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A Review of Commonly Used Prosthetic Feet for Developing Countries: A Call for Research and Development

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Abstract

Major advances in research and development of prosthetic feet have increased the function and quality of life for many individuals with lower limb amputations residing in industrialized nations in the last two decades. A negative aspect of this new R&D is that the vast majority of end users reside in developing nations and are not able to benefit from this new technology due to the cost, durability, maintenance and accessibility of these components. Research is needed in this area for design and development of a cost effective prosthetic foot that meets economic, environmental, and physical standards which can handle adverse climates and working conditions. Information on this subject is limited and through more research and feedback from this population a more functional design may be developed. The current review attempts to synthesize available data on commonly used prosthetic in developing countries to include; demographics, engineering, materials, design and current issues in order to help guide the future of low-cost prosthetic foot development. Of all the prosthetic feet reviewed only two of (>25) low-cost prosthetic feet have passed international standards organization testing (ISO). Based on the available research the current prosthetic feet feasibly available to individuals with lower limb amputations in developing nations fall short in providing durable, cost effective and/or biomechanically appropriate options. It is our belief that through standardized testing and research a more versatile foot can be designed and manufactured to be functional and affordable in developing countries. End user feedback directly from the majority will help direct future research and development so developing countries can have an optimal, yet logical option for prosthetic feet.

Keywords: Prosthesis; Low-cost; Prosthetic Foot; Developing countries; Affordable; Amputee

Introduction

The future of prosthetics has led to the development of highly advanced components with technology that closely mimics the biomechanics of the anatomic human limb. With regards to the prosthetic foot, research has focused on enhancing energy storage and return properties and upgrading the technology in order to simulate anatomical foot dynamics to give the user a more natural gait pattern. One problem with this current research and development focus is that these advanced prosthetic feet are only realistically available to consumers in developed countries, predominantly insured consumers or service members and veterans. The average cost for a prosthetic foot in the western world ranges from $5,000-$15,000 USD. Highly advanced prosthetic feet such as Bionic limbs may cost over one hundred thousand dollars. While cost alone is prohibitive, these designs are also unfeasible for developing countries due to their required maintenance from a skilled technician, the inadequate adaptation to adverse environments and inability to achieve and maintain a reliable power supply [1].

Methodology

This review was conducted by examining the literature on low cost prosthetic feet through Medline, CINAHL, Scopus, Medscape, and PubMed databases. These sources were used in order to extract articles addressing ISO 10328 standard testing results, clinical field test outcomes, benchmark standards developed from prosthetic and orthotic centers on performance, and subjective information from user compliance, practitioner surveys, and quality of life questionnaires. Furthermore, in order to obtain research that may have not been circulated in peer-reviewed journals, secondary sources were also reviewed. These included engineering design reports and methodology, state of the science symposiums, ISPO international consensus conference proceedings, and annual organizational reports for prosthetic delivery demographics available worldwide. Information was also acquired on the developing world environment, psychosocial and socioeconomic factors, and statistics on causes of amputations in third world countries in order to gain a comprehensive background on the issues and appraisal of features necessary surrounding prosthetic foot delivery in developing countries. Articles were excluded if they did not specifically address prosthetic feet or did not directly correlate with the above criteria.

There have been several prior reviews, which similarly provide information on prosthetic technologies in developing countries [1-10]. All of these reviews, with the exception of one, give a broad overview on overall prosthetic technology (sockets, feet, knees, and systems), encompassing other mobility aids such as wheelchairs and do not provide specific concentration on feet and its component failure as provided in this review. The reviews by Jensen, Strait, and Andrysek also combine clinical lab and field-testing results into a chart comparing the various common low-cost prosthetic foot types that assess their durability by survival rate [5,6,8]. Andrysek's review adds

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valuable study information by referencing levels of evidence, revealing the need for higher quality, clinically relevant, peer-reviewed published research [6]. Ikeda's second review also produced a chart comparing delivery of prosthetics by major organizations, however did not provide as in depth of a comparison of regional differences specific to feet as this review [9]. Here we provide an updated and comprehensive review of the majority of low-cost prosthetic foot (>25 total) designs available in the developing world market instead of just a small selection by the prior reviews (4-16 range). Several reviews [1,2,4,7,8] focus on providing historical backgrounds or addressing current prosthetic models and status of service provision with respect to legislation instigators, region-specific issues and demographics, fabrication methods (CAD/CAM), assessment procedures, media, and programs. The main objective of most of the previous reviews was to evaluate progress on outcomes effect from the ISPO 1996 consensus conference [10] for prospective scientific studies to identify issues with prosthetic technology durability, affordability, performance, user satisfaction and services in developing countries.

Background

A major issue with current prosthetic foot development is that it doesn't target the majority of end users. Approximately 80% of individuals with amputations worldwide reside in developing countries [11]. In 2013, the World Health Organization estimated approximately 30 million amputees live in developing countries with up to 95% lacking access to prosthetic devices [11]. A typical limb made in a developing country costs approximately $125 to $1,875 USD [2,8]. However, the annual income of an individual with an amputation in a developing country averages around $300 [8], with a large portion of the population of making less than $2 a day, including 38% of Vietnam, 57% of Cambodia, 88% of Tanzania, 91% of Malawi, and 28% of Columbia [2,12]. One suggestion to make an affordable option would be to reduce prosthesis cost to 3% or less of the annual income of user [2]. This is only considering the cost for the initial prosthetic limb and not the additional costs for maintenance and replacements. Most adult amputees require a prosthetic foot replacement every three-five years and can easily transition through 15-25 limbs in their lifetime [8,13]. Factors depending on age, onset of amputation, activity level, and occupation all contribute to the cost of prosthetic care. These expenses may cost thousands of additional dollars in prosthetic expenses over their lifetime. Many amputees resort to pole and crutch limbs that are not conducive for activities of daily living and lead to complications such as contracture and upper limb dysfunction [2]. In developing countries, many limb deficient individuals are farmers, herdsman, nomads or refugees who rely on physical labor for survival. Thus, having affordable, functional and readily available prosthetic limbs is essential. The most common low-cost prosthetic foot used is the solid ankle, cushion heel (SACH) foot, which was designed for household or limited community ambulation [1,10]. The lack of low-cost, durable and mechanically efficient lower limb prosthetics makes it difficult for individuals with amputations to earn a living and many are left to beg on the streets. This decrease in available manual labor capacity can further impact developing countries' economies.

Low Income Country Demographics for Prosthetic Usage

There are many differences between developed and developing countries. Compared to the metropolitan western world, the developing world is characterized by rugged environments with extreme climate variations, infection, farm-based economies, dangerous explosives, and wars that have a major effect on prosthetic foot wear and should be taken into account. In developed countries, most amputations are due to disease processes such as diabetes, reporting incidence rates of 36 to 55 per 100,000 [14]. In contrast, demographics of amputees in developing countries have shown that anti-personnel mines (120 million spread over 71 countries since 1997) and their delayed detonations are a major factor [15] that has resulted in 15,000 deaths and 1/3 of the injuries resulting in amputations [16]. Newman et al. reports that landmines continue to pose a large threat with an estimated 60-70 million currently still in the field that injure 1,200 and kill 800 people each week [12]. The majority of amputations in these areas are a result of trauma injuries, such as injuries from landmines, gunshot wounds, and traffic accidents, while the next largest are due to infections [3,4,17,18]. In countries such as Cambodia, Iran, and Afghanistan, 80-85% amputations are due to landmines while in India, 90% are due to traffic accidents [4,8]. Further increasing the risk of amputation in these regions are prolonged armed conflicts, natural disasters, and depleted resources, which have led to the breakdown of health services and inability to control progression of certain disease processes [3,18].

Demographics on the use of various low-cost prosthetic feet worldwide are difficult to obtain. Annual reports collected from major institutions that develop low-cost feet give overall data on prosthetic fit for amputees in the regions they supply but the specific statistics on user preference, failure rates, and compliance has not been collected. Table 1 categorizes the number of prostheses delivered by major low-cost prosthetic foot organizations by region as tabulated in their 2013 annual reports [12]. It is difficult to clearly determine demographics for prosthetic feet al. one as some of these organizations also count other prosthetic limbs they manufacture in total delivered. International Committee of the Red Cross (ICRC) and Jaipur organizations are comparable and have the highest number of prosthetics delivered to the countries they supply worldwide. Asia and the Pacific receive the majority of prosthetics from the organizations listed and may indicate the greatest need for limbs followed by Africa, the Middle East, and last, Europe and the Americas. Throughout the review, it is noted that for a specific region, there is little user preference due to availability. The specific foot type used in a certain region is prevalent due to the institutional organization that supplies that region; in most developing countries amputees have limited selection of prosthetic foot type.

Major Organizations Delivering Prosthetics (# countries located in)	**Middle East**	**Africa**	**Asia & the Pacific**	**Europe and the Americas**	**Overall (Current and Total Amount)**
VI (1)	--	--	317 (feb-sep 2013) 572 in 2011 (Cambodia)	--	317 in feb-sep 2013 16,465 (1993-2013)
ICRC (27)	4496 (Gaza, Iraq, Yemen)	4750 (Algeria, Burundi, Chad, the Democratic	12033 (Afghanistan, Bangladesh,	840 (Columbia, Guatemal	22,119 in 2013

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		Republic of the Congo, Ethiopia, Guinea-Bissau, Libya, Niger, South Sudan, Sudan, Uganda)	Cambodia, China, the Democratic People's Republic of Korea, India, Myanmar, Nepal, Pakistan, Sri Lanka, Philippines)	a, Mexico)	1972-2012: 395,690
Special Fund for the Disabled (14)	--	1203	2779 (India, Laos, Vietnam, Tajikistan)	1442 (Argentina, Bolivia, Cuba, DR, Ecuador, El Salvador, Haiti, Nicaragua, Panama, Peru)	5,424 in 2013
Handicap International (59)	1008 (Jordan, Lebanon, Syria)	--	--	--	16,465 (2013)
Jaipur (22)	1263 (Lebanon, Iraq)	2788 (Nigeria, Nairobi, Rwanda, Zimbabwe, Sudan, Zambia, Senegal)	18867 (India Afghanistan, Bangladesh, Indonesia, Malawi, Nepal, Philippines, Papua New Guinea, Pakistan Somalia, Sri Lanka, Vietnam, Fiji)	1500 (Panama, Trinidad, DR, Honduras)	24,418 in 2013 440, 6s90 limbs in India from 1975-2013
Mobility Outreach International (1)	--	--	261 (Vietnam)	--	261 in 2013 3000 overall (Vietnam)
The Princess Mother Prostheses Foundation (1)	--	--	--	--	22,531 overall from 1992-Dec 2011 (Thailand)

Table 1: Low Cost Prosthetic Limb Demographics.

Necessary Attributes for Prosthetic Feet in Developing Countries

The prosthetic foot has been the subject of many studies as it is considered the weakest part of the prosthesis and the component that fails most often [19]. According to Prosthet Orthot Int(POI), the target for minimal life expectancy of prosthetic feet in developing countries is three years and should last up to five years [20]. However, the majority of feet utilized in these regions fail considerably sooner. Structural failures in feet can be caused by; rot (due to excessive moisture), excessive wear of the sole resulting in the penetration of the keel (more prevalent in cultures where shoes are not customarily worn), fracture of the forefoot with delamination between foam layers with repeated loading, and deterioration due to direct exposure to sunlight [5,6,17,19]. According to the POI, several factors should be considered for constructing a prosthetic foot for developing countries. These factors include: durability, low cost, local availability, manual fabrication capability, local climate and working conditions, simple repair, simple processing capability using local production, reproducibility by local personnel, technical functionality, biomechanically appropriate, and lightweight as possible [19].

Beyond environmental, economic and physical characteristics, there are a variety of psychosocial aspects to consider in the fabrication of a functional prosthesis in developing countries. For one, to engage in the cultural norms of some developing countries, such as sitting cross-legged, squatting, barefoot walking, and genuflecting to elders or in religious ceremonies, a prosthesis must be capable of maneuvering appropriately [21]. Therefore, in order to accomplish these positions, the prosthetic foot should be able to rotate on the leg to accommodate. In addition, the component of physical appearance of the prosthetic has been reported to be critical to user satisfaction in both high and low economic regions around the world [22]. Children in Cambodia specifically addressed wishes to obtain prosthetic limbs that looked like a natural limb in both shape and color [21]. Developing a prosthesis that resembles the natural limb is critical to positive self-esteem, well-being, and cultural integration [21,22].

It would be tempting to assume that bringing in prosthetic feet from developed countries would provide a solution to these issues but unfortunately this is not the case. While there are organizations that engage in many altruistic endeavors, importing prosthetic and orthotic technology from industrialized countries often fails to meet the needs of individuals with disabilities in developing countries [1]. The high functional level feet such as the Flex-Foot or College Park Tru-Step require regular maintenance and are not designed for the harsh environment or lifestyle [19]. They have a tendency to deteriorate rapidly when worn without shoes and exposed to extremes of climate and labor conditions [19].

Current Low-Cost Prosthetic Foot Issues and International Organization for Standardization (ISO) Testing

There are several issues with the current prosthetic feet currently used in developing countries. The ISPO 1996 conference consensus suggests prosthesis use should undergo clinical audits by ISO standard physical testing in order to avoid the unsatisfactory method of waiting to assess prosthetic life, especially when many users live in rural areas far from service providers [10]. Out of 24 low-cost prosthetic feet tested, only two, the Niagara and Shape and Roll (S&R) foot, have passed ISO-10328 testing [16,23,24]. In an ISO-10328 standard testing study by Jensen et al., 21 prosthetic feet commonly used in developing countries underwent mechanical testing and the results reported that none passed the strictest ISO-10328 protocol [23]. The ISO protocol specifies three test levels: P3, P4, and P5 that correspond to testing by respectively increasing patient size by weight [25]. Jensen's study selected the P5 strength level testing for a foot appropriate for a patient with a mass exceeding 100 kg, allowing highest probability to accommodate for all patient types. There are four main tests for the ISO protocol. In the first, the Static Proof test, a 2240 N single momentary compressive force is applied on the prosthetic foot and the maximum and permanent deformation length is recorded. This force represents the occasional overload experienced by the foot during ambulation without loss of function. The optimal result is less than 5 mm of permanent deformation undergone by the forefoot or heel of the prosthetic foot. Of all the 21 feet tested, only the Ho Chin Min City (HCMC) natural rubber foot passed the test with an average of three to four mm permanent deformation [23]. The Static Strength test applies a higher force of 4480 N to the foot and represents a higher momentary overload where increasing maximum and permanent deformation is expected. For static tests, natural rubber non-Jaipur feet deformed the least, followed by SACH feet, and last, Jaipur feet, with the greatest deformation. Third is the cyclic test where the foot undergoes 2 million cycles of loading for fatigue testing [23]. This number represents the average of 2 years of walking for a 100 kg amputee [3]. After the Cyclic testing, instead of undergoing the ISO Final Proof test, the prosthetic feet were cut in half longitudinally and their internal architecture examined for failure. The most common failures were; 1) deformation of the rubber or polyurethane (PU) foam under the keel of forefoot and/or heel, 2) delamination from the keel, or 3) delamination between foam layers. The Cyclic test revealed the relationship between internal architecture and failure and materials selection [23]. Regarding failure, additional literature also reported the common issues were delamination of vulcanized rubber from the keel or a failed keel due to wear [3]. Overall, the results of the ISO-10328 testing raise concern that the permanent deformations observed in most feet would result in the loss of forefoot support that can lead to early knee flexion during walking and knee collapse proximal to the knee joint for amputees [23]. The results of the average maximal and permanent forefoot deformation in descending order of least to greatest elongation respectively were; natural rubber feet with the least (22.4+4.1 mm /8.3+3.4 mm), then PU feet, EVA, and Jaipur feet with the greatest (52.9+5.6 mm /22.5+5.4 mm). The average permanent deformation for the heel of prosthetic feet followed the same pattern with rubber feet deforming the least (2.5+2.3 mm) and Jaipur feet the most (3.8+1.5 mm). The only difference was that in the results of maximal deformation, Jaipur and rubber feet had similar deformation lengths and polymer feet deformed the most. Natural rubber (non-Jaipur) feet performed the best in laboratory setting and its permanent forefoot deformation was the closest of all the feet to meeting the ISO-10328 standard [23]. Moreover, even taking into account the standard deviation ranges of average permanent deformation, the highest amount that they deformed was still less than the lowest deformation experienced by any of the other feet. The HCMC rubber foot was the only one that passed the ISO Static proof test and was found to have rubber deformation under the keel at the forefoot and heel after the cyclic test but with UV exposure, it resulted in less maximal deformation and creep [23]. While fatigue testing did not translate in the field with the HCMC foot (only 32% survival rate at 19 months) [26], natural rubber feet were shown overall to perform the best clinically. Results from a 2006 field study in Vietnam and Cambodia by Jensen et al. indicated that the Veterans International (VI) rubber foot deformed the least (19.5 mm max and 5.5 perm) and only had one failure (of 31 feet tested for > two years) with wear to the sole [11]. Due to its performance, natural rubber material appears to be one of the best options for low-cost prosthetic foot material. Further studies have shown that vulcanized rubber is waterproof and impervious to rust/rot [18]. Vulcanization crosslinks the polymers to make natural rubber more durable however, it does undergo plastic deformation.

There are several components of the ISO-10328 standard testing that do not translate into field experience. One is that the ISO experiments only test the foot in the sagittal plane with axial compressive loading forces, disregarding the frontal and transverse plane loads experienced throughout gait. The testing also only accounts for static and not dynamic forces encountered by the foot in daily experience. Another issue with ISO standard testing is that the laboratory loading plate utilizes ball-bearings that are designed to remove friction. Hence, the testing fails to replicate the breakdown of the sole of the prosthetic foot from plantar surface wear that is observed clinically with barefoot walking [3,23]. An added concern is that the ISO cyclic testing only represents an average of two years walking which is below the minimal critical prosthetic foot life expectancy of three years.

The main criticism with ISO-10328 testing is that it does not simulate realistic conditions experienced by the prosthetic foot during use such as forces imparted over uneven terrain and environmental extremes. In order to account for environmental exposure, specifically tropical climate, Jensen's testing involved each foot undergoing humidity and ultraviolet (UV) exposure. Then, these exposed feet were tested following ISO-10328 protocol and compared to the non-exposed feet. For UV light exposure, the feet were subjected to UV light (315-400 nm) for 20 weeks to simulate 8 hours of intense sunlight per day for one year. Overall, the testing showed that the UV light exposure was a benefit, resulting in less maximum deformation and creep of the prosthetic feet [23]. High humidity (98-100%) exposure for 20 weeks showed minimal influence (deformation) of environmental factors for natural rubber feet. Creep did increase with exposure to humidity for some of the natural rubber feet but then decreased with UV exposure [23].

Not only do these prosthetic feet fail relatively quickly under cyclic testing but carry over is seen in regular use under the normal in-country conditions of rough terrain and/or high humidity and ambient temperatures. Heim observed that in the developing countries being studied, the shortest life span for a foot was about 3-9 months (SACH with foam cover) with some lasting 12–18 months (HI rubber foot) [10,27]. The exception was the Jaipur foot with life spans between two and five years, even when used in locations such as Honduras, India, and Uganda where many feet were worn without footwear [27,28]. A prospective study on prosthetic feet used in the tropical setting of Vietnam compared the HCMC (ICRC), BAVI, VI, and Handicap International (HI) foot. The results found that four of five BAVI feet, seven of nine HCMC feet, and four of ten HI feet failed after one year on average, whereas none of ten VI feet had failed after 19 months, even though its users had the highest walking distance and wettest terrain conditions [26]. Jensen et al. noted that only the VI feet and the Jaipur-rubber feet "stood the test" after 24 months [5,29]. He reported that the survival rate amounted to 82% (73–89%) after 18 months and 53% (42–63%) after 36 months, which was considerably better than the results reported with the SACH foot modifications tested in small numbers in Vietnam [26]. These studies, along with Jensen's durability report presented to the World ISPO Congress was the basis for influencing change in these major organizations' design and manufacturing of prosthetic feet for the environment of the developing country reached.

There are a variety of other factors that can affect prosthetic foot performance, one of which is poor craftsmanship during prosthetic foot manufacturing. This is especially seen with Jaipur feet because of unstandardized production practices. A clinical field test study by

Jensen in 2004 found defective craftsmanship in 56% of cases for a Jaipur foot and for 19% of cases of PU feet [3,26]. A 2010 study by Jensen found inadequate craftsmanship in prosthetic foot fitting that was not optimal resulting in mostly wide fits, which could not sustain suspension and comfortable walking [5]. Inadequate craftsmanship also led to leg length asymmetries (>1 cm difference) and inadequate socket wall height/fit, resulting in muscles being unable to transfer forces to the artificial limb [3,5]. Over half of the pain reported from use of the Jaipur foot was attributed to these errors leading to decreased functional capacity. Only half of the amputees were actually able to sit cross-legged and approximately 60% were able to squat. The clinical field testing of the current high-density polyurethane (HDPE) Jaipur foot concluded that it was not acceptable due to reports of higher user discomfort (38%) even with just low to moderate activity levels [5].

Jensen et al. conducted a clinical field study in 2006 in El Salvador, Vietnam, and Cambodia comparing low-income prosthetic feet. The CIREC foot was found to have the best performance compared to CR-SACH, SACH, ICRC, and Fujian feet, even with a majority of high intensive users (75% survival after two years) [3]. However, craftsmanship continued to be a critical issue as the CIREC users reported high complaints, dropouts, and low confidence and user compliance [3].

An additional issue with current prosthetic feet is versatility. Most feet do not have adjustable toe stiffness (making walking difficult and running even more so) or are not multi-purpose for barefoot walking or shoe accompaniment. Lee et al. reported on experiences with modified SACH feet (BAVI, HI, HCMC, and VI) in a tropical developing world setting. The feet lacked interchangeability due to dimensional differences in the ankle portion and height of the foot device among different designs [15]. Most low-cost prosthetic feet, including Jaipur feet, are not height adjustable [2]. Bartkus et al. addressed this height issue with the design of a prosthetic foot in 1994 that utilized low-cost E glass fiber reinforced vinyl ester sheet molding compounds in an alignment adjustment system [20]. The system is composed of interchanging conical retaining sleeves that are slotted over an inner bore that is incrementally angled in one-degree steps from zero to eight degrees [20]. This alignment method is used to modify the prosthesis for each amputee's gait. The heel stiffness can also be changed easily with different durometer heel inserts [20].

With regard to obtaining prosthetic feet in developing countries, there can be problems importing material or the foot itself may be unaffordable. It is suggested that locally available, low cost materials be used in prosthetic foot production [2,16]. It has been estimated that local production can reduce costs of the prosthesis by 90%. This may lead to a compromise in the reliability and durability of the prosthesis [15]. As seen in Jensen's 2006 PU feet study, the locally made CIREC foot outperformed the centrally manufactured CR-SACH foot [9,26] and in the 2006 study, two locally manufactured vulcanized rubber feet were found to have acceptable durability [3,9].

Engineering Principles: Overall Designs and Materials

In order to best address the functionality of a low-cost prosthetic foot, it is important to consider the overall engineering principles affecting the design. One issue with prosthetic feet used in developing countries is that the majority of designs have been reported to have international rather than local origin [9]. Most consideration for design centered on resources or services with less than 8% reporting end-user involvement [9]. Cost, durability, environmental resistance, and ease of local or mass manufacturing (Jaipur and S&R feet) are crucial factors to target in the design strategy for fabrication. The Center for Rehabilitation advocates that the price of a low-cost prosthetic foot should be based on a percentage of the average wage of an individual in the specific country. For instance, in Sierra Leone, the cost should be approximately $1.00-$2.50 while in El Salvador a prosthetic foot can range from $30.00-$40.00 and the consensus for the very poor is $5 a foot [30]. Therefore, the cost of materials and machinery to construct the foot should meet these criteria. Currently a low-cost prosthetic foot typically ranges from about $5-$70 with the Jaipur foot costing $5 and Niagara foot, $35 [9]. It should also be noted that additional costs encompass transportation to and accommodation at the fitting center [10]. In terms of durability, warranty standards (5-year ideal) low-cost prosthetic feet should at least meet ISO 10328 standards. However, this time length may not apply to the cosmetic cover due to its direct environment exposure. As stated earlier, most of the feet designs are not meeting the durability requirements essential in developing country environments [27]. Ease of local manufacturing entails that the foot is designed to be constructed with simple tools or machines such as a lathe. Alternatively, to reduce costs via mass production, the foot material should be processed using thermoplastic methods or cutting and injection molding.

Most developing countries have tropical climates characterized by humidity and high UV exposure and rough terrain that predispose the foot to deterioration. Therefore, the design must take into account corrosion and wear resistance. Polymerization was introduced into material composition to make cells inert to prevent breakdown of the sole and forefoot due to exposure to the high humidity in tropical climates. Co-polymers are considered best for a strong stabilizing structure that has to endure repetitive shock [31]. Traditional PU foam was replaced with natural rubber in order to prolong the foot's life in tropical settings (Jaipur and VI feet) as it was shown to outperform the lighter foam [21]. However, a compromise still exists, as rubber tends to be heavier than PU foam. The issue remains to make use of alternative construction materials to make components lighter without compromising durability, not forgetting the outer cosmetic shell [21].

The prosthetic design should be multifactorial, including material composite properties along with internal componentry. These include geometry and orientation of the heel, keel, ankle-adapter and cosmetic appearance. Shock resistance is a crucial factor due to the high activity level and rough terrain exposure of individuals in developing countries. The keel is designed with the function to provide energy transfer in the phase of the gait cycle from heel strike through toe off and the dorsiflexion required for natural ambulation. The quality of the material surrounding it determines additional rotational properties such as eversion and torsion. Most of the keels have a narrow ankle block design in order to provide larger torque. The design has developed to the adaptation of a C-shaped section to the keel to improve impact absorption characteristics [31]. Early feet were designed using solid wood for the keel. Due to wood's inability to deflect under normal body loads, leading to a shortened contralateral limb step length, the keel material has switched to using foam and rubber [6]. The heel of the foot is designed for the function of impact absorption at heel strike via compression. Also, it provides the kinetic energy required for a smooth transition between heel strike and toe off. The heel is commonly shaped as a triangular wedge to afford greater absorption due to the larger end's exposure to heel strike [31]. This feature, when used in conjunction with the C-shaped keel design, allows for necessary extra impact absorption by the foot. The filler used above the keel is kept to a minimum to retain the keel's elastic properties. The low-cost prosthetic feet that deviate from the common SACH design are the Niagara and the S&R feet. The Niagara foot was designed for highly active individuals who work in rugged conditions with use of impact resistant materials and shape engineering for energy-return [10,18,24]. Its design separates the foot keel from the cosmetic cover. This extends its durability, preserving biomechanical function and allowing cover replacement when worn, as this accommodates it to a variety of cultural cosmetic considerations [24]. Field-testing in Thailand showed no keel failures after 6 and 12 months in contrast to the SACH feet, consistent with laboratory testing [6,24].

The engineering analysis, materials and component testing, and manufacturing evaluation consists of continuous clinical (lab-based) evaluation (biomechanical and gait analysis and neuromuscular assessment), clinical field testing, and independent field testing as the basis for improving design. Mechanical testing of the prosthetic feet in the lab setting according to ISO standards show that the mechanism of internal derangement differs between the types of material composition of the feet. Vulcanized rubber feet show deformation of rubber or PU foam under the keel of the forefoot and/or heel. The HI Mozambique and PHN foot failure was also the result of delamination from the keel, showing penetration of the foot sole. Overall, the heel generally deformed less than the forefoot. All the Jaipur feet showed delamination between foam layers. This shows that the environment is less of a factor for failure for rubber feet but inconsistent for polymer feet, especially in the forefoot. Also, the failures seen in ISO testing did not always relate to field-testing. The SACH feet designed with a wooden keel and functional foam cosmesis can only be used for low activity individuals due to its rigidity. Vulcanized rubber feet have high durability and cosmesis and outperform PU feet in field-testing (83% vs. 21% survival at 2-year outcomes but still have high sole wear (70%) [9,11,17]. Feet using PU as a filler or coating were shown to deteriorate rapidly in humidity [3,14] with high failure at 18 months such that it not recommended for use in tropical areas [3,6]. Overall, prosthetic foot field testing has shown internal structural failure from rot due to excessive moisture, excessive sole wear leading to keel penetration due walking barefoot, forefoot fracture, delamination between foam layers with repeated loading due to high walking levels, and deterioration due to direct sunlight exposure [21]. Lab and field-testing results for the types of feet are shown in the Table 2 and are separated into categories by major material type utilized. Overall, vulcanized rubber feet have a 37% survival rate, ranging from 20% to 97% at 18 months and lasting between 7-32 (20 average) months before failing. Of these feet, the VI-Solid foot from Cambodia had the highest durability, lasting over 2 years with only 3% failure. Over 18 months, clinical field studies show that Jaipur India feet have a 59% to 89% survival rate and last 2-47 months before failure with HDPE foot having the highest durability (up to 63% at 3 years). Overall, the Jaipur survival rate was 42%. The polymer feet performed the worst in the field with an overall 31% survival rate and ranged from 0% to 80% at 18 months and a time to failure of 1-35 months. The CIREC Columbia foot was found to have the highest durability, 75% survival after 2 years and Fujian Vietnam foot the worst. The S&R foot had no survivals at 18 months and lasted only between 1-9 months, though failure was related to the cover, not the foot itself. The Niagara foot had no failures after 6 months in Thailand field-testing but it is unknown how it would perform long term and this data limits the clinical relevance for durability. Overall, though the Niagara and S&R foot are the only feet to have passed ISO 10328 testing, they have limited field testing to support their use, while the VI Solid and HDPE Jaipur foot are shown to have the highest durability with least failures and longest time to failure, respectively, and thus, greater clinical relevance for use.

Rollover Pattern

Gait cycle analysis in the sagittal plane has revealed that the physiological ankle foot complex demonstrates what is called the rollover shape pattern. This is a circular arc to which the ankle foot complex conforms to from heel strike, or initial contact of one foot, to that of the opposite foot that is dictated by mechanical structure [6,17]. The issue with most low-cost prosthetic feet in testing is that the physiological rollover shape is not produced due to lack of toe support or toe extension into distal forefoot regions [6]. There is a sudden discontinuous change in material and corresponding rollover shape from the loading of the keel component to the surrounding foam/rubber such that it curves upwards (7). This is because the foam/belting materials of the forefoot can no longer support the weight bearing force imposed on the foot during the last step period [6,17]. The center of pressure (COP) doesn't advance beyond the inner foot structure because the toes deflect off early during rollover, leading to early foot deterioration [3,17]. As a result of forefoot deflection, what is known as a "drop off" is experienced during end of single limb stance in gait that leads to a shortened effective contralateral limb step length and increased loading on the contralateral side. In a 2004 study by Sam et al. of mechanical COP testing in the sagittal plane of the 11 different prosthetic feet used in developing countries, forefoot deflection was noted in all but the Jaipur foot [6]. It allowed for a smooth progression from the keel to metatarsal area, permitting greater dorsiflexion. Yet, its small radius still results in a lack of toe support, which contributes to early foot deterioration [16,20]. The Shape and Roll (S&R) foot was designed in response to this, as it is seen in most other low-cost prosthetic feet. The S&R foot accomplished this with a series of forefoot cuts in the rectangular middle piece. These relief cuts allow for a controlled bending radius (according to stature) and twisting motions desired under loading force imposed on the foot throughout the gait cycle. Its design allows for forefoot bending to occur up until full compression of the upper cut edges, at this point no further bending is accomplished and this results in a semi-rigid forefoot that allows full weight bearing at end of stance phase [3,16]. As such, deflection is constrained to follow the physiological rollover shape. The designer's suggestion for improvement of the S&R foot was to have the bottom plate vary in thickness to adjust foot stiffness in order to accommodate different weights and activity levels while still allowing forefoot cuts to achieve full compression at the end of bending [16]. An all-terrain foot with a convex sole was developed in 1994 in the US for farmers with the same concept in mind to provide a smooth transition in the gait cycle. This sole design appears to be a good choice due to its superior use over uneven terrain.

Clinical field testing of the S&R foot in El Salvador using a Direct Ultrasound Ranging System found that the foot expanded the speed range for amputees to walk both faster and slower as well as walking further distances (>2.5 km which is above the 2-km maximum reported in most clinical field testing), even above 5 km, in 25% of users [17]. These outcomes reveal that it was a useful design for prosthetic feet with regards to walking function but, this may not be the most important factor to the end user [9]. In another study performed in Cambodia, severe wear of the sole at the heel was observed in 57% of the feet in combination with failure of the cover over the first toe or loss of all the cover and sole distal to the level of the metatarsal heads after 5 months (1-9 months) on average [5,9].

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Eventually, the whole keel was expulsed, and the foot filled up with water and mud in the many open relief cuts. New feet were needed in 86% of cases within 9 months and the recommendation was to stop the foot's use or change its PU cover to rubber [5].

Discussion

The purpose of this literature review was to evaluate the current issues with low-cost prosthetic feet used in developing countries. The critical factors in prosthetic foot componentry were analyzed from an engineering methodology, in an effort to provide factors to incorporate for new low-cost prosthetic foot design, testing and production. The focus separating this review from previous reviews was to organize information from an engineering and materials standpoint and to add details comparing each foot's component failure sites, survival rate, and costs.

The literature revealed several issues with current prosthetic feet routinely used in developing countries. Common problems include; lack of aesthetics, poor craftsmanship, and low durability, as well as significant cultural, biomechanical and functional deficits. Of all the prosthetic feet reviewed only two of (>25) low-cost prosthetic feet have passed international standards organization testing (ISO). This is a prominent issue as ISO testing does not simulate natural multiplaner gait, alterations in load carriage or harsh environmental factors.

Review of the current literature also illustrated design factors which are important for a functional low-cost prosthetic foot. The foot should accommodate to a wide range of body weight [15], especially since weight gains are commonly observed following limb amputations. The foot should adjust to shoes with different heel heights. It should have adequate shock absorption at heel strike [6,15]. The foot should provide energy storage and return through multiple load ranges as farm-based economies will require carrying a wide range of loads over various distances through harsh environments. The prosthetic foot should match all planes of movement experienced by the physiological foot, specifically with respect to anterior to posterior braking impulses [15] and medial-lateral motion in order to give the user confidence of weight bearing support. All of this while maintaining durability, lasting a minimum of three years, and maintaining affordability, a tall task indeed.

(Ref #)	Country	Forefoot	Keel	Keel form	Heel	Heel form	Sole	Cover	ISO test failure type	Clinical Field Observations	Durability (% failure/ time (months)) or time to failure
Vulcanized Rubber Feet											
HCMC (14, 18, 19, 24)	Vietnam	Foam-rubber flat belt drive	Ebonite	Big tooth	Foam-rubber	Cushion	Tyre-rubber	Rubber	Foam under keel deformed Failed sole	Failed keel and sole	78%/19 m
VI-Solid (2, 14, 19, 24, 35)	Cambodia	Rubber reinforced	PP	Big tooth, rubber band anchor holes	Rubber-foam	Square	Tyre-rubber	Rubber	Foam under keel deformed	Cracks Rotting Heavy wt No wear w/ 14 hr daily use	3%/24 m 0%/19 m 3%/18 m
VI cavity heel (2, 14, 19, 24, 35)	Cambodia	Rubber reinforced	PP	Big tooth, rubber band anchor holes	Rubber-foam	Square with cavity form	Tyre-rubber	Rubber		Sole fracture and keel penetration	14%/24 m 11%/18 m 3%/12 m 7-32 m
EB-1 (14, 19, 24)	Vietnam/ USA/POF	Rubber/ cotton sandwich	Wood	Wedge leashed, perforated	Stacked plates of rubber	Cushion	Rubber cotton-rubber	Rubber	Foam under keel deformed		33%/24 m 3%/18 m 0%/12 m 16-22 m
BAVI (14, 19, 24, 35)	Vietnam	Rubber	Wood	V	Rubber	Wedge	Cotton/ rubber	Rubber	Foam under keel deformed	Fail at keel tip where thin at sole	80%/19 m
HI (14, 19, 24)	Cambodia	Foam-rubber	PP	V	PE foam-rubber	Cushion	Tyre-rubber	Tyre-rubber	Foam under keel deformed		40%/19 m 20%/12 m 0%/6 m 7-17 m
ICRC (14, 19, 24)	Myanmar	Rubber	Wood	Wedge, 3 holes	Rubber	Cushion	Rubber	Rubber	Foam under keel deformed		

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HI (14, 19, 24)	Mozambique	Rubber	HDPE or PP	Big tooth	Rubber	Triangle	Rubber	Tyre-rubber	Foam under keel deformed, delamination		
HI (14, 19, 24)	Angola	Foam-rubber flat belt	Wood	Dog tail	PE Foam-rubber	Cushion	Rubber	Tyre-rubber	Foam under keel deformed		
PHN (14, 19, 24)	Cambodia	Rubber	PP	Wedge	Rubber	Cushion	Rubber	Rubber	Foam under keel deformed, delamination		62%/18 m 7%/12 m 10-29 m
TATCOT (14, 19, 24)	Tanzania	Rubber	Wood	Big tooth	Rubber	Cushion	Rubber	Rubber	Foam under keel deformed, delamination Cyclic testing: >5 million cycles		
Jaipur Feet (vulcanized rubber shell)											
BMVSS Jaipur-HDPE (8, 14, 18 19, 24)	India Honduras Uganda	Foam rubber cotton	Rubber cotton stacked	Big tooth	Rubber cotton stacked	Square	Tread Rubber	Rubber	Delamination of foam layers Skin fracture and heel block layer gliding	Met benchmark standards for technical quality but not provision – decreased walking and high discomfort	37-58%/36 m 15-35%/ 32 m 11-41%/ 18 m 6-30%/12 m 2-47 m (Honduras, Uganda, India 2001, 2002)
NISHA Jaipur (14, 19, 24)	India	Rubber cotton	Rubber cotton stacked	Big tooth	Rubber cotton stacked	Square	Rubber	Rubber	Delamination of foam layers High keel wear		28%/16 m 34%/12 m 15-17 m
MUKTI Jaipur (14, 18, 19, 24)	India	Foam rubber cotton	Metatarsal wedge layered cotton-foam rubber	Big tooth	Layered cotton-foam rubber	Square	Rubber	Rubber	Delamination of foam layers High keel wear		27%/16 m 25%/12 m 5-16 m
OM Jaipur (14, 19, 24)	India	Foam rubber cotton	Rubber cotton stacked	Big tooth	Rubber cotton stacked	Square	Rubber	Rubber	Delamination of foam layers		
Polymer Feet											
Kingsley Strider-SACH (8, 14, 19, 24)	USA	Flat belt drive	Wood	Dog tail	PU-foam (reinforced)	Cushion	PU	PU-foam	PU-foam under keel deformed		61%/24 m 55%/18 m 27%/12 m 1-35 m
CR-SACH (8, 14, 19, 24)	Cambodia	PU-foam	PP	Dog tail fenestrated	PU-foam	Cushion	PU	PU	PU-foam under keel deformed Foot cover failure (d/t high sun exposure) but not sole		100%/24 m 69%/18 m 44%/12m 4-18 m

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PF Thai (14, 19)	Thailand	PU-foam	Nylon	Finger	PU-foam	Cushion	PU-foam	PU-foam	Failed static strength after UV exposure		
CIREC (8, 14, 19, 24)	Colombia	PU-foam, 2 spring blades	PP	Wedge	PU-foam	Cushion	PU	PU	PU-foam under keel deformed, delamination		25%/24 m 20%/18 m 15%/12 m 7-22 m
Fujian (8, 14)	Vietnam	Flat belt drive	Wood	Big tooth	Reinforced PU foam						100%/ 18-24m 57%/12 m 52%/10 m 4-11 m
Afghan (14)	ICRC	EVA	Wood	Big tooth	Tyre-rubber	Wedge	Glued EVA	Glued EVA	Failed static strength test		
Alimco ASB (14)	India	PU-foam, flat belt drive	Wood	Dog tail	PU	Cushion	PU	PU	Failed static failure test		
ASB-ICRC (14)	Ethiopia	PP/EVA-foam	4 blades	Spring-blades	3 blades PP	Cushion	EVA	EVA	Permanent deformation into banana shape		
Shape and Roll (6, 7, 24, 31)		PP-PU Delrin plastic	PP-PU Delrin plastic	Saw cuts	PP-PU plastic	Flange in heel	PP-PU Delrin plastic	PU	5 passed ISO (3.8 million cycles)		100%/18 m 69%/12 m 1-9 m
Niagara (10, 24, 25, 34)	Canada Thailand	Delrin plastic	Delrin plastic		Delrin plastic		PU-rubber	PU rubber	Passed ISO (>3 million cycles) Cover wear	Limited testing (34) Improved gait performance at 6/12 months	0%/6 m No keel failures at 6 and 12 m
All-terrain (29)		Stainless steel	Rubber	Compression molded	Rubber		HD-rubber Convex sole	HD-rubber		Superior use over rough terrain	

Table 2: Comparison of Low Cost Prosthetic Feet Types, Structure and Durability.

Conclusion

In conclusion, the direction of prosthetic foot development should be geared to the user majority, which are individuals with amputations living in developing countries. In order to accommodate to the tropical climates, rough terrain, farm work conditions, mass barefoot walking, and small annual user income ($300/yr.), a prosthetic foot for developing countries should include the following factors. It should be low cost, locally available, durable, water and corrosion resistant, capable of simple and fast reproducible fabrication by local personnel, lightweight, adequately cosmetic, and psychosocially acceptable. The developing country prosthetic foot should represent a compromise between biomechanical appropriateness and use of economical materials. Because even the advanced prosthetic feet have difficulty simulating foot mechanics beyond a unidirectional sagittal plane to allow for medial-lateral and rotational motion, a low-cost prosthetic foot should at least aim to replicate the sagittal plane dynamics as closely as possible to the physiological ankle foot complex. Current issues for improvement should target the foot's lack of versatility to adjust for height, weight, and toe and heel stiffness achieve by varying bottom plate thickness. Other critical factors for improvement include the fatigue life of the sole and shock absorption at heel strike. The foot should aim to pass ISO standards in fatigue testing, but the most important goal should be durability (>3-year survival) in the clinical field. Finally, this review provides a comprehensive examination with a concentration on prosthetic feet and reveals critical factors to guide future design and development that are currently lacking for developing countries.

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