

Design Considerations for Prosthetic Knees in Developing Countries

by

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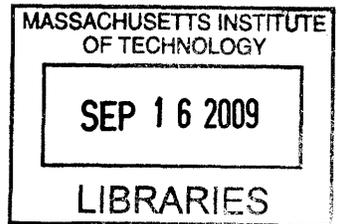
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CHAPTER

1. Introduction

1.1. Motivation

The design of prosthetic limbs is a complicated problem that continues to receive significant attention in research labs and in industry throughout the world. The idea of getting a machine to match human performance is an enticing one, and thus research continues to pursue the challenge of designing devices that can replace the functionality lost via limb amputation.

Designers of prosthetics for developing countries face similar challenges. However, that challenge is also supplemented with a number of other contextual factors and considerations that must be made as a designer. As described by Cummings¹, these factors are social, economic, cultural, and geographic, and also include locally available forms of technology and time and distance constraints. These considerations further complicate the design process, especially for an engineer inexperienced with designing for the developing world and unfamiliar with the specific developing world environment being designed for. These topics have been covered in bits and pieces throughout the literature; this document attempts to cover them all thoroughly and in a logical way. This thesis also aims to provide some mechanism by which the challenge of designing a prosthetic knee for the developing world can be broken down and tackled effectively to yield an appropriate knee design. As amputees in the developing world are often subject to an inescapable life of poverty because they are unable to work and support their families, there is a strong impetus to design effective limbs for this population. This document intends to help facilitate that process.

This thesis is inspired by a prosthetic knee design project that began in the class Developing World Prosthetics at the Massachusetts Institute of Technology in its inaugural term, spring 2008. Though the project was successful in many ways, the design process maybe could have been more effective with a stronger foundation in all the areas that will be covered below.

1.2. Overview of Thesis

This thesis primarily uses literature review to provide insight into human gait and amputee characteristics, as well as developing world considerations for designers of prosthetic limbs. The aim is to provide a foundation by which one can design effective and appropriate prosthetic devices.

A metric is also developed by which those developing world considerations can be managed, weighed and incorporated into the design. In this case, experience and observations from the author's work on prosthetics in India are used to assess the contexts and contributions of various developing world factors to the successful incorporation of a prosthetic knee design into that environment. The document uses India as a case study; however, the thesis should serve as a generalized manual for developing world prosthetic knee design.

This document begins with a presentation of human gait characteristics presented in a variety of contexts that can be useful to the designer of a prosthetic knee for the developing world. Then, basic mechanical components that are often used in prosthetic knee design are described, using examples. Finally, a thorough description of the many developing world factors that must be understood to design a sustainable prosthetic knee are discussed, and a table is presented by which those factors can be simply reviewed (Table 5-1).

CHAPTER

2. Model of Human Walking Gait

2.1. Non-walking modes of propagation

The analysis below summarizes the components and characteristics of walking, as seen in the sagittal plane, for walking in a straight line on a flat surface. It is noted that walking is three-dimensional, but this thesis mostly considers the sagittal plans as most of the torques, powers, and motions occur in that plane.

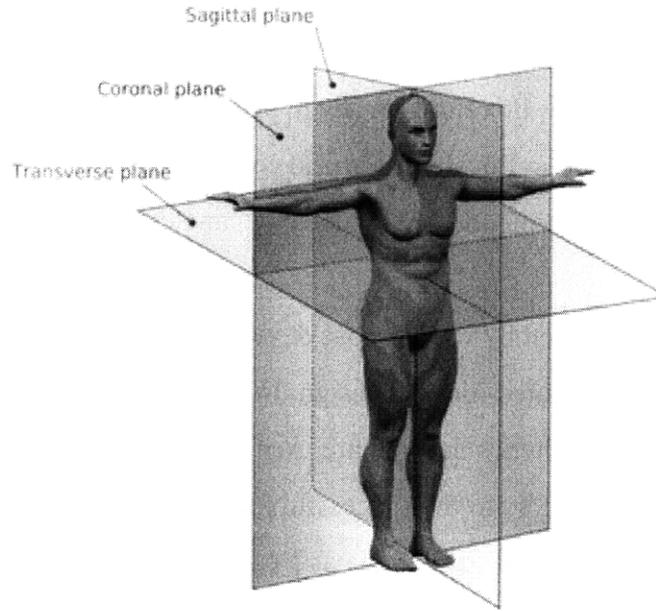


Figure 2-1. The three transecting anatomical reference planes for an upright human. Walking is analyzed primarily in the sagittal plane. (Wikipedia)

Walking is the most basic and prolific mode of transport for humans, and straight walking on flat surfaces is the simplest fundamental walking model to analyze. However, it is noted that humans find importance in other forms of pedal transportation, such as running, crawling, swimming, walking on inclines, driving, riding horses, and climbing. Also, users of a prosthetic limb will likely need to walk on inclines and on uneven surfaces, which introduces different dynamics than the straight, flat walking model. These should not be ignored when assessing the performance of a prosthetic limb, especially if some of these modes are particularly important in the particular region being designed for. For example, the Jaipur Foot Organization boasts the ability of amputees using their Jaipur Foot to climb trees and walk on rugged terrain². Wading through water may also be important for herders or farmers in various parts of the world. Again, the mobility of the amputee may have a strong influence on his ability to find employment. Most importantly, though, it is important to learn the basic elements of human gait, but to understand that they do not exhaustively describe the requirements that need to be met or in a successful prosthetic knee design.

2.2. Unimpaired human gait

2.2.1. Phases of a stride

Gait is a periodic phenomenon, where one period is known as a stride. A stride is defined as the duration from when the heel of one leg strikes the ground (0% of stride) to when that same heel strikes the ground again (100% of stride). Key points of that stride are foot flat (8%), heel off (43%) and toe off (62%). A stride can be broken into stance phase (0-62%) and swing phase (62-100%). Figure 2-2 and Figure 2-3 characterize gait in a few different ways, identifying important parts of the gait cycle.

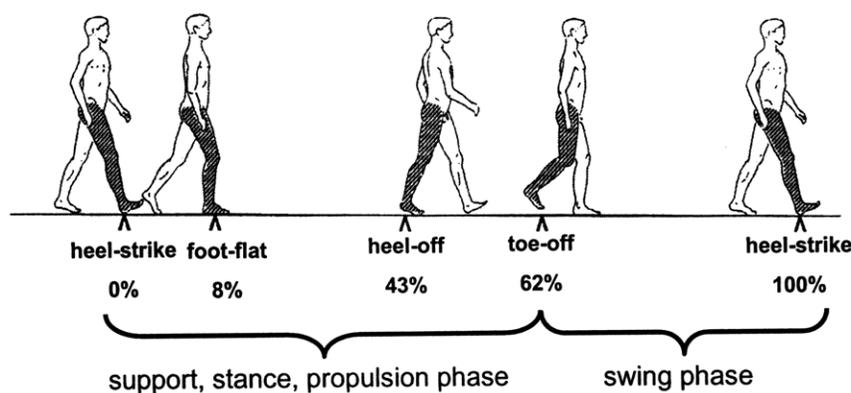


Figure 2-2. Key reference points during a stride. (Herr, 2008)

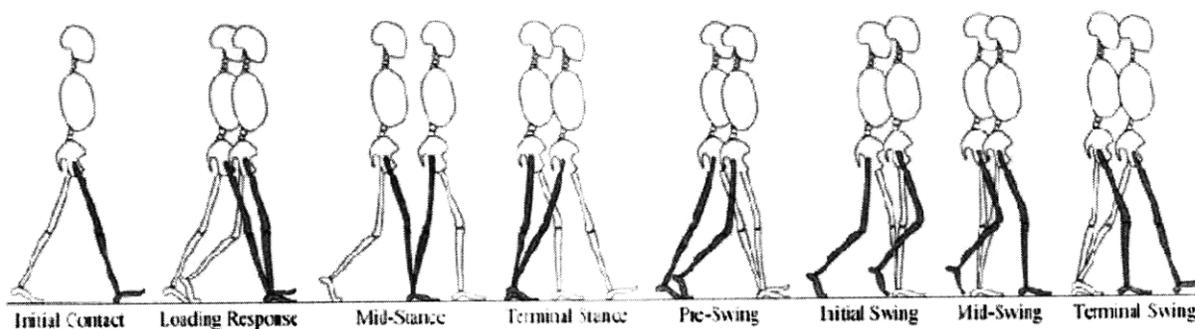


Figure 2-3. The eight main phases of the walking cycle from heel strike to heel strike (Perry, 1992)

The vocabulary associated with phases of gait is important to know. Looking at gait in this context is critical to understanding what a knee performance should look like throughout the gait cycle, and gives some context with which to assess a patient's walking.

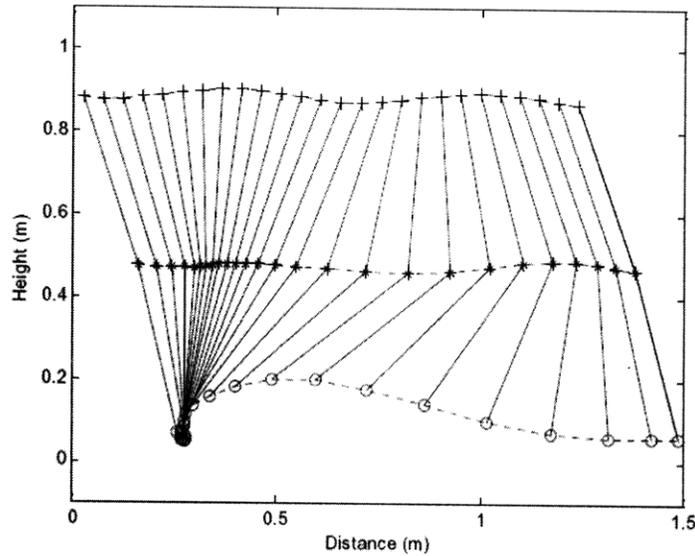


Figure 2-4. A plot of the gait data showing the trajectory of the hip, knee and ankle joint. (Kirtley,1998).

2.2.2. Joint torque, power, angle during stride

The angles of each joint during stride have been measured³. Being able to achieve these angles is critical to prosthetic knee design. However, knowing the range of motion of the ankle, knee, and hip is important to design for allowing patients to participate in normal, everyday postures and motions, such as sitting, crouching and kneeling. It is also important to know the postures that are culturally and religiously important to the population being designed for (see section 4.2.4).

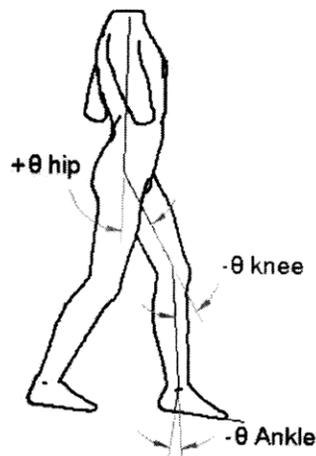


Figure 2-5. Sign convention used for joint angles. Each joint angle is measured as the positive counterclockwise displacement from the distal link to the proximal link (Chu *et al.*, 2005).

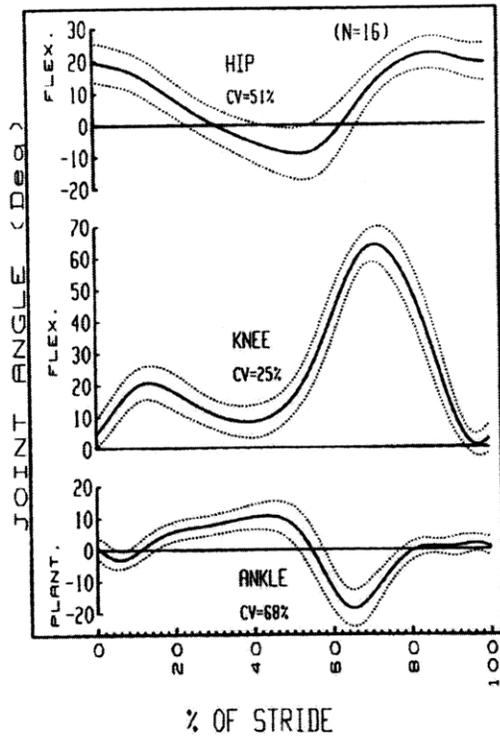


Figure 2-6. Average joint angles during natural cadence. (Winter 1983)

Winter (1983) also calculated the torque on the knee joint, and then subsequently calculated the power generation and absorption at the knee.

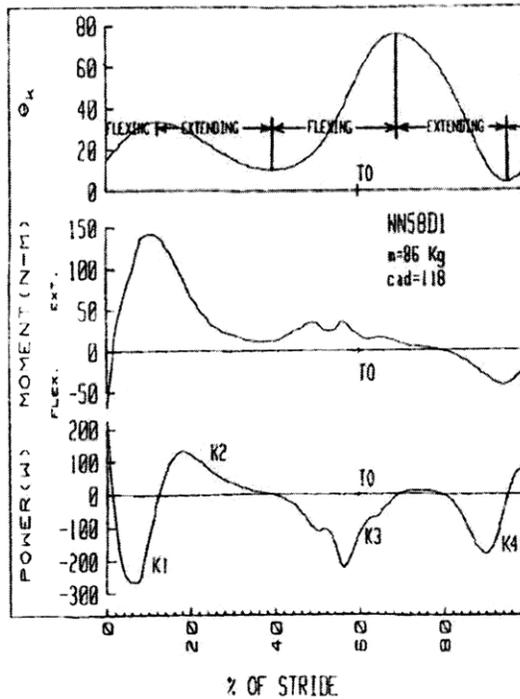


Figure 2-7. Power and torque at knee joint calculated using joint angle and force plate data. (Winter, 1983)

2.2.3. Clinical determinants of gait⁴

Many researchers have tried to characterize the determinants of human gait. In the Developing World Prosthetics class at MIT in Spring 2008, Biomechanics Professor and amputee Hugh Herr identified nine determinants summarized below⁵. These determinants have application to the prosthetist in assessing an amputee's walking with a prosthetic limb. As a designer of prosthetics, an assessment of currently available limbs in a developing world region can be performed using these determinants, and then areas to improve upon in new designs can be identified. Generally speaking, these nine determinants help smoothen the movement of a person's center of mass during gait, consequently lowering muscular effort in walking. Additionally, these determinants reduce angular momentum fluctuations about the whole-body center of mass.

Fundamentally, it is important to understand that during a gait cycle, the center of mass of the individual shifts in a periodic fashion. It shifts both in the transverse and sagittal plane.

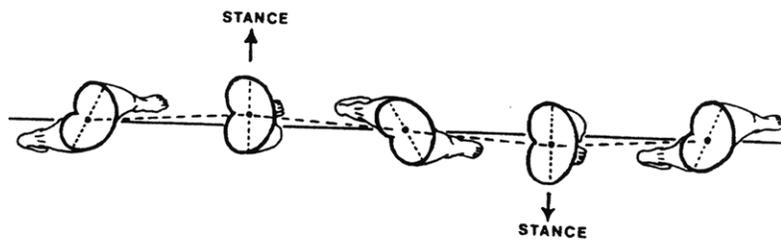


Figure 2-8. Shift of human center of mass in transverse plane during gait. (Herr 2008)

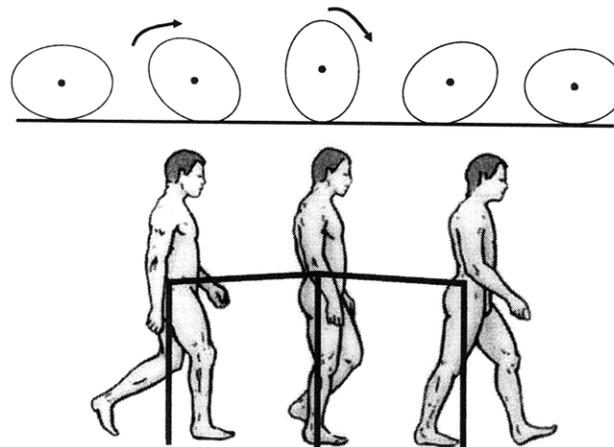


Figure 2-9. During gait, the center of mass moves the way the trajectory of the center of a rolling ellipse moves, as seen in the sagittal plane. (Herr 2008)

Determinant #1 – Pelvic rotation. Rotation of the pelvis increases step length, smoothes the trajectory of the center of gravity, and helps regulate angular momentum in the vertical direction.

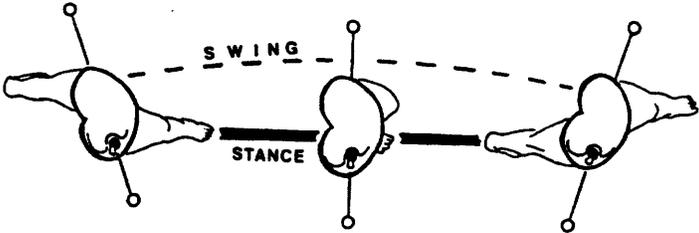


Figure 2-10. Change in pelvis angle due to rotation during gait. (Herr 2008)

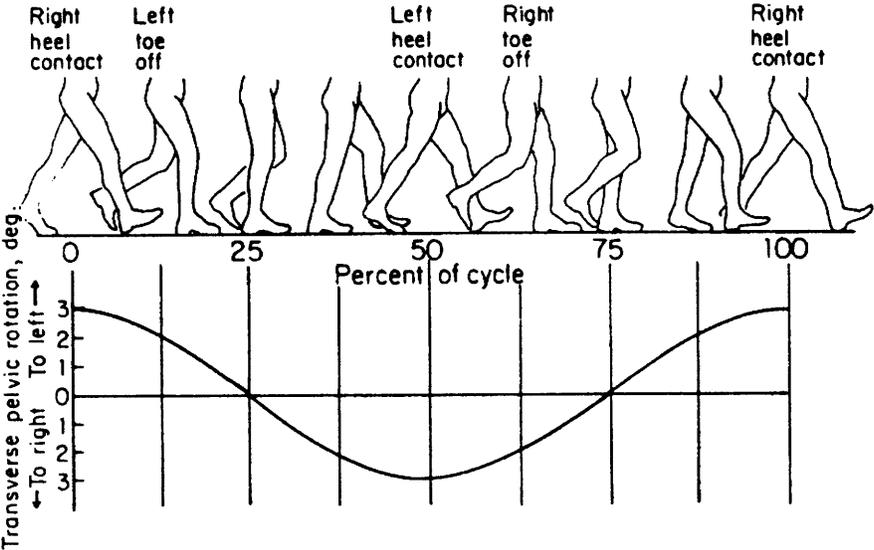


Figure 2-11. Plot of change in pelvis angle, spanning a total of 6°, during gait. (Herr 2008)

Determinant #2 – Pelvic tilt. Pelvic tilt helps augment knee extension and Achilles tendon energy storage. It also helps regulate angular momentum in anterior-posterior direction.

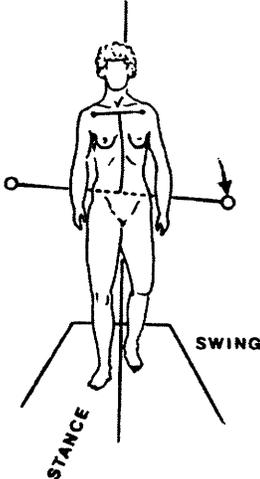


Figure 2-12. Tilt of pelvis in frontal/coronal plane view during gait. (Herr 2008)

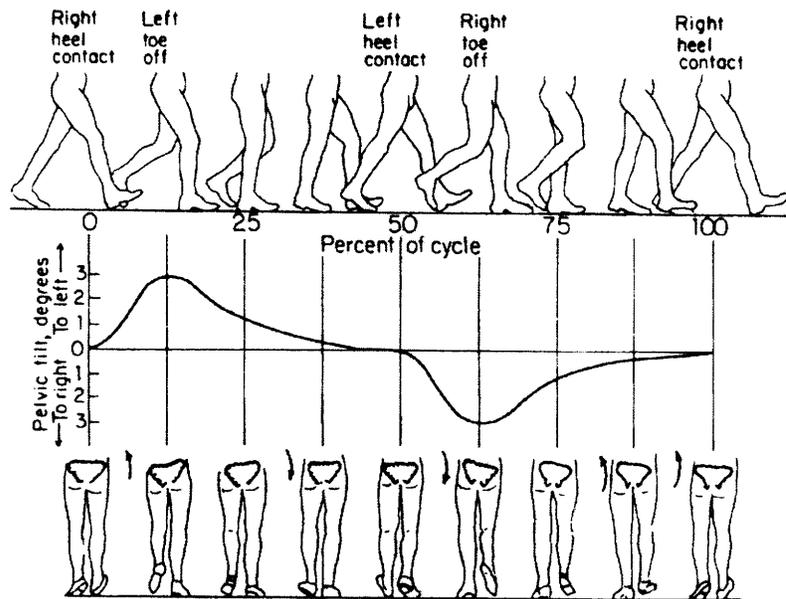


Figure 2-13. Plot of pelvic tilt, spanning a total of 6°, during gait. (Herr, 2008)

Determinant #3 – Knee flexion during early support phase. The knee flexion upon heel strike helps with shock absorption, transferring energy from the knee to the ankle, and regulating angular momentum in the medio-lateral direction.

Determinant #4 – Controlled plantarflexion. When the ankle plantarflexes, it helps with shock absorption and regulating angular momentum in the medio-lateral direction.

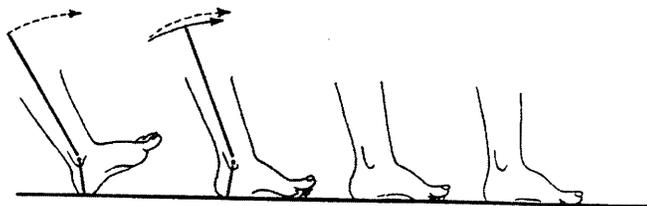


Figure 2-14. Plantarflexion at heel strike. (Herr 2008)

Determinant #5 – Powered plantarflexion. Powered plantarflexion in the ankle also helps regulate angular momentum in the medio-lateral direction.

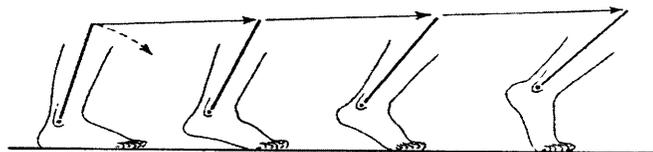


Figure 2-15. Plantarflexion at toe-off. (Herr 2008)

Determinant #6 – Lateral displacement of the pelvis. Lateral displacement helps to keep the center of mass of the person centered over the center of support (the weight shifts to the leg that is supporting the body). See Figure 2-8.

Determinant #7 – Inversion-eversion-inversion sequence at subtalar joint. The effects of this sequence at the subtalar joint include shock absorption and accommodation of the rotation of the tibia during gait.

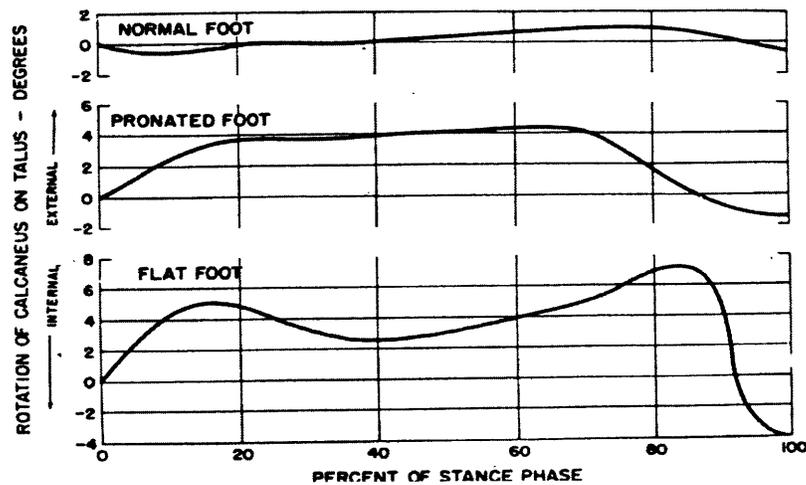


Figure 2-16. Motion at the subtalar joint during gait. (Herr 2008)

Determinant #8 – Lateral flexion of the trunk. This lateral flexion helps regulate angular momentum in the anterior-posterior direction.

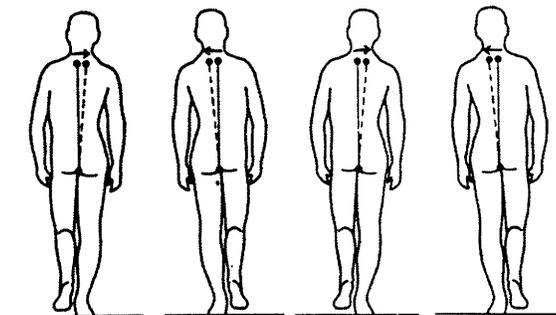


Figure 2-17. Lateral flexion of the trunk during gait. (Herr 2008)

Determinant #9 – Anteroposterior flexion of the trunk.

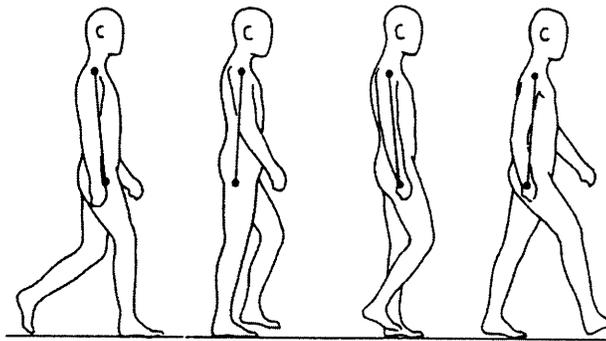


Figure 2-18. Antero-posterior flexion of the trunk during gait. (Herr 2008)

Other elements of gait are important to become familiar with as well, and knowing common problems seen in impaired gait is important. Hip hike and drop foot are two common side effects of gait impairment with individuals suffering from a variety of medical conditions. Communication with a trained clinical prosthetist can be invaluable to learning about human gait prosthetic selection, fitment, alignment, and patient physical therapy to create a normal gait. Abnormalities in gait can have undesirable long term implications and side effects such as hip and back problems.

2.3. Modeling human walking gait

Both simple and highly sophisticated theoretical models of the leg have been used to create model gait for a variety of applications. The simplest model of walking is known as the inverse pendulum. Likewise, intricate bipedal walking figures have been created, ranging in form from having many actuators to being passive-dynamic.

These models help to explain the kinematics of walking, which are very complex but sometimes adequately represented in simple form. It is important to learn about these models over the course of one's learning about human gait and prosthetic limb development, as they reveal useful insights about gait.

3. Above-Knee Prosthetic Systems

3.1. Components of a limb for a transfemoral amputee

For above knee amputees, a prosthetic limb system is composed of three main components: a socket, a knee, and a foot. The pylon or shank linking the knee to the foot is another part of the system, but is simply a rigid beam and thus is not considered an additional component. The components (and the shank) will be summarized here.

3.1.1. The socket

The socket component is the interface between the prosthetic and the patient's residual limb. It is a critical part of the system because the residual limb is very sensitive, and thus it is easy for the socket to cause unbearable discomfort for the patient that must be resolved in order for the patient to be willing to use the limb. Three parts of the socket must be designed carefully. First, the inner lining of the socket makes direct contact with the residual limb, and problems with the fit or material can cause rubbing, redness, or rawness. Additionally, the shape of the socket is critical to making sure that the stress on the residual limb countering the person's mass is distributed on parts of the limb that are least tender. This is an art that only a clinician skilled in the fabrication of sockets can do well, and is mastered over time. A comfortable stress distribution in the socket varies slightly for each patient, especially so in the developing world when many patients will come in having had poorly conducted surgeries and poor post-operative healing that leads to especially sensitive areas on the residual limb. The most obvious situation is a protrusion of bone that has not been well padded on its end with tissue and muscle⁶. Finally, a suspension system for holding the limb in place must be incorporated into the socket. Currently, a harness system that wraps around the patient's waist, called a Silesian belt or total elastic suspension system, is commonly used in the developing world, although the first world offers other designs such as a suction system.⁷

3.1.2. The shank

The shank is generally characterized by one of two main designs: endoskeletal versus exoskeletal. The difference between these two is simply that the former is a pylon/rod while the latter is a shell. As the shank serves only as a rigid body, either of these designs are suitable, and both are available in commercially available prosthetics and in prosthetics for the developing world. In the developing world the selection of one of these designs over the other is based on availability of materials and the interface between these components and the knee and ankle components of the system. Endoskeletal systems, which by their nature are less real-looking, may be supplemented by an aesthetic covering.

3.1.3. The foot

The foot should dampen the impulse upon impact with the ground during heel strike. The foot component is also responsible for providing some plantar and dorsiflexion. One of the most popular and recognized foot designs today is the Jaipur Foot produced by the Jaipur Foot Organization in India, which provides substantial plantarflexion, allowing people to climb trees, walk on rugged terrain, and squat. However, its abilities lend to challenges in knee design, which must adapt to the foot's unnatural range of motion. Also, variations of the German SACH foot are often manufactured in developing world environments using wood and rubber⁸.

The foot is also the part of both above- and below-knee systems that is characteristically first to fail, and thus is the limiting factor of the life of the entire prosthetic unit (though patients often continue to use the systems with broken components⁹). Improvements in the robustness and life of prosthetic feet is definitely an area needing significant improvement in developing world prosthetic limb design.

3.1.4. The knee

The knee is the element of the design most critical for patient stability, and that has the most complex requirements in terms of performance to achieve normal gait. Above-knee patient collapse is most often a consequence of buckling at the knee, whether walking, running, squatting, or otherwise, and thus designing a knee that contributes both stability and minimal resistance to performing regular knee behaviors (uninhibited knee rotation at various parts of gait, for example, and stability in stance with the knee either straight or bent). There are many mechanical elements that can be incorporated into a knee design, many material considerations

to be made, trade studies to be performed, and specifics of gait to be considered and incorporated (see sections 2.2.1 and 2.2.2).

3.2. Mechanisms for use in prosthetic knee design

There are many basic components that can be incorporated into a prosthetic knee design in order to achieve certain parts of the naturally observed gait characteristics. Each of the basic elements have different capabilities and modes of implementation. Understanding each of these mechanisms and their limits thoroughly is key to designing well. This understanding must be matched with a clear understanding of the desired features of the new knee design.

Elements to study include springs, dampers, pneumatic and hydraulic elements, and powered actuators. Other commonly used mechanisms in prosthetic knee design include multi-bar linkages and multiple-axis joints. Multiple-axis joints imply stance-flexion, where the free-swinging axis locks during stance to prevent buckling, while a nearby, independent axis rotates just slightly to allow flexion during stance.

These elements can be studied through the knee designs of Ossur, Otto Bock, and Endolite, the world's leading designers and manufacturers in prosthetic knee design.

3.3. Categories of prosthetic knees¹⁰

Many basic knee designs have been established and time tested and are used today in both developing world and developed world knee designs. Many different prosthetic knees can fit into the same categories describing what functions they offer, and typically include many of the same components discussed in Section 3.2.

Prosthetic knees can be divided into two main categories – pure mechanical systems and computer-driven systems. Because of the cost and complexity of computer driven systems, and their unfeasibility in being used for developing world knee design, only mechanical knee classifications will be described below. The purely mechanical systems are subdivided into classifications based on their degree of stance-phase stability and swing-phase responsiveness. Stance and swing phase are discussed in chapter 2.

3.3.1. Single axis hinge knee

A simple hinge can function as a knee. By shifting the axis of rotation behind the natural location of the axis of rotation, the center of gravity line from the patient falls in front of the axis, generating an extension torque to stabilize the system for up to a few degrees of rotation. A friction cell can also be added to the system to provide some damping during swing phase. Such a knee with a single axis and constant friction is mechanically simple, rarely needs servicing, and is the most inexpensive prosthesis design.

There are two main drawbacks to this knee. First it is stable only for a few degrees during stance; bending past the point where the moment arm changes directions causes the knee to buckle abruptly. Secondly, because it is constant friction, the damping provided during swing is only good at one cadence. The swing phase will not time properly at faster or slower cadences.

Based on experience, the acceptance of free-swing knees by the majority of the developing world amputee population is low; most patients reject it due to a fear of falling/buckling during stance, which can be injurious or even fatal.

3.3.2. Fluid controlled knee

Over the last several decades, pneumatically and hydraulically controlled knees have overcome some of the challenges discussed in 3.3.1. Today these systems can be small and relatively inexpensive, and complex designs can have numerous stance- and swing-control features.

Pneumatic dampers are unaffected by changes in the ambient temperature, and are recommended for slow to moderate cadence walkers (because fast patients may outwalk a pneumatic system). Hydraulic systems allow patients to walk at any speed.

Overall, fluid swing phase control offers the smoothest, mostly nearly normal swing phase movement possible. These fluid systems can additionally augment stance stability, allowing patients to walk down ramps.

3.3.3. Polycentric knee

Finally, polycentric knees offer several advantages over simpler knee designs. Most are four-bar linkage systems, which have a complexity that optimizes some gait features, both in stance and swing phase. Stance stability, sitting appearance, toe clearance at midswing, and ease of flexion during preswing can all be improved with a multi-bar linkage knee.

A four-bar polycentric knee has been designed by a group of Stanford students and tested at the Jaipur Foot Organization for intended application in third world countries.

3.4. Additional design elements

Nonetheless, designing a prosthetic knee that most robustly and accurately mimics normal human gait for a minimal cost with considerations of the technology's sustainability is only one element of design. Remember, user interface is key, and because prosthetic systems interact so closely and intimately with the user, a number of other elements of the design that impact the user are equally important to the prosthetic's ability in terms of gait. These include weight, comfort of socket (dependent on materials selection, weather condition, state of amputee stump upon arrival), the presence of a knee pad to aid in comfortable kneeling, and the range of motion necessary for other postures (sitting, laying, cross-legged sitting, etc.) – should be assessed with respect to considerations described in section 4.2.4. All these have to do with the device's interface with the user, which is huge because if it is not a good one, the patient will rather do without it – and thus the ultimate goal in the design is for the prosthesis to feel like an essential and natural part of their body and their life.

CHAPTER

4. Considerations in Developing World Prosthetic Design

4.1. Design and component considerations

4.1.1. Methods for assessing the currently available limb systems

The first step in prosthetic knee design is to survey the currently available limb systems for amputees in the region of interest. Assessing how successful each of the design aspects (materials selection, aesthetics, components/performance, product life, etc.) are will help give an understanding of where the currently available systems fall short, and thus where a new design could improve on the current system.

Information about the currently available prosthetics can come from the providers of prosthetic limbs in the region of interest, which are often international NGOs. Sometimes literature can be found on the limb components, such as with the internationally recognized Jaipur Foot produced in India^{11 12 13}, but in most cases, published studies with quantitative assessment of developing world component performance are hard to find and have probably not yet been performed. Additionally, communicating with users of these prosthetic devices could be a very useful way to acquire data about the available limb, but there are many challenges to finding such people. Finding a translator to the native language and making contact with the clinics providing limbs in the country of interest may be feasible. However, often the patients are uneducated to the point that they do not know how to care for themselves. During my travels to India I saw patients at a clinic who had raw skin being eaten away by maggots and not being treated, and the workers there told me that the reason they are like that is partly because the patients don't know that they are supposed to treat and take care of these things to help them heal. Thus, many patients may be unable to proficiently answer questions about the knee system because they simply accept things as they are without question or hope for change. Moreover, many amputees come from poor, rural areas far away from clinics, and are unable or choose not to return to the clinics to get help with their prosthetics as they wear over time. Thus, it is difficult to find a population of long-time users of a limb who can be kept in touch with and can give feedback on their experience with the device over time.

After exhausting these sources of information on a clinic's limb systems, often designers of developing world prosthetic devices must acquire samples of the available components and assess and test them on their own. For this, they must use the foundation derived below about the needs of the area to assess the strengths and weaknesses of the available technology in meeting those needs.

4.1.2. Interactions of the knee with other components of the limb system

Prosthetic knees interact with other parts of the limb, including the socket, shank/pylon, and ankle/foot. A good design for the knee-shank interface and knee-socket interface is critical. These interfaces must hold strong given whatever tolerances and quality control can be maintained in their manufacture. In order to facilitate the integration of the prosthetic design into the clinic's production line, the designer must communicate with the local manufacturer of the socket and shank systems to work with the tolerances of their machines.

Additionally, initial alignment of the prosthetic limb on the patient generally happens between the knee and socket components. This must be incorporated into the knee design, and the tooling to make adjustments to the alignment should be available from the outside of the knee-socket system so that adjustments can be made while the patient is wearing the device. For alignment design, it will be useful to study the pyramid and inverse pyramid adapters used almost universally on all available limb systems, which allow for all desired directions of alignment, using a system of four set-screws to hold the alignment. The pyramid is an effective tool though not often used in the first world because of high part count and cost, and unavailability of materials. Often in developing world prosthetic limbs, components are aligned manually at the clinic and then rived rigidly into place. Whether an adjustable system is desired is something that should be thought through by the designer. It may also be useful to study the ARC knee alignment system, as well as other developing world knee designs and alignment components.

It is important to understand the behavior of the other dynamic parts of the limb system. One critical area that impacts prosthetic knee design is foot performance. Often the degrees of plantar- and dorsi-flexion available in the foot do not match what is seen in normal gait, and those specifications must be included in an assessment of the walking model used and the dynamic requirements of the knee design. It is also important to note that feet are often the first component to fail in both AK and BK systems; thus, they are often the limiting factor on the life of the system, though developing world patients will often perform simple fixes to the failed feet and continue using the prosthetic¹⁴.

4.2. Physical environment, economics, and societal considerations

4.2.1. What makes designing for the developing world different?

One of the primary misconceptions about designing for the developing world is that it means designing the cheapest device possible. Walking into a design project with the idea of designing cheaply is a very limiting approach and will constrain the design process, inhibiting the likelihood of a good design. In fact, it is not the unit cost of manufacturing the limbs that constrains the number of units that can be distributed annually to patients. Patient access to clinics and the limited number trained clinicians, among other factors, play a more prominent role in limiting limb distribution.

Therefore, the goal is not to copy existing devices while decreasing the manufacturing cost, but rather to improve performance of what exists while not significantly influencing cost. This reconfiguration of the problem definition changes the design problem from a limiting one to a design puzzle seeking a clever solution. It is important to not walk into this design project with the mindset that quality of the product is not a value of the clinic providing the limb simply because it is in a developing world setting. All considerations should be made, including aesthetics and comfort, that would be made in a prosthetic limb design for the developed world. Those considerations may not be given the same weight, but still must not be ignored.

The developing world is also different by the sheer magnitude of the problem of amputation, especially due to trauma. Staats¹⁵ published a table (Table 4-1), quantifying the per capita incidence of trauma-induced amputations in a few sample developing countries and in the USA (for comparison). The numbers are estimates extrapolated from partial surveys.

Table 4-1. Per capita incidence of trauma-induced amputations in some sample countries.

Cambodia	1 amputee per 256 people
Angola	1 amputee per 470 people
Somalia	1 amputee per 1000 people
Vietnam	1 amputee per 2500 people
USA	1 amputee per 22,000 people

Finally, striking differences have been noted in patient treatment, patient access to care, and availability of manufacturing materials, tools, and other resources, among other factors, in the developing world as compared to the developed world. These factors will be explored below. This leads to additional challenges that must be worked with in the design. Thus, typical design processes that are often invoked in the first world design industry cannot be fully employed in the developing world case. However, common first world prosthetic knee designs should be studied in this thesis to learn about knee design features that may be applicable to developing world design.

4.2.2. Geographic conditions

The environmental conditions of the developing world community are involved in the prosthesis design, mostly because of their impact on materials selection. Developing world

environments range in climate primarily from dry to wet, and are generally warm environments¹⁶.

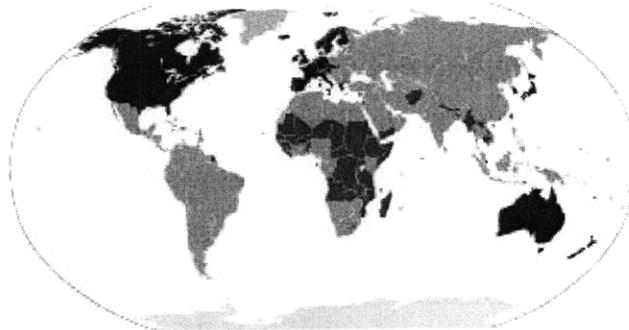


Figure 4-1. Map of world. Countries in blue indicate advanced economies. Countries in orange indicate emerging and developing economies (not least developed). Countries in red indicate emerging and developing economies (least developed). (Wikipedia 2009)

Material wear will need to be assessed for the climate of the region being designed for, and will need to be compared to patient access to replacement parts, frequency of visit, and other parameters such as patient education, in order to optimize design material selection. Material yield, rotting and rusting, are just a few wearing conditions that should be considered for all materials studied. Additionally, climate may have an affect on the comfort of the residual limb's fit in the socket. Itchiness and development of sores or rashes are common responses to sweating in the socket when the socket does not fit properly or does not use the proper sock or liner material. Many patients will only be fit once with a socket, even if their residual limb changes over time, and thus ensuring the comfort of that socket and liner is essential but tricky, as the residual limb will change over time when exposed to supporting one's weight regularly within the confines of the socket.

In nearly all cases, design of components must be water-resistant for handling both rainy conditions and wading in streams and lakes and swampy conditions.

In addition to moisture, other environmental conditions such as the terrain (forest, mountainous, etc.) may have an affect on the design and should be taken into consideration. A more exhaustive search of other environmental factors that may have an impact should be made.

4.2.3. Clinic conditions

Consideration must be made of the infrastructure present in the region for fitting patients. It is important to know about the clinic that offers the limbs, their procedures and protocols, and

their reach. How hard is it for patients to get to them? Some organizations have travelling caravans that reach some rural areas, while others are based in high-density areas where they can reach a large population of patients, but where amputees from rural villages often cannot afford to or are afraid to go. Whether the organization at work is domestic or foreign may also have an impact. Internationally sponsored NGO's residing in the area have different structure, relation to the community, and perspective on and relationship with American designers of prosthetic limbs. The training of the clinicians is important to understand as well – how many trained prosthetists are on staff¹⁷. It is important to know which of these people the patients get to see when they come to the clinic. More about the clinics, etc., is described in section 4.2.6 below on manufacturing conditions.

4.2.4. Patient conditions

Some of the most important data to collect before designing a knee is about the patients themselves. A breakdown of the relative contribution of each cause of amputation to the total amputee population may yield better understanding of the problem in the region, and may have implications such as trends in the ages of amputees. The socio-political-economic state of the government in the region also plays a role in the situation. Governments torn apart by wars (even wars that are now ended) cite landmines as the most prevalent cause of amputation, whereas in peaceful countries vehicle accidents (which fit in the general category of trauma) are the leading cause of amputation, among other causes such as workplace accidents and disease (leprosy, tumors, snakebites). Loro¹⁸ and Staats¹⁹ reported further on cause of amputation in the developing world.

Culture plays a considerable role in the patient makeup. Patients of different regions of the world will have markedly different physiology from what is found in textbook averages – differences in mean patient size (height and weight) should be considered in knee design. Additionally, cultural considerations should be made for typical postures and conditions that a patient needs to be able to achieve. For example, in India, cross-legged sitting on the ground is important and requires some extremes in range of motion that are not necessary in high-tech limbs offered in the U.S. Additionally, the ability to walk barefoot is mainstream in many parts of India, and prosthetic feet must be designed accordingly. Given the typical types of work that people in the region of study do, consideration must be made of whether that work requires any special postures, motions, or other abilities. This is absolutely critical, as in most regions,

designing a prosthetic that enables a person to go back to work and earn money to provide for his family is maybe the most important function of the limb, and a requirement for the amputee to survive and to help support his family. It is also true for everyday living and house chores, etc.

It is important to know more about the amputee demographic, their location, living conditions, and employment, because those things influence the patients' access to medical care. Patients in rural areas may not have means to pay for medical help, may not be able to reach adequate medical help for days or weeks, or may receive poor treatment from a small, local clinic that may not offer the tools or training necessary for the proper treatment. Some rural clinics may offer surgeries or other treatments that may cause further complications and lead to cause more harm than good, meaning that corrective treatments and surgeries may be in store when the patients reach access to better treatment, if they are still medically feasible. Access to medical care and quality of available care are critical elements to assess in the region of interest, because they have a strong impact on amputation quality and healing and proper post-operative care, and the patients' ability to be fitted well and comfortably with a prosthetic limb. Knowing the patient demographic is important too because the age of the amputee affects their fitness and ability to respond well to healing, to learn to walk on different kinds of prosthetic limb systems, and also affects their needs in terms of prosthetic performance. It is furthermore important to be able to assess whether the patient will be in a place where they have access to follow-up care either with the prescribing clinic or another facility with qualified/trained staff, and whether the patient has a level of education that would prompt him to know to seek care when needed.

It is also good to know about the clinic that is being worked with. Do they charge their patients? What quality of service to the patients receive? What is the organization's mission? If your goals as a designer do not align with their philosophy as a provider, your knee may never be successfully integrated into their system. Additionally, it is important to understand how rooted the facility is in their traditional ways of doing things; many domestically- funded organizations may be rooted in a certain way of doing things and not very open to Western ideas or to new ideas or ways of doing things.

4.2.5. Post-operative and post-prescriptive care for patients.

When designing for the developing world environment, it is important to know the fitment procedure employed by the clinic that is being worked with. It is also important to know what the patient's long-term access to medical care is going to be. The Jaipur Foot Organization

takes pride in seeing their patients, fitting them with a limb, and going through a basic physical therapy procedure to get them comfortably walking in one day. This minimizes the time that the patient must be away from home and from work, and the simple fact that patients can feel comfortable walking on their limb systems in a day is a testament to not only the clinic, but also to the patients as well.

This one-day fitment process is substantially different from the rehabilitation process recommended in the U.S., which should reasonably take several years. In the U.S., the preferred situation is for patients to have selected a prosthetic and to be planning for post-operative fitment before the planned amputation happens. Patient interaction with the prosthetic should happen immediately after surgery, and the first socket should be built for the patient's limb immediately after surgery. Wearing the socket will help reduce swelling and improve the way that the residual limb heals so that it heals in a way that is comfortable with wearing a prosthetic limb. The patient's residual limb will change significantly over the next years, and it is estimated that a patient will use approximately many different sockets over the first 12 months post-operative, as new sockets are built to accommodate the changing limb. Likewise, the patient will participate in physical therapy over a long term period to maximize their rehabilitation and ability to walk naturally and comfortably on the prosthetic.

Despite the success of this prosthetic prescription protocol in the U.S., it may not be appropriate or feasible for developing world clinics to offer the same care. It is important to know what that process looks like at the clinics, and to assess how well a new knee design will fare in the current physical therapy infrastructure.

4.2.6. Manufacturing conditions

In developing a sustainable technology for the area of interest, considering the manufacturer is essential. It is critical to know whether the parts are being machined in-house (at the clinic site) or outsourced, and if outsourced, to where. If the clinic buys the components from a third party, keeping cost down is critical. Knowing where the manufacturing happens is also important for materials selection, because it is important to choose materials that the machinists are accustomed to working with, have the necessary tooling for working with, and have natively or readily available to them. Knowing the skillset of the laborers doing the manufacturing is important; however, typically in the developing world the skills of the locals are far superior to what we typically find here in the U.S. It is finally important to know what kind of machines are

available to the clinic, and to design for manufacturing in a way that meets their capabilities but minimizes build times. Trying to minimize part count and maximize the number of those parts that are standardized and highly repeatable is key to maximizing the way that you ensure the knees built behave the way that you design them.

4.3. Relevant Literature

These many factors to be understood in the target region have been discussed thoroughly in literature. Cummings²⁰ offered a thorough list of literature on prosthetic devices, including studies of prosthetic feet. Papers describing developing world designs for other prosthetic components are provided, but quantitative studies of currently available systems are not presented, mostly because I think they do not exist in published literature. Staats²¹ offered characterization of the main causes of amputation, a list of programs (NGOs and others) that work with amputees in the developing world, and also some cultural, geographical, and economic impediments to amputee rehabilitation that should be assessed for the region being worked with. Loro²² gave a more detailed description of the main causes of amputation in the developing world. Meanly²³ assessed the materials being used today for developing world prosthetic limbs in different regions of the world (considering material availability and effects of climate). He also characterized cultural considerations that should be made in prosthetic design. Sethi²⁴ discussed the cultural considerations that should be made for design in India, articulated different responses to prosthetic limbs observed in urban versus rural patients, described the qualifications of the local craftsmen and of the trained prosthetists who work at their clinic, and assessed the materials used in the components they offer. Finally, Day²⁵ quantified the relative contributions of the various causes of amputation in developing countries and compared them for different countries. He also characterized the levels of expertise seen in various types of clinic workers. Day described various prosthetic components and providers of those systems, and also did an assessment of typical product life, cost, and sustainability.

CHAPTER

5. Developing a Strategy for Design

Ultimately, the designer of a prosthetic knee must learn deeply in a variety of areas in order to design effectively and sustainably. Table 5-1 summarizes the areas of learning and available sources through which to effectively learn.

One key resource that has not yet been mentioned is the Atlas of Limb Prosthetics, available online at <http://www.oandplibrary.org/alp/>. Nearly all topics pertaining to amputation and prosthetic prescription are covered comprehensively in this text.

Table 5-1. Key areas of learning and learning resources for the designer of prosthetic knees.

Area	Topics to Consider
Assessing Current Systems	<ul style="list-style-type: none"> - Product life - System functionality for different patient types (ages, abilities, etc.) - Product cost - Patient feedback
Knee Interactions with Other Components	<ul style="list-style-type: none"> - Tolerances of interacting parts - Rigidity of interface - Ability to adjust/align for patient
Geographic Conditions	<ul style="list-style-type: none"> - Temperature - Terrain
Clinic Conditions	<ul style="list-style-type: none"> - Goals - Background (local vs. international, where funding comes from, etc.) - Training of employees - Location
Patient Conditions	<ul style="list-style-type: none"> - Performance needs in order to work - Rural vs. urban background - Age and ability - Culturally important looks, postures, behaviors, abilities
Post-Operative Care Conditions	<ul style="list-style-type: none"> - Ability to receive post-prescriptive care, adjustment - Ability to access replacement parts
Manufacturing Conditions	<ul style="list-style-type: none"> - Tools and machines available (CNC?) - Tolerances of machines - Repeatability of processes - Materials available - Abilities of craftsmen

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