ORIGINAL ARTICLE

3D Printed Assistive Writing Device for Phocomelia Patient

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ABSTRACT

Introduction: Phocomelia is a rare congenital illness that occurs at birth due to an inherited genetic disease or the thalidomide teratogenic impact. The patient had tetra-phocomelia, which caused her upper and lower limbs to shorten, making it difficult for her to write correctly. Thus, this project aims to develop an assistive device that will assist the patient in writing independently. **Methods:** Patient assessment, device design and analysis, and fabrication with 3D printing technology were all part of the product development process. The anatomical shape of the patient's limb was captured using a 3D scanner, and the socket design was sketched using the information. The different thicknesses of the socket were analyzed using finite element analysis to evaluate the product design. The device was then printed using the best parameter setting available. **Results:** The socket was designed in response to the demands and requests of the patient. One of the unique features was adjusting the fitment of a pen at various rotations and linear motion angles. The thickness of 3.0mm was found to be sufficient for printing the socket by computational analysis. Following that, the printed socket was delivered to the respective patient. During the device's functional evaluation, the patient demonstrated the ability to write her name clearly within 1 minute of recorded time with good readability. **Conclusion:** The finalized design of the socket was successfully analyzed and found to be safe. The patient fitted the socket well and was capable of writing appropriately, using the developed adaptive device.

Keywords: Phocomelia, Assistive Device, Finite Element Analysis, 3D Printing, Socket Thickness

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INTRODUCTION

Phocomelia is a rare congenital physical disorder that manifests as missing or shortening limbs at birth (1). It illustrates a radiological disease in which the shoulder joint is absent, and the bone is abnormally shortened. The teratogenic effect of thalidomide medications or inherited genetic abnormalities may contribute to the development of this clinical condition (2). One in every 150,000 births is estimated to have this clinical condition (3). This condition receives less attention than other disorders such as cerebral palsy or down syndrome due to its infrequent occurrence, lack of public awareness, and a lack of adequate technology to assist in managing this condition. To the authors' knowledge, no study has been conducted to date that aims to improve the quality of life for patients with this type of disability. Thus, this study was conducted to benefit both patients and caregivers. The purpose of this study is to demonstrate how product design, fabrication, and manufacturing processes can aid in and potentially improve the dysfunction associated with this condition. This study served as a model or demonstration of how technology can improve the quality of life for a patient diagnosed with a rare disease associated with certain types of disabilities. The study focused on a patient who is a student at a nearby school, and writing ability is a requirement for students participating in learning sessions. Due to her incapacity to write, the patient felt abandoned. Due to her extremely short upper limb and unsteady shoulder joint, she has difficulty writing

An assistive device enables disabled individuals to carry out daily activities with little or no assistance from others (4). The term "assistive device" is not limited to prosthetics and orthoses; it can also refer to something as simple as a walking aid that provides support while walking. It has decreased reliance on caregivers. There are no adaptive devices available for patients with tetra-phocomelia as it requires customized devices to fit the patient's upper limb perfectly. As a result, the best alternative was to develop a personalized product using 3D printing technology. Fused filament fabrication (FFF) is a 3D printing process that utilizes extruded molten thermoplastic material to create 3D objects layer by layer from a 3D model (5, 6). 3D printing's versatility and ability to fabricate complex geometrical shapes enable customization of specific anatomical features (7).

To the best of the researchers' knowledge, there is a shortage of multidisciplinary methods integrating 3D Printing technology in the prescription and development of such devices in our local clinical setting, particularly for rare diseases and complex disabilities. It is critical that the adaptive assistive device developed is conformed to and customized to its disability and needs. The current traditional method is only confined towards what is available in the clinical setting, which 'doesn't involve the technical expert, lack of sophisticated technology, materials, and designing skills. Hence, customization is difficult to be achieved especially in a device that requires complicated biomechanical features considerations.

The main objective of this study is to design and fabricate a device that will aid a patient diagnosed with tetra-phocomelia in performing daily living activities. The patient requested a function that would assist her in writing solely with her upper limb. There is no other role to be considered in this study. The second objective is to analyze the effects of various device thicknesses before initiating 3D printing fabrication. Perfect fit, lightweight, and safety are critical components of this process. The assistive devices need to be correctly designed and fabricated to accommodate the patient's specific impairment, functional limitation, and anatomical characteristics. This step is critical to ensuring that the device performs as intended, safe, and comfortable to use regularly (8). This study served as a model for developing a similar device for a condition characterized by comparable physical disabilities.

MATERIALS AND METHODS

This study involves four (4) significant steps in developing the assistive device, which is (i) patient's assessment, (ii) product design, (iii) computational analysis, and (iv) fabrication using 3D printing technology.

Patient assessment

A rehabilitation physician evaluated the patient. The assessment will determine the patient's ability to lift and her remaining limb's angle of freedom. She has a mild reducible scapulohumeral subluxation with a range of motion (ROM) of 90 degrees forward flexion, 70 degrees abduction, and 0 degrees adduction, all of which are classified as 5/5 by the Medical Research Council (MRC). The residual right limb is approximately 130mm in length from the scapulohumeral joint to the distal tip. She is a right-side dominant individual who performs most of her activities by manipulating the right shoulder joint. However, due to the lengthy rigid column spinal stabilization surgery for scoliosis, truncal forward and lateral bending are severely restricted, limiting her movement and shoulder joint manipulation to perform her daily activities. She made no complaints about the pain associated with scapulohumeral joint movement. Following the evaluation, the anatomical shape of the patient's limb was scanned at approximately 30cm from the limb using a hand-held 3D scanner (Sense3D) to obtain the correct size, measurement, and geometric shape of the limb illustrated in Figure 1A. This information is critical for designing a customized socket that fits the patient properly. The process may need to be repeated several times to achieve the best result with no or very little noise on the scan. Standard Triangle Language (STL) files are used to save the data.

Device development

The raw 3D scanned data was processed and filtered to remove the undesired surface and noise using Meshmixer software. The scanned file was used as a reference to create a customized socket that perfectly fit the patient. It is to ensure a good fitting and comfort during the donning process of the device. The socket design was developed based on three previous writing aid products, as shown in Figure 1B. Each product has different concepts and approaches which may not be suitable to the dedicated patient. Thus, the best idea was identified and adapted to improve socket development. A commercial Computer-Aided Design (CAD) software, AutoDesk Fusion360, was used to design the 3D model of the socket that best fit with the scanned limb data (Figure 1C). Five models with different socket thicknesses (3.0, 3.5, 4.0, 4.5, and 5.0mm) were developed to determine the best thickness performance to the weight ratio.

Computational analysis of the device

The device was analyzed using finite element analysis to predict the device's performance at different thicknesses. The socket was designed at various thicknesses, which were 3.0mm, 3.5mm, 3.5mm, 4.0mm, 4.5mm and 5.0mm. Factors of maximum stress, displacement and performance to the weight ratio are the parameters to be investigated. The socket model was assigned as polylactic acid (PLA) material by Polymaker with 20% infill density. The maximum tensile strength for the material is defined as 46.6MPa as published by the manufacturer, Polymaker. The model was mesh using tetrahedral elements and analyze using CAD software, namely CATIA v20. The loading condition of upward force at 10N was applied, which imitating the power needed to write (max force exerted to the pencil) and fixed at the strap slot, as illustrated in Figure 1D.

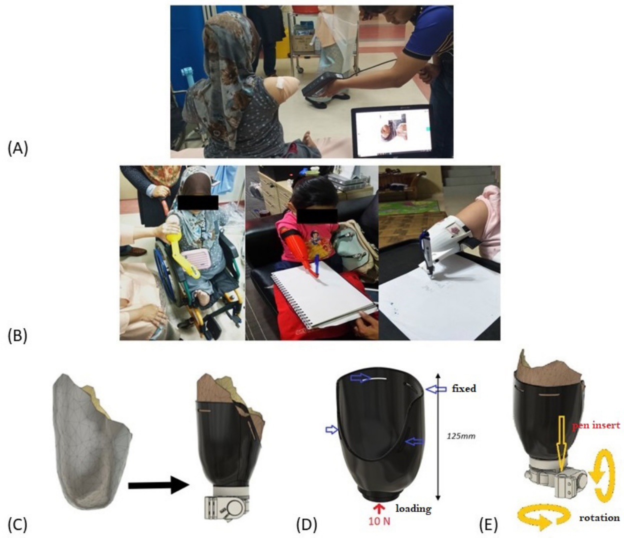

Figure 1 : Several processes in developing the assistive device **(A)** 3D scanning of a patient's limb using a 3D scanner to get the anatomical shape of the limb. **(B)** Different designs of the writing assistive device were available before. They were set as a reference to create a better device. **(C)** The 3D scanned limb data was established as a guide to creating a customized and patient-specific socket. The fitment of the socket to the patient's limb has ensured a snug fit and better comfort. **(D)** Loading and boundary conditions are applied in the finite element analysis to predict the performance of the socket. **(E)** The final design of the socket with two adjustable rotations and pen socket fitting.

Device fabrication and outcome

The socket was fabricated based on the results of the computational analysis. To demonstrate the socket's functionality, it was 3D printed in sections and assembled. The CAD file was exported as an STL file format into a slicer software for the 3D printing process. The data was converted to a G-Code file that could be read by the 3D printer and used to initiate printing. Polymaker's polylactic acid (PLA) material was used at the factory-recommended printing setting of 3 wall perimeters and 20% infill density. The finished product included a harness that provided external support for the socket, ensuring a secure fit and stability during writing.

RESULT

Design of the writing assistive device socket

The development of the socket design had considered all comments and feedback during the patient assessment and previous devices. The cross-sectional dimension of the socket needs to be a bit smaller in measurement compared to the actual size of the limb to ensure a snug-fitting socket. The socket was attached with an adjustable fitment for the pencil, rotating in two angles and linear motion (Figure 1E). It allows for the best writing position for the patient, and the setting could be locked at the preferred position. The pencil holder is adjustable to accommodate different types and sizes of writing tools such as pens, markers, and paintbrushes.

Effects of Different Thickness of the Socket

Due to the integral role of the socket in the whole device development, the analysis was carried out only to the socket part to ensure the device is safe and not causes harm to the patient without compromising the durability, as it is attached directly towards the residual limbs. The socket performance shown in Figure 2A indicates the variation of von mises stress and the correlation between the socket thickness to the maximum stress and product weight. The high stress was predicted at the strap slot in all models, suggesting that stress is dominant within the thin structure. The socket with 3.0mm thickness indicates the highest stress with minimum product weight. Meanwhile, the thicker socket has minimized the maximum stress but increase the product weight. Figure 2B shows the safety and performance-to-weight ratio for the assistive device at different socketthicknesses.

Fabrication and testing of the socket

The final design of the assistive writing socket was selected based on the computational analysis findings. The fabrication of the socket was conducted on a 3D printer, model Creality CR-5 Pro with the recommended setting from the factory, which was 60mm/s printing speed, three wall perimeters using 0.4 nozzles, 20% infill with four layers of top and bottom surface. The printed socket was supported with a custom-made leather harness to provide extra support and stability. Besides, it distributes the device load to other parts of the body and enhances body fitting, as shown in Figure 3A. Figure 3B portrays the device fit to the patient and the ability to write independently with the assistive device. The device only assists the patient in controlling the motion of the limb in two different rotations. Previously, the patient could not handle it due to the absence of a joint on the lower arm. Before testing, the harness and socket were fitted and adjusted to the patient to comfort the patient.

The patient was allowed to get comfortable moving around the device before the patient was tested for a writing test. She was given a pen and a paper on a table (adjusted to suit the patient's height on a wheelchair), and others were not allowed to aid her in the test.

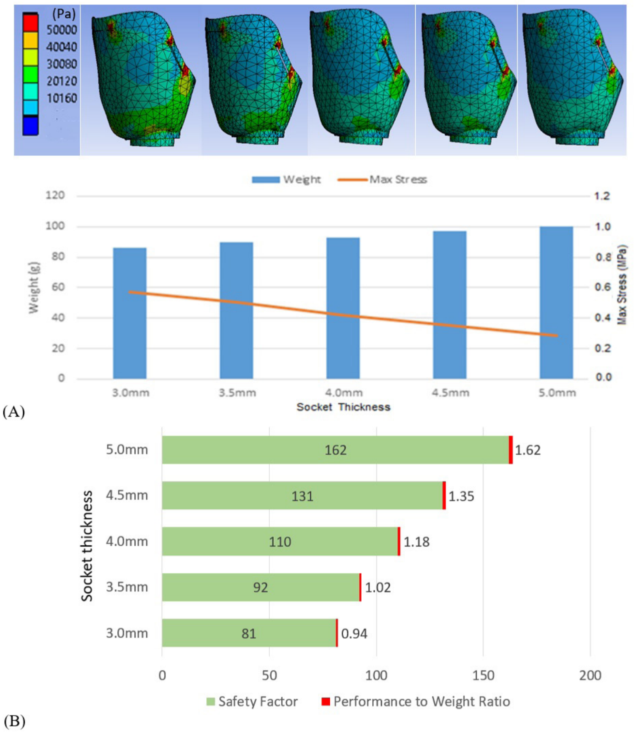

Figure 2 : Effects of different socket thickness in developing the assistive device (A) Variation of von mises stress, maximum stress, product weight, safety factor, and performance to weight ratio of the assistive device at different socket thickness (from left) 3.0mm, 3.5mm, 4.0mm, 4.5mm, and 5.0mm. The findings are evaluated to select the best parameter to print the socket. **(B)** Correlation between socket thickness to the product weight and maximum stress of the product. A thicker socket has minimized the maximum stress but has increased the product weight.

Functionality Device Assessment on Writing Performance

During the device's functional evaluation, the patient demonstrated the ability to write her name clearly within 1 minute of recorded time with good readability. Linear, horizontal and curve lines can be performed by presenting the ability to draw flowers. She did not complain of any pain or discomfort during the donning of the developed device.

DISCUSSION

It is essential to understand the patient's clinical and functional condition by assessing the patient first with the guidance of a rehabilitation physician specialist. A rehabilitation expert assessed the patient to understand the patient's capability, limitations, and functional requirements. Besides, it is also essential to ensure that the device is safe and does not cause any harm to the patient. The 3D scanning process needs to be conducted delicately to reduce any unnecessary noise in the raw file data and thoroughly cover the whole area of the required limb. It is to avoid errors during the editing process, which may require the patient to be scanned again. The 3D scanned file was used as a reference to sketch the socket device for the best fitment and to avoid any sharp edges or open spots within the socket. It is to give a better patient-specific value for the device itself. The previous devices (as illustrated in Figure 1B) had failed to adhere to the patient's limb due to the absence of a locking mechanism. The weight of the device also was too heavy to be lifted by the patients. The device's current design was made to make sure the socket would cover most of the limb for better adherent and lightweight. Besides, the invention is to allow the pen to be adjustable in two rotational axes. Since the patient has the upper arm segment, she can only control one rotational axis for movement of the limb, thus limiting the pen placement and writing for the patient.

Figure 3 : Fabrication and testing process (A) The socket was supported with a harness to allow better fit and adherent to the patient's limb and prevent the socket from loose off the limb. **(B)** The patient fit well with the devices and manage to write on the first trial

The need for computational analysis was determined to identify the most critical part of the whole design. It can reduce the risk of failure part after fabrication. A 10N of axial force is considered in the analysis to present the maximum strength the patient could exert using her limb. The physical condition had limit maximum loading to the socket. The force was applied at the bottom part as the pressure was exerted from the pen extension. The maximal stress occurs at the 3.0 mm socket thickness, which is only 0.573MPa, while the maximal tensile strength of the material is 46.6MPa. Thus, the safety factor of the socket is 80, and the values are acceptable and safe. The other socket with a higher thickness also demonstrates a higher safety factor with lower maximum stress. The thicker socket has minimized the maximum stress and increase the safety factor. However, the product weight has increased and may not be comfortable for the patient. Besides, the higher safety factor implies that the design was over design and may cost a higher price. The socket with 3.0mm thickness was selected despite having a minor performance to weight ratio as it appears to be lighter than other thicknesses. The device needs to be lightweight due to the short limb of the patient. It has provided less surface contact, and the unstable shoulder joint holds the device's load.

The fabrication of assistive sockets using 3D printing technology had proven the engineering capability to develop a customized and patient-specific device. Besides, the method was also cost-effective, giving future hope to a patient with rare disease disabilities. Inter-disciplinary work between the medical practitioners and engineers has expedited the process and minimized any errors. Besides PLA material, the availability of different materials such as ABS, TPE, PETG, and Nylon (6, 7) at reasonable prices and various colors will allow customers to customize the products. Furthermore, the fabrication process may also be conducted using a standard desktop 3D printer available in the market. The current socket device should pair it with a harness due to the limited contact surface on the limb, making it hard to maintain a firm grip on the limb. The harness was also to reduce the force needed to maintain a grip on the limb as it may cause discomfort in the long run. The patient could move and control the pen using the device without any help from others when writing. The patient could not note before using the device; thus, a comparison between before and after using the appliance cannot be shown.

Long-term assessment of the device is required to assess the conformability, usability, durability, and functionality after some periods are given to the patient to allow such device adaptability. How the device significantly improves her quality of life should be measured objectively.

CONCLUSION

The development of an assistive writing device for tetra-phocomelia patients was successfully achieved. Patient assessment, computational analysis, and 3D printed technology are essential methods to predict the performance of the developed device. The socket thickness of 3mm demonstrates the best safety factor, performance to weight ratio, and minimum weight compared to other models. The device has served its intended function and is reasonably fit for the patient. However, the design may need some improvisation in the future to attain any feedback from the user. The study would be more accurate if there were more significant sample sizes, but due to the condition's rarity, it was only limited to 1 sample size. This research would be an excellent reference in the future for a similar related assistive device for the procedure. Similar studies may follow the methods or improve as needed to develop other devices that may be used for different kinds of the patient with different types of disabilities. It is a starting point for improving the quality of life for the disabled.

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