THE RIGHTFIT PROSTHETICS INITIATIVE

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INTRODUCTION

Globally, there are over 10 million amputees, and over fifty percent are lower-limb amputees, according to the World Health Organization (WHO). Every year, over five-hundred thousand new lower extremity amputations result from traumatic injuries, diabetes, and other chronic diseases. In other countries with high prevalence of landmines, war, and natural disasters, trauma is the primary cause (Strait). Unfortunately, 80% of people who are in need of a prosthetic device are unable to obtain one (Necmioglu). Without a leg, patients are often unable to contribute to society, and many cannot afford to travel to a prosthetic clinic or pay for the device and its maintenance over time. To meet that need, we have developed an adjustable and modular thermoforming prosthetic socket that can be reshaped to maintain an intimate fit with the patient’s residual limb, thus maximizing function and comfort. With our device, we can help amputees integrate back into their communities worldwide.

Our socket design addresses three of the most prominent obstacles to prosthetic care in the developing world: prohibitive cost, time, and travel distance. The thermoplastic can be re-molded and recycled for replacement sockets, reducing initial and long-term maintenance costs. Directly molding the socket reduces fabrication time from days to hours. Additionally, socket fabrication does not require specialized equipment, so a technician could fit a device in a hospital or even a home. Lastly, our socket is designed to be compatible with components on the market, so organizations that receive donated components can apply our technology to the parts they already have. We intend to connect with and distribute care through local health or rehabilitation clinics within each country, but the flexibility of our solution widens the potential sphere of influence.

METHODS

A mechanical assessment of the socket was performed in adherence to the ISO 10328 standard for “Prosthetics – Structural testing of lower-limb prostheses.” The protocol and testing set-up were based on a study conducted by Campbell (2012). The socket was affixed to a load cell via a ball socket joint and loaded vertically, ramping to failure at 100 N/s (Fig. 1a).

The mechanical testing was then simulated using a computer model in Creo. Static loads of increasing force were delivered to the model until failure occurred (Fig. 1b).
During our field assessment, we concluded that India would be an excellent location for additional clinical trials and collaborations. However, India should be considered a secondary market given the competitiveness and the strong local roots of other prosthetic devices e.g. the Jaipur foot. Before entering the Indian market, RightFit should develop a presence in another location (e.g. South America, Africa, or the US).

SUMMARY AND CONCLUSIONS

The goal of the RightFit Prosthetics Initiative is to design appropriate prosthetics that holistically fit patients’ lives, improving access to appropriate prosthetics while reducing the time and cost required to make a device. A prosthesis is a unique and integral part of an amputee’s life. We want to design a solution that will help provide rehabilitation, mobility, and independence.

REFERENCES


ACKNOWLEDGEMENTS

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INTRODUCTION

In Cambodia, there are many people who were lost their foot by an anti-personnel mine. 73% of the total workforce in Cambodia engages in agriculture. When they do farm work using the lower limb prosthesis, they have to walk safely on an uneven terrain such as a truck farm, a paddy field and wilderness.

Conventional lower limb prosthesis just realizes the shape and the hardness of the foot such as SACH foot. To walking on an uneven terrain, the angle of the tarsal joint (permits dorsiflexion-planter flexion) and the subtalar joint (permits inversion-eversion) should adapt to the ground. To realize these joint function, Masum et al. proposed a powered ankle-foot prosthesis using a spring and damper. However, it is challenging to design prostheses that work with the materials and technologies available in developing countries.

In this paper, we proposed a design for the ankle-foot coupling called Multi-Axis Rubber Coupling (MARC). That can adapt the ankle joint angle to the ground surface while walking on an uneven terrain. It can be produced with cheap materials that are available in developing countries.

METHODS

MARC is composed of the ball joint for adapting motions in multi-axis direction and the rubber cushion for controlling joint angle and absorbing the shock. The hardness of the rubber we used is equivalent to natural rubber that is major product in Cambodia. Figure 1 shows the structure of MARC. The rubber cushion inserted between the leg and foot adapter. The outer walls of the rubber cushion suppress the rotation around z-axis. In addition, the rubber cushion has holes above the heel to absorb the shock of the heel strike.

We validated a basic effort of MARC by comparing the ankle joint angle under 3 conditions: 1) the artificial leg with MARC and SACH foot, 2) with only SACH foot, 3) without the artificial leg (normal barefoot walk). The ankle joint angle was measured using the 3D motion capture system (Raptor-E). We used a leftward-sloping board as the uneven terrain that is inclined 5° for comparing to the flat ground.

![Cross-section view](image)

**Figure 1:** Structure of MARC consist of the ball joint and the rubber cushion
RESULTS AND DISCUSSION

Figure 2 shows the dorsiflexion-planter flexion angle during a gait cycle under the conditions of the flat ground and the slope. While the stance phase, the angle of SACH foot with MARC moves more likely to that of barefoot than SACH foot. SACH foot that is made of the rubber can move at the MP joint. However, SACH foot mostly impossible to move at the tolecular joint as shown in Figure 2. Therefore, MARC can append the role of the tolecular joint to SACH foot.

Figure 3 shows the inversion-eversion angle during a gait cycle under the conditions of the flat ground and the slope. While the

SUMMARY/CONCLUSIONS

To walk on the uneven terrain, the ankle joint movement is important for successful adaption to the terrain. In this paper, we proposed MARC as the ankle-foot coupling for walking on the uneven terrain such as a truck farm. We used only the ball joint and the rubber cushion that are available in developing countries.

We validate MARC by calculating the joint angle during walking on the flat ground and the left-ward slope. The results show that dorsiflexion-planter flexion and inversion-eversion movements using MARC are more likely to the barefoot than SACH foot only.

In future work, we will validate a feasibility of MARC by doing the experiment with more subjects and the lower limb amputees. Simultaneously, we should evaluate the efficiency of MARC as the durability and reliability.

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DEVELOPMENT OF A LOW-COST ENERGY STORAGE AND RETURN CARBON FIBER PROSTHETIC FOOT

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INTRODUCTION

This main objective of this project is to develop an Energy Storage and Return (ESAR) prosthetic foot that satisfies the demands of amputees in the developing world. This project will focus on a low-cost, repairable, adaptable, energy storage and return design that offers a flexible prosthetic foot configuration for a wide range of patients. The projected cost of the prototype will be below $100.00. Thus, this prosthetic foot will target the medium-low class in the developing countries.

METHODS

Prototypes were designed to be repairable and adaptable. Therefore, a set of techniques and methodologies were implemented to facilitate the replication of the prosthetic foot in developing countries. Each toe and heel layer was manufactured from carbon fiber using a compression molding technique. An aluminum mold and 5 C-Clamps were used to keep the mold in place during the curing period of the carbon fiber. The ankle connector is a Delrin wedge cut and shaped using a conventional milling machine. Then a final cosmetic finish was given to the prototype by using a dremel and belt sand.

RESULTS AND DISCUSSION

The static load test was performed using a tension-load machine provided by UTEP Materials Engineering department. Fatigue testing was performed using a custom ISO 22675 fatigue tester provided by Limbs international lab. The prototype successfully
passed the international ISO 10328 static test at the P4 level. Conversely, the ISO 22675 fatigue test failed at 450,000 Cycles which was the point where delamination abruptly occurred in the carbon fiber lamina. The P4 test level used for testing the prototype relate to a patient weight of 176 lbs. (80kg) (ISO, 2006a, 2006b).

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It was seen that the energy return of the prosthesis fell below the desired results. The results the Ossur variflex size 27 category 4 prosthesis compared to the prototype prosthetic Foot (PPF).

SUMMARY/CONCLUSIONS

During fatigue testing, interlaminar stresses were concentrated at a common spot where the ankle and toe section interact. This led to an early delamination stage at the toe section. An improvement to the current design must be implemented in order to achieve a more uniform stress distribution. Additionally, the hysteresis results suggested that a better heel design is needed in order to enhance the energy storage and return of the prosthesis. Carbon fiber manufacturing methods offer wide prosthetic foot stiffness configurations that customize patient’s needs. Carbon fiber is an anisotropic material that offers an excellent fatigue life and the best weight, deflection, strength and cost ratio among composite materials. In conclusion, design improvement is a key factor for the further development of this prototype and based on the manufacturing methods and materials used to replicate this prosthetic foot, reliability and affordability of this prosthetic foot can be readily available to patients in developing countries.

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Roger V Gonzalez, PhD, Joshua Scott Bowen, Author and Aaron Nystrom, Director of Engineering Operations LIMBS International
INTRODUCTION

Head, neck and spine injuries account for up to 17% of all fractures in Tanzania (Rutta, 2001). Citizens in developing countries have limited access to cervical neck collars. Immobilization in a hospital bed is one of the only viable treatment options, but this puts undue strain on hospital resources, and reduces patient quality of life.

Therefore, to address these issues, the aims of this sustainable design initiative are to develop a cost competitive, comfortable and supportive brace that is locally sourced. By testing these braces against commercial braces, we plan to provide our Tanzanian partners with verified designs that our team has proven effective.

Working with the Tanzanian weavers, we have gone through two generations of designs for neck braces made from basket woven grass materials. The 1st generation woven collar (blue collar) was designed in Tanzania from a model commercial cervical collar. This designed was assessed and refined to create an improved 2nd generation woven collar (red collar) that could better stabilize the neck by increasing the length of the lateral struts and incorporating an improved tightening mechanism.

In addition to providing a solution for patients with neck injuries, this system could act as a local economic driver promoting the development of small businesses aimed at producing woven grass neck braces and other orthopaedic orthoses on a larger scale.

DESIGN AND METHODS

The collars were all hand-woven by basket weavers in Haydom, Tanzania using locally sourced grasses and reeds. The 1st generation neck brace design was created to closely mimic the size and dimensions of a standard hard “Philadelphia” collar. It was noted that within a month, the weaving loosens substantially so that the collars become significantly shorter and larger than their original dimensions. The 2nd generation collars were created from the modified design specifications to account for the woven materials’ mechanical properties. While the collars are shorter than a standard hard collar, the weave is tighter and lateral struts are incorporated to provide more rigid support. To simulate long-term used, the woven collars were subjected to prolonged (1 week) exposure to a hot (37°C) and humid (>90%) environment using an incubator.

Testing of the woven grass collars was carried out following guidelines detailed in the journal Orthotics and Prosthetics. Forward/backward flexion, axial rotation and lateral flexion were measured during forcible patient perturbations to determine functional stiffness of the woven neck braces, as compared to biomedical-standard collars.

Two subjects were tested in this preliminary work. Each wore all four braces and
underwent three trials. The subjects sat stationary against a wall and wore a helmet with an attached antenna to track their angular neck movement (Fig. 2). The patient sat in front of a large-scale protractor and moved their head in the indicated directions until the neck brace inhibited their movement. The subjects were asked not to forcefully try to extend further than the neck brace allowed. The degrees of motion were recorded for each trial and averages and standard deviations were calculated.

RESULTS AND DISCUSSION

Unlike the 1st generation collars, the 2nd generation collars were able to maintain their shape and dimension over long (>6months) times. In addition, their shape and mechanical properties remained stable even after prolonged exposure to hot and humid environments.

As seen is Figures 3 and 4, the 2nd generation collar better restricted motion compared to the 1st generation collar because it more closely matched the anatomy of the human neck. The 2nd generation collar showed improvement in restricting motion based off changes in design that allowed the neck brace to tighten more effectively. The 2nd generation collar restricted neck movement more than the foam collar for both subjects in all planes of motion. The hard brace was significantly stiffer than any of the other braces and had the greatest percent restriction.

Figures 3 and 4 (Top Right): The stiffness of the 2nd generation brace fall between the stiffness of the hard and soft braces

SUMMARY/CONCLUSIONS

Testing through The American Orthotic and Prosthetic Association testing procedures suggest that this system may offer a uniquely powerful solution to the problem of neck injury stabilization for patients in the developing world. This project accelerates the development of an economically sustainable small-business model for locally manufactured medical devices using locally sourced materials, thus supporting the Tanzanian economy.

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