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

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Abstract

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

A mechanical artificial foot model has been designed, based on 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, which can damage the lateral ankle ligaments [3].

To prevent from ankle sprains or treat them in their acute stage, laceup braces or semi-rigid orthoses are commonly used and recommended [1, 4]. Ankle braces are intended to facilitate return to everyday life and work, during rehabilitation through their mechanical support function. In order to increase function-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 functional testing of ankle braces to quantify the mechanical stability of different designs.

Material & Methods

For characterizing the mechanical properties of ankle braces, a new sensory integrated artificial foot was developed, based on human anatomy and biomechanics [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

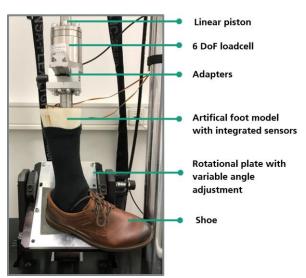


Fig. 1: Machine setup with artificial foot model

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° plantar flexed position of the foot model, to simulate a sprain during walking/running with heel landing.

Maximum load on the foot model was set to 400N 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 five different orthotic designs and one test without test specimen (reference) were performed. The tested orthoses offer support through different design structures.

On the medial side, Push® Aequi (Design A) has a rigid element, which runs under the heel from medial to the lower lateral side. An attached diagonal inelastic strap offers additional support and prevents the external rotation and adduction of the talus vis-a-vis the calcaneus. A base of reinforced foam is integrated on the inside and lateral side. 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. *See Note

Design B consists of two rigid plastic shells on the medial and lateral side. The shells have a continuous outer aircell on the inner side and an integrated inner aircell in the ankle area. With each movement, the aircell between the rigid shells and the leg is compressed. The shells are closed by two non-elastic straps around the leg and held together by a third strap on the plantar side.

Design C uses similar technology to Design B and also has bilateral rigid shells with air cells that 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 medial and lateral sides. The hard structure is cushioned with internal silicone material. 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 closed 1.5 times diagonally around the ankle anterior-laterally via a hook closure.

Design E has a bilateral rigid support structure integrated into a textile brace. The orthoses are closed with two elastic straps on the medial and lateral side, each with a half winding. Additionally, the orthosis has lacing on the front, similar to a shoe.

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

- All samples were first put on a human test person to get a rough 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 photodocumented to ensure repeatable tightening conditions



Design B







Fig. 2: Overview of the tested orthoses designs

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 (compare

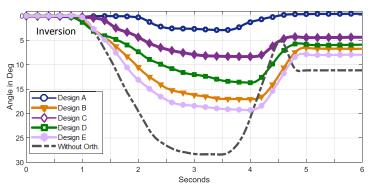
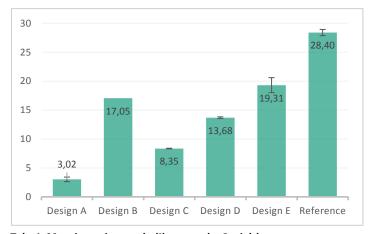


Fig.2: Results of dynamic inversion ankle brace test (mean graphs, n=3)

table in Tab.1) in the range of motion (from 3.02° to 19.31°) compared to the reference without orthosis (28.40°).

Design E allows movement up to 19.31° (0.40° SD) due to the structural design and lacing in the front part.

Design A (Push® Aequi) shows the highest stability effect for inversion movements with 3.02° (0.40 SD). Design B indicates a high degree of stability due to its stable construction. Due to the rigid shape of the separate elements, the foot still has the possibility to move within the system (17.05° | 0.05 SD).



Tab. 1: Max. inversion angle (°) - mean (n=3 trials)

Due to a loose ankle joint of the artificial foot, a backswing was observed during the measurement without orthosis. This can be explained by the missing support function without orthosis. For all samples, the starting position differs from the end position after the foot has been unloaded. Therefore, the foot is returned 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. 3. Upper graphs represent movements in the talocrural joint (plantarflexion) and lower graphs correspond to the subtalar joint (inversion). Results without orthosis

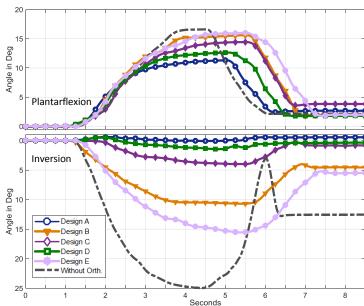
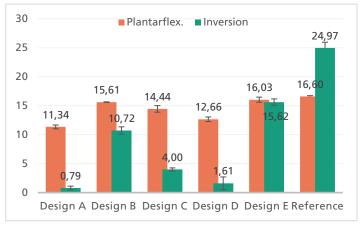


Fig. 3: Results of dynamic combined movement (inversion & plantarflexion) brace test (mean graphs, n=3)

show a maximum of 16.60° (0.13 SD) in plantarflexion and a maximum of 24.97° (0.98 SD) in inversion. In comparison to the inversion test, the tested braces showed a similar tendency in the combined test. Only Design D showed different behavior in the combination test. The diagonal orientation of the rigid shells supports the foot especially in the combined movement.



Tab. 2: Max. inversion & plantarflexion angle (°) - mean (n=3 trials)

In plantarflexion, all tested orthoses are within a range of about 4.69° close to each other (from 11.34° to 16.03°) compared to the test without orthosis (16.60° | 0.98 SD).

There are clear differences (up to 14.83°) in the inversion direction. Design A showed the highest stability in inversion with 0.79° (0.33 SD) and allows almost no movement in this direction. Design E allows the most inversion and moves up to a position of 15.62° (0.56 SD). 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.

Interindividuality is the most important 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 with clinical results and can be used during 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 frontal plane movements should be ensured without limiting mobility in the sagittal plane too much. The tested orthoses show significant differences in ankle stability. The support function primarily depends on the design of the orthotic system.

Further research 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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