Solid Freeform Fabrication 2024: Proceedings of the 35th Annual International
Solid Freeform Fabrication Symposium – An Additive Manufacturing Conference

DECISION-MAKING FRAMEWORK FOR CUSTOMIZED ADDITIVELY-MANUFACTURED LOWER-LIMB PROSTHETICS

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Abstract

This work developed a novel decision-making process for designing additively manufactured thermoplastic lower-limb prosthetics. The framework is based on analytic hierarchy process (AHP), where patient information, stakeholder (doctor, patient, others) wishes, and realistic manufacturability constraints using material extrusion additive manufacturing are all considered. Instead of a process where a single design or alternative is selected, the AHP method allows the stakeholders to rank and simultaneously evaluate several close or imperfect options for design in order to make the best decisions under uncertainty and imperfect information. A usable tool written in MS Excel and Python was developed, along with a tutorial for use in realistic scenarios. A detailed long-form case study using primitive shape optimization and topology optimization was created to better demonstrate the concepts and procedure. Patient data for the case study was taken from existing published literature sources, so no human subjects were directly used for this project and Institutional Review Board approval was not necessary. This tool will support the design of more effective lower-limb prosthetics where manufacturability is a concern and provide additional information-gathering and decision-making by patients, doctors, and other stakeholders relative to what can be realistically customized for patients.

Keywords: Prosthetics, Analytic Hierarchy Process, Decision-Making Framework, Material Extrusion Additive Manufacturing

1. Introduction

The purpose of this work is to develop a novel framework using the analytic hierarchy process (AHP) model to help or guide prosthetists, clinicians, researchers, and users of prosthetics in choosing a suitable prosthetic which is customized for the patient via additive manufacturing. Amid a tech boom, amputees face a daunting array of options, making it challenging to pinpoint the right choice [1]. Numerous important aspects that drive the decision-making process, like comfort and fit of the prosthetic, lifestyle of the amputee, the durability of prosthetic components, health of the amputee and other body parameters, and cosmetics, will be examined. These factors and the currently available alternatives of prosthetic components will be used in the framework systematically. They will enable the best possible list of combinations for all lower-limb prosthetic components, including sockets, suspensions, knee units, feet, and pylons. This research only focuses on lower limb amputations as they are more common than upper limb amputation and have a larger impact on the post-amputation life quality of the user [2-4]. Surveys have shown that 60%

of amputee patients are dissatisfied with their prostheses, 57% report discomfort, and over 50% experience actual pain while using them [5]. One of the causes for this dissatisfaction is inadequate/inefficient customized decision-making.

There are five main types of prostheses: postoperative, initial, preparatory, definitive, and special purpose [6]. The selection process starts with getting the requirements of the patients via various methods like questionnaires, interviews, medical tests etc., followed by involving the patients in the decision-making process by letting them compare between various factors that affect the final output, then in the next step multiple experts rate the various alternatives based on the users' inputs to narrow down the best possible components for that individual. This ensures structured and informed shared decision-making and can lead to better satisfaction rates. Typically, this process is not structured and obtaining a suitable post-amputation lower-limb prosthetic remains complex, time-consuming, and lacks a structured decision-making framework. This procedure necessitates many clinical visits for casting, fitting, and assembling components, potentially overloading consumers and adding uncertainty to the process. As a result, there is a need to provide a comprehensive decision-making framework to aid individuals, particularly those with below-knee (Transtibial) or above-knee (Transfemoral) amputations, in navigating the prosthetic component selection process.

The typical process for selecting and fabricating prostheses is:

- *Initial post-operative care:* Following an amputation, the patient undergoes an initial phase of post-operative care or dressing [1, 7].
- *Wound monitoring and healing during pre-prosthetic care:* The patient is closely monitored for several weeks to ensure the wound heals properly. During this period, regular wound checks are conducted [7]. The pre-prosthetic phase includes management of the residual limb including wound care, edema control, shaping, desensitization, and increasing joint and muscle flexibility [1].
- *Prosthesis prescription, fitting, and training:* Once the wound has healed completely, the patient is referred to an experienced prosthetist. A prosthetic prescription provides a comprehensive description of all the features of the finished prosthesis, including: (a) socket design, (b) skin-socket interface, (c) suspension strategy, and (d) additional modular components. For transtibial prostheses, the components are typically limited to feet, shock absorbers, torque absorbers, and dynamic pylons. The prosthetic prescription is determined by team consensus, and the prosthetic components are then fabricated [1]. The process includes:
    - Measurements: The prosthetist takes precise measurements to create a personalized prosthesis for the patient.
    - Fabrication of prosthesis: The prosthesis is custom-made based on the measurements. Once a prescription for a custom orthosis or prosthesis is created, the fabrication process begins, typically following these six steps [1] (Traditional Method):
        1. Measure the limb accurately.
        2. Make a negative impression (cast).
        3. Create a three-dimensional positive model of the limb or body segment.

        4. Modify the positive model to incorporate desired controls.
        5. Fabricate the orthosis or prosthetic socket around the positive model.
        6. Fit the device to the patient.

    A common fabrication method is thermoforming, where a thermoplastic sheet is heated in an oven until it becomes pliable. It is then shaped over a positive model typically by vacuum forming [1].

  - Training: The prosthetist provides thorough training to the patient and their relatives on how to use the prosthesis for rehabilitation.

- *Rehabilitation and follow-up:* Post-fitting, the patient undergoes a rehabilitation program to adapt to the prosthesis. Follow-up appointments are scheduled to monitor progress and make any necessary adjustments to the prosthesis [1].

The proposed framework will not entirely change the process, but it will introduce structured decision-making, improve patient involvement, improve visibility and accountability in the process and optimize the selection of prosthetic components. It also integrates manufacturability constraints for additive manufacturing, ensuring that the design produced is manufacturable as well as being a good long-term support for the patient. It should be noted that all patient data used in this project was taken from published literature and therefore IRB or ethics approval was not necessary. After the framework development and

2. Framework Development

2.1. Analytic Hierarchy Process

The goal was to create a structured process that can be utilized as an aid for decision-making. This decision-making process involves multiple criteria decision making as it involves addressing decision and planning problems with multiple criteria. There are various available methods for Multi-Criteria Decision Making (MCDM) like Analytic Hierarchy Process (AHP), Analytic Network Process (ANP), Grey Theory, MAUT (Multi-attribute Utility Theory) [8], and similar, out of which AHP was selected for this model. It is validated and increasingly being used in healthcare and provides valuable support in complex healthcare decisions [9-10]. AHP is a method that provides a priority score by comparing multiple options pairwise. It is easier to compare options with each other than to assign absolute values to them. AHP converts the problem into a hierarchy and uses multiple comparisons to determine the relative weights of each option [10-12]. It allows multiple stakeholders to be involved in the decision-making process and facilitates shared decision-making. If the goal, criteria, and alternatives are clearly defined, AHP can be comfortably used. Due to the consistency checks, the ease of comparing two criteria, and the inclusion of stakeholders, this research utilized the AHP model/method as the base of the framework or framework design [13].

AHP, introduced by Saaty in 1980, is a method for making decisions involving multiple criteria. It involves three key steps: (1) organizing a problem into a hierarchy as shown in the Figure 1, (2) comparing elements at each level, and (3) combining these comparisons to make overall decisions [10-12]. AHP utilizes a pairwise comparison of factors and alternatives to get the final weights of alternatives based on the preferences of the user and the ratings from experts. Each comparison is based on a verbal or numerical scale. In this study, a numerical scale ranging from

1-9 is used as shown in Table 1 [11]. In the evaluation phase of AHP, elements in a hierarchy are compared to determine their importance or contribution to a specific criterion. This comparison helps create a relative scale of measurement, showing how each element stands concerning the criterion being considered. The final weights of the elements at the bottom level of the hierarchy are obtained by adding up their contributions from the level above, following the principle of hierarchic composition [12-14]. The final weights of alternatives can be used to narrow down a few options out of myriad of possibilities. Then, the experts and users can make the final decision together.

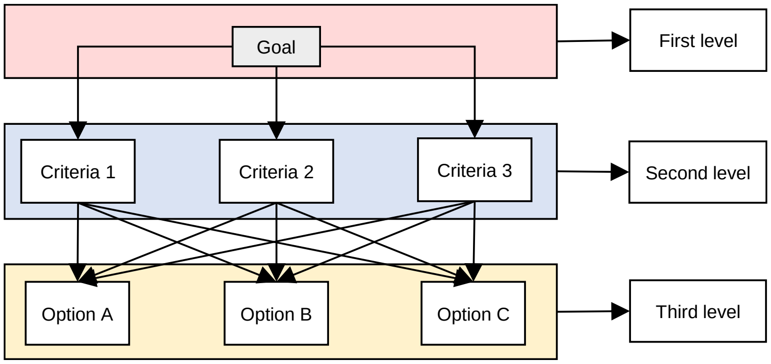


Figure 1. Hierarchy for AHP

Table 1. 1-9 importance scale [11]

Importance /10	Definition	Explanation
1	Equal importance	Two activities contribute equally
3	Moderate importance of one option	Experience and judgment favor one activity over another
5	Essential or strong importance of one option	Experience and judgment strongly favor one activity over another
7	Very strong importance of one option	An activity is strongly favored, and its dominance demonstrated in practice
9	Extreme importance of one option	The evidence favoring one activity over another is of the highest possible order of affirmation
2,4,6,8	Intermediate values between two adjacent judgments	When compromise is needed

2.2. Decision-Making Framework

This framework encompasses eight well-defined steps that must be done before the design and manufacturing process of the actual prosthetic can be started. These assist in identifying and selecting the most suitable sockets, suspensions, knee units, and other vital components which will not be automatically-generated during the manufacturability-driven stage. The final stage of the framework involves a user-driven optimization process that helps to fine-tune the topology of the connecting rod, ensuring optimal performance and reliability. This framework serves as an essential tool for professionals and academics in the field of mechanical engineering, as it streamlines the selection process and allows for the creation of customized and efficient connecting rods. The steps for selection of components are given as follows-

1. Defining the problem
2. Understanding the user's preferences
3. Amputees use the 1-9 scale to rate the criteria that drives decision-making process
4. Setting up the decision hierarchy
5. Experts rate the alternatives based on the factors
6. Calculating the priority vector
7. Consistency Check
8. Calculating the final weights

Before using the framework, the stakeholders (patient, doctor, designer, etc.) should be aware of all the important criteria that drive decision-making and how these criteria should be documented and communicated to the other stakeholders. To properly rate the criteria, it is important to understand and evaluate the factors that drive the decision-making process. In the context of this project, these are:

- *Comfort and fit:* In the context of lower limb prosthesis, comfort refers to how comfortable and well-fitting the prosthetic is. A comfortable interface/socket is required for proper functionality and movement. Individuals' needs and lifestyles impact their level of comfort and fit. Discomfort is one of the leading causes of prosthetic device abandonment across all device types (passive, body-controlled, myoelectric, and hybrid). Comfort and fit are primarily determined by socket fit, cushioning and liners, range of motion, balance and weight, suspension, liners, and skin irritation. A pleasant prosthetic does not cause socket discomfort, sweat, poor fit, pain, or skin infections. Socket discomfort arises when the socket fit is overly loose or tight. This causes friction, soreness, and pressure points. Liners and padding should also be used to tackle issues like soreness, friction, etc. Pressure should be applied uniformly, avoiding pressure-sensitive areas that are vulnerable. A comfortable prosthetic enables normal ambulation and feel. When a prosthetic is comfortable, the user never feels burdened by it.
- *Lifestyle of the amputee:* Certainly, everyone is distinctly unique, with their own specific needs and preferences, and these factors are profoundly influenced by their lifestyle. Every person’s life experiences, career choices, and hobbies shape their physical requirements and prosthetic needs. Some examples relevant to design include:
    1. *The desk job enthusiast:* Some individuals are passionate about desk jobs, spending extended hours working with computers. Their prosthetic requirements might prioritize ease of use, comfort, and appearance over heavy-duty performance.
    2. *The active construction worker:* On the other hand, individuals engaged in physically demanding jobs, such as front-line workers, often require prosthetic limbs that can withstand substantial wear and tear. Their prostheses must be robust, well-balanced, and durable to endure the rigors of the job. These individuals need the prosthetic equivalent of heavy-duty tools to perform their tasks safely and efficiently.

3. *The athlete and sports enthusiast:* Athletes have a distinct set of requirements due to their active lifestyle. Their prosthetic limbs must be finely tuned for optimum performance and endurance. For instance, a sprinter may require a running-specific prosthesis with carbon-fiber blades to maximize speed, while a swimmer might need a waterproof prosthetic designed for aquatic activities.

In essence, an individual's lifestyle profoundly influences the type of prosthetic required. It's not a one-size-fits-all solution. The prosthetic limb should be customized to accommodate their unique physical attributes, demands, and aspirations. Tailoring prosthetic design to a person's daily activities and preferences ensures that they can lead a fulfilling life while overcoming physical challenges. The lifestyle of a person determines the type of prosthetic required.

- *Durability and maintenance:* The durability of prosthetics refers to the ability of prosthetic limbs to withstand adverse situations and stresses, wear and tear, and environmental conditions. Prosthetics should be durable; they should have longer lifespans with fewer replacements. Along with durability, maintenance is also an important factor. The prosthetics should be easy to maintain and repair when necessary. They should be easy to don and doff and clean. Users should be able to replace worn components or adjust without extensive downtime. The durability of prosthetics can be influenced by individual factors, but it is also dependent on the design and materials used in the prosthetic components.
- *Health and body parameters:* Body parameters and health play very crucial in the design of limb prosthetics level of functionality and mobility required and ensure that the prosthetic limb is comfortable, safe, and effective.

2.3. Step-by-Step: Navigating the Decision Framework

As mentioned earlier, this framework consists of 8 steps for the selection of the components like socket, suspension, knee unit, etc., and a final optimization stage where the user's inputs drive the optimization and manufacturability-driven design of the connecting rod.

- *Step 1: Defining the problem.* Defining the problem is the first and most crucial step of any framework. The foundation sets the tone for the rest of the process. Therefore, it is essential to determine the problem correctly as it affects the way the subsequent steps will be carried out. To adequately define the problem, it is necessary to have a clear understanding of the factors that contribute to the issue. By addressing all aspects of the issue and establishing clear boundaries, the problem can be approached effectively, leading to successful outcomes. Example: If a woman intends to buy a vehicle, it's essential to understand her exact needs to provide better assistance. It's crucial to know whether she wants a sedan, a truck, or a bike and whether she has any preferred company or specific technical requirements before suggesting the most suitable options.
- *Step 2: Understanding the User's Preferences.* Once a problem has been defined clearly, it's important to understand the user's requirements to provide the best possible solution. During this stage, a detailed questionnaire encompassing multiple questions directly or indirectly impacting the problem is designed. Based on the responses obtained from the survey, an indicative preference ranking can be obtained. In this research, out of all the factors, three to five (but not limited to) of the most important ones are chosen to be implemented in the framework. These key factors are the ones that will have the most

significant impact on the problem and will be essential to finding a solution that meets the user's requirements. Two types of data collection methods should be implemented: first, gathering comprehensive medical data including patient limb size, condition, weight, height, and other relevant parameters; second, understanding users' needs and preferences through surveys, questionnaires, and interviews.

Example questionnaires for customizing the sockets, suspension, knee, and foot units are given in the **Appendix**. The amputee's desired level of activity is crucial, as it allows for classification based on mobility and functional requirements. To assess activity levels in individuals with lower limb amputations, widely employed scales include the Medicare Functional Classification Level (commonly known as the K-level scale) [15, 16] and the Special Interest Group in Amputee Medicine (SIGAM) scale [17]. These scales often serve as essential criteria for guiding the selection of prosthetic components in clinical practice

- *Step 3: Amputees use the 1-9 scale to rate the criteria that drive the decision-making process.* The user's requirements and the research conducted for this thesis will provide an ideal set of primary factors to test. Once we have identified these primary factors from Step 2, we undertake a comparative analysis to rank them. When it comes to decision-making, there exist several factors that influence our choices. For instance, we may consider factors such as cost, quality, convenience, and reliability, among others. In this case, we will consider four factors that we will call C1, C2, C3, and C4. We aim to determine the relative weights of these criteria based on user ratings. To accomplish this, we must perform a pairwise comparison of all the factors. In other words, we compare each factor to every other factor to determine their relative importance. For example, we must compare C1 - C2, C1 - C3, C1 - C4, C2 - C3, C2 - C4, and C3 - C4. By doing so, we get an idea of how important each factor is relative to the others. To determine the importance of each factor to the patient and other stakeholders, we will use a 1-9 rating scale, an example of which is shown in Figure 2. Note that the comparison goes both ways, so a pairwise matrix is generally the best approach for modeling this.

	9	7	5	3	1	3	5	7	9	
C1	Absolutely More Important	Very Very Important	Much More Important	Somewhat More Important	Equal Importance	Somewhat More Important	Much More Important	Very Very Important	Absolutely More Important	C2

Figure 2: 1-9 Scale for the pairwise comparison

- *Step 4: Setting up the decision hierarchy.* When dealing with a problem, it can be helpful to establish a clear and concise objective and then narrow down the factors and options; this is done in the first two steps. To visualize this hierarchy, a hierarchy diagram can be used to demonstrate the AHP model. This model consists of three levels: Goals, Criteria, and Alternatives, which form the basic structure of the model. The AHP diagram is an effective tool to better illustrate this structure. Once the criteria have been established, the alternatives are evaluated based on the criteria. These alternatives are the potential solutions provided after assessing the first two levels of AHP. This step is unique for each part, such as prosthetic sockets, feet, joints, etc., and varies according to the user's preferences.

- *Step 5: Experts rate the alternatives based on the factors.* Experts consider several steps before rating the alternatives. They first look at the user preferences and consistency ratio, and then rate the alternatives based on various factors using a 1-9 scale, as explained before.
- *Step 6: Calculating the priority vector.* Once we have the comparison matrix, calculating the priority vector is the next step.
  - *Normalize the Matrix: For each column, divide each element by the sum of its column. This ensures that each column represents a probability distribution.*
  - *Calculate the relative weight: For each row, calculate the sum of each element and divide it by the total elements in that row. This gives the average value of for that row.*
- *Step 7: Consistency Check.* It is important to check the consistency level of both the user and expert responses when answering questions and providing ratings. To assess the consistency of judgments, the Consistency Ratio (CR) is used. This ratio compares the degree of consistency in the judgments to that of a randomly generated inconsistent matrix [**10-12**]. The CR is calculated using the eigenvalue and provides a measure of the reliability of the decision-maker's judgments. If the result shows that factor A is two times more important than factor B and factor B is two times more important than factor C, then the comparison is inconsistent. In such cases, we need to adjust the study and recalculate the result.
- *Step 8: Calculating the final weights.* Calculate the final weights after determining the priority vector of factors and priority vectors of alternatives based on factors in the AHP model.

3. Integrating Manufacturability Constraints

3.1. Constraint Definition and Mapping

During product design, it is crucial to consider the advantages, limitations, and best practices associated with specific manufacturing processes to ensure that the final design is manufacturable. This becomes particularly important when using complex design methods, such as topology optimization algorithms, as the final design may not be feasible without incorporating manufacturability constraints. Mapping for the general manufacturing process consists of three main things (Figure 3) [**18**]:

- *Manufacturing considerations* that explains the type of process, the family, advantages, and disadvantages
- *Manufacturing constraints* provide limitations on the process and materials
- *Manufacturability constraints* are formal constraints that are derived from manufacturing constraints, and they provide constraints on the design, not the process.

Mapping manufacturing knowledge into design-focused constraints is a rigorous process aimed at narrowing down design options to those that can be effectively manufactured using specific processes while also considering different design scales. The manufacturing process involves a subset of possible steps, and the manufacturability constraints, imposed on the design, are the smallest domain among manufacturing considerations, bounding the design space based on relevant constraints from the specific process and material used. These considerations, which can be conceptual and range from process type to specific process and material combinations, can be converted into manufacturing constraints that define the applicability of the process [18].

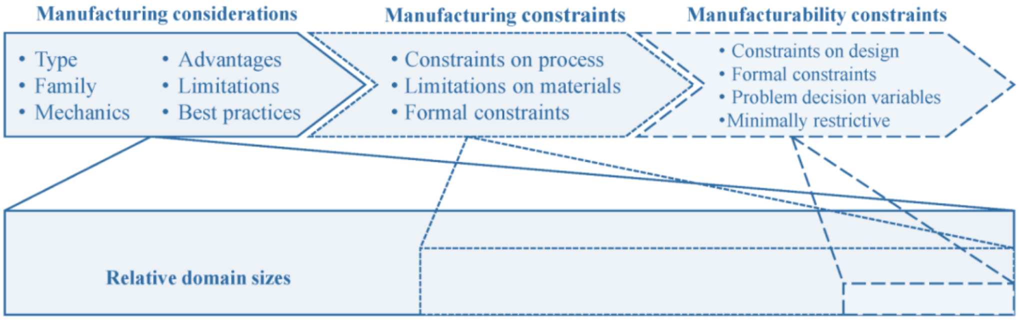


Figure 3. Mapping for general manufacturing process [18]

In this research, the focus will be on the connecting rod of the lower limb prosthesis and its design and manufacturing using fused deposition modeling (FDM). This area has not been extensively explored, with limited studies exploring and mapping the manufacturing constraints within the context of FDM-based components. FDM offers a good solution for printing complex 3D models. However, it is challenging to incorporate all the necessary guidelines, and soft constraints that designers should adhere to [18]. To ensure that the FDM fabricated connecting rods are lightweight, stiff, and easily customizable, incorporating topology optimization is crucial. The optimization of a product's weight without compromising its structural integrity relies on the removal of redundant layers. This process entails several steps, starting with the creation of a design space, followed by the definition of the material and its properties. Subsequently, a mesh is produced, and boundary conditions are applied. The objective of the process is then defined, and constraints are established to ensure that the final product meets all requirements. By following these steps, the strength-to-weight ratio is optimized without sacrificing the product's performance. To ensure the manufacturability of products made with typical thermoplastic materials, it is important to follow a checklist of the major problem formulation activities.

- *Step 1. Collection of constraints:*
    - Environmental Conditions
    - Minimum and maximum extruder temperature
    - Ambient temperature
    - Minimum and maximum print speed
    - Maximum shrinkage allowed on cooling
    - Minimum and maximum packing density
    - Minimum and maximum extruder nozzle size
    - Minimum and maximum layer height
    - Minimum feature length to dissipate heat/stress
    - Minimum and maximum raster angle

  - Minimum number of layers
  - Nominal density
  - Number of shells or contours
  - Printing Orientation
- *Step 2. Refine:*
  - Environmental conditions: Environmental conditions should follow typical ASTM/ISO standards (e.g., 22–24°C, 40–60% relative humidity). Any deviation should be carefully recorded and reported with experimental results. This is essential as very cold environments can cause warping or cracking and in hot environments, material flow can be affected.
  - Minimum and maximum extruder temperature: The configuration of the FDM hardware will mainly drive this.
  - Ambient temperature: When possible, printing should be done inside of an enclosure which may or may not be heated directly. It will prevent the spread of toxins in the air and provide a more consistent environment.
  - Minimum and maximum print speed: Similarly, to the extrusion temperature, the values are determined by the hardware configuration used.
  - Maximum % shrinkage allowed on cooling: The manufacturer of the filament typically used by the authors (and used in the case study) promised an error of less than 3% including cooling-related shrinkage. The true rate of shrinkage should be the value given by the manufacturer or less, or a new filament source should be found.
  - Minimum and maximum packing density: The realistic packing density will depend on which material is used. Generally, amorphous materials have a better final packing density than semi-crystalline materials.
  - Minimum and maximum extruder nozzle size: The constraint for this can be set by the available nozzle sizes. The standard sizes range from 0.2 mm to 1.0 mm in increments of 0.05 mm. Nozzle size choice is a trade-off between print speed and degree of homogeneity/defect tolerance. 0.4–0.6 mm nozzles are the most commonly used sizes.
  - Minimum and maximum layer height: For the materials in use, the experience of the author and common best practice directs that the element height-to-width ratio should not be larger than 2/3. Element width is determined mainly by the nozzle size.
  - Minimum feature length to dissipate heat/stress: Based on the authors' experience and previous work, the minimum macro-scale feature scale should be 2.5 times the nozzle diameter for any parts taller than the part length scale. An exception to this is for thin-walled structures that do not need the same support due to their geometry, which keeps the part stable during printing or 2.5D parts with stable features.

    - Minimum and maximum raster angle: The raster angle for the work described in this dissertation was limited to the range from 0° to 90°.
    - Minimum number of layers: Based on the experience of the author, a minimum of 5 layers should be printed for structural parts. Soft constraint for most FDM cases.
    - Nominal density: This is the maximum realistic density (<100%) or the initial volume fraction.
    - Number of shells or contours: A minimum number of shells = minimal stable layer boundary, the maximum number of shells ≤ smallest layer dimension divided by 2× nozzle size.
    - Printing orientation: Printing orientation is limited by the number of degrees of freedom (DoF) for printing hardware (most printers are limited to three DoF).
- *Step 3: Additional data if needed*
- *Step 4: Simplify and combine.* To simplify the constraints in each scenario, it is important to remove any that are redundant or duplicated. For instance, when dealing with Environmental Conditions and ambient temperature, both are very similar, and one can be used as a constraint in place of the other. Therefore, it is possible to remove either, either ambient temperature or environmental conditions, to make the constraints more straightforward to work with.
- *Step 5: Apply to the problem at hand*

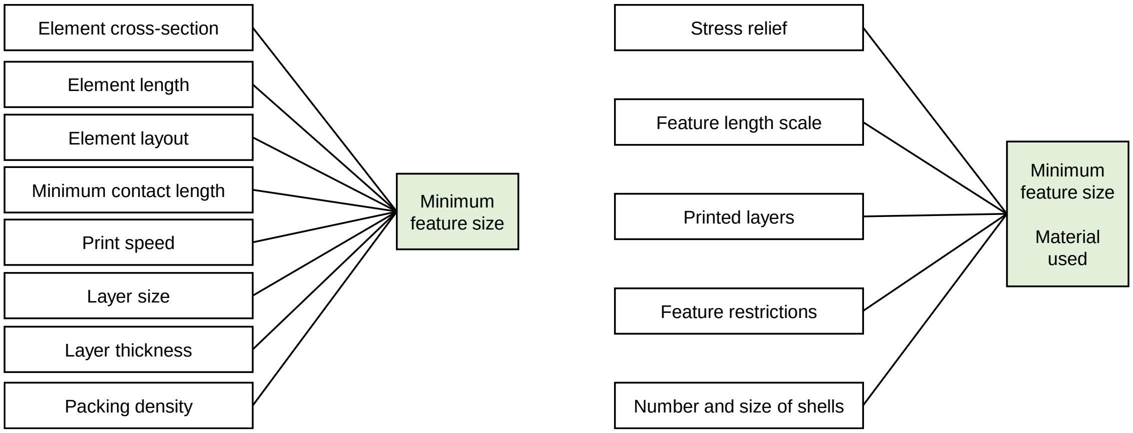


Figure 4. Mapping from manufacturing constraints to manufacturability constraints

3.4. Constraint Mapping

This research focuses on the topology optimization of the connecting rod in a lower limb prosthesis. For the product to meet the users' requirements, it needs to be appropriately 3D printed. The 3D printing manufacturing constraints are mapped with TO (Topology Optimization) to obtain a customizable solution using nTopology. The objective function of interest is minimization of compliance, or alternatively, maximization of stiffness. For PLA, the voids range from 12-16% of the volume [19]. For 15% voids and inclusions in the material, the nominal density will be 85%

i.e., 0.85. As, the nominal density = 1 - void fraction. To compensate for the voids, we need to consider the 1/0.85 = 1.17 for the calculation of the true factor of safety in the topology optimization. The mapping process developed for this problem is shown in Figure 4, where it is shown that the mapped design constraints can be refined down to (1) minimum feature size, (2) the material properties, and (3) a realistic-use set of boundary conditions. These can be added directly to the TO algorithm as constraints, which is demonstrated in Figure 5.

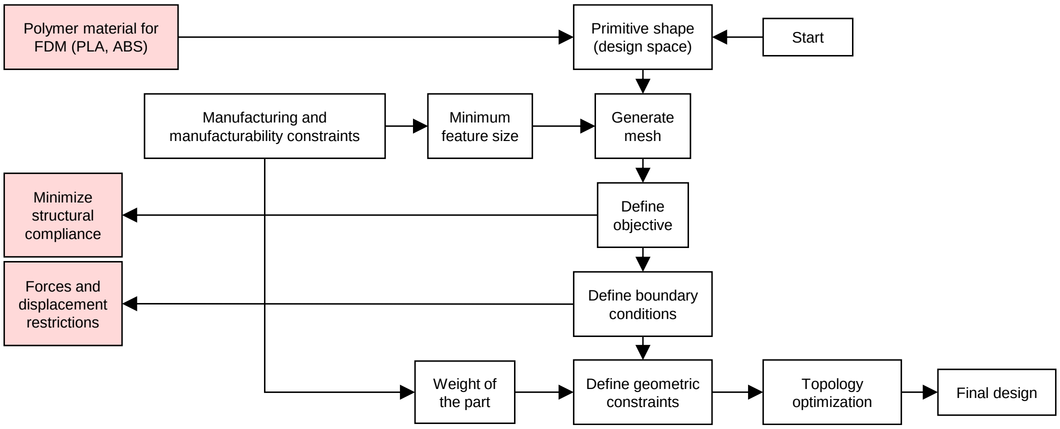


Figure 5. Formulation and solution approach with manufacturability constraints

4. Case Study

4.1. Patient Information from Published Literature

The amputee chosen to demonstrate this framework was a 20-year-old man with a right transtibial amputation in a car accident [20]. Note that this information was taken from Reference [20] and that no human subjects were directly used for the current study. He weighed 62.5 kilograms (kg). The length from the medial tibial plateau to the stump was 18.2 centimeters (cm). The overall health of the amputee was good and his gait was classified as being significantly different from the norm.

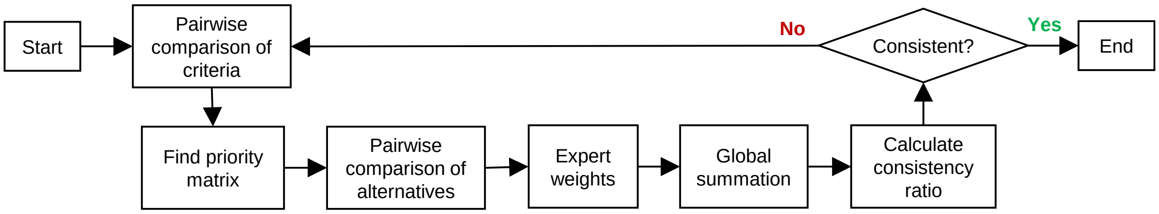


Figure 6. Decision steps

4.2. Framework evaluation and outcome

In this case study, the objective is to demonstrate and test the framework. The primary limitation of this case study is the lack of direct involvement of the amputee in the decision-making process.

The data presented in the study were not manipulated, as the individual under consideration was not actively engaged in the decision-making aspects related to the personalized prosthetic framework. The decision-making framework used is shown in Figure 6, with Figure 7 showing the approach for selecting the prosthetic components that will not be designed using topology optimization in this case study.

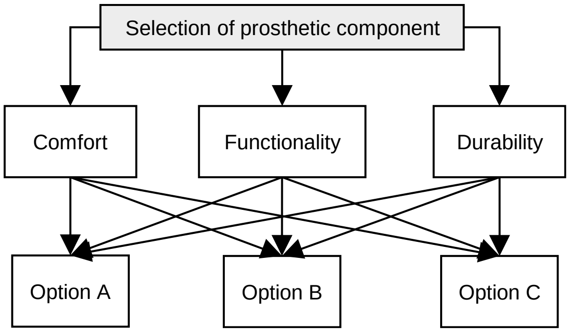


Figure 7. Hierarchy for selecting a prosthetic component

STEP 1: Selecting a socket

Task 1: Defining the problem

Selecting a socket is very tricky. This framework can be used to narrow down and choose a suitable socket as per the patient's requirements and health.

Task 2: Understanding the user's preferences

After inquiring about the specific details of the amputee, the prosthetists observed the following:

The individual isn't actively involved in sports but maintains an active lifestyle due to the walking demands of his job. His recreational activities have no bearing on the prosthetic decision, and the cost factor is not considered in this framework. The residual limb is both short and sensitive, with no material allergies or sweating issues. Exposure to water and extreme temperatures is minimal. Aesthetically, he is open to any option that serves him well. Being a single male, he currently resides with his parents and sister, receiving mental support. He has opted for a K2 level of activity and a D SIGAM level.

Task 3: Amputees use the 1-9 scale to rate the criteria that drive the decision-making process

3 pairwise comparisons:

1. Comfort and Functionality: Equal importance
2. Comfort and Durability: Comfort is much more important
3. Durability and Functionality: Functionality is very strongly important than durability

So, we get the comparison matrix as follows:

$$\begin{bmatrix} 1 & 5 & 1 \\ 0.2 & 1 & 0.14 \\ 1 & 7 & 1 \end{bmatrix}$$

It is consistent and we get the priority vector

$$\begin{bmatrix} 0.44 \\ 0.08 \\ 0.49 \end{bmatrix}$$

Task 4: Setting up the decision hierarchy

Here, we have three alternatives for transtibial sockets -

1. Plug-fit socket
2. PTB socket
3. TSB socket

Functional: Plug-fit sockets are not suitable as they are now obsolete, and they don't provide functionality. TSB and PTB provide the same functionality

Comfort: PTB is suitable for new users. PTB is good for sensitive limbs so more comfortable. Easy to don and doff and good for users with poor hand dexterity and poor eyesight.

Durability: TSB is not suitable for primary amputees due to volume changes in the first 12-18 months post-amputation. TSB is unsuitable for patients with short residual limbs, less than 10cm long, which require higher trim lines for stability around the knee.

Task 5: Experts rate the alternatives based on the factors

Now, the experts rated the alternatives based on the user's choices and the amputee's medical record. Using the information obtained in step 2 and step 4, the experts rated alternatives based on comfort. The pairwise matrix obtained was

$$\begin{bmatrix} - & Plug\ fit & PTB & TSB \\ Plug\ fit & 1 & 0.14 & 0.33 \\ PTB & 7 & 1 & 5 \\ TSB & 3 & 0.2 & 1 \end{bmatrix}$$

Task 6: calculating the priority vector

After normalizing, the priority vector was obtained. These priority vectors show the weight of each alternative for that criterion. For example: The priority vector for functionality is:

$$\begin{bmatrix} 0.08 \\ 0.72 \\ 0.19 \end{bmatrix}$$

This means that the relative weight of PTB is 72% and of TSB is 19%. The weight of the plug fit is 8% only.

Task 7: Consistency Check

The user or the experts are often inconsistent in answering questions and rating, so checking the consistency level is of utmost importance. The consistency of the judgments is assessed using the Consistency Ratio (CR), which compares the degree of consistency in the judgments to that of a randomly generated inconsistent matrix. The CR is calculated using the eigenvalue and provides a measure of the reliability of the decision-maker's judgments. For the above problem, the consistency was calculated by:

1. Calculating a new vector by calculating the product of pairwise comparison matrix and priority vector.
2. Calculate the eigenvector by dividing the new vector by its corresponding element in the priority vector.
3. Calculating the maximum eigenvalue by taking the average of all the numbers in the eigenvector λ_{max}
4. Calculating the consistency index using the formula:
$$\frac{\lambda_{max} - n}{n - 1}$$
5. Calculating CR = CI/RI. Here RI is a random index that is obtained by approximating random indices for matrices of order 1 to 10 using a sample size of 500. $\lambda_{max} = n$ is a necessary and sufficient condition for consistency. RI depends on n or the matrix size. The table for getting the CI values is:

Matrix size	Random consistency index (RI)
1	0.00
2	0.00
3	0.58
4	0.90
5	1.12
6	1.24
7	1.32
8	1.41
9	1.45
10	1.49

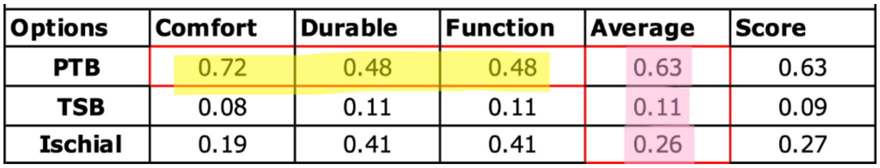
For socket selection, $n = 3$ and the consistency vector after matrix multiplication is:

$$\begin{bmatrix} 3.01365532 \\ 3.141081563 \\ 3.042719129 \end{bmatrix}$$

Then calculate the λ_{max} by taking the average of all the values in the matrix above. We get, λ_{max}= 3.06581867. Using the RI chart and the λ_{max}value, we get CR = 0.06328718. Since CR <= 0.1 for the matrix to be consistent. So, the comparison matrix is consistent, and the weights of each alternative based on their comfort are given by the priority vector.

Task 8: Calculating the final weights

After calculating the relative weights based on comfort, the same steps were followed to calculate the relative weights of all alternatives based on the remaining 2 criteria namely - functionality and durability as shown in Figure 8. The final weights of the alternatives were then calculated by matrix multiplication. In this example, the priority vector for factors is [0.63, 0.09, 0.27] and this vector is multiplied by the row vectors formed by PTB, TSB, and Ischial to final weight. For example: The yellow highlighted row represents weights for the PTB alternative based on the criteria and we multiply that by the pink vector or priority vector of factors. Here, we multiply the priority of the PTB weights for all factors like comfort, durability, and functionality with the weights of all the criteria(factors) and we get the final weight of PTB as 0.59 or 59%. Similarly, the weight of TSB is 33% and that of Plug fit is 8%.



Options	Comfort	Durable	Function	Average	Score
PTB	0.72	0.48	0.48	0.63	0.63
TSB	0.08	0.11	0.11	0.11	0.09
Ischial	0.19	0.41	0.41	0.26	0.27

Figure 8. Matrix multiplication

After rating each alternative based on the factors, the final priority vector is:

$$\begin{bmatrix} 0.08 \\ 0.59 \\ 0.33 \end{bmatrix}$$

This means PTB is the first choice with 59% weight and then TSB with 33% weight. This does not mean that PTB is only suitable. But this narrows down the list. And now we have two best options.

STEP 2: Selecting a suspension

Task 1: Defining the problem

Selecting a suspension for transtibial amputees can be challenging as there are multiple options. The most used suspension systems are - Thigh corset, Lanyard, Pin and Lock, Straps, Anatomic Suspension, Sleeve suspension, Silicone Suction Suspension(3-s), Vacuum Suspension, Seal In, and VASS (Vacuum Assisted Socket Suspension). With the help of the framework, one can narrow down the options. Firstly, the user rates the criteria and addresses the questionnaire. Once this is done, one can understand what the prosthetic users want, and which criteria are more important for them as we get the priority vector.

Task 2: Understanding the user's preferences

The individual aiming for a K2 activity level expressed a preference for daily high-speed ambulation, demonstrating a readiness for an active lifestyle. Although devoid of allergies, the residual limb is somewhat sensitive to pressure. Myopia is present, necessitating the use of glasses, but it doesn't significantly impede prosthetic interaction. Financial considerations were not explicitly provided. The individual is comfortable with a suspension system adding weight to the prosthesis and can handle it effectively, despite occasional dexterity issues. Bending down is a mandatory part of the daily routine. Lubricants for donning are not favored. Engaging occasionally in heavy work involving lifting and moving substantial objects, the user desires a prosthesis that can accommodate such activities. When assessing knee health, symptoms include occasional pain, numbness, tingling, frequent injuries or knee dislocation, muscle spasms, and joint clicking or cracking. Increased knee range of motion remains uncertain.

Task 3: Amputees use the 1-9 scale to rate the criteria that drive the decision-making process

Our user used the rating scale to compare three factors that drive the decision making namely - Comfort, Durability, and functionality. After 3 pairwise comparisons, we get the pairwise comparison matrix as follows:

$$\begin{bmatrix} 1 & 5 & 1 \\ 0.2 & 1 & 0.14 \\ 1 & 7 & 1 \end{bmatrix}$$

It is consistent and we get the priority vector:

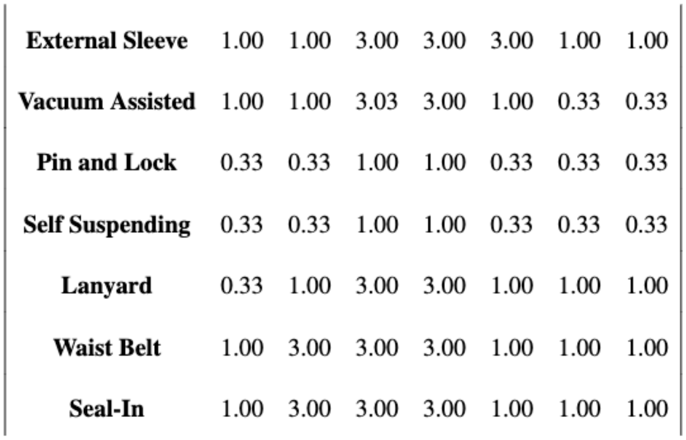
$$\begin{bmatrix} 0.44 \\ 0.08 \\ 0.49 \end{bmatrix}$$

Task 4: Setting up the decision hierarchy

After carefully going through the questionnaire (see Appendix) and the patient's data, experts can eliminate some types easily. The thigh corset suspension, strap and cuff suspension, osseointegration, and suction suspension with liner were all eliminated due to high cost, poor fit, design issues, or incompatibility with the patient’s lifestyle. The remaining viable options were external sleeve suspension, vacuum-assisted suspension, pin-and-lock, self-suspending socket, lanyard suspension, waist belt suspension, and seal-in suspension.

Task 5: Experts rate the alternatives based on the factors

After rating the seven options based on comfort, the pairwise matrix obtained was:



External Sleeve	1.00	1.00	3.00	3.00	3.00	1.00	1.00
Vacuum Assisted	1.00	1.00	3.03	3.00	1.00	0.33	0.33
Pin and Lock	0.33	0.33	1.00	1.00	0.33	0.33	0.33
Self Suspending	0.33	0.33	1.00	1.00	0.33	0.33	0.33
Lanyard	0.33	1.00	3.00	3.00	1.00	1.00	1.00
Waist Belt	1.00	3.00	3.00	3.00	1.00	1.00	1.00
Seal-In	1.00	3.00	3.00	3.00	1.00	1.00	1.00

Task 6: Calculating the priority vector

After pairwise comparison, the priority vector is normalized. Normalizing means dividing the elements of each column of the matrix by the sum of that column, then adding the elements in each resulting row and dividing this sum by the number of elements in the row (average). The need for normalization arises because, during pairwise comparisons, inconsistencies may occur in the judgments. Inconsistency can lead to unreliable results and affect the quality of the decision-making process. The normalization process addresses this by making the matrix consistent and improving the reliability of the computed priorities. After this, we get the normalized matrix as follows:

$$\begin{bmatrix} 0.20 & 0.10 & 0.18 & 0.18 & 0.39 & 0.20 & 0.20 \\ 0.20 & 0.10 & 0.18 & 0.18 & 0.13 & 0.07 & 0.07 \\ 0.07 & 0.03 & 0.06 & 0.06 & 0.04 & 0.07 & 0.07 \\ 0.07 & 0.03 & 0.06 & 0.06 & 0.04 & 0.07 & 0.07 \\ 0.07 & 0.10 & 0.18 & 0.18 & 0.13 & 0.20 & 0.20 \\ 0.20 & 0.31 & 0.18 & 0.18 & 0.13 & 0.20 & 0.20 \\ 0.20 & 0.31 & 0.18 & 0.18 & 0.13 & 0.20 & 0.20 \end{bmatrix}$$

After normalizing, the priority vector is calculated by calculating the average of the elements in the row:

$$\begin{bmatrix} 0.21 \\ 0.13 \\ 0.06 \\ 0.06 \\ 0.15 \\ 0.20 \\ 0.20 \end{bmatrix}$$

This vector represents the relative weight of each element in comparison to others. The priority vector is associated with the largest eigenvalue of the matrix.

Task 7: Consistency Check

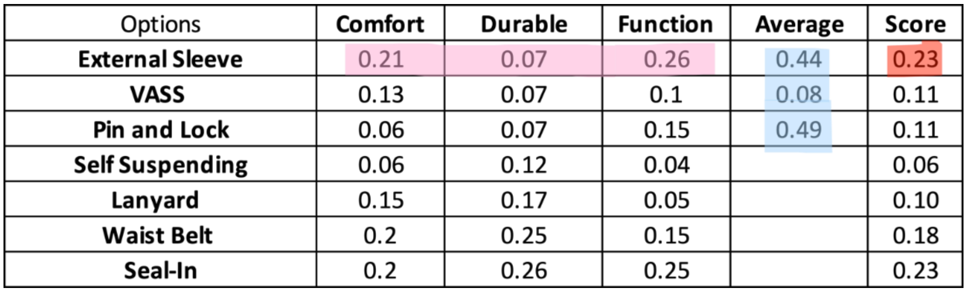
For suspension selection, $n = 7$ and the consistency vector after matrix multiplication is:

$$\begin{bmatrix} 7.38 \\ 7.31 \\ 7.23 \\ 7.23 \\ 7.23 \\ 7.48 \\ 7.48 \end{bmatrix}$$

From this, we get, λ_{max} = 7.34. Using the RI table and λ_{max} value we get CR = 0.06282048. Since CR <= 0.1 for the matrix to be consistent. So, the comparison matrix is consistent, and the weights of each alternative based on their comfort are given by the priority vector.

Task 8: Calculating the final weights

After calculating the relative weights based on comfort, the same steps were followed to calculate the relative weights of all alternatives based on the remaining 2 criteria: functionality and durability. The final weights of the alternatives were then calculated by matrix multiplication as follows:



Options	Comfort	Durable	Function	Average	Score
External Sleeve	0.21	0.07	0.26	0.44	0.23
VASS	0.13	0.07	0.1	0.08	0.11
Pin and Lock	0.06	0.07	0.15	0.49	0.11
Self Suspending	0.06	0.12	0.04		0.06
Lanyard	0.15	0.17	0.05		0.10
Waist Belt	0.2	0.25	0.15		0.18
Seal-In	0.2	0.26	0.25		0.23

Figure 9. Matrix multiplication for suspension

From Figure 9, the top 3 choices are Seal-In, External sleeve, and Waist belt with weights 23%, 22%, and 18% respectively.

STEP 3: Selecting a foot unit

The same 8 steps were followed for selecting a foot unit and the top three choices were Articulated Feet, ESAR Feet, and Conventional Feet are weighted at 57%, 34%, and 9%, respectively.

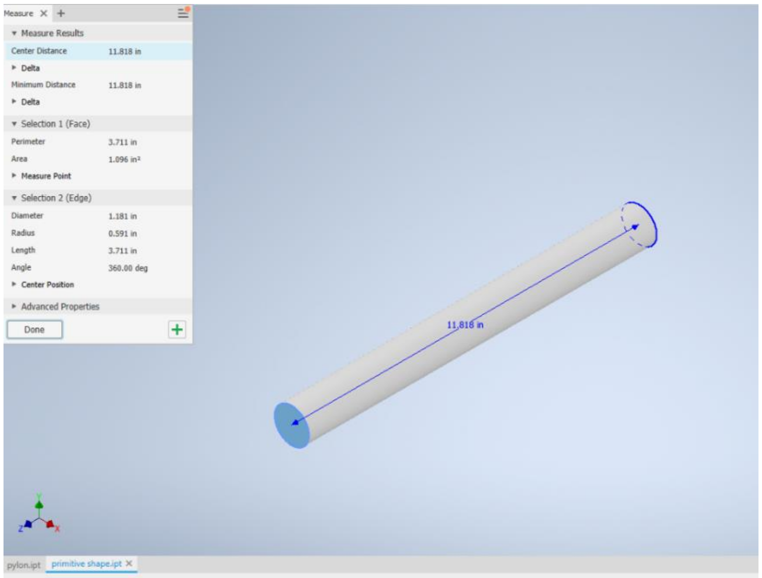
STEP 4: Designing a suitable pylon or connecting rod

The weight of the lost limb is not known. An online Estimated Body Weight Loss calculator [21] provides the following data, giving an estimate of 2.1875 kg for the BKA.

Table 2. Estimates body weight loss factors from [21]

Level of Amputation	Percentage of EBWL
Foot	1.5%
Below-knee amputation (BKA)	3.5%
Above-knee amputation (AKA)	11%
Hip disarticulation	16%
Hand	0.7%
Forearm	1.5%
Entire arm	4%

For the patient to feel normal and get natural ambulation, the weight of the prosthetic leg should be the same as the lost limb. So, using the above calculator, we got the approximate estimate of the weight of the lost limb. We can use that to design and manufacture a lightweight and optimized pylon/connecting rod. The total weight of the system will be determined by experts in practice, but for this case study we will assume that the other components weigh 1.88 kg. This allows a weight target of 0.3705 kg for the pylon. The basic CAD model to define the design space was created using Autodesk Inventor (Figure 10). Two methods were used to design the pylon, one generating the design using nTopology and one using the shape generator tool in Inventor. Different methods and boundary conditions were expected to generate different solutions. The material selected was polylactide (PLA), a common renewable and biodegradable thermoplastic normally made from corn, sugar cane, and other biomass. The diameter of the design space was set at 30mm in order to be compatible with a wide range of adapters available on the market.



Measure Results
Center Distance 11.818 in
Minimum Distance 11.818 in
Selection 1 (Face)
Perimeter 3.711 in
Area 1.096 in^2
Selection 2 (Edge)
Diameter 1.181 in
Radius 0.591 in
Length 3.711 in
Angle 360.00 deg

Figure 10. Primitive shape of pylon

After assigning PLA material with 1.30 g/cc as density, modulus of elasticity as 2.35 GPa, and thermal conductivity as 0.0439 W/m-K, the volume of the primitive shape turned out to be 12.948 cubic inches along with a relative error of 0.1615%. With a weight target of 0.3075 kg, the mass fraction target for the design should be 0.4014. By mapping the constraints, the two most important driving constraints are the nominal density and the minimum feature size that is utilized during design and optimization. Based on FDM machine settings on the printed expected to be used for manufacturing, the minimum feature size was set to 2mm.

- *METHOD 1: nTopology*

Then, the force and fixed faces were created from the body so that later the boundary conditions could be applied to these faces whenever needed. After that meshing is done with a minimum feature size of 2 mm and edge length of 1.5 mm. PLA material was considered as isotropic and later sensitivity analysis will be done for this. After applying a boundary force of 300 N and fixing one end, static analysis was conducted. After this objective function was defined, which minimized the structural compliance a volume fraction of 0.4 was applied to ensure that the target weight was near 0.307 kg. After performing topology optimization, the result obtained was then processed by simply using the smooth part block, with the final model shown in Figure 11.

pylon

Add description...

Material: Isotropic Material

Boundary Condition

FE Restraint_1: Displacement Restraint

FE Force_1: Force

Create FE model using FE component

FE Model: FE Model

Static Analysis

Static Analysis: Static Structural Result_0

Designate design responses and optimization objectives

Design Response: Structural Compliance R...

Optimization Constr...: Volume Fraction C...

Value: 0.4

Run toplogy optimization

Topology Optimizati...: Single Body To...

Final body: Construct Optimized Body

Weight savings

Weight Savings: Scalar_0 60.682

Mass Properties from Body: Mass properties_0

Mass Properties from Body: Mass properties_1

Topology Optimization: Iso-contour

Threshold: 0.500

Iteration: 46

Figure 11. Topology Optimized rough part

- *METHOD 2: Autodesk Inventor Shape Generator*

Using the same settings as in the previous case, the Autodesk Inventor Shape Generator was used. While less refined and sophisticated than nTopology, this method produces solutions relatively quickly with much lower computational expense. Therefore, two different sets of boundary conditions were used, one mirroring the one used for the nTopology solution and one with a 20 N-m torsion load. The two solutions are shown in Figure 12.

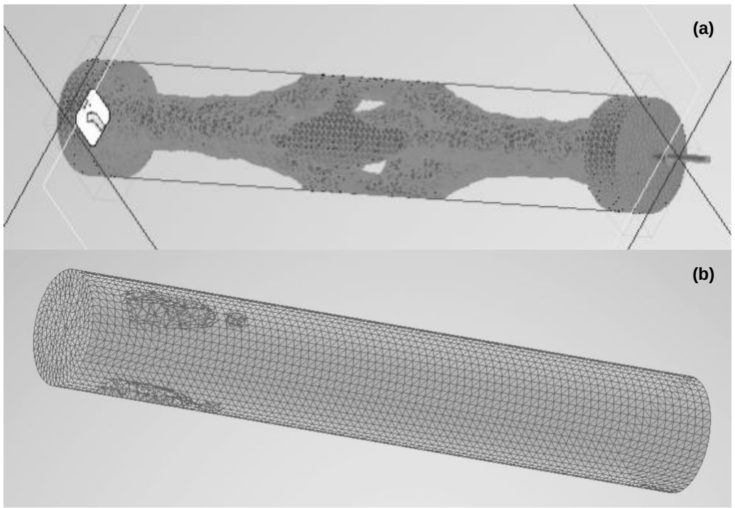


Figure 12. Inventor shape optimization tool results: (a) compression-only case and (b) compression + torsion case

The three generated solutions, along with a simple shape design with extra material removed to achieve the weight target, are shown in Figure 13. These were printed using the applicable manufacturability constraints using a Creality Ender 6 printer. For scale, the pylons are approximately 300 mm tall in the figure.

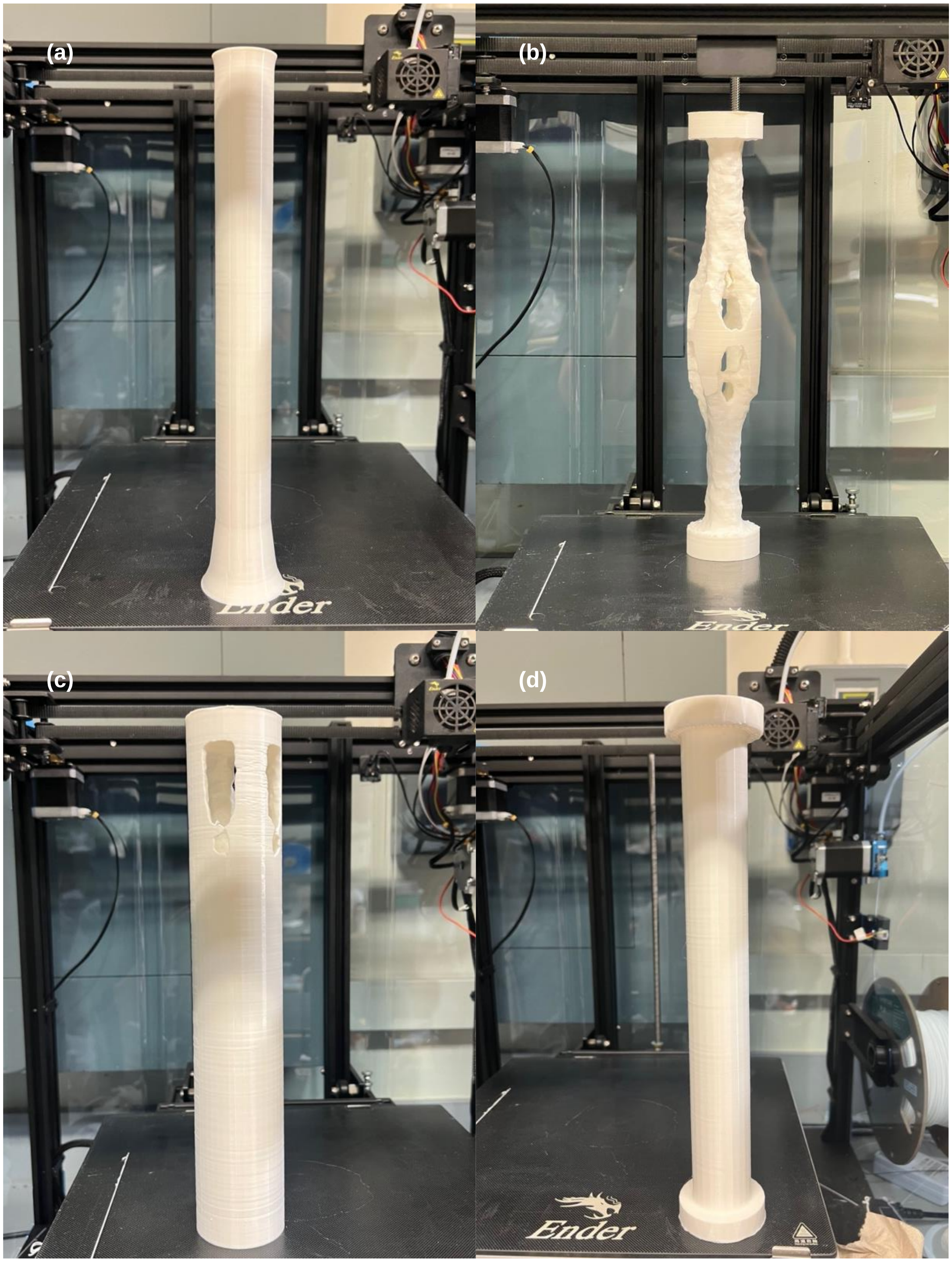


Figure 13. Printed pylon designs: (a) nTopology solution, (b) Inventor solution for compression force only, (c) Inventor solution for compression + torsion, and (d) baseline design with material removed to meet weight target.

5. Conclusions and Recommendations

This research has demonstrated the benefits of using a shared decision-making approach in the field of prosthetics. By involving the user in the decision-making process, ensuring that they are well-informed of all available options, and considering their requirements, this approach can result in better decisions that are tailored to the individual's needs. Moreover, the use of advanced technology such as questionnaires, the AHP model, and software tools like nTopology and Inventor can further aid in the decision-making process by providing more accurate and customizable solutions.

This research elegantly underscores the critical role of shared decision-making (SDM) in navigating the complexities of lower-limb prosthetic customization. It identifies limitations in current practices and proposes a framework that incorporates both SDM and standardized processes to empower users and optimize outcomes. Moreover, it empowers them to make informed choices, leading to higher levels of satisfaction and a greater sense of ownership over their prosthetic solutions. Shared decision making is the key tool that drives this framework. Without good communication between the stakeholders, it is not possible to efficiently conduct shared decision-making. The framework acknowledges the crucial role of effective communication in successful SDM. Tools like questionnaires and surveys, when carefully designed, can facilitate information exchange and data gathering for informed decisions. This data empowers stakeholders to make informed decisions that are tailored to the individual's needs and preferences. This tool can be used by experts, novices, and users to guide them in the selection process and cannot be used as a stand-alone tool. The final decision lies in the hands of the expert. This framework is user-centric its potential to empower individuals, improve communication, and ultimately, lead to optimized prosthetic solutions is demonstrated in the case study. The framework emphasizes the importance of tailoring solutions to the user's unique physical characteristics, activity levels, and goals. This ensures a truly person-centered approach.

Along with shared decision-making, the need to standardize the SDM process is emphasized. This helps decision-makers narrow down options while respecting user preferences and unique needs. This is crucial for lower-limb prosthetics, where fit and comfort depend on individual characteristics. The framework ensures that user preferences and unique requirements remain at the forefront, acknowledging that fit and comfort are highly dependent on individual characteristics. This standardization of the process will help decision-makers in narrowing down the options available keeping in mind the importance of users' choices and their requirements. This is essential for lower-limb prosthetics as one cannot simply prescribe a lower-limb prosthetic as the fit and the comfort depend on the unique aspects of the user.

Additionally, all the components of lower-limb prosthetics are readily available (mass-produced). But components like sockets and pylons cannot be used without customization as comfort and fit depend on person to person. So, optimizing the socket and pylon as per the user is very crucial. This study focuses on the optimization of pylon using different optimization techniques. Before the design and manufacturing of the pylon, the design constraints, manufacturing constraints, and manufacturability constraints should be defined. This is a very crucial step as it controls the product and oversimplifying or under simplifying the manufacturability constraints will lead to low-quality products/prints. The study also rightly highlights the crucial role of mapping design, manufacturing, and manufacturability constraints before pylon design and 3D printing. This ensures efficient resource allocation, improved design efficiency, standardized processes, informed decision-making, and ultimately, higher-quality parts.

Data and Sharing

All raw data, full texts of cited documents, search keywords, and other relevant information from this review is available upon request from the corresponding author. The software and Excel tools used in this study can be found at the permanent link in [22-23] under a CC-BY-ND license. Free non-commercial share-alike use is allowed with proper credit and citation to the authors.

Acknowledgments and Conflicts of Interest

The authors declare no conflicts of interest. No external funding was used to produce this work nor fund its publication. All opinions and conclusions are solely those of the authors and do not necessarily represent the views of their institutions or nor the publisher of the article. The authors thank nTop for allowing the use of an academic license for nTopology for this work, as well as providing training materials for the first author.

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Appendix – Questionnaires

Table A1. Socket questionnaire

Type (Socket)	***Question***
Engaging in Activities	Tell me about the activities you enjoy. Are you into sports, running, hiking, or any specific physical activities?
Hobbies and Interests	Considering your hobbies and interests, are there specific things you're passionate about?
Financial Considerations	Understanding different budget preferences, what comfortable spending range are you looking at for your prosthetic device?
Vocational Aspirations	Thinking about your work and career goals, how do you envision your prosthetic fitting into your daily professional life?
Functional Needs and Goals	What functions or goals are you hoping to achieve with your prosthetic limb?
Comfort and Pain	Are there areas of discomfort or pain that you currently experience?
Residual Limb Sensitivity	Could you share how your residual limb responds to different pressures or materials to ensure a comfortable fit?
Allergies	Are you allergic to any materials or substances that we need to be mindful of during the prosthetic design?
Environmental Considerations	Thinking about your surroundings, do you encounter specific environmental conditions, like exposure to water or extreme temperatures, that we should consider in the prosthetic design?
Cosmetic Expectations	What are your expectations regarding the appearance of the prosthetic? Any specific cosmetic features you have in mind?
Support System	Do you have a network of friends, family, or healthcare professionals who will be part of your journey with the prosthetic?
Level of Activity Needed	Considering your activity level, could you share more about the intensity and types of activities you engage in? This will help us match your prosthetic to your specific needs (K-level and SIGAM scales)

Table A2. Suspension questionnaire

Title (Suspension)	***Questions***
Residual Limb Sensitivity	How sensitive is your residual limb to pressure and materials?
Eyesight Issues	Do you experience any eyesight problems that could affect your interaction with the prosthetic device, such as adjusting or securing components?
Strength and Suspension	Assessing your strength, do you feel capable of handling a suspension system that may add weight to the prosthesis?
Dexterity Challenges	Do you have any dexterity issues, especially with hand movements? This is important for tasks like donning and doffing the prosthesis.
Bending Capability	Is bending down easily a part of your daily routine?
Lubricant for Donning	For putting on the prosthesis, are you comfortable using a lubricant if needed? This can aid in the donning process and enhance overall comfort.
Suspension Weight Acceptance	Are you comfortable with a suspension system that may add some weight to the prosthesis? This can affect factors like balance and overall prosthetic experience.
Heavy Work - Lifting and Moving Things	Considering your daily activities, do you engage in heavy work that involves lifting and moving substantial objects?
Experience with Prosthetics	Could you please share if this is your first time using a prosthetic device? If not, could you provide some insights into your past experiences and any specific features you found beneficial or challenging?
Socket Connection Preference	In terms of the connection between your residual limb and the prosthetic socket, do you prefer a close and direct connection for a more secure fit, or are you more comfortable with a different type of connection? Please share any specific preferences or concerns you may have.

Table A3. Knee questionnaire

Title (Knee)	Question
Muscle Power for Stabilization	Are you comfortable using your muscle power to stabilize the knee during movement?
Open to Servicing	Are you open to servicing, as some components of the knee unit may require periodic maintenance?
Active Engagement in Stance Phase	In the stance phase without a microprocessor-controlled knee, active engagement is needed to prevent the knee from buckling. How do you feel about actively contributing to generating a knee extension moment for stability during walking? Do you have specific concerns or preferences in this regard?
Manual Locking of Knee	Are you comfortable with a knee unit that can be manually locked?
Familiarity with Techniques	Are you familiar with techniques like circumduction and hip hitch for foot clearance?
Weight Preference	Do you have a preference regarding the weight of the knee unit? Are you comfortable with a heavier knee unit?
Responsibility for Maintenance	Are you willing to take on the responsibility of maintaining the knee unit as needed?
Gait Re-education	Are you open to learning and undergoing gait re-education as part of adapting to the new knee unit?

Table A4. Foot questionnaire

Title (Foot)	Questions
Weakness in Knee Extensors	Do you experience weakness in knee extensors or face challenges with balance?
History of Overuse Injuries	Is there a history of overuse injuries due to elevated activity levels, higher walking speeds, or a younger age?
Comfort with Added Weight	Are you comfortable with the potential added weight of a prosthetic foot?
Feelings about Servicing	How do you feel about the need for frequent servicing of the prosthetic foot?
Stability Concerns	Have you faced stability issues in the past, and is this a consideration for your prosthetic foot choice?
Preparedness for Cost Implications	Are you prepared for the potential cost implications, as some prosthetic feet may be more expensive?
Stiffer Keel for Lower Activity Levels	For individuals with lower activity levels, are you open to using a prosthetic foot with a stiffer keel?
Openness to Battery Activation	Are you open to considering a prosthetic foot that is battery-activated?
Importance of Waterproof Capability	Is waterproof capability important to you in the selection of your prosthetic foot?
Feelings about Range of Motion Limitations	How do you feel about potential limitations in the range of motion for the prosthetic foot?
Adaptive Feet for Uneven Surfaces	Do you want feet that adapt to uneven surfaces? If yes, are you okay with the weight as it is heavier than the single axis? If yes, then ask whether you are okay with a higher price.