Protocol for the clinical validation of a valgus knee brace for gonarthrosis

Presented to the Véritas IRB Research Ethics Committee

TOPMED

Version 02

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SCHEDULED START AND END DATES

From March 2023 to March 2024

RESEARCH PROJECT DESCRIPTION

Issues

Valgus knee braces (VKB) is one form of treatment to help 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 of the biomechanical effect, as well as tolerance to it. Comfort, ease of fitting and effectiveness are essential components a quality orthosis. With this in mind, Laboratoires Victhom Inc. would like to test its new knee brace attachment system.

State of knowledge and project relevance

There are 2 main types of orthosis for gonarthrosis: soft and rigid. Soft orthoses use malleable materials such as fabric or rubber to apply forces to the leg, while rigid orthoses use plastic or metal braces. What's more, three main types of fastening system are used on these types of orthoses: velcro, hybrid and cable-tied. Different configurations are therefore used to compensate for the biomechanical deficits attributable to the pathology.

Each fastening system has its advantages and disadvantages. Velcro fasteners are quick and intuitive to use, but there are a number of issues that come up when using them: adjustment difficulties, cleaning the system, the number of straps needed to hold the leg in position, and the noise produced when the velcro is released. Hybrid systems regularly contain velcro fasteners, to which quick-release fasteners have been added to simplify strap installation and removal. However, they retain most of the disadvantages of velcro systems. Cable tightening systems also feature quick-release fasteners. The advantage of cable clamping is that belts can be adjusted easily and precisely, with minimal noise.

The essential components of a quality orthosis are comfort, efficiency and ease of fitting. Comfort is paramount, as it is directly related patient adherence to treatment. The effectiveness of orthotic treatment can be measured by a reduction in gonarthrosis symptoms or medication use, and potentially an increase in the patient's ability to perform problematic movements. The ease with which the orthosis can be fitted is a component that needs to be optimized, as the user-friendliness of the treatment is important to increase patient adherence to it. The system developed in partnership with Laboratoires Victhom for this project is designed to simplify orthosis fitting, while maintaining comfort and effectiveness.

Research objectives

The aim of this research is to compare two fastening systems for VKB, one consisting of Velcro straps and the other of 3D-printed straps with cable clamping.

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

- Is the new cable-tightened belt system as effective at controlling symptoms as the Velcro fastening system currently on the market?
- Is the new cable-tightened strap system more comfortable than the Velcro fastening system currently on the market?
- Does the new fastening system make it easier to install the brace than the one currently on the market?

Our hypotheses are that the new attachment system will be more comfortable and easier to install than the one currently on the market.

Financing

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

Partner company

Laboratoire Victhom Inc.

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RESEARCH METHODOLOGY

Research location

On TOPMED's premises at 755 Grande-Allée Ouest, Collège Mérici, Quebec City. Impression taking, orthosis delivery and adjustments prior to the trial period will be carried out at the balance clinic (1825 Boul. Henri-Bourassa Suite 103, Quebec City, Qc, G1J 0H4).

Type of test

Repeated measurements on single-factor groups with crossover: Attachment system (2 conditions).

Measurement, assessment and data collection tools

Logbook :

An electronic diary will be completed each day for the duration of wear of each orthotic condition. The diary will detail total wearing time, as well as sitting time, physical and sporting activities performed during the day, number of orthosis removals and adjustments, discomfort experienced and medication taken.

Questionnaires :

A questionnaire containing general information: age, sex, height, weight, whether they wear a knee brace on both legs, and the length of time since they purchased their personal brace. This questionnaire will be completed at the first trial meeting.

A subjective questionnaire (Satisfaction) will be completed by participants to assess the ease with which they put on and take off the brace, and to validate the comfort, fit and aesthetic appearance of the brace. This questionnaire will be completed 5 or 6 times, depending on the order of the participant's conditions.

A Quebec version of the Knee injury and Osteoarthritis Outcome Score (KOOS) 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 4 times (delivery meeting and trial meetings 1 to 3).

A Quebec version of the Psychological Symptoms Inventory (Ilfeld 1976), abbreviated ISP hereafter, will be used to quantify the evolution of participants' psychological symptoms. This questionnaire will be completed 4 times (delivery session and trial sessions 1 to 3)

At each session, participants showing a clinically significant interpretation of their total score, anxiety (questions 2, 3, 9, 11, 13, 15, 16, 20, 22, 23, 29), depression (questions 1, 5, 6, 8, 10, 14, 18, 19, 21, 24), hostility (questions 12, 25, 26, 27) or concentration (questions 4, 7, 17, 18) will be contacted by e-mail to offer them mental health resources. Participants who chose an answer other than "never" to question 24 will also receive this e-mail. Links to these resources can also be found at the end of the questionnaire.

A fastening system comparison questionnaire will be completed at Trial 3 to ascertain participants' preferences regarding the installation and de-installation process, as well as their orthotics.

Photos of the fitted leg wearing the orthosis will be taken 5 or 6 times, depending on the order of the participant's conditions.

Estimated duration of participants' activities

A new knee brace will be made for each participant. To this end, an impression and anthropometric measurements will be taken during the first meeting with the participant to obtain an orthosis fitted to the patient's leg. Once the orthosis has been assembled, the participant will return to the balance clinic to receive his or her new orthosis. In addition, 3 questionnaires will be completed (ISP + KOOS + PAd1 Satisfaction) and photos of the fitted leg will be taken

Following the delivery meeting, a 14-day wearing period begins. Each time the brace is adjusted at the participant's request, the counter for the adjustment period is reset to zero. This wearing period will always be performed using the Velcro fastening system currently available on the market.

Once the fitting period is over, the first trial meeting will take place(d1). The 1st attachment system (C1) will be installed on the participant's orthosis. The order of attachment system conditions is randomized for participants. In addition, 4 questionnaires will be completed (General Info + ISP + KOOS + PAd14

Satisfaction). A 5th questionnaire (Satisfaction C1j1) will be added if the participant's first trial condition is the cable-tightening attachment system. This questionnaire will be completed after a few minutes' wear of the brace. Photographs of the fitted leg will be taken with all brace systems used during the trial. Following the first trial meeting, the first 14-day trial period begins. During this period, the participant must fill in an electronic logbook on a daily basis.

When the first trial period is over, the second trial takes place (d14). The 1st attachment system(C1) is removed and the 2nd system(C2) is installed on the participant's orthosis. In addition, 4 questionnaires are completed (ISP + KOOS + Satisfaction C1d14 + Satisfaction C2d14). Photos of the fitted leg will be taken, with all attachment systems used during the session. Following this meeting, the second 14-day trial period begins. Again for this period, the participant will be required to complete an electronic logbook on a daily basis.

The third and final trial meeting will take place following the 2nd trial period. The brace will be collected during this meeting. In addition, 4 questionnaires will be completed (ISP + KOOS + C2d28 Satisfaction + Attachment System Comparison). Photos of the fitted leg will be taken during the meeting.
Impression appointment: 45-minute appointment at the clinic.

Delivery meeting: 1 hour 45 minutes at the clinic. 3 questionnaires will be completed and photos of the fitted leg will be taken.

Adjustment meeting(s): These meetings are optional, will be held at the client's request and last a maximum of 45 minutes.

1st trial session: This session lasts 2 hours at TOPMED. If no change is made to the brace attachment system, 4 questionnaires will be completed. However, if the brace attachment system is changed during the session, 5 questionnaires will be completed. Photographs of the fitted leg will be taken.

2nd trial meeting: This meeting lasts 2 hours at TOPMED, with 4 completed questionnaires and verification of logbooks. Photos of the fitted leg will be taken.

3rd trial meeting: This meeting lasts 1 hour at TOPMED, with 4 completed questionnaires and verification of logbooks. Photos of the fitted leg will be taken. The orthosis will be picked up during this meeting.

PARTICIPATION OF LIVE HUMAN, ANIMAL OR MATERIAL PARTICIPANTS

10 adult participants will be recruited to test the different orthoses. Participants should have mainly worn an ODRA 2.0 orthosis to allow a shorter orthosis fitting period . Participants with lower-limb wounds should be excluded, as wearing the orthosis could aggravate these.

Participant inclusion criteria:

- Be 18 years of age or older;
- Have worn an ODRA 2.0 orthosis for an average of several hours a day over the past 6 months

Participant exclusion criteria:

- People with wounds on the lower limbs.

SCIENTIFIC JUSTIFICATION FOR USING LIVE SUBJECTS

The participation of human participants representative of the clientele is essential for the validation of the new cable-tightening fastening system. Participant feedback will provide us with essential information on the brace's ease of installation, comfort and symptom control, enabling us to confirm the desired properties and, if necessary, modify certain aspects to better match the needs and problems of the target clientele. In addition, the new attachment system needs to be tested on participants to measure the potential biomechanical effects of this new technology

RECRUITMENT

Victhom Laboratories will contact identified customers to request their consent to share their personal information with the research team. If consent is obtained, the customer's full name and e-mail address will be transferred to TOPMED. These consenting customers will then be contacted by TOPMED with an offer to participate in the current project. Candidates may express their interest by writing to TOPMED. A member of the project team (Marianne Lancelot/Catherine Lavoie/Élizabeth Lafrance, Orthotics-Prosthetics Research Professional) will be available to answer questions, 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 fitted limb, due to poor orthotic fit or incorrect positioning. The orthotist will be present to ensure the best possible fit of the orthosis during the session. Injuries due to appliance breakage are 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 Laboratoire Victhom Inc.

FREE AND INFORMED CONSENT

The Information and Consent Form (ICF) will be e-mailed to them once the candidate has shown interest by contacting us again. A period of two (2) weeks will be allowed for reading and reflection. Upon receipt of the signed CIF, the first meeting will be scheduled.

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 the research despite the withdrawal. In this case, they will be preserved according to the measures described below, which will be applied to all other participants.

CONFIDENTIALITY AND PROTECTION OF PERSONAL INFORMATION

Information collected from questionnaires, photos, logs, anthropometric measurements, videos and gait

pattern analysis data is confidential and will be used only for the purposes of this research project, unless otherwise agreed by the participant. All data collected, notes, photos and computer recordings 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 questionnaires and digital logs have been created using the Lime Survey platform. The information processed 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 following the completion of the prototype validation test, participants will be promptly notified.

DISSEMINATING RESULTS

No disclosure to patients will be made following the trials.

Results will not be published.

COMPENSATION

If necessary, a parking sticker will be provided to participants during their visit. A compensation of $50 will be given for their participation in each meeting of the validation protocol. The total amount awarded may not exceed $350, equivalent to the full protocol with 2 adjustment meetings. The first payment will be made after the first trial meeting. The remainder of the amount will be distributed at the last meeting or when the participant chooses to end his or her participation.

RESPONSIBILITY

The legal rights of each participant will be maintained.

PROTOCOL SEQUENCE

First contact

Email to candidates

- *0241_VICD_Courriel_Recruitment*

Admission

Demonstrate interest by responding to e-mail/phone call

Sending documents and explanations :

- *0241_ VICD_CourrielFIC*
- *0241_ VICD_Consent_form*

Receipt of signed consent

Telephone contact for impression appointment

COVID call

Self-evaluation confirmation 24 hours before each meeting.

Impression meeting

45-minute meeting at the balance clinic

Anthropometric measurements of the thigh and digital impression taken

Delivery meeting

Meeting at the Balanced Clinic 1h45

Questionnaires: Satisfaction + KOOS + ISP

- *0241_ VICD_Questionnaire_Satisfaction*
- *0241_ VICD_Questionnaire_KOOS*
- *0241_ VICD_Questionnaire_ISP*

Photos

Adjustment meeting

These meetings are optional and will be held at the client's request at the balance clinic. They last a maximum of 45 minutes.

1st trial meeting

2-hour meeting on TOPMED premises

Logbook explanations

- *0241_ VICD_JdB*

Questionnaires: KOOS + ISP + 2 Satisfaction questionnaires (one for the end of the adjustment phase, if condition 1 is different from the adjustment phase, a second comfort questionnaire is filled in)+ general information

- *0241_ VICD_Questionnaire_Satisfaction*
- *0241_ VICD_Questionnaire_KOOS*
- *0241_ VICD_Questionnaire_ISP*
- *0241_VICD_General_Questionnaire*

Photos

2nd trial meeting

2-hour meeting on TOPMED premises

Checking logbooks

- *0241_ VICD_JdB*

Questionnaires: KOOS + ISP + 2 Satisfaction questionnaires (one for the end of condition 1, another for the beginning of condition 2)

- *0241_ VICD_Questionnaire_Satisfaction*
- *0241_ VICD_Questionnaire_KOOS*
- *0241_ VICD_Questionnaire_ISP*

Photos

3rd trial meeting

1-hour meeting on TOPMED premises

Checking logbooks

- *0241_ VICD_JdB*

Questionnaires: KOOS + ISP + 1 Satisfaction questionnaires for the end of condition 2

- *0241_ VICD_Questionnaire_Satisfaction*
- *0241_ VICD_Questionnaire_KOOS*
- *0241_ VICD_Questionnaire_ISP*
- *0241_VICD_Questionnaire_Comparison*

Photos

Data processing

Data recording: Questionnaires and logbooks

BIBLIOGRAPHY

Ilfeld, F. W. (1976). Further validation of a psychiatric symptom index in a normal population. *Psychological Reports, 39*(3, Pt 2), 1215-1228. https://doi.org/10.2466/pr0.1976.39.3f.1215