DESIGN AND DEVELOPMENT OF AN ANKLE JOINT ROTATOR FOR LOWER LIMB PROSTHESIS

BY:

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Declaration

This work has not previously been accepted in substance for any degree and is not being concurrently submitted in candidature for any degree.

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Acknowledgement

First and foremost, I would like to thank my research supervisor, Dr. Md. Sayem Hossain Bhuiyan. Without his assistance and dedicated involvement in every step throughout the project, this paper would have never been accomplished. I would like to thank you very much for your support and understanding over this past year. You have raised many precious points in our discussions during the early versions of the title of the project and I hope that I have managed to address several of them here.

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List of Symbols

ε	direct strain
δ	change in length produced by tensile or compressive axial load
L_0	length of the member in its unloaded state

List of Abbreviations

SACH	Solid Ankle Cushioned Heel
2D	Two dimensional
CNC	Computer Numerical Control
EDM	Electrical Discharge Machining
ISO	International Organization for Standardization
Ti	Titanium
Al	Aluminium
V	Vanadium

Abstrak

Kelemahan yang biasa didapati pada rotator pergelangan kaki yang sedia ada di pasaran adalah bahawa mereka tidak mampu berputar dalam arah sagittal yang membolehkan postur mencangkung and melutut. Sesetengah rotator juga tidak dapat digunakan secara meluas kerana tidak mempunyai reka bentuk yang universal. Projek ini bertujuan untuk mereka bentuk sesuatu rotator pergelangan kaki yang mampu berputar secara sagittal supaya pengguna dapat mencangkung dan melutut dengan mudah dan selesa. Reka bentuk ini dicipta berdasarkan empat parameter kritikal iaitu kepelbagaian gerakan, saiz dan jisim, tahap kebebasan dan beban luaran. Reka bentuk yang dimuktamadkan telah dimodel untuk menjalankan simulasi. Simulasi statik telah dilakukan dengan menggunakan perisian Solidworks 2019 untuk mengesahkan fungsi reka bentuk rotator tersebut. Reka bentuk baru ini telah dibuktikan bahawa mampu menahan daya luaran sebanyak 3000N dengan faktor keselamatan sebanyak 5.18. Reka bentuk pergelangan kaki ini dapat mencapai objektifnya dengan memberikan sudut putaran untuk kedua-dua postur iaitu mencangkung dan melutut. Dengan menjalankan penambahbaikan yang lebih lanjut, reka bentuk ini boleh dipertingkatkan lagi fleksibiliti dan fungsi berdasarkan standard ISO.

Abstract

The common drawback in current existing ankle joint rotators are that they are incapable of providing sagittal plane rotations for squatting and kneeling postures. Some are also not universally adaptable which limits the usability of the device. This work aims to design an ankle joint rotator that is capable of providing users the experience to be able to squat and kneel with ease and comfort. The design was created based on four main parameters which are range of motion, size and mass, degree of freedom and external load. The finalized design was then modelled and assembled for further simulation. A static simulation was done using the Solidworks 2019 software to verify the functionality of the design. The new ankle joint rotator was proven to be able of withstanding external force of *3000N* with a safety factor of *5.698*. The design of the new ankle joint rotator is capable of achieving its objectives by providing the rotational angles for both squatting and kneeling postures. With further improvements, the design can acquire higher flexibility and function based on ISO standards.

Chapter 1 Introduction

Amputation is often translated as a gruesome and highly undesirable medical operation, yet it is one of the most necessary procedure for survival when it comes to fatal sicknesses or diseases. According to statistics provided by the World Health Organization (WHO), an average of 0.5% of the population in developing countries have a disability that will require a prosthesis or orthosis and related rehabilitation services [1]. This prediction suggests that around 162,000 of Malaysia's population of 32.4 million [2] need prosthetic or orthotic devices in the year 2018 [3]. However, this assumption might be inapplicable in Malaysia as there is no reliable source that keeps track to amputation statistical records. As stated in an article published by The Star newspaper in 2014, there were about 400,000 amputees in the country (exceeds approximately 25% of the estimated number in 2018) who have lost their limbs due to congenital disorders, automobile or industrial accidents, and diseases such as diabetes, leprosy and cancer [4]. This leads to a conclusion which proves actual number of patients who went through amputation is much larger than expectation.

Amputation can occur in the upper limb or lower limb of the body. By focusing only on lower limb amputation (hip to foot area), this category of amputation can be categorized into toe amputation, ray amputation, transmetatarsal amputation, mid-foot amputation, ankle-level amputation, below-knee amputation (BKA), through-knee amputation, above-knee amputation (AKA)/ transfemoral amputation and hip disarticulation and hindquarter amputation [5].

Regardless of the type of amputation being executed, the aftermath of the operation will jeopardize the patient's physical and mental capability. Losing a limb can be a devastating experience for patients and people around them as they no longer can function properly even after sufficient rehabilitation.

To help patients go through amputation, here comes the use of the upper or lower limb prosthesis. According to medical dictionaries, prosthesis can be defined as an artificial substitute for a missing part, such as an eye, limb, or tooth, used for functional or cosmetic reasons, or both [6]. A well-planned rehabilitation plan with clearly defined objectives being delivered can help maximize patients physical, psychological, social and vocational functions [7].

By focusing on the lower limb prosthesis, a basic ankle rotation joint is an accessory installed in the ankle part of a prosthetic leg to imitate movements that can be achieved by a healthy ankle joint. It can be integrated as part of the prosthetic leg based on patients' needs or wants. However, majority of the accessories available in the market only provide abduction/adduction (lateral/medial rotation in the transverse plane) [8] which disables the function for certain movements and postures such as squatting and kneeling. In addition, most Asian countries such as Japan, Thailand, Indonesia and China widely use squatting toilet bowls. Besides, most of the religions followed by Asians require kneeling in their religious activities. This has posed significant difficulties for prosthetic leg users to maneuver as most common accessories do not provide rotation in the sagittal plane (plantarflexion and dorsiflexion rotation) [9] [8]. Unfortunately, ankle joints that can provide the required rotation are not being further developed and commercialized. Being restricted on mobility does not only cause difficulties in handling daily routines but worse comes for the cost required for a prosthetic limb.

If an ankle rotation joint can be designed and developed, the future of lower limb prosthesis can be funneled towards the direction of being capable of providing a more comfortable experience for amputation patients by increasing the mobility through usage of accessories in prosthetic legs.

1.1 Research background

The use of squat toilets is rather common in many Asian countries. In Malaysia, squat toilets can be commonly found in public areas or households. They are normally found in the form of a toilet pan or bowl at floor level. A squat toilet requires users to squat down as the default defecation posture. This culture is still largely practiced in Malaysia until today as it might be due to the Muslim or Hindu culture where post-defecation cleansing with water is common and squat toilets allow easier access for this process [10]. Furthermore, Malaysia's cultural diversity has brought in many different religions and beliefs practiced by people from different backgrounds. However, there is still one common characteristic despite all of the differences: kneeling is still one of the most required posture whenever a religious activity such as praying is being done. As stated above, both major common practices require squatting and kneeling postures that are actually a challenge for those who underwent lower limb amputation. Current lower limb prostheses especially at the ankle joint allows axial rotation of the foot relative to the shank. The absence of the latter facility necessarily limits the function of such a prosthesis and could cause potential discomfort to prosthesis users [11].

By focusing on the ankle joint rotator in the lower limb prostheses, the most basic lower limb prosthesis combination includes a socket, a liner, a pylon and a prosthetic foot [12]. Ankle adaptors that functions as accessories were invented, modified and implemented to further aid patients in imitating the actual gait cycle for better mobility and experience. However, the lower limb prostheses market does not offer an ankle joint rotator that is capable of rotating in the sagittal plane (plantar- and dorsiflexion) [8] which is one of the most important movements in the ankle. Movements such as squatting and kneeling require such rotation and movement of the ankle.

There are different types of ankle joint rotators whether they provide no-axis rotation, single-axis rotation or multi-axes rotation. The most common adaptors with no rotation are the foot adaptors used in SACH feet. They are fixed between the foot and the pylon rigidly. Single-axis rotators provide rotation only in one axis which is either for lateral and medial rotation or plantar- and dorsiflexion rotation. This can be observed in patent US 20170216054A1 [13]. Multi-axes rotation ankle joints as in patent US005766264A [14] provide rotation more than one axis which is capable of providing the most similar experience to motions of a natural ankle.

In existing patents that are focused on the rotatability of the ankle joint, different mechanisms and concepts were used to imitate the natural operation and motion of the replaced limb. By referring to patent US005766264A [14], it is an ankle joint capable of multi-axial rotation as it uses two polyurethane dampeners that comprise as front and rear bumpers. This design also includes a ball and socket ankle joint integrally connected to the foot component through a serrated connection. However, this design is not universally adaptable for use between any manufacturer's lower leg and foot component and due to its larger size, a special serrated adapter is needed for attachment to the foot [14].

Although there are many existing patents of ankle joint rotators but none has been proven to be capable of being further commercialized or publicized. Furthermore, majority of the patents do not have an ankle joint that functions independently as an additional accessory. They are either being attached with the foot or the shin or functions as a whole prosthetic leg. As shown in patent US 20090082878A1 [15] and US4865611 [11], the ankle rotators do not work independently and are non-removable.

In short, the research and design in this project will focus on the rotatability of the ankle joint mechanism to help amputees to have better access to squatting and kneeling positions at the same time ensuring the adaptability of the design to universal prostheses' compatibility.

Figure 1.1 A typical no-rotation ankle joint (Össur Sach Foot Adapter)

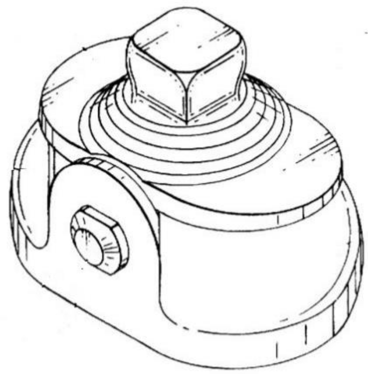

Figure 1.2 Multi-axes ankle joint [14]

1.2 Problem statement

From initial investigation on the prostheses available in the market for lower limb amputees, numerous kinds of ankle rotation joint that acts as an additional accessory can be found in the market yet one equipped with the feature to rotate in the sagittal plane (dorsiflexion and plantarflexion rotation) that enables squatting and kneeling is rare. Common ones can only be rotated medially and laterally. Lacking in this quality results in increasing patients' effort throughout their rehabilitation. Without further development and modifications in terms of mechanism and universality in the ankle joint rotator, a good quality prosthesis that provides the desired feature and capable of being used universally will be hard to find.

1.3 Objective

- To develop a universally adaptable ankle joint rotator for lower limb prosthesis that enables squatting and kneeling movements.

1.4 Scope of research

By focusing on the most basic and economical lower limb prosthesis that is equipped with a socket, a pylon and a SACH foot, an ankle joint rotator that allows rotation in the sagittal plane (plantar- and dorsiflexion) was designed based on existing rotators that allows lateral and medial rotation. The research and designing in this project focused only on two angles of rotation for the squatting and kneeling movements respectively. The design and mechanism of the ankle joint rotator were modelled and assembled using the SolidWorks 2019 software. A simulation was run on the assembly of the ankle joint rotator to determine the maximum stress that can be withstood and the displacement that will occur. After finalizing the design, a prototype was fabricated using a 3-axes CNC high speed milling machine (model Alpha T2liFB) in the Fabrication Centre (SM 0.53) of School of Mechanical Engineering. Material used was Aluminium Grade 6061.

1.5 Thesis organization

In the Chapter 2: Literature Review, related issues were discussed in terms of design and function of the existing ankle joint rotator. Advantages and disadvantages of existing designs were further discussed and analyzed. Research was done on basic techniques of using the SolidWorks simulation.

Chapter 3: Methodology described the flow and methods used to carry out the project by starting with problem identification. Assumptions made, justifications and verification methods of the proposed design were elaborated in detail in this section.

Results obtained from the project will be explained and discussed in Chapter 4: Results and Discussions. Chapter 5: Conclusion and recommendations and further work is the last section in the thesis. References and appendices will be included in Chapter 6 and 7.

Chapter 2 Literature Review

2.1 Ankle joints

The ankle joint plays an important role in the gait cycle during forward progression of the human body. According to Błażkiewicz et al. [16], walking requires coordination and work of various muscles in the leg to work dynamically. The foot and ankle act as a medium between the body and ground adjust themselves flexibly in order to achieve a harmonious coupling for successful movements [17, 18]. The major role of the ankle is to propel the center of mass forward during push-off phase of walking [19] and reduce energy losses due to heel strike [20]. During the pre-swing phase, the ankle acts as an energy generator and stores 80% of the needed energy during walking [21]. To help amputees through rehabilitation, the role of a prosthesis as a technical aid that aims at substituting missing body parts is crucial [22]. Since prosthesis can be categorized as active or passive [23], studies on the properties of prostheses especially the ankle joint is important to further improve the design and functionality of prostheses.

Discussed by Popović [24], there are several factors affecting the design of a prosthetic device. These factors include: functionality, ease of use, comfort, mass, size, visual appearance, sound, energy, variability of use, durability, personalization, modularity and cost. By considering these factors, both users' requirement and technical feasibilities can be achieved and fulfilled. The ankle joint rotator that acts as one of the prosthetic devices should be designed by focusing on these aspects.

According to Argunsah Bayram and Bayram [25], the stiffness of a functional prosthetic ankle was hypothesized to be a variable in different daily activities and the magnitude of the stiffness determines the degree of energy storage element sufficiency in terms of harvesting and returning energy. Therefore, prosthesis should be designed in a way such that it is capable of mimicking the ankle movements during different activities. Based on the research and experiment done by Major et al. [26], ankle joints with low dorsiflexion stiffness perform better for unilateral transtibial patients as they produce a prosthetic plantarflexion motion that better matches the physiological ankle joint. When walking, there is a ground reaction force (GRF) resulted from the interaction of foot and terrain that will affect the movement of the prosthetic foot. This force influences the stability, necessary propulsion and body weight support in the gait cycle. [27].

2.2 Design of existing ankle joint rotators

The idea of designing an ankle joint that enables squatting and kneeing postures do exist in the current market. Various concepts were implemented in new designs with their respective advantages and disadvantages.

In the patent US20090082878A1 [15], the ankle joint was designed to be multi-axial which enables rotation in the sagittal and transverse plane. In this design, the ankle joint was developed to provide a smooth and steady multi-axial rotation to aid amputees in gaining a natural medial to lateral roll-over of the prosthetic foot in response to uneven terrain. The core of this design is having a rod that has a substantially spherical head and a shank extending from the head. A connector was then pivotally coupled to the spherical head of the rod. A spring was installed in between the shank of the rod and apart from the wear plate with a predetermined distance. It will compress when an axial load is being applied to the rod and during compression, space is created between the connector and the wear plate which allows for multi-axial movement of the prosthetic foot. The advantage of this design is that the ankle joint is capable of providing multi-axial rotation which contributes significantly in helping amputees imitate the natural gait. However, this ankle joint is only more advantageous in providing transverse plane rotation and is incapable of providing extreme ankle rotations that are required in kneeling and squatting postures as the angle of rotation is limited. Furthermore, the wear plate has to be sized and shaped accordingly to reduce contact of the connector with the foot member to minimize wear and tear due to abrasion from the moving connector. [15] Figure 2.1 shows the design of ankle joint by Christensen.

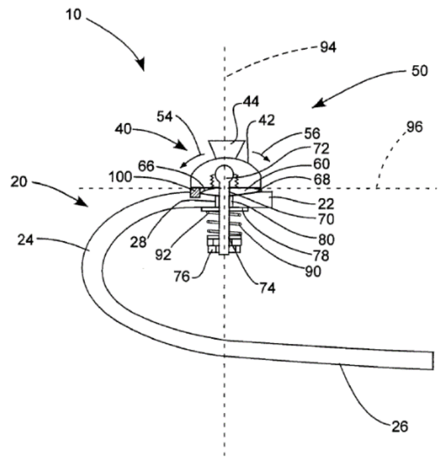

Figure 2.1 Ankle joint designed by [15]

In patent US4865611 [11], the ankle joint rotator was designed mainly to amend the drawbacks of common ankle joints in the market that are incapable of allowing axial rotation of the foot relative to the shank piece. This limits the function of the prosthesis if the user were to be a Muslim who needs to fulfill his religious duties. In this design, the ankle joint was designed in such a way that axial rotation can be achieved and is controlled with a locking mechanism. Installation of the ankle joint enables the foot component (with a foot connector) of the prosthesis to safely and smoothly axially rotate internally or externally (±90°) with respect to the shank component of the prosthesis. The rotator was designed to be installed in between the shank and foot component with low friction interaction in the form of thrust bearing fitted into a bearing housing. The foot component was locked using pins and holes on the annulus to prevent rotation during gait. A cable control handle is used to release a pin that secures the connection between the ankle joint and foot connector from the hole for rotation [11].The advantage of this design is that the ankle joint is universally adaptable to any foot component and conventional shank prosthesis which indicates no modification of any sort is required. Being only capable of axial rotation is the downside of this ankle joint design. The feature of sagittal plane rotations in the ankle joint that is required in kneeling and squatting postures is neglected. Furthermore, the external cable cord attached to the ankle component might pose a risk on users being hitched onto something and fall. Although the cable cord is a core mechanism to control the press-release locking system of the ankle rotation yet its design might cause an inevitable threat to occurrence of accidents for users. Figure 2.2 and 2.3 show the details of the ankle joint designed by Mohammed H.S. Al-Turaiki.

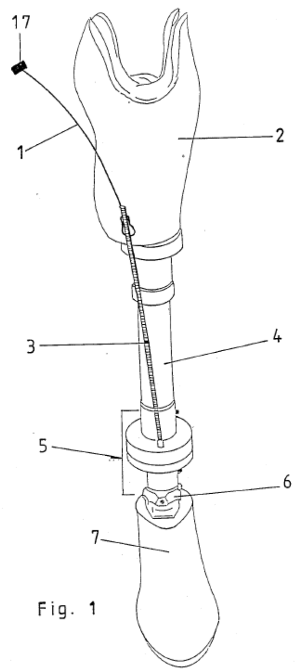

Figure 2.2 Installed ankle joint in below knee prosthesis [11]

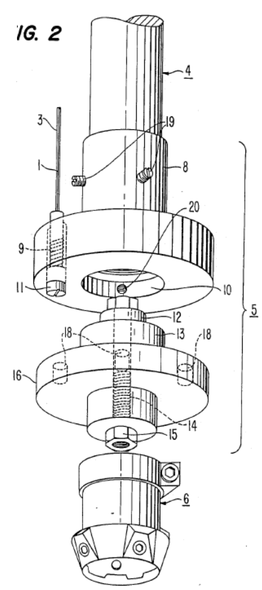

Figure 2.3 Exploded view of ankle joint [11]

Lundt [14] has designed a multi-axis prosthetic ankle joint with the patent number US005766264A. The ankle joint was designed in a holistic approach by providing rotation in the sagittal, transverse and frontal planes. This feature enables amputee to be capable of maneuvering on relatively even and uneven ground. The "Multiflex" prosthetic foot and ankle combination manufactured by Blatchford Endolite was able to provide multiple-axes rotation but was restricted in its usage and commercialization due to its adaptability for use between any manufacturer's lower leg and foot component. Lundt's design overcome this disadvantage by modified it in terms of size and its requirement for a special serrated adapter. The ankle joint was mainly sectioned into two main parts: the upper and lower portions. By applying the dampening properties of polyurethane into the design, dampeners were positioned within the housing between the upper and lower portions and comprised a front bumper and a rear bumper. The front bumper required a higher durometer hardness compared to the rear bumper to aid users to stop in the mid-stance position. The durometer hardness for both the front and rear bumpers can be adjusted based on the weight, preference and activity level of the user. It was also suggested to provide users with dampeners of different hardness so that they are able to change them anytime to suit their immediate needs. The complete assembly of components of the ankle joint were all connected through aligned holes and pins. This ankle joint is advantageous in terms of capability in providing dynamic foot motions (multiple-axes rotations) and yet at the same time universally adaptable with most of the lower leg and foot components in the market. Being compact, lightweight, and inexpensive to manufacture are its plus points. [14] However, there are still shortcomings in the design as this ankle joint only provides limited and minimal angle of rotation in each plane. This disables the feature of an ankle being capable of squatting and kneeling postures. Amputees might be able to have a comfortable experience in using this ankle joint when walking yet execution of certain postures that require extreme rotation angle might still be challenging. Besides, the dampeners used in the ankle joint must be capable of withstanding exertion of continuous force. Cost in maintenance and replacement of parts might be burdening to some users.

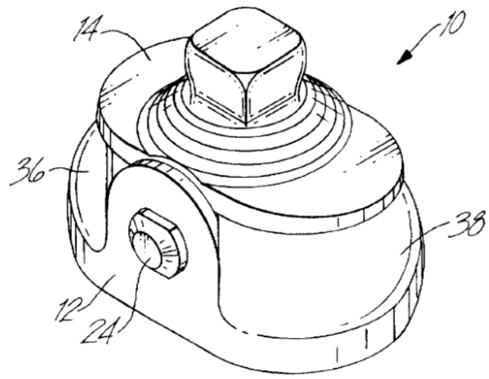

Figure 2.4 Multi-axis prosthetic ankle joint designed by Lundt [14]

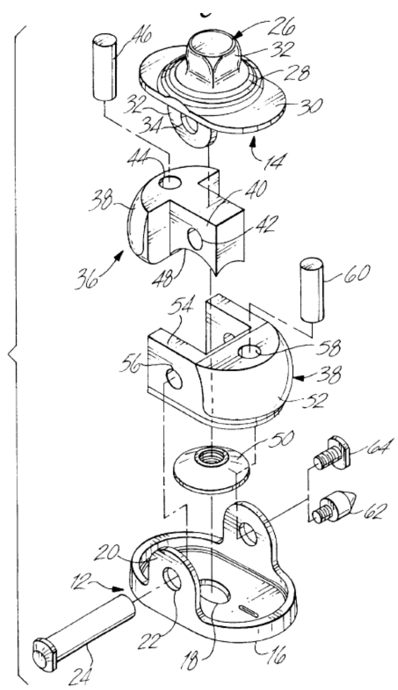

Figure 2.5 Exploded view of multi-axis prosthetic ankle joint [14]

In Lee et al.'s design with patent number USOO669929.5B2 [28], the multi-axes prosthetic ankle joint invented is aimed to provide a smooth walking experience especially on uneven grounds. Low stiffness ankle joints will cause unnatural and uncomfortable gait for users. Conventional multi-axes ankle joints require extensive maintenance as they need elastic members to slide in contact with either a rigid or elastic surface. Material deformation is a common issue in joints with conventional surface-to-surface sliding motions. This design focused on the usage of an elastomeric material to act as the vibration dampening and rotation medium. The ankle joint consisted of a bottom component which will be connected to a prosthetic foot and a top component that acts as a lower leg connection component that is to be connected to a prosthetic lower leg. The elastomeric material was used to connect the bottom and top component together with support of suspended mechanical devices. The mechanical elements float in the elastomeric material without direct contact for allowance of movement for the top and bottom components through deformation of the material. This property allows natural ankle movement of the ankle by providing plantarflexion, dorsiflexion, inversion, eversion, translation and internal/external rotational movement. The elastomeric material will deform, providing absorption and damping in both rotational and linear impacts when force is applied. To prevent the elastic material from exceeding its elastic limit, at least one mechanical stop is required to avoid excessive angular ankle movement [28]. Lee et al.'s design is advantageous and creative in terms of its concept of using an elastomeric material to replace mechanical sliding mechanisms to enable multi-axes movement and rotations. Although the elastic material provides flexible motions but its rotation is only limited to an average angle of 10° to 15°. Users cannot ben their ankle for squatting or kneeling postures. Furthermore, the elastic material was designed to be injected into the mold then hardened. This indicates the material is non-removable when it is damaged which is troublesome for repair or replacement.

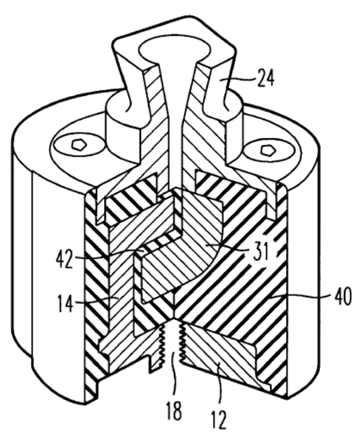

Figure 2.6 Sectional view of the ankle joint by Lee et al. [28]

Moore has designed a rotator for the prosthetic ankle joint [29] to connect the prosthetic foot to a prosthetic ankle block at the same time enabling the ankle joint to pivot about the vertical axis, allowing the user to pivot on the prosthetic leg while the prosthetic foot remains in place. This design focused on using spools by securing an outer spool in the adapter and an inner spool in the former by a pair of axially spaced bearings. A resilient rubber annulus was bonded to both the spools and disposed therebetween elastically deforms during rotation of the foot and restores the foot to forward orientation. In the rotator, two bearings were joined to the lower end of the outer spool. The ball bearing provides rotational freedom as well as vertical support for the inner spool. This rotator was designed to provide rotation in each direction but in limited angles. Although this rotator enables rigid ankle joints for natural rotary motions that imitates the human ankle and allows the foot to return to the normal forward orientation, but the angle of rotation is significantly limited. Besides, the design and mechanism of the rotator is complex as it requires assembly of many small components. This might cause excessive surface-to-surface sliding motions and cause surface damage of parts and components. Figure 2.7 shows the rotator designed by Moore.

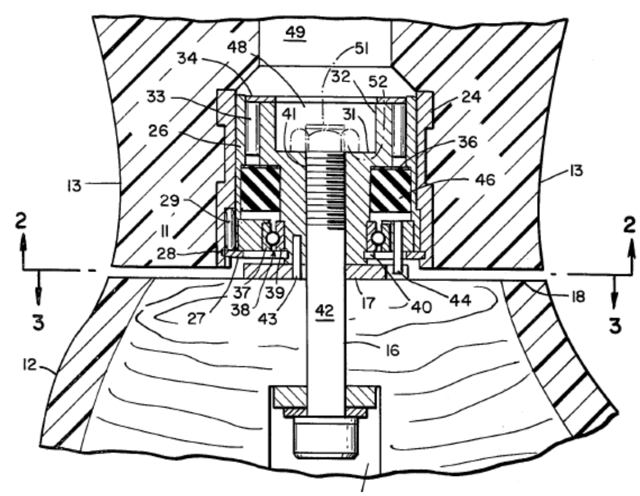

Figure 2.7 Cross-sectional side elevation of the rotator assembly installed in an ankle block [29]

2.3 Ankle joint rotator designing parameters

Biomimetic is a research field in which structures and functions of living creatures are utilized to fabricate industrial materials or machines [30]. As mentioned in Section 2.1, functionality is the most important factor in designing a prosthetic device [22], such as the ankle joint to make it more biomimetic. Ease of use, comfort, mass and size are the subsequent important factors that will significantly affect the amputees' experience in using the prosthetic device. In order to achieve these requirements, several parameters have to be included in the design consideration. In Masum et al.'s conceptual design for an ankle-foot prosthesis [31], the main function of the design is to facilitate the terrain adaptability in maintaining natural gait patterns and stability for person with single limb transtibial amputation. Consequently, the following aspects of the prosthesis were taken into consideration: structural strength, weight, passive support, output power and torque delivery, lateral flexibility and shock tolerance. These factors are to ensure the feasibility of the ankle joint in achieving the objective of the design. The size of the prosthetic device should be near to or equivalent to the size of the missing biological limb and the height should be kept minimal to facilitate for a wide range of amputees. The desired mass of the device should be 2.5% of total body mass of the amputee as it is equal to the percent mass of the missing biological limb at a point 18 cm from the ground surface [32]. Besides, the range of rotation (in different planes) and degree of rotation (none, single or multi-axes) have to be determined so that the mechanism in the ankle joint can be designed to fulfill the requirements set in the objectives. After finalizing all parameters, a finalized design was then proposed and fabricated.

2.4 SolidWorks simulations

In the experiment done by Gómez-López [33], simulation was done using the Solidworks® software. To create a Solidworks® simulation environment, the required component must first be modelled and assembled if necessary. To start a simulation, the materials of different parts have to be applied with the definition of the material properties and the material behavior model. Contacts between different parts have to be defined and constraints (boundary conditions) be established. The direction and magnitude of external load is then applied to the system then run after creating mesh. The results will be shown. The stresses, displacements and strains can be registered during the simulation. Solidworks® provides the results by graphics with different colors that are related to the value of the parameter that is being considered. The maximum stress can be obtained from the simulation to be compared with the yield stress of the material to determine any occurrence of plastic deformation. [33]

Chapter 3 Methodology

This chapter discusses the steps and methods used to execute the project in designing an ankle joint rotator.

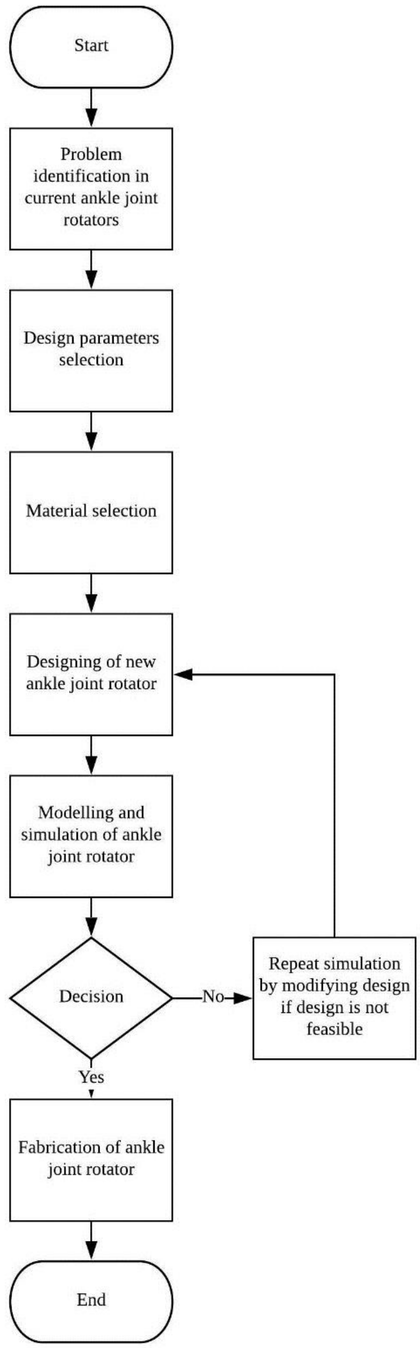

Figure 3.1 Flow chart of project

The project aims to design an ankle joint rotator that enables the two angles of rotation in the ankle for squatting and kneeling postures.

The characteristics required to be focused on the design were the functionality, ease of use, mass and size. The design must be capable of providing the rotation angles needed which are *60°* and *45°* respectively for squatting and kneeling postures [34]. The mass and size were ensured to be in the appropriate range. The total mass of the designed ankle joint rotator was *0.384kg* with a height of *85mm*. The material chosen was titanium alloy of grade Ti-6Al-4V.

Conceptualization of design was done using SolidWorks 2019. Static simulation was carried out to verify the technical feasibility of the ankle joint rotator. The maximum applicable load was set to be *3000N* and simulated for the maximum stress it can withstand. A prototype was produced using rapid prototyping to verify its theoretical functions.

3.1 Design parameter selection

The design of the ankle joint rotator must be capable of providing rotation angles for both squatting and kneeling movements to achieve the objective of the design. The rotation plane selected was the sagittal plane. The squatting angle was set as *60°* while the kneeling angle was set as *45°* [34] from the standing position (*0°*) as shown in Figure 3.4. The angle for kneeling was modified from *40°* to *45°* due to the limitations of the dimension of the male component of the rotator. The graphical representations of the angles are as shown in Figure 3.2 to Figure 3.4.

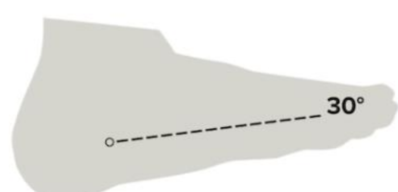

Figure 3.2 Angle of foot when squatting [34]

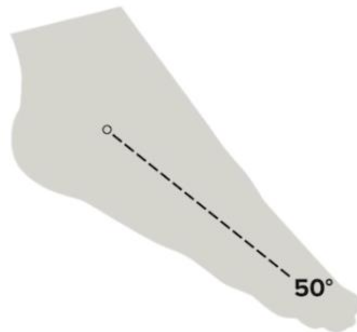

Figure 3.3 Angle of foot when kneeling [34]

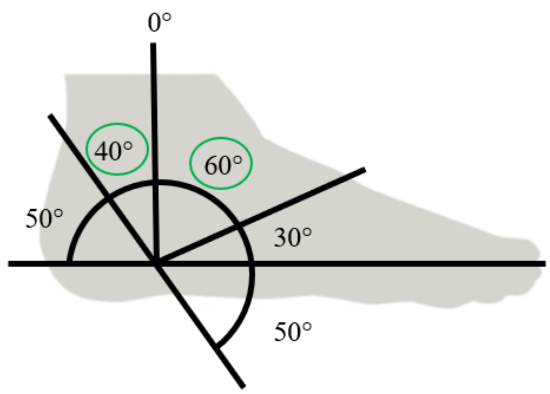

Figure 3.4 Angles of rotations

Since there are no clinical guidelines that clearly state the standard size and mass of the prosthetic ankle joint, these two parameters were set to be at its minimum as less weight is better. The height of the ankle joint was maintained at a minimum to facilitate a wider range of amputees with needs for different types of prosthetic components. The ideal prosthetic mass (ankle-foot) should be *2.5%* of total body mass of the amputee [31] but within certain limits, prosthetic mass does not influence the gait pattern or efficiency [35]. Consequently, the mass for the ankle joint rotator was ensured to be lesser than *2.5kg* (2.5% of a user of *100kg*). The required rotation is only in the sagittal plane for both squatting and kneeling postures. Thus, the ankle joint rotator has single degree of freedom.

In the simulation, an external force that represents the human weight is required to be exerted on the ankle joint rotator model. Majority of the prosthetic ankle joints in the market are designed to withstand a weight of *100kg*. Thus, the selected weight to be withstood by the ankle joint rotator design is *100kg*. The safety factor was set at a value of *3*.

$$100kg \ x \ 3 \ x \ 9.81ms^{-2} = 2943N \approx 3000N$$

Thus, the value of the external force to be applied in the simulation model is *3000N*.

Table 3.1 Design parameters (boundary conditions) selected and their descriptions

Design parameter(s)	Description(s)
Range of motion	*60°* and *45°* in sagittal plane
Size and mass	As minimal as possible
Degree of freedom	Single degree of freedom
Load applied	*3000N* (normal force)

3.2 Material selection

Based on Wong et al. [36], the most common materials used in prosthetic devices are steel, aluminium and titanium.

Stainless steel that contains nickel and chromium equips the resistance to corrosion, oxidation and fatigue. Being durable and high strength, stainless steels are used frequently in prosthetic devices. However, it is relatively heavier compared to other metals.

Aluminum alloyed with copper and manganese is well suited for prosthesis functions as it is low in weight and has high resistance to corrosion. However, it can only be applied in devices that are subjected to lower stresses. Aluminum alloy 2024 which provides a shiny well-finished component is widely used in the prosthesis industry.

Titanium alloys are very strong, lighter in weight than steel, and corrosion resistant. Titanium is used when simultaneous strength and light weight are required. This material is commonly chosen to decrease the total weight of device.

In this project, Aluminium 6061 was chosen as the material for fabrication due to the limited availability of material in the material store of School of Mechanical Engineering. In the SolidWorks simulation, Titanium alloy grade Ti-6Al-4V was chosen as the material for the ankle joint rotator as it as widely used in prosthetic applications [37].

3.3 Designing the ankle joint rotator

Referring to the parameters set and criteria required, the rotator must be able to rotate in the sagittal plane, light, and with as minimal height as possible.

In the ankle joint rotator, three parts were designed and modelled to function as a whole after assembly. The parts were a female component with a male component and a rotator pin.

The female component has two main functions which are to act as a connector to the lower limb prosthesis and as the angle adjuster. The inverted pyramid on the top section of the female component is to be connected to the lower limb prosthesis by means of tightening four screws on each of the surfaces. The size of the inverted pyramid was designed to be universally adaptable. The internal hemispheric shape provides a rotational movement for the male component. The three holes with diameter of *6.00mm* on the female component represents three respective angles for standing, squatting (*60*°) and kneeling (*45*°). The hole with diameter of *10.20mm* is to be fitted with a M10 screw to assemble with the male component. Figure 3.5 shows the dimensions of each feature in the female component.

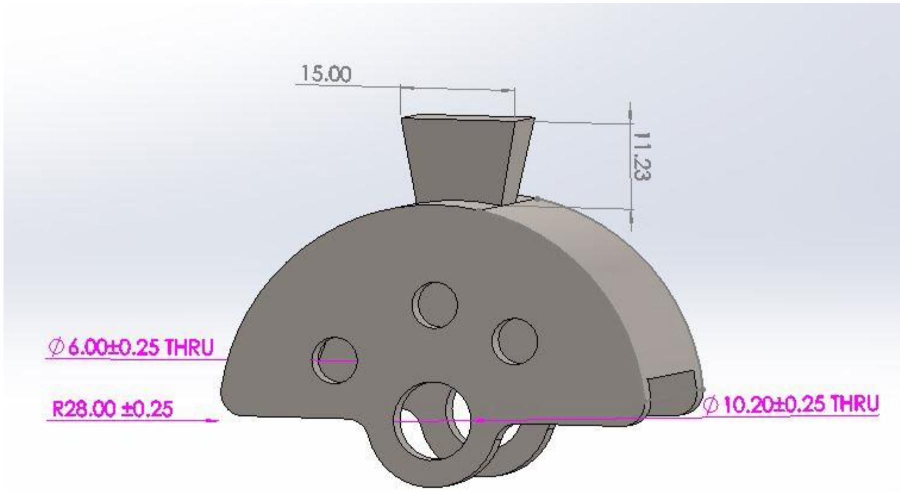

Figure 3.5 The female component in the ankle joint rotator with dimensions

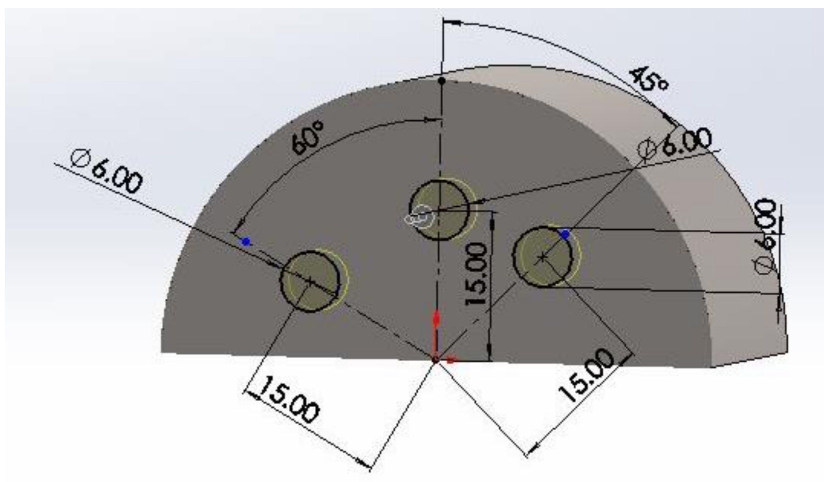

Figure 3.6 Angles used for the *6.00mm* holes in the female component

The male component was designed to be fitted with the female component and the cylindrical shape aims to provide rotation when the angle of the ankle has to be adjusted. The *6.00mm* hole on the male component is to be aligned with any of the three holes in the female component for angle adjusting. The *10.20mm* hole is to be aligned with the same diameter hole on the female component and assembled with a M10 screw. The extension of the cylinder is a connector that connects to the prosthetic foot by screwing the four respective *7.00mm* holes. The holes are slightly slanted at *10°* to provide a stronger grip to the foot.

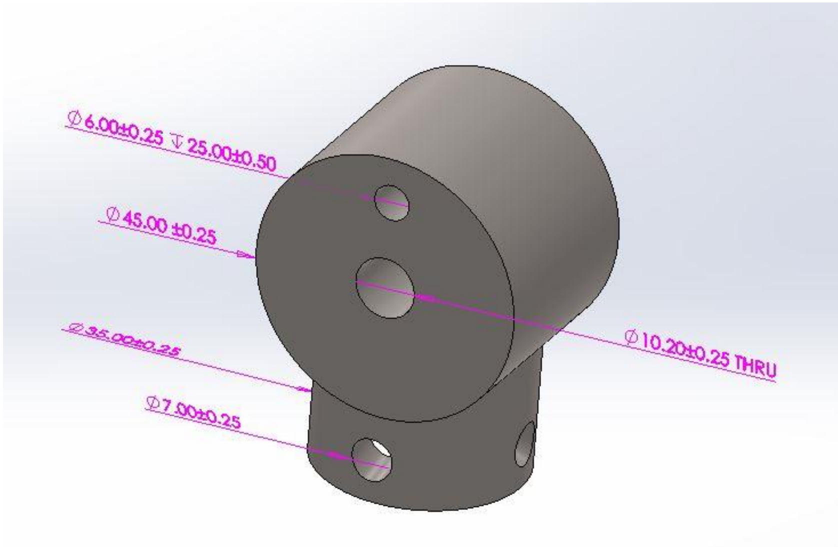

Figure 3.7 The male component in the ankle joint rotator

The rotator pin acts as a locking mechanism for the angle for both the male and female components. After assembling and aligning the male and female components at the standing angle ($0°$), the rotator pin is attached to a spring and connected to the base of the hole of standing position ($0°$) in the male component. The spring is positioned in the highlighted “Box A” shown in Figure 3.9. Both parts will be locked in position by the rotator pin. When rotation is required, the rotator pin will be pushed into the hole of the female component to allow the male component to rotate. After the hole with the desired angle is aligned, the rotator pin will be released to lock both the male and female components again.

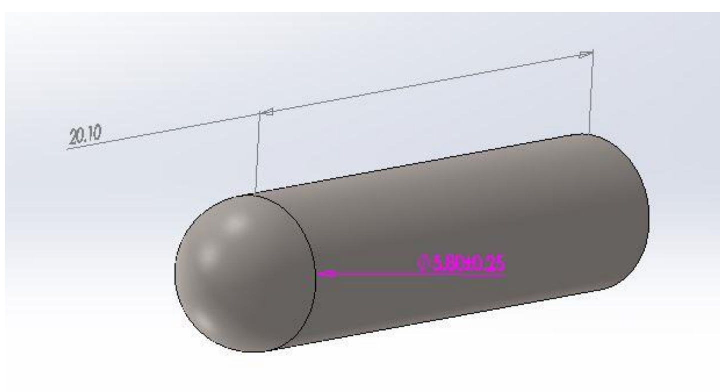

Figure 3.8 Rotator pin in the ankle joint rotator

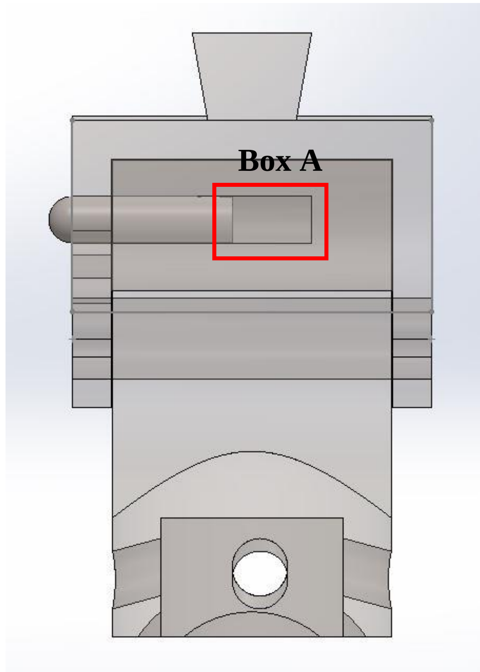

Figure 3.9 Connection between rotator pin and male component

The final assembly of the ankle joint rotator is as shown in Figure 3.5. The male component is connected under the female component while the rotator pin will fix both parts in place in the *6.00mm* hole.

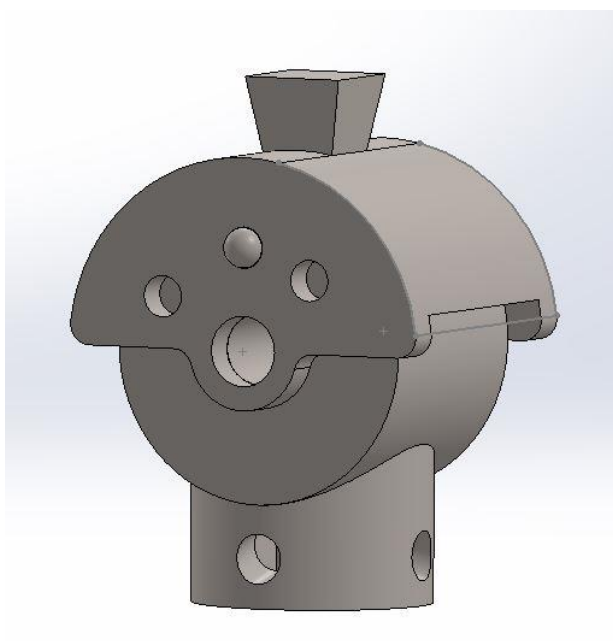

Figure 3.10 Assembly of the ankle joint rotator