Low Cost Transfemoral Prosthetic for Developing Countries

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Section 1: Needs Finding

1.1: Strategic Focus

There is no doubt that there is an overwhelming need for affordable, functional prosthetics for those in developing countries. In terms of specific need, prosthetics for legs are in greater need than other prosthetic categories. A leg amputation debilitates an individual in a way few other amputations do, through immobilization and increase in their reliance on others. This fueled the choice to choose a lower limb prosthetic over other options. Because of the increase in the prevalence of rapid prototyping technology, crowdsourcing design expertise and manufacturing opportunities, it is ideal time to develop this kind of customized medical device. It is a field which will only grow, and creating a prosthetic that can be designed, altered, and produced in this way means a greater number of less expensive limbs for those who need them.

Team Foot Fighters is qualified to develop this technology because of our unique skill sets and areas of expertise. Foot Fighters is comprised of two mechanical engineers, a civil and environmental and biomedical engineer, and an industrial designer. In addition to Foot Fighter’s group interest in serving underserved populations, the members of the team all have skills that will be essential to developing this kind of device. Deepak and Angela have experience working in developing nations, and have a unique perspective on their specific needs. Veronica has previously conducted research in the engineering of artificial joints, and Lea has extensive experience conducting user-centered research, and developing user-centered products.

1.2 Needs Exploration

People in developing countries do not have ready access to customized prosthetic limbs, resulting in removal from the workforce, disintegration from local society and general illn. Most current prosthetics are too expensive or too crude to provide a long term solution. Few existing solutions for leg prosthetics such as the Jaipur-Knee and Niagara Foot offer excellent performance at a low price point but still significant improvements can be made in comfort, gait, and durability. Providing a durable, low-cost, natural gait above-knee prosthetic leg would improve daily living for millions. There is a tremendous market of more than 20 million amputees worldwide in rural and urban impoverished areas with incomes of only a few hundred dollars annually that require such a device. Based on key stakeholders, Foot Fighters can see the positive end result to be one of increased mobility and re-assimilation into society and the workforce allowing better economic status and quality of life for both the amputee and their family.

Problems experienced by users include abnormal posture, limp, stride length, and speed [4]. These can be a result of the prosthetics length, shape, or weight. A prosthetic that is too heavy affects the user’s speed and energy. A prosthetic that is too long can affect the user’s posture and cause long-term issues like back pain, pelvic pain, osteopenia, and osteoarthritis [6].

Meanwhile, the prosthetic-human interface is crucial for reducing discomfort, limp, and pain. A customized fit is needed to create a functional limb that does not negatively affect the user. A prosthetic that slips off in rain or sweat can be a discomfort and inconvenience. If the prosthetic fit does not take into account the person’s physiology, the device would be uncomfortable to wear and could cause pain and osteopenia. Most above-knee prosthetic users, for instance, have lost function of their hip or pelvis [2]. Furthermore, those without the ischial bone have more difficulty distributing their weight, making
them more prone to pain, bone fracture, and/or bone reabsorption. An effective prosthetic therefore requires a combination of mechanical and biomedical skills to design.

A prosthetic must be useful and convenient. Users should be able to use their prosthetic limbs in different environments. The prosthetic must also be accessible, meaning they can acquire it close to home, repair it close to home, and be at an affordable price [1]. Ideally, the users would not have to travel long distances for purchase and maintenance of limbs.

There is some level of risk to the provider if the prosthetic malfunctions, and it is best to reduce this risk. If the prosthetic breaks easily or can only be used in particular environments, the customer may be dissatisfied. The provider would likely object to selling a prosthetic that breaks easily in determined environments, since customers demanding money back would cause problems for the provider’s business. Providers also do not want to be liable for injuries incurred while using the prosthetic. The provider runs a risk of being seen as responsible for prosthetic failure or problems developed after immediate/long-term wear.

Typical solutions for current amputees range from very crude methods to well-engineered prosthetics which are only available through NGOs. Solutions such as pole legs bamboo-plaster limbs are not durable and can harm the user over time due to an unnatural motion. JaipurFoot offers prosthetics free of charge, but relies on donations which have less reach than a robust free-market solution [1]. However, the leg is still expensive to make. Typically, prosthetic legs built for extended use cost between $50 to $125.

1.3 Needs Development

Our low cost above-knee prosthetic is a way to address transfemoral amputation and birth defects in impoverished rural and urban communities in developing countries. This device can positively improve their livelihood by increasing mobility and thus re-integrating users into the local society and economy.

A successful solution would be affordable by the majority of users. By using materials accessible in target areas we can reduce purchase and repair costs. The device must be safe & compatible with the user, and superior to existing designs in this way. The design must be ergonomic so that it does not cause immediate or long-term pain. It would also have to be useful in different environments and activities for it to be fully functional. Users require a design they can use on different types of terrain and use to perform daily-to-day activities.

Our final solution will thus be a mix of blue-sky and incremental approaches to create much lower cost prosthetics using existing technologies. Incremental solutions will be used for some parts of the prosthetic such as the modification of the existing Jaipur-Knee to focus on durability and affordability. We need to address the shortcomings of this device when making our design. We will also need to implement some blue-sky ideation to create a cheaper more comfortable socket and natural gait using advanced designs in a cost-effective manner.
Section 2: Needs Screening

2.1 Disease State Fundamentals

The needs of a leg amputee are multi-faceted, and these need to be considered during the design process. A leg amputation results in a disabling condition in which the amputee cannot walk without support. With modern prostheses and treatment methods, good musculature and circulation, many amputees can do several of the things they could before amputation. However, many people in developing countries cannot afford to get these modern prostheses and treatment options.

Amputation is generally caused by accidents, diseases, and congenital disorders. In developing countries, 80-85% of amputees are land-mine survivors. Other causes of amputation include industrial or environmental accidents, terrorist attacks, and the lack of public health which leads to diabetes, gangrene, and infection. Congenital birth defects can also result in no leg. A trans-femoral amputation is the second largest type of amputation. [11]

A trans-femoral amputation is above-knee. Surgeons preserve as much of the leg as possible, avoiding leaving unnecessary skin and muscle. The longer the stump, the better control over the prosthesis. Many surgeons separate bones at the knee to preserve the entire thigh, helping the stump carry a substantial portion of body weight. Many of our interested party may not have had access to a surgeon experienced in amputation, so stump length may vary, as well as strength.

Depression occurs after amputation, as well as edema, or swelling of the stump. Without proper care, such as dressing and exercising, the muscles and contractures may tighten, preventing effective use of a prosthesis.

When fitted with a prosthesis, it may take several weeks or months to get accustomed it. This recovery is not without a cost. This takes a huge economic toll on the amputee, as they most likely can no longer work their previous job, need assistance to rehabilitate, and take on the huge cost of many prosthesis over their lifetime.

2.2: Existing Solutions

There are three standards for comparison for a low cost prosthetic for the developing world:

1. High quality, high cost prosthetics that may somehow be made cheaper.
2. Low quality, low cost prosthetics, often makeshift, that may somehow be improved.
3. Low cost, mid quality prosthetics that are already aimed at the developing world that may be made cheaper, more available, or higher quality.

There are several types of high quality prosthetics in use today. In the 1990’s, Sabolich Prosthetics introduced sockets with a patient contact model designed for each particular patient. These sockets are made to attach like a glove to lock in place, and are made to fit a patient’s residual limb, rather than the square “bucket” that was used before. This technology is now the standard in high quality limbs, and has expanded into bio-elastic sockets, sense-of-feel technology, and suction sockets.
Ottobock is now an industry leader in prosthetic limbs, and has several models that represent the technology available today. The C-leg (Figure 1), introduced in 1997, uses a microprocessor and a battery to mimic movements of the knee and create a dynamic gate. The C-leg consists of a carbon-fiber foot that absorbs shock, a tube adapter, and a knee joint with either a pyramid or screw-top connector. It also comes with a protective cover to give a more human-like shape to the leg, as well as a smooth surface that won’t catch on clothing. The user can adjust the leg via a mobile app to configure it for different activities. The C-leg senses when the user is on insecure terrain, and will increase its resistance to provide support until it senses that it is stable [12].

Ottobock’s Genium leg (Figure 2) is an additional microprocessor limb that automatically adjusts itself under a variety of conditions, such as walking speed and direction, whether the user is sitting or standing, and is the only microprocessor leg that allows the user to climb stairs under their own power. Both the Genium and C-leg resemble the form of a human leg, although they look bionic, not like human skin. The cost of both these legs can range from $50,000 to $70,000 based on specific features and add-ons [12].
Ottobock and Ossur both make a fitness leg (Figure 3) with a carbon-fiber foot that has a cheetah-like form, and stores vertical forces and translates them into a horizontal motion. These legs do not include a microprocessor, because they are not meant for moving at different speeds. They consist of a carbon fiber foot with a textured sole, a lightweight knee, and a thin socket with a liner. The legs are extremely lightweight and compact. Fitness legs are not meant to replicate the shape of a human leg. A custom fitted fitness leg can cost up to $30,000 [12, 14].

In the developing world, makeshift limbs are often the only option for amputees. Handheld pole legs and sawed off crutch legs (Figure 4), which consist of a crutch and either a leather strap or a handheld pole with a platform to support the leg. With these crutch solutions, contractures can easily form very rapidly in the knee if the leg is not stretched and rotated daily. Plaster, bamboo, and PVC limbs (Figure 5) are a step above crutch legs, in that they keep the leg in a natural position. The leg is padded, bandaged, and plastered. A piece of PVC pipe or bamboo is attached to the plaster to create a shin, and a foot is fashioned out of wood and rubber. None of these options remotely resembles the form of a human leg, yet are very inexpensive, if they have any cost at all. However, other than allowing the wearer to balance weight on the limb, have no feedback or suspension to aid in walking, running, or other tasks [11].
Lower fidelity, but still functional products made specifically for the developing world, have the advantage of being made from locally or easily transportable materials, and the opportunity to be produced by those in the local area. The bicycle limb (Figure 6) is made from the disassembled parts of a bicycle. The foot and shin are made of the bike seat and the seat support frame. The foot and shin are attached to the wheel support frame which acts as the calf. A socket is made over the residual limb, which is padded, plastered, and attached to the bicycle limb [11].

The Jaipur Knee (Figure 8) is a $20 mechanical joint-replacement made for the developing world. The knee replicates normal human gait by providing stability in stance and easy movement. Although it is not a full-functionality limb replacement, it has level of functionality higher than is usually provided from a low-cost joint. It accomplishes this through four-bar linkage geometry. It is constructed of an upper and lower body block, two side linkages, and a mid-linkage, held together with four bolts.
The Mukti limb (Figure 7) is made of high-density polyethylene irrigation pipe, and can be custom made in five hours. The HDPE is flesh-toned and can be molded easily when heated. First a plaster mold is made of the residual limb, then the HDPE is heated in an oven, attached to the cast of the leg, formed, and allowed to cool. A pre-made foot is then attached. A Mukti leg can also function as a brace for a remaining limb that is lacking some functionality. These legs take on the human form, and achieve a believable human color [11].

![Figure 8](image1.png) ![Figure 9](image2.png)

The most advanced prosthetic legs available in a reasonable price range for the developing world are customized and created via CAD software. The Monolimb (Figure 8) is a popular leg prosthetic, costing only $35. A plaster cast is taken of the residual limb, and digitized in a remote location. A socket is manufactured from a thermoplastic sheet, and a Patellar tendon bar is used for suspension of the leg. To increase height, plastic spacer discs are placed in between the foot and the socket. A cosmetic shell is made from polyethylene material, and flesh-tone plastic or surface coloring is used to match various skin tones [14, 15].

Enabling the Future is a crowdsourced effort to provide 3d printed “Limbitless” arms (Figure 9) to those who cannot afford a professionally fitted solution. CAD files of various hand models are available online, and can be adjusted digitally to fit the user. Arms are then 3d printed, assembled, and fitted with a muscle sensor, an Arduino, and an Aircraft Servo motor. The limbs are held on with foam inserts and Velcro straps, and include rubber finger grips. The estimated cost of a Limbitless arm is $350, which may fall on the wearer or the manufacturer. Limbitless arms can be color-customized and take the form of human hands, but are not a cosmetically convincing limb replacement [13].

Our above knee limb replacement should be more comfortable, useful, and lifelike than the makeshift solutions currently in place, and may be more advanced that solutions such as the Mukti limb. However, for cost and knowledge resource restrictions, cannot be as responsive as the C-leg or Genium leg. Our limb will most likely resemble the model of the Limbitless arm, in which a 3d scan is taken of the residual limb, and a CAD model of our prosthetic leg will be adjusted and 3d printed to fit the user.
### Benefits and Disadvantages/Risks Chart

<table>
<thead>
<tr>
<th>Treatment Category</th>
<th>Treatment Opportunity</th>
<th>Benefits</th>
<th>Risks/Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete limb replacement (functionality)</td>
<td>C-leg Genium leg</td>
<td>Provides feedback to user, automatically adjusts for different conditions, most functionality out of a prosthetic.</td>
<td>Extremely expensive, artificial appearance, cannot be locally or quickly made</td>
</tr>
<tr>
<td>Agility-focused replacement</td>
<td>Fitness leg</td>
<td>Carbon-fiber foot stores energy like a leg could, opportunity for material application</td>
<td>Can only be used for fast speed, no feedback</td>
</tr>
<tr>
<td>Low Cost alternative</td>
<td>Makeshift limbs (category)</td>
<td>Cheap and easy to produce, provides opportunity to be mobile</td>
<td>No feedback, no joint replacement, can cause strain to other parts of body, can damage residual limb</td>
</tr>
<tr>
<td>Low Cost alternative</td>
<td>Bicycle limb</td>
<td>Cheap and easy to produce, more comfortable than plain crutch</td>
<td>No feedback or joint replacement</td>
</tr>
<tr>
<td>Low cost</td>
<td>Mukti limb</td>
<td>Cheap and easy to produce, more comfortable than plain crutch, more lifelike appearance</td>
<td>No feedback or joint replacement</td>
</tr>
<tr>
<td>Moderate limb replacement (functionality)</td>
<td>JaipurKnee</td>
<td>Cheap, functional</td>
<td>May not be able to produce locally, no ankle joint</td>
</tr>
<tr>
<td>Low cost</td>
<td>Monolimb</td>
<td>Inexpensive, easily customizable and adjustable, can simulate ankle joint</td>
<td>No feedback, knee replacement. Some production must be done remotely</td>
</tr>
<tr>
<td>Low cost</td>
<td>Limitless arm</td>
<td>Relatively inexpensive, easily customizable, efficient means of production</td>
<td>Not full functionality, still can be expensive, rely on crowdsourcing</td>
</tr>
</tbody>
</table>

2.3 Stakeholder Analysis

The stakeholders that would be affected by an amputation are the individual amputee and their families and other care providers. Losing a leg injures a person's chance to work, do activities of daily living, and more. In many developing countries, many amputees were farmers, herders, nomads, etc., and relied on physical labor for survival. Without a leg, many of these amputees are out of a job and have to become a beggar to survive. Activities of daily living in a developing country may include the collection of water or buying supplies. These activities may require long walks on rough terrain, and without
support, may not ever occur again for an amputee. In addition, they may live in a house that is inaccessible. Transportation is not as easy as it is in modern day urbanized cities, without cars, buses, and public transportation with handicap accessibility, it is unlikely that the amputees will travel far. Not only does the amputation hurt the ability to work and do activities of daily living, it also has an impact on a person’s physical ability and appearance, causing profound psychological damage, and can degrade their social status.

The families themselves will be impacted. Many families in the developing world depend on each other for chores and wages. A family member losing their leg still has to be fed, but no longer can work, raising expectations for everyone else in the family to both work and take care of that family member. In some cases physiotherapy is a necessity and family members may have to administer physiotherapy. In the case where a “bread-winner” is injured, other members of the family may have to pull out of education and other endeavors for support. In addition, a cost of a prosthetic limb can cost more than what the family makes on average, putting additional stress on the family. It can take some families a decade to earn money for initial prosthesis, not even counting on the future prosthesis. Many NGOs these days are helping finance prosthetics, so that the amputees can afford them and work, but it is hard to identify the need of prosthetics in developing countries due to lack of communication and census [16].

To earn money for their families or raise money for a prosthesis, our stakeholders may go into the streets and beg for money, lowering the social status of the community. Social standards are very important in developing countries. The higher societies will have access to technology, information, and communication. Those societies will be the ones with more direct access to NGOs, and the lower societies may be skipped entirely, lessening the chance of financing for prosthetics. In most cases, amputation puts a strain on relationships, trickling down to the immediate home, and then society at large [17].

2.4 Market Analysis

The World Health Organization estimates that in Africa, Asia and Latin America combined, as many as 30 million people require prosthetic limbs, braces and other such devices for daily living [19]. Child amputees need new prosthetics every 6 to 12 months or about 25 for a child who was amputated at the age of 10. Adults typically need 15 to 20 prosthetics throughout their lives. Since the individual statistics are difficult to obtain due to the nature of amputations in developing nations, we can estimate some figure using the United States’ demographics as a conservative measure. In the US, about 18.5% of amputees are transfemoral amputees. Thus on the developing nation level out of the total 30 million amputees there may be as many as 5.5 million that require transfemoral prostheses. And considering that
adults need a new prostheses about every 3 years, there is a demand of about 1.8 million prostheses—annually.

Mine explosions, train and motorcycle accidents and general lack of care against infection are increasing the amount of amputations worldwide, and thus the need for prosthetic limbs. In locations such as Cambodia, Angola, Somalia, and Vietnam up to 1 in 256 people undergo amputations due to trauma. In such regions “the amputee volume imperative” describes a tipping point at which the region simply contain sustain the number of amputees and collapses economically and ecologically.

In most developing countries there is a distinct lack of expertise toward prosthetic design, construction, and implementation causing a high unfulfilled demand for prosthetic legs [11]. Furthermore there is a lack of targeted products designed for the rugged agricultural or urban poor environments where conventional prosthetics simply cannot perform. Many entering prosthetics organizations attempt to use modern or non-appropriate technology which cannot sustain the durability or reparability needed for 5 to 10 years of hard use sought after by amputees.

Cost and affordability is yet another market issue with most available prosthetics in the region costing $125 to $1875, while the local salary for rural agricultural workers is on average $300. In developed nations, specialized prosthetics range from $5000 to $15000. Many organizations are currently run as non-profits utilizing overseas donations to provide prostheses to locals in developing areas. The average costs for creating a prosthetic currently range from $30 and up. This can be improved upon by utilizing mass-production techniques in a more modular approach and using local employment. Furthermore, an installment based model could support a free market based approach which could reach more users than the current charity-based paradigm. Thus there exists a key market within the global low cost transfemoral prostheses need with a total potential annual revenue stream of about $54 million dollars.
Porter’s Five Forces

 Threat of New Entrants

- Low
  - Limited profitability, Difficult low resource environment

Bargaining Power of Suppliers

- Low
  - Vertical Integration, Small volumes

Threat of Substitutes

- Low
  - Crude Substitutes, Lack of “True Prostheses”

Bargaining Power of Buyers

- Low
  - Underserved population, required need

Industry Rivalry

- Low
  - Collaborative Industry of non-profits

Porter's Five Forces analysis is a framework that attempts to analyze the level of competition within an industry. The forces are the threat of new competitors, the bargaining power of suppliers, the bargaining power of buyers, substitute of products or services, and intensity of rivalry.

The realm of low-cost prosthetics is very open to new competitors due to a low cost of entry and limited government regulation in the targeted regions. However, the low industry profitability, where most competitors are non-profits, prevents a flood of new competitors as does the scarcity of industrial resources in the targeted locations.

Suppliers have limited bargaining power due to the relative low volumes of materials and parts that would be ordered. Thus the low volume of parts allows for switching between multiple suppliers. In addition, the nature of the prosthetic requires some degree of internal vertical integration to customize and drive costs low utilizing local manufacturing.

Again, due to the nature of the problem, buyers have limited power to pressure the firm beyond a call for affordability. The aim of the project itself is to reach underserved populations thus it is evident the buyers lack access to adequate alternate sources for medical grade prosthetics. Furthermore, prosthetics are required by amputees as a return to a nominal life thus the customer value is of life changing magnitude.
There do exist substitute products which are used primarily due to their low cost and lack of access to “true” prosthetics. They include such devices as pole legs, pegs legs, and bicycle seat legs. However, these are substandard solutions as they are not durable and do not provide adequate mobility for amputees as a “true” prosthetic does.

The intensity of rivalry is very low in the low-cost prosthetic industry--to the contrary there is a large amount of collaboration and open innovation. Many discoveries and designs such as the Jaipur knee are not patented to stimulate a culture of knowledge sharing. In addition, each region may have only one organization in operation thus limiting the firm concentration ratio.

**SWOT Analysis**

<table>
<thead>
<tr>
<th>STRENGTH</th>
<th>WEAKNESS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strong Mechanical and Design Background</td>
<td>Lack of Prostheses Experience</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OPPORTUNITY</th>
<th>THREAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low cost of entry</td>
<td>Foreign Environment</td>
</tr>
<tr>
<td>Market demand</td>
<td>Government Regulation</td>
</tr>
</tbody>
</table>

SWOT Analysis identifies strengths, weaknesses, opportunities, and threats of a team and the issue or project they face. Foot Fighters' strengths are that we have a strong mechanical and design backgrounds, and have experience in developing nations. However, we have limited prior experience with prosthetics, and limited on-site research opportunities. Our opportunities include that we are in a time of advances in rapid prototyping technology, and most markets we are targeting have little to no competition. Our threats include the global rise in manufacturing costs, possible government regulation, and working in a foreign environment. Due to decreased regulation, low cost of entry, and large market need, the low cost prosthetic is best implemented in nations such as India, Haiti, Angola, and Vietnam.
2.5 Needs Specifications

Need Statement

People in developing countries in need of a prosthetic leg seek a low-cost, accessible, and functional solution.

The Problem

Quality above-knee prosthetics tend to be expensive and inaccessible for transfemoral amputees and those affected by congenital birth defects in impoverished rural and urban communities. These people need improved mobility to contribute to their local society and economy.

Absolute Requirements

Absolute requirements include the minimum of supporting the amputee's weight, enduring cyclic loading, and allowing the amputee to be mobile again. In addition, it must be low cost and durable so the user does not have to save up for years and buy several prostheses over his or her lifetime. The prosthetic must be useable in their community's environment, and unlikely to fail in uneven terrain.

Desirable Requirements

One desirable but not required quality of the design is aesthetics. A user would probably want a leg that is aesthetically pleasing and does not make them alienated. Another desirability is customizable and adjustable - make larger/smaller, wider/thinner, taller/shorter as the user grows they do not have to keep on getting fitted for more prosthesis. Foot Fighters also wants this leg to be culturally appropriate. This can be done in the color of the prosthesis, as well as the foot being bare, so it can follow religious culture such as in India [11]. In addition, Foot Fighters wants the product to be manufactured within the country, to help provide jobs and increase economic stability, and so if any problems occur, the amputees can work directly with the producers instead of waiting through language barriers and customs that the United States productions might have. This also warrants the production to be easy to produce. The product itself should be made from local available materials, to not take away from the current economy and again to booster jobs. Many users do not have the opportunities to travel far, so Foot Fighters would want this product to be mobile and travel to villages easily, as well as be produced within the day, with as little training needed, so that the user does not have to have any extra strain with traveling and rehabilitation. The rehabilitation, training, and fitting should be productive and effective.
References


