EVALUATION OF AN ANKLE-FOOT-ORTHOSIS DESIGNED FOR CHILDREN WITH SPINA BIFIDA

Hasan Kemal SURMEN
Department of Automotive Technology, Vocational School of Technical Sciences, Istanbul University
hasan.surmen@istanbul.edu.tr

Nazif Ekin AKALAN
Department of Physiotherapy and Rehabilitation, Faculty of Health Sciences, Istanbul University
akalan@istanbul.edu.tr

Yunus Ziya ARSLAN
Department of Mechanical Engineering, Faculty of Engineering, Istanbul University
yzarslan@istanbul.edu.tr

Yener TEMELLI
Department of Orthopedics and Traumatology, Faculty of Medicine, Istanbul University
temelli@istanbul.edu.tr

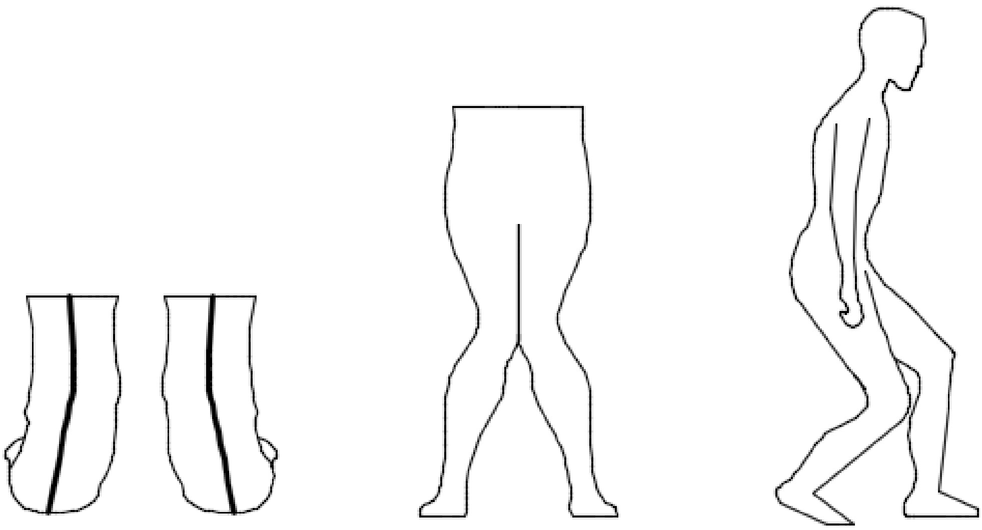
ABSTRACT: Spina bifida is a birth defect which is caused by the incomplete closing of the backbone and membranes around the spinal cord. Children with spina bifida have motor skill problems, as well as problems with a various level of insensitivity and organization. Motor skill problems especially influence the ambulation patterns of children. In order to control the ankle motion and to provide an optimal gait skill in patients with spina bifida, different types of ankle-foot-orthoses (AFOs) were designed and manufactured. AFOs are the externally applied assistive devices and prescribed to the patients with neuromuscular dysfunctions to improve the abnormal lower limb motor functions. In this study, a patient-specific, modified AFO was designed and manufactured in accordance with the patient's need considering the results of the mechanical analysis of the AFO using finite element method (FEM). The mechanical responses of the novel AFO were compared with those of the classical one. Merits and shortcomings of the novel AFO were comparatively evaluated and discussed in the paper.

Key words: Ankle foot orthosis, spina bifida, finite element analysis, mechanical analysis.

INTRODUCTION

Spina bifida (SB) is a birth defect that belongs to a group of disorders known as neural tube defects (Watson, 2008). Three types of functional deficits, that is, hyperpronation, knee valgus and crouch gait pathology (Figure 1) are usually observed in patients with SB (Esposito, Blanck, Harper, Hsu, & Wilken, 2014). These types of functional deficits could be managed by Ankle-Foot-Orthoses (AFOs) which are orthopedic devices used to assist or limit the lower leg motion to improve the ambulation of patient with SB (Duffy, Graham, & Cosgrove, 2000).

AFOs are usually produced using a vacuum molding technique and the final form of the AFO is done by an orthotists (Ford & Grotz, 1984). Orthotists produce orthosis devices according to prescription of the patients and they decide the severity of trimline which is significant to determine the rotational ankle stiffness of AFO (Bielby et al., 2010). In AFO design, it is difficult to reach an optimal trimline severity by experience. In addition, wrong designs lead to high stress points on the critical sections of the AFO under dynamic loading conditions and hence, plastic deformation could occur. Moreover if the trimmed area could not be determined properly, the AFO could prevent the movement of the patient more than the desired limitation and therefore, the rotation of the ankle could not be implemented with proper angle. In this study, it was aimed to design and produce an AFO using an alternative trim method allowing less stress and providing required dorsiflexion angle. Design parameters were defined with the help of software based on finite element method (FEM) which is a numerical technique for obtaining approximate solutions. Required trim size and position were determined according to the results of finite element analysis (FEA) before manufacture of the AFO. Furthermore, the novel AFO was experimentally compared with the conventional AFO, which was produced by an experienced orthotist, to see the efficiency of the novel AFO design.



(a) (b) (c)

Figure 1. Functional Deficits Associated with SB: (a) Hyperpronation, (b) Knee Valgus, (c) Crouch Gait

METHODS

First step in the study was to obtain the gait patterns of the patient. To determine the temporospatial, kinematic and kinetic parameters of the patient, gait analysis was implemented using the data obtained by means of the motion capture system and the force plate.

It was observed from the gait analysis results that the ankle dorsiflexion angle of the patient was out of the range of normal gait pattern along the gait cycle (Figure 2). By taking the range of the normal gait patterns into account, the trim line of the novel AFO model was determined to be such that the dorsiflexion angle of the patient should be between the upper and lower limits of the normal gait pattern.

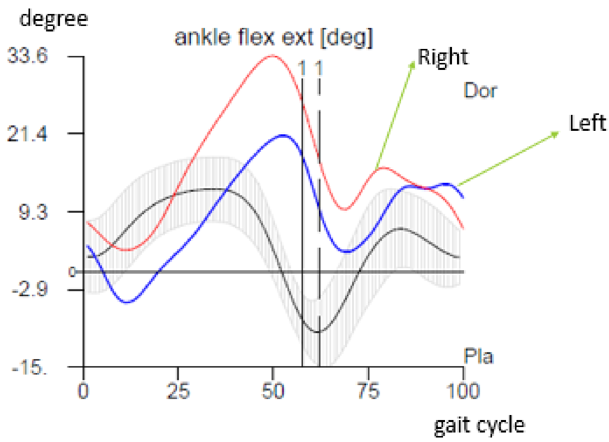


Figure 2. Dorsiflexion and Plantarflexion Angles around the Ankle Joint of the Patient

In the manufacture stage of the study, a rigid AFO model with standard trimline was fabricated from a positive mold, which belonged to a young patient with SP, using vacuum molding technique. The AFO model was converted to a 3D CAD model using optical 3D scanner and relevant software (Figure 3). To obtain a high resolution CAD model, the AFO model was constructed from 5000 surfaces. The CAD model was successfully imported to a CAD software and the measurements of the model were checked and compared with the measurements of the real AFO.

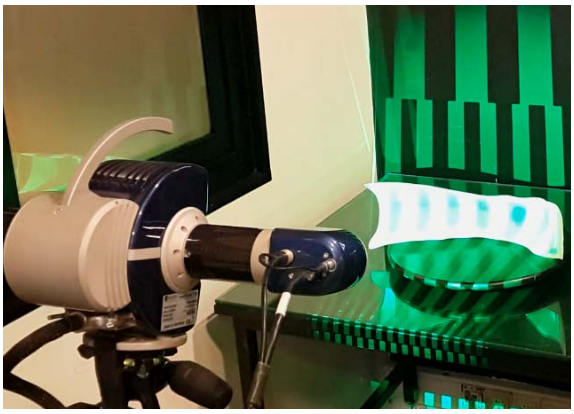


Figure 3. 3D Scanning Process

In the next step, the forces applied by the patient during walking were measured by a hand dynamometer (Figure 4). The strain-gauge based isometric hand dynamometer was located between patient's anterior leg and knee strap of a rigid AFO. The patient walked between two predefined locations during 20 s for several trials and force values were recorded. His walking speed decreased while he was approaching to the turning points.

Figure 4. Measurement of the Forces Applied by the Patient

During the walking trial for duration of 20 s, maximum force applied by the patient to the AFO straps along anteroposterior axis was found about 85 N (Figure 5). This force value was used as a loading condition in FEA of the AFO model.

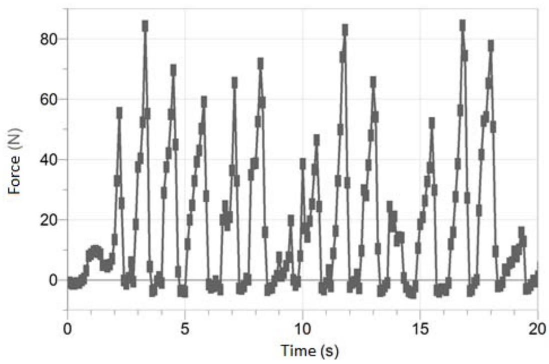


Figure 5. Force Fluctuations over the Course of Gait Trials of the Patient

A finite element model was set up considering the real loading and boundary conditions. In FEA, polypropylene copolymer material was assigned as the AFO material and defined as a linear elastic material. In the conventional AFO design, medial and lateral sections of the solid AFO are trimmed and by this by a dynamic AFO is produced. In our proposed model, an alternative trim form that has an elliptical geometry was applied to the dorsal side of the AFO to have more efficient design in terms of the homogenous stress and displacement distribution.
Dorsiflexion angle should be around 12 degree by taking the normal gait pattern into consideration. Target elastic deformation along the anteroposterior axis was calculated to provide required dorsiflexion angle by taking the AFO size into account. The displacement value along the value anteroposterior axis was calculated as 43,32 mm.

In the FEA, force of 85 N was applied from the strap-lower limb connection site. Trim size was modified according to the target displacement value along the anteroposterior axis. In the next step, the real AFO model was trimmed according to the results of FEA. The novel AFO design was compared with the conventional AFO which was produced according to the patient's feedbacks by an experienced orthosis.

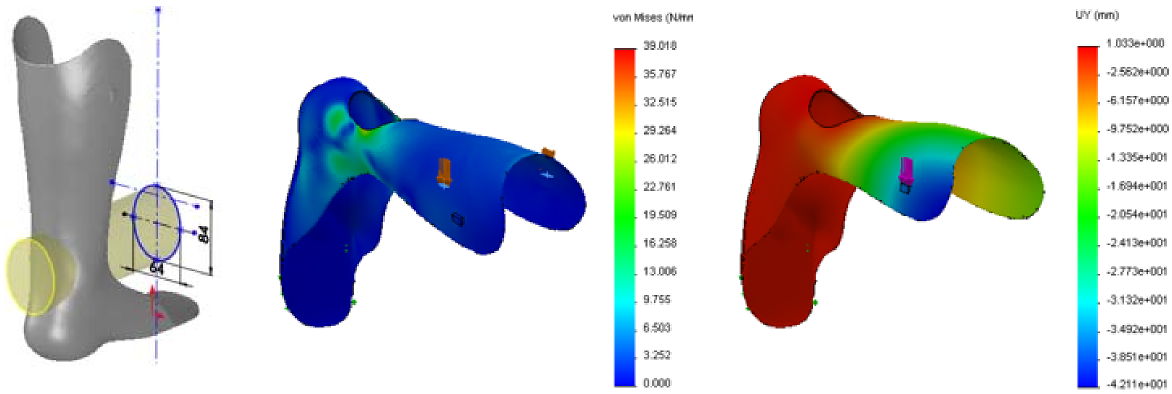
RESULTS AND FINDINGS

Two different AFO models were designed. First model was trimmed from lateral and medial sides of the AFO as implemented in the conventional trimming method (Model I). The second model was trimmed from dorsal side of the AFO (Model II). To compare the stress distribution over the surface of both designs under equivalent condition, total trimmed area was kept the same for both of the AFO models. Finite element analysis was implemented under the loading condition of 85 N. The maximum stress and displacement results were obtained for each of the AFO designs (Table 1). It can be deduced from the results that the maximum displacement value occurred in Model II was greater than that of the first model. And maximum stress value observed in the Model I.

Table 1. Maximum Stress and Displacement Values over the Classical and Novel Designed AFOs

	Model I 	Model II 
Maximum displacement along the anteroposterior axis (mm)	21,28	22,65
Maximum Von-Mises Stress (MPa)	37,97	16,75

AFO model was trimmed from its dorsal side using a vertical elliptical geometry and performed a finite element analysis to catch the 12 degree under the maximum force applied by the patient (Figure 6). The finite element model was set up and 85N force applied from the locations strap linked. Trim size was modified and FEA was repeated by reaching the target displacement value along the anteroposterior axis. The displacement value was obtained 42.11 mm that was close to the target displacement.



(a) (b) (c)

Figure 6. (a) Trimmed AFO Model, (b) Von Mises Stress, (c) Disp. along the Anteroposterior Axis

In the next step, real novel AFO model was trimmed according to the vertical elliptic trim geometry used in FEA considering its position and size (Figure 7). A loading test was performed using hand dynamometer according to force that the patient was applied from strap during walking. And the displacement values were observed. The displacement along the anteroposterior axis was measured between 4.1 and 4.2 cm. The experimental and theoretical (finite element analysis) results were found to be close to each other. Another loading test was performed for the AFO trimmed lateral and medial side that was produced by an experienced orthoptist and the results were observed. The displacement along the anteroposterior axis was measured as 2.3 cm. This value is quite away of the target displacement (4.3 cm).

(a) (b) (c)

Figure 7. (a) Classical AFO Design (Model I), (b) Novel AFO Design (Model II), (c) Experimental Measurement of the Displacement along the Anteroposterior Axis

CONCLUSION

In this study, a novel AFO design was developed and mechanical properties of this new design, i.e. stress and displacement distribution were determined using finite element method. Theoretical results of the mechanical analysis were also verified by the experimental measurements. The novel design was also compared with the conventional design and positive results were observed for the new model design. It was found that Model II with dorsal trim line would provide a proper dorsiflexion angle, unlike Model I which is of medial and lateral trim lines. It was deduced that an AFO manufactured by an orthotist in the classical approach could be out of the desired targets which was required for the rehabilitation of the patient. In future study, it is planned to determine an experimental protocol for the novel design to evaluate the performance with the participation of many other patients.

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