Division of Solid Mechanics

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PROSTHESIS ATTACHMENT DEVICE FOR INDIVIDUALS WITH TRANS-RADIAL AMPUTATIONS

Master's Dissertation by

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Preface

This Master's Thesis concludes a Master of Science degree in Mechanical Engineering at Lund University, Faculty of Engineering. The project was carried out between September 2011 and March 2012 at Integrum AB, Mölndal. The aim of the thesis was to investigate new solutions for bone-anchored prosthesis attachment that allows natural forearm rotation and is compatible with new emerging technologies for myoelectric prosthesis control.

First of all I would like to thank Dr. Rickard Brånemark and Integrum AB for giving me the opportunity to do this thesis project within the interesting and novel field of bone-anchored prostheses.

I would also like to thank Stewe Jönsson, Leg. Orthopedic technician and CPO at TeamOlmed, for his valuable input and help during this project.

I would like to thank my supervisor at Integrum AB, Maria Elena Lopez and my supervisor at Lund University, Ingrid Svensson for helping and encouraging me in my work.

Lastly, I want to reach out and thank my colleges at Integrum AB for their support and cheerful spirits.

Gothenburg, March 2012

Lukasz Szychlinski

Abstract

The aim of this thesis is to find a functional attachment device solution for bone-anchored prostheses that allows natural forearm rotation. Patients with trans-radial amputations can benefit from such solution in form of greater motoric skills and thereby better quality of life.

Rotation of the human forearm involves complex biomechanics and has almost exclusively been studied on healthy limbs. An amputated individual will have losses in muscle and bone that limits the range and strength of the biological motion. There is a smaller group of patients that have the mobility and strength to produce a good range of forearm rotation.

Integrum AB is searching for a standardized attachment solution that can be fitted to all patients that can benefit from a functional device. Development of a standardized solution requires full understanding of the complex biomechanics and individual anatomy of a greater group of patients. The timeframe and resources for this master thesis project do not allow extensive research or patient measurement and is limited to the development of a customized solution that can be further developed to fit a greater group of patients.

There is no commercially available competing technology for bone-anchored attachment of upper extremity prostheses and no patient today uses a prosthesis system that allows natural rotation at the forearm. This sets the development process to a highly conceptual level and restricts the possibilities to perform a wider benchmarking and technology research. The development process of this thesis is mostly linear but sets a basis for more iterative work. Based on basic patient measurements and mapping of customer needs, several functional concepts are presented. The concept with the greatest potential is chosen and further developed.

The most important issue when working with prosthetic technology is patient safety. Both final product and testing of prototype solutions have to be safe because there is always a risk of injury to the patient. The complexity of the human forearm makes it hard to simulate. Therefore, the best way to test a prototype is straight on the patient. Testing can also be performed through computer aided simulations and on test rigs but these methods won't provide the same reliability of the results.

Keywords:
Bone-anchored prostheses, forearm rotation, Integrum AB, osseointegration, trans-radial amputation

Sammanfattning

Målet med detta projekt är att hitta en funktionell kopplingsanordning för benförankrade proteser som tillåter naturlig rotation av underarmen. Patienter med trans-radial amputation kan gagnas av en sådan anordning i form av bättre motorik och där med bättre livskvalitet.

Rotationen av människans underarm innefattar komplex biomekanik och har nästan uteslutet studerats på friska individer. På grund av förlust av muskler och ben så har amputerade individer nedsatt styrka och räckvidd i rörelsen. Det finns en mindre grupp patienter som har rörlighet och styrka att genomföra en användbar rotation av underarmen.

Integrum AB söker efter en standardiserad kopplingslösning som kan användas på alla patienter som gynnas av en funktionell anordning. För att utveckla en standardiserad lösning, krävs full förståelse av den komplexa biomekaniken och den individuella anatomin av en större grupp patienter. Den avsatta tidsramen och resurserna för detta projekt räcker inte för en djupare undersökning och mätning av patienter och begränsningar görs till framtagning av en mer specialgjord lösning som senare kan utvecklas till att fungera på en större grupp patienter.

Det finns ingen kommersiellt tillgänglig konkurrerande teknik för koppling av benförankrade armproteser och i dagsläget finns det ingen patient som använder en funktionell lösning som tillåter naturlig rotation av underarmen. Utvecklingsprocessen hamnar därför på en väldigt konceptuell nivå och en bredare undersökning av markanden och tekniken kan ej genomföras. Utvecklingsmodellen som används för detta projekt är till största delen linjär och står som grund för ett mer iterativt framtida arbete. Baserat på enklare mätningar på patienter och en kartläggning av kundbehoven så presenteras flera funktionella konceptlösningar. Konceptet med störst potential väljes för vidare utveckling.

Den viktigaste frågan när man arbetar med proteser är patientsäkerheten. Både den slutliga produkten och prototyptester måste vara av säker natur då det alltid finns en risk att patienten kan skadas. Den komplexa uppbyggnaden av den mänskliga underarmen är svår att simulera och det bästa sättet att testa en prototyp är direkt på patienten. Tester kan också genomföras genom datorstödd simulering eller via testrigg men kan aldrig ge lika tillförlitliga resultat.

Terminology

Abutment	Surgically inserted titanium implant that penetrates the skin and makes it possible to connect prostheses.
Bone-anchored prostheses	Artificial limbs directly connected to the patient's skeleton, through technology based on osseointegration.
Fixture	Surgically inserted titanium screw, specially designed for the marrow cavity of the bones of an amputation stump.
Myoelectric prostheses	Externally powered prostheses controlled through signals from muscles and/or nerves.
NCAL	Natural Control of Artificial Limbs– control system for myoelectric prostheses that uses implantable electrodes that are fitted through the bone anchored implant.
OPRA	Osseointegrated Prostheses for the Rehabilitation of Amputees – implant treatment system for bone-anchored prostheses based on osseointegration.
Osseointegration	Direct anchorage of an implant by the formation of body tissue and integration with the surrounding bone tissue.
TRA	Trans-radial amputation - amputation between the elbow and the wrist.

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1. Introduction

This chapter provides a brief presentation of the background and aim of this thesis project.

1.1 Background

With a growing market for bone-anchored amputation prostheses and emerging technologies for myoelectric control of prostheses there is a need for new mechanical components that can meet the user demands and are compatible with the new technologies. Integrum AB believes that transradial amputees will benefit from an attachment solution that permits natural forearm rotation. A mechanical construction could also relieve the electrical components for myoelectric prosthesis control.

1.2 Subject of Study

This report describes the development process of an attachment device for bone-anchored prosthesis systems for trans-radially amputated individuals. The attachment device will be a part of the OPRA product-line marketed by Integrum AB.

1.3 Aim

The objective of this thesis project is to investigate the possibilities and develop a new concept solution for bone-anchored prosthesis attachment that allows natural forearm rotation. The main goal is to research, design and present new conceptual attachment solutions for patients with trans-radial amputation (TRA). The attachment device solutions should be compatible with myoelectric prostheses and the Natural Control of Artificial Limbs (NCAL) project.

1.4 Delimitations

This project only addresses the development of components distal to the abutments and proximal to the terminal device. The project is limited to the development of a customized solution, tailored to the anatomy of one patient. This customized solution can later be used in the development of a more standardized attachment device. Redesign proposals for the abutment heads are encouraged but are not the main objective of the thesis.

1.5 Integrum AB

Integrum AB presents itself as: “A Swedish Medical Technology Company Developing Devices for Direct Skeletal Anchorage of Amputation Prostheses”. From now on Integrum AB will sometimes be referred to as “the company”.

1.6 Osseointegration

Osseointegration is the direct anchorage of an implant by the formation of body tissue around an implant. In the 1952 Professor Per-Ingvar Brånemark discovered that titanium does not create a foreign body reaction and integrates with the surrounding bone tissue.

The term Osseointegration was first used by Brånemark and co-workers in 1977 [1]. The technology was initially used for prosthetic replacement of teeth but has since then been further developed and is used for the rehabilitation of amputated individuals. Commercially pure titanium has most extensively been used for osseointegrated implants.

2. Methodology

This chapter briefly presents the development and research methods used for this thesis project.

2.1 Development method

The development work flow of this project follows a generic development process presented by Ulrich & Eppinger [17]. The development process of this project is mostly linear and only includes a few iterative steps. This thesis sets a starting point for a more iterative process with testing and verification.

2.2 Research methods

Method	Description	Purpose
Literature study	Broad study of scientific articles and reports, books, brochures, and other qualified written information. LibHub and related database search services have been used to find scientific articles and reports.	Primary method for the collection of scientifically qualified statistics, results and other information within the frames of this thesis project.
Interviews/Discussions	Interviews with potential product users and expert prosthetist within the field of bone anchored upper limb prostheses. Discussions with manufacturers and experts within the field of bone anchored prostheses.	To get an overview of the attachment technology for Osseo integrated TRA prostheses. To understand what has been done in the field and what the future expectations are.
Questionnaires	Two different questionnaires were sent out to potential users and upper limb prosthetists. Questions about the existing attachment device and the needs of improvement.	To get a qualified evaluation of the product from potential users and other stakeholders.
Patent search/Technology transfer	Patent search through Google Patents and other similar services on the internet. Search for interesting technology through the internet.	To find solutions for sub problems within other fields of technology.
Observations	Observations of how TRA patients handle and use the existing attachment device. Observations of the prototype solution.	To see how the existing product works and see how well the prototype solution functions.
Brainstorming session	Brainstorming session at Integrum AB with the company employees and other thesis workers.	To get construction ideas and feedback on solutions for the pro-supination problem.
Study visits	Study visits at Volvo PV and SKF with problem presentation, brain storming and discussions with employees within construction and mechanical testing.	To get inspiration and find interesting technology that can be transferred to the prosthesis attachment project.

3. Biomechanical concepts

This chapter presents the biomechanical theory needed for the development process and decision making during the project.

3.1 Basic anatomical concepts

Standard anatomical position

To describe the relationships between different parts of the human skeleton and body, it is assumed that the body is in the standard anatomical position; standing upright, with the arms at the side of the body, the hands palm forward (Figure 1) [18].

Anatomical planes

The human body can be divided along three different planes; the sagittal, coronal, and transverse plane (Figure 1).

The *sagittal plane* divides the body vertically along the plane of symmetry and creates a right and left side.

The *coronal plane* divides the body vertically and is perpendicular to the sagittal plane.

The *transverse plane* divides the body horizontally and can be made at any level.

Anatomical terms of direction

There are six different sets of anatomical terms of relative direction in the human body (Figure 1). Four are of importance in this thesis. They are:

Medial or *lateral* refer to the sagittal plane. Medial is towards the sagittal plane and lateral is away from the sagittal plane.

Anterior or *posterior* refer to the coronal plane. Anterior is to the front, and posterior is to the back of the body.

Superior or *inferior* refer to the relative placement along a vertical axis. Superior indicates a position closer to the head and inferior a position closer to the feet.

Proximal and *distal* refer to the relationships among the bones and structures of limbs. Proximal is closer to the trunk and distal is farther away from the trunk.

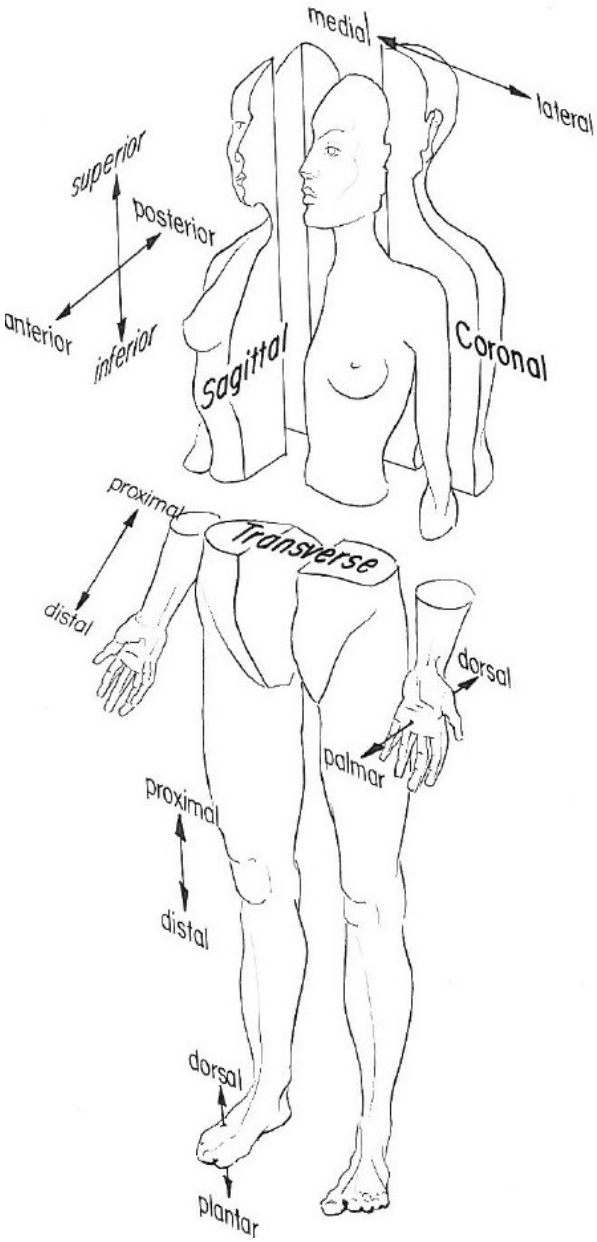


Figure 1 - Anatomical planes and terms of direction

3.2 Biological tissues

3.2.1 Bone

The major bones in the upper limb, e.g. humerus, radius and ulna are long bones. Their length exceeds their width and thickness and they are quite cylindrical along their length.

Bone structure

Bone as a material has a complex and unique composite structure built up by collagen; a fibrous organic polymer and the mineral; hydroxyapatite. Collagen has a low modulus of elasticity, good tensile strength but pure resistance to compression. Hydroxyapatite is a stiff and brittle material that has a high resistance to compression. Together they give bone its special properties as a two-phase, anisotropic material that has higher strength than its components and can resist tension, compression and shear [19]. The softer collagen prevents the stiffer hydroxyapatite from brittle cracking, while the hydroxyapatite prevents the collagen from yielding [20].

Mechanical properties of bone

The most important mechanical properties of bone are its strength and stiffness. Bone has viscoelastic properties and its response depends on the rate load is applied. Bone gets stiffer at higher strain rates and has a tensile strength that is comparable to that of cast iron. Bone is three times lighter and ten times more flexible than cast iron [1].

Compact bone works in compression, tension and shear. Compact bone can withstand greater stress in tension than in shear and bone will fail first in shear.

[1] shows reported strength and stiffness of compact bone.

Table 1- Mechanical properties of bone

Load		Strength	Young's modulus
Longitudinal	tension compression	78.8-151MPa 131-224MPa	17-20GPa
Transverse	tension compression	51-56MPa 106-133MPa	6-13GPa
Shear		53.1-70MPa	3.3GPa

3.2.2 Muscles

The muscular system of the body consists of three muscle types: cardiac muscle (heart), the smooth muscle that builds hollow internal organs and the skeletal muscle that is attached to the skeleton via tendons. The human body has more than 430 skeletal muscles that provide strength and protection to the skeleton, distribute loads, absorb shocks and enable movement of the bones at the joints. Both dynamic work in form of body motion and fairly static work in form of body posture and position are performed by the skeletal muscles

3.2.3 Tendons and ligaments

Tendons, ligaments and joint capsules are passive structures. Ligaments and joint capsules connect bone with bone and give mechanical stability to the joints and prevent excessive motion. Tendons function as attachment between muscle and bone, and form a muscle-tendon unit that gives the body dynamic control.

3.3 The upper limb

The human shoulder and upper extremity are very complex structures and provide a functional anatomy where bone, joint and muscle together determine the range of motion.

3.3.1 Anatomy of the upper limb

The anatomy of the upper limb is divided into three main regions: the arm, the forearm and the hand. The arm consists of the shoulder girdle and the part of the limb proximal to the elbow; the forearm is the region distal to the elbow and proximal to the wrist; and the hand is the region from the wrist to the fingertips. There are 32 major bones in the upper limb (Figure 2) [18] that articulate in eight different joints.

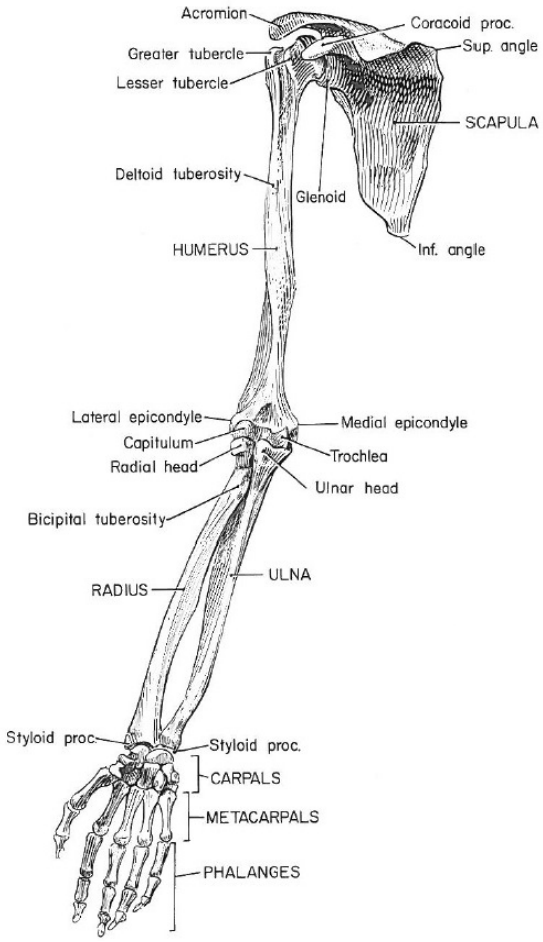


Figure 2 – The bones of the upper limb

3.3.2 The forearm

The forearm consists of two long bones, the radius and the ulna. The two bones articulate with the humerus and with each other in the elbow joint. The elbow joint is a complex joint capsule that holds three different joints; the humeroradial, humeroulnar, and radioulnar joint. Distally the radius articulates with the ulna in the distal radioulnar joint (DRUJ) and with two carpal bones in the radiocarpal joint. The radius is the larger more laterally placed of the two forearm bones (Figure 2). The ulna is more slender and slightly shorter than the radius and with the proximal end thicker than the distal end.

The Interosseous Membrane

The interosseous membrane (IOM) of the forearm is responsible for the load distribution and stability of the forearm. The interosseous membrane consists of 2 components: a thin, flexible membrane and a stiff and relatively thick central band [2]. The central band transfers load from the distal radius to the proximal ulna and changes the proximal load distribution between the two bones.

3.3.3 Biomechanical control of the upper limb

Movements and actions of the body are the product of contracting muscles anchored to bones, which articulate with other bones at joints. The movement for each joint is defined by the shape of the bones participating, the structure of the joint capsule, and by the placement of muscles about the joints.

Seven different actions can be produced by the movement of bone through muscle contractions: flexion, extension, abduction, adduction, rotation, gliding, or circumduction. All these movements are reciprocal or occur in a pair with another action. The upper limb is complex and permits a wide range of motion. Figure 3 [6] describes the movement system in a simplified way that is adequate for the purposes of upper-extremity prosthetics [6].

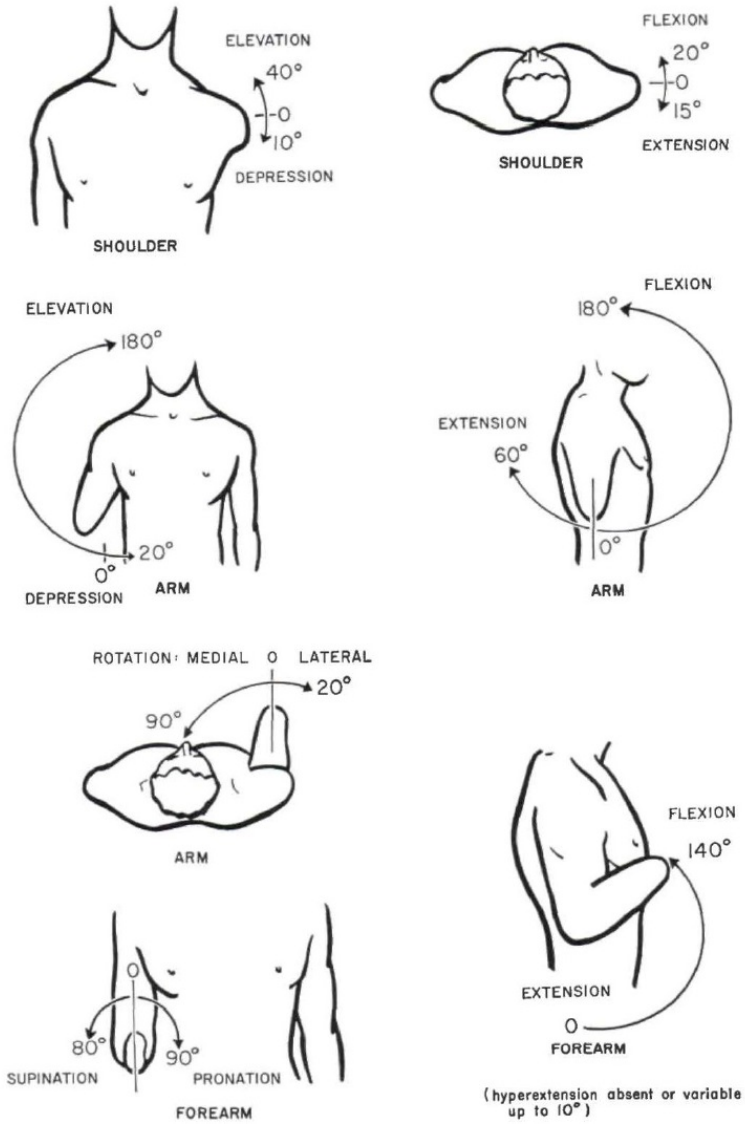


Figure 3 - Movements of the upper limb

3.3.4 Forearm rotation

Forearm rotation or pro-supination refers to the medial and lateral rotation of the forearm in which the radius bone rotates around the ulna bone. In anatomical position, the hand is supinated when the palm is forward and the shafts of the ulna and radius are parallel to each other. The hand is pronated when the radius has rotated medially about its long axis and the palm faces posteriorly. In the prone position the radius has crossed the ulna. The curved anatomy of the two bones allows them to cross without any interference. The relative rotation from supinated to pronated position is called pronation and the relative rotation from pronated to supinated position is called supination.

If the humerus is held rigidly, the radius appears to follow a greater and the ulna a lesser, arc around a common axis where the ulna has to perform a lateral swaying and a small axial sliding with respect to the humerus in order to avoid tilting of the wrist and ensure parallelism between the hand and the forearm [3].

Fixating and using the ulna as a reference instead of the humerus constructs a simplified model for pro-supination. If the ulna is held rigidly most texts on biomechanics indicate that the rotation of the forearm occurs along an axis extending from the approximate center of the capitulum (Figure 2) to the distal head of the ulna [4]. The center of rotation is located in the proximal radius head and the radius performs a fixed-point rotation in relation to the humerus. The mechanical axis of forearm rotation lies in an angle to the anatomical axis of the radius [19] see Figure 4 [5].

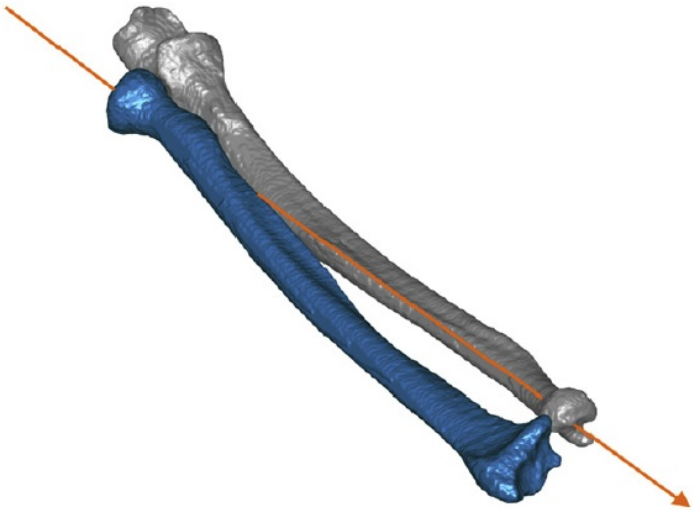


Figure 4 - Axis of rotation with ulna fixed

Figure 5 [18] shows the four main muscles that are involved in the pro-supination movements. The pronator teres and pronator quadratus muscles control the pronation of the forearm. The biceps brachii and the supinator muscles control the supination [18].

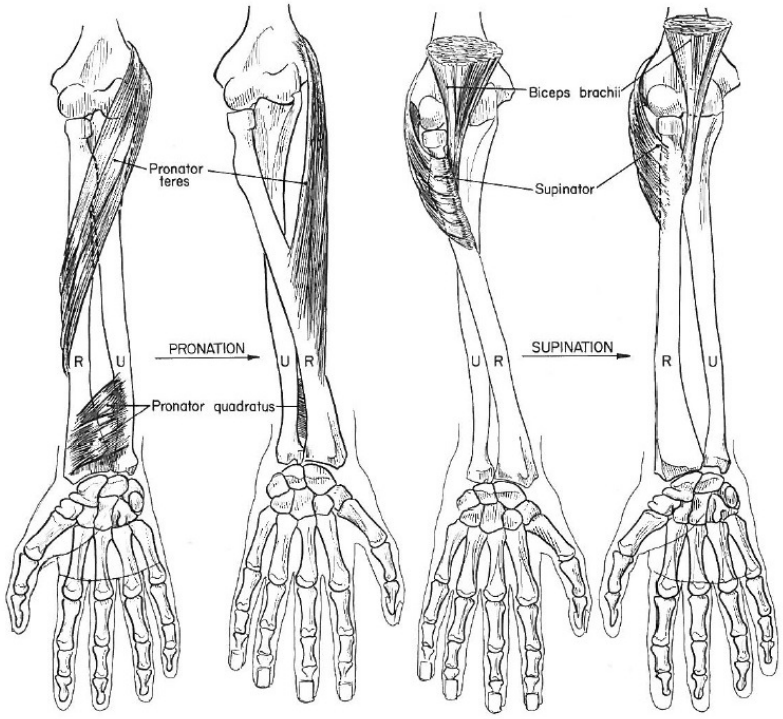


Figure 5 - Forearm anatomy

Proximally the radius articulates with the humerus and ulna in the humeroradial and proximal raioulnar joints during pro-supination. Distally the radius articulates with the ulna in the distal radioulnar joint (DRUJ) where the bones are pressed together and constrained by the palmar and dorsal radioulnar ligaments to attain stability in the pro-supination movement [3].

In the DRUJ a concavity of the distal radius articulates against a cylindrical surface on the distal ulna. The cylindrical surface appears to be angled perpendicularly to the longitudinal axis of the ulna, see Figure 6 [5]. A study performed by Matsuki et al. [5] revealed that the rotation axis at the DRUJ moved during rotation and that the ulna head translates about 4mm dorsally relative to the radius from maximum supination to maximum pronation.

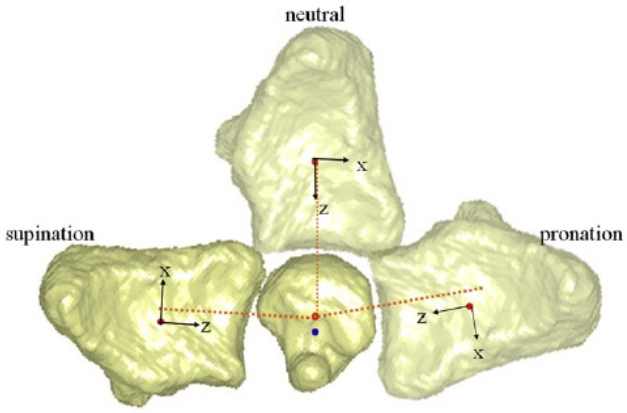


Figure 6 - Articulation in the DRUJ

3.3.5 Limitations in forearm rotation

Rotation of the forearm is a function of the whole forearm length [6]. The forearm rotation range increases distally, being 180 degrees at the wrist in a healthy arm.

The muscle activity in an amputated limb is considerably impaired [7] and pronation and supination of the forearm is extensively limited due to muscle loss and absence of the distal radius and ulna. There is also a loss of stability in the forearm and change of load distribution through the ulna and radius due to disruption of the interosseous membrane.

The level of amputation at the forearm can differ from long to very short depending on the cause of the initial injury. The ability to perform natural forearm rotation is highly dependent on the level of amputation. Figure 7 [6] shows the range of motion in a healthy and injured forearm.
The geometry of the human forearm and the interaction of the radius and ulna during forearm rotation set the amount of rotation in each section of the forearm.

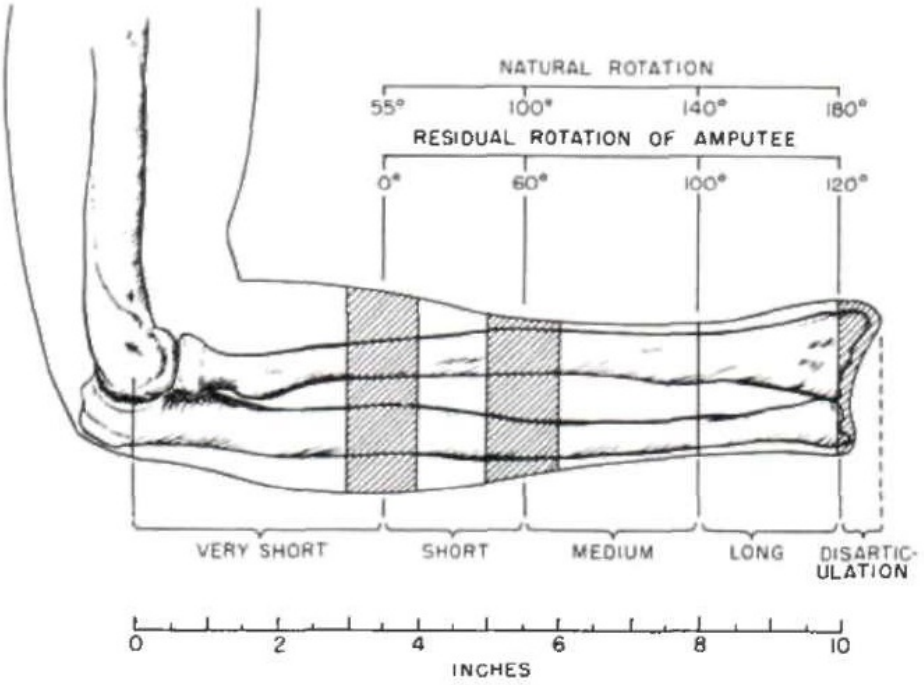


Figure 7 - Range of forearm rotation

4. Preliminary study

This chapter presents the results of a primary study within prosthetic technology, the OPRA-system, consumer identification and mechanical loading of the prosthesis system.

4.1 Prosthetic technology

Prosthesis can be defined as "replacement of a missing part by an artificial substitute, such as an artificial extremity" [21].

4.1.1 Upper extremity prostheses

There are mainly four different types of prostheses for upper extremity amputated individuals.

- Cosmetic prostheses
- Body-powered prostheses
- Externally powered prostheses
- Hybrid prosthesis

A cosmetic or passive prosthesis either does not have moving parts, or requires that you reach over with your other hand to move it. Cosmetic prostheses are often chosen if the user wants light weight, comfortable prosthesis that looks much like their biological arm [8].

A body-powered prosthesis is controlled by the user's upper body movements. Metal or nylon cables are used to control the prosthetic arm and hand. Body-powered prostheses are durable and relatively light and inexpensive. The user needs a good strength and range of motion to operate the sometimes bulky and uncomfortable prosthesis [8].

Figure 8 - ErgoArm body powered prosthesis from Otto Bock

In an externally powered prosthesis small motors are used to provide force and control to perform different functions. Compared to body-powered prostheses, externally powered prosthesis are less bulky, allow more grip force with less physical effort by the user. The disadvantages are that they are heavier, more expensive and run on batteries that have to be charged [8].

Externally powered prosthesis can be controlled by electric signals from the user's muscles and/or nerves. These kinds of prostheses are called myoelectric prostheses and use electrodes that transfer the user's electrical signals for the myoelectric control of the prosthesis system.

Figure 9 - DynamicArm myoelectric elbow joint from Otto Bock

Hybrid prosthesis systems use both body-powered and externally powered components to control different functions.

Even if there is a great range of commercially available prosthesis solutions on the market today, about half of the individuals with upper limb amputations choose not to use a prosthetic device [1]. This often due to that the technology commercially available today is not satisfactory enough for the user. There is still a great need for improvements in the field of upper-limb prostheses [33]. If improvements in the technology were made at a reasonable cost, 68% of non-users would be willing to reconsider prosthesis use [9].

Terminal device

A terminal device is the component of an upper extremity prosthesis that substitutes for the functions of the hand. The prosthetic system that the attachment device is intended for will be fitted with a myoelectric hand. Four of the commercially available myoelectric hands on the market are; Michelangelo Hand from Otto Bock, Vincent Hand from Vincent Systems, i-limb Ultra from Touch Bionics, and bebionic hand from bebionic. Even more advanced terminal devices for myoelectric control are under development and not yet commerciallt available. One of these is Smart Hand from Lund University.

Figure 10 - Commercially available myoelectric hands

Cosmetics

A cosmetic glove is worn over most types of terminal devices and upper limb prostheses to protect the mechanisms and improve appearance. Most cosmetic gloves are made of PVC that is durable but stains easily. Some gloves are made of silicone that is more expensive but more stain-resistant. A high-quality silicone cosmetic can be customized to look almost identical to the natural limb, see figure 11. The cosmetic covers for the prosthetic assembly are always customized to the anatomy of the patient but are tailored so that they can fit standard size prostheses [34].

Figure 11 - Prosthetic glove from bebionic

4.1.2 Socket attachment

The conventional way to attach upper extremity prostheses today is through individually shaped sockets that fit around the patient's residual limb. The socket is fastened to the residual limb through application of vacuum and this tight fit often leads to excessive perspiration, sores and pain. Another limitation with socket prostheses is that they are hard to secure and tend to slide during longer periods of use or when more athletic tasks are performed. Application of any socket prosthesis will also extensively limit the forearm rotation or hinder it totally.

4.1.3 Bone-anchored attachment

The most recent application of the osseointegration technology is for bone-anchoring of amputation prosthesis for the upper and lower extremities [10]. Bone anchored prostheses are attached directly to the bone and do not have any contact with the skin. Direct bone anchoring of prosthesis solves many problems related to the use of a socket. The prosthesis always fits, always attaches correctly and is always held firmly in place.

The first bone-anchored amputation prosthesis based on the Brånemark technology was installed in 1990, and is still in use today [10]. Integrum AB presents its osseointegrated implant system as the OPRA (Osseointegrated Prosthesis for the Rehabilitation of Amputees) system. Today over 200 patients have been treated with the OPRA system.

4.1.4 Natural Control of Artificial Limbs (NCAL)

Integrum AB is currently working with Chalmers University of Technology with a project that allows natural control of active prosthetic limbs. The project uses implantable electrodes that are fitted through a bone anchored implant. This technology goes under the name Osseointegrated Human-Machine Gateway (OHMG) and allows permanent access to both muscular and nerve signals without the environmental dependency of surface electrodes [11].

When the neural and muscular signals exit the human body through the OHMG, they are amplified and filtered before they are interpreted in terms of muscular activity through pattern recognition algorithms in the robotic prosthesis controller. Due to signal degradation over distance it is important

that the amplifying units can be placed as close to the abutment connections as possible [35]. A set of batteries supplies the prosthesis system with power. The robotic prosthesis controller and power supply are placed inside of the sleeve that connects the attachment device with the terminal device.

In total 12 electrodes exit the human limb, 6 through each abutment. The electrodes then connect to the controller and through multi pin connectors that can be repeatedly attached and detached with the prosthetic device. It is important to avoid electrode entanglement or disconnection during prosthesis use.

4.1.5 Wrist positioning

Prosthetic hands can include wrist units that allow hand rotation through electrical motors or manual prepositioning of the terminal device so that the user can perform specific tasks. An active prosthesis with motor controlled rotation of the wrist requires more information from the robotic prosthesis controller and takes up axial space. A wrist unit provides rotation of the wrist to compensate for the loss of rotation in the forearm. The rotation at the wrist is very unnatural and is not esthetically pleasant for the user.

4.2 The OPRA prosthesis system

4.2.1 Surgical components

The OPRA treatment consists of two surgeries. In the first surgery, called Stage I, a specially designed titanium screw (Fixture) is inserted in to the marrow cavity of the bones of the amputation stump. After the first surgery, the fixture is left unloaded for at least six months. In the second surgery (Stage II), a titanium abutment is attached to the end of the fixture through an abutment screw. The abutment penetrates the skin and makes it possible to attach a prosthesis. For patients with TRA, two sets of fixture, abutment screw and abutment are used, one for the ulna and one for the radius.

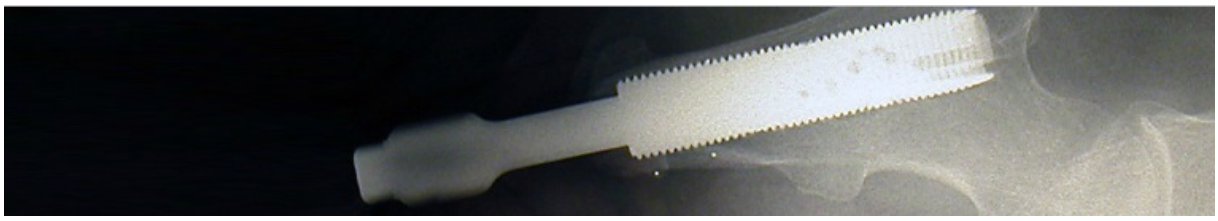


Figure 12 - Abutment and fixture in a femur bone

The main advantage of the OPRA Implant System is that load is directly transferred to the skeleton instead of the skin and soft tissue. This provides a more stable attachment of the prosthesis and the user can move more freely and on a more regular basis. The direct bone contact also provides better perception for the user, through small vibrations from contact with objects [10]

Other advantages of the OPRA Implant System are:

- Less pressure, sores and pain on the amputation stump
- No discomfort from heat and sweating in the prosthetic socket
- Fast and easy attachment and detachment

4.2.2 Abutment design

The surgically inserted components of the OPRA system are individualized for each TRA user. The dimensions of the components are highly dependent of which bone they will be anchored to, the anatomy of the patient and the level of the amputation.

Simplified, the abutment consists of a shaft and an abutment head. The shaft is the more proximal part of the abutment that fits in to the fixture and penetrates the soft tissue, the abutment head is the more distal part where the prosthesis attaches.

There are abutment heads with different shapes and dimensions. Generally two different abutment head designs are used for TRA patients: cylindrical and spherical (Figure 13).

Figure 13 - Abutments with cylindrical head (left) and spherical (right)

During the last years there have been several thesis projects at Integrum AB that address the abutment deign. This thesis project does not have the purpose to find new design solutions for the abutment heads but it should be considered how the attachment device will interact with the abutment heads.

4.2.3 Abutment connection

The existing attachment device for upper extremity prostheses used by the company today consists of an epoxy puck and quick release clamp system. See Figure 14. The puck system was developed in 1991 and 1992.

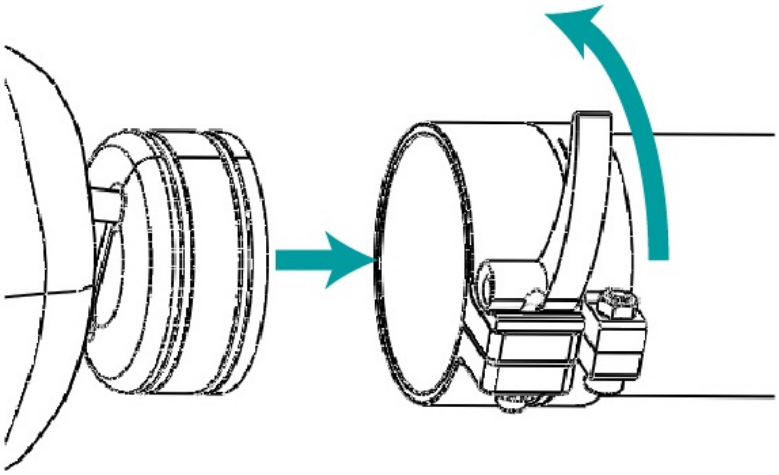


Figure 14 - Puck and clamp attachment

The principle of the puck and quick release clamp system is that the user first attaches the puck to the abutments. The puck is made out of two equal halves that split during attachment and latches around the abutment heads (Figure 15). The two halves are held together with silicon O-rings. When the puck is in place, the rest of the prosthetic device is attached to the puck through the clamp. The clamping force and friction between the clamp and the puck defines how much load the attachment system can hold. The puck and clamp system is provided in two different diameters, 40mm and 50mm. Most TRA patients need to use the bigger of the two diameters because of their individual anatomy. The main benefits of the puck system are that parts are easy to replace and easy to clean and that it can be customized to the patients anatomical needs.

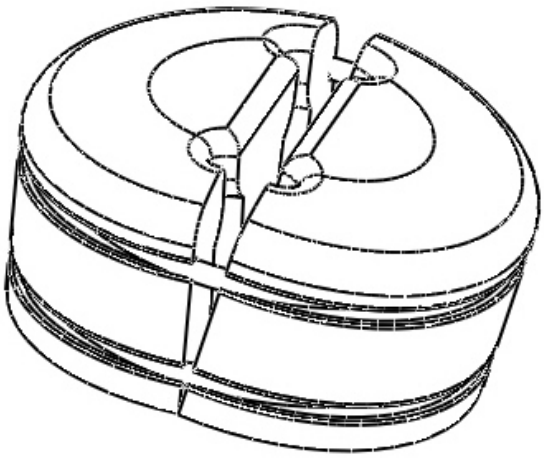


Figure 15 - Puck

The puck is individualized for each patient and holds a molded impression of the abutments. The individual impressions in the puck align the prosthetic device in an anatomically correct position for the patient and no adjustment of the alignment is needed. The current design of the prosthesis attachment device holds both the ulna and radius bones fixed. No relative movement between the radius and ulna is possible, which makes natural forearm rotation impossible.

4.2.4 Distal adapter and spacer

Distally the attachment device attaches to a spacer through a distal adapter. Depending on the type of prosthesis system that is used the spacer and adapter can have different designs. This project focuses on a prosthesis system intended for a myoelectric terminal device. The spacer in the case of a prosthesis system for myoelectric control is commonly a thin walled (1-1,5mm) carbon fiber pipe that is attached through a clamp. The thin profile of the pipe leaves more space for components for the myoelectric control.

Figure 16 shows a prosthesis system for trans-radial level.

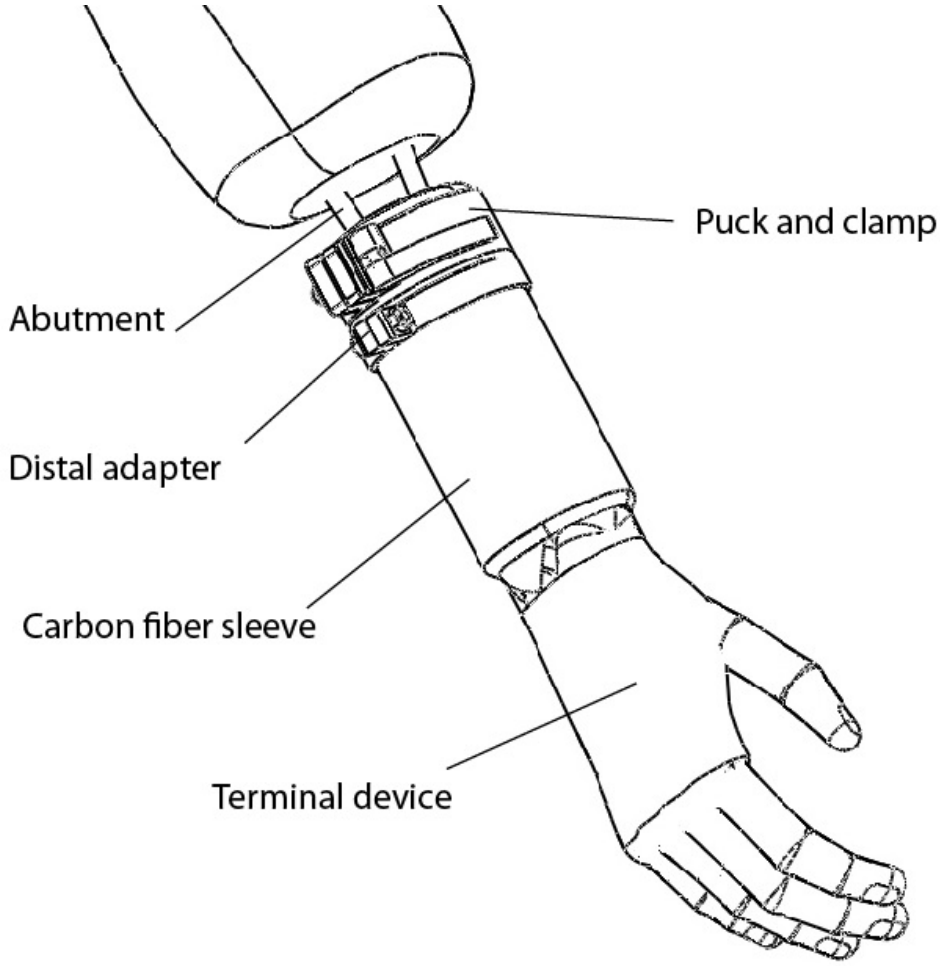


Figure 16 - The OPRA prosthesis system for trans-radial level

4.2.5 Torque safety

To prevent excessive torque loading of abutments and fixation, most attachment devices are fitted with a Torque limiter that is set to dislocate at a certain load and prevent damage to the patient and prosthetic device. In bone-anchored prosthesis safety against torque loads is of great importance. Torque forces can loosen or tighten the fixture and cause fractures in the bone. The safety device is usually set to dislocate at 5 Nm, but it is common that patient consider this limit to low. There are opinions that the torque safety should be set to 8 Nm [34]. In the TRA case the attachment device connects to the terminal device, where any torque limiting adjustments can be made. There is no need for a torque limiting safety in the attachment device.

4.3 Competing technology

The osseointegration technology for amputation prostheses is most commonly used for lower extremity prostheses. In a greater extent, only Integrum AB has used osseointegrated implants in rehabilitation of upper extremity patients [12]. Due to that bone anchored fixation of upper extremity prostheses is a fairly new phenomenon and is only used in a minor extent outside of Integrum AB, there are no commercially available attachment solutions for upper extremity osseointegrated prostheses.

Stanmore Implants Worldwide

Stanmore Implants Worldwide is a company that develops orthopedic implants and is based in Stanmore, London, United Kingdom. Stanmore implants work with bone anchored prostheses but have no commercial attachment device for the treatment of TRA patients [26]. The treatment system provided by Stanmore Implants is called intraosseous transcutaneous amputation prosthesis (ITAP) and uses osseocutane integration to integrate with bone and soft tissue simultaneously. In osseointegration, there is no integration with the soft tissue [12]

4.4 Costumer needs

It is essential to gather information from potential customers early in the product development process to ensure that the product will meet the customer needs [17]. The final product will not only be handled by the end user but also by medical and technical personnel that help to rehabilitate the patient's injuries. For a development process to be successful the project has to be based on a strong set of requirements and needs.

4.4.1 The costumer

Patient

Currently, only 40 patients have received the OPRA treatment for upper extremity prostheses. Of these, only 10 are at trans-radial level. All the trans-radial surgeries have been performed in Sweden. The low number of patients is due to that the OPRA treatment for upper extremity prostheses is a fairly new possibility and that upper extremity amputations are far less common than lower extremity amputations. In Sweden there are approximately 50 upper extremity amputations every year [27].

Prosthetist

The prosthetist is a clinician who fits individuals with prosthetic solutions. It is the prosthetist who assembles, fits, adjusts and maintains the prosthetic system. Sometimes the prosthetist has to construct and manufacture fully customized components for the patient. When the patient receives the finished prosthesis, the prosthetist will make sure that he or she knows how to operate all of the features of the prosthesis and inform about care and maintenance for the device. The patient will return occasionally for adjustments and minor repairs. All parts distal to the abutment connection should only be reachable for the prosthetist.

Occupational therapist

The occupational therapist helps the patient to use the prosthesis in daily life task and how to perform task without the prosthesis. The occupational therapist also teaches the patient how to put on and take off the prosthetic device.

4.4.2 Research methods

Questionnaires
Costumer statements are collected through questionnaires that address the existing attachment system and preferences in a new attachment solution. The demand and interest for an attachment device that allows natural forearm rotation is investigated.

Due to the confidential nature of the questionnaires the patients were contacted through Sahlgrenska Univesity Hospital. All ten Swedish TRA patients that currently use the OPRA system were contacted and asked to answer the questionnaire. Three answered. See Appendix A for patient questionnaire.

The OPRA system for upper extremities is fairly new and the number of treated patients is low. Only a few professionals have been in contact with the attachment device. Questionnaires were sent out to experts in upper extremity prostheses at two Swedish orthopedic companies. Unfortunately no answers were received. See Appendix B for prosthetist questionnaire.

Patient interview
During the development phase there has been continuous contact with a male TRA patient who was treated with the OPRA system in 2011. A shorter interview and recurring discussions with a TRA patient were performed during checkup visits at the hospital. The patient has been willing to help in the project and is very interested in a solution for natural forearm rotation.

Interview with Orthopedic engineer
Stewe Jönsson, Orthopedic engineer, CPO at TeamOlmed at Kungsbacka hospital was contacted to collect valuable information about the prosthetic attachment device, the problems related to forearm rotation and past work that has been done on the issue. Stewe Jönsson has a long time experience within prosthetic technology for bone anchored prostheses and is one of the developers of the puck and clamp system used today.

4.4.3 Identification of needs

Needs expressed by Integrum AB
The company is not satisfied by their product. The attachment device that is in use today was developed in the 1991 and 1992 and is outdated. The puck and clamp connector works well for prosthesis attachment but does not allow any relative movement between the abutments and won't allow full compatibility with the myoelectric project. A prosthesis attachment solution that can transfer natural forearm rotation is of great interest for the company and they want to find new and innovative solutions for the problem.

The requirements expressed by Integrum AB can be summarized as:

- Safe
- Functional
- NCAL compatible
- Modular
- Easy to manufacture
- Esthetic

Patient statements and needs

The questioned patients expressed satisfaction in the design of the attachment device and thought it was fairly easy to attach and detach it from the abutments. All patients showed great interest in an attachment device that would allow natural rotation. One patient described the concern that the attachment device has detached when not supposed to and did not consider the product safe. Other patient statements were:

- Today I can lift 5kg with my prosthetic hand but I wish to carry at least 10 or 12kg.
- The bone anchored prosthesis allows me to train my biceps; the socket prosthesis prevented me from doing this.
- I clean the puck once every day or when it gets dirty.
- I would really want to have an attachment device that would allow me to naturally rotate my forearm.
- I decided to change to a bone-anchored prosthesis so that I could get greater movement and get rid of the sweaty socket.
- The most important thing for me is that the prosthesis looks as human and normal as possible. I want to feel comfortable and look normal.
- I don't like to wear T-shirts because the transition between my arm and prosthesis is exposed.
- I like the puck system. It is easy to attach and detach.
- I really dislike the external clamp. It looks bad under the cosmetic cover and makes the whole thing to wide.

Statements from Stewe Jönsson

- Always try to make a prosthesis as light as possible
- In the ideal case the weight distribution in the prosthetic device would mimic the weight distribution in the biological limb.
- If you get rid of the external clamp there will be more internal space for the abutments or the diameter can be kept smaller.
- Bilateral patients have difficulties to operate the clamp. Optimal placement of the quick release is on the medial side of the prosthesis.
- An inner diameter of 50mm is enough to cover all fixed TRA cases, for an attachment device with built in forearm rotation there might be a need for more space.
- There is cosmetic benefit to the amputee in achieving pronation and supination movements in the right manner.

Consumer design priorities

The collected costumer statements are complemented with a study performed by E. Biddiss et al. [9] that presents a list of design priorities for future developments in upper limb prosthetics. The study measured patient satisfaction, regardless of level and origin of limb absence or age.

The findings are that weight is the most important design priority for all types of prosthetic systems. The weight should be low and well distributed throughout the whole of the limb. Consumers expressed interest in advanced materials for lighter weight; non-conductive polymers, carbon fiber and titanium. There is also a need for increased dexterity and fine motor skills. Greater sensory feedback was of interest for all prosthesis users.

Consumers expressed their visions on future prosthetic design as; streamlined, lightweight, life-like and functional. Findings in this research also express needs in alternative socket designs and techniques (i.e. osseointegration) and functional developments that enable wrist rotation [9].

4.5 Mechanical issues

4.5.1 Mechanical complexity of forearm rotation

Setting clear design principles for a prosthetic device for the human upper-limb is complicated. There are variations between individuals and the tissues of the human body don't always have that clear properties. Full range of motion can't be expected from individuals with amputations. Muscles are weakened or missing and the patient does not have the full range of the forearm bones. The goal is to make use of all available pro-supination and transfer it to the prosthetic device in the most efficient way possible.

The biomechanics of a limb treated with the OPRA system are even more complex than the ones of a healthy limb. The ulna and radius bones are curved along their length and the abutments are inserted so that they follow the skeleton in the anatomical direction. This result in a complex and unique geometry that will behave differently for each individual during forearm rotation, see Figure 17. The individual nature of the abutments makes it hard to find a self-adjusting standard component.

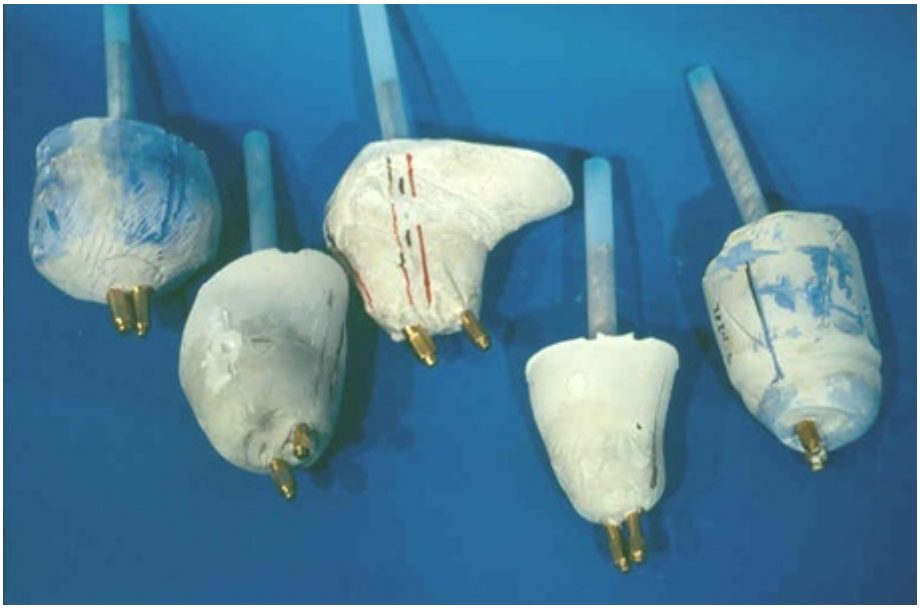


Figure 17 - The abutments follow the individual anatomy of the patient (Photo: Stewe Jönsson).

4.5.2 The attachment device as an artificial joint

An individual with TRA is missing the biological DRUJ and will have an injured IOM. The attachment device must substitute for the functions of the biological structures. The attachment device should be able to stabilize the abutments and transfer and convert the bone motions into prosthesis rotation. The attachment device has to provide freedom of motion in the same time as it aligns the prosthesis and transfers loads.

Since 1991 several trail version mechanisms that allow natural forearm rotation have been built in to the existing puck system. No solution could balance the load between the ulna and radius in a safe manner. In practice, usually the ulna bone carried a greater load which in turn led to overloading of the ulna abutment in bending moment [33]. No patient has natural forearm rotation built in today [34].

4.5.3 Finding a standard solution

There is a need for a standard component that allows forearm rotation and can be fitted to all patients [34]. The aim of a future development project should be to find a standard attachment device solution that can be used by all patients who can benefit from natural forearm rotation. This requires full understanding of the complex biomechanics and individual anatomy of greater selection of patients.

Forearm rotation in an injured limb is an unexplored subject and all papers and tests on the issue of the biomechanics of the forearm have been made on healthy forearms. To get an understanding of the individual biomechanics of TRA patients, measurements have to be made directly on the patients. Due to limited patient accessibility and resources for detailed measurements, the aim of this thesis project will be to find a customized solution that works with the one patient that later can be used to find a standard solution that works for all TRA patients.

4.5.4 Customized patient solution

To find a customized solution, measurements and documentation were made on the interviewed male patient that was presented earlier in this report. The patient is young and active and works out on a regular basis. The great physics of the patient and the length of the residual limb give him great range in forearm rotation. Measurements on the patient have been made through the help rulers, calipers, modeling clay and a digital camera and camcorder. The patient measures L=170 mm from the center of his elbow joint to the amputation stump. This is equal to a medium length amputation in Figure 7. The total range of forearm rotation is measured to approximately 150° where the patient can reach 70° of supination and 60° of pronation. Figure 18 shows the anatomy of the tested patient.

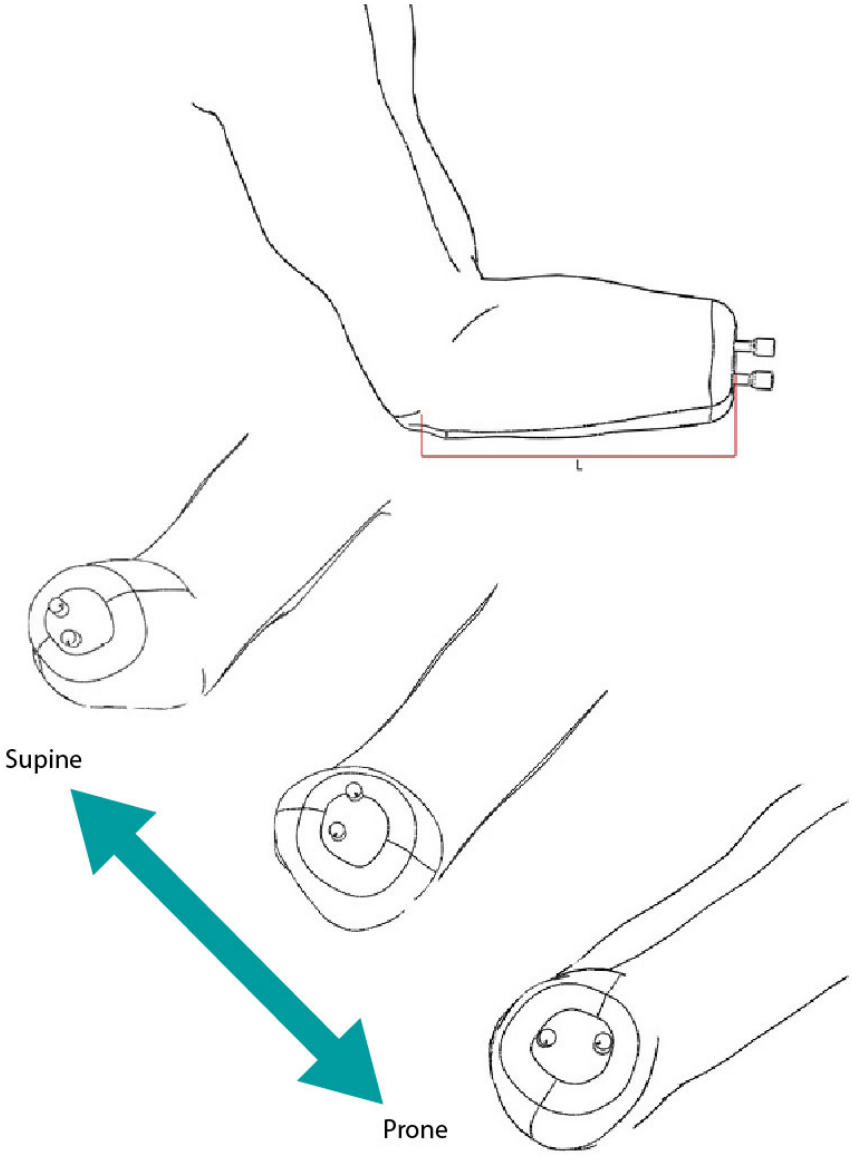


Figure 18 – Testing patient anatomy

The patient uses two identical abutments for the radius and ulna bones. The abutment head has a circular cross-section with a 10mm diameter and an abutment head length of 15 mm. The flat radial surface of the abutment head has an axial length of 11.178 mm and has been machined with h8 shaft tolerance.

4.5.5 Simplified pro-supination model

From the patients measurements a simplified model of the pro-supination problem is created.

To track and document the abutment movements in the coronal and sagittal plane individually requires better measuring equipment than the one available for this project. Instead the movement in these two anatomical planes is simplified through a plane that goes through the abutment centers at any given forearm position. Let us call this plane; the abutment center plane (ACP).

The documented movements of the abutments during forearm rotation are:

- Inclination of the abutments against the transverse plane in the ACP
- Relative inclination of the abutments in the ACP
- Oscillatory rotation of abutments around their central axis
- Change in relative distance of the abutment centers in the ACP
- Relative translation of the abutments in the transverse plane

Table 2 – Abutment movements during forearm rotationshows the abutment movements during forearm rotation for the testing patient.

Table 2 – Abutment movements during forearm rotation

	70° supination	Neutral	60° pronation	difference
Ulna Inclination	-7°	-12°	7°	19°
Radius Inclination	-12°	-4°	5°	17°
Relative Inclination	5°	8°	2°	6°
Ulna rotation*	1°	0°	1°	2°
Radius rotation*	70°	0°	60°	130°
ACP distance	18mm	20mm	27mm	9mm
Relative translation**	1mm	2mm	-1mm	3mm

* The reference angle for the abutment is set at the neutral position
**The relative position is calculated as (ulna position – radius position)

Figure 19 shows an overview of the abutment movements of the testing patient.

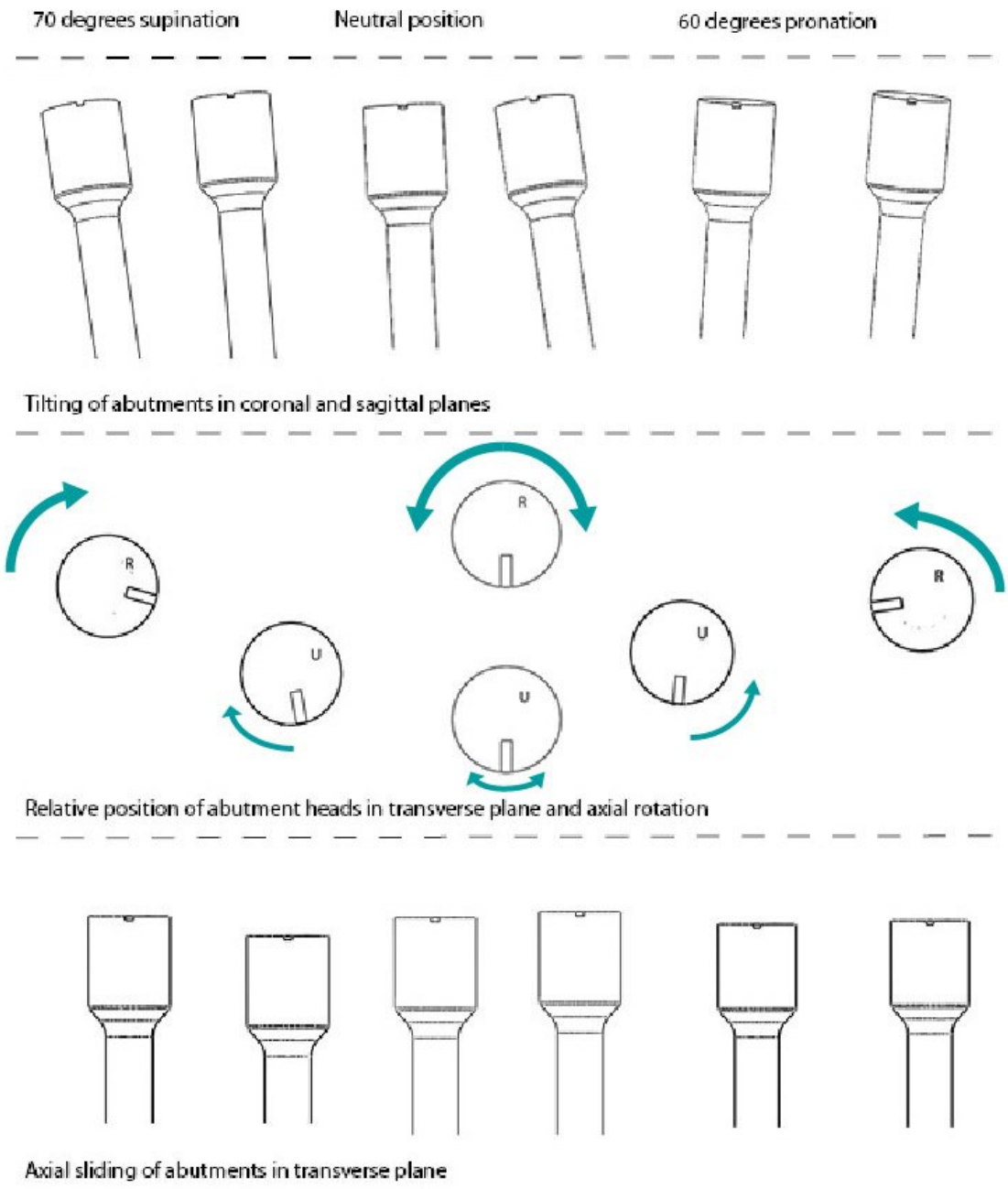


Figure 19 - Testing patient abutment movements

Allowing all degrees of freedom at the same time can lead to an unstable attachment device. Rotation of the radius bone around its axis is crucial during forearm rotation and should not be locked. It should be investigated and tested; which and how many degrees that can be limited or restricted and still get a fair range of pro-supination.

4.5.6 Loading of prosthetic device

The user should be able to use the attachment device in everyday life, without the risk of mechanical failure. Carrying grocery bags, shoveling snow, turning doorknobs and leaning against objects are just some examples of everyday tasks that the user should be able to perform. When using a prosthesis device it is important that the user is aware of the limitations of the prosthesis system. The mechanical components and the structural material of the attachment device differ in physical behavior compared to the biological structures of the human arm. The integrity of the bone and ligament structures of the wrist and forearm are important for the functional load transmission through the forearm [13]. The loads will be distributed differently through an injured limb than through a healthy limb. All loads from the prosthesis and attachment are transmitted to the bones, through the abutments. The abutments will take up axial, radial, bending moment and torque loads (Figure 20). Figure 21 shows an overview of the external loads of the prosthesis system.

It should be emphasized that safety is the primary concern when designing prosthetic devices. Patient safety always comes first when developing a prosthetic device. In terms of attachment device means that loads should be transferred and distributed in a way that does not overload the abutment and fixture and that the prosthetic system should be stable and sit firmly.

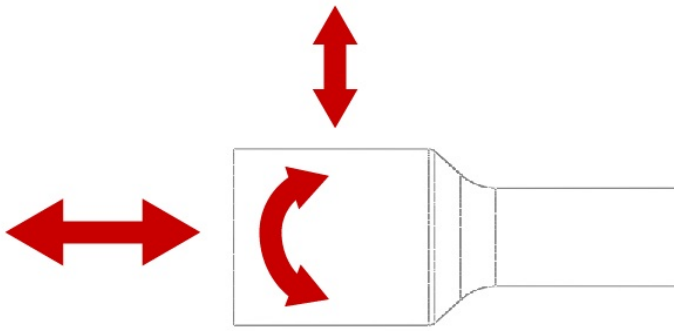


Figure 20 - Loading of abutment

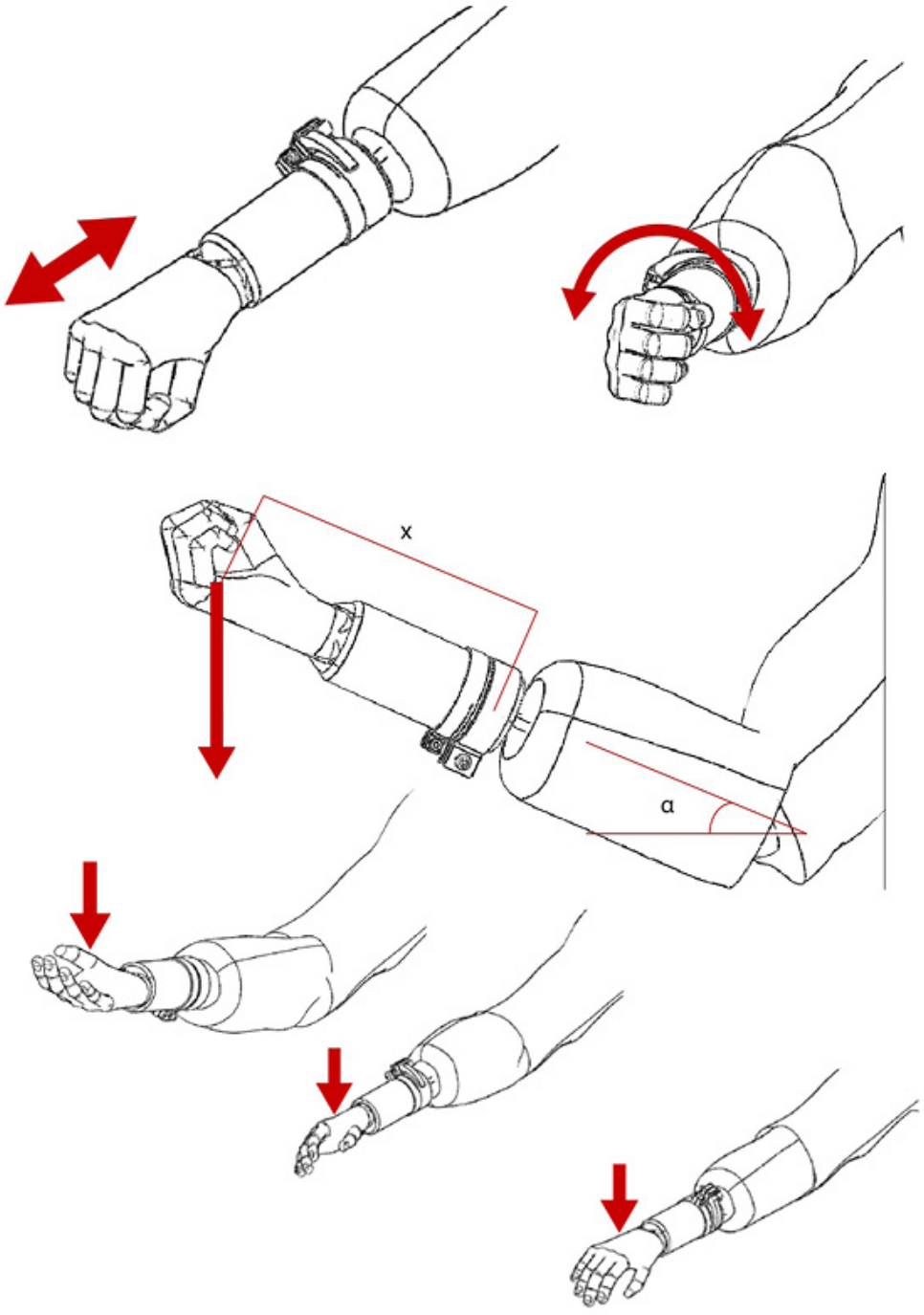


Figure 21 - External loading of the prosthesis system

The human limb is loaded in a complex way and the prosthesis will be exposed to varying forces and moments during all times. The loads acting on the prosthetic device during everyday use can be divided in to push and pull, torque and bending loads.

Push/Pull

Directional push and pull loads will for instance occur when the user wants to open and close drawers or doors, hold something with the arms extended along the body or wants to push or pull an object.

In a simplified model, push and pull loads are applied in the transverse plane. The axial force is transmitted through the ulna and radius and is directly related to the applied axial load [13]. The axial force transmitted through the ulna significantly changes throughout the arc of forearm rotation. The axial force transmitted through the ulna is at a maximum of 46% between 30 and 60 degrees of supination.

Torques

Torque will for instance occur in the prosthesis system when the user wants to use the forearm to turn something around with the terminal device.

All scientific tests on forearm torque strengths during pronation and supination have been performed with healthy limbs. These tests determine the maximum user controlled torques that can act on the prosthetic system if the user has all biological strength remaining in the upper limb. In reality, an amputated individual will have great loss in muscle strength and will not be able to generate the same amount of torque.

Tests show that the mean values of torque are greater during supination than during pronation. Tests performed on an arm with 90 degrees of elbow flexion show that the greatest mean torque value for forearm rotation is 15.3 Nm during supinating movements in a pronated angle [14]. In reality both the forearm and elbow angle determine how much torque force that can be transferred from the forearm to the hand. The greatest mean torque recorded was 16.2 Nm for 75% prone forearm with the elbow flexed at 135%. The greatest pronation torque was recorded as 13.1 Nm [15]**.** Figure 22 and Figure 23 show how supination and pronation torques change with forearm and elbow angle [15].

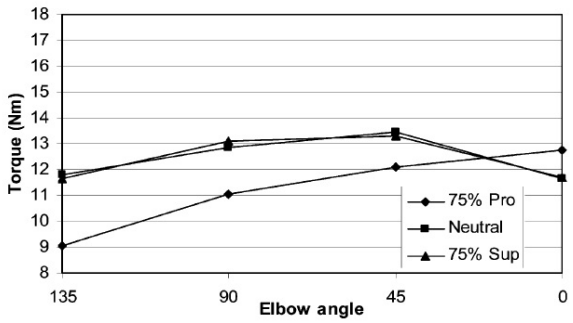


Figure 22 - Maximum pronation torque for elbow and forearm angle

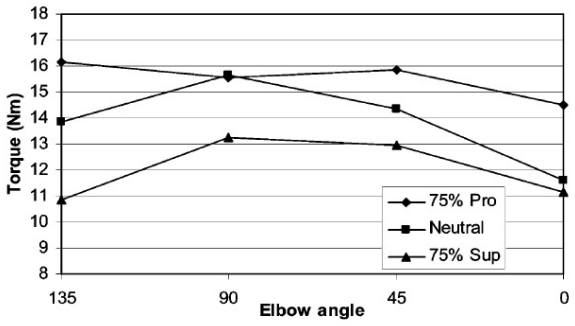


Figure 23 - Maximum supination torque for elbow and forearm angle

Bending Loads

The prosthesis system will be exposed to bending loads whenever something is carried in the terminal device or when the user wants to use the terminal device as a lever when performing a task. Bending loads of the prosthesis system are the most dangerous for the attachment device, abutments and fixtures. The abutment shafts are due to their thin cross-section the weakest structures of the surgical components for the OPRA system and can fail in bending.

A prosthetic hand with myoelectric control is heavier than a biological hand and is the heaviest component in an upper limb prosthesis system [34]. Prosthetic systems in general, tend to be heavier than the natural limb they replace and the heavier weight of the terminal device will distally shift the center of mass compared to a healthy limb. The attachment device and surgical components have to hold for both prosthesis weight and the load applied at the terminal device.

The abutment shaft can be assumed to have a thin walled cross section and the maximum load that it can carry in bending can easily be calculated. The abutments are made of Grade 5 Titanium that holds yield strength of 897MPa. For the abutment shaft measurements see Appendix A. Calculations are made for the loading of the terminal device at a distance of 160 mm from the abutment shaft, where one abutment takes the entire load.

$$W_b = \pi a^2 t = \frac{\pi}{32}(D+d)^2(D-d)$$

$$\sigma_y = \frac{M_{max}}{W_b} = \frac{m_{max} g l}{W_b} \rightarrow m_{max} = \frac{\sigma_y W_b}{g l}$$

$$m_{max} = \frac{897 * 10^6 * \frac{\pi}{32}(0{,}00553 + 0{,}00301)^2(0{,}00553 - 0{,}00301)}{9{,}81 * 0{,}16} = 10{,}31kg$$

The maximum load a patient is allowed to carry is highly individual and depends on the quality of the skeleton and osseointegration, which is evaluated by a physician. There are no predefined load limits or safety factor but the prosthesis should never be loaded so that the patient feels pain [34].

5. Conceptual embodiment

This chapter describes the development process of the thesis project.

5.1 Target functions

Table 3 – Summary of target functions

Classification	Function	Desirability		
		R	H	L
Functionallity	fixates prosthesis	R		
	allows attachment (to abutments)	R		
	allows detachment (from abutments)	R		
	withstands directional forces	R		
	withstands rotational forces	R		
	transfers directional forces	R		
	transfers rotational forces	R		
	transfers vibrations			L
	can be fitted to different users		H	
	alignes the prosthesis		H	
	provides comfortable and easy forearm rotation		H	
	transfers all avaiable forearm rotation		H	
	alignes the prosthesis during forearm rotation		H	
	can be used with existing abutment design			L
Safety	prevents damage to prosthesis	R		
	prevents overloading of abutments	R		
	prevents loosening of abutments and fixture	R		
	prevents unbalanced load on abutments	R		
	prevents excessive shocks to fixture			L
	prevents undesired play in abutment connection		H	
	prevents accidental detachment from abutment		H	
	prevents tampering by user		H	
Maintenance	resistant to corrosion and dirt		H	
	easy to clean		H	
	can be disassembled/assembled by technician		H	
	easy to dissassemble/assemble by technician			L
	allows replacement of components		H	
Ergonomics	communicates attachment/detachment method			L
	minimized attachment/detachment effort		H	
	minimizes attachment/detachment time			L
	can be attached by bilateral individuals		H	
	does not need external tool (for patient)		H	
	provide feed-back when attached		H	
	is comfortable to wear		H	
	prevents thermal conduction into body		H	
Myoelectrics	allow connection of abutment electrodes		H	
	route wiring from abutment to prosthesis		H	
	prevent inproper electrode connection		H	
	prevent accidental electrode disconnection		H	
	prevent wiring entangelment		H	
	facilitate amplifiers			L
	shield the electric components		H	
Dimensions	minimized weight		H	
	minimized axial length		H	
	minimized diameter		H	
Semantics	communicates safety		H	
	communicates product values		H	
	communicates correct anatomy		H	
Manufacturing	make use of standard parts		H	
	easy to assemble			L
	modular assembly		H	
	can be manufactured trough current partners			L
	can be manufactured with a low cost			L

R=required
H=High desirability
L=Low desirability

The function list presented in Table 1 summarizes the requirements for the attachment device that have been gathered during the research phase of this project. The requirements are ranked after how important they are in a prosthetic device and by the desirability expressed by Integrum AB. A required (R) function is crucial for the attachment device and has to be fulfilled. A function with higher desirability (H) should be achieved by the attachment device, but is not an absolute requirement. Functions with lower desirability (L) are highly interesting but are not prioritized in the development process.

Target specification

With no competing technology to benchmark against and no prototype solutions in active use, it is hard to set target values for an attachment device. The dimensions of the attachment device can be related to the fix puck and clamp system and adjusted for a functional solution. Load capacity and range of motion is discussed within the company and with the consultancy of Stewe Jönsson. Table 4 shows an initial list of metrics for a functional attachment device solution. The load values presented are conservative and will leave a safety margin against device failure.

Table 4 - List of Metrics

Metric No.	Metric	Target value	Acceptable Value	Units
1	Maximum Push/Pull load	500	250	N
2	Maximum Torque load	16	8	Nm
3	Maximum bending load	25	10	Nm
4	Maximum device diameter	50	60	mm
5	Attachment device length	20	30	mm
6	Attachment device weight	0.1	0.2	kg
7	Time for attachment/detachment	10	30	s
8	Pronation range (of available)	100	70	%
9	Supination range (of available)	100	70	%

5.2 Structural components

At this stage, structural components for different sub-functions are analyzed. They can later be combined to form concept solutions for the attachment device.

The main mechanical functions that have to be considered are:

- Abutment head latching
- Permission of abutment rotation
- Permission of relative movement between abutments
- Mechanical stability in motion
- Movement transfer from abutments to prosthesis
- Structural Material

5.2.1 Couplings

The abutment fastening mechanism is the part of the attachment device that the user interacts with on a daily basis. The choice of coupling determines the performance of many attachment functions. The main function of the coupling is to connect the abutments to the attachment device. The coupling should be easy to connect and disconnect and keep clean. It should provide a stable connection and hold for everyday use and loading of the prosthetic device. It is also of great interest that the coupling does not add to the total dimensions of the attachment device.

Figure 24 shows some commercially available coupling components collected for this project. These include; screw joints, clamps, straps, bayonet couplings, ball bearing couplings and a variety of quick release couplings. Pins and lock rings can be used together with other structural components to latch and hold the abutments (Figure 25).

Different coupling solutions are compatible with different abutment head designs and should be chosen accordingly.

Figure 24 - Commercially available coupling components

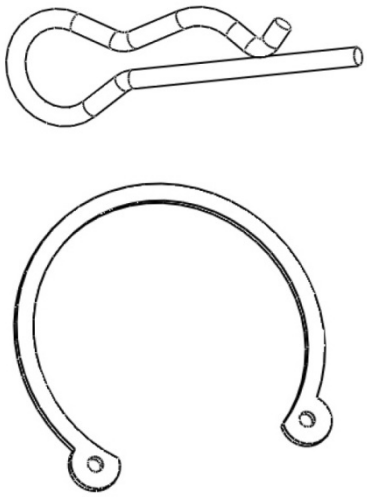


Figure 25 - Pin and lock ring

Volvo components

At the study visit at Volvo PV, the project group was presented to different coupling components used for wire connection between gear shift, gear box and other transmission components. All components are specifically compatible with the spherical head abutment design (Figure 26).

Figure 26 - Coupling components from Volvo PV

Bal Latch

Bal Seal Engineering Inc provide connectors for industrial and medical purposes. Bal Latch is a latching solution based on coiled spring technology that can be tailored to fit specific purposes (Figure 27). The Bal Latch attachment solution is simple and very compact, with coiled diameters down to 0,51mm [28]. The Bal Latch technology also permits wider tolerances than for instance sliding bearings.

A Bal Latch connector can be used on both cylindrical and spherical head abutments. If a cylindrical head abutment is going to be used, it must have a chamfered edge for axial connection and one or more slot with chamfered edges to hold the coiled springs (Figure 28).

Figure 27 - Bal Latch connection solution

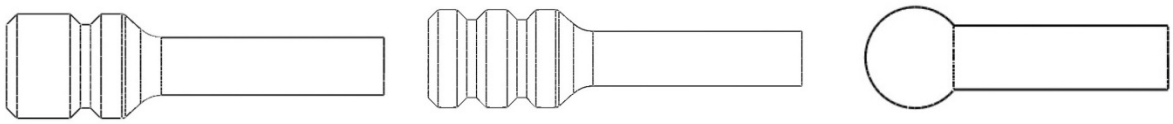


Figure 28 - Abutment head designs compatible with Bal Latch technology

A Bal Latch connector is attached and detached through application of axial force against the spring. The connection and disconnection force can easily be engineered to fit a specific application. The connector will hold for the same axial loads as it is designed to detach at. The connector does not only latch and hold the shaft but also works as a bearing. When attaching a spherical head abutment, connector it will also permit tilting against the connection plane.

If a Bal Latch is going to be used for prosthesis attachment, it has to be dimensioned so that it detaches at a force that is greater than the axial loads applied during everyday use of the prosthesis system. In the same time it should be easy for the user to attach and detach the prosthetic device.

5.2.2 Bearings

To allow constrained relative motion between two mechanical components, bearings of different kinds can be used. Bearings can broadly be classified in to rolling and plain bearings. Rolling bearings use mechanical components like balls or rollers to allow relative motion. Plain bearings provide relative motion based on the principle of friction between two surfaces. The main purpose of a bearing solution in the attachment device will be to allow the oscillatory rotation of the abutments against the connection components.

When finding a bearing solution for the prosthesis attachment device, the criteria are:

- Resistance to corrosion
- Resistance to dirt and dust
- Requires no lubrication
- Can transmit combined loads (radial and axial)

- Can transmit moment loads
- Are provided in small diameters

Commercially available bearings are dimensioned for high rotation velocity and high frequency oscillatory rotation under heavy loads. Bearing use in a prosthesis attachment device will only expose the bearing to relatively low loads at a low velocity and it can be assumed that the bearings will hold for the loading conditions of everyday prosthetic device use.

Rolling bearings

Rolling bearings can broadly be classified in to two categories depending on the design of the rolling elements; ball bearings and roller bearings. Generally, roller bearings are able to support greater loads than similar sized ball bearings. There are many different kinds of rolling bearings but only a few can carry both the moment and combined loads in all directions. Some rolling bearings can be fitted in pairs to manage the loading conditions, but will also take up more space in the construction. Figure 29 shows different rolling bearings from SKF that can be suitable for an attachment device [29].

Most rolling bearings are not provided in standard dimensions that will fit the abutments and will have to be customized. All rolling bearings need lubrication to run correctly. Rolling bearings also have built in play and are susceptible to shocks and dirt that can dent the rolling elements [36].

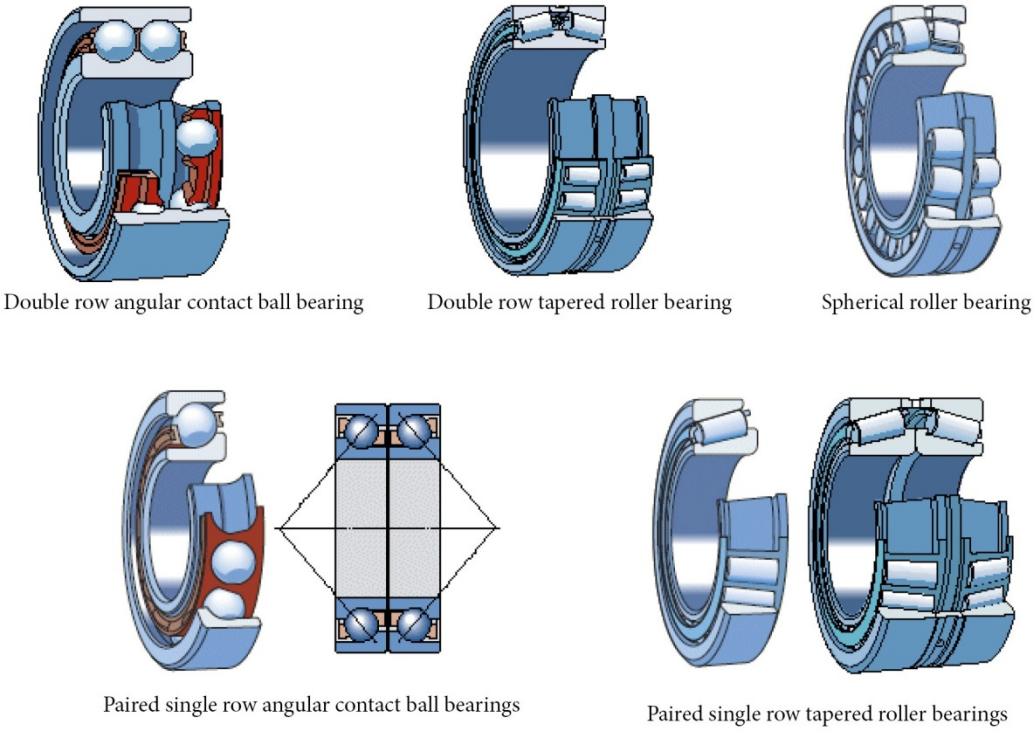


Figure 29 - Rolling bearings from SKF

Plain bearings

Plain bearings can be simple and compact and in general less expensive than rolling bearings. The two main types of plain bearings are spherical plain bearings and bushings. Most plain bearings need lubrication to work correctly, but there are some composite and surface coated bearings that work properly in dry conditions.

Spherical plain bearings allow tilting of the attached shaft through relative movement of an inner and outer ring. This tilting angle is highly dependent to the dimension series and size of the bearing. A spherical plain bearing can carry both combined and moment loads.

Bushings are the most common types of plain bearings and can be described as a sleeve with an inner and outer diameter that provides a bearing surface for rotary applications. To get good stability, a bushing should be designed so that the axial length is equal or greater than the inner diameter of the shaft. Figure 30 shows some standard plain bearings from SKF.

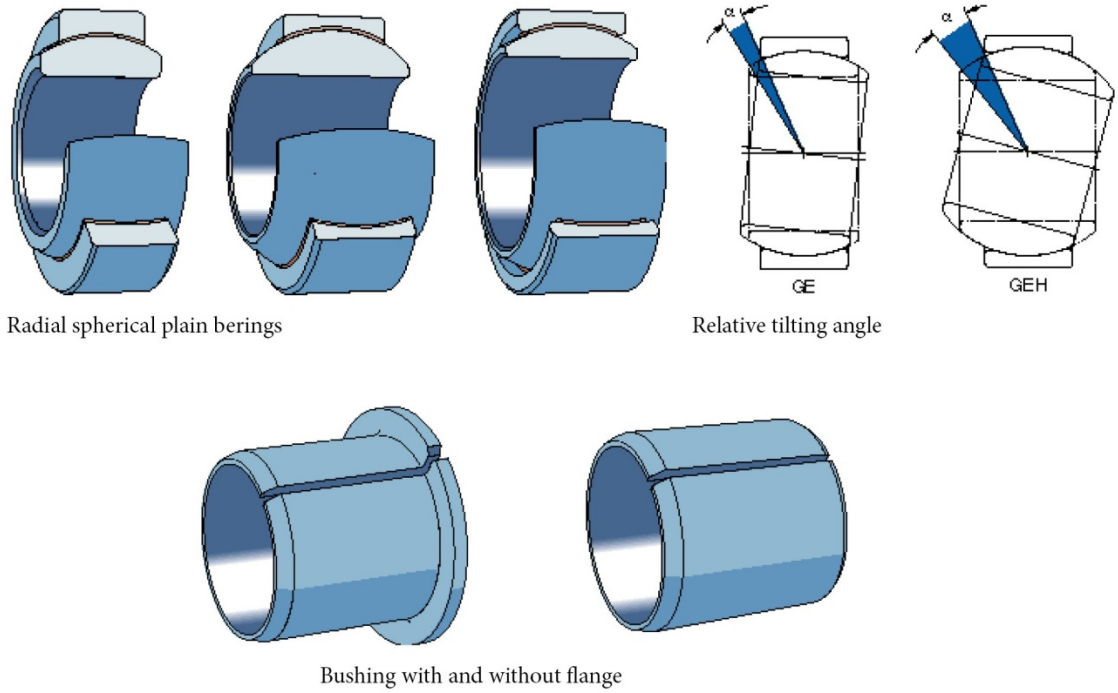


Figure 30 - Plain bearings from SKF

5.2.3 Surface coating

An alternative to standard plain bearings is surface coating of customized components. High performance tools and precision components are often surface coated to reduce friction and wear during use. The method is more expensive than use of standard bearings, but allows the sliding surfaces to be customized for the intended use.

Oerlikon Balzer is a world leading company that provides coating solutions under the BALINIT® trade mark. The company provides a wide range of coatings for different applications including coatings that are bio-compatible and approved for food processing.

BALINIT® C and BALINIT® DLC are two coatings that are suitable for use in medical devices and provide a very low coefficient of friction even without lubrication (0.1-0.2 against steel) [30]. The coatings do not only provide great sliding surfaces but also great corrosion resistance and protection against abrasion.

Figure 31 - Tools coated with BALINIT®

5.2.4 Joints and tracks

Linking mechanisms that connect two components and allow relative motion are widely used in the industries. In the automotive industry one can find mechanical components like; rod ends, sway bars, suspension links, Hooke's Joints and tripod knots (Figure 32Figure 32).

Relative motion between the attachment device and abutments can be allowed through some kind of mechanical track or slot that can be combined with bearing elements or components for motion control and stability.

Figure 32 - Joint components; suspension link (left), Hooke's Joint (center) and tripod knot (right).

5.2.5 Springs

Springs can be used for motion control, load distribution and stability in the mechanical structure. There are many ways to put springs to work in a mechanical structure and different springs can be combined to provide different characteristics at different load rates or load directions [22]. Figure 33 shows different types of springs that can prove to be useful in mechanism for abutment motion control.

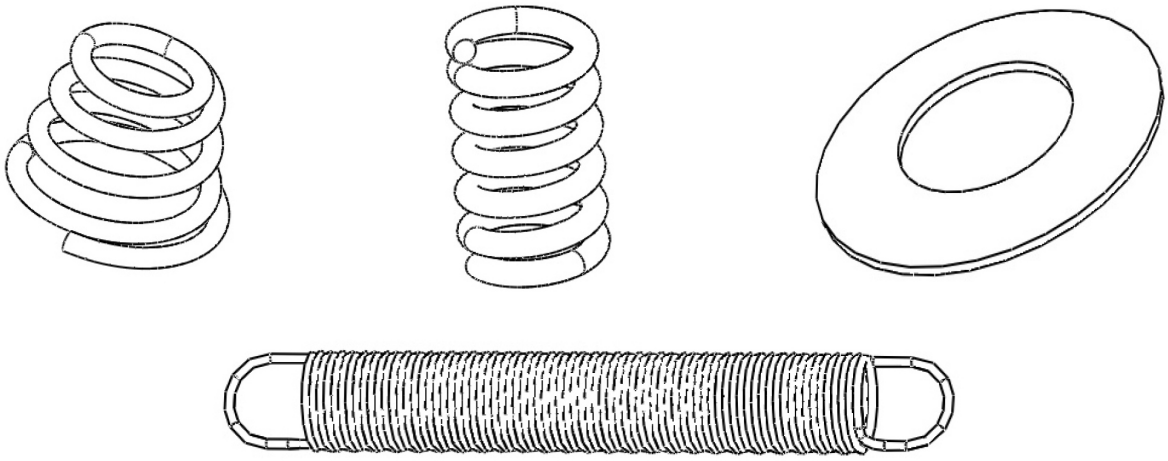


Figure 33 - Compression springs (top left/center), Belleville spring (top right) and compression spring (bottom).

5.2.6 Elastic materials

Elastic materials or elastomer can be used to provide freedom of movement, motion control and redistribution of loads. Elastic materials can also be used to seal of and protect susceptible components e.g. wires and electric components for myoelectric control.

An elastomer is a polymer with viscoelastic properties that has a low Young's modulus and high yield strain compared with other low density materials. Elastomeric materials have the ability to be deformed to great deformations and then elastically spring back to their original form [23].

An important characteristic of elastic materials is its hardness that is a measure of a material's resistance to localized plastic deformation or in other terms the resistance to surface indentations and wear [23]. Hardness is a measure of an elastomers response to stress localized over a small area and is presented in the Shore hardness scale. Another important characteristic for an elastic material is its resilience or the capacity of the material to absorb energy upon elastic deformation and recover it when unloaded [23].

Polyurethane (PU) and Silicon Rubber are two elastomer materials that have been recognized to be particularly useful for this project

Polyurethane

Polyurethane can be manufactured in both thermoset and thermoplastic form and can be either soft or stiff [24]. Polyurethane elastomers can range in hardness from 10-15 Shore A to over 90 Shore D. Polyurethane is commonly used in specialized industrial applications and is more expensive then silicon rubber. Polyurethane is a great material choice for serial production of components that require high strength.

Silicone Rubber

Silicones are extremely well tolerated by the body [19] and are widely used for medical devices. The hardness of Silicon Rubber ranges in 10-90 Shore A. Silicon rubbers can mainly be divided in to two categories: addition cure and condensation cure silicon. Some types of addition cure silicon can cure in room temperature and are very easy to work with. Silicon rubber is in general cheaper than polyurethane and more suitable for smaller production series or prototypes.

5.3 Early prototype

Before the start of this thesis, the company had a simple prototype mechanism manufactured for testing on a patient. This prototype consists of two abutment holders that are allowed to slide along a track or be locked relative to it. The prototype was attached to the abutment heads of the testing patient that was asked to supinate and pronate his forearm. The abutments were allowed to rotate and translate relative to the mechanism. The test showed that movements in the supine range could be performed by the patient without difficulties. The mechanism stuck and locked movements in the prone range. Because of the risk of injury the patient was asked not to force more forearm rotation then what felt comfortable.

The limited movement in the prone range can be tracked to the fact that the force between the two abutments is transferred in such a way that the shape and friction between the track and attachment joints lock further movement.

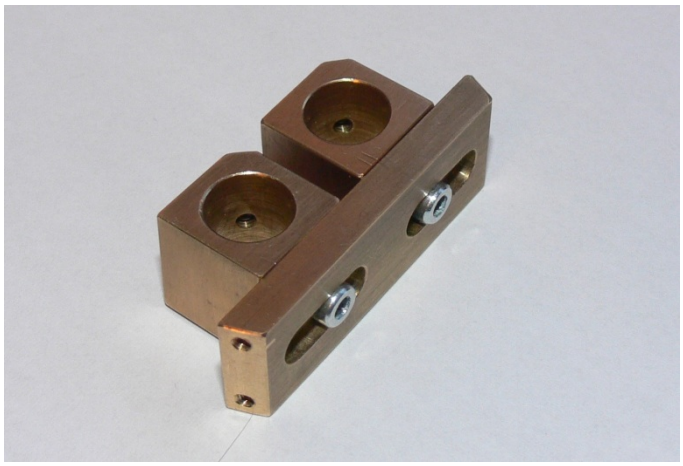


Figure 34 - Early prototype at Integrum AB

5.4 Concept development

On the basis of the functions list, mechanical solutions for different sub functions of the attachment device are generated and assembled to conceptual solutions for the pro-supination mechanism. At a starting point, all ideas are welcome. The applicability and usefulness of the different solutions will be examined in a later stage.

Primary ideas for the mechanism are freely generated from different inspirational sources, existing mechanical solutions and brainstorming meetings at Volvo PV, SKF and Integrum. During the brainstorming sessions issues like bearing application, movement restriction, latching solutions and load distribution were discussed.

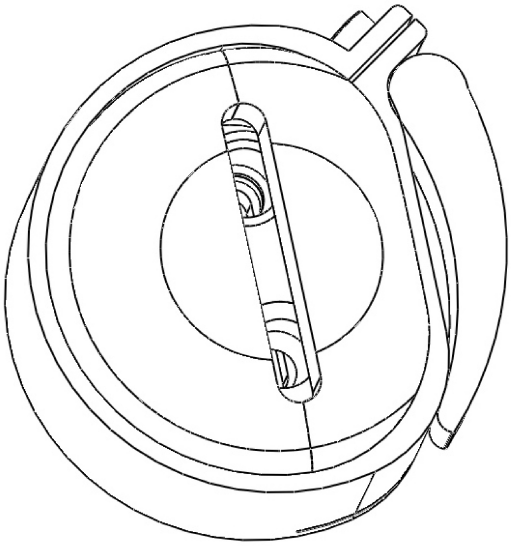
5.4.1 Concept generation and screening

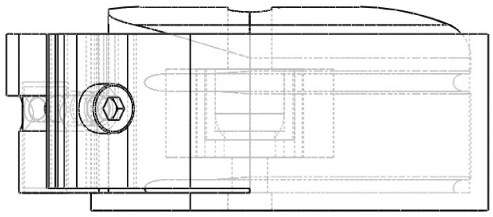
Through the use of different mechanical components, nineteen different concept solutions were assembled for a first review. Comparison of the concepts was made through the screening process presented by Ulrich & Eppinger [17]. The different concepts are compered in relation to twelve criteria that are based on the function list. One concept that is considered straight forward and median is chosen as reference for the concept screening. Each concept is rated in comparison to the reference concept for each criterion and given a relative score of “better than” (+), “same as” (0) or “worse than” (-). The concept screening matrix is presented in Appendix D. The reference concept for each criterion is highlighted in the screening matrix.

Three concepts are chosen for further evaluation. Two more concepts are refined before further evaluation. Four other concepts are combined to form two new concepts that include interesting functions and components. A total of seven concepts are presented for further refinement and scoring.

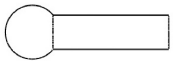
5.4.2 Concepts for scoring

Concept: Elastic Puck (A+)

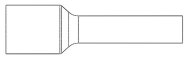




Ulna abutment:

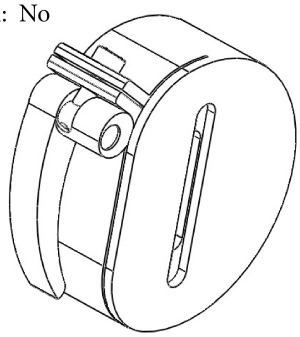


Radius abutment:

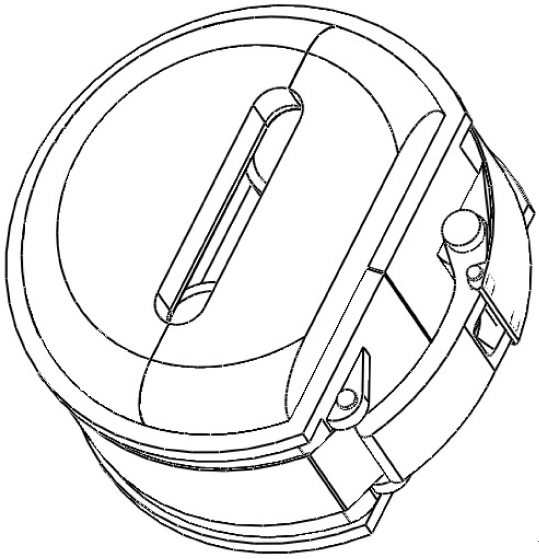


A modified puck with a recessed clamp design, latches and holds the abutments in place. The abutment heads are allowed to move in a track filled with elastic material, that allow controlled freedom of movement.The radius abutment is attached to a bushing for freedom of rotation.

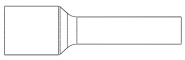
Use of existing abutment design: No
Use of puck system: Yes



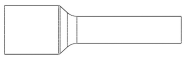
Concept: Boot Strap (B)



Ulna abutment:

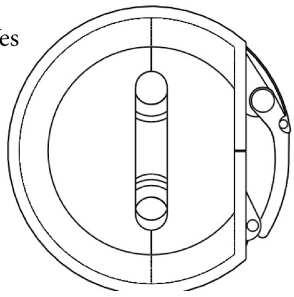


Radius abutment:



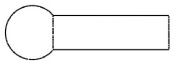
A modified puck is clamped together with a flexible band and with recessed clamp design. It latches and holds the abutments. The abutments are allowed to move in a track filled with elastic material that allow controlled freedom of movement. Both abutment heads are attached to a bushing for freedom of rotation.

Use of existing abutment design: Yes
Use of puck system: Yes

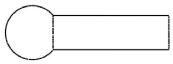


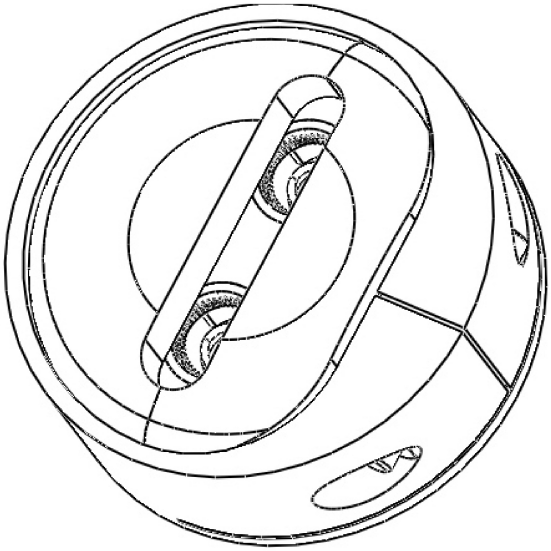
Concept: Lock Ring (D)

Ulna abutment:



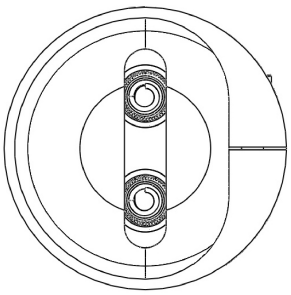
Radius abutment:

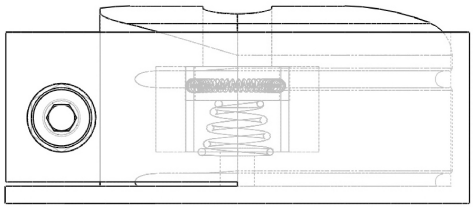




A modified puck holds two Bal-Latch meachnisms that latch and hold the abutment heads. The puck is held in place with a screw clamp and is not removed when the abutments are detached from the prosthetic device. Springs are used to provide controlled translational freedom of the abutments.

Use of existing abutment design: No
Use of puck system: Yes

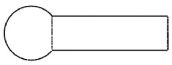


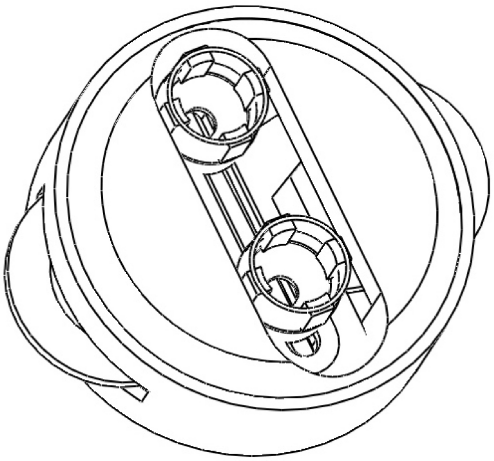


Concept: Claw Latch (EN)

Ulna abutment:

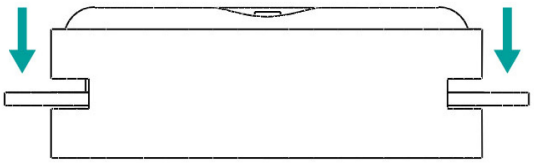
Radius abutment:

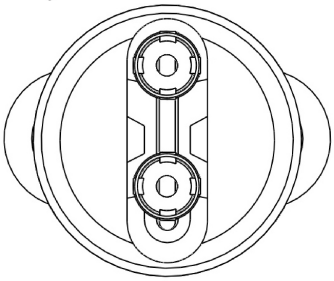




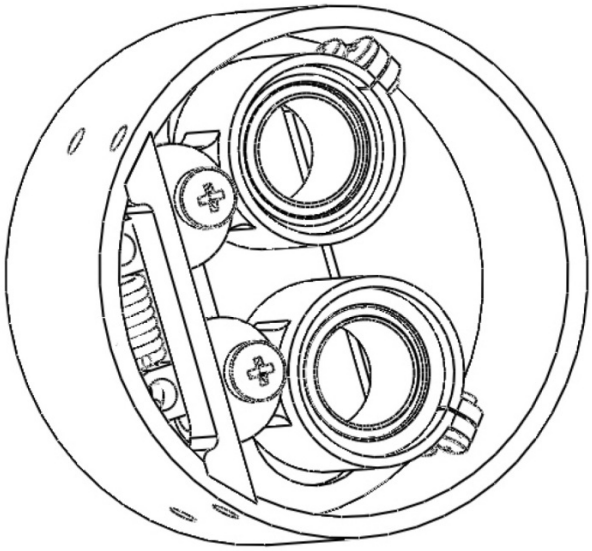
Claw like latching elements, connected to a track, are placed in a modified puck. The puck only provides protection and does not latch or hold the abutments. The claws are released by a quick release lever similar to the ones found in steering wheel hubs. Translational freedom is controled through springs .

Use of existing abutment design: No
Use of puck system: Yes

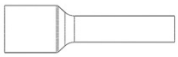




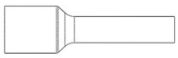
Concept: Track and Joint (HJ)



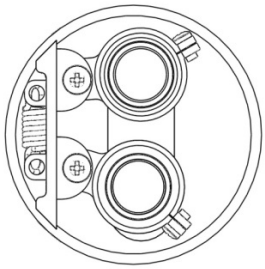
Ulna abutment:



Radius abutment:

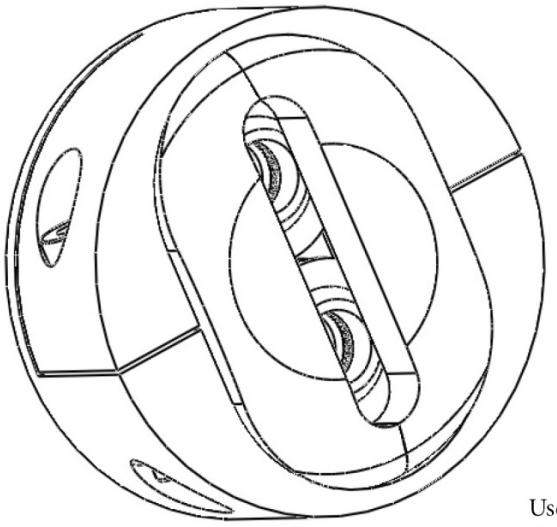


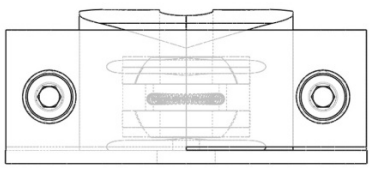
The abutments are are latched through adjustable holders that can be combined with lock rings or guick release clamps. The holders are allowed to move on a track, with either a spring or elastic band to controll the movements. Each holder has a set of elastic material and bushing that allows controlled freedom of movement for the abutments.



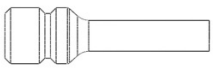
Use of existing abutment design: Yes
Use of puck system: No

Concept: Spherical Plain Latch (O)

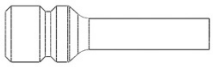




Ulna abutment:

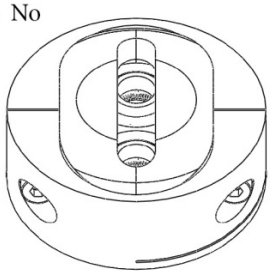


Radius abutment:

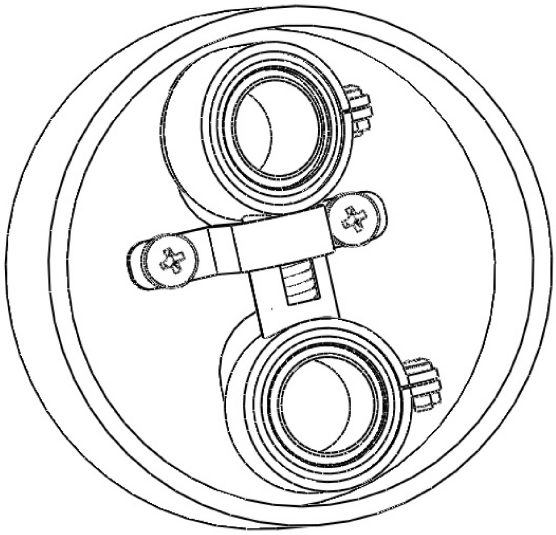


A modified puck holds two sets of angular spherical plain bearings and Bal-Latch mechanisms. The components move along a track inside of the puck. The puck is not removed when the abutments are detached. The puck is clamped with screws on both sides of the puck.

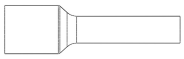
Use of existing abutment design: No
Use of puck system: Yes



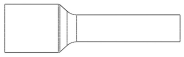
Concept: Swaybar (R+)



Ulna abutment:

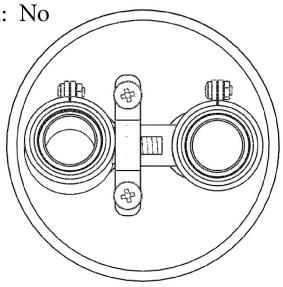


Radius abutment:



The abutments attach through mechanism much like a swaybar. The abutment heads are placed in bushings surrounded with elastic material. The abutments can be latched through lock rings or guick release clamps. The conncection points are linked with sliding pipes controlled by a spring.

Use of existing abutment design: No
Use of puck system: No



5.4.3 Concept scoring

The refined concepts are scored through criteria that reflect the product functions. The concept scoring consists of a greater set of criteria and a more resolute ranking system then the concept screening. The concept scoring follows the methods presented by Ulrich & Eppinger [17].

The criteria are weighted by allocating 100 percentages among them. As mentioned earlier the safety of the device is crucial and criteria that directly relate to the safety are weighted with a high percentage. So do functional criteria like the ability to transfer forearm rotation and that the attachment device is adjustable for different users. The weight and low dimensions criteria also get a high weight.

The concepts are rated on a scale from 1 to 5 on each criterion. Each rating is made in relation to a reference concept that is different for each criterion.

Much worse than reference	1
Worse than reference	2
Same as reference	3
Better than reference	4
Much better than reference	5

To rank the concepts, a weighted score is used:

$$S_j = \sum_{i=1}^{n} r_{ij} w_i$$

where

$r_{ij} = rating\ of\ concept\ j\ for\ the\ ith\ criterion$
$w_i = weighting\ for\ ith\ criterion$
$n = number\ of\ criteria$
$S_j = total\ score\ for\ concept\ j$

The concepts are ranked corresponding to the total score. The concept scoring matrix is presented in Appendix E. The reference concept for each criterion is highlighted in the scoring matrix.

The “Boot Strap” (B) and the “Track and Joint” (HJ) concepts get the best scores in the concept scoring matrix. Both concepts make use of bushings for rotational freedom, elastic materials for freedom of motion and a track for relative movement of the abutments in the ACP. The main difference between the two concepts is that concept B uses puck structure to latch the abutments while in concept HJ the abutment heads are individually latched to the mechanism.

After further evaluation of the final concepts, it is decided that concept HJ will be developed. The advantages of concept HJ over concept B is a more open construction where all parts are easily distinguished. The concept holds similarities with the early prototype at Integrum which has proved to work fairly well.

5.4.4 Structural Material

The main mechanical structure of the attachment device will transfer loads from the prosthesis to the abutments and vice versa. The structure should withstand the applied loads and in the same time not be too bulky or heavy. Since the main mechanical structure makes the major part of the structural volume, it is important that the structural material has a fairly low density. The structural material used for the attachment device should have high strength in relation to its density i.e. it should have a high specific strength. The specific strength will be calculated as the materials yield strength divided by its density.

The structural material of the attachment device must be corrosion resistant. It is common that the user wears the prosthetic device during the whole day. It will be exposed to perspiration and pus from the user and will come in contact with liquids and ambient damp environments on a daily basis.

Low thermal conductivity is another desired characteristic of the structural material. The prosthesis system can transfer ambient heat and cold through the abutments and fixture to the patient's body. This can be harmful to the user and should be avoided in the greatest extent.

High electrical resistivity (low electrical conductivity) is desired from all components in the attachment device. The NCAL project sets an isolative requirement on all components in the prosthetic system.

The attachment device will not have direct contact with the patient's body and there is no requirement for the structural material to be medically approved. The material must be non-toxic and non-irritating to prevent irritation of skin and skin penetration area.

Other desirable material characteristics are low price, recyclability and good visual appearance.

Interesting materials that fit the presented criteria are presented below.

Aluminum alloys
Aluminum is resistant to corrosion in most common environments but has low electrical resistivity (265 – 269 μΩm) and high thermal conductivity (209 W/(m·K)) (ASM, 2012). Aluminium is characterized by a relatively low density (2.7 g/cm^3) and has a fairly low mechanical strength (35 – 505 MPa) and modulus of elasticity (70 GPa) [23] Strength can be enhanced through cold work or alloying at the cost of reduction in resistance to corrosion.

Magnesium alloys
Magnesium has a very low density that can range down to 1.7 g/cm^3 [23]. This is the lowest density of all structural metals. Magnesium is therefore used in applications where weight is of greatest importance. Compared to other structural metals, Magnesium has a low strength (130-285MPa) and is not suitable for constructions that have to withhold greater loads. Magnesium is also relatively soft with a low modulus of elasticity (45GPa). Magnesium has a fairly good corrosion resistance in normal atmosphere but is s susceptible to corrosion in marine environments. Magnesium has an electrical resistivity of 4390 μΩm and thermal conductivity of 418 W/m·K [31].

Stainless steel

Stainless steel is highly resistant to corrosion in most environments and has a wide range of mechanical properties [23]. As all steels, stainless steel has a high density (around 8.0 g/cm^3) compared too many other structural metals. Stainless steel also has high strength (up to 1650MPa). The modulus of elasticity is in the range of 189 to 210 GPa. The electrical resistivity of stainless steel is 64-107μΩm and the thermal conductivity is 12 – 24 W/m·K [31].

Titanium alloys

Titanium is a relatively new engineering material [23]. Titanium is a very strong material and can reach a tensile strength at room temperature of up to 1400 MPa. The modulus of elasticity is in the range of 110 to 120 GPa. It has relatively low density (4.5 g/cm^3) and is one of the most corrosion-resistant metals in existence [19]. The material is considered immune to air, marine and most industrial environments. Titanium also has high electrical resistivity (100 - 170 μΩm) and low thermal conductivity (7-14 W/m·K) [31]. Titanium is an expensive material compared to most other relevant structural metals.

5.4.5 Material selection

After further research, magnesium and its alloys is not considered strong enough for the application in an attachment device with the required low structural dimensions. A search for suitable structural materials within aluminum alloys, stainless steels and titanium alloys resulted in nine candidates. Table 5 shows the strength and density of the candidate materials [23][32].

Table 5 - Suitable structural materials

Material	Ultimate strength (MPa)	Yield strength (MPa)	Density (kg/m3)	Specific yield strength (kNm/kg)
Aluminum 2024	515	440	2780	158
Aluminum 5052	290	255	2680	95
Aluminum 6061	460	455	2700	169
Stainless Steel Type 410	1050	927	7800	119
Stainless Steel 17-7PH	1650	1590	7800	204
Titanium R50700	550	480	4510	106
Titanium R54520	861	827	4480	185
Titanium R56400	950	880	4430	199
Titanium R56620	1050	980	4540	216

Both Titanium R56400 and Titanium R56620 are light and have great specific strengths. Titanium R56400 is common use within biomedical implants and known to Integrum AB. The attachment device should preferably be manufactured in Titanium R56400.

Standard components like bolts, nuts and washes should be made in stainless steel to avoid problems with corrosion.

5.4.6 Further concept development

The main goal in the further development of the “Track and Joint” concept is to find a customized solution that fits the testing patient. The use of standard components like bearings and latching components is highly restricted by the small dimensions required for the attachment device. Most commercially available components are not available in the required dimensions. The further development of the concept will be driven by the goal to achieve small dimension and low weight of the whole structure.

There are several possible bearing arrangements for the chosen concept, see Figure 35. The holder arrangement can be fitted with a slim spherical bearing, a standard bushing and elastic material or a customized bushing and elastic material. The disadvantages of standard bearings in the attachment device are that they won’t provide sliding surface for the whole abutment head and it will be more difficult to find a good abutment latching solution. The construction of customized bearings will be less cost effective but enables a more effective latching solution that can be combined with a bearing surface that can handle loads in all directions.

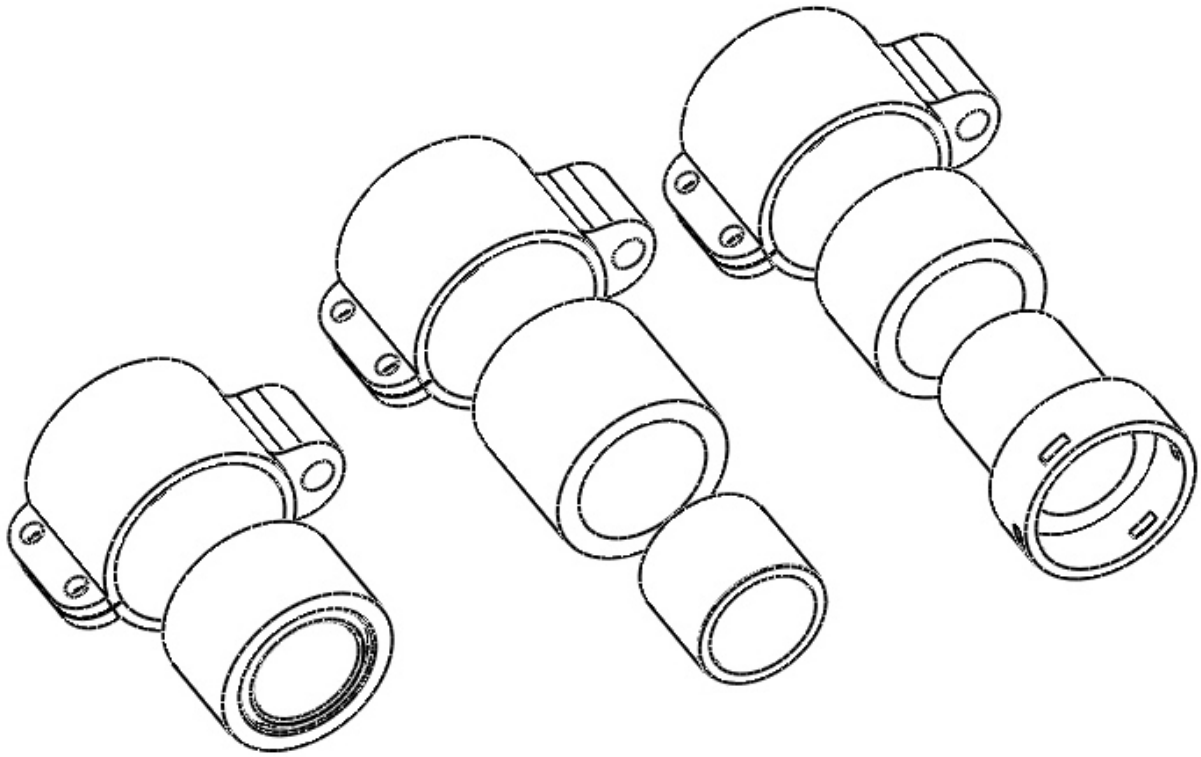


Figure 35 - Holder with different bearing solutions

Dimensioning

The main concern when dimensioning the mechanical structure of the attachment device is the intermediate space between the two latching components when the abutment heads are close to each other. Many standard bearings have diameters that limit the range of motion between the abutment heads. The diameter of the latching and bearing components also sets the required diameter of the attachment device.

To optimize the movement range of the track, the abutment holders are set on separate tracks and designed so that they optimally use the available space in the attachment device frame.

Manufacturing

The concept is constructed for machining manufacturing that makes use of standard material removing machines like drills, mills and lathes. No parts will be manufactured through casting or other methods that requires expensive customized tools.

The attachment device should be constructed and dimensioned for easy and effective manufacturing and assembly. Design for Manufacture and Assembly (DFMA) is a systematic procedure that aims to maximize the use of manufacturing processes and minimize the number of components in a product [16]. The design guidelines provided in the DFMA should be considered during this stage of the development process.

6. Concept presentation

This chapter presents the chosen concept solution for the attachment device.

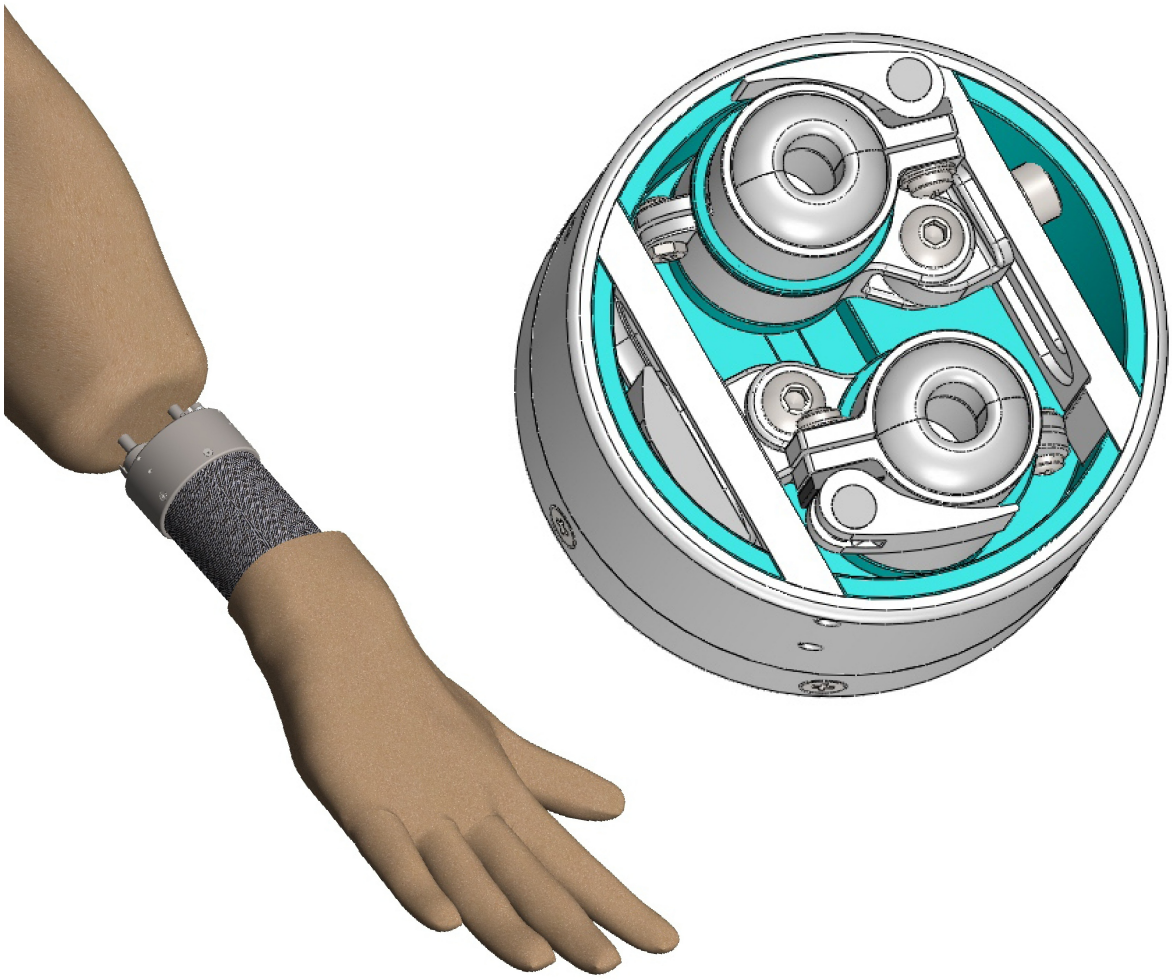


Figure 36 - Chosen concept solution for the attachment device

The chosen concept latches the abutments through individual connectors that interact through a track framework. Distally the attachment device connects to the carbon fiber sleeve through radially placed screws. Each abutment is connected through a customized puck that holds the abutments in place against customized bearing surfaces that can take loads in all directions. Latching of the puck can either be done by a lock pin or a quick release clamp. While the clamp solution is more bulky and includes more parts it will also provide a stronger and more stable connection to the attachment device.

The inner surfaces of the customized bearing and the puck provide a sliding surface that encloses the whole abutment head. Bearing surfaces are coated to reduce friction and wear. See Figure . The puck holds the abutment in place in the axial direction.

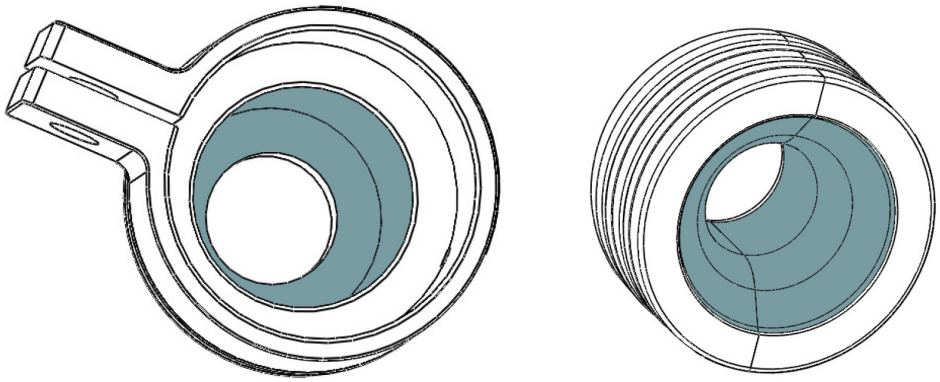


Figure 37 - Surface coating of bearing elements

The connection components are connected to the rest of the mechanical structure through a silicon rubber sleeve. The sleeve allows smaller amounts of angulation and translation of the abutments during forearm rotation. The sleeve can also be used to compensates for misalignment of the abutments during connection and provide smoother interaction between components. When constructing components made of elastic materials like silicon rubber, it is crucial to understand how component geometry and mechanical properties correlate. The silicon rubber sleeve has to be hard and stable enough to transfer loads and maintain stability in the attachment device. It also has to be elastic enough to provide sufficient freedom of angulation and translation of the interacting components. It is important to test the behavior of the silicon rubber sleeves during use and find the optimal geometry and material hardness. Figure shows the use of holes in the silicon rubber sleeve to enhance the deformation capability and functionality of the component.

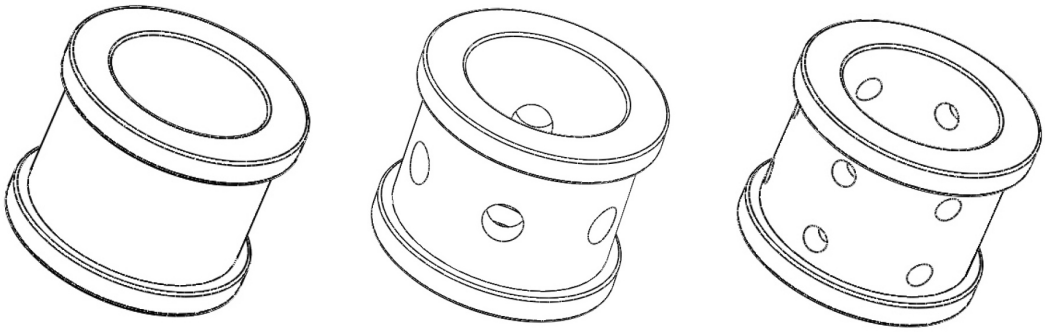


Figure 38 - Design of elastic elements

The silicon rubber sleeve is clamped to the framework through screw holder joints, one connected to a fix position in relation to the frame and the other connected to a track, where it is allowed to slide in the transverse plane. General assessment of the pro-supination problem indicates that the distal radius bone defines the motion of the forearm and should also be fixed against the attachment device. Primarily the ulna abutment will be latched to the sliding holder and radius to the fixed one. The attachment device can easily be turned 180 degrees if a reverse connection would provide a more effective and anatomically correct forearm rotation.

The holder is clamped to the track and the sliding elements are fitted tightly to limit undesired play in the connection. The curved shape of the track and sliding elements helps to distribute the loads in the slider interface and provides greater sliding capabilities (Figure). The interacting surfaces of the sliding elements are coated to lower friction and wear (Figure).

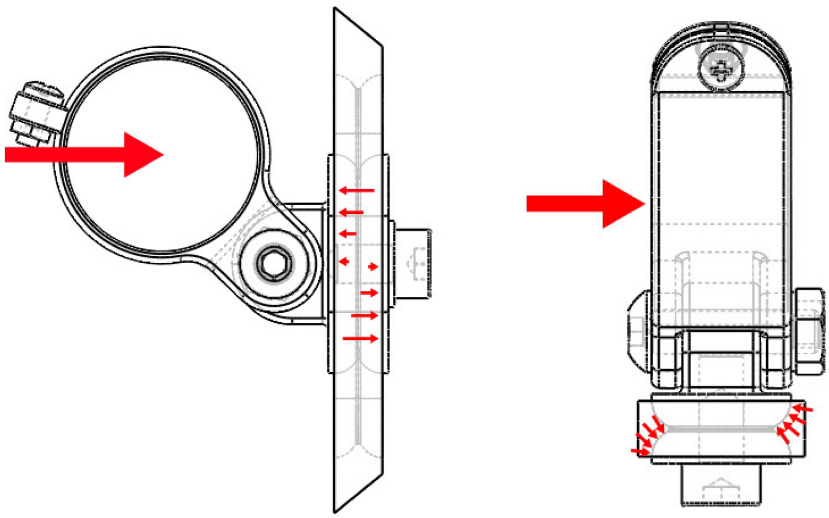


Figure 39 - Loading of sliding track

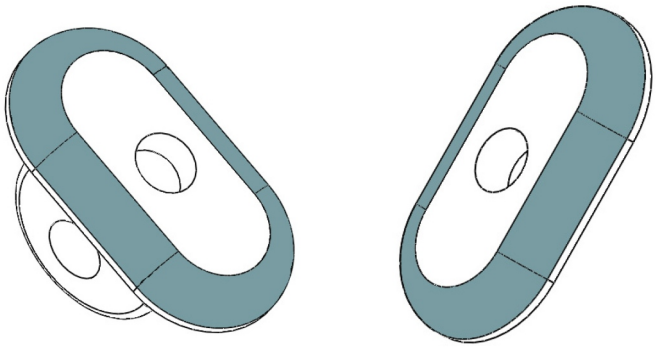


Figure 40 - Surface coating of sliders

Slider motion in the most extreme positions of the track is damped when a chocking component interacts with the silicon seal that covers the inside of the attachment device frame (Figure).The silicon seal does not only have the purpose to work as dampener but also to seal off and protect the electrical components of the prosthetic system.

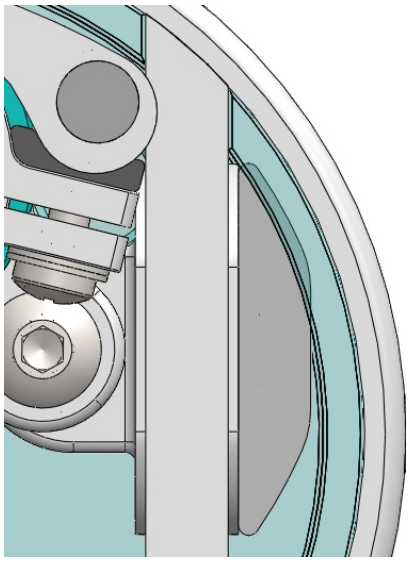


Figure 41 - End point motion dampening

The fix holder can be set in an angle to the sliding holder in the coronal plane (Figure). By adjusting the holder angle to the abutment geometry, an intermediate position can be set for easier attachment. This position is also a reference position for the deformation of the elastic sleeve in the coronal plane.

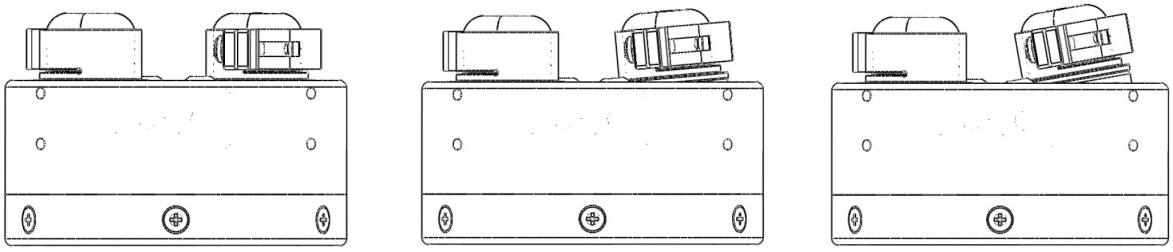


Figure 42 - View in coronal plane; abutment holder in three different preset positions

If both abutment holders are parallel in the transverse plane and the dampening chocker is allowed to reach the inner wall, the attachment device allows the distance between abutment centers to range from 18 mm to 32 mm. The maximum distance between abutment centers is decreased to 28 mm if the holders are assumed to stop when they reach the silicon rubber seal. Figure shows the attachment device in the transverse plane, with the abutment connector centers at a 28 mm, 23 mm, and 18 mm distance. An increase of the angle between the abutment connectors in the coronal plane will decrease the range of motion between the abutment centers.

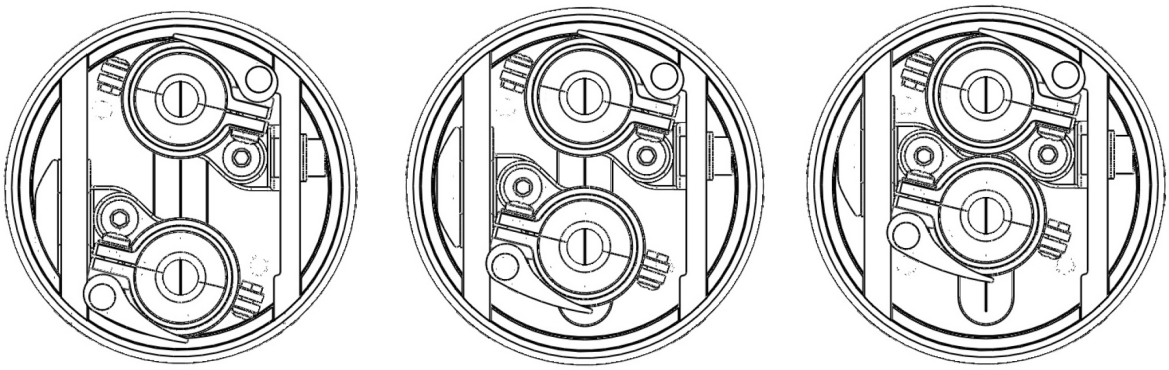


Figure 43 - Transverse view; three different abutment distances

All components allow free passage of electric wiring from the abutments to the components for myoelectric control. The current concept does not incorporate any solution for connector alignment or handling of excess wiring.

7. Concept Testing

This chapter presents results from concept testing and discusses testing methods that can be used in further development of the attachment concept.

7.1 Testing issues

It is difficult to adapt mechanical components to the complex biomechanics of the forearm and it is important to test how well the construction performs during forearm rotation. The best way to test a prototype solution is directly on the user. Other ways to test loads, movements and alignment of the attachment device is through computer-aided simulations or through a test rig that can imitate the movements and anatomy of the human forearm.

Fundamental issues that are important to test are:

- Load distribution to the abutments during movement (dynamic)
- Load distribution to the abutments in preset positions (static)
- The load distribution in the attachment device structure
- Prosthesis alignment to patient anatomy
- Prosthesis alignment and rotation during forearm rotation
- Connector attachment/detachment
- The patient comfort level during forearm rotation
- Ease of movement during forearm rotation

7.1.1 Testing load distribution

The aim is to measure the load distribution through the two abutments and not the magnitude of the load. In an ideal case the two abutments will be equally loaded but in a healthy forearm the load distribution is uneven [13]. It should be accepted that maybe a load distribution of 40/60 or 30/70 through the abutments is enough for a safe attachment device.

Tests of the load distribution in the abutments can be measured by placing load cells on the abutments. If test are going to be made on patients, this requires ethical approval and difficulties related to application of adhesive components to a surgically inserted component. An easier but less reliable test method is through load cells on abutments placed in a test rig.

Static load distribution in the abutments should be tested in different positions along the forearm rotation, from fully supine to fully prone. Tests should also be performed for different elbow angles, from fully extended to fully flexed. Testing load distribution in the abutments during movement requires more from the simulation model or test rig. A model for dynamical testing of the loads requires a lot of parameters to work correctly. It is important that the movements and articulations of the human forearm are mapped and simulated in a correct manner. This requires detailed measurements of a larger group of amputated individuals.

7.1.2 Patient testing

There are limitations with patient testing that are difficult to get around. Testing on patients' requires ethical approval, patient's time and time-consuming contact with the hospital. To find a standardized solution that works for all users requires on a larger group of patients with different levels of amputation and anatomy. Patient safety can't always be ensured, especially during tests where the device is loaded.

At some level and for some variables, testing has to be performed on a patient. To get a measurement of the patient comfort level and ease of movement during attachment device use, the patient must leave a personal statement. An effective way to get an understanding of the comfort level and ease of movement during forearm rotation is through graded charts that communicate patient feelings, see Figure 37 and Figure 38.

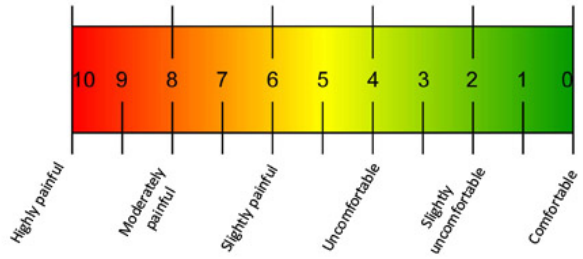


Figure 37 – Scale for patient comfort

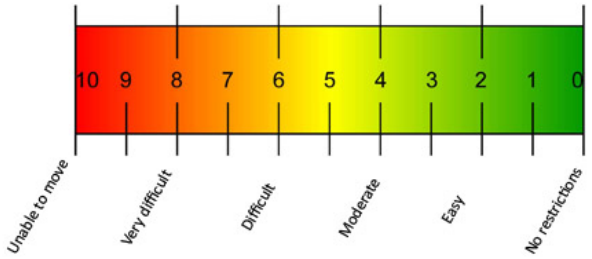


Figure 38 – Scale for ease of movement

7.2 Prototype construction

A prototype based on the concept described in earlier chapters, is manufactured through a local partner, see Figure . To decrease the manufacturing costs, the prototype is constructed in aluminum. Where sliding and bearing surfaces are required, POM is used as the structural material. Elastic components are manufactured by hand in silicon with Shore A 35 hardness. The prototype is manufactured without any CNC machines and simplifications for faster and easier manufacturing are made.

The POM bushings and silicon sleeves are glued together with standard purpose glue, which only will hold for a small amount of load. If the prototype is going to be tested in loaded conditions, a silicon specific adhesive has to be used and the POM has to be coated for better adhesion.

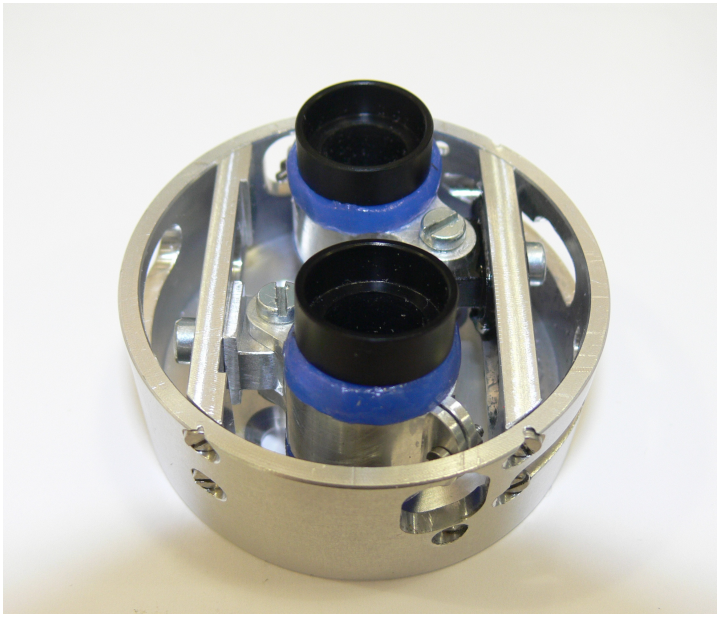


Figure 46 - Manufactured concept prototype

7.2.1 Prototype testing

The prototype is fitted to the testing patient for testing and validation of the basic functionality of the concept, see Figure . No prosthesis was attached to the device and no external loads were applied. The patient was asked to rotate his injured forearm with the prototype attached and give his opinion on the ease and comfort of the operation. The patient found it easy to rotate his forearm and could comfortably perform the full range of motion. The device was attached in neutral position and the slider slid in to an initial position, where the abutment head centers were separated with about 20mm.

Due to the flexibility of an injured forearm, the slider only moved a minor distance during the motion. The test indicates that the change in relative distance between the abutment head centers in the attachment device is less important than earlier expected. This means that the device can be given smaller dimensions and still function in a correct manner for the testing patient.

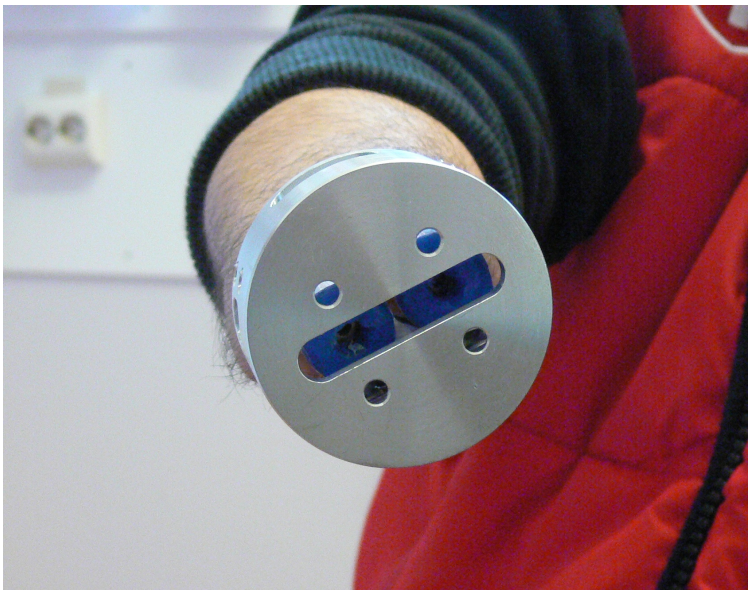


Figure 47 - Prototype on patient

7.3 Test rig development

A test rig can be constructed to test concept and prototype solutions for the attachment device. The rig can be simple and only allow static testing in predefined abutment positions or be more complex and allow actual simulation of the forearm rotation. Even the most complex test rig won't be able to fully simulate the complex biomechanics of the human forearm. As a part of this thesis, a proposal for a functional test rig is constructed and presented. However, manufacturing of a test rig is expensive and time-consuming and is not a part of this project.

7.3.1 The test rig

The constructed test rig (Figure) consists of a main frame with a fixed rod representing the ulna bone. Pronation and supination movements are controlled through a lever that articulates along a track and curved surface and simulates rotation of the radius bone. Both the ulna and radius rod can be adjusted in length to simulate an amputation level of 170 +- 20mm from the elbow joint. The abutments can be angled to represent different patient anatomy and the frame can be set in different angles at the mechanical elbow joint, to represent flexion and extension of the elbow. The radius and ulna rods of the test rig are straight and do not imitate the curved geometry of human bones. To avoid collision, the ulna rod is constructed of several parts. Figure shows the working components of the test rig.

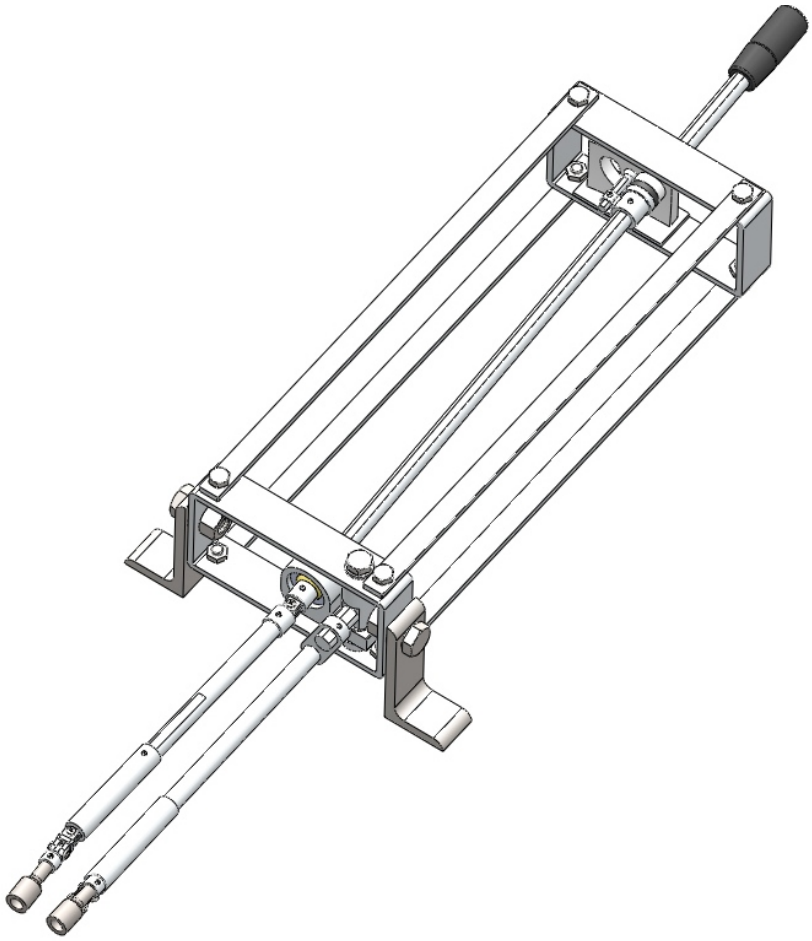


Figure 48 - Test rig

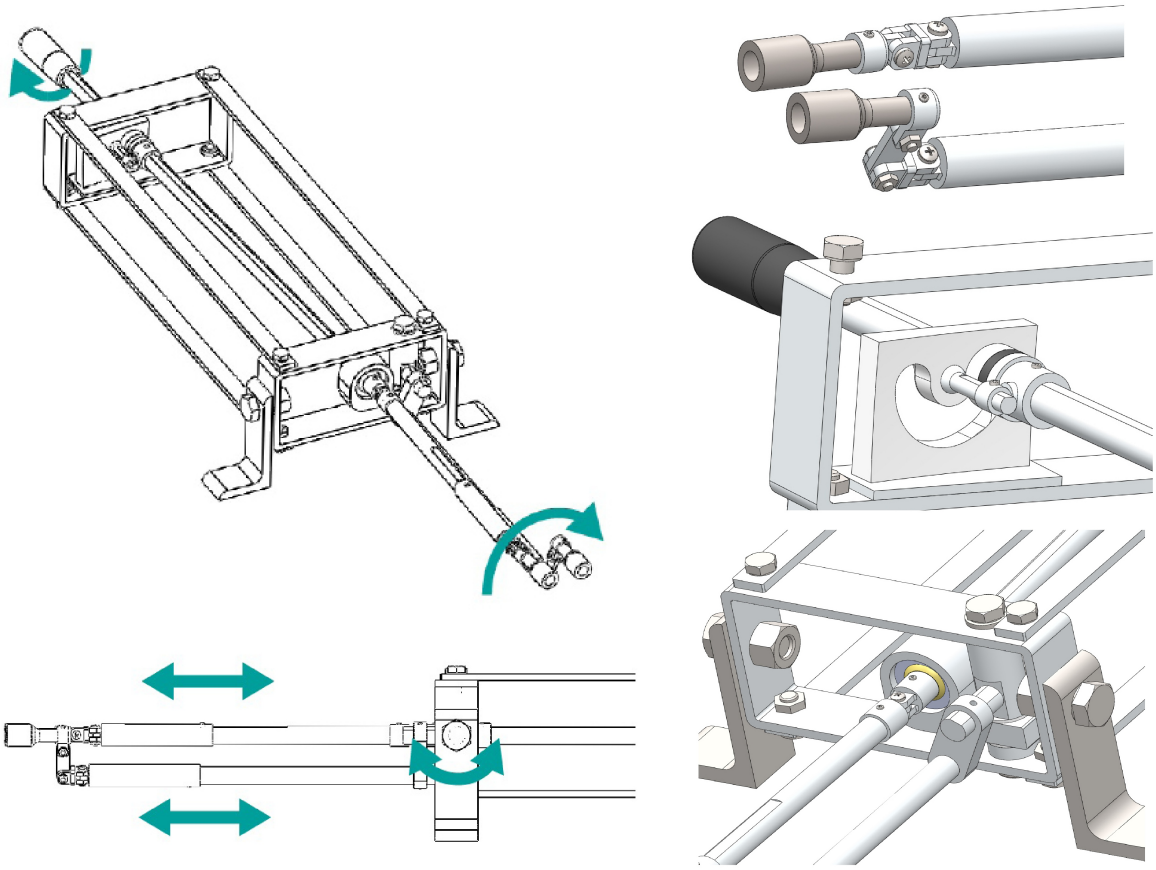


Figure 49 - Test rig working components

The test rig construction is based on a case study where a set of forearm joints are developed to simulate the movements of a healthy limb (Figure) [4]. The test rig represents an amputated limb, based on a simplified two-dimensional trigonometric analysis in the coronal plane of a healthy forearm (Figure) [4]. The blue line represents the ulna bone from the center of the trochlea notch to the distal center of the ulna head and measures 250 mm. The distance between the center of the capitulum and the trochlea groove (Figure 2) is estimated to 22 mm. The radius of the cylindrical surface of the distal ulna I estimated to a mean of 10 mm.

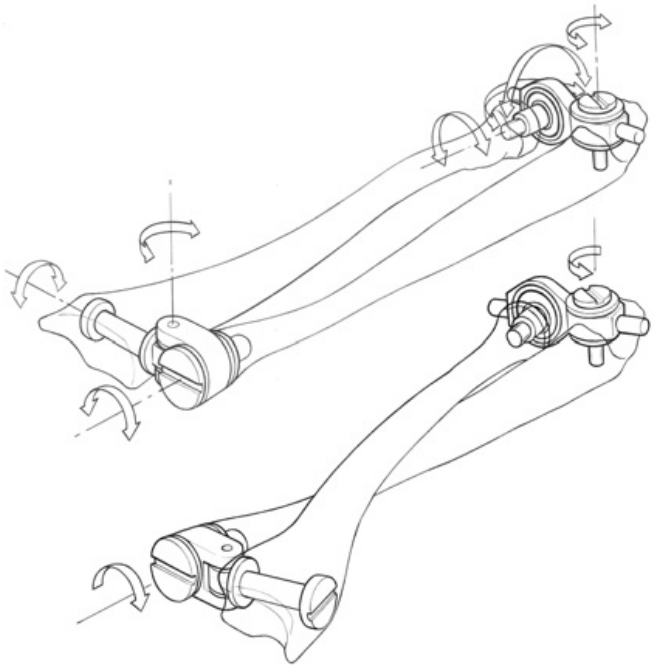


Figure 50 -Mechanical joints used in case study

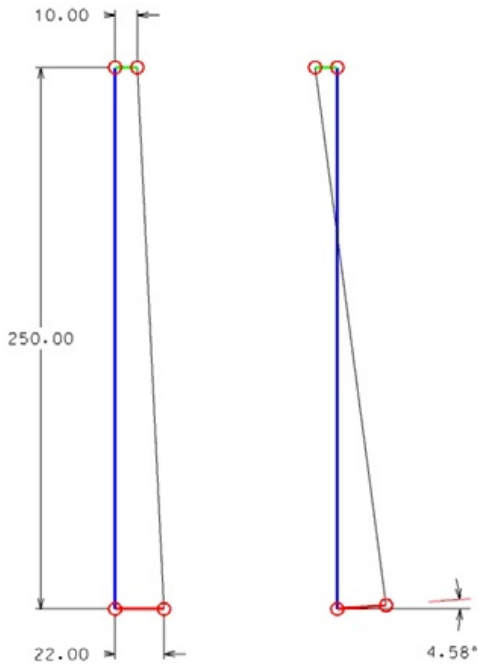


Figure 51 - Two-dimensional trigonometric analysis used in case study

The elbow joint mechanism of the test rig is based on the case model while the mechanical DRUJ presented in the case study is replaced by the articulator track (Figure). This is the most vital part of the test rig and it defines the way the manipulation lever and the radius rod will rotate. The angled shape of the articular surface and the track produces a controlled angulation in coronal and sagittal plane and a controlled translation in the transverse plane.

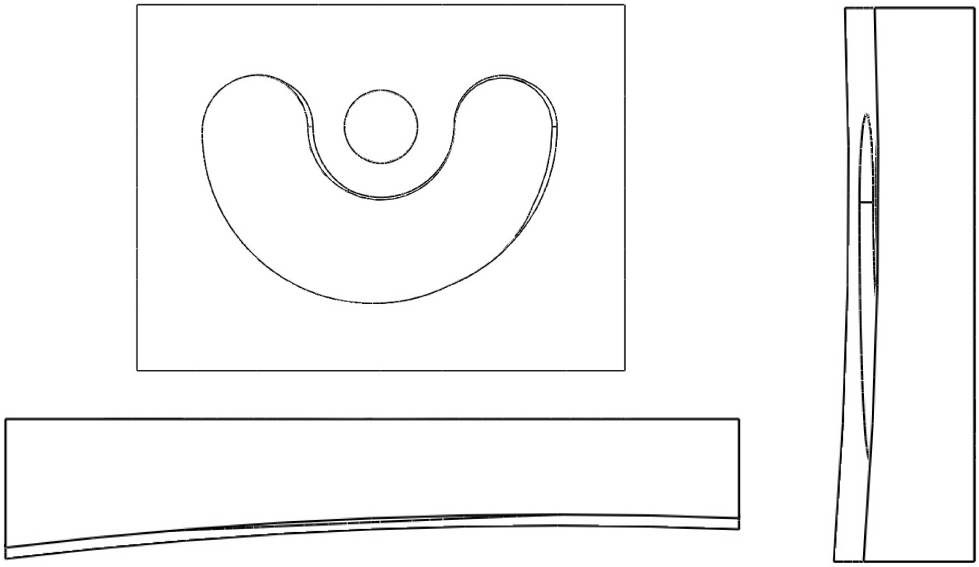


Figure 52 - The complex shapes of the articulator track

When the lever moves in the track, a spherical head abutment is pressed against the rotation center of the track and forces the radius to rotate around its own axis. When the articulation lever moves in the track, the movement is mirrored through the center of a spherical plain bearing and projected to simulate rotation over the articular surface of the DRUJ. Figure shows the projected trigonometry in the coronal plane.

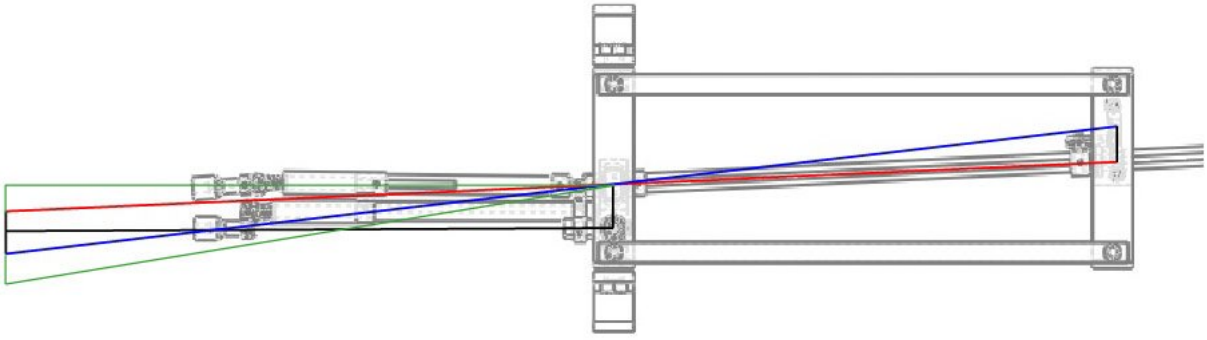


Figure 53 - Test rig trigonometry

The manipulation lever and thereby rotational axis of the radius rod is angled 2.75 degrees against the ulna rod in supine position. This is represented by the red colored line in Figure . In the prone position the lever has rotated 180 degrees and the angle against the ulna rod has increased with 4.58 degrees. The prone position is represented by the blue line in Figure . In the sagittal plane, the lever tilts 2.29 degrees from supine to natural position and then returns to the starting angle at prone position.

The distance from the center of the distal radius to the radius arc is estimated to 15 mm. In the test rig, the radius rod is angled with 3.44 degrees against the manipulation lever, to simulate center of the projected radius. The radius rod will rotate around the central axis of the manipulation level and will follow a greater arc around the ulna rod. This is illustrated by the green colored line in Figure .

Figure 39 shows the projected movement of the abutments in the transverse plane.

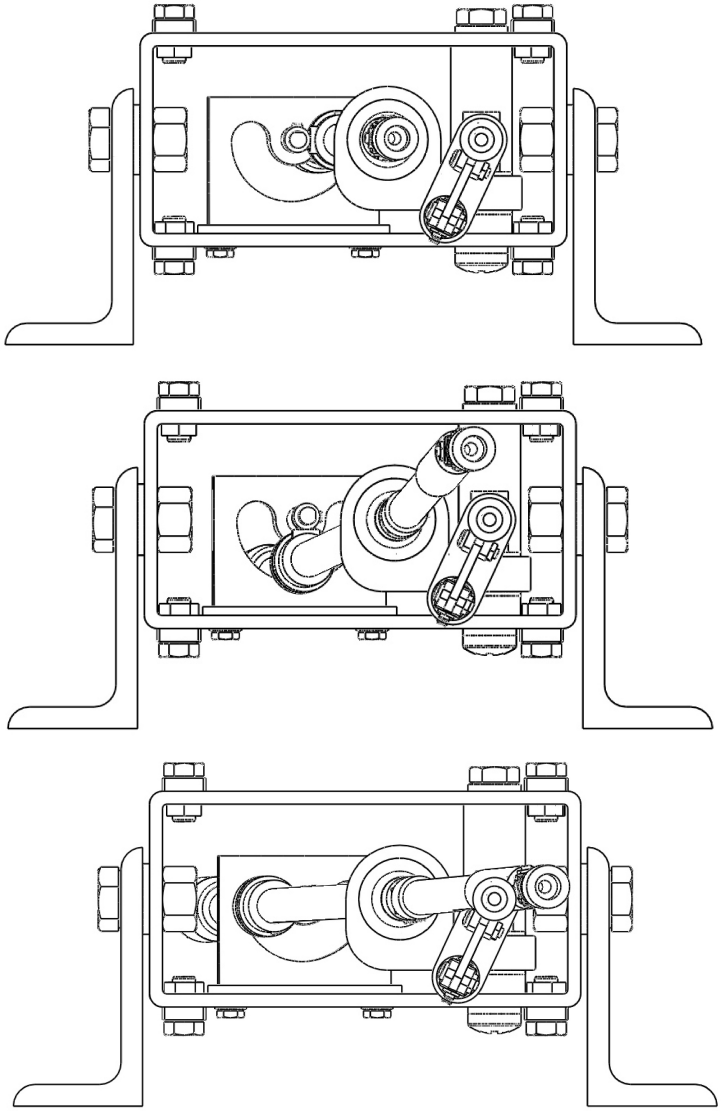


Figure 39 - Test rig function in transverse plane, from supine to prone position.

7.4 FEM analysis

The load bearing capability of the mechanical structure and frame of the attachment device (Figure 55) is tested in Solidworks Simulation module. A simplified static model is run through different load scenarios to get an overview of the solid mechanics of the load bearing components.

Simplifications made in analysis model:

- Rigid connections were set between all parts i.e. all relative movement between parts is prevented.
- There by all bolts and screws are assumed to hold the structure fixed under the loading conditions used in the analysis.
- The elastic material for mechanical freedom and the bearing were excluded from the analysis due to insufficient material data and the complex behavior of the elastic material.

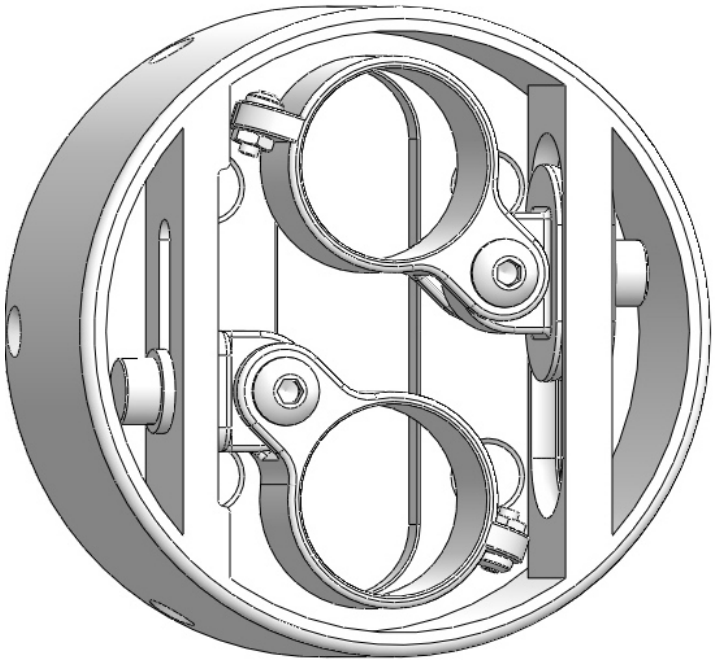


Figure 55 - Mechanical structure for FEM analysis

The loads were applied in two preset positions of the abutment holders (Figure 56). These are the most extreme collision free inner and outer position of the sliding abutment holder and the fixed holder set in the most extreme outer position. The distance between the centers of the abutments in the two positions is 18.2 mm and 28.0 mm respectively. Both holders are set parallel to the transverse plane at all time.

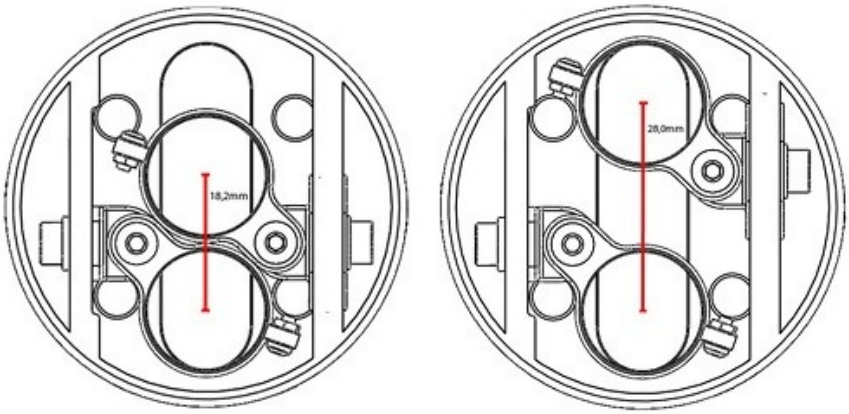


Figure 56 - Preset holder positions 18.2mm (left) and 28.0mm (right)

Fixtures, static loads and a mesh with adequate resolution was set up in Solidworks Simulation. The inner surfaces that should clamp around the elastic material are set to be fixed supports for the analysis, see figure 57. The loads are applied to the inner circumference surface of the distal adapter (figure 58); this is where the attachment device clamps to the carbon fiber sleeve. The figures show the settings for the 28.0 mm model. The same settings were used for the 18.2 mm model. Figure 59 shows the meshed structure for analysis.

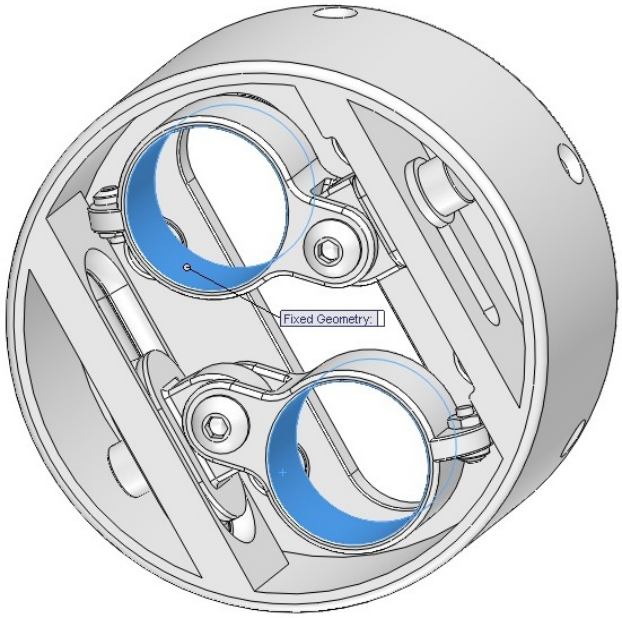


Figure 57 - Fixed support for FEM analysis

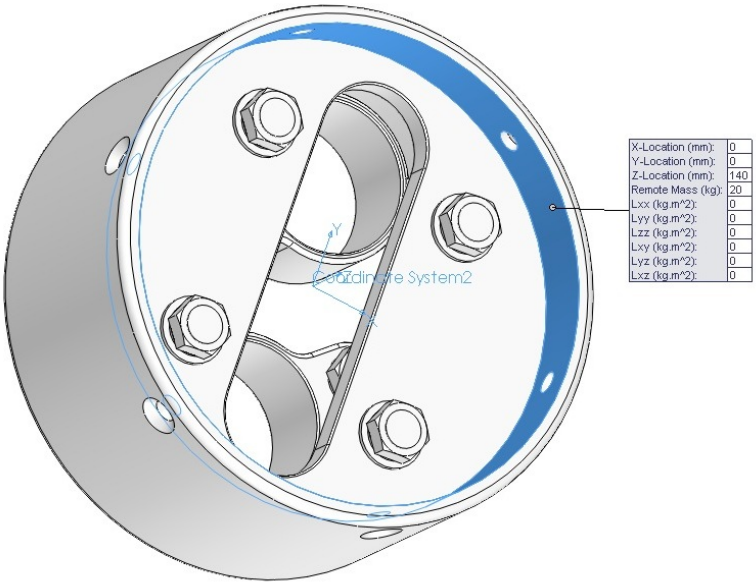


Figure 58 - Surface for load application in FEM analysis

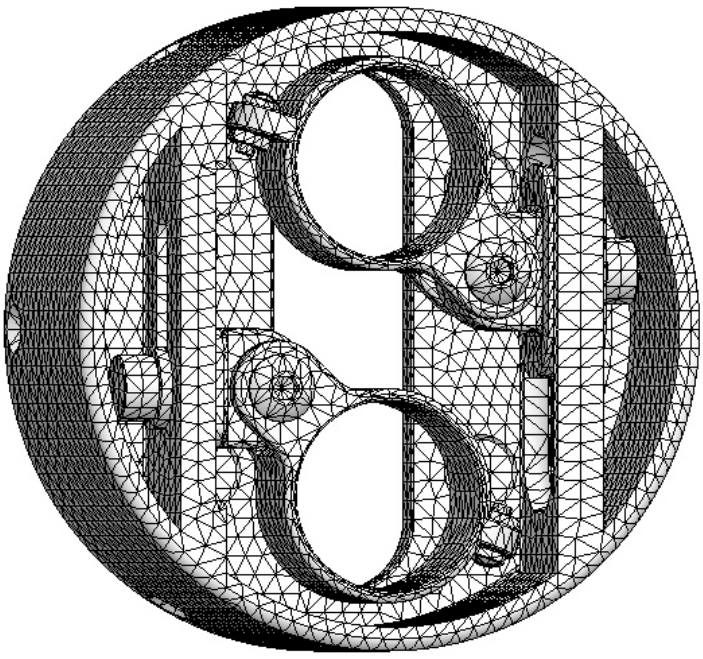


Figure 59 - Meshed mechanical structure for FEM analysis

The loads analyzed:

- Push/Pull loads in transverse plane at 250 and 500 N
- Torque loads in transverse plane at 8 and 16 Nm
- Bending loads in 7 different forearm angles for 10 and 20 kg at a 150 mm distance

The bending load is applied perpendicular to the attachment plane with the elbow in 90 degrees flexion, at a distance of 140 mm from the bottom of the proximal component that is approximately 150 mm from the center of the abutment head. See Figure . The bending load is applied at the neutral position of the forearm and in 30, 60 and 90 degrees of supination and pronation respectively.

The following material data for Titanium R56400 was used in the analysis. For material data sheet see Appendix G.

Table 6 - Material data for FEM analysis

Physical property	σ_u (MPa)	σ_y (MPa)	E(GPa)	G(GPa)	ε	P (kg/m^3)
Value	950	880	113.8	44	0.342	4430

See Appendix D for full specification of the material data for Titanium R56400.

The factor of safety (FOS) is set to half of the structural materials yield strength (440MPa). The conservative FOS leaves a margin to dynamical loading of the structure and compensates for the simple nature of the analysis. The FOS is defined so that the maximum Von Mises stress in the structure divided by the stress limit of 440MPa does not exceed the value of 1.

$$\frac{\sigma_{vonMises}}{\sigma_{Limit}} < 1$$

A FOS value equal or higher than 0.5 indicates that the structure has not started to yield at the current loading condition.

An initial FEM analysis was performed on an earlier version of the mechanical structure. This construction showed high local stress concentration at the abutment holder joints. Abrupt changes in cross section and sharp opposing edges will lead to stress concentrations in the structure [25]. To lower the stresses in the construction, changes were made so that transitions in cross-section were more gradual. The edges of the two joint components were rounded off so that less stress concentration arises at the angular contact area.

The Von Mises stress and FOS values for all loading conditions for the redesigned mechanical structure are shown in Table 7. The table also shows the loads at which the structure starts yielding.

Table 7 - Results from all loading conditions

	18.2mm			28.0mm		
Load	**σmax**	**FOS**	**Fmax**	**σmax**	**FOS**	**Fmax**
Pull/Push 250N	91MPa	4.84		139MPa	3.17	
Pull/Push 500N	82MPa	2.42	1200N	278MPa	1.58	790N
Torque 8Nm	126MPa	3.49		122MPa	3.6	
Torque 16Nm	252MPa	1.75	28Nm	245MPa	1.8	28.8Nm
Bending Supinated 90° 10kg	350MPa	1.25		356MPa	1.24	
Bending Supinated 90° 20kg	705MPa	0.62	12.4kg	712MPa	0.62	12.4kg
Bending Supinated 60° 10kg	371MPa	1.19		267MPa	1.65	
Bending Supinated 60° 20kg	742MPa	0.59	11.8kg	535MPa	0.82	16.4kg
Bending Supinated 30° 10kg	301MPa	1.46		244MPa	1.81	
Bending Supinated 30° 20kg	602MPa	0.73	14.6kg	487MPa	0.9	18kg
Bending Neutral 10kg	217MPa	2.03		258MPa	1.71	
Bending Neutral 20kg	425MPa	1.01	20kg	515MPa	0.85	17kg
Bending Pronated 30° 10kg	249MPa	1.77		345MPa	1.28	
Bending Pronated 30° 20kg	497MPa	0.88	17.6kg	689MPa	0.64	12.8kg
Bending Pronated 60° 10kg	275MPa	1.6		389MPa	1.13	
Bending Pronated 60° 20kg	550MPa	0.8	16kg	778MPa	0.57	11.4kg
Bending Pronated 90° 10kg	353MPa	1.25		356MPa	1.24	
Bending Pronated 90° 20kg	705MPa	0.62	12.4kg	712MPa	0.62	12.4kg

Due to the static and simplified nature of the analysis, the stresses in the structure increase linearly with higher loads. The structure does not yield at any analyzed loading scenario.

The mechanical structure is resistant to both push/pull loads and torque loads. The structure is weaker in bending load and the analysis results show that the structure in 18.2 mm position is weakest at 60° of supination and the 28.0 mm structure is weakest at 60° of pronation. Plot charts of the stress, FOS and deformation for the two loading conditions are presented in Appendix H.

8. Discussion

In this chapter the development process, results and future work are discussed.

8.1 Goal Achievement

The main goal for this thesis was to investigate and develop a new functional concept solution for the attachment of bone-anchored prosthesis. Goal achievements for this thesis project have been partially reached. The goal of finding concept solution that can provide natural forearm rotation for the user has been met but the developed concept requires more testing and validation. The initial goal was to have more numerical values and to carry through a set of tests to validate results and plan for further work.

Seven concept ideas were presented and evaluated. The chosen concept bears similarities with the existing prototype at Integrum AB and can be seen as a further development of the concept. The basic tests performed in the final stage of this project showed that the concept solution provides comfortable freedom of motion for the patient, at an unloaded state.

The concept solution presented in this report is customized to the anatomy and abutment design of one individual. The concept is still on an early stage in the development process and does have the potential to develop into a more standardized solution.

The complexity, dimensions and mass of the concept were kept low and the concept is considered to fulfill these criteria well. The small dimensions of the attachment device have limited the use of standard parts, which have not been used in the same extent as initially desired.

The industrial design in this thesis has been driven by the functionality of the mechanical components and has not been major part of this project. Still the concept has aesthetic values and is considered pleasing for the eye.

8.2 Methodology and research

The methodology for product development used for this thesis project is used in the education at the university for which this thesis was conducted and is also the work of respected engineers from major universities. The methodology should be considered appropriate for this master thesis. The development process for this project is mostly linear. The timeframe, resources, and patient accessibility for concept testing limit a more iterative development process. With no major competing technologies it is not possible to perform a proper benchmarking, which limits the development process further.

Bone-anchoring of upper limb prostheses is a novel technology and only a small amount of research has been made on the mechanics of injured upper limbs. These facts make it hard to collect valuable data for a development project like this. Most sources gathered for this project address biomechanics of healthy limbs or prosthesis systems in a more general way. The available sources have been used to assess and understand the problems related to forearm rotation and prosthetic devices and are still highly relevant for this project.

8.3 Recommendations for future work

More testing of the concept solution must be performed, before any further development is done. It has to be investigated how each part of the prototype performs during forearm rotation and from there decided where to go next. Further development should transit from the current customized solution, to a more standardized solution.

It is of outer most importance to gather accurate data from a large group of patients with different levels of amputation. The measurements have to be performed in a more accurate way then through rulers and photo recordings. The gathered numerical data for broader range of patients can be used to construct a model for computer aided analysis and testing of future concepts.

It is encouraged to further develop a physical test rig based on gathered numerical data for the biomechanics of an injured forearm. To develop and manufacture a test rig is time-consuming and expensive, but allows the development team to directly test changes in a prototype solution without the risk of patient injury.

A future recommendation is to investigate how well different abutment head designs perform in a device that permits natural forearm rotation. A standardized attachment solution will be easier to implement if a standardized abutment design for the trans-radial level is used.

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[35] Max Ortiz, Bionics Engineer, Integrum AB.

[36] Hans Lindén, Development Engineer, SKF Industrial Division.

Appendix A– Patient Questionnaire

There are ten questions in total, six that should be answered in written text and four where the answer should be marked. Feel free to answer the questions in Swedish or English.

1. What do you like about the existing attachment device?

2. What do you dislike about the existing attachment device?

3. Have you experienced any problems related with the attachment device?

4. What improvements would you make to the attachment device?

5. Do you feel limited to perform certain moves or tasks due to the design of the attachment device?

6. Describe a good attachment device in your point of view.

See next page for more questions.

Answer the following statements by marking in what extent you agree with them.
1= strongly disagree, 2= moderately disagree, 3= mildly disagree,
4=mildly agree, 5=moderately agree, 6= strongly agree

The following statements are about the abutment connector, part B (B1 and B2).

1. The abutment connector feels safe.

1 2 3 4 5 6

2. The abutment connector is esthetic.

1 2 3 4 5 6

3. The abutment connector is easy to attach and detach from the abutment(s).

1 2 3 4 5 6

The next statement should only be answered by individuals using the trans-radial attachment device.

4. It is desirable to have an attachment device that allows forearm rotation (pro-supination).

1 2 3 4 5 6

Thank you for participating

Appendix B – Prosthetist Questionnaire

Feel free to answer the questions in Swedish or English.

Please state your profession:

First two questions about your familiarity with the OPRA-system.

1. Have you heard about the OPRA system for upper limb prostheses before?

2. Have you been in contact with the OPRA attachment device for upper limb prostheses?

Even if you have answered NO to any of the two questions above, please try to answer the following questions based on your impression from the description and pictures.

There are ten questions in total, seven that should be answered in written text and three where the answer should be marked.

1. What do you like about the existing attachment device?

2. What do you dislike about the existing attachment device?

3. Have you experienced any problems related with the attachment device?

4. Have you had any complains about this attachment device?

5. What improvements would you make to the attachment device?

6. Describe a good attachment device (in your opinion) for upper limb prosthesis.

Answer the following statements by marking in what extent you agree with them.
1= strongly disagree, 2= moderately disagree, 3= mildly disagree,
4=mildly agree, 5=moderately agree, 6= strongly agree

7. The attachment device is safe.

1 2 3 4 5 6

8. The attachment device is easy to attach and detach.

1 2 3 4 5 6

9. The puck and clamp connection is a good system for prosthesis attachment.

1 2 3 4 5 6

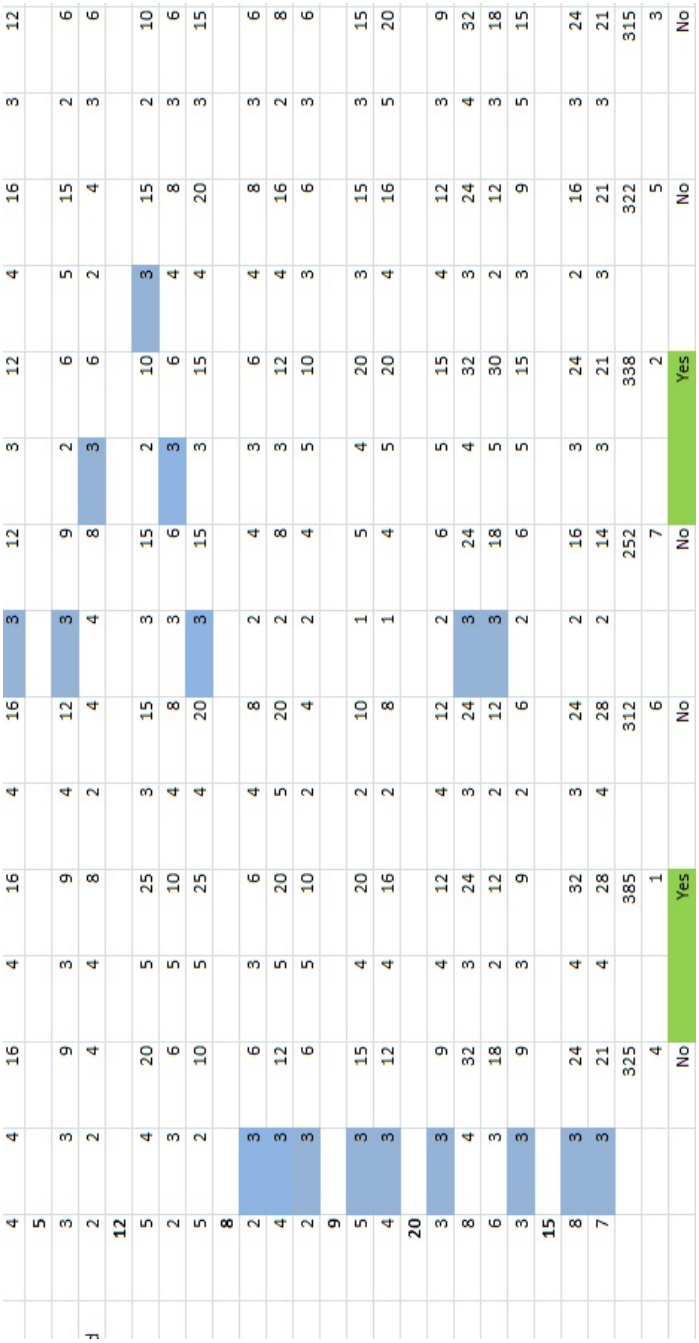
10. What is your professional opinion about the puck and clamp connection?

Thank you for participating

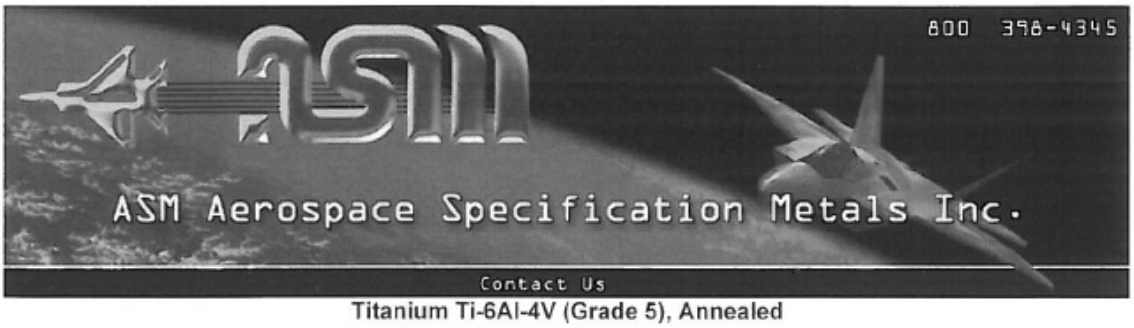
Appendix C – Concept Screening

Selection Criteria	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S
Safe design	+	+	+	0	0	0	-	0	-	0	0	+	-	0	0	0	+	0	-
Configurabillity	0	0	0	0	-	-	+	+	0	+	0	0	+	+	0	0	0	+	-
Ease of use	+	+	0	+	+	0	-	0	-	0	-	0	-	0	+	+	0	+	-
Conveys biological functions	0	0	0	0	0	-	+	+	+	0	-	0	0	0	0	-	0	0	0
Compatability with Myoelectric project	0	0	-	0	0	-	-	0	0	0	0	0	-	0	0	0	0	0	-
Ease of maintenance and cleaning	0	0	0	0	0	-	-	-	-	-	-	-	-	-	0	-	-	-	-
Simple design	+	+	0	+	+	0	-	-	-	0	-	-	0	-	+	0	0	0	-
Ease of manufacture	+	+	0	+	0	0	-	-	-	0	-	-	0	-	+	-	-	-	-
Use of standard parts	+	+	+	+	+	-	-	0	0	0	-	0	+	-	+	-	-	0	-
Calculability	+	+	+	+	0	0	0	0	0	0	-	-	0	0	+	0	0	0	-
Minimized dimensions	+	+	0	+	0	0	-	-	-	0	-	-	0	-	+	-	0	0	-
Lightweight	0	+	-	0	0	0	0	0	-	0	-	-	0	0	0	0	-	0	-
Sum of +	7	8	3	6	3	0	2	2	1	1	0	1	2	1	6	1	1	2	0
Sum of 0	5	4	7	6	8	7	2	6	4	10	3	5	6	6	6	6	3	8	1
Sum of -	0	0	2	0	1	5	8	4	7	1	9	6	4	5	0	5	4	2	11
Score	7	8	1	6	2	-5	-6	-2	-6	0	-9	-5	-2	-4	6	-4	-3	0	-11
Rank	2	1	7	4	6	15	17	11	17	8	18	15	11	13	4	13	12	8	19
Design statements																			
Use of existing abutment design	No	Yes	No	No	No	No	Yes	No	Yes	No	No	No	No	No	No	No	No	No	No
Use of puck system	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No	No	Yes	No	Yes	No	No
Pass	Revise	Yes	No	Yes	Combine	No	No	Combine	No	Combine	No	No	No	Combine	Yes	No	No	Revise	No

Appendix D – Concept Scoring



Appendix E – Material Information



Titanium Ti-6Al-4V (Grade 5), Annealed

Subcategory: Alpha/Beta Titanium Alloy; Metal; Nonferrous Metal; Titanium Alloy

Close Analogs: 4 other heat treatments of this alloy are listed in MatWeb.

Key Words: Ti-6-4; UNS R56400; ASTM Grade 5 titanium; UNS R56401 (ELI); Ti6Al4V, biomaterials, biomedical implants, biocompatibility

Component	Wt. %
Al	6
Fe	Max 0.25
O	Max 0.2
Ti	90
V	4

Material Notes:
Information provided by Allvac and the references. Annealing Temperature 700-785°C. Alpha-Beta Alloy

Applications: Blades, discs, rings, airframes, fasteners, components. Vessels, cases, hubs, forgings. Biomedical implants.

Biocompatibility: Excellent, especially when direct contact with tissue or bone is required. Ti-6Al-4V's poor shear strength makes it undesirable for bone screws or plates. It also has poor surface wear properties and tends to seize when in sliding contact with itself and other metals. Surface treatments such as nitriding and oxidizing can improve the surface wear properties.

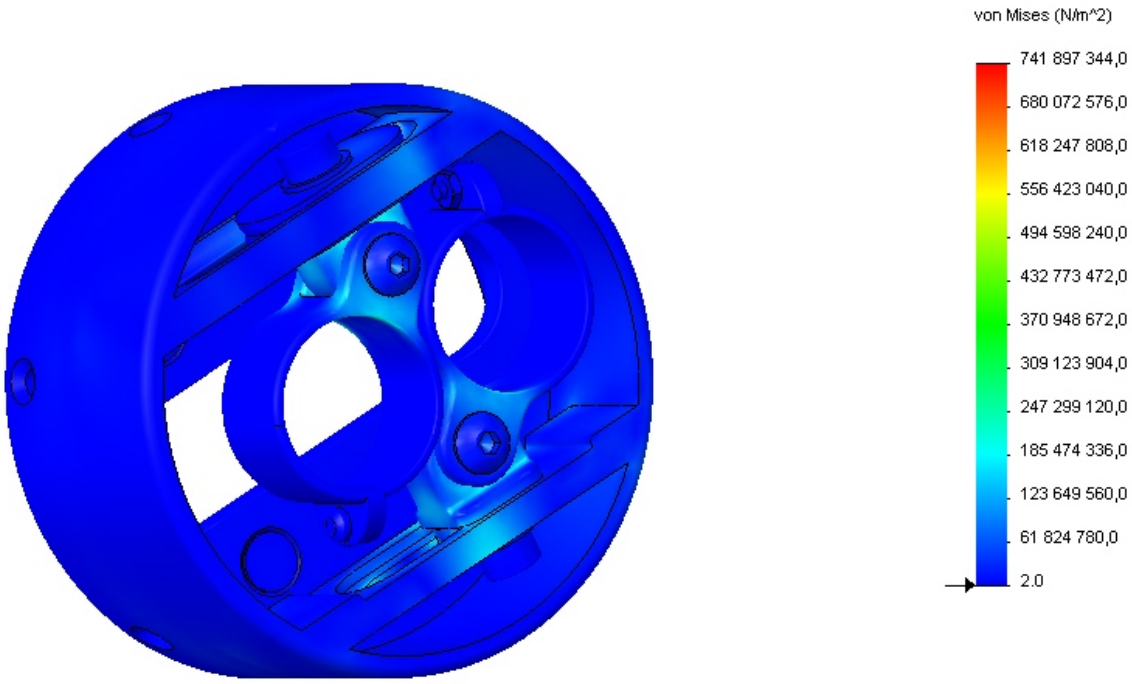
Physical Properties	Metric	English	Comments
Density	4.43 g/cc	0.16 lb/in³	
Mechanical Properties			
Hardness, Brinell	334	334	Estimated from Rockwell C.
Hardness, Knoop	363	363	Estimated from Rockwell C.
Hardness, Rockwell C	36	36	
Hardness, Vickers	349	349	Estimated from Rockwell C.
Tensile Strength, Ultimate	950 MPa	138000 psi	
Tensile Strength, Yield	880 MPa	128000 psi	
Elongation at Break	14 %	14 %	
Reduction of Area	36 %	36 %	
Modulus of Elasticity	113.8 GPa	16500 ksi	
Compressive Yield Strength	970 MPa	141000 psi	
Notched Tensile Strength	1450 MPa	210000 psi	K_t (stress concentration factor) = 6.7
Ultimate Bearing Strength	1860 MPa	270000 psi	e/D = 2
Bearing Yield Strength	1480 MPa	215000 psi	e/D = 2
Poisson's Ratio	0.342	0.342	
Charpy Impact	17 J	12.5 ft-lb	V-notch

Fatigue Strength	240 MPa	34800 psi	at 1E+7 cycles. K_t (stress concentration factor) = 3.3
Fatigue Strength	510 MPa	74000 psi	Unnotched 10,000,000 Cycles
Fracture Toughness	75 MPa-m½	68.3 ksi-in½	
Shear Modulus	44 GPa	6380 ksi	
Shear Strength	550 MPa	79800 psi	Ultimate shear strength
Electrical Properties			
Electrical Resistivity	0.000178 ohm-cm	0.000178 ohm-cm	
Magnetic Permeability	1.00005	1.00005	at 1.6kA/m
Magnetic Susceptibility	3.3e-006	3.3e-006	cgs/g
Thermal Properties			
CTE, linear 20°C	8.6 µm/m-°C	4.78 µin/in-°F	20-100°C
CTE, linear 250°C	9.2 µm/m-°C	5.11 µin/in-°F	Average over the range 20-315°C
CTE, linear 500°C	9.7 µm/m-°C	5.39 µin/in-°F	Average over the range 20-650°C
Specific Heat Capacity	0.5263 J/g-°C	0.126 BTU/lb-°F	
Thermal Conductivity	6.7 W/m-K	46.5 BTU-in/hr-ft²-°F	
Melting Point	1604 - 1660 °C	2920 - 3020 °F	
Solidus	1604 °C	2920 °F	
Liquidus	1660 °C	3020 °F	
Beta Transus	980 °C	1800 °F	

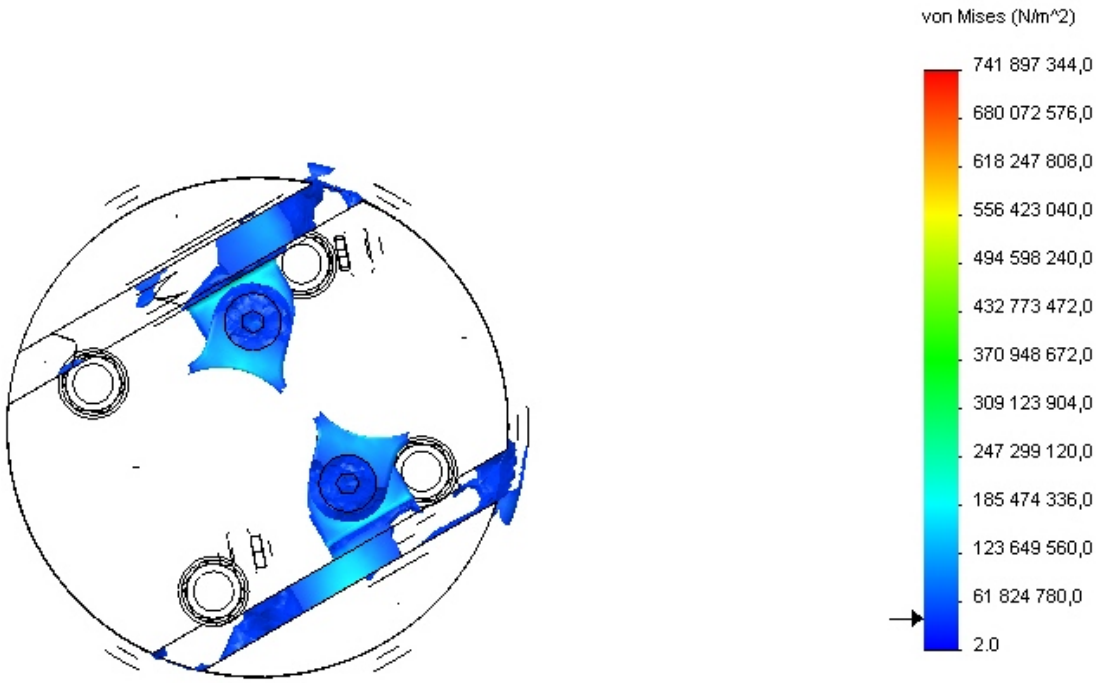
References for this datasheet.

Appendix F – FEM Plot Charts

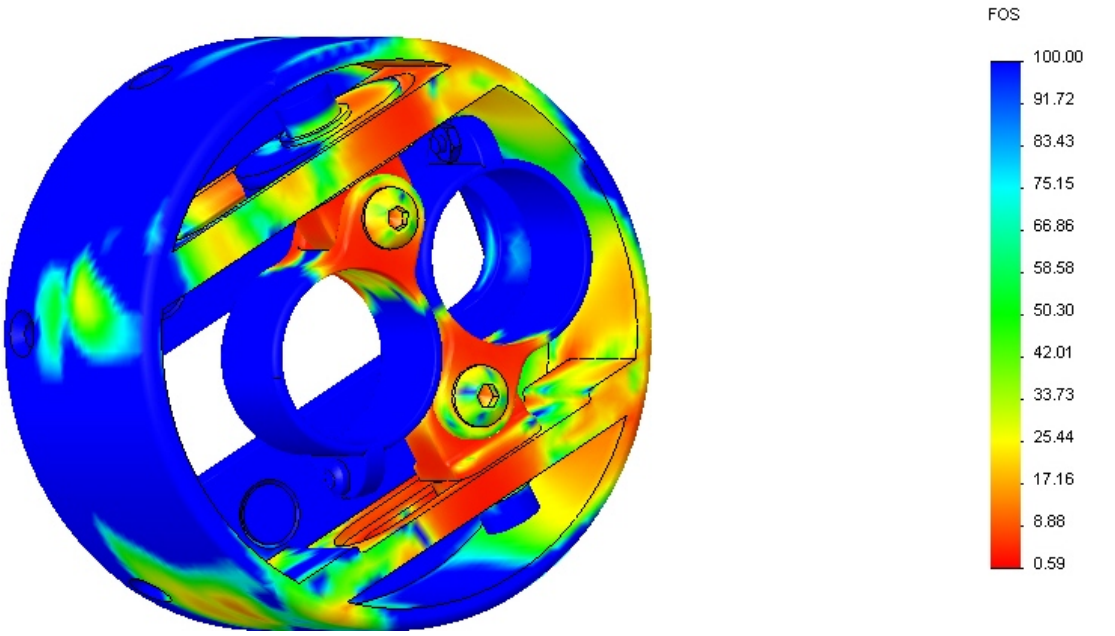
Stress plot at 18.2mm and 60 degrees of supination



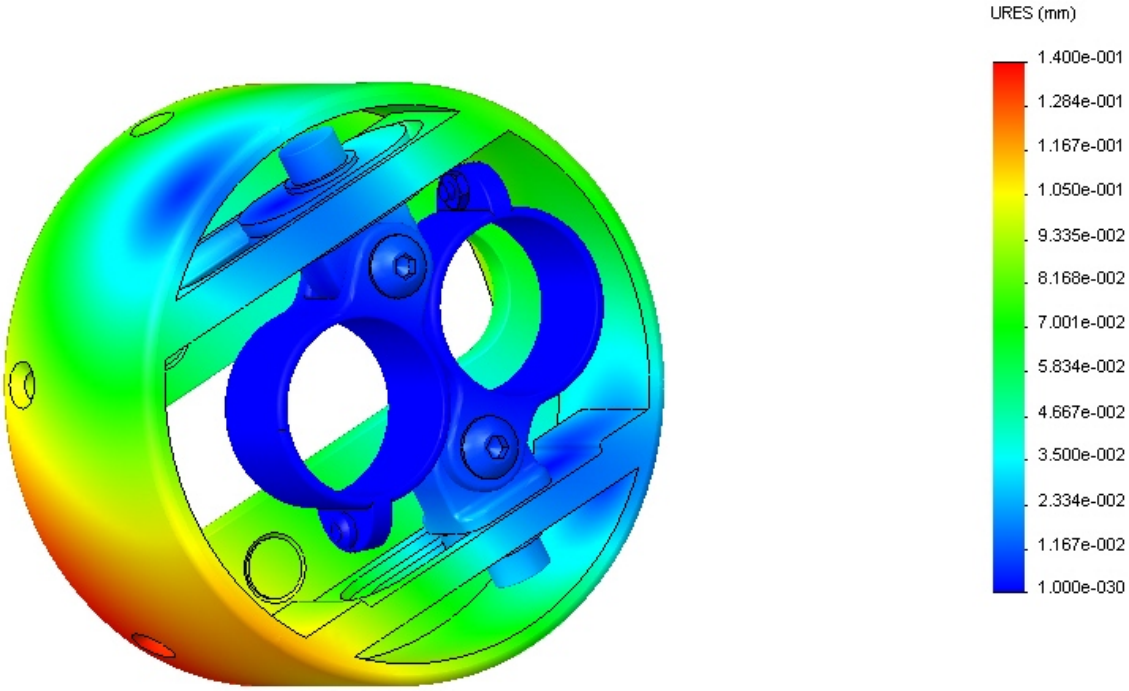
Stress plot of areas with stress levels above 44MPa at 18.2mm and 60 degrees of supination



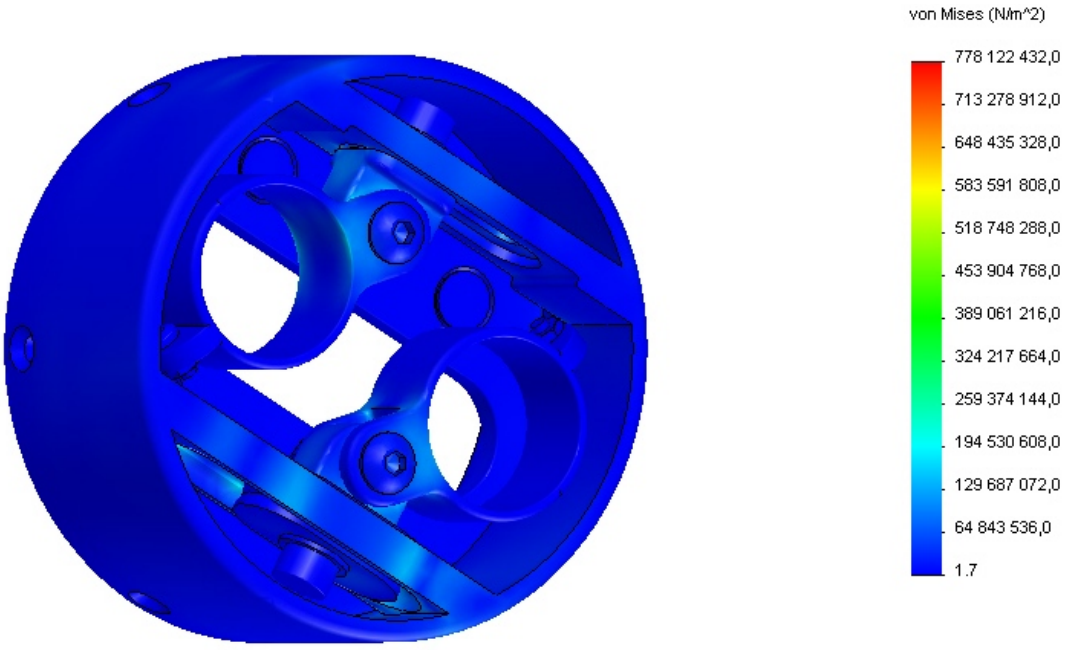
FOS plot for 18.2mm and 60 degrees of supination



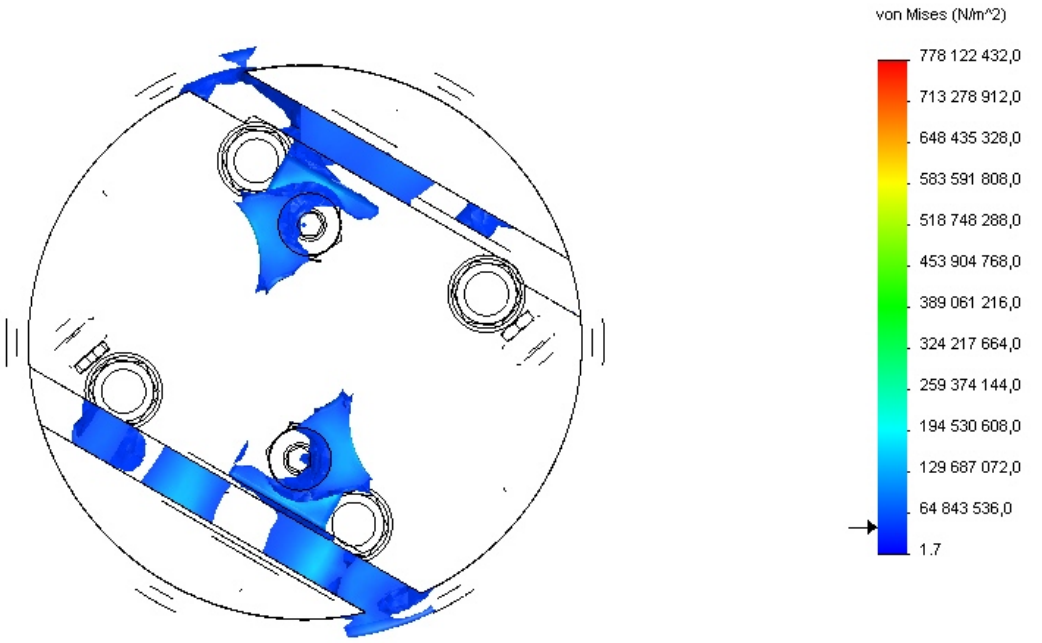
Deformation plot for 18.2mm and 60 degrees supination



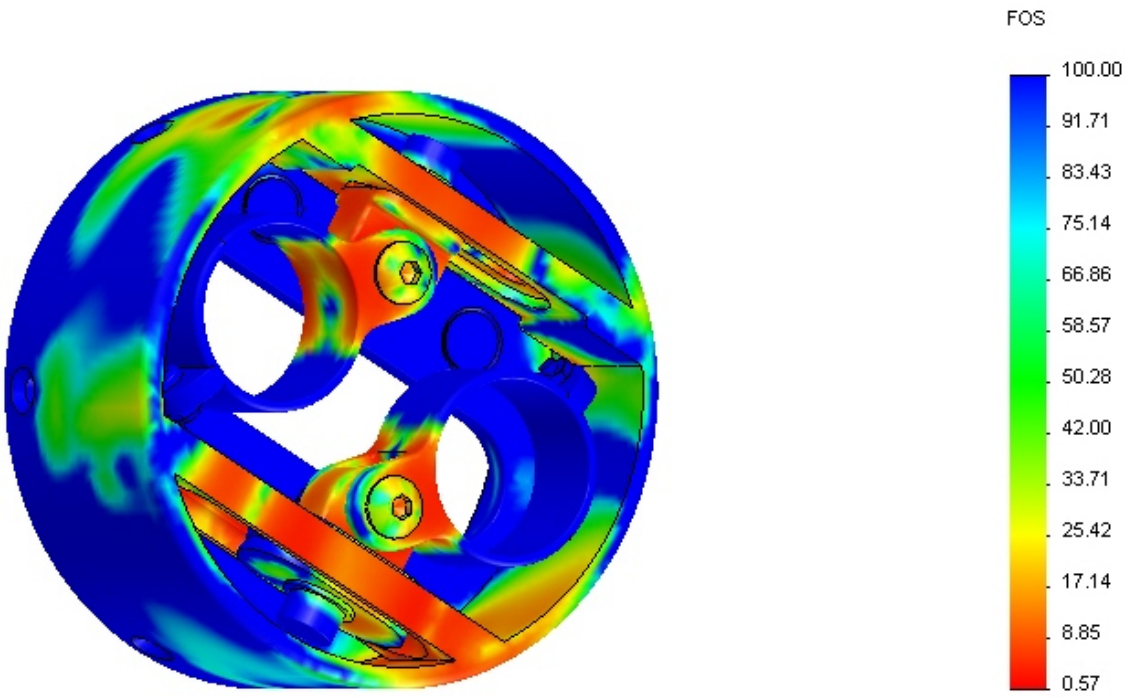
Stress plot at 28.0mm and 60 degrees of pronation



Stress plot of areas with stress levels above 44MPa at 28.0mm and 60 degrees of pronation



FOS plot for 28mm and 60 degrees of pronation



Displacement plot for 28mm and 60 degrees of pronation