Anderson Orthopedics Inc. Project
Design Report
BIOE 4950 Biosystems Engineering Design 4
March 21st, 2025

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EXECUTIVE SUMMARY

Anderson Orthopedics seeks to improve the production of transtibial sockets for individuals with below-the-knee amputations by addressing inefficiencies in its existing manufacturing processes. This design solution develops a streamlined and sustainable set of standard operating procedures that incorporate digital technologies. This approach reduces production time and hands-on labour, while maintaining high-quality patient care and satisfaction.

The design solution combines Anderson Orthopedics' traditional manual casting method with advanced digital technologies. These technologies include the Vorum Spectra Scanner for 3D scanning and the Canfit computer automated design software for socket modification. To 3D print the sockets, two new programs are introduced in the standard operating procedures for designing. These programs are SolidWorks and SuperSlicer. 3D printing the sockets with two chosen filaments will significantly reduce hands-on labour, eliminate the need for external outsourcing, and reduce production time for both non-weightbearing and weightbearing sockets. Preliminary testing has assessed the design solution's feasibility through physical property tests (e.g., socket volume retention, diameter retention, subtractive modification), satisfaction surveys, and evaluations of overall manufacturing efficiency. This testing has proven the new process meets Anderson Orthopedics' standards for quality and patient care.

The design solution presented encountered key limitations in 3D printer access, and future recommendations have been provided to improve socket aesthetics, transparency, and structural performance. Addressing these limitations can further improve both the socket quality and the patient experience at Anderson Orthopedics.

The new process reduces hands-on labour time by 22.1% for both the weightbearing and non-weightbearing sockets. Additionally, it decreases overall production time by 6.7% for the weightbearing socket and 26.4% for the non-weightbearing socket. This design solution offers valuable insights into an innovative and efficient prosthetic manufacturing approach for Anderson Orthopedics, reinforcing their commitment to sustainability and excellence.

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LIST OF ABBREVIATIONS

Abbreviation	Definition
AO	Anderson Orthopedics
BKA	Below-the-Knee Amputation
CAD	Computer Aided Design
CNC	Computer Numerical Control
DLD	Distal Limb Disc
MOT	Myrdal Orthopedic Technologies Inc.
NWB	Non-Weightbearing
PETG	Polyethylene Terephthalate Glycol
PLA	Polylactic Acid
P&O	Prosthetics and Orthotics
PVB	Polyvinyl Butyral
SOP	Standard Operating Procedures
TTS	Transtibial Socket
3D	Three Dimensional
WB	Weightbearing

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1.0 PROJECT CONTEXT

Anderson Orthopedics (AO) is a private prosthetics and orthotics (P&O) clinic with locations in Winnipeg and Brandon. Prosthetic devices are artificial replacements for missing or impaired body parts [1]. Orthotic devices are devices used to correct alignment, reduce pain and/or provide additional support to any part of the body [1]. AO also provides full-care service which includes assessment, design, fabrication, fitting, and follow-up care for individuals in need of P&O devices.

This project is focused on improving the production of a transtibial socket (TTS), which is an essential aspect of a prosthetic leg for individuals with below-the-knee amputations (BKA). The components of a transtibial prosthesis and the pin-liner suspension system are depicted in Fig. 1.

AO's current manufacturing processes for TTSs are time-consuming and labour-intensive, creating inefficiencies for technicians and clinicians. To address these issues, AO has requested a redesigned manufacturing process that will incorporate digital components to their current method.

This section will provide an overview of the problem background and problem definition. The problem background will discuss the existing challenges with the manufacturing process and the need for a more efficient solution. The problem definition will outline the specific goals, design functions, and deliverables expected from this project.

1.1 PROBLEM BACKGROUND

This section provides an overview of the current TTS manufacturing processes at AO, including both traditional and hybrid methods. It outlines the two types of TTS sockets and highlights the roles of clinicians and technicians in the production process. The section also details the project's design functions, client deliverables, and target specifications, which focus on improving manufacturing efficiency, reducing labor time, and maintaining high-quality standards to ensure patient satisfaction.

1.1.1 Current Manufacturing Processes

AO currently uses both a traditional and hybrid method of manufacturing TTSs. The information regarding the processes was obtained from clinical observation, tailored specifically to this project [1], [4].

The traditional process to create TTSs begins with evaluating the patient's medical history, skin condition(s), and residual limb. Anatomical points on the limb are marked, and plaster bandages are applied and molded to create a negative cast. This negative cast is then converted into a positive mold by filling it with industrial plaster. Once the plaster sets, the positive mold is stripped from the bandages. The clinician then modifies the plaster mold as needed for a customized fit. After the plaster modifications are complete, the mold is dried in an oven before being thermodraped with a heated sheet of plastic. The plastic is vacuum sealed over the positive mold, capturing its shape. Once the plastic is cool, trim lines are marked, and excess plastic is removed. The plaster is then removed from inside the socket with an air chisel. Finally, the socket is smoothed along the trim lines and a distal hole is drilled. A simplified flowchart of this process can be seen in Fig. 2. The steps for this process are detailed further in Section A-3.1.

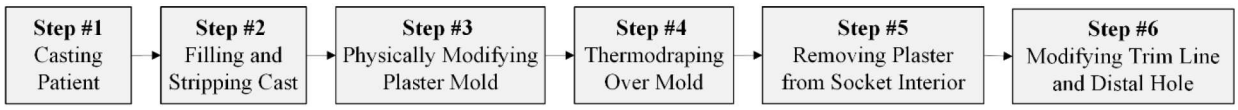


Figure 2 - AO's traditional process, simplified

Certain steps are spread across several days due to machine availability and scheduling priorities but are completed within a five-day work week. The clinician and patient meet after step six to check the fit of the non-weightbearing (NWB) socket, with a standard one-week interval between

casting and fitting. This process is then repeated for the weightbearing (WB) socket, after which the patient begins a trial period, which is beyond the project scope. A value-stream map detailing the traditional prosthetic process is in Appendix Fig. A21.

The hybrid process at AO currently employs aspects of the traditional process and incorporates additional technology. AO's hybrid process is the same for steps one and two as seen in Fig. 3.

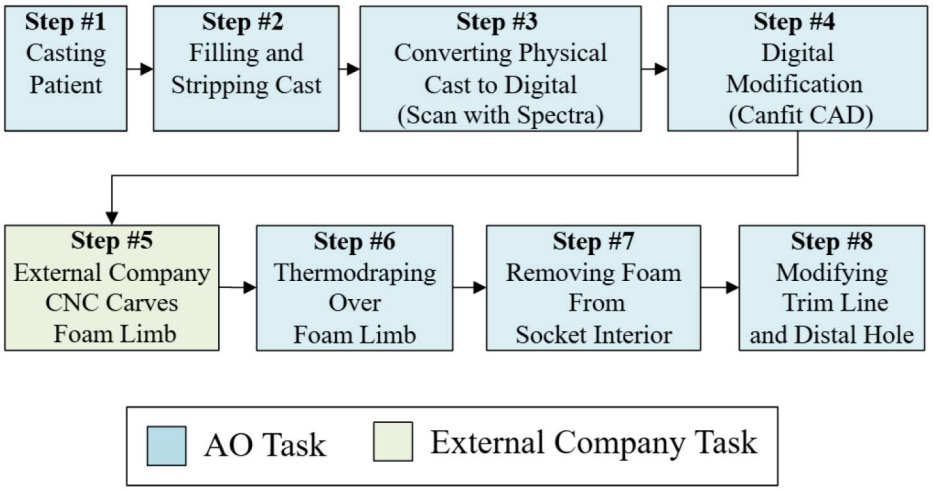


Figure 3 - AO's hybrid process, simplified

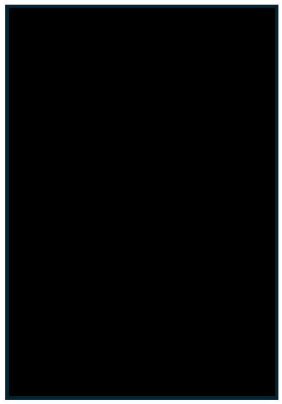
However, in this method after the positive mold has set, technicians use a light scanner to scan the mold, then upload it to a Computer Aided Design (CAD) program. The file is then outsourced to a secondary company, Myrdal Orthopedic Technologies Inc. (MOT), to produce a carved foam model. Once AO receives the foam model, the remaining steps are the same as the traditional process. Further detail on the hybrid process can be found in Section A-3.2.

1.1.2 Types of Sockets

For TTSs, there are two types of sockets: NWB and WB.

- NWB sockets (Fig. 4), are used for fitting purposes, to ensure proper alignment with the residual limb. These sockets do not include modular components.
- WB sockets (Fig. 5) are structurally stable TTSs that enable mobility testing. Producing the WB TTS involves additional steps to integrate the modular components. These extra steps ensure that the socket is strong enough to bear weight and allow for gait assessments and adjustments [1].

Figure 4 - NWB TTS



This project will improve the process for both NWB and WB TTS's.

1.1.3 Clinician and Technician Differentiation

The P&O profession is made up of clinical and technical professionals that are uniquely trained [5]. At AO, the clinicians are the primary patient contact and are responsible for the patient casting, the modification of the mold, and the fitting of the TTS. The technician's responsibilities include the cast filling and stripping as well as the manufacturing of the TTSs.

1.2 DESIGN FUNCTIONS AND DELIVERABLES

The primary goal of this project was to develop a set of standard operating procedures (SOP) for TTS manufacturing at AO. The SOP incorporates digital technologies to reduce production time and labour costs, while maintaining the integrity of the TTS and ensuring continued patient satisfaction.

1.2.1 Design Functions

The proposed process meets the specific design functions that have been determined by both AO and the project team. These design functions are listed below:

- Time Reduction: Streamline the production process to reduce overall manufacturing time.
- Labour Reduction: Integrate technology to reduce hands-on labour time, improving efficiency in production.
- Socket Integrity: Ensure the structural stability and comfort of the TTS, maintaining high-quality standards for patient safety.

To reduce the overall production time, select steps in the TTS manufacturing process have been altered. The changes in the process minimize manual labor by incorporating advanced technology, ensuring that AO can continue to meet its established standards.

1.2.2 Client Deliverables

AO has outlined specific deliverables that must be fulfilled to meet expectations. Each of these deliverables will help AO determine if the project solution can be implemented. The client deliverables are listed below:

- Standard operating procedures
- CAD program instructions
- 3D (three dimensional) printing analysis of NWB and WB filament
- 3D print of NWB and WB TTSs
- Recommended 3D printer specification

The project solution presents a detailed SOP. Each procedure includes a clear explanation of the process and the explanatory steps for integrating the CAD and 3D printing software into the manufacturing process. The workflow includes the materials, hardware, and software required for efficient TTS manufacturing.

As described in Section 1.1.2 Types of Sockets, there are two types of sockets that require different materials. The client has requested an analysis of 3D printing filaments to identify a translucent option suitable for NWB sockets and a strong option capable of supporting WB socket conditions. Having a translucent filament is essential, as it provides visual feedback to clinicians during the fitting process, allowing for the detection of redness or irritation on the residual limb to improve patient comfort and safety [1]. Furthermore, the transparency simplifies alignment and adjustment, ensuring a more efficient and precise fitting [1]. A strong filament is crucial to ensure the durability and structural integrity of the WB socket.

All deliverables will be provided to the client in varying forms of documentation by April 2025. The SOP, 3D printing filament analysis, and recommended 3D printer specifications are contained within section 2.4.1, 3D Printer Specifications.

1.2.3 Target Specifications

Table I outlines the technical specifications that were used to assess the success of the proposed solution. The evaluation and verification of the specifications are in Section 3.0.

TABLE I

TECHNICAL SPECIFICATIONS

Socket Type	Spec.	Target Specification	Verification Procedure
NWB	1.1	Retain mold volume of socket (within ± 2% of traditionally manufactured socket)	4.1
NWB	1.2	Δ thickness ≤ 0.028mm after sanding	4.2
NWB	1.3	Retain dimensions within ± 3mm of traditionally manufactured socket	4.3
NWB	1.4	Tramsmittance of printed filament ≥ 25%)	4.4
WB	2.1	Retain mold volume of socket (within ± 2% of traditionally manufactured socket)	4.1
WB	2.2	Δ thickness ≤ 0.028mm after sanding	4.2
WB	2.3	Retain dimensions within ± 3mm of traditional/hybrid socket manufacturing method	4.3
WB	2.4	Socket compressive load capacity ≥ 1112 N	4.5
-	3.1	Clinician satisfaction	4.6
-	3.2	Technician satisfaction	4.6
-	3.3	Patient satisfaction	4.6
-	4.1	Overall manufacturing time reduction	4.7
-	4.2	Hands-on time reduction	4.8

The design functions and deliverables of this project focus on integrating advanced technologies to streamline TTS manufacturing, reduce production time labor, and maintain high-quality standards, ultimately fulfilling client expectations and ensuring patient satisfaction.

2.0 DESIGN SOLUTION

This section provides a thorough description of the proposed SOP that digitizes the current TTS manufacturing processes. This will ensure a more efficient approach to TTS production. By incorporating advanced technologies, the SOP facilitates a cohesive integration of socket shape and components which results in the development of a functional patient-specific solution.

2.1 OVERVIEW OF THE KEY PROCEDURE STEPS

The eight key procedure steps based on the SOP are depicted in Fig. 6, indicating whether the task would be assigned to a prosthetic clinician or a technician.

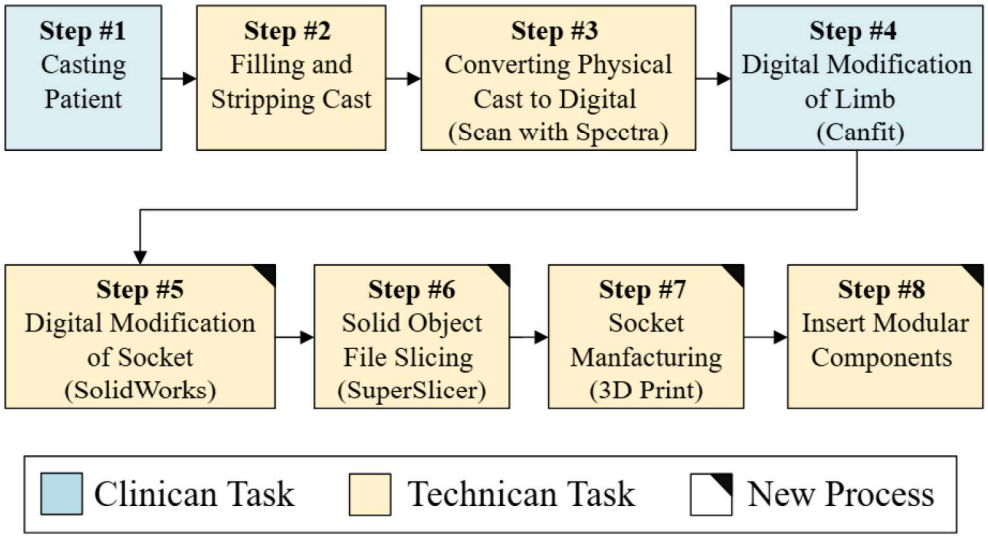


Figure 6 - The eight key procedure stages

The patient will meet with the clinician during the casting step and after the 3D printing step. AO has advised that a one-week interval between appointments is used as the standard duration between appointments, as patient availability varies. These eight steps will replace the current method for producing the NWB socket and the WB socket. The clinician and patient will meet to check the fit of the NWB socket after step seven. After the fitting appointment, the process is repeated from step one to create the WB socket. The patient and clinician will then meet to allow the patient to bring the socket home for a trial period. The trial period and onwards is beyond the project scope.

2.2 PROCEDURE OVERVIEW: FROM PATIENT SHAPE CAPTURE TO SOCKET DESIGN

The stages outlined in this portion of the SOP form the procedure of transitioning from patient shape capture to digital socket design. These steps involve using the manual casting method, the Vorum Spectra Scanner, and the Canfit CAD Program. This section will provide an overview of each of these technologies and explain their use in the SOP.

2.2.1 Manual Casting

Manual casting the residual limb remains a part of the SOP as requested by AO. Manually casting the patient provides tactile feedback, allowing the clinician to feel bony prominences, scar tissue, and the patient's unique anatomy [2]. Therefore, directly scanning the limb is not an element of the SOP as requested by the client [2].

The method for casting the patient's residual limb will remain the same as the traditional method. AO clinicians will cover the patient's residual limb with wet plaster bandages and manipulate the patient's tissue as the bandages dry. The resultant cast will be a different shape than the residual limb. This will be done intentionally to support the patient's anatomy. The detailed description of this process can be found in Section A-2.1. This cast is referred to as the 'negative mold', as it is the inverse of the patient's residual limb.

2.2.2 Filling and Stripping the Cast

The method for filling and stripping the cast will remain the same as the traditional method. Wet plaster will be poured into the negative mold, and a mandrel will be placed in the center. Once dried, the plaster and attached mandrel will be separated from the cast. The plaster is referred to as the 'positive mold'. The positive mold will resemble the patient's modified residual limb. The detailed description of this process is in Section A-2.2.

2.2.3 Converting the Positive Mold to a Digital Scan

Converting the positive mold to a digital scan will be performed in the same way as AO's hybrid process. The positive plaster mold will be held in place, mandrel side down, as seen in Fig. 7.

Figure 7 - Positive mold prepared for scanning

The positive mold will be scanned using the Vorum Spectra Scanner. The scan will be rendered in Vorum's proprietary software, currently used at AO. Additional scanning images and details are in Section A-3.1.

2.2.4 Vorum Spectra Scanner

The Vorum Spectra Scanner, shown in Fig. 8, is a handheld optical scanner used in P&O that captures high-resolution 3D models [6].

It features a built-in program for real-time visualization and anatomical landmarking [6]. This scanner is integrated into the SOP as it is owned by AO.

2.2.5 Digitally Modifying the Limb Shape

Digitally modifying the limb shape will remain the same as AO's hybrid process until exporting the limb shape file. This step takes the scanned limb shape and outputs a modified TSS shape with thickness. This process is performed entirely in Canfit by the clinician. Fig. 9 shows an example of the scanned plaster positive before digital modification.

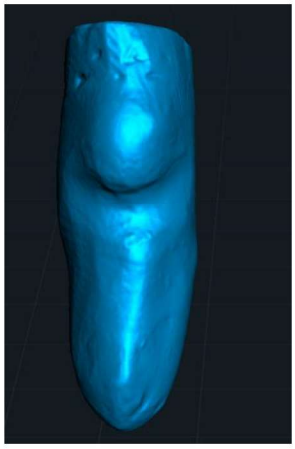


Figure 9 – Scanned plaster positive before digital modification

2.2.6 Canfit CAD Program

The Canfit program is a CAD software designed for the rapid creation of custom prosthetic devices. It features automated workflows with custom macros, which are pre-designed modifications that save time during the modification process [7]. Currently owned by AO, this CAD program is incorporated into the SOP. Fig. 10 shows the digital positive shape after modifications in Canfit.

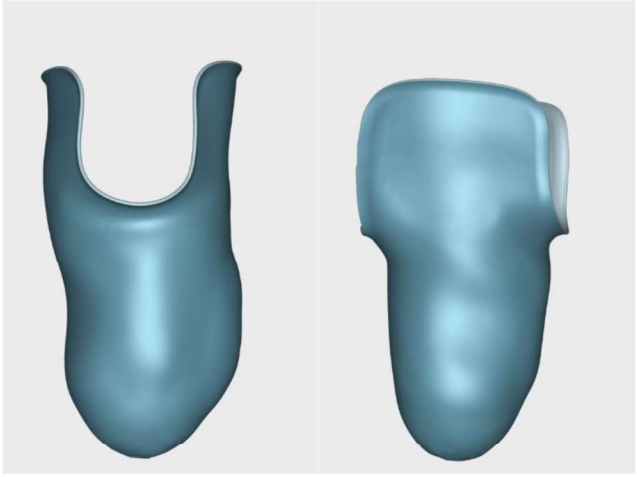


Figure 10 – Views of the digital positive shape after modifications

The clinician uploads the scanned file into Canfit, and the modifications are made to support the residual limb. These modifications could include a surface smoothing, volume reduction, buildups for anatomy and the addition of trim lines [1]. After all modifications have been completed, the clinician will use Canfit's built-in 3D printing options to add three millimetres of thickness to the socket shape. This clinician will export this TTS as an STL file. The following

series of steps introduces the Modular Attachment System, SolidWorks, SuperSlicer, and 3D printing.

2.3 PROCEDURE OVERVIEW: FROM SOCKET DESIGN TO SLICING

The stages outlined in this portion of the SOP form the procedure of converting the digital socket design to a file ready for slicing. This section introduces the Coyote drop-in air-lock, SolidWorks, and SuperSlicer, along with their uses.

2.3.1 Coyote C10A Drop-In Air-Lock

The Coyote C10A drop-in air-lock, pictured in Fig. 11, is the designated socket attachment system specified by AO. The Coyote system is designed to provide a secure, airtight seal for prosthetic sockets, enhancing the comfort, fit, and performance of the device [9]. This product is a type of valve system that allows for quick and simple installation into a prosthetic socket. This design eliminates the need for complex assembly or extensive modifications, allowing for simple integration of the valve system.

2.3.2 Solid Works Program

SolidWorks is a 3D parametric CAD software that will be used in the SOP to modify the TTS shape [8]. These modifications are specific to the WB TTS and involve creating the cavity for modular for the Coyote and support system for the leg. It is recommended that all SolidWorks part and assembly files be saved in a single folder per patient.

2.3.3 Digitally Modifying the Weightbearing Socket Shape

This step is for the WB TTS only. The process takes the STL of the modified limb shape and outputs an STL of a socket that includes a modular component cavity and the distal limb disc (DLD), shown in Fig. 12.

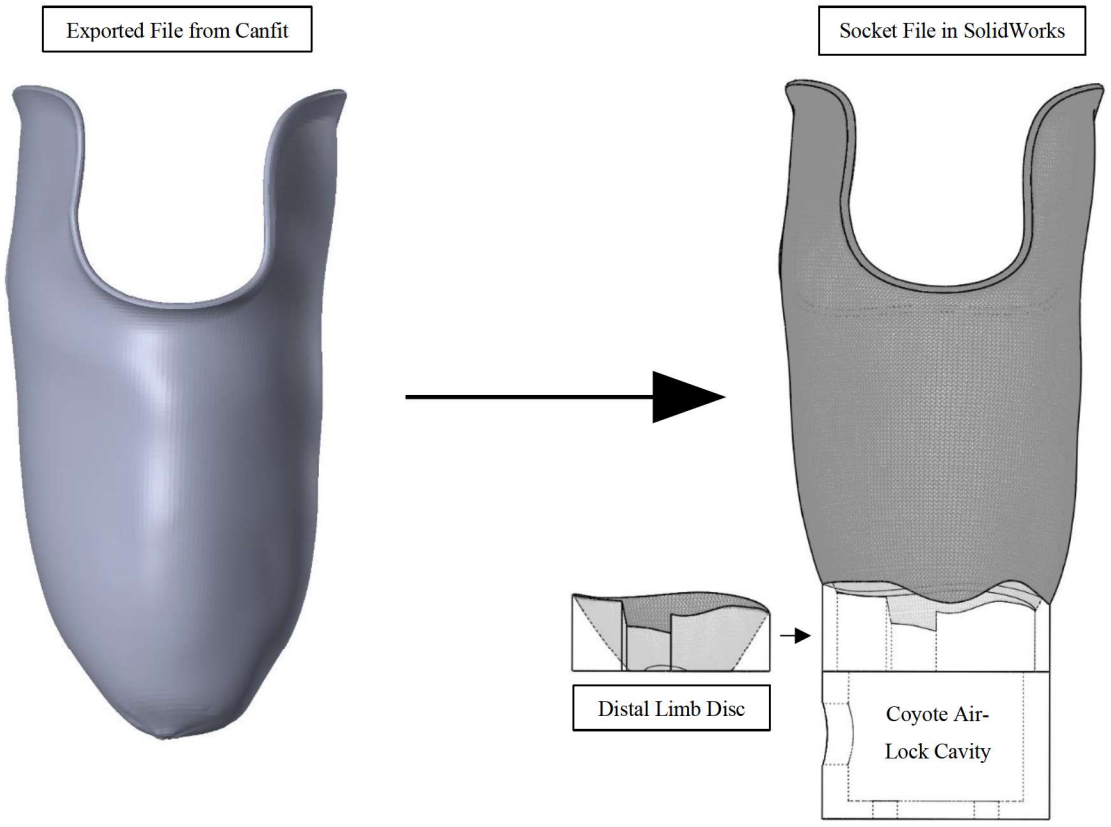
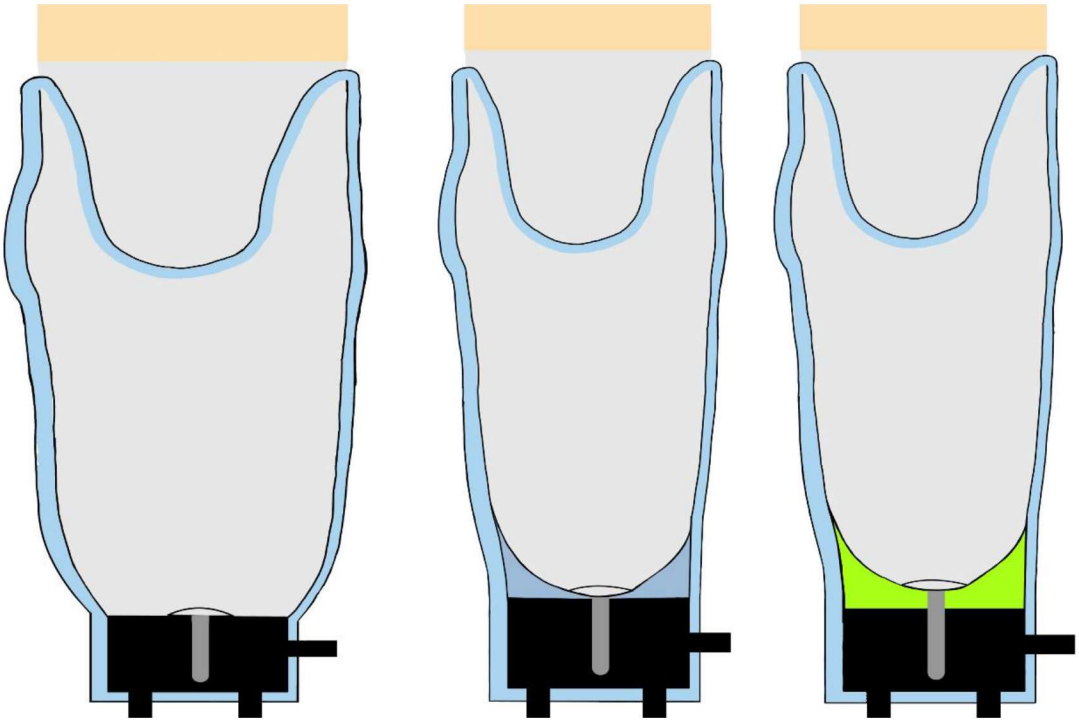


Figure 12 - Canfit STL (left) and final socket and DLD STL (right)

The DLD is only required in limb shapes that have a smaller distal diameter than the Coyote system. As seen in Fig. 13 (middle), the dark blue void space between the socket-limb interface will cause the patient's limb to lose contact with the socket surface. This would result in an ill-fitting socket that will cause discomfort to the patient [1]. The solution to this issue is the addition of the DLD. As seen in Fig. 13 (right) the DLD depicted in lime green creates an interface that fills the void volume and permits a proper fitting socket. The DLD is not required for limb shapes that have a greater distal diameter than the Coyote system as seen Fig. 13 (left), as a void space does not exist.



LEGEND OF FIGURE 13			
RESIDUAL LIMB	VOID SPACE BETWEEN SOCKET AND LIMB	DISTAL LIMB DISC	COYOTE C10A SYSTEM

Figure 13 - Sagittal view of socket without (left & middle) and with DLD (right)

This process of creating a cavity for the modular component is performed in SolidWorks. While various modular components can be added to a socket, the scope of this project uses only the Coyote system, as requested by the client. This is the modular component that will serve as the connection from leg to the TTS in addition to connecting the TTS to the pylon and foot.

The portion of the WB socket that holds the Coyote modular component is referred to as the modular cavity. A 3D model of the modular cavity was acquired from the Coyote Company and replicated in SolidWorks. The SolidWorks modular cavity part is shown in Fig. 14. The cavity features four holes at the bottom for the four pegs of the Coyote part, enabling attachment of modular components and a medial hole for the protruding arm of the Coyote system.

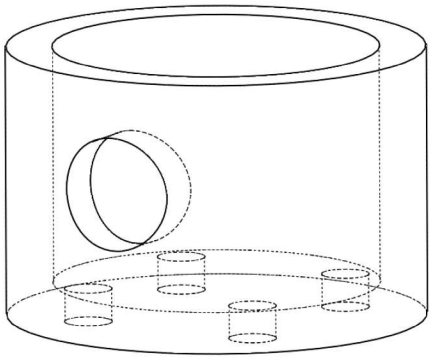


Figure 14 - SolidWorks replica of the Coyote C10A drop-in air-lock cavity

Adding the modular cavity to the exported Canfit socket requires four steps: adding the bridge to the socket, aligning the cavity to the bridge, combining the socket, bridge and cavity into one part, and exporting the part for 3D printing.

2.3.4 Adding the Bridge to the Weightbearing Socket STL

In this step, SolidWorks is used to add an appropriate connection between the proximal coyote cavity and interior socket surface.

The steps are as follows: open SolidWorks, create a new part, set units to "MMGS (millimeter, gram, second)" and import the modified limb STL. A reference plane must be created parallel to the transverse plane intersecting the modified limb. The height of this plane is where the coyote modular component meets the patient's limb. The clinician will determine this height based on their expertise, as the height of the reference plane is patient specific. An example reference plane is shown in Fig. 15 where it is located eight millimeters above the transverse plane.

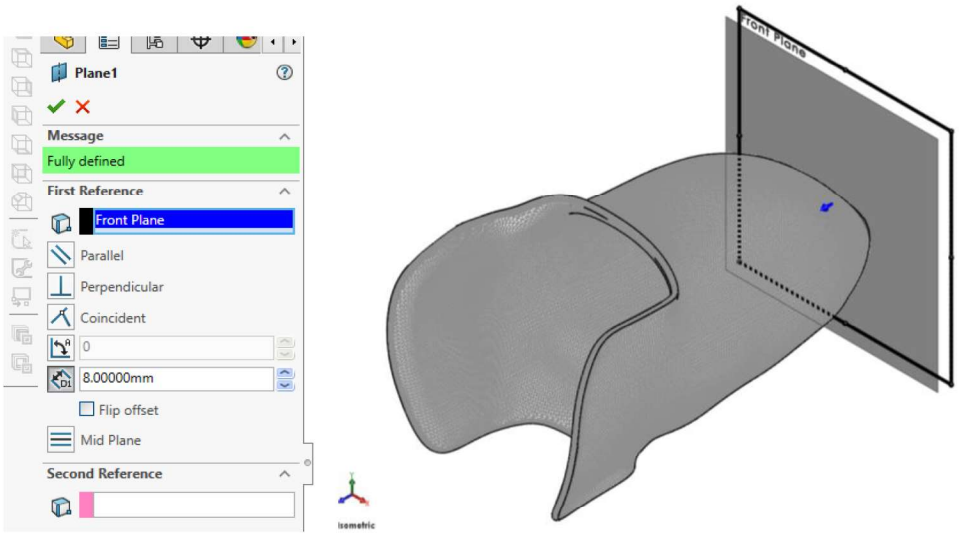


Figure 15 - New reference plane offset from the transverse plane

On the newly created reference plane, a sketch of the coyote cavity must be created or imported. The sketch of the coyote cavity wall must then be extruded to the socket-limb interface using the Boss-Extrude feature. This extrusion is the bridge between the proximal coyote cavity and interior socket surface. The sketch and resultant extrusion are shown in Fig. 16.

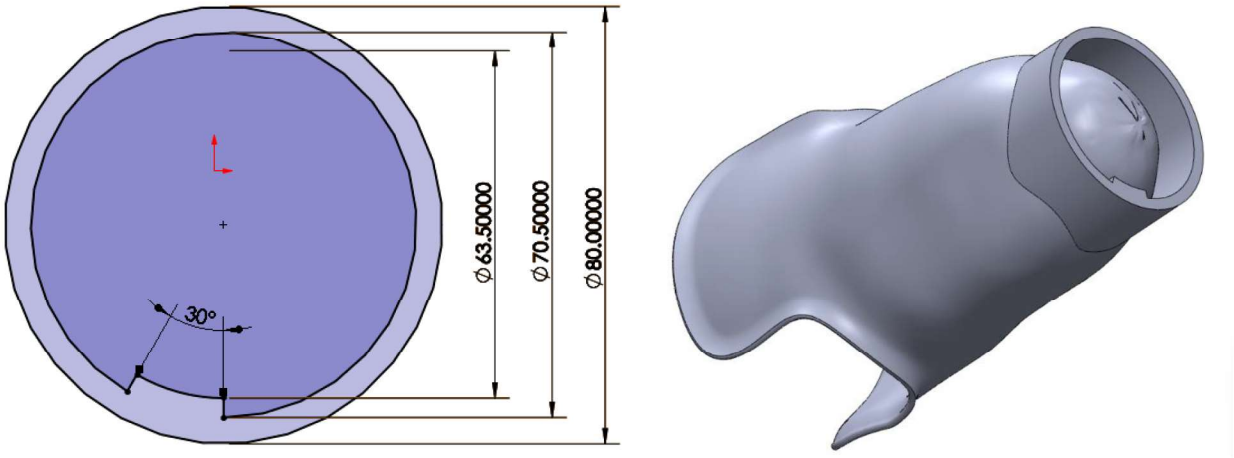


Figure 16 - Sketch to extrude from the reference plane to the interior socket surface (left) and the resultant extrusion (right)

The sketch of the inner wall (70.5mm) is translated as a copy to the surface of the socket. The translated sketch is then Extrude-Cut through all objects. The resultant part is shown in Fig. 17.

Figure 17 - Resultant bridged WB socket

This part is saved and duplicated within the same folder to be modified for creating the DLD.

2.3.5 Creating the Distal Limb Disc

The DLD part is created by modifying a copy of the previously created bridged socket file. The socket file shown in Fig. 17 is duplicated and renamed appropriately. Using the configuration menu in SolidWorks, the sketch is accessed from the Boss-Extrude action enabling editing. The 80mm circle is set to be a construction line. The remaining circular diameters are re-defined to match the values shown in Fig. 18. The 70.5mm circle must become 69.5mm, and the 63.5mm circle must become 62.5mm. The purpose of reducing these diameters is to account for the tolerances associated with 3D printing inset parts. After changes to the diameters have occurred, the sketch is saved.

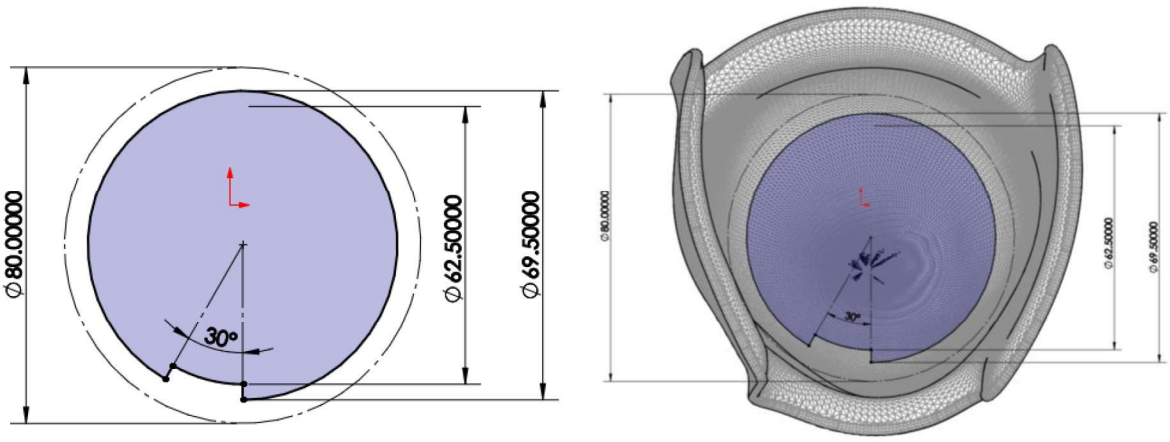


Figure 18 - Updated Boss-Extrude sketch

In the configuration menu, the Cut-Extrude feature for the previous sketch is opened to edit. The directions of the extrusion are set to only extrude the distal end of the socket, shown in Fig. 19.

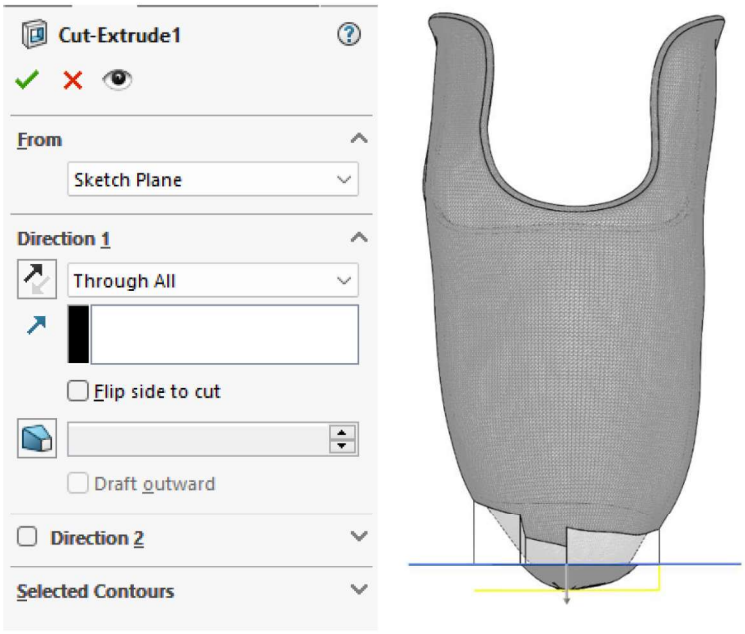


Figure 19 - Cut-Extrude settings

The sketch created from the Cut-Extrude function is duplicated. An additional circle is added to the sketch. The circle must exceed the width of the socket but is shown to be 180mm in Fig. 20.

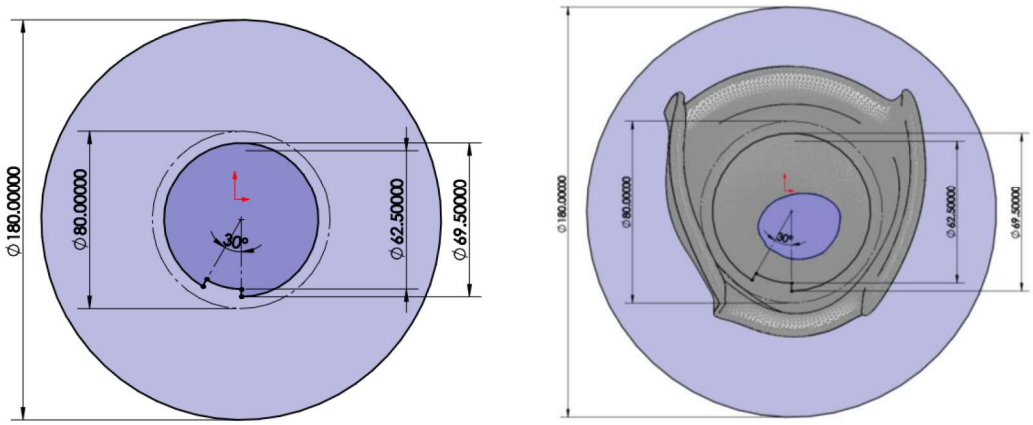


Figure 20 - Extrude-Cut sketch to remove the remaining socket

An extruded cut is performed with this sketch, cutting through all objects in both directions. The menu settings to perform this extruded cut are show in Fig. 21.

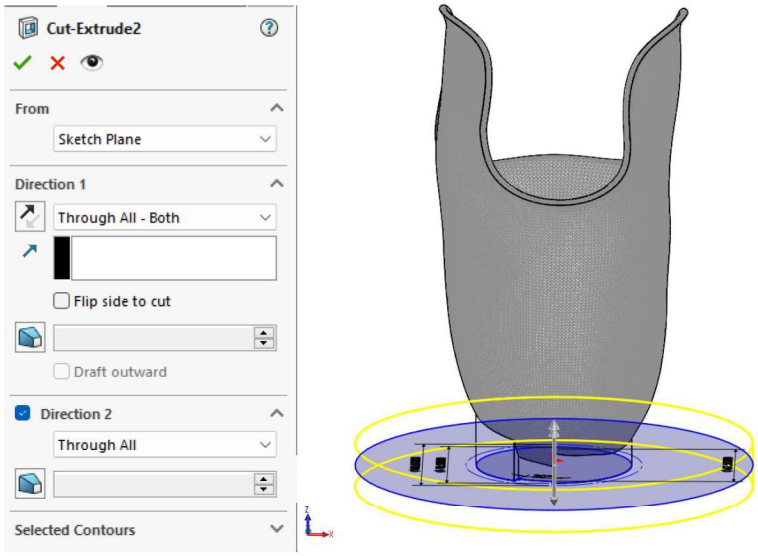


Figure 21- Extrude-Cut settings

At this point the DLD is complete. However, in certain circumstances an individual's distal limb contouring may overlap with the area needed to pass a pin through. In the event the pin cannot pass through the DLD due to obstruction within the central axis, additional modifications are required. The distal planter face of the DLD must be selected for editing. A new sketch is created on the distal planter surface and a circle sketch from the central axis is created. As an example, a 20mm circle has been sketched in Fig. 22.

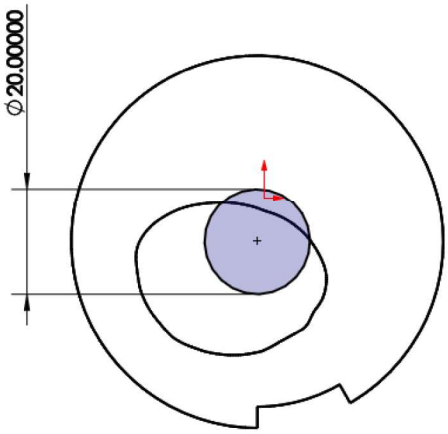


Figure 22 - Extrude-Cut sketch to allow for pin passage

The circle sketch is then Extrude-Cut with the setting "Through All – Both". This process will result in the pin relief space for the DLD shown in Fig. 23.

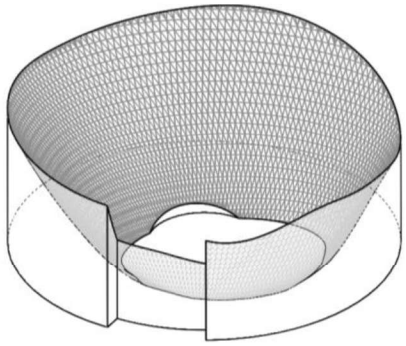


Figure 23 - Resultant DLD with pin relief space

At this stage, the DLD is complete and can be saved as an STL with the "Save As" function.

2.3.6 Aligning the Weightbearing Socket and Cavity

To align the socket and the cavity, a new SolidWorks assembly is created, and the newly modified socket part and the Coyote cavity part are imported into this assembly. The circular faces of the bridge and cavity concentrically and coincidentally mate, resulting in the alignment shown in Fig. 24.

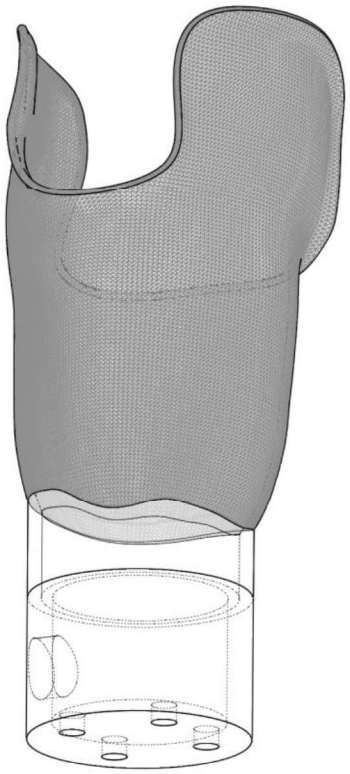


Figure 24 - Concentrically and coincidentally mated socket and cavity

The socket is fixed in place and cavity sketch is rotated until the side hole is oriented medially and the bottom four holes are rotated to be in line with the front as shown in Fig. 25.

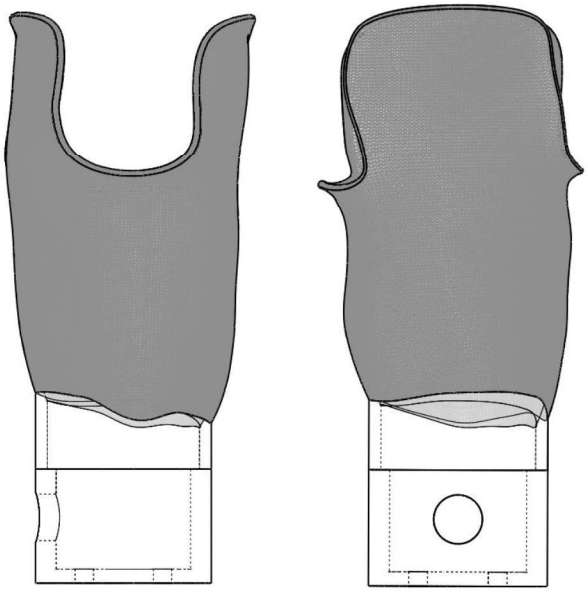


Figure 25 - Orientation of cavity hole from anterior (left) and medial view (right)

2.3.7 Combining the Weightbearing Socket and Cavity

Combining the socket and cavity into one part requires the following series of steps within the same assembly:

1. Select "Insert → Component → New Part"
2. Select any part face then exit the sketch
3. Select "Insert → Features → Join"
4. Select the socket and the cavity parts
5. Select "Hide Parts" and then "Accept"
6. Exit the part

This creates a new part that is the combination of both separate parts.

2.3.8 Exporting the Weightbearing Socket and Distal Limb Disc for 3D Printing

To export for 3D printing, the socket and DLD must be exported as a STL, which can be performed with the "Save As" function in SolidWorks.

2.3.9 SuperSlicer Program

The SuperSlicer program is a powerful and versatile 3D printing slicer software designed to provide users with a highly customizable and efficient tools for preparing 3D models for printing [10]. This will be included into the SOP as it is a free program and has the capabilities to alter the printing specifications.

2.3.10 Slicing and Printing the Socket

This step is performed in SuperSlicer for both the NWB and WB TTSs. This step takes the completed socket STLs and outputs a GCODE which can be directly input into a 3D printer. A GCODE file is a plain text file that contains instructions for controlling computerized machine tools and 3D printers.

The slicing steps are the same for all pieces involved in the NWB and WB TTSs, except for the addition of supports for the NWB TTS. The process begins by opening SuperSlicer and using the Import function under the File menu to import an STL file. All files are printed with the distal end placed on the print bed. To create this orientation, the Place on Face function is selected. The Place of Face icon is shown in Fig. 26.

Figure 26 - Place on face function icon

Pressing this icon causes a white surface to appear for each face of the imported STL. The distal face is selected, resulting in the following orientation shown in Fig. 27.

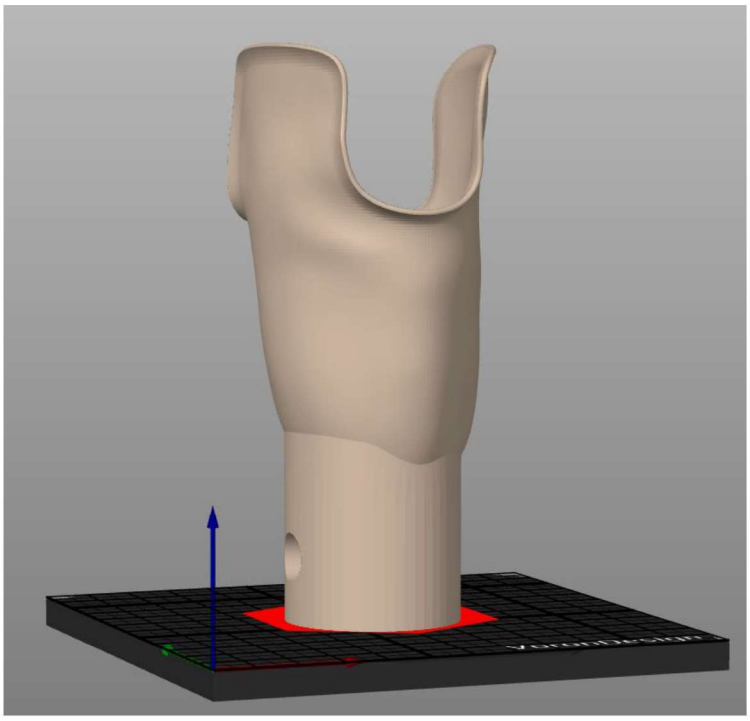


Figure 27 - WB socket oriented with distal face on the print bed

The NWB TTS is the only part that requires supports for printing. These supports are added via the Paint-on Supports function. The Paint-on Supports icon is shown in Fig. 28.

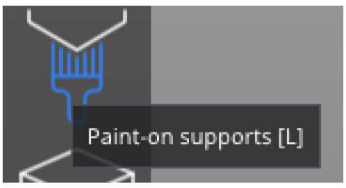


Figure 28 - Paint-on supports icon

In the Paint-on Supports menu all 45° overhangs are selected. A blue area on the model indicates where there will be supports, shown in Fig. 29.

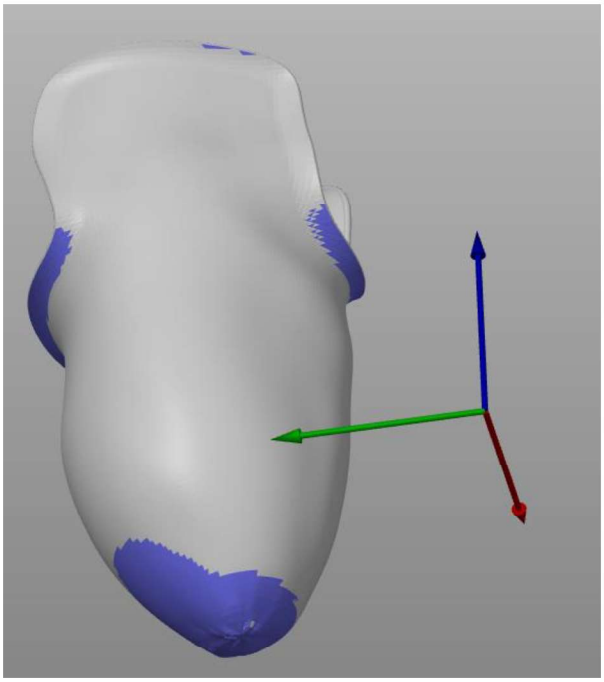


Figure 29 - NWB TTS with supports for 45° overhangs

The NWB TTS requires supports only on the distal end of the socket, so the non-distal overhangs are erased. At this point all components of the NWB and WB TTSs are sliced by selecting "slice now", and the resultant GCODE is then exported to a 3D printer.

2.4 PROCEDURE OVERVIEW: FROM SLICING TO SOCKET FITTING

This section will outline the procedure for 3D printing to the patient socket fitting, detailing each step involved. Additionally, it will provide the recommended specifications for selecting an appropriate 3D printer to ensure optimal performance and quality.

2.4.1 3D Printer Specifications

The 3D printer that AO would require to 3D print within their clinic is determined by several key identifying factors. These factors for the 3D printer are as follows:

- SuperSlicer compatibility
- Print volume capabilities
- Capabilities to print Polylactic Acid (PLA) and Polyethylene Terephthalate Glycol (PETG)
- Compatible nozzle sizes

The specific values and printers recommended are in Section 6.2, Recommended 3D printer specifications.

2.4.2 Configuring the 3D Printing Settings

Before slicing and printing an STL, SuperSlicer's print, filament, and printer settings must be configured. Basic printer and nozzle presets are available within SuperSlicer for a large range of standard hobbyist printers, such as Voron and Creality models. Custom printer and nozzle settings can be created when necessary.

Given that the scope of the project did not involve creating custom settings, the print presets provided by SuperSlicer were utilized and modified as necessary to accommodate the Voron v0 3D printer available at the University of Manitoba's lab. In SuperSlicer the printing parameters and printing pattern must be defined. The printing pattern employs a solid infill every layer executed in a concentric manner, ensuring consistent strength and structural integrity throughout the socket. This method optimizes material usage while maintaining the necessary support for functional performance. Table II contains the print and filament settings for the WB and NWB filament.

TABLE II

KEY SUPERSLICER FILAMENT AND PRINT SETTINGS

SuperSlicer Setting	**Top Non-Weightbearing Filament (Eryone)**	**Top Weightbearing Filament (Elegoo)**
Filament Settings		
Filament Type	PETG	PLA+
Extrusion Multiplier	1.2	1
Nozzle Temp First Layer	250°C	225°C
Nozzle Temp Other Layers	245°C	215°C
Bed Temp First Layer	80°C	55°C
Bed Temp Other Layers	80°C	55°C
Print Settings		
Perimeters	3	2
Infill – Solid/Top/Bottom	Monotonic (Filled)	Monotonic (Filled)
Infill – Bridge	Monotonic	Monotonic
Infill – Sparse	Monotonic	Rectilinear

KEY SUPERSLICER FILAMENT AND PRINT SETTINGS - CONTINUED

SuperSlicer Setting	Top Non-Weightbearing Filament (Eryone)	Top Weightbearing Filament (Elegoo)
Print Settings		
Infill Angle – Angle – Fill	0°	0°
Infill Angle – Modifiers – Alternate Fill Angle	Deselected	Deselected
Support Material – Generate Support Material	Selected	Selected
Support Material – Auto Generated Supports	Deselected	Deselected
Support Material – Style	Snug	Snug
Support Material – Pattern	Rectilinear Grid	Rectilinear Grid

The extrusion multiplier, nozzle temperature, and bed temperature may vary with printers or batches of filament. SuperSlicer's bed leveling, filament flow, filament temperature, and extruder retraction calibration settings must be performed when getting a new printer, nozzle, or filament. Once these settings are solidified, printing of sockets and DLDs can occur.

2.4.3 Fitting the Socket and Final Modifications

The NWB TTS requires no further adjustments prior to fitting the patient. However, the WB TTS needs the Coyote system to be inserted and the pylon and foot system to be attached. The pylon and foot system are secured using standard, off-the-shelf P&O products. The identification of specific recommended products is beyond the scope of this project as it is a clinician-based decision.

In summary, the proposed SOP integrates the technologies of manual casting, the Vorum Spectra Scanner, and the Canfit, SolidWorks and SuperSlicer Programs. The eight key stages of the SOP cover the process from casting the patient's limb to the final 3D printing of the socket, ensuring a streamlined workflow. The integration of these technologies enhances the socket development process by increasing precision, reducing manual labour, and supporting the creation of functional, patient-specific solutions.

3.0 VERIFICATION PROCEDURES

This section outlines the verification procedures that will be used to ensure the target specifications in Table I in Section 1.2.3 will be met. The verification will be conducted through three types of procedures. The first type of procedures focus on verifying the physical characteristics of the socket target specifications. This ensures the design meets all required dimensional and material standards. The verification procedures for the physical characteristics of the socket specifications have been outlined in Section 3.1. The second type of verification procedures evaluate the patient, clinician, and technician satisfaction of the proposed manufacturing method of the socket. This ensures the solution aligns with user expectations and practical usability. The verification procedures for the satisfaction of the socket have been outlined in Section 3.2. The third and final verification procedure compares the overall and hands-on time required to complete both manufacturing processes for a socket, as detailed in Section 3.3. It should be noted that some procedures use the traditional manufactured socket as the standard of comparison. The passing criterion for these procedures will depend on the tested values of the traditionally manufactured socket during testing. Full methodology for each verification procedure can be found in Appendix B.

Table III, a summary table consolidating the results from all verification procedures has been presented to provide an overview of the findings. A green cell indicates that the criteria were met in all aspects, a yellow cell signifies that the test failed in certain areas but was still considered acceptable, and a red cell shows that the test failed, making the solution unsuitable.

TABLE III

VERIFICATION PROCEDURES AND RESULTS SUMMARY

Procedure	Passing Criteria	Results	
4.1: Socket Volume Retention	Volume retention within ± 2% of total volume of traditionally manufactured socket	0.24% volume difference	
4.2: Post-Print Sandability	Thickness change ≤ 0.028mm after sanding. Criteria fail if samples deform or break	Polymaker 1 (NWB): 0.018 ERYONE 1 (NWB): 0.021 OVERTURE (NWB): 0.023 IEMAI (NWB): 0.023	Polymaker 2 (NWB): 0.018 ERYONE 2 (WB): 0.012 Polymaker 3 (WB): 0.013 ELEGOO (WB): 0.011
4.3: Dimension Replicability Test	Measured dimensions of the 3D-printed socket must be within ±3 mm of the traditional socket	Dimension A: +3 Dimension B: +6	Dimension C: -2 Dimension D: +1
4.4: Transparency Test	Tramsmittance of printed filament ≥ 25%	Polymaker 1: 25.74% ERYONE 1: 29.20% OVERTURE: 21.74%	IEMAI: 25.46% Polymaker 2: 25.37% Guideline: 17.08 %
4.5: Compressive Load Capacity	Printed filament can withstand 1112N (250lbs) of force using a limb-like shape for dynamic compression testing	PLA filament can withstand average compressive force of 5338 N	
4.6: Satisfaction Surveying	Match or exceed the Likert scale score of the traditionally manufactured TTS	Patient: Traditional (24) < 3D (29.11) Clinician: Traditional (22) < 3D (32.44) Technician: Traditional (20) < 3D (21.86)	
4.7: Overall Manufacturing Time Reduction	The overall manufacturing time for two 3D printed sockets (NWB and WB) must be less than or equal to the overall time for two traditionally manufactured sockets (NWB and WB)	NWB socket: 26.4% time reduction	WB socket: 6.7% time reduction
4.8: Hands-On Manufacturing Time Reduction	The hands-on manufacturing time for two 3D printed sockets (NWB and WB) must be less than or equal to the overall time for two traditionally manufactured sockets (NWB and WB)	NWB socket: 22.1% time reduction	WB socket: 22.1% time reduction

3.1 VERIFICATION PROCEDURES FOR PHYSICAL SOCKET

The verification procedures in this section are used to verify the physical characteristics of the 3D printed TTS. These procedures serve to confirm the design's consistency with the established benchmarks of a traditionally manufactured TTS to ensure it is suitable for practical applications.

3.1.1 Socket Volume Retention

The purpose of the socket volume retention test is to identify any discrepancies between the two manufacturing methods for a TTS. This was assessed by measuring the amount of water required to fill each socket and comparing their recorded masses. After filling the socket with water, the traditionally manufactured socket had a recorded mass of 1355.1 g, while the 3D-printed socket from the same patient measured 1351.9g.

TABLE IV

SOCKET VOLUME RETENTION

Specification 1.1: Retain mold volume of socket (± 2%)	
Procedure #	4.1
Purpose	To determine if the 3D printed TTS retains the same volume as the traditionally manufactured socket
Equipment	Digital scale with a range of: 2g – 5000g and accuracy to two decimal places, 1L beaker
Materials	Traditionally manufactured TTS, 3D printed TTS
Passing Criteria	Volume retention within ± 2% of total volume of traditionally manufactured socket
Results	Pass: 0.24% volume difference
Appendix	B-1.1

To assess whether the 3D-printed socket retained its volume within the established criteria, calculations were performed. First, the volume of each socket were calculated using Equation 1. This value was then compared to the volume of the traditionally manufactured socket to

determine if the retention fell within the acceptable range of ± 2%. Sample calculations showing this process are provided below.

$$V = \frac{m}{\rho} \quad (1)$$

$$Volume\ of\ water\ in\ traditionally\ manufactured\ socket = \frac{1355.1\ g}{1.00\frac{g}{cm^3}} = 1355.1cm^3$$

$$Volume\ of\ water\ in\ 3D\ printed\ socket = \frac{1351.9g}{1.00\frac{g}{cm^3}} = 1351.9cm^3$$

$$Percent\ Difference = \frac{(V_{ts} - V_{ps})}{V_{ts}} * 100\% \quad (2)$$

$$Percent\ Difference = \frac{(1355.1cm^3 - 1351.9cm^3)}{1355.1\ cm^3} * 100\% = 0.24\%$$

Since the 0.24% volume difference is less than the 2% target, it can be concluded that 3D printing did not significantly impact the volume retention of the TTS. Therefore, the passing criteria set for Specification 1.1 was met.

3.1.2 Post-Print Sanding Feasibility

To ensure the design solution can withstand subtractive modification after being 3D printed, a test was conducted to measure the change in thickness after sanding a 3D printed sample. Sanding is used after 3D printing a socket to smooth edges if any imperfections occur, which is why the filament must be able to withstand the subtractive modification without deforming. As outlined in Appendix B-1.2, the verification process involved sanding a 3D printed piece using both 60 and 120 grit sandpaper and taking before and after thickness measurements. A sample from a traditionally manufactured socket was gathered as a baseline passing condition, giving a change in thickness of 0.028mm. Based on this baseline, each filament must have a change in thickness less than or equal to 0.028mm after sanding occurs. Visual observations of how filament felt before and after sanding and if any deformation occurred were also noted during this testing.

TABLE V

POST-PRINT SANDING FEASIBILITY

Specification 1.2: Δ thickness ≤ 0.028mm after sanding	
Procedure #	4.2
Purpose	To determine if the filament can be sanded for modifications after printing
Equipment	Micrometer, Sharpie
Materials	60 and 120 grit sandpaper, three pieces of baseline PETG from traditional manufacturing, three 3D printed 5cm x 5cm x 3mm pieces made with NWB TTS filament and three made with WB TTS filament
Passing Criteria	Change in thickness before and after sanding ≤ 0.028mm. If the samples deform or fall apart during sanding the criteria cannot be met
Results	Pass: Reference Table VI for details
Appendix	B-1.2

The average measurements taken between three samples of each printed filament type are shown in Table VI.

TABLE VI

POST-PRINT SANDING FEASIBILITY RESULTS

Socket Type	Brand	Filament Type	Initial Thickness (mm)	Final Thickness (mm)	Change in Δ Thickness (mm)	Result
NWB	AO Baseline	PETG (thermomold)	4.241	4.213	0.028	Baseline
NWB	Polymaker 1	Polyvinyl Butyral (PVB)	2.934	2.916	0.018	Pass
NWB	ERYONE 1	PETG	3.349	3.328	0.021	Pass
NWB	OVERTURE	PETG	3.252	3.229	0.023	Pass
NWB	IEMAI	PETG	3.302	3.279	0.023	Pass
NWB	Polymaker 2	PETG	3.182	3.164	0.018	Pass
WB	ERYONE 2	Carbon Fiber PLA	3.108	3.096	0.012	Pass
WB	Polymaker 3	PLA Pro	3.425	3.412	0.013	Pass
WB	ELEGOO	PLA+	3.067	3.056	0.011	Pass

Based on the results shown in Table VI, all eight tested filaments passed. This shows that the tested filaments would all be suitable for subtractive modification after 3D printing at AO. None of the filaments deformed or fell apart during the testing. It was noted that the ERYONE 2 carbon fiber PLA WB filament was rougher in texture than the other WB PLA filaments. The ELEGOO PLA+ filament appeared to be the smoothest WB filament when printed and had the

lowest change in thickness after sanding. From these observations it can be inferred that this filament is durable and may not need sanding modifications after printing.

3.1.3 Dimension Replicability

A dimension test was conducted to ensure the 3D-printed socket replicates the critical dimensions of the traditionally manufactured TTS without significant dimension alterations.

TABLE VII

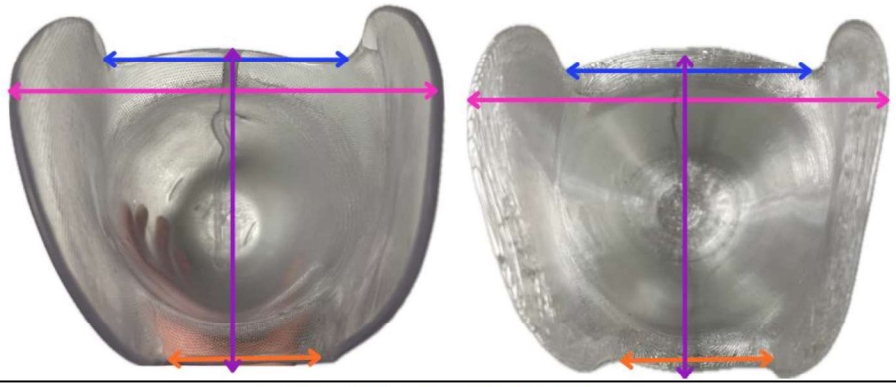
DIMENSION REPLICABILITY TEST

Specification 1.3: Retain dimensions within ± 3mm of traditionally manufactured socket	
Procedure #	4.3
Purpose	To determine if the dimensions at four points are ± 3mm of traditionally manufactured TTS
Equipment	Soft tape measure
Materials	Traditionally manufactured TTS, 3D printed TTS
Passing Criteria	Measured dimensions of the 3D-printed socket must be within ±3 mm of the traditional socket
Results	Pass: Reference Table VIII for details
Appendix	B-1.3

As outlined in Appendix B-1.3, the verification process involves measuring the critical dimension at four specific points on each socket and determining the variation between them. The equation describing this relationship is provided in Equation 3 where ΔW represents the change in width dimension, W_{3D} represents the width dimension of the 3D printed TTS and W_T represents the width dimension.

$$\Delta W = W_{3D} - W_T \qquad (3)$$

Measurements were taken at four designated points on both the traditionally manufactured socket and the 3D-printed socket and are indicated in Figure 30.



LEGEND FOR FIGURE 30							
A	FRONT	B	BACK	C	TOP	D	BACK TO FRONT

Figure 30 - Designated measurement points on traditionally manufactured TTS (left) and 3D printed socket (right)

The measurements taken at each of four points for the two sockets are recorded in Table VIII.

TABLE VIII

DIMENSION REPLICABILITY RESULTS

Measurement Location	3D Printed Socket (cm)	Traditional Socket (cm)	Δ W (cm)	Δ W (mm)	Results
A (Back)	10.9	10.6	+0.3	+3	Pass
B (Front)	7.2	6.6	+0.6	+6	Fail
C (Top)	11.6	11.8	-0.2	-2	Pass
D (Front to Back)	14.1	14.0	0.1	+1	Pass

Three of the four measured points met the passing criteria, with the differences between the 3D-printed and traditionally manufactured sockets remaining within ± 3mm. However, measurement B (Front) exceeded the allowable difference by 3mm, resulting in a failure for that specific point. Although measurement B exceeded the allowable difference by 3mm, resulting in failure for that specific point, the fact that three of the four measured points met the passing criteria within ± 3mm suggests that the 3D-printed socket is still a suitable solution. The minimal difference at one point indicates that 3D printing TTSs are generally reliable, with only a small variation at one specific measurement location.

It has been discussed with the client that the 3D printed socket may provide a more accurate representation of the intended socket design. This is due to human error that is introduced during the addition step of the trim line in the traditional manufacturing process. When traditionally manufacturing a TTS, the clinician uses a marker either on the positive plaster mold or directly on the PETG to indicate where the trim line should be located. When the technician cuts the trim line for the socket, the marked line is not always accurately followed and is highly susceptible to human error. In contrast, when designing the trim line for a 3D-printed socket, the clinician first selects multiple points around the limb in Canfit. These points are then connected in the program to form the final trim line. The use of Canfit eliminates the potential for human error and creating a more representative trim line of what the clinician indicated.

3.1.4 Transparency Testing

The client has indicated the importance of finding a transparent filament as it allows for a visual assessment of the residual limb during fitting and use. This verification procedure was conducted to determine which of the filaments selected by the team would provide the most transparent results.

TABLE IX

TRANSPARENCY TEST

Specification 1.4: Transmittance of 25%	
Procedure #	4.4
Purpose	To determine if the socket transparency is sufficient
Equipment	UV-Vis Spectrophotometer and 3D printer
Materials	Five samples of each filament printed in a solid matrix pattern with dimensions shown in B-1.5, distilled water, cuvettes and Kimwipes
Passing Criteria	Tramsmittance of printed filament ≥ 25%
Results	Pass (4/6): Reference Table X for details
Appendix	B-1.4

Transparency testing was conducted using the BioMate 3 UV-Vis Spectrophotometer. All measurements taken were at the 600 nm wavelength. This wavelength was selected for two reasons. This wavelength falls within the visible light spectrum, making it the relevant range for qualitative visual assessments of transparency. Secondly, this wavelength was selected as the

differences in transparency were best reflected during preliminary testing using the 600 nm wavelength.

To determining pass/fail criteria for the 3D printed filaments, a transmittance of 25% will be used as the minimum threshold for a passing measurement. A transmittance of 25% was selected as it represents a level of transparency that allows for adequate visibility while maintaining the structural integrity of the socket. This threshold was determined based on qualitative assessments by AO during preliminary testing. Filaments exhibiting transmittance values below 25% were considered insufficiently transparent, as they did not allow for adequate visibility of the residual limb through the socket. Conversely, filaments exceeding this threshold demonstrated a balance between clarity and mechanical performance, making them suitable for further evaluation in prosthetic applications.

There were six different filaments of various brands tested. Of the six filaments, five of the filaments were made of PETG material (ERYONE 1, OVERTURE, IEMAI, Polymaker 2 and Guideline) and the remaining filament (Polymaker 1) was polyvinyl butyral (PVB). PETG was a primary focus of this project, as the client's experience indicated it provided the best results for socket modification.

The UV-Vis spectrophotometer measures the absorbance of each filament. To express the results in terms of transparency, absorbance values were converted to transmittance using Equation 4 providing a quantitative assessment of each filament's transparency, where A is the absorbance measured by the UV-Vis spectrophotometer and T is the transparency of the material expressed as a percentage of light transmitted through the filament.

$$T = 10^{-A} * 100 \qquad (4)$$

The transparency results showed a range of optical transmittance values across the six filaments tested with the data summarized in Table X.

TABLE X

TRANSPARENCY TESTING RESULTS

Filament Brand	Type	Absorbance @600nm					STDEV	Mean	Transmittance [%]	Results
		S1	S2	S3	S4	S5				
Polymaker 1	PVB	0.560	0.597	0.544	0.633	0.613	0.0369	0.589	25.74	Pass
ERYONE 1	PETG	0.574	0.504	0.532	0.507	0.556	0.0305	0.535	29.20	Pass
OVERTURE	PETG	0.631	0.669	0.631	0.676	0.707	0.0323	0.663	21.74	Fail
IEMAI	PETG	0.616	0.637	0.602	0.56	0.556	0.0353	0.594	25.46	Pass
Polymaker 2	PETG	0.494	0.591	0.494	0.695	0.704	0.1028	0.596	25.37	Pass
Guideline	PETG	0.766	0.752	0.8	0.764	0.755	0.0191	0.767	17.08	Fail

The transparency results indicated varying levels of transparency among the six filaments tested. ERYONE 1 PETG demonstrated the highest transmittance at 29.2%, making it the most transparent filament in this study. The Polymaker 1 PVB filament followed closely at 25.7%. Among the filaments tested, Guideline and OVERTURE exhibited the lowest transmittance at 17.1% and 21.7% respectively. Both filaments failed as they do not meet the minimum 25% transmittance requirement to pass. Despite PVB offering slightly higher transparency than most of the PETG filaments, the results suggest that the difference between PVB and the best performing PETG filament is relatively small. These findings support the client's preference for PETG, as its transparency performance is sufficient given its additional advantages in mechanical properties and ease of socket modification. There are two important observations about the materials tested that were noted during testing. Polymaker 2 PETG exhibited poor print quality, with noticeable fibrous material attached, potentially influencing its transparency. Guideline PETG was noted for its yellowish color, which could impact its appearance and desirability for the client when compared to other filaments.

3.1.5 Compressive Load Capacity

Research was conducted into different studies performed on the additive manufacturing of transtibial sockets. The passing criteria of the socket withstanding 1112N of compressive force was determined from studies using filaments that have already been tested for P&O applications. Filaments that satisfy this criterion will be chosen for 3D printing WB TTSs. The testing

includes dynamic compression testing, using a force applicator that simulates a patient wearing the socket.

TABLE XI
COMPRESSIVE LOAD CAPACITY

Specification 2.4: Socket compressive load capacity ≥ 1112 N	
Procedure #	4.5
Purpose	To determine the maximum compressive load of the socket
Equipment	N/A
Materials	N/A
Passing Criteria	Printed filament can withstand 1112N (250lbs) of force using a limb-like shape for dynamic compression testing
Results	PLA filament can withstand well above the compression force passing criteria
Appendix	N/A

The ISO 10328 "Structuring testing of lower-limb prostheses – requirements and test methods [12]," standard was used in the comparison of standard and 3D printed prosthetic sockets, giving valuable insight into filament options and testing data [11]. From the sockets tested in this study, it was shown that 3D-printed polylactic acid (PLA) sockets had comparable strength to current traditionally made PETG sockets. The printer settings as stated by Owen and DesJardins are 7mm thickness and 40% infill. It should be noted that these are not the same settings as being used for this project, but the data is relative to the type and thickness of the PETG traditionally manufactured sockets. The data gathered from this study showed that the 3D printed socket with a distal plate attached had an ultimate strength of 3837N [11]. Therefore, the 3D printed socket using PLA filament exceeds the passing criteria for the patients at AO and for Specification 2.4.

A systematic review was conducted by Kim *et al.* on 3D printed transtibial prosthetic sockets and corresponding testing data [13]. The PLA filaments tested in this review were the focus as they showed the greatest failure force. 3D printed sockets using carbon fiber and polypropylene filaments were also showcased in this review. Fully carbon fiber filament was determined as inadequate for this design solution as it can quickly wear out printer nozzles. Polypropylene was determined inadequate for this design solution as it can be easily warped when printing which would alter the socket shape, ultimately leading to an uncomfortable fit for the patient. All testing data using PLA filament had a failure force of well above the passing criteria of 1112N.

The data gathered from this review is showcased in Table XI. The extraneous variable in Table XI is defined in the review as dependent variables that have the potential to affect the results.

TABLE XII

COMPRESSIVE STRENGTH DATA FOR WB TTS [13]

Author	Year	Fabrication	Material Type	Extraneous Variable	Overall Sample Size	Avg Failure Force (N)
Owen et al.	2020	Traditional	PETG (thermomold)	Manufacturers, limb type	5	4092
Pousett et al.	2019	3D printed	PLA	Locking attachment	6	5338
Pousett et al.	2019	3D printed	PLA	Cushion attachment	6	5988

As a comparison, data is shown from a traditionally manufactured socket using thermomolded PETG as is used to traditionally manufacture sockets at AO. The 3D printed PLA socket with a locking attachment, similar to what is used at AO, was found to have an average failure force of 5338N. This is above the passing criteria for the patients at AO and for the passing criteria of Specification 2.4, meaning PLA is sufficient for the WB 3D printed socket

3.2 VERIFICATION PROCEDURES FOR SOCKET SATISFACTION

This section details the verification procedures for patient, clinician and technician satisfaction. Specifications 3.1, 3.2, and 3.3 use voluntary surveys with a Likert scale to assess satisfaction of the 3D printing manufacturing method.

TABLE XIII

SATISFACTION SURVEYING

Specifications 3.1, 3.2, 3.3: Clinician, technician, and patient satisfaction	
Procedure #	4.6
Purpose	To determine the satisfaction of the socket quality using a 5-point Likert scale
Equipment	N/A
Materials	Traditionally manufactured TTS, 3D printed TTS, pen, 5-point Likert scale-based survey in printed form
Passing Criteria	Achieve a score that is equal to or greater than the Likert scale evaluation for the traditionally manufactured TTS
Results	[redacted]
Appendix	Surveys can be found in B-2.1, B-2.2, and B-2.3

To evaluate whether 3D printing the TTS socket-maintained satisfaction among patients, clinicians, and technicians, surveys were sent to AO. Baseline data was collected from the client through a separate set of surveys that asked the same questions but were specifically focused on assessing the traditional manufacturing process for comparison. For the patient survey, the client answered the baseline questions based on feedback provided over the years regarding the traditional process since the patients who received a traditionally manufactured socket did not have a 3D printed socket to compare it to. Similarly, the clinician and technician baseline data were filled out by one clinician and one technician, who answered the same questions based on their experiences with the traditionally manufactured sockets over time.

A total of nine surveys were completed by patients and clinicians, while technicians completed seven surveys. Respondents completed the survey using a 5-point Likert scale, where 1 represented strong disagreement and 5 indicated strong agreement with each statement. The results from all surveys were compiled into tables XIV, XV and XVI.

3.2.1 Patient Satisfaction Survey Results

To assess whether the 3D printing method provided a satisfactory experience for patients, individual survey responses were compared to baseline scores from traditionally manufactured sockets. Table XIV summarizes the results, including average ratings, standard deviation, and sample size for each question.

TABLE XIV

PATIENT SATISFACTION SCALE RESULTS

	Baseline	Average	Standard Deviation	Sample Size
1: The socket is comfortable				
2: The socket fits me well				
3: I feel no pain or discomfort when wearing the socket				
4: The socket feels stable while walking or standing				
5: The socket allows me to perform my daily activities well				
6: I am satisfied with the cosmetic appearance of the socket (for WB socket only)				
7: I am satisfied with the overall fit of my transtibial socket				
Total				

To determine whether switching to the 3D printing method was desirable for patients, individual results were compared to the baseline scores. [redacted]

This aspect could be improved by using different filament colors and will be further addressed in the recommendations to the client. [redacted]

3.2.2 Clinician Satisfaction Survey Results

Similar to the patient satisfaction surveys, to determine whether the 3D printing method was well-received by clinicians, survey responses were compared to the baseline scores from traditionally manufactured sockets. Results from the clinician satisfaction surveys were tabulated and included below in Table XV.

TABLE XV

CLINICIAN SATISFACTION SCALE RESULTS

	Baseline	Average	Standard Deviation	Sample Size
1: The socket provides an optimal fit for the patient	[redacted]	[redacted]	[redacted]	[redacted]
2: The overall quality of the socket meets clinical standards	[redacted]	[redacted]	[redacted]	[redacted]
3: The socket is easy to work with the during the fitting process (ex: heat gun modifications)	[redacted]	[redacted]	[redacted]	[redacted]
4: The socket is easy to modify on Canfit	[redacted]	[redacted]	[redacted]	[redacted]
5: The socket is easy to physically modify (ex: sanding, glue application of cork)	[redacted]	[redacted]	[redacted]	[redacted]
6: The socket appears durable and well-constructed for long-term use	[redacted]	[redacted]	[redacted]	[redacted]
7: The socket supports the patient's mobility and daily activities effectively	[redacted]	[redacted]	[redacted]	[redacted]
8: Overall, I am satisfied with the socket's performance	[redacted]	[redacted]	[redacted]	[redacted]
Total	[redacted]	[redacted]		

Similar to the patient satisfaction, to assess whether the 3D printing method was favorable for clinicians, responses were compared to the baseline scores. [redacted]

3.2.3 Technician Satisfaction Survey Results

Finally, to assess the feasibility of the 3D printing method from a manufacturing standpoint, a survey was conducted among technicians. Table XVI summarizes their responses, including average ratings, standard deviation, and sample size for each question.

TABLE XVI

TECHNICIAN SATISFACTION SCALE RESULTS

	Baseline	Average	Standard Deviation	Sample Size
1: The socket was easy to fabricate	[redacted]			
2: The materials used for the socket are of high quality and suitable for fabrication	[redacted]			
3: The socket was completed in a reasonable amount of time without compromising quality	[redacted]			
4: The socket was easy to modify during the fabrication process	[redacted]			
5: Overall, I am satisfied with the process of fabricating and working with the socket	[redacted]			
Total	[redacted]			

[redacted]

3.3 VERIFICATION PROCEDURES FOR MANUFACTURING PROCESSES

The verification procedures outlined in this section must be tested multiple times to ensure consistency. As new technology is introduced within the design solution, it is important to recognize that a learning curve may affect the process durations over time. Initially the time required for each step may vary as users familiarize themselves with the technology, but with repeated testing and practice, efficiency is expected to improve.

Manufacturing times were recorded for each part of the traditional process at the beginning of the project for future comparison with the new method. After determining the design of the TTS using CAD software and 3D printing, the processing times for this method were recorded and compared to those of the traditional approach. Times were split between the hands-on manufacturing time and overall manufacturing time. Furthermore, times were recorded for how long it takes to manufacture a NWB socket and how long it takes to manufacture a WB socket. If the 3D printing method takes less time than the traditional method, these verification methods will be considered a pass.

3.3.1 Overall Manufacturing Time

To evaluate the 3D printing method's efficiency, the total manufacturing time for WB and NWB sockets were recorded and compared to the traditional process. Table XVII outlines the details of the target specification, while Table XVIII details the recorded times for each step.

TABLE XVII

OVERALL MANUFACTURING TIME REDUCTION

Specification 4.1: Overall manufacturing time reduction	
Procedure #	4.7
Purpose	To determine the time reduction in the overall manufacturing process
Equipment	Cellphone stopwatch
Materials	All materials required to manufacture a traditional and 3D printed TTS
Passing Criteria	The overall manufacturing time for two 3D printed sockets (NWB and WB) must be less than or equal to the overall time for two traditionally manufactured sockets (NWB and WB)
Results	NWB socket: 26.4% time reduction; WB socket: 6.7% time reduction
Appendix	B.3.1

TABLE XVIII

OVERALL TIME COMPARISON

Task	Traditional Method NWB	Task	Traditional Method WB	Task	3D printing Method NWB	Task	3D printing Method WB
Cast patient	35 mins	Cast patient	35 mins	Cast patient	35 mins	Cast patient	35 mins
Fill cast	40 mins	Fill cast	40 mins	Fill cast	40 mins	Fill cast	40 mins
Strip cast	10 mins	Strip cast	10 mins	Strip cast	10 mins	Strip cast	10 mins
Modify plaster of positive mold	70 mins	Modify plaster of positive mold	70 mins	Convert physical positive model to digital	20 mins	Convert physical positive model to digital	20 mins
Dry positive mold	121 mins	Align modular component dummies	3 mins	Digitally modify the limb shape	30 mins	Digitally modify the limb shape	30 mins
Thermomold socket	185 mins	Dry cast	121 mins	Export the STL file of socket	1 min	Digitally modify the socket shape	7 mins
Remove excess plastic	4 mins	Thermomold socket	183 mins	Slice the solid object file	2 mins	Export the STL file of socket	1 min
Remove plaster	7 mins	Modify trim line of socket	25 mins	Print NWB TTS	216 mins	Slice the solid object file	2 mins
Modify trim line of socket	8 mins	Add modular components onto socket	3 mins			Print WB TTS & DLD	312 mins
Create distal	1 min						

hole								
Total Time	**481 mins**		**490 mins**		**354 mins**		**457 mins**	

As shown in Table XVIII, the 3D printing method is more time-efficient than the traditional manufacturing process. The total manufacturing time for the NWB and WB sockets using the traditional method is 481 minutes and 490 minutes, respectively. In comparison, 3D printing reduces the total time to 354 minutes for the NWB socket and 457 minutes for the WB socket. This results in a 26.4% reduction for the NWB socket and a 6.7% reduction for the WB socket, highlighting 3D printing as a faster, more efficient alternative without compromising the essential steps of socket production.

3.3.2 Hands-on Manufacturing Time

Similar to the overall manufacturing time, the hands-on manufacturing time for the traditional and 3D printing methods was compared. Table XIX presents the target specification, while Table XX details the recorded times for each step.

TABLE XIX

HANDS-ON MANUFACTURING TIME REDUCTION

Specification 4.2: Hands-on time reduction	
Procedure #	4.8
Purpose	To determine the time reduction in the hands-on manufacturing process
Equipment	Cellphone stopwatch
Materials	All materials required to manufacture a traditional and 3D printed TTS
Passing Criteria	The hands-on manufacturing time for two 3D printed sockets (NWB and WB) must be less than or equal to the overall time for two traditionally manufactured sockets (NWB and WB)
Results	NWB socket: 22.1% time reduction; WB socket: 22.1% time reduction
Appendix	B.3.2

TABLE XX

HANDS-ON TIME COMPARISON

Task	**Traditional Method NWB**	**Task**	**Traditional Method WB**	**Task**	**3D printing Method NWB**	**Task**	**3D printing Method WB**
Cast patient	30 mins	Cast patient	30 mins	Cast patient	30 mins	Cast patient	30 mins
Fill cast	10 mins	Fill cast	10 mins	Fill cast	10 mins	Fill cast	10 mins
Strip cast	10 mins	Strip cast	10 mins	Strip cast	10 mins	Strip cast	10 mins
Modify plaster of positive mold	60 mins	Modify plaster of positive mold	60 mins	Convert physical positive mold to digital	20 mins	Convert physical positive mold to digital	20 mins
Dry positive mold	1 min	Align modular component dummies	3 mins	Digitally modify the limb shape	30 mins	Digitally modify the limb shape	30 mins
Thermomold socket	5 mins	Dry cast	1 min	Export the STL file of socket	1 min	Digitally modify the socket shape	7 mins
Remove excess plastic	4 mins	Thermomold socket	3 mins	Slice the solid object file	2 mins	Export the STL file of socket	1 min
Remove plaster	7 mins	Modify trim line of socket	25 mins	Print NWB TTS	3 mins	Slice the solid object file	2 mins
Modify trim line of socket	8 mins	Add modular components onto socket	3 mins			Print WB TTS	3 mins
Create distal hole	1 min						

Total Time	**136 mins**		**145 mins**		**106 mins**		**113 mins**

The 3D printing method not only shortens the total manufacturing time but also reduces the hands-on labor time required for socket production. As shown in the table above, the traditional NWB and WB methods require 136 minutes and 145 minutes of hands-on time, respectively. In contrast, the 3D printing method reduces this to 106 minutes for the NWB socket and 113 minutes for the WB socket. This results in a 22.1% reduction in hands-on time for the NWB socket and an 22.1% reduction for the WB socket. This allows AO to allocate fewer resources to manual tasks, cut labor costs, and improve efficiency, ultimately lowering overall production costs.

The results of the verification procedures indicate that the proposed design solution meets the performance criteria outlined in terms of physical properties, patient satisfaction and manufacturing time reduction. While minor variations were observed in diameter retention and transparency, these deviations remain within acceptable limits for implementation in the clinic. The overall satisfaction ratings from patients, clinicians and technicians further validate the feasibility of adopting 3D printing as an alternative manufacturing method. The findings from this section support the proposed 3D printing method as a viable method of creating TTS at AO.

4.0 SUSTAINABILITY

This section outlines five elements of sustainability related to the design solution with each being analyzed according to the Triple Bottom Line framework. These aspects are closely related, focusing on prosperity, people, and the planet. Each element is given an initial numerical score from 1-5, and a score for after the proposed changes are implemented. The change in each score is tallied and noted as an average for all elements at the end to determine the overall lifespan lens project score. A positive change score will determine that the proposed design solution is a sustainable option for AO to implement into their manufacturing process.

TABLE XXI
TRIPLE BOTTOM LINE FRAMEWORK

Element	Situation Description	Potential Impact	Impact Score Before	Proposed Response	Impact Score After	Change
		Prosperity Impacts				
Business Case Analysis	AO's current manufacturing processes use traditional and hybrid methods. These methods require a large amount of technician and clinician hands on time.	These two processes are labor-intensive and time-consuming. The inefficiencies within these processes result in increased costs for the company as technicians spend a significant amount of time manually fabricating each prosthetic socket.	1	Develop SOP to incorporate digital technologies and eliminate outsourcing to make the TTS manufacturing process more cost and labour efficient.	4	+3
Flexibility/ Optionality	Only hands-on manufacturing method is commonly used at AO.	This slows company flow and can affect quantity of patients that can be accepted. Problems during manufacturing may cause the need to restart from patient casting.	2	Adding digitally modified and 3D printed sockets adds a practical option with further flexibility.	5	+3
		People Impacts				
Project Health and Safety	There are no formal SOP for either the traditional TTS manufacturing process or the 3D-printed socket process.	Users may face operational risks when working with the 3D printer due to the absence of standardized procedures.	1	Develop and distribute clear SOP and provide training for the 3D-printed socket manufacturing process.	5	+4
Training and Qualifications	Currently only one employee at AO is trained to use the hybrid method.	This causes a bottleneck if no other employees are trained on any digital methods for production.	1	Establish training videos and new SOP for digital manufacturing methods.	4	+3
		Planet Impacts				
Waste Generation (Operational use of the device)	Current process produces large amounts of plastic waste. This comes from multiple test socket iterations from manual tasks, and a whole plastic sheet being needed to make one socket.	Large portions of the plastic sheet are removed and discarded, not being used for the TTS. This excess waste is thrown into landfills and not reused or recycled.	1	Digital modification and 3D printing with only the required amount of material instead of multiple thermodraping iterations. This will reduce large portions of waste at AO.	4	+3

The scores from Table XXI have been averaged to determine the overall lifespan lens project score, which is outlined in Table XXII.

TABLE XXII
AVERAGE SUSTAINABILITY IMPACT SCORES

Overall Lifespan Lens Project Scores:	
Impact Score Before	1.2
Impact Score After	4.3
Change	+3.2

The overall change in score of the Triple Bottom Line framework is 3.2. Each element was analyzed based on the sustainability impact of the current situation, as well as the proposed response to the current problem. With an initial score of 1.2 and new score of 4.3, this project is proven to be sustainable, and its implementation will be beneficial for AO and the planet.

5.0 LIMITATIONS AND RECOMMENDATIONS

There are several limitations to the design solution. While the presented solution meets all the clients' standards and requirements. Certain aspects, such as aesthetics, transparency, and long-term structural performance, can be further improved. These areas are addressed in detail through various considerations, including enhancements to the 3D printer system, post-print transparency improvements, filament choices, and strategies for managing structural integrity and durability. The following subsections address these limitations and provide recommendations for improving the design in the future.

5.1 RECOMMENDATION TO INCREASE AESTHETICS OF TTS

It has been shown that when a prosthetic is perceived as aesthetically pleasing by the user, it can improve their physiological acceptance [14]. This was demonstrated within question 6 of the patient Likert surveys, "I am satisfied with the cosmetic appearance of the socket." [redacted], which corresponds to the fact that no aesthetics were taken into consideration while 3D printing the TTS's. Cosmetic appearance and other aesthetics were outside of the project scope, and therefore [redacted]

To improve the aesthetics of future TTS's it is recommended to trial different methods of changing the colour and design on the outer socket face. Patient surveys should be conducted to determine their overall satisfaction after cosmetic and aesthetic modifications have been made to their TTS. These changes can be made by using spray paint, different filament colours, or laminating a design on the socket. This could be accomplished by using printed fabric material and lamination with epoxy resin.

5.2 RECOMMENDATIONS FOR 3D PRINTERS

Currently AO does not have a printer, which is a piece of equipment needed to implement this design solution. There are several commercially available 3D printers. It was outside of the project scope to purchase and trial printers. However, a set of recommended printers for AO to trial has been created. The recommended printers all have the following features:

1. A SuperSlicer preset
2. A minimum printing bed size of 200 x 200 x 300mm

3. The ability to print PETG and PLA
4. Compatibility with nozzle sizes ≥ 0.8mm

Ideally the recommended printers also have a commercially available hotend for 2.85mm filament, as the commercial standard is 1.75mm [15]. However, preliminary searches did not give conclusive results for every printer. The list below contains the printers that met the four specifications. Details regarding each numbered specification, along with pricing, available hotend sizes, and compatible filament size(s) are contained in Table B-IX in Appendix B-4.0.

- Creality CR-5 Pro [16]
- Creality Cr-6 Max [17]
- Creality Ender-3 Max [18]
- Creality Ender-5 Plus [19]
- Creality Ender-6 [20]
- Meltingplot MBL 136 [21]
- Meltingplot MBL 308 [22]
- Meltingplot MBL 480 [23]
- TriLAB AzteQ Industrial [24]
- TriLAB DeltiQ 2Plus [25]

Purchasing a printer with an existing SuperSlicer preset removes a workload for AO. If AO wishes to use a different printer without a SuperSlicer preset, settings may be provided by the printer company or found online.

5.3 3D PRINTER SYSTEM ENHANCEMENTS FOR TRANSPARENCY

This section highlights key recommendations for investigation on improving the transparency of the NWB TTS in relation to the 3D printer system. These include nozzle width and volume control, printing without supports for enhanced external smoothness, and optimizing printer flow rate and extrusion speed. Full comprehensive testing of these parameters was not possible due to limited time and access to nozzles sizes greater than 0.8mm. Enhancement suggestions made below are derived from observations using the 0.4mm and 0.8mm nozzles during printing.

5.3.1 Nozzle Width and Volume Control

In 3D printing, nozzle width and extrusion width are crucial for controlling the volume and detail of the printed TTS. The nozzle diameter affects the range of possible layer heights and extrusion width dictating the width of the extruded line [26]. Further investigation into both parameters would allow for a potential reduction in bridging between each printer layer, increasing the transparency and reducing the volume, as the surface may be smoother.

5.3.2 Printing Without Supports for External Smoothness

The NWB and WB TTS should be printed without any additional 3D support. The shape of a standard TTS does not include any drastic overhangs or change in angles. This means that no supports are structurally required for 3D printing [27]. This ensures a smooth exterior surface free of any unnecessary texture, increasing the transparency.

5.3.3 Printer Flow Rate and Printing Speed

When printing, the speed and filament flow rate directly affect a print's transparency. When a filament is printed slower, there is a more consistent flow volume. The consistency in filament flow volume results in consistent spacing between adjacent layer lines. Consistent space between adjacent layer lines indicates whether the filament flow rate is too low or too high. In addition, a slower printing speed allows time for filament to adhere to the layer below as it is printed, resulting in a stronger and clearer print. While a faster printing speed would reduce the overall printing time, it is recommended that AO attempt printing at varying speeds to maximize their print transparency and socket printing time.

5.4 POST- 3D PRINT TRANSPARENCY ENHANCEMENTS

This section highlights key factors that are recommended to improve the transparency of the NWB TTS after 3D printing is complete. The filaments tested during the verification procedures have met the client's transparency standards, however, some improvement in transparency could be achieved. As each socket is 3D printed, additively layer by layer, lines between the layers can affect the socket's transparency. These layers cause small ridges on the socket and cause the light to refract in different directions. Affecting the transparency under certain lighting conditions or when viewed at specific angles. potentially impacting the aesthetic and functional quality of the socket. These recommendations include the addition of a clear coating and uniform heat treatment to the TTS.

5.4.1 Clear Coating

To improve the transparency of future TTS's, it is recommended that a clear coating be applied to the outside of the transtibial sockets. Applying a clear coating such as an acrylic paint or similarto thc outsidc of a transtibial sockct can rcducc rcfraction of light causcd by thc ridgcs of

each layer. This is achieved through filling in the ridges to minimize the directions light can refract.

5.4.2 Uniform Heat Treatment

To further improve filament transparency a uniform heat treatment is recommended. Uniform heat treatment, also known as plastic annealing, is a process where plastic materials are heated to a controlled temperature, held at that temperature and then cooled gradually. This treatment relieves internal stresses that may potentially be developed during the 3D printing process [28]. Relieving the internal stresses can improve the mechanical stability and durability of the TTS. Without annealing, the internal stresses leave the TTS susceptible to warping or cracking over time. By eliminating internal stresses, uniform heat treatment may reduce the risk of surface defects such as tiny fissures that scatter light and diminish transparency. It is recommended that further investigation into implementing a uniform heat treatment to the TTS occurs. Post-print enhancement could contribute to a more transparent and structurally reliable socket with improved longevity.

5.5 RECOMMENDED FILAMENT CONSIDERATIONS

This section covers key recommendations related to the filaments used in the printing process. The recommendations in this section are for the way the filament is stored and considerations for carbon fiber composite filaments, especially regarding the type of nozzle used.

5.5.1 Filament Storage – Humidity Control

When storing any filament, the storing environment must be considered. When 3D printer filament absorbs moisture, it may lead to printing issues such as bubbling, uneven layers, and poor adhesion both to the filament itself and or the print bed [29]. Moisture can also cause discoloration and fading of filament color, which could affect the transparency of the TTS print [29]. Improper storage of filament will compromise the quality of the TTS prints. It is recommended to keep the filament in temperature-stable and dry environment.

5.5.2 Carbon Fibre Composite Filament Considerations

One of the filaments considered for the WB TTS was a composite material containing carbon fiber to enhance strength. It is important to note that most standard 3D printers are equipped with brass nozzles [30]. However, the abrasive nature of carbon fibers can quickly wear down these

brass nozzles, leading to clogging and premature failure [30]. To mitigate this, it is recommended to utilize a specialized nozzle made from hardened steel or a nozzle with a ruby insert. Implementing this recommendation can significantly improve nozzle durability and reduce friction, making it more suitable for printing with abrasive materials [30].

5.6 RECOMMENDATIONS FOR STRENGTH TESTING

Although compression or cyclic loading tests were not conducted on the printed sockets due to project scope limitations, it is understood that compressive failure may occur over time. Certain areas of the socket are more prone to failure due to experiencing higher pressure and stress concentrations. Therefore, to better understand the durability of the design, it is recommended that AO perform cyclic loading and dynamic compression testing to determine the socket's lifespan and identify the first points of failure. It has been shown by Kim *et al*. that the typical point of failure for 3D printed sockets is at the distal end of the socket or the modular components attachment [13]. Increasing thickness or adding reinforcement in this region could enhance durability and socket longevity. By analyzing failure patterns after repeated use, targeted design improvements can be made to strengthen the socket and extend its life cycle.

5.7 RECOMMENDATIONS FOR SUSTAINABILITY TRACKING

Based on the sustainability results shown in Table XXI, waste generation is an aspect that was improved with the design solution when compared to the traditional manufacturing method. The exact amount of waste reduction was not within the scope of this project, and therefore no data was gathered on how much plaster and PETG waste occurs from a traditional socket being manufactured. Similarly, the amount of waste generated during the 3D printing manufacturing method was not determined because this solution has not yet been implemented at AO.

To further understand the sustainability impact of this design solution further testing and data collection is recommended to determine the amount of waste produced from each manufacturing method. The most effective way to gather this data is to determine the amount of waste produced by each manufacturing method throughout a one-year period. This can give further insight into the full sustainability impact of this design solution and where future improvements can be made.

5.8 RECOMMENDATIONS FOR FUTURE FOLLOW UP PATIENT SURVEY

To ensure that the 3D printed TTS remains a viable long-term solution for patients, it is recommended that AO implements a patient follow-up survey after the distribution of the 3D-printed TTS's. This survey should be conducted at multiple time intervals such as one month, six months, one year and five plus years to assess long-term comfort, durability and overall satisfaction with the socket. The follow up survey should contain questions that evaluate the fit and comfort during daily activities and any wear or degradation of the socket. Finally, any aesthetic concerns should also be addressed within this survey. Collecting this feedback will provide AO with information on how the 3D printed sockets can be better improved.

While the proposed design solution successfully meets the client's requirements, there are several areas where the design can be improved upon for future iterations of the TTS. The key considerations for improving the overall quality and longevity of the TTS's include aesthetic enhancements, improving transparency, optimizing filament storage environments, addressing the compressive failure under cyclic loading and implementing a patient follow-up survey. By implementing the recommended modifications such as alternative finishes, refining 3D printing parameters and conducting further mechanical testing and gathering user feedback, future developments of this design can provide a more durable and visually appealing solution. These recommendations if implemented will not only improve the interaction between the user and the socket but will also ensure that the 3D printed TTS will remain as a viable alternative to traditional manufacturing methods.

6.0 CONCLUSION

This report outlines an innovative approach to improving the production of TTSs at AO. The proposed solution integrates manual casting with advanced tools, including the Vorum Spectra Scanner, Canfit CAD, SolidWorks, and SuperSlicer, indicated in Fig. 6. These tools enable the NWB socket to be 3D printed using a translucent filament, while the WB socket is printed with a high-strength PLA filament. These additions reduce hands-on labour time, eliminate outsourcing, and improve efficiency while maintaining AO's high standards of patient care.

Verification procedures were conducted, including physical property tests, satisfaction surveys, and efficiency assessments, ensuring the design solution meets the required performance metrics set by AO. The results of these verification procedures indicate that the design solution meet the set performance criteria.

Following the Triple Bottom Line framework for sustainability, the overall change score for the proposed solution is +3.2. This indicates that based on the five elements chosen, the solution will be beneficial for AO to implement into their manufacturing process, while also benefiting the environment.

During the development of the design solution, key limitations were encountered related to socket aesthetics, transparency, and structural performance. Appropriate recommendations were provided to enhance aesthetics and improve transparency through clear coating or heat treatment. Conducting further testing into the durability and integrity of the design solution is recommended for further improvements.

This design solution gives AO a refined process that not only enhances production efficiency but also reinforces the organization's dedication to sustainability and patient-focused care. By embracing this innovative solution, AO is positioned to deliver cutting-edge, effective prosthetic solutions that improve the lives of their patients.

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APPENDIX A

LIST OF APPENDIX FIGURES

LIST OF APPENDIX TABLES

A-1.0 BILL OF MATERIALS

BILL OF MATERALS	
PROJECT NAME	Proposed TTS Manufacturing Solution for AO
APPROVED BY	Team 1
APPROVAL DATE	March 21st, 2025
PART COUNT	19
BOM TIMEFRAME	September 2024- March 2025
TOTAL COST	$ 12,069.92

ITEM #	NAME	DESCRIPTION	CATEGORY	SUPPLIER	LINK	COMMENTS	UNIT COST	QTY.	TOTAL PART COST
1	Navaris Plaster Cloth Rolls (Pack of 10) - 4" W x 118" L	Plaster bandages to be used for the manual casting process	Design Solution	NAVARIS	https://a.co/d/bGpr25S	AO regularly purchases this product	$ 48.99	1	$ 48.99
2	Koh-I-Noor Copying Pencil - Blue (Pack of 12)	Indelible penciles to be used for anatomical marking on patients' limb	Design Solution	Koh-I-Noor	https://a.co/d/iN4uQEC	AO regularly purchases this product	$ 16.80	1	$ 16.80
3	Spectra™ 3D Prosthetics and Orthotics Scanner	Pre-owned scanner used by AO to scan positive mold	Design Solution	Vorum	https://vorum.com/canfit-op-cad-software/	Quote was requested, but has not been received	N/A	1	N/A
4	Canfit™ Orthotics and Prosthetics CAD	Pre-owned CAD software used by AO to make modifications to scanned positive mold	Design Solution	Vorum	https://vorum.com/spectra-3d-scanner/	Quote was requested, but has not been received	N/A	1	N/A
5	Solidworks Yearly Subscription	Secondary CAD software to be used to make modifications before 3D printing	Design Solution	Solidworks	https://www.solidworks.com/how-to-buy/solidworks-plans-pricing	SOLIDWORKS Professional with Cloud Services was chosen	$ 4,970.00	1	$ 4,970.00
6	Super Splicer Software	Slicing software to be used to prepare the .stl file for 3D printing	Design Solution	Super Slicer	https://superslicer.net	Free software	$ -	1	$ -

BILL OF MATERIALS, CONTINUED

ITEM #	NAME	DESCRIPTION	CATEGORY	SUPPLIER	LINK	COMMENTS	UNIT COST	QTY.	TOTAL PART COST
7	Coyote C10A Drop-In Air-Lock	Designated socket attachment system specified by AO	Design Solution	Coyote	https://www.coyote.us/dropin	Price provided by AO	[redacted]	1	[redacted]
8	3D Printer	Used to print full scale sockets	Design Solution	Unspecified		Recommendations made in section 5.2. The unit cost is an estimation	$ 5,000.00	1	$ 5,000.00
9	ERYONE Transparent PETG Filament	Transparent filament to be used to make a NWB socket	Design Solution	ERYONE	https://a.co/d/alAmfEi	This is enough to make at least one socket	$ 25.19	1	$ 25.19
10	ELEGOO PLA+ Filament	Filament to be used to make a WB socket	Design Solution	ELEGOO	https://a.co/d/7FqgHNg	This is enough to make at least one socket	$ 25.99	1	$ 25.99
11	1L Beaker	1 L beaker used for verification procedure 4.1 (socket volume retention)	Testing Component	Stonylab	https://a.co/d/7OIhtHf	The University of Manitoba was able to provided this for testing purposes	$ 21.99	1	$ 21.99
12	Bonvoisin Lab Scale 5000g x 0.01g	Digital scale to be used for verification procedure 4.1	Testing Component	Bonvoisin	https://a.co/d/iGse838	The University of Manitoba was able to provide this for testing purposes	$ 157.88	1	$ 157.88
13	Outside Micrometer, 0-1" Machinist Micrometer	Micrometer to be used for verification procedure 4.2 (subtractive modification of socket)	Testing Component	HDLNKAK	https://a.co/d/6PSDGOH	The University of Manitoba was able to provide this for testing purposes	$ 19.99	1	$ 19.99
14	Sandpaper 60 Grit, Wet Dry Sanding Sheets 9 x 3.6 Inch, 21 Sheets	60 grit sandpaper to be used for verification procedure 4.2 (subtractive modification of socket)	Testing Component	Shineboc	https://a.co/d/9OL5lKV		$ 8.99	1	$ 8.99

BILL OF MATERIALS, CONTINUED

ITEM #	NAME	DESCRIPTION	CATEGORY	SUPPLIER	LINK	COMMENTS	UNIT COST	QTY.	TOTAL PART COST
15	Sandpaper 120 Grit, Wet Dry Sanding Sheets 9 x 3.6 Inch,21 Sheets	120 grit sandpaper to be used for verification procedure 4.2 (subtractive modification of socket)	Testing Component	Shineboc	https://a.co/d/gKuSAQ4		$ 8.99	1	$ 8.99
16	Body Measuring Tape, 1.5m Dual Sided Tape Measure for Body Measuring	Soft tape measure to be used for verification procedure 4.3 (diameter test)	Testing Component	CeAnGye	https://a.co/d/3L1fPJK	The University of Manitoba was able to provide this for testing purposes	$ 5.99	1	$ 5.99
17	Thermo Scientific BioMate 3 Spectrophotometer	Spectrophotometer to be used for verification procedure 4.4 (transparency testing)	Testing Component	Thermo Scientific	https://sonoransurplus.com/product/biomate-3-spectrophotometer/?v=3bf5155da51b#:~:text=%243%2C051.00%20Current%20price%20is%3A%20%243%2C051.00.	The University of Manitoba was able to provide this for testing purposes	$ 1,570.00	1	$ 1,570.00
18	Polystyrene 2.5-4.5ml Macro Spectrophotometry Cuvette (Pack of 100)	Spectrophotometry cuvettes to be used for verification procedure 4.4 (transparency testing)	Testing Component	BrandTech	https://a.co/d/3vKcIyh	The University of Manitoba was able to provide this for testing purposes	$ 62.27	1	$ 62.27
19	Kimtech Science KimWipes Delicate Task Wipers; 4.4 x 8.4 in. (11.2 x 21.3cm)	KimWipes to be used for verification procedure 4.4 (transparency testing)	Testing Component	Kimberly-Clark	https://a.co/d/g7b04BG	The University of Manitoba was able to provide this for testing purposes	$ 13.47	1	$ 13.47
	TOTAL							**19**	**$12,069.92**

A-2.0 AO TRADITIONAL METHOD FOR INITIAL TRANSTIBIAL SOCKET

Section 2.1 outlines the eight steps of AO's method for creating the initial TTS. These eight steps are: a casting of the patient's residual limb, an initial cast filling, stripping of the cast, the clinician modifying the mold, the drying of the mold, thermodraping over the mold, the socket retrieval, and conclusively the trim line and distal hole modification.

A-2.1 CASTING OF THE PATIENT'S RESIDUAL LIMB

The first step of AO's TTS process is the patient casting. A clinician will evaluate the patient's medical history, skin condition(s) and other pertinent information. Then the clinician will evaluate the residual limb. Using an indelible pencil, the clinician will indicate important anatomical marks on the patient's limb as seen in Fig. A1. Once all the identifiable features have been designated, the limb will be wrapped in plaster bandages that have been saturated with water. The clinician will mold the plaster bandages using their hands and create a cast that simulates weightbearing as seen in Fig. A2. The clinicians use their hands to apply force upon pressure tolerant regions also known as load zones as seen in Fig. A1. Once the bandage cast has set, it will be removed off the patient's residual limb either with a cast saw or by being slipped off.

A-2.2 INITIAL CAST FILLING

The initial cast of the residual limb, which is a negative mold, needs to become a positive. This negative cast will have the inedible marks transferred onto the interior, but they will likely be faint. The marks will be retraced with an indelible pencil. To prevent the plaster bandages from adhering to the industrial plaster, a surfactant mix of soap and water, will be sprayed to coat the interior of the cast. Next, a metal mandrel will be aligned within the socket to ensure it does not interfere with the exterior layers of the cast as seen in Fig. A5. The cast will then be filled with an industrial plaster mix.

Figure A3 - Adding plaster to water

Figure A4 - Mixing plaster mix

Figure A5 - Pouring plaster mix into cast

A-2.3 STRIPPING OF RESIDUAL LIMB CAST

Once the plaster has set, the positive cast will be stripped from the plaster bandages as seen in Fig. A6. The cast is cut along the one side, and the layers of plaster bandages are peeled back. This creates creating a positive mold of the residual limb.

Figure A6 - Stripping cast from positive mold

A-2.4 CLINICIAN MODIFICATION OF RESIDUAL LIMB CAST

The prosthetist will take the positive cast and make plaster modifications to the shape. This step clinician and patient specific. Smoothing of the plaster cast is also a crucial step as it ensures that the socket will have a smooth interior, see Fig. A7 and Fig. A8.

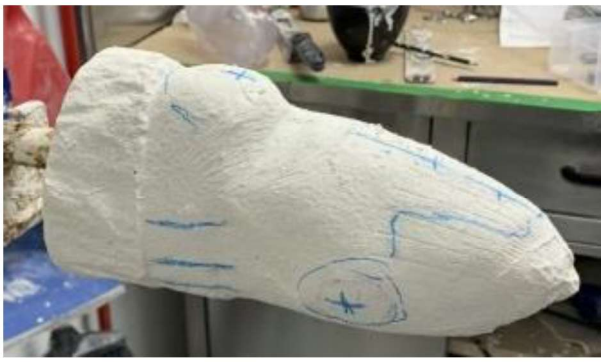


Figure A7 - Cast mid-modification

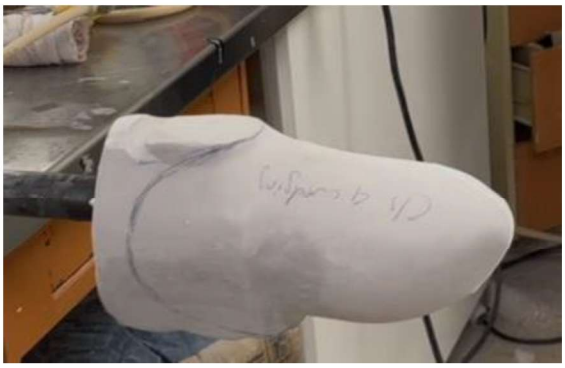


Figure A8 - Cast post-modification

A-2.5 DRYING OF THE CAST

Once all the plaster modifications that the clinician has done are set, the cast must dry. The plaster cast will be placed in a drying oven prior to being thermodraped with plastic.

A-2.6 THERMODRAPING OF THE CAST

Once the positive cast is dry, it can be removed from the oven. The mandrel will be placed into a vise that allows it to be under vacuum, a seal will be created on the mandrel out of a putty or foam. See Fig. A9. A sheet of polyethylene terephthalate glycol (PETG) will be placed in the oven. The heating time will vary based on the material's thickness. Once the plastic sheet is ready it will be removed from the oven and immediately thermodraped over the positive mold, as seen in Fig. A10. The vacuum and the seal will ensure that the shape of the cast is properly captured. The plastic will then set and cool.

A-2.7 SOCKET RETRIEVAL FROM PLASTER CAST

Once the plastic has set, the trim lines will be drawn with a marker as a guideline. Then an oscillating saw will cut off the excess plastic exposing the initial positive cast, as seen in Fig. A11. The plaster is removed from the inside of the socket using an air chisel as seen in Fig. A12.

Figure A9 - Positive mold with putty on mandrel

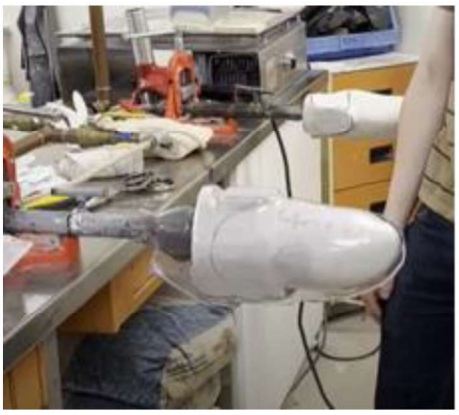


Figure A10 - Positive mold with thermodraped plastic

Figure A11 - Oscillating saw cutting

Figure A12 - Air chisel removing plaster

Figure A13 - TTS prior to finishing

A-2.8 TRIM LINE MODIFICATIONS AND DISTAL HOLE CREATION

This socket will then be smoothed down to the trim line, using a grinding machine with regular grit and fine grit cones as seen in Fig. A14. A step drill bit will be used to create a hole at the distal end of the TTS. Then, a lighter will be swiped over the edges to smooth the plastic as seen in Fig. A17.

Figure A14 - Grinder smoothing trim lines

Figure A15 - Stepwise drill adding distal hole

Figure A16 - Deburring tool on distal hole

Figure A17 - Trim line smoothing

A-2.9 NON-WEIGHTBEARING SOCKET

This is the NWB socket. The PETG used allows the clinician to make slight modifications with a heat gun if needed. Both the initial cast from the patient, the plaster that was used to fill the cast and the excess plastic will be waste products of this process.

A-3.0 AO HYBRID METHOD FOR INITIAL TRANSTIBIAL SOCKET

The hybrid method replaces the traditional steps four and five, digitizing the modification of the plaster limb plaster mold. The process from the new step four and onward is as follows:

A-3.1 SCANNING THE PLASTER LIMB

To scan the mold, AO uses their in-house Spectra Scanner or Creality Raptor Scanner. Each has their own proprietary software. However, the set-up and operation are identical. The plaster limb is placed with the mandrel in the center of a stool as seen in Fig. A18. The scanner is operated from approximately 50 – 80cm away from the limb, while rotating the stool to catch all features. Fig. A19 Shows the resultant scan after post-processing in the proprietary software.

Figure A18 - Scanning set-up

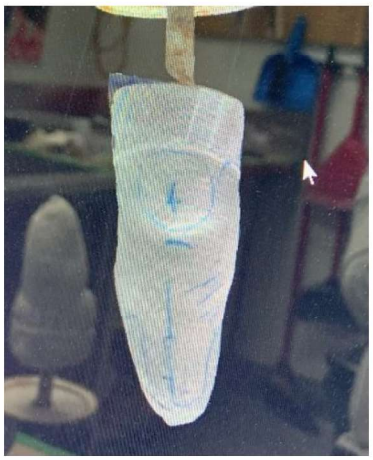


Figure A19 - Scan post-processing

A-3.2 MODIFYING THE MOLD IN CANFIT

The scan from step four is then sent to Canfit, to be anatomically modified by the clinician. The resulted modified scan is Fig. A20.

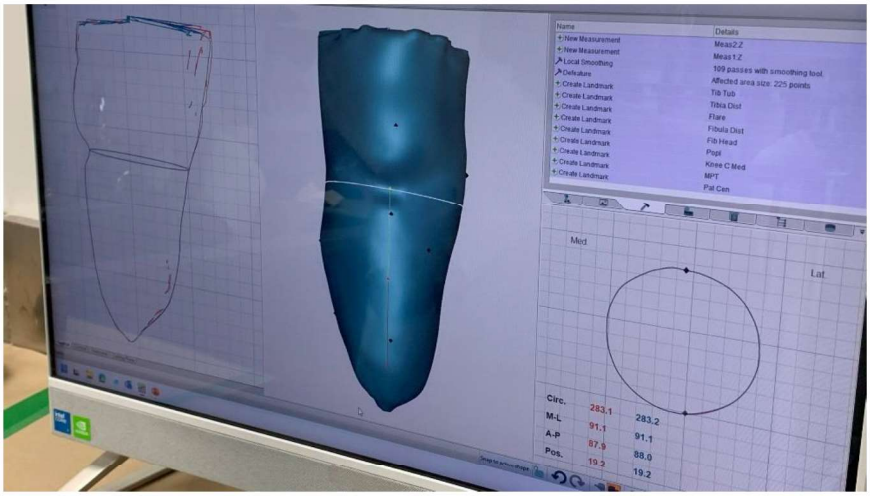


Figure A20 - Modified scan in Canfit

A-3.3 SEND FILE TO BE CNC FOAM CARVED

The resultant STL is then sent to the company Myrdal Orthopedic Technologies Inc. This company manufactures a foam version of the model via computer numerical control (CNC) carving. Within 24 hours, the Foam Model is returned to AO to continue the tradition process.

A-3.4 CONTINUE TRADITIONAL STEPS A-3.6 TO 3.9

The thermodraping process continues as described in the traditional method, now using the foam carved limb instead of the modified plaster mold. This process still arrives at the same NWB socket.

A-4.0 VALUE-STREAM MAPPING & PROCESS TIMING

Fig. A21 contains a current-state value-stream-map to produce a single socket, focusing on hands-on, hands-off, and machine time.

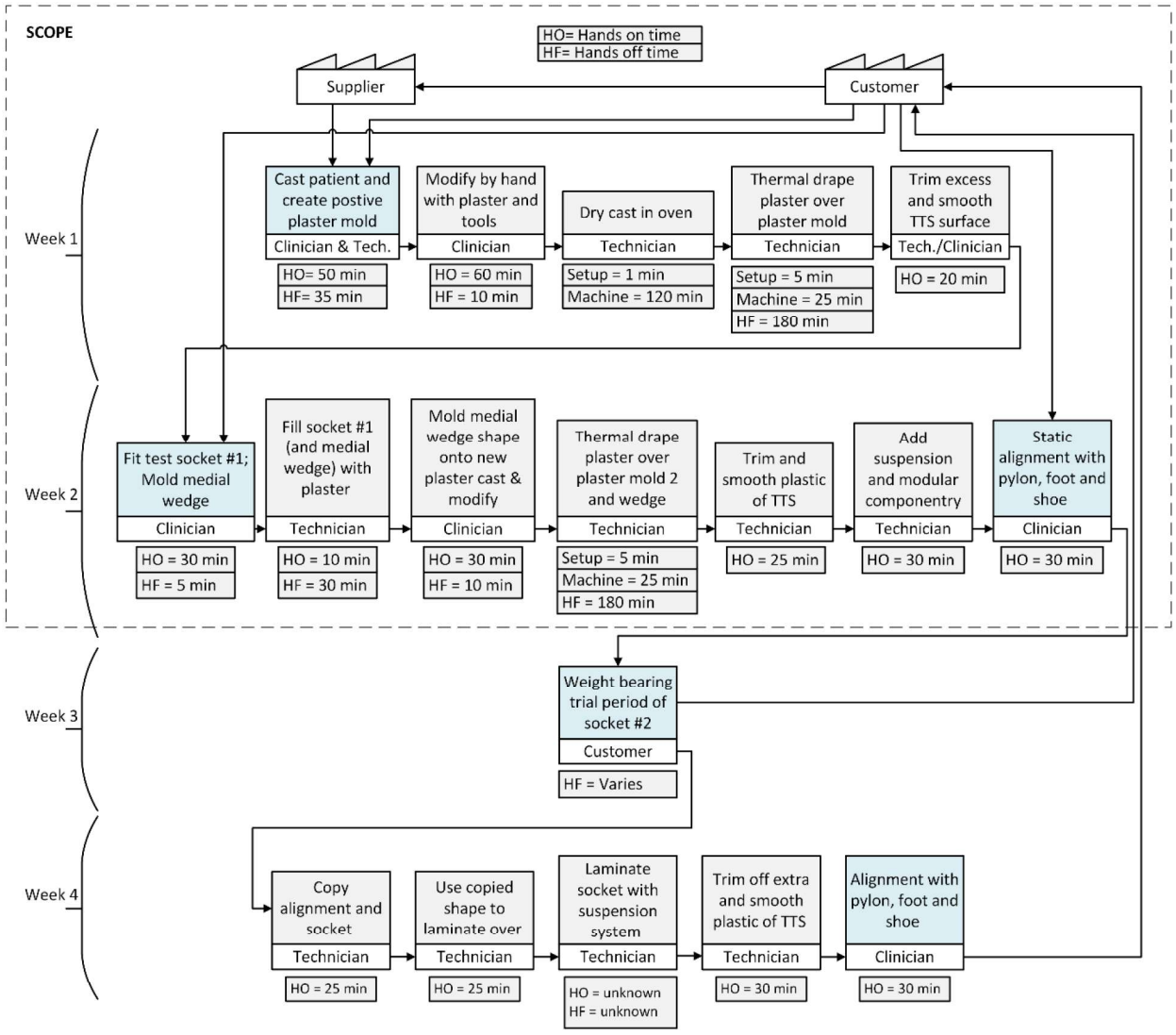


Figure A21 - Current-state value-stream map

The steps highlighted in light blue correspond to patient visits, which are assumed to be booked in one-week intervals. Fig. A22 below contains a future-state value-stream-map, using the proposed process.

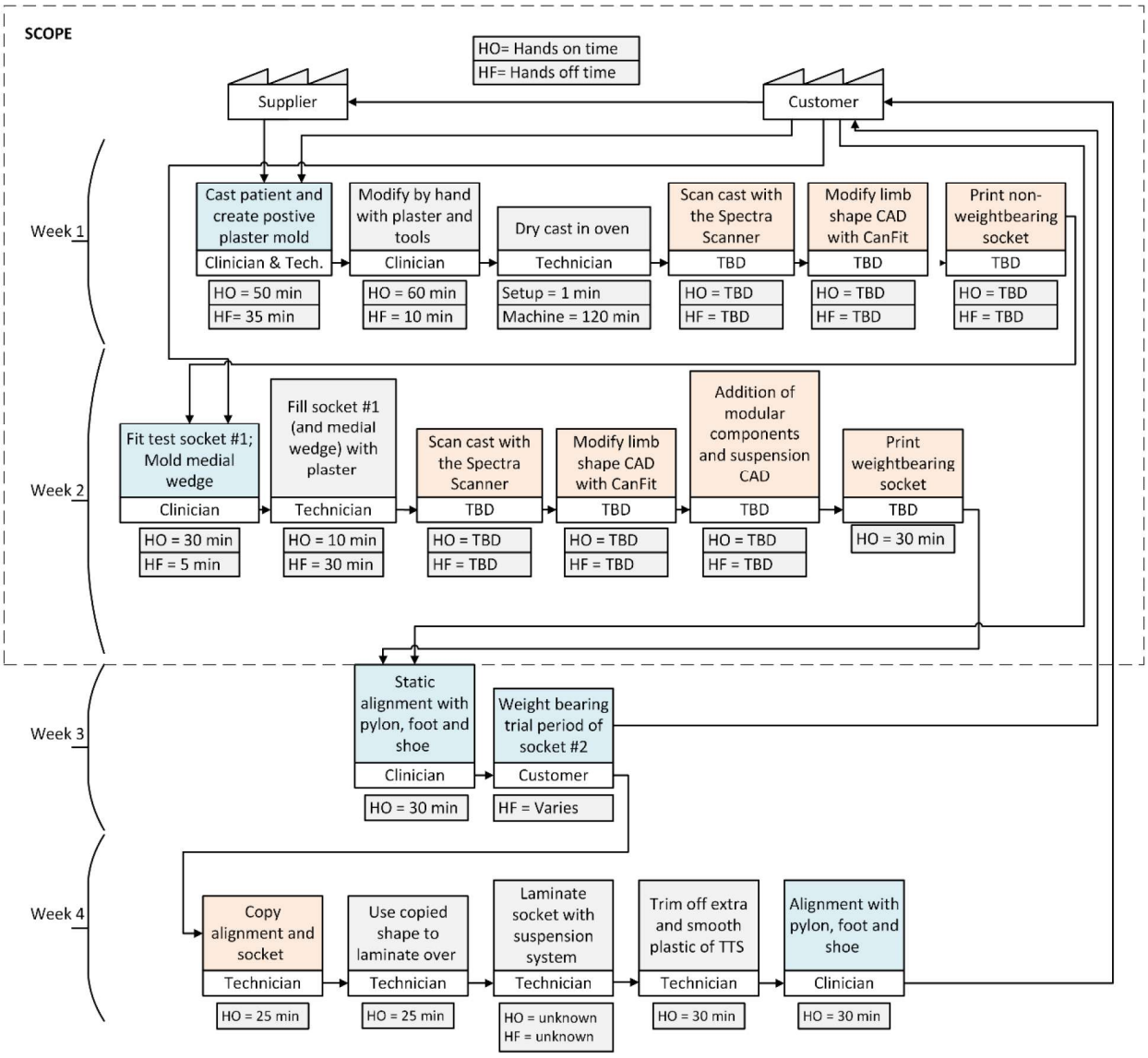


Figure A22 - Future-state value-stream map

The steps highlighted in light blue correspond to patient visits, which are assumed to be booked in one-week intervals. Times of new processes will be determined via testing.

APPENDIX B

B-1.0 PHYSICAL SOCKET VERIFICATION METHODOLOGIES

This section outlines the physical verification procedure methodologies.

B-1.1 SOCKET VOLUME RETENTION PROCEDURE

TABLE B-I

SOCKET VOLUME RETENTION

Procedure 4.1: Socket volume retention	
Equipment	Digital scale with measuring range of: 2g – 5000g and displays measurements with at least two decimal places, 1L beaker
Materials	Traditionally manufactured TTS, 3D printed TTS
Passing Criteria	Volume retention within ± 2% of total volume of manufactured socket method
Procedure	1. To calibrate the scale, ensure it is clear of any objects, then press the zero or tare button. 2. Place an empty 1L beaker on the digital scale and press the zero or tare button. 3. Fill the traditionally manufactured socket up with water. 4. Once the socket is full, pour the water into the 1L beaker, ensuring no water is lost in the process. 5. Place the beaker on the scale and record the mass of the water. 6. Repeat steps 3 - 5 with the 3D printed TTS. 7. Calculate the volume of each socket using Equation 1: $$V = \frac{m}{\rho} \quad (1)$$ Where: V = volume of the socket [cm^3] m = mass of the water in the socket [g] ρ = density of water [g/cm^3] 8. Calculate the percent difference in volume between the 3D printed TTS and the traditionally manufactured TTS with Equation 2: $$Percent\ Difference = \frac{(V_{ts} - V_{ps})}{V_{ts}} * 100\% \quad (2)$$ Where: V_{ts} = volume of traditionally manufactured TTS [cm^3] V_{ps} = target volume of 3D printed TTS [cm^3] 9. Compare the volume of the 3D printed socket to V_{target}.

B-1.2 POST PRINT SANDING FEASIBILITY PROCEDURE

TABLE B-II
POST PRINT SANDING FEASIBILITY

Proccdurc 4.2: Post-print sand-ability tcst	
Equipment	Micrometer, 60 and 120 grit sandpaper, Sharpie
Materials	Three pieces of baseline PETG from traditional manufacturing, three 3D printed 5cm x 5cm x 3mm pieces made with NWB TTS filament, and three made with WB TTS filament. The printed pieces should be printed with a solid matrix pattern.
Passing Criteria	Change in thickness $\leq$ 0.028mm after sanding. If the samples deform or fall apart during sanding the criterion is not be met.
Procedure	1. Calibrate the micrometer by zeroing it, the micrometer should be fully closed. Ensure the line is lined up with the zero mark. 2. Mark a dot in the center of the 3D printed sample on both sides with the sharpie. 3. Measure the thickness on the dot in the center of the 3D printed piece using the micrometer and record this value. 4. Hold the 3D printed piece with non-dominant hand. 5. Hold a piece of 120 grit sandpaper with dominant hand. 6. Place the sandpaper on the 3D printed piece and perform 15 firm back and forth strokes, ensuring it passes over the dot on the center of the square each time. 7. Hold a piece of 60 grit sandpaper with dominant hand. 8. Place the sandpaper on the 3D printed piece and perform 15 firm back and forth strokes, ensuring it passes over the dot on the center of the square each time. 9. Repeat step 3. Calculate the difference in sample thickness from before sanding to after. 10. Repeat steps 1-9 for each 3D printed piece. 11. Calculate the average thickness from the three samples for the final result. 12. Repeat steps 1-11 for both the NWB and WB filaments. 13. Repeat steps 1-11 for the baseline PETG sample. 14. Ensure the same person performs each test ensuring the same amount of force is used each time

B-1.3 DIMENSION REPLICABILITY PROCEDURE

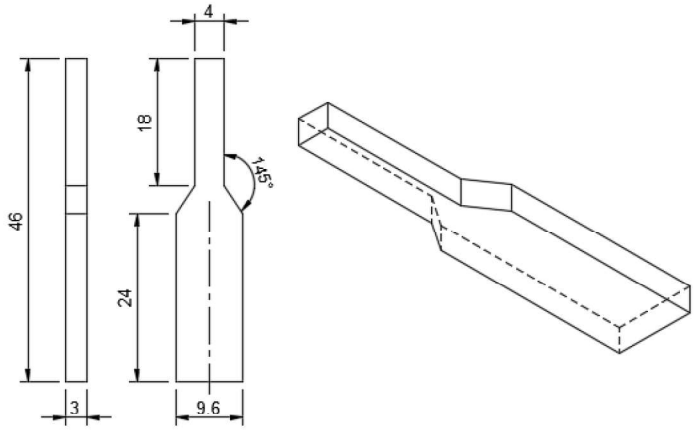
TABLE B-III DIMENSION REPLICABILITY

Procedure 4.3: Dimension Replicability Test	
Equipment	Soft tape measure
Materials	Traditionally manufactured TTS, 3D printed TTS
Passing Criteria	Three of the four measured dimensions of the 3D-printed socket fall within ±3mm of those on the traditionally manufactured socket
Procedure	1. Identify the widest area of the traditionally manufactured TTS by visually inspecting the socket. 2. Use a marker to make small marks along the circumference of the socket at the widest points. a. Rotate the socket slowly, making marks at different spots to ensure that the entire widest section is indicated. 3. Position the soft tape measure at the markings indicating the widest point of the socket. 4. Take the measurement and record the widest diameter. 5. Use a marker to make small marks where the ends of the flat cutout are at the front of the socket (this should be done by the same person on both sockets to ensure similarity of mark placement) 6. Repeat step 5 for the flat cutout on the back of the socket 7. Place a mark on the seam in the middle of the back cutout, and a mark in the middle of the front seam, with the middle being measured with the soft tape measure 8. Take and record the measurement between the two marks on the front cutout of the socket 9. Take and record the measurement between the two marks on the back cutout of the socket 10. Take and record the measurement between the two marks from the back seam to the front center of the socket 11. Repeat Steps 1-10 two more times to ensure consistent and accurate measurements at each point on the socket. Each repetition should confirm the reliability of the previous measurements. 12. After three of each measurement is recorded for the traditionally manufactured socket, repeat Steps 2-8 for the 3D printed TTS. There should be a total of 12 measurements for each socket recorded.

B-1.4 TRANSPARENCY TEST PROCEDURE

TABLE B-IV

TRANSPARENCY TEST

Procedure 4.4: Transparency test	
Equipment	UV-Vis Spectrophotometer and 3D printer
Materials	Five samples of each 3D printed filament with solid matrix pattern and dimensions specified in step 2 below, distilled water, cuvettes, and Kimwipes
Passing Criteria	The measured absorbance is less than or equal to the absorbance of the traditionally manufactured TTS
Procedure	Steps 7-16 of this procedure follow a modified version of ASTM D1746-15 [B3]. 1. Using a preferred CAD application (SolidWorks was used for this portion of the test), design five cuvette samples for each filament. The samples should be sized to fit the cuvettes of the UV-Vis spectrophotometer that will be used for testing. For this project, the filament samples have been designed to fit into the cuvettes of the BioMate 3 UV-Vis spectrophotometer. The thickness of each sample should be 3mm, which is typical for a TTS. 2. A diagram showing the dimensions of the filament samples for the BioMate UV-Vis spectrophotometer is provided below. It should be noted that the dimensions in the figure are all in mm.  *Figure B1 - Cuvette sample dimensions* 3. Once the design is complete in the CAD application, export the file as an STL format and open it in the 3D printing slicer application such as SuperSlicer. 4. Refer to the filament information sheet and adjust the slicer settings accordingly.

Procedure	5. Print five cuvette samples based on the adjusted slicer settings. 6. Once the cuvette samples are done printing, remove them from the 3D printer bed to cool off. 7. Ensure the sample has been at 23 ± 2°C and 50 ± 10% relative humidity for ≥ 40 hours prior to testing. 8. A disposable, lint-free dry wipe should be used to wipe the interior of the testing chamber ensuring there are no dust particles that can interfere with the reading. 9. Acquire six empty cuvettes and fill the cuvettes to the fill line with distilled water. 10. Set aside one cuvette filled with water. This will be the benchmark sample for the spectrophotometer to measure the filament samples against. 11. With the next five cuvettes, insert a 3D printed sample into each cuvette. Ensure that one side of the sample is flush against the left side of the cuvette. 12. Place each cuvette into the sample holders within the spectrophotometer. 13. Close the spectrophotometer chamber. 14. Click 'run' on the spectrophotometer. 15. Run the analysis on the spectrophotometer and record the absorbances of each of the five samples.
	Repeat for each 3D printed filament sample.

B-1.5 SATISFACTION SURVEYING PROCEDURE

TABLE B-V

SATISFACTION SURVEYING

Procedure 4.6: Satisfaction surveying	
Equipment	N/A
Materials	Traditionally manufactured TTS, 3D printed TTS, pen, 5-point Likert scale-based survey in printed a printed form
Passing Criteria	The 3D printed TTS score must equal or exceed the overall satisfaction score for the traditionally manufactured TTS by the relevant user
Procedure	For the satisfaction surveys, there are three distinct user groups: the patient, clinician, and technician. Each group will receive a tailored survey based on their specific role as a patient, clinician, or technician. The survey corresponding to patients, clinicians and technicians can be found in Appendix B-2.1, B-2.2, and B-2.3 respectively. 1. Provide the satisfaction survey to the patient, clinician, or technician based on their role. 2. Allow the user to complete the survey at their convenience, ensuring they have sufficient time to answer all questions. The user should use check marks to indicate their choice. 3. Collect the completed surveys from each user group. 4. Add the scores of the survey responses for each user group to calculate the overall satisfaction score.

B-2.0 SOCKET SATISFACTION VERIFICATION PROCEDURE METHODOLOGIES

This section outlines the socket satisfaction verification methodologies used.

B-2.1 PATIENT SATISFACTION SURVEY

The survey in this section will be used to evaluate the patient's satisfaction with the fit and comfort of the TTS.

PATIENT SATISFACTION SURVEY

#	Question	Strongly Disagree (1)	Disagree (2)	Neutral (3)	Agree (4)	Strongly Agree (5)
1	The socket is comfortable					
2	The socket fits me well					
3	I feel no pain or discomfort when wearing the socket					
4	The socket feels stable while walking or standing					
5	The socket allows me to perform my daily activities well					
6	I am satisfied with the cosmetic appearance of the socket (for WB socket only)					
7	I am satisfied with the overall fit and comfort of my transtibial socket					
TOTAL						**/35**
Additional Feedback:						

Figure B2-Patient Satisfaction Survey

B-2.2 CLINICIAN SATISFACTION SURVEY

The survey in this section will be used to assess the clinician's satisfaction with the socket, focusing on its fit, quality, and ease of use.

CLINICIAN SATISFACTION SURVEY

#	Question	Strongly Disagree (1)	Disagree (2)	Neutral (3)	Agree (4)	Strongly Agree (5)
1	The socket provides an optimal fit for the patient					
2	The overall quality of the socket meets clinical standards					
3	The socket is easy to work with during the fitting process (ex. heat gun modifications)					
4	The socket is easy to modify on Canfit					
5	The socket is easy to physically modify (ex. sanding, glue application of cork)					
6	The socket appears durable and well-constructed for long-term use					
7	The socket supports the patient's mobility and daily activities effectively					
8	Overall, I am satisfied with the socket's performance					
TOTAL						**/40**
Additional Feedback						

Figure B3 -Satisfaction Survey

B-2.3 TECHNICIAN SATISFACTION SURVEY

The survey in this section will be used to assess the technician's satisfaction with the socket, focusing on its ease of fabrication and overall functionality during the production process.

TECHNICIAN SATISFACTION SURVEY

#	Question	Strongly Disagree (1)	Disagree (2)	Neutral (3)	Agree (4)	Strongly Agree (5)
1	The socket was easy to fabricate					
2	The materials used for the socket are of high quality and suitable for fabrication					
3	The socket was completed in a reasonable amount of time without compromising quality					
4	The socket was easy to modify during the fabrication process					
5	Overall, I am satisfied with the process of fabricating and working with the socket					
TOTAL						**/25**
Additional Feedback:						

Figure B4-Technician Satisfaction Survey

B-3.0 MANUFACTURING PROCESS VERIFICATION PROCEDURE METHODOLOGIES

This section outlines the manufacturing process verification procedure methodologies used to document the times for each process.

B-3.1 OVERALL MANUFACTURING TIME REDUCTION TEST PROCEUDURE

TABLE B-VI

OVERALL MANUFACTURING TIME REDUCTION

Procedure 4.7: Overall manufacturing time reduction test	
Equipment	Stopwatch
Materials	All materials required to manufacture a traditional and 3D printed TTS
Passing Criteria	The overall time for the two 3D printed socket (NWB and WB) manufacturing must be equal or less than the overall time for two traditionally manufactured sockets (NWB and WB)
Procedure	For the purpose of this procedure, "overall" time can be defined as the time including handling of materials and tools, also including hands-off work when no tools or materials are being handled. 1. Ensure all necessary materials and tools are prepared and readily available for the manufacturing process of a traditionally produced TTS. 2. Beginning from patient casting, start a stopwatch. 3. Have one technician make both sockets without stopping the stopwatch. 4. When the WB TTS is ready for the patient testing, stop the stopwatch and record the time. 5. Repeat steps 1-4 for the 3D printed TTS

B-3.2 HANDS-ON MANUFACTURING TIME REDUCATION TEST PROCEUDRE

TABLE B-VII

HANDS-ON TIME REDUCTION

Procedure 4.8: Hands-on manufacturing time reduction test	
Equipment	Stopwatch
Materials	All materials required to manufacture a traditional and 3D printed TTS
Passing Criteria	The hands-on time for the two 3D printed sockets (NWB and WB) manufacturing must is equal or less than the overall time for the two traditionally manufactured sockets (NWB and WB)
Procedure	For the purpose of this procedure, "hands-on" time can be defined as the time for activities requiring active handling of materials or tools. 1. Ensure that all necessary materials and tools are prepared and readily available for the manufacturing process of a traditionally produced TTS. 2. Use a stopwatch or timing software to measure the time. Start timing when hands-on work begins for the first step of casting the patient. 3. Pause the stopwatch during inactive periods such as machine processing, curing, or drying. 4. Resume timing when hands-on work recommences. 5. Record the time for each step immediately after its completion, and document any delays or deviations encountered. 6. At the end of the process, add the recorded times for all hands-on activities to calculate the total hands-on time for the production cycle. 7. Repeat Steps 1-6 for the 3D printed TTS

B-4.0 RECOMMENDED PRINTER SPECIFICATIONS

This section outlines the recommended printer settings that have been selected. The details have been outlined in Table B-VIII

TABLE B-VIII

3D PRINTER RECOMMENDATIONS

Printers Compatible with SuperSlicer		Est. Price CAD	Bed Size (mm)			Printing Volume (m^3)	Compatible Filament (mm)	Maximum Nozzle Size (mm)	PLA and PETG Compatible?	Available 2.85 mm Hotend
Company	**Model**		**Length**	**Width**	**Height**					
Creality	CR-5 Pro [B4]	$1,250	300	225	380	0.0257	1.75	1.2	YES	Requires further research. Preliminary searches did not result in a direct answer of yes or no.
Creality	Cr-6 Max [B5]	$1,250	400	400	400	0.0640	1.75	1.2	YES	
Creality	Ender-3 Max [B6]	$500	300	300	340	0.0306	1.75	1.2	YES	
Creality	Ender-5 Plus [B7]	$850	350	350	400	0.0490	1.75	1.2	YES	
Creality	Ender-6 [B8]	$800	250	250	400	0.0250	1.75	1.2	YES	
Meltingplot	MBL 136 [B9]	$26,000	850	405	396	0.1363	2.85	2	YES	N/A
Meltingplot	MBL 308 [B10]	$32,600	850	405	896	0.3084	2.85	2	YES	N/A
Meltingplot	MBL 480 [B11]	$39,000	850	405	1396	0.4806	2.85	2	YES	N/A
TriLAB*	AzteQ Industrial [B12]	$1,200	300	300	400	0.0283	1.75	1.2	YES	Requires further research. Preliminary searches suggest there is a 2.85mm version of their E3D Volcano V6 hotend.
TriLAB*	DeltiQ 2Plus [B13]	$5,300	250	250	500	0.0245	1.75	1.2	YES	

* TriLAB printer beds are circular; length and width values represent print bed diameters.

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