Optimization of Vacuum Pump Device for Use in Rapid Fitment of Prosthetic Limbs

By

Philip Thomas Garcia

Submitted to the Department of Mechanical Engineering in
Partial Fulfillment of the Requirements for the Degree of

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ABSTRACT

Developing World Prosthetics NGO has been in contact with the Jaipur Foot Organization in order to create a human powered vacuum pump for a new technique in prosthetic fitment. The new technique would provide mobility to fitment camps due to the non-reliance of an electrical grid. The design however would need to meet the demands of third-world conditions and heavy, continuous usage. This thesis seeks to explore a variety of mechanisms in order to meet the required specifications of the JFO and the new technique.

Thesis Supervisor: Daniel Frey
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1. Introduction

1.1 Background

Every year, there are over 25,000 new amputees in India as a result of disease, and agricultural, industrial and road accidents. About half of these victims receive a prosthetic device that is specifically made for their residual limb. The other half will not receive a 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. Also, service organizations are limited in their patient throughput by the finite resources that they can allocate per patient for the lengthy treatment. Each patient is give individual care, as shown in Figure 1, throughout the fitment process. Advancements in rapid manufacturing techniques of the prosthetic limbs have allowed for more amputees to be fitted than ever before. Work is being done continually in order to attempt to shorten the shaping process, specifically creating something that could take the technology out of the bound of an urban area.

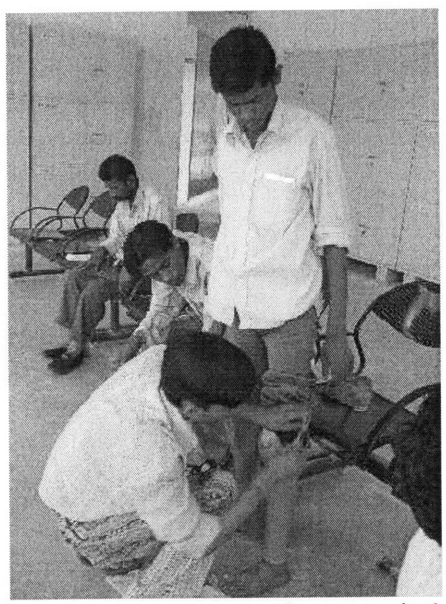


Figure 1: Patient being adjusted with new prosthetic limb.

Initially this project to work on developing a new human powered prosthetic limb fitment technique began in the D-Lab in association with the Jaipur Foot Organization (JFO) to help tackle many of the problems that the JFO faces with the current technique. A new fitment technique was developed in order to help increase the patient output and locations across India. Unfortunately, despite being able to fit patients at a greater rate, it has a major boundary condition; it was reliant on electrical power. The project was brought to D-Lab with the hopes that a group could focus on solving the issues regarding the rapid prosthetic fitment technique.

1.1.1 Community Partner

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 totally free of cost. 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.

1.1.2 New Fitment Technique

The new sand-casting fitting technique could increase patient throughput by a factor of five. This technique however cannot be deployed because its main support equipment, an electric vacuum device, is too costly and electricity intensive for a clinic to bear.

JFO and the Center for International Rehabilitation (CIR) co-developed a new sand casting technique to eliminate this deterrent of seeking treatment. The rapid sand-cast (SC) fitting process represents a cost savings both from operational expenses and the extensive per patient resource allocation in POP usage. Using SC, an amputee places his residual limb into a vat of sand, shown in figure 2(a), over which a vacuum is drawn. Through the dilatancy principle, the sand maintains a rigid negative mold (figure 2(b)). 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 hollow mandrel. In about 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.

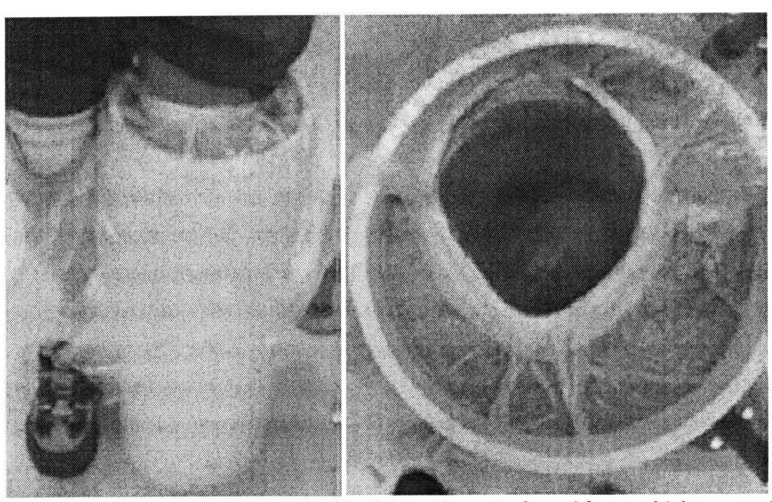


Figure 2: (a) An amputee putting his residual limb into the vat of sand from which a negative mold will be cast and (b) a negative mold of the amputee's residual limb using vacuum sand-casting.

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 cannot be distributed to all JFO clinics. Consequently, the majority of JFO clinics cannot employ the highly successful SC technique, and are relegated to antiquated POP molding techniques.

1.2 Objectives

The overall goal of this thesis is to take an existing system, the human-powered vacuum pump constructed by DWP team last August (2007) for SC fitment, and improve its performance. The prototype that was created had a list of problems that the JFO had created in order to aid in the creation of a new product. The biggest setback was the lack of volumetric flow rate from the device.

This thesis seeks to explore the vacuum pump system as a whole. Attempt to find a solution to increasing the flow rate, maintaining vacuum, and the finding the best and most user-friendly actuation of the pumps. The solution must also be within the scope of capabilities of a third world manufacturing system. Low cost and simplicity are the paramount attributes for the device. When the design and fabrication is complete it will be transferred to the JFO in order to be implemented into the field stations all over the developing world.

1.3 Summary of Results

The new technique of casting and created a prosthetic fitting is a promising method. The process requires a large electrically operated vacuum device which limits its use in rural camps. Design for a possible solution to the problem lies in the creation of a human-powered vacuum device. Exploration of the solution to the best human-powered device mainly was found around the scope of actuation. Developing a solution that is low cost, user-friendly, easy to repair and robust has had its many challenges.

The final design was relatively simple and generated enough vacuum for the process to take place. It eliminated any easy failure points that could occur during operation, and completely removed any sliding actuation. The completed prototype will be transferred to the JFO so that a system can be put in place to reproduce the device for all the rural satellite facilities. The technology transfer will enable the JFO to implement the new system in all of its fitment camps and drastically reduce the time per patient fitment.

2. System Integration

The predominant fitment in existing JFO facilities consists of a multi-day, per patient fitment and prosthetic manufacturing process based on POP casting (Figure 3). Mobile camps that execute this rudimentary process must also transport nearly half a ton of POP to other satellite 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 more 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 cannot 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 individual technician attention 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.

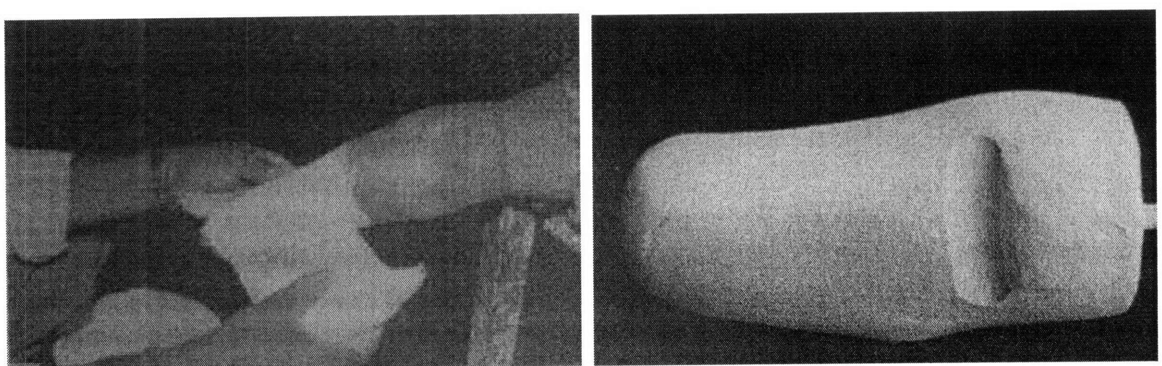


Figure 3: (a) Wrapping of the limb in POP soaked cloth to make negative mold and (b) a positive mold made from the negative composed of entirely POP.

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.

The new SC technique would help eliminate unnecessary wasted time for drying and preparation. To overcome the existing limitations of deploying the sand-casting technique, work on development of a simple alternative to the vacuum machine in current use has been underway and this thesis seeks to explore as well.

The significant challenges to address are the robustness and reliability of the system, the availability of parts, and acceptance for use in fitment camps. Since the device is intended to serve thousands of patients in adverse conditions, such as those conditions found in disasterstricken, developing areas, the device must withstand heavy use. So, transportation and long operation cycles are very important factors to take into consideration.

2.1 Brake Bleeder Pumps

The initial D-Lab prototype used the pumps shown in figure 4, the U.S. General 92474. This technologies primary purpose is to bleed brake fluid into a small container. Its main cylinder is about 8.5 cm in length, the length of the lever and handle are both about 16 cm and the maximum distance between the two is about 8.5 cm. The stroke moves about 2.5 cm back and forth. The given statistics for the pump are that the pressure drop is between 0-30 inches Hg or 0-76 cm Hg.

Figure 4: U.S. General 92474 Brake Bleeder Hand Pump

Understanding the mechanics of the pump is one of the first steps to take when integrating them into a new system. The pump utilizes a spring in order to help retract the handle to its equilibrium position. Unfortunately no data was available from the manufacturer about the spring constant. Therefore, using a force meter available in the 2.671 lab, by placing the gauge about 2cm from the end of the lever and securing it firmly benchmark testing of the constant can commence. By pulling and holding steady an approximate force then recording the change in position for the applied force the constant can be determined.

Knowing that the lever arm came into play the results needed to be modified in order to find the exact force on the spring. The distance from the position of the force meter (Position 1) to the pivot was about 9cm, and the distance from the pivot to the plunger (Position 2) is about 5cm. Now, by multiplying the recorded force by the ratio of the two we can determine that force the spring actually felt. After converting all of the experimental data into workable units, the slope of the plot can be determined giving an estimate of the spring constant inside the pump.

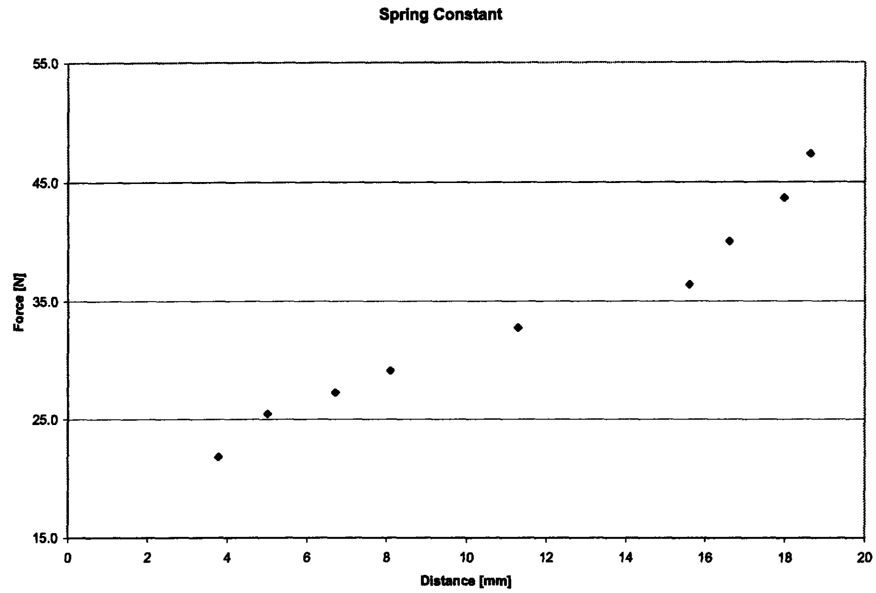


Figure 5: Experimental Results giving Spring Constant Found in Pumps

The data plots the graph above, figure 5. Using a regression function available on the spreadsheet system used to plot the graph the constant of the spring is found to be 1.46 Newton's per millimeter. That constant translates to about one pound per three millimeters moved. Now, assuming that the force to work the vacuum pump is primarily from the spring inside the pump, a better understanding of the system can be utilized for a more efficient design.

2.2 Air Evacuation

Now, knowing what technology will be used for the design, the next step is to find out how much air is in the volume of sand used in the sand casting process in order to find the flow rate necessary to evacuate the air in a couple of minutes. Using the 50-pound bag of play sand that was available, and using about 500 milliliters for experimentation. Then using a kitchen measure cup and two containers, it is possible to separately obtain the same volume of both the sand (with the volume of air in-between) and the water.

The two were then combined and left alone in order for the new mixture of sand and water to settle. This was done twice for both 100mL and 200mL combinations. Next, the container for the evacuation needed to be measured in order to find an approximate value for the amount of air that is to be evacuated. The inner diameter and height were used for the estimation of volume. Knowing that the process should be completed in about two minutes and given that $V_{cylinder} = \pi h r^2$ and the estimate of the volume of air in-between sand the flow rate can be determined.

Below are the results of the sand experiment. This experimentation relies on the displacement of the volume of air in-between the sand with the water that was mixed in.

	Air+Sand [mL]	Water [mL]	Sand+Water [mL]	Air [mL]	Fraction
1	100	100	175	25	25%
2	200	200	360	40	20%

Table 1: Results of Air in Sand Experiment

3. Optimization

3.1 Alpha Prototype

The initial prototype utilized the hand pump brake bleeders described above. Since the main design goal is to increase the flow rate and ease of use of a premanufactured hand pump, the device simply adapts this manual pump to continuous operation via a hand crank actuator. The rotary cam actuator eliminates the squeezing motion used to actuate the pump while also giving the user a mechanical advantage that reduces the strength needed for pump operation. Moreover, using two vacuum pumps not only doubles the performance of the device but also to create a useful pre-load on the cam actuator. By using a chain and gear drive, crank handle, and cam preloading, the device (Figure 5) is able to get both continuous pump actuation and vacuum.

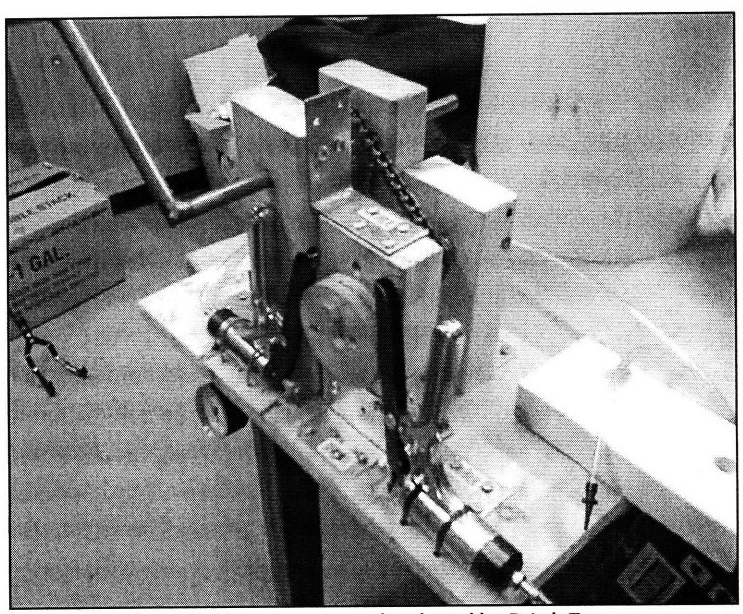


Figure 5: Alpha prototype developed by D-Lab Team

'Pre-loading' the cam is essential due to the rough wooden construction; without this design component, the unbalanced 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 cam is positioned such that when one pump is in full extension, it is pushing on the cam to assist in extension of the second pump.

In the alpha prototype, most of the components including the base, cam, bearing blocks, flywheel, and crank web are all made of wood. The most complicated components of the mechanism are the chain and gear which are locally available as old bicycle parts. Additionally, the gears acquired only have a ratio of 2:1. So it achieved its goal of being relatively simple to make with readily available parts.

The device was a step in the right direction in terms of making an easy to use human powered vacuum device, but it also had a myriad of problems associated with it. The sliding motion from the cam was very rough and inconsistent, and that cause the cranking motion to stick during operation. It was clear that a different approach needed to be taken.

3.2 Beta Prototype

The second prototype that was created utilized the same brake bleeders but, in order to gain higher flow rate, used two pairs of pumps. Also, to eliminate the many problems associated with sliding motion a linear push-pull lever system (Figure 6(a)) was implemented to actuate all four pumps. The main feature of the design is the ability to utilize the spring force, as shown in figure 6(b), in each of the pumps against each other in order to facilitate the pumping motion. With that in mind, it was possible to actuate using a lever arm due to the play in the piston motion. The linear design, and set-up, made it possible to place two more pumps parallel to each other, totaling to four pumps used in every stroke.

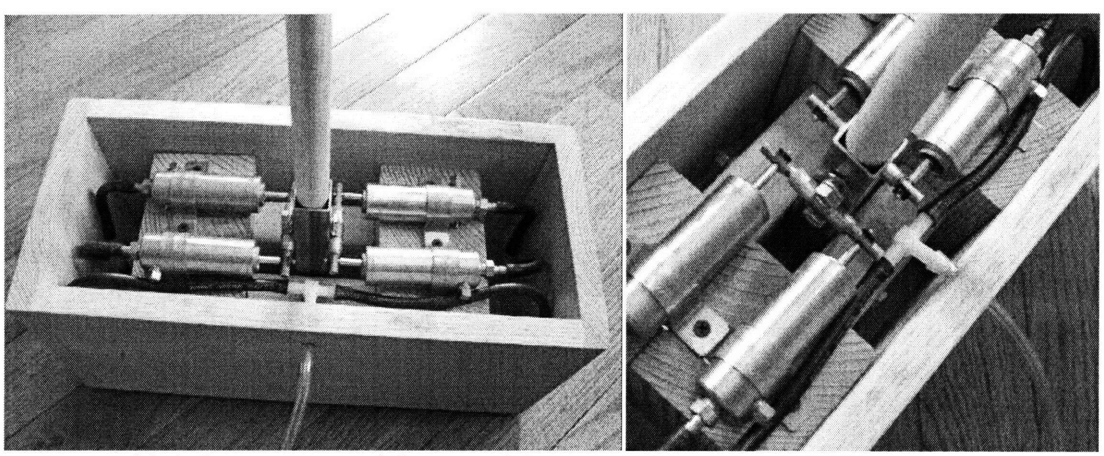


Figure 6: (a) The beta prototype in full view and (b) a close up of the push-pull linkage utilizing the springs inside the pumps

The pumps themselves are designed to evacuate about one cubic inch for each stroke. The observation above is a good indicator of the prototype stroke volume performance. When the prototype was tested it was able to evacuate a half liter bottle in about 18 strokes. The experimental results can be confirmed by the pump characteristics available. Due to the preloading each stroke takes about two cubic inches of air out of the container.

The table below shows some evacuation time estimates for the current prototype as a function of volume of air and stroke per minute (SPM).

Volume	Number of Strokes	SPM	Time [s]
1L	30	60	30
1L	30	120	15
2L	60	60	60
2L	60	120	30
1gallon	115	60	115
1gallon	115	120	58

Table 2: Results of evacuation rate experiment

The materials used were available at the local hardware store. The pumps were ordered from Harbor Freight. Going in line with the initial goal of creating something within the capabilities of a third world nation, this device was a bit more complex. It required some common plumping accessories, such as the head plug, clamps and nipples, which could be a burden to find in rural India.

Material	Cost	Per	Quantity	Total
8 inch Oak Board	$3.95	Foot	8	$31.60
Pipe Nipple	$1.56	Unit	2	$3.12
1 inch Box Extrusion	$3.33	Foot	3	$9.98
Pipe Clamps	$0.19	Units	4	$0.76
7/8 inch Dowel	$1.83	Foot	1	$1.83
2 inch x 4 inch stock	$0.51	Foot	3	$1.53
Rubber Feet	$0.62	Units	4	$2.49
1/8 inch Square Head Plug	$1.24	Units	4	$4.96
Tubing	$1.13	Foot	3	$3.39
Y' Connectors	$0.67	Unit	3	$2.00
1/4 inch Steel Rod	$0.99	Foot	3	$2.98
Pumps	$19.99	Unit	4	$79.96
			Grand Total	***$144.60***

Table 3: Breakdown of Costs and Materials for Beta Prototype

The cost itself was relatively low for a prototype. Once a manufacturing process is laid out and materials are bought in bulk it will cut the cost down significantly. As shown above, in Table 3, the most expensive item was the integrated technology itself, the pumps. Ideally what would happen if this process is adopted the pumps would have to be shipped to the manufacturing sites directly with aid from DWP in order to be available.

Unfortunately when testing in the field, in Delhi and Jaipur, the device again did not have enough flow rate evacuation in order to create and hold the necessary vacuum to fit a patient. The four pumps working together did not have enough volume. In addition, the handle after continuous use began to become loose and lost rigidity. Once again, improvements were made on the existing device although fundamentally the equipment is flawed.

3.3 Gamma Prototype

Unfortunately the brake bleeders, which were designed for vacuum, do not have enough volumetric displacement per pump. Due to the finite number of bleeder pumps that can be install on a reasonable sized device, a new focus of looking towards other means of creating the vacuum is needed. A direction to explore lied in simple portable bike pumps. These pumps were not designed to create vacuum, but to pump air into a cavity. But, by reversing the one-way valves they would be able to be utilized in the next iteration of the device.

Initially an attempt was made to use the push-pull actuation as in the beta prototype but the previous push-pull lever could not be used due to the large increase in size of the pump cylinders. The arc that a single pivot push-pull system would be too large for linearly constrained pumps to handle. Also, it would not have a mechanical advantage as in the other prototype due to the lack of spring force helping the pump return to equilibrium.

The new bike pumps have about 3 cubic inches of volume available as opposed to one cubic inch in the previous technology. Therefore, these new reversed bike pumps would ideally increase the volumetric flow rate by 3 when compared to the bleeder pumps. This, in theory, would be able to solve the most pressing problem of increasing the flow rate to maintain a strong and steady vacuum.

Unfortunately these pumps also had some negative aspects as well. As stated before, unlike the brake bleeders these pumps did not have springs to set an equilibrium position. This presented new problems in terms of actuation due to the lack of assistance by the spring. After looking at many methods of trying to couple these pumps in a user friendly fashion the final design fell back on a somewhat modified alpha prototype cam design. This actuation method would incorporate rotational motion to linear displacement through means of large cams, as shown in figure 7.

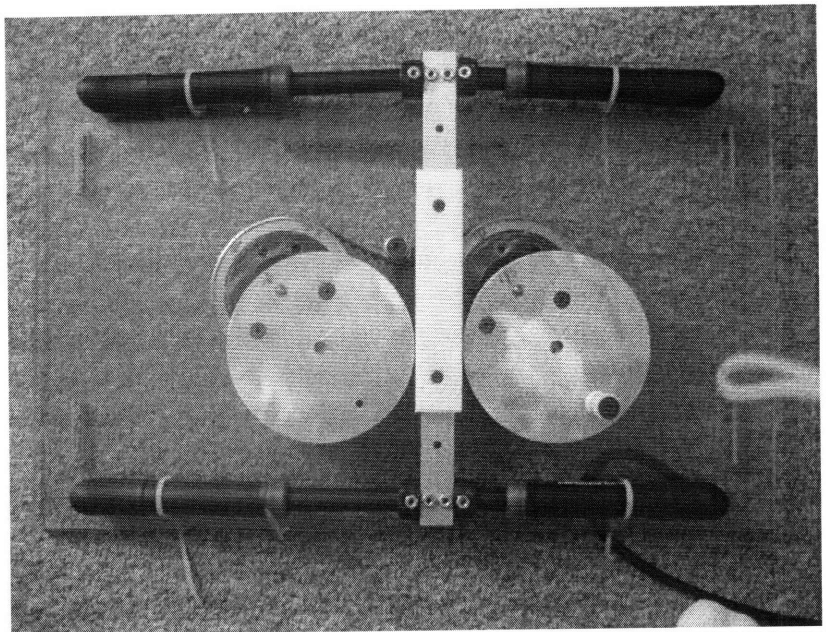


Figure 7: Gamma Prototype design with two large rotating cams displacing a linear linage bar

One problem with initial design drawings and models dealt with the maximum extension of one side of pumps and the jamming that could occur. A solution to the problem is to have the two large cams connected to a timing belt and sprockets so that the cams would not lock up and any position during the stroke. One cam would have a handle sticking off in order for the user to operate. While the cam is in motion it would slide against the Teflon link bar and move the pumps in a linearly.

This version of the solution was taken to India and tested by the author during a clinical trial. Although the device did work, it doesn't meet the other set requirements for the technology transfer to occur. It was not nearly robust enough to take the wear and tear of daily use, it could barely handle several sessions without some adjustments. The use of many components, sliding action, and choice of materials eventually led to the dismissal of this model.

3.4 Final Design

After discovering the fact that using bike pumps with inverted valves will increase the flow rate to the operating condition, the other pieces of the problem needed to be addressed. The new design needed to be more user-friendly, robust and durable.

The pump actuation has a fairly close parallel to an engine and the pistons pumping inside. Those pistons inside the engine are actuated through the rotational crank shaft. After a careful look at possible designs, that very same system could be used with the bike pumps. Not only has the crank shaft actuation eliminated the sliding motion associated with the cams, but also increases the ergonomic feel of the system. The more natural user interface of a vertical rotational crank will be added in order to rotate the crank shaft.

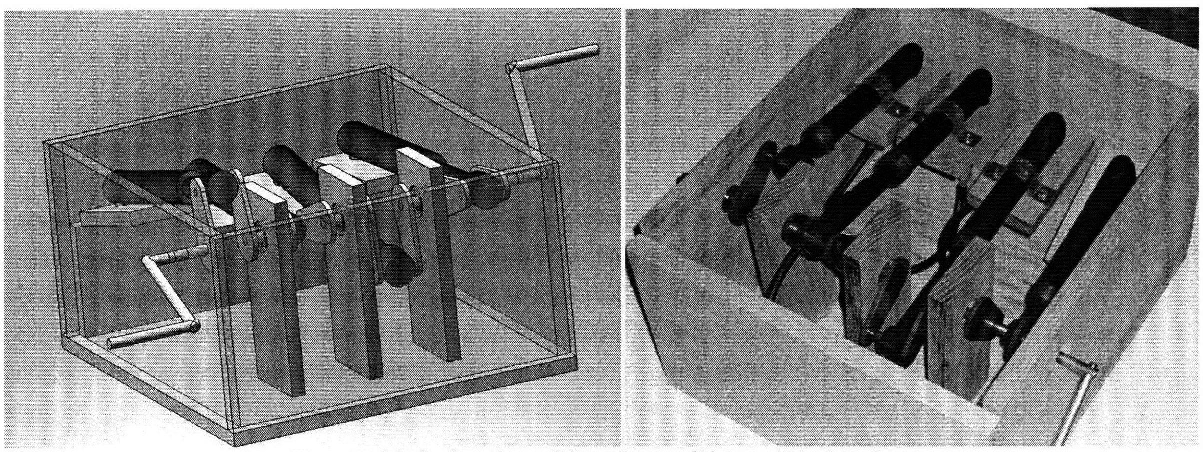


Figure 8: (a) Final Design solid-model and (b) Actual Final Design

Work was done especially on trying to make the system run as smoothly as possible. And like an engine, there is an order in which the cylinders must 'fire'. Firing order is critical to reducing unnecessary torques and vibrations in engines and the same concepts can be used to help increase the smoothness of the operation of the device.

The crank design itself was mainly governed by the pumps. The cranks range of motion uses all of the extension provided from the pump for maximum suction continuously. One problem faced was how to constrain the pumps and let them be actuated by the shaft. That range of motion is allowed by having the pumps themselves constrained to a hinged board. The board would have a hole for the end nipple of the pump to constrain rotation, and the pumps would be constrained to the plane through the use of pipe clamps.

The bearing blocks were also essential in the design. Due to the fairly precise motion, and the length of the shaft it need to have support to prevent any sagging or bending. Using rolling element bearings supported by a block, the shafts are supported enough to handle the torque generate during operation.

Material	Cost	Per	Quanitity	Total
9 inch Oak Board	$4.25	Foot	8	$34.00
3/4 inch Pipe Clamp	$0.19	Unit	4	$0.76
4"x12"x3/16" Steel Plate	$11.12	Unit	2	$22.24
3'x2'x3/4" Pine Sheet	$4.99	Unit	1	$4.99
Tubing	$1.13	Foot	3	$3.39
Rubber Feet	$0.62	Unit	4	$2.48
Ball Bearings	$5.42	Unit	5	$27.10
Hinges	$1.23	Unit	4	$4.92
Y Connectors	$0.67	Unit	3	$2.01
Pumps	$5.99	Unit	4	$23.96
3/8 inch Steel Rod	$7.07	Foot	3	$21.21
Grand Total				**$147.06**

Table 4: Breakdown of materials and costs for Final Design Prototype

Once again the device is low in cost. The most expensive items are the oak board, steel plate, steel rod, and ball bearings. The wood type can be interchangeable with most reasonable hard woods, which will make it easy to assemble in India. The steel plate was used to make the extensions for the crank shaft, but could also be replaced with more steel rod. The rod is another easy to find piece of scrap in India, and can be changed in thickness to accommodate to what is available. Finally, the ball bearings can be neglected completely if they are unavailable. A simple greased wood bearing can be used for the crank shaft. It will undoubtedly increase the resistance of the turning, but it will still be at a tolerable level. These adjustments will bring the cost down to about $50 per unit.

4. Analysis

4.1 Design Advantages

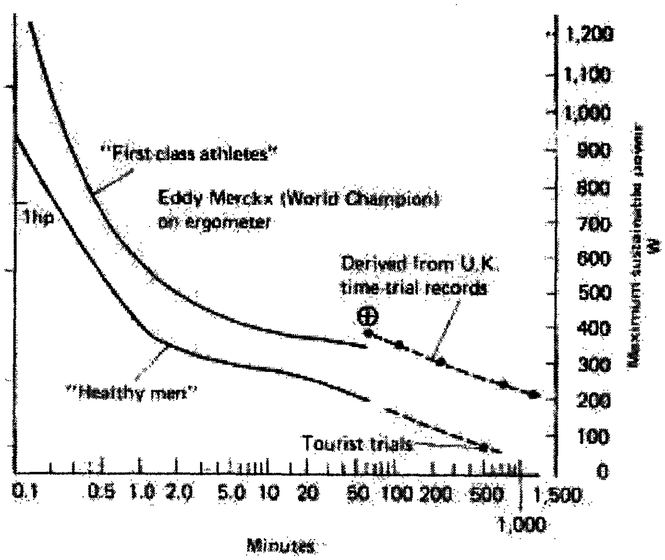
The mechanism does not rely on the existence of grid electricity to operate and it is also relatively small and lightweight. It saves money by eliminating the use of electricity that the current vacuum procedure requires and the non-reusable materials used in the POP procedure. Manufacturing and distribution costs are also much lower with the design than the commercially available electric device as shown above. 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 heavy-duty truck for distribution or to moving a half ton of POP.

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 due to the low part count and mechanical transparency. Also, since most components of the device are relatively simple, technicians in the field will only be required to know basic mechanics in order to repair it.

CIR 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. The device would enable this proven SC treatment to improve the lives of thousands more people worldwide than the current commercial vacuum device can support.

4.2 Ease of Use

While the overall SC technique requires the presence of a trained technician, the mechanism will be usable by most adults and without any prior training due to the simple design. 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. A good estimate of the power require in order to produce the pressure drop necessary to induce sand dilatancy is about 20W. A power output of 20W should be comfortable for most adults, who are capable of producing 200W for 10-20 minutes with limb power (figure 9).



[NASA. 1964]

Figure 9: Maximum sustainable human power output as a function of time

5. Future Direction

Now that the device had been completed and ready to be shipped, it will be taken to India for an official technology transfer.

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

6. Conclusions

The performance has increased steadily through the different iterations. Although, there is an assortment of ways to make the system better, specifically through pump performance. Ideally, this device would find a way to manufacture pumps with vacuum valves in order to minimize losses. The configuration of the pumps currently does not allow for an easy disassembly, and steps could be taken in order to remedy that problem. Those problems and future considerations will undoubtedly be discusses and mitigated in the fitment system implementation this summer.

7. References

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