IMPACT OF PROSTHETIC KNEE JOINTS AMONG TRANSFEMORAL AMPUTEES ON FUNCTIONAL OUTCOMES IN SAUDI ARABIA

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ABSTRAK

IMPAK PROSTETIK SENDI LUTUT DI KALANGAN TRANSFEMORAL AMPUT DALAM HASIL KEFUNGSIAN DI SAUDI ARABIA

Program untuk penerima amputasi atau kehilangan anggota kongenital kebanyakannya memerlukan intervensi prostesis. Pemilihan komponen prostesis yang berlainan jenis memberikan hasil pemulihan yang berbeza kepada pengguna. Prostesis transfemoral termasuklah kaki, lutut dan soket. Pemilihan prostetik sendi lutut merupakan elemen yang sangat penting untuk hasil pemulihan. Kajian terhadap impak kawalan mikroprosesor prostetik sendi lutut (MCPK) dan prostetik kawalan bukan mikroprosesor sendi lutut (NMCPK) adalah terhad dan tidak konsisten. Objektif kajian ini bertujuan untuk mengkaji impak penggunaan Genium kawalan mikroprosesor prostetik sendi lutut (MCPK) berbanding prostetik kawalan bukan mikroprosesor sendi lutut (NMCPK) melalui hasil penilaian soal selidik prostetik (PEQ) dan hasil ukuran fungsi keberdikarian. Kajian keratan rentas terhadap 76 peserta amputasi unilateral transfemoral direkrut dan dibahagikan kepada dua kumpulan, kumpulan pertama seramai 38 orang peserta menggunakan Genium kawalan mikroprosesor prostetik sendi lutut (MCPK) dan kumpulan kedua menggunakan prostetik kawalan bukan mikroprosesor sendi lutut-(NMCPK) bersama empat jenis sendi lutut hidraulik 3R80, 3R95, 3R106 dan sendi lutut penuh. Kesemua peserta menjawab soal selidik penilaian prostetik (PEQ) 9 skala: Utiliti (UT), bunyi (SO), penampilan (AP), kesihatan anggota lebihan (RL), kekecewaan (FR), tindak balas yang diterima (PR), bebanan sosial (SB), ambulasi (AM) dan kualiti kehidupan skor ukuran fungsi keberdikarian adalah termasuk penjagaan diri, kawalan sfinkter, kemampuan untuk berpindah dari satu tempat, pergerakkan, pertuturan dan kognitif sosial. PEQ ukuran fungsi keberdikarian adalah selepas temujanji susulan di klinik prostetik melalui skala analog visual (VAS) dan dianalisis dengan SPSS versi ke 23 menggunakan sampel bebas ujian T dan korelasi Pearson. Peserta MCPK menunukkan peningkatan yang signifikan dalam utiliti ($t67.780=2.291$, $P=0.025$), penampilan ($t74=2.097$, $P= 0.039$), ambulasi ($t74= 3.115$, $P=0.003$) dan jumlah permarkahan daripada PEQ ($t74= 0.200$, $P=0.014$). Tiada bukti yang signifikan diperoleh dalam skala PEQ yang lain (kekecewaan, tindak balas yang diterima, kesihatan anggota lebihan, bebanan sosial, bunyi, dan kualiti kehidupan). Pengguna dikalangan dewasa pertengahan (25-40 tahun) MCPK menunjukkan perbezaan yang signifikan pada utiliti ($t42= 2.415$, $P=0.020$), kekecewaan ($t35.872= 2.034$, $P=0.049$), ambulasi ($t42= 3.704$, $P=0.001$) dan jumlah pemarkahan daripada PEQ ($t42= 0.285$, $P=0.012$) berbanding awal dewasa (18-24 tahun) dan akhir dewasa (41-60 tahun). Peserta MCPK yang terlibat dengan amputasi disebabkan penyakit menunjukkan nilai ambulasi yang lebih tinggi ($t19= 3.564$, $P=0.002$) berbanding peserta amputasi yang disebabkan trauma dan kongenital. Semua pemarkahan PEQ menunjukkan nilai yang lebih tinggi kepada pengguna MCPK berbanding NMCPK. Hubungan signifikan yang jelas dilihat antara skala PEQ untuk MCPK kecuali utiliti dengan kekecewaan, bunyi dengan bebanan sosial dan kehidupan perubahan yang mendadak dalam skor ukuran fungsi keberdikarian melalui MCPK dibandingkan dengan NMCPK. Penggunaan MCPK meningkatkan utiliti, penampilan, dan ambulasi peserta. Tiada impak yang signifikan dilaporkan terhadap prostetik bunyi, kesihatan anggota lebihan, tindak balas yang diterima, bebanan sosial dan kehidupan. MCPK meningkatkan nilai kepada jangkaan amputasi transfemoral dalam skala tertentu tetapi bukan secara umum dalam program pemulihan prostetik. Ciri-ciri pemilihan prostetik

sendi lutut dan prosthesis yang dinyatakan oleh badan penyelian kesihatan disokong oleh hasil kajian berdasarkan keperluan pengguna, matlamat yang realistik, dan hasil pemulihan yang boleh dicapai.

ABSTRACT

IMPACT OF PROSTHETIC KNEE JOINTS AMONG TRANSFEMORAL AMPUTEES ON FUNCTIONAL OUTCOMES IN SAUDI ARABIA

Acquired amputation or congenital limb loss rehabilitation program requires mostly prosthesis intervention. Selection of different types of prosthesis components impact the user rehabilitation outcomes. Transfemoral prosthesis includes foot, knee and socket. Prosthetic knee joint selection is a crucial element for rehabilitation outcome. The literature on the impact of microprocessor controlled prosthetic knee joint (MCPK) and non-microprocessor-controlled knee joint (NMCPK) were limited and inconsistent. The objective of this study is to highlight the impact of use of Microprocessor Controlled Prosthetic knee (MCPK) Genium compared to Non microprocessor controlled prosthetic knee (NMCPK) through prosthetic evaluation questionnaire (PEQ) and functional independence measure FIM outcomes. A cross-sectional study with a total of 76 unilateral transfemoral amputees were recruited and allotted into two groups, first group 38 participants using the Microprocessor controlled prosthetic knee MCPK Genium and second group using non-microprocessor controlled prosthetic knee NMCPK with four different types of hydraulic knee joints 3R80, 3R95, 3R106 and total knee joints. All participants answered the Prosthetic Evaluation questionnaire PEQ 9 scales: Utility (UT), Sounds (SO), Appearance (AP), Residual limb health (RL), Frustration (FR), Perceived response (PR), Social burden (SB), Ambulation (AM) and Quality of life /Well-being. FIM score includes self-care, sphincter control, transfer, locomotion, communication, and social cognition. PEQ and FIM were filled after follow-up appointments in Prosthetic clinics analysed with SPSS version 23 using independent sample T test and Pearson correlations. MCPK participants had significant improvement in the utility ($t67.780=2.291$, $P=0.025$), appearance ($t74=2.097$, $P= 0.039$), ambulation ($t74= 3.115$, $P=0.003$) and total score of PEQ ($t74= 0.200$, $P=0.014$). No significant evidence was found in other PEQ scales (frustration, perceived response, residual limb health, social burden, sounds, and quality of life/ well-being). Middle adulthood (25-40 years) users of MCPK had significant difference in Utility ($t 42= 2.415$, $P=0.020$), Frustration ($t35.872= 2.034$, $P=0.049$), ambulation ($t42= 3.704$, $P=0.001$) and total score of PEQ ($t42= 0.285$, $P=0.012$) compared with early adulthood (18-24 years) and late adulthood group (41-60 years). MCPK participants with amputations caused by diseases had significant higher ambulation ($t19= 3.564$, $P=0.002$) compared with traumatic and congenital causes. All scores of PEQ had higher values in MCPK users compared to NMCPK. A strong significant relationship was observed between PEQ scales for MCPK except utility with frustration, Sound with Social burden and Wellbeing. In the FIM score, there were significant improvements with MCPK compared to NMCPK ($t67= 2.09$, $P=0.039$). Using MCPK improved participants' utility, appearance, and ambulation. No significant impact was reported to Prosthetic sound, residual limb, Perceived response, social burden and well-being. MCPK added values to the transfemoral amputee expectations in certain scales but not general during the prosthetic rehabilitation program. Criteria of selection for prosthetic knee joint and Prosthesis claiming from the heath regulatory bodies are supported by the study findings based on the user needs, realistic goal sitting and achievable rehabilitation outcomes.

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APPROVAL

I certify that an Examination Committee has met on ddth mm yyyy to conduct the final examination of Abdallah Mohammad Alzeer, on his thesis entitled 'Impact of Prosthetic Knee Joints Among Transfemoral Amputees on Functional Outcomes in Saudi Arabia' in accordance with the regulations approved by the Senate of Universiti Sultan Zainal Abidin. The Committee recommends that the candidate be awarded the relevant degree, and it has been accepted by the Senate of Universiti Sultan Zainal Abidin as fulfilment of the requirements for the Master of Science. The members of the Examination Committee are as follows:

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DECLARATION BY CANDIDATE

I hereby declare that the thesis is based on my original work except for quotations and citations, which have been duly acknowledged. I also declare that it has not been previously or concurrently submitted for any other degree at Universiti Sultan Zainal Abidin or other Institutions.

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The research conducted and the writing of this thesis was under my supervision.

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LIST OF ABBREVIATIONS

ADL	Activity of daily living
AMP	Amputee mobility predictor
AM	Ambulation
AP	Appearance
BADL	Basic activity of daily living
ESAR	Energy storage and return foot
FIM	Functional independent measure
FR	Frustration
GSE	General Self-Efficacy
IRB	Institutional research board
LCI	Locomotor Capability Index
MFCL	Medicare functional classification level
MCPK	Microprocessor controlled prosthetic knee
MMT	Manual muscle testing
NMCPK	Non-microprocessor controlled prosthetic knee
PEQ	Prosthetic evaluation questionnaire
PFFD	Proximal femoral focal deficiency
PR	Perceived response
QOL	Quality of life
Q-TFA	Questionnaire for persons with a transfemoral amputation
RL	Residual limb
ROM	Range of motion
RTA	Road traffic accidents
SSWS	self-selected walking speed
SB	Social Burden
SBAHC	Sultan bin Abdul-Aziz Humanitarian city
SO	Sounds
TFA	Transfemoral amputation
TUG	Time up and go
UHREC	Universiti Sultan Zain Abidin Human Research Ethics Committee
UniSZA	Universiti Sultan Zain Abidin
UT	Utility
WB	Well-being

CHAPTER 1

INTRODUCTION

Human beings are exposed to loss of their limbs during life activities or treatment plans and being defined as amputees, others were born without limbs. An acquired amputation happens at any age and with different reasons. Amputation procedure was known in history as treatment, penalty, or as war result. Currently, Amputation is a procedure seen in orthopaedic intervention when there is no option to save the limb. Also, a stump revision is commonly seen in orthopaedic interventions mainly with paediatric bone overgrowth. 1.6 million Americans are living with amputations and the number will be doubled in 2050 (Ziegler-Graham et al., 2008). In Saudi Arabia, there are no statistics summarising the disability prevalence and the expected percentage is 3.3% (Bindawas and Vennu, 2018). Amputations are still reported under hospitals and there is no national registration for limb loss and acquired amputation (Shahine et al., 2022; Alshehri et al., 2022).

Amputation rehabilitation is the treatment plan that deals with amputation levels, acquired or absences of limbs (congenital limb loss) to restore functional ability and cosmetics perspectives. Amputation rehabilitation contains a multidisciplinary team approach focusing on the patient. Amputee rehabilitation needs mostly but not always prosthetic intervention.

Amputation procedure is a constructive process that leads to the best stump shape, length, muscle power, bone, tissue, and skin conditions and is free of neuroma (Alkenani et al., 2021). Orthopaedic surgeons involve rehabilitation teams in the level of amputation selection, criteria of pre- and post-surgical intervention management. Design amputation operation is possible when the case is tumour excision, and this

enables the team to have preoperational management and plans. Rehabilitation objectives for future amputation procedures usually include psychological preparation, prosthetic orientation, increasing muscle power for the primal joints from the proposed amputation level and orientation of activity daily living adaptation. Other acquired amputations are not designed like war victims with major limbs injuries and only life saving decisions are considered. Postsurgical management focuses on surgical complications and suture healing.

Amputation rehabilitation program started in limb loss assessment after stump healing. Usually for future prosthetic candidates, it includes pre-prosthetic rehabilitation program, Prosthetic intervention, post-prosthetic rehabilitation program. Conditioning program for non-capable prostheses candidates. Conditioning program covers basic activities of daily living BADL for amputees, Personal hygiene or grooming, dressing, toileting, transferring or ambulation and eating. Wheelchair options and transferring machines are included in the patient/caregiver training program. Most of the candidates enrolled in this program have further complications rather than the amputations like cardiac failure with low ejection fraction.

Prosthetic candidates started their amputation rehabilitation journey by pre-prosthetic rehabilitation program. Goals usually for achieving ADLs, stump volume management, using assistive devices like crutches, canes and walkers and managing the sensitivity of stump. For lower limb amputees, ability to sustain standing and ambulation for unilateral amputees, distal weight bearing for joint disarticulation levels, and improve the muscle power (Maffi, Mulè and Taveggia, 2015). For upper limb amputees, usually the focus includes improving the extracted signals of electromyography EMG to move the articulated joints of the prosthesis.

Prosthetic intervention is providing the compensation for the amputated/absent limb.

Post-prosthetic rehabilitation program goals focus on proper use and safe ADLs during using the prosthesis, adaptation with prosthesis as part of the body. psychological acceptance and committee contribution with the prosthesis (Gohy, 2016).

1.1. Background of the Study:

1.1.1 Amputee Assessment

Amputee assessment requires multidisciplinary team members. Physiatrist, prosthetist, nurse, physiotherapist, occupational therapist, and psychologist are usual attendees. Other members can be called based on the need like orthopaedic surgeon, diabetic educator, or nutrition. Medical history, cause and date of amputation, level of in/dependency, career and lifestyle, and capability of amputation rehabilitation is reviewed with the team. Clinical assessment includes stump clinical examinations: skin condition, suture lines, ability to tolerate the touch and load, history of skin grafts, skin colour, hair, and dryness. Muscle power and range of motion ROM of proximal joint if applicable. Stump length for bone and tissue. Neuroma or any hypersensitivity. Stump pain, phantom sensation, and phantom pain.

Sound side condition, nails and skin condition, joints range of motion ROM, Muscle power. Rehabilitation history and patient expectation. Prosthetist role is to assess the ability of the best prosthesis option to restore the lost function, cosmetic appearance, and ability to use the recommendation in activity of daily living ADL. Prostheses options usually contain the socket design which will be the attachment part between the prosthesis and the body (suspension place), force interaction, control of prosthesis and the place of coverage for the amputation or limb absence. Stump clinical examinations outcomes:

a. Stump shape (conical, cylindrical, bulbous, or irregular) and length of cut bone and tissue.

b. Skin condition for suture's healing, sensitivity condition, scar, any other skin issues.

c. Soft tissue condition like floppy tissue.

d. Stump muscles condition through manual muscle testing MMT.

e. Bone condition, distal bone condition and ability of distal bearing on the stump.

f. Nerve condition, Neuroma or tolerant of forces on the tissue.

g. Functional range of motion ROM and contractures of all proximal joints if applicable.

h. Pain management, stump pain, phantom pain, and phantom sensation.

i. Edema and usage of stump shrinkers.

j. Mental and psychological conditions.

k. Combination of other amputation or deformities.

Previous history of used devices is also an important part in the coming future components selection and prosthesis suspension (Sansam et al., 2014).

1.1.2 Level of Amputations

Amputation levels can be transverse or longitudinal. Usual transverse amputation named through the major bone has the amputation, like transtibial or transfemoral amputations, shows the level of transverse level of amputation. Longitudinal amputations are named based on the absence or removed bone, like Longitudinal tibia. Level of amputation usually decides which joint must be replaced by prosthesis (Krajbich et al., 2016) as shown in Figure lower limb amputation levels .1-1 Orthopedics, 202)1).

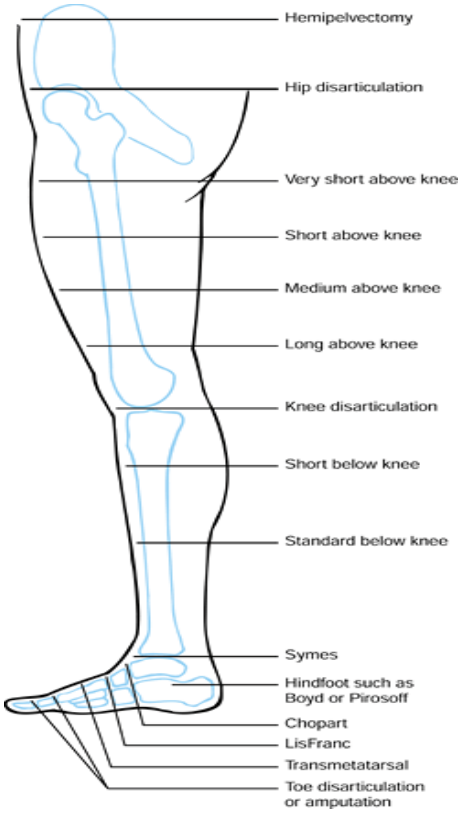

Figure 1.1 lower limb amputation levels)Orthopedics, 2021(

Common transverse lower limb amputation levels (Krajbich et al., 2016):

a. Partial foot amputation: it includes any amputation through the foot segment and usually categorised for transverse amputation as:

1. Forefoot amputation:

Toe amputation for complete or partial phalanges of any toe, usually all named by the distal remaining bone either distal phalanx, middle phalanx or proximal phalanx. Metatarsal disarticulation for the amputation through the metatarsal and phalanges of toes, Transmetatarsal through the metatarsal bones.

2. Lisfranc amputation through the tarsometatarsal articulation services.

3. Chopart amputation for keeping only Calcaneus and Talus tarsal bones.

4. Boyd amputation, Pirigoff/Pirsoff amputation which covered the distal end of Tibia and Fibula by Talus, in Boyd amputation and by distal part of Calcaneus in Pirigoff/Pirsoff.

b. Ankle disarticulation (Symes) amputation: complete removal of the foot.

c. Transtibial (below knee) amputation: partial removal of the Tibial bone with distal tissue and bone, usually divided based on the length of the tibia and reported by distal, middle, proximal third of Tibia.

d. Knee disarticulation amputation: complete removal of Tibia and Fibula bones and tissues without any amputation in femur bone. Most surgeons keep the patella bone.

e. Transfemoral (above knee) amputation, partial removal of femur with all distal tissue and bone. Based on the remaining length of the femur, the reporting for the exact level of amputation.

f. Hip disarticulation amputation: complete removal of the femur and all distal tissues and bone.

g. Hemipelvectomy amputation: partial removal of pelvic and all the lower limb.

Longitudinal amputation is also known as ray amputation and mostly seen with congenital amputation like absence of Fibula with/without lateral tarsal, metatarsal and toes. Another seen indicator for the prosthetic intervention is leg length discrepancies when its more than 5cm. Such as proximal femoral focal deficiency PFFD.

1.1.3 Prosthetic Intervention:

Prosthetist is a member of an amputation rehabilitation team. Main rules focus on providing the prosthetic intervention recommendation, taking measurements of prosthesis, sound side and stump, fabricating, fitting and being involved in training of the amputees.

Prosthesis fabrication is a long process, it takes a few days and weeks in some situations. Fabrication started with casting by Plaster of Paris POP bandaging the stump is the first status which secures the stump shape and volume. Recently special scanners took the shape of a stump and provided the exact details instead of casting. The outcome of this status is known as Negative cast. Plaster power filling for negative cast leads to having the positive cast which will be the same shape and volume of patient stump. Cast rectification to resize the volume and identify the suspension, bearing and offloading areas. Plastic blocking for the trim line of positive rectified cast will make the socket which the patient wears as the first interface between body and prosthesis.

1.1.4 Criteria of Component Selection

Lower limb prosthesis components are categorised based on mobility level, weight category, system heights and control system for articulation parts.

1.1.4.1 Mobility Levels

Medicare Functional Classification Levels K-levels (Borrenpohl, Kaluf and Major, 2016) is classifying the mobility level for lower limb amputees in the Table 1-1 Medicare function classificationlevels K-Levels, fitting, and components design.

Table 1.1 Medicare function classification levels K-Levels, fitting, and components .design

K-Level	Amputee condition	Fitting goals	Design of components
K0	Unable to ambulate or transfer with or without assistance, prosthesis fitting will not enhance the amputee quality of	Cosmetic purposes and no even transferring goals	Very light components, foam covers, slight suspension. Occasional use. Not designed for

	life and not impact the ADL		weight bearing and ambulation.
K1	Has potential to transfer, indoor ambulate and use of prosthesis, in even ground and fixed cadence.	Indoor ambulation and transferring	High safety locking system, light weight, easy use, and less adjustment needs. Daily but limited use.
K2	able to transfer and move with or without prosthesis, early fatigue and cannot tolerate duration of ambulation.	restricted outdoor ambulation, few steps in up/downstairs or uneven grounds.	Safety and ambulation. Exposed to different environments with restrictions of movement.
K3	Able to transfer and move outdoors with assistive devices like crutches and not using a wheelchair for ambulation. Active in community activities.	Ambulation, ability to reach functional activities like job, social, and any out-door activities without restriction	Different cadence, sophisticated components, long term user, ability to have different cadence and walking speeds.
K4	Able to perform sport activities and athletic life.	Special activities like running, high active jumping,	Long distance walking, less energy consumption and active outcome from prosthesis. Special designs to accommodate the uniqueness of the sport requirements like running prosthesis.

K level is usually mentioned to reflect the MCFL

1.1.4.2 Weight Category

It is the maximum weight the prosthesis component tolerates, usually each prosthetic component labelled with its maximum weight limit. Prosthesis weight limit decided based on lowest limit in the component selection. Mostly for paediatrics: 35 KG or 45 KG and for adults 75 KG, 100 KG, 125 KG, and 150 Kg. The user weight should not exceed the limits of the selected components as this impacts the safety of the user and the expected life of the components itself.

1.1.4.3 System Height

It is the minimum distance available from the amputation level to the distal articulation joint, it is only needed with unilateral amputees and can be fixed by different options available from the same component's edition. Usually, challenges of fitting appear during the fitting of long stumps or even short height of users. Proper joint alignment requires consideration of the mechanical pivot of joint matched with sound side pivot joint. Improper consideration also impacts the cosmetics of prosthesis.

1.1.4.4 Suspension and Weight Bearing Design

Prosthetic socket is the container that covers the stump and affords suspension and bearing, force interaction during stance and swing phases. Prosthesis suspension is essential for prosthesis functioning during walking, weak suspension leads for difficulty of foot clearance during swing phase. Prosthesis bearing is the area where the user weight bearing passes through during the stance phase. Comfort prosthesis socket achieved by having a good suspension during swing phase and good bearing areas during stance phase.

Suspension options include silicon liners with shuttle lock, suction suspension, lanyard suspension and magnetic suspension (Gholizadeh et al., 2014). Non silicon liners options include suction direct to skin as seen in transfemoral level of amputation, self-suspension based on anatomical tuberosity or condyles like supracondylar transtibial prosthesis. Last few years a new suspension and bearing system widely used, Osseointegration which includes a metal rod inside the long bone tibia and connects to the prosthetic foot directly in transtibial prosthesis. Such effective force transmission, control of prosthesis and proprioception input for the user, while the stoma is the challenge in such cases (Hobusch et al., 2020).

1.1.4.5 Lower Limb Prosthetic Components Overview:

Lower limb prosthesis components include prosthetic feet, knees, hips, shock absorbers and their connectors. Prosthetic foot: is the replacement of the anatomical foot, usually contains metal connection in the proximal part for assembly purposes. Fore foot usually has toes shape and designed from flexible foam after rolling over line to influence the easy and smooth terminal stance. Hind foot contains the keel part and the heel part, Keel represents the force distribution lines in mid stance phase and the heel is the responsible part for landing and shock absorption.

Prosthetic foot design even has rigid keel (wood) like Solid ankle cushion heel SACH foot or flexible keel like Energy storage and return feet ESAR feet. Sport prosthetic feet like runner feet contain high carbon keels to accommodate the need of long steps and fast reaction of weight in the swing phase. Last few years, Meridiam prosthetic foot released with Microprocessor controlled prosthetic foot to provide higher foot clearance during mid swing phase, up stair function, different heel height selection and relaxed forefoot on floor after sitting for cosmetic purposes (Hahn et al., 2018; Ernst et al., 2022). Prosthetic foot BioM is Powered prosthetic foot with active plantar/dorsiflexion

and can afford easier terminal stance gait, more functional gait cycle and less energy expenditure than other prosthetic feet (Ingraham et al., 2018).

Prosthesis knee joint is the part that will replace and imitate the anatomical knee joint in shape and function. There are more than 220 prosthetic knee joint designs available all over the world, with different shapes, types, prices, functionality, mobility levels, weight categories, external powered, mechanical, hydraulic and pneumatic (Sawers and Hafner, 2013). The prosthetic knee joints are mainly classified according to their control in both stance and swing phases (Krajbich et al., 2016).

Mechanical knee joints are usually controlled by constant friction on the line of articulation with single axis designs, As the prosthetist has the ability to tighten or release the service articulation lines and manage the speed or rotation. Weight activation (loading and unloading) as the main function in this design is lock and unlock the joint based on the user load. This design usually is single axis design lock after heel strike and open in pre-swing phase, it is commonly known design as safety knee joint, it elongates the stance phase duration. Polycentric knee joint is controlled by ground reaction force related to the joint pivot (instantaneous centre of rotation), Alignment of such joints in the sagittal plane is crucial and male alignments may lead to unsafe use for the prosthesis. Manual lock knee is locked kneed and only unlocked by even a cable traction or key unlocking.

Hydraulic and pneumatic joints control flexion/extension via management of the amount of fluid (liquid or air) passing in and out of hydraulic or pneumatic, this function may impact stance phase, swing phase or both. Some of hydraulic/Pneumatic systems are weight activated, poly centric and mono centric knee joints. All these designs are categorised as non-Microprocessor controlled prosthetic knee joints (NMCPK) as all

mentioned designs never have any sensor control or even regulators for gait phases and user activities like sitting, transferring and stair claiming.

Microprocessor Controlled Prosthetic knee (MCPK) is defined as "a system that includes a computer to control a mechanism that senses user-specific needs and adapts to implement variable and complex functions" (Berke and Geil, 2013). Microprocessor controlled Prosthetic Knee MCPK Designs are not powered knees and do not contain any engine to generate movement. MPCK only controls and manages gait phases during amputee walking through controlling the hydraulic unit based on the measurements from the sensors on the tube, and the knee joint. Some MCPK control stance phases only like Compact C-Leg, from Ottobock company. Other types from MCPK control swing phase only such as Smart IP from Endolite company. C-leg from Otto Bock and Rheo Knee from Ossur control both stance and swing phases. Genium and X3 are MCPK for both stance and swing phases from Ottobock, both have six sensors to control the degree of flexion/extension, torque resistance and toe, heel loads. Different additional modes can be programmed like cycling mode. Easy programming and software alignment recommendation is most advantageous for prosthetist, with sensors, the software guide for proper alignment in flexion/extension foot and knee, measures shear forces between the shoe (prosthetic foot) and floor, also measures load bearing in the prosthetic side (Thibaut et al., 2022). MCPK are heavy in general due to batteries, hydraulic unit, and smart chips, and long system height which sometimes does not fit some short users with long stumps. Only adult size is available, and it is too bulky for early teenager amputees. These are very expensive knee joints with only seven years of expected life. Mobility users are outdoor unrestricted and highly active, while in 2015 a new MCPK joint KENEVO was launched for elderly patients with limited mobility.

Powered prosthetic knee joints afford active knee extension and flexion, usually such prosthetic knee designs are still limited in use and rarely reported in article reviews.

Prosthetic hip design is even mechanical joints and controlled either through load line alignment or lock joint, or Polycentric hip joints with hydraulic units and used mainly with MCPK joints.

1.1.5 Prosthesis Recommendation in Lower Limb

Partial foot amputation distal to tarsal bones effects are cosmetic more than functional, and it is managed with high-definition silicon to restore shape, colour, hair, and nails of body extension. While other proximal levels of amputation need intensive rehabilitation programs to adapt with new challenges and restore ambulation. Prosthesis recommendation includes socket design to afford the bearing areas and suspension options, Component selection, and cosmetic options. Matching the components based on patients' condition and expected outcome is essential for a successful prosthetic rehabilitation program.

1.1.6 Prosthetic Evaluation Questionnaire PEQ

Self-reported outcome measure used to evaluate the lower limb prosthesis usage. PEQ validated for nine scales: ambulation, appearance, frustration, perceived response, residual limb health, social burden, sounds, utility, and well-being. Patients answered based on visual analogue scale from 0 to 100.

1.1.7 Functional Independence Measure FIM

FIM is an assessment tool used to evaluate the functional status of rehabilitation patients. It includes self-care, sphincter control, transfers, locomotion, communication, and social cognition, with 18 categories both motor and cognition functions. Each

category is rated from 1 to 7 and the total score will be from 18 to 126. Usually, FIM measures the case progression during rehabilitation intervention.

1.2. Transfemoral Amputation

Transfemoral amputation includes partial removal of femur bone with complete distal parts of the limb. Transfemoral amputation TFA is applied mainly with vascular patients when there is insufficient blood supply to distal to the knee joints. Distal femur bone tumour also indicates TFA. Other diseases and injuries may lead to this level of amputation. Proximal femoral focal deficiency PFFD is also treated with prosthetic intervention like TFA when the required height compensation exceeds the sound side prosthetic knee joint height. TFA stump healing and edema management is the process in the early phase after fresh amputation, gradually the patient starts desensitisation for the stump to reduce the hypersensitivity and control the pain. Distal bearing on distal cut femur bone is not possible. Stump shrinkers are usually provided during the preparation period in addition to muscle strengthening. After the patients achieve the pre prosthetic rehabilitation goals in muscle power, range of motion ROM, stump volume control, stump pain, phantom pain and general health condition stable will be ready for prosthetic intervention.

1.2.1 Prosthesis Design

Transfemoral prosthesis contains Prosthetic foot, prosthetic knee, transfemoral socket and metal connectors as essential parts, additional components like foam cover, adapter of rotation, and shock absorber are options. Proximal bearing on Ischial tuberosity bone is the common seen bearing place for transfemoral prosthesis. Socket designs for transfemoral amputees are ischial containment socket ICS, Quadrilateral socket, and Marlo Anatomical Socket MAS. Suspension system, pinlock silicon system for medium

and short stumps and suction system with or without silicon liners and osseointegration suspension direct to the bone. Prosthetic knee joints are the focus attention of this study. Prosthetic feet are usually classified as the same as prosthetic knee joints according to the mobility MFCL (K level) of the amputee.

1.2.2 Prosthesis Cost

Wide range of prosthesis components are available in worldwide markets and different manufacturers are producing their designs. Prices of prosthesis variations based on manufacturer designs, materials, weight, usage, durability, added values like special sport prosthesis, maintenance and programming options, includes microprocessor or not, user preferences like colour or cosmetic options, and safety measures. Average mechanical prosthesis price is 14000 USD, Average Hydraulic Prosthesis price is 22000 USD, and the average microprocessor prosthesis is 100000 USD based on the Saudi Arabia market. There are huge differences in prices between Microprocessor and non-Microprocessor prosthesis due to the price of the prosthetic knee joint. While the difference in the price is high, the added values in the comparison of MCPK to NMCPK is not yet clear enough and supported with the evidenced based practice.

1.3. Problem Statement

Transfemoral Prosthesis contains socket, prosthetic knee, prosthetic foot, metal connectors and cosmetic parts. Prosthetic knee joint is a significant part for the prosthetist during component selection and for the patient during the rehabilitation program journey. Using different options of prosthetic knee joints leads to different outcomes during the amputation rehabilitation program (Palumbo et al., 2022). Studying the impacts of different prosthetic knee joints among transfemoral amputees from user perspective based on the quality-of-life outcome measure is crucial and will

align patient expectation with the prosthesis fitting goals. Patients usually are expecting the impacts of MCPK higher than NMCPK in all their life activities, while not all the challenges of prosthetic usage are related to the prosthetic knee joint options. In This work the comparative between the prosthetic knee joint will highlight the added value of NMCPK and MCPK. Reporting the impact of MCPK and NMCPK were limited and not covering the available options of person served perspectives.

Inconsistency of the outcomes for using MCPK compared to NMCPK during and after rehabilitation program is reported in literature review, the expected value of this comparison is still underreported (Thibaut et al., 2022; Stevens and Wurdeman, 2019). Outcome of use among transfemoral amputees based on their mobility, is reporting the criteria of selection based on the amputee interest and needs. Expected outcome of this work will impact the criteria of prosthetic knee selection. As current clinical practice guidelines have not been formalised in the field (Sedki and Fisher, 2015), lack of significant knowledge in the prosthetic provision (Geertzen et al., 2015). Genium Prosthetic knee joint is MCPK joint launched last decade, the manufacturer claims that the joint is improving the Quality of life and enhance the patient experience, while still many articles recommend further studies to support and approve the effectiveness of use (Thibaut et al., 2022; Mileusnic et al., 2021). This Study will analyse based on clinical outcome measure the effectiveness of using different prosthetic knee joints as MCPK and NMCPK.

1.4. Significance of the Study

Criteria of component selection for prosthetic knee joints usually depends on prosthetists mainly and interdisciplinary rehabilitation members. it affects the outcome

of the prosthetic rehabilitation program. The study will show the effectiveness of using MCPK joints compared to NMCPK on functional outcome based on user perspective.

Importance of the study:

1. Study will report the functional outcome based on different prosthetic knee joints as the prosthetic knee joint type is significant to the patient's fall and quality of life (Palumbo et al., 2022). Using the prosthetic evaluation questionnaire PEQ outcome measure with nine scales: Utility, Sound of prosthesis, Appearance, residual limb, Perceived response, Frustration, Social burden, Ambulation and Wellbeing/Quality of life.
2. Analysing functional outcomes questionnaire enables the rehabilitation team member to design therapy goals and manage the amputee expectations.
3. Enable the prosthetist to understand and decrease the gap of functional restoration between the manufacturer of MCPKs and the prosthesis users. Inconsistency of findings between different articles for the added values of MCPK and NMCPK (Hahn et al., 2021; Thibaut et al., 2022; Howard et al., 2018).
4. The study will highlight the real added values of MCPK usage among the participant population and the equivalent values of NMCPK usage.
5. Study will review the relationship between cause of amputation, age, and gender with functional outcomes.
6. Feedback of the user related to the prosthesis usage is the most common discussion during patient-prosthetist follow ups, patient to patient discussion, studying the quality of life will point directly to the user needs and satisfaction review.
7. Extreme difference in price of MCPK and NMCPK with inconsistent reports of the effectiveness of use on quality of life and functional outcomes.

8. Up to our knowledge, there are no studies reporting quality of life and functional outcomes among Saudi Arabia amputees after their prosthetic fitting.

9. Genium knee joint MCPK has few studies that only reported the impacts of use compared to previously commonly used MCPK like C-leg (Stevens and Wurdeman, 2019). Genium outcome is also under-reported and still needs further studies (Mileusnic et al., 2021).

10. Still there are no guidelines for clinical practice in the criteria of joint selection in most countries and the study will empower the user's perspective for having the best selection (Geertzen et al., 2015; Sedki and Fisher, 2015; Mileusnic et al., 2021).

1.5. Research Question

The study will look for:

1. How is the effectiveness of Microprocessor controlled prosthetic knee joint MCPK impacts the functional outcomes for transfemoral prosthesis users?

2. How is the effectiveness of non-Microprocessor controlled prosthetic knee joint NMCPK impacts the functional outcomes for transfemoral prosthesis users?

3. What is the difference between MCPK and NMCPK impacts in functional outcomes for transfemoral prosthesis users?

4. Is there a relationship between MCPK and NMCPK on functional outcomes subscales of PEQ and FIM?

1.6. Research Objectives

Study will highlight the effectiveness of using MCPK on functional outcome for PEQ subscales: Utility, Sound of prosthesis, Appearance, residual limb, Perceived response, Frustration, Social burden, Ambulation and Wellbeing/Quality of life and FIM

subscales: self-care, sphincter control, transfers, locomotion, communication, and social cognition for transfemoral amputees through:

1. To evaluate the impact of MCPK on functional outcomes for transfemoral prosthesis users.
2. To evaluate the impact of NMCPK on functional outcomes for transfemoral prosthesis users.
3. To compare the impacts of using MCPK and NMCPK on functional outcomes for transfemoral prosthesis users.
4. To review and report the relationship between the outcomes measure subscales PEQ and FIM on MCPK and NMCPK.

Parallel to all mentioned objectives, the study will report the dependent variables like age, gender, cause of amputation, age categories and nationality of the prosthetic users. This will highlight the relationship between the added values based on the dependent variables. The impact of use will be specified based on the dependent variables for PEQ and FIM subscales and totals scores also.

1.7. Research Hypothesis

Null hypothesis: there are no significant associated impacts between using the MCPK or NMCPK among transfemoral prosthesis users on functional outcomes.

Alternative hypothesis: there are significant differences in the impact of using MCPK or NMCPK among transfemoral prosthesis users based on their functional outcomes.

CHAPTER 2

LITERATURE REVIEW

Amputation is a surgical procedure applied when the surgeon cannot save the limb life. Delayed amputation decisions may reach life threatening or higher amputation levels required. In acquired amputation with a privilege of amputation designing like the tumour removal, the level of amputation and the shape of stump can be designed perfectly, while in the war victims' injuries, the life threatening and the urgency of plan of care usually lead to inappropriate stump condition and rehabilitation difficulties. Literature review for amputation is heavily reported and mainly covers the surgical construction procedures, aetiology of amputations and the prevalence of amputations. 1.6 million Americans are living with amputations and the number will be doubled in 2050 (Ziegler-Graham et al., 2008). In Saudi Arabia, there are no statistics summarising the disability prevalence, but the expected percentage is 3.3% (Bindawas and Vennu, 2018). Amputations are still reported under hospitals and there is no national registration for limb loss and acquired amputation (Shahine et al., 2022; Alshehri et al., 2022).

Lifestyle, food habits, and less sport activities are factors that increase the vascular and diabetic diseases in Saudi Arabia. Road traffic accidents RTA are increasing, and leads to more traumatic amputations, mainly with driving cars without considering safety measures like seat belts or speed limits (Alshehri et al., 2022). The first amputation article reporting amputation in Saudi Arabia from 1977 to 1990 mentioned that the Traumatic amputation is the highest cause of amputation (al-Turaiki and al-Falahi, 1993). Current reported studies are showing that the highest cause of amputation

becomes vascular disease amputation (Shahine et al., 2022; Alshehri et al., 2022). The decrease in the percentage of traumatic causes was mostly due to safety awareness and more safety considerations in work environments, and the RTA national plans which stand on the reasons for mentioned change in condition.

Gender reporting showed that the ratio of population of amputation in the studies was 6.1:1 for Male to Female (al-Turaiki and al-Falahi, 1993). Latest study on Sultan Bin Abdulaziz Humanitarian City reported the percentage of male amputees as 75.7 percent (Shahine et al., 2022). Alshehri et al., 2022 also reported the percentage for gender as 75 percent of amputees in the study were males. General summary is showing more male prevalence for amputations, this is mostly because the records in the three previous studies included the amputations reported for rehabilitation facilities only, and not the cases operated with orthopaedic surgeons. Another important factor justifying the gender variations as previously mentioned percentages is trauma based on RTA and work mainly for males, as the female driving was not allowed before 2019 and the culture also is not supporting the women working in industrial jobs which may lead to amputation injuries. Finally, under reporting for disability in general is due to stigma in culture mainly when it comes for females.

Average reported age of amputees in Saudi Arabia was mentioned in (al-Turaiki and al-Falahi, 1993) as 32.5 years old with slightly more for males than female, in same time the Prof. Al-Turaiki mentioned the average age for lower limb amputees is 32.6 years old and the upper limb amputees is 21.8 years old. (Alshehri et al., 2022) reported the average age of the amputees in his study is 45.6±19.9 years old, Gender average age and amputation level average age were not reported. (Shahine et al., 2022) reported average amputee age in the study as 43 years old in general, 45 years old for males and

36 years old for females. Both studies (Shahine et al., 2022; Alshehri et al., 2022) reported that the traumatic cause of amputations is the commonest in the age category more than 20 and less than 40, while the vascular cause of amputation is mainly after 60 years old. (Shahine et al., 2022) reported that congenital amputation is the main cause of amputation seen in the age of 10 years and less. Results of reported studies are showing a clear relationship between the age of amputees and the cause of amputation, and the higher age of males compared to females. Even though Saudi Arabia has a young population, still the average age of amputations is high, this indicates the improvement in the healthcare sector and the better management of medical interventions out of amputations options, mainly with vascular, tumours and even RTA managements. As mentioned earlier, female driving and more involvement of females in the work sector may reduce the differences in age and the average age becomes closer to males.

The main cause of amputations for upper limbs was the trauma with 86.9%, for lower limbs the trauma was 52.9% and the disease was 35.9%, so trauma was the most cause of amputation reported in the study, based on the number of the patients treated in the study sites between 1977 to 1990 with 3210 total amputees (al-Turaiki and al-Falahi, 1993). (Alshehri et al., 2022) reported 412 amputees treated in the study site between 2013 and 2018 with following percentages of the cause of amputation, Trauma 51.5%, Vascular 42.5%, tumour 4.9% and infection 1.2%. The authors reported a breakdown for the trauma causes and confirmed the conclusion that vascular becomes the most cause of amputation. (Shahine et al., 2022) study reported 1409 amputees treated in Sultan Bin Abdulaziz Humanitarian city between 2010 and 2020 with following percentages of cause of amputations, 42.3% vascular, 36.8% trauma, 14.4% congenital, and 6.3% infection. For the gender breakdown of the cause of amputations, 81.8% from

the trauma were males and 18.2% females, vascular males were 80.2% and vascular females were 19.8%, congenital males were 53.4% and congenital females were 46.6% and the infection males were 50.5% and infection females were 40.5%. Cause of amputations in Saudi Arabia has changed in the last decade and currently the reduction in traumatic causes of amputation is raising the disease's cause of amputation percentages mainly with age less than 40 years old.

Level of amputation was reported in (al-Turaiki and al-Falahi, 1993) as the common seen level of amputation is transtibial level of amputation 45.2%, transfemoral 21.6%, trans radial 7.6%, partial hand 4.8% and trans humeral 4.7%. (Alshehri et al., 2022) reported the level of amputation percentages, transtibial 48.8%, trans-femoral 23.3%, partial foot 11.9, partial hand 9.9%, trans humeral 6.8% and trans radial 4.1%. (Shahine et al., 2022) study includes 1409 amputees with the following level of amputation percentages, transtibial 36.5%, transfemoral 30.2%, partial hand 7.2%, trans radial 6.8%, trans humeral 5.3% and partial foot 3.5%. Also the relationship between the level of amputation and cause of amputation was reported with (Shahine et al., 2022) as transtibial level of amputation had 22.6% and transfemoral had 14.1% caused by vascular disease. Trauma had the highest percentage in transfemoral level with 10.9% and then transtibial 9.6%. Congenital cause of amputation in transradial was 2.4%, followed by partial hand 1.8%, and trans-femoral 1.6%.

Prosthetic intervention is rarely reported directly in literature review in Saudi Arabia. One Study reviewed the complications of the surgical interventions (Alkenani et al., 2021). Prosthetic intervention is unique in research in Saudi Arabia and reporting the user functional outcomes is extremely important. The gaps in the literature about the prosthesis appliance in Saudi Arabia is clear and under-reported. Services provision for

prosthetic fitting focuses on providing the best updated technology which provides the best patient experience. This study reviewed the literature related to microprocessor prosthetic joints and their outcomes.

Different prosthetic knee joints have been reviewed in literature, comparing between the design and the impact of use is the usual discussion. Prosthetic knee Joint designs, features and benefits are mentioned by manufacturer but not always supported by user findings. Prosthetic knee joints and components in general are manufactured by biomedical engineers and research centres in the prosthetic companies. Describing the outcomes after fitting is seen by a prosthetist, interdisciplinary team members of amputee speciality program and the patient. Also, some features require the experienced prosthetist or patient's training to handle the designed function, like upstairs function in MCPK. Impact of use for C-leg joints as the first widely used MCPK is widely reported in the literature body.

C-leg is MCPK and used since 1997, many studies compared the C-leg outcomes and the added values of MCPK with NMCPK. While the review of the Genium joint as MCPK versus NMCPK is not yet widely reported (Stevens and Wurdeman, 2019). Varying levels of evidence indicate that the prescription, fitness, and use of different types of MCPK improves the outcomes for individuals with unilateral transfemoral amputees compared to NMCPK (Sawers and Hafner, 2013). Impact of MCPK compared to NMCPK is summarised in the literature review in following findings:

2.1. Gait Symmetry:

As MCPK includes sensors, it can regulate and control different behaviours of hydraulic units during stance and swing phases. Gait labs input was reported in literature review by analysing and comparing between MCPK and NMCPK. Different gait phases are

affected with MCPK patients, increased walking speed on uneven ground, increased self-selected walking speed SSWS and increased knee movement in early stance phase were reported in systematic review (Sawers and Hafner, 2013). Significant improvement in kinetic gait symmetry was reported when the MCPK users were walking in SSWS on level floor (Kaufman, Frittoli and Frigo, 2012). Improvement in gait symmetry following patients' provision with MCPK was reported but not in level of significance (Carse et al., 2021). As well as reduction in the degenerative musculoskeletal changes with farther walking and continuity of using the prosthesis (Kaufman, Frittoli and Frigo, 2012). In comparison between C-leg and Genium, gait analysis for Genium showed more flexion in stance and swing phases (more symmetry) than C-leg (Lura et al., 2015). On the other hand, using MCPK compared to NMCPK significantly improved the walking speed but not clearly the other gait parameters (Lansade et al., 2018; Şen et al., 2020).

Literature review related to gait symmetry highlighted the added values of the MCPK in general, detailed added value on gait cycle based on the exact MCPK designs and mechanism of work is still a gap in the literature body. Prosthetists can program the MCPK by selecting the values for stance and swing phase measure but still the accuracy and the impact of the selected values are theoretical and depend on the patient preferences during the programming phase. Another gap in the literature is that the reported studies are still not exactly selecting the impact per design like studies reporting the C-leg impact of use in gait cycle and comparing the results to other types of MCPK which may not support stance and swing control phases. Reported results of mentioned studies in relation to gait symmetry are showing that the MCPK impacts the physiological gait cycle of the transfemoral amputee, while kinetics and kinematics are still underreported and inconsistent results. The optimum literature reporting for gait

cycle should be based on each prosthetic joint design analysis and creating the relationship of the design and added values. Genium software programming enables the prosthetist to program resistance of flexion and maximum knee flexion on terminal stance, these values in addition to the patient weight will regulate the stance and swing performance based on the toe and heel loads and the load line in relation to ground reaction load line. If the selected values do not match the patients, or the program is not functioning properly, the patient gait will not be optimised as expected. MCPK prosthesis users may suffer in their gait from other factors not related to the prosthetic knee joint itself, like socket borders, prosthesis is short or long, or the patient had pain in the distal femur bone. Such issues should be clarified as part of the study when reporting the gait measure for comparison between any two prosthetic joints.

2.2. Oxygen Consumption and Energy Expenditure:

Oxygen consumption measurement will indicate the spent energy during walking with the prosthesis. Different energy expenditures explain the efficiency of prosthetic knee joint. Using MCPK as C-leg compared to NMCPK significantly decreases the oxygen consumption (Seymour et al., 2007). An increment of energy efficiency occurs when using MCPK as C-Leg (Highsmith et al., 2010), and reduction in oxygen consumption happens at self-selected walking speed SSWS (Sawers and Hafner, 2013). A study showed significant increase in physical activities related to energy expenditure levels in participants using MCPK in a free-living environment (Kaufman et al., 2008), while the same study found there is no significant difference in energy efficiency with walking. There are no comparisons directly reporting the fatigue of users. Most reported comparisons for different levels of brain cortex occupancy during walking and the

impact of more brain usage during walking with NMCPK highlight the user's mental fatigue (Möller et al., 2018; Möller et al., 2019).

MCPK as C-leg was reported in earlier studies in relation to energy expenditure by reviewing the oxygen consumption. Various levels of evidence reported the added values of the C-leg compared to various options of NMCPK. Energy expenditure with Genium knee joints is still underreported in the literature body compared to C-leg or other MCPK joints. Clinical measures for the efficiency of using are also important. Prosthesis users always expect that they can do more with MCPK as the electronic devices add more for them based on the simple understands which are usually reported in the clinic. Fatigue measure in physical ability is important and the current reported studies are based on the oxygen consumption, detailed studies with longer periods of use for prosthesis will highlight the gap in the literature body and create the outcome measure with reference values based on the prosthetic components used in the experimental studies. Mental fatigue is clearly decreased when the patient used MCPK as reported in the literature, this was derived from the sensor setup regulating certain functions for the patient like obstacle function when the prosthesis toes touch the ground in middle swing phase, MCPK will immediately increase the resistance for flexion and the patient may not fall on floor as usually occurs with NMCPK prosthesis users. Mental fatigue is combined with safety measures.

2.3. Physical Activities, Mobility, and Safety:

Using MCPK improves the functional status and mobility level compared to NMCPK (Thibaut et al., 2022; Sawers and Hafner, 2013; Highsmith et al., 2010). Using MCPK compared to NMCPK significantly improves the activity of daily living and physical functions (Şen et al., 2020). Significant effectiveness on increasing safety was reported

with MCPK in uneven floor, stair, and ramps and number of obstacles over time, that was part of the main variation between MCPK and NMCPK (Sawers and Hafner, 2013). Significant improvement on Stair descent score and hill descent time, significant decrease in frequency of stumbles, falls, and frustration with falling was reported in MCPK users (Hafner et al., 2007). Using NMCPK hydraulic/Pneumatic (Fluid) prosthetic knee joints exposes the patients during rehabilitation programmes to more falling than MCPK (Palumbo et al., 2022). Furthermore, increased safety was reported in general (Highsmith et al., 2010; Kaufman, Frittoli and Frigo, 2012). Decrease in the number of steps and time needed to finish the study obstacle course was noted with MCPK compared to NMCPK (Seymour et al., 2007).

A systematic review comparing the outcomes of patients moved from C-Leg to Genium reported improvement in mobility of patients (Mileusnic et al., 2021). In comparison between Genium, C-leg and non-amputees in relation to endurance, balance and flexibility of upper and lower body, the Genium has significant improvement in endurance, balance and flexibility of the body compared to C-leg, while only endurance is significantly lower than non-amputees (Highsmith et al., 2016). There is a relationship between the general self-efficacy and mobility with prosthesis whether the prosthesis is MCPK or NMCPK, there is no significant differences between MCPK and NMCPK in self-efficacy, distance, gait speed and steps (Möller et al., 2019; Möller et al., 2018).

Reported results for MCPK in safety agreed almost with most of the research, as the initial plan to have MCPK in 1997 with Cleg was to improve the safety of users. Other measures were related to increased mobility level and related with the safety measures, like a patient feeling safe to move in uneven grounds so he performs that, while the

prosthetic knee joint may not afford him with more endurance to ambulate better. Still the gap in the literature related to prosthesis knee joint design and the mobility level is not reflected in the outcome measures. Special functions in ambulation are clear as the safety measures and reported falls are clear, like up and down stairs and ramps. Such features are supported by the design of the prosthetic joint and there are additional sensors in the Genium but not in the C-leg joint that enable the prosthesis user to handle the situation of the up and down ramps and stairs. Feeling of ability of the user to ambulate more with MCPK also impact positively the outcome of the prosthesis users which is also detected in self-reported ambulation outcome measures. The importance of studying the physical activities with MCPK is much easier than NMCPK as the joint records all steps and stairs ambulation, there are no studies reporting the performance of the users in their usual life activities based on comparison of same activities. Different outcome measures reviewed different functions in mobility like 6 minutes' walk test, 10-metre walk, time to stand and go, FIM and other outcomes reviewed the self-reported outcome measure in ambulation like PEQ, in general the results are not easily compared to each other. Last gap available is that different prosthesis joints are reported under MCPK with different functions added or removed from the design.

2.4. Low Mobility Levels:

Patients with Medicare functional classification MFCL level 1 and 2 can ambulate indoor and restricted outdoor. Usually, they have low cadence speed. Special MCPK was designed for this mobility level. MFCL 1 and 2 have significantly improved safety related to fall when using MCPK compared to NMCPK (Kaufman, Bernhardt and Symms, 2018; Hahn et al., 2021; Kannenberg, Zacharias and Pröbsting, 2014; Stevens and Wurdeman, 2019). Significant improvement was reported in gait symmetry, safety

and self-reported measures in low ambulation patients using C-Leg as MCPK (Jayaraman et al., 2021). There were no significant differences between MCPK and NMCPK in Quality of life and gait profile score for low mobility patients, while there was improvement with MCPK in mobility, fall and balance confidence in statistical level but not significant (Davie-Smith and Carse, 2021). On the other hand, there was a significant improvement with MCPK Kenevo knee joint compared to NMCPK in quality of life and no change in fall rate for low mobility patients (Lansade et al., 2018).

There was an inconsistency of reported results in the literature review for the added values of MCPK in indoor and restricted outdoor ambulatory. Safety is more needed with such amputees rather than increasing the mobility and activities range. Programming of the joint and proper settings to match the prosthesis users play major points in the added values in the safety, quality of life and performance. The gap in the literature, some of MCPKs are only designed for low mobility and it's compared to others NMCPK or MCPK with higher mobility functions like unrestricted ambulators MCFC K level 3 and 4. Studying low mobility prosthetic impacts are important to be separated as their required attention is different in the scope from the other mobility levels when it comes to weight of the prosthesis, charging time and the elderly age issues.

2.5. Economical and Cost Effectiveness:

Even though MCPK is extremely expensive, mainly Genium, it is still compared with NMCPK, the article reviews showed an increment of economic efficiency when using MCPK (C-Leg) compared to NMCPK (Kuhlmann et al., 2020). While (Chen et al., 2018; Sawers and Hafner, 2013) showed that there was equivalent cost between MCPK and NMCPK. Initial fitting will cost more with MCPK, while the full warranty period

and restoration of function (ability to return to work) will decrease the difference of the cost and make the prediction of cost more efficient, additional studies in the field of cost effectiveness is needed and inclusion of the return values in community should be clearly counted (Donnelley et al., 2021).

Detailed studies are highly recommended in this area as the gap is clear based on the huge price comparison and the different outcomes achieved between MCPK and NMCPK. The condition of the prosthesis user with MCPK and with NMCPK should be analysed based on the time of use, adjustment required and other factors like regular maintenance and programming appointments. Other important points in the cost and return analysis should include the reported failure conditions in the MCPK compared to NMCPK. More sample sizes and different region analysis based on different prosthesis cost countries will add better understanding for the cost analysis of the MCPK usage.

2.6. Quality of Life:

Different studies reviewed the impact of microprocessor controlled prosthetic joints in relation to quality of life (Sawers and Hafner, 2013; Mileusnic et al., 2021; Theeven et al., 2013; Thibaut et al., 2022). Using MCPK improves the quality of life, better life satisfaction and participation in community compared to NMCPK (Burçak et al., 2021). Using MCPK increases personal satisfaction and preference and reduces self-reported cognitive demand (Sawers and Hafner, 2013). Significant increase in preference and satisfaction of users, and decrease difficulty in multitasking were reported while using the MCKP (Hafner et al., 2007). On the other hand, there was no significant difference between MCPK as I-Knee and NMCPK in comfort during walking in self-selected walking speed SSWS (Cao et al., 2018). A systematic review comparing the outcomes

of patients moved from C-Leg to Genium reported improvement in quality of life for patients; additional studies are required to increase the evidence level (Mileusnic et al., 2021). The results of PEQ for the patients transferred from C-leg to Genium reported significant improvements in Perceived Response, Social Burden, Utility, and Well-Being. No differences between C-leg and Genium on Ambulation, Frustration and Residual Limb Health. Physical performance was significantly improved with the Genium compared to C-leg (Highsmith et al., 2014). No significant differences detected between MCPK and NMCPK on social participation, physical role, pain score and mental health (Şen et al., 2020). From a psychological perspective, MCPK improves the patient's perception of vitality and depression symptoms (Şen et al., 2020).

Quality of life was reviewed in literature with different outcome measures, studies adopted subscales from the quality of life outcome measures. Reported quality of life improvement in many studies based on sub scales of the outcome measures, other studies reported only single questions from the outcome measure to cover the quality of life and the prosthetic user feedback. This gap is clearly reflected in the literature review as the reported outcome measures are based on the subscales only and reported as quality of life outcome measures. Another gap is that each quality of life outcome measure includes different subscales to cover different sides of the welling of the prosthesis users, commonly seen that the reported ambulation of PEQ subscale was reported alone or even one question in some studies reported as subscale. Third gap is related to quality of life. It was reported for prosthesis users based on the general outcomes which were designed for general disability of rehabilitation phases, such as sensitive quality of life measures which may not detect the comparison variables and not even reporting the required quality of life changes. Quality of life is an important concept reflecting the prosthesis experience, the PEQ for example is a specialised

outcome measure sensitive for the prosthesis issues and still the results of each subscale add value for the analysis, total score of the outcome measure is not enough to reflect the results. Social participation and the community interaction with prosthesis are also important topics under reported in the literature review, and patients usually show more attention for such issues. Outcome measures related to participation in the community, frustrations, social burden, and depression are affecting the prosthesis user quality of life achievements. MCPK influences the prosthesis users to use their prosthesis in the community more than NMCPK as the feeling of using the advanced developed devices is more recognised.

2.7. Conceptual Framework:

The conceptual framework is in Figure Conceptual Framework .1-2

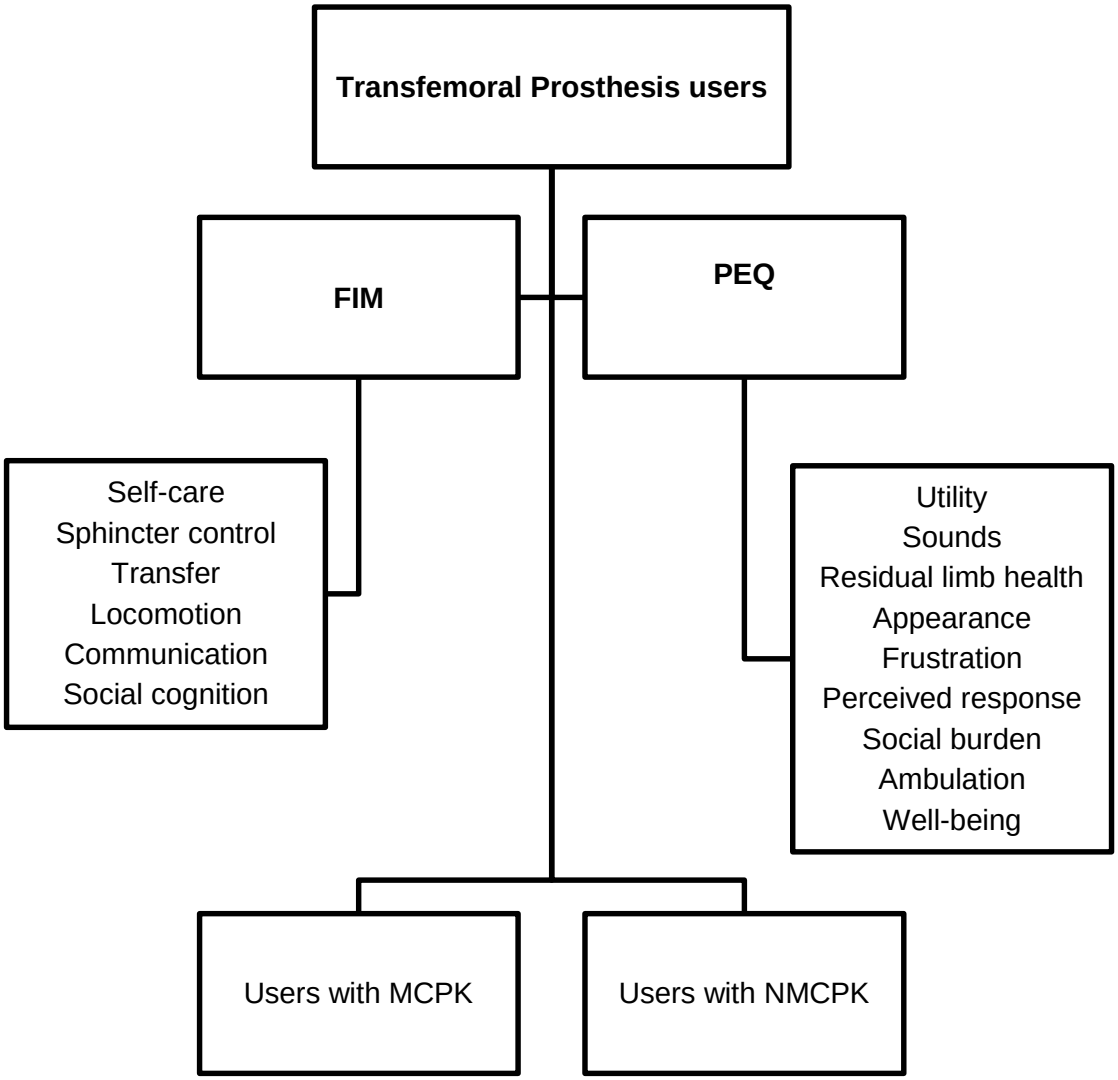

Figure Conceptual Framework .1-2

2.8. Literature Review Summary and Limitations:

Inconsistency of studies' results showed that additional variables should be fixed during studies, like different types of joints which were reported under the same topic as NMCPK including mechanical or hydraulic joints together, all these variables affect the study results. Genium prosthetic knee joint is not yet identified as well as C-leg or other MCPK. The added values in Genium design are still not clear in the participant self-reported information (Thibaut et al., 2022).

Future studies are needed to report the effects of MCPK compared to NMCPK (Thibaut et al., 2022). Inconsistency of findings between studies comparing MCPK and NMCPK (Hahn et al., 2021; Howard et al., 2018). Also, sample size for studies is a challenge mentioned in literature review (Şen et al., 2020). More longitudinal studies are needed to identify the added values for the MCPK (Ramstrand, Rusaw and Möller, 2020). Following Table Literature review sum .1-2mary summarising the literature review findings and limitations based on the study design:

Table 2.1 Literature review summar

Reference	Study design	Prosthetic knee joint	Outcome/ title	Results
(Sawers and Hafner, 2013)	systematic review	Different joints	Gait, energy consumption, QOL	· MCPK Increased walking speed on uneven ground, increased self-selected walking speed SSWS and increased knee movement in early stance phase · Reduction on oxygen consumption at self-selected walking speed SSWS. · Using MCPK increases personal satisfaction and preference and reduces self-reported cognitive demand.
(Kaufman, Frittoli and Frigo, 2012)	Cross sectional study	Mechanical and MCPK	Gait and safety	· MCPK significantly improved kinetic gait symmetry when the MCPK users walk in SSWS on level floor. MCPK reduced the degenerative musculoskeletal changes with farther walking and continuity of using the prosthesis. No change in kinematics. · Increase safety
(Carse et al.,	Retrospective cohort	Pre-Post	Gait	· MCPK significantly improved gait symmetry,

2021) (Davie-Smith and Carse, 2021)				still there are large gaps in studies about the MCPK and people gait cycle. · No significant differences between MCPK and NMCPK in Quality of life and gait profile score for low mobility · Improvement with MCPK in mobility, fall and balance confidence but not in significant level.
(Lura et al., 2015)	RCT	C-leg and Genium	Gait lab (3D) others	· Genium shows more flexion in stance and swing phases (more symmetry) than C-leg. · better stair function
(Lansade et al., 2018; Şen et al., 2020)	RCT	Kenevo	QOL, fall, land Locomotor Capability Index (LCI), time up and go TUG	· MCPK improved the walking speed, but not clearly the other gait parameters. · shorter TUG, better SF36 and better LCI. No differences between falling rate.
(Seymour et al., 2007)		C-Leg and NMCPK		· MCPK as C-leg is significantly decreasing the oxygen consumption. · MCPK decreased in the number of steps and time.
(Highsmith et al., 2010)	Cross sectional	C-leg to Genium	endurance, balance and	· Increment of energy efficiency when using MCPK as C-Leg
(Highsmith et al., 2014; Highsmith et al., 2016)		Genium, C-Leg, able participant	flexibility of upper and lower body, the	· No differences between C-leg and Genium on Ambulation, Frustration and Residual Limb Health, physical performance were significantly improved with the Genium compared to C-leg. · Genium have significant improvement in endurance, balance and flexibility of the body compared to C-leg, while only endurance is

				significantly lower than non-amputees.
(Thibaut et al., 2022)	systematic review	Mechanical, Hydraulic, C-Leg, Genium	Mobility and QOL	· The added values of MCPK are not clear · further studies required for that.
(Şen et al., 2020)	clinical trial	C-leg, Orion, Rheo	LCI SF36	· MCPK significantly improves the activity of daily living and physical functions. · No significant differences detected between MCPK and NMCPK on social participation, physical role, pain score and mental health · From a psychological perspective, MCPK improves the patient's perception vitality and depression symptoms. · Improvement on physical function, not emotional feeling, not including pain, social and mental. Improvement in LCI
(Hafner et al., 2007).	Cross sectional	Mechanical and MCPK	Stair function, ambulation, fall, QOL	· Significant improvement on Stair descent score and hill descent time, significant decrease in frequency of stumbles and falls, frustration with falling · Significant increase preference and satisfaction of users, decrease difficulty in multitasking while using the MCKP.
(Palumbo et al., 2022)	Retrospective	Lock, Mechanical, Hydraulic and MCPK	Safety	Using NMCPK hydraulic/Pneumatic (Fluid) prosthetic knee joints exposed the patients during rehabilitation programmes for more falling than MCPK.

(Mileusnic et al., 2021)	systematic review	Mechanical, Hydraulic, C-Leg, Genium	Mobility, QOL	· Improvement in mobility of patients with MCPK · Improvement in quality of life for patients with MCPK · additional studies are required to increase the evidence level.
(Möller et al., 2019; Möller et al., 2018)	Cross sectional	Cleg, Genium Rheo and VGT	Questionnaire for person with a transfemoral amputation (Q-TFA)	· There is a relationship between the general self-efficacy and mobility with prosthesis whether the prosthesis is MCPK or NMCPK, there is no significant differences between MCPK and NMCPK in self-efficacy, distance, gait speed and steps.
			10 Meter test and 6 minutes' walk and steps	· There is no comparison reported directly for fatigue of users, the reported comparison for different levels of brain cortex occupancy during walking, and the impact of more brain usage during walking with NMCPK highlights the user mental fatigue.
			6 minutes' walk and steps	· no difference reported in GSE and no found difference in Q-TFA.
(Jayaraman et al., 2021).	RCT	C-Leg	Gait, Safety, reported measures	Significant improvement reported in gait symmetry, safety, and self-reported measures in low ambulation patients
(Lansade et al., 2018)	RCT	Kenevo	QOL, fall, land Locomotor Capability Index (LCI), time and go TUG	· There is significant improvement with MCPK Kenevo knee joint compared to NMCPK in quality of life and no change in fall rate for low mobility patients · shorter TUG, better SF36 and better LCI. No differences between falls

				· MCPK improve LCI, less falls on MCPK, improvement on SF36.
(Burçak et al., 2021)	Clinical Trail	Not identified	6 minutes' walking test, SF 36	Using MCPK improves the quality of life, better life satisfaction and participation in community compared to NMCPK. Faster with MCPK
(Cao et al., 2018)	Cross sectional	I-Knee	QOL comfort	No significant difference between MCPK as I-Knee and NMCPK in comfort during walking in self-selected walking speed SSWS.
(Theeven et al., 2013)	Systematic review	Different options	72 outcomes	General evidence of added values is limited.
(Kaufman, Bernhardt and Symms, 2018) (Kaufman et al., 2008)	clinical trial	C-leg compact, Ossur RHEO, Endolite Orion, Freedom innovation Plie 3	gait, special functions sitting and fall. Mobility	· no significant change in gait, better activities with MCPK, less fall with MCPK and less sitting times with MCPK. · Special MCPK designed MFCL 1 and 2 have significantly improved safety related to fall · Significant increase in physical activities related to energy expenditure levels in participants in a free-living environment. · No significant difference in energy efficiency with walking.

CHAPTER 3

METHODOLOGY

3.1. Study Design

This is a hospital based comparative study based on the feedback of patients who had previously been fitted with transfemoral prosthesis. Study focused on the user's feedback as a self-reported response based on prosthesis used last month. The usual discussion during a prosthetist clinic is user experience and the outcome of use. Using different types of prosthetic knee joint is a matter that impacts both prosthetist and patient at the same time (Highsmith et al., 2014). Study compared the different feedback of previously fitted patients with transfemoral prosthesis. Study design is collecting the participants' response to the prosthetic evaluation questionnaire PEQ, and Functional independence measure FIM score.

3.2. Study Location

Prosthetic and Orthotic department, Rehabilitation services and programs, Sultan Bin Abdul Aziz Humanitarian City SBAHC, Riyadh, Kingdom of Saudi Arabia. The study duration is one year.

3.3. Reference Population

Transfemoral adult unilateral amputees fitted and used prosthesis in their daily life activities. Patients following their services in Prosthetic centre, cross sectional study based on patient arrival schedule, up to reach the required number of participants per group.

3.4. Study Participants

Seventy-six Transfemoral prosthesis users met the inclusion criteria. 38 participants were using MCPK joints, while the other 38 participants were using NMCPK with different types: Total 2000/2100 from Ossur manufacturer, 3R60, 3R106, 3R80, and 3R95 from Ottobock manufacturer. All participants got a post prosthetic rehabilitation program, including all different training modalities. Socket fitness was assured to meet the criteria of exclusion. All the participants were on regular follow up in Prosthetist clinics.

3.5. Inclusion and Exclusion Criteria

The criteria for participant selection controlled as following:

3.5.1 Inclusion Criteria

Participant criteria of selection was the following:

1. 18- 60 years old.
2. Medically stable.
3. Intact cognition.
4. Transfemoral Amputees.
5. Prosthesis user for two months or more with proper socket.
6. Arabic speakers (can read and write).
7. Have Genium, or X3 as MCPK or Total 2000/2100, 3R60, 3R106, 3R80, 3R95 as NMCPK.
8. Outdoor ambulatory patients with Medicare functional classification level K 3 and 4 (Borrenpohl, Kaluf and Major, 2016).

3.5.2 Exclusion Criteria

1. Prosthesis users with other amputation or disability.
2. Prosthesis users with weights less than 50KG and more than 150Kg.
3. Pregnant prosthesis users
4. Has prosthesis adjustment for the last two months.

3.6. Sample Size Determination

Based on published studies (Boone and Coleman, 2006) and to assure type 1 error rate of 0.05 and power of analysis as 0.8 and based on the mean of the previous published article (Hafner et al., 2007) for same study design (comparing MCPK with NMCPK) the average mean for the MCPK was 80.44 and the standard deviation is 7.78 and for NMCPK the mean was 74.61 and the standard deviation was 10.52, through the sample size calculation website: Sample Size Calculator (clincalc.com) https://clincalc.com/stats/samplesize.aspx (Kane, 2019). The suggested sample size was 28, the study sample size was 76 transfemoral participants, 38 participants per group.

3.7. Sampling Framework and Methods

Criteria of selection followed the sequence of scheduled patients, any transfemoral prosthetic user matching the criteria of inclusion invited to participate in the study. Based on the used prosthesis the collected data categorised as MCPK and NMCPK.

3.8. Randomization and Blinding

There is no randomization or blinding during participant enrolment, while there are no participants attended to the prosthetic centre and matched the inclusion criteria without requesting to participate in the study, up to having the complete required number.

3.9. Data Collection

Participants signed both a research information sheet and a consent form. Case report forms include all the participants' data. The validated form of PEQ (Legro et al., 1998) by using the Arabic translated form (Day and Buis, 2012) introduced for each participant and answered individually after following up appointments. Extra safety measures have been taken during COVID-19 pandemic to assure less exposure of participants to non-essential medical/ hospital attendance, this led to data collection extension from IRB of SBAHC for additional 4 months. No sampling techniques were used, the sequence of the appointments was followed. After the first group was achieved with 38 MCPK participants, only NMCPK Prosthesis enrolled to reach the second group with 38 participants. For PEQ two participants did not answer completely the frustration and the social burden under condition, sensitive and personal information was requested. Following figures showing the different transfemoral prosthesis types during different gait cycle phases, activities and transfemoral prosthesis fabrication steps.

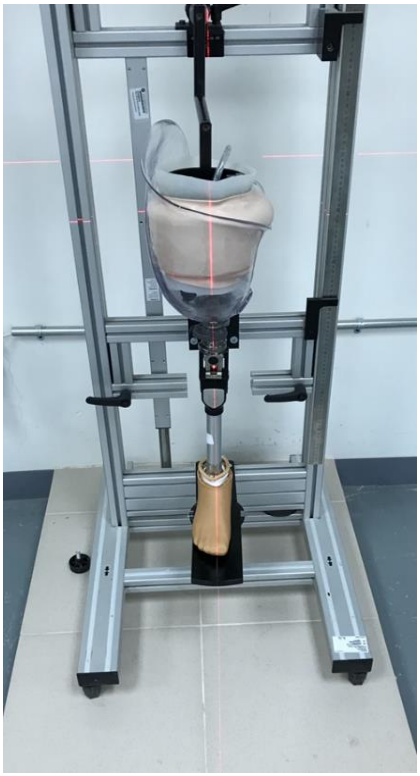

Figure 3.1. Transfemoral prosthesis with Total knee joint during frontal prosthesis assembly

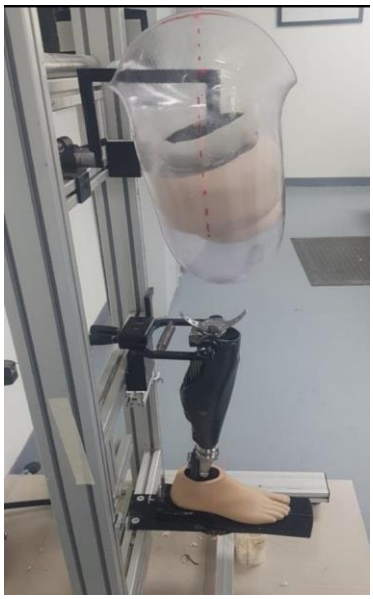

Figure 3.2 Transfemoral prosthesis with Genium knee joint during sagittal prosthesis assembly

Figure 3..3 patient standing on trial transfemoral prosthesis with Genium knee joint

Figure 3.4 Patient on midstance trial transfemoral prosthesis with 3R80 hydraulic knee joint

Figure 3.5 Transfemoral patients using trial hydraulic prosthesis during recreational activities

Figure 3.6 Patient on terminal stance with final transfemoral prosthesis with 3R60 hydraulic knee joint

Figure 3.7 Standing patient with her final transfemoral prosthesis with Total knee joint and half foam cover

Figure 3.8 Patient on terminal stance with final transfemoral prosthesis with Genium knee joint

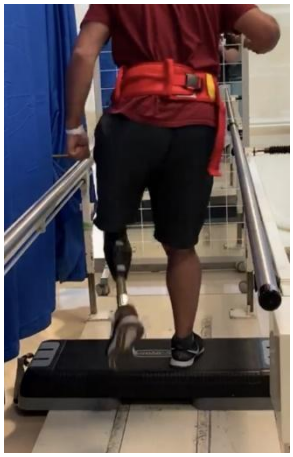

Figure 3.9 Upstairs training for transfemoral prosthesis patient with Genium knee joint

Figure 3.10 Downstairs function on transfemoral prosthesis patient using Genium knee joint

Figure 3.11 Patient standing on final transfemoral prosthesis with Genium knee joint

Figure 3.12 patient walking with his final transfemoral prosthesis after cosmetic foam cover

Figure 3.13 Adjusting the running prosthesis for World champion Heinrich Papow

Figure 3.14 Training on prosthesis types

3.10. Variables under Study

Dependent variables of the study are PEQ and FIM and the independent variables are MCPK, NMCPK, age, gender, cause of amputation and nationality.

3.11. Measurement Tools

Study had two outcome measures:

3.11.1 Prosthetic Evaluation Questionnaire PEQ

This study is a self-reporting study based on validated quality of life Outcome measure questionnaire 'Prosthetic Evaluation Questionnaire' PEQ. PEQ is a quality-of-life outcome measure tool for lower limb prosthesis users. PEQ contains eighty-two questions divided on nine scales (ambulation, appearance, frustration, perceived response, residual limb health, social burden, sounds, utility, and well-being), and other individual questions related to satisfaction, pain, transfer, prosthetic care, self-efficacy, and importance. The study used PEQ design with 41 questions for the validated nine scales. Visual analogue scale VAS from 0 -100 mm was answered for each question. The sequence of questions was categorised based on eight groups. Each question reviewed the experience of use in the last four weeks. Average for each category was counted and considered as the score, based on PEQ analysis recommendation. A permission of using the PEQ (Legro et al., 1998) and its Validated Arabic version (Day and Buis, 2012) was granted. PEQ has been used to compare MCPK and NMCPK in literature review previously (Highsmith et al., 2014). The following nine scales were the areas of the study:

3.11.1.1 Utility (UT):

Essential user findings during daily use were summarised in the questions of (UT). Eight questions were covered (UT):

1. General fitting of the prosthesis is related to the socket (volume matching between stump and socket).
2. Prosthesis weight represents the needed forces that the user must carry in each step, it also reflects the relation of muscle power and stump length.
3. Standing is static alignment and the stage of the balance which the amputee needs to handle before initiating the first swing phase.

4. Balance during walking is the mechanism to sustain a safe and efficient gait cycle. Handling the centre of gravity inside the base of support will prevent any fall. This is the task all amputees try to keep during their ambulation. Feeling balanced allows them to have the ability to function more in the community and less concerns of fall consequences.

5. Energy consumption is the needed energy to move with the prosthesis. In the user understanding how easily you become tired and unable to walk or move more with the prosthesis. In science, energy consumption/ expenditure is measured through monitoring oxygen consumption.

6. Sitting while wearing the prosthesis is so important for transfemoral prosthesis, the users should flex the joint and sit over the socket that reaches ischial tuberosity.

7. Donning/Doffing was required daily at least once, wearing, and removing the prosthesis is reflecting the independency with usage of the device, ability to get ready of standing and walking while the device is not worn, donning/doffing difficulties are generally the most related reason to stop to use the prosthesis.

8. Feeling of the user toward his prosthesis and how the user feels toward the return function formed the prosthesis usage.

3.11.1.2 Sounds (SO):

Prosthesis articulated parts generate sounds, mainly with the foam covers compressed with trousers of the user. Prosthesis users' feedback was reported through these two questions:

1. Frequent sounds during prosthesis usage. How the user reported the sound in the last four weeks.

2. Bothering from sound and how the user was annoyed from the sounds.

3.11.1.3 Appearance (AP)

Prosthesis appearance is part of the restoration of body image. Prosthesis will never compensate for the exact skin colour, shape, and touch in addition to the function. Five questions reviewed the appearance of the prosthesis:

1. Prosthesis looking is the external shape and colour. Usually, amputees have high attention for their final prosthesis mainly when the community is not familiar with disability issues. Any feeling of difference noted by others adds tension for the prosthesis users.
2. Prosthesis damages clothes, usually appearing in the level of the ischial area if the user sits over a rigid chair, or in front of the prosthetic knee joint if the user kneels on the floor.
3. Prosthesis damaged foam/plastic cover, seen regular in transfemoral prosthesis as an effect of flexion/ extension movement in the prosthetic knee joint.
4. Ability to choose shoes directly affects the user's biomechanics and influences the location of ground reaction force lines. Prosthesis users face challenges to choose different heel heights as it affects their ability of safe walking and balance.
5. Ability to choose clothes affected based on the prosthesis design, mainly socket volume and foot.

3.11.1.4 Residual Limb Health (RL)

Residual limb or stump health condition is important for each prosthesis user as it represents the bearing area (interface for forces of load and ground reaction), suspension forces and the control of the distal prosthetic part like knee and foot with transfemoral amputees. Health condition for residual limb was reported from the following six questions:

1. Skin sweating, as the stump compresses, has a closed system of silicon, plastic and load forces, and prosthesis users complain of skin sweating. Prosthetic users face regular challenges in managing the sweating.

2. Prosthesis/stump smell, because of sweating and closed system of ventilations inside the socket, bad smell was reported from most prosthesis users.

3. Residual limb/Stump swelling, which directly affect volume matching, donning/ doffing and functional use of the prosthesis.

4. Skin rash, daily use of prosthesis and hygienic issues reflected the skin rash condition.

5. Hair under skin, usually seen after shaving of hairs and leads to skin rashes.

6. Skin sores, as results of skin itching, compression and continuous degeneration of skin, sores appear and stop the prosthesis users from their ability to use their devices.

3.11.1.5 Frustration (FR)

Depression in related to prosthesis use was reviewed through two questions:

1. Frequent frustration happened based on the prosthesis use.

2. Worst depression happened and assessed how frustrated the user was during that time.

3.11.1.6 Perceived Response (PR)

Responds from surrounded family members and people, following five questions covered the prosthetic user’s response.

1. Frequency of willing to avoid others' attention to prosthesis issues, the question was reporting how the prosthetic user must avoid the attention of other people out of his family.

2. Partner’s response to the prosthetic issues the users faced and dealing with daily life activities.

3. The effect of a partner's response for prosthetic users.

4. First closest family member's response toward the prosthetic issues.

5. Second closest family member's response toward the prosthetic issues.

3.11.1.7 Social Burden (SB)

Reviewed in the different levels with three questions:

1. Partner burden of having a prosthesis user and challenges of prosthesis within family activities.

2. Social burden for the prosthesis user with community activities.

3. Ability of prosthesis users to give care for others and share the family responsibilities.

3.11.1.8 Ambulation (AM)

Prosthesis users were reporting ambulation based on their daily activities. Prosthetists were assessing ambulation through clinical outcomes measuring and analysing gait cycle kinetic and kinematics. Study collects the Prosthesis users’ feedback based on their experience of ambulation in different services. Eight questions were reporting the ambulation of the

1. General walking with prosthesis during daily life activities.

2. Walking in close space and limited passes. The tight areas may force the prosthesis users to exactly select the place of the foot and the safe gait cadence needed to secure the pass.

3. Up stair function is the ability to get upstairs even alternatively, or one leg follows the other.

4. Down stair ability to have downstairs alternatively or one leg follow the other. Prosthesis users are exposed to stair function during their life activities.

5. Uphill, ability of claiming up ramps.

6. Downhill, ability to move down ramps.

7. Sidewalk on streets and outdoor activities which may have uneven grounds, this reflects the nature of ground the patient may walk during community activities.

8. Walking on slippery services, as it affects the friction of shoes with the floor, balance of the prosthesis users may be difficult compared to others.

3.11.1.9 Quality of Life /Well-Being (WB)

General evaluation of prosthesis user's life based on:

1. Satisfaction since amputation happened.

2. Quality of life in general perspective.

3.11.2 Functional Independence Measure FIM

The FIM score is a measure of the person's level of disability. It is useful in clinical settings of rehabilitation as it assesses a patient's progress in response to rehabilitation therapy. The evaluation is usually performed by a single professional, but the FIM should be rated by consensus opinion of a multidisciplinary team. It takes around 30-45 minutes to evaluate the patient. The score includes 18 items in terms of burden of care, each item is scored from 1 to 7 depending on the amount of assistance required to perform each item as the following:

1. Requires total assistance from the helper, patient performs < 25% of the tasks.

2. Requires maximal assistance from the helper, the patient performs 25-49% of the tasks.

3. Requires moderate assistance from the helper, patient performs 50-75% of the tasks
4. Requires minimal assistance from the helper, patient performs >75% of the task.
5. Requires supervision or setup from the helper.
6. Modified independence requiring device help without helper.
7. Complete independence without a helper.

Expected scores range from 18-126. If a patient obtained a higher score, he will be considered more independent in ADL. Usually, the FIM score is applied on admission and on discharge from the rehabilitation service. In our study we applied the questionnaire only after placement of the prosthesis to evaluate the functional status of the patients using the prosthesis and compare the outcomes of MCPK results to NMCPK. The FIM 18 items are assessing 6 areas of function. The items fall into two domains: Motor is 13 items and Cognitive is 5 items. The items are listed as following:

3.11.2.1. Motor Domain

Motor domains involve the following:

A. Self-Care

Self-care included: eating, grooming, bathing/showering, dressing of upper limbs, dressing of lower limbs, toileting, and swallowing. In grooming the patient was scored 7 if he was cleaning his teeth, combing hair, washing face with hands, shaving/applying makeup alone without help and safely. If he required equipment or help to make grooming or took more time than needed or there was any safety consideration, he was sored 6. In our study all patients were not having any problems in upper limb function.

In dressing, patient was scored 7 if he was dressing and undressing by himself, and 6 if he needed assistance to don dressing including lower limb prosthesis as part of equipment that help in dressing, so none of our patients got 7 in lower limb dressing as all needed help by either using the prosthesis during lower limb dressing or using chair or bed to sit while dressing.

B. Sphincter Control

Sphincter control involves 2 items: bladder management and bowel management. Patient was scored 7 if he had total bowel and bladder control and 6 if he needed a urinal, bed pan, catheter, diaper, etc. and he can indicate the need of the bathroom but unable to control it.

C. Mobility

Mobility measures included:

1. Transfer from bed to chair, to wheelchair or to standing. Toilet transfer by getting on and off a toilet. Bathtub/shower transfer by getting into and out of a tub or shower. If patient was performing these activities alone and safely, he was scored 7, if he was needing mild help or equipment support, he was scored 6, if he needed supervision or setup from helper to maintain safety, he was scored 5, if he needed assistance from helper, he was scored 4 or less according to the degree of help from the assistant.

2. Locomotion by walking, using a wheelchair and going upstairs. If the patient was transferring safely by walking without any fall, he was scored 7, if he used a helping

equipment like grab bars or sliding board, he was scored 6. In upstairs movement, the patient was scored 7 if he was going up and down one flight of stairs indoors without help and was scored 6 if he was using side bars or supporting equipment.

3.11.2.2 Cognitive Domain

The cognitive demands are review in the FIM based on the follow:

A. Communication

Communication involved assessment of expression, comprehension, reading, writing and speech intelligibility. Patient was scored 7 if he was expressing his ideas clearly and fluently and scored 6 if he was having some difficulties in expression. Although all patients of our inclusion criteria were mentally intact and got high scores in cognitive domains, it was necessary to include them as part of routine FIM assessment.

B. Social Cognition

Social cognition involves assessment of problem solving, memory, orientation, concentration, and safety awareness. Patient was scored 7 if he was solving his daily problems without difficulties, and 6 if he was recognizing the problem but faced mild difficulty in making decisions. The patients were assessed based on direct observation and clinical evaluation in the clinic. Each subject was scored depending on what he does in his daily life after he applied the prosthesis, not on what he could or expect himself to do.

3.12. Study Flow Chart

Study flow chart is show in Figure Study flow chart .1-3:

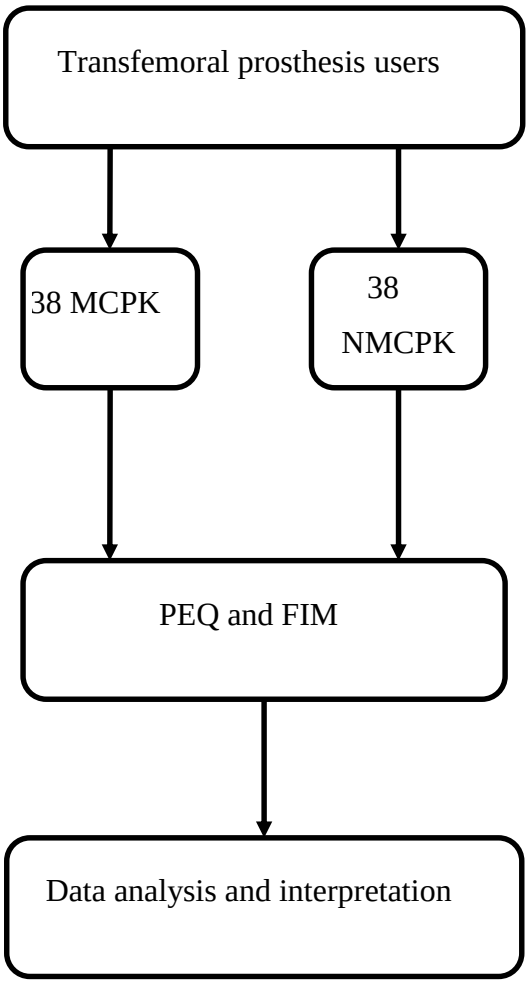

Figure 3.15 Study flow chart

3.13. Intended Statistical Analysis

SPSS version 23.0 was used for all analyses. Collected data were tested for normal distribution and analysed using T-Test for paired samples to detect the differences between the two groups results (P value=0.05) and Pearson correlation to detect the similarities. Chi square test was used to have the P-value for demographic information of study participants. The Shapiro-Wilk test for normality was applied.

3.14. Ethical Considerations

Study was approved by the Institutional Research board IRB in Sultan bin Abdul-Aziz Humanitarian city (SBAHC), Riyadh, Kingdom of Saudi Arabia with reference number 12/SBAHC/RH2020. Universiti Sultan Zainal Abidin UniSZA Human Research Ethics Committee (UHREC) reviewed the IRB of SBAHC and approved the study design with approval code UniSZA/UHREC/2020/178.

CHAPTER 4

RESULTS

4.1. Participant's Information:

Seventy-six transfemoral prosthesis users met the inclusion criteria and were accepted to enrol in the study. Participants were classified based on prosthetic knee joints for two groups.

4.1.1 Prosthetic Knee Joint:

First group had thirty-eight participants using MCPK with Genium knee joint. Second group had thirty-eight participants using NMCPK including three different hydraulic designs: 3R60 / 3R106 was used by ten participants, 3R80 / 3R95 was used by ten participants, and Total 2000 / 2100 for 18 patients.

4.1.2 Age:

Average age for participants was 33.8 (18-58) years, classified into three age categories; details of distributions in the group are mentioned in Table Age .1-4 categories for all study participants per type of prosthesis.

Table 4.1 Age categories for all study participants

All Participant age category	Frequency	Percent
Early adulthood 18-24 years	14	18.4
Middle adulthood 25- 40 years	44	57.9
Late adulthood 41-60 years	18	23.7
Total	76	100.0

4.1.3 Gender

Sixty-six (86.84%) participants were males and ten (13.16%) were females. Details of the group distributions are mentioned in Table Demographic information details .2-4 .for all studied participants per type of prosthesis

4.1.4 Amputation Aetiology

Amputation aetiology was categorised as Traumatic if it was one of the following:

1. Road traffic accidents, work injuries, bomb explosions, gun shots, criminals' banality, animals' injuries, and burns.
2. Disease aetiology when the amputation happens after one of the following: Bone tumours, deep vein thrombosis, failure of orthopaedic procedure like knee replacement, Osteomyelitis, diabetic complications.
3. Congenital reasons when the patient was born with absent body part, either there was a stump revision or not, Proximal femoral focal deficiency PFFD, and leg length discrepancies more than the leg segment height.

Traumatic aetiology was reported in forty-nine participants (64.5%), Diseases in twenty-one participants (27.6 %), and congenital six participants (7.9%). Details of distribution in groups is mentioned in Table Demographic information details for .2-4 .all studied participants per type of prosthesis

4.1.5 Nationality

Sixty-three participants were of Saudi nationality, and thirteen participants were residents in Saudi Arabia with different nationalities. Details of type of prosthesis, age, gender, amputation aetiology and nationality were given in Table Demographic .2-4 .information details per type of prosthesis

Table 4.2 Demographic information details per type of prosthesis

Variables	Sub-categories	Total N (%)	MCPK 38 (%)	NMCPK 38 (%)	P-value
Age	Early adulthood	14 (18.4)	4 (10.5)	10 (26.3)	0.078
	Middle adulthood	44 (57.9)	21 (55.3)	23 (60.5)	0.648
	Late adulthood	18 (23.7)	13 (34.2)	5 (13.2)	**0.030**
Gender	Male	66 (86.8)	34 (89.5)	32 (84.2)	0.497
	Female	10 (13.2)	4 (10.5)	6 (15.8)	0.499
Amputation	Traumatic	49 (64.5)	27 (71.1)	22 (57.9)	0.232
aetiology	Disease	21 (27.6)	10 (26.3)	11 (28.9)	0.801
	Congenital	6 (7.9)	1 (2.6)	5 (13.2)	0.089
Nationality	Saudi	63 (82.90)	35 (92.1)	28 (73.7)	**0.034**
	Non-Saudi	13 (17.1)	3 (7.9)	10 (26.3)	**0.034**

P-value based on chi square test

4.2. Outcome Measure PEQ:

Results of PEQ analysis based on:

4.2.1 Prosthetic Knee Joint:

All the PEQ items have higher results in MCPK compared to NMCPK based on average results of participants as shown in Figure PEQ results for MCPK and .1-4 .NMPCK

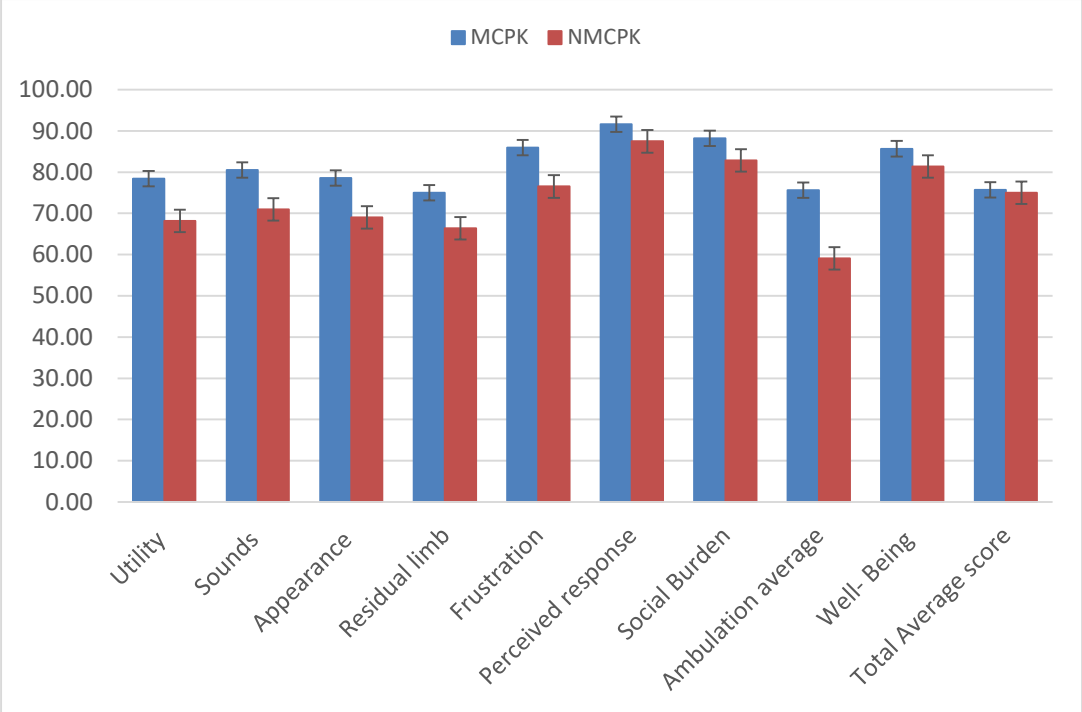

Figure 4.1 PEQ results for MCPK and NMPCK

PEQ: Study found significant improvement in Utility (P Value=0.02), average appearance (P Value=0.04), ambulation (P Value=0.01) and total PEQ average (P Value=0.01), no significant difference in other items as shown in Table PEQ .3-4 results based on prosthetic knee joint types.

Table 4.3 PEQ results based on prosthetic knee joint types

PEQ	**MCPK** Mean ± SD	**NMCPK** Mean ± SD	**t statistics (df)**	**P-value**
Utility Average	78.41 ± 16.22	68.20 ± 22.18	2.29 (67.78)	**0.025**
Sounds average	80.54 ± 26.2	70.95 ± 30.88	1.46 (74)	0.149
Appearance average	78.58 ± 19.54	69.02 ± 20.18	2.10 (74)	**0.039**
Residual limb average	75.03 ± 21	66.41 ± 22.94	1.71 (74)	0.092
Frustration average	85.97 ± 24.67	76.53 ± 27.15	1.58 (73)	0.119
Perceived response average	91.62 ± 13.04	87.48 ± 16.37	1.22 (74)	0.226

Social Burden average	88.23 ± 17.81	82.85 ± 21.51	1.18 (73)	0.241
Ambulation average	75.61 ± 22.09	59.11 ± 24.06	3.12 (74)	**0.003**
Well- Being average	85.68 ± 17.95	81.39 ± 23.95	0.88 (74)	0.38
Total Average score	82.14 ± 14.92	73.53 ± 14.8	0.2 (74)	**0.014**

SD for standard deviation, t for T-test result, df is degree of freedom and P-value based on Sig. (2-tailed).

4.2.2 Age

Age groups: For middle adulthood MCPK users, study found significant improvement in Utility (P Value=0.02), Residual limb (P Value=0.05), Frustration (P Value=0.05), and ambulation (P Value=0.00). Early adulthood and late adulthood had no significant difference as shown in Table PEQ .4-4 for age groups based on their prosthetic knee joint types.

Table 4.4 PEQ for age groups based on their prosthetic knee joint types

PEQ	**Prosthetic Knee**	**Early adulthood**			**Middle adulthood**			**Late adulthood**		
		Mean ± SD	t statistics (df)	P-Value	Mean ± SD	t statistics (df)	P-Value	Mean ± SD	t statistics (df)	P-Value
UT	MCPK	80.59 ± 6.86	0.99 (11.24)	0.346	79.64 ± 17.91	2.42 (42)	**0.02**	75.76 ± 15.92	0.21 (16)	0.832
	NMCPK	74.99 ± 14.38			64.07 ± 24.08			73.63 ± 25.46		
SO	MCPK	61.25 ± 43.28	-0.15 (12)	0.884	86.02 ± 19.12	1.54 (36.7)	0.132	77.62 ± 29.22	0.46 (16)	0.651

	NMCPK	64.25 ± 30.41			74 ± 31.59			70.3 ± 32.95		
AP	MCPK	68.60 ± 21.71	-0.2 (12)	0.847	78.48 ± 19.64	1.55 (42)	0.129	81.81 ± 19.28	0.7 (16)	0.5
	NMCPK	66.16 ± 20.63			69.01 ± 20.77			74.8 ± 19.37		
RL	MCPK	74.71 ± 14.12	0.52 (12)	0.613	76.46 ± 22.57	1.99 (42)	0.053	72.8 ± 21.27	-0.6 (16)	0.564
	NMCPK	68.58 ± 21.55			62.63 ± 23.46			79.47 ± 22.08		
FR	MCPK	60.00 ± 44.16	-1.31 (12)	0.216	90.05 ± 15.7	2.03 (35.87)	**0.049**	87.69 ± 26.31	1.29 (16)	0.217
	NMCPK	81.50 ± 19.59			76.43 ± 27.34			67 ± 40.87		
PR	MCPK	85.42 ± 14.62	-0.77 (12)	0.456	93.41 ± 10.89	1.661 (42)	0.116	90.65 ± 15.92	0.52 (16)	0.612
	NMCPK	90.92 ± 11.07			86.36 ± 17.21			85.75 ± 23.05		
SB	MCPK	97.08 ± 5.83	1.27 (11)	0.232	86.71 ± 20.5	0.50 (42)	0.623	87.95 ± 15.44	0.79 (4.77)	0.468
	NMCPK	84.44 ± 19.17			83.62 ± 20.84			76.4 ± 31.33		
AM	MCPK	58.54 ± 31.28	-1.11 (12)	0.289	80.28 ± 20.46	3.7 (42)	**0.001**	73.34 ± 20.52	1.55 (16)	0.14

	NMCPK	72.2 ± 15.87			54.09 ± 25.83			56.03 ± 23.12		
	MCPK	88.00 ± 8.12			87.36 ± 18.58			82.27 ± 19.56		
WB			0.29 (12)	0.776		1.14 (42)	0.263		0.8 (16)	0.938
	NMCPK	85.85 ± 13.64			79.48 ± 26.37			81.3 ± 31.55		
	MCPK	74.91 ± 16.9			80.34 ± 15.26			81.1 ± 14.18		
PEQ			0.29 (12)	0.794		0.29 (42)	**0.012**		0.68 (16)	0.447
	NMCPK	76.46 ± 5.72			72.19 ± 15.23			73.85 ± 25.39		

SD for standard deviation, t for T-test result, df is degree of freedom and P-value based on Sig. (2-tailed).

4.2.3 Gender

Gender: For male MCPK users, study found significant improvement in Utility (P Value=0.05), Appearance (P Value=0.05), Residual limb (P Value=0.05), and ambulation (P Value=0.01), compared to NMCPK. Females had no significant difference as shown in Table P .5-4EQ for gender based on prosthetic knee joint types.

Table 4.5 PEQ for gender based on prosthetic knee joint types

		Male			**Female**		
PEQ	**Prosthetic Knee**	Mean ± SD	t statistics (df)	P-value	Mean ± SD	t statistics (df)	P-value
UT	MCPK	78.62 ± 17.12	2.02 (64)	**0.048**	76.66 ± 4.37	1.34 (5.81)	0.23
	NMCPK	68.58 ± 23.06			66.17 ± 18.39		

SO	MCPK	79.54 ± 27.31	1.55 (64)	0.126	89 ± 12.5	0.29 (8)	0.781
	NMCPK	68.36 ± 31.21			84.75 ± 27.34		
AP	MCPK	79.8 ± 19.76	2.03 (64)	**0.047**	68.18 ± 15.82	0.27 (8)	0.791
	NMCPK	69.83 ± 20.19			64.72 ± 21.45		
RL	MCPK	76.31 ± 20.93	1.99 (64)	0.051	64.13 ± 21.09	-0.68 (8)	0.515
	NMCPK	65.32 ± 24.01			72.21 ± 16.54		
FR	MCPK	88.01 ± 21.97	1.83 (64	0.072	62.83 ± 45.95	-0.46 (7)	0.662
	NMCPK	76.95 ± 27.06			74.25 ± 30.14		
PR	MCPK	92.54 ± 12.85	0.93 (64)	0.359	83.81 ± 13.8	0.52 (8)	0.621
	NMCPK	89.5 ± 13.85			76.67 ± 25.02		
SB	MCPK	89.28 ± 17.1	1.2 (63)	0.234	79.25 ± 23.99	0.03 (8)	0.976
	NMCPK	83.65 ± 20.73			78.72 ± 27.02		
AM	MCPK	76.57 ± 22.85	2.8 (64)	**0.007**	67.47 ± 13.1	1.22 (8)	0.258
	NMCPK	60.1 ± 24.98			53.83 ± 19.44		
WB	MCPK	86.62 ± 17.96	0.65 (64)	0.521	77.75 ± 18.21	0.43 (8)	0.68
	NMCPK	83.33 ± 23.29			71.08 ± 27.05		
PEQ	MCPK	83.03 ± 15.37	0.66 (64)	**0.015**	74.56 ± 7.81	-0.98 (8)	0.763
	NMCPK	73.93 ± 14.2			71.38 ± 19.06		

SD for standard deviation, t for T-test result, df is degree of freedom and P-value based on Sig. (2-tailed).

4.2.4 Amputation Etiology

MCPK users whose amputations were caused by diseases had significantly improved ambulation ability (P Value=0.00). Traumatic and congenital causes of amputation had

no significance as shown in Table PEQ for the cause of amputation based on .6-4 prosthetic knee joint type.

Table 4.6 PEQ for cause of amputation based on prosthetic knee joint type

PEQ	Prosthetic Knee	Traumatic cause			Disease cause			Congenital cause		
		Mean ± SD	t statistics (df)	P-value	Mean ± SD	t statistics (df)	P-value	Mean ± SD	t statistics (df)	P-value
UT	MCPK	76.13 ± 17.03	1.35 (36.66)	0.169	82.41 ± 12.62	1.9 (19)	0.074	100 ± 0	1.49 (4)	0.211
	NMCPK	67.7 ± 25.1			69.17 ± 18.56			68.3 ± 19.47		
SO	MCPK	77.65 ± 28.84	0.77 (57)	0.441	88.9 ± 17.72	0.61 (19)	0.55	75 ± 0	0.87 (4)	0.432
	NMCPK	71 ± 30.9			83.36 ± 23.21			43.4 ± 33.02		
AP	MCPK	75.37 ± 20.39	1.28 (47)	0.208	85.59 ± 15.88	1.42 (19)	0.171	95 ± 0	1.82 (4)	0.143
	NMCPK	67.63 ± 22.03			75.25 ± 17.29			61.45 ± 16.86		
RL	MCPK	72.24 ± 22.66	1 (47)	0.322	80.06 ± 14.45	0.62 (19)	0.546	100 ± 0	2.32 (4)	0.081
	NMCPK	65.7 ± 22.78			74.93 ± 22.44			50.77 ± 19.39		
FR	MCPK	86.35 ± 23.66	1.42 (46)	0.162	83.6 ± 29.17	0.22 (19)	0.826	100 ± 0	0.87 (4)	0.435

	NMCPK	75.66 ± 28.51			81 ± 24.37			70.5 ± 31.04		
PR	MCPK	91.44 ± 13.82	0.83 (47)	0.414	91.28 ± 11.78	0.48 (19)	0.64	100 ± 0	0.66 (4)	0.543
	NMCPK	88.27 ± 12.77			87.73 ± 20.74			83.4 ± 22.84		
SB	MCPK	86.46 ± 19.62	0.44 (46)	0.665	91.83 ± 12.36	0.84 (19)	0.411	100 ± 0	0.82 (4)	0.459
	NMCPK	83.97 ± 19.69			85.33 ± 21.4			72.67 ± 30.49		
AM	MCPK	74.19 ± 24.5	1.43 (47)	0.158	77.01 ± 14.06	3.56 (19)	**0.002**	100 ± 0	1.6 (4)	0.185
	NMCPK	64.06 ± 24.79			48.25 ± 21.69			61.23 ± 22.12		
WB	MCPK	85.35 ± 19.68	0.33 (47	0.744	85.15 ± 13.54	0.58 (19)	0.57	100 ± 0	0.77 (4)	0.484
	NMCPK	83.32 ± 23.61			80.09 ± 24.47			75.8 ± 28.66		
PEQ	MCPK	80.51 ± 16.38	0.51 (47)	0.149	85.09 ± 9.93	-1.13 (19)	0.152	96.67 ± 0	1.88 (4)	0.159
	NMCPK	74.11 ± 13.59			76.13 ± 16.43			65.28 ± 16.59		

SD for standard deviation, t for T-test result, df is degree of freedom and P-value based on Sig. (2-tailed).

4.2.5 Nationality

Nationality for Saudi patients using MCPK, study found significant difference in Utility and ambulation. Non-Saudi patients had no significant findings. Details are illustrated in Table PEQ results for Saudi participants based on their prosthetic .7-4 knee joint type.

Table 4.7 PEQ results for Saudi participants based on their prosthetic knee joint type

PEQ	Prosthetic Knee	Saudi Nationality			Non-Saudi nationality		
		Mean ± SD	t statistics (df)	P-value	Mean ± SD	t statistics (df)	P-value
UT	MCPK	77.67 ± 16.46	1.98 (61)	**0.047**	87.08 ± 11.88	1.16 (11)	0.27
	NMCPK	68.06 ± 21.12			68.60 ± 26.16		
SO	MCPK	80.01 ± 27.13	1.2 (61)	0.236	86.67 ± 11.54	0.81 (11)	0.435
	NMCPK	71.38 ± 30.12			69.75 ± 34.61		
AP	MCPK	77.94 ± 20.00	1.83 (61)	0.072	86.00 ± 13.11	1.16 (11)	0.271
	NMCPK	68.72 ± 19.70			69.86 ± 22.57		
RL	MCPK	74.50 ± 21.69	1.81 (61)	0.075	81.22 ± 10.22	0.61 (11)	0.558
	NMCPK	64.44 ± 22.17			71.93 ± 25.34		
FR	MCPK	85.47± 25.57	1.42 (60)	0.16	91.67 ± 10.40	0.82 (11)	0.428
	NMCPK	75.80 ± 27.88			78.55 ± 26.30		
PR	MCPK	91.48 ± 13.40	0.74 (61)	0.46	93.33 ± 9.46	1.14 (11)	0.323
	NMCPK	88.61 ± 17.23			84.30 ± 13.96		
SB	MCPK	88.36 ± 17.91	0.85 (61)	0.397	86.67 ± 20.27	0.55 (10)	0.594
	NMCPK	84.08 ± 21.91			79.00 ± 21.00		
AM	MCPK	74.65 ± 22.49	2.9 (61)	**0.005**	86.88 ± 14.93	1.45 (11)	0.175
	NMCPK	57.88 ± 23.25			62.56 ± 27.23		

WB	MCPK	85.74 ± 18.45	0.53 (61)	0.602	85.00 ± 13.22	0.48 (11)	0.639
	NMCPK	83.02 ± 22.80			76.85 ± 27.72		
PEQ	MCPK	77.07 ± 14.03	0.64 (61)	0.522	60.05 ± 26.56	-1.64 (11)	0.129
	NMCPK	74.44 ± 18.41			76.52 ± 11.30		

SD for standard deviation, t for T-test result, df is degree of freedom and P-value based on Sig. (2-tailed).

4.2.6 Correlations:

Correlation reflects the relationship between the PEQ subscales.

4.2.6.1 Correlation for All

PEQ subscales have a strong relation (highly significant correlation P value < 0.01 (**)) with almost all subscales except sound with social burden, ambulation, and well-being. Significant correlation P value <0.05 (*) found between Frustration with utility, appearance, and residual limb. Details of the correlation shown in Table .8-4 .Correlation of PEQ subscales for all participants

Table 4.8 Correlation of PEQ subscales for all participants

PEQ		**UT**	**SO**	**AP**	**RL**	**FR**	**PR**	**SB**	**AM**	**WB**	**PEQ**
UT	**r**	1	.37**	.625**	.667**	.295*	.47**	.57**	.64**	.52**	.091
	P-value		.001	.001	.001	.010	.001	.001	.001	.001	.434

	r	1	.469**	.498**	.304**	.32**	.202	.185	.194	.006
SO	**P-value**		.001	.001	.008	.005	.083	.109	.092	.962
	r		1	.60**	.25*	.42**	.49**	.37**	.3 **	.064
AP	**P-value**			.001	.030	.001	.001	.001	.009	.585
	r			1	.27*	.33**	.42**	.46**	.25*	.10
RL	**P-value**				.017	.004	.001	.001	.027	.389
	r				1	.60**	.43**	.50**	.43**	.13
FR	**P-value**					.001	.001	.001	.001	.264
	r					1	.61**	.52**	.75**	.05
PR	**P-value**						.001	.001	.001	.690

	r	1	.51**	.55**	.082
SB	**P-value**		.001	.001	.484
	r		1	.54**	.056
AM	**P-value**			.001	.632
	r			1	.019
WB	**P-value**				.870

** very strong correlation with P-value less than .01, strong correlation with P-value less than 0.05. Pearson Correlation: r

4.2.6.2 Correlation of MCPK

MCPK users PEQ scales showed highly significant correlation P value < 0.01 (**) between all scales: utility, sounds, appearance, residual limb, frustration, perceived response, social Burden, ambulation and well- being, with significant correlation P value <0.05 (*) between frustration-residual limb and wellbeing, except utility-frustration, sound-social burden, and sound well-being which showed no correlation Table Correlation of PEQ subscales for MCPK participants .9-4.

Table 4.9 Correlation of PEQ subscales for MCPK participants

PEQ		UT	SO	AP	RL	FR	PR	SB	AM	WB	PEQ
UT	r	1	0.50**	0.61**	0.66**	.321	.497**	.510**	.620**	.696**	-.071
	P-value		0.001	.001	.001	.053	.001	.001	.001	.001	.670
SO	r		1	0.59**	0.51**	.446**	.520**	.231	.472**	.307	-.178
	P-value			.001	.001	.006	.001	.164	.003	.061	.285
AP	r			1	0.56**	.496**	.550**	.569**	.454**	.421**	.086
	P-value				.001	.002	.001	.001	.004	.009	.608
RL	r				1	.367**	.492**	.547**	.551**	.497**	.075
	P-value					.026	.002	.001	.001	.001	.654

FR	r	1	.785**	.438**	.572**	.402**	.092
	P-value		.001	.007	.001	.014	.586
PR	r		1	.598**	.670**	.726**	.127
	P-value			.001	.001	.001	.446
SB	r			1	.487**	.645**	.096
	P-value				.002	.001	.568
AM	r				1	.600**	-.056
	P-value					.001	.739
WB	r					1	.019
	P-value						.911

** very strong correlation with P-value less than .01, strong correlation with P-value less than 0.05. Pearson Correlation: r.

4.2.6.3 Correlation of NMCPK

NMCPK users' PEQ scales showed highly significant correlation P value < 0.01 (**) between: utility with appearance, residual limb, perceived response, social burden, ambulation, and well-being, sound with residual limb, appearance with residual limb, frustration with perceived response and well-being, social burden with ambulation and well-being, and ambulation with well-being. NMCPK users' PEQ scales showed significant correlation P value <0.05 (*) between appearance with sound and social burden, ambulation with residual limb, frustration and perceived response, and frustration with social burden. Other PEQ scales have no correlations between them Table Correlation of PEQ subscales for NMCPK participants .10-4.

Table 4.10 Correlation of PEQ subscales for NMCPK participants

PEQ		UT	SO	AP	RL	FR	PR	SB	AM	WB	PEQ
UT	**r**	1	.246	.608**	.651**	.224	.432**	.597**	.620**	.420**	.197
	P-value		.137	.001	.001	.176	.007	.001	.001	.009	.235
SO	**r**		1	.335**	.462**	.160	.159	.151	-.121	.101	.143

	P-value	.040	.004	.336	.341	.371	.469	.545	.390
AP	**r**	1	.604**	-.022	.283	.394*	.192	.186	.036
	P-value		.001	.896	.085	.016	.248	.265	.829
RL	**r**		1	.148	.178	.292	.330*	.064	.117
	P-value			.374	.284	.080	.043	.704	.485
FR	**r**			1	.445**	.402*	.397*	.439**	.161
	P-value				.005	.014	.014	.006	.335
PR	**r**				1	.612**	.396*	.765**	-.018
	P-value					.001	.014	.001	.914

SB	**r**	1	.500**	.475**	.071
	P-value		.002	.003	.677
AM	**r**		1	.509**	.142
	P-value			.001	.396
WB	**r**			1	.016
	P-value				.926

** very strong correlation with P-value less than .01, strong correlation with P-value less than 0.05. Pearson Correlation: r.

4.3. Outcome Measure FIM

FIM scale was applied on the patients upon discharge after fitting with prosthesis and post prosthetic rehabilitation program. The results of the scale came as the following:

4.3.1 Prosthetic Knee Joint:

Patients using MCPK reported higher means in self-care, transfer, locomotion, and higher average score compared to NMCPK as shown in Figure FIM results for .2-4 MCPK and NMPCK. Equal mean was achieved between the two categories in sphincter control, communication, and social cognition

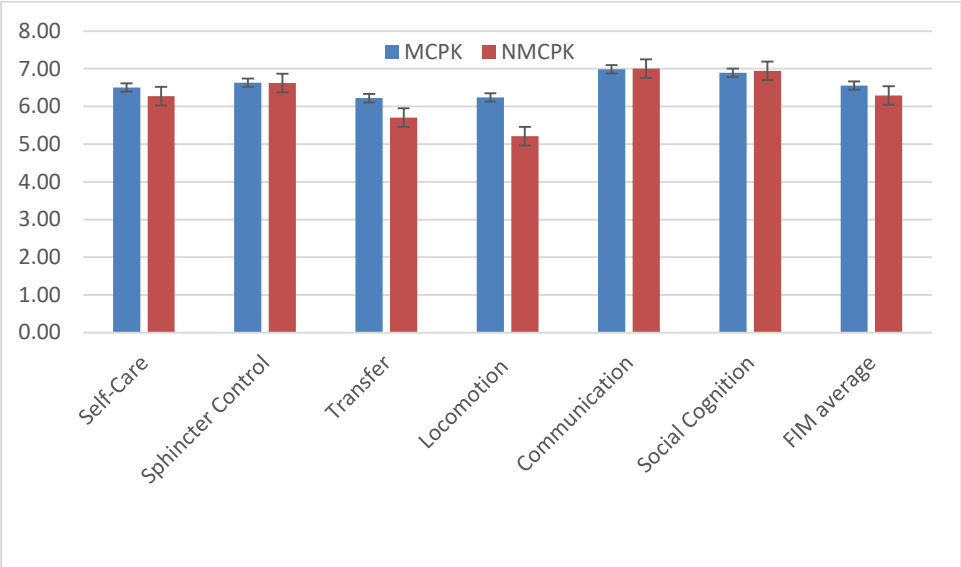

Figure 4.2 FIM results for MCPK and NMPCK

Patients with MCPK showed significant variance in Transfer (p-value 0.04), locomotion (p-value 0.04), and total FIM score (p-value 0.04) compared to NMCPK. No significant variation was noted in self-care, sphincter control, communication, and social cognition as shown in Table FIM based on Prosthetic knee joint categories .11-4.

Table 4.11 FIM based on Prosthetic knee joint categories

FIM		**MCPK Mean ± SD**	**NMCPK Mean ± SD**	**t statistics (df)**	**P-value**
Motor	Self-Care	6.5 ± 0.54	6.28 ± 0.61	1.7 (74)	0.093
	Sphincter Control	6.63 ± 1.04	6.62 ± 0.81	0.06 (74)	0.951
	Transfer	6.22 ± 0.88	5.7 ± 1.26	2.07 (74)	**0.042**
	Locomotion	6.24 ± 0.88	5.21 ± 1.87	3.05 (52.68)	**0.004**
Cognitive	Communication	6.99 ± 0.08	7 ± 0	-1 (74)	0.324
	Social Cognition	6.89 ± 0.65	6.95 ± 0.2	-0.48 (74)	0.634
Total		117.97 ± 8.24	113.18 ± 11.41	2.1 (67.37)	**0.04**

SD for standard deviation, t for T-test result, df is degree of freedom and P-value based on Sig. (2-tailed).

4.3.2 Age

Patients were classified into three age categories, early adulthood (18-24), middle adulthood (25-40), and late adulthood (41-60) as explained in Table Patients of .1-4 middle age category showed significant variance in self-care in MCPK users compared to NMCPK (p-value 0.04). Also, there was a significant variation in locomotion in MCPK users compared to NMCPK (p-value 0.04). No significant variation was noted in sphincter control, transfer, communication, social cognition, and total score between the two prosthetic types, as explained in Table FIM for age groups based on their .12-4 prosthetic knee joint types.

Table 4.12 FIM for age groups based on their prosthetic knee joint types

FIM Score	**Prosthetic Knee**	**Early adulthood**			**Middle adulthood**			**Late adulthood**		
		Mean ± SD	**t statistic (df)**	**P-Value**	**Mean ± SD**	**t statistic (df)**	**P-Value**	**Mean ± SD**	**t statistic (df)**	**P-Value**
Self-Care	MCPK	6.58 ± 0.22	1.34 (12)	0.2	6.60 ± 0.32	2.12 (42)	**0.04**	6.32 ± 0.80	0.74 (16)	0.47
	NMCPK	6.08 ± 0.72			6.29 ± 0.58			6.6 ± 0.37		
Sphincter Control	MCPK	6.75 ± 0.56	0.41 (12)	0.7	6.81 ± 0.40	0.64 (42)	0.53	6.31 ± 1.69	0.12 (16)	0.91
	NMCPK	6.6 ± 0.65			6.71 ± 0.54			6.2 ± 1.79		
Transfer	MCPK	6.08 ± 0.57	0.84 (12)	0.42	6.16 ± 1.11	1.14 (42)	0.26	6.36 ± 0.48	0.86 (16)	0.41
	NMCPK	5.3 ±			5.783 ± 1.09			6.13 ± 0.56		

Locomotion	MCPK	1.79 6.38 ± 0.48	2.14 11.26	0.06	6.17 ± 1.08	2.15 (34.14)	**0.04**	6.31 ± 0.63	0.8 (16)	0.44
	NMCPK	5 ± 1.89			5.13 ± 2.02			6 ± 1		
Communication	MCPK	7 ± 0			6.98 ± 0.11	-1 (20)	0.33	7 ± 0		
	NMCPK	7 ± 0			7 ± 0			7 ± 0		
Social Cognition	MCPK	7 ± 0			7 ± 0	1.66 (22)	0.11	6.69 ± 1.11	-0.61 (16)	0.55
	NMCPK	7 ± 0			6.91 ± 0.25			7 ± 0		
Total	MCPK	119 ± 4.32	1.13 (12)	0.28	118.90 ± 7.10	1.97 (37.59)	0.06	116.15 ± 10.75	-0.25 (16)	0.8
	NMCPK	110.6 ± 14.25			113.39 ± 11.21			117.4 ± 4.10		

SD for standard deviation, t for T-test result, df is degree of freedom and P-value based on Sig. (2-tailed).

4.3.3 Gender

In male category there was significant variation in locomotion in MCPK male users compared to NMCPK (p-value 0.03). Other FIM score categories showed no significant variations in male MCPK users and NMCPK. IN female category there was a significant variation in locomotion between female MCPK users compared to NMCPK (p-value 0.04), no significant variation was noticed in other FIM categories as explained in Table FIM for gender based on prosthetic knee joint types .13-4.

Table 4.13 FIM for gender based on prosthetic knee joint types

FIM Score	Prosthetic Knee	Male			Female		
		Mean ± SD	t statistic (df)	P-value	Mean ± SD	t statistic (df)	P-value
Self-Care	MCPK	6.5 ± 0.56	1 (64)	0.32	6.46 ± 0.28	1.78 (6.34)	0.12
	NMCPK	6.38 ± 0.49			5.75 ± 0.91		
Sphincter Control	MCPK	6.6 ± 1.1	-0.22 (64)	0.83	6.88 ± 0.25	1.41 (6.55)	0.2
	NMCPK	6.66 ± 0.83			6.42 ± 0.74		
Transfer	MCPK	6.22 ± 0.93	1.24 (64)	0.22	6.25 ± 0.32	2.13 (5.39)	0.08
	NMCPK	5.93 ± 0.97			4.5 ± 1.97		
Locomotion	MCPK	6.21 ± 0.91	2.2 (46.58)	**0.03**	6.5 ± 0.58	2.64 (5.9)	**0.04**
	NMCPK	5.45 ± 1.72			3.92 ± 2.29		
Communication	MCPK	6.99 ± 0.09	-0.98 (64)	0.33	7 ± 0		
	NMCPK	7 ± 0			7 ± 0		
Social Cognition	MCPK	6.88 ± 0.69	-0.44 (64)	0.67	7 ± 0		
	NMCPK	6.94 ± 0.21			7 ± 0		
Total	MCPK	117.88 ± 8.69	1.31 (64)	0.19	118.75 ± 2.87	2.17 (45)	0.08
	NMCPK	114.94 ± 9.56			103.83 ± 16.49		

SD for standard deviation, t for T-test result, df is degree of freedom and P-value based on Sig. (2-tailed).

4.3.4 Amputation Aetiology

There was significant variation in transfer and locomotion categories between MCPK users whose amputations were caused by disease compared to NMCPK users of the same cause, (p-value 0.01) in both categories. No significant variation in other FIM score categories between the MCPK users and NMCPK regarding the cause of

amputation as explained in Table FIM for cause of amputation based on .14-4 prosthetic knee joint type.

Table 4.14 FIM for cause of amputation based on prosthetic knee joint type

FIM Score	**Prosthetic Knee**	**Traumatic cause**			**Disease cause**			**Congenital cause**		
		Mean ± SD	t statistic (df)	P-value	Mean ± SD	t statistic (df)	P-value	Mean ± SD	t statistic (df)	P-value
Self-Care	MCPK	6.58 ± 0.32	1.96 (47)	0.56	6.25 ± 0.89	0.82 (19)	0.42	6.83 ± 0		
	NMCPK	6.36 ± 0.48			5.95 ± 0.77			6.63 ± 0.48		
Sphincter Control	MCPK	6.7 ± 0.52	0.62 (47)	0.64	6.4 ± 1.9	0.38 (19)	0.71	7 ± 0		
	NMCPK	6.77 ± 0.51			6.14 ± 1.23			7 ± 0		
Transfer	MCPK	6.1 ± 0.99	0.97 (47)	0.34	6.53 ± 0.48	2.76 (19)	**0.01**	6.33 ± 0		
	NMCPK	5.82 ± 1.04			5.06 ± 1.62			6.6 ± 0.43		
Locomotion	MCPK	6.13 ± 0.99	1.41 (47)	0.17	6.45 ± 0.5	3.26 (10.99)	**0.01**	7 ± 0		
	NMCPK	5.64 ± 1.46			4.09 ± 2.34			5.8 ± 1.64		
Communication	MCPK	6.98 ± 0.17	-0.9 (470	0.37	7 ± 0			7 ± 0		
	NMCPK	7 ± 0			7 ± 0			7 ± 0		
Social Cognition	MCPK	7 ± 0	1.42 (21)	0.17	6.6 ± 1.26	-1 (9)	0.34	7 ± 0		

	NMCPK	6.92 ± 0.25			7 ± 0			6.93 ± 0.15
Total	MCPK	118.37 ± 6.61	1.37 (47)	0.18	116.4 ± 12.15	1.76 (19)	0.09	123 ± 0
	NMCPK	115.14 ± 9.84			106.45 ± 13.56			119.4 ± 6.5

SD for standard deviation, t for T-test result, df is degree of freedom and P-value based on Sig. (2-tailed).

4.3.5 Nationality

In Saudi nationality, there was significant variation in transfer and locomotion, and total score between MCPK users and NMCPK users, (p-value 0.03, 0.04, and 0.04 respectively). Non-Saudi nationality showed no significant variation in all FIM score categories. These results are explained in Table FIM results for Saudi participants .15-4 based on their prosthetic knee joint type.

Table 4.15 FIM results for Saudi participants based on their prosthetic knee joint type

FIM Score	**Prosthetic Knee**	**Saudi Nationality**			**Non-Saudi nationality**		
		Mean ± SD	t statics (df)	P-value	Mean ± SD	t statics (df)	P-value
Self-Care	MCPK	6.48 ± 0.54	1.83 (51.88)	**0.67**	6.72 ± 0.48	0.93 (11)	0.37
	NMCPK	6.2 ± 0.66			6.5 ± 0.33		
Sphincter Control	MCPK	6.63 ± 1.08	-0.14 (61)	0.89	6.67 ± 0.58	0.21 (11)	0.83
	NMCPK	6.66 ± 0.59			6.5 ± 1.27		
Transfer	MCPK	6.2 ± 0.89	2.32 (43.76)	**0.03**	6.44 ± 0.96	0.43 (11)	o.67
	NMCPK	5.5 ± 1.39			6.27 ± 0.52		

Locomotion	MCPK	6.23 ± 0.88	3.04 (35.12)	**0.04**	6.33 ± 1.15	0.6 (11)	0.56
	NMCPK	4.98 ± 2.02			5.85 ± 1.25		
Communication	MCPK	6.99 ± 0.08	-0.89 (61	0.38	7 ± 0		
	NMCPK	7 ± 0			7 ± 0		
Social Cognition	MCPK	6.89 ± 0.68	-0.5 (61)	0.61	7 ± 0	0.53 (11)	0.61
	NMCPK	6.95 ± 0.2			6.93 ± 0.21		
Total	MCPK	117.74 ± 8.27	2.16 (44.32)	**0.04**	120.67 ± 9.24	0.87 (11)	0.4
	NMCPK	111.75 ± 12.72			117.2 ± 5.09		

SD for standard deviation, t for T-test result, df is degree of freedom and P-value based on Sig. (2-tailed).

4.3.6 Correlations:

Correlation reflects the relationship between the subscales of FIM.

4.3.6.1 Correlation for All

Significant correlation was noticed between self-care category and sphincter control, transfer, locomotion, social cognition, and total score categories, (p-values were 0.000 in all categories). Significant correlation was noticed between sphincter control category and transfer, locomotion, social cognition, and total score (p-values were 0.04, 0.03, 0.00, 0.01 respectively). Also, significant correlation was noticed between transfer category and locomotion and total score categories (p-value was 0.00 in both categories). Social cognition showed significant correlation with total FIM score (p-value 0.00). These results are explained in Table Correlation of FIM subscales .16-4 for all participants

Table 4.16 Correlation of FIM subscales for all participants

FIM		Self-Care	Sphincter control	Transfer	Locomotion	Communication	Social cognition	Total
Self-Care	r	1	.588**	.622**	.679**	-.089	.546**	.930**
	P-value		.000	.000	.000	.443	.000	.000
Sphincter Control	r		1	.235*	.241*	.016	.700**	.627**
	P-value			.041	.036	.893	.000	.000
Transfer	r			1	.797**	-.039	-.065	.805**
	P-value				.000	.738	.579	.000
Locomotion	r				1	-.058	-.012	.828**

	P-value	.616	.919	.000
Communication	r	1	-.019	-.050
	P-value		.869	.665
Social Cognition	r		1	.430**
	P-value			.000

** very strong correlation with P-value less than .01, strong correlation with P-value less than 0.05. Pearson Correlation: r.

4.3.6.2 Correlation of MCPK

MCPK users showed significant correlation between self-care category and sphincter control, social cognition and total score (p-value was 0.01 in all categories). Sphincter control showed significant correlation with social cognition and total score (p-value was 0.00 in both categories). Transfer category was significantly correlated with locomotion and total score (p-values were 0.00 and 0.01 respectively). Locomotion and social cognition were significantly correlated with the total score (p-value were 0.01 and 0.00 respectively).

As explained in Table Correlation of FIM subscales for MCPK participants .17-4.

Table 4.17 Correlation of FIM subscales for MCPK participants

FIM		Self-Care	Sphincter Control	Transfer	Locomotion	Communication	Social cognition	Total
Self-Care	r	1	.799**	.140	.195	-.103	.827**	.877**
	P-value		.000	.403	.241	.537	.000	.000
Sphincter Control	r		1	.066	.097	.021	.899**	.816**
	P-value			.695	.562	.900	.000	.000
Transfer	r			1	.829**	-.022	-.148	.531**
	P-value				.000	.898	.376	.001
Locomotion	r				1	-.050	-.144	.537**

	P-value	.767	.389	.001
Communication	r	1	-.027	-.041
	P-value		.872	.807
Social Cognition	r		1	.706**
	P-value			.000

** very strong correlation with P-value less than .01, strong correlation with P-value less than 0.05. Pearson Correlation: r.

4.3.6.3 Correlation of NMCPK

NMCPK users showed significant correlation between self- care category and sphincter control, transfer, locomotion, and total score (p-values were 0.01, 0.00,0.00, 0.00 respectively). Sphincter control was significantly correlated with transfer, locomotion and total FIM score results (p-values were 0.00, 0.01, and 0.00 respectively). Significant correlation was also noticed between transfer and locomotion and total categories (p-value was 0.00 in both categories). Locomotion showed significant correlation with the total FIM score (p-value 0.00). All results explained in Table .18-4 Correlation of FIM subscales for NMCPK participants

Table 4.18 Correlation of FIM subscales for NMCPK participants .

FIM		Self-Care	Sphincter Control	Transfer	Locomotion	Communication	Social cognition	Total
Self-Care	r	1	.391*	.899**	.900**		.200	0.968**
	P-value		.015	.000	.000		.229	0.000
Sphincter Control	r		1	.420**	.398*		.124	0.535**
	P-value			.009	.013		.457	0.001
Transfer	r			1	.784**		.116	0.926**
	P-value				.000		.489	0.000
Locomotion	r				1		.249	0.933**

	P-value		.131	0.000
	r			
Communication	P-value			
	r		1	.260
Social Cognition	P-value			.115

** very strong correlation with P-value less than .01, strong correlation with P-value less than 0.05. Pearson Correlation: r.

CHAPTER 5

DISCUSSION

Study results for both PEQ and FIM are aligned together, even both outcome measures had different perspectives but still the findings have the same direction and highlight the same findings. Following headers present the discussion of the results.

5.1. Prosthetic Knee Joint:

Study results of PEQ outcome measure found that MCPK users had significant differences in utility, appearance, ambulation, and total score of PEQ. The other six scales of PEQ (sound, residual limb, frustration, perceived response, social burden, and wellbeing) had higher results for MCPK but not in level of significance. Utility, appearance, and ambulation also had strong positive correlation. Self-reporting questionnaires for these scales reflect the participants' understanding of the added values of MCPK toward ambulation in different services, general fitting and use of prosthesis and the device looking when it includes Microprocessor technology. Even that was not reflected in frustration, social burden, perceived response, and wellbeing. The physical impact toward the user was significant but not reflected in the user community interaction, the user’s well-being, frustration, perceived response, and social burden were not significantly impacted.

Results of the FIM outcome measure showed that MCPK users had significant differences in Transfer, Locomotion, and total score of FIM. The other two scales of motor subscales had higher scores but not to the significant level. Transferring and locomotion added a clear and significant impact for the users. Sphincter control and self-care did not add any variations between MCPK and NMCPK. Strong positive correlation between transferring and locomotion in both MCPK and NMCPK. No

significant impact in cognitive scales for communication and social cognition. As the study participant criteria of selection was not limiting or including any communication issues, the study did not detect any impact for the cognitive issues.

Both FIM and PEQ results agree on the mobility factors as PEQ reported ambulation and FIM score for transfer and locomotion were measured by the clinicians. Scales of PEQ related how the prosthetic user's life affected by community like frustration, perceived response and social burden were matched with social cognition in FIM score and both were not in level of significance during comparison of MCPK to NMCPK. Final scores for both outcomes reported a significant level toward the MCPK. Following topics review the comparison between study results and literature review in relation to type of prosthetic knee joint:

5.1.1 Mobility

The PEQ ambulation scale had 8 questions for walking with prosthesis, walking in close space, up stair, down stair, uphill, downhill, sidewalk, and walking on slippery services, all reported under ambulation. FIM transferring and locomotion were reported separately. Comparison of literature review for mobility, using MCPK improves the functional status and mobility level compared to NMCPK (Thibaut et al., 2022; Sawers and Hafner, 2013; Highsmith et al., 2010). Using MCPK compared to NMCPK significantly improves the activity of daily living and physical functions (Şen et al., 2020). MCPK users were able to walk more than NMCPK users (Yazgan, Kutlutürk and Lechler, 2021). Furthermore, increased safety was reported in general (Highsmith et al., 2010; Kaufman, Frittoli and Frigo, 2012). There was a decrease in the number of steps and needed time to finish the obstacle with MCPK compared to NMCPK (Seymour et al., 2007). Using NMCPK hydraulic/Pneumatic (Fluid) prosthetic knee

joints expose the patients during rehabilitation programmes for more falling than MCPK (Palumbo et al., 2022). Furthermore, increased safety was reported in general (Highsmith et al., 2010; Kaufman, Frittoli and Frigo, 2012). Study results for both outcomes were aligned with the finding of literature review based on the participants criteria of inclusion and exclusion.

Regarding the Patients with Medicare functional calcification MFCL level 1 and 2 can ambulate indoor and restricted outdoor. Usually have low cadence speed. Literature review of comparison studies for low mobility reporting highlight special MCPK significantly improved safety related to fall when using MCPK compared to NMCPK (Kaufman, Bernhardt and Symms, 2018; Hahn et al., 2021; Kannenberg, Zacharias and Pröbsting, 2014; Stevens and Wurdeman, 2019). Significant improvement reported in gait symmetry, safety and self-reported measures in low ambulation patients using C-Leg as MCPK (Jayaraman et al., 2021). There are no significant differences between MCPK and NMCPK in Quality of life and gait profile score for low mobility patients, while there is improvement with MCPK in mobility, fall and balance confidence in statistical level but not significant (Davie-Smith and Carse, 2021). As the study design did not review this type of participant as exclusion criteria, so results cannot be compared here.

Mobility between the different MCPK types, comparing the outcomes of patients moved from C-Leg to Genium reported improvement in mobility of patients (Mileusnic et al., 2021). A comparison between Genium, C-leg and non-amputees in relation to endurance, balance and flexibility of upper and lower body, the Genium had significant improvement in endurance, balance and flexibility of the body compared to C-leg, while only endurance was significantly lower than non-amputees (Highsmith et al., 2016). There was a relationship between the general self-efficacy and mobility with

prosthesis whether the prosthesis was MCPK or NMCPK, there was no significant differences between MCPK and NMCPK in self-efficacy, distance, gait speed and steps (Möller et al., 2019; Möller et al., 2018). This Also justified the different functions extracted from different MCPKs. As the developers have different functions in the MCPK, the reflect on participants is different and still under reporting in the literature body clearly.

From Prosthetist point of view and based on clinical intervention, Patients with mobility level 3 and 4, will be able to ambulate, transfer and handle their mobility safety properly, Providing MCPK for this category extends their abilities and remove their mobility boundaries to move and reach farther services (uneven ground). This reflects the return back and impact of financial outcome based on MCPK fitting. On the other hand, fitting of MCPK requires regular joint service for both the joint and charger by the initial manufacturer and exposes the user for more clinical interviews than the NMCPK.

In Summary, MCPK influences and impacts the user's mobility by affording additional abilities to ambulate over different services, up and down ramps and stairs, and increases safety measures. NMCPK allows the users to achieve certain levels of mobility but not equal to MCPK.

5.1.2 Community Interactions

PEQ scales reviewed the interaction between the prosthetic user and his/her community on different levels. Scales of utility, sound, appearance, frustration, perceived response, and social burden were measuring the user and community interactions. At the same time, FIM scales measured the level of dependency by scoring the assessment of self-care level, sphincter control, communication, and social cognition. Study results for

PEQ found that, using MCPK significantly improved the utility and appearance, and higher scores for other scales in sound, frustration, perceived response and social burden. Results of FIM for self-care and sphincter control were higher but not in level of significance, on the other side for communication and social cognition scales were slightly higher for NMCPK. Utility and appearance were the most appearing physically to the community from other six subscales of the PEQ, Psychosocial experience was summarised under the perceived response, frustration, and social burden. Utility and appearance showed significance while the sound did not, as MCPK had sound alerts when batteries were going to empty or unusual failure happening like disconnection of tube or magnetic field areas. This justified the added values only in utility and appearance. Study results were unique and had not been reported in the literature body in this level of details. Sawers and Hafner, 2013 reported in his systematic review that using MCPK reduces the required cognition to handle the prosthetic knee joints and enables the users to walk with less attention to the Prosthetic knee joint condition. (Davie-Smith and Carse, 2021) reported improvement but not in significant level for confidence. (Burçak et al., 2021) reported that MCPK increased the participation in the community compared to NMCPK. Comparison between C-leg and Genium (Highsmith et al., 2014) utilising PEQ outcome measure, Genium had significant improvement in utility, perceived response, social burden and wellbeing. Study results agree only with utility as the other elements of this study are still shared in both C-leg and Genium. Study also agreed with the finding of (Şen et al., 2020) as MCPK had no significance in social participation. And with the study of (Möller et al., 2019; Möller et al., 2018) there were no differences in General Self-Efficacy (GSE) and Questionnaire for Persons with a Transfemoral Amputation (Q-TFA). Residual limb scale showed improvement in study results but not reaching a significant level.

5.1.3 Quality of Life

General Quality of life outcome measure was reported and showed improved quality of life with MCPK, as the study results reported a significant total PEQ score and total of FIM improvement for MCPK compared to NMCPK. Scales of both outcomes showed improvement and some areas were not in level of significance. Literature review includes many studies for QOL with MCPK and NMCPK (Sawers and Hafner, 2013; Mileusnic et al., 2021; Theeven et al., 2013; Thibaut et al., 2022). Using MCPK improves the quality of life, and better life satisfaction compared to NMCPK (Burçak et al., 2021). Low mobility MCPK users have higher satisfaction (Howard et al., 2018). From a psychological perspective, MCPK improves the patient's perception of vitality and depression symptoms (Şen et al., 2020). Using MCPK increases personal satisfaction and preference (Sawers and Hafner, 2013). Significant increase in preference and satisfaction of users, decrease difficulty in multitasking while using the MCKP (Hafner et al., 2007).

Mentioned studies are reporting general QOL, or using sub scales of QOL measures, usually, different scales in the same outcome measure may have different results as the results of this study reported. Other perspectives to have always unify the other factors impacted the prosthetic user outcomes, like socket, foot or general mobility or health condition may affect the QOL.

Comparing MCPK in relation to QOL, a systematic review comparing the outcomes of patients moved from C-Leg to Genium reported improvement in quality of life for patients; additional studies are required to increase the evidence level (Mileusnic et al., 2021). The results of PEQ for the patients transferred from C-leg to Genium showed significant improvements in Perceived Response, Social Burden, Utility, and Well-

Being, no differences between C-leg and Genium on Ambulation, Frustration and Residual Limb Health, physical performance were significantly improved with the Genium compared to C-leg (Highsmith et al., 2014).

5.1.4 Price Comparison

The price differences are high between MCPK and NMCPK as mentioned earlier. Still the reported outcome of mobility and the QOL can compensate for the additional expenses. Patient ability to go back to their work and social life will decrease the dependency level and add outcome for the community. Future options of MCPK and more market competitors may afford the ability to have cheaper options matched to the patients or the sponsors limits to afford the prosthesis. Literature review of economic studies reported efficiency of using MCPK (Kuhlmann et al., 2020). While (Chen et al., 2018; Sawers and Hafner, 2013) showed that there is equivalent cost between MCPK and NMCPK. Initial fitting will cost more with MCPK, while the full warranty period and restoration of function (ability to return to work) will decrease the difference of the cost and make the prediction of cost more efficient, additional studies in the field of cost effectiveness is needed and inclusion of the return values in community should be clearly counted (Donnelley et al., 2021).

5.2. Gender

In male MCPK users, a study found that PEQ results reported significant differences in Utility, Appearance, ambulation, and total score of PEQ. FIM results reported significance in Male and Female for locomotion. The number of male participants was 66, and the number of female participants was 10. Study reported that no variations were impacted based on gender. There was no literature reporting gender variations between MCPK and NMCPK users.

5.3. Age

Study results for PEQ outcome based on three age categories, middle adulthood (25-40) MCPK users had significant differences in utility, frustration, ambulation, and total PEQ. Early adulthood (18-24) and late adulthood (41-60) users had no significant findings. For FIM outcome measure, MCPK users had significant improvement in both self-care and locomotion in the middle adulthood age category. No significance was noted in the other two age categories.

Frustration reduction or improvement over MCPK participants and Self-care reported unique results for the study and reflected that the age of participant is important in Frustration and self-care. Early adulthood usually has more worries for their future and the same with late adulthood as they have more worries about their geriatric's life. For self-Care also, the independence of middle adulthood improved more than early and late adulthood.

5.4. Amputation Aetiology

Study participants with traumatic cause of amputation were 49 participants 64.5%, diseases caused by amputations were 21 participants 27.6 %, and congenital limb loss were 6 participants 7.9%. The cause of amputation for MCPK had significant differences in Ambulation. Traumatic and congenital causes of amputation had no significant findings. Same findings also reported in FIM results as disease cause of amputation had significant improvement toward MCPK in both transferring and locomotion. Both outcome measures' findings were aligned for cause of amputation impaction toward MCPK than NMCPK. Traumatic and congenital causes of amputations reflected less ambulation/ locomotion(mobility) added value of MCPK compared to diseased cause of amputation.

Participants with disease caused by amputation reflected the self-reported ambulation in different services and walks as it was not achievable with NMCPK. Usually, traumatic patients are looking to restore their previous high mobility level of prior injury and their rehabilitation in faster duration compared to other disease and congenitality. As the finding of the study aligned with the low ambulation patients can get more benefits from MCPK, the study enrolment was only for active users. The relationship here is the lower level of functionality when it comes to tolerance and endurance for disease caused by amputation compared to traumatic or congenital limb loss. Self-reported ambulation was significantly improved with participants having disease because of amputation as well the score of FIM for locomotion and transferring significantly improved. A study reviewed the outcomes of amputation rehabilitation (Karmarkar et al., 2014) reported the relationship between the FIM outcomes and level of amputation based on length of stay during rehabilitation, cause of amputation and level of amputation and reported certain limits for FIM outcomes during discharge, but this study did not analyse the type of the prosthesis as variable. This was a unique finding and never reported in the literature body, as the relationship between cause of amputation to be linked and aligned with the patient's expectations during initial assessment.

5.5. Nationality

For Saudi Patients using MCPK, study results for PEQ found significant differences in Utility, and ambulation. For FIM score, Self-care, Transferring, and locomotion were significantly improved with Saudi MCPK compared to NMCPK. No Non-Saudi patients had significant findings in both outcome measures. Study had 63 participants of Saudi nationality, 13 participants were residents in Saudi Arabia with different

nationalities, 3 participants used MCPK and 10 used MCPK. The limited number of non-Saudi is limited to show the clear findings.

5.6. Study Limitations

Different types of comparisons were reported in literature and still inconsistent results are not formalised. Reference methodology based on clear outcomes and selection of certain levels of variables are important and required. Different types of MCPK are available in the market, as well as different types of NMCPK in hydraulic or mechanical designs. Proper criteria to have the reference comparison based on MFCL and some other prosthesis components were fixed during the study, including socket suspension and design, prosthetic feet, and the time between the date of amputation and the fitting date. Comparison also between the MCPK types is important to detect the variations and report the differences between the MCPK types based on clinical findings and user reporting outcomes.

Using different satisfaction questionnaires makes the comparison of the results difficult (Baars et al., 2018). Nine scales of PEQ original were used and other modified edits like PEQ-MS 13/11, PEQ-MS 12/5 and PEQ-MS 13/7, these modifications made the comparison of findings difficult (Balk et al., 2018). At the same time, the sensitivity of outcome measures for selected components and mainly with MCPK is not yet clear if the outcome was reported under the total results in place of sub scales. The findings of both used outcome measures during the study, PEQ and FIM total results, in comparison of MCPK to NMCPK showed significance but that was not in all scales, and this showed the importance of reporting the full scales during studying the QOL or the clinical outcomes.

Other important factors that impacted studying MCPK usage and from clinical experience included the culture of amputees, the expensive device should be better and the smart, sophisticated, and advanced options always provide better outcomes. This is not scientifically yet approved. Regional and based on study location, the spending for prosthetics and rehabilitation from sponsors is not limited and usually the clinical decision is driven based on the best clinical outcomes.

No evidence suggests that NMCPK provides improved clinical outcomes when compared with MCPK within the body of literature (Sawers and Hafner, 2013) General evidence in adding value for MCPK compared to NMCPK is limited (Theeven et al., 2013). Additional research is needed to emphasise the outcome of MCPK (Sawers and Hafner, 2013). Varying levels of evidence indicate that the prescription, fit and use of different types of MCPK lead to changes in outcomes for individuals with unilateral transfemoral amputees when compared with NMCPK (Sawers and Hafner, 2013). Future studies are needed to report the effects of MCPK compared to NMCPK (Thibaut et al., 2022). Literature gap of inconsistency of finding between studies comparing MCPK and NMCPK (Hahn et al., 2021; Howard et al., 2018). Also, sample size for studies is a challenge mentioned in literature review (Şen et al., 2020). More longitudinal studies are needed to identify the added values for the MCPK (Ramstrand, Rusaw and Möller, 2020). Mentioned points are important to achieve the final conclusions and have clear findings to fulfil the gaps in the literature for the comparison of use between MCPK and NMCPK. Future studies are recommended to fix all the variables, for both participants and prosthetist, suggesting to have a prosthetic knee joint with same external frames (shape and colour) matched, and the participants and prosthetist are blindly selecting the joints. Proper outcome measures to detect the impact and the added values of each type should be used.

5.7. Study Strength

The study strength focused on the reported results and the relationship between the study variables. The study reported the functional outcome measures for both PEQ and FIM for transfemoral amputees, as this reporting has never been provided for any amputees in Saudi Arabia based on the best knowledge on the literature review. This study is the first reported study about the impact of use of certain prosthetic joints in Saudi Arabia. The study was focused on one level of amputation of actively fitted prosthetic users, which showed direct and important findings based on the enrolled participants. Another important point, as Saudi Arabia considered one of high income countries, the MCPK is affordable by the governmental sector or public services, the impact of use for the MCPK was not improving all the subscales reviewed in subscale level.

Prosthetic services are important in the health industry worldwide, limited and rarely studies are covering the field compared to pharmaceutical or other medical field divisions. The study reviewed important topics belonging to the growing need for more smart and automated technology. The microprocessors are included in our life more than any time in history, this also reviews and answers the benefits for the amputees' prosthetic devices. Microprocessor usage in prosthetic knee joints is still not matching the prosthesis user expectations and the prosthetist as a professional in the field based on the return values. Future prosthetic knee design may require more algorithms of analysis, less weight and easier programming functions.

Cause of amputation, Gender, and age of participants are uniquely reviewed and analysed in the study. Reporting the results and creating the relationships between the findings allows the healthcare providers and the patients to know what they may

achieve prior to the prosthesis fitting, for example the disease cause of amputation reported significant ambulation results than other causes of amputation. Such findings direct the prosthetist to consider the added values based on the cause of amputation and prior operative patient's condition. Study found a relationship between demographic information and criteria of prosthetic knee joint selection and impact of use for MCPK joint, prosthesis users age as example showed significance in middle adulthood (25-40) years compared to other age categories.

CHAPTER 6

CONCLUSION AND RECOMMENDATIONS

6.1. Introduction

This chapter includes the study main findings, recommendation for prosthetist and amputee speciality team members, and future research recommendations and conclusion.

6.2. Summary of Finding

MCPK improves the transfemoral amputee's experience in the following PEQ subscales: utility, appearance, ambulation, and total score of PEQ, and following FIM subscales: Transfer, locomotion, and total score of FIM. No evidence that NMCPK provides better outcomes than MCPK in any subscales of both PEQ and FIM outcome measures.

Middle adulthood (25-40) years MCPK users have significant differences in Utility, Residual limb, Frustration, and ambulation in relation to PEQ and in self-care and locomotion in FIM compared to early and late adulthood. No gender variations found except residual limb with male users in PEQ results. MCPK users with disease because of amputation have a significant ambulation score in PEQ, and transfer and locomotion in FIM more than traumatic and congenital. MCPK has higher PEQ in all scales.

6.3. Recommendations for Prosthetist and Amputee Speciality Members

Prosthetists should be aware of the expected added values from the prosthesis fitting, impact of used components in the prosthesis, and the participant objectives for the transfemoral amputees in the initial evaluation clinics. MCPK improves some but not all subscales in the patient experience based on the study finding. Prosthetists should

be knowledgeable for all the design specifications in each prosthetic knee joint, programming function and criteria of use, contraindications, and the expected outcomes of the participants. Patient expectations are important but not always manageable during the prosthesis fitting, mainly when the patient compares his prosthesis to his leg prior to amputation. Prosthetist knowledge of options and functions in MCPK and NMCPK will enable the patient to have a clear understanding of functional restorations. Prosthesis components are wide range and there are huge differences in the functions, and the certified prosthetist orthotist is the responsible healthcare provider to match the best option based on the patient needs and the projected post prosthetic rehabilitation goals to match the other multi-interdisciplinary team plan of care.

Physiotherapist, occupational therapist, recreational therapist, and physiatrists should have the basic knowledge of prosthesis components to set the plan of care based on affordable outcomes and within the safety measures. Team communication and unifying goals are essential mainly during initial assessment. The best matched prosthetic knee joint to the patient will afford the required safety, outcome, and highest satisfaction score. Training duration, intensity and goals mainly for physiotherapy require consideration of the type of prosthesis, mainly the prosthetic knee joint, for example post prosthetic rehabilitation program with mechanical weight activated knee joint is completely different from post prosthetic rehabilitation program with Genium knee joint.

6.4. Recommendations for Future Studies

Future studies are recommended to highlight the relationship between the users' feedback and the Prosthetic knee joint mechanisms. Different outcomes reported in QOL, mobility and other subscales, more outcome details reporting will clarify the

condition and derive better conclusions. Proper comparison based on the design of the Prosthetic knee joint and fixation of the Prosthetic components like Prosthetic foot and socket are important. More studies are recommended to analyse the relationship between cause of amputation, patient age and gender. More studies including more sample size with specified goals on specific levels of amputation. MCPK usage is increasing and many patients are still not satisfied with achieved goals from the fitting. Finally, future economic studies are required to analyse the cost and the return from the MCPK fitting, sponsor decisions usually avoid paying MCPK and consider this as additional and not enough justified to be provided for amputees.

6.5. Conclusion

Improvement in transfemoral amputees using MCPK prostheses in terms of expression in quality of life increases the expectations of prosthetic rehabilitation. These prostheses were also associated with improved performance in gait and daily activities throughout our study period. MCPK improves the transfemoral amputee's overall experience among different gender, age categories, and causes of amputations.

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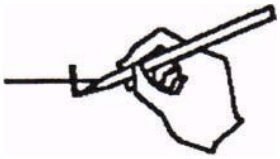
Appendices A: PEQ English version

Prosthesis Evaluation Questionnaire

Seattle, WA, USA *Instructions*

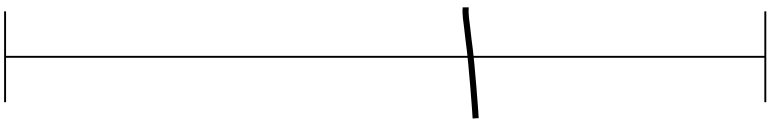


As you read each question, remember there is no right or wrong answer. Just think of YOUR OWN OPINION on the topic and make a mark THROUGH the line anywhere along the line from one end to the other to show us your opinion.

If you use different prostheses for different activities, please choose the ONE you use more often and answer all the questions as though you were using that prosthesis.

Example

How important is it to you to have coffee in the morning?



NOT AT ALL IMPORTANT EXTREMELY

Over the past four weeks, rate your morning coffee.

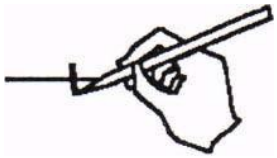
TERRIBLE **EXCELLENT**

OR check I haven't drunk coffee in the morning in the past four weeks.

This example shows that the person who answered these questions feels that having coffee in the morning is important to him. He also thinks the coffee he has had lately has not been very good.

If he hadn't drunk any coffee in the last four weeks, he would have put a check by that statement instead of putting a mark on the line between TERRIBLE and EXCELLENT.

As in this example, make a mark across the line rather than using an X or an O.



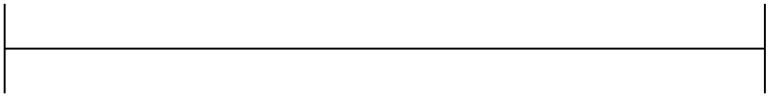
Please answer all the questions.

Support for development of the PEQ was provided by the U.S. Department of Veterans Affairs.

Group 1

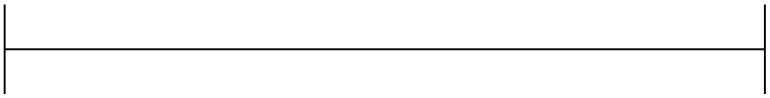
These first questions are about YOUR PROSTHESIS.

Over the past four weeks, rate how happy you have been with your current prosthesis.



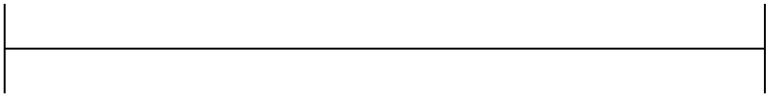
EXTREMELY UNHAPPY EXTREMELY HAPPY

Over the past four weeks, rate the fit of your prosthesis.



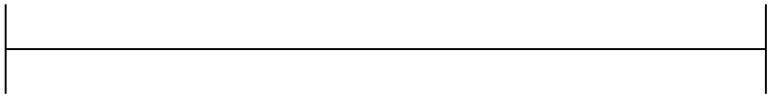
TERRIBLE EXCELLENT

Over the past four weeks, rate the weight of your prosthesis.



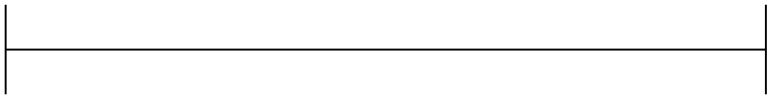
TERRIBLE EXCELLENT

Over the past four weeks, rate your comfort while standing *when using your prosthesis.*



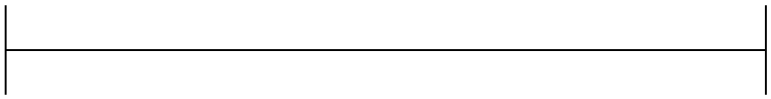
TERRIBLE EXCELLENT

Over the past four weeks, rate how often you felt off balance *while using your prosthesis.*



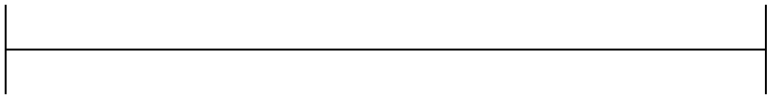
ALL THE TIME NOT AT ALL

Over the past four weeks, rate how much energy it took to use your prosthesis for as long as you needed it.



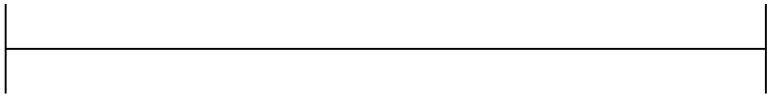
COMPLETELY EXHAUSTING NONE AT ALL

Over the past four weeks, rate the feel (such as the temperature and texture) of the prosthesis (sock, liner, socket) on your residual limb (stump).



WORST POSSIBLE BEST POSSIBLE

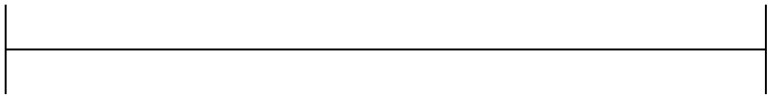
Over the past four weeks, rate the ease of putting on (donning) your prosthesis.



TERRIBLE EXCELLENT

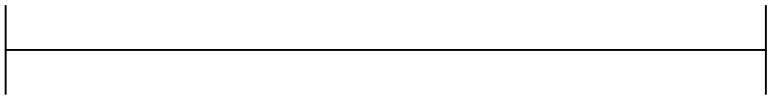
TERRIBLE EXCELLENT

Over the past four weeks, rate how often your prosthesis made squeaking, clicking, or belching sounds.



ALWAYS NEVER

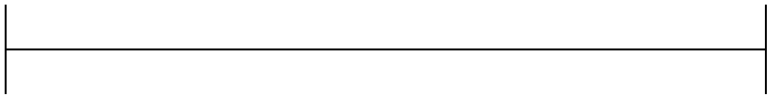
If it made any sounds in the past four weeks, rate how bothersome these sounds were to you.



EXTREMELY BOTHERSOME NOT AT ALL

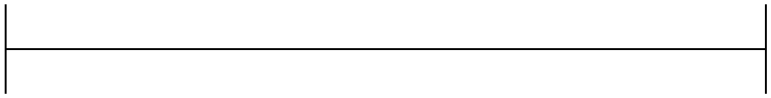
OR check____It made no sounds.

Over the past four weeks, rate the damage done to your clothing by your prosthesis.



EXTENSIVE DAMAGE NONE

Over the past four weeks, rate the damage done to your prosthesis cover.

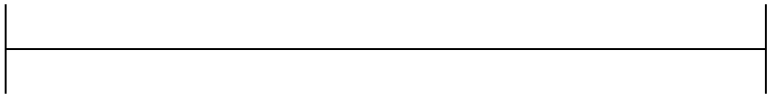


EXTENSIVE DAMAGE NONE

OR check____There is no cover on my prosthesis

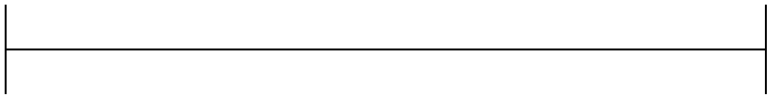
CANNOT NO PROBLEM

Over the past four weeks, rate how limited your choice of clothing was because of your prosthesis.



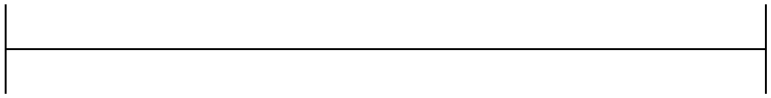
WORST POSSIBLE NOT AT ALL

Over the past four weeks, rate how much you sweat inside your prosthesis (in the sock, liner, socket).



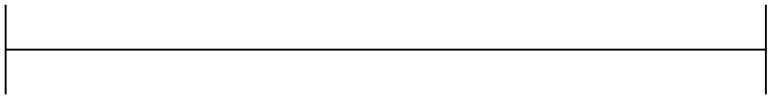
EXTREME AMOUNT NOT AT ALL

Over the past four weeks, rate how smelly your prosthesis was at its worst.



EXTREMELY SMELLY NOT AT ALL

Over the past four weeks, rate how much of the time your residual limb was swollen to the point of changing the fit of your prosthesis.

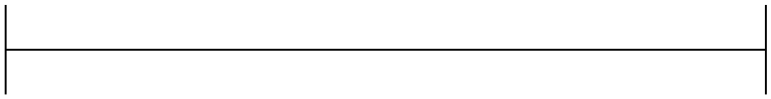


ALL THE TIME NEVER

EXTREMELY BOTHERSOME NOT AT ALL

OR check I had no rashes on my residual limb in the last month.

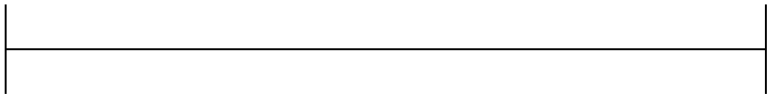
Over the past four weeks, rate any ingrown hairs (pimples) that were on your residual limb.



EXTREMELY BOTHERSOME NOT AT ALL

OR check I had no ingrown hairs on my residual limb in the last month.

Over the past four weeks, rate any blisters or sores that you got on your residual limb.



EXTREMELY BOTHERSOME NOT AT ALL

OR check I had no blisters or sores on my residual limb in the last month

Group 2

7he next section covers very SPECIFIC BODILY SENSATIONS. Here are our definitions:

SENSATIONS are feelings like "pressure", "tickle" or a sense of position or location, such as the toes being curled. Amputees have described sensations in their missing (phantom) limb such as "the feeling that my (missing) foot is wrapped in cotton."

PAIN is a more extreme sensation described by terms such as "shooting", "searing", "stabbing", "sharp", or "ache".

PHANTOM LIMB refers to the part that is missing. People have reported feeling sensations and/or pain in the part of the limb that has been amputated — that is, in their phantom limb.

RESIDUAL LIMB (STUMP) refers to the portion of your amputated limb that is still physically present.

REGARDING SENSATIONS IN YOUR PHANTOM LIMB

Over the past four weeks, rate how often you have been aware of non-painful sensations in your phantom limb.

_____ never

_____ only once or twice

_____ a few times (about once/week)

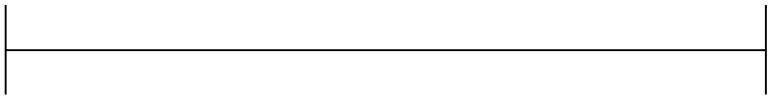
_____ fairly often (2-3 times/week)

_____ very often (4-6 times/week)

_____ several times every day

_____ all the time or almost all the time

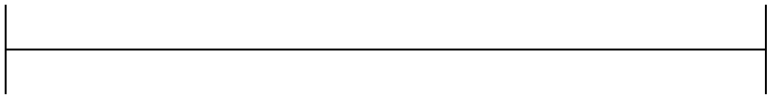
If you had non-painful sensations in your phantom limb during the past month, rate how intense they were on average.



EXTREMELY INTENSE EXTREMELY MILD

OR check____I did not have non-painful sensations in my phantom limb.

Over the past month, how bothersome were these sensations in your phantom limb?



ALL THE TIME NEVER

OR check____I did not have non-painful sensations in my phantom limb.

REGARDING PAIN IN YOUR PHANTOM LIMB

Over the past four weeks, rate how often you had pain in your phantom limb.

_____ never

_____ only once or twice

_____ a few times (about once/week)

_____ fairly often (2-3 times/week)

_____ very often (4-6 times/week)

_____ several times every day

_____ all the time or almost all the time

How long does your phantom limb pain usually last?

_____ I have none

_____ a few seconds

_____ a few minutes

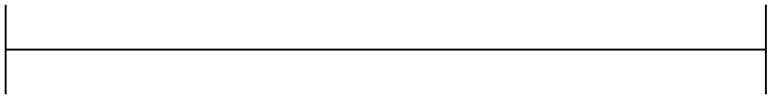
_____ several minutes to an hour

_____ several hours

_____ a day or two

_____ more than two days

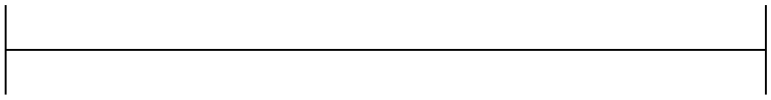
If you had any pain in your phantom limb this past month, rate how intense it was on average.



EXTREMELY INTENSE EXTREMELY MILD

OR check____I did not have any pain in my phantom limb.

In the past four weeks how bothersome was the pain in your phantom limb?



EXTREMELY BOTHERSOME EXTREMELY MILD

OR check____I did not have any pain in my phantom limb

REGARDING PAIN IN YOUR RESIDUAL LIMB (STUMP)

Over the past four weeks, rate how often you had pain in your residual limb.

_____ never

_____ only once or twice

_____ a few times (about once/week)

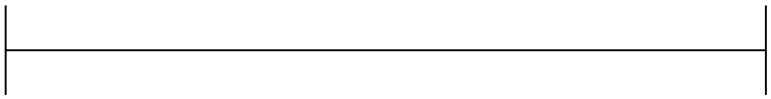
_____ fairly often (2-3 times/week)

_____ very often (4-6 times/week)

_____ several times every day

_____ all the time or almost all the time

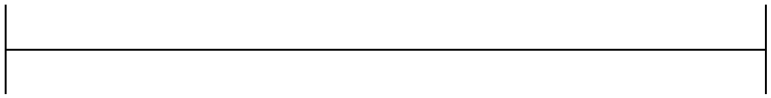
If you had any pain in your residual limb over the past four weeks, rate how intense it was on average.



EXTREMELY INTENSE EXTREMELY MILD

OR check____I did not have any pain in my residual limb.

OVER THE past four weeks how bothersome was the pain in your residual limb?



EXTREMELY BOTHERSOME NOT AT ALL

OR check____I did not have any pain in my residual limb.

REGARDING PAIN IN YOUR OTHER (NON-AMPUTATED) LEG OR FOOT

Over the past four weeks, rate how often you had pain in your other leg or foot.

_____ never

_____ only once or twice

_____ a few times (about once/week)

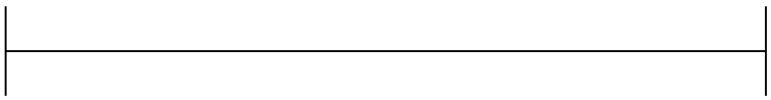
_____ fairly often (2-3 times/week)

_____ very often (4-6 times/week)

_____ several times every day

_____ all the time or almost all the time

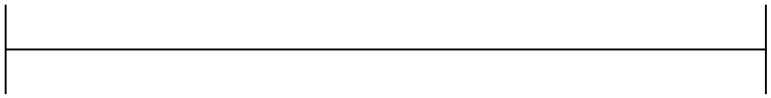
If you had any pain in your other leg or foot over the past four weeks, rate how intense it was on average.



EXTREMELY INTENSE EXTREMELY MILD

OR check____I had no pain in my other leg or foot.

OVER THE past four weeks how bothersome was the pain in your other leg or foot?



EXTREMELY BOTHERSOME NOT AT ALL

OR check____I had no pain in my other leg or foot.

REGARDING BACK PAIN

Over the past four weeks, rate how often you experienced back pain.

_____ never

_____ only once or twice

_____ a few times (about once/week)

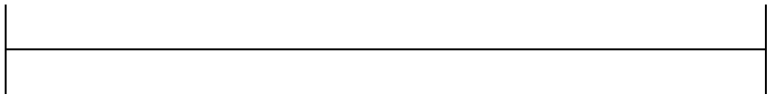
_____ fairly often (2-3 times/week)

_____ very often (4-6 times/week)

_____ several times every day

_____ all the time or almost all the tune

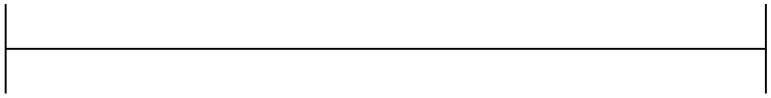
If you had any back pain over the past four weeks, rate how intense it was on average.



EXTREMELY INTENSE EXTREMELY MILD

OR check____I had no back pain.

OVER THE past four weeks how bothersome was the back pain?



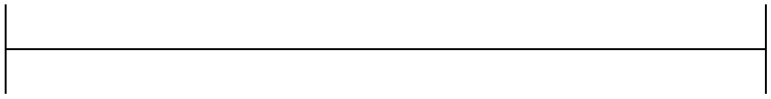
EXTREMELY BOTHERSOME NOT AT ALL

OR check____I had no back pain.

Group 3

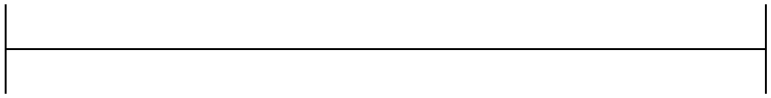
This section is about some of the SOCIAL AND EMOTIONAL ASPECTS OF USING A PROSTHESIS.

Over the past four weeks, rate how often the desire to avoid strangers' reactions to your prosthesis made you avoid doing something you otherwise would have done.



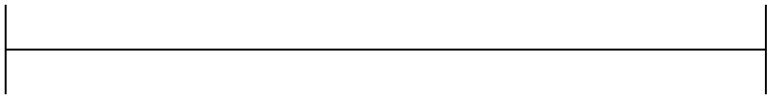
ALL THE TIME NEVER

Over the past four weeks, rate how frequently you were frustrated with your prosthesis.



ALL THE TIME NEVER

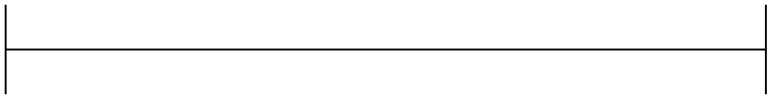
If you were frustrated with your prosthesis at any time over the past month, think of the most frustrating event and rate how you felt at that tune.



EXTREMELY FRUSTRATED NOT AT ALL

OR check____I have not been frustrated with my prosthesis. *We understand that sometimes you will have both positive and negative experiences with those close to you. Please try to answer these questions considering all the reactions you have had .*

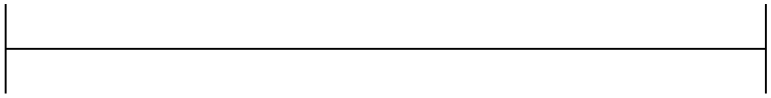
Over the past four weeks, rate how your partner has responded to your prosthesis



VERY POORLY VERY WELL

OR check I don't have a partner.

Over the past four weeks, rate how this response has affected your relationship.



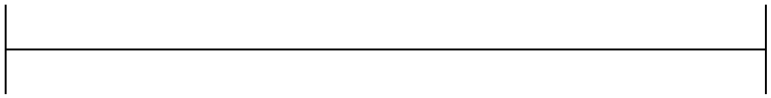
VERY BADLY VERY WELL

OR check____I don't have a partner.

Think of two close family members (other than your partner) and write down their relationship to you, like mother or son. #1__ #2 ____

OR check____I don't have any close family members.

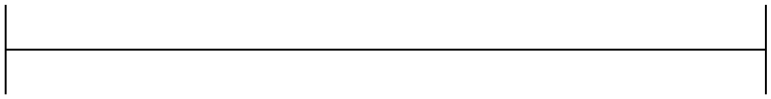
Over the past four weeks, rate how Family Member #1 has responded to your prosthesis



VERY POORLY VERY WELL

OR check____I don't have close family members.

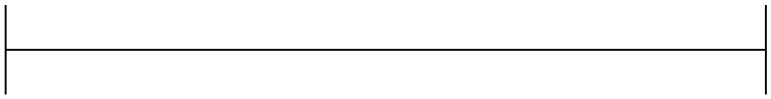
Over the past four weeks, rate how Family Member #2 has responded to your prosthesis.



VERY POORLY VERY WELL

OR check____I don't have a second close family member.

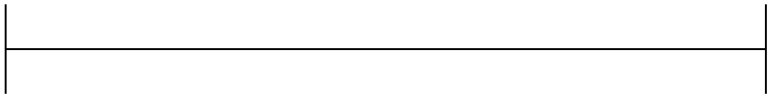
Over the past four weeks, rate how much a burden your prosthesis has been on your partner or family members.



EXTREMELY BURDENSOME NOT AT ALL

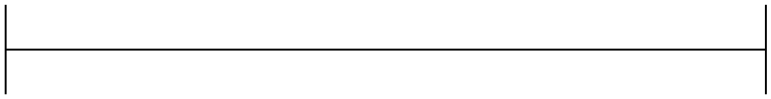
OR check____I don't have a partner or family members.

Over the past four weeks, rate how much having your prosthesis has hindered you socially.



A GREAT DEAL NOT AT ALL

Over the past four weeks, rate your ability to take care of someone else, (e.g. your partner, a child, or a friend).



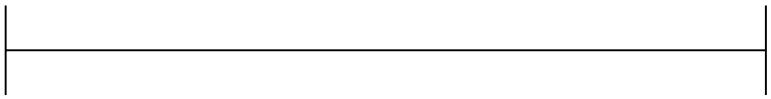
CANNOT NO PROBLEM

OR check____I don't take care of someone else.

Group 4

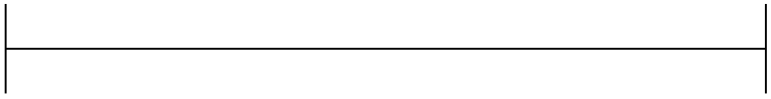
This section is about YOUR ABILITY TO MOVE AROUND.

Over the past four weeks, rate your ability to walk *when using your prosthesis.*



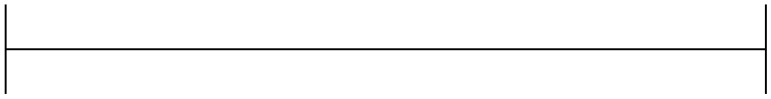
CANNOT NO PROBLEM

Over the past four weeks, rate your ability to walk in close spaces *when using your prosthesis.*



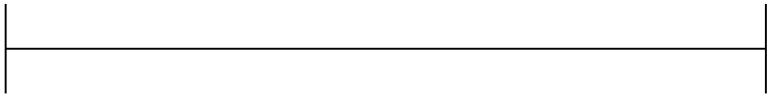
CANNOT NO PROBLEM

Over the past four weeks, rate your ability to walk up stairs *when using your prosthesis.*



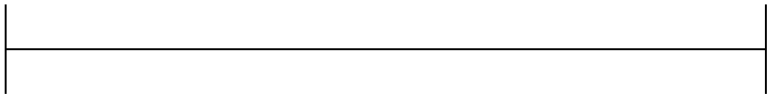
CANNOT NO PROBLEM

Over the past four weeks, rate how you have felt about being able to walk downstairs *when using your prosthesis.*



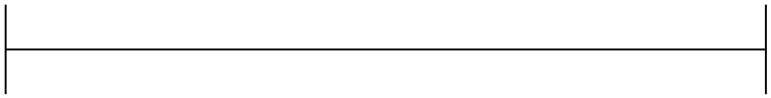
CANNOT NO PROBLEM

Over the past four weeks, rate your ability to walk up a steep hill *when using your prosthesis.*



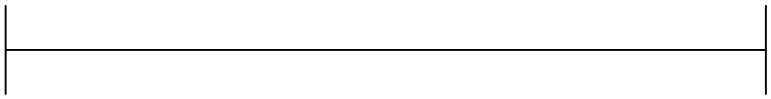
CANNOT NO PROBLEM

Over the past four weeks, rate your ability to walk down a steep hill *when using your prosthesis.*



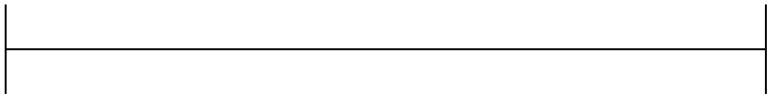
CANNOT NO PROBLEM

Over the past four weeks, rate your ability to walk on sidewalks and streets *when using your prosthesis.*



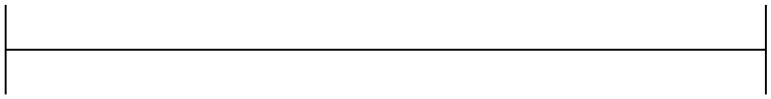
CANNOT NO PROBLEM

Over the past four weeks, rate your ability to walk on slippery surfaces (e.g. wet tile, snow, a rainy street, or a boat deck) *when using your prosthesis.*



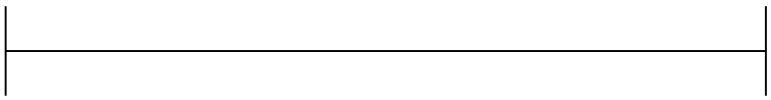
CANNOT NO PROBLEM

Over the past four weeks, rate your ability to get in and out of a car *when using your prosthesis.*



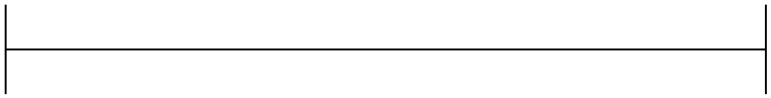
CANNOT NO PROBLEM

ever the past four weeks, rate your ability to sit down and get up from a chair with a high seat (e.g., a dining chair, a kitchen chair, an office chair).



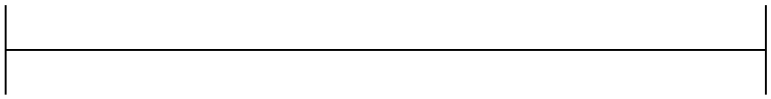
CANNOT NO PROBLEM

Over the past four weeks, rate your ability to sit down and get up from a low or soft chair (e.g. an easy chair or deep sofa).



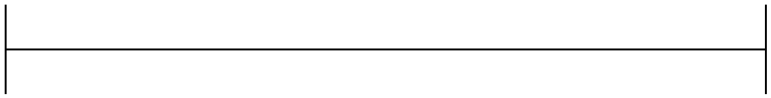
CANNOT NO PROBLEM

Over the past four weeks, rate your ability to sit down and get up from the toilet.



CANNOT NO PROBLEM

Over the past four weeks, rate your ability to shower or bathe safely.

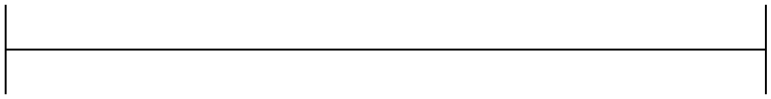


CANNOT NO PROBLEM

Group 5

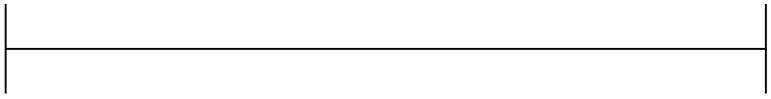
The following section asks about YOUR SATISFACTION WITH PARTICULAR SITUATIONS given that you have an amputation.

Over the past four weeks, rate how satisfied you have been with your prosthesis.



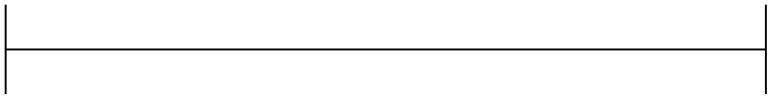
EXTREMELY DISSATISFIED EXTREMELY SATISFIED

Over the past four weeks, rate how satisfied you have been with how you are walking.



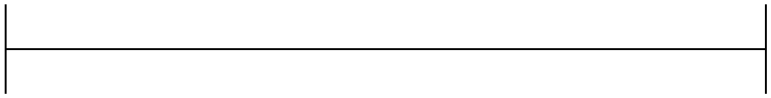
EXTREMELY DISSATISFIED EXTREMELY SATISFIED

Over the past four weeks, rate how satisfied you have been with how things have worked out since your amputation.



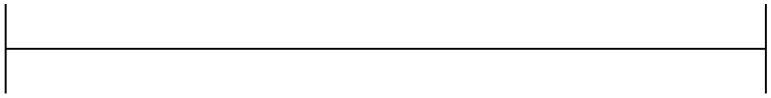
EXTREMELY DISSATISFIED EXTREMELY SATISFIED

Over the past four weeks, how would you rate your quality of life?



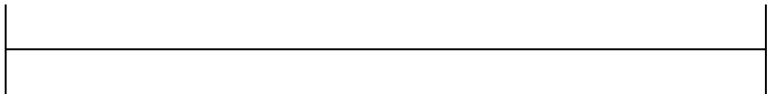
WORST POSSIBLE LIFE BEST POSSIBLE LIFE

How satisfied are you with the person who fit your current prosthesis?



EXTREMELY DISSATISFIED EXTREMELY SATISFIED

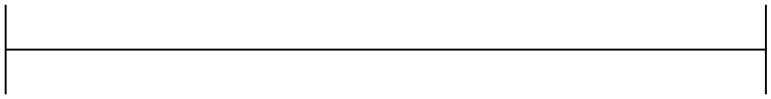
How satisfied are you with the training you have received on using your current prosthesis?



EXTREMELY DISSATISFIED EXTREMELY SATISFIED

OR check _ I have not had any training with my current prosthesis.

Overall, how satisfied are you with the gait and prosthetic training you have received since your amputation.



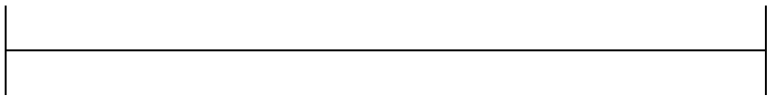
EXTREMELY DISSATISFIED EXTREMELY SATISFIED

OR check _ I have not had any training since my amputation.

Group 6

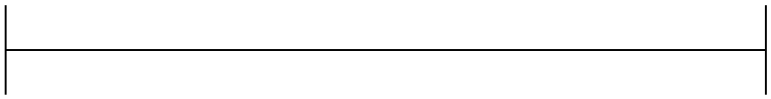
This next section asks you to rate your ability TO DO YOUR DAILY ACTIVITIES when you are having problems with your prosthesis.

When the fit of my prosthesis is poor, I will get...



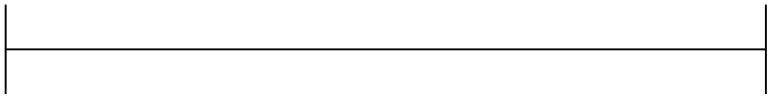
NOTHING DONE EVERYTHING DONE

When the comfort of my prosthesis is poor, I will get...



NOTHING DONE EVERYTHING DONE

Without my prosthesis, I will get...

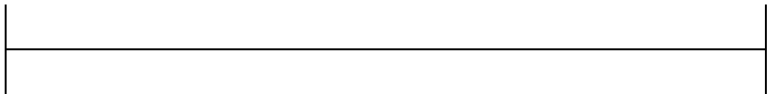


NOTHING DONE EVERYTHING DONE

Group 7

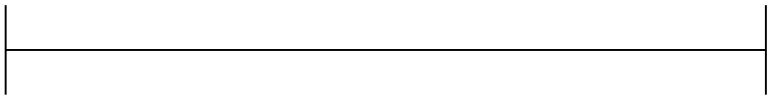
This last section asks you to rate HOW IMPORTANT different aspects (or qualities) of your prosthesis are to you.

How important is it that the weight of your prosthesis feel right?



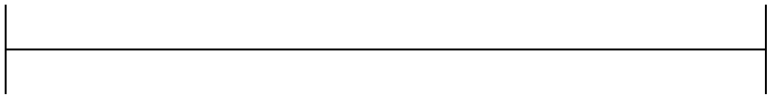
NOT AT ALL EXTREMELY IMPORTANT

How important is the ease of putting on (donning) your prosthesis?



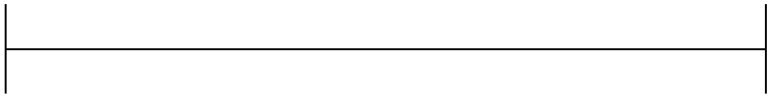
NOT AT ALL EXTREMELY IMPORTANT

How important is the appearance of your prosthesis (how it looks)?



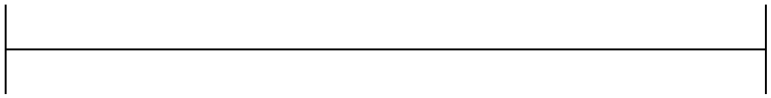
NOT AT ALL EXTREMELY IMPORTANT

How important is it to you to be able to wear different kinds of shoes (heights or styles)?



NOT AT ALL EXTREMELY IMPORTANT

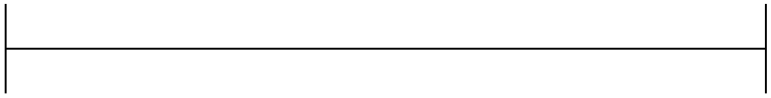
How important is it that your prosthesis' covering is durable (cannot be torn, dented, easily scratched, or discoloured)?



NOT AT ALL EXTREMELY IMPORTANT

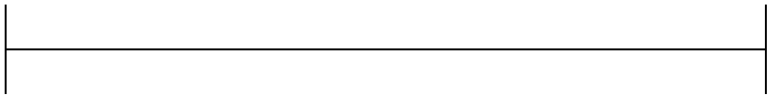
OR check There is no covering on my prosthesis.

How bothersome is it when you sweat a lot inside your prosthesis (in the sock, liner, socket)?



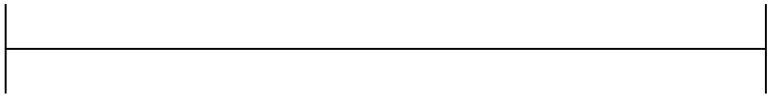
EXTREMELY BOTHERSOME NOT AT All

How bothersome to you is swelling in your residual limb (stump)?



EXTREMELY BOTHERSOME NOT AT ALL

How important is it to avoid having any ingrown hairs (pimples) on your residual limb (stump)?



NOT AT ALL EXTREMELY IMPORTANT

How bothersome is it to see people looking at you and your prosthesis?

EXTREMELY BOTHERSOME NOT AT ALL

How important is being able to walk up a steep hill?

NOT AT ALL EXTREMELY IMPORTANT

Final Notes

If any of the following have happened in the past four weeks, please check off and give a brief description:

_____ a serious medical problem (yours)

_____ a noticeable change in pain

_____ a serious personal problem (yours)

_____ a serious problem in the family

_____ some other big change has occurred in your life

If you checked any of the five previous items, please give a brief description.

Please share with us anything else about you or your prosthesis that you think would be helpful for us to know (continue on the back of this page if you need more space).

THANK YOU VERY MUCH!

Acknowledgement: Roorda LD, Roebroeck ME, Lankhorst GJ, van Tilburg T, Bouter LM. Measuring functional limitations in rising and sitting down: Development of a questionnaire. Arch Phys Med Rehabil 1996;77;663-669 for their influence on questions

Guide for the Use of the Prosthesis Evaluation Questionnaire

The PEQ is composed of 9 validated scales that are each comprised of multiple questions, and there are a number of additional individual questions. The scales have been validated for internal consistency and temporal stability and are scored as a unit. The scales are not dependent on each other, so it is reasonable to use only the scales that are pertinent to your research question. The PEQ does not include standard demographic questions you may also wish to ask such as level of amputation, years since amputation, age, cause of amputation, etc.

Most questions in the PEQ use a visual analog scale format. Each visual analog scale is scored as a continuous numerical variable measured as the distance in millimeters from the left endpoint of the line to the point at which the respondent's mark crosses the line. Each line is 100 mm long and is always measured from the left (0-100). The questions are all worded so that a higher number (toward the right) will correspond with a more positive response. Take care in copying the forms to assure that photographic reduction or enlargement has not occurred!

This guide contains coding instructions for all the questions. Note that the questions that offer the option of making a check mark to indicate that the question is not applicable to the respondent are sometimes coded "100" and sometimes "nr (no response)". Follow the guide for each question. Question F, on page 11, is provided for the respondent's own reference and does not need to be coded. Any question that is left blank is scored "nr" and treated as missing.

To calculate any of the scale scores, compute the average (arithmetic mean) of all the questions which make up that particular scale (see table below) and which the respondent(s) answered. If an individual only answered 5 questions of a 6-item scale, be sure you divide by 5 when calculating their mean. At least half the questions of a scale should be answered with a number score not "nr" for the scale to be valid (round up if the number of items is odd).

The PEQ Scales

Validated Scale Name	**Questions for each scale by page number and question letter**
Ambulation (AM)	13A, 13B, 13C, 13D, 14E, 14F, 14G, 14H
Appearance (AP)	3J, 3M, 3N, 4O, 4P
Frustration (FR)	10B, 10C
Perceived Response (PR)	10A, 11D, 11E, 11G, 12H
Residual Limb Health (RL)	4Q, 4R, 4S, 5T, 5U, 5V
Social Burden (SB)	12I, 12J, 12K
Sounds (SO)	3K, 3L
Utility (UT)	1B, 1C, 1D, 2E, 2F, 2G, 2H, 2I
Well Being (WB)	16C, 16D

The questionnaire is divided into Groups, or topical sections, for ease of looking at similar issues at one time. The items in a section include different scales. The user should take care when computing scale scores to identify the correct questions for each scale. There are also individual questions in the PEQ which should not be combined into scale scores. In the code book these are listed as satisfaction, pain, transfer, prosthetic care, self efficacy, and importance questions. They are all individual items.

If you plan use the PEQ or if you have suggestions for improvement please let us know. We will do our best to answer any questions you may have about using the PEQ. Please e-mail to peq@prs- research.org or FAX to (USA) (206) 903-8141. The PEQ may be used free of charge, however, all portions are copyrighted by Prosthetics Research Study. Use of any part of the PEQ must be accompanied by appropriate acknowledgement of Prosthetics Research Study. Thank you.

Support for development of the PEQ was provided by the U.S. Department of Veterans Affairs

Coding of All Questions in the PEQ

Questions about Your Prosthesis

Page/ Item	Scale or Single Question	Variable Name	Question "Over the past four weeks,.."	Scoring code
1A	Satisfaction Question	SAhapypros	...rate how happy you have been with your current prosthesis.	0-100
1B	Utility Scale	UTfit	...rate the fit of your prosthesis.	0-100
1C	Utility Scale	UTweight	...rate the weight of your prosthesis.	0-100
1D	Utility Scale	UTstand	...rate your comfort while standing when using your prosthesis.	0-100
2E	Utility Scale	UTsit	...rate your comfort while sitting when using your prosthesis.	0-100
2F	Utility Scale	UTbalance	...rate how often you felt off balance while using your prosthesis.	0-100
2G	Utility Scale	UTenergy	...rate how much energy it took to use your prosthesis for as long as you needed it.	0-100
2H	Utility Scale	UTfeel	...rate the feel (such as the temperature and texture_ of the prosthesis (sock, liner, socket) on your residual limb (stump).	0-100
2I	Utility Scale	UTdon	...rate the ease of putting on (donning) your prosthesis.	0-100

3J	Appearance Scale	APproslook	... rate how your prosthesis has looked.	0-100
3K	Sounds Scale	SOfreqsoun	... rate how often your prosthesis made squeaking, clicking, or belching sounds.	0-100
3L	Sounds Scale	SObotsoun	If it made any sounds in the past four weeks, rate how bothersome these sounds were to you. - Or check It made no sounds.	0-100 If checked score 100
3M	Appearance Scale	APdamagclo	... rate the damage done to your clothing by your prosthesis.	0-100
3N	Appearance Scale	APdamagcov	... rate the damage done to your prosthesis cover. — or check There is no cover on my prosthesis.	0-100 if checked score as "nr" (no response)
4O	Appearance Scale	APshoechoi	... rate your ability to wear the shoes (different heights, styles) you prefer.	0-100
4P	Appearance Scale	APclothchoi	... rate how limited your choice of clothing was because of your prosthesis.	0-100
4Q	Residual Limb Health Scale	RLsweat	... rate how much you sweat inside your prosthesis (in the sock, liner, socket).	0-100
4R	Residual Limb Health Scale	RLsmell	... rate how smelly your prosthesis was at its worst.	0-100
4S	Residual Limb Health Scale	RLswollen	... rate how much of the time your residual limb was swollen to the point of changing the fit of your prosthesis.	0-100
5T	Residual Limb Health Scale	RLrash	... rate any rash(es) that you got on your residual limb. — Or check 1 had no rashes on my residual limb in the last month.	0-100 if checked score 100

5U	Residual Limb Health Scale	RLhair	... rate any ingrown hairs (pimples) that were on your residual limb. — Or check 1 ad no ingrown hairs on my residual limb in the last month.	0-100 if checked score 100

5V	Residual Limb Health Scale	RLsore	... rate any blisters or sores that you got on your residual limb. — Or check 1 had no blisters or sores on my residual limb in the last month.	0-100 if checked score 100

Questions about Specific Bodily Sensations

Page/ Item	Scale or Single Question	Variable Name	Question "Over the past four weeks,..."	Scoring code
6	Pain Question	PAfrephsen	...rate how often you have been aware of non-painful sensations in your phantom limb. never only once or twice a few times (about once/week) d fairly often (2/3 times/week) very often (4-6 times/week) several times a day all the time or almost all the time.	a=0 b=1 c=2 d=3 e-4 f=5 g=6
6B	Pain Question	PAintphsen	If you had non-painful sensations in your phantom limb during the past month, rate how intense they were on average. Or check I did not have non-painful sensations in my phantom limb.	0-100 If checked score as "nr" (no response)
6C	Pain Question	PAbotphsen	... how bothersome were these sensations in your phantom limb? Or check 1 did not have non-painful sensations in my phantom limb.	0-100 If checked score as "nr" (no response)

7D	Pain Question	PAfrephpa	...rate how often you had pain in your phantom limb. never only once or twice a few times (about once/week) d fairly often (2/3 times/week) very often (4-6 times/week) several times a day all the time or almost all the time.	a=0 b=1 c=2 d=3 e-4 f=5 g=6
7E	Pain Question	PAdurphpa	How long does your phantom limb pain usually last? 1 have none a few seconds a few minutes several minutes to an hour several hours a day or two more than two days	a=0 b=1 c=2 d=3 e-4 f=5 g=6
7F	Pain Question	PAintphpa	If you had any pain in your phantom limb during the past month, rate how intense it was on average. Or check I did not have any pain in my phantom limb.	0-100 If checked score as "nr" (no response)
7G	Pain Question	PAbotphpa	... how bothersome was the pain in your phantom limb? Or check 1 did not have any pain in my phantom limb.	0-100 If checked score as "nr"

8H	Pain Question	PAfrerlpa	...rate how often you had pain in your residual limb. a. never b. only once or twice c. a few times (about once/week) d fairly often (2/3 times/week) e. very often (4-6 times/week) f. several times a day	a=0 b=1 c=2 d=3 e-4 f=5 9=6

			g. all the time or almost all the time	
8I	Pain Question	PAintrlpa	If you had any pain in your residual limb during the past month, rate how intense it was on average. Or check I did not have any pain in my residual limb.	0-100 If checked score as "nr" (no response)
8J	Pain Question	PAbotrlpa	...how bothersome was the pain in your residual limb? Or check I did not have any pain in my residual limb.	0-100 If checked score as "nr" (no-response)
8K	Pain Question	PAfreolpa	...rate how often you had pain in your other leg or foot. a. never b. only once or twice c. a few times (about once/week) d fairly often (2/3 times/week) e. very often (4-6 times/week) f. several times a day g. all the time or almost all the time	a=0 b=l c=2 d=3 e=4 f=5 g=6
9L	Pain Question	PAintolpa	If you had any pain in your other leg or foot during the past month, rate how intense it was on average. Or check I had no pain in my other leg or foot.	0-100 If checked score as "nr" (no-response)
9M	Pain Question	PAbotolpa	...how bothersome was the pain in your other leg or foot? Or check I had no pain in my other leg or foot.	0-100 If checked score as "nr"

				(no-response)
9N	Pain Question	PAfrebapa	...rate how often you experienced back pain a. never b. only once or twice c. a few times (about once/week) d fairly often (2/3 times/week) e. very often (4-6 times/week) f. several times a day g. all the time or almost all the time	a=0 b=1 c=2 d=3 e-4 f=5 g=6
9O	Pain Question	PAintbapa	If you had any back pain during the past month, rate how intense it was on average. Or check I had no back pain.	0-100 If checked score as "nr" (no-response)
10P	Pain Question	PAbotbapa	...how bothersome was the back pain? Or check I had no back pain.	0-100 If checked score as "nr" (no-response)

Questions about Social and Emotional Aspects of Using a Prosthesis

Page/ Item	Scale or Single Question	Variable Name	Question "Over the past four weeks,..."	Scoring code
10A	Perceived Response Scale	PRavoidoth	... rate how often the desire to avoid stranger's reactions to your prosthesis made you avoid doing something you otherwise would have done.	0-100
10B	Frustration Scale	FRfreqfrus	...rate how frequently you were frustrated with your prosthesis.	0-100

10C	Frustration Scale	FRmostfrus	If you were frustrated with your prosthesis at any time over the pat month, think of the most frustrating event and rate how you felt at that time. Or check 1 have not been frustrated with my prosthesis.	0-100 if checked score 100
11D	Perceived Response Scale	PRpartresp	...rate how your partner has responded to your prosthesis. Or check 1 don't have a partner.	0-100 If checked score as "nr" (no-response)
11E	Perceived Response Scale	PRrelafct	... rate how this response has affected your relationship. Or check 1 don't have a partner.	0-100 If checked score as "nr" (non-response)
11F	This question prepares for following questions by having the respondent identify two particular people in their mind, giving minimal identification.		Think of two close family members (other than your partner) and write down their relationship to you, like mother or son. Or check 1 don't have any close family members.	This question is not scored
11G	Perceived Response Scale	PRfamlres	...rate how Family Member #1 has responded to your prosthesis. Or check I don't have close family members.	0-100 If checked score as "nr" (no-response)
12H	Perceived Response Scale	PRfam2res	...rate how Family Member #2 has responded to your prosthesis. Or check I don't have a second close family member.	0-100 If checked score as "nr" (no-response)
12I	Social Burden Scale	SBpartburd	...rate how much of a burden your prosthesis has been on your partner or family members. Or check I don't have a partner or family members.	0-100 If checked score as "nr" (no-response)
12J	Social Burden Scale	SBsochind	...rate how much having your prosthesis has hindered you socially.	0-100
12K	Social Burden Scale	SBcaregive	...rate your ability to take care of someone else, (e.g. your partner, a child, or a friend). Or check I don't take care of someone else.	0-100 If checked score as "nr" (no-response)

Questions about Ability to Move Around

Page/ Item	Scale or Single Qeustion	Variable Name	Question 'Over the past four weeks,..."	Scoring code
13A	Ambulation Scale	AMwalk	...rate your ability to walk when using your prosthesis.	0-100
13B	Ambulation Scale	AMclose	...rate your ability to walk in close spaces when using your prosthesis.	0-100
13C	Ambulation Scale	AMupstair	...rate your ability to walk up stairs when using your prosthesis.	0-100
13D	Ambulation Scale	AMdwnstair	...rate how you felt about being able to walk down stairs when using your prosthesis.	0-100
14E	Ambulation Scale	AMuphill	...rate your ability to walk up a steep hill when using your prosthesis.	0-100
14F	Ambulation Scale	AMdownhill	...rate your ability to walk down a steep hill when using your prosthesis.	0-100
14G	Ambulation Scale	AMsidewalk	...rate your ability to walk on sidewalks and streets! when using your prosthesis.	0-100
14H	Ambulation Scale	AMslip	.....rate your ability to walk on slippery surfaces (e.g. wet tile, snow, a rainy street, or a boat deck) when using your prosthesis.	0-100
14I	Transfer Question	TRcar	...rate your ability to get in and out of a car when using your prosthesis.	0-100
15J	Transfer	TRhichair	... rate your ability to sit down and get up from a chair with a high seat (e.g., a dining chair, a kitchen chair, an office chair).	0-100
15K	Transfer Question	TRIochair	...rate your ability to sit down and get up from a low or soft chair (e.g. an easy chair or deep sofa).	0-100
15L	Transfer Question	TRtoilet	...rate your ability to sit down and get up from the toilet.	0-100
15M	Transfer Question	TRbath	...rate your ability to shower or bathe safely.	0-100

Questions about satisfaction with particular situations

Page/ Item	Scale or Single Question	Variable Name	Question "Over the past four weeks,..."	Scoring code
16A	Satisfaction Question	SAsatpros	...rate how satisfied you have been with your prosthesis.	0-100
16B	Satisfaction Question	SAsatwalk	...rate how satisfied you have been with how you are waking.	0-100
16C	Well Being Scale	WBsincamp	... rate how satisfied you have been with how things have worked out since our amputation.	0-100
16D	Well Being Scale	WBqol	... how would you rate your quality of life?	0-100

17E	Prosthetic Care Question	PCprostist	How satisfied are you with the person who fit your current prosthesis?	0-100
17F	Prosthetic Care Question	PCcurtrain	How satisfied are you with the training you have received on using your current prosthesis? Or check I have not had any training with my current prosthesis.	0- 100 if checked score as "nr" (no-response)
17G	Prosthetic Care Question	PCalltrain	Overall, how satisfied are you with the gait and prosthetic training you have received since your amputation. Or check I have not had any training since my amputation.	0-100 if checked score as "nr" (no-response)

Questions about ability to do daily activities under difficult conditions

Page/ Item	Scale or Single Question	Variable Name	Question	Scoring code
18A in Gp6	Self Efficacy Question	SEfitpoor	When the fit of my prosthesis is poor, I will get...	0-100
18B	Self Efficacy Question	SEcomfpor	When the comfort of my prosthesis is poor, I will get ...	0-100
18C	Self Efficacy Question	SEnopros	Without my prosthesis, I will get…	0-100

Questions about the Importance of different aspects of experience with the prosthesis

Page/ Item	Scale or Single Question	Variable Name	Question	Scoring code
18A inGp7	Importance Question	IMimpwt	How important is it that the weight of your prosthesis feel right?	0-100
19B	Importance Question	IMimpdon	How important is the ease of putting on (donning) your prosthesis?	0-100
19C	Importance Question	IMimpapear	How important is the appearance of your prosthesis (how it looks)?	0-100
19D	Importance Question	IMimpshoe	How important is it to you to be able to wear different kinds of shoes (heights or styles)?	0-100
19E	Importance Question	IMimpcover	How important is it that your prosthesis' covering is durable (cannot be torn, dented, easily scratched, or discolored)?	0-100
19F	Importance Question	IMsweatbot	How bothersome is it when you sweat a lot inside your prosthesis (in the sock, liner, socket)?	0-100
20G	Importance Question	IMswellbot	How bothersome to you is swelling in your residual limb (stump)?	0-100
20H	Importance Question	IMnohair	How important is it to avoid having any ingrown hairs (pimples) on your residual limb (stump)?	0-100,
10I	Importance Question	IMIookubot	How bothersome is it to see people looking at you and your prosthesis?	0-100
20J	Importance Question	IMimpuphil	How important is being able to walk up a steep hill?	0-100

Appendices B: PEQ Arabic version

_____ رقم الدراسة

_____ التاريخ

استبيان تقييم الأطراف الصناعية

تعليمات

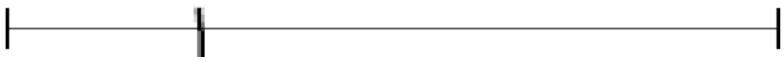
تذكر عند قراءتك لكل سؤال من الأسئلة التالية أنه لا توجد إجابة صحيحة أو خاطئة، بل فكر حول الموضوع وضع إشارة في المكان المناسب على الخط لتدلنا على في رأيك الشخصي رأيك. وإذا كنت تستخدم أطرافاً صناعية مختلفة للقيام بأنشطة متعددة فاختر الطرف الأكثر استخداماً وأجب على كافة الأسئلة حسب استخدامك لذلك الطرف الصناعي.

مثال

ما مدى أهمية تناول القهوة في الصباح بالنسبة لكم؟

غير مهم على الإطلاق — مهم جدا

خلال الأربعة أسابيع الماضية، قيّم قهوتك الصباحية.



ممتــازة — سيئـة

أو ضع إشارة هنا ـــ في حال أنك لم تتناول القهوة في الأسابيع الأربعة الماضية.

يُوضح هذا المثال أن تناول قهوة الصباح مهم بالنسبة للشخص الذي أجاب عن تلك الأسئلة، كما أنه يعتقد بأن القهوة التي تناولها مؤخراً غير جيدة. ولو لم يكن قد تناول القهوة في الأسابيع

الأربعة الماضية لوَضَع إشارة عند الجملة التي تدل على ذلك بدلاً من وضعها على الخط الذي بين ممتازة وسيئة.

o. أو **X** وكما في هذا المثال ضع علامة على الخط بدلاً من أن تضع

من فضلك أجب عن جميع الأسئلة التالية:

١ المجموعة

الأسئلة الأولى تدور حول طرفك الصناعي.

خلال الأسابيع الأربعة الماضية، ما مدى رضاك عن الطرف الصناعي الذي تستخدمه حالياً.

|----------|

راضٍ جدا غير راضٍ على الإطلاق

خلال الأسابيع الأربعة الماضية، ما مدى ملائمة الطرف الصناعي من ناحية المقاس.

|----------|

ممتاز سيء

خلال الأسابيع الأربعة الماضية، قيم وزن الطرف الصناعي.

|----------|

ممتاز سيء

خلال الأسابيع الأربعة الماضية، قيّم مدى راحتك خلال وقوفك باستخدام الطرف الصناعي.

|----------|

ممتاز سيء

قيّم مدى راحتك خلال جلوسك باستخدام الطرف الصناعي خلال الأسابيع الأربعة الماضية.

|----------|

ممتاز سيء

خلال الأسابيع الأربعة الماضية، ما مدى شعورك بعدم التوازن خلال استخدامك للطرف الصناعي.

|----------|

أبدا دائما

خلال الأسابيع الأربعة الماضية، ما مدى الطاقة التي تستهلكها عند استخدامك للطرف الصناعي عند احتياجك له.

|----------|

أبدا مرهق جدا

خلال الأسابيع الأربعة الماضية، كيف كان إحساسك بمحفظة الطرف الصناعي على طرفك المبتور (مثل درجة حرارة وملمس المادة المصنوع منها كل من جورب الطرف الصناعي وبطانته وتجويفه).

|----------|

الأفضل على الإطلاق الأسوأ على الإطلاق

خلال الأسابيع الأربعة الماضية، ما مدى سهولة عملية لبس ونزع الطرف الصناعي.

|----------|

ممتاز سيء

خلال الأسابيع الأربعة الماضية، كيف كان مظهر الطرف الصناعي.

|----------|

ممتاز سيء

خلال الأسابيع الأربعة الماضية، ما معدل إصدار الطرف الصناعي لأصوات مثل الصرير أو الطقطقة أو الفرقعة.

|----------|

أبدا دائما

وإذا كانت قد صدرت أصوات خلال الأسابيع الأربعة الماضية، فما مدى انزعاجك من تلك الأصوات.

|----------|

غير منزعج منزعج جدا

أو ضع إشارة هنا _____ في حال أنها لم تصدر أصوت.

خلال الأسابيع الأربعة الماضية، قيم التلف الذي ألحقها الطرف الصناعي بملابسك.

|----------|

لا يوجد ضرر كبير

خلال الأسابيع الأربعة الماضية، قيم التلف الذي لحق بغلاف طرفك الصناعي.

|----------|

لا يوجد تلف كلي

أو ضع إشارة هنا _____ في حال عدم وجود غلاف لطرفك الصناعي

خلال الأسابيع الأربعة الماضية، قيم قدرتك على ارتداء الأحذية التي المفضلة لكم (بارتفاعاتها وتصاميمها المختلفة).

|----------|

لا مشكلة لا أتمكن

خلال الأسابيع الأربعة الماضية، كيف كان تقيمك لمحدودية اختيارك للملابس بسبب استخدام الطرف الصناعي.

|----------|

لا مشكل سيء جدا

خلال الأسابيع الأربعة الماضية، قيم كمية التعرق عند ارتدائك الطرف الصناعي (في الجورب أو البطانة أو تجويف الطرف الصناعي).

|----------|

لا يوجد كميات كبيرة

خلال الأسابيع الأربعة الماضية، كيف كانت رائحة طرفك الصناعي في أسوأ حالاته.

|----------|

لا توجد رائحة قوية

خلال الأسابيع الأربعة الماضية، ما مدى تضخم الجزء المبتور إلى درجة تدعو لإعادة تعديل طرفك الصناعي.

|----------|

لم يحدث أبداً دائما

خلال الأسابيع الأربعة الماضية، قيّم مدى إصابة الجزء المبتور بأي طفح جلدي.

|----------|

غير مزعجة مزعجة جدا

أو ضع إشارة هنا _____ في حال لم تصب بأي طفح جلدي في الجزء المبتور خلال الشهر الماضي.

خلال الأسابيع الأربعة الماضية، هل لاحظت أي شعيرات تنمو تحت الجلد على الجزء المبتورة.

|----------|

غير مزعجة مزعجة جدا

.أو ضع إشارة هنا _____ في حال لم يوجد لديك أي شعيرات تحت الجلد خلال الشهر الماضي

.خلال الأسابيع الأربعة الماضية، ما مدى إصابتك ببثور أو تقرحات في طرفك المبتور

|----------|

غير مزعج إطلاقاً مزعج جداً

.أو ضع إشارة هنا _____ في حال لم تُصب بأي بثور أو تقرحات في طرفك المبتورة خلال الشهر الماضي

٢: المجموعة

وفيما يلي تعريفاتنا أحاسيس محددة للغاية في الجسم، يغطي الجزء التالي المستخدمة للمصطلحات:

الأحاسيس: هي الشعوربـ "الضغط" أو "الوخز الخفيف" أو الإحساس بالوضع أو الموقع كانحناء أصابع القدم. يصف ذوو الأطراف المبتورة إحساسهم (الوهمي) بأطرافهم المفقودة كالشعور بأن قدمي المفقودة ملفوفة بقطن"".

الألم: هو إحساس أكثر حدة يوصف بأنه "وخز" أو "لسع" أو "طعن" أو "جرح" أو "وجع".

"الطرف الوهمي" يطلق مصطلح على الجزء المفقود من الجسم. يذكر الناس شعورهم بإحساس و/أو ألم في الطرف الذي تم بتره- أي الغير موجود.

"الطرف المتبقي" أو **"الجزء المبتور"** يطلق مصطلح على الجزء الذي لا يزال موجوداً من الطرف الذي تم بتره.

فيما يتعلق بالإحساس بالطرف الوهمي:

.خلال الأسابيع الأربعة الماضية، ما معدل شعورك بإحساس غير مؤلم في طرفك الوهمي

ً.لم أشعر به إطلاقا ___

.مرة أو مرتين فقط أسبوعياً ___

.(مرات قليلة (حوالي مرة أسبوعياً ___

.(في أحوال كثيرة نوعاً ما (2-3 مرات أسبوعياً ___

.(في أحوال كثيرة (4-6 مرات أسبوعياً ___

.عدة مرات يومياً ___

.طوال الوقت أو طوال الوقت تقريباً ___

في إذا كان لديك إحساس غير مؤلم في طرفك الوهمي خلال الشهر الماضي، فما معدل شدة ذلك الإحساس .الغالب

|----------|

طفيف جداً شديد جدا

.أو ضع إشارة هنا _____ في حال لم يسبق وأن شعرت بإحساس غير مؤلم في طرفك الوهمي

خلال الشهر الماضي، ما مدى انزعاجك من ذلك الإحساس في طرفك الوهمي؟

|----------|

أبدا طوال الوقت

.أو ضع إشارة هنا _____ في حال لم يسبق وأن شعرت بإحساس غير مؤلم في طرفك الوهمي

:فيما يتعلق بالألم في طرفك الوهمي

.خلال الأسابيع الأربعة الماضية، ما معدل إصابتك بألم في الطرف الوهمي

ً.لم أشعر به إطلاقا ___

.مرة أو مرتين فقط أسبوعياً ___

.(مرات قليلة (حوالي مرة أسبوعياً ___

.(في أحوال كثيرة نوعاً ما (1-3 مرات أسبوعياً ___

.(في أحوال كثيرة (4-6 مرات أسبوعياً ___

.عدة مرات يومياً ___

.طوال الوقت أو طوال الوقت تقريباً ___

كم من الوقت يستمر الألم في طرفك الوهمي في الغالب؟

.لا يوجد الم ___

.بضع ثوان ___

.بضع دقائق ___

.من عدة دقائق إلى ساعة ___

.عدة ساعات ___

.يوماً أو يومين ___

.أكثر من يومين ___

.إذا كان لديك أي ألم في طرفك الوهمي خلال الشهر الماضي، فما معدل شدة ذلك الألم في الغالب

|----------|

طفيف جدا شديد جداً

.أو ضع إشارة هنا _____في حال عدم شعورك بأي ألم في طرفك الوهمي

خلال الأسابيع الأربعة الماضية، ما مدى انزعاجك من ألم طرفك الوهمي؟

|----------|

جدا غير مزعج مزعج جداً

.أو ضع إشارة هنا _____في حال عدم شعورك بأي ألم في طرفك الوهمي

فيما يتعلق بالألم في طرفك المبتور

.خلال الأسابيع الأربعة الماضية، ما معدل شعورك بألم في طرفك المبتور

ً لا يوجد الم ___

.مرة أو مرتين فقط أسبوعياً ___

.(مرات قليلة (حوالي مرة أسبوعياً ___

.(في أحوال كثيرة نوعاً ما (2-3 مرات أسبوعياً ___

.(في أحوال كثيرة (4-6 مرات أسبوعياً ___

.عدة مرات يومياً ___

.طوال الوقت أو طوال الوقت تقريباً ___

خلال الأسابيع الأربعة الماضية، إذا كان لديك أي ألم في طرفك المبتور فما مدى شدة ذلك الألم في الغالب؟

|----------|

أبدا مزعج جدا

.أو ضع إشارة هنا _____ في حال لم تشعر بأي ألم في طرفك المبتور

خلال الأسابيع الأربعة الماضية، ما مدى انزعاجك من الألم في طرفك المبتور؟

|----------|

غير مزعج إطلاقا مزعج جداً

.أو ضع إشارة هنا _____ في حال لم تشعر بأي ألم في طرفك المبتور

(فيما يتعلق بالألم في الساق أو القدم الأخرى (غير المبتورة

خلال الأسابيع الأربعة الماضية، ما معدل شعورك بألم في ساقك أو قدمك الأخرى غير المبتورة؟

ً.لم أشعر به إطلاقا ___

.مرة أو مرتين فقط أسبوعياً ___

.(مرات قليلة (حوالي مرة أسبوعياً ___

.(في أحوال كثيرة نوعاً ما (2-3 مرات أسبوعياً ___

.(في أحوال كثيرة (4-6 مرات أسبوعياً ___

.عدة مرات في اليوم ___

.طوال الوقت أو طوال الوقت تقريباً ___

خلال الأسابيع الأربعة الماضية، إذا كان لديك شعور بالألم في ساقك أو قدمك الأخرى فما مدى شدة ذلك الألم .في الغالب؟

|----------|

طفيف جداً شديد جدا

أو ضع لإشارة _____ في حال لم تشعر بألم في ساقك أو قدمك الأخرى

خلال الأسابيع الأربعة الماضية، ما مدى انزعاجك من الألم في ساقك أو قدمك الأخرى؟

|----------|

أبدا مزعج جداً

.أو ضع إشارة هنا_____ في حال لم تشعر بأي في ساقك أو قدمك الأخرى

فيما يتعلـق بألم الظهـر

خلال الأسابيع الأربعة الماضية، ما معدل تكرار شعورك بألم في الظهر؟

لا يوجد الم ___

.مرة أو مرتين فقط ___

.(مرات قليلة (حوالي مرة أسبوعياً ___

.(في أحوال كثيرة نوعاً ما (2-3 مرات أسبوعياً ___

.(في أحوال كثيرة (4-6 مرات أسبوعياً ___

.عدة مرات في اليوم ___

.طوال الوقت أو طوال الوقت تقريباً ___

في حال شعورك بألم في الظهر خلال الأسابيع الأربعة الماضية، فما مدى شدته في الغالب؟

|----------|

طفيف جداً جدا شديد

.أو ضع إشـارة هنا _____ في حال لم تصب بألم في الظهر

خلال الأسابيع الأربعة الماضية، ما مدى شعورك بالانزعاج الناتج عن ألم الظهر؟

|----------|

لا يوجد مزعج جداً

.أو ضع إشـارة هنا _____ في حال لم تصب بألم في الظهر

٣ المجموعــة

الجزء التالي سيتناول بعض الجوانب الاجتماعية والعاطفية لاستخدام الأطراف الصناعية.

خلال الأسابيع الأربعة الماضية، قيّم مدى تأثير رغبتك في تجنب ردود فعل الآخرين تجاه طرفك الصناعي لتجنب أمر كنت تنوي القيام به.

|----------|

أبدا دائماً

خلال الأسابيع الأربعة الماضية، ما مدى تكرار إصابتك بالإحباط جراء استخدامك لطرفٍ صناعي؟

|----------|

أبداً دائماً

في حال إصابتك بالإحباط نتيجة استخدامك لطرف صناعي خلال الشهر الماضي، تذكر الحدث الأكثر إحباطاً وقيم مدى شعورك بالإحباط في ذلك الوقت.

|----------|

محبط جداً أبدا

.أو ضع إشـارة هنا _____ في حال عدم شعورك بالإحباط مطلقاً نتيجة استخدامك طرفاً صناعياً

نحن ندرك أنك ستمر في بعض الأوقات بتجارب جيدة وسيئة على حد سواء مع أولئك المقربين منك. فضلاً حاول الإجابة عن هذه الأسئلة مع الأخذ بعين الاعتبار جميع ردود الفعل التي .مررت بها

.خلال الأسابيع الأربعة الماضية، قيّم كيفية استجابة زوجك لطرفك الصناعي

|----------|

جيدة للغاية سيئة جـداً

.أو ضع إشـارة هنا _____ في حال لم تكن متزوجاً

خلال الأسابيع الأربعة الماضية، ما مدى تأثير استجابة زوجك على علاقتكما؟

|----------|

جيـدة للغاية سيئــة جـداً

.أو ضع إشـارة هنا _____ في حال لم تكن متزوجاً

.تذكر شخصين قريبين إليك من أفراد العائلة (عدا زوجك)، واكتب صلة قرابتهما إليك كوالدتك أو ابنك

١. _____ ٢. _____

.أو ضع إشـارة هنا _____ في حال عدم وجود أفراد قريبين إليك من العائلة

.خلال الأسابيع الأربعة الماضية، قيّم كيفية استجابة الشخص الأول تجاه استخدامك طرفاً صناعياً

|----------|

جيدة للغاية سيئة جـداً

.أو ضع إشـارة هنا _____ في حال عدم وجود أفراد قريبين إليك من العائلة

.خلال الأسابيع الأربعة الماضية، قيّم كيفية استجابة الشخص الثاني تجاه استخدامك طرفاً صناعياً

|----------|

جيدة للغاية سيئة جـدا

.أو ضع إشـارة هنا _____ في حال عدم وجود شخص آخر قريب إليك من العائلة

خلال الأسابيع الأربعة الماضية، إلى أي حد شكّل طرفك الصناعي عائقا لزوجك أو أفراد عائلتك؟

|----------|

أبدا عائق كبيـر

.أو ضع إشـارة هنا _____ في حال لم تكن متزوجاً وليس هناك أفراد قريبين إليك من العائلة

خلال الأسابيع الأربعة الماضية، كيف أعاقـك طرفـك الصناعي اجتماعيـاً؟

|----------|

أبدا بشكل كبير

؟(خلال الأسابيع الأربعة الماضية، ما مدى قدرتك على رعاية شخص آخر (كزوجك أو طفلك أو صديقك

|----------|

ليس لديّ أي مشكلة لم أستطع

.أو ضع إشـارة هنا _____ في حال كونك لا تقوم برعاية شخص آخر

٤ المجمـوعة

.هذا الجزء سيتناول قدرتك على الحركة

خلال الأسابيع الأربعة الماضية، ما مدى قدرتك على المشي باستخدام طرفك الصناعي؟

|----------|

ليس لديّ أي مشكلة لا أستطيع

خلال الأسابيع الأربعة الماضية، ما مدى قدرتك على المشي في المساحات الضيقة باستخدام طرفك الصناعي؟

|----------|

ليس لديّ أي مشكلة لا أستطيع

خلال الأسابيع الأربعة الماضية، ما مدى قدرتك على صعود السلالم باستخدام طرفك الصناعي؟

|----------|

ليس لديّ أي مشكلة في ذلك لا أستطيع

خلال الأسابيع الأربعة الماضية، كيف كان شعورك حيال قدرتك على نزول السلالم باستخدام طرفك الصناعي؟

|----------|

ليس لديّ أي مشكلة لا أستطيع

خلال الأسابيع الأربعة الماضية، ما مدى قدرتك على صعود مرتفع شديد الانحدار باستخدام طرفك الصناعي؟

|----------|

ليس لديّ أي مشكلة لا أستطيع

خلال الأسابيع الأربعة الماضية، ما مدى قدرتك على نزول مرتفع شديد الانحدار باستخدام طرفك الصناعي؟

|----------|

ليس لديّ أي مشكلة لا أستطيع

خلال الأسابيع الأربعة الماضية، ما مدى قدرتك على المشي على الأرصفة والشوارع باستخدام طرفك الصناعي؟

|----------|

ليس لديّ أي مشكلة لا أستطيع

خلال الأسابيع الأربعة الماضية، ما مدى قدرتك على المشي على الأسطح الزلقة (مثل أرضية مبتلة أو جليد أو طريق ممطر أو ظهر سفينة) باستخدام طرفك الصناعي؟

|----------|

ليس لديّ أي مشكلة لا أستطيع

خلال الأسابيع الأربعة الماضية، ما مدى قدرتك على الصعود إلى السيارة والنزول منها باستخدام طرفك الصناعي؟

|----------|

ليس لديّ أي مشكلة لا أستطيع

خلال الأسابيع الأربعة الماضية، ما مدى قدرتك على الجلوس على كرسي عالي المقعد والوقوف منه (ككرسي المائدة أو المطبخ أو المكتب).

|----------|

ليس لديّ أي مشكلة لا أستطيع

خلال الأسابيع الأربعة الماضية، ما مدى قدرتك على الجلوس على كرسي منخفض أو لين المقعد والوقوف منه ((مثل كرسي مريح أو أريكة).

|----------|

ليس لديّ أي مشكلة لا أستطيع

خلال الأسابيع الأربعة الماضية، ما مدى قدرتك على الجلوس على المرحاض والوقوف منه؟

|----------|

ليس لديّ أي مشكلة لا أستطيع

خلال الأسابيع الأربعة الماضية، ما مدى قدرتك على الاستحمام في المغطس أو أخذ حمام بأمان؟

|----------|

ليس لديّ أي مشكلة لا أستطيع

٥ المجموعــة

باعتبار أحد أطرافك الجزء التالي سيتناول مدى رضاك حيال أوضاع عملية معينة مبتورة.

خلال الأسابيع الأربعة الماضية، ما مدى رضاك عن طرفك الصناعي؟

|----------|

راضٍ تماماً غير راضٍ أبداً

خلال الأسابيع الأربعة الماضية، ما مدى رضاك عن كيفية مشيك؟

|----------|

راضٍ تماماً غير راضٍ أبداً

خلال الأسابيع الأربعة الماضية، ما مدى رضاك عن كيفية سير الأمور منذ بتر أحد أطرافك؟

|----------|

راضٍ تماما غير راضٍ أبداً

خلال الأسابيع الأربعة الماضية، ما تقييمك لمستوى الحياة التي تعيشها؟

|----------|

أفضــل ما يكون أســوأ ما يكون

ما مدى رضاك عن الشخص الذي صمّم لك طرفك الصناعي الذي تستخدمه حالياً؟

|----------|

راضٍ تماما غير راضٍ أبداً

ما مدى رضاك عن التدريب الذي تلقيته بخصوص استخدام طرفك الصناعي الحالي؟

|----------|

راضٍ تماماً غير راضٍ أبداً

.أو ضع إشارة هنا _____ في حال لم تتلقَ أيّ تدريب بخصوص استخدام طرفك الصناعي الحالي

بشكل عام، ما مدى رضاك عن التدريب الذي تلقيته بخصوص استخدام طرفك الصناعي وكيفية المشي به منذ بتر أحد أطرافك؟

|----------|

راضٍ تماماً غير راضٍ أبداً

.أو ضع إشارة هنا _____ في حال لم تتلقَ أيّ تدريب بخصوص منذ بتر أحد أطرافك

٦ المجموعـــة

عندما يكون لديك الجزء التالي سيتناول مدى قدرتك على القيام بالأنشطة اليومية .مشاكل تخص طرفك الصناعي

... عندما يكون طرفي الصناعي غير مناسب عند الاستخدام فإنني

|----------|

أقوم بكافة الأنشطة لا أقوم بأي نشاط

.....عندما يكون طرفي الصناعي غير مريح فإنني

|----------|

أقوم بكافة الأنشطة اليومية لا أقوم بأي أنشطة

..... بدون طرفي الصناعي

|----------|

قوم بكافة الأنشطة اليومي لا أقوم بأي نشاط

٧ المجموعـــة

الجوانب المختلفة لطرفك الاستفسارات الأخيرة ستدور حول مدى أهمية .الصناعي(أو جودته) بالنسبة إليك

ما مدى أهمية أن يكون وزن الطرف الصناعي مناسباً؟

|----------|

مهــم جــداً غيــر مهـم إطلاقــاً

ما مدى أهمية سهولة ارتدائك لطرفك الصناعي؟

|----------|

مهــم جــداً غيــر مهـم إطلاقــاً

ما مدى أهمية مظهر (شكل) طرفك الصناعي بالنسبة إليك؟

|----------|

غيــر مهـم إطلاقــاً مهــم جــداً

؟(ما مدى أهمية قدرتك على ارتداء أنواع مختلفة من الأحذية (بارتفاعاتها وتصاميمها المختلفة

|----------|

مهــم جــداً غيــر مهـم إطلاقــاً

ما مدى أهمية أن يكون غلاف طرفك الصناعي متيناً (بحيث لا يتلف ولا ينقطع ولا يُخدش بسهولة ولا يتغير لونه)؟

|----------|

مهــم جــداً غيــر مهـم إطلاقــاً

.أو ضع إشارة هنا _____ في حال عدم وجود غلاف لطرفك الصناعي

؟(ما مدى انزعاجك من التعرق كثيراً داخل طرفك الصناعي (في جورب الطرف الصناعي أو بطانته أوتجويفه

|----------|

غير مزعــج إطلاقــاً مزعـج جــداً

ما مدى انزعاجك من تورم طرفك المبتور؟

|----------|

غير مزعـج إطلاقــاً مزعـج جــداً

ما مدى أهمية تجنب نمو الشعر تحت الجلد (البثور) على طرفك المبتور بالنسبة إليك؟

|----------|

مهـم جــداً غيـر مهـم إطلاقـاً

ما مدى انزعاجك من نظرات الآخرين إليك وإلى طرفك الصناعي؟

|----------|

غير مزعــج إطلاقـاً مزعـج جـداً

ما مدى أهمية قدرتك على صعود مرتفع شديد بالنسبة إليك؟

|----------|

مهـم جــداً غيـر مهـم إطلاقـاً

نقــاط أخيــرة

أ- إذا كان أيّ من الأمور التالية قد حدث لك خلال الأسابيع الأربعة الماضية، فضلاً ضع إشارة أمامها مع كتابة وصف مختصر عنها:

تعرضك لمشكلة صحية خطيرة. _____

تغير ملحوظ في الألم. _____

تعرضك لمشكلة شخصية خطيرة. _____

حدوث مشكلة خطيرة في العائلة. _____

أي تغير كبير آخر حدث في حياتك. _____

في حال حدث لك أيّ من الأمور السابقة، فضلاً اكتب وصفاً مختصراً عنها.

ب- في حال وجود معلومات أخرى تخصك أو تخص طرفك الصناعي قد تساعدنا في اعتقادك، فضلاً قم بكتابتها أدناه.

(يمكنك إكمال الكتابة على ظهر الصفحة في حال احتجت لمساحة أكبر للكتابة).

شكــراً جزيــلاً لــك!

Appendices C: FIM

FUNCTIONAL INDEPENDENCE MEASURE (FIM) ASSESSMENT WARD: _ DOCTOR: _____	SURNAME	UMRN	
	GIVEN NAMES	DOB	GENDER
	ADDRESS		POSTCODE
		TELEPHONE	

	START	**FINISH**
Episode Dates	___/___/____	___/___/____
AROC Impairment Code		

(See over page for listing of valid codes)

FIM Performance Levels

1 – Total contact assistance with helper
2 – Maximal contact assistance with helper
3 – Moderate contact assistance with helper
4 – Minimal contact assistance with helper
5 – Supervision or setup with helper
6 – Modified independence with helper
7 – Complete independence

FIM ASSESSMENT

Refer to the FIM Performance Level for available scores		**ADMISSION**	**DISCHARGE**
Assessment Date		___/___/____	___/___/____
Motor subscale	Eating		
	Grooming		
	Bathing		
	Dressing Upper Body		
	Dressing Lower Body		

	Toileting		
	Bladder Management		
	Bowel Management		
	Transfer bed/chair/wheelchair		
	Transfer toilet		
	Transfer bath/shower		
	Locomotion		
	Stairs		
	Motor Subtotal Score *(max. score 91)*		
Cognition subscale	Comprehension		
	Expression		
	Social interaction		
	Problem solving		
	Memory		
	Cognition Subtotal Score *(max. score 35)*		
TOTAL FIM SCORE *(max. score 126)*			

Assessor Details

Full name (please print)	**Designation (please print)**
Signature	**Date**

Appendices D: Ethical approval letter from UniSZA:

Jawatankuasa Etika Penyelidikan Manusia UniSZA | UniSZA Human Research Ethics Committee (UHREC)

Our Ref : UniSZA.C/2/UHREC/628-2 Jld 2 (82)
Date : 27th July 2020

Mr. Abdallah Mohammad Alzeer
Postgraduate Candidate
Faculty of Health Sciences
UniSZA, Gong Badak Campus

Dear Mr. Abdallah Mohammad Alzeer,

THE APPROVAL OF HUMAN RESEARCH ETHICS

It is my pleasure to inform you that your study protocol has been reviewed and is hereby granted an ethics approval by Universiti Sultan Zainal Abidin Human Research Ethics Committee (UHREC). This study has been assigned with a study protocol code (UniSZA/UHREC/2020/178) which should be used for all communications with UHREC related to this study.

Title	Impacts of Microprocessor/ Non Microprocessor Controlled Prosthetic Knee Joints among Transfemoral Amputees on Functional Outcomes - A Comparative Study		
Protocol No.	-	**Principle Investigator**	Abdallah Mohammad Alzeer
UHREC Code	UniSZA/UHREC/2020/178		
Date of Approval • Protocol received • Reviewed by Committee • Received Amended Protocol	 14th June 2020 15th June 2020 -	**Co-investigator (s)**	Dr. Naresh Bhaskar Raj (Supervisor)
Study Site	Prosthetic and Orthotic department, Rehabilitation services and programs, Sultan bin Abdel Aziz Humanitarian City, Riyadh, Kingdom of Saudi Arabia	**Duration of Study**	12 months
Financial Support	-	**Validity of Ethical Clearance**	30th June 2021

The following items (√) were received and reviewed in the process of approval.

(√) Research proposal
(√) Research information sheet (English)
(√) Informed consent form (English)
(√) Approval letter from faculty/ Institute research committee
(√) Curriculum Vitae (CV) of researchers
(√) Research tool (Data collection forms)

Secretariat of UniSZA Human Research Ethics Committee (UHREC), Blok E, Aras 1, UniSZA Kampus Gong Badak, 21300 Kuala Nerus, Terengganu Darul Iman, Malaysia
tel: +609-668 8763 email : uhrec@unisza.edu.my

Investigator(s) are required to :-

a) follow instructions, guidelines and requirements of the UniSZA Human Research Ethics Committee (UHREC)
b) report any protocol deviations/amendments to UniSZA Human Research Ethics Committee (UHREC)
c) comply with International Conference on Harmonization – Guidelines for Good Clinical Practice (ICH-GCP)
d) note that UniSZA Human Research Ethics Committee (UHREC) may audit the approved study

Thank you.

Yours truly,

PROF. DR. NYI NYI NAING @ SYED HATIM NOOR
Chairperson
UniSZA Human Research Ethics Committee

Appendices E: Ethical approval letter from SBAHC:

مدينة سلطان بن عبد العزيز للخدمات الإنسانية
SULTAN BIN ABDULAZIZ HUMANITARIAN CITY

Date: 13/2/2020
IRB No.: 16/2020/IRB

To: Mr. Abdallah Alzeer
PI: "Impacts of microprocessor/ non microprocessor controlled prosthetic knee joints among transfemoral amputees on functional outcomes- A comparative study"
Sultan Bin Abdulaziz Humanitarian City"
PI's E-mail: alzeer186@hotmail.com

Subject:	Approval for Research Project No. 12/SBAHC/RH/2020
Study Title:	"Impacts of microprocessor/ non microprocessor controlled prosthetic knee joints among trans femoral amputees on functional outcomes- A comparative study" Sultan Bin Abdulaziz Humanitarian City
Study Code:	12/SBAHC/RH/2020
Date of Approval:	13/02/2020
Date of Expiry:	04/06/2020
Board approval:	All members except the absentees (Dr. Mohammed Zaben, Dr. Mohammed Khalil and Mr. Mosaab Al Manaa)

Dear Mr. Abdallah,

Your Project has been approved and you have the permission to conduct this study following your submitted documents as follow:

1. Curriculum Vitae for the PI researcher
2. Letter from researcher's affiliating Organization/College
3. Letter from the researcher requesting SBAHC participation in the clinical study
4. Letter from the researcher's supervisor requesting supervision in the clinical study
5. Research proposal according to SBAHC IRB Guidelines
6. SBAHC Informed Consent Template (English and Arabic)
7. Research Obligatory Agreement. Available upon the completion of the other requirements

You are required to obey by the rules and regulations of the Government of Saudi Arabia, the SBAHC IRB Policies and procedures and the ICH-GCP guidelines. You have to note that this approval mandate responding to IRB's periodic request and surveillance result. Drawing your attention to the following:

- Amendment of the project with the required modification to providing Periodical report for this project specially when study extension is required or expiry before study completion
- All unforeseen events that might affect continued ethical acceptability of the project should be reported to the IRB as soon as possible
- Any serious unexpected adverse events should be reported within 48 hours (2 days)
- Personal identifying data should only be collected when necessary for research.

Page 1 of 2

- Monitoring: projects may be subject to an audit by the IRB at any time.
- The PI is responsible for the storage and retention of original data pertaining to the project for a minimum period of five (5) years.
- Data should be stored securely so that a few authorized users are permitted access to the database.

The IRB registered with the IRB KACST Registration No. H-01-R-090. It is authorized to conduct the ethical review of clinic studies and operates in accordance with ICH-GCP Guidelines and all applicable national/local and institutional regulations and guidelines which govern Good Clinical Practices.

For Future Correspondence, please quote the project number and project title above and you are requested to keep IRB informed about your study progress and submit project progress report every six (6) months. A final report should be provided upon completion of the study.

Wish you a success in your research project.

Yours sincerely,

Prof. Khalid Al-Rubeaan
Chairman-IRB
Sultan Bin Abdulaziz Humanitarian City

LIST OF PUBLICATIONS:

Alzeer, A. M., Raj, N. B., Shahine, E. M. and Nadiah, W.-A. (2022). 'Impacts of Microprocessor-Controlled Versus Non-microprocessor-Controlled Prosthetic Knee Joints Among Transfemoral Amputees on Functional Outcomes: A Comparative Study', *Cureus*, *14*(4).

Shahine, E. M., Silarbi, M. T., Alzeer, A., Bukhamseen, M., Alzaraa, K. M. and Saba, I. (2022). 'Amputation in Kingdom of Saudi Arabia: Etiology, Characteristics and Clinical status from a Large Tertiary Rehabilitation Center', *medRxiv*, pp. 2022.03.09.22272172.

CANDIDATE BIODATA

Abdallah Mohammad Alzeer was born on 4th July 1986 in Hebron city, Palestine. He received his early education at Majed Abu-sharar school. Between 2004 and 2008, he Graduated on with bachelor's degree in Orthotics and Prosthetics, faculty of rehabilitation science, University of Jordan. Between 2014-2017, he graduated with Postgraduate certificate in rehabilitation science from Strathclyde university, UK. Holding licenced certificates in Upper and lower limb Prosthetic advance technology for prescribing and service provision with international valid username and password accounts. The list of the certificates: Genium, certificate, C-Leg4 certificate, C-Leg3 certificate, Kenevo Certificate, Helix hip certificate, Meridiam foot certificate, Myo basic, Myo advance, Dynamic Elbow, Be bionic hand, Michelangelo hand, C-Brace. He is working as Prosthetics and Orthotics manager in Sultan Bin Abdelaziz Humanitarian City SBAHC since 2019, which is the most advance Rehabilitation facility in Middle East, located in Riyadh, KSA. He is doing master studies at universiti Sultan Zainal Abidin UniSZA in the field of rehabilitation studies under the supervision of Dr. Naresh Bhaskar Raj. His research focused on the amputation rehabilitation and the Microprocessor prosthetics. He has also interest in 3D printing prosthesis and advance technology.