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The design and manufacture of a prototype personalized liner for lower limb amputees

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Abstract

The objective of personalization is to create a product that matches the exacting requirements of the individual consumer. Where these products must interface with the changing dynamics of the human form, traditional manufacturing techniques, coupled with traditional manufacturing paradigms do not enable efficient generation of personalized products. Particularly when they must encapsulate body-parts susceptible to variations in dimension through daily activity. Emerging 3D printing methods are limited to non-conforming rigid materials, with wide tolerance bands. This can make it difficult to generate soft material conforming products that precisely match a consumer's needs. One such application is the creation of a personalized prosthetic liner for lower limb amputees. A residuum liner is the interface that amputees wear between their residual limb and prosthesis. The comfort of a prosthetic liner/socket can determine the daily duration for which patients use their artificial limbs and can also prevent further pathological issues. The purpose of this liner is to enable correct fitting. Current methods use a range of silicon 'socks' that encapsulate and cushion the residuum before placement inside the prosthesis socket. The silicon sock can cause skin irritation and damage and are not designed specifically for the individual. Our novel method enables the precise and rapid generation of soft material conforming products and is termed cryogenic CNC machining. This process involves the rapid, physical alteration of soft polymers to enable efficient and direct CNC machining. This paper presents a new data driven design and manufacture methodology that enables the creation of fully personalized residuum liners for a transtibial amputees.

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1. Introduction

Personalized design is a term used to describe products that are suited to an individual's precise requirements and has been applied to number of domains including shoe soles [1]. Where these products must interface with the changing dynamics of the human form, traditional manufacturing techniques, coupled with traditional manufacturing paradigms do not enable efficient generation of personalized products. Particularly when they encapsulate body-parts susceptible to variations in dimension through daily activity. 3D printing is limited to non-conforming specified rigid materials, with a wide tolerance band. This can make it difficult to generate soft material conforming products.

One such application is the creation of a personalized prosthetic liner for lower limb amputees. A residuum liner is the interface that amputees wear between their residual limb and prosthesis to compensate for volume and shape changes

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after the amputation. The comfort of a prosthetic liner/socket can determine the daily duration for which patients use their artificial limbs and can also prevent further pathological issues. The purpose of this liner is to enable correct fitting. Current methods use a range of silicon 'socks' that encapsulate and cushion the residuum before placement inside the prosthesis socket. The silicon sock can cause hygiene problems, skin irritation and damage and are not designed specifically for the individual [2 and 3]. Figure 1 shows a silicone sock for a transtibial amputee.

Figure 1. Silicone sock example for a transtibial amputee (from Queensland Prosthetics, http://www.artlimb.com/) [4]

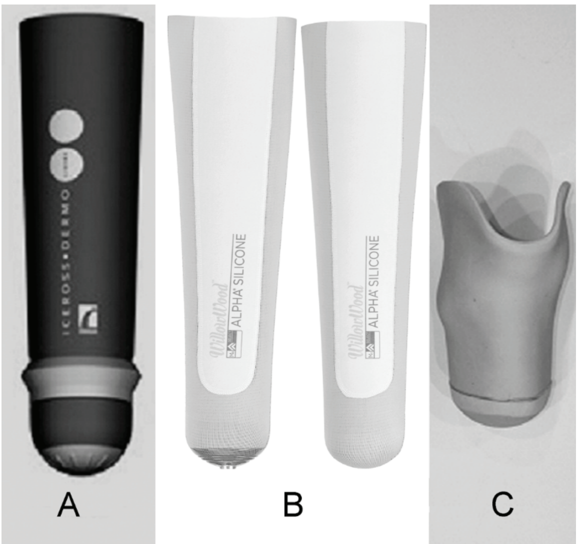

Figure 2. Examples of liners: polyethylene foam liner (A), silicone liners with and without shuttle lock (OrthoEurope) (B), and silicone seal-in liner (C) [5].

This paper presents the design and manufacture of a fully personalized prototype residuum liner for a transtibial amputee. The first half of the paper presents literature on state-of-the-art residuum prosthesis and orthoses design, followed by a broad overview of personalized design, reverse engineering techniques and appropriate manufacturing methods. The second half of the paper describes the methodology and the design and manufacture of the fully personalized residuum. Finally, conclusions are presented based on the findings from the developed methodology and recommendations are made for future work.

1.1. Prosthesis device design

Prosthetic devices are used for a large range of corrective measures associated with different patient conditions and requirements. These can be for various amputations (lower or upper body), through to devices such as orthotic insoles and sockets, which are designed to improve a patient's skeletal kinematic chain and gait. The following describes the state of the arts in the field of the artificial limbs (both for upper and lower body prosthesis).

1.1.1 State-of-the-art prosthesis

There are four common types of prosthesis: transtibial (a prosthetic lower leg attached to an intact upper leg), transfemural (a prosthetic upper leg, including an artificial knee joint, transradial (a prosthetic fore arm) and transhumeral (a prosthetic lower and upper arm, including a prosthetic elbow). A traditional prosthesis for amputees consists of an inner socket/liner to interface with the patient's skin and an outer socket over it to incorporate the mechanisms that comprise the distal structure which may be a joint to function as a prosthetic foot or hand [6]. The two main prosthetic choices for people with upper limb amputation are: i) body-powered arm prosthetics (attached to the body with a harness and cable) controlled by movement of the opposite arm; ii) myoelectric prostheses controlled by electric signals from the brain [7]. For lower limb amputees, device design is dominated by the challenges of recreating the function of key joints for ambulatory movement (the ankle and knee). Numerous prosthetic foot/ankle models are currently on the market. These include conventional feet, energy-storing-and-returning feet (capable of storing energy and returning it to the individual to assist in forward propulsion) [8] and recent 'bionic' feet that generate net positive work by using a battery, allowing amputees to walk in a manner akin to pre-amputation [9]. For individuals with a transfemural amputation, prosthesis are more complex and recent models additionally incorporate microprocessors to stabilise and help control the knee joint and allow amputees to achieve a greater range of movements for functional activities such as the climbing of stairs [10].

Regardless of the type of amputation, amputees need an interface/liner to fit the prosthesis with their residual limb. This is particularly important for lower limbs, where significant forces are transferred through potentially complex wound sites. Liners are often categorised in terms of their material type (e.g. silicone), profile (e.g. conical), thickness and features (e.g. distal matrix). Some suspension mechanisms are integral to the design of the liner (e.g. Iceross Seal-In) while others are not (e.g. polyethylene foam liner in a socket with cuff suspension), (Figure 2) [11]. Despite the development of complex and robotic prosthesis, the inner socket/liner remains a critical component of the prosthesis. It requires further design work to ensure a best fit that is reproducible, comfortable and personalis-able around the recipient's residuum site, activity levels and environment (e.g. local temperature and humidity).