DESIGNING FOR AFFORDABILITY, APPLICATION AND PERFORMANCE: THE INTERNATIONAL TRANS-RADIAL ADJUSTABLE LIMB (ITAL) PROSTHESIS

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ABSTRACT

A multi-disciplined team of engineers, prosthetists, physicians, and amputees has developed a new trans-radial prosthesis currently completing second-year validation testing. The International Trans-radial Adjustable Limb, or ITAL, comprises an innovative variable-compression, variable-geometry interface, a new body-powered prehensor with adjustable pinch force, control harness, and cable. Globally, prosthetic options are increasingly limited by cost and lack of infrastructure required to fit and maintain them. The ITAL was purposefully designed to overcome these barriers, providing a new option for economically disadvantaged amputees in the USA and developing countries. Designed to withstand harsh environments, ITALs are relatively low-cost and restore bimanual capacity to perform strenuous physical labor, enabling amputees to earn a living and be self-reliant.

Packaged in kits, units can be taken directly to amputees and fit or serviced inside approximately one hour using simple hand tools, without requiring amputees visit or be transported to a central facility. Amputees in Jamaica, the USA, and Thailand have shown the ITAL to be an appropriate solution, and now use it for daily activities. Users rate the ITAL’s comfort at approximately 75% that of custom-fabricated prostheses but equivalent in utility. Future work aims to further increase comfort while refining the aesthetics to address cultural needs.

INTRODUCTION

Trans-radial amputation largely occurs due to trauma, disease or illness and is not generally the preferred option if healthy restoration and rehabilitation of a functional limb is possible. Incidence rates of upper-extremity amputation in nation states around the world are currently unknown; there are, however, general estimates that more than thirty (30) million people need orthotic and prosthetic services. Murdoch [1] estimates that potentially one hundred thousand (100,000) prosthetists would be necessary to meet the developing world’s needs using current fitting and fabrication methods. Approximately 80% of the world’s population makes less than US$ 2.00 a day, a figure often inferred as directly proportional to the resources of persons with amputation who require P&O services [2, 3].

Consequently, the cost of prostheses is a limiting factor in providing access to the vast majority of amputees [4]. In order to provide prosthetic tools to amputees who live in remote, rural, and difficult-to-access areas, the logistics necessitate a design paradigm based on the operating environment, affordability, and performance. A selected approach will only be successful if it correctly accommodates available resources and requirements of users. Clinical experts have urgently encouraged researchers and manufacturers to “strive for developments that ultimately culminate in clinically practical, integrated, and affordable techniques”, [5] and to develop affordable devices for targeted applications such as farming [6]. Several groups have heeded this call to action; this research and development effort was initiated specifically to create a low-cost, biomechanically appropriate upper-extremity prosthesis for below-elbow amputees.

METHODOLOGY

To initiate the development process, design specifications were obtained from peer-reviewed articles, and a multi-national survey of prosthetists, doctors, and amputees who owned their own devices, and individuals who had access to none. The main measures of UE prosthesis acceptance identified were the comfort, suspension, and aesthetics. Specifically, among many users surveyed, minimum required suspension ranged from 20-25 lbs. Comfort was equally important, with users wanting to be able to perform manual tasks for a minimum of three hours daily. Comfort ranked particularly important for many individuals who depend upon manual labor as their only means of employment. Based upon published literature, it is clear that despite relative simplicity and more limited dexterity, body powered (BP) prosthetic systems remain very popular; the majority of UE amputees either use them exclusively or keeps them as backup for myoelectric devices [7, 8, 9]. The primary reasons for their popularity are comparatively lower cost, low weight, mechanical robustness, preservation of proprioceptive feedback, and ease of maintenance in comparison to myoelectric devices.

Invariably, even amputees who had no access to devices wanted aesthetic options; function, however, was equally important for many individuals. Passive cooling was requested by many prosthetists who work with more-active amputees. Prosthetists and doctors working in
remote regions repeatedly requested technologies that can be deployed (i.e. fit and adjusted for use) rapidly—with minimal use of materials, electricity, tools, and the ability to be fit outdoors. In many cases, high corrosion resistance and the ability to withstand constant exposure to dust, dirt, and fluids (including perspiration, brine, and those associated with farming and raising animals) were also specified as performance specifications. Body powered users requested hooks that eliminated the need to use numerous latex bands to provide grip forces sufficient for rigorous tasks.

Collectively, these design and performance specifications describe a simple, relatively inexpensive technology that incorporates flexibility in function and application; especially if alterations for certain users become necessary. Emphasis was placed on balancing cost and functional requirements in a complete prosthesis design which would include all elements necessary for immediate use, including a harness, terminal device (TD), and socket. As an alternative to developing a rigid, fixed-geometry socket, a variable-geometry ‘mechanism’ was devised to provide most of the requisite suspension. In contrast to a full-contact socket, a patent-pending open-frame “interface design” was developed to permit rapid installation with simple and easily accessed hand tools. A new terminal device was also developed that permits adjustment of pinch force to match task need, while also reducing the physical stresses imposed on users’ by existing split-hook that come with the use of multiple bands on a standard voluntary-opening hook TDs. Throughout the design process, materials were selected that are widely available from other industries to reduce the cost of repair and maintenance.

The Interface

A modular two-component interface comprising a “humeral cuff” and forearm adaptor were developed, and each can be manually adjusted with simple hand tools. The humeral cuff was iteratively designed to be comfortable under considerable loads while providing the major proportion of suspension. Figure 1(a) illustrates the cuff location on the humerus. Affixed to the distal humerus, the cuff directly contacts the olecranon process and the medial/lateral condyles—three-point contact to establish stability. Each contact point incorporates a combination of rigid and compliant materials shaped to engage the user’s residuum. Condyle contacts were devised based on observations of anatomical structures of biological gripping mechanisms. A mechanism analogous to bone and soft tissue of the finger pads of the distal phalanges was developed, comprising an inner rigid core encapsulated by a combination of elastomers.

Along with a simple fastening mechanism, this arrangement creates a comfortable mechanical lock surrounding the distal humerus. The epicondyle contact configuration is shown in Figure 2. Correctly adjusted, the cuff effectively minimizes rotation and migration below the condyles, and prevents point loading on the humerus, thereby increasing comfort and consequently also reduces the life of this cuff component.

Readily replaceable sleeves minimize the inconvenience of replacing worn parts. In conjunction with the humeral cuff, an open-frame bivalve forearm adaptor design provides additional interface suspension and stability. The humeral cuff is shown suspending 40 lbf (178 N) in Figure 3. Three cuff sizes accommodate the desired range of anthropomorphic dimensions, and can be used on either the left or right arm. Humeral cuffs can be adjusted to fit an amputee in less than one hour using a single Allen-wrench. Together, the humeral cuff and the forearm adaptor constitute a variable compression, variable-geometry open exoskeletal interface.
The Terminal Device

A terminal device was developed that incorporates grip force adjustment. Movement of the band attachment point is accomplished using a patent-pending dual-ramp ratchet mechanism. Moving the band attachment location varies both the initial pre-stretch and the effective tensile force, shown in Figure 4. This allows user-adjustable pinch force to match task need and to conserve muscular exertion. Users select one of six (6) discrete positions by pushing or pulling a carriage tab, making it index to the next available position. This is done using the sound hand or by pressing the tab against nearby objects.

The Cable and Harness System

A Figure-of-9 harness was selected for use with the interface and TD for its simplicity. To keep costs relatively low and increase ease of repair, new harness components using fasteners instead of one-shot crimped ball terminals were developed. Bicycle cabling was incorporated into the new cabling configuration as a comparatively inexpensive alternative to current existing cable housing components. Additionally, bicycle cable, conduit and housing, is available worldwide.

RESULTS

This effort resulted in the creation of the International Trans-radial Adjustable Limb® or the ITAL®. This name was chosen because some in remote areas have no language equivalent for the term ‘prosthesis’. Among those surveyed, the term ‘artificial limb’ is already widely accepted and translates in the local language. Volunteer evaluators comprising both new amputees and experienced prosthesis users (i.e. those having used a prosthesis for a minimum of two years) who perform routine robust tasks. A total of 10 amputees were included in the evaluation group. Among experienced evaluators, interface comfort was rated at 70 to 75% of regular custom prostheses. All volunteer evaluators were allowed to keep the ITAL and use it based upon their own preferences and needs. The experienced prosthesis users were willing to use the ITAL for a few hours a week, and for extended periods during recorded tests.

Typically they did not want to give up the comfort of their own interfaces. Comfort and suspension were evaluated doing routine tasks such as changing a car tire, shoveling, and manipulating multiple objects. After refining the design using feedback from the experienced users, volunteer evaluators were identified in Jamaica, Thailand, and Ecuador. During the initial evaluation stages, susceptibility of both the TD and the interface to rust necessitated the redesign of both to incorporate stainless steel and engineering polymers. This became particularly evident during the first week of testing by amputees who lived within a mile of the sea. Six amputees were tracked at different stages over a two-year period. One individual was an experienced prosthesis user, and two individuals received units within 8 months of amputation; the other three were amputees for five years or more and who had not used any device.
Figure 5, shows person with the ITAL using it for building construction. The experienced user continues to use the device as a backup unit, for activities including weightlifting, house cleaning, and some sporting activities. Of the two who received the ITAL within 8 months of amputation, one uses the device daily as a farm laborer, and the other uses the device occasionally. The latter of the two was not fully satisfied with the appearance of the ITAL but did use it initially for subsistence-type farming and building wooden structures. Over time he developed considerable more muscle mass in his residuum that caused secondary discomfort. He currently uses the ITAL only for heavy lifting tasks where bimanual capacity is needed.

Contact with another individual has only been by phone as schedule conflicts have prevented directly meeting to discuss usage details. Finally, two have reported satisfaction with the device and they are now able to work in the field more effectively and participate in building additions to their homes. An unanticipated effect of the variable-geometry design, variable tension/compression mechanism is that the evaluators began adjusting the device (both the interface and the TD) in real-time to maximize comfort. For heavy duty or light duty tasks, they sometimes opt to modify the cuff fit to vary the suspension and overall comfort based on anticipated activities. Similarly, they use the dual ramp ratchet mechanism to adjust TD pinch force “on the fly” almost continuously to vary grip based on their current task.

CONCLUSIONS & FUTURE WORK

In its present form, the ITAL is lower in performance than custom-fit BP UE interfaces, but performance was deemed very satisfactory overall. Total manufacturing cost for the basic ITAL unit is less than US$400. Evaluators have expressed a desire and willingness to purchase complete units for personal use, specifically for sporting activities and as backup prostheses. The ITAL is presented as an appropriate alternative prosthetic device for use in both the developed and developing world. Given its high-functionality, low-cost, and ability to be readily distributed, its ultimate benefit-to-drawback ratio may prove significantly higher than available devices. Continuing refinement is focusing on improving the aesthetics of the design to reduce this barrier which remains among many potential users. Prosthetists and amputees involved in this project are currently determining best practices for fitting and adjusting the interface for long-term usage; these recommendations are being captured in a comprehensive fitting instruction set. The ITAL has proven to be an appropriate alternative to standard trans-radial prostheses, especially as an option for the poor and uninsured.

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