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Material Proposal and Shape Design of a Transfemoral Prosthetic Socket

"Boom! There's Your Socket" ™

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ABSTRACT

The socket is the critical component for user comfort and biomechanical functionality in a prosthetic. This project researches and designs an improved material and shape for a transfemoral prosthetic socket. Accessibility of material and manufacturing technique are selected for use in developing nations as well as developed nations. Features from the biodesigns HiFi™ socket, Martin Bionics Socket-less Socket™, the Quorum Quatro™ socket, and the Jaipur Foot Artificial Limb are combined in the new socket design. The proposed socket design is made using SolidWorks. The proposed socket is made from high density polyethylene, utilizes four alternating struts of tissue compression and release, and has a cable-tightening system for socket volume expansion. The socket design was simulated in SolidWorks using a nonuniformly distributed normal force load of 6,250.0 N applied on the internal faces. Computer aided design and simulations, written report, and a 3D display-only showcase unit are delivered.

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1 INTRODUCTION

A prosthesis is an artificial device to replace or enhance a missing or damaged body part [1]. These include legs, feet, arms, eyes, noses, and others. These body parts could be missing due to trauma (e.g. car crash, war injury), chronic vascular disease (e.g. diabetes, arteriosclerosis, thromboembolism), or birth defects [1], [2]. Common regions for prostheses are the upper and lower limbs. Lower limb transfemoral (TF) prostheses replace the leg from above the knee downward (see Figure 1) and are also called above knee. Indeed, transfemoral means “across the femur”. In cases of trauma or disease, an amputation might be necessary. In cases of birth defects, this is known simply as limb loss. The part of the limb that remains is called the stump, residual limb, or simply the limb. A generic transfemoral prosthesis and user are shown in Figure 2.

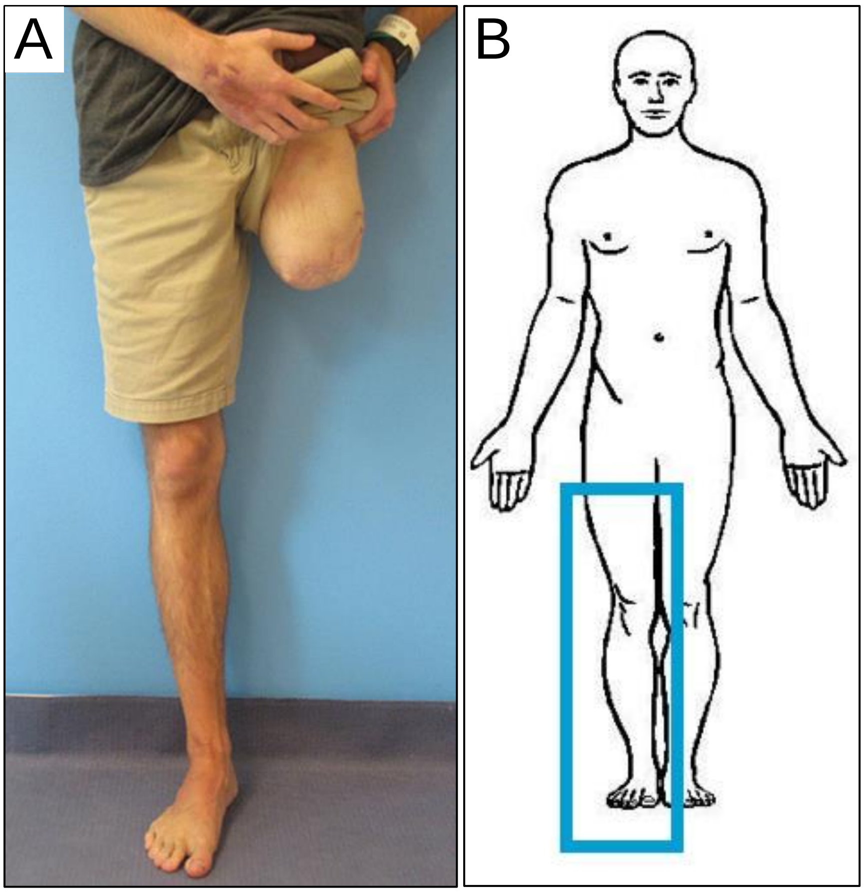

Figure 1. (A) Transfemoral amputation [3] and (B) Transfemoral location (In anatomical position) shown by blue square (Modified image taken from Google Images)

Figure 2. User with a generic transfemoral prosthesis [4]

A transfemoral prosthesis typically consists of a liner, socket, and components such as a knee, pylon, and foot. The residual limb is inserted into a liner (often made of silicone or neoprene). This provides cushion and in some cases suction to the socket. The limb and liner is then inserted into the socket. The remainder of the prostheses (e.g. knee joint, pylon, foot) is pre-attached to the socket (see Figure 3).

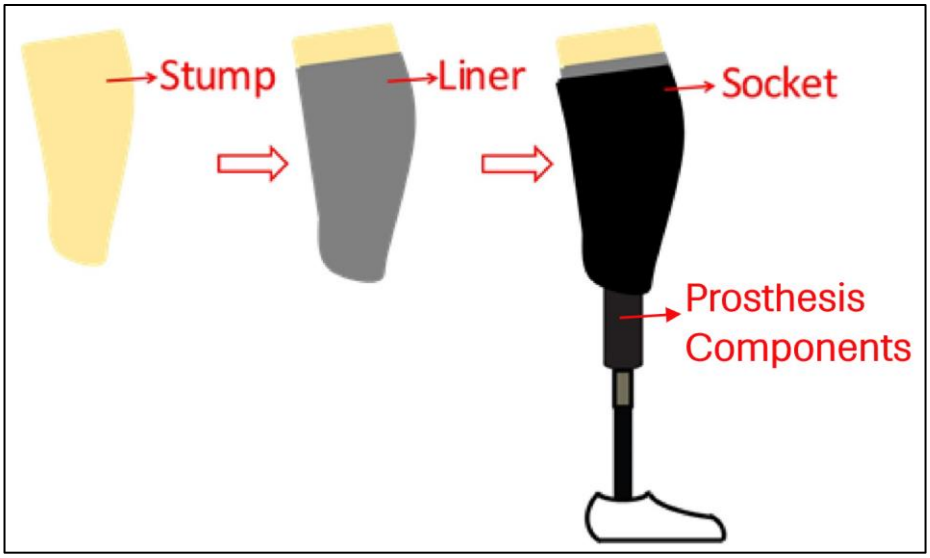

Figure 3. Prosthesis components (Modified from [5])

Concerning limb prostheses, Paternò et al. say that the "field of prosthetics dramatically evolved in the last decades. However, many amputees still reject their prostheses or report a low satisfaction level, mainly due to socket-related issues" [5]. The stump-socket interface is critical in prosthesis comfort and biomechanical function [5], [2], [6] (see Figure 4).

Figure 4. Traditional rigid transfemoral prosthetic socket [7]

1.1 STATEMENT OF PROBLEM

Jay Martin, certified prosthetist, inventor, scientist, and human, said about prosthetics, "It's not about replacing a limb and walking again, but about maximizing comfort and quality of life, to live life to the fullest" [7]. Bella May, physical therapist, professor at the Medical College of Georgia, and the president of BJM Enterprises, said in 1996 that "prosthetic replacements have been designed to improved function" of the limb [1], and consequently, the wellness of life of the amputee. But, according to Martin, "Ninety-five percent of amputees in developing nations won't have access to any kind of prosthetic technology in their lifetime – this equates to roughly 30 million amputees globally." He continues, "Accessibility of a comfortable socket is equally as important in developing nations and for those in developed countries" [7] (see Figure 5). For comparison, in the U.S. in 2023 there is an estimated 2,000,000 amputees [8].

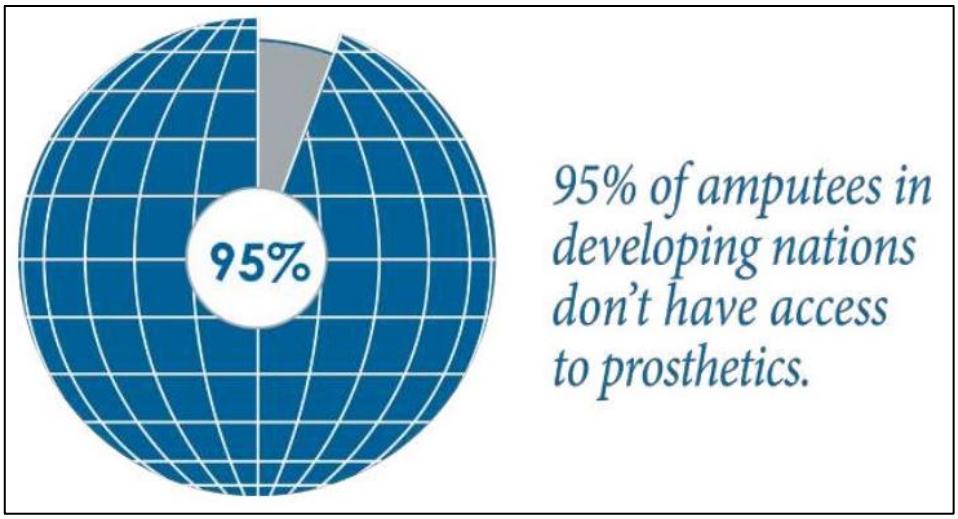

Figure 5. Jay Martin on the need for accessible prosthetic technology (95% of amputees in developing nations is roughly 30 million amputees) [7]

Joel Sadler from Stanford University for ReMotion Designs at a science, technology, and innovation forum in 2010 said that some high-end knee joints alone cost 1,000-10,000 USD [REF]. Dr. Krista Donaldson with Design Revolution (the group that made the ReMotion knee with the BMVSS and Dr. Pooja Mukul) said that in the U.S., polycentric knees start around $400 [REF]. Again, this is only for the knee joint, let alone the remainder of the prosthesis.

Traditional socket materials can be expensive, difficult to produce, and problematic for comfort. The material and shape of the prosthetic liner is also important but this project did not focus on the liner. Additionally, prosthetic sockets and prostheses themselves are expensive. A simple

Google search found the average pricing of a prosthesis in the U.S. is 5,000-50,000 USD, the low end representing basic prostheses.

Therefore, two main problems with prosthetics are inferred: poor accessibility and high cost of prosthetics. Having a prosthetic socket that works well and is easy to get is important for many people around the world.

As stated before, the stump-socket interface, i.e. the socket, is the critical connection between the user's (natural) residual limb and the prosthetic (artificial) device. In 2018, Linda Paternò et al. published an overview of the current technologies and challenges in prosthetic sockets. In the last decades, prosthetics have dramatically improved. "However," they say, "many amputees still reject their prostheses or report a low satisfaction level, mainly due to socket-related issues" [5]. The most important problems in traditional prosthetics are interfacial stresses (caused by the movement of limb tissue relative to the socket [9]), poor pressure distributions (caused by an incorrectly fitting socket), volume fluctuations of the stump (caused by the flow of bodily fluids and tissues in the limb), and temperature imbalance (since the limb is still part of the living human body). These four main socket issues are summarized in Figure 6.

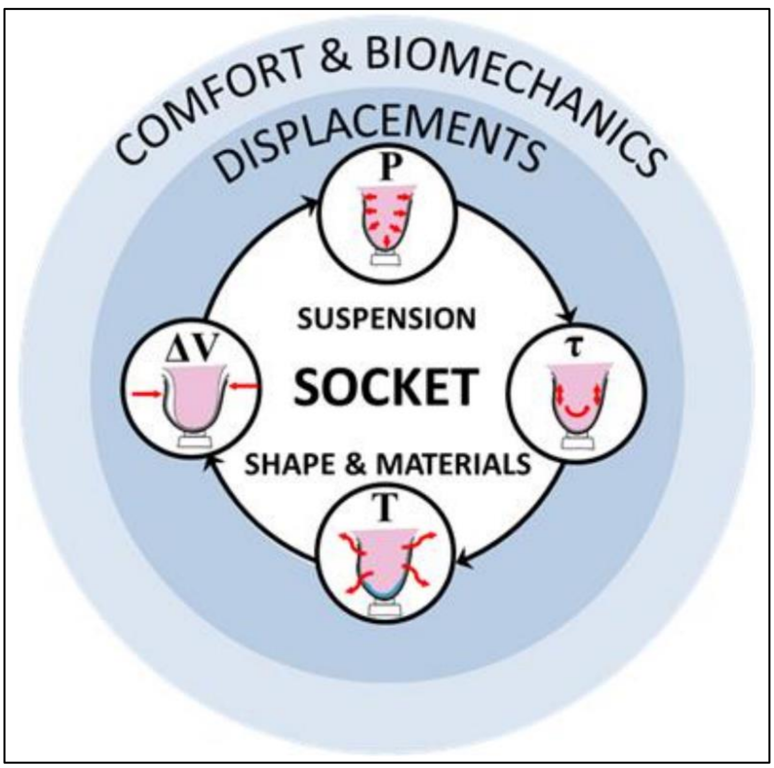

Figure 6. Main issues of prosthetic sockets [5]

Interfacial stresses “can cause skin problems and pain, affecting the whole comfort and, consequently, the gait biomechanics”. Additionally, “the friction between limb and socket produces shear stresses, which lead to tissue deformation and increase the risk of injuries” [5] “Human limbs consist of bone covered by a layer of muscle, which is covered, in turn, by a layer of adipose tissue and skin” [9]. In traditional sockets, the socket wall can be moved relative to the skin which creates friction and shear stresses.

Poor pressure distributions – traditionally distal end pressure – decrease stump-socket stabilization, proprioception, comfort, range of motion, and more [5], [9]. These can create displacements between the limb and the socket and increase what is known as the “pistoning effect”.

Volume fluctuations “alter the socket fitting, donning and comfort” [5]. The residual limb may change volume because of muscle contractions or movements of bodily liquids. Volume can fluctuate minute by minute, daily, and even yearly. Volume fluctuations affect socket fit and therefore both comfort and functionality, interfacial shear stresses, and pressure distributions, which, as stated before, connect the other problems. “In general, the stump is subjected to daily volume fluctuations which range from -11% to +7% or even more” [5].

Paternò et al. say that previous “studies have found that more than 53% of prosthetic users feel discomfort due to excessive heat or sweating, and an increment of 1-2°C is sufficient to trigger this (sic.) kind of problems” [5]. This, connected with interfacial stresses and the prosthetic liner type, can produce “sweating, irritation and smell” [5]. Traditional sockets and liners can prevent dispersion of heat and sweat.

All four of these issues are interrelated. These socket issues create a prosthesis that is uncomfortable for the user and that decreases normal biomechanical functionality such as gait symmetry and load bearing. Since “prosthetic replacements have been designed to improve function [of the amputated part]” [1], prostheses must “be comfortable, functional, and cosmetic, usually in that order” with the lowest expenditure of user energy [1]. The success of the prostheses depends on the success of the socket.

1.2 PROJECT OBJECTIVE

After considering the poor accessibility, high cost, and socket issues present in international prosthetics, the following objective for this project was created: *To design an improved transfemoral prosthetic socket that could be accessible in most developing nations. This will be done by changing the socket material and shape.*

The improved material and shape should increase accessibility and availability to amputees in developing and developed countries. The improved material and shape should also increase user comfort and functionality specific to the transfemoral socket. This project should consider processes that decrease the traditional socket manufacturing time, designs (conceptual and/or computer-aided) that are customizable for each patient, decreasing clinical wait time for fitting, structure and durability (and therefore overall wear life) of the socket, the patient's lifestyle needs (such as waterproof ability), and the cost of the overall prosthetic, among other factors.

1.3 PROJECT DELIVERABLES

The following items will be delivered for this project:

1. Report proposing a new material and shape for a transfemoral prosthetic socket
2. Computer-aided design rendering (using SolidWorks)
3. Computer-aided design stress and load simulations (using SolidWorks)
4. Socket showcase unit (for demonstration only)

To clarify, a complete, formal, actual, or prosthetic prototype, model, or device ready to be used in a clinical setting will not be delivered; only the above enumerated items will be delivered. A sample full-sized model may be delivered for display or demonstration purposes only.

The proposed final socket design is shown below in Figure 7.

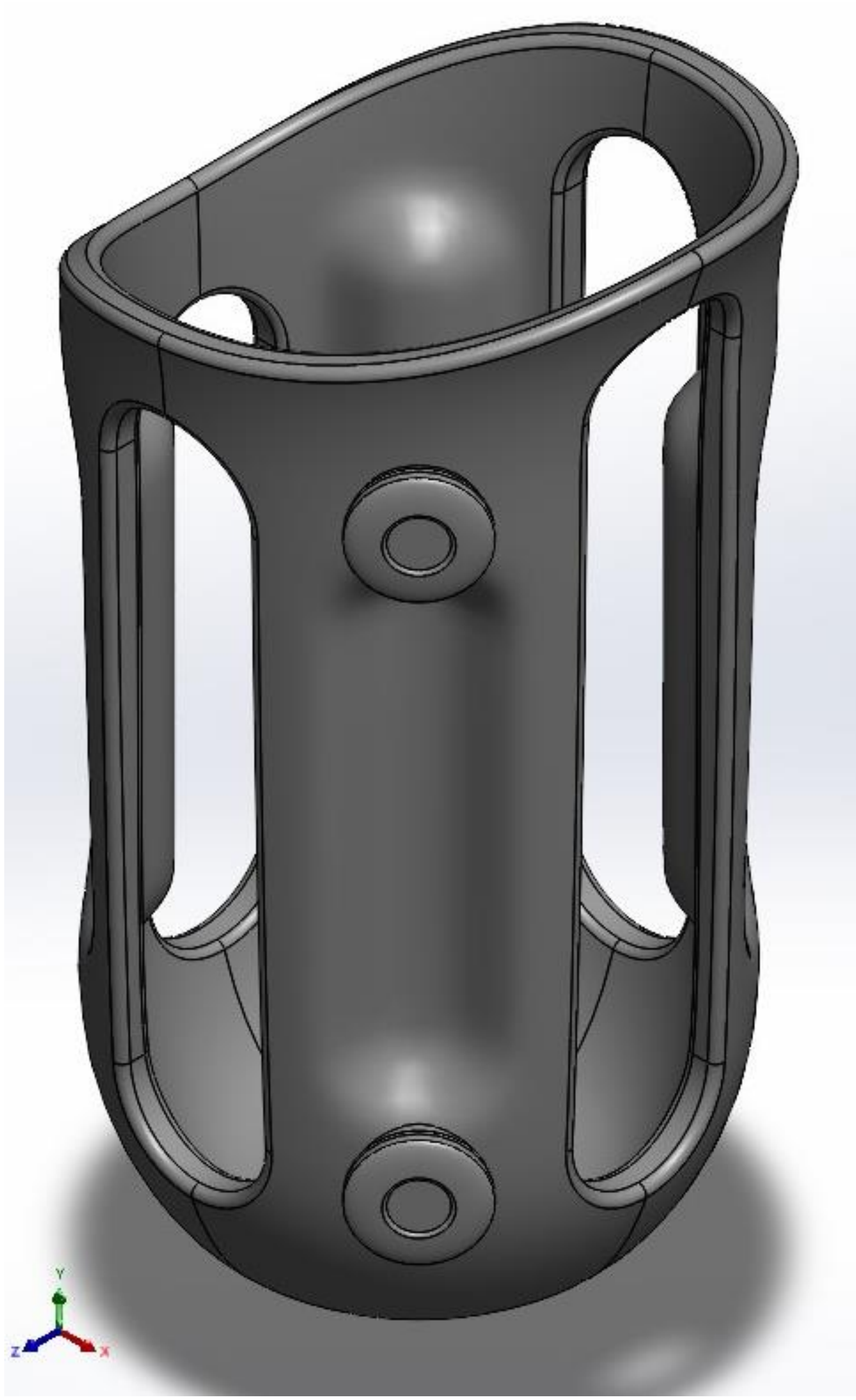

Figure 7. Proposed final socket design

1.4 TERMS AND DEFINITIONS, AND ANATOMICAL DIRECTIONS

Important terms and anatomical directions used in this report are summarized below.

user – the person using the prosthesis; the patient; the amputee

prosthesis – (noun); an artificial device to replace or augment a missing or impaired body part

prostheses – (noun); plural of prosthesis

orthosis – (noun); an artificial device to support, immobilize, or straighten muscles, joints, or skeletal parts which are weak, ineffective, deformed, or injured; a brace; also **orthotic** or **caliper**

orthoses – (noun); plural of orthosis

prosthetic – (adj.); describes a prosthesis, relates to a prosthesis

prosthetics – (noun); the study or field of prostheses

prosthetist – (noun); a person who does prosthetics; the licensed, clinical technician who makes artificial limbs for the upper or lower limbs, works with the user to obtain and fit a prosthetic;

residual limb – (noun); the remaining part of the amputated (or missing) limb; also **stump** or **residuum** or **limb**

stump-socket interface – (noun); the connection between the user's (natural) residual limb and the prosthetic (artificial) device

proprioception – (noun); the reception of stimuli produced within an organism; tactile feeling transmitted from the ground, through the prosthesis, and to the residual limb

distal – (adj.); anatomical direction situated away from (distant from) a central point; abbreviated as "dist." or "D"; see Figure 8

proximal – (adj.); anatomical direction situated close to (in close proximity to) a central point; abbreviated as "prox." or "P"; see Figure 8

anterior – (adj.); anatomical direction situated in front of or toward front; also **ventral**; abbreviated as "ant."; see Figure 8

posterior – (adj.); anatomical direction situated behind or toward back; also **dorsal**; abbreviated as "post."; see Figure 8

lateral – (adj.); anatomical direction situated toward the side; abbreviated as "lat."; see Figure 8

medial – (adj.); anatomical direction situated toward the middle; abbreviated as "med."; see Figure 8

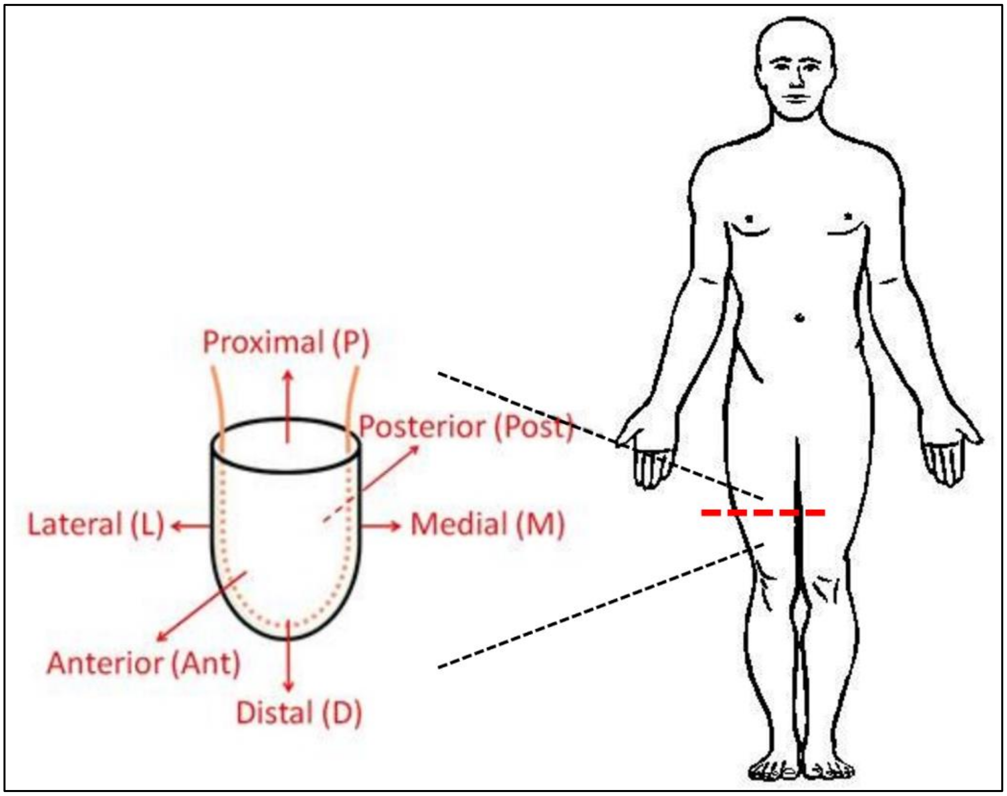

Figure 8. Anatomical directions at the transfemoral level (Modified from [5] and from Google Images)

1.5 STAKEHOLDERS

In a clinical setting, the stakeholders for a project like this are the user (since they will be using the socket for their life and well being), the prosthetist who selects this socket (since their occupational reputation depends largely on relationships and the success of their patients), the family of the user (since their lives will be affected by the user's life), the company that owns the socket (since their reputation depends on the success of the socket), and the company that manufactures this socket (since their reputation also depends on the success of the socket).

1.6 APPLICABLE STANDARDS OF PROSTHETICS AND ORTHOTICS INDUSTRY

The International Organization for Standardization (ISO) has two international standards for testing and product requirements pertaining to prostheses and orthoses: ISO 10328:2016(E) "Prosthetics – Structural testing of lower-limb prostheses – Requirements and test methods" [10] and ISO 22523:2006(E) "External limb prostheses and external orthoses – Requirements and test methods" [11]. These detail methods for testing prostheses and orthoses and include load and material requirements. Bella May also lists basic requirements which prosthetic sockets must accomplish [1]. Standard 10328 was seen many times in the literature. In the case where standards overlap or conflict, the more stringent one shall be kept.

These standards provide design requirements for the transfemoral prosthetic socket of this project. These requirements drove the design and decision process.

The International Society for Prosthetics and Orthotics (ISPO) and the Food and Drug Administration (FDA) are other organizations which have standards applicable to this project. However, these standards were not researched.

1.7 REPORT PREVIEW

This report discussed the prosthetics field and problem, the issues related to prosthetic sockets, the project objective, deliverables, terms and definitions, and stakeholders, and applicable standards. This report will further discuss similar research, conceptual designs, the material and shape selection process, other factors related to this project, and recommendations for future work. A summarizing conclusion, references, and appendices finishes this report.

2 BACKGROUND

Listed below are four similar projects, devices, and research.

2.1 HIFI™ SOCKET BY BIODESIGNS

Randall Alley et al. documented their findings and research on their new socket design that is stabilized by alternating areas of tissue compression and release [9]. A version of their socket is shown in Figure 9. Due to the amount and flexibility of muscle, fat, connective tissue, and skin that comprise human limbs, "the latter two layers are easily displaced longitudinally along the limb or rotationally around the limb before the connective tissue limits further motion."

[9]. This creates interfacial stresses (between the skin and the socket) and sloppiness in biomechanical function. Figure 10 (a)-(b) show this phenomenon. Here, the bone must push through the limb's soft tissue before transferring substantial load. Transferred motion is lost and energy is expended before the bone can move the socket and, therefore, the rest of the leg.

Alley et al. used a socket with longitudinal depressions that compress the tissue nearly until no more motion is possible. “This compression is possible because release areas are provided between the depressions for the displaced tissue to move into.” [9]. These alternating compressive struts and release areas (fenestrations) stabilize the underlying bone, as shown in Figure 10 (c)-(d) and Figure 11. Limb control is achieved by radial forces being applied along the entire shaft of the bone, instead of traditional distal areas. This socket creates a reduction in volume fluctuation, improves gait stability, limb cooling, proprioception, “comfort, energy efficiency, ROM, and the perceived weight of the prosthesis by providing a better, more intimate fit that allows increased functionality.” [9], [12]. They caution readers, though, because of the lack of research on tolerable amounts of pressure applied to limb tissue and bone. They admit they must further research how prolonged compressions affect tissue health, blood flow, and user comfort and helpfulness.

Figure 9. The HiFi™ CRS socket (An early version of a finished frame shown here) [9]

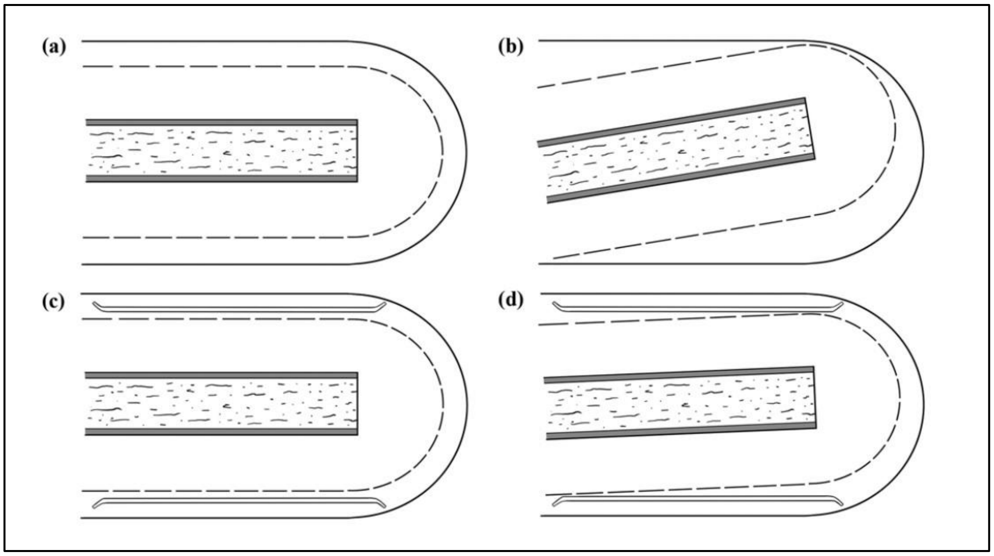

Figure 10. Longitudinal cross-sections of limb show response of limb tissue to movement of bone. Cross-Sections (a)-(b) show the traditional socket and (c)-(d) show the CRS socket. Dashed line represents level to which tissue must be compressed for load transfer. In (d), compression strut transfers load quickly with little change in bone angle. [9]

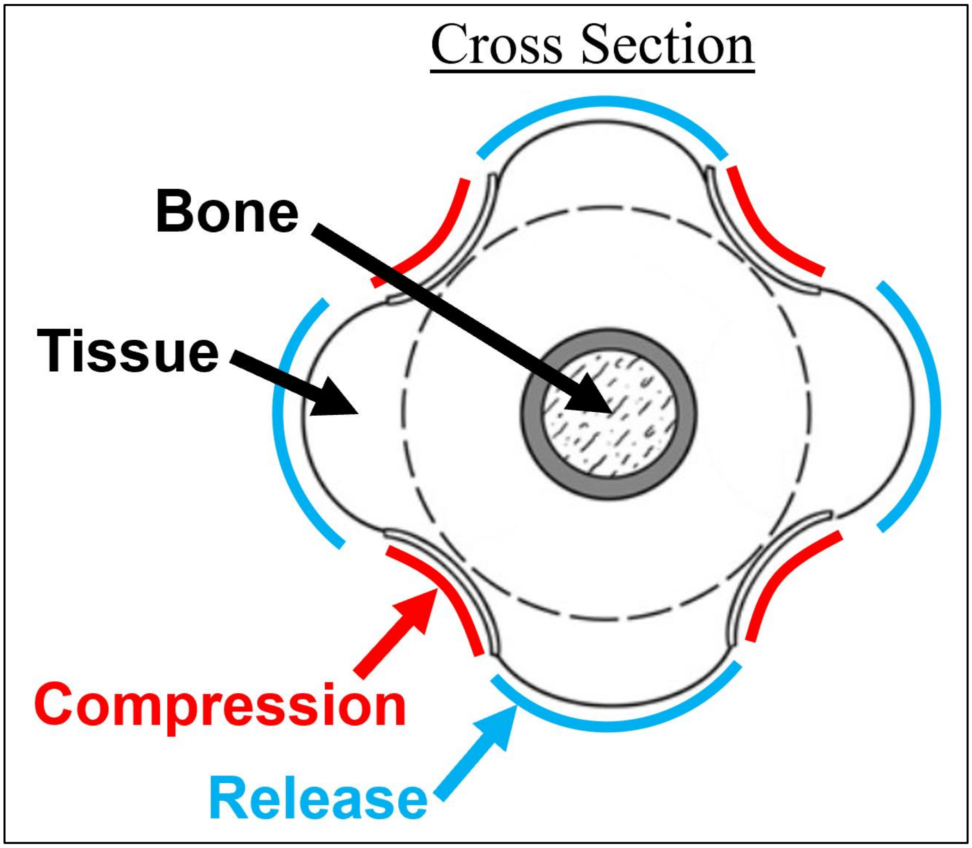

Figure 11: Transverse cross-section showing the four-depression design and how it works (Modified from [9])

2.2 SOCKET-LESS SOCKET™ BY MARTIN BIONICS

In 2019 Jay Martin published a patent for a Transfemoral Level Interface System Using Compliant Members. This socket uses at least two compliant stabilizing units "to control bone position and support the limb within the interface" [13]. The result is the Socket-less Socket™ by his company Martin Bionics and is shown in Figure 12 on the right. This socket uses flexible, lightweight materials and its clinical outcomes are numerous. It is 3.3x more comfortable, 50% more even weight distribution, a 94% increase in sitting comfort, ROM, and socket conformity, 44% increase in stability and ambulation confidence, 77% fewer issues with skin breakdown and 2.6x cooler, 50% fewer reports of distal discomfort, 42% increase in daily wear time, and more, all compared against users' previous, traditional rigid sockets as shown in Figure 12 [14]. Their goal, evidently, is "The End of Rigid Sockets" [14]!

Figure 12. A traditional, rigid socket (Left) compared to the Socket-less Socket™ (Right) [14]

2.3 *QUATRO™ SOCKET BY QUORUM PROSTHETICS*

In 2019 Joe Johnson patented a "disarticulated compression socket configured to secure a residual limb" [15]. This socket uses compression inserts that can be coupled with an actuator to adjust the shape of the socket. This adjusting allows the user to fine-tune the shape and fit of the socket to their desires. The Quatro™ is shown in Figure 13. This design uses a Boa® Fit System ratcheting mechanism to tighten or loosen the compression inserts. This socket can also be 3D printed. Quorum used Lubrizol's HP multi jet fusion (MJF) 3D printing and ESTANE 3DP TPU M95A material for the flexible inner socket [16], [17]. "This polymer provided the flexibility and durability necessary for prosthetic inner sockets as well as an adequate level of softness for enhanced patient comfort" [16]. The "outer hard socket [was] printed out of PA12" [16].

In an online article by Loveland, CO-based *Amplitude Magazine*, "former MMA professional Rustin Hughes calls it 'the closest thing to my real leg that I've ever experienced.'" [18]. Hughes added in a different article by The Denver Post, "If it weren't for Joe and the socket, I don't know where I would be at." [19]. The benefits of this socket are "a superior, secure fit", improved proprioception which "makes for less falls and greater control", is 3D printed, “can be donned on and off in as little as twenty seconds”, and the technology is adaptable to various socket designs [20].

Figure 13. Quorum Quatro™ socket (Patented: 100004614, 10406003) [20]

2.4 JAIPUR FOOT ARTIFICIAL LIMB BY BHAGWAN MAHAVEER VIKALANG SAHAYATA SAMITI

The Bhagwan Mahaveer Vikalang Sahayata Samiti (BMVSS) a hospital in Jaipur, India was founded in 1975 by Padma Bhushan Shri. D.R. Mehta to “provide artificial limbs … with a focus on the rehabilitation [of the] poor” [21]. BMVSS produces artificial limbs at costs of 45-60 USD [22], [23], but provide these prostheses free of charge to the patients [24].

While their sockets and prostheses might not be as state-of-the-art as the previous sockets, they used skin-colored high density polyethylene (HDPE) drainpipes. This decreases the cost of the socket and makes the manufacturing process simpler and quicker. The Jaipur Foot Artificial Limb and socket are shown in Figure 14.

Figure 14. Jaipur Artificial Limb and Jaipur Foot [25]

3 PRELIMINARY DESIGN

This section discusses the preliminary design concepts for a transfemoral socket with a new material choice and new shape to help improve socket outcomes.

3.1 PROJECT REQUIREMENTS

After research of the topic, the issue, and the current technology, the question was asked, "What must the socket meet in order to be considered successful?" The following requirements were created to address this.

- *The socket shall restore amputee's normal functionality and autonomy.*

  1. The socket shall hold onto the residual limb during all activities.
  2. The socket and all socket components shall fail at no less than 6,245.0 N of vertical force.
     a. The socket shall support $(7.8) \times (Body\ Weight)$ without failing.

3. The socket shall not exceed 1.6 kg in mass (± 0.2 kg).
    a. The total prosthesis weight shall not exceed 4.1 kg in weight (± 0.2 kg).
4. The socket shall conform to ISO 22523:2006 for material, etc.
    a. The socket shall also conform to ISO 10328:2016 for prosthesis testing.
5. The socket shall control the location of the residual limb's underlying bone with respect to the socket walls.
6. The socket shape shall not cause tissue breakdown of skin or of residual limb.
7. The socket shape and material shall allow for proprioception.

- *The socket shape and material shall decrease displacements within the socket.*

8. Displacements between the residual limb and the socket during all tested activities shall not exceed 4.2 mm (± 1.2 mm) for anterior/posterior, proximal/distal, and medial/lateral movements.

- *The socket shape and material shall allow for daily volume fluctuations of enclosed residual limb.*

9. The socket shape and material shall expand -11% to +7% of enclosed volume of residual limb.

- *The socket shape and material shall improve thermal homeostasis of the residual limb.*

10. The socket shape shall allow for airflow around the residual limb.
11. The socket material shall have a thermal conductivity ≥ 1 $\frac{W}{mK}$.
12. The socket shape and material shall be permeable to moisture.

- *The socket design shall be adaptable to users.*

13. The socket shape design shall be adaptable to unique measurements of individual users.

- *The socket design shall be accessible to users in most developing and developed countries.*

14. The socket material and production costs shall be less than 400.00 USD.

A table was created in 4.6 to verify if the proposed design met these requirements.

3.2 *PRELIMINARY CONCEPTS*

Discussed below are four preliminary concepts. One concept was selected and pursued to final design.

3.2.1 Concept 1: Plant-Based Materials Socket

The first concept used plant-based materials in place of traditional fiber and epoxy materials. In an article published in 2012, the University of Strathclyde, Glasgow, UK compared plant-based resin and fiber composites with conventional resin and fibers such as 80:20 acrylic resin and Nyglass, as shown in Figure 15. The results suggested that plant-based fibers could effectively replace traditional materials. These plant-based materials, depending on their accessibility, could reduce the cost of the socket compared to a socket made of traditional materials.

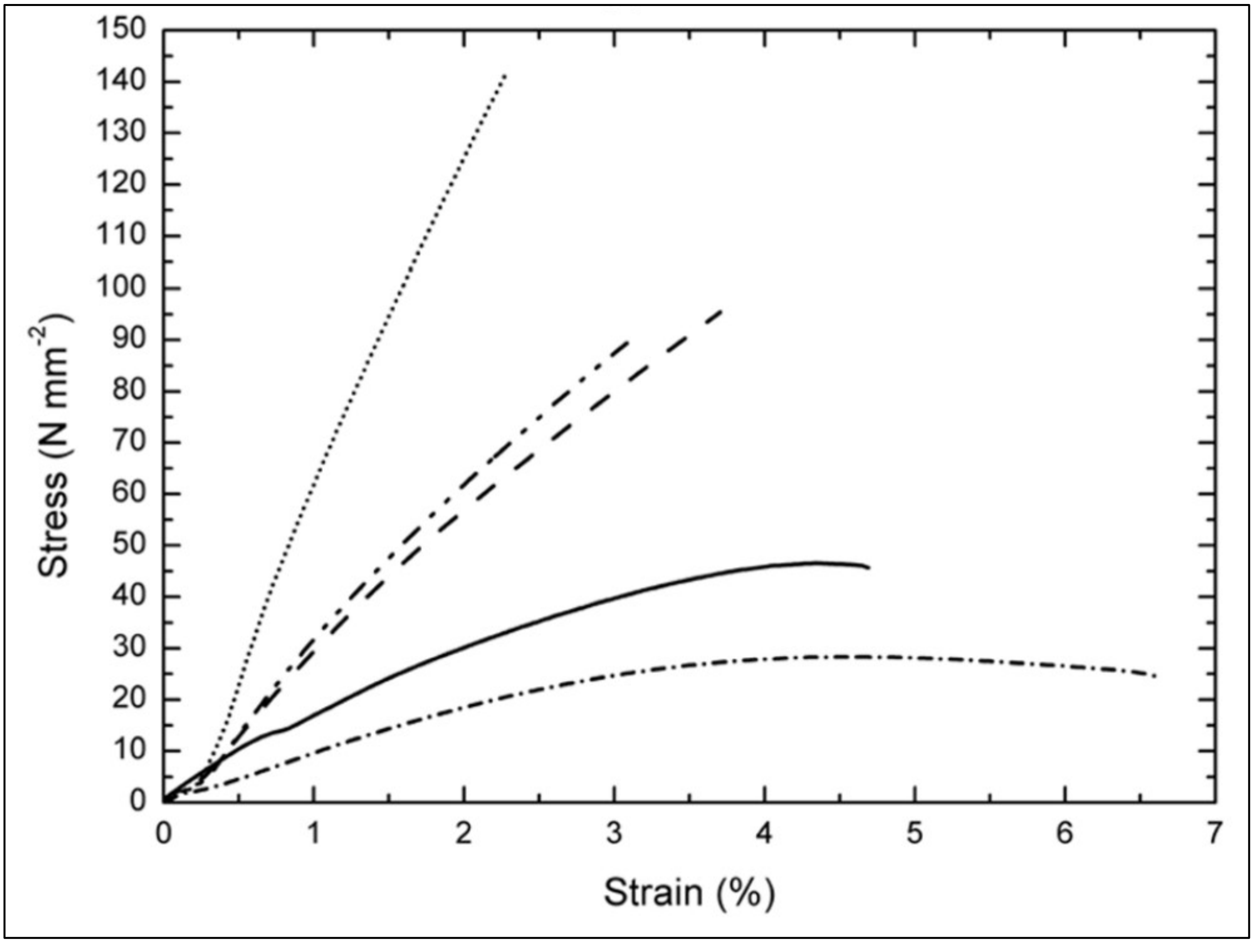

Figure 15. Tensile strength results of composite test pieces. The test pieces were composed of either plant oil resin without any fibers (-.-), plant-oil resin and carbon fiber (...), plant oil resin and ramie fiber (- . . -) or plant oil resin and banana fiber (- -). For comparison the tensile test results of a test piece made using 80:20 acrylic resin and Nyglass is shown (solid line). [2]

3.2.2 Concept 2: Compression/Release Stabilized Socket

The first concept used the CRS shape, similarly to the HiFi™ socket. This socket would use carbon fiber, have three or four compression struts, and three or four release windows. As discussed before, this socket design would stabilize the underlying tissue and bone of the residual limb.

3.2.3 Concept 3: Cable-Tightened Socket

The second concept used a mechanism with a cable to tighten the socket and change its shape. Similarly to the Quatro™ socket, this would be made using additive manufacturing such as MJF. Using a cable-tightening mechanism to change the socket shape would enable the socket to adapt to the volume changes of the residual limb. This, in turn, would maintain a close fit and decrease displacements between the limb and socket.

3.2.4 Concept 4: Combined Features Socket

The fourth concept combined some of the best features of the existing technology into one socket (Figure 16). The features would be the CRS shape (like the HiFi™ socket), the cable-tightened shape (like the Quatro™ socket), an open shape (like the Socket-less Socket™), and a highly accessible material (like the Jaipur Foot Artificial Limb). Combining these features would alleviate three of the four main socket issues (Figure 6) and the prosthesis accessibility issue.

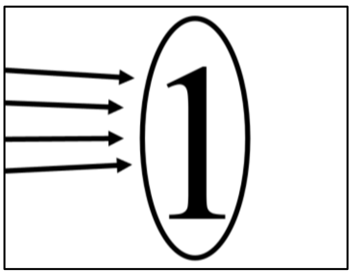

Figure 16. Concept 4: Combining several features into one socket

3.2.5 Concept Selection Result

After review the four above concepts, the fourth concept was selected. This combination concept was selected because of its ability to alleviate three of the four main socket issues and the prosthesis accessibility issue as discussed above. This concept was pursued to final design.

4 DESIGN REFINEMENT

This section details the design process of selecting a material and shape of the improved transfemoral socket.

4.1 CALCULATIONS

A prosthetic socket must hold at least the force of a body without breaking. This is illustrated in the free body diagram at the transfemoral level in Figure 17.

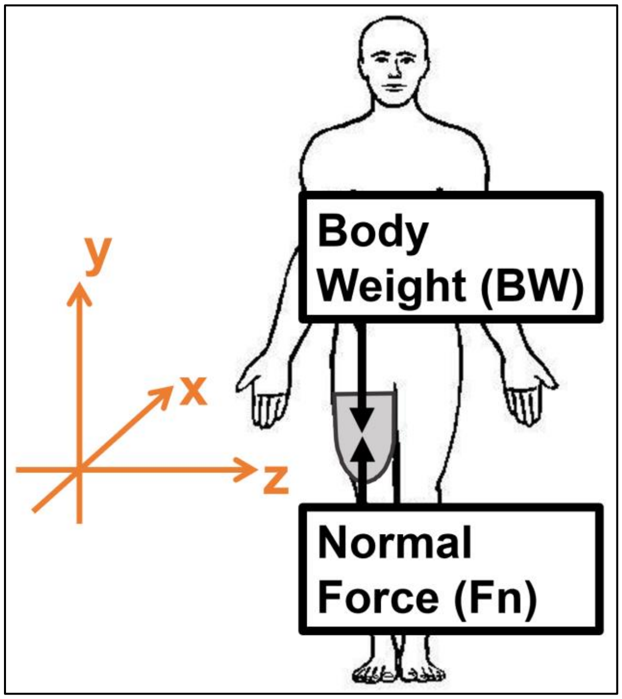

Figure 17. Free body diagram at transfemoral level (Modified image taken from Google Images)

In the initial research, to calculate the size of the socket (primarily wall thickness), the socket was calculated as a thin-walled pressure vessel. In this case, the user's body mass and gravity would provide the internal pressure the socket would withstand. After discussing with Dr. Nelson and further researching thin-walled pressure vessels and prosthetic socket load capabilities, this calculation method was determined to be inaccurate. Dr. Nelson provided Nigg & Herzog's "Biomechanics of the Musculo-skeletal System, Third Edition" [26] and Young, Budynas, & Sadegh's "Roark's Formulas for Stress and Strain, Eighth Edition" [27]. These both summarized external reaction forces (in the hip joint and from the ground) during a one-gait walking cycle during various activities such as walking, running, and jumping. Nigg & Herzog defined two types of reaction forces – active and impact forces. They further showed "that the maximal external impact forces can exceed 10 BW (body weight)" as shown in **Error! Reference source not found.**, exceeding 12 BW in a take-off jump [26].

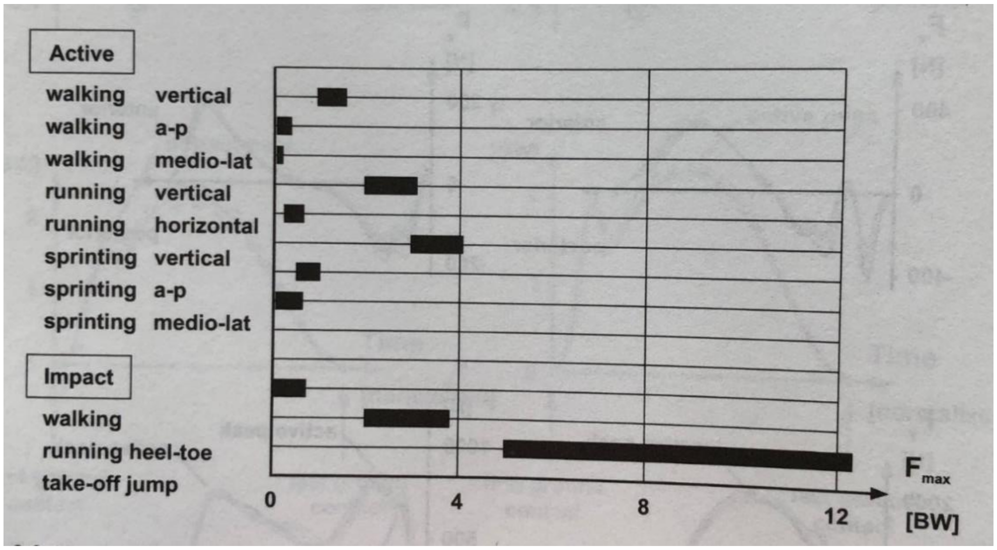

Figure 18. Nigg & Herzog's summary of reaction forces during various activities [26]

This means the prosthetic socket must withstand these forces without failing. Otherwise the socket will be not be useful for the user. Young, Budynas, & Sadegh showed similar values [27]. Online videos show prosthetic users skipping rope, jumping, running, and even doing CrossFit [28]. This particular socket usage certainly exceeds 2 BW. This is comparative with Nigg & Herzog and Roark's Formulas.

Initially, the socket was designed to support $\frac{1}{2}$ BW. This, as Nigg & Herzog and Roark's Formulas showed, is incorrect.

Using a table of values (an averaged summary of which is shown in Table 1), a BW = 800 N (180.0 lbf) (the weight of the author), the maximum external vertical impact force peak would be

Equation 1. Force withheld in terms of body weight

$$(F_{max}/BW) \times BW = \ Force\ Withheld$$

A factor of safety (FS) was used in the preliminary design. However, this was neglected since no information about factors of safety was found in the literature.

Table 1. Summarized Table 3.3.2 [26] for Fmax/BW (Value selected is boxed in red)

BW = 700 N (157.37 lbf)			
Movement	**V (m/s)**	**Fmax/BW (avg. shown)**	**Fmax (N) (avg. shown)**
Walking	1.3	0.40	278
Running	4.0	2.2	1,540
Take-off for	4.0	3.1	2,150
jump	8.0	$\boxed{8.3}$	5,700

However, in Campbell et al., a maximum force of 16.6 BW seems high; their traditional layup socket (Nyglass fibers with 80:20 acrylic resin) failed at 5,808 N of downward force [2]. Considering the end prosthetic users, if using a BW = 800.64 N (180 lbf) and if <u>not</u> targeted for sprinting, jumping, or athletic users, 16.6 BW is rather high. This would require the socket to withstand 13,290.6 N of downward force.

Considering the International Organization for Standardization (ISO) International Standard 10328:2016(E), in Annex B and Annex D, even for the highest loading level (P8 – a body mass < 175 kg) and at the highest loading condition (Condition I – see **Error! Reference source not found.**), the maximum force required to be withstood is the proof test force during the principal structural test of F_{max} = 6,840 N [10]. This renders a F_{max}/BW = 8.5. Table 2 summarizes these comparisons.

Table 2. Preliminary design Fmax/BW source summary for force withstood

Source	**Fmax/BW**	**FS**
Nigg & Herzog	16.6	2
Liebert & Lindner (secondary)	6.6	2
Roark's	14	2
ISO (modified)	17	2

Therefore, it is reasonable to assume that the maximum force load withstood by the socket is

$$F_{max} = 6.5 \times BW \times FS$$

Equation 2. Max force

$$F_{max} = 6{,}250.0\ N$$

using a BW = 800.64 N and a FS = 1.2. This is equivalent to 7.8 BW. These values must be researched further to be verified.

4.2 CAD MODELING

SolidWorks was the computer aided design (CAD) modeling software used for this project. Knowing that a simple circular extrusion would not suffice for a non-circularly-shaped transfemoral limb, a YouTube search was done on designing a socket in SolidWorks. The first method used an image trace and surface feature technique (Figure 19). A profile image of the HiFi™ socket was selected, the edges were traced, the traced lines were created into revolved surfaces, and the surfaces were extruded. This method could not choose varying thickness of the wall (which was desired), had difficulty joining two halves, and followed only a circular revolution.

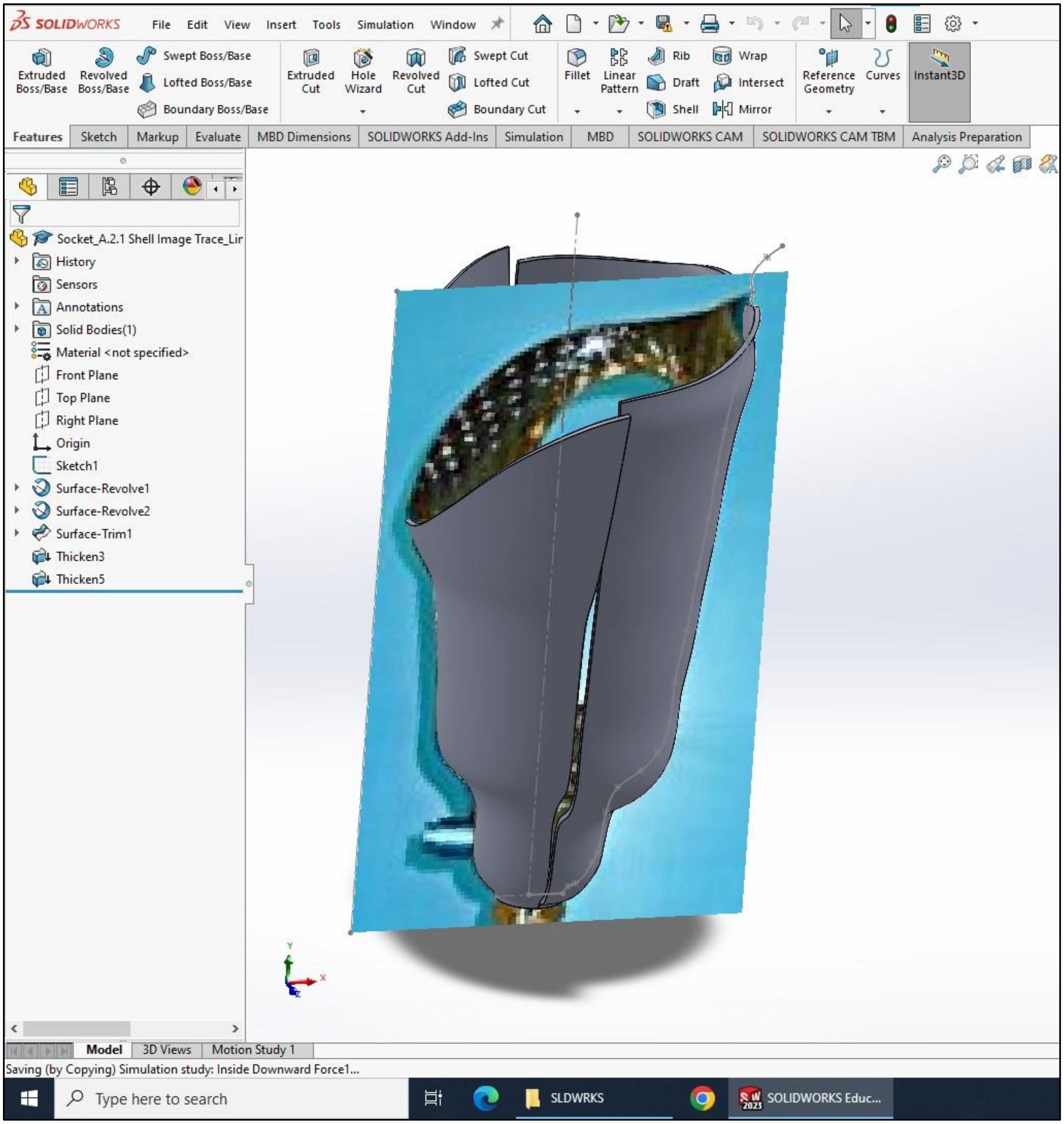

Figure 19. Surface-image-trace attempt

For this project several techniques and features had to be learned.

4.3 MATERIAL DETERMINATION

4.3.1 Carbon Fiber and Acrylic Resin

Carbon fiber and acrylic resin was selected because they are very commonly used materials in prosthetics. Both biodesigns and Quorum use it for some of their sockets. A summary of the pros and cons of carbon fiber and acrylic resin are shown in Table 3 below.

Table 3. Pros and cons of carbon fiber and acrylic resin

Carbon Fiber and Acrylic Resin	
PROS	**CONS**
-High strength-to-weight ratio -Commonly used	-High cost -Medium manufacturing time

4.3.2 PA12 and ESTANE 3DP TPU M95A

Quorum Prosthetics uses Lubrizol's PA12 and ESTANE 3DP TPU M95A for their MJF-printed sockets. Table 4 summarizes the pros and cons of these.

Table 4. Pros and cons of Lubrizol's PA12 and ESTANE 3DP TPU M95A

Lubrizol's PA12 and ESTANE 3DP TPU M95A	
PROS	**CONS**
-High customization -Low manufacturing time	-Expensive MJF Printers -Not widely accessible

4.3.3 High Density Polyethylene

Following Jaipur Foot, HDPE was considered. Table 5 summarizes the pros and cons of this material.

Table 5. Pros and cons of HDPE

High Density Polyethylene	
PROS	**CONS**
-Widely accessible -Low cost -Easily molded	-Not state-of-the-art -Outgasses

4.3.4 Ramie Fibers and Plant-Oil Resin

Following the research by Campbell et al. [2], ramie fibers and plant-oil resin were considered. The pros and cons of these materials are summarized in Table 6. Unfortunately, the accessibility of this material was not researched.

Table 6. Pros and cons of ramie fibers and plant-oil resin

Ramie Fibers and Plant-Oil Resin	
PROS	**CONS**
-Stronger than traditional materials -Renewable (plant-based)	-Accessibilty is unknown

4.3.4 Material Determination Result

After considering the above pros and cons of each of the three materials, HDPE was selected. This was due to its high accessibility, low cost, and easy moldability.

4.4 FEA STUDIES

Finite element analysis (FEA) was used to verify if the socket iterations met the project requirements.

4.4.1 Loading and Boundary Conditions

SolidWorks was used to simulate the sockets. To begin, the most distal (bottom) surface was fixed as shown in Figure 20 and Figure 21. This most distal surface represented the connection point between the socket and the pylon as shown in Figure 22.

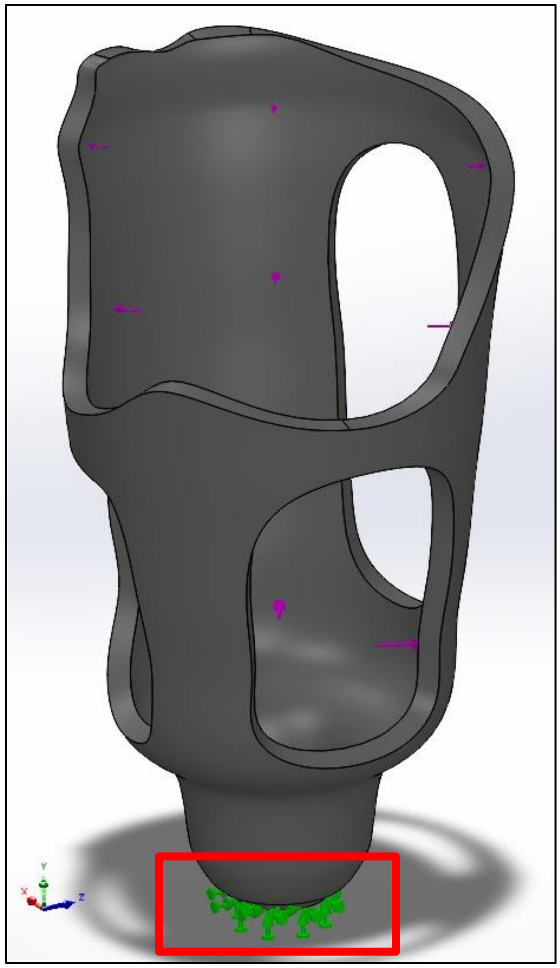

Figure 20. Fixed distal surface of socket iteration 1 shown in red square

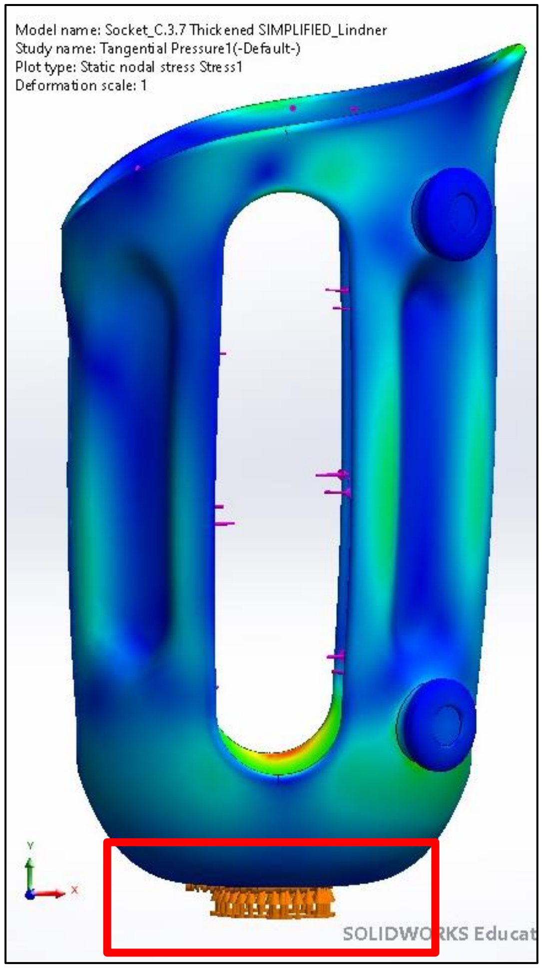

Figure 21. Fixed distal surface of socket iteration 4 shown in red square

Figure 22. Connection point between socket and pylon shown in red square

A nonuniformly distributed normal force load was used on the inner faces of the socket, as shown in Figure 23, to represent the force of the user in the socket. Conforming to the project requirements, the force used was 6,250 N (the extra 5 N was added simply to make the value a round number and to slightly over-estimate).

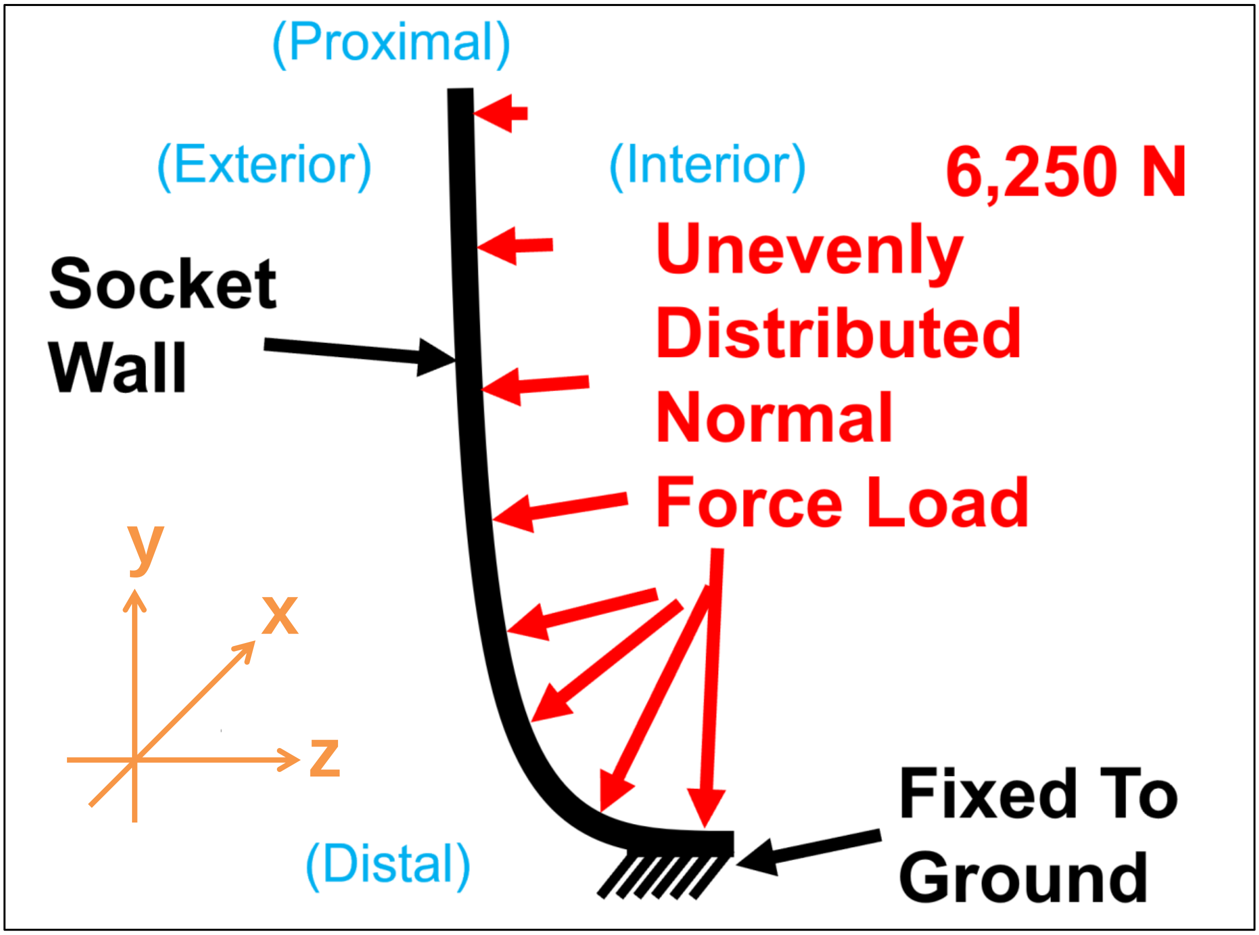

Figure 23. Loading and boundary conditions used in finite element analysis ("unevenly" means "nonuniformly") (Shown is a profile view of half of the socket)

The equation used for the nonuniform (uneven) distribution is shown in Equation 3

Equation 3. Nonuniformly distributed force load function

$$F(x, y, z) = \frac{1.5 \times h - y}{h}$$

where $F(x, y, z) = force\ as\ function\ of\ Cartesian\ coordinates\ x, y, and\ z$ and $h = height\ of\ socket$ (as measured from bottom surface to highest point of socket) and $y = variable\ of\ vertical\ direction$. This equation was provided by Dr. Nelson.

The 1.5 coefficient was an assumed value. This value must be researched further to provide accurate socket simulation. Since the literature showed little to no information on how to accurately simulate the loading of a prosthetic socket, this nonuniform distribution was assumed.

The 1.5 value was selected based on personal judgement, knowing that during real life conditions, pressure distributed to the socket would include the part of the leg above the socket brim. This part of the leg above the socket brim would apply force to the proximal part of the socket greater than zero. This 1.5 value assumption is a source of inaccuracy and must be researched further.

The normal force was selected based on the discussion by Al-Shammari et al. [29].

4.4.2 Mesh, Settings, and Material Property

The maximum element size used in the mesh was 7 mm, chosen because of its fine size.

Large displacements were turned off.

Because HDPE was the material selected, a value for its tensile yield strength was needed. The tensile yield strength was used as opposed to the ultimate tensile strength or the failure strength (see Figure 24). This was because with ductile materials, the yield strength is the point at which deformations change from elastic to plastic. Because this device – a prosthetic socket – would be used by people, a sign that the socket is failing would be important. Therefore, the yield strength was used.

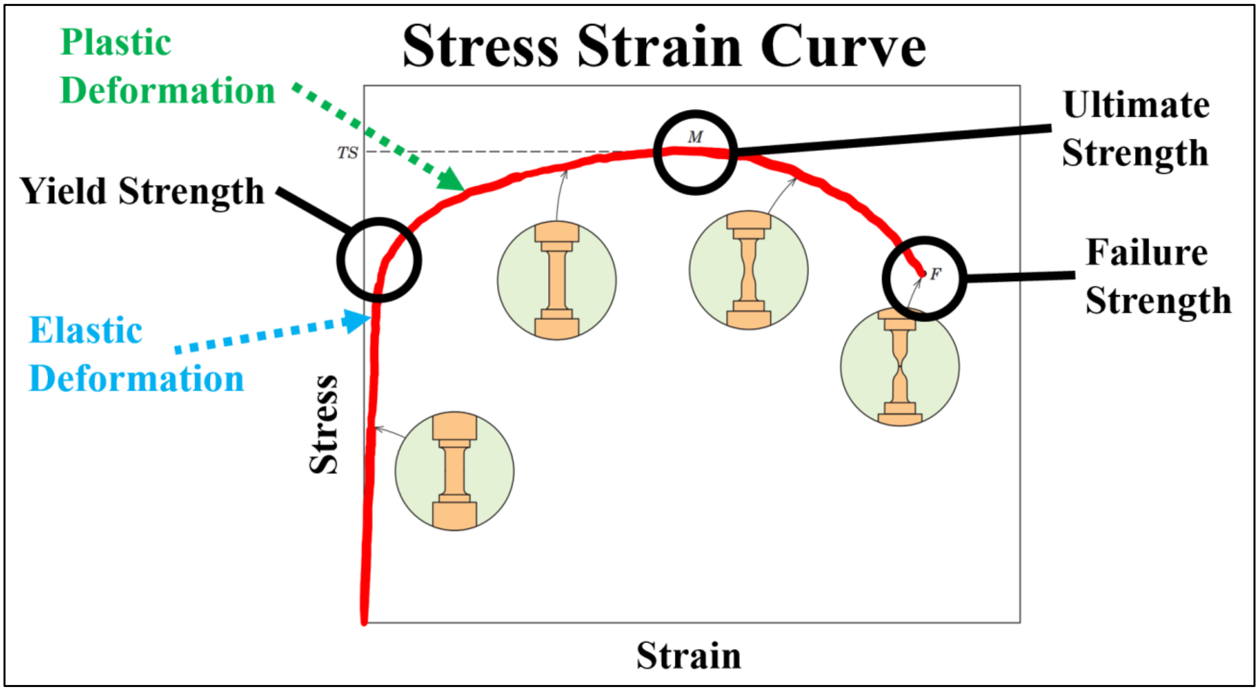

Figure 24. Typical stress strain curve for ductile materials (Modified from [30])

Using values for HDPE tensile yield strength found from Google and MatWeb, an average of averages was found as shown in Figure 25. This average was compared against values in “Materials Science and Engineering” by Callister & Rethwisch. Therefore, a tensile yield strength for high density polyethylene of 23.18 Mpa is a reasonable and conservative estimate.

	#	TENSILE STRENGTH AT YIELD (Mpa) (Average)	SOURCE
RESEARCHED	1	20.68	[Creek Plastics LLC. Low end]
	2	27.58	[Creek Plastics LLC. High end]
	3	22.1	[MatWeb - Formosa HP4401]
	4	22.1	[MatWeb - Formosa HP4000]
	5	24.8	[MatWeb - Formosa E900]
	6	24.4	[MatWeb - Overview of HDPE]
	7	20.6	[MatWeb - Overview of HDPE]
	AVERAGE USED	**23.18**	
COMPARED	1	26.2	[Callister & Rethwisch HDPE Low end]
	2	33.1	[Callister & Rethwisch HDPE High end]
	AVERAGE TO COMPARE	**29.65**	

Figure 25. HDPE yield strength determination and comparison

4.5.2 Simulation Results

The same loading conditions were used for each of the four socket iterations. Their full simulation results are shown in Appendix A

BIOMECHANICS LITERATURE

Shown below are tables and figures obtained from biomechanics literature concerning reaction forces associated with the transfemoral level in terms of body weight (BW).

Table 3.3.2 Selected experimental results for external vertical impact force peaks in walking and running (from Nigg, 1985, with permission). Values shown with an * have been calculated assuming a body weight BW = 700 N.

MOVEMENT	FOOTWEAR	v [m/s]	F(max) [N]	F(max)/BW	AUTHOR	YEAR
WALKING	barefoot	1.3	385	0.55	Cavanagh	1981
	army boots	1.3	259	0.37	"	"
	street shoes	1.3	189	0.27	"	"
RUNNING (HEEL)	run. shoe	4.5	1540	2.2	Cavanagh	1980
	run. shoe hard	4.0	2000	2.9	Nigg	1980
	run. shoe soft	4.0	1100	1.6	"	"
	run. shoe	3.4	1365	2.0	Frederick	1981
	run. shoe	3.8	1590	2.3	"	"
	run. shoe	4.5	1963	2.9	"	"
	run. shoe	3.0	1345	2.0	Nigg	1987
	run. shoe	4.0	1521	2.2	"	"
	run. shoe	5.0	1799	2.6	"	"
	run. shoe	6.0	2070	3.0	"	"
RUNNING (TOE)	run. shoe	4.0	300	0.4	Denoth	1980
TAKE-OFF FOR JUMP	spikes	2.0	1000	1.4	Nigg	1981
	spikes	4.0	2300	3.3	"	"
	spikes	6.0	3700	5.4	"	"
	spikes	8.0	5700	8.3	"	"
	run. shoe	2.0	1400	2.0	"	"
	run. shoe	4.0	2000	2.9	"	"
	run. shoe	7.0	2900	4.2	"	"

Figure 40. Table 3.3.2 from : Forces acting on body in terms of body weight (Relevant value shown in red)

the reaction force from the force pl... the second half of ground contact, the foot pushes in the posterior direction. Consequently, the reaction force from the force plate is in the anterior direction. The force component in the m-l (medio-lateral) direction is less consistent intra- and inter-individually. The medio-lateral component often shows an initial reaction force in lateral direction that results from a medial (inward) movement of the foot during landing. This initial lateral force is usually shorter than 20% of the total contact time. It is usually followed by a reaction force in the medial direction that is often present during the rest of the ground contact time and that is usually smaller than the initial lateral force.

The intra- and inter-individual variability is much bigger for the medio-lateral than for the vertical and the anterior-posterior force-time curves. In addition, substantial differences may exist in the ground reaction force components between the left and the right foot fall for one subject.

Values of impact and active ground reaction force peaks during different movements have been reported by various authors. A summary of these results (Figure 3.3.11) illustrates that the maximal external impact forces can exceed 10 BW (body weight) while the maximal external active forces do not exceed 5 BW.

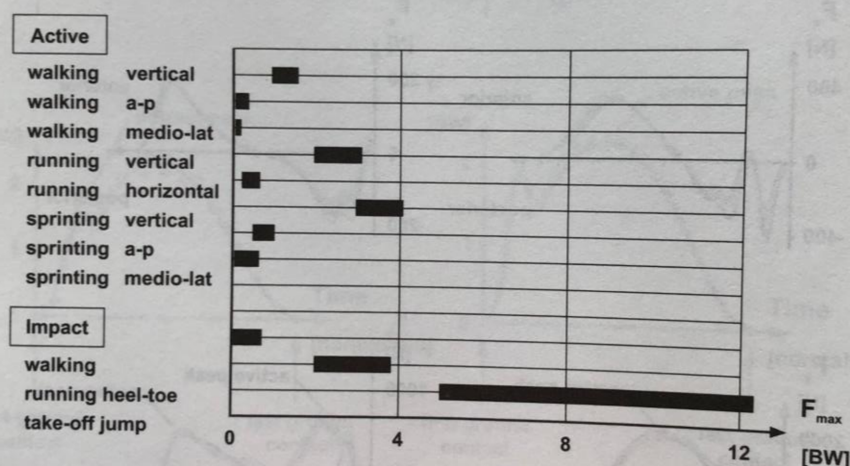

Figure 3.3.11 **Magnitude of actual impact and active ground reaction force peaks measured with a force plate during various activities (from Nigg, 1988, with permission).**

Figure 41. Figure 3.3.11 from : Impact forces acting on body in terms of body weight (Relevant values underlined in red)

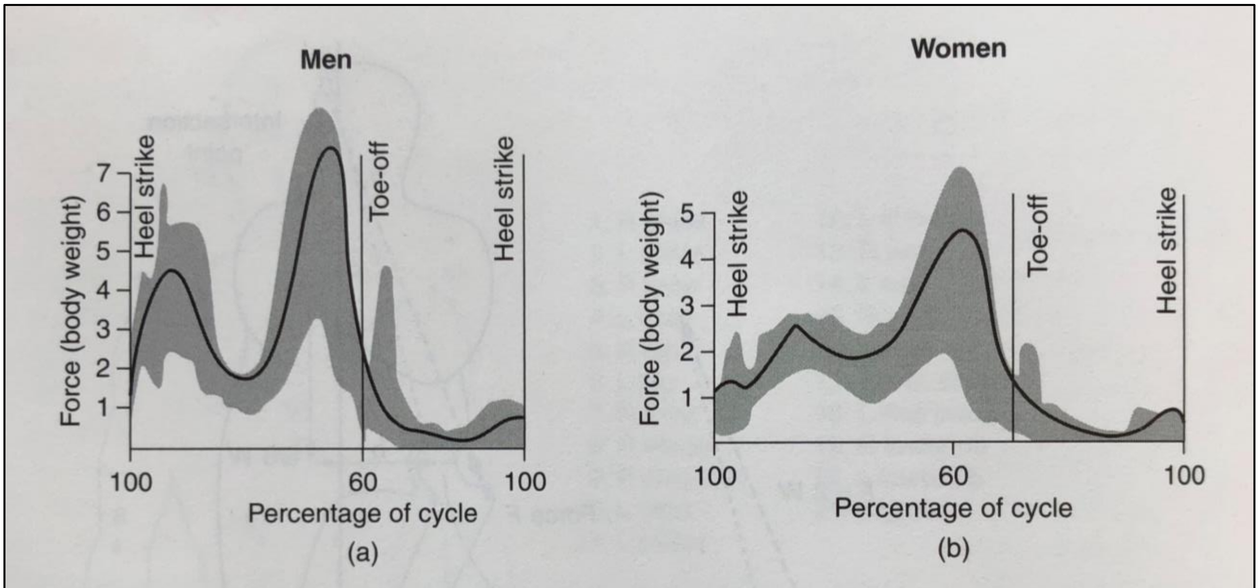

FIGURE 21.18 Hip-joint reaction forces in units of body weight during a one-gait walking cycle. Shaded area indicates variations among subjects for (a) men and (b) women. *Adapted from Paul (Ref. 50).*

Figure 42. Figure 21.18 from : Hip joint reaction forces in terms of body weight (Relevant values shown in red)

Appendix .

In certain situations (as with socket iteration 3), the scales of the simulation results were adjusted to identify the locations and amounts of the stresses. Shown in Figure 70 and Figure 78 are the initial and the adjusted scales of socket iteration 3. The initial scale displays 23.18 Mpa as the max stress shown. The adjusted scale displays 100.00 Mpa as the max stress shown. From this adjusted scale, the locations and magnitudes of stress on the socket could be studied.

4.5 GEOMETRY DETERMINATION

Four main socket shape iterations were made and simulated. Many steps and variations were made to create these four iterations. The shape selection process was as follows:

1. Model a socket
2. Simulate the model
3. Adjust the model shape based on stress areas
4. Repeat

4.5.1 Iteration 1

Using the initial surface-image-trace shape (Figure 19), the first iteration was reached, as shown in Figure 26.

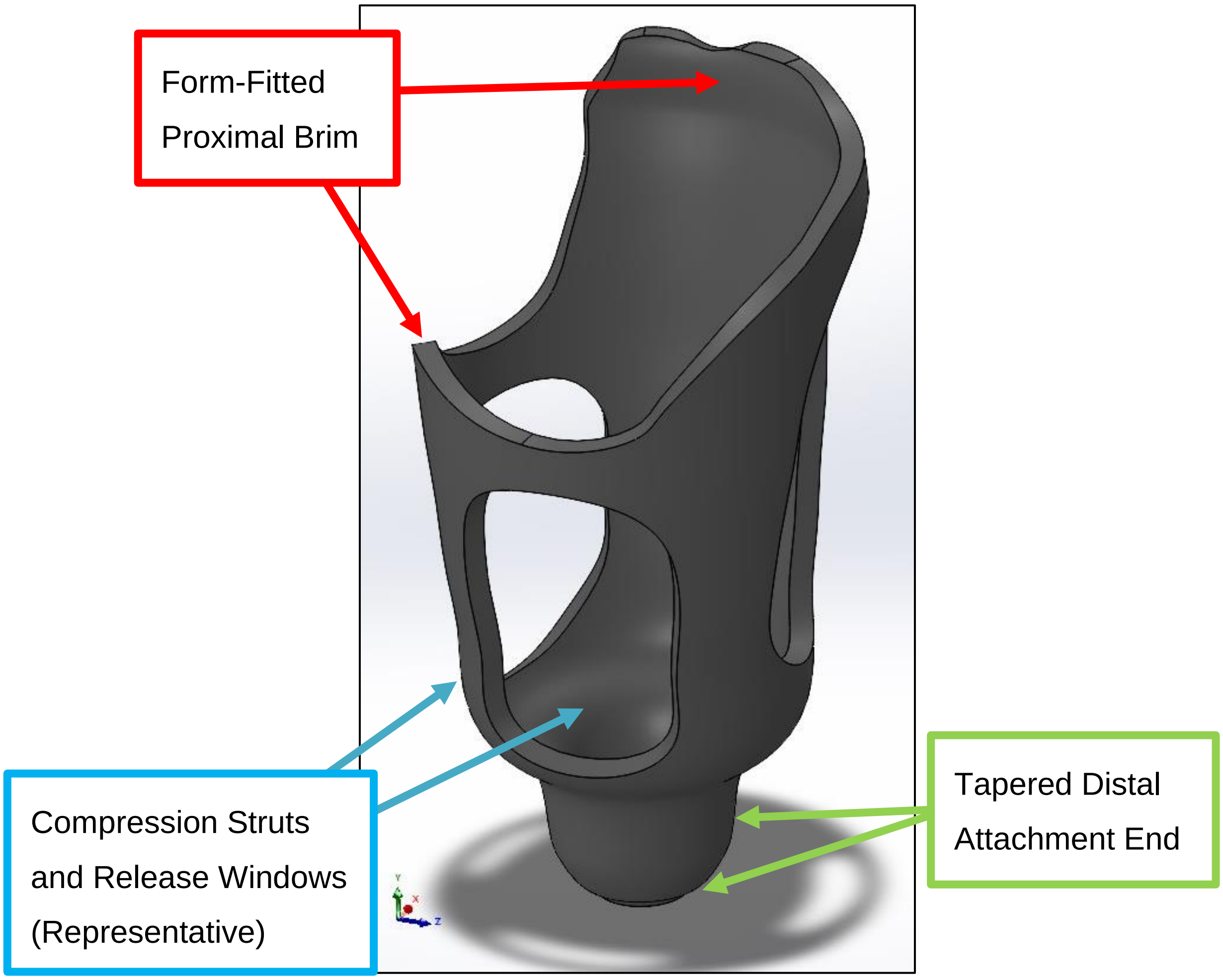

Figure 26. Socket iteration 1 (Model A.4.3) distinct features

This iteration incorporates compression struts and release windows (shown by blue), a proximal brim form-fitted to the user's upper thigh/hip/buttocks area (shown by red), and a tapered distal end for attachment to the prosthesis pylon (shown by green). The compression struts shown are not truly compression struts but representations of the compressions. This was because the SolidWorks technique to incorporate the compressions had not yet been mastered. This was the case for both iterations 1 and 2. Intended anatomical directions are shown in Figure 27. This iteration (and all iterations) was simulated using the loading conditions discussed above.

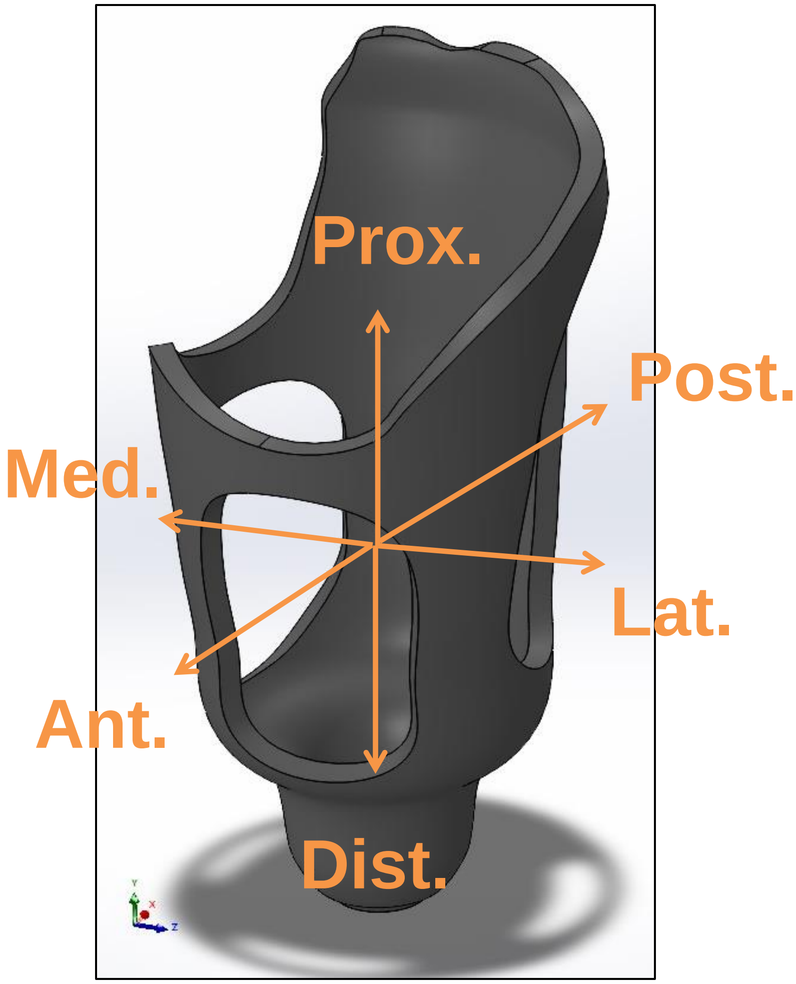

Figure 27. Socket iterations 1 and 2 anatomical directions

Simulation showed about ten areas of high stress concentration with the maximum stress being 130 Mpa at the most distal part (shown in Figure 53) and the maximum displacement being 35.63 mm at the most proximal part (shown in Figure 56).

4.5.2 Iteration 2

Based on the results of iteration 1, changes were made and iteration 2 was reached, as shown in Figure 28.

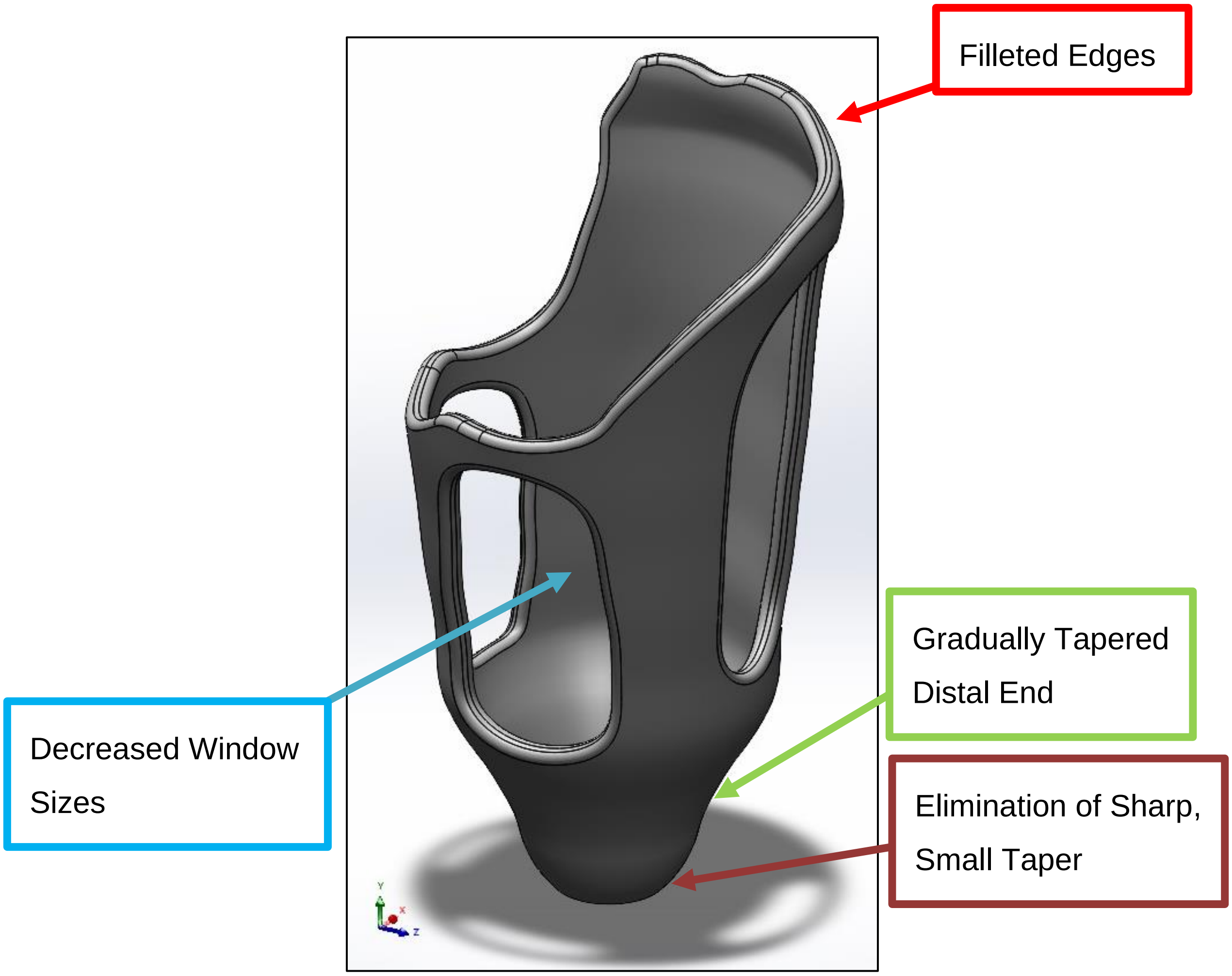

Figure 28. Socket iteration 2 (Model A.4.7) adjusted features

The tapered distal end was tapered more gradually to decrease such a large stress concentration (shown by green). The most distal, small, sharp fillet at the most distal part was removed since that was the location of the maximum stress in iteration 1 (shown by dark red). All edges were filleted in order to decrease any potential of stress concentrations in those areas (shown by red). The size of the release windows was decreased and subsequently the size of the compression struts was increased (shown by blue). The anatomical directions for iteration 2 are the same as those for iteration 1, as shown in Figure 27.

Simulation showed about 9 areas of high stress concentration (Figure 57). In fact, the results of iteration 2 closely resembled those of iteration 1. The maximum stress for iteration 2 was 161 Mpa at the most distal part (shown in Figure 66) and the maximum displacement was 40.09 mm at the most proximal part (shown in Figure 68).

4.5.3 Iteration 3

Based on the simulation results of iterations 1 and 2, it was decided to start the design over from scratch. This new iteration used sample geometry as discussed in Al-Shammari et al. [29] shown below in Table 7. Iteration 3 is shown in Figure 29 and the intended anatomical positions are shown below in Figure 30.

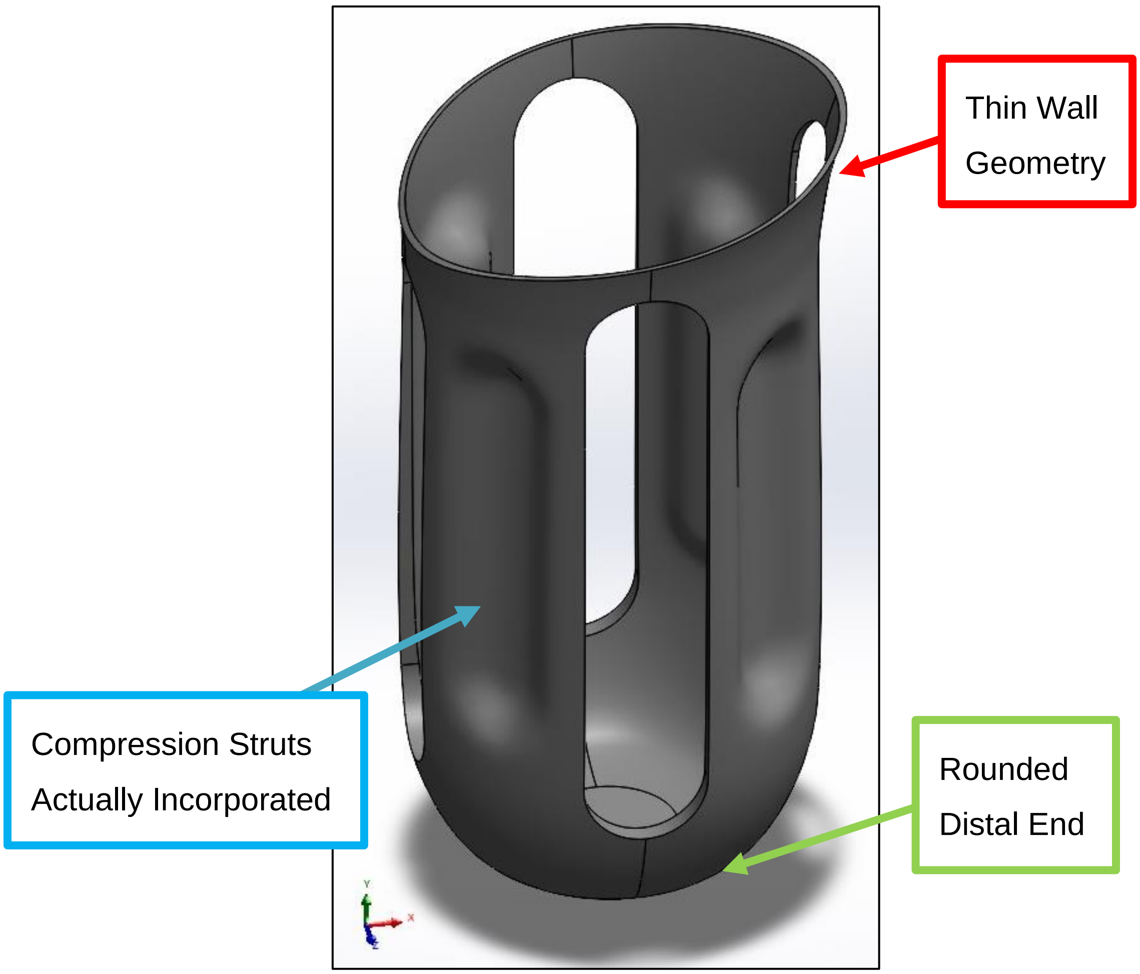

Figure 29. Socket iteration 3 (Model C.3.3) adjusted features

This iteration featured thin walls, greater in the distal walls and less in the proximal walls (shown by red). Fully incorporated compression struts were included (shown by blue). Because of the sample geometry suggested by Al-Shammari et al. this shape also features a very rounded distal end (shown by green). Not that this end is different than those of iterations 1 and 2.

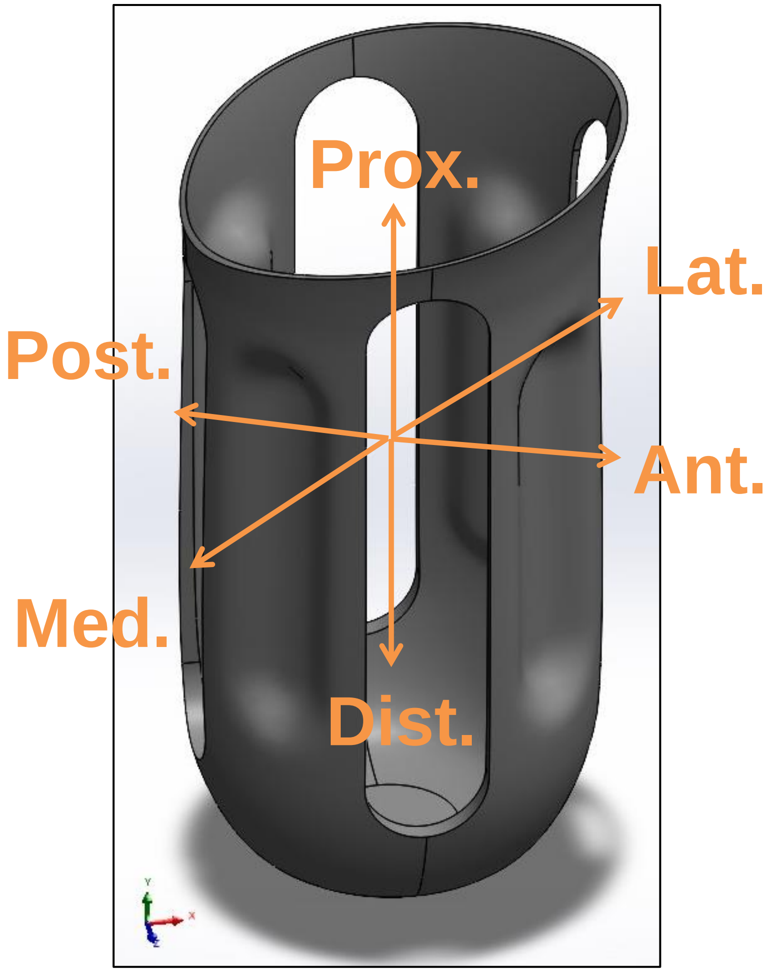

Figure 30. Socket iteration 3 anatomical directions

Table 7. Sample socket geometry used in socket iteration 3 suggested by Al-Shammari et al. [29]

	UPPER DIAMETER	TOLERANCE	NOTES
(cm)	14.5	± 5.0	
(in.)	5.71	± 2.0	

	LOWER DIAMETER	TOLERANCE	NOTES
(cm)	13.5	± 5.0	
(in.)	5.31	± 2.0	

	HEIGHT	TOLERANCE	NOTES
(cm)	20.0	± 5.0	
(in.)	7.87	± 2.0	

	UPPER THICKNESS	TOLERANCE	NOTES
(cm)	0.22	± 0.05	Set at 3.0 cm from top point.
(in.)	0.087	± 0.020	

	LOWER THICKNESS	TOLERANCE	NOTES
(cm)	0.66	± 0.05	Set at 6.0 cm from base point.
(in.)	0.26	± 0.020	

Simulation showed a severely deformed and almost exploded socket (Figure 70). The stress scale displayed nearly the entire socket in red (areas higher than the HDPE yield strength of 23.18 Mpa). The maximum stress for iteration 3 was 715 Mpa at the proximal-lateral release window's distal side (shown in Figure 78) and the maximum displacement was 200.14 mm at the anterior-lateral compression strut, on the lateral side, aligned with the proximal start of the compression (shown in Figure 79).

4.5.4 Iteration 4

Because of the failure of iteration 3, the sample geometry (specifically the wall thickness of 0.22 cm and 0.66 cm) suggested by Al-Shammari et al. was questioned. Iteration 4 is shown below in Figure 31 and its anatomical directions are shown in Figure 32.

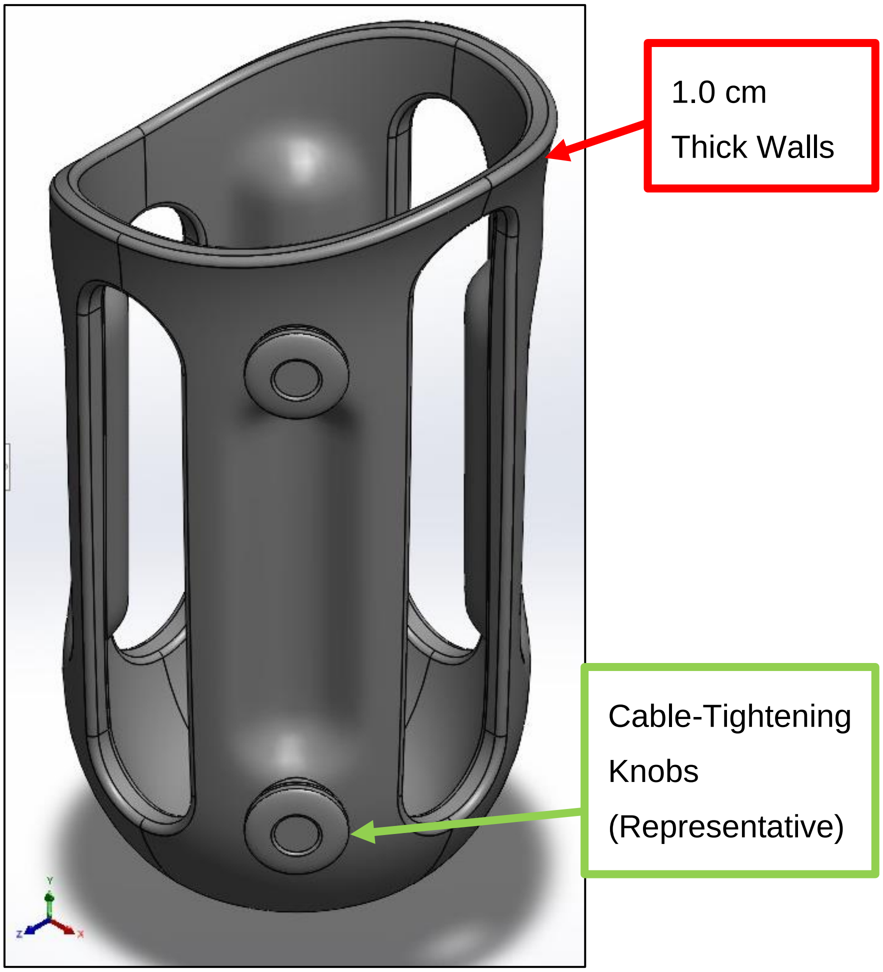

Figure 31. Socket iteration 4 (Model C.3.7) adjusted features

Both upper and lower wall thicknesses were increased to 1.0 cm (shown by red). Cable-tightening knobs were incorporated to represent a cable-tightening system. As discussed before, this feature was selected to address the issue of limb volume fluctuations. It was desired to incorporate guides where the cables would be placed (shown in Appendix) but this SolidWorks technique was not mastered in time.

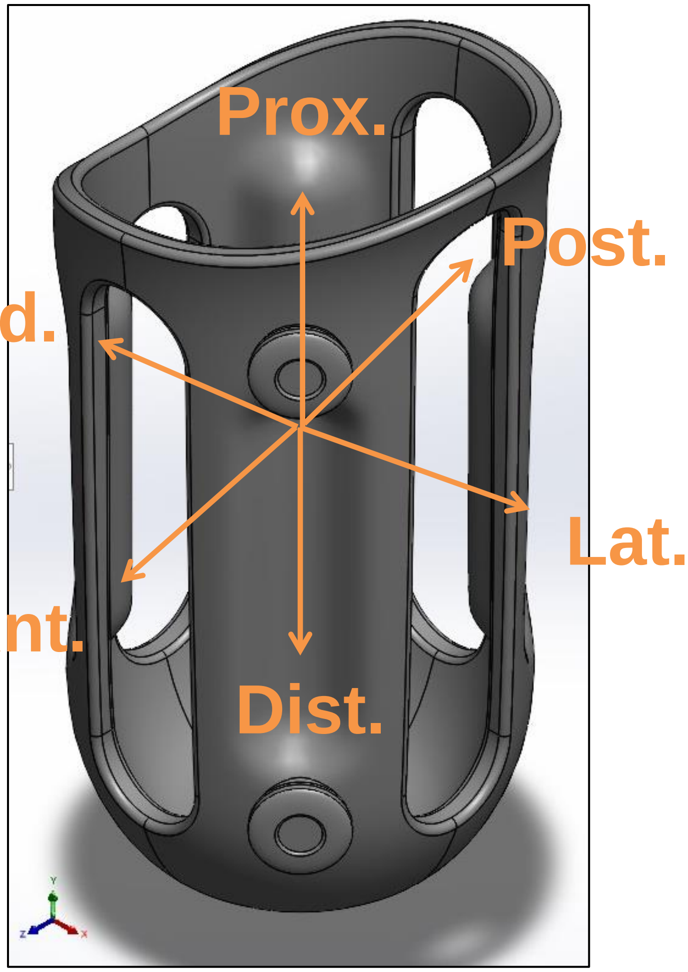

Figure 32. Socket iteration 4 anatomical directions

Simulation results showed a uniform distribution of stresses on the socket and at smaller magnitudes (Figure 87). There were six areas of high stress. These were all located on the "armpits" of the release windows, i.e. the proximal and distal curves of the release windows. The maximum stress was 28.9 Mpa at the distal curve of the lateral release window (shown in Figure 87) and the maximum displacement was 7.80 mm in the middle of the lateral edge of the posterior-lateral compression strut (shown in Figure 88).

4.5.5 Geometry Determination Result

After simulating each of the four socket iterations, socket iteration 4 was selected. This was due to the many areas of high stress concentrations in iterations 1 and 2, the certain failure of iteration 3, and the uniformly distributed and relatively low stresses in iteration 4.

4.6 Requirements Check

The fourth iteration socket was analyzed to determine if it met the project requirements. The following table (Table 8) of design objectives, target values, and achieved values was made. As shown many requirements remain unverified. This is due to the user-oriented nature of prosthetics. These requirements must be tested later in laboratory testing or human trials. This testing was not completed during this project due to a lack of time.

Table 8. Requirements check for socket iteration 4

DESIGN OBJECTIVE		TARGET VALUE	ACHIEVED VALUE	SYMBOL
1.	Stump-Socket Connection	Holds Onto Limb During All Activities	TESTABLE LATER	☐
2.	Load Force Withheld	> 6,245.0 N	6,250 N	☑
2.b	Load Force Withheld	7.8 x BW	(BW=180lbf=800.64N) 7.8 x BW = 6,244.99 N	☑
3.	Mass - Socket	< 1.6 kg (± 0.2 kg)	1.14 kg	☑
3.a	Mass - Total Prosthesis	< 4.1 kg (± 0.2 kg)	3.75 kg	☑
4.	International Standards	Conforms to ISO 22523:2006	TESTABLE LATER	☐
4.a	International Standards	Conforms to ISO 10328:2016	TESTABLE LATER	☐
5.	Location of Underlying Bone	Controlled by Socket	TESTABLE LATER	☐
6.	Tissue Breakdown	Shape Causes No Breakdown of Skin or Residual Limb	TESTABLE LATER	☐
7.	Proprioception	Allowed by Shape and Material	TESTABLE LATER	☐
8.	Displacements Between Socket and Limb	< 4.2 mm (± 1.2 mm) in Ant./Post., Prox./Dist., and Med./Lat.	TESTABLE LATER	☐
9.	Volume Expansion	-11% to 7% of Enclosed Volume of Residual Limb	TESTABLE LATER	☐
10.	Airflow Around Residual Limb	Allowed by Shape	YES	☑
11.	Material Thermal Conductivity	≥ 1 W/mK	0.48 W/mK	☒
12.	Shape and Material	Permeable to Moisture	YES	☑
13.	Shape Design	Adaptable to Unique Users	YES	☑
14.	Material and Production Cost	< 400.00 USD	175.00 USD	☑

4.7 *FINAL DESIGN*

After the material and shape selection process, the final design for this project was determined. The final socket design is shown below in Figure 33. The anatomical directions are identical to those shown in Figure 32. The material is high density polyethylene drainpipe.

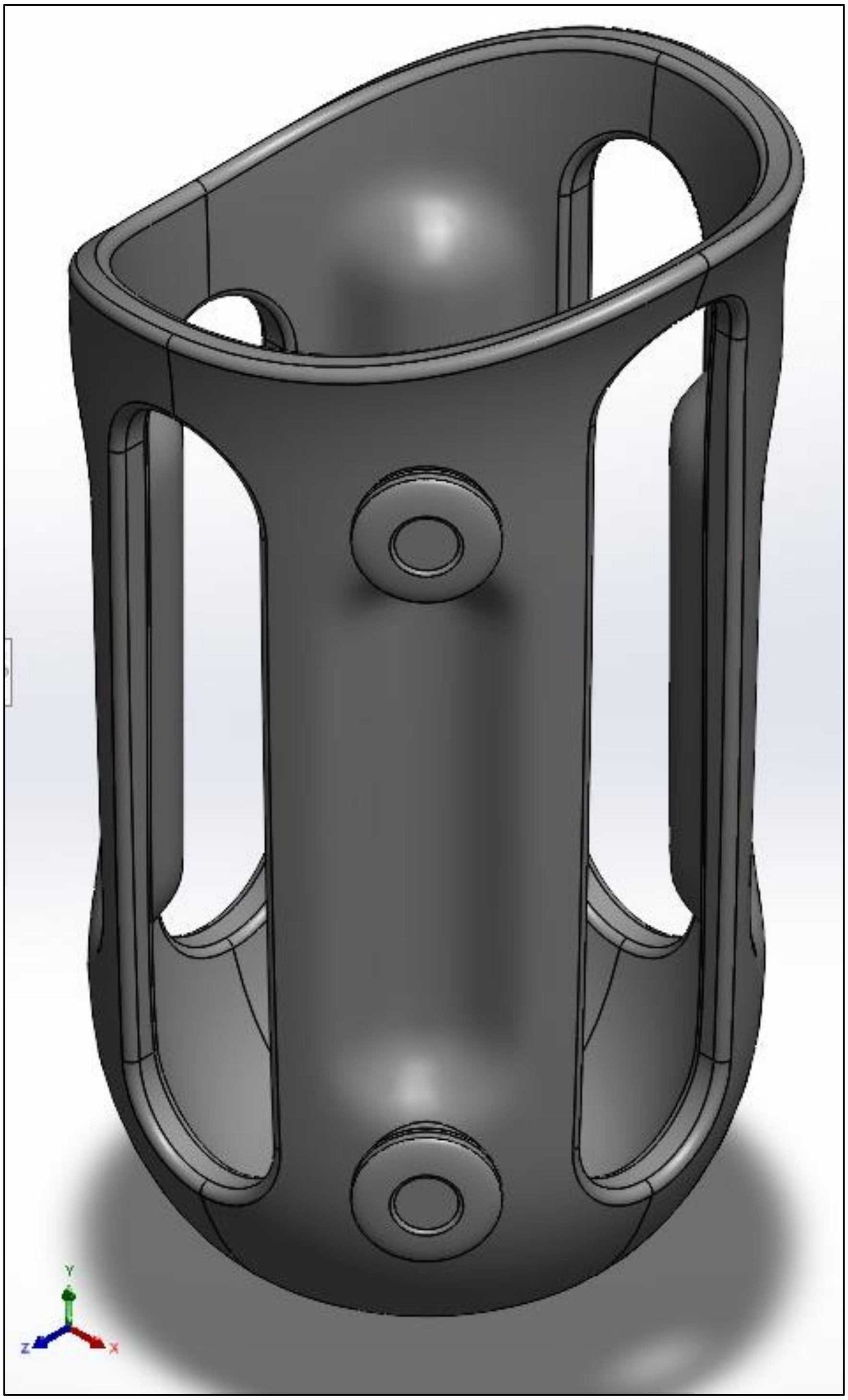

Figure 33. Final socket design (Material: high density polyethylene drainpipe)

5 DISCUSSION

5.1 BUDGET CONSIDERATIONS

Because no formal finished product was delivered for this project, the physical money spent was low. A showcase unit was 3D printed using one roll of polylactic acid (PLA) 3D printer filament. This roll, which would typically cost 30.00 USD, was provided for free.

5.2 CULTURAL CONSIDERATIONS

The Jaipur Foot artificial limb was designed with their end users in mind. The foot's technology and appearance allow for socially comfortable use. The Jaipur Foot artificial limb can be used to sit cross-legged, ride a bike, enter temples, and walk barefoot. In India, where this limb is distributed and used, these cultural considerations are very important to the end users.

5.3 MANUFACTURABILITY

The process for manufacturing the proposed final socket design would be very similar to that used by Jaipur Foot for their sockets. The process for the proposed final socket design would be as follows:

1. Take necessary measurements of residual limb
2. Make plaster cast of residual limb using plaster of paris (POP)
    a. Apply a device to compress the tissue (similar to biodesigns' patented High-Fidelity™ Imager, shown in Figure 34)
3. Remove plaster cast from limb
4. Make positive mold of limb using POP
5. (A handheld 3D laser scanner may be used in place of the plaster-casting process)
6. Shape positive mold as necessary
7. Heat high density polyethylene drainpipe
8. Place pliable HDPE pipe over positive mold of limb
9. Shape cooling HDPE pipe to positive mold
10. (Vacuum suction may be used)
11. Remove HDPE pipe from positive mold
12. Make final adjustments and measurements
13. Fix socket to remainder of prosthesis

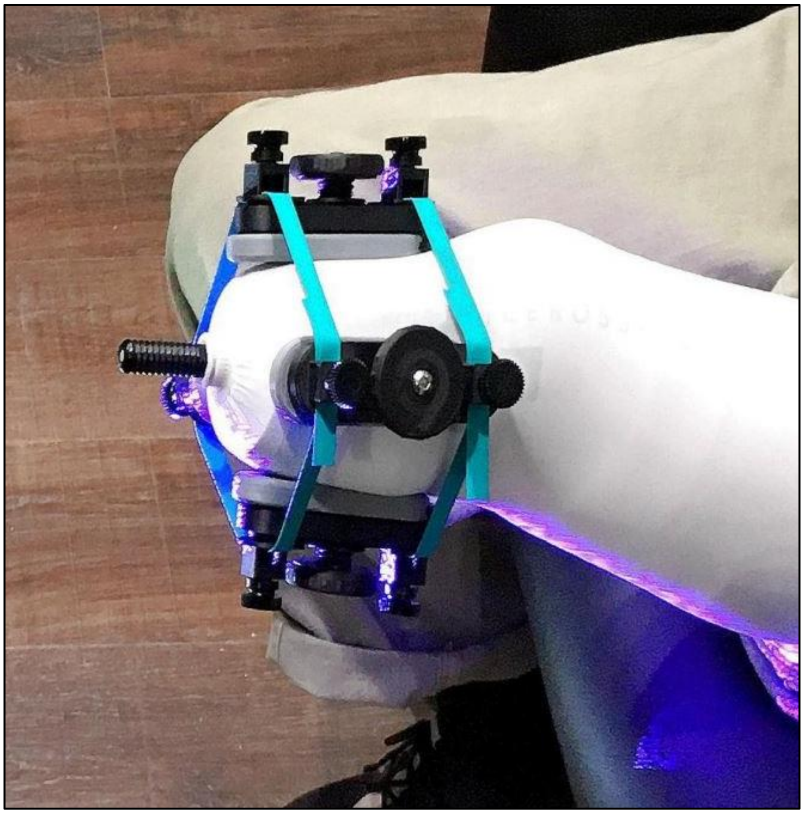

Figure 34. High-Fidelity™ Imager by biodesigns

Because HDPE becomes pliable around 250°C, the heat molding process is easy if an industrial oven is used. This is how Jaipur Foot creates their sockets. After making a positive mold of the limb, flesh-colored HDPE pipes are cut to a rough length, placed in an oven, heated until they are pliable, removed from the oven, placed over the positive mold, and shaped.

HDPE material might outgas harmful chemicals. This would require further research. However, if temperatures are kept low enough outgassing might not be an issue. Also, if proper ventilation or breathing masks are used, outgassing might also not be an issue.

The plaster-casting or 3D laser scanning methods would enable the proposed final socket design to be adapted and form-fitted to each user's unique shape. This ability is vital for socket manufacturing, since each user's limb will vary between length, shape, size, pressure-tolerant and pressure-sensitive areas, user needs, socket needs, and many more.

5.4 PROSTHESIS SUSPENSION SYSTEM

In some cases a socket using the CRS design needs no suspension system such as the typical VAS sleeves. Common suspension systems are shown in Figure 35. For the proposed final socket design, the suspension system to be used must be researched further.

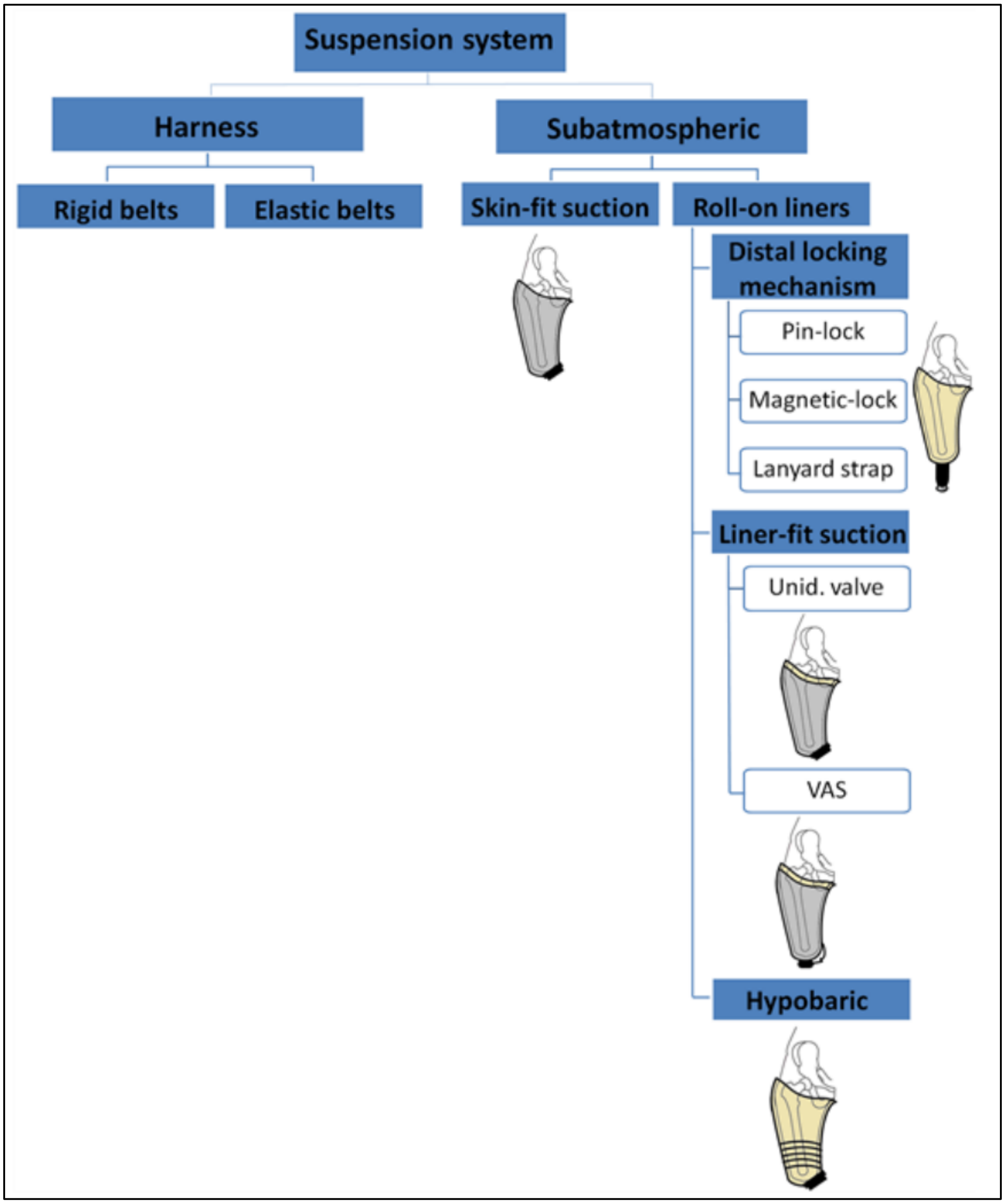

Figure 35. Classification of common socket suspension systems. The figure depicts such systems for transfemoral amputees, but they can be applied to all socket types [5].

5.5 *ACCESSIBILITY*

Accessibility of the final socket design was an important aspect of this project. HDPE drainpipes can be accessed in many countries for low cost, whether from an industrial supplier or salvaged from a household for instance.

A prosthesis estimate is shown in Table 9. This shows that an entire TF prosthesis using the proposed final socket design could cost 175.00 USD. This estimate excludes any overhead costs (e.g. industrial oven, POP, hand tools, facility), cost due to employment of craftsmen, and manufacturing costs. This estimate includes only material cost.

Considering that both Mukti Limb [31] and Jaipur Foot [24] provide their prostheses for free and that an average person's daily income could be 3 USD/day [22], a prosthesis cost of 175.00 USD is still too high to be easily accessible. However, when compared to a cost of 5,000-50,000 USD for a prosthesis in the U.S., a prosthesis cost of 175.00 USD is extremely accessible.

Table 9. Rough cost estimate of entire prosthesis using proposed final socket design

ITEM	DESCRIPTION	ESTIMATED PRICE (USD)	REFERENCE
Socket	HDPE Drainpipe	2.60	[alibaba.com, HDPE Pipe, 1-99 pieces]
Tightening System	Boa IP1 Kit	47.50	[Louis Garneau Boa IP1 Replacement Kit Black Right]
Pyramid Adapter	Pyramid Adapter	40.00	[Ottobock Titan 4R51 Rotatable Socket Adapter]
Knee	ReMotion Knee	80.00	[Hamner et al., 2015]
Pylon	HDPE Drainpipe	2.60	[alibaba.com, HDPE Pipe, 1-99 pieces]
Foot	Jaipur Foot	0.00	[jaipurfoot.org]
	TOTAL (USD)	**172.70**	
	ROUGH ESTIMATE (USD)	**175.00**	

5.6 *Attachment to Prosthesis*

The socket could be attached to the rest of the prosthesis by a mechanical pyramid joint like the one shown in Figure 36. This would need to be researched further.

Figure 36. Prosthetic pyramid adapter (Image taken from Google Images)

5.7 ACCURATE SOCKET SIMULATION

For this project only one load condition was used. In this condition the majority of the load was downward and outward pressure. However, forces would not always be directed in these directions. While little research was done on this issue, this project acknowledges that accurate simulation conditions would require different loading directions, like those shown in Figure 37 and Figure 38. These simulations would require advance simulation techniques and practices that were not possible during this project.

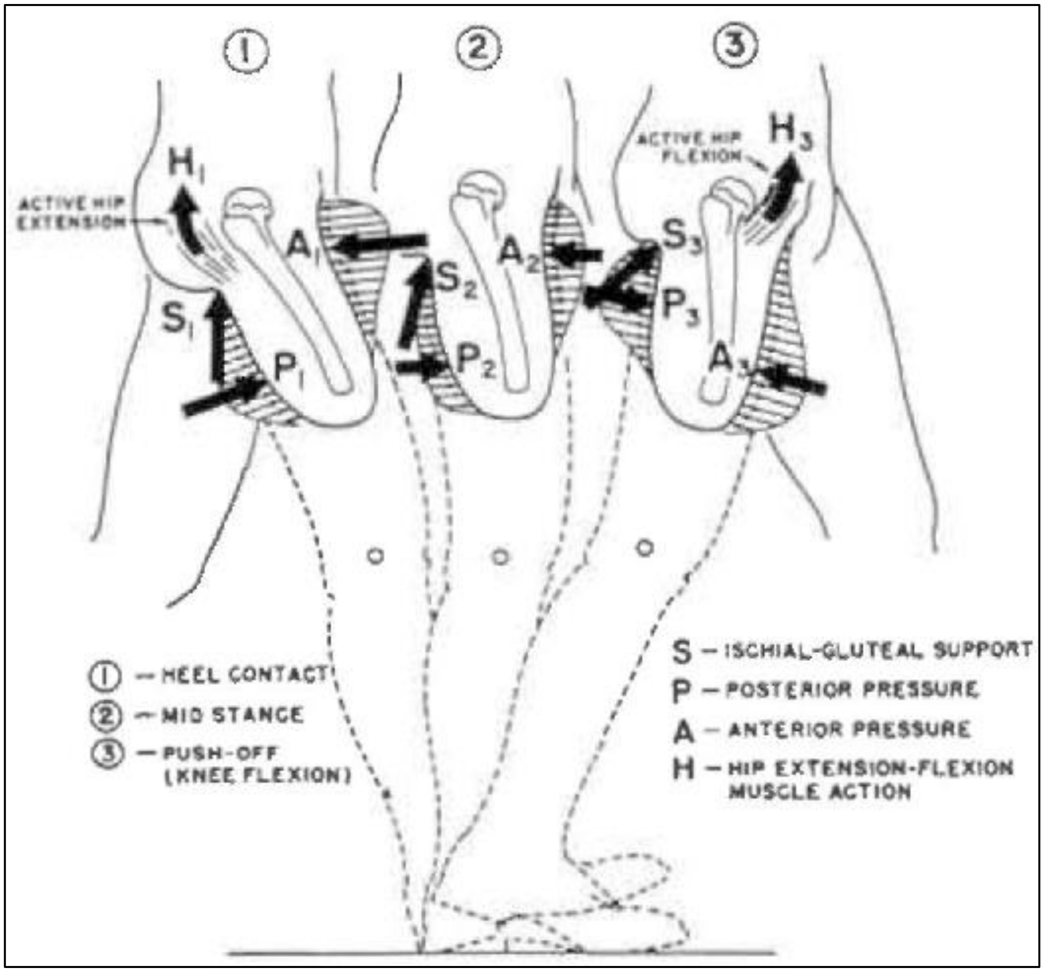

Figure 37. Possible directions of force (Shown in black arrows) for accurate simulations (Lateral view) (Image taken from Google Images)

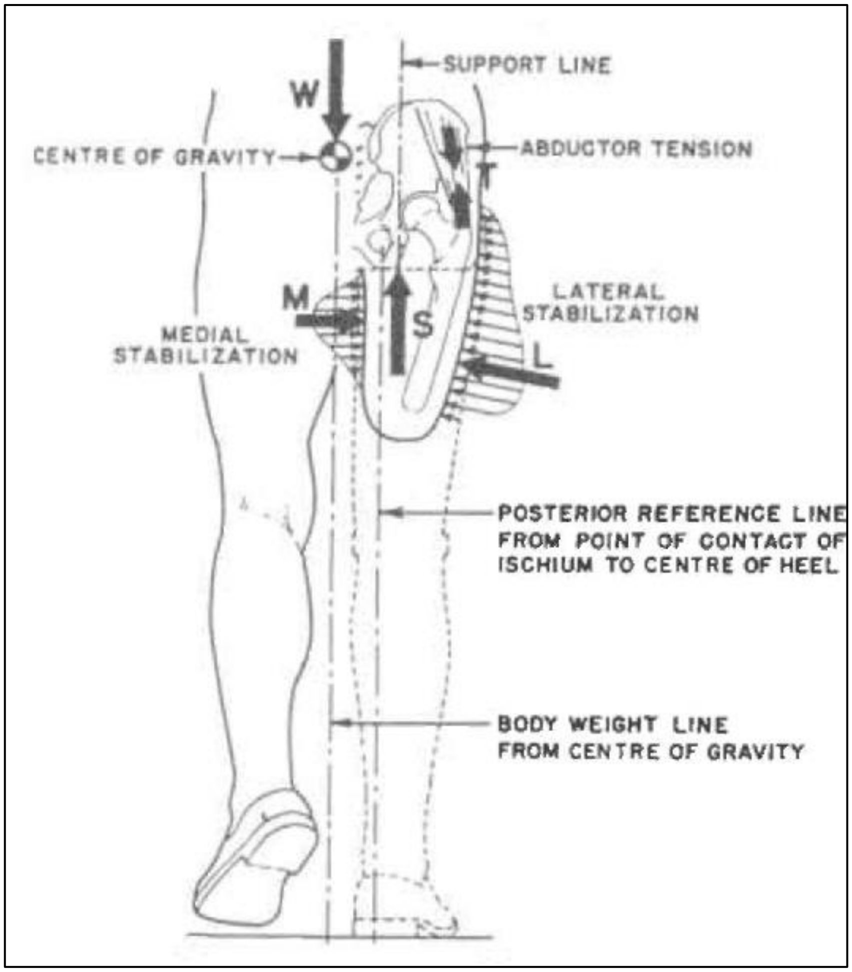

Figure 38. Possible directions of force (Shown in black arrows) for accurate simulation (Posterior view) (Image taken from Google Images)

6 RECOMMENDATIONS FOR FUTURE WORK

6.1 IMPROVING ACCURACY OF SIMULATIONS

As discussed briefly above, the accuracy of socket load simulations must be researched further. Since little information was found in the literature on how to do this, it might be necessary to shift to experimental testing. However, the author believes that with enough discussion, research, practice, and trial and error accurate socket load simulations could be achieved.

6.2 INCORPORATING TEXTILES

Incorporating textiles into the socket would be interesting. Martin Bionics already does this with their Socket-less Socket™. They boast this socket conforms just like a hammock for your leg. They make the point that our clothes, our shoes, our backpacks, etc. are made out of flexible, conforming materials – textiles. They question, why are sockets the exception? I would like to see textiles and fabrics incorporated into the proposed final design. This improvement would affect the overall function of the socket more than its international accessibility.

6.3 *HUMAN TRIALS*

Due to the user-oriented nature of prosthetics, human trials would be necessary to ensure verification of project requirements as well as comfort of the proposed final socket design.

6.4 *LOAD TESTING*

The proposed final socket design should be tested under the ISO 10328 standards for testing prosthetic sockets.

7 CONCLUSIONS

7.1 *FINAL DESIGN SUMMARY*

The proposed final socket design is shown below in Figure 39 and is made out of high density polyethylene. This design features a cable-tightening system for volume fluctuations and compression struts and release windows for underlying bone and tissue stabilization.

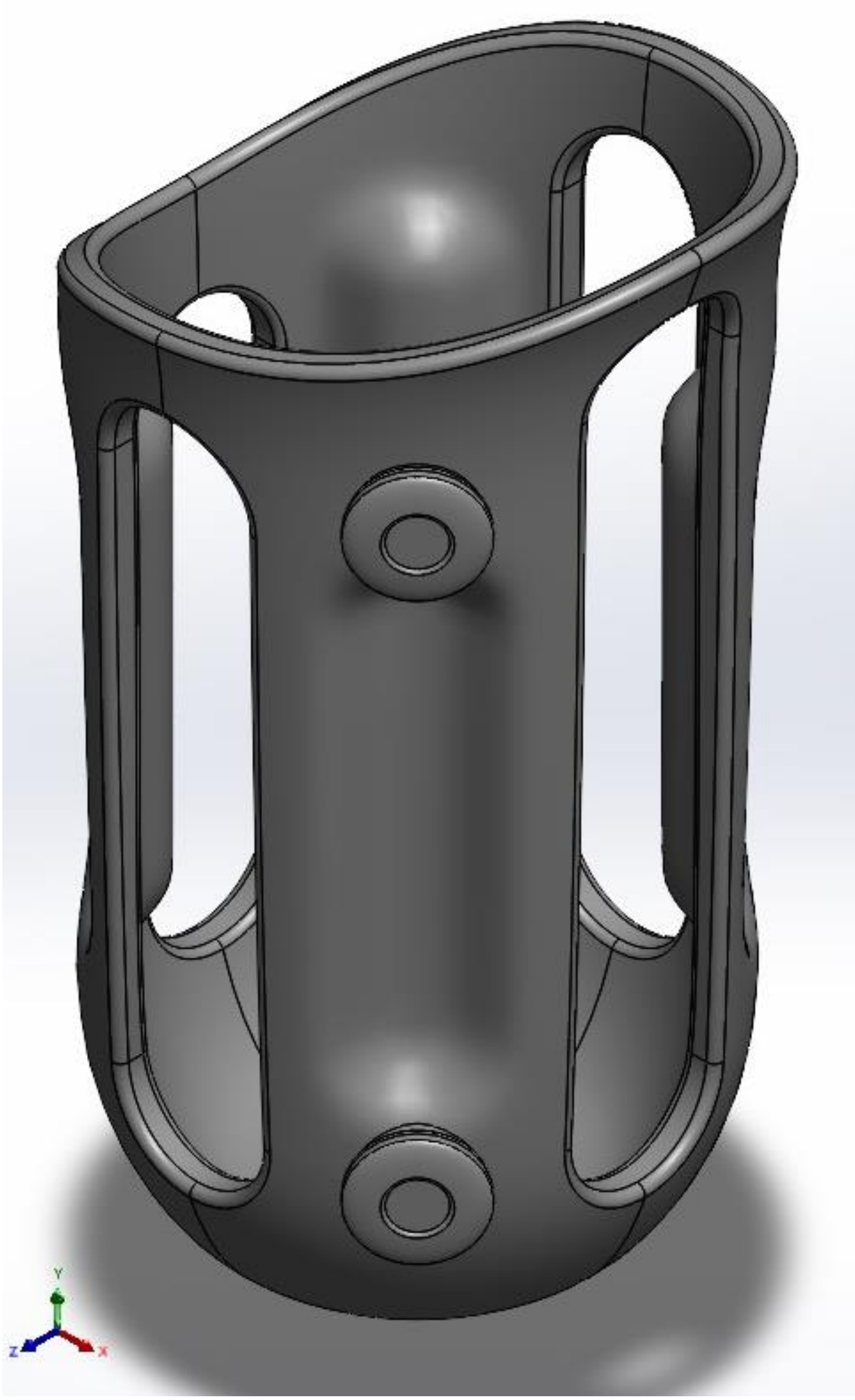

Figure 39. Proposed final socket design

7.2 PROJECT AND REPORT SUMMARY

In summary, this report discussed the prosthetics field and problem, the issues related to prosthetic sockets, the project objective, deliverables, terms and definitions, and stakeholders, and applicable standards. Similar research, conceptual designs, the material and shape selection process, other factors related to this project, and recommendations for future work were also covered.

The project itself entailed doing major research into existing technology, learning SolidWorks techniques, consulting with team members and faculty members, report writing, and giving presentations on project work done.

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APPENDIX

APPENDIX A

BIOMECHANICS LITERATURE

Shown below are tables and figures obtained from biomechanics literature concerning reaction forces associated with the transfemoral level in terms of body weight (BW).

Table 3.3.2 Selected experimental results for external vertical impact force peaks in walking and running (from Nigg, 1985, with permission). Values shown with an * have been calculated assuming a body weight BW = 700 N.

MOVEMENT	FOOTWEAR	v [m/s]	F(max) [N]	F(max)/BW	AUTHOR	YEAR
WALKING	barefoot	1.3	385	0.55	Cavanagh	1981
	army boots	1.3	259	0.37	"	"
	street shoes	1.3	189	0.27	"	"
RUNNING (HEEL)	run. shoe	4.5	1540	2.2	Cavanagh	1980
	run. shoe hard	4.0	2000	2.9	Nigg	1980
	run. shoe soft	4.0	1100	1.6	"	"
	run. shoe	3.4	1365	2.0	Frederick	1981
	run. shoe	3.8	1590	2.3	"	"
	run. shoe	4.5	1963	2.9	"	"
	run. shoe	3.0	1345	2.0	Nigg	1987
	run. shoe	4.0	1521	2.2	"	"
	run. shoe	5.0	1799	2.6	"	"
	run. shoe	6.0	2070	3.0	"	"
RUNNING (TOE)	run. shoe	4.0	300	0.4	Denoth	1980
TAKE-OFF FOR JUMP	spikes	2.0	1000	1.4	Nigg	1981
	spikes	4.0	2300	3.3	"	"
	spikes	6.0	3700	5.4	"	"
	spikes	8.0	5700	$\boxed{8.3}$	"	"
	run. shoe	2.0	1400	2.0	"	"
	run. shoe	4.0	2000	2.9	"	"
	run. shoe	7.0	2900	4.2	"	"

Figure 40. Table 3.3.2 from [26]: Forces acting on body in terms of body weight (Relevant value shown in red)

the reaction force from the force plate is ... the second half of ground contact, the foot pushes in the posterior direction. Consequently, the reaction force from the force plate is in the anterior direction. The force component in the m-l (medio-lateral) direction is less consistent intra- and inter-individually. The medio-lateral component often shows an initial reaction force in lateral direction that results from a medial (inward) movement of the foot during landing. This initial lateral force is usually shorter than 20% of the total contact time. It is usually followed by a reaction force in the medial direction that is often present during the rest of the ground contact time and that is usually smaller than the initial lateral force.

The intra- and inter-individual variability is much bigger for the medio-lateral than for the vertical and the anterior-posterior force-time curves. In addition, substantial differences may exist in the ground reaction force components between the left and the right foot fall for one subject.

Values of impact and active ground reaction force peaks during different movements have been reported by various authors. A summary of these results (Figure 3.3.11) illustrates that the maximal external impact forces can exceed 10 BW (body weight) while the maximal external active forces do not exceed 5 BW.

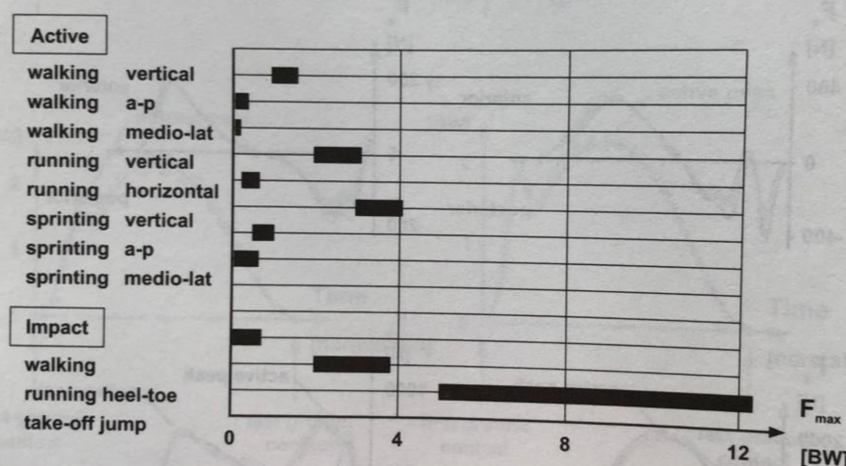

Figure 3.3.11 **Magnitude of actual impact and active ground reaction force peaks measured with a force plate during various activities (from Nigg, 1988, with permission).**

Figure 41. Figure 3.3.11 from [26]: Impact forces acting on body in terms of body weight (Relevant values underlined in red)

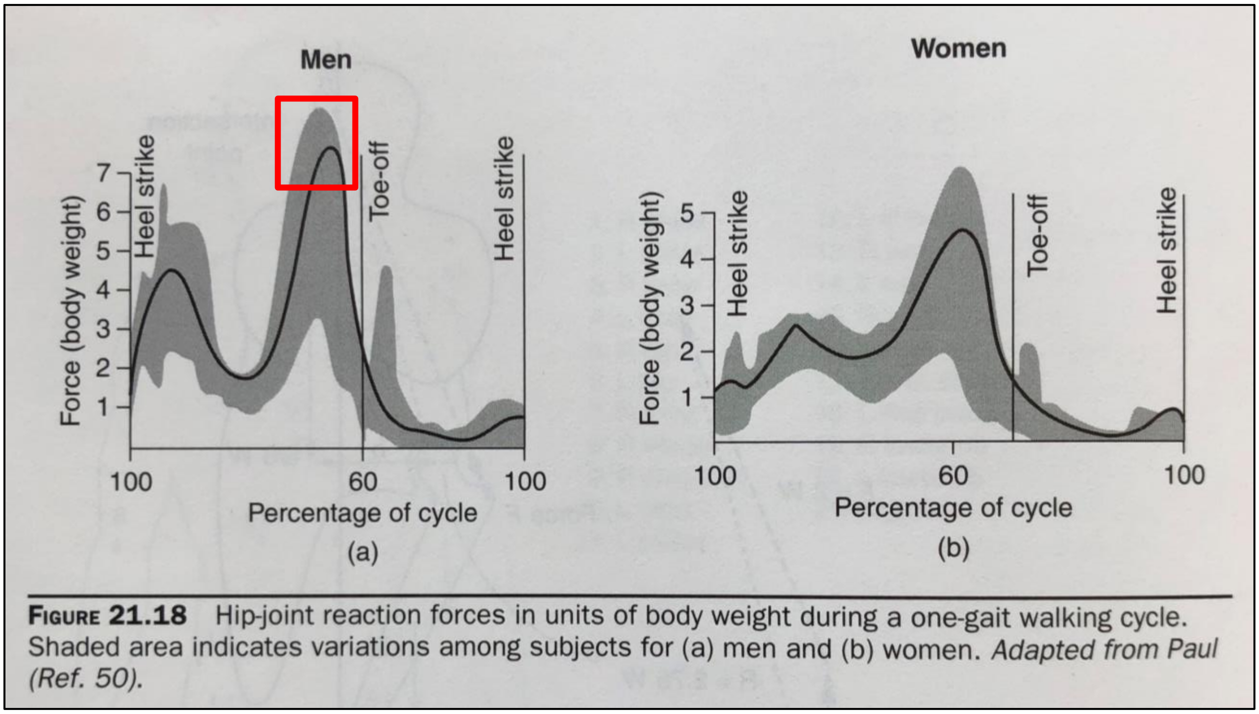

FIGURE 21.18 Hip-joint reaction forces in units of body weight during a one-gait walking cycle. Shaded area indicates variations among subjects for (a) men and (b) women. *Adapted from Paul (Ref. 50).*

Figure 42. Figure 21.18 from [27]: Hip joint reaction forces in terms of body weight (Relevant values shown in red)

APPENDIX B

FEA SIMULATION RESULTS

SOCKET ITERATION 1:

Shown below are the FEA simulation results for socket iteration 1 (model A.4.3). Nonuniformly distributed normal force load of 6,250 N applied to inner faces. HDPE material with yield strength of 23.18 Mpa used. Maximum element size of 7 mm used for mesh. Large displacements turned off.

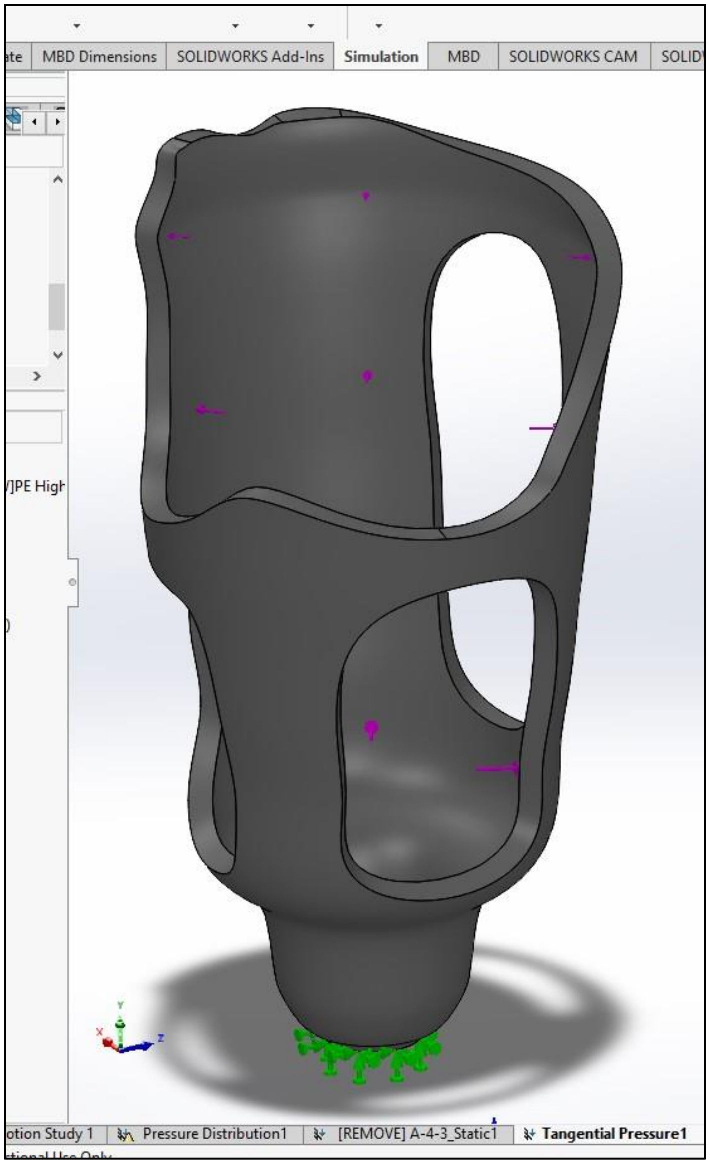

Figure 43. Socket iteration 1: Isometric (Before simulation)

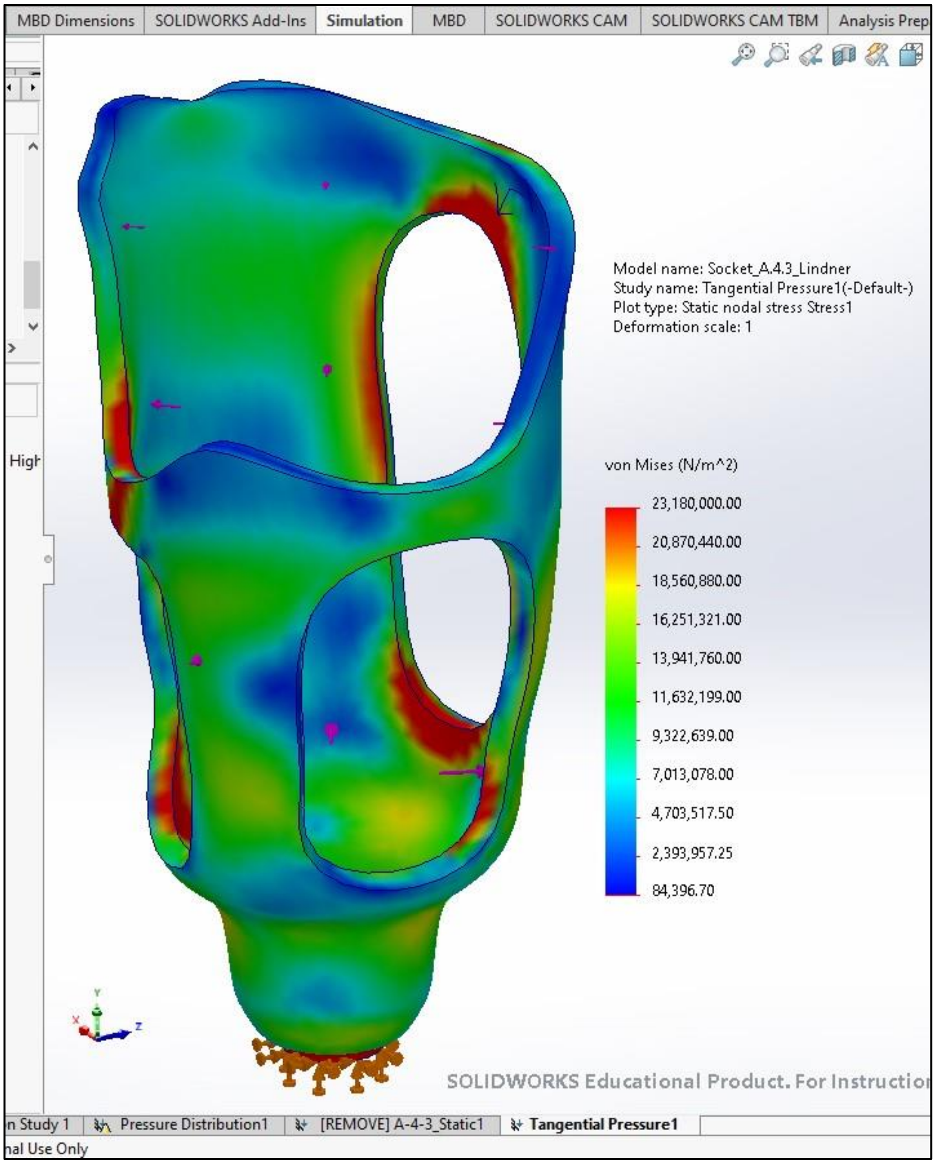

Figure 44. Socket iteration 1: Isometric (After simulation)

Figure 45. Socket iteration 1: Lateral looking Medial (Before simulation)

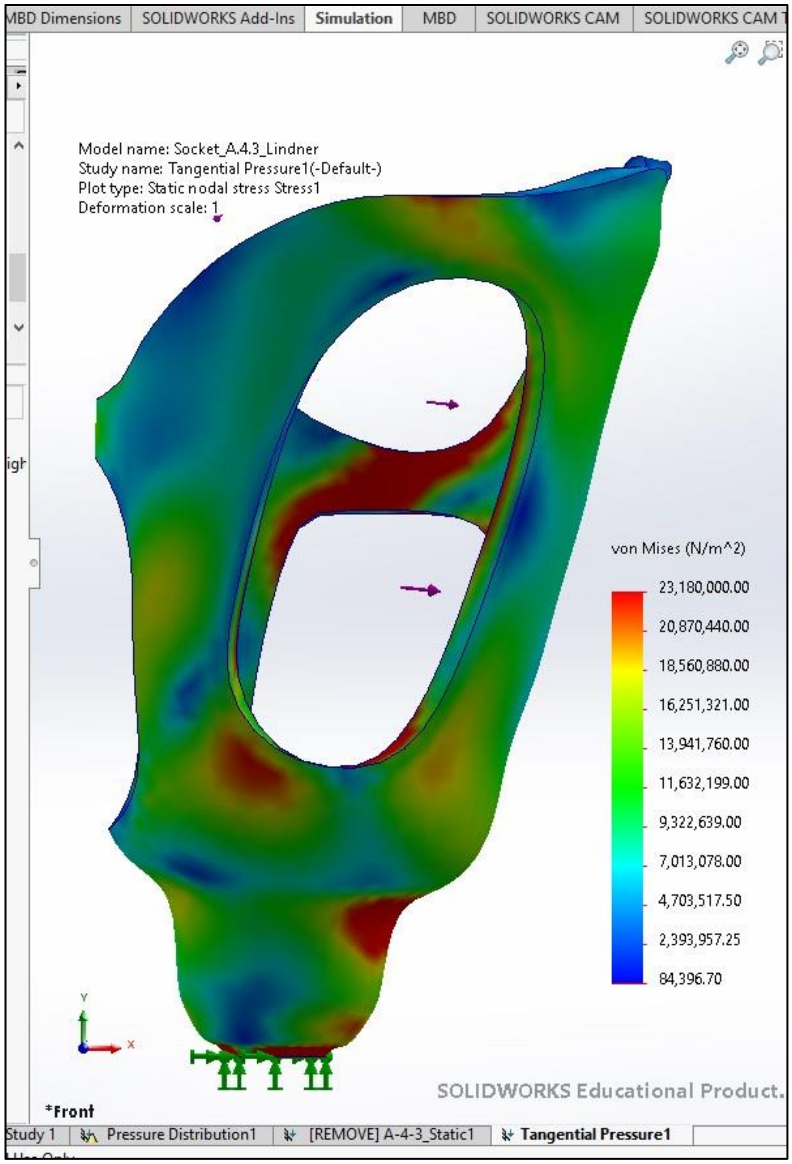

Figure 46. Socket iteration 1: Lateral looking medial (After simulation)

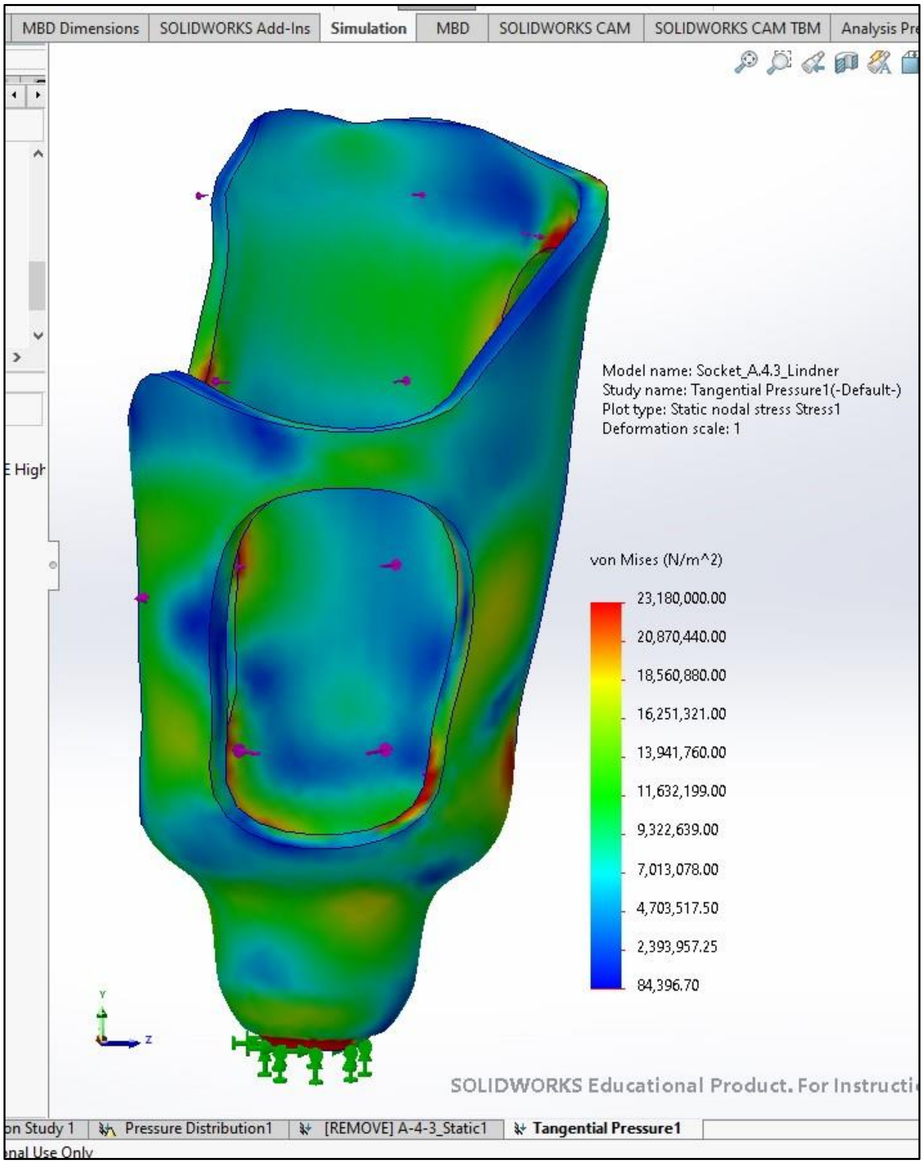

Figure 47. Socket iteration 1: Anterior looking posterior

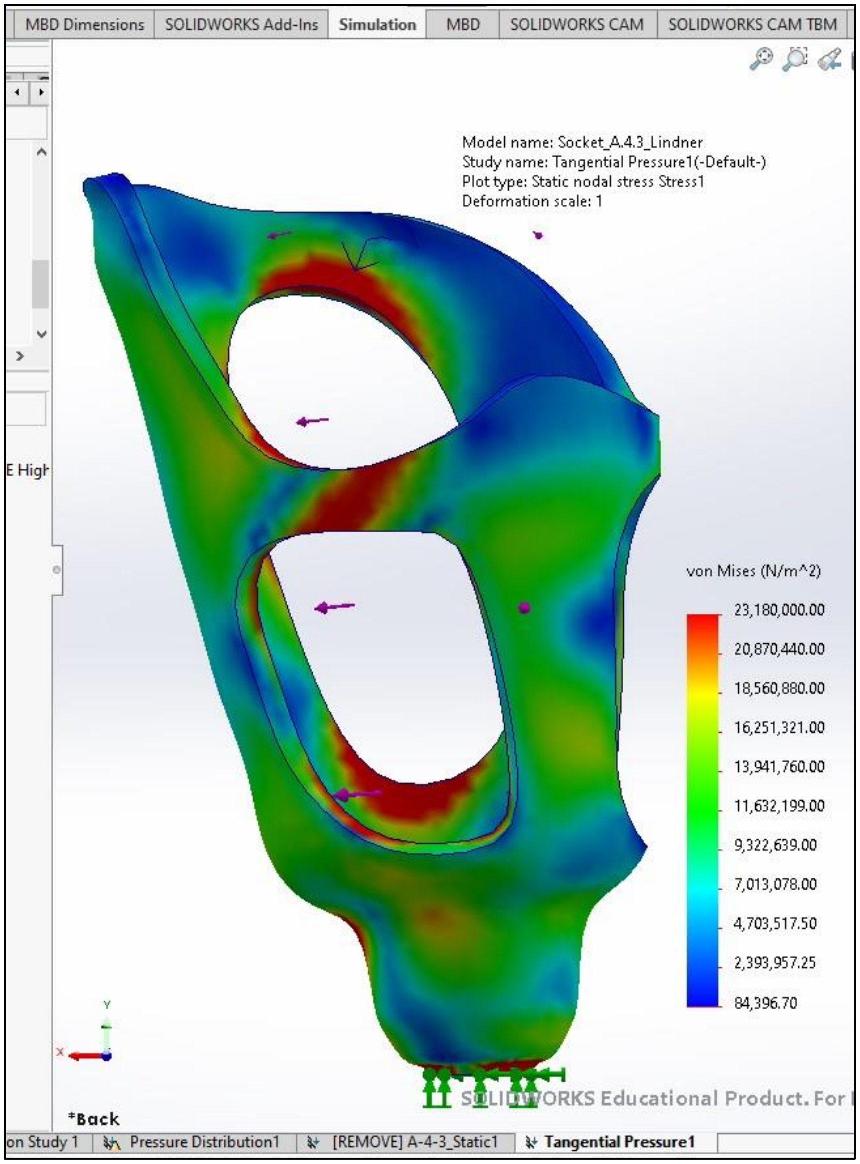

Figure 48. Socket iteration 1: Medial looking lateral

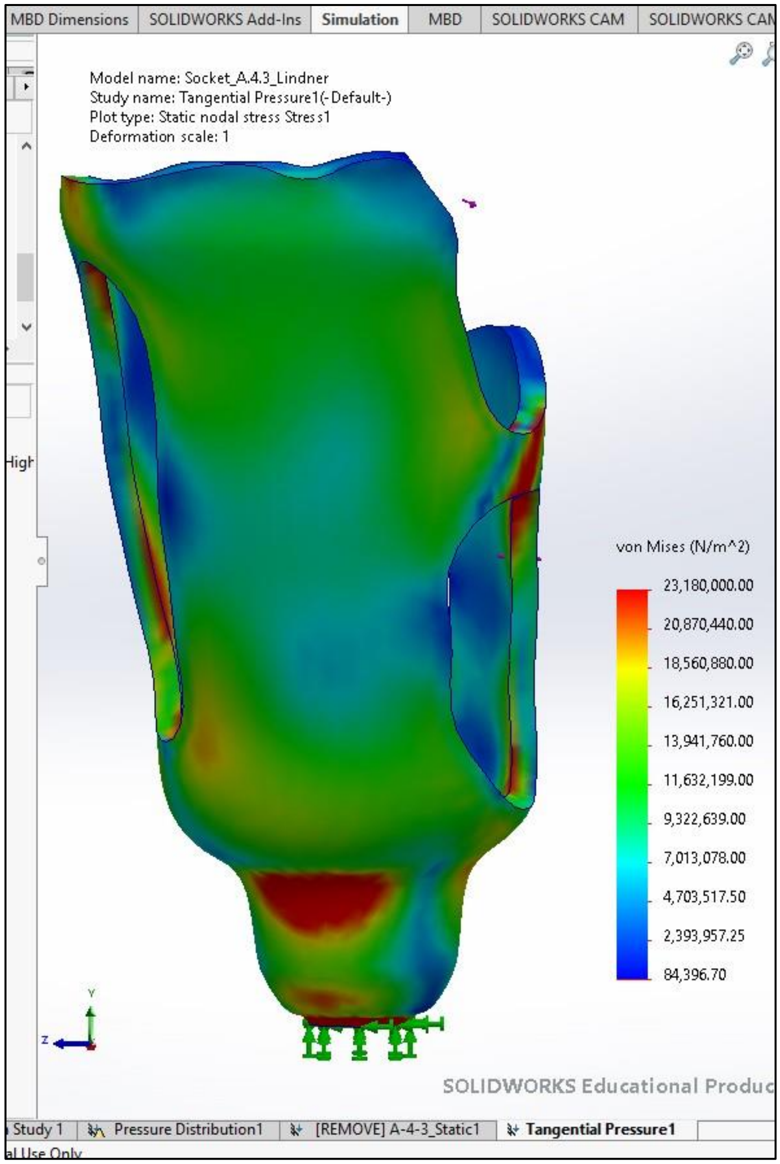

Figure 49. Socket iteration 1: Posterior looking anterior

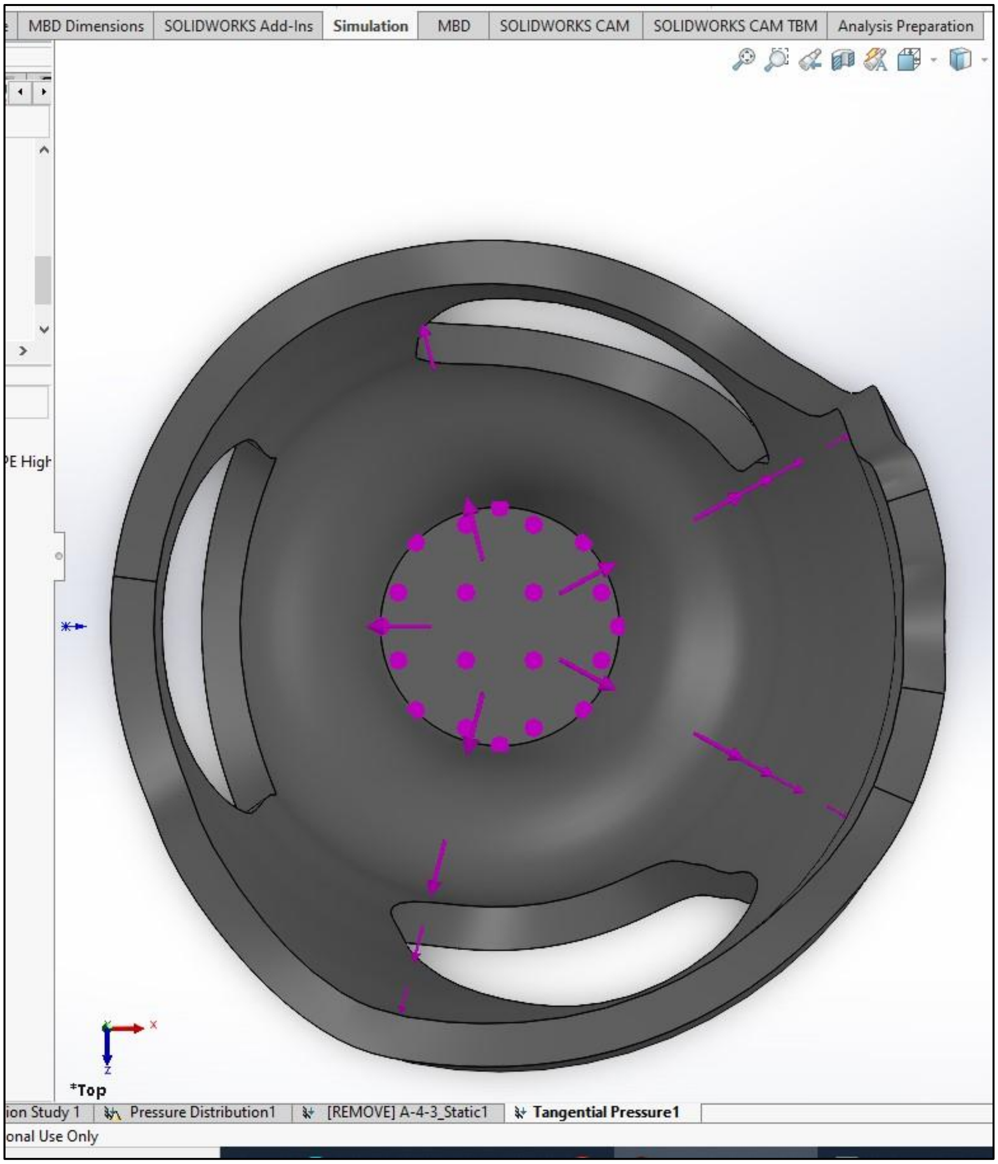

Figure 50. Socket iteration 1: Proximal looking distal (Before simulation)

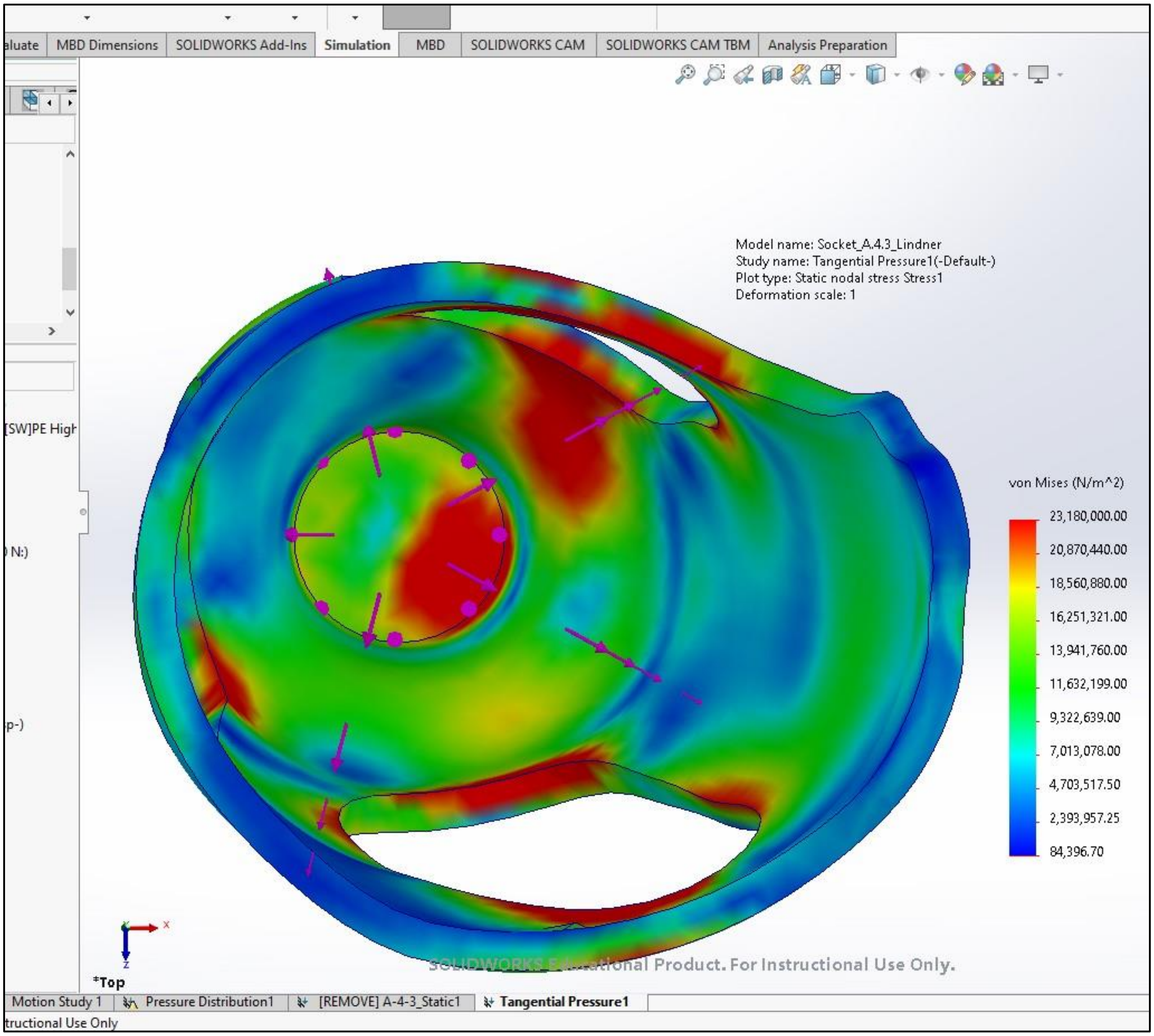

Figure 51. Socket iteration 1: Proximal looking distal (After simulation)

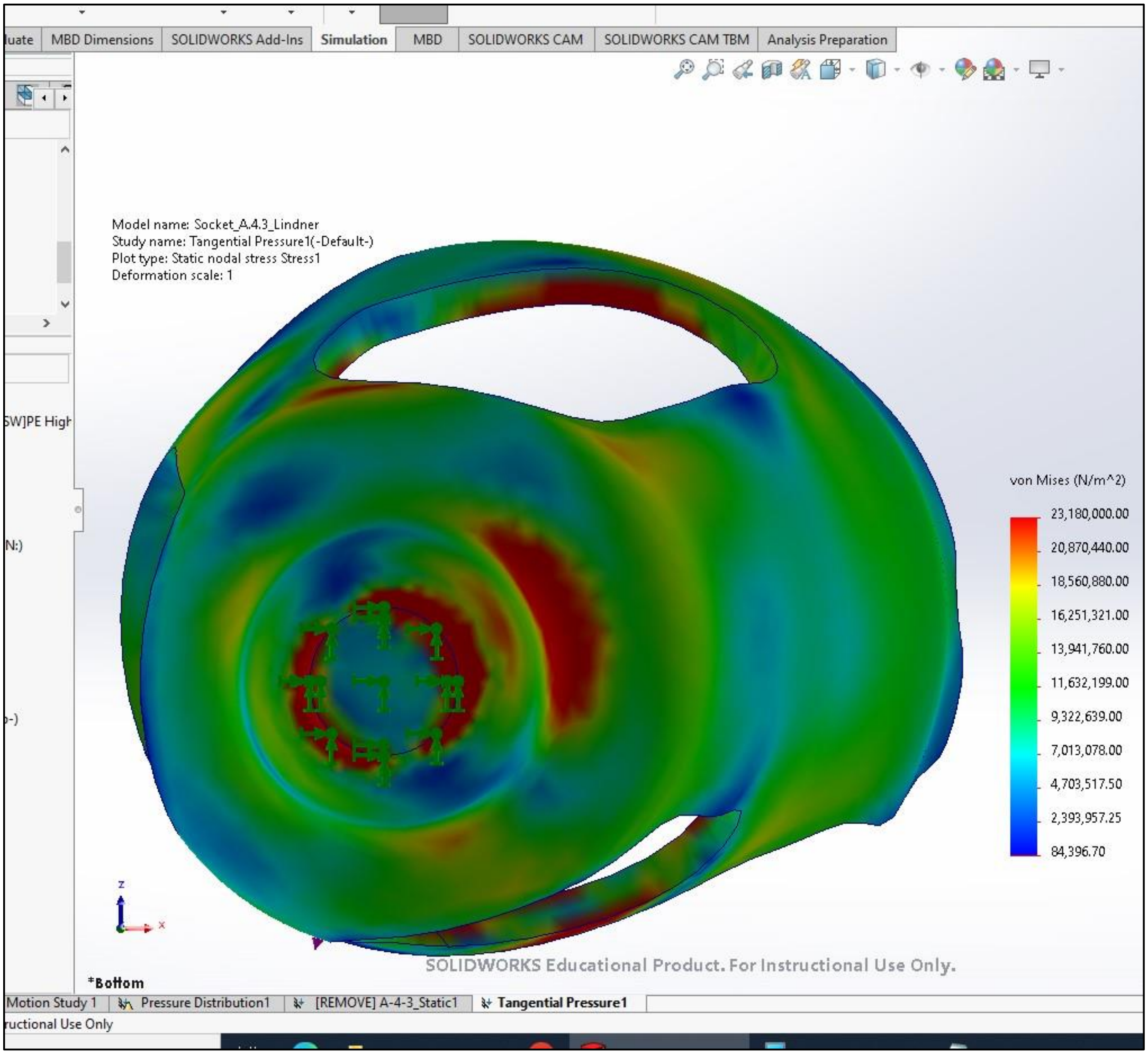

Figure 52. Socket iteration 1: Distal looking proximal

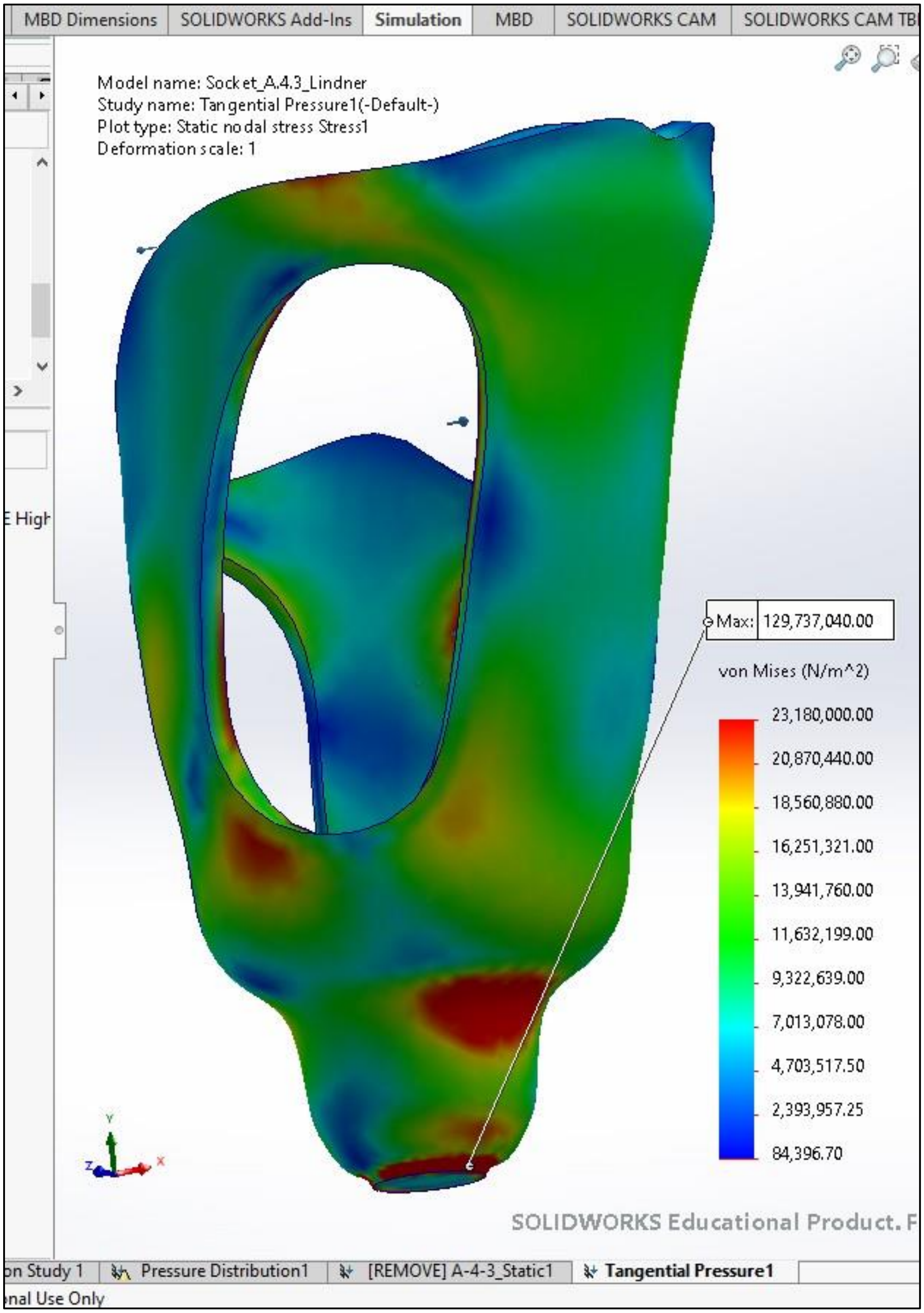

Figure 53. Socket iteration 1: Max stress

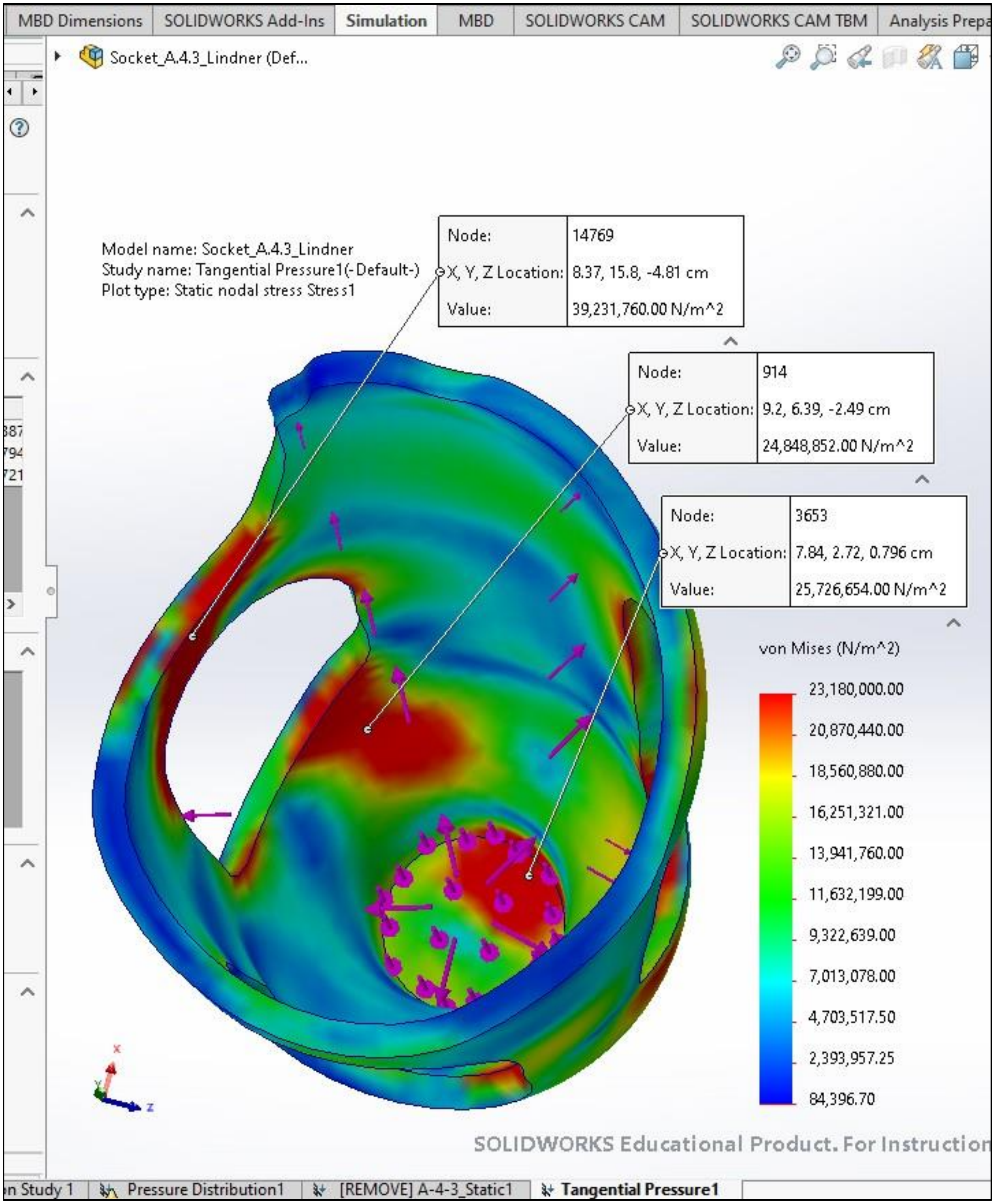

Figure 54. Socket iteration 1: Stress probes (Proximal view)

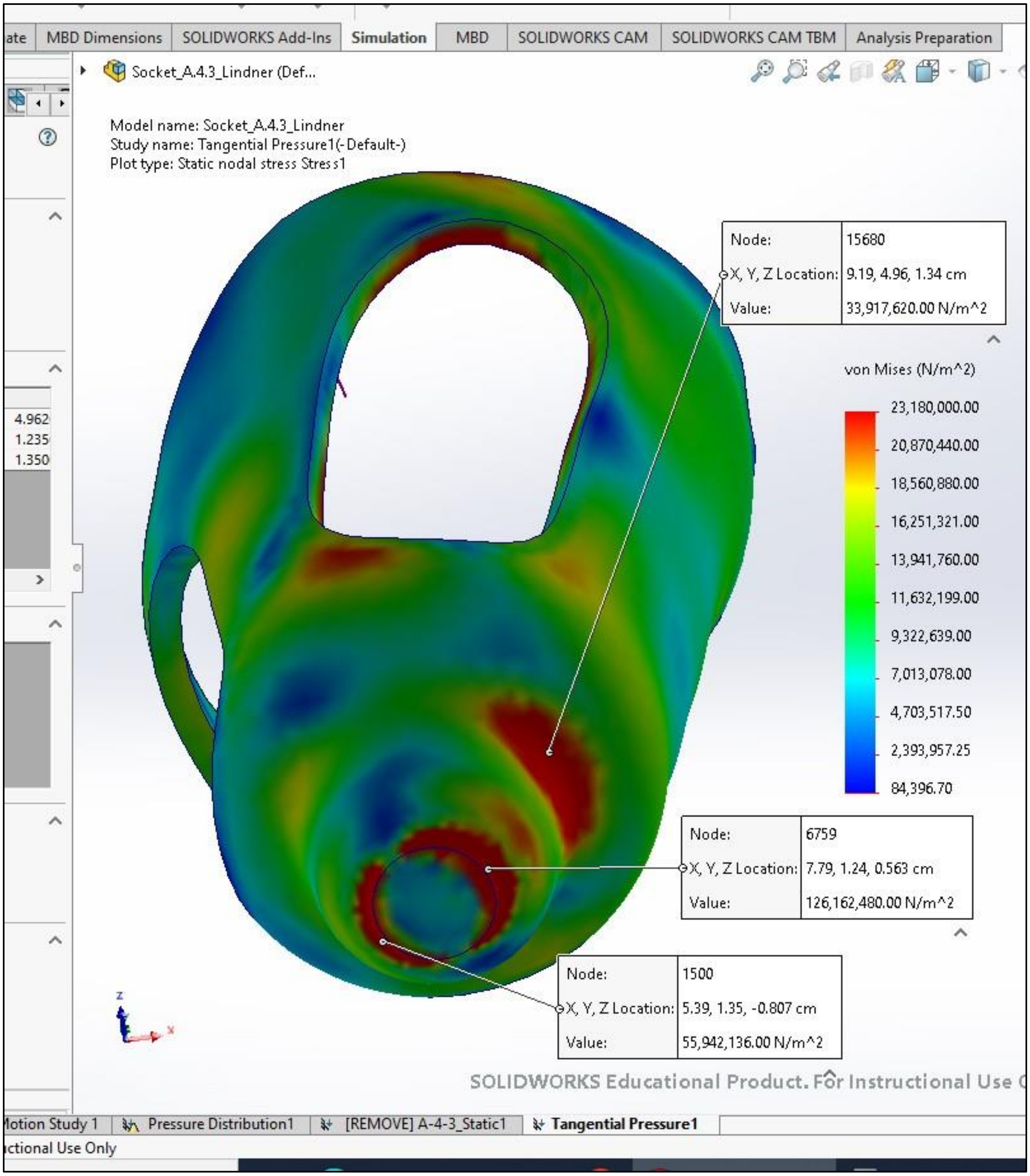

Figure 55. Socket iteration 1: Stress probes (Distal view)

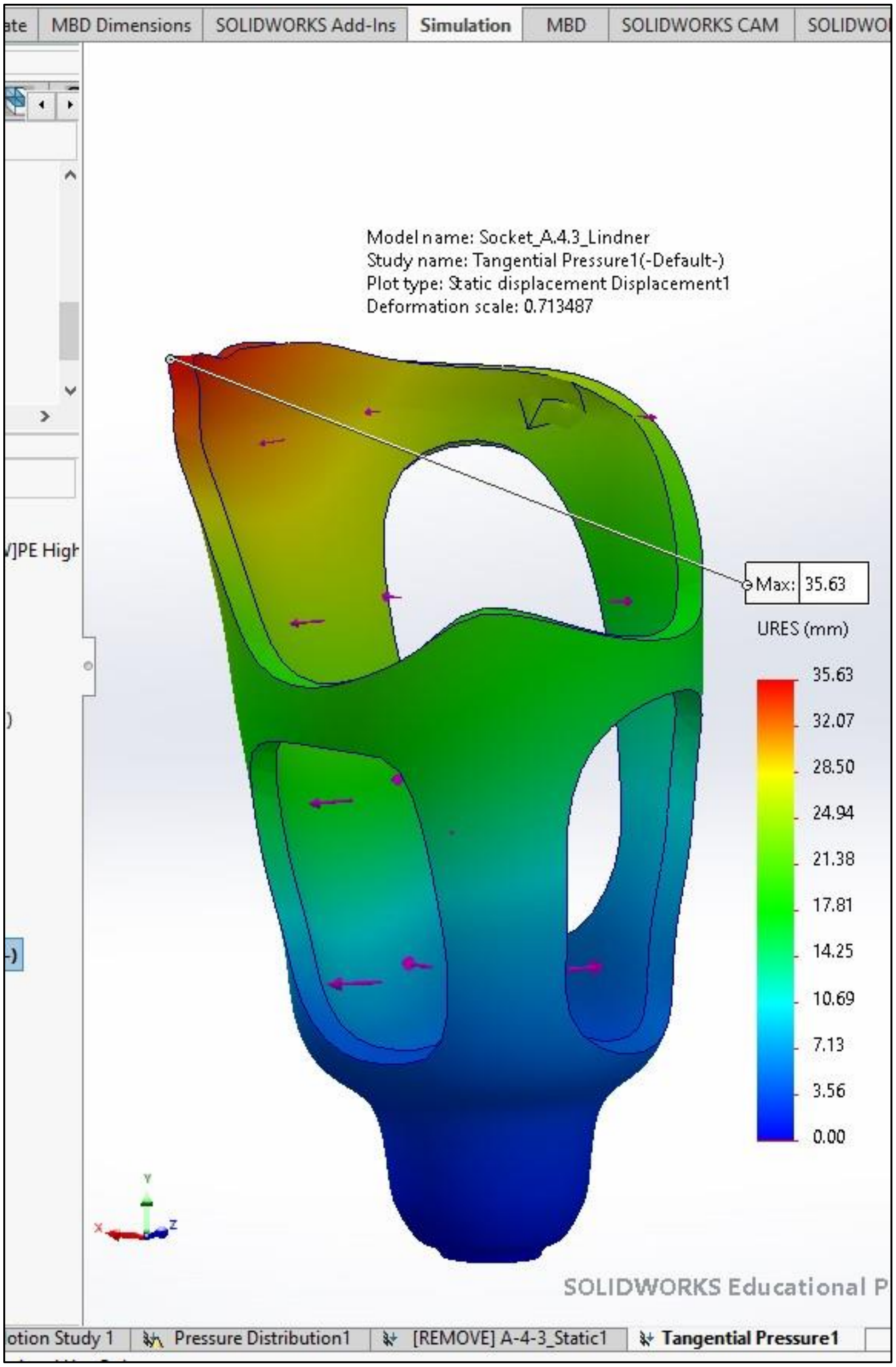

Figure 56. Socket iteration 1: Max displacement

SOCKET ITERATION 2:

Shown below are the FEA simulation results for socket iteration 2 (model A.4.7). Nonuniformly distributed normal force load of 6,250 N applied to inner faces. HDPE material with yield strength of 23.18 Mpa used. Maximum element size of 7 mm used for mesh. Large displacements turned off.

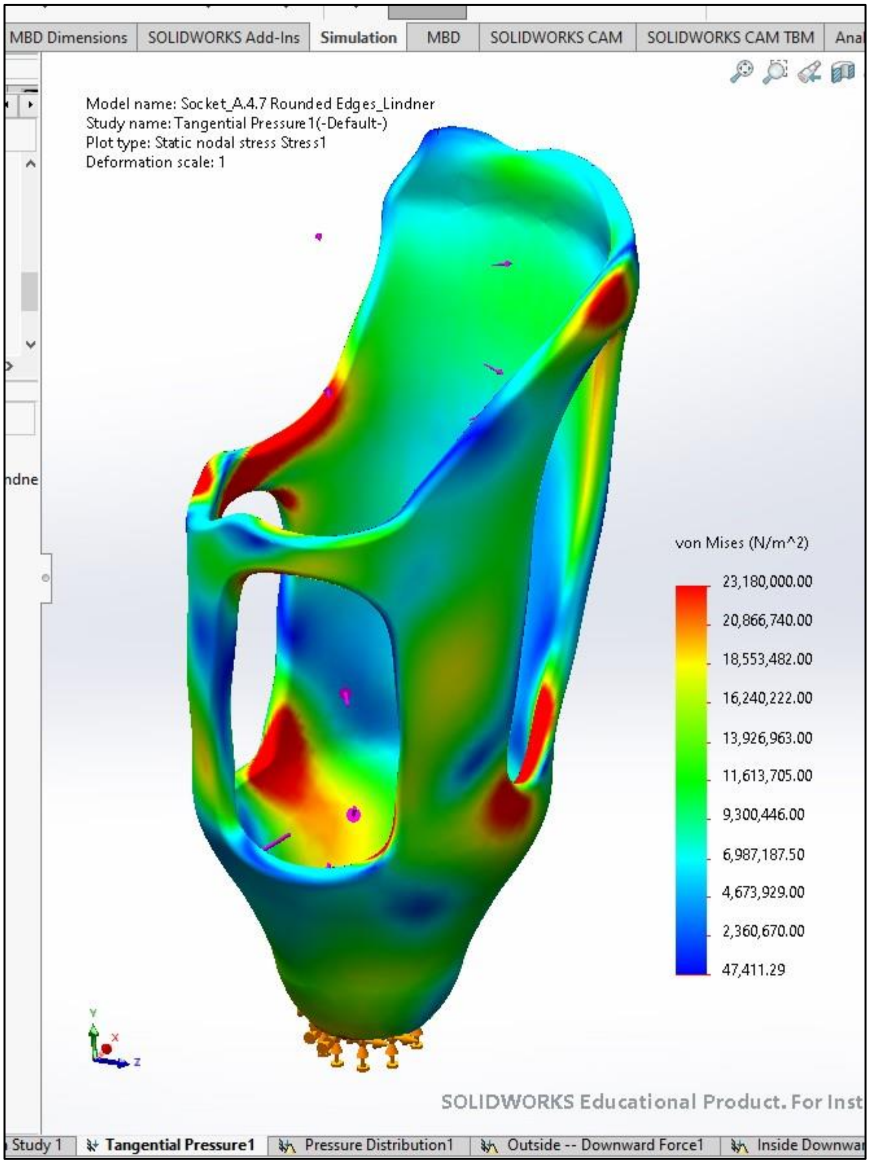

Figure 57. Socket iteration 2: Isometric (After simulation)

Figure 58. Socket iteration 2: Lateral looking medial (Before simulation)

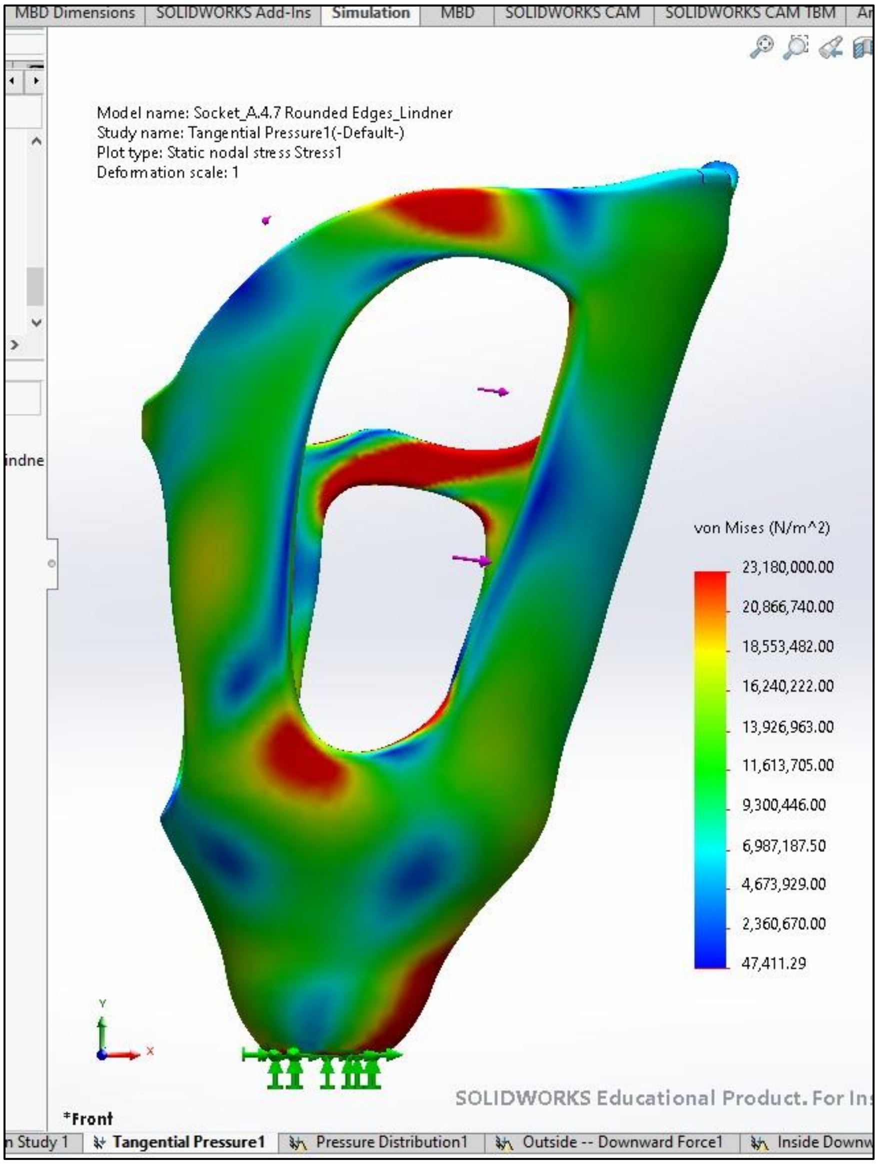

Figure 59. Socket iteration 2: Lateral looking medial (After simulation)

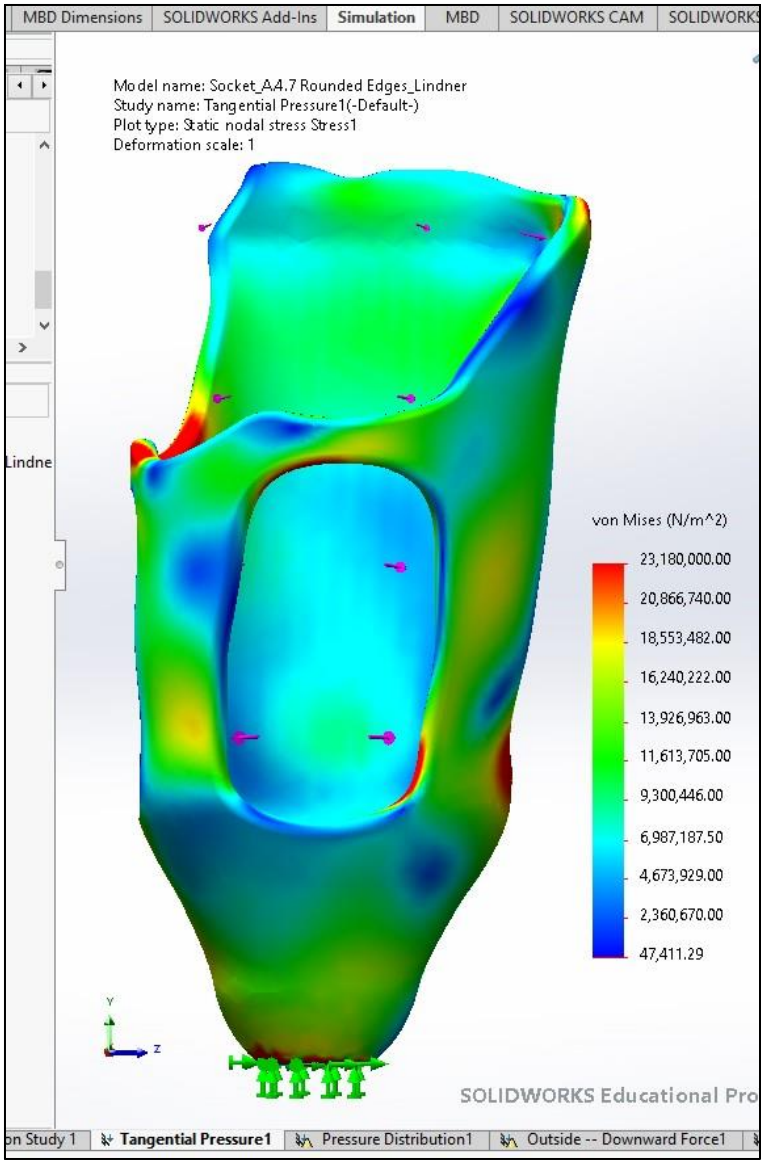

Figure 60. Socket iteration 2: Anterior looking posterior

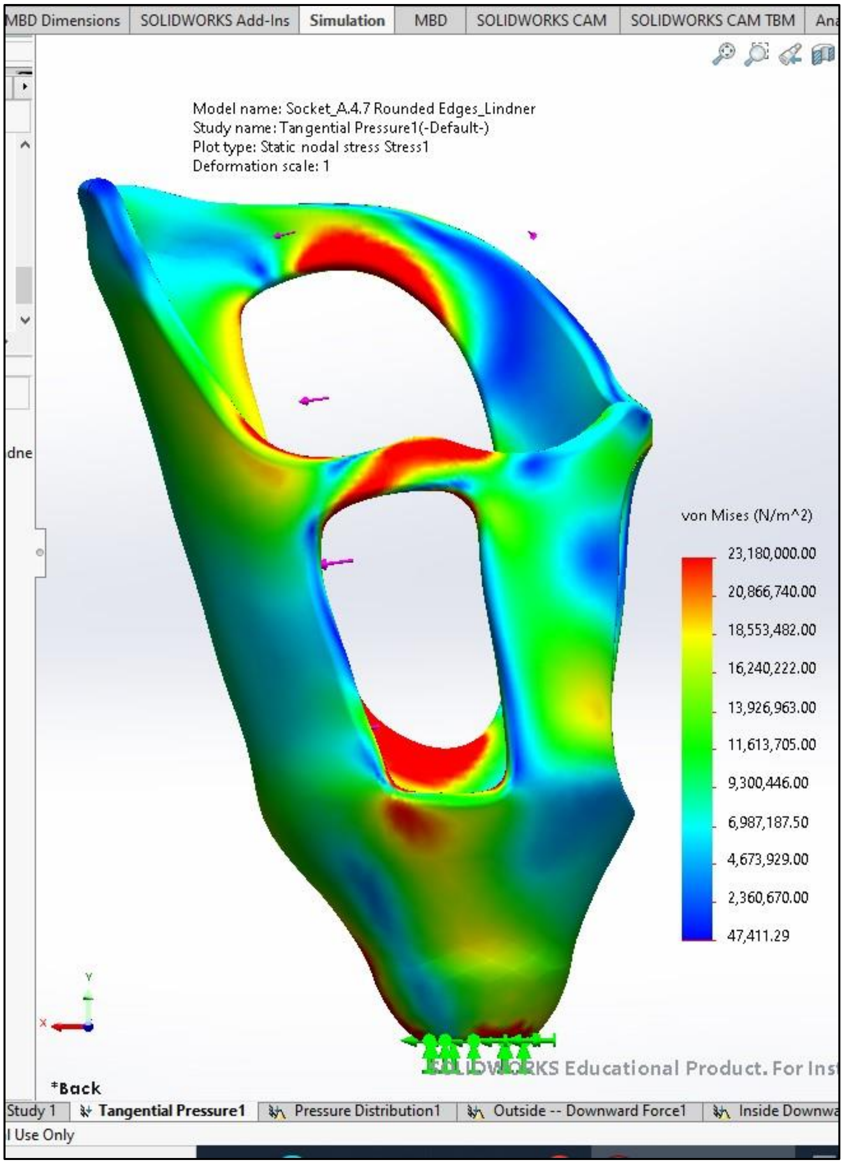

Figure 61. Socket iteration 2: Medial looking lateral

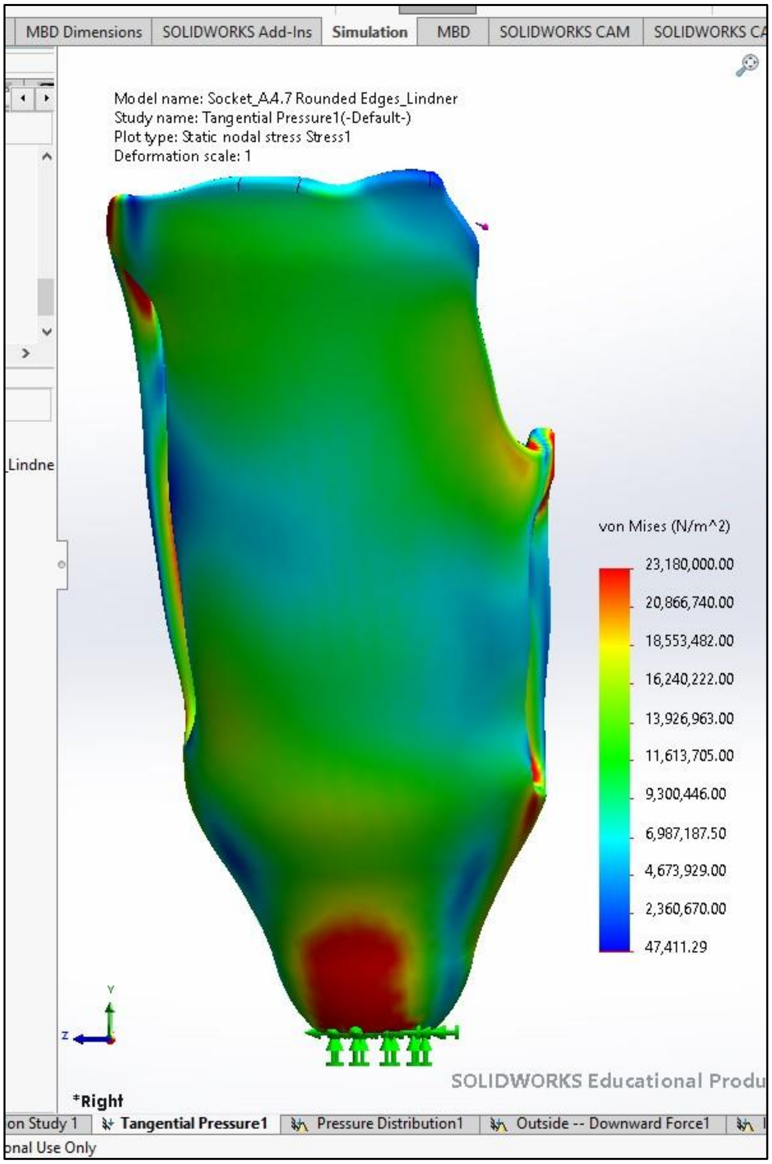

Figure 62. Socket iteration 2: Posterior looking anterior

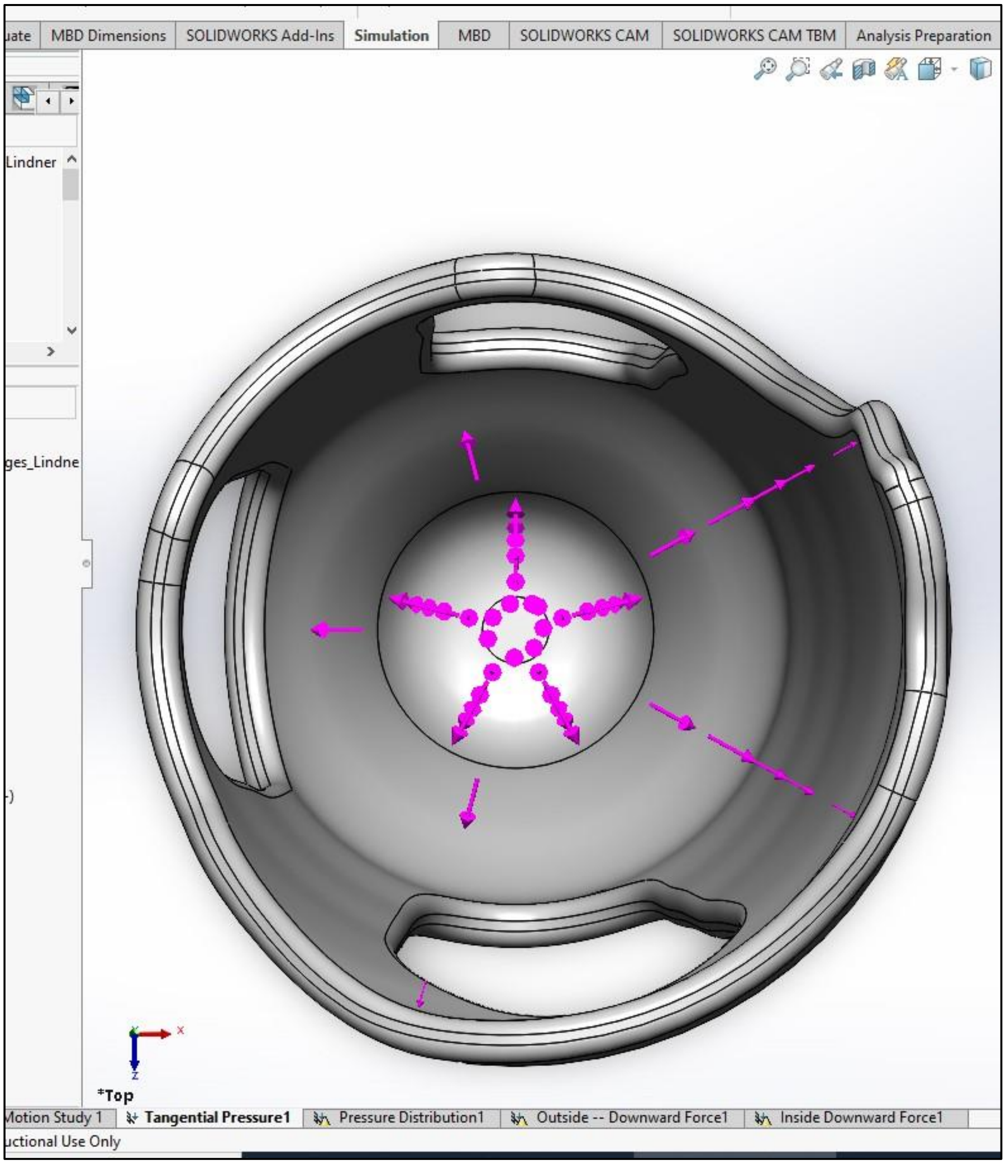

Figure 63. Socket iteration 2: Proximal looking distal (Before simulation)

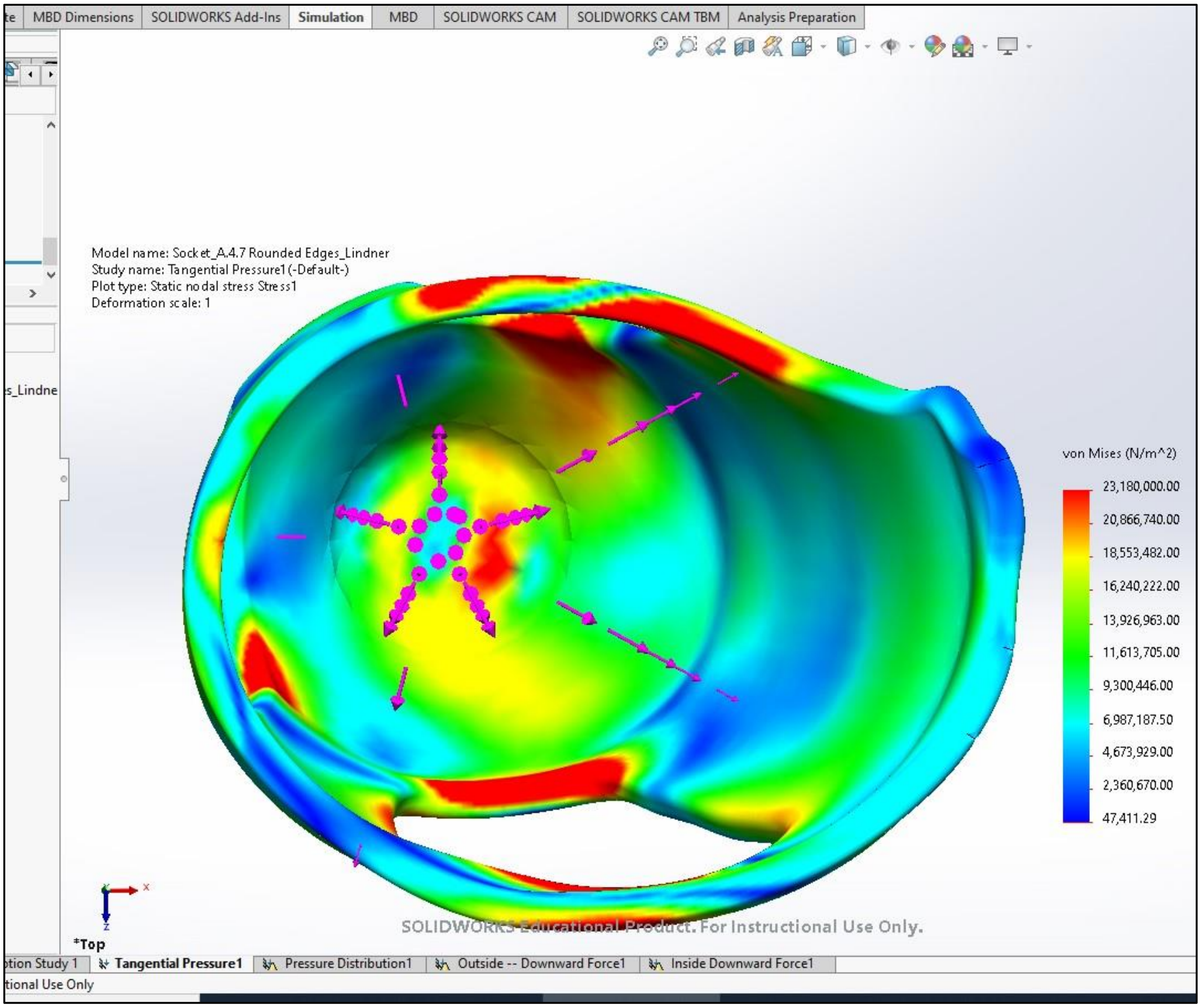

Figure 64. Socket iteration 2: Proximal looking distal (After simulation)

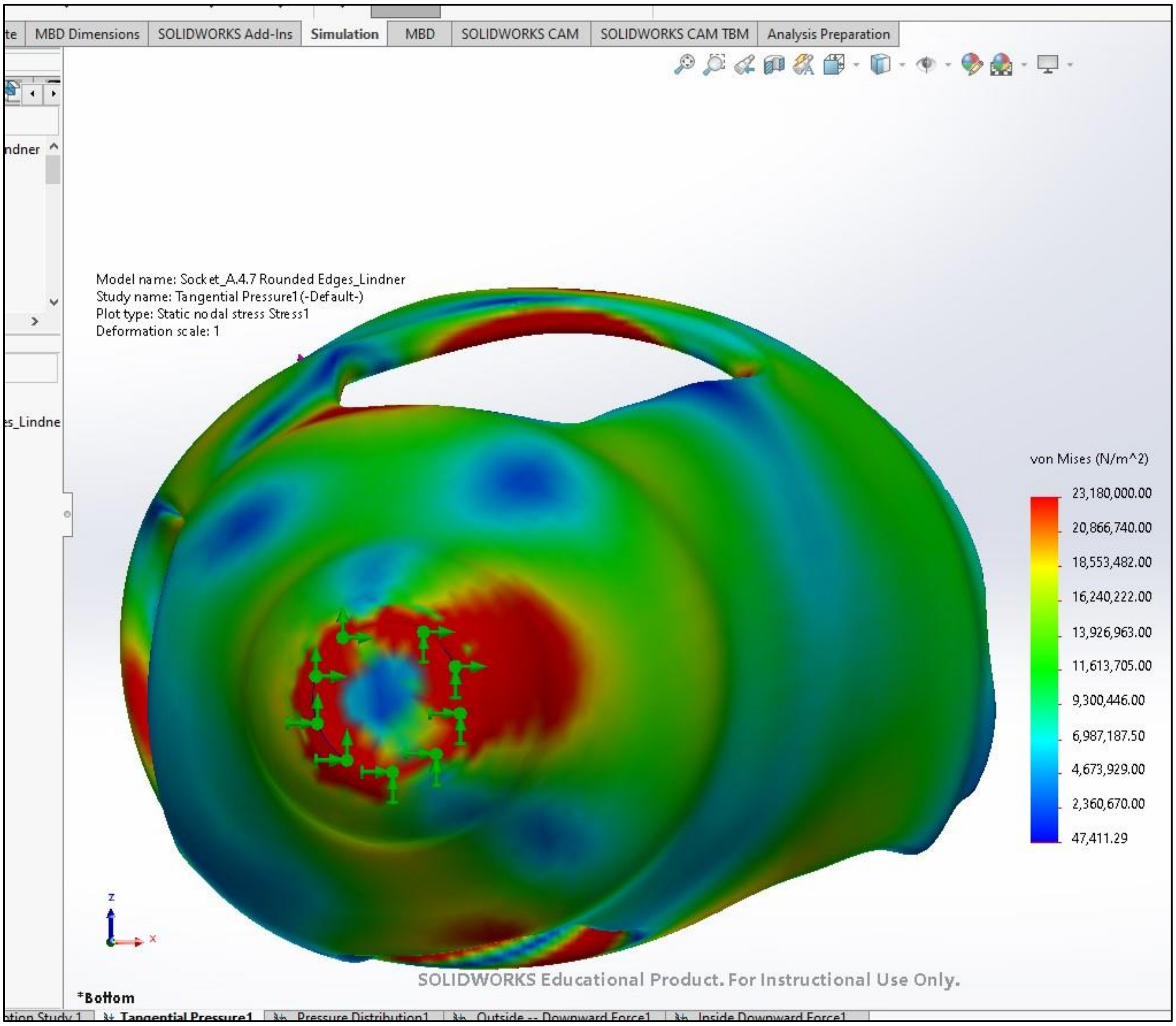

Figure 65. Socket iteration 2: Distal looking proximal

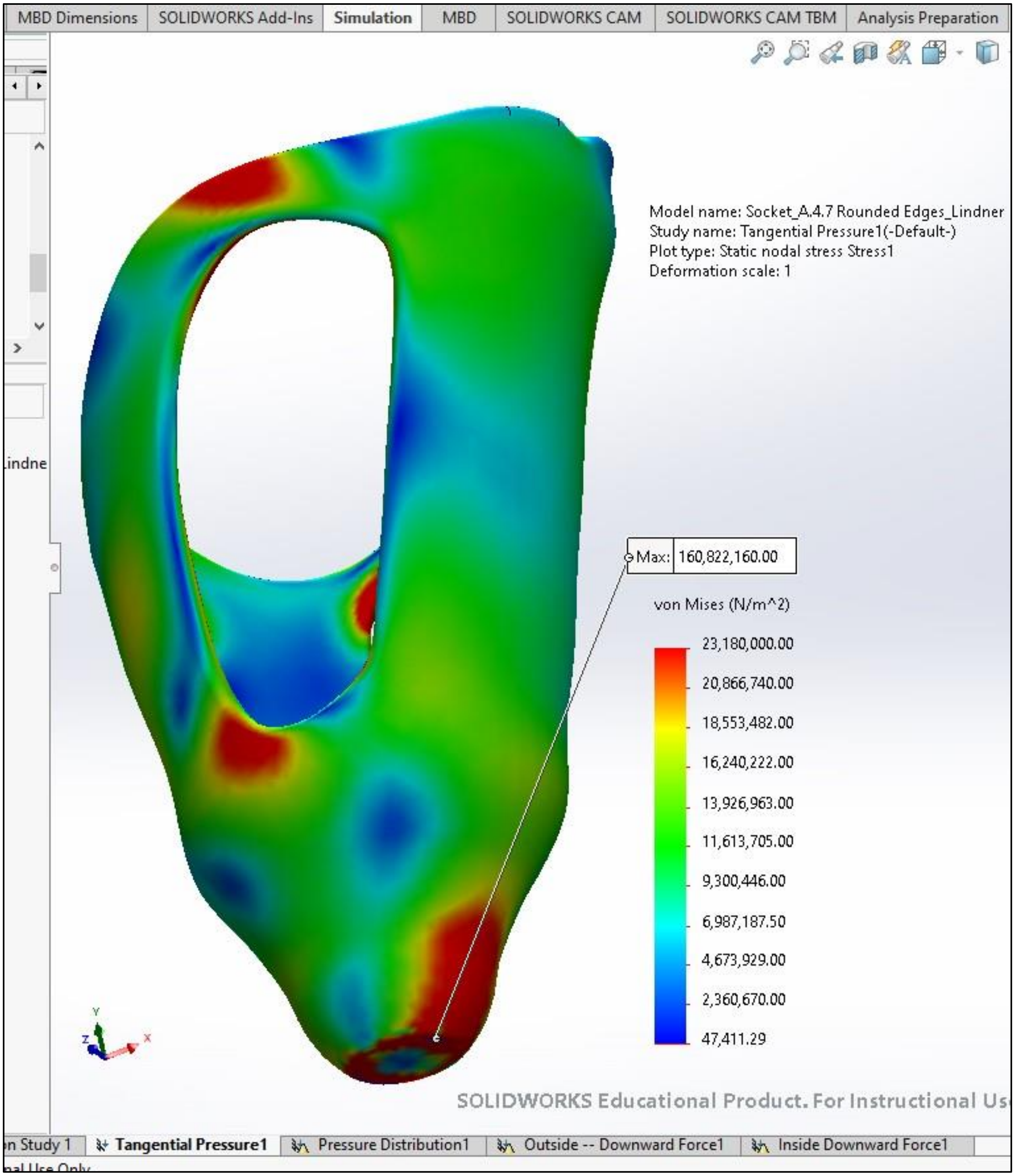

Figure 66. Socket iteration 2: Max stress

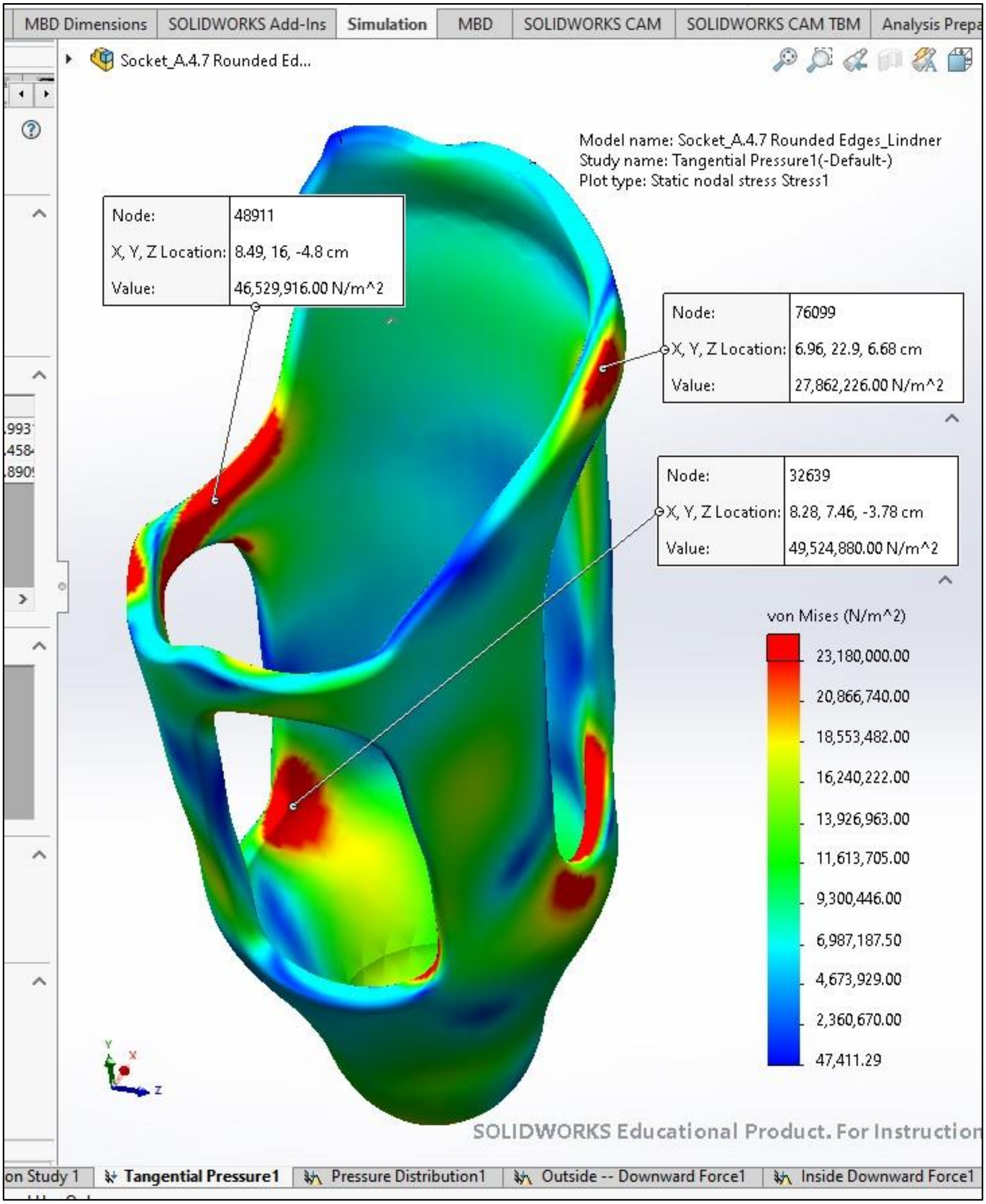

Figure 67. Socket iteration 2: Stress probes (Proximal view)

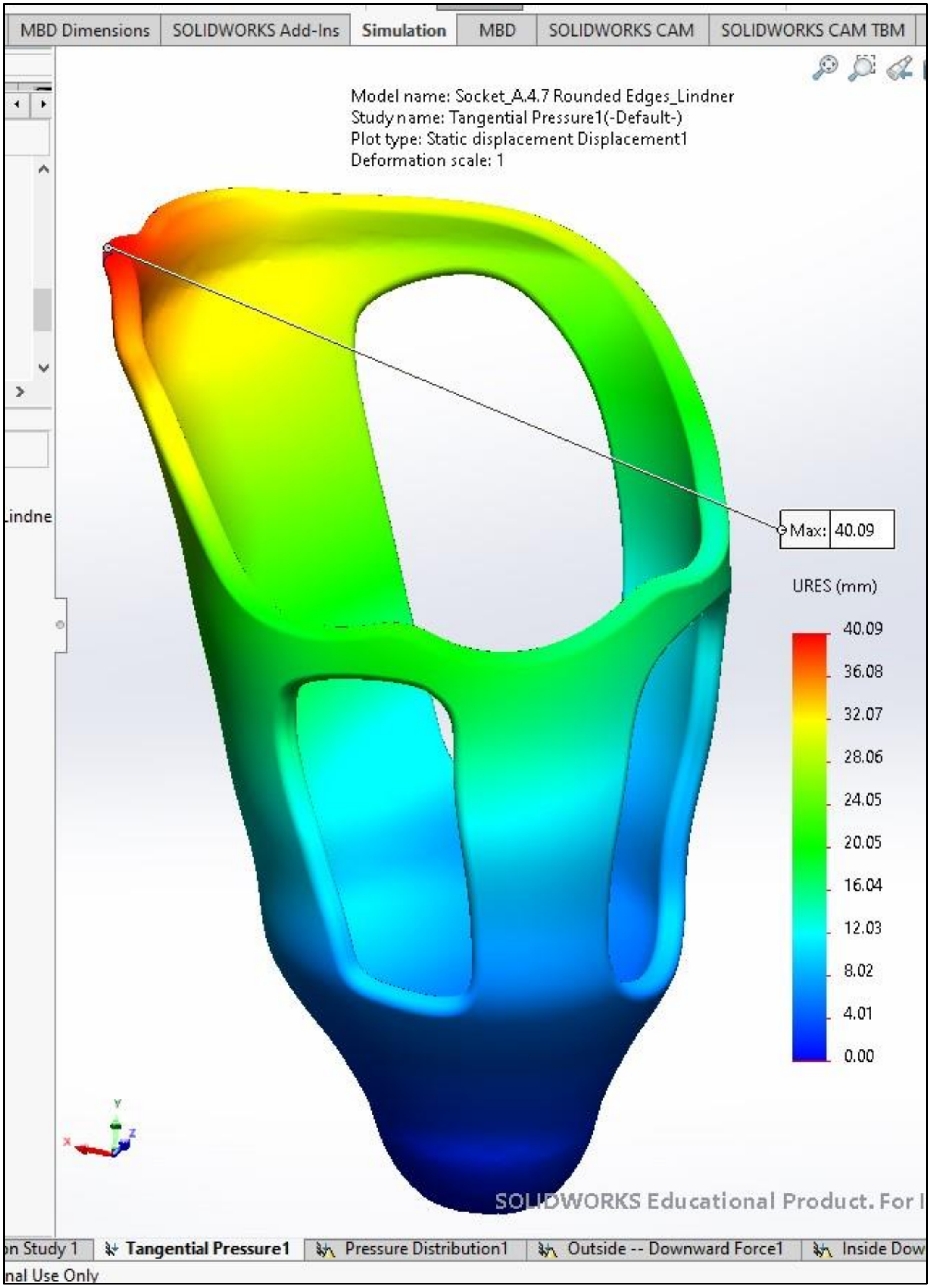

Figure 68. Socket iteration 2: Max displacement

SOCKET ITERATION 3:

Shown below are the FEA simulation results for socket iteration 3 (model C.3.3). Nonuniformly distributed normal force load of 6,250 N applied to inner faces. HDPE material with yield strength of 23.18 Mpa used. Maximum element size of 7 mm used for mesh. Large displacements turned off.

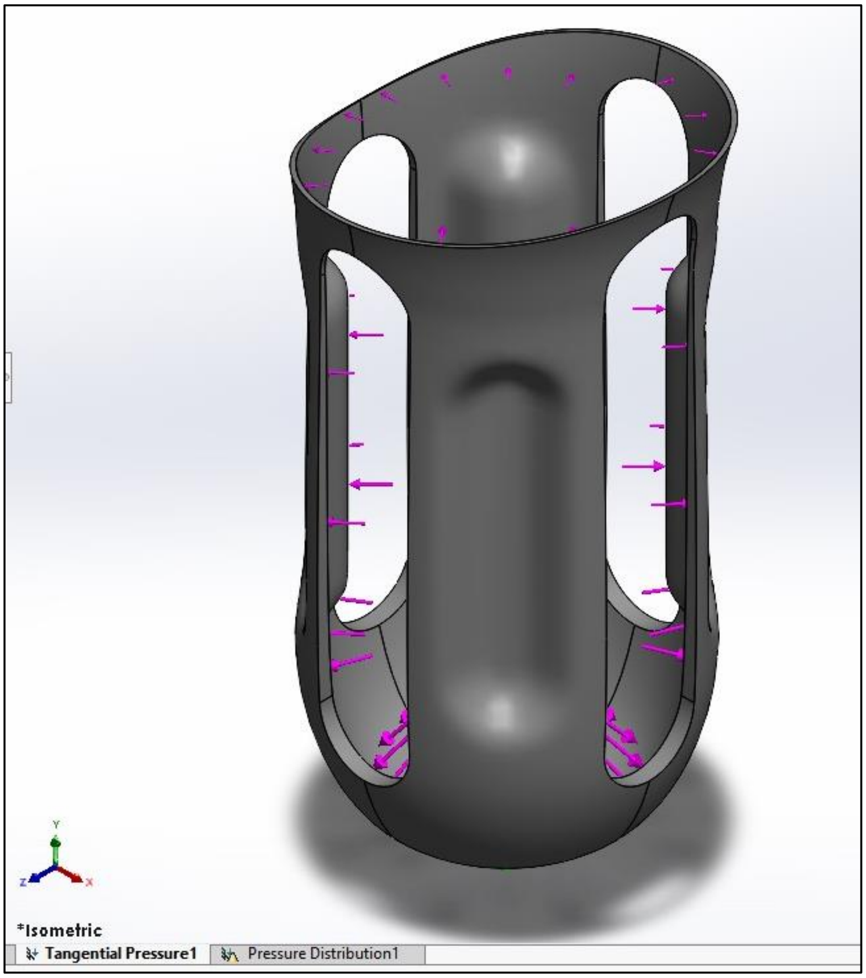

Figure 69. Socket iteration 3: Isometric (Before simulation)

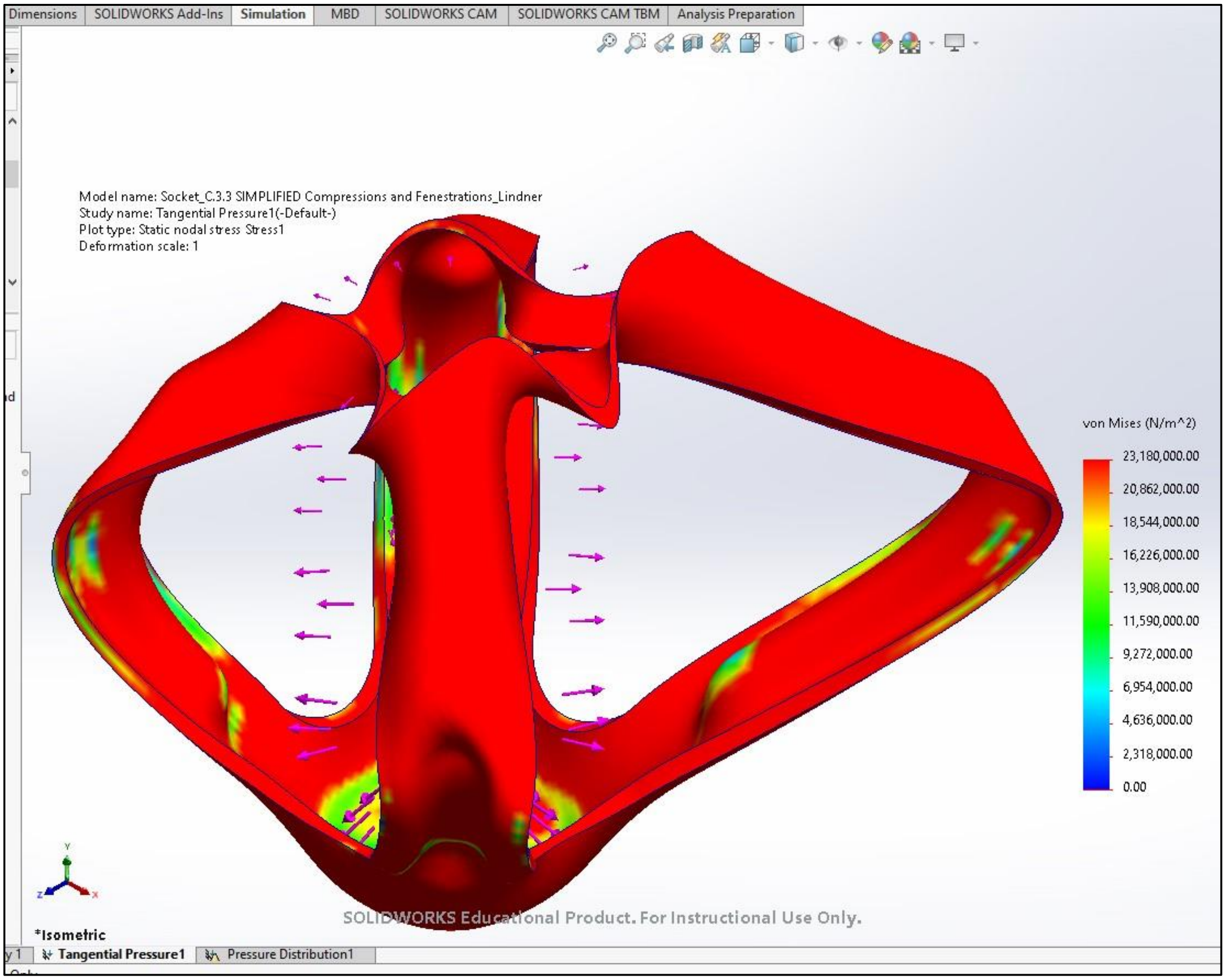

Figure 70. Socket iteration 3: Isometric (After simulation)

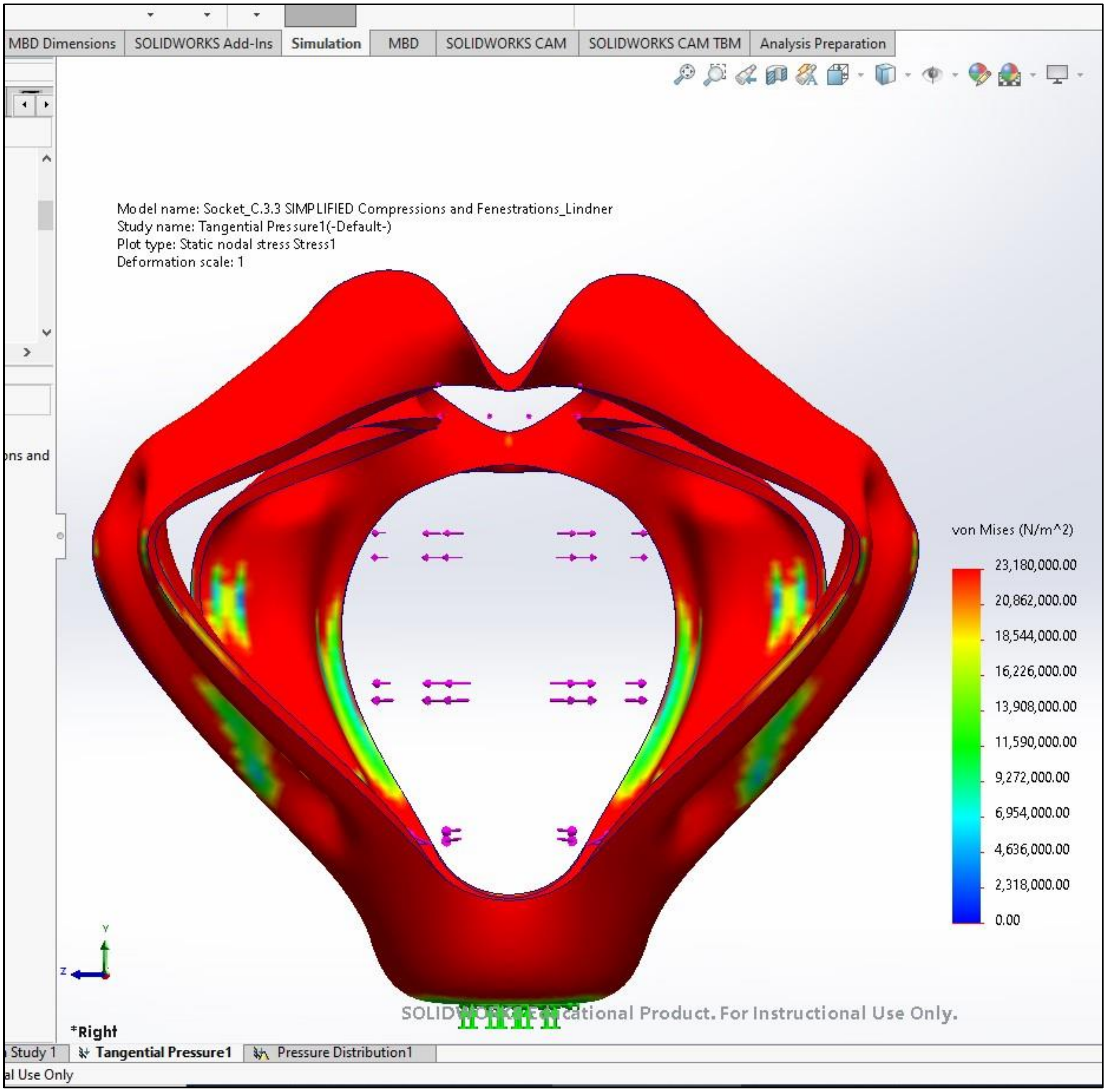

Figure 71. Socket iteration 3: Lateral looking medial

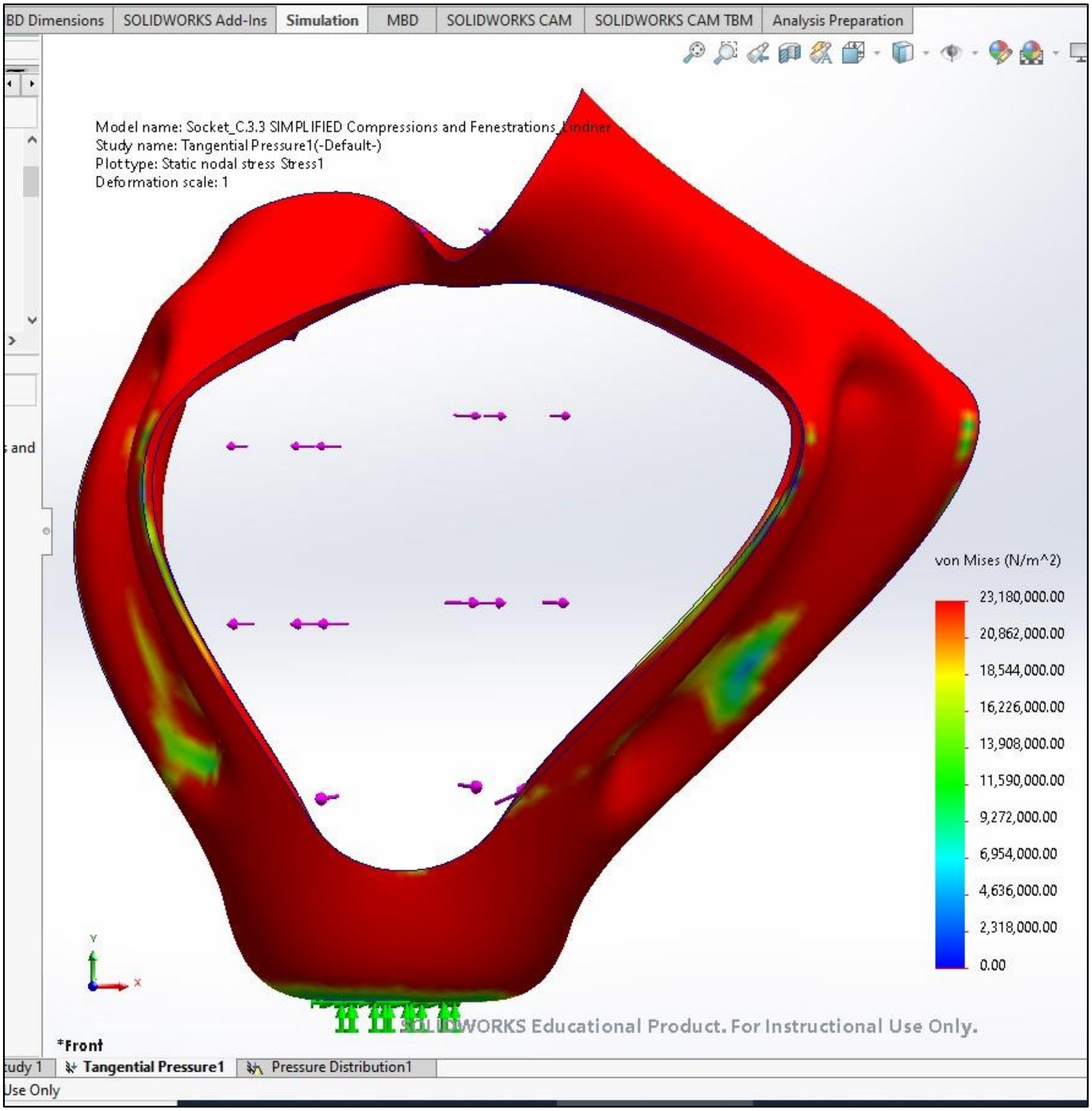

Figure 72. Socket iteration 3: Anterior looking posterior

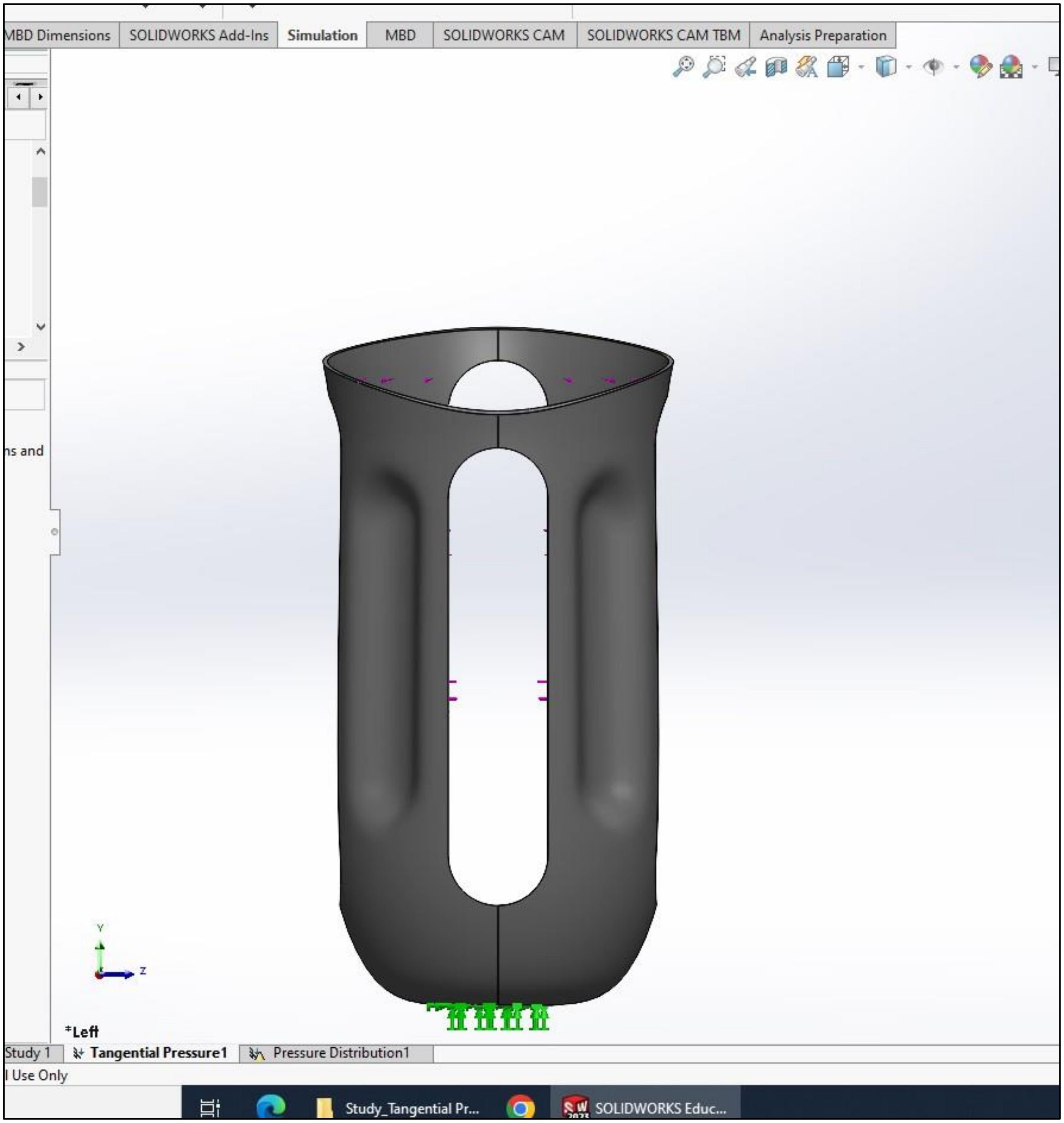

Figure 73. Socket iteration 3: Medial looking lateral (Before simulation)

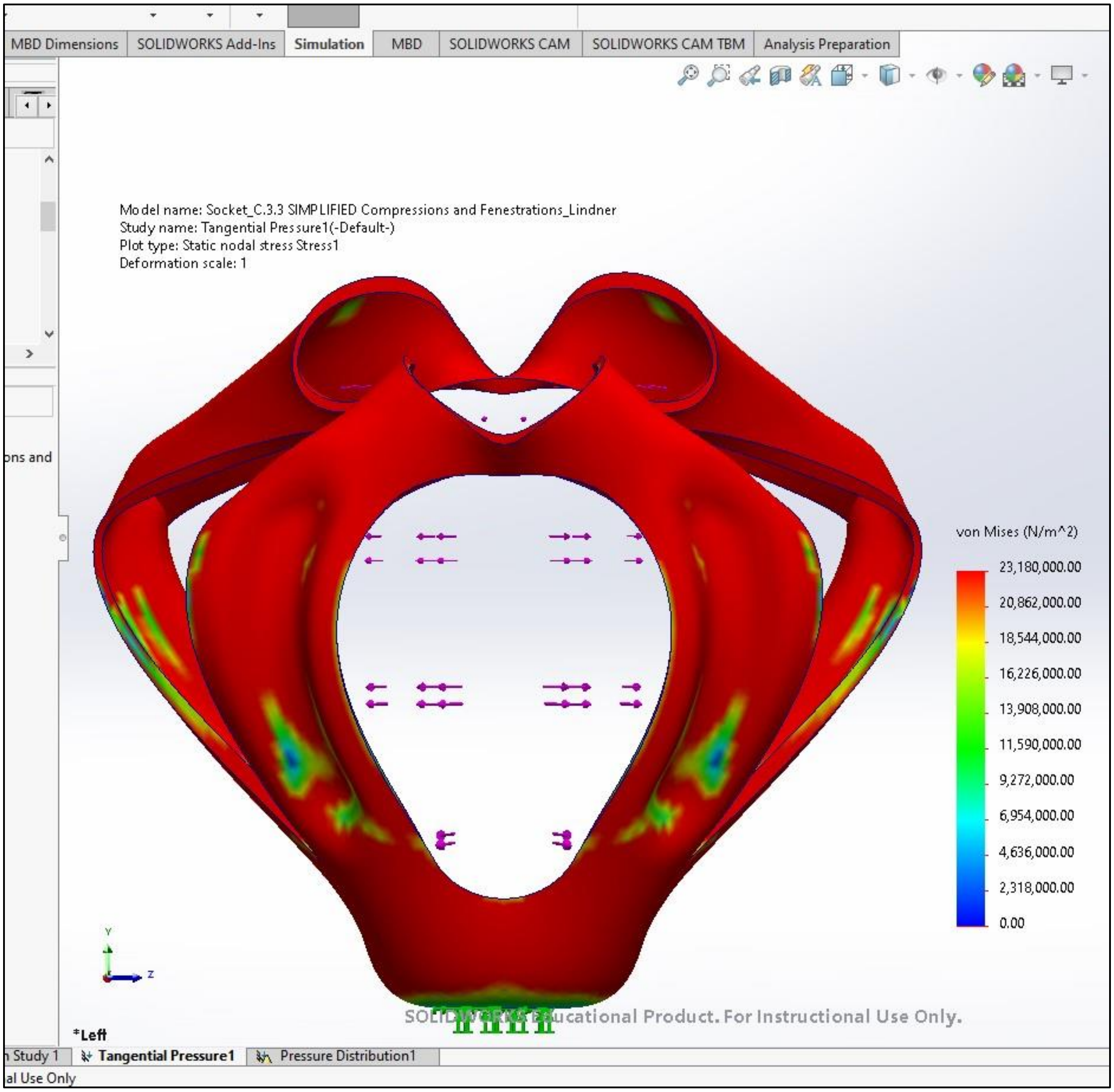

Figure 74. Socket iteration 3: Medial looking lateral (After simulation)

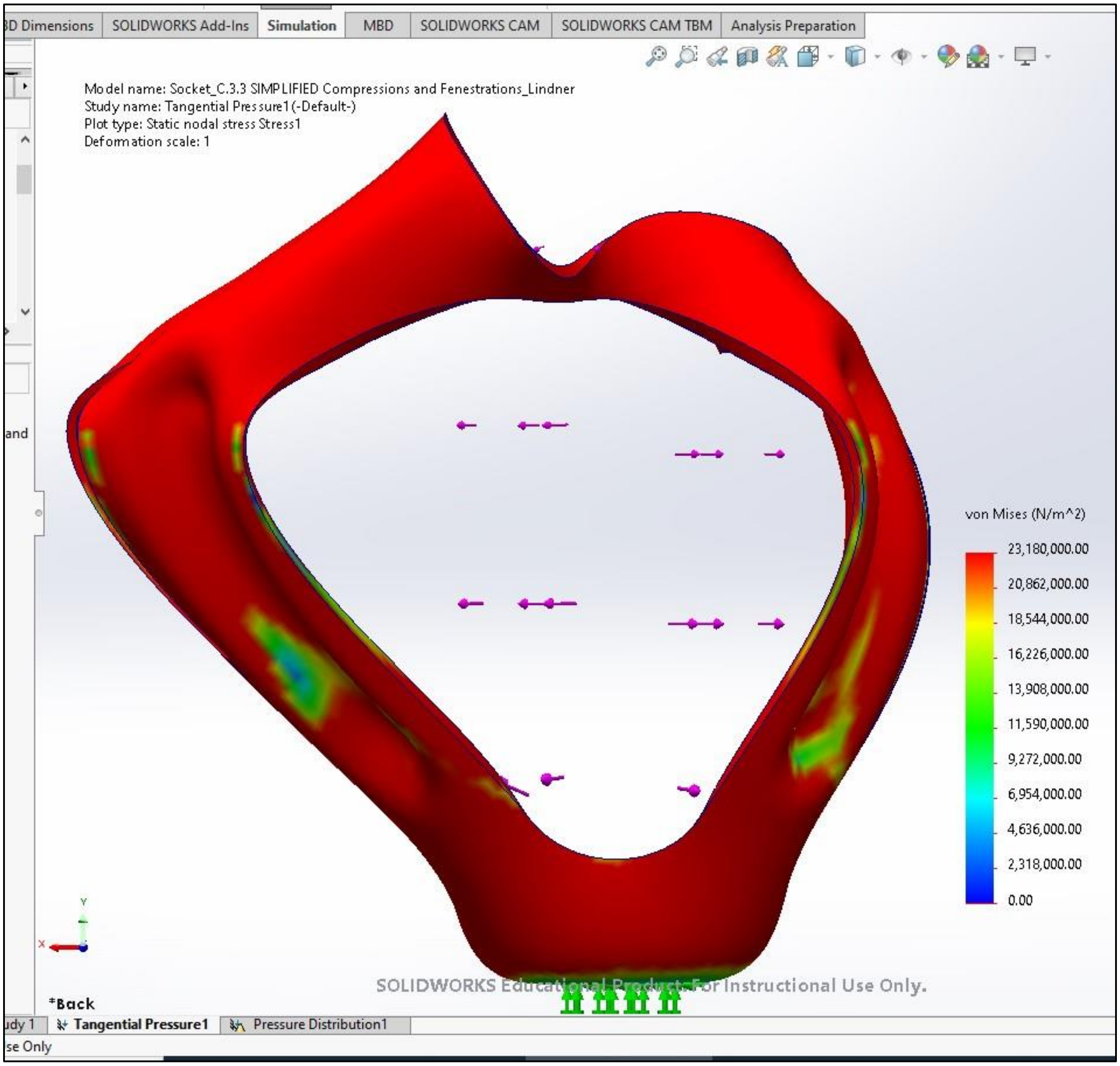

Figure 75. Socket iteration 3: Posterior looking anterior

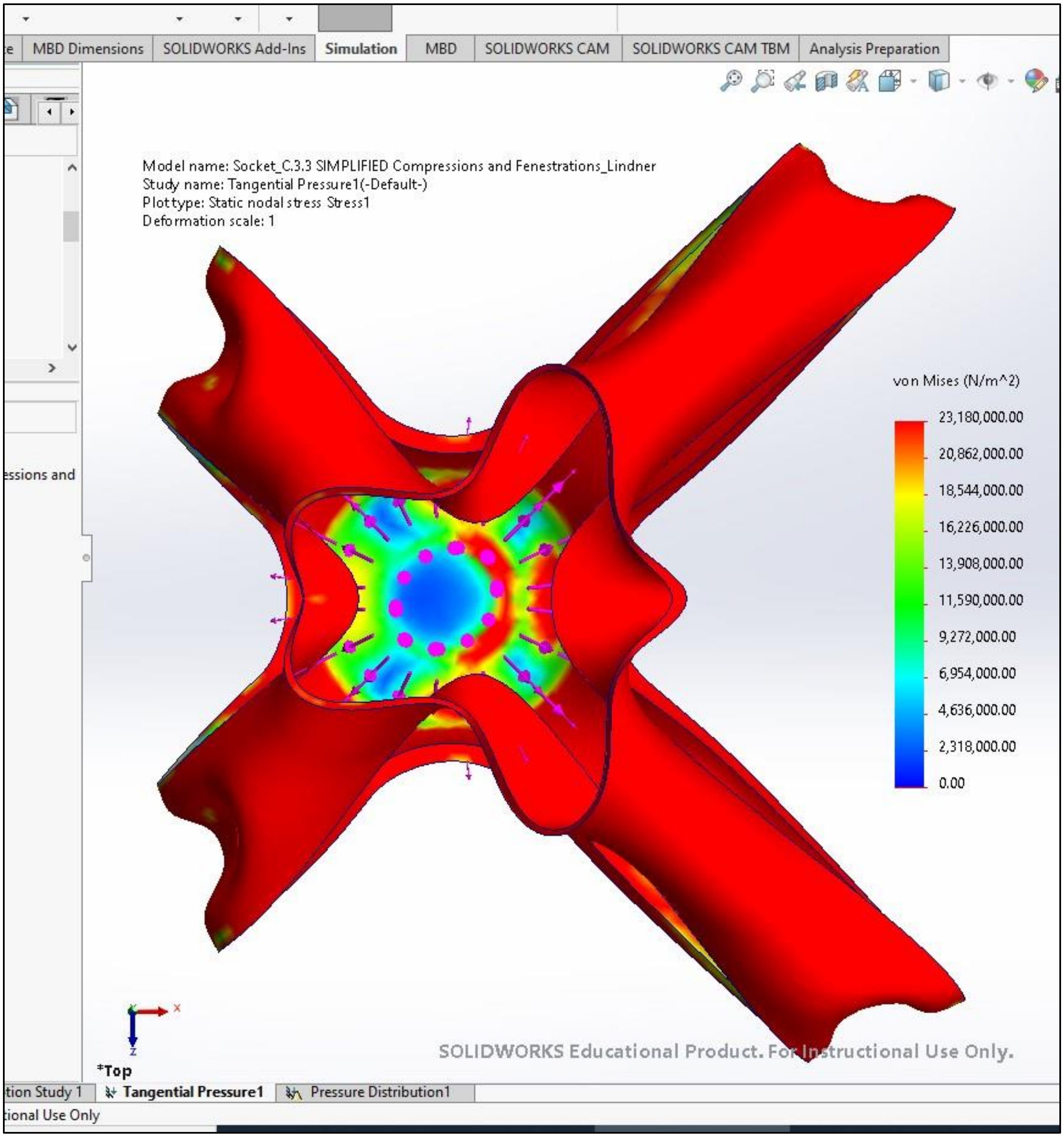

Figure 76. Socket iteration 3: Proximal looking distal

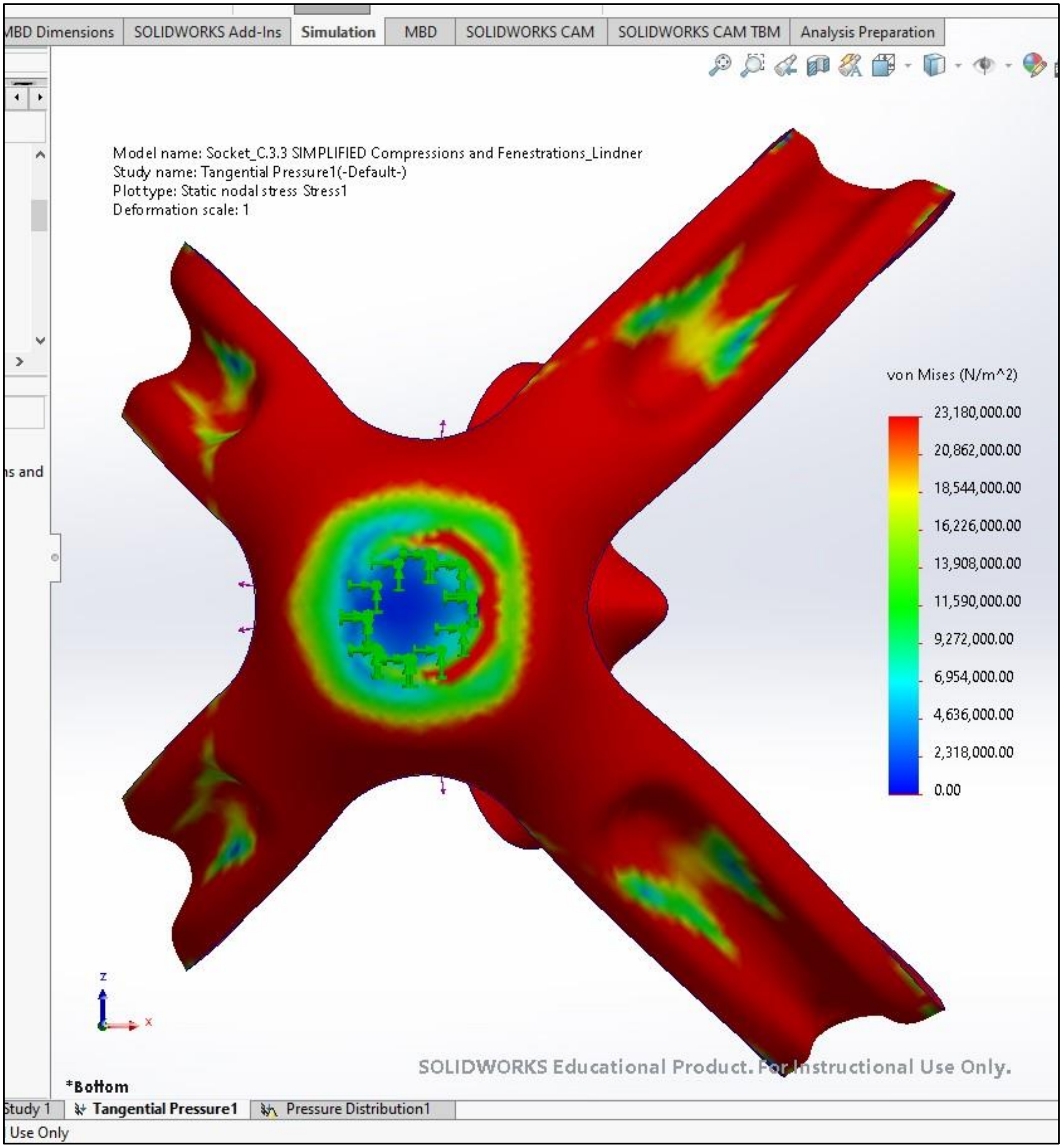

Figure 77. Socket iteration 3: Distal looking proximal

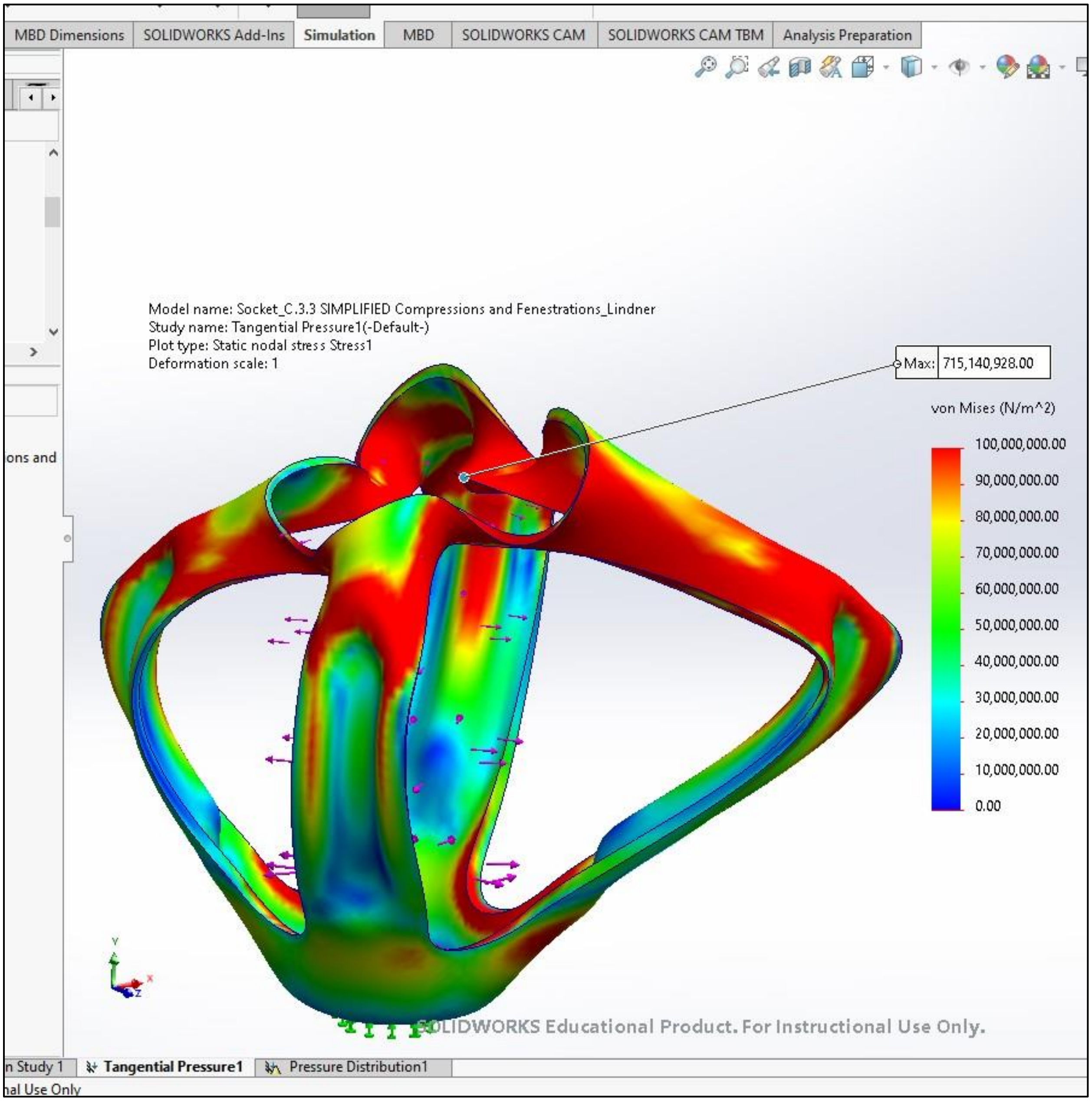

Figure 78. Socket iteration 3: Max stress - ADJUSTED SCALE

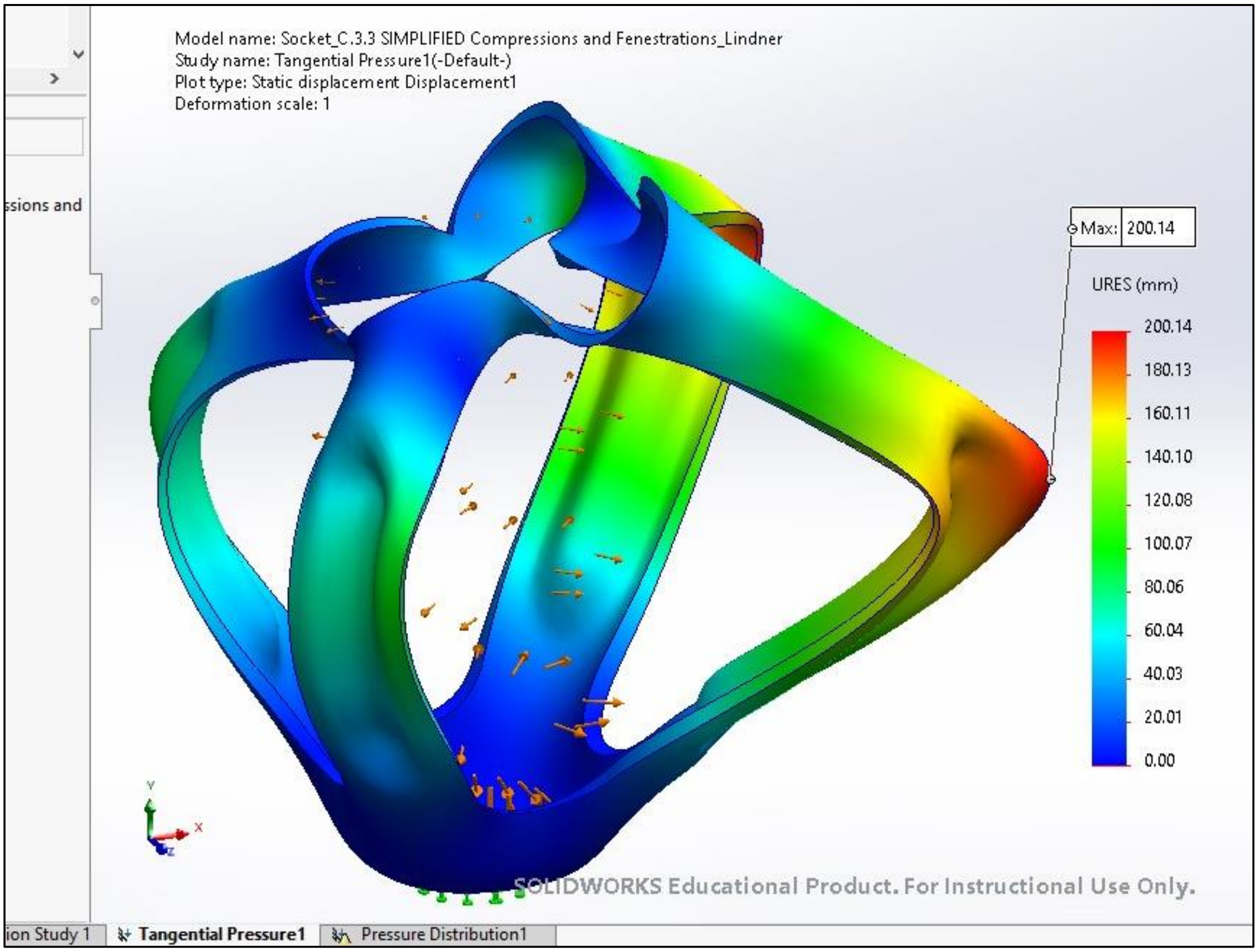

Figure 79. Socket iteration 3: Max Displacement

SOCKET ITERATION 4:

Shown below are the FEA simulation results for socket iteration 4 (model C.3.7). Nonuniformly distributed normal force load of 6,250 N applied to inner faces. HDPE material with yield strength of 23.18 Mpa used. Maximum element size of 7 mm used for mesh. Large displacements turned off.

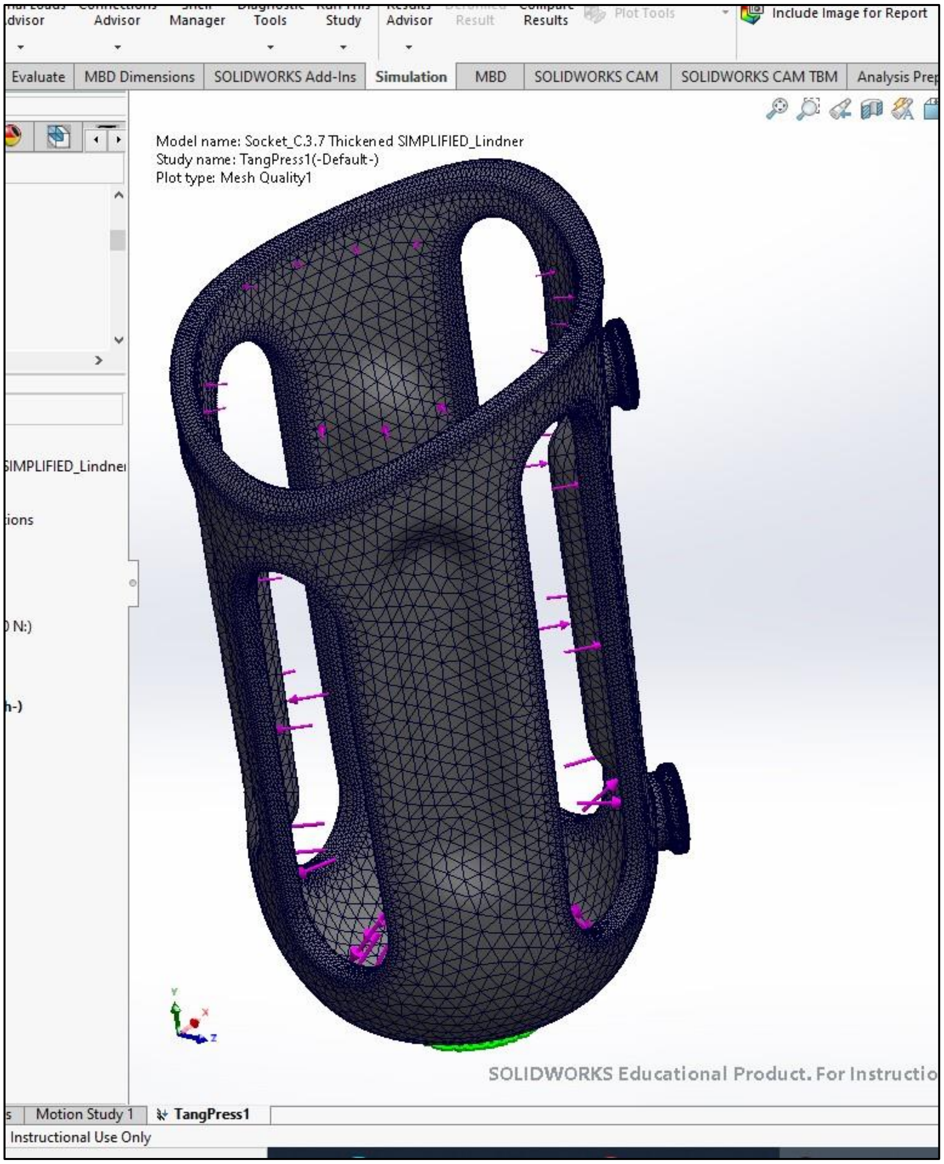

Figure 80. Socket iteration 4: Finished mesh

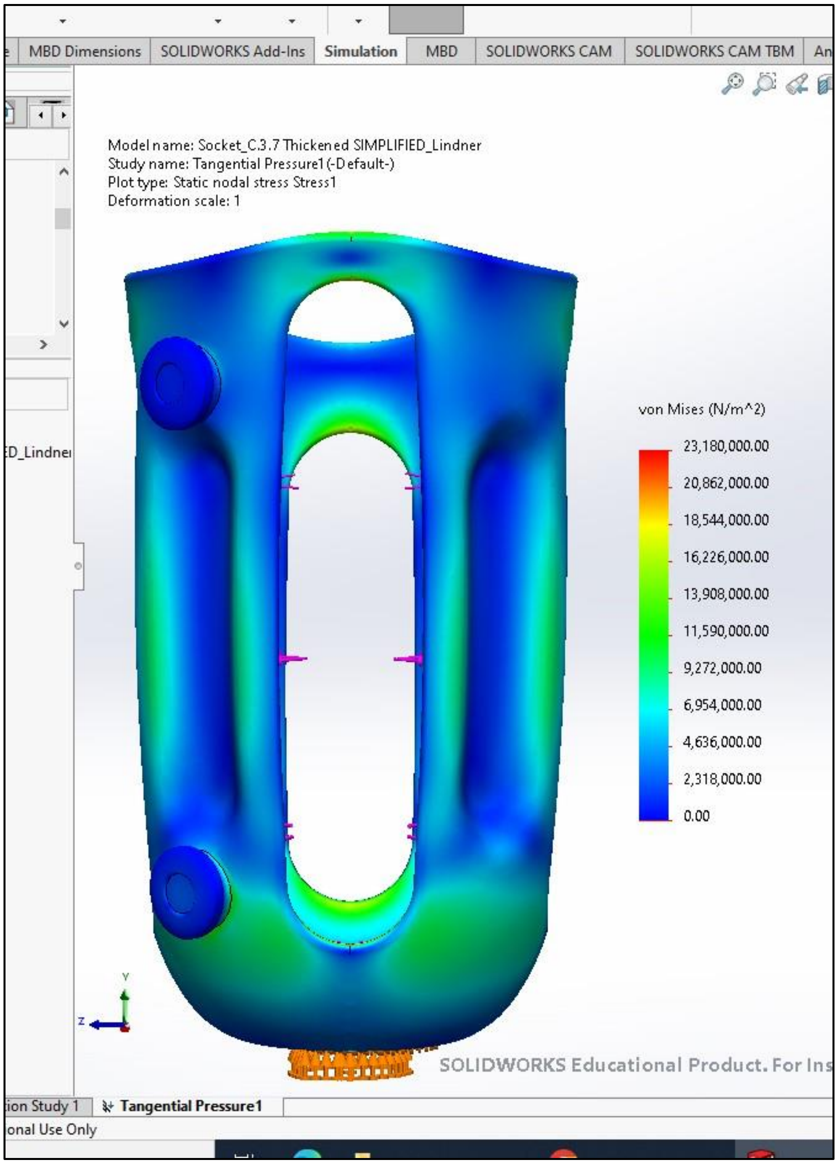

Figure 81. Socket iteration 4: Lateral looking medial

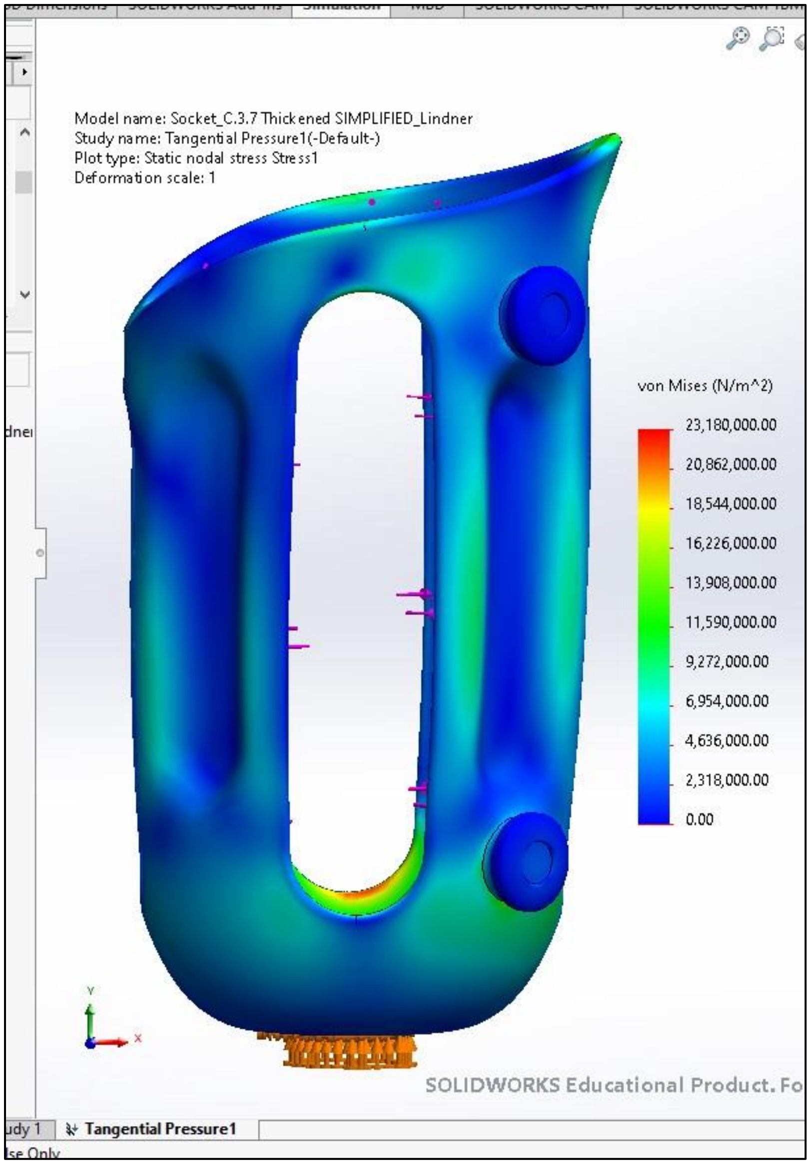

Figure 82. Socket iteration 4: Anterior looking posterior

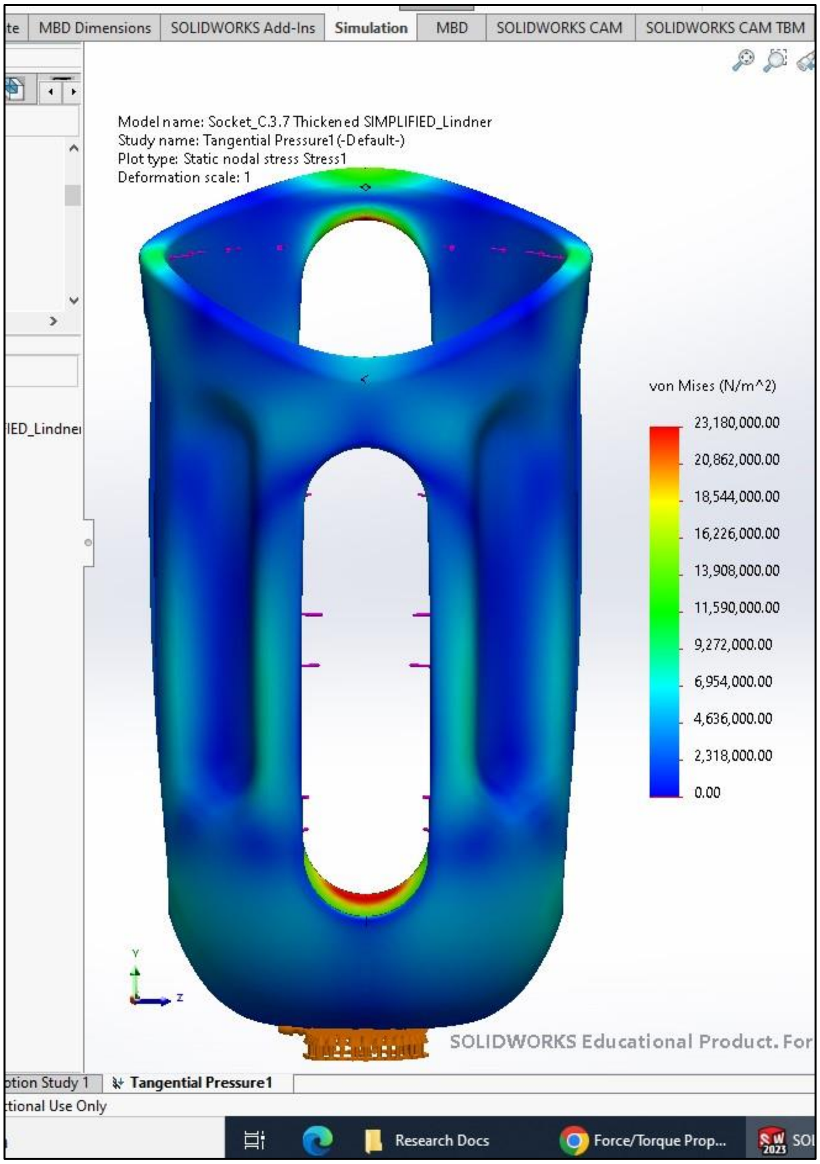

Figure 83. Socket iteration 4: Medial looking lateral

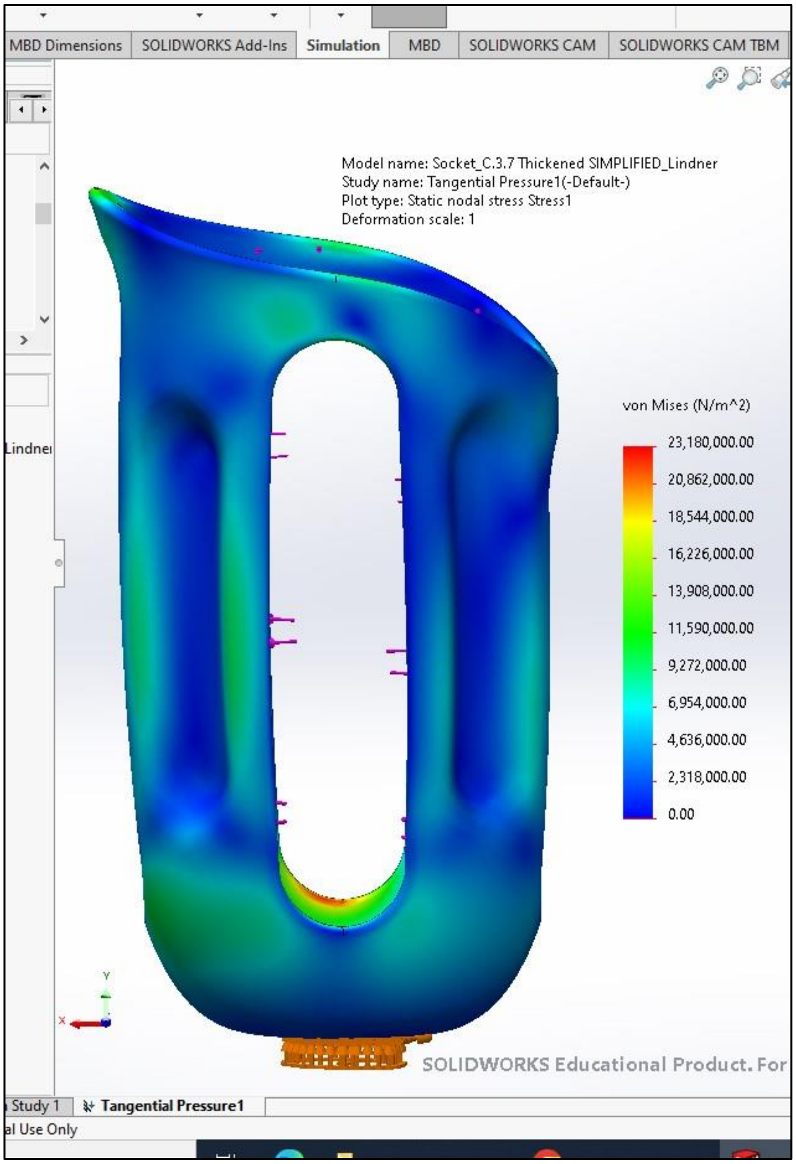

Figure 84. Socket iteration 4: Posterior looking anterior

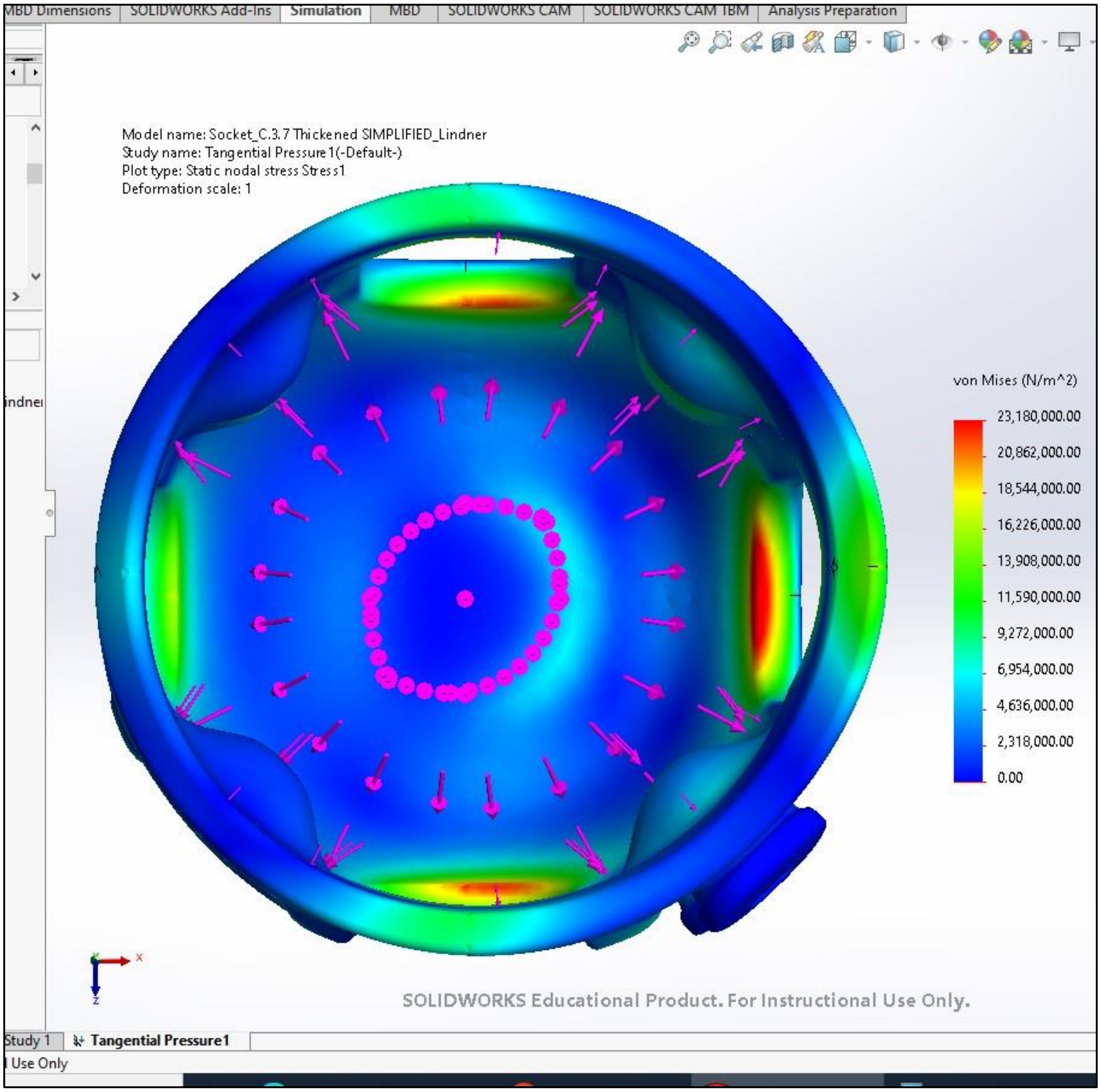

Figure 85. Socket iteration 4: Proximal looking distal

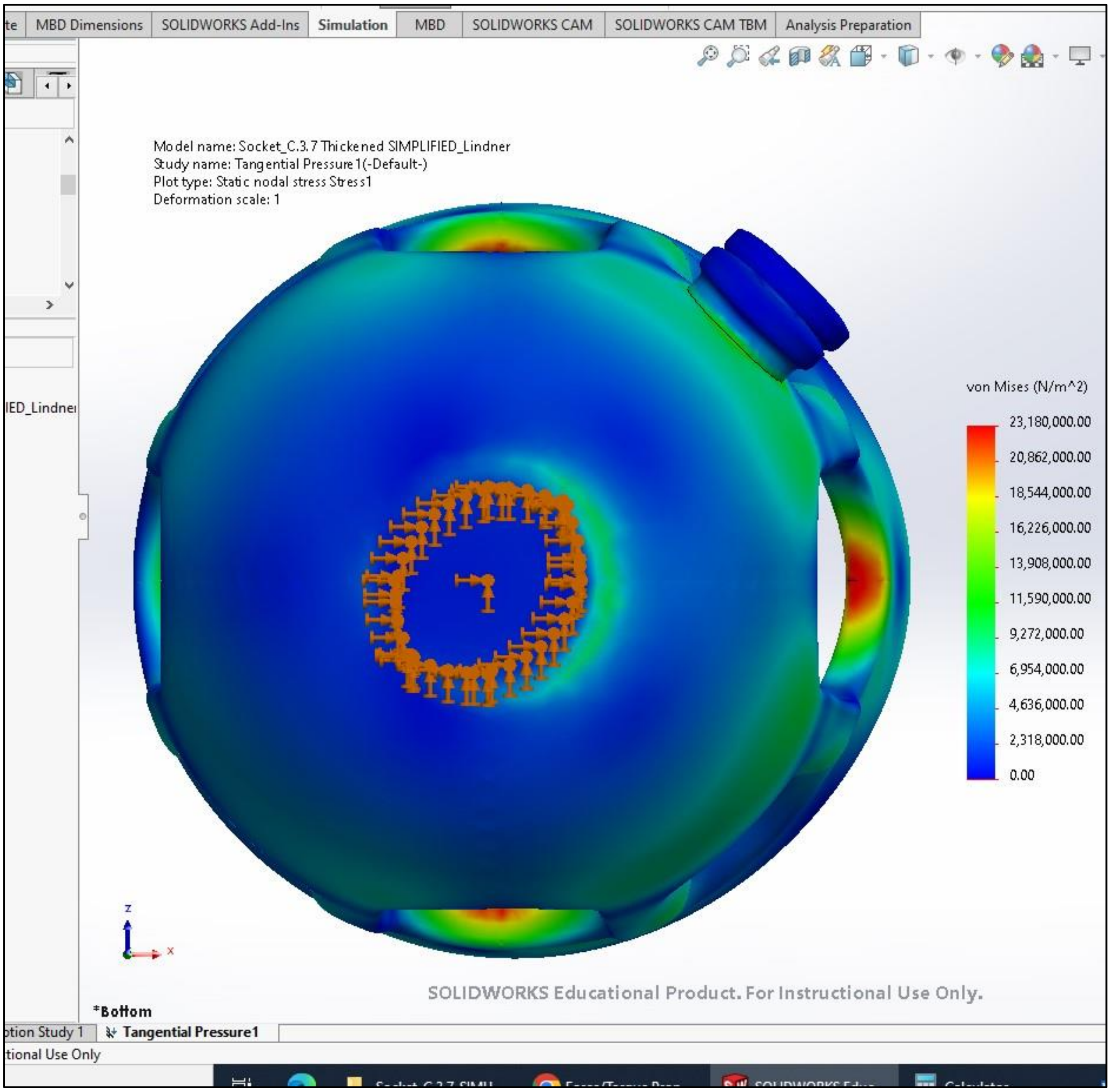

Figure 86. Socket iteration 4: Distal looking proximal

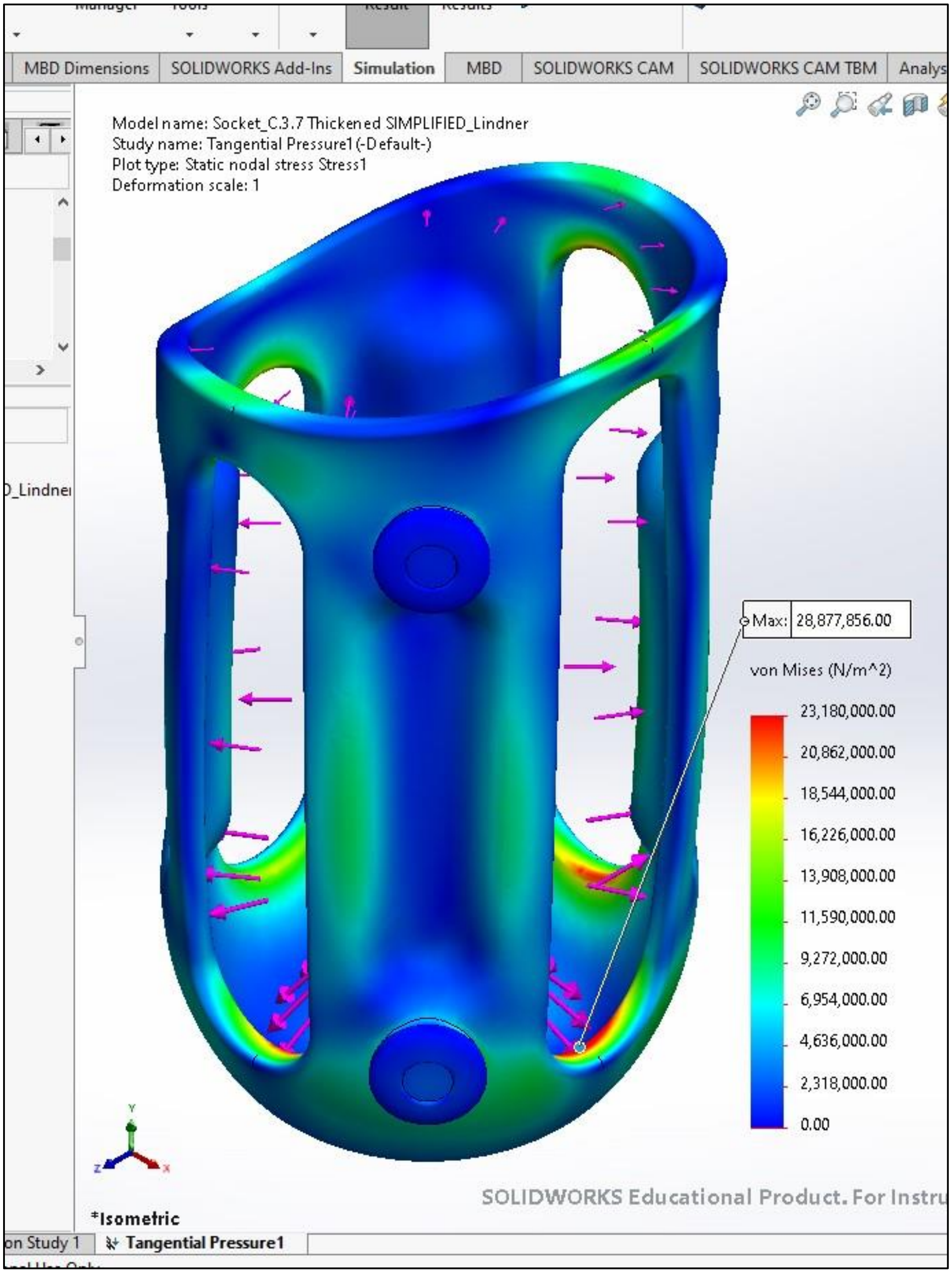

Figure 87. Socket iteration 4: Max stress

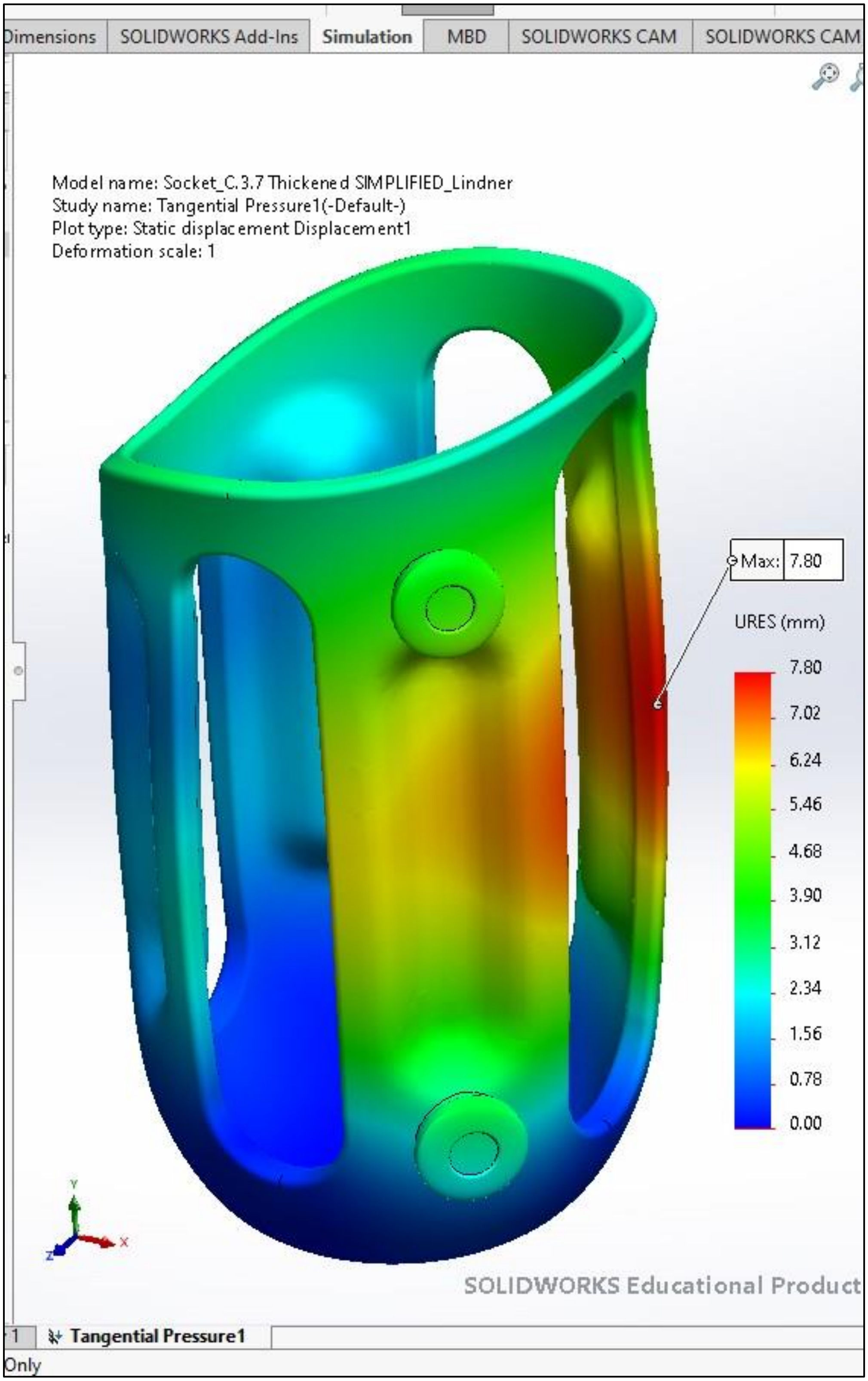

Figure 88. Socket iteration 4: Max displacement

APPENDIX C

ADDITIONAL SOCKET MODELS OR SOLIDWORKS FEATURES

CABLE GUIDES:

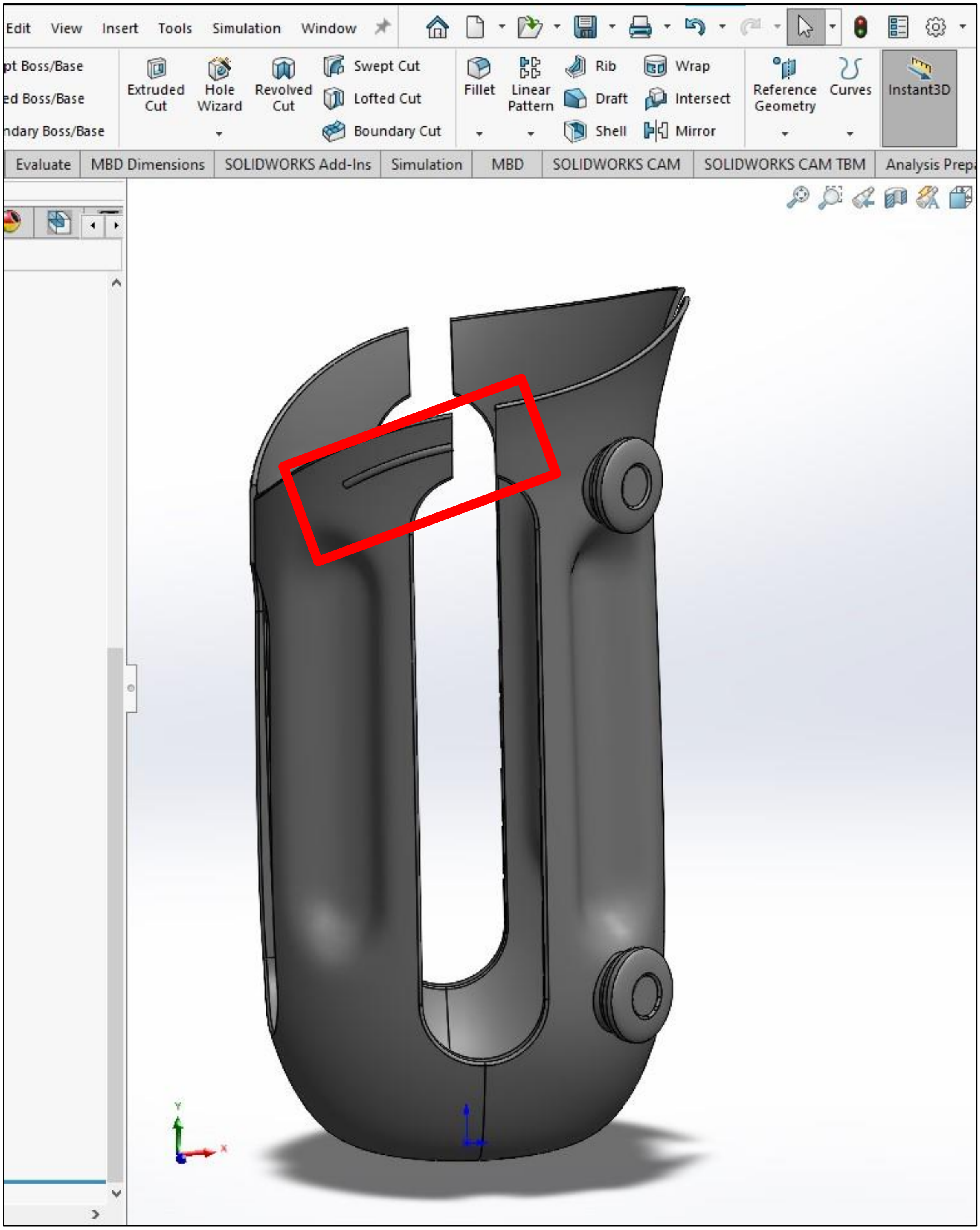

Figure 89. Cable guide for cable-tightening system (shown in red)