

# Innovative Biomedical Design Competitions and Scenarios Exploring Underserved Populations

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## Abstract

Collegiate undergraduate biomedical engineering continues to emerge and mature as a discipline that provides a sound grounding in engineering fundamentals with the promise of advancing health solutions around the world. As volunteerism and service learning within engineering programs has grown, so has the diversity of approaches for undergraduate biomedical engineering design projects associated with underserved populations. One project that works toward meeting the needs of developing countries is the LeTourneau Engineering Global Solutions (LEGS). National student design competitions such as the Biomedical Engineering Innovation, Design, and Entrepreneurship Award (BMEidea), and the Engineering World Health (EWH) Projects That Matter Program provide students with a showcase for the results of service learning and social entrepreneurship projects. Another vehicle is in-class paper design projects, containing simplified versions of real-world hands-on scenarios.

## Introduction

With regard to engineering education, biomedical engineering offers attributes common to the other engineering disciplines while also offering unique opportunities specific to its relationship with the healing professions. Engineering and engineers have long been agents in protecting the safety, health, and welfare of the public (ASME 2007). Biomedical engineering holds a unique position within the engineering spectrum in that it deals intimately with human health and wellness. In today's business and global climate, ethics is increasingly a principle cannon of engineering practice (NSPE 2007). It has been a relatively recent phenomenon that increasing and planned opportunities for volunteerism and service learning, whether based on moral values, ethics, or faith convictions, are a component associated with engineering programs (Creane 2006).

Technology is frequently a central need in designing and solving solutions. Often these valuable opportunities are in association with community service agencies, non-profit organizations, and religious groups (Kelley 2006). These types of organizations must generally rely on volunteers, especially when the need is to deliver a technical solution (Jamison 2002). Biomedical engineering education and design projects offer useful opportunities to improve the quality of life for individuals or groups where often the impact can be seen profoundly and immediately.

## Capstone, Service Learning, and Academic Perspectives

Senior capstone design projects provide students with the opportunity to develop their design, analytical, project management, communication, and interpersonal skills while applying the knowledge acquired during their undergraduate careers. Capstone projects are often cast in a team environment where formal "classroom" instruction includes the topics of teamwork, economics, ethics, and societal context. Depending on the project's scope, a robotic design for example, capstone projects may also cross engineering departmental boundaries to include computer science and even business students. Many employers consider skills and knowledge related to the social sciences (communication, teamwork, and ethics) to be more important than those related to engineering or the natural sciences to the successful performance of new engineers. Six of the eleven outcomes required of engineering programs by the Accreditation Board for Engineering and Technology (ABET) are

related to the social sciences (economic and political issues, cultures, societies, and communication). To produce these required outcomes, engineering students need knowledge of the social sciences. The senior capstone design project experience can serve as a way to link engineering with the social sciences, and more specifically here, biomedical engineering with underserved populations.

Service learning can be defined as “action and reflection integrated with the academic curriculum to enhance student learning and to meet community needs” (O’Grady 2000). It exposes students to ethical situations and provides community interaction that stimulates reflection, helping students contemplate engineering solutions in a global and societal context (Haws 2001). Students involved in service learning perceive an increase in their personal development, tolerance, and communication skills. They are also more motivated to understand technical information and devote more time and thought toward the technical and social tasks at hand (Eyler 1997).

Components of many biomedical engineering service learning projects are associated with underserved populations and developing countries. In such cases students gain the additional benefits of learning soft skills such as customer service and cultural awareness (Selingo 2006). The hands-on experiences and sense of helping have been shown to increase student retention, especially among women (Matusovich 2006). Service learning opportunities for undergraduates have become so prevalent and institutionalized in some universities that they have been organized into special centers or programs including HEILA (Marquette 2007), Service and Leadership Enterprise (Boersma 2005), Joint Educational Project (Johnson 2007), Engineering World Health (Malkin 2002), EPICS (Jamieson 2002), and Engineers with a Mission (Baylor 2007). Examples of biomedical engineering projects aimed at underserved populations include maintaining biomedical instrumentation, designing medical instrumentation for use in developing countries (Mulrine 2006), drug-delivery nebulizers (Olson 2007), and above-knee prostheses (Gonzalez 2007).

## **Design Competitions**

National design competitions allow biomedical engineering students and faculty to showcase the results of senior design projects. They provide an opportunity for teams working on service learning or social entrepreneurship projects to compete. Some emphasize entrepreneurship and potential for commercialization and provide awards in the form of cash to be used for further development of the design concept. Others focus more on technical aspects and how well the design meets the needs of a specific patient population. EWH sponsors a Design Projects that Matter series through which students can obtain funding for senior design projects resulting in designs that meet specifications determined by the organization. The Biomedical Engineering Innovation, Design, and Entrepreneurship Award (BMEidea) is a national student design competition of interest to the biomedical engineering community. It emphasizes entrepreneurship and potential for commercialization (or sustainability) and provides cash awards of up to \$10,000. It is sponsored by the National Collegiate Inventors and Innovators Alliance (NCIIA), the National Science Foundation, Canon Communications, LLC, the Industrial Design Society of America (IDSA), the Biomedical Engineering Society (BMES), and the Council of Chairs of Bioengineering and Biomedical Engineering Programs.

This competition seeks student design projects that focus on health-related technology and meet a relevant clinical need. Teams must submit a project description including documentation of the final design, proof of functionality, assessment of patentability (patent search and search for prior art), anticipated regulatory pathway, estimated production costs, and a business plan with a market analysis and details regarding the strategy for commercialization. Judging criteria include 1) technical, economic, and regulatory feasibility, 2) contribution to healthcare and quality of life, 3) technical innovation, and 4) potential for commercialization or the ability to benefit underserved populations and improve access to healthcare. Awards are presented at the Medical Design Excellence Awards ceremony during the MDM East Convention in the presence of many of the top medical device designers and manufacturers. The competition provides students with the opportunity to win substantial product development funding, gain exposure to the medical device industry, and develop industry contacts.

The first place winner of the 2007 BMEidea competition developed a product that allowed for oral delivery of a rotavirus vaccine via a dissolvable wafer. The wafers do not require refrigeration, making storage and distribution of the vaccine throughout sub-Saharan Africa and other underdeveloped regions feasible. It was designed to meet the needs of an underserved population with problems and requirements different than those typically encountered in

the United States. The potential for commercialization (in terms of profitability) was not as great as other entries to the competition; however, this project had the greatest potential to improve the quality and accessibility of healthcare worldwide. Submission of service learning and social entrepreneurship projects (such as the rotavirus wafer) to the BMEidea competition is encouraged and welcomed.

## **LeTourneau Engineering Global Solutions (LEGS)**

There are also examples of projects and initiatives at academic institutions that target specific geographic regions and population needs, are multi-year in commitment, and capture the imagination and loyalty of a committed team. One example of such an endeavor is a project at LeTourneau University where students and faculty work together to design and provide biomedical devices and solutions to developing countries.

Citizens of developing countries are an underserved population when it comes to engineering advances and appropriate technology. 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. 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. It is estimated that between three million and 11.2 million amputees worldwide are in need of a prosthesis, with approximately 80% of those living in low-income countries (Murdoch 1985; World Health Organization 2005).

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 is a junior-senior design option for engineering students at LeTourneau, and also involves faculty and staff. For each student team member, LEGS is a two-year exposure with a first year of observation and their senior year spent on designing, testing, and building. LEGS team members, including students, 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 surrounding area. The LEGS project operates through donations, necessitating significant fundraising. Student participants have found their association with the LEGS project to be a valuable learning experience. One student stated she “liked the idea of making something that would have a lasting impact” and found it “not so much like class, but a research project” (Vaughan 2006).

### **Product Development, Design and Testing**

LEGS focuses on training international prosthetists to manufacture prosthetic devices with the tools and materials locally available. 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. These constraints force the LEGS team to design components that minimize the use of moldings or castings. As a result, the team must typically design components that can be made out of simple plastics and common hardware items.

Project design constraints are assessed during a preliminary site evaluation; the set of requirements is determined for each location. Student teams’ designs employ these requirements in their design constraints and reviews. A design that meets those requirements 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.

Two sites have successfully implemented the LEGS device over the last several years: The AIC-CURE clinic in Kijabe, Kenya, and Memorial Christian Hospital (ABWE) in Malumghat, Bangladesh. The AIC-CURE hospital is a well-equipped medical clinic with a small prosthetics and orthotics (P&O) workshop nearby. In total, eighteen patients have been fitted with the device at the Kenyan clinic, with fourteen subsequently available for follow-up. Memorial Christian Hospital also contains a P&O workshop manned by trained prosthetists. Six patients have been fitted with the device at the Bangladeshi clinic.

A fundamental design criterion regarding the LEGS device was the choice to create it as an assembly of easily interchangeable modules. Additionally, the flexibility of the design to interface with standard components has

enabled clinics to make emergency replacements and meet special needs. Once a component has been designed, it is put through a series of rigorous static and dynamic tests. Biomechanical tests are conducted with the assistance of US amputees and prosthetists in the biomedical engineering motion analysis lab at the university. Mechanical testing is performed under the guidelines set by ISO 10328 A-80 loading, using both static and fatigue tests.

There are two current versions of the LEGS device: one for Kenya and one for Bangladesh. 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.

The LEGS knee is a polycentric four-bar linkage design with an instantaneous center of rotation (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 provide higher toe clearance (Radcliffe 1977). A single bolt interface at the top 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, 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. Each socket type has a similar interface attached at the end to ensure a solid connection to the knee.

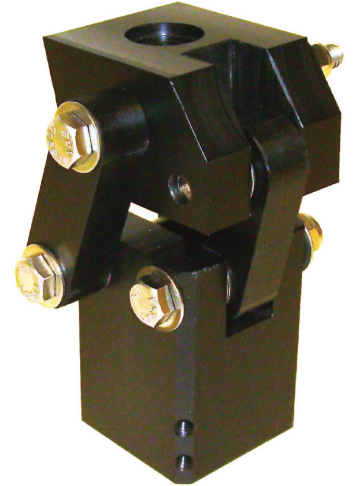


Figure 1. LEGS polycentric knee

### Field Trials and Evaluations

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. The first priority is to train the clinic staff how to manufacture and integrate whatever design changes have been made. 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. One of the greatest challenges has been the difficulty of gathering patient gait data without the use of onsite technical equipment. A Timed Up-and-Go test can be used to measure patients' mobility and comfort level with the prosthesis (Schoppen 1999).

More technical test results can be gathered using a video camera and contrasting body markers. It is possible to simulate the data capture that can be performed in an infrared motion analysis lab, with ProAnalyst® software (Figure 2). Gait data for field evaluations has also been captured with the use of a GAITRite portable walkway system.

### LEGS Results and Continuing Development

By far, the easiest result to focus on is patient satisfaction. In a recent follow-up with Kenyan patients, satisfaction with the device was on average eight out of ten. Nine patients who had been wearing the LEGS device for at least one year had their gait assessed by the GAITRite system. Preliminary analysis suggests that short-term gait training can increase gait symmetry. There are currently twenty-four patients who use the LEGS device and, of the twenty who have been available for follow-up, nineteen have expressed overall satisfaction.

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.

Work on the LEGS project is continuing this year, with a new class of senior design students and a focus on assembling a completed knee technology package for dissemination to interested service providers. Additional



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

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.

## In-Class Design Scenarios

While the student learning benefits to biomedical engineering design projects for underserved populations have been demonstrated, it is not practical for all undergraduates to participate in situ on these projects. In an effort to bring forward some of the positive benefits of these undertakings, in-class design scenarios were prepared that contain some elements of on-site service learning projects. These projects contain design fundamentals consistent with the learning stage of students in intermediate undergraduate biomedical engineering courses. They reinforce the biomedical engineering applications of traditional engineering principles, reference economics, design constraints and societal factors, and permit open-ended solutions.

Complete details of two examples of these projects are included in the supplemental conference materials. Both provide a somewhat realistic/relevant storyline to make the situation consistent with current societal issues. The first scenario deals with a low-cost lower-leg prosthesis for patients with severe injuries or diseases. While the design loads are provided, the goal of the problem for the students' design is to adjust/specify the wall thickness based on the maximum stress along the length of the prosthesis. Because the stresses due to bending are so much greater than the shear stresses, the solution essentially involves managing the longitudinal stresses by manipulating the second moment of inertia via the wall thickness. The constituent relationships that predicts longitudinal bending stress  $\{\sigma = M y / I\}$  is linear with respect to the bending load (M) and shape factors ( $R_o$ =outside radius;  $I$ =moment of inertia). However, the moment of inertia for an annular cross section is related to the fourth power of the radius  $\{I = \pi (R_o^4 - R_i^4) / 4\}$ , causing the solution to be nontrivial ( $R_i$ =inside radius). Further, practical limits on the diameter of the prosthesis and the wall thickness call for individual judgments to be inserted by student designers. By adjusting  $R_o$  ( $R_i$  is fixed), the longitudinal stress can be restricted to its upper limit.

The second design example requires the specification of the size and angle of a cone-and-plate viscometer. The circumstances presented for this project are that of a rural clinic where there is the need to monitor the blood viscosity of patients with sickle cell anemia. The stated design criterion is that the entire blood sample being tested be maintained under a constant shear rate. For a Newtonian fluid (a simplification since blood is non-Newtonian), viscosity is characterized as the ratio of the shear stress to the rate of shear. In practical terms, the mathematical relationship for the rate of shear in a cone-and-plate viscometer  $\{\dot{\gamma} = \omega / \tan \theta\}$  is dependent upon the rotational velocity of the viscometer ( $\omega$ ) and the angle between the plate and the cone ( $\theta$ ). The shear stress for this configuration  $\{\tau = 3 T / 2 \pi R^3\}$  is a function of the measured torque (T) and the radius of the viscometer's cup/cone (R). Although the constitutive equations may appear menacing, the shear-stress:shear-rate expression is straightforward and easily manipulated. The viscometer design dimensions, therefore, are determined by a combination of selecting a realistically small cone angle and a practical blood sample volume.

Neither of these design scenarios is overly complicated from a mathematical perspective, though for both cases that is not immediately apparent. Both problems require an analysis whereby the student gains intimate familiarity with the forms and applications of the governing equations, thereby increasing their understanding. As students begin exploring these design problems outside of class, it is necessary to occasionally spend class time anticipating what approaches may be useful and how to avoid unnecessary pitfalls. Students appear to appreciate and be sensitive to the societal circumstance of the scenario, particularly with regards to their privileged position as a soon-to-be college graduate and an individual of high intellect.

## Conclusions

The exposure of undergraduate biomedical engineering students to design problems is a valuable learning and understanding tool. When the design scenario involves aspects relating to underserved populations, several favorable educationally related enhancements are possible. These may include improved student retention, appreciation of sociological factors, and cultural and global awareness. National student design competitions

such as the BMEidea and Engineering World Health (EWH) Projects That Matter Program provide students with a showcase for the results of service learning and social entrepreneurship projects. Awards to the winners of these design competitions can provide the funding needed to further advance these projects, allowing students to realize the potential positive global impact of the technologies they developed on the quality and accessibility of healthcare. Despite the challenges of strict design constraints, student 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. Some of the attributes of this type of design problem can be mimicked in paper-only in-class designs, with resulting favorable outcomes resembling those of real-world, hands-on projects.

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