A new approach to implement a customized anatomic insole in orthopaedic footwear of lower limb orthosis

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Abstract. This paper concerns the development of a new approach for orthopaedic footwear to apply in KAFO orthosis (acronym for Knee Ankle Foot Orthosis). This procedure starts with full characterization of the problem with the purpose to characterize a plantar of a patient's foot with polio. A 3D Scanner was used to collect their feet's data to produce an anatomic insole. After this step, the patient performs a study of his gait using a static and dynamic study with the aim of characterizing the parameters to improve quality in the footwear. The insole was produced using a 3D printing technology. It was essential to optimize manufacturing processes and it was developed a footwear prototype with innovative characteristics, which is 25% lighter, allowing the user to consume less energy in daily routines.

Key words: Orthopaedic footwear, biomechanics, 3D insole, KAFO, polio, gait analyses

1. Introduction

This paper reports on the investigation that is being undertaken at the University of Minho concerning the development of orthopaedic footwear to be used in KAFO orthosis (acronym for Knee Ankle Foot Orthosis) [1].

The development of footwear associated with orthosis hasn't received significant attention; for the last twenty years, the only concerns have been the robustness and durability of the system's elements. Important issues, such as: the applications of advanced materials to achieve functionality and give better aesthetic values are usually neglected. The authors in previous papers have proposed several solutions, including laminating lining with hydrophilic membranes with functional products. With these solutions, it was attained a very high efficiency, reducing or eliminating the bromhidrosis problem and waterproof property has been achieved [2, 3, 4]. Additional and relevant aspects to reduce or even eliminate the humidity inside of footwear, toe puffs, counters and insoles, were considered in the development of the orthopaedic footwear.

Nowadays, production of anatomic insoles, using a nonconventional methodology, has been evaluated. This methodology consists of using scan 3D system to digitalize the end user foot and sending all the

information to be used on 3D printing to create an insole customized. The polymer insole base, latex foam, is coated with a fabric to create a material with very high absorption capability of fluids. The present insole is already ten times faster than leather to reduce the fluids [4].
The main motivation for this research comes from current interest in developing new technical solutions that allows for the improvement of the life quality of people with physical handicap. In fact, over the last decades, the attention to design and analysis of technical aids for treatment and rehabilitation of people with mobility limitations has been growing a very significant manner [5]. In particular, the scientific and technical domain of Biomechanics of Motion plays a crucial role, in the measure that it permits to quantify the kinematic and dynamic parameters associated with the human daily activities [6]. Thus, this study deals with the design and development of a new customized insole to be employed on orthopaedic footwear. This work is part of a broader research project that has been developed at the Textile and Mechanical Departments of the University of Minho, main purpose of which is to develop a new manufacturing process of orthopaedic footwear.

Material and methods

The general methodology followed in this research has been divided into three main phases, namely (1) study of the human gait cycle to characterize the dynamic loads generated during the different motion phases; (2) development of a customized anatomic insole by collecting feet's data with a 3D scanner FastScan® and producing it with 3D printing; (3) incorporation of the insole in orthopaedic footwear on KAFO orthosis and tested by the user.

The firstly phase of this paper determinates the distribution of pressure, developed on the patient's feet during gait, measured using pressure plates. The dynamic measurements were performed individually for each foot; the patient walks on the pressure plate to record the selected variant. In this study, the pressure measurements were performed using the FootScan® 3D Gait Scientific 2m System. Due to the FootScan® 3D interface, the user has the possibility to synchronize his system with other measurement tools, namely force plates. The characterization of the human gait for normal and pathological cases is performed based on the biomechanics of motion, which allows the identification of the worst scenarios in terms of loads during human gait [7].

The 3D scan uses an innovative development of the implicit modelling method, Radial Basis Functions (RBF). An implicit modelling algorithm determines how known data points are used to imply (or estimate) unknown data points to create surfaces.

Fused Deposition Modelling (FDM) is the most common 3D printing method used in desktop 3D printing, using thermoplastic filament heated and extruded through an extrusion head that deposits the molten plastic in *X* and *Y* coordinates, while the build table lowers the object layer by layer in the *Z* direction.

During the third phase, the developed insole is incorporated in the new footwear, KAFO orthosis, and tested on a patient daily routine.

2. Results and discussions

Static Gait Analysis

This section includes some of the earlier of this study. Firstly, two different devices, Lux Stabilometric footboard and Podata footboard, are used to carry out a stabilometric analysis. The Lux Stabilometric footboard has three load cells while the Podata footboard is provided with six cells (bipodalic), which can be adjusted in order to record the load under the 1st, 5th metatarsal and calcaneus of each foot. Fig. 1 ant table 1 illustrates main parameters considered for the static analyses. The number of measurements is 4000, between 20 seconds

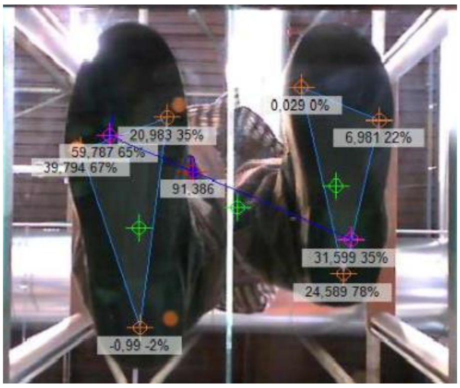


Figure 1- Podata footboard

Table 1 illustrates one atypical foot, as results of polio pathology. It is possible to verify that the force applied on the right calcaneus is equal to 24.589 kg, which represents 78% of total weight on right leg. It is also possible to observe that the left leg of the user has a different forces distribution.

Table 1 – Results of static analysis

Parameters	**Left foot**	**Right foot**
Total mass (kg)	91.386	
Mass on left foot (kg)	59.787	x
Mass on right foot (kg)	x	31.599
Mass of the 1st metatarsal	20.983	0.029
Mass of the 5th metatarsal	39.794	6.981
Mass of the calcaneus (kg)	0.990	24.589

Dynamic Gait Analysis

The experimental data used in this biomechanical simulation was obtained in a human gait laboratory. A polio patient male of age 43, mass 93 kg and height 178 cm have been dressed with a special suit with 37 reflective markers attached, as illustrated in Fig. 2. The polio patient was wearing a traditional KAFO orthosis on his right leg.

For the experimental procedure, the subjects walk on a walkway with two AMTI AccuGait force plates, located in such a way that each plate measures the ground reactions of one foot during the gait cycle. The motion is captured by an optical system composed by 12 Natural Point OptiTrack FLEX: V100 cameras (100 Hz) [5].

Fig. 3 Knee joint angle during the entire gait cycle for the polio patient and centre-of-pressure curves (COP) during moment-of-force entire gait cycle for the polio patient.

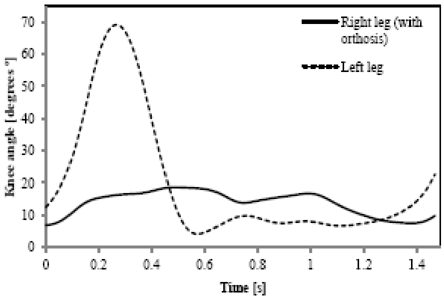
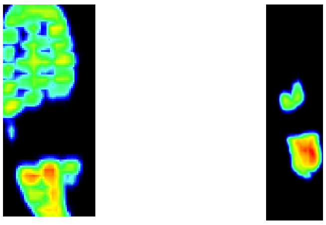


Figure 2- dynamic test

Figure 3 – knee flexion degree

The figure 4 depicts the dynamic results associated with human gait for one foot normal and one foot with cavus foot pathology. These plots represent the gait of the user considered in the present study. The intensity of pressure increases from green to red colours. In the dynamic analysis it can be verified that the differences between right and left feet responses during the gait. It is also possible to observe the high pressure on right foot located in calcaneus zone.



(a) (b)

Figure 4 (a) Left/normal foot (b) Right/cavus foot.

The user considered in the present study has 93 kg mass, which is equivalent to 912 N. Another important factor to analyse the forces applied by the user during his gait, is the pronation angle, which is equal to 20° in the present case. Initial contact with the ground during the stance phase occurs with the calcaneus. With the ground during the stance phase occurs with the calcaneus. This contact area supports the entire body weight, as described in Fig. 5 by Fp (912 N, which corresponds to the force applied when the foot is in the normal position. In this particular case, there is an excessive pronation that produces an extra force Frs (970 N) that corresponds to ground reaction. This force can be decomposed by the amplitude of pronation angle (γ) in Fp. This movement causes beyond, a horizontal force Fh (330 N) towards the medial edge, perpendicular to the sagittal plane, applied at the joint of the talus and tibia[8]..

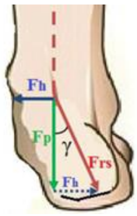


Figure 5 Forces representation reaction force.

Plantar Surface Data Acquisition

FastSCAN™ instantly acquires three-dimensional surfaces by gathering measurements made by smoothly sweeping a handheld laser scanning wand over. The object's image instantly appears on a computer screen without the need to place untidy or unwanted registration marks on the object. The finished scan is processed to combine any overlapping sweeps, significantly reducing the time to develop surface models of virtually any object with minor or no metal content.

The figure 6 show the planter surface of polio patient with a pathological cavus foot and fig. 7 show a 3D scan of a insole

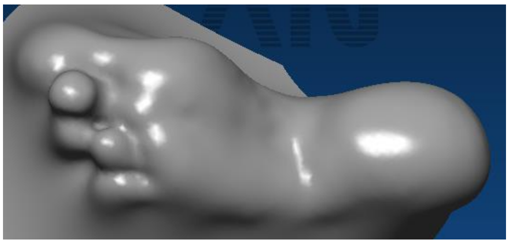


Figure 6 – 3D scan plantar foot

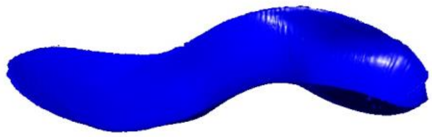


Figure 7 – 3D scan insole

Insole 3D Production

Much like traditional printers, 3D printers use a variety of technologies. The most commonly known is fused deposition modelling (FDM), also known as fused filament fabrication (FFF). In it, acrylonitrile butadiene styrene (ABS), polylactic acid (PLA), or another thermoplastic is melted and deposited through a heated extrusion nozzle in layers. Digital light projector (DLP) 3D printing exposes a liquid polymer to light from a digital light processing projector, which hardens the polymer layer by layer until the object is built and the remaining liquid polymer is drained off.

Polylactic Acid (PLA) bioplastics dominate in 3D printing. A biodegradable thermoplastic aliphatic polyester, PLA is made from renewable, organic resources like corn starch or sugarcane. It's commonly used to make food packaging and biodegradable medical devices and implants. PLA is great for 3D printing because it's easy to work with, environmentally friendly, available in a variety of colors, and can be used as either a resin or filament.

The figure 8 and 9 show 3D printing manufacturing process of making three dimensional solid insole layer by layer, In this case the image is capture from 3D scanner of plantar foot of polio patient referenced in this study.

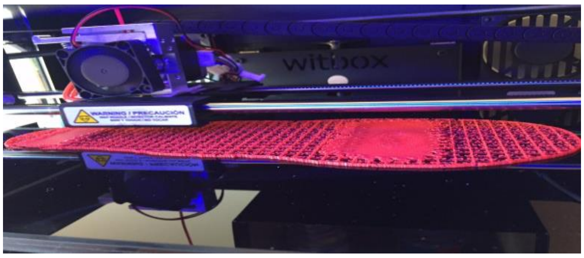


Figure 8 – 3D printing process

Figure 9 – 3D printing insole

3. Conclusions

The high potential of new technologies such as 3D scanner, 3D printer, to produce anatomic insoles and how the static and dynamic analysis gait improve the prospective of developing high quality footwear to apply on orthosis has been demonstrated in this work. It must be highlighted that the new model is 25% lighter than the conventional footwear, which is a crucial issue in terms of user's usability. Furthermore, based on the user's experience it is reduced the fatigue during gait so the new approach is appropriate and functional for daily activities.

4. References

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