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Development of Patient-Specific Adaptive Assistive Devices for Brachial Plexus Injury

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Abstract. Injury to the brachial plexus prevents the arm, wrist, and hand from communicating with the spinal cord in whole or in part. The 'patient's upper arm limb appears to be completely incapable of performing any type of independent movement. The aim of this project is to design and develop a customized adaptive assistive device for patients with brachial plexus injury and to fabricate the prototype using 3D printing technology. The development of the device involved adapting the mechanical engineering design process, including conceptual design and finite element analysis, to predict the performance of the design and to select the best printing materials. The patient's left arm was 3D scanned to create a customized part that perfectly fit the patient. The 3D model of the prototype was developed using Autodesk Fusion 360 and Autodesk TinkerCAD. Two different materials, namely Polylactic Acid (PLA) and Acrylonitrile Butadiene Styrene (ABS), were considered in the computational analysis. Results show that the maximum von Misses stress of PLA is observed at 2.464 MPa, slightly higher than the ABS material (2.451 MPa), indicating a greater stress tolerance imposed on the material's strength. However, PLA has a smaller maximum displacement than ABS, at 0.019 mm and 0.030 mm, respectively. The PLA material was chosen for 3D printing based on several considerations, including mechanical qualities, cost, printing time, durability, and data evaluation. The adaptive device for brachial plexus injury was successfully delivered to the patient and demonstrated the capability to assist in arm movement.

Keywords: Adaptive assistive device; Brachial plexus injury; Finite element analysis; Patient-specific; 3D printing

1. Introduction

An injury to the brachial plexus, the network of nerves that carries impulses from the spinal cord to the shoulder, arm, and hand, is referred to as a brachial plexus injury (BPI), sometimes known as a brachial plexus lesion (National Institute of Neurological Disorders and Stroke, 2008). Injury to the brachial plexus prevents the arm, wrist, and hand from

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communicating with the spinal cord in whole or in part. Frequently, brachial plexus injuries also leave the area completely numb (Johns Hopkins Medicine, n.d.). Brachial plexus injuries are a major indication of shoulder arthrodesis (Sousa *et al.*, 2013). An injury that suddenly affects these nerves, commonly referred to as a brachial plexus injury, can cause various symptoms such as pain, weakness, numbness, or limited movement in the shoulder, arm, and/or hand (Cleveland Clinic, n.d.).

An assistive device is a device that allows a patient or user with a disability to perform any daily activity with little to no assistance from others (Mazlan *et al.*, 2021; Oliver, 2019). Most patients with illnesses or impairments who receive rehabilitation use assistive devices. These devices not only reduce their reliance on caregivers but also enhance their level of functioning and participation in the community (Levesque and Doumit, 2020). To ensure the safety of users while using assistive devices, it is crucial to design them with their limitations in mind. Muscles, which constitute 45% of body weight, are the predominant type of tissue in the body (Volpi *et al.*, 2022). With the aid of the nervous system, the muscular system provides the capacity for movement and performing everyday activities. Due to a lack of product development experience, medical personnel are having problems creating suitable assistive equipment that could benefit them. Even engineers who are skilled in product development lack the medical knowledge necessary to diagnose any issue that could endanger the patient further (Abas *et al.*, 2023; Devin *et al.*, 2023; Cutti *et al.*, 2023). The study, analysis, design, and production of an adaptive assistive device for a patient with a brachial plexus injury are the focus of this project.

This adaptive aid was created for Patient A, a programmer with a left arm brachial plexus injury. Due to his left arm's brachial injury, he finds it challenging to carry out his duties, such as utilising a laptop or computer while resting his hand on a table. The patient has a history of brachial plexus damage stretching a few years ago. He is unable to spontaneously raise his left arm like other individuals. The primary goal of this study is to develop an orthosis that will allow the patient to raise his left arm independently without assistance from the other hand. The left limb of the patient will be 3D scanned to determine how the limb should be shaped for the device.

The design will be carried out using commercial computer-aided design (CAD) software, using the 3D scanned limb as a reference for dimensions (AutoDesk Fusion 360). Before modelling it in a CAD programme, a few design concepts will be created by referring to the various adaptive assistive devices that are available to create the best design under the direction of an expert in rehabilitation. The study will only concentrate on the Fused Deposition Modelling method of 3D printing (FDM). In order to achieve the maximum accuracy for the mechanical properties, the 3D Printing settings will be as follows: 0.1mm layer height, 20% infill, 3 shell layers, and 4 top/bottom layers. For the analysis, only the commercial program AutoDesk Fusion 360 will be used to simulate Finite Element Analysis (FEA). Different kinds of materials will not be tested experimentally. Other options include using 3D Printing technology, which is significantly more affordable, produces devices more quickly, and allows for patient-specific customisation (Jonnala, Sankineni, and Kumar, 2023).

Consequently, the objectives of this project are to (i) design and develop a customized adaptive assistive device for a patient with brachial plexus injury, (ii) predict the performance of the design on the resulting stress and displacement, and (iii) fabricate the adaptive device using 3D Printing technology.

2. Methods

The project starts with the problem identification from the patient consultation. The concepts can be filtered by using the Pugh method. The final selection of engineering design was modelled using CAD software. A static finite element analysis was performed to predict the product performance before 3D printing fabrication.

2.1. Patient Consultation

In this stage, meeting with the patient was essential to identify and understand the problems before proceeding to generate ideas and concepts to develop a suitable device. The literature review and benchmarking were extensively explored to better understand. Thus, various ideas and concepts were successfully interpreted and generated based on different types of assistive devices (Ahmed and Al-Shammari, 2023; Scherb *et al.*, 2023; Rashid *et al.*, 2012). Figure 1 shows the process flow in this project. The project was initiated by patient consultation with the rehabilitation specialist to identify the problems. The process is followed by a 3D scanning process to capture digitization data of the patient for patient-specific device development. The idea and several concepts were then generated before coming out with a preliminary design. The detailed design was created and analysed computationally before proceeding to the fabrication and testing of the product. In the analysis stage, stress concentration and safety factors were part of the criteria to be considered for the pass-and-fail statement.

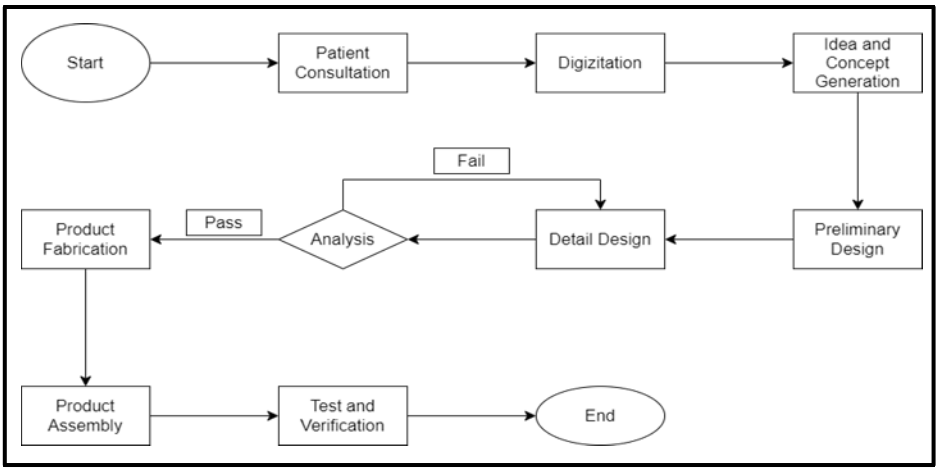


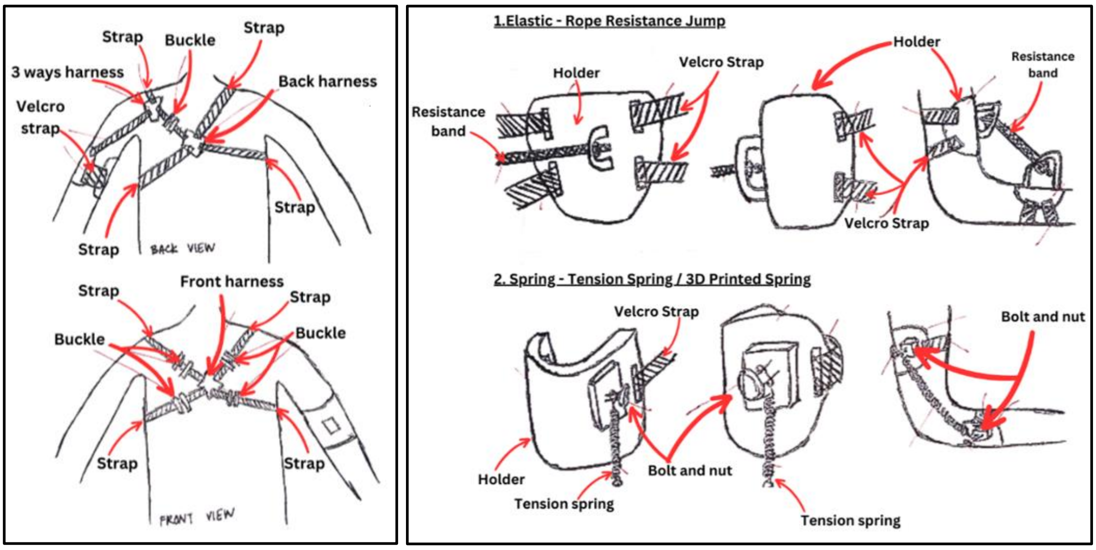
Figure 1 Project flow in developing the patient-specific adaptive assistive device

2.2. Conceptual Design

Several ideas to solve the problem were sketched to get better pictures of the solution. Figure 2 illustrates the proposed solution, which consists of (a) a harness and (b) an upper and lower arm holder. The purpose of the holder is to fit the patient's arm securely, preventing any movement or loosening. Additionally, a harness utilizing a customized strap has been proposed to support the fixation to the patient's body.

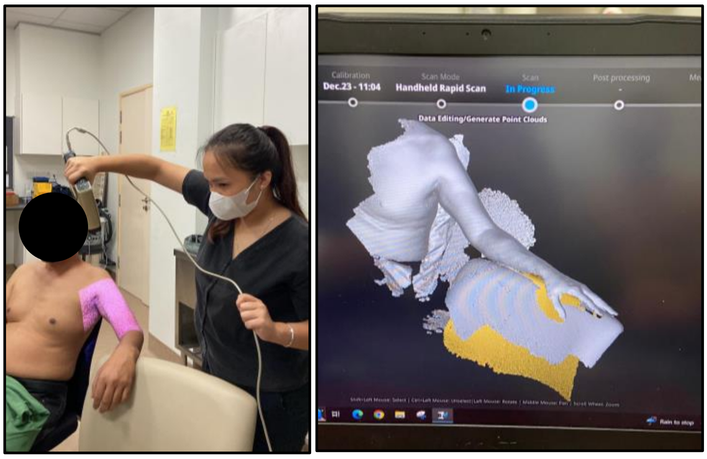
2.3. CAD Design and Modeling

3D scanning technology was adapted to capture the shape of the 'patient's arm. The scanning process was conducted at the Hospital Al-Sultan Abdullah, UiTM, under observation by a rehabilitation specialist using a handheld 3D scanner machine (Shining 3D, China). Figure 3(a) shows the 3D scanning process on the left arm (affected arm) of the patient, while Figure 3(b) indicates the raw images of the scanned data. The arm model was reconstructed and smoothened using Meshmixer software to obtain a precise and identical shape of the patient's left arm. To ensure that the design seems proportionate, the arm holder must resemble the geometry of the left arm. CAD software is used to design all parts of the device. Figure 4 illustrates the final design of the arm orthosis, which consists of two parts: (a) the upper arm holder and (b) the lower arm holder. After designing the arm using Autodesk Fusion 360, the file is converted to .stl files and then imported to the AutoDesk TinkerCAD software, as shown in Figure 5. This is for designing the slot for the resistance band and straps for the harness to be tied together.



(a) (b)

Figure 2 Sketches of the proposed assistive device, which consists of the (a) harness and (b) upper and lower holder

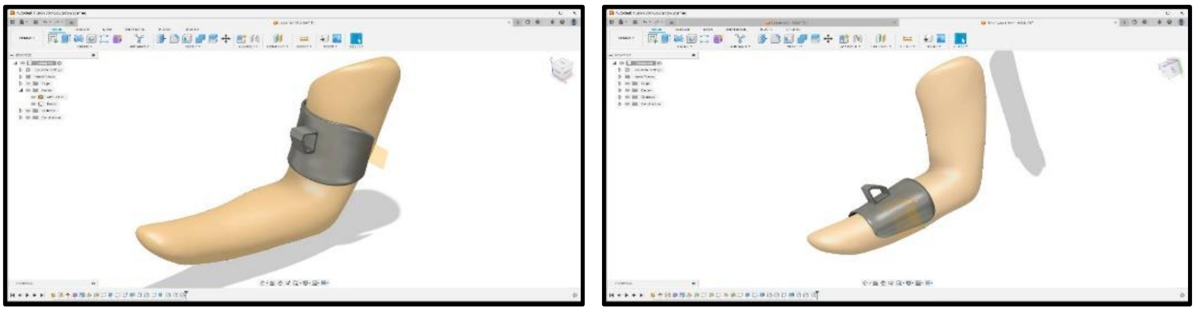


(a) (b)

Figure 3 (a) 3D scanning process on the left arm of the patient with the observation by the rehabilitation specialist, and (b) raw images of 3D scanned data

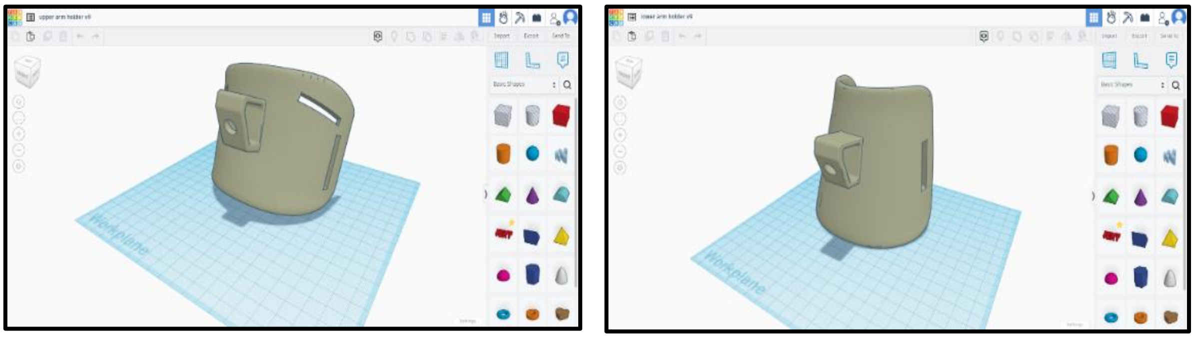
2.4. Finite Element Analysis

Computational analysis is the fundamental approach to predicting a 'product's strength, material selection, and optimized design, which is widely used in medical science and engineering design (Hamza *et al.*, 2023; Faadhila *et al.*, 2022; Ahmad *et al.*, 2020, Nor-Izmin *et al.*, 2020; Abdullah *et al.*, 2012). A static finite element analysis was performed to predict the 'product's performance before proceeding to 3D printing fabrication. This provided optimum parameter setting and design. The Autodesk Fusion 360 software was used for the static stress analysis on both upper and lower arm holders to observe the force-loading effects in the resistance band slot area of the holder. Two different materials, namely Polylactic Acid (PLA) and Acrylonitrile Butadiene Styrene (ABS), were evaluated to predict the suitability of these materials for the device.



(a) (b)

Figure 4 Designing the (a) upper arm holder and (b) lower arm holder using AutoDesk Fusion 360



(a) (b)

Figure 5 Designing the slot for the resistance band and strap harness for (a) the upper arm and (b) the lower arm holder using AutoDesk TinkerCAD

Figure 6 illustrates the loading and boundary conditions conducted in this study. The boundary condition (constraints) was set on the four-hole slots on the corners for the upper arm holder and two-hole slots on the corners (labeled in red line) for the lower arm holder where the strap of the harness is tied. Constraints are applied to a model to prevent it from moving in response to applied loads. A 10N structural load/force (labeled blue arrow) was applied onto the slot of the resistance band where the weight of the upper arm and lower arm react toward each other. The blue labels indicate the loading condition, while the red labels show the constraints. The resulting von Mises stress, displacement, and safety factors were the main focus of this simulation to assess the design's validity in real-world conditions (Farah, Anderson, and Langer, 2016).

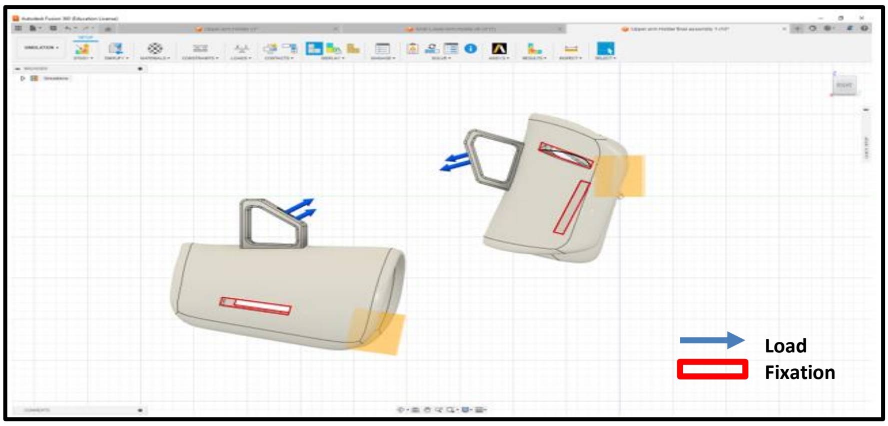


Figure 6 Loading and boundary conditions setting in the analysis

2.5. *Fabrication of the Assistive Device*

In the fabrication procedure, both the upper and lower arm holders were created using a 3D printer capable of working with PLA and ABS materials. The selection of these materials was based on their widespread availability and common use in the development of adaptive devices and prototypes, as highlighted in previous studies (Wahid *et al.*, 2022; Mazlan *et al.*, 2021). The design model was generated using Autodesk Fusion360 CAD software and then exported in stereolithography (.stl) format to the slicing software Ultimaker Cura. Subsequently, the file was converted into a g-code file for the Creality Ender-3 V2 after the slicing process. For both arm orthosis components, a thickness of 5mm and an infill density of 20% were selected for 3D printing manufacturing. These parameter settings were informed by prior research (Wahid *et al.*, 2022; Mazlan *et al.*, 2021; Hamzah *et al.*, 2019) while considering printing cost and orthosis weight. Safety factors and the weight-to-performance ratio were crucial in achieving a promising product. It's worth noting that increasing infill values will raise the young modulus and product weight (Mazlan *et al.*, 2023). Additionally, PLA filament, chosen for its ease of printing and higher stiffness compared to ABS, exhibits a tensile strength greater than 37 MPa. The upper arm holder required 12 hours for printing, while the lower arm holder took 14 hours.

3. Results and Discussion

3.1. *Comparison between PLA and ABS Materials*

The performance of both materials was compared on the resulting von Mises stress, displacement, and safety factor, as shown in Table 1 (a), (b), and (c), respectively. The maximum von Misses stress of PLA is observed to be higher in comparison to the ABS material, indicating a greater tolerance of stress imposed on the material's strength. However, PLA has a smaller maximum displacement than ABS, at 0.019 mm and 0.030 mm, respectively. The reaction forces and reaction moments are often produced by applied force actions. Structure failure can occur when reaction forces exceed action forces, resulting in fracture and corrosion. When comparing the two materials in Table 1(a), PLA had lower maximum reaction forces than ABS, indicating that PLA opposes less force from the applied force from the detachable arm orthosis, which is also influenced by gravity force. The most common approach to express a safety factor is as a ratio between a measurement of the maximum load that will not cause the stated type of failure and a comparable measurement of the maximum load that is expected to be applied. The factor of safety is the most straightforward and extensively utilized strategy in handling variability and uncertainty in engineering design (Nigro and Arch, 2023; Moreland, 2009). The application of safety considerations to ensure that a building can fulfill its intended function reduces the chance of failure to an acceptable level (Amitrano *et al.*, 2023; Sarma *et al.*, 2020). Both materials have the same safety factor of 15, which is relatively high and considerably above one, indicating that neither material will fail under the current conditions. As a result, PLA is superior to ABS as a suitable material for producing this arm orthosis. One of the reasons for choosing PLA is to save cost, and the failure difference between PLA and ABS does not affect the design of arm orthosis and the 'patient's comfort when using the arm orthosis.

3.2. *Prototype of the Assistive Device*

The prototype of the patient-specific assistive device was successfully developed and printed. Although the finite element analysis had been conducted earlier, issues of fit- to-patient and comfort are subjective and need to be tested on the patient. Therefore, the prototype of the device was essential to observe the highlighted issues. Design changes, revisions, and improvements were made to each 3D-printed prototype. The patient's feedback and observations are critical for obtaining the greatest quality 3D-printed arm orthosis. Table 2 illustrates the changes implemented as a result of patient feedback and observations during multiple attempts. Furthermore, Figure 7 depicts the fitting process with the patient, which directly contributes to the enhancement and modification of the device.

Table 1 Variation of (a) von Mises Stress, (b) Displacement, and (c) Safety factor for the assistive device at different material properties, namely PLA (left) and ABS (right)

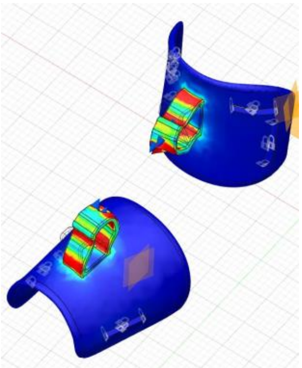
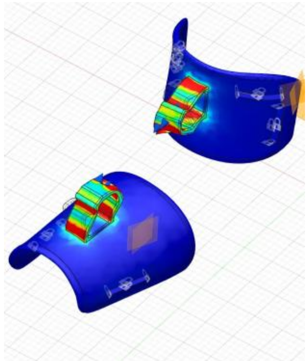
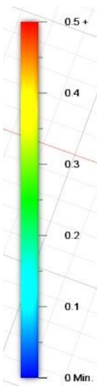
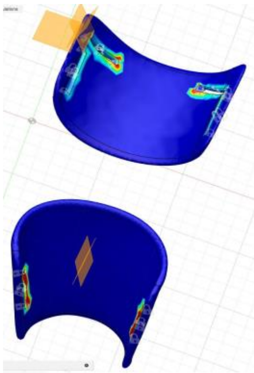
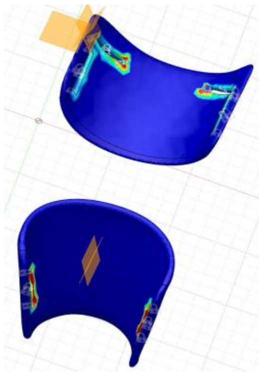
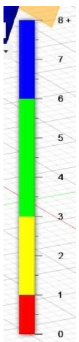
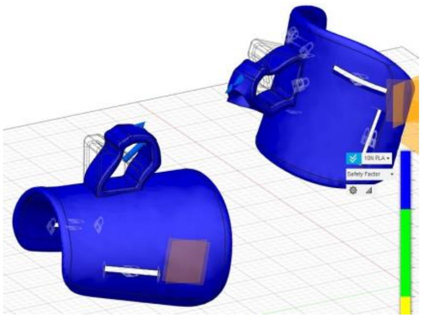
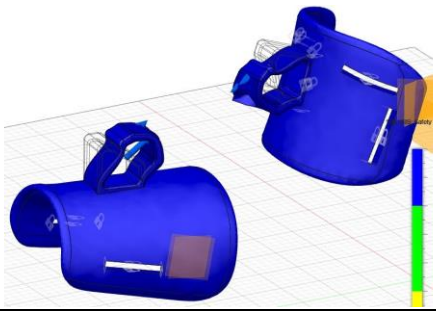
	(a) von Misses Stress	
	PLA	ABS
	Maximum von Misses Stress = 2.464 MPa Minimum von Misses Stress = 0 MPa	Maximum von Misses Stress = 2.451 MPa Minimum von Misses Stress = 0 MPa
		
	(b) Displacement	
	PLA	ABS
	Maximum Reaction Forces = 1.414 N Minimum Reaction Forces = 0 N	Maximum Reaction Forces = 1.421 N Minimum Reaction Forces = 0 N
		
	(c) Safety factors	
	PLA	ABS
	Maximum Safety Factor = 15	Maximum Safety Factor = 15
		

Table 2 Changes and modifications of the design model based on the patient feedback

Model	1	2
Upper Arm Holder		
	The presence of sharp edges and a small hole diameter for the resistance band posed concerns. Additionally, the harness system lacked security and exhibited a flimsy structure.	We have filleted the edges, increased the diameter of the hole to a larger size, and introduced a new slot for the strap harness.
Lower Arm Holder		
	The resistance band slot was difficult to secure and prone to slipping. Additionally, the overall weight of the holder proved too burdensome for the patient.	The slot for the resistance band has been redesigned, aligning it with the upper arm holder's design. The total weight of the holder has been adequately addressed and deemed satisfactory.

Figure 7 Patient fitting and testing the functionality of the device

4. Conclusions

A patient-specific adaptive assistive device for brachial plexus injury has been successfully developed. Computational analysis was employed to assess the strength of the arm orthosis under various parameter settings before proceeding with 3D printing fabrication. This device works in tandem with resistance bands secured to the arm holders. The final concept design was chosen through a rigorous conceptual evaluation method. The overall analysis, using different materials of the same thickness under the same load, indicated that PLA exhibited the highest stress and the lowest maximum displacement. Subsequently, the device was fabricated using 3D printing technology, with the choice of material based on the prior analysis. The resistance band acted as an elastic force, enabling the patient to perform daily activities more easily. One notable limitation is that the developed prototype has not undergone quantitative testing on the patient in this manuscript. At this stage, the project's focus has been on creating a prototype that offers an ideal fit for the patient and is functional. Further research is recommended to assess the performance of the printed product, ensuring the project's continuity and refinement.

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