Validation protocol of foot orthoses for abnormal plantar arch using a new non-invasive clinical imaging system

Presented to the Véritas IRB Research Ethics Committee

TOPMED

Version 02

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SCHEDULED START AND END DATES

September 2021 to June 2023

RESEARCH PROJECT DESCRIPTION

Issues

Plantar arch deviations, flat feet or hollow feet, are common problems that lead to loss of stability, poor posture and gait, and are thus at the root of many ailments and injuries. Cryos Technologies Inc. is a Quebec-based company specializing in the development of custom-made 3D foot orthotics, as well as equipment to promote the efficient production and fitting of these orthotics.

State of knowledge and project relevance

Made up of 26 bones and supporting up to 70kg/cm2, the foot is the foundation of the body. It holds the whole in balance thanks to just three points of support. Any misalignment, however minor, has repercussions for the whole body. The abnormal tension caused by this imbalance is amplified from one joint to the next. Ankles, knees and hips, as well as muscular chains, can be disrupted, resulting in a change in the person's overall posture and potentially causing pain.

Foot orthotics, regardless of how they are produced (molded or 3D printed), are the standard in the treatment of foot pain and pathologies, including hollow feet and flat feet. A foot orthosis is a custom-made orthopedic insole that fits into a shoe and is applied to all or part of the plantar surface. By restoring balance between the foot's three support points, the foot orthosis helps stabilize joints and rebalance muscular tension.

Cryos' unique process, from digital impression taking to software design to orthotic printing, offers the many advantages of digital methods over conventional manual methods: speed of execution, elimination of consumables (space saving, no waste production, no water use), reproducibility, precision and reliability of volumetrics. The Cryos global system, which combines the Cryovizion posture analysis system with the production of Cryos foot orthotics, is already in use in several podiatry establishments, but has never been formally validated in terms of the effect of manufactured orthotics and postural analysis.

Research objectives

The aim of this project will be to validate a new non-invasive clinical imaging system for assessing the effectiveness of foot orthoses and to evaluate the biomechanical effectiveness of foot orthoses for flat-footed and hollow-footed people. The cryovizion system should detect changes in participants' posture with 95% accuracy, while the orthoses should improve the body's postural symmetry index.

Financing

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

Partner company

Cryos Technologies 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

Repeated measurements on a single group with pre-tests and follow-up at 2, 6 and 12 months.

Measurement, assessment and data collection tools

Assessment :

An orthotist will take measurements and photos of the participants' feet, and assess their range of motion.

Scanning :

A Cryoscan 3D optical scanner (https://www.cryos.com/en/professionals/cryoscan-3d/) will be used to generate digital impressions of the participants' feet. These prints will be used to extract statistical data on morphological proportions and to model custom orthotics. This measurement system is non-invasive and harmless to health.

Analysis of walking pattern :

The *Vicon* motion capture system will provide more precise data as participants walk. The system consists of 8 infrared cameras that triangulate the exact spatial position of the sensors, which will be strategically positioned at anatomical landmarks on the participants' lower limbs. (https://www.vicon.com/about-us/what-is-motion-capture/). This validation system is non-invasive and harmless to health.

Load distribution between the legs will be analyzed using two AMTI force platforms (https://amti.biz/AMTIpibrowser.aspx).

Assessment of body symmetry will be performed using Cryovizion©, a non-invasive medical imaging tool (https://www.cryos.com/produits/cryovizion/). The Cryovizion imaging system uses LED light technology combined with a soft-tissue reflection enhancement filter following primary imaging, which generates a secondary image where color tones on skin surfaces vary according to distance from the camera. During image capture, subjects are instructed to stand up straight, wearing their underwear. Images are acquired from the front, side and back, from head to toe.

Questionnaires :

Subjective questionnaires and a logbook will be completed by participants to validate comfort when wearing the orthosis, and to target the extent to which and how pain is reduced.

Estimated duration of participants' activities

People with normal arches

1st session : 2h

People with flat or hollow feet

1st session : 1h to 1h30

2nd session : 2h

12-month trial phase

Telephone call (2 weeks): 5 minutes

3rd session (2months) : 1h30 to 2h

4th session (6 months) : 1h30 to 2h

5th session (12 months) : 1h30 to 2h

PARTICIPATION OF LIVE HUMAN, ANIMAL OR MATERIAL PARTICIPANTS

80 human participants aged between 18 and 50 will be recruited. Participants will be divided into three distinct groups: 20 participants with feet having a normal arch (control group), 30 participants with flat feet and 30 participants with hollow feet. The first session will be devoted to taking anthropometric measurements of the limb to be instrumented. The second session will be used to try on and adjust the orthoses, and to take pre-test biomechanical data. The following three sessions will be follow-up visits, and will consist in taking biomechanical data

Inclusion criteria

- Common
    - Between the ages of 18 and 50
    - BMI<30
    - No pain
    - No musculoskeletal problems
    - No balance problems
    - No central nervous system pathologies
    - No drugs that affect balance
- Participants with flat feet
    - Flat feet according to foot posture index 6 (FPI6, confirmed by clinical assessment)
- Participants with hollow feet
    - Hollow feet according to foot posture index 6 (FPI6, confirmed by clinical assessment)

Exclusion criteria

- Common
    - People with foot pathologies other than arch pathologies;
    - Diabetics ;
    - Severely obese people ;
    - People who regularly wear high-heeled shoes;
    - People with degenerative diseases ;
    - People with neuromuscular pathologies ;
    - People with circulatory disorders ;
    - People who have had major lower-body surgery.
    - Inability to walk for 30 minutes continuously.

SCIENTIFIC JUSTIFICATION FOR USING LIVE SUBJECTS

The participation of human participants representative of the clientele is essential for validation of the imaging system and evaluation of the foot orthoses. The acquisition of comparison data with a validated system will enable us to validate the biomechanical effects of the orthoses observed thanks to the Cryovizion system, and follow-up over several months will also enable us to determine the biomechanical effect of the orthoses over the medium term.

RECRUITMENT

Postings will be made in private orthotics and prosthetics laboratories, in traditional media, on social media and on the Collège Mérici bulletin boards. Candidates can express their interest by calling or writing to TOPMED. A member of the project team will be able to answer questions, assess eligibility, send documentation and/or arrange 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.

Ecchymosis or phlyctena may appear at certain pressure points due to poor orthosis fit or incorrect placement. A follow-up telephone call will be made after 2 weeks' wear to ensure that the participant is comfortable with the fit. If any subsequent discomfort is experienced, the participant should stop wearing the brace and contact the orthotist.

No potential damage when capturing data with the Cryovizion system.

ADVANTAGES AND BENEFITS

The advantage of their participation is that it will provide empirical data on the system and on orthotic wear. This is an advantage for Cryos Technologies Inc.

FREE AND INFORMED CONSENT

The consent form will be provided and explained to them when they make the appointment for the 1st session. A period of two (2) weeks, or more if necessary, will be allowed to give the participant time to read and reflect. At the 1st session, a paper consent form will be handed out and explained point by point by the orthotist, before the participants decide whether or not to sign it.

CONFIDENTIALITY AND PROTECTION OF PERSONAL INFORMATION

The information collected in the questionnaires, the video captures by the Vicon system, the photos and the biomechanical data collected are confidential and will only be used in the context of this research project, unless otherwise agreed by the participant. All data, notes and computer recordings (including the Cryovizion system, photos, Vicon motion capture and foot scans) are encrypted on servers. Unless required by law, no information that could directly or indirectly reveal their identity will be released or published without their prior explicit consent.

The data will be kept for a period of five (5) years, then anonymized in a database for retention for a period of ten (10) years for the purpose of reference statistics.

Surnames, first names, telephone numbers and/or e-mail addresses will be collected for communication purposes exclusively related to this project. Participants will not be identified by name in trial documentation. They will be assigned a number, relative to the order of their recruitment, which will be used to reference the data collected. The list of codes linking a name to a research file will be kept in the office of the responsible researcher, in a locked filing cabinet at TOPMED at Mérici Collégial Privé, 755 Grande Allée Ouest, Québec, Qc, G1S 1C1.

Any scientific publication resulting from this research project will present statistical data only, and under no circumstances will the names of the participants be published or divulged to anyone.

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

No remuneration will be paid. If necessary, a parking sticker will be provided to participants during their sessions. Compensation of $25 per participant in the control group. A compensation of $200 per participant for the hollow/flat feet group will be given for their full participation in the validation protocol. This amount will be distributed over the last four sessions ($30 at the 2nd session, $40 at the 3rd session, $50 at the 4th session and $80 at the 5th session). In addition, participants in the hollow/flat foot group will be able to keep their foot orthotics if they complete all sessions.

RESPONSIBILITY

The legal rights of each participant will be maintained.

PROTOCOL SEQUENCE

Display

Postings in private orthotics and prosthetics labs, traditional and social media, on our website and on Mérici College bulletin boards

0241_CrA_Recrutement_Affichage_Normaux_V2

0241_CrA_Recrutement_Affichage_PlatsCreux_V4

Admission

Validation by e-mail or telephone.

0241_CrA_Recrutement_Formulaire_Admission_VF

Appointment: 2 weeks (or more if necessary) between delivery of consent form and first session.

Sending documents :

- *Hygiene_clinical measures*
- *Self-evaluation_visitor form*

Sending documents and explanations :

- *0241_CrA_Rencontre1_Consent_form_VF*

COVID call

A self-assessment confirmation will be issued 24 hours before each session.

Sessions schedule

The following abbreviations stand for the different conditions under which measurements are taken: PN = barefoot; SO = shod without orthotics; AO = shod with orthotics.

	Control	flat/hollow	documentation
Session 1	FPI6 Joint assessment Cryovizion PN+ SO Vicon PN+ SO	FPI6 Joint assessment Cryoscan3D (impression) Cryoscan2D Cryovizion PN	0241_CrA_Rencontre1_Consent_form_VF Compensation $25 for inspection only
Session 2 (Day 0)	No session for this group	OP delivery Cryovizion SO+ AO Vicon SO+ AO	Compensation $30
12-month trial phase	No session for this group	Telephone follow-up after 2 weeks	0241_CrA_Rencontre2_Journal_VF
Session 3 (2 months)	No session for this group	Cryovizion SO+ AO+ PN Vicon SO+ AO+ PN	Compensation $40 0241_CrA_QuestionnaireSession345_VF 0241_CrA_Rencontre2_Journal_VF (Verification)
Session 4 (6 months)	No session for this group	Cryovizion SO + AO + PN Vicon SO + AO + PN	Compensation $50 0241_CrA_Questionnaire_Rencontre345_VF 0241_CrA_Rencontre2_Journal_VF (Verification)
Session 5 (12 months)	No session for this group	Cryovizion SO + AO + PN Vicon SO + AO + PN	Compensation $80 0241_CrA_QuestionnaireSession345_VF 0241_CrA_Rencontre2_Journal_VF (Verification)

The orthoses are modeled and manufactured by 3D SLS printing for plat/creux participants only, with data from encounter 1 by partner company Cryos. They are then sent to Topmed.

Data processing

Biomechanical data processing.

Cryovizion data processing

Data recording: Questionnaires.