Frugal Innovation of Prosthetic Socket for Developing Countries

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Frugal Innovation of Prosthetic Socket for Developing Countries

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Preface

This thesis is submitted for one year degree of master program in engineering at Halmstad University. The work outlined in this thesis was carried out under the supervision of Pär-Johan Lööf in the department of mechanical engineering, and with collaboration of Lindhe Xtend AB.

This thesis is the result of my work and includes nothing which is the outcome of work done in collaboration, except for a few instances which are stated in the text. Neither, this, nor any substantially similar thesis has been or is being submitted for any other degree, diploma or other qualification at any other university.

This was a beautiful project to work on, not only challenging and enriching, but it is also satisfying to know that the work done, even if it's only a very small part of the puzzle, can eventually help people in developing countries walk with less cost and easy customized prosthetic socket.

I would like to thank Prof. Bengt-Göran Rosén; he was always willing to take time for adding new ideas to my project, teaching me techniques to fix the problem I faced during my work.

I am grateful to my supervisors, Pär-Johan Lööf and Christoffer Lindhe, CEO of Lindhe Xtend AB, for their patience, for being inspirational, and for teaching me the importance of using curiosity as the driving force behind the work. I would like to thank them for invaluable lessons about the importance of guidance and for the freedom they granted to me during my works. I would like to thank Anna Fransson, Orthopaedic engineer at Team Olmed, she gave me technical support on prosthesis device, and I would like to thank Claes Gyllensvaan, he arranged rawhide for this work. Finally, I thank my parents, family and my friends for their support.

Support

The work described in this thesis would not have been possible without material and technical support of Lindhe Xtend AB, Science Park, Kontrollhudar International and Team Olmed Halmstad. I would like to express my gratefulness their management and staff members.
Abstracts

In this thesis, we presented a frugal product and methodology for customizing prosthetic socket for developing countries where an overwhelming number of prostheses are necessary, and the availability, accessibility and cost of prosthetics are significant concerns to limb deficient persons that without the assistance of a prosthetic device may not be able to function. In order to design a frugal prosthetic socket, a design methodology is sought that will best achieve an appropriately designed, low-cost, with simple production method. Through the study of modern design methodologies, a strategy is proposed that emphasizes the intersection of the mechanical design process (contemporary design tools), biomechanics, and low-cost design. Key components of this methodology are previous research and frugal innovation in the design process. Along with a review of the state of the art, provide the groundwork for both the proposed new methodology as well as generating a new concept of prosthetic socket. The result of this study, using the generated concept and simple methodology, a frugal prosthetic socket (FPS) is developed to demonstrate the basic functionality of the concept and manufacturability of the proposed method. Finally, Frugal Prosthetic Socket is found as a solution for the problems since it can reduce one heavy complex process for optimizing customization of the prosthetic socket and reduce 70% of the cost of the prosthetic socket by using local material (rawhide), local manufacturing technique and implementing frugal innovation concept.
Table of Contents

List of Tables........................................................................................................................................ v 
List of Figures........................................................................................................................................ v 
List of Abbreviations ............................................................................................................................ VI 
1 Introduction........................................................................................................................................1 
   1.1 Background ..................................................................................................................................2 
   1.1.2 Lindhe Xtend AB .........................................................................................................................3 
   1.1.3 Developing countries ..................................................................................................................3 
   1.2 Aim of the study ............................................................................................................................4 
   1.2.1 Problem definition .....................................................................................................................5 
   1.3 Limitations ...................................................................................................................................5 
   1.4 Study environment .........................................................................................................................5 
2 Methodology.......................................................................................................................................6 
   2.1 Contemporary design methods and tools .....................................................................................7 
   2.1.1 Product definition phase ...........................................................................................................7 
   2.1.2 Conceptual design phase ...........................................................................................................7 
   2.1.3 Product development phase .....................................................................................................7 
   2.2 Frugal Engineering method .........................................................................................................8 
3 Literature Review ............................................................................................................................9 
   3.1 Patient characteristics ..................................................................................................................9 
   3.2 Selection procedures for standard components ...........................................................................11 
   3.2.1 Amputee parameters .................................................................................................................11 
   3.3 Socket procedures and rules ........................................................................................................12 
   3.3.1 Circumference reduction ..........................................................................................................12 
   3.3.2 Identification of critical areas ..................................................................................................14 
   3.3.3 Critical areas manipulations .....................................................................................................15 
   3.4 Socket Design Methodology ......................................................................................................16 
4 Design Process ..................................................................................................................................17 
   4.1 Product definition .........................................................................................................................17 
   4.1.1 Customers .................................................................................................................................17 
   4.1.2 Customers’ requirements ..........................................................................................................18
4.1.3 Benchmarks........................................................................................................19
4.1.4 Engineering specification and Target setting.......................................................20
4.2 Conceptual Design of FPS.........................................................................................21
4.3 Conceptual Evaluation and Selection.......................................................................22
  4.3.1 Conceptual Evaluation.........................................................................................22
  4.3.2 Concept Selection...............................................................................................25
4.4 Design of Frugal Prosthetic Socket (FPS).................................................................26
  4.4.1 Configuration of FPS..........................................................................................26
  4.4.2 Material and Process Selection of FPS...............................................................27
4.5 Results from the prototype of FPS............................................................................29
  4.5.1 Prototype and customization Analysis.................................................................30
  4.5.2. Discussion.........................................................................................................31
5 Conclusion and Recommendation..................................................................................34
  5.1. Conclusion.............................................................................................................34
    5.1.1 Recommendation to future activities.................................................................35
6 Critical Review............................................................................................................36
References.......................................................................................................................38
Appendix.........................................................................................................................39
    Appendix I – Amputation level..................................................................................39
    Appendix II - Traditional socket manufacturing method...........................................40
    Appendix III –QFD for FPS.......................................................................................41
    Appendix IV – SWOP analysis of FPS.......................................................................42
    Appendix V – Frugal Prosthetic Socket.....................................................................43
    Appendix V I – Flexible moulding.............................................................................44
List of Table

Table 2.1: Typical Phases of the Product Development Process ........................................7
Table 3.1 Patient Characteristics ..........................................................................................9
Table 3.2: Reference parameters to evaluate the downsizing of the positive plaster cast in relation to patient characteristics .................................................................13
Table 3.3 Correlation to the stump tonicity .........................................................................15
Table K-code for Medicare classification for patients with prosthesis .........................38
Table: Questionnaire to identify amputee life style ...........................................................38

List of Figure

Figure: 1.1 Lindhe Xtend AB’s logo ....................................................................................3
Figure 1.2 Hand- held pole and sawed-off crutch homemade leg in developing countries ........4
Figure 2.1: Frugal engineering within the general Product Design Space .......................6
Figure 2.2 Mechanical design processes (Contemporary design methods) .....................8
Figure 3.1: Scheme of anthropometric measure used to design TF prosthesis ...............11
Figure 3.2: Scheme of anthropometric measure used to design TT prosthesis ...............11
Figure 3.3: General scheme of the load and off-load zones for Trans femoral stumps .........14
Figure 3.4: General scheme of the load and off-load zones for transtibial stumps .............15
Figure 4.1 Mukti Foundation’s prosthetic socket ...............................................................19
Figure 4.2 Össur’s prosthetic socket ..................................................................................20
Figure 4.3: Concept of FPS ...............................................................................................22
Figure 4. 4: a scheme of a horizontal section of a quadrilateral socket .........................23
Figure 4.5: some examples of flexible sockets ...................................................................23
Figure 4.6: an example of MAS socket .............................................................................24
Figure 4.7: Examples of PTB (A), SCSP (B) and SC (C) sockets .....................................24
Figure 4.8: Prosthetic socket decision matrix ...................................................................26
Figure 4.9: rawhide material ..............................................................................................27
Figure 4.10 density vs price material selection ...............................................................28
Figure 4.11: FMEA for FPS ............................................................................................30
List of Abbreviations

CAN - Customer need analysis
FL - Foot length
FMEA - Failure modes and effect analysis
FPS - Frugal prosthetic socket
H - Height
HDPE - High-density polyethylene
ISNY - Iceland-Swedish-New York (flexible socket)
KH - Knee joint height
KS - Knee joint-stump top
MAS - Marlo Anatomic Socket
POP - Plaster of Paris
PTB - Patellar Tendon Bearing
QFD - Quality function deployment
RL - Residual limb length
SC - Supracondylar Suspension
SCSP - Supracondylar Suprapatellar Suspension
TF - Trans femoral
TT - Transtibial
TL - Thigh length
TRH - Trochanter height
1. Introduction

Frugal innovation or frugal engineering is the process of reducing the complexity and cost of a goods and its production. Usually this refers to removing nonessential features from a durable good, such as a car or phone, in order to sell it in developing countries. Designing products for such countries may also call for an increase in durability and, when selling the products, reliance on unconventional distribution channels. Sold to so-called "overlooked consumers", firms hope volume will offset razor-thin profit margins. Globalization and rising incomes in developing countries may also drive frugal innovation. Such services and products need not be of inferior quality but must be provided cheaply.

In May 2012 The Financial Times newspaper called the concept "increasingly fashionable" Several US universities have programs that develop frugal solutions. Such efforts include the Frugal Innovation Lab at Santa Clara University and a two quarter project course at Stanford University, the Entrepreneurial Design for Extreme Affordability program.

Many terms are used to refer to the concept. "Frugal engineering" was coined by Carlos Ghosn, the joint chief of Renault and Nissan, who stated, "Frugal engineering is achieving more with fewer resources." In India, the words "Gandhian" or "jugaad", Hindi for a stop-gap solution, are sometimes used instead of "frugal". Other terms with allied meanings include "inclusive innovation", "catalytic innovation", "reverse innovation", and "BOP innovation", etc. At times this no frills approach can be a kind of disruptive innovation.

With the concept of frugal engineering, this paper mainly focuses on reducing nonessential features, processes and cost of prosthetic socket that can be used in developing countries. The main functions of socket are to support and protect the residual limb. It modifies and transfers forces from the residual limb to the prosthesis throughout the patient's leg moments; it need to ensure comfort to the patient; being lightweight and with optimum design. In spite of the advancements made in understanding prosthetic socket fit and improvements in socket technology, issues of great concern to amputees lack of simple customize and comfort its expansive cost. In regions, developing countries where cost is a factor in the replacement prosthetic leg, the need for an inexpensive and an easy customize, prosthetic socket design is very important.

One of the main problems in developing countries is the lack of trained personnel. Properly constructing, fitting, aligning, and adjusting a prosthetic limb requires a high level of skill and despite the high demand for this expertise, there are very few training programs in low-income countries. Studies by the World Health Organization (WHO) indicate that while the current supply of technicians falls short by approximately 40,000, it will take about 50 years to train just 18,000 more skilled professionals (Walsh 2003).

Another problem is that importing components from industrialized countries to build prosthetic limbs are not only costly, but these parts are designed for very different lifestyles and usually do not hold up to the challenges which nature presents in rural environments. These countries have a farm-based economy and a tropical climate. In these harsh environments, conventional limbs made of wood and resin only have a lifespan of about 18 months (Erin Strait 2006).
The costs of prosthetic limbs vary substantially by country, but a typical prosthetic limb made in a developing country costs approximately $125 to $1,875 USD, depending upon the region in which they are made. When the costs to make a limb in a developing country can be cut to as little as $41 USD (well below the $5,000-$15,000 USD average cost for a prosthesis in the United States), the costs over a lifetime of replacements and maintenance can still amount to thousands of dollars. This presents a major problem since the average family income in rural areas is typically around $300 USD annually. Bartering for goods is a natural aspect of their lives, but getting a prosthetic limb requires cash. It can take victims a decade or more to earn the money for an initial prosthesis. This thesis, therefore, focuses on designing a prosthetic socket that accommodates the needs of amputees with affordable cost in developing countries.

In order to design a frugal prosthetic socket, a design methodology is sought that will best achieve an appropriately designed, low-cost, with simple production method. Through the study of modern design methodologies, a strategy is proposed that emphasizes the intersection of the mechanical design process (contemporary design tools), biomechanics, and low-cost design. Key components of this methodology are previous research and frugal innovation in the design process. The results of this study, along with a review of the state of the art, provide the groundwork for both the proposed new methodology as well as generating a new concept of prosthetic socket. Using the generated concept and simple methodology, a frugal prosthetic socket (FPS) is developed.

1.1 Background
The industrial revolution brought about prosthetic advancement fuelled by money available to amputees following the American Civil War. After WWII, many soldiers returned with missing limbs and people became more aware of the problems these soldiers faced while trying to return to a normal lifestyle. With an escalated number of amputees and increased awareness, this forced the development of functional prosthetics for the masses. These functional prostheses were still by no means comfortable to wear, but the user was much more mobile and independent with the use of such a device. From heavy, immovable limbs to lighter, more functional limbs, prosthetics has come a long way.

Today, modern materials such as plastics, carbon fibre, and strong but lightweight metals like titanium and aluminium, are water resistant and better able to withstand harsh environments. These materials are now widely used along with advanced designs, both of which allow the patient to expend less energy. Fundamental proven prosthetic principles are never outdated, only the methods to accomplish them are refined. Ideas are endlessly being recycled from the past. Concepts that may have been impractical at the time of their inception become possible with developments in materials and technology. Prosthetic limbs have become increasingly complex and capable of great improvements in amputee rehabilitation. However, with this increase in complexity, the cost of these devices has also increased. This has made obtaining prosthetic sockets for those with low incomes or needing frequent component changes difficult. When faced with financial constraints, a simplified prosthesis is commonly provided to amputees.
Prior to jumping into the design of a frugal prosthetic socket, it is helpful to be known as background for which the context and concepts associated with this design opportunity is formulated. Of course, the idea is first raised from Lindhe Xtend AB to produce inexpensive and easy customized socket for developing countries.

1.1.2 Lindhe Xtend AB

The Lindhe Xtend AB is company working on innovating prosthesis which gives the user natural movement throughout life. It was started in 2013 in Halmstad, Sweden by Christoffer Lindhe and a group of members. It is working with partners like “Lightness by Design” “Science Park Halmstad” and “Almi Invest”. The center focuses its efforts toward rehabilitating amputee and become the world leader in user friendly prosthesis. Lindhe Xtend AB strives to develop prosthesis that allows the user to cope with all kinds of activities.

1.1.3 Developing countries

It has been estimated by the World Health Organization that “ten percent of the global population, or more than five hundred million people, have a disability. Two thirds of those people live in developing countries, and that number is rising due to poverty, poor healthcare, disasters, landmines, war, and other forms of violence” (Stanton 2006). Other causes of
amputation in these war-torn countries include industrial or environmental accidents, terrorist attacks, and the lack of basic public health which often leads to diabetes, gangrene, and infection. All of these causes are adding to the number of amputations at an alarming rate.

In third world countries, many limb deficient people are farmers, herdsman, nomads or refugees and rely on physical labour for survival. In some cases, they become beggars on the streets in order to survive. Not only does the loss of a limb have a grave impact on a person’s physical ability and appearance, it causes profound psychological damage and often contributes to the degradation of their social status since there is no still affordable prosthetic limb, but they prepare their own homemade prosthetic leg as hand-held pole legs and sawed-off crutch leg. Having affordable and readily available prosthetic limbs is vital for everyone that needs them.

![Figure 1.2 Hand-held pole and sawed-off crutch homemade leg in developing countries (prosthetic Resident)](image)

### 1.2 Aim of the Study

Mobility is oftentimes a task that does not require much thought for the able-bodied. However, for patients of amputation, it is a task that is painstakingly difficult. Daily livelihood is a difficult one, as war affected citizens’ struggle not only with their own physical limitations, but due to limited infrastructure to support them. The amount of time, energy and investments in rehabilitation can be significant, due to the aging technologies available in developing nations. Also, poor terrain and lack of funding resources is also a hurdle. Once amputees are fitted with prosthetics, life with it is much improved than not having an assistive device. Unfortunately, the excessive cost associated with so many prostheses leads to deprivation in developing countries.

The prosthetic is a modular product of four parts which are socket, knee/elbow, tube and foot/hand. From these parts, socket is the major and important part which is custom product interfaces with the residual limb and customized according to size and shape or contour of
The central focus of this thesis is to design a prosthetic socket that can be customized easily for amputees and allows a full range of motion, while allowing comfort and durability to withstand harsh terrain and other physical demands. Hence, the scope of the project is designing prosthetic socket, looking for local materials, which are found more and easily in developing nations, producing a prototype of the prosthetic socket, and test the prototype.

Therefore, the objective of this thesis is to design a cost-effective frugal prosthetic socket that can be customized easily for amputees in developing countries.

1.2.1 Problem definition

The main problems in providing prosthetic limbs to developing countries are the lack of trained personnel on orthopaedic engineering due to the complex process of customization of prosthetic socket, and importing socket from industrialized countries to build prosthetic limbs is very expensive.

The goal of this project is looking for a solution that can reduce one heavy complex process for optimizing the customization of the prosthetic socket, and that can reduce 70% of the cost of the prosthetic socket for developing countries.

1.3 Limitations

There are two main limitations. First, there are no more research papers which deal with prosthesis on developing countries and there is no documented material for determining mechanical properties of rawhide material. The other limitation is the studying place where project has been studied is so far from the place where the project will be implemented. This distance barrier is limitation for interviewing the amputees and visiting some of the organizations which prepare the prosthetic leg in developing countries in order to know exact demand or feedback of the customer from testing of the prototype.

1.4 Study Environment

There was very good studying environment with Professors, Supervisor and Company’s advisor. They were very supportive deliberately, we have good consensus and understandable discussion with all concerning bodies. It was very interesting and enjoyable. However, the weather of Sweden is not suitable for FPS, because the material, which is selected for frugal prosthetic socket, requires warm air at least room temperature. So finding favourable working place for this project was a very tough task instead of concentrating only on the project. Generally, the studying environment is so conducive for studying mechanical engineering in master program.
2. Methodology

In order to design a product that satisfies the objectives of this project, a mechanical design methodology is needed that will effectively generate an appropriate solution. Recent developments in design techniques have produced a variety of effective tools for developing frugal products for world markets. More application-specific methods have also been developed that focus on the particular needs of individual industries.

When a design opportunity overlaps multiple areas, the methodology used must also accommodate the particular needs of a range of industries. No single design technique may satisfy all the needs of a multidisciplinary design problem. To accomplish this, the intersection of the design methodologies of the relevant areas for innovation for a particular design problem must be identified in order to develop a more comprehensive design methodology. As this project focuses on applying mechanical design techniques to a biomechanical device for consumers in developing countries, the primary areas of innovation are: mechanical design process, low cost, and biomechanical technology. By understanding these areas and the way they intersect, a final design methodology can be established specifically for this project – as illustrated through the use of a Venn Diagram Figure 2.1, the overlapping, shaded region denotes the target design space for this project.

![Figure 2.1: Frugal engineering within the general Product Design Space](author 2015)

Beginning with an understanding of modern design techniques, a general design framework can be obtained. A more customized methodology can be further crafted using techniques specific to the other design domains of biomechanical and low cost devices. For this project, identification of design considerations outlined by experts in low-income and biomechanical component design provides the additional theory to be combined within the general design framework to develop a customized design process for low-cost biomechanical devices.
2.1 Contemporary Design Methods and Tools

Product design processes consist of three basic stages: defining the design problem, development of a concept, and embodiment of that concept. Table 2.1 summarizes these three product design phases, and their key activities, as defined by Ullman (2010).

<table>
<thead>
<tr>
<th>Product definition</th>
<th>Develop a Concept</th>
<th>Implement a Concept</th>
</tr>
</thead>
<tbody>
<tr>
<td>Define the problem</td>
<td>Generate Concepts</td>
<td>Design a product</td>
</tr>
<tr>
<td>Customer Needs Analysis</td>
<td>Evaluating the concepts</td>
<td>Physical/Analytical Modeling</td>
</tr>
<tr>
<td>Competitive Analysis</td>
<td>Select a concept</td>
<td>Evaluate the model</td>
</tr>
<tr>
<td>Generate specification</td>
<td></td>
<td>Redesign</td>
</tr>
<tr>
<td>Set up target</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 2.1: Typical Phases of the Product Development Process (Ullman 2010)

2.1.1 Product definition phase

The first phase of the design process requires the designer to implement measures to ensure they understand the opportunity at hand. This understanding is most effectively obtained through communicating with the customer/user in an effort to understand their perception of the product and their pattern of usage. This can be achieved using interviews, questionnaires, designers attempting to ‘be the customer’, focus groups, or previous research etc. This information will help the designer be able to quantify final requirements and constraints for their product.

2.1.2 Conceptual design phase

The Solutions to satisfy customer needs are developed in Phase 2 of the design process developing a concept. This first requires understanding the basic functions the final product must be capable of performing. Functional modeling, as described by Ullman. The concept generation is the point in the design process where solutions for the opportunity identified in Phase 1 begin to emerge. A variety of techniques exist for generating a range of possible solutions, such as: Brainstorming with Mind-Mapping, 6-3-5, and Design by Analogy (Ullman 2010). While evaluating different concepts, the focus should be on producing solutions for the problem that identified in phase 1.

2.1.3 Product development phase

The Phase 3 of the design process consists of taking the preferred concept(s) through to final embodiment. This often requires system modeling and analysis - including both physical and virtual models. A range of analyses, such as wear, stress, fit, or cost, can then be completed on these models prior to full embodiment. Using evaluation tools such as Failure Modes and Effects Analysis. The performance of the embodied product is compared to the requirements identified in Phase 1 and revised as needed before distribution.
2.2 Frugal Engineering method

By applying contemporary design techniques to the intersection between design of biomechanical and low-cost products, reducing complexity and nonessentials feature and a systematic method for developing biomechanical devices, for developing countries can be obtained. The information was identified through a review of low-cost and biomechanical component design in the literature. The methodology resulting from the blending of these considerations from a variety of literature is summarized here. In order to design an appropriate low-cost biomechanical device, during the entire design process, the low-income consumer should be viewed as a co-creator and customer in the design process (Pollak, 2008; Prahalad, 2010). This is even more important due to the potential for physical and psychological risk.

As designers we must provide “long term benefit to the poorer amputees in the third world, culture specific designs and materials,” (Meanley, 1995). This design methodology is, therefore, utilized and documented in the following chapters in the development of a low-cost lower limb prosthetic socket. Each phase of the design process utilizes contemporary design tools and implements the key considerations identified here. In following this methodology through to completion in this research, an appropriately designed prosthetic socket is achieved.
3. Literature Review

3.1 Patient Characteristics

Most of decisions taken by the technicians and the design procedures to realize the prosthesis are guided by patient characteristics. Identified characteristics have been divided in three main categories (see scheme in Figure 3.1):

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient Evaluation</strong></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td>M,F</td>
</tr>
<tr>
<td>Age [y]</td>
<td>&lt;number&gt;</td>
</tr>
<tr>
<td>Patient force</td>
<td>very low, low, medium, high</td>
</tr>
<tr>
<td>Life-Style</td>
<td>K1, K2, K3, K4</td>
</tr>
<tr>
<td>Pathologies</td>
<td>YES, NO</td>
</tr>
</tbody>
</table>

| **Stump Evaluation** |                              |
| Amputation type     | TT, TF                       |
| Amputation Side     | L, R, BOTH                   |
| Stump stability     | YES, NO                      |
| Shape              | cylindrical, conical, non-std|
| Bone protuberances  | widespread, on top          |
| Skin conditions     | sensitive, normal, scars, scratches |
| Toxicity           | low, normal, good, very good|

| **Anthropometric Measures** | |
| Weight [kg]             | <number>                     |
| Height [mm]             | <number>                     |
| Trochanter height [mm]  | <number>                     |
| Residual limb length [mm]| <number>                     |
| Thigh length [mm]       | <number>                     |
| Dist. knee joint-stump top [mm]| <number>         |
| Knee joint height [mm]  | <number>                     |
| Foot length [mm]        | <number>                     |

Table 3.1 Patient Characteristics (Knowledge-based design of lower limp prosthesis)

In the following, a description will be provided according to Knowledge-based design of lower limp prosthesis by S. Gabbiadini.

- **Patient evaluation**: the general data about the patient are:
  - *Gender*: the sexual gender of the patient, male or female;
  - *Age*: the patient age in years;
  - *Patient force*: the general patient physical force, divided in 4 levels (very low, low, medium and high). For example, for an old patient who just walks only few steps at home, the level is very low; while for a patient who has a dynamic life and practices sport, the level is high;
  - *Life style*: from the indications of Medicare guidelines for functional classification of patients with prosthesis, it is classified in 4 ambulation levels from K1 to K4 (see Appendix IA). To select the right one we have elaborated a questionnaire, shown in Appendix I B, to identify in automatic way the appropriate patient life style.

Questions are divided in three categories:

I. **Physical general conditions**: questions to evaluate the general patient health;

II. **Ambulation evaluation**: questions to evaluate the patient level of mobility indoor and/or outdoor

III. **Ground adaptation**: questions to understand types of grounds and obstacles the patient has to overcome
- **Pathologies**: it is considered the presence or not of pathologies which can influence the patient mobility or quality of life.

- **Stump evaluation**: the general data about the stump are:
  - **Amputation type**: if it is a transtibial (TT) or a transfemoral (TF) amputee;
  - **Amputation side**: the left, the right or both limbs;
  - **Stump stability**: in relation to the time passed from the limb amputation, the stump undergoes changes of volume; for example for a quite recent amputation (less than 1-2 years) the stump undergoes a significant volume reduction, while for less recent amputation (more than 4 years) the stump volume modification are quite slow;
  - **Shape**: the shape of the residual limb normally can be cylindrical, conical. For the other rare cases, the shape is considered not standard;
  - **Bone protuberances**: where bony protuberances are located on the stump, if they are widespread or only at the top;
  - **Skin**: the sensibility of the skin, and presence of scars or scratches;
  - **Tonicity**: the level of tonicity of the residual limb muscles strictly correlated to the patient daily activity before the amputation. In fact, after the amputation, the muscles of the residual limb are partially used by patient, and slowly they undergo a process of atrophization. It is divided in 4 levels: low, normal, good or very good) For example a young patient, amputated from less than 3 years, tonicity is still good; while a middle-aged patient, amputated from more than 10 year, tonicity starts to be low.

- **Anthropometric measures**: general measures of the patient’s body (see general scheme for TF amputees in Figure 3.1 and for TT amputees in Figure 3.2):
  - Weight: patient weight in kg;
  - Height (H): patient height;
  - Trochanter height (TRH): trochanter height measured on the contralateral lower limb;
  - Residual limb length (RL): total length of the residual limb;
  - Knee joint height (KH): contralateral knee joint height;
  - Foot length (FL): length of the contralateral foot;
  - Thigh length (TL): length of the thigh, only for TT amputees;
  - Distance knee joint-stump top (KS): it is the vertical distance between the stump top and the contralateral knee joint, calculated as follows:

  For TT: \[ KS = RL - TL \text{ [mm]} \] \hspace{1cm} (3.1)

  For TF: \[ KS = TRH - RL - KH \text{ [mm]} \] \hspace{1cm} (3.2)

In the particular case of both limb amputations, the mentioned heights are identified on the base of the patient height before the amputation. In some case, patients present unique factors that should be considered in the design of the prosthesis. For example, someone who lives near the ocean may need a prosthesis designed with maximum protection from salt corrosion and water damage. Cultural background is also significant. Asian amputees require a foot that allows the shoes to be removed easily when entering a home since that is custom, etc. Such personal factors should be added to the more generic factors discussed previously to ensure the proper match between prosthetic configuration and amputee goals.
3.2 – Selection Procedures for Standard Components

As previously said all prosthesis components, apart the socket and rarely the liner, are standard components available on market and selectable from commercial catalogues. For the extrapolation of guidelines to select the standard components, the indications given in commercial catalogues have been studied by the most known prosthetic brands, and the rules adopted by technicians on the base of their personal expertise. Thus, parameters have been elaborated to choose automatically the appropriate components for each kind of amputee (transfemoral and transtibial) and accordingly size them according to S. Gabbiadini.

3.2.1 Amputee parameters

Accordingly to what said before, main patient characteristics that guide the selection are:

- **Life style**: calculated on the base of the questionnaire described in § 3.1. It the most important parameter which influences the components selection, since where and how a patient lives is strictly correlated to the required prosthesis performance. For example, a patient who has very dynamic life and walks for more than 1 km everyday needs a more performing prosthesis than a patient who spends all day at home;
Age: It has been divided in 2 categories: less than 65 years and equal or more than 65 years old. It can influence life style; for example a 30 years old patient can have a more active life, than a 70 years old patient;

Weight (w): patient weight in kg, divided in 4 groups: w ≤ 75 kg, 75 kg < w ≤ 100 kg, 100 kg ≤ w < 125 kg, and w ≥ 125 kg. The weight can influence the selection since some components cannot carry an elevate weight, while others are indicated for heavy patients. For example a high energy foot is appropriate for young patients who weight more than 100 kg, because this typology can better support elevate stress;

Physical force: it is divided as said in 4 levels (§ 3.1). For example an 80 years old patient normally has low force level, while a 25 years old sportive patient has a high force level. This means that in the first case the patient will be able to use prosthesis with heavier components than the second case;

Residual limb length: called also stump length, divided in 3 levels short, normal and long which influences the calculation of Life style, since short stumps allow a weaker control of the prosthesis, while long stumps guarantee an elevate control and stronger interaction prosthesis-stump.

3.3 Procedures and Rules for Socket

The socket functionality is strictly linked to the technician ability. The design guidelines to model the socket have been extrapolated from the analysis of operations performed by the technicians to reach an optimal shape. This lead to the identification of which stump zones are manipulated and where add or remove materials in the positive model to ensure a correct prosthesis functionality and comfort. S/he first highlights on the positive model the areas to be modified and, then, starts to modify them adding or removing plaster. Essentially, three types of operations have been identified according to S. Gabbiadini.

- Initial plaster circumference reduction (see 3.3.1)
- Identification of critical zone (see 3.3.2)
- Critical zones manipulation (see 3.3.3)

In the following we describe the design guidelines derived for these three operations.

3.3.1 Circumference reduction

In general, the socket must be tighter for young or recently amputated patients, since the muscles and the body are still strong and tonic. Instead, for elderly or long standing amputated patients, since the muscles and the body are not anymore fully efficient; the socket needs to be looser and not too much tight to allow an easier ambulation or physical therapy. We have identified and collected in a table the appropriate reduction in relation the specific patient characteristics.

The range of percentage varies from 1% to 6%. It is not uniform on the stump, but it starts with 1% at 4 cm over the stump top, and increases gradually going up until the stump upper art. For example, for a tonic stump and a patient very active, the reduction is low since the muscles are strong (e.g. for a young amputee, dynamic and without particular disease, the...
reduction starts from 1% until to 2%). These parameters influence the decision about the appropriate values:

- **Stump stability:** stable stumps need a looser socket and therefore a lower reduction (1÷3%), while unstable stumps a tighter socket and a higher reduction (3÷6%);
- **Stump tonicity:** less tonic are the stump muscles, more reduction is necessary to obtain an appropriate socket fitting. For this reason a reduction of 4÷6% is appropriate for low stump tonicity, 3÷5% for normal, 2÷3% for good, and 1÷2% for very good;
- **Stump skin:** more sensitive is the skin and looser must be the socket, so we have for sensitive skin a reduction of 1÷2%, for normal of 2÷6%, and for skin with scratches maximum 1÷3%;
- **Patient weight:** normally heavy patients need a well tight socket, since they normally have a flaccid stump. For this reason for patients who weight more than 100 kg the reduction is 3÷6%, for patients between 75 and 100 kg is 2÷6%, and for patients less than 75 kg it is sufficient 1÷5%;
- **Life style:** the patient life style influences the reduction since a patient with an intense or very intense life needs a stable and tight socket (respectively 3÷6% and 4÷6% of reduction), a normal life style needs a moderately looser socket (2÷5% of reduction), while patients with a low profile need only a looser socket (1÷5% of reduction);
- **Patient pathologies:** the presence of pathologies, which can influence the patient mobility, requires a socket not too much tight (1÷3% of reduction). While a patient in good health needs a well-fitting socket (3÷6% of reduction)

<table>
<thead>
<tr>
<th>SOCKET EVALUATION</th>
<th>SCALING</th>
</tr>
</thead>
<tbody>
<tr>
<td>STABILITY</td>
<td>1÷2%</td>
</tr>
<tr>
<td>Stable</td>
<td>×</td>
</tr>
<tr>
<td>Unstable</td>
<td></td>
</tr>
<tr>
<td>TONICITY</td>
<td>Low</td>
</tr>
<tr>
<td>Low</td>
<td>×</td>
</tr>
<tr>
<td>Normal</td>
<td></td>
</tr>
<tr>
<td>Good</td>
<td></td>
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<tr>
<td>Very good</td>
<td></td>
</tr>
<tr>
<td>SKIN</td>
<td>Sensitive</td>
</tr>
<tr>
<td>Sensitive</td>
<td></td>
</tr>
<tr>
<td>Scratch</td>
<td></td>
</tr>
<tr>
<td>WEIGHT</td>
<td>&lt; 75 kg</td>
</tr>
<tr>
<td>&lt; 75 kg</td>
<td>×</td>
</tr>
<tr>
<td>75 ÷ 100 kg</td>
<td></td>
</tr>
<tr>
<td>100 ÷ 125 kg</td>
<td></td>
</tr>
<tr>
<td>&gt; 125 kg</td>
<td></td>
</tr>
<tr>
<td>LIFE STYLE</td>
<td>Low</td>
</tr>
<tr>
<td>Low</td>
<td>×</td>
</tr>
<tr>
<td>Normal</td>
<td></td>
</tr>
<tr>
<td>Intense</td>
<td></td>
</tr>
<tr>
<td>Very Intense</td>
<td></td>
</tr>
<tr>
<td>PATIOLOGIES</td>
<td>Yes</td>
</tr>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td></td>
</tr>
</tbody>
</table>

Table 3.2: Reference parameters to evaluate the downsizing of the positive plaster cast in relation to patient characteristics (Knowledge-based design of lower limp prosthesis)

The most appropriate reduction, accordingly to the patient characteristics, is selected identifying the range with the highest number of occurrences.
3.3.2 Identification of critical areas

In the traditional process the technician first identifies with markers the areas, which have to be modified on the positive model. In particular, we have divided these areas in two categories:

a) Load zones, where there are not bony protuberances or tendons and it is necessary to constrict the socket closer to the limb and therefore create a pressure to sustain the body weight;

b) Off-load zones, where there are bony protuberances or tendons and the socket does not have to press the limb and in the meantime not to be much wide since it could cause other physical problems.

Figure 3.4 shows a map of identified areas for a transfemoral amputation and Figure 3.5 for a transtibial amputation. For a transfemoral socket, the most important critical areas are in particular the inguinal canal off-load zone, the Scapa triangle support zone, the trochanter off-load zone, the lateral support zone and the femur support zone. While for a transtibial socket, the most important critical areas are the off-load zones of anterior fibula, patella, tibial epiphysis and posterior tendons.

Figure 3.3: General scheme of the load and off-load zones for Tran femoral stumps (Knowledge-based design of lower limp prosthesis)
3.3.3 Critical areas manipulations

Once identified the critical areas, these have to be modified adding or removing plaster. In detail, in the off-load zones, the technician removes material from the positive plaster cast since in that zones the socket does not have to press the stump and be quite loose. While in the load-zones the plaster has to be added in order to have a socket better tight and also self-supporting. Regarding to the amount of chalk added or removed by the technician in the critical areas we have identified eight manipulation levels, from 1 to 8 mm of thickness, in correlation to the stump tonicity, as shown below. For example, for a stump with normal tonicity, the plaster thickness to be removed or added will be 3-4 mm.

\[
\text{Socket thickness} \text{ [mm]} = \frac{\text{Patient weight} \text{ [kg]}}{20} \quad (3.3)
\]

Finally the socket thickness will be

\[
\text{Socket thickness} \text{ [mm]} = \frac{\text{Patient weight} \text{ [kg]}}{20} \quad (3.3)
\]
3.4 Socket Manufacturing Methodology

Traditional prosthetic socket manufacturing processes invariably is an artistic or a labour intensive process. In this method prosthetist must know the complete topology of the amputee’s stump and needless to say, there are many factors that affect the quality of fit (refer Appendix II).

The traditional socket manufacturing has different steps: after taking some reference measurements of the stump, making negative mould, cross checking the dimension of the negative mould with the stump dimension, making positive moulding of the stump, making adjustment, and finally cast the socket of stump. The stump was evaluated for muscle strength, joint function, skin condition, scarring, pain and condition of limb. Present conventional measuring, adjustment and moulding procedures, are still very time consuming.
4. Design Process

On the basis of previous study and analysis of product and process knowledge required for prosthetic socket manufacturing, we will design frugal prosthetic socket (FPS) and propose a new methodology, which guides to develop prototype.

4.1 Product definition

Vossberg writes in Prosthetics and Orthotics International that imported products strain the local budget and require developing countries to be dependent upon foreign aid. He suggests the following six factors that one must be aware of when providing technical assistance: economic, social, cultural, pathological, environmental, and humanitarian. A country should be assessed and each factor established when research is being done for the prosthetic design and implementation procedures. Economic factors are a concern because if the cost is too high then a country will not be able to sustain its growth. Since most of the amputees in need of prosthetics are destitute, they will not be able to provide for their medical costs, nor will they likely be able to receive assistance from their governments. Socially, people in some cultures may not be accepting of those with prosthetics, so the prosthesis should aim to bring someone back into society. Additionally, cultures have different needs, making it unfeasible to create a universal design. Pathological factors are a concern where many of these countries are located in disease ridden areas. Environmental factors limit the resources that are available to produce the prosthetics. The humanitarian factor means that not all of the most costly donated items will be the best in non-industrialized environments (Vossberg 1999). The consideration of all these factors can increase the chances that a prosthetic will be accepted and continually used.

4.1.1 Customers

Due to the increasing rate of amputations, there is an ever-growing demand for prosthetic socket. Not only is there an immediate need for a person’s initial prosthetic limb, but also multiple replacement limbs and repairs are necessary over a lifetime. Children between the ages of four and sixteen grow at an average rate of 0.75” annually. A prosthetic replacement is needed typically every 12 months for children, and every 3-5 years for adults. For example, if a child becomes limb deficient at the age of 10, he will need approximately 25 limbs throughout the course of his or her lifetime. However, if a person becomes limb deficient while they are adults, they typically will go through about 15-20 limbs during their lifetime (Prosthetics Outreach Foundation, 2005).

Other customers are governmental and non-governmental organization which are funding for working on rehabilitation of prosthesis to the amputees in developing countries. Of course, they have their own agents, and there are some western countries agents like SIDA for Sweden, World Health Organization for UN, and non-profitable organizations like The Red Cross, The Center for International Rehabilitation, and those want to assist people with disabilities in achieving their full potential especially in Africa, Middle East, Asia and South America. Basically most of these agents do not only fund their money to the product, but they work also on distributing and fitting the product directly to the amputees. Hence, before they fund their money, first they want to know about product’s quality and they must be convinced. Then they will rely on the product to distribute and fit to the amputees. Therefore,
in this thesis study, the amputees those are primary consumer and these agents are considered as potential customers to Frugal Prosthetic socket (FPS).

4.1.2 Customers’ requirements

As Pollak recommends, a visit to meet users in their local environment is desirable during the CNA (customer need analysis) process in order to better understand the users’ needs (2008). Interviews for this CNA were conducted in two locations in the research paper of Meagan Renee 2014 for design of low cost adjustable socket: Centro de Miembros Artificiales (CMA, La Paz, Bolivia) during August 17-27, 2011 and the Audie Murphy Veterans Administration (VA) Memorial Hospital and Texas Diabetes Institute (San Antonio, TX) intermittently during 2011-2013. These locations were selected in order to identify differences between needs of users in developed vs. lead users in underdeveloped communities.

With the assistance of CMA staff in scheduling patient appointments during the visit, thirty-minute prosthesis use and comfort interviews were conducted with twelve lower limb amputees. Interviews were conducted with amputees following or while waiting on their appointments with the prosthetic technicians. An interpreter assisted with translating between English and Spanish during the interviews and was provided with a Spanish translation of the interview questions in advance. When given permission, audio recordings were made of each interview.

The responses from the interviews were grouped according to similarity and customer needs were interpreted from the statements. Importance of particular needs was determined by ranking according to frequency of occurrence across all participants at the location. Eight major categories were identified from the interpreted needs: Problems with Fit, Maintenance, Longevity, Working Environment, Cost, and Performance of Volume Adjustments, and Safety.

As with amputee interviews in Bolivia, clinician interviews were conducted during the same visit to La Paz. Three clinicians were interviewed from two separate prosthetic labs in Bolivia, two from CMA and the other from Cochabamba. All three had at least 25 years of experience working with amputees in Bolivia. Grouping their responses according to similarity and interpreting the statements again identified similar customer needs as those identified in the customer interviews. Five need categories were identified from the UDC clinician interviews: Problems with Fit, Maintenance, duration, Cost, and Performance of Volume Adjustments. From this analysis one of the problems is cost, the customers want inexpensive socket with a minimum effort to maintain.
4.1.3 Benchmarks

As frugal innovation, this project focuses on reducing of complexity of a prosthetic socket and decreasing its weight, uncomfortability and cost by comparing with the existing competitors’ socket. Some of these competitors are Mukti Limb Foundation and Össur.

The Mukti Limb Foundation has set up camps around India and presently has 350 camps internationally. The Mukti limb is very lightweight and is custom-made for amputees in just 5 hours. The Mukti limb can be made in remote villages. These quality legs can be made quickly and are provided free of cost by the Mukti organization to all amputees. With little skill or training needed on the part of the technicians to make these legs, the Mukti limb has grown in popularity. The Mukti limb is normally made by a mobile outreach program equipped with tools needed to produce these limbs. Small vans travel to remote villages for 5-6 day workshops. A team of 5 technicians can make up to 60 limbs in 5 days and send the patients back to their families within one day according to Erin S. (2006)

A high-density polyethylene (HDPE) irrigation pipe (3” in diameter) is used to make the socket and the shank of the limb. The pipe is skin-colored and molds easily once it has been heated. Once a plaster mold is made of the residual limb, a cardboard cone is adhered to the bottom of the mold and the cone is filled with plaster to make a positive mold for the shank of the limb. The HDPE pipe is cut to the desired length and then put over a wooden stick and heated in the oven until pliable. It is then stretched over the cast of the leg. The plaster is removed from the inside of the mold and a pre-made foot is attached. Leather straps for suspension hold the prosthesis on the residual limb. The toughness and durability of the limbs and the mobility of the vans that travel to make these limbs accessible to many people has made the Mukti limb a success.

![Figure 4.1 Mukti Foundation’s prosthetic socket (Prosthetic Resident)](image)

Össur headquarters are in Iceland and the Company maintains an extensive global presence with operational centers in the Americas, Europe, and Asia and beyond. Their mission is to improve people’s mobility. As a global leader in non-invasive orthopaedics, they have nurtured an innovative mind-set, continuously pushing the boundaries to create the best products and services in the fields of Prosthetic, Osteoarthritis and Injury Solutions.

Össur’s state-of-the-art bionic technology combines mechanics and electronics to effectively mimic the amputee’s natural sensory and motor control functions. This advanced technology helps to reproduce accurately certain functions that have been lost due to amputation. Össur
offers a full spectrum of premium lower-limb prosthetic products, including mechanical knees and feet and silicone liners. The Company’s prosthetics line includes artificial limbs and related products for amputees. From simple check sockets to complex definitive sockets, from Symes to hemipelvectomy sockets, and everything in between, it can be counted on the skilled Össur Custom Fabrication team to quickly design and fabricate TT and TF socket.

Figure 4.2 Össur’s prosthetic socket (Össur Life without Limitations)

These two competitors were also considered in this project as benchmarks in order to develop frugal prosthetic socket for developing countries. They have extremely different and large gap between them in their quality and cost perspective. Hence, FPS is being developed to have a place in the gap of Mukti and Össur.

4.1.4 Engineering specification and Target setting

Prosthetic socket is a custom-fit product, how well it performs and how cosmetically appearing, it is depending on many variables including mould of the limb, cost, the skills that technicians have to make the limbs, and the materials that are available to fabricate the socket.

Prosthetic design involves making a replacement of a missing body part of the appropriate shape and size. The prosthetic socket must support the patient’s body weight and hold the residual limb firmly and comfortably during all activities. Since the principal function of the residual limb is to serve as the lever to power and control the prosthesis. As such, the prosthetic socket should be designed to support the residual limb tissues, facilitate control of the prosthesis during stance and swing, provide suspension during swing, and facilitate alignment of the artificial. In addition to this, the socket should be light in weight to walk and it should be simple to wear and off, and customized easily to the amputees.
In order to define and generate engineering specifications for developing a product such as frugal prosthetic socket (FPS), one of the best and currently most popular methods is Quality Function Deployment (QFD). The QFD method is that it is organized to develop the major pieces of information necessary to understand and define the problem (see Appendix III). In addition to this it shows that FPS has a place to be competent product between Mukti’s and Össur’s prosthetic socket products. The target of this design is reducing the cost of the prosthetic socket to 30% of the existing socket and optimizing the step of the process for producing FPS.

4.2 Conceptual Design of FPS

The prosthetic limb consists of different components: the socket, which is the interface between the limb and the mechanical support system, the extension (or pylon) which replaces the length of the lost limb and may also incorporate a knee joint if the amputation is above the knee, and lastly, an artificial foot. Each module has its own principles for designing them. However, the basic principles for socket design vary from either distributing most of the load over specific load-bearing areas or more uniformly distributing the load over the entire limb. Since the skin and the underlying soft tissues of the residual limb are not particularly adapted to the high pressures, shear stress, abrasive relative motions, and the other physical irritations encountered at the prosthetic socket interface. The residual limbs consist of mainly bone and soft tissue. This tissue does not have much contribution for supporting the weight of human body, but the bone is more responsible to withstand all the weight of human, which is why the bone should be supported firmly rather than hold in socket.

In order to support the bone over the soft tissue of the limb in FPS, there are four pillars (anterior, posterior, lateral and medial), and four curved holes which can be made between two adjacent pillars on the socket itself, and four belts (two for upper and two for lower part of pillar). These pillars create load zones where less soft tissue does exist, and create small distance to the central bone of the residual limbs. The curved holes create off-load zone where more soft tissue does exist and create ways which allow this soft tissue to purge out from the socket. Belts are used for tying up parallel pair of pillar and for suspension system of the socket. The anterior and posteriora pair of pillar is tied up together and the lateral and medial a pair of pillar is also being together. When the anterior and posterior pillars are tied up together, the soft tissue is squeezed and purges out toward lateral and medial side of the socket. And then the lateral and medial pillars are also tied up together, the soft tissue is squeezed again and purges out from the socket through curved hole. Hence, the pillars have a chance to near the bone and support it. If the bone is tied up and supported with these four pillars, then it will not have a chance to move inside the socket, so the amputee does not require exerting large amount of force in order to move his limb forward.
As frugal innovation the concept of FPS is so simple just supporting the bone with the pillars, and tying up them together with belt to be strong as a single part and finally connect them to the mechanical extension of the limb. FPS can be made from hide, which is raw skin of cattle, or thermoplastic.

4.3 Conceptual Evaluation and Selection
The socket, as a human-device interface, should be designed properly to achieve satisfactory load transmission, stability, and efficient control for mobility. Some early designs of the prosthetic socket, such as the "plug fit," took the form of a simple cone shape, with very little rationale for the design.

4.3.1 Concept Evaluation

**Quadrilateral:** it is the most traditional socket shape, most diffused from the ‘60s and then slowly substituted from the CAD-CAM from the ‘80s. It is still nowadays used by patients accustomed from the total contact between stump and socket, without liner, above all seniors and who has skin problems. It gives a particular sensation of control on the prosthesis. It is suggested for long and tonic stumps. This socket has 4 sides with irregular edge and different heights, which basically compress the stump.
**Flexible or ISNY:** this is not a traditional socket, designed in the ‘80 by Kristinsson of Iceland and then exported to the U.S.A., and so called ISNY (Iceland-Swedish-New York). It is indicated only for stable stump, normal and long, and who has great need of. It has an internal flexible thermoplastic part sustained by and external rigid or semi-rigid structure. The flexible part gives a good sensation of prosthesis control and reduces the internal temperature, and it is quite more comfortable than traditional socket.

**MAS:** this is the last generation of TF socket, not still very diffused; it is a kind of evolution of the CAD-CAM socket. It was invented at the end of the ‘90s by Marlo Ortiz Vazquez, and so called MAS design or Marlo Anatomical Socket. It is indicated for dynamic amputees, with very tonic stumps. Compared to a traditional ischium containment socket, the back part reduced, leaving free the entire buttock, better containing ischium and giving to the amputee more mobility freedom. Excluding in this way all the buttock weight, all the force distribution is directed to the lateral and frontal side without any problem. For this socket it is necessary a totally perfect coupling between socket and stump.
PTB: Patellar Tendon bearing has been the most diffused TT socket until the end of the ‘90s. This socket has higher pressure distribution areas to support socket itself and more comfortable area with protuberances and difficult blood circulation. It is not appropriate for sensitive skin. It has also two other sub typologies

- **Supracondylar Suprapatellar Suspension (SCSP):** this is a PTB socket but it has also higher medial, lateral and frontal walls, which cover the entire patella. Good for patients with very short stumps but slim. Aesthetically more visible but gives a great stability;
- **Supracondylar Suspension (SC):** similar to the SCSP but frontally leaves visible part of the patella. Appropriate for patient with good cruciate ligaments conditions, it permits a good knee flexion. Aesthetically less visible;

The previous development shows that biomechanical understanding of the interaction between the prosthetic socket and the residual limb is fundamental to the improvement of socket design. With an understanding of the residual limb anatomy and the biomechanical principles involved, more reasonable socket designs. These designs intended to provide a more effective distribution of loads around the residual limb. These sockets are so designed that the load-tolerant areas can chiefly take the load, while relief can be given to the sensitive areas, and the bone of the residual limb moves freely inside the socket, these designs allow
amputees to exert large amount force to move, since they are designed only fitting the limbs without considering the bone is the primary mover for human body support and movement.

**FPS:** there are four pillars (anterior, posterior, lateral and medial), and four curved holes which can be made between two adjacent pillars on the socket itself, and four belts (two for upper and two for lower part of pillar). These pillars create load zones where less soft tissue does exist, and create small distance to the centeral bone of the residual limbs. The curved holes create off-load zone where more soft tissue does exist and create ways which allow this soft tissue to purge out from the socket. The belts are used for tying up parallel pair of pillar and for suspension system of the socket. The FPS is somewhat different from the previous prosthetic sockets, because it is not used as only an interface between the limb and the mechanical support system, but it is also used as a connector mechanism of the bone of the residual limb and the mechanical support system, the extension (or pylon) which replaces the length of the lost limb. The principle of FPS is that before it connects the lower part of mechanical system, first it should support and hold the bone of residual limb firmly, then connect to the extension of the limb.

### 4.3.2 Concept Selection

In order to select the concept of easy customized and cost effective prosthetic socket for developing countries from the above five concepts, the decision matrix-Pugh’s method is used (see Fig4.8). The selection criteria are minimum environmental impact of the socket or the process when it is produced, less cost of the socket, less complexity when it is customized and used, and less complexity for raw material availability, comfort while it is being used, easy manufacturability when it is processed and produced with minimum cost, easy maintenance when it loses its functionality and durability and minimum effort to customize, wear to and remove from the limbs. The total importance of all criteria is 100%, which is distributed for each criteria based on its impotency. The alternative concepts, which are FPS, MAS, PTB and ISNY, are evaluated based on their impotence with their references. -1 (minimum) and 1 (maximum) are value of the concept according to the criteria. Zero is the datum, quadrilateral socket which is an old concept and it is used as reference for every new born socket.

The highest value of the weighted total is ranked at first place to be selected and the lowest value is at the last place.

1. Frugal Prosthetic Socket (FPS)
2. Flexible Socket (ISNY)
3. Marlo Anatomic Socket (MAS)
4. Patellar Tendon Bearing (PTB)

Therefore, according to the rank, Frugal Prosthetic Socket (FPS) is the best concept for designing and producing easy customized and cost effective prosthetic socket for developing countries and see appendix IV for SWOT analysis of FPS:
4.4 Design of Frugal Prosthetic Socket (FPS)

If FPS is selected as the best concept for easy customizing and cost effective prosthetic socket, we put here attention on the socket design phase, which is the core of the framework and the process of producing sockets. As frugal innovation, FPS has to be designed and produced without any complexity. In fact, a good manufacturing of the socket means a correct functionality and usability of the whole prosthesis. Typically, a socket is mainly hand-made and the technician really needs high professional skills to realize it. Since the socket is strongly dependent on the human body anatomy and it has to be perfectly close fitting to each patient’s residual limb.

4.4.1 Configuration of FPS

All prosthesis components, apart the socket and rarely the liner, are standard components available on market and selectable from commercial catalogues. The socket is custom fit device because the shape and the size of the stumps are not the same patient to patient, so socket has more constraints of shape and size. FPS has been developed to reduce the shape constrain of the prosthetic socket. There are four pillars and vertical ellipse curved holes on FPS. These curved holes relief the shape constrain of the socket because the soft tissue of the stump purge out through them and this situation is also used as suspension system of FPS.

The main suspension mechanism four belts of FPS configures with four pillars (anterior, posterior, lateral and medial). The anterior and posteriora pair of pillar is tied up together and the lateral and medial a pair of pillar is also being together. When the anterior and posterior pillars are tied up together, the soft tissue is squeezed and purges out toward lateral and
medial side of the socket. And then the lateral and medial pillars are also tied up together, the soft tissue is squeezed again and purges out from the socket through curved hole (see appendix V)

4.4.2 Material and Process Selection of FPS

The essential reason behind high cost of prosthetic socket is the material it made of. Moreover current creation of the sockets is also always an artful job and time consuming process. Here is another topic where concept of frugal innovation is implemented in this project. In order to reduce the cost and complexity of the process of the socket, FPS is produced by using local material (rawhide) and simple process (flexible molding) to customize.

**Rawhide** is selected to build the main body of FPS. The rawhide a hide or animal skin that has not been exposed to tanning. It is similar to parchment, much lighter than leather made by traditional vegetable tanning. The skin from buffalo, deer, elk or cattle from which most rawhide originates is prepared by removing all fur, meat and fat. The hide is then usually stretched over a frame before being dried. The resulting material is hard and translucent. It can be shaped by rewetting and forming before being allowed to thoroughly re-dry. It can be rendered more pliable by 'working', i.e. bending repeatedly in multiple directions, often by rubbing it over a post, sometimes traditionally by chewing. It may also be oiled or greased for a degree of waterproofing.

![Rawhide Material](image)

**Figure 4.9: rawhide material**

It is thought to be more durable than leather, especially in items suffering abrasion during use, and its hardness and shapability render it more suitable than leather for some items. For example, rawhide is often used to cover saddle trees, which make up the foundation of a western saddle, while wet: it strengthens the wooden tree by drawing up very tight as it dries, and resists the abrasion regularly encountered during stock work or rodeo sports. It can also be used as a backing on a wooden bow. Such a backing prevents the bow from breaking by taking a share of the tension stress. Bows made from weaker woods such as birch or cherry benefit more from a rawhide backing. Rawhide is, however, more susceptible to water than leather, and will quickly soften and stretch if left wet unless well waterproofed. Wet rawhide has been used by some earlier cultures as a means of torture or execution, gradually biting into or squeezing the flesh of body parts it encloses as it dries. On the other hand, it has also been used in the context of medicine by First Nations peoples, such as the Sioux Nation: wet rawhide would be wrapped around a long bone fracture and it would dry, slowly setting the
bone, the rawhide worked exactly as a plaster cast does today. Rawhide laces often sold for boots or baseball gloves are made of normal tanned leather rather than actual rawhide. Rawhide is not pliable when dry and would be unsuitable for this use.

Traditional gaucho's "boots" are made with horse feet rawhide. Gauchos skin the animal, then put the freshly skinned hides on their feet like socks, where they are left to dry, taking the user's feet shape. Like moccasins they are soft soled. Like ancient Roman cothurnus, these rudimentary boots have no toe box and don't cover completely the toes. The rawhide has been used for making fighting shield which used to defend spear, sword and high impact load in ancient Ethiopian soldiers, since it is so strong as steel when it dries and the price of dried rawhide is cheaper than other materials which have the same mechanical property.

![Figure 4.10 density vs price material selection](image)

**Leather** is selected for suspension belts. **Napa leather** is leather, typically dyed, and made from kid-, cow-, calf-, lamb- or other skin by tanning. Wood or thermoplastic polymer is selected for socket adapter and bolt-nut, and rubber for washer.

Nowadays, prosthesis socket design carried out mostly following a hand-made technique which is depends on instruments used and operator skills. Moreover it consumes a lot of money because of its long consecutive steps and time consuming process. For example, refer the literature review in section of socket design methodology. In order to overcome these complex procedure and expensive cost, FPS has been designed with new and simple methodology which is called **Flexible Moulding**.

Flexible moulding is developed and proposed by author to reduce the complex process of moulding for prosthetic socket. It is a method of capturing the shape of the stump, and it is so simple procedure and no need high skilled man power, only requires measuring, cutting and sewing. Materials which it requires are sheets clothed, string and sand. For preparing flexible moulding, the procedures are:
1. Measure the length of the stump and the diameter of the distal of the stump
2. Sum up the value of the length and the diameter
3. Draw a circle on the sheet cloth with a diameter of the value of step 2 and inscribe in square then mark four tangents points and label then 1,2,3 and 4 counter clockwise or clockwise.
4. Cut out the square from the sheet and label the tangent point again according to stump feature A (anterior) for 1, M (medial) for 2, P (posterior) for 3 and L (Lateral) for 4
5. Tie up bandage on the stump tightly, cover the stump with square sheet correspondence to the label and sew the square sheet with the bandage at only four points according to the stump feature and make sure the sheet is straight up on stump.
6. Stretch and sew the remaining four opening of sheet with respect to the diameter and the shape of the stump until it creates a negative mould of the stump.
7. Take off the negative mould of the sheet and cut out unnecessary the sheet outside the diameter of the mould careful,
8. Let the strings untie from the mould; the negative mould will be changed to a plus sign (+) shape. This plus shape sheet is a mould for preparing FPS.
9. Prepare wet rawhide on the workbench and repeat step 1-4 for rawhide instead of sheet clothe
10. Copy the shape of the plus sign sheet mould to the surface of the square rawhide correspondence to the label and cut out the rawhide as the same shape and size of the plus sign sheet. Finally we get a plus sign of rawhide.
11. Sew the plus sign rawhide to get a negative mould as we have done step 6, and we get negative mould the stump from rawhide.
12. Fill and push in the sand into the negative mould of rawhide until it stretches and get the shape of the stump and let it dry. When it is dried very well, it can be very strong and sustain its shape as it is.
13. Remove the sand and trim out socket to form pillars, file the edges and drill holes for suspension and socket adapter
14. Assemble the belts on the pillar and socket adapter at distal top of the socket, finally we get FPS.

If we gain experience, we can use direct rawhide instead of using sheet clothe. Then these 14 steps can be reduced to 10 steps. Flexible moulding process is easier than the previous socket manufacturing process and it is also easy for amputees to customize their own FPS socket and see appendix VI

4.5 Results from the prototype of FPS

Two prototypes were fabricated by flexible moulding and plaster moulding for visualization of the final design and to identify any issues. This prototype demonstrates the basic functionality of the concept and manufacturability of the proposed method. As a prototype, this attempt at manufacturing the device did not include all features. This preliminary embodiment exhibited the desired functionality and confirmed the concept can be manufactured using simple shop tools and local materials.
This analysis was focused on high-risk areas through the use of Failure Modes and Effects Analysis (FMEA). FMEA is a qualitative technique where the user breaks a product design into its functional components to identify possible sources of failure through inductive reasoning (Otto & Wood, 2001). FMEA was completed for FPS socket to isolate possible problem areas for improvement. Summarized in Table, this analysis revealed three failure modes that need to be addressed prior to initiating deployment. Four avenues to address these failure modes were identified:

1. Provide clear and detailed manufacturing and user manuals.
2. Include inspection of sourced materials.
3. Provide a maintenance schedule.
4. Provide user training.

<table>
<thead>
<tr>
<th>FMEA (Failure Modes and Effects Analysis)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product:</strong> FPS</td>
</tr>
<tr>
<td><strong>Organization Name:</strong> Halmstad University</td>
</tr>
<tr>
<td><strong>#</strong></td>
</tr>
<tr>
<td>1</td>
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</table>

*Figure 4.11: FMEA for FPS (author 2015)*

The final phase of the design process sees a product taken from embodiment through full concept of the design. The goal of this prototype for this design process is to determine the effect of the suggested solution of FPS to the stump of the amputees and optimizing the customization of a prosthetic socket, the cost of the socket. Of course the initial targets of this thesis were producing easy customized and inexpensive prosthetic socket.

### 4.5.1 Prototype and customization Analysis

**Weight of FPS:** Socket weight and mass distribution have been shown to effect amputee gait symmetry (Mattes, 2000). Lower weight sockets are preferred; therefore the FPS socket design has been weighed and compared to the previous carbon fiber socket. The weight of FPS lighter than that of carbone fiber socket, 3% percent lesser than the weight of the previous socket.
**Shape of FPS:** it does not have more constraint on shape since 50% of its part is removed and being curved hole through which the soft tissue that is the factor for shape constraint purge out from the socket. However, the two prototypes that produced by flexible moulding and plaster molding have the same shape of the stump of the amputee.

**Thickness of FPS:** the thickness is one of the factors that can determine the strength of the socket. As the specification, the minimum thickness of the socket is one-twentieth of the weight of the amputee. However, the thickness of FPS might be below the limit due to the material rawhide, when it dries, its thickness will be below the limit. In order to maintain the thickness of FPS, tanned leather can be laminated outside of the socket with either shoe-adhesive material or epoxy.

**Supportive system of FPS:** the main supportive parts of the FPS are the four pillars, distal and femur. The pillars and femur support the bone or the stump laterally, and distal parts of the FSP socket support the stump vertically. Each part has good resistance on impact and compression loads but overall the socket is laterally flexible due to the connection point. This lateral flexibility is very important to support the bone firmly since the pillars can move toward the bone laterally, and it is important to wear on and off the socket from the stump. The disadvantage of this lateral movement of the socket is to let the connection be losen.

**Suspension system of FPS:** it is belt suspension system on two places, at bottom of femur and upper of distal, in order to prevent pistoning of the stump. The material is either leather or canvas which can fine local market easily. The comfort of the belt suspension system is the same as trouser belt. Its maintenance is so easy and not requires much effort to fit with main part of the socket and the stump of the amputee.

### 4.5.2. Discussion

There are two main points for discussion in this paper. The first one is the cost of the prosthetic socket. The main benefit of FPS socket design is the anticipated reducing the expensive cost of the socket for developing countries. In order to manufacture this socket, a higher initial capital investment is not required due to the local material (rawhide), manpower and time required to manufacture the socket. Producing of a single FPS socket can be completed in a work day and it is estimated to cost ten times lesser than that of definitive socket due to the proposed method that is flexible moulding process, which can be done by one simple trained person just measuring, cutting, sewing and ramping sand. These tasks take maximum two hours; the remaining time is for drying the socket since the wet rawhide should be dried very well. It can be dried by sun light; otherwise the cost of electric energy is incurred for drying hide of FPS.

The overall cost of the definitive carbon fiber volume adjustable sockets can be purchased for $1850 (15,316 SEK) and typical definitive carbon fiber sockets for $650 (5381 SEK) (including labor and material), but the FPS socket is estimated at $10 -$50 (83-414 SEK) if the rawhide and labor are from developed countries. The cost of FPS will more reduce if it is produced in developing countries because man power and rawhide is cheaper in developing countries. One of the targets of this design is developing a new prosthetic socket whose cost is 70% lesser than the existed prosthetic socket or 30% of existing prosthetic socket.
Regarding to the cost, the target is now achieved more than expected. Hence, there is freedom to upgrade the FPS as the customer needs.

Another discussion point is the proposed methodology. As frugal innovation, the focus point of this thesis is finding simple solution by reducing complexity of a product or a process without affecting the basic function of a product.

Nowadays, prosthesis socket design carried out mostly following a hand-made technique which is depends on instruments used and operator skills. Moreover it consumes a lot of money because of its long consecutive steps and time consuming process. For example, the measures stump length by normal tap from head of the fibula to distal end of the stump. Circumferences of the stump are measured at mid patellar level, then after every 2 inches below till distal end of the stump. After that it is covered via cling film or plastic bag of amputee’s limb by technician.

Make a chalk bandage for produce negative mould of the stump through a mix of plaster of Paris and water. Subsequently, wrapping plaster of Paris (POP) bandages around the limb for creating a negative mould and capture the stump by casting. Positive mould was made. After the plaster wrap has been applied to the stump, Use of the hands to shape cast while plaster is hardening. Thumbs compress bandage in and around patella. At the same time, light counter pressure is exerted with the fingers across the back of the stump. Then remove the negative cast of stump from limb after drying and fixed negative mould on bench vice then positive mould is subsequently created by filling the wrap cast with plaster of Paris. When the plaster was set completely, the POP wrap cast was slit open and positive mould of the stump was obtained. The chalk negative cast is utilized to acquire a positive model, which is modified when necessary and used to produce the socket. After checking all measurements, it was ready for modification. This is so long process for preparing only mould for the stump. It is also labor intensive and time consuming long process, but it is versatile to use for any kind of material like carbon fiber, thermoset, thermoplastic, etc.

The proposed methodology, Flexible moulding is developed for only this project reducing the complex process of moulding for customizing prosthetic socket as a frugal innovation. It is a method of capturing the shape of the stump, and it is so simple procedure and need simple trained man power for only measuring, cutting and sewing. Materials, which it requires, are sheets clothed, string and sand. 80% of the shape of the stump can be capture by flexible moulding since it focuses on the load zone which is very important area for fitting FPS.

This method can be implemented by the amputee himself because it does not require more skill, it is so simple and short procedures for example view the procedures on process selection. It is easy to customize for the stump, and very useful for amputees who live in rural or remote area where there is no rehabilitation center. The objective of this thesis is optimizing customization. Hence, according to the prototype which was produced by this method, it shows that the proposed method can be a solution for customizing for the stump of the amputee.
In general, this project has found solutions which can reduce one heavy complex process for customizing the prosthetic socket easily and reduce 70% of the cost of the prosthetic socket by using local material and implementing frugal innovation concept.
5. Conclusion and Recommendation

5.1. Conclusion

In this thesis, the author presented a frugal product and methodology with customizing prosthetic socket for developing country where the availability, accessibility and cost of prosthetics are significant concerns to limb deficient persons who without the assistance of a prosthetic device may not be able to function. Mobility is oftentimes a task that does not require much thought for the able-bodied. However, for patients of amputation, it is a task that is painstakingly difficult. Daily livelihood is a difficult one, as war affected citizens’ struggle not only with their own physical limitations, but due to limited infrastructure to support them. The amount of time, energy and investments in rehabilitation can be significant, due to the aging technologies available in developing nations.

Once amputees are fitted with prosthetics, life with it is much improved than not having an assistive device. Unfortunately, the excessive cost associated with so many prostheses leads to deprivation in developing countries. Having affordable and readily available prosthetic limbs is vital for everyone that needs them. In third world countries, many limb deficient people are farmers, herdsmen, nomads or refugees and rely on physical labour for survival. In some cases, they become beggars on the streets in order to survive. Not only does the loss of a limb have a grave impact on a person’s physical ability and appearance, it causes profound psychological damage and often contributes to the degradation of their social status. Therefore, the purpose of this thesis is to design a cost-effective frugal prosthetic socket that can be customized easily for amputees in developing countries.

When a design opportunity overlaps multiple areas, the methodology used must also accommodate the particular needs. No single design technique may satisfy all the needs of a multidisciplinary design problem. To accomplish this, the intersection of the design methodologies of the relevant areas for innovation for a particular design problem must be identified in order to develop a more comprehensive design methodology. As this project focuses on applying mechanical design techniques to a biomechanical device for consumers in developing countries, the primary areas of innovation is frugal engineering. By understanding the concepts of this area, a final design methodology can be established specifically for this project. The information was identified through a review of low-cost and biomechanical component design in the literature. The methodology resulting from the blending of these considerations from a variety of literature is summarized here in order to design an appropriate low-cost biomechanical device.

In order to design a frugal prosthetic socket, a design methodology is sought that will best achieve an appropriately designed, low-cost, with simple production method. Through the study of modern design methodologies, a strategy is proposed that emphasizes the intersection of the mechanical design process (contemporary design tools), biomechanics, and low-cost design. Key components of this methodology are previous research and frugal innovation in the design process. Along with a review of the state of the art, provide the groundwork for both the proposed new methodology as well as generating a new concept of prosthetic socket. The result of this study, using the generated concept and simple methodology, a frugal
prosthetic socket (FPS) is developed to demonstrate the basic functionality of the concept and manufacturability of the proposed method. Finally, Frugal Prosthetic Socket is a solution for the problems of amputees in developing countries since it can reduce one heavy complex process for optimizing customization of the prosthetic socket and reduce 70% of the cost of the prosthetic socket by using local material (rawhide) and implementing frugal innovation concept.

5.1.1 Recommendation to future activities

- Further development and evaluation of the frugal prosthetic socket (FPS) design.

Based on gait study and user feedback, there are opportunities for optimization and refinement of socket design. This includes improving the strength of the pillars, the distal end attachment, reducing wear and minimizing stretch in the joint.

- Mechanical properties of the rawhide material of FPS

Static, fatigue and static strength testing of the final socket should also be completed. This could then be followed with additional user studies and initiation of product deployment to non-profit centers.
6. Critical Reviews

**Ethical point of view:** an appropriate code of ethical behavior is an essential framework for the activities of any professional responsible for solving a problem or addressing to the society. This paper is formulated with the principle of engineering ethics. This implies that we used books, articles, journals and websites as references for literature review to know the principles of prosthesis and method of mechanical design, but the concepts to solve the problems are my own innovation in order to add value for the previous studies. This paper may use as reference for researchers who want to study further on frugal innovation of prosthetic socket.

**Social point of view:** ten percent of the global population, or more than five hundred million people, have a disability. Two thirds of those people live in developing countries, and that number is rising due to poverty, poor healthcare, disasters, landmines, war, and other forms of violence. In third world countries, many limb deficient people are farmers, herdsman, nomads or refugees and rely on physical labour for survival. In some cases, they become beggars on the streets in order to survive. Socially, people in some cultures may not be accepting of those with prosthetics, so the prosthesis should aim to bring someone back into society. Not only does the loss of a limb have a grave impact on a person’s physical ability and appearance, it causes profound psychological damage and often contributes to the degradation of their social status.

In developing countries, many organizations, which are working on rehabilitation of prosthesis, are trying helping amputees being functional in the society, but they are not able to reach rural and remote area in order to achieve their mission. They are limited in city or town because the complex characteristics and difficult fabrication methods of prosthetic socket requires rehabilitation center for facilities and equipment. Most of the parts of the prosthetic limb are available in the market with affordable price or they can be modified according to the specification since they are standard products, but prosthetic socket a custom fit product, which is a big problem for rehabilitation organization and amputees who specially live in rural or remote area, and could not be modified or ready-made due to different characteristics of the stump, the anthropometric measures and life style of the amputees. Frugal Prosthetic socket will solve those problems and play a crucial role for having affordable and readily available prosthetic limbs for every amputee that needs them to be active in the society.

**Economical point of view:** economic factors are a concern because if the cost of prosthetic socket is too high in developing countries then the amputee or even a country itself will not be able to sustain its growth. Since most of the amputees in need of prosthetics are destitute, they will not be able to provide for their medical costs, nor will they likely be able to receive assistance from their governments.

This paper found out frugal prosthetic socket (FPS) to solve this problem. FPS can be produced by local material (cattle rawhide), which is available all over the world with the cheapest price and can be customized easily by amputees himself or technician with simple flexible moulding methods. If the amputee himself can customize his own socket, the remaining complimentary parts of the limb can be found in the market with affordable price or can be modified by the amputee. Hence FPS may be a solution for either amputee who live in rural and remote area where there is no rehabilitation center, or amputees who want low price and light weight prosthetic socket.
Environmental: environmental factors limit the resources that are available to produce the prosthetics, but frugal prosthetic socket is made of rawhide from cattle. It is 100% a green product which can be degradable easily.

Occupational Health & Safety: naturally, when processing with wetted rawhide, there is uncomfortable odor, which does not any effect to human being, but requires some care for safety to have comfortable working area.

Generally, this paper has achieved 90% of its design target and addresses the problem, initially aimed to solve through the concept of frugal innovation and the study of modern design methodologies, a strategy is proposed that emphasizes the intersection of the mechanical design process (contemporary design tools), biomechanics, and low-cost design.
Reference

17. [www.frugal-innovation.com](http://www.frugal-innovation.com)
18. [www.rawhide.com](http://www.rawhide.com)
Appendix

Appendix I – Amputation level

- Life style: from the indications of Medicare guidelines for functional classification of patients with prosthesis, it is classified in 4 ambulation levels from K1 to K4.

<table>
<thead>
<tr>
<th>K Code Level</th>
<th>Functional Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>K0</td>
<td>Not a potential user for ambulation or transfer</td>
</tr>
<tr>
<td>K1</td>
<td>A potential household ambulator including transfers</td>
</tr>
<tr>
<td>K2</td>
<td>A potential limited community ambulatory</td>
</tr>
<tr>
<td>K3</td>
<td>Community ambulator using variable cadence including therapeutic exercise or vocation</td>
</tr>
<tr>
<td>K4</td>
<td>High activity user which exceeds normal ambulation skills</td>
</tr>
</tbody>
</table>

Table K-code for Medicare classification for patients with prosthesis

Table: Questionnaire to identify amputee life style

Table: Questionnaire to identify amputee life style
Appendix II - Traditional socket manufacturing method

The traditional socket manufacturing has different steps: after taking some reference

- Measurements of the stump: the measures stump length by normal tap from head of the fibula to distal end of the stump. Circumferences of the stump are measured at mid patellar level, then after every 2 inches below till distal end of the stump. After that it is covered via cling film or plastic bag of amputee’s limb by technician.

  ![Figure: Stump measurement of amputee’s limb](image)

- Mould and adjustment preparation: Make a chalk bandage for produce negative mould of the stump through a mix of plaster of Paris (POP) and water bandages around the limb for creating a negative mould and capture the stump by casting. Positive mould was made as described by Radcliffe & Foot. After the plaster wrap has been applied to the stump, Use of the hands to shape cast while plaster is hardening. Thumbs compress bandage in and around patella. At the same time, light counter pressure is exerted with the fingers across the back of the stump (popliteal area). Then remove the negative cast of stump from limb after drying and fixed negative mould on bench vice then positive mould is subsequently created by filling the wrap cast with plaster of Paris. When the plaster was set completely, the POP wrap cast was slit open and positive mould of the stump was obtained. The chalk negative cast is utilized to acquire a positive model, which is modified when necessary and used to produce the socket. After checking all measurements, it was ready for modification

  ![Figure wrapping plaster of Paris bandages, mark and modification of pressure relief area](image)

- Casting and finishing of the socket: A circular pipe of polypropylene was placed in a preheated oven at 1250-1300°C for 10-15 minutes (fig. 3.8). The positive mould with mandrel was clamped in a vise. The cast was powdered homogenously. Now the preheated pipe sleeve is pulled down tightly over the cast, making sure that it
conformed closely to the distal end. A casing was pulled over this and vacuum was applied. The distal end of the soft insert was then beveled. Plaster is added to the stump model in bony areas to provide relief then, remove plaster mould from socket and destroy the modified positive mould.

Figure forming and finishing of socket

Appendix III – QFD for FPS

The QFD method is that it is organized to develop the major pieces of information necessary to understand and define the problem. In addition to this it shows that FPS has a place to be competent product between Mukti’s and Össur’s prosthetic socket products. The target of this
design is reducing the cost of the prosthetic socket to 30% and optimizing the step of the process for producing FPS.

**Appendix IV – SWOP analysis of FPS**

<table>
<thead>
<tr>
<th>Strengths:</th>
<th>Weaknesses:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Lindhe Xtend wants to do this project</td>
<td>• FPS is custom-fit product</td>
</tr>
<tr>
<td>• FPS can be produced with simple equipment and easy process</td>
<td>• Mass production is impossible or requires further studies</td>
</tr>
<tr>
<td>• FPS can be produced with local material (hide) which is mostly found in developing countries</td>
<td></td>
</tr>
<tr>
<td>• FPS has new concept for supporting and suspension system</td>
<td></td>
</tr>
<tr>
<td>• FPS can be applied for upper or lower knee prosthesis</td>
<td></td>
</tr>
</tbody>
</table>

| Opportunities:                                                            | Threats:                                        |
|                                                                          | • FPS is water and oil sensitive                |
| • FPS is Green product                                                    | • not so much durable                           |
| • FPS will open new market for Lindhe Xtend                               |                                                 |
| • Amputees will have the cheapest price of prosthetic socket               |                                                 |

*Figure SWOT of FPS*
Appendix V – Frugal Prosthetic Socket
Appendix VI – Flexible moulding

Measuring the stump length, from the top of femur to the top of distal of the residual limb.

Draw circle with radius of the stump length
Draw square tangent to the inscribed circle, mark A (anterior), P (posterior), L (lateral) and M (medial) and cut the sheet as square.

Cover the square sheet cloth and cut the sheet four places where excess or uncover the stump.
Finally the plus sign will be formed. This is the negative mould of the stump. Paste to the wetted rawhide and cut the hide as the same as the mould. We get the four pillars then connect them by sewing and fill with sand, finally the shape of the stump will be appear.
I came from Ethiopia. I completed my first degree in Industrial Engineering, and I worked as production manager in private company for 2 years and as flight engineer in Ethiopia Airlines for 4 years. My motto "Tell me what to do; I'll show you how to do it better!!!"