Safe Shower Solution for Below-the-Knee Amputee

PRODUCT DESIGN SPECIFICATIONS (PDS)

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HydroStep

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Function/Problem Statement:

Below the knee amputees are unable to wear their standard prosthetic in the shower due to non-waterproof materials, corrosion risk, and slip hazards. This often forces individuals to either remove their prosthesis and shower while seated or attempt to stand on one leg using unsafe workarounds, both of which carry fall risk and limit autonomy [1]. The objective of this project is to design, fabricate, and test a specialized assistive device that gives our client, a 75 year old, 6-foot, 160lb transtibial amputee with a knee spacer and ongoing volume loss, the autonomy to safely enter, stand, and bathe in the shower without using his primary prosthetic. The device must provide adequate traction on wet surfaces, accommodate leg geometry and load bearing capacity of our user, withstand moisture and cleaning chemicals, and retain independence during daily bathing routines.

Client Requirements:

The client requires that the device eliminates the dangerous hopping transition current required for him when transferring from a walker to the shower seat or bath. The client requests that the device must reject complex buckling straps and kneeling pads due to pain at the spacer in his knee. It also must incorporate a high friction, non-slip, waterproof, non-porous material and allow comfortable sitting to standing mechanics in a wet environment. It must explore the idea of a step in socket similar to the Lytra concept that enables direct standing rather than kneeling [2]. It also needs to ensure socket adjustability to compensate for the residual limb volume loss over time. Lastly, it must require single user operation without assistance from another person.

Design Requirements:

1. Physical and Operational Characteristics
    a. Performance Requirements
        i. The mechanical frame must sustain a static load equal to 1.5x the maximum user mass for 60 to 70 seconds without cracking, permanent deformation, or structural failure [3].
        ii. Ground contact foot tips or pads must maintain non-slip friction on wet tile floor and withstand repeated abrasion to prevent slip hazards during sitting to standing transitions [3].
        iii. Dimensions must be customized to the user's leg geometry to ensure a secure and comfortable fit. The prosthesis also should not stick out straight when in a sitting position.
        iv. Total assembly weight should be < 1.8 kg to allow single handed carrying and easy maneuvering in a tight bathroom area, and packing for travel.
        v. The step in socket mechanism or donning and doffing speed should allow the user to do it independently in < 60 seconds.

    b. Safety

i. Stationary frame gaps or gaps between relative moving parts accessible to fingers must remain < 8 mm or > 25 mm throughout the full range of motion to prevent finger entrapment [3].
ii. The frame parts of the prosthetic in direct contact with the skin for 10 minutes or longer must not exceed 41 C under normal operating conditions [3].
iii. Non-porous surfaces must withstand manual washing with a 0.5% disinfectant solution at 70 C without material breakdown or fluid retention [3].
iv. All locking latches and adjustment mechanisms within the prosthetic need to be operable by a single user using one hand, which will eliminate fall hazards when transitioning.
v. Contact surfaces need to be padded to distribute weight evenly over the residual limb to prevent pressure injuries or falls due to faulty weight distribution.

c. Accuracy and Reliability
i. The device must have a non-rigid contact surface with the residual limb so that minor changes to the shape of the residual limb do not prevent usage.
ii. Forces of 1068.75 N must be able to be supported by the device without losing structural integrity to maintain a safety factor of 1.5 from the client's weight[3].

d. Life in Service
i. The iWALK previously used by the client does not have a quantified life span on the frame but the tread needs to be replaced every 3-10 weeks depending on usage [4].
ii. Higher grade materials such as carbon fiber, nylon, polyvinyl chloride, and polyurethane will last longer than materials that are only water-resistant [5].
iii. The device must be able to withstand an estimated length of 182.5 hours per year (30 minute showers everyday) for the next 5 years.

e. Shelf Life
i. Residual limb shape changes every 1-3 years so contact surfaces will need to be reevaluated and adjusted accordingly to confirm comfort [6].

f. Operating Environment
i. The device is intended for daily use in the shower and must be resistant to water, soap, cleansers and other shower products.

ii. The client will mostly be using the device at home in his shower. When the client does travel, the Americans with Disabilities Act (ADA) showers do not adequately meet his needs, and many hotels have bathtubs or lack suitable seating.
iii. The client's shower has a sliding glass door and a ledge that must be stepped over. The shower measures 30 x 46 inches.
iv. The device must prevent slipping in the shower for safety and be easy to place in and remove from showers and bathtubs.

g. Ergonomics
   i. The device must safely support the client's full body weight without structural failure, proving sufficient stability for standing in the shower.
   ii. Padding should be included at all points of contact with the client's leg, knee, and other sensitive areas to provide adequate cushioning and comfort.
   iii. The device should include an adjustable strap to secure the device to the limb to provide an adjustable fit, similar to the Lytra Shower Prosthetic. [7]
   iv. The client must be able to enter and exit the shower easily and safely transition between sitting and standing without the device interfering with their movement.

h. Size
   i. The client's stump length is roughly 10 inches from the center of the kneecap to the bottom of the stump.
   ii. Client is 6 feet tall and weighs about 72.6 kg.
   iii. A 6 feet tall male has a popliteal height of about 18 inches (45.7cm), and a foot length ranging from 10.5 inches to 11 inches (26.7cm to 27.9cm) [8].
   iv. The device will most likely be the same length as the client's missing lower leg and foot for maximum comfort and functionality.
   v. The width of the foot component of the device will be designed to approximate the dimensions of a standard-sized foot or wider to provide stability. The average foot width of a 6 feet tall male is 4.0 to 4.2 inches (10.2 to 10.7 cm) [9].

i. Weight
   i. The total assembled device should not exceed 1.8 kg to allow effortless single-handed maneuvering, positioning, and transport into and out of the shower by a 75-year-old user. This target is set below the weight of the

client's current iWALK crutch (2.1 kg) [10], which the client has directly reported as too heavy during use.

ii. Individual hand-carried subcomponents (e.g. a handle, leg piece, or socket) should each weigh less than 1 kg to support one-handed handling by the client.

iii. Weight distribution should keep the center of mass concentrated proximally, targeting ≤ 47% of the distance from the knee joint to the ground contact point to minimize hip strain and foot dragging when lifting the leg over a shower ledge [11].

j. Materials

i. The frame/support pole will be 6061-T6 aluminum with a hardcoat (Type III) anodized finish, adjustable for height. The 6061-T6 aluminum was chosen for its light weight of 2.7 g/cm^3, low cost of ~$2.50-$4.00 per kg, high strength with a yield strength of 276 MPa, and high resistance to corrosion [12].

ii. All exposed 6061-T6 aluminum components will feature a MIL-A-8625F Type III hardcoat anodize finish to provide increased surface hardness and improved corrosion resistance against daily soap, water, and disinfectant exposure [13].

iii. Straps will be made out of nylon webbing with a silicone lining. Nylon provides strap durability delivering a breaking strength between 13.3 kN to 18.6 kN [14], while the silicone layer improves grip and comfort against skin.

iv. The socket will be 3D-printed using thermoplastic polyurethane (TPU) for its soft, rubbery grip against wet skin and high wear resistance, printed in a direction that aligns layer lines with body-weight forces to prevent cracking and gradual sagging over time [15].

v. An interchangeable silicone insert will line the socket interior for comfort and hygiene, matching Lytra's approach. This aligns with the client's stated preference for a "squishy" material near his sensitive knee. Medical-grade silicone used for this insert should fall in the 15-40 Shore A hardness range typical of commercial prosthetic liners, and carry ISO 10993 biocompatibility certification [16][17].

vi. The handgrip will be 3D-printed polyethylene terephthalate glycol (PETG) for its good impact resistance, water resistance, and chemical resistance to soap and cleaning agents [18].

vii. The foot tread must feature a rubber sole achieving a Dynamic Coefficient of Friction (DCOF) ≥ 0.60 on wet, soapy tile per ASTM F2913 footwear testing protocols, meeting ADA guidelines.

viii. Ferrous metals are prohibited due to rust risks in wet environments. Natural rubber latex is prohibited to avoid allergic reactions on sensitive skin.

k. Aesthetics, Appearance, and Finish
   i. Outer surfaces must incorporate smooth, rounded edges (≥ 3 mm fillets) with zero sharp internal corners.
   ii. The handgrip and socket pieces must have an ergonomic textured finish to facilitate a secure grip under wet conditions while avoiding deep grooves that allow for accumulation of water.
   iii. The device will feature neutral tone finishes to maintain a medical-grade visual presentation. Materials chosen must resist discoloration from daily exposure to soaps and shampoos.
   iv. Adjustment mechanisms must be internal or flush with the device to maintain a smooth, hygienic surface that resists buildup of soap.

2. Production Characteristics
   a. Quantity
      i. For the scope of this project, a functional, standalone shower prosthetic prototype will be designed, fabricated, and delivered to the client. The primary focus is on developing a single custom unit tailored specifically to validate user safety, maneuverability, and structural performance during shower entry, exit, and use. Rather than focusing on mass production or commercial manufacturing, the goal of this phase is simply to deliver a reliable, dedicated prototype that meets the client's needs.

   b. Target Product Cost
      i. A budget of $800 has been established between the team and the client for all materials, fabrication, and prototyping.
      ii. The team has been provided a $50 stipend from UW–Madison for use toward prototyping and fabrication materials in university design labs.
      iii. To optimize financial resources, the team aims to incorporate components from the client's current devices, reducing the need for raw material purchases and lowering overall prototyping costs.

3. Miscellaneous
   a. Standards and Specifications
      i. International Standards
         1. ISO 13485:2016: Medical devices: Quality management systems [19]

        a. Covers requirements for the quality management system for medical devices. Globally recognized and expected by regulators worldwide.
    2. ISO 14971:2019: Medical devices: Application of risk management to medical devices [20]
        a. Methodology for identifying, evaluating, and controlling device risks.
    3. ISO 10993-1:2018: Biological evaluation of medical devices: Evaluation and testing within a risk management process [21]
        a. Provides framework for biological safety assessment of materials in contact with the patient's skin or body.
    4. ISO 15223-1:2021: Medical devices: Symbols to be used with information to be supplied by the manufacturer [22]
        a. Standardized labeling process for medical devices.
    5. ISO 22523:2006: External limb prostheses and external orthoses: Requirements and test methods [23]
        a. Brings attention to essentials for structural integrity, dynamic loading, fatigue testing, static strength, and environmental limits of prosthetic limbs.
    6. ISO 17966:2016: Assistive products for personal hygiene that support users: Requirements and test methods [24]
        a. Covers structural safety, slip resistance, and stability specifically for bathing and showering assistive products.
ii. United States Regulations
    1. 21 CFR Part 820: Quality System Regulation [25]
        a. The mandatory U.S. quality standards that medical device companies must follow by law.

b. Customer
    i. The user is a 75 year-old outdoorsman looking for a prosthetic leg to assist him with his daily shower. A lightweight design that can be placed in and out of a car is preferred.
    ii. He has struggled finding a prosthetic that is not only water proof and comfortable to use, but also that can be adjusted to his shrinking leg muscles. He has tried using the iWalk prosthetic in the shower, but states it is heavy, clumsy, and uncomfortable on his knee.
    iii. A big issue for the customer is that his knee is fairly sensitive near the amputation. He prefers a squishy material that provides comfort and relief from the pressure on his wound.

iv. The customer prefers a prosthetic that does not involve kneeling due to a medical spacer in his knee cap.
v. He looked into the Lytra prosthetic and liked the 3 component design which features a hand grip, a cone shaped leg socket, and a height adjustable base.

c. Patient-related concerns
  i. The prosthetic will be used in a slippery environment for daily use. It will need to maintain enough friction on a shower surface to prevent slipping and any potential injuries.
  ii. The device should be designed for easy cleaning and sanitization. Because it will be in contact with water, soap, and the user's skin, it is possible for moisture and dirt to accumulate.
  iii. The material used for design must be able to withstand frequent exposure to water and soap. They will need to resist deterioration and corrosion that could potentially interfere with the safety and performance of the prosthetic.
  iv. The customer is a frequent outdoorsman who travels often. The device should be easy to travel with, as he will be taking it with him. A lightweight and compact design would allow for easy transportation of the prosthetic.

d. Competition
  i. Harry Teng's Lytra Prosthetic
    1. This product is designed to be an adjustable prosthetic that can serve many different kinds of leg amputations and different sized amputees [2].
    2. Teng intends for this product to be affordable to the public, as current prosthetics can cost thousands of dollars [2].
    3. It features an adjustable button leg, a nylon and silicon strap fitted to the thigh , a 3D printed socket made from polyurethane including a drainage hole, handgrip, and foot made from rubber [2].
    4. This design is not available to the public yet and it is still in the prototype stage [2].
  ii. Collapsible Prosthetic Shower Leg
    1. This prosthetic is designed to be collapsible, lightweight, and easy to travel with [26].
    2. This design consists of four parts: the suspension, socket, pylon, and foot [26].

    3. It factors in the tilt of a human leg by having a bend of 2.5 degrees to fit the natural knee position . It also features a knee brace that can be adjusted to fit the size of the leg [26].
    4. Water resistant materials such as rubber, nylon, anodized aluminum, stainless steel are used for the prosthetic [26].

iii. The Antler
    1. A design that is designed for both above-knee and below-knee amputations. The prosthetic is height adjustable via a button leg [27].
    2. It consists of a Paracord 550 netting in which the amputated limb rests. This netting can support up to 550lbs and allows water to drain through. Polyethylene vinyl acetate is used to resist slipping in wet conditions. The frame of the device is made from a sturdy ABS plastic [27].
    3. The prosthetic can safely support up to 900 lbs with a factor of safety of 2 [27].
    4. It is not open to the public yet, but has a planned retail value of $150-$250 [27].

iv. iWalk
    1. This design is only meant for below the knee amputees. It requires a minimum of 4’’ of residual limb below the knee for the device to function properly [28].
    2. The device is meant for the user to be kneeling on the leg rest, which requires the user to tolerate weight on that shin without pain [28].
    3. It features a strap that wraps around the leg, quick-release straps that allow the user to adjust the height and fit. Thick foam padding and nonslip rubber tread are utilized to provide support and traction on smooth or uneven surfaces [28].
    4. The iWalk can safely support up to 275 lbs, fit to thigh circumferences up to 28 inches, and be used by customers from 5 '2" to 6 '2" tall. It currently costs $179 to purchase [28].

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