

Study, Development and Application of a Prosthetic Foot for a Transtibial Amputation of Traumatic Etiologic

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Abstract: In Portugal, the evolution of the number of amputations up to the present day has increased, with 553 annual transtibial amputations and 958 annual transfemoral amputations (Matos, 2014). Therefore, based on the limitations of current conventional prosthetic feet and the needs of their users, this dissertation gave rise to an alternative prosthetic foot for the extremity of the lower limb. This prosthetic foot presents an alternative as it uses low-cost mechanisms and materials. Therefore, the main objective of this study is to develop a prosthetic foot for a population with physical limitations. Initially, a model will be designed in Solidworks software, then printed and applied and tested on patients with different levels of activity in order to extract the maximum potential from the prototype. Make a summary of what this paper covers, highlighting the difference of what has been done in relation to what already exists and indicate the conclusions in summary.

Keywords: Amputation; Prosthetic Foot; low cost prosthesis, amputee simulations.

INTRODUCTION

Amputation derives from the word *ambiputatio*, in which *ambi* means "around" and *putatio* "to withdraw", being defined as the total or partial removal of a member of the body. This type of intervention is often associated with mutilation and disability. However, currently, it must be seen as a treatment, a procedure that provides a better quality of life to the patient, since a member of their body, which had no possibility of cure and which causes them suffering, is removed (Pastre, Salioni, Oliveira, Micheletto, & Netto Júnior, 2005; Pereira, 2014).

The amputation of a limb is an intervention that has irreversible effects on the physiological integrity of the human being. It was due to the great wars that humanity resorted to the use of prostheses to compensate for this limitation. In the area of orthoprosthetics, there are two types of prostheses: upper limb prostheses and lower limb prostheses (Pastre. *et al.*, 2005; Pereira, 2014).

Lower limb prostheses are determined by the extent of the amputation level - major or minor (P. Senthil Selvam, M. Sandhiya & Karthikeyan, 2016).

Major amputations are:-

Hemipelvectomy – in cases of hemipelvectomy surgery

Hip disarticulation

Transfemoral amputation

Knee disarticulation

Transtibial amputation (P. Senthil Selvam, M. Sandhiya & Karthikeyan, 2016).

And the minor amputations are:

Disarticulation of the foot;

Partial amputation of the foot;

Amputation of the foot and toes (P. Senthil Selvam, M. Sandhiya & Karthikeyan, 2016).

In the area of Orthoprosthetics, there are several prosthetic feet in which, for each patient, there is a prosthetic foot, depending on their age, weight, daily physical activity, patient specifications, among others. Currently, there are numerous prosthetic feet on the market for individuals with transtibial amputation, which comply with the 3C rules – control, comfort and cosmetics – with slightly different characteristics (Chiriac & Bucur, 2020).

Prosthetic feet can be classified into three categories: conventional feet (CF), feet that store and return energy (ESR) and bionic feet, these being the most recent (Chiriac & Bucur, 2020).

The SACH foot – or conventional foot – was first patented by AA Marks in 1880. The patent describes layers of rubber used to provide sufficient elasticity, causing the prosthetic foot to begin to restore gait and allow the feet to amputees complete basic day-to-day tasks. These types of prosthetic foot were quite basic, but allowed future prostheses to focus on the patient's weight and functionality. However, in early designs the prosthetic foot used to be a solid piece of wood. SACH foot has a rigid internal structure surrounded by a compressible foam cosmetic liner (Chiriac & Bucur, 2020).

As for the ESR foot, they are different from conventional feet, as they store energy at the

beginning of the gait cycle and release this energy on impulse, at the time necessary to move the body forward, also known as "dynamic elastic response" (Chiriac & Bucur, 2020).

The letters S.A.F.E correspond to the acronym for Stationary Attachment Flexible Endoskeleton, that is, it is a prosthetic foot that is screwed to the ankle with a flexible keel (Chiriac & Bucur, 2020).

Advanced ESR feet have improved properties compared to earlier ESR feet. This type of foot increases patient comfort, however, its ability to mimic the human ankle-foot complex is limited. The amputee's gait speed is even slower than normal walking, and many studies have shown that ESR feet have not resolved the issue of increased metabolic energy consumption that leads to early fatigue (Chiriac & Bucur, 2020).

Finally, there is the bionic foot, which is defined as a mechanical device with one or more active principles to stabilize the foot or provide active characteristics of flaccidity, i.e., used by a person with a transtibial amputation. Currently, most tibial prostheses use actuation to help stabilize the ankle complex (Chiriac & Bucur, 2020).

However, despite the impact that lower limb amputation has on the patient's life. The truth is that, despite technological advances, the solutions present on the market do not completely satisfy the needs and desires of users (Herr, Whiteley, & Childress, 2017).

Therefore, the concern to improve the quality of life of individuals with specific pathologies about health is a cross-sectional area that does not only belong to health professionals, but increasingly to the scientific community in general. It is with this thought that researchers from different areas, which naturally include biomedical engineering, seek to apply the innovative technical knowledge of their specific skills in the development of products that respond to this need (Announced, 2014).

Over the years, there has been a significant increase in amputations, especially between 60 years and 90 years of age, surpassing 50% of the Portuguese population (Matos, Carolino, & Ramos, 2018).

Among the most frequent causes that culminate in amputation are cardiovascular complications; diabetes; obesity and an aging population (Herr. *et al.*, 2017).

Recent studies indicate that the number of limb amputations will increase substantially, largely due to the lifestyle we have today in Western society (Herr. *et al.*, 2017).

However, the largest percentage of amputations is due to group VII diseases - Circulatory System, corresponding to 43.86% of the Portuguese population in 2015. The second cause of amputation belongs to group II of Endocrine, Nutrition and Endocrine Gland diseases. Metabolism and Immune Disorders, corresponding to 26.22% of the population in the same year (Matos. *et al.*, 2018).

METHODS

The goal of the project was the mechanical study of the prosthetic foot and the production of a product to be used by a true amputee with physical limitations.

For this, there were several stages of elaboration.

The main purpose of this study is: developing a prosthetic foot, for a population with physical limitations, the modeling and simulation was used.

Initially will be designed a model with resource year solidworks software., being The model was then printed and applied in a patient who used it and tested it in patients with various levels of activity, in order to contribute to the improvement of the model with its experience of using extract the maximum potential of the prototype.

However, this study will also have secondary objectives was a decisive factor that the prosthesis produced obey the following challenges:

- a) have a low cost to produce
- b) be capable of being printed on current-use printers
- c) Be customizable according to the physical characteristics of the wearer (weight, level of physical activity, foot size, height of the tachoön).

the gait cycle is subdivided into seven phases, in four of them correspond to the support phase – when the foot is on the ground – and the remaining three to the swing phase – when the foot is moving forward and in the ^{air}¹³.

The support phase lasts from the initial contact to the tiptoe and is divided into:

Response loading
Intermediate posture
Terminal posture

Pre-balance¹³

The hard swing phase from tiptoe to the next initial contact is divided into:

- Initial balance sheet
- Intermediate balance
- Terminal ^{balance}¹³.

Finally, the duration of a complete gait cycle is known as cycle time in which it is divided into support time and balance ^{time}¹³.

Regarding biomechanical analyses, the data are divided into two groups: kinetics and kinematics. Kinetics studies the forces and moments, without any detailed knowledge of the position or orientation of the structures involved. However, kinematics describes the movement, but without reference to the forces ^{involved}¹².

In gait analysis, variations in angles and moments of strength in the ankle, knee and hip joints are used as variables. However, the human body is considered an articulated system, any change will affect the overall gait ^{result}¹².

Gait of a Lower Limb Amputee

In the gait of an amputee of this type, the lower limbs behave differently to each other and differently from the non-amputee. The lack of a lower limb also affects the behavior of the other member because the response loading and prebalance phases are changed: the response loading phase receives a different weight distribution than that of a non-amputee of this type, and the prebalance phase must be different in order to be able to compensate the amputated member in its response loading phase. The type and level of amputation performed has a great

influence on the postural strategies developed by the patients, since differences in body distribution and position along the axes and stabilization of amputated patients ^{were found}¹⁴. As such, there is an optimization of the alignment of the prosthesis is based on the gait analysis of an amputee, which can be aided by instrumentation – such as force plates and motion capture systems – and also by subjective feedback provided by the patient, reducing inefficiencies, asymmetries and gait instabilities¹⁵.

The amputee patient resorts to compensation with the non-amputated limb and will cause intuitive reduction of the raise and reduction of gait speed, decreasing the maximum load or the first peak of the ground reaction force. There is a decrease in the knee angle during the support phase (15° for a normal person and average of 7° for an amputee), which leads to the visual indication of less load transmitted to the residual limb – due to the shortening of the stride and reduction of speed. Gait speed and stride length are also shorter, however, these variables are related to the alignment and adjustment of the prosthesis. However, several studies that demonstrate that the lateral step of the prosthesis has a shorter time of initial double support, which is less symmetrical between the ^{legs}^{15,16}.

The measurement of the speed of the gait is done in an easy and reliable way, in which it is enough a stopwatch to measure the time between passes and a treadmill of 20 or 6 meters, as we have shown in Figure 2.

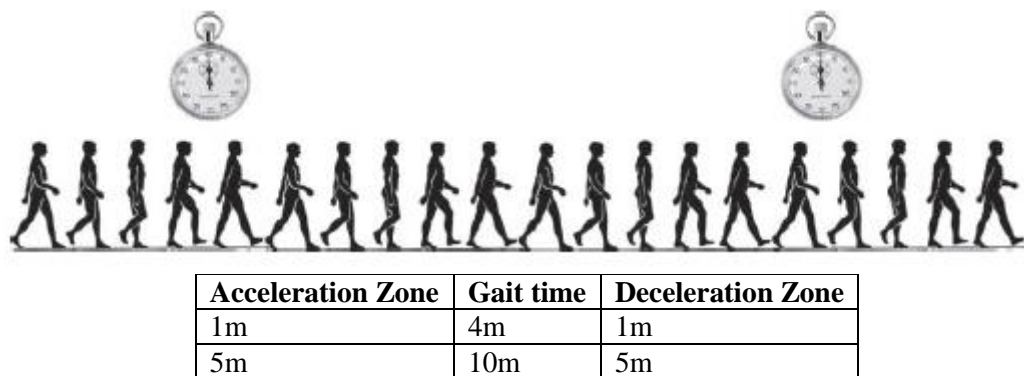


Figure 1: Strategy to evaluate the time of fast or normal gait, either at a central distance of 10m or 4m, allowing acceleration and deceleration at both ends so that the constant velocity is the closest.

Finally, there is one more variable for the evaluation of the energy consumption of human gait: heart rate (HR) and physiological consumption. It has been reported that there are high correlations between heart rate and oxygen

consumption during gait in healthy children and young ^{adults}^{28,29}.

Although reports suggest that HR monitoring may be a reliable substitute for oxygen consumption, it

should be taken into account in the elderly due to age-related cardiopulmonary changes. The PCI may be a more appropriate indicator of walking

$$PCI = \frac{(FC_{caminhar} - FC_{descanso}) \left[\frac{\text{batimentos}}{\text{metro}} \right]}{\text{Velocidade da marcha}}$$

Equation 1: Determination of PCI17.

After measuring the heart rate per meter away, the PCI reflects the effort of walking³⁰.

For children between 3 and 12 years of age, the average PCI at normal gait speed is between 0.38 and 0.40 beats/metro³¹;

For adolescents and young adults, the PCI varies between 0.3 and 0.4 beats/metro³²;

For healthy adults 65 years of age and older, the average pci value when walking on a flat track of 10m was 0.43 beats per meter; when walking on a treadmill the average PCI increased to 0.60 beats/metro³³.

The PCI is used to compare the energy consumption of gait in different types of transfemoral prostheses¹⁷.

energy expenditure in the elderly¹⁷. The PCI is calculated as follows:

Currently, there are many lower limb prosthetic devices, these incorporate several components and present several forms, being able to perform only one or multiple functions varying, according to the needs and capacities of patients^{40,41}. The lower limb prostheses are composed of a suspension, pylon, a unit of knee and prosthetic foot, as shown in Figure ⁴⁴⁰.

Prostheses can replace amputated limbs, improve independence and mobility patients. However, the prosthetic device does not have the capacity to generate energy, leading to increased stress for the other joints and, consequently, an asymmetric gait⁴².

Each constituent component of the prosthesis plays a crucial role, since they have to work so that the device can mimic extremely complex mechanisms of a healthy leg⁴⁰.

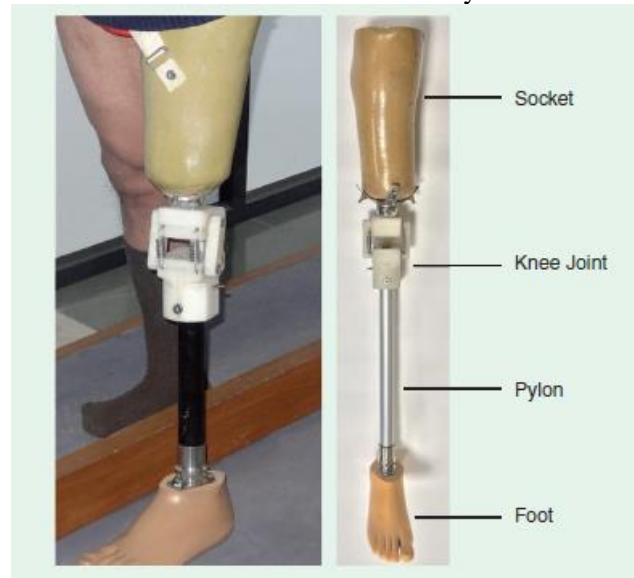


Figure 2: Constituents of a lower limb prosthesis⁴⁰

Endoskeletal prostheses can be used for all lower limb amputation levels, with the exception of partial foot and ankle amputations. They can be considered superior to exoskeletal ones from the functional and aesthetic point of view and also by the system of fixing the components with screws that allows to make adjustments and alignment changes, such as rapid changes of components. These types of prostheses are composed of a suction stocking, modular parts, a tubular module and a prosthetic foot. The suction sock

(highlighted in red in Figure 6) is the region of the prosthesis that accommodates the residual limb and fixes the prosthesis in the patient and is the main mechanism of suspension of any prosthesis at any amputation level⁴³.

Exoskeletal prostheses are usually made of wood or plastic (bath and geriatric prostheses) and serve as a connection between the fitting of the residual limb and the foot. This type of prostheses have a single rigid structure that is responsible for body

weight support. The main characteristics of this type of prostheses are: high strength, light, but also have limitations in prosthetic alignment and few exchange options⁴⁰.

In view of the arguments presented, a mild lower limb prosthesis minimizes the action of shear force on the residual limb and on the metabolic cost of the patient. Nowadays, with the advances of materials studies and technology, there is the possibility of manufacturing lighter members⁴⁰.

the three main types of fittings for transtibious amputations that differ according to the weight support regions over the residual limb and the fitting format⁴³, can be named as:

KBM (Kondylen Bettung Münster): It is the most used for transtibial amputations that provide a better result in all aspects. Weight discharge is done on the patellar tendon by exerting pressure above the medial condyle. In this type of suspension, the upper edge of the flaps should be modeled slightly facing the outside, because if they face the inner side they can damage the tissues⁴³.

PTS (Prosthesis Tibiale Suprecondylienne): is a prosthesis more suitable for short transtibial amputations, since it encompasses the entire patella and have elevated lateral edges. It is indicated for patients with amputation who also have knee instability. In the PTS fitting, the suspension is made above the patella and femoral condrites requiring a good modeling of the suction stocking that fully surrounds the knee and patella, in which it is totally or partially free⁴³.

PTB (Patella Tendon Bearing): It is the oldest after evolution of the prosthesis confection technique. The suspension is made by means of a supracondyile belt, which wraps the leg in order to circulate just above the knee, made of leather or plastic. The use of circular belts with medial and lateral anchorage in the prosthesis is vetoed, as it

can cause strangulation of the region above the knee, which can inhibit blood circulation and atrophy the thigh muscles⁴³.

The prosthetic foot is the component of the prosthesis that mechanically simulates the functions of the amputated foot. There are several types of prosthetic feet that vary according to the articulation system, suspension, mechanisms, materials, among others⁴³.


The prosthetic foot system partially replaces the energy control capabilities of the normal physiological system by means of two main components, the heel and keel, in which both components absorb shocks, store and release energy. The keel serves as a stable positioning surface and some prostheses as a propulsion mechanism to propel the amputee to the next step of the gait. Together, the heel and keel, in a motion of absorption and release of energy, replicate normal ambulation⁴³.


There are six aspects to consider when choosing a prosthetic foot:

- Alignment;
- Length of toe lever surface;
- Width of keel;
- Keel flexibility;
- Heel foam density;
- Adjustment of the prosthetic foot inside the shoe⁴³.

In order to meet the needs of all patients, there are several models available on the market, the most popular being SACH (*Solid Ankle Cushion Heel feet*). These types of prosthetic foot have no joint, are lightweight and have a high durability. However, dynamic response feet, that is, prosthetic feet that have an energy storage and release system, tend to provide better ambulation by releasing the energy stored in the heel of the prosthetic foot during gait^{5,43}. Table 1 shows the different materials and characteristics of each SACH foot.

Table 1: Comparison of materials and characteristics of different feet SACH's^{5,43}

| | |
|---|---|
|  | <p>Material: Carbon Fiber Maximum Patient Weight: 136kg Maximum Approximate Prosthesis Weight: 575g Impact Level: Low Features: active tibial progression, proportional response, is water proof.</p> |
| <p>Össur® Model Vari-Flex®</p> | |

| | |
|--|---|
|  <p><i>Ottobock Triton Low Profile Model®</i></p> | <p>Material: Carbon Fiber and Titanium Maximum Patient Weight: 150kg Approximate Prosthesis Weight: 460g Impact Level: Medium to High Features: Multiaxial, waterproof.</p> |
|  <p><i>Conforpés Foot Epirus Model</i></p> | <p>Material: Carbon Fiber and Nylon Maximum Patient Weight: 100kg Impact Level: Medium Features: Multiaxial, supplied with cosmetic foot, connecting bead and protective stocking in Kevlar.</p> |

The selection of the material for the manufacture of a prosthesis is an extremely important factor, since it can directly affect the comfort of the fitting and the level of mobility of the amputee. A comfortable gait is associated with the strength and weight of the material, and the balance between these two factors is ^{fundamental}₄₄.

For a more detailed selection of the material, it depends on several factors concerning amputee, such as its needs and capabilities – that is, financial capital, professional and leisure activities, level of physical activity, durability, comfort and aesthetics. However, the availability of materials will also be a factor to be taken into account when choosing ^{them}₄₄.

However, there are several materials suitable for the manufacture of prostheses, from the most advanced carbon fibers to the simplest copolymers, in which they require less technology in molding and are easily ^{manipulated}₄₄.

Currently, there has been a very significant increase in the application of composite materials in the most varied fields of engineering, due to their high strength and specific stiffness, lightness, good fatigue performance and good corrosion ^{resistance}₄₅.

According to ASTM D3878-95, composites are multiphase materials consisting of a mixture of two or more miscible materials. Thus, by controlling the morphology and distribution of the same, it is possible to obtain a third and new macroscopically homogeneous material that has properties different from those presented by the initial components. Usually, this combination of

materials is synergistic, that is, the combination of the properties of the phases that constitute it are ^{beneficial}₄₅₋₄₇.

The properties that can be improved during the formation of a composite material are: weight, strength, stiffness, ^{corrosion}_{resistance}, conductivity and thermal ^{insulation}_{44,47}.

A composite consists of two phases: the matrix phase and the reinforcement phase. The matrix phase is responsible for the physical-chemical properties and structural cohesion of the material, having as main function the support and protection of fibers, as well as the transfer of stresses between fibers. The matrix is present in a smaller amount, is considered low density, rigid and stronger than ^{fibers}₄₄₋₄₆.

As for reinforcement, this is the dispersed constituent in the matrix, in which it is usually a fiber – it continues or discontinues – or a particle. This phase is very important in the formation of the composite material, since it is responsible for defining the mechanical properties of the material: length, orientation and volumetric fraction of the ^{reinforcement}₄₄₋₄₆.

Finally, the composite can be classified according to its origin:

Polymer matrix – composites based on synthetic polymers, since high pressures and temperatures are not required for their processing;

Metallic matrix - have rigidity and intermediate strength, but high ductility;

Ceramic matrix – have high strength and rigidity, but are ^{fragile}_{45,46}.

Metal and ceramic matrix composites often require very high temperatures and high processing pressures, making them more expensive than polymer matrix composites. However, they have a much better thermal stability^{45,46}.

RESULTS

Metal and ceramic matrix composites often require very high temperatures and high processing pressures, making them more expensive than polymer matrix composites. However, they have a much better thermal stability^{45,46}.

Simulations of two prosthetic foot models, which must support the weight of the 90 kg (900 N) patient);

Simulations with 3 different materials (Onyx, Onyx + CF, Al 6061-T6);

Filling has not been counted in the models, which will be incorporated into the current part when printed;

As such, the simulated models are hollow and all walls are 1 mm thick;

First 3 studies with the initial model (v5), and the last 2 studies with the reinforced model in the connection area between the connecting element and the heel part (v6).

Materials

Onyx - Study 1:

$E=1.4 \text{ GPa}$; $G=3.6 \text{ GPa}$; $\sigma_y=36 \text{ MPa}$; $\sigma_u=30 \text{ Mpa}$

Onyx + Carbon Fibers (rule of mixtures1) - Studies 2 and 4

$E=4.85 \text{ GPa}$; $G=6.39 \text{ GPa}$; $\sigma_y=81 \text{ MPa}$; $\sigma_u=75.32 \text{ Mpa}$

Aluminium 6061-T6 - Studies 3 and 5

$E=69 \text{ GPa}$; $G=25.95 \text{ GPa}$; $\sigma_y=259 \text{ MPa}$; $\sigma_u=313 \text{ MPa}$

Rule of Mixtures

$V_{\text{Onyx}}=249.28 \text{ cm}^3$; $V_{\text{CF}}=15.59 \text{ cm}^3$;
 $V_{\text{Total}}=264.87 \text{ cm}^3$

Simulation Data

Mesh model v5

Dimension of elements: 3 mm

nodes: 92391

elements: 46234

Total applied force: 500 N on the cylindrical surfaces of the 4 holes

Recessed support in the foot plant,:front region

Simple support, displacement $Y=0$, in the heel region

Mesh model v6

Dimension of elements: 5 mm

nodes: 31972

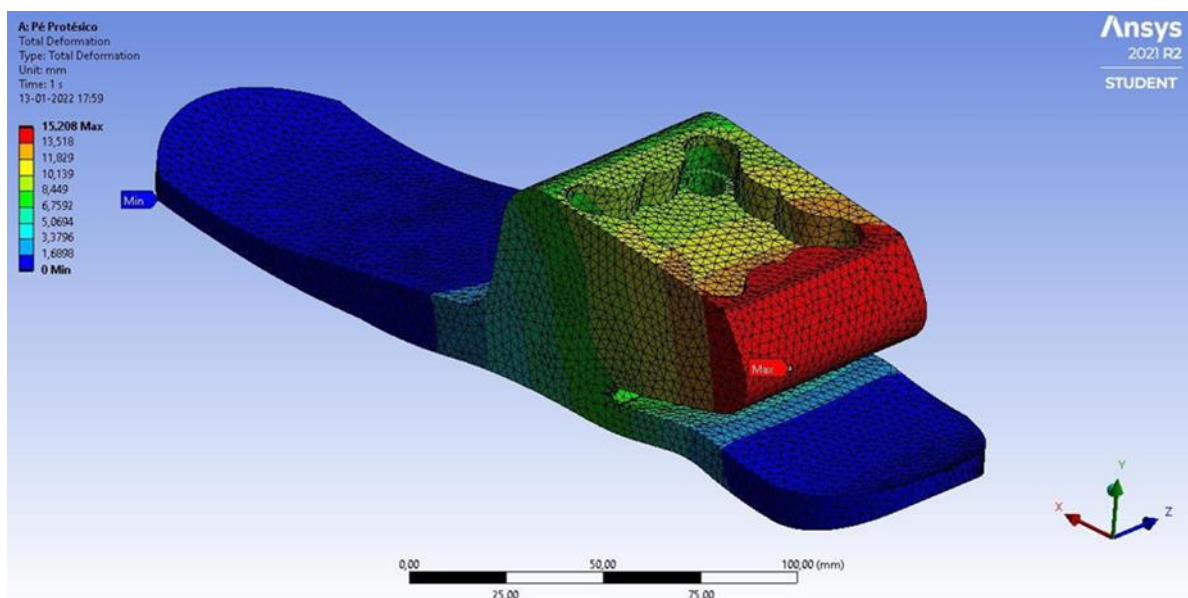
Elements:16001

Total applied force: 900 N on the cylindrical surfaces of the 4 holes

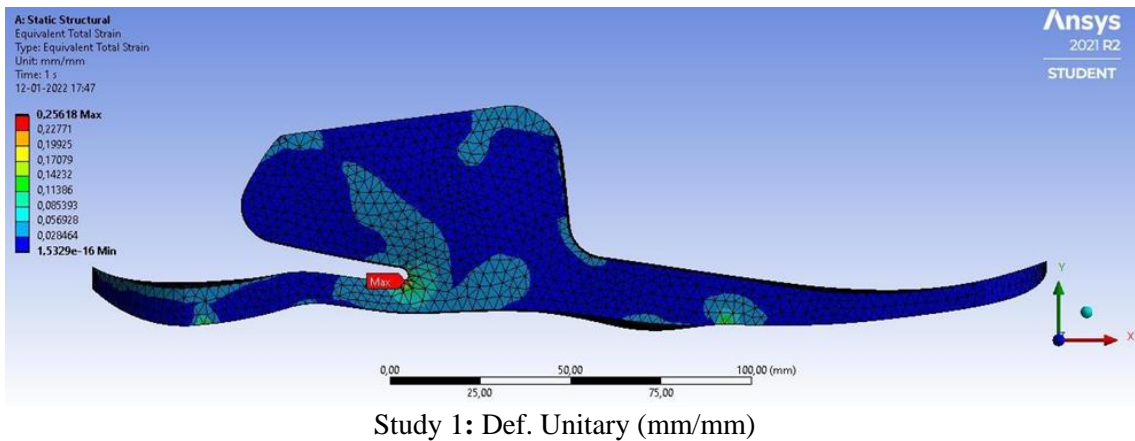
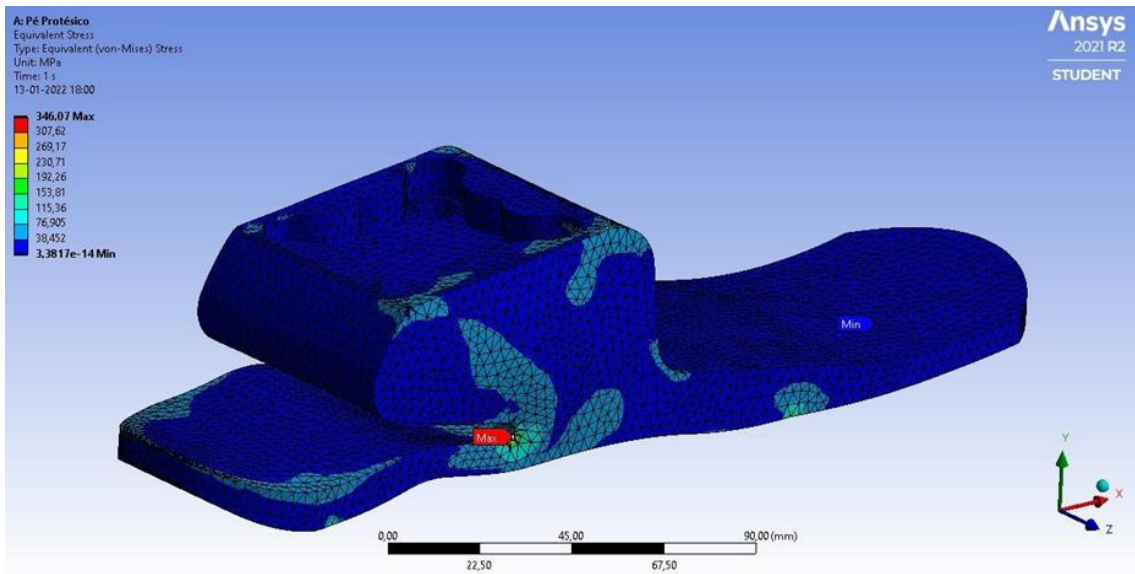
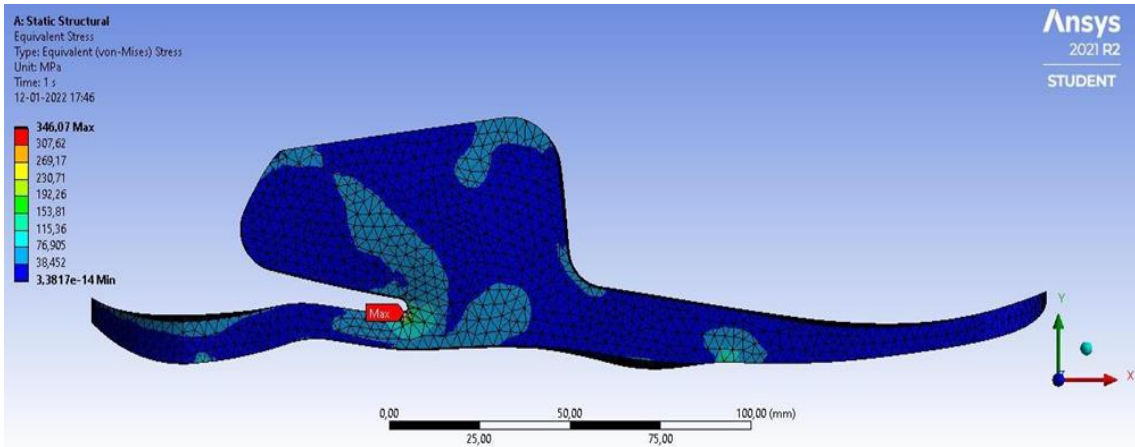
Recessed support in the foot plant: front region

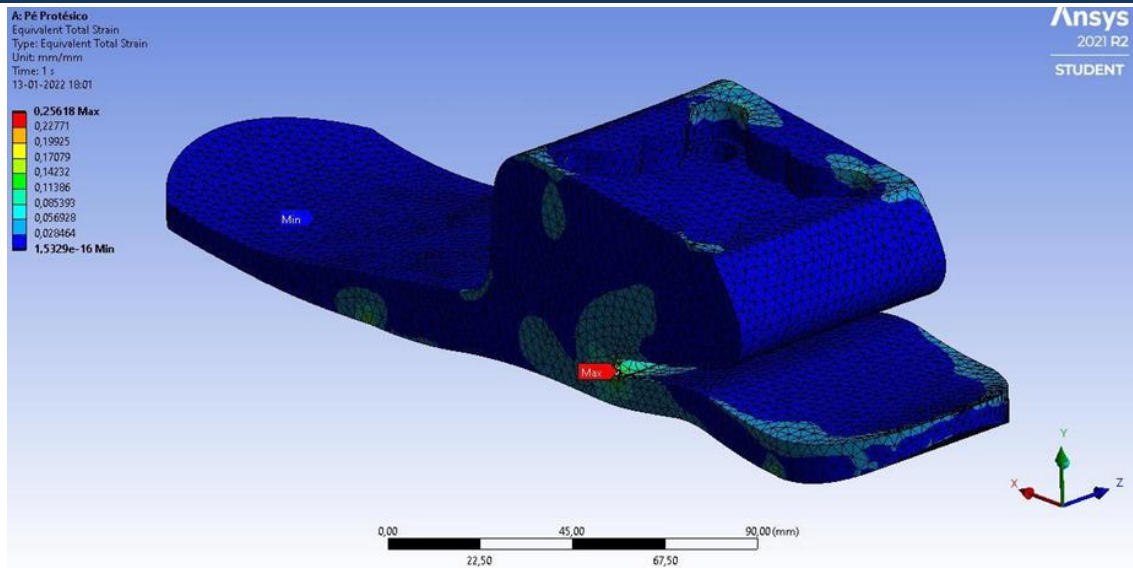
Simple support, displacement $Y=0$, in the heel region

Simulation Results by simulation in Ansys 2021

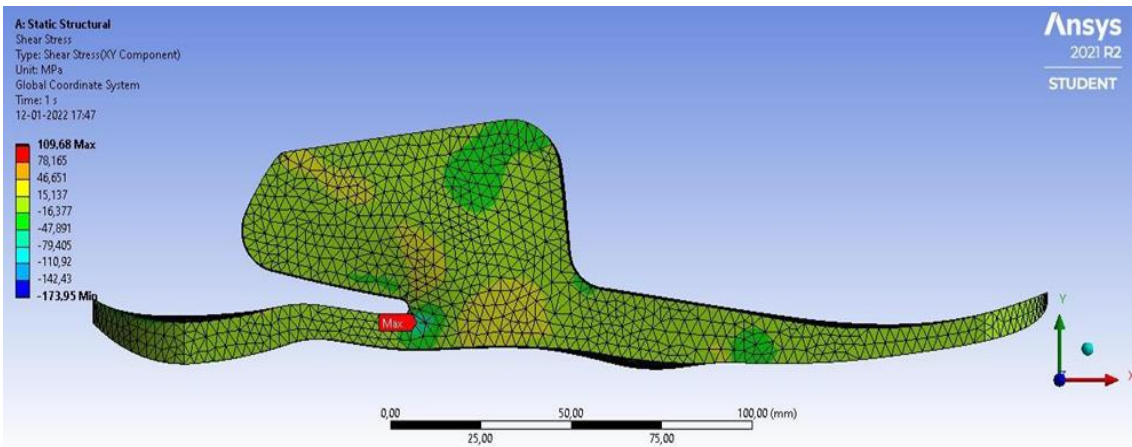


Study 1 - Total Deformation (mm)

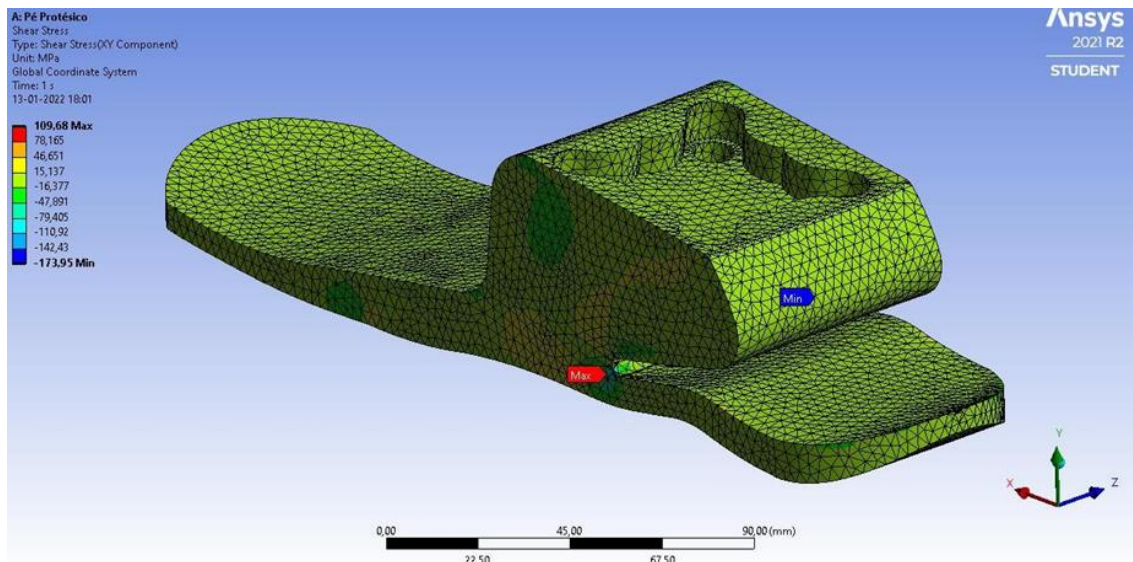




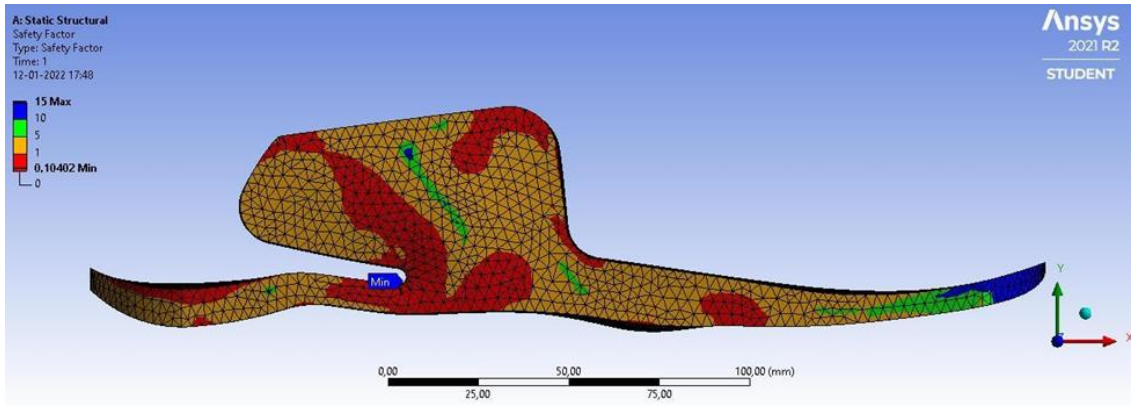
Study 1: Cutting Stresses (MPa)



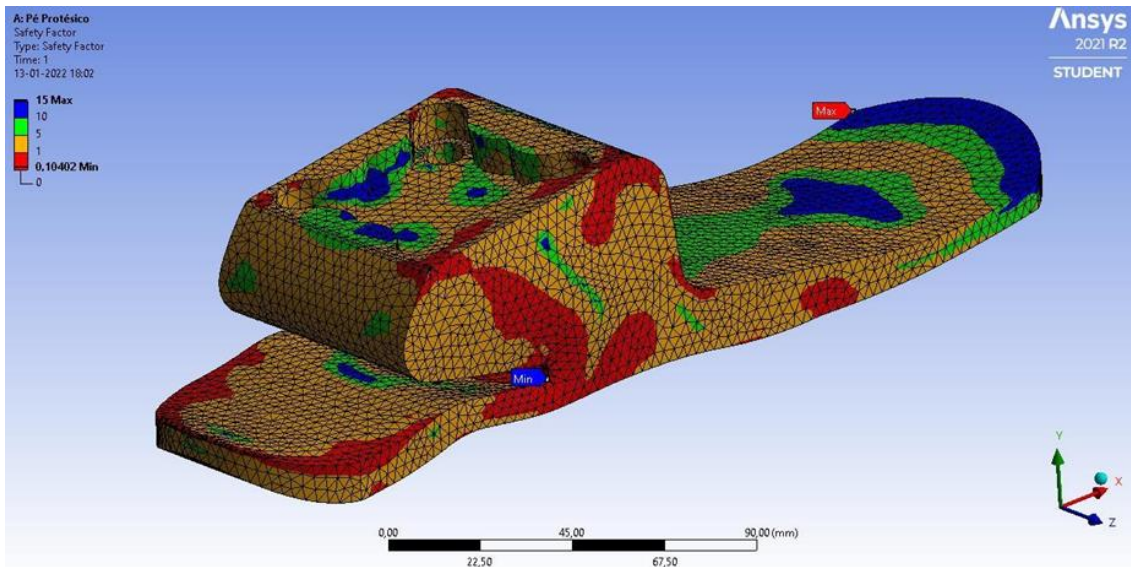
Study 1: Cutting Stresses (MPa)



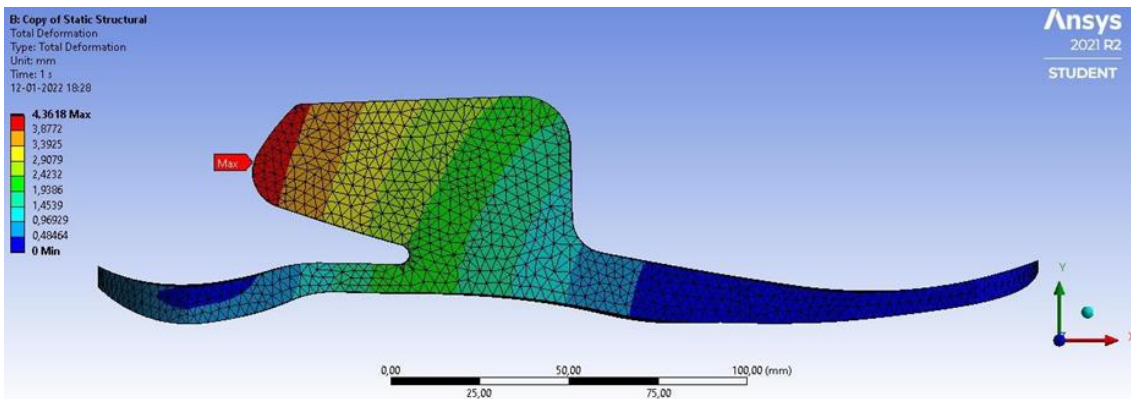
Study 1: Safety Factor (ad.)



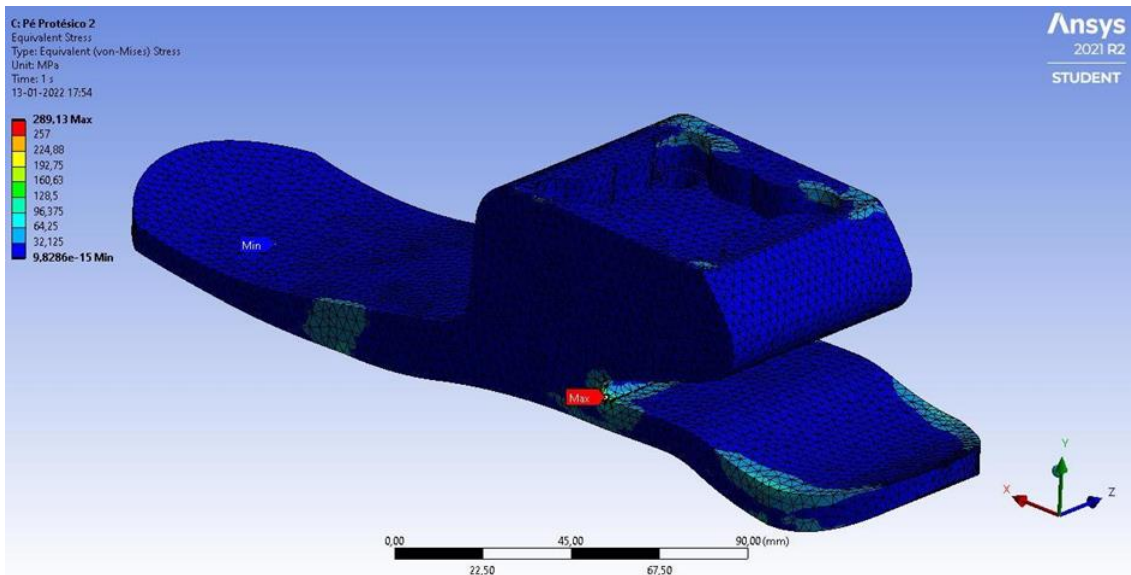
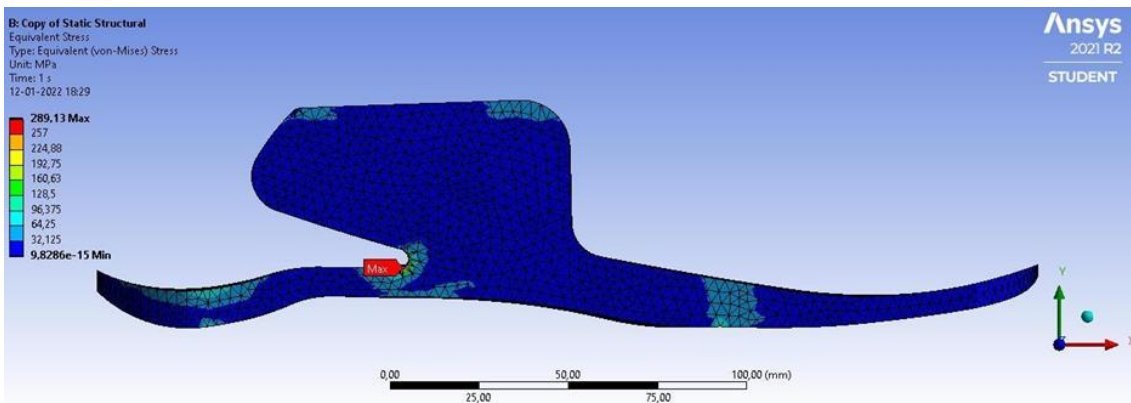
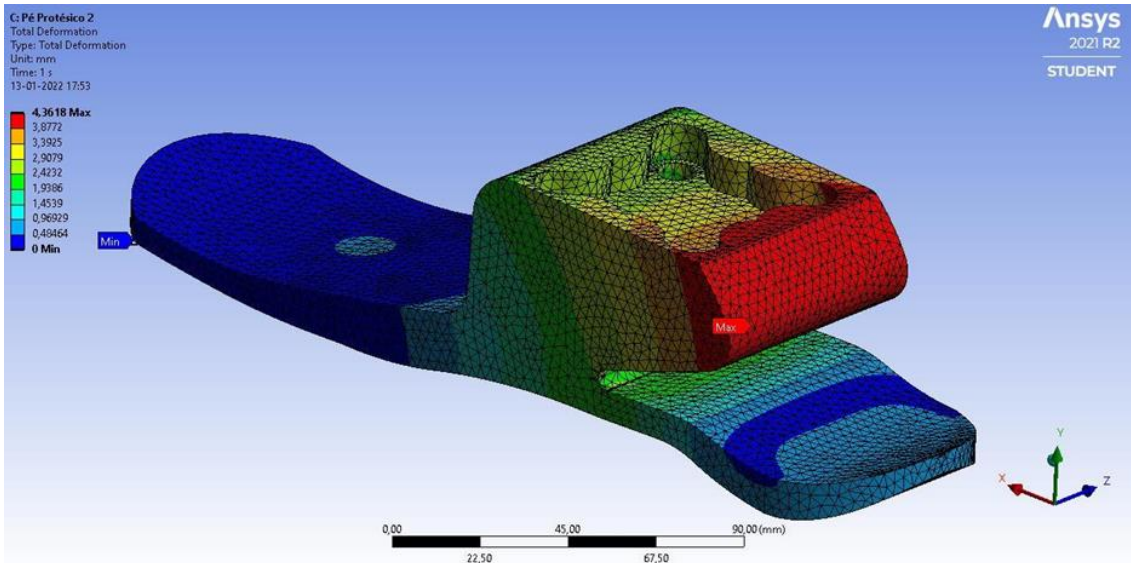
Study 1: Safety Factor (ad.)

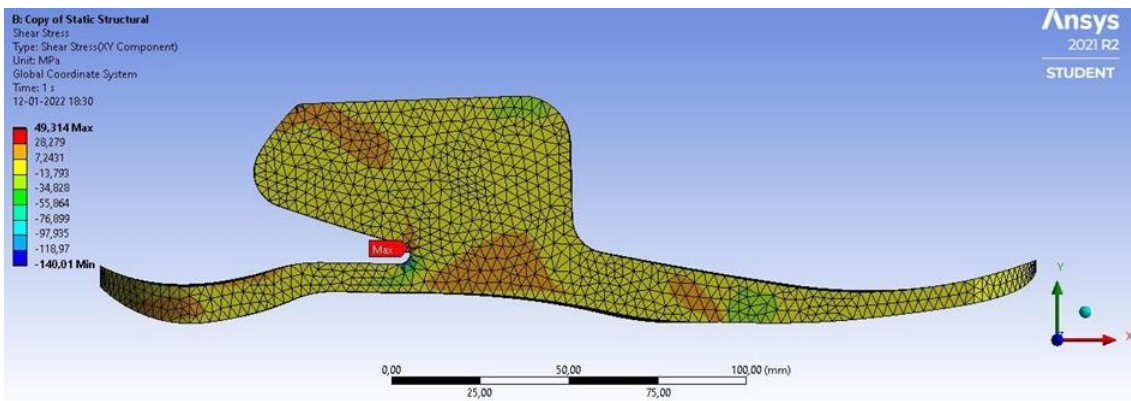
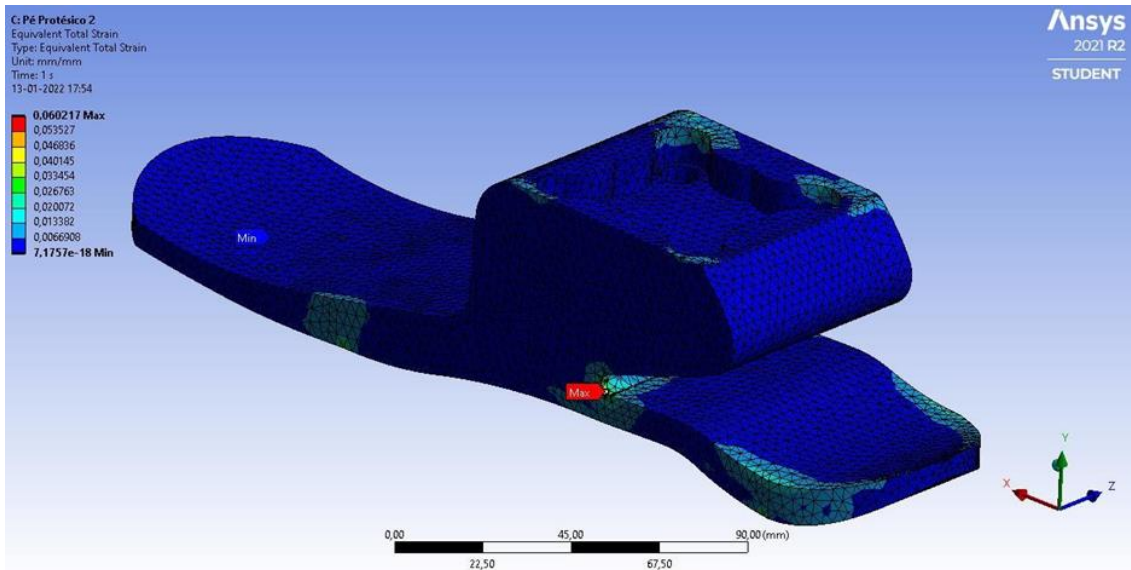
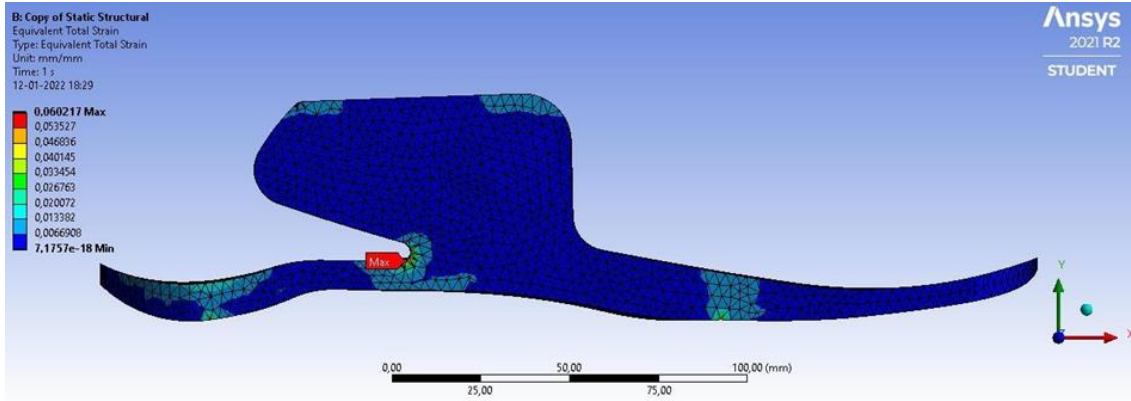


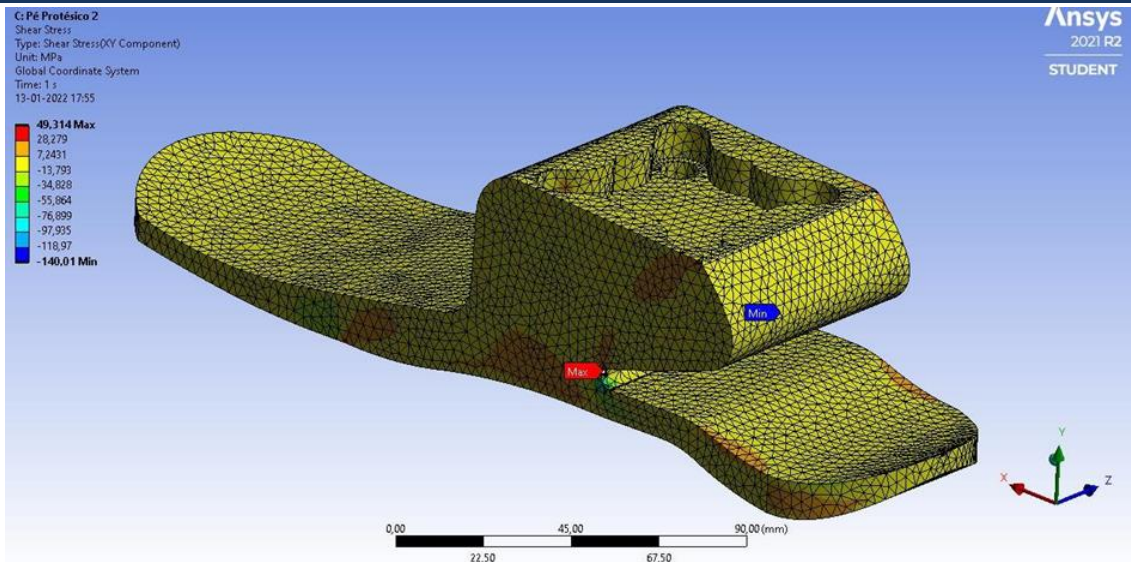
Study 2: Total Deformations (mm)



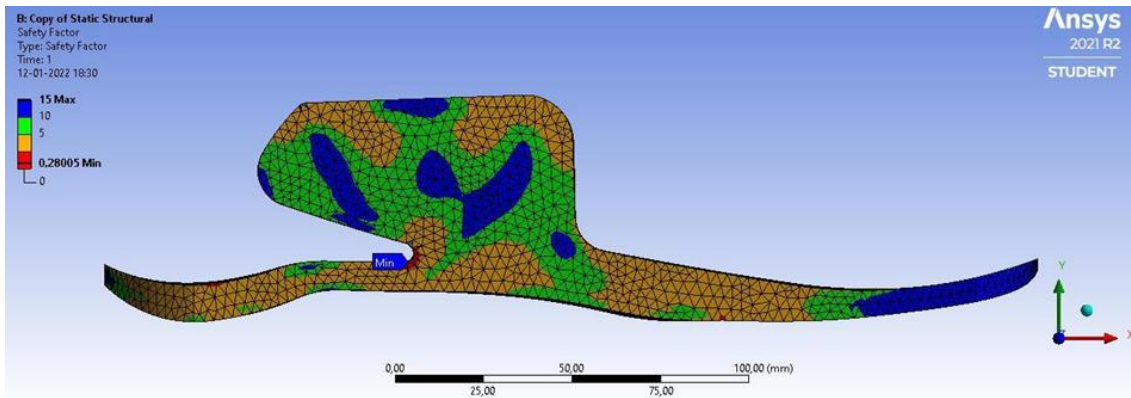
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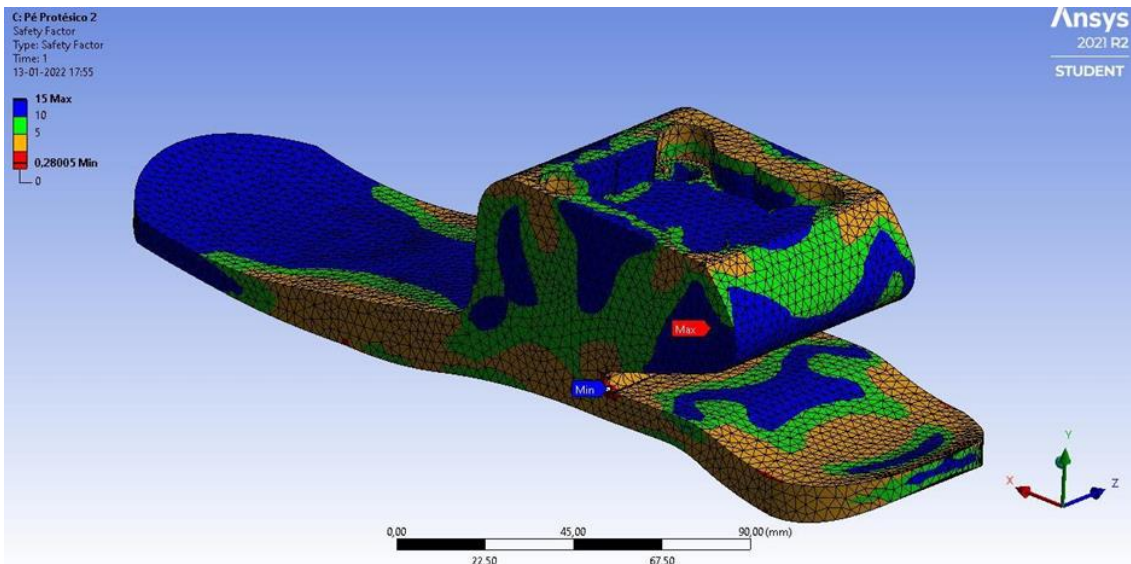




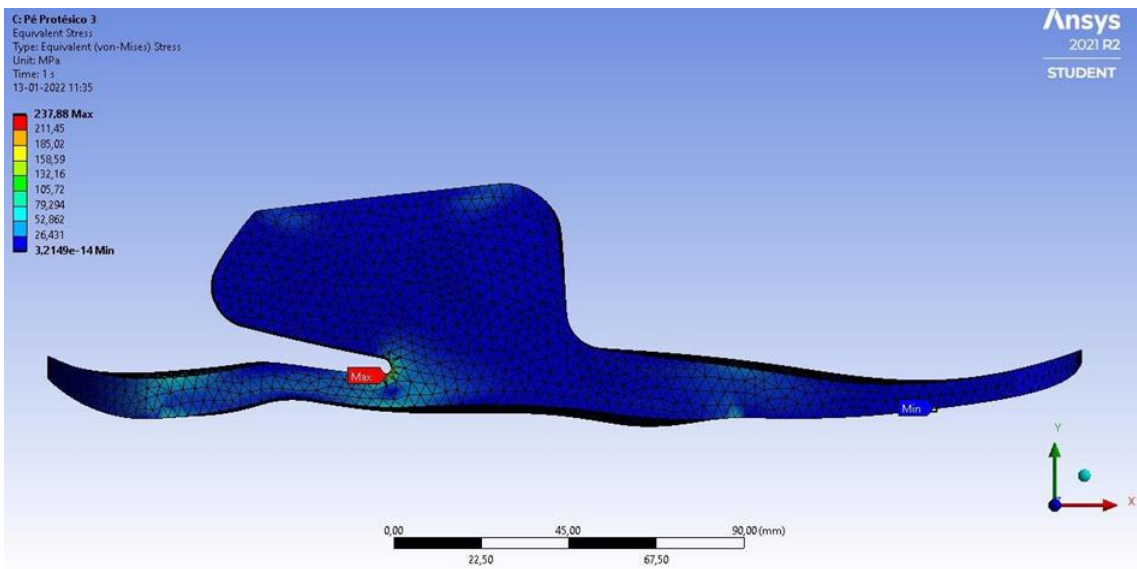
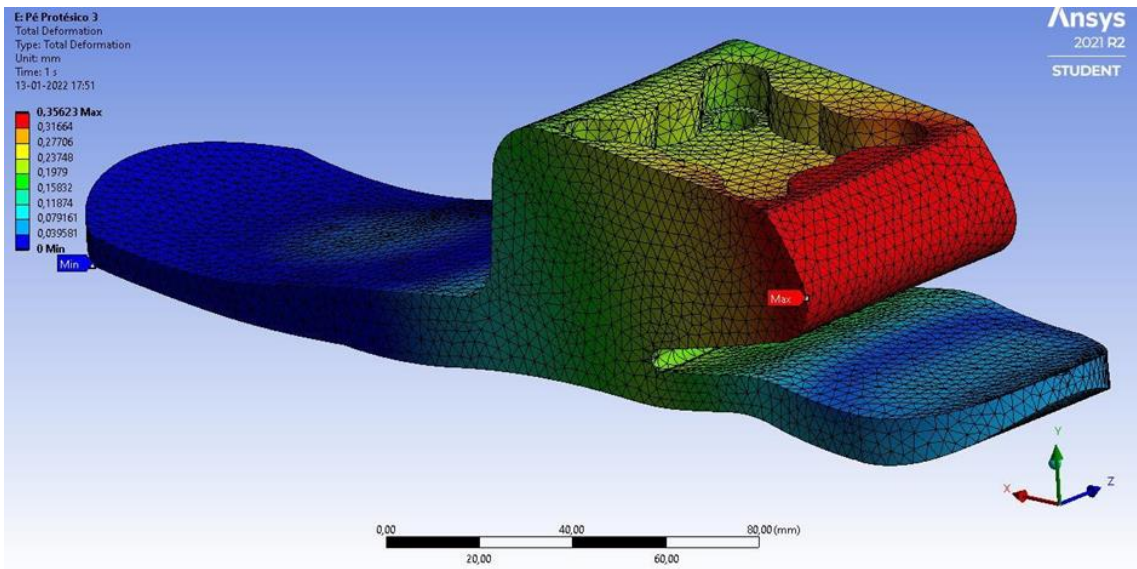
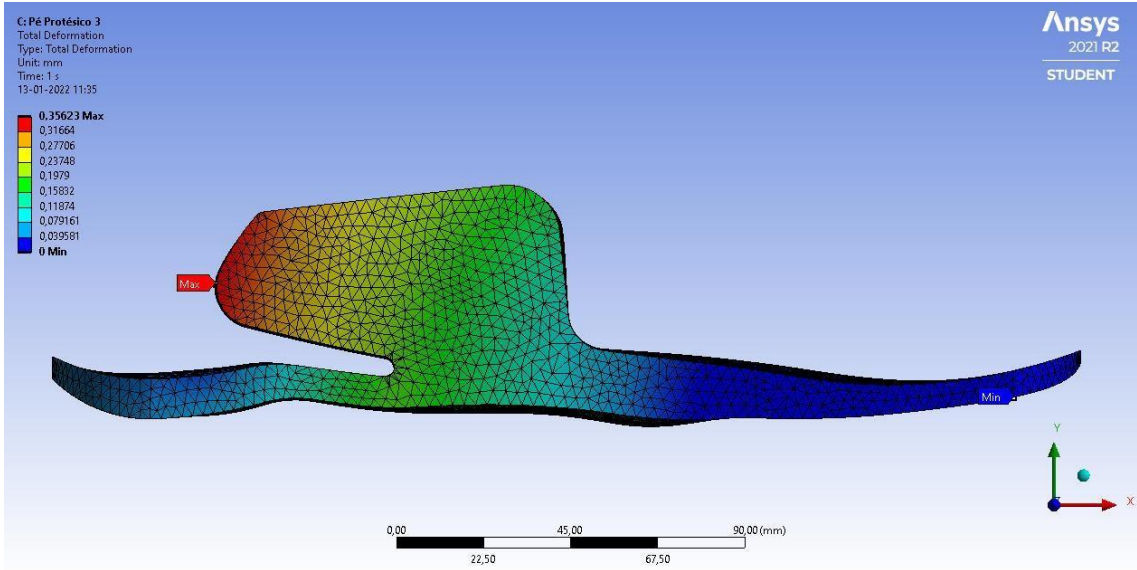
Study 2: Safety Factor (ad.)

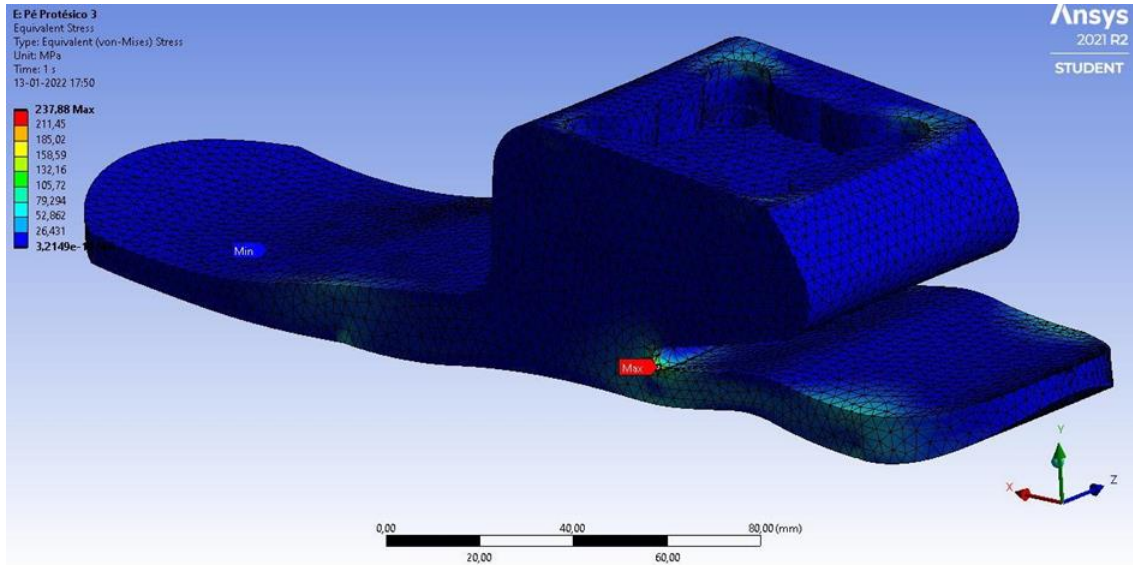


Study 2: Safety Factor (ad.)

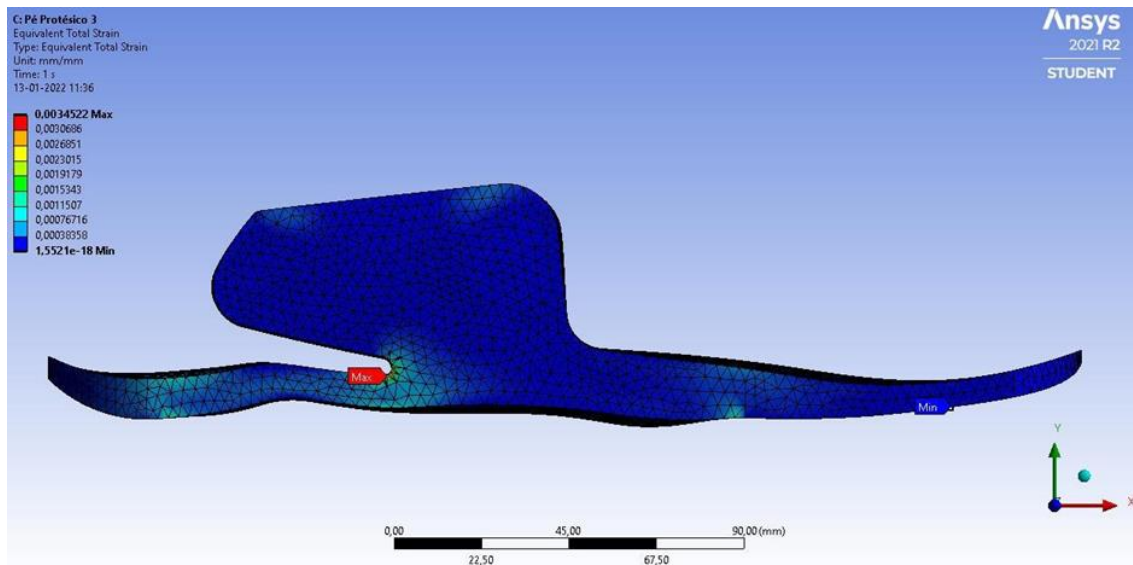


Study 3: Total Deformations (mm)

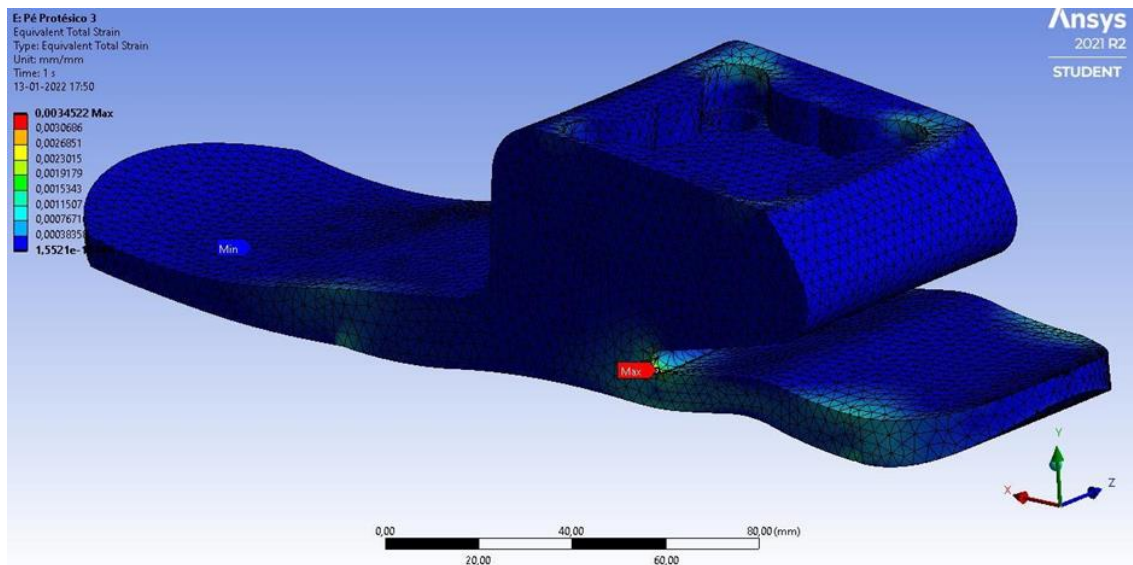




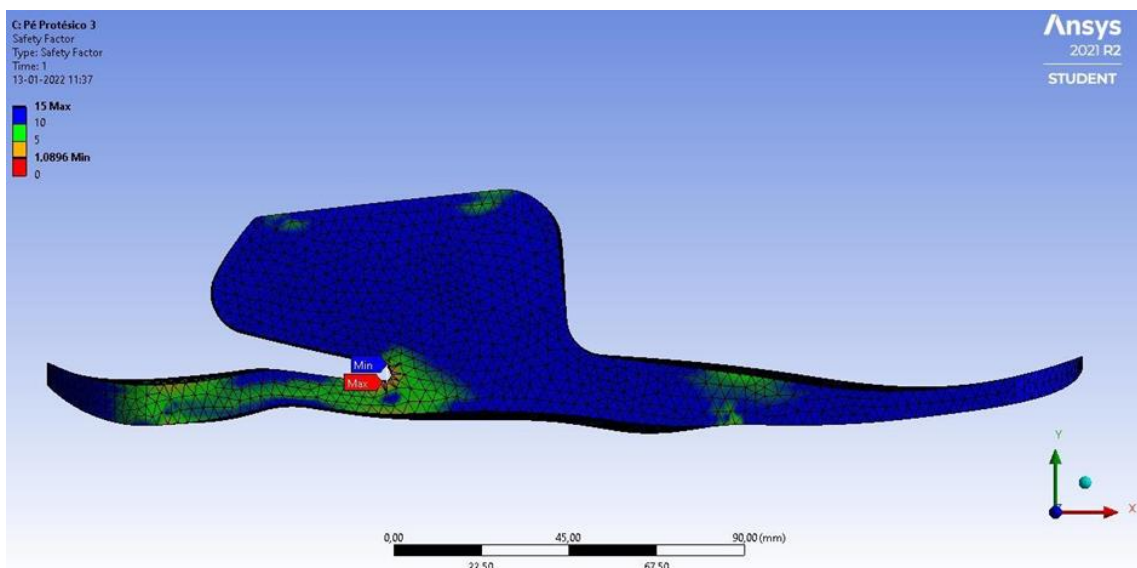
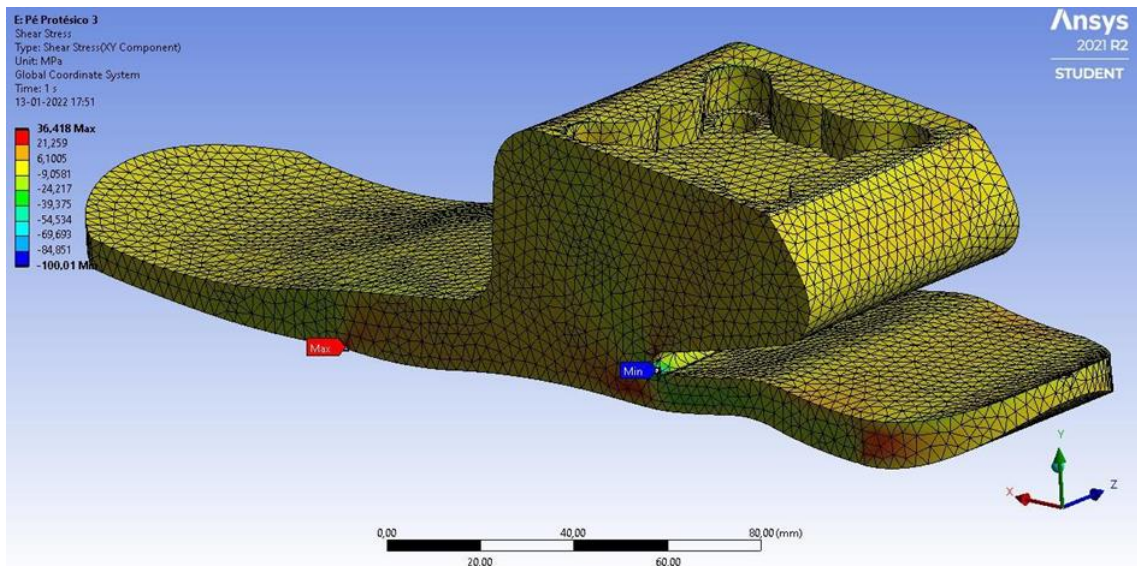
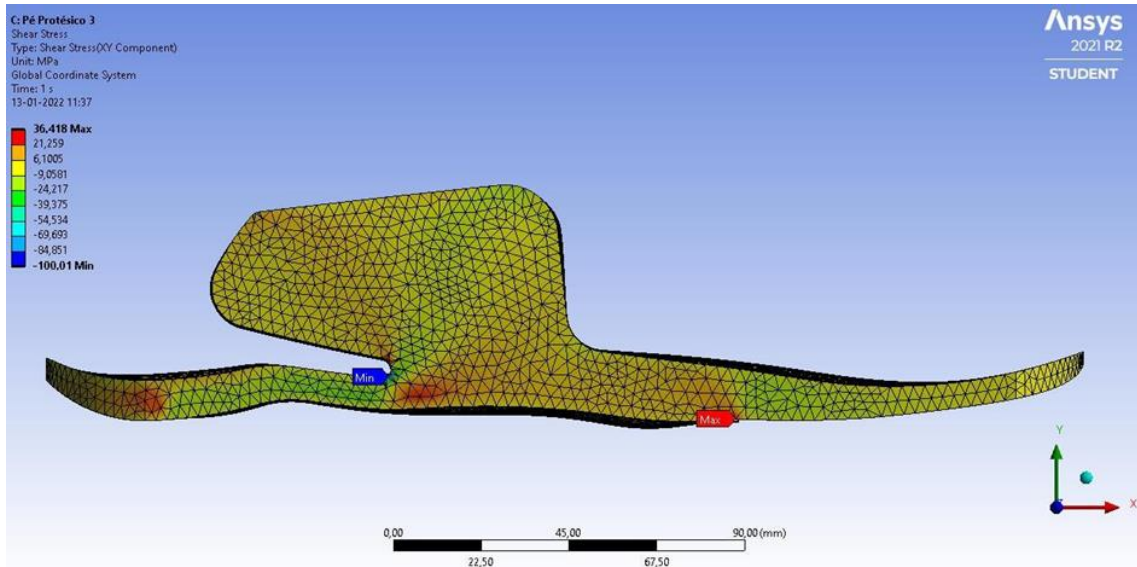
Study 3: Def. Unitary (mm/mm)



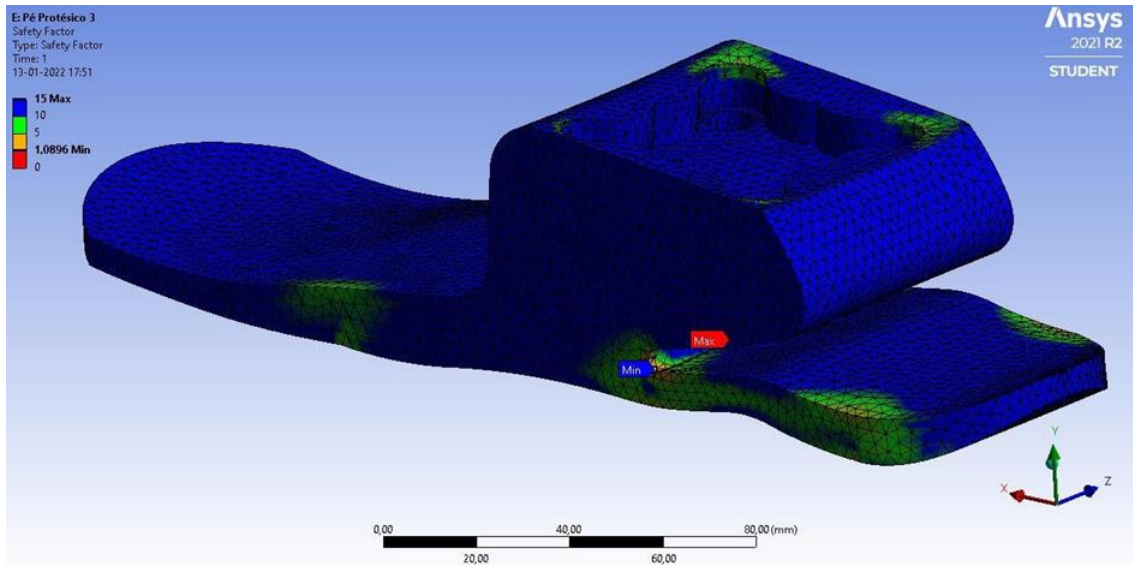
Study 3: Def. Unitary (mm/mm)



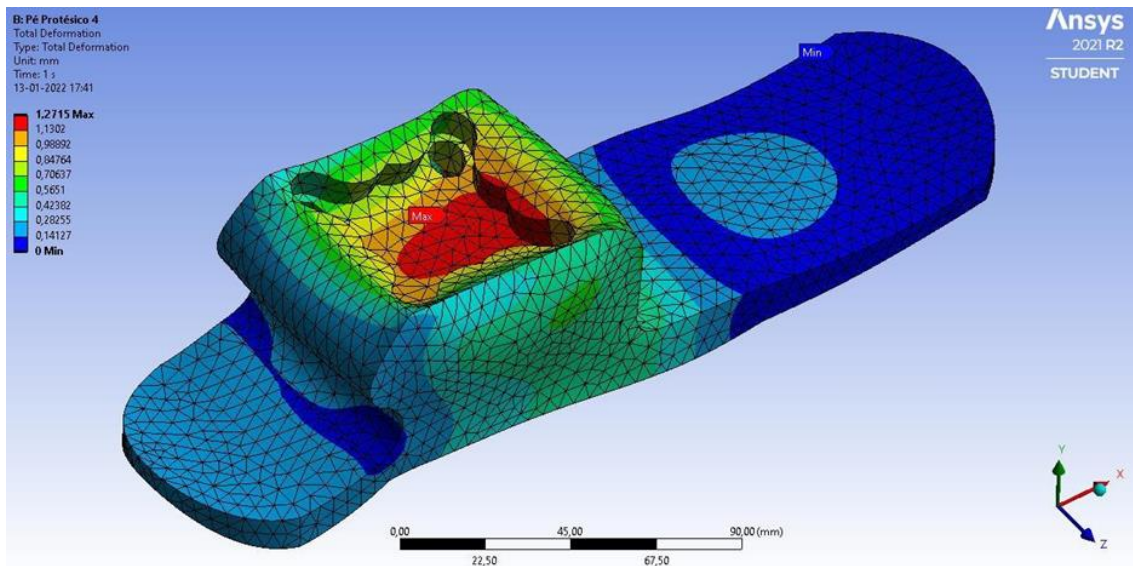
Study 3: Cutting Stress (MPa)



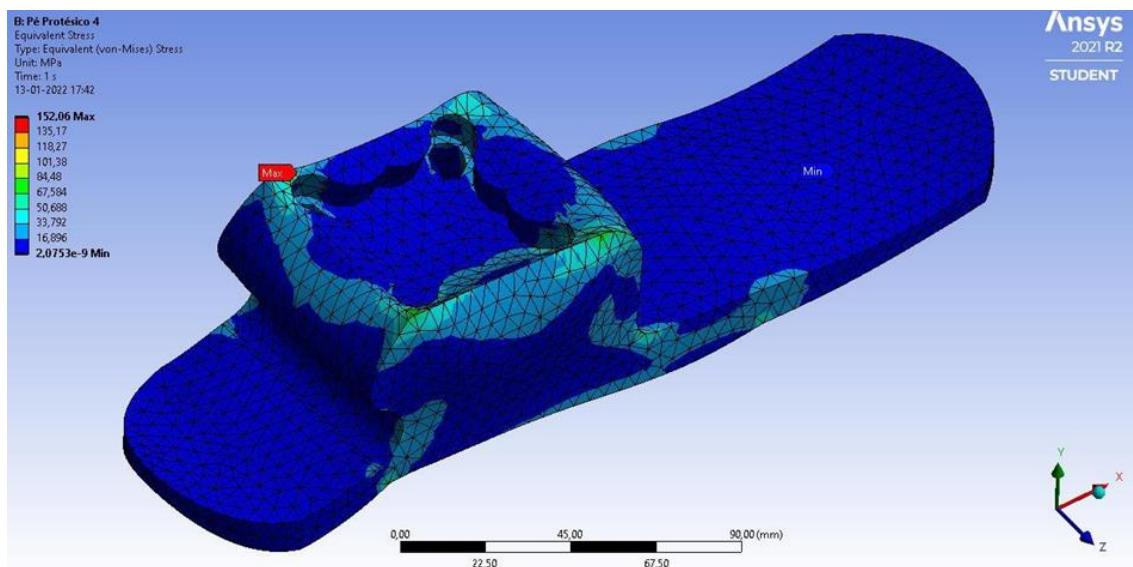
Study 3: Safety Factor (ad.)



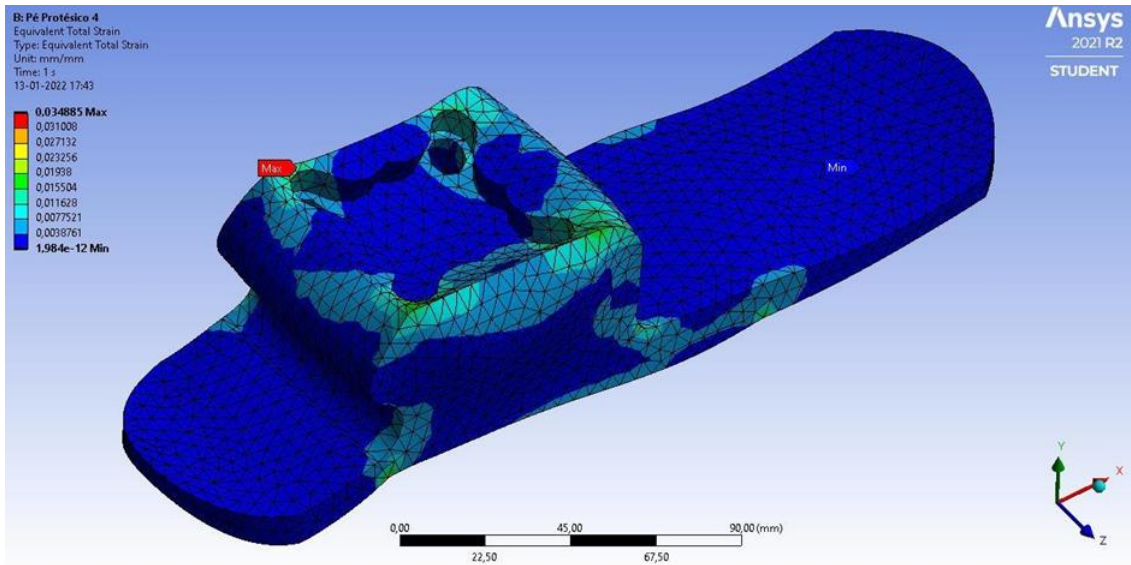
Study 4: Total Deformations (mm)



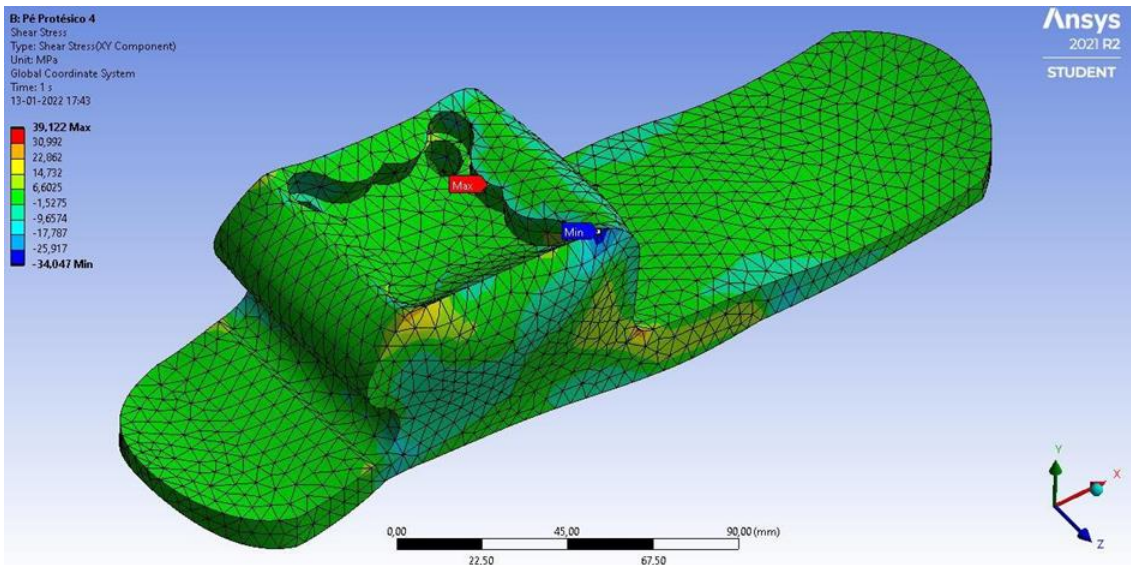
Study 4: Equivalent Stresses (MPa)



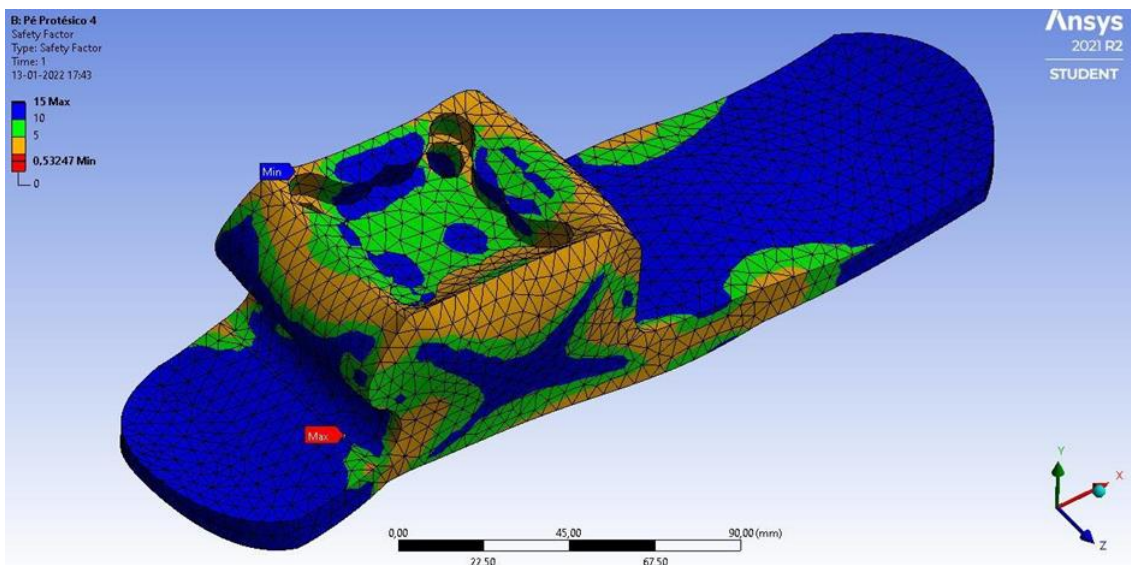
Study 4: Def. Unitary (mm/mm)



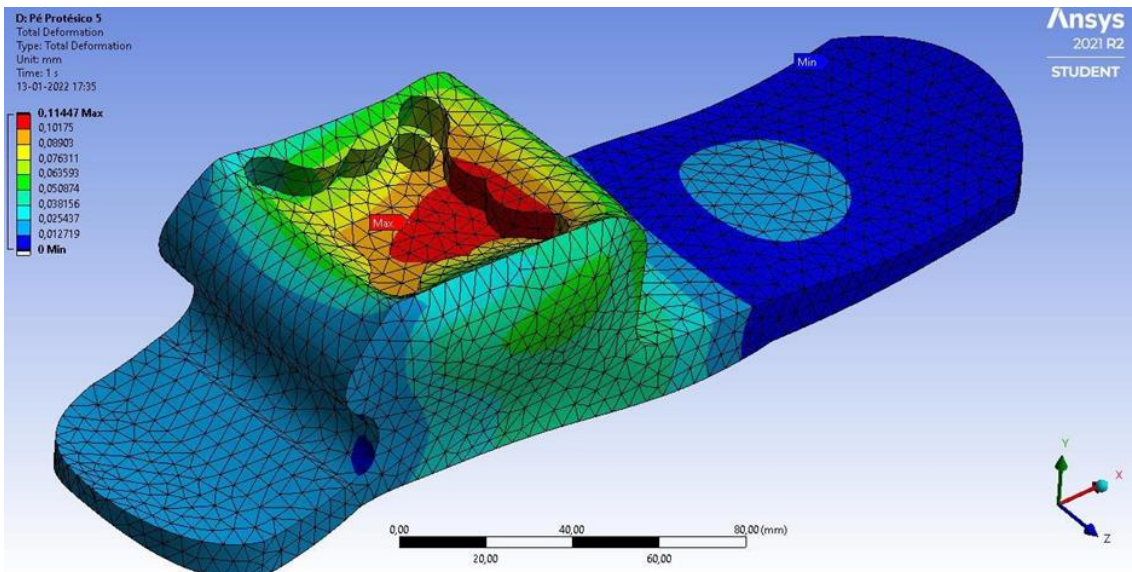
Study 4: Cutting Stress (MPa)



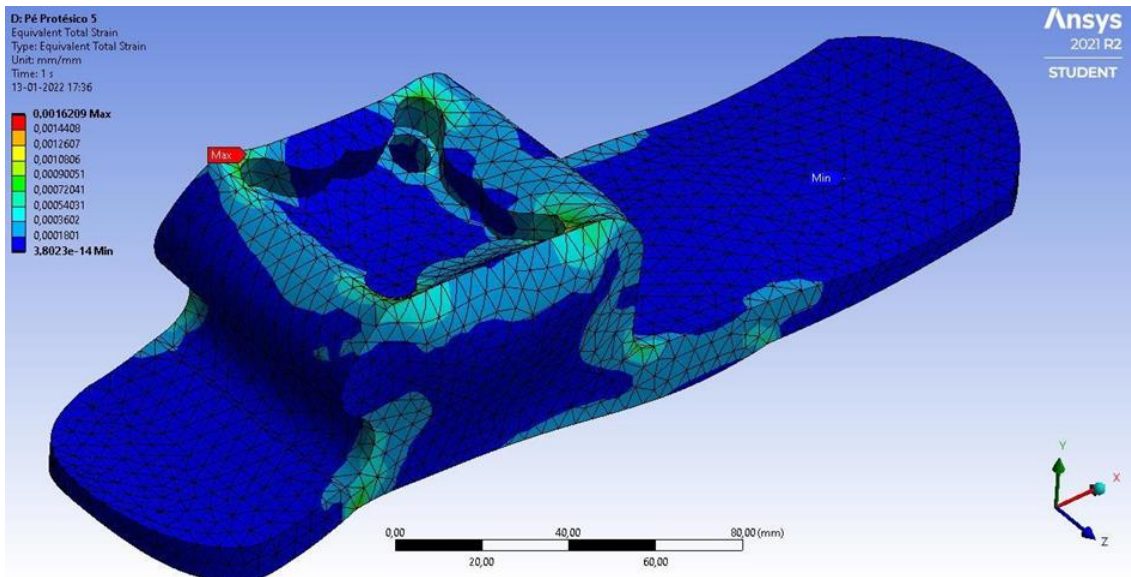
Study 4: Safety Factor (ad.)



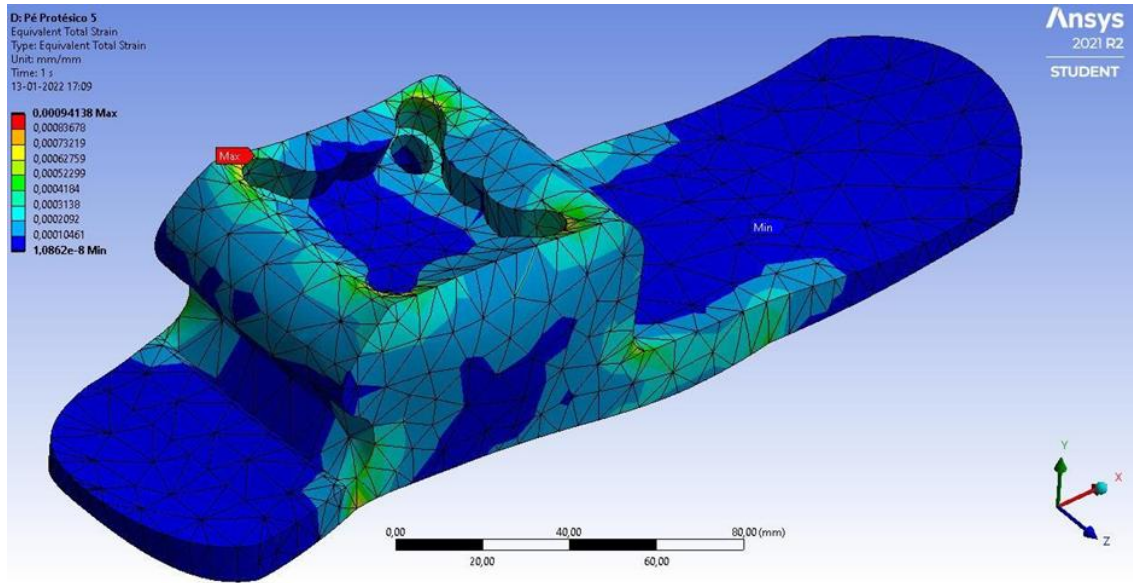
Study 5: Total Deformations (mm)



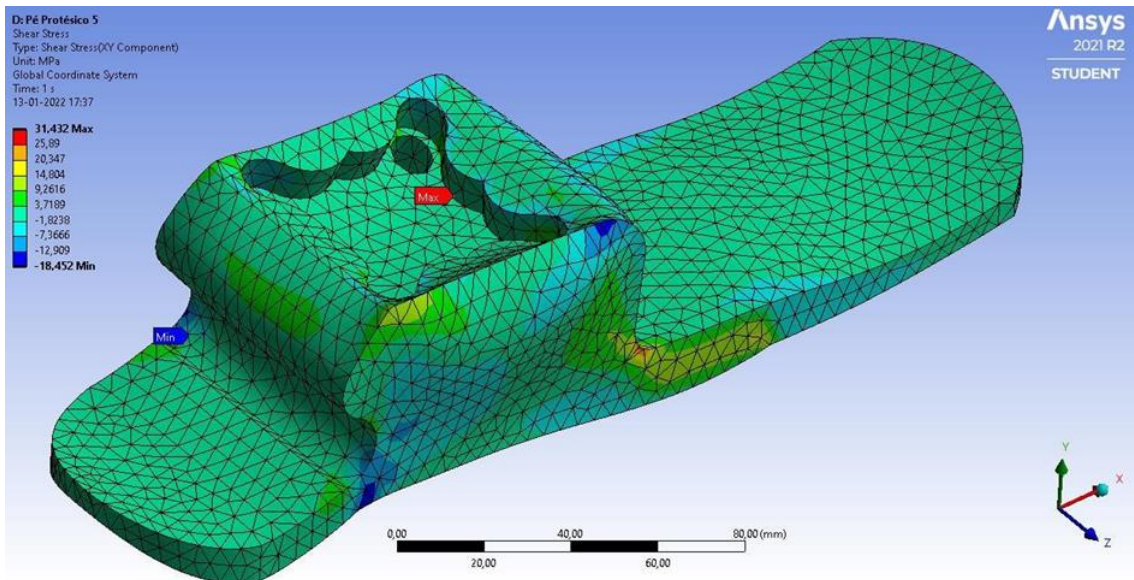
Study 5: Equivalent Stresses (MPa)



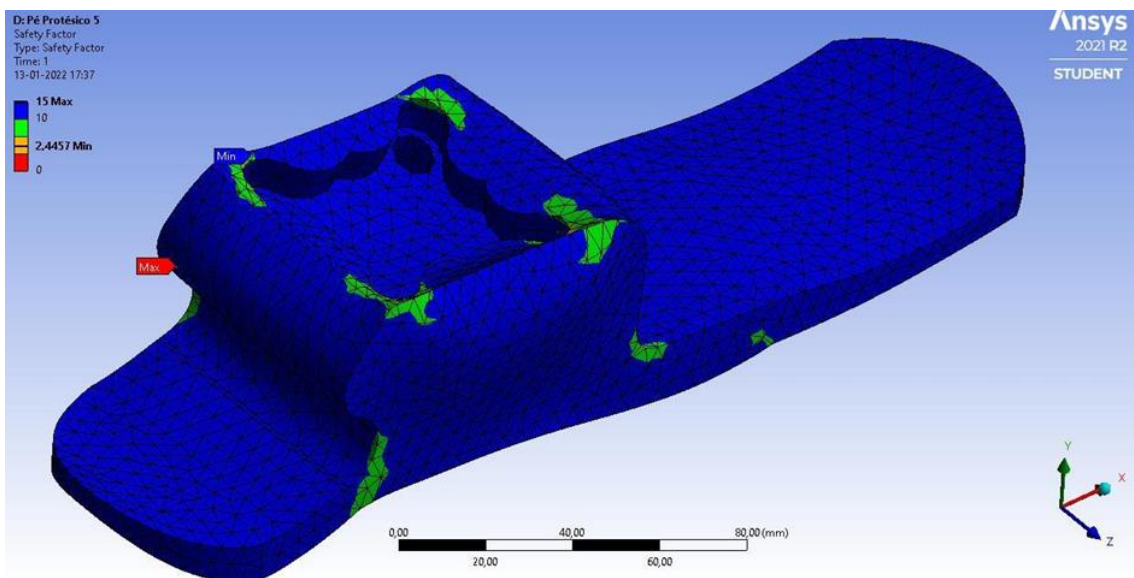
Study 5: Def. Unitary (mm/mm)



Study 5: Cutting Stress (MPa)



Study 5: Cutting Stress (MPa)



Study 5: Cutting Stress (MPa)



Figure 3: Prosthetic foot fixation devices

DISCUSSIONS

Studies with model v5 show that there is not enough support in the heel area to transfer the load applied to the prosthetic foot to the ground;

In studies 1,2 and 4 the models exceed the supply stress of the material (safety factor less than 1);

The estimated deformations in all studies do not take into account the distribution of the load by filling the printed part. Therefore, deformations in actual tests should be considerably lower;

It is suggested to perform mechanical tests on the prosthetic foot, in order to measure the real mechanical resistance, and to be able to verify whether the results of these studies are close to a real situation (or not);

Studies with model v6 show a substantial reduction in deformations and stresses in the model, even with an increase in applied load (500 vs. 900 N);

The current prosthetic foot, printed on Onyx and reinforced with continuous carbon fiber, will have mechanical strength to withstand loads higher than those applied in these studies, due to the distribution of the loads through the triangular filling structures.

CONCLUSIONS

Using simulations has the following main advantages:

Decrease in the number of physical prototypes;
Optimize production costs;

Eliminate delays in prototyping;
Facility for innovation;
High quality end product.

It was possible to conclude that the simulations were met in practice with amputee patient.

The low cost prototype was easily adapted and well adjusted to a real patient. The real tests in person proved that it is feasible to produce them with better quality of life.

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