A Short Review on the Cost, Design, Materials and Challenges of the Prosthetics Leg Development and Usage

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***Abstract*—Prosthetic is an artificial limb that helps an individual with amputation to restore the lost part of the body and neuroskeletomotor function. The existence of prosthetic makes it possible for individual with amputation to perform their daily task and remove the barrier of social participation. An ideal prosthetic usually constitutes characteristic as having the ability of 20° dorsiflexion, 20° eversion movement and 117% energy return efficiency. Prescription of prosthetic is restricted to follow according to amputee's functional level or K-level. Common prostheses can be classified as socket-suspended or bone-anchored prosthesis where commonly known as osseointegrated prosthesis. In the process of making prosthesis, common materials that are used widely known are metals, polymers, carbon fibers and few other materials such as Kevlar. The cost of prosthesis in nowadays is a very subjective and depending on the type of design, materials and functions. This short review paper is discussing the use of prosthesis leg for human regarding the functional level, cost, materials, challenges, current researches and future recommendations for the research and development of prosthesis leg.**

Keywords*— *prosthetic, gait, amputation, design, difficulties

I. INTRODUCTION

According to International Classification of Functioning, Disability and Health (ICF), prosthetic can be defined as an artificial limb that is functioned to restore or replace the lost part of body's limb either due to congenital defect, accident, surgery, trauma or illness resulting in daily activity limitation and participation restriction towards the amputee [1]. Meanwhile, prosthetic design is categorized as biomechanics study branch where it is known as the uses of science in mechanical devices that works accordingly to human's muscle, skeleton, and nervous system in the effort to restore individual's motor function [2]. During the designation of any prosthetic limb, prosthetist or engineer should emphasize on the main function of the prosthetic limb, where it supposes to meet the daily requirement and performance as in the natural limb and at the same time providing comfort and ease for the user. Amputee with leg amputation either transtibial (leg amputation located below the knee) or transfemoral (leg amputation located above the knee) will use prosthetic leg to enable them performing gait for daily life requirement. Usually, transfemoral amputation is conducted in account of removing ischemic, infected, or irreversibly impaired tissue [3]. In Africa, amputation rate has significantly rise about 52% since the past decade and most of the affected individual are those who were hospitalized due to diabetic foot ulcer [4]. Individual with lower limbs amputation are normally associated with secondary risk such as back pain and greater metabolic cost during walking compared to able-bodied individual [5]. In the case of transtibial amputation, stability is the main concern as falling is prevalence [6]. Thus, having a prosthetic leg can aid amputee's gait and reduced the need of assistant in doing their daily task. An ideal prosthetic leg usually have characteristics such as able to dorsiflex up to 20° angle, have eversion movement of 20° angle and have 117% energy return efficiency [2].

The first earliest written evidence of prosthetic was noted in a poem in Rig Vida, a sacred Indian scripture between 3500 and 1800 BC. The poem tells about a story of Warrior-Queen, Vishpla who had her leg amputated due to a battle, fitted with an iron made prosthesis [7]. In the fifteenth century BC, the famous prosthesis which is known as The Greville Toe made by cartonnage was found during the reign of Amenhotep II during the Ancient Egypt era. In the ancient time, prosthesis is used for functional purpose, cosmetic appearance, religious and spiritual purpose [8]. Greek historian, Herodotus of Halicarnassus used to mentioned in his book record that in 484 BC, an imprisoned Persian soldier had escaped his misfortune by cutting off his leg and replaced them with wooden leg however he was caught and then was decapitated [7]. Marcus Sergius, a Roman general has sustained almost 23 injuries and had his right hand amputated due to war used a prosthesis made by iron that allowed him to return to his battle [7]. During the Dark Ages, prostheses were made mainly for battle. They are not economically comfortable since many of them are heavy, crude devices made by easy availability materials such as leather, wood and metal. Even until the Reinassance Era, the procedure of prosthesis attachment remained barbaric where no anesthesia is used causing the affected individual to become more susceptible to infection, hemorrhage and death during the surgery [7]. Ambroise Paré (1510 – 1590) was a famous military surgeon whom also an innovator invented the ‘Le Petit Lorrain’, a mechanical hand operated by springs and catches for French soldiers, a kneeling pegs and prosthetics fully applied with a locking knee and suspension harness [7]. Despite the early introduction of prosthetic, this industry only started to develop around the time during World War I when thousands of soldiers faced amputation due to war. In 1912, an aviator named Marcel Dessoutter lost his legs in WWI where he then designed an artificial leg by using aluminium [9].

The general function of leg prosthesis, as shown in Figure 1, is to replace the lost parts of the lower limb as well as restoring the neuroskeletomotor system function by means of orthopaedic or externally controlled that is normally powered either by myoelectric or separate power supply such as battery [10]. Prescription for lower limb amputation differs according to amputation level, amputation aetiology, and the amputee’s daily life activities. Hence, to ensure the independence and social integration of amputees is achieved, provision of high-quality prosthetic services is crucial [1].

Fig. 1 Example of prosthetic leg [11].

The objectives of this review paper are 1) to present the cost overview of prosthetic leg available in the market, 2) to classify the prosthetic leg design according to the need and function of users, 3) to highlight the difficulties and challenges faced by user of prosthetic leg, 4) to analyze the current researches and 5) to project the future recommendations for the development of prosthetic industry suggested by researchers.

II. FUNCTIONAL LEVEL

Prescription of prosthetic must follow accordingly to the classification of user’s functional status that is mainly known as K-level or Medicare Functional Classification Level (MFCL) proposed by The Center of Medicare and Medicaid Services in which it represents the potential of success of using prosthesis. Prescription shall come along with user’s anticipated goal and medical comorbidities and the design must be decided based on team decision that includes patient, physiatrist, physical therapist, and prosthetist [12]. Patients in functional level zero (K0) are classified as fully lost the ability and potential to ambulate and performing gait with or without assistant. Despite with the prescription of prosthesis, it may not assist amputee in improving their gait [13]. Functional level one (K1) is a category where patients used a prosthetic to ambulate over level surfaces for short household distances. Special consideration for comfort during sitting and easy don and doff are an important component in designing prostheses for this category. Functional level two (K2) is a functional category where patients have the ability to perform limited community ambulation and traverse environmental barriers. In this case, the design must focus on the alignment of components and the form of prosthetic foot where it is suggested to be in a multiaxial or flexible keel-type to accommodate gait over uneven terrain. Functional level three (K3) is a group of patients with the ability to traverse most of the environmental barriers and ambulate with variable cadence/rhythms. Type of prosthetic foot is the most important component in designing this type of amputation where energy storing prosthetic foot (dynamic response) is usually used that includes dynamic pylon which features accommodate user better over uneven terrain. Functional level 4 (K4) is when the patients potential ability for ambulation exceeds the normal requirements and it usually include sports or recreational activities that requires high impact, high stress and high energy levels. In general, kids, athletes and high-activity adult are involved in this category. Designing a prosthetic for this category is a challenge since it demands specialty components such as running feet, waterproof foot and special ankle components and adjustable heel height. Usually a backup or secondary suspension is needed to avoid catastrophic disruption and special consideration should be taken for pediatric patients due to growth factor [12].

III. COST

The uplifting demand of prosthesis over the years is due to the demand for a better quality of life by those who are affected. Over the time, tremendous technological advancement has been applied and tested in prosthesis componentry in order to produce a quality and cost-effective prosthesis for users [1]. However, prescription of prosthesis must be in lined according to the K-level and for a few cases of amputation, amputee has no choice but to use a custom made prosthesis in order to improve their quality of life. Technically, common prostheses can be divided into 2 main categories, either socket-suspended or bone anchored prostheses or formally known as osseointegrated prostheses. Socket-suspended prosthesis functioned by mean of mechanical where it consists of socket, suspension, knee and many other components. Development of clinical application of socket suspended prosthesis had introduced the microprocessor-implement prosthesis to replace non-microprocessor prosthesis. Non-microprocessor prosthesis requires much attention during walking while microprocessor prosthesis requires less attention and reduce the risk of falling among its users [11]. Microprocessor-implement prosthetic or also known as computerized leg (C-leg) is designed with sensor in the shin of prosthesis to allow the movement of user to be continually assessed and then fed the data to the microprocessor which in turn adjust the hydraulic damper hence optimize the gait in the amputee [14]. An empirical study carried out by a group of researchers have concluded that electronically controlled knee prostheses require less oxygen consumption as compared to fully mechanical prostheses [15]. Although with the development of microprocessor-implement prosthesis, some user might still experience discomfort upon using the prosthesis. The last resolution of this problem is by prescribed the bone-anchored prosthesis or osseointegrated prosthesis. Bone-anchored prosthesis (BAP) is directly attached to the residual limb by surgical procedure called as osseointegrated fixation without having the need of using any socket to the prosthesis. In comparison to socket suspended, BAP is proven to possess more beneficial criteria in terms of quality of life, user-ease, osseoperception, ability of gait and sustained extended daily activities. However, it is infamously known for its clinical risks where it is susceptible toward infection, implant instability, effect of falling and breakage of fixation parts [16].

In Malaysia, the typical cost of prosthesis varies in between RM 4,000 to RM 5,000 however the price might strike up even more if the prostheses involved any computerized or activated system. Geography factor also plays role in affecting the market price of these prostheses. Since the optimal services are usually available only in West Malaysia, the price range differ in other part of Malaysia since transportation cost and other expenses will be taken into account [1]. Based on study conducted in Italy, C-leg cost around €18,616 including the technology acquisition, trial period and 3 years guarantee while an addition of €1,440 for each year guarantee extension. In comparison to mechanical based prosthesis which only cost around €3,000 without any guarantee but somehow the cost of repairs, replacements and other services would be around €600 per year [15]. Meanwhile, according to a study conducted by American researchers, the price of regular custom made manufacturing socket-suspended prosthesis is around $6,203 to $20,070. In Australia, the interim prosthesis cost is less than $2,000 and BAP cost is fixed at around $3,000 [16]. The prices mentioned are the average cost of prosthetic leg in Malaysia, Italy and Australia. However, the price might slightly differ because prescription of prosthetic for each individual differs according to their functional status and limb condition. A few other factors such as age, comfort, aesthetical features and attachments might also resulting in variation of price of prosthetic since every individual has different preferences.

IV. MATERIALS OF PROSTHETIC

Generally, materials used for prosthesis design can be divided into few categories such as metals, polymers, carbon fibers and other materials such as Kevlar that are meant for support. Common metals that are used to design prosthesis are aluminium, titanium, magnesium, copper and stainless steel which either used purely or alloyed. During 18th century, titanium was first discovered as a suitable metal for prosthetic design due to its good strength for weight ratio and density ratio, excellent corrosion resistance, low density and lightweight [17]. Additionally, titanium is also commonly alloyed with aluminium or valadium to accommodate in low modulus elasticity as in natural bone resulting in more natural gait [17]. However, long term used of metals might cause corroded prosthesis and lead to heavier tubes [9, 18].

Fabricated hard polymers such as the hardest one named polyoxymethylane (POM), pliable and softer polymer named polyurethane (PU), poly vinyl chloride (PVC) that is normally used for coating and polymer dimethyl silicone are the common polymers to be applied as components and in specialized features in prosthesis [18]. Although PVC is durable and resists stain but it possesses less stable characteristic when is exposed to heat or light and requires addition of stabilizer to improve the stability. PVC is known to be a complex polymer as it is added with various constituents upon using it as a prosthetic. This however contributes PVC degradation when relating to the environmental factor [18]. PU were first used as a replacement for rubber since it possesses pliable and softer characteristic but it is agreed among researchers that it is easily degrade when expose to UV and radiation, high temperature and when in contact to acids [18]. POM is known to be the hardest form of polymer compared to PU and PVC. Due to this, it have far better characteristics where it resists high impact, high resistance to various chemicals such as lubricants, oils, and lubricants, and supports dimensional stability. Silicone or dimethylsiloxane constitutes characteristics as elastomer like able to maintain its stability across wide range of temperature (-120°C to 300°C) due to the silicone-oxygen backbone structure [18]. Normally, soft liner that conceals the stump is made out from silicone as silicone characteristic may accommodates the skin due to its elasticity, tear strength and good in pressure redistribution [19]. Polyethylene polymer usually are used in designing prosthetics for aquatic sport (Figure 2) because of its waterproof ability, flexibility, capable of performing swim motion and comfortable [20]. Ionometic polymers is a type of electro-active polymer actuation that are electrically induced bending, possesses mechanical stability, low induced voltage and density and easy to fabricate [2]. A few scientists have conducted a research to use thermoplastic materials for prosthetic manufacture such as polypropylene phomopolymer [9].

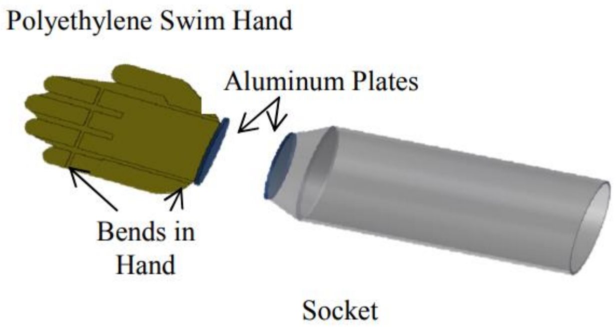

Fig. 2 Combination of polymer and aluminum for the materials prosthetic hand [20].

Carbon fibers reinforced composite is proven to be three times higher elastic modulus compared to steels and wood [19]. Carbon fibers exhibits properties such as high stiffness, high tensile strength, low weight, high chemical resistance, high temperature tolerance, low thermal expansion, high specific strength and modulus, and high responsive elastic deformation which able to support heavy weight amputee [19]. Synthetic fibers is fibers reinforced with another material is also used in prosthetic where it is usually thicker but more lightweight and very strong and stiff [19]. In 1980, a flexible prosthetic foot was introduced made by two laminated carbon fibers which is more lightweight, sturdy and high strength [9]. Limb performance depends on the type of carbon fiber, weave style and resin composition. In order to maximized the energy storage and ensuring the elasticity, varying the degree of fiber orientation is another method to vary the bending stiffness [19].

Kevlar has also been used in prosthetic design and is found to be the lightest material compared to carbon fiber and fiber glass with excellent chemical resistance but the most expensive among those three [21]. Despite of its high cost, Kevlar is bad at maintaining structure under load and five times weak under compression than under tension [21]. In choosing material for supporting part in prosthetic, a few aspect should be stressed such that it must be biocompatible and not harmful to skin and tissue [22]. This is because constant movement during gait may cause the skin become painful which may result in skin blister, cyst and ulcer as the skin is being in contact with prosthesis. Few examples of common material used as supporting materials are Spenco, Poron, Nylon-Reinforced Silicone and Nickelplast [22].

different preferences.

V. CHALLENGES

Amputation is an irreparable event that resulting in numerous physical and psychosocial challenges [19]. Energy consumption or metabolic cost is one the most common difficulties as gait in amputee is not as efficient and smooth as a person with fully functional lower extremities [12]. For a specific distance range, the energy consumption for transtibial amputee with prosthesis is around 25% and for transfemoral amputee with prosthesis is around 63% [12]. At a similar walking speed, a unilateral transfemoral amputee is estimated to use 20% to 60% more energy consumption as compared to non-amputee [23]. In the case of dysvascular amputation (amputation due to ischemia) the metabolic cost increment exceeded to 40% and 120% for transtibial and transfemoral amputation respectively. This is due to the higher oxygen consumption rate that results in slower walking speed [12]. However, a study on relatively young and fit individuals with limb loss suggests that mitigation of high metabolic cost of walking is possible if the muscle strength during ambulation is maintained [5].

Individual with amputation often faces lower back pain on their daily basis. Lower back pain is troublesome as it affect one’s functionality, quality of life and independence and more bothersome than having to deal with phantom pain [24]. According to [25], severe low extremity trauma and low extremity amputation may result in confusion in regard of the clinical procedure and management of low back pain. In comparison with natural gait, gait with the assistance of prosthesis is more complex in the mean of biomechanics as amputee has to face consequences namely altered lumbopelvic, movement and coordination that increase the mechanical load, reduced in intersegmental motion and altered neuromuscular motor that contribute to low back pain [25].

Trauma towards limb also means trauma to peripheral nerves which might account to altered and dysfunction of signal processing to the central nervous system [25]. Amputee who suffers from phantom pain might have to experience central sensitization or hypersensitivity where there is drastic increase of neuronal response towards a stimulus and it usually appears when an individual is exposed to a prolonged pain [25]. This situation may influence them to develop secondary pain conditions such as low back pain. Persons with amputation also have possibility of developing alteration in their pain-processing areas in their brain. A study by [26], concluded that individuals with amputation have a decreased grey matter in the posterolateral thalamus which affect their pain-processing signal. Other central processing finding that contribute to low back pain among amputee are cortical reorganization of the sensorimotor cortex and changes of neuroplasticity associate to phantom pain [25].

VI. CURRENT RESEARCHES

One of the most important system in prostheses either mechanical control or active is the damper which accounted for maintaining the knee angle for both swing and stance phase [27]. In order for prosthesis user to achieve a normal gait, an adequate rotational movement of prosthetic socket controlled by user’s hip movement and prosthetic damper is significant [27]. Thus, an optimal damper parameter is necessary to achieve that goal. A study conducted by [27] have used a grid searching and optimization method where the researchers utilized on the ground reaction force in determining the optimal values of dampers parameter in transtibial amputation. From the research, they concluded that optimization-based searching was far more efficient than grid searching in simulating the auto-adjustment of damping parameters for a better coordination of lower limbs.

It is found that amputees tend to walk slower and consumed large effort as compared to able-bodied individual where they also tend to show an asymmetrical pattern of gait [28]. Studies have shown that adding an active element in prosthesis can aid in attaining the similar energy as if in the real limb and reduced metabolic cost but somehow it increases the weight that is also correspond to added energy during walking and resulting in asymmetric gait [29]. In order to prevent these comorbidities, many researches have been done to investigate the series and parallel elasticity for power amplification and energy storage and at the same time reduces the actuation unit weight as shown in Figure 2 [30]. Addition of series and parallel elasticity can reduce the peak power and reducing the torque values where reducing the energy consumption at the same time [31]. Addressing motor design, gearbox and springs and studying the operating range for each component in the actuated prosthesis is necessary to reduce the energy consumption, perform a better dynamic response, reduce size and weight [30].

A person with transtibial amputation commonly uses contemporary prosthesis feet made by carbon fiber leaf string or formally known as energy storing and returning feet (ESAR) instead of solid-ankle cushion heel foot (SACH). This is due to the functional impairment of their ankle in result of inoperative calf muscles namely the soleus and gastrocnemius muscles that play an important role during forward movement [32]. However, ESAR feet is proven to have lower positive power generation during stance phase as compared to normal stance [33]. A study conducted by [34], proposed a novel foot (NF), a serial layout carbon fiber leaf springs connected with multi-center joint construction to compare the range of motion between NF with the conventional ESAR. From the finding, it is proved that NF exhibits potential advantages over ESAR as it accommodates sufficient foot leverage and offer larger range of motion which resulting in larger ability of dorsiflexion.

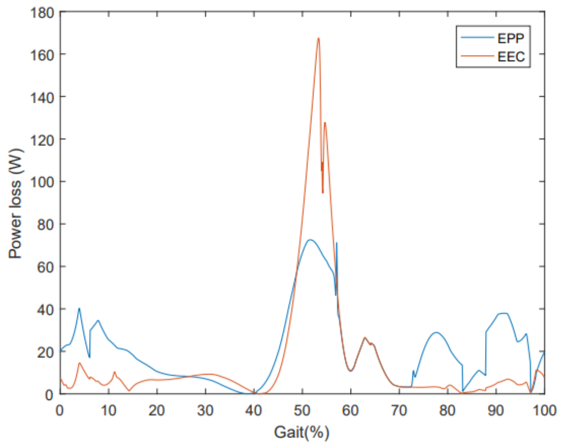

Fig. 3 Power losses over a gait cycle. EPP for electrical peak power and EEC for electrical energy optimization [30].

Another prominent research conducted by [35] is regarding the development of semi-active prosthetic knee which can works in both way either active or passive depending on the user's requirement and daily task needed. The uniqueness of this prosthesis is that it has back-driven capability where an assistive power actuator will be only available in actuated phase and during unactuated phase the prosthesis will be passively functioned. During carrying out daily activities, some tasks require net positive power such as climbing up on the stairs while some tasks require net negative such as during descending the stairs. Knee joint is one great example of lower limb part that does not continuously requires power to function. Semi-active prosthesis is essential as it can be recharged during passive stage thus energy can be regenerated during other gait sub-phases. The design of semi-prosthesis is also equipped with biopotential and mechanical sensors to replace the function somatosensory system in which a person with amputation is missing in their lower limb. Additionally, this type of prosthesis is plugged in with haptic feedback to compensate the proprioceptive and sensory feedback where this feedback also assists in improving amputee's stability and providing leg's information such as detecting whether the leg touches the ground or otherwise [35].

VII. FUTURE RECOMMENDATIONS

The future of prosthetic industry is expected to develop the best prosthetic that is able to imitate the exact movement in gait and energy cost as if in the natural lower extremity without resulting any bad consequences in later time as the aforementioned difficulties above. Based on the numerous researches conducted, each one of them has stated a few recommendations and suggestions for future research references.

A study conducted by [36], suggested that the current prosthetic available for athletes are not necessarily reduce the metabolic cost of running. They then recommended on the improvement of prosthetic design by taking into the consideration of both affected and unaffected biomechanics in order to develop an optimize-running prosthetic for athletes to improve their performance. In developing the semi-active prosthesis, researchers have suggested on focusing to develop the control algorithm in making the add in auto-setting and tuning capability for both active and passive mode [35]. This in turn will make user's life at ease since the prosthesis can work perfectly according to the user's requirement.

Nowadays robotic industry has become so much relevant with prosthetic industry. A new method by means of introducing human gait inference (HGI) in prosthetic where it able to predict the movement of amputated leg parts namely the shanks, thigh and foot has been proposed. This gait inference prosthesis is being called as GaIn, targeting individual with double transfemoral amputation where it is designed to predict the movement of lower legs based on the thighs movement [37]. However, it is expected that GaIn will cause discomfort to the user and adjustment should be applied so that adaptation towards the diversity and urban situations can be achieved [37].

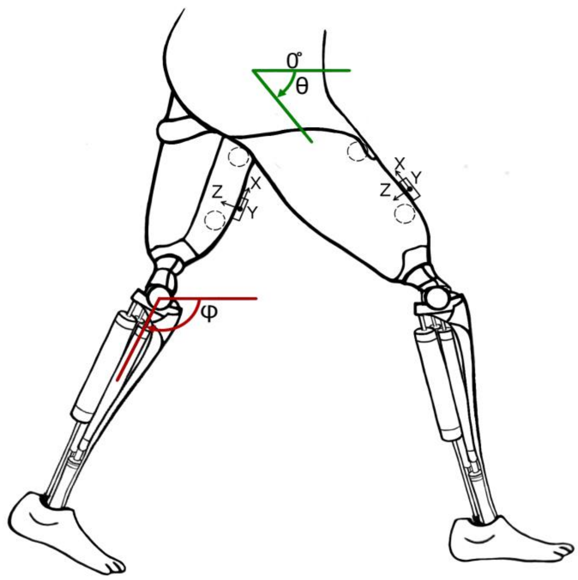

Fig. 4 A concept in GaIn system [37].

VIII. CONCLUSION

Thousands of researches have been done from many years ago to develop and improve the current prosthetic available in the market. Numerous researchers are also working on to develop prosthetic that is affordable by experimenting many materials, design and method to substitute the current one as well as reduce the bad after effect of using prosthesis. However, until today there is no prosthetic that is able to fully imitate the real limb in terms of energy used, muscle works and neural process.

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