World Academy of Science, Engineering and Technology
International Journal of Biomedical and Biological Engineering
Vol:12, No:6, 2018

Orthosis and Finite Elements: A Study for Development of New Designs through Additive Manufacturing

M. Volpini, D. Alves, A. Horta, M. Borges, P. Reis

Abstract**—**The gait pattern in people that present motor limitations foment the demand for auxiliary locomotion devices. These artifacts for movement assistance vary according to its shape, size and functional features, following the clinical applications desired. Among the ortheses of lower limbs, the ankle-foot orthesis aims to improve the ability to walk in people with different neuromuscular limitations, although they do not always answer patients' expectations for their aesthetic and functional characteristics. The purpose of this study is to explore the possibility of using new design in additive manufacturer to reproduce the shape and functional features of a ankle-foot orthesis in an efficient and modern way. Therefore, this work presents a study about the performance of the mechanical forces through the analysis of finite elements in an ankle-foot orthesis. It will be demonstrated a study of distribution of the stress on the orthopedic device in orthostatism and during the movement in the course of patient's walk.

Keywords**—**Additive manufacture, new designs, orthoses, finite elements.

I. Introduction

According to the report of the Brazilian Institute of Geography and Statistics (IBGE) in 2014, approximately 8 million people in Brazil have some deficiency related to motor limitations in the lower limbs [1]. Considering this scenario, there was an expressive increase in the use of orthoses to treat neuromotor dysfunctions in order to generate biomechanical alignment and consequent prevention of muscle shortening, bone deformities and improvement of gait functioning [2], [3].

Used for the treatment of lower limb-related motor dysfunctions, the ankle-foot orthesis is a rehabilitative therapeutic device that aims to limit the movement of the ankle's plantar flexion, keeping the tibiotarsal joint in a rigid posture at 0° of dorsiflexion of the ankle [4], [5], as shown in Fig. 1. However, the current process of manufacturing orthopedic devices, especially ankle-foot orthesis, is extremely handcrafted, requiring intensive operational effort, as well as presenting limitations on the flexibility of the model produced, in other words, designs that could be offered to users [5], [9], [10]. Thus, it is necessary to search for uses of new orthesis manufacturing technologies capable of generating speed in the manufacturing process, maintaining product quality and the potential to bring benefits to patients in terms of comfort, the practicality of delivery of the product and the possibilities of design diversification associated with a contemporary aesthetic, as well as a functional and pleasant result [11].

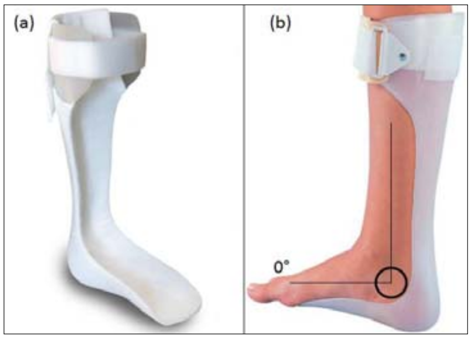

Fig. 1 (a) Rigid ankle-foot orthesis (b) Application of ankle-foot orthesis [6], [7]

As a possible solution to the demands of the manufacture of complex objects, Additive Manufacturing (AM) presents feasible solutions for the development of non-conventional geometry orthopedic devices through the use of computational models and fabrication by deposition of layers [8], [12], [13]. However, in order for the functionality of the ankle-foot orthesis to correspond to the required need, preliminary tests must be carried out for acceptance of the orthoses according to the postulated mechanical strength specifications. These tests can be performed by means of computational tests based on Finite Elements (FE) [14], [15].

The present study aims to address the application of Computer Aided Design (CAD) tools to aid the development of orthopedic devices through AM. The main focus is the application of EF tests associated to the computational drawings with the purpose of elucidating and evaluating the actions resulting from mechanical forces on the ankle-foot

M. A. is with the OhLab - orthotics for humans, Belo Horizonte, MG BRA (corresponding author, phone: +55 3133041300; fax: 3304-1327; e-mail: marianavolpini@amr.org.br).

A. D. is with OhLab - orthotics for humans, Belo Horizonte, MG BRA. He is now with the Department of Design, Universidade do Estado de Minas Gerais, Belo Horizonte, MG BRA (e-mail: dneivaalves@gmail.com).

H. A., was with OhLab - orthotics for humans, Belo Horizonte, MG BRA. He is now with the Department of Design, Universidade do Estado de Minas Gerais, Belo Horizonte, MG BRA (e-mail: andersonhorta@amr.org.br).

B. M., was with OhLab - orthotics for humans, Belo Horizonte, MG BRA. He is now with the Department of Electrical Engineering, Universidade Federal de Minas Gerais, Belo Horizonte, MG BRA (e-mail: marcoborges@amr.org.br).

R. P., was with OhLab - orthotics for humans, Belo Horizonte, MG BRA. He is now with the Department of Industrial Engineering, Universidade Federal de Minas Gerais, Belo Horizonte, MG BRA (e-mail: pauloreis@amr.org.br).

orthesis in a virtual model. The results of this analysis indicate the areas of greatest mechanical effort employed in its use, which, therefore, demarcates the regions that can be withdrawn from the design proposals, respecting the project limits.

II. Bibliografic Review

A. AM in Support of Bioengineering

The demand for advanced confection of functional and structural prototypes, prompted by the need to develop research in manufacturing and the growing shortage of industrial sectors to respond quickly to market demands, consolidated the development of the concept of AM [16], [17].

According to Raja e Fernandes [15], the AM is the class of manufacturing technologies used in the fabrication of physical objects from material deposition, layer by layer, taking as reference the virtual representation of the object by 3D-CAD systems. According to the authors, AM techniques are the best existing manufacturing process for the manufacture of small components and complex parts.

AM technologies allow the rapid and accurate development of objects by depositing material layer by layer without the need for any other tool, which generates a great manufacturing advantage in contrast to conventional manufacturing methods [18], [19].

The production of functional models by AM has proven to be an agile, low-cost and affordable solution for several areas, especially for bioengineering [20]. The demand for the advanced preparation of bio-prototypes, promoted by the need to develop research on medical artifacts and the increasing lack of rehabilitation orthopedics to offer a fast and efficient response to emergency requests, promoted the use of AM at the aid of device manufacturing medical [18], [21]. The development of biological and anatomical models was one of the key factors for the introduction of 3D printing technologies in the biomedical field. The models in question, especially orthopedic devices, require high personalization in the developed product, according to the patient's morphological characteristics, or of the applied field of study, to provide an accurate diagnosis and an effective treatment of the clinical case [20], [13], [22]. Fig. 2 illustrates orthopedic devices produced through AM.

Fig. 2 Orthopedic devices produced through AM [22], [23]

AM techniques were initially employed in medicine in the early 21st century, with the development of dental implants and custom prostheses [24], [25]. Since then, development and use of 3D printing in medicine has become a constant practice, and has shown steady evolution. The medical uses of AM can be organized into several categories, such as the manufacture of tissues and organs creating prostheses, implants and anatomical models and pharmaceutical research [24]. Currently, the main applications observed for models and biomodels generated through 3D printing are surgical training, medical research and teaching, patient-medical interaction, surgery planning, tissue engineering and orthopedic rehabilitation [2], [26].

B. Finite Elements

The continuous media mechanics, especially elasticity theory, has as a basic precept, the development of mathematical models that can adequately represent the actual physical situation of components subject to mechanical stresses. In structural analysis, the objective can be the determination of the displacements field, the internal deformations or the tensions acting in the system due to the application of loads [27]-[29].

Considering the tools and methods of solving equations with a large number of variables, the Finite Element Analysis (FEA) is presented as a numerical procedure that aims at solving partial differential equations that can hardly be solved analytically [28]. The method consists of determining the fractional geometry of a surface (Fig. 3), and, through a system of algebraic equations, determines the relationships between fractioned points. Due to this geometric subdivision it is possible to test the performance of differential equations representative of mechanical tests on surfaces with predetermined parameters, thus making it possible to estimate the mechanical properties of this surface [27], [30].

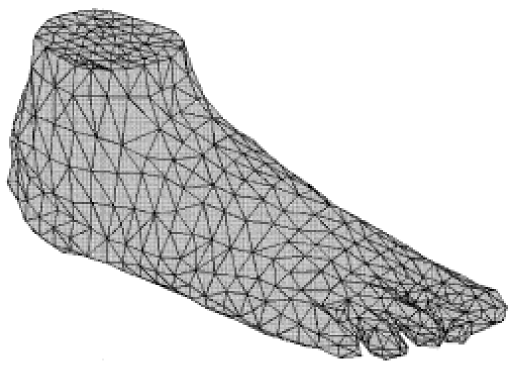

Fig. 3 Representation of virtual surface fractionation in an FE study [29]

FE systems allow the analysis and testing of surfaces in a computational environment, without the need to perform destructive tests, which is why the use of this tool has been widely feasible in tests required to simulate forces in a given material [29]. It is important to notice that the FE method is an estimation of the mechanical behavior of an object submitted to the forces acting, so it does not replace mechanical tests that aim to qualify the mechanical properties of a study material.

The major advantage of the FE test is the ability to represent the geometric details, structure materials, as well as the application of multiple design concepts. The major disadvantage of this method is cost/time, since to develop a model of complex structures may require a lot of time due to the geometric divisions of the elements and execution of the computational mesh [30], [31].

III. Method

A. Generation of the FE Model

Considering the central objective of this work, the tools used at the virtual level were objectified in the data supply and spatial coordinates for the execution of the FE study. In order to achieve this goal, an orthosis was developed using computational tools for modeling virtual solids, as shown in Fig. 4. As can be seen in Fig. 4, the developed orthosis has dimensional references compatible with the morphology of an adult of average height, with dimensions of 182.69 mm in Z, 99.05 mm in Y and 55.69 mm in X. The performance of the applied simulation forces was estimated considering the compression of the foot in the orthosis and the performance of the forces exerted on the Achilles tendon and the tendons of the flexor and extensor muscles during foot movement, such as dorsal flexion, foot rotation and compression of the sural triceps in the region of contact with the orthosis. The performance of ground contact forces was simulated by nodal forces equivalent to the reaction forces.

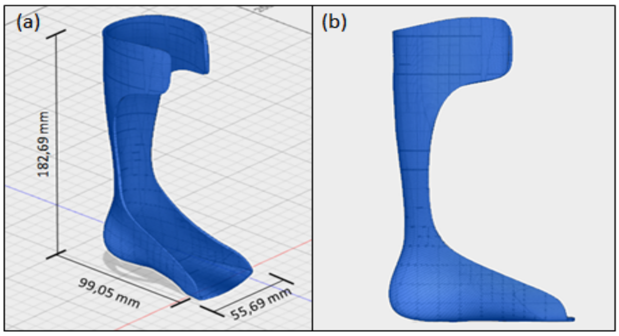

Fig. 4 (a) Dimensions of the virtual orthosis. (b) Side view of the virtual orthosis

From the virtual orthesis presented, the segmentation of the surface of the model was developed to perform the EF tests. The tests performed sought to simulate the gait condition of the ankle-foot orthesis patient, with correction forces acting in the regions observed by Manee [32] in his studies on the corrective action of the suropodal orthosis.

The results obtained for the FE method in this study are conditioned by the design of the developed orthosis, with the resulting factors of forces coming from the gait and the physical characteristics represented for this work. It is important to emphasize that the mechanical resistance and the resulting stress distribution differ from the results of this study according to the variation of the parameters used.

B. Material Properties

The material used as a parameter for conducting the EF tests was DuraForm ProX PA nylon thermoplastic developed by the manufacturer 3D Systems. The material in question features high strength and durability, being a functional production base for parts produced by AM in the automotive, aerospace and consumer goods industries. The technical specifications of the material are shown in Table I.

TABLE I
DURAFORM PROX PA MECHANICAL PROPERTIES [33]

Material Property	Value
Density (sintered part)	0.95 g/cm³
Flexural Modulus (MPa)	1650
Flexural Strength, ultimate (MPa)	63
Tensile Modulus (MPa)	1770
Tensile strength, Ultimate (MPa)	47
Elongation at break	22 %
Impact strength (J/m) Notched Izod, 23 °C Unnotched Izod, 23 °C	45 644
Heat deflection temperature	182 °C 97 °C
Flammability	HB
Hardness	73D

IV. Results

As an experimental result, the analysis of the FE method provides the quantification of the global stress distribution and the deformation of the structure analyzes from the forces resulting acting. For the study in question, the results of the simulation of the gait by FE were presented in two variations observed in the simulation, namely: the percentage displacement of the orthosis in the gait and the stress tests, which demonstrated the regions of greater performance of the mechanical forces and consequent greater abrasion of the orthosis. The presentation of these result variations are important because they directly influence the corrective action of the orthopedic device, since the corrective clinical actions are due to the rigidity of the orthosis. Fig. 5 shows the first variant, displacement of the orthosis in gait.

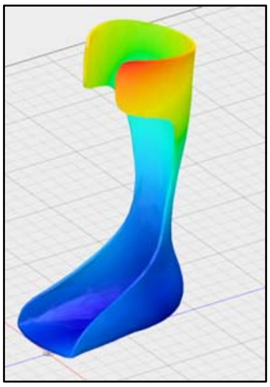

Fig. 5 Displacement of the orthosis in gait

The largest deformation modulus as a function of the displacement of the virtual orthotic model is observed in the upper left region of the device, extending, to a lesser extent, along the rod. The greatest displacement intensity was in the clamp that holds the device fixed in the lower limb of the orthosis user, reaching a maximum deformation of 65.51 mm. The observed fact can be explained considering the relation of the structural arrangement of the orthosis at the cited point versus the force exerted by the patient's limb in the anchoring clips. The second result variant was the stress simulation of the studied material, which can be observed in Fig. 6.

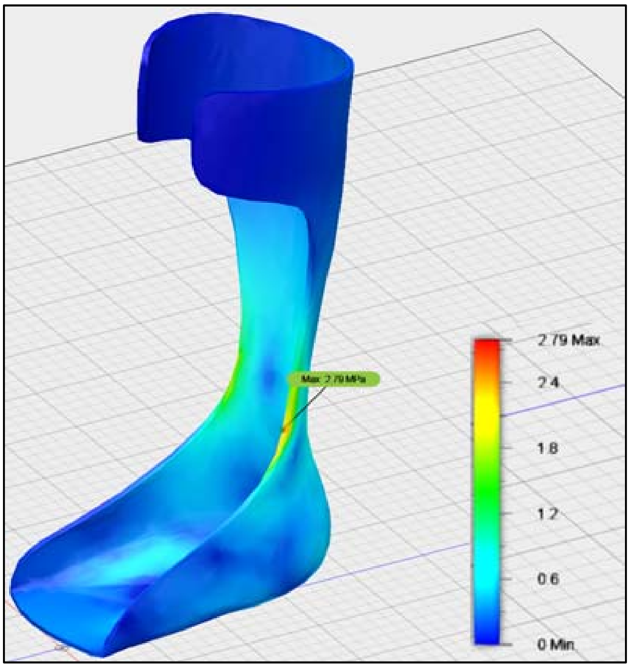

Fig. 6 Stress distribution on the orthosis

The greatest abrasion in the study model was observed in the lower region of the orthosis stem. Because it is a region that demands greater rigidity, due to the purposes of correction of the device, the flexion at this point has a relatively low tolerance when compared to other regions of the orthosis. Fig. 7 shows the observed region of greatest stress.

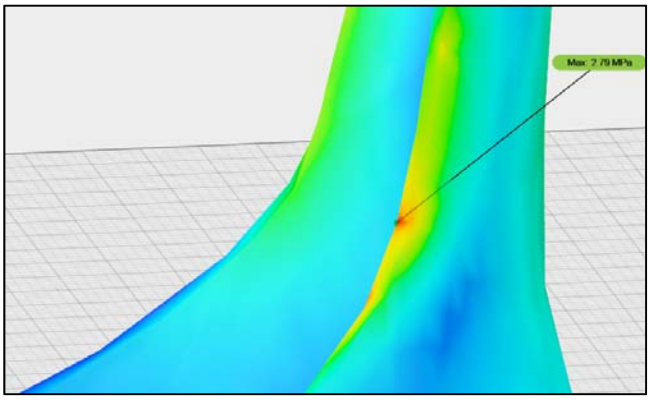

Fig. 7 Observed region of greatest stress acting

The stress region of forces resultant greater acting had a modulus of 2.79 Mpa, and is the region more prone to abrasion and consequent fracture of the surface of the material.

Considering the forces from the foot acting during the gait in the plantar region of the orthosis, the resistance to the abrasion, as well as the resistance to the deformations did not demonstrate significant values acting. This fact can be explained by the greater deposition of material in the plantar region of the orthosis in the analyzed model, which promotes mechanical properties of greater importance in this region.

For purposes of comparative analysis, Fig. 8 shows the relative overall displacement of the orthosis fabricated with the study material of this study, DuraForm ProX PA, through AM compared to the orthosis manufactured using the traditional method from high density polypropylene. The observed values for this comparison are derived from computational simulations based on the same force and structure parameters.

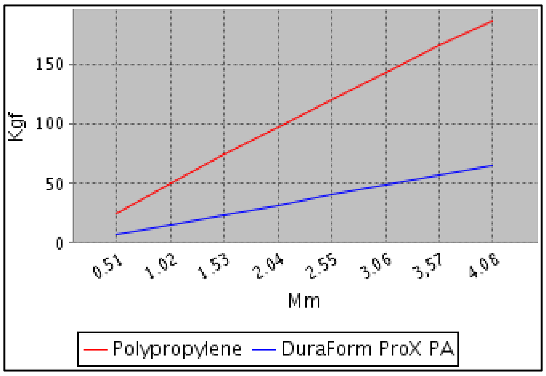

Fig. 8 Global displacement of bracing as a result of forces

As observed, the orthosis manufactured by MA showed less overall displacement compared to the polypropylene orthosis, demonstrating greater structural rigidity, thus favoring the actuation of the corrective forces necessary for the orthopedic device clinical performance.

V. Final Considerations

This work aimed to support the design activity of new designs for AM of orthopedic devices for lower limbs. The simulation of EF performed showed relative displacement and stress in certain regions of the orthosis, however, the deformations and mechanical forces observed by the FE analysis did not make it impossible to fabricate the ankle-foot orthosis by the 3D impression technique and a parameter of material used to perform this study, because it does not interfere with the fixation of the device in the limb and does not affect the stiffness required for the immobilization of the regions of interest. It is important to notice that as the use of the orthosis occurs, there will be more material abrasion in the region highlighted by the stress simulation, where the metatarsals are located in the device, it is suggested, therefore, greater deposition of material in the highlighted region, so that the durability of the cycle of use of the orthosis is prolonged.

Considering the regions of the orthosis that suffer less stress by the applied forces, both in march and at rest, demonstrated in the present study, it is possible to visualize and delimit areas where the interferences by withdrawal of material would not interfere in a negative way in the resistance of the orthopedic device.

The material removal capabilities for designing new designs for orthotics are important in the visual configuration and comfort ratios and practicality of use. This is because, unlike the addition of material could hinder its use, especially considering the footwear and clothing used by the patient.

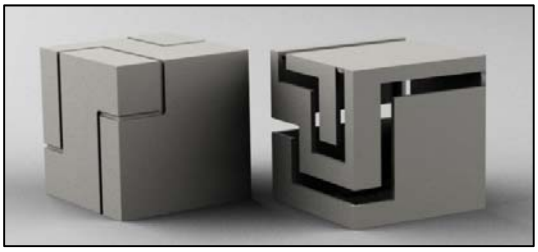

Fig. 9 Demonstration of withdrawal material use

As shown in Fig. 8, the use of embossing details and perforations of specific surface shapes are part of the aforementioned material removal capabilities that allow for a wider range of alternatives for design projects in orthotic proposals. Especially in the case of production by the method of AM in Rapid Prototyping machines, which allows the use of these resources with facility.

With the results obtained here, the use of these resources becomes more precise and safer, avoiding problems with the decrease of the mechanical resistance of the orthopedic devices in issue.

REFERENCES

[1] IBGE. Censo Demográfico 2014 – Características Gerais da População. Resultados da Amostra. IBGE,2014. available inhttp://www.ibge.gov.br/ home/estatistica/populacao/cnso2014/default_populacao.shtm.
[2] L. Deberg, A. Taheri, M. Andani, M. Hosseinipour, M. Elahinia passive ankle foot orthosis: Design, modeling, and experimental evaluation. Smart Materials Research. 2014.
[3] M. Kelly, M. C. SpiRES, J. A. Restrepo, Orthotic and prosthetic prescriptions for today andtomorrow. Physical medicine and rehabilitation clinics of North America. V. 18. 2007
[4] M. C. Faustini, R. R. Neptune, R. H. Crawford, S. J. Stanhope. Manufacture of passive dynamic ankle-foot orthoses using selective laser sintering. IEEE Trans Biomed Eng. 2008
[5] S. Milusheva, E. Tosheva, D. Tochev, Y. Toshev. Personalized ankle foot orthosis with exchangeable elastic elements. Journal of Biomechanics; V.40, 2007
[6] Healt, C. S. (2017). AFO. available in http://www.medicalexpo.es/prod/conwell medical/product68102-506020.html acess in Aug. 2017.
[7] Direct, K.-R. (2017). SmartKnit AFO Liner for Adults. available in http://www.knitritedirect.com/afo- socks.html acess in Aug. 2017.
[8] J. H. Pallari, K. W. Dalgarno, J. Woodburn: Mass customization of foot orthoses for rheumatoid arthritis using selective laser sintering. IEEE Trans Biomed Eng. 2010.
[9] S. Salles, D. E. Gyi: An evaluation of personalised insoles developed using additive manufacturing. J Sports Sci. 2013.
[10] S. Salles, D. E. Gyi: The specification of personalised insoles using additive manufacturing. Work. 2012.
[11] Y. Jin, J. Plott, R. Chen, J. Wensman, A. Shih Additive Manufacturing of Custom Orthoses and Prostheses – A Review. Procedia CIRP. V. 36, Pages 199-204, 2015.
[12] S. Schrank, L. Hitch, K. Wallace, R. Moore, S. J. Stanhope: Assessment of a virtual functional prototyping process for the rapid manufacture of passive-dynamic ankle-foot orthoses. J Biomech Eng. 2013.
[13] Horta, A.; Borges, M. A.; Volpini, M.; Reis, P. H.. Viability of Optical scanning techniques for digitization of Lower limbs. 1019080/CTBEB.2017.05.5555659, v. 5, p. 5555659, 2017.
[14] Pawale, V. N. Chougule, W. N. Tamboli, A. V. Mulay. Review: Analysis and Manufacturing of Ankle Foot Orthosis for Foot Drop. IOSR Journal of Mechanical and Civil Engineering (IOSR-JMCE). Pages. 12-15. 2012.
[15] B. Rogers, G. W. Bosker, M. F. Faustini, G. Walden, R. R. Neptune, R. H. Crawford. Variably Compliant Transtibial Prosthetic Socket Fabricated Using Solid Freeform 'a case study'. Journal of Prosthetics and Orthotics. V. 20. 2008.
[16] Raja.; V. J. Fernandes. Reverse engineering: an industrial perspective. London: Springer Verlag, V. 1, pp. 156–179, 2008.
[17] N. Volpato; C. H. Ahrens,; C. V. Ferreira,; G. Petrush; J. Carvalho, J. R. L. Santos, J. V. L. Silva. Prototipagem rápida: tecnologias e aplicações. São Paulo: Edgard Blucher, Pages 154-210. 2007.
[18] L. K; Gibson, S. P. Cheung. The use of rapid prototyping to assist medical applications. Rapid Prototyping Journal. Pages 53-58. 2006.
[19] P. F. JACOBS, Rapid prototyping & manufacturing: fundamentals of stereolithography, Society of Manufacturing Engineers, Michigan, USA, 1992.
[20] P. A. Webb: A review of rapid prototyping (RP) techniques in the medical and biomedicalsector. Journal of Medical Engineering & Technology. V. 24. 2000.
[21] N. Herbert, D. Simpson, W. D. Spence, W. Ion. A preliminary investigation into the development of 3-D printing of prosthetic sockets. Journal of Rehabilitation Research & Development. V. 42 2005.
[22] Rengier, A. Mehndiratta, L. Giesel. 3D printing based on imaging data: a review of medical applications. Int J Comput Assist Radiol Surg. 2010.
[23] N. G. Harper, E. M. Russell, J. M. Wilken, R. R. Neptune. Selective laser sintered versus carbon fiber passive-dynamic ankle-foot orthoses: a comparison of patient walking performance. Journal of biomechanical engineering; 2014.
[24] J. L. Gross. S. Y. Erkal. Lockwood. Evaluation of 3D printing and its potential impact on biotechnology and the chemical sciences. Anal Chem. Pages 3240–3253. 2014.
[25] X. Cui, T. Boland, D. D. D'Lima, M. K. Lotz. Thermal inkjet printing in tissue engineering and regenerative medicine. Recent Pat Drug Deliv Formul. Pages 149–155. 2012.
[26] J. Banks. Adding value in additive manufacturing: Researchers in the United Kingdom and Europe look to 3D printing for customization. IEEE Pulse. Pages 22–26. 2013.
[27] L. Agarwal, L. Broutman, "Three-dimensional finite element analysis of spherical particlecomposites," Fibre Science and Technology, vol. 7, no. 1, pp. 63–77, 1974
[28] L. Segerlind, Applied finite element analysis. Wiley, 1976.
[29] W. Chen, F. Tang, C. Ju. Stress distribution of the foot during mid-stance to push-off in barefoot gait: a 3-D finite element analysis Clinical Biomechanics. V. 16. Pages 614-620 Aug. 2001.
[30] M. Jakubinek, D. Whitman, and M. White, "Negative thermal expansion materials," Journal of Thermal Analysis and Calorimetry, vol. 99, no. 1, pp. 165–172, 2010.
[31] U. Gandhi, Data based models for automobile side impact analysis and design evaluation. Internationaljournal of impact engineering. V. 18, n 5, p.517 – 537.
[32] T. Manee, Optimal dorsal strap placement and angulation to prevent pistoning in an ankle foot orthoses.Presented at the American Orthotic and Prosthetic Association National Assembly, Las Vegas,September 2011.
[33] 3d Sytems, Material Selection Guide For Selective Laser Sintering – SLS available in https://br.3dsystems.com/sites/default/files/2017-05/3D Systems_SLS_Material%20Selection%20Guide_USEN_2016.12.20_WEB.pdf acess in Aug. 2017.