EUROPEAN MECHANICAL SCIENCE

e-ISSN: 2587-1110

RESEARCH ARTICLE

Numerical analysis of a novel silicone sole-based passive orthosis for home gait rehabilitation training

Hamid Asadi Dereshgi[1*], Dilan Demir[1]

[1]Department of Biomedical Engineering, Istanbul Arel University, 34537 Istanbul, Turkey

Orcid: H. Asadi Dereshgi (0000-0002-8500-6625), D. Demir (0000-0001-7413-1597)

Abstract: Drop foot syndrome is a neuromuscular disease characterized by weakness of the muscles in the front of the lower leg. This disease can cause partial or complete loss of control over the foot and affects the ability to lift the foot from the ankle. Orthoses are used to help improve the gait of patients with limited control over the foot muscles. The most important advantages of passive orthoses are that they are light and inexpensive. Thermoplastic materials are generally preferred in lower extremity orthoses due to their high strength and elasticity. The novelty of this study was to perform a silicone sole between the housing sole and the shoe sole in order to minimize the mechanical changes caused by the weight force. Thus, the mechanical behavior of the proposed passive Ankle Foot Orthosis (AFO) at different weight forces was investigated. It was observed that displacement, stress, and strain values increased with the increase of weight force and vibration frequency. Consequently, Polypropylene-based orthosis was accepted as the ideal design material as it exhibits higher elastic behavior than Polyetherimide and Polylactic Acid-based orthoses. Consequently, this study enables researchers a useful reference on passive orthosis parameters such as modeling, material behavior, shape control, geometry, and size optimization for key biomechanical engineering applications.

Keywords: Passive orthosis, Rehabilitation system, Finite Element Analysis, Polypropylene, Polyetherimide, Polylactic Acid

1. Introduction

Drop foot syndrome is the loss of dorsiflexion movement of the foot from the ankle. It often occurs in cases of stroke and disorders of the muscular system. This condition, which reduces the quality of life of the patients, is treated with electrical stimulation, gait training, foot support, and splints. Foot orthoses, one of these treatment methods, provide improvement by keeping the feet of the patients in plantar flexion [1]. Foot orthoses are divided into three parts as passive, semi-active, and active actuators [2]. Passive orthoses have been preferred in recent years due to the development of technology and ease of fabrication. Literature survey shows that there are many studies about the foot orthosis. For example, Jamshidi et al. (2010) designed a passive foot orthosis to reduce the stress on the sole of the foot. The sole of the presented orthosis was formed in three layers as the inner, middle, and outer parts, additionally, elastic and hyper-elastic material was defined and the kinematics changes during walking were examined. As a result of the study, it was observed that the stress in the midfoot decreased [3]. Deberg et al. (2014) proposed a Shape Memory Alloy (SMA)-based passive foot orthosis. The passive AFO was equipped with a hinged brace and SMA wires. It was aimed to store mechanical energy thanks to these super elastic wires. It was observed that the SMA AFO presented in this study has the ability to meet the torque angle requirements much better than the traditional passive AFO [4]. Kubasad et al. (2020) designed a passive orthosis in order to prevent foot drop disease. In this study, 3 mm and 4 mm thick polypropylene and high-density polyethylene material were used for static analysis. In addition, dynamic calculations were carried out to determine the situations in the gait analysis. In order to analyze the force of a 55 kg human weight, 275 N was used in the analysis. As a result, the tensile strength was obtained by Finite Element Analysis (FEA) to be 30 MPa [5]. Gautam et al. (2021) designed an AFO with 4 mm thickness and polypropylene material. Stress analysis of the proposed model was performed with FEA. A force of 294 N was applied to the simulated orthosis for a 60 kg patient and the maximum stress was obtained as 31.26 MPa [6].

In this study, passive AFO based on Polypropylene, Polyetherimide, and Polylactic Acid was designed and analyzed by the Finite Element Method (FEM). The purpose of the study was to investigate the mechanical behavior of

* Corresponding author.
Email: hamidasadi@arel.edu.tr

European Mechanical Science (2022), 6(4): 251-256
https://doi.org/10.26701/ems.1123082
Received: May 29, 2022 — Accepted: September 19, 2022

the lower sole of the proposed orthosis at different weight forces. The paper is organized as follows. The working principle of the new AFO and the finite element modeling procedure is presented in Section 2. In Section 3, the results of FEM simulations are presented and discussed. Finally, the concluding remarks are reviewed in Section 4.

2. Material and Method

In this study, passive AFO based on Polypropylene, Polyetherimide, and Polylactic Acid was investigated (see Figure 1). The proposed AFO consisted of a housing and a silicone sole, which were 2 mm and 3 mm thick, respectively. The material properties of AFO were given in Table 1. The mechanical behavior of the proposed orthosis at applied dynamic weight forces was investigated for three different materials. It should be noted that forces ranging from 50 kg to 100 kg were applied to the upper sole of the AFO in 10 kg increments. In addition, dynamic forces were applied at 1 Hz to 4 Hz intervals in 1 Hz increments. Analyzes were performed using the FEM with a sensitivity of 0.001. Moreover, mesh convergence analysis was performed to determine the accuracy of the analyzes (see Figure 2). Therefore, Normal, Fine, and Finer meshes (see Figure 3) were defined for the AFO model. The physical properties of the meshes were given in Table 2. As a result of the mesh convergence analysis, 6.48% and 0.90% error rates were obtained between the first meshing step (Normal), the second meshing step (Fine), and the third meshing step (Finer), respectively. Therefore, Fine mesh was accepted as the ideal mesh. The results of the mechanical behavior of the orthoses were given in Section 3.

3. Results

In this study, a novel passive orthosis was proposed for the treatment of foot drop patients. The properties of Polypropylene, Polylactic Acid, and Polyetherimide materials were numerically defined separately for the presented orthosis. The mechanical behavior of three different materials was investigated against the weight force. The me-

Table 1. Mechanical properties of materials used in AFO's housing.

Materials	Density (kg/m³)	Young's modulus (GPa)	Poisson's Ratio
Polypropylene (PP)	900	2.4	0.43
Polylactic Acid (PLA)	1250	3.7	0.35
Polyetherimide	1340	2.5	0.36
Silicone Rubber	3800	1.90	0.50

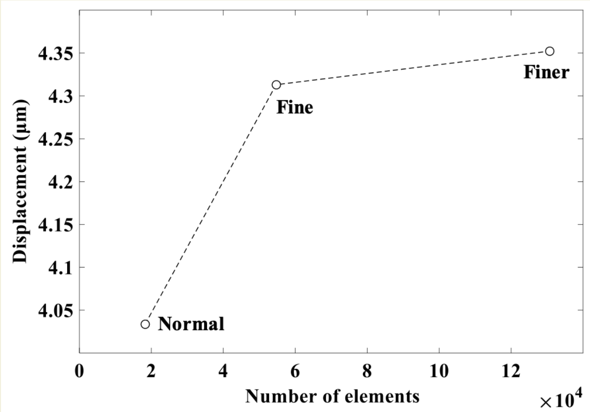

Figure 2. Mesh convergence analysis for the model displacement.

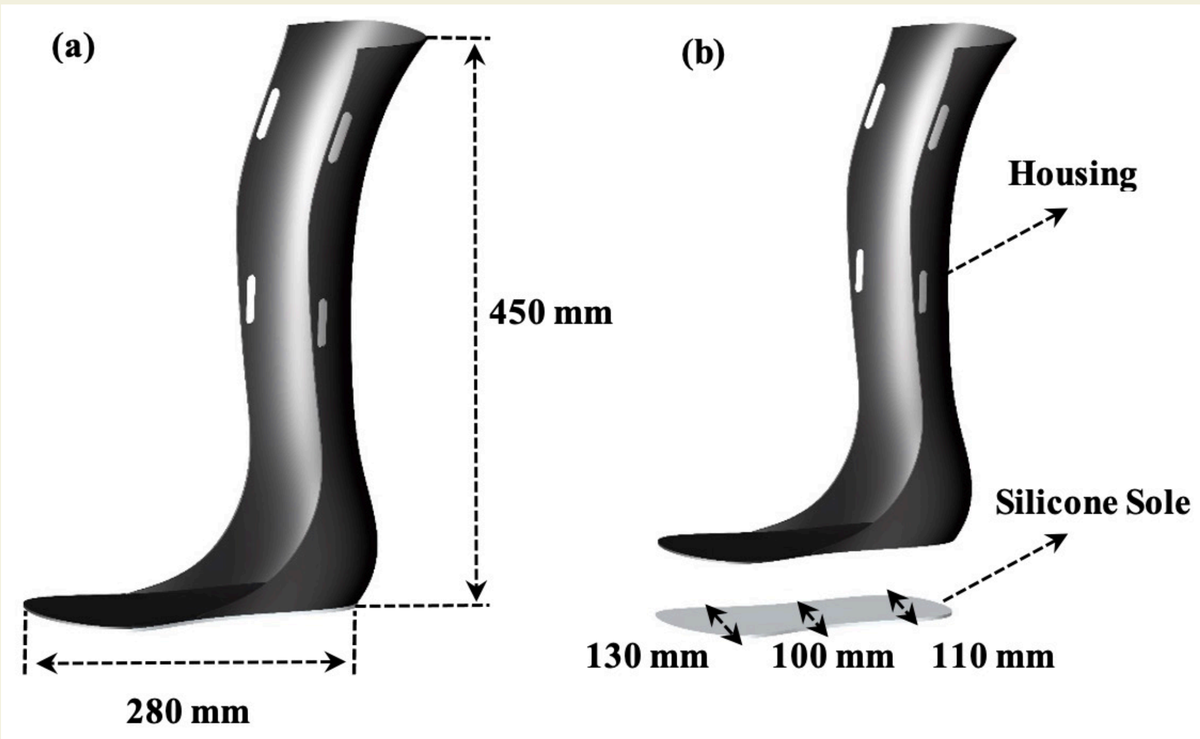

Figure 1. Proposed AFO view, **(a)** integrated, **(b)** exploded.

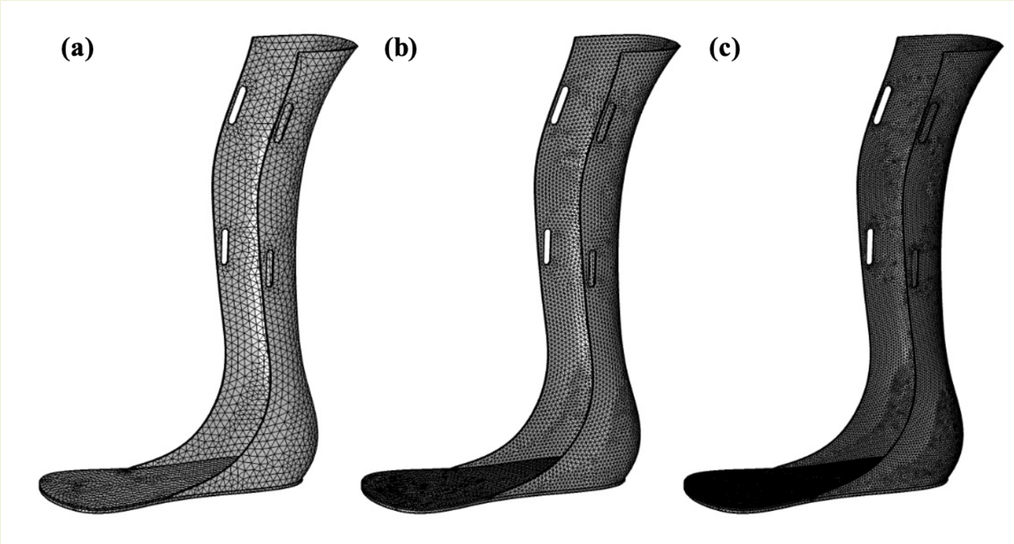

Figure 3. Mesh types of the finite element model, a) Normal, b) Fine, and c) Finer

Table 2. Specifications of Finite Element Method (FEM).

Domain element statistics	Number of elements	Minimum element quality	Average element quality	Element volume ratio	Mesh volume (µm^3)
Normal	18237	0.04002	0.3488	0.002276	3.316E14
Fine	54673	0.1695	0.5423	0.002881	3.316E14
Finer	130710	0.1635	0.6704	0.002966	3.315E14

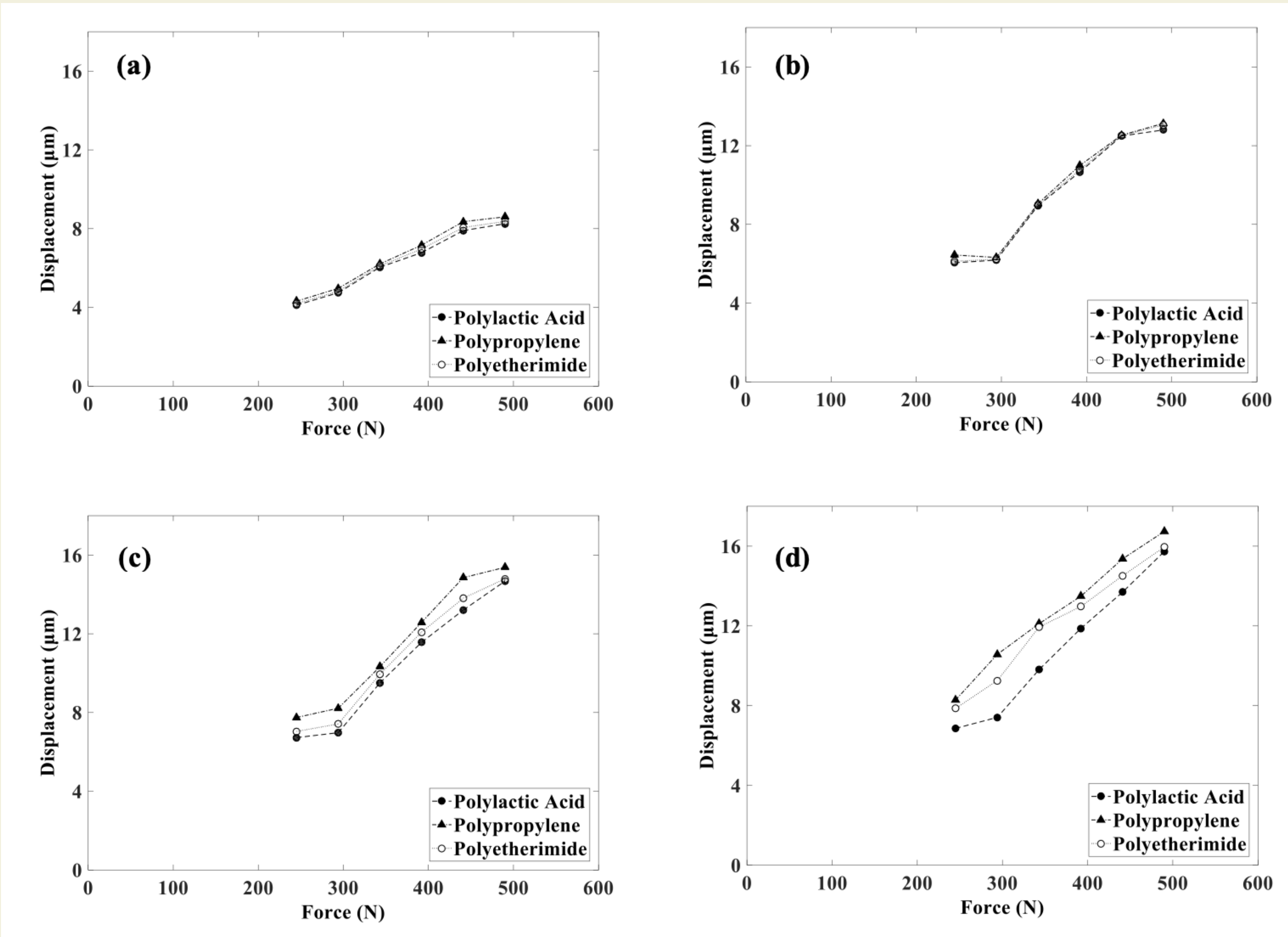

Figure 4. The maximum displacement results at (a) 1 Hz, (b) 2 Hz, (c) 3 Hz, and (d) 4 Hz.

chanical behavior of the proposed orthosis was analyzed between 50 kg and 100 kg by 10 kg steps. It is worth noting that dynamic analysis was performed for the optimized design to examine the behavior of the AFO in the walking condition. Dynamic forces were applied to the upper sole of the orthosis in 1 Hz steps between 1 Hz and 4 Hz. Consequently, displacement (See Figure 4) and stress-strain (See Figure 5) values of Polypropylene were higher than Polyetherimide and Polylactic Acid materials since it has a more flexible structure. Maximum displacements of Polypropylene, Polyetherimide, and Polylactic Acid based orthoses were obtained as 16.74 µm, 15.96 µm, and 15.73 µm at 490 N, and 4 Hz, respectively. In addition, the minimum displacement was obtained as 4.31 µm, 4.2 µm, and 4.10 µm for Polypropylene, Polyetherimide, and Polylactic Acid materials at 245 N and 1 Hz, respectively. The vibrational frequencies of the dynamic forces were less than the resonance frequency of the proposed materials. Therefore, a linear correlation was observed between mechanical behavior and vibration frequencies. Accordingly, the same registrations were obtained for the stress-strain parameters. The maximum stress achieved on the upper sole of the Polypropylene, Polyetherimide, and Polylactic Acid based orthosis was 1800373.729 N/m^2, 1798258.732 N/m^2, and 1767058.128 N/m^2, respectively. In addition, the minimum stress values were obtained as 453257.1671 N/m^2, 422823.2138 N/m^2, and 402392.4274 N/m^2, respectively.

It is clear that the displacement, stress, and strain results achieved in this study are less than the orthoses with the same mechanical and material properties proposed in the open literature [6,7]. As mentioned in Section 2, the proposed AFO has two soles and the bottom sole was silicone. Thus, the mechanical behavior of AFO was low due to the high elastic property of the silicone sole. In addition, the silicone sole absorbed the weight forces due to its compression feature, hence, there were 95% to 99% linear correlation was obtained between force and displacement, which was 92% to 100% between force and stress-strain. In this study, it was obtained that the stress and strain relationship was linear in different materials, forces, and frequencies. Thus, it is evident that the materials foreseen for the AFO design are suitable for the treatment of patients weighing up to 100 kg, as they remain in the elastic region as a result of deformation.

4. Discussion

Many studies have been carried out on passive AFOs. However, none of them contain detailed information about design parameters, mechanical and material effects on physical therapy and rehabilitation. In addition, new designs have been proposed by different researchers, but

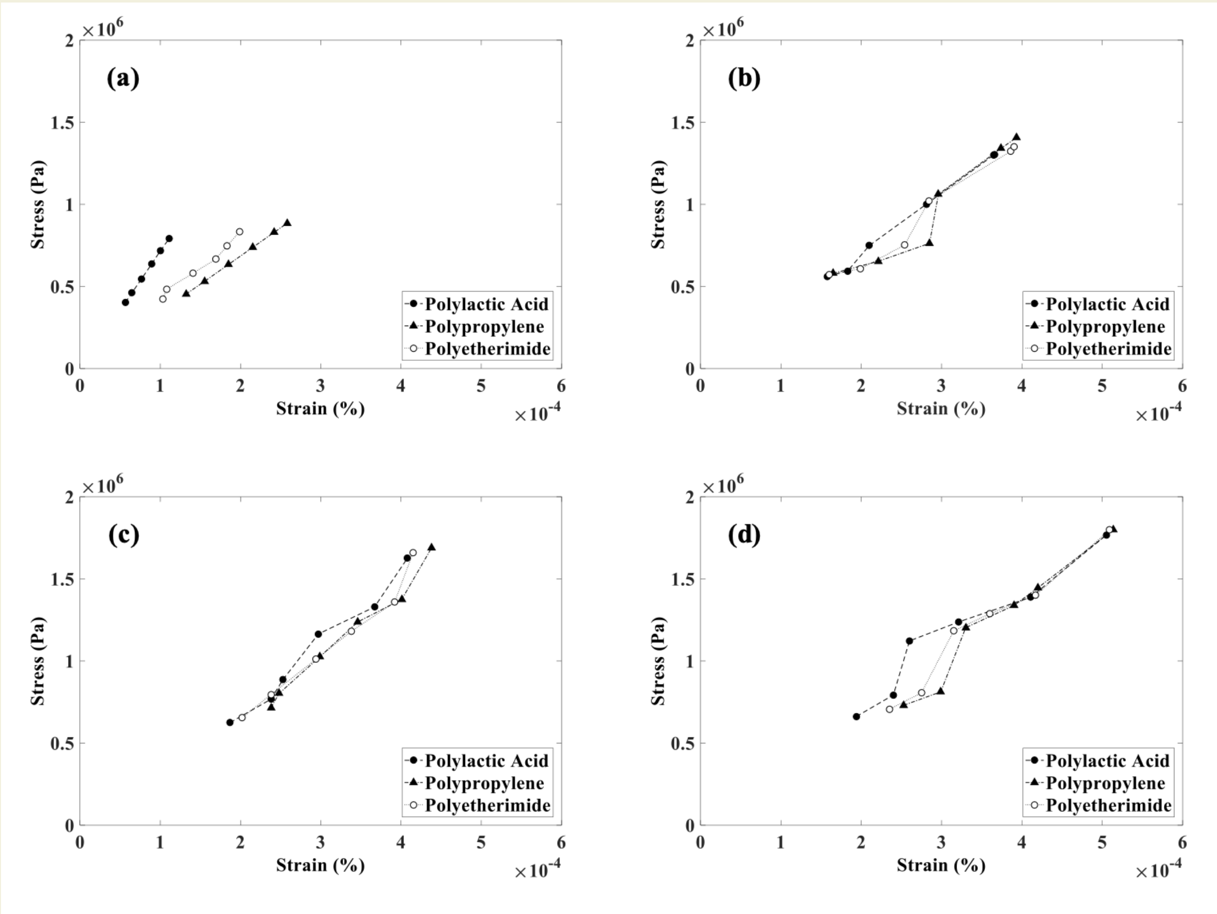

Figure 5. The maximum stress-strain results at (a) 1 Hz, (b) 2 Hz, (c) 3 Hz, and (d) 4 Hz.

there are no studies supporting each other. For example, Cha et al. (2017) fabricated a polyurethane-based AFO using rapid prototyping technique [8]. Biocompatibility, durability and minimum elastic deformation are important parameters to be considered in the housing design of passive AFO [9,10]. The elastic modulus of Polyurethane (~0.24 GPa) is very low compared to Polypropylene (~8.25 GPa), Polyetherimide (~56 GPa), and Polylactic Acid (~13.8 GPa). Therefore, the AFO recommended by Cha et al. (2017) has been durable up to 300,000 repetitions. The main purpose of passive AFOs is to stabilize the patient's foot in the desired position. The low elastic modulus indicates that it is not suitable for this purpose. Additionally, Polyurethane contains toxicity compared to Polypropylene, Polyetherimide, and Polylactic Acid materials. However, non-isocyanate synthesis methods are preferred for biomedical applications, hence its tensile stress is reduced [11-13]. Accordingly, it is clear that Polyurethane is not very compatible in terms of durability and biocompatibility compared to Polypropylene, Polyetherimide, and Polylactic Acid materials.

Kubasad et al. (2020) numerically analyzed the proposed polypropylene-based AFO [5]. Housing thickness of the presented model was 3 mm and 4 mm. The mechanical behavior of the AFO was obtained in the walking scenario. As a result of dynamic analysis, 14.69 mm deformation was obtained in the lower sole of the AFO. A high deformation value may cause the AFO to break or crack. Therefore, the touch points of the foot and the AFO should be predetermined by biomechanical analysis. By contrast, the deformation of our proposed orthosis was 4.63 μm at the same conditions. This is due to the spring-like behavior of the silicone sole.

Gautam et al. (2021) investigated a polypropylene-based passive AFO [6]. The purpose of the study was to keep the patient's foot in a stable position. Therefore, the mechanical behavior of the AFO was studied under the influence of static forces. However, dorsiflexion and plantarflexion movements apply dynamic forces to the AFO. The frequency of dynamic forces directly affects the durability of the AFO housing. Therefore, we applied different dynamic forces to analyze the durability of our proposed AFO under walking conditions. It is worth mentioning that there is an inverse correlation between the housing thickness of the AFO and the stress-strain curve. Additionally, Gautam et al. (2021) also examined the relationship between the housing thickness and durability of AFO. In this study, the housing of AFO was simulated from a 4 mm thick polypropylene material. Consequently, a maximum stress of 31.26 MPa was obtained with the application of 294 N. However, a maximum stress of 0.53 MPa was obtained at 294 N in our proposed 2 mm thick polypropylene-based AFO. Although the housing thickness of the AFO presented by Gautam et al. (2021) was two times that of our proposed model, there was a 98.30% decrease in stress at the same force conditions. The reason for the reduction of stress was the housing, silicone sole and shoe sole designed in sandwich appearance. Thus, this feature is the outstanding innovative aspect of our study.

5. Conclusion

Foot drop is a complication characterized by difficulty in raising the front of the foot. It can be temporary or permanent, depending on the degree of muscle weakness or paralysis. This disorder can occur in one or both feet. Toe walking is common in children just beginning to learn to walk, but they usually return to normal walking after the age of two. Some people may continue walking with this model due to habituation or because their cuff muscles and tendons shorten over time. This disorder is not usually a separate disease in itself and is a symptom of a significant problem. Foot drop is usually diagnosed by physical examination. Foot drop is characterized by the inability or impairment of the ability to lift the toes or flex the ankle inward (dorsiflexion). Passive foot orthoses help patients stabilize their feet and ankles in a normal position. Moreover, the therapeutic use of passive AFOs has proven beneficial in the open literature [14]. Therefore, many studies have been carried out on passive AFO. However, none of them contain detailed information about design parameters and material effects on mechanical behavior. In this study, the effects of material behavior on AFO performance were investigated using the FEM. In addition, a silicone sheet was preferred to minimize the effect of the weight force applied to the orthosis. Physically, silicone showed spring property against applied forces. Thus, it has increased the resistance of the orthosis against forces and its useful life. In addition, silicone is a good biocompatible material and was appropriate for biomedical applications [15]. After the proposed AFO is studied experimentally, it will have significant contributions to rehabilitation and clinical applications.

6. Acknowledgement

The authors would like to acknowledge the technical support provided by Artificial Intelligence Studies, Application and Research Center (ArelMED-I) of Istanbul Arel University related to the numerical analysis.

7. References

[1] Grissom, S.P., Blanton, S. (2001). Treatment of upper motoneuron plantarflexion contractures by using an adjustable ankle-foot orthosis. Archives of physical medicine and rehabilitation, 82(2): 270-273, DOI:10.1053/apmr.2001.19018.

[2] Chen, B., Zi, B., Zeng, Y., Qin, L., Liao, W.H. (2018). Ankle-foot orthoses for rehabilitation and reducing metabolic cost of walking: Possibilities and challenges. Mechatronics, 53: 241-250, DOI:10.1016/j.mechatronics.2018.06.014.

[3] Jamshidi, N., Hanife, H., Rostami, M., Najarian, S., Menhaj, M.B., Saadatnia, M., Salami, F. (2010). Modelling the interaction of ankle-foot orthosis and foot by finite element

methods to design an optimized sole in steppage gait. Journal of medical engineering & technology, 34(2): 116-123, DOI:10.3109/03091900903402063.

[4] Deberg, L., Taheri Andani, M., Hosseinipour, M., Elahinia, M. (2014). An SMA passive ankle foot orthosis: Design, modeling, and experimental evaluation. Smart Materials Research, 2014: 1-11, DOI:10.1155/2014/572094.

[5] Kubasad, P.R., Gawande, V.A., Todeti, S.R., Kamat, Y.D., Vamshi, N. (2020). Design and analysis of a passive ankle foot orthosis by using transient structural method. In Journal of Physics: Conference Series, 1706(1): 1-12, DOI:10.1088/1742-6596/1706/1/012203.

[6] Gautam, G.Y., Jain, M.L., Gehlot, V. (2021). Design and Analysis of Thermoplastic Polypropylene Ankle Foot Orthosis. Journal of Manufacturing Engineering, 16(3): 087-091, DOI:10.37255/jme.v16i3pp087-091.

[7] Chen, R.K., Chen, L., Tai, B.L., Wang, Y., Shih, A.J., Wensman, J. (2014). Additive manufacturing of personalized ankle-foot orthosis. Proceedings of transactions of the North American manufacturing research institution of SME (NAMRC42), 42.

[8] Cha, Y.H., Lee, K.H., Ryu, H.J., Joo, I.W., Seo, A., Kim, D.H., Kim, S.J. (2017). Ankle-foot orthosis made by 3D printing technique and automated design software. Applied bionics and biomechanics, 1-6, DOI:10.1155/2017/9610468.

[9] Shorter, K.A., Xia, J., Hsiao-Wecksler, E.T., Durfee, W.K., Kogler, G. F. (2011). Technologies for powered ankle-foot orthotic systems: Possibilities and challenges. IEEE/ASME Transactions on mechatronics, 18(1): 337-347, DOI:10.1109/TMECH.2011.2174799.

[10] Chaudhari, R., Loharkar, P.K., Ingle, A. (2022). Medical Applications of Rapid Prototyping Technology. In Recent Advances in Industrial Production, 241-250.

[11] Ozimek, J., Pielichowski, K. (2021). Recent advances in polyurethane/POSS hybrids for biomedical applications. Molecules, 27(1): 1-31, DOI:10.3390/molecules27010040.

[12] Heijkants, R.G.J.C., Schwab, L.W., Van Calck, R.V., De Groot, J.H., Pennings, A.J., Schouten, A.J. (2005). Extruder synthesis of a new class of polyurethanes: Polyacylurethanes based on poly (ε-caprolactone) oligomers. Polymer, 46(21): 8981-8989, DOI:10.1016/j.polymer.2005.06.089.

[13] Banoriya, D., Purohit, R., Dwivedi, R.K., Baghel, U. (2019). Development and testing of polyurethane based composites using rapid prototyping techniques for biomedical applications-a review. Materials Today: Proceedings, 18: 5410-5415, DOI:10.1016/j.matpr.2019.07.569.

[14] Asadi Dereshgi, H., Dal, H., Demir, D., Türe, N.F. (2021). Orthoses: A Systematic Review. Journal of Smart Systems Research, 2(2): 135-149.

[15] Saddow, S.E. (2012). Silicon carbide biotechnology: a biocompatible semiconductor for advanced biomedical devices and applications. Elsevier, Amsterdam.