# NATURAL BASED BIOCOMPOSITE MATERIAL FOR PROSTHETIC SOCKET FABRICATION

**Rosalam Che Me[a,*], Rahinah Ibrahim[a,b] and Paridah Md.** … [a]

[a]Institute of Tropical Forestry and Forest Product (INTROP)
[b]Faculty of Design and Architecture,
Universiti Putra Malaysia

*Corresponding author: rosalamcheme@yahoo.com



## ABSTRACT

*Artificial limbs may be needed for a variety of reasons including diseases, accidents, and congenital defects. As the human body changes over time due to growth or change in body weight, the artificial limbs have to be changed and adjusted periodically. This constant need for change or adjustment may become costly if the material used is expensive. This study will emphasise the prosthetic legs by focusing on the socket part as it is often changed and replaced with natural-based bio composites. We posit that natural fibre-based bio composites, such as the natural based reinforced plastic, have the same qualities of existing materials that can be used in various applications,. The results of this study are based on the compatibility of the properties of existing and proposed materials which contribute towards providing alternative materials that are more cost efficient, eco-friendly and yet maintaining the features required for artificial limbs. The findings are expected to help patients or wearers to live independently when they are young, who cannot afford to have this essential.*

***Keyword***: *Artificial limb, prosthetic leg socket, lamination method, natural fibre-based bio composites.*

## 1. INTRODUCTION

Prosthesis is a mechanism designe… …stitute the function or appearance of a missing limb or body part (A… …derstrm, Albck, Aho, Venermo & Lepntalo, 2010). Therefore, ideally… …hesis must be comfortable to wear, easy to put on and remove, light… …t, durable, cosmetically pleasing, functioning well mechanically … …quires reasonable maintenance. Bierbaum, Nairus, Kuesis, Morriso… …ard (2002) mention that at present, to have all these qualities in a pro… … leg is possible but the expensive cost of manufacturing will result i… …ially burdened wearers having the difficulty to afford these prosthetic… …ecause of this, a solution for more affordable and less expensive parts… …nponents should be sought after to enable many wearers to have the … …nity to enjoy ambulation with less expensive and high quality prosthe… … as agreed by McCarthy, Bono and O'Donnell (1997).

An artificial limb is a type of prosth… …t replaces a missing limb or part of the body, such as the arm or leg (K… …Iansen, Fatone & Edwards, 2010). The type of artificial limb used is… …ined largely by the extent of the amputation or loss and the location … …issing limb. Horne and Neil (2009) state that artificial limbs may be n… …or a variety of reasons, including diseases, accidents, and congenital … A congenital defect can create the need for an artificial limb when a p… …s born with a missing or damaged limb. Cancer, infection and circula… …eases are the leading ailments that may lead to amputation. Furtherm… …lustrial, vehicular and war related accidents are the leading causes of … …tion in many developing countries, such as Africa. On the other hand, in most developed countries, such as the North America and Europe, diseases are the leading cause of amputation. Thus, the demand for prosthetic legs is high for many amputees around the world at present.

As agreed by Ramachandran, Lakshmi, Arun, Samith Shetty and Snehalatha (2010), the advancement of design and manufacturing in the field of prosthetics has been notable due to the common demands from either the war victims in war-hit countries or those who are handicapped from birth. Thus, as the human body changes over time due to growth or change in body weight, the artificial limbs have to be replaced or adjusted periodically (Kobayashi et al., 2011). This constant need to change may become costly if the material used is expensive especially with regard to the production cost of the parts and components of the prosthetic legs.

Limb prosthesis characteristically has three main parts, namely, the interface, the components, and the cover. As for the prosthetic legs, they consist of a socket, a pylon and a foot which make up the main parts. Since these parts have different standards and requirements based on their usage, such as strength, aesthetic and flexibility, consequently, they are made of different materials - either synthetic or bio-based materials. However, none of the materials has used bio-based materials to produce the sockets of prosthetic legs at present (Rayegani, Aryanmehr, Soroosh, & Baghbani, 2010). Thus, this research study emphasizes the lamination method of the socket for prosthetic legs using a composition of biocomposite materials. This is so because universally the socket is made up of thermoplastic or copolymer (i.e. propylene and ethylene) materials which are not eco-friendly since they are not biodegradable. Based on the 'green house effect' principle and low-cost production, this research proposes that bio composite materials, potentially the kenaf-based material, should be developed and tested on the layering of the socket.

During the small-scale interviews conducted with the manufacturers in the Klang Valley who produce or import prosthetic legs, the respondents stated that the cost of one prosthetic leg can reach between RM4 to RM8 thousand per pair. Highsmith, Carey, Koelsch, Lusk and Maitland (2009) state that 20% of the cost of a prosthetic leg is dependable on the socket excluding the workmanship of the prosthetic leg. Therefore, if this 20% of cost-saving socket can be lessened, it will benefit greatly on the total production cost of the prosthetic leg. Hence, based on the survey of related literature, this research proposes that lower limb prosthetic legs made of alternative materials (such as kenaf-based biocomposite) could be the alternative way to save production cost, which are also potentially eco-friendly.

The structure of this paper is divided into six main sections. This paper begins with a brief introduction of prosthesis and lays out the general and specific objectives of the research. The following section clarifies the background of the study that exhibits the two important implications of this research study: (1) to lessen the manufacturing cost of the socket, and (2) to promote the use of kenaf-based material which is biodegradable and eco-friendly. Furthermore, this paper will expound on the lower limb prosthesis which will foresee the need to focus on materials used for prostheses and also the techniques. This paper also reviews some of the main causes of prosthetic wearers and the need for this study to be carried out. This paper goes on to explain the manufacturing and materials available in the market at present both in the developed and developing countries. Finally, this paper focuses on the prosthetic leg socket manufacturing process and materials used as well as the need to provide new materials which are eco-friendly and low in manufacturing cost for the prosthesis components.

## 2. LOWER LIMB PROSTHESIS

Lower limb prosthesis is an artificial replacement for any or all parts of the lower leg extremity (Moxey, Hofman, Hinchliffe, Jones, Thompson & Holt, 2010). The loss of lower limb can profoundly influence an individual's quality of life. However, many amputees reject lower limb prostheses or use them less than needed because of discomfort. The main cause of acquired limb loss is poor circulation in the limb owing to arterial disease, with more than half of all the amputations occurring among people with diabetes mellitus, as explained by Berke *et al*. (2010).

Facoetti, Gabbiadini, Colombo and Rizzi (2010) describe that there are two main subcategories of lower extremity prosthetic devices (lower limb prosthesis), which are:

1. trans-tibial (any amputation transecting the tibia bone or a congenital anomaly resulting in a tibial deficiency), and
2. trans-femoral (any amputation transecting the femur bone or a congenital anomaly resulting in a femural deficiency).

In the prosthetic industry, a trans-tibial prosthetic leg is often referred to as "BK" or below the knee prosthesis, while the trans-femoral prosthetic leg is often referred to as "AK" or above the knee prosthesis (Facoetti *et al*. 2010). Besides these two main subcategories, there are other less prevalent lower extremity cases that include the following:

1. hip disarticulations - this usually refers to when an amputee or a congenitally challenged patient has either an amputation or anomaly at or in close proximity to the hip joint;
2. knee disarticulations - this usually refers to an amputation through the knee disarticulating the femur from the tibia; and
3. symes - this is an ankle disarticulation while preserving the heel pad.

Facoetti *et al*. (2010) also explain that conventional lower limb prostheses (i.e. AK and BK) consist of three main parts, which are the socket (which always comes with the flexible soft socket), the pylon and the foot..

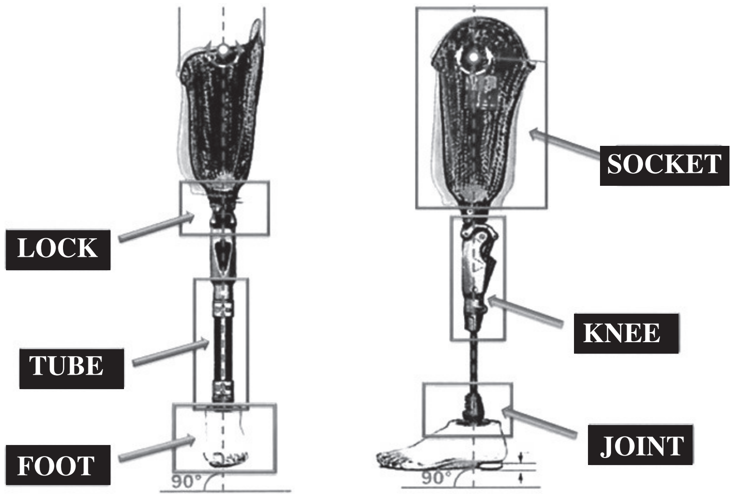


*Figure 1: Trans-femoral or above the knee prosthesis, frontal (left) and lateral (right) view (source: Facoetti et al. (2010))*

More often than not, many parts, especially the foot and pylon parts and components, are manufactured in the factory which will be sent to the prosthetic manufacturers and assembled at the manufacturing facility in accordance with the patient's specific need (Reist, Andrysek & Cleghorn, 2010). However, the sockets, for instance, are custom made and cannot be manufactured in mass productions because they are specially made based on the patient's residual stump. At a few facilities, the limbs are custom made from the start to finish, as mentioned by Nair, Hanspal, Zahedi and Saifand Fisher (2008).

This study emphasizes lower limb prostheses of the AK and BK precisely on the socket part. The significance of this scope of research (i.e. the socket of the prosthetic leg) is based on the unique individuality of the socket itself in terms of manufacturing (custom-made materials) and its functionality (necessity). In their study, Blough, Hubbard, McFarland, Smith, Gambel, and Reiber (2010) report that, the single most critical aspect of any prosthesis is the quality of interface between the limb remnant (stump) and the prosthesis. The portion of the prosthesis fits neatly over the limb remnant, whereby the "socket" determines the amputee's comfort and ability to control the artificial limb. Therefore, it shows that the prosthetic leg wearer's comfort is dependable on the socket part since it functions as the connector between the residual limb and the prosthesis. Hence, this reassurance can be realized by giving considerations on the design, mechanic and material aspects.

### *2.1 Causes and Needs of Lower Limb Prosthesis*

Ide (2011) states that limb losses affect a variety of people in the United States and the world, which include peoples of all races, ethnicities and backgrounds regardless of geographic locations, occupations or economic levels. In developed countries, the main cause of lower limb amputation is due to circularly dysfunction. The prime reason for this is arthrosclerosis, although up to a third of patients have concomitant diabetes (Dromerick, Schabowsky, Holley, Monroe, Markotic & Lum, 2008). These people are usually in their 6th decade or older and most have additional health problems that limit their working ability.

In the United Kingdom, there are about 5000 major new amputation cases a year. This is in sharp contrast with other developing countries where most amputations are caused by traumas related to either industrial conflict or traffic injuries (Arya & Klenerman, 2008). Global extrapolations are problematic, but in the recent US study, it is stated that the amputation rate among combatants in the recent US military conflict remains at 14-19% and the devastation caused by land mines continues, particularly, when displaced civilians return to mine areas and resume agricultural activities (Fergason, Keeling & Bluman, 2010).

The National Limb Loss Information Centre reports that the main cause of acquired limb loss is poor circulation in the limb due to arterial disease, with more than half of all amputations occurring among people with diabetes mellitus. The amputation of a limb may also occur after a traumatic event or for the treatment of bone cancer. Congenital limb difference is the complete or partial absence of a limb at birth. As reported by Johannesson, Larsson, Ramstrand, Lauge-Pedersen, Wagner and Atroshi in their study, the risk of limb loss increases with age, in which persons aged 65 years or older have the greatest risk of amputation. As with diabetes and heart diseases, smoking, lack of exercise and proper nutrition may also increase the risk of limb loss. The causes of limb loss vary from one region to another. At present, the cost of producing prosthetic legs is expensive. Hence, an alternative way to produce cheaper prosthetic legs is crucially needed to ensure that low-income wearers get to enjoy cheap and comfortable prosthetic legs. Thus, in this case, cutting down the cost of manufacturing by offering a cheaper material will be one of the solutions.

## 3. MANUFACTURING AND MATERIALS OF PROSTHESIS

Due to the market demand, Eklund (1995) highlights that prosthetic limb manufacturers are currently undergoing changes at many levels; some of which concern with the choice of materials used in developing the lamination of socket or all parts and components in total. A prosthetic device should be light weight, hence, much of it is made from plastic. The socket is usually made from polypropylene-resistant to many chemical solvents, bases and acids.

Traditionally, lightweight metals, such as titanium and aluminium, have replaced much of the steel in the pylon. Furthermore, alloys of these materials are most frequently used. The newest development in prosthesis manufacturing has been the use of carbon fibre to form a lightweight pylon, as agreed by Linda and John (2001). Before the introduction of today's advanced resins thermoplastics and composites, Myradal (2009) states that prosthetic sockets were fabricated from materials, which among others included leather, wood, latex and metal. For centuries, certain types of wood or leather were carved, soaked, stretched and stitched into prosthetic forms. Once dried, sealed or lacquered, they proved to be very durable. Moreover, according to Myradal (2009), early leather sockets were often suspended in a structural metal or wood frame. Certain parts of the limb (e.g. the foot of the prosthesis) had traditionally been made of wood (e.g. maple, hickory basswood, willow, poplar, and linden) and rubber. Even at present, Myradal (2009) adds that, the foot of the prosthesis is made from urethane foam with a wooden inner keel construction, but due to uneconomical and hazardous effects on the environment, the use of leather or wood, for instance, has been replaced by polypropylene-based materials, such as polyethylene, polypropylene, acrylics, and polyurethane.

Similar to the way dentures or eyeglasses are recommended, prosthetic limbs are first prescribed by a medical doctor in conjunction with the prosthetist's and the physical therapist's advice, as posited by Lawrence and Davies (1981). Apparently, only some parts of the prosthetic legs, such as the socket, are custom made while other parts (i.e. the foot and pylon) are manufactured in the factory. These parts are sent to the prosthetist and assembled at the prosthetist's facility in accordance with the patient's need. It is very rarely that the artificial limbs are custom made from the start to finish in a factory - once again, cost is a concerned factor here.

Material selection plays an important role in meeting the requirements of the prosthesis parts in order to make them effectively functional. The cost of the material chosen has to be relevant (i.e. economical and affordable to low-income amputees, for instance) to be manufactured in mass productions since the material cost itself does contribute a lot in total manufacturing cost for each part. Therefore, based on the related review as preceded above, this research tries to propose more studies on material engineering in providing alternative materials for the same purpose.

### *3.1 Manufacturing Processes and Materials of Prosthetic Leg Sockets*

Generally, the technique of constructing the sockets of prosthetic legs is initiated by constructing the positive cast of the patient's residual limbs. Faustini, Neptune, Crawford, Rogers and Bosker (2006) agree that this can be done using computer aided design and manufacturing (CAD/CAM) equipment and software, or manually by filling the negative impression of the amputee's residual limbs with a plaster mixture of Paris and other materials (depending on the socket's manufacture). This process continues with the next stage, which is fabricating the socket itself.

Myradal (2009) explains the socket fabrication process using lamination or sandwich layering technique. The socket produced is called laminated socket. This fabrication process is basically conducted by sandwiching several layers of selected materials over a cast and between two layers of polyvinyl alcohol (PVA), polyvinyl chloride (PVC) or optional advanced materials. Then, the selected resin is injected into the material using a vacuum assistance. Here, the cast is ensured to be smooth with no sharp edges and dried or sealed to avoid trapped moisture. Fabrication process will be improved if readily available industry-standard acrylic resins are used.

Rogers, Gordon, Mario, Richard and Richard (2007) mention that epoxy resins are commonly used with advanced laminating materials, such as carbon fibres, hybrid matt and stockinette, due to their mechanical strength in holding the number of layers together. Accordingly, the most important aspects to be considered in advanced socket fabrication, especially if it is made of a composite material, are the fibre orientation and the manufacturer's resin-to-matrix, as stated by William and Wool (2000). This is to ensure the capability of resin's optimum strength.

This method of socket fabrication is adopted for this study, due to the fact that it involves laminating a number of material layers. Since the proposed materials are made of natural-based biocomposites and that natural fibre can be woven into a layer form, this technique seems to be applicable. One of the layers used which gives the most strength to the laminated socket is the fibre-glass (Myradal, 2009), and this material is also in the woven form (glass fibre stockinette or tubular glass cloth). Thus, it is proven that this particular layer is potentially to be replaced with the natural fibre materials.

The twist to this exploratory experimentation is to replace the common synthetic fibres with natural fibre in the existing laminated material structure. Indirectly, this method provides a platform for proposing alternative materials which possess the same or better quality in order to lessen the cost of material while improving the strength of the socket.

There is one more technique to fabricate sockets which involves the vacuum-casting technique. The socket produced from this technique is called seam draping socket, as described by Myradal (2009). Faustini *et al*. (2006) in their study, also explain that this particular technique engages these steps: a) creating a positive cast of a patient's residual limb, b) positioning mechanical press on a distal end of positive cast, c) moulding a prosthetic socket component over the positive cast and mechanical press, and d) activating the mechanical press such that the prosthetic socket is pushed apart from the distal end of the positive cast.

Accordingly, a sheet of copolymer thermoplastic is first heated in a large oven and then vacuum starts to form around the positive mould. In this thermoplastic-heating process, the heated sheet is simply laid over the top of the mould in a vacuum chamber, and if necessary, the sheet is re-heated to ensure zero air tolerance space. This step requires that the air in between the sheet and the mould is totally sucked out of the chamber as well as collapsing the sheet around the mould and forcing it into the exact shape of the mould (Faustini *et al*., 2006).

The type of material available for this thermoplastic-heating technique includes a clear thermoplastic material, a polypropylene polymer material, and a flexible thermoplastic material (Mak, Zhang & Leung, 2007). This second method of socket fabrication involves higher technology since it uses a special machine to soften the very high melting point of material used.

In this study, the proposed material is made of a natural-based composite. The very high temperature applied in the process could damage the quality of composite in terms of physical and mechanical properties due to the fact that this proposed composite will be reinforced with natural fibres, as agreed by Sgriccia, Hawley and Misra (2008). Therefore, the similar heating process in the second technique is not appropriate to be implemented, and thus, the alternative way is to employ the lamination technique (the first method mentioned earlier).

## 4. LOW COST MANUFACTURING OF PROSTHESIS

The goal for most of the new prosthetic design is to duplicate the motion of natural limbs as closely as possible for some expected ambulation, and some designs may also be made moisture resistant, and therefore, suitable for use in the shower or on the beach and provide comfort for the wearer (Liu, William, Liu & Chien, 2010). However, the problem at present with the prosthetic and orthotic productions is the costly design and development phases using expensive software applications although some CAD/CAM applications can precisely model near exact ambulation, in which the cost of manufacturing is still high (Bové, 2010).

The study agrees with both Arya and Klenerman (2008), as well as Jensen and Raab (2006), who believe that with minimal use of software applications and less costly technology to design and produce prosthetic and orthotic products, many low socio-economic users will benefit from this research study. Presently, as affirmed by Marks and Micheal (2001), the contemporary industrial fabrications, for instance, principally with the injection moulded plastic technique can create lightweight and low-cost components with satisfactory functions for limited walking, and this may be quite adequate for today's typical elderly amputees and without the assistance of expensive software applications. This is especially true for those amputees who live in economically less fortunate countries, such as in the developing or Third World countries. The Third World countries' amputees who are less financially able to afford expensive prosthetic devices will most of the time seek for cheaper but cosmetically attractive prostheses (Meanley, 1995).

In Malaysia, the number of Type-2 diabetic amputees is increasing exponentially each year as reported by the National Diabetes Institute (2010). In their article, Ooi, Abu Saman and Wan Abas (2010) report that in the Malaysian context, the Malaysian Department of Social Welfare (JKKM) registered about 58,371 amputees in 2005, 66250 amputees in 2006 and 73,559 amputees in 2007. This increasing number of amputees reveals the need to have low-priced prosthetic devices. Therefore, cost-efficient prosthetic parts and components as well as devices which are produced using inexpensive technology are indeed crucially needed and sought after (Sewell, Noroozi, Vinney, Amali & Andrews, 2010). In addition, Jensen and Raab (2006), as well as McFarland, Winkler, Heinemann, Jones and Esquenazi (2010) argue that with restricted financial resources offered by many governments around the world to help the low-income amputees, prosthetic components and devices ought to reach more amputees, and thus, less expensive production cost for these components and devices should be proposed. However, in Malaysia, this is not the case because many components are still imported especially in terms of design or the ready built prosthetic devices. Hopefully, the study proposes to fill this gap by providing alternative ways to produce much cheaper prosthetic devices.

Nevertheless, regardless of geographical areas, the production cost of prostheses is still high. Moreover, if the parts are imported, the price may be even higher (Jensen & Raab, 2006). For instance, Strait (2006) reports that a typical prosthetic limb made in the developing country costs between USD125 to USD1875 each.

Since prosthetic and orthotic productions are often based on imported components, especially in developing countries (such as ready-made feet and knee joints for prosthesis), the locally made invention of prosthetic and orthotic products will economically save the flow of money exchange out of the countries. As agreed by Eklund (1995), imported prosthetic and orthotic products are used in high quality orthopaedic appliances, but because of the high cost of production at present, only a limited number of people will benefit from these exclusive prosthetic and orthotic products. If a less sophisticated technology is used without compromising the quality, many low-income amputees can be fitted with the advent of low cost but cosmetically attractive prostheses.

The argument by many opponents would be that the advent of these low cost but cosmetically attractive prototypes will still be expensive in terms of production cost. However, the logic here is that, if less imported raw materials are used in the production of prosthetic and orthotic products, it will cut down manufacturing cost somehow or rather (Jensen & Raab, 2006; McFarland, Winkler, Heinemann, Jones & Esquenazi, 2010).

In sum, low cost and high quality prosthetic parts and components are highly sought after by many prosthetic and orthotic producers. If this is the case, then one possible solution is to propose inexpensive parts and components to reduce production cost.

### *4.1 New Materials for Manufacturing Prosthesis Components*

The lower manufacturing cost of prosthetic devices may permit the less fortunate and financially disabled wearers in most developing and Third World countries the chance to get affordable prosthetic legs. For this to happen, the cost of production should be lessened (Jensen & Raab, 2006). There are many examples carried out throughout the world to help building cheap yet cosmetically pleasing prostheses. For instance, motivated to find the inexpensive prosthetic parts and components, Saito et al. (1997) have developed a low cost transtibial prosthesis made of fibre reinforced plastic (FRP). The FRP prosthesis is comprised of an aluminium pylon, a cosmetic cover and constant cross-section composite feet into which the aluminium support is screwed to increase load bearing capacity. Likewise, another effort to reduce the cost of manufacturing is evident in the research done by Hahl, Taya and Saito (2010), in which the researchers replace this aluminium support with the integrated FRP stiffener that reduces manufacturing cost, and at the same time, provides high strength, great durability and smooth ambulation. Another cost-saving prosthetic device invention is a prosthetic foot made of rubber, popularly known as the Jaipur Foot developed by Dr. P. K. Sethi in India. This invention has the advantages of low cost, flexible and water proof, which gives the financially disabled wearers across the world to have this essential (Sethi, Udawat, Kasliwal & Chandra, 1978).

Those successful findings suggest that the low-cost materials applied in prosthetic applications could lessen the cost of manufacturing. These findings have inspired the present study to probably produce low-cost manufacturing of prostheses made of the proposed composite. Additionally, it may prove that some components of prostheses can be locally produced, and more importantly, the quality of products is maintained. This can cut the cost of production and lessen the number of imported parts.

## 5. CONCLUSION

In sum, the analysis of this related literature review is to find out: (1) the most suitable manufacturing method to design and produce inexpensive prosthesis, and also (2) the most suitable material to be used in the making of prostheses so that the low-income wearers could afford to buy them.

This research proposes the combination of a natural-fibre based biocomposite with the existing material to fabricate prosthetic leg sockets. The literature has found that natural fibres, such as kenaf and corn starch, can be reinforced with plastic in many other applications. The use of natural fibre-based biocomposites as one of the layers in socket lamination will reduce the manufacturing cost of artificial lower limbs in terms of material costing, and at the same time, provide an eco-friendly alternative to plastic-based materials. Theoretically, if the proposed natural fibre-based biocomposite has the same quality with the existing materials, probably, it can be used to make artificial limbs (especially the socket of prosthetic legs).

Therefore, the study proposes a new material which is more cost efficient and yet maintaining the features required for artificial limbs. Its additional advantages include biodegradable, recyclable and renewable. At the same time, it is expected to contribute to the poor countries or poor people who cannot afford to have expensive artificial limbs.

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