

DESIGN AND EVALUATION OF A PROSTHETIC KNEE JOINT BASED ON  
AUTOMATIC STANCE-PHASE LOCK (ASPL) TECHNOLOGY FOR  
CHILDREN WITH TRANSFEMORAL AMPUTATIONS

by

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A thesis submitted in conformity with the requirements  
for the degree of Master of Health Science in Clinical Engineering  
Institute of Biomaterials and Biomedical Engineering  
University of Toronto

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# **Abstract**

Design and Evaluation of a Prosthetic Knee Joint based on Automatic Stance-Phase Lock  
(ASPL) Technology for Children with Transfemoral Amputations

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The objectives of this study were to adopt the automatic stance-phase lock (ASPL) technology to a paediatric prosthetic knee, optimize and incorporate the extension assist to the proposed design, structurally and clinically validate the prototype of the knee in a structural testing and single subject pilot study, and use a questionnaire to evaluate its efficacy. Biomechanical models were used to analyze the gait characteristics of the participant with the proposed knee and the conventional knee joint used by the participant in the clinical pilot study. A questionnaire pertaining to the functions and characteristics of the proposed knee joint was administered to the participant. The results of the clinical study indicated that the stance phase performance of the proposed design is comparable to the conventional knee. Questionnaire results revealed participant was very confident with the design, and was able to participate in many activities such as running and playing dodge ball.

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## List of Acronyms

PAPSL-Knee	Paediatric ASPL Knee
AT-Knee	All Terrain Knee
RL-Knee	Rear-Locking Knee
ASPL	Automatic Stance-Phase Lock
6MWT	Six-Minute Walk Test
PCI	Physiological Cost Index
HR	Heart Rate
GRFV	Ground Reaction Force Vector
IC	Instantaneous Centre of Rotation
SACH	Solid Ankle Cushioned Heel
CAD	Computer-Aid Drawing
FEA	Finite Element Analysis
LC I	Loading Condition I
LC II	Loading Condition II
SI	Symmetry Index
UHMW	Ultra-High-Molecular-Weight

# Chapter 1

## Introduction

### 1.1 Problem Statement

Living with a lower extremity amputation strongly affects an individual's mobility and quality of life. According to the World Health Organization (WHO), approximately 30 million people around the world live with a major lower-limb amputation and require prosthetic and orthotic services [1]. The purpose of a prosthesis is to restore the functions of the missing limb such as mobility, and this allows for participation in physical, recreational and occupational activities. For children, good prostheses enable independence and facilitate normal physical and psychological development. Studies have demonstrated that up to 95% of children who are fitted with appropriate prostheses become functional walkers, among them between 62 - 93% are actively engaged in physical and recreational activities with their peers [2, 3]. Hence providing well-functioning prostheses for child amputees is an important priority.

Many commercially available paediatric prosthetic joints incorporate either four- or six-bar linkage mechanisms and are widely accepted by users as they offer good stance phase control. But due to the size constraints, many paediatric prosthetic knees often neglect the incorporation of damping control and extension assist, thus affecting gait characteristics of the users such as limited toe clearance and increased energy expenditure [4].

Ongoing research at the Bloorview Research Institute lead by Dr. Jan Andrysek has resulted in the development of an adult prosthetic knee joint with an Automatic Stance-Phase Lock (ASPL) mechanism called the All-Terrain Knee (AT-Knee). It offers outstanding stance phase stability with ASPL mechanism while providing variable friction control and extension assist for better swing phase control. In clinical field trials from around the world, it was found that the AT-Knee provided significant functional improvements compared to existing technology in the commercial market [5].

Hence, guided by the AT-Knee, we propose to develop a paediatric ASPL knee (PASPL-Knee) that is light-weight, compact, yet structurally-sound and highly functional to accommodate the

needs of child amputees. We hypothesized that by adopting the novel stance-phase controlled mechanism and optimizing the extension assist from the AT-Knee, the PASPL-Knee joint can offer excellent stance phase stability and improve gait characteristics such as increased walking speed and reduced energy expenditure in comparison to conventional paediatric prosthetic knees.

## 1.2 Design Challenges

There were two main challenges in developing the PASPL-Knee joint: the adoption of the ASPL mechanism from the AT-Knee, and the incorporation of the extension assist into the design.

Due to the size of the targeted users, the knee joint must be compact and lightweight for it to be operated by the paediatric amputees' population. Therefore, it implied that the ASPL mechanism must be modified from the AT-Knee in order to be adopted into the paediatric knee. However, with the limited space within the knee joint due to its compactness, it presented a challenge to scale down the locking mechanism without compromising the structural integrity of the knee and affecting the effectiveness of stance phase function.

The other design challenge was to optimize and incorporate the existing extension assist from the AT-Knee into the size constrained PASPL-Knee. Due to the size limitation, it was difficult to incorporate a mechanical spring with the appropriate size that had a high spring rate to generate the desired torque for the knee extension assist and long cyclic life. Still further, the compactness of the knee joint also made it problematic to provide adequate clearance for the extension assist unit for the knee to achieve at least 140° of maximum knee flexion, as well as provide a flexion stop to protect the extension assist unit when the knee was flexed. Finally, perhaps the greatest challenge was to reduce/remove the noise generated by the knee during gait by optimizing the extension assist system in the PASPL-Knee.

In the later sections of this dissertation, it would present the solutions for the main design challenges listed above, as well as validating their effectiveness and performance via the structural and clinical testing.

### 1.3 Objectives

The principal objective of this project was to develop and evaluate a paediatric prosthetic knee based on the ASPL technology. This was accomplished by setting the following objectives:

- Analyze previous implementations of the ASPL technology in the adult's prosthetic knee joints
- Design and model a "paediatric-sized" prosthetic knee employing the novel ASPL mechanism
- Optimize and incorporate the extension assist unit from the AT-Knee to the paediatric prosthetic knee joint design
- Use Finite Element Analysis to structurally optimize the model based on the standard published by the International Organization for Standardization (ISO)
- Construct and structurally test a functional prototype of the new design
- Validate the design clinically with a single subject pilot study and compare results to the conventional knee and published data on able-bodied individuals
- Provide a questionnaire to evaluate the user's feedback

### 1.4 Overview of Thesis

Chapter 2 | This chapter presents a basic background of knowledge pertaining to the work in this thesis. Concepts such as the effect of amputations, various gait patterns and gait analysis, different components of a lower-limb prosthesis, and commercially available prosthetic knee joint products are introduced.

Chapter 3 | This chapter introduces the methodologies used in each phase of this thesis project. While some of the work was conducted concurrently, the sections are presented in the order which offers the most logical flow of the development process.

Chapter 4 | In this chapter, the results of all aspects of this thesis project are presented, including a detailed breakdown of the development of the PASPL-Knee, the results from the structural testing, and the gait analysis data from the single subject pilot study.

Chapter 5 | This chapter discusses the previously presented results of the completed study and identifies how related research literature compares to the findings presented here. Successes and limitations are identified and explained.

Chapter 6 | This final chapter of the thesis summarizes all of the contributions and insights gained from the work completed as part of this thesis. Recommendations for future work are also presented. Overall, the development of the PASPL-Knee was the main goal of this thesis, however all sections contributed toward improving the design and analysis process.

Appendices A and B | Additional information pertaining to the Research Ethics Board (REB) application process, and technical drawings and parts list of the PASPL-Knee, are presented as appendices.



## Chapter 2

### Background

This chapter presents a basic background of knowledge pertaining to the work in this thesis. Concepts such as the effect of amputations, various gait patterns and gait analysis, different components of a lower-limb prosthesis, and commercially available prosthetic knee joint products are introduced.

#### 2.1 Effect of Amputations

The knee is one of the most complex joints in the body; connecting the femur (thigh) to the tibia (shin). It acts as a pivotal hinge joint permitting flexion and extension of the leg, and the musculoskeletal and nervous anatomy of the knee joint facilitates walking while providing stability. Able-bodied individuals typically walk with a smooth and coordinated gait by maintaining a symmetrical, low amplitude displacement of the center of gravity of the head, arms, and trunk in the vertical and lateral directions, resulting in an efficient and effective movement [6]. In contrast, individuals with transfemoral amputations typically exhibit gait deviations and various functional limitations related to mobility.

Unilateral transfemoral amputees often exhibit asymmetrical profiles between the intact and prosthetic limb, which result in a significantly slower walking speed due to a longer gait cycle duration [7, 8]. Due to these gait abnormalities, studies have demonstrated that one of the most substantial physiological disadvantages for an amputee in comparison to an able-bodied individual is the increased in mechanical energy expenditure on walking [9, 10].

Beside its physiological disadvantages, an amputation also has a significant impact on the psychological development and growing experience of the individual. For children, an amputation can present unique stressors for both the child and his/her family members. More importantly, studies have shown that living with an amputation has a significant impact on a child's sense of bodily integrity [11]. Also, the inability to engage in physical activities with peers affects a child development, as physical activity significantly contributes to the physical,

social, and emotional well-being of children [12, 13]. Therefore, one of the most important steps towards recovery is to provide child amputees with a highly functional prosthetic knee joint. Along with therapy and rehabilitation, it will provide an opportunity for child amputees to participate in and enjoy doing physical activities with friends and family. This not only reduces the risk of developing long term health problems, but also enables children to develop their motor skills, psychological well-being as well as social competence [14].

## **2.2 Gait**

Gait refers to the manner of locomotion, which is achieved through the movement of the limbs; a gait cycle is defined as the time interval between two successive occurrences of one of the repetitive events of walking [15].

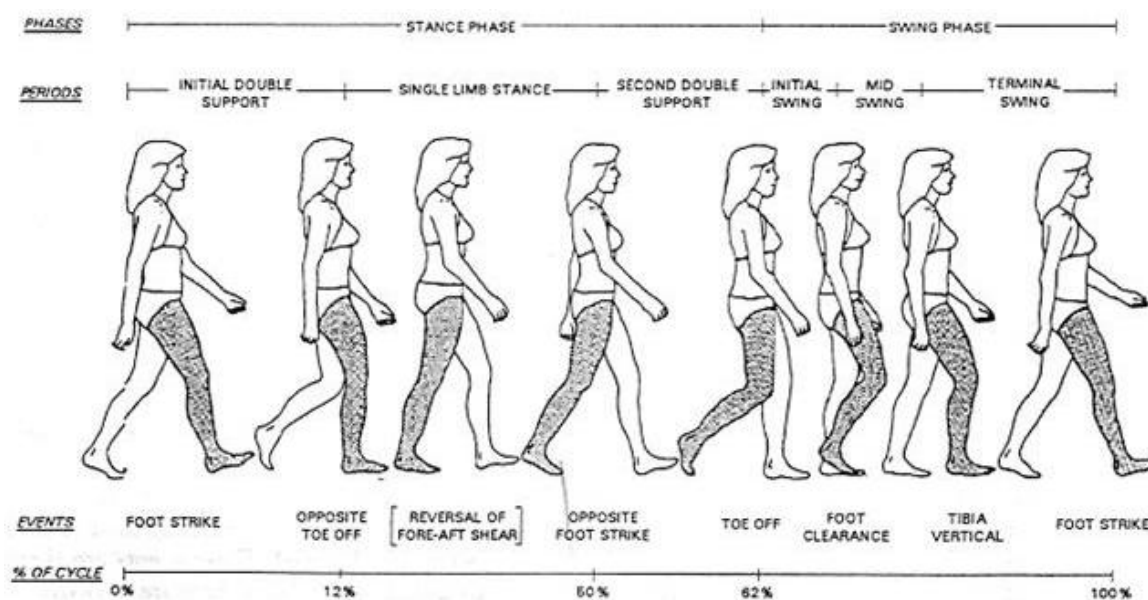
### **2.2.1 Normal Gait**

The gait cycle can be divided into two general phases: stance and swing phase. The stance phase, also called the support phase, is defined as the time period of the cycle when the foot is in contact with the ground. The swing phase is defined as the time when the foot is in the air. There are 7 major events within one cycle [16]:

- 1) Initial contact (also known as heel strike)
- 2) Opposite toe off
- 3) Heel rise
- 4) Opposite initial contact
- 5) Toe off
- 6) Feet adjacent
- 7) Tibia vertical

Furthermore, the time between initial contact to toe off is subdivided into [16]:

- 1) Loading response
- 2) Mid-stance
- 3) Terminal stance
- 4) Pre-swing



**Figure 2.1: Gait cycle**

a) Initial Contact

Initial contact is the beginning of the gait cycle, which is frequently called the heel strike. It is the start of the loading response. At this phase, the knee extends rapidly toward the end of the swing phase, and would become more or less straight prior to the initial contact [16].

b) Loading Response

Loading response is the double support period between initial contact and opposite toe off. In this phase, body weight is transferred onto the forward limb as the ground reaction force increases rapidly in magnitude at the front foot. From its nearly fully extended position at initial contact, the knee flexes during loading response, initiating the “stance phase flexion” for shock absorption and stability of weight bearing [16].

c) Opposite Toe Off

Opposite toe off signals the end of the loading response, and the beginning of single support. In this phase, the forefoot contacts the ground fully, which marks the end of stance phase and the beginning of swing phase on the opposite side (the trailing foot in this case). At the opposite toe off, the knee would continue to flex, reaching the peak of stance phase flexion then begin to extend again after. As the quadriceps muscles contract, the knee performs as a shock absorber to reduce the stress on the knee [16].

---

d) Mid Stance

Mid-stance describes the period between opposite toe off and heel rise, in which the knee has reached its peak of stance phase flexion and is brought back to a fully extended position. At this phase, the entire body weight must be supported in one limb while the other limb is advancing forward past the stationary foot [16].

e) Heel Rise

Heel rise is the time at which the heel begins to lift, which marks the transition from mid-stance to terminal stance. The knee remains extended, but the ground reaction force vector has moved to the anteriorly due to the active ankle plantarflexion [16].

f) Opposite Initial Contact

Opposite initial contact is the final phase of the stance phase and marks the second double stance interval of the gait cycle. The body weight is rapidly transferring to the opposite foot as the opposite foot is already planted onto the walking surface. During this period, the knee is starting to flex as the force vector has moved posterior to the knee which will aid its flexion [16].

g) Toe Off

Toe off is the beginning of the swing phase. At this point, the body weight has completely transferred to the opposite limb. In this phase, the main objective is foot clearance off the ground, which is aided by the increased knee flexion coupled with ankle dorsiflexion. By the time of toe off, the knee has already flexed. The flexion is aided by the positioning of the ground reaction force vector posterior to the knee [16].

h) Feet Adjacent

Feet adjacent, called the mid swing, is the time when the swinging leg passes the stance phase leg and the two feet are side by side. In this phase, the flexion of the knee during the swing phase results largely from the flexion of the hip, which enable above-knee amputees to achieve swing phase knee flexion in their prosthetic limb [16].

i) **Tibia Vertical**

Tibia vertical occurs prior to the terminal foot contact and is marked by the vertical position of the tibia of the swinging leg. During this period, the vertical position of the swinging leg is due to the rapid knee extension, as the knee goes from the peak of the swing phase flexion to a full extension at the terminal stance phase [16].

### 2.2.2 Amputees

Despite of the variability of gait between different people, there is a generally identifiable normal pattern and range for walking. The absence of function of the ankle and knee joints in transfemoral amputees commonly result in a number of deviations from normal gait and physiological deficits. This would especially impose a problem for the elderly and infants because of the feelings of insecurity and fear of secondary disorder [17]. The following are common gait deviations observed in transfemoral patients.

a) *Lateral Trunk Bending*

Lateral trunk bending describes the condition of the amputee bending the trunk towards the side of the amputated leg when the prosthesis is in stance phase. When lateral trunk bending occurs, it will bring the trunk across to the amputated side, thus significantly increasing the forces exerted on the hip of the amputated side. This can be caused by weak hip abductors, poor or uncomfortable socket fit, or unequal leg length, implying that the prosthesis is not at the right length [18].

b) *Circumduction*

Due to the leg length discrepancy or the insufficient flexion of the knee because of the feeling of insecurity of the prosthesis, an amputee may avoid ground contact and weight bearing by swinging the prosthesis outward, in a movement known as circumduction. This condition may be caused by inadequate suspension of the knee joint allowing the prosthesis to drop or by a socket size that is too small for the user [18, 19].

c) *Vaulting*

Vaulting occurs when the amputee goes up on the toes of the stance phase leg in order to provide more ground clearance for the prosthetic leg. This causes an exaggerated vertical

movement of the trunk, thus increasing the energy expenditure. Vaulting is caused by excessive length of the prosthesis, or ineffective swing-phase control in the prosthetic knee, which will shorten the period for swing phase and fail to clear the ground as the prosthetic leg swings through [18, 19].

*d) Wide Walking Base*

An important cause of an increased walking base is instability and the fear of falling, thus influencing the amputees to place their feet wide apart to increase their area of support [18, 19].

*e) Uneven Heel Rise*

When the prosthetic knee has insufficient/excess friction, or absence/too much tension at the extension aid, it will affect the amputee's gait and present the problem of having an uneven heel rise, either on the prosthetic limb or the sound limb. Such asymmetry may cause back and hip problems for the user [19].

*f) Terminal Impact*

Terminal impact is the moment at which the prosthetic knee becomes fully extended when the shank comes to a sudden stop with a visible and possibly audible impact at the end of the swing phase. This is due to insufficient friction at the prosthetic knee to reduce the speed of the shank, or too much tension on the extension aid [19].

### **2.2.3 Children**

The general sequence of the early development of human mobility following birth from an observation standpoint is well established. For newborn infants, generally they are capable of sitting upright around 6 months old, begin crawling around 9 months, and typically begin to walk independently between 12 – 14 months [20, 21]. It is obvious that the walking patterns of small children are different than those of adult's, Whittle et al. (2012) has listed out the main differences between their gait patterns [16]:

- 1) Young children have a wider walking base;
- 2) They walk with a lower walking speed and stride length, and the cycle time is shorter (higher cadence);

- 3) When children are at a very young age, they do not have heel strike, instead initial contact is being made by the flat foot;
- 4) There is very little stance phase knee flexion in small child's gait;
- 5) During swing phase, the small child's whole leg is externally rotated;
- 6) There is an absence of reciprocal arm swinging during gait for children.

Small children have unique gait patterns from adults' and their gait patterns slowly mature with increasing age [22]. Noticeable changes in step length, cadence, and walking velocity show evidence of both central nervous system maturation and growth until 4 years old. After, changes in cycle time, stride length, walking speed are attributed to changes in limb length, and those parameters would be reaching normal adult values around the age of 15 [16, 21].

#### **2.2.4 Gait Analysis**

##### *a) Spatiotemporal Variables*

Spatiotemporal variables are sometimes referred to as the general gait parameters, which include step length and gait speed and others [23]. When describing gait ability, velocity is the most important factor to measure as it is the most descriptive variable and all other gait variables are correlated to velocity [22]. It is a widely used indicator of an individual's mobility function as it is considered to be a reliable, valid and a sensitive measure to predict the status of the patient [24].

In abnormal gait, marked asymmetry has been noted between the affected and unaffected limb, characteristics such as uneven step length, shorter stance time, and prolonged swing time have been reported on prosthetic limbs relative to the sound limb [25]. Step length is the distance by which the named foot moves forward in front of the other one; stance time refers to the duration of the stance phase, between initial contact and toe off; and swing time is the duration of the swing phase between toe off and initial contact.

##### *b) Kinematics and Kinetics Variables*

Kinematics describes the motion during gait, and kinetics is the study of forces, moments, masses, and accelerations. Both are commonly used in gait analysis and are complementary to each other to describe the walking activity.

Kinematics study includes observing the patterns of motion of the hip and knee joints of both legs, parameters such as hip flexion and extension, and knee flexion and extension are commonly observed in gait analysis [26]. During the normal gait cycle, the hip flexes and extends once. It flexes at the beginning of swing phase and remains flexed until initial contact to provide adequate toe clearance during swing phase; then it starts to extend during mid-stance and reaches the peak hip extension before the end of the stance phase as the knee is in an extended position to ensure the stance phase stability. On the other hand, the knee shows two flexion and two extension peaks during each normal gait cycle. The knee is fully extended before initial contact, slightly flexes during the loading response phase, fully extends during mid-stance, then starts to flex again and reaches the flexion peak during the swing phase [16]. It is important to observe the changes in hip angle and knee flexion/extension angle during the gait cycle, as the reason for developing a highly functional prosthetic knee joint is to allow amputees to walk as close to a normal gait cycle as possible in order to produce a smooth, efficient gait.

Hip moment and knee moments are originated from the ground reaction forces. These forces are equal and opposite to the force exerted on the ground during gait. By examining the kinetic profiles and joint moments, we can study the internal adaptation of the lower limb amputees with the prosthesis. Also, since our muscle groups consume majority of the metabolic energy during physical activities such as walking, it is important to study the kinetics as it indicates the metabolic cost for the user to walk [27]. If any of the recorded moments or forces are significantly different than the normal walker's gait, it represents that the walker is not walking efficiently. For lower limb amputees, improvements can be implemented on the prosthesis to enhance their walking performances, such as adjusting the axis alignment at the prosthetic knee to create a better response to the ground reaction force vector, which can help the users to activate the knee mechanism relatively easier thus reducing muscle effort and energy expenditures.

### c) *Energy Expenditure*

Walking is a complex act that demands very fine coordination between numerous muscle groups to produce a smooth, highly efficient gait. For normal walkers, due to their well-developed musculoskeletal system and walking patterns, they only require relatively negligible energy consumption when walking at optimum speed [28]. But for lower limb amputees, it is well accepted that their metabolic energy consumption during ambulation is significantly higher than



normal walkers. Due to the loss of limb and gait deviations, the normal energy conserving characteristics of the trunk and limb motion are interrupted, thus resulting in increased energy expenditure [6, 29]. Therefore, energy expenditure is one of the most critical parameters that needs to be studied when validating and comparing various prosthetic knee joint design.

Functional walk tests are exercise tests that evaluate the ability of an individual to undertake physically demanding activities of daily living. The six-minute walk test (6MWT) is a standard test of choice for clinical or research purpose because it is easy to administer, well tolerated by most patient groups, and is more reflective of activities of daily living than other existing walk tests such as 2 minute and 12 minute walk test and [30]. 6MWT measures the distance that the individual can walk on a flat, hard surface in a period of 6 minutes at a self-selected walking speed. The self-paced walk test assesses the submaximal level of functional capacity, in which most participants do not achieve the maximal exercise capacity. However, since most activities of daily living are performed at the submaximal level, the test may better reflect participant's functional exercise level in comparison to other walking speed and provide an index of the patient's ability to perform daily physical activities [31].

It has been previously shown that heart rate (HR) and walking speed are linearly related to oxygen uptake at submaximal exercise levels; therefore, by using the combination of these two parameters, a single value can be calculated in beats per meter, the physiological cost index (PCI) [32, 33]. By measuring the HR and gait speed of the participant during the walk test, we can then calculate the PCI and estimate the energy expenditure of the participant. When comparing different PCI values, a smaller PCI values represent lower energy expenditure.

Although the PCI was introduced as a simple tool to estimate the energy cost in the clinical setting and should not be considered as "gold standard", the PCI tool is proved to be a valid and reliable measure of energy expenditure [32, 34]. Study has shown that the within-day test-retest reproducibility of the PCI was excellent among individuals with lower limb amputations and healthy adults [34]. Also, another study had shown that in terms of gait speed, heart rate changes, and non-steady state, PCIs have good repeatability when measured over short walks, which indicates that the PCI can provide a rapid physiological assessment and a method for measuring changes in functional status in healthy subjects and most patients [35].

## 2.3 Lower Limb Prosthesis

### 2.3.1 Prosthesis Components

A lower limb prosthesis for transfemoral amputees consists of three major parts: the socket, knee joint, and foot/ankle unit. The lower limb prosthetic socket is a fixed volume into which the residual limb is placed. These sockets are usually made of plastic polymer laminates, reinforcement textiles such as fibreglass, carbon fibre, and nylon are added to provide the structural support. These sockets are usually custom fitted according to the anatomical shape, as it cannot be too tight or too loose in order to protect the residual limb and allow users to transmit the load to the rest of the prosthesis [36, 37]. The socket is directly connected to the prosthetic knee.

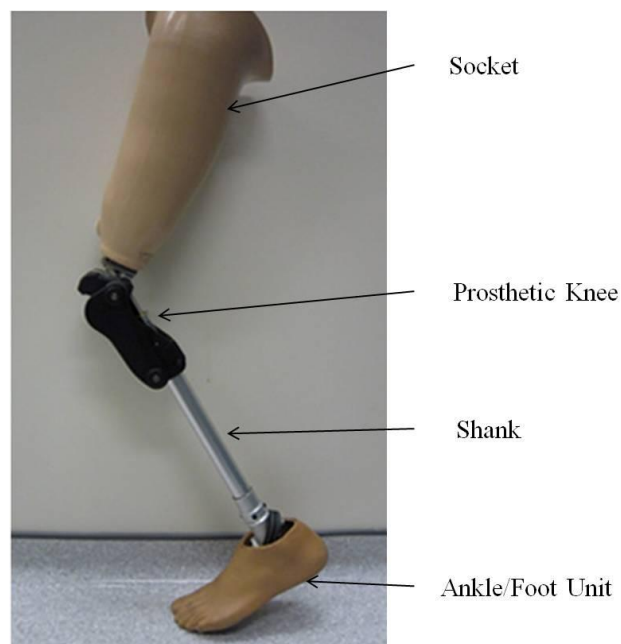
For transfemoral amputees, the prosthetic knee joint is the most critical component of the prosthesis, as its purpose is to replace the knee. The function of the good prosthetic knee joint is to mimic the function of the normal knee, such as providing structural support and stability during stance phase but able to flex in a controllable manner during swing phase. Hence it allows users to have a smooth and energy efficient gait and minimize the impact of amputation. The prosthetic knee is connected to the prosthetic foot by the shank, which is usually made of an aluminum or graphite tube.

The function of the foot and ankle is to provide a stable weight-bearing platform while offering mobility function by changing position and responding to ground reaction force vector (GRFV) during gait on different walking surfaces. The ankle is a synovial hinge joint that allows for dorsiflexion and plantar flexion. The foot is divided into 3 categories: the fore foot, mid foot, and hind foot. During the stance phase in the gait cycle, the ankle plantarflexes after the initial contact which will bring the forefoot down on to the ground; during mid-stance, the ankle joint becomes dorsiflexed as the entire foot is in contact with the ground and support the weight of the walker; approaching the terminal stance, the ankle angle changes and a major plantarflexion will take place before toe off and the load is transferred to the fore foot prior to swing phase [16]. Although prosthetic foot designs do not replicate the exact characteristics of a normal human foot due to the anatomical complexities, they do perform some of the desired functions effectively [38]. In general, the most commonly used prosthetic ankle-foot designs include the solid ankle cushioned heel (SACH), the single-axis, and the multi-axis foot. The design

principle behind most prosthetic feet is to improve amputee gait by storing and releasing elastic energy during stance and to provide some level of shock absorption [39].

### 2.3.2 Prosthesis Alignment

The alignment of a lower-limb prosthesis depends on the spatial relationship of the socket relative to other components of the prosthesis, such as the knee joint and foot unit, and these alignments are critical to the successful utilization by the user. Optimal prosthetic alignment is achieved in three steps: bench, static, and dynamic alignment. In the bench alignment, the



**Figure 2.2: Lower-limb prosthesis**

knee joint and socket are fixed in the aiding apparatus and the foot unit and other prosthetic components are mounted. The prosthetist will perform the initial set up for the prosthesis according to the alignment recommendations provided by the manufacturer, such as the sagittal plane alignment. In this case, the axis placement of the prosthetic knee joint will play a major role in the alignment process as it will affect the stability of the entire lower limb prosthesis as well as how the prosthetist would align the prosthesis. The impact of the axis placement of the prosthetic knee joint will be discussed in Section 2.3.6. After the initial set up, the height and general orientation of the prosthetic components are adjusted in static alignment, which is performed when the user is wearing the prosthesis and is in a standing position. Dynamic

alignment is a final iterative tuning process that includes clinical observation of walking and collaborative communications with the amputee [40].

The alignment of a lower limb prosthesis dictates its functionality, and significantly influences the gait of the user. The orientation of GRFV governs the stability of the passive prosthetic knee joint, and the stability of the lower limb prosthesis is dependent upon on the knee joint. The GRFV is very sensitive to alignment changes; slight changes in alignment will result in either altering the duration of the swing phase, or changing the duration of the peak extending moment about the knee [41]. It should be noted that improper alignment will alter the amputee's normal manner of walking due to the attempt to compensate for any problems with regards to the comfort and function of the prosthesis, resulting in even greater gait deviations.

### **2.3.3 Ground Reaction Force Vector**

Ground reaction force is the force exerted by the ground opposite to the force equal in magnitude a body exerts on it, and the Ground Reaction Force Vector (GRFV) plays a significant role in the stability and control of the prosthetic knee joint. Silver-Thorn et al. (2008) stated that there are two contributing factors to the stance phase stability of a prosthetic knee design: the voluntary stability provided by the remaining hip musculature of the transfemoral amputee, and the inherent mechanical stability of the mechanism itself [42]. For a passive prosthetic knee joint, its stability is based upon the orientation of the GRFV as the vector either engages the locking mechanism or generates a flexion moment at the knee, and is particularly relevant in quantifying the stability characteristics a prosthesis during stance phase.

It is very important to measure the ground reaction forces in the biomechanical analysis of gait and other motor activities, as it combines the loading effect of the body's mass and acceleration into a single vector. A force plate is commonly used in gait analysis, which it gives a single resultant force and the orientation of the force vector applied by the foot to the ground.

### **2.3.4 Stance Phase Control**

The function of stance-phase control is to prevent the leg from buckling when the limb is loaded during weight acceptance. This ensures the stability of the knee in order to support the single limb support task of stance phase and provides a smooth transition to the swing phase. Stance phase control can be achieved in several ways including the mechanical locks, relative

alignment of prosthetic components, weight activated friction control, and polycentric mechanisms [43].

a) *Mechanical Lock*

In order to increase the stance phase stability, many prosthetic knee joints incorporate mechanical locks or latches to prevent the knee from buckling thus preventing falls during stance phase. Once the lock is engaged, knee flexion is prevented and the amputee does not need to generate any hip moments to remain stable [5]. Some designs require the lock to be engaged manually during gait, which will prevent the knee from bending throughout the entire gait cycle and will result in a stiff-legged gait. Alternatively, the mechanical lock can also be operated automatically, such as the automatic stance phase control locking (ASPL) technology, which will be discussed in section 2.3.5 in more details.

b) *Relative Alignment of Prosthetic Components*

By utilizing the alignment of the lower limb prosthesis (socket, knee joint, shank, and socket) and the use of hip musculature, stance phase control remains capable of achieving stance phase stability to some degrees in a single axis knee without any additional stance phase control mechanism. Using the trochanter, knee, and ankle (the T.K.A. line) as a reference, prosthetist can strategically shift the position of the socket anteriorly to the knee centre to maintain stability in late stance [44].

c) *Weight Activated Friction Control*

Some knee mechanisms resist flexion in stance phase through application of mechanical friction, which increases the friction between two surfaces substantially during stance phase. Such control can be achieved by increasing the coefficient of friction between two mating surfaces, or by a system similar to a brake drum. Regardless of the precise mechanism with which this is achieved, this stance phase control design is dependent on the body weight applied on the prosthetic knee in order to activate the friction lock [44].

d) *Polycentric Mechanisms*

A four bar linkage knee is a specific class of polycentric knees, and it is characterized by four elements, the thigh, shin, and two links, joined at four separate points. The study conducted by

Greene provided an in depth analysis on four bar linkage knees [45]. With regards to the stance phase control mechanism of a four bar linkage knee, it is determined by the relative position of the T.K.A. line to the instantaneous centre of rotation (IC). IC is a theoretical point in the plane of motion (sagittal plane) that can be perceived as the axis of the four bar linkage knee; however, unlike the axis of a single axis knee, the location of IC continues to vary during gait depending on the positions and lengths of each link. In general, if the GRFV passes anteriorly to the IC, the system is considered to be stable and unstable when it passes posteriorly. Therefore, when the knee is in an extended position, the GRFV will be located anterior to the IC to ensure the stance phase stability during weight acceptance in a four bar linkage knee.

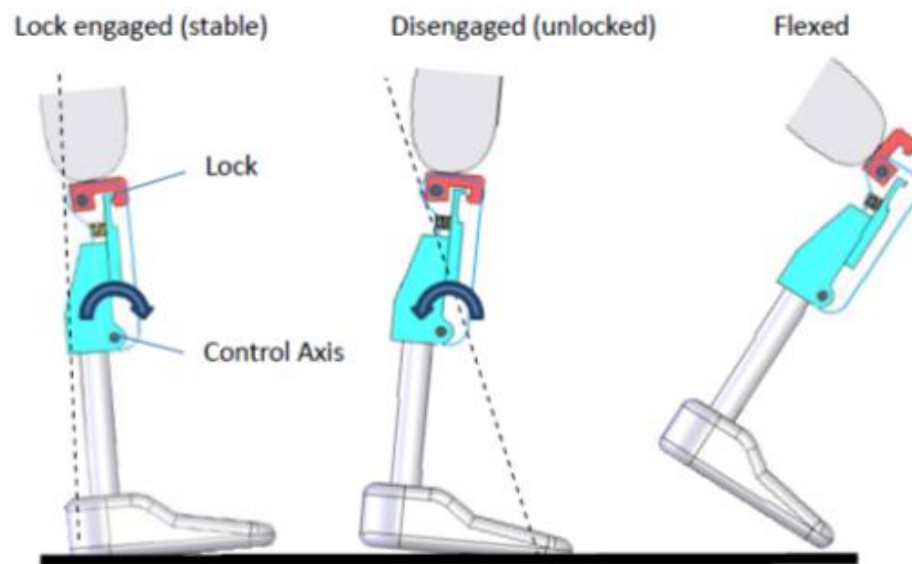
A six bar knee is another class of polycentric knees, and it works like a four-bar knee but also gives the user the ability to set the knee into a positively locked state, simulating the stability at initial contact of a mechanically locked knee. The added complexity of the linkage mechanism allows the potential for increased toe clearance during swing [5].

### **2.3.5 Automatic Stance-Phase Control Locking (ASPL) Technology**

Dr. Jan Andrysek and his research team at the Holland Bloorview Kids Rehabilitation Hospital have developed a single axis prosthetic knee for individuals with transfemoral amputations, the All-Terrain Knee (AT-Knee). It features a novel stance-phase control mechanism that offers a high level of stability during weight bearing without compromising the natural movements during gait, namely at toe-off. The stance-phase control mechanism, termed "automatic stance-phase lock" (ASPL), is comprised of a lock that automatically engages to prevent the knee from flexing during weight bearing. In late-stance-phase, as the forefoot is loaded, the lock disengages to allow the knee to flex during swing-phase.

The prosthetic knee joint design featuring the automatic stance-phase locking mechanism contains two stability-affecting axes, termed "knee axis" and "control axis". The stability of the knee is based on the position of the control axis in relation to the pivoting axis of the knee. Therefore, the basis for the ASPL mechanism is a lock that engages/disengages to lock/unlock based on the moment created at the control axis. Such design is weight-activated, as the moment created at the control axis is generated through the ground reaction force. Based on the design described in Andrysek et al. (2005), during gait, the lock is engaged to secure the knee when the knee is fully extended at the end of swing-phase and immediately before the initial contact. The

locking engagement is facilitated by a lock spring to push against the lock component. This ensures the stability of the amputee as the prosthetic limb begins to accept the body weight of the amputee. From initial contact to mid-stance, the lock remains engaged to maintain the knee at full extension and support the amputee. This is caused by the flexion moment generated by the prosthetic loading at the control axis, as the ground reaction force vector is located posterior to the control axis. As the weight is being transferred to the forefoot near the terminal stance phase, the lock disengages allowing the knee to freely flex during the swing phase which can create adequate toe clearance to allow for a natural gait for the user [46].



**Figure 2.3: Automatic stance phase lock (ASPL) mechanism**

Over the past several years, studies were conducted and the results suggested that the ASPL technology based knee joints provided significant functional improvements and confidence for amputees. According to the study conducted in 2005, when asking participants to evaluate and compare the conventional knee joints and the ASPL knee joint after wearing each of the knees for a minimum of four weeks, it had been reported that all participants experienced an improvement in stance-phase stability with the ASPL knee. All participants were more confident when walking with the ASPL knee in comparison to the conventional knees, and they preferred the ASPL knee over the conventional knees unanimously [46]. These results demonstrated that the ASPL knee provided a sense of stability and confidence for the users. In Andrysek et al. (2007, 2011), both studies indicated that participants with unilateral amputations have a significantly faster walking speed when comparing the ASPL knee to the conventional

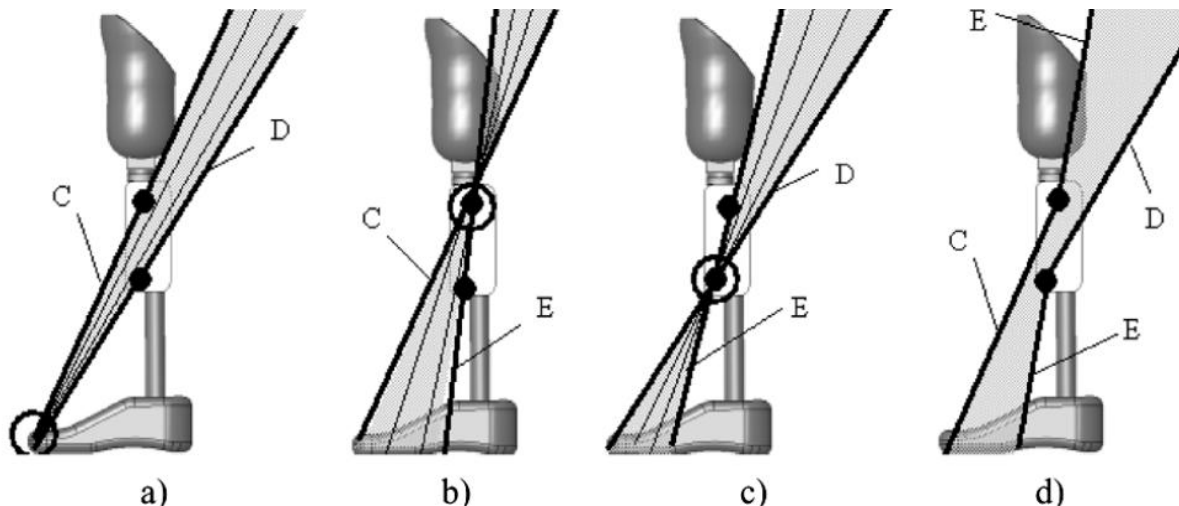
low-end knees. Although the ASPL knee was slower than conventional high-end prosthetic knees, it was more closely matched to the high-end than low-end prosthetic knee joints [33, 47]. These evidences illustrate that the ASPL knee joint offers great stance-phase stability and function and is comparable to conventional knee joints in the market.

### **2.3.6 Knee Stability**

The ASPL technology provides stance phase control during gait via a secondary axis, termed control axis. It is located distal and anterior to the main knee joint axis; therefore, the placement of the knee axis in the ASPL knee determines its stability characteristics and function. The stability of a prosthetic knee is based on the location of the GRFV in relation to the knee's axis of rotation. The knee instability diagram can be used as an effective tool for assessing the knee joint stance-phase characteristics by visualising how the knee response to the GRFV (load line vector) [48, 49]. The zone of instability for knees with two stability-affecting axes is determined by the following procedure, illustrated in Figure 2.4: a) all the load line vectors originating at the toe, creating a flexion moment at the main knee axis and an extension moment at the control axis; b) all the load line vectors passing through the main knee axis, not exceeding the toe-load boundary on the plantar foot and creating an extension moment at the control axis; and c) all the load line vectors passing through the control knee axis, not exceeding the toe-load boundary on the plantar foot and creating a flexion moment at the main knee axis [46]. When these three zones are superimposed, this creates an overall zone of instability diagram which illustrates the stability characteristics of a specific knee joint prosthesis. If the load line is originating from the foot and passes through the zone, the knee would be unstable as the knee is prone to bending; on the other hand, if the load line lies outside of the zone, the knee would be stable.

Andrysek et al. (2004) has listed out the theoretical relationships between the functions of the knee and the placement of the knee axis. They stated that when the knee pivoting axis is moved posteriorly, the knee will become more stable but it will be more difficult to initiate the swing phase, thus providing less toe clearance. Reversely, when the axis is moved anteriorly, the knee will become less stable but it will be easier to initiate the swing phase which can provide more toe clearance [43]. Thus it is important to maintain the balance between stance phase stability and ease of swing phase initiation.





**Figure 2.4: Knee stability analysis for a knee joint with two stability-affecting axes**

### 2.3.7 Swing Phase Control

The purpose of incorporating swing phase control in the prosthetic knee joint design is to emulate the action of leg musculature and help users to control the duration of the swing phase. Swing phase control has the following three functions: 1) to limit the maximum knee flexion angle and cause the shank-foot to swing forward smoothly in a manner similar to quadriceps action about a normal knee; 2) allow the knee to extend smoothly into full extension without impact; 3) provide automatic changes in the level of the resistance patterns to allow walking over an extended range of walking speeds [50]. Systems with various complexities have been developed to achieve different levels of swing phase control, and such mechanisms typically consist of mechanical friction or fluidic damping control, as well as incorporating extension assist aids such as internal springs or external elastomeric straps.

#### a) *Mechanical Friction*

Mechanical friction control is usually implemented in a hinge type knee joint design that swings in both flexion and extension. It is the simplest way to limit the maximum flexion angle during swing phase, as it is low in cost, light in weight, easy to adjust, and requires relatively little maintenance [51]. The friction between the interface of the rotating parts limits the extension caused by the inertia of the shank during swing. Therefore, by tightening the bolt and bushing that applies friction to the knee, the amount of friction can be adjusted thus optimizing the damping effect for a particular walking speed. But due to the lack of automatic adjustment for changes in walking speed, it may result in a suboptimal swing phase performance [50].

b) *Fluidic Damping Control*

In comparison to mechanical friction, fluidic damping offers better swing phase control and can match the desired joint kinematics and kinetics curves very closely, thus providing a more effective swing phase control with a smoother and more natural gait [52]. Fluidic control is usually achieved through hydraulic and pneumatic devices. A typical hydraulic design incorporates multiple holes in the cylinder wall which are progressively covered by the piston to reduce the available flow area and create highly non-linear resistance characteristics. The pneumatic devices rely upon a combination of air compression and controlled leak rate to achieve an approximation of the desired moment characteristics [50]. Although fluidic damping controls enhance the responsiveness to different walking speeds, it is impractical in paediatric prosthetic knee joint designs because of their maintenance requirements as well as excessive size and weight [51].

c) *Extension Assist*

The role of the extension assist is to reduce the length of swing phase and energy expenditure of the user by facilitating the extension of the leg. Extension assist can be achieved in the form of mechanical springs or elastic band-type assistance. In effect, the inertia of the shank that naturally flexes the knee during mid-swing is counteracted by the force applied by the extension assist, thus resulting in a shorter, more symmetrical swing phase duration [5, 53].

## 2.4 Commercially Available Paediatric Above-Knee Prostheses

As shown in Table 2.1, most of the commercially available knees have a length between 100 to 160 mm, and the weight of the knees ranges between 150 - 400g. In addition, most of these offer at least 145° of maximum flexion angle, and are capable of supporting weight of up to 45 kg. Therefore, for the design of the PASPL-Knee must stay within the range of these parameters and aim to further reduce the weight of the design while maintaining the structural integrity.

Most paediatric prosthetic knees are designed with 4-bar linkages or single axis mechanisms. Four bar linkage knees are characterized by four elements joined at four separate points. Such designs have instantaneous centers of rotation at full knee extension that are posteriorly located to the T.K.A. line and are superiorly located to the level of the mechanical knee center

throughout the gait cycle, thus providing better stance stability and reducing the knee buckling moment [45]. But one of the major disadvantages of four-bar knee joints is that they tend to be larger and heavier than their single-axis counterparts, thus making them unsuitable for very small children [43]. Due to the simplicity of the design, single axis knees are more durable, lighter, and have a lower cost, which are very important features as children are active community ambulators who would use the knee frequently [3]. Moreover, a study conducted by Andrysek et al. (2005) showed that significant decreases in falls were observed when children were using the single axis prosthetic knee design with ASPL mechanism instead of 4-bar linkage knees [46]. This suggests that single axis knees could also offer a high degree of stability for users.

As mentioned in the previous section, swing phase control is used to emulate the action of the quadriceps and hamstring musculature which act about the normal knee joint during the swing phase of gait. It is critical to incorporate the swing phase control into the prosthetic knee joint design as it will not only shorten the duration of the swing phase to produce a more symmetrical gait pattern, but will also reduce the energy expenditure on walking [54]. Despite the documented importance of a good swing phase control, many paediatric prosthetic knee joints in the market neglect to incorporate both the damping control and extension assist for better swing phase control. This will affect the user's gait as it may introduce gait abnormalities such as asymmetric gait pattern, inadequate toe clearance, and/or increased energy expenditure.

**Table 2.1: Summary of the commercially available paediatric prosthetic knee joints**

Manufacturer	Model	Type*	Max. Knee Flexion	Weight (g)	Length (mm)	Max. Weight of User (kg)	Ext. Assist + Damping Control
Ottobock	3R38	SA	145°	<b>160</b>	<b>64</b>	45	✗
	3R65	SA	145°	315	119	45	✓
	3R66	4-Bar	<b>165°</b>	310	120	<b>35</b>	✗
Fillauer LLC	MiniMac	SA	145°	315	86	<b>60</b>	✗
	MightyMite	4-Bar	<b>130°</b>	270	108	<b>60</b>	✓
Trulife	Child's Play Knee	4-Bar	140°	310	110	55	✓
Ossur	Total Knee Junior	4-Bar	160°	<b>395</b>	<b>156</b>	45	✗
Ortho Europe	SA Knee	SA	140°	169	NA	45	✗
	4-Bar Knee	4-Bar	160°	344	NA	45	✗

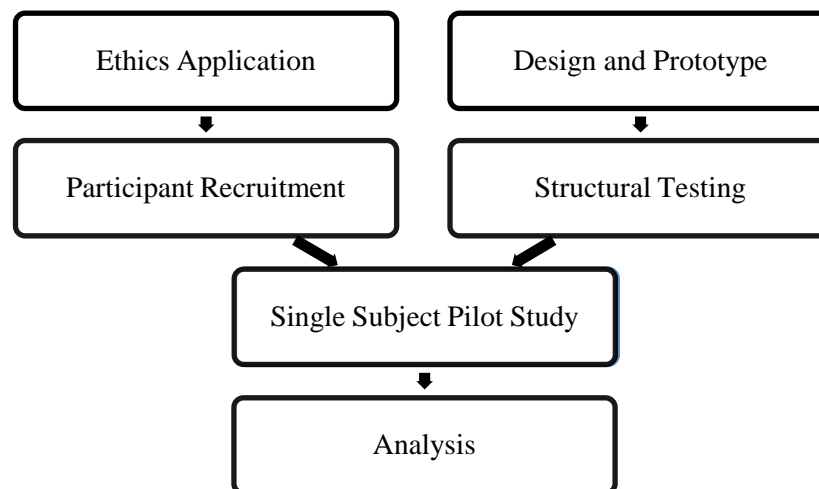
SA = single axis; Ext. Assist = extension assist; Reference: [55-63]

## Chapter 3

### Methods

This chapter introduces the methodologies used in each phase of this thesis project. While some of the work was conducted concurrently, the sections are presented in the order which offers the most logical flow of the development process.

#### 3.1 Project Overview



#### 3.2 Design and Prototype

There were four main phases in the computer modelling process: 1) establishment of design criteria, 2) modeling of axis alignment, 3) 3D modelling of the knee assembly using Computer-Aided Design (CAD) software, and 4) Finite Element Analysis (FEA).

##### 3.2.1 Establishment of Design Criteria

Before establishing the design criteria for the paediatric prosthetic knee, we conducted an extensive literature review to consider various aspects of the design. This included gait characteristics and variances of normal individuals and amputees, the control mechanism of different prosthetic knees, and previous implementations of the ASPL technology and other commercially available paediatric prosthetic knee joints.

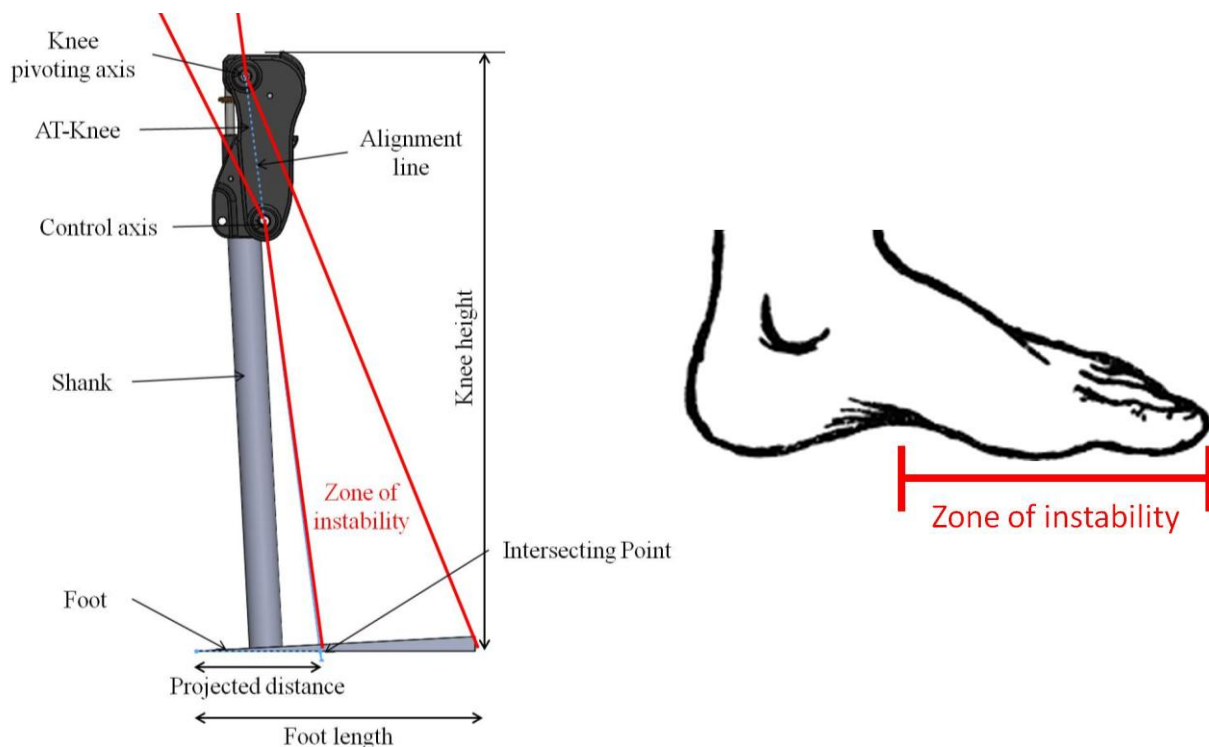
By studying common gait deviations exhibited by transfemoral amputees, we had a better understanding of the relationship between the design and functions of a prosthetic knee and the gait of the user. This allowed us to focus on specific functions and features, such as stance phase control, adequate toe clearance, and extension assist. Previous implementations of the ASPL technology were also studied and analyzed, which inspired various ideas for the implementation of the ASPL technology. At the end, we also examined and compared various commercial products systematically to identify the functions and physical constraints that were featured in those designs. All of these aspects were taken into consideration when establishing a list of design criteria and constraints prior to the start of the design process.

### **3.2.2 Axis Alignment**

As mentioned previously, the alignment between the knee pivoting axis and the control axis is critical to the function of an ASPL knee joint as it plays a major role on the stance phase stability as well as the initiation of the swing phase control in the knee joint design. Referring back to Section 2.3.5, studies have demonstrated that the existing AT-Knee and other ASPL technology based knee joint designs could provide excellent stance phase control and allowed users to have a smooth and efficient gait. This suggested that the alignment used within the AT-Knee would be an ideal starting point when establishing the axis alignment for the paediatric ASPL (PASPL) knee.

Due to the differences in height and the length of the body segments between adults and children, the axis alignment established on the AT-Knee (adult's prosthetic knee) might not be applicable to the PASPL-Knee and needed investigation. In addition, as illustrated in Figure 3.1, the current axis alignment on the AT-Knee requires the prosthetic foot to be shifted anteriorly in order to achieve the optimal prosthesis alignment, as the shank is tilted by  $3^\circ$  to facilitate the establishment of the zone of instability. It is the optimal area on the forefoot that allows the knee to be stable but also reliably unlock. The tilted shank means that the shank hole at the bottom component of the AT-Knee is not perpendicular to the inferior surface of the knee, which is considered to be a challenge and inefficient in the manufacturing process. In order to have the shank hole perpendicular to the inferior surface of the bottom component, the axis alignment needs to be adjusted in the PASPL-Knee. Therefore, we were not able to transfer the axis alignment directly from the AT-Knee to the PASPL-Knee.

To analyze the axis alignment on the AT-Knee, we first created simplified shank and leg computer models using SolidWorks (CAD software) based on anthropometric reference data for adults, which are shown in Table 3.1. Then by combining these pieces with the AT-Knee model, we formed the adult knee-shank-foot assembly and proceeded to measure the axis alignment on the AT-Knee. The assembly model was observed from the sagittal plane with the knee assumed to be in a locking position. As shown in Figure 3.1, a straight line, termed the "alignment line", was drawn from the knee pivoting axis to the control axis, and was extended to intersect the bottom of the foot model. The distance between the heel and the "intersecting point" was recorded, termed the "projected distance". After which, by dividing the projected distance by the foot length, we obtained a ratio and used it as a reference for establishing the axis alignment on the PASPL-Knee joint. In terms of zone of instability, the percentage of the area would be equal to "1 - the ratio".



**Figure 3.1: Adult knee-shank-foot model and zone of instability illustration**

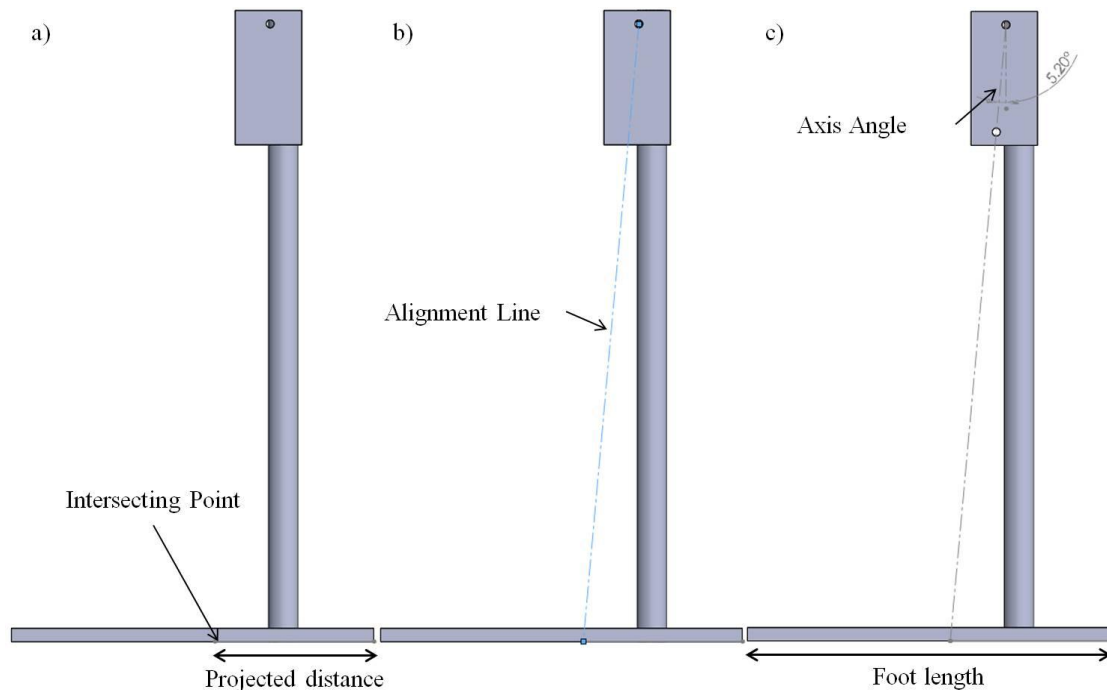
**Table 3.1: Anthropometric data for average adults [64]**

Dimensions (mm)	Male	Female	Average
Knee Height	567	456	512
Foot Length	273	229	251

**Table 3.2: Anthropometric data for children [65]**

Dimensions (mm)	Age 6.5 - 7.5	Age 11.5 - 12.5 (50th Percentile)	Age 11.5 - 12.5 (95th Percentile)
Knee Height	312	400	447
Foot Length	189	232	253

Since the PASPL-Knee joint is intended for use of a wide range of individuals at different ages, it is important to include dimensional data from different age groups. Therefore, we created three sets of simplified shank and foot models based on the anthropometric data for children at ages of six and twelve years old, as listed in Table 3.2. To observe whether the axis alignment on the AT-Knee would be applicable to the paediatric users, we formed three knee-shank-foot assemblies by combining the AT-Knee and the sets of simplified shank and foot model for child. Then by repeating the same procedures as previous step, we calculated the ratio for all three assemblies and compared the result to the adult's assembly. The results obtained from the child's models were very different from the adult's model, which indicated that the axis alignment needed to be adjusted. The results are presented in Section 4.1.2.

**Figure 3.2: Establishing the axis alignment on PASPL-Knee**

After, to establish the axis alignment on the PASPL-Knee, we constructed a basic knee model to form three simple child knee-shank-foot models, assumed in a standing posture. A horizontal

line was drawn from the heel towards the anterior side of the foot model, and its length (the projected distance) was calculated using the ratio obtained from the adult's model from the previous step. The end point was marked as an "intersecting point" similar to the adult knee-shank-foot model (see Figure 3.2a). After that, another line was drawn from the "intersecting point" towards the knee pivoting axis, which was equivalent to the "alignment line" (see Figure 3.2b). Finally, the angle of the "alignment line" was measured. This procedure was repeated for all three sets of child knee-shank-foot models. Finally, by comparing and analyzing all the measured angles as well as the zone of instability from different sets of knee-shank-foot models, we determined the optimal offset angle between the two axes hence the axis alignment for the PASPL-Knee joint.

### **3.2.3 SolidWorks Modelling**

After establishing the design criteria and the alignment of the knee axis, we constructed a computer model of the knee joint using SolidWorks. This phase of the project allowed us to translate the conceptual design into a visual representation and use the model to assess specific design features such the ASPL mechanisms and the extension assist system. While putting the model through the motion of gait, we observed the interactions and clearances between various components, as well as accessing the feasibility of the incorporating both the swing phase control and stance phase control features into the design. We proceeded to modify and optimize the design when any problems or issues were detected.

### **3.2.4 Finite Element Analysis**

The Finite Element Analysis (FEA) is an effective tool for solving engineering problems using numerical method. FEA had previously been used effectively in similar applications, such as the investigations of both the feasibility of a compliant member in a knee employing an ASPL mechanism and a rear-locking prosthetic knee [5, 66]. Therefore, in designing the PASPL-Knee we also conducted FEA. The purpose of employing an FEA was to study and optimize the strength of the design. When a part of the design exhibited predicted stresses beyond the yield strength of the material or excessive displacements, the design was then adjusted to improve the model design prior to the subsequent simulation. Some adjustments included modifying the material and changing part dimensions or geometry.



The loading conditions in the simulation were based on the requirements and methods outlined by the International Organization for Standardization, ISO 10328 - structural testing of lower-limb prostheses standard [67]. The document specified two loading conditions for all prosthetic knee joints: loading condition I (LC I) and loading condition (LC II), which were related to the instant of maximum loading occurring early and late in the stance phase of normal walking respectively. In addition, the document also included special tests such as the knee lock test, which was dedicated to locked knee units such as the PASPL-Knee that would subject to flexion loading during the stance phase of walking.

The first step in setting up the simulation was to incorporate all the reference planes into the model. The positions of all the reference planes are specified and shown in Figure 3.3 and Table 3.3. Based on the choice of loading condition as well as the test load level, we proceeded to define the loading application points on each of the reference planes in order to generate the desired load line. Dimensions are shown in Table 3.4. The subsequent step was to determine the test forces based on the combination of the test load level and the loading condition. We selected the A60 test load level in this study since we were designing a paediatric prosthetic knee that could support a 60kg weighed user. Test forces are listed in Table 3.5.

**Table 3.3: Reference plane configuration**

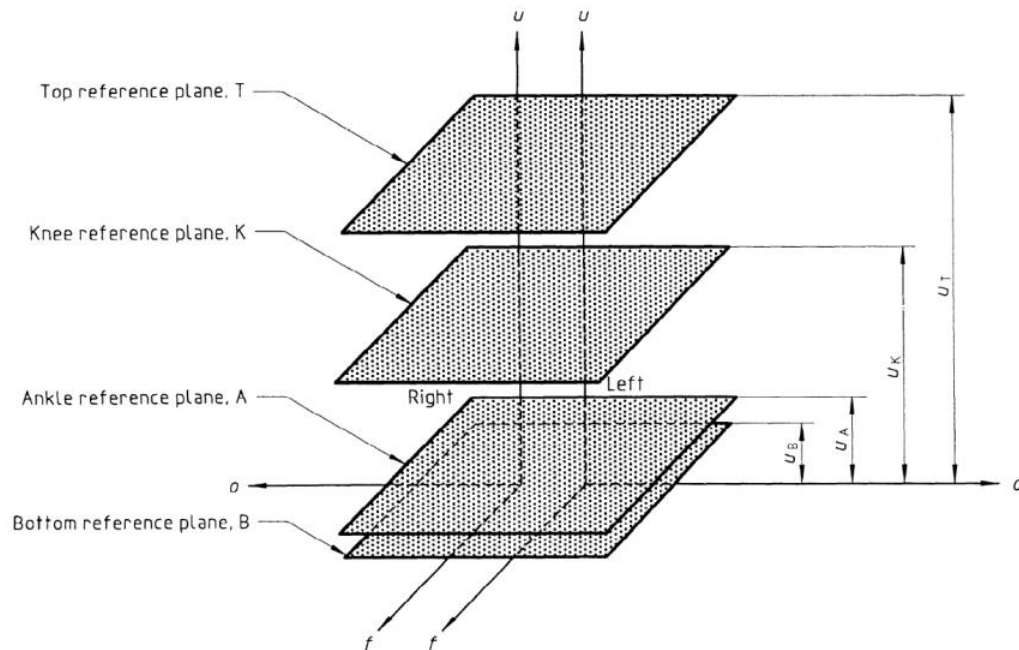
Reference Plane Level ( $h_r =$ recommended heel height; dimensions in millimetres)	
$u_T$	$u_T - u_K = 150$
$u_K$	$u_K - u_A = 440 - h_r$
$u_A$	$u_A - u_B = 60 + h_r$
$u_B$	$u_A - u_B = 60 + h_r$
Total Length	650

**Table 3.4: Dimensions for loading conditions I, II, & knee lock test for A60 test level**

Reference plane	Direction	Loading condition (mm)		
		I	II	Knee lock
Top	$f_T$	81	51	not applicable
	$o_T$	-85	-49	
Knee	$f_K$	49	68	-50
	$o_K$	-57	-43	0
Ankle	$f_A$	-41	115	-50
	$o_A$	24	-26	0
Bottom	$f_B$	-58	124	not applicable
	$o_B$	39	-23	

**Table 3.5: Test forces for different loading conditions**

Test Load Level	Loading Condition	Ultimate Test Force (N/lbs)
A60	I	3220/723
	II	2790/626
	Knee Lock	2100/471

**Figure 3.3: Structural test configuration**

### 3.3 Structural Testing

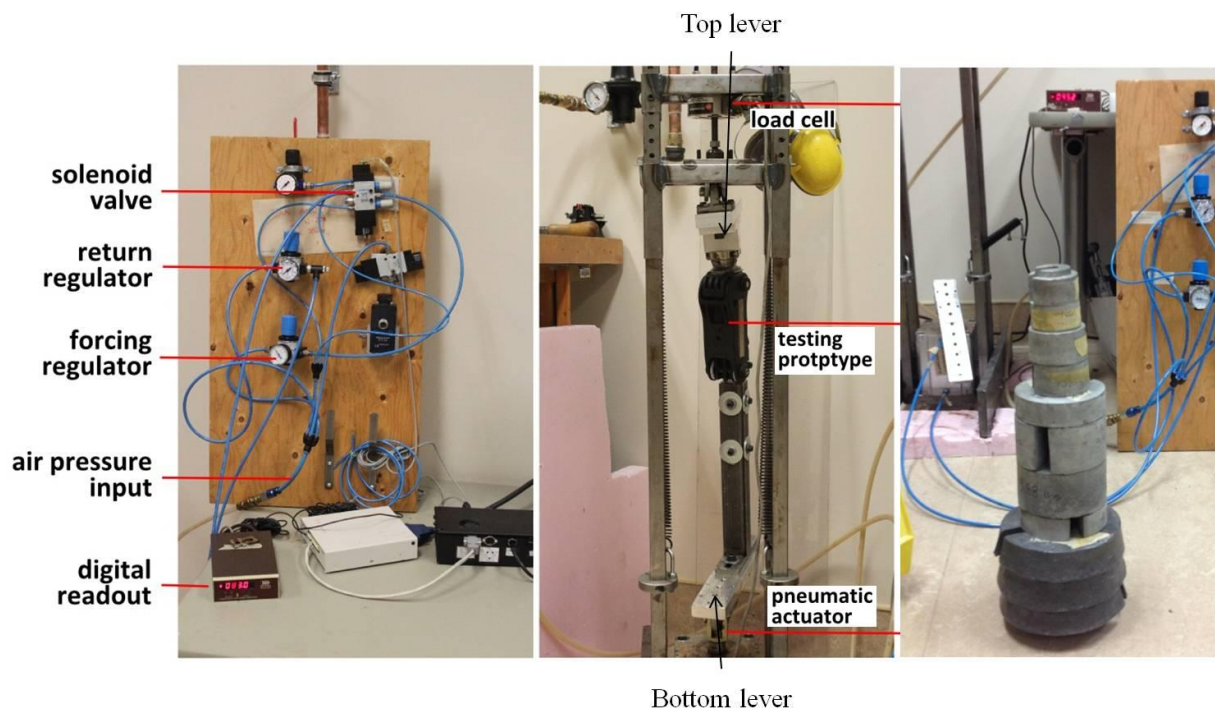
Upon finalizing the conceptual design of the PASPL-Knee, the subsequent step was to construct a prototype and conduct structural testing to evaluate its structural integrity using the ISO-Tester developed at the Holland Bloorview Kids Rehabilitation Hospital. The ISO-Tester is comprised of a mechanical test unit, a patch box, a power control box, a computer, a digital display box, and a series of solenoid valves for compressed air. For the testing procedure, we followed the static load strength test procedure specified in the ISO 10328 – structural testing of lower-limb prostheses document. Successful completion of the structural tests, including loading conditions I and II, were required prior to conducting a clinical pilot study involving a human subject.

Prior to the structural testing, the orientation of the prosthetic knee joint inside the test unit had to be determined first as it would affect the orientation of the load line on the prosthetic knee.

The loading application points were specified in the ISO standard documents, listed in Table 3.4. Using the specified dimensions for the loading application points, we calculated the required distances to shift the top and bottom lever from the centre line of loading, as well as the angles between the knee and the attachments in order to achieve the required orientation inside the tester for each specific loading condition. Results are shown in Table 3.6.

**Table 3.6: Dimensions required for each loading condition inside the tester**

Loading Condition	Top Lever		Bottom Lever	
	Distance (cm)	Angle (degrees)	Distance (cm)	Angle (degrees)
I	9.7	47	-7.1	34
II	6.7	40	12.3	10.5
Knee Lock Test	5.7	0	5.7	0



**Figure 3.4: Pneumatic control setup, testing rig, & digital box calibration**

Aside from the alignment of the prosthetic knee, it was also important to properly connect and check all of the components of the test unit before testing, including pneumatic system and the digital control system, as well as calibrating the digital display box. The digital display box was connected to the load cell and served as a primary indicator for showing the amount of force applied to the test unit. This helped avoid excessive amounts of force being applied to the knee joint during the structural testing. Therefore, it was very critical to calibrate it before testing. By

reviewing the factory documentations on the digital display box, we performed a series of calibrations and reconfigurations in order to have the display box show the proper amount of pound force that was being exerted on the load cell. We placed known weights onto the load cell and verified that the digital box was indeed showing the correct amount of forces. Lastly, a computer program was used to control the solenoid valves. The program was activated to control the flow of the air, thus activating the pneumatic actuator at the bottom of the test unit to apply the load. The air pressure was adjusted via the forcing pressure regulator to achieve the desired load force on the prosthetic knee. Once all of the components were examined and the prosthetic knee was properly aligned inside the tester, structural testing was performed for both loading condition I and loading condition II at the test load level A60.

### **3.4 Single Subject Pilot Study**

#### **3.4.1 Overview**

To investigate the functionality of the design of the PASPL-Knee, a single subject pilot study was conducted. There were two parts in the study, the six-minute walk test and the instrumented gait analysis. During the study, the participant was asked to repeat the testing procedures three times, once with participant's own prosthetic knee and twice with the PASPL-Knee, to examine and compare the performance of both designs.

#### **3.4.2 Ethics**

Before any clinical testing involving human subjects can take place at Holland Bloorview Kids Rehabilitation Hospital, the testing protocol had to be approved by the Research Ethics Board (REB) at the hospital. The items in the final and completed ethics application package are listed below.

- 1) Ethics Application Checklist
- 2) TAHSN Ethics Application Form
- 3) Full Research Proposal
- 4) Scientific Review Form and Documentation
- 5) Letter of Support for Recruitment
- 6) Information Letter

- 7) Consent Form
- 8) Demographics Form
- 9) Email Script
- 10) Telephone Script
- 11) Knee Joint Design Performance Interview
- 12) Research Participation Opportunity Flyer

The Toronto Area Health Sciences Network (TAHSN) ethics application form is a standardized document that consists of the objectives, methodologies, procedures, and precautions of any research protocol involving human subjects. The Research Proposal provides a detailed protocol of the study, including the background, goals, and methodologies of the research. The Scientific Review Document was included to show that the revisions and suggestions from the review board had been incorporated in to the ethics application package. After, the Letter of Support for Recruitment was signed by a senior director at the hospital. Finally, the entire package, including other non-standardized documents such as the information letter, consent form, questionnaire and interviewing scripts were included and submitted to the REB. An itemized response was prepared if there are any written comments from the REB and then resubmitted for final approval of the study.

### **3.4.3 Objectives**

The objective of the single subject pilot study was to evaluate the functionality of the PASPL-Knee. This clinical study was completed in two sessions which were three weeks apart. During each session the participant was asked to perform the six-minute walk test and gait trial to measure the participant's energy expenditure, spatiotemporal, kinematics and kinetics parameters during gait.

#### *a) Acclimatization Period*

The acclimatization period is the length of time required for the user to learn to operate the new prosthesis [68], and it is important to provide sufficient time for a person with an amputation to become familiarized with a new prosthesis. It is deemed preferable for the participant to try knee mechanisms for at least 3 weeks in order to ensure that pertinent gait parameters are stabilized [69]. Therefore, PASPL-Knee was prescribed to the participant at the first session of study, and

the second session of testing was held three weeks after. The prosthesis was aligned by a certified prosthetist at the Holland Bloorview Rehabilitation Kids Hospital (Amy Richardson). The participant was asked to wear the PASPL-Knee throughout the acclimatization period in order to practice and adapt to the knee joint.

*b) Participant Inclusion/Exclusion Criteria*

- The participant must be an above-knee unilateral amputee between the age of 6 – 12 years, with a maximum weight of 60 kg
- The participant must have used a high-end knee designated for high-activity (i.e. K3 and K4 level)
- Must be able to communicate in English or have an English-speaking family member

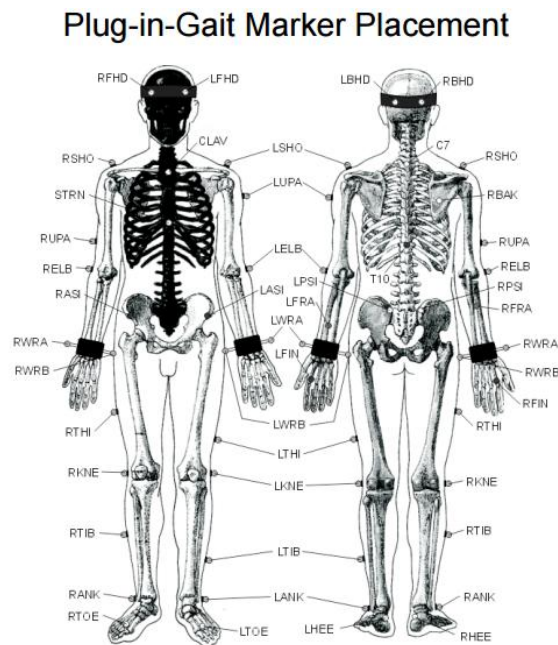
*c) Recruitment Plan*

While a client was at the Centre accessing prosthetic and orthotic services, client and parents was asked by the clinician if they were interested in finding out more about this study. If the client was interested, the clinician then asked permission for a research team member to come speak to the client. Someone from the research team then came and spoke to the client in person to provide them with more information about the study. The client was still interested in participating then her family was provided with an information sheet to take home. A follow up phone call was used to help answer any outstanding questions that the client might have, and to get the client and their parents' verbal consent. An appointment was then scheduled for first visit of the protocol and written consent was obtained during first visit as well.

*d) Instrumentation*

A VICON Nexus 1.8.5 software connected to 7 MX13 motion-capture cameras recording at 100Hz was used in the instrumented gait analysis along with two force plates on the ground. This motion analysis system allowed us to measure the kinematics and kinetics variables mentioned in Section 2.2.4. The Plug-In Gait model was used in the study, with 16 optical markers placed on the client using double-sided tape on left and right anterior superior iliac spine, left and right posterior superior iliac spine, lateral side of mid-thighs, lateral epicondyles of knee on the sound limb and on the lateral side of prosthetic knee's pivoting axis, lateral mid-

tibia and mid-shank, lateral ankles, posterior side of heels, and medial side of first metatarsals. It is a commonly used gait model for gait analysis [70].



**Figure 3.5: Plug-in-Gait model**

*e) Protocol*

This study was conducted on two separate days, three weeks apart to accommodate the acclimatization period. At the beginning of the study, demographic information such as age and gender of the participant were collected, as well as anthropometric measurements such as height and weight. The PASPL-Knee was presented to the participant for the first time on the first day of testing, and the knee was fitted and aligned on the participant by a professional prosthetist. The participant was then given 30 - 45 minutes to practice with the new design. This period enabled the participant to recognize any discomfort or concerns with the knee joint or alignment and to be able to report them to the prosthetist so that appropriate adjustments could be made.

Then the participant was asked to perform the six-minute walk test and the gait trial with both her own conventional prosthetic knee and the new design. Throughout the acclimatization period, we contacted the participant regularly to monitor the status and usage of the PASPL-Knee. During the second data collection session of the study, the participant was asked to perform the same tests and was asked to complete a questionnaire regarding her experience and feedback for the PASPL-Knee. The testing took 2 - 2.5 hours to complete.

**Six-Minute Walk Test:** As introduced in Section 2.2.4, functional walk tests are effective tools to evaluate the ability of the participant to undertake physically demanding activities of daily living. Following the guidelines for the 6MWT established by the American Thoracic Society [31], the test was performed indoor, along the hallway with a hard surface on the 4th floor of Holland Bloorview Kids Rehabilitation Hospital. The participant was instructed to walk along the hallway for 6 minutes, and to cover as much distance as possible within the time period. Prior to each test, the participant was asked to rest in a chair for at least 10 minutes, and her resting heart rate (HR) was then measured. Immediately after the completion of the test, her working HR was recorded again within 2-3 seconds. A stop watch was precisely adjusted to the 6-minutes mark, and a measuring tape was also used to measure the distance participant had covered in the test. The recorded data was used to calculate the average gait speed of the participant during the walk test, as well as the PCI value for energy expenditure comparison.

**Instrumented Gait Analysis:** For the gait analysis, the gait trials were performed to evaluate the walking ability of the participant in both prostheses. This test was performed in a straight line in the Human Movement Lab at the Holland Bloorview Kids Rehabilitation Hospital. A data capture system consisting of 7 IR cameras and two offset force platforms inside the laboratory was utilized for motion analysis. Reflective markers were placed onto the lower body of the participant based on the Plug-in-Gait model. The participant was instructed to walk at a comfortable, self-selected walking speed in the walk test [17, 33, 47, 71]. Five trials for each knee were conducted. In order to minimize the effect of fatigue, participant took breaks in between each trial. During each trial, the VICON camera data and the force plate data were recorded. They were processed to calculate the spatiotemporal variables such as gait speed, step time, step length, stride time, stride length, single support duration and double support duration, as well as the kinematics and kinetics variables such as ankle angle, knee angle, hip angle, ankle moment, hip moment, knee moment, hip power, knee power, and ankle power. These were parameters used for determining signs of abnormal gait that the subject might exhibit [47, 72].

e) *Analytical Plan*

In this study, a descriptive statistical analysis approach was employed. It implied that this study aimed to understand the functions of the design with the selected participant, rather than using the data to generalize the entire amputee populations. The outcome measures for the PASPL-Knee were compared to the participant's conventional knee, as well as relevant results from



previous studies on able-bodied individuals and paediatric amputees. Differences in the key parameters in those comparisons would provide a measure of how functional the PASPL-Knee was, as well as indicating areas of the design that needed to be addressed and improved.

**Spatiotemporal:** The spatiotemporal parameters that were measured in the study are summarized in Table 3.7. All parameters were measured for both the conventional knee and the PASPL-Knee at a self-selected walking speed. The results for both knee joints were compared to the data from previous studies, including the gait measurements on able-bodied children by S. Menkveld et al. and measurements on paediatric above knee amputees by R. Ashley et al.

Symmetry index (SI) is the most common approach used to define gait asymmetry [73]. Although this method has its limitations, it facilitates interpretation and provide a general indication of asymmetry [74-78]. In the equation,  $X_L$  and  $X_R$  are the values of the specified parameter for the left and right limb. The SI values can range from -100% to +100% where  $SI = 0$  indicates that the gait is absolutely symmetrical [79]. The SI values of the selected parameters for the PASPL-Knee and participant's conventional knee were compared to the normative values of SI indicators in health subjects.

$$SI = \frac{|X_L - X_R|}{0.5 \cdot (X_L + X_R)} \cdot 100\%$$

**Table 3.7: Measured spatiotemporal parameters**

Spatiotemporal Parameter	
Walking speed (m/s)	Stride length (m)
Step time (s)	Single support (%)
Step length (m)	Stance phase (%)
Stride time (s)	Swing phase (%)

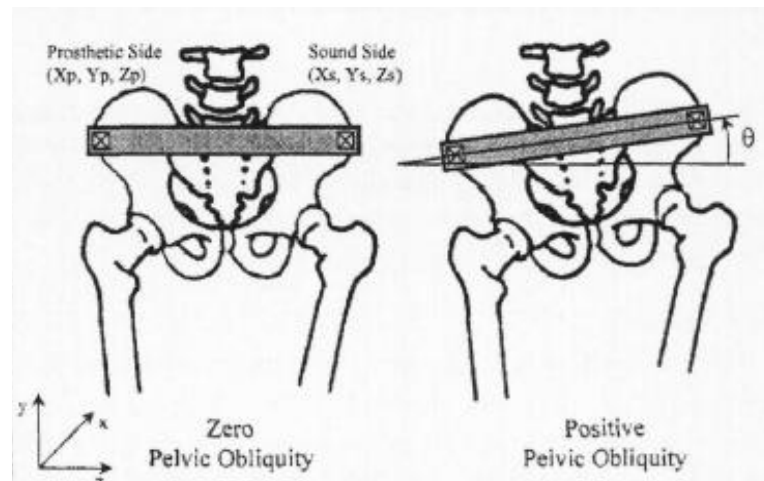
**Energy Expenditure:** The six-minute walk test was used to compare the walking energy expenditure of the user with her conventional knee to the PASPL-Knee. The recorded data, such as the resting HR, working HR, and distance covered, was used to calculate the average gait speed of the participant during the walk test and the Physiological Cost Index (PCI). The values were compared to the results from the studies conducted by S. Ulrich et al. and N. Pathare et al. on six minute walk test performance in young able-bodied children [80, 81].

$$PCI = \frac{\text{Working HR (beats/min)} - \text{Resting HR (beats/min)}}{\text{Walking Speed (meter/min)}}$$

**Kinetics and kinematics:** The kinetics and kinematic parameters were used to examine the mechanics of the hip, knee ankle, and pelvis. Differences in the joint mechanics between the conventional knee and the PASPL-Knee were characterized by the following parameters (see Table 3.8). Since there are lack of age-related difference in joint kinematics [82], the kinematics data collected in this study was compared to the results from T. Oberg et al. and M. Kadaba et al. with able-bodied young adults [83, 84]. The kinetic data collected in this study was compared to the study conducted by S. Shultz et al. on able-bodied children [85].

Pelvic obliquity is an important indicator of the compensatory action of hip hiking that commonly prevails in above-knee prosthetic gait [47]. It was calculated as the angle in the coronal plane of the walking subject that is formed between the line connecting the two ASIS markers and a horizontal plane, as shown in Figure 3.6. Pelvic obliquity was calculated by the equation below, where  $(X_s, Y_s, Z_s)$  AND  $(X_p, Y_p, Z_p)$  are the three-dimensional coordinates of the sound and prosthetic side ASIS markers respectively [86].

$$\theta = \frac{180}{\pi} \cdot \tan^{-1} \frac{(Y_s - Y_p)}{\sqrt{(X_s - X_p)^2 + (Z_s - Z_p)^2}}$$



**Figure 3.6: Pelvic obliquity**

**Table 3.8: Parameters for characterizing the joint mechanics**

<b>Mechanics</b>	<b>Parameter</b>	<b>Function</b>
Hip	Hip range of motion (ROM)	Indicate abnormal gait
	Internal peak hip moment in terminal stance	Initiate swing phase
	Peak hip power in early stance	Effort in weight acceptance
	Peak hip power in terminal stance	Initiate swing phase
Knee	Knee range of motion (ROM)	Indicate abnormal gait
	Peak knee-flexion angle during swing	Effectiveness of the swing phase control
	Internal peak knee moment in terminal stance	Flex the knee during pre swing
Ankle	Ankle range of motion (ROM)	Indicate abnormal gait
	Internal ankle dorsiflexion moment	Work as spring for loading response
	Internal ankle plantarflexion moment	Functioned during heel strike
Pelvis	Pelvic obliquity	Indicate hip hiking

### 3.5 Qualitative Evaluation

After the second session of the single subject pilot study, the participant was interviewed for the qualitative evaluation of the function of the PASPL knee joint. The questionnaires used in this study were specifically developed and used in previous similar studies. One of the questionnaires was originated from the study conducted by J. Andrysek et al. (2005) to evaluate the lower limb prosthetic function for the paediatric populations [46]. The questions assessed the user's experience and addressed factors such as appearance, fatigue, stability, discomfort and pain, and types of activities. All questions were close-ended, and the majority of the questions were answered with a yes/no or using a five point Likert scale.

Another set of questionnaire that was used in this study was developed by D. Wyss (2012) on developing a prosthetic knee based on the rear-locking mechanism [5]. The questions were developed to obtain qualitative feedback on the level of function, performance, and comfort of the PASPL-Knee. Questions were open-ended, and they were delivered in such way that would be easy for the participant to understand. Based on the feedback from the user, this allowed the researcher to gain a deeper understanding of how the user perceived the design and how effective the design was in enabling the user to walk.

## Chapter 4

### Results

In this chapter, the results of all aspects of this thesis project are presented, including a detailed breakdown of the development of the PASPL-Knee, the results from the structural testing, and the gait analysis data from the single subject pilot study.

#### 4.1 Design

The principle objective of this project was to develop a paediatric prosthetic knee joint that is light-weight, compact, yet structurally-sound and highly functional based on the ASPL technology. As a result, the PASPL-Knee was developed.

##### 4.1.1 Design Criteria

Below is a list of design criteria that were established prior to the design process and they must be satisfied in the PASPL-Knee.

**Table 4.1: Design criteria of the PASPL-Knee**

Most Important	- Adopt the ASPL mechanism into the paediatric prosthetic knee to provide stance phase control
	- Adopt and optimize the extension assist mechanism from AT-Knee to complement the ASPL mechanism
	- Incorporate a compression spring with a high spring rate and long cyclic life for extension assist
	- Integrate a flexion stop to protect the extension assist unit when the knee is flexed
	- Has a weight-bearing capacity of 60 kg
	- Achieve at least 145° of knee flexion angle
Less Important	- The weight of the prosthetic knee joint should not exceed 500g
	- The overall length should no longer than 150 mm
	- Aesthetically Pleasing

Stemming from the objectives of the project, the prosthetic knee joint design was based on the ASPL mechanism. Incorporation of the ASPL mechanism has to ensure that the knee would be structurally sound to prevent any catastrophic failures during gait and ensure the safety of the

user. Also, the axis alignment on ASPL mechanism had to be checked and modified for the paediatric users due to the differences in height and the length of the body segments, as the axis alignment established on the AT-Knee (adult's prosthetic knee) might not be ideal for the paediatric users.

Aside from providing stance-phase stability, it was also critical to offer a swing phase control for a smoother and enhanced gait pattern. Therefore, the knee extension assist feature from the AT-Knee must be adopted into the prosthetic knee joint design. However, instead of directly transferring the design, the extension assist must be optimized, such as reducing the interference between components and noise level, in order to improve its performance as well as fit within the size-constrained PASPL-Knee.

Additionally, a compression spring with a high spring rate and a long cyclic life needed to be incorporated in order to generate the desired torque to aid the extension of the knee, and ensure the mechanism is durable and reliable. Refer to the clinically-proven AT-Knee, we decided that the selected spring in the PASPL-Knee must be capable of generating close to 60% of the generated torque in the AT-Knee, and the cyclic life should exceed 1-million cycles. The rationale will be discussed in Sections 4.1.3c. Still further, a flexion stop feature must be included in the prosthetic knee joint design to ensure that the extension assist unit is well protected when the knee is hyper flexed. This is to prevent potential damage to the knee joint.

In comparison to other conventional paediatric prosthetic knees shown in Table 2.1, the majority of them offer at least  $140^\circ$  of maximum knee flexion angle, and the median is  $145^\circ$ . Therefore, the design must also achieve at least  $145^\circ$  of maximum knee flexion. The advantage of achieving a high knee flexion angle is that it will allow users to be in a crouching or sitting position comfortably.

The length and weight of all the conventional prosthetic knee joint products were listed in Section 2.4, and they range from 100 - 160 mm and 150 - 400 g respectively. Comparing the length and weight restrictions of this design to all the conventional knee joints, which were listed at 150 mm and 500 g, these limits would make this prosthetic knee joint among the longest and heaviest conventional prosthetic knees listed above. This appeared to be contradicting the objective of producing a lightweight and compact design. However, since this design was the first paediatric prosthetic knee to incorporate the ASPL mechanism from the AT-Knee to a paediatric prosthetic knee, we suspected that there would be many uncertainties and

problems that we could not have envisioned. Therefore, we did not want to restrict ourselves with length and weight limit for the design. The main priority was to demonstrate that the ASPL technology could be applied to the paediatric knee joint design, as well as producing a highly functional knee that incorporated both stance phase control and swing phase control. As the design further develops, the weight and size of the design will be prioritized.

#### 4.1.2 Axis Alignment

Following the procedure outlined in Section 3.2.2 and illustrated in Figure 3.1, an adult's knee-shank-foot assembly model was formed with the AT-Knee model. Then we measured the distance from the heel to the intersecting point, the projected distance, and calculated the ratio of the projected distance to the foot length of the model. The procedure was repeated with the child's shank and foot models. As shown in Table 4.2, the zone of instability from the paediatric models were different compared to the adult's model, as this was more evident in the younger age group. The smaller zone of instability in the paediatric model suggested that the axis alignment on the AT-Knee was not suitable for the paediatric users, as it would make it more difficult for the paediatric users to initiate swing phase.

**Table 4.2: AT-Knee axis alignment analysis**

Results	Adult	Age 6.5 -7.5	Age 11.5 - 12.5 (Mean value)	Age 11.5 - 12.5 (95th Percentile)
Projected distance (mm)	111.12	103.38	110.18	113.60
Foot length (mm)	251	189	232	253
Ratio of the projected dist to the foot Length	<b><u>0.442</u></b>	0.547	0.475	0.449
Zone of instability (%)	<b><u>55.8</u></b>	45.3	52.5	55.1

**Table 4.3: Results using the ratio obtained from the AT-Knee (ratio = 0.442)**

Results	Age 6.5 - 7.5	Age 11.5 - 12.5 (50th Percentile)	Age 11.5 - 12.5 (95th Percentile)
Foot length (mm)	189	232	253
Projected distance (mm)	83.54	102.54	111.83
Alignment angle (degrees)	5.07	5.13	4.27

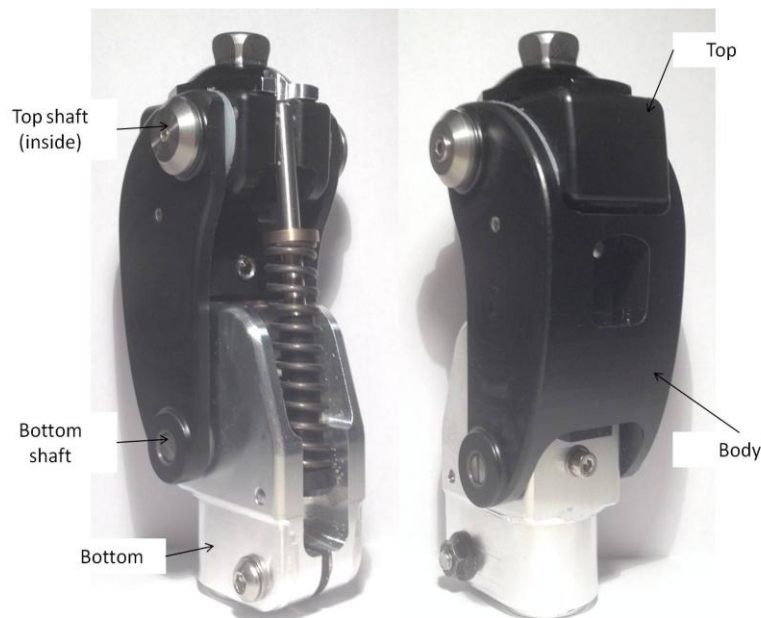
**Table 4.4: Results with the alignment angle of 5°**

Results	Age 6.5 - 7.5	Age 11.5 - 12.5 (50th Percentile)	Age 11.5 - 12.5 (95th Percentile)
Projected distance (mm)	83.17	101.62	117.75
Ratio of the projected dist to the foot Length	0.465	0.440	0.438
Zone of instability (%)	53.5	56.0	56.2

Therefore, we proceeded to modify and establish the axis alignment for the PASPL-Knee. Following the procedures listed in Section 3.2.2 and illustrated in Figure 3.2, we obtained the projected distance for each child model by multiplying the foot length to the ratio obtained from the AT-Knee. The alignment angle with all three child knee-shank-foot models were then measured. The results are shown in Table 4.3. By comparing the alignment angles from different sets of knee-shank-foot models, the final alignment angle for the PASPL-Knee was set to be at 5°. This alignment angle allowed the paediatric users across all ages to establish the similar zone of instability as the AT-Knee, which is the optimal area on the forefoot that allows the knee to be stable but also reliably unlock. This can be seen by comparing their ratios to the ratio on the AT-Knee (shown in Table 4.4).

### 4.1.3 Computer Modelling

#### a) Final Design Overview

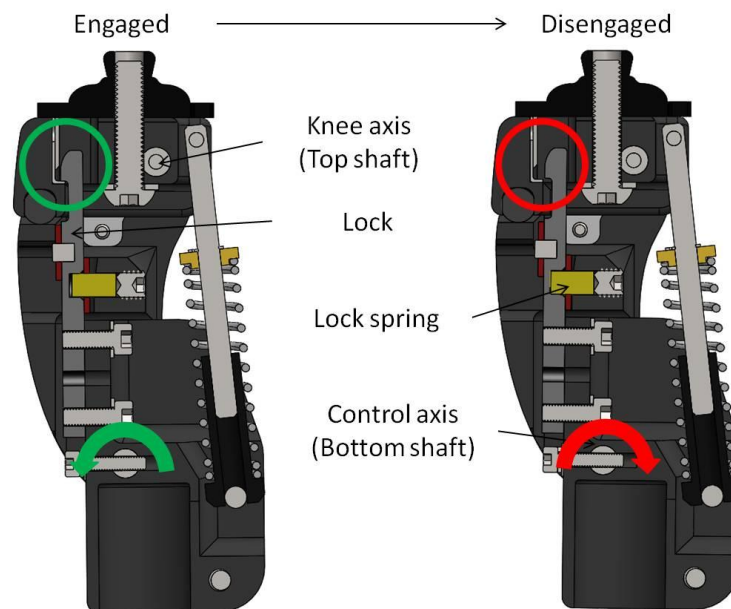
**Figure 4.1: Prototype of the PASPL-Knee**

**Table 4.5: Design summary of the PASPL-Knee joint**

<b>PASPL-Knee Design Summary</b>
Adopt the automatic stance-phase lock (ASPL) technology
Optimize and incorporate the extension assist from the AT-Knee to the PASPL knee
Has a weight-bearing capacity of 60 kg
Provides maximum of 152° of knee flexion angle
134.5 mm in length and weighs 430 g

*b) Automatic Stance-Phase Lock Technology*

The ASPL technology was adopted into the PASPL-Knee design. Though its operating mechanism of the knee is identical to the AT-Knee, the lock mechanism in the PASPL-Knee has been reduced in size, thus reducing the weight and height of the PASPL-Knee by 38.6% and 18.4% respectively in comparison to the AT-Knee. Yet, the mechanism in the PASPL-Knee is proven to be structurally sound in the structural testing, and functional and effective in the single subject pilot study, which all will be discussed in later sections.



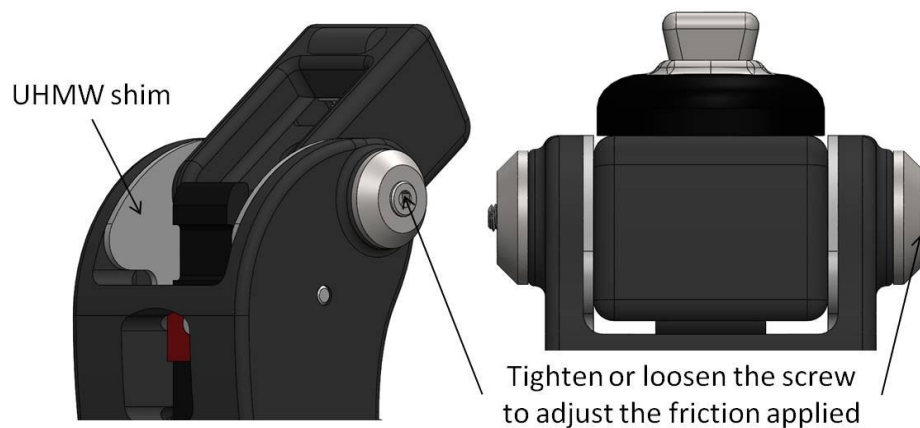
**Figure 4.2: ASPL technology implementation at PASPL-Knee**

*c) Swing Phase Control Mechanism*

The swing phase control mechanism in the PASPL-Knee contains two features: the variable friction control and the extension assist. The variable friction control is achieved by placing two shims made of ultra-high-molecular-weight (UHMW) polyethylene at the interfaces between the



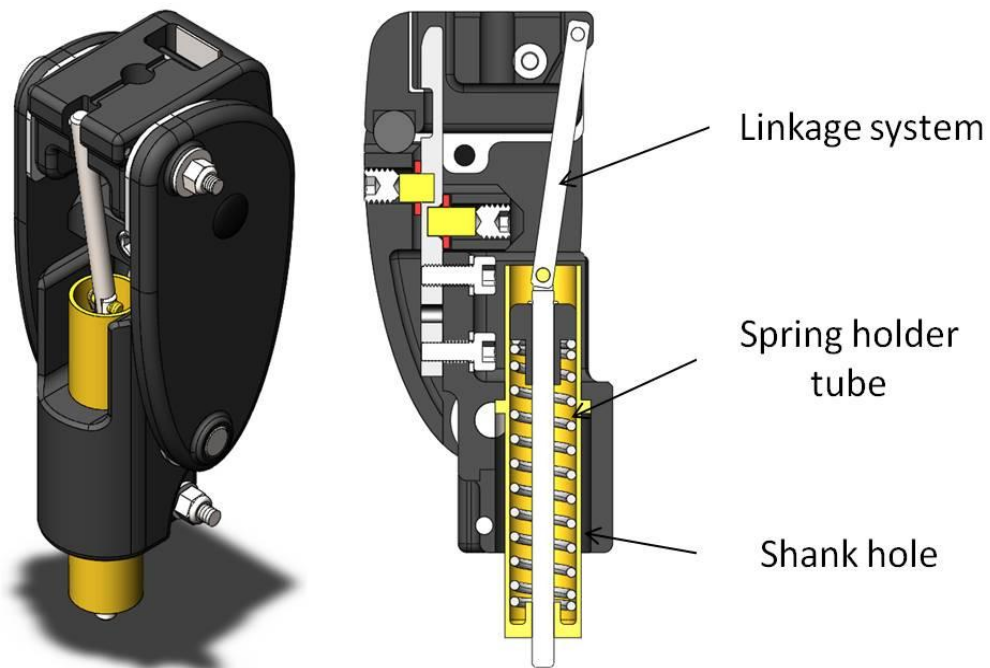
top and body piece on both sides. Based on the walking speed and preference of the user, the amount of friction applied can be adjusted by tightening the screw placed inside the top shaft (as illustrated in Figure 4.3. This can offer the damping effect and reduce the speed of the knee extension motion. The extension assist system in this design is achieved through the use of a compression spring. The compression spring is pressed when the knee flexes, therefore the stored energy within the compressed spring will be able to assist the knee during extension, resulting in a shorter, more symmetrical swing phase duration.



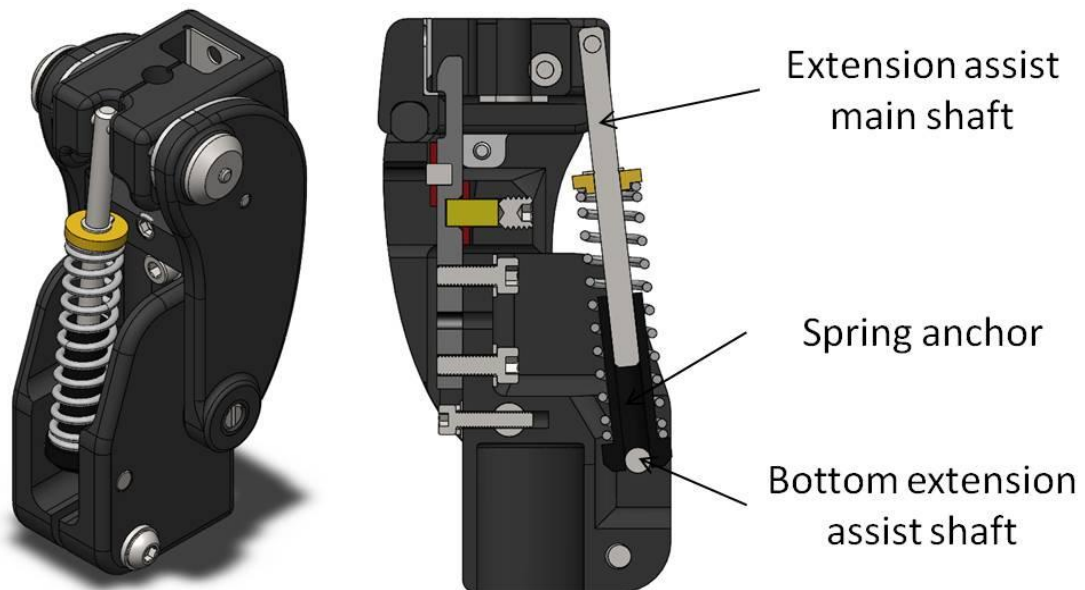
**Figure 4.3: Variable friction control**

But as stated in Section 1.2, due to the size limitation, it was difficult to incorporate a mechanical spring with the appropriate size that had the adequate spring rate to generate the desired torque (~60% of torque in the AT-Knee) for the knee extension assist, and also had a cyclic life over 1-million cycles. Furthermore, the compactness of the knee joint also made it problematic to provide adequate clearance for the extension assist unit for the knee to achieve at least 140° of maximum knee flexion. Therefore, the PASPL-Knee design had continued to evolve until the final design came to fruition. The final design had satisfied the listed criteria, and also was optimized from the AT-Knee to aid the overall performance of the knee joint.

**Version I (Figure 4.4):** In version I of the PASPL-Knee conceptual design, a linkage system was utilized to achieve the extension assist feature. The linkage system was consisted of two stainless steel links with a bronze pin connecting them. In order to maximize the space available for a compression spring, the compression spring was placed inside the spring holder tube, and the spring holder tube was designed to slot into the shank hole. The shank would be utilized to keep the spring holder secure when the prosthetic knee is in use.



**Figure 4.4: Version I of the PASPL-Knee**



**Figure 4.5: Final design of the PASPL-Knee**

***Final Version (Figure 4.5):*** In the final version of the PASPL-Knee design, the linkage system in the first version is eliminated and replaced by a single long shaft, termed the extension assist main shaft. In order to accommodate the main shaft into the design, the shank hole is moved anteriorly and the bottom component is also extended in length posteriorly and inferiorly.

Instead of utilizing the spring holder tube, a single shaft (bottom extension assist shaft) and the spring anchor are incorporated to contain the compression spring, which is the same as the AT-Knee. The spring anchor pivots on the bottom extension assist shafts, and is used to secure the compression place in place. However, the major difference between the AT-Knee and the PASPL-Knee is that the bottom extension assist shaft at the PASPL-Knee is placed more posterior at the bottom component in comparison to the AT-Knee. This change serves an important role in the optimization of the extension assist unit, which will be further discussed in Section 5.1.2.

**Extension Assist Spring:** With the lack of literature studies discussing the ideal amount of torque that should be provided in a compression spring extension assist system, the selection of a compression spring for the PASPL-Knee was referenced to the clinically proven AT-Knee. The AT-Knee is designed to support a maximum user weight of 100 kg, and the PASPL-Knee has a weight-bearing capacity of 60 kg. Therefore, we presumed that should the PASPL-Knee able to provide approximately 60% of the torque generated in the AT-Knee during knee extension, it would be adequate to provide satisfactory extension assist for the PASPL-Knee users. The analysis of the AT-Knee extension assist system is shown in Table 4.6. As presented in Table 4.7, the selected spring in the PASPL-Knee has a spring rate of 8.93 N/mm in the final PASPL-Knee design. With a suggested maximum deflection listed at 23.88 mm for the selected spring, it is higher than the maximum deflection of 16.58 mm within the PASPL-Knee design. Therefore, according to the mechanical spring manufacturer, the selected spring should have a cyclic life over 10-million cycles theoretically.

**Table 4.6: Analysis of the compression spring in AT-Knee**

		AT-Knee							
Spring constant (N/mm)		7.77							
Flexion angle		0°	30°	45°	60°	70°	80°	90°	112° (Max. compression)
Lever arm distance (mm)		14.66	16.82	16.27	14.46	12.51	9.97	7.02	0.55
Compression distance (mm)		6.35	14.14	18.54	22.55	24.92	26.91	28.38	29.64
Compression force (N)		49.45	110.1	144.4	175.6	194.1	209.5	221.0	230.8
Torque generated (N-m)		0.73	1.85	2.35	2.54	2.43	2.09	1.55	0.13

**Table 4.7: Analysis of the PASPL-Knee's extension assist system**

Properties		PASPL-Knee							Value
		0°	30°	45°	60°	70°	80°	90°	
Spring constant (N/mm)									8.93
Free length (mm)									63.50
Outer diameter of spring (mm)									15.24
Dia. of wire (mm)									2.16
Suggested max. deflection (mm)									23.88
Flexion angle		0°	30°	45°	60°	70°	80°	90°	105° (Max. compression)
Lever arm distance (mm)		11.58	12.43	11.57	9.77	8.10	6.07	3.79	0.03
Compression distance (mm)		3.18	9.59	12.75	15.59	17.14	18.39	19.25	19.76
Compression force (N)		28.40	85.80	114.05	139.42	153.32	164.53	172.20	176.77
Torque generated (N-m)		0.33	1.07	1.32	1.36	1.24	1.00	0.65	0.01
% Torque of the AT-Knee		45.4	57.6	56.2	53.6	51.2	47.8	42.1	4.8

*d) Aesthetics*

Functionality and aesthetics are important determinants of consumers' preferences and choices in product design. It is simple to understand that the functionality of the product is the most important element when considering how good a product is. A great design must provide the functions or services that can meet the requirements and needs of the targeted group first and foremost. However, aesthetics has been shown to critically affect a variety of constructs such as perceived usability, satisfaction, and pleasure, and it is an important way of differentiating products in order to provide a competitive advantage in the marketplace filled with similar ones [87, 88]. Therefore, the aesthetics of the design cannot be neglected.

The exterior design of the PASPL-Knee joint is defined by an element of smooth curvature. As the knee joint design is made up of three separate main structural components (top, body, and bottom), the goal from an aesthetic standpoint is to merge all three pieces and establish a continuity on the outside, which further highlights the compactness of the design. Therefore, there exists a smooth contour throughout the knee joint design, best illustrated at the front of the

knee joint, in order to provide a smooth transition between all three pieces. The employment of smooth contour is also used to avoid a boxlike design in order to further contribute to the idea of a sleek and modern-looking design. Towards the back of the knee, the spring is revealed and highlighted, as it can establish the sense of robustness and mechanical look in the design. Overall, by combining all the above mentioned elements, the idea is to present the PASPL-Knee joint as a highly function, compact, and forward thinking design.



**Figure 4.6: Prototype of the PASPL-Knee**

*e) Material*

The part list of the PASPL-Knee is shown in Appendix B, where all the components and their respective materials are summarized. The majority of the raw materials used in the PASPL-Knee were purchased in retail hardware stores, such as the stainless steel, polyurethane, and aluminum. But the material used for the top, body, and bottom component, Zytel®, were generously provided to us by DuPont™.

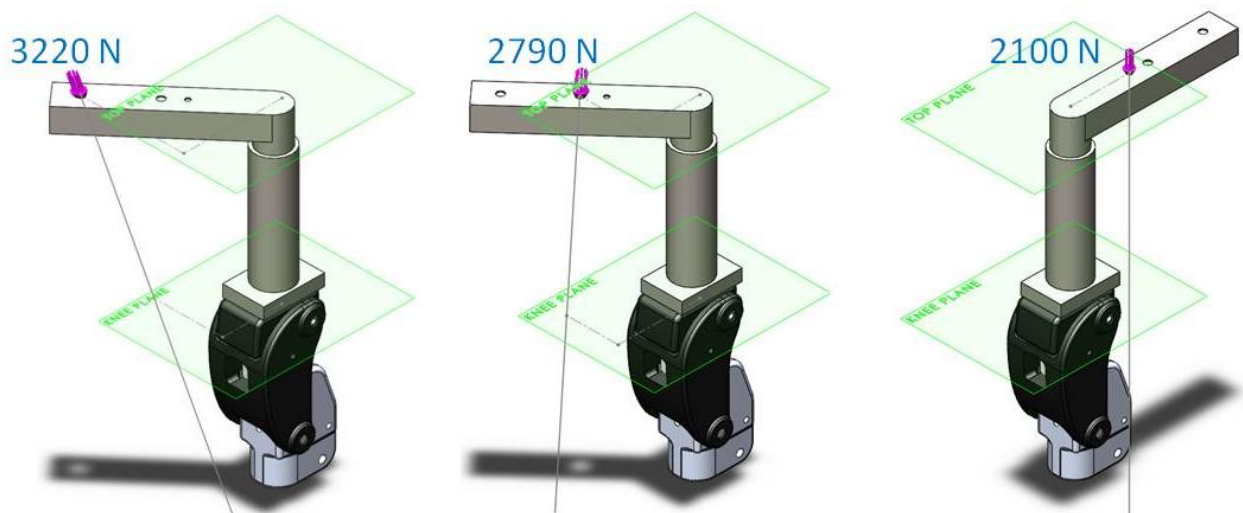
Zytel® is a fibre-reinforced nylon resin product. It is usually used in an injection moulding process therefore does not come in a block-form for machining. But through previous collaborations with DuPont™, the Zytel® materials were given to us in block-form for prototyping by laminating multiple plates using a plastic welding technique.

#### 4.1.4 Finite Element Analysis

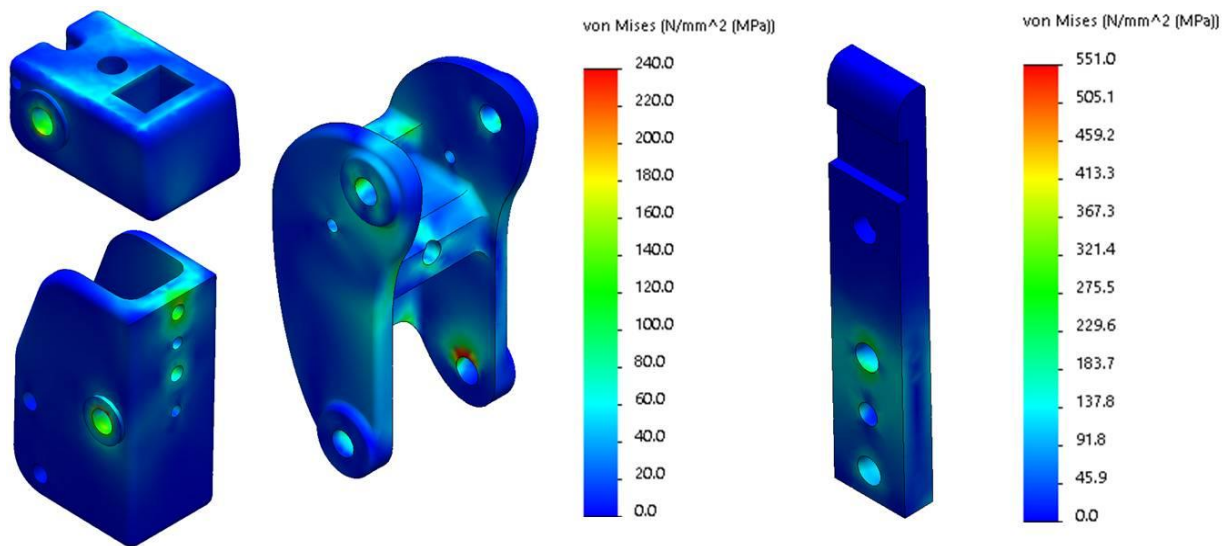
##### a) Initial Results

Due to the failure which occurred during the initial structural testing, which will be discussed in Sections 4.2 and 5.1.2, there were two sets of FEA data presented. Figure 4.7 shows the set up for each loading conditions. The initial FEA results of the static tests, including the loading condition I, loading condition II, and knee lock test, are summarized in Figures 4.8 - 4.10.

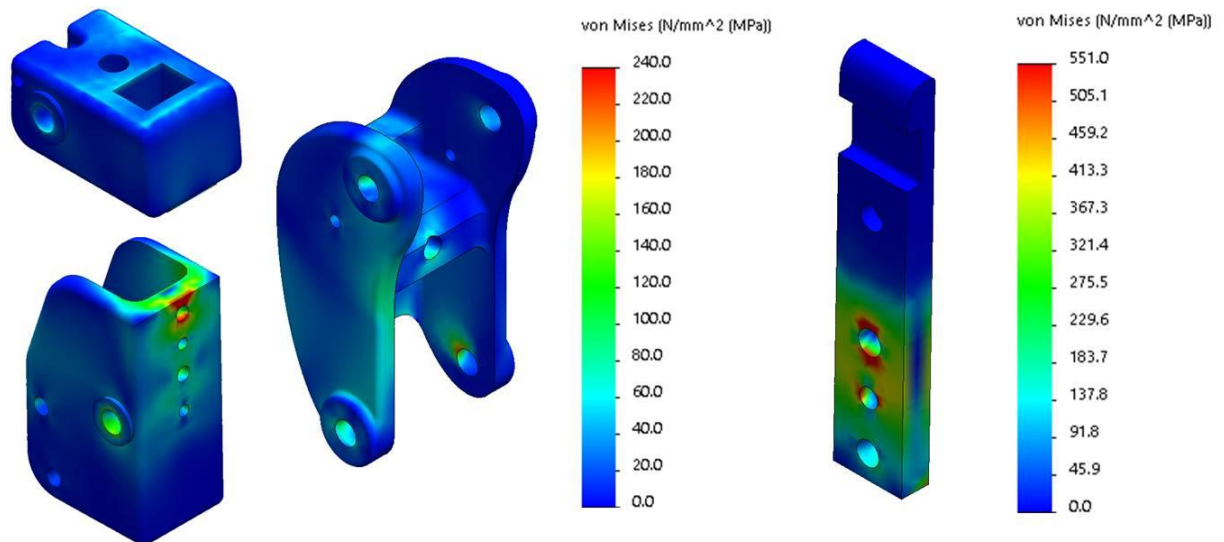
The FEA results for the top, bottom, and body components of the PASPL-Knee, and the knee lock are shown. The upper stress limits in both scales represented the yield strength of the respective materials. In the first set of data, the stress distributions were shown at the top, body, and lock, demonstrating the bending profile seen in the body. The stress distributions were also shown at the lock and the upper region of the bottom component in both loading condition I and II, and the knee lock test. All of these stress distributions were under the break strength of the material, therefore the components were considered to be structurally sound. However, it should be noted that there were minimal stresses shown in the lower region of the bottom piece, which later proved to be a major flaw in the constraints in the FEA for the bottom component. The bottom component had fractured during the initial structural testing, which indicated that the FEA results were false.



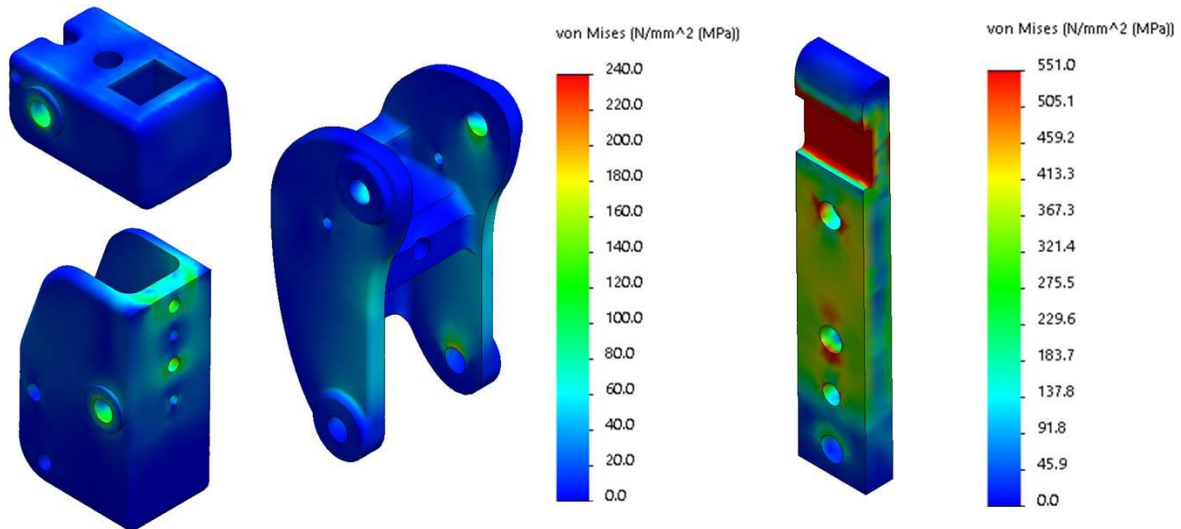
**Figure 4.7: FEA setup for (a) LC I; (b) LC II; (c) Knee Lock Test**



**Figure 4.8: Initial FEA results (loading condition I)**



**Figure 4.9: Initial FEA results (loading condition II)**



**Figure 4.10: Initial FEA results (knee lock test)**

*b) Re-evaluation*

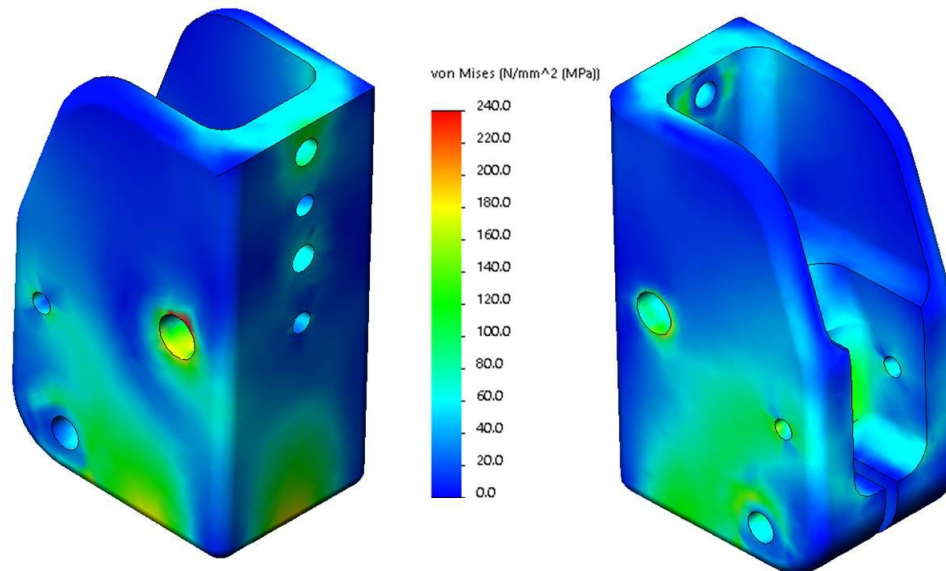
The failure that occurred during the initial structural testing had indicated that there were issues with the constraints in the analysis, which led to a false prediction of the stress distribution in the design. Therefore, the constraints and the model were updated prior to the second set of FEA.

Under loading condition I and II, while there were no differences in the predicted stress distributions in the other components, there was a noticeable increase in stress distribution at the frontal side of bottom component compared to the initial FEA results. As shown in Figure 4.11 and 4.12, particularly under loading condition II, the predicted stress concentration exceeded the yield strength of the material and potentially leading to a mechanical failure of the part during structural testing.

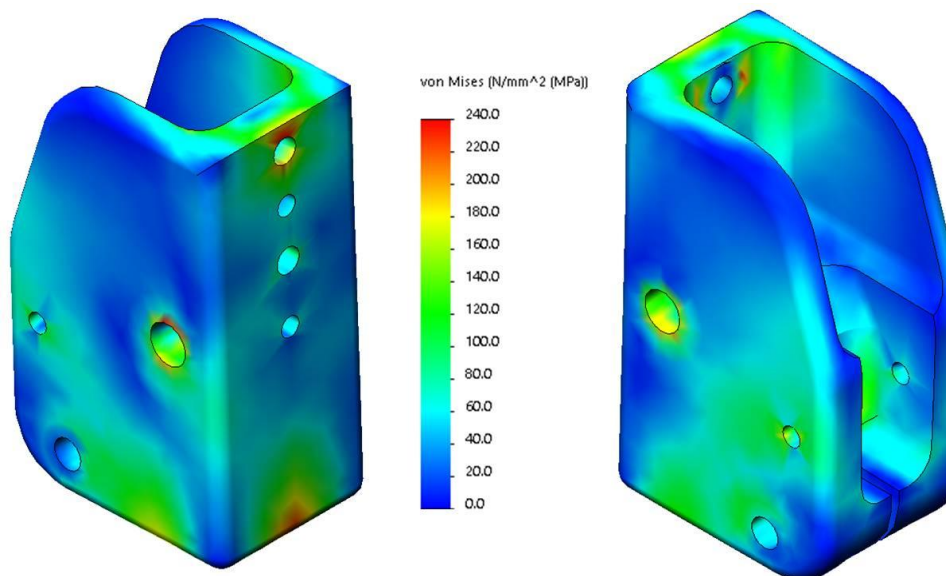
At this point, it was already evident that the updated FEA provided a more accurate prediction on stress distribution when comparing the results from the updated FEA to the fracture points on the bottom component of the prototype after the initial structural testing, as all fracture points closely corresponded to the stress concentrations indicated in the FEA model (shown in Figure 4.13). Interestingly, although there was a higher predicted stress concentration at the front of the bottom piece under loading condition I, it remained under the yielding strength of the material, and yet the bottom piece was fractured at 420 lbs, which was merely 58% of the desired load, 723 lbs, during the initial structural testing. This will be further discussed in details in Section 5.1.2.



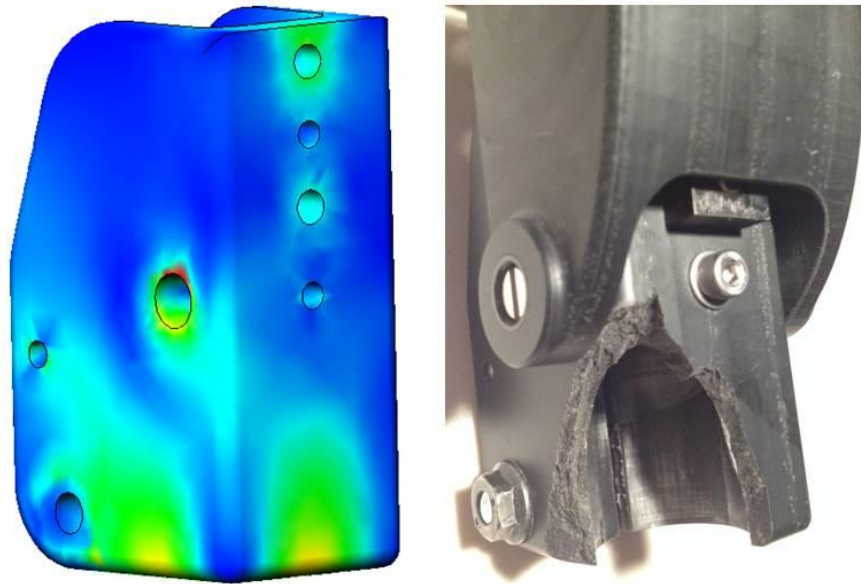
Since there were design and material issues with the initial bottom component, the bottom component was redesigned and fabricated with 7075 Aluminum instead of Zytel® for this prototype. As shown in Figure 4.14, the FEA result demonstrated that the stress was presented at the same place in the new bottom component as the previous one. However, the stress did not exceed the yield strength of the material (490 MPa), thus it should be safe for the structural testing as well as for clinical use.



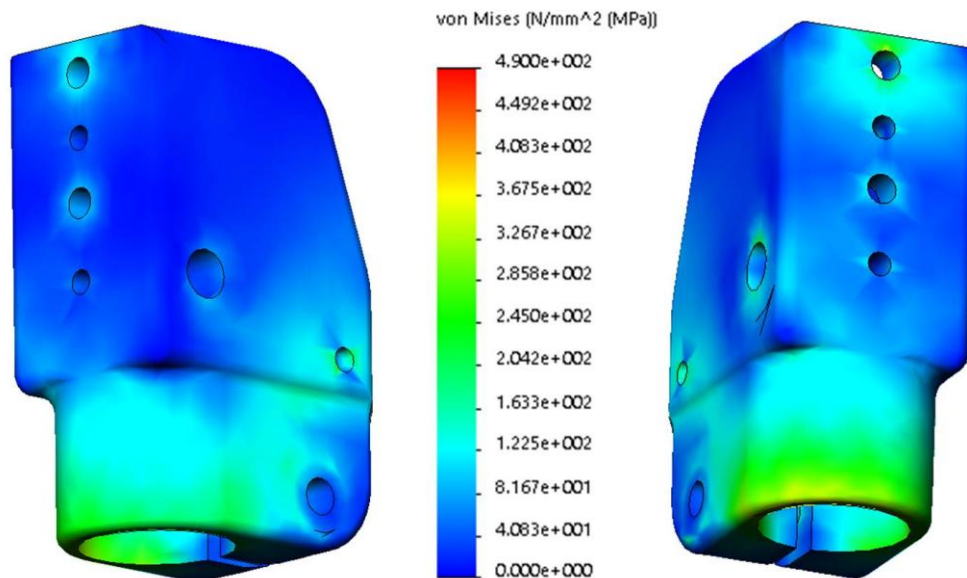
**Figure 4.11: Updated FEA result under Loading Condition I**



**Figure 4.12: Updated FEA result under Loading Condition II**



**Figure 4.13:** Comparison of the results from the updated FEA and the initial structural testing



**Figure 4.14:** FEA Result of New Bottom Component under LCI (left) and LCII (right)

## 4.2 Structural Testing

**Table 4.8: Summary of the structural testing**

<b>Initial Structural Testing</b>			
	Prescribed Test Load (lb)	Actual Test Load (lb)	Conclusion
Loading condition I	723	420	Failed
Loading condition II	626	Did not proceed	
Knee lock test	471	Did not proceed	
<b>Second Structural Testing</b>			
Loading condition I	723	725	Passed
Loading condition II	626	627	Passed
Knee lock test	471	475	Passed

As shown in Table 4.8, the specimen had resulted in a catastrophic failure under loading condition I during the initial structural testing, in which the bottom component was fractured. After first examination of the fracture, we first determined it to be a classic brittle fracture possibly due to high stress concentration. However, as briefly mentioned in Section 4.1.4, though the fracture points did indeed correspond to the predicted stress distribution on the updated FEA model, the stresses were well under the yield strength of the material, therefore the bottom component should have theoretically been able to withstand the applied load on the structural test. Interestingly, upon closer examination, we found that one of the points of fracture occurred at the joint of the laminations, thus it was not illogical to consider the failure might be due to the material. This issue will be discussed in more detail in Section 5.2.1. With the new aluminum-made bottom component, the knee assembly successfully passed the structural testing for both loading condition I and II.



**Figure 4.15: Fractured testing specimen during the initial structural testing (bottom component)**

### 4.3 Single Subject Pilot Study

This clinical testing served primarily as a pilot test to validate some of the design choices and to indicate any major areas of concern before beginning a longer, more comprehensive test. This study compared the energy expenditure, spatiotemporal, kinematic, and kinetic gait variables of a single participant wearing the PASPL-Knee and a conventional knee joint. Although gait data were collected 3-dimensionally, the majority of parameters presented here were limited to the sagittal plane. This is a common and verified approach in describing prosthetic gait, because the majority of the gait deviations occur in this plane [47]. The exception includes the kinematic data for the pelvis, where pelvic obliquity was used as an indicator of hip hiking.

This study was supposed to be divided into two sessions. As stated in the protocol, the lower-limb prosthesis with the PASPL-Knee was given to the participant on the first session of the study. The second session was held three weeks after the first session to accommodate the recommended acclimatization period for the participant to practice with the PASPL-Knee at home. However, due to the issue with the prosthetic foot of the prosthesis with the PASPL-Knee, as well as the availability of the participant's family, the participant was only able to wear the PASPL-Knee for the first three days in the acclimatization period. Therefore, since the acclimatization period was absent, only the data collected in the first session will be shown in this thesis.

#### 4.3.1 Subject

**Table 4.9: Characteristics of the participant**

	Participant
Gender	F
Age (Years)	10
Years with currently conventional knee joint	4
Body mass (kg)	27.5
Height (cm)	153
Side of amputation	Right
Amputation level	Transfemoral
Amputation cause	Traumatic
Conventional knee joint type	Total Knee Junior

### 4.3.2 Six-Minute Walk Test

The results of the six-minute walk test for each of the two different knees are summarized in Table 4.10. The starting HR, working HR, and total distance walked in meters are shown alongside with the calculated walking speed and Physiological Cost Index (PCI). As mentioned in Section 2.2.4c, smaller PCI values indicate lower energy expenditure. The participant was able to walk a greater walking distance and a smaller PCI value with the conventional knee compared to the PASPL-Knee. This could be implied that she had a more efficient gait with the conventional knee during the first session of the study.

**Table 4.10: Results of the six-minute walk test in the first day of study**

Parameters	Conventional Knee	PASPL-Knee
Resting HR (beats/min)	66	66
Working HR (beats/min)	96	102
Distance (m)	438.75	413.05
Walking Speed (m/min)	73.13	68.84
PCI	0.41	0.52

### 4.3.3 Instrumented Gait Analysis

#### a) *Spatiotemporal Variables*

The results of the spatiotemporal parameters from the gait trials are summarized in Table 4.11. When comparing the conventional knee to the PASPL-Knee, while all the parameters were very similar between both knee joints, it was evident that the participant had a greater step and stride length with the PASPL-Knee compared to the conventional knee.

The symmetry index was calculated to compare the gait symmetry of the participant between the conventional knee and the PASPL-Knee. We compared the step time, step length, single support duration, stance phase duration, and swing phase duration (as shown in Table 4.12). As mentioned in Section 3.4.3e, ideally a symmetry index of 0 signifies a perfect symmetry.

In general, it was evident that the participant had better gait symmetry with the conventional knee compared to the PASPL-Knee, as all the values were closer to 0. However, in order to determine if the gait patterns were symmetrical, all of the values had to be compared to the normative values of those five listed parameters in the healthy subjects, which will be discussed in further details in Section 5.3.3.

**Table 4.11: Spatiotemporal parameters for both prosthetic knees**

Spatiotemporal Parameter	Average Values ( <i>Standard Deviation</i> )		
	Conventional Knee	PASPL-Knee	Sound Limb
Walking Speed (m/s)	1.14 (0.07)	1.28 (0.06)	
Step Time (s)	0.53 (0.02)	0.53 (0.02)	0.57 (0.04)
Step Length (m)	0.63 (0.01)	0.69 (0.02)	0.63 (0.05)
Stride Time (s)	1.09 (0.03)	1.06 (0.03)	1.14 (0.09)
Stride Length (m)	1.24 (0.02)	1.36 (0.03)	1.33 (0.08)
Single Support (%)	44.08 (2.69)	43.07 (1.52)	43.36 (1.96)
Stance Phase (%)	56.27 (0.38)	55.29 (2.50)	57.43 (1.44)
Swing Phase (%)	43.73 (0.38)	44.71 (2.50)	42.57 (1.44)

Values are averages, with SD in parentheses

**Table 4.12: Symmetry index for spatiotemporal parameters**

Parameter	Symmetry Index (%)	
	Conventional Knee	PASPL-Knee
Step time	5.77	5.77
Step length	0.44	8.99
Single support	1.65	0.67
Stance phase	2.04	3.80
Swing phase	2.68	4.90

*b) Kinematic and Kinetic Variables*

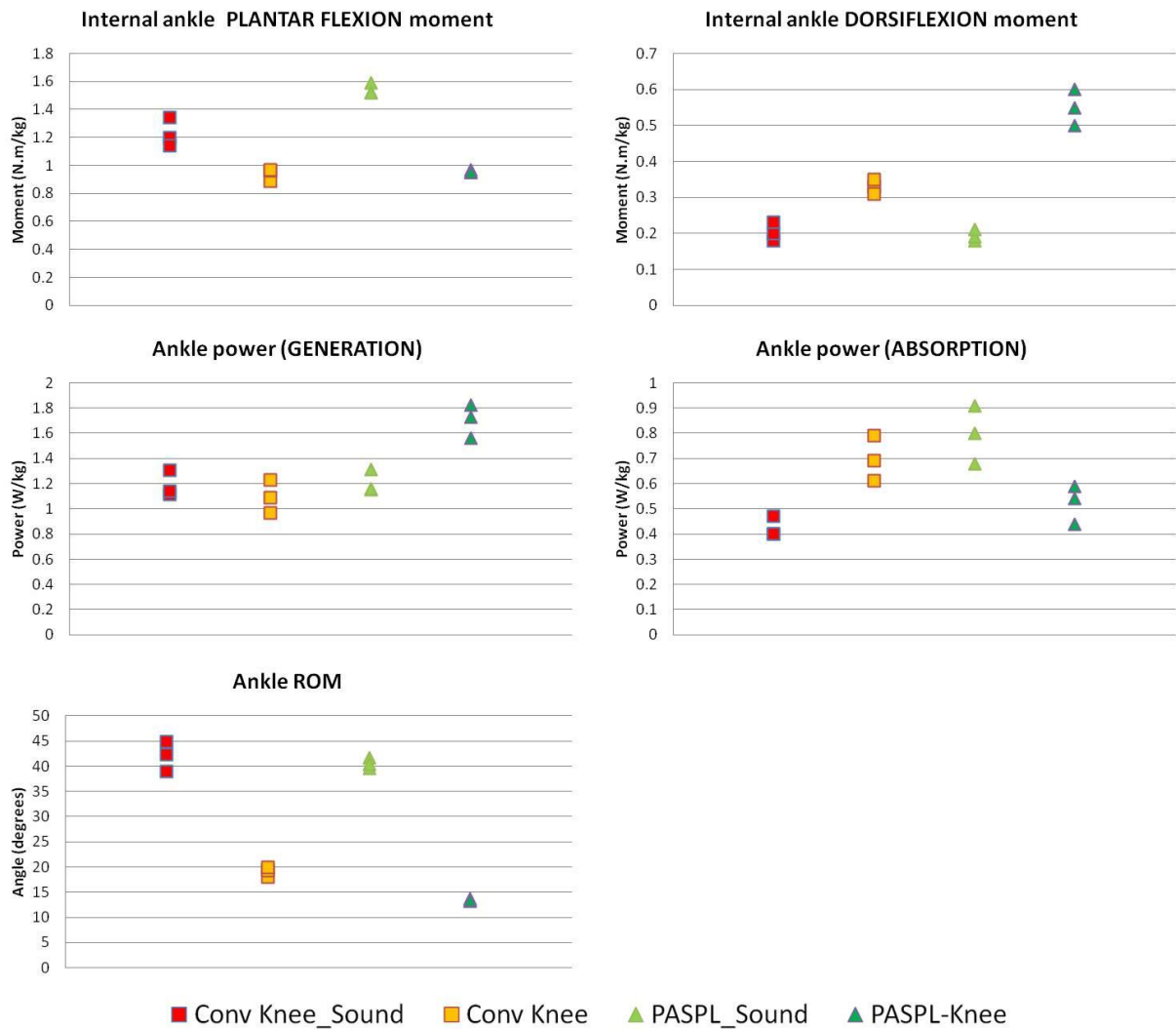
The kinematics and kinetics data of the ankle are shown in Figure 4.16. There were no major difference in the ankle ROM, internal plantar flexion moment, and ankle power (absorption) between the prosthesis with the conventional knee and the PASPL-Knee. There was however a greater internal ankle dorsiflexion moment and ankle power (generation) with the PASPL-Knee in comparison to the conventional knee.

The kinematic and kinetic data for the hip of the sound limb, the PASPL-Knee, and the conventional knee are shown in Figures 4.17. The hip ROM and peak hip power in early stance were consistent between the conventional knee and the PASPL-Knee. The PASPL-Knee had a lower internal peak hip flexion moment and peak hip power in terminal stance compared to the conventional knee.

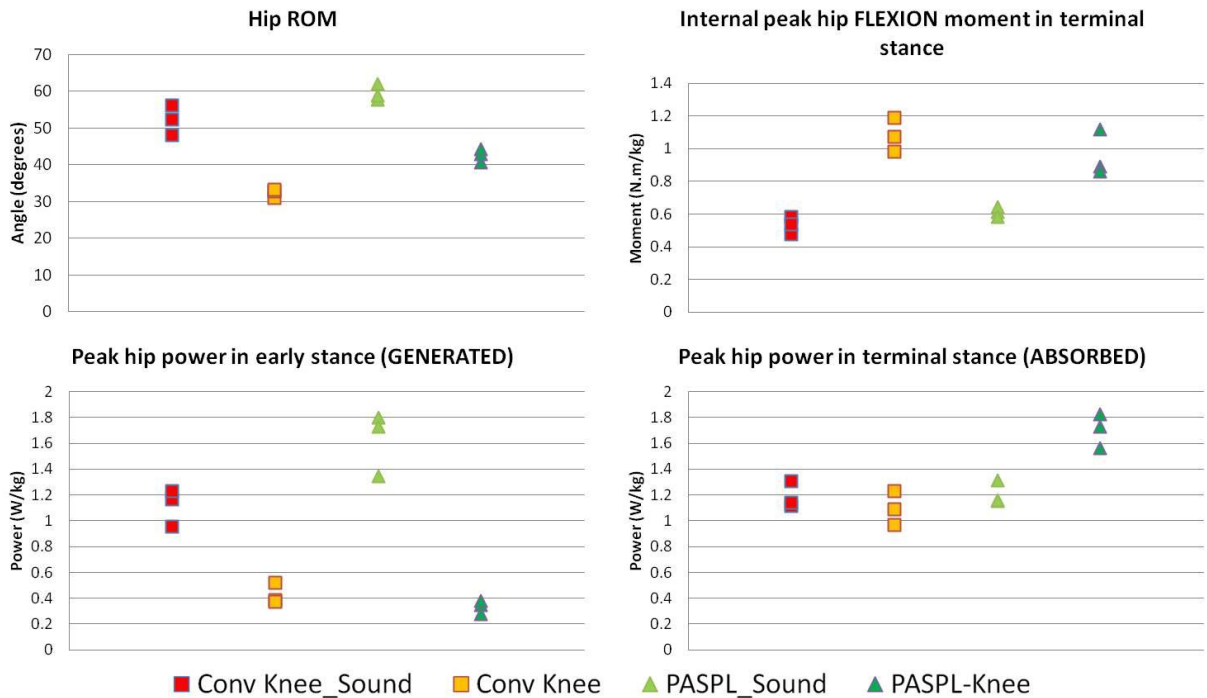
Results for the comparison of prosthetic knee biomechanics are shown in Figure 4.18. In terms of knee ROM and peak knee-flexion during swing phase, the results between the PASPL-Knee

and the conventional knee were similar. But the internal peak knee flexion moment in terminal stance was greater with the PASPL-Knee than the conventional knee.

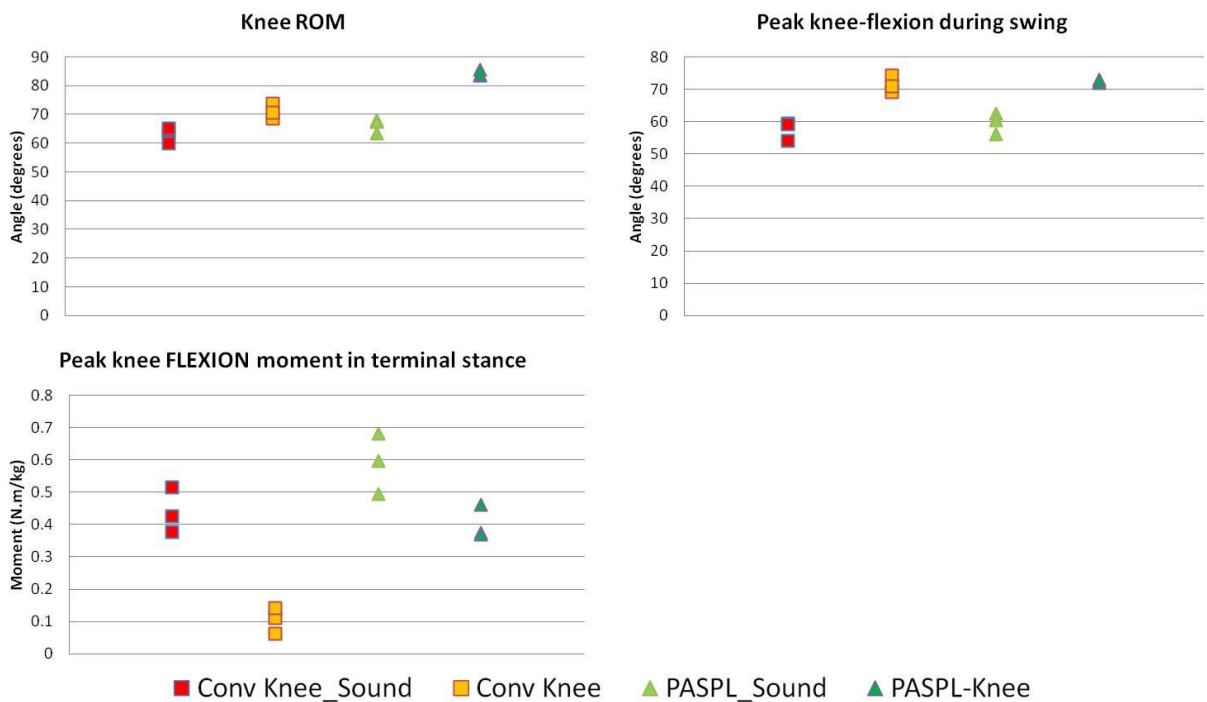
Result for the comparison of the pelvic obliquity is shown in Figure 4.19. The results were fairly consistent between the conventional knee and the PASPL-Knee.



**Figure 4.16: Ankle mechanics of the conventional knee and the PASPL-Knee**

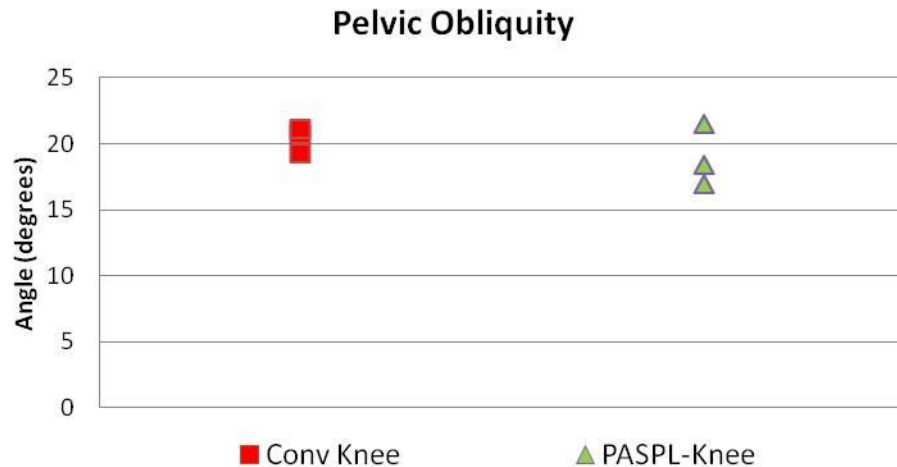


**Figure 4.17: Hip mechanics of the conventional knee and the PASPL-Knee**



**Figure 4.18: Knee mechanics of the conventional knee and the PASPL-Knee**





**Figure 4.19: Pelvic obliquity**

#### 4.4 Qualitative Evaluation

The overall result of the qualitative evaluation was primarily positive. Participant indicated that she has been performed all types of day-to-day activities with the PASPL-Knee, including running, swimming, and participating in gym class. She mentioned that the PASPL-Knee was very stable and rated her concern about falling when walking with the PASPL-Knee 0 out of 5, with 0 being not at all concerned. Participant mentioned she was able to walk on uneven ground, up the stairs, and up and down a hill with the PASPL-Knee. In a scale of 0 - 5 (0: Easy - 5: Very difficult), participant rated the difficulty of walking up a hill 3 out of 5 and mentioned that it was not very difficult for her to walk up the hill. Participant rated the difficulty of walking down a hill and up the stairs 0 out of 5, indicating it was easy for her to complete those tasks. When asked the participant how tired she felt when she walked for a long time, she rated her fatigue level 3 out of 5, with 0 being not at all tired and 5 being very tired.

In general, participant was very confident about walking with the PAPSPL-Knee and thought the lock was operating reliably. In contrast, the biggest complaint the participant had for the PASPL-Knee was the knee joint was too stable during stance phase, thus it was not as easy to initiate swing phase in comparison to her conventional knee joint. She mentioned that the PASPL-Knee required her to apply the load much close to the tip of the toe compared to her conventional knee in order to initiate swing phase and flex the knee.

In terms of quietness and aesthetics of the PASPL-Knee, the participant enjoyed the overall aesthetics of the knee and said it looked "really cool"; however, she remarked that it would be better if the PASPL-Knee was smaller in size. On the other hand, she thought the PASPL-Knee was much quieter compared to her conventional knee.

At the end, the participant mentioned that the best thing she felt about the PASPL-Knee was that she could perform all types of activities with it, including swimming, in which it saved her a lot of time and trouble of switching between different prosthetic knees.

## Chapter 5

### Analysis & Discussions

This chapter discusses the previously presented results of the completed study and identifies how related research literature compares to the findings presented here. Successes and limitations are identified and explained.

#### 5.1 Design

##### 5.1.1 Comparison to the Design Criteria

The final design of the PASPL-Knee has satisfied all of the design criteria listed in Section 4.1.1, such as the weight and length limit, the weight-bearing capacity, the incorporation of the ASPL mechanism and extension assist. The PASPL-Knee can be considered as the miniature AT-Knee; it captured all the elements in the AT-Knee and integrated them into the PASPL-Knee. The PASPL-Knee is under 134.5 mm in length and weights 430 g, which is 18.4% smaller in length and 38.6% lighter in comparison to the AT-Knee. The PASPL-Knee can flex to 152° and has a weight-bearing capacity of 60 kg.

The PASPL-Knee adopted the proven ASPL technology by miniaturizing the lock mechanism and modifying the axis alignment to provide stance-phase control for the paediatric users. Both the mechanical friction control and the extension assist unit were also implemented in the design. The extension assist unit was optimized from the AT-Knee by adjusting the geometry of the components to improve the overall performance of the prosthetic knee joint, which will be discussed in details in later section. It also incorporated a compression spring with a high spring rate and a long cyclic life to provide a functional and durable swing phase control. Lastly, a flexion stop was integrated into the design to protect the extension assist unit.

##### 5.1.2 Extension Assist

In this section, we discuss the optimization that was made from the AT-Knee to the PASPL-Knee.

**Table 5.1: Summary of the extension assist design in version I**

Version I	
Pro	Compact design
Con	Compression spring not easily accessible
	Unknown Linkage system performance
	Potentially affect the functionality of the ASPL mechanism

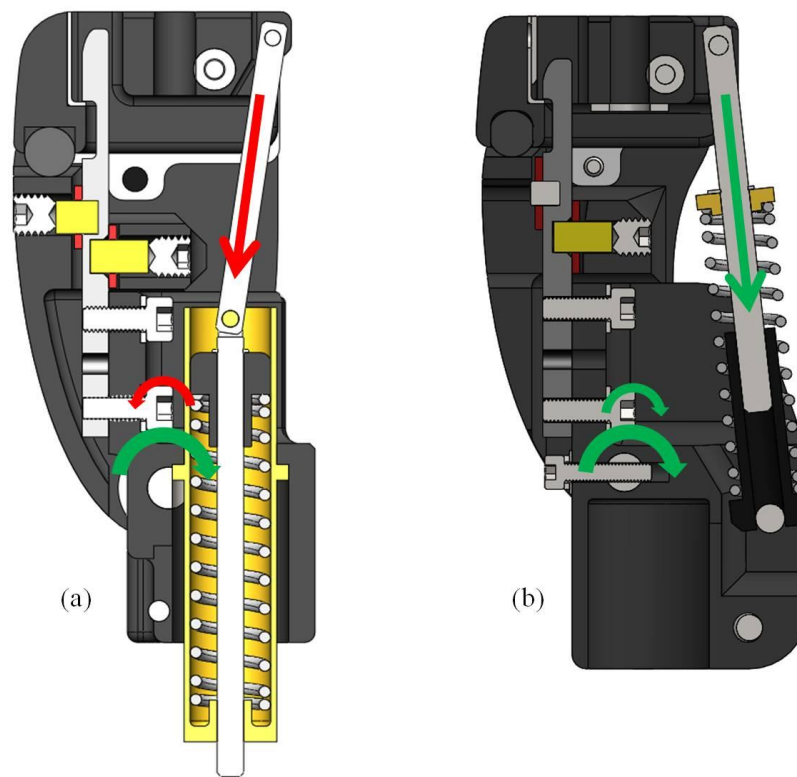
**Version I:** The biggest advantage of the version I of the PASPL-Knee design is its compactness. The implementation of linkage system eliminates the incorporation of a single long shaft like the final design. This means that the prosthetic knee joint design does not require its bottom component to be increased in size in order to create extra spaces for the extension assist unit. Therefore, the size of the knee joint can be reduced. Additionally, the spring holder tube is introduced into the design. The compression spring can be placed inside the tube, and the tube assembly can be slotted into the shank hole in the bottom component. By using the shank pylon to keep the spring holder tube in place, this can fully utilize the available cavity within the PASPL-Knee, which will effectively keep the knee design as compact as possible (as shown in Figure 4.4).

Though this design is compact, the spring is not easily accessible, thus it will be difficult for the user to switch or service the spring if needed. In addition, the performance of the linkage system remains unknown. There are many uncertainties about the effectiveness of the linkage system, particularly about the wear and tear on the interfaces between the two linkages and the connecting pin, as well as a potential noise problem when the metallic surfaces are interacting.

Perhaps the biggest concern about the linkage system is its potential of affecting the function of the ASPL mechanism during knee extension. As mentioned in previous sections, the disengagement of the lock in the ASPL mechanism is due to the magnitude and the position of the GRFV. If the GRFV is positioned anterior to the control axis, the flexion moment generated will cause the bottom component of the knee joint to rotate on the control axis toward the posterior of the knee, thus causing the knee to flex. In the version I of the knee joint design, when the knee is flexing, the top link in the linkage system will move downward and toward the anterior of the knee naturally. This may prove to be problematic to the functionality of the ASPL mechanism. Illustrated in Figure 5.1, as the top link moves inward, the force vector along the link is also orientated to the same direction. Therefore, it will apply a force onto the wall of

the spring holder, consequently pushing the bottom component and the lock towards the anterior of the knee. This will generate an extension moment along the control axis, which will cause the extension assist on the knee design to work against the unlocking action at the ASPL mechanism. Therefore, the version I of the PASPL-Knee is not an ideal solution.

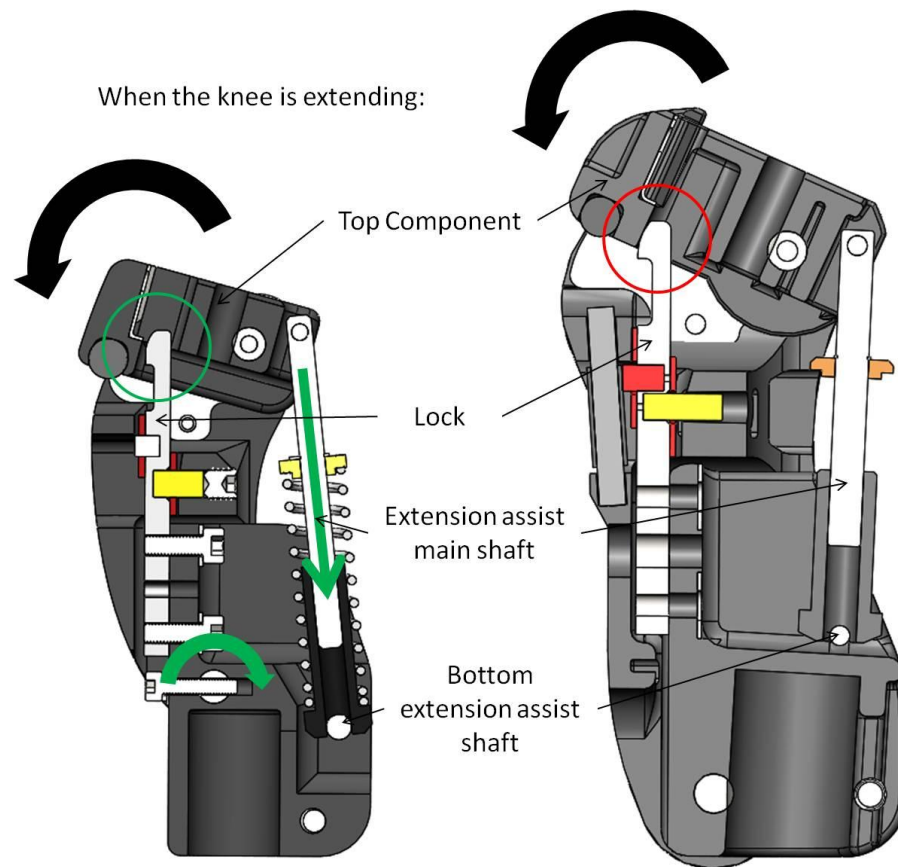
**Final Version:** Unlike the first version, the final version of the PASPL-Knee is designed to address all of the previous problems and seek the balance between compactness and functionality. This design solution is optimized from the AT-Knee, as well as satisfying all the design criteria established prior to the designing process.



**Figure 5.1: Illustrations of the relationships between the ASPL mechanism and the extension assist**

The extension assist in the PASPL-Knee is optimized from the AT-Knee by moving the bottom extension assist shaft toward the posterior of the knee, thus directing the extension assist main shaft outward in the PASPL-Knee design. In contrast to the version I of the design, a force will be directed toward the posterior of the bottom component as the knee is flexing, and generating the unlocking moment that will complement the ASPL mechanism. The major advantage of this subtle yet effective change however is the reduction of the interference between the top and lock

component when the knee is extending, thus reducing the noise generated. As the knee begins to extend during swing phase, the ASPL mechanism will already be restored to its original position due to the lock spring as well as the absence of the GRFV to produce the flexion moment. Therefore, as the top component of the knee is traveling to its original position, it will interfere with the lock component thus generating noise. However, by moving the bottom extension assist shaft more posterior, it will increase the pre-extension unlocking moment along the control axis (see Figure 5.2). Therefore, it will slow down the lock from restoring to its original position, thus reducing the interference between the top and the lock as the knee is extending. Consequently, it will reduce the noise level when the knee is extending. It is important because quietness is one of the measures in the user's impression of the knee function [89].

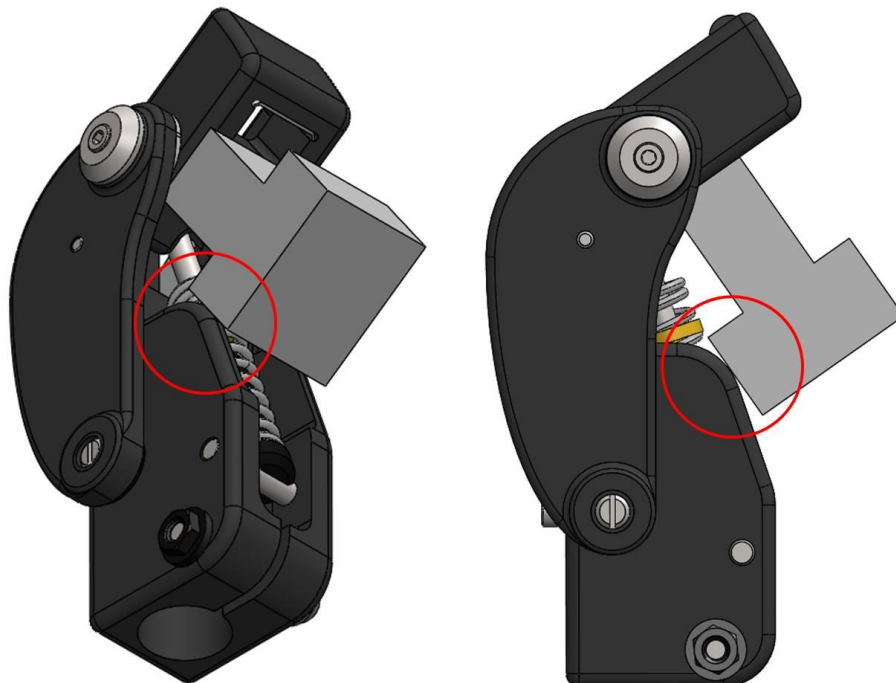


**Figure 5.2: Optimization of the extension assist in PASPL-Knee (left) from AT-Knee (right)**

Aside from reducing the noise level when the knee is extending, by shifting the bottom shaft, it creates more clearance between the extension assist unit and the knee structural components;

therefore it permits a spring with a bigger diameter to be selected. The increased flexibility enables a much greater selections on springs, thus we can find a spring that has the desired attributes, such as long cyclic life and great spring rate for the PASPL-Knee.

Lastly, a flexion stop is implemented in this design without drastically increasing the size of the bottom component and affecting the aesthetics of the overall design. The existing walls on the bottom component are now used as a stop; that avoids incorporating a new component into the design as a flexion stop, which would likely increase the size and weight of the design.



**Figure 5.3: Flexion stop in the final version**

### 5.1.2 Finite Element Analysis

Due to the failure which occurred during the initial structural testing, the FEA constraints were revised prior to the subsequent sets of analysis. The major differences between the initial and the updated analysis were the inclusions of the bottom fixture model, as well as the fastener at the posterior side of the bottom component that was used for providing the clamping force to keep the shank secured. As shown in Section 4.1.4b, the updated FEA has proven to illustrate a more accurate prediction on the stress distribution in the knee joint when compared to the result from the initial structural testing.

In the initial FEA model, the constraints were identical to the RL-Knee FEA model from previous study [5], which the inner surface of the shank hole was set as the fixed point instead of incorporating a fixture model into the analysis (Figure. 5.4). Under this constraint, the results showed that there were minimal stresses exhibited on the anterior side of the bottom component.

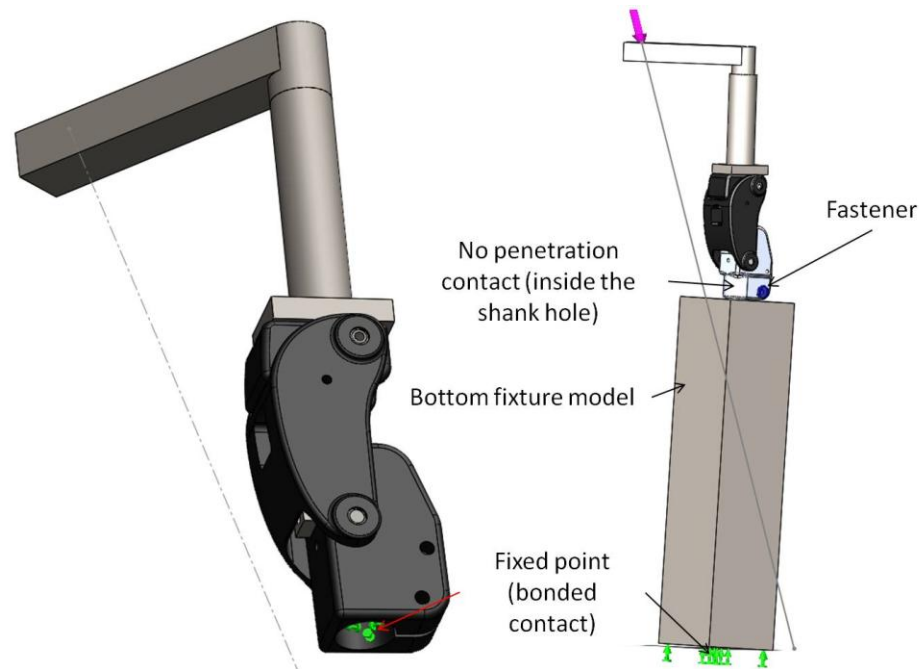
There are various bonding conditions defined in the FEA software, including bonded contact and no penetration contact. Bonded contact defines the situation where if two objects are set to be bonded, then the bonded entities will behave as if they are welded. The no penetration contact implies that the selected components or bodies do not penetrate each other during simulation and remain to behave as separate entities.

We believe that the false bonding condition setting was the reason that caused the incorrect prediction of the stress distribution in the initial FEA results. The FEA program might have considered the entirety of the bottom component as a fixture by default instead of just the inner surface of the shank hole as intended. In this scenario, when the inner surface of the shank hole was selected to be the fixed point, it could be viewed as an imaginary shaft that was inserted into the shank hole at one end, and the other end of the shaft was anchored securely elsewhere in space. When the imaginary shaft was in contact with the bottom component, that is, the inner surface of the shank hole, the FEA program was likely to define the contact as a "bonded contact". However, in reality, this should be considered to be a "no penetration contact" instead. This led to the program falsely recognizing the entire bottom component as a fixture, thus eliminated any displacements the bottom component might have experienced under load. This caused the bottom component to show minimal, or lack of stress distributions on the anterior side in the FEA results. To address this problem, the bottom fixture model was incorporated into the FEA instead. The bottom surface of the fixture was defined as a fixed geometry, while the cylinder at the top of the model was inserted into the shank hole of the knee, and the contact area was defined to be a "no penetration contact". This way we eliminated the potential problem of setting the entire bottom component as a fixture.

In addition, the fastener that was used to provide clamping force to keep the shank secured had not been originally incorporated into the model. The torque on the fastener was also entered into the program for the stimulation, and this alteration had greatly contributed to the accuracy of the stress prediction. In reality, when the bolt is being tightly fastened at the posterior of the bottom



component, it will cause the side walls of the component to compress, hence providing the needed clamping force to secure the shank. However, it will also induce an internal stress at the anterior side of the bottom component due to tension. By including the fastener into the simulation, the model became more representative of reality, thus resulting in a more accurate stress distribution prediction in the updated FEA.



**Figure 5.4: Difference in constraints between the initial FEA and updated FEA**

## 5.2 Structural Testing

As shown in Section 4.2, the bottom component of the knee joint fractured at 420 lbs, merely 58% of the expected load of 723 lbs, during the initial structural testing on loading condition I. However, the updated FEA result demonstrated that the knee joint should have been able to support up to the desired load under loading condition I. Therefore, this suggested that the failure might be related to the material instead of the structural design of the bottom component.

The material that was used for the prototype was called Zytel®, a fibre-reinforced nylon resin product developed by DuPont™. As mentioned in Section 4.1.3e, the Zytel® materials were generously given to us in block-form for prototyping by DuPont™, and they were formed by

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laminating multiple plates using a plastic welding technique. This may have been a source of the failure in the initial structural testing.

One of the factors that determines the strength of the fibre-reinforced composite material is the cross-linking between the matrix and the reinforcements, as the duty of the fibre is to attain strength of the composite and the matrix has the responsibility of bonding of the fibres [90]. Therefore, the continuity of the matrix throughout a component plays a major role in the structural strength of the part.

Therefore, fabricating a component by welding multiple plates together instead of using techniques such as injection moulding is not ideal, because it will affect the degree of bonding between the matrix and the fibre throughout the structure thus affecting the structural integrity of the component. If the layers are not welded perfectly, the fabricated part will then have a structural weakness. This scenario will disallow the composite material to achieve its maximum failure stress, and the lamination joint between two plates will become the weakest point of the material.

We summarize and consider all the factors in our scenario: 1) one of the failure points occurred at the lamination joint of two plates; 2) noticeable stress but not failure stress was predicted near the lamination joint in the updated FEA model; and 3) the FEA had indicated that the structure of the design should be able to withstand at least 723 lbs under loading condition I. These were evidence that led toward a highly probable conclusion that the cause of the failure was the less than ideal bonding of the composite material at the lamination joint. We speculated that when the force was increased up to the 420 lbs mark during the initial structural testing, the stress had then overcome the bond strength between two jointed plates. It induced the de-lamination at the joint subsequently compromising the structural integrity of the bottom component which led to the catastrophic failure. More investigations and testing will be needed to determine the exact cause of the failure, but it is very plausible that the cause of the failure was the material and the way that it was prepared.

## 5.3 Single Subject Pilot Study

### 5.3.1 Energy Expenditure

As expected, when comparing the results of the conventional knee and the PASPL-Knee to the studies conducted by N. Pathare et al. and S. Ulrich et al. [80, 81], the able-bodied children covered a greater distance and therefore have a faster walking speed. The able-bodied children achieved at least 20% increase in the walking distance and speed compared to the both knees used in this study. But in terms of the PCI values, the results for both knees were very similar to the able-bodied children.

**Table 5.2: Comparison of the results from the six-minute walk test to able-bodied children**

Parameter	Conventional	PASPL-Knee	Able-Bodied Children	
	Knee		N. Pathare et al.	S. Ulrich et al.
Resting HR (beats/min)	66	66	87.1 (12.7)	95 (16)
Working HR (beats/min)	96	102	116.7 (15.7)	136 (23)
Distance (m)	438.75	413.05	525.4 (58.1)	618 (79)
Speed (m/min)	73.13	68.84	87.6 (9.7)	103 (13)
PCI	0.41	0.52	0.34 (0.23)	0.40 (0.28)

For the able-bodied children reference, values are averages, with SD in parentheses

The six-minute walk test results demonstrated that the participant was able to achieve a slightly more efficient gait with the conventional knee in terms of gait speed and energy expenditure compared to the PASPL-Knee. The difference could be attributed to the distinctly short acclimatization period the participant had with the PASPL-Knee prior to testing. Prior to the first session of the study, the participant had only practiced and got familiarized with the PASPL-Knee for no more than 45 minutes. This was significantly shorter compared to her own conventional knee that had been used for 4 years. Better results with the conventional knee may have caused a bias as the study conducted by R. English et al. suggests at least 3 weeks for new users to establish and stabilize gait parameters with a new knee mechanism [69]. Therefore, it should be acknowledged that the differences in the results were likely due to the difference in acclimation period and familiarity that the participant had with both knees. On the other hand, the participant was able to achieve similar value compared to the able-bodied individual and the conventional knee, despite with the limited time of acclimatization. This served as an indicator that the PASPL-Knee is highly functional, and has a great potential for helping the users to achieve efficient gait.

### 5.3.2 Spatiotemporal Variables

**Table 5.3: Summary of gait speed and stride length measured during gait trials**

Parameter	Conventional Knee	PASPL-Knee	Paediatric above-knee amputee (R. Ashley et al.) [91]
Speed (m/s)	1.14 (0.07)	1.28 (0.06)	0.92 (0.14)
Stride length (m)	1.24 (0.02)	1.36 (0.03)	1.14 (0.36)

Values are averages, with SD in parentheses

**Table 5.4: Spatiotemporal parameters comparison**

Parameter (%)	Conventional Knee	PASPL-Knee	Able-bodied children (S. Menkveld et al.) [92]
Stance	56.27 (0.38)	55.29 (2.50)	56.85 (0.61)
Swing	43.73 (0.38)	44.71 (2.50)	43.14 (0.64)

Values are averages, with SD in parentheses

When comparing the gait speed and stride length achieved by the PASPL-Knee to the study conducted by R. Ashley et al. on other above-knee amputees, it is clear that the PASPL-Knee could help amputee to achieve a faster walking speed. This was an encouraging sign as the gait speed is a significant indication that the PASPL-Knee may be effective in restoring and possibly improving user function during gait. In addition, percentages of the stance and swing were compared between the conventional knee and the PASPL-Knee to the able-bodied children. All values were similar. As such, it may be concluded that the participant was able to exhibit a natural gait cycle with the PASPL-Knee in terms of stance and swing phase duration.

### 5.3.3 Symmetry Index

**Table 5.5: Normative values of SI indicators in the healthy subjects ( $n=58$ ) [78]**

Symmetry Index (%)	High symmetry	Normal	Low symmetry
Step time	< 1.57	1.58 - 5.21	> 5.22
Step length	< 0.81	0.82 - 4.21	> 4.22
Single support	< 1.70	1.71 - 6.67	> 6.68
Stance phase	< 0.82	0.83 - 3.27	> 3.28
Swing phase	< 1.39	1.40 - 5.31	> 5.32

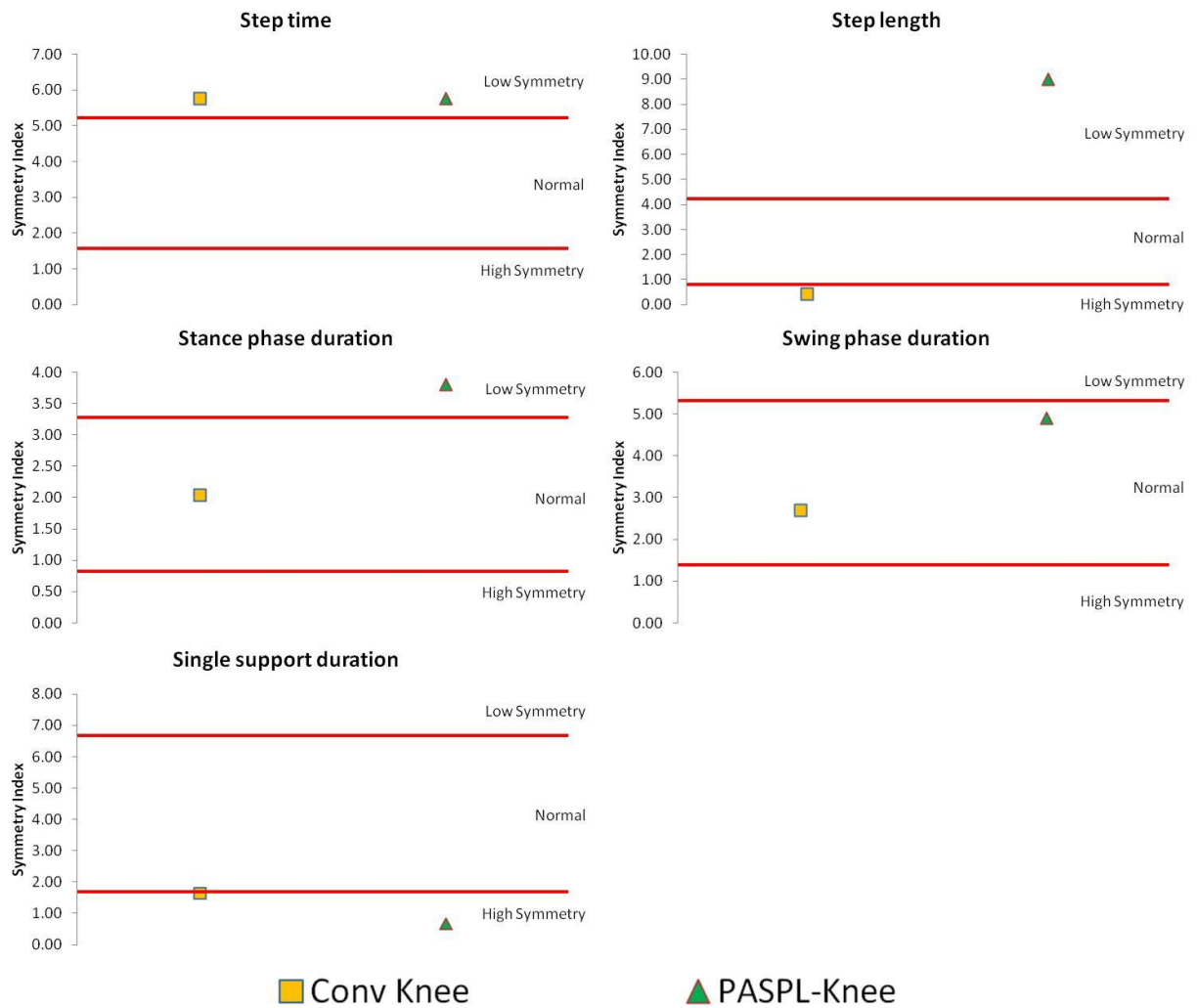
In Figure 5.5, the symmetry index (SI) indicators for the conventional knee and the PASPL-knee were compared to the normative values of SI indicators in the healthy subjects shown in Table 5.5. The graphs are divided into three regions by the red lines, and it is based on the information listed in Table 5.6. Any value that is in the bottom region indicates that there is a high symmetry

in that feature in comparison to the able-bodied individuals. In contrast, any value that is in the top region indicates that there is a low symmetry. The middle region represents the normal range of SI indicators in the healthy subjects.

As shown, the majority of the symmetry index indicators for the conventional knee and the PASPL-Knee were within the normal range. However, the participant exhibited a highly asymmetrical step length and stance phase duration with the PASPL-Knee. Asymmetrical step lengths are generally indications of underlying impairments and problems during gait [93]; thus the PASPL-Knee might have affected the gait in this study. Due to the asymmetrical step and based on the results from the hip and pelvis mechanics, we suspected that the varying step length might be related to the extension assist of the PASPL-Knee, as it might potentially be suboptimal for the users.

As shown in Figure 4.17, when comparing the peak hip power in early stance on the sound limb, it was obvious that more power was generated at the hip joint on the sound side when the participant was ambulating with the PASPL-Knee. This indicated that when the prosthetic limb with the PASPL-Knee was going through swing phase, the participant required more effort to provide stability on the sound side. These might be the indicators suggesting that the extension assist of the PASPL-Knee needed to be improve as it did not provide enough torque to fully assist the user to move the knee into the extended position fast enough.

Therefore, in order to compensate for the extension assist and to provide enough toe clearance, the participant needed to raise her hip to allow the prosthesis to swing through and become fully extended. This led to the increase of the pelvic obliquity. As shown in Figure 4.19, the pelvic obliquity for both knees were around  $20^\circ$ , which were much greater than the value obtained from the able-bodied individuals, which was listed at  $8.50^\circ$  (see Table 5.6).



**Figure 5.5: Comparison of the symmetry index to healthy subjects**

### 5.3.4 Kinematics and Kinetics

**Table 5.6: Summary of kinematics data from previous studies**

Parameter (degrees)	Average Value (standard deviation)			
	F. Bugane et al. [94]	M. Kadaba et al. [83]	T. Oberg et al. [84]	S. Shultz et al. [85]
Pelvic Obliquity	8.50 (2.67)	8.4	NA	NA
Hip ROM	NA	43.2	45.3 (5.8)	NA
Knee ROM	NA	56.7	NA	NA
Max. knee flexion during swing	NA	NA	63.0 (6.1)	55.8 (9.69)

\* only presented in the table if it is provided in the source; NA = Not available

When comparing the joint kinematics between the sound limb and the prosthetic limb for both the conventional knee and the PASPL-Knee, there was an increased range of motion of the sound limb and it was attributed to the restriction of the prosthetic ankle movement. As shown in Figures 4.16 and 4.17, the hip and ankle ROM were higher in the sound limb.

When comparing the joint kinematics of prosthetic limbs with the conventional knee and the PASPL-Knee to the able-bodied individuals, it was shown that the hip ROM and the maximum knee flexion angle during swing were similar to the normal values. The pelvic obliquity was similar in both the conventional knee and the PASPL-Knee, but both were much greater than the normal values. As mentioned in previous section, it could be attributed to the issue with the extension assist.

The prosthetic limb with the PASPL-Knee exhibited a similar or lower internal peak hip flexion moment at terminal stance compared to the conventional knee. This might be an indication of the relative ease of initiating swing phase with the PASPL-Knee for the participant. This also suggested that the PASPL-Knee had successfully adopted the ASPL mechanism to offer stance phase control. The PASPL-Knee exhibited a much higher internal peak knee flexion moment in terminal stance than the conventional knee. The higher internal peak knee moment in terminal stance with the PASPL-Knee compared to the conventional knee seemed to reflect the ease of knee flexion during pre-swing for the PASPL-Knee, further suggesting the stance-phase control of the PASPL-Knee performed well.

## 5.4 User Feedback

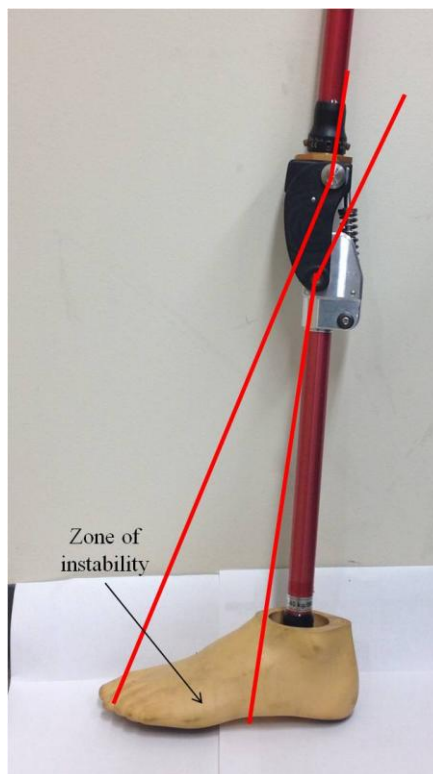
Overall the participant was confident walking with the PASPL-Knee and happy with its stance-phase stability the PASPL-Knee. However, as mentioned in Section 4.4, at times she thought the PASPL-Knee joint was too stable. This was likely to do with the alignment of the prosthesis and the tightness of the lock spring.

As briefly mentioned in Section 2.3.2, the alignment of a lower-limb prosthesis depends on the spatial relationship of the socket relative to other components of the prosthesis, such as the knee joint and foot unit, and these alignments are critical to the successful utilization by the user. Since the PASPL-Knee was a pilot design, its optimal prosthesis alignment remains uncertain,

so the prosthesis was aligned using the recommendation from the AT-Knee manual prior to the clinical testing. To address the problem of the prosthesis being too stable, we believe that the issue can be resolved by moving the foot unit on the prosthesis anteriorly, thus increasing the area of the zone of instability on the forefoot. This change would make the PASPL-Knee more susceptible to flexing, therefore increasing the ease of initiating swing phase (see Figure 5.6).

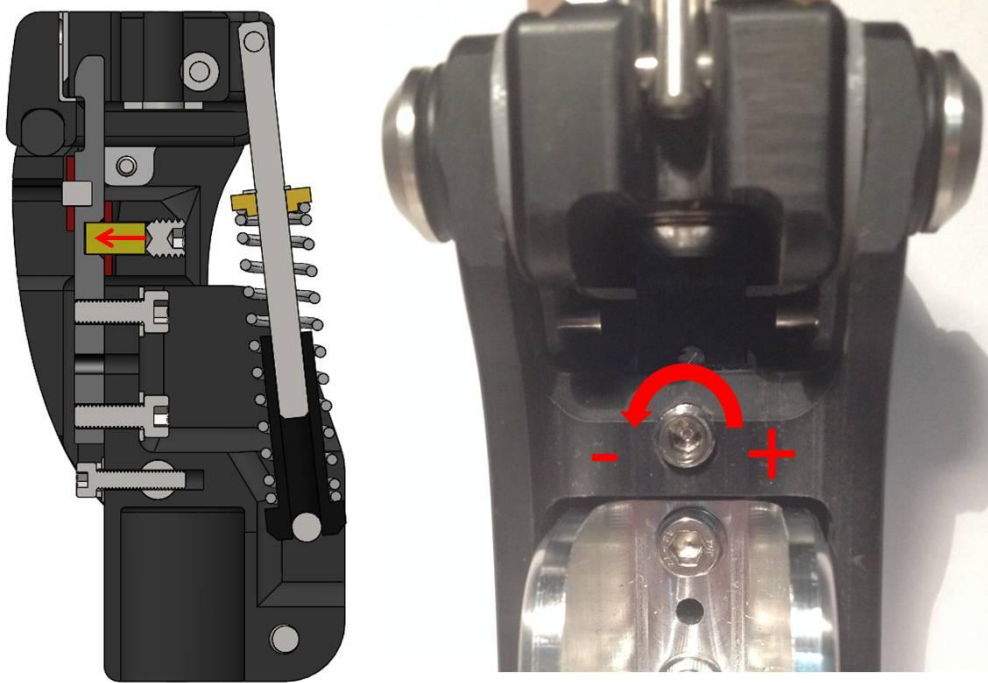
Also, we can also adjust the tightness of the lock spring to make the locking mechanism to unlock easier. In the PASPL-Knee design, the lock spring is incorporated to apply a constant force on the lock, so that the lock will be engaged to keep the PASPL-Knee extended during stance phase. The lock can only be disengaged when the flexion moment on the control shaft is greater than the force applied by the lock spring. Therefore, by adjusting the set screw at the posterior side of the lock, the tightness of the lock spring can then be adjusted, thus making the lock more susceptible to disengaging, allowing the users to initiate the swing phase relatively easier (see Figure 5.7).

But at the same time, this issue might be related to the axis alignment on the knee. Therefore, we need to re-examine the establishment of the axis alignment as well.



**Figure 5.6: Shifting the foot unit anteriorly**





**Figure 5.7: Adjusting the tightness of the lock spring**

## Chapter 6

The final chapter of this thesis summarizes all of the contributions and insights gained from the work completed as part of this thesis. Recommendations for future work are also presented. Overall, the development of the PASPL-Knee was the main goal of this thesis, however all sections contributed toward improving the design and analysis process..

## Conclusions and Recommendations

### 6.1 Conclusions

The PASPL-Knee represents a newly developed prosthetic knee joint that utilized the automatic stance-phase lock (ASPL) technology for children with transfemoral amputations.

- The axis alignment on the PASPL-Knee was established by first analyzing the axis alignment on the clinically-proven adult's prosthetic knee, the AT-Knee, and then modified to adapt to paediatric populations.
- Although the size of the ASPL mechanism is reduced by 53% in comparison to the AT-Knee in order to fit into the size-constrained PASPL-Knee, the lock is proved to be structural sound through the Finite Element Analysis and structural testing, and was highly functional in the single subject pilot study.
- The extension assist mechanism in the PASPL-Knee has been optimized from the AT-Knee. The change of geometry increases the pre-extension unlocking moment at the PASPL-Knee, as it is proved by the reduction in interference between the top and the lock component, and successfully reducing the noise level during knee extension. The participant thought that the PASPL-Knee was much quieter than her conventional knee. Additionally, the PASPL-Knee is able to incorporate a compression spring with that can provide at least 60% of the torque generated in the AT-Knee, and a cyclic life over 10 millions cycles. These are the listed design criteria at the beginning of the design.
- A single subject pilot study was conducted to validate the design. The collected data such as energy expenditure, spatiotemporal variables, and joint kinematics and kinetics parameters for the PASPL-Knee were compared to the conventional knee as well as the

- published data on able-bodied individuals. The results suggest that the PASPL-Knee provide excellent stance-phase control, as it require less internal hip flexion moment for participant to initiate swing phase. However, the asymmetrical step length, higher pelvic obliquity and higher hip power in early stance suggest that the extension assist in the PASPL-Knee might be suboptimal as the knee joint did not extend fast enough during gait.
- A questionnaire was provided to the participant to evaluate her feedback on the PASPL-Knee. Overall the participant was very confident with the prosthetic knee as she felt that the prosthetic offers excellent stance phase stability. The participant indicated that she was able to perform all types of the activities with the PASPL-Knee, including running, playing dodge ball, and swimming. This highlights the versatility of the knee and proves that it allows the paediatric user to perform day-to-day tasks and be independent. Also, the participant enjoyed the overall aesthetics and quietness of the PASPL-Knee. But one complaint that the participant had was that she thought the PASPL-Knee was more difficult to flex compared to her conventional knee. We believe that this problem can be addressed by changing the overall prosthesis alignment and the tightness of the lock spring inside the PASPL-Knee.

## **6.2 List of Significant Contributions**

The PASPL-Knee, a novel prosthetic knee joint for children with transfemoral amputations, was developed and functionally validated. It proves that the ASPL mechanism can be downsized without affecting the structural integrity of the knee joint, and can effectively provide stance phase stability for a paediatric user. This pilot design build a solid foundation for the future development of this technology, as the statistical data collected and the user's feedback highlight the advantage and disadvantages of the PASPL-Knee design. This allows future iterations of the design to further improve on those features.

## 6.3 Limitations and Recommendations

### 6.3.1 PASPL-Knee Design

The structural and clinical testing revealed several design issues with the PASPL-Knee that must be addressed in order to improve its performance.

#### a) *Extension Assist*

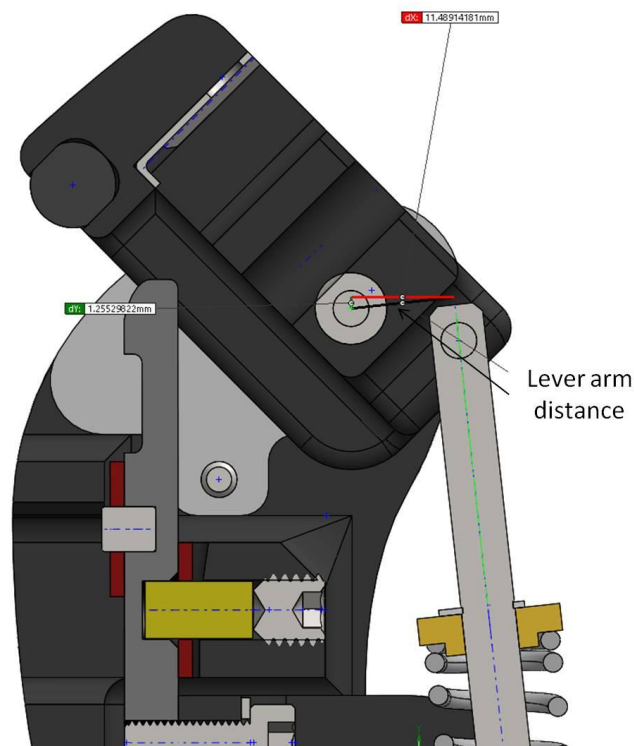
First, the clinical study indicated that the extension assist of the PASPL-Knee might be suboptimal for the users as it appeared to not be able to assist the user to move the knee into the extend position fast enough. There are several ways of increasing the effectiveness of the extension assist for the user. First, a stiffer spring, that is, a spring with a higher spring rate, can be implemented to increase the stored energy in the spring when the knee is flexed, thus increasing the torque to aid the knee extension. However, it should be noted that the selection of a spring with a higher spring rate should not compromise the cyclic life of the spring. Second, the geometry of the extension assist mechanism can be altered to increase the torque for knee extension. The amount of torque is determined by the force on the spring, as well as the lever arm distance. By increasing the distance of the lever arm, we will be able to increase the amount of torque simultaneously. However, the change in the geometry of the extension assist should not drastically affect the maximum knee flexion the PASPL-Knee can provide (see Figure 6.1).

From the result of the single subject pilot study, it indicated that the extension assist unit in the conventional knee is potentially superior to the PASPL-Knee. Therefore, in order to determine the new targeted amount of torque that the PASPL-Knee need to generate, we recommend to analyze the extension assist system in the conventional knee. This is to examine the amount of spring force and torque the conventional knee generate for extension assist, then we can compare the value to the PASPL-Knee to determine how much more torque the PASPL-Knee need to generate.

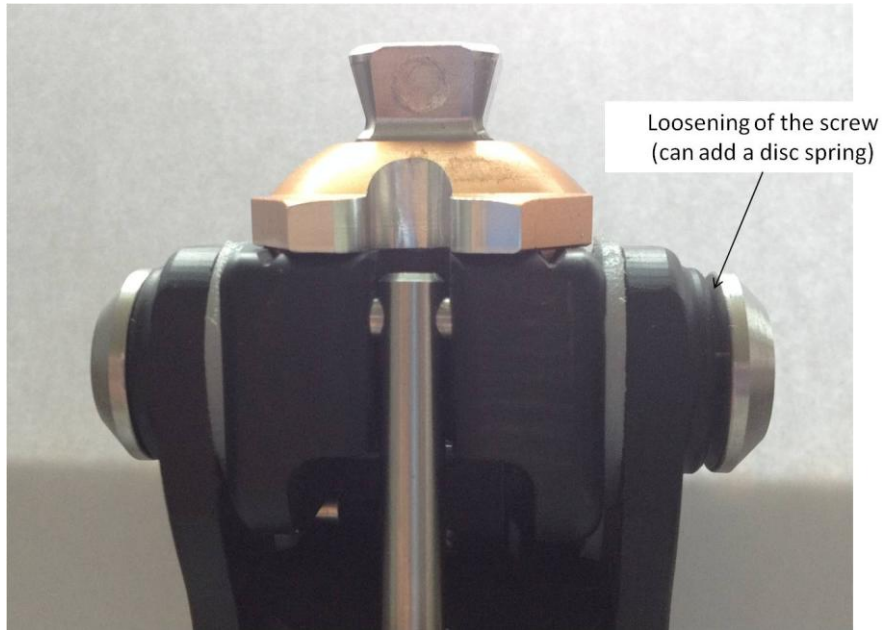
Also, at the beginning of the clinical study, there was noticeable noise from the extension assist unit. It was caused by the friction between the extension assist main shaft and the spring holder. To address this issue, the shaft can be lubricated to remove the noise. Better fabrication process can also be considered to ensure that the inner surface of the spring holder is smooth to eliminate the noise.

b) *Variable Friction Control*

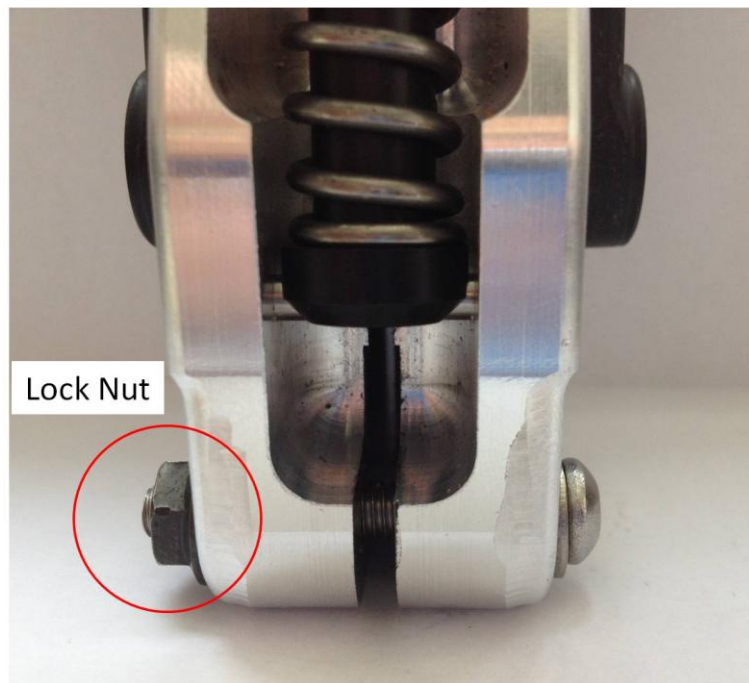
The variable friction control was incorporated into the PASPL-Knee design to offer damping effect during knee extension to reduce terminal effect.. However, one of the biggest concerns from the prosthetic clinician was that screw for the variable friction control system would come loose automatically during testing. It implied that the variable friction control could not function properly. To address this problem, the new design should incorporate disc springs between the screw cap and the body component on both sides. This will apply a tension force between the screw cap and the screw, thus potentially avoiding the screw from coming loose (see illustration in Figure 6.2).



**Figure 6.1: Lever arm distance**



**Figure 6.2: Loosening of the screw for variable friction control**



**Figure 6.3: Shank clamping bolt and lock nut**

c) *Prosthesis Assembly*

In terms of the prosthesis assembly, the clinician indicated the use of a screw and a lock nut on the PASPL-Knee to secure the shank was not preferable (see Figure 6.3). She mentioned that that was very inconvenient as it would require her to use two separate tools to tighten the clamp. It took away her ability to hold the prosthesis with a free hand as well, therefore she would require assistance from another person to hold the prosthesis or rest the prosthesis against the wall to keep it from falling. To address this problem, the new design can consider incorporating a metal thread insert to replace the lock nut. In this way, it will then only require a clinician to use one tool to tighten the bolt, while freeing up the other hand to hold the prosthesis from falling.

The current bottom component of the PASPL-Knee is made with aluminum. Although it offers a higher material strength in comparison to the Zytel®, the aluminum increases the weight of the design. As the updated FEA results indicated, the previous bottom component made with the Zytel® was a false design, as it would not be able to pass the ISO structural tests. Therefore, the geometry of the bottom component will need to be redesigned in order to use the Zytel® material.



**Figure 6.4: Change in material for bottom component**

*d) Axis Alignment*

As mentioned previously, the biggest complaint that the participant had with regard to the performance of the PASPL-Knee was its swing phase initiation. The participant mentioned that she had to place her foot closer to the toe area in order to initiate swing phase with the PASPL-Knee in comparison to her conventional knee. This might be related to the overall prosthesis alignment and/or the axis alignment in the PASPL-Knee.

To address this problem, first we should look at the relationship between the axis alignment on the PASPL-Knee and the overall prosthesis alignment. By using the technique outlined in Section 2.3.6, we can examine the direction and location of the GRFV in relation to the zone of instability. In this case, we will then have a better idea of how the overall prosthesis alignment is affecting the swing phase initiation, as well as if the axis alignment on the PAPSPL-Knee is suitable for the participant.

After the theoretical analysis, we also recommend to conduct the instrumented gait analysis with a participant. In order to examine the effect of the overall prosthesis alignment, we will ask the participant to repeat the gait trial multiple times, and the instruction and procedures will be identical to the gait trials conducted in the single subject pilot study. However, prior to each trial, we will dynamically tune the alignment of the prosthesis to the satisfaction of the prosthetist and the participant [40]. By comparing the kinematics and kinetic data in each trial, we will be able to gain better knowledge of which alignment is the most suitable for the participant and to see if the results are corresponding to the theoretical analysis. Also, we will also ask for the feedback from the participant with regard to the ease of swing phase initiation for each alignment, this will also provide us with more information to establish the optimal overall prosthesis alignment.

### **6.3.2 Clinical Testing**

The clinical testing served primarily as a pilot test to validate some of the design choices and to indicate any major areas of concern before beginning a longer, more comprehensive test. There was a lack of any statistical power to conclude the performance of the knee. Also, the different foot used on the conventional knee and the PASPL-Knee adds a possible confounding factor in the comparisons to the two knees. The results from the test prompted several design



improvements and once those issues have been addressed a larger scale clinical trial is recommended.

First, by increasing the number of subjects the statistical power is increased allowing true comparisons to published work and amongst other knee joint technologies. Also, the adjustability of the PASPL-Knee should be tested by including subjects of different abilities and activity levels as well as testing the knee at different walking speeds. A complete gait study with the knees, and many subjects will lead to a better conclusion on the performance of the PASPL-Knee.

For the testing, at least 3 weeks of acclimatization period must be incorporated and achieved prior to the data collection. As mentioned previously, since the prosthetic foot component was broken, the participant was not able to practice with the PASPL-Knee and establish a stabilized gait pattern. Therefore, we were not able to know just how efficient and the performance of the PASPL-Knee really was. Therefore, in the more comprehensive study, the acclimatization period needs to be included to allow the participants to get familiarized with the knee prior to the testing, thus allowing the research team to get more accurate data on the performance of the PASPL-Knee in comparison to the participants' conventional knees.

## **Appendix A**

### **Research Ethics Board Document**

1. Letter of Support for Recruitment
2. Itemized response to the Research Ethics Board feedback for the PASPL-Knee testing study
3. Demographics Form
4. Knee Joint Design Performance Interview

## Holland Bloorview

Kids Rehabilitation Hospital

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Kids Rehabilitation Hospital  
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Toronto ON Canada M4G 1R8  
T 416 425 6220  
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A teaching hospital affiliated  
with the University of Toronto.

### Holland Bloorview Research Ethics Board Ethics Approval Notification

The Holland Bloorview Research Ethics Board operates in compliance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans, the Ontario Personal Health Information Protection Act, 2004, ICH Good Clinical Practice Consolidated Guideline E6, and Health Canada Part C Division 6 of the Food and Drug Regulations.

**Study Title:** Design and Evaluation of a Prosthetic Knee Joint Based on Automatic Stance-Phase Lock (ASPL) Technology for Children with Transfemoral Amputations

**File Number:** 14-513

**Principal Investigator:** Jan Andrysek

**Co-Investigators:** Calvin Ngan

**Original Approval Date:** June 8, 2015

**Expiry Date:** June 8, 2016

**Review Type:** Delegated

June 8, 2015

Dear Dr. Andrysek,

The Holland Bloorview Research Ethics Board (REB) has reviewed the above named study. This was a delegated review. The board is granting ethics approval for a period of one year. The approval of this study includes the following documents:

- Protocol (version dated April 2015)
- TAHSN form received May 8, 2015
- Information Letter and Consent Form (version dated April 2015)
- Assent Form (version dated April 5, 2015)
- Knee Joint Performance Interview (version dated September 2014)
- Participant Information Form (version dated April 2014)
- Email Script (version dated April 2015)
- Telephone Screening Script (version dated April 2015)
- Bloorview Internal Ad (version dated April 2015)

This study must be conducted in accordance with the description in the application and any supplementary documents for which ethics approval has been granted. The REB needs to be notified of any unanticipated or unintentional divergence or departures from the protocol through a "Protocol Deviation Form". Any intentional changes to the protocol need be submitted through an "Amendment Form" to the REB for approval before the changes are implemented, except where necessary to eliminate immediate hazards to the participants.

Any adverse events that occur as a result of your study must be reported to the REB by submitting an "Adverse Event/Unanticipated Problem Form".

If the study is expected to continue beyond the new expiry date, you must request another renewal, at least thirty days prior to the expiry date, by submitting an "Annual Renewal Form". When the study is completed or terminated, you need to submit a "Study Closure Form" to the REB.

Best wishes for the successful completion of your project.

A world of possibility

Sincerely,



James A. Anderson, PhD  
Bioethicist, Holland Bloorview Kids Rehabilitation Hospital  
P: 416 425 6220 ext. 6224  
janderson@hollandbloorview.ca

## Itemized Responses: Design and Evaluation of a Prosthetic Knee Joint based on Automatic Stance-Phase Lock (ASPL) Technology for children with Transfemoral Amputations

### Protocol

1. TAHSN 14C: Please indicate whether the child participant will be replaced should he/she choose to withdraw from the study.

**Response:** *Should the participant choose to withdraw from the study, a new participant will be recruited for the study.*

2. TAHSN 15D: The total number of participants is unclear. You indicate in TAHSN 15A that you will recruit a child 6-12 and also an able bodied adult however for the total number to be recruited you've indicated 1. Please clarify whether there are two groups to be recruited and adjust the total as necessary.

**Response:** *For the testing and validation study of the new paediatric prosthetic knee joint design, **ONE** participant who is between the age of 6 - 12 years old will be recruited. As for the axis alignment study, it is no long in the scope of the project, therefore no able-bodied adults will be invited to participant in the study.*

3. TAHSN 18D: states that there is an able-bodied initial axis study. Please clarify. Further, please indicate how is this group will be recruited?

**Response:** *The axis alignment study is no longer in the scope of the project, therefore no able-bodied individuals will be recruited.*

4. Please comment on the rationale for including an adult able-bodied group for the axis study rather than an able-bodied child.

**Response:** *The axis alignment study is no longer in the scope of the project, therefore no able-bodied individuals will be recruited.*

### Risks and Benefits

5. TAHSN 15A: Please comment on whether the child must have a stable hip in order to participate.

**Response:** *The child must have a stable hip and able to ambulate freely with the prosthesis in order to participate.*

6. TAHSN 19A: Please comment on any safety training the child will receive regarding the LC knee and if they will be warned of the potential risks of falls or prosthetic malfunctions. Further, please indicate how the investigators will manage falls should they occur.

**Response:** *Prior to the training session, the control mechanism of the prosthetic knee joint will be thoroughly explained to the participant and his/her parents to ensure that they fully understand how the design operates and the potential risks, and what actions or misuses will lead to falls. In the incident that the participant falls, we will inform his/her parents immediately, as well as ask the participant whether they are hurt or not. If they feel uncomfortable or injured, we will contact a nurse immediately and bring medical attention to the participant as soon as possible.*

7. Please indicate the frequency of the safety monitoring telephones calls between the investigators and the participant. Further, indicate whether there are any resources available in the event of a research related injury.

**Response:** *During the first week of the adaptation period, we will call the participant everyday to ensure that he/she is comfortable with the prosthetic knee, and there are no major issues with regard to the use*

of the knee and the safety of the participant. After the first week, if the participant and his/her parents are satisfied with the performance of the design, we will then only call the participant every 3-4 days. We will encourage participant's family to contact us immediately should the participant feels discomfort with the prosthetic knee or obtain any research related injury. By collaborating with the participant's family, we will determine whether the injury is caused by malfunction, misuses of the prosthetic knee, or other reasons. Depends on the cause, participant will be invited back and we will invite the onsite prosthetist to adjust the knee for the participant or an physiotherapist to train the participant with the new knee.

8. Please comment on whether the investigators feel that the new knee design will be superior to the child's current knee.

**Response:** We feel that our new knee design will be superior to the child's current knee. As listed in the problem section in the proposal, many commercially available knee joint tends to be bigger and heavier, and neglect the incorporation both the swing phase control and extension assist. In contrast, our new knee design prototype has a comparable weight and length to the prosthetic knee in the market, and yet offers good stance phase stability by utilizing the automated stance phase lock technology, and also incorporates friction control and extension assist to enhance the swing phase control for the user. Furthermore, our knee design is waterproof, which allows users to partake in various water activities.

9. Please comment on whether there are any risks associated with a trial of the new knee and then switching back to the original knee.

**Response:** There is no risk associated with a trial of the new knee and then switching back to the original knee. It is because how the participant controls and uses the new knee is very similar to using the original knee, as the goal of both design is to emulate the natural gait as closely as possible, and all knee designs essentially utilizing the Ground Reaction Force as the control of the stance phase mechanism; therefore, the participant will utilize the same groups of muscles for either knee. It might take a short time period for the user to adjust back to the original knee, but it should not be a problem and should be resolved quickly.

10. If the new knee is found to be superior to the child's original knee prosthetic, please indicate whether they get to keep the prototype after they complete the study.

**Response:** Unfortunately, participant does not get to keep the prototype after the study

11. Please indicate whether the child will be allowed breaks during the testing session should they become tired.

**Response:** Participant will be allowed breaks in between testing session/events to ensure they are not tired.

### **Recruitment and Consent Processes**

12. Please note that external email is not secure and you must disclose the potential privacy risk. If participants verbally accept the risk, then you may communicate using this medium. Confirm.

**Response:** Confirm.

13. Please describe the capacity assessment process and submit a capacity assessment tool.

**Response:** Student will access capacity by following the guide provided at <http://research.hollandbloorview.ca/Assets/research/Documents/Research%20Ethics%20Board/Consent%20and%20capacity%20guidance%20-%20Revised%20March%2031.pdf>

14. Please provide further detail regarding the consent and assent processes.

**Response:** While a client is at the Centre accessing prosthetic and orthotic services, the client and his/her family will be asked by their clinician whether they are currently enrolled in any other studies at the Centre and if they are interested in finding out more about this study. If the client and his/her parents are interested, the clinician will ask permission for a research team member to come speak to the family. Someone from the research team will come speak to them in person to provide them with more information about the study. The research team member will thoroughly explain the goals and objectives of the study and the design of the knee joint, also letting the family to understand what the benefits and potential risks are in partaking the research study. If the family is still interested in participating or need more time for consideration, they will be provided with an information sheet to take home which will list out the objectives, procedures, benefits and potential risks associated with the study. After 1 week, research team member will contact the family to help answer any outstanding questions that the family may have, and to get their verbal consent. An appointment will then be scheduled for visit 1 of the protocol and written consent will be obtained during visit 1 as well. Should the family wants to opt out of the study at any point, they are freely to do so.

15. Please clarify how you will obtain email addresses for the able-bodied participant group.

**Response:** *The axis alignment study is no longer in the scope of the project, therefore no able-bodied individuals will be recruited.*

16. Email Script: Axis Alignment Study

- a. Indicate you are from the BRI and HB

**Response:** *The axis alignment study is no longer in the scope of the project, therefore no able-bodied individuals will be recruited.*

17. Email Script: the child pilot

- a. Typo – ‘..that you and your child would had agreed...’
- b. Indicate that the child will use the new knee at home for 3 weeks.

**Response:** *The typo is fixed, and the three weeks trial with the new knee has been included.*

18. Telephone scrip: (needs a version date)

- a. There is a statement about being with the child at least 5 hours per day and this being eligibility criteria. Please clarify as this isn't in the protocol.
- b. You indicate that the study will be done in two days, this is not accurate given the three week trial at home.

**Response:** *The statement about being with the child at least 5 hours per day and this being eligibility criteria has been deleted from the telephone script, as it is a mistake I overlooked when I first making the this telephone script draft. The indicated length of the study has also been adjusted, and now it clearly states that the study will last approximately three weeks, which including two one-day visits.*

19. Bloorview internal advertisement:

- a. Please indicate where this advertisement will be posted.
- b. You indicate here that young children are being recruited however you've indicated elsewhere that you're only recruiting one child. Please clarify.
- c. The inclusion stated on this ad is 9-12 however the TAHSN application states 6-12. Please confirm.
- d. Include information about the three week trial period with the new knee.

**Response:** *This advertisement will be posted inside the hospital at different poster board locations after obtaining approval from the corresponding department. In the flyer, I have changed the statement from "young children" to "a young child", and the age from "9-12" to "6-12". These were mistakes I overlooked initially. The three week trial period with the new knee has been included into the flyer.*

## **Information and Consent Form**

20. TAHSN 15A: Please submit Mandarin translations of the recruitment information, flyers and informed consent forms if you also propose to recruit participants who speak only Mandarin.

**Response:** *For participants that speak only Mandarin would not be able to participate in the study unless they have an English-speaking family member. It is now stated in the flyer.*

21. Is there a consent form for the able-bodied adult axis alignment study?

**Response:** *The axis alignment study is no longer in the scope of the project, therefore no able-bodied individuals will be recruited.*

22. Assent -

- a. remove the sentence 'everything will be our secret'.
- b. Add a signature line for children able to write their names

**Response:** *The sentence is removed and a signature line is added*

23. Submit an information letter and consent form for the able-bodied adult axis study.

**Response:** *The axis alignment study is no longer in the scope of the project.*

24. ICF Child Pilot: there is inconsistent use of you and your child throughout.

25. Introduction:

- a. Address this to both the parent and the child. Some older youth may have capacity to sign the consent for themselves.
- b. Say that you are affiliated with the BRI
- c. Indicate the funder of the study

26. How will my child and I be involved in this study?

- a. Indicate that you are recruiting one child.
- b. Minor typo – '...we will have your child to walk with the new knee..'
- c. You need to describe that the child will take the knee home and use is exclusively for 3 weeks between Visit 1 and 3.

27. Will anyone know what I say?

- a. You've included a statement about a separate consent for using video clips for educational presentations however this separate consent was not included in the study package. Further, the REB requests that you incorporate the consent for secondary use into the main consent form

28. What are the risks and benefits?

- a. There is reference to a walker...please remove.
- b. If the knee works well for the child, can they keep it? Either way, this should be described here.

29. Signature page:

- a. Include the version date in the text 'I read the attached information letter dated and understand..'
- b. Include a signature line for the client.

30. Please clarify whether the parent has any involvement in this study other than to support the child's decision and bring them to the appointments.

**Response:** *Comment #24-30 have been addressed.*



## **Privacy and Confidentiality**

31. TAHSN 18G: To preserve confidentiality, the REB suggests that you discuss the nature of the study with the prospective participant to make this determination rather than contact the PI of another study.

**Response:** The response has been modified.

*"The clinician from the Centre making initial with the potential participants will also ask if the client is enrolled in any other studies. If so, the client will be asked if they would be comfortable participating in both studies. If the client is interested, clinician will ask for permission to let a research team member to come in and speak to the prospective client. Team member will then explain the nature of the study, the plan and procedures of the project. If the client is still interested and feel comfortable to participate in both studies, research team member will then give the client an information sheet to take home and follow up phone call will be used to help any outstanding questions and get the client's and parents' verbal consent"*

32. TAHSN 23E: Could age of year and month of birth be used rather than full dob?

**Response:** Yes it could, it is now stated in the demographics form and the TAHSN form that only month and year of birth will be recorded.

33. TAHSN 23F: Data must be retained for 7 years post study closure.

**Response:** It is now stated that the data will be kept for 7 years.

34. TAHSN 25F: you've checked off that recording will be coded however you didn't indicate video or audio in 25E. Please clarify.

**Response:** The video or audio recordings checkboxes have been checked now.

35. TAHSN 25P: Please describe when you propose to delete the key code that links the data to identifiable information.

**Response:** Hard copy documents with personal health information will be disposed of through the Holland Bloorview Kids Rehabilitation Hospital secure document shredding program. All electronic personal health information held will be permanently deleted. The shredding and deletion of personal information will occur in December, 2015.

## **Other Concerns**

36. Please add a version date to the protocol.

**Response:** A version date is added

37. Knee joint performance interview – please add a version date. Further please describe how the interview information will be recorded.

**Response:** A version date is added. After the clinical test is concluded, the research team member will interview both the client and his/her parents with the questionnaire that is developed and used in previous study. The team member will ask the family the questions, and write down their responses onto the questionnaire. No video or audio will be recorded during the interview.

38. Budget: Please clarify why there is \$1000 allotted for the fitting of prosthetics if it costs \$100/client and there is only one participant. Further, please comment on the travel costs as indicated in TAHSN 20. Is it \$80 total or per visit?

**Response:** Budget is now updated. The travel cost is \$40 per visit, \$80 in total since there will be two visits.



**Subject ID:**

**Date:**

## **KNEE JOINT PERFORMANCE INTERVIEW**

### **Holland Bloorview Kids Rehabilitation Hospital**

In this interview, we want to find out how well you think the new knee joint is working and how it compares to your usual knee. We will ask you a few questions about what things you can do, how you do them and what difficulties you might have.

Usual Knee Joint: \_\_\_\_\_

- 1) How confident are you walking with the new knee? Do you feel that the lock is operating reliably?
- 2) How well do you feel you can control the bending/straightening of the knee?
- 3) How comfortable are you walking with the new knee?
- 4) Are you satisfied with the quietness of your prosthesis? Do you feel particularly tired after walking with the new knee?
- 5) How do you like the overall look of the knee? Is there a part of the prosthesis that you don't like the look of?
- 6) What is the best thing about this prosthesis?
- 7) What is your biggest complaint about this prosthesis?

## KNEE JOINT PERFORMANCE INTERVIEW

### Holland Bloorview Kids Rehabilitation Hospital

CATEGORY	QUESTIONS	RESPONSE OPTIONS
GENERAL	<b>Q1:</b> Types of activities performed:	1. Walk fast; 2. Walk fast & jog; 3. Walk fast, jog & run
	<b>Q2:</b> In certain situations does the knee give out from under you?	Yes/No
	<b>Q3:</b> How often does the knee give out:	H = Hour; D=Day; W=Week, M=Month (i.e. twice per day = 2/D)
WALK	<b>Q4:</b> When you are walking, does your knee ever collapse on you?	Yes/No
	<b>Q5:</b> When you are walking do you worry about whether your knee will collapse on you?	5 Point Scale (0: Not at all – 5: All the time)
	<b>Q6:</b> When you walk for a longer time, how tired do you feel?	5 Point Scale (0: Not at all – 5: Very tired)
RUN	<b>Q7:</b> In the last four weeks has your knee collapsed on you while running?	Yes/No
	<b>Q8:</b> When you are running do you worry about whether your knee will collapse on you?	5 Point Scale (0: Not at all – 5: All the time)
UNEVEN GROUND	<b>Q9:</b> When you encounter uneven (rough) ground, do you:	1. Continue as normal, 2. Avoid it, 3. Move slowly/cautiously
	<b>Q10:</b> How stable is your prosthesis on uneven (rough) ground?	5 Point Scale (0: Very Stable – 5: Unstable)
	<b>Q11:</b> Over uneven (rough) ground, do you worry about tripping?	5 Point Scale (0: Not at all – 5: All the time)
INCLINES AND STAIRS	<b>Q12:</b> Rate the difficulty of walking up a hill or ramp	5 Point Scale (0: Easy – 5: Very difficult)
	<b>Q13:</b> Rate the difficulty of walking down a hill or ramp	5 Point Scale (0: Easy – 5: Very difficult)
	<b>Q14:</b> Rate the difficulty of walking up stairs	5 Point Scale (0: Easy – 5: Very difficult)
	<b>Q15:</b> Knee preference	1. Conventional; 2. Prototype

## **Appendix B**

### **Prototype Drawings and Parts List**

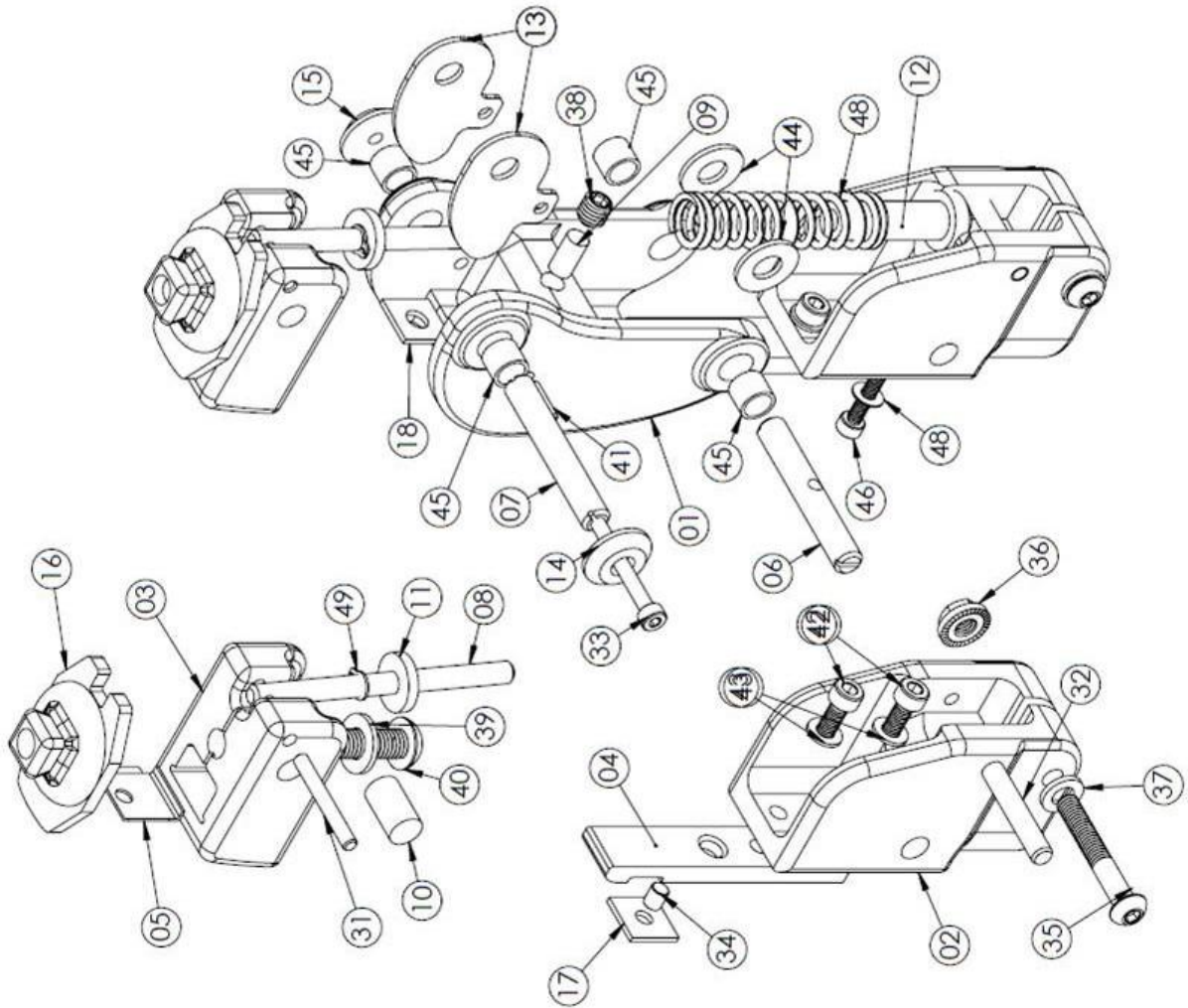
1. Parts and components
2. Knee assembly
3. Drawings of custom-made component

**Table B.1: PASPL-Knee's bill of material**

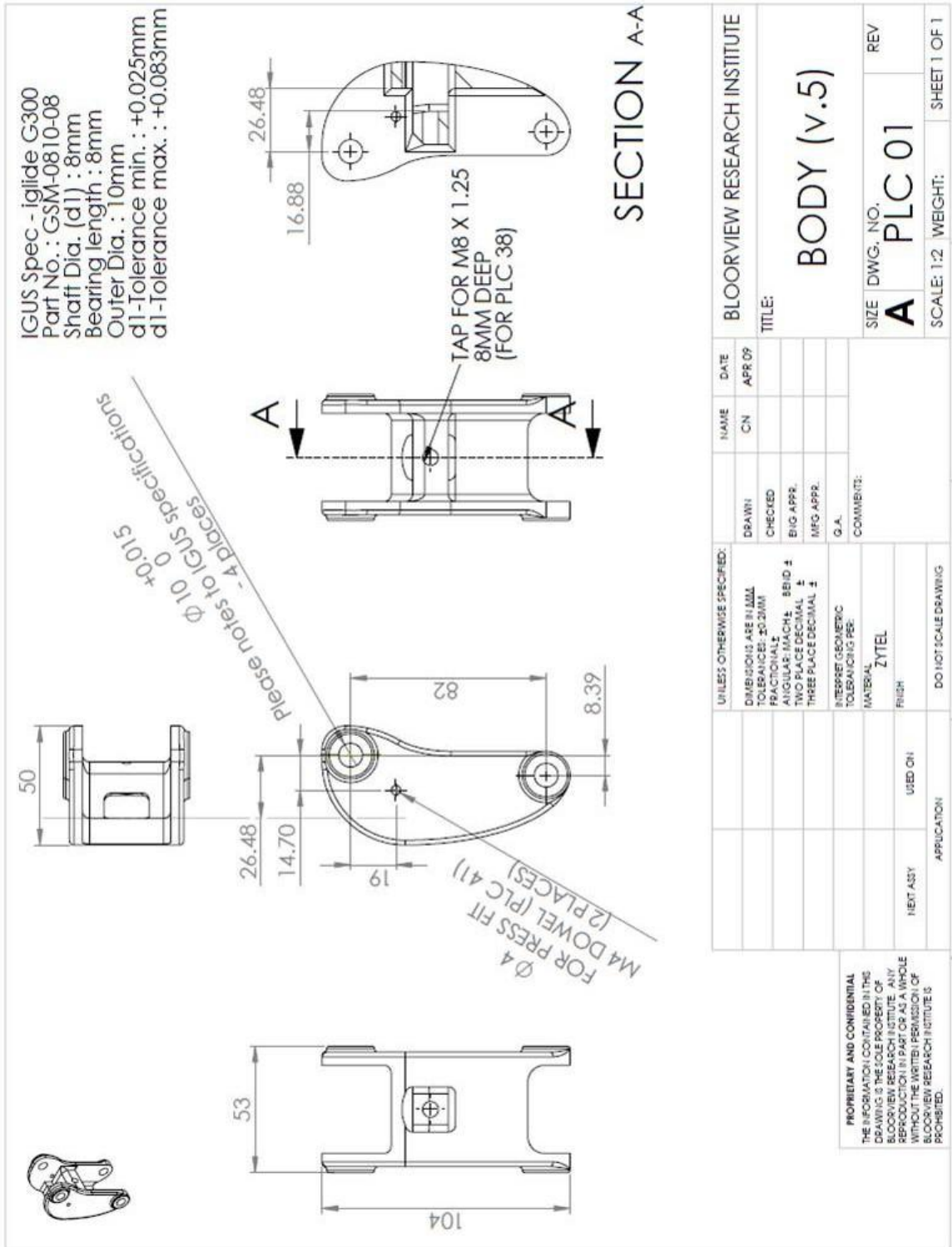
Part #	Part Name	Material	Quantity
<b>Custom-made / Modified</b>			
PLC 01	Body	Zytel	1
PLC 02	Bottom	7075 Aluminum	1
PLC 03	Top	Zytel	1
PLC 04	Lock	Tool Steel	1
PLC 05	Lock Insert	Stainless Steel Sheet	1
PLC 06	Bottom Shaft	17-4 Stainless	1
PLC 07	Top Shaft	17-4 Stainless	1
PLC 08	Extension Assist Main Shaft	18-8 Stainless Steel	1
PLC 09	Lock Spring	Polyurethane 60A	1
PLC 10	Front Bumper	Polyurethane 60A	1
PLC 11	Spring Top Anchor	Aluminum Bronze	1
PLC 12	Spring Bottom Anchor	Delrin	1
PLC 13	Top Shim	UHMW	2
PLC 14	Friction Control Screw Head Cap	303 Stainless Steel	1
PLC 15	Friction Control Screw End Cap	303 Stainless Steel	1
PLC 16	Adaptor	Stainless Steel	1
PLC 17	Front Lock Pad	Polyurethane 60A	1
PLC 18	Rear Lock Pad	Polyurethane 60A	1
<b>Off the shelf</b>			
PLC 31	Extension Assist Top Shaft	18-8 Stainless Steel	1
PLC 32	Extension Assist Bottom Shaft	18-8 Stainless Steel	1
PLC 33	Friction Control Screw (Top Shaft)	18-8 Stainless Steel	1
PLC 34	Front Lock Pad Dowel	18-8 Stainless Steel	1
PLC 35	M6 Shank Locking Screw	18-8 Stainless Steel	1
PLC 36	M6 Shank Locking Nut	18-8 Stainless Steel	1
PLC 37	M6 Washer	18-8 Stainless Steel	1
PLC 38	Lock Spring Set Screw	18-8 Stainless Steel	1
PLC 39	M8 Adaptor Washer	18-8 Stainless Steel	1
PLC 40	M8 Adaptor Screw	18-8 Stainless Steel	1
PLC 41	Top Shim Dowel Pin	18-8 Stainless Steel	2
PLC 42	M5 Lock Bottom Screw	18-8 Stainless Steel	2
PLC 43	M5 Washer	18-8 Stainless Steel	2
PLC 44	Bottom Plastic Washer	Plastic	2
PLC 45	Sleeve Bushing	Plastic	4
PLC 46	M4 Bottom Shaft Lock Screw	18-8 Stainless Steel	1
PLC 47	M4 Bottom Shaft Lock Washer	18-8 Stainless Steel	1
PLC 48	Spring	Music Wire	1
PLC 49	Retaining Ring	18-8 Stainless Steel	1

PART LIST

- PLC 01 - BODY
- PLC 02 - BOTTOM
- PLC 03 - TOP
- PLC 04 - LOCK
- PLC 05 - LOCK INSERT
- PLC 06 - BOTTOM SHAFT
- PLC 07 - TOP SHAFT
- PLC 08 - EXTENSION ASSIST MAIN SHAFT
- PLC 09 - LOCK SPRING
- PLC 10 - FRONT BUMPER
- PLC 11 - SPRING TOP ANCHOR
- PLC 12 - SPRING BOTTOM ANCHOR
- PLC 13 - TOP SHIM
- PLC 14 - FRICTION SCREW HEAD CAP
- PLC 15 - FRICTION SCREW END CAP
- PLC 16 - ADAPTOR
- PLC 17 - FRONT LOCK PAD
- PLC 18 - REAR LOCK PAD
- PLC 31 - EXTENSION ASSIST TOP SHAFT
- PLC 32 - EXTENSION ASSIST BOTTOM SHAFT
- PLC 33 - FRICTON CONTROL SCREW
- PLC 34 - FRONT LOCK PAD DOWEL
- PLC 35 - M6 SHANK LOCKING SCREW
- PLC 36 - M6 SHANK LOCKING NUT
- PLC 37 - M6 WASHER
- PLC 38 - LOCK SPRING SET SCREW
- PLC 39 - ADAPTOR WASHER
- PLC 40 - M8 ADAPTOR SCREW
- PLC 41 - TOP SHIM DOWEL
- PLC 42 - M5 LOCK SCREW
- PLC 43 - M5 WASHER
- PLC 44 - BOTTOM THRUST WASHER
- PLC 45 - SLEEVE BUSHING
- PLC 46 - M4 BOTTOM SHAFT LOCK SCREW
- PLC 47 - M4 WASHER
- PLC 48 - COMPRESSION SPRING
- PLC 49 - RETAINING RING

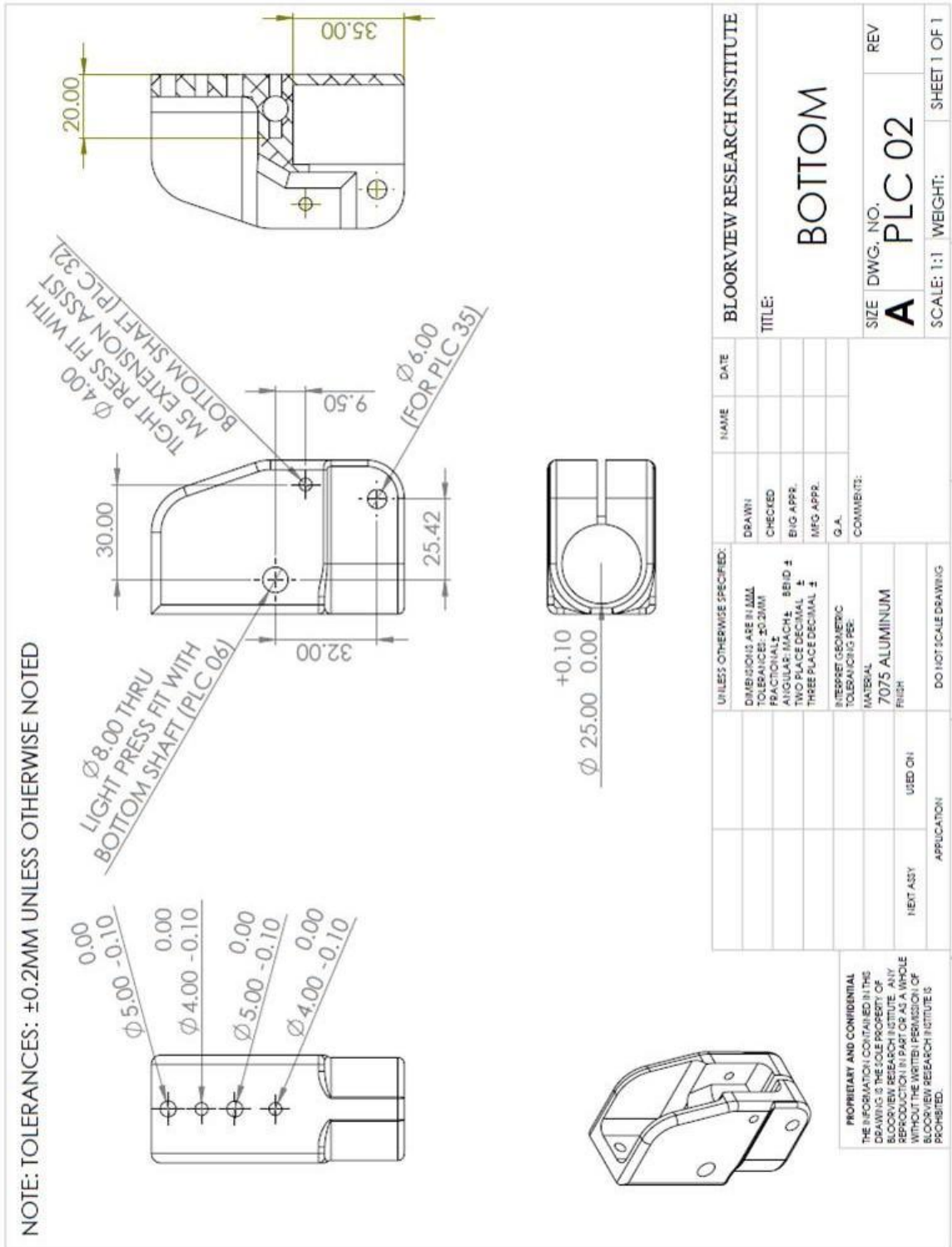


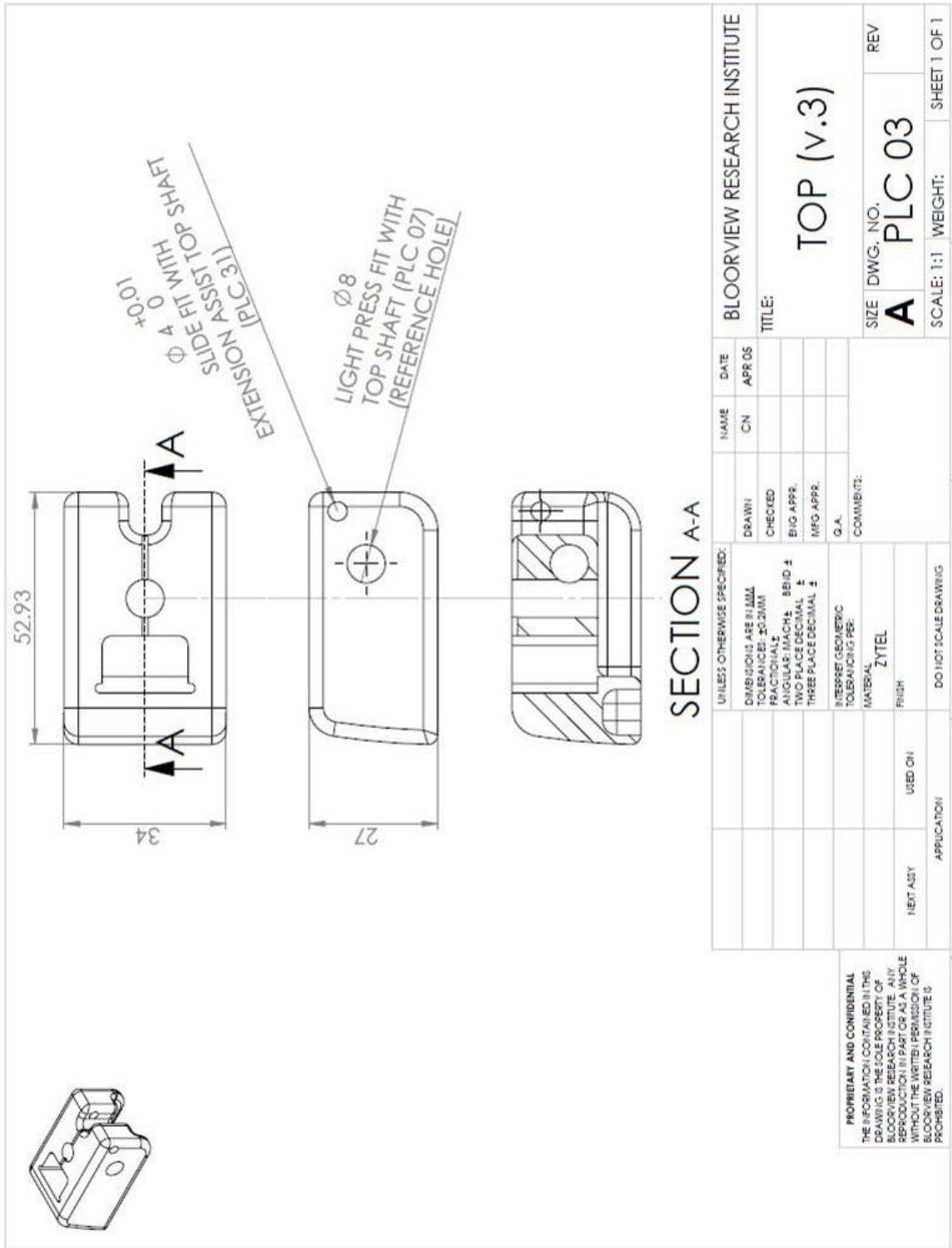
CALVIN NGAN



NAME	DATE	APR 09
NAME	CN	
DRAWN	CHECKED	
ENG APPR.	MFG APPR.	
G.A.	COMMENT:	
UNLESS OTHERWISE SPECIFIED:		
DIMENSIONS ARE IN MILLIMETERS		
TOLERANCES FRACTIONAL		
ANGULAR: MACH		
TWO PLACE DECIMAL		
THREE PLACE DECIMAL		
INTERPRET GEOMETRIC TOLERANCING PER:		
MATERIAL: ZYTEL		
FINISH:		
DO NOT SCALE DRAWING		
APPLICATION	USED ON	
NEXT ASSY		
1	2	3
4	5	

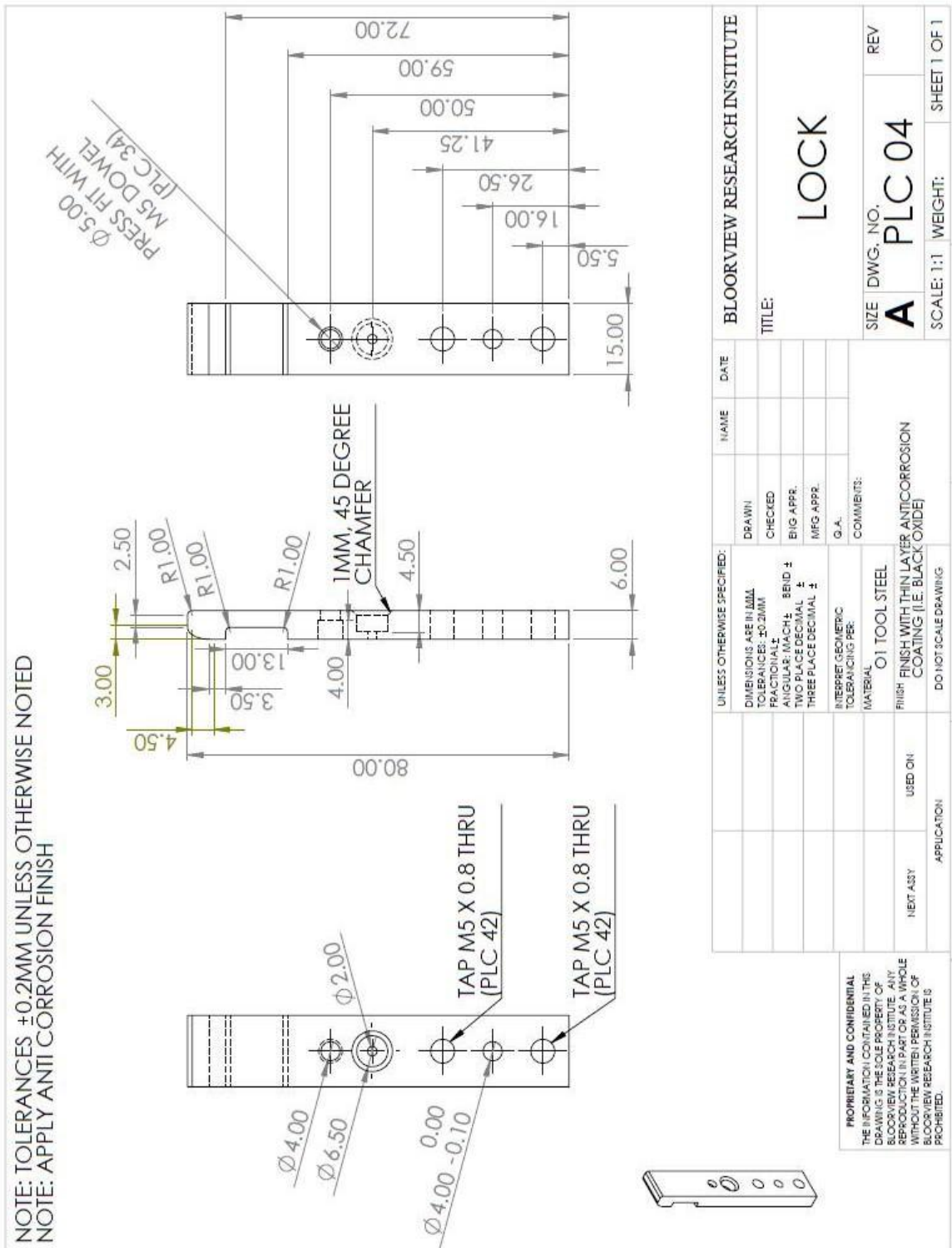


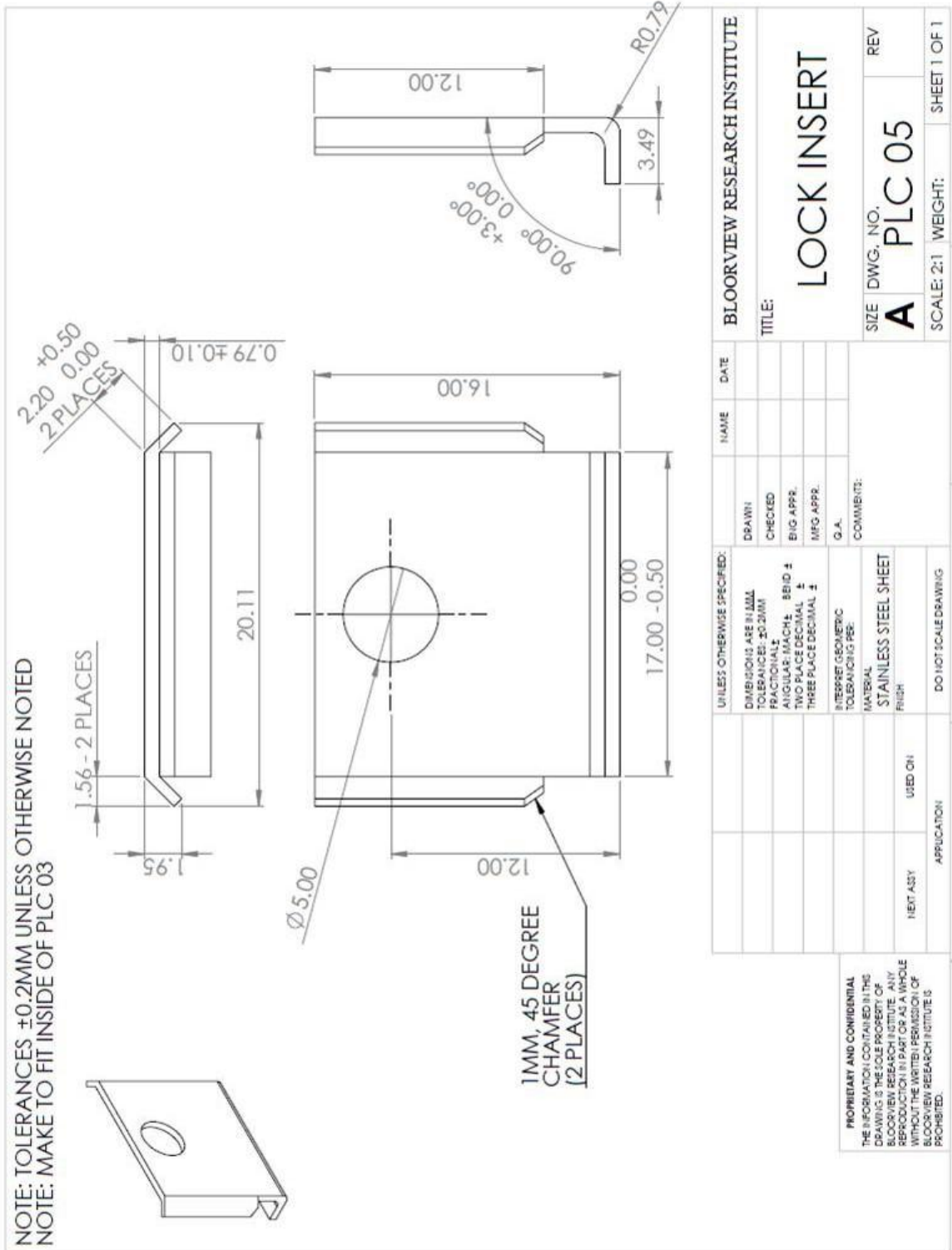


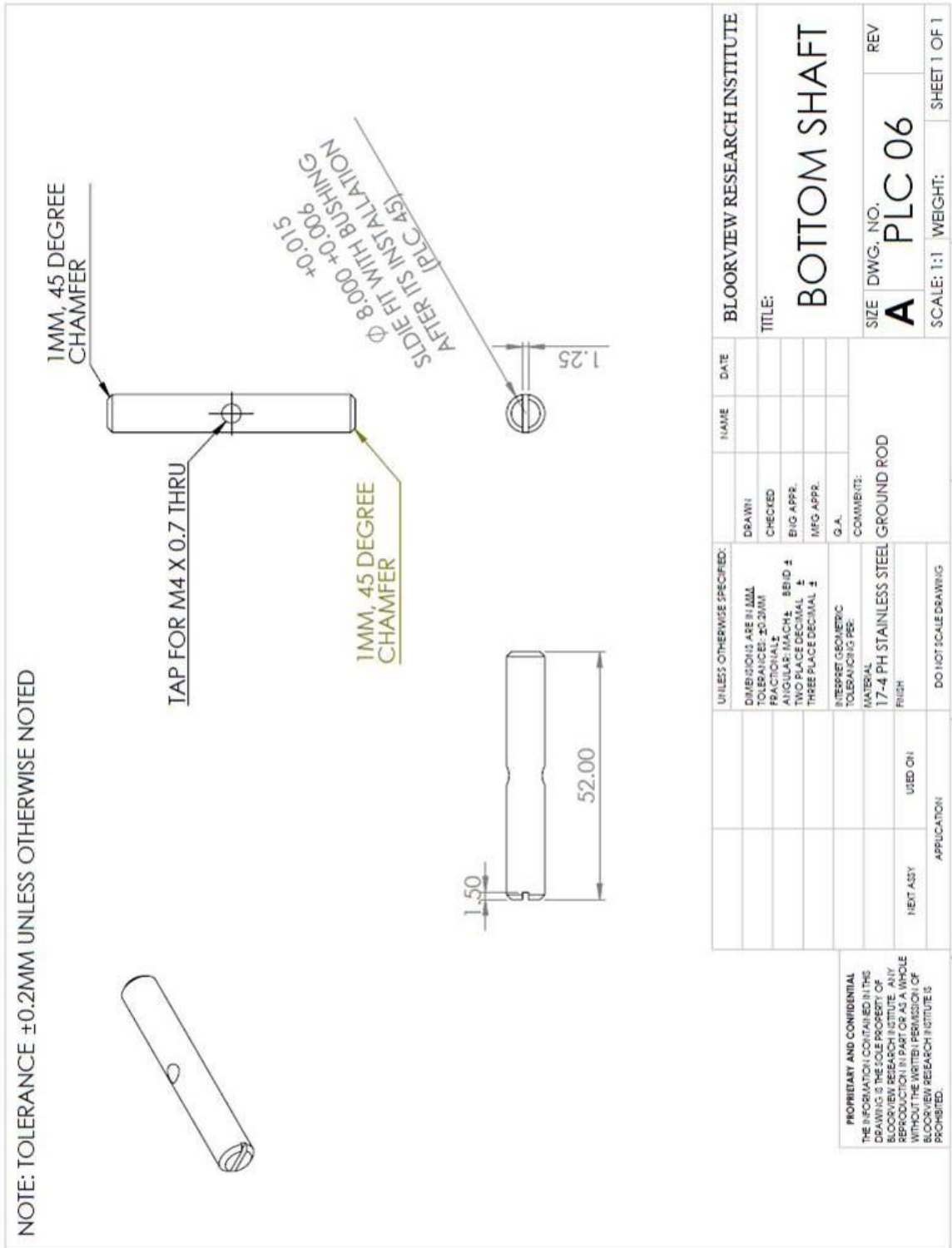


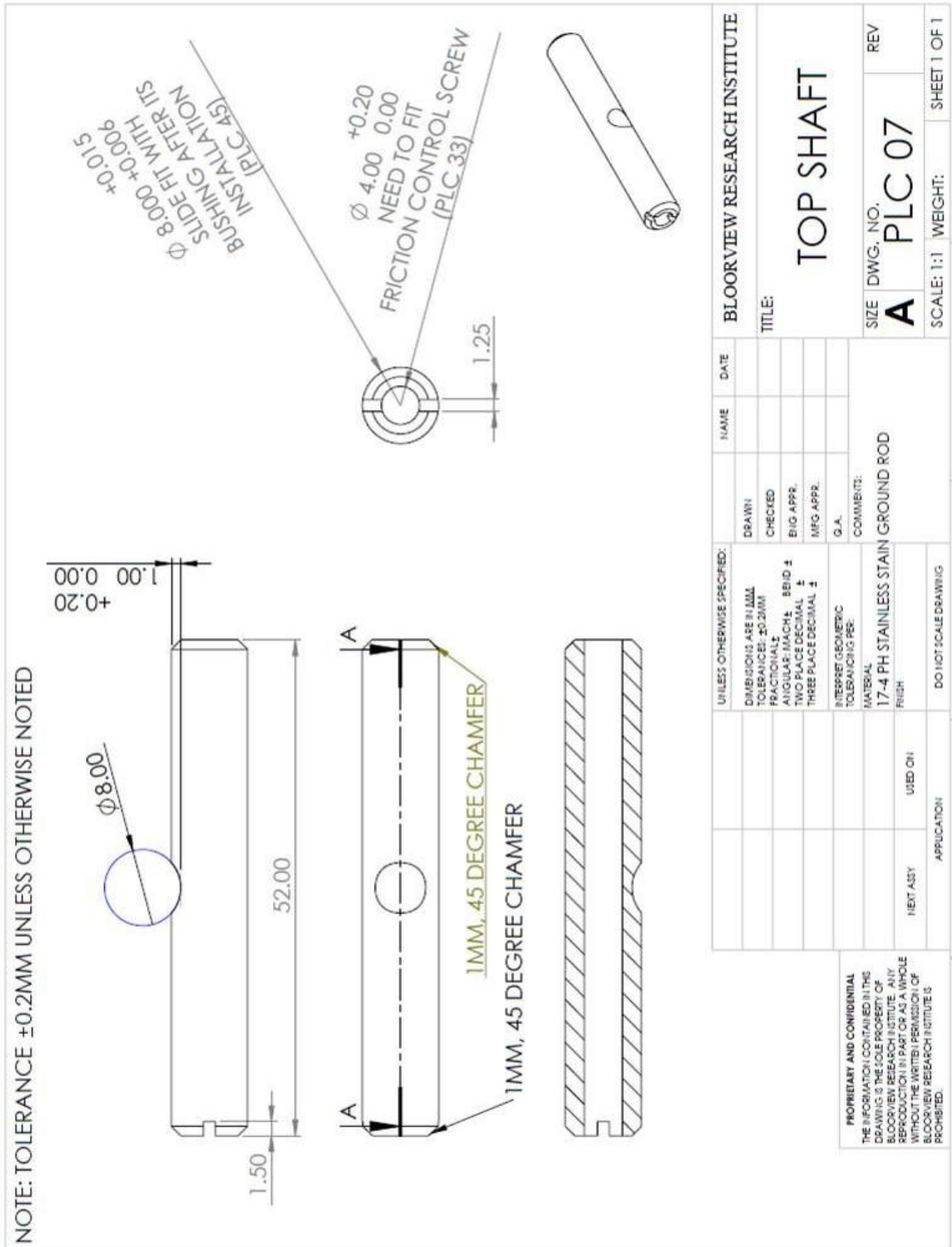
SECTION A-A

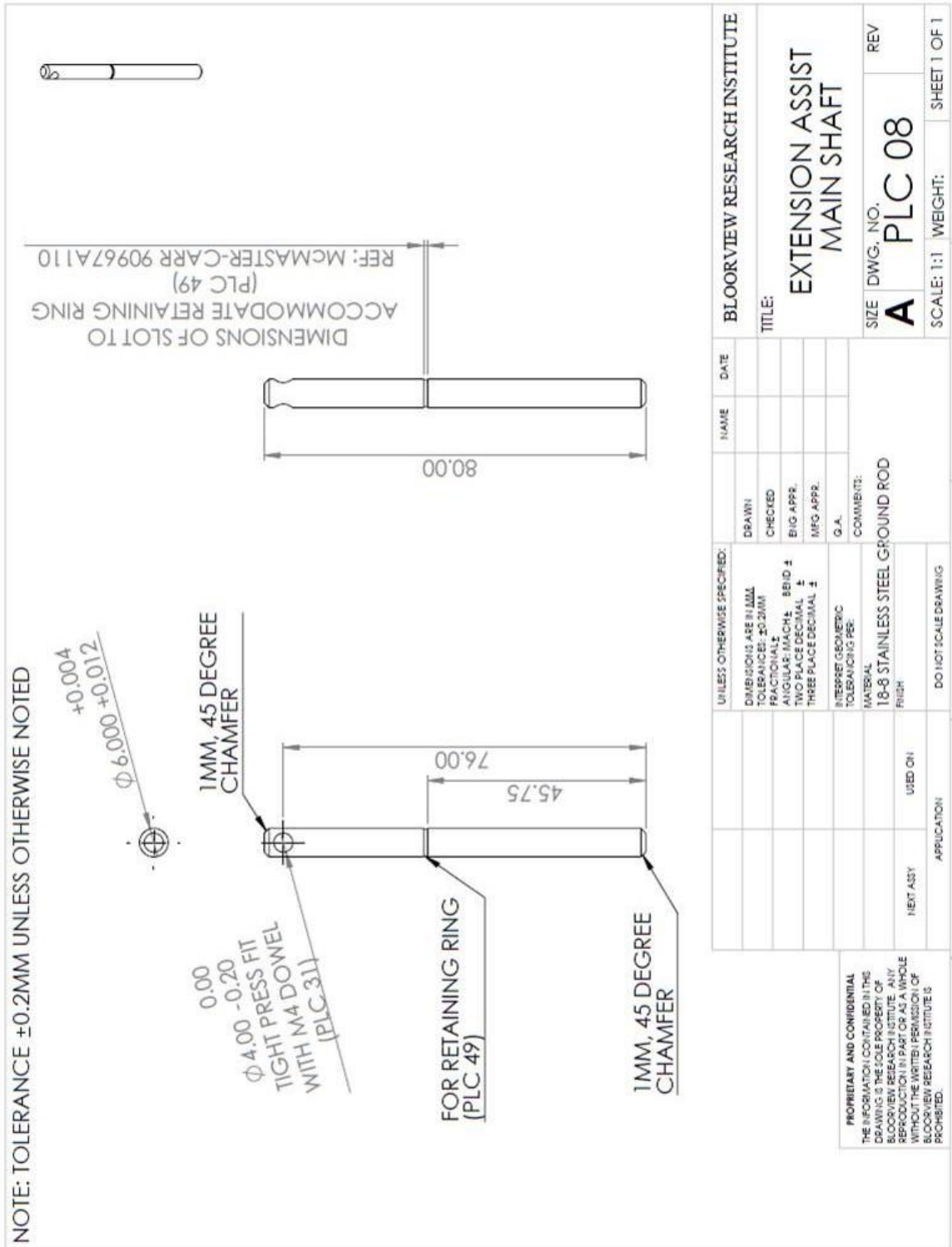
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THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF BLOORVIEW RESEARCH INSTITUTE. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF BLOORVIEW RESEARCH INSTITUTE IS PROHIBITED.					
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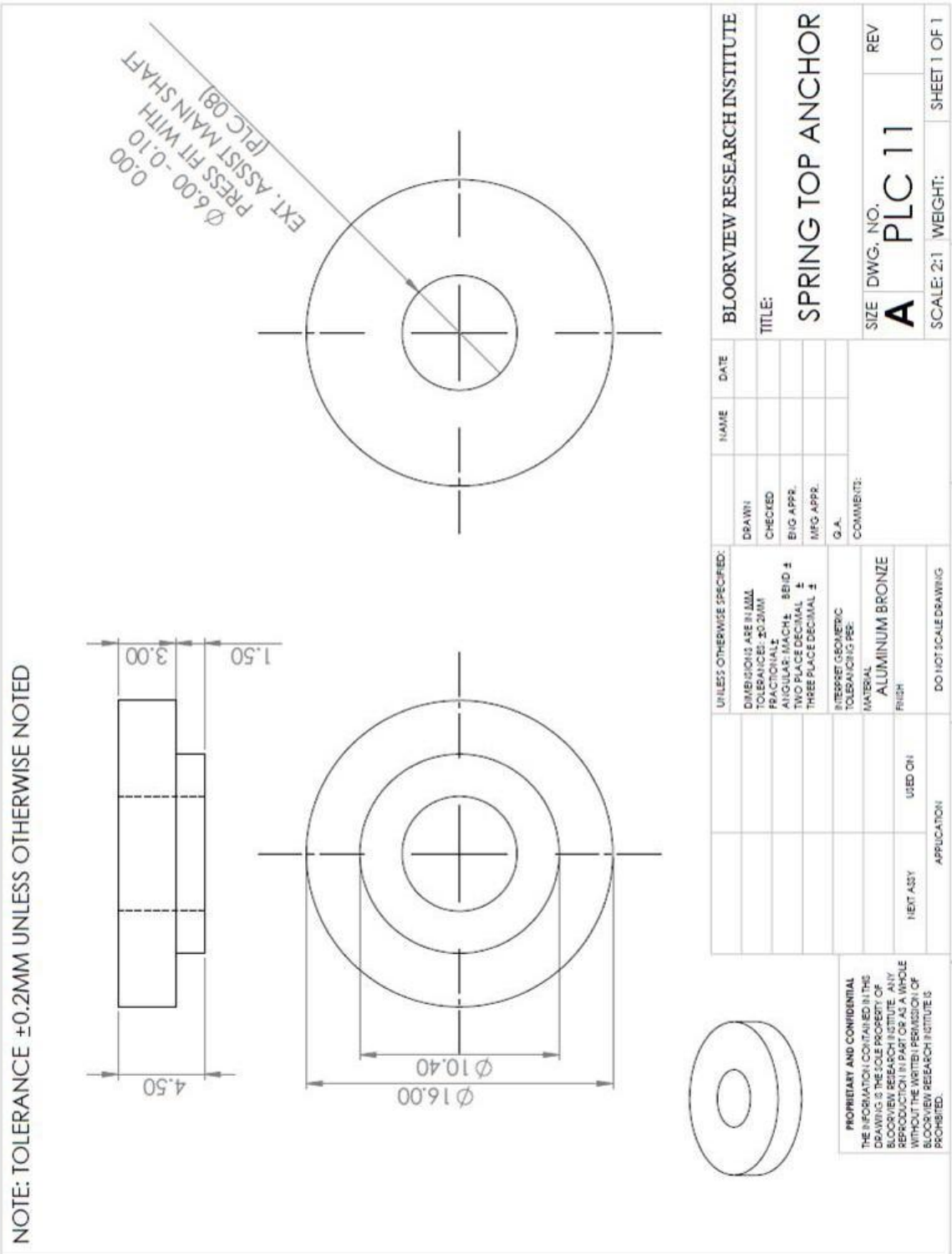




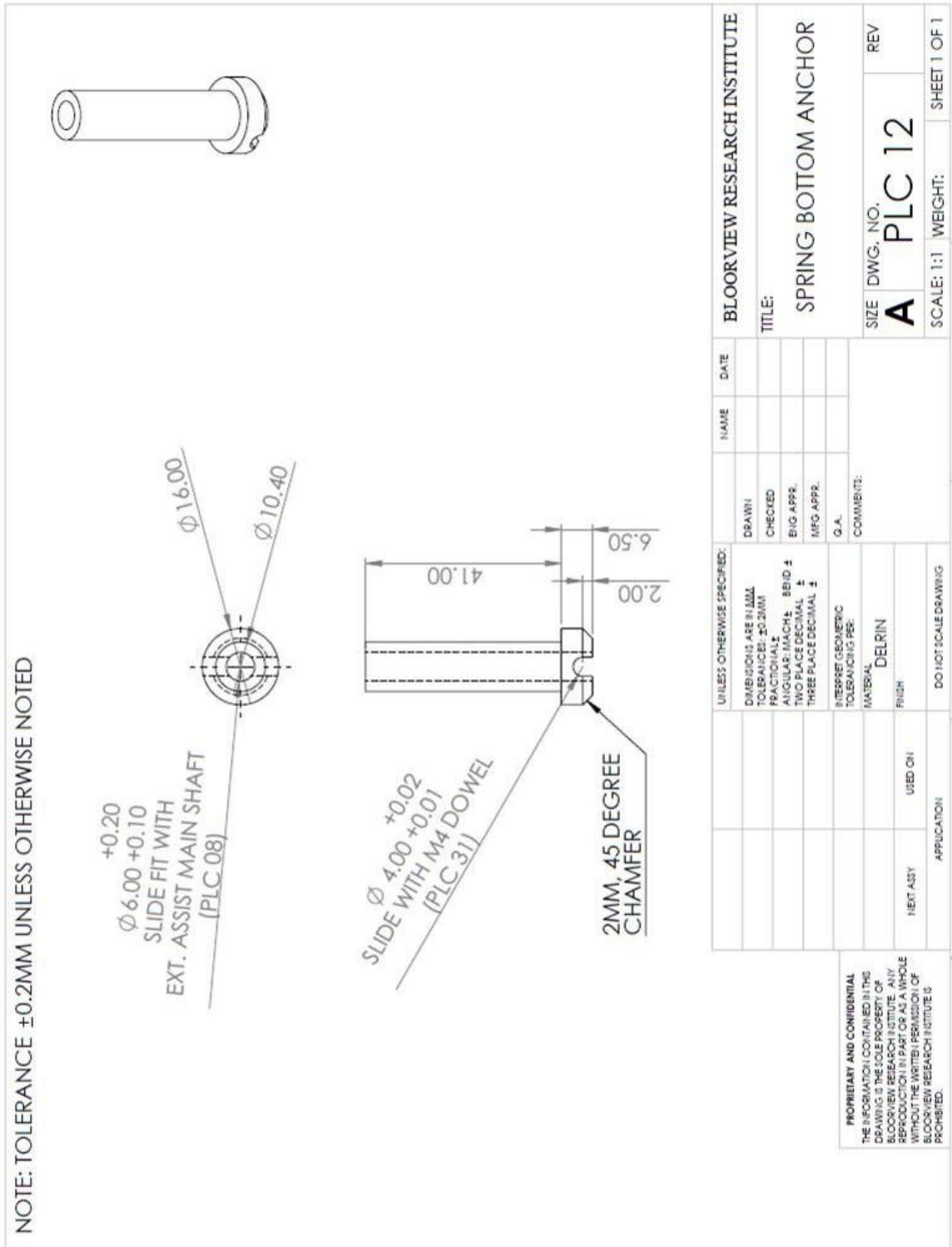


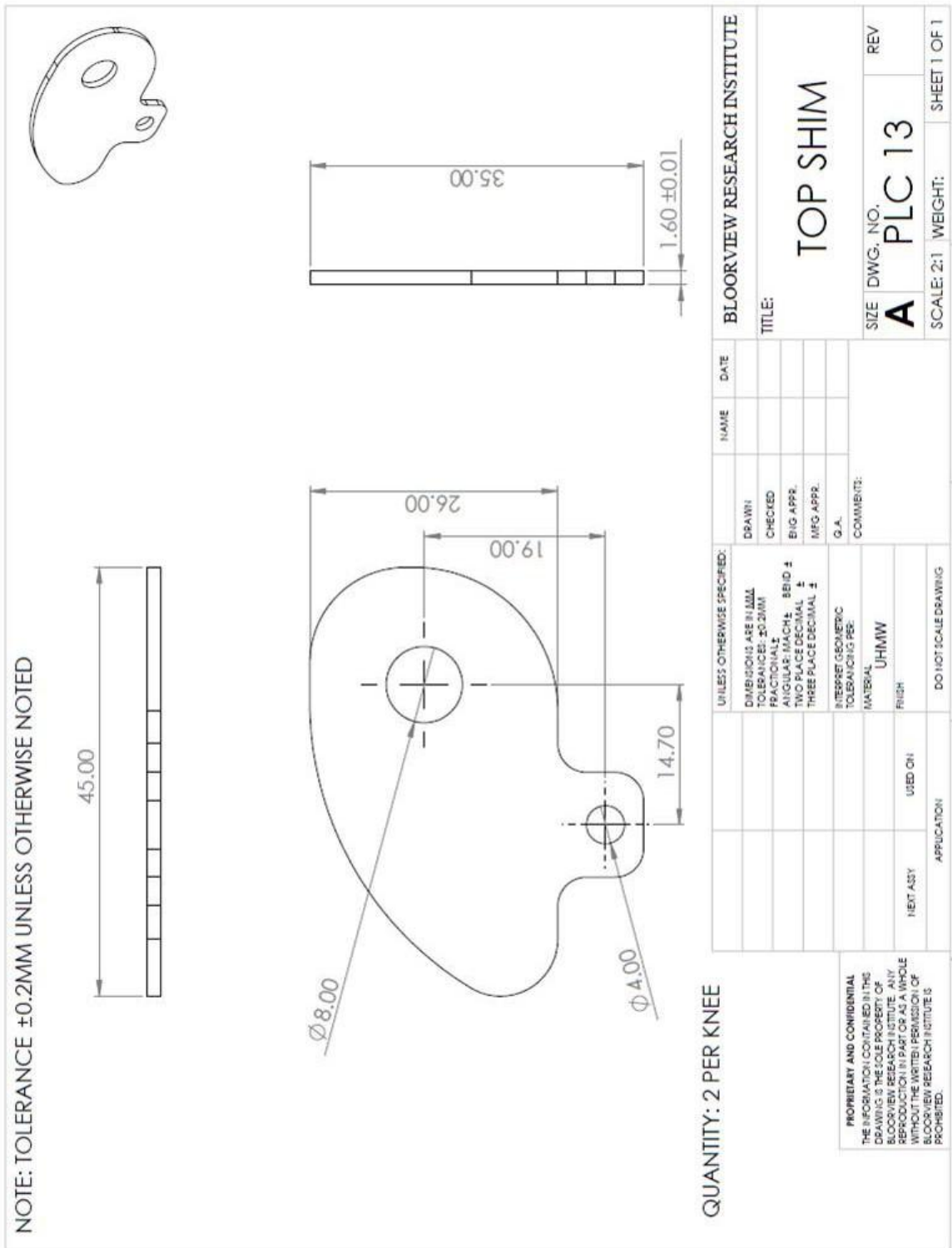




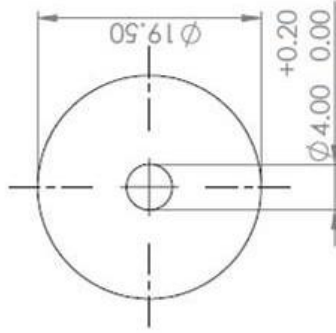
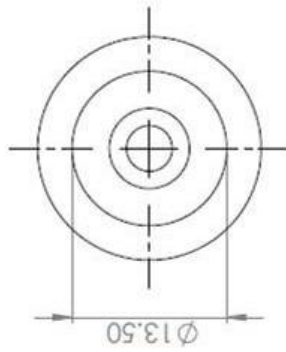
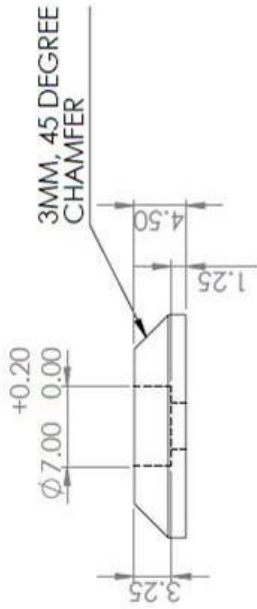
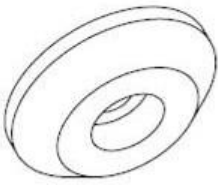






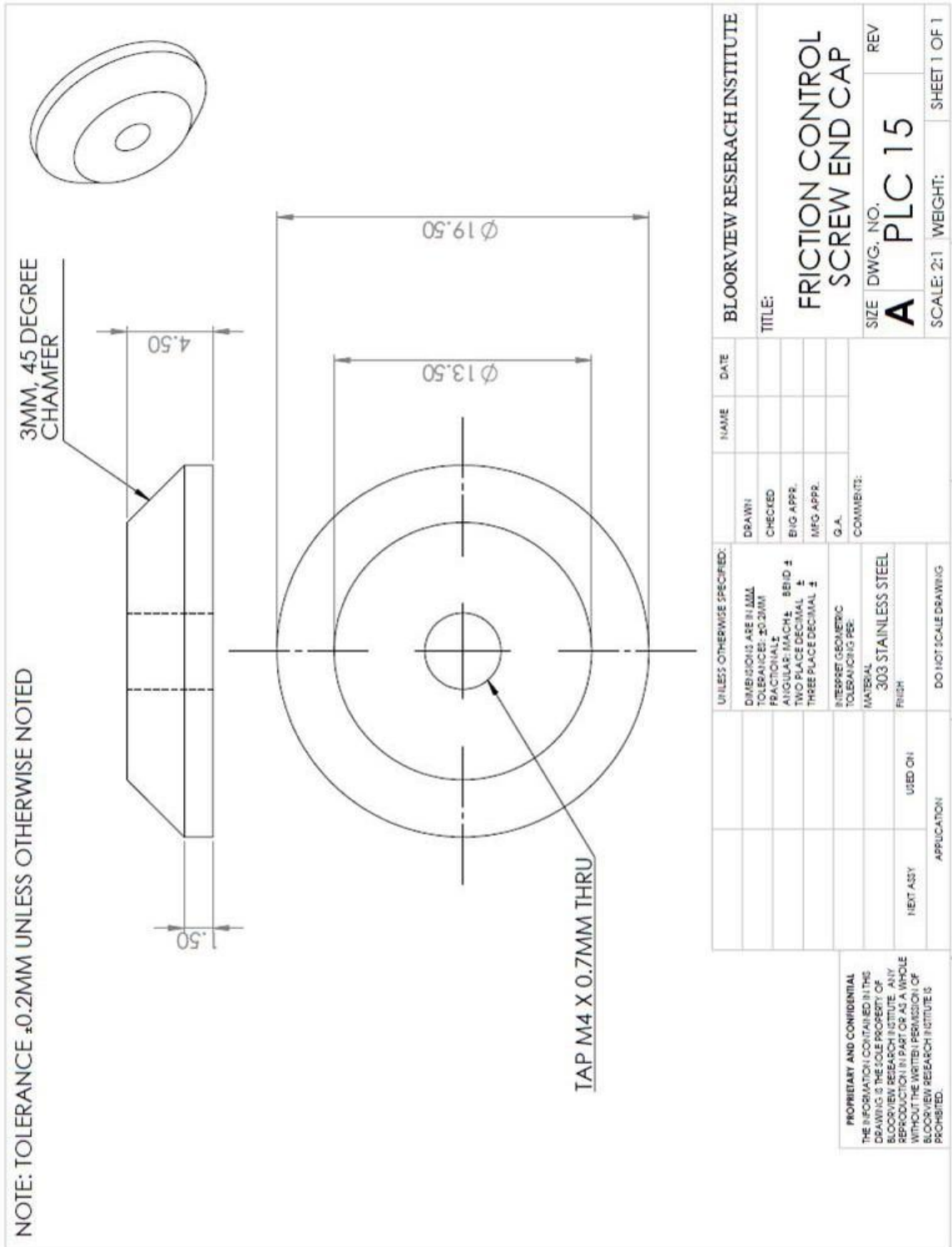


NOTE: TOLERANCE  $\pm 0.2\text{MM}$  UNLESS OTHERWISE NOTED



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