DESIGN OF PROTOTYPE PROSTHESIS FOR A CANINE WITH A RIGHT FRONT LIMB DEFORMITY AS AN ALTERNATE APPROACH TO STABILIZE GAIT AND WITHSTAND GAIT FORCES

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ABSTRACT

Design of Prototype Prosthesis for a Canine with a Right Front Limb Deformity as an Alternate Approach to Stabilize Gait and Withstand Gait Forces

Tayler Kastlunger

Congenital and developmental limb deformities in canines are rare and can occur as a genetic disorder or be caused by extrinsic factors. Without surgery to correct the deformity, conservative management can be implemented to manage exercise and restrict high-intensity activity of the canine. However, any alteration to the normal gait and locomotive biomechanics of a canine can have significant long-term effects on the musculoskeletal health and quality of life of the canine. To improve quality of life and provide an alternative and more cost-effective approach to surgery, a custom prosthetic was designed and developed for a canine born with a congenital right forelimb deformity. Since canine prosthetics that are currently on the market are limited and expensive, the goal of this thesis was to create a durable and inexpensive prosthetic to stabilize the gait of a canine. A 1-year-old German Shepherd was the single subject of this research project. The major results indicated that the custom-designed, 3D printed prosthetic parts, which included the foot and the body of the prosthetic, were strong enough to withstand the high-impact forces and stresses experienced during the gait of a canine. The results also indicated that the prosthetic was comfortable and did not cause any pain or discomfort to the canine, as well as the prosthetic leg and foot being the correct length to stabilize the gait of the canine and redistribute the body weight of the tripod canine to that of a tetrapod canine. This study also developed and outlined a feasible fabrication process that could be repeated and used to produce other custom prosthetics for canines with rare congenital or development limb deformities as an alternative to surgery. In a future study, fatigue testing, tensile testing, and impact testing should be performed to determine the failure points. Fatigue testing is a critical factor in determining failure of a part.

Keywords: Canine, Limb Deformity, Custom Prosthetic, Musculoskeletal Health, Gait

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Chapter 1

INTRODUCTION

Limb deformities in canines can occur during birth, as congenital deformities, or during growth, as developmental deformities, and can occur as a genetic disorder or be caused by extrinsic factors [1]. Congenital deformities in canines are very rare, and thus, there is not much known or published background on the etiology or pathogenesis of these types of deformities. In canines, the forelimbs are typically more prone to deformities than hind limbs since the forearms consist of the radius and ulna growing separately alongside each other at individual rates of growth [1]. Canine limb formations typically occur during the third to fifth week of gestation. Hereditary and environmental or extrinsic factors play a role in the development of limb formation and can result in deformations during bone and joint formation [2]. Environmental factors, such as teratogens, which are toxins that have been found to cause birth defects, can result in permanent structural or functional deformations and malfunctions in the fetus before birth [3]. One congenital defect found in canines and other domesticated animals is known as anterior amelia, which is the absence of a limb or multiple limbs, either partially or completely [4][5]. When the defect consists of a partial limb being deformed, it is usually the result of an angular deformity. When the entire segment of the limb is missing, it is due to the limb(s) being undeveloped caused by environment factors, genetic factors, or a combination of both [5]. There currently is no available treatment for management of congenital limb deformities; some mild congenital deformities can be managed without surgery if they do not cause any pain or discomfort to the canine. Rather, the canine can go about its daily life normally but with conservative management, such as restricted exercise and limited high-intensity activity.

Even with conservative management, any deviation from normal gait of a canine can negatively impact the distribution of joint forces and overall health of a canine, potentially leading to instability, muscle disfunction, pain, or a decrease in the range of motion of joints [6]. As a tripod canine with one forelimb ages, the extra weight experienced on the single forelimb can lead to carpus joint issues. The soft connective tissues of canines, including ligaments and carpus joints, have specific functions that can be performed under certain loads and certain orientations;

if incorrect alignment and increased force and stress occurs due to a missing limb, long term trauma and health issues can result [7]. In a study about kinetic and kinematic analyses of canines with total limb amputations, it was found that there were significant alterations to the locomotive biomechanics in tripod canines when compared to tetrapod canines [8]. These alterations in the normal gait of a canine can have long-term effects on the musculoskeletal health of the canine, lowering its quality of life with age. Studies have shown that a prosthetic limb reestablished quadruped gait and structure of the canine, preventing the on-set development of secondary musculoskeletal diseases [8].

In long-legged tetrapod canines, such as German Shepherds, the two legs on the same side of the body can support the canine without the canine's body tending to roll [9]. However, in tripod canines, an undeveloped limb can affect the canine's balance, causing its body to roll and become unstable during motion. Studies have shown that canines missing a front limb are at greater risk of experiencing orthopedic issues than canines missing rear limbs due to the increased body weight distributed to the forelimbs [7]. The forelimbs of a tetrapod canine carry most of the body weight, with approximately 30% of the canine's body weight distributed to each of the forelimbs and 20% of the body weight distributed to each of the hind limbs [10]. However, for a three-legged canine with a residual forelimb, the weight distribution is shifted, with an additional 17% of the body weight to the singular intact forelimb and the additional 13% of the body weight to the hind limbs during stance phase [6]. Since the front limbs are responsible for stabilizing and steering during high-intensity gait of a canine, it is necessary to stabilize the gait of the canine in order to restore some functionality and stabilize weight distributions to the other limbs. Dogs with mobility impairments due to limb deformities have limited options for an inexpensive and feasible approach to stabilize gait and reduce the stresses experienced at other regions of the body caused by increased muscle forces, as well as increased joint reaction forces and moments, during three-legged stance [11]. To restore some functionality of the missing limb, the use of a prosthetic to replace the residual limb would stabilize the gait and increase the mobility of the canine, reducing the chance of osteoarthritis over time and improving overall quality of life.

Even though there have been significant achievements in the development of human prosthetics, the same cannot be said for the development of animal prosthetics. Animal prosthetics have become more accessible as technology advances, however, most animal prosthesis are currently catered towards animals that have undergone limb amputations [12]. Limb braces are more common for canines with lameness of the forelimb or hindlimb relating to partial anterior amelia, and canine wheelchairs are common for canines missing more than one limb [13]. However, full-body prosthetics for canines missing only one limb or part of a limb are not as common or available on the market. Due to variations in congenital and developmental limb deformities, there is a need for cost-efficient and customizable prosthetics that can be tailored to a specific user and a specific deformity [12].

1.1 Statement of Problem

The design and development of customizable prosthetics for canines with congenital or developmental limb deformities could be an alternate and inexpensive approach to stabilize the gait of canines and improve quality of life rather than undergoing surgery. Since surgeries are typically expensive and the recovery process can be prolonged, a prosthetic device is a more realistic and inexpensive alternative to stabilize the gait of canines.

Canine prosthetics that are currently on the market are limited and expensive and are typically designed for canines with amputated limbs rather than residual limb deformities. The design of a customizable prosthetic for canines will improve upon the design of canine prostheses that are currently on the market and will be more cost-effective to manufacture. Custom prosthetics will be tailored towards congenital and developmental limb deformities of canines rather than canines with amputations. Alternate approaches for the development of the prosthesis will focus on inexpensive prototyping methods in order to make the prosthetic as affordable for the user as possible.

1.2 Prior Work

Orthopedic and prosthetic devices are an arising market for canines with certain limb deformities or dysfunctional limbs, such as lameness of the limb. Canine braces, prosthetics, and wheelchairs have been developed and advanced to provide support and stabilize the gait of canines with these deformities. Canine braces and socket prostheses are typically considered over a canine wheelchair or full body prosthetic for canines that have a partial limb due to amputation or congenital defects [14]. Braces for the knee, ankle, wrist, and elbow of canines are currently on the market, with knee braces being the most prominent currently, specifically for cranial cruciate ligament rupture [15]. Even though braces can restore and improve overall function of the affected limb, canine braces cannot withstand high loading conditions experienced during high-intensity activity [16].

For canines that must undergo amputation of more than one limb, or for canines that have severe physical impairment, a wheelchair can be used to increase mobility. Unlike braces and prosthetics, which are more often used for rehabilitation of a limb deformity, wheelchairs can be used for limb deformities or neurological disorders, such as rehabilitation from spinal surgery or to manage osteoarthritis [17]. Wheelchairs can be used during recovery and rehabilitation to support the canine in an upright position and redistribute the loads at an affected joint or bone.

The use of braces to restore functionality of a partial limb and the use of canine wheelchairs to improve mobility due to physical impairment or neurological disorders are examples of orthopedic devices to aid canines in rehabilitation of a missing limb or other disorder. However, a prosthetic device for canines born with a total limb deformity are not as prominent on the market and are typically expensive. Most current full-body canine prosthetics available on the market are catered towards amputees. This is typically because any portion of a residual limb that is present may interfere with daily movement or become traumatized or injured over time with the use of a prosthesis. There is a need for canine prosthetics catered towards total congenital and developmental limb deformities that is cost effective, durable enough to withstand the gait forces of a canine and that will provide comfort at the socket of the residual limb to further reduce musculoskeletal dysfunction and discomfort.

1.3 Objectives

The objective of this study is to design and develop a prosthesis for a canine with a congenital limb deformity that is a feasible, comfortable, durable and affordable approach to stabilize the gait of the canine and improve mobility to withstand normal and high-intensity gait forces.

In terms of feasibility, the prosthetic has to be developed using methods that are commonly practiced and utilize parts that are easily accessible. Common prototyping methods that will be used include casting using medical-grade casting tape, 3D scanning of the cast for computer-aided design (CAD) modeling, and 3D printing, also known as additive manufacturing, for the final prototype of the prosthetic. Additional parts necessary to build the prosthetic are commonly found and available on the normal market.

In terms of comfort, the prosthetic has to be designed to provide support for the canine in order to stabilize its gait while also reducing the discomfort already experienced by the tripod canine. According to Marissa Greenberg, DVM, at VCA South County Animal Hospital in Arroyo Grande, CA, comfort is the most critical aspect to focus on for the socket of the prosthetic, especially since the congenital deformed residual limb is still present and active.

Durability is the most critical aspect to focus on for the foot of the prosthetic since the greatest force experienced on the prosthetic will be the impact force during high-intensity gait motion. The foot of the prosthetic must also be able to support 30% of the canine's body weight since the two forelimbs are responsible for carrying a majority of canine's the body weight [10]. Thus, a suitable design and durable material will need to be taken into consideration for additive manufacturing in order to provide the greatest functionality during motion.

As an alternate approach to surgery, the goal of this prosthetic is to be affordable for the user, and thus economical to manufacture. With typical animal prosthetics ranging between $500 for small canines and $1500 for medium-sized and large canines, the budget for this large canine customized prosthetic is between $600 to $800.

Chapter 2
METHODS

2.1 Subject Information

A 1-year-old German Shepherd born with a congenital right forelimb deformity is the singular subject of this research project (see Appendix A). The canine is female and was born into a liter of eleven puppies. She was the runt of the litter. She was born at a slightly lighter weight than average, weighing less than 3.17 kg (7 lbs) at birth. At 14 months, the canine is the same size as an average German Shepherd her age, with a current body weight of 30.84 kg (68 lbs). The canine is currently healthy and has no underlying health conditions.

2.2 IACUC Protocol To Conduct Animal Testing

A protocol for animal use and care was completed and submitted to the California Polytechnic State University Institutional Animal Care and Use Committee for review and approval to perform animal testing (see Appendix B). This protocol was submitted to be able to make a casting of the canine's torso and residual limb in order to 3D scan the cast for CAD modeling, as well as to fit the final prototype of the prosthetic on the canine to ensure that it fits properly. The latter will serve as one aspect of testing to ensure that the prosthetic fits securely and comfortable around the canine's torso and residual limb, as well as to ensure that the leg of the prosthetic is of proper length dimensions to stabilize gait and provide support and balance. This minimally invasive type of testing should not provide any pain or discomfort to the canine. The protocol was approved by the IACUC committee in order to create the cast and conduct testing.

2.3 Model Development

The custom prosthesis consists of two components to properly suit the canine's needs; these custom components are the body of the prosthetic and the foot of the prosthetic. Both parts are 3D printed in polylactic acid (PLA). The other components used for the assembly of the prosthesis are commercially available parts. These parts include an aluminum rod for the leg of the prosthetic, bolts for assembling the device, and foam padding to provide comfort for the canine during use.

Since the prosthesis is being designed for a canine with a small congenital front right limb deformity, a prosthetic that attaches around the canine's body rather than attaching to the residual limb would be more comfortable and secure. The body of the prosthetic was designed by making a cast of the canine's torso and front right residual limb. The cast was then 3D scanned using an Xbox 360 Kinect (Microsoft, Redmond, WA) and the computer software, ReconstructMe (PROFACTOR, Steyr, Austria), to convert the molding of the canine's torso and residual limb into a computational mesh for editing and for finite element analysis (FEA). The 3D scan was trimmed, smoothed, and edited using Meshmixer (Autodesk Inc., San Rafael, CA) and Solidworks (Dassault Systems, Waltham, MA) to convert the model from the raw scanned part to a functional component for attachment of straps and a top-loading component for the attachment of the prosthesis leg. FEA on the body of the prosthetic was performed using Autodesk Fusion 360 (Autodesk Inc., San Rafael, CA).

The foot of the prosthetic was designed in Solidworks. The foot is symmetrical and flat on the bottom to provide balance for the canine during stance phase. The front and back of the foot are curved to resemble heel-strike and toe-off during gait of the canine. FEA was performed on the prosthetic foot using Abaqus (Dassault Systems, Waltham, MA).

2.3.1 Casting

A cast of the canine's torso was necessary in order to develop a customized prosthesis with a suitable socket that properly fit the canine's body type and accounted for her congenital residual limb. Before the cast material was applied, the canine's chest and upper torso were wrapped in 5.08 cm thick medical wrap and press and seal cling wrap to protect the canine's fur and skin from adhering to the casting material. 10.16 cm thick 3M Scotchcast casting tape was then fully soaked in room-temperature water for five seconds to activate the water-activated resin before applying the casting tape on the canine.

Once the casting tape was fully soaked and became more malleable, it was wrapped around the canine's body, beginning at the torso and moving upward on the body, covering the residual limb and chest of the canine. The casting tape was wrapped loosely as to not restrict normal breathing of the canine and with overlapping layers to ensure one solid cast without holes or gaps. Two layers of the casting material were applied for the cast to be thick enough for 3D scanning and modeling. This process is shown in Figure 2.1

Figure 2.1: Making cast of canine's torso and front right residual limb.

The cast dried and hardened after approximately five minutes. The cast was carefully removed along the top, along the canine's spine, using shears, as seen in Figure 2.2. Since the upper portion of the cast would later be removed to get rid of undercuts for 3D scanning, this cut would not affect the design of the body of the prosthetic.

Figure 2.2: Removing hardened cast along the top.

The original cast with the top slit and no modifications is shown in Figure 2.3. The top flaps on the upper region of the cast were removed to ensure that there were no undercuts or concave walls that could disrupt the impressions of the body cast during 3D scanning. Removal of the flaps also allows for more adjustability and secureness of the final prototype around the canine with the addition of straps and buckles at the side regions of the prosthetic body. The modified cast for 3D scanning is shown in Figure 2.4.

Figure 2.3: Front view (top) and isometric view (bottom) of cast before removing top flaps.

Figure 2.4: Front view (top) and isometric view (bottom) of cast after removing top flaps to get rid of undercuts for suitability for 3D scanning.

2.3.2 3D Scanning

The modified cast of the canine's body without the presence of undercuts or concave walls was scanned from a 360-degree angle view using an Xbox 360 Kinect and uploaded onto the computer using the software ReconstructMe. The scan was saved as a .mix file and viewed and edited using the software MeshMixer. The raw scan of the cast in MeshMixer is shown in Figure 2.5 and Figure 2.6

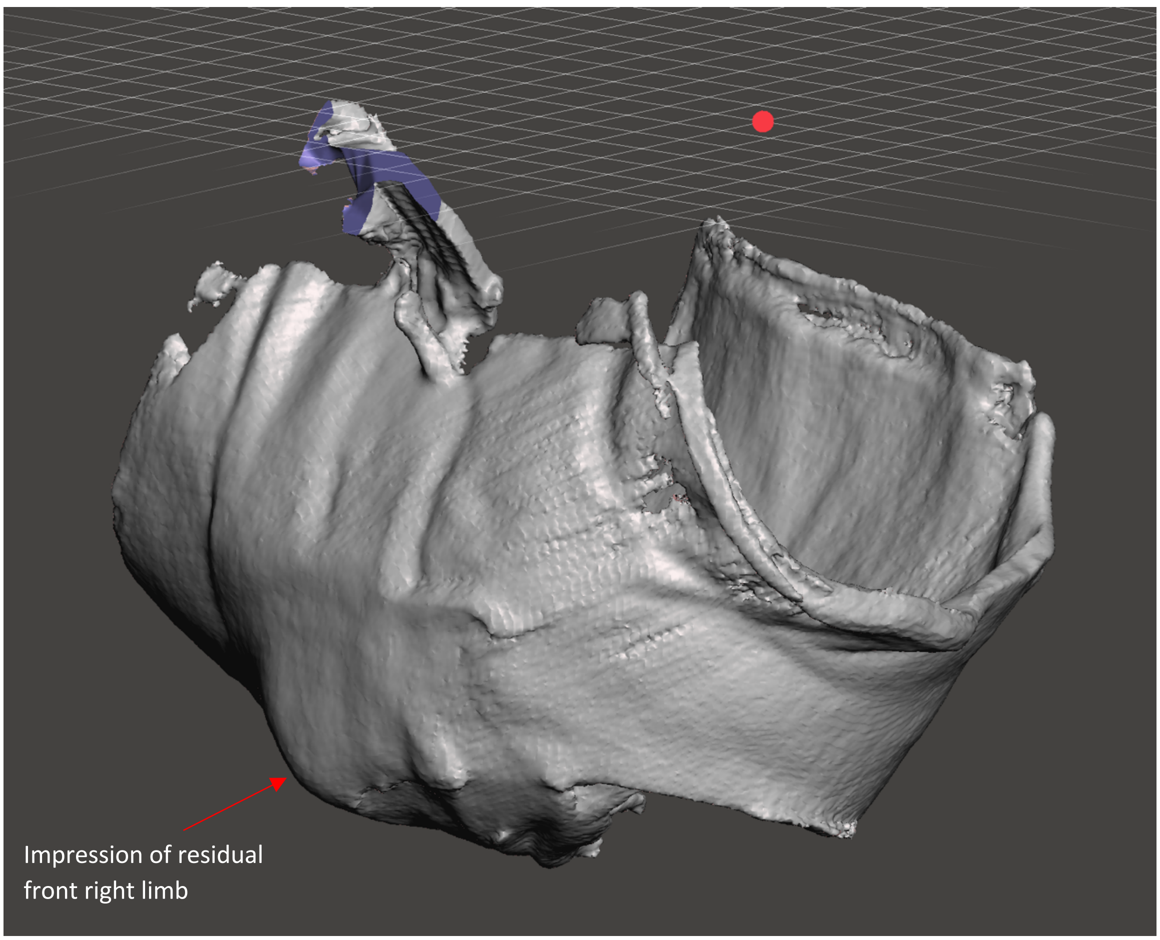

Figure 2.5: Right-side view of the raw scan of canine's cast from ReconstructMe and viewed on MeshMixer.

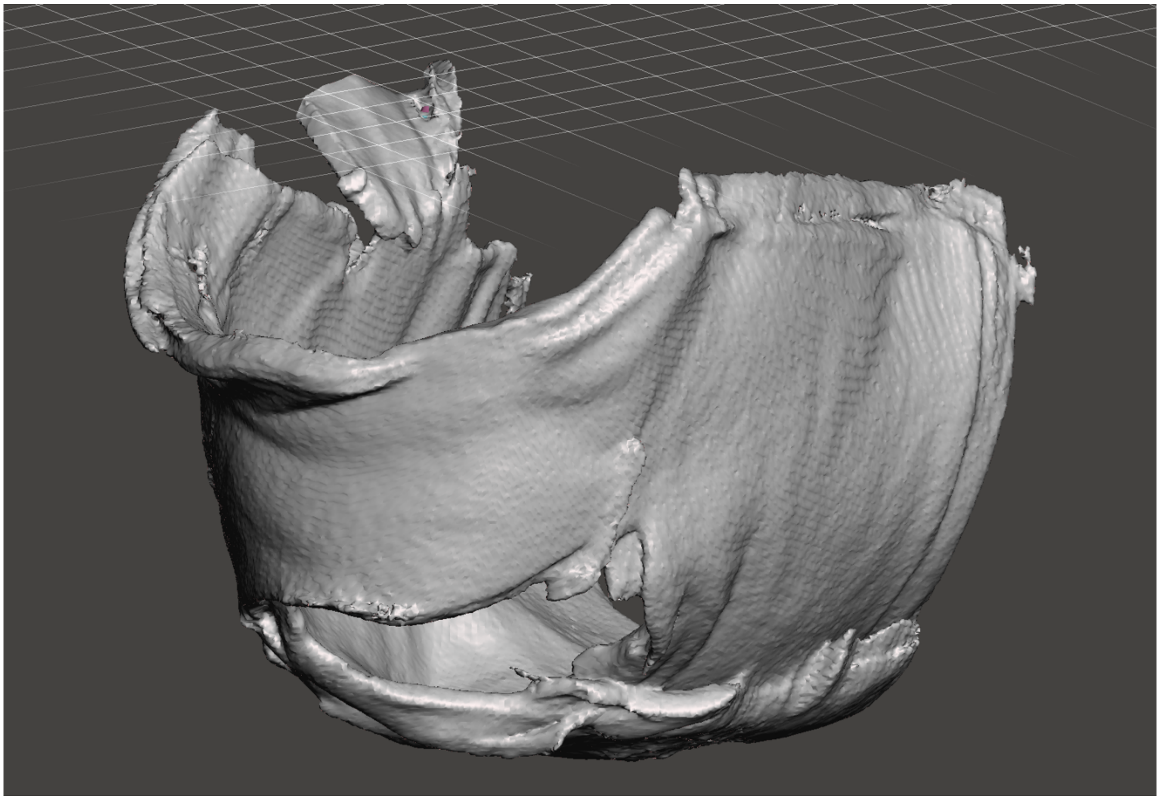

Figure 2.6: Left-side view of the raw scan of canine's cast from ReconstructMe and viewed on MeshMixer.

The raw scan was modified and edited using MeshMixer. The scan was trimmed by removing access material using plane cuts along the edges and surface of the body by trimming in the x-plane, y-plane, and z-plane at varying degrees. The surface of the body was smoothed using different brushes and techniques to flatten and even the surface of the scan, shown in Figure 2.7 and Figure 2.8 The dimensions and critical features of the initial scan of the body were not significantly altered during trimming and smoothing of the model.

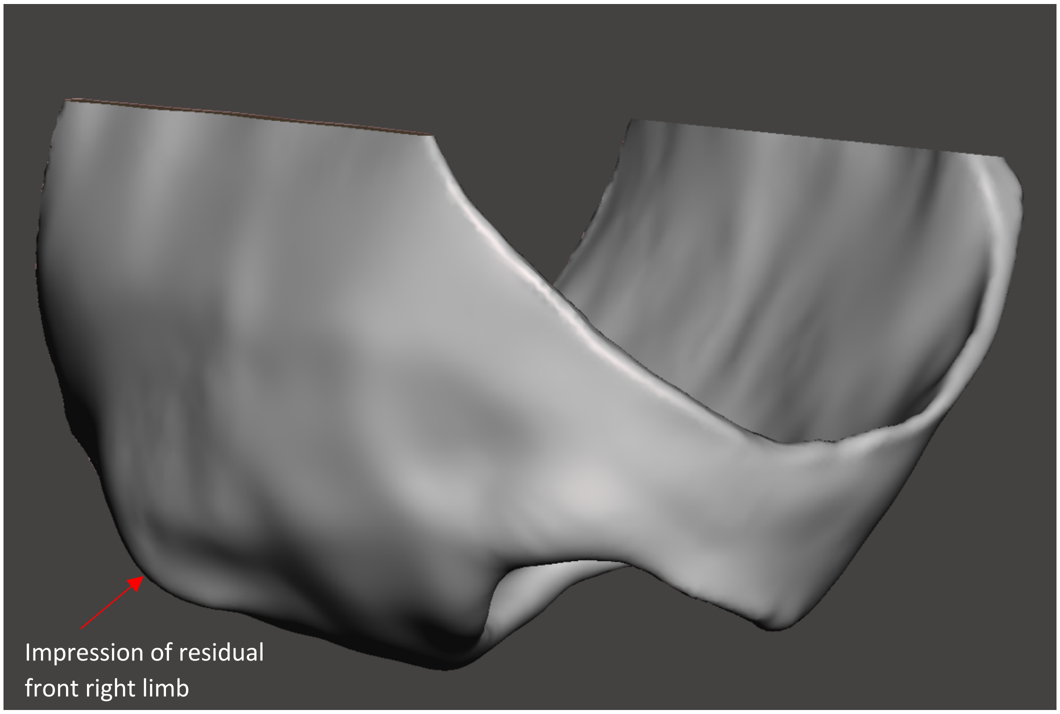

Figure 2.7: Right-side view of the edited scan of canine's cast using MeshMixer.

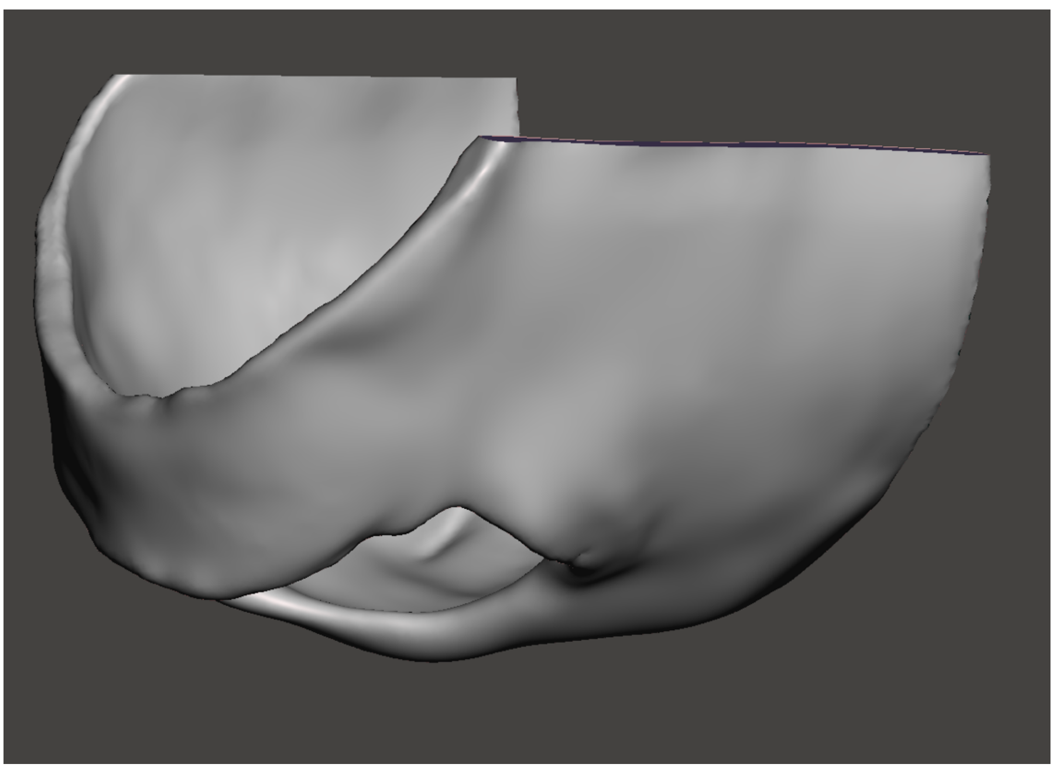

Figure 2.8: Left-side view of the edited scan of canine's cast using MeshMixer

The mesh body was converted to a solid body before being uploaded to Solidworks and edited to add slots for the straps and a component for the assembly of the prosthetic leg.

2.3.3 CAD Modeling

The custom canine prosthesis consists of two customizable components—the body of the prosthetic and the foot of the prosthetic. The prosthetic foot was created and designed using Solidworks. The geometry was designed as a symmetric part and is flat on the bottom to resemble flat-foot stance during gait and curved on both sides near the bottom to resemble heel-strike and toe-off strides during gait of the canine. The design of the prosthetic foot is shown in Figure 2.9.

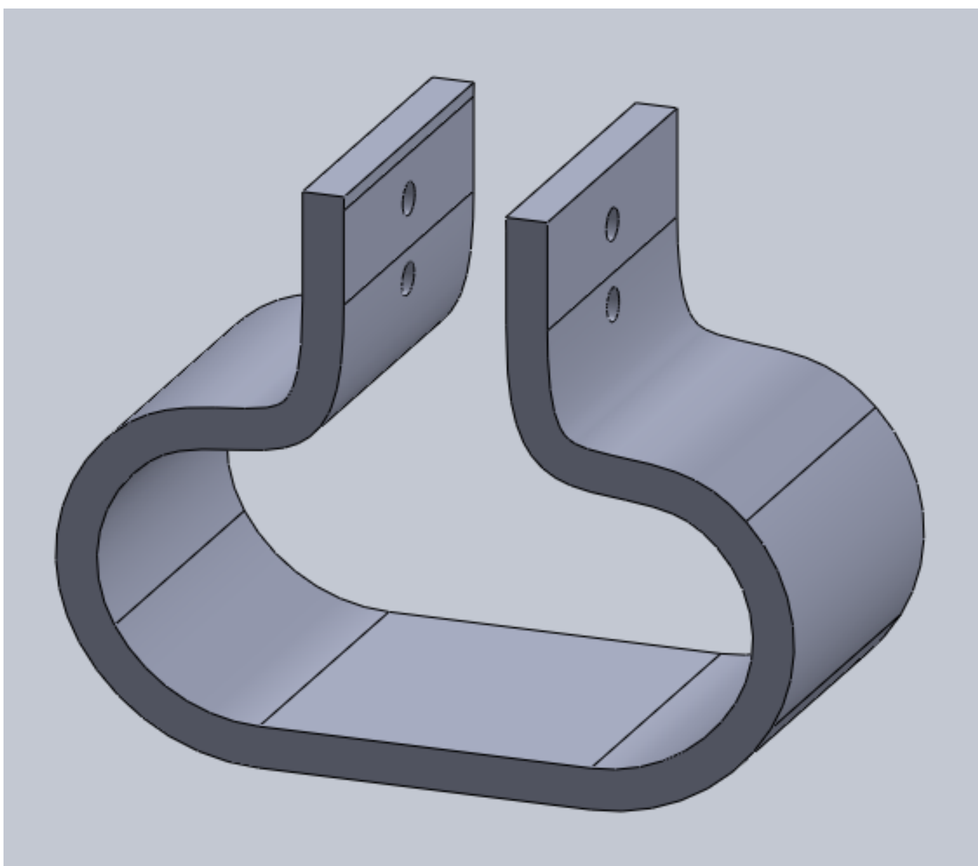

Figure 2.9: Model geometry of prosthetic foot.

The 6.6 mm holes on the upper portion of the prosthetic foot allow for the attachment and assembly of the prosthetic leg. A diameter of 6.6 mm is recommended for the clearance hole for use with an M6 bolt thread size to assemble the prosthetic foot to the aluminum rod [18]. The top portion of the foot consists of a 30 mm distance that allows for the insertion of a 30 mm diameter aluminum rod for the leg of the prosthetic. The thickness of the foot is 7.62 mm to ensure that it is durable enough to withstand high impact forces, seen later in the results under FEA on the prosthetic foot. The height from the bottom of the foot to the top (ankle) is 10.67 cm and the width of the foot is 6.35 cm to resemble the height and width of the canine's foot as accurately as possible. These measurements are compared in Table 2.1.

Table 2.1: Dimensions for foot design

	Dimensions of prosthetic foot CAD design (cm)	Dimensions of canine's left intact limb and paw (cm)
Length of paw	13.59	10.16
Width of paw	6.35	6.35
Height from bottom of paw to ankle	10.67	8.89

The length of the prosthetic foot is 3.43 cm longer than the original paw length to provide more surface area for balance and stability of the prosthesis. The height from the bottom of the prosthetic foot to the ankle is greater than the distance from the bottom of the intact paw to the intact ankle to allow for attachment of the leg on the upper portion of the prosthetic foot.

The second customizable part was the body of the prosthetic. Once the model of the prosthetic body was trimmed, smoothed, and edited in MeshMixer, it was imported into Solidworks as a solid body. The body was scaled 2% to accommodate for foam padding that would later be added to line the inside of the final prototype of the prosthetic body. Two 5.08 cm extruded rectangular cuts were made on each side of the model for the slots where the 5.08 cm width straps were added, shown in Figure 2.10. A 115 mm diameter extruded boss component was added to the bottom of the modified scan at the position where the right limb would be. A 65 mm hole pattern with a cut depth of 18 mm was added to the bottom of the extruded boss component for the assembly of the top-loading component where the prosthetic leg will be attached, shown in Figure 2.11.

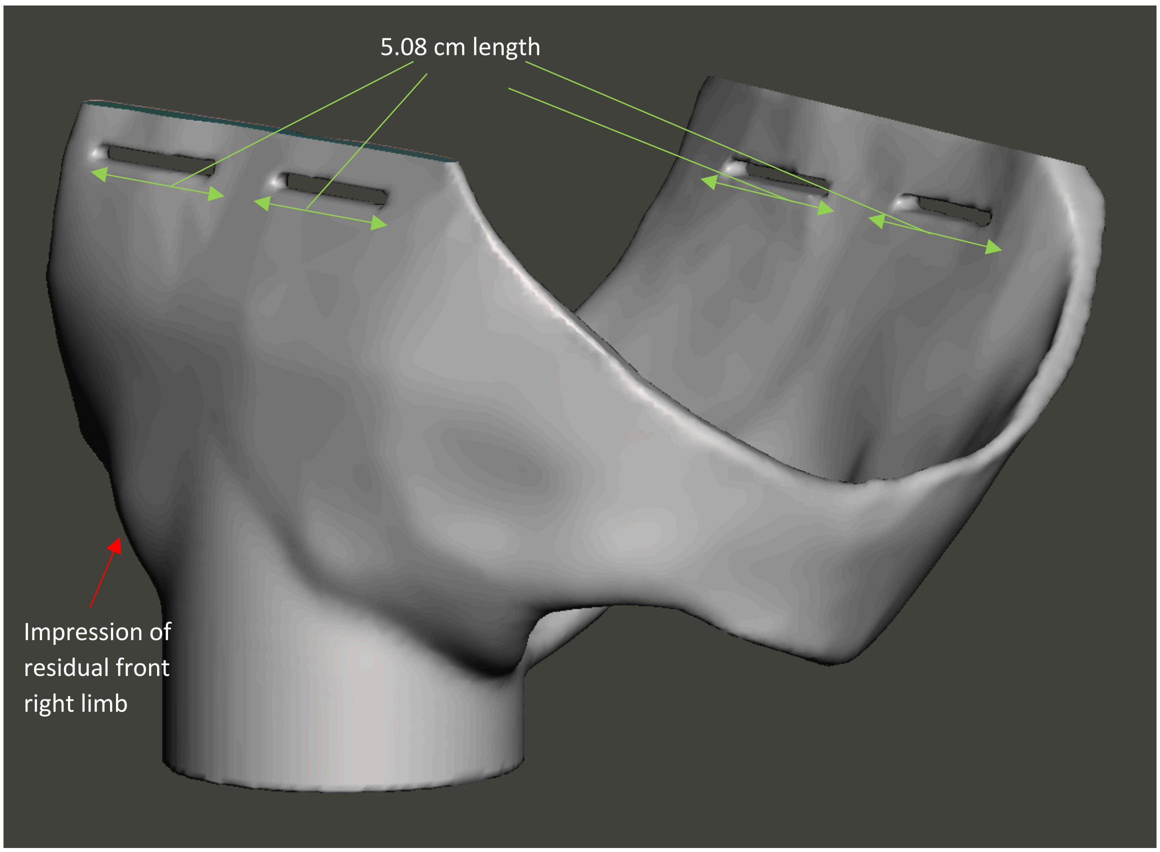

Figure 2.10: Right-side view of final model of prosthetic body.

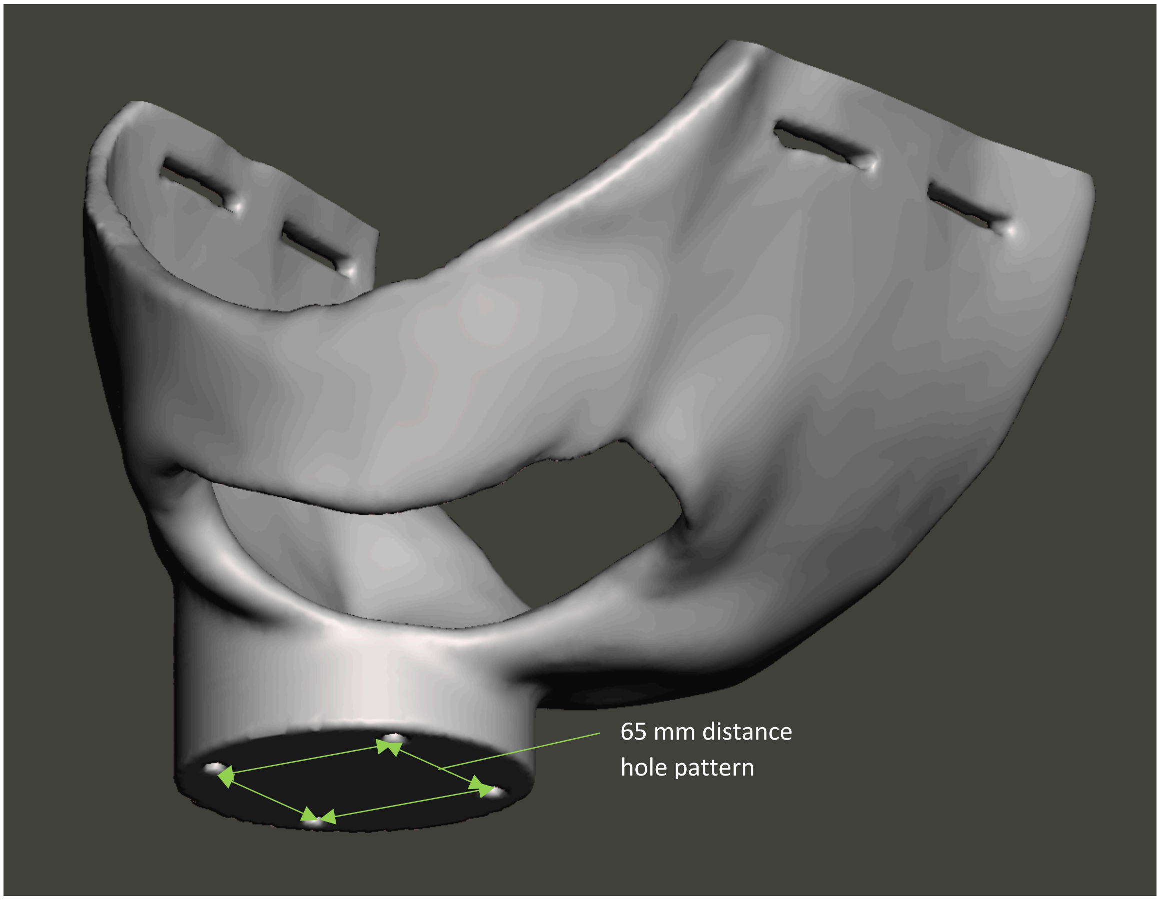

Figure 2.11: Bottom left-side view of final model of prosthetic body.

2.3.4 Prototyping

Both customizable components, the prosthetic foot and the body of the prosthetic, were 3D printed using polylactic acid filament. Polylactic acid (PLA) was the thermoplastic material used to print both of the customizable components since it is both an inexpensive and durable filament for 3D printing. A cost-effective process and material were essential as an alternate and low-cost approach to stabilize the gait of the canine. The body of the prosthetic was printed using fused deposition modeling (FDM) processing, which uses a continuous filament of thermoplastic material. The body was printed at a layer height of 0.2 mm and 25% infill to reduce the outsourced 3D printing costs. Since the body of the prosthetic is primarily used to secure the whole prosthesis around the canine and will not be experiencing high impact forces like the foot, an infill of 25% on the body is suitable. The foot of the prosthetic was printed using a layer height of 0.12 mm, a shell thickness of 0.8 mm, and 30% infill. Since structure is the main focus of the foot rather than material consumption, an infill between 30% and 50% is suitable [19]. The material properties of PLA are found in Table 2.2.

Table 2.2: Material properties for PLA [20][21][22]

Material Property	Maximum value (units)
Elastic modulus	3.5 GPa
Tensile strength	36-55 MPa
Poisson’s ratio	0.36
Mass density	1.25 g/cm^3

These custom components were assembled using commonly available parts, which include 6 mm screws and nuts, 8 mm outer diameter threaded inserts, a 30 mm diameter aluminum rod for the prosthetic leg, a top-loading component and tube clamp adaptor for attachment of the leg, straps and buckles to secure the device on the canine, and foam padding to provide comfort for the canine during use of the prosthesis.

2.3.5 Assembly Development

The foot of the prosthetic, the aluminum rod, and the body of the prosthetic were assembled together with the commonly available parts described above to build a functional prosthesis for the canine. The straps were attached first onto the prosthetic body. Four straps were cut to an initial length of 50.8 cm and trimmed down as needed to fit the canine’s body size. The straps were inserted through the 5.08 cm slots on the top sides of the prosthetic body and hand sewn on using a backstitch box pattern. This specific stitch pattern provides a sturdy and strong hold. The buckles were sewn onto the straps using the same stitch pattern.

The body of the prosthetic was secured around the canine’s upper body by tightening the straps to an appropriate length so that the prosthetic body was flush against the canine’s body.

The measured height from the bottom of the extruded component on the body of the prosthetic to the ground was 29.21 cm. The 30.48 cm aluminum rod was cut to a length of 26.16 cm to accommodate for the thickness of the prosthetic foot that will be attached to the bottom end of the rod and the top-loading socket adaptor and tube clamp adaptor attached to the top of the rod.

To assemble the foot to the aluminum rod, two 6.4 mm holes were drilled 1.143 cm apart on the rod through both sides. The bottom hole was drilled 7.19 cm from the bottom end of the rod. Two 6 mm bolts were inserted through the clearance holes on the rod and the upper portion of the foot and tightened with washers and nuts to attach the foot of the prosthetic to the leg of the prosthetic.

Unlike the hole pattern that was designed for attachment of the top-loading socket adaptor shown in Figure 2.11, the 3D printed prosthetic body was printed with a solid, flat bottom surface rather than a 4-hole pattern when it was received. Since the body of the prosthetic was printed from an outsourced company, it is not clear why the hole pattern was not printed. Thus, four holes had to be drilled on the bottom of the extruded component for attachment of the socket adaptor. Each hole was drilled 14 mm deep and 39 mm apart in a square pattern. In the 4-hole pattern seen in Figure 2.11, the holes were incorrectly designed 65 mm apart rather than the diagonals of the holes being spaced 65 mm apart. Figure 2.12 shows the new hole pattern drilled into the body of the prosthetic for assembly of the top-loading socket adaptor for attachment of the prosthetic leg.

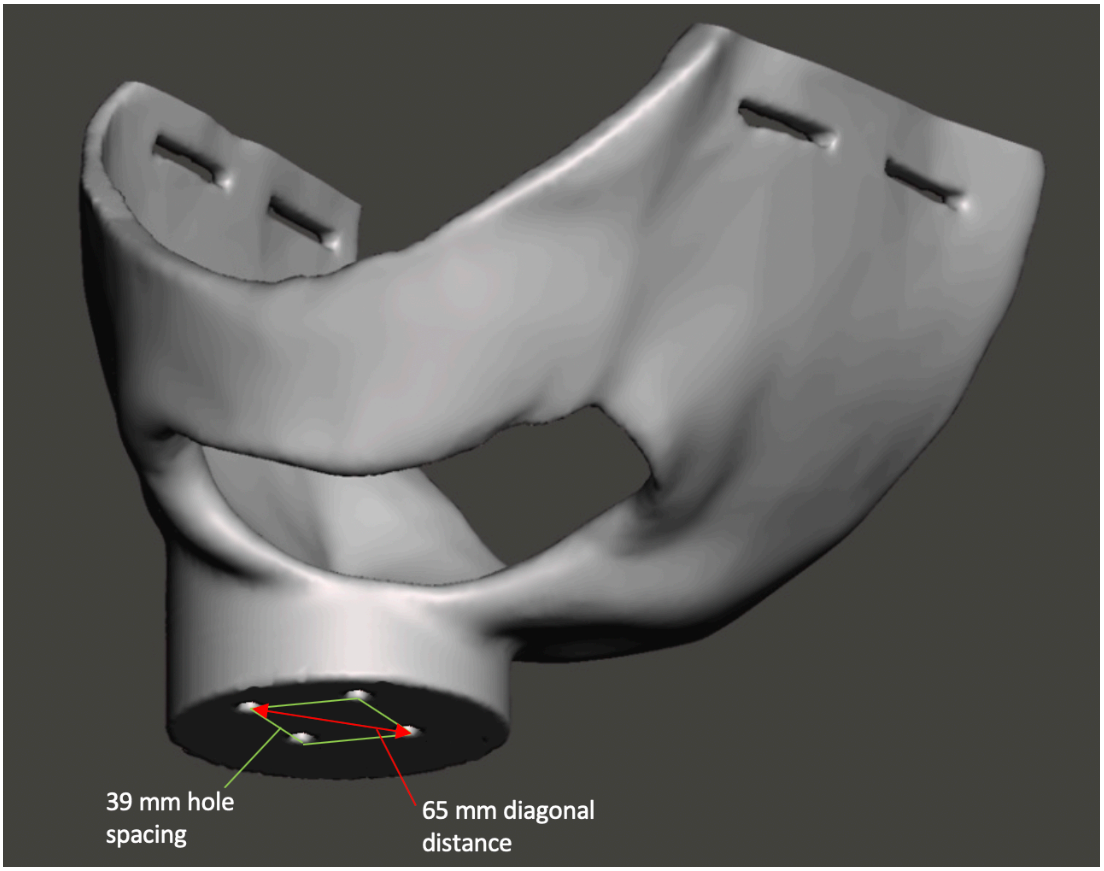

Figure 2.12: 4-hole pattern drilled into PLA prosthetic body.

Since the body of the prosthetic was printed using 25% infill to reduce costs, the drilled holes were filled with liquid PLA filament using a 3D printing pen to solidify the structure as best as possible around the holes to compensate for the greater infill recommended for use of threaded inserts. A threaded insert was put into place in one of the holes using a soldering tip. Threaded inserts were not used in the other three holes since the PLA filament used to solidify the drilled holes was not a suitable enough approach to compensate for the reduced infill for the prosthetic body. Rather, the top-loading socket adaptor was attached to the extruded component on the prosthetic body by drilling M6 screws into the three holes without the threaded insert to hold the top-loading component in place. A 10 mm length M6 bolt was screwed into the fourth hole with the single threaded insert to hold the socket adaptor in place.

With the final prototype of the canine prosthesis fully assembled, a thin padding was added to the bottom of the prosthetic foot, shown in Figure 2.13, and a 2.54 cm thick foam padding was added to the inside of the prosthetic body, shown in Figure 2.14. Padding was added to the bottom of the prosthetic foot to reduce the stresses experienced during high-impact forces. Padding was added to line the inside of the prosthetic body to provide comfort for the canine during use and to make the device more secure around the canine's body. Comfort is the most critical aspect at the extruded socket of the prosthetic body for the canine's residual limb since the residual limb is the most sensitive.

Figure 2.13: Foam padding on bottom of prosthetic foot.

Figure 2.14: Foam padding lining inside of prosthetic body.

2.4 FEA Model Validation

The durability of the model was validated using Abaqus and Autodesk Fusion 360 to perform finite element analysis to determine the maximum principal stresses experienced by the foot of the prosthetic and the body of the prosthetic. FEA is necessary to investigate the durability of these two custom components to determine if they can withstand the applied loads experienced by the prosthesis during use. The foot of the prosthetic must withstand 30% of the canine's body weight during stance phase and normal gait since this is the total distributed weight experienced by the front right limb of an average canine. The body of the prosthetic must withstand the pulling force experienced at the slots by the straps when the device is tightened around the canine and during use. For the final prototype of the prosthesis to be functional, the prosthesis must fit comfortably and securely around the canine during use and not provide discomfort or pain to the canine. The length of the prosthetic leg and foot must be of equal length to the left intact limb to properly stabilize the gait and balance of the canine. Failure to meet these criteria would result in a non-functional prototype.

2.4.1 Finite Element Analysis on Prosthetic Foot

A finite element analysis study was performed using Abaqus to determine how the stance phase during standing and quasi-static phases during running gait of a canine affects the maximum principal stresses experienced by the foot of the prosthetic, as well as to determine if the material and design geometry used would be able to withstand impact forces during high-intensity activity. Since durability is the most crucial aspect to take into consideration when designing the foot of a prosthetic, it is important to analyze how these forces act on the prosthetic and how they impact the stresses experienced on different regions of the model. Finite element modeling combined with gait analysis allows for certain parameters of interest to be calculated that are not obtainable with gait analysis alone [23].

A load of 9.253 kg, or 90.74 N, was applied on the prosthetic foot designed for a 30.84 kg canine since one forelimb carries approximately 30% of the canine's body weight [10]. The load was applied as an impact force on the bottom of the foot during stance phase during standing and during quasi-static gait phases during running. The material properties applied to the model to resemble PLA are listed in Table 2.2 under section 2.3.4. The canine prosthetic foot was defined as a solid, homogeneous model and was meshed using quadratic, tetrahedral elements. An element size of 0.89 cm, which resulted in a mesh with 52,287 degrees of freedom, was used as the finest seed size at which the model converged, shown in Figure 2.15.

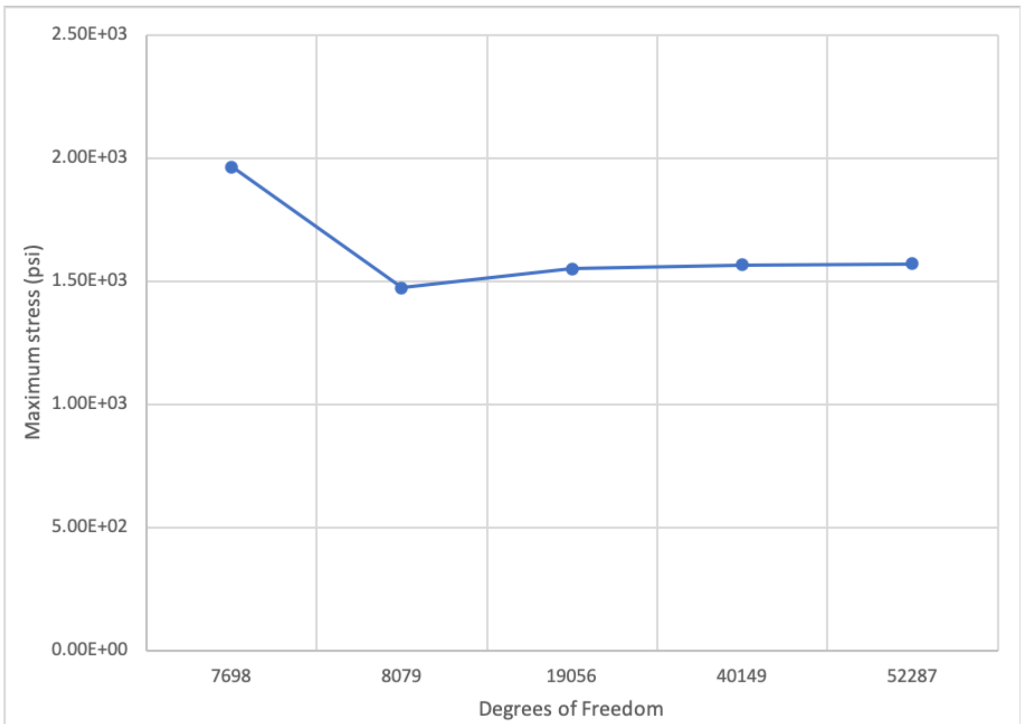

Figure 2.15: Mesh convergence study for Abaqus FEA.

During the static stance phase analysis, the loading condition was applied as an upward force of 90.74 N distributed equally (30.25 N at each of the three locations) to the bottom flat portion and to the two curved portions of the foot, as shown in Figure 2.16. This stance phase analysis represents the loads experienced on the prosthetic foot during standing. The boundary condition was applied at the holes on the top portion of the foot where the prosthetic leg will attach. Rotation and displacement in all directions remained fixed. In addition, static analyses at three different phases during gait of a canine, which include heel-strike, flat-foot stance, and toe-off, were used to resemble a quasi-static analysis of a canine's gait during motion. For these quasi-static analyses, the assumption was made that 30% of the canine's weight that is experienced by one of the forelimbs is experienced at each region where the total force is applied in Figure 2.17 through Figure 2.19. For the second analysis, a 64.14 N concentrated force (see Appendix C) was applied in both the x- and y-directions at the bottom-right curved surface of the foot to resemble loading conditions during heel-strike, as shown in Figure 2.17. For the third analysis, the 90.74 N concentrated force was applied on the flat surface at the bottom of the foot to resemble loading conditions during flat-foot stance, shown in Figure 2.18. Unlike stance phase during static gait analysis in which the force of 90.74 N was equally distributed to the flat surface on the bottom of the foot and the two curved regions on the bottom of the foot, during flat-foot stance during quasi-static analysis, a 90.74 N concentrated force was applied only on the flat portion on the bottom of the foot. For the fourth analysis, a 64.14 N concentrated force was applied in both the x- and y-directions at the bottom-left curved surface of the foot to resemble loading conditions during toe-off, shown in Figure 2.19.

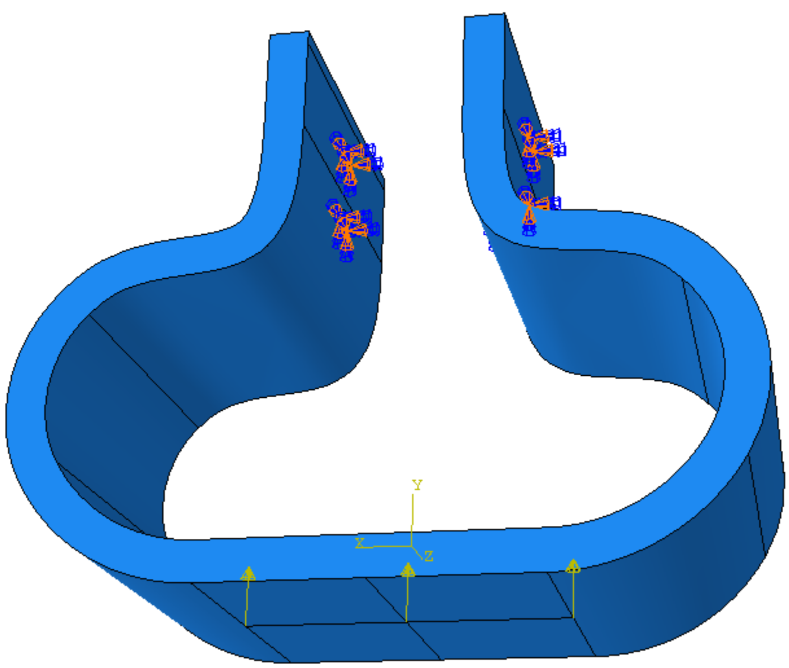

Figure 2.16: Boundary and loading conditions during static stance phase with concentrated forces of 30.25 N equally distributed across three regions at the bottom of the foot.

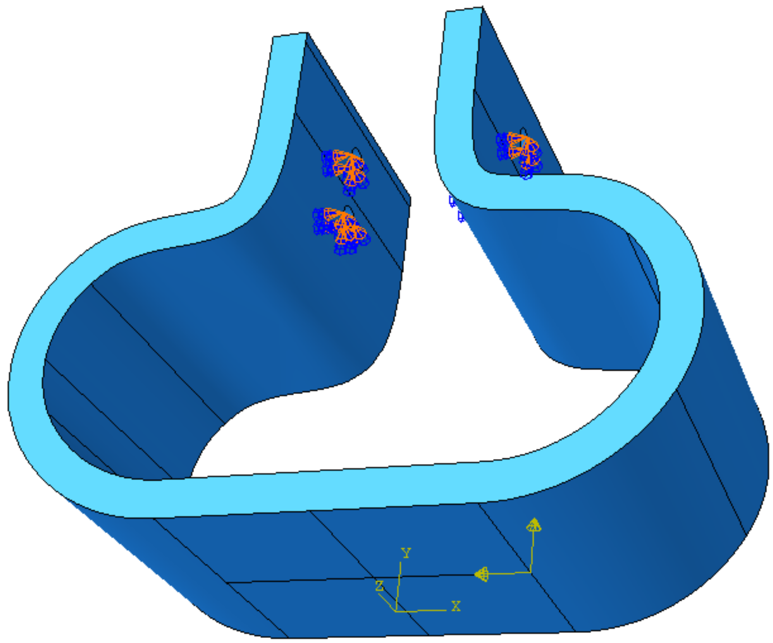

Figure 2.17: Boundary and loading conditions during heel-strike with a concentrated force of 64.14 N in both directions at the heel region of the foot.

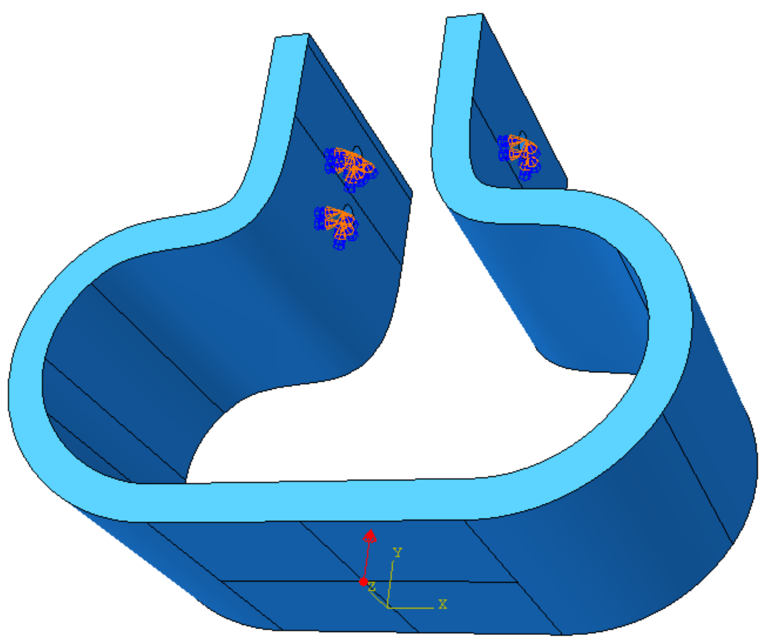

Figure 2.18: Boundary and loading conditions during flat-foot stance with a concentrated force of 90.74 N at the center region of the foot.

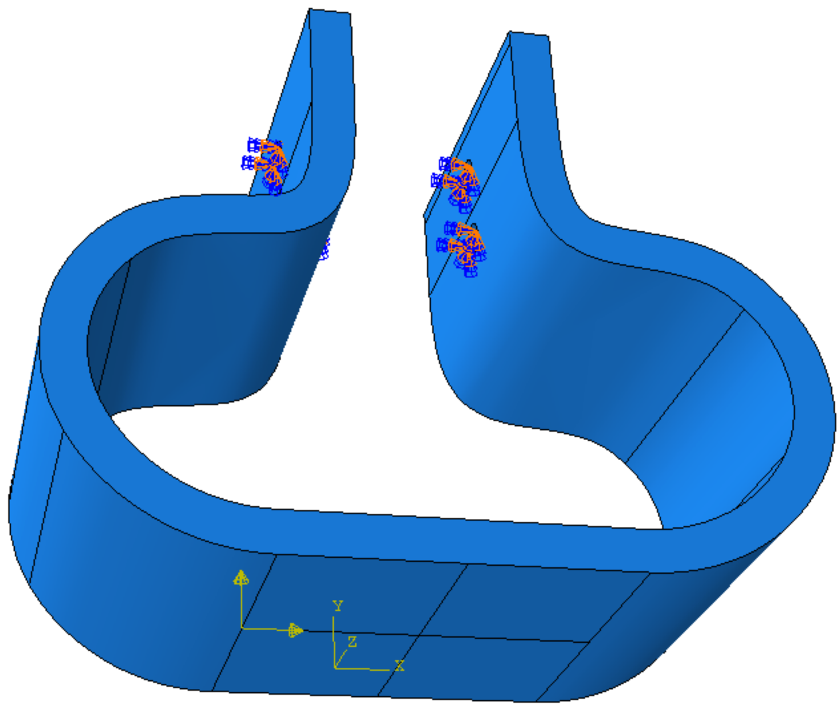

Figure 2.19: Boundary and loading conditions during toe-off with a concentrated force of 64.14 N in both directions at the toe region of the foot.

2.4.2 Finite Element Analysis on Prosthetic Body

A finite element analysis study was performed using Autodesk Fusion 360 to determine how the tension force from the straps and buckles at the slots of the prosthetic body affects the maximum principal stresses experienced by the body of the prosthetic, as well as to determine if the material and design geometry used would be suitable. The straps provide a tension force on the body when the device is tightened and secured on the canine.

A load of 2 N was applied at the slot locations on the prosthetic body where the straps are assembled to resemble the tension force experienced from the straps during use. The 2 N force was used as the tension force on the straps since that is the tension force experienced on a leash of a canine during use [24]. A 2 N load was assumed to resemble the tension force experienced during static use when the straps are secured in the buckle. The load was applied as a point force along the 5.08 cm slots to different regions along the slots during two different scenarios: first, a 2 N force was applied at the top region of the slot to resemble a “pulling up” force of the straps, shown in Figure 2.20; second, a 2 N force was applied on the outer surface of the body directly above the slots to resemble a tension force during tightening of the prosthetic body when it is secured on the canine, shown in Figure 2.21.

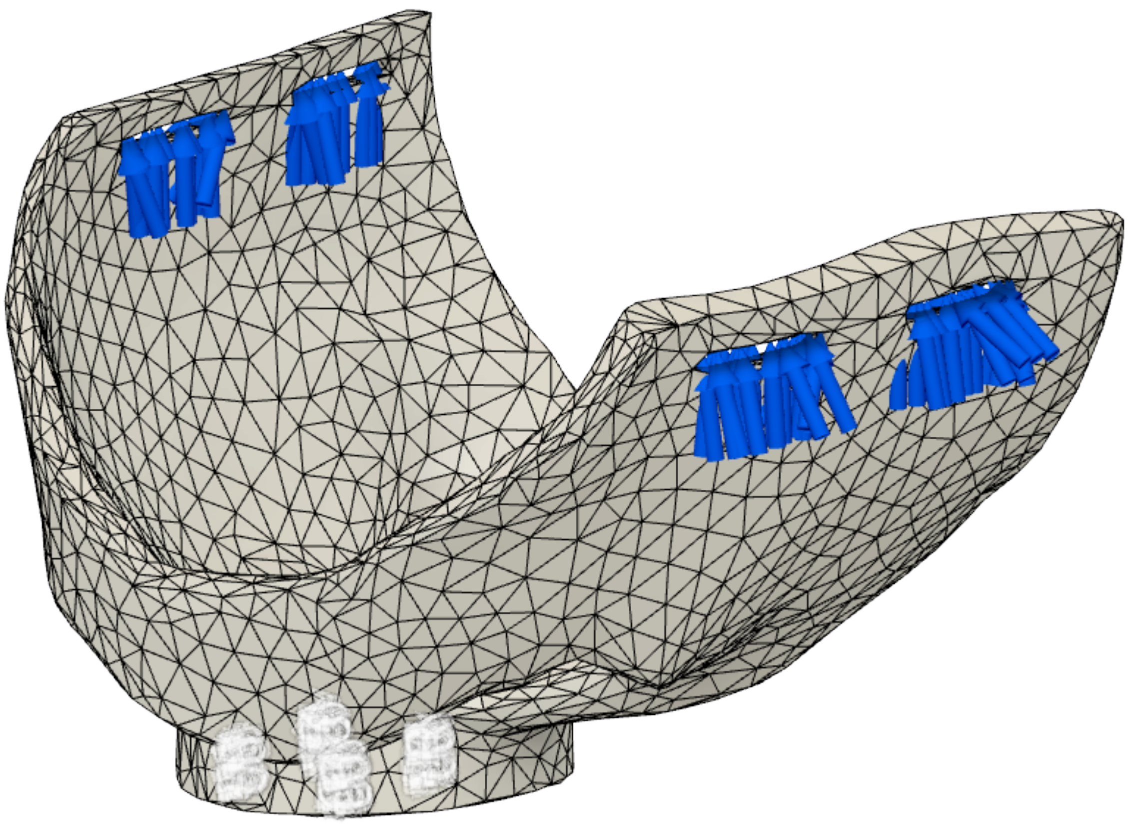

Figure 2.20: Boundary conditions (white) and tension force (blue) applied at top region of slot during “pulling up” action of straps under loading condition 1.

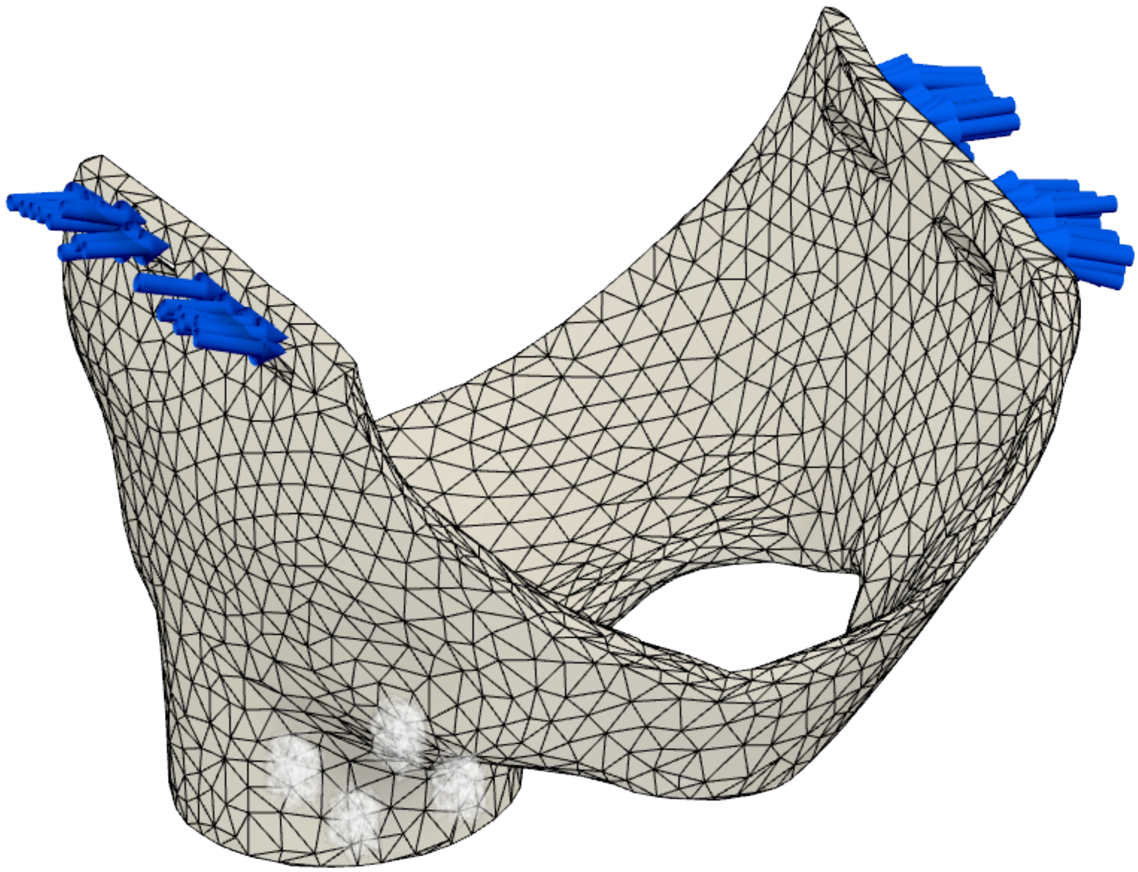

Figure 2.21: Boundary conditions (white) and tension force (blue) applied above the slot region on the outer surface of the body under loading condition 2.

Boundary conditions were applied on the prosthetic body at the bottom extruded part where the top loading component is assembled as shown by the white marks in both Figure 2.20 and Figure 2.21. Rotation and displacement in all directions were fixed. The material properties applied to the model to resemble PLA are listed in Table 2.2 under section 2.3.4. The canine prosthetic body was defined as a solid, homogeneous model and was meshed using tetrahedral elements with an average element size of 14.69 mm. An adaptive mesh refinement study was performed using a finer mesh with an average element size of 3% element-to-model size and a 5% convergence tolerance to determine the minimum number of mesh refinements and number of elements at which the model converged.

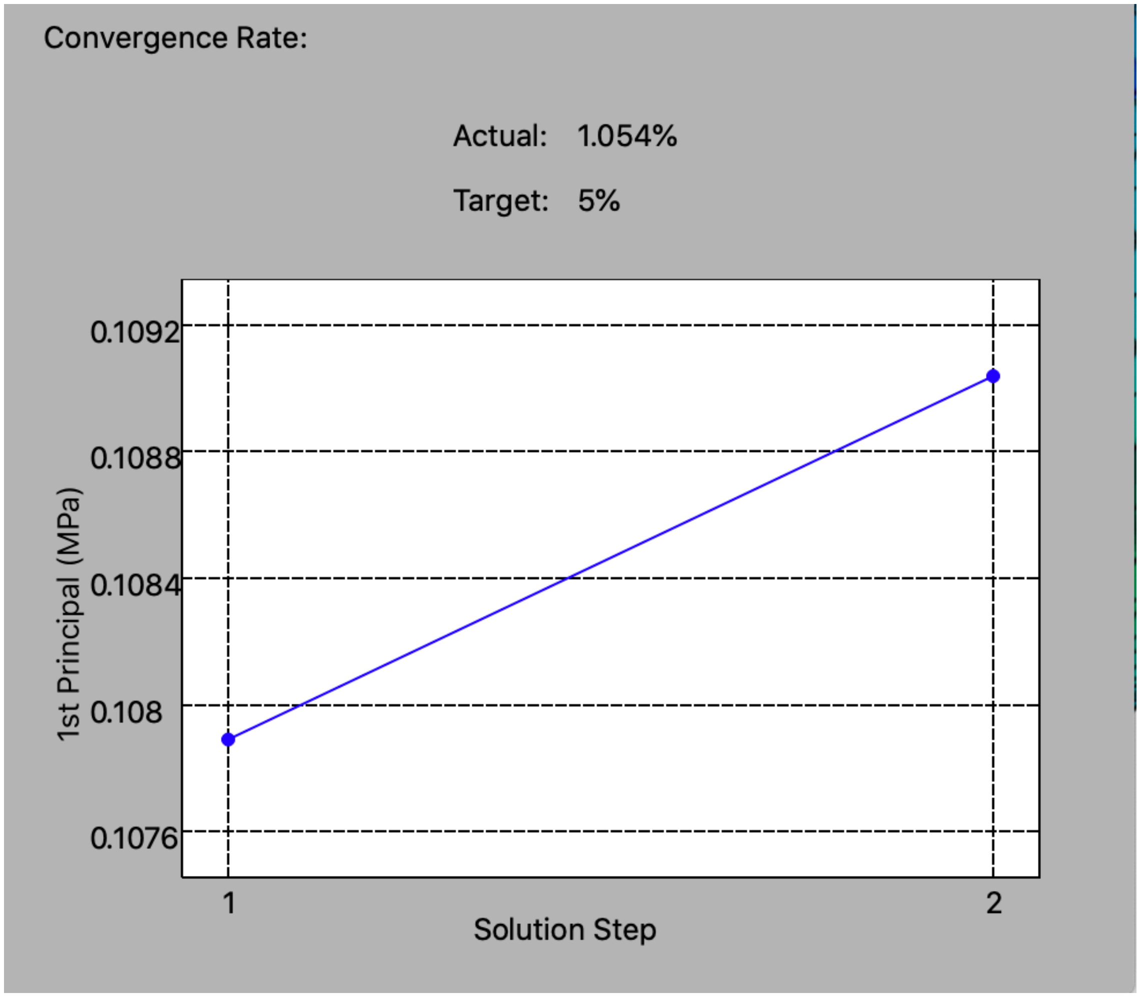

Figure 2.22: Mesh refinement study for maximum stress under first loading condition for Autodesk Fusion 360 FEA.

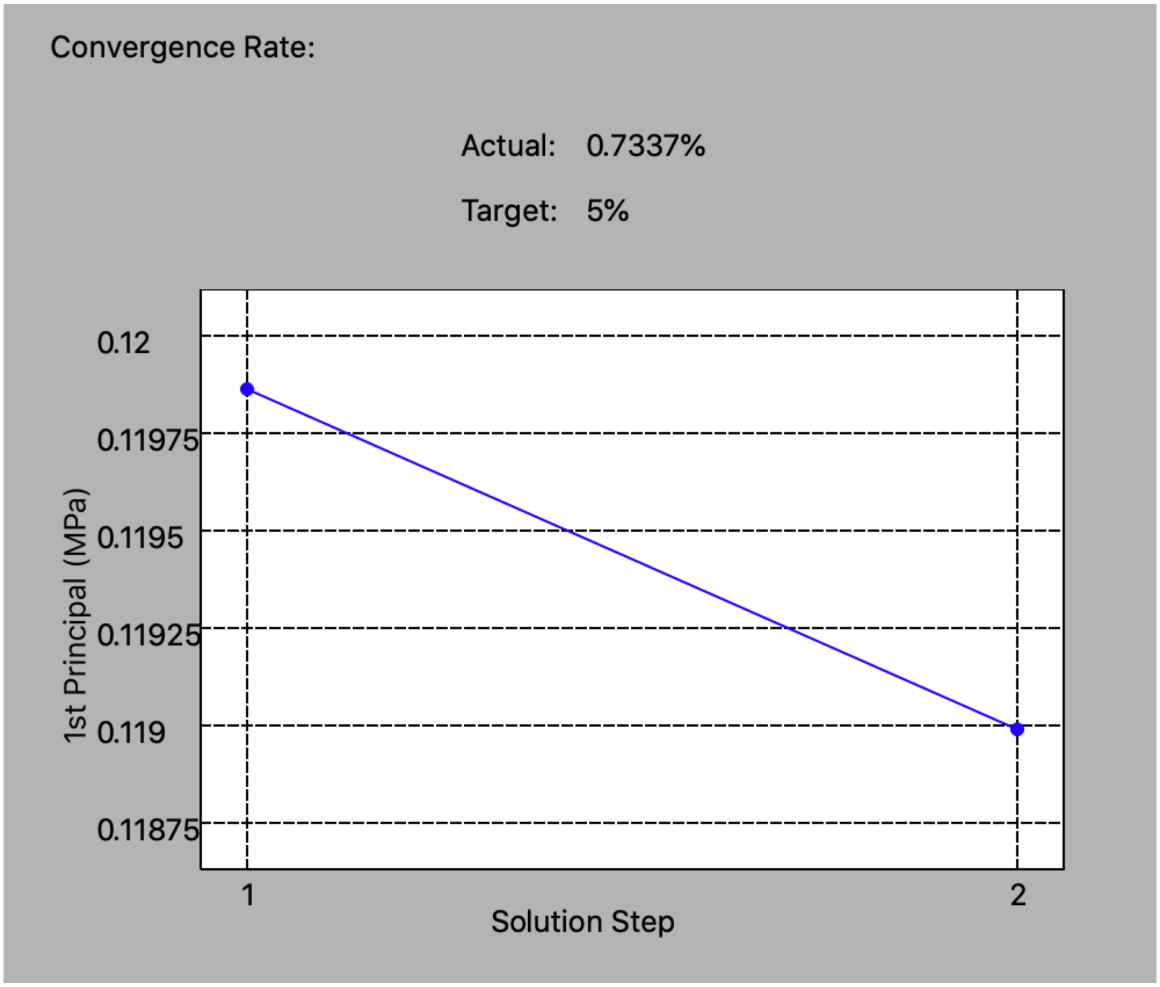

Figure 2.23: Mesh refinement study for maximum stress under second loading condition for Autodesk Fusion 360 FEA.

A mesh refinement was performed for the maximum stress under both loading conditions. The mesh converged within 1.054% for the maximum stress under the first loading condition and within 0.7337% for the maximum stress under the second loading condition, shown in Figures 2.22 and 2.23. For the first loading condition, the mesh refinement converged with 19,720 elements. For the second loading condition, the mesh refinement converged with 20,354 elements.

2.5 Cost Analysis

One goal of this custom prosthetic was to be affordable and feasible for the user, and thus, economical to manufacture. With typical animal prosthetics ranging between $500 for small canines and $1500 for medium-sized and large canines [7], the budget for this large custom prosthetic was between $600 to $800. The cost breakdown is shown in Table 2.3.

Table 2.3: Cost of final device assembly

Item Description	Purpose	Cost/Unit	Total Cost
3M Scotchcast Plus Casting Tape	Create cast of canine's body for 3D modeling	$5.025/roll	$15.08
Strapworks Heavyweight Polypropylene Webbing	For adjustability and secureness of device on canine	$1.48/yard	$4.44
Strapworks Plastic Single Adjustable Side Release Buckles	For secureness of device on canine	$1.62/each	$3.24
4-hole top loading stainless steel male, concave base	For attachment of tube adaptor to prosthetic body for pole assembly	$16.63/each	$16.63
Aluminum 30 mm tube clamp adaptor	For attachment to top loading component for assembly of tube for prosthetic leg	$17.85/each	$17.85
3D printed prosthetic foot	Prosthetic foot of the device	N/A	$0.00
3D printed prosthetic body	Prosthetic body of the device	$601.90	$601.90
Brass Heat-set Inserts for Plastic	For insertion of threaded screws to assemble rod to prosthetic body	$0.419/each	$1.67
M6 X 1mm thread, 10 mm length Philips Flat Head Zinc Plated Machine Screw	To assemble top loading component and prosthetic foot into 3D printed parts	$0.375/each	$1.50
M6 X 1mm thread, 60 mm length Class 8.8 Zinc Plated Hex Bolt	To assemble top loading component and prosthetic foot into 3D printed parts	$0.87/each	$1.74
30 mm Aluminum Tubing 12 inch	Prosthetic leg of the device	$12.70/each	$12.70
SoftTouch Self-Stick Non-Slip Surface Grip Pads	For bottom of prosthetic foot to reduce maximum principal stresses	$0.688/each	$4.13
1 inch highly versatile thick rubber sheets	To line inside of prosthetic body to provide comfort	$3.99/each	$11.97
		Total Cost	$692.84

Commonly available parts and inexpensive manufacturing methods were used to develop and produce the final prototype of the prosthesis. A large portion of this cost came from outsourcing for 3D printing of the prosthetic body since it was too large-scale to print using Cal Poly resources or other local resources.

Chapter 3
RESULTS

3.1 FEA Results

Finite element analysis was performed on the foot of the prosthetic and body of the prosthetic. These two custom-designed components must be strong enough to withstand the high-impact forces experienced during gait of a canine. Typically, fatigue testing would be performed to determine the durability of the custom prosthetic parts since fatigue is a big factor in determining failure. Since fatigue testing could not be performed due to unforeseen circumstances, the maximum principal stresses experienced by these components and where the stresses are located on the part was determined by performing FEA. Durability is the most critical aspect of the foot of the prosthetic since it is bearing 30% of the canine's body weight during stance phase and is undergoing repeated loading during use. Since fatigue loading was not measured to evaluate the durability of the prosthetic foot, it should be examined in a future study.

3.1.1 Finite Element Analysis Validation

To validate the maximum principal stress results on the prosthetic foot, the principal stress at the bottom of the prosthetic foot during quasi-static flat-foot phase was calculated. Due to the curved geometry of the prosthetic foot and maximum stress occurring at one of the boundary conditions, too many assumptions would have been made for a stress calculation at that region. A point probe in Abaqus was used to verify the stress at the bottom of the prosthetic foot. The FEA results and theoretical results from the hand calculations (see Appendix C) for the principal stress at this location are shown in Table 3.1.

Table 3.1: Principal stress at bottom of prosthetic foot during stance phase

	Maximum stress during flat-foot stance (MPa)
Stance phase quasi-static model	1.898
Hand calculation for stance phase	2.291
Percent difference (%)	18.76%

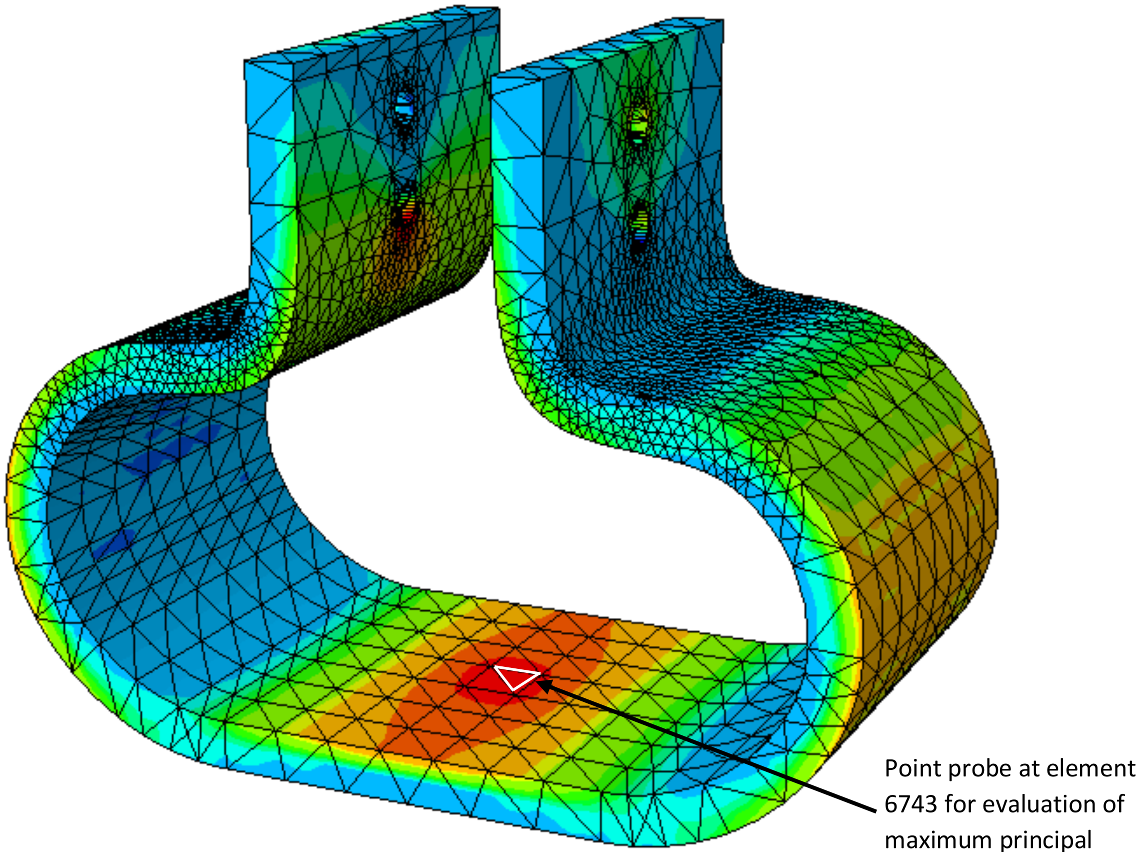

Figure 3.1: Principal stress (in MPa) at bottom of prosthetic foot.

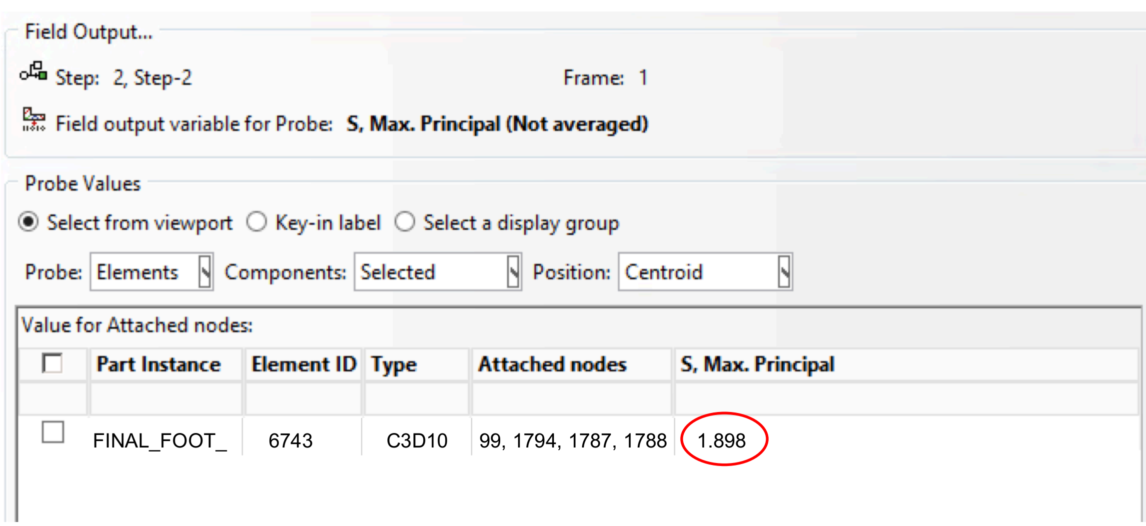

Figure 3.2: Abaqus output of principal stress at selected element using point probe.

The maximum principal stress of 1.898 MPa was located at the bottom of the prosthetic foot directly above the applied load, shown in Figure 3.1, where an area of high stress that could be of concern was experienced. The maximum principal stress at the bottom region of the foot was specifically located at element 6743, shown in Figure 3.2. This resulted in a 18.76% error from the theoretical calculation of 2.291 MPa.

To validate the FEA results on the prosthetic body under the two different loading conditions, the maximum principal stresses experienced at and above the slot region of the prosthetic body were calculated (see Appendix C). The first loading condition applies a 2 N tension force at the top region of the slot and the second loading condition applies a 2 N force on the outer surface of the body directly above the slots. The stress at the slot was used to validate the FEA results since the maximum principal stress on the body occurred at the curved bottom region near the extruded component. Due to the geometry of the prosthetic body, too many assumptions would have been made for a stress calculation at that point. A point probe in Autodesk Fusion 360 was used to verify the stress at the slot locations. The FEA results and theoretical results from the hand calculations for the principal stresses at these locations are shown in Table 3.2.

Table 3.2: Principal stress at slot under loading conditions

	Loading condition #1: Pulling up force	Loading condition #2: Tightening straps force
First principal stress at rectangular slot (Pa)	269.6	117.4
Theoretical principal stress from hand calculation (Pa)	257.8	151.6
Percent difference (%)	4.47%	25.43%

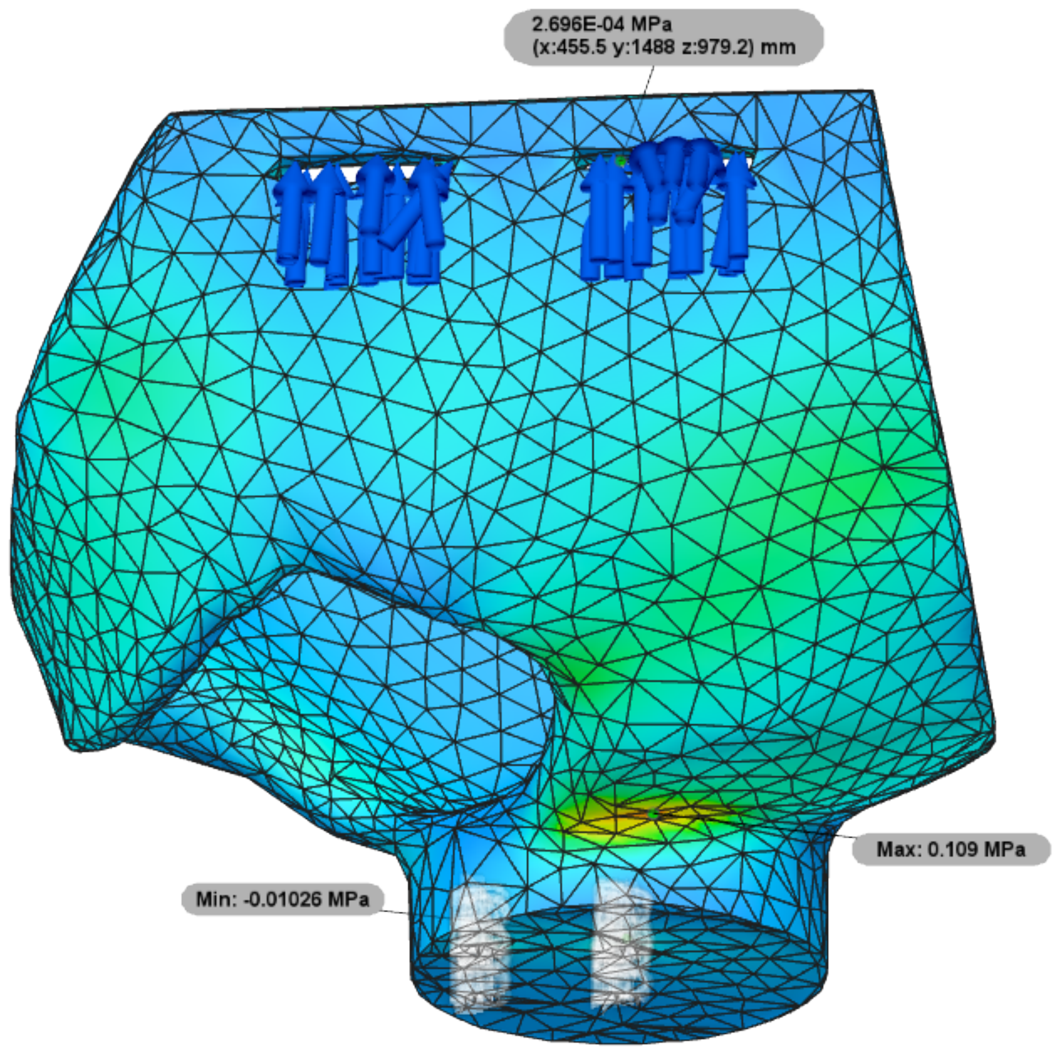

Figure 3.3: Maximum principal stress (in MPa) at slot region under loading condition 1.

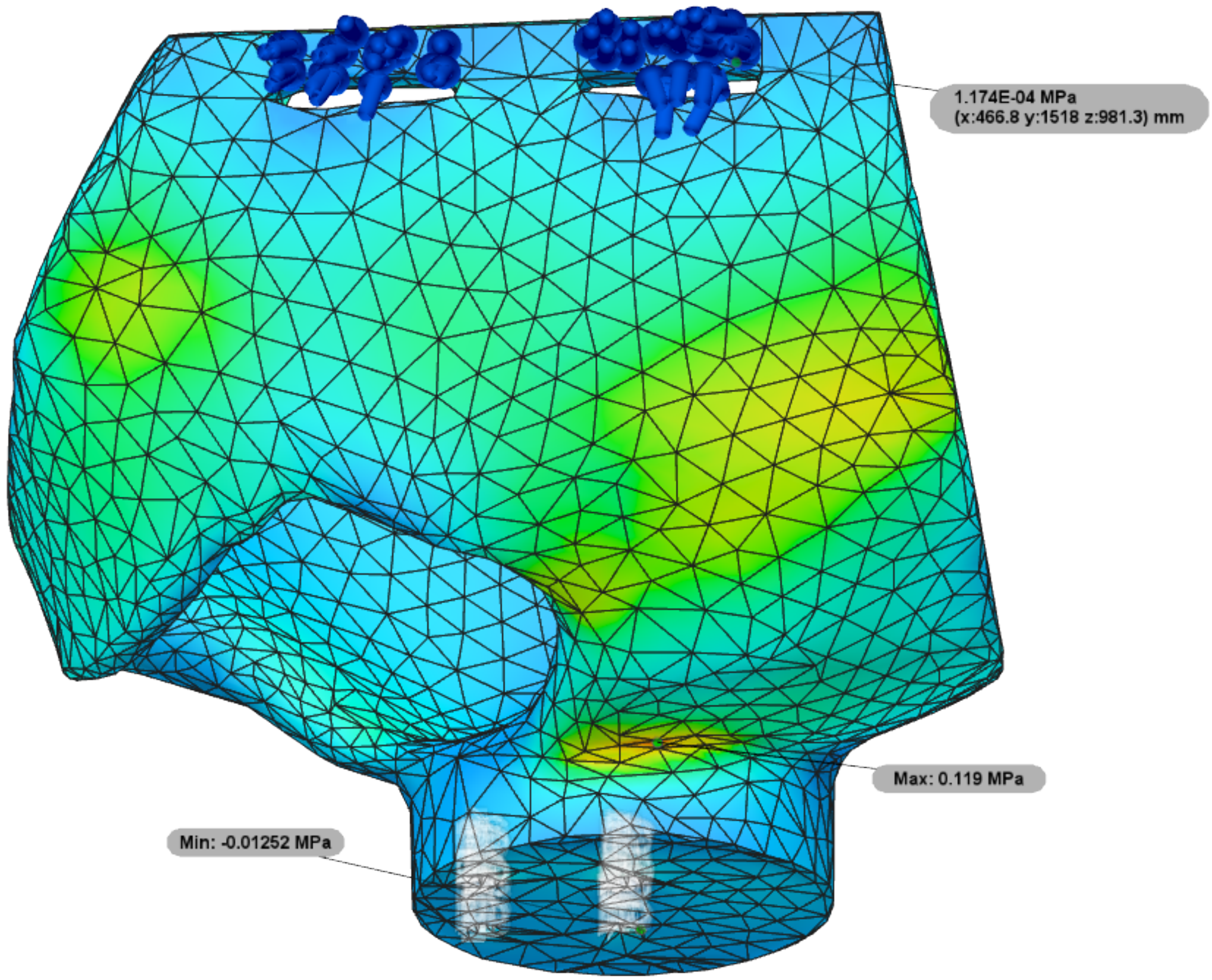

Figure 3.4: Maximum principal stress (in MPa) at slot region under loading condition 2.

Under the first loading condition, the principal stress of 269.6 Pa was located at the top inner region of the slot, seen in Figure 3.3. This resulted in a 4.47% difference from the theoretical calculation of 257.8 Pa. Under the second loading condition, the principal stress of 117.4 Pa was located above the slot where the force was applied, seen in Figure 3.4. This resulted in a 25.43% difference from the theoretical calculation of 151.6 Pa.

3.1.2 Finite Element Analysis Results on Prosthetic Foot

The results from the finite element analysis for the maximum stress experienced by the prosthetic foot during standing and for different phases of gait, as well as the factor of safety, are shown in Table 3.3. The maximum principal stresses experienced during stance phase are shown in Figure 3.5. The maximum principal stresses experienced during the different gait phases, including heel-strike, flat-foot stance, and toe-off, are shown in Figures 3.6, 3.7, and 3.8.

Table 3.3: Maximum stresses during static gait of canine

Model Used	Maximum Stress (MPa)	Factor of Safety
Stance phase (standing)	5.207	6.193
Heel-strike (gait)	13.65	2.637
Flat-foot stance (gait)	5.829	6.176
Toe-off (gait)	14.05	2.562

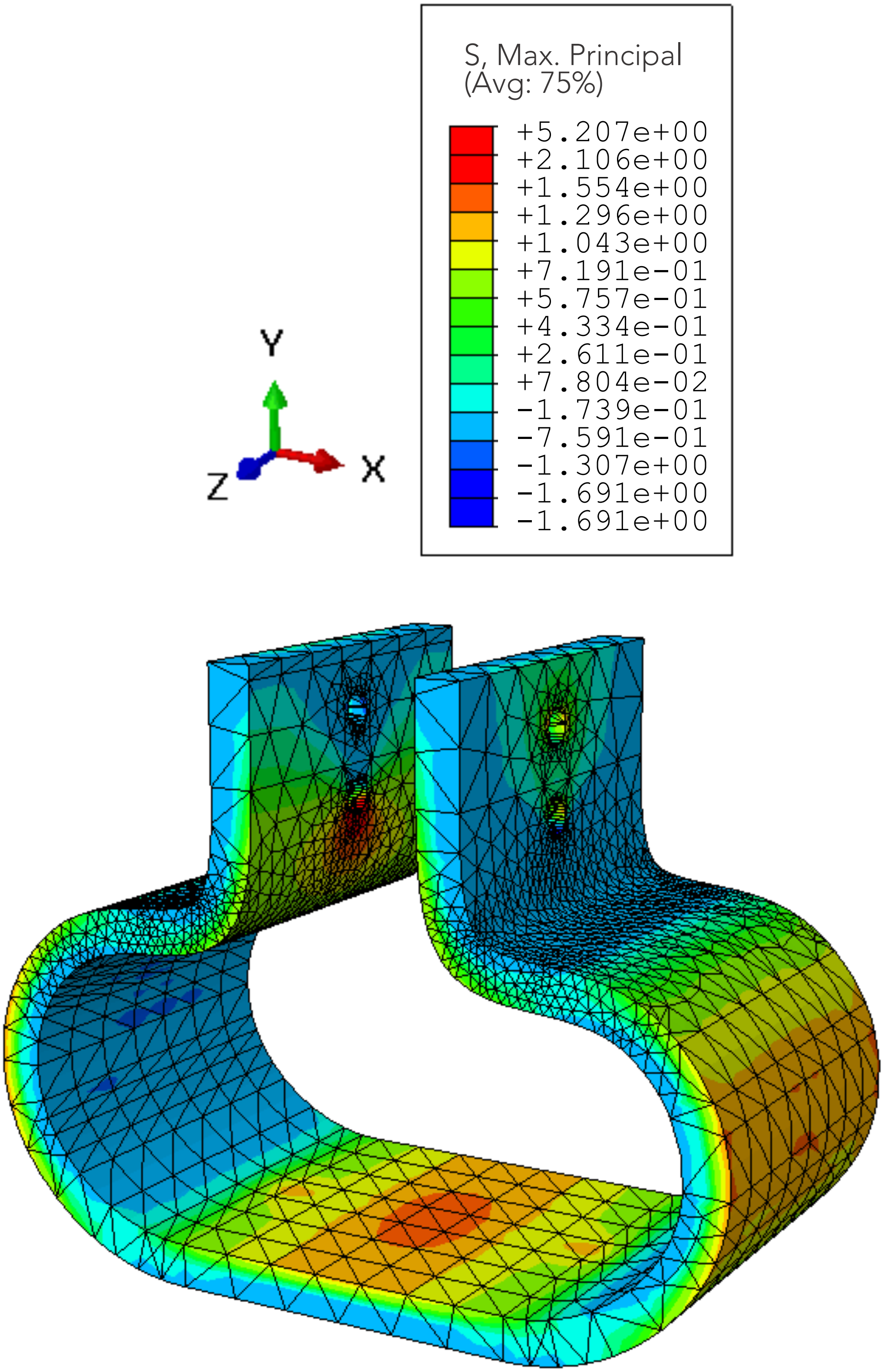

Figure 3.5: Maximum stress (in MPa) on prosthetic foot during static stance phase.

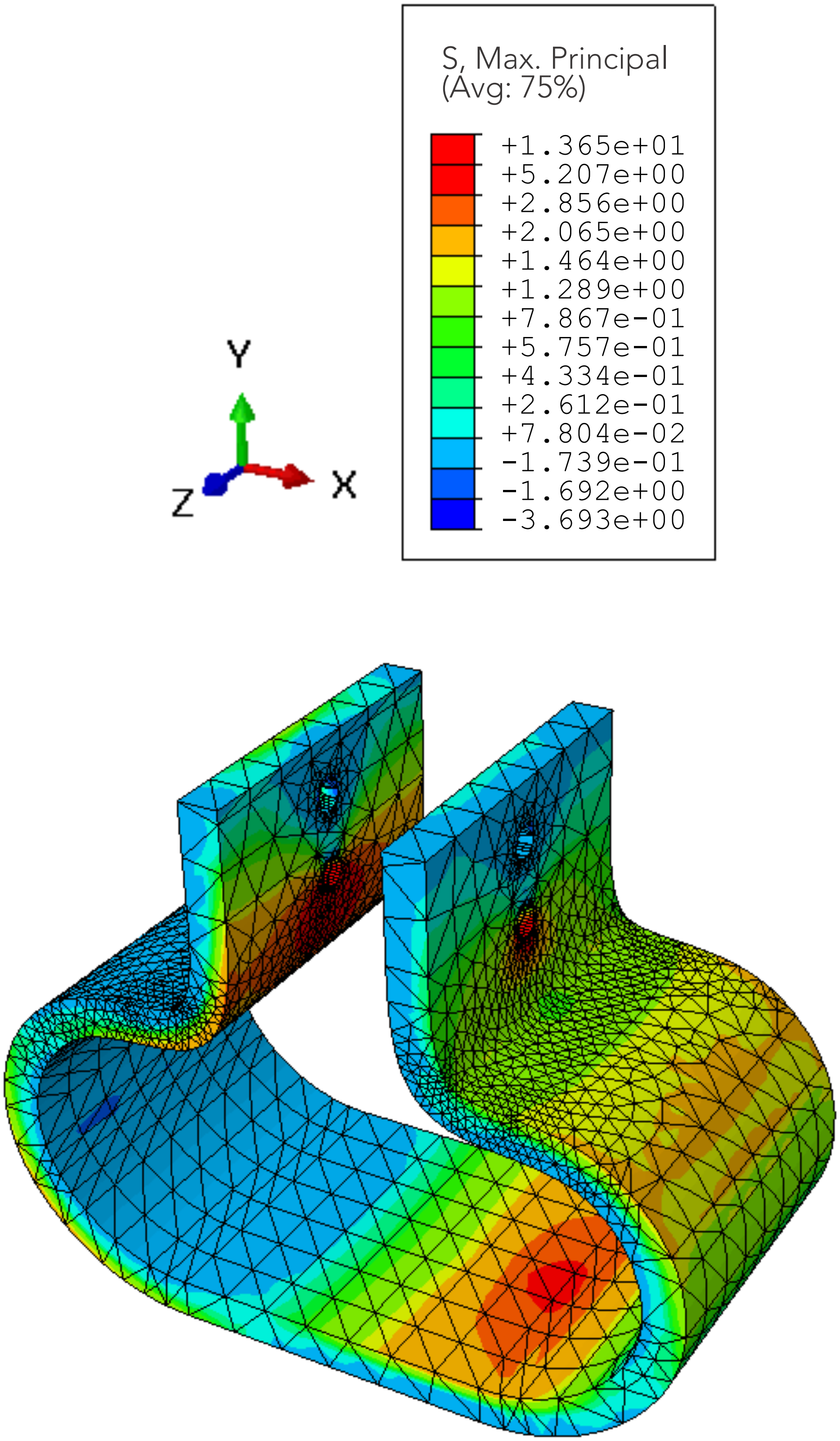

Figure 3.6: Maximum stress (in MPa) on prosthetic foot during heel-strike during static gait.

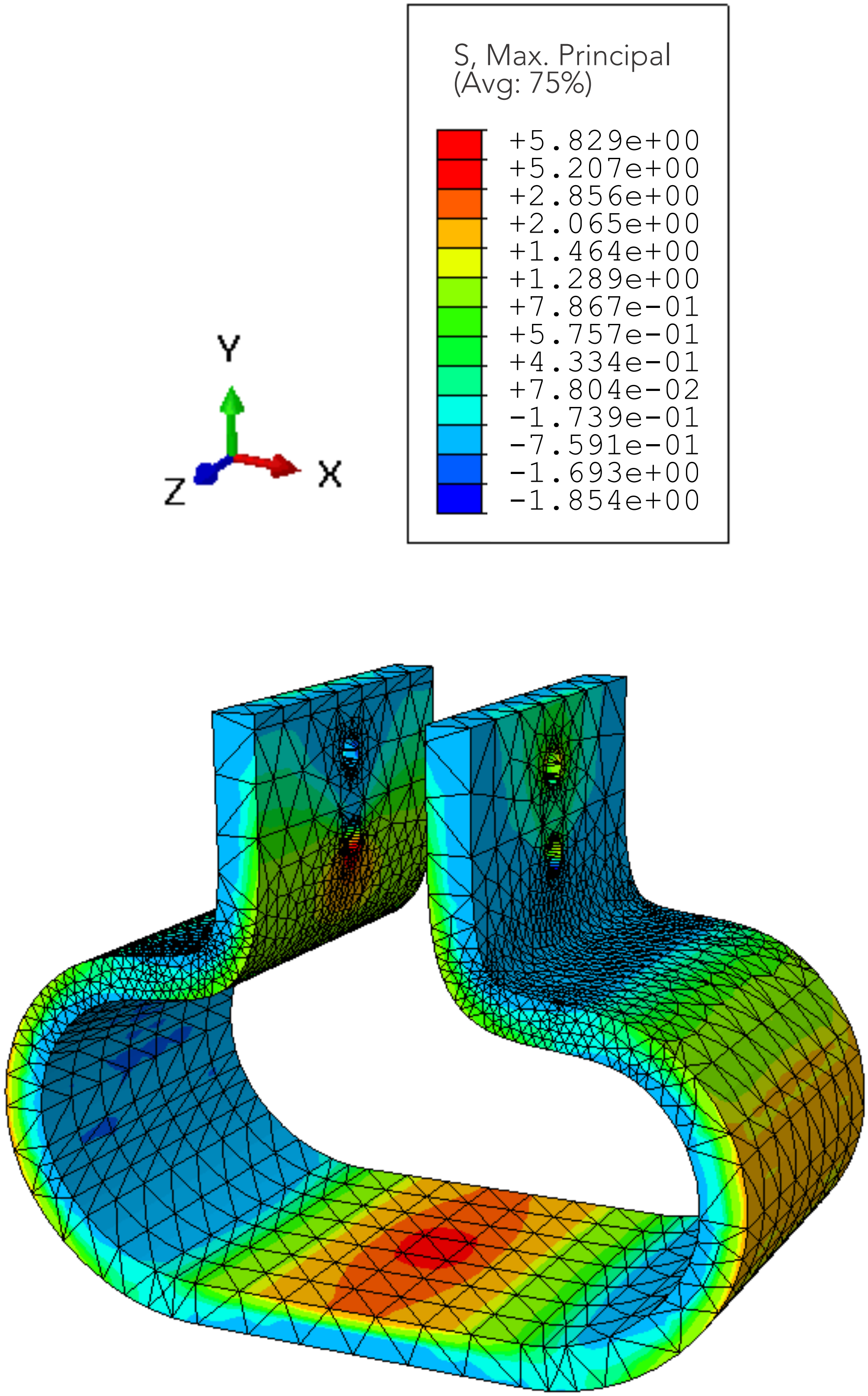

Figure 3.7: Maximum stress (in MPa) on prosthetic foot during flat-foot stance during static gait.

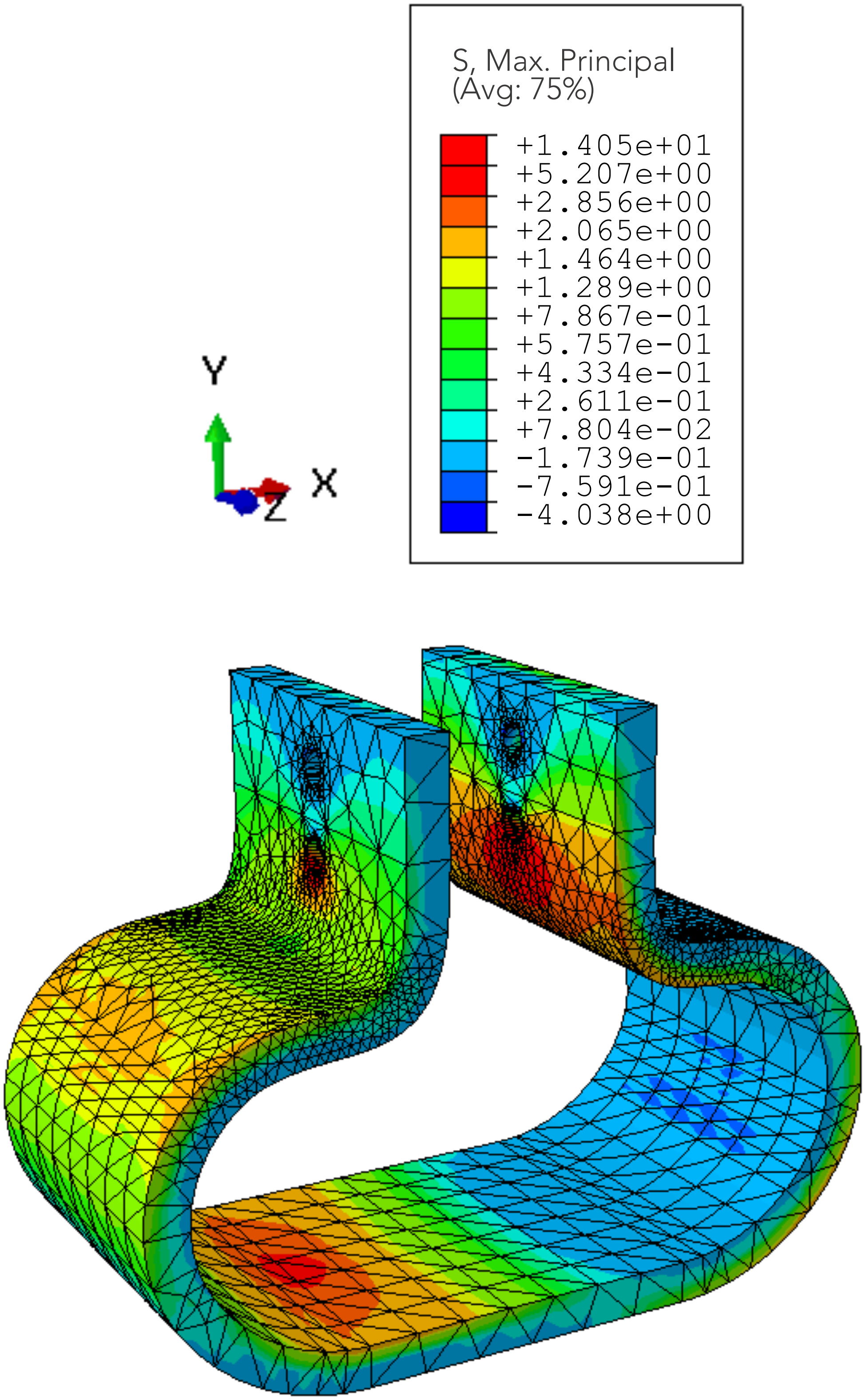

Figure 3.8: Maximum stress (in MPa) on prosthetic foot during toe-off during static gait.

The maximum stress during static stance phase of 5.207 MPa was experienced at each of the inner bottom holes where the leg attaches to the foot. The curved sections on the front and back of the prosthetic foot, as well as the region above where the load was applied, are areas that experienced high stress that could be of concern, but the holes are the biggest concern for maximum principal stresses. The factor of safety for the foot during static stance phase was 6.913. The maximum stress experienced during heel-strike was 13.65 MPa, the maximum stress experienced during flat-foot stance was 5.829 MPa, and the maximum stress experienced during toe-off was 14.05 MPa. The maximum stress during all three phases of quasi-static analysis were located at the inner bottom holes of the upper portion of the foot. During flat-foot stance, the bottom of the foot directly above where the force was applied experienced a high stress concentration. During heel-strike the factor of safety was 2.637, during flat-foot stance the factor of safety was 6.176, and during toe-off the factor of safety was 2.562 (see Appendix C). For brittle materials, such as PLA, where loading and environmental conditions are not severe, a factor of safety between 2.5 and 3 is ideal [25]. A thin padding will be added to the bottom of the prosthetic foot to alleviate some of the high stress experienced at this region.

3.1.3 Finite Element Analysis Results on Prosthetic Body

The finite element analysis results for the maximum stress experienced by the prosthetic body during two different loading conditions are shown in Table 3.4. The first loading condition applies a 2 N tension force at the top region of the slot to resemble a “pulling up” force of the straps. The maximum principal stresses under this loading condition are shown in Figure 3.9. The second loading condition applies a 2 N force on the outer surface of the body directly above the slots to resemble a tension force during tightening of the prosthetic body when it is secured on the canine. The maximum principal stresses under this loading condition are shown in Figure 3.10.

Table 3.4: Maximum principal stress under loading conditions

Loading condition	Maximum stress (MPa)
#1: Pulling up force	0.109
#2: Tightening straps force	0.1199

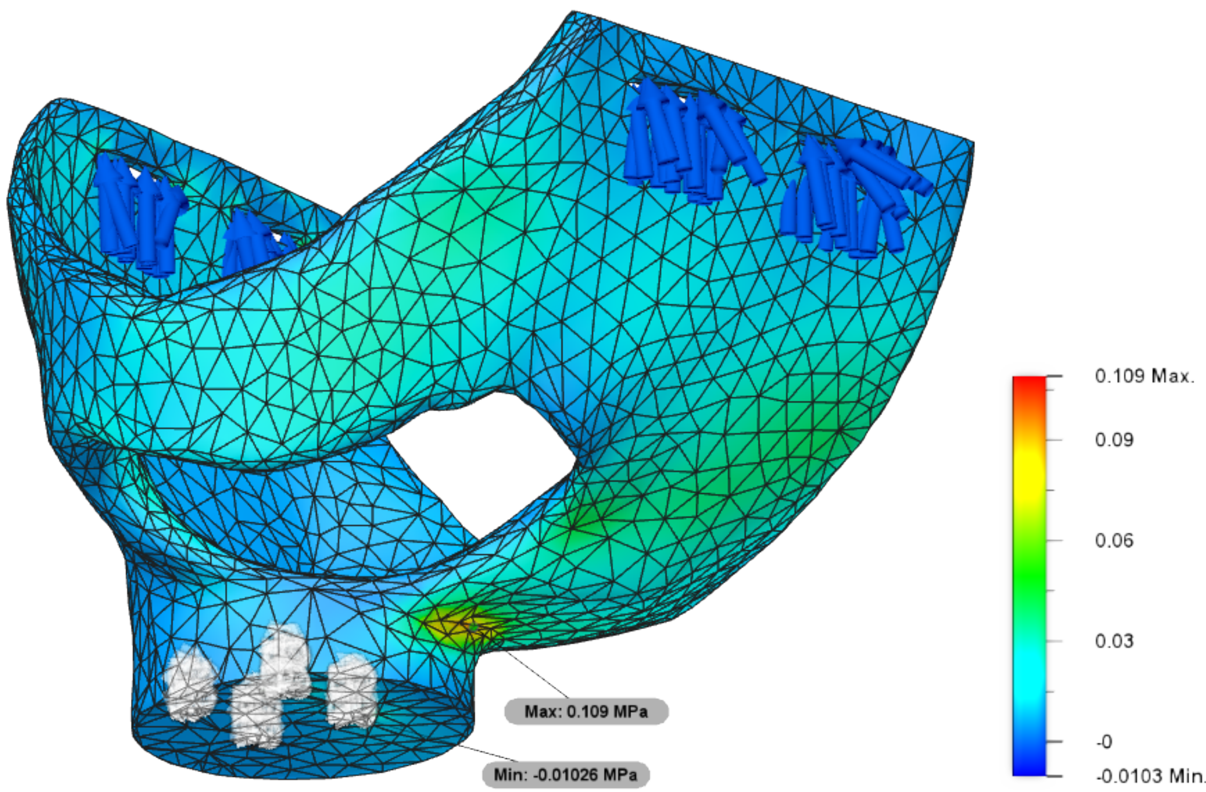

Figure 3.9: Maximum principal stress (in MPa) on prosthetic body under loading condition 1.

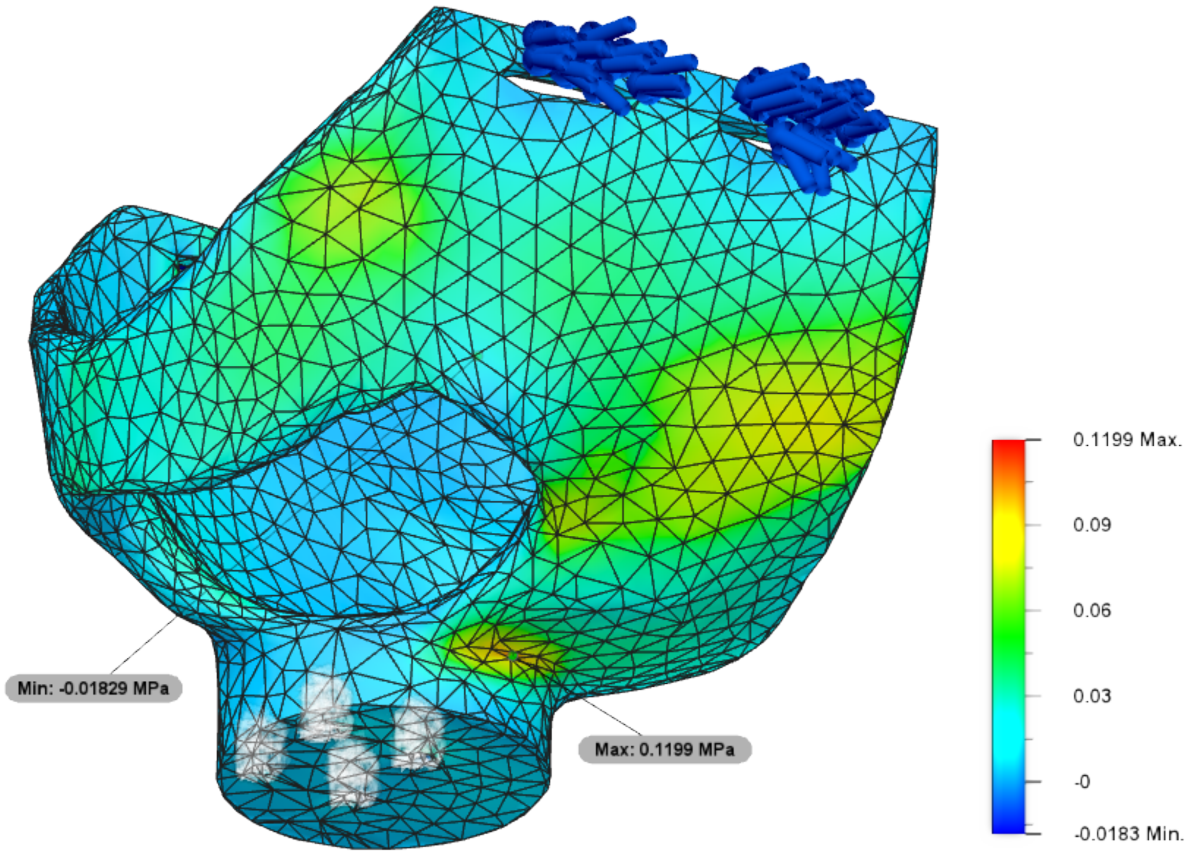

Figure 3.10: Maximum principal stress (in MPa) on prosthetic body under loading condition 2.

The maximum stress of 0.109 MPa under the first loading condition was experienced at the bottom of the prosthetic body near the extruded component for the attachment of the leg. The maximum stress of 0.1199 MPa under the second loading condition was also experienced at the bottom of the prosthetic body near the extruded component. The factor of safety for the prosthetic body was well above the Autodesk Fusion 360 output of 15 (see Appendix C), indicating that the model can easily withstand the applied loads, as determined by the finite element analysis results for maximum stress.

3.2 Subject Final Prototype Fitting and Functionality

For the final prototype of the canine prosthesis to be functional, it must fit correctly on the canine by fitting securely and flush against the canine's torso and chest, as well as being the correct length to not cause discomfort or imbalance for the canine during use.

Figure 3.11: Fit testing for correct height of prosthesis.

Figure 3.12: Fit testing for comfort of prosthesis on canine's body.

During stance phase, the canine was able to stand without any imbalance and discomfort, seen in Figure 3.11. This indicates that the leg of the prosthesis was the correct dimension to stabilize the gait of the canine, as well as to redistribute the body weight of the tripod canine to that of a tetrapod canine. The prosthesis was evaluated on the canine during stance phase, sitting, and during gait to determine if any pain or discomfort was experienced by the canine. Figure 3.12 shows the canine using the prosthesis while sitting. The prosthesis with the padding lining the inside of the prosthetic body was flush against the canine's skin and did not appear too tight. The dog did not whine or limp to indicate discomfort caused by the prosthesis. The final weight of the prosthetic device was 1.24 kg (12.16 N).

Chapter 4

DISCUSSION

One of the main objectives of this study was to design and develop a comfortable, durable, and inexpensive custom prosthesis for a tripod canine born with a total limb deformity in order to stabilize the gait and redistribute the joint forces of the canine, as well as to improve mobility of the canine to withstand normal and high-intensity gait forces. In terms of durability, the objective that the custom foot of the prosthetic had to be strong enough to withstand high impact forces experienced during normal gait was supported by the FEA results on the prosthetic foot. In terms of comfort, the objective that the body of the prosthetic, specifically at the socket where the residual limb rests, had to provide enough cushion to not add additional discomfort or pain to the canine was supported by the final prototype fitting and functionality testing in which the dog did not appear to be in any distress or pain. The objective that a custom canine prosthetic could be an inexpensive alternative for the owner was supported by a cost analysis, in which the manufacturing cost of building the prosthesis prototype did not exceed the predicted budget.

The maximum stress from the finite element analysis results experienced on the prosthetic foot was greatest during heel-strike and toe-off during quasi-static analysis than during static stance phase or quasi-static flat-foot stance. The greatest overall maximum stress of 14.05 MPa occurred during quasi-static toe-off phase. The maximum stress during static stance phase was the lowest of all the models, with a principal stress of 5.207 MPa. The maximum principal stress during heel-strike was 13.65 MPa and the maximum principal stress during flat-foot stance was 5.829 MPa. These maximum stress values were less than the tensile strength of 36 to 55 MPa specified for PLA. Due to different variations in polylactic acid filament used for 3D printing, there was not one definitive value specified for the tensile strength. The maximum stresses for all the models were significantly less than the ultimate tensile strength, indicating that the prosthetic foot will not fracture or fail under these conditions. The maximum stress for each static and quasi-static model occurred at the inner bottom hole on the top portion where the prosthetic leg was attached. Even though PLA has a tensile strength and elastic modulus comparable to other plastics, such as polyethylene terephthalate, plastic deformation can occur at higher stress levels, such as at screws or fracture fixation plates [26]. The greatest maximum stresses of 14.05 MPa and 13.65 MPa experienced during quasi-static toe-off gait and during quasi-static heel-strike gait, respectively, seen in Figure 3.6 and Figure 3.8 in section 3.1.2, will be reduced by adding a thin rubber padding on the bottom of the prosthetic foot. This rubber padding will absorb a majority of the impact forces experienced during gait, reducing the stress experienced on the part overall. Since rubber has both elastic and viscous properties, the viscoelastic properties of this material allow it to maintain a constant shape after deformation while simultaneously absorbing mechanical energy [27].

The body of the prosthetic device was designed to wrap around the canine's torso and chest to properly secure the device around the canine, as well as to provide adjustability of the device. Since the prosthetic body was primarily designed to secure the device on the user and serve as an attachment point for the prosthetic leg and foot, it did not need to withstand high impact forces like the foot. Rather, the prosthetic body needed to provide enough comfort at the socket for the canine so that the prosthesis did not inflict pain or cause discomfort during use. The maximum stress from the finite element analysis results experienced during the first loading condition, which simulated a "pulling up" tension force on the straps while adjusting the straps on the device, was 0.109 MPa; the maximum stress experienced during the second loading condition, which simulated a tension force pulling both straps inward during tightening of the device around the user, was 0.1199 MPa. Both of these maximum principal stresses, located at the bottom of the prosthetic body near the extruded component for the top-loading socket adaptor, were significantly less than the ultimate tensile strength of PLA of 36 MPa.

The final prosthesis prototype was fit and tested on the canine to make sure it fit on the canine properly without causing imbalance or discomfort. The final weight of 1.24 kg of the prosthetic was lightweight enough to not cause discomfort for the canine. The use of the prosthesis was intended to stabilize the gait and redistribute the body weight of the tripod canine to that of a tetrapod canine. Studies have found that tetrapod canines carry 30% of their body weight on each forelimb and 20% of their body weight on each hindlimb, while tripod canines carry an additional 17% of their body weight on their single forelimb [6]. This results in 47% of their body weight distributed to one forelimb and the additional 53% distributed to the two hindlimbs. Even though a tripod canine can continue its daily life with conservative management, deviations from the normal gait of a tetrapod canine or alterations to normal locomotive biomechanics of a tetrapod canine can lead to long-term effects on the musculoskeletal health of a tripod canine, resulting in lowered quality of life [6][8].

Even though the prosthesis fit properly and was flush and snug against the canine's body, as well as being the proper length to not cause imbalance of the canine and stabilize its gait, the canine was not able to properly walk with the prosthetic on. Since the canine was born with a congenital limb deformity and has never experienced walking with four limbs, it has accommodated to walking on three limbs by centering its front left intact limb during gait. Thus, the canine's front left intact limb interfered and crossed with the leg and foot of the prosthetic when it tried to walk. The learning curve of the canine during rehabilitation with the prosthetic device on is dependent on the owner's dedication and commitment to train the canine how to properly walk and get accustomed to the prosthetic. A majority of the intensive training and rehabilitation with the prosthetic typically occurs in the first three months [28]. Proper daily exercises are crucial to improve balance and increase proprioception, or the awareness of the body's position and movement, when using the prosthetic device. However, every canine is different, and thus, the time required to learn how to use the prosthetic could vary and be longer for a tripod canine born with a total limb deformity.

Orthopedic and prosthetic devices have been designed for canines with certain partial limb deformities, dysfunctional limbs, canines with severe physical impairment, and canines with partial or total amputated limbs. However, full body prosthetics for canines are not as commonly available as canine braces or canine wheelchairs. A full body prosthetic developed by Bionic Pets uses 3D scanning and printing from a casting kit using flexible anti-microbial thermoplastic polyurethane (TPU) and foams to ensure a proper fit, as well as providing comfort and function for the canine [29]. However, this first-of-its kind prosthetic is catered towards canines that have recently undergone amputation or surgery to correct a limb deformity rather than as an alternative to surgery for congenital or developmental limb deformities. A cast mold of the existing leg before surgery is taken and used to fabricate an immediate post-operative prosthesis that can be used directly after surgery [29]. The full-body prosthetics designed by Bionic Pets start at $1,500, which might not be an affordable option for some owners. Thus, one of the main goals of this custom canine prosthesis was to develop inexpensive manufacturing methods to make the prosthetic as affordable as possible for the owner. The final cost of the custom prosthetic was $692.84.

One limitation of this study was the material choice of PLA for 3D printing over other more flexible 3D printing materials. PLA is a cost-effective filament for 3D printing, which makes it advantageous for prototyping when cost is a main concern. Since 3D printing for the prosthetic body had to be outsourced due to its large size, PLA was the most affordable material choice to keep the prosthesis prototype within the budget of $600 to $800. PLA was also a commonly available filament that was easily accessible using campus resources. Due to unforeseen circumstances during the COVID-19 pandemic, the foot of the prosthetic had to be 3D printed using a personal 3D printer. The only available filament for the personal 3D printer was PLA.

However, PLA is a brittle material, resulting in poor toughness with repeated loading. Another limitation of this study was not being able to perform mechanical testing, specifically fatigue loading, due to campus resources being shut down due to COVID-19. Typically, fatigue testing would be performed to determine the durability of the prosthetic parts since fatigue is a big factor in determining fracture or failure. In a future study, fatigue testing, as well as other mechanical testing, such as tensile testing and impact testing, would be performed to validate the durability of the custom prosthetic components and materials. In another future study, the prosthetic device could be worn by the canine and its gait could be monitored and analyzed using a motion analysis system and OpenSim to determine the joint loads in the limbs while wearing the prosthetic device compared to the gait of a similar-sized tetrapod canine. Neuromuscular coordination, athletic performance, and musculoskeletal loads would be evaluated in both the tripod and tetrapod canines to assess any differences from normal gait activities while wearing the prosthetic.

In a future study, more flexible plastic materials with a high tensile strength and greater elasticity should be considered and tested for fatigue to determine the durability of the material. Tensile and impact testing under different loading conditions should also be conducted on these materials to determine if the material can withstand high-intensity gait forces of a canine. The use of a flexible yet strong material would allow for a more springy foot design while not deforming too much for more fluid motion during running gait of a canine rather than a rigid foot design that does not absorb the impact forces as well and can fracture or fail more easily. Other inexpensive 3D printing plastics with high tensile strength and greater flexibility include flexible PLA, thermoplastic elastomer (TPE), and thermoplastic polyurethane (TPU). Flexible PLA is a softer and more flexible yet durable PLA filament with material properties similar to a durable rubber [30]. Unlike standard PLA that is rigid and brittle, flexible PLA is resistant to impact. TPE, on the other hand, is a thermoplastic rubber with both thermoplastic and elastomeric properties [31]. The hardness of TPU material, which is a type of TPE, can be customized to be soft, resembling a more rubber-like material, or hard, to resemble a more rigid plastic. A dual-extruder 3D printer could be used to print the top portion of the foot in a rigid or flexible plastic to maintain the structure of the foot, while the bottom of the foot that comes in contact with the ground during gait forces could be printed in a flexible yet durable thermoplastic material. In terms of the leg of the prosthetic, the leg could be laterally oriented so that the canine’s front left intact limb does not interfere and cross with the leg and foot of the prosthetic when it walks. Since the canine has adjusted its gait on three limbs by centering its front left limb, it would be much more feasible to orient the leg laterally outward rather than training the canine to adjust its gait with its left limb not centered. The design of the foot bed of the prosthetic would also have to be modified with a greater thickness applied to the region of the foot that comes in contact with the ground. In terms of the body of the prosthetic, a future design could incorporate a more comfortable and flexible socket design to provide increased support and comfort for the residual limb. A future study could also improve upon the casting method used to create a mold of the canine’s torso, chest, and residual limb. A socket covering the entire upper body of the canine would result in a smoother cast mold, producing a more precise impression with less editing required.

Chapter 5
CONCLUSIONS

The purpose of this thesis was to design and develop a custom and cost-effective prosthetic for a canine with a congenital right forelimb deformity. Comfort, durability, and feasible yet affordable manufacturing methods were the main objectives of the prosthetic design. In terms of comfort, the socket was the main concern to prevent discomfort and reduce pain at the residual limb while wearing the prosthesis. The body of the prosthetic has an indentation created from the residual limb impression from the cast molding for the residual limb to rest. Even though foam padding was not added to the socket, padding was added on the interior sides of the prosthetic to create cushion between the canine's body and the prosthetic body. In terms of durability, the foot of the prosthetic was the main concern since it would be experiencing the greatest impact forces during gait. PLA was used to 3D print the foot of the prosthetic. Since PLA is a brittle material, a thin rubber padding was added to the bottom of the PLA foot to absorb some of the impact forces and reduce the high stresses experienced by the prosthetic foot. In terms of feasibility and affordability, inexpensive manufacturing methods and commercially available parts were used to assemble the final prototype of the prosthetic. Outsourcing for 3D printing of the body was the costliest component of this project. 3D printing costs could be greatly reduced with a personal 3D printer that could print large-scale parts or by printing smaller sections of the prosthetic body and assembling them together with a strong adhesive.

In a future study or development of this thesis project, fatigue testing should be performed to determine the durability of the custom prosthetic parts since fatigue is a critical factor in determining failure. Due to COVID-19, no mechanical testing could be performed on the custom prosthetic foot and body since campus resources, including the Instron mechanical testing machine, were not available. Along with fatigue testing, tensile testing and impact testing should also be performed to determine the failure points of the custom parts. Tensile testing would measure the material's response to a stress and applied force. Impact testing would determine the amount of energy absorbed by a material during fracture and would measure the material's toughness. To improve upon the design on this custom prosthesis, a thorough study should be conducted to determine the most durable yet flexible and affordable materials to manufacture the custom parts, specifically the foot and body of the prosthetic. The leg of the prosthetic should also be oriented laterally for easier rehabilitation with the prosthetic device in which the left intact limb of the canine will not interfere with the leg and foot of the prosthetic. Alternative manufacturing methods could also be investigated to reduce high outsourcing costs for fabrication of the device.

In spite of these limitations, a customized, low-cost proof of concept prosthesis was successfully developed for a canine with a front right limb deformity. The final prototype prosthesis achieved the initial goals of this thesis project. With continued research and improvement, the procedure outlined in this thesis could be used to mass produce cost-effective, custom prosthetics for canines with congenital and developmental limb deformities as an alternative to surgery.

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APPENDIX A: Canine Subject Background

The canine that was the sole subject of this study was born into a litter of eleven puppies. The canine was the only puppy born with a congenital limb deformity. The canine and its liter can be seen in Figure A.1 and Figure A.2. The canine as a puppy can be seen in Figure A.3. The canine at one year old can be seen in Figure A.4.

Figure A.1: The subject canine with multiple puppies from its litter.

Figure A.2: The subject canine with litter.

Figure A.3: The subject canine with a congenital limb deformity as a puppy.

Figure A.4: The subject canine with a congenital limb deformity at one-year-old.

APPENDIX B: IACUC Protocol

PROTOCOL FOR ANIMAL USE AND CARE

Email to: dpeterso@calpoly.edu

PROTOCOL:	
EXPIRES:	

	Investigator			Contact
Last Name:	Kastlunger; Hazelwood		Last Name:	Hazelwood
First:	Tayler; Scott		First:	Scott
Middle:	Renee; J		Middle:	J
email:	tkastlun@calpoly.edu; shazelwo@calpoly.edu		email:	shazelwo@calpoly.edu
Department:	BMED		Department:	BMED
Phone / Fax:	(805) 756-6304	N/A	Phone:	(805)756-6304
After hrs. #:	(619)623-5245		After hrs. #:	N/A

Check one:

X☐Research Project ☐Class ☐Enterprise Project

X☐New protocol

☐Addendum to previously approved protocol (protocol number).

☐Renewal of previously approved protocol (protocol number).

X☐As investigator, I accept responsibility to ensure that individuals providing care will be properly trained in animal care, maintenance, and handling.

X☐As investigator, I ensure that personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.

Species (common names):	Number used in project, or per quarter if class.	Source:
Canine	1	Pet

Project Title	Prosthetic for Canine with Right Forelimb Deformity		
Overnight housing location:	With owner	Site of methodology:	Santa Maria
Animals will be maintained by:	X☐Vivarium ☐Investigator *(If investigator maintained, attach husbandry SOP's.)*		

Timeline:

Starting date of project: February 1, 2020

End date of project: June 10, 2020

Please note that an approved protocol is only valid until completion of the project for a maximum of 3 years. Extension of approval beyond 3 years must be requested to the IACUC chair.

Procedures: Provide a one or two sentence layman's description of the procedures employed on the animals in this project. This information will help the animal care staff understand any conditions they may encounter while caring for your animals.

A canine prosthetic is being designed and 3D printed for a German Shepherd born with a right front limb deformity. A molding of the canine's torso and residual limb will be casted and used to develop and create a prosthetic. The 3D printed prosthetic will be fit on the canine after prototyping to ensure it fits properly. This minimally-invasive testing is part of a thesis research project.

Special Husbandry Requirements: Describe any special requirements your animals have with respect to **food**, **water**, **temperature**, **humidity**, **light cycles**, **caging type**, **bedding**, or any other conditions of husbandry.

N/A

Dog lives with its owner and is maintained by the owner in Santa Maria, CA.

Other instructions for animal caregivers: (check applicable entries)

Sick Animals	Dead Animals	Pest Control
☐ Call Investigator	☐ Call Investigator	☐ Call Investigator
☐ Clinician to treat	☐ Save for Investigator	☐ OK to use pesticides
☐ Terminate	☐ Bag for disposal	☐ No Pesticides in animal area
☐ Necropsy	☐ Necropsy	

Hazardous Materials:

Infectious Agents?	☐ Yes X☐ No	Agent(s):	
Radioisotopes?	☐ Yes X☐ No	Agent(s):	
Chemical Carcinogens?	☐ Yes X☐ No	Agent(s):	
Toxic Chemicals?	☐ Yes X☐ No	Agent(s):	
Biohazardous/Medical Waste, including sharps	☐ Yes X☐ No	Agent(s):	

Funding source:	BMED Department	Previously approved?	☐ Yes X☐ No
Is the project already funded?	☐ Yes X☐ No	Previous protocol number (if any):	

What is the source of primary veterinary care for your animals? (check one)

Note: Investigator will be responsible for ensuring proper health care and maintenance.

A list of local veterinarians available for service is available through the Cal Poly Veterinary Clinic.

☐ Cal Poly Veterinary Clinic (6-2539)   X☐ Another Veterinarian

If you checked "Another Veterinarian", please provide:

Veterinarian:	Dr. Greenberg	Address:	205 El Camino Real
Day phone:	(562)708-8369		Arroyo Grande, CA 93420
Emergency phone:	562)708-8369	Email:	Mgreenberg.dvm@gmail.com

X☐ Primary veterinarian has been consulted.

What is the source of backup veterinary care for your animals? (check one; must be different than primary care veterinarian)

X☐ Cal Poly Veterinary Clinic (6-2539)   ☐ Another Veterinarian

If you checked "Another Veterinarian", please provide:

Veterinarian:	Dr. Staniec	Address:	Cal Poly Veterinary Clinic 1 Grand Ave, Bldg. 57
Day phone:	805-756-2539		San Luis Obispo, CA 93407
Emergency phone:	805-235-2401	Email:	jstaniec@calpoly.edu

X☐ Backup veterinarian has been consulted.

Summary of Procedures:

a) Briefly describe the **overall intent** of the study. Include in your description a statement of your hypothesis, the objectives and significance of the study. Your target audience is a faculty member from a discipline unrelated to yours. Do not use jargon.

The objective of this study is to create a casting of a canine's torso and front right residual limb in order to 3D scan the cast and prototype a functional prosthetic that fits properly. If the prosthetic fits properly, then it will provide support and balance for the three-legged canine during use. The significance of this study is to develop an inexpensive method for prototyping prosthetics and braces for canines. Literature on canine braces and prosthetics, as well casting of an animal, has been consulted prior to this project to guide the methods used. Consultation with two veterinarians has also been conducted about canine rehabilitation with the prosthesis and to ensure that these methods and testing procedures will not harm the canine in any way.

b) Procedures employed in this project:

Please check the appropriate boxes if any of these procedures will be employed in your project:

☐ Monoclonal Antibody Production **	☐ Food or water restriction	☐ Special diets; food or water treatment.
☐ Polyclonal Antibody Production **	☐ Non-recovery surgical procedures	☐ Induced illness, intoxication, or disease
☐ LD 50 or ID50 studies.	☐ Survival surgical procedures	☐ Death as an endpoint (see **i** below)
☐ catheters, blood collection, intubation	☐ Multiple survival surgery***	☐ Trapping, banding or marking wild animals
☐ Prolonged restraint. (8 hrs+)	☐ Behavioral modification.	
☐ Fasting prior to a procedure.	☐ Aversive conditioning.	

**** If this protocol only describes antibody production, you may use the attached antibody production page in lieu of completing section c below.**

*****General anesthesia required. Guidelines for multiple survival surgery must be met. See guidelines.**

c) Describe the use of animals in your project in detail, with special reference to any of procedures checked above. Include any physical, chemical or biological agents that may be administered. List each study group, and describe all the specific procedures that will be performed on each animal in each study group. Use terminology that will be understood by individuals outside your field of expertise. *(Note: This cell will expand to whatever length you require. You may make this section as long as you wish, but try to be concise. Some projects may require one or two pages.)*

Testing will be performed on one animal, for which the custom prosthetic is specifically designed for. The animal is a 1-year old canine born with a right forelimb deformity. A cast of the canine's torso and front right residual limb will be created and will be 3D scanned and used in the development of a 3D-printed prosthetic prototype. For casting, a stockinette will be wrapped around the canine before wrapping the canine's torso and right residual limb with press-and-seal cling wrap. The stockinette and cling wrap will be used to protect the canine's body and fur from the cast material. A 2-inch layer of cast material will be applied around the canine's torso and front residual limb. After the cast dries, it will be carefully removed by hand without any pain or discomfort to the canine. The cast will be 3D scanned and used to develop and 3D print a prosthetic prototype. The prosthetic prototype will then be tested on the canine to ensure it fits. This type of testing will simply require fitting the prototype on the canine to ensure it fits correctly and flush against the skin. This minimally invasive type of testing should not provide any pain or discomfort to the canine.

d) Study Groups and Numbers: Define, in the form of a table, the numbers of animals to be used in each experimental group described above. The table may be presented on a separate page as an attachment to this protocol if you prefer. The Normal format should be three columns: Study Group, Procedure, Number of animals. The number of rows should follow from the number of study groups; **you may add as many rows as you require**. The chart must fully account for the number of animals you intend to use under this protocol. Assign each group to an invasiveness category according to the chart below.

Group	Procedures / Drugs	Number of Animals	Category
1	Fitting of canine prosthetic	1	1

Categories of invasiveness

Category	Description
1	Little or no discomfort or stress **Examples:** domestic flocks or herds being maintained in simulated or actual commercial production management systems; the short-term and skillful restraint of animals for purposes of observation or physical examination; blood sampling; injection of material in amounts that will not cause adverse reactions by the following routes: intravenous, subcutaneous, intramuscular, intraperitoneal, or oral.
2	Minor stress or pain of short duration **Examples:**: cannulation or catheterization of blood vessels or body cavities under anesthesia; minor surgical procedures under anesthesia, such as biopsies or laparoscopy; short periods of restraint beyond that required for simple observation or examination, but consistent with minimal distress
3	Moderate to severe distress **Examples:** major surgical procedures conducted under general anesthesia, with subsequent recovery; prolonged (several hours or more) periods of physical restraint; induction of behavioral stresses such as maternal deprivation
4	Severe pain near, at or above the pain tolerance threshold **Examples:** exposure to noxious stimuli or agents whose effects are unknown; exposure to drugs, chemicals, or infectious agents at levels that markedly impair physiological systems and which cause death, severe pain, or extreme distress: Surgical experiments which have a high degree of invasiveness.

Further descriptions of these categories are included in the instructions following this document.

e) Rationale for species and numbers: How did you determine that: 1) the species choice was appropriate, and 2) the number of animals in each study groups was the minimum number necessary to achieve sound scientific results? If the project is a classroom activity, justify the need for the number of animals indicated.

1) The species was chosen after finding an animal with a limb deformity that could be used for the project research and prototype development.
2) The prosthetic is being designed and customized for one specific animal, so only the one animal for which the prosthetic is designed for is needed for testing.

f) Surgery: If the project involves survival surgery, where will the surgery be conducted?

Building: N/A Room: N/A

Who will be the surgeon? N/A

g) Anesthetics, Analgesics, Tranquilizers, Neuromuscular blocking agents:

Post procedural analgesics should be given whenever there is possibility of pain or discomfort that is more than slight or momentary. If postoperative analgesics are not to be given, justify the practice under part (i) below.

Provide the following information about any of these drugs that you intend to use in this project.

Species	Drug	Dose (mg/kg)	Route	When and how often will it be given?
N/A	N/A	N/A	N/A	N/A

What physiologic parameters are monitored during the procedure to assess adequacy of anesthesia?

N/A

Under what circumstances will incremental doses of anesthetics-analgesics be administered?

N/A

h) Neuromuscular blocking agents can conceal inadequate anesthesia and therefore require special justification. If you are using a neuromuscular blocking agent, please complete the following:

Why do you need to use a neuromuscular blocking agent as opposed to general anesthetic?

N/A

What physiologic parameters are monitored during the procedure to assess adequacy of neuromuscular blocking agent?

N/A

Under what circumstances will incremental doses of neuromuscular blocking agent be administered?

N/A

i) Adverse effects:

Describe any potential adverse effects of the experiment on the animals (such as pain, discomfort; reduced growth, fever, anemia, neurological deficits; behavioral abnormalities or other clinical symptoms of acute or chronic distress or nutritional deficiency)

Potential adverse effects could include slight discomfort during casting or testing for fit.

How will the signs listed above be ameliorated or alleviated? If signs are not to be alleviated or ameliorated by means of post-operative analgesics or other means, explain why this is necessary.

Potential adverse effects will be mediated by ensuring the casting material and/ or prosthetic is not too tight on the canine. Foam padding will be used as a lining in the prosthetic to provide comfort and reduce rubbing between the prosthetic and the canine’s skin.

Note: if any unanticipated adverse effects not described above do occur during the course of the study, a complete description of those effects and the steps taken to mitigate them must be submitted to the committee as an amendment to this protocol.

Is death an endpoint in your experimental procedure? ☐Yes X☐No

(Note: "Death as an endpoint" refers to acute toxicity testing, assessment of virulence of pathogens, neutralization tests for toxins, and other studies in which animals are not euthanized, but die as a direct result of the experimental manipulation). If death is an endpoint, explain why it is not possible to euthanize the animals at an earlier point in the study. If you can euthanize the animals at an earlier point, describe the clinical signs which will dictate that an animal will be euthanized.

N/A

j) Alternatives and unnecessary duplication:

Federal law specifically requires this section. You are required to conduct a literature search to determine that either 1) there are no alternative methodologies by which to conduct this class/lab, or 2) there are alternative methodologies, but these are not appropriate for your particular class/lab. "Alternative methodologies" refers to reduction, replacement, and refinement (the three R's) of animal use, not just animal replacement. You must also show that this use of animals is not ***unnecessarily*** *duplicative of other studies.*

What were your findings with respect to alternative methodologies?

There are no other alternative methodologies in which to conduct this form of testing since it is being performed for a specific purpose on a specific animal. Since the prosthetic prototype is customized for a specific and unique congenital forelimb deformity, this methodology must be performed.

Has this study been previously conducted? ☐Yes X☐No

If the study has been conducted previously, explain why it is scientifically necessary to replicate the experiment.

Similar studies and experiments have been conducted on other species of animals that require custom braces and prosthetics, but since the prosthesis is being custom designed for a specific canine with a specific limb deformity, a similar type of experiment must be conducted for this project. Literature on canine braces and prosthetics has been consulted prior to this project to guide the methods used. Consultation with two veterinarians has also been conducted about canine rehabilitation with use of the prosthesis and to ensure that these methods and testing procedures will not harm the canine in any way.

k) Disposition of animals: At what point in the study, if any, will the animals be euthanized?

The animal will not be euthanized at any point.

l) Methods of euthanasia: Even if your study does not involve killing the animals, you should show a method that you would use in the event of unanticipated injury or illness. If anesthetic overdose is the method, show the agent, dose, and route.

Species	**Method**	**Drug**	**Dose (mg/kg)**	**route**
N/A	N/A	N/A	N/A	N/A

m) Surplus animals: What will you do with any animals not euthanized at the conclusion of the project?

There will not be any additional animals used during this study.

n) Carcass and Animal Waste Disposal:

Animal carcasses must be labeled and disposed of as follows:

- ☐ Biohazardous Waste Container
- ☐ Bury
- ☐ Solid Waste (regular garbage)
- ☐ Radioactive Waste
- ☐ EH&S will pick-up
- ☐ Other, please describe

All contaminated waste (soiled bedding or other animal waste) must be properly labeled and disposed of as follows

- ☐ Biohazardous Waste Container
- ☐ Bag and Autoclave
- ☐ Bury
- ☐ Disposed as surface waste
- ☐ Other, please describe:
- ☐ Solid Waste (regular garbage)
- ☐ Radioactive Waste
- ☐ EH&S will pick-up
- ☐ Compost

n) Project Roster: Please provide the names of all the individuals who will work with animals on this project. This page will not be made available to the public. Give either the University Employee ID # **or** a valid Cal Poly email address so that we can document training and occupational health compliance for regulatory agencies. Include all investigators, student employees, post-doctoral researchers, staff research associates, post-graduate researchers and laboratory assistants who will actually work with the animals. You don't need to include the staff of the vivarium in which your animals will be housed.

The principal investigator is responsible for keeping this roster current. If any staff is added or subtracted from this project, you must amend the protocol by sending the campus veterinarian a memo describing any changes.

Last Name	**First Name**	**Middle Initial**	**Cal Poly Empl ID Number**	**Email Address**	**Animal Care Training (IACUC USE ONLY)**
Hazelwood	Scott	J	004019024	Shazelwo@calpoly.edu	
Greenberg	Marissa		N/A	Mgreenberg.dvm@gmail.com	

Occupational Health Program:

Supervisors must enroll their employees in the campus Occupational Health Program if the workers are at increased risk of illness or injury (such as allergy, physical injury, or infectious disease) because of their work.

Training:

Supervisors are responsible for insuring that their employees are adequate trained, both in the specifics of their job and in the requirements of the Federal Animal Welfare Act.

Categories of Invasiveness in Animal Experiments

Use these categories when completing item d), Study Groups and Numbers

Each year, the US federal government requires a report from the campus in which animal projects are categorized as to degree of invasiveness. Please assist the IACUC in this determination by assigning the animal procedures in your project to one of the categories below. The *US Government Principles Regarding the Care and Use of Animals* state, “Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.”

1. Experiments which cause little or no discomfort or stress.**

Examples: domestic flocks or herds being maintained in simulated or actual commercial production management systems; the short-term and skillful restraint of animals for purposes of observation or physical examination; blood sampling; injection of material in amounts that will not cause adverse reactions by the following routes: intravenous, subcutaneous, intramuscular, intraperitoneal, or oral, but not intrathoracic or intracardiac (Category 2); acute non-survival studies in which the animals are completely anesthetized and do not regain consciousness; approved methods of euthanasia following rapid unconsciousness, such as anesthetic overdose or decapitation; short periods of food and/or water -deprivation equivalent to periods of abstinence in nature.

2. Experiments which cause minor stress or pain of short duration.

Examples:: cannulation or catheterization of blood vessels or body cavities under anesthesia; minor surgical procedures under anesthesia, such as biopsies or laparoscopy; short periods of restraint beyond that required for simple observation or examination, but consistent with minimal distress; short periods of food and/or water deprivation which exceed periods of abstinence in nature; behavioral experiments on conscious animals that involve short-term, stressful restraint: short term exposure to noxious but non-lethal levels of drugs or chemicals. Such procedures should not cause significant changes in the animal’s appearance, in physiological parameters such as respiratory or cardiac rate, or fecal or urinary output, or in social responses.

3. Experiments which cause moderate to severe distress or discomfort

Examples: major surgical procedures conducted under general anesthesia, with subsequent recovery; prolonged (several hours or more) periods of physical restraint; induction of behavioral stresses such as maternal deprivation, aggression, predator-prey interactions; procedures which cause severe, persistent or irreversible disruption of sensorimotor organization; the use of adjuvants which cause clinically evident swelling or abscesses.

Other examples include induction of anatomical and physiological abnormalities that will result in pain or distress: the exposure of an animal to noxious stimuli from which escape is impossible; the production of radiation sickness; exposure to drugs or chemicals at levels that impair physiological systems.

Note: procedures used in Category 3 studies should not cause prolonged or severe clinical distress as may be exhibited by a wide range of clinical signs, such as marked abnormalities in behavioral patterns or attitudes, the

** The text of these categories has been freely adapted from a document originally published by the Canadian Council on Animal Care (CCAC).

absence or grooming, dehydration, abnormal vocalization, prolonged anorexia, circulatory collapse, extreme lethargy or disinclination to move, and clinical signs of severe or advanced local or systemic infection, etc.

4. Procedures which cause severe pain near, at, or above the pain tolerance threshold of unanesthetized conscious animals

Examples: exposure to noxious stimuli or agents whose effects are unknown; exposure to drugs or chemicals at levels that (may) markedly impair physiological systems and which cause death, severe pain, or extreme distress: completely new biomedical experiments which have a high degree of invasiveness; behavioral studies about which the effects of the degree of distress are not known; use of muscle relaxants or paralytic drugs without anesthetics; burn or trauma infliction on unanesthetized animals; a euthanasia method not approved by the American Veterinary Medical Association; any procedures (e.g. the injection of noxious agents or the induction of severe stress or shock) that will result in pain which approaches the pain tolerance threshold and cannot be relieved by analgesia (e.g. when toxicity testing and experimentally-induced infectious disease studies have death as the endpoint).

ANIMAL ROOM SAFETY INFORMATION

Complete this form if you will be using biohazards, radioisotopes, carcinogens, or toxic chemicals in the animal room.

PROTOCOL#_____
EXPIRES: _____

RUA#: __________ BUA#: _________ CCA#: _________

Identity of Hazard:

Investigator Last Name:		Department:	
First Name:		Phone:	
Email:		Fax:	

Provide a short description of the agent:

This agent / material is hazardous for: ☐ Humans only ☐ Animals only ☐ Humans and Animals
For which Animal Species?

The agent can be spread by:
☐ Blood
☐ Saliva/nasal droplets
☐ Other:
☐ Feces/urine
☐ Does not leave animal

Describe any human health risk associated with this agent:

The precautions checked below apply to this experiment:

☐ The researcher or his/her technicians are responsible for the feeding and care of these animals.
☐ The following items must be assumed to be contaminated with hazardous material and must be handled only by the researcher or his/her technicians.
  ☐ Cage ☐ Stall ☐ Water Bottle ☐ Animal Carcasses
  ☐ Bedding ☐ Other:

☐ Cages must be autoclaved before cleaning.
☐ Label cages and remove label after decontamination.
☐ Animal carcasses must be labeled and disposed of as follows:
  ☐ Incineration ☐ Biohazardous Waste Container
  ☐ Bag and Autoclave ☐ EH&S will pick-up (6-6661).
☐ All contaminated waste (soiled bedding or other animal waste) must be properly labeled and disposed of as follows
  ☐ Incineration ☐ Biohazardous Waste Container
  ☐ Bag and Autoclave ☐ EH&S will pick-up (6-6661).

Personal Protective Equipment Required:

☐ The following personal protective equipment must be worn/used in the room:
  ☐ Lab Coat/Coveralls ☐ Shoe Covers/Booties
  ☐ Disposable Gloves ☐ Head Cover
  ☐ NIOSH Certified Dust Mask ☐ Disinfectant footbath
  ☐ Eye Protection/Face Shield ☐
  ☐ Fitted Respirator Type:
  ☐ Other: Describe:
☐ Personal protective equipment must be removed before leaving the room.
☐ Personal protective equipment must be discarded or decontaminated at the end of the project
☐ Hands, arms, and face must be thoroughly washed upon leaving the room
☐ Full shower, including washing of hair, must be taken upon leaving the room.
☐ Decontaminate Room (Inform ARS area supervisor when cage and/or room can be returned to general use).

Provide any other information needed to safely work in this room:

APPENDIX C: FEA Validation Calculations

During static stance phase and quasi-static flat-foot stance, a load of 90.74 N was applied in the upward y-directions as an impact force during gait. During heel-strike and toe-off, a force of 64.14 N was applied in both the x- and y-direction, calculated using equation (C1) and equation (C2).

Force in x-direction: $90.74 * \cos(45°) = 64.14\ N$ **(C1)**

Force in y-direction: $90.74 * \sin(45°) = 64.14\ N$ **(C2)**

The stress at the bottom of the prosthetic foot during stance phase (σ_{bottom}) was calculated using equation (C3). A concentrated force of 9.253 kg, or 90.74 N, which is 30% of the canine's body weight, was applied at the bottom of the foot in the center. The area where the maximum force was experienced was 3.96*10^{-5} m^2.

$$\sigma_{bottom} = \frac{F}{A} \quad \textbf{(C3)}$$

$$\sigma_{bottom} = \frac{F}{A} = \frac{90.74\ N}{3.96 \times 10^{-5}\ m^2} = 2.291\ MPa$$

The stress at the top of the slot opening was calculated under loading condition 1 and loading condition 2 using equation (C4). A 2 N force was applied at each tetrahedral mesh component along the top of the 5.08 cm slot, resulting in a 0.1016 N tension force applied at the slot region.

$$\sigma = \frac{F}{A} \quad \textbf{(C4)}$$

The principal stress at the top of the slot opening under the first loading condition is:

$$\sigma_1 = \frac{F}{A_{top\ of\ slot}} = \frac{0.1016\ N}{(0.007766\ m)(0.0508\ m)} = 257.8\ Pa$$

The principal stress above the slot under the second loading condition is:

$$\sigma_2 = \frac{F}{A_{above\ slot}} = \frac{0.1016\ N}{(0.01319\ m)(0.0508\ m)} = 151.6\ Pa$$

The factor of safety was calculated for the maximum principal stress experienced on the prosthetic foot during static stance phase and during each phase of quasi-static gait analysis. The factor of safety was also calculated for the maximum principal stress experienced on the body of the prosthetic under the two different loading conditions. The factor of safety was calculated using equation (C5).

$$FS = \frac{\sigma_{ultimate}}{\sigma_{actual}} = \frac{ultimate\ tensile\ stress}{actual\ maximum\ principal\ stress} \quad \textbf{(C5)}$$

For the foot of the prosthetic, the factor of safety was calculated during static stance phase (FS_1), during heel-strike (FS_2), during flat-foot stance (FS_3), and during toe-off (FS_4).

$$FS_1 = \frac{36\ MPa}{5.207\ MPa} = 6.193$$

$$FS_2 = \frac{36\ MPa}{13.65\ MPa} = 2.637$$

$$FS_3 = \frac{36\ MPa}{5.829\ MPa} = 6.176$$

$$FS_4 = \frac{36\ MPa}{14.05\ MPa} = 2.562$$

For the body of the prosthetic, the factor of safety was calculated during the “pulling up” tension force under the first loading condition (FS_{B1}) and during the “tightening” tension force experienced under the second loading condition (FS_{B2}).

$$FS_{B1} = \frac{36\ MPa}{0.109\ MPa} = 330.275$$

$$FS_{B2} = \frac{36\ MPa}{0.1199\ MPa} = 300.2$$