FE analysis and design of the mechanical connection in an osseointegrated prosthesis system

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Abstract
In this master thesis the connection between the two major parts of an osseointegrated prosthesis system for lower limb amputees has been investigated by finite element (FE) analysis. The prosthesis system is developed by Integrum and the current design consists of a fixture, which is integrated in the residual bone, an abutment that penetrates the skin and an abutment screw that holds the parts together. The connection between the fixture and the abutment has a hexagonal section and a press-fit section that together form the connection. Due to wear and fracture problems it is desired to improve the connection. A tapered connection could be an alternative and three different taper angles, the effect of the length of the taper and the smoothness of the outer edge of a tapered fixture have been investigated. The results show that the taper has potential to function well and that a longer connection will give lower stresses in the system, but further investigations are needed.

Keywords: abutment, finite element analysis, gait analysis, implant, Integrum, Morse taper, osseointegration, prosthesis, titanium
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Preface
This master thesis has been conducted during the spring semester 2011 at Integrum in Gothenburg, Sweden. The supervisor at Integrum was Rickard Brånemark and the supervisor at Linköping University was Lars Johansson and Ulf Edlund was the examiner, both at the Division of Mechanics at the Department of Management and Engineering.

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First I would like to thank my supervisors, both Rickard Brånemark at Integrum and Lars Johansson at Linköping University and also my examiner Ulf Edlund at Linköping University. Further, I would like to thank Simulia for letting me use Abaqus during the work with this thesis, and specially Jan Rydin at the Gothenburg office for the support. I appreciate the help and assistance I have received from my co-workers at Integrum and also from Roy Tranberg and Roland Zügner at Sahlgrenska University Hospital and Martin Smedstad at Epsilon.

Emelie Magnusson
1 Introduction
In this master thesis, an osseointegrated prosthesis system is analyzed. The stresses in the connection of the current system have been evaluated and compared with another type of connection with a tapered design. The work has been conducted in collaboration with Integrum.

1.1 Background
The osseointegrated prosthesis system was developed as an alternative to conventional prostheses, when the usage of these is problematic. Osseointegration means that one part of the prosthesis is anchored to the bone. The current system consists of three parts – a fixture, an abutment and an abutment screw. The fixture is integrated into the residual bone of the amputee stump and connected to the abutment, which penetrates the skin. The abutment is fastened to the fixture from the outside by the abutment screw, see Figure 1.

The fixture has a threaded outer surface to get a larger attachment area to the bone and an outer diameter that can vary depending on the size of the bone in the amputee stump. The size of the connection to the abutment is constant and the connection is 16 mm long and has a hexagonal section that is 7 mm and a press-fit that is 4 mm and the diameter of the abutment shaft is 11 mm, see Figure 2.

When walking on the prosthetic leg, each step will induce stresses and micro-slip in the osseointegrated prosthesis system and by time this causes wear and fracture problems. The system is designed such that failure is directed to the abutment and the abutment screw, i.e. outside the body. Information about the causes behind failure of these parts have been collected by Integrum.
and they are for example overloading by fall or tripping, wear that leads to play in the connection, and applying to high torque to the abutment screw when attaching it. About one third of all replacements of the abutment, abutment screw or both are due to wear.

1.2 Purpose
The purpose of this master thesis is to investigate the strength of the connection between the fixture and abutment in the osseointegrated prosthesis system for the lower limb and to try to find another connection that reduces the problems with wear and fatigue.

1.3 Scope and limitations
The loads that the prosthesis system is exposed to are investigated and connections described in the literature are reviewed. Based on that, some design suggestions with the ability to handle the loads are created. One of these proposals is more thoroughly investigated by FE analysis. Prototypes are tested mechanically and all methods and results are documented so that they can be used if a new design is implemented.

In this master thesis only the titanium and titanium alloy that are used in the current system is considered. In addition, the thesis is limited to the coupling between the fixture and the abutment and not between the fixture and the bone. Only the proximal end of the abutment is considered and the design of the abutment head will be kept as it is.

1.4 Report disposition
The thesis will start with a theory section, where some information about prostheses, osseointegration, loads on the implant and properties of bone and titanium will be provided. In addition, the theory part will contain a section about different kinds of connections. In the next chapter the method used to perform FE analysis, calculations and tests will be described. Thereafter, the results from the investigations will be given and then there will be a discussion and finally conclusions and suggestions of further work.
2 Theory
This section contains information about the osseointegrated prosthesis system, but first there is a part about amputees and conventional prostheses. Next, the gait cycle and the evaluation of the loads on the implant are explained and thereafter the properties of bone and titanium are given. The last part of the theory section covers different connection methods and joints.

2.1 Integrum
Integrum was founded in 1998 by Rickard Brånemark as a company in the field of osseointegrated prosthesis systems. Osseointegrated prosthesis means that an implant is integrated in the bone in the amputee stump and a prosthesis is attached to the implant. The technology developed from the dental industry and since the beginning of the 1990s more than 150 individuals have received an osseointegrated prosthesis.

2.2 Lower limb amputation and conventional prosthetics
An amputation is performed to remove a limb or other outgrowth that is not needed or even harmful to the body. Amputations of the lower limbs are caused by, for example, peripheral vascular disease, trauma, infection, tumor and congenital limb deficiency. In the western world, most of the amputations are performed due to peripheral vascular diseases, followed by trauma and tumors (Hierton 1995). An amputation of the lower limb could be either transfemoral, i.e. between hip and knee, transtibial i.e. between knee and foot or disarticulation of the knee (Hagberg 2006).

Traditionally there are mainly two ways to attach a prosthetic device on the amputee stump. These are non-suction sockets that are attached by braces or other suspension devices and suction sockets, which are the most used attachment nowadays (Hierton 1995). Unfortunately, there are several disadvantages with the conventional socket prosthesis such as discomfort, sores, rashes and pain. Back pain and pain in the joints in the other limb are also relatively common issues among lower limb amputees. (Hagberg 2006) It can also be difficult to establish good attachment of a conventional prosthesis if the amputee stump is very short.

2.3 Osseointegrated prosthesis
During the 1950s, Per-Ingvar Brånemark discovered that commercially pure titanium can be anchored in bone tissue and in 1965 the first osseointegrated dental implant was attached (Brånemark et al. 1977). The osseointegrated prosthesis system has been developed from dental implants and it is designed to fit in the amputee stump and to withstand the estimated loads.

Patients fitted with an osseointegrated prosthesis increase their ability to walk. This implies an increase in the number of gait cycles and thereby more load cycles on the implant. The mean age of individuals going through the first surgery to get the osseointegrated prosthesis system is relatively low, which means that the expected time of use of the implant is long. The implant has to withstand the induced stresses during a high number of load cycles without failure. With more users the typical load patterns become more apparent and the design of the implant system has been improved in steps to increase the resistance to failure.

The osseointegrated prosthesis system gives better control of the prosthesis and also an increased comfort and sensory feedback (Hagberg et al. 2008). Comparing the range of movement and the pelvic tilt in amputees using a socket prosthesis to amputees using an osseointegrated prosthesis,
shows that both the range of movement and the pelvic tilt are improved (Tranberg et al. 2011). However, one disadvantage with the osseointegrated prosthesis system is the potential risk of infection, since there is a hole through the skin (Tillander et al. 2010). The osseointegrated prosthesis is not the first choice of prosthesis system and the option of an osseointegrated prosthesis will only be given if there is a proven need. The amputee also has to have a fully grown skeleton and a good physical condition of the bone in the amputee stump (Hagberg et al. 2008).

There are several steps that the patient has to go through before it is possible to walk on the osseointegrated prosthesis. During the first surgery the fixture is inserted in the distal part of the bone in the residual limb. The fixture has a threaded outer surface to increase the attachment area to the bone, which grows into the material and after approximately six months of healing a second surgery is performed. In the second surgery the abutment is inserted and the abutment penetrates the skin and is fastened in the fixture by the abutment screw. To gain strength in the bone and the surrounding tissue a period of training follows the second surgery before it is possible to walk on the prosthetic leg. (Hagberg et al. 2008)

![Image of osseointegrated prosthesis system](image.png)

**Figure 3** – The osseointegrated prosthesis system is located in femur and the abutment penetrates the skin and the abutment head is connected to the safety device (Rotasafe), which in turn is connected to the prosthesis.

### 2.4 Loads on the implant

The gait cycle consists of a stance and a swing phase, starting with the initial floor contact of one foot and ending when the same foot reaches the floor again. During the gait cycle there is one stance and one swing phase for each leg. The step length is the distance between the heel contact of the left and the right foot. (Hierton 1995)
The implant and the prosthesis are exposed to different loads when walking and performing daily activities. Moments and forces are divided into components in the anteroposterior direction – forward backward, mediolateral direction – to the sides and along the longitudinal axis, see Figure 3. The movement in the hip in the anteroposterior direction is called flexion when the thigh is moved towards the trunk and extension in the opposite direction. Abduction is the movement of the leg outward in the mediolateral direction and adduction is when the leg is moved inwards. Along the longitudinal axis rotation in the hip joint is possible, both externally and internally.

The magnitude of the loads depends on the activity, the anthropometric characteristics and the gait pattern of the person. The loads will be within a certain range while walking and under normal activities with higher peak values that occur more rarely.

2.4.1 Gait analysis
A gait analysis can be performed in different ways, but generally the kinematics, i.e. movement of the body is recorded by video cameras and the ground reaction forces are measured by force plates (Hierton 1995). This gives the possibility to calculate the kinetics, i.e. internal and external forces, that cause the movement of the body (Winter 2009).

Markers are placed on landmarks of the body, which makes it possible to track the movement of the different body segments. Each of the body segments are approximated by a geometrical shape with a known center of gravity and moment of inertia. Since both the directional and angular velocities and accelerations are known and also the forces and the position of the segments, inverse dynamics can be used to calculate the moments in each joint. (C-Motion 2011)

2.4.2 Load cell
A specially developed load cell can be used to record the loads that the prosthesis system is exposed to. The load cell is placed above the prosthetic knee and the loads are measured and then processed, so that gait patterns and magnitudes are established. Measurements of the moments and forces in the implant have mainly been performed in level walking, but the advantage with the load cell is that it is not necessary to perform the measurements in a laboratory environment and daily activities can be recorded as well.

The measurements from the load cell and the calculations of the moments and forces in the implant by inverse dynamics in the gait analysis show the same pattern and magnitude (Dumas et al. 2009). In the gait analysis only one or two steps are taken into account. However, the step-to-step variability is small when measuring over many gait cycles with a load cell and this indicates that one or two steps adequately reflect the loads induced. The variation of the body-weight normalized moment in the implant between different persons is high and this can be caused by different anthropometric characteristics, gait pattern and different prosthetic components. (Lee et al. 2008)

2.5 Bone
The main functions of the skeletal system are leverage, support, protection, storage and formation of blood cells. The bone consists of compact and spongy bone tissue. The compact bone has a high density and brings strength and stiffness to the structure, while the spongy bone has a high porosity and can absorb a lot of energy and is thereby good at distributing loads (Hamill et al. 1995). The shape of the bone is designed to have as high strength to weight ratio as possible, with compact bone where the forces are transferred and spongy bone elsewhere. Depending on the loading on the
bone it can remodel by growth or removal of bone tissue. If there is not enough stress acting on the bone it becomes weaker and too much stress also weakens it. (Fung 1981)

The strength of bone depends on age, sex, where in the body the bone is situated, the direction of the load, the strain rate and if the bone is tested in a dry or wet state (Fung 1981). In Table 1 are some of the mechanical properties of human femoral bone presented.

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultimate tensile strength [MPa]</td>
<td>24 ± 1.1</td>
<td>(Fung 1981)</td>
</tr>
<tr>
<td>Ultimate elongation [%]</td>
<td>1.41</td>
<td></td>
</tr>
<tr>
<td>Modulus of elasticity in tension [GPa]</td>
<td>17.6</td>
<td></td>
</tr>
<tr>
<td>Ultimate compressive strength [MPa]</td>
<td>170 ± 4.3</td>
<td></td>
</tr>
<tr>
<td>Ultimate contraction [%]</td>
<td>1.85 ± 0.04</td>
<td></td>
</tr>
<tr>
<td>Ultimate shear strength [MPa]</td>
<td>54.1 ± 0.6</td>
<td></td>
</tr>
<tr>
<td>Torsional modulus of elasticity [GPa]</td>
<td>3.2</td>
<td></td>
</tr>
<tr>
<td>Ultimate bending strength [MPa]</td>
<td>160</td>
<td></td>
</tr>
</tbody>
</table>

2.6 Titanium

All the parts of the osseointegrated prosthesis system are made of titanium. Titanium is a biomaterial and has many interesting properties, among others its high strength to weight ratio and biocompatibility. Because of the good properties of pure titanium and titanium alloys, they are often used in the aerospace industry, turbines and medical applications. Titanium is divided into grades as defined by ASTM and ASME, where the four lowermost grades are commercially pure titanium and the grades above are alloys with different content of other elements (ASTM 1993).

Titanium is a common metal in the earth crust but it is an expensive material, since it takes a long time and much energy to refine. Compared to other biomaterials, such as cobalt-chrome alloy, niobium and tantalum, titanium still has a lower volume price. One of the reasons for this is that titanium can be processed by the same methods as more common metals. To be defined as a biomaterial some requirements has to be fulfilled regarding corrosion resistance, biocompatibility, osseointegration, mechanical properties and processability. Titanium is reactive at room temperature, but because of a thin layer of titanium oxide that forms on the metal surface it becomes stable and extremely corrosion resistant. This is an important factor, since corrosion can lead to loss of ions which can disturb the natural flow of ions in the body. A concentration of inorganic compounds can then create toxic reactions. Titanium has a relatively low elastic modulus which makes it more similar to the stiffness of human bone than other available materials and titanium is for example used in artificial hip and knee joints and in dental implants. (Leyens et al. 2003)

2.6.1 Crystal structure

Titanium appear in two crystal structures, \( \alpha \) and \( \beta \), where \( \alpha \) crystallizes at a low temperature and consist of a modified ideally hexagonal closed packed structure and \( \beta \) of a body-centered cubic structure. Pure titanium and the majority of the titanium alloys consist of the \( \alpha \)-phase and the hexagonal closed packed structure gives the material anisotropic properties. Titanium alloys can also be in a \((\alpha + \beta)\)- or \( \beta \)-phase. (Leyens et al. 2003)
Depending on the atomic configuration, titanium in α- and β-phase have different properties. Titanium in α-phase has for example, a higher resistance to plastic deformation, a reduced ductility and a higher creep resistance than β-phase. (Leyens et al. 2003)

2.6.2 Friction

To design useful components it is important to understand friction, since friction has a huge impact on the function. Friction can be described as the resistance to motion between bodies. Even if all the factors behind friction are not established, some of the major ones in friction between solid surfaces are adhesion properties of very clean surfaces, asperity deformation and wear particles between the surfaces. (ASM International 1992)

Friction coefficients for titanium are shown in Table 2, but the values are only valid for the test conditions used and if a high precision of the friction coefficient is needed, a test in the exact conditions has to be performed (ASM International 1992).

Table 2 – The frictional properties of titanium. Test geometry POF means pin sliding on flat surface and FOF means flat surface sliding on another flat surface (ASM International 1992).

<table>
<thead>
<tr>
<th>Fixed specimen</th>
<th>Moving specimen</th>
<th>Test geometry</th>
<th>Friction coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Static</td>
</tr>
<tr>
<td>Ti</td>
<td>Ti</td>
<td>POF</td>
<td>0.47</td>
</tr>
<tr>
<td>Ti</td>
<td>Ti</td>
<td>FOF</td>
<td>0.55</td>
</tr>
<tr>
<td>Ti</td>
<td>Ti6Al4V</td>
<td>POF</td>
<td>0.43</td>
</tr>
<tr>
<td>Ti6Al4V</td>
<td>Ti6Al4V</td>
<td>FOF</td>
<td>0.36</td>
</tr>
<tr>
<td>Ti6Al4V</td>
<td>Ti6Al4V</td>
<td>POF</td>
<td>0.36</td>
</tr>
</tbody>
</table>

2.6.3 Surface damage

Wear will cause the material in the surface to deform or be removed when the surfaces in contact move relative each other. The wear becomes greater if the materials in the surfaces are similar and metals are particularly sensitive to this. The relative hardness between the surfaces is an important factor for wear. If fatigue due to high contact pressure is not a problem, a higher hardness of the material would decrease the risk of wear. Wear could also be decreased by lubricants, which will reduce friction and also transport heat and debris. (ASM International 1992)

Fretting is a kind of wear that occurs when two surfaces in contact moves repeatedly against each other with a small amplitude. Fretting often occurs due to stress concentrations and highly polished surfaces have a higher risk of fretting than rougher surfaces. Fretting could be reduced by increasing...
the roughness of the surfaces, by for example shot peening and coating of the surfaces, inserts of softer materials and lubricants. (ASM International 1992)

2.6.4 Fatigue

Fatigue failure occurs when a structure is exposed to cyclic loading. The fatigue behavior is influenced by the environment and corrosion and high contact pressure can speed up the process. Temperature variations can induce stress cycles and cracks can be created by fretting. The fatigue life of a material can be estimated by a Wöhler-diagram, see Figure 5, where the number of cycles, \( N \), before failure is displayed on the x-axis and the stress, \( \sigma \), on the y-axis. If the cyclic stresses are below the horizontal line, the fatigue life will be very long. (Dahlberg et al. 2002)

![Figure 5 - Wöhler-diagram with cyclic stress on the y-axis and a logarithmic scale of the number of cycles on the x-axis.](image)

Factors that are important for the fatigue behavior of titanium are microstructure, texture, amount of interstitial elements and the surface properties. The microstructure and texture depend, on for example, grain size and arrangement of \( \alpha \)- and \( \beta \)-phase. Higher oxygen, nitrogen, hydrogen and/or carbon content will increase the strength of titanium, but it will decrease both the ductility and the fracture toughness. The surface properties can be improved by shot peening, mechanically polishing or deep rolling the surface, but the residual compressive stresses that are created are not stable and can be eliminated. (ASM International 1996)

2.6.5 Tables of the properties of titanium Grade 4 and Grade 5

In the implant titanium Grade 4 and Grade 5 are used and in Table 3 some of the material properties are displayed. Grade 4 is commercially pure titanium and Grade 5 is the most common titanium alloy Ti-6Al-4V. Many of the properties stated in the table depend on crystal structure and content of interstitial elements, so the values can vary.
Table 3 – Mechanical properties of titanium Grade 4 and Grade 5.

<table>
<thead>
<tr>
<th>Property</th>
<th>Grade 4</th>
<th>Grade 5</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yield strength (0.2% offset), min [MPa]</td>
<td>483</td>
<td>828</td>
<td>(ASTM 1993)</td>
</tr>
<tr>
<td>Tensile strength, min [MPa]</td>
<td>550</td>
<td>895</td>
<td>(ASTM 1993)</td>
</tr>
<tr>
<td>Elongation, min [%]</td>
<td>15</td>
<td>10</td>
<td>(ASTM 1993)</td>
</tr>
<tr>
<td>Reduction of area, min [%]</td>
<td>25</td>
<td>25</td>
<td>(ASTM 1993)</td>
</tr>
<tr>
<td>Density [kg/m³]</td>
<td>4510</td>
<td>4430</td>
<td>(ASM International 1990)</td>
</tr>
<tr>
<td>Modulus of elasticity [GPa]</td>
<td>104.1</td>
<td>113.8</td>
<td>(ASM International 1990)</td>
</tr>
<tr>
<td>Modulus of rigidity [GPa]</td>
<td>38.6</td>
<td>42.1</td>
<td>(ASM International 1990)</td>
</tr>
<tr>
<td>Poisson’s ratio</td>
<td>0.34</td>
<td>0.342</td>
<td>(ASM International 1990)</td>
</tr>
</tbody>
</table>

2.7 Mechanical design

2.7.1 Requirements

The current design of the osseointegrated prosthesis system consists of three parts; the main advantage of this configuration is that failure can be directed to occur outside of the body so that the broken parts can be replaced. This is a desirable property of the system, which should be kept and/or developed in future designs. Therefore the fixture and the abutment should be kept as separate parts, but the connection between them and the way they are attached can be altered.

The coupling between the abutment and the fixture has to:

- keep the parts together
- eliminate motion between the parts
- withstand at least 10 years of usage, i.e. handle static and cyclic loading during this time
- be easy to assemble and disassemble
- be possible to use inside the body
- be possible to manufacture, both parts and individual spare parts

In addition, it is preferred that the design is as simple as possible, to make both the production and assembly as easy as possible. This could affect the quality of the product and also influence the cost. Another factor that is important, even if it has nothing to do with the functionality, is the aesthetics.

The choice of joint for a specific purpose is determined by the loading situation of the structure. The more complicated the load case is, the poorer the performance of the joint. The functionality of the joint is the most important feature, but it is also necessary to consider manufacturability, aesthetics and costs. (Messler 2004)

2.7.2 Mechanical fastening and integral mechanical attachment

Joints can be divided into three major groups; mechanical joining, adhesive joining and welding (Messler 2004). For the purpose of this system where the possibility to disassemble is crucial, only mechanical joining can be used, whereas the name indicates only mechanical forces hold the parts together. Friction is an important factor in the mechanical joints and motion can be restricted in one or more directions and loads transferred from one part to another. Mechanical joints consist of the two subgroups mechanical fastening and integral mechanical attachment. (Messler 2006)
2.7.2.1 Mechanical fastening

In mechanical fastening, the parts of the connection are joined and positioned by a fastener. Methods using mechanical fastening are for example; bolting, screwing, nailing, pinning and riveting. In some of these methods, for example in bolting, a clamping force will be introduced in the structure. (Messler 2006)

The clamping force will be established by a pre-tension in the fastener and the magnitude of the pre-tension is important to make the structure resist static and dynamic loading. A higher pre-tension will make the connection more robust than a lower pre-tension, though it is important that the yield strength of the fastener material is not exceeded. (Carlunger et al. 1999)

A high length to diameter ratio will improve the behavior of the fastener and this could for example be accomplished by washers. Washers could also be used to spread the load, to lock or to compensate for relaxation of bolt tension. Stress concentrations in the bolt can be reduced by keeping at least three threads above the attachment and the same amount within or below the same. To reduce the stress concentrations, the thread run-out should not be in the shear plane of the joint. (Messler 2004)

2.7.2.2 Integral mechanical attachment

Integral mechanical attachment uses integrated features to join the parts. It is possible to disassemble these joints without destroying the parts and compared to mechanical fasteners they are often more simple to assemble. Examples of integral mechanical joints are key joints, splines, flanges, jaw couplings, interference-fits and tapered joints. (Messler 2006)

Key joints are held together by a key and a keyway, see Figure 6. This prevents rotation and allows torque transmission and it could be designed to carry axial loading as well (Messler 2004).

Splined joints, see Figure 6, have a high resistance to torsion. They are easy to assemble and disassemble, but the complex geometry leads to higher production costs. To prevent wear a moderate length is required and wear could also be reduced by lubricants. (Nystrom et al. 2007)

Flanges are used to connect cylindrical shafts or thick walled pipes. The flanges have a larger diameter than the rest of the structure and are located at the ends of the shafts, where they can be connected to a similar structure by bolts, see Figure 6. The flanges can transmit torque, shear forces and tensile loads. (Messler 2006)

Interference fits, like press-fits and shrink-fits, only contain two parts, see Figure 6, and they are assembled by temporarily increasing the inner diameter of the outer part and decrease the outer diameter of the inner part. The construction must be thick-walled to tolerate the high pressure between the mated surfaces and this high pressure makes it hard to disassemble. (Nystrom et al. 2007)

Jaw couplings are, for example, used in clutches, see Figure 6. The teeth can have different geometrical shape, like squared, rounded or v-shaped.
Tapered joints are frequently used in industry when, for example, attaching shafts that transmit torque. It is found in many machines with rotating parts as for example lathes and drilling and milling machines (Messler 2004). It consists of a conical shaft that fits into a mating part with the opposite geometry, see Figure 6. To function properly it is important that the taper angle in both the male and female parts is exactly the same.

The tapered joint is also used in conical friction clutches. The two main functions of this joint is the transmission of torque and the possibility to disengage the surfaces. If the angle is too small it would not be possible to disengage the parts and if it is too large it would not transmit as high torque as needed. This leads to a compromise choice of angle, and a value between 10° and 15° is considered good. (Shigley et al. 2004)

The usage of tapered connections in medical applications has increased during recent years. It is, for example, used to connect the artificial femoral head to the stem in hip implants. In medical applications the connection is called Morse taper, even if it not have the same length or angle as the original Morse taper system.
3 Method

The approach is to investigate the loads on the osseointegrated prosthesis system, creating design suggestions and analyzing the designs by the finite element method.

3.1 Loads

The loads that are applied on the implant are found through literature studies and by evaluating data from gait analysis.

Gait analysis data of four individuals is used to investigate the loads in the implant. Three of the persons (subject 1-3) are known to have high moments in the hip joint and for the fourth person (subject 4) data from load cell measurements are available for comparison. Demographics of all four test subjects are found in Table 4. The gait analyses were performed at Sahlgrenska University Hospital, where six cameras are used to record the movements and two force plates in the floor record the ground reaction forces. The kinetics is calculated by Visual 3D (C-Motion, Germantown, MD, USA). When performing analyses on persons with osseointegrated prostheses, markers are also placed on the Rotasafe in addition to the markers that are placed on predefined landmarks on the body.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Weight [kg]</th>
<th>Sex</th>
<th>Side of amputation</th>
<th>Length of stump as percentage of hip to knee length</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>85.5</td>
<td>Male</td>
<td>Left</td>
<td>62</td>
</tr>
<tr>
<td>2</td>
<td>89</td>
<td>Male</td>
<td>Left</td>
<td>56</td>
</tr>
<tr>
<td>3</td>
<td>100</td>
<td>Male</td>
<td>Right</td>
<td>84</td>
</tr>
<tr>
<td>4</td>
<td>85</td>
<td>Male</td>
<td>Right</td>
<td>53</td>
</tr>
</tbody>
</table>

There are several recordings for each subject, and the recording with the highest sum of the maximal moment in each direction in the stance phase of the amputee leg is further processed. The hip and knee moments of this leg is extracted as well as the ground reaction forces and the coordinates of the markers. To estimate the moments in the implant the system is considered to be static, while it in fact is dynamic. All calculations and plots are made with Matlab (MathWorks Inc., Natick, MA, USA).

The coordinates and the forces are given in the global coordinate system and have to be translated to the local coordinate system of femur, in which the hip and knee moments are given. The local z-axis is defined between the knee and hip joints with the positive direction towards the hip. The y-axis in the local coordinate system is directed anteriorly in the same direction as a perpendicular vector between the local z-axis and the marker on the top of the patella. Perpendicular to the local y- and z-axis is the local x-axis defined.
Figure 7 – The leg is divided into three sections – hip to implant, implant to knee and knee to foot. The forces and moments for each free body diagram is displayed. To the left is the local coordinate system shown, with the z-axis in the direction between the knee to the hip.

Moments of forces can generally be calculated as the cross product between the distance vector and the force vector (Meriam et al. 1998). As mentioned above, the system is considered to be static so that forces and moments are in equilibrium in any free body diagram. The moment in the implant, e.g. head of abutment can then be calculated in three ways, by a free body cut from the hip down to the implant, from the implant to the knee or by combining the last two parts in Figure 7, i.e. implant to foot, see equation 1-3. In the equations the moments are denoted $M$ with a subscript of where the moment is located. The coordinates, $\text{coord}$, have the same subscripts, $F$ are the forces and all the vectors are expressed in the local coordinate system. The forces have to be in equilibrium, which means $F = F_{\text{foot}} = F_{\text{knee}} = F_{\text{implant}} = -F_{\text{hip}}$ and it is assumed that $M_{\text{foot}} = 0$.

\[
\begin{align*}
M_{\text{implant-hip}} &= -M_{\text{hip}} + (\text{coord}_{\text{hip}} - \text{coord}_{\text{implant}}) \times F \\
M_{\text{implant-knee}} &= M_{\text{knee}} + (\text{coord}_{\text{knee}} - \text{coord}_{\text{implant}}) \times F \\
M_{\text{implant-foot}} &= M_{\text{foot}} + (\text{coord}_{\text{foot}} - \text{coord}_{\text{implant}}) \times F
\end{align*}
\]

### 3.2 Design suggestions

The design suggestions are formulated after literature studies and brainstorming. In the literature study different methods of joining parts were studied, in particular connections that can withstand both torsion, bending and compressive loads, as the joints described in chapter 2.7. Two brainstorming sessions have been held, where all suggestions were welcomed and noted. Further ideas have sprung from conversations and have also been written down.
3.2.1 Benchmarking
In hip implants the Morse taper is widely used to connect the stem with the femoral head. The properties of the taper are not standardized and the angles of some stems were investigated. First, specifications of different brands were found by searching the internet and secondly a physical measurement was performed on three examples. The brand names of these are Biomet, Anatomica and DePuy. The inner and outer diameter, $D_{\text{inner}}$ and $D_{\text{outer}}$ and the length of the side, $L_{\text{side}}$ of the cone, see Figure 8, were measured with a calipers. The angles where then calculated by trigonometry and the result is displayed in Table 9 in the chapter with results.

![Figure 8 – The outer and inner diameter and length of the side of the cone.](image)

3.3 Analysis
To enable comparisons, both the current design and the chosen design suggestion have to be analyzed. The analyses are performed through theoretical calculations, FEM and a physical test.

3.3.1 Theoretical calculations
The shape of a conical friction clutch and the implant are similar even if the clutch is larger. The function is partly the same, since the clutches transmit torque without slipping and must be disassemblable. The pressure on the conical surface and the transmittable torque can be calculated for the friction clutch. If there is an agreement between the surface pressure in the theoretical calculations with the geometry of the implant and the pressure in the FE analysis, the calculations can be used to estimate the transmittable torque before slipping. There are two ways to calculate the pressure and the torque, by uniform pressure and uniform wear. After the first wear-in period the theory of uniform wear are used. (Shigley et al. 2004)
The expressions for pressure and maximal transmittable torque for the uniform wear theory are given in equation 4 and 5. In these expressions the geometry of the cone is given by $D$, the larger diameter, $d$, the smaller diameter and $\alpha$, the cone half-angle as seen in Figure 9 and in the same figure is the pressures $p_{\text{max}}$ displayed. If no external axial force is applied, $F$ is equal to the pre-tension in the abutment screw. $M_v$ is the maximal transmittable torque and $\mu$ is the friction coefficient.

$$p_{\text{max}} = \frac{2F}{\pi d(D - d)}$$  \hspace{1cm} (4)

$$M_v = \frac{\mu F(D + d)}{4 \sin \alpha}$$  \hspace{1cm} (5)

### 3.3.2 FEM

Since Integrum does not have any computer program that can be used for FE analysis, a list of available programs was made. After being in contact with a few companies Simulia, offered to lend a license of Abaqus/CAE 6.10 (Dassault Systèmes Simulia Corp., Providence, RI, USA) for use in this master thesis.

#### 3.3.2.1 The model

The model that is going to be analyzed with FEM consists of a fixture, an abutment and an abutment screw, see Figure 10. The fixture comes in several different diameters and the analyses are made on the smallest diameter to represent a worst case scenario. The abutment and abutment screw have standardized sizes.

$$Figure 10 – The osseointegrated prosthesis system with the fixture, abutment and abutment screw.$$
fixture only exists as a 2D drawing and a 3D model is created in Abaqus. The outer surface of the fixture consists of threads with different pitch for different outer diameters and to simplify the model the threads are excluded and the outer diameter is set to the diameter used when defining the tensile stress in a bolt (Carlunger et al. 1999), see equation 6. In the equation is \( d_2 \) the pitch diameter and \( d_3 \) is the inner diameter of the thread.

\[
D_{\text{tensile stress}} = \frac{d_2 + d_3}{2}
\]  

(6)

The diameter \( d_2 \) is calculated by equation 7, where \( d \) is the major diameter, \( P \) is the pitch. The value of \( d_3 \) can also be calculated but the diameter given in the drawing is used instead, since this value is smaller and gives more conservative calculations.

\[
d_2 = d - 0.6495P
\]  

(7)

To simulate the tapered connection the original fixture and abutment is modified, while the design of the abutment screw is kept constant. The taper angle is set to 3\(^\circ\) and a play of 1 mm is introduced in the bottom of the connection, see Figure 11. To investigate the effect of the angle, tapers with 1\(^\circ\) and 2\(^\circ\) are also created. While keeping the angle constant at 3\(^\circ\), the influence of a smoother edge of the fixture (radius = 0.05 mm) is investigated as well as a 5 mm longer taper and a longer taper with a smooth edge. The location of the smoother edge can be seen in Figure 11.

![Figure 11 – The tapered connection with a 3\(^\circ\) angle. The play and the outer edge are indicated in the figure.](image)

There will be both twisting and bending moment acting on the implant, as well as axial forces. Due to symmetry only half of the implant needs to be modeled to investigate how the system behaves during bending moment. This will decrease the number of elements and thereby the computation time. The whole model is needed to investigate the effects of torsion though.

### 3.3.2.2 Elements

Both the fixture and the abutment are meshed with quadratic tetrahedron elements, called C3D10 and the abutment screw has linear hexahedral elements, called C3D8R. To get a better mesh, the parts are divided into smaller regions. The parts are seeded and the mesh is refined to get more accurate results. The mesh independence is checked by investigating the averaging factor in the results.
3.3.2.3 Material model
The fixture consists of titanium Grade 4 and the abutment and the abutment screw consist of titanium Grade 5. The material is considered to be isotropic and Young’s modulus and Poisson’s ratio given in Table 3 are used as input to the FE program. The yield limit, the fatigue limit and the ultimate tensile stress is also important properties that are necessary to interpret the output from the FE program.

3.3.2.4 Boundary conditions
In reality the fixture is integrated in the bone; in the FE analysis this connection is approximated with a fixed connection. This rigid connection is set on the proximal part of the fixture, see Figure 13, to simulate a worst case scenario. This scenario could occur because of severe bone resorption, due to for example infections or stress shielding (Integrum OPRA Teknisk dokumentation 1999).

This simplified way of modeling is evaluated by modeling a cylinder of bone around the fixture and tie them together and fix the bone instead, see Figure 14. The elastic modulus of bone is taken from Table 1 and Poisson’s ratio is estimated to 0.3.
In torsion the whole model is used and when analyzing bending moments only one half of the model is used and symmetry conditions are applied to the surface as displayed in Figure 15.

![Figure 15 – The symmetry boundary condition.](image)

The analysis is performed stepwise and the sequence is the same as it is when assembling the real implant. First the fixture is fixed and then the interactions between the parts are created and another boundary condition is applied to temporary hold the abutment and abutment screw in place, while tightening the screw. The results are presented in 4.3.2.

### 3.3.2.5 Pre-tension

The abutment screw is retained with a torque, 12 Nm, and when doing FE analysis, this torque is translated to an axial tension in the shaft of the screw. The relation between the axial force, $F_F$ and the torque, $M_v$, depends on the friction in the threads, $\mu_g$, and the friction in the bearing surface, $\mu_u$, as well as the average diameter of the threads, $d_2$, and the bearing surface, $D_k$. Equation 8 describes this relation. (Carlunger et al. 1999)

$$M_v = F_F(0.161P + 0.583d_2\mu_g + 0.5D_k\mu_u) \quad (8)$$

Since the friction coefficient between the parts in the osseointegrated prosthesis system is not known, $\mu_g$ and $\mu_u$ are assumed to have the same value.
3.3.2.6 Contacts

Friction is also an important factor between the surfaces that are in contact. The model is simplified by assuming that the friction coefficient is the same between all surfaces, even if the different parts have different material properties. The interaction between the surfaces, highlighted in Figure 17, will be in both the normal and the tangential direction. In the normal direction, contact pressure between the surfaces can be transmitted. The tangential behavior has a penalty formulation and this method uses the Coulomb friction model, which means that the surfaces will stick together until the shear stresses are too high and the surfaces start to slip relatively to each other (Abaqus 6.10, 2010).

Figure 16 – The relation between pre-tension and moment.

Figure 17 – The tapered fixture and abutment with the surfaces that are in contact colored red. All the surfaces except the threads in the fixture are affected by friction. The threaded surface is tied to the abutment screw.

The threads of the abutment screw are simplified with a tie-constraint. The diameter of the threaded area is set to the tensile stress diameter, as explained for the threaded outer surface of the fixture.

Figure 18 – Distributed coupling constraint.
A coupling constraint is added between the flat surfaces of the abutment head and the reference point is located in the center of the hole entrance in the abutment head, see Figure 18. The coupling could be either kinematic or distributed. A kinematic coupling will move the coupling nodes like a rigid body relative to the reference point and in a distributed coupling the motion of the coupling nodes are still coupled to the reference point but the nodes can move relative each other (Abaqus 6.10, 2010). In this model distributed coupling is used.

3.3.2.7 Evaluation

The implant is loaded with bending moment, a torque and axial forces. When walking, the implant is exposed to all of these in the same time, but to be able to distinguish the effect they have, bending and torsion are simulated separately.

The contact pressure between the conical surfaces in the fixture and the abutment is compared to the theoretical calculations. The mean value of the contact pressure is calculated by the contact pressure of all the nodes in the tapered part of the abutment, see Figure 19 and then dividing by the number of nodes.

![Figure 19 – The contact pressure in the abutment cone.](image)

To verify the FE analysis a comparison between the model and a physical test (Thompson et al. 2011) is made. In the physical test a 2°-taper is bent by a load and the strain in the longitudinal direction is measured. The whole outer area of the fixture is fixed in the test and this boundary condition is transferred to the FE analysis, but the diameter of the abutment is slightly larger in the test and it is also 1 mm shorter than the FE model. In both cases the loads tested are 178 N, 267 N, 356 N, 445 N and 534 N.

The hex and the cone system are compared, both with the outer diameter of the fixture set to 16 mm and with the diameter set to 18 mm. The friction coefficient is set to \( \mu = 0.36 \), but to evaluate the effect of friction, it is varied between 0.2, 0.36 and 0.5 in the surfaces in the connection. It is only the friction coefficient in the connection, i.e. the hex and press-fit and the cone that are varied, while it is kept constant between the other surfaces, which means that the pre-tension is also kept constant at the value found at \( \mu = 0.36 \).

The different configurations with different taper angles, different lengths of the connection and smoothness of the outer edge of the fixture are tested in both bending and torsion and the loads applied are displayed in Table 5.

| Table 5 – The loads in bending and torsion. |
|-----------------|---|---|---|---|
| Bending [Nm]    | 50 | 60 | 70 | 80 |
| Torsion [Nm]    | 20 | 30 | 40 | 50 |
3.3.3 Test
A test is performed to verify that the conical connection can withstand enough torsion. The test specimens – one in current design and one with a 2° taper – have already been used in a bending test (Thompson et al. 2011).

The fixture is simplified with no outer threads and both the specimens are prepared by introducing a chamfer in the fixture to be able to hold it when applying the torque, see Figure 20. On the abutment with the taper connection there are visible marks indicating that the taper angle is not exactly the same in the fixture and to get a better fit the taper in the abutment are polished.

![Figure 20 – The test specimen is hold in place by a vise and to the right is the torque applied with the digital wrench.](image)

The test specimens are assembled and fixed in a vise and the recommended tightening torque of 12 Nm is applied with a digital torque wrench (Draper). A line is drawn on the fixture and the abutment to identify movements. The socket of the torque wrench is changed to fit the head of the abutment and a torque of 30 Nm is applied counterclockwise. The line is controlled and the system disassembled and reassembled again and a torque with the same magnitude is applied in the other direction. The procedure is carried out once more and this time the tightening torque is set to 20 Nm and the torque applied to the abutment head is again set to 30 Nm in a counterclockwise direction.
4 Result

4.1 Loads
The different free body cuts, i.e. hip to implant, implant to knee and implant to floor, give different values of the moments in the implant. In Figure 21 the range of the moments in flexion/extension, abduction/adduction and rotation is displayed. The first bar for every subject and every direction is the range of moment in the hip, the second line is the first free body cut, the third line the knee moment, the fourth line the second free body cut and the fifth is the last free body cut. For the fourth subject, the range of moments from load cell measurements is also included. The range of the ground reaction forces is displayed Figure 22.

**Figure 21** – The range of moments in different directions for four subjects, the three first are known to have large moments and the fourth are compared to load cell data.
In Figure 21 it is seen that the range of the calculated moments in the implant is sometimes larger and sometimes smaller than the given moments in the hip and the knee and this depends on the location of the implant. The leverage is, for example, both positive and negative during the gait cycle in flexion/extension. The load cell values for subject 4 are much smaller than the hip moments in flexion/extension and rotation and the range is smaller than the hip values in abduction/adduction, even if the load cell is more on the negative side. Except for abduction/adduction the range of the load cell values is smaller than the knee moment.

From the literature study, values of the moments in the three directions are gathered, and in Table 6 the maximum absolute value from each study is listed.

Table 6 – The moments in the implant measured by a load cell.
4.2 Design suggestions

The brainstorming sessions and other methods gave several suggestions of how the connection between the abutment and the fixture could be designed and some of which are listed in Table 7.

Table 7 – List of design suggestions.

<table>
<thead>
<tr>
<th>Design suggestions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Taper</td>
</tr>
<tr>
<td>Inverse taper, i.e. cone in fixture</td>
</tr>
<tr>
<td>Semi-spherical</td>
</tr>
<tr>
<td>Bevel</td>
</tr>
<tr>
<td>Geometrical shape (triangle, square, rectangle, ...</td>
</tr>
<tr>
<td>Wave-shaped bottom to increase contact area</td>
</tr>
<tr>
<td>Jaw connection</td>
</tr>
<tr>
<td>Bayonet connection</td>
</tr>
<tr>
<td>Shrink fit</td>
</tr>
<tr>
<td>Threads on abutment</td>
</tr>
<tr>
<td>Magnets</td>
</tr>
<tr>
<td>Vacuum</td>
</tr>
<tr>
<td>Rubber inside to increase friction</td>
</tr>
<tr>
<td>Smooth surface, like gauge block</td>
</tr>
<tr>
<td>Split mandrel</td>
</tr>
<tr>
<td>Increased length of connection</td>
</tr>
<tr>
<td>Spring function, like in crutches</td>
</tr>
<tr>
<td>Key joint</td>
</tr>
<tr>
<td>Torx</td>
</tr>
<tr>
<td>ISIS, bike pedal connection</td>
</tr>
</tbody>
</table>

Of the designs suggested in Table 7, it was decided to proceed with a taper connection and to investigate some different cone angles and also what effect a change in length has to such a connection. In the table below the result of the literature study of different tapers is summarized. It is important to notice that the angle given is the angle of the whole cone, in both this table and in Table 9, where the angles from the physical measurements are shown.

Table 8 – Taper angles in different hip implants and machine tapers.

<table>
<thead>
<tr>
<th>Product</th>
<th>Name</th>
<th>Taper Angle [°]</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hip implant</td>
<td>SM straight stem</td>
<td>4.09°</td>
<td>(aap Implantate AG 2010)</td>
</tr>
<tr>
<td>Hip implant</td>
<td>Classic Universal Stem</td>
<td>6°</td>
<td>(Fabrique d'Implants et d' Instruments chirurgicaux)</td>
</tr>
<tr>
<td>Hip implant</td>
<td>Selectiv Stem</td>
<td>6°</td>
<td></td>
</tr>
<tr>
<td>Hip implant</td>
<td>Stabilock Stem</td>
<td>6°</td>
<td></td>
</tr>
<tr>
<td>Hip implant</td>
<td>AQD</td>
<td>5.73°</td>
<td></td>
</tr>
<tr>
<td>Hip implant</td>
<td>Consensus: UniSyn</td>
<td>4.09°</td>
<td>(Consensus Orthopedics 2008)</td>
</tr>
<tr>
<td>Hip implant</td>
<td>Biomet: M2a-magnum</td>
<td>4.09°</td>
<td>(Biomet Uk Ltd. 2011)</td>
</tr>
<tr>
<td>Hip implant</td>
<td>DePuy: C-Stem</td>
<td>4.09°</td>
<td>(DePuy Companies 2011)</td>
</tr>
<tr>
<td>Hip implant</td>
<td>DePuy: Corail</td>
<td>4.09°</td>
<td>(DePuy Orthopaedics, Inc. 2010)</td>
</tr>
<tr>
<td>Hip implant</td>
<td>Excia</td>
<td>3.82°</td>
<td>(Aesculap Implant Systems 2011)</td>
</tr>
<tr>
<td>Machine taper</td>
<td>Morse Taper</td>
<td>1.43°-1.51°</td>
<td>(Tools-n-Gizmos 2010)</td>
</tr>
<tr>
<td>Machine taper</td>
<td>NMTB Taper</td>
<td>16.71°</td>
<td></td>
</tr>
<tr>
<td>Machine taper</td>
<td>Jacobs taper</td>
<td>2.82°-4.66°</td>
<td></td>
</tr>
<tr>
<td>Machine taper</td>
<td>Jarno Taper</td>
<td>2.86°</td>
<td></td>
</tr>
<tr>
<td>Machine taper</td>
<td>Brown &amp; Sharp Taper</td>
<td>2.38°-2.40°</td>
<td></td>
</tr>
</tbody>
</table>

The three hip implants that is measured in the benchmarking as described in chapter 3.2.1, are shown in Figure 23 and angles are shown in Table 9.
Figure 23 – The three hip implants on which the taper angle where measured. To the left is DePuy Corail, in the middle Anatomica and to the right Biomet, with its two Morse tapers.

Table 9 – Taper angle from physical measurement.

<table>
<thead>
<tr>
<th>Name</th>
<th>Taper angle [°]</th>
</tr>
</thead>
<tbody>
<tr>
<td>DePuy Corail</td>
<td>5.4</td>
</tr>
<tr>
<td>Anatomica</td>
<td>5.4</td>
</tr>
<tr>
<td>Biomet (top)</td>
<td>4.0</td>
</tr>
<tr>
<td>Biomet (middle)</td>
<td>1.4</td>
</tr>
</tbody>
</table>

4.3 Analysis

4.3.1 Theoretical calculations

The pressure and maximal transmittable torque is calculated for a cone as described in 3.3.1 and the results for a cone with the angle 1°, 2° and 3° are displayed in Figure 24.

Figure 24 – The pressure as a function of the friction coefficient to the right and to the left the torque these cones can transmit.

From the theoretical calculations, it is seen that a smaller angle of the cone will give a higher contact pressure and that it also can transmit a higher torque. It is also seen that a lower friction coefficient between the surfaces will give a higher contact pressure, but at the same time lower values of the torque.

The mean value of the contact pressure in the FE model, calculated as described in 3.3.2.7 is presented in Table 10. Altering the friction coefficient will give a variation of the pre-tension in the
abutment screw, but for the values in Table 10, the pre-tension is kept constant and only the friction between the tapered surfaces is altered.

Table 10 – The contact pressure from the FE analysis.

<table>
<thead>
<tr>
<th>Taper angle [°]</th>
<th>μ [-]</th>
<th>Contact pressure [MPa]</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.36</td>
<td>20.0</td>
</tr>
<tr>
<td>2</td>
<td>0.36</td>
<td>22.1</td>
</tr>
<tr>
<td>3</td>
<td>0.36</td>
<td>21.3</td>
</tr>
<tr>
<td>3</td>
<td>0.2</td>
<td>34.6</td>
</tr>
<tr>
<td>3</td>
<td>0.5</td>
<td>15.9</td>
</tr>
</tbody>
</table>

4.3.2  FEM

The result from the FE analysis is processed and the maximum stresses are extracted and plotted. In the following graphs the outer diameter of the fixture is 16 mm, the friction coefficient is 0.36 and the taper angle of the cone is 3° if nothing else is stated. The stresses that are shown are von Mises equivalent stresses and to be able to compare the plots of the stresses the maximum value is set to 483 MPa, which is the yield limit of titanium Grade 4. It is important to notice that the axes in the graphs are non-consistent.

4.3.2.1  Verification of FE model

As described in 3.3.2.7 the FE model is compared with a physical test (Thompson et al. 2011). In Figure 25 and Figure 26 is the strain in the longitudinal direction of the abutment displayed. The left side of each plot is where the connection to the fixture start and to the right is the transition to the abutment head. In both figures the range is set to the same values and this shows that the strain is higher in the FE analysis, but the pattern of the strain is similar in the two cases.

Figure 25 – The strain along the shaft of the abutment of the tapered design, where the abutment screw is pre-tensioned with 12 Nm. (Thompson et al. 2011)
4.3.2.2 Bending

With different connections both the magnitude of the stresses and their distribution vary. In bending of the hex system three areas with stress concentrations arise, in the threads, in the hex and in the outer edge and the maximum stress is in the hex itself — expressed as (hex) in the graphs. The maximum stress is located in the outer edge of the fixture in the cone system. The maximum stress in the outer edge of the fixture is extracted and in the hex system the overall maximum stress is also extracted.

Figure 26 – The strains in the shaft of the abutment. At the left side the pictures are cut where the fixture starts and to the right they are cut at the beginning of the abutment head.

Figure 27 – The von Mises stress, distributed in the fixture. To the left is a cone 3° and to the right the hex fixture and the applied bending moment is 50 Nm. The cone has one stress concentration at the outer edge, while the hex has stress concentrations at the outer edge, the hex and in the threads.
The maximal von Mises stress in the fixture in bending. To the left are the stresses in a 16 mm and 18 mm cone and hex system compared. In the hex system are both the maximal stresses in the edge and in the (hex), i.e. the overall maximal stress, given. To the right, the effect of friction is evaluated.

From the graph to the left in Figure 28 it can be seen that the stresses in the outer edge of the fixture are lower when the thickness of the fixture is increased in the hex system and it is the opposite in the hex structure and in the cone system. A plot of the stress distribution in the cone fixture, see Figure 29 shows that even if the maximal stress is higher in the 18 mm fixture, the overall stresses are lower. The cone system has a higher stress than the hex system at the outer edge of the fixture, but the overall maximal stresses in the both systems are similar.

The graph to the right in Figure 28 shows the dependence of friction and for both systems it is clear that a lower friction coefficient will give higher stresses in the fixture when bending moments are applied.
Different taper angles will give rise to different stress distributions in the fixture. Figure 30 shows that a longer connection will give a lower maximal stress and that a smooth outer edge of the fixture will also give a lower maximal stress. The combination of a long connection with a smooth edge will give an even lower maximal stress.

There is a difference in how bending affects the stress in the threads in the fixture. The stresses are much higher in the hex system as seen in Figure 27.

Figure 31 – To the left is the path from which the displacement in the downward direction is measured. To the right are the paths, where the stresses along the abutment are extracted. The arrow indicates the location of the maximum von Mises stress in the conical connection.

Figure 32 – The displacement of the abutment along the path showed in Figure 31. The vertical line indicates where the connection to the fixture ends. The applied bending moment is 50 Nm.
The type of connection and the thickness of the fixture affect the displacement of the abutment as seen in Figure 32. The hex connection gives smaller displacement than the tapered joint and a thicker fixture gives smaller displacements than a thinner.

When a bending moment is applied, there will be tensile stresses in the upper part of the abutment and compressive stresses in the lower, as seen to the right in Figure 31. The magnitude will be higher on the compression side and the highest peak seen in Figure 33 corresponds to where the connection between the fixture and the abutment ends, which is indicated by an arrow in Figure 31. The difference in stress level between the hex and the cone system are not that big along the shaft and the differences towards the left in the graph depends on the different geometries.

Figure 33 – The stress along the abutment on the upper side (tension) and on the lower side (compression). The vertical line corresponds to where the connection between the abutment and the fixture ends. The applied bending moment is 50 Nm.

Figure 34 – The stress in the abutment in the point marked in Figure 31 and in the hex structure. To the left is the influence of the outer diameter of the fixture displayed and to the right of the dependence of friction.

The relation is almost linear between the applied moment and the stress in the abutment, as shown in Figure 34 and Figure 35. To the left in Figure 34 it is seen that an increased outer diameter of the fixture will increase the stresses in the abutment at the point marked in Figure 31 and the differences between the cone and the hex systems become smaller when the diameter is increased. The stress in the hex structure is decreased when the diameter is increased, but the gradient of those curves are steeper, so the hex is more sensitive to an increase in bending moment. The graph to the right shows
that a higher friction coefficient gives higher stresses in the marked point in both the hex and the cone systems, but the opposite yields for the hex shape in the hex system.

The difference between different cone angles, length and curvature of the edge is not so big, the only configuration that stands out a little is the longer connection that has a little lower stresses.

![Stress in abutment - bending](image1)

**Figure 35** – Stresses in the abutment at the lower distal connection to the fixture.

In Figure 36 it is seen that a larger outer diameter of the fixture gives lower stress in the abutment screw and the differences between the cone and the hex system are higher when the bending moments are higher. When the fixture is larger, the location of the maximal stress is moved from the threads to the compression side of the screw shaft. The effect of the friction between the abutment and the fixture is larger in the hex than in the cone, since the distance between the hex curves are larger than the distance between the other curves, as seen in the graph to the right in Figure 36.

![Stress in abutment screw - bending](image2)

**Figure 36** – The maximal stresses in the abutment screw in bending. The effect of the outer diameter of the fixture is displayed to the left and the influence of the friction between the surfaces to the right.

Different cone angles will not influence the stress in the abutment screw, but the length of the abutment screw will, as seen in Figure 37.
4.3.2.3 Torsion

The stresses that are shown in Figure 39 are the average of the stress in the circumference, see Figure 38. The location of the red path is picked manually where the stresses appear to be highest. The stresses in the hex structure, displayed to the right in Figure 39 are taken as the maximum stresses. The stresses in the edge of the fixture are higher when the outer diameter is smaller and the cone system also gives rise to higher stresses at the edge than the hex system. The stresses in the hex structure are, on the other hand, much higher than any stresses found elsewhere, as seen when comparing the left and the right graph of Figure 39.

Figure 37 – Stresses in the abutment screw for different cone angles, lengths and appearance of the outer edge.

Figure 38 – The paths from which the stresses are extracted.
The averaged stress in the outer edge of the fixture in torsion comparing the cone and hex systems and different outer diameters to the left and to the right is the maximal stress in the (hex).

The influence of friction is higher on the cone system, as displayed in Figure 40. The lower friction allows the abutment to slip deeper into the fixture, which gives rise to the large stresses.

Most of the curves in Figure 41 are aligned, but the stresses in the $1^\circ$-cone are much higher than the rest. The longer connection gives lower stresses and the long+smooth connection gives higher stresses than the rest.
Figure 42 – The points along the abutment where the original and deformed coordinates are extracted. The point marked with an arrow is located where the fixture starts.

Figure 43 – To the left is the rotation along the shaft of the abutment when it is exposed to torsion, 20 Nm, and to the right the effect of friction.

In the hex system there is not as much rotation in the abutment shaft as in the cone system, and from Figure 43 it is also visible that a larger outer diameter of the fixture gives less rotation. To the right in the same figure it is seen that a lower friction coefficient allows more rotation of the abutment.

Figure 44 – The rotation of the abutment with different cone angles and other configurations.

The stresses in the abutment screw are lower in the cone system than in the hex system for lower torques and they become more similar when the torque is increased, which can be seen in both graphs in Figure 45.
Figure 45 – The stresses in the abutment screw when a torque is applied. A comparison between the 16 mm and 18 mm fixture to the left and the effect of friction to the right.

Figure 46 – The stresses in the threads in the abutment screw. The maximal values for the long and long+smooth are found in the head of the screw and are also plotted.

Figure 47 – The von Mises stress distributed in the fixture when exposed to bending 50 Nm surrounded with bone to the left and just fixed in the proximal part to the right.

In Figure 47 it is seen that the overall stresses in the fixture are reduced when it is surrounded by bone and the maximal stress in the lower edge is also reduced.
4.3.3 Test

The result from the physical test is gathered in Table 11.

Table 11 – The results of the test.

<table>
<thead>
<tr>
<th>Tightening torque [Nm]</th>
<th>Direction</th>
<th>Movement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Taper 12</td>
<td>Counterclockwise</td>
<td>Yes</td>
</tr>
<tr>
<td>Taper 12</td>
<td>Clockwise</td>
<td>Yes</td>
</tr>
<tr>
<td>Taper 20</td>
<td>Counterclockwise</td>
<td>Yes</td>
</tr>
<tr>
<td>Hex 12</td>
<td>Counterclockwise</td>
<td>Yes</td>
</tr>
<tr>
<td>Hex 12</td>
<td>Clockwise</td>
<td>No</td>
</tr>
<tr>
<td>Hex 20</td>
<td>Counterclockwise</td>
<td>Yes</td>
</tr>
</tbody>
</table>
5 Discussion

5.1 Loads
The static calculations using three different free body cuts give three different results. This might indicate that it is not possible to use a static approach to estimate the moments in the implant and the effect of the acceleration of the leg is too large to neglect. The length of the residual limb affects the results and if the stump is short the free body cut from the hip to the implant probably gives better results and the cut from implant to knee gives better result if it is longer. The residual limb for subject 4 is around half of the length of the thigh and it is hard to draw any conclusions from the comparison between the load cell measurements and the gait analysis data.

In the graph of the range of the moments it is seen that there is considerable variation between the subjects and this is due to factors such as weight, length of residual limb, gait pattern and prosthetic components.

5.2 Design suggestions and benchmarking
Several design suggestions were collected during the brainstorming sessions and the decision to proceed with the tapered design was made on the basis that this joint seems to work well in other medical applications, such as artificial hip joints.

From the benchmarking and the literature studies it is not possible to draw any conclusions of the angle of the taper, other than it should be relatively small. It might be that the taper angle has to be optimized for every specific problem and that is the reason behind the variation of angles. The lower joint of the Biomet hip implant has for example a smaller angle and are longer than the tapers that fits to the hip ball. The loads on this joint are similar to the loads in the osseointegrated prosthesis system and this might give an indication that the cone angle should be smaller than 3° and that a longer connection is a good idea.

5.3 Theoretical calculations
The theoretical calculations of the contact pressure and the transmitted torque seem plausible, since they give a higher pressure when the taper angle is smaller, and the smaller angle will transmit a higher torque. A lower friction coefficient would allow the cone to slip deeper into the mating part and this could cause the higher pressure at lower friction coefficients, but since the friction coefficient is lower it will introduce more slip and the transmitted torque will be lower. The FE analysis follows the same pattern when it comes to the friction and a lower friction will give a higher contact pressure and a higher coefficient will give a lower pressure. The different cone angles do not follow the same patterns as in the graph in Figure 24, since the 1°-taper gives the lowest pressure, 2° gives the highest and the 3° gives the value in the middle. The values from the FE analysis are approximately ten times lower than the theoretical values of the contact pressure and according to the theory, i.e. equation 4, it means that the applied force would be ten times lower. In analogy, the transmittable torque, calculated by equation 5, is ten times lower, which means 15 Nm, 22 Nm and 46 Nm for the 3°, 2° and 1° tapers respectively.

The lower contact pressure in the FE analysis might be an issue of how the bolt load functions, but it might also be how it works in reality. To fully understand this, further studies has to be conducted.
5.4 Verification
The FE analysis is verified by a comparison with a physical test (Thompson et al. 2011). The result from the FE analysis follows the same strain pattern as the physical test, but the magnitudes are higher. The reason behind this could, for example, be that the actual friction coefficient between the surfaces is different than the one used in the FE analysis. A different friction coefficient would change the pre-tension and as seen in the result section, different friction coefficients between the surfaces in the connection give a variation in both stresses and displacements. Another reason behind the different magnitudes could be the differences in the geometry. This will make the test dummy resist bending a little more, since the lever is shorter and the greater thickness of the shaft will make it more robust.

Because there is a difference between the magnitudes in the physical test and the FE analysis, the calculated magnitudes of stresses and displacements has to be interpreted with caution. The pattern is the same though and this indicates that the results from the FE analysis still can be used, at least to compare different solutions and distinguish which configuration gives lower stresses in the structures, even if the absolute values should be used carefully.

5.5 Comparing hex and cone, friction and other designs
In chapter 4.3.2.2 and 4.3.2.3 the hex and the cone systems are compared in bending and torsion. In the comparison between the systems with different fixture diameter, it is seen that the stresses and displacements in the whole system is depending on the diameter. In the cone system a larger fixture diameter will increase the stresses in the end of the fixture during bending and the stresses at the corresponding point in the abutment will also increase. The reason behind this might be that the larger diameter makes the fixture more robust and it will not follow the bending movement of the abutment as much and the bending of the abutment will be more like bending it over the edge. When the fixture diameter is smaller, the fixture will bend more with the abutment and the bending over the edge will not be as pronounced. The overall stresses in the fixture will however be lower with a larger diameter of the fixture. In the hex system the stresses in the edge of the fixture are lower with an increased outer diameter, but the stresses in the hex structure are increased. The press-fit might have something to do with the lower stress in the fixture edge. Otherwise, the stresses in the abutment screw and the displacements of the abutment are generally lower when the thickness is increased. The fixture with the larger outer diameter does not deform as much and this leads to the abutment having smaller displacements already when it leaves the connection and the slope of the abutment shaft is also smaller at this point when the diameter is larger.

The stresses in the edge of the fixture will be higher in the cone system than in the hex system, both when comparing bending and torsion. The maximal stress in the hex fixture is located in the hex structure and in the cone fixture it is located in the edge. Comparing the maximal stresses between both systems gives that the magnitudes are similar in the case of bending. In torsion the stresses in the hex will be more than ten times higher in the hex than in the cone. The high stresses in the hex structure are probably caused by problems in the geometry that makes the element in the fixture and abutment in the hex section overlap.

In the hex system, stress concentrations also appear in the threads and this is not visible in the cone system. The reason behind this could be that loads are transmitted by the abutment to the fixture since the abutment reaches the bottom in the hex system. In the cone system there is a play
between the fixture bottom and the abutment. Another, possibly coupled explanation could be a
different pressure on the abutment screw that in turn creates the stress concentration and in the
graphs it is seen that the stresses in the abutment screws are higher in the hex system than in the
cone system.

Looking at the dependence of friction, it is possible to say that a lower friction coefficient between
the surfaces in the connection generally gives higher stresses in the structure. One exception is that
bending of the abutment gives lower stresses with lower friction coefficients. This could be because a
higher friction coefficient makes the surfaces in the connection more resistant to motion and the
abutment will be bent over the fixture edge like in the case of a larger outer diameter of the fixture
in the case of a tapered connection. When the friction coefficient is lower, more slip is allowed and
this makes the bending over the edge less noticeable. The relation between friction and stress is not
always obvious like in the graph of torsion of the fixture, where the line corresponding to the friction
coefficient in the middle gives the lowest stresses and the lines in the graph of stresses in the
abutment screw cross each other.

Of the different cones that have been analyzed, the long 3° taper gives the lowest stresses in the
structure. It gives the lowest stresses in the structure in almost all tested cases, but one exception is
bending of the fixture, where the long+smooth connection shows the lowest values. The stresses in
the threads of the abutment screw are lowest in these longer connections, but they show a high
maximal value in the head of the screw.

The purpose of the smoother edge was to decrease the stresses at the fixture edge in bending and
the analysis confirms that this happens. However, the stress in the fixture edge is increased in torsion
and this is the case for the 1° taper as well. Higher stresses in the edge in torsion might indicate that
it resist movement better, even if that is not seen in the graph of rotation of the abutment.

5.6 Test

The surface of the tapered connection is polished prior the test to get more aligned surfaces in the
connection. It is not known if this defect of the alignment of the surfaces is from the production or if
it appeared in the prior bending test. After the torsion test it was found that the surface of the
tapered abutment has new marks, which means that it still does not align perfectly. The new marks
are situated on a larger portion of the cone though, which indicates that a greater part of the
surfaces are in contact. The outcome of the test shows that the hex connection holds for 30 Nm in
the clockwise direction, while the tapered connection does not hold in any tested case. The socket
that is fitted over the abutment head probably interferes with the abutment screw and when
applying the torque in the counterclockwise direction the screw is un-tightened. In reality the
abutment head is connected to a safety device and this does not affect the abutment screw.

As discussed in 5.3, all pre-tension force might not transfer to the abutment and if that is the case
the 2° taper will not withstand a torque of more than approximately 20 Nm. To verify this, a new test
has to be performed and lower torques tested. To get a more reliable result, test specimens with
more aligned surfaces should be used and a machine that records all motion would give more
accurate results. When the system is assembled in the patient, he or she has to walk a little bit after
the abutment screw is tensioned to press the parts together and thereafter the abutment screw is
controlled and tensioned again if needed. Simulating this could maybe also give more realistic
results.
6 Conclusions
The present work illustrates the benefits of FE modeling, but also the need to verify the theoretical calculations by testing. The studied joint is a complex mechanical system, despite the fairly simple geometries. However, the study shows that a conical design can be a potential design to use.

7 Future work
Further evaluations of the tapered design is needed and the cone angle and the length of the connection have to be optimized. To do so, the FE model must be refined and the material properties, like friction and plasticity, should be further investigated. The proceeding should also include additional tests to verify the findings.
References


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