anthropometric measurements.

RECRUITMENT

Potential candidates will receive information about the research project and a link to the study page on our website when they visit us for impressions to make a regular model of an O3D orthosis. Candidates must register their interest via our website. The information and consent form will be sent to the e-mail address provided. The research team will be available to answer any questions candidates may have (etudes@topmed.ca), assess eligibility, send documentation and/or set up a telephone appointment at a later date**.**

RISKS AND DRAWBACKS, AND PROPOSED MITIGATION MEASURES

An allergic skin reaction (redness) due to wearing the brace is a potential injury. The participant should stop wearing the brace, if necessary.

Bruises, corns, scratches and/or pain may appear on the braced limb, due to improper fitting of the brace or incorrect positioning of the brace. Injuries due to brace breakage are also possible.

ADVANTAGES AND BENEFITS

No immediate benefit for participants, except the benefit of trying a new orthosis that could improve their quality of life. The advantage of their participation is that it will provide empirical data on orthosis wear. This is an advantage for O3D Inc.

FREE AND INFORMED CONSENT

The Lime Survey link containing the Information and Consent Form (ICF) will be e-mailed to them once they have shown interest. A delay of one (1) week will be allowed for reading and reflection. In order to participate in the study, participants must have completed the first questionnaire before the orthosis delivery date.

Participants may terminate their participation at any time without negative consequences or prejudice and without having to justify their decision. In this case, participants must inform the responsible researcher or a member of the research team. Thereafter, all material allowing the identification of the participant and the data provided will be destroyed, unless the participant authorizes the researcher to use them for research purposes despite the withdrawal. In this case, the information will be retained as described below and will be applied to all other participants.

CONFIDENTIALITY AND PROTECTION OF PERSONAL INFORMATION

The information collected in the questionnaires and anthropometric measurements is confidential and will be used only for the purposes of this research project, unless otherwise agreed by the participant. All data collected, notes and computer records are encrypted on servers. Unless required by law, no information that could directly or indirectly reveal your identity will be disseminated or published without your prior explicit consent.

All digital questionnaires have been created using the Lime Survey platform. The processed information is hosted in Canada on the platform's encrypted servers (Secure Socket Layer procedure), which comply with the RGPD standard.

Data will be stored in coded form for a period of five (5) years, then anonymized in a database for retention for a period of ten (10) years for statistical reference purposes.

CONTINUOUS EXAMINATION

Should any inconvenience arise during or as a result of the research project, participants will be promptly notified.

DISSEMINATING RESULTS

No disclosure to patients will be made following the trials.

A scientific publication of the results is planned.

COMPENSATION

No compensation will be offered for participation in this study.

RESPONSIBILITY

The legal rights of each participant will be maintained.

PROTOCOL SEQUENCE

First contact

Demonstration of the participant's interest by answering via the TOPMED website's research page.

Admission

Sending documents and explanations :

- *0241_O3DA_CourrielFIC* (contains link to FIC and online questionnaire)
- *0241_O3DA_CourrielQuest* (contains link to online questionnaire)

Receipt of signed consent and questionnaire

Receiving anthropometric measurements

8-week lead time

Final questionnaire sent

Data processing

Data recording: Questionnaires and anthropometric measurements