AN INDIGENOUS DESIGNED EXCURSION AMPLIFIER FOR SHOULDER DISARITICULATION PROSTHESIS

V. Nandhini[1], Parthasarathi Swain[2], Dewendra Prasad[3]

[1]B.P.O. Intern, National Institute for Empowerment of Persons with Multiple Disabilities (Divyangjan), ECR, Muttukadu, Kovalam Post, Chennai-603112, Tamil Nadu

[2]Assistant Professor (P&O), National Institute for Empowerment of Persons with Multiple Disabilities (Divyangjan), ECR, Muttukadu, Kovalam Post, Chennai-603112, Tamil Nadu

[3]BPO Programme Coordinator, National Institute for Empowerment of Persons with Multiple Disabilities (Divyangjan), ECR, Muttukadu, Kovalam Post, Chennai-603112, Tamil Nadu

Corresponding Author: Parthasarathi Swain
Assistant Professor (P&O),
National Institute for Empowerment of Persons with Multiple Disabilities (Divyangjan),
ECR, Muttukadu, Kovalam Post, Chennai-603112, Tamil Nadu
9101510331
parthampo9@gmail.com

ABSTRACT

Background: *The main problem with shoulder disarticulation prosthesis is to generate sufficient muscular force for the prosthetic operation due to higher level of amputation. Such amputee lost anatomical shoulder joint that restrict active shoulder range of motion and ultimately lack excursion. The excursion amplifier makes it possible to convert available muscular force and ROM into additional excursion. A body-powered prosthesis becomes more effective when both excursion and force are used efficiently.Considering this designed and developed excursion amplifier, which can convert a small force with large excursion with less energy expenditure & improve prosthesis function and user satisfaction.*

Objective: *This study aimed to design an Indigenous Excursion Amplifier for Shoulder Disariticulation Prosthesis which will provide more excursion convenient for actuation for shoulder disarticulation/ higher level of upper extremity prosthetic control.*

Study design: *Single-Case study*

Methods: *A 31-years-old adult male unilateral shoulder-disarticulation amputee was reported to the institute and was fitted with the newly Indigenous Excursion Amplifier in the Shoulder Disariticulation Prosthesis & improve prosthesis function and user satisfaction. The excursion measurement test was conducted with the newly designed excursion amplifier.*

Results: *Santschi WR, 1958: Study suggests that to perform most efficient function of SD prosthesis the minimal excursion 2:1 ratio is required. Based on such studies the newly developed combined excursion amplifier is designed such that it provides 2.5:1 excursion ratio, i.e when 3.2 cm excursion generated by patient it converted to 8 cm excursion displacements of S-lever design and it sufficient for full operation of Shoulder disarticulation prosthesis.*

Conclusion: *The basic idea of this new designed born to overcome the limitation of the prosthetic operation, acceptance and comfort. To obtain a better efficacy of the shoulder disarticulation prosthetic management and to avoid the patient rejection, we have combined the S- lever & Pulley type excursion amplifier. In this way it has increased the amount of cable excursion with a ratio of 2.5:1, therefore patient can generate more excursion with an application of least amount of force.*

Keywords: *Body powered prosthesis, Excursion amplifier, Shoulder disarticulation, 3D printing Techonolgy.*

INTRODUCTION:

The successful use of the prosthesis by the amputee is governed by the effectiveness of the harness in capturing substitute motions, and by the skill and judgment of the prosthetist in fitting the harness. The cable control system must transmit muscle power as efficiently as possible to enable the amputee to obtain a maximum of prosthetic function with minimal efforts. The fundamental pattern for a shoulder amputee harness consists of a chest strap along with a dual control cable system. In higher level of upper limb amputee faces challenges in operating the prosthesis effectively and comfortably with the basic shoulder harness, an add-on mechanism (Newly designed excursion amplifier) has proven to be beneficial for them. This modification entails adding a combined excursion amplifier.[1]

The design and development of an Indigenous modified excursion amplifier for shoulder disarticulation body-powered prosthesis is a significant endeavour. Typically, an excursion amplifier is devised for amputees who struggle to operate the prosthesis with the basic shoulder harness due to insufficient excursion in term of limited Range of Motion and aviable muscle power in the amputeed shoulder. The author believes that the most effective excursion amplifier is a mechanical device that converts a lesser amount of force into increased excursion to facilitate the operation of the prosthesis. Designs employing levers and pulleys or sheaves have shown some degree of success in achieving this enhanced excursion.

It is important to transfer the effect of the shoulder action efficiently for improved prosthetic function. Where body action is transferred through a harness, an ordinary upper limb amputee may produce a cable excursion of about 100mm and a force of about 100N or more. A body-powered prosthesis becomes more effective when both excursion and force are used efficiently. For this purpose a force transfer mechanism using a pulley and a harness and utilising a housing containing a highly slippery plastic (UHMW) liner was developed.[2]

The lever-type excursion amplifier Design operates on a ratio of approximately 2:1. This means that 1 inch of excursion, with a force of 4 pounds exerted by the amputee, is converted to 2 inches of excursion with a force of 2 pounds. On the other hand, pulley or sheave-type excursion amplifier Design which can be externally or internally installed on the prosthesis. Externally mounted design is limited to a 2:1 ratio of amplification, whereas internally mounted design have constraints in their range of amplification.[1]

In this Reserch project an effort was made to design fabricate, fit an indigenous-designed excursion amplifier and perform single case study to know the excursion amplification efficacy in shoulder disarticulation prosthesis.

MATERIALS AND METHODS:

Single-Subject Case Study

An adult 31 years male unilateral shoulder-disarticulation amputee reported at National Institute for Empowerement of Persons with Multiple Disabilities (Divjangjan) [NIEPMD] for fitting of Functional Body Powered Prosthesis. He was referred to the Material Development-Aids & Appliances / Prosthetics and Orthotics unit for the fitment of a suitable prosthetic management. Right Shoulder disarticulation amputation was performed due to osteosarcoma in year 2020. After detail assessment and examination body-powered shoulder disarticulation prosthesis with modified excursion amplifier was prescribe. The informed written consent obtained from the patient to participate in this study, and appropriate approval was also obtained from the Institutional Ethical Committee. A detailed assessment was performed with demographic data, medical history, radiographic image, and functional outcome. The standard Shoulder Disarticulation Prosthetic fitment protocol were followed with the newly design modified 3D printed excursion amplifier.

Fig-1:Rt. Shoulder Disarticulation Amputee

DESIGN CONCEPT:

Stratasys F370 3D printer and GeoMagic Design X and Grab CAD system was used in desging and printing the 3D excursion component available in NIEPMD, Chennai. The component wasprinted with ABS-CF10 as Model material and QSR(Quick Support Relief) as support material. It has two major components:

1. S-Lever Design
2. Pulley Design

1. S-Lever Design:

It is an S-shaped lever works on principle of IIIrdcclass lever mechanism. The S-Lever design is affixed to the posterior shoulder body socket at the mid- scapular level. It is attached vertically, featuring three holes. The proximal hole is connected to a Fulcrum (equipped with ball-bearings) on the socket. Middle hole is connected to the control cable and distal hole is connected to the harness. The lever designed having dimensioned: - Length- 6 cm and Width & Height - 1.5cm.

Working Mechanism: When the patient activate the prosthesis with help of biscapular abduction that time s-lever distal hole, which is connected to the harness will be move towards the sound side, the middle hole part generate the excursion as it is connected to the control cable of terminal device followed by the lower hole.

Fig-2: S-Lever Design Model

2. Pulley Design:

It works on principle of pulley system. It is placed on the forearm shell. The Pulley type is designed with one centre holeand riveted to the forearm shell and 2 slot pulley in which one slot around the pulley provide channel for proximal cable and another slot for terminal device Control Cable. The pulley designed having dimensioned: - Diameter 4cm and Length-1.6 cm.These 2 design first draw 2D diagram on CAD and correct the measurement of the design, then convert to 3D diagram use of **AUTO CAD software.**

Working Mechanism: The Pulley Design is positioned on the proximal third of the forearm shell of the prosthesisat lateral one third. It is linked to the S-Lever design of middle hole connected to the control cable. This design features two slots: one slot for the proximal cable it is surround the pully and another slot intended for the terminal device attachment. Once the control cable voluntarily activated voluntary by the user, the pulley rotates in clock-wise direction and the proximal cable engaged over the slot and the same time the distal cable engaged to open the terminal device. Once the control cable is disengage by the user the working principle works reverse.

Fig-3: Pulley Design Model

FABRICATION PROCEDURE:

a) 2D&3D : AUTO-CAD

b) SOFTWARE : Geo magic Design X and Grab CAD

c) 3D PRINTING MACHINE : STRATASYS F370

d) MATERIALS : Model material (ABS-CF-10) and Support material (QSR- QUICK SUPPORT RELIEF)

e) TIME DURATION : 4 Hours

In fabrication process, preparation starts to make a layout of the entire design, that represent the overall shape, which includes elements like circles and S- shaped curves. Following this, provide specific measurements and dimensions such as length and width, tailored to the prosthesis size. Once these details are finalized, a comprehensive blueprint of the model was created.

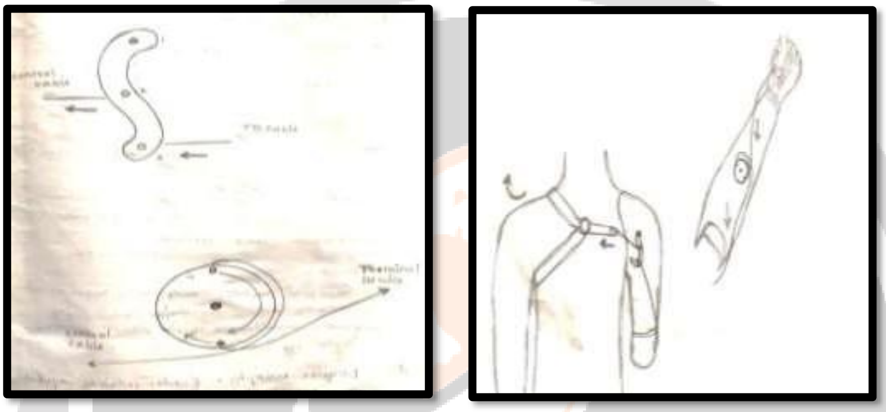

Fig-4: Layout of S-Lever design and Pulley design

Subsequently, proceeded to develop a 2D diagram using the AUTO-CAD software for more precisize and details in the design. Using the 2D commands to design the S- lever and pulley with accurate dimensions.

3D Fabrication Procedure:

In AUTO-CAD App, first to make the 2D models of S-Shaped & Pulley design following step-by-step 2D commands. Firstly, for the S-shaped design, we access the AUTO-CAD App and employ the 'x-line' command to generate a construction line on the screen. Next, the cursor is directed to the centre point to create three inner circles along the x-axis line (3mm, 6mm, and 3mm). These three inner circles are then used to form outer circles (15mm), seamlessly connecting to each other by use of 'TAN TAN circle' 2D command. Any surplus lines subsequently were erased and trimmed by using respective 2D commands. The diagram is zoomed in on to ensure there are no gaps between the lines and boundaries, ensuring that all components are integrated into one cohesive diagram. Auto-CAD's dimensioning tools are crucial in producing precise and comprehensive 2D drawings of S-shaped design . The final 2D diagram of the S-shaped design is saved in the (.obj) file format as it is convenient for 3D Printing machine (Figure-5).

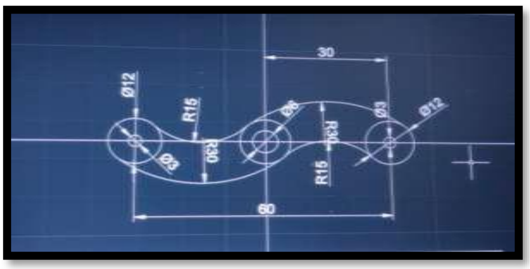

Fig-5: 2D-Diagram of S-Lever Design

For the Pulley-shaped design, the same procedure were followed with some variations in commands due to the shape variation of the object. Primarily, the 'circle dia' command was utilized, inputting inner dimensions of 6mm and 40mm outer dimensions to draw the circle. Additionally, a mid-circle is created for the cable path slot, with dimensions of 3mm and 3mm for the two circles. Following this, inspected for any overlapping and extraneous lines and trimming them as necessary. The dimensions are then verified, and the final 2D diagram of the Pulley-shaped design saved in (.obj) file format (Figure-6).

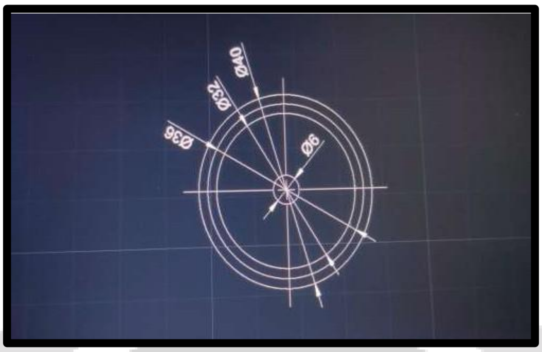

Fig-6: 2D-Diagram of Pulley Design

Before commencing with 3D modelling, it's crucial to fine-tune the 3D views, orbits, shades, and World Coordinate System (WCS). The initial step involves placing the 2D drawings of the Pulley design and S-Shaped design on the screen. Subsequently, all faces are extruded using the 'add' command, with the Pulley design having a thickness of 16mm and the S-Shaped design a thickness of 15mm.

The height of extrusion is specified, followed by executing the extrusion of the objects. Afterward, the design is rotated to thoroughly examine all angles and three-planar views. The objects are selected, specifying the first axis point and the angle of rotation. If any necessary corrections required at this stage need to be correct. The 3D drawing is then saved in the (.stl) file format (Fig-7 and Fig-8).

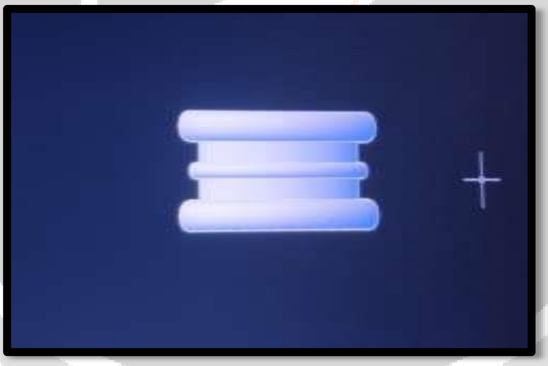

Fig-7: 3D-Diagram of Pulley design

Fig-8: 3D-Diagram of S-Lever design

Next, the process moves to the Grab CAD software, where the 3D objects were saved, and a slicing process is undertaken to adjust the object's height, printing timing, and to generate machine-readable instructions for the printer. This data is then transferred to the STRATASYS F370 printer with help of pendrive, 3D Printer operates on the principles of Fused Deposition Modelling (FDM). The printer employs two materials for printing: ABS- Carbon Fibre-10 for the model and QSR (Quick Support Relief) for support material.

The printing process for both the S-Shaped and Pulley designs were initiated. After two hours the final 3D model of S-Shaped & Pulley design printed , the printing build tray removed from machine and use water soluble machine for cleaning and removing the support material. Then the final 3D printed model of s-shaped design and pulley design is ready for fitment & trail in prosthesis (Figure-9).

Fig-9: Final 3D printed of S-lever and Pulley Design

The process begins with the creation of the Shoulder Disarticulation Prosthesis, followed by a thorough assessment of the patient's needs and precise measurements. Manual fabrication procedures are then carried out. These includes assessment, measurement, marking the landmarks, and performing the casting procedure. Subsequently, the negative cast is poured with a mandrel. Afterward, the positive mould undergoes necessary modifications and rectifications.

The flexible socket is draped, with help of flexible Polypropylene sheet and then outer body socket made of plastic lamination and then attention turns to preparing the forearm section with a wrist collar, as well as the arm section with a turntable, do prepare modification with help of measurements and Laminates are applied to all sections, and trim lines are carefully cut, followed by the smoothing of the shoulder socket and forearm socket. Finally, all components are aligned with the elbow unit, wrist unit, and terminal device. And then attached the newly designed excursion amplifier on shoulder disarticulation prosthesis to improve its functions and operations (Figure-10).

Fig-10: Newly designed excursion amplifer with SD prosthesis

RESULT & DISCUSSION:

Around the prosthetic field, the two major issues seen in the operations of prosthetic limbs are that either required more energy consumption or limited control mechanism. However, in this project a novel design concept attempted to reduce cost as well as make the prosthetic operation easier. This design requires the patient to use his healthy shoulder and bi-scapular abduction for actuation of the excursion amplifier, but with significant reduction in actuation force requirement.

OUTCOME MEASURE	EXCURSION	TERMINAL DEVICE (TD) OPENING
Standard SD Prosthesis	5	5
Newly Designed Excursion Amplifier	3.2	8

*All measurements are in "cm"

Table-1: Statistical Results

In this study, the patient has participated and provided the prosthesis followed by the documentations of information sheet and the informed consent. The patient was fitted the prosthesis with the newly designed excursion amplifier and checked the excursion and effectiveness of prosthesis. On the trail & fitment day the newly designed excursion amplifier along with prosthesis had been provided to the participant and given 2 months of usage period. After 2 months the patient had been called to check the excursion and effectiveness of prosthesis. After the usage period,it is found that the patient was generating 2.5:1 excursion to operating the prosthesis comfortably with improved patient compliances.

The embedded excursion amplifier system appropriately drives the control cable of TD to open or close with required graspping force to hold various commonly used items such as a glass of water. The patient can grip objects of various sizes and also control the magnitude of graspping force through hshoulder movement. This dual excursion amplifier unit was designed, developed and applied on a SD amputee and found to be effective.. It achieved the goal and overcome the issues faced by the SD amputees i.e.; the subject utilizes maximum force to functioning the prosthesis and with a low energy expenditure.

Santschi WR, 1958: Study suggests that to perform most efficient function of SD prosthesis the minimal excursion 2:1 ratio is required therefore, 1 inch excursion with a force 4 pounds exerted by the amputee converted to 2 inches excursion with a force of 2 pounds[1] . Based on such studies the newly developed combined excursion amplifier is designed such that it provides 2.5:1 excursion ratio, i.e when 3.2 cm excursion generated by patient it converted to 8 cm excursion displacements of S-lever design and it sufficient for full operation of Shoulder disarticulation prosthesis. So, this mechanical invention helps to carry out daily living activities with a less energy consumption.

Fig-11: Shoulder disarticulation Prosthesis with newly designed excursion amplifiers with patient

(Anterior view and Lateral view)

CONCLUSION:

The basic idea of this new design born to overcome the limitation of the prosthetic operation, acceptance and comfort. To obtain a better efficacy of the shoulder disarticulation prosthetic management and to avoid the patient rejection, a combined S- lever & Pulley type excursion amplifier was introduced. In this way it has increased the amount of cable excursion with a ratio of 2.5:1, therefore patient can generate more excursion with an application of least amount of force. The first experimental test on a shoulder disarticulation amputee with the prototype of the newly designed excursion amplifier attached with the properties is shown. The results show that the S-lever & Pulley type excursion amplifier can be really innovative and prescription feasibility option for shoulder disarticulation and higher-level upper extremity amputee population.

Future research in excursion amplifier can be expected to influence redesign of desirable operational characteristics of the shoulder disarticulation prosthesis now available and to encourage the development of wholly new and improved prosthetic components and required more sample size to get clinical validation.

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