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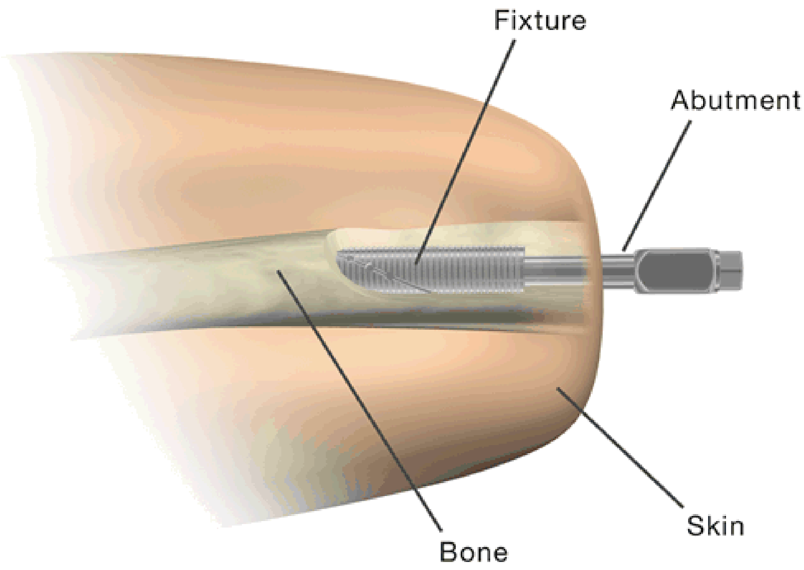

Finite element study of osseointegrated orthopaedic implants

Master's Thesis in Applied Mechanics

DAVID FORS

Department of Applied Mechanics
Division of Material and Computational Mechanics
CHALMERS UNIVERSITY OF TECHNOLOGY
Göteborg, Sweden 2013
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Cover:
Picture of the OPRA implant inside the bone (source: Integrum 2013).

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ABSTRACT

An alternative way to attach lower limb prostheses on amputees, from the traditional vacuum sockets, has been developed by Integrum using so-called osseointegration, called OPRA. The system named OPRA is based on the technique where titanium implants are operated into the bone of the stump to act as a bridge between the bone and prosthesis. Integrum are now in the process of developing a new generation of implants. The purpose of the master thesis has been, to compare the fatigue strength of the new and the old design. The analyses have been performed by comparing results from finite element (FE) simulations on the implants. The results shows that the old implants have two different fatigue weak points: i) fretting fatigue on the contact between abutment and fixture and ii) plain fatigue failure in the screw due to high stress amplitude, especially with a gap in the contact between the fixture and abutment. The result also shows that the fatigue life is longer on the new generation of implants.

Key words: Osseointegration, finite element, prostheses, lower limb prostheses, Integrum, fretting, fatigue.

Contents

Preface

This master thesis project has been conducted during the spring of 2013 in collaboration with Uniso Technologies and Integrum as the final part of the master program Applied Mechanics. Firstly I would like to thank my supervisors Mats Johansson at Uniso, Håkan Lindström at Integrum and Martin Fagerström at Chalmers University, for the support and help with my master thesis. I would also like to thank the colleagues at Uniso for their help.

Integrum are in the process of developing a new version of lower limb implants in order not to expose Integrums company's secrets to the public, some pictures and result have been placed in a confidential Appendix.

Göteborg June 2013

David Fors

1 Introduction

This master theses project, has studied the structural strength of lower limb osseointegrated bone implants using the finite element method. In particular FE-simulations of the mechanical bending tests have been performed to explain the fatigue mechanics of the OPRA system.

1.1 Background

A person with amputees often uses prostheses to improve the quality of day to day life. Integrum has introduced an alternative way to fasten the prosthesis to the body. Using titanium implants operated into the bone of the patient, replacing the vacuum sockets that traditionally are used to fasten prostheses to the body. The Technique of attaching titanium implants to the body is based on titanium's capacity to osseointegrate which is defined as "the formation of a direct interface between an implant and bone, without intervening soft tissue" (Hagberg et al. 2008) resulting in a strong bound between titanium and bone.

Integrums implants for attaching prostheses to the stumps located at the lower limb are called OPRA (Figure 1). The OPRA implants consist of three parts: a fixture that is surgically operated in to the bone of the lower limb stump, an abutment which is the part connecting the prosthesis to the fixture inside the bone and the screw which is used to join the abutment and fixture through applying clamping pressure between them.

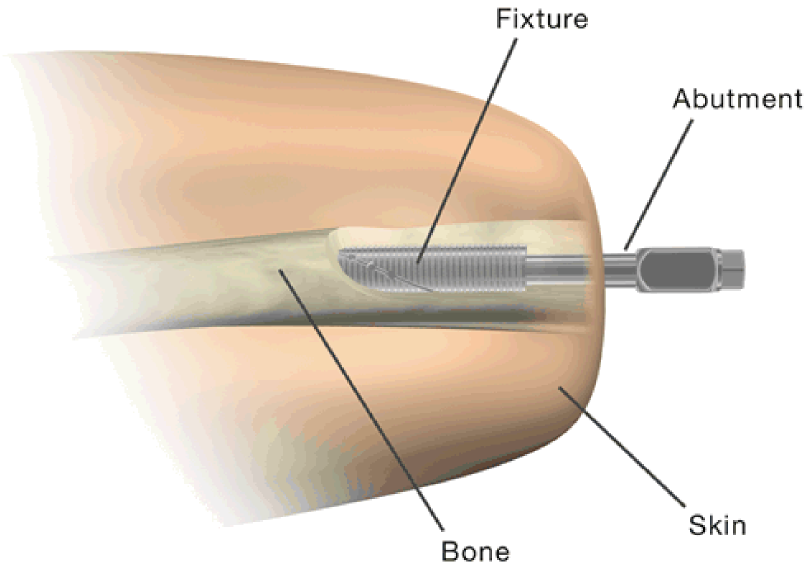

Figure 1: Picture of the OPRA implant inside the bone (source: Integrum 2013).

The prosthesis is supposed to act as the missing leg of the patient helping them to support and move their body, resulting in that the fixture and abutment is subjected to a wide variation of mechanical loads due to the activities of the patient. It is therefore important to ensure that the parts can withstand the forces applied to them and that, if they fail, they fail in a way that makes it possible to replace the parts. To ensure that the OPRA implants can withstand the forces applied, finite element analysis becomes a key part. By the use of finite element analysis a final product with longer life can be achieved, which increases the sustainability of the product by lowering the number of replacement parts needed.

Integrum has to this day installed over 200 OPRA implants on patients from all over the world (Integrum 2013). For most patients, the implants work fine but for some of the patients the implants are failing due to mechanical failure. Integrum has therefore started to develop a new generation of implants called OPRA 2.

1.2 Purpose

The purpose of this thesis is to better understand the fatigue properties and mechanisms of the osseointegrated bone implants (OPRA systems), so that the old and new generations of OPRA prostheses can be compared in terms of fatigue strength.

1.3 Limitations

The load data used for the FE-simulations has only been taken from the mechanical testing performed by Integrum, meaning that all simulations and comparisons have been made against mechanical tests. No attempt to create or simulate real load cases for patients has been made. The project has not included any testing on the implants, other than Integrums validation testing, because of limitations in testing resources.

The focus of the thesis is on the mechanical strength of the implants. The bone and prostheses mechanical strength will not be analysed. In the FE-analysis, the effects of the bone have not been considered because of the large uncertainties of the material properties of bone. The fixture has been assumed to be perfectly fixed in the bone.

1.4 Report disposition

The remaining part of the report is structured in the following way. First, a background chapter describing Integrum, lower limb amputees and the OPRA product. This is followed by a theory chapter in which the fatigue and fretting mechanisms are more closely presented. The subsequent method chapter describes the finite element simulations and how fatigue and fretting is evaluated. After the method chapter, an analysis chapter provides more detailed descriptions, results and conclusions for the analysis. The thesis is concluded with a discussion about the loads used in the simulations followed by a conclusions and further recommendation chapter.

2 Introduction to OPRA and Integrum

In the chapter below follows a short introduction of the company Integrum and its product for lower limb amputees OPRA.

2.1 Integrum

Integrum is a company in the field of osseointegration founded by Rickard Brånemark in 1998. Integrum produces titanium-bone implants that act as the link between the bone and the prosthesis. Integrum's main product is lower limb prostheses, but they also provide osseointegrated prostheses for arms and fingers. The technology of osseointegrated bone implants originates from the dental industry.

2.2 Osseointegration

In 1952, Per-Ingvar Brånemark conducted research on blood flow in rabbit bones. During the experiments, Brånemark utilized a titanium chamber and when it was time to remove the titanium from the rabbit bone it was discovered that the bone and titanium had intergrown forming a strong bond between the titanium and the bone without any intervened soft tissue. In 1965, the world's first osseointegrated dental implant made in titanium was installed. The technique has since then grown to become a standard treatment in dental applications. The osseointegration technique has also been further improved to become widely used in several other medical applications.

2.3 Lower limb prostheses

There are several reasons for a patient to need lower limb prosthesis. The most common reasons are peripheral vascular disease, trauma, infection, tumour and congenital limb deficiency. Prostheses are often used to increase amputated patients quality of living.

The standard way to fasten prostheses is to use a vacuum socket. A vacuum socket is a mould that is manufactured after the amputated stump. The cast is mounted on the amputee with vacuum or back pressure between the stump and cast to ensure that the prosthesis is secured to the body. For most patients, the vacuum socket works fine but the technique has some disadvantages. Some patients that use the sockets experience sores, rashes and pain in their stump. Back pain and pain in the other limbs may also appear (Effeney et al. 1983). Vacuum sockets also requires long mounting time every day, up to five minutes, and the socket has to be recasted every time the stump is changed, typically every second year. If the amputee is short, it can be impossible to fasten the prostheses using a socket since the length is not sufficient to give enough support and retention (Hagberg et al. 2008).

Integrum are producing an alternative to the traditionally socket prostheses using an osseointegrated titanium implant called OPRA (Osseointegrated Prostheses for the Rehabilitation of Amputees). The OPRA works as a bridge between the bone of the amputee and the prosthesis, see Figure 1 and Figure 2. The technique is based on so-called osseointegration that provides many advantages for the patient life such as decreased mounting time, increased comfort, and control of the prostheses, leading to an increased ability to walk. Some patients may also experience sensory feedback; so-called osseoperception.

One weakness with skin piercing bone implants is that patients have an increased sensitivity to infections due to the hole in the skin. Osseointegrated implants also require an amputee with full grown skeleton in good condition to be able to install the implant in the amputee (Hagberg et al. 2008 and Lundberg et al. 2011).

Figure 2: Picture of a patient with the OPRA implant and prosthesis (source: Integrum 2013).

For a patient to be able to walk on an OPRA implant, there are several steps the patient has to go through. First a hole is drilled in the center of the amputee's bone and the fixture is installed. The bone is then left to heal for approximately six months to intergrow with the titanium fixture. After six months, a second operation is performed in which the abutment and screw are assembled on the fixture. After the second operation, the patient has to go through a period of rehabilitation so that the bone and tissue can support the prostheses. Finally, the prosthesis is attached to the abutment through a security coupling device, similar to those on downhill skis, to ensure that the implant will not be exposed to extreme loads caused by for example falling.

2.4 Original OPRA implants

The original OPRA implant consists of three parts, see Figure 3, all manufactured in titanium. The abutments are manufactured in titanium grade four for old implants and titanium alloy Ti6Al4V for new implants. Titanium has many advantageous properties for biomechanical applications. Firstly it has the ability to osseointegrate. It also has a god corrosion resistance, strength to weight ratio and it is biocompatible, meaning that it is not harmful to the body. On the negative side, titanium is a relatively expensive material because of its high production costs.

The abutments have a cylindrical shape with a quadratic head on which the prosthesis is attached. A hole is drilled through the abutment for the screw. The bottom of the abutment has a hex shape to transform torque from the abutment to the fixture. In the middle of the abutment there is a press fit on which the forces are transferred from the abutment to the fixture. The screw is used to create clamping pressure between the fixture and abutment and is made of titanium Ti6Al4V also known as Ti grade 5. The fixture is hollow. The cavity towards the bone side is there to help the bone and fixture grow together and form a strong connection. On the other side of the fixture, the screw and abutment are connected. The inside of the fixture includes the counter parts of the press fit and the hex geometry. The fixtures are manufactured in commercially pure (Cp) titanium with diameters of the fixture ranging from 16 to 20mm in order to fit the patient's bone. The fixture has threads on the outside of the fixture to improve the connection between the bone and the fixture.

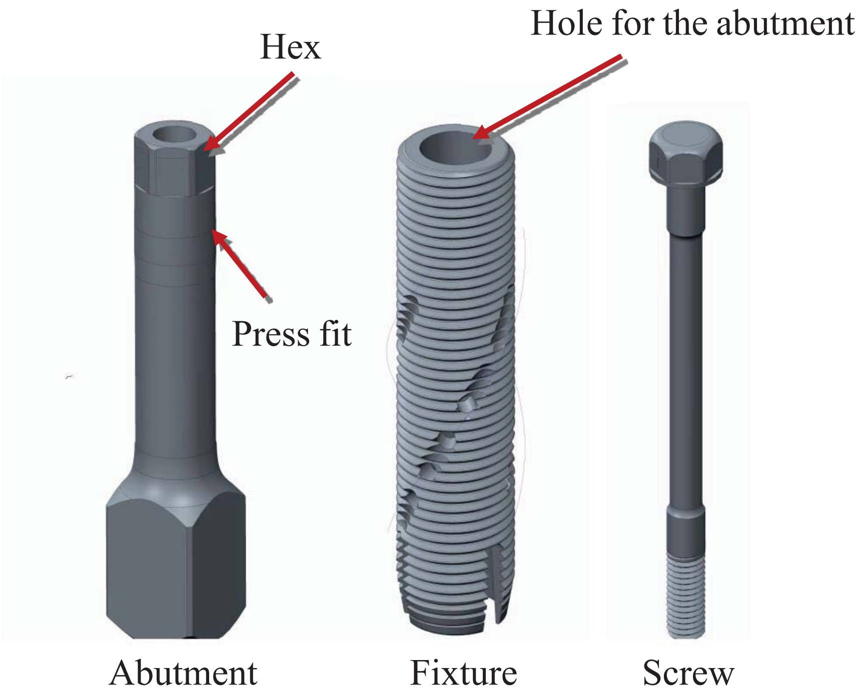

Figure 3: Figure with the parts in the OPRA system.

2.4.1 Original OPRAs weakness

The OPRA system is designed according to the weakest-link concept, which means that parts that are easier to replace shall fail before parts that are difficult to replace. For OPRA, this means that the abutment and screws are designed to fail before the fixtures. However, experience has shown that these failures sometimes happen earlier than desired, mainly because of fatigue fracture.

Failure of the system due to single overload happens very rarely, and if it happens it is mostly in conjunction with an accident such as a fall.

2.5 OPRA 2

To increase the capability of the OPRA system a new version of OPRA called OPRA 2 is under development by Integrum. See Appendix 1for a description of OPRA 2.

2.6 Dynamic bending tests

As a part of Integrums verification process of the new OPRA 2 design, dynamic bending tests were conducted in order to ensure that the implants have sufficient fatigue life.

2.6.1 Test setup

The tests were conducted in a test rig (see Figure 4) in which a hydraulic arm were pushing on the implant creating a force on abutment. The implants where tightly attached to the test rig by a block in which the fixture was squeezed lock tight to approximately two thirds of its length. In the tests, the smallest fixture diameter was used because it is presumed to be the weakest variant. The tests was conducted under there different load levels 100Nm, 80Nm and 70Nm measured at the end of the fixture 44mm from where the force is applied. The magnitude of the force was calculated accordingly. The forces were applied in a sinusoidal manner resulting in the time varying moment loads of 52.5Nm ± 47.5Nm, 45Nm ± 35Nm and 40Nm ± 30Nm with a frequency of 12Hz.

$$Force = \frac{Bendig\ load\ (100Nm, 80Nm\ and\ 70Nm)}{Length\ to\ force\ (44mm)} \tag{1}$$

The screws were tightened to apply a compression force on the abutment and fixture of 12kN but all the implants lost approximately 3kN in compression force during the first 5-10 cycles of bending load (Johansson. T 2012). During the 100Nm test, the screw lost clamping force and was therefore redrawn. During the last part of the 100 Nm test, the screws were tightened to 13kN which is higher than intended. A total of three specimens were tested. This is obviously too few to give reliable test results. Hence the results should be treated as indications.

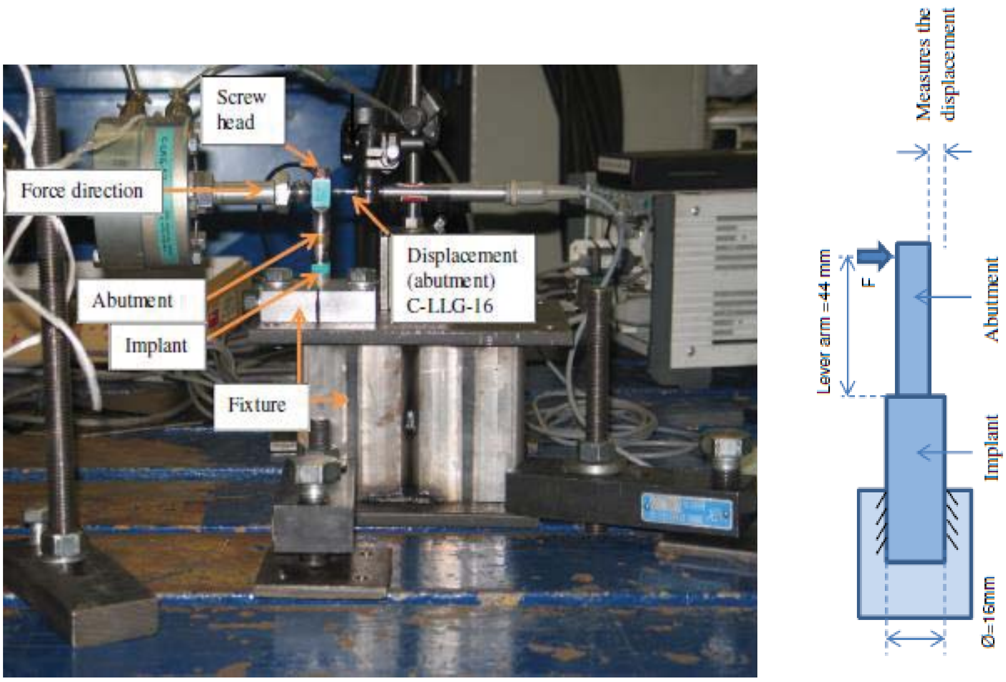

Figure 4: Picture of the fatigue test setup (source: Johansson. T 2012).

2.6.2 Results from dynamic bending tests

The three tests failed in different parts of the implants. The first 100Nm test is believed to have failed in the threads of the screw. Unfortunately, no close inspection of the screw was made making it hard to understand the failure mechanism. The 80Nm test failed in the fixture at the height where the fixture is attached to the test rig (see Figure 5). At the attachment interface, the bending moments become largest causing large stress amplitudes on the fixture where a fatigue crack starts grow. The last test with the bending moment 70Nm failed in the abutment, see Figure 32 Appendix 1. The fatigue crack started in the beginning of the contact region making it likely that some type of contact mechanism affected the crack that caused failure.

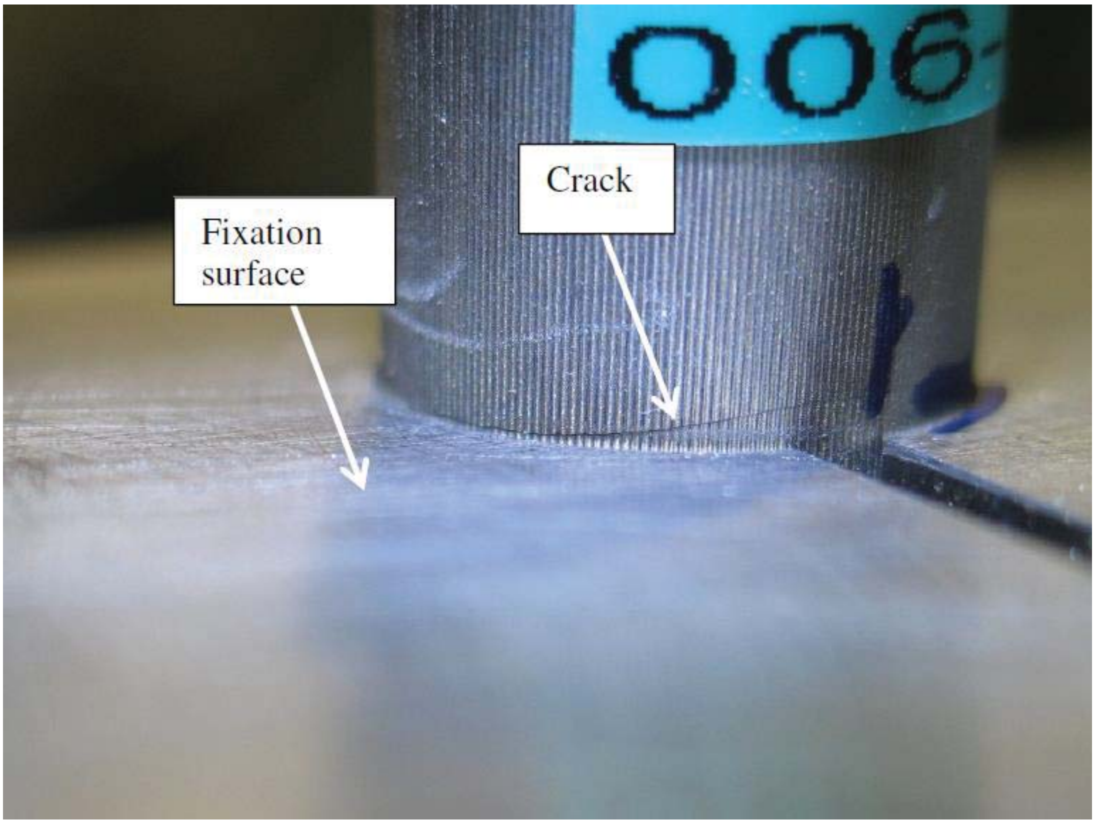

Figure 5: The crack at the attachment for OPRA 2 after 80Nm bending load (source: Johansson. T 2012).

3 Theory

In this chapter, the relevant theory for the thesis is presented.

3.1 Fatigue

Fatigue is local damage that occurs because of cyclic loading creating cracks which propagate until they reach critical length when complete failure occurs. Fatigue is a complex mechanism with many parameters involved in fatigue, like load, material, surface, environment and contact between different surfaces.

Shear stresses often initiate cracks. Fatigue cracks are mainly driven by tension load because tension loads open the cracks and make them grow while compression closes the cracks. The amount of damage caused by each loading cycle is related to both the amplitude and the mean value of the corresponding load cycle. The material properties have a large effect on the fatigue life. Environmental effects like corrosion, can speed up the fatigue process. A smooth surface has generally longer fatigue life than rough surfaces because the smooth surfaces have less crack initiation spots. If the surface is in contact with other surfaces the contact mechanism can lead to a phenomenon called fretting, further described in the Chapter 3.2.

The number of cycles to fatigue failure can be calculated using either stress or strain based methods. In the stress based method, the global stress amplitude is related to the number of cycles to crack initiation using test data and curve fit equations. The stress based method is derived from fatigue tests where identical specimens are subjected to cyclic loads at different magnitude with constant mean value. The results can then be plotted in a stress to number of cycles curve, a so-called S-N curve. For many materials, the S-N data can be approximated as a straight line in a log-log plot. Using curve fitting parameters, the following expression can be derived to represent the S-N data

$$\boldsymbol{\sigma_{ar}} = \boldsymbol{\sigma_f}\left(2\boldsymbol{N_f}\right)^{\boldsymbol{b}} \tag{2}$$

where $\boldsymbol{\sigma_f}$ and $\boldsymbol{b}$ are material parameters, $\boldsymbol{N_f}$ is the number of cycles to failure, $\boldsymbol{\sigma_{ar}}$ is the mean stress compensated amplitude.

The strain based method works the same way but in this case, the strain instead of the stress is linked to the number of cycles to crack initiation. In the strain based method, is often used for lower number of cycles to failure because it capture plastic behaviour, while the stress based method only captures elasticity. When there already exists a crack, fracture mechanics are to be used to predict the remaining life. In fracture mechanics, the local stress amplitude in front of the crack is used to estimate the numbers of cycles to a specific crack length using Paris' law.

3.2 Fretting

In this chapter follows a short introduction to fretting fatigue and how it affects titanium. Fretting is a surface damage phenomenon that occurs in contact between metallic surfaces. Fretting occurs in contacts that are subjected to small cyclic movement between the surfaces, referred to as slip. Fatigue life is greatly reduced by fretting, because wear caused by fretting speed up the crack initiation phase (Ekberg 2004). Fretting is a known phenomenon that can occur in contacts between mechanical structures. Typical cases where fretting occurs are at the attachments of the blades in a turbine engine, rubbing between cables and ropes, joints in fatigue loaded structures (like rivets or shrink-fitted components) and bio implant devices such as total hip replacements. Suresh (1998) lists the following components to be affecting fretting fatigue:

- The amplitude of cyclic slip displacement (typically 5-50μm).
- The mismatch in the elastic and plastic properties between contacting surfaces.
- Cyclic frequency, waveform and time length between load periods.
- The normal contact pressure.
- The coefficient of friction between the fretted surfaces which is strongly influent by the roughness of the surface asperities.
- Environment and temperature.
- Residual stress induced by surface modification techniques such as shot peening or coating, or by heat treatments, welding and other joining operations.
- Mechanical loads imposed on one or both members engaged in fretting contact.
- Microstructural changes and phase transformations, if any, produced by the local temperature rise in the vicinity of fretted surfaces.

3.2.1 Fretting mechanism

The explanation to why fretting is reducing the fatigue life is, according to Ekberg (2004), that fretting promotes early crack growth. The reduction in fatigue strength is directly linked to the time spent under fretting conditions. Specimens exposed to fretting under a short time will have little reduction in fatigue life because fretting heavily promotes early crack growth and if only a short period of fretting is present, the early cracks have not had time to start.

The cracks caused by fretting fatigue typically consist of two phases. In the first phase the crack is growing in a 45 degrees angle to the surface and is driven by the shear stress created by the friction between the surfaces. In the second phase, the cracks are growing in a 90 degree angle to the surface, driven by the global stress.

When uneven surfaces collides, large shear stresses can occur when the peaks of these surfaces collides. This will cause cracks or damage in the material. Furthermore, frictional heat from the movement in the contact can cause the material to weld together; so-called galling. Subsequent load cycles will break this bond causing more damage. Most metals have an oxide film on the surface that acts as a barrier for corrosion. Fretting on oxide layers can create hard particles that lie between the surfaces causing additional damage. Damaged oxide films makes the surfaces vulnerable to corrosion, in a corrosive environment this can have a large effect on the life of the metal. This is why literature often describes fretting as a combined problem between fretting and corrosion called fretting corrosion. For titanium, corrosion has an only slightly larger effect when fretting is present than for plain fatigue (Waterhouse 1973).

3.2.2 Contact force between the surfaces

An increase in contact pressure has been shown to give larger wear. However the literature is inconsistent on the effects of clamping pressure regarding fatigue cracks. This might be suspected when fretting is governed by several different complex parameters (Jaap 2009). The experiments for titanium show that for low contact pressures up to 25MPa the fatigue life decreases rapidly. The fatigue life decline is then slowed until it reaches a threshold value at 150MPa after which the increase of the contact pressure will have small effects of the fatigue life, see Figure 6 (Jaap 2009).

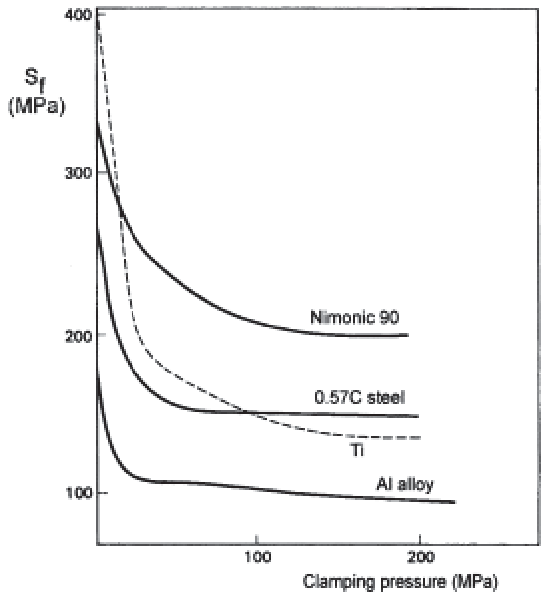

Figure 6: The fretting fatigue life as a function of with the contact pressure. S_f is the stress level under which the life is considered unlimited (source: Jaap 2009).

3.2.3 Amplitude of the slip between the surfaces

The contact between the surfaces can be divided into different types. In the case of small lateral load or high friction, the contact bodies experience no relative displacement between the bodies. This contact is called sticking. The opposite case with large loads and small friction causing the bodies to have a large relative displacement is called full slip. There is also an intermediate case called mixed stick-slip where parts of the body experience slip, and other parts experience sticking. According to Ekberg (2004), the surfaces experience no damage the condition of full stick. Instead, fretting fatigue is dominating in mixed stick-slip contacts where the slip amplitude is small, while wear is the dominating damage mechanism in regions of high slip (full slip) amplitude. For steel, fretting is dominant up to a slip amplitude of 50µm after which wear is dominant, see Figure 7. Like the clamping force, increasing the amplitude will have a larger effect for low values of slip amplitude while the effect is limited for higher values of amplitude see Figure 8 (Jaap 2009).

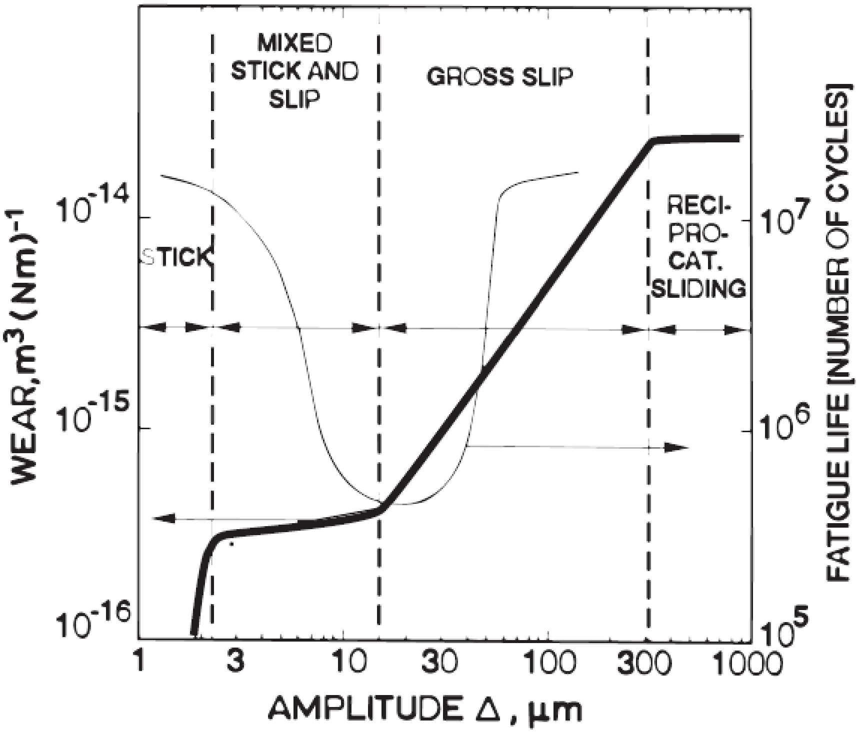

Figure 7: The relation between wear and fretting for steel (source: Ekberg 2004)

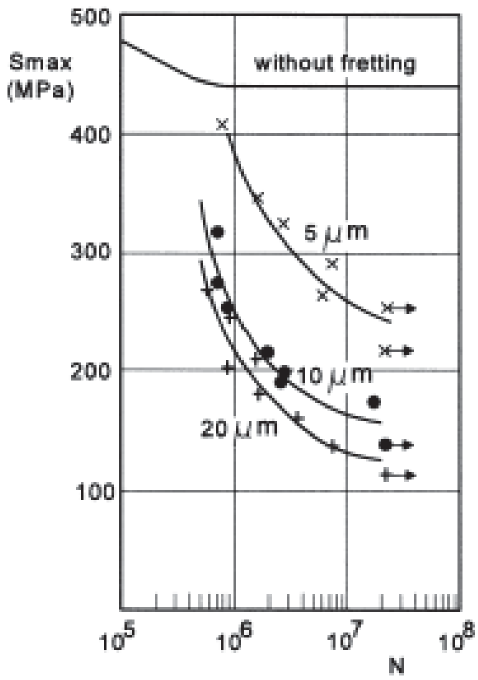

Figure 8: The effect of slip amplitude on fretting fatigue life (source: Jaap 2009).

3.2.4 Materials

Fretting is a material damage mechanism so the material can be more or less sensitive to fretting fatigue. There are several aspects of the material that affects fretting;

- The general fatigue resistance against plain fatigue
- The wear resistance
- The coefficient of friction
- The resistance to corrosion

Generally, high strength alloys loose a larger portion of its fatigue life than a low strength alloy. A factor 2-4 (fatigue life /fretting fatigue life) is common for higher strength alloys while lower has a factor 1.5 (Waterhouse 1973). The better fatigue properties of high strength alloys still make them superior to the low strength ones. In tests conducted by Waterhouse (1973), Titanium grade 5 lost 63% of its fatigue life when fretting was present in the experiments

3.2.5 Contribution from the environment

Most metals corrosion resistance comes from a thin surface oxide layer. Fretting will remove or damage this oxide layer making the metal much more sensitive to corrosion. In a corrosive environment, the removal of the protective layer may lead to an accelerated corrosion process. On the other hand, some environments can have positive influence on fretting. Introducing a lubricant or having an environment that acts as lubricant can lower the friction and thereby reduce the shear stresses. Furthermore it is possible that friction induced welding is worse in a dry environment than in a humid environment (Jaap 2009). The OPRA implants are inside the body exposing them to the environment inside the body. It is therefore possible that the blood will have both a lubricating and corrosive effect, on the implants.

3.2.6 Loading

An increasing mean stress will result in shorter fretting fatigue life. Studies have shown that the mean stress has a larger effect when fretting is present than for plain fatigue (Jaap 2009). As for plain fatigue, the fretting fatigue life seems fairly independent of the randomness of the load. The Palmgern-Miner linear damage rule can therefore be used to predict the total fretting fatigue life for varied loading. Generally high load frequency gives shorter fatigue life, but studies have also showed that the fatigue life is independent of the frequency (Ekberg 2004).

3.2.7 Surface condition

It is well-known that rough surfaces decreases the fatigue resistance for plain fatigue, the opposite correlation are present on fretting fatigue. The explanation is thought to be that it is beneficial for fretting to have a large number of small contact areas (as for rough surfaces) compared to a small number of large contact surfaces (as for smooth surfaces), (Ekberg 2004). Vadiraj (2009) have studied the fretting fatigue for different types of surface treatment on titanium alloy TI6Al4V. They have found that the fatigue life can be greatly improved by introducing surface heat treatments like nitriding or PVD TiN coating, see Figure 9 . Lee (2006) has studied the effect of shot peening on fretting for titanium and has showed that the residual stress introduced on the surface has a positive effect on the fatigue life.

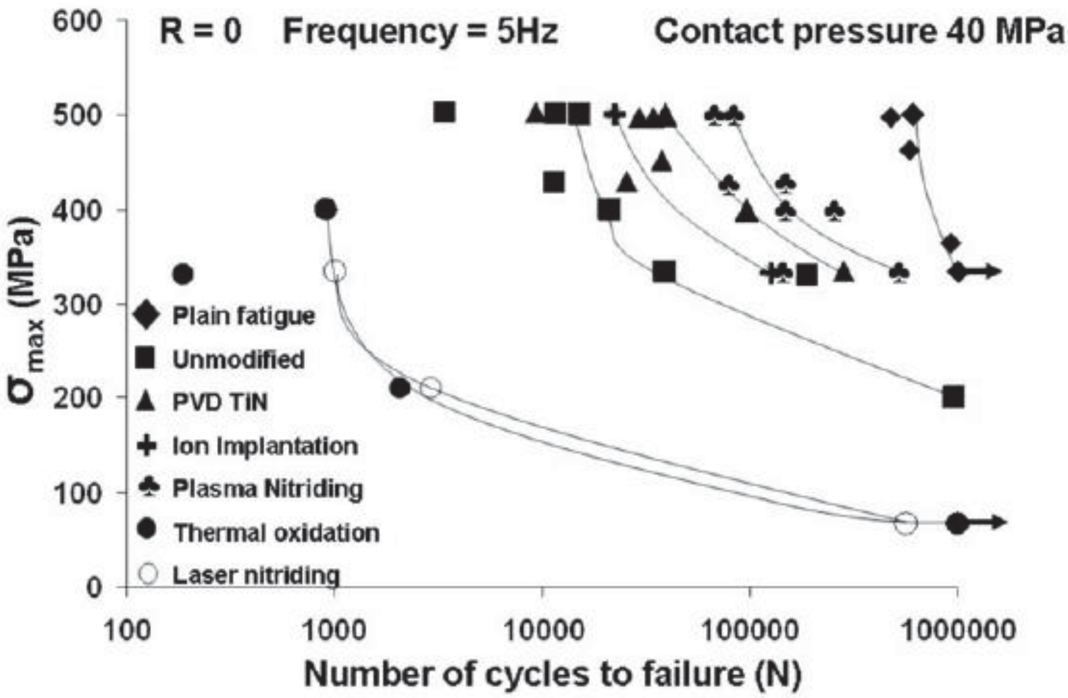

Figure 9: S-N curve showing the effect of different surface treatments. (Source: Vadiraj 2009).

3.2.8 Means of avoiding fretting

According to Jaap (2009) there are two ways to avoid fretting. Either by removing the metal on metal contact or by alleviation of fretting damage. The first method can be described as to cure the disease while the other is lingering the symptoms of the disease.

3.2.8.1 Prevention of metallic contact

The best way to remove fretting is to prevent metal contact from occurring. An example of how metal contact can be removed is presented in Figure 10. A lug is loaded in vertical direction and by removing a small part of the side on the hole, metal contact is only possible at the top and bottom of the hole where the stress is much lower than on the sides. The stress on the sides of the holes becomes slightly larger but the difference in stress is small enough to be neglected, due to small difference in cross sectional area. It is also possibility is to introduce a thin non-metallic layer between the surfaces. This is mainly why the adhesive-bonded joints have better fatigue properties than riveted joints (Jaap 2009).

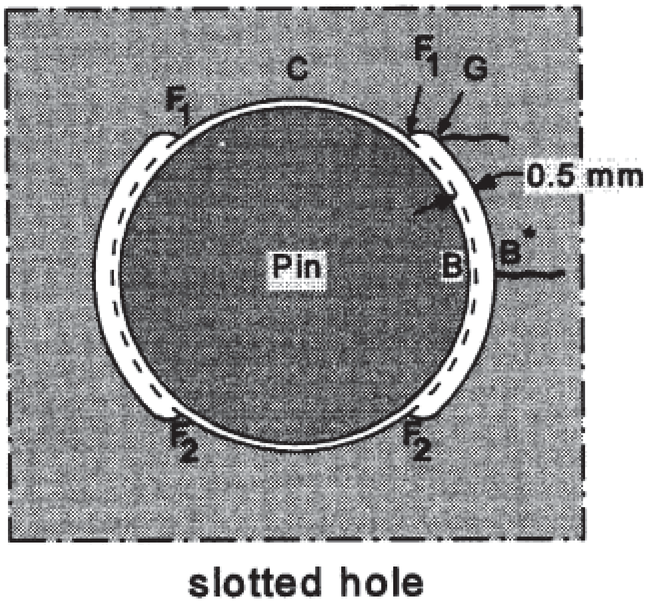

Figure 10: Lug with fretting protection (source: Jaap 2009).

3.2.8.2 Alleviation of fretting damage

The fretting damage can be reduced by surface treatment. The way surface treatments can reduce the fretting fatigue is to lower the coefficient of friction between metallic surfaces, and to harden the surface to make it more wear resistant. Nitriding is one of the most common surface treatments for reducing fretting. In nitriding, nitrogen particles are diffused into the surface of the metal either by placing the metal in an oven with a nitrogen atmosphere or by using electric fields to create nitrogen plasma. Research done by Vadiraj (2009) shows that Nitriding can increase fretting fatigue life, with a factor of ten, see Figure 9. Nitriding hardens the surface and reduces the coefficient of friction makes the surface more resistant to wear and surface damage. Introducing residual stress by shot peening will have a positive effect on the fatigue life (Lee 2006). Shot peening will also increase the roughness of the surface which increase the resistance to fretting but decrease the plain fatigue life. Lubricating surface treatments will increase the fatigue by reducing the coefficient of friction. A disadvantage with lubricants is that it can wear off with time.

4 Method

This chapter describes the method used to analyse the OPRA implants.

4.1 FE-simulations of OPRA implants

Finite element (FE) simulations have been used to better understand the fatigue properties of the OPRA implants. The finite element simulations were set up to reproduce the test conducted on OPRA 2, see Chapter 2 Section 2.6. All simulations were conducted using Ansys APDL version 14.5.

4.1.1 Geometry

The geometries used in the FE-simulations where gathered from recent finite element studies conducted on the OPRA implants by Uniso (Johansson 2012). The major part of the implants is axisymmetric except the head of the abutment, the hex in the bottom of the abutment and the treads. These regions are judged to be in regions of small interest and are therefore modelled as axisymmetric. The dimensions of the fixture and abutment are the same as in the dynamic bending tests of the smallest fixture so that presumably the worst case scenario is tested. The FE simulations where considering only half of the implant (with proper symmetry conditions) in order to allow high model detail to computational cost ratio, see Figure 11. The half model allows for loads in the longitudinal direction and bending in one plane which is enough to mimic the test, where only one load is applied in the longitudinal direction by the preload in the screw and in one plane normal to the longitudinal direction from the external force. The implants are in real life subjected to a more complicated load scenario with bending loads in several directions as well as a torque load. The meshes where created from second order twenty node, parabolic elements with an approximate element size of 0.5-1.5mm. The geometries on OPRA, have sharp edges that will give peaks in contact pressure. In reality the sharp edges will be smoothened out by wear and plasticity. The FE model can be said to only represent the initial stage where wear and plasticity has not affected the geometry's sharp edges.

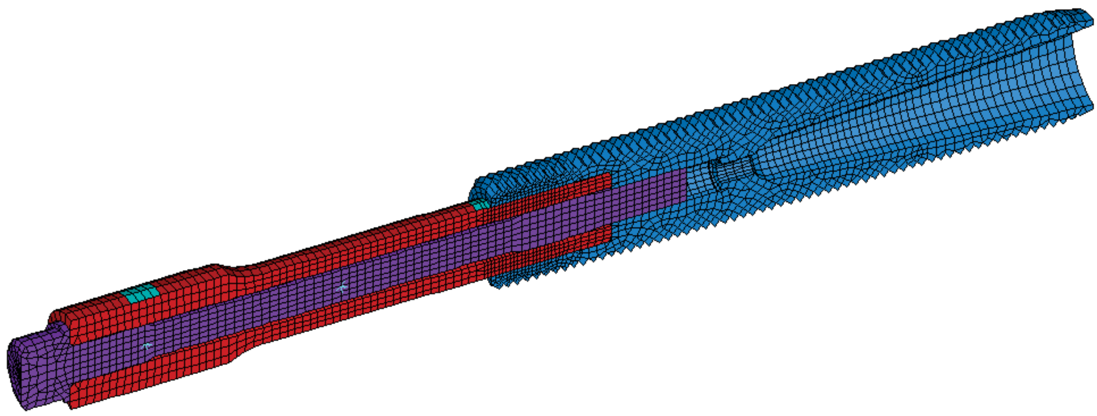

Figure 11: Picture of the FE model.

4.1.2 Material data

All the parts of both OPRA 1 and 2 designs consist of commercially pure titanium or titanium alloys. On the new OPRA 2 design, all parts are manufactured in titanium alloy Ti6Al4V which is one of the most common types of titanium. The original OPRA design has different materials for the different parts of the implants. The fixture is manufactured in titanium grade 1 (also called pure titanium), the screw consists of titanium alloy Ti6Al4V, the abutments are manufactured in titanium Ti6Al4V for new implants and Titanium grade four for old implants. In Table 1, the material data used during the simulations is listed.

The coefficient of friction of for titanium is between 0.35 and 0.4 for two dry titanium surfaces sliding against each other. Human body fluids will be present on the friction surface and can have a lubricating effect on the contact. The friction coefficients of 0.35 have proven to be sufficient (see Johansson 2012).

Table 1: Table with material data for the OPRA implants (source Johansson 2012).

	Material	**Young's modulus E [GPa]**	**Poisson's ratio ν**	**Yield limit [MPa]**
Fixture (OPRA)	Titanium grade 1	110	0.3	385
Screw (OPAR)	Ti6Al4V	110	0.3	890
Abutment (OPRA)	Ti6Al4V/Titanium grade 4	110	0.3	890/ 595
OPRA 2 (all parts)	Ti6Al4V	110	0.3	890

4.1.3 Load

The load cases on the implants are created to represent the loads used in the dynamic bending tests. In reality, the loads are more complex, see Chapter 6 for a longer discussion of the loads. The loads were applied in several steps. In the first step, the bolt pre tension was applied as a force on a node linked to the node around the screw. In the second step, the compression of the screw where measured at the load point and the force was replaced with a coupling equation prescribing the relative movement. In the third and last step the bending load was applied as a force. The force is applied on a point that is linked to the surface nodes on the abutment using coupling equations according to Figure 12. The stresses on the implant where only calculated for one cycle meaning that no effects of repeated loading and unloading, such as sliding in friction joints and plastic deformation, where accounted for in the FE simulations. This will lead to an overestimation of the contact pressure on sharp edges.

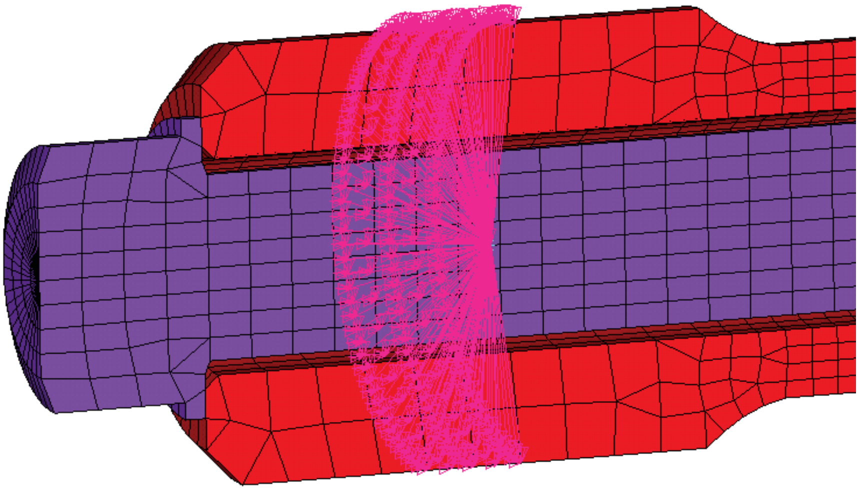

Figure 12: Picture of the loading point location and how the load is distributed to the surface.

4.2 Plain fatigue calculations

The implants were evaluated against plain fatigue using the stress based method described in Dowling (2012). According to Dowling (2012), the high cycle fatigue method is accurate from 10^4 cycles to failure. Since all the tests conducted on OPRA 2 survived more than 10^5 cycles, the high cycle fatigue method is used to calculate fatigue. The stress on the implants from the bending tests is mainly in longitudinal direction. Because the stress is approximately unidirectional, no multiaxial compensation for the stress has been made.

The curve fitting or material parameters $\boldsymbol{\sigma_f}$ and $\boldsymbol{b}$ used in Equation 2 are according to Dowling (2012) for titanium Ti6Al4V $\boldsymbol{\sigma_f} = 2030[\text{MPa}]$ and $\boldsymbol{b} = -.104$. The stress vs. life data is determined from zero mean stress data. In order to compensate for the mean stress effects, the Smith Watson Topper or SWT method is used

$$\boldsymbol{\sigma_{ar}} = \sqrt{(\boldsymbol{\sigma_{max}\sigma_a})} \tag{3}$$

were $\boldsymbol{\sigma_{max}}$ is the maximum stress and $\boldsymbol{\sigma_a}$ is the stress amplitude. Similar high cycle fatigue data for titanium alloy Ti6Al4V in the form of S-N curves (Figure 13) from U.S. Department of Defense (2003) was also used to calculate the fatigue life.

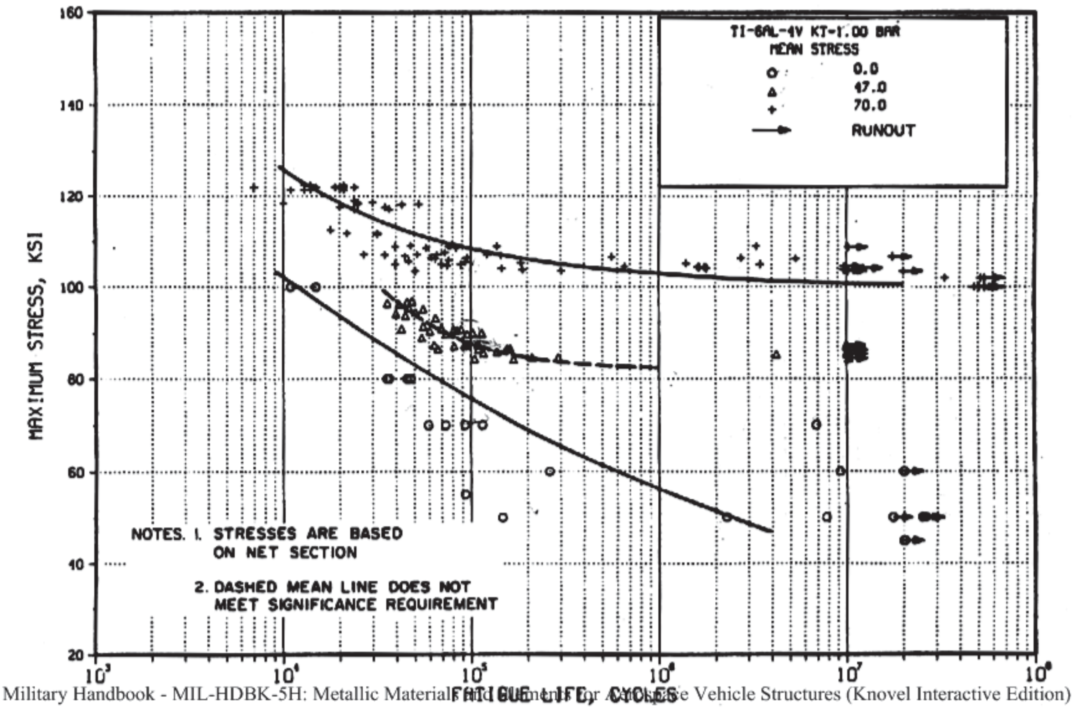

Figure 13: S-N curve for titanium alloy Ti6Al4V (source: U.S. Department of Defense 2003).

4.3 Fretting

Predicting the fatigue life when fretting is present is difficult because of the many complicated mechanics that are present. Perhaps the simplest way to predict the impact of fretting is to regard the slip amplitude (Ekberg 2004). This can be improved by studying the frictional work per unit area by including the shear stress on the surface as

$$F1 = \delta\tau \tag{4}$$

To account for tensional stress on the surface, the following alternative fretting parameter is suggested

$$F2 = \delta\tau\sigma \tag{5}$$

Studies have showed that the fretting parameters F1 and F2 are fairly accurate in predicting where fretting fatigue cracks occur but has no correlation to the number of cycles to failure (Ekberg 2004). The F1 parameter is a measure of the frictional work per unit area which is linked to wear on the surface, while the F2 parameter also include the tension stress and is therefore better at predicting fretting.

An alternative way to predict the fatigue life is to use experimental data in the form of S-N curves, accounting for contact between parts. Waterhouse (1973) and Lee (2006) have conducted research where S-N curves for titanium specimens of Ti6Al4V are determined, see Figure 14. The tests are conducted in a similar manner as for normal fatigue tests with a specimen exposed to cyclic tension stress. The difference is that friction pads that slide and push against the side of the specimen are added to simulate the contact that lead to fretting. The disadvantage of using S-N data is that the curves are conducted for one contact case and if the contact is not identical to that of the tests, the comparisons do not become entirely accurate. They can however be used to see how the different stress levels can affect fretting.

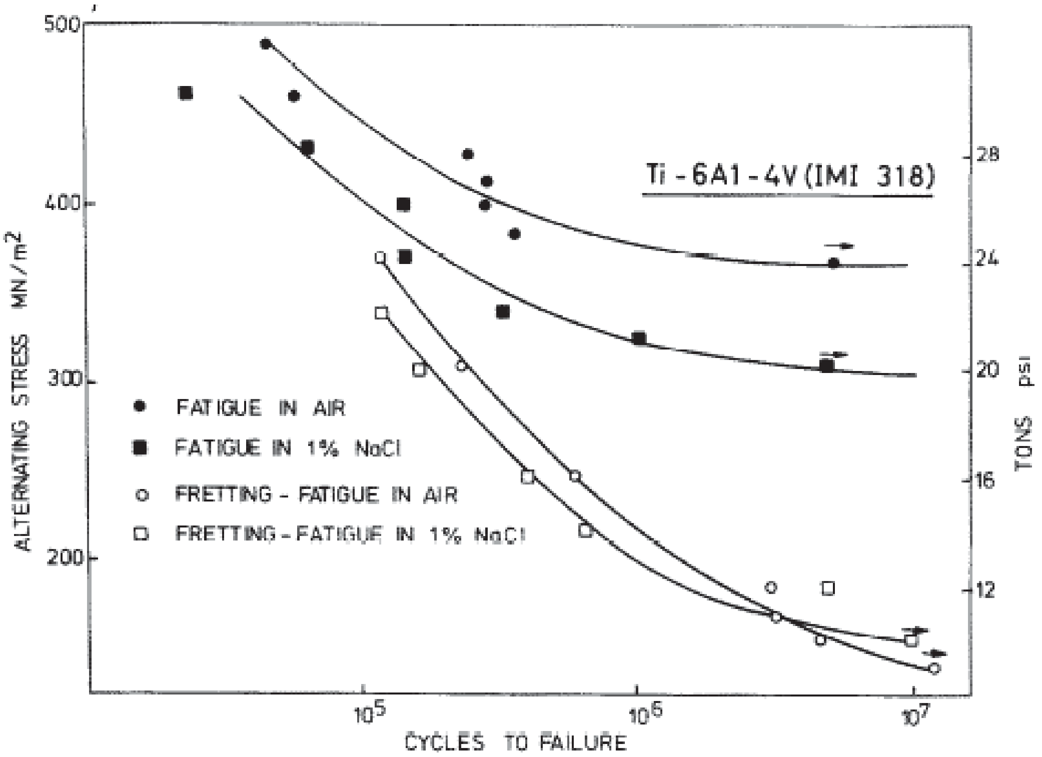

Figure 14: S-N curve with fretting source: Waterhouse (1973).

There are several possible ways to calculate fretting fatigue life not used in this study. One can use fracture mechanics, by assuming that a small crack appears within the first cycles of loading. Or by linking fretting fatigue life to S-N curves using reduction parameters dependent on the notch sensitivity, coefficient of friction, contact load, contact area, Young's modulus, slip amplitude and other parameters. The accuracy of reduction of S-N curves has been proven to be low (Ekberg 2004) and was therefore not used.

Both the method of using fretting parameters and fretting S-N data lack the ability to predict the numbers of cycles to failure for fretting fatigue accurately. Comparisons between similar cases can be made using these methods but a large uncertainty regarding the fretting effects on fatigue life still remains.

5 Analysis and Discussion

In the chapter below follows a description of the analyses conducted on the OPRA models and a discussion of the results from the FE-simulations.

5.1 Reconstructing OPRA 2 tests

To better understand the general fatigue properties of OPRA 2, and in particular the results from the dynamic bending tests, a finite element model was created. In the model, the maximum and minimum stress in longitudinal direction was calculated so that fatigue life predictions can be made from the one dimension stress amplitude. The model consists of three parts (see Appendix 1 Figure 33 or Figure 16 for the corresponding OPRA 1 figure) fixture in blue, abutment in red and screw in purple. The fixture and the abutment are connected with a frictional contact at the taper with a coefficient of friction of 0.35. The head of the screw and the abutment were connected through a matching mesh with coinciding nodes between the two surfaces in contact, meaning that the surfaces always stick together. To model the fastening of the fixture at the test rig, a zero displacement boundary condition was used on the outside of the fixture.

The three implants were loaded with the varying loads 52.5Nm ± 47.5Nm, 45Nm ± 35Nm and 40Nm ± 30Nm in the dynamic tests measured at the abutment-implant interface. To capture the maximum and minimum stress in the implant, load levels of 5Nm, 10Nm, 70Nm, 80Nm and 100Nm where used. As mentioned above, during the tests the preload achieved was different for the different tests. During the 100Nm test the screw lost clamping force and was therefore redrawn to a new level. Both the lower and higher level was simulated creating the load cases listed in Table 2.

Table 2: Load cases for OPRA 2.

Case	Bending load [Nm]	Preload [kN]
100Nm max load 1	100	8.5
100Nm max load 2	100	13
100Nm min load 1	5	8.5
100Nm min load 2	5	13
80Nm max load	80	10
80Nm min load	10	10
70Nm max load	70	9.55
70Nm min load	10	9.55

5.2 Comparing FE-simulations with test results for OPRA2

In this section follows a comparison between the results from the mechanical tests and the results from the FE simulations using the previously described methods to approximate the fatigue life for both fretting and plain fatigue.

5.2.1 100Nm tests

The 100Nm test is believed to have failed in the threads of the screw. Unfortunately no closer inspection of the screw was made after the test and it is therefore hard to know what happened to the screw during the dynamic bending test. The calculated fatigue life from the FE simulations results in a 200 times higher number of cycles to failure than the test result achieve. The big difference in accuracy can be explained by the fact that the FE model was never meant to calculate the stress in threads of the screw and are therefore not accurate in that region.

5.2.2 80Nm tests

The 80Nm test failed due to crack at the attachment point of the test rig in the fixture, see Figure 5. When comparing the test result with the stresses calculated in the FE-simulations (see Appendix 1 Figure 34) one can see that the highest stress appeared at the place where the centre of the crack is located. The FE simulations where over-estimating the stresses in the attachment due to the singularity caused by the boundary condition. To eliminate the effect of the stress singularity the hot spot method was used. The hot spot method uses two points close to the stress concentration and linear interpolation between them to get the stress in the singularity. The maximum stress on the implants was in the screw but the fixture has larger stress amplitude due to the bending load which means that the fixture is the weakest spot against plain fatigue, see Figure 34 in Appendix 1 for maximum stress on the implants and Figure 35 in Appendix 1 for the minimum stress. Table 6 in Appendix 1 shows that calculated fatigue life and the hotspot stress amplitude for the different parts in the 80Nm test. The fixture has considerable lower life than the rest of the parts indicating that it is the weakest point against plane fatigue. Both Dowling (2012) and U.S. Department of Defense (2003) are over estimating the fatigue life.

5.2.3 70Nm tests

The 70Nm tests failed in the abutment at the start of the taper, see Appendix 1 and Figure 15 and Figure 32. Comparing with the result from the FE calculations (see Appendix 1 Figure 36) the stress was lower in this region than in both the fixture and the screw. The maximum longitudinal stress in the screw and fixture where approximately 90% and 50% (see Figure 36 Appendix 1) higher which indicates that the abutment is unlikely the most sensitive spot to plain fatigue. The fatigue life approximated with the stress based method where 350 times larger than the life achieved in the mechanical bending tests, see Table 7 in Appendix 1. The large differences between the plain fatigue and the test value indicate that there was other mechanisms present causing failure on the abutment. In Figure 15, the area around the crack can be seen where local surface damage in form of wear is present. It is possible that the surface damage in combination with the bending load created the crack. The contact pressure calculated in the FE simulations varies between zero and 10MPa during the load cycle of bending load from 5Nm to 70Nm (see Appendix 1 Figure 37 and Figure 38). In the literature presented in Section 3.2.2 there is a threshold value in that region of contact pressure in the vicinity of what the FE simulations predict. The slip amplitude between the abutment and the fixture was 0.03mm. To conclude, both the contact pressure and the relative movement measured in the FE-simulations where sufficiently large to cause fretting damage. The exact contact pressure in the tests are unknown due to small imperfections in manufacturing of the taper but the tests show signs of these types of damages. Inserting the stress values in an S-N curve created for fretting, the number of cycles that the S-N curve predicts are half of what the test survived which is a much closer prediction compared to the plain fatigue one see Table 7 in Appendix 1. The under estimation of the fretting fatigue life can be explained by the fact that the S-N curves for fretting fatigue has a more aggressive fretting case than the bending tests.

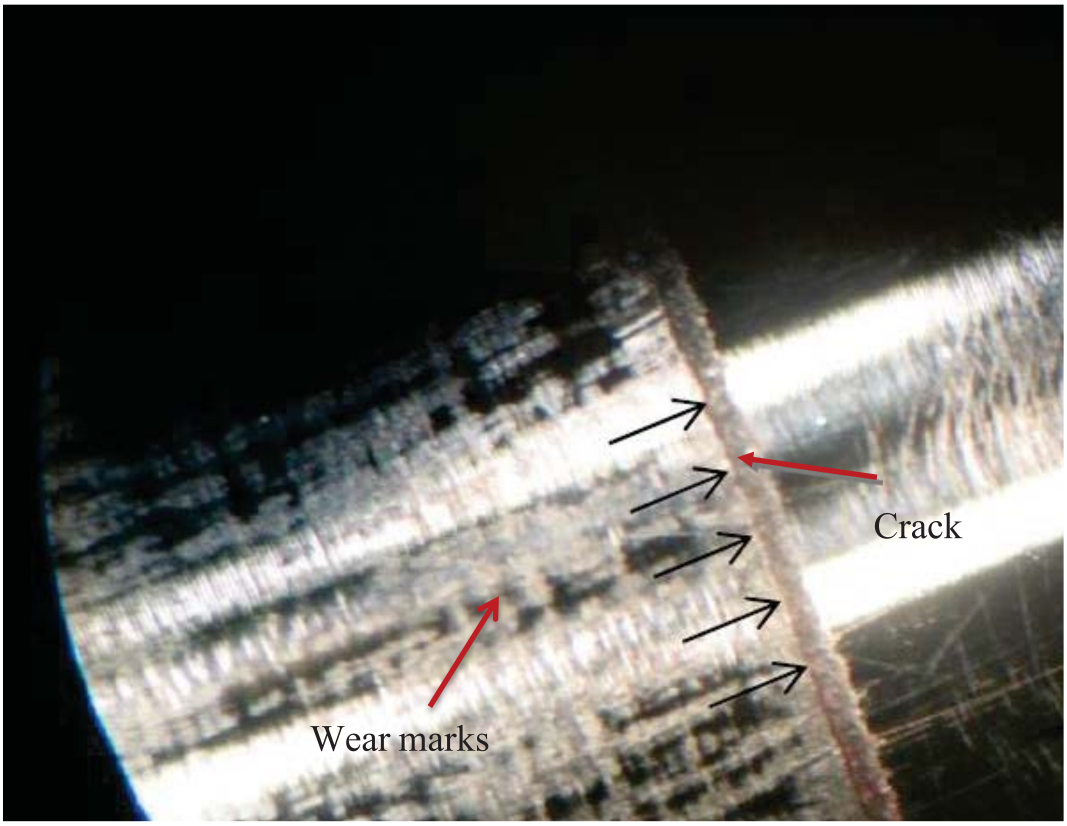

Figure 15: Zoomed picture of the crack on the abutment for the 70Nm bending load. The original opera model (source: Johansson. T 2012).

5.3 Reconstructing OPRA 1 tests

To better understand why implants are failing prematurely, and be able to compare the results form OPRA 2, a similar FE study has been conducted. The FE model of OPRA 1 was modelled in the same way as OPRA 2 with the fixed boundary condition on the fixture. In Figure 16 the fixture is marked in blue, screw in purple and the abutment in red

The press fit was modelled with a frictional contact with a coefficient of friction of 0.35 and an interference of $5\mu m$. In order simulate wear on the press fit, an interference of $0\mu m$ and a $5\mu m$ gap case has also been studied. Matching mesh with coinciding nodes to the fixture and the abutment respectively so that surfaces always stick together, where used both to link the screw to the fixture and the screw to the abutment. As for the OPRA 2 model, the FE model was never meant to calculate the stress in threads of the screw and is therefore not accurate in that region. The screw is tightened so that a preload of 4kN is achieved in the fixture and the abutment. A bending load of 70Nm is applied. The screw load and the bending load where applied in the same manner as the for the OPRA 2 simulations.

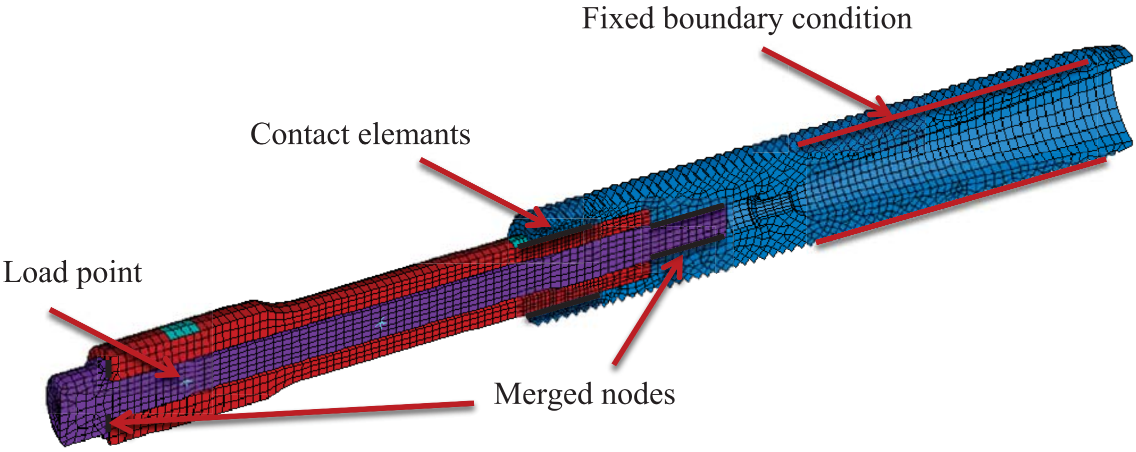

Figure 16: The FE model for original OPRA.

5.3.1 Results of OPRA 1

In the following section, the results from the FE calculations of OPRA 1 and 2 are compared. All results are for a bending load of 70Nm and boundary conditions similar to the physical test, see Section 2.6.

The maximum longitudinal stress on the fixture was 100% higher for OPRA 2 compared with OPRA 1 but on both parts, the fatigue life was infinite according to the stress based method. The maximum bending stress, on the screw in OPRA where approximately 20.5% higher than for OPRA 2, see Figure 17. The large difference in maximum stress can be explained by the smaller radius of the screw in the original OPRA design as compared to OPRA 2.The fatigue life according to the stress based method was infinite for OPRA 2 while the original OPRA have a finite life see Table 8.

The screw was affected by wear in the contact region between the fixture and the abutment. The difference in maximum longitudinal stress between press fit of $5\mu m$ and a gap of $5\mu m$ were approximately 11% (or 100MPa) leading to a 50% decrease in fatigue life of the screw compared between the initial press fit and the worn abutment, see Table 8 in Appendix 1. In Figure 17 below it can be observed that the maximum stress in the simulation appears at the boundary condition between fixture and screw (indicated with a red arrow) for OPRA 1. This is a singularity effect due to coinciding nodes contact condition to the fixture. The real maximum value appears on the stress concentration to the left (indicated with a blue arrow) where the screw becomes thinner. The mesh of the screw was relatively course so the accuracy of the stress in the screw was fairly poor, but all the cases were done using the same mesh size so comparisons should be valid.

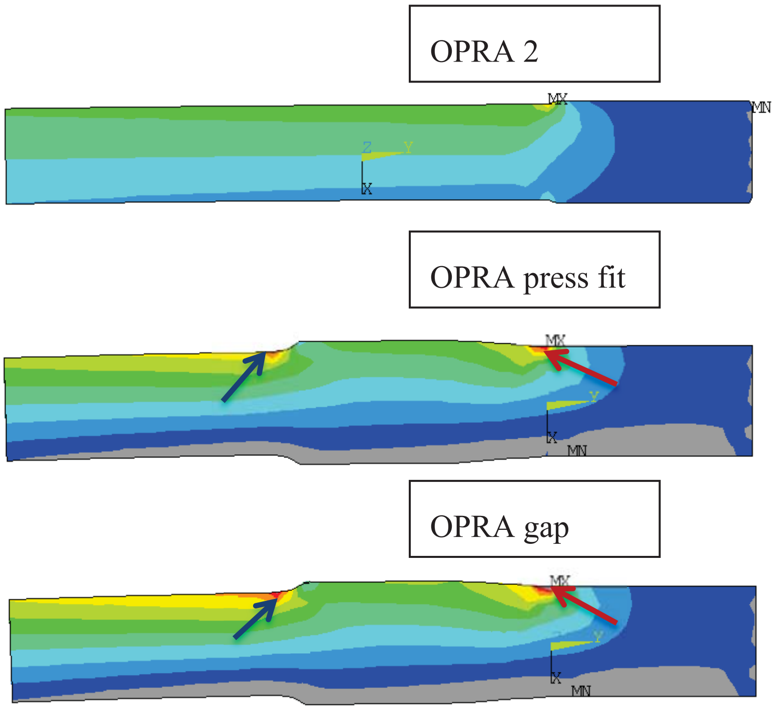

Figure 17: The stress on the screw in longitudinal for the load 70Nm.

The maximum longitudinal stress on the abutment was approximately 75% larger on the original OPRA than OPRA 2 (see Appendix 1 Figure 39 and Figure 40). Both the original and the OPRA 2 implants fatigue lives according to stress based method are more than ten million cycles. When calculating the fretting fatigue life using S-N curves from Waterhouse (1973) for fretting, the OPRA 2 fatigue life approximately was four times longer to that of OPRA 1 (see Table 9 in Appendix 1), assuming that fretting has the same effect on fatigue life as in the test done to create the S-N curve. The pressures on the contact region of the abutment were larger and located on a smaller area for the OPRA 1 compared with OPRA 2 (see Figure 18). The slip was also larger (see Table 3) so all three parameters that control fretting are bigger on the original OPRA indicating that fretting is present on the original OPRA as well. The higher fretting parameter F2 for OPRA 1 indicates that it is more sensitive to fretting than OPRA 2 (see Figure 19). F2 becomes negative when the stress is acting as compression.

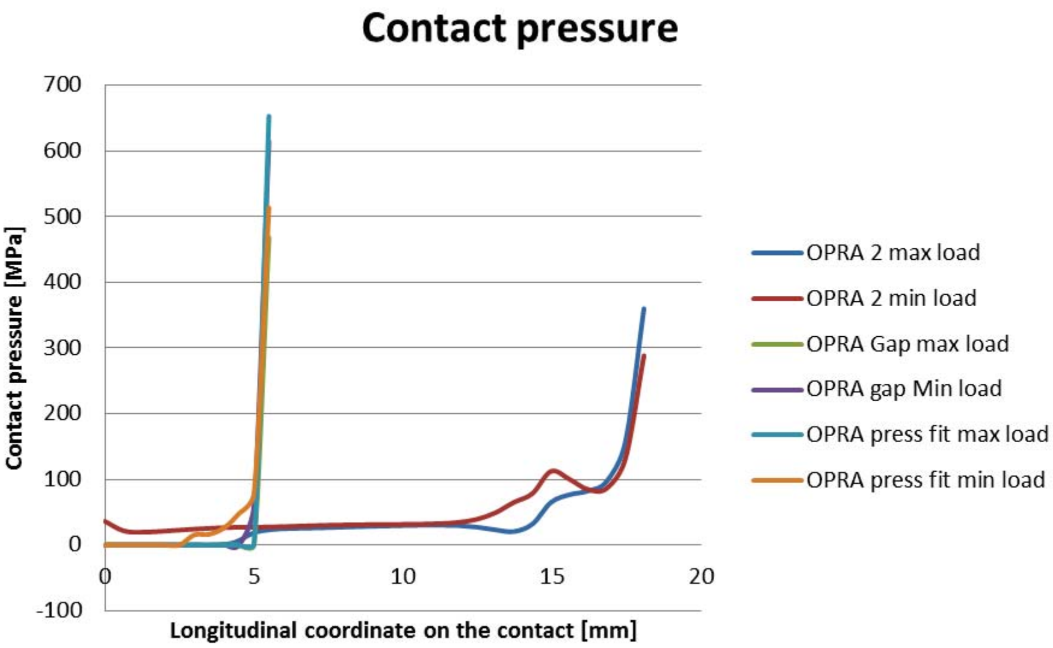

Figure 18: Graph of the contact pressure on the tension stress side of the contact.

Table 3: Maximum slip amplitude between the abutment and fixture.

Case	Slip amplitude mm
OPRA 2	0.03
ORPA press fit	0.04
ORPA gap	0.05

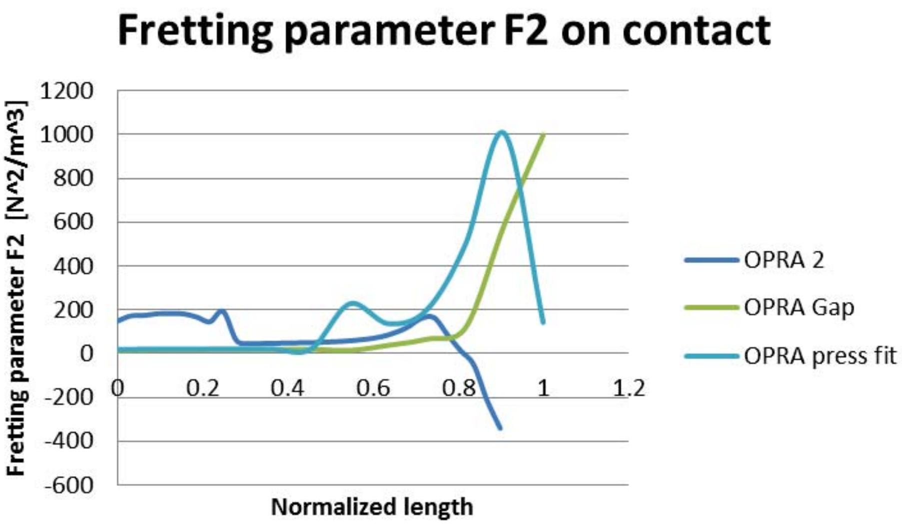

Figure 19: Graph of the fretting fatigue parameter F2 over the contact area.

5.3.2 Conclusions of OPRA 1

OPRA 2 is subjected to lower stresses than OPRA 1 on all parts of the system except on the fixture close to the zero displacement boundary condition. OPRA 2 is however in this part made of a more fatigue resistant material than OPRA 1, so the fixture of the OPRA 2 is stronger with respect to plain fatigue. All parts of the OPRA 2 system are calculated to survive infinite life and have much longer life than the OPRA 1 for the load level 70Nm according to the stress based method for plain fatigue (see Table 6 in Appendix 1). The weakest point with respect to plain fatigue failure on OPRA 1 implant was the screw, particularly when the contact between the abutment and fixture has a gap.

Gap in the contact region of the implant led to an increase of stress in the screw and a large decrease in fatigue life. It is therefore important to keep the wear in the contact low so that gap does not occur. For refitted implants it is important to make sure that there is no interfering gap between the fixture and abutment. A simple way to make sure that there is a tight fit between abutment and fixture when wear has created a uneven shape of the hole in the fixture is to smoothen out the wear on the fixture, by increasing the radius of the hole in the fixture.

The parameters sliding and contact pressure that drives fretting was larger on the OPRA 1 than OPRA 2 making it likely that OPRA 1 will experience more fretting than OPRA 2. The larger longitudinal stress in the abutment for OPRA 1 makes fretting fatigue life of OPRA 2 double to that of OPRA 1.The theory presented in Section 3.2.3 predicts that for a large slip amplitude the wear is the dominating damage mechanism and that the threshold for steel is somewhere around $50\mu m$ so it is possible that the large relative moment lead to wear instead of fretting.

The large peak in contact pressure on the OPRA 1 model, both with and without the gap, will most likely be smoothened out to a larger area due to wear and plasticity in reality. This will also smooth out the F2 parameter because the shear stress is closely linked to the contact pressure.

5.4 Means of avoiding fretting on OPRA

Alleviation of fretting damage includes both shot peening and the introduction of a lubricant, neither of which is possible to do. In the case of shot peening, finding a supplier that can accomplish shot peening under the strict medical requirement to a reasonable price is not possible. The second point of introducing a lubricant is also not possible, both due to the problems of finding a lubricant that fulfils medical requirements and the impossibility of applying the lubricant after the surgery. Nitriding were nitrogen particles are defused into the surface of the abutment to lower the coefficient of friction and increase the hardness of the surface to make it more wear and fretting resistant is however possible. The advantage with nitriding is that no changes in geometry have to be performed in order to implement it. As a result of this work, Integrum are planning to test implants with a Nitriding surface treatment in mechanical tests similar to those done on the OPRA 2 implants. Vadiraj (2009) has studded the effect of surface treatments on fretting fatigue life, and found that Nitriding can increase the fretting fatigue life with a factor of 10, see Figure 1.

Preventing metallic contact in the most critical regions can be made by separating tension stress that drives cracks from the contact region where fretting is present, using so-called shielding geometry. An attempt to create a geometry that fulfils this is described in the next Section.

The last option is to change the materials involved. The fixture is impossible to change due to the fact that it is already operated into the body. But the materials of the abutment and screw are possible to replace. In practice, the strict medical requirement makes ranges of material available narrow.

5.4.1 Fretting shielding geometry for OPRA 1

The fretting shielding geometry suggested, consists of a shelf that is supposed to shield the bending stress away from the contact region, see Figure 20. The idea behind this is that if there are no tensional stresses in the contact region, cracks – although formed by eg. fretting – cannot start to grow. The disadvantage with this shelf geometry is that it creates a stress concentration in the fillet. The notch stress will be unaffected by fretting and can be handled by nominal stress dimensioning criteria, which is by far more accurate and allows for much higher stress levels.

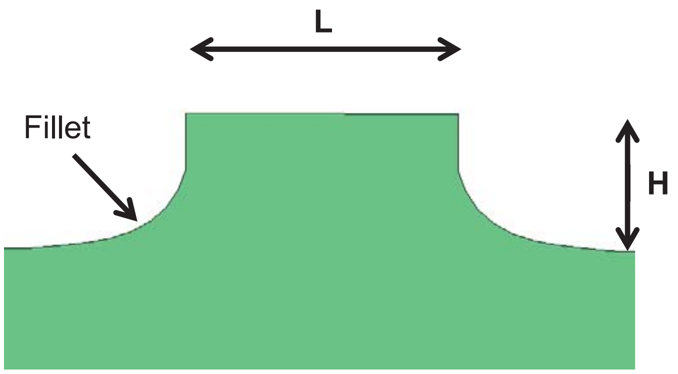

Figure 20: Schematic figure of the shelf for stress shielding.

There are several factors that need to be considered when designing the shelf. Firstly the idea behind the shelf is to remove tension stress. In order to achieve zero stress on the surface of a shoulder or shelf, Walter (2008) suggests that the following equation should hold for a shelf with a 90° angle fillet

$$H = 0.5L \tag{6}$$

with H and L defined in Figure 20. It is beneficial for both wear and fretting to have a low contact pressure. The contact pressure is directly linked to the length of the shoulder (L); small length gives high contact pressure. The stress concentration in the fillet is directly linked to how smooth the fillet transforms the geometry. Walter (2008) suggests a method of minimizing the stress concentration in a fillet by dividing the sides of the fillet into an infinite number of subdivisions and draw lines between them according to Figure 21. However, a smooth fillet will increase the stress on the surface of the shelf. To investigate the potential of using this kind of shielding geometry, three different FE models were created with different shelf geometries according to Table 4. In the first case, the radius increase of 0.5mm is used with the length of shelf equal to that of the press fit region in the original design and a fillet with a fixed radius of 0.5mm. The second shelf geometry used represent the maximum increase in radius that Integrum thinks is possible to create; 0.75mm. The length L of the shelf used is given by Equation 6 and the fillet used is according to Walter (2008) model with a ratio of ½. The ratio is how long the transition (I) from the larger radius to the smaller is in compression to the difference in radius (H). A ratio of ½ means that transition length (I) is dubbed the difference in radius (H). The last geometry used where a combination of the two previous with a radius increase of

0.5mm and a length of 1,5mm. The fillet was a smooth transition according to Walter (2008) with a ratio of ¼ and a larger radius of the fixture was used. The stress shielding geometries that are tested are listed in Table 4.

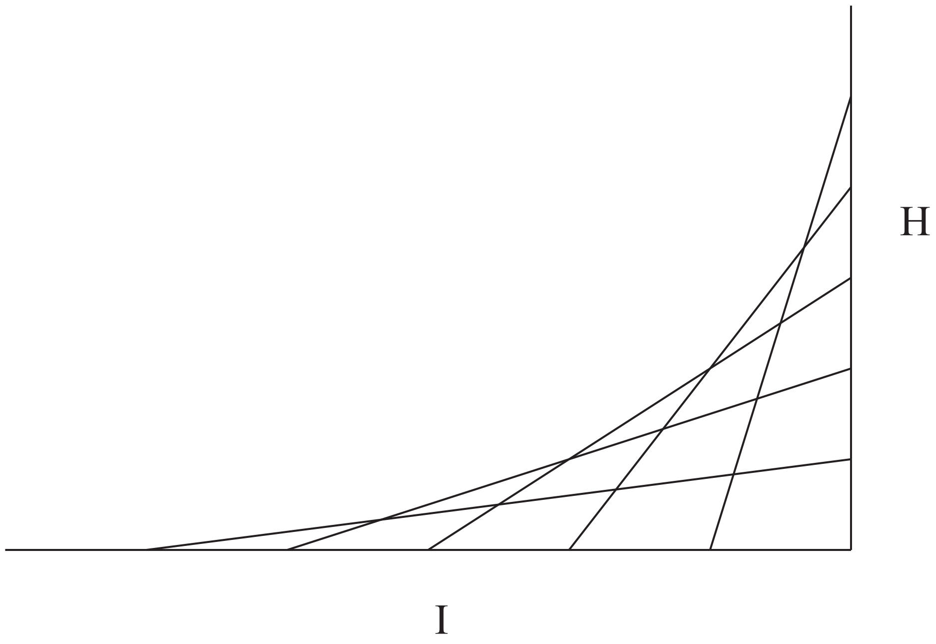

Figure 21: Walter (2008) methods for reducing the stress concentration for a ratio of 1.

Table 4: Shelf geometries tested.

Case	H[mm]	L [mm]	Fillet type	fixture
Shelf 1	0.5	2	Radius of 0.5	16
Shelf 2	0.75	1.5	One to two	16
Shelf 3	0.5	1.5	One to four	18

5.4.2 FE model of shelf geometry

To compare the fretting shielding geometry with the original OPRA design, FE models of the three shelves were created (see Figure 22). The model consists of only the fixture and abutment. The preload is applied as a force of 4kN on the abutment. The implant is loaded with a bending moment of 70Nm applied at the end of the fixture. The moment is applied through a force at a point 44.4 mm from the end of the fixture, the load point where linked to the end of the structural model of the abutment with a rigid coupling. On the right side of the fixture, a fixed displacement boundary condition is applied. The fixture and abutment where linked with a frictional contact at the top of the shelf to simulate the contact region. The bottom of the fixture and the right side of the abutment where linked through a matching mesh with coinciding nodes between the two surfaces.

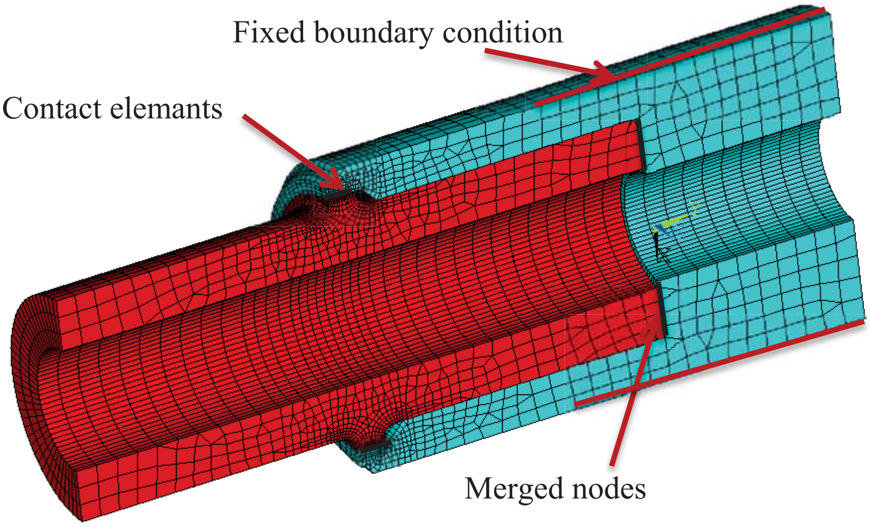

Figure 22: Picture of the FE-model for the shelf geometry.

This simplified contact interface creates an error where the contact pressure in the frictional contact is underestimated. The error appears because the coinciding nodes can transform both tension and compression loads. The real implants can only transform pressure on this contact. Consequently, the model is accurate as long as the contact only has pressure. With this boundary condition, a larger part of the bending moment is absorbed through the contact condition between the fixture and the abutment than in reality. The bigger the fixture is, the smaller the error becomes because the fixture is stiffer and more force is absorbed in the contact.

5.4.3 Results from FE analysis OPRA with shelf

The main goal with the stress shielding geometry was to decrease the stress on the surface of the contact region. Figure 23 shows the stress on the contact surface divided with the maximum stress on the abutment from the original design. The figure shows that for the shelf geometries one and three, the stress was reduced to less than half of that measured on the contact of the original design. When inserting the new stress levels in an S-N curve for fretting fatigue, the fatigue life is predicted as ten times longer than the original case (see Table 10 in Appendix 1). On the second shelf geometry, the tension stress becomes zero making it impossible for fatigue cracks to grow.

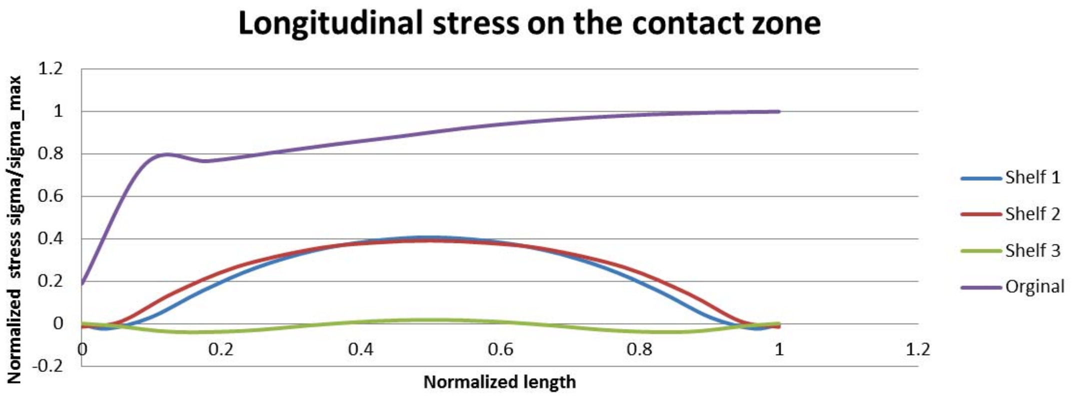

Figure 23: Stress on the tension side of the contact region as function of the maximum stress on the OPRA model without shelf.

As discussed above, the fillet of the shelf introduces a stress concentration, see Figure 24 to Figure 26. The stress concentration factor where dependent of the type of fillet geometry used. Table 10 displays the different stress concentration factors for the different geometries tested. For the case with constant radius there exists an analytical formula to predict the stress concentration. Using Walter (2008) the stress concentration factor was calculated to approximately 1.9 which was similar to what the FE studies predicted. When using a more smooth transition according to Walter (2008), the stress concentration becomes much lower. In this study it has been possible to decrease the notch effect to 1.23 as a minimum.

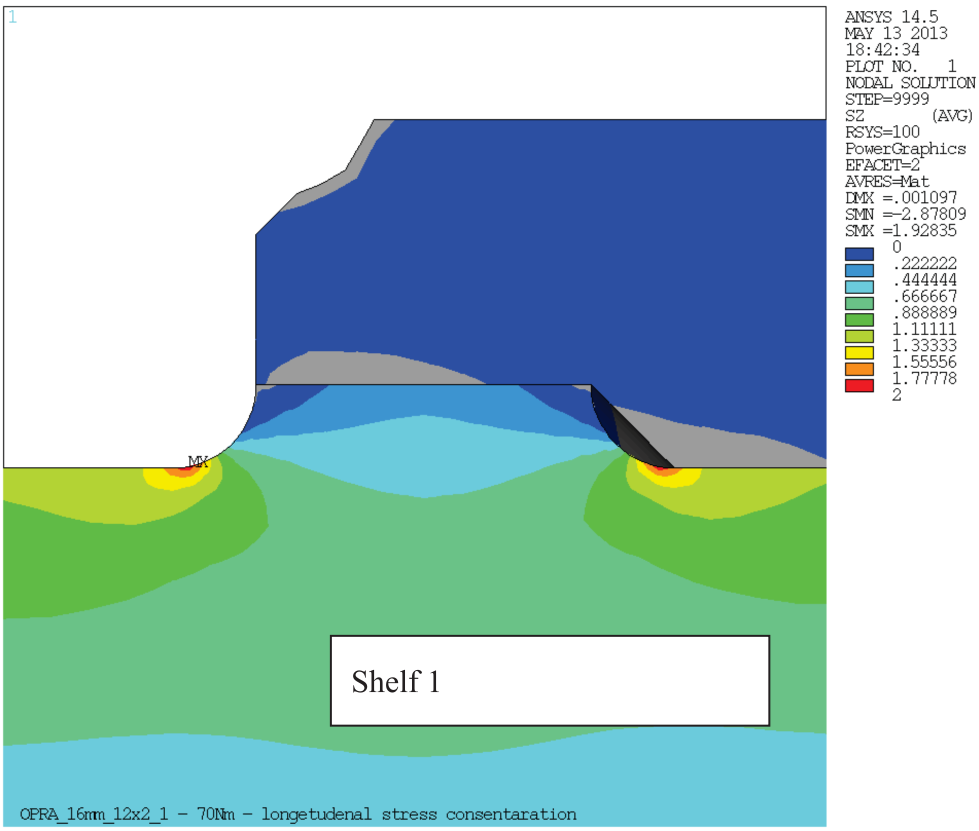

Figure 24: The stress in longitudinal or Y-direction concentration on the tension side.

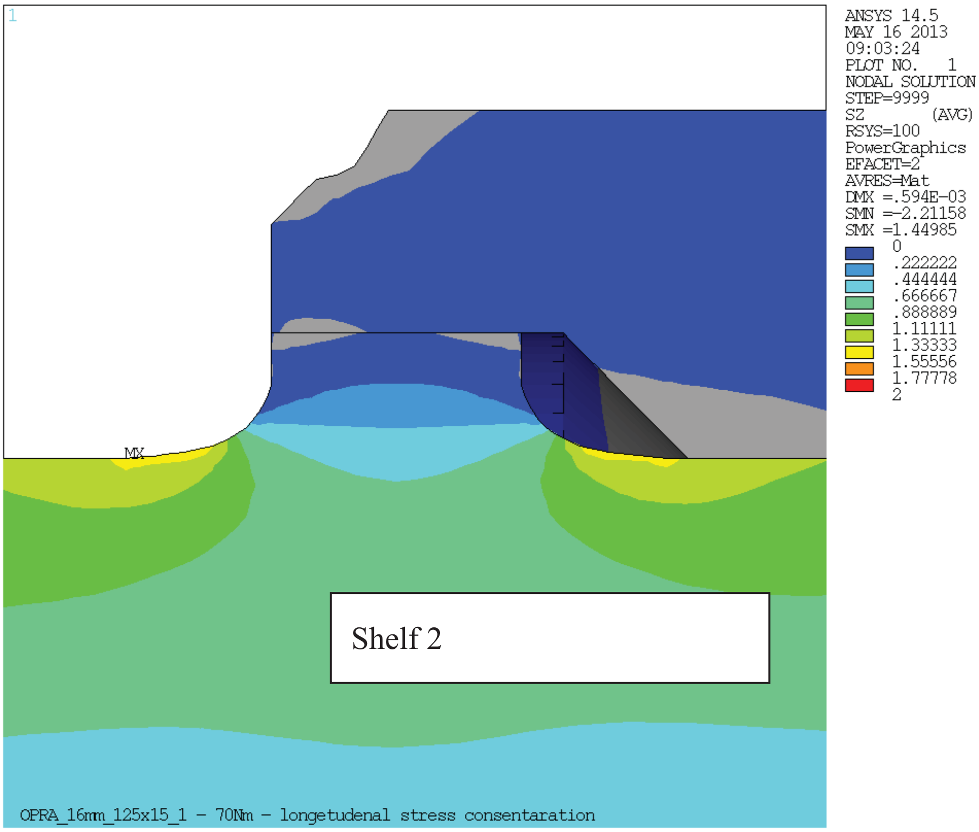

Figure 25: The stress in longitudinal or Y-direction concentration on the tension side.

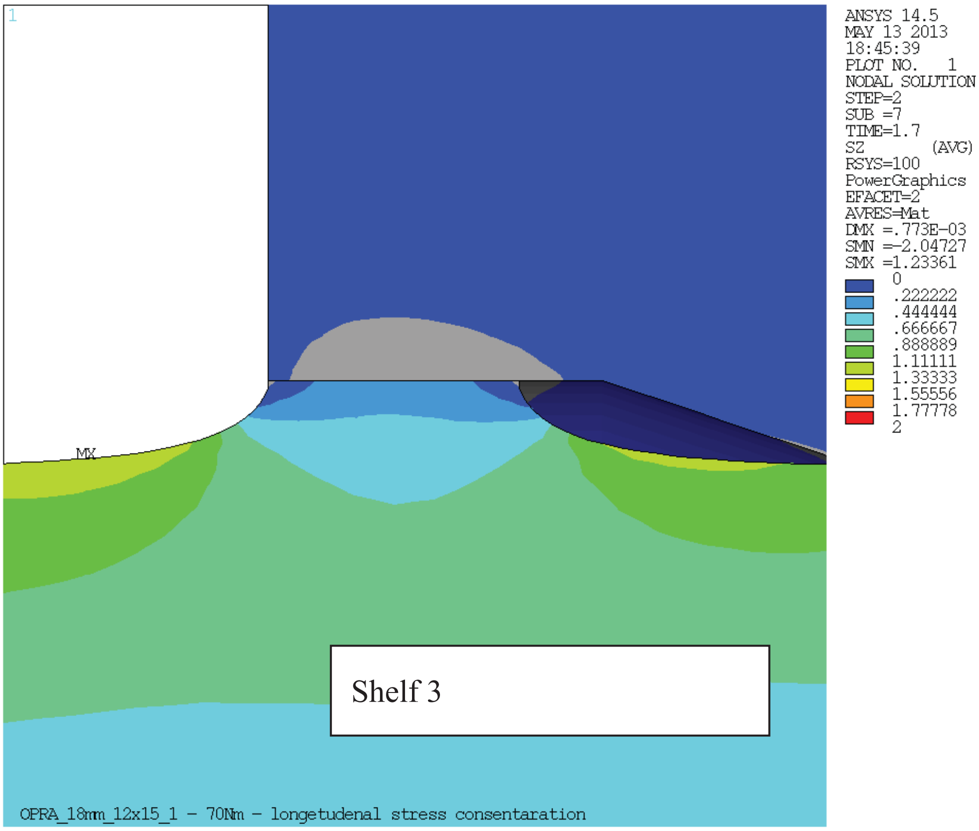

Figure 26: The stress in longitudinal or Y-direction concentration on the tension side.

Figure 27 shows how the tension stress in the middle of the contact region varies with depths on the abutment for the shelf geometries two and three. The x-axis on in the figure starts with zero on the surface of shelf two and shelf three starts at 0.25mm because the increase in radius was smaller on shelf three. The width of the shelf was identical on both shelves. If the surface stress was independent of the fillet, the red line should follow the blue closely but the smoother fillet of shelf three increased the stress on the surface from 20% to 40% of the stress measured at the abutment without a shelf.

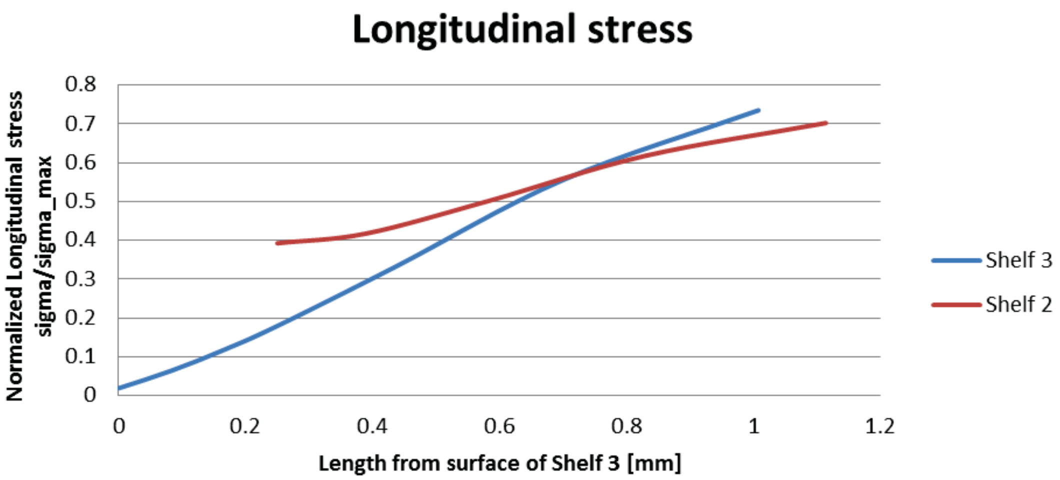

Figure 27: Graph of the longitudinal stress at different depths.

Figure 28 shows the pressure distribution on the compression side at the contact area for the different shelf geometries and the original case. All the shelf geometries are separated in the contact area at the tension side leading to contact gaps on the tension side. The difference in contact pressure can be explained by the difference in stiffness caused by the varying diameters of the fixture. The high contact pressure close to the normalized length 1 is an effect of the sharp edge on the shelves.

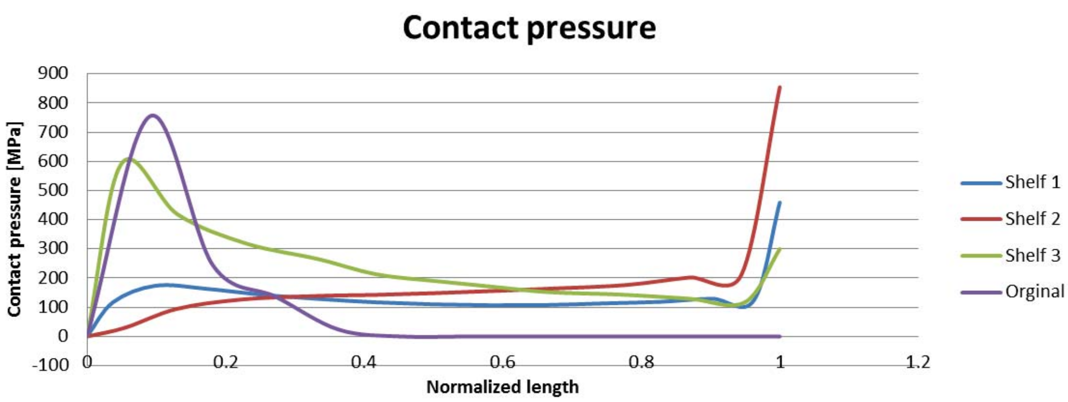

Figure 28: Contact pressure at the compression side of the OPRA models.

The relative maximum movement between the abutment and fixture at the tension side are listed in Table 5. In the table we can see that the differences in relative motion are small between the original case and of shelf geometries.

Table 5: Slip amplitude for the shelf models and original OPRA model.

Case	Slip amplitude
Original	0.032
Shelf 1	0.032
Shelf 2	0.035
Shelf 3	0.029

5.4.4 Conclusions for tests with a shelf geometry

Using a fillet with geometry according to the method described above gave surprisingly good results with regard to the stress concentration factor. Of the cases studied, the one with a ¼ fillet ratio gave a stress concentration of 1.2 which was sufficiently small to be neglected in comparison to the effect of fretting. The longer length that the fillet can be smoothed out over, the lower the stress concentration factor becomes. The ratio is not limited to a ¼ ratio on the OPRA, an even larger ratio can be used but the beneficial effects are decreasing, so it is likely that the beneficial effects will be small for a larger ratio. Also, the smoother the fillet is the bigger the stress will become on the surface of the contact area. The smooth fillet transition suggested creates some challenges due to the fact that it is hard to draw this type of geometry on a blueprint. It will also be challenging to manufacture with adequate tolerances.

As described in Section 3.2, the most likely place for fretting fatigue cracks to occur are the edges of the contact surface. This is also where the pressure is largest making it most sensitive to fretting. The stress on the contact surface of the shelves was U shaped with zero stress on the edges making the critical edges more protected, see Figure 23.

The tension stress is also decreased so the potential for fretting fatigue is lowered both through the gap and the lower stress levels. The contact pressure and slip are approximately the same on the compression side of the contact region indicating that wear will be as present on the shelf geometries as on the original.

The OPRA 1 implants were sensitive to both fretting on the contact and fatigue failure in the screws when there is a gap in the contact region. The FE simulations show that the fretting problem can be reduced by using a shelf geometry without the stress concentration becoming too large. The fatigue life of the screws is not affected by the shelf geometries. The shelves only protects the abutment against fretting by lowering the stress. The wear between the abutments and fixture is not affected, so the problem with shorter life due to gap caused by wear is still present.

5.5 Similar studies on OPRA 2

A similar idea with a stress shielding geometry (see Appendix 1 Figure 41) to increase the fretting fatigue properties of OPRA 2 has also been tested. The idea is to introduce a neck right before the taper so that the tensional stresses on the initial part of the taper become reduced. The maximum reduction of radius due to the neck was 0.5mm. To smooth the fillet of the neck, the same procedure suggested by Walter (2008) described in Section 5.4.1 is used with a ratio of one to four.

A similar FE-model as for the tests on ORPA 1 was created with the only exception for the neck change in geometry. During the simulation, the implant was loaded with a bending load of 70Nm and the preload was set to 12Nm.

5.5.1 Results from FE-simulations of OPRA 2 with neck

Figure 29 shows tension stress divided by the maximum stress on the contact region of the taper for both the OPRA 2 design with and without a neck loaded with 70Nm. The zero is located where the tapers starts and are widest. The longitudinal stress is lower larger part the taper geometry and the stress are much lower during the first 2mm.

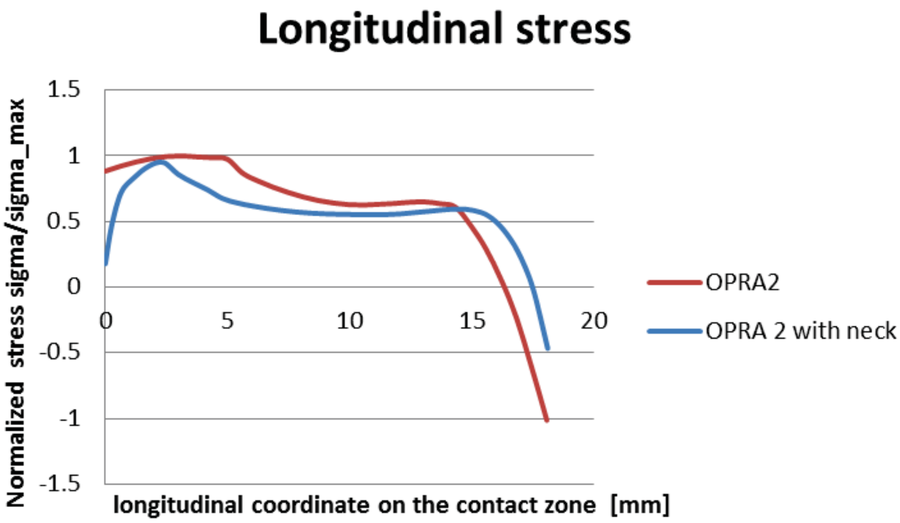

Figure 29: The longitudinal stress in the contact area for the OPRA 2.

Figure 43 (Appendix 1) displays the stress in longitudinal direction on the abutment. The stress concentration factor for the neck becomes 1.76. Figure 44 and Figure 45 (Appendix 1) displays the contact pressure on the taper with and without the neck plotted with the same colour bar. The maximum value of the pressure was the same for both cases but the taper without the neck has a larger contact area. The contact pressure on the taper only loaded with the preload from the screw is more compressed for the abutment with a neck, see Figure 45 and Figure 46.

Figure 30 shows the fretting parameter F2 for both the abutments with and without neck on the contact geometry. The slip amplitude was 0.25 for both with and without the neck.

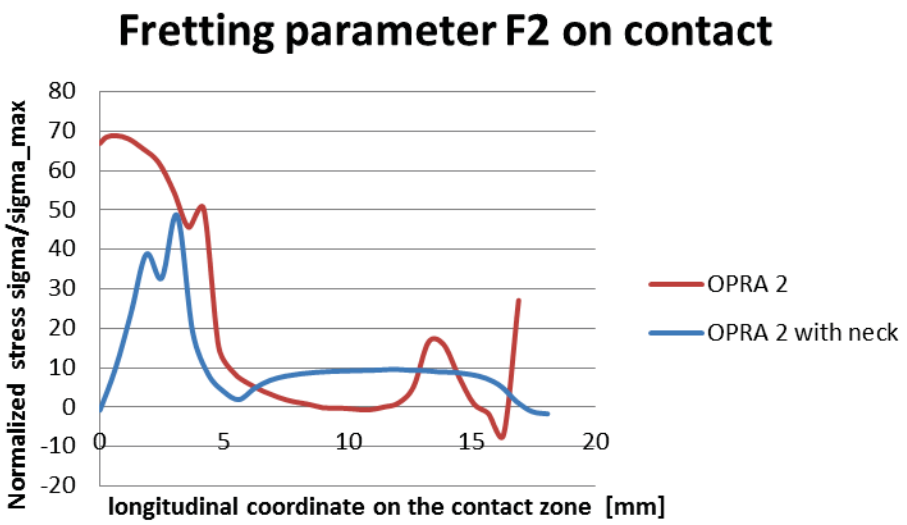

Figure 30: The fretting parameter F2 for OPRA 2 with and without neck plotted for the tension side of the contact.

5.5.2 Conclusions for the OPRA 2 with neck

The main point with the neck geometry was to reduce the tension stress on the contact surface. In Figure 29, where the stresses for both OPRA 2 with and without neck where plotted over the contact region, the figure displays that the neck affects the stress during the first 2 mm of the taper. The neck geometry will have a positive effect on the fretting fatigue life because the stress is lower. The stress and the F2 parameter are reduced close to the neck where the maximum load and F2 was for OPRA 2 without a neck. However, both the stress and the F2 parameter grow rapidly for OPRA 2 with a neck to the values achieved without a neck, so it is possible that the fretting problem is only moved from the beginning of the taper to a few millimetres towards, the fixture where the stress is similar to that of the beginning of taper without neck. The contact pressure and the slip amplitude were almost identical on both with and without neck.

The neck creates a stress concentration located beneath the neck with a stress concentration of 1.76. When calculating fatigue life on the stress caused by the neck, the fatigue life was larger than what is considered to be unlimited life. But the stress on the compression side of the abutment is larger because the bending and pretention is acting in the same direction. With the stress concentration, the stress becomes larger than the yield limit for titanium. Considering that the load of 70Nm is not a maximum load, the neck become sensitive to extreme loads. The same type of fillet geometry is applied when designing the neck as for the shelf, therefore the same problems regarding manufacturing. With a more easily manufactured geometry it is likely that the stress concentration factor will become even larger. To conclude, the neck geometries have potential to reduce fretting but needs further investigation to find a neck with both smaller stress concentration and larger effect on fretting. Considering that only one geometry was tested which gave promising results, it is definitely worth investigating other neck geometries.

6 Loads on the OPRA system

Lee et al (2008) has studied the loads on osseointegrated bone implants during walking on a flat surface. The study has found that the variation between different patients is large and that loads are more dependent on the patients gait cycle than the weight of the patient. In the study, forces and moments are measured according to the coordinates system in Figure 31 where AP is the walking direction and ML is the perpendicular direction to the walking direction. The loads in the tests are applied in the AP, ML plane. This way of loading catches the maximum load component of the combined AP and ML loads. The test does not take the force in z-direction into account. The force in z-direction will lower the tensional stress created by bending and thereby increase the plain fatigue life of the implants. The moment around AP is in positive direction while the moment around ML is both negative and positive (Lee et al 2008). The FE-simulations in previous Chapter 5 gives that the contact pressure is bigger at the compression side of the contact which results in more wear on that side. The more complex load cycle with both positive and negative bending moment will probably increase the fretting because the same part of the contact will experience high contact pressure during the negative bending phase of the loads cycle and high tension during the positive bending phase.

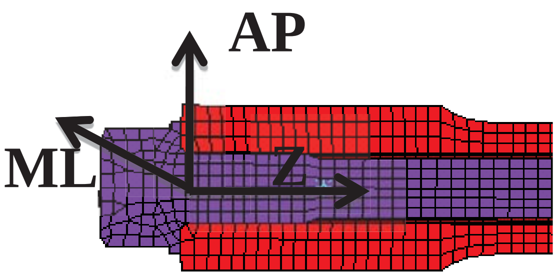

Figure 31: Coordinates system for measuring loads.

7 Conclusions

Both the simulations and the experience from real cases show that the OPRA 1 has two weak spots in terms of fatigue. The screws are sensitive to plain fatigue when time and wear in the surface interface between abutment and fixture has caused a gap. The second weak spot is the press fit zone of the abutment where the contact mechanics is producing fretting. Introducing shelf geometry in the contact will lower the stress on the surface, making the abutment more resistant to fretting fatigue. But considering that the shelf creates a stress concentration and do not affect the fatigue life of the screws, the shelf is not solving the problem with failing implants by its own. If it is possible to modify the screws so that they become more fatigue resistant by for example changing the material, the problems in the screw and abutment are solved. Another way to improve the fatigue life would be to surface treat the contact zone on the abutment to decrease the surface damage. This would potentially increase both fretting resistance of the abutment and decrease the gap between abutment and fixture that increased the stress on the screw.

OPRA 2 has lower tensile stress on the screw due to the increased diameter making it more resistant against plain fatigue. Thereby one of the weak spots from OPRA 1 is removed. The second fatigue weak spot on the OPRA implants caused by fretting on the abutment is still present in the OPRA 2 system but is likely smaller because of the decreased stress and pressure levels in the contact region. The neck geometry tested in this thesis had little effect on the properties of fretting and resulted in a large increase in compression stress due to the notch. It is possible that using optimal neck on the taper will decrease the tension stress on the contact surface. However, the increased compressive stress will still be an issue. Also for OPRA 2, the fretting fatigue on the abutment can be reduced by surface treating the contact area. The highest stress amplitude on OPRA 2 is in the fixture at the boundary condition, indicating that the 16mm fixture is the weakest part against plain fatigue. This is far from optimal because the fixture is the hardest part to replace. The fixed boundary condition that ends abruptly, resulting in a stress concentration is probably not an accurate way of describing the connection between the fixture and bone. In reality the connection is kinder to the fixture. The weakest point on OPRA implants all things considered is the abutment due to fretting.

The OPRA 2 is much stronger against plain fatigue in all parts compared with OPRA 1. Contact pressure and relative moment are smaller for OPRA 2 but the difference is not large enough to say that OPRA 2 is better protected against fretting than OPRA 1. The smaller longitudinal stress for OPRA 2 on the abutment will however give longer fretting fatigue life.

8 Recommendations and future work

Both OPRA 1 and 2 main fatigue weaknesses come from fretting and wear in the contact region between the abutment and fixture. Therefore, the possibility to increase wear and fretting resistance with a surface treatment should be further investigated. On existing OPRA 2 implants, it is important to maintain the interference fit between the fixture and the abutment to protect the screws against plain fatigue. On fixtures with unsymmetrical wear, it is probably a good idea to smooth out the hole by machining a larger radius. Furthermore, it is possible to use a shoulder to decrease fretting on the abutment of OPRA 1 but the screws are still sensitive to wear on the contact that crates gap.

It is worth investigating if a stronger material can be used in the screws to make them more resistant to fatigue. Using a neck on OPRA 2 have a greater potential because the screws are not so sensitive on OPRA 2, but the neck geometry tested in this thesis had little effects on fretting parameters of OPRA 2, while introducing a large compressive stress concentration. It is possible that a different type of neck could have a larger impact on fretting while keeping the stress concentration low. Further studies are needed to confirm this.

Only three tests on OPRA 2 has been made and of them only two where closely inspected. To get a better understanding of why the OPRA 2 failed, repeating the same tests with more specimens is needed to give a deeper understanding of the fatigue weaknesses. In the fatigue tests, loading the parts in both compression and tension should be considered, in order to better represent the load cases found form gait measurements.

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Appendix I

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