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Testing Procedures for Ankle-Foot Orthoses

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The article describes the options for checking functional properties and fatigue strength of ankle-foot orthoses. The test procedures developed allow a standardised, precise characterisation of ankle-foot orthoses and in the future may form a basis for the exact clinical classification of orthoses.

Key words:

AFO, testing procedure, function test, fatigue strength test, instrumented orthosis

Introduction

Ankle-foot orthoses (AFOs) are used in clinical practice for a number of indications. The orthoses take on different biomechanical functions, from limiting plantar flexion in patients with foot drop following a stroke to stabilising the mid-stance phase to improving the so-called crouch gait in infantile cerebral palsy. Though orthoses can be roughly distinguished by design and type of material used, it is generally not possible to optimally match an orthosis to a certain patient on this basis.

That is why it is necessary to first have a standardised classification of orthoses according to their functional characteristics. Several experimental test models [1, 2, 3] of varying complexity and validity have been described in literature. Test benches with anatomically defined ankle joints [4, 5] can currently be viewed as state-of-the-art technology.

However, it is not sufficient to assess the characteristics of an unused orthosis only. In order to be clinically effective, the orthosis should also show these characteristics at the end of its period of use. The applicable international standard EN ISO 22523 requires the manufacturer to define and document required strength parameters and the attendant test methods. There are, however, no specifications laid down regarding the test load or length of the test method. A few experimental AFO test benches for fatigue strength have been described in literature. These range from simple systems which carry out dorsal extension movement, e.g. with the use of a crank mechanism [6] or centrifugal force [7], to highly complex robotic systems that are difficult to reproduce.

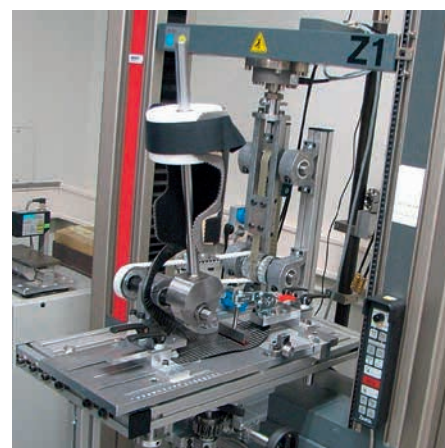


Fig. 1 Mechanism for measuring AFO characteristics

Testing functional characteristics

Ottobock HealthCare has developed a test apparatus (Fig. 1) that allows a standardised and precise assessment of the functional parameters of the orthosis (ankle stiffness, forefoot stiffness, heel stiffness). To a large extent, the measuring principle corresponds to the clinically validated BRUCE test bench [5]. However, load and deformation of the orthosis are measured using a universal material test machine (Zwick).

The test apparatus allows relative motion around joints defined according to the anatomical situation and can be adjusted to different AFO sizes. The orthosis is secured to the test apparatus without being damaged by means of a clamping mechanism and a lower leg dummy that can be linearly aligned. The material test machine places defined loads on the orthosis in pre-determined directions of motion (plantar flexion/dorsal extension of the ankle joint, flexion/extension of the forefoot and heel area) during



Fig. 2 Modular lower leg model.

the measuring process. The resulting moment of resistance of the orthosis and accompanying angle of rotation are continuously registered. Functional orthosis parameters are calculated on the basis of these values after compensating for friction loss.

The investigations conducted to characterise the test method showed very good replicability (CV < 2% for ankle stiffness, CV < 5% for forefoot/heel stiffness).

Testing fatigue strength

Analogy observation lends itself to the evaluation of fatigue strength of ankle-foot orthoses. The international standard EN ISO 22675 defines a dynamic test method for ankle-foot components for exoprostheses of the lower limbs. A test bench complying with this standard generates a composite load, such as the load when walking, by synchronising the vertical force component with the angle of a tilt platform and is thus well suited for use in AFO testing. However, it is also necessary to develop a lower leg model that takes into account the relevant interplay between the limb and the orthosis. Among other things, it is necessary

- to replicate the anatomically correct position of the ankle to avoid reactive forces between the orthosis and the model of the leg,
- to configure dimensions suited to anthropometric data,
- to integrate a metatarsophalangeal joint to enable physiological rollover,



Fig. 3 Instrumented orthosis for measuring loads.

- to replicate the soft tissue and skin friction characteristics for realistic migration behaviour.

The modular lower leg model can be seen in Fig. 2. It consists of soft tissue and skin replication in the proximal and distal lower leg region and a modified prosthetic foot connected over a joint. The prosthetic foot was modified to enable a natural rollover over the forefoot with dorsal extension in the metatarsophalangeal joint. The prosthetic ankle was also modified to enable a physiological range of motion.

The amount of loading during walking in a lower limb orthosis is not known. A literature search did not yield any relevant publications. However, this knowledge is essential for adjusting the test method and for its final validation. To provide the missing information, an instrumented orthosis with integrated laminated fabric strain sensors was developed for measuring bending strain at various locations (forefoot, heel etc.) in subject and patient tests (Fig. 3).

A final determination of test conditions was made on the basis of the data generated. Test conditions (angle and position of the foot platform, point of force transmission, etc.) were adjusted until they sufficiently conformed to the results of patient examinations.

A load of 800 N corresponding to EN ISO 22675 was retained for the standard test procedure. The maximum tilting angle of the foot platform, however, in deviation from EN ISO 22675, was set at -10° and 25°

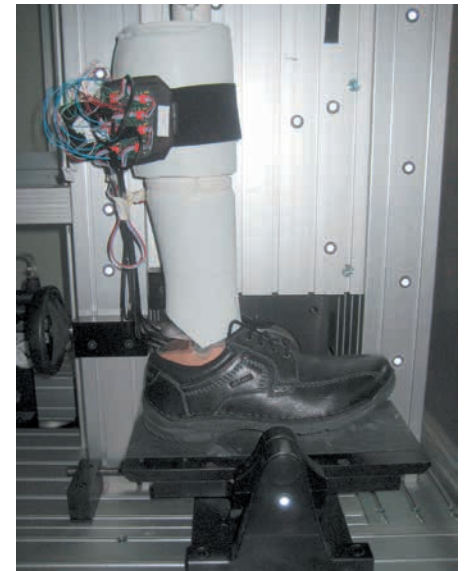


Fig. 4 AFO in ISO 22675 test bench.

(corresponding to a maximum force of -7.3° and 13.5°). However, the test conditions selected can be varied as required depending on the characteristics of the patient collective to be replicated (size, weight, muscle status etc.). In addition, higher loads can intentionally be selected to simulate a worst-case scenario.

The ankle-foot orthosis is attached to the lower leg model for the test and mounted to a test bench that conforms to EN ISO 22675 (Fig. 4). The orthosis is normally tested using firm mid-height footwear.

Example of application of the test method

The test methods that were developed were used to compare the newly developed WalkOn Reaction ankle-foot orthosis with a „gold standard“ dynamic carbon ankle-foot orthosis that is frequently used clinically.

For each of the orthoses, a fatigue strength test as per the standard test method described above was conducted for 2 million load cycles, which corresponds roughly to 2 years usage as studies of the mobility of patients with drop foot [9] have shown. The functional parameters were measured before the start and during the fatigue strength test (at 400,000, 800,000, 1,600,000 and 2,000,000 load cycles). Three exemplars of each orthosis were tested and the results showed that there were very few deviations between the individual exemplars tested.

The results of the tests showed that the WalkOn Reaction ankle-foot or-

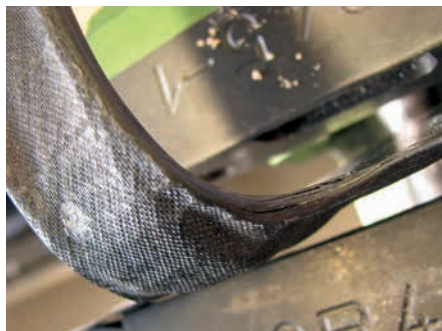


Fig. 5 Delamination damage.

thosis had a loss of stiffness in the ankle of ca. 13% following the first 400,000 load cycles. At the end of the simulated useful life (2 million load cycles), a loss of stiffness of 20% of the initial value was noted. In comparison, the „gold standard“ orthosis lost ca. 35% of its stiffness after the first 400,000 load cycles and ca. 40% after 800,000 load cycles. Further testing of the „gold standard“ orthosis was no longer relevant because „false joints“ or cracks had formed due to delamination (Fig. 5) at the junction between the upright and the sole. This greatly reduced the functional capability of the AFO though there was no danger of injury to the patient.

The experimental testing showed that the test method that has been developed is able to accurately differentiate between the different orthosis models.

Summary

The test methods introduced here allow for a standardised, precise characterisation of ankle-foot orthoses and in the future may form a basis for the exact clinical classification of orthoses for optimal patient care. The newly developed ankle-foot orthosis, WalkOn Reaction, showed very positive fatigue strength properties in the tests that were carried out.

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Reviewed paper

With compliments

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REFERENCES:

- [1] Yamamoto S, Ebina M, Iwasaki M, Kubo S, Kawai H, Hayashi T. Comparative study of mechanical characteristics of plastic AFOs. *Journal of Prosthetics and Orthotics*, 1993; 5 (2): 59
- [2] Sumiya T, Suzuki Y, Kasahara T. Stiffness control in posterior-type plastic ankle-foot orthoses: effect of ankle trimline. Part 1: a device for measuring ankle moment. *Prosthetics and Orthotics International*, 1996; 20 (2): 129-131
- [3] Polliack AA, Swanson C, Landsberger SE, McNeal DR. Development of a testing apparatus for structural stiffness evaluation of ankle-foot orthoses. *Journal of Prosthetics and Orthotics*, 2001; 13 (3): 74
- [4] Novacheck TF, Beattie C, Rozumalski A, Gent G, Kroll G. Quantifying the spring-like properties of ankle-foot orthoses (AFOs). *Journal of Prosthetics and Orthotics*, 2007; 19 (4): 98
- [5] Bregman DJJ, Rozumalski A, Koops D, de Groot V, Schwartz M, Harlaar J. A new method for evaluating ankle foot orthosis characteristics: BRUCE. *Gait & Posture*, 2009; 30 (2): 144-149
- [6] Lunsford TR, Ramm T, Miller JA. Viscoelastic properties of plastic pediatric AFOs. *Journal of Prosthetics and Orthotics*, 1994; 6 (1): 3
- [7] Carlson JM, Day B, Berglund G. Double short flexure type orthotic ankle joints. *Journal of Prosthetics and Orthotics*, 1990; 2 (4): 289
- [8] Lai HJ, Yu CH, Kao HC, Chen WC, Chou CW, Cheng CK. Ankle-foot simulator development for testing ankle-foot orthoses. *Med Eng Phys*, 2010; 32 (6): 623-629
- [9] Shaughnessy M, Michael KM, Sorkin JD, Macko RF. Steps after stroke: capturing ambulatory recovery. *Stroke*, 2005; 36 (6): 1305