Application of the finite element method to the design of an ankle orthosis

D Stefańczak, J Gajewski and M Rogala
Lublin University of Technology, Faculty of Mechanical Engineering, Department of Machine Design and Mechatronics, Nadbystrzycka 36, 20-618, Lublin, Poland
daria.sagan@pollub.edu.pl, j.gajewski@pollub.pl, m.rogala@pollub.pl

Abstract. AFO (Ankle-Foot Orthosis), which covers the ankle and foot, protects and supports the ankle joint as well as the structures around it. It contributes to the maintenance of the correct gait cycle. Owing to orthoses, the functional capacity of the body part is significantly improved, and so is the quality of life for the user. Personalized orthoses, which are adapted to the anatomy of the user, are more and more often produced by the additive methods. The use of 3D printing for the manufacturing medical devices is becoming increasingly common due to the low cost of the whole process, short production time and the possibility of the product personalization. One of the stages in manufacturing AFOs with the additive method is to create a three-dimensional model of the orthosis in CAD software. Finite element analysis was performed to assess the mechanical properties of the orthosis. The influence of geometry and the materials used were investigated with FEM analysis software. As a result of structural analysis during the design stage, the assessment of the medical device in terms of its durability and mechanical resistance without putting the user at risk is possible. On the basis of the obtained results, the structure strength was compared.

1. Introduction
Ankle-Foot Orthoses (AFOs) have been widely used for many years. Nowadays, orthoses are more and more often used as a cast replacement. Control of the ankle when standing and walking is improved by creating the orthoses that combine the different functions of [1,2]. AFOs have been demonstrated that to improve gait speed, energy cost, weight bearing on the affected leg, stance and double stance duration in gait, as well as stability during balance [3]. The production of AFOs is a complex process. There are many factors to consider during planning and engineering designing. The time-consuming nature of the entire process depends on the type of orthosis as well as the manufacturing method.

Over the years, the methods of manufacturing orthoses have been developed significantly. In the past, the AFOs were usually made of pure leather and wood. Currently, owing to the development of manufacturing techniques and the development of material engineering, products such as orthoses are of increasingly better quality, have better parameters and are and user-oriented [4]. After analyzing the literature, it was found that there are two ways to manufacture AFOs, namely:

- manufacturing technology using impressions or moulage, and then thermoplastic polymer materials (traditional method) [4,6,7],
- additive-manufacturing, i.e., 3D printing [5-7].
The additive method allows designing the orthosis in advance and performing the analysis of mechanical strength properties before the product is made. The design of the orthosis is made by modeling based on 3D scans or the data from medical imaging. The 2D images from CT or MRI scans are processed and edited in order to generate highly accurate 3D models. Proper selection of an orthosis is a key condition for its effectiveness. The effectiveness of the orthosis is influenced, among others, the effect of geometry, material and production process [8-10].

The aim of the article was to design a model of an ankle orthosis. In carrying out this task, the technical and functional requirements of the orthosis design process should be taken into account. Therefore, the influence of geometry and building material was tested on the basis of the strength analysis performed using the Finite Element Method (FEM).

2. Foot joints
The function of the joints in the human body is to maintain the bones while allowing for movement. Joints, as an element of the motor system, have various types of movement. The structure of some joints allows for sustaining heavy loads and performing scopic movements. Others, however, only provide minimal motion [11].

The three main joints of the foot, due to its movement, are the talocruial joint (ankle joint), the talonavicular joint and the subtalar joint (Figure 1).

![Figure 1. Human foot anatomy [12].](image)

The ankle joint allows the foot to hinge (upwards and downwards movements). This is the joint that connects the talus bone to the shin bone. The subtalar joint provides sideways movements. The talonavicular joint allows twisting movements of the foot. By combining the functions of these joints, the foot receives three degrees of freedom of movement. This functionality is analogous to that of the Cotyloid joint. The other joints combine to form a chain, which is characterized by a low possibility of movement. The range of motion of the ankle joint is complex and depends on many factors [11].

The correct distribution of pressure on the foot is divided into the points of support. They include the first metatarsal bone, which is loaded with 30% of the total weight. Another 20% of the weight is on the 5th metatarsal bone. The rest, i.e., 50% of the total weight, takes the third point of support, the heel bone. If the percentage distribution of pressure on the foot is not correct, it results in a disturbance of the foot biomechanics and, as a consequence, improper load transfer through the ankle joint [11].
3. Orthoses
Orthoses are orthopedic devices that stabilize, immobilize, support or provide physiological improvement of the mobility of the human musculoskeletal and neuromuscular systems. This product is classified as medical. This product is worn directly on the body. An orthosis put on by a patient with a given dysfunction exerts a certain force on him. Force parameters, such as the value or the point of application, influence the performance of the orthosis.

The functionality of each orthosis should be at least one of the following points:

- protecting from external factors,
- supporting weakened muscles,
- restoring lost mobility,
- reducing the risk of deformity,
- preventing contractures,
- stabilization or correcting the position of a specific part of a limb or other body part,
- relieving or distributing forces,
- reducing pain, fighting inflammation,
- supporting or limiting specific joint movement.

Orthoses increase users’ ability to function and thus improve their quality-of-life. The use of this type of solutions in some cases helps to prevent or fight pain [13].

There are many types of orthoses and thus possibilities of their division. The classification can be made, among other things, on the basis of design and functionality. The first classification distinguishes rigid, semi-rigid (semi-flexible) and soft (flexible) orthoses. Compressive, corrective, compensatory and stabilizing orthoses are classified according to their function. Another division is made on the basis of the joint or body part it covers. This division also determines the nomenclature of orthoses [13,14].

3.1. Ankle-foot orthosis
AFO is one of the most commonly used orthoses. It covers the foot and ankle area. It reaches up to but does not cover the knee. The orthosis performs the function of the ankle joint. It supports the user's ankle and foot. It can influence the dorsiflexion of the foot and thus improve the gait. It provides protection and support for the ankle joint and structures near it. AFOs often affect the stability of the knee and are also used to counteract contractures of the calf muscles. AFO functions are accomplished by supporting or assisting the human neuromusculoskeletal system [15]. There are orthoses on the market that can be anatomically fitted with Velcro or adjustable straps, as well as those that are custom made and personalized to the needs of the individual user. AFOs are available in many variations to meet different needs [14,16].

4. Manufacturing of AFO orthoses with the additive method
An increasingly popular technique for producing orthoses is the additive (incremental) method. In this method, when fabricating AFO orthoses, the first step is to scan the lower limb. Owing to the use of a 3D scanner, a 3D model is created in the CAD [15] software. An alternative to the 3D scanner may be to make a model using photogrammetry. For this purpose, a series of photos of a stationary object (patient's legs) is taken. The photos must be of good quality and one point must appear in the photos at least three times. In practice, there are many more photos taken [17]. The resulting model is exactly matched to the anatomical shape of the patient's leg, which is undoubtedly an advantage of the incremental production of orthoses. At this stage, other advantages of this method become noticeable, such as: reduction of waste and thus the costs associated with the creation of plaster casts (negative and positive). Owing to the CAD model of the orthosis, it is possible to examine the mechanical properties already at the design stage and to select the appropriate material by means of simulation tests. When the design is approved, 3D printing takes place. A three-dimensional object is manufactured by applying successive layers of building material and its selective bonding. There are
different forms of additive manufacturing, the most popular of which are SLS (Selective Laser Sintering), SLA (stereolithography) and FDM (Fused Deposition Modeling). For the production of AFOs, the FDM method is most often used, in which the building material is a thermoplastic in the form of a filament – a line, which becomes semi-liquid under the influence of the temperature of the printer head. The extruded material builds the designed model layer by layer. The FDM method uses, among others, PLA, ABS, ASA, FLEX, HIPS, NYLON (PA6, PA12), and PET-G. The list of materials with their properties is presented in the table below [4,7,18].

| Material | Properties |
|----------|------------|
| PLA      | - odorless  
- heats up quickly  
- produced on the basis of organic compounds (sugar cane or corn starch)  
- biodegradable  
- does not tend to deform  
- high stiffness  
- does not require a hot platform during printing  
- biocompatible and non-toxic  
- low material shrinkage |
| ABS      | - optimal cost  
- impact resistance  
- abrasion resistance  
- low electrical conductivity  
- large material shrinkage  
- during printing, a working chamber is required (maintaining a constant temperature) and a heated table (preventing material shrinkage) |
| ASA      | - mechanical properties similar to ABS  
- resistant to weather conditions |
| HIPS     | - suitable for contact with food  
- little flexibility  
- during printing, a working chamber (maintaining a constant temperature) and a heated bed are required |
| PET-G    | - impact resistance  
- flexible  
- resistant to chemicals  
- moisture resistant  
- resistant to UV radiation |

The material of the orthosis has a great influence on its mechanical properties. That is why it is so important to choose the right type of material.

5. Methodology
This research aims to investigate and compare the mechanical properties of AFO models by conducting a Finite-Element analysis in the ABAQUS software. Four models differing in geometry and building material were analyzed.
The CAD models of the AFO were designed in SolidWorks software. The dimensions and geometry of the orthosis have been anatomically custom-fit to the individual user, i.e. a woman with the weight of 50 kg and height of 160 cm. The orthosis is 4 mm thick. Two models of the orthosis have been designed with different ventilation openings. The first model is full (without holes). The second model has vents in the shape of circles with a radius of \( r = 4 \) mm. The AFO models are illustrated in Figures 2 and 3.

![Figure 2. Model of the orthosis without holes.](image1)

![Figure 3. Model of the orthosis with circle-shaped holes](image2)

The strength analysis was carried using the Finite Element Method (FEM). Finite Element Method is a computational method, owing to which it is possible to solve complex, time-consuming problems of mathematical analysis and those that do not have analytical solutions. This is possible by performing discretization and then determining differential or algebraic equations [19-25]. The strength analysis was performed in the Abaqus program. The analysis was performed for two materials: PLA (polylactide) and ABS (acrylonitrile-butadiene-styrene). After importing the models, material properties were assigned. The main mechanical properties used for these materials are shown in Table 2.

**Table 2. Mechanical properties of materials used in the FDM method for the production of orthoses [26].**

| Material | Young’s Modulus [GPa] | Poisson’s ratio [-] | Tensile strength [MPa] |
|----------|-----------------------|---------------------|------------------------|
| PLA      | 3500                  | 0.36                | 50                     |
| ABS      | 2300                  | 0.35                | 110                    |
The model was divided into the regions where the forces were applied and the fixed support as well (Figure 4). The applied force values are 240 N in the negative Z direction, 500 N in the negative Y direction. The force in the Z direction is determined by the user’s weight. The force in the Y direction occurring while walking was taken from the literature data [27]. The structure was fixed in place of the orthosis base. The analyzed model has a complex geometry; therefore, the Tet 5 mesh was imposed on the model (Figure 5).

**Figure 4.** Distribution of applied loads and fixed support.  
**Figure 5.** Discretized orthosis model.

### 6. Results

Strength analyses allowed obtaining maps of distribution of stresses and displacements of the orthosis presented below (Figure 6-17). The diagrams show the maximum values of displacements and stresses (Figure 18).

**Figure 6.** Von Mises stress distribution for the ABS orthosis without holes  
**Figure 7.** Von Mises stress distribution for the ABS orthosis without holes (back).
Figure 8. Von Mises stress distribution for the ABS orthosis with ventilation holes.

Figure 9. Von Mises stress distribution for the ABS orthosis with ventilation holes (back).

Figure 10. Von Mises stress distribution for the PLA orthosis without holes.

Figure 11. Von Mises stress distribution for the PLA orthosis with holes (back).

Figure 12. Von Mises stress distribution for the PLA orthosis with holes.

Figure 13. Von Mises stress distribution for the PLA orthosis with holes (back).
Figure 14. Distribution of dislocations for the ABS orthosis without holes.

Figure 15. Von Mises stress distribution for the ABS orthosis with ventilation holes (back).

Figure 16. Dislocations distribution for the PLA orthosis without holes.

Figure 17. Dislocations distribution for the PLA orthosis with ventilation holes.

Figure 18. Values of a) stresses b) dislocations in the analyzed orthosis models.

Table 3. The weight of each model.

|         | holes  | no holes |
|---------|--------|---------|
| ABS     | 320.6 g| 331.9 g |
| PLA     | 396.9 g| 410.9 g |
The analysis of the obtained results showed that the greatest reduced stresses for a given load are located in the area of the ankle joint. The stresses occurring are at the level of $\sigma = 45$-50 MPa. The displacements are from 8.47 mm to 14.73 mm. Higher reduced stresses result in greater displacements. The most rigid model was the orthosis without ventilation holes made of PLA.

Slightly higher maximum stresses were recorded for the orthoses made of ABS. While comparing the influence of the vents, it was found that both for ABS and PLA, higher reduced stresses occur for the variant with vents. However, this is a slight difference. The tensile strength limit for ABS is 110 MPa, while for PLA it is 50 MPa [16]. The ABS version of the orthosis with holes has a reduced stress of 50.64 MPa. It follows that the obtained result is almost two times lower than the critical value for ABS. On the other hand, the version of the PLA orthosis with holes is characterized by reduced stresses of 48.12 MPa. This is a result almost equal to the critical value of the material used. Therefore, the use of ABS material will be a better choice for the manufacturing of the modeled orthosis due to reduced stresses.

The relationship between stresses and displacements and the weight of each model was analyzed. It was noticed that the models with lower weight (made of ABS) exhibit higher stresses and, at the same time, greater displacements.

7. Conclusions
The designed CAD model of the orthosis and the performed FEM analysis allow for the optimization of the structure in terms of geometry, material and functionality of the orthosis. The strength analyses carried out showed that the orthosis will not lose its structural integrity in any of the analyzed cases. The obtained results showed that the most sensitive areas are in the ankle area. Taking into account the ultimate strength values, ABS turned out to be a better material, despite slightly higher stress values compared to PLA. One of the goals of an AFO is to provide a better lifestyle for patients. Adding ventilation holes only slightly increases the stresses, so for increased comfort of use it is preferable to choose this variant of the orthosis.

Owing to the possibility of performing FEM analysis already at the design stage, it is possible to adjust the optimal conditions. The selection of the appropriate material and the creation of the optimal geometry is carried out on the basis of simulation tests. The use of FEM enables the determination of the degree of stress, which allows for the assessment of the risk of failure. This reduces the costs and time spent on making unsuitable prototypes of orthoses. The results of the FEM analysis can therefore be a valuable help in the process of designing AFOs.

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