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Full Length Article

Evaluation of various design concepts in passive ankle-foot orthoses using finite element analysis

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ABSTRACT

Ankle-foot orthoses (AFOs) are typically prescribed to improve the gait function of ambulatory children with neurological conditions such as cerebral palsy or spina bifida. Due to the excessive and repetitive loading conditions, plastic material deformation can be observed in AFOs, especially over the lateral and medial parts of the ankle, which limits the effect of AFOs in the stabilization of the ankle joint. Trimline design and severity influence the rotational stiffness of an AFO considerably. In this study, we proposed novel trimming approaches for AFOs such that the trimlines were performed on the dorsal side rather than lateral and medial sides to reduce the magnitude of peak stresses and provide a homogenous stress distribution over AFOs. We analyzed eight dorsal trimline designs having different basic geometries by using the finite element method. To objectively evaluate the stress levels, the same boundary and loading conditions were considered for all design alternatives. We found that low peak stress values were observed in the AFO models with trimline geometries of the circle, ellipse, and slot variations. The vertical elliptic trimline on the dorsal side of the AFO was the most effective to decrease the magnitude of the peak stresses. The findings of our study are expected to contribute a complementary solution to orthotists in the fabrication of AFOs with high durability.

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1. Introduction

Ankle-foot orthoses (AFOs) are supporting devices that provide angular motion control and joint stabilization in the lower limb of ambulatory children with neurological conditions such as cerebral palsy or spina bifida [1]. An AFO covers the ankle and foot, extends above the ankle, and is fastened around the lower leg above the ankle [1–4]. AFOs are made of metal, leather, and some kinds of plastics such as polypropylene (PP), polyethylene (PE), acrylic, and nylon [4,5]. Plastic AFOs are more preferred because they are lighter, more cosmetic, and more supportive in compensation of the ankle weakness [6]. Solid AFOs with a stiff body structure strongly reduce excessive ankle plantar flexion [7]. This design has been developed to restrict the motion of the ankle and compensate for weakness [8].

Passive dynamic AFOs, unlike solid AFOs, have the feature of flexibility due to their trimlines at the medial and lateral parts of the ankle [9,10]. Bielby et al. [10] investigated how the trimline's depth (trimline severity) affects the stiffness of AFO and

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accordingly applied three different trimline approaches (conservative, moderate, and aggressive) to the medial and lateral parts of an AFO. It was reported that the stiffness of the AFO changed with the change of the depth of the trimline and hence the trimline would directly affect the stress distribution [10]. Furthermore, Sumiya et al. [11] demonstrated the effect of trimlines created with circular arcs of different sizes in the medial and lateral parts for posterior-type plastic ankle-foot orthoses on stiffness control. Although it is possible to adjust the stiffness by expanding the trimline, the increased stresses as a result of the expansion of the trimline can cause material failure to AFO, which would lead to insufficiency in maintaining the stability of AFO.

With finite element (FE) analysis, it is possible to examine the mechanical behavior of assistive devices under certain loading and boundary conditions [12]. For the assistive devices that need to be constantly adapted and examined such as orthoses, the FE method provides great convenience in terms of time and cost. Studies to determine the stress distribution occurring in AFOs started to be carried out in more detail with the development of the FE method [13,14]. Today, the FE method continues to be used frequently in the development of new AFO designs, along with new technologies such as 3D scanning [15,16] and 3D printing [16,17].

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(a) (b) (c)

Fig. 1. (a) Representative images of the scanned data obtained from different angles of the AFO (b) combination of the scanned data (c) solid model of the AFO.

Stresses in AFOs are usually concentrated in the lateral and medial parts of the ankle [15,18,19]. In our previous study, we proposed a novel circular trimline design such that we moved the trimline from the lateral and medial sides to the dorsal region [15]. By doing so, peak stress values could be reduced by half without the need for additional reinforcements and straps and a homogeneous stress distribution was obtained over AFO. Within the concept of this new trimline approach on the dorsal side, we hypothesized that exploring different geometries and dimensions at the dorsal side would enable us to reach more homogenous stress and strain distribution, leading to a novel AFO design with more functional and durable. Accordingly, in this study, we aimed to find the most appropriate dorsal trimming design in terms of homogenous stress–strain distribution over passive dynamic AFOs by using FE analysis.

2. Materials and methods

2.1. Manufacture and computer-aided model of the AFO

We first produced a solid AFO based on the anthropometry of a child with spina bifida (age: 12, mass: 60 kg, height: 161 cm) by the vacuum molding technique [4]. In this technique, vacuum pressure is used to press a sheet of plastic which is pre-heated and stretched onto a mold by an orthotist. Stress and strain values obtained from FE analysis are two key metrics for determining the trim geometries of ankle-foot orthosis (AFO) design. Obtaining a 3D model of AFO with high geometric accuracy is indispensable

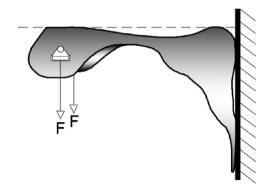


Fig. 2. Bending test set up constructed to determine the maximum force without causing large plastic deformation along the anteroposterior direction.

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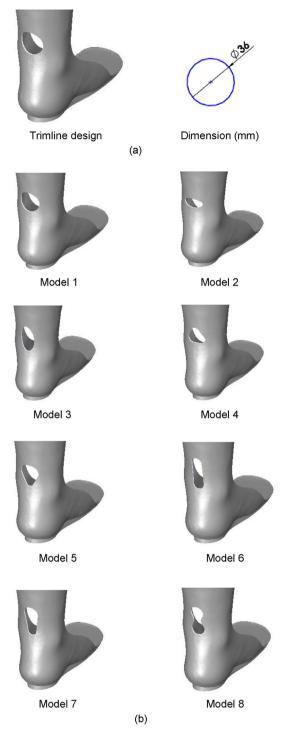


Fig. 3. (a) The AFO model with the trimline performed on the dorsal part having circle geometry (b) Concept designs of the dorsal trimlines with eight alternative geometries. Model 1: circle, Model 2: horizontal ellipse, Model 3: vertical ellipse, Model 4: rounded triangle, Model 5: rounded inverse triangle, Model 6: slot, Model 7 and Model 8: slot variations.

for the success of the FE simulation. Hence, in our study, a structured light scanner (Breuckmann GmbH, Germany) was used to obtain the 3D AFO model with high-resolution. A cloud model of the AFO was created by combining 20 scanned images (Fig. 1). This model was then transformed into a surface and solid model, and made ready for use in CAD software, SolidWorks (Concord, MA, USA). 5000 surfaces have been used to ensure surface sensitivity. For the model, the tolerance value was 0.1 mm, which was confirmed for the whole object by the deviation analysis.

Model Trimline design Dimension (mm) No

Fig. 4. Dorsal trimline designs with eight alternative geometries determined according to a reference displacement value (9.05 mm).

2.2. Experimental bending text on the AFO

In our study, to determine the peak lateral external force that the AFO can be exposed to without causing large deflections, we

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Table 1 Mechanical properties of the assigned material (polypropylene copolymer).

Tensile strength yield	27.6 MPa
Elongation at yield	16%
Elastic modulus	896 MPa
Tearing modulus	315.8 MPa
Mass density	890 kg/m3
Poisson's ratio	0.4103

conducted bending tests on the AFO within the sagittal plane. In the experiments, the AFO was supported by fixed joints from the plantar surface and, lateral and medial loads in the anteroposterior direction with varying amplitudes and small increments were successively applied (Fig. 2).

In the bending tests, the minimum total force value that caused large rotational deformations to the AFO was found 34 N (17 N from the medial superior and lateral superior to the ankle each) (Fig. 2). This force value was taken into account as the loading condition for all FE AFO models with alternative trimline designs.

2.3. Alternative dorsal trimmed AFO models

In our previous study [15], we observed that the magnitude of the peak stress values over AFO was decreased by approximately 50% by moving the trimline from the medial and lateral parts to the dorsal region of the AFO. In that study, the trimline performed on the dorsal part had a circular geometry with a diameter of 36 mm (Fig. 3(a)). By taking these findings into account, we investigated how the stress values would change with the alternative dorsal trimlines having different geometries and whether it would be possible to further reduce the peak stresses in this study.

Deep and sharp-edged trimline geometries would cause high stresses. On the other hand, the trimlines with curvilinear-edged and rounded angular geometries would enable homogeneous stress distribution. Besides, stress concentrations that occur due to aggressive trimlines can be reduced with wider trimlines [10,20]. Therefore, in this study, eight alternative fundamental geometries with round corners (namely circle, horizontal ellipse, vertical ellipse, rounded triangle, rounded inverse triangle, slot and its variations) were determined as concept models of trimlines (Fig. 3(b)). The defined geometries could be trimmed practically using conventional manufacturing methods.

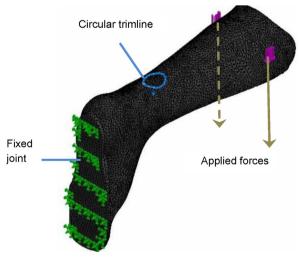


Fig. 5. Boundary and loading conditions of Model 1.

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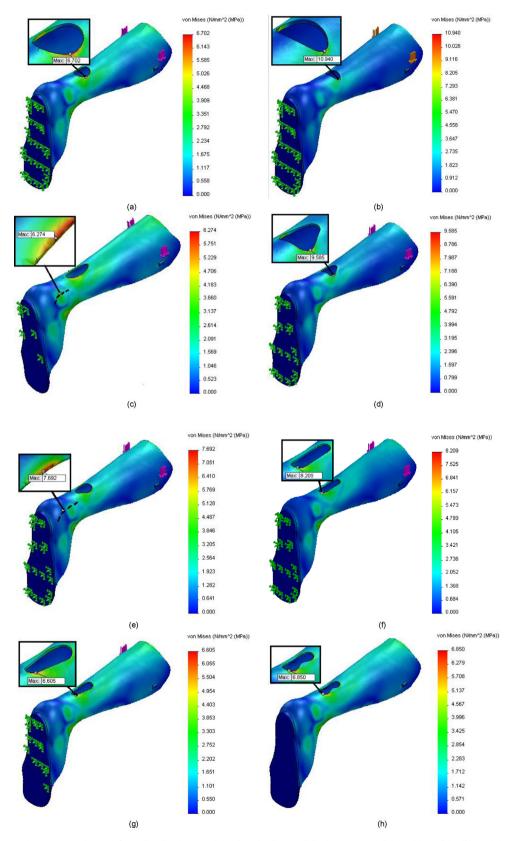


Fig. 6. Finite element von Mises stress analysis performed under the same boundary, loading, and displacement conditions. (a) Model 1 (b) Model 2 (c) Model 3 (d) Model 4 (e) Model 5 (f) Model 6 (g) Model 7 (h) Model 8.

Trimming was performed in the ankle region so that the AFOs can be compatible with the flexion/extension motions of the ankle

joint. The centers of all trimlines geometries were determined concentrically in the dorsal part of the AFO model (Fig. 3(b)).

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3. Finite element analysis of the AFO models

In the FE analysis stage of this study, we aimed to achieve the same displacement value under the same loading and boundary conditions; thus we would objectively (namely, under the same loading and boundary conditions) compare the stress and strain results obtained from eight alternative trimline designs. Dimensions of the trimline geometries shown in Fig. 3(b) were determined according to a threshold displacement value (9.05 mm) which was calculated for the model with circular trimline (Model 1, Fig. 3(b)) under the loading condition of 34 N along the anteroposterior axis. Accordingly, the dimensions of each trimline design were adapted until the same displacement result (9.05 mm) was obtained in the FE strain analysis along the same axis and between the same reference points defined on the AFO models (Fig. 4). By doing so, we were able to objectively compare the stress values while external loads and displacements were the same for all alternative designs.

FE analysis of the AFO models was carried out in the Simulation module of the SolidWorks software (SolidWorks Corporation, Concord, MA, USA), where the trimline designs were constructed. Thus, possible computational errors and time consumption that may occur in the transfer of the AFO models to another FE analysis software were prevented.

The polypropylene copolymer was assigned to the AFO model from the material library of Solidworks as the material type and was defined as linear, isotropic, and elastic (Table 1).

The parabolic tetrahedral solid element was used to better define free form surfaces in the mesh network. Mesh structure and boundary conditions of Model 1 are shown in Fig. 5. The model was fixed from its entire plantar surface. Two external forces (each 17 N) were applied from medial and lateral sides which are representing the strap forces acting on the AFO. For the FE models created for all other models, the boundary and loading conditions were considered to be the same as in Model 1.

4. Results

The von Mises stress distributions obtained from the FE analysis of eight different trimline models are given in Fig. 6. In the analysis, the maximum displacement (9.05 mm) of the models in the anteroposterior axis was kept constant.

The peak von Mises stress values obtained for all eight models are shown in Table 2. All values were below the yield strength limit (27.6 MPa). Model 1, Model 3, and Model 7 produced relatively lower stresses and among them, Model 3 generated the lowest peak stress value.

In the FE strain analysis, all elongation rates taken place over the AFO models were below the elongation at the yield point (16%). In Model 3, it was observed that the maximum strain did not occur on the trimmed edge, but on the medial edge of the

Table 2The peak von Mises stress values obtained for all eight models.

Model No	Maximum displacement along the anteroposterior axis (mm)	Maximum strain (%)	Maximum von Mises Stress (MPa)
1	9.06	0.59	6.70
2	9.06	0.73	10.94
3	9.05	0.58	6.27
4	9.05	0.77	9.58
5	9.04	0.65	7.69
6	9.05	0.67	8.20
7	9.05	0.58	6.60
8	9.03	0.60	6.85

orthosis (Please see Appendix for the representation of strain distributions in detail).

5. Discussion

To be able to provide a flexible feature to the conventional passive AFOs, trimming is performed on the lateral and medial sides. However, since the stresses are concentrated around these sides during walking, such stress levels more increase as a result of the trimming process. On the other hand, the dorsal trimming approach leads to more homogeneous stress distribution over AFOs and reduces the stress levels occurring in the lateral and medial parts [15]. In this way, the material failure that may occur during the use of AFO can be prevented or delayed.

In our study, to further develop the advantage obtained by dorsal trimming and investigate the presence of a more efficient dorsal trimline, the stress-strain analysis was performed on eight different AFO models with different geometrical features using the FE method. By keeping the loading, boundary, and displacement conditions applied to all models equal, the stress values of the models were compared. As a result of the FE analysis, relatively low-stress values were observed in the AFO models with trimline geometries of the circle (Model 1), vertical ellipse (Model 3), and two slot variations (Model 7 and 8). The vertical elliptic trimline (Model 3) on the dorsal side of the AFO was the most effective to decrease the magnitude of the peak stress value. It is understood that during the bending of the vertical ellipse geometry with the applied load, the AFO distributes the stress concentrations along the edges of the ellipse and thus high stresses could be prevented. As for the strain analysis, we found all elongation rates below the yield point.

It was reported that peak stresses over AFOs occur around the lateral and medial segments of the ankle during gait [19,20] and microcracks and then material failures may take place in these segments. Lautenschlager et al. [21] reported that using a larger radius trimline would reduce peak stresses but realized that this would also change the stiffness value of AFO and cause fatigue damage. However, using a webbing strap would provide resistance to tension during plantar flexion, thereby preventing fatigue failure. Although this system is still used today, many other studies have been carried out to reduce the stresses occurring in AFOs to prevent plastic deformation [22,23]. These studies are generally based on the reinforcement of AFO with some structural additions. In our study, we examined the way of improving the structural strength of AFOs without using additional reinforcement structures by using a novel trimming approach. Reducing the peak stress values and distributing the stresses homogeneously would increase the structural strength of AFO without extra costs. Our study may provide a complementary solution to orthotists in the fabrication more durable AFOs having homogeneously distributed stresses.

There are some limitations to our study. First, the mechanical properties of the AFO material were assumed linear, isotropic, and elastic, which would not precisely represent the mechanical behavior of the material. Second, the FE analysis was performed for the static case in which the probable fatigue behavior of the AFO material would not be observed [24]. And lastly, the defined loading and boundary conditions would not represent the actual biomechanical loading and boundary conditions that would be experienced during gait. Moreover, since the AFO dimensions are patient-specific, the eight trimline designs may result in different biomechanical effects for each patient. Therefore, it is necessary to experimentally observe the pros and cons of dorsal trimline design and evaluate the possible effects of the above-mentioned limitations in practice. More specifically, a randomized control study that analyzes the gait characteristics of spina bifida patients wearing custom-made AFOs trimmed at the dorsal side is

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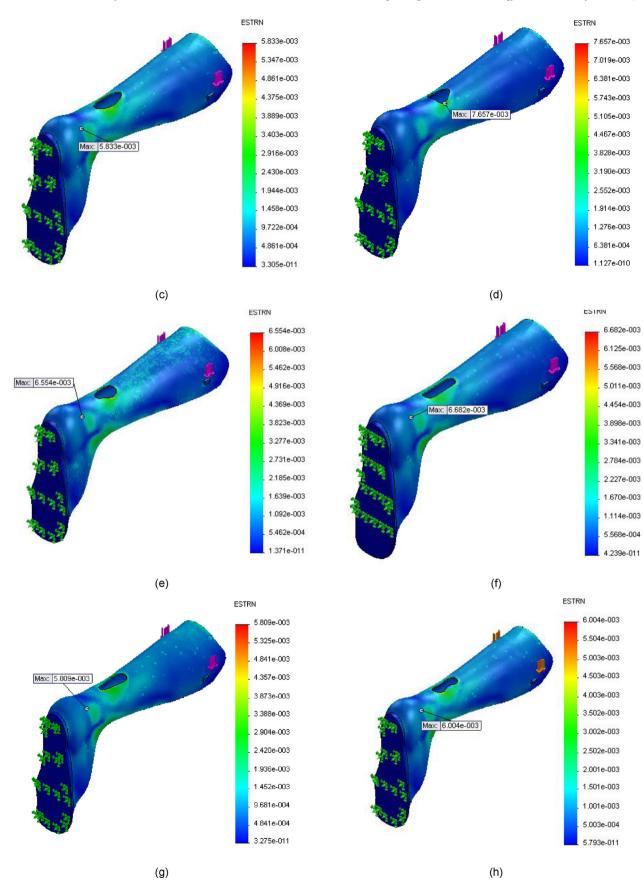


Fig. A1. Finite element strain analysis performed under same boundary, loading, and displacement conditions (a) Model 1 (b) Model 2 (c) Model 3 (d) Model 4 (e) Model 5 (f) Model 6 (g) Model 7 (h) Model 8.

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recommended. The advantage of the structural strength provided by the trim design we have developed may bring up the use of this trim concept in AFOs used in orthopedic diseases other than spina bifida. However, before conducting such an experimental study, an AFO with the novel trim designs suggested in our study should be produced and the mechanical response of the prototyped model should be tested using a fatigue-induced mechanism that simulates the loading and boundary conditions seen at the ankle joints. Such an experimental protocol would enable the measurement of the stiffness and displacement of an AFO at the ankle joint, thereby, deepening the understanding of the innovation brought by this trim design. Furthermore, the proposed trim design can be further improved by conducting a topological optimization study. In this context, a topological optimization study based on stress flow can be performed to maximize the performance of the AFOs with different amounts of material. In addition, alternative methods could be developed for the trimming procedure so that the dorsal trimming process can be applied practically and accurately.

In conclusion, the vertical elliptic trimline on the dorsal side of the AFO is the best solution to decrease the peak stress values. The findings of our study are expected to contribute a complementary solution to orthotists in the fabrication of AFOs with high structural strength. The next step will be the implementation of AFOs having different trimlines with the cooperation of the patients with spina bifida.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix

The strain distributions under the same loading, boundary, and maximum displacement conditions obtained from finite element analysis for eight different trimline models are given in the Fig. A1.

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