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Design of a flexible neck orthosis on Fused Deposition Modeling printer for rehabilitation on regular usage

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Abstract

The usage area of Additive Manufacturing (AM) already spread into the medicine and rehabilitation sphere. The advantages of AM become a driving force for fabricating prostheses, human organs, and implants. The recent studies in AM indicate excellent manufacture of limbs that possesses characteristics of market versions and, at the same time, outperform them in comfortability. Although there is a vast amount of investigation on orthosis development, only a few applications connected with neck orthosis. This paper proposes customized cervical orthosis designed through 3d scanner device and produced by Fused Deposition modeling. TPE (thermoplastic elastomer) FLEX filament used to provide the model with flexible features on par with the lightweight. FEA analysis assessment confirmed the durability of the prototype. Furthermore, the specific construction of orthosis allows patients to comfortably dress and utilize it in daily life, whereas the hole pattern of frame addresses ventilation problems. Obtained results indicate the capability of using TPE (flex) material and show that the FDM printed model able to compete with market analogs.

Keywords: Type your keywords here, separated by semicolons ;

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1. Introduction

The capability of fabricating complex objects with high precision in a short period allowed Fused Disposition modeling untie the hands of engineers in different fields. Development of new materials and the auxiliary system as 3D scanners expanded the application area of 3D printers. Particularly, the implementation of additive manufacturing is undergoing a revolution in rehabilitation engineering, which consists of printing personalized prostheses, organs, and implants, etc. [1]. Simple technology and low-cost material enable the printing of cheaply replaceable hand prostheses [2]. ABS filament-based foot prosthesis under FEA (Finite Element Analysis) design was suitable for low-activity movement [3]. Andrea Vitali et al. [4] designed a primary model of the socket, and after pressure distribution analysis, they performed validation procedure, which let them develop high-quality socket prosthesis. The microfluidic valve is printed with multi-material and compared to a stiff single material valve, and it is flexible enough to form intricate shapes [5]. Simultaneous photo-polymerization approach brings similar results of the compressive modulus of injecting printed cartilage with natural human cartilage [6]. Satisfactory anatomic structured kidney phantom manufactured using Computed tomography and polymer molding [7].

Another branch of rehabilitation medicine is a production of the orthosis, used during treatment of a certain problem. Mainly orthosis performs movement assistance, muscle support actions. Patients wear it after surgeries to immobilize body parts. An orthosis is suitable for movement limitation of the limb in a certain direction, and it promotes shape correction of the body. Personalized production of orthosis is more favorable in the rehabilitation procedure compared to prefabricated orthosis because it takes into account comfort and individual distinction of each patient. The recent papers on this topic mainly focused on wrist orthosis, where authors mention the drawbacks of traditional methods and highlight the potential of 3D printing [8-10]. They print lightweight, breathable casts that satisfy unique anatomy and consider the thermal comfort of the patient [11]. The traditional labor-intensive and imprecise molding process of an ankle-foot orthosis (AFO) is replaced by digital and additive manufacturing technologies. FDM (Fused Deposition Modeling) produced stronger and flexible models that are capable of constraining ankle motion during regular activities through analyzing static and dynamic load on a computer [12-14].

Although many authors remarked about the benefits of 3D printing technology in orthosis production, there only a few researchers who focused on the design of cervical orthosis. This could be attributed to the design complexity of orthosis and a sufficient amount of prefabricated ones, which satisfy patient demand. However, Rita Ambu et al. [15] listed complications related to the market orthosis. Moreover, Mohammad Karimi et al. [16] fully analyzed the efficiency of neck orthosis types on the review paper. Also, they revealed shortcomings such as uncomfortable swallowing, pin loosening infections, muscle atrophy, and skin rash. A. Prates [17] expanded this problem list with pain, discomfort, and odor.

Visscher et al. [18] modeled neck slits for patients with burn wounds. The benefit of such 3D printed orthosis was the simplicity of certain parameter adjustments during healing. Rita Ambu et al. [15] used innovative Hemp Bio-Plastic composite that has an antibacterial property. Computer tomography allowed scanning neck parts of the patient, and after image editing, they got a precise 3D model. Afterward, the authors printed light cervical orthosis with elliptical holes pattern that was better than a honeycomb pattern based on FEA analysis. Despite the fact of hygienic surface, this design is still rigid. Lack of elasticity will cause pain on the chin. Both designs [15-16] have a common restriction, and models do not take into account dressing action. The orthosis has not got a special section or part where the patient could take off it. Nevertheless, it was highlited the superiority of 3D printed orthosis over market ones regarding comfortability, because proportion of orthosis satisfy patient personal anatomy and design pattern eliminate problem of odor. The next advantage related to lower weitgh and size. Another important aspect concern production cost and time. Fabrication of FDM printed orthosis will took few days, whereas development of new filament enhance their mechanical characteristics.

In this paper, customized lightweight neck orthosis design is reported. The model is printed by the Fused Deposition Modeling technique. The FEA analyse employed to assess and modify orthosis shape. The TPE (thermoplastic elastomer) filament was chosen for fabrication of orthosis. This filament possess flexible bending property. Compared to other material, that kind of characteristics allows model to extend it during wearing process.The patient can easily dress and take off orthosis thanks the special section located behind the orthosis, where the Velcro used for bracing. At stationary mode FLEX printed model is strong enought to immobilize neck at

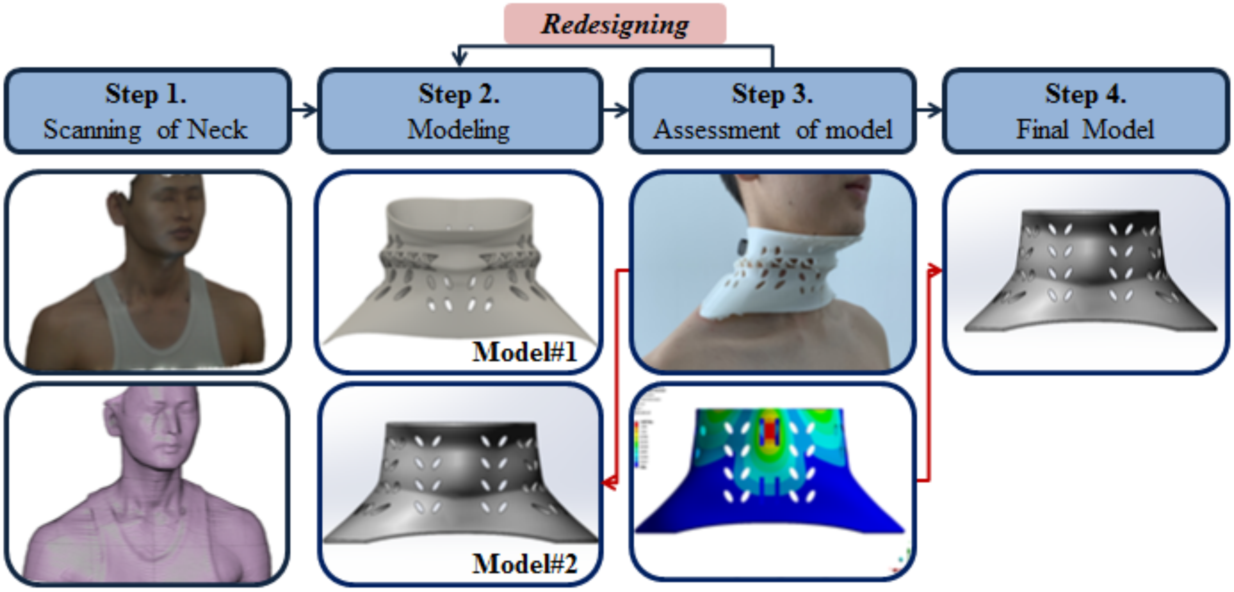

Fig. 1. Designing process algorithm

early stage of treatment, but also could bend a little if patient apply certain force at last stage of treatment. Thus, it helps to reduce muscle spasms and start gradually bend the neck and use neck muscles. Furthermore, the design is suitable for daily use for people who work a lot with computers and have poor ergonomics of the cervical part, they could utilize it during working hours and pull off after. Additionally, the potential of using portative 3D scanner was emphasized in this paper. Modern scanners has user comprehensible interface and comfortable design, which lead to increase usage rate in future for orthosis and prosthesis modeling.

2. Design

The design process is divided into four parts. The first part of modeling the 3D model of the neck is scanned via a 3D Scanner. The second part related to modeling on the 3D software program "Fusion 360". The further step requires an assessment of drawn model redesigning of the neck model. Then, the final model with is created. The whole process algorithm is drawn in Fig. 1.

2.1. 3D scanning

The first stage of the designing process is the reconstruction of the 3D neck model. The quality of the model directly impacts the comfort of the patient and further mathematical analysis; therefore, high precision is required. In this paper, the Sense (2nd generation) 3D scanner device was used to obtain a digital view of the neck. The design of the scanner is intended to maximize the convenience of usage. The scanner has a suitable interface for new users and automatic settings to process small objects. Digital models of the object provided in "STL" and "PLY" formats via USB connection.

To acquire the precise model of the neck, a sensor device was installed on a fixed position, whereas the patient was placed on the chair. During the scanning, process chair was slowly rotated around its axis, and at the same time computer was monitored to ensure proper processing of the 3D model. In Fig. 2 (a) illustrated a scan of the upper torso of the patient and (b) its view in the "STL" format.

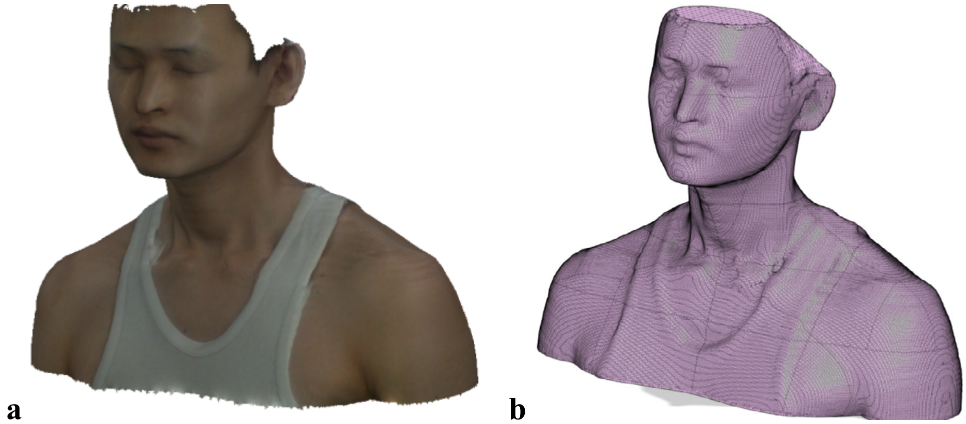

Fig. 2. (a) 3D scan of the model; (b) STL format of model

3. Modeling & assessment of model #1

The digital model of the patient allowed us to design neck orthosis with high accuracy. Furthermore, the STL model has a full top body view; thus, during the development of the model transition region between the neck and shoulders (top trapezius muscle) is also taken into account. Construction of model performed on Fusion 360 software.

Fig. 3 is shown a view of neck orthosis model#1 from the front, left side, and backside. The model construction is similar to conventional rigid orthosis on the market, which supports neck from chest to neck. However, the design has extra support on both sides (left, right), and that lies on the trapezius muscle. It is intended to make orthosis more comfortable and stable. The main feature of our design is the flexibility of the model. The bending geometry helps to treat minor problems, decreasing pain on the chill, and still immobilize the neck for a certain degree. To avoid bending of the model to the inside direction and possible neck skin harm, special convex shape designed around the center of the orthosis. It allows the model to bend outside. Additionally, this region solves the problem of swallowing. The bending region around the center of the neck has not solid fill. The triangular pattern holes improve the bending characteristics of the model, and as a result, less force is required to move the neck.

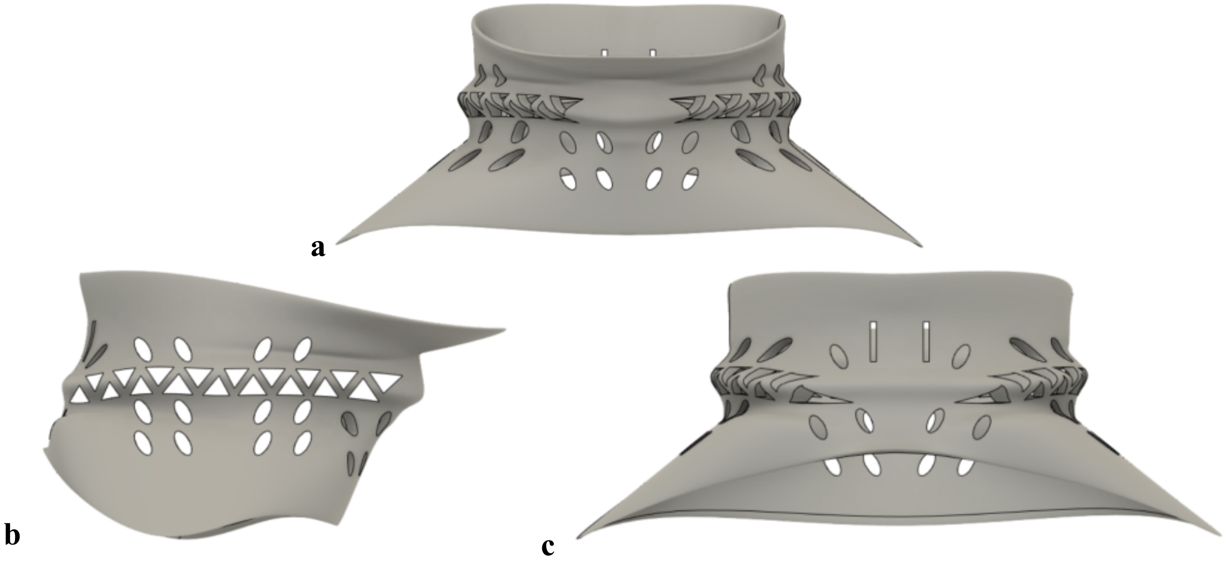

Fig. 3. Neck orthosis design model #1: (a) front; (b) left side; (c) backside view

The general infill pattern of design has an elliptical pattern of holes, which was better compared to honeycomb concerting total displacement, according to the paper of Rita et al. [15]. In the case of different load conditions of lateral bending, flexion, and extension, the maximum enlargement was less in elliptical pattern design. Additionally, that kind of geometric pattern improves the breathability of an orthosis. The thicknesses of models are 3.5mm, which is less than average market prefabricated ones. This value gives a balance between lightweight and structural strength. Extra 2 quadrangular holes added on the backside of models dedicated to the facilitation of the dressing up process.To assess this design, it was decided to print the model and make further decisions and changes. The TPE (flex) material fabricated by REC [19] company was developed under printing parameters presented in Table 1.

Table 1. Printing parameter during fabrication of design #1.

Parameter	Value
Nozzle temperature	230C
Bed temperature	100C
Nozzle diameter size	0.4mm
Fill density	80%
Nozzle speed range	40-60 mm/s

Generally, the fabricated prototype has several advantages and few drawbacks. On fig. 4 shown pictures of model#1. It was indicated a high comfortability of the model for patients. The photo on a Fig. 4(d) demonstrated extension of a back part of a model without damaging orthosis itself; this makes the dressing process continent. The left and right parts that sit on trapezius muscles made construction fixed. The section which supports chin possesses a large contact area with chin compared to conventional neck orthosis, acting as a platform where chin lies down. Therefore, the pressure applied to the chin is decreased. The hole pattern fulfills the problem of ventilation, and it was planned to increase the number of ellipsoids. The density of flex material is 1.1g/cm3, [19], which is lower compared to popular PLA filament (1.27 g/cm3) [20]. Consequently, despite the large form, it weights considerably low, and the patient does not feel its mass. Regarding the drawbacks of design, the convex shape situated on the center of the design with a triangular hole, dedicated to increasing bending, was useless. Applied natural force by the patient did not even bend it. Hence, it was decided to remove it around the neck. Another disadvantage of the model is shown in Fig. 4 (c). The Velcro utilized for bracing orthosis was not fully satisfy its task. It could be observed (see Fig. 4 (c)) that the bottom part is separated.

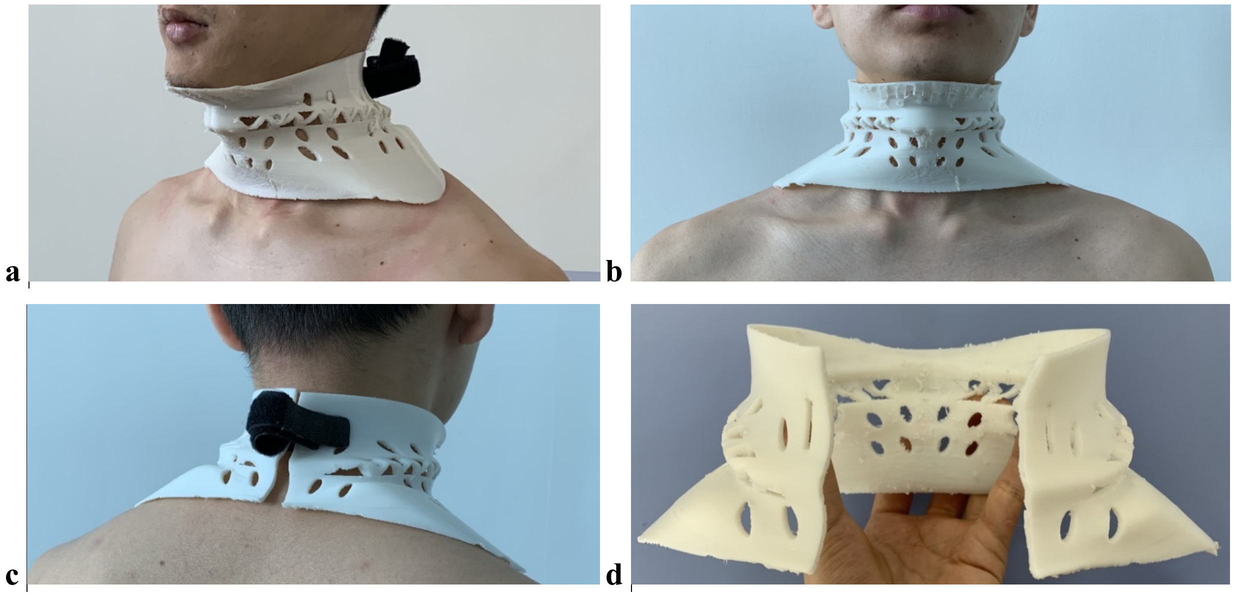

Fig. 4. Prototype version of model #1: (a), (b) front view; (c) backside view; (d) stretching

4. Modeling & assessment of model #2

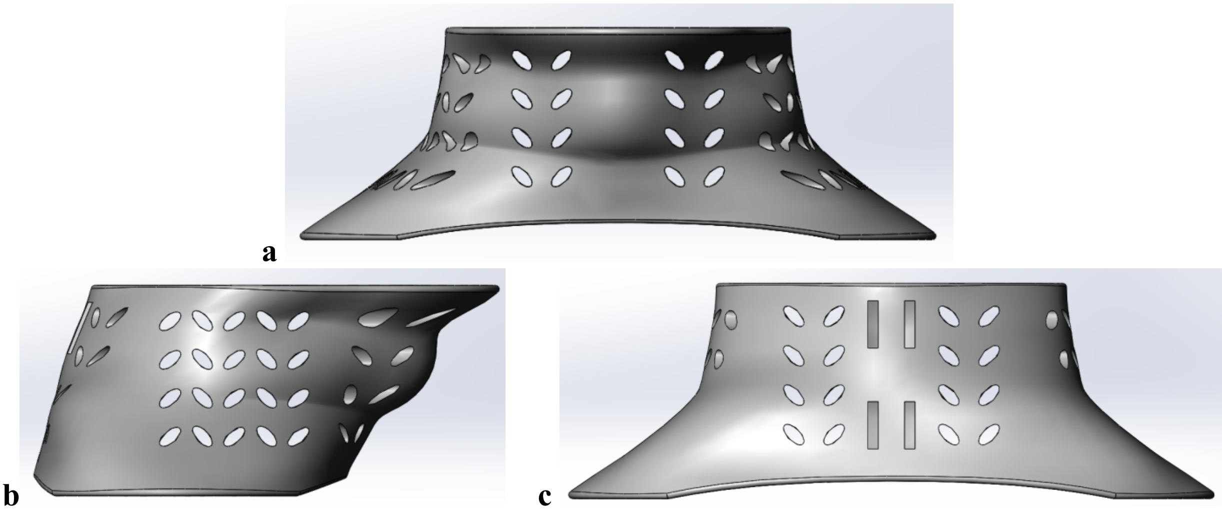

Fig. 5. Neck orthosis design model #1: (a) front; (b) left side; c) backside view

Based on the elimination of drawbacks of model#1 the new design was drawn. To fasten orthosis properly, additional rectangular holes at the bottom part of the backside for Velcro were cut out. The view of model #2 from different sides is shown in figure 5. The convex around the central perimeter was removed. The number of elliptical holes increased, additional ones added on the left and right support regions (trapezius muscles part). For convince of swallowing, the front middle part was extended. Another change is related to thickness, which was increased up to 4mm, and the sharp edges along the perimeter of the model were rounded.

The finite element analysis method on ANSYS software was used to assess the mechanical behavior of model #2. The numerical simulation approach shows the effect of applied force on the object and consequent displacement and load distribution along with the model. The initial step begins with setting filament parameters on software. Thermoplastic elastomer (TPE) material has both features of plastic and rubber. TPE fabricated orthosis includes strong, flexible, and durable properties. On table 2 listed the mechanical properties of TPE (flex) filament by REC company [19]. ANSYS software utilized to perform FEA analysis of design model #2. The purpose of numerical assessment is to observe how neck orthosis behaves under an applied force. The fine mesh formed by 799699 elements and 1208407 nodes ensure accurate simulation (see Fig. 6(a)).

Table 2. Mechanical properties of TPE (flex) filament

Parameter	**Value**
Density	1.1 g/cm3
Tensile strength along with layers	17.5MPa
Tensile modulus along with layers	63.7MPa
Bending strength	5.3 MPa
Bending modulus	72.9MPa
Young's Modulus	900 MPa
Maximum bending load	8N
Maximum tensile load	633N
Shore hardness (scale A)	88
Poisson's ratio	0.41

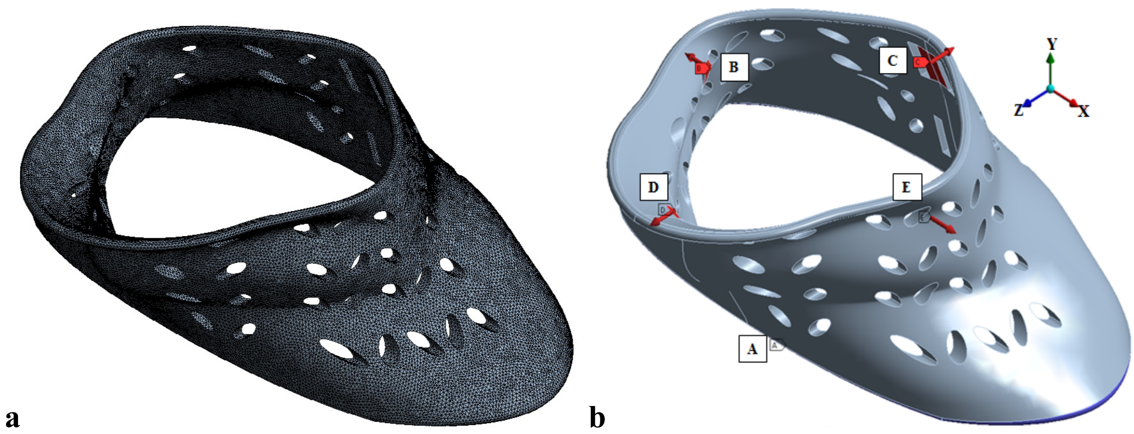

Fig. 6. (a) mesh view of design #2; (b) applied force direction and boundary condition.

Experimental work carried out by Vasavada et al. [21] intended to analyzed and characterize the moment of the neck. During the investigation process, both gender members at different age categories participated. The spontaneous formations of muscles allow calculating flexion, extension, and lateral bending moments. Based on this experiment, applied forces and direction for an average value of men were formed. Fig.6 (b) illustrates the directions of forces, the letter “B” and “E” corresponds to lateral bending (left and right side of orthosis). Extension force relates to the letter “C” and the backside of the model. To the forward part of the neck applied flexion force (“D”).

The lower edge of the model was chosen as a fixed boundary, which is indicated with the letter “A” and blue color region. The value of forces applied from the inner surface for flexion, extension, and lateral bending is 210N, 190N, and 165 N, respectively.

The influence of the applied force on stress distribution is represented in Fig. 7 in the Iso-colour view. On the left side of Fig. 7 (a) is shown color-bar, where the highest pressure is represented with red color, whereas the lowest corresponds to blue color. The unit of stress parameter is “MPa”. It could be seen that the region affected the most by pressure is the backside of the model, while the left and the front side is minor.

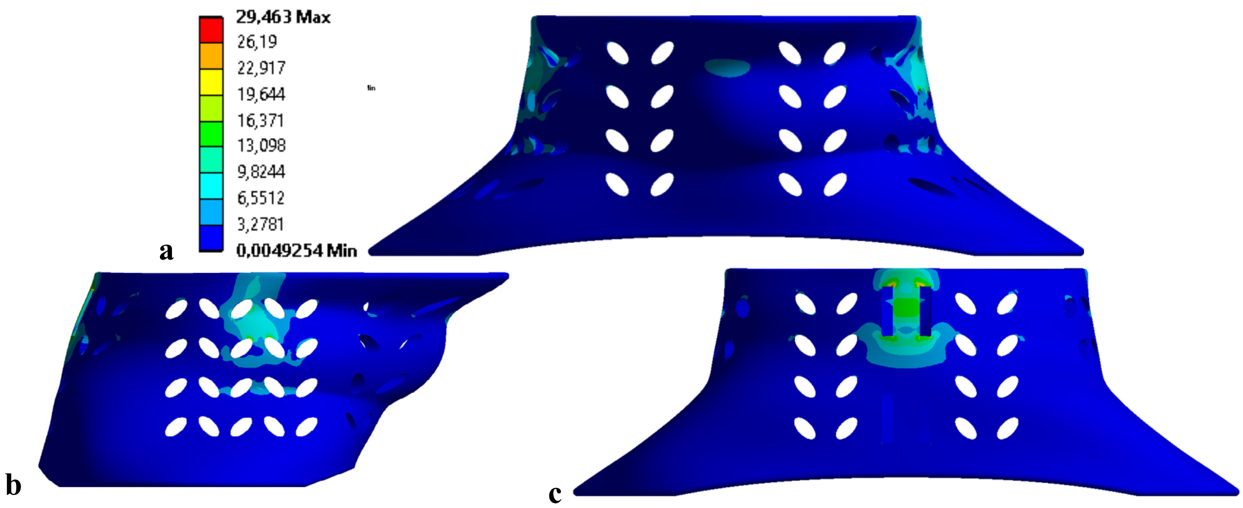

Fig. 7. Stress distribution along model#2: (a) front; (b) left side; (c) backside view

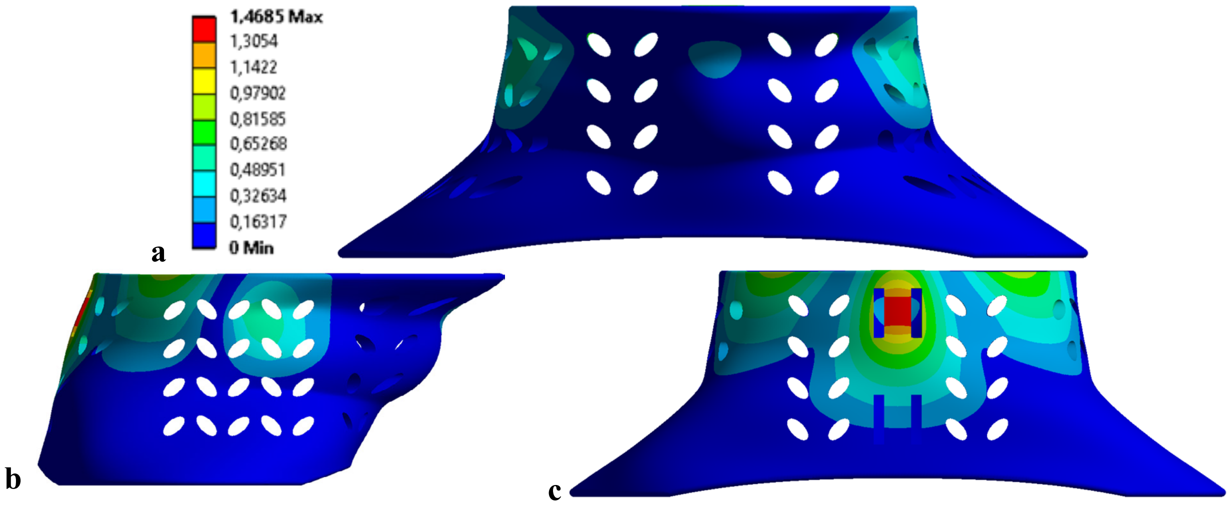

Fig. 8. Deformation (displacement) along model#2: (a) front; (b) left side; (c) backside view

Fig. 8 shows that the maximum displacement caused by applied force is 1.4685mm. Similar to stress distribution, the highest total displacement occurred on the backside of the model. The left side has almost 0.5mm enlargement, while deformation on the front side is negligible According to simulation analysis, it could be concluded that the weakest part of design #2 is the backside region. Nevertheless, the small deformation value is inappreciable. Moreover, on the nape side is oriented rectangular holes for Velcro, designed for comfortable dressing. During wearing, it could be regulated and tied hard.

Design and print of model #1 enable us to be confident about the dimensions of orthosis and its comfortability. The further step was the removal of its drawbacks. The improved design #2 was tested via ANSYS software, which highlighted the durability of orthosis under an applied force.

5. Conclusion

An original design of neck orthosis for personalized usage is reported in this paper. The fabricated orthosis model possesses high accuracy in terms of the neck shape of the patient. This was accomplished through 3D scanning and further processing of the CAD model. The developed model is capable of performing the task of healing patients by immobilization. The unique structure of the model (platform for chin) decrease the pain usually occurred on the chin. The extended support section, which is positioned on trapezius muscles, improved comfortability, and stability. The breathability of skin achieved via well distributed elliptical holes. The convex shape at the front model gives convenient swallowing. Application of flexible TPE (flex) material adds flexible property, hence enhance the dressing process. Comparative to PLA material, it has a lower density, which defines low weight. The negligible deformation during numerical assessment emphasized the strength of design. Finally, the advantage and applicability of new cervical orthosis design and the flexible filament were demonstrated.

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