

Attachment 1

FINITE ELEMENTS ANALYSIS STUDY

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| | | | TENZOR ANSYS |
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Management Summary

The goal of this **Final Elements Analysis (FEA)** is to conduct a stress analysis and compute the Fatigue Limit of a Dental Implant under compressive Load IAW ISO 14801. 1 Abutments-Implant Configurations will be analyzed. FEA is achieved using commercial FEA software package – Ansys 16.1

Steps taken:

1. Setting up FEA numerical model for static loading
2. FEA Dynamic (fatigue strength limit) simulation
3. Analysis results.
4. Conclusions

Abstract:

FEA model of EAAS25 Abutment and BIO3 ATI 3.3x13 Implant, fixed together by a Titanium screw, is subject to static & dynamic loadings to compute the static and fatigue strength, similar to a lab experiment. FEA simulation is done using **Ansys Workbench 16.1** software. FEA model complies with the same instructions and setup preparations set forward in ISO 14801.

After validating the FEA method as equivalent to the mechanical test method as shown in the Static Loading Curve (Figure 25), an S-N diagram of the Implant Material is constructed. This S-N diagram will be used for the purpose of fatigue strength analysis due to cyclic loading.

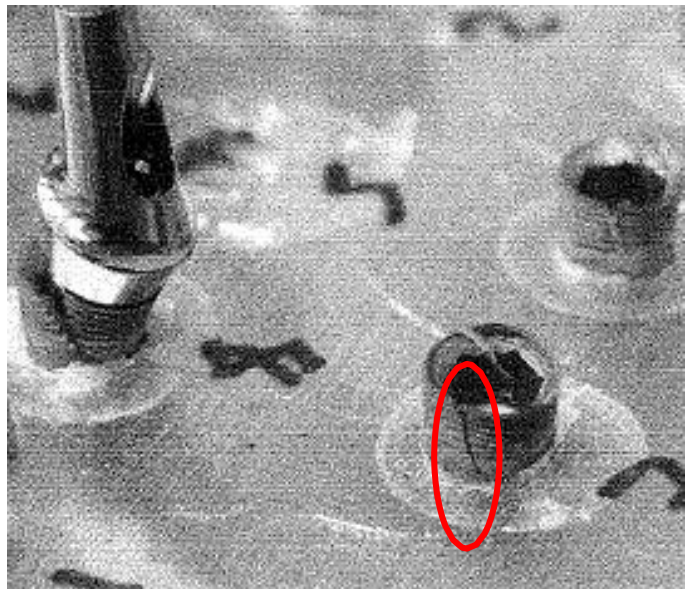
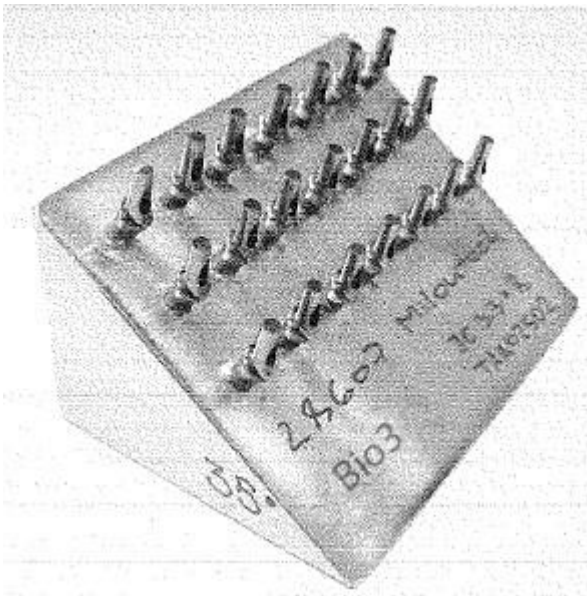


Figure 1 - Test Bench Fixture

Phase 1 – Model Setup

Geometry

The Model Geometry assembly consists of the following parts:

- 1 BIO3 ATI 3.3x13 Implant;
- 2 Screw;
- 3 EAAS25 Abutment;
- 4 Hemispherical Loading Member;
- 5 Loading Device;
- 6 Loading Machine;

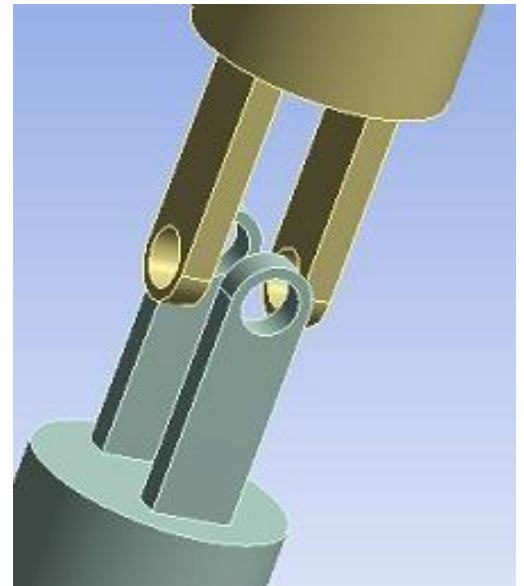
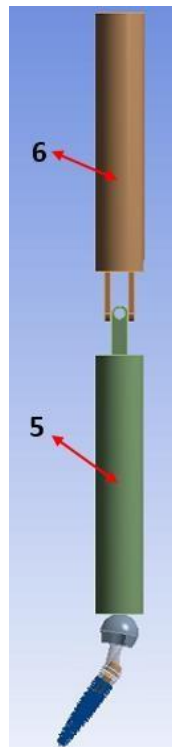
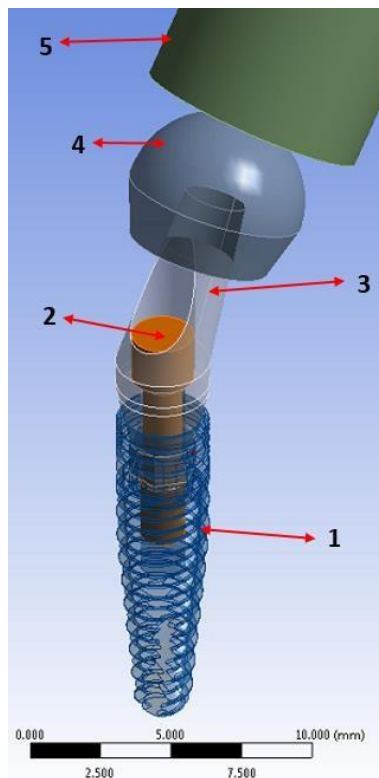


Figure 2 – CAD Assembly

IAW ISO 14801, The loading center is located at the intersection of the longitudinal axis of the free end of the connecting part and the plane normal to the longitudinal axis of the implant and located 8 mm from nominal bone level. Loading direction is applied at a 35 deg angle with respect to the implant axis (figure 3).

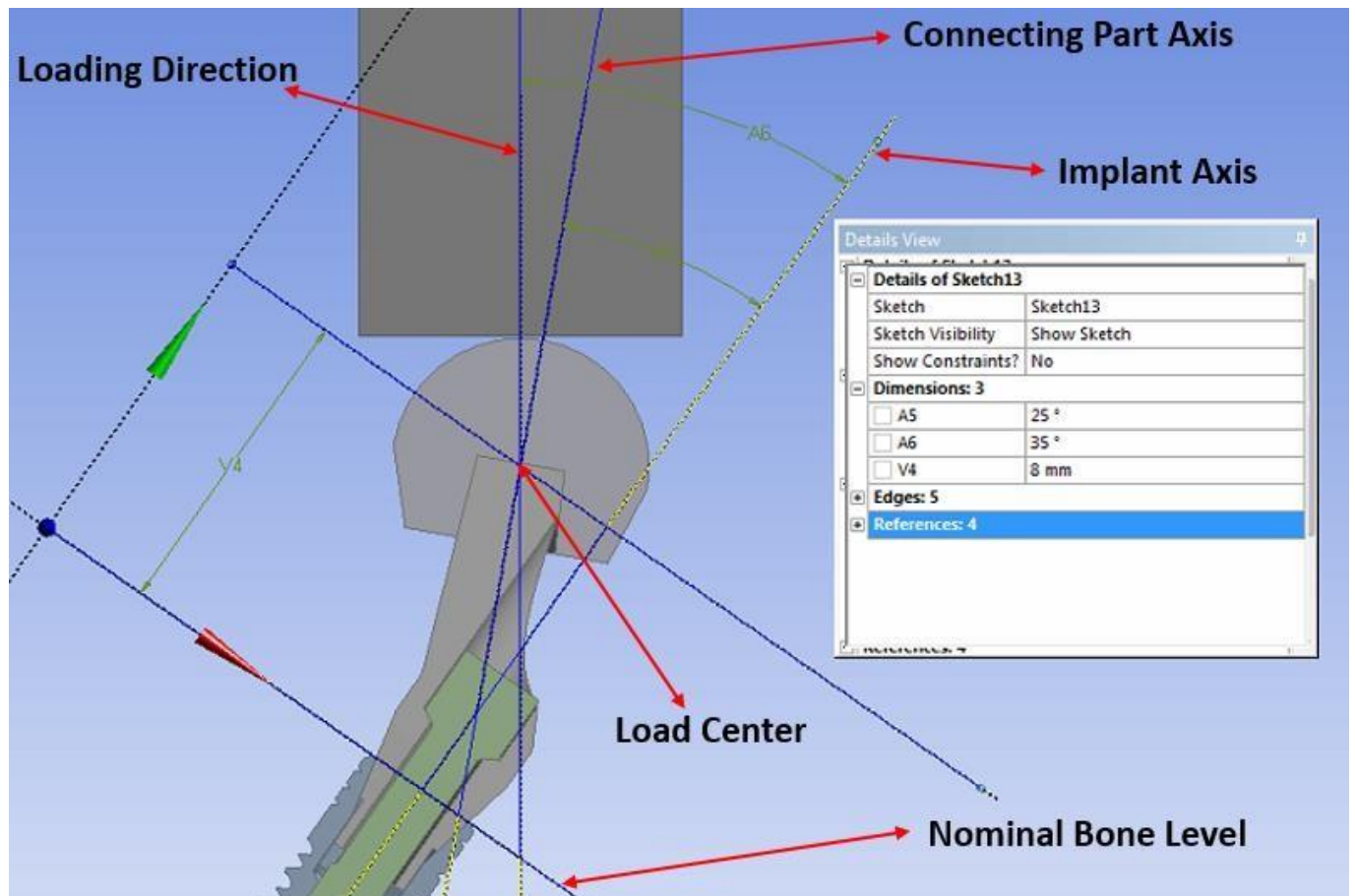


Figure 3

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Material Properties (constitutive Model):

ISO 14801 specifies a method of fatigue testing for dental implants by means of applying cyclic loading.

Figure 1 describes a common implant failure due to fatigue testing

In order to accurately account for the cyclic plastic deformation - which is an essential component of the fatigue damage process – elastic plastic constitutive model will be applied for the FEA model material.

To model plasticity, 2 materials properties are needed:

- **A Yield Function (Yield Critrion):**

Ansys uses Von Misses Yield Criterion which stipulates that yielding initiates when the equivalent Stress

$$\sigma_e = \sqrt{\frac{1}{2}[(\sigma_1 - \sigma_2)^2 + (\sigma_2 - \sigma_3)^2 + (\sigma_3 - \sigma_1)^2]}$$

Equals the Material Yield Strength.

- **Hardening Rule:**

If plotted in 3D Principal Stress space, the Von-Mises Surface is a cylinder aligned with the $\sigma_1 = \sigma_2 = \sigma_3$ Axis and with the radius of the material Yield Strength (Figure 4).

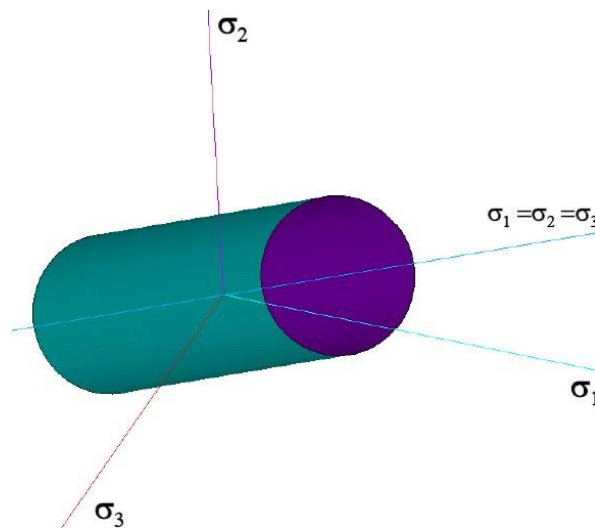


Figure 4

When the state of stress is inside the cylinder, no plastic strain exists. On the edges of the cylinder, yielding will occur and plastic deformation initiates. Outside of the cylinder there is stress state, there for,

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we need an hardening rule which will modify the cylinder as we continue to increase the plastic deformation.

For this Analysis we will use Isotropic Hardening which states that the yield surface expands uniformly during the plastic flow (Figure 5)

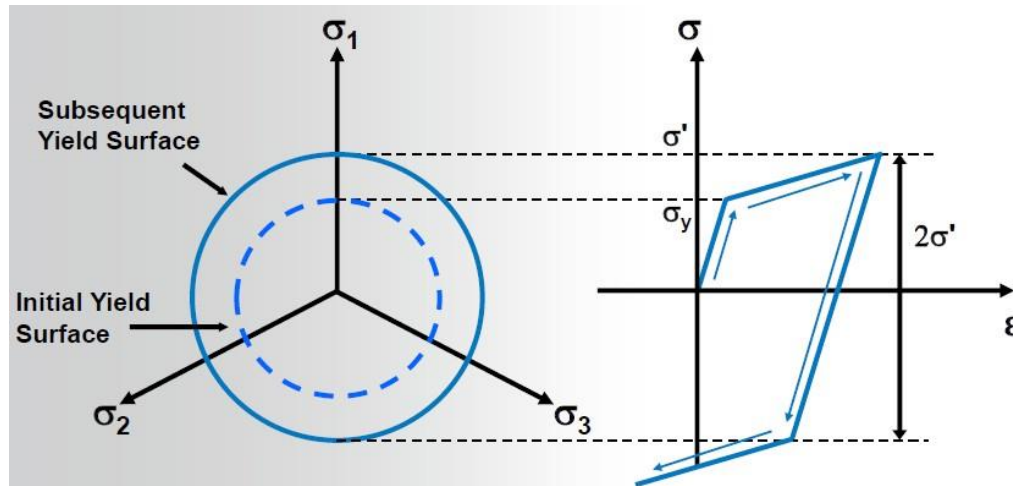


Figure 5

All parts are made of Titanium Alloy Ti6-AL-4V ELI modeled as an isotropic, rate independent solid with a bilinear elastic-plastic constitutive relation assuming isotropic hardening. The following Uni-Axial Tension experiment data (Figure 6) reveals that the material has a module Young of 110 GPa , Yield criterion of 900 MPa and Hardening Module of 1.25 GPa. Poisson Ratio will be taken as 0.3 which is a standard value for titanium alloys.

The Loading Device & Loading Machine are modeled as Perfect Rigid Body to conserve elements and reduce the FEA Analysis Run Time. This assumption is correct due to the very small strains (negligible) these parts are subject to in contrast to the Abutment, Screw & Implant.

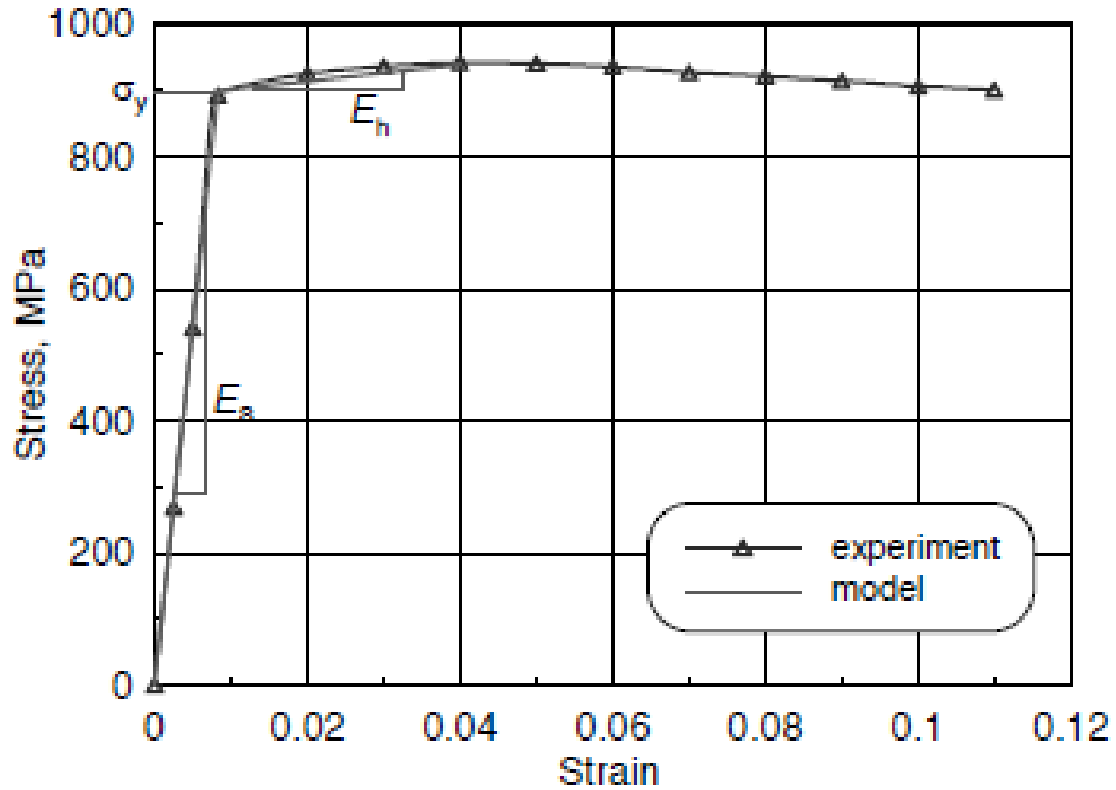


Figure 6 -

Experimental stress-strain curve obtained for Ti-6Al-4V alloy and bilinear elastic-plastic relationship used in FE calculations (E_s – Young's modulus, E_h – hardening modulus)

Source: W.Ziaja, 2009, Finite element modelling of the fracture behavior of surface treated Ti-6Al-4V alloy

In Ansys Workbench 16.1 we insert the material properties via the Engineering Data module (figure 7 & 8).

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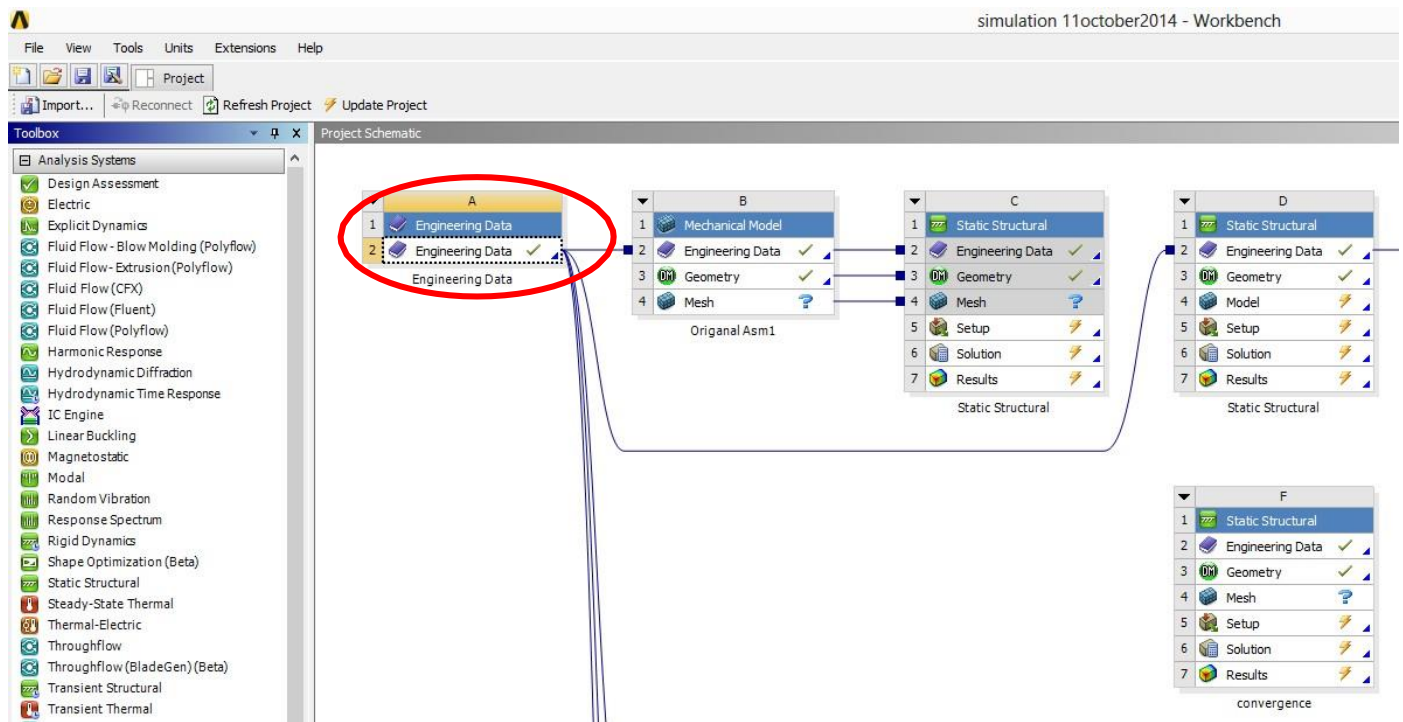


Figure 7

| Outline of Schematic I2, J2, L2: Engineering Data | | | |
|-----------------------------------------------------------|------------------------------|-------------------------------------|--------------------|
| | A | B | C |
| 1 | Contents of Engineering Data | source | Description |
| 2 | Material | | |
| 3 | Titanium Alloy - TI6AL4V ELI | | |
| Properties of Outline Row 3: Titanium Alloy - TI6AL4V ELI | | | |
| | A | B | C |
| 1 | Property | Value | Unit |
| 2 | Density | 4620 | kg m ⁻³ |
| 3 | Isotropic Elasticity | | |
| 4 | Derive from | Young's Modulus and Poisson's Ratio | |
| 5 | Young's Modulus | 1.1E+11 | Pa |
| 6 | Poisson's Ratio | 0.3 | |
| 7 | Bulk Modulus | 9.1667E+10 | Pa |
| 8 | Shear Modulus | 4.2308E+10 | Pa |
| 9 | Field Variables | | |
| 13 | Bilinear Isotropic Hardening | | |
| 14 | Yield Strength | 9E+08 | Pa |
| 15 | Tangent Modulus | 1.25E+09 | Pa |

Figure 8

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Boundary conditions:

According to ISO 14801, when conducting a Static & Cycling Loading Test, Implant is to be clamped 3 mm below nominal bone level. Clamping is achieved by inserting the implant into holes, drilled inside an Aluminum Block, and using EPOXY Adhesive as a filler material between the implant and the Block (Figure 1). The specimen Holder (Aluminum Block) is then clamped rigidly.

In the FEA, the Aluminum Block & Epoxy Adhesive were not modeled. Instead, An Elastic support Boundary Condition (figure 9) having a Constant Foundation Stiffness of $14000 \frac{N}{mm^3}$

This support is chosen over a fixed support due to the fact that the epoxy has a 4.5 GPa Modules of elasticity as well as the fact that the aluminum block also is not perfectly rigid. Thus, when subjected to the compressive force of the Loading Cell, the Epoxy and Aluminum Block allow some small displacement (in the magnitude of 10^{-3} mm) in the Implant clamped bottom.

The Value $14000 \frac{N}{mm^3}$ is chosen as part of a past calibration process with respect to a Static Loading Curve of Experimental Bench results.

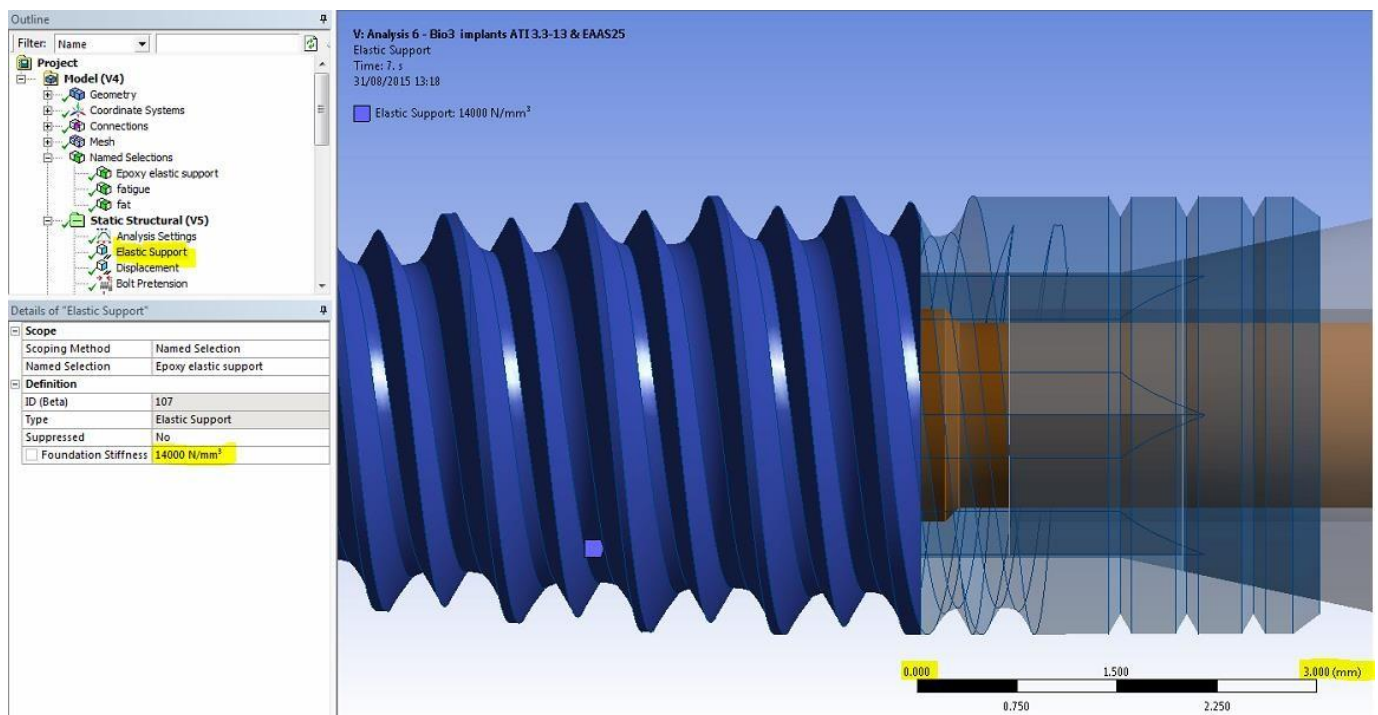


Figure 9 – Elastic Support 3 mm below nominal Bone Level

Loading:

The FEA includes 2 Loading steps:

- Tightening the Screw to secure the Abutment to the Implant;
- Applying Load via the Loading Device;

1st Loading Step - Tightening the screw

During laboratory testing, screw was torqued to a 30 [N]X[cm] value.

Although it is possible to simulate the tightening of the Abutment to the implant by means of applying a moment to the screw, a full threads mesh will result in a large number of elements and a long duration of the analysis (Figure 10).

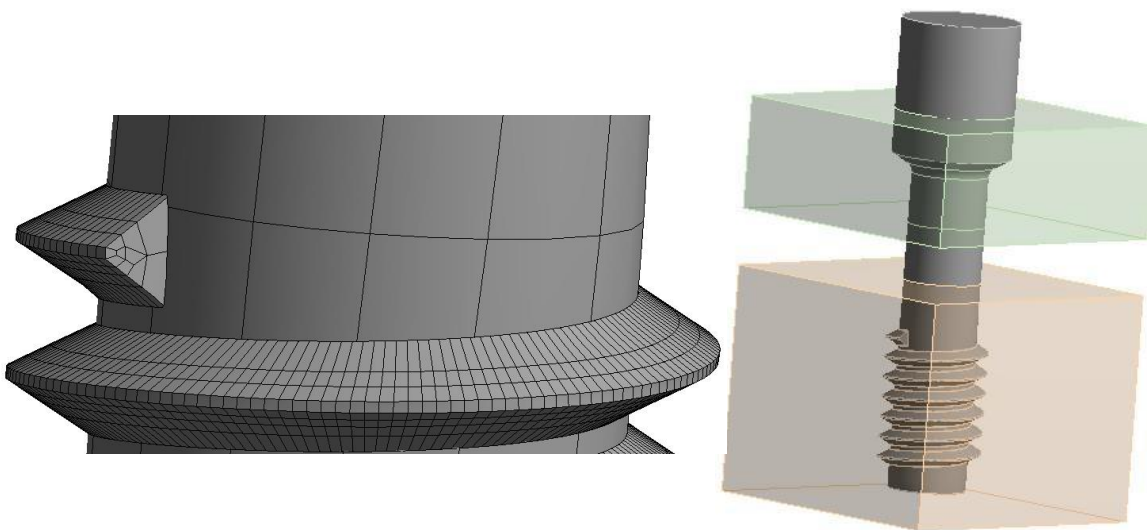


Figure 10

As an alternative, Ansys Workbench 16.1 offers a unique Load Type – Bolt Pretension – to simulate the effect of tightening the bolt as a result of a moment without meshing the threads (Figure 12), instead, the bolt body is modeled as a simple cylinder and a compressive Axial force is applied. During FEA setup a 450 [N] was used to simulate the torquing of the screw, thus fastening the connecting part (abutment) to the implant.

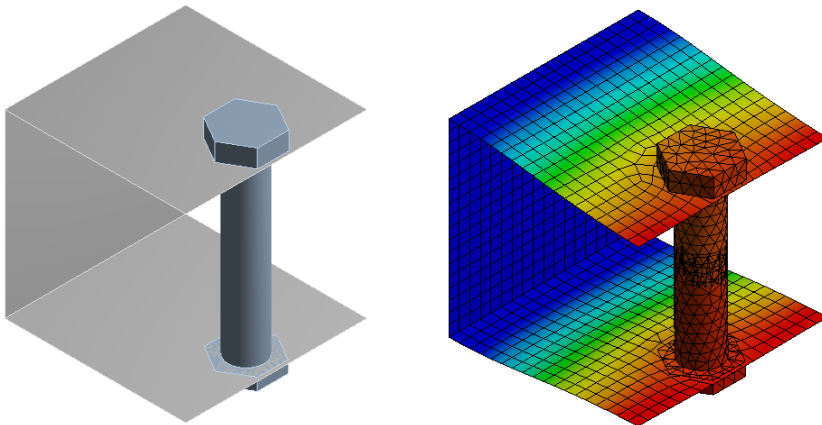
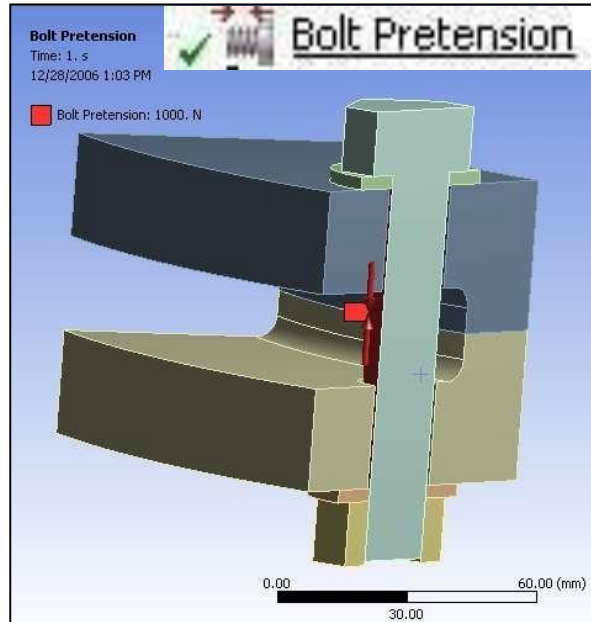


Figure 11

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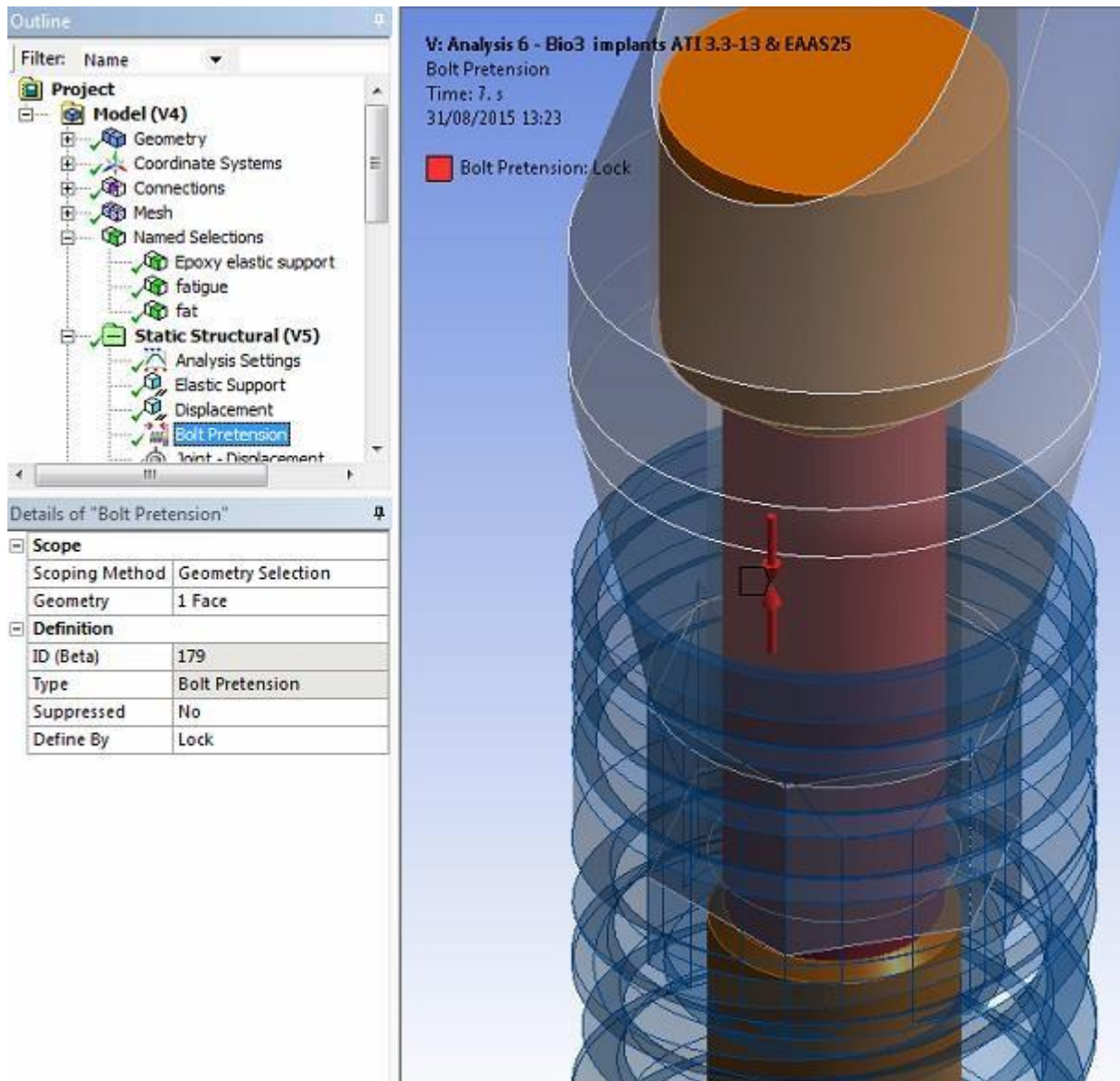


Figure 12

2nd Load Step - Applying Load Via the loading device (Figure 16)

Load Cell is applying a compressive Load at an Angle of 35 Deg with respect to the Implant Axis. A static loading curve of Applied force Vs Loading Device Vertical Displacement is plotted (figure).

Contact Regions & Joints:

The FE model has 5 contact regions and 1 Universal Joint as depicted in Figures 13-18.

Contact, in this FEA, is defined by choosing a CONTACT & TARGET surfaces, to define each contact regions.

Contact Algorithm is Augmented Lagrange which applies Repealing Force as a function of the penetration distance of the CONTACT body into the TARGET body.

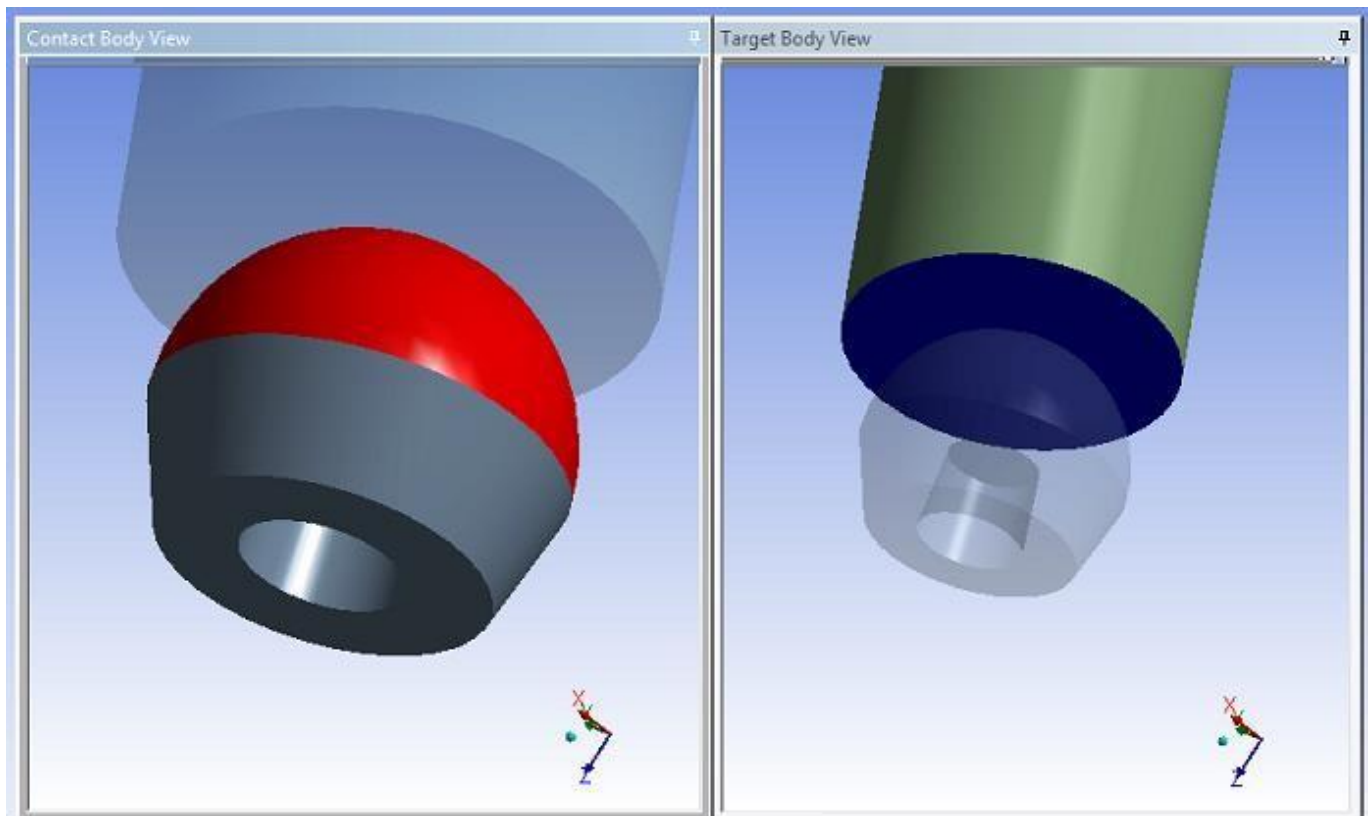


Figure 13 - Bonded Contact between the Screw and the Implant.

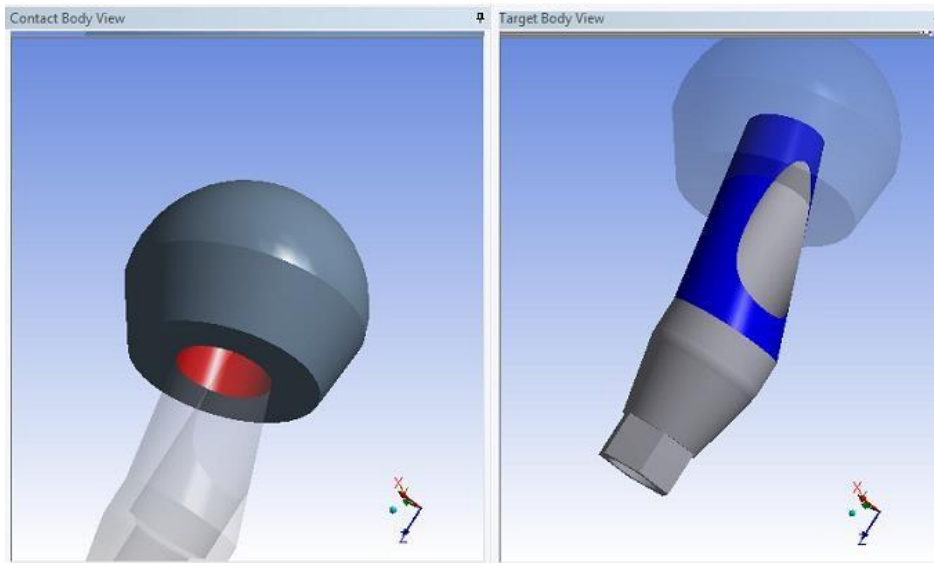


Figure 14 - Frictional Contact between the Abutment and the Implant. Friction coefficient 0.1

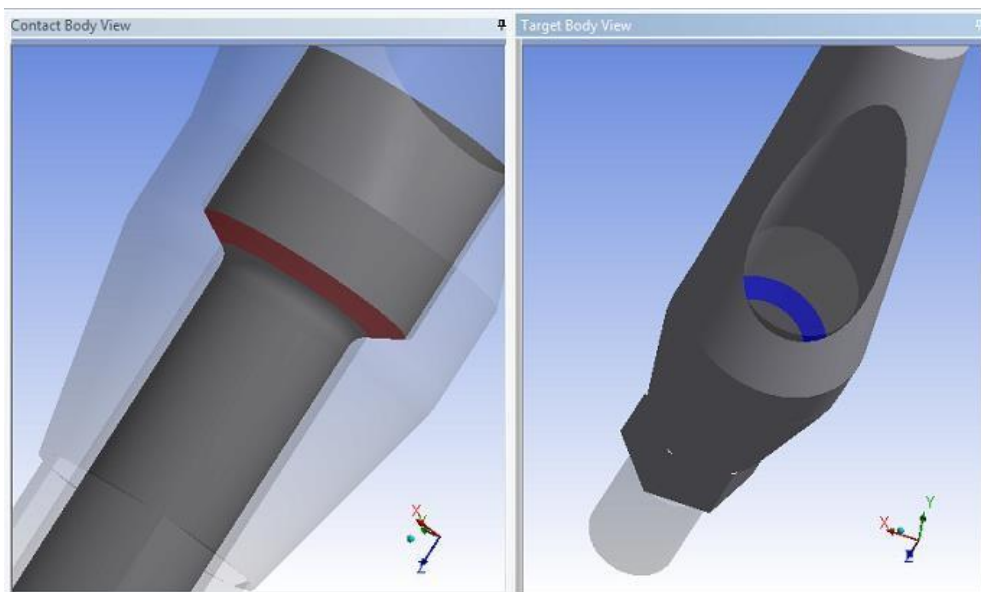


Figure 15 - Frictional Contact between the Abutment and the Implant. Friction coefficient 0.1

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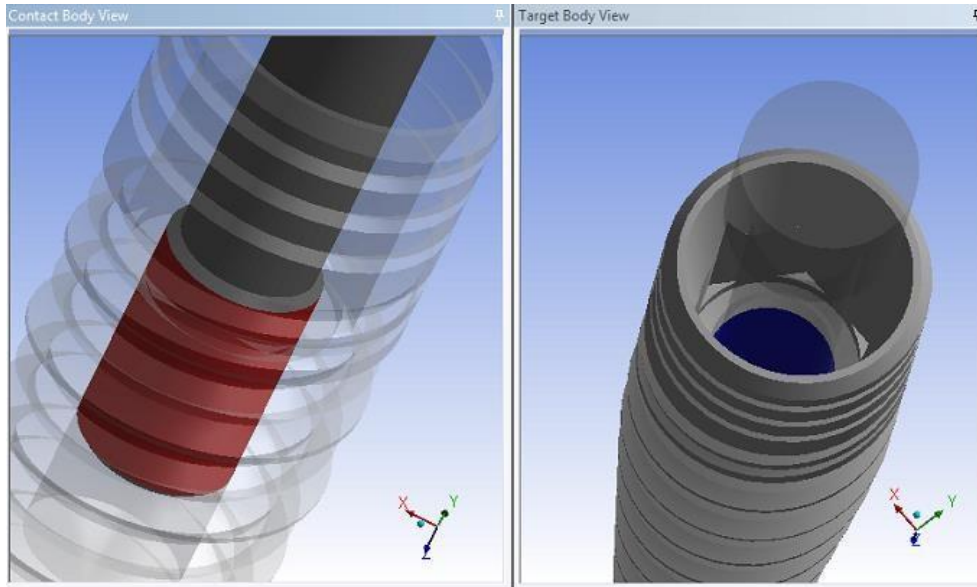


Figure 16 - Frictional Contact between the Screw and the Abutment. Friction coefficient 0.1

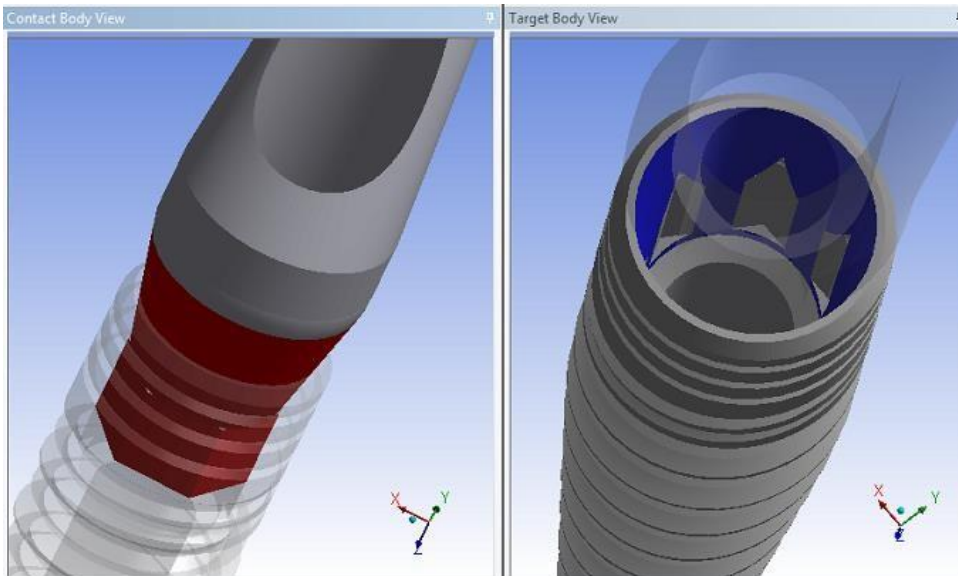


Figure 17 – Frictional Contact between the Hemispherical Loading Member and the Abutment. Friction coefficient 0.1

According to ISO14801, the Loading Device shall be clamped to the loading machine by means of a universal joint in order to maintain the loading direction at a 35 angle to the implant axis (figure 17). In the FEA Analysis setup we insert a universal joint. The joint has a local Coordinate system (figure 18) such that the rotations around the X & Z axis are free – no reaction moment can form in these directions.

ISO 14801:2007(E)

5.2.6 The loading force shall be applied to the hemispherical loading surface by a loading device with a plane surface normal to the loading direction of the machine. The loading device shall be unconstrained in the transverse direction, so as to not reduce the magnitude of the applied bending moment. This shall be accomplished by means of a universal joint or point contact at the junction of the loading member and the test machine structure. The junction shall be located at least 50 mm from the hemispherical loading surface.

Figure 17 – Section 5.2.6 of ISO 14801

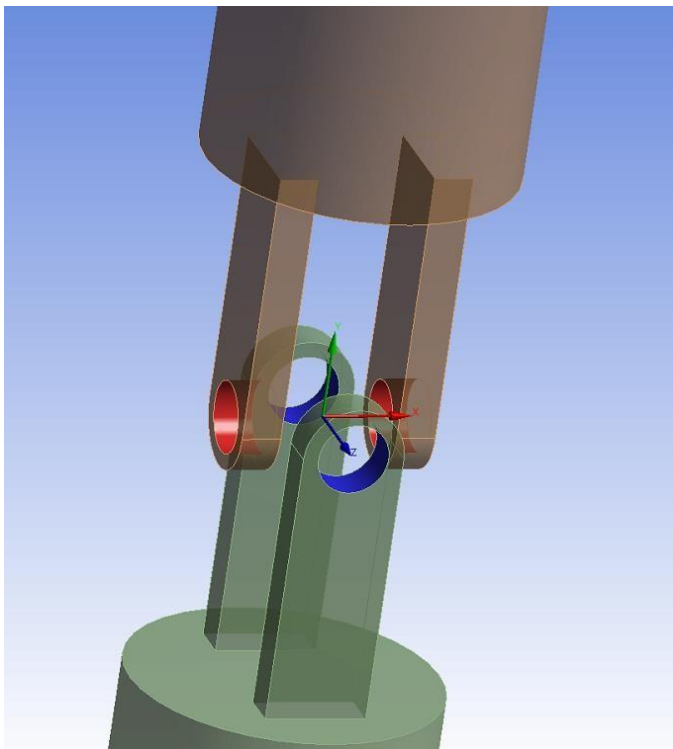


Figure 18 – Universal Joint

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Phase 2 – FE Fatigue Analysis

Similar to the Static Loading Test, ISO 14801 also includes guidelines for testing the implant for Fatigue related failure. From the static loading test, we extract the value in which static failure occurs, 80% of this Load is defined as the peak value. For Fatigue testing, the load shall vary sinusoidally between 100%-10% peak value until failure occurs, in which case the peak value of the load is lowered and a new fatigue test is conducted, thus generating a curve which describes the peak Load (exerted by the test Machine) Vs the No. of cycles to failure:

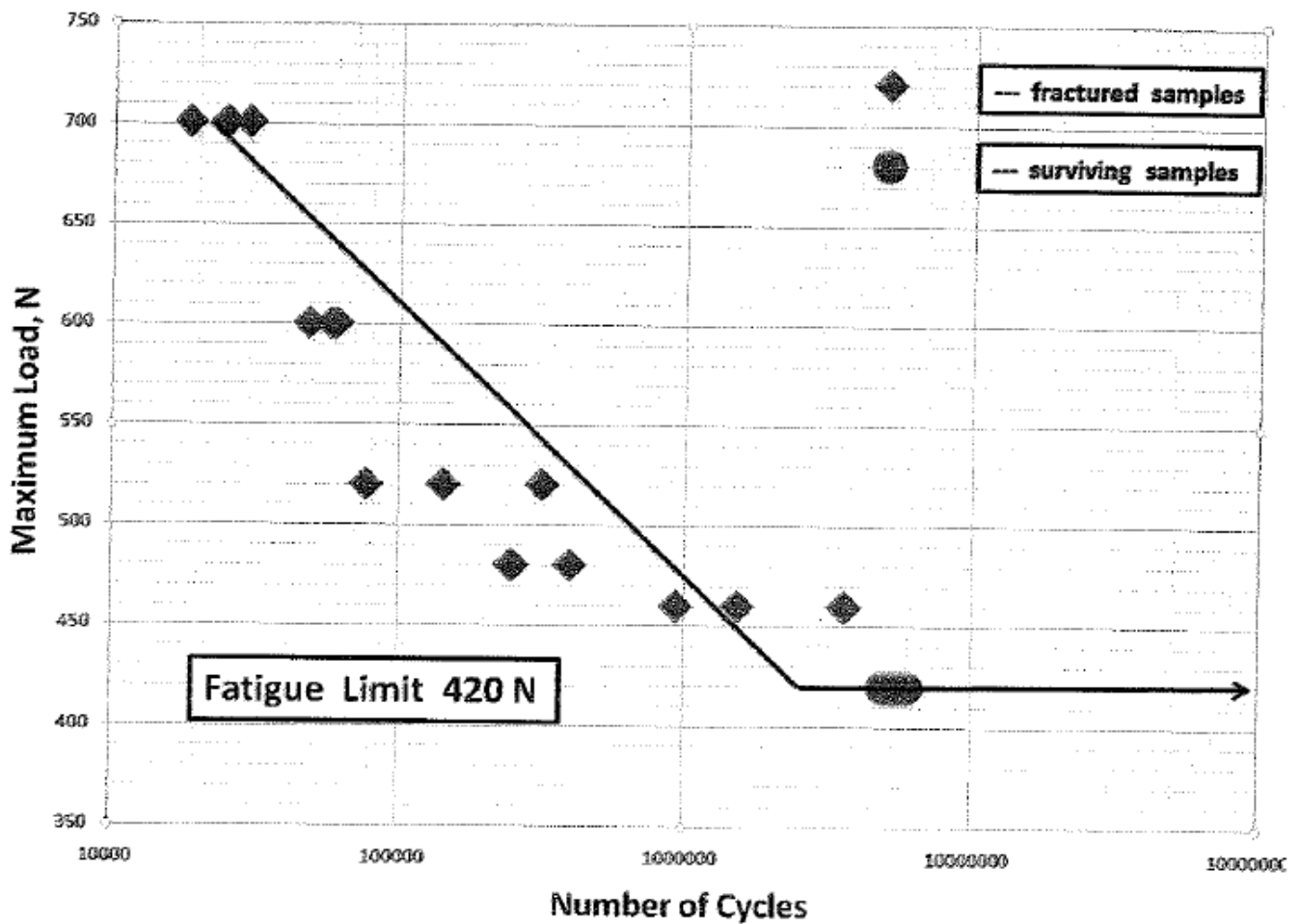


Figure 19 – Fatigue Test Results, Report # B/112637 (Different Implant & Abutment), dated July 3, 2011.

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Ansys Workbench 16.1 Fatigue Module:

Ansyes Workbench 16.1 leverages the ability to simulate fatigue related failure based on several technics available for standard evaluation of a product Life span under variable repeated loading cycles.

In order to perform Fatigue Analysis in Ansys Workbench 16.1, the following characteristics need to be defined:

- Fatigue Analysis Type
- Loading Type
- Mean stress effect
- Multiaxial Stress correction

Fatigue Analysis Type:

We will use for this model the Stress-Life approach which is based on S-N curves of materials and is suited for HCF (>100000 cycles). Stress Life deals with Total Life and not initiation or propagation of cracks. Stress Life analysis determines the equivalent alternating stress at each point in the model, from that, the expected life is derived immediately using the Material S-N curve (Which needs to be defined as a material property).

After we have the S-N curve of Ti6-AL-4V ELI we can continue analyzing the the Abutment-Implant configurations. The S-N curve of the Titanium Alloy Ti6-AL-4V ELI is inserted as material property in the Ansys Workbench 16.1, Engineering Data Module (Figure 20).

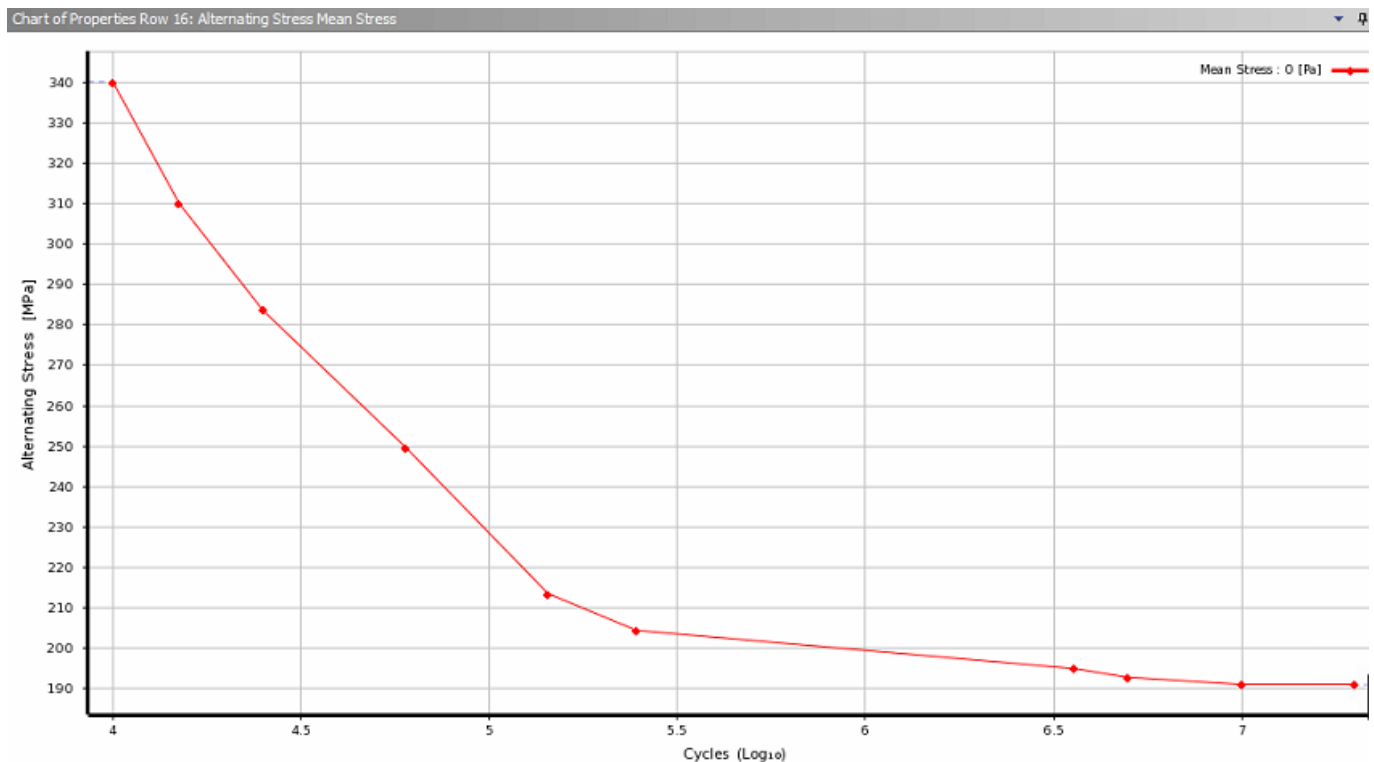


Figure 20 – Ti6-AL-4V ELI S-N curve

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Loading Type:

For this model, we'll use a Loading type of Constant Amplitude-Non proportional Loading. This loading type is best use when Bolt Loads and Non-Linear contact are present in the model (as in our case). This loading type consist out of two load cases, such as applying an alternating load superimposed on a static load – similar to our case, where we have one static load case - the Bolt Load – and the alternating Load caused by the Testing Machine.

Mean Stress Effect:

No mean stress diagrams were applied. The calibration process (with respect to the Test results) will serve as a good reference for the accuracy of the results

Multiaxial stress correction:

Experimental test data is mostly uniaxial whereas FE results are usually multiaxial. Stress must be converted from a multiaxial state to a uniaxial one. In Ansys fatigue module we can choose Von-Misses stress or Max shear, or any of the principal stress or any of the 6 stress components and much more. In this model we have chosen to use the σ_y since it has a maximum value in the upper part of the implant (Figure 22), where test results have shown cracks will initiate from, and progress. The σ_y is also an opening stress, which will cause microscopical cracks to propagate under MODE I. In figure 21 we can see a Side & Top View of Implant deformation pattern. It is notable that the implant stretches the most at the sides resulting in high Y-Direction Normal Tensile stress.

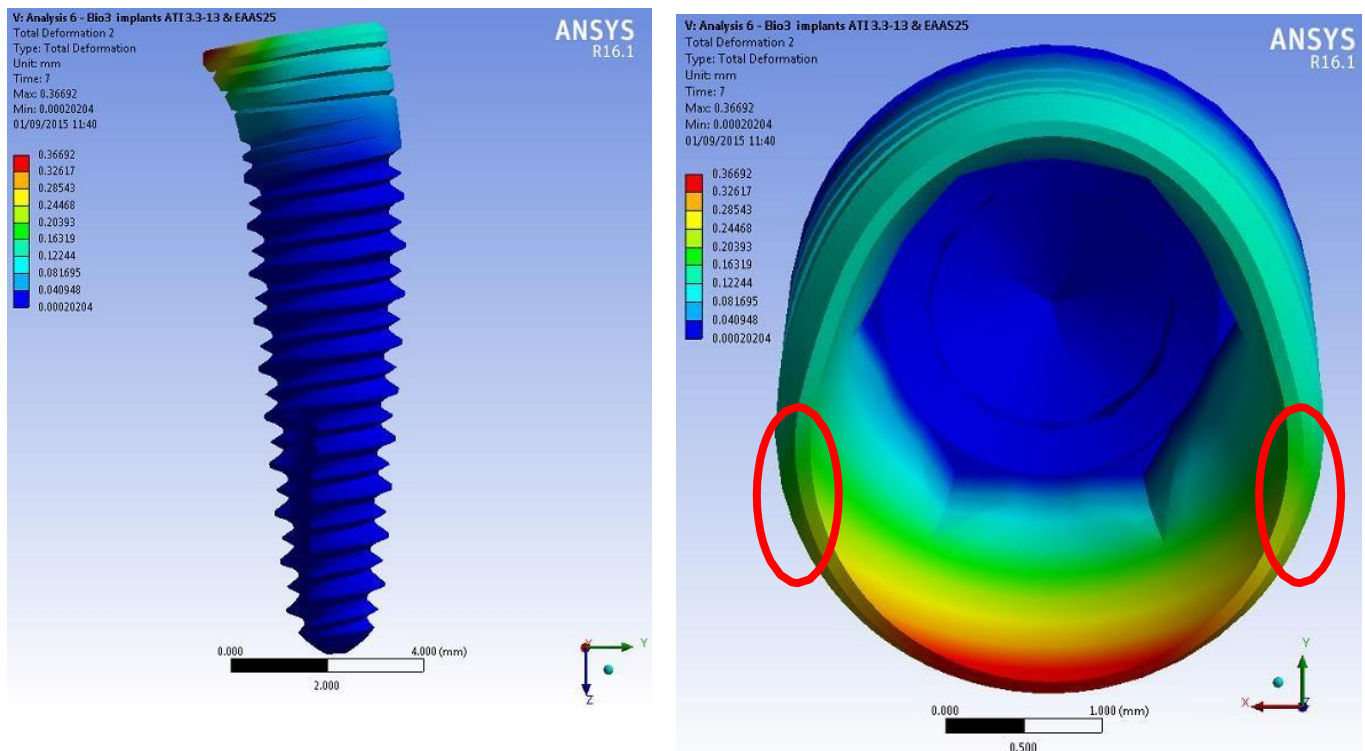


Figure 21 – deformation scale X 3

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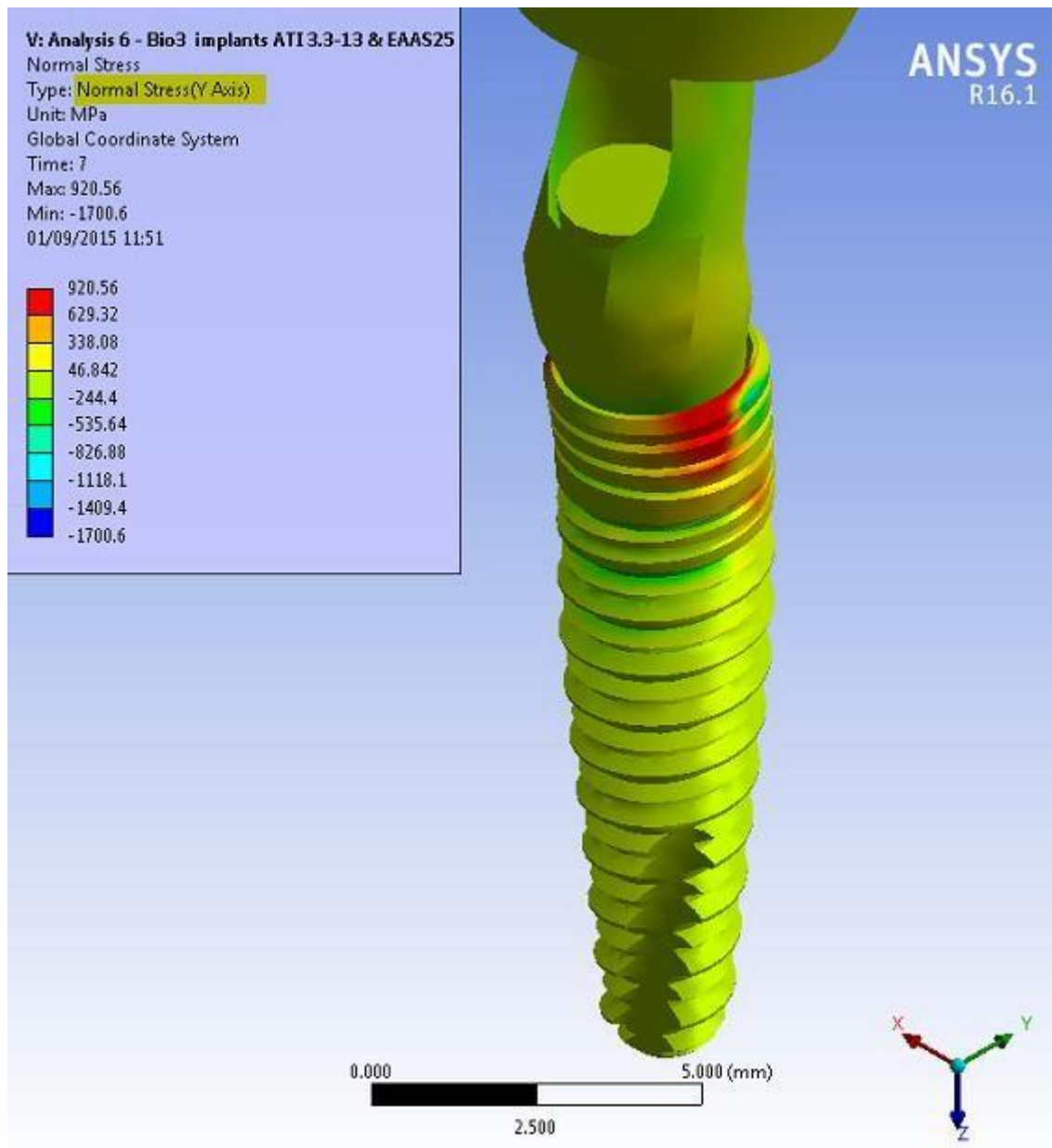
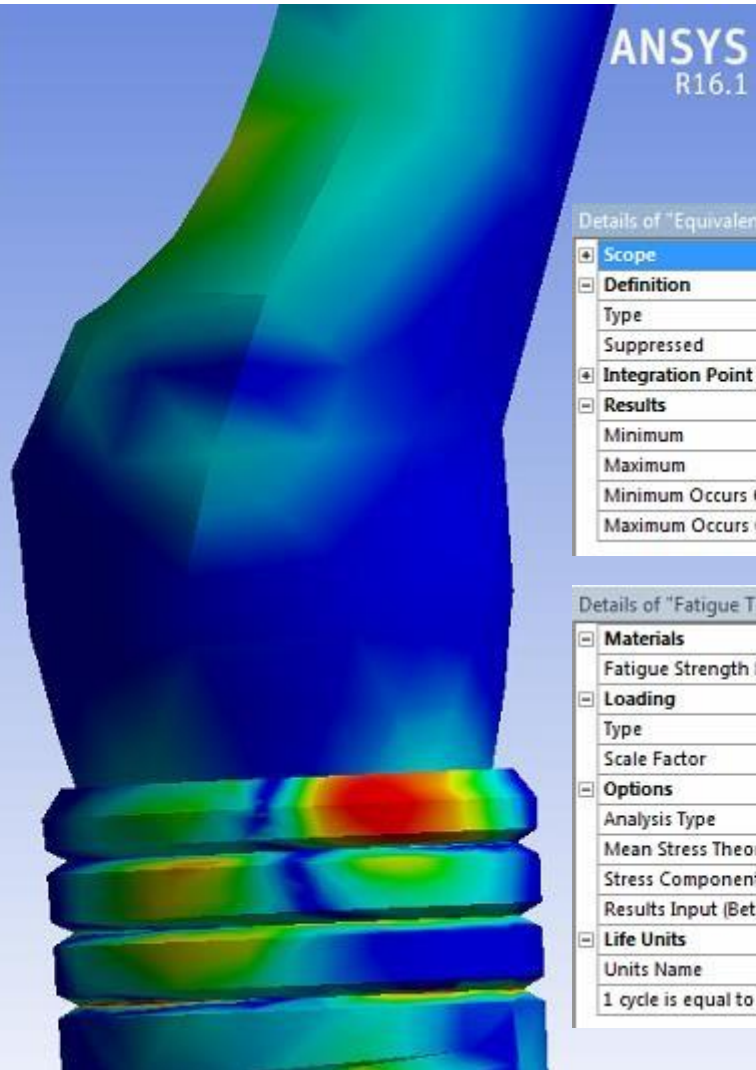
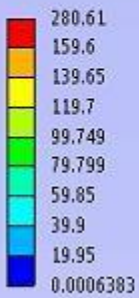


Figure 22 – Normal Stress in the Y-Direction

We apply all of these Fatigue setting into Ansys Workbench 16.1 by a simple GUI and results of equivalent alternating stress and Life to failure are visible (Figure 23 & 24).

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Equivalent Alternating Stress 4
 Type: Equivalent Alternating Stress
 Unit: MPa
 Max: 280.61
 Min: 0.0006383
 01/09/2015 12:09



Details of "Equivalent Alternating Stress 4"

| | |
|---------------------------|-------------------------------|
| Scope | |
| Definition | |
| Type | Equivalent Alternating Stress |
| Suppressed | No |
| Integration Point Results | |
| Results | |
| Minimum | 6.383e-004 MPa |
| Maximum | 280.61 MPa |
| Minimum Occurs On | implant |
| Maximum Occurs On | implant |

Details of "Fatigue Tool"

| | |
|------------------------------|------------------|
| Materials | |
| Fatigue Strength Factor (Kf) | 1. |
| Loading | |
| Type | Non-Proportional |
| Scale Factor | 1. |
| Options | |
| Analysis Type | Stress Life |
| Mean Stress Theory | None |
| Stress Component | Component Y |
| Results Input (Beta) | Stress |
| Life Units | |
| Units Name | cycles |
| 1 cycle is equal to | 1. cycles |

Figure 23 – Equivalent Alternating Stress

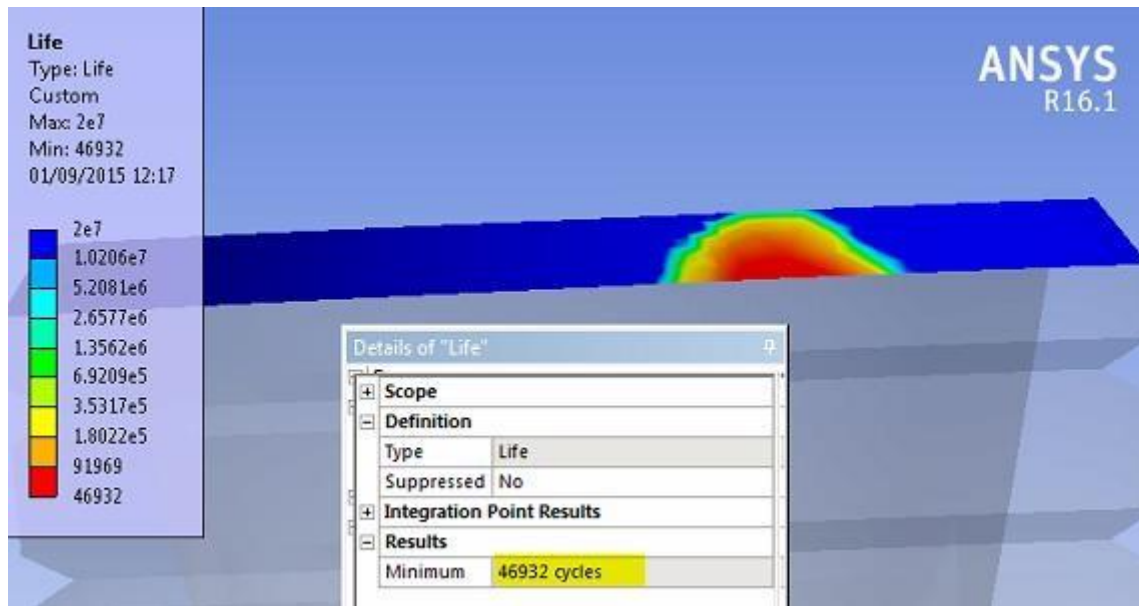


Figure 24 – Expected Life Span (in Cycles) due to Equivlant Alternating Stress

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Phase 3 – Results

Static Loading

FEA results show the same tendency as in the Test results, mainly the linear relation at the beginning of the Static Load Test. This "Stiffness" of this Abutment-Implant configuration (which may be represented by the derivative of the curve) remains constant for the beginning of the loading cycle and becomes smaller and smaller as the Loading Device extends further and further until a Limit Peak Load is reached. From that point on, the Loading device exerts a lower and lower force, since the Abutment bending is so high and the Loading machine needs not exerts a high force in order to continuing with the bending of the Abutment-Implant Configuration.

This can be visualized by looking at the deformation at different extensions of the loading machine. At the linear phase, it is hard to see the difference in the deformation, however, toward the end of the static loading test, the deformation changes rapidly.

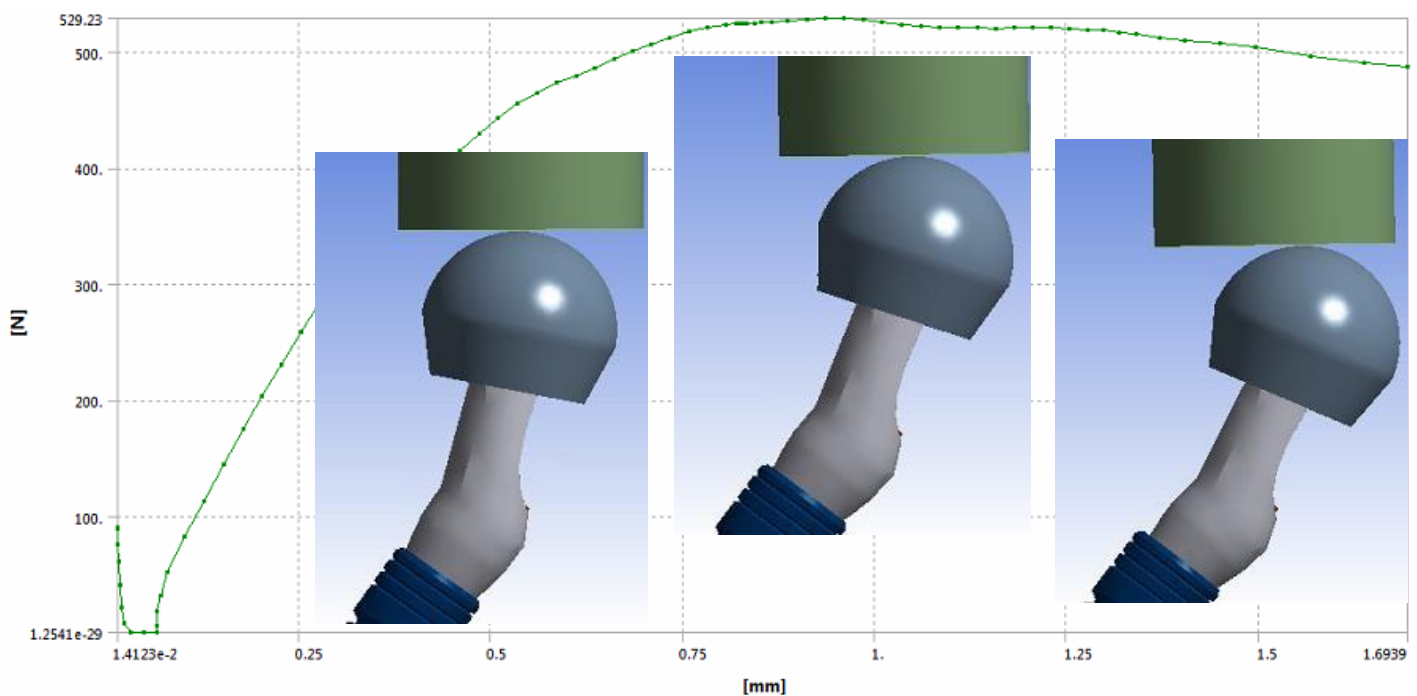


Figure 25 – Static Loading Curve

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The derivative of the linear phase and the peak Load are the 2 features of the curve that are the most important, in terms of validating with experimental bench testing due to the fact that fatigue testing will be conducted at Load level which match the linear phase of the curve.

The Elastic Support Boundary condition (described earlier) has the biggest effect on the curve pick Load and derivative of the Linear Phase. The stiffer the elastic support is, the higher the derivative and the peak load will be. This is another reason not to choose fixed support for the implant lower side, since fixed support can be thought has the equivalent of an elastic support with infinite "Foundation Stiffness".

Fatigue results

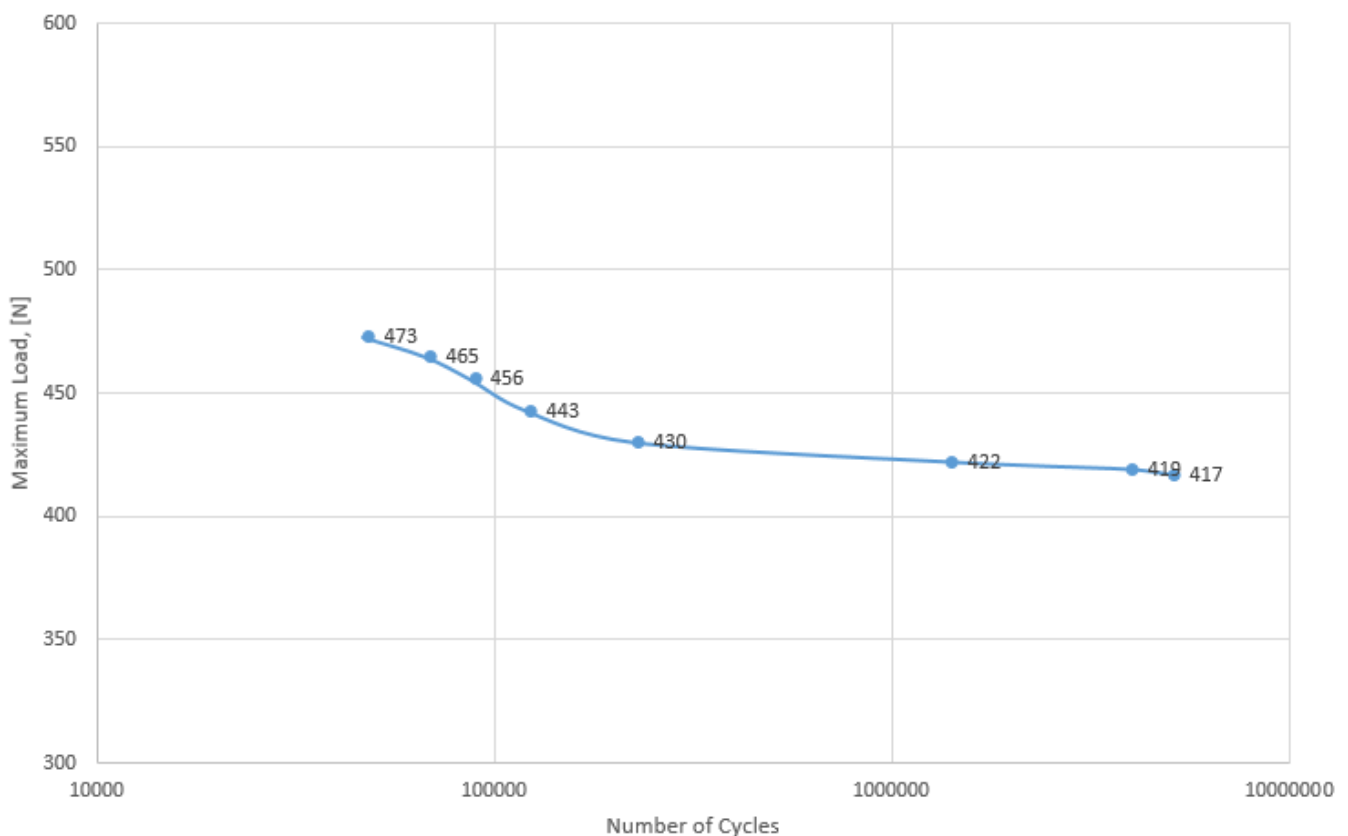


Figure 26–Fatigue Limit Curve – Bio3 Implants ATI 3.3x13 & EAAS25

Phase 4 – Conclusions

The following Implant-Abutment configuration were FE analyze using Ansys workbench 16.1:

- Bio3 Implants ATI 3.3x13 & EAAS25 Abutment

The resulted Static Limit predicted by the FEA is:

- Static Limit: 529 [N]

The resulted Fatigue Limits predicted by the FEA for the different Abutments are:

- Fatigue Limit: 417 [N]