LECTURES 7-8: DESIGN AND MANUFACTURING OF LOWER LIMB PROSTHETIC

7.1 Introduction

The prosthesis is a system that may be within or outside the human body that covers the missing portion or structure. Prostheses are the parts of the artificial body made for amputees.

Over time, advancements made it possible to replace a plain artificial leg of wood or iron with advanced instruments that got closer to imitating biological functions. Suspension devices are important parts of the prosthesis of the lower limb that are used to establish a comfortable coupling between the residual and prosthesis limbs. Many advanced suspension systems make use of silicone liners as the preferred suspension system.

Our mission is to provide a solution to this issue that is cost-effective, has a flexible degree of work and can be tailored to the needs of the customer.

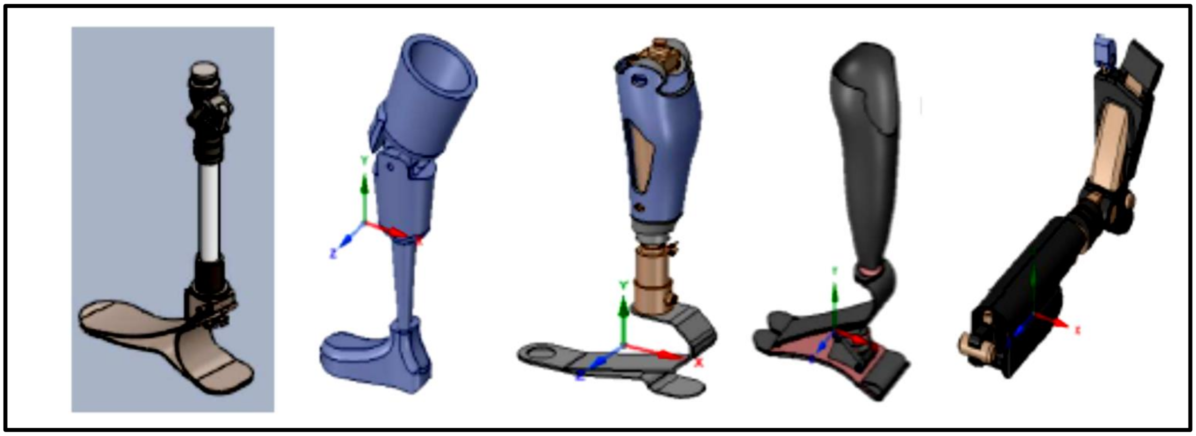
The work is based on the "Prosthetic Lower Limb" concept, which involves several parts. Hips, elbows, feet, suspension, liner, connector and construction materials are the core components for prosthetics.

7.2 Selection of an Appropriate Design

In terms of serving four main functional functions, existing architecture solutions are organized:

- Help for the body
- The Propulsion
- Flexibility for Tasks

- Relief loading



7.2.1 Selected Design:

The selected design Benefits of Design are:

- Ideal for cross-fitness, running, games of bat and ball
- Acceleration and deceleration regulated
- Alignment ease
- Adjustment wedge for heel stiffness

The majority of amputees should be used with routine prosthetic therapy. Particularly for those with a moderate degree of movement, meaning they adjust their walking speed, travel longer distances, and easily change direction. Some feet have a split-toe mechanism that helps the foot to imitate inversion and eversion. It normally allows individuals to progress from moderate to higher levels of activity due to the complex reaction of the foot.

Active knee prosthetics will do work that is a normal routine. This could include stair climbing, ramps and transition to the sit-stand role. It needs an actuator for this form of active knee. The actuator is a part consisting of a driving engine, a ball screw, springs and dampers.

7.3 Mechanical Properties and Stability of Design

The stiffness of the foot-ankle mechanism is another element of the prosthetic prescription that greatly affects comfort and work. The option of suitable stiffness is largely dependent on the body weight of the patient, his/her choice of activities, and the level of severity of those activities, but other considerations can also be considered, such as residual limb duration, residual limb discomfort, and the patient's sense of equilibrium.

Almost all suppliers encourage the doctor (or prosthetics) to select the desired stiffness from a range of components available. The Seattle Foot (Seattle Orthopaedics Group, Poulsbo, WA), for example, is available in seven different keel stiffness’s, and there are nine stiffness groups for the Flex-Foot.

The doctor must weigh the different variables and use a single rigidity to serve all situations that a patient can encounter. Increased metabolic costs, irregular muscle activity patterns, reduced gait symmetry, tissue damage associated with improper residual-limb and intact-limb loading, and discomfort may occur from an incorrect choice of stiffness.

7.4 Mechanical Principles of Design

7.4.1 Minimal Weight Design

It is possible to make prosthetic feet from wood, rubber, urethane, titanium, glass fiber, and carbon fiber. They can be lightweight, energy-storing or dynamic, and some can allow heel height adjustability. Passive plantar flexion in the early position, neutral position in the mid position, and toe hyperextension in the late position should be provided by both prosthetic feet.

7.4.2 Centre of Gravity

The center of gravity (COG) of the human body is a metaphysical position from which the force of gravity continues to work. It is the point where the combined mass of the body appears to be concentrated. As it is a conceptual point, the COG does not have to lie within the physical limits of an object or individual.

7.4.3 Safety Factor

The safety factor (SF) describes how much stiffer a device is than an expected load needs to be. Using thorough research, safety considerations are also measured because rigorous testing is impossible for certain projects, such as bridges and houses, so the capacity of the system to support a load must be evaluated to a fair precision.

7.4.4 Stresses

Stress is a physical quantity that expresses the internal forces exerted on each other by neighboring particles of a continuous material, while strain is the measure of the material's deformation.

7.4.5 Strain

Geometric deformation calculation that describes the relative displacement of a material body between particles. Different processes, like stress exerted by external forces on the bulk material (like gravity) or to the surface, may create strain inside a material (like contact forces, external pressure, or friction). Every pressure of a rigid material creates an internal elastic stress, equivalent to a spring's reaction force, which helps to return the material to its original non-deformed state.

7.4.6 Deformation

Total Deformation is the transformation of a body by continuum mechanics from a reference configuration to a new configuration.

1.4.7 Fatigue

Fatigue is the weakening of a substrate that results in structural damage, gradual and localized, and crack formation caused by cyclic loading.

7.4.8 Ergonomics

In the production of a commodity for human consumption, ergonomics is an important factor. The different things that are taken into consideration, such as the comfort design, the practical design, and the framework known as the human and ergonomic factor (HF&E), create a product that communicates with the product and the general public using the product. Commitments from various controls, such as brain science, architecture, biomechanics, mechanical outline, physiology, and anthropometry, were seen in the sector. It is usually the study of representing hardware and equipment that complement the human body and its subjective capabilities. In theory, the two terms "human variables" and "ergonomics" are synonymous.

7.5 Manufacturing

The metal may be aluminum, titanium or steel in the manufacturing process. The prices can vary. All of these are stronger and harder, but aluminum is not approved for adults because they are heavier and taller than infants. Steel is not too expensive and has higher prices of power.

7.5.1 Materials:

Materials for limb and their properties

Table 1 Materials for Prosthetic Foot

• **Titanium**	• **Stainless Steel**	• **Carbon Fiber**

• **Excellent in biocompatibility** • **Excellent in design properties** • **Excellent resistance to corrosion** • **Lightweight** • **High Power** • **Magnificent in elasticity** • **Excellent tenacity in low temperatures** • **Low thermal conductance** • **Elevated electrical resistance**	• **Resistant to corrosion.** • **Elevated tensile power.** • **Very robust.** • **Immune to temperature.** • **Simple formability and manufacturing.** • **Lower-maintenance (long-lasting)** • **Appealing look.** • **Environmentally sustainable (recyclable)**	• **Strong Ratio of strength to weight** • **Rigidity** • **Resistance to corrosion** • **Resistance to Exhaustion** • **Strong power for stress, but Fragile** • **In certain ways, High Thermal Conductivity** • **Low thermal expansion coefficient** • **Relatively Expensive**

The metal may be titanium, steel, or carbon Fiber in the manufacturing process. The prices can vary. All of these are stronger and harder, but aluminum is not approved for adults because they are heavier and taller than infants. And the carbon fiber can be expensive and somehow not commonly availability. We would use steel for our project as it is not too expensive and has higher prices of power. Selected Material for the project is Stain less steel 304 due to its superior properties than other materials.

7.5.2 Stainless Steel:

Stainless steel is a collection of iron-based alloys with a minimum of around 11% chromium, a structure that keeps the iron from rusting and also offers properties that are heat-resistant. The elements carbon (from 0.03 percent to more than 1.00 percent), phosphorus, aluminum, silicon, Sulphur, titanium, nickel, copper, selenium, niobium, and molybdenum are various kinds of stainless steel. Specific stainless-steel types are also marked with a three-digit number, e.g. stainless steel 304.

7.5.3 Benefits of Stainless Steel 304:

- Lowest coast corrosion resistance option.
- Resistance to oxidation
- No limitation on fabrication

7.6 Size

Size is taken from former standard published data (Blatchford).

Table 2 Specification of Prosthetic Foot

Max. User Weight	20-60kg (44 - 132 lb)
Activity Level	3-4
Spring Range	1-3
Component Weight	450g (1 lb)
Build Height	168mm

7.7 Safety

The different parts of the artificial limb, are assembled so that a natural limb is replicated. The position of the knee and ankle joints, like the axis of rotation of the joints, must be right. The joint orientation must be right, so that the body weight moves just behind the axis of the knee joint while seated, creating support when the joint is slightly hyperextended.

Any part of the layout: mechanical, electrical, applications. Any new device used with patients must be approved by international standards such as FDA regulations and

ISO specifications. Quality management planning includes an understanding of international guidelines that address such fields as:

- Risk estimation is carried out by ISO 149711.
- Electrical protection is validated in compliance with IEC 606011,
- Verification of biocompatibility is carried out according to the ISO 109933 requirements.
- The validation of sterility is carried out according to ISO 116077.
- Transit specifications for packaging are checked according to ASTM and ISTA criteria.

7.8 Aesthetics

Designed to offer a complete solution, via the split toe and traction heel, excellent flexibility, ground compliance, and increased comfort, while the C-shaped toe spring is primed for optimum energy response.

7.9 Lower Limbs Type and Classification

There are two forms of prostheses used. One of them is passive indicating that they do not absorb external energy and by body activity all their tasks are done. The other kind is active, which uses actuators such as the AC motor or stepper motor of the DC motor to operate.

7.10.1 Design Calculation

To proceed with the part design, we have to categorize the patients according to their usual activities.

We have certain body measurements after evaluating the activity level of the patients, called the anthropometric measure described by the equations below. The lengths are all taken in mm. In this section below, the nomenclature of the concept is being used.

$RL = LENGTH\ RESIDUAL\ LIMB$

$KH = KNEE\ JOINT\ HEIGTH\ HEIGT\ JOINT$

$TL = THIGH\ Length\ K$

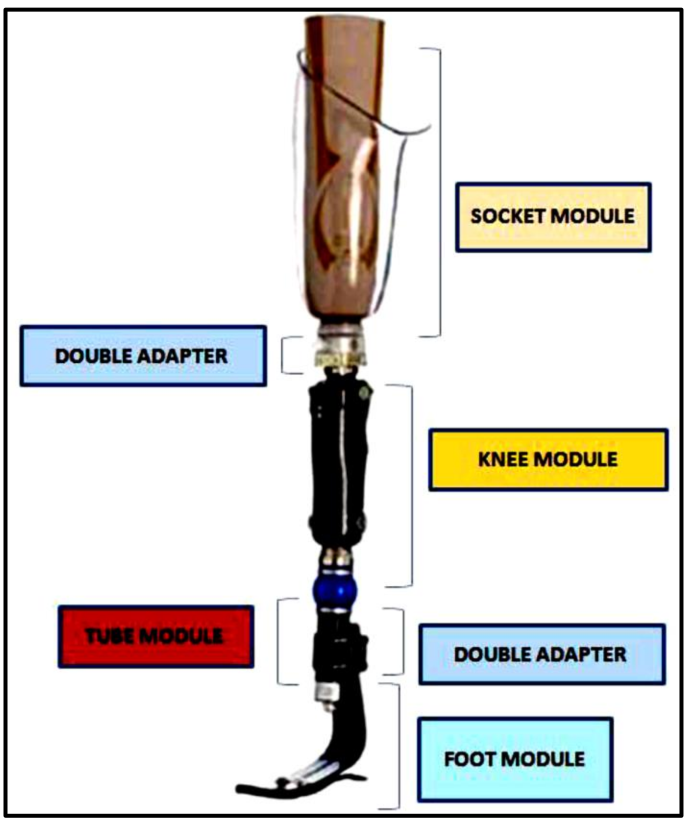
$S = RESIDUAL\ KNEE\ JOINT\ LEG\ TOP$

$TH = Absolute\ HEIGHT\ OF\ PROSTHESIS$

$TM = HEIGHTH\ of\ TUBE\ MODULE\ S$

$M = HEIGHT\ OF\ SOCKET\ MODULE$

$FM = HEIGHTT\ OF\ FOOT\ MODULE$



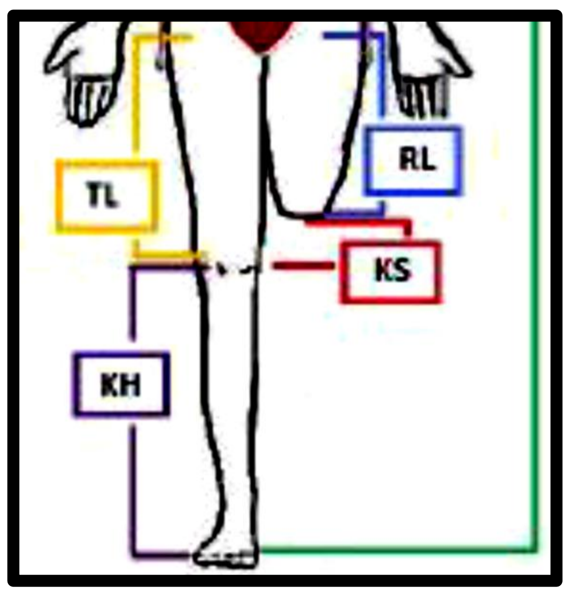


Figure 2: Prosthetic Lower Limb Component

$$\boldsymbol{KS = TL - RL}$$

$$TH = KH - KS$$

$$TM = TH - SM - FM$$

$$TH = KH + KS$$

7.11 Design of Lower Limb Prosthesis

7.11.1 Geometry

The prosthetic lower limb construction is achieved using SolidWorks. Several drawbacks have restricted the prosthetic structure's design requirements. These restrictions rely only on the individual's weight, the speed of the amputee's locomotion, and the situation in which the leg would be used. The key goal of the nature of the project is to make amputees able to live an enjoyable and natural life by themselves.

7.11.2 Final Model of Lower Limb Prosthetic Foot:

The following figure shows the model for the final design of Prosthetic foot. This model is created by use of Solid Works with the help of selected dimensions and data. Material for this design is stainless steel 304. This design is further analyse in the ANSYS by importing the geometry file of model

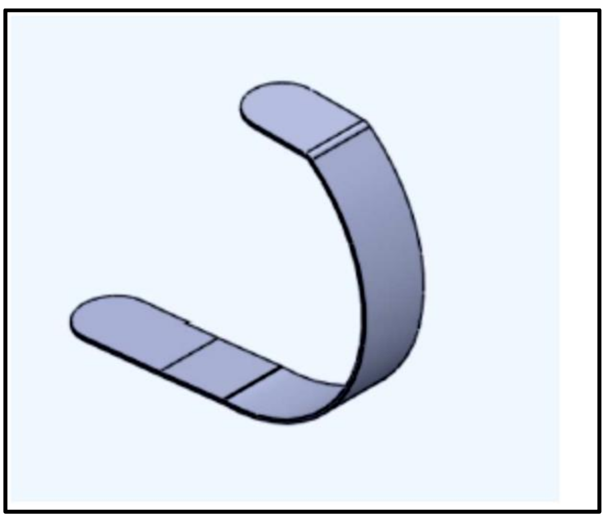


Figure 2: Created Model on Solid Works

7.11.3 FEA Analysis:

The final created model is analyzed on FEA software under static loading conditions. All the related analyses were performed to check the stability of the model and material. Analysis includes Stress, Strain, Deformation, and Fatigue. Under the fatigue tool, there are further parts that are Factors of safety, Biaxial Stress, and Equivalent alternating Stress.

7.11.4 Force and Moment

Force is the major part of the analysis at which the analysis is being done. This applies at the top side of the upper limb transfers by the leg on the foot. The selected design shape gives the effect of spring. This Performs a responsive behavior during walking as like of original feet. The shape is compressed during the force.

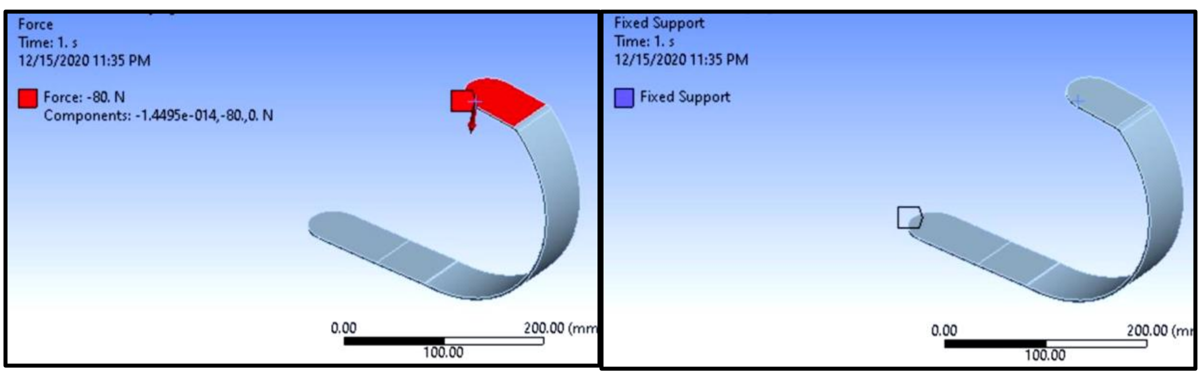


Figure 3: Force and Fixed Support

7.12 Results:

The results obtained by the analysis of prosthetic feet on ANSYS are given below, described in the form of figures. Results for Stress, Strain, Deformation, and Fatigue related analysis are obtained from ANSYS.

7.12.1 Stress

Equivalent stress is evaluated by the analysis of Prosthetic foot design. The maximum value obtained by analysis for equivalent stress is 92.197MPa and the minimum value is 1.52e-9MPa. The values obtain by the application of 80N.

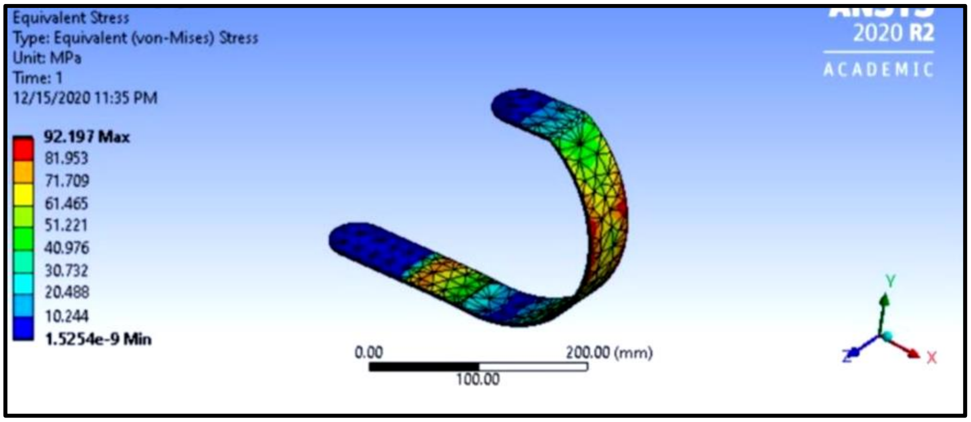


Figure 3: Equivalent Stress Results

7.12.2 Strain

The maximum value for strain obtained by applying 80N force is 0.00047897 and the minimum value is 2.1787e-14.

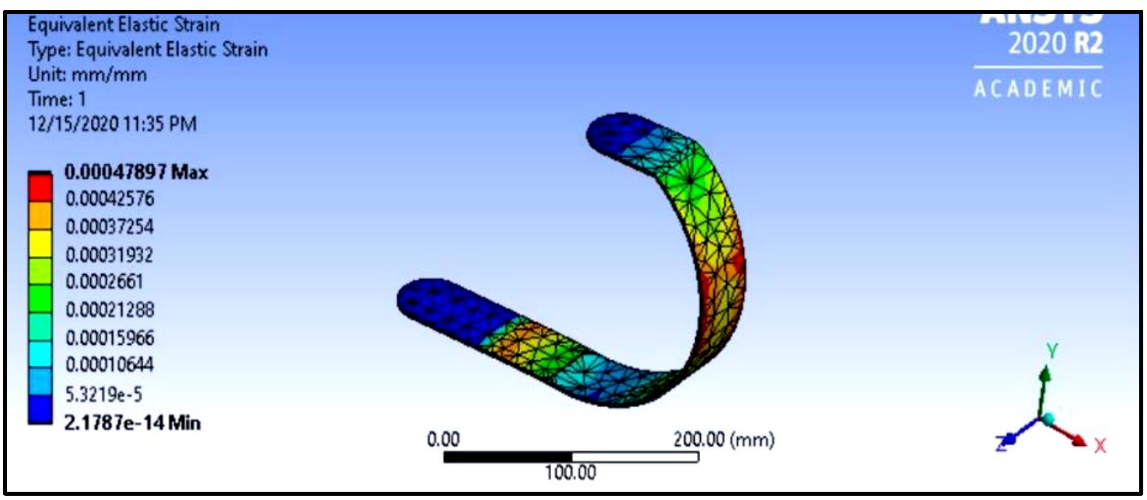


Figure 4: Equivalent Elastic Strain Results

7.12.3 Deformation

Deformation is the main analysis for this design which is the displacement of material under loading. The value obtain for deformation analysis is vary from 0 to 7.3976mm.

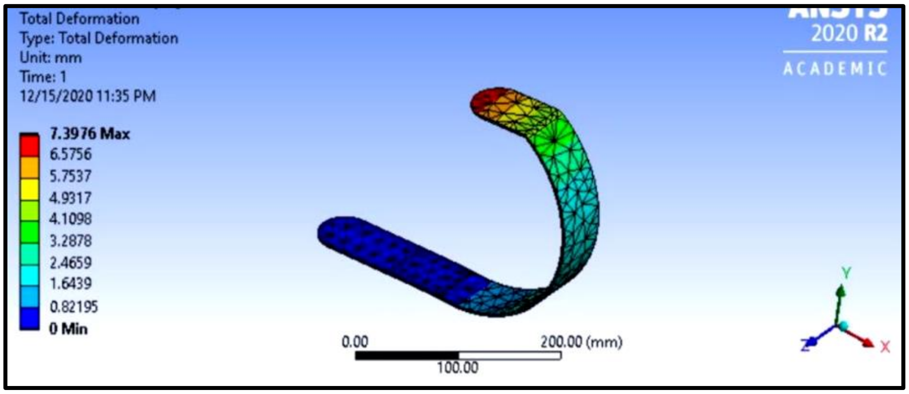


Figure 5: Deformation Results

7.13.4 Safety factor

The factor of safety plays a vital role in material life. It limits the value of stresses to gain or achieve a better life for structure material and gives safety from sudden failure. The value obtain through analysis is up to 15.

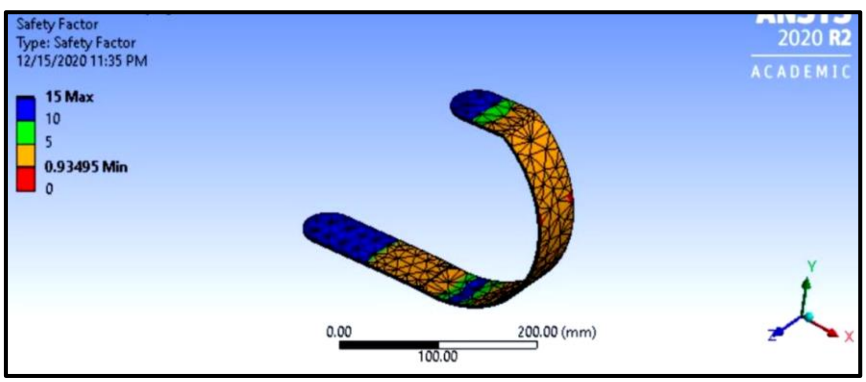


Figure 6: Factor of Safety Results

7.14.4 Fatigue

The cyclic loading on any structure will result in fatigue. Two analyses are done under the fatigue tool analysis, Biaxiality Stress and Equivalent Alternating Stress. The values obtained for the biaxiality stress analysis 0.94493 and -0.99353 as a maximum and minimum respectively. In the equivalent alternating stress analysis, the maximum value obtain is 92.197MPa and the minimum value is 1.5254e-9.

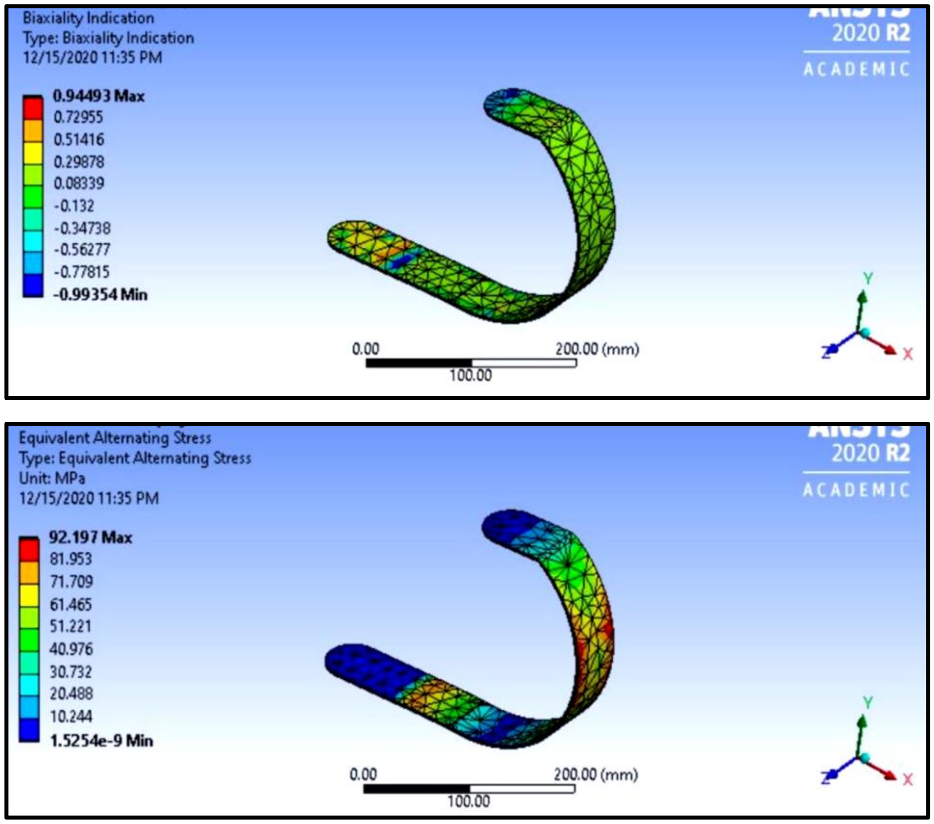


Figure 7: Fatigue Results