There are no differences between transfemoral amputation patients with a CMK vs. AAK with regard to problems at work and absenteeism

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Abstract

Objective: After a lower limb amputation, patients often get a conventional mechanical knee prosthesis (CMK) or an auto adaptive knee prosthesis (AAK). When returning to work, lower limb amputation patients frequently experience barriers during this process. However it is unknown how often this happens and whether patients with a CMK experience more problems and continued absenteeism compared to those with an AAK. The aim of this study is to investigate differences in amount and severity of the problems at work and continued absenteeism between CMK and AAK users. *Materials and methods*: In a cross-sectional retrospective design, a self-report questionnaire is used. The questionnaire is developed from two validated questionnaires. Inclusion criteria for the study participants were: having a unilateral transfemoral amputation for the period of > 1 year, having a paid job, and being aged > 18 years. The data was collected in RedCap and analyzed in SPSS. *Results*: 35 participants were included of which 86% (N = 30) was male. After employing the Chi square and the Mann Whitney U test, this study did not find any significant differences regarding the amount of experienced problems and the severity of these between the CMK and the AAK group. Furthermore, with regard to continued absenteeism also no significant differences were found between the groups. *Conclusion*: Current study found no differences between CMK and AAK patients regarding the amount and severity of problems at work and continued absenteeism. Various explanations could be given to describe the findings. Future research is recommended to investigate both the qualitative and quantitative aspects of this topic.

Keywords: CMK, AAK, transfemoral amputation, problems at work, absenteeism

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Background

A lower limb amputation can greatly impact a patients' life. Although it is unclear what the prevalence of lower limb amputees exactly is, in the Netherlands at least one third of the lower limb amputations is at a transfemoral level (Geertzen & Rietman, 2018). This means that the amputee must learn how to walk again with a prosthesis. There are various knee prosthesis available, of which the conventional mechanic knee and the auto adaptive microprocessor knee are primarily employed ones. Current article first presents a literature review, followed by a questionnaire study conducted in adults with a transfemoral amputation.

Diabetes mellitus

A lower limb amputation might be necessary due to vascular or non-vascular causes. 95% of the lower limb amputations is due to vascular causes, only 4% is caused by trauma, and 1% by malignancy (Rommers et al., 1997). Diabetes plays a large role in vascular lower limb amputation. Although exact numbers are unknown, in 2017 451 million people had diabetes worldwide, and this is expected to increase to 693 million by 2045 (Cho et al., 2018).

Type 2 diabetes mellitus (T2DM) is most often caused by a combination of genetic and environmental factors, such as being overweight and having a sedentary lifestyle. In healthy individuals, the beta-cells of the pancreas produce insulin, which causes the glucose from the blood to be taken up by the cell. However, in T2DM this mechanism is impaired in which cells become insulin resistant and cannot take up the glucose from the blood, causing hyperglycemia. Additionally, the beta-cells of the pancreas eventually become unable to produce the amount of insulin needed to overcome the glucose-resistant cells. Hyperglycemia can damage the capillaries, causing visual problems, as well as nerve and kidney damage. In the larger blood vessels, hyperglycemia increases the risk of heart disease or stroke (Kahn, Cooper, & Del Prato, 2014). According to Cho and colleagues (2018) it is not possible to measure the exact numbers of individuals with T2DM, however it is estimated that T2DM comprises 85-95% of the total number diabetic patients (Mobasseri et al., 2020).

Contrary to T2DM, Type 1 diabetes (T1D) is an autoimmune disease in which the beta-cells of the pancreas are attacked by auto-antibodies. The FC-receptor on the antibodies is recognized by immune system derived macrophages and dendritic cells, which can produce inflammatory cytokines. For example interleukin (IL)-12, released from the macrophages and dendrites, activates CD4+ T cells. The CD4+ T cells release IL-2 to activate beta-cell antigen

specific CD8+ T cells, which differentiate into cytotoxic T cells. These CD4+ T cells and CD8+ cytotoxic T cells are shown to be involved in destruction of the pancreatic beta-cells (Yoon & Jun, 2005). Destroyed beta-cells are unable to produce insulin and consequently cause hyperglycemia. Therefore, contrary to T2DM, providing insulin from an external source would be beneficial to manage T1D. The onset of T1D seems to be a combination of genetic and environmental risk factors such as prevalence of the disease within the family and diet or vitamin D deficiency, however environmental factors are still being investigated (Gan, Albanese-O'Neill, & Haller, 2012). T1D makes up only 5-15% of the diabetic patients, and numbers vary from 3.5 per 10 000 persons in Africa to 12.2 per 10 000 in Europe and America (Mobasseri et al., 2020).

Peripheral neuropathy

The incidence of a vascular lower limb amputation is eight times higher in diabetic compared to nondiabetic individuals over the age of 45 (Johannesson et al., 2009). One of the causes that might lead to a lower limb amputation is the prevalence of foot ulcers, which is an open infection which cannot heal for a long period of time (Steed et al., 2008). Peripheral neuropathy is the most significant risk factor for developing a foot ulcer. One of the proposed mechanisms associated with neuropathy includes blocking nitric oxide, a vasodilator. Within the vessels, the endothelium is a major source of nitric oxide. Hyperglycemia in diabetic patients inhibits the production of nitric oxide, which leads to higher levels of reactive oxygen species (ROS), and superoxide in particular (Pitocco et al., 2010). Superoxide binds to nitric oxide and produces peroxynitrite, which plays a role in lipid peroxidation, generation of reactive aldehydes and nitrogen oxides, and the production of proatherogenic low density lipoproteins (Alavi et al., 2014). All these processes contribute to cell damage and degradation of the vessels that supply the peripheral nerves, resulting eventually in neuropathy, and leading to numbness in the affected area.

Furthermore, a mechanism called the Maillard reaction is thought to play an important role in the complications of diabetes. This is a reaction between the reduction of sugars and amino groups from biomolecules such as protein or carbohydrates, which leads to the production of advanced glycation end products (AGEs) (Ferreira et al., 2003). Excess glucose is converted to sorbital in a metabolic pathway that depletes nicotinamide adenine dinucleotide phosphate (NADPH). In addition, the activation of the hexosamine pathway further inhibits NADPH,

resulting in a reduction of synthesized antioxidants by NADPH. The decrease in antioxidants and increased production of ROS play crucial roles in diabetes (Alavi et al., 2014).

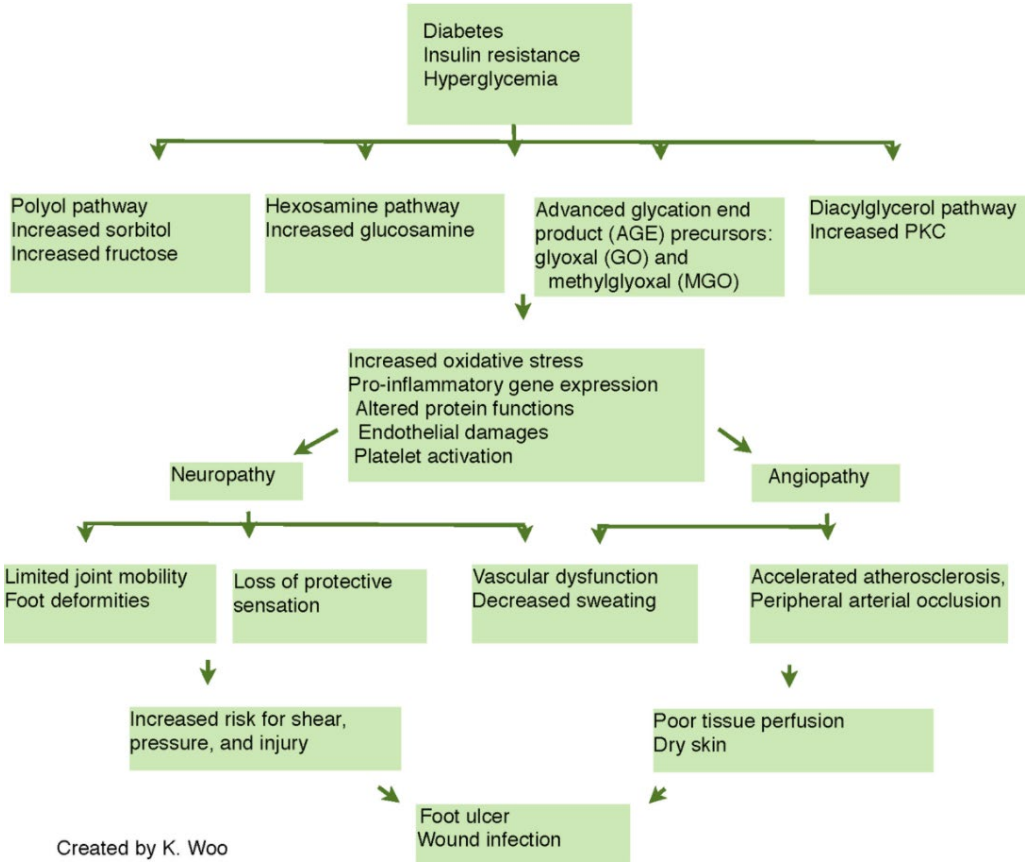

Figure 1: Pathophysiology of diabetic foot ulcers. Source: Alavi et al., 2014.

As seen in figure 1, developed by Alavi and colleagues (2014), the processes of increased oxidative stress and endothelial damage leads to damage of the nerves (neuropathy) and damage of the blood vessels (angiopathy). This results in increased pressure on the foot and along with small undetected foot injury it leads to inflammation, necrosis, and ulceration (Lavery et al., 2007).

Non-vascular causes

Besides vascular causes of a lower limb amputation, examples of non-vascular causes for an amputation could be a tumor or major injury. In cancer patients, an amputation rather than limb sparing might be considered if the cancer has grown into the blood vessels around the tumor, or if an infection has developed after limb sparing surgery (Cancer research UK, 2017). Tumors might be classified according to the tissue that is involved. Although there are no exact numbers on the tissue of the tumor in relation to amputation, malignant bone tumors are most prevalent in participants in lower limb amputation studies (Jain & Stewart, 1989). Osteosarcoma (OS) is

the most prevalent bone tumor (Klein & Siegal, 2006), often occurring in regions of bone growth. It is thought that dysfunctions in the retinoblastoma protein (RB) gene and the tumor protein p53 gene might be involved in the emergence of a bone tumor (Berman et al., 2008). Normally, the RB protein works as a tumor suppressor by preventing excessive cell growth, while the p53 gene can activate DNA repair, regulates the cell cycle, and initiates apoptosis. The OS often expands intramedullary from the metaphysis of long tubular bones (Hameed & Dorfman, 2011), regarding the lower limbs frequently affecting the distal end of the femur or the proximal end of the tibia.

Amputation levels

Although maximum preservation of the limb is desired, some levels of amputation might result in a difficult fit for prothesis in the residual limb, such as the hind foot or the distal third of the leg (Ragnarsson & Thomas, 2000). If possible, it is important to preserve the knee joint to maintain a more normal gait pattern and minimize energy use while walking.

Depending on the location of the trauma, a suitable amputation level can be considered. Figure 2 shows the most common levels of lower limb amputation. A transtibial amputation is the most often performed procedure, followed by a transfemoral amputation (Geertzen & Rietman, 2018). In the interest of our research, current literature review will predominantly focus on transfemoral amputation patients.

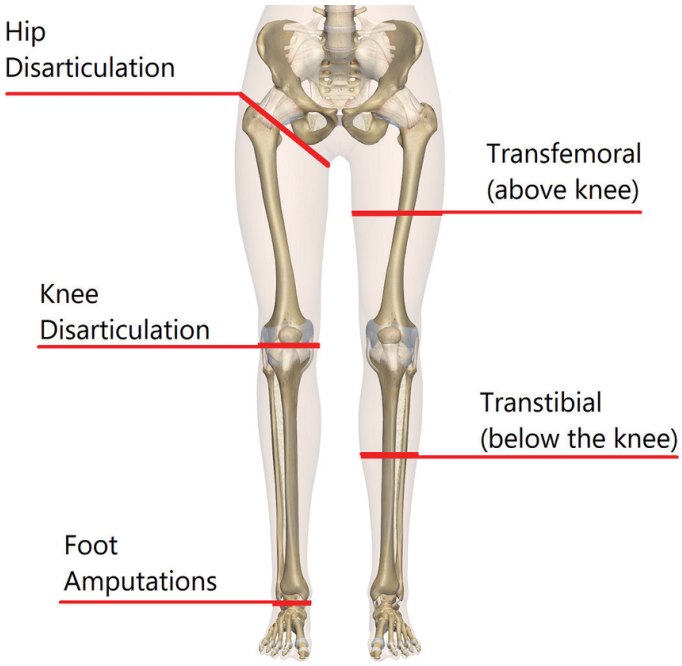

Figure 2: Lower limb amputation levels. Source: Hussain, Shams, & Khan, 2019.

Mechanism of a human knee

In order to understand the mechanism of the various transfemoral protheses, it is important to first understand the general anatomy and working mechanism of a human knee.

The knee is a synovial joint, involving the tibiofemoral joint and the femoropatellar joint. The surfaces of the bones are covered with articular cartilage and connected by ligaments which are lined by synovial membrane secreting synovial fluid to lubricate the joint. The knee joint is reinforced and strengthened by several ligaments to prevent the femur and tibia of sliding too far forwards, backwards, or sidewards (McArdle, 2006).

The knee joint plays a crucial role in the walking mechanism. Figure 3 shows the phases of a normal gait cycle. During the heel strike, the stance knee flexes slightly, allowing for shock absorption. During the mid-stance phase, the angle of the knee joint increases until full stance extension. In the terminal stance and pre-swing phase, the knee of the supporting leg flexes to prepare for the swing phase. In the toe-off phase, the swing flexion begins, and the knee extends forward. After reaching full knee extension, the foot is placed on the ground to repeat the gait cycle (Azahari et al., 2017; Martinez-Villalpando & Herr, 2009). The knee joint is crucial to provide stability during the walking cycle.

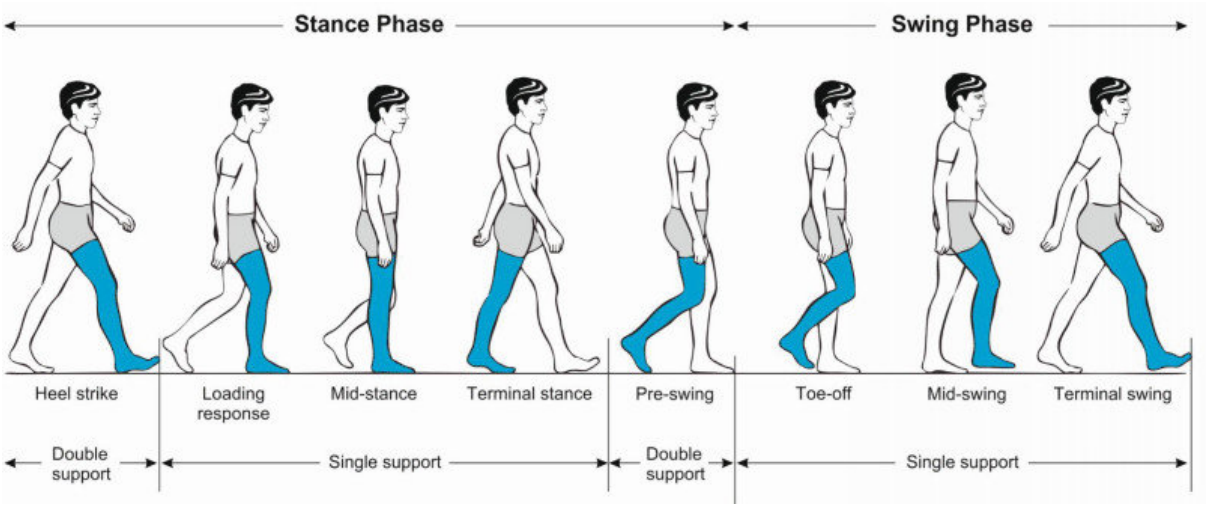

Figure 3: Phases of a normal gait cycle. Source: Pirker & Katzenschlager, 2017.

In patients with a transfemoral prosthesis, this walking mechanism could be slightly altered. A transfemoral prosthesis is an artificial limb that replaces any amputated limb above the knee (Hafner et al., 2006), and generally includes a socket, knee, pylon, and foot. Compared to for example a wheelchair, prostheses allow patients greater mobility and locomotion along with increased independence.

Types of transfemoral prostheses available

With regard to a transfemoral prosthesis, three categories of prosthetic knees can be identified; 1) passive devices, working as a fixed spring and damper to offer basic functionality (conventional mechanic prosthesis), 2) semiactive prosthesis that can adapt to the walking situation of the amputation patient (auto adaptive microprocessor controlled knee prosthesis), and 3) active prostheses that produce external power and act accordingly (active motorized knee prosthesis) (Windrich et al., 2016).

A single axis mechanic knee can have a free swing or be weight activated. Prosthetic knees with a free swing have a manual lock to control the swing and stance phases during walking (Hafner et al., 2006). This manual locking knee is primarily used in patients who are unable to control the knee or have short residual limbs. A single axis knee could also be provided with weight activated stance control, which activates a braking mechanism when weight is put on the knee. To bend the knee, the weight must be unloaded which allows for a safe walking mechanism. Additionally, polycentric knee prostheses allow for more stability and the possibility to walk at various speeds. The polycentric knee has a mechanism which collapses better and hereby bends easier. Moreover, a hydraulic or pneumatic knee can adjust to the speed of gait using hydraulics or pneumatics (liquid or air, respectively), and are often provided in more active amputees (Kingsley, 2020; Michael, 1999).

In contrast, the microprocessor controlled knee contains an automated system to adapt to the speed and walking manner of the amputee. The prosthetic knee involves three components. 1) the knee actuator, controlling the systems' movement in response to command signals, 2) sensors, measuring force and moment as the amputee is moving, and 3) a controller, which has a memory and is adapted to command signals and receives input from the sensors (Herr, Wilkenfeld, & Bleck, 2003). Microprocessor knees often described in published literature are the Otto Bock C-Leg, the Otto Bock Kenovo, Otto Bock Genium, and the Össur Rheo knee. Compared to a mechanical prosthesis, a microprocessor controlled knee might offer several advantages for the amputee, which will be discussed later.

The most recently discovered category is the active knee prostheses, which are able to produce positive mechanical power and hereby act like a human knee (Martinez-Villalpando & Herr, 2009). Currently, very little to no clinical trials have evaluated the benefits of a powered

prosthesis compared to a conventional one, and in practice they are not used very often (Windrich et al., 2016).

Deciding which prosthesis to use

According to Michael (1999) to determine a type of prosthesis, four questions can be asked to the amputation patient. Can this person be expected to use their remaining neuromuscular capacity to: 1) control prosthetic knee stability under all circumstances, 2) flex the prosthetic knee in a controlled manner during pre-swing, 3) walk with a prosthesis at differing speeds, and 4) walk with a prosthesis at a moderate or faster pace? Patients that are able to control the stability of the prosthesis under all conditions might use a basic design, while the remaining majority might want to use a more stable knee prosthesis according to their functional needs (Michael, 1999). Moreover, a more recent scale looking at mobility is the Special Interest Group in Amputee Medicine (SIGAM), comprising six clinical grades of post-amputation mobility. The grades are ranging from A-F in which at grade A the amputation patient is not using the limb or uses it for cosmesis only, and grade F is allocated if the amputation patient van walk anywhere in any weather without a walking aid (Ryall et al., 2003). This scale was recently found to have an excellent test-retest reliability (De Laat et al., 2020).

Furthermore, classification systems are being used, that assign a code to an amputee based on their functional status. Theeven and colleagues (2011) for example used the Medicare Functional Classification Level (MFCL) index (k-levels) (Centers for Medicare, 2001). A MFLC score of 0 (also called: k-level 0) means that the amputee does not have the ability to ambulate safely with or without assistance, and a prosthesis would not enhance their quality of life or mobility. While a MFCL score of 4 (k-level 4) indicates that the amputee has the ability for prosthetic ambulation that exceeds the basic ambulation skills, exhibiting high impact, stress, or energy levels, typically of the prosthetic demands of a child, active adult or athlete (Centers for Medicare, 2001).

Comparing the prostheses

In 2007, Hafner and colleagues assessed the differences between the mechanical and a microprocessor prosthetic knee with regard to performance, functioning, and personal preference. All 21 subjects had the possibility to try both the mechanical and the microprocessor prosthesis two times in a controlled reversal study design. While using the microprocessor prosthesis, participants experienced significantly increased ability to descend

stairs; decreased time to descend a slope; decreased self-reported falling, stumbling, and frustration. No significant differences were observed in actual activity. However, satisfaction was improved while wearing the microprocessor prosthesis and thus most participants preferred this prosthesis.

Also in 2007, Seymour and colleagues compared the C-leg microprocessor knee with a non-microprocessor prosthesis in thirteen participants with unilateral limb loss. Energy expenditure and obstacle course performance were measured by walking paces at a treadmill and completing a standardized obstacle course. Additionally, participants filled out the SF-36, a questionnaire to assess quality of life. When utilizing the C-leg, participants had a significantly lower oxygen consumption, and a significant decrease in steps and time to perform the obstacle course. The scores on the SF-36 were higher than the mean for norms for limitation in the use of an arm or leg, which indicates a minimal quality of life impairment in participants using a C-leg.

Furthermore, Theeven and colleagues (2012) performed a similar study, examining the effects of a mechanical prosthesis compared to two variations of the microprocessor knee. Participants perceived significantly higher satisfaction, utility, ambulation, and residual limb health with the microprocessor prostheses compared to the mechanic knee. However, the actual activity levels did not differ between the prostheses.

Contrarily, Kaufman and colleagues (2008) demonstrated that participants utilizing a microprocessor knee did have significantly increased physical activity related energy expenditure compared to wearing a mechanical prosthesis, and the participants showed increased quality of life with the microprocessor knee. In this study, no significant differences in energy efficiency were found.

Moreover as seen in the above discussed studies, Samuelsson and colleagues (2012) found inconclusive results regarding activity, participation, and cost-effectiveness in a systematic review. Solely quality of life and use/non-use were improved in the microprocessor knee compared to a non-microprocessor knee prosthesis.

In another systematic review, Sawers and Hafner (2013) identified outcomes that are associated with the use of microprocessor prosthetic knees compared to non-microprocessor knees in transfemoral amputees. 27 studies were included and 9 outcome categories have been identified; metabolic energy expenditure, activity, cognitive demand, gait mechanics,

environmental obstacle negotiation, safety, preference and satisfaction, economics, and health and quality of life. Moderately strong evidence showed that microprocessor knees increase the patients confidence in ambulation, increased self-reported mobility, reduced self-reported cognitive demand, and improved self-reported well-being. This study found no evidence that suggested that non-microprocessor knees might improve clinical outcomes compared to a microprocessor prosthetic knee. However, the microprocessor knee might be provided to those patients who require an increase in safety or improved ability for walking stairs or uneven terrain.

Additional to investigating the differences between mechanical and microprocessor prosthetic knees, active or powered prostheses have also been studied. However, as mentioned before, the study evidence of these prostheses is very limited. Studies have shown that powered prostheses compared to passive prostheses, are more representative of healthy gait for (stairs) walking (Lawson et al., 2012; Ledoux & Goldfarb, 2017). These limitations of passive transfemoral prostheses might be a contributing factor in the onset of for example lower back pain in individuals with an transfemoral amputation (Esposito & Wilken, 2014).

As seen in the research discussed above, inconclusive study results have been demonstrated, which might partially be contributable to different measures and procedures that are being used evaluate the prostheses. Theeven and colleagues (2013) found in a systematic review, that two thirds of the examined studies utilized patients' actual performance, whereas the remaining studies focused on activity and participation of the patients. Body functioning was often examined according to the International Classification of Functioning (ICF), or using self-report questionnaires, such as the Prosthesis Evaluation Questionnaire (PEQ). Possible response or recall bias should be taken into account, along with the fact that these studies cannot be performed blinded. Moreover, in a systematic review, Highsmith and colleagues (2010) found that methodologic quality varied greatly among studies looking at safety, energy efficiency, and cost-effectiveness in microprocessor prosthetic knees. For example, non-vascular amputees were not represented proportionally, limiting generalization of this group. Besides this, studies often did not standardize variables, such as functional level and its rating, and control conditions (Highsmith et al., 2010).

Improvements in functional performance and psychosocial functioning are important, however at what cost? A financial evaluation is of importance with regard to the health insurance companies, often paying for the prosthesis. Therefore the next section will discuss the cost-

effectiveness of a mechanical prosthetic knees and comparing this to a microprocessor prosthetic knee.

Cost effectiveness of prostheses

Although a large number of studies show promising results on auto adaptive knee prostheses, little attention is paid to the cost of such prostheses. When providing a prosthesis, the patient factors are being examined first, looking at the level of amputation, body condition, and the condition of the contralateral leg according to the k-levels. Then an aimed level of functioning and use of the prosthesis is determined, considering the activity- and participation levels of the patient. Finally, together with a rehabilitation doctor and prosthetist, an application for an authorization from the health insurance company is requested, along with a quotation from the prosthesis developing company (or prosthetist). When the health insurance company approves the application, the prosthesis developing company manufactures the prosthesis for the patient (Geertzen & Rietman, 2018). However, the health insurance company must make a well informed decision, in which the cost-effectiveness of prostheses plays an important role.

In the studies discussed below, both the cost-effectiveness and cost-utility are being analyzed. Cost-effectiveness studies measure effectiveness as life-years saved, cost-utility studies however measure quality adjusted life years (QALYs), saved life years when an intervention reduces the risk of premature death (Tengs, 2004).

In 2009, Seelen and colleagues looked at the direct and indirect cost and functional health of patients utilizing a microprocessor prosthesis compared to a mechanical prosthesis in transfemoral amputation patients. The study was conducted in the Netherlands and included 26 participants. The intervention cost of the microprocessor prosthesis was approximately 30% higher compared to the mechanical prosthesis. However, patient and family costs and housekeeping costs were higher in the mechanical prosthesis participant group, along with a larger loss in productivity in these participants. This indicates that higher purchasing costs of the microprocessor prosthesis might be compensated by the lower costs in other domains compared to a mechanical prosthesis.

In 2008, Brodtkorb and colleagues compared the cost effectiveness of a C-leg to a non-microprocessor controlled knee. 20 participants with a transfemoral prosthesis were included and studied over the duration of 8 years. The data was collected by participant interviews and cost-effectiveness and QALY analyses. The main outcome measure was the incremental cost

per quality adjusted life year (QALY). A result was found that using a C-leg, rather than a non-microprocessor controlled knee, is associated with a cost per QALY of €3218, which is a fairly low cost in the health care sector. However, the limitations of this study should be taken into account. A large part of the results is based on informed judgements, since actual data is not available. Moreover, QALY calculation towards the C-leg might have been biased since all participants were using this prosthesis.

Likewise, in 2018 Chen and colleagues calculated the incremental cost-effectiveness ratio (ICER) in a modeling study, comparing the incremental cost of a microprocessor controlled knee to a non-microprocessor controlled knee per QALY. ICER is defined as the additional resource requirements per unit of additional health gained, usually measured by quality adjusted life years (QALYs). The model includes various factors such as physical functioning, quality of life, direct and indirect costs such as healthcare, caregiving expenses, transportation, work productivity. These parameters were validated by an expert panel. The model showed that a microprocessor amputee gains 0.91 QALYs compared to a non-microprocessor prosthesis user. This can be explained by the improvements in mobility, safety, daily activities, and satisfaction in microprocessor prosthesis users. Furthermore, the study found that the microprocessor knee prosthesis has an ICER of $11,606 per QALY. Therefore, this study demonstrates that microprocessor controlled knee prostheses are superior to non-microprocessor controlled knees at an acceptable cost. However, it should be taken into account that this study is only presenting a model, and that actual clinical trials in which microprocessor and non-microprocessor prostheses are compared are lacking.

Furthermore in 2009, Gerzeli, Torbica & Fattore compared a C-leg with a polycentric mechanical prosthetic knee in a cost-utility analysis (CUA) in Italian transfemoral amputees. A cost utility analysis is a full economic evaluation analysis focusing on the quality of the health outcome (Drummond et al., 1997), which in this study was measured as quality of life. 100 participants participated in two equal groups utilizing the C-leg and the mechanical prosthesis. Quality of life was measured based on answers from the EuroQol (EQ-5D) questionnaire, a standardized questionnaire to measure QALY (Rabin & Charro, 2001). Financial data was collected in retrospect for a period of 12 months, including costs such as health care resources, transportation costs, informal care, and productivity loss of the patient. This study found that the C-leg significantly improved quality of life compared to a mechanical prosthesis. The incremental cost-utility ratio (ICUR) is €35,971 per gained QALY, which falls

reasonably between the acceptable range from US $30,000-100,000 (Eichler et al., 2004). Therefore, this study concluded that the C-leg is likely to be cost-effective and for this reason might be worth funding.

Finally, Cutti and colleagues (2016) performed a cost-utility analysis of the C-leg versus a mechanical knee prosthesis in Italian participants. In this retrospective cohort study, prosthesis costs such as acquisition, maintenance, and transportation were taken into account, while utility was measured in QALYs assessed based on answers from the EQ-5D. As various studies have shown before, the C-leg appeared to have a larger effect of patients' quality of life, with an incremental cost utility ratio of €40.155,45 per QALY, which is below the acceptability threshold of €54.120 per QALY (Dakin et al., 2015). The higher costs of the C-leg were balanced by significant improvements for its users in dimensions such as physical mobility and usual activities. However, in older patients this is not the case, both the C-leg and the mechanical prosthesis seemed to negatively affect these patients psychosocially and psychophysically. Nevertheless, current study suggested that the C-leg should be provided as the first prosthesis since it might have significant impact on mobility in patients, but that low-cost physical and psychosocial interventions are required to balance the costs.

When looking at the cost-effectiveness and cost-utility of the mechanical prosthesis compared to the microprocessor, studies show different results. However, all studies agree that the ICER or ICUR cost per QALY for the microprocessor knee is below the acceptability threshold, something that also seems to vary between studies. Moreover, there is no standardized method to measure cost-effectiveness or cost-utility. Where some studies use models and expert opinions to estimate the costs, others use retrospective designs. Clinical trials to investigate cost-effectiveness are hardly conducted, and might be expensive and time-consuming. And finally, as one study (Cutti et al., 2016) showed, in older patients both protheses negatively affect quality of life, and it can be argued that the type of prosthesis is then less important and that maintenance of the quality of life should be acquired through other means, such as focusing on an individuals' physical and mental health, social belonging, comfortability, and employment.

Introduction

When investigating the cost-effectiveness of knee prostheses, the occupational aspect is crucial to involve. Not only does employment contribute to the financial situation of lower limb amputees, it is also an important factor in maintaining and improving independence, well-being, and a social environment (Bruins et al., 2003; Fugl-Meyer et al., 1991).

In a qualitative study, Schoppen et al. (2001, 1) looked at work-related experiences of lower limb amputees in the Netherlands. The work rate of the participants was 64%, which is comparable to the work-rate of the Dutch population. This study found that many participants shifted to less physically demanding work, and that often limitations are experienced when returning to work after an amputation. Moreover, participants who had to quit their job because of the amputation, showed worse health outcomes compared to participants who were still working. Furthermore, in another study Schoppen et al. (2001, 2) investigated which factors affect a successful job reintegration after a lower limb amputation. Age at the time of amputation, wearing comfort of the prosthesis, and educational level significantly influenced job reintegration. As shown in the previously mentioned study from Schoppen et al. (2001, 1), after a lower limb amputation, participants often shifted to less physically active work. A shift that might be easier for younger patients, and which might require a higher level of intellectual skills. Furthermore in a literature review, Burger and Marincek (2007) demonstrated similar results. The return to work rate was around 66%, and between 33-88% of the subjects had to change occupation. A variety of return to work factors have been found including age, gender, educational level, amputation level, support from the employer, and social support network. In another study in the Netherlands, Bruins et al. (2003) found that the most recurrent barriers for job reintegration after a lower limb amputation were stump problems, wound healing problems, along with little support of the employer. Similar to the study of Burger and Marincek (2007), 50% of the patients changed jobs after the amputation. Primary motives to return to work were useful day spending and social contacts. Furthermore, in a more recent study, Stuckey et al. (2020) identified barriers and facilitators for work participation in lower limb amputees in Bangladesh. Traditional gender roles, meaning of work, and social support were among the most important factors.

From the studies mentioned before, it is clear that a growing body of literature has focused on work reintegration of lower limb amputees. However, the majority of these studies emphasize the qualitative aspects of this reintegration rather than quantitatively investigate how often

these patients actually experience problems at their job. After an extensive literature review, no studies were found reporting such results.

Moreover, none of the studies report the type of prosthesis that is being used by the participants or makes a distinction between types, even though this might influence the problems and severity of these problems that are being experienced while working.

As mentioned in the background, both the mechanical knee (CMK) and auto adaptive knee prostheses (AAK) are often used by transfemoral amputation patients. The AAK however, is often reported to have higher outcomes on quality of life (Chen et al., 2018; Gerzeli, Torbica & Fattore, 2009), which therefore might positively influence patients' experiences regarding job reintegration. However, this has not yet been investigated.

Therefore the purpose of this study is to investigate the differences between an AAK and a CMK regarding the amount of lost working hours and the amount and severity of physical and psychological problems in the first 6 months of the prosthesis during work in persons with a transfemoral amputation aged <60? The primary outcomes are the amount of working days with physical and psychological problems and the severity of these problems. Secondary outcomes will be the amount of lost working days/hours, and continued absenteeism longer than 4 weeks. It is hypothesized that patients wearing an AAK will experience less physical problems and less severe problems compared to patients with a CMK. Moreover, patients with an AAK might have less lost working hours and continued absenteeism than patients with a CMK. This, because studies have demonstrated improved quality of life in patients with an AAK compared to a CMK (Chen et al., 2018; Gerzeli, Torbica & Fattore, 2009).

By means of a self-report questionnaire current study will investigate the occupational situation in transfemoral amputation patients. The results of this study will contribute to the existing body of knowledge of vocational reintegration of and problems experienced by transfemoral amputation patients. In addition, the quantitative results can be used in cost-effectiveness studies comparing the AAK and CMK.

Methods

Study design

This questionnaire study used a cross-sectional quantitative design in which, in retrospect, the first six months of the current prosthesis were investigated.

Participants and procedures

Current study is part of a larger study investigating the cost-effectiveness in AAKs compared to CMKs. For both this and the larger study, the study population was recruited from five prosthesis developing companies in the Netherlands. Inclusion criteria for the larger study were: having a unilateral transfemoral amputation or knee disarticulation for the period of > 1 year, the amputation patient uses the prosthesis daily, the prosthesis is obtained according to the Dutch Prosthesis Prescription Protocol (PPP), aged > 18 years old, and sufficient understanding of the Dutch language. The inclusion criteria for our study were almost the same, including transfemoral amputation patients with a prosthesis socket, having a paid job during the first 6 months of the current prosthesis, and being aged between 18 and 60 years old. Patients currently wearing their first prosthesis were excluded because previous research found that the average period between amputation and return to work was 11.5 months (Bruins et al., 2003). Moreover, the participants had to be able to fill in the paper questionnaire and return it to the University Medical Centre of Groningen (UMCG). No sample size calculations were employed for this study due to time limitations.

For the larger study, the prosthesis developing companies had given permission to contribute to the study. These companies sent the questionnaire and informed consent along with an accompanying letter and a participant code to their clients who fit the inclusion criteria. The participant codes were assigned to the participants by the companies and were unknown by the researchers, and therefore anonymity of the study participants was guaranteed. The completed questionnaires were directly returned to the researchers in the UMCG in sealed envelopes. The participants were asked to return the forms within three weeks.

Questionnaire

The questionnaire (appendix 1) used in this study was originally developed to measure cost-effectiveness of a CMK compared to an AAK, and is based on the Medical Consumption Questionnaire (iMCQ) and the Productivity Costs Questionnaire (iPCQ). The iMCQ is a standardized self-report questionnaire to assess healthcare costs of patients in economic evaluations, developed by Bouwmans and colleagues (2013), including visits to the general practitioner, the psychologist and home care. While the iPCQ, developed by the same research group (Bouwmans et al., 2014), is a standardized questionnaire to evaluate productivity cost, asking about paid and unpaid work, absenteeism, and physical or mental problems during work.

The latter questionnaire in particular is of importance in this study, focusing on the loss of productivity.

Rather than including a time period of only four weeks (iPCQ) or three months (iMCQ), our questionnaire focuses on the first 6 months participants' current prosthesis. This, because the first 6 months is the time period in which amputees have to grow accustomed to the new prosthesis and therefore might need additional health care as compared to having more experience with the prosthesis.

As a combination of the iMCQ and the iPCQ, our questionnaire included various themes, such as patient characteristics and amputation-related factors. Furthermore, job characteristics and experienced job-related problems were addressed, and the utilization of informal and professional care, such as appointments at the physiotherapist of home care. Answer categories varied from yes/no answers, to open answers, and one question involving a 1-10 point Likert scale.

Current study will focus on the amount of working days with physical and psychological problems and the severity of these problems. Question 8 asks about how many days participants were experiencing problems during the first 6 months of the prosthesis, and participants could answer with a number. Question 9 focuses on the severity of the problems, asking how much work could be performed on the days filled in in question 8. Participants could answer with a number ranging from 0-10 with 0 meaning that nothing was possible on these days and 10 meaning that work could be performed like usual. The second part of the study focuses on lost working days and continued absenteeism. Question 4 asks whether participants were absent during work, and answer options were: no; yes, I have been absent for 6 months; and yes, I have been absent for … days. In this last option, participants could fill in the number of days that they were absent. If question 4 was answered with "yes", question 5 could be filled in. Question 5 asked about continued absenteeism longer than 4 weeks, and answer options here were yes or no.

Data analysis

The participant characteristics were divergent and therefore, to describe the data, the median, and interquartile ranges were calculated. The participants were divided into two groups; participants currently using an AAK and participants using a CMK (either free moving or a rigid knee prosthesis). To test whether there is a systematic difference between the type of

prosthesis and the amount of working days with physical and psychological problems (question 8) and the severity of these problems (question 9), the Chi^2 test was employed. Furthermore, a Mann-Whitney U test, an equivalent of the independent samples T-test, was employed to test for any significant differences between the AAK and CMK group. This because a normality test (Shapiro-Wilk Test of Normality) has shown that the data was not normally distributed, and because of the small sample sizes (< 30 individuals) (Field, discovering statistics, p.134).

The second part of the research question aims to investigate the amount of lost working days (question 4) and continued absenteeism > 4 weeks (question 5), which will also be analyzed using the Chi^2 test and a Mann-Whitney U test.

The computer program SPSS (version 23) was used, and a p-value of 0.05 was employed for all analyses.

Ethical considerations

Current study is part of a larger study investigating the cost-effectiveness in AAKs compared to CMKs. Therefore, current study fell under the same ethical considerations.

The Medical Ethical Committee at the University Medical Centre Groningen has approved that this study is not included in studies involving individuals as being written in the law of medical scientific research involving humans.

Results

This study included 35 participants of which 86% (n=30) were male. The median age of the participants was 60.0 years and the median age at which participants had their amputation was 22.0 years. The characteristics of the CMK and AAK groups are shown in table 1.

Table 1: Participant characteristics according to group

	CMK	*AAK*
Number of participants (n)	15	20
Median age (years)	60 (Q1: 50; Q3: 70)	60 (Q1: 54.5; Q3: 66.8)
Median age of amputation (years)	21 (Q1: 16; Q3: 32)	25 (Q1: 19; Q3: 46.8)
Gender: men/women (%)	93.3%/6.7%	80.0%/20.0%
Median working hours (h/week)	40 (Q1: 40; Q3: 40)	36 (Q1: 32; Q3: 40)

In both groups, men are over represented, and participants in the AAK group had their amputation approximately 4 years later than participants in the CMK group. Furthermore, it is remarkable that both the CMK and the AAK group work (almost) a full 40-hour work week.

The primary aim was to investigate the difference in quantity and severity of physical and psychological problems in the CMK and AAK group, corresponding with the outcomes of question 8 and 9. Question 8 asks about the amount of working days in which patients experienced physical and psychological problems, and participants could fill in a number. The median answer to this question was 0, filled in by 57,1% of the participants, and which was also the lowest value, while the highest value was 15. Furthermore question 9 asks about the severity of the problems that were experienced during the days filled in in question 8. Participants could score a number between 0 and 10, in which 0 means that nothing was possible on these days, and 10 means that they could do everything like usual. The median answer here was 8.0, the lowest number participants gave was 1.0 and while the highest number was 10.0.

First, the relationship between the type of prosthesis and whether problems were experienced was tested for significance. These variables were categorical and therefore the Pearson Chi-Square was employed. A value of 1.146 was found with a p=0.284 (table 2, appendix 2), which is higher than the significance threshold of p=0.05 and is therefore not significant. This indicates that there is no significant relationship between the type of prosthesis and whether or not someone experiences physical or psychological problems at work.

When comparing the CMK and AAK group regarding the number of days that physical and psychological problems were experienced (question 8), a non-significant difference was found between the groups with a Mann-Whitney U value of 116.5 with a p=0.319 (table 3, appendix 2).

Furthermore, for question 9, the severity of the experienced problems which was scored with a number between 0 (participant could not do anything) to 10 (participant could do everything). The median score in the CMK group was 6.5 compared to 8.0 in the AAK group, however this difference was found to be not significant (p=0.294).

The secondary aim of the research question focused on lost working hours and continued absenteeism of longer than four weeks (question 4 and 5, respectively). Question 4 asks whether participants were absent from work during the first 6 months of the prosthesis. Answer

options were no; yes, I could not work during the full 6 months; and yes I was absent for … days. In this last option, participants could fill in the number of days which they were absent from work. If participants answered question 4 with yes, question 5 could be filled in. Question 5 looks at the continued absenteeism longer than 4 weeks. Here, participants could answer with 'yes' or 'no'.

As shown in table 4 (appendix 2), the Chi-Square has a value of 2.141 along with a significance of p=0.143, which is above the significance threshold of p=0.05 and is therefore not significant. This demonstrates that there is no significant relationship between the type of prosthesis and absenteeism from work. Furthermore, since only one participant had filled in an amount of days in question 4, absence during the first 6 months due to the prosthesis, it was decided not to perform the analysis on this variable.

The Mann-Whitney U test for continued absenteeism longer than 4 weeks had a value of 20.0 along with a significance value of p=1.0 (table 5). This p-value indicates that the relationship between the type of prosthesis and continued absenteeism is based on coincidence and is therefore not statistically significant.

Finally, in all of the performed tests, whether or not it was the participants' first prosthesis, could have been a confounding factor, and therefore participants having their first prosthesis were not included in these analyses.

Discussion

Aim of the study

The aim of present study was to describe the occupational situation in transfemoral amputation patients, and to compare the differences between patients with a CMK and an AAK.

Summary of the results and comparison to existing literature

The results showed no significant differences between these two groups of participants regarding the number of days that physical and psychological problems were experienced and the severity of these problems during the first 6 months with the current prosthesis. Furthermore, the results on lost working hours and continued absenteeism were found to be non-significant. This indicates that there are no differences between CMK and AAK patients with regard to problems at the occupational situation during the first 6 months of using the prosthesis.

It is notable that this study that more men than women were included, 93,3% and 80% in the CMK group and the AAK group respectively. This can be explained by the fact that men more often have a prosthesis than women, 1.7 times as much to be precise in the Netherlands in 2020 (GIPdatabank, 2020).

Furthermore the median age of the participants was 60.0. In the original research question we aimed to include participants under the age of 60. However, if participants older than 60 years, would have been excluded, almost half of the current participants would not have been included in this study. Therefore, to include more participants, it has been decided to include amputation patients at all ages with a paid job during the first 6 months of their current prosthesis.

Previous research

To our knowledge there is no existing literature that has investigated the quantitative differences on employment between CMK and AAK users. However, a study performed in 2001 looked at qualitative work-related experiences in lower limb amputation patients (Schoppen et al., 2001, 2). After the amputation, participants shifted to lower physically demanding jobs, and adjustments at the workplace were made in changing the workload and getting helping aids. If in our study this was the case in participants with both the CMK and the AAK, this might explain that there are little differences between the type of prosthesis. However, this is just a possible explanation and cannot be checked in the data.

Furthermore, because patients with their first prosthesis were not involved, a second possible explanation could be that participants were already in a stable job position. As mentioned before, when patients first start working post amputation, they might experience barriers such as wound healing problems (Bruins et al., 2003). However, after a longer period of time, these problems most likely will be solved or a new job is found. This leads to a stable work situation in which a new prosthesis might not change much. This might also explain the relatively high amount of weekly working hours in both the CMK and the AAK groups as seen in table 1.

Type 2 diabetes mellitus

When looking at one of the largest causes of a lower limb amputation, type 2 diabetes mellitus (T2DM) plays a large role. Unfortunately, the questionnaire that was used in this study did not assess the cause of amputation, but it is expected that T2DM is the cause of amputation in at least a small part of the study population (Geertzen & Rietman, 2018). Previous research has shown that people with T2DM experience decreases in work performance (Lavigne et al.,

2003), work loss, and health related work limitations (Tunceli et al., 2005). Moreover, a recent study in South Africa demonstrated that employed T2DM patients did not adhere to self-management practices (Copeling & Jooste, 2020) leading to worse disease outcomes. These problems at work and self-management problems might increase after having an amputation due to vascular causes. Roberts (2018) stated that a positive mindset is of importance in diabetic patients after an amputation, which can lead to lower levels of depression and increased self-esteem. A literature review found that depression, anxiety and activity restriction are high up to 2 years after the amputation, and decrease afterwards (Horgan & MacLachlan, 2004). This might indicate that patients start job reintegration after more than 2 years post-amputation, and therefore our study, focusing on the first 6 months, might not have included a part of participants which might have influenced the results.

Strengths and limitations

The primary strength of this study is the measurement instrument. The questionnaire that was used in this study has been developed from two validated questionnaires, the iMCQ and the iPCQ. This indicates that the concept aimed to measure in this study, problems at work and absenteeism, is accurately measured by means of this questionnaire. Furthermore, the questionnaires were send out to prosthesis developing companies all over the Netherlands, increasing the geographical heterogeneity, and anyone with an amputation within the inclusion criteria could participate.

Besides a strength, the questionnaire in this study could also have been a limitation. Originally, the questionnaire was intended to be utilized to evaluate the cost-effectiveness of lower extremity prostheses. Therefore sometimes important information was not assessed. For example the reason of amputation, which would have helped to explain some of the study results.

A final limitation of this research is the small study population. This study is part of a larger study investigating the cost-effectiveness of prostheses, which required a broader study population, for example regarding age and employment. Consequently, we focused on a relatively small group that was actually employed during the first 6 months of their current prosthesis.

Recommendations for future research

The results of present study contribute to the existing body of knowledge investigating the quantitative differences between the CMK and the AAK. This information can be of value for patients themselves, who might need to choose a type of prosthesis, and for the health insurance companies, who approve (or decline) a prosthesis application and fund it accordingly.

For future research it is recommended that the development and implementation of a questionnaire that involves both quantitative and qualitative aspects of working after a lower extremity amputation. Although this study gave a valuable insight in the quantitative differences between the CMK and the AAK regarding the vocational situation of these patients, it was difficult to determine to which variable these differences could be ascribed to. Furthermore, existing research has mainly focused on functional differences, for example ability to walk stairs, when comparing the two prosthesis types, rather than prioritizing prosthesis usage in daily life. In the future, research might focus on including both the quantitative and qualitative differences between the CMK and the AAK in everyday life to improve the decision making process for the right knee prosthesis for both the health insurance company and the patient.

Conclusion

In conclusion, this study found no differences regarding continued absenteeism and problems and severity of these at work in lower extremity amputation patients with a CMK versus an AAK. Various explanations could be given to describe these findings. It is recommended to further investigate this topic on both quantitative and qualitative aspects.

References

Alavi, A., Sibbald, R. G., Mayer, D., Goodman, L., Botros, M., Armstrong, D. G., ... & Kirsner, R. S. (2014). Diabetic foot ulcers: Part I. Pathophysiology and prevention. *Journal of the American Academy of Dermatology*, *70*(1), 1-e1.

Azahari, A., Siswanto, W. A., Ngali, M. Z., Salleh, S. M., & Yusup, E. M. (2017, January). Dynamic Simulation and Analysis of Human Walking Mechanism. In *IOP Conference Series: Materials Science and Engineering* (Vol. 165, No. 1, p. 012027). IOP Publishing.

Berman, S. D., Calo, E., Landman, A. S., Danielian, P. S., Miller, E. S., West, J. C., ... & Lees, J. A. (2008). Metastatic osteosarcoma induced by inactivation of Rb and p53 in the osteoblast lineage. *Proceedings of the National Academy of Sciences*, *105*(33), 11851-11856.

Berry, D., Olson, M. D., & Larntz, K. (2009). Perceived stability, function, and satisfaction among transfemoral amputees using microprocessor and nonmicroprocessor controlled prosthetic knees: a multicenter survey. *JPO: Journal of Prosthetics and Orthotics*, *21*(1), 32-42.

Borrenpohl, D., Kaluf, B., & Major, M. J. (2016). Survey of US practitioners on the validity of the medicare functional classification level system and utility of clinical outcome measures for aiding K-level assignment. *Archives of physical medicine and rehabilitation*, *97*(7), 1053-1063.

Bouwmans, C., Krol, M., Brouwer, W., Severens, J. L., Koopmanschap, M. A., & Hakkaart, L. (2014). IMTA productivity cost questionnaire (IPCQ). *Value in Health*, *17*(7), A550.

Bouwmans, C., LH-v, R., Koopmanschap, M., Krol, M., Severens, H., & Brouwer, W. (2013). Handleiding iMTA Medical Cost Questionnaire (iMCQ). In Rotterdam: iMTA, Erasmus Universiteit Rotterdam.

Brodtkorb, T. H., Henriksson, M., Johannesen-Munk, K., & Thidell, F. (2008). Cost-effectiveness of C-leg compared with non–microprocessor-controlled knees: a modeling approach. *Archives of physical medicine and rehabilitation*, *89*(1), 24-30.

Bruins, M., Geertzen, J. H. B., Groothoff, J. W., & Schoppen, T. (2003). Vocational reintegration after a lower limb amputation: a qualitative study. *Prosthetics and orthotics international*, *27*(1), 4-10.

Burger, H., & Marinček, Č. (2007). Return to work after lower limb amputation. *Disability and rehabilitation*, *29*(17), 1323-1329.

Centers for Medicare and Medicaid Services, & US Department of Health and Human Services. (2001). HCFA Common Procedure Coding System (HCPCS) 2001. *Springfield (VA): US Department of Commerce, editor. National Technical Information Service*.

Chen, C., Hanson, M., Chaturvedi, R., Mattke, S., Hillestad, R., & Liu, H. H. (2018). Economic benefits of microprocessor controlled prosthetic knees: a modeling study. *Journal of neuroengineering and rehabilitation*, *15*(1), 62.

Cho, N., Shaw, J. E., Karuranga, S., Huang, Y., da Rocha Fernandes, J. D., Ohlrogge, A. W., & Malanda, B. (2018). IDF Diabetes Atlas: Global estimates of diabetes prevalence for 2017 and projections for 2045. *Diabetes research and clinical practice*, *138*, 271-281.

Copeling, N., & Jooste, K. (2020). A spotlight on the surfacing of self-management of employees with diabetes seen by professional nurses in selected occupational health clinics in Cape Town. *Health SA Gesondheid*, *25*.

Cutti, A. G., Lettieri, E., Del Maestro, M., Radaelli, G., Luchetti, M., Verni, G., & Masella, C. (2017). Stratified cost-utility analysis of C-leg versus mechanical knees: findings from an Italian sample of transfemoral amputees. *Prosthetics and orthotics international*, *41*(3), 227-236.

Dakin, H., Devlin, N., Feng, Y., Rice, N., O'Neill, P., & Parkin, D. (2015). The influence of cost-effectiveness and other factors on nice decisions. *Health economics*, *24*(10), 1256-1271.

de Laat, F. A., Roorda, L. D., Geertzen, J. H., & Rommers, C. (2020). Test–retest reliability of the special interest group on amputation medicine/Dutch working group on amputations and prosthetics mobility scale, in persons wearing a prosthesis after a lower-limb amputation. Disability and rehabilitation, 42(12), 1762-1766.

Drummond, M.F., O'Brien, B.J., Stoddart, G.L., Torrance, G.W.: Methods for the Economic Evaluation of Health Care Programmes, 2nd edn. Oxford University Press, Oxford (1997)

Eichler, H.G., Kong, S.X., Gerth, W.C., Mavros, P., Jo¨nsson, B.: Use of cost-effectiveness analysis in health-care resource allocation decision-making: how are cost-effectiveness thresholds expected to emerge? Value Health 7, 518–528 (2004)

Esposito, E. R., & Wilken, J. M. (2014). The relationship between pelvis–trunk coordination and low back pain in individuals with transfemoral amputations. *Gait & posture*, *40*(4), 640-646.

Ferreira, A. E., PONCES FREIRE, A. M., & Voit, E. O. (2003). A quantitative model of the generation of N∈-(carboxymethyl) lysine in the Maillard reaction between collagen and glucose. *Biochemical Journal*, *376*(1), 109-121.

Fugl-Meyer, A. R., Eklund, M., & Fugl-Meyer, K. S. (1991). Vocational rehabilitation in northern Sweden. III. Aspects of life satisfaction. *Scandinavian journal of rehabilitation medicine*, *23*(2), 83-87.

Gan, M. J., Albanese-O'Neill, A., & Haller, M. J. (2012). Type 1 diabetes: current concepts in epidemiology, pathophysiology, clinical care, and research. *Current problems in pediatric and adolescent health care*, *42*(10), 269-291.

Geertzen JHB, Rietman JS. 2018 Amputatie en prothesiologie van de onderste extremiteit (3e druk) Assen, Nederland: Uitgeverij Koninklijke van Gorcum

Gerzeli, S., Torbica, A., & Fattore, G. (2009). Cost utility analysis of knee prosthesis with complete microprocessor control (C-leg) compared with mechanical technology in trans-femoral amputees. *The European Journal of Health Economics*, *10*(1), 47-55.

GIPdatabank (Zorginstituut Nederland). (2021, May 19). Assessed from https://www.gipdatabank.nl/databank?infotype=h&label=00-totaal&tabel_h_00-totaal=B_03-lftgesl&geg=gebr&spec=&item=J02 at May 26, 2021.

Grimmer M, Seyfarth A. Mimicking human-like leg function in prosthetic limbs. In: Neuro-robotics: from brain machine interfaces to rehabilitation robotics. Berlin: Springer; 2014.

Hafner, B. J., Willingham, L. L., Buell, N. C., Allyn, K. J., & Smith, D. G. (2007). Evaluation of function, performance, and preference as transfemoral amputees transition from mechanical to microprocessor control of the prosthetic knee. *Archives of physical medicine and rehabilitation*, *88*(2), 207-217.

Hameed, M., & Dorfman, H. (2011, February). Primary malignant bone tumors—recent developments. In *Seminars in diagnostic pathology* (Vol. 28, No. 1, pp. 86-101). WB Saunders.

Hargrove, L. J., Simon, A. M., Lipschutz, R., Finucane, S. B., & Kuiken, T. A. (2013). Non-weight-bearing neural control of a powered transfemoral prosthesis. *Journal of neuroengineering and rehabilitation*, *10*(1), 62.

Herr, H. M., Wilkenfeld, A., & Bleck, O. (2003). *U.S. Patent No. 6,610,101*. Washington, DC: U.S. Patent and Trademark Office.

Highsmith, M. J., Kahle, J. T., Bongiorni, D. R., Sutton, B. S., Groer, S., & Kaufman, K. R. (2010). Safety, energy efficiency, and cost efficacy of the C-Leg for transfemoral amputees: a review of the literature. *Prosthetics and orthotics international*, *34*(4), 362-377.

Horgan, O., & MacLachlan, M. (2004). Psychosocial adjustment to lower-limb amputation: a review. *Disability and rehabilitation*, *26*(14-15), 837-850.

Hussain, S., Shams, S., & Khan, S. J. (2019). Impact of Medical Advancement: Prostheses. In *Computer Architecture in Industrial, Biomechanical and Biomedical Engineering*. IntechOpen.

Johannesson, A., Larsson, G. U., Ramstrand, N., Turkiewicz, A., Wiréhn, A. B., & Atroshi, I. (2009). Incidence of lower-limb amputation in the diabetic and nondiabetic general population: a 10-year population-based cohort study of initial unilateral and contralateral amputations and reamputations. *Diabetes care*, *32*(2), 275-280.

Kahn, S. E., Cooper, M. E., & Del Prato, S. (2014). Pathophysiology and treatment of type 2 diabetes: perspectives on the past, present, and future. *The Lancet*, *383*(9922), 1068-1083.

Kaufman, K. R., Levine, J. A., Brey, R. H., McCrady, S. K., Padgett, D. J., & Joyner, M. J. (2008). Energy expenditure and activity of transfemoral amputees using mechanical and microprocessor-controlled prosthetic knees. *Archives of physical medicine and rehabilitation*, *89*(7), 1380-1385.

Kingsley, J. (2020, September 20st). Prosthetic Knee Options. Assessed at January 28th 2021, from https://www.scheckandsiress.com/patient-information/care-and-use-of-your-device/prosthetic-knee-options/

Klein M.J., Siegal G.P.: Osteosarcoma: anatomic and histologic variants. Am J Clin Pathol 2006; 125: pp. 555-581

Lavery, L. A., Higgins, K. R., Lanctot, D. R., Constantinides, G. P., Zamorano, R. G., Athanasiou, K. A., ... & Agrawal, C. M. (2007). Preventing diabetic foot ulcer recurrence in high-risk patients: use of temperature monitoring as a self-assessment tool. *Diabetes care*, *30*(1), 14-20.

Lavigne, J. E., Phelps, C. E., Mushlin, A., & Lednar, W. M. (2003). Reductions in individual work productivity associated with type 2 diabetes mellitus. *Pharmacoeconomics*, *21*(15), 1123-1134.

Lawson, B. E., Varol, H. A., Huff, A., Erdemir, E., & Goldfarb, M. (2012). Control of stair ascent and descent with a powered transfemoral prosthesis. *IEEE Transactions on Neural Systems and Rehabilitation Engineering*, *21*(3), 466-473.

Ledoux, E. D., & Goldfarb, M. (2017). Control and evaluation of a powered transfemoral prosthesis for stair ascent. *IEEE Transactions on Neural Systems and Rehabilitation Engineering*, *25*(7), 917-924.

Legro, M. W., Reiber, G. D., Smith, D. G., del Aguila, M., Larsen, J., & Boone, D. (1998). Prosthesis evaluation questionnaire for persons with lower limb amputations: assessing prosthesis-related quality of life. *Archives of physical medicine and rehabilitation*, *79*(8), 931-938.

Martinez-Villalpando, E. C., & Herr, H. (2009). Agonist-antagonist active knee prosthesis: a preliminary study in level-ground walking. *Journal of Rehabilitation Research & Development*, *46*(3).

McArdle, W. D., Katch, F. I., & Katch, V. L. (2006). *Essentials of exercise physiology*. Lippincott Williams & Wilkins.

Michael, J. W. (1999). Modern prosthetic knee mechanisms. *Clinical Orthopaedics and Related Research®*, *361*, 39-47.

Mobasseri, M., Shirmohammadi, M., Amiri, T., Vahed, N., Fard, H. H., & Ghojazadeh, M. (2020). Prevalence and incidence of type 1 diabetes in the world: a systematic review and meta-analysis. *Health promotion perspectives*, *10*(2), 98.

Mundell, B., Maradit Kremers, H., Visscher, S., Hoppe, K., & Kaufman, K. (2017). Direct medical costs of accidental falls for adults with transfemoral amputations. *Prosthetics and orthotics international*, *41*(6), 564-570.

Neumann, P. J., & Greenberg, D. (2009). Is the United States ready for QALYs?. *Health Affairs*, *28*(5), 1366-1371.

Pirker, W., & Katzenschlager, R. (2017). Gait disorders in adults and the elderly. *Wiener Klinische Wochenschrift*, *129*(3), 81-95.

Pitocco, D., Zaccardi, F., Di Stasio, E., Romitelli, F., Santini, S. A., Zuppi, C., & Ghirlanda, G. (2010). Oxidative stress, nitric oxide, and diabetes. *The review of diabetic studies: RDS*, *7*(1), 15.

Prinsen, E. C. (2016). Adapting to change: influence of a microprocessor-controlled prosthetic knee on gait adaptations.

Rabin, R., & Charro, F. D. (2001). EQ-SD: a measure of health status from the EuroQol Group. *Annals of medicine*, *33*(5), 337-343.

Ragnarsson, K. T., & Thomas, D. C. (2000). Principles of cancer rehabilitation medicine. In *Holland-Frei Cancer Medicine. 5th edition*. BC Decker.

Roberts, K. (2019). The Role of Positivity: Physical and Mental Aspects of Lower Limb Amputation Due to Diabetes.

Rommers, G. M., Vos, L. D. W., Groothoff, J. W., Schuiling, C. H., & Eisma, W. H. (1997). Epidemiology of lower limb amputees in the north of The Netherlands: aetiology, discharge destination and prosthetic use. *Prosthetics and Orthotics International*, *21*(2), 92-99.

Ryall, N. H., Eyres, S. B., Neumann, V. C., Bhakta, B. B., & Tennant, A. (2003). The SIGAM mobility grades: a new population-specific measure for lower limb amputees. Disability and rehabilitation, 25(15), 833-844.

Samuelsson, K. A., Töytäri, O., Salminen, A. L., & Brandt, Å. (2012). Effects of lower limb prosthesis on activity, participation, and quality of life: a systematic review. *Prosthetics and orthotics international*, *36*(2), 145-158.

Sawers, A. B., & Hafner, B. J. (2013). Outcomes associated with the use of microprocessor-controlled prosthetic knees among individuals with unilateral transfemoral limb loss: a systematic review. *JPO: Journal of Prosthetics and Orthotics*, *25*(4S), P4-P40.

Schoppen, T., Boonstra, A., Groothoff, J. W., de Vries, J., Göeken, L. N., & Eisma, W. H. (2001). Employment status, job characteristics, and work-related health experience of people with a lower

limb amputation in The Netherlands. *Archives of physical medicine and rehabilitation*, *82*(2), 239-245.

Schoppen, T., Boonstra, A., Groothoff, J. W., van Sonderen, E., Göeken, L. N., & Eisma, W. H. (2001). Factors related to successful job reintegration of people with a lower limb amputation. *Archives of physical medicine and rehabilitation*, *82*(10), 1425-1431.

Seelen, H. A., Hemmen, B., Schmeets, A. J., Ament, A. J. H. A., & Evers, S. M. A. A. (2009). Costs and consequences of a prosthesis with an electronically stance and swing phase controlled knee joint. *Technology and Disability*, *21*(1-2), 25-34.

Seymour, R., Engbretson, B., Kott, K., Ordway, N., Brooks, G., Crannell, J., ... & Wheeler, K. (2007). Comparison between the C-leg® microprocessor-controlled prosthetic knee and non-microprocessor control prosthetic knees: a preliminary study of energy expenditure, obstacle course performance, and quality of life survey. *Prosthetics and orthotics international*, *31*(1), 51-61.

Steed, D. L., Attinger, C., Brem, H., Colaizzi, T., Crossland, M., Franz, M., ... & Wiersma-Bryant, L. (2008). Guidelines for the prevention of diabetic ulcers.

Stuckey, R., Draganovic, P., Ullah, M. M., Fossey, E., & Dillon, M. P. (2020). Barriers and facilitators to work participation for persons with lower limb amputations in Bangladesh following prosthetic rehabilitation. *Prosthetics and Orthotics International*, *44*(5), 279-289.

Surgery to remove a limb (amputation). (2017, December 04). Retrieved February 15, 2021, from https://www.cancerresearchuk.org/about-cancer/bone-cancer/treatment/surgery/surgery-remove-limb-amputation

Tengs, T. O. (2004). Cost-effectiveness versus cost–utility analysis of interventions for cancer: does adjusting for health-related quality of life really matter?. *Value in Health*, *7*(1), 70-78.

Theeven, P. J., Hemmen, B., Brink, P. R., Smeets, R. J., & Seelen, H. A. (2013). Measures and procedures utilized to determine the added value of microprocessor-controlled prosthetic knee joints: a systematic review. *BMC musculoskeletal disorders*, *14*(1), 333.

Theeven, P. J., Hemmen, B., Geers, R. P., Smeets, R. J., Brink, P. R., & Seelen, H. A. (2012). Influence of advanced prosthetic knee joints on perceived performance and everyday life activity level of low-functional persons with a transfemoral amputation or knee disarticulation. *Journal of rehabilitation medicine*, *44*(5), 454-461.

Theeven, P., Hemmen, B., Rings, F., Meys, G., Brink, P., Smeets, R., & Seelen, H. (2011). Functional added value of microprocessor–controlled prosthetic knee joints in daily life performance of Medicare functional classification level–2 amputees. *Journal of rehabilitation medicine*, *43*(10), 906-915.

Tunceli, K., Bradley, C. J., Nerenz, D., Williams, L. K., Pladevall, M., & Lafata, J. E. (2005). The impact of diabetes on employment and work productivity. *Diabetes care*, *28*(11), 2662-2667.

Wilkenfeld, A., & Herr, H. (2000). An auto-adaptive external knee prosthesis. *Artificial Intelligence Laboratory, MIT*, 1-3.

Windrich, M., Grimmer, M., Christ, O., Rinderknecht, S., & Beckerle, P. (2016). Active lower limb prosthetics: a systematic review of design issues and solutions. *Biomedical engineering online*, *15*(3), 140.

Yoon, J. W., & Jun, H. S. (2005). Autoimmune destruction of pancreatic β cells. *American journal of therapeutics*, *12*(6), 580-591.

Appendix 1: questionnaire

Doelmatige zorg van beenprothesen

Toestemmingsformulier en vragenlijst

Deelnemerscode: ……..

Deze vragenlijst is gebaseerd op de iMTA PCQ en iMTA MCQ. De iPCQ en iMCQ zijn in 2013 ontwikkeld door de Productivity and Health Research Group, bestaande uit Drs C Bouwmans, Dr L Hakkaart-van Roijen, Dr M Koopmanschap, Dr M Krol, Prof dr H Severens en Prof dr W Brouwer.

Deel A: Toestemmingsformulier deelnemer

- Ik heb de informatiebrief gelezen. Ook kon ik vragen stellen. Mijn vragen zijn voldoende beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe.
- Ik weet dat meedoen vrijwillig is. Ook weet ik dat ik op ieder moment kan beslissen om toch niet mee te doen of te stoppen met het onderzoek. Daarvoor hoef ik geen reden te geven.
- Ik geef toestemming voor het opvragen van informatie bij mijn specialist(en), instrumentmaker en eventueel andere betrokken behandelaars over alle zorg gerelateerd aan mijn amputatie en beenprotheses, inclusief de PPP-documentatie (PPP = Prothese Prescriptie Protocol).
- Ik weet dat sommige mensen mijn gegevens kunnen inzien. Die mensen staan vermeld in deze informatiebrief.
- Ik geef toestemming voor het verzamelen en gebruiken van mijn gegevens op de manier en voor de doelen die in de informatiebrief staan.
- Ik geef toestemming om mijn gegevens op de onderzoekslocatie nog 15 jaar na dit onderzoek te bewaren.
- Ik geef ☐ **wel**
  ☐ **geen** toestemming om mijn gegevens te gebruiken voor eventueel toekomstig onderzoek, zoals in de informatiebrief staat.
- Ik wil meedoen aan dit onderzoek.

Naam deelnemer:

Handtekening: Datum:____ /_____/_____

Deel B: Vragenlijst

Lees dit alstublieft eerst!

Voor wie is deze vragenlijst?
Deze vragenlijst is voor u. Er zijn verschillende mogelijkheden:

- U heeft de lijst in het ziekenhuis gekregen.
- U heeft de lijst per post gekregen en uw naam staat op de envelop.

Kunt u de lijst niet zelf invullen?
Als u de lijst niet zelf kunt invullen, kan iemand u misschien helpen. Bijvoorbeeld een familielid.

Waar gaat de vragenlijst over?
De vragenlijst gaat over uw gezondheid, werk en zorggebruik in de eerste zes maanden dat u uw huidige prothese gebruikte. We beginnen met algemene vragen. Bijvoorbeeld over uw geslacht en leeftijd.

Hoe lang duurt het om de lijst in te vullen?
Het duurt ongeveer 30 minuten om de lijst in te vullen.

Hoe moet u de lijst invullen?

- Begin bij de eerste vraag en volg de nummering.
- Kruis voor iedere vraag 1 hokje aan, behalve als er bij de vraag staat dat u meer dan 1 hokje mag aankruisen.
- Bij sommige vragen kunt u een getal of iets anders invullen op de stippellijn.
- U kunt geen foute antwoorden geven.

Wilt u een antwoord veranderen?

- Streep het oude antwoord door.
- Kruis een nieuw antwoord aan.
- Zet een pijl voor het nieuwe antwoord.

☒ ~~oud antwoord~~
→ ☒ nieuw antwoord

Wat gebeurt er met uw antwoorden?
Uw antwoorden worden gebruikt voor onderzoek. Alleen de onderzoekers zien uw antwoorden. Dus niemand anders.
De onderzoekers schrijven uw naam nergens op. En zij vertellen aan niemand dat u aan het onderzoek heeft meegewerkt.

Fijn dat u de lijst voor ons wilt invullen!

Algemene vragen

Vraag A1. Op welke datum vult u deze vragenlijst in?

……../……../.....(dag/maand/jaar)

Vraag A2. Wat is uw leeftijd?

….. jaar

Vraag A3. Wat is uw geslacht?

- ☐ Man
- ☐ Vrouw

Vraag A4. In welke provincie woont u?

……..

Vraag A5. Aan welke kant mist u (een deel van) uw been?

- ☐ Links
- ☐ Rechts
- ☐ Beide

Vraag A6. Mist u (een deel van) uw been sinds uw geboorte of door een amputatie?

- ☐ Sinds geboorte
- ☐ Door amputatie op …..-jarige leeftijd

Vraag A7. Wat is het niveau van uw amputatie of aangeboren defect?

- ☐ Onder de knie (transtibiaal)
- ☐ Door de knie (knie-disarticulatie)
- ☐ Boven de knie (transfemoraal)
- ☐ Anders, namelijk: …….

Vraag A8. Heeft u een prothese met een koker, of heeft u een pin in uw bot (osseointegratie) om de prothese te bevestigen?

- ☐ Prothese met een koker
- ☐ Prothese met osseointegratie (ijzeren pin in bot en door de huid van uw stomp)

Vraag A9. Welk type prothese gebruikt u? *Indien u meerdere protheses heeft, omcirkel dan al deze antwoorden.*

A. Een prothese met een mechanische knie met vaststelling (stijve protheseknie)
B. Een prothese met een vrij bewegende mechanische knie
C. Een prothese met een auto-adaptieve of microprocessor gestuurde knie (bijvoorbeeld een Rheo, Kenevo of C-leg)
D. Een badprothese
E. Een sportprothese
F. Ik gebruik geen prothese
G. Anders, namelijk: …….

Vraag A10. Indien u meerdere protheses heeft, welke gebruikt u het meest?

…..

Vraag A11. Sinds welk jaar gebruikt u uw huidige prothese? *Het gaat om de prothese die u het meest gebruikt.*

……..

Vraag A12. Is de prothese die u nu gebruikt uw eerste prothese of heeft u hiervoor al een andere prothese gebruikt?

- ☐ Dit is de eerste prothese
- ☐ Ik heb hiervoor een andere prothese gebruikt

Deze vragenlijst gaat verder op de volgende pagina.

Vraag A13. Wat is de hoogste opleiding die u heeft afgemaakt? *Zoek uw hoogste opleiding en kruis het hokje daarvoor aan.*

- ☐ Ik heb geen school of opleiding afgemaakt
- ☐ Lagere school of basisschool
- ☐ Huishoudschool, vbo, lbo, lts, leao of lhno

- ☐ Mavo, mulo, ivo of vmbo
- ☐ Mbo, mts, meao, mhno, inas of intas
- ☐ Havo, vwo, hbs, mms, atheneum of gymnasium

- ☐ Hbo, hts, heao of hhno
- ☐ Universiteit
- ☐ Ik heb een andere opleiding afgemaakt, namelijk

  ……..

Vraag A14. Wat doet u in het dagelijks leven? *Kruis aan wat u de meeste tijd doet.*

- ☐ Ik zit op school, ik studeer
- ☐ Ik werk in loondienst
- ☐ Ik ben zelfstandig ondernemer
- ☐ Ik ben huisvrouw, huisman

- ☐ Ik ben werkloos
- ☐ Ik ben arbeidsongeschikt, voor …….%
- ☐ Ik ben met pensioen of prepensioen
- ☐ Ik doe iets anders, namelijk

  ……

Vraag A15. Had u betaald werk gedurende de eerste 6 maanden met uw huidige prothese?

- ☐ Nee
- ☐ Ja

De volgende vragen gaan over uw baan. Dus over werk waarvoor u betaald wordt. Het gaat om de baan die u had gedurende de eerste 6 maanden met uw huidige prothese.
Hebt u geen betaalde baan? Ga dan verder met vraag 10. *Lees eerst de toelichting boven vraag 10.*

Vraag 1. Wat was uw beroep gedurende de eerste 6 maanden dat u uw huidige prothese gebruikte?

.....

Vraag 2. Hoeveel uur per week werkte u gedurende de eerste 6 maanden dat u uw huidige prothese gebruikte? Tel alleen de uren waarvoor u betaald werd.

…… uren

Vraag 3. Hoeveel dagen in de week werkte u gedurende de eerste 6 maanden dat u uw huidige prothese gebruikte?

…… dagen

Vraag 4. Bent u gedurende de eerste 6 maanden dat u uw huidige prothese gebruikte afwezig geweest van uw werk omdat u ziek was? *Het gaat om afwezigheid of een ziekmelding in verband met de prothese of amputatie.*

☐ Nee

☐ Ja, ik heb de volledige 6 maanden niet kunnen werken

☐ Ja, ik ben ongeveer …… dagen afwezig geweest
(Tel alleen de werkdagen in de afgelopen 6 maanden)

Heeft u “Ja” aangekruist? Beantwoord dan vraag 5.
Ga anders verder met vraag 7.

Vraag 5. Was u langer dan 4 weken afwezig van uw werk doordat u ziek was gedurende de eerste 6 maanden dat u uw huidige prothese gebruikte? *Het gaat om een aaneengesloten periode van werkverzuim.*

☐ Nee

☐ Ja

Heeft u ‘’Ja” aangekruist? Beantwoord dan vraag 6.
Ga anders verder met vraag 7.

Vraag 6. Hoe lang bent u ziek geweest? *Het gaat om afwezigheid of een ziekmelding in verband met de prothese of amputatie.*

Ongeveer …… weken

Vraag 7. Waren er in de eerste 6 maanden dat u uw huidige prothese gebruikte dagen waarop u wel gewerkt heeft, maar tijdens uw werk last had van lichamelijke of psychische problemen? *Het gaat om klachten in verband met de prothese of amputatie.*

☐ Nee

☐ Ja

Heeft u ‘’Ja’’ aangekruist? Beantwoord dan vraag 8 en 9.
Ga anders verder met vraag 10. *Lees eerst de toelichting boven vraag 10.*

Vraag 8. Op hoeveel werkdagen had u tijdens uw werk last van uw lichamelijke of psychische problemen? Tel alleen de werkdagen in de gedurende de eerste 6 maanden

Ongeveer …… werkdagen

Vraag 9. Op de dagen dat u last had, kon u misschien niet zoveel werk doen als normaal. Hoeveel werk kon u op deze dagen gemiddeld doen? *Kijk naar de cijfers hieronder. Een 10 betekent dat u op deze dagen net zoveel kon doen als normaal. Een 0 betekent dat u op deze dagen niets kon doen. Zet een cirkel om het goede cijfer.*

Ik kon op deze dagen niets doen				Ik kon onge-veer de helft doen					Ik kon net zoveel doen als normaal
0	1	2	3	4	5	6	7	8	9	10

Toelichting vraag 10 en 11: onbetaald werk
Ook bij onbetaald werk kunt u last hebben van uw lichamelijke of psychische problemen. Soms kunt u daardoor minder doen. U kunt bijvoorbeeld niet goed voor de kinderen zorgen of vrijwilligerswerk doen. Of geen boodschappen doen of in de tuin werken. Daarover gaan de volgende vragen.

Vraag 10. Waren er dagen gedurende de eerste 6 maanden dat u uw huidige prothese gebruikte waarop u minder onbetaald werk kon doen door uw lichamelijke of psychische problemen? Het gaat om problemen die zijn gerelateerd aan uw prothesegebruik gedurende de eerste 6 maanden dat u uw huidige prothese gebruikte

☐ Nee

☐ Ja

Heeft u ‘’Ja’’ aangekruist? Beantwoord dan vraag 11.
Ga anders naar vraag 12.

Vraag 11. Op hoeveel dagen was dit zo? Tel alleen de dagen in de eerste 6 maanden dat u uw huidige prothese gebruikte

…… dagen

Deze vragenlijst gaat verder op de volgende pagina.

Toelichting
Wij willen graag weten met welke dokters u in de eerste 6 maanden dat u uw huidige prothese gebruikte een afspraak had. Het gaat om afspraken voor uzelf. Ook andere zorgverleners tellen mee. Bijvoorbeeld de fysiotherapeut of de orthopedisch instrumentmaker.

Welke afspraken tellen mee?
- Controles
- Afspraken omdat u een lichamelijke of psychische klacht had
- Afspraken waarbij de dokter bij u thuis kwam
- Telefonische afspraken
- Telefoontjes met de receptenlijn

Wat telt niet mee?
- Afspraken voor een ander, bijvoorbeeld voor uw partner of kind
- Telefoontjes om een afspraak te maken

Weet u niet precies hoeveel afspraken het waren? Schrijf dan op hoeveel het er ongeveer waren.

Vraag 12. Heeft u in de eerste 6 maanden dat u uw huidige prothese gebruikte afspraken gehad met de huisarts of praktijkondersteuner? Praktijkondersteuner wordt ook wel POH genoemd.

☐ Geen enkele afspraak

☐ ….. afspraken

Vraag 13. Hoeveel afspraken had u in de eerste 6 maanden dat u uw huidige prothese gebruikte met een maatschappelijk werker?

☐ Geen enkele afspraak

☐ ….. afspraken

Vraag 14. Hoeveel afspraken had u in de eerste 6 maanden dat u uw huidige prothese gebruikte met een orthopedisch instrumentmaker?

☐ Geen enkele afspraak

☐ ….. afspraken

Vraag 15. Hoeveel afspraken had u in de eerste 6 maanden dat u uw huidige prothese gebruikte met een fysiotherapeut? Of met een caesartherapeut, therapeut mensendieck of een manueel therapeut? Het gaat alleen om afspraken buiten het ziekenhuis of revalidatiecentrum. Tel alle afspraken met deze therapeuten bij elkaar op.

☐ Geen enkele afspraak

☐ ….. afspraken

Vraag 16. Hoeveel afspraken had u in de eerste 6 maanden dat u uw huidige prothese gebruikte met een ergotherapeut? Het gaat alleen om afspraken buiten het ziekenhuis of revalidatiecentrum.

☐ Geen enkele afspraak

☐ ….. afspraken

Vraag 17. Hoeveel afspraken had u in de eerste 6 maanden dat u uw huidige prothese gebruikte met een psycholoog? Of met een psychotherapeut of psychiater? Het gaat alleen om afspraken buiten het ziekenhuis of revalidatiecentrum. Tel alle afspraken met deze zorgverleners bij elkaar op.

☐ Geen enkele afspraak

☐ ….. afspraken

Vraag 18. Hoeveel afspraken had u in de eerste 6 maanden dat u uw huidige prothese gebruikte met de bedrijfsarts?

☐ Geen enkele afspraak

☐ ….. afspraken

Deze vragenlijst gaat verder op de volgende pagina.

Vraag 19a. Heeft u in de eerste 6 maanden dat u uw huidige prothese gebruikte hulp van de thuiszorg gehad? *Het gaat hierbij alleen om thuiszorg die u heeft ontvangen in verband met de prothese of amputatie.*

☐ Nee

☐ Ja

Heeft u ‘’Ja’’ aangekruist? Beantwoord dan vraag 19b tot en met 19d.
Ga anders verder met vraag 20.

Vraag 19b. Wat voor hulp van de thuiszorg heeft u gehad in de eerste 6 maanden dat u uw huidige prothese gebruikte?

☐ Huishoudelijke hulp
voorbeeld: stofzuigen, bed opmaken, boodschappen doen

☐ Verzorging van uzelf
voorbeeld: hulp bij douchen of aankleden

☐ Verpleging
voorbeeld: verband omdoen, medicijnen geven, bloeddruk meten

Vraag 19c. Hoeveel weken heeft u deze thuiszorg gehad? Tel alle weken in eerste 6 maanden dat u uw huidige prothese gebruikte bij elkaar op. Let op: een periode van 6 maanden telt 26 weken.

Huishoudelijke hulp:	….. weken
Verzorging van uzelf:	….. weken
Verpleging:	….. weken

Vraag 19d. Hoeveel uur thuiszorg kreeg u in deze weken gemiddeld?

Huishoudelijke hulp:	Gemiddeld ….. uur in de week
Verzorging van uzelf:	Gemiddeld ….. uur in de week
Verpleging:	Gemiddeld ….. uur in de week

Vraag 20a. Heeft u in de eerste 6 maanden dat u uw huidige prothese gebruikte hulp van een familielid of bekende gehad vanwege uw lichamelijke of psychische problemen? *Het gaat hierbij alleen om hulp die u heeft ontvangen in verband met de prothese of amputatie*

☐ Nee

☐ Ja

Heeft u ‘’Ja’’ aangekruist? Beantwoord dan vraag 20b tot en met 20d.
Ga anders verder met vraag 21.

Vraag 20b. Wat voor hulp van familieleden of bekenden heeft u gehad in de afgelopen 6 maanden? *U kunt meer dan 1 hokje aankruisen*

☐ Huishoudelijke hulp
Bijvoorbeeld stofzuigen, bed opmaken, boodschappen doen, klaarmaken van eten en drinken, verzorgen van kinderen

☐ Verzorging van uzelf
Bijvoorbeeld hulp bij douchen of aankleden, hulp bij het eten en drinken of het geven van medicijnen

☐ Praktische hulp
Bijvoorbeeld ondersteuning bij het wandelen, het maken van uitstapjes of bezoekjes aan bekenden, bezoeken aan de huisarts of het ziekenhuis, het regelen van hulp of het regelen van financiële zaken

Vraag 20c. Hoeveel weken heeft u deze hulp ongeveer gehad? Tel alle weken in het afgelopen half jaar bij elkaar op. Let op: een periode van 6 maanden telt 26 weken.

Huishoudelijke hulp:	….. weken in de afgelopen 6 maanden
Verzorging van uzelf:	….. weken in de afgelopen 6 maanden
Praktische hulp:	….. weken in de afgelopen 6 maanden

Vraag 20d. Hoeveel uur hulp kreeg u gemiddeld in deze weken?

Huishoudelijke hulp:	….. uur in de week
Verzorging van uzelf:	….. uur in de week
Praktische hulp:	….. uur in de week

Vraag 21. Heeft u, of hebben uw familieleden, in de eerste 6 maanden dat u uw huidige prothese gebruikte extra geld uitgegeven aan één van de volgende uitgavenposten? *Het gaat om uitgaven in verband met uw beenprothese*

Categorie	**Nee**	**Ja**	**Geschat bedrag (euros)**
Reparaties aan de prothese voor eigen rekening			€
Aanpassingen in huis voor eigen rekening			€
Hulpmiddelen voor eigen rekening			€
Aanpassingen aan vervoersmiddelen voor eigen rekening (auto, fiets, motor)			€
Hulpmiddelen voor het uitvoeren van een hobby/sport voor eigen rekening			€
Anders, namelijk: ……			€

Vraag 22a. Heeft u in de eerste 6 maanden dat u uw huidige prothese gebruikte medicijnen gebruikt? *Het gaat hierbij alleen om medicijnen die u heeft ontvangen in verband met de prothese of amputatie.*

☐ Nee

☐ Ja

Heeft u ‘’Ja’’ aangekruist? Vul dan bij vraag 22b in welke medicijnen en hoeveel.

Vraag 22b. Welke medicijnen heeft u gebruikt in de eerste 6 maanden dat u uw huidige prothese gebruikte? Met medicijnen bedoelen we alle medicijnen die u hebt gekregen op recept en geneesmiddelen die u hebt gekocht bij de apotheek of de drogist. U ziet eerst drie voorbeelden.
Let op: pak de verpakking erbij! Daarop staat hoeveel u per keer moest innemen. En hoe vaak u dat moest doen. ***Heeft u meer of minder gebruikt? Vul dan in hoeveel u ook echt gebruikt heeft.***

Hoe heet het medicijn?	***Hoeveel heeft u per keer ingenomen?*** *Kijk op de verpakking*	***Hoe vaak op een dag heeft u dit gedaan?*** *Kijk op de verpakking*	***Op hoeveel dagen in de afgelopen 6 maanden heeft u het medicijn gebruikt?***
voorbeeld 1 Metoprolol (tegen hoge bloeddruk)	*voorbeeld* 100mg	*voorbeeld* 1 keer	*voorbeeld* 90 dagen
voorbeeld 2 Furosemide (plastabletten)	*voorbeeld* 40mg	*voorbeeld* 1 keer	*voorbeeld* 26 dagen (2x per week; 13 weken)
voorbeeld 3 Hydrocortison crème	*voorbeeld* -	*voorbeeld* 1	*voorbeeld* 14 dagen
……	……	……	……
……	……	……	……
……	……	……	……
……	……	……	……
……	……	……	……
……	……	……	……
……	……	……	……
……	……	……	……

Toelichting
De volgende vragen gaan over de gemaakte kosten in verband met een bezoek aan het ziekenhuis, revalidatiecentrum en instrumentmaker.

Vraag 23. Bij welk revalidatiecentrum bent u bekend voor uw huidige prothese?

- ☐ Universitair Medisch Centrum Groningen / Beatrixoord
- ☐ De Hoogstraat Revalidatie
- ☐ Rijndam Revalidatie
- ☐ Roessingh, Centrum voor Revalidatie
- ☐ Vogellanden, Centrum voor Revalidatie
- ☐ Anders, namelijk ……

Vraag 24. Bij welke instrumentmakerij bent u bekend voor uw huidige prothese?

- ☐ OIM Orthopedie
- ☐ Livit Orthopedie
- ☐ ProReva
- ☐ De Hoogstraat Orthopedietechniek
- ☐ Rijndam Orthopedietechniek
- ☐ Roessingh Revalidatie Techniek
- ☐ Anders, namelijk ……

Vraag 25. Welke wijze van vervoer heeft u gebruikt om van huis naar het ziekenhuis, revalidatiecentrum of de instrumentmaker te gaan?

- ☐ Niet van toepassing
- ☐ Lopend
- ☐ Fiets
- ☐ Auto
- ☐ Rolstoel of scootmobiel
- ☐ Openbaar vervoer
- ☐ Taxi
- ☐ Anders, namelijk ……

Vraag 26. Wat is de enkele reisafstand tussen uw huis en het ziekenhuis, revalidatiecentrum en instrumentmaker?

Ziekenhuis:..... kilometer

Revalidatiecentrum: ..... kilometer

Instrumentmaker: ..... kilometer

Dit was de laatste vraag.

Heeft u vragen of opmerkingen?
Misschien heeft u nog vragen of opmerkingen? Schrijft u deze dan hieronder op.

……

……

……

……

……

……

Wat vragen wij u te doen met de ingevulde vragenlijst?
Stuur de ingevulde vragenlijst en het getekende toestemmingsformulier retour met de bijgevoegde retourenvelop. Een postzegel is niet nodig.

Hartelijk dank!

Appendix 2: results; tables

Table 2: Chi-Square test of prosthesis type and problems (yes/no)

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	1,146[a]	1	,284		
Continuity Correction[b]	,504	1	,478		
Likelihood Ratio	1,145	1	,285		
Fisher's Exact Test				,472	,239
Linear-by-Linear Association	1,111	1	,292		
N of Valid Cases	33				

a. 0 cells (0,0%) have expected count less than 5. The minimum expected count is 5,52.

b. Computed only for a 2x2 table

Table 3: Results of the Mann-Whitney U test on the primary outcome

Test Statistics[a]

	Question 8	Question 9
Mann-Whitney U	116,500	18,500
Wilcoxon W	306,500	54,500
Z	-1,012	-1,123
Asymp. Sig. (2-tailed)	,312	,262
Exact Sig. [2*(1-tailed Sig.)]	,372[b]	,281[b]
Exact Sig. (2-tailed)	,319	,294
Exact Sig. (1-tailed)	,159	,149
Point Probability	,004	,036

a. Grouping Variable: CMK_of_AAK

b. Not corrected for ties.

Table 4: Chi-Square test of prosthesis type and absenteeism from work

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	2,141[a]	1	,143		
Continuity Correction[b]	,851	1	,356		
Likelihood Ratio	2,141	1	,143		
Fisher's Exact Test				,283	,179
Linear-by-Linear Association	2,078	1	,149		
N of Valid Cases	34				

a. 2 cells (50,0%) have expected count less than 5. The minimum expected count is 1,65.

b. Computed only for a 2x2 table

Table 5: Mann-Whitney U test for continued absenteeism (yes/no)

Test Statistics[a]

	Question 5
Mann-Whitney U	20,000
Wilcoxon W	30,000
Z	-,603
Asymp. Sig. (2-tailed)	,546
Exact Sig. [2*(1-tailed Sig.)]	,851[b]
Exact Sig. (2-tailed)	1,000
Exact Sig. (1-tailed)	,733
Point Probability	,733

a. Grouping Variable: CMK_of_AAK

b. Not corrected for ties.