

Customizable BioMechanical Orthotic Knee Joint for Exoskeletons Thesis

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Abstract

Current research demonstrates that the shank (lower leg) linearly extends as the knee flexes, in a roughly quartic trajectory. However, most actuated orthotics do not consider this tibiofemoral relationship. This thesis presents a customizable biomechanical orthotic knee joint for medical rehabilitation which can follow this relationship. The design is easily manufacturable with common machining tools and FDM 3D printing techniques. Most importantly, it is customizable to each patient with the simple replacement of one component. Finally, this thesis will present a software workflow and tools to identify this tibiofemoral relationship in patients using motion capture technologies.

Chapter 1

Introduction

Sudden walking disabilities, such as lower limb paralysis, change a person's mobility, and often have quite a significant effect on a person's lifestyle and health. Paraplegia can introduce a significant challenge to maintain healthy bone and muscle mass, as the patient usually will have a much harder time exercising. However, research has shown that controlled rehabilitation can actually help reconnect a patient's injured neurons, reducing the effects of the injury and regaining mobility and/or feeling in their lower limbs [8]. As such, a large part of a paralysis victim's life is devoted to rehabilitation and physical therapy.

Exercises for rehabilitation come in many forms, from stretching to strength training, to hydrotherapy. Gait training has specifically been shown to improve the quality of life of a lower-limb paralysis patient, but this exercise is very hard to do, especially with severe cases of paraplegia. Robotics and exoskeletons have been proposed and tested to help with this cause. A mechanical system with intelligent

software control can be used to assist and hold a person's weight as they perform exercises as called for by their doctor. Such systems can decrease bone and muscle atrophy and help fight the side effects of paraplegia.

Most rehabilitation exoskeletons have placed their focus on the software control, and assumed joints like the hip, knee, and ankle to be pin joints. However, the knee joint specifically is known to not be a pin joint, as it linearly throughout flexion. This tibiofemoral relationship is often ignored, which can cause skin complications due to poor fitting when exoskeleton usage expands from just small clinical trials. This thesis aims to design and test a biomechanical actuated knee orthoses that can be customized to the natural tibiofemoral motion of a patient. It also aims to identify the tibiofemoral relationship in a person using modern imaging systems, such as motion capture systems and magnetic resonance imaging (MRI).

Chapter 2

Background

2.1 Paraplegia and Rehabilitation

Paraplegia is a medical term used to define where a patient loses feeling and/or movement in their lower two limbs. In comparison, quadriplegia (also sometimes known as tetraplegia) is the loss of control in all four limbs. It is important to note that not all feeling/movement needs to be lost in order for someone to be considered paraplegic [6]. Only 30% of all paraplegic and quadriplegic patients are considered complete lesions, where there is no sensation and no mobility in the lower limbs [15].

Paralysis is usually caused by trauma, such as sports injuries, vehicle accidents, or accidental falls, when the spine gets injured (see Figure 2.1). However, it can also be caused by specific diseases, including multiple sclerosis, amyotrophic lateral sclerosis, stroke, and in specific cases cancer [22]. Common effects of

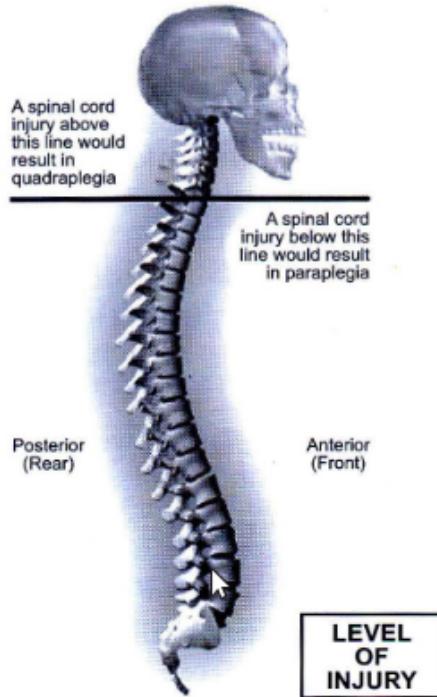


Figure 2.1: Location of spinal chord injury will determine type of paralysis [15]

paraplegia include:

- Loss of mobility, reflexes, and sensation
- Muscular weakness and atrophy
- Hormonal variations
- Gastrointestinal and bowel/bladder problems
- Muscle spasms
- Reduced cardiorespiratory fitness and increased likelihood of cardiorespiratory issues

Paraplegic and quadriplegic patients also have a higher likelihood of developing skin complications due to their limited mobility and feeling. The limited feeling make skin complications more dangerous, while reduced blood flow to affected limbs increase the recovery time of any dermatological issues [13]. Pressure ulcers are a common example of skin complications in patients suffering from spinal chord injuries, with those suffering from higher levels of paralysis at a higher risk. In fact, a study [9] discovered that 1/3 of its subjects suffered from at least 1 pressure ulcer in both pre-study analysis as well as throughout the four stages of its study. Therefore, any device to be used with paralysis patients must more-so consider the safety and comfort of the patient.

Rehabilitation can play a key role in reducing these side effects in patients who experience paraplegia. Mainly, physical therapy for paralysis patients focus on three main types of exercises: stretching, strengthening, and aerobic. Additionally, paralysis patients may go through gait training with the assistance of medical devices.

2.1.1 Physical Therapy for Paralysis Patients

Stretching

Stretching is considered one of the most important exercises [15], more-so than any other form of exercise because it can be done often and at home. Carefully designed exercises (like seen in Figure 2.2) can improve flexibility, reduce muscle spasms, reduce the chance of injury, and relieve contractures [21] [11]

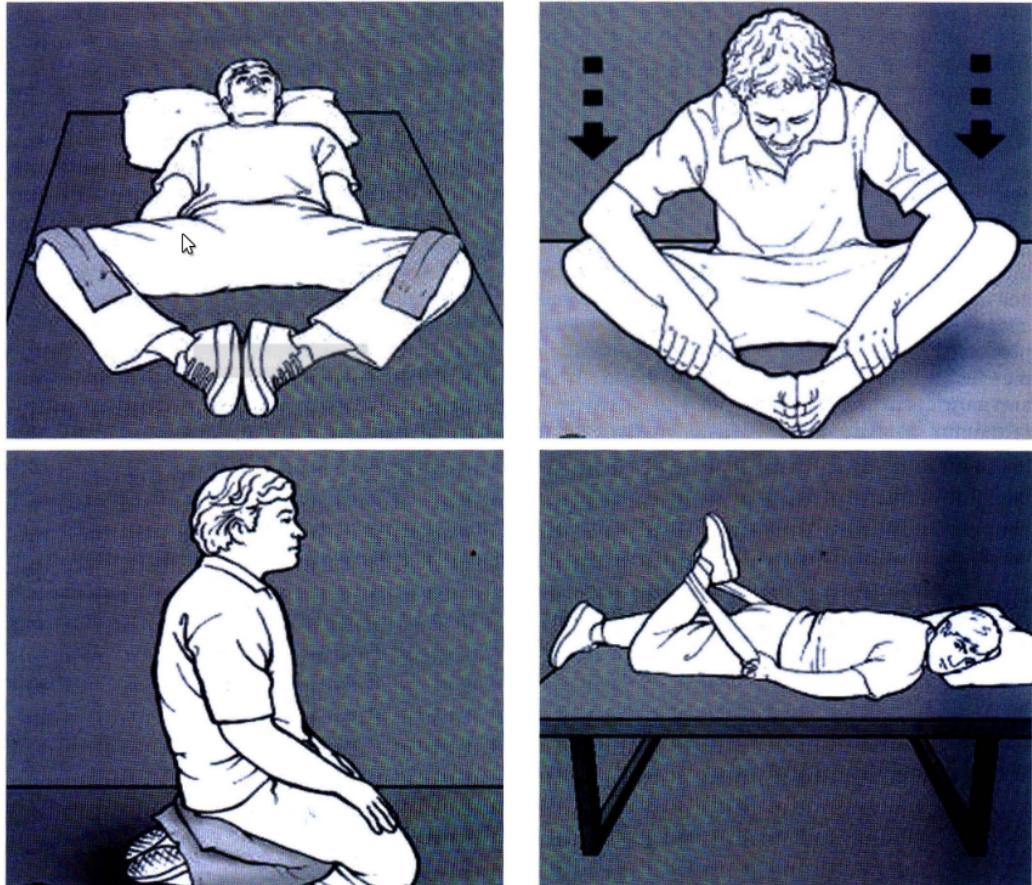


Figure 2.2: Bilateral Adductor Stretches (top) and Quadriceps Stretches (bottom) for paraplegic and quadriplegic patients [15]

[23]. Some common stretches include bilateral adductor stretches, quadriceps stretches, and hip flexor stretches.

Cardiorespiratory and Cardiovascular Training

Due to the difficulty of exercise, cardiovascular and cardiorespiratory activities are also very important to maintain health in paralysis patients. Aerobic ex-

ercises can increase energy levels, improve lung and heart function, control body weight, and reduce fatigue [15] [7]. A study showed that patients who suffer from neuromuscular deficiencies such as paraplegia suffered decreasing VO₂max¹ compared to control subjects with no issues [7]. The combination of the upper and lower body exercise in paraplegic patients can strengthen the paralyzed limbs while also activating healthy limbs, and ultimately improve the overall health of the patient. Some researchers have even proposed introducing wheelchair racing as a sport in an effort to help with rehabilitation after paraplegia [20].

Strength Training

Improving strength in muscles may actually partially reverse the loss of mobility in partially paralyzed patients, while also improving muscle tone [7] and preventing bone atrophy [21]. This type of exercise can be split into two major regions: training of affected limbs and muscles, and the training of non-affected regions. Affected limbs can benefit from an increase in mobility and definition, and can generally reduce the likelihood of muscular atrophy. Additionally, strong hip and leg muscles in partially paraplegic patients can help in gait training and increase the possibility of usage in life. On the other side, increasing or maintaining strength in unaffected regions can help with quality of life improvement. Often, paraplegic patients may elect to use crutches or canes as an assisted mobility device in the real world. Increasing arm/shoulder strength and endurance will

¹VO₂max is a common metric that measures the maximum rate of oxygen utilization during heavy exercise.

also increase capability for patients to use some of these assisted devices. Finally, back and abdomen muscles are very important to strengthen to maintain posture and improve gait performance [4].

Hydrotherapy

Hydrotherapy (exercising in water) is a notable way for patients suffering from paraplegia to better strengthen muscles and improve cardiovascular health. Due to similar buoyancy, water can reduce the effects of gravity without any external assistive devices. At the same time, the increased density of the water (in comparison to air) creates a natural resistance without the use of weights or elastics. Therefore, hydrotherapy is used in paraplegic patients to increase muscle power, increase endurance, and even help with gait training (see subsection 2.1.2). In minor cases of paralysis, some patients even use swimming as a way to exercise [15] [26].

2.1.2 Gait Training

Gait training has become the best way to improve motor functions in those who have partially or fully lost mobility in their legs and torso. The premise of this exercise is to have patients do similar movements to what one would do without their disability, like walking and climbing stairs. Essentially, the goal is to help the patient relearn the gaits they previously knew. Spinal neuronal circuits degrade quickly - in just a year, they can lose most of their potency, essentially unlearning any gait abilities the patient had in the past [8] [15] [4]. Gait training

can help reconnect the broken spinal neurons, and improve motor function and balance in a patient. In fact, several studies have shown that some patients with full spinal chord injuries have been able to recover part or even all of their walking capabilities through gait training [8] [27]!²

Use of Assistive Devices for Gait Training

Since most patients suffering from paralysis won't be able to hold themselves up, there have been many different proposals to compensate for gravity. At lower levels of paralysis, canes, walkers, and other walking assisted devices can help. Hydrotherapy has also been used with gait training due to the similar densities of humans and water [26]. With more serious cases of paralysis, robotic solutions and other active orthotics have been proposed and used in clinical settings.

Standard solutions like canes and walkers will only work for patients with mild paralysis. Canes are designed to support only 25% of body weight [15]. They can also be fairly unstable, since they usually only have at most 4 points of contact with a very small ground contact area. Walkers are better than canes, since they can support up to 50% of body weight [15]. However, canes, walkers, and crutches have one downside: the required upper-body strength. Mild lower-limb paralysis cases usually can benefit from these inexpensive tools to help with gait training. However most patients will struggle holding themselves up during gait training.

²There is significant research in the benefits of gait training for paraplegic and quadriplegic patients. Not all prior work is cited here.

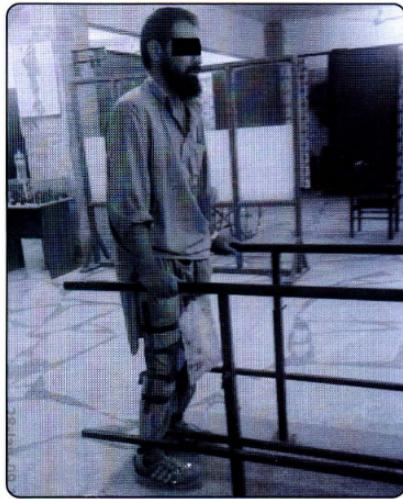


Figure 2.3: Patient using basic splint orthosis [15]

Orthosis are the next level up in assistive devices. They can come in many different shapes and can be designed to fit a patient's progress. At the lowest levels are specialty splints or braces (seen in Figure 2.3) that can help keep joints locked or reduce load of a joint through passive springs. These solutions often cost very little in material, and apply normal loads on the user's skeletal system - helping to prevent bone atrophy. Actively powered orthosis also exist with various levels of research and clinical trials (see section 2.3), and can be separated in two major groups.

Actively compensating exoskeletons (see left image in Figure 2.4) are orthosis devices that use various types of actuators, sensors, and gait controllers to help keep patients standing and walking with little to no strength required (from the patient). These types of exoskeletons use up a significant amount of energy, since they must essentially do all the physical work that leg muscles would normally do.

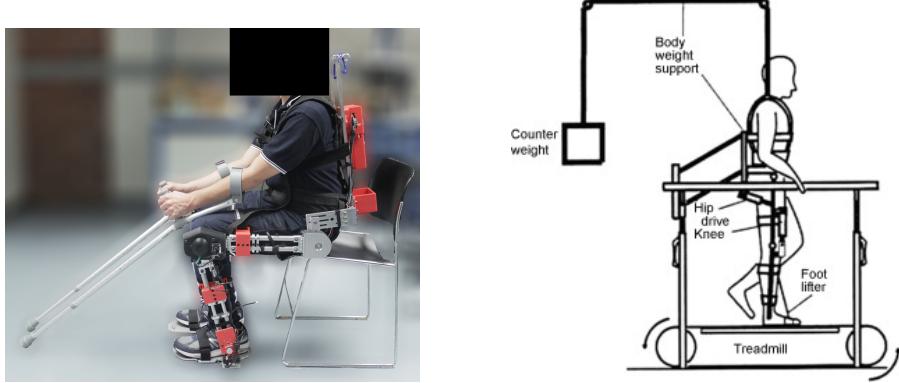


Figure 2.4: Comparison between an exoskeleton with active gravity compensation (left) and an exoskeleton with passive gravity compensation (right) [8]

This usually means very powerful actuators and motors with precise and stable control, and large batteries (which add to overall weight) or a large/long tether. Such power increases the overall flexibility of the system, however, at a cost. It also increases complexity of the control software, and introduces a safety risk of attaching powerful actuators to patient limbs.

To mitigate some of these risks, some solutions separate the exoskeleton and the gravity compensation (see right image in Figure 2.4). A separate mechanical system supports the weight of the user usually through a counterweight system or a gantry of some sort. This allows for the actuator in the exoskeleton orthosis to be weaker or power (current) limited to prevent injury in case of a malfunction. However, such systems are much more limited in their uses, since the power is hardware limited and more infrastructure is needed to use the device. Additionally, any actively compensating exoskeleton orthosis can be current limited and be

used with a mechanical gravity compensation system.

However, one of the biggest struggles with orthoses is the dermatological problems that they may cause. As explained earlier, patients suffering from paralysis are at an increased risk of developing skin complications [10]. This can be at least partially attributed to reduced sensitivity in paralyzed areas of the body. Therefore, any assisted devices that attach to a patient's skin should accurately follow the natural trajectory of the skin to avoid unnecessary rubbing.

Robotics for Paralysis Rehabilitation

Robotics have a very large opportunity to improve the rehabilitation process in paraplegic patients. Clinical research in using robotic orthosis for gait training and other rehabilitation exercises show positive improvement in most patients when considering quality of life [14] [3].

2.2 Human Knee Model

The human knee was initially considered as a pin joint, but research as early as 1992 suggested differently [18]. This study showed that the joint does extend as it bends by attaching motion capture markers to the femur and tibia of 5 different subjects. It also suggested that there was a difference between loaded and unloaded knees.

Several studies since then have confirmed a non-linear knee flexion and extension relationship, as well as the difference between loaded and unloaded knees.

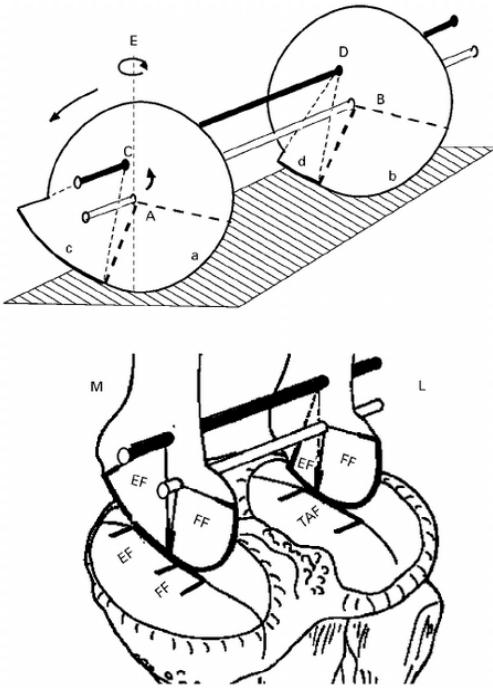


Figure 2.5: Diagram from [16] depicting the internal anatomy of a knee with respect to the movement patterns. The movement characteristics can be closely related to a cam mechanism

Instead of intrusive motion capture markers, modern Magnetic Resonance Imaging (MRI) and advanced motion capture systems [17] has allowed for more precise bone tracking for both unweighted and weighted knee joints, since a 3 dimensional model can be built of the joint. A study performed by Iwaki *et. al* using MRI data of cadaver knee joints found that the femur posterior circular arc is responsible for the linear extension of the leg through the flexion process, similar to the movement of a mechanical cam (see Figure 2.5) [16]. Through the bending process, the joint didn't rotate much outside the plane of flexion. These results were further confirmed during the dissection of the cadavers as well as in the fol-

lowup research with live human knee joints [12]. Additionally, the research also showed tibiofemoral motion moved forward roughly 4mm when the knee joint was loaded.

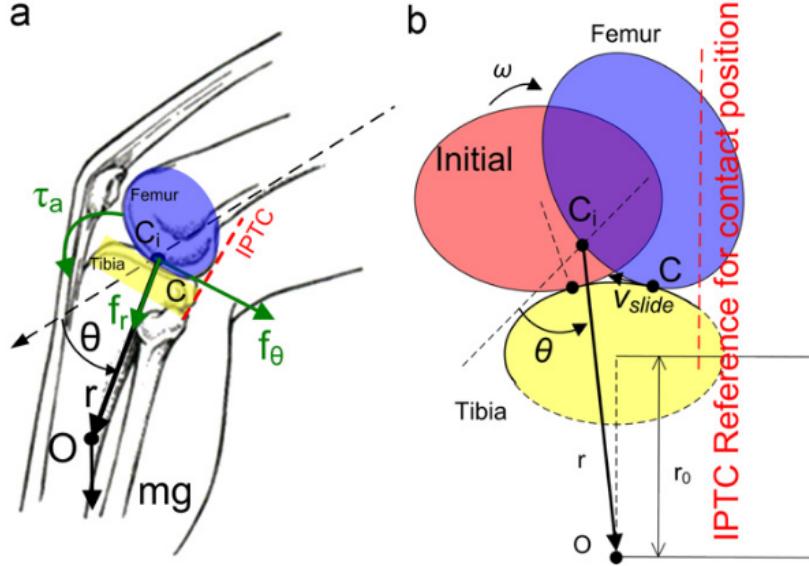


Figure 2.6: Diagram showing knee rotation [19]: (a) demonstrates the tibia's rotation around an initial contact point C_i . (b) shows the femur and tibia relationship using parameterized shapes between the distance r and flexion angle θ

This research was taken a step further with the parameterization of a knee joint's flexion and extension. The goal was to define a knee joint model to better create artificial mechanisms for rehabilitation exoskeletons. Based on MRI data of unloaded knees from [16], ellipses were fitted to the ends of the tibia and femur to approximate the relationship between the distance r and flexion angle θ . The resultant tibia to femur relationship can be seen in Equation 2.1 and Figure 2.7

[19].

$$r(\theta) \text{mm} = 1.078\theta^4 - 11.184\theta^3 + 26.524\theta^2 - 0.825\theta + 263.59 \quad (2.1)$$

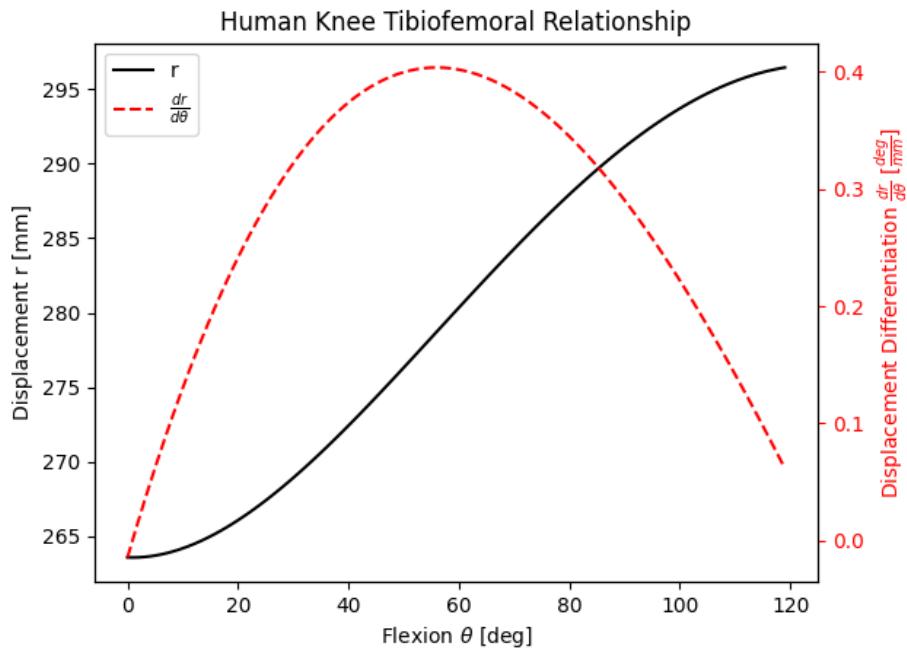


Figure 2.7: Relationship between tibia and femur during the flexion of the joint. $r(m)$ is the distance between joint point of contact (C_i in Figure 2.6) and center of mass of the tibia.

These studies measure the relationship of the bones in the knee joints, and not the skin movement around the joint. However, exoskeleton orthosis are usually connected directly to the skin. In order for the research presented above to be applicable to orthosis, a relationship between the skin and femur/tibia must be

made. A study by Benoit *et. al* looked at 8 healthy males to compare the bone and skin movement in and around the knee joint in order to identify if skin markers are sufficient to determine bone kinematics around the knee. Each subject had intra-cortical bone-pins inserted in the proximal tibia and distal femur with 3 motion capture markers on each pin. Then, 8 total motion capture markers were attached directly to the skin to measure the difference in the movement (see Figure 2.8).

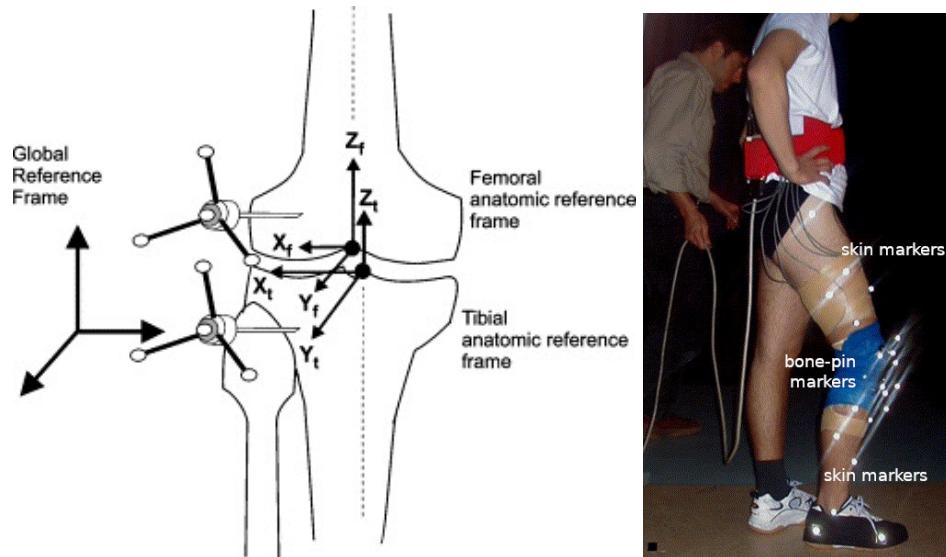


Figure 2.8: Depiction of the research showing the relationship between skin and bone movement: (left) a figure illustrating the location of the bone-pins and (right) showing an image of a subject with all markers attached to them [2]

The results of this study seemed to show a significant difference between the skin and bone movement during several different gaits; average rotational errors were between 4.4° and 13.1° while translational errors averaged up to 16.1mm [2]. What is more interesting is that the errors measured remained relatively constant between different movements, seemingly demonstrating that the error comes from

the different connection methods (skin vs bone) and not via measurement tolerances. The researchers were able to conclude that skin-marker kinematics around the knee are not representative of the motion of the bone inside the knee joint. We may be able to therefore inversely conclude that bone kinematics may not be a good representation when designing knee orthoses. However, the research had a relatively small sample size due to the invasive nature of the experiment, and attached markers directly to taped up thighs (see Figure 2.8), which may have failed to represent the actual skin movement. Therefore, more research is needed to conclude the relationship between a skin connection on the thigh and a skin connection on the shank (calf) for the purpose of rehabilitation exoskeletons.

2.3 Exoskeleton Orthosis

Exoskeletons are an interesting application to help those with paralysis rehabilitate and exercise their muscles. They can take programmatically reduce or add bodyweight to the user to aid with safe gait training and muscle development. Additionally, powered exoskeletons can help move patient legs in the motion of a gait to help with relearning gait cycles such as walking and climbing stairs. The flexibility these rehabilitation devices offer have been noticed, and several different solutions exist at different levels of clinical implementation.



Figure 2.9: The WPI LARRE rehabilitation exoskeleton [24]

2.3.1 WPI LARRE

The WPI LARRE (Legged Articulated Robotic Rehabilitation Exoskeleton) is an exoskeleton project developed by the Worcester Polytechnic Institute (WPI) Automated and Interventional Medicine (AiM) Lab. The research presented in this thesis directly contributes to the AiM Lab's effort to develop an exoskeleton for rehabilitation of lower-limb paralysis patients.

The project was originally started and named as the HEX Gen-1. It's goal was to help with studying rehabilitation of patients who have suffered from spinal chord injury using exoskeletons. The project also offers a platform to develop software and hardware technology for rehabilitation exoskeleton. Therefore, it is designed to be adaptable to research different control systems and joint types.

The hip joint is powered by a brushless DC motor (Maxon EC90, Maxon Group), while the knee and ankle joints aren't actively powered by any motor. Instead, the knee joint contains a spring wrap clutch/brake to help provide support to patients throughout their gait cycles as proposed by [24]. Additionally, the ankle joint included a spring to add force during dorsiflexion to help in walking gaits.

2.3.2 H2



Figure 2.10: The H2 Exoskeleton, with 6 powered joints and lithium polymer batteries [5]

The H2 robotic exoskeleton is designed by the University of Houston to help stroke survivors with gait training and physical rehabilitation. It has 6 powerful DC motors (3 on each leg on the hip, knee, and ankle joint) geared down with harmonic gearboxes. Each motor is powered by its own local motor controller, with all electronics connected to a main controller via CAN bus. An assistive gait controller is used to apply torque when patients deviate from a planned gait pattern. The device itself was tested on 3 hemiparetic stroke patients, and was safe and effective throughout the 4 week testing period. The pilot clinical study demonstrated the "assist-as-needed" control system was able to benefit the stroke patients, and help them recover [5].

2.3.3 ReWalk

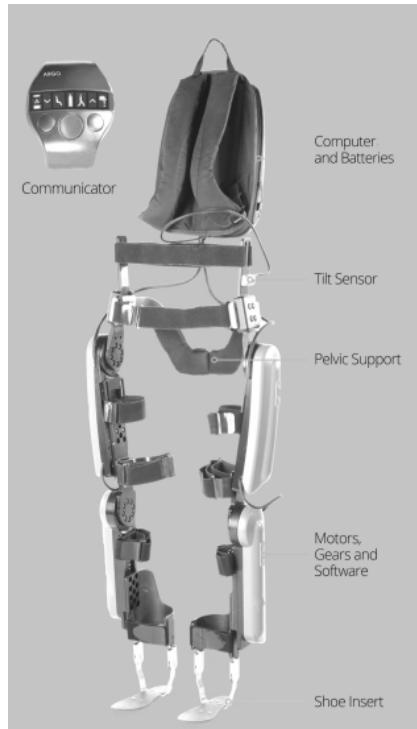


Figure 2.11: The ReWalk exoskeleton: an commercial exoskeleton with knee and hip powered joints [25].

The ReWalk™ exoskeleton (ReWalk Robotics) is a commercial exoskeleton for lower-limb paralysis patients. Unlike most medical exoskeletons, ReWalk is designed for daily use - not just for rehabilitation in controlled environment. It consists of a lower-limb exoskeleton with powered rotary joints. The joints do not consider tibiofemoral joint trajectory, and have a static center of rotation. The system is all powered by a computer and batteries in a backpack worn by the user. Research by Talaty *et. al* in [25] demonstrated that assistive devices such as

Rewalk are able to improve the walking capability of lower-limb paralysis patients with some practice.

2.3.4 EksoNR



Figure 2.12: The Ekso exoskeleton is a commercial rehabilitation system currently used in hospitals and rehabilitation centers.

The EksoNR exoskeleton (EksoBionics, Richmond California) is a commercial rehabilitation exoskeleton currently in clinical use since February 2012. EksoBionics - the company that manufactures this device - claims to be the only FDA-cleared exoskeleton for use with patients with acquired brain injury which has lead to paralysis. It has similar functionality and features to the Rewalk; the hip, knee, and ankle joints are all actuated pin joints. The exoskeleton holds the control electronics and batteries in a backpack-like container, which doubles as a

way to stabilize the patient's upper body during use [1].

Chapter 3

Knee Joint Design

3.1 Design Requirements

The following are the design parameters layed out at the beginning of the project:

Follows the defined knee tibiofemoral trajectory

The knee joint must be able to follow a tibiofemoral trajectory. As referenced in [19], human knee joints can be generally defined by a quartic trajectory. This project will use the parameters of a cadaver, which can be seen in Equation 3.1. The design of the joint must be easily customizable for each patient/user. Ideally, all parts except a few should remain the same to increase simplicity and reduce

cost of manufacturing.

$$r(\theta)mm = 1.078\theta^4 - 11.184\theta^3 + 26.524\theta^2 - 0.825\theta + 263.59 \quad (3.1)$$

Supports the weight of a person

Each joint should be able to support half of the weight of a 85kg human plus a 15kg exoskeleton (total of 100kg) with an additional safety factor.

Power/Torque-Speed for walking gaits and sit/stand exercises



Figure 3.1: Joint kinematics and dynamics during a walking gait cycle [24]

The knee joint has two rehabilitation requirements to fulfill: walking gaits and sit/stand gaits. Prior research has shown that walking gaits require roughly up to

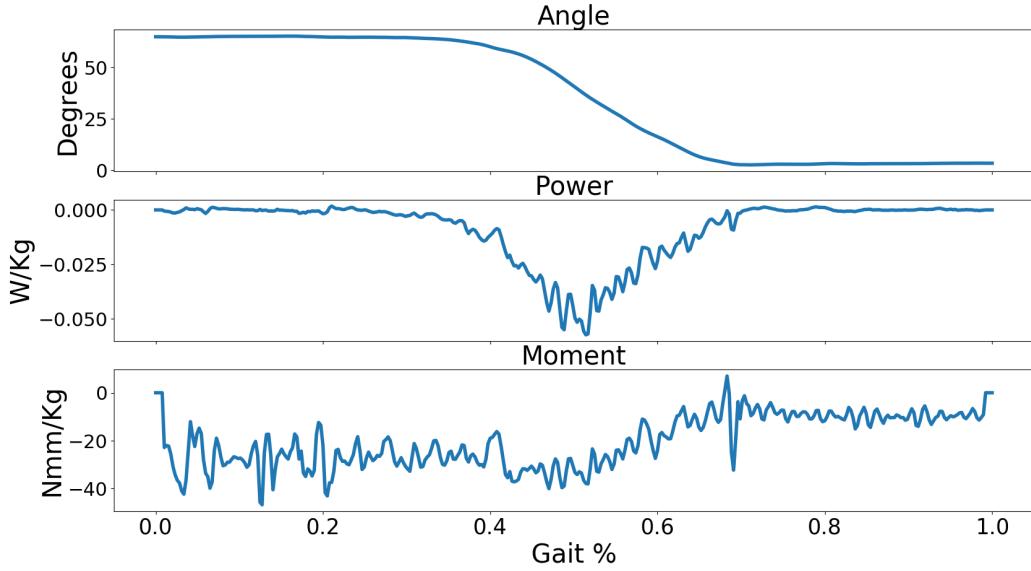


Figure 3.2: Joint kinematics and dynamics during a sit/stand gait cycle [24]

$0.65 \frac{W}{kg}$ and $0.25 \frac{Nm}{kg}$, (see Figure 3.1), while a sit/stand gait requires roughly up to $0.5 \frac{W}{kg}$ and $0.04 \frac{Nm}{kg}$. Speed requirements are roughly $12^\circ/sec$ for walking gaits and $15^\circ/sec$ for sit/stand gaits. Therefore, the designed knee joint for the $100kg$ weight specification should be capable of mechanically outputting $65W$ and $25Nm$ at $15^\circ/sec$.

Senses the joint angle

Sensors must be able to accurately encode the rotational position of the joint. The rationale behind this requirement is for research, debugging, and most importantly accurate and safe position control. Therefore, the joint must be able to read its own position in both passive (non-powered) modes and active (powered)

modes. It should also have a minimum accuracy of $\pm 0.5^\circ$ during position control, and be able to maintain position measurement through power cycles (absolute positioning).

Simple to manufacture and assemble

The joint must be designed with manufacturing and assembly in mind. All components must be easily sourced and generally available. Any machining requirement must be achievable with common machining techniques.

Integrates into the WPI LARRE

This research supports the advancement of the WPI LARRE project introduced in subsection 2.3.1. Therefore, the designed joint must be able to integrate into the universal exoskeleton joint connector developed in the LARRE project.

3.2 Mechanical Design

The orthotic joint design proposed uses a similar idea to how a human knee joint works; a cam mechanism extends the shank link as it is rotated relative to the thigh link. The joint therefore has two degrees of freedom: rotation around the center of rotation (output shaft of the motor and gearbox) and translation in the direction of the shank. However, since there is only one actuator, the joint is underactuated; this underactuation can be taken advantage of to match a patient's knee trajectory, where the center of mass of the shank extends away from the joint

center as the joint bends. For ease of assembly, the entire joint is held together by 4 M5 shoulder bolts, which also act as the axles for a total of 10 bearings.

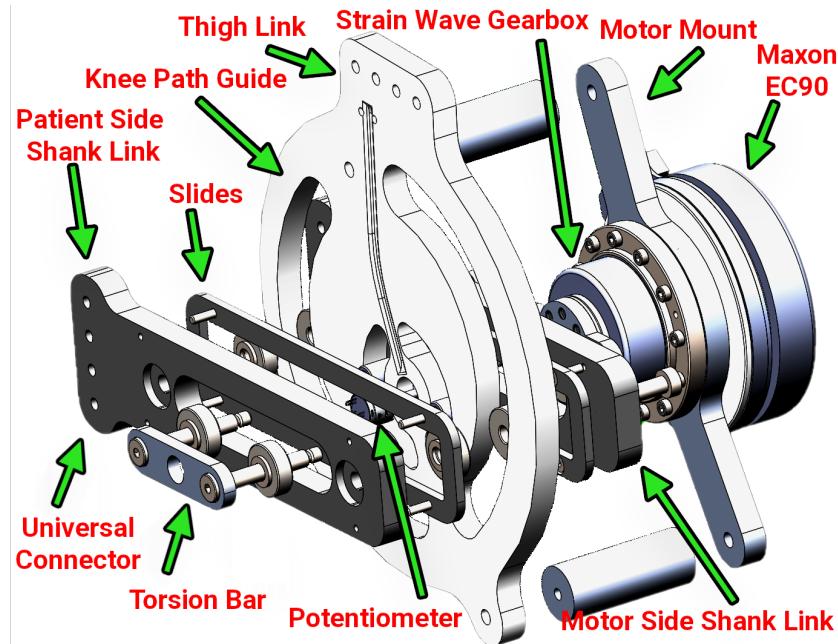


Figure 3.3: Exploded view of the knee joint, with all relevant components labeled

Torsion Bars

The center of rotation of the joint is designed to match the axis of rotation of the actuator. The output of this actuator is directly connected to the torsion bar using M5 shoulder bolts. Each bolt is designed to support 3 bearings: 2 on the motor side and 1 on the patient side. The reduced count on the patient side allows for the torsion bar to be partially recessed in the shank link to reduce the distance between the center of mass between the patient and the joint. The 6 bearings are still able to support the forces necessary throughout a walking gait cycle (see

section 3.2).

Shank Links

The 2 shank links attach to the lower part of the exoskeleton, and are responsible for taking the rotational energy created by the motor and partially changing it to translational energy to help linearly extend the shank. The bearings connected to the torsion bars ride in a guide built into the shank link. This guide is slightly larger than the bearing diameter (0.3mm) to prevent rubbing without creating much of a backlash (0.39° backlash, see calculation on Equation 3.2).

$$\text{Backlash} = \text{atan}\left(\frac{\frac{0.3\text{mm}}{2}}{22\text{mm}}\right) = 0.39^\circ \quad (3.2)$$

The surface of the guide must be smooth and parallel to the axis of the bearings to avoid damaging them. Depending on the material and manufacturing method chosen, the surface may require additional machining to ensure it can match these requirements. The length of the guide must be larger than the distance between the centers of the two shoulder bolts plus the maximum distance of linear extension by the knee (Equation 3.3). For this prototype, this length was 78mm.

$$\text{GuideLength} \geq \text{TorsionBarC2C} + \text{MaxKneeExtension} = 44\text{mm} + 34\text{mm} = 78\text{mm} \quad (3.3)$$

The shank link is also responsible to connect to the lower part of the exoskeleton. Just like the thigh link, this is done through the universal exoskeleton con-

nector developed throughout the WPI LARRE project [24].

The connection between the thigh link and the shank link is very important, as it adds torsional stability and overall rigidness to the entire joint. It was therefore imperative during the design process to create wide surface contact between the thigh and shank links. To reduce the energy lost to friction between these plates, 3.2mm thick Delrin® slides were laser cut and attached to the shank link.

Similarly to the torsion bar, the shank link also uses 2 shoulder bolts to clamp the two shank links on the thigh link as well as to give the bearings that ride on the knee path guide a precise surface to mount to. To maintain a consistent clamping force, lock nuts are used since they do not easily back out with movement and vibration.

Thigh Link

The thigh link acts as the main mounting point for most things, as well as contains the knee path guide. Just like the shank link, the thigh link has the universal exoskeleton connector used throughout the WPI LARRE project. The motor bracket is connected to the thigh link at two locations using $20mm\phi \times 50mm$ spacers. These spacers must be strong and stiff, as they transmit the torque between the thigh and shank connector in high load situations. A potentiometer is also mounted inside the thigh link to measure the current angle of the joint, as shown in Figure 3.4. The wire connecting to it is routed through a slot in the thigh link to avoid any interference with the moving shank links. This wire comes out the top and is connected to the main controller of the exoskeleton.

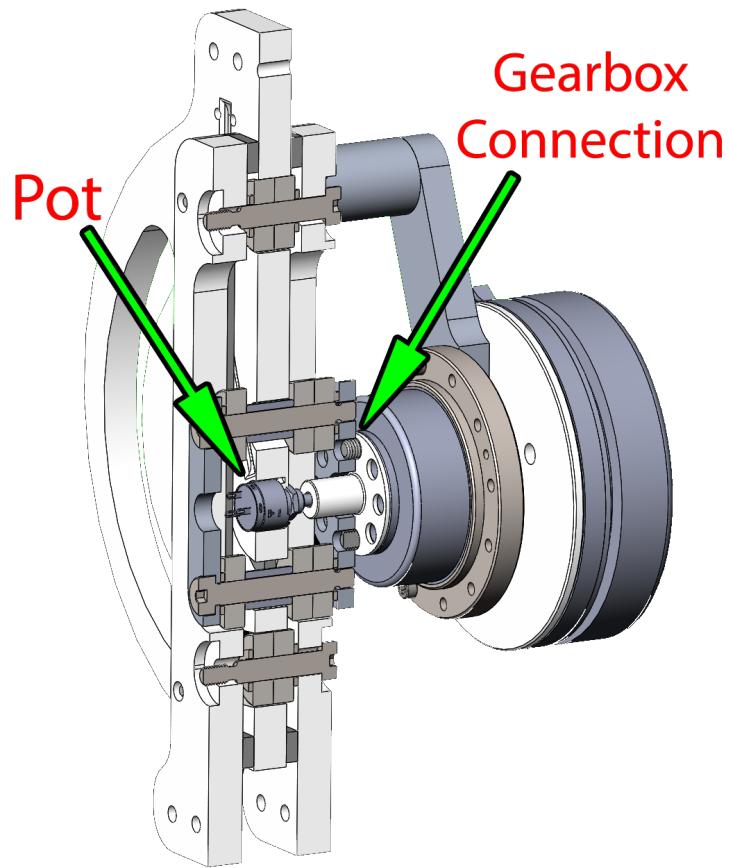


Figure 3.4: A cross section of the knee joint in a 0° position

Knee Path Guide

The knee path guide is built into the thigh link as a slot. The geometry is calculated using several point measurements connected in SolidWorks with a spline. Each point is split by 15 degrees, and calculated from a pre-determined equation. This equation can be measured from a patient knee (see chapter 4), but throughout the design and testing of this knee joint, Equation 3.1 from [19] is used. Figure 3.5

shows the equation above overlayed on the thigh link.

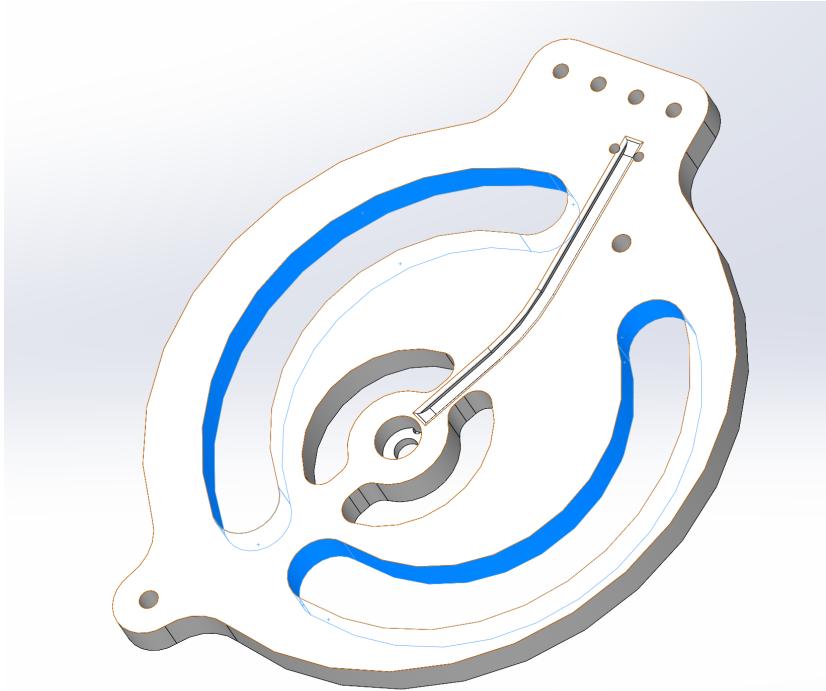


Figure 3.5: The thigh link contains the geometry (highlighted in blue) which the bearings ride on to mimic the tibiofemoral relationship

The joint is designed to be easily adaptable between patients. Therefore, the only customized part in the entire system is the thigh link which holds the knee path guide. All other parts remain the same to decrease cost and improve repairability.

Torque Requirements & Actuator Selection

The design parameters specified in section 3.1 are an output of at least $65W$ and $25Nm$ at $15^\circ/sec$. The Maxon EC90 was chosen, with a peak power output of

Input (Motor) Power	P_{input}	90Watts
Input (Motor) Torque @ Nominal	τ_{input}	0.560Nm
Input (Motor) Speed @ Nominal	ω_{input}	2510rpm
Input (Motor) Stall Torque	τ_{in_stall}	7.480Nm
Gearbox Ratio	$\frac{n_1}{n_2}$	100 : 1
Output Power	P_{output}	81Watts
Output Torque @ Nominal	τ_{input}	50.4Nm
Output Speed @ Nominal	ω_{input}	15°/sec
Output Stall Torque	τ_{out_stall}	673.2Nm

Table 3.1: Motor/gearbox specifications and output power specifications of the proposed joint. See Appendix A for all equations and calculations used.

90W and a max continuous torque of 0.560Nm at 2510rpm (see Appendix B). To match the speed and torque requirements, a 100 : 1 gearbox ratio is needed. Due to its high reduction to size ratio, a strain wave gearbox from Harmonic Drives™ was chosen.¹ Estimated efficiency of this gearbox is roughly $\varepsilon = 90\%$.

The output power of the joint is 81W, with a nominal torque of 50.4Nm at 15°/sec. Power, torque, and speed specifications of the joint theoretically exceed the requirements. Physical testing is needed, however, to ensure that these numbers are accurate and sufficient for a rehabilitation exoskeleton.

Potentiometer and Rotary Encoder

A potentiometer was embedded into the knee design to act as an absolute rotary encoder to measure the current angle of the joint. Its purpose is twofold: to provide for an absolute angle at any given time and to provide for rough rotary encoding when a the motor (for passive experimentation). As mentioned above, the

¹The gearbox used is proprietary, and no datasheet is available

integration needed to protect the sensitive connection points. The potentiometer chosen was the Vishay PRV6, with 200° of travel, a linear resistance, and $\pm 1\%$ tolerance, which equates to a sensed tolerance of $\pm 2^\circ$.

The motor used also has 3 hall sensors used for pinpointing the position of the rotor versus the stator. Since the motor has a 12 poles and 3 sensors (totaling 36 pulses per revolution) as well as a 100:1 reduction through the gearbox, the hall effect sensors can be used to create an effective 3600 pulses per revolution encoder. When used in conjunction with the absolute encoder, the encoded angle can be very precise.

Bearings

All 10 bearings used in the design are the same (for simplicity and reduction of cost): 19mm outside diameter x 6mm inside diameter x 6mm thick double shielded ball bearings (Model 626ZZ). Each is rated for $2.6kN$ dynamic load and $1.05kN$ static load. Before selecting these bearings, two calculations were required to ensure these bearings could support the forces required.

The first is the requirement of the torsion bar. Given the max torque requirement for the project is $25Nm$ and the torsion bar is $44mm$ from center to center, Equation 3.4 calculates that the total load on all 6 bearings used is $1136N$, equal-

ing to roughly $190N$ per bearing.

$$\text{Total Load per Torsion Bar Bearing} : \frac{1}{6} \times \frac{25Nm}{44mm/2} = \frac{1}{6} \times \frac{25Nm}{0.022m} = 189.4N \quad (3.4)$$

The second force requirement for these bearings were in the knee path cam. Each knee joint must be able to hold half of the weight requirement of $100kg$ statically. Equation 3.5 demonstrates that each of the 4 bearings used in the cam will see a maximum static load of $245N$ per bearing.

$$\text{Total Load per Cam Bearing} : \frac{1}{4} \times 100kg \times 9.81m/s = 245.3N \quad (3.5)$$

3.3 Material Selection & Manufacturing

The concept behind the joint is not dependent on material choice. However, when it came time to manufacture the prototypes, two materials were selected as potential options: aluminum and polylactic acid (PLA) plastic. Aluminum benefits from its strength to weight ratio and manufacturing simplicity when it is being machined. PLA plastic, on the other hand, can be injection molded or 3D printed using fused deposition modeling (FDM) printers. This makes PLA more flexible and less expensive, at the cost of softness and strength when compared to aluminum.

Material	Aluminum	PLA
Mass Density [kg/m^3]	2700	1420
Tensile Strength [N/mm^2]	124.08	57.3
Yield Strength [N/mm^2]	55.15	14.3
Shear Modulus [N/mm^2]	26000	55000

Table 3.2: Material properties used when analyzing each material in FEA simulation in SolidWorks

Other plastics and metals were initially considered. Out of the 3D printable plastics that were accessible with the tools available, PLA is strongest, stiffest, and hardest. Other FDM 3D printable plastics considered were acrylonitrile butadiene styrene (ABS) and polyethylene terephthalate (PET). On the metals, side, steels were considered as a material option. However, its density and higher complexity to machine when compared to aluminum ruled it out as a material option.

Material Analysis

To decide between aluminum and PLA, the materials were analyzed in finite element analysis (FEA) simulation inside Dassault SolidWorks. Table 3.2 shows the material properties used. It is important to note that manufacturing methods were not considered in the analysis; therefore, layer adhesion was not considered when calculating the strength of the material.

PLA was chosen as the best material for our experimentation. Analysis demonstrated that it can support the stresses required at angle (shown in Figure 3.8). It can also be manufactured very quickly and easily with access to a conventional FDM 3D printer, allowing for quick revisions during the prototyping process. The

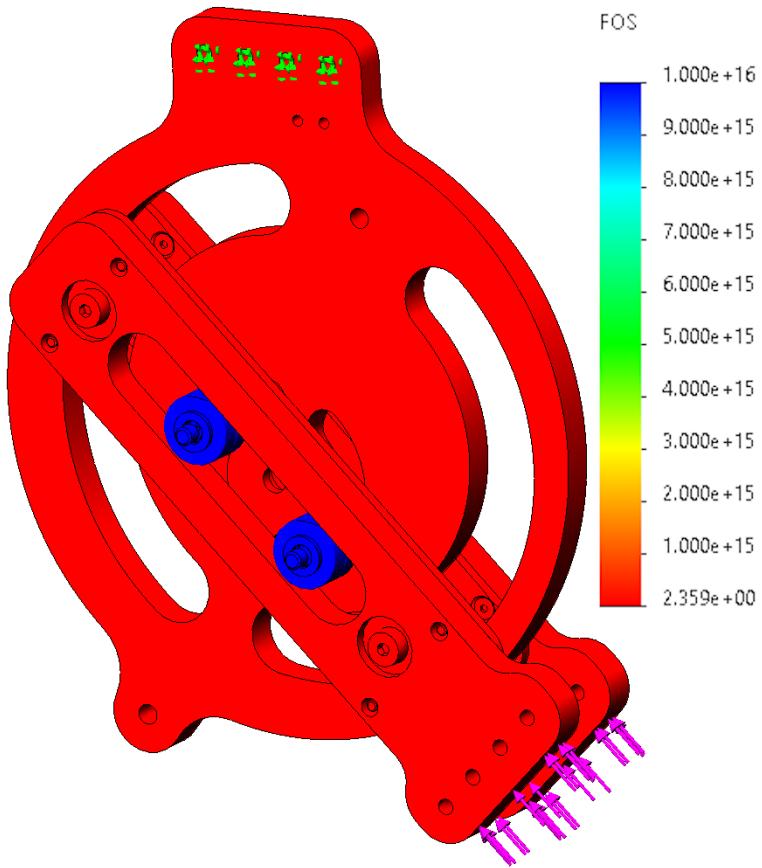


Figure 3.6: FEA of knee joint manufactured from PLA. Force applied (at arrows) is 500N, the resultant safety factor is 2.359.

final prototype was manufactured out of both aluminum and PLA; the thigh and shank links were 3D printed in PLA plastic while the torsion bar was machined out of aluminum to support the torque required.

However, if this joint were to be manufactured for use outside of prototype development and clinical trials, I would recommend using aluminum, as the joint would likely be more resilient and last longer. It would also increase torsional

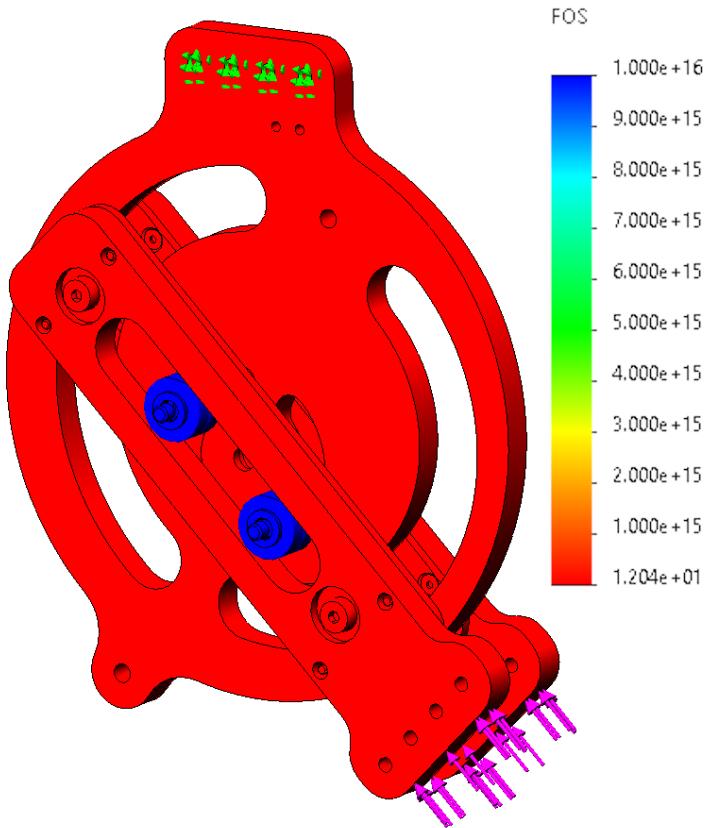


Figure 3.7: FEA of knee joint manufactured from Aluminum. Force applied (at arrows) is 500N, the resultant safety factor is 12.04.

stiffness in the joint and reduce the likelihood of the bearings creating divots in the surface of the knee path guide.

Manufacturing

The manufacturing process between the two materials is very different as well. While there are many different ways of creating parts in either material, the research will focus on the most common ways as to be easily replicated by others if

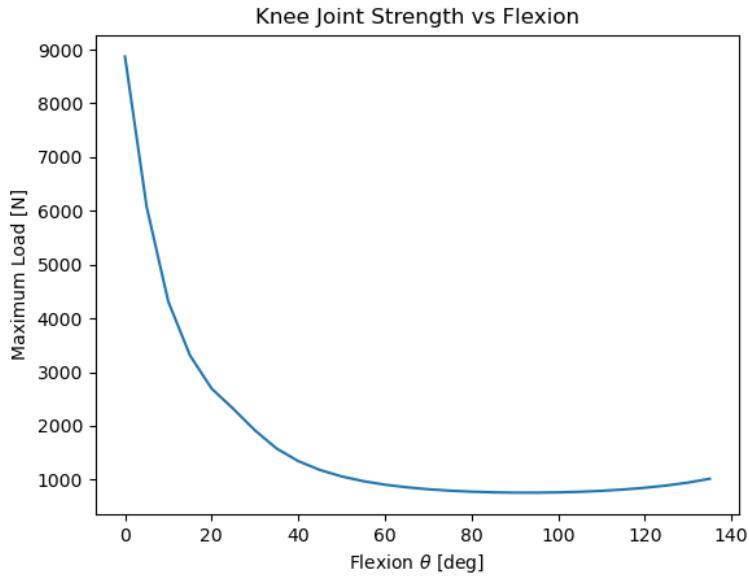


Figure 3.8: Analysis of the joint with major components manufactured out of PLA shows that the design is weakest at a 90° flexion, with a maximum static load of 757N per joint.

desired.

As a plastic, PLA has many options for manufacturing. While PLA can be injection molded or machined, the most common use case for it is through FDM 3D printing. The accessibility and low cost at low production numbers makes this method of manufacturing the best for our use cases for the larger of our parts as well as any part that doesn't deal with big forces. For this project, a Creality Ender 3 was used to 3D print the parts required.

Aluminum can also be 3D printed, but this requires some very specific tools to achieve. It can also be casted (similarly to injection molding for plastics), but this requires specific machining for the molds, and the parts still usually need

to be machined to the final correct dimensions (the best option for high volume manufacturing). Therefore, all aluminum parts were designed to be manufactured using conventional lathes and mills. The manufacturing process, however, can be further simplified with access to a water jet or metal laser cutter. Such a tool can cut out all parts to a rough dimension, and a quick machining pass can finish the surfaces that need to be precise, such as the knee path guide and the slot in the shank link. If water jetting is selected as the preferred method of manufacture, parts may have a slight bevel due to the conical output of the water jet.

3.4 Knee Trajectory Testing

Motion capture and SolidWorks motion simulations were used to verify the joint's trajectory based on an inputted tibiofemoral trajectory. The motion simulation outputted a perfect match to the input equation (Equation 3.1), since the simulation platform is using a perfect model which directly inputs the equation above.

To further verify the relationship, a 10-camera Vicon Vantage 5 motion capture system was used. 9 motion capture dots were placed strategically around the knee joint. Two rigid bodies were used (each containing 4 motion capture dots) to be able to measure position and orientation in all 6 degrees of freedom. One rigid body was placed on the connector on the shank link, while the other was attached to the connector of the thigh link. A final motion capture dot was placed at the joint center. Then, the joint was manually actuated through its range while collecting

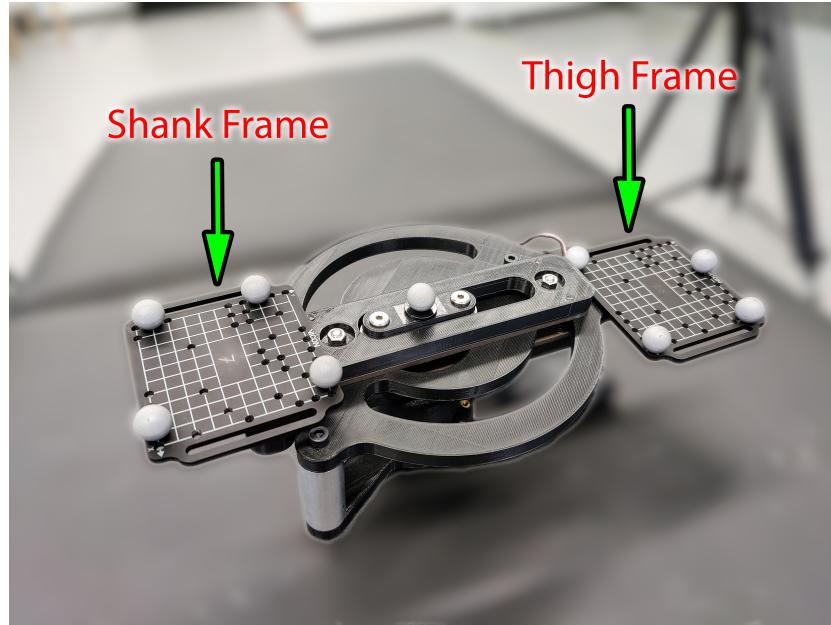


Figure 3.9: Experimental setup for measuring the trajectory of the manufactured joint. 9 motion capture dots were used to measure any movement in all 6 degrees of freedom.

data from the motion capture system. The data was processed using software tools developed in chapter 4 for measuring human tibiofemoral relationships. To ensure the data collected remained representative of the test and was not modified by any processing tools developed, only data importing tools were used. These tools simply took the raw data from the Vicon system and imported it into Python in a cleaner way.

The motion capture analysis data in Figure 3.10 demonstrates the effectiveness of the joint; it was able to follow the desired trajectory layed out in Equation 3.1 with minimal error (deviation from goal trajectory under 1mm).

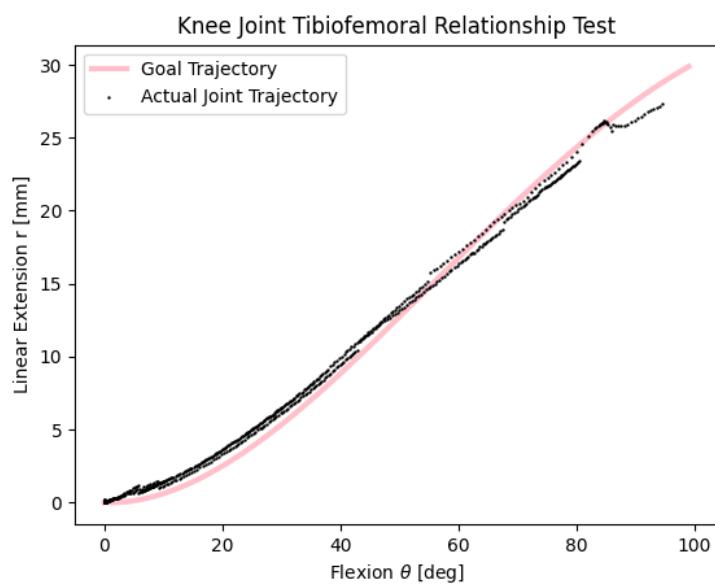


Figure 3.10: Results from the motion capture system demonstrates that the designed knee joint can follow a desired trajectory very closely, only deviating by 1mm maximum

Chapter 4

Parameterization of Human Knee Joints

In order for the designed knee joint to work on real patients, a system needs to be developed which can parameterize a person. A successful system will be able to non-invasively create a relationship between flexion of the knee joint and the linear movement of the shank away from the joint center. There have been several attempts to parameterize the human knee joint using many different methods, including [18], [16], [12], and [17] just to name a few. All of these studies focus on the tibiofemoral relationship, i.e. the bone movement within the lower limbs. However, rehabilitation exoskeletons connect to the skin of its user. Therefore, an imaging workflow and software processing program needs to be developed to be able to parameterize a patient's knee movement with consideration to skin movement.

4.1 Proposed Method of Imaging

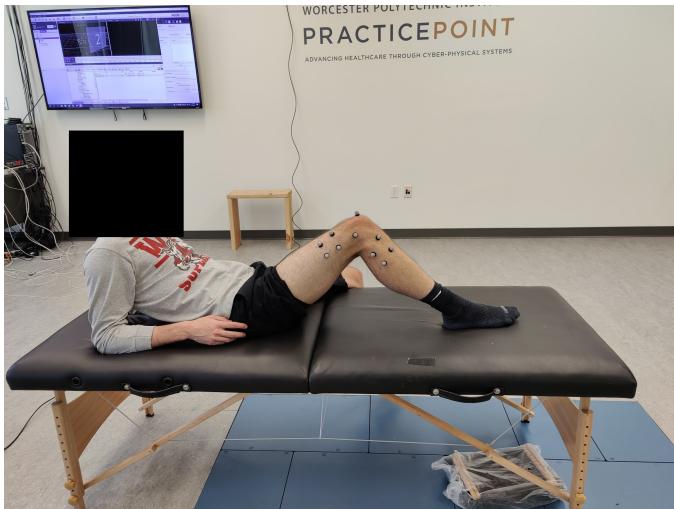


Figure 4.1: Depicts the patient position during motion capture. The patient will then flex and extend their knee while keeping their heel on the table.

The proposed imaging workflow can be split up into two major parts: the imaging session and the software processing. For flexibility and speed, the usage of a motion capture system is proposed, which can develop accurately track the position of motion dots. In this study, the motion capture system used was a 10-camera Vicon Vantage 5¹, but any motion capture system is usable given enough precision.

To measure the knee flexion, a patient is placed on their back, shown in Figure 4.1. Motion capture dots are then placed on the patient to track the positions where the exoskeleton will attach to the skin. Two additional points can be placed on the knee for extra feedback and the final joint position, but are not necessary

¹See Vicon system here: <https://www.vicon.com/hardware/cameras/vantage/>

for the software system. Then, the patient will flex and extend their knee joint while keeping the heel on the table to stabilize the knee and prevent shanking. The placement of the patient should allow for a technician to help the patient bend their knee if their condition does not allow them to do so themselves. Once the data is collected, it can be processed by the parameterization software system.

4.2 Parameterization Software

The collected data first goes through a Vicon workflow for processing. This will properly format the data, create virtual joints, and determine joint centers. This is done using the built-in tools called SCoRE (Symmetrical Center of Rotation Estimation) and SARA (Symmetrical Axis of Rotation Analysis). Additionally, a built-in tool will determine the angle of the knee joint using the four dots on each section of the patient's leg. This Vicon specific workflow can be exported, shared, and reused for others who are using a similar system. The output of the workflow is a CSV file which can be parsed by a custom script.

To finish the parameterization of the knee, custom software was developed and written in Python. This software utilizes the AiM Vicon Python module² which parses the CSV file from above. The joint angle, SARA, SCoRE, and marker positions are extracted from the data and placed in their specified datatypes. Since the AiM Vicon module did not have all the tools needed for this project, I developed and contributed to the Python module. Additional features added include

²The AiM Vicon Python module is an open-source project found here: https://github.com/WPI-AIM/AIM_Vicon

SARA and SCoRE support, a new 3D visualizer, and stability improvements when importing different workflows.

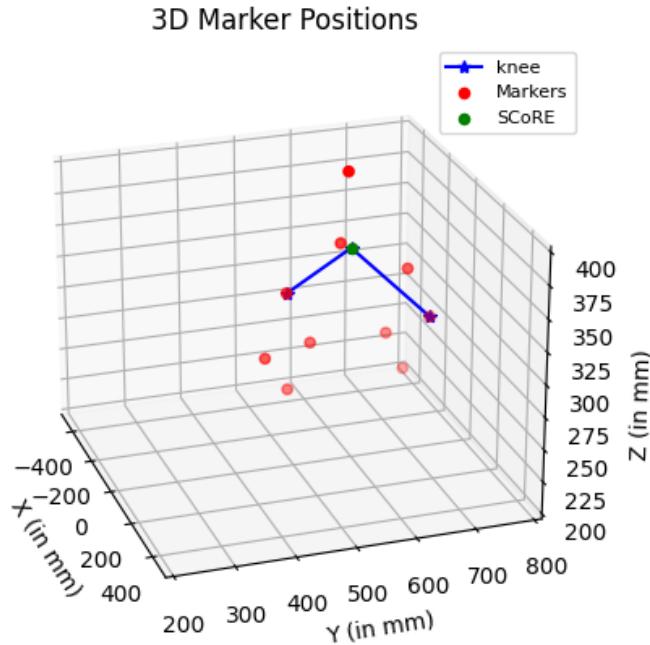


Figure 4.2: An example of a possible output from the Parameterization Software System shown in a visualizer

With the data parsed and imported, the final step is to calculate the final joint angles and determine the linear extension between the thigh and shank. The axis of rotation from SCoRE and all marker positions are projected onto a plane, which is calculated to be approximately the same as the plane of the manufactured joint. Then the final distance and angle are calculated by drawing two virtual lines as

shown in Figure 4.2: 1. from the projected primary thigh marker to the projected SCoRE location and 2. from the projected SCoRE location to the projected primary shank marker. The lengths of these lines then become the calculated linear extension and the angle between these two lines become the flexion. These two metrics are then combined into a dataset, and a best fit quartic curve is selected to become the patient's knee parameters.

4.3 Study Outline

As a part of this thesis, an study was designed to test the developed parameterization software as well as the knee joint's capability to be customized to a specific person. However, due to time constraints, IRB (Internal Review Board) approval to run the human study was not obtained, and therefore the study was not run. The study's methodology is outlined below, and the IRB proposal documents are attached in Appendix C.

Up to 6 subjects are to be selected to partake in this study. Each subject should not have any prior severe knee injury, and should be cleared to be imaged with an MRI. The study will start with imaging the knee using the motion capture procedures outlined in section 4.1, and parameters will be selected using the parameterization software developed. These parameters will be used to manufacture an MRI safe personalized knee joint. Additionally, a second non-personalized pin joint will be manufactured and used as a control.

The second stage of the study will compare the fit of the two joints. The subject

will undergo MR scans at up to 3 different knee angles, first with no joint and then subsequently with each type of joint. The movement (if any) of the joint in reference to the subjects body will be measured. A successful experiment should demonstrate that the customized knee joint moves less than a non-customized pin joint. Additionally, the tibiofemoral movement can be compared to the measured parameters to determine how much the skin moves relative to the knee joint.

Chapter 5

Conclusion & Future Work

5.1 Conclusion

The proposed knee joint developed and tested in this thesis succeeded in all design requirements, even exceeding them in some scenarios. Experimentation showed that the knee could follow a defined tibiofemoral joint trajectory within 1mm of accuracy. The joint itself can also be easily customized to each patient, with only one custom part needing to be manufactured per person per joint. Integrated sensors allow it to sense joint position and report it to the WPI LARRE hardware controllers. Strength analysis demonstrated that the joint can be manufactured from either PLA plastics using a conventional FDM 3D printer or machined out of aluminum. The joint will be able to support the stresses that come from common rehabilitation exercises including sit/stand exercises and walking gait exercises. Finally, the joint will be able to be integrated in the WPI LARRE



Figure 5.1: A picture of a left-sided knee joint prototype manufactured as a part of this thesis

(Legged Articulated Robotic Rehabilitation Exoskeleton). However, the design proposed is not limited to exoskeletons; the concept of using a cam mechanism to match tibiofemoral relationships can be applied to other orthoses that need to be powered.

Additionally, a workflow for determining parameters for the customizable knee joint was proposed. The Vicon workflow as well as the custom software system was developed and set up for testing. This included development on the Python AiM Vicon module used to process Vicon data sets as well as the software system designed to generate the parameters needed to customize a knee joint based

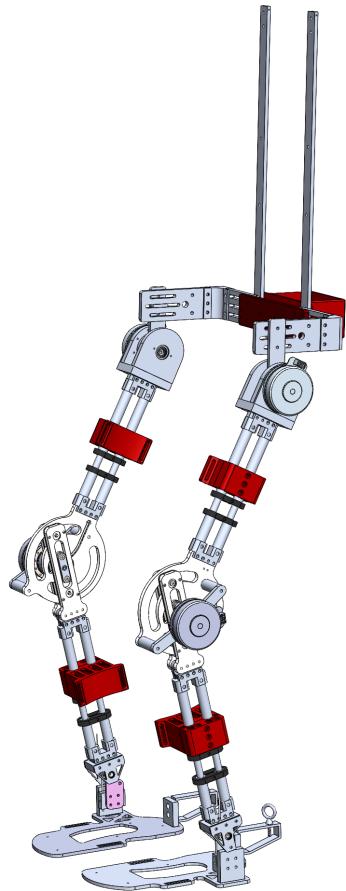


Figure 5.2: Proposed knee joint mounted to a model of WPI LARRE

on a person's anatomy. Additionally, a full human trial study to test both the developed knee joint and the software system to choose parameters was planned and set up.

5.2 Future Work

While the design was able to match and even exceed the design requirements, more research is needed. From a design perspective, the joint can be made much smaller than the existing design. The motor and gearbox can be integrated in the joint to offer a lower profile exterior. Additionally, a more efficient and less expensive no-backlash gearbox such as a cycloidal gearbox can be integrated to replace the Harmonic™ gearbox used in this study.

Additionally, more research is needed in knee movement in an exoskeleton. The research discussed in section 2.2 demonstrates the relationship between the tibia and femur, and does not look how skin movement changes the trajectory. Studies using the parameterization method discussed in chapter 4 may demonstrate a more accurate relationship to be used with this knee joint, as well as determine the parameters of a patient’s knee. This would create a future where a lower-limb paralysis patient would be able to receive a perfectly personalized knee joint for their rehabilitation exoskeleton using an imaging system.

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Appendix A

Joint Power/Torque/Speed Calculations

Input (Motor) Power	P_{input}	90Watts
Input (Motor) Torque @ Nominal	τ_{input}	0.560Nm
Input (Motor) Speed @ Nominal	ω_{input}	2510rpm
Input (Motor) Stall Torque	τ_{in_stall}	7.480Nm
Gearbox Ratio	$\frac{n_1}{n_2}$	100 : 1

Table A.1: Motor/Gearbox Specifications

Power Calculation

$$P_{output} = \epsilon P_{input} = 0.9 * 90W = 81W \quad (\text{A.1})$$

Torque Calculation

$$\tau_{output} = \epsilon \tau_{input} \frac{n_1}{n_2} = 0.9 * 0.560 Nm * \frac{100}{1} = 50.4 Nm \quad (A.2)$$

Speed Calculation

$$\omega_{output} = \omega_{input} \frac{n_2}{n_1} = 2510 rpm * \frac{100}{1} = 2.510 rpm = 15^\circ/sec \quad (A.3)$$

Output Power	P_{output}	81Watts
Output Torque @ Nominal	τ_{input}	50.4Nm
Output Speed @ Nominal	ω_{input}	15°/sec
Output Stall Torque	τ_{out_stall}	673.2Nm

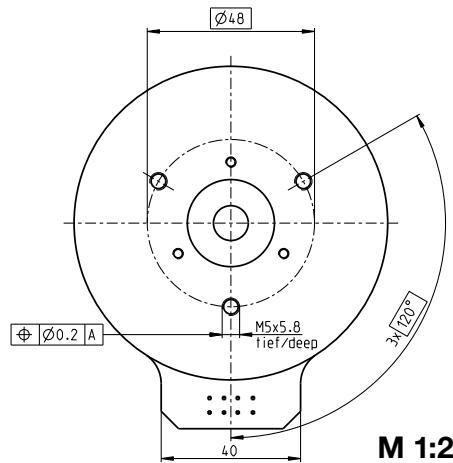
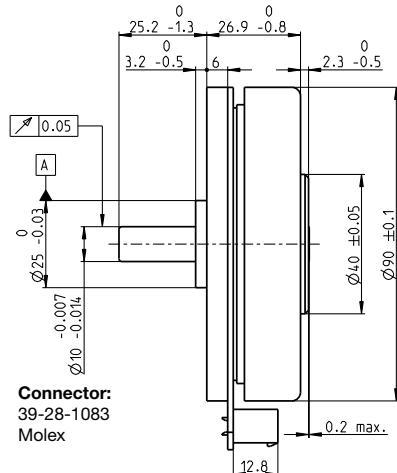
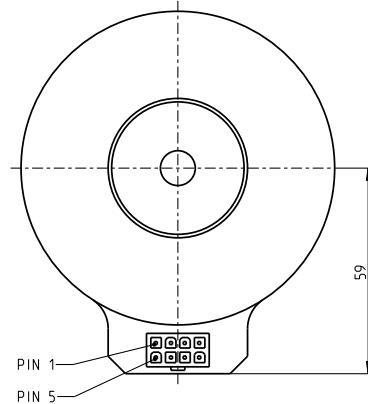
Table A.2: Joint Output Specifications

Appendix B

Maxon Motor EC90 Datasheet

Below is the datasheet for the motor chosen for this project: Maxon EC90 part number 429271 (highlighted)

EC 90 flat Ø90 mm, brushless, 90 Watt



 Stock program
 Standard program
 Special program (on request)

Part Numbers

with Hall sensors

323772 **429271** **244879**

Motor Data

Values at nominal voltage

1 Nominal voltage	V	24	36	48				
2 No load speed	rpm	3190	3120	2080				
3 No load current	mA	544	348	135				
4 Nominal speed	rpm	2590	2510	1610				
5 Nominal torque (max. continuous torque)	mNm	444	560	533				
6 Nominal current (max. continuous current)	A	6.06	4.76	2.27				
7 Stall torque	mNm	4940	7480	4570				
8 Stall current	A	70	69	21.1				
9 Max. efficiency	%	84	87	85				

Characteristics

10 Terminal resistance phase to phase	Ω	0.343	0.522	2.28				
11 Terminal inductance phase to phase	mH	0.264	0.625	2.5				
12 Torque constant	mNm/A	70.5	109	217				
13 Speed constant	rpm/V	135	88	44				
14 Speed/torque gradient	rpm/mNm	0.659	0.423	0.462				
15 Mechanical time constant	ms	21.1	13.6	14.8				
16 Rotor inertia	gcm²	3060	3060	3060				

Specifications

Thermal data

17 Thermal resistance housing-ambient	1.91 K/W							
18 Thermal resistance winding-housing	2.6 K/W							
19 Thermal time constant winding	46 s							
20 Thermal time constant motor	283 s							
21 Ambient temperature	-40...+100°C							
22 Max. winding temperature	+125°C							

Mechanical data (preloaded ball bearings)

23 Max. speed	5000 rpm							
24 Axial play at axial load < 15 N	0 mm							
> 15 N	0.14 mm							
25 Radial play	preloaded							
26 Max. axial load (dynamic)	12 N							
27 Max. force for press fits (static)	183 N							
(static, shaft supported)	8000 N							
28 Max. radial load, 5 mm from flange	68 N							

Other specifications

29 Number of pole pairs	12							
30 Number of phases	3							
31 Weight of motor	600 g							

Values listed in the table are nominal.

Connection

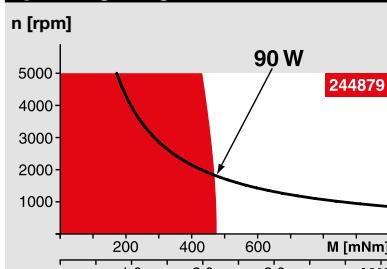
Pin 1	Hall sensor 1
Pin 2	Hall sensor 2
Pin 3	V _{hall} 4.5...18 VDC
Pin 4	Motor winding 3
Pin 5	Hall sensor 3
Pin 6	GND
Pin 7	Motor winding 1
Pin 8	Motor winding 2

Wiring diagram for Hall sensors see p. 43

Cable

Connection cable Universal, L = 500 mm	339380
Connection cable to EPOS2, L = 500 mm	354045

Operating Range



Comments

Continuous operation

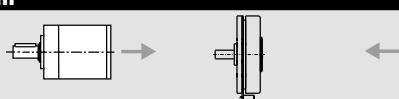
In observation of above listed thermal resistance (lines 17 and 18) the maximum permissible winding temperature will be reached during continuous operation at 25°C ambient.
= Thermal limit.

Short term operation

The motor may be briefly overloaded (recurring).

Assigned power rating

maxon Modular System



Overview on page 28-36

Planetary Gearhead

Ø52 mm
4 - 30 Nm
Page 351

Encoder MILE
512 - 6400 CPT,
2 channels
Page 390

Recommended Electronics:

Notes	Page 32
ESCON Mod. 50/4 EC-S	427
ESCON Mod. 50/5	427
ESCON 50/5	428
ESCON 70/10	428
DEC Module 50/5	430
EPOS2 24/5, 50/5, 70/10	435
EPOS2 P 24/5	438
EPOS4 Module/CB 50/5	442
EPOS4 Module 50/8	443
EPOS4 Comp. 50/8 CAN	443
MAXPOS 50/5	447

Appendix C

Knee Parameterization Study

Research Documents

C.1 Research Proposal

C.1.1 Project Summary

Powered exoskeletons have the potential to help paraplegic patients' physical rehabilitation through exercise and bone loading. The human knee joint has usually been approximated as a pin joint to simplify designs of exoskeletons, but this simplification can cause discomfort from the rubbing between the exoskeleton and the patient's skin. Studies have shown that the knee joint does not have a fixed rotation axis but rather extends as it bends.

This project aims to develop a customizable bio-mechanical knee joint to bet-

ter follow the flexion and extension patterns of the human knee. Using a motion capture system, knee trajectories will be measured for each subject and a customized bio-mechanical joint will be manufactured based on the trajectories. The knee design and trajectory will then be verified by magnetic resonance imaging (MRI), through which the movement between a plastic version of the customized exoskeleton joint and the subject's underlying skeleton will be quantified.

C.1.2 Human Research Summary

Up to 6 subjects with no prior severe knee injury will be recruited. A motion capture study will capture their knee movement with the subject both in a standing position and a lying down position. These marker trajectories will be processed by a custom algorithm which will generate a 3D model of their customized exoskeleton knee joint. To verify the joint works as expected, the joint will be manufactured from 3D printed plastic, and standard MR markers will be attached to the plastic. This non-powered MRI safe joint will be attached to the corresponding subject with Velcro straps and imaged with the knee in 3 different positions. Additionally, a generic MRI safe pin-joint knee with MR markers embedded will be constructed and attached to each subject and imaged with the knee in 3 different positions. A successful study will demonstrate less movement between the customized knee and the subject's skeleton than a generic pin joint.

C.1.3 Research Methodology

1. Up to 6 subjects will be selected to partake in the study. Subjects with prior severe knee injury (such as knee replacements or knee surgery) or any MR contraindications will be excluded from the study.
2. Each subject is expected to have 1 motion capture session and 1 MR imaging session. These sessions will take place on 2 separate days. Their name, age, gender, mass, and height will also be collected, but will be separated from all images and motion capture data collected in the study. Each subject will remain anonymous within study data.
3. Subjects will first have their knees' flexion and extension measured during the motion capture session. Motion capture markers will be placed on the right thigh and right lower leg using Velcro straps. Subjects will be asked to lay down on a table and bend their knee back and forth several times, capturing the knee motion when the leg is unloaded. Subjects will then be asked to stand and walk back and forth several times through the motion capture area, capturing the knee motion while the leg is loaded. The position of each marker will be recorded by the motion capture system and analyzed by custom software to determine flexion and extension. These parameters will be stored with their corresponding subject numbers as the only identifiable marker.
4. The parameters generated during the motion capture session will be used to manufacture a custom knee joint for each of the subjects. The knee will be printed from ABS or PLA plastic and have no metal components. It will not be powered by a motor; it will only move passively with the motion of the subject's

leg. Standard MR imaging markers will be attached at 3 locations of the plastic knee.

5. A second, generic joint will be constructed using the same materials. This joint will have a simple pin joint and be used to compare the performance of the customized joint against.

6. After the custom and generic joints are constructed, they will be reviewed and tested by PracticePoint's MR safety manager who will determine to be MR Safe.

7. Each subject will return for an MR imaging session. MR scans will be taken at up to 3 different knee angles with the customized joint attached to the subject. These scans will then be repeated for the generic knee. The imaging sequences used will be standard 3D sequences from the GE knee imaging protocol library. The angles will be decided at the time of the scan and chosen to allow maximum range of motion. Subjects will be allowed to change into clean scrubs/gowns provided by PracticePoint. All image metadata will refrain from using subjects' real names to avoid any identifiable exposure. A key matching subject number to their corresponding persons and their contact information will be kept in locked cabinet in a locked room in PracticePoint.

C.2 Informed Consent Agreement

Informed Consent Agreement for Participation in a Research Study

Investigator: Alex Tacescu

Contact Information:

Tel. : [Redacted]

Email: [Redacted]

Title of Research Study: Development of a Customizable Bio-Mechanical Actuated Knee Joint for Exoskeleton

Introduction

You are being asked to participate in a research study. Before you agree, however, you must be fully informed about the purpose of the study, the procedures to be followed, and any benefits, risks or discomfort that you may experience as a result of your participation. This form presents information about the study so that you may make a fully informed decision regarding your participation.

Purpose of the study:

Human knees tend extend as they are bent at a different rate between people. This study aims to look at the flexion and extension patterns in different people using a motion capture system and a Magnetic Resonance Imager (MRI).

Procedures to be followed:

This study will specifically look at the shape and internal structure of your knee and mid-leg skeletal system. The study will comprise of two separate days.

1. On the first day, you will go over this consent form. You will also fill an MRI screening form, which asks about your past medical history to determine if there are contraindications for your participation in the study. All medical history data will be kept confidential and will **NOT** be publicized with the results of the study.
2. After the onboarding process (step 1), you will go through the first part of the study: the motion capture session. You will have special dots placed on you, and a system will determine and track the position of those dots.
3. You will be asked to come back on a later day (roughly in a week) and a new customized biomechanical joint will be manufactured in the meantime.
4. On the day of the MRI, you will once again go over your MRI screening form with an MRI technician to ensure your medical history has not changed. You will also be given a chance to change into clean scrubs (provided by PracticePoint).
5. You will have an MRI safe biomechanical joint attached to you before you enter the MRI. The MR imaging session will consist of approximately 3 imaging sequences of your knee at approximately 3 different angles. Each scan should take

roughly 15 minutes, with a short setup period beforehand. Pictures of your knee at each angle will also be taken before you enter the MRI system.

Motion Capture Study time to complete: **roughly 1 hour**

Magnetic Resonance Imaging (MRI) Procedure time to complete: **roughly 1 hour**

All image data will be anonymized, and your name will be omitted from all published material. A key will be kept ensuring continuity between the first and second scan. To read more about the study's privacy policy, please see the section titled *Record Keeping and Confidentiality* below.

This study involves a magnetic resonance imaging (MRI) scan. MRI is a technique for taking images of the body's internal structures. It uses a magnetic field and radio waves – no ionizing radiation is used. We will take you to the MRI imaging suite at WPI's PracticePoint research facility and ask you a series of safety questions before we bring you into the MRI room. Some of these questions might be repetitive but it is important that we make sure it is safe for you to have an MRI scan.

Because the scanner contains an extremely strong magnet you will be asked to remove all metal objects on you and place them in a provided locker. This includes items including watches, rings, necklaces, bracelets, earrings, and other body piercings, belts, loose change, wallet (with credit cards), items of clothing containing magnetic materials (for example, under wire bras, certain types of zippers), and shoes. It is recommended that you leave valuables and jewelry at home. We will ask you to change into a provided hospital gown or scrubs in our screening/changing room before you go into the scanning room. Your clothing and personal items will be locked up in a safe place until the session is completed.

You will spend approximately 45 minutes in an MRI scanner, which looks like a large cylinder with a tube running down the center. You will be asked to lie down on your back on a foam padded table. An imaging coil will be placed on or around the part of the body we are scanning. The table slides inside the "hole" of the scanner. Soft foam sponges may be placed on both sides of your head or next to various parts of your body to help keep you still. A headset with microphone allows you to hear and talk to the technician operating the scanner at all times.

During the scanning procedure, you will hear a number of different sounds. These sounds, which can be loud, are part of the normal operation of the scanner. These noises vary with the particular scan being performed, and include sounds like a hammer hitting a piece of wood, repetitive buzzing noises, and long series of loud beeps. Some scans are silent. These sounds, or combinations of them, will then be repeated several times, depending upon the specific scan sequence being used. The sounds you hear during the scanning session will not harm your hearing, but you will be given a pair of earplugs to wear for your comfort. Even with these earplugs in you will always be able to hear the technician because they do

not block all sound. You are free to talk during the preparation time and during breaks, but you should not talk during the actual scanning process. During these sessions, you should try to remain as still as possible.

The entire duration that you will be in the scanner is not expected to be longer than 60 minutes. When the session is over the technician will move you out of the scanner and assist you from the table. You will then exit the scanner room, return to the screening/changing room to change back into your clothes and retrieve your belongings.

The MR images are stored digitally. Thousands of patients across the country safely undergo MR imaging in radiology departments every day. The MR imaging itself is not experimental; rather, it is well known to be safe.

Risks to study participants:

Magnetic Resonance (MR) imaging does not use ionizing radiation like an X-ray. Instead, it uses strong magnetic fields and radio-frequency waves to collect the images and data. There are no known serious health hazards or risks associated with these techniques for most people. However, significant risks may exist for people with:

- Cardiac pacemakers
- Aneurysm clips (in your brain) and other vascular stents (tubes in your veins), filters, clips, or other devices that have been surgically put in you for any reason.
- Prosthetic heart valves (a mechanical device that helps your heart pump blood)
- Other prostheses (a piece of equipment that replaces a missing part of the body)
- Neuro-stimulator devices (a piece of equipment that activates nerves)
- Implanted infusion pumps (a device that stays in your body and helps give you medicine)
- Cochlear (ear) implants (a device used to help you hear)
- Ocular (eye) implants (a device put in your eye to help you see)
- Metal fragments or pieces in eyes
- Contact with metal filings (people who are sheet metal workers, welders, or others could have this contact)
- Any surgeries where something metal was put in you
- Certain tattoos (please tell the study doctor if you have a tattoo so that we can make sure it is safe)
- Certain intrauterine contraception devices (IUD's)

You will be asked whether you have such devices and if so, you will not be able to participate in this study. Significant risks also can arise if certain types of metal objects are brought into the scanning area, as they can become hazardous projectiles. These types of items are not permitted in the scanning area, a locker will be provided for you to keep your belongings secure during the study. It is important to remember that *the Magnet is*

ALWAYS On even when a scan is not taking place. The exams are painless, and except for the pulsating sounds, you will not be aware that MR scanning is taking place.

This study will be conducted in an MR scanner which has been approved by the FDA for clinical and research studies. Although there are no known significant health risks from these scans, there could be adverse effects that are delayed or very mild, such that they have not yet been recognized. Most people experience no ill effects from the large magnetic field, but some people do report claustrophobia (fear of being in small spaces), dizziness, mild nausea, headaches, a metallic taste in their mouth, double vision or sensation of flashing lights. These symptoms, if present, disappear shortly after leaving the MR machine. If you experience discomfort from being in the scanner, you should notify the examiner immediately and you will be removed from the scanner. You will be provided a squeeze ball that sounds an alarm at the operator's console for this purpose. You should also note you will be asked to remain as still as possible during the scanning session. Remaining motionless can result in discomfort.

You may feel cramped inside the scanner. The technologist will be able to hear you at all times and you are free to end the procedure at any time.

In rare cases, a very slight, uncomfortable tingling of the back due to the rapid switching of the magnetic field has been reported during certain types of scans. In case you have such a sensation, you are asked to report this immediately, so the scan can be changed to avoid this. Although these precautions will avoid all known risks associated with MR, this procedure may involve risks to you that are currently unforeseeable.

Benefits to research participants and others:

There may be no benefit to being in this study. The images in this study are not being collected for the purpose of diagnosing a medical condition. The images will not be reviewed by a medical professional. If you feel that you have a medical condition requiring an MRI scan, you should schedule a visit with your primary care physician for a referral to a clinical imaging facility. In the unlikely event that a finding warranting further consultation with a physician is identified in your scans, you may be contacted by the study personnel. Any additional medical work or consultation needed as a result of this study will be the responsibility of the participant.

Record keeping and confidentiality:

All images will be labeled with an anonymized subject number. Images will be transferred off the scanner console at the end of each imagining session. Only anonymized images which do not reveal any personally identifying features will be used in publications or uploaded to open-source medical image repositories.

MR screening forms will be handled carefully by research staff. Once reviewed, these forms will be stored in a locked drawer inside of a locked room. They will only be reviewed by the research staff, the PracticePoint designated MR safety supervisor, and consulting medical professionals when required.

A key will be kept matching anonymized subject numbers and personally identifiable information – including contact information - in order to match data between the first and second scan. This key will be encrypted and password-protected and will be deleted at the end of the study. The key will not be shared with anyone except the investigators.

Records of your participation in this study will be held confidential so far as permitted by law. However, the study investigators, the sponsor or its designee and, under certain circumstances, the Worcester Polytechnic Institute Institutional Review Board (WPI IRB) will be able to inspect and have access to confidential data that identify you by name. Any publication or presentation of the data will not identify you.

Compensation or treatment in the event of injury:

If you are injured while participating in this study, seek treatment and contact the study principal investigator as soon as you are able.

WPI does not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, you should seek treatment as you would normally. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available.

You do not give up any of your legal rights by signing this form.

Cost/Payment:

Participating in this study will NOT require a payment, co-payment, or insurance charge. There will be no cost to you from being in this research study other than the cost of your transportation to WPI.

For more information about this research or about the rights of research participants, or in case of research-related injury, contact:

Primary Investigator: Alex Tacescu

Tel. : (559) 301-6222

Email: actacescu@wpi.edu

IRB Manager: Ruth McKeogh

Tel.: (508) 831-6699

Email: irb@wpi.edu

Human Protection Administrator: Gabriel Johnson

Tel.: (508) 831-4989

Email: gjohnson@wpi.edu

Your participation in this research is voluntary. Your refusal to participate will not result in any penalty to you or any loss of benefits to which you may otherwise be entitled. You may decide to stop participating in the research at any time without penalty or loss of

other benefits. The project investigators retain the right to cancel or postpone the experimental procedures at any time they see fit.

There are no risks to dropping out of this study.

By signing below, you acknowledge that you have been informed about and consent to be a participant in the study described above. Make sure that your questions are answered to your satisfaction before signing. You are entitled to retain a copy of this consent agreement.

Study Participant Signature

Date: _____

Study Participant Name (Please print)

Signature of Person who explained this study

Date: _____

Person who explained this study (Please Print)

Additional clauses to add to Consent Agreements, as appropriate:

Significant new findings or information, developed during the course of the research, may alter the subject's willingness to participate in the study. Any such findings will be promptly communicated to all research participants.

Should a participant wish to withdraw from the study after it has begun, the following procedures should be followed:

1. Please email the primary investigator as soon as possible. Make sure you get a confirmation from them. You may contact them at the following email:
actacescu@wpi.edu

There are no consequences from withdrawing from this study.

Special Exceptions: Under certain circumstances, an IRB may approve a consent procedure which differs from some of the elements of informed consent set forth above. Before doing so, however, the IRB must make findings regarding the research justification for different procedures (i.e. a waiver of some of the informed consent requirements must be necessary for the research to be "practicably carried out.") The IRB must also find that the research involves "no more than minimal risk to the subjects." Other requirements are found at 45 C.F.R. §46.116.