Vac-Cast
A Milestone in Prosthetic Sand-Casting
IDEAS 2007 Proposal

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Project Summary

Every year, there are over 25,000 new amputees in India as a result of disease, and agricultural, industrial and road accidents. Roughly half of these victims receive a prosthetic device that is specifically tailored to their residual limb. The other half receive no prosthetic, despite the fact that organizations exist to provide this prosthetic fitting and manufacturing service at no cost to the patient. One of the deciding factors for a patient to opt for that service is whether they can devote the two to three days needed to be treated with the prosthetic fitting and fabrication process. Conversely, service organizations are limited in their patient throughput by the finite resources that they can allocate per patient for the lengthy treatment.

Fortunately, there is a novel sand-casting fitting technique that could increase patient throughput by a factor of five. This technique however can not be deployed because its core support equipment, an electric vacuum device, is too costly and electricity intensive for a clinic to bear. To overcome the existing limitations of deploying this sand-casting technique, we have developed a simple alternative to the vacuum machine in current use. Our technology is a unique and easy-to-use human-powered evacuation device that costs under $200, is built from tools commonly found in a mechanic shop, uses no electricity and can be integrated seamlessly with the other sand-casting treatment devices.

Our community partner in this endeavor is Jaipur Foot Organization (JFO), the world leader in the fitting and manufacturing of prosthetic limbs. We have developed this device in collaboration with JFO affiliates in order to guarantee that our technology will meet the same needs currently supported by the electric vacuum machine. We will work with JFO to field test the device in August 2007 in Jaipur, India, with the expectation of continued collaboration to manufacture and distribute our vacuum device to JFO clinics worldwide.

1. Background

We are currently working with the Jaipur Foot Organization (JFO) in India and the Center for International Rehabilitation (CIR) in Chicago to develop a human-powered vacuum pump for vacuum sand casting of residual limbs to create prosthetic sockets. JFO is the world's largest prosthetics provider, fitting over 16,000 prosthetics a year. Over the last 30 years, they have fitted more than 290,000 amputees in India and about 15,000 amputees in other nations. JFO currently serves about 60 patients a day in their main facility in Jaipur, one of their 16 urban treatment centers in India. Financed by donors at $30 per patient, JFO coordinates tickets for the patient and their family to travel to the closest treatment center, living accommodations for their several day stay, and the prosthetic and fitting services.

1.1 Need

Even with three dozen existing facilities around the world JFO can only treat roughly half the total number of new amputees every year. To increase their treatment capacity, JFO and CIR developed a rapid sand casting (SC) technique that employs the principle of sand dilatancy. By reducing the time to fabricate a socket, the new SC technique can increase patient throughput by a factor of five and drastically decrease the amount of non-recyclable materials used during treatment. The resulting dramatic increase in throughput efficiency of JFO's facilities increases its impact along two lines: an increase in effectiveness and quantity of deployed mobile camps for rural and disaster-stricken areas, and an increase in participation by patients who otherwise could not commit to a multi-day treatment.

The key limiting factors to globally deploying the SC technique are the electrical requirements and costs of acquiring the support devices that enable the rapid SC fitting technique. The core component of the SC technique is a $4000 vacuum device that is imported from Germany, requires a dedicated electrical circuit during operation, and is difficult to transport with mobile treatment clinics. To enable JFO to overcome existing SC limitations we have developed a simple alternative to the vacuum machine in current use. Our technology is a unique and easy to use human-powered evacuation device that costs under $200, is built from locally available materials, uses no electricity and can be integrated seamlessly with the other SC devices.

1.2 Prior Art

The predominant treatment in existing JFO facilities consists of a multi-day, per patient fitment and prosthetic manufacturing process based on Plaster-of-Paris (POP) casting (see fig. 1). Mobile camps that execute this rudimentary process must also transport nearly half a ton of POP to rural camps. The POP technique involves wrapping the residual limb of an amputee with a cotton bandage soaked in wet plaster. The plaster cast takes approximately 10-20 minutes to set, after which it is removed and then used as a negative mold of the patient's residual limb. This negative mold is then filled with additional POP, which requires an additional 2 hours to fully set as a positive mold of the amputee's residual limb. Once dry, the mold is adjusted according to standard prosthetic fitting practices that ensure comfort during walking and lengthy use. The POP positive mold is used to thermoform HDPE and LDPE sheets into the amputee's completed prosthetic socket to which a prosthetic leg is attached. The old POP molds can not be recycled, and hence treating each patient generates roughly 4 kg of POP waste. All together, the POP process, from preparation of the residual limb to thermoforming of the socket, requires 3-5 hours of clinical resources per patient. From the perspective of a rural based patient, the entire treatment process may require them to be absent from their normal activities for up to three days. This excursion prevents patients from performing the daily activities that may be essential to their family's survival. This departure from family duties may be unacceptable and deters certain patients from seeking treatment.

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Fig. 1 The POP technique, currently used in rural fitment camps, requires several hours of preparation of the residual limb, heavy involvement of a prosthetist in creating the POP cast, and several hours of waiting for the positive mold to set before a thermoformed socket can be made. There is also a large amount of waste created from the completed positive mold of the residual limb, made entirely of solid POP.

JFO and CIR co-developed a new sand casting technique to eliminate this deterrent of seeking treatment. Moreover, the rapid SC fitting process represents a cost savings both from operational expenses and the extensive per patient resource allocation in POP molding. Using SC, an amputee places his residual limb into a vat of sand, over which a vacuum is drawn. Through the dilatancy principle, the sand maintains a rigid negative mold (fig. 2). A positive sand cast of the residual limb can then be made by pouring sand into the negative cavity and drawing vacuum on the positive cast through a mandrel (tube). In less than a minute, a positive sand cast of the residual limb can be manufactured, and then adjusted by a prosthetist and used to thermoform a prosthetic socket that is more accurate than those made from POP molds. The entire SC process, from residual limb preparation to fitting the prosthetic into the thermoformed socket, takes only one fifth the time required for the POP method. The critical component of this forming process is the vacuum device which initiates sand dilatancy.

Fig. 3 in Yeongchi Wu et al. "CIR Casting System - A New Approach for Making Transtibial Sockets." CIR Technical Brief, March 2004. http://www.ideanet.org/uploads/gallery/03-2004tech_brief.pdf

Fig. 2 (a) An amputee putting his residual limb into the vat of sand from which a negative mold will be cast and (b) a negative mold of the amputee's residual limb using vacuum sand-casting.

In some JFO clinics, an electrically powered vacuum device enables vacuum sand-casting of the residual limb and fitting the resulting socket with a prosthetic in under an hour and a half. The vacuum pumps used in these JFO-SC clinics are German-made and cost $4,000. Due to their high cost and dependence on grid electricity, commercial vacuum devices can not be distributed to all JFO clinics. Consequently, the majority of JFO clinics can not employ the highly-successful SC technique, and are relegated to antiquated POP molding techniques.

2. Innovation

We have modified an existing technology: a small, hand-operated vacuum pump, to suit the needs of our application. The chamber in the hand-operated vacuum pump has a capacity of one cubic inch, and it takes eight pounds of force to complete one pump stroke by squeezing the handle about 2.5 inches. This pump was originally designed for short-term, low pressure-drop operations such as bleeding brake lines on automobiles. Our redesign enables the pump to create and sustain a pressure drop of 17-25 mmHg from atmospheric in a 30 gallon sealed air tank.

2.1 Mechanical Design

Since our main design goal is to increase the flow rate and ease of use of a pre-manufactured hand pump, our product simply adapts this manual pump to continuous operation via a hand crank actuator. By using a chain and gear drive, crank handle, and creative cam pre-loading, we were able to get both continuous pump actuation and rapid tank de-pressurization. The rotary cam actuator eliminates the tedious squeezing motion previously used to actuate the pump while also giving the user a mechanical advantage that reduces the strength needed for pump operation by four. Moreover, we employed two vacuum pumps not only to double the performance of the device but also to create a useful pre-load on the cam actuator. Pre-loading the cam is essential due to our wooden construction; without this design component, the un-balanced force on the cam shaft would eventually wear down the wooden bearing block and thereby induce jostling of the cam and device performance degradation.

The most complicated components of our mechanism are the chain and gear which are locally available as old bicycle parts. All the other components are relatively simple and we are experimenting with different ways of fabricating them (see fig. 3 for a labeled photograph of the alpha prototype). In our alpha prototype, most of our components including the base, cam, bearing blocks, flywheel, and crank web are all made of wood. Additionally, the gears we acquired only have a ratio of 2:1.

2.2 Future Modifications

Based on preliminary tests of our alpha prototype, we plan to implement several changes for construction of a beta prototype. Specifically, we will replace our current 5/16” aluminum drive shaft with a 1/2” steel shaft to increase stiffness and mechanical transmission efficiency. We will also replace the wooden flywheel with a simpler crank handle to drive the shaft. A metal ring with greater rotational moment of inertia may be added to improve the operational smoothness. Check valves in the vacuum lines from the pumps to accumulator tank will isolate the accumulator tank and reduce the impact of leaks. To further increase our per-rotation output, we will regear the shaft and pump to a 4:1 ratio. Finally, future design work will focus on diversifying our material usage to make our machine more robust so that it will not be damaged in transit to rural areas or during intense use. For example, we would like to replace our wood components with mild steel because it is more robust but still relatively inexpensive, commonly available, easy to machine, and able to withstand the forces we are considering without breaking or deforming.

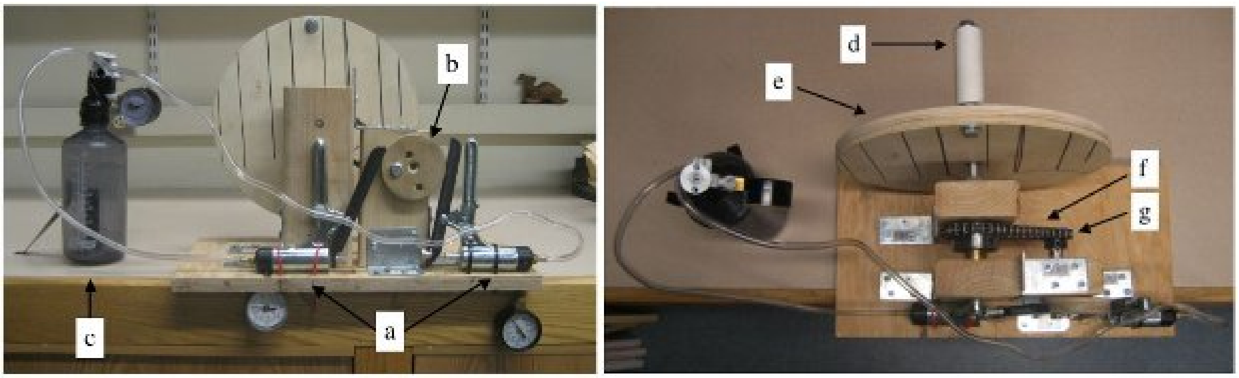

Fig. 3 The components of our alpha prototype are (a) two vacuum hand-pumps, (b) a wooden cam coupling the flywheel to the pumps, (c) a reservoir tank, (d) a handle to rotate the flywheel, (e) a wooden flywheel, (f) a chain, and (g) a gearing system.

2.3 Ease of Use

While the overall SC technique requires the presence of a trained technician, our mechanism will be usable by most adults and without any prior training. We measured that our device required 20W of human power input in order to produce the pressure drop necessary to induce sand dilatancy. A power output of 20W should be comfortable for most adults, who are capable of producing 200W for 10-20 minutes with limb power (fig. 4). For future prototypes we will also investigate the ergonomic and mechanical advantages of arm versus leg power in our design. At this point, it is best to first see how the technicians in India respond to an arm actuated device before declaring that an arm or leg actuation is preferable. Design research with our US affiliate, CIR, and JFO led to our first design choice of an arm actuated device.

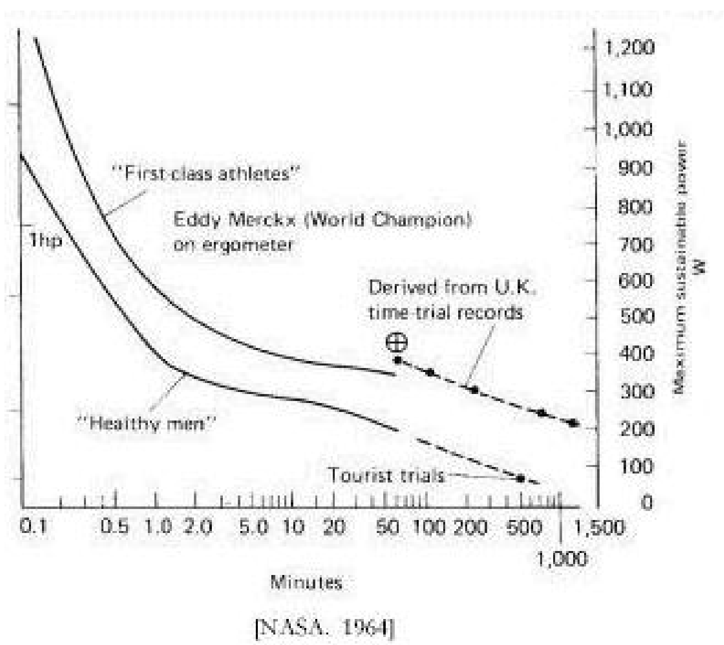

Fig. 4 The maximum sustainable power by a healthy human over the period of an hour.

While familiarity with a cranking motion is not necessary, many adults in rural areas will have experience using water wells, which require similar physical activity. In addition, we will incorporate different gear ratios into our design so that operators can elect with which setting they are most comfortable while they are preparing the reserve tank, which is the most strenuous step in the process. After the reserve tank is prepared, it can be sealed off with a ball valve until the technicians are ready to work with the patients and do vacuum casting. At that point, a hose will be attached between the reservoir and our device; during use, the reservoir will ensure that there is no vacuum loss in the plastic bag used for casting even if there is a pause in pumping. The tank essentially acts to isolate any discontinuous or variable pump actuation so that the SC process only sees the constant vacuum needed for the treatment. Since most components of our device are relatively simple, technicians in the field will only be required to know basic mechanics in order to repair it. In addition, we will design such that our machine will be able to withstand continuous, long term use.

2.4 Design Advantages

- **Mobility:** Our mechanism does not rely on the existence of grid electricity to operate and it is also small and lightweight. Therefore, transporting the device to rural areas is significantly easier than moving half a ton of POP. Additionally, rural areas that do not have access to grid electricity are unreachable by the current vacuum-casting technique, but could be served with the adoption of our machine.
- **Cost:** This machine saves money by eliminating the use of electricity that the current vacuum procedure requires and the non-reusable materials used in the POP procedure. Manufacturing and distribution costs are also much lower with our design than the commercially available electric device. The Vac-Cast manufacturing processes, as we envision them for the final design, are performable directly in India. The resulting lightweight machine is easily distributed to rural areas in a regular vehicle, which is in contrast to the commercial electric device that requires a truck for distribution.
- **Rate:** The complete vacuum-casting process takes approximately ten minutes to complete for every customer, a vast improvement over the hours required by the POP technique. Set-up time is also minimal with this device, as it would arrive at fitment camps and clinics completely ready for use. The technology is also easy and low-cost to repair, should something break.
- **Success Rate:** Field tests in Vietnam concluded that vacuum sand-casting produces a higher success rate in making a mold of the residual limb than the current in-field POP method. The vacuum-casting procedure had a success rate of approximately 90% and was deemed to contribute to a higher consistency of good fits. Our device would enable this proven SC treatment to improve the lives of thousands more people worldwide than the current commercial vacuum device can support.

3. Feasibility

3.1 Work to date

The Vac-Cast Prosthetics team formed in the D-Lab Design class shortly after the IDEAS Generator Dinner in February 2007. Since then, we have constructed an alpha-prototype and begun a beta-prototype of our portable vacuum pump that can be integrated into the CIR/JFO prosthetics molding system. Our first working device was a single linear piston adapted from a commercially available hand vacuum pump. The pump normally operates by squeezing a handle to load a spring and releasing the handle to allow the spring to drive a piston back through a cylinder creating suction. Since this relies on the use of muscles in the hand, the motion is very tiring. In our first device, operation was changed to a hand crank with a gear and chain that included a 2:1 speed increase and drove a cam that pushes the pump handle. Testing provided significant information and we are currently constructing an improved beta-prototype that will be finished in the coming weeks.

3.2 Implementation Plan and Scope

This summer, team members will travel to India with our prototype to work with members of JFO in Jaipur to improve the device design. Specifically, we will focus on better integrating our pump into the existing vacuum casting system and implementing user feedback from the doctors, technicians, and patients. This will be followed by locally building third-generation design that combines our efforts from the US and India.

Upon returning to the US, we will further re-design for manufacturing and failure in order to create a preliminary product for standard manufacturing. The final prototype will be subject to design review by CIR, local US prosthetists, and JFO. In addition to product generation, we will also document the trip and write a manual for fabricating, operating, and repairing the system. In anticipation of mass-production, we will reach out to US based vacuum pump manufacturers in September in order to find manufacturing and commercialization partners.

3.3 Timeline

Date	**Stage Completed**
	Alpha and Beta Prototypes
4-16-07	Complete alpha prototype
4-16-07	Analysis of alpha prototype
4-27-07	Complete beta prototype
5-05-07	Analysis of beta prototype
	First Trial
8-12-07	Travel to India
8-15-07	Build gamma prototype using locally available parts
8-19-07	Test and get feedback in urban clinic
8-23-07	Test and get feedback in fitment camp
9-02-07	Return from India
	Revisions and Manufacturing
9-10-07	Document trip to India and evaluate future work
Fall 07	Build delta prototype
Winter 07	Analysis and modifications to delta prototype
Spring 08	Set up manufacturing partners and procedures
	Technology transfer
Spring 08	Write manual (fabrication, operation, repair)
Summer 08	Introduce technology to other prosthetics providers

3.4 Challenges

The significant challenges we are addressing are the robustness and reliability of the system, the availability of parts, and acceptance for use in fitment camps. Since our machine is intended to serve thousands of patients in adverse conditions, such as those conditions found in disaster-stricken, developing areas, our device must withstand heavy use. Consequently, transportation and long duty cycles are very important factors to take into consideration. The most critical components of our system are the two hand vacuum pumps. Currently, these types of low cost vacuum pumps are used as a low tech diagnostic tool on automobiles and will be available in India.

The final challenge is to integrate the new component we are designing into the existing SC system and gain adoption by JFO and their clinical technicians. We will have to carefully track the adoption response if the hand powered pump is perceived to require additional labor or under-perform the electrically driven systems. Conversely, securing adoption will also depend on our ability to make it visible that the lack of electricity dependence in deploying the SC technique is an immense boon to the JFO mission. We expect that eliminating the material and transportation costs of the POP technique and decreasing the process time in fitment camps will accelerate the adoption of our device.

3.5 Support Network

Goutam Reddy is a member of our team. Having traveled to India and worked with JFO, he has helped us establish a support network of prosthetists and other professionals in both the United States and India. Additionally, Goutam has designed prosthetics and has a profound understanding, from his work with patients through JFO, of the potential impact of our device.

Yeongchi Wu is a prosthetist, the director of research at the Center for International Rehabilitation in Chicago, and an Associate Professor in the Department of Physical Medicine and Rehabilitation at Northwestern University. He is the inventor of the vacuum sandcasting technology currently being used by JFO.

Bob Emerson is an orothotist/prosthetist in Boston who does work with the Biomechatronics lab at MIT. He is helping us with questions on orthotics/prosthetics, amputees, and the fitment process in general.

Tarun Kulshrestha is the head of the sand casting project at JFO. He is based in the Delhi branch office. Goutam is in contact with Tarun concerning questions about the fitment process, camps, and materials used there.

M. K. Mathur is the chief medical consultant at JFO in Jaipur, India.

Amy Smith is a senior lecturer in the Department of Mechanical Engineering at MIT specializing in design for the developing world. She is the instructor for D-Lab, a class four of the team members are taking.

4. Community Connection and Impact

Since its inception in 1975, our community partner, the Jaipur Foot Organization (JFO) has provided over one million rehabilitative devices through treatment centers and camps all over India, along with 20 facilities in other developing countries such as Afghanistan, Rwanda, the Dominican Republic and Sudan. JFO, in collaboration with the Center for International Rehabilitation (CIR) in Chicago, Illinois, have since developed a rapid prosthetic fitting and development technique based on residual limb sand casting. This technique has been extremely useful for the rapid treatment of trans-tibial (below the knee) amputees.

Even with three dozen existing facilities around the world, JFO can only treat a fraction of the total number of new amputees each year. The pre-dominant treatment in the existing facilities consists of a lengthy fitment and prosthetic manufacturing process based on Plaster-of-Paris (POP) residual limb casting. For mobile camps to execute this rudimentary process nearly half a ton of POP must be transported. The new SC technique can reduce that fitment and manufacturing process to under an hour and a half per patient, with no material waste during treatment. The resulting dramatic increase in throughput efficiency of these facilities will allow the JFO to increase its impact along two lines; an increase in effectiveness and quantity of deployed mobile camps for rural and disaster-stricken areas, and an increase in the participation by patients who otherwise could not commit to a multi-day treatment.

In addition to individuals in India, we are in constant communication with the director of the JFO project at CIR, Dr. Yeong-Chi Wu, and a US based affiliate of JFO, Goutam Reddy. Both individuals were integral to the development of our technology as a real solution to the current technical issues that JFO faces in deploying SC at their facilities. Based on collaboration with Dr. Wu and Mr. Reddy, the device was designed specifically for manufacturing anywhere in the world, at minimal cost and mechanical complexity. Consequently, the principal component of our technology is a vacuum line testing device that is widely available in all parts of the world; it is a common tool in vehicle mechanic shops. Other pre-fabricated components include bicycle gears and chains, steel angle brackets and common fasteners. The device is also designed to meet the technical abilities of the JFO technicians who already use more complicated machinery to accomplish the same results as our technology provides.

During the first year of deployment, we will work with the prosthetics technicians to make further improvements that increase the utility of our innovation. Following success in Jaipur, India, we will assist JFO in creating a simple step-by-step pamphlet that details the manufacturing of the device. JFO can then either deploy the pamphlet to its associated clinics so that each group can build their own device, or we will work with JFO to organize a small, centralized manufacturing facility to produce our vacuum-casting device.

Budget

Item	Estimated Cost
Pre-summer	
Alpha prototype	$ 200
Beta Prototype	$ 300
Summer 2007	
Flight expenses (2 people)	$ 2200
Housing (2 people, 3 weeks)	$ 300
Food (2 people, 3 weeks)	$ 400
5 local prototypes	$ 1000
Post-summer	
Documentation	$ 200
Total	**$ 4 600**

The support of an IDEAS award will make it possible for our team to finish developing the portable vacuum pump and to perform trial runs to refine its design. Input and testing with experienced prosthetists and technicians will show us where we should focus our efforts. An IDEAS grant will allow us to travel to India to work with the people who will be using our device on a daily basis, improve our design, document and disseminate our work, and ultimately produce them to serve amputees in the hardest to reach areas.

Team Members

Goutam Reddy did his EECS and Math B.S., and Masters of Engineering at MIT working in the Biomechatronics Group (formerly the Leglab) on robotic prosthetics and orthotics. He spent 3 months in India working with JFO, studying their amputee fitment operations, and developing project ideas that MIT students can work on. He is currently trying to start a non-profit, Developing World Proshtetics, that leverages off of MIT students, classes, and projects to work on rehabilitation devices for the developing world.

Stephen Samouhos is a 1st year PhD student and Hertz fellow in the Mechanical Engineering Department, under the mentorship of Professor Leon Glicksman. Stephen has been a member of the MIT community since 2000, when he began his undergraduate studies in mechanical engineering. Over the past seven years, he has participated in over two dozen research and development projects, at MIT and beyond, in subjects ranging from tissue regeneration and waste heat recovery, to magnetic liquids and building design. Stephen's primary expertise is in thermal-fluids engineering, with an emphasis on the design of energy conversion devices. His role in this project is as a product designer, lending his diverse experience to the development of an effective total solution for the current limitations experienced by the Jaipur Foot Project.

Irina Azu is a junior in Mechanical Engineering with the intent to concentrate on sustainability for international development. She is interested in how mechanical engineering can be applied to formulate sustainable solutions for problems in developing countries, which is why she is taking a class in designing for developing countries. Her mechanical engineering related experience comes from working in the Laboratory for Manufacturing and Productivity, and the Pappalardo lab where she has had experience with CAD-CAM tools and basic machine tools. Among the different development related projects that she has been involved with a project through MIT that aimed at introducing alternate environmentally friendly energy sources for cooking in her home country of Ghana. On this same trip to Ghana she participated in the implementation and dissemination of human powered machines for processing agricultural products, namely a peanut-sheller and a cassava grater.

Maria Luckyanova is a third year undergraduate student in the Mechanical Engineering department. She is interested in thermodynamics and energy research, as well as appropriate design for international development and is currently taking a class in design for the developing world. Maria has experience in the MIT Lab for Manufacturing and Productivity, and the Edgerton Machine Shop. Additionally, she has been a machining instructor in the Pappalardo Machine Shop. She is also familiar with basic circuitry, basic welding, CAD-CAM tools, and mathematical modeling tools. She has international experience living in Berlin and working for Siemens modeling heat transfer through fault bearings for drives for large machines such as trains and submarines.

Tess Veuthey is a third-year undergraduate student studying Brain and Cognitive Science and Mechanical Engineering with a concentration in international development. She is interested in the empowerment of disabled people, demining, and the development of prosthetics and wheelchairs. She has machining and mechanical engineering design skills through working in the Pappalardo lab, the Laboratory for Manufacturing and Productivity, and the Edgerton

Machine Shop. She was a team leader for a group of students who traveled to Asia to teach science to high school students and is currently training new teams for that program. She is taking classes about the design and dissemination of technologies in the developing world.

Aron Zingman is a senior in Mechanical Engineering interested in machine elements and design. After graduation he will be working on mechanical design of endoscopic surgical tools. He has previously approached the issue of amputees in the developing world in MIT's Design for Demining seminar, trying to reduce the number of cases by developing a safer hand tool for excavating and removing land mines in very hard soils. The tool has undergone blast tests and is now in field testing with deminers in Sri Lanka. Other work for developing countries with limited electricity includes design and installation of a wind powered water pumping system and a biogas digester in Honduras with his D-Lab team during the fall semester of 2006 and IAP 2007. He is continuing work on the windmill in his senior thesis.

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