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# A System for Supporting the Design of Total Surface Bearing Transtibial Sockets

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**ABSTRACT**

This study developed an easily-used system for designing a transtibial socket that will be fabricated by a rapid prototyping (RP) machine. This proposed system is to improve the quality of uncertainty of plaster-based process of fabricating thetranstibial socket. In this study, the concept of total surface bearing (TSB) is employed to obtain stump model of an amputee under appropriate pressure. Using TSB stump model, editing complex surface can be avoided, and the quality of sockets can be improved by the simplified design process.In the plaster-based production process, the plaster stump mold must be destroyed in order to fabricate a prosthetic socket. If a socket should be reproduced, it will be difficult to clearly point out the difference between the previous and the new stump molds. If a proper CAD system can be used, the difficulty of reproducing a socket will be easily resolved. Currently, manufacturing RP sockets is not an important issue as a convenient RP service bureau already exists. The lack of an appropriate system for designing transtibial sockets is the major barrier. The development of an easily-usedtranstibial socket design system is required.To demonstrate the feasibility of this proposed system, two case studies including a resin-reinforced RP transtibial socket and an RP stump mold for replacing the plaster mold used in plaster-based method were designed and fabricated for a volunteer amputee. The motion analysis and trial use of the prosthetic sockets verified the applicability of this prototype CAD system. Recruiting more amputees to examine and validate this developing system is being arranged.

**Keywords:** transtibial sockets, rapid prototyping, Windows application.
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## 1 INTRODUCTION

With advancement in technology and development of reverse-engineering, more and more assistive products are produced with reverse-engineering concepts.With the maturation of rapid prototyping technology in recent years, the use of RP output sockets is one possible way. Computer-assisted editing of transtibial sockets also has commercial applications, in light of the present number of computer-assisted editing systems which lack perfection, with such editing modes too awkward with complex interfaces, causing many prosthetiststo still prefer to use manual production processes. Therefore, this research attempts to develop a complete interface system for computer-aided design of transtibial sockets, as the bridge between three-dimensional scanner and RP machine. Looking forward to the summary of the user interface, efficient editing methods to assist the prosthetist to successfully use the transtibial sockets design system to improve the quality and stability of sockets as well as production efficiency. A transtibial socket is a highly customizable product. Prosthetists must accumulate long periods of training and clinical experience before being able to produce prosthetic sockets by a hand-casting process. In addition, manual casting is a non-reversible process; when a similar socket needs to be tailored to the requirements of the user, difficulties arise making such a task hard to accomplish. Furthermore, this manual method is also difficult to accurately quantify and record. If digitized methods can be employed in the design of transtibial sockets, such issues can effectively be addressed. This study implements Unified Modeling Language object-guided analysis to collect user requirements and analyze the needed structural system. Then the MFC/C++ with OpenGL graphics library is employed to develop a system [1], to provide use for transtibial socket design[2]. Fig.1 is a comparison chart of old and new systems.Old processes needed to use 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 / CAM software and simplify operational processes for customization needs, the new system (prosthetic socket grid-editing design system, PSGDS) within this research will be able to operate independently with direct connection between three-dimensional scanner and rapid prototyping which can then be used in socket production, thus verifying the feasibility of this system.

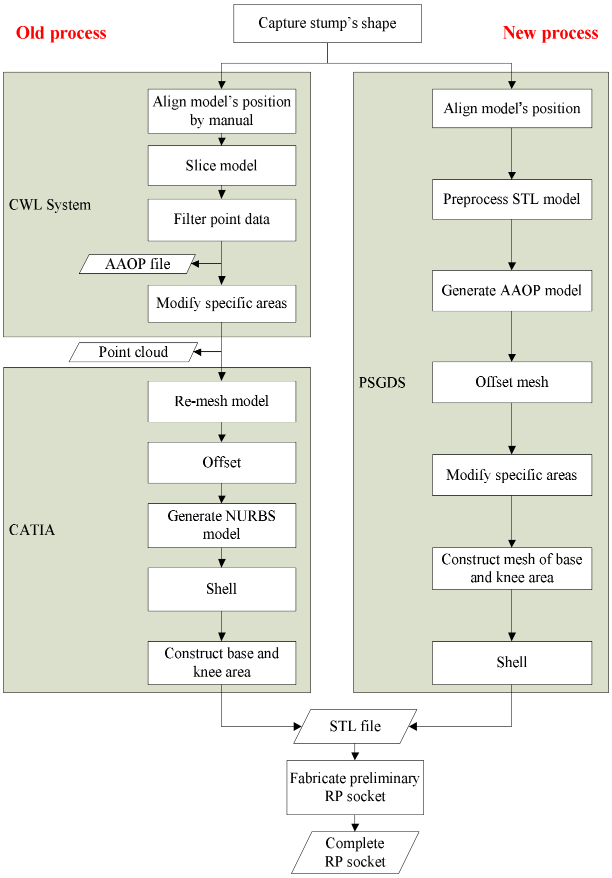


Fig. 1: Comparison chart of old and newprocess systems.

### 1.1 Total Surface Bearing Transtibial Socket

A transitibial prosthesis is composed mainly by three parts: the socket, shank and foot. Unlike normalpeople who rely upon bones to support the body, users of prosthesis incur stump surface pressures which can be classified into pressure-tolerant areas(Fig.2) [3] like muscle tissue and ligaments that carry larger pressures, as well as pressure-relief areas (Fig.3), normally the prominencesof the bone which carry less load pressure. Various different socket shapes are developed according to varying theoretical basis. Early socket design, such as a patella tendon bearing (PTB) socket (Fig. 4), saw weight bearing concentrated on pressure-tolerant areas, while avoiding load-bearing on pressure-relief areas. Such design can sometimes cause stress concentration in a certain area resulting in discomfort. Staats [4], who in 1987 proposed a Total Surface Bearing (TSB) socket, the main concept being irrespective to pressure-tolerant and pressure-relief areas with the load-bearing scattered throughout the stump and socket on the contact surface (Fig. 5). This method would not produce the issue of excessive pressure concentration thereby increasing comfort and reducing the complexity of modification while substantially enhancing the ability of the socket to total contact the stump. Therefore, current transtibial sockets usually rely upon the TSB production method.

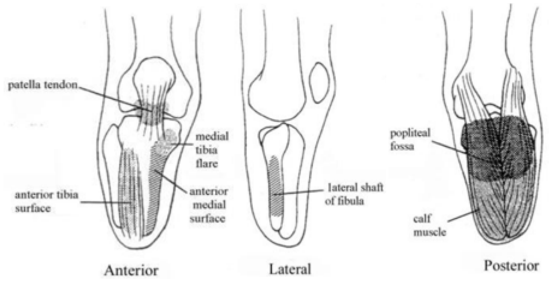


Fig.2:Pressure-Tolerant areas [Bowker,1992].

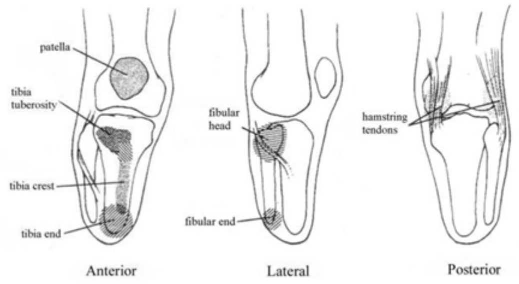


Fig.3:Pressure-Relief areas [Bowker,1992].

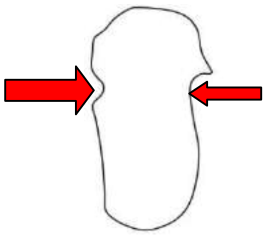

Fig. 4: PTB socket.

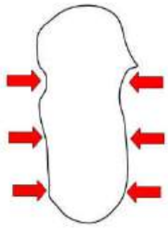

Fig. 5: TSB socket.

### 1.2 Use of RP Technology on Transtibial Socket Fabrication

Due to the complicated outer-shape of the transtibial socket, currently most CAD/CAM production methods utilize RP technology. Rogers [5], who uses the RP socket production, maintains complete contact between stump and socket with no editing of the inner-socket in design concept. Whereas the UTHSCSA software [5] is used for pressure-relief areas selected towards the outer shell of varying thickness. Fig.6, for example, illustrates a socket width of 6mm with the circled pressure-relief areas only 1.3mm at its thinnest, arriving at comfortable results at P-R areas by using flexible materials. Rogers and others believe that the use of RP technology is useful in fabrication of sockets, facing only issues of a lower cost and user-friendly socket design software.

Fig. 6: UTHSCSA software interface [5].

### 1.3 Use of Commercial CAD/CAM Systems for DesigningTranstibial Sockets

Beginning in 1997, commercial CAD/CAM systems applications have numbered ten or more with many systems including measurement apparatuses and editing software. The OMEGA Tracer [6], for example, includes a measurement and manufacturing system with editing software. The OMEGA measurement system is also quite diversified complete with stump-design and contact-pressure scanners utilizing TracerCAD editing software. McGarry[7] tested the capabilities of OMEGA Tracer scanner and got the better stump model .

## 2 METHODS

Based on the concept of TSB socket, a vacuum forming tool proposed by Wu [8] is used to duplicate a stump shape under an appropriate pressure. The scanned data of the duplicated stump is then used to design RP preliminary socket to tailorthe specifications of the specific amputee.
Due to the commercial CAD/CAM systems for designing transtbial sockets are too complex to operate by prosthetists. Therefore this study developed an easily-used system for designing a transtibial socket. This proposed system is to improve the quality of uncertainty of plaster-based process of fabricating a transtibial socket and to write a specific purpose program based on the expertise of prosthetists.

## 2.1 VacuumForming Tool

A proposed vacuum forming tool (Fig. 7) is composed of a vacuum pump, a latex chamber with Styrofoam pelletsfilling, a latex sleeve, a mandrel, a stack of silicon sand and a set of flexible tubes for the connection of the whole system. The steps of using the vacuum forming tool to produce a stump model include: inserting the transtibialstump into a latex chamber; vacuuming the internal air of the latex chamber under a pressure that the amputee can tolerate and the latex chamber can be solidified (The pressure usually under atmospheric pressure 100~200 mmHg); a negativemold of stump shape created by extracting the stump; the negative mold filled with silicon sand and the mandrel inserted; sealing the latex sleeve containing mandrel and sand; connecting the flexible tubes to the mandrel; and then vacuumingthe remaining air in the sleeve(Fig.8). The whole process will not spend more than five minutes. A stump moldis then created for the use of scanning process.

Fig.7: The usage of vacuum forming tool.

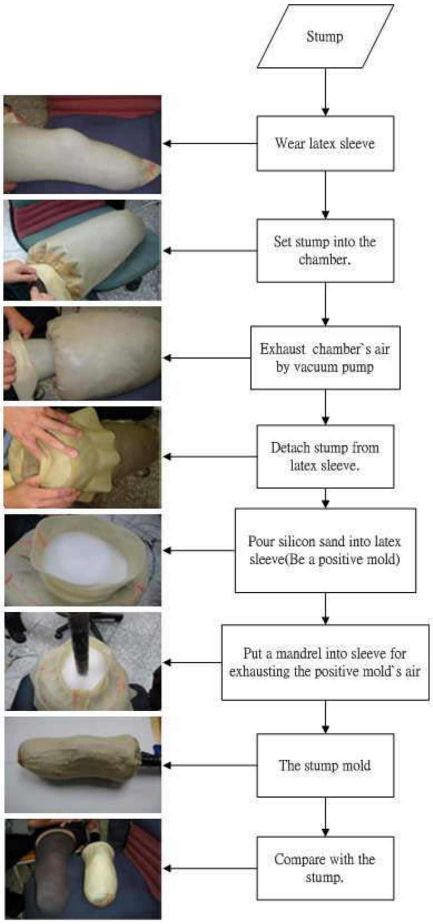


Fig.8:The process of using vacuum forming tool.

## 2.2 An Interface System for Computer-Aided Design of Transtibial Socket

In regard to this system, as seen in Fig.9, the main functions which the system must produce include reading scanned files, alignment of the mesh coordinate system, filter slicing, mesh offsetting, top extension and base construction, mesh shelling, and output of STL files.The details of the proposed process will be described in Case Study section.

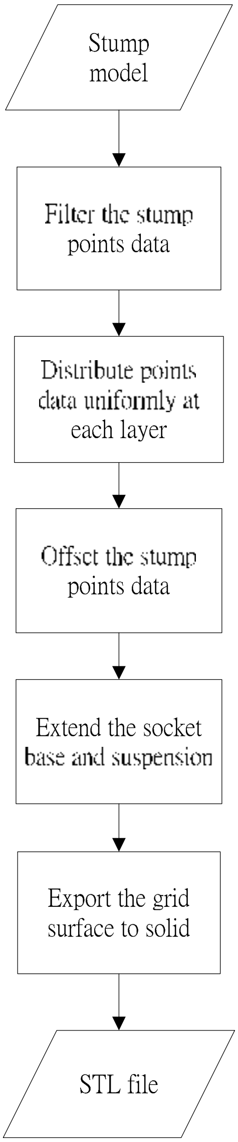


Fig.9: The interface system functions and design process for computer-aided design transtibial sockets.

## 3 CASE STUDY AND RESULTS

### 3.1 Case I – RP Preliminary Socket Used as a Mold

This case study is of a 26-year-old male with a left transtibial amputation, and the goal is to fabricate a transtibial prosthesis using a RP output stump model. Fig.10 depicts the stump model file obtained by a vacuum forming mold at 200mmHg vacuum pressure for the pressure tolerant stump model.

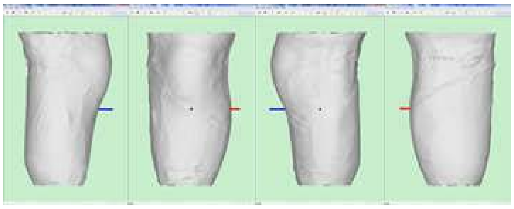

Fig.10: The stump model four directions of view.

The positive mold of the transtibial socket is fabricated using an RP machine, which replaces hand-cast plaster positive molds for purposes of digitizing the design. Shown in Fig.11 is the stump feature data, with Tab.1 showing the actual stump data, both of which are factors considered in designing the appropriate mold. Granted that the stump length directly affects the socket length, with regard to the experience of the prosthetist, the socket base requires 15-25mm in length reserved to avoid excessive contact with stump end. The distance between the patellar tendon and the popliteal fossa, as well as the width of the knee cap, are key in determining if the user will have a secure fit. Normally, the two stump mold parameters must be close to actual measured parameters, and the femursupracondylar area circumference determines the design of the supracondylarsuspension. Measuring such parameters have great positive influence on the comfort-quality of the socket.


Fig.11:The parameters of limb feature.

| Name of parameter | Value(mm) |
|---|---|
| Length of residual limb | 150 |
| Perimeter of supracondylararea | 345 |
| Perimeter of patellar tendon area | 319 |
| Distance between patellar tendon and popliteal fossa | 110 |
| Width of knee area | 110 |

Tab.1: The actual measured value of limb features.

Because the comfort-level of transtibial sockets greatly depends upon the set position angle, this study employed feature points and parameters to help adjust socket position. As shown in Fig. 12, with feature points used at patellar tendon, tibial end, and fibular head, corresponding points on the model were selected, then angle and amount of translation were entered, whereby the final position could be completed upon verification. With the position set, the origin layer at the height of the patellar tendon area was set. Then with the triangular mesh, point data was divided across 80 layers each with 80 filter points, as seen in Fig.13

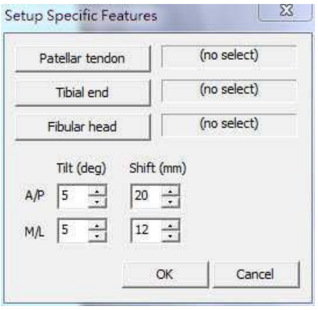


Fig.12:The parameters of aligned socket.

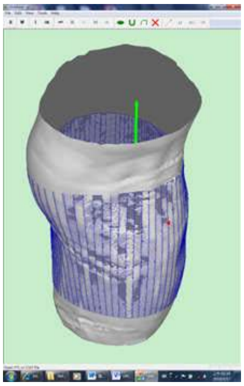

Fig.13:Filter the points of each layer.

Because the socket must be wider and larger than the stump in order to be worn properly, extra space is filled with liner. Normally the lateral offset of the stump mold is 4mm( Fig.14), but if RP molding is used in place of the manual cast plaster mold, then this offset step can be skipped.

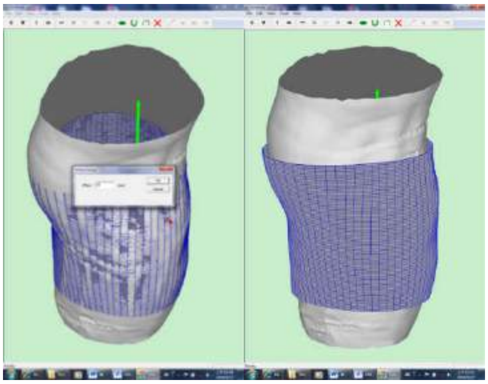

Fig.14:Offset the grid surface.

Parameters are then inputted to construct the base(Fig.15), including base length, diameter, center coordinates, and outer shape. Base length parameter is based upon the length required without touching the distal end of the stump when worn.The base diameter considers the metal connector size, about 55mm. The exterior style of the base can be changed to meet requirements.

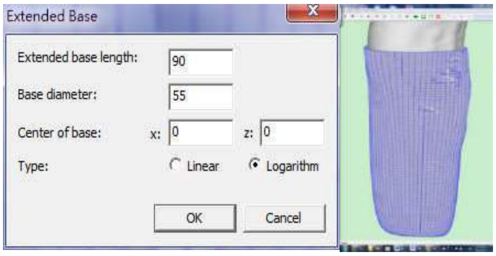


Fig.15:Extend the socket base.

The actual surface mesh model is fabricated by the shell function (Fig.16), then upon output of the STL file, providing the necessary output model required by the rapid prototyping machine. The shell thickness is about 1.5 mm, the thickness which ensures both RP output time savings as well as a model without holes.

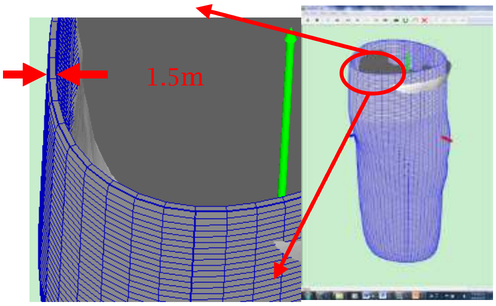


Fig.16:Export the grid surface to solid.

Fig.17shows this case study's initial positive model, which must be fabricated by hand-cast plaster after internal perfusion to produce the transtibial socket.

Medial view Front view Lateral view Top/Button view

Fig. 17:The RP positive mold all directions of view.

Fig.18 shows the resin socket product with liner, socket base with fixed connector, used to connect prosthetic shank and foot. Fig.18(right) shows the completed transtibial prosthesis assembly, including the stockinette and sock which gives the prosthesis an appearance similar to a human leg.When pants are worn by the user, the visual perception of a missing leg can be avoided.


Fig.18:The Transitibial socket with liner and the transtibial prosthesis.

### 3.2 Case II –RP Preliminary Socket Used as the Inner Layer of a Resin-Reinforced Socket

The user in Case II is the same as in Case I, both using TSB concepts. The initial socket was made by RP and wrapped in a unsaturated polyester resin (UPR) layer to provide added strength to the socket(Fig. 19). Design parameters from Case I were kept the same, with the difference being a design with the lack of anliner which was present in Case I. Therefore, the prosthetic mold has an outer offset of only 2 mm in order to provide a good fit. Fig.20 shows the finished product of this case.

Fig. 19:RP layer and UPR layer.

Fig.20:Case II'stranstibial socket.

### 3.3 Trial Result of Using Transtibial Sockets

The research completed in these two case studies has confirmed that this system can quickly and easily design Rapid Prototyping transtibial sockets. In addition to confirming the feasibility of the system functions, the most important aspect is to verify the usefulness of the socket. The most direct way is to understand the socket user's subjective feelings, because highly customized products often cannot be fabricated in full compliance with user requirements. Therefore, the user trials can provide understanding of user subjective experience and what the user hopes to gain from the product. Based upon feedback from the prosthetist, sockets set into place that are produced by this design system require no further complicated modificationin order to complete assembly and can raise the positioning quality of the sockets. The user's feedback of the socket from Case I reported no problem with regard to positioning and motion with stability. While other sockets must undergo complex adjustments in order to achieve correct positioning, the socket also provided adequate support around the patellar tendon without any occurrence of a sunken prosthesis. The inner socket is quite workable due to the TSB casting process without uncomfortable excessive pressure placed upon the stump node area. Sockets from Case II, with design absent of a liner, wearable comfort was less. Although TSB design principles were used in socket design, the advantages of TSB cannot be realized without a liner between the socket and stump. Judging from the feedback and suggestions of the prosthetists and socket users, in addition to simplifying the fabrication process this design systemcan met the needs of the users. Furthermore, in order to scientifically record and analyze the effectiveness of the socket, this research used motion analysis to verify the sockets which be made by this system not causing harmful gait .Fig. 21shows Tracer Trak system data collected during trial walk. The analysis result of knee joint angle shows that the comparison of the gait characteristics between sound limb, acceptable transtibialprosthsisand that of normal people(Fig. 22). In addition, the tested socket will undergo interface pressure measurement using a socket sensor to verify the pressure distribution, and also employ finite element analysis technique to analyze the socket model.

Fig. 21:Motion analysis.

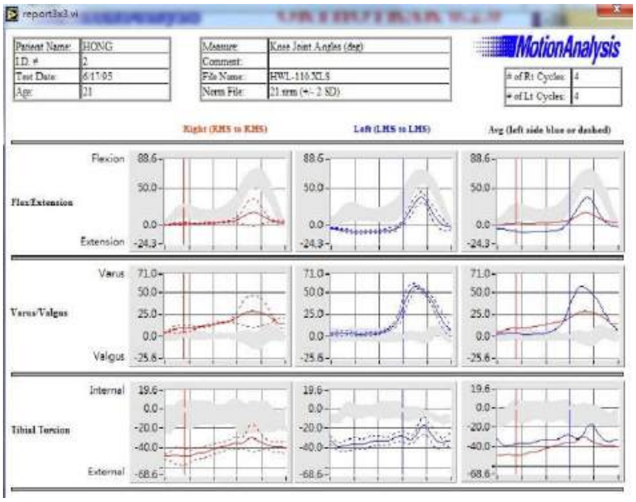


Fig.22:Motion analysis result of knee joint angle.

## 4 DISCUSSION AND CONCLUSION

**(1) Comparison of hand-cast with CAD/CAM processes.**

According to the prosthetist, when compared with the hand-cast plaster mold transtibial socket, CAD/CAM designed sockets are still considered unfamiliar territory. However, the advantages of digital design, including reusable models, key measurements taken in a virtual environment, and reduction in production times while increasing efficiency, are all motivations for willingness to consider CAD/CAM fabrication.

**(2)TSB vacuum mold extraction technique**

Use of a vacuum forming tool to duplicate a stump mold under proper pressure can effectively reduce the possibility of complex errors within the computer-aided transtibial socket design system. This provides for a more convenient CAD/CAM fabrication process, increasing socket comfort and fabrication reliability.

**(3)The features of computer-aided transtibial socket design system**

The Total Surface Bearing transtibialsocket design interface system implemented within this research can provide more comprehensive pre-and-post processing functions. Main functions include definition of design point and feature parameters to assist in design and appearance of socket in fabrication of the socket base and supracondylar suspension, bringing the mesh surface shell to be fabricated.

At present, sockets produced at this institute have only undergone short-term testing, and expect to have at least six-month of testing at a future date to discuss differences in subjective usage in both long and short terms. Because the target system operator is the prosthetist, it is hoped that the prosthetists can provide insight into system deficiencies over the course of clinical tests to act a basis for implementation of future system improvements.

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