Innovative Approaches to Providing Developing Countries with Appropriate Lower-Limb Prosthetic Technology

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Abstract

In an effort to meet the needs of developing countries that are unable to reliably import or manufacture high-end prosthetic components, the LeTourneau Engineering Global Solutions (LEGS) design initiative aims to develop prosthetic components within a successful distribution system. Having already worked for several years with clinics in Kenya and Bangladesh, LEGS has become familiar with the constraints set by working in developing countries and has designed appropriate devices. Each component undergoes mechanical and biomechanical laboratory testing, and is implemented at one of the international sites. There are currently 24 patients using the LEGS prosthesis and patient satisfaction level has been very good. In addition to providing a unique education experience for engineering students, the project has the potential to make a worldwide impact by meeting the needs of an underserved population.

Introduction

Citizens of developing countries are an underserved population when it comes to engineering advances and appropriate technology. Few sectors of engineering research are aiming to satisfy specific objectives that target low-income economies. As a result, there is an increasing need for affordable technology to be introduced in these countries to provide viable products to the overwhelming number of nationals who are unable to afford products targeted at

first-world incomes. One of the areas of greatest need is the lack of appropriate biomedical engineering solutions. In a culture where manual labor is the only available occupation, any sort of debilitating disease or injury can greatly threaten both an individual's ability to work and their social status, decimating their financial stability and quality of life.

A common condition that immediately disables a person from being able to perform manual labor is a limb amputation, particularly a leg amputation since many developing countries rely on walking as the primary means of transportation. Leg amputations often may result from trauma, disease, or congenital defects. In developing countries there are far greater numbers of lower-limb amputees than there are adequately staffed and supplied facilities to provide them with prosthetic devices. It is estimated that somewhere between 3 million and 11.2 million amputees worldwide are in need of a prostheses, with approximately 80% of those living in low-income countries (Murdoch 1985; World Health Organization 2005). The introduction of an appropriate, affordable, and available lower-limb prosthetic device to this market has the potential to have an immediate and lasting impact.

Product Integration in a Developing Country

There are two economically feasible ways to make a prosthetic device available in a developing country. One option is to manufacture the components off-site, allowing for local hospitals to import the parts as needed. The International Committee for the Red Cross (ICRC) currently uses this method; the ICRC manufactures its polypropylene parts at a centralized European location and then ships them to clinical locations all over the world (International Committee of the Red Cross 2001). Advantages of using a centralized strategy are the high level of quality control, the advanced level of manufacturing technology available, and the ease of

introducing improvements and upgrades. The alternative manufacturing development plan focuses on teaching and training local prosthetists to manufacture the components themselves from locally available materials. This strategy has the challenges of maintaining quality control and limited available tooling, and can be more difficult to introduce improvements and upgrades. However, it can be made available to the numerous clinics that cannot afford to import parts, that are restricted by government regulations on importing, or that are too remotely located. Additionally, it enables a clinic to be internationally independent, empowering prosthetists to run a stable and consistent business, capable of maintaining their own components since they are able to manufacture all spare parts.

LeTourneau Engineering Global Solutions (LEGS) focuses on meeting the needs of international prosthetic clinics that have limited manufacturing capabilities yet are unable to regularly import components. LEGS team members travel to these clinics to teach and train local prosthetists how to manufacture components. Long-term plans for the project involve the creation of training hubs in each country or region that may be used to independently spread the technology to clinics in the surround area. Networking in this way will allow for new technology to be introduced more easily, with design modifications communicated to the training centers, which will then diffuse the information to other regional clinics. Quality control will also be stressed at the training centers; specific tolerances and other parameters will be emphasized to ensure that unmonitored device iterations do not occur.

Product Development

Because LEGS focuses on training international prosthetists to manufacture prosthetic devices with the tools and materials locally available, the limitations of those parameters set very

restrictive design constraints. One of the general expectations LEGS holds for the clinics that are being considered for field implementation is that the workers be trained prosthetists and have at least some manufacturing talent, which is measured with a manufacturing test during an exploratory visit. Additionally the clinics must have access to some basic power tools; at minimum a band saw or table saw, a drill press, a sander, and in most cases an oven. These constraints force the LEGS team to design components that minimize the use of moldings or castings, and that minimizes the required level of manufacturing training. As a result, the team must typically design components that can be made out of simple plastics and common hardware items.

Project constraints are the determining factors behind the majority of design decisions. Once the constraints are assessed during a preliminary site evaluation, the set of requirements is determined for each location. A design that meets those requirements it is put through a series of tests in the laboratories at LeTourneau University. If test results are satisfactory, the device is implemented in a field evaluation where a limited number of patients at one of our international clinics will wear the device for between one and three years. Repeated evaluations of the device's performance, patient satisfaction, and walking ability determine whether improvements and modifications are needed.

Sites Visited

Two sites have successfully implemented of the LEGS device over the last several years: The AIC-CURE clinic in Kijabe, Kenya, and Memorial Christian Hospital (ABWE) in Malumghat, Bangladesh. Both clinics have assisted LEGS personnel in fitting several patients

with the experimental prostheses and the different design constraints of each clinic have allowed the team to practice developing site-specific components.

The AIC-CURE hospital is a well-equipped medical clinic with a small prosthetics and orthotics (P&O) workshop nearby; the workshop has the required machine tools readily available and each of the six-person staff has some degree of P&O training and manufacturing ability. Before the LEGS team first traveled to the clinic in 2004, the workers relied on modifying donated used prosthetic components in order to provide prostheses for needy patients. However, the workers already had the ability to produce fiberglass sockets and the team was able to teach them to make an interface between the fiberglass and the knee joint to attach the rest of the LEGS device. As the initial location chosen for implementation, there are several patients at this clinic who have worn the LEGS device for over two years. In total, 18 patients have been fitted with the device at the Kenyan clinic, with 14 subsequently available for follow-up.

Memorial Christian Hospital also contains a P&O workshop manned by trained prosthetists, although the Bangladeshi workers exhibited greater manufacturing abilities than their Kenyan counterparts. In addition to the machine tools available in Kenya, the clinic in Bangladesh also frequently uses an oxyacetylene welding torch to create aluminum sockets. Before the LEGS team first traveled to the clinic in 2006, the prosthetists used an outdated version of an exoskeletal aluminum Jaipur prosthesis, which used a weak, locked knee joint and a non energy-returning foot. Interfacing the knee with the aluminum socket was a major challenge for the LEGS team, but was met with the invention of an aluminum endcap that would be welded onto the end of the socket. Six patients have been fitted with the device at the Bangladeshi clinic.

Design and Testing

A fundamental design criterion regarding the design of the LEGS device was the choice to create it as an assembly of easily interchangeable modules. This choice has been essential to the success of the project; prosthetists can now replace individual components instead of having to replace the entire device when making repairs. Additionally, the flexibility of the design to interface with standard components has enabled clinics to make emergency replacements and meet special needs. The design of quality interfaces between the components also allows for alignment capabilities that are essential to attaining proper gait.

Once a component has been designed, it is put through a series of rigorous static and dynamic tests with the goal of confirming that each component is both biomechanically sound and mechanically capable of withstanding three or more years of patient wear. Biomechanical tests are conducted with the assistance of US amputees and prosthetists in the biomedical engineering motion analysis lab at the university. Local amputees volunteer their time to be fitted with a device by a local prosthetist and data is gathered to compare the biomechanical qualities of the LEGS prosthesis with the amputee's US prosthesis. Comparison is based off of the dynamic characteristics of knee flexion angle, pelvic tilt, propulsive and braking forces, symmetry, center of pressure assessment and other measurable data. These quantities can be reapplied to the design to make the necessary alignment, weight, and geometrical changes. Mechanical testing is performed under the guidelines set by ISO 10328 A-80 loading, using both static and fatigue tests. Custom-made pneumatic fatigue testing equipment, with application forces comparable to those required by the ISO test, put each component through 2-3 million cycles of simulated fatiguing, and the maximum loading force is determined on a tensile testing machine. Components are submitted for redesign if they do not pass the desired testing levels.

Patient feedback is also measured and is one of the most highly weighted considerations in the design process. The best example of patient feedback having a direct influence on component design resulted from the discovery that international patients strongly desired to have cosmetically appealing devices. While cosmetic appearance is not of very high importance in high-income countries, amputees in developing countries desire realistic cosmetic appearance, at times even more so than functionality. As a result of this patient feedback, a silicone shin cosmesis was designed, tested, and implemented last year, and additional cosmeses to cover the knee and foot are in the early stages of design.

Current Device

There are two current versions of the LEGS device – one for Kenya and one for Bangladesh – as well as a third preliminary version for a potential Sierra Leone site. The most universal component is the LEGS knee design (patent pending), which may be used with any of the versions thanks to its simplicity and easy interfaces.

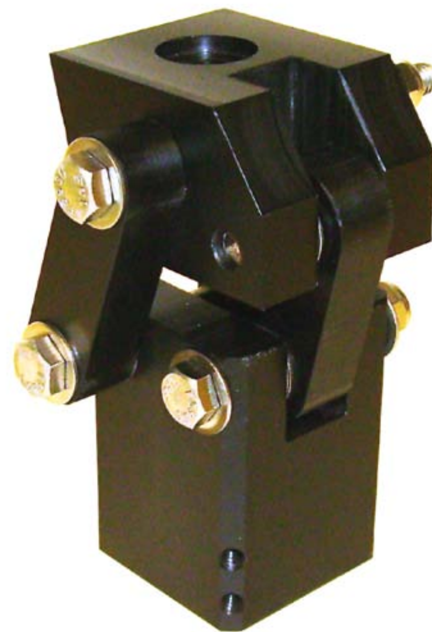

Figure 1 - LEGS polycentric knee

The LEGS knee is a polycentric four-bar linkage design with an instantaneous center of rotation (see Figure 1). Polycentric knees have been shown to provide better gait results than simple hinged knees thanks to their ability to more accurately mimic the motion of a biological knee and to provide higher toe clearance (Radcliffe 1977, 5-7). A single bolt interface at the top (with the potential for adding a standard pyramid adapter) and a clamping set-screw interface at the bottom used for

attaching the pylon (shin) make the LEGS knee very simple to adjust or replace when needed. Manufactured from Delrin (Acetyl Copolymer, a common, hard plastic available from DuPont), the knee can be made using only a drill press and band saw or table saw. Stainless steel hardware has been used for assembly to resist corrosion and may be tightened or loosened to adjust knee tension.

Socket designs are different for each site: in Kenya the prosthetists use a fiberglass socket, in Bangladesh an aluminum socket, and in Sierra Leone LEGS has begun experimentation with a polypropylene socket. Each socket type has a similar interface attached at the end to ensure a solid connection to the knee. Incorporated into this interface are angled discs that may be rotated to modify the knee-socket alignment.

Interfacing between the knee and the foot is an aluminum pylon made from tube stock that is cut to length with a pipe cutter. The pylon is then covered with a shank cosmesis made of Styrofoam and silicone. This durable, waterproof cosmetic device can be custom sized and colored to closely match the patient's biological leg.

The foot/ankle component is again different at our sites – Bangladesh uses an aluminum ankle connector with a Jaipur foot, while Kenya uses a pyramid adapter and a modified North Western University polypropylene foot. Both ankles allow for a large degree of adjustment, but a better foot design is desired and will be targeted in future research.

Field Trials

Because the conditions that can be met in a developing country's environment are difficult to accurately model in laboratory tests, the ability to fit patients and perform long-term field trials has been essential to the development of the LEGS device. Patients accept the terms

of being a part of this experimental process in order to help with the development of new lower-limb prosthetic options for developing countries as well as to receive the more functional LEGS limb to replace their old prostheses. A field trial generally consists of a deployment of a group of LEGS team students and faculty for a few weeks on location at one of the international sites.

While onsite, there are a number of different tasks that must be performed simultaneously to have a successful field trial. The first priority is to train the clinic staff how to manufacture and integrate whatever design changes have been made. Secondly, if patients have already been fitted at the site, they are brought in again to fill out a follow-up questionnaire and perform a series of data collecting tests. If any modifications, replacements, or device updates are needed they are carefully performed and recorded. If there ample time remains after follow-ups are completed, new patients are fitted. The more experience the clinic has had with building the prosthesis and the more training they have received, the less LEGS team members will be involved with this step, eventually taking on a purely observatory role. Fitting and alignment is done only by local prosthetists, while LEGS team members may be involved in data gathering, patient care, manufacturing, and some gait training.

Field Evaluations

One of the greatest challenges to the continuing development of the LEGS device has been the difficulty of gathering patient gait data without the use of onsite technical equipment. The simplest data to gather onsite is through patient interviews, where the patient is questioned about their usage, satisfaction, and walking ability. Unfortunately, verbal expressions often seem to be inaccurate and additional, more quantitative approaches are needed.

A Timed Up-and-Go test can be used to measure patients' mobility and comfort level with the prosthesis (Schoppen et al. 1999). In this timed test the patient must stand up from a seated position, walk a short distance, turn 180 degrees and return to the chair. Recorded times can be compared to the patient's time using their old prosthetic device or can be compared to times taken in follow-up visits to determine how much the patient has improved.

Figure 2 - Comparison between laboratory gait analysis and field gait analysis

More technical test results can be gathered using some simple and easily transportable equipment. Using a video camera and contrasting body markers, it is possible to simulate the data capture that can be performed in a fully equipped infrared motion analysis lab, with ProAnalyst® software (see Figure 2). Gait data for field evaluations has also been captured with the use of a GAITRite portable walkway system. GAITRite consists of a software package that works in conjunction with a 15-foot long sensor mat. The mat may be rolled up and easily transported, and has been taken to both Kenya and Bangladesh. Using GAITRite, the team can take accurate measurements of specific gait characteristics such as cadence, stride length, and symmetry, storing that data for easy reference. Teams are able to collect data before and after gait training in order to assess the effects of a single day of training. In the future, new patients may be assessed using both their old device and their new LEGS device to see if a quantitative trend exists that indicates that the LEGS device can directly improve gait, as has been evidenced by qualitative evaluation.

Results

By far, the easiest result to focus on is patient satisfaction. In a recent follow up with our Kenyan patients, satisfaction with the device was on average eight out of ten. Although they often have suggestions on what they think would make the prosthesis even better, nearly every patient who has been successfully fitted has worn the prosthesis daily for at least a year and has appreciated the mobility it has granted them. There are currently 24 patients who use the LEGS device and, of the 20 who have been available for follow-up, 19 have expressed overall satisfaction.

Mechanical testing has shown that the socket interface, knee joint, and ankle connector should last for at least two years under ISO 10328 loading conditions. This appears to be the case from recent follow-ups with patients, but conclusive data has not yet been collected since nearly all of the patients who have had the device for two years had at least one component replaced in the course of updating the prostheses.

In Kenya, nine patients who had been wearing the LEGS device for at least one year had their gait assessed by the GAITRite system. Data was collected with the both before and after a single day of gait training for each patient. Preliminary analysis seems to suggest that short-term gait training can increase gait symmetry, at least temporarily. Testing patients over a longer period of time will provide the team with more advanced biomechanical data.

The objectives of making the device durable, low-cost, and maintenance free have all been reasonably met. The current LEGS device costs less than 72 USD, has had no failures in at least two years of use, and has required only light maintenance in the form of occasionally retightening bolts or making alignment adjustments.

Continuing Development

Work on the LEGS project is continuing this year with a focus on assembling a completed knee technology package for dissemination to interested service providers. To accomplish, this the team is reexamining the material and geometry of the knee and running mechanical tests to confirm that it is capable of withstanding ISO 10328 loading conditions. Additional calculations and tests will be run using materials other than Delrin to provide design alternatives in areas where Delrin is difficult to obtain. Biomechanical tests will offer data comparing the knee's gait performance to a US-made prosthesis using GAITRite and Motion Analysis. Finally, a cross-lingual manufacturing and assembly manual will be created with complete plans for building the LEGS knee. There are several international organizations that are already interested in procuring the LEGS knee design, and once testing and design confirmation is completed the LEGS team will begin the process of effectively distributing its technology.

Educational Impact

Working on the LEGS team has a lasting impact on the engineering students involved, and is one that could not be obtained through lectures or more theoretical projects. By working in foreign cultures students are not only educated in engineering design, but also in cultural competency, global interconnection, and social impact. The project is funded largely by donations and each student must raise funds before traveling with the team, lending even more value to what students are trying to achieve overseas. While it is difficult to balance end-user needs with educational outcomes, careful structuring of the project and the setting of proper context can help achieve both goals.

Conclusion

Despite the challenges of strict design constraints, members of the LEGS team have an opportunity to develop innovative products that can have a far-reaching impact on amputee populations all over the world. The project has already enhanced the lives of the patients who have been fitted and made a lifelong educational impact on the students involved. Through sustained development of appropriate prosthetic components, the LEGS initiative may continue to expand its international impact, bringing a life-changing biomechanical product to the poorest of the poor.

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