A NOVEL METHOD FOR ANKLE BRACES FUNCTIONAL TESTING BASED ON A MODIFIED PROSTHETIC FOOT TESTING MACHINE-UPDATED

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Abstract

The aim of this study is to investigate the feasibility of a new dynamic testing method for ankle braces, to quantify the mechanical stability of different orthotic designs.

A mechanical, artificial foot model has been designed, considering the anatomy and biomechanics of the human foot. Sensors were built into the ankle joint, based on medical and technical principles. Together with an actuator, they were used as a test bench for validating ankle braces.

For a first feasibility study, the influence of five different types of ankle orthoses for selected movement sequences was investigated.

Introduction or Purpose

Ankle sprains are one of the most common sport-related injuries [1, 2]. More than 80% of all cases are inversion sprains [2]. The most common injury mechanism is an excessive inversion of the foot in plantar flexion, which can damage the lateral ankle ligaments [3].

To prevent ankle sprains or treat them in their acute stage, lace-up braces or semi-rigid orthoses are commonly used and recommended [1, 4]. By their mechanical support function, ankle braces should facilitate return to everyday life and work, during rehabilitation.

To increase evidence-based practice in the manufacturing of ankle braces, a better understanding of their mechanical properties is needed. For the verification of their function, the quantitative measuring procedures must be adjusted and improved.

In addition to biomechanical evaluations, a reproducible mechanical function test in a controlled environment without patients should be performed to validate the mechanical properties of a novel orthopedic system.

The aim of this study is to investigate the feasibility of a new test method for dynamic testing of ankle braces to quantify the mechanical stability of different designs.

Material & Methods

For characterizing the mechanical properties of ankle braces, a new sensor integrated artificial foot was developed, based on anatomical and biomechanical analogies [5–7]. This foot is used together with an actuator to test the braces dynamically. The artificial foot model contains multiple axes:

- One axis for talocrural joint
- One axis for subtalar joint
- Combined axis for metatarsal joint
- Combined axis for toe motion

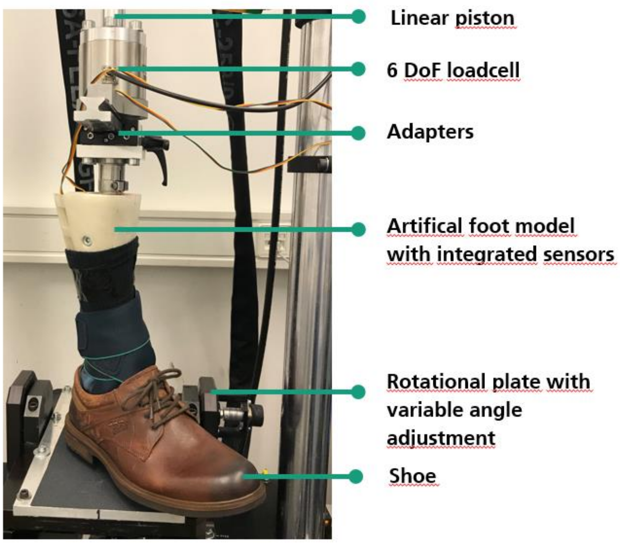

Fig 1: Machine setup with artificial foot model

Test bench Overview

A hydraulically controlled prosthesis test rig (Shore Western KS 2-07, California USA) was used at Fraunhofer IPA to move the artificial foot passively into desired positions (see Fig 1). Vertical loads are applied via the linear piston to the test samples at variable plate angles. Inversion with or without plantarflexion can be simulated with the setting of the plate.

Several tests, driven by force, were performed to investigate the mechanical characteristics of different orthosis designs. The position of the foot was measured by the built-in sensors with 4000Hz. Furthermore, machine sensor data (axial height, forces, torque) is recorded with 1000Hz for comparison.

Inversion test

The inversion test was performed with the adjusted plate, resulting in an inversion position around 28° of the foot model, to simulate a sprain during realistic normal walking.

Combined movement test:

The combined movement test was performed with the adjusted plate, resulting in a maximum 25° inversion and 20° plantarflexed position of the foot model, to simulate a sprain during walking/running with heel landing.

Maximum load on the foot model was set to 600N with a sinusoidal shape for both test cases.

Test specimen

During the experiment, all trials were performed with the same type of neutral shoe (men's leather shoe size 43).

Three trials for six different orthotic designs and one test without test specimen (reference) were performed. The tested orthoses offer support through different design structures.

Design A (Push® Aequi Flex – 2022 version) consists of a shell that includes a rigid element on the medial side. The rigid part runs under the heel from medial to the lower lateral side. The rigid part of the shell is embedded in a softer material, on the inside and towards the edges, covering the ankle and heel. An attached diagonal closing system, including soft elastic material and an inelastic strap, offers additional support and prevents the exorotation and adduction of the talus vis-a-vis the calcaneus. The orthosis is wrapped around the ankle and the lower leg approx. 1,5 times by two elastic straps of medial-proximal and lateral-proximal direction. The orthosis was compared with products available on the market.

Design B consists of two connected semi-rigid plastic parts positioned in a 60 degree angle. The plastic parts are covered with foam, and are positioned on the medial and lateral side. The plastic parts are integrated in a textile brace. Above the ankle, the brace is closed with a non-elastic strap.

Design C has two rigid plastic shells on the medial and lateral side. The shells have a cushioning aircell lining. The shells are connected by a neoprene element. The shells are integrated into a textile structure. The orthosis is closed by an additional strap, which is diagonally closed on the distal-lateral side towards the medial-proximal side. A second strap is closed proximal at the level of the achilles tendon.

Design D has a 3-dimensionally shaped shell that encloses the ankle joint on the lateral side. The rigid structure is cushioned with silicone material lining. The orthosis is closed with an upper strap that is located above the ankle around the lower leg. A second strap is used, which is wrapped 1,5 times diagonally around the ankle anterior-laterally via a hook-and-loop closure.

Design E has a bilateral rigid support structure integrated into a textile brace. The brace is closed with a dial lacing closure on the front. Two elastic straps on the medial and lateral side conclude the closing of the brace, each with a half winding.

Design F is a textile brace with a lace-up closure on the front. Two non-elastic straps supports the ankle. Above the ankle an elastic strap is positioned.

The tightening of the ankle braces has a significant influence on the functionality and stiffness of the supporting system. The following procedure was used to ensure repeatable results:

1. All samples were first put on a human test person to get an impression for the needed force of each strap to be adequately tightened, according to information from the product manual, controlled by an expert.
2. Subsequently, the ankle brace test sample was put on the artificial foot with a similar strapping-force, controlled by an expert.
3. Markings on the samples are applied and photo-documented to ensure repeatable tightening conditions

Results

For each test sample, three measurements were carried out. Fig 2 shows the mean graphs of these three test series for the inversion movement test. All tested samples showed clear differences (Fig 3) in the range of motion (from 17,18° to 25,66°) compared to the reference without brace (44,77°).

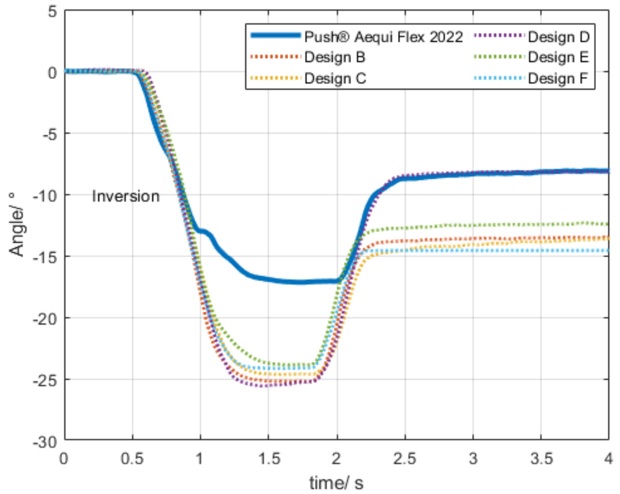

Fig 2: Results of dynamic inversion ankle brace test (mean graphs, n=3)

The Push® Aequi Flex 2022* shows the highest stability effect for inversion movements with 17,18° (0,35° SD).

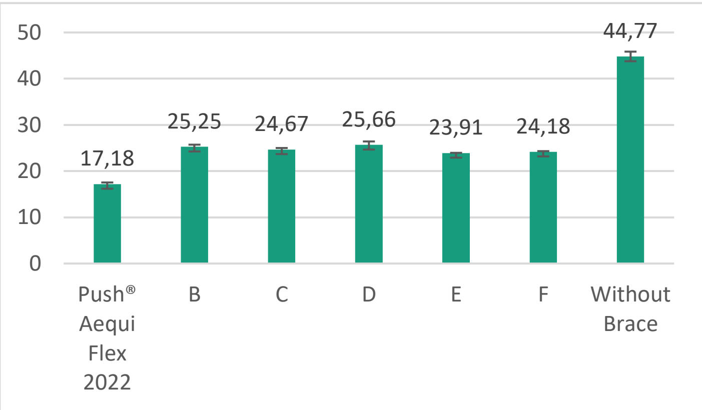

Fig 3: Max. inversion angle (°) - mean (n=3 trials)

For all samples, the starting position differs from the end position after the foot has been unloaded. This can be explained by the fact that there is no resetting torque implemented within the artificial foot model. Therefore, the foot is reset to its neutral position automatically by the actuator before starting each trial.

Mean graphs for the combined movement test (inversion & plantarflexion) are plotted in Fig 4. Upper graphs represent movements in the talocrural joint (plantarflexion) and lower graphs correspond to the subtalar joint (inversion). Results without orthosis show a maximum of 12,71° (0,19 SD) in plantarflexion and a maximum of 47,65° (1,38 SD) in inversion (Fig 5). In comparison to the inversion test, the tested braces showed a similar tendency for subtalar joint (inversion).

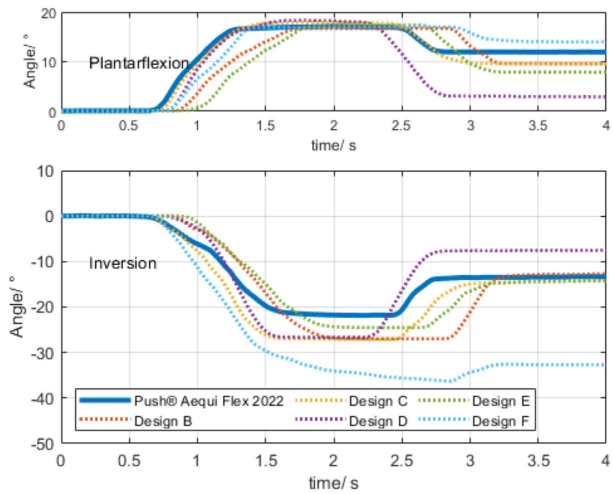

Fig 4: Results of dynamic combined movement (inversion & plantarflexion) brace test (mean graphs, n=3

In plantarflexion, all tested orthoses are within a range of about 1,7° close to each other (from 16,7° to 18,4°) compared to the test without orthosis (12,7° | 0,19 SD).

There are clear differences (up to 15,6°) in the inversion direction (Fig 5). Push® Aequi Flex 2022 shows the highest stability in inversion with 21,9° (0.7 SD). Design F allows the most inversion and moves up to a position of 37,5° (3,7 SD).

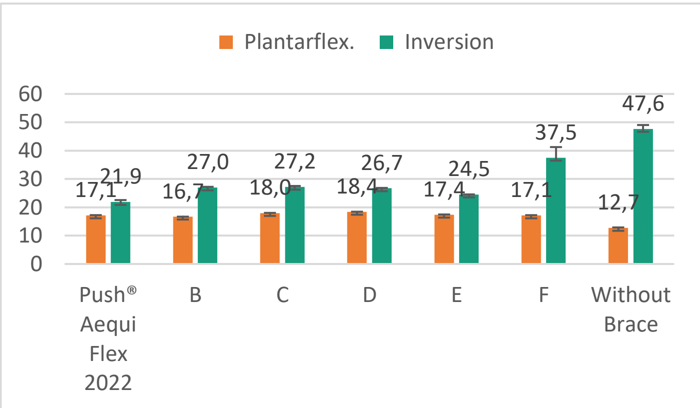

Fig 5: Max. inversion & plantarflexion angle (°) - mean (n=3 trials)

In contrast to the other specimen, with design F the foot remained in the deflected position. It has to be noted, that the results of the combined movement test should not be used to conclude isolated plantarflexion mobility. Separate tests are required to investigate pure plantarflexion, e.g. when walking.

Discussion

The tests in this study were all performed with the same initial conditions. The properties of the orthoses may show different results among other machine or test settings. Next to the construction of the artificial foot, inter alia the following parameters influence the test results: tightening of the orthoses, load, speed, range of motion and direction of the movement.

Interindividual characteristics are the most reason for varying results in clinical investigations. In comparison to clinical tests, mechanical testing procedures are much more reliable and can provide repeatable results. So statements can be made about the stability function of different ankle brace designs in the early prototype-phase as well as for the quality management of existing products before testing with subjects. These measured mechanical properties can be compared to clinical results and used for different product development phases.

Conclusion

The results demonstrate, that the developed test method is suitable for characterizing the mechanical function of ankle braces. The feasibility study showed sufficient precision and repeatability.
As manufacturers intend, protection against excessive inversion movements should be ensured without limiting mobility in the sagittal plane to much. All in this study tested orthoses have shown significant differences in ankle stability. The support function primarily depends on the design of the orthotic system.

Further research work is necessary to improve the test procedure. Based on individual activity profiles, realistic test scenarios can be generated. User behaviors can be adapted by variation of several conditions, like load, speed, range of motion and direction of the movement.

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