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The ISO 10328:2006 Static Testing and Finite Element Analysis of the ICRC Prosthetic Knee for Use in Low Income Countries

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Signed: Date:

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Abstract

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The prosthetic knees currently available in developing countries have inadequacies concerning durability and mobility. People living in non-industrialised countries represent 80% of disabled population in the world, and the majority has no access to basic health services. The aim of this project was to test one of those knees in order to verify if it conforms to the ISO Standard 10328:2006 for prosthetics.

An assembly was made by means of the International Committee of the Red Cross (ICRC) prosthetic knee and seven of the original polypropylene components. Additional mechanical components such as two metal plates were manufactured. Static tests were based on the ISO 10328:2006 structural testing of lower-limb prostheses protocol. All static tests were carried out using an Instron ElectroPuls^{TM} E10000 machine. The stress-strain characteristics of the assembly were determined from each test.

Because of the presence of a crack in the knee component and the separation of the weld between the conical cup and the convex disc while performing the ultimate strength test, the machine was manually stopped before the load had reached the desired loading value. Even so, the test was passed as the lower load limit P3 was achieved.

The assembly was then investigated through a finite element analysis computer programme, COSMOSWorks. The model was created with the same dimensions of the assembly and a static linear analysis was performed. Subsequently, the results were displayed through contour plots. The data output was analysed to determine the maximum Von Mises stresses and overall stress and strain distributions. The displacement present was examined, paying particular attention to the deformation across the polypropylene components, as these proved to be the parts most

vulnerable during testing. The ISO Test Standard 10328, was used as the basis for testing. The results show that despite a displacement up to 28.77mm and the application of a 2390N load, there are few areas where Von Mises stress are higher than the material yield strength, therefore suggesting that no structural failure of the assembly is expected during testing.

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Chapter 1: Introduction

1.1 Introduction

The World Health Organization (WHO) estimates that 10% of the world's population, around 650 million people is disabled. While amputees living in industrialised nations use advanced prostheses, worldwide the vast majority of these patients lack access to either devices of this type and to the clinics essential to support them. Population growth, ageing, advent of chronic diseases and medical advances that preserve and prolong life are the major causes for the increase in the global impaired population. Other reasons include chronic diseases such as diabetes, cardiovascular disease and cancer, injuries such as those due to road traffic accidents, war and conflicts, falls, landmines, mental impairments, birth defects, malnutrition, HIV/AIDS and other transmittable diseases. These trends are creating overwhelming demands for health and rehabilitation services (WHO, 2006).
About 80% of people with disabilities live in low-income countries where the majority is poor and experience difficulties in accessing basic health services, including rehabilitation services. This causes immobility, isolation, dependency, inequality, often-premature death and increased poverty. With proper health care and rehabilitation services, this picture could be significantly changed and people with disabilities could become an integral part of society (WHO, 2006).

The prosthetic systems currently in use in developing countries have inadequacies concerning durability and comfort. Early failure of prosthetic feet along with inadequate prosthetic socket fit, poor prosthetic alignment and poorly functioning components, including knee joints, are the major sources of such failures (Andrysek, 2010).

Along with the lack of financial resources and trained personnel, amputees can only rely on few and limited resources. In particular, availability of materials and skilled personnel, together with a variety of cultural differences make third world prosthetics a subject in itself. In 2004, 25.5 million of the people living in Africa, Asia and Latin

America required a prosthetic or orthotic device (Orthotics, 2005) and the World Health Organization estimates that it will have increased to 30 million by 2011 (Harkins, McGarry & Buis, 2013). Further, landmines represent another major issue. The United Nations estimate that there could be 100 million un-cleared land mines around the world, and therefore there will be an ever-growing number of new amputees in developing countries each year. Particularly, 26,000 amputations per year and 300,000 amputees worldwide are attributed to mines. To give an example of the seriousness of the problem, Berry estimated that land mines have caused more deaths and injury in the second half of the 20th century than both nuclear devices exploded in Hiroshima and Nagasaki (Berry, 2005). Other causes of amputation in low-income countries include industrial or environmental accidents, terrorist attacks, and the lack of basic public health, which often leads to diabetes, gangrene, and infection. All of these causes are increasing the number of amputations at an alarming rate.

There are significant differences between typical lower limb amputees in developing countries and those living in industrialised countries. Because of the low average life expectancy, amputees in developing countries are often young, likely to rely on physical labor for survival and to be located rurally with travel often difficult if at all possible (Strait, 2006). The amputation performed may have been done in several stages, increasing the risk of infection, and may not be to a high standard making the fitting of a prosthetic socket more difficult. The performance and cosmetic appearance of limbs depend on several variables including cost, the skills that technicians have to make the limbs, and the materials that are available to fabricate the limb. A properly fit limb is the result of a close working relationship between the prosthetist and the patient. Finally, the design and fit of the socket is what determines the patient's acceptance, comfort, suspension, and energy expenditure.

The lack of trained personnel is another major problem. A high level of skill is required to correctly constructing, fitting, aligning, and adjusting a prosthetic limb and despite the high demand for this expertise, training programs in low-income countries are scarce and, as reported by the WHO, it will take about 50 years to train just 18,000 more skilled professionals (Walsh & Walsh, 2003).

Another obstacle is that those components imported from industrialised countries to build prosthetic limbs in developing countries are not only more expensive, but also they are designed for different lifestyles and are usually not suitable to address the challenges existing in rural environments. Indeed, these countries have a farm-based economy and a tropical climate. In these harsh environments, conventional limbs made of wood and resin last 18 months at most. The costs of prosthetic limbs vary considerably by country, but a typical prosthetic limb made in non-industrialised countries costs approximately $125 to $1,875 USD, depending upon the region in which they are manufactured. Whilst the costs to make a limb in a developing country can be reduced to as little as $41 USD (far below the $5,000-$15,000 USD average cost for a prosthesis in the United States), the costs over a lifetime of replacements and maintenance can still amount to thousands of dollars. This represents a particular complication since the average family income in rural areas is typically around $300 USD per year. It can take victims a decade or more to earn the money for an initial prosthesis (Walsh & Walsh, 2003)

1.2 Aims of the Project

This study aims to test the ICRC prosthetic knee for use in developing countries with the goal of evaluating whether it conforms to the ISO 10328:2006 static loading Standard. The main objectives of this project are:

- To create a set-up for the assembly such as it complies with the criteria specified in the ISO 10328.

- To test the assembly to ensure whether it conforms to the ISO 10328 standard.

- To determine which areas are the most exposed to deformation during testing and to comprehend the stress distribution throughout the assembly.

Chapter 2: Literature Review

2. 1 Prosthetic Industry in Developing Countries

Technology designed for use in the developing world should be of low cost, simple to operate and be easy to maintain (Morton, 2009). The implementation of such a technology should not have a negative impact on employment and be accepted by the people for whom it is intended. If possible, the technology should either be manufactured from materials readily available in the country of intended use, or use locally available standard components for the production of new devices. Eyre-Brook reported that in Khartoum difficulties were encountered funding or procuring the materials required to produce prostheses, and in Bangladesh the amputees had to provide the plaster bandages required to manufacture their own sockets. It is evident that the supply of prostheses manufactured in the developing world cannot be based on Western standards and consequently locally available materials and craft s need to be adapted (Eyre-Brook, 1986).

Most of the patient population in low-income countries lives in rural areas with some African nations having up to 90% of people living in the countryside. Also, as a consequence of the low life expectancy, there exist an ever-growing pediatric population, which ultimately creates even greater demand, as devices must be continually replaced (Cameron et al., 2005). In this regard, a study conducted by prosthetic and orthotic services in India emphasised that there were four times as many males as females and all patients were under 30 (Agarwal & Goel, 1978). Particularly, most females were below 10 years old (Pollard & Sakellariou, 2008). This is revelatory of the actual situation in developing countries, where men carry out manual labor while women remain at home.

A major cause of amputation in developing countries is landmines. In such countries amputees tend not to receive basic levels of service and consequently find it difficult to fully integrate back into society. Trauma victims often lack affordable transportation to go to hospitals and rehabilitation centres (O'connell, 2000). People living in the countryside represent at least 80% of those needing care in developing

countries and most of them cannot afford it (Cummings, 1996). Further, for 25% of landmine victims, hospital care is up to 6 hours away and 15% are required to travel for more than 3 days to receive aid (Walsh & Walsh, 2003). Landmine victims often face social stigmatisation, rejection and unemployment, however the provision of a functional prosthesis to a landmine survivor can increase their chances of employment (Burger & Jaeger, 2004)

The medical costs of treatment, physical rehabilitation, and prosthetics to treat individuals with landmine amputations vary from country to country. Factors that contribute to the costs include the importation of all materials, the need to use expatriate workers, and the need to transport personnel and materials by air (Coupland, 1997).

The effective utilisation of prostheses is highly associated with a satisfactory prosthetic durability and comfort. The reason for this is that damaged prostheses that cannot be easily repaired are useless, and those that are uncomfortable to use (resulting in stump pain, fatiguing gait or back problems etc.) are likely to become underutilised or abandoned altogether. In addition, standardisation of procedures and outcome measures still need to be developed in order to better evaluate and compare technologies, so that existing devices could be improved and/or better utilised (Andrysek, 2010).

Inability to perform daily activities and economically productive professions cause decreases in family income and worsening in living standards. Reduced income, poor housing, and lack of sanitation contribute to increases in infectious diseases. Thus begins a vicious cycle: disability leading to poverty leading to disease leading to more disability and further poverty (Maulik, 2004).

Also, as reported by the WHO, the rehabilitation services in developing, war-torn countries, are almost absent and the few present generally reach less than 5% of the disabled population (Walsh & Walsh, 2003).

ICRC reports that the initial phase is the most economically demanding. Hospitalisation costs, including transportation costs, are approximately US$ 120 per patient per day. Coupland estimates that for patients with landmines amputations the

overall charge in an ICRC hospital ranges from US$ 3000 to US$4000. The cost of a prosthetic limb is approximately between US$ 125 and US$ 1875 (Coupland, 1997). In Colombia, the ICRC provides the national rehabilitation centre (CIREC) with prostheses for below-knee amputation at approximately US$ 212 each. In Vietnam the manufacturing cost of prostheses from 1989 to 1995 varied between US$ 38–64 per prosthesis. Considering that individuals usually require a new limb every two years, ICRC calculates the average total cost of fitting one person to be about US$ 1000 (Coupland, 1997); it would take most victims at least ten years to earn this amount. In addition, an adult typically requires the prosthesis to be replaced every 3–5 years, and a child with a lower limb amputation could be expected to need 15–20 artificial limbs in a lifetime (DFID, 2000), (Walsh & Walsh, 2003).

Given the low production rates for prostheses manufactured in developing countries (see Table 2.1), the poor quality of the devices produced, the insufficient number of trained prosthetists and the lack of long-term funding, the following recommendations may be beneficial:

- Governmental agencies should set up programs that monitor and evaluate prosthetic services according to well-defined criteria.
- A prosthesis provided should be of a custom fit.
- Prosthetic services should be developed locally.
- Long term local sustainability should be included in the planning of prosthetic services (Convention, 2002).

		Lower Limb Level					
	Total number of amputees	Trans-tibial incidence	Trans-femoral incidence	No. of TT prostheses produced/year	No. of TF prostheses produced/year	Cost of a TT prosthesis (USD)	Cost of a TF prosthesis (UDS)
Cambodia	30000	60%	30%				
China				18262	9779		
India	1000000	60%	10%	15000	2000	0-100	0-200
Indonesia				17	17	40	40
Korea	92000	32.80%	24.50%	10230	7857	600	1000
Malaysia	2500/year	60%	33%			200-800	800-2000
Myanmar	7000			243	106	28	45
Nepal	83000	55%	25%	348	199	60-100	150-180
Pakistan	25000	45%	30%	104	60	45	45-65
Singapore	10000	30%	20%	427	54	500-2000	100-4000
Taiwan	40000	50%	40%	1300	1000	1100	1600
Vietnam	200000	37%	34%	6000	3000	3-45	80-120

Table 2.1: Prosthetic provision in developing countries (ISPO, 1998). *TT = transtibial, TF = transfemoral.*

The data in Table 2.1 should be treated with caution. The number of trans-tibial (TT) prostheses produced per year in China appears low, however it was reported by the Hong Kong Trade Development Council in 2007 that there are less than 200 prosthetic limb manufacturers in China (Yongji, 2007). It was claimed that there are over 10 million people in China with some form of limb disability and this has resulted in an increasing level of demand for assistive devices. Those devices that are produced locally have a life cycle of one year and are, therefore, inferior to those prostheses imported from the US or Hong Kong with a standard life cycle of three years. It has been estimated that there are 44 million landmines in Africa, representing one third of the total mines disseminated worldwide (Madava, 1999). Angola is the worst affected region, with 15 million landmines and 23,000 amputees. For every four hundred and seventy people living in Angola, one is an amputee (Ukabiala, 1999). In 2001, the ICRC reported that 16,734 among prostheses, orthoses, crutches and wheelchairs were needed in Afghanistan only (Verhoeff, 2002).

To draw a comparison between the developed and the developing world, statistics regarding the number of amputees living in the US and the UK are worthy of examination. According to the information published by the US National Limb Loss

Information Centre (NLLIC) regarding the cause and incidence of amputation in the US, there are approximately 185,000 new amputations per year in the US with the main causes related to vascular disease (54%) including diabetes and peripheral arterial disease, trauma (45%) and cancer (less than 2%) (Ziegler-Graham et al., 2008). Figure 2.1 shows the number of amputations between 1988 and 1996 in relation to the cause. Of the 97% lower limb dysvascular related amputations, 25.8% were transfemoral (TF) and 27.6% were TT (Centre, 2008).

In the UK, the Amputee Statistical Database for the United Kingdom collects information within the prosthetic centres throughout Northern Ireland, Scotland, England and Wales. In the year 2004/05, there were 2511 TT and 1797 TF amputations, with the main cause related to dysvascular disease and the most common level of amputation is transtibial (see Figure 2.2). Further, the major cause of lower-limb amputation was dysvascularity (see Table 2.2)

It is evident that in the UK and US, the main cause for amputation is dysvascular disease. This is not the case in developing countries where landmines continue to kill or maim one person every 20 minutes (Morton, 2009).

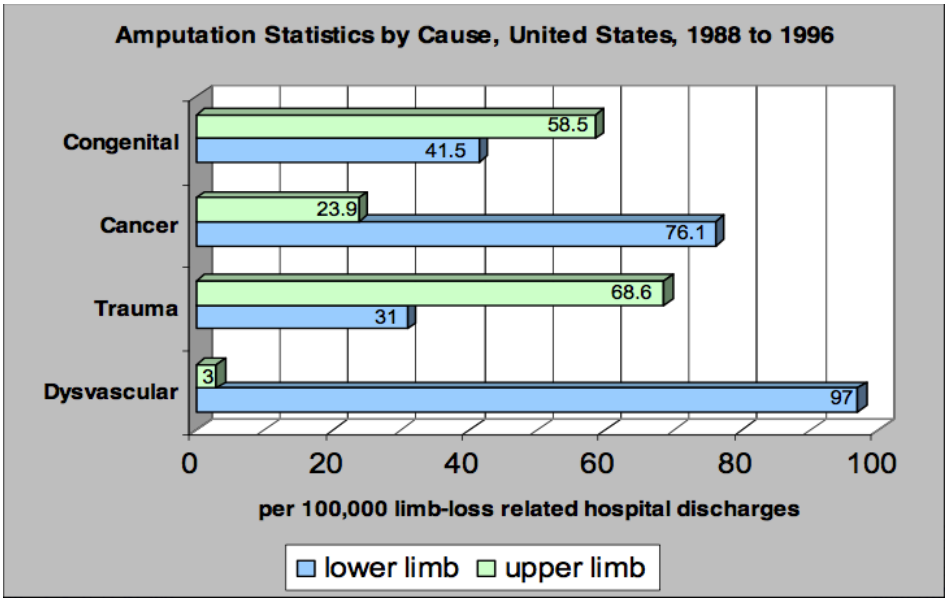


Figure 2.1: US Amputations between 1988 and 1996 (Centre, 2008). *Scaled as a percentage of every 100,000 amputations with relation to cause and level (eg. For every 100,000 congenital related amputees, 58.5% are of the upper limb).*

It was reported in the New Internationalist Magazine that 61% of the mine victims in Cambodia, and 84% in Afghanistan went into debt to pay for their medical treatment (Godrej, 1997). Eyre-Brook has discussed how the disabled are often disregarded for necessary surgical procedures due to the low numbers of surgeons working in developing countries. Those surgeons that are available, normally concentrate their services on life or death problems (Eyre-Brook, 1986). Tuli states that in some cases an orthosis may be the best treatment, providing more acceptability and ease of maintenance than a prosthesis (Tuli, 1985). Walsh and Walsh (Walsh & Walsh, 2003) found that crutches are widely used for landmine victims with a lower extremity amputation. In the same study the following treatment barriers were identified: access, protection, security, poverty, funds, coordination, interagency rivalry, education and social structure, politics and administration.

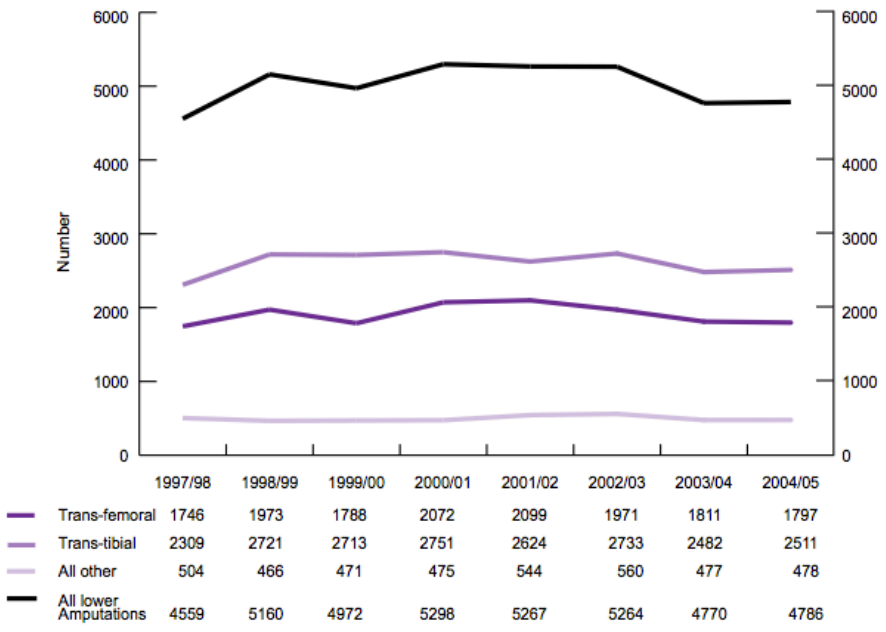


Figure 2.2: Number of lower limb amputations by level and year April 1997 to March 2005 (NASDAB, 2005).

Cause of amputation	Level of amputation[1]									
	Hemi pelvec-tomy	Hip disartic-ulation	Trans-femoral	Knee disartic-ulation	Trans-tibial	Ankle disartic-ulation	Partial foot	Lower Digits	Double lower amp.	
Trauma	**2**	**6**	**126**	**15**	**236**	**4**	**17**	**1**	**19**	**426**
No Additional Detail	1	3	35	6	69	2	7	1	5	**129**
Mechanical	1	3	81	8	149	1	7	-	10	**260**
Electrical	-	-	4	1	7	-	2	-	-	**14**
Thermal	-	-	2	-	9	1	-	-	3	**15**
Chemical	-	-	4	-	2	-	1	-	1	**8**
Dysvascularity	**3**	**9**	**1,385**	**38**	**1,891**	**7**	**25**	**6**	**216**	**3 580**
No Additional Detail	1	5	393	13	399	-	2	-	40	**853**
Diabetes Mellitus	1	-	364	9	995	5	13	2	101	**1 490**
Non-diabetic Arteriosclerosis	-	3	530	15	409	1	7	4	60	**1 029**
Embolism	-	1	35	-	29	-	1	-	-	**66**
Vasospatic Conditions (inc. Raynauds)	-	-	3	-	4	-	-	-	1	**8**
Disseminated Intravascular Coagulation	-	-	2	-	3	-	-	-	2	**7**
Endovascular Chemical Trauma (Substance Abuse)	1	-	8	-	3	-	-	-	1	**13**
Buergers Disease	-	-	5	-	5	1	-	-	3	**14**
Iatrogenic Vascular Trauma	-	-	4	-	2	-	-	-	1	**7**
Arteritis (inc. Rheumatoid Arthritis, Autoimmune Disease)	-	-	18	1	21	-	2	-	4	**46**
Venous Disease	-	-	23	-	21	-	-	-	3	**47**
Infection	**-**	**9**	**123**	**4**	**174**	**5**	**6**	**-**	**15**	**336**
No Additional Detail	-	4	35	-	45	1	-	-	4	**89**
Acute	-	3	28	1	27	3	1	-	8	**71**
Chronic	-	2	60	3	102	1	5	-	3	**176**
Neurological Disorder	**-**	**1**	**12**	**1**	**52**	**5**	**-**	**-**	**4**	**75**
No Additional Detail	-	-	1	-	10	1	-	-	1	**13**
Diabetic Neuropathy	-	-	5	-	29	1	-	-	2	**37**
Infective	-	1	1	-	1	-	-	-	-	**3**
Spina Bifida	-	-	1	-	6	2	-	-	1	**10**
Poliomyelitis	-	-	1	1	2	-	-	-	-	**4**
Peripheral Nerve Injury	-	-	3	-	4	1	-	-	-	**8**
Neoplasia	**6**	**8**	**61**	**1**	**36**	**-**	**4**	**3**	**-**	**119**
No Additional Detail	-	2	4	-	3	-	-	-	-	**9**
Benign	-	-	3	-	2	-	-	-	-	**5**
Malignant - Primary	6	6	49	1	27	-	4	3	-	**96**
Malignant - Secondary	-	-	5	-	4	-	-	-	-	**9**
Other	**-**	**3**	**46**	**3**	**70**	**3**	**4**	**1**	**11**	**141**
No Cause Provided	2	-	44	2	52	-	2	1	6	**109**
All causes[1]	**13**	**36**	**1 797**	**64**	**2 511**	**24**	**58**	**12**	**271**	**4 786**

1 Excludes congenital absence.

Table 2.2: Level of amputation by cause of amputation in the UK: 2004/05 (NASDAB, 2005)

2.2 Amputations and Prostheses

2.2.1 Introduction

In the developing world, where the level of medical care available is limited, those unfortunate enough to require an amputation may either die during or following the surgery, or live with the pain developed from their disability. As the developing

world's societies continue to develop, it is the indigenous diseases that require the most treatment. With development comes the use of machinery for agriculture, industry and transportation and, as a consequence, the number of patients admitted in hospitals for trauma will grow. Statistics from the developing world concerning the number of amputations carried out in hospitals and their causes are not readily available, and therefore, those that are available should be treated with caution (Morton, 2009).

2.2.2 Amputation

Amputation may be amongst the oldest surgical procedures carried out and should only be performed in the event where no lesser procedure is adequate. Amputation can be described as a mutilation that is attended by physical and functional loss, severe physiological trauma with the body image altered and distorted (Murdoch, 1996). In the case of trans-tibial (TT) amputation, the main objective for the surgeon should be to preserve a functioning knee joint so that in biomechanical terms, the patient has only lost the function of the foot and ankle. Preservation of the knee joint should retain the function of power for lifting, lowering and maintenance of balance (Wittmann & Markowitz, 2010). With the knee joint retained the amputee should have the opportunity to regain a similar style of gait to that which they had before the procedure. The main goal of treatment is to provide the optimum functional result, physically, cosmetically and psychologically (Huston, Dillingham & Esquenazi, 1998).

2.2.3 Causes of Amputation

In the developing world the main cause of amputation is trauma resulting from landmines, traffic or work related accidents. Other causes may include uncontrolled infection, snake bites, peripheral vascular disease (PVD), leprosy and tumours (Rankin, 1996). The incidence of peripheral vascular disease is increasing in developing countries as they become more westernised in terms of lifestyle and diet (Engstrom & Van De Ven, 1999). Table 2.3 compares the causes for lower limb

amputations in the developed and developing world.

Rankin reports that transtibial amputation may be the most common amputation carried out in the developing world despite the fact that it is often performed poorly (Rankin, 1996). He also states that a good working relationship between an experienced surgeon and prosthetist is fundamental to accomplish an effective rehabilitation of the transtibial amputee. However, this is seldom the case in developing countries where experienced surgeon and prosthetist are rarely consulted before the amputation. Hence, the chances of the amputee making a full and successful recovery are lowered before the procedure is carried out as there is a lack of appreciation of the importance of stump length or quality with respect to the prosthetic fit. A successful rehabilitation of the amputee requires the creation of the best possible stump in terms of both sensory and motor function in order that a prosthetic substitute may be fitted to restore some element of function (Murdoch & Wilson, 1996).

Developed Countries Cause	Relative %	Developing World Cause	Relative %
PVD	85-90	Trauma	55-95
Trauma	9	Disease	10-35
Congenital deficiency	3	Tumour	5
Infection	1	Congenital deficiency	4
		Infection	11-35

Table 2.3: Relative % of the Cause of Lower Limb (Engstrom & Van De Ven, 1999)

2.3 Rehabilitation

Mobility of the amputee should begin the day following surgery in order to prevent deconditioning (Bowker, 1996). According to Huston et al (Huston, Dillingham & Esquenazi, 1998), rehabilitation, intended as the restoration of function, is dependent on:

- The abilities of the patient, both mentally and physically

A patient who rejects the thought of losing a limb is not good candidate for rehabilitation.

- The level of amputation

The higher the amputation level, the more difficult the rehabilitation process as more joints are lost, there is less power available due to muscle loss and there is a loss of leverage required to control a prosthesis.

- The condition of the amputation stump

It may not be possible to remove the cause of amputation and as a result the original disease could affect the condition of the amputation stump and hence the level of rehabilitation.

- The prosthesis

In developing countries, there is other power source than that of the stump or other parts of the body to control a prosthesis.

- The rehabilitation process

The rehabilitation process should enable the patient to become mentally and physically restored to society. The aim of rehabilitation is to make the best use of the remaining abilities of the patient so that the best possible level of function is achieved. Rehabilitation is normally considered in four stages:

- *Pre-amputation*
- *Post-amputation, pre-prosthetic fitting*
- *Temporary prosthesis*
- *Permanent prosthesis*

The goals of rehabilitation are:

1. Prevention of complications of immobility
2. Patient education
3. Conditioning
4. Functional training
5. Psychological support

2.3.1 Rehabilitation in Developing Countries

In 1976, the member countries of the World Health Organization (WHO) agreed to include rehabilitation in their goal of "Health for all by the year 2000" (Habicht, 1981). Because of the extreme poverty of the majority of patients in low-income countries, the organization decided to adopt a rehabilitation model appropriate for use as a supplement for existing institution-based services in developing countries. This rehabilitation model initiated by the WHO was promoted as a strategy to improve access to rehabilitation services for people with disabilities in developing countries.

Ideally, CBR services consist of three levels that interact to provide appropriate rehabilitation services (Cummings, 1996):

1. Community level
2. Intermediate level
3. Specialised or tertiary level

Maulik pointed out that rehabilitation in developing countries is not covered appropriately in medical schools (Maulik, 2004). The reason for this is that, because of the low national income, priority is given to primary health-care whereas rehabilitation takes second place. Corruption, poor management of financial resources and lack of natural resources by the government are additional factors contributing to the negligence of rehabilitation services (Pupulin, 2001).

According to Walsh and Walsh (Walsh & Walsh, 2003), there are two main phases of the rehabilitation process: the pre-prosthetic rehabilitation and the prosthetic rehabilitation. The former deals with retaining as much function as possible of the amputated limb, as this aids to prevent joint contractures, which in turn can make fitting and wearing a prosthetic limb difficult or even impossible. On the other hand, the prosthetic phase of amputation rehabilitation concentrates on fitting the prosthesis and on gait training activities. The fit is essential, as comfort will help to determine the acceptance of the limb by the patient as well as the resulting function. In addition, thanks to a prosthetic lower limb, crutches are no longer necessary and

hence, the individual is more likely to integrate back into society.

Although developing countries may not have access to the same range of healthcare professionals available in western societies, the combined roles of a complete rehabilitation team are necessary to ensure that an optimal rehabilitation of an amputee is achieved (Engstrom & Van De Ven, 1999). Such a team should involve a physiotherapist, occupational therapist, surgeon, nurse, social worker, prosthetist and rehabilitation consultant. The few rehabilitation facilities that can be found in low income countries are biased in their selection of patients with soldiers gaining priority (Levy & Sidel, 2000). Walsh and Walsh (Walsh & Walsh, 2003) reported that developing war-torn countries lack the systems required for rehabilitation service delivery and have few trained rehabilitation professionals. The WHO has stated that almost all developing countries have some form of rehabilitation services, with most based in hospitals in urban areas, but as a result of prohibitive costs and limited accessibility they reach less than 5% of the disabled population.
The ICRC has developed a leadership position in physical rehabilitation in developing countries through its Physical Rehabilitation Programme (ICRC, 2013). In 2012, the Physical rehabilitation programme of the ICRC provided support to 96 projects in 27 countries and more than 240,000 people. The programme also included the production of 20,345 prostheses and 60,372 orthoses along with 3,414 wheelchairs. Appropriate physiotherapy was provided to 113,454 people (ICRC, 2013). The WHO reports that the total charge for a patient suffering from a landmine injury is approximately $3000-4000 if treated in an ICRC hospital. According to the UN, this leads to a total expenditure of $750 million for the 250,000 amputees they have registered worldwide. Despite this, the rehabilitation facilities available to amputees remain inadequate (Levy & Sidel, 2000).

2.4 Prosthetic Knee Design

Of all prosthetic components, the knee is arguably the most complex. It must provide "reliable support when standing, allow smooth, controlled motion when walking, and permit unrestricted movement for sitting, bending and kneeling" (Dupes, 2008). The

primary goal of prosthetic knee technology is to restore a natural gait to an above knee amputee (Dupes, 2008). There exist a vast assortment of prosthetic knees and they greatly differ in function and complexity. For transfemoral (including hip and knee disarticulation) amputees, successful function depends on selecting the correct knee to fit the person's age, health, activity level and lifestyle. The latest or advanced knee is not necessarily the best choice for everyone. Indeed, for some patients, safety and stability are a priority when compared to functional performance. Active amputees, on the other hand, may prefer a knee with a higher level of function even if it requires greater control.

Despite hundreds of knee mechanisms commercially available, two are the major classifications: mechanical and computerised.

Mechanical knees can be further divided into two groups: single-axis knees and polycentric knees. Regardless of their complexity, all knee units require supplementary mechanisms to achieve stability (manual or weight activated locking systems) and additional mechanisms for motion control (constant or variable friction and "fluid" pneumatic or hydraulic control) (Dupes, 2008).

Single-axis knee units simulate a simple hinge and allow the prosthetic shin to swing freely in flexion and extension. Stance-phase knee stability is achieved by a combination of positioning the knee unit with respect to the weight line (alignment) and muscular control (activity or hip extensors). The knee is lightweight, durable and low maintenance, but because of its unrestricted movement, it has no inherent mechanical stability. In addition, it is free-swinging meaning that the shin of the prosthesis will swing forward at the same rate, regardless of gait speed (Lusardi & Nielsen, 2006).

Figure 2.3: ORT- 50T single axis knee joint with stance control and constant friction (ortotek.com, 2011).

Polycentric knees have a "four-bar" design, which makes the instantaneous centre of rotation continuously changing through the range of motion (ROM). Furthermore, to simulating the anatomical axis of motion more closely, the mechanical characteristics of this type of knee unit enhance stance phase stability in gait. As the knee unit flexes during swing phase, the polycentric axis of motion leads to relative "shortening" of the distal prosthesis, which enhances toe clearance throughout swing phase (Lusardi & Nielsen, 2006).

Figure 2.4: Hosmer 4-bar polycentric knee with constant friction (oandp.com, n.d.)

Stance phase control systems may incorporate either manual locking or weight-activated mechanisms. Manual locking knee units are the most stable units available and consist of a pin mechanism, which automatically locks with a distinctive click when the knee is fully extended and can be unlocked voluntary. Although a locked knee provided maximum mechanical stability in stance, it also significantly compromises mobility and toe clearance in swing. Weight-activated knee units have a breaking mechanism, which is activated when weight is applied through the knee during stance phase of gait. The intent of this mechanism is to prevent unwanted knee flexion during stance. The sensitivity of it can be adjusted to match the individual's level of activity and ability to control the knee voluntarily (Lusardi & Nielsen, 2006).

Swing phase control systems are required for all knee systems in order to maintain a consistent gait. This can be achieved with either mechanical constant-friction units or fluid cadence responsive units. Constant friction units are simple, lightweight and dependable. Their major shortcoming is that the knee is adjusted for a single walking speed at any given time. Variable friction provides increased resistance as the knee bends from full extension. This allows simulating the actions of the quadriceps and hamstrings muscles of the thigh. However, frequent adjustment and replacement of moving parts are required.

Pneumatic knee units offer the prosthetic user a varied cadence capability, using air pressure dynamics. Because air is compressible, the channels within the knee can be adjusted to affect the rate of swing.

Hydraulic knee units are cadence-responsive as the pneumatic units but they use hydraulic fluid rather than air. In particular, the flow of the fluid through narrow channels within the knee unit provides a frictional resistance, which increases with the speed of compression (Lusardi & Nielsen, 2006).

Figure 2.5: Endolite pneumatic (on the left) and Hosmer hydraulic (on the right) knee units (endolite.de, 2014) (hellotrade.com, n.d.)

Microprocessor knees represent the latest development in prosthetic technology. Onboard sensors detect movement and timing and then adjust a fluid/air control cylinder accordingly. These computerised units lower the amount of effort amputees must use to control their timing, resulting in a more natural gait (Lusardi & Nielsen, 2006).

Figure 2.6: Rheo by Ossur, Adaptive 2 by Endolite and C-Leg by Otto Bock microprocessor knee units (computerleg.com, 2008)

2.5 Prosthetic knees used in developing countries

The primary function of a prosthetic knee joint is to provide articulation, allow knee flexion in swing-phase, and to resist flexion during weight bearing. The technologically simplest and most widely used mechanism is a single-axis hinge joint (see Table 2.4). In such a system, resistance to knee flexion is provided to some extent by aligning the prosthesis so that the knee axis is posterior in respect to the weight-bearing line and by voluntary control of the residuum hip muscles. However, rough and uneven terrain increases stability demands for many individuals in developing countries, thus decreasing the effectiveness of this approach. To address this limitation, many prosthetic knees have been developed (Andrysek, 2010).

Name of technology (country of origin)	Brief description	Highest level of evidence*
ICRC knee (Switzerland)	Single-axis with manual lock	IF
ATLAS knee (UK)	Weight-activated friction	IF
POF/OTRC knee (US)	Single-axis with ext. assist	F
DAV/Seattle knee (US)	Compliant polycentric	F
LEGS M1 knee (US)	Four-bar	F
JaipurKnee (US)	Four-bar	F
LCKnee (Canada)	Single-axis with automatic lock	F
None provided (Nepal)	Single-axis	F
None provided (New Zealand)	Roto-moulded single-axis	F
None provided (India)	Six-bar with squatting	T
Friction knee (US)	Weight-activated friction	T
Wedgelock knee (Australia)	Weight-activated friction	T
SATHI friction knee (India)	Weight-activated friction	Limited data available

*T, Technical development; F, Fiedl testing; IF, Independent field testing.

Table 2.4: List of knee joint technologies based on the literature review (Andrysek, 2010).

2.5.1 International Committee of Red Cross

The ICRC knee is an alignment stabilised single-axis knee joint equipped with manual locks. It is offered in two sizes and three colors (Nury, 2006). Despite its simplicity, this design results in stiff-legged gait, which has been deemed an unacceptable long-term solution. This polypropylene modular below knee prosthetic system consists of an alignment device below the socket, an endoskeletal pylon, an

alignment device above the foot and is commonly connected to a rubber SACH foot. The prosthetic knee and alignment components are illustrated in Figure 2.6. All the plastic components are manufactured from injection-moulded polypropylene and are then assembled using either a screw and bolt assembly or mirror welding. The system is considered to be aesthetically pleasing and replaces a previous design based on components manufactured from local materials.

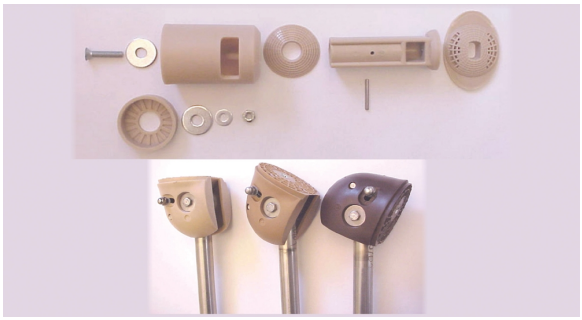


Figure 2.6: Components of a transfemoral ICRC prosthesis for an adult (ICRC, 2002)

Figure 2.7: ICRC transfemoral prosthetic system (ICRC, 2010)

2.5.2 The Atlas Knee

The Atlas knee is a weight-activated prosthetic knee developed to augment stability of the knee joint. Although it was claimed by the manufacturer that this prosthetic system would be highly functional and durable, research carried out on it has been relatively unsuccessful and demonstrated its unreliable function and high rates of structural failure (Jensen & Raab, 2003). Consequently, its production has been ceased.

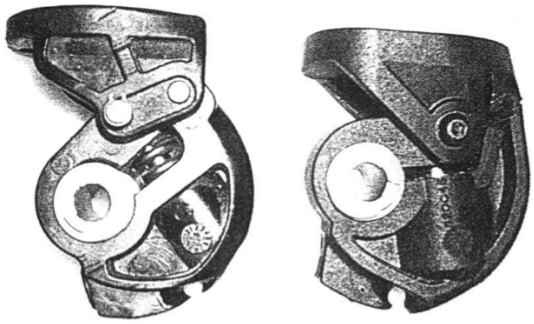


Figure 2.8: The Atlas knee by Blatchford & Sons Ltd (Jensen & Raab, 2003)

The ICRC manually locking and ATLAS weight-activated knees systems are also the only technologies to be evaluated as part of independent field trials in a developing country location. Based on those studies, the ATLAS knees were deemed to be unacceptable due to failures (defined as non-use and breakdowns) being reported in 83% of cases after only 7–10 months, compared to the ICRC knee, which had a more acceptable failure rate of 32% after 15 months. For the ATLAS system, in addition to excessive structural failure, unreliable function of the knee stabilising mechanism was a major problem. Whereas, the ICRC knee was relatively successful, likely due to the simplicity of the design (Andrysek, 2010).

However, the major drawback of the ATLAS knee, is related to the breaking mechanism and changes in coefficients of friction due, for example to exposure to humid or wet environments.

2.5.3 The LCKnee

The LCKnee (see Figure 2.9) is a prosthetic knee joint intended for individuals with a transfemoral amputation. It features a robust design for use in a variety of environments including water. The design is based on a novel stance-phase control mechanism that provides a high level of stability during weight bearing while preserving natural movements during gait. This results in high-level mobility function (Andrysek et al., 2011). Particularly, The LCKnee^{TM} utilises an inherent stance-phase control mechanism, named the 'automatic stance- phase lock' or ASPL. It consists of a knee lock that is automatically engaged as the knee becomes fully extended thus preventing the knee from bending. A combination of a hip flexion moment and loading of the forefoot unlocks the knee. This is a natural sequence of events that occurs at each step of walking and allows the knee to be stable as needed while facilitating natural swing-phase flexion.

The LCKnee has been testing now for 18 to 24 months in Chile and Myanmar, where it has been fitted to 15 young and active patients. The manufacturer states that no major problems have been reported so far. Also, no maintenance or repairs have been necessary. However, independent field testing is needed.

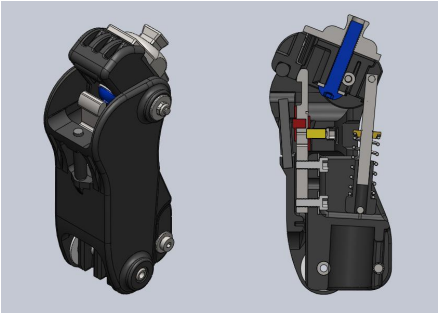


Figure 2.9: The LCknee (Andrysek, 2012).

2.5.4 LIMBS M1 Relief Knee

The LIMBS M1 Relief knee is a polycentric, low-cost engineered prosthetic knee with a weight-activated mechanism. As the patient transfers their weight over the extended knee, it will automatically lock for stability and safety. Also, it provides maximum biomechanical functionality and durability with minimum expense (limbsinternational.org, n.d.). To date, the manufacturer claims the M1 knee has passed all International Organization for Standardization (ISO) tests and is on track to be CE (European Conformity) certified. It has been tested in developing countries since 2004 and it is amazingly cheap, just $15 to $20 each and, although it is mass-produced in Bangladesh, it is designed for local manufacture and maintenance (Goodier, 2010). Roger V. Gonzalez in 2010 carried out principal static torsion and fatigue tests at the highest (P5) loading level held by ISO 10328 on the LEGS M1 knee. He reported that it successfully demonstrated compliance in all of these tests (Stanfield, 2010). Independent field trials are required.

Figure 2.9: The LIMBS M1 Relief Knee (Goodier, 2010)

2.5.5 The Jaipur Knee

The Jaipur Knee is a high-performance, polycentric, polymer-based, low-cost prosthetic knee joint. It consists of five plastic pieces and four fasteners, which give the knee a modular design that is simple to mass manufacture. Also, it is affordable (< $30) and reliable to use for at least 2 years. The Jaipur Knee is innovative in both its cost and its design. It consists of five self-lubricating plastic components, which help to reduce manufacturing costs. It is also a durable product that lasts 3-5 years with regular use. The device weighs only 700g and allows for 165 degrees of motion, which enables more natural movement. A major advantage of the Jaipur Knee is its compatibility with standard prosthetic leg systems, further reducing cost and considerably simplifying logistics. Among the almost 5,000 people who have been fitted with the Jaipur Knee, consumer reception has been excellent. Furthermore, 95% of patients reported no failures in their Jaipur Knees. These new knees are expected to improve patients' quality of life by making everyday tasks easier, and increase their potential to earn a living by enabling them to access a larger range of job opportunities (Fullerton, 2013).

Figure 2.10: The v1 ReMotion JaipurKnee (d-rev.org, n.d.).

2.5.6 The Otto Bock 3R20

The Otto Bock 3R20 is a modular knee joint made of stainless steel. The unit is stable from heel strike to mid-stance phase and it is intended to be used for patients of up to 100Kg. Because of its better material quality and its manufacture for developed countries, the cost of such a unit is greater than the other knee units listed above. However, when purchased in bulk, the cost of a single unit can be significantly reduced up to $50, making the 3R20 a competitive knee for use in developing countries.

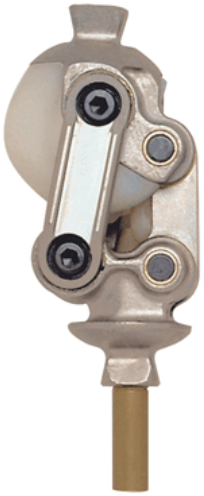


Figure 2.11: Otto Bock 3R20 knee unit (cascade-usa.com, 2010)

2.5.7 Summary

In summary, although the single-axis prosthetic knee joint with manual lock appears to be a proven technology for developing countries, a number of potentially more functional alternatives are at various stages of development and evaluation. The trend is toward the use of polymers for construction, and in the majority of cases, moulding to allow for the adoption of mass production to reduce costs. However, long-term independent field testing is needed to demonstrate the feasibility and appropriateness of these technologies.

2.6 Testing Conducted on Prosthetic Knee Systems designed for Developing Countries

2.6.1 International Committee of the Red Cross

Jensen and Heim (Jensen & Heim, 1999) and Jensen and Raab (Jensen & Raab, 2004) have conducted patient trials regarding the suitability and performance of the ICRC polypropylene system in developing countries.

Jensen and Heim selected 32 male transtibial amputees for an evaluation study and found that 23 of the 32 amputees had a preference for the PP prosthesis. The majority of the remaining amputees had a preference for an aluminium prosthesis with the others preferring the prosthetic system manufactured using the 'Automated Fabrication of Mobility Aides' technique developed by the Prosthetics Outreach Foundation. The main points which may be taken from Jensen and Heim's study are that many of the prosthesis providers in Vietnam are not interested in the repair of worn or damaged components, and that it is common for amputees to have difficult stumps as a result of improper surgery. However, the alignment of the prosthesis evaluated was considered to be satisfactory in the majority of cases as few gait deviations were observed and patient compliance was satisfying. Secondary to intensive use, amputees had a fear of the prosthesis becoming unusable as a result of damage to the foot. Jensen and Heim recommend that the foot should be treated as a separate issue that deserves particular attention given that it is the most limiting factor for an amputee who normally receives a new prosthesis every 3 years.

Jensen and Raab conducted a study to evaluate the use of two different transfemoral prosthetic systems, a conventional wood-resin design and an ICRC polypropylene design, in a developing country when implemented by teachers and their associates at an ISPO Category II recognised training establishment. In this study, 27 young amputees were fitted with the conventional design of prosthesis and 35 with the ICRC design.

Although patient satisfaction reported with both types of prostheses was high (92%) and so was the compliance (98%), relevant failures were encountered. Particularly,

despite the fact that no ICRC prosthetic knee required replacement, 20% of failure of stability of the knee joint was reported along with 20% of poor socket fit and 35% of additional problem due to the slackness of the fixation bolts for the knee axis. Further, the failure rate of the prosthetic foot was found to be 31% and misalignment was found in 35%, due in part to poor training and prosthetist error.

It was concluded that no significant differences were identified between the two models used in this study, and neither did the results differ from the previous publications. In addition, it was noted that there still is a need to improve the fixation and locking of the knee axis in the ICRC knee in order to reduce the requirements for repair.

Lastly, both prostheses provide clinically acceptable standard of prosthetic service provision.

2.6.2 The Blatchford Atlas System

Jensen and Raab (Jensen & Raab, 2003) conducted a clinical field test of the transtibial Atlas system in 2003 and found that due to the low heel height of the foot (0.5cm), dorsiflexion of the foot was a frequent observation. Most patients preferred the Atlas system to the older polypropylene or resin wood prostheses partly because of a higher comfort level with it during walking and running. This is due to the Atlas system having a less rigid shank and ankle system over the older designs. Although patient compliance was recorded at 84%, some patients did not use the Atlas system as a consequence of a noise present on walking. Others requested that the cosmetic cover be replaced with the normally used plastozote, brown PELite, cover. A high number of system related failures were recorded with 32% of these as a result of a fracture of the shank. It was considered that the noise was due to a lack of adherence with motion between the keel and foot plate and the heel padding and cushion. 22% of the feet had deteriorated after a period of between 5 and 31 months, and considering the shin and keel are moulded into the foot this is a serious and costly repair problem. Jensen and Raab concluded that under general use it has been identified that the Atlas system is prone to serious failures that endanger the safety of the user.

2.6.3 The Legs M1 Knee

Rispin et al. (Rispin et al., 2010) carried out a research to quantify functional characteristics of active transfemoral amputees using the LEGS knee compared to the most commonly available alternative, a prosthetic leg with a knee kept locked in gait (Locked). In this study, 19 transfemoral amputees from Kenya and Bangladesh who had worn the LEGS knee for a year or more were examined. Temporal and spatial gait data were collected along with energy cost data. From the statistical tests, it turned out that LEGS knee was perceived to have a higher ease of swing through, more normal looking gait, less energy cost, less effort, more ease sitting down and standing up, more noise, and less standing balance than Locked. Spatial gait parameters showed a narrower heel-to-heel base of support, and greater prosthetic step length for LEGS than Locked.
It was concluded that with an approximate cost of $20 a knee, the LEGS M1 knee provides an affordable and stable articulating knee option to prosthetic clinics in low-income nations.

Ayers and Gonzalez (Ayers & Gonzalez, 2010) conducted a review of the strategy used for dissemination of the M1 Knee technology to clinics in the developing world. He pointed out how important is the creation of an environment where technology is pulled into the marketplace by the end-users rather than pushed by a technology developer. Part of this strategy includes a 5 day in-service training programme for clinics seeking to implement the knee. It provides hands-on training in knee manufacture, fitting and rehabilitation issues specific to articulating polycentric knees. Programs involve 3 to 4 clinics from a local region with each attending clinic providing several key prosthetics personnel. It is also reported that feedback from attendees has been extremely positive.
The author concludes saying that by utilising an end-user “pull” strategy for both technology development and initial information diffusion, researchers have successfully provided users in the developing world with an improved prosthetic knee option.

2.6.4 The Otto Bock 3R20 Knee

Taheri and Karimi (Taheri & Karimi, 2012) recruited seven above-knee amputees who were asked to walk with a comfortable speed to investigate their gait function by means of 3D motion analysis. They reported a good performance and walking speed in the subjects. Boonstra et al. (Boonstra et al., 1996) studied the pattern of walking of the above-knee amputees wearing the 3R20 knee. However, all these studies were conducted in developed countries and hence, there is a lack of research about the use of the 3R20 in non-industrialised countries.

2.6.5 The LCKnee

Andrysek et al. (Andrysek et al., 2011) compare the LCKnee joint to both low-end and high-end prosthetic knee joints. The research, which involved 14 individuals with lower-limb amputations recruited from Canada and San Salvador, aimed to evaluate the performance of the stance phase control mechanism of the LCKnee. Participants were asked to conduct a minimum of three sessions. Results showed an average walking speed faster than conventional low-end knees but slower than conventional high-end knees. The authors concluded that the LCKnee could represent a functional and cost effective solution for active transfemoral amputees.

Chapter 3: Design Considerations

This chapter identifies appropriate design parameters to be used when considering the production of prosthetic knees. Such parameters are discussed in the next section. Although there are many specifications involved in the design process, engineers should take into account that a "well designed" prosthetic system for amputees in low-income countries is not necessarily the most expensive one and that an adequate design can sensibly reduce the costs of products or make them more durable and of better quality. Hence, devices would be "well designed" if they are appropriate to their market (Murray, 2005). Indeed, as a matter of fact, mass production can help to reduce the overall cost of a product along with the time required for production. The primary concern is therefore to develop and fabricate affordable prosthetic components for anyone who needs them by means of mass production (Nations, 1997).

3.1 Prosthetic Design Criteria for Developing Countries

There are many difficulties in the developing world that make the prosthetic market there unique. For this reason, many authors have tried to come up with the most appropriate factors to be considered for the design and development of prostheses in the Third World (Salmond, 2010).

Meanley (Meanley, 1995) considers that a high priority should be given to developing a prosthesis which is cost effective, durable, can be easily maintained by local craftsmen, is simple in design and suitable for local climatic, cultural and occupational need.

According to Jacobs (Jacobs, 2007), an appropriate technology is one which can provide a proper fit and alignment based on sound biomechanical principles which suit the needs of the individual, and can be sustained by the country at the most economical and affordable price In terms of materials, Jacobs recommends that the following criteria should be considered; cost, availability, adjustability, durability, cultural requirements, biocompatibility, worker safety, sustainability, climate and terrain, ease of repair and available equipment.

Chatel (Chatel, 1979) has noted that appropriate technology should correspond with the tastes and cultures of developing countries, to their needs, purchasing power and local materials.

According to Bigelow et al (Bigelow et al., 2004) the cosmetic appearance of a prosthetic limb is a primary concern for amputees in developing countries and that the local environmental conditions should have an influence on the design and materials used by prosthetic agencies.

Poonekar (Poonekar, 1992) identifies a list of dominant factors affecting prosthetics and orthotics in the developing world. He feels that a prosthetic/orthotic device to be appropriate for lower income countries must be: low cost, locally available, capable of manual fabrication, considerate of local climate and working conditions, durable, simple to repair, simple to process using local production capability, reproducible by local personnel, technically functional, biomechanically appropriate, as lightweight as possible, adequately cosmetic, psychosocially acceptable.

Layne Salmond (Salmond, 2010) stated that the most relevant issues facing prosthetic development in third world nations are the cost, availability, functionality, durability, and cleanliness of the prosthetics.

1. The prosthetic's cost is often the decisive factor when determining what prosthetics are available to amputees in developing nations. Indeed, they cannot afford advanced prosthetics such as those available in developed countries, and sometimes even those models locally manufactured. For example, Jivacate (Jivacate, 2002) stated that 60% of Thailand's population consists of rural farmers that earn U.S. $200 per family, per year. Walsh & Walsh asserted that the costs of prosthetics varied from U.S. $125 to U.S. $1875 (Walsh & Walsh, 2003). Hence, for people in Thailand, a prosthetic may cost several times the amount that they earn in a year, as a family unit. As illustrated by this example, high-tech prosthetic devices are often inaccessible for many patients living in low-income countries. Low-cost prosthetic devices are therefore vital for amputees in developing countries.

   However, the effective cost of prosthetics is not easy to determine due to the lack of consistency of material prices and labor costs across the world. The real cost is

defined by evaluating the general expense of obtaining the material to create the prosthetic, plus the cost that may be charged for the labor and training involved in manufacture. The ideal prosthetic is made from inexpensive materials and has a simple design. Considering the annual income of many amputees' families, an ideal prosthetic should cost less than U.S. $35, which is equivalent to about two month's pay (Salmond, 2010).

2. The availability of a prosthetic is also a major topic. Whilst on the one hand the supply of prosthetics to amputees is crucial, on the other hand it is also important that the amputee is able to repair and replace prosthetics when necessary. Vivian Cheng (Cheng, 2004) claims that "adults generally need their prosthetics replaced every 2 years and children need replacements every 6 months due to growth". Availability is a fundamental factor for those who must first gain access to a prosthetic device, then maintain it, and finally be able to replace it when it fractures. Two elements contribute to the availability criteria: the availability of the product and the accessibility of clinics.

One availability issue deals with the materials that form the prosthetic. In case the material of the prosthetic is not made locally or must be shipped to the location, then the material is either impossible to obtain or the price increases significantly due to shipping costs (Walsh & Walsh, 2003). However, developing nations often rely on materials that are inferior to those available in industrialised countries. While western countries like the U.S. use high-tech plastics, rubbers, alloys, foams, and other materials, developing countries frequently resort to basic materials such as bamboo, wood, plaster, basic plastics, rubber, and PVC pipe.

Another aspect of product availability relates to ease of manufacturing. If a prosthetic takes too long to be manufactured, then there might be difficulties to provide it to amputees who need them. In this regard, Mark Geil, during his visit in the Republic of Georgia, found that only three prosthetic clinics serve the whole population. Particularly, he discovered that each of these clinics could only produce seven prosthetics per week. As a result, there was a two and half years waiting list for prosthetics in Georgia for the 6,000 amputees in the country (Hainsworth, 2000). In conclusion, the ideal prosthetic would be widely accessible

because it would have a simple design that is easy to manufacture with available materials.

The second availability problem is the amputee's accessibility to clinics. It is often challenging for third-world citizens to travel great distances to prosthetic clinics for care. Jivacate reported that in Thailand amputees in rural areas often do not have the means to travel to government hospitals where they could receive free care (Jivacate, 2002). As a consequence, the government in Thailand has instituted mobile prosthetic units which can help 150–300 people in one week, but which require extensive planning and time to initiate. Tools available in prosthetic clinics highly affect their work capability. Clinics may even create their own tools, which can be elementary and difficult to work with, resulting in a slowdown of production. Sepp Heim (Heim, 2002) found that a simple model is more likely to prevail over an advanced model due to the more expensive training and tools required. To sum up, the availability of the tools and training that is required for a prosthetic has a large impact on the success of prosthetic distribution.
A high-rated prosthetic under availability also requires little training and inexpensive tools to manufacture. If a prosthetic can be produced easily, quickly, and with simple tools, it can be more available through the small clinics or mobile units, which are usually more accessible to impoverished amputees than the big-city clinics. It is hard to quantify accurately how many of each type of prosthetic is available in a particular country. Nevertheless, a prosthetic's availability may be determined by studying the availability of materials, complexity of the design, and whether the design requires specialised tools and training.

3. The integration of a simple and inexpensive prosthetic with the nation's culture and lifestyle is also a primary factor. This means that an ideal prosthetic has to be functional for working amputees and look as natural as possible. The culture and conditions of developing countries can be harsh for amputees. Berry noticed that they were often treated poorly and child amputees were often seen as a liability to the family. As a consequence, many families were obliged to abandon their children because they couldn't contribute to the family by working in fields or

factories, but still required food and care (Berry, 2005). It is therefore vital for a prosthetic to be functional in a rural setting so that amputees can continue to work. The weight, surface area, and flex of the prosthetic can really affect the person's ability to work for long periods of time.

Along with being functional, the prosthetic should also have aesthetics as human as possible so that the amputee is not treated as a lower class citizen. India addressed this issue with the creation of the Jaipur foot. Indeed, Indians do not like Western prosthetic designs as they prevent amputees to go barefoot, squat or sit cross-legged, which are important elements to life in India (Cheng, 2004). The Jaipur knee allows the user to squat, sit cross-legged, and walk barefoot on uneven terrain (Wittmann & Markowitz, 2010). This, in particular, is a key aspect to Indian amputees because those who could not do these things would stand out to others as different or incomplete.

4. Another important part to take into account is that a prosthesis has to endure rough environmental conditions and allow amputees to work. Unfortunately, many designs lack this durability. The SACH foot, a design widely used in westernised countries, is comfortable, but stiff, and is therefore appropriate for patients with low levels of activity. Such a design is inadequate for active rural lifestyle, and may limit the amputee's ability to support their family. Prosthetics meant for less active lifestyles are not the only ones to encounter durability issues. Sun and heat may indeed deform some plastics used in prosthetics (Salmond, 2010). These kinds of inefficiencies can make a difference in determining whether an amputee will be bed-ridden or able to work.

Thus, the durability of each design is difficult to quantify. However, prosthetics will be evaluated based on high-stamina design features and the characteristics of the raw materials.

5. Finally, cleanness and comfort must be present in a prosthetic design. The rough rural work, along with the humidity and lack of sanitation, can inevitably lead to infection of an amputee's residual limb. For example, wooden prosthetics and many kinds of filling are porous and can grow bacteria that cause infection and

ultimately lead to further injury to the amputee. Prosthetists in developing nations try to ensure that the patient's residual limb is protected. A ventilation system in the socket is used in Thailand to decrease the risk of fungal infection, which is a high risk in Thailand's humid and hot climate (Jivacate, 2002). This demonstrates that the cleanness and comfort of a prosthetic are primary elements when the aim is to protect the patient's limb and well-being.

In conclusion, high-rated prosthetics should contain no porosity and be easy to clean, and also provide form-fitting comfort for the residual limb.

3.2 The Contents of a Product Design Specification

3.2.1 *Design Brief*

To compare three knee joint currently being utilised in non-industrialised countries.

3.2.2 Performance

- The prosthetic knee is required to withstand a maximum user weight of 60Kg
- The prosthetic knee is required to withstand the vector and torsion forces as described in the ISO 10328 Standard

3.2.3 Environment

- The prosthetic knee should be resistant to UV degradation
- The prosthetic knee is required to be resistant to climate and storage changes as a result of transportation
- The prosthetic knee is required to be water resistant
- The prosthetic knee is required to be suitable for use under working conditions
- The prosthetic knee will be used in developing countries where the temperature can range from 10-45ºC

3.2.4 Life in Service

The prosthesis is required to withstand an operating time of nine hours per day for three years (based on the ISO fatigue tests).

3.2.5 Maintenance

It is desirable for the product to be maintenance free throughout its life span except for a recommended service after each year. Spare parts for the prosthetic knee should be available for 5 years after the initial fitting. The prosthetic knee should be easy to clean and require no special tooling for minor repairs. Any required maintenance work should be free of charge to the user.

3.2.6 Target Product Costs

Wherever possible, a small proportion of the total cost of the prosthetic knee should be paid by the end user in order to give some perception of its value. The cost of manufacture is required to be less than £15 per prosthesis. The costs for transportation and packaging should be no more than 15% of the manufacturing cost.

3.2.7 Competition

Although there are many other organisations providing the same type of product to the specified target market, they should not be approached as being competitors. It is a requirement that a relationship is established between the government, NGO's, technical and professional organisations, and end users in each developing country the prosthesis is to be made available to. Cooperation between groups working in the same regions is required to enable partnerships in bulk purchase of materials and off the shelf components, sharing facilities and the possible development of a common database.

3.2.8 Shipping

Depending on the manufacturing requirements, the prosthesis may be required to be transported by air, sea or road.

3.2.9 Packaging

Packaging costs should be minimal and any packaging used should be recycled and reusable.

3.2.10 Quantity

5,000 units should be produced in the first year and capacity should exist to increase production by 10% per year.

3.2.11 Manufacturing Processes

Capacity is required to meet market demand with the scope to increase production after 1 year. The manufacturing process is required to be easy to utilise, manage and be cost effective. Wherever possible, off the shelf components should be utilised.

3.2.12 Size and Weight Restrictions

- The overall weight of the prosthetic knee should not exceed 0.5kg
- The length of the prosthetic knee is required to be no more than 15cm.

3.2.13 Aesthetics

The prosthesis is required to be as life-like as possible; however, form can follow function.

3.2.14 Materials

The materials used are required to be recyclable, easy to store, readily available, durable, biocompatible, easy to process and of low cost.

3.2.15 Product Life Span

The prosthetic knee should be available for 10 years with spare parts available for a further 5 years after that.

3.2.16 Standards and Specifications

The prosthesis is required to be tested to ISO 10328 Standard.

3.2.17 Ergonomics

- The prosthetic knee should be easy to fit and remove
- A relevant rehabilitation period is required to familiarise the user with the prosthetic knee and ensure that a suitable fit has been achieved
- The prosthetic knee is required to provide a comfortable gait
- The overall shape of the prosthetic knee should be as close as possible to a real human knee joint

3.2.18 Customer Requirements

The customer requirements are that the prosthetic knee enables them to return to a normal, functional, working life, provide a comfortable gait and be durable enough to withstand the forces and loads imposed on it during its required life span.

3.2.19 Quality and Reliability

The quality of the prosthetic knee should be that no single component fails within a three years period. It is required that only 1 in 50 of the prosthetic knee should fail within the first year. Any failure within the first year should be easy to repair and not deem the prosthetic knee unfit for purpose.

3.2.20 Shelf Life

As the prosthetic knee may not be assembled and distributed in the same country as it was manufactured, the shelf life of each individual component is required to be at least three years.

3.2.21 Testing

Testing should be carried out on 5% of the prostheses produced and they should comply with the ISO 10328 Standard.

3.2.22 Safety

Any failure that may occur within the prosthetic knee should not instantaneously endanger the health of the user. Any failures that may lead to user injury should be easy to identify. Within the workshop there is a requirement for maximal safety of installation and machinery however, the ability to control work practises may be limited.

3.2.23 Legal

The possibility of litigation lies in the user suffering from an injury as a result of a major failure of the prosthetic knee within its expected life span.

3.2.24 Disposal

All parts should be recycled wherever possible.

3.3 Conceptual Design

The conceptual phase of the design core is primarily concerned with the generation of solutions to meet the stated need; in other words, it involves generating solutions to meet the PDS. During the conceptual phase, engineers are concerned with ideas and the generation of solutions. Particularly, this phase breaks down into two major components (Pugh, 1990):

1. The generation of solutions to meet the stated need.
2. The evaluation of these solutions to select the one that is most suited to matching the PDS.

In order to generate solutions we need our general knowledge base together with knowledge of technology and engineering. In addition to that, we also need to acquire information specific to the product area (the context) and then come up with as many ideas as possible (single solutions are usually not successful).
Once generated, solutions have to be evaluated. The purpose of any method of evaluation is to allow design principles to emerge visibly in a context and to be articulated (Pugh, 1990). Design evaluation's purpose is to check that the design solution is in accordance with the original design objectives. The PDS provides the criteria against which the design can be evaluated (Murray, 2005). Design evaluation is then used to eliminate those solutions, which do not satisfy the criteria and can also provide a means of deciding between different design solutions. Analytical evaluation of design solutions can be accomplished by establishing a list of criteria. (Murray, 2005). It is essential that the criteria chosen are unambiguous, understood and accepted by all, and written down for future reference (Pugh, 1990).
The next step is to choose a datum with which all other concepts are to be compared. For the purpose of this project, the ICRC knee was chosen as the datum since it is,

among the designs under evaluation, the most widely used prosthetic knee in developing countries.

In considering each concept/criteria against the chosen datum, the following legend should be used:

+ (plus): meaning better than, less than, less prone to, easier than, etc., relative to the datum.
- (minus): meaning worse than, more expensive than, more difficult to develop than, less aesthetic than, harder than, etc., relative to the datum.
- S (same): meaning same as datum.

Afterwards, using the nomenclature just outlined an initial comparison between the selected datum and all the other concepts has to be carried out. This establishes a score pattern in terms of the number of +'s, -'s and S's achieved relative to the datum. The scores or numbers must not, in any sense, be treated as absolute.

For the aim of this study, five different prosthetic knee designs for use in low income countries have been compared. These have been selected according to the designs discussed in the literature review. The data used to fill in the matrix for those designs that are still under evaluation (LIMBS M1 Knee, LCKnee and Jaipur Knee) are manufacturer's claims.
The matrix is shown is Table 3.1.

Concept / Criteria	ICRC	Ottobock 3R20	JAIPUR KNEE	LIMBS M1 KNEE	LCKNEE
	1	2	3	4	5
Cost	DATUM	-	S	+	-
Availability		-	-	-	-
Durability		+	-	+	S
Functionality		+	+	+	+
Reparability		S	S	S	S
Maintenance		S	S	S	S
Climate acceptability		+	S	S	+
Aesthetics		S	-	-	-
$\sum +$	/	3	1	3	2
$\sum -$	/	2	3	2	3
$\sum S$	/	3	4	3	3

Table 3.1: PDS matrix showing all the knee designs that have been compared to the datum.

From the matrix above, it can be noted that the strongest knee designs are the Ottobock 3R20 and the LIMBS M1 knee. However, the only commercially available

design other than the datum is the Ottobock 3R20, which already conforms to the ISO:10328 British standard.

3.4 Finite Element Analysis (FEA)

Finite Element Analysis, first developed in 1943 by R. Courant, consists of a computer model of a material or design that is stresses and analysed for specific results (Widas, 1997). FEA is usually performed to determine any points of weakness in a design before it is manufactured. The analysis is carried out by creating a grid called mesh made of a complex system of points known as nodes. These are allotted at a certain density throughout the material depending on the stress levels of a particular area. Regions that will receive large amounts of stress usually have a higher node density than those that experience little or no stress. While performing the analysis, the model is divided into a specific number of elements with a certain number of degrees of freedom (Morton, 2009).

3.4.1 Linear and Non-Linear Analysis

When using FEA, it is essential for engineers to choose between a linear analysis and a non-linear analysis. A linear analysis is recommended when the element under evaluation is expected to obey Hook's law. This involves that the element will return to its original configuration once the load is removed and also, that the relationship between stress and strain is proportional. Conversely, a non-linear FEA is used when the component is loaded beyond the elastic limits of the material of interest. The structure experiences a plastic deformation and hence, it will not return to its original configuration (samtec.com, 2007).

When the behaviour of the element is unknown, it is preferable to perform a linear analysis first. The subsequent comparison of Von Mises' stress level in structure and the yield strength of the selected material will then determine whether a non-linear analysis is required. In case that the Von Mises' stress level is higher than the yield

strength of the material, engineers may either run a non-linear analysis, or change the geometry of the component or look for a better material.

Given the lack of permanent deformation after testing the assembly and the almost linear relationship between stress and displacement recorded during testing, a linear static FEA was carried out during this project.

3.4.2 Cosmosworks

The assembly was analysed in Cosmosworks after testing to determine which areas and components were most subject to stress and deformation. Cosmosworks is a design analysis system fully integrated with SolidWorks (clear.rice.edu, 2004). The program can import solid models created in SolidWorks without any defects or changes in geometry. It was appropriate for this project as it is a fast finite element solver that can give an indication of the performance of a design modeled in Solidworks. Stress analysis is based on the Von Mises theory described below (Jong & Springer, 2009):

$$\frac{1}{\sqrt{2}}\left[\left(\sigma_{xx} - \sigma_{yy}\right)^2 + \left(\sigma_{yy} - \sigma_{zz}\right)^2 + \left(\sigma_{zz} - \sigma_{xx}\right)^2 + 6\left(\tau_{xy}^2 + \tau_{yz}^2 + \tau_{zx}^2\right)\right]^{\frac{1}{2}} \geq \sigma_y$$

where: $\sigma_{xx}, \sigma_{yy}, \sigma_{zz}$ *represent the stress with respect to principal axes*

$\tau_{xy}^2, \tau_{yz}^2, \tau_{zx}^2$ *represent the stress with respect to non-principal axes*

The left hand side of the above equation is denoted as Von Mises stress, whereas the right hand side is the yield strength for ductile material (σ_y). Thus, as a failure criterion, engineers can check whether Von Mises stress induced in the material exceeds yield strength of the material.

The steps involved in running any type of analysis in Cosmosworks are (clear.rice.edu 2004):

- Define the model dimensions
- Define the study type and related options
- Define material properties
- Specify loads and boundary conditions
- Mesh the model
- Run the study
- Analyse the results

Cosmosworks has been used to evaluate the performance of the assembly's components. The mesh size for the assembly was chosen such that the features of the model required minimal adjustments and the processing times were reduced.

Chapter 4: Materials and Methodology

In order to achieve the objectives of this study, a prosthetic prototype was created. This was accomplished by using the original components of the selected knee design (ICRC knee) along with two metal plates, which were custom-made for the project. This chapter will detail the procedure that was followed in order to obtain results that were further analysed to complete the study.

4.1 Structural Testing of Prosthetic Knee

Structural mechanical testing of the prosthetic knees is necessary to ensure that they have the structural integrity, durability and safety required for amputee use (Neo, Lee & Goh, 2000). There are a set of regulations which describe the required static and cyclic tests a prosthetic knee component should conform to before being deemed suitable for patient use: the ISO 10328 Standard. For this project, due to the lack of time, static tests only have been carried out.

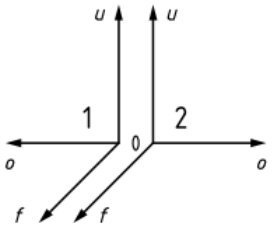
4.1.1 ISO 10328

The International Test Standard, ISO 10328, has been used as the basis for the testing. This standard describes the testing procedure for lower limb prosthetic devices. Also, it dictates the proper coordinate system to use while testing, as well as the required forces and loading locations. The purpose of this standard is to ensure that all prosthetic devices are properly tested and will perform to a certain level of excellence before being utilised by patients; therefore, our coordinate system, forces, and force locations have all been derived from the specified values in the standards.

4.1.2 Coordinate System

The ISO Test Standard 10328 specifies the coordinate system that should be used for testing. It illustrates the directions of axes for testing prostheses (see Figure 4.1). It

must be noted that this system only applies in relation to a prosthesis, which is standing on the ground in an upright position (ISO, 2006).



Key

1	right	*f*	forward
2	left	*o*	outward
0	origin	*u*	upward

Figure 4.1: ISO 10328 coordinate systems for right (1) and left-sided (2) application (ISO, 2006)

For the aim of this project, we used a left-sided prosthetic knee, and therefore the coordinate system 2.
According to the *o-u-f* coordinate system:

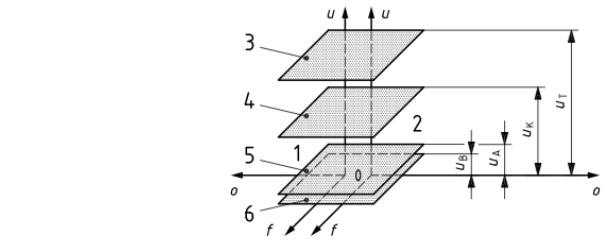
- The *u-axis* extends from the origin 0 of the coordinate system and passes through the effective ankle-joint centre and the effective knee-joint. Its positive direction is upwards (in the proximal direction).
- The *o-axis* extends from the origin 0 perpendicular to the *u-axis* and parallel to the effective knee-joint centerline. Its positive direction is outward (in the lateral direction), which is to the left for a left prosthesis and to the right for a right prosthesis.
- The *f-axis* extends from the origin 0 perpendicular to both the *o-axis* and the *u-axis*. Its positive direction is forward towards the toe (in the anterior direction).

This coordinate system is used to dictate the process for locating the effective knee and ankle joint centres. The effective knee joint centre was coincident with the joint flexion axis since the testing ICRC knee is a monocentric knee (see ISO 10328 6.7.5.1); the effective ankle joint centre was calculated as explained in 4.1.4.

4.1.3 Reference Planes

The ISO 10328 standard refers to three different reference planes. These planes lie parallel to each other and perpendicular to the *u-axis* (see Figure 4.2).

The reference planes are used to identify the line of action along which the load is applied (see Figure 4.3).



Key

1	right	4	knee reference plane, K
2	left	5	ankle reference plane, A
3	top reference plane, T	6	bottom reference plane, B

Figure 4.2: Coordinate systems according to Figure 4.1 (ISO, 2006)

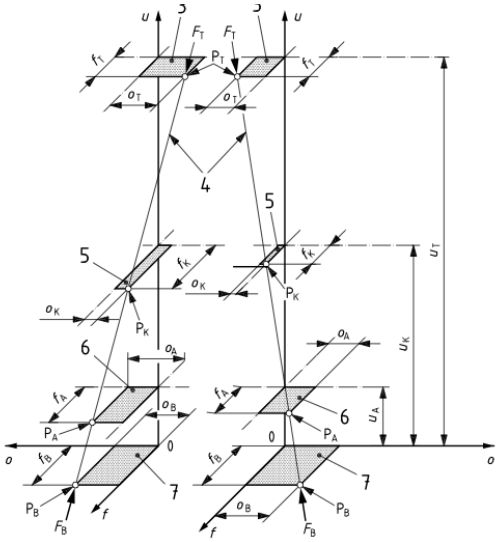


Figure 4.3: Specific configuration with $u_B = 0$ showing coordinate systems with reference planes, reference lines, reference points and test force, F, for right and left-sided application. 1: right leg. 2: left leg. 3: top reference plane, T; 4: load line; 5: knee reference plane, K; 6: ankle reference plane, A; 7: bottom reference plane, B; P_T: top load application point; P_K: knee load reference point; P_A: ankle load reference point; P_B bottom load application point (ISO, 2006)

4.1.4 Total Length and Alignment

1. The ISO 10328 requires the testing sample's total length to stick with some requirements (see Table 5 of ISO 10328:2006). However, in case the test sample is a prosthetic structure, the segmental length $u_T - u_K$ is too short and needs to be increased as required by increasing the total length $u_T - u_B$ (see footnote *b* in Appendix A). In this case the standard values of the offsets f_T and o_T specified in Table 6 of the ISO need to be adapted. With respect to this study, the combination of segmental lengths is as follows:

   - $u_T - u_K$ = 153mm
   - $u_K - u_A$ = 420mm
   - $u_A - u_B$ = 80mm

The test sample was prepared and aligned using the required offsets for the P3 load level II condition. The ISO Standard defines offsets as " the perpendicular distances of the reference points P_A, P_B, P_K and P_T specified in Figure 4.3 from the *o-u* plane and the *u-f* plane of the coordinate systems specified in Figure 4.1" (ISO, 2006).

2. The adapted values of offsets for the lever arms at P3 load level II are shown in Table 4.1.

Reference plane	Offset	
	Direction and location	Numerical value (mm)
		Test loading level P3 II
Top	f_T	50.9
	o_T	-49.2
Knee	f_K	68
	o_K	-43

Ankle	f_A	115
	o_A	-26
Bottom	f_B	124
	o_B	-23

Table 4.1: Required offsets for the P3 load level II condition

The new values of the offsets f_T and o_T were calculated by means of the following formulae (see Figure 12 of ISO 10328):

$$f_{T=} f_K + \left\{\frac{(f_K - f_A)(u_T - u_K)}{(u_K - u_A)}\right\}$$

$$o_{T=} o_K + \left\{\frac{(o_K - o_A)(u_T - u_K)}{(u_K - u_A)}\right\}$$

The offsest values in Table 4.1 provide the following angular offsets:

- Proximal lever arm: $\tan\alpha = \frac{49.2}{50.9}$

$$\alpha = 44°$$

- Knee lever arm: $\tan\beta = \frac{43}{68}$

$$\beta = 32.3°$$

- Ankle lever arm: $\tan\gamma = \frac{26}{115}$

$$\gamma = 12.7°$$

- Distal lever arm: $\tan\delta = \frac{23}{124}$

$$\delta = 10.5°$$

Figure 4.4 illustrates graphically how the angular offsets were calculated. Top view is shown.

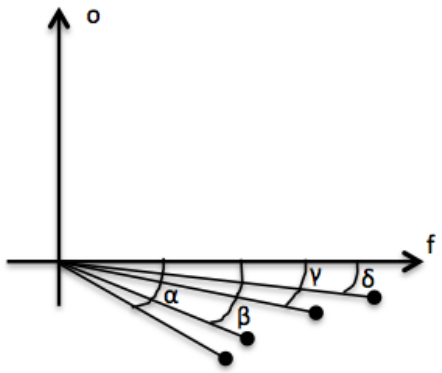


Figure 4.4: Angular offsets.

These values were utilised to offset the four reference planes

3. A distal lever arm was used to replace the foot component. According to the ISO Standard, the required size for this component should be such that it allows the application of the load in accordance with the combined bottom offset S_B. S_B is calculated using the equation $S_B = \sqrt{{f_B}^2 + {o_B}^2}$. Using the values in Table 4.1, S_B = 126.1mm. The effective ankle joint centre is calculated as being a quarter of the overall length of the foot, this is shown in Figure 4.5. The distal metal plate was made with an overall length of 205mm. This means that the effective ankle joint centreline lies at 51.25mm from the most posterior part of the foot (0.25L). It is considered that the ankle joint lies along the centre axis of the shank in the ML and AP planes. The shank has therefore been connected to the extension plate such that its centreline is coincident with that of the *u-axis*.

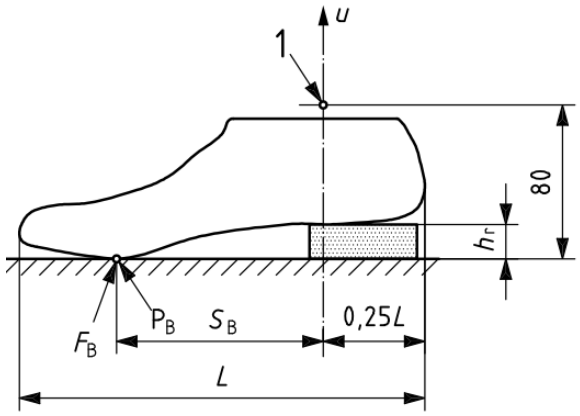


Figure 4.5: Determination of the effective ankle-joint centre for test loading conditions I and II and of combined bottom offset S_B for test loading condition II (ISO, 2006)

4. Along with S_B, the ISO Standard also requires other three combined offsets to be respected. In particular, for P3 load level II condition we have:

   - S_T (combined top offset): 71mm
   - S_K (combined knee offset): 81mm
   - S_A (combined ankle offset): 118mm

   The ISO Standard indicates that in case the total length of the assembly exceeds the value specified in Table 5 of the same document, the combined offset S_T needs to be adapted using the formula $S_T = \sqrt{{f_T}^2 + {o_T}^2}$ (see footnote b in Appendix C). Considering the accuracy tolerance of ± 1mm for linear dimensions defined in chapter 14.3 of the ISO Standard and a value of adapted combined offsets identical to the specified one, it can be stated that all the combine offset values were respected when assembling the prototype.
   The ISO 10328 Standard defines combined offsets as "the perpendicular distances of the reference points P_A, P_B, P_K and P_T from the *u-axis* of the coordinate system specified in 4.1.2" (ISO, 2006). A schematic illustration of how the combined offsets values were used is shown in Figure 4.6.

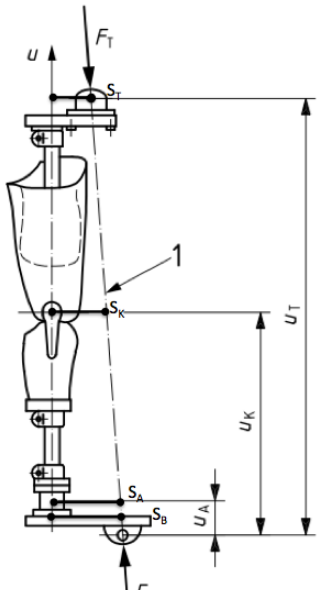


Figure 4.6: Illustration of test loading principle applied to the assembly. The inclination of the load line (1) is obtained by using the combined offsets (S_T, S_K, S_A, S_B) (ISO, 2006)

4.1.5 Fabrication process

The ICRC knee and seven of the original components of the ICRC design were taken from the National Centre for Prosthetics and Orthotics. They were then assembled together as indicated in the Manufacturing Guidelines of the ICRC (ICRC, 2006). Apart from the prosthetic knee, which consists of polypropylene and metal parts, all the other components were purely made of polypropylene (see Figure 4.7). Namely, the following components were utilised:

1. Conical cup Transfemoral adult: D85 x L128mm
2. Convex disc: D80 x L14mm
3. Concave cylinder with T-nut M10: D25mm
4. Convex ankle
5. Coiled spring expansion pin: D5 x L45mm
6. Countersunk head bolt, full thread: M10 x 50mm
7. Flat washer – steel: D54 x d15 x H3mm

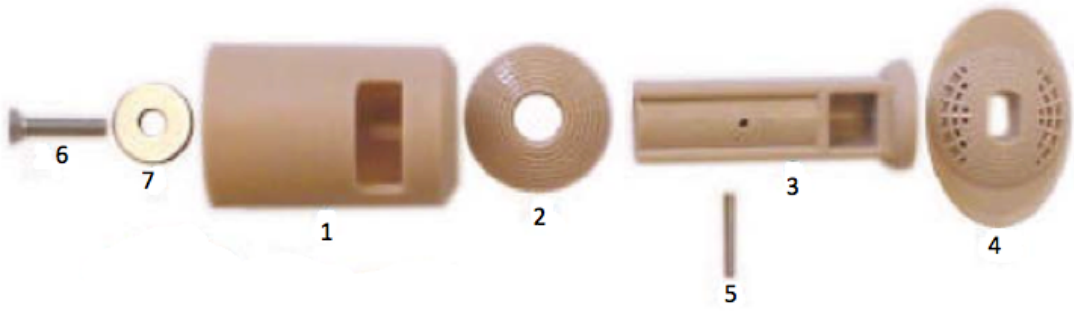


Figure 4.7: ICRC design components used to create the testing prototype.

Next, two metal platens made of mild steel (see Figure 4.8) were attached to the assembly by means of the original ICRC screws (M10x50mm).

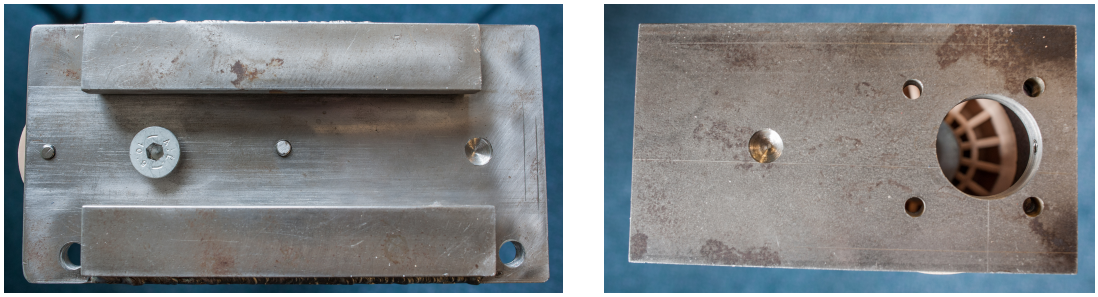


Figure 4.8: The lower metal platen (left side) and the upper metal platen (right side).

The ISO Test Standard 10328 was consulted to ensure that the testing procedure complied with the guidelines set forth for lower limb prostheses. The coordinate system, load location, and force load components were all extracted from the standards and applied to the model.

The conical cup, the convex disc and the prosthetic knee were then welded together by means of a polypropylene rod in order to reduce any relative movement between these components during the testing. The same was made for the concave cylinder and the convex ankle (see Figure 4.9).

Additional screws were also added to firmly attach the two plates with the polypropylene components but also the shank with the concave cylinder.

All these procedures were conducted at the National Centre for Prosthetics and Orthotics and at the Department of Biomedical Engineering of the University of Strathclyde.

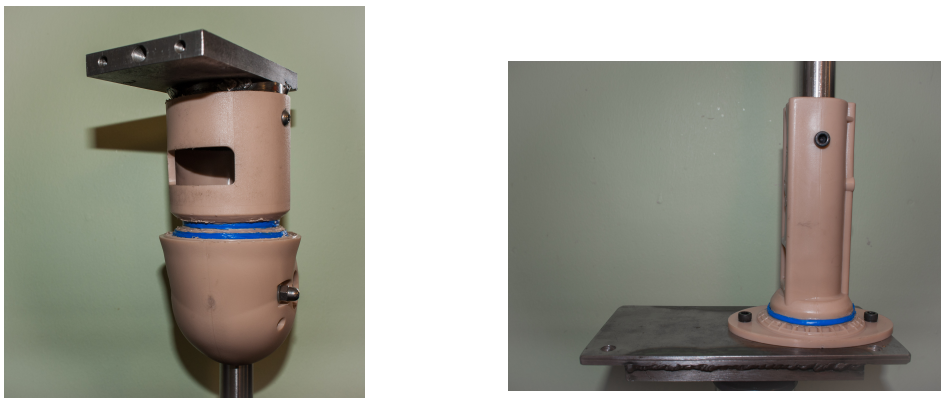


Figure 4.9: The upper (left) and the lower (right) sections of the assembly. The blue parts are the polypropylene rods used to weld the components together.

The final assembly is shown below.

Figure 4.10: The whole assembly fully extended in the sagittal plane (on the left), fully extended in the coronal plane (in the centre) and fully flexed in the coronal plane

4.2 Mounting

1. A custom-made component was fabricated and attached to the load cell of the Instron machine in place of the original grip (see Figure 4.11). This was due to the impossibility for the assembly to be fitted into the machine with the original grip.

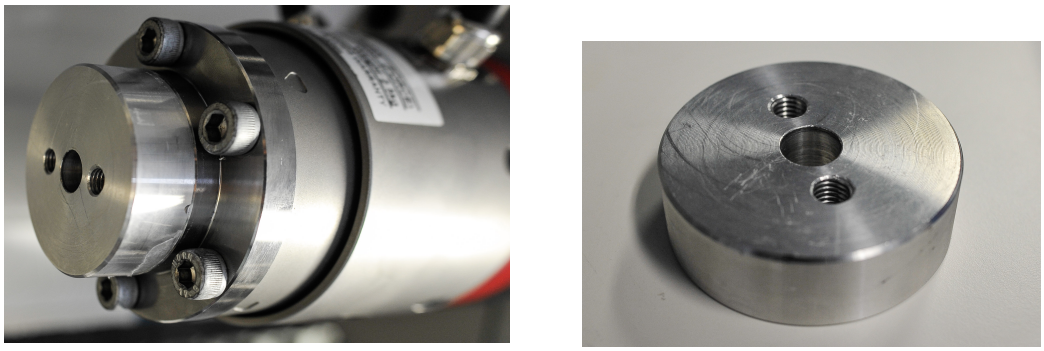


Figure 4.11: Custom-made grip used to attach the assembly directly to the load

2. The test sample was mounted in the test equipment (see Figure 4.12 and 4.13).

Figure 4.12: The assembly mounted in the Instron machine

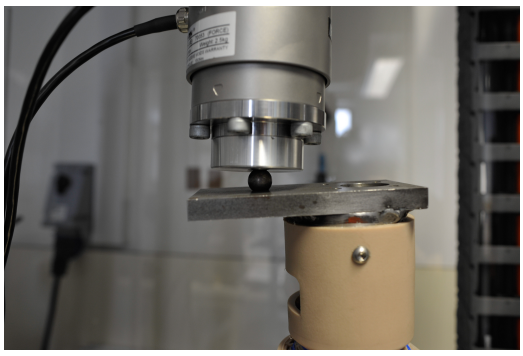


Figure 4.13: The upper ball bearing

4.3 Testing Levels

In the ISO Test Standard 10328, there are four testing levels, which can be applied to the test setup and procedure of adult lower limb prostheses. These levels are P3, P4, P5, and P6. However, as it is stated in the ISO, "Field experience has shown that there is no need for lower limb prostheses which sustains loads above the level covered by the test loading level P5" (ISO 10328 7.2.3, note 1). The average male height in third world countries is 167.6 cm (see Table 4.2), whereas the average male mass is 64.65 Kg. Therefore, the lowest loading condition, P3, was determined to be the most appropriate level for the testing in this study. The loading values associated with this level have been applied to the models to be tested.

Region	male height (cm)	female height (cm)	male mass (kg)	female mass (kg)
Argentina	172.6	160.7	68.52	59.40
Bahrain	165.1	154.7	62.69	55.04
Brazil	168.99	158	65.68	57.42
China (PRC)	164.8	154.5	62.47	54.90
Côte d'Ivoire	170.11	159.11	66.56	58.23
Ghana	169.46	158.53	66.05	57.80
Gambia	168	157.8	64.92	57.27
India	161.2	152.1	59.77	53.21
Indonesia	158	147	57.42	49.70
Iraq	165.4	155.8	62.92	55.83
Israel	175.6	162.7	70.92	60.88
Korea, South	173.6	161.1	69.32	59.69
Malawi	166	155	63.38	55.26
Mexico - State of Morelos	167	155	64.14	55.26
Philippines	163.5	151.8	61.48	53.00
Singapore	172	160	68.04	58.88
South Africa	169	159	65.69	58.15
Taiwan	172.04	159.68	68.07	58.64
Vietnam	162.1	152.16	60.44	53.25

Table 4.2: Average height and mass of a sample population in developing countries (Morton, 2009)

4.4 Type of Testing

The complexity of the load actions to which limb prostheses are actually subjected during use by the amputee cannot be simulated by a single test procedure (Morton, 2009).

Particularly, the types of testing deemed as most appropriate for this analysis are

called the static proof test and the ultimate strength test. The former is defined as a "static load representing an occasional severe event, which can be sustained by the prosthetic device/structure and still allow it to function as intended" (see ISO 10328 3.1); the latter is defined as a "static load representing a gross single event, which can be sustained by the prosthetic device/structure but which could render it thereafter unusable" (see ISO 10328 3.2) (Richardson, 2008). Both test procedures have been extracted from the ISO Test Standard 10328 and detailed throughout this report.

Each test loading condition is characterised by a specific test load acting along or about a specific line of load application and producing axial compression, shear forces, bending moments and/or torque as single components of loading or compound loadings.

The ISO 10328 comprehends two different test loading conditions (I, II) of principal structural tests relating to the maxima occurring at different instants during stance phase of normal walking. Only the test loading condition II was applied during the testing. It corresponds to the instant of maximum loading occurring late in the stance phase of walking (ISO, 2006).

4.5 Test Procedure

The static proof test and the ultimate strength test were both performed using the Instron compressive machine ElectroPuls^{TM} E10000 (see Figure 4.14). It is an all-electric test instrument designed for dynamic and static testing on a wide range of materials and components (instron.co.uk, 2014).

Figure 4.14: The Instron ElectroPuls^{TM} E10000 machine (instron.co.uk, 2014).

The machine's features are:

- Oil-Free linear motor technology for clean conditions
- Designed for both dynamic and static testing on a variety of materials and components
- High dynamic performance, capable of performing up to 100 Hz
- Up to ±10 kN dynamic load capacity and ±7 kN static capacity
- Electrically powered from single phase main supply, no need for hydraulic or pneumatic air supplies
- Temperature-controlled air-cooling system
- High-stiffness, precision-aligned twin column load frame with actuator in upper crosshead
- Versatile T-slot table for regular and irregular grips and specimens
- Compact instrument - frame requires less than 0.8 m^2 (8.6 ft^2) of floor space

The static proof test consisted in the following steps:

1. A settling test force of F_{set} = 638N was applied at a rate of 100N/s and maintained for a period of 20s. The force was removed and the sample was allowed to rest for 15 min.

2. The stabilising force of F_{stab} = 50N was applied and maintained for 2min to allow the following measurements to be taken:
    - Lengths L_a and L_k: perpendicular distances from the load line to the effective joint centre
    - Length L_{bt} (L4): distance between P_b and P_t

3. The test force was increased smoothly to the proof test force F_{sp} = 1395N at a rate of 100N/s and maintained for 30s.

4. The test force was decreased to the stabilising force of F_{stab} = 50N and maintained until the following measurements were completed:

- Lengths L_a and L_k: perpendicular distances from the load line to the effective joint centre
- Length L_{bt} (L5): distance between P_b and P_t

This was completed in 20 min.

5. The permanent deformation D3 = L4-L5 between the bottom and top application points was calculated and recorded.
- If the permanent deformation D3 was over 5mm the test sample had failed.
- If the sample complied with the standard, the failure test proceeded.

The ultimate strength test consisted in the following steps:

1. A settling test force of F_{set} = 638N was applied at a rate of 100N/s and maintained for a period of 20s. The force was removed and the sample was allowed to rest for 15 min.

2. The stabilising force of F_{stab} = 50N was applied and maintained for 2min to allow the following measurement to be taken:

   • Ankle and knee offsets (f_A, f_K, o_A, o_K): perpendicular distances of the reference points (P_K, P_A) from the *o-u* plane and the *u-f* plane of the coordinate system specified in 4.1.2

3. The test force F was increased smoothly at a rate of 100N/s until the test sample failed or sustained the ultimate test force $F_{su,\ upper}$ = 2790N. The maximum value the test force F reached was recorded.

   - The test sample satisfied the requirements of the test if ductile failure occurred at a load exceeding this value.

   - If failure occurred, the specimen was inspected to detect the mode of

failure and the results were recorded in the test report.

4.6 FEA

The assembly used for testing was created in Solidworks. Considering that the conical cup and the knee will be welded together along with the upper arm with the metal cylinder and the bottom concave cylinder with the convex ankle, a static linear study was performed using these criteria.

In order to determine the distribution of stress and strain during the testing, a FEA was carried out under the P3 load level II condition. For the purpose of this analysis, the assembly has been assumed as linearly elastic, isotropic and homogeneous. The tables below show the materials properties used for the analysis.

Polypropylene Copolymer		
Properties	Value	Units
Elastic Modulus in X	896	N/mm^2
Mass Density	890	Kg/m^3
Tensile Strength in X	27.6	N/mm^2
Poisson's Ratio in XY	0.4103	N/A

Table 4.3: Polypropylene copolymer material properties

1020 Mild Steel		
Properties	Value	Units
Elastic Modulus in X	200000	N/mm^2
Mass Density	7900	Kg/m^3
Tensile Strength in X	420	N/mm^2
Poisson's Ratio in XY	0.29	N/A

Table 4.4: 1020 mild steel material properties

316 Stainless Steel		
Properties	Value	Units
Elastic Modulus in X	2000000	N/mm^2
Mass Density	8027	Kg/m^3
Tensile Strength in X	485	N/mm^2
Poisson's Ratio in XY	0.265	N/A

Table 4.5: 316 stainless steel material properties

A new study was performed for each value of load (1395N, 2390N). A solid mesh was created for each study using an element size of 4mm and a tolerance of 0.3mm, and resulted in 349,460 nodes and 242,902 elements (see Figure 4.15).

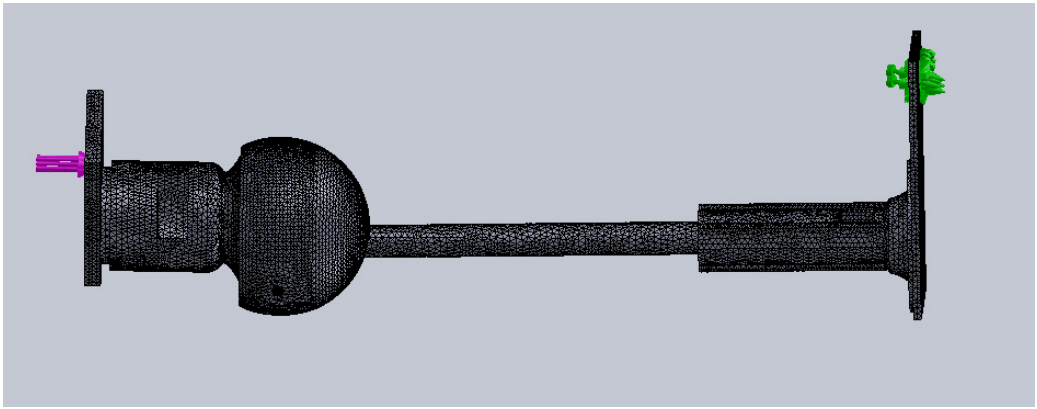


Figure 4.15: Mesh adopted to perform the static analysis.

Once the study was defined, the appropriate constraints and loads were applied. The contact between components was set to global and bonded with no provision of sliding and to represent welds between the components. In the first study, a load of 1395N was applied to the ball bearing of the upper arm while a fix constraint was applied to the groove of the lower arm. Once COSMOSWorks finished running the test, the results were plotted to examine the Von Mises stresses, strain and

displacement that occurred during the application of the load. They were reported in the form of contour plots, which were displayed through colors corresponding to different stress and displacement levels. The color scale of the contour plots was then adjusted to ensure that the same values corresponded with the same stress and displacement values throughout all of the models. This was done to provide consistency throughout the testing and analyses of this study.

The Von Mises stress failure criteria was applied by comparing the Von Mises stresses for the model with the yield strength of the polypropylene and metal materials respectively. The Von Mises theory is considered to be the most accurate for ductile materials (Norton, 2006).
In particular , the following formula was utilised:

$$\frac{\sigma_{Von\ Mises}}{\sigma_{Limit}} < 1$$

According to this criterion, those areas with a Von Mises stress values ($\sigma_{Von\ Mises}$) below the limit stress (σ_{Limit}) were considered to have successfully withstood the loading conditions for the ISO:10328 Test Standard. Those areas whose Von Mises stress values were above the yield strength were considered to fail the test and consequently to provoke a fracture in the material.

An useful feature of COSMOSWorks that has been used to better illustrate the overall Von Mises stress was the Factor of Safety, which allows to select a specified value and then to plot regions of the model with a factor of safety smaller than that in order to identify weak areas of the design. Essentially, a factor of safety larger than 1 at a location, indicates that the material at that location is safe. Specifically, the yield strength value of polypropylene and 1020 mild steel was applied as σ_{Limit} in order to show up the areas with a ratio greater than 1 and present them in red. Stainless steel components were ignored because of an optimal overall stress distribution.

ISO Clipping was another feature frequently used to isolate only those areas with a stress, strain or factor of safety value greater than a specified value. This allows a

better understanding of where the assembly is experiencing either stresses or strain that exceed the limits.
The probe tool was sometimes used to have a more accurate value.

Next, displacement was also examined to investigate the flexibility and the deformation caused by the bending loads on the assembly.

Finally, strain was taken into account in order to determine those areas most vulnerable to deformation during testing.

Chapter 5: Results

5.1 Set-up

All static tests were performed in an Instron ElectroPuls™, model E10000. The software programme, Wavemaker, recorded the time, load and displacement data, which was then exported analysed in Excel.

5.2 Preliminary Tests Results

Two identical tests were conducted before the static proof test and the static ultimate strength test in order to allow for any temperature or creep effects to stabilise.
The assembly was mounted on ball bearings to the Instron machine and held in position under the application of 50N load. Load-time graphs and Load-displacement graphs of these two studies are shown in the figures below.

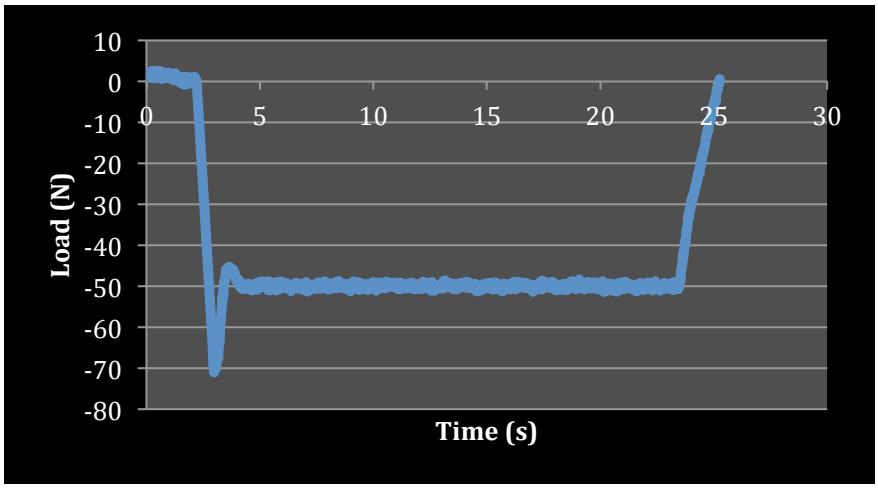


Figure 5.1: Load versus Time for the first preliminary test

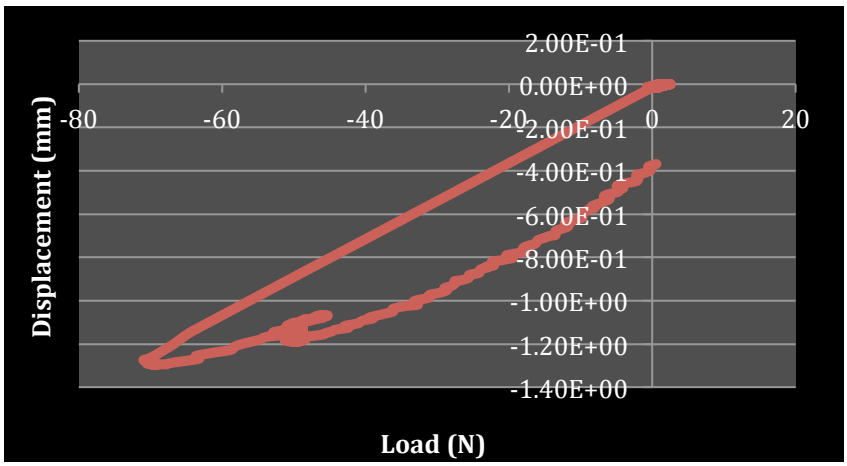


Figure 5.2:Displacement versus Load for the first preliminary test

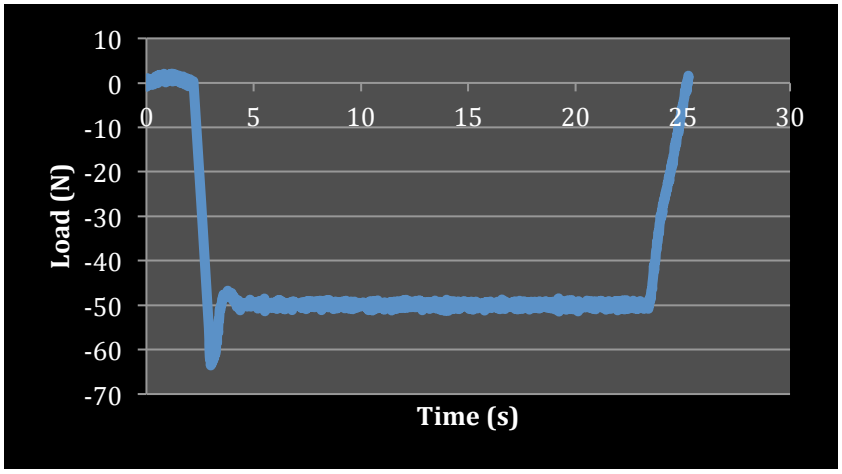


Figure 5.3: Load versus Time for the second preliminary test

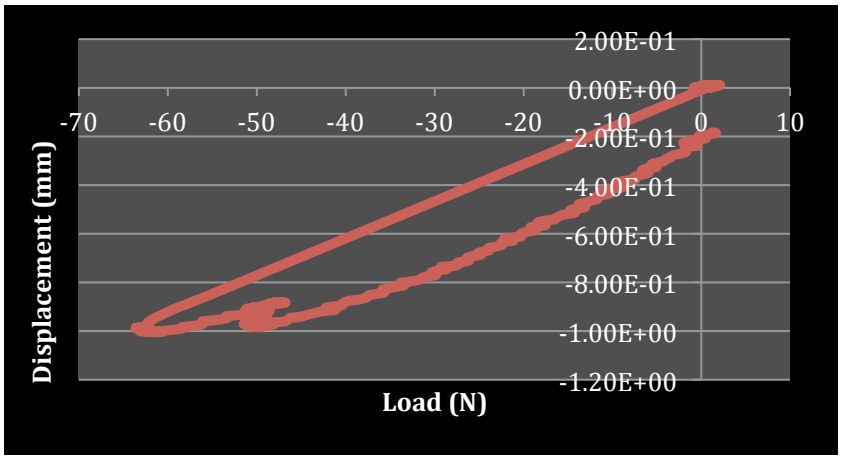


Figure 5.4: Displacement versus Load for the second preliminary test

5.3 Static Proof Test Results

The static proof test was carried out on the assembly at the P3 load level II condition. The assembly was loaded at 100N/s to the static proof test force F_{sp} = 1395N. However, because of the 15min resting time, the Instron was programmed to load the test sample in two different steps. It was initially loaded to a settling 638N test force and then at rate of 100N/s to the static proof test force of 1395N.
Graphs recorded by Wavemaker during testing are shown in the figures underneath.

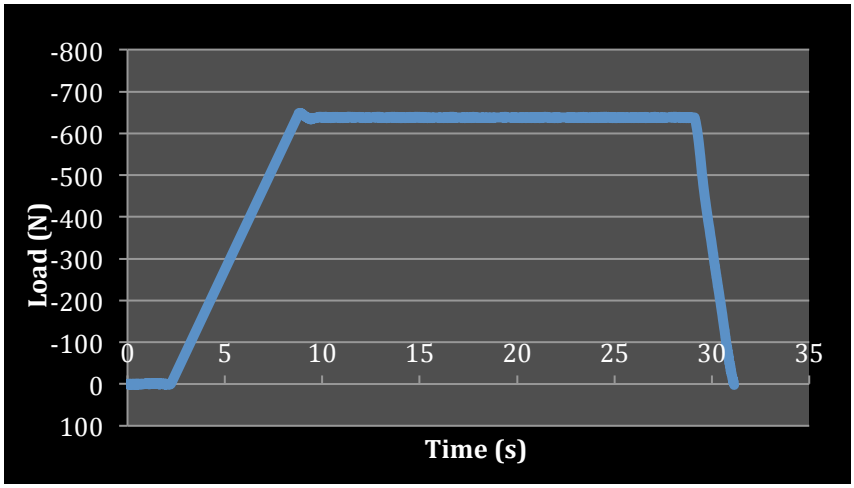


Figure 5.5: Load versus Time for the first step of static proof test

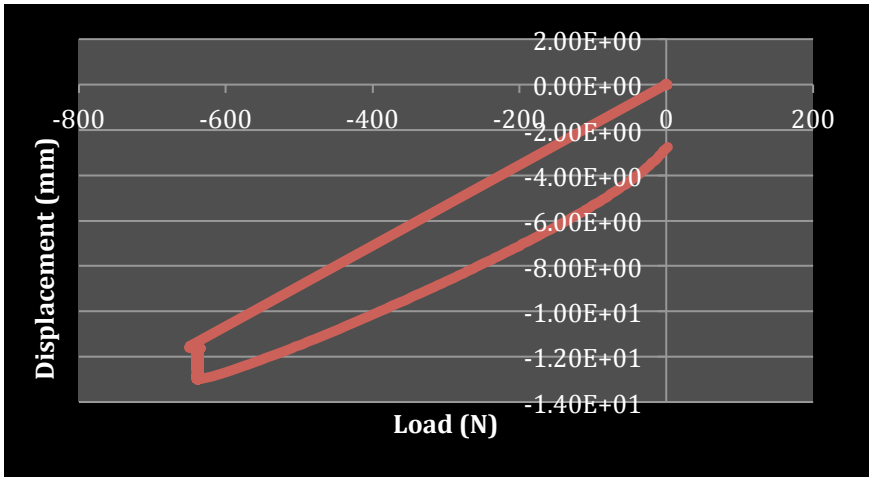


Figure 5.6: Displacement versus Load for the first step of static proof test

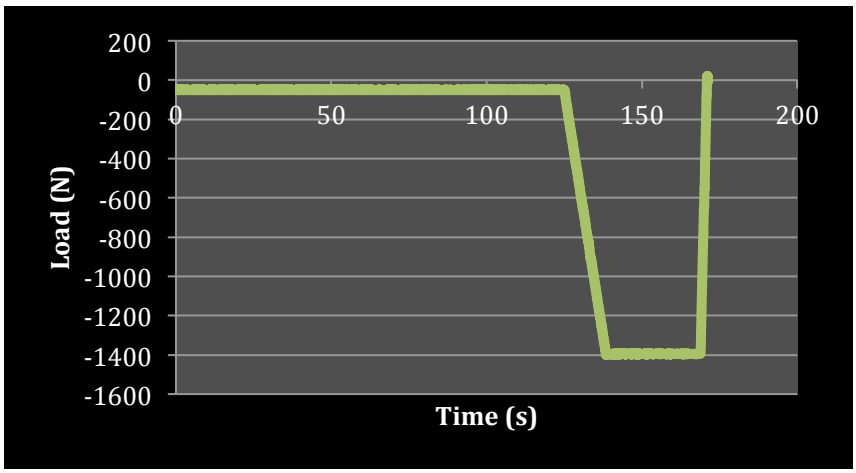


Figure 5.7: Load versus Time for the second step of static proof test

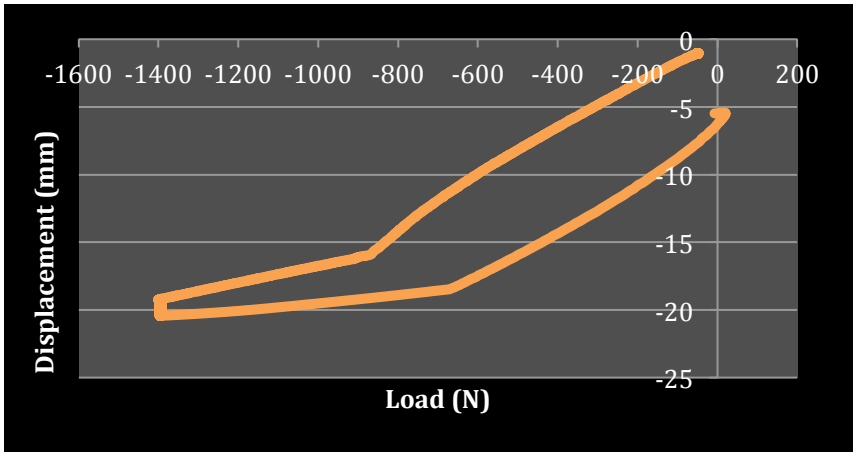


Figure 5.8: Displacement versus Load in the second step of static proof test

From Figure 5.8 it is noticeable that during testing the test sample experienced a maximum flexion of 20.6 mm under a load of 1395N. Also, when the load is removed from the test sample, a deformation of 5mm was still present. However, within the 5min period devoted to measurements at the end of the test, the total length was 651mm that is 2mm less than the initial length.

5.4 Static Ultimate Strength Test Results

The static ultimate strength test was carried out on the assembly at the P3 load level II condition.

The assembly was loaded at 100N/s to the ultimate test force $F_{su,\ upper\ level}$ = 2790N.

However, because of the 15min resting time, the Instron machine was programmed to load the test sample in two different steps: from 0N to 638N; from 0N to 2790N. During loading a crack was heard and the test was subsequently stopped. This occurred at 2390N. Inspection of a video recording of the test showed that the weld between the conical cup and the convex disc loosened, resulting in a significant deformation. Also, a breach in correspondence of the screw connecting those two components with the prosthetic knee was noted.

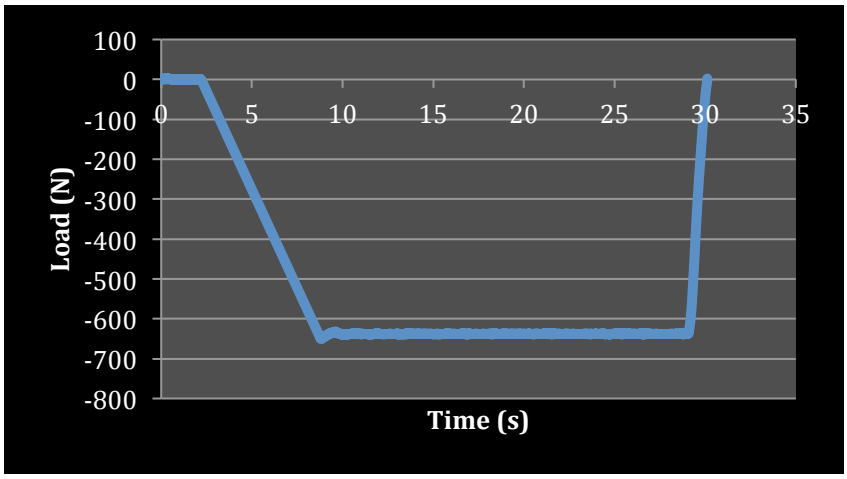


Figure 5.9: Load versus Time in the first step of ultimate strength test

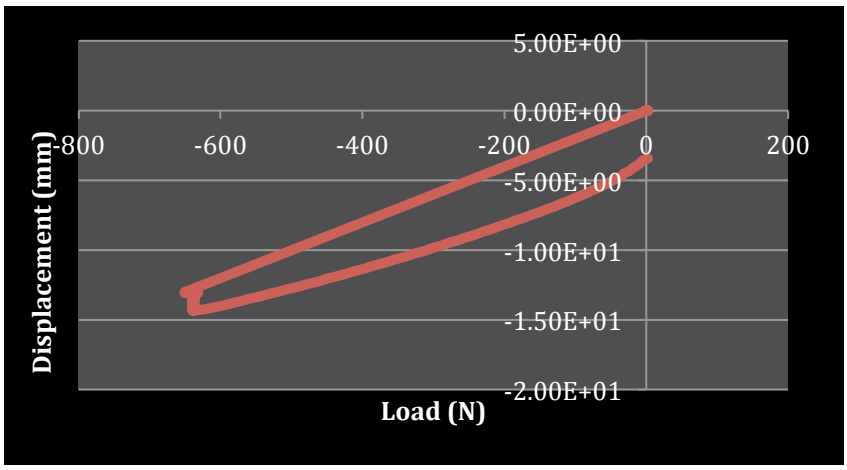


Figure 5.10: Load versus Displacement in the first step of ultimate strength test

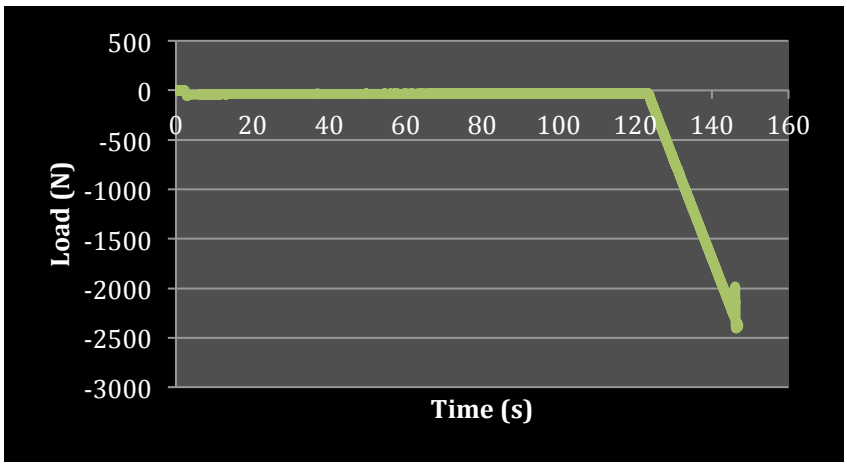


Figure 5.11: Load versus Time in the second step of ultimate strength test

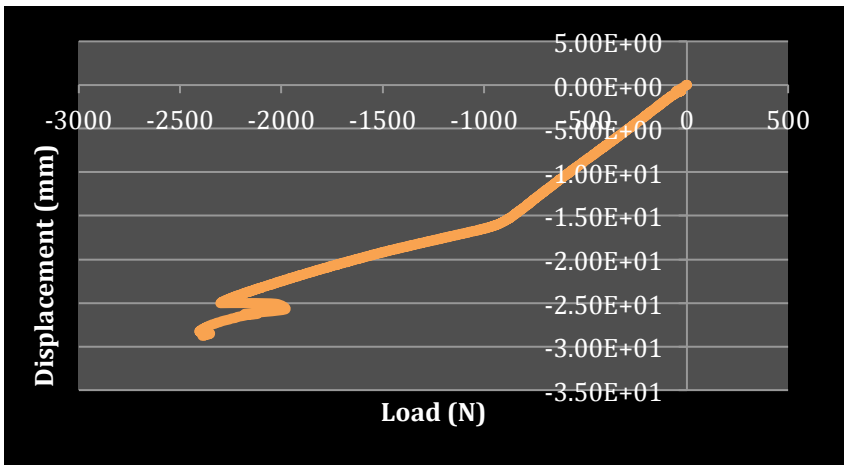


Figure 5.12: Load versus Displacement in the second step of ultimate strength test

5.5 Post-testing Results

Five days after the test, the length of the assembly was of 653mm which the same length as we had before testing. This means that, despite the great deformation observed during testing, this was not permanent. In this regard, it can be noted that there exist an almost linear relationship between stress and displacement. This confirms that the assembly obeys Hook's Law.

5.6 FEA

The results of the finite element analysis performed in COSMOSWorks were analysed using contour plots. These images have been included showing the lateral view of the assembly; this was chosen as the most appropriate to display the results.

5.6.1 Static Proof Test

The results from the static proof test are presented in this section. The maximum Von Mises stress was 406.4MPa and it was concentrated in correspondence of the contact surface between the ball bearing and the groove in the lower arm. This phenomenon is known as Hertz contact stresses and it implies that when the two curved bodies pressed together have different radii of curvature along the co-ordinate axes, the pressure acting over the contact region has an elliptical distribution and the initial contact occurs at a single point or along a line (Dwyer-Joyce, 1997). This is shown in Figure 5.13. For ball bearing in particular, this is true when the load is applied radially. Figure 5.14 illustrates the contact between two curved bodies. In case of a ball bearing, the contact between the sphere and the spherical groove can be seen as the contact between a sphere (the ball bearing) and another sphere with a negative radius (the spherical groove) (The University of Utah, 2004).

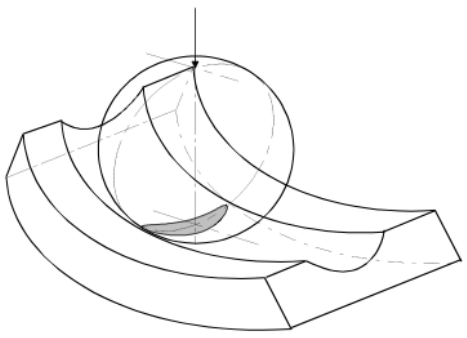


Figure 5.13: Sketch of the contact between the ball and the outer raceway in a ball bearing (Dwyer-Joyce, 1997).

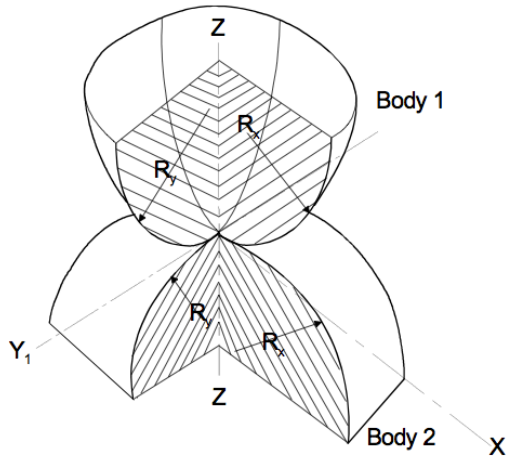


Figure 5.14: Contact between curved bodies of different radii along the x and y axes (Dwyer-Joyce, 1997).

The Von Mises stress distribution is shown in Figure 5.15. By means of the ISO clipping feature of COSMOSWorks, it can be noted that the stress value in all the polypropylene components was lower than the tensile strength of the material (27.6MPa) and in the metal parts the maximum stress value was below the tensile strength of both mild steel (420MPa) and stainless steel (485MPa) respectively. This is shown in Figure 5.16.

A factor of safety study was conducted to determine which areas have a value lower than 1 (see Figure 5.18). Because of the lack of sufficient information about polypropylene copolymer in Solidworks, the plastic parts of the model are not visible in the plot (see Figure 5.17).

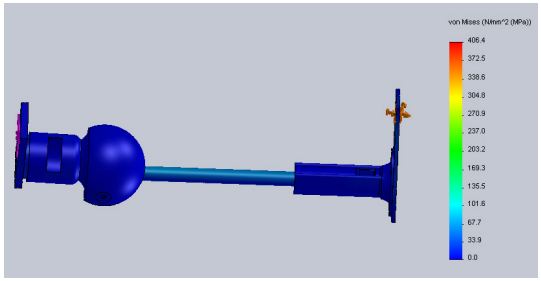


Figure 5.15: Von Mises stress distribution for static proof test

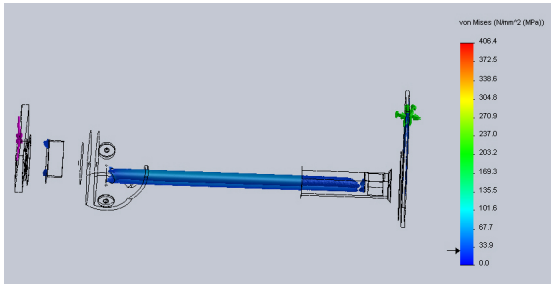


Figure 5.16: ISO clipping at 27MPa for static proof test

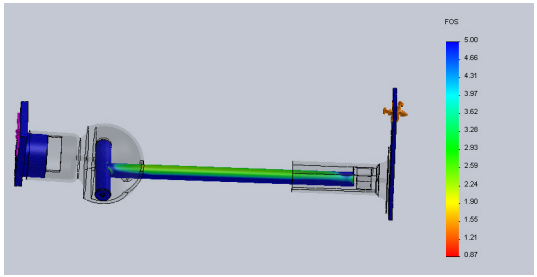


Figure 5.17: Factor of safety distribution for the static proof test

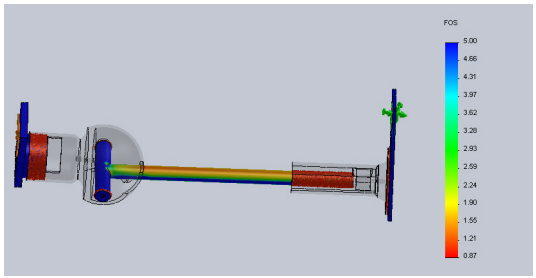


Figure 5.18: ISO clipping at 1 FOS for the static proof test. In red are depicted those areas where polypropylene was in contact with metal

The strain plot is shown in Figure 5.19. It is noticeable that the areas most subject to deformation during testing are the concave cylinder and the opening in the conical cup.

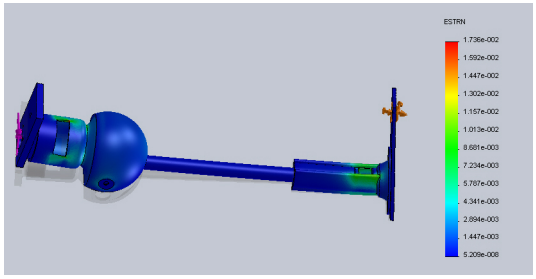


Figure 5.19: Strain distribution for static proof test

5.6.2 Ultimate Strength Test

Using the same set-up as above, a linear static ultimate strength test was created. The 1395N load was changed to 2390N and the same mesh quality was created. The results are shown below. The maximum Von Mises stress is 782.2MPa and it was recorded in correspondence of the spherical groove in the lower arm. The Hertz contact stress theory explains this event. Figure 5.21 shows the contour plot of the ISO clipping with 27.6MPa. It can be noted that those areas in the polypropylene components with a stress value higher than the one specified are minimal and located at the bottom corners of the opening in the conical cup. The ISO clipping performed with a value of 420MPa (see Figure 5.22) showed that a Von Mises stress value higher than that was recorded only at the spherical groove of the lower arm. Indeed, the analysis of the factor of safety displays a value grater than 1 in the whole lower arm except for the area around the groove (see Figure 5.23).

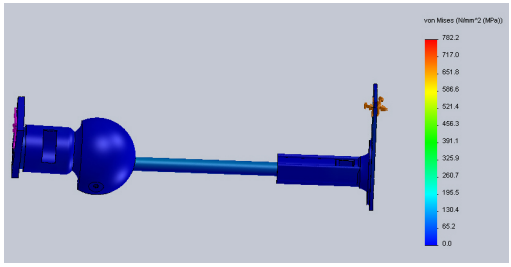


Figure 5.20: Von Mises stress distribution for ultimate strength test

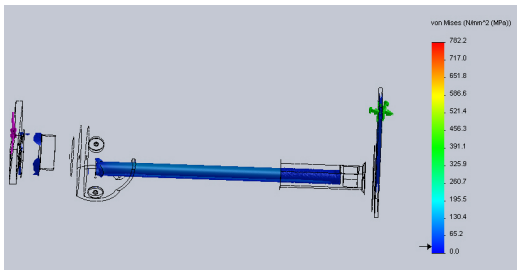


Figure 5.21: ISO clipping at 27MPa for ultimate strength test

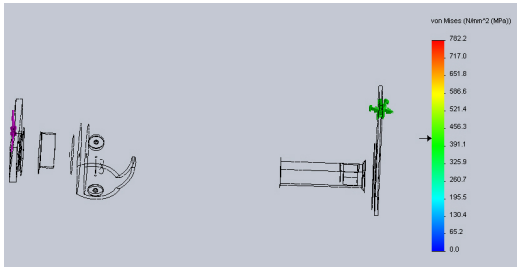


Figure 5.22: ISO clipping at 420MPa for ultimate strength test

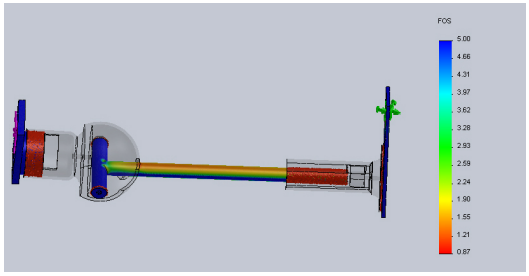


Figure 5.23: ISO clipping at 1 FOS for the ultimate strength test. In red are depicted those areas where polypropylene was in contact with metal

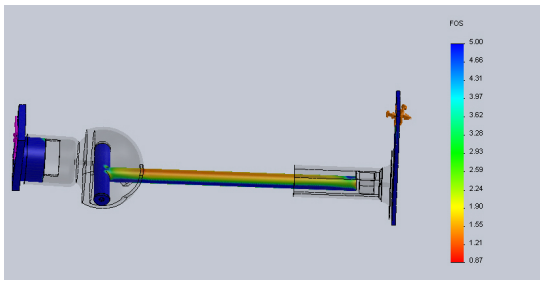


Figure 5.24: Factor of safety distribution for the ultimate strength test.

From the strain plot in Figure 5.25, we can notice how the areas most subject to deformation are the concave cylinder and the opening in the conical cup.

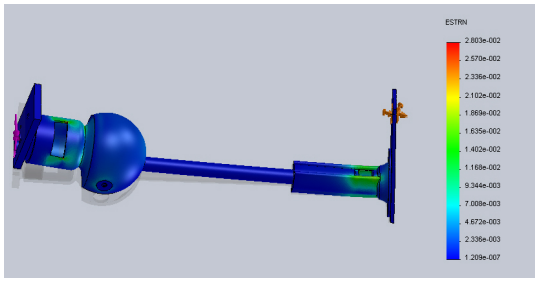


Figure 5.25: Strain distribution for ultimate strength test

Chapter 6: Discussion

The results from the testing procedure indicate that the sample of ICRC prosthetic knee used for testing conforms to the ISO 10328:2006 static loading Standard despite the following issues experienced during the ultimate strength test:

- A maximum deformation of 28.77mm.
- The presence of a crack in the knee.
- The separation of the weld between the conical cup and the convex disc.

In this regard, the ISO 10328 Standard states that in order for a test sample to pass the static ultimate strength test, it shall sustain either the upper ($F_{su,\ upper\ level}$) or the lower ($F_{su,\ lower\ level}$) load level. For the purpose of this project, $F_{su,\ lower\ level}$ = 2092N. As the three issues listed above occurred at 2390N, it can be asserted that the assembly successfully passed all the static tests without loss of its structural integrity. However, it must be noted that according to the ISO 10328 Standard, a minimum number of two tests for each type of testing are required to fully claim compliance with the International Standard. Although both static tests were successfully passed, they were carried out only once due to time constraints of the project.

The accuracy criteria of procedure specified in chapter 14.3 of the ISO states that there is a tolerance of $\pm$2mm for segmental lengths and of $\pm 1°$ for angular dimensions except for the angular position of the prosthetic feet, which shall be set with a tolerance of $\pm 3°$. The alignment and measurement procedure followed in this study was conducted within these criteria.

When investigating stress distribution, it is noticeable that the areas with a stress level higher than the yield strength value of the respective material are minimal and they did no affect in any way the integrity of the assembly while being tested.
The analysis of strain distribution revealed that the conical cup and the concave cylinder were the most vulnerable parts of the model and therefore, the most subjected to deformation.

A factor of safety greater than 1 was reported for the entire model except for extremely small areas in correspondence of the contact surface between the ball bearing and the spherical groove on the distal surface of the lower arm. This can be attributed to Hertzian contact stresses. In fact, the Hertzian theory relates, to some extent, to contact stress of circular surfaces. Particularly, according to this approach, ball bearings are common examples of elliptical point contact between a sphere with appositive radius and a spherical groove with a negative radius (Dwyer-Joyce, 1997). In conclusion, the FEA indicates that the assembly complies with the ISO Standard and therefore that there is a high probability that this conformity will be maintained also for further tests of additional ICRC knees.

6.1 The Need

Worldwide, the number of amputees in third world countries is increasing every year. Due to the increasing rate of amputations, there is an ever-growing demand for prosthetic limbs (lowcostprosthesis.com, 2012). For amputees in low-income countries, modern prosthetics are prohibitively expensive, typically costing thousands of dollars or more. Further, even if amputees are able to pay, most likely they do not have access to a prosthetics clinic that fits their needs (d-rev.org, n.d.). In his literary review about lower limb prosthetic technologies in the developing world, Andrysek illustrates all the different prosthetic knee designs currently available on the market for use in low-income countries (Andrysek, 2010). He reports that, even though the ICRC knee have many advantages, such as availability, low cost and reparability, there remain shortcomings to deal with, namely cosmetic appearance, functionality and mobility. Particularly, the prosthetic knee design used for this project is a single-axis knee joint, which can buckle on rough terrain leading to a sudden and unsafe loss of balance (d-rev.org, n.d.). Besides, he underlines the fact the ICRC and the Atlas knees are the only prosthetic technologies that have been evaluated so far as part of independent field trials in a developing country (Andrysek, 2010). Lastly, as a matter of fact, the ICRC knee was the only knee for use in developing countries that was commercially available on the market and that had not been tested yet to ISO Standard. Hence, the main focus of this project has been on

the testing of such a knee.

6.2 Polypropylene

Polypropylene is considered the most suitable material for the manufacture of prosthetics (Morton, 2009). It is currently used throughout the developing world. In particular, the ICRC decided to use it because it is: relatively cheap, long-lasting, easy to store, easy to process, versatile, recyclable. At a global level, in the early 2000s polypropylene production and demand were dominated by low-income countries. An ever-growing population, improved lifestyle and rapid industrialisation have resulted in the substantial growth of polypropylene demand in the developing markets of the Asia-Pacific region. Three of the major polypropylene producers in the world are from China and a similar growth pattern has been observed in the Indian polypropylene market. Geographically, the demand for polypropylene increased exponentially between 2000 and 2011 in the Middle East and Africa region. North America was the only region where polypropylene demand registered a net decline. The global polypropylene market is expected to grow at a compound annual growth rate (CAGR) of 6.3% between 2013 and 2019 (Publication, 2014).

Further, the properties of polypropylene make it suitable for use in tropical climates (Morton, 2009). Although it is UV-sensitive, certain additives can make it more resistant and co-polymerisation with polyethylene can make it more flexible (ICRC, 2007). In addition, as reported by Heim (Heim, 1996), the possibility of recycling polypropylene allows waste material to be reprocessed, thus further reducing overall costs. Verhoeff et al. (Verhoeff et al., 1999) also reported polypropylene relative durability for transtibial prostheses.
Finally, polypropylene is not a volatile compound and hence, it can be transported by plane without any problems. On the contrary, resin, which is usually employed to fabricate prosthetic sockets, is an unstable compound and it is likely to cure in the storage container when transported to hot environments.

6.3 Static Tests

6.3.1 Static Proof Test

Prior to the test, two preliminary tests were conducted with a load value equal to 50N maintained for 25s. The reason for this was to give the assembly a "warming up" period to allow for any temperature or creep effects to stabilise.

The test sample successfully managed to sustain the static loading at the prescribed value for 30s and the value of permanent deformation (D_3) did not exceed 5mm. Average maximum deformations of 12.52mm in the first step and of 20.06 mm in the second step were recorded during the test. No fracture occurred during testing.

The load-displacement graphs in Figure 5.6 and Figure5.8, exhibit a large amount of linearity, suggesting that the material under analysis is obeying Hooke's law.

In view of these considerations, it can be stated that the test sample satisfied all the requirements to pass the principal static proof test (see ISO 16.2.1.2).

The results from the FEA show that the entire model is expected to withstand the load without failing. This is evident from the factor of safety analysis, from which it is inferable that the components are fit for purpose.

Also, from the strain graph in Figure 5.19, it is clear that the conical cup and the concave cylinder are the components most subjected to deformation. In particular, significant levels of strain have been observed in correspondence of the opening in both the conical cup and the concave cylinder.

The Von Mises stress analysis revealed that the maximum stress value occurred at the contact surface between the ball bearing and the groove in the lower arm. This can be ascribed to the Hertzian contact stress theory, according to which in case of contact between a sphere and a spherical groove, the highest levels of stress occur either at a single point or along a line. In this case, this phenomenon happened at the edge of the groove hosting the ball bearing, where a stress value of 406.4MPa was observed.

Regarding the polypropylene components, no stress value above 27.6MPa was observed and hence, failure of any parts is not expected.

As all the parts of the assembly experienced a stress level lower than the material's yield strength value and therefore, the model is expected not to fail.

6.3.2 Ultimate Strength Test

Average maximum deformations of 13.89mm in the first step and of 28.77mm in the second step were recorded during the test. A crack was heard when the assembly was subject to a load of 2390N and a deformation was clearly noticeable. For this reason, the test was manually ceased. After inspection, the crack was found to be occurred in correspondence of the screw connecting the conical cup with the knee and the separation of the weld between the conical cup and the convex disc was also reported. Despite this, the load-displacement graph shown in Figure 5.12, presents a behavior almost linear before the occurrence of the crack.
Although the test sample did not reach the upper ultimate strength value, the test was considered to be passed as it managed to withstand an ultimate test force value greater than $F_{su,\ lower\ level}$ = 2092N (see ISO 10328 16.2.2.2 for details).

The results from the FEA analysis reveal the presence of minimal areas in the assembly with a maximum Von Mises stress higher than the yield strength of the respective material. In particular, the ISO clipping performed with a value of 27.6MPa (see Figure 5.21) shows that the posterior bottom right corner in the opening of the conical cup experienced a stress level greater than the one specified. With the help of the probe tool, it turned out that only an extremely small area in that corner effectively sustained a stress value equal to 31.4MPa. However, since the area is minimal, no failure is expected to occur in the component.
As in the static proof test, high levels of stress were observed in the inner part of the lower spherical groove that was in contact with the ball bearing. In particular, a maximum stress of 782.2MPa was measured. This value is almost double the yield strength of mild steel. However, the probe tool revealed that the area that experienced such a high level of stress was small and hence, it can be considered negligible. The Hertzian stress theory is considered appropriate to explain this phenomenon.

Chapter 7: Conclusion and Recommendations

7.1 Conclusion

This project aimed to test the ICRC prosthetic knee to see whether it conforms to the ISO 10328:2006 British Standard. An assembly was made by following the specifications in the ISO Standard and the methodology adapted for the testing complied with the one stated in the same document.
The results from both the static testing and the FEA reveal that the sample of ICRC knee tested in this study successfully conforms to the ISO static loading Standard as it maintained its structural integrity in both the static tests. However, full compliance of the ICRC knee cannot be claimed as the two tests were performed only once. Indeed, to claim compliance with the ISO Standard, each test has to be performed at least twice. Despite this, the FEA study performed suggests that the ICRC prosthetic knee is likely to pass future tests as no failure is expected to occur.

The presence of a crack and the separation of the conical cup from the convex disc during the ultimate strength test were not relevant for the passing of the test since they occurred beyond $F_{su,\ lower\ level}$. Considering this, it is the author's opinion that the aims of this project have been met. However, it is relevant to take into consideration that cyclic strength tests were neglected in this project. These represent an essential part in order to determine whether the ICRC knee can sustain a cyclic load for a given number of cycles.

The following conclusions can be made:

- It is considered that the test sample of ICRC prosthetic knee used in this study had passed the ISO 10328 static proof test.

- It is considered that the test sample of ICRC prosthetic knee used in this study had passed the ISO 10328 static ultimate strength test.

- It is considered that the ICRC prosthetic knee design is appropriate for use in low-income countries

7.2 Limitations

Both the static proof test and the ultimate strength test were performed once. The International Standard for prosthetics requires the accomplishment of a minimum of two tests for each type of testing. Although this represents a major limitation of this study, future testing are highly expected to comply with the Standard, as indicated by the FEA.

Despite the passing of both tests, in the ultimate strength test a crack occurred along with the rupture of the weld between the conical cup and the convex disc. This can be ascribed to either a manufacturing issue or to the age of the knee component itself or to a bad weld. In fact, the knee used for testing was not a brand new sample and it might have been subject to wear.

Further, fatigue tests were not performed due to the lack of time.

7.3 Recommendations for Future Work

This study has identified issues worthy of further investigation. In particular:

- A minimum of two tests have to be performed for each type of test in order to claim full compliance with the ISO 10328 static Standard.

- Test loading condition I shall be applied to evaluate the performance of the ICRC prosthetic knee during the instant of maximum loading occurring early in the stance phase of walking.

- Additional original parts of the transfemoral ICRC system such as the foot unit and the socket are recommended to be attached to the complete structure in order to better recreate the authentic design of it.

- A more detailed and accurate FEA is recommended in order to obtain results closer to the real behavior of the assembly during testing. This in particular can be accomplished by means of a finer mesh, a more accurate design and a non-linear test taking into account also the plastic behavior of the assembly.

- Cyclic tests are necessary to guarantee the complete conformity of the ICRC knee to the ISO 10328 Standard.

- Other prosthetic knee designs for use in low-income countries are recommended to be investigated in order to verify whether they conform to the ISO 10328 Standard.

Appendices

Appendix A

Table 5 of the ISO 10328:2006 Standard – Total length and segmental lengths of different types of test samples for principal tests and separate tests on knee locks, for all test loading conditions and test loading levels.

Dimensions in millimetres

Reference plane level	Typical combinations of segmental lengths of test samples [a,b]		
	A	B	C
u_T	—	—	—
	$(u_T - u_K) = 150$ [b]	$(u_T - u_K) = 150$ [b]	
u_K	—	—	$(u_T - u_A) = 570$
	$(u_K - u_A) = 420$		
u_A	—	$(u_K - u_B) = 500$	—
	$(u_A - u_B) = 80$		$(u_A - u_B) = 80$
u_B	—	—	—
Total length $(u_T - u_B)$ [a,b]	650	650	650

NOTE The total length and the segmental lengths also apply to the additional test loading level P6 specified in Annex D [see D.3 a)].

[a] The total length of 650 mm can be achieved by different combinations of segmental lengths. Examples of the combinations of segment lengths specified in columns A, B and C, typical of the different types of test sample, are shown below.

- Complete structure: A
- Partial structure: A, B, C
- Any other structure: A, B, C

[b] For the testing of samples of prosthetic structures including knee-disarticulation or transfemoral (above-knee) sockets (see 10.3.3), the value of 150 mm specified in columns A and B for the segment length $(u_T - u_K)$ and the value of 570 mm specified in column C for the segment length $(u_T - u_A)$ are too short and need to be increased as required, by increasing the total length $(u_T - u_B)$. In this case the values of the offsets f_T and o_T, specified in Table 6, need to be replaced by new values adapted to the increased total length $(u_T - u_B)$, to be calculated using the formulae in Figure 12 (see also footnote b in Table 6).

Appendix B

Values of offsets for all principal tests

Dimensions in millimetres

Reference plane	Direction and location [b]	Offset [a]					
		Numerical value mm					
		Test loading condition					
		Test loading level P5		Test loading level P4		Test loading level P3	
		I	II	I	II	I	II
Top [c]	f_T	82	55	89	51	81	51
	o_T	– 79	– 40	– 74	– 44	– 85	– 49
Knee	f_K	52	72	56	68	49	68
	o_K	– 50	– 35	– 48	– 39	– 57	– 43
Ankle	f_A	– 32	120	– 35	115	– 41	115
	o_A	30	– 22	25	– 24	24	– 26
Bottom [c]	f_B	– 48	129	– 52	124	– 58	124
	o_B	45	– 19	39	– 22	39	– 23

NOTE The offsets specified for P5 also apply to the additional test loading level P6 specified in Annex D [see D.3 b)].

[a] See 6.8.1.

[b] For individual values of total length $(u_T - u_B)$ deviating from the value specified in Table 5, the offsets f_T and o_T specified in this table need to be adapted, using the formulae in Figure 12 [see also footnote b in Table 5].

[c] Only for guidance in aligning test samples.

Appendix C

Values of combined offsets related to the values listed in Appendix B

Dimensions in millimetres

Reference plane	Dimension and location [b]	Combined offsets $S_x = \sqrt{f_x^2 + o_x^2}$ [a]					
		Numerical value mm					
		Test loading condition					
		Test loading level P5		Test loading level P4		Test loading level P3	
		I	II	I	II	I	II
Top	S_T	114	68	116	67	117	71
Knee	S_K	72	80	74	78	75	81
Ankle	S_A	44	122	43	118	48	118
Bottom	S_B	66	130	65	126	70	126

NOTE The combined offsets specified for P5 also apply to the additional test loading level P6 specified in Annex D.

[a] For the determination of the size of prosthetic feet and the setting of the length of load application levers, specific values of combined offsets (see 6.8.2) may be required. This table states values of combined offsets related to the values of offsets listed in Table 6.

[b] For individual values of total length ($u_T - u_B$) deviating from the value specified in Table 5, the combined offset S_T specified in this table needs to be adapted, using the formulae in the heading [see also footnote b in Table 5].

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