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A SIMPLIFIED INTEGRATION SYSTEM FOR THE FABRICATION OF TOTAL SURFACE BEARING TRANSTIBIAL SOCKET BY EMPLOYING RAPID PROTOTYPING TECHNOLOGY

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ABSTRACT

This project is to validate the preliminary result of rapid prototyping (RP)-based transtibial socket that was reinforced by wrapping a layer of unsaturated polyester resin. By employing contemporary technologies including a scanner, computer-aided engineering systems, a rapid prototyping machine, together with the expertise of a prosthetist, RP-based prosthetic sockets with a comfortable fit to volunteer amputees can be fabricated. However, the expensive cost and complex procedure of using current commercial scanners and CAD systems will be barriers experienced by clinical professionals. As the existing service bureau infrastructure and cheaper RP technology are easily accessed, fabrication and technology cost barriers will be reduced. The remaining problems include the availability of easily-used CAD systems for designing prosthetic sockets, simple scanner and stump duplicating tool. This study therefore focuses on the integration of simplified systems including a vacuum forming tool, compact scanner and an interface system for designing prosthetic sockets.

Although the type of PTB (patella tendon bearing) transtibial socket is widely adopted in plaster-based manual process, TSB (total surface bearing) sockets are more acceptable by amputees. Since the concept of TSB socket should obtain the stump mold of an amputee under appropriate pressure by using a specific stump forming tool, editing complex surfaces can be avoided when using a TSB-based stump model to design a socket. The quality of socket fit is expected to improve by a simplified design process in which an interface system based on grid-editing algorithms is utilized.

In addition, cheaper RP technology, such as 3-D printing or droplet binding process, can be alternative means to fabricate RP-based prosthetic sockets. By combining TSB stump mold, simplified design process and a cheaper RP machine, this study proposes a simplified integrating system to manufacture RP stump mold. Using this RP stump mold together with the traditional lamination method of infiltrating resin into cotton layers, the RP-based transtibial sockets will then be fabricated easily. The expected result will demonstrate the feasibility of employing cheaper emerging technologies to assist an unskilled prosthetist who will be able to produce good quality of prosthetic socket.

Keywords: Transtibial socket, Rapid prototyping, Below-knee stump, Vacuum forming tool, Total surface bearing socket

INTRODUCTION

For transtibial amputees, the patella tendon bearing (PTB) prosthesis (Fig. 1) is the most widely adopted type of prosthetic devices. The socket should be custom-made for each individual amputee and affects the comfortableness of wearing the prosthesis. Figure 2 shows the process of fabricating a PTB socket by using plaster-based method. There are five main steps: Step 1: getting the negative mold of the stump; Step 2: duplicating the positive mold of the stump; Step 3: rectifying the positive mold; Step 4: forming the socket; Step 5: trimming the socket.

Patellar Tendon Bearing Socket

The PTB socket has been accepted as the standard approach since the 1960's. As known, the philosophy of PTB

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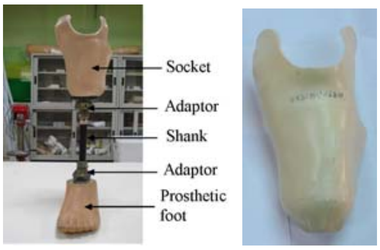


Figure 1. A PTB-SC PROSTHESIS AND ITS SOCKET.

Figure 2. THE STEPS OF FABRICATING A PTB SOCKET.

sockets is to increase load on the pressure-tolerant areas and relieve load on the pressure-sensitive areas, therefore, some rectification must be done in the step 3 (Fig. 2). The areas of plaster removal for increasing the weight bearing and the areas of plaster build-up for relieving pressure during weight bearing [1] and it decides whether the socket is comfortable to the transtibial amputees. However, this conventional manual process for manufacturing a prosthetic socket is complicated and artificial, making it time-consuming and labor-intensive. The fabrication procedure is not so easy to follow for a novice and even a qualified prosthetist could not be certain to make two identical shapes when creating a PTB socket.

For a PTB socket, there are many common errors made during wrap casting of transtibial stumps as listed below [2]:

(1) External rotation of amputee femur during casting.
(2) Cast sock too loose.
(3) Stump at incorrect angle of flexion.
(4) Plaster bandage too tight or too loose
(5) Position of hands incorrect for molding A-P dimension, and application of pressure incorrect.
(6) Insufficient wrap over end of stump, or too much wrap, or wrap not uniform.
(7) Rubbing or molding of cast after it has started to harden.
(8) Removal of cast from stump before cast is hard.
(9) Use excessive pressure causing wrap cast to be pushed onto the stump.
(10) Marking incorrectly located after casting.

Pressure Casting Sockets

To improve the complicated manufacturing process of transtibial sockets, some pressure casting systems have developed since the end of 1960's. So far, there are different

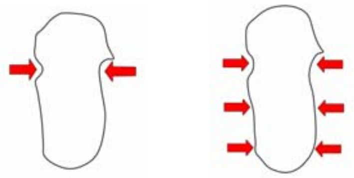


Figure 3. THE SCHEMATICS OF PTB AND TSB SOCKETS UNDER LOADS.

types of pressure casting. The so-called "Dundee" socket uses the sealed hydrostatic tank to produce the pressure by the amputee's body weight [3]. Another pneumatic system was designed by Gardner [4]. He used a pressure sleeve applied over the cast, inflated to 2psi (i.e. 13.8kPa) or 100mmHg (i.e. 13.3kPa) and held for approximately 10 minutes. Isherwood [5] developed the controlled pressure distribution (C.P.D.) casting technique to improve the homogeneous application of external pressure. The other pressurized casting instrument is ICECAST, which consists of an acrylic cylinder, with attached silicon bag, pressure relief and a proximal ring for sealing of the end [6, 7]. Later, the technique combined casting, manufacturing and fitting of a prosthetic socket in one simple session. It spends less than one hour to make a total-contact transtibial socket.

The philosophy inherent in the pressure cast technique was to eliminate all of the factors relating to manual dexterity [8]. The experience of hydro-cast sockets in Strathclyde University [9] has been applied for several years. Since 1991 over 100 sockets have been made. Most users feel it is better than their conventional sockets. One research study [10] also showed it has the best potential to produce a safe and comfortable prosthesis, due to the hands-off casting method.

In Strathclyde University experience, interface pressure measurements were performed using the F-Scan system. The results showed the peak pressures were more even and lower in amplitude in the hydro-cast socket than those in the PTB socket of a male amputee subject [9].

Total surface bearing. The philosophy of designing TSB socket is the same as the total contact socket (Fig. 3). In short, the pressure casting system could simplify the process of manufacturing a socket and also provide a total contact socket which could improve circulation, prevent oedema and increase the proprioceptive sensation of the stump [2, 11, 12].

In order to cost down the transtibial socket fabrication, Dr Wu and his group in the Centre for International Rehabilitation developed the CIR sand casting system [13] to replaces plaster of Paris with sand for forming both a negative sand mold and a positive sand model. Later, it was modified as the CIR casting system [14]. The main difference from the CIR Sand Casting System is that the CIR casting system uses light-weight, polystyrene beads in place of silica sand as the primary material for casting the negative mold. "With the new plaster-less casting system, the prosthetist can fabricate a transtibial prosthesis in about one hour. It reduces the set-up cost, overall weight and size of the casting system, and increases portability for service in remote areas. The system also creates minimal waste and is energy-conserving and environmentally-friendly" [14].

The Rapid Prototyping Technology

Since the emergence of rapid prototyping technology, a variety of prosthetic sockets have been designed and fabricated using various types of RP machines that include stereolithography (SLA), selective laser sintering (SLS), fused deposition modeling (FDM), and droplet/binding [15, 16].

In the review of Rogers et al. [16] concluded that although RP technology has been employed to develop prosthetic sockets for almost two decades, RP sockets are yet adopted by prosthesis industry. Possible reasons may include quality uncertainty, strength of RP socket, cost of fabrication and technology barrier experienced by clinical professionals. Herbert et al. [17] at Strathclyde University in Scotland developed a 4-mm-thickness RP transtibial socket wrapped a resin-reinforced carbon fibber layer to improve the limited strength for bearing the amputee weight. Although the strength and durability of the socket remain unproven, this investigation has demonstrated that the use of a cheaper, low-end RP technology, such as 3-D printing or the droplet/binding process, can be an alternative means to fabricate prosthetic sockets. Combing the use of a scanner, a CAD system, and an FDM machine to design and fabricate a type of resin-reinforced RP socket was proposed by Hsu et al. [18]. The development of a resin-reinforced RP-based prosthetic socket demonstrated that integrating the emerging technologies may assist a prosthetist to easily fabricate good quality of an assistive device.

METHODS

In this project reported in this paper, we proposed a new transtibial TSB socket manufacturing system which could make the socket cheaper and more comfortable to the amputees. This simplified integrating system is also expected to assist an unskilled prosthetist who will be able to produce good quality of prosthetic socket. The contemporary technologies employed in this proposed system include a self-developed stump forming tool based on the concept of the CIR casting system [14], a portable scanner, an in-house socket design system, and a cheaper RP machine as described in the following subsections.

A Stump Forming Tool and a Scanner

Previously, a hand-held scanner is used to acquire the digitized shape of a stump (Fig. 4). However, as the scanning process takes 3-4 setups at different orientation, and it lasts several minutes, the stump unavoidably trembles and leads to uncertain accuracy of the digitized model.

Figure 4. USE OF A HAND-HELD SCANNER.

Figure 5. DUPLICATING A STUMP MOLD USING A SELF-DEVELPOED FORMING TOOL.

Figure 6. USE OF A SIMPLE SCANNER AND A DIGITIZED STUMP MODEL CONSTRUCTED.

Based on the concept of TSB socket [11], the stump mold of an amputee should be duplicated under appropriate pressure. Using TSB stump model, editing complex surface can be avoided, and the quality of socket fits is expected to be improved by employing the simplified design process. Several duplicating tools, like CIR casting system [14], hydraulic forming tool [9], and Ice-cast device [7], a commercial device, have been developed. Following the principle of CIR casting system invented by Dr. Wu [13, 14], this study fabricated a forming tool (Fig. 5) and has been a trial use to duplicate a stump mold of a volunteer amputee. This duplicated stump mold was then digitized by using a compact scanner (Fig. 6). In this simple and easily-used scanner, there is a transparent glass stand to rest the scanned object. The object is firmly steady during scanning process that merely takes less than 20 seconds. The digitized model in STL format can be easily exported to a CAD system for the following steps of socket design.

An In-house Socket Design System

A CAD system must be used to construct the CAD model of an object that is expected to fabricate in an RP machine. The previous process [18] needed to use a commercial system such

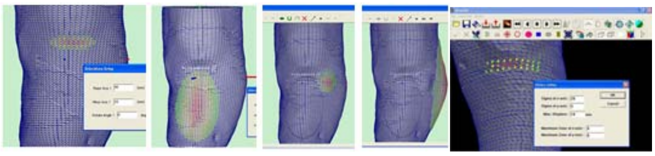
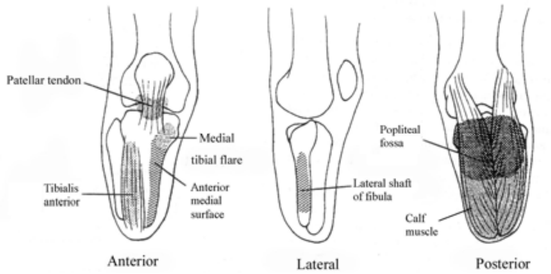
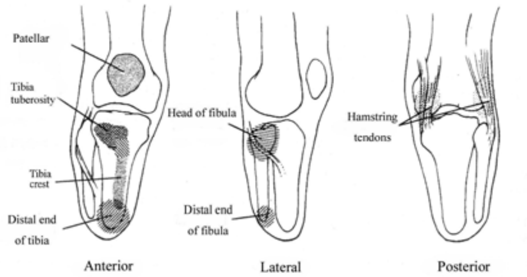


Figure 7. EDITING THE PT/PR AREAS DURINNG DESIGNING A PTB SOCKET.



(a) PRESSURE TOLERANT (PT) AREAS.



(b) PRESSURE RELIEF (PR) AREAS.

Figure 8. THE PT/PR AREAS OF A STUMP.

as CATIA, mainly to assist the conversion the transtibial socket point cloud data already edited into the model surface to then build the shell, base, and knee covering. In order to avoid dependence on commercial CAD software and simplify operational processes for customization needs, a prototype system [19] to design a PTB socket was proposed (Fig. 7). However, during designing a PTB socket, the shape of PT and PR areas of a stump (Fig. 8) should be modified to meet biomechanical assessment of interface pressure between socket and stump. The expertise and skill of an experienced prosthetist is therefore required. That is one of the difficult steps to fabricate transtibial sockets with good quality of socket fitting the stump.

As stated earlier, the type of TSB sockets is widely accepted because of more areas of a stump contacting socket (Fig. 3) with appropriate pressures. Using the TSB-based stump model duplicated by a vacuum forming device (Fig. 5), the shape design of a socket will be simplified. An updated system (prosthetic socket grid-editing design system, PSGDS [21, 22] will be able to operate independently with direct connection between 3D scanner and RP machine which can then be used in socket production. The PSGDS interface system allows an unskilled user to operate easily to design a good-fit quality of

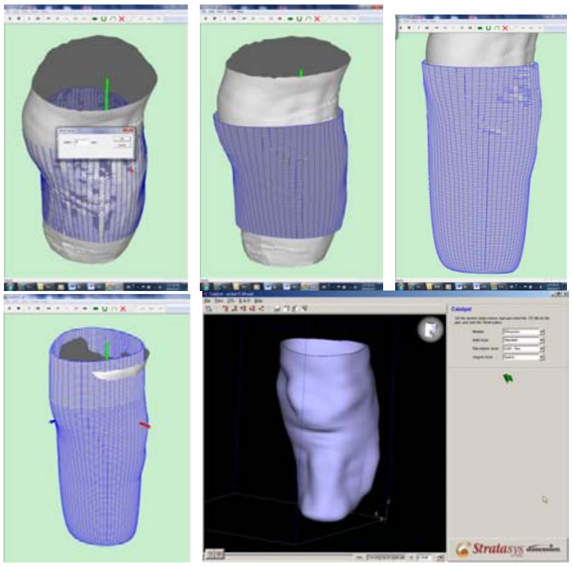


Figure 9. THE STEPS OF OFFSETTING, EXTENDING TO FORM SOCKET BASE AND KNEE COVER OF A TSB SOCKET MODEL.

sockets. Figures 9 depicted the outputs of the simple process of model design. These steps (Fig. 9) include offsetting the duplicated stump model to form the main portion of weight bearing regions of a TSB socket, extending the lower portion to construct socket base for accommodating adaptor, and generating knee cover to suspend the socket at upper part. The complete socket model will then be transferred to an RP machine. The feasibility of this integration system will thus be verified by undergoing measured interface pressure to verify TSB socket.

Use of an RP Machine

Currently, the process of using an RP machine is rather simple. And, its operation cost has been dramatically reduced since the types of droplet/binder and paper rapid prototyping (PRP) processes emerge. The cost of a droplet/binder RP machine is less than half of other types, such as FDM machine. The cost of PRP is around one-third of a droplet/binder machine. This study employed a PRP machine [22] to fabricate the socket mold (Fig. 10). This RP socket mold replaced plaster positive mold used in the hand-cast process and the unsaturated polyester resin (UPR) is then infiltrated on cotton socks using the exactly same traditional lamination method. The UPR socket is then dismantled at the end of curing process (around three hours) and ready for the use of the following step.

The proximal brim of that UPR socket is manually trimmed to allow the stump inserting into and fitting the customized socket. After a shank and a prosthetic foot assembled and aligned, a set of below-knee prosthesis can be ready for trial use (Fig. 11).

Figure 10. AN RP SOCKET MOLD AND USE FOR LAMINATION.

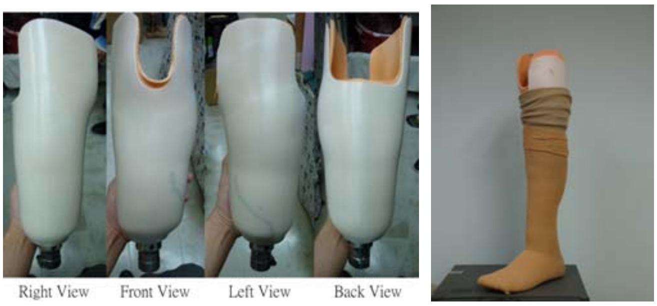


Figure 11. THE PROPOSED SOCKET AND A COMPLETE SET OF TRANSTIBIAL PROSTHESIS.

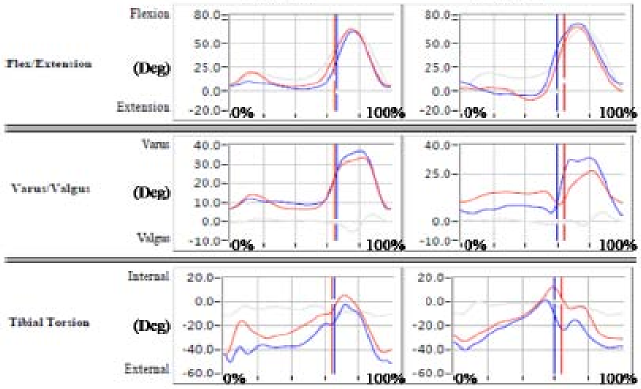
RESULT OF A CASE STUDY

Employing the propsed system, a TSB-based socket for a unilateral amputee was designed and fabricated recently. After the safety of trial walk of wearing the prosthesis has been confirmed by the amputee himself and a registered prosthetist, a trial use was arranged (Fig. 12). To verify the applicability of the proposed TSB socket, a motion analysis system was used to measure the gait pattern while trial walk. Figure 13 illustrated the variation of knee joint angle and comparison between a traditional plaster-based socket and the proposed TSB socket. This experimental result showed that the gait patterns of using two different sockets are similar. Since the stump mold was duplicaed using a pressure casting tool (Fig. 5), an RP model could be designed by following the procedure shown in Fig. 9 without the assistance of a prosthetist. This case study indicated that as long as a duplicated stump mold using appropriate pressure forming device, a good quality socket with a comfortable fit can be easily fabricated.

CONCLUSION

The implementation result of the proposed process has demonstrated that integrating the easily-used and less expensive systems, including a vacuum casting tool, a compact scanner, a simple interface system to design socket, and a cheaper rapid prototyping machine, is possible to fabricate a transtibial socket with good-fit quality. Further efforts should be needed to improve the process deficiencies over the course of clinical tests by the prosthetist. Firstly, more friendly interfaces of using an in-house system to design RP socket model should be improved. Secondly, less efficiency of using

Figure 12. TRIAL WALK USING TSB-BASED SOCKET.



(a) SOUND LIMB (b) RESIDUAL LIMB

Figure 13. THE VARIATION OF KNEE JOINT ANGLE (RED: PLASTER-BASED SOCKET, BLUE: PROPOSED TSB SOCKET, GRAY: NORMAL PEOPLE).

the vacuum forming tool to duplicate a stump mold for creating digitized stump model has to be redesigned. Furthermore, recruiting more amputees to validate this proposed integration system is also an important future work.

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