ENABLING NATURAL FOREARM ROTATION
IN BONE-ANCHORED PROSTHESES

JASON MILLENAAR

TU Delft Delft University of Technology

Integrum

Thesis submitted in partial fulfilment of the requirements for the degree of

MASTER OF SCIENCE
in
BIOMEDICAL ENGINEERING
with specialisation in
MEDICAL INSTRUMENTS & MEDICAL SAFETY (MIMS)

at

Delft University of Technology

June 24, 2016

Thesis committee:	Dr.Ir. Dick H. Plettenburg,	TU Delft
	Prof. Frans C.T. van der Helm,	TU Delft
	Ir. A.L.M. Minnoye (Sander),	TU Delft

PREFACE

Performing this thesis was a great experience, and it would not have been possible without the help and support of a number of people. Firstly I would like to thank my supervisor at the TU Delft Dick Plettenburg for introducing me to the topic of osseointegration and helping me contact Integrum, the company where the work in this thesis was performed. He has given me the freedom to shape the project and has steered it in the right direction when needed.

Secondly I'd like to express my gratitude to my supervisor at Integrum Max Ortiz. Thanks to Max' attitude of getting things done a large number of steps have been made during this project, like the quick development of a prototype and test set-up, the application for a patent, and contacting professionals and patients in order to get valuable input for the project.

Last but not least, thank you to my colleagues and friends at Integrum who have helped me out throughout the project and made me a part of the team right from the start, and Estefanía for making me feel at home in a new country.

TABLE OF CONTENTS

1. ABSTRACT

As a ways of avoiding issues with conventional socket suspended prostheses, a new type of fixation for limb amputees has been developed and is gradually gaining popularity around the world. Rather than tightly clamping the prosthesis around the skin of the residual limb, a titanium fixture is implanted into the bone and a transcutaneous pin is used to anchor the prosthesis directly to the skeleton. This method, called osseointegration, has been common practice for dental implants for decades but since it is relatively new for limb amputations some challenges still remain. One of these challenges concerns below-the elbow amputations. As there are two bones in the forearm, two titanium implants and transcutaneous pins are present. When performing pronation and supination of the forearm, these two pins make a complicated motion that has proven to be difficult to preserve in a prosthetic attachment device while maintaining stability and reliability.

In this thesis an attachment device is designed and validated that preserves natural forearm rotation for below-the-elbow amputees making use of osseointegrated prostheses. Tests are performed to examine how well the motion is preserved, how the ability to perform the motion affects the performance of everyday tasks, and how the device distributes loading over the two implants.

The developed device was tested by a single patient. Nearly the full range of pronation and supination was preserved, performance improved in a number of tasks requiring forearm rotation, and it was shown that it can be predicted which implant receives the majority of the loads when carrying weight so an as natural distribution as possible can be simulated. A number of challenges remain present for existing patients. These include issues with satisfactory prosthetic control through surface electrodes, carrying of large weights, and adjustability to various patients. Future developments will hopefully tackle some of these challenges, further enabling the device developed in this thesis to contribute to the development of the next generation of prosthetic limbs.

2. INTRODUCTION

OSSEOINTEGRATED LIMB PROSTHESES

Limb amputations have a tremendous impact on everyday life. It is estimated that in the US, 1 in 200 people has had an amputation [1]. The predominant cause of limb amputation is vascular disease (82% of the cases), with nearly all (97%) of the amputations of this cause being a lower limb amputation (LLA). Upper limb amputations (ULA's) are mostly caused by trauma and to a smaller extent by cancer or infection [2]. Even though trauma-based amputations usually form less than a fifth of total amputations, the prevalence of this type of amputation is much higher due to the typically younger and healthier patients [3]. Of the upper limb amputations, approximately half are below the elbow [2], [4], [5]. A way of restoring function and appearance of the amputated limb is by the use of a prosthesis, which is often opted for.

Although prosthetic limbs have been around for a very long time, several problems are often experienced by amputees making use of a traditional socket attachment [6], [7], [8]. These include dermatological problems, a limited range of motion, and reduced control and feedback of the prosthesis due to elasticity of the skin. Depending on the type of prosthesis, these and various other usage issues have led to rejection rates of sometimes higher than 50%, though accurate percentages of prosthetic use and abandonment on a large scale are difficult to obtain [9].

A prosthesis that is anchored directly to the skeleton avoids socket-related problems and could therefore improve prosthesis use and quality of life substantially.

A way in which this is achieved is through osseointegration, a term first used and described by Per-Ingvar Brånemark in 1952 [10]. It is a bone-anchoring technique making use of the discovery that an implant made of commercially pure titanium facilitates bone ingrowth, to the point that attempts to remove the implant lead to bone fracture. This property of the material showed much promise during studies in the early 1960's and led to the first human patients being treated with osseointegrated dental implants in 1965 [11]. Since then, osseointegrated dental implants have become widely adapted and common practice. Other early applications of the technique included bone anchored hearing aids and joint reconstruction [12].

More recently the technique has been adapted to limb prostheses. Amputees that are treated with this type of prosthesis receive a titanium fixture which is implanted into the bone of the residual limb and later connected to a transcutaneous abutment, to which the prosthetic limb can be attached directly [35].

Largely responsible for these developments is Integrum, a medical company in Gothenburg that has developed the OPRA (Osseointegrated Prostheses for the Rehabilitation of Amputees) Implant System.

The OPRA system consists of several components (Figure 1): A fixture that is screwed into the residual bone, a transcutaneous abutment which is connected to the artificial limb, and an abutment screw to keep the two components together [35].

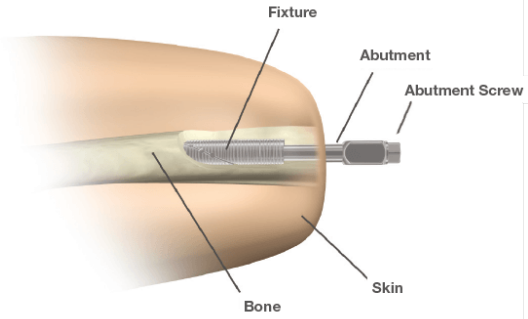


Figure 1: The OPRA system [6]

The three components are implemented in two different surgeries [6]. During the first surgery, first the stump of the residual limb is opened up and the skeleton is exposed. The commercially pure titanium fixture is then screwed into the medullary cavity of the bone of the residual limb. To enable osseointegration to occur, the wound is closed after installation of the fixture. Between surgeries the patient will often be fitted with a custom socket that prevents loads being transmitted to the distal end of the stump, so the patient can still use their prosthesis for the time being, albeit with some limitations. It takes around six months for sufficient osseointegration to occur, so after that time the second stage of surgery is performed. In this second surgery the abutment is inserted into the fixture and the two components are fixed together.

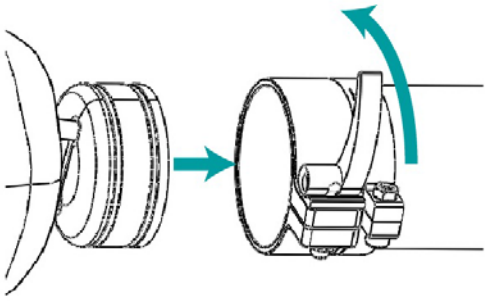


Figure 2: The current attachment mechanism for TRA patients called the puck system [34]

After an intensive rehabilitation process the patient is able to use the osseointegrated prosthesis. It is attached to the implants in different ways, depending on the location and the level of the amputation. Currently, all upper extremity amputees make use of the so-called puck system (Figure 2). Two plastic parts, held together by elastic bands, are snapped around the abutment of the implant. The patient then places a metal ring over the elastic connection and fastens it with a bicycle clamp.

Several studies have shown that making use of an osseointegrated prosthesis improves quality of life when compared to using a socket-suspended prosthesis [8], [13], [14]. The term (health-related) quality of life is broad and without a clear-cut definition and measuring protocol, but through the use of various self-reporting questionnaires valid attempts can be made to describe patients' personal perceptions of well-being. One of these questionnaires, the QTFA (Questionnaire for Trans-Femoral Amputees) was developed specifically for above-the-knee amputees who are using a prosthetic limb and are in relatively good health. This generally represents patients using an osseointegrated prosthesis well, since these patients need to be in decent health in order to be eligible for the procedure.

Three studies specifically investigating the health-related quality of life of patients using osseointegrated prostheses by means of among other measurement tools the QTFA all conclude that an osseointegrated prosthesis results in more use of the prosthesis, a higher patient mobility, and less prosthesis-related problems when compared to socket-suspended prostheses. Furthermore, patients are able to better perceive various sensations through a bone-anchored

artificial limb than a skin-suspended one [15]. This phenomenon, osseoperception, improves the feedback that is received through the prosthesis and can be said to be one of the reasons why patients report that an osseointegrated artificial limb feels more as a part of themselves than when a conventional suspension is used [16]. Lastly, clinic visits are necessary nearly half as much with osseointegration [17] due to the maintenance and adjustments that sockets generally require. Most of these studies exclusively considered lower limb prostheses because there are more patients treated with osseointegration at this level (over 400 as opposed to less than 100 for the upper limb). Still, advantages of osseointegration are considerable and will also be present in the upper limb.

However, a number of adverse phenomena are associated with osseointegrated limb prostheses. First of all, the skin-penetration site is reported to often get a superficial infection. Various studies have been published concerning this topic and report that superficial skin infections occur in between 31% and 55% of the patients after at least three years with the implant. These superficial infections are easily treated with oral antibiotics and often do not affect prosthesis use [7], [8]. Superficial infections almost never develop into an infection of the implant, but implant infections do occur at times. These infections can lead to implant loosening, which is considered as a failure of the treatment. This loosening also occurs without an infection being present, most often due to unsatisfactory initial osseointegration or excessive loading of the prosthesis. It should be noted that deep infections and implant loosenings usually occur within two years after implantation and later loosenings have not been reported. Mechanical complications like bending or breaking of the abutment or abutment screw occur too, though these can be treated in a simple procedure without replacing the implanted fixture due to the modular design of the implant system.

Complications like infections, loosenings and mechanical failures occur considerably less frequent over time, as the implant system is continually improved and the treatment protocol becomes increasingly standardized.

A big challenge with modern limb prostheses, especially for the upper limb, is to control them effortlessly and naturally. Powered prostheses are usually either body powered or myoelectric. Rejection rates for this kind of prostheses are often high due to slowness or unresponsiveness of the device, maintenance of the prosthesis, weight, and limited power [9]. Myoelectric devices are nearly always operated by the use of surface electrodes placed on the skin of the residual limb. These devices often make use of advanced prosthetic hardware and decoding algorithms, but problems remain present with the quality of the signals due to interference from other muscles and various soft tissues, co-

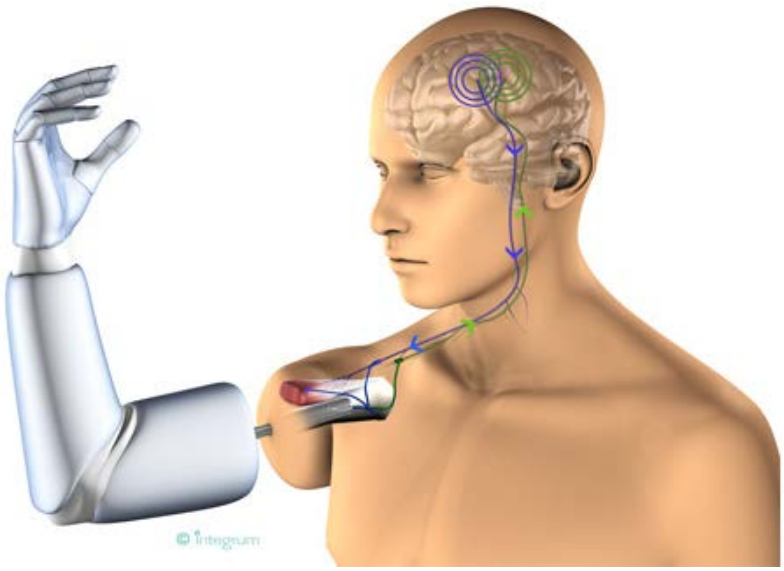


Figure 3: Illustration of the OHMG system [42]

contraction in certain limb positions [36] and environmental limitations [20]. These problems are largely inherent to the use of surface electrodes. Osseointegration provides developers with a unique opportunity: during the installation of the implant, the surgeon has access to the inner structures of the residual limb. This means that not only the bone is accessible, but other tissues such as nerves and muscles are as well. This opportunity led to the development of the Osseointegrated Human-Machine Gateway: a system of electrodes implanted into the nerves and muscles of the residual limb which is used to control the prosthesis and incorporate tactile feedback by means of stimulating nerves when sensors in the prosthesis are activated (see Figure 3). So far this technique has been successfully implemented in one human trans-humeral amputee who has been using the technology since 2013. It has resulted in more precise control of the prosthesis, accurate signals in a larger range of motion, and usability in more environments [20]. The technique is currently also being developed for below-the-elbow amputees.

PROBLEM STATEMENT

Integrum is looking for a new attachment mechanism between the prosthetic limb and the abutments of below-the-elbow amputees, also called trans-radial amputation (TRA) patients. These patients have an implant in each of the forearm bones, the radius and the ulna. The prosthesis is currently attached to both of these implants with the puck mechanism. The two implants are both fixed within the puck, so they cannot move with respect to each other when the prosthesis is attached. This means that the forearm cannot rotate naturally, limiting the freedom of motion for patients. An attachment mechanism is sought after which enables the patient to perform natural rotation of the forearm. This improves the number of actions that the patient can perform effortlessly and thus improves quality of life. The reason this has been a challenge in the past is that the anatomy and the movement of the forearm bones is quite complex.

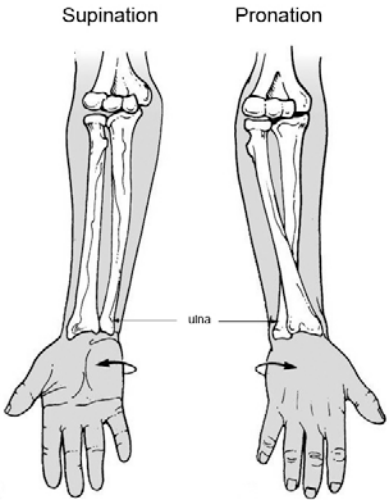


Figure 4: Pronation and supination.

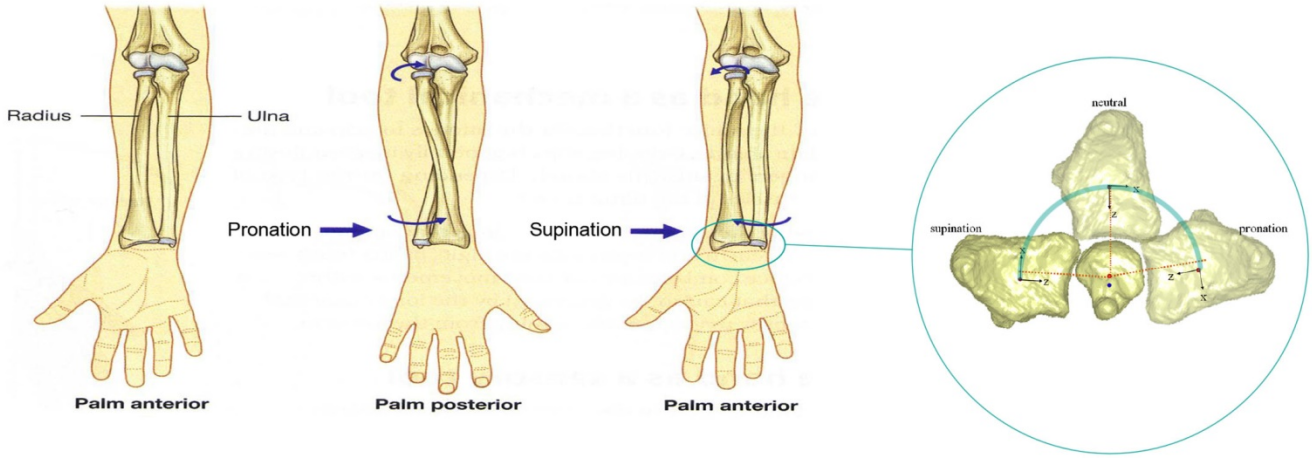


Figure 5: The motion of pronation and supination in the wrist joint [22].

PROBLEM BACKGROUND

The arrangement of the two bones in the forearm allows for different movements which together with the ranges of motion of the wrist and shoulder provide humans to assume almost any position with their hands [21]. The ulna functions mainly as a hinge joint with the upper arm [36], while the arrangement of both the ulna and radius provides the ability to rotate the forearm around its axis. This latter motion is also called pronation (turning the thumbs inward if viewed from the anatomical position) and supination (the opposite) and is illustrated in Figure 4.

Pro- and supination has been described as "an indispensable motion in daily living" [22] and is indeed used in a large number of common tasks such as eating, handling small objects, typing, and maintaining personal hygiene [23], [24]. The importance of this motion is arguably increasing with time [18], as typing and hand-held electronic devices are becoming more integrated with professional and personal life.

The complicated motion of the forearm bones results in a relatively clean, circular motion of the radius going around the ulna in the wrist or distal radio-ulnar joint (DRUJ) as illustrated in Figure 5.

However, even in the wrist small deviations of occur in this circular motion. These deviations have been studied a number of times and generally findings indicate that the ulna moves dorsally a small amount during pronation, and in the volar direction during supination [18], [19]. To make the matter a little more complicated, in order to keep the hand parallel to the elbow both bones need to make some evasive motions [18].

So even in the wrist joint the motion is not perfectly circular. Over the length of the forearm it becomes even more inconsistent: Since the ulna mainly functions as a hinge joint, the radius slides over it in a complicated way during forearm rotation. Due to the curvature of both bones this sliding motion makes for an even larger variability in positioning of the bones with respect to each other. This results in a complex rotational axis which is still subject of discussion [26], [22]. Generally it is found that the axis varies over the range of pro-and supination but that it always starts from the head of the radius in the elbow or proximal radioulnar joint (PRUJ) and goes to the head of the ulna in the DRUJ, as shown in Figure 6.

Some attempts have been made to simplify this motion and create a usable model that simulates pronation and supination in a healthy forearm [18], [19]. In one of these studies a conclusion was drawn to actually "respect the anatomy rather than to aim at a simple physical model" due to the complexity and variance of the natural situation. Another study resulted in the formulation of a set of vectors describing a closed kinematic chain depicted in Figure 7. This chain replaced the natural anatomy

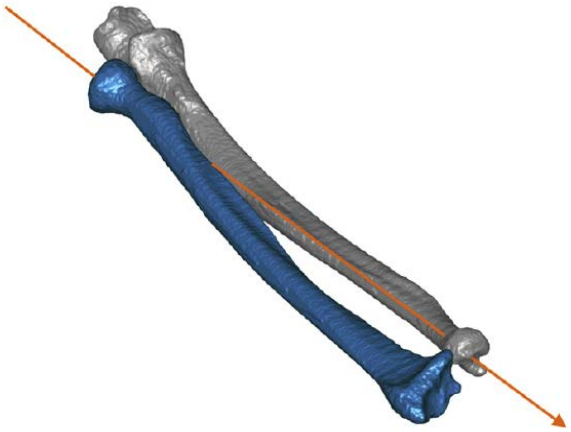


Figure 6: The axis of forearm rotation [26].

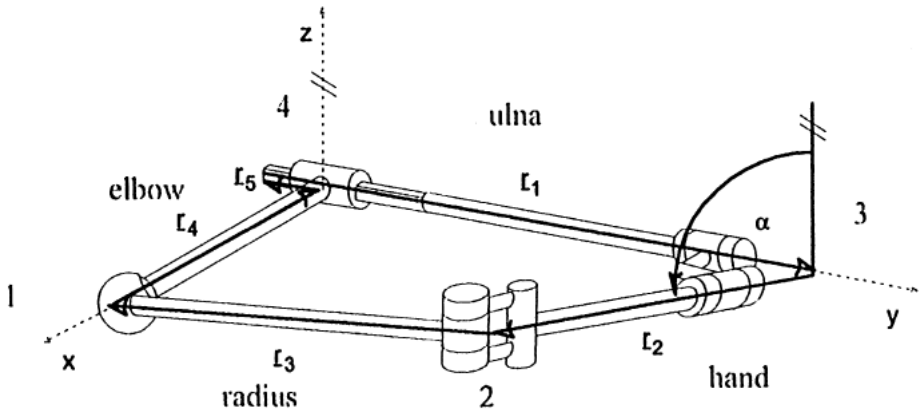


Figure 7: Kinematic forearm of the forearm consisting of elements and a vector chain [18].

with a series of rods and joints that results in an accurate prediction of the movement of the hand for healthy forearms and for forearms that sustained a certain type of fractures, but did not take into account the positions of the bones over the length of the forearm. In conclusion, no simplified model of pronation and supination seems to have been developed that accurately describes the position of the radius and ulna along the entire length of the intact forearm.

In the case of a forearm amputation, this complexity only increases. The absence of the wrist joint undoubtedly reduces the stability of the motion, as does the impairment of a membrane between the radius and the ulna called the interosseous membrane [28]. The motion of the abutments which is observed when a trans-radial amputee with osseointegrated implants performs pronation and supination is highly irregular for these reasons and it will take extensive research to try and capture it in a simplified and structured way.

The range of pronation and supination differs among patients. Depending on individual anatomy and the level of amputation (Figure 8), the muscles that enable forearm rotation are no longer present or severely damaged. This especially impacts the ability to pronate the forearm, as the insertion points of the responsible muscles, the pronator teres and the pronator quadratus, are located more distally than those of the muscles enabling supination, the supinator muscle and the biceps brachii. The most distal forearm rotator muscle, the pronator quadratus, has also been shown to be involved with stabilizing the motion of forearm rotation [27]. For TRA patients this means that it is important that a prosthetic device that returns the ability of forearm rotation retains as much of the range of motion of the user as possible rather than impair the motion any further.

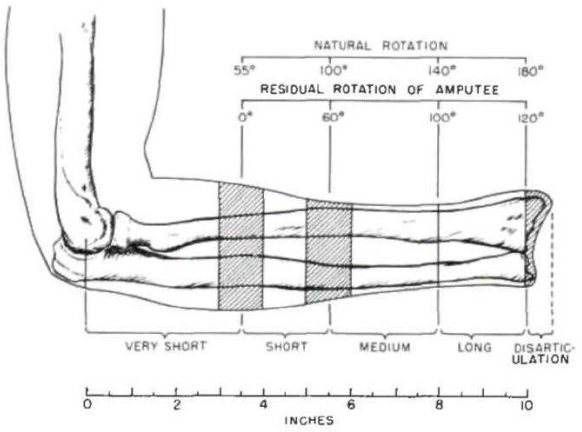


Figure 8: The range of pro-and supination depends on the length of the residual limb [21].

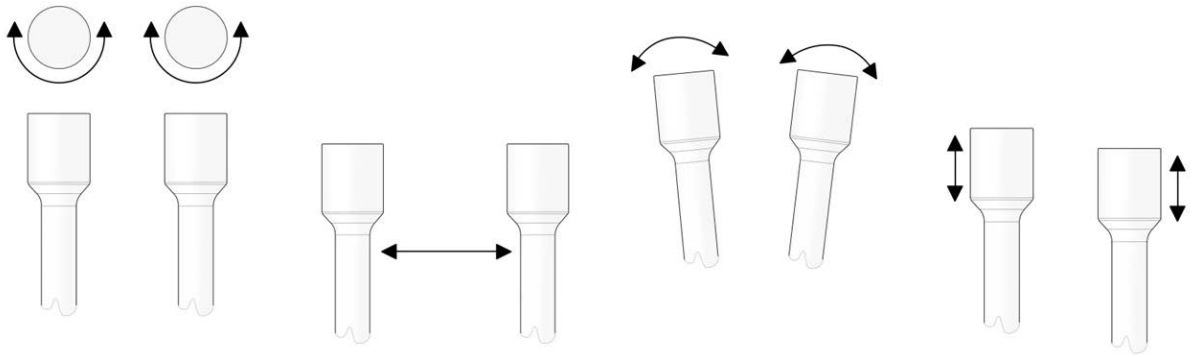


Figure 9: The various motions that the abutments of trans-radial patients could exhibit based on the motions from the forearm bones during pro/supination. From left to right: Axial rotation, variable distance, angular deviations, and distal translations.

Due to anatomical differences in TRA patients and the complex kinematics playing a part, there is no clear consensus as to which and how much of the different motions of the radius and ulna needs to be accommodated in order to preserve the ability of pronation and supination. In order to obtain the versatility needed to function for different patients, an attachment device aiming to do this should accommodate all of the motions shown in Figure 9 to some extent. Axial rotation is necessary because the radius rotates around the ulna, and the ulna in turn makes small deviations. This means that the rotation of the two abutments needs to be independent from each other within the attachment device. Furthermore, due to the curvature of the bones, the distance between the radius and ulna at a section of the forearm varies as the radius moves around the ulna. For the same reason small angular deviations can be present during the motion, which also need to be accounted for. Lastly, due to both the curvature of the bones and due to evasive maneuvers of the ulna, small translations in the distal direction are often present. These variations do not only need to be accounted for to accommodate forearm rotation, but also because the positioning of the abutments themselves varies among patients.

As mentioned, in a healthy forearm an interosseous membrane is present between the radius and the ulna. This membrane is not only important in maintaining stability of the distal radio-ulnar joint but according to some research plays a role in load sharing between these bones [28]. The exact distribution of loads between the radius and the ulna seems to differ depending on the position of the forearm, but various studies report that around two-thirds of the loading from axial compression is transmitted through the radius, with the remaining loading being transmitted through the ulna [28], [29].

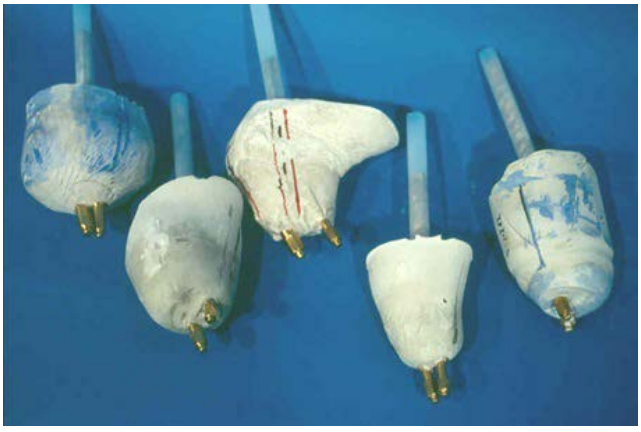


Figure 10: Various configurations of abutments of existing TRA patients [33].

It is unknown how a trans-radial amputation affects the way loading is distributed over the forearm bones. The interosseous membrane will be damaged and some muscles responsible for rotation will mostly be missing, decreasing the stability of the wrist joint. In the case of a socket suspension, loading will be put directly on

the soft tissues of the forearm, so load distribution between the bones will most likely not be an issue. However, in osseointegrated patients each forearm bone receives an implant and the prosthesis is attached directly to both. With the currently used puck system both implants are attached to the prosthetic device in an identical way and are fixed with respect to each other, resulting in what should be an equal distribution of loads most of the time [38]. However, because of varying personal anatomy across patients the implants have a unique position in every case, as can be seen in Figure 10. This could affect the distribution of loads even if both implants are fixed while wearing a prosthesis. Furthermore, when an attachment device is developed that enables the abutments to move freely with respect to each other, this load distribution becomes even more difficult to predict.

In conclusion: Enabling natural forearm rotation in osseointegrated TRA patients is a complicated issue with many different aspects playing a role, such as the kinematics of the forearm bones during pronation and supination, the load distribution between the radius and ulna, the variations in patient anatomy, and the fact that an upper extremity prosthesis must support a broad range of daily tasks ranging from heavy lifting to precise handling of small objects.

THESIS STRUCTURE

This thesis describes the development and evaluation of a novel attachment device which preserves the use of natural forearm rotation. Both the methods and results sections are divided into two parts: the design of the device and its evaluation. The evaluation is further divided in different subjects: The user experience (consisting of range of motion and task performance) and the device's load bearing properties.

The first part of the methods section explains the process that led to the eventual concept choice. The second part describes tests which are done to validate the performance of the device. To this end, first the range of pro-and supination of a patient with the device was compared to this range when not wearing any prosthesis or attachment device. Secondly task performance was evaluated with and without the device: A pair of standard evaluations of hand functioning was performed at the local prosthetic clinic as a means of quantifying improvements in general prosthetic ability. Lastly, the evaluation of the device contains a test in which it is examined how the device distributes loading over the two abutments.

The first part of the results section explains the working principle of the device in detail and discusses the materials and production processes that should be used in further development. Next the results are discussed of the validation process, which is again separated in the assessment of the range of motion, task performance, and load distribution.

In the discussion the outcomes of each test that was performed to validate the design are reflected upon and it is discussed how these outcomes will translate to the ability to implement the attachment device. Furthermore, attention is paid to how the device that is designed meets the requirements and wishes that are defined early in the process.

The overall successfulness of the designed device is evaluated in the conclusion. The company has stressed the importance of the realization of an attachment device which is relatively easy to

produce and implement, and attempts to solve this issue in the past have turned out unfruitful. Depending on how well the requirements and wishes are fulfilled in this project and how successful tests with a high quality prototype have been, statements can be made about whether this project has truly solved this issue. Furthermore some limitations of this project have been acknowledged, and it is emphasized that even if pro- and supination is enabled in TRA patients, there is still a long way to go before artificial hands function as well as natural limbs.

3. METHODS

DESIGN OF AN ATTACHMENT DEVICE

This section describes the methods that were used to synthesize a concept solution for the attachment device. For each part of the process first the methods used are explained and motivated. These methods were chosen based on experiences with the designing process as taught in the BSc program of Industrial Design Engineering of the Delft University of Technology or in various courses from the MSc Biomedical Engineering of the same institute. After the methods are described they are applied to this project for each part of the process.

First the user setting is specified with a function- and user analysis. This leads to the development of the program of requirements and wishes, which is necessary to evaluate future concept solutions. Then the concept generation is discussed, which is based on the product's function analysis and can be said to have a structure of "divergence-analysis-convergence". This means that early on in this phase (the synthesis) an emphasis should be placed on exploring as many different aspects, functions, and areas as possible to find a maximal number of different solutions. These solutions should then be analyzed systematically so the possibilities can be narrowed down in a structured manner and in accordance to the previously set requirements and wishes. A schematic illustration of this process is shown in Figure 11.

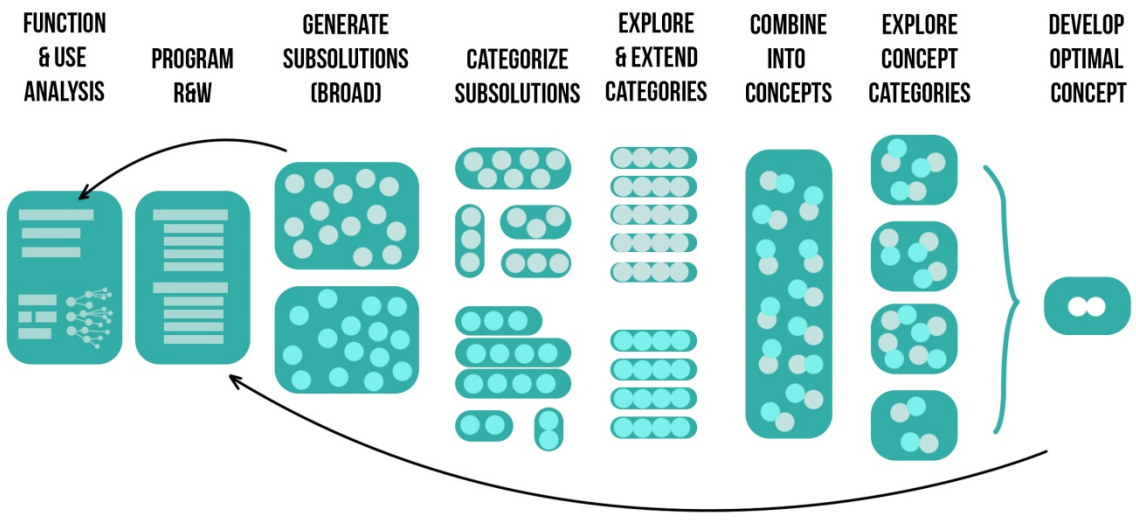


Figure 11: Illustration of the performed design process.

Function- and use analysis

Performing a function- and use analysis is an often used approach to get more acquainted with the setting of the project and a future design solution. These two processes are interdependent and reiterative [30].

A function analysis considers the product as a "black box" that creates accomplished goals from a current problematic situation. A function is described as a *verb* followed by a specification (*grind* beans, *conduct* heat, *allow* for easy access) [31]. It is often useful to discriminate between the main function(s) of a product and multiple sub-functions. The main function should be defined as broad as possible to avoid that solutions will be searched for in too small of an area. However, in order to be able to come up with a practical solution that does not elude the scope of a project, the main function then needs to be specified in significant sub-functions of the device. These functions are important in a later stage of the process, where in order to synthesize concept solutions each sub-function can be explored separately.

Conducting a use analysis is an important way of finding requirements for the product that is to be designed. It explores how the future product should be used, could be misused, and could create problems. An easy and quick way of doing this is to think about the life cycle of the product and create a so-called process tree. Furthermore, special attention can be paid to unintended use and general risks.

The main and sub-functions of the device to be developed in this project are listed in Table 1. Categories of unintended use and risks specific to this project are specified in Table 2. The process tree can be found in Appendix A. Attention was paid to the different stages of a product's lifecycle: Emergence, Distribution, Use, and End of Life [31].

These functions of the product, possible misuses and inherent risks of the product were derived from the literature regarding the topics of osseointegrated prostheses and forearm kinematics, as well as from discussions with patients, prosthetic specialists and employees of Integrum.

Table 1: Functions of an attachment device.

MAIN FUNCTION
• Allow TRA patients to retain their natural rotating ability of the forearm when using an osseointegrated prosthesis.
SUB-FUNCTIONS
• Connect a prosthesis to the two abutments; • Allow for a robust fixture between a prosthesis and abutments that enables normal use; • Preserve the range of pronation that the patient possesses; • Preserve the range of supination that the patient possesses; • Allow access for connectors of the OHMG system; • Prevent the implants from being damaged; • Prevent the patient from being injured.

Table 2: Unintended use and possible risks with an attachment device.

UNINTENDED USE
• Using the product in a function which it was meant to fulfill, but in excess (e.g. carrying too much); • Using the product in a way it was not intended to (e.g. extreme sports, using it as a tool/weapon/toy, misuse due to a poor understanding of the product).
PRODUCT RISKS
• Damaging electrodes in the case of OHMG (water, dirt, loading); • Injuring the patient (damaging the radius or ulna, cutting or scratching the patient); • Damaging the implants; • Damaging the prosthesis (attachment not fitting correctly, wear); • Damage to the surroundings (hitting/scratching other people, damaging the environment when dropped).

Program of requirements and wishes

Perhaps the most important part of a design process is a complete and valid program of requirements and wishes. Requirements are criteria that concepts have to meet in order to form an acceptable solution to the problem at hand. If a concept doesn't meet all requirements, it needs to be discarded or adjusted. A program of requirements should be accurate, non-redundant, and above all complete [31]. To decrease the chance of missing important requirements certain checklists can be used (Pugh's is a common one and was used here) and adapted to the project. Additionally, a use analysis is an excellent source of requirements. In this case a previous thesis on the same subject is used as an additional source [33]. Lastly and perhaps most importantly relevant published literature was reviewed to formulate specific functional requirements for the attachment device (see Appendix E).

In order to decrease redundancy, requirements from these different sources are combined into one list.

Wishes are criteria that do not necessarily have to be met, but can be used later on to compare different concepts with each other. The same sources can be used as for requirements. Setting up the program of requirements and wishes is a continuous and iterative process, as during the project criteria become more numerous and more specific.

The requirements of the attachment device are listed in Table 3 and are divided into functional requirements (criteria crucial to the principal functioning of the device) and general requirements. This same division has been made for the wishes, which are listed in Table 4.

Table 3: The program of requirements.

FUNCTIONAL REQUIREMENTS
1. The initial position of the abutments within the device must be adjustable. 2. Both abutments must be able to rotate around their own axis. 3. The prosthesis must not make unintended motions when loaded. 4. The abutments must be able to move distally with respect to each other. 5. The device must be usable for trans-radial OHMG users in the future. 6. The ulna must not carry more than 55% of the loading on the device at any time.
GENERAL REQUIREMENTS
7. Donning and doffing the prosthesis must be possible using one hand. 8. It must be possible to make a prototype with currently used facilities. 9. The product must be usable in cold and warm weather. 10. The product must be usable in rain and snow. 11. The product must be usable in dirty and dusty environment. 12. Flammable materials must not be used. 13. Attaching the device must result in an indication of completion (user feedback) 14. It must be possible to clean the product regularly. 15. The product must not contain sharp or protruding components with respect to the rest of the prosthesis.

Table 4: The program of wishes.

FUNCTIONAL WISHES

1. Loading should be distributed over the abutments in the following way:
    a. The ulna should carry between 25% and 50% of the load when handling large weights.
    b. The radius should carry between 50% and 75% of the load when handling large weights.

GENERAL WISHES

2. It should be possible to attach the prosthesis to both abutments simultaneously.
3. The product should enable the user to vary as much as he can with his current attachment device.
4. The product should be able to carry as much loads as possible.
5. The product should enable the user to handle items with the at least the same precision as his current attachment device does.
6. Cleaning the product should be as easy as possible.
7. Cleaning the product should be possible using one hand.
8. The product should not include a protruding clamp.
9. The attachment to the prosthesis should be as reliable as possible.
10. The product should be usable for as long as possible.
11. The product should shield any connectors of the OHMG system from water or dirt during use.
12. The dimensions of the product should be minimal.
13. The weight of the product should be as low as possible.
14. The product should be as easy to produce as possible.
15. The product should cost as less as possible.
16. The product should contain standard parts wherever possible.
17. Materials used should be as resistant to wear and corrosion as possible.
18. The product should be as comfortable in use as possible. It should:
    a. Minimize the number of user actions;
    b. Minimize the number of repeated motions;
    c. Be used with minimal forces;
    d. Be used in as little time as possible;
    e. Have reachable components.
19. The product should be as safe to use as possible. It should:
    a. Minimize the chance of injury to the patient;
    b. Minimize the chance of injury to the patient's environment.

Synthesis

The function analysis that is made in the beginning of a project is especially valuable at this stage. Different "sub-solutions" can be thought of for each sub-function that was defined. The individual sub-solutions can be found using several methods, for example in brainstorm sessions and while spending some time looking for analogies in other product ranges or in nature [30].

Making use of a categorizing approach is a way to make sure that as many solutions per function as possible are thought of. This involves finding common properties among solutions and dividing them into groups depending on these properties. When looking at these groups in an overview, thought can be given to whether there are any categories logically missing that could provide more solutions or whether specific categories could be explored further. This last action takes a step away from the actual design setting and functions of the device. This abstraction often results in a larger number of possible solutions.

Looking at all of the sub-solutions in the categories, a large number of combinations can be created. These combinations of sub-solutions form concept solutions, which could meet the program of requirements.

When looking at the function analysis, the sub-functions can be summarized as two actions that need to be performed: *Free* the abutments to move with respect to each other, and *Fix* the prosthesis to both of them in a satisfactory manner. Sub-solutions for these functions were developed separately.

When searching for solutions in the *Fix* category, first a brainstorming method was utilized. This involved asking mainly two questions: "How can you attach one item to another?", and "How can you keep two items fixed together?"

A number of creative sessions were held that each lasted around 15 minutes. As many answers to these questions as could be thought of were sketched or described in each of these sessions, and the next session continued with the results of each previous one. Aside from these sessions time was taken to look for solutions in other product branches or in nature. Many sub-solutions arose from this process; some sketches are shown in Figure 12. These could be roughly divided in five categories:

1. Clamping, defined as placing the abutment in a holder and then exerting force on this holder to keep the abutment in place;
2. Screwing, defined as using threaded parts in order to create a connection;
3. Locking, defined as placing the abutment in a holder and then place a second part that physically blocks the abutment from exiting the holder;
4. Deforming, defined as making sure that placing the abutment requires first exerting force on an elastic material or hinge, which then exerts force on the abutment by trying to return to its initial position;
5. Adhering, defined as any solution that involves a medium or material property that keeps the two parts

Figure 12: Sketches for the "fix" category.

together without them exerting a direct physical force on each other (e.g. gluing, magnets, suction, high friction surfaces, etc.).

When looking at this list no other categories logically came to mind. Attempts to reformulate the categories also did not result in the addition of groups of sub-solutions. Exploring each category separately, however, did result in more sub-solutions being generated.

The process for the *Free* function was similar to that for *Fix*. Again brainstorm sessions yielded a number of sub-solutions (Figure 13) and taking time to explore other areas once again helped to increase this number. Again the sub-solutions could be divided into a number of categories.

1. Partly free one abutment and fix the other: This group of ideas translates a motion of one abutment into a rotation of the whole device. Due to the kinematics of the forearm bones, allowing one abutment to move distally from the other in a track results in the motion being translated into a rotation of the entire forearm;
2. Completely free one and fix the other: This category explores the possibility of connecting each abutment to a different holder and letting one of these holders rotate in the other, rather than enabling the abutments to move with respect to each other in a single holder. The rotating holder now contains an abutment that moves freely from the other holder in a rotating manner but it will also need to move distally. This can be done using a spring, hinge or track;
3. Free both abutments and extend them into a "new wrist": Each abutment forms an extension of one of the forearm bones, which naturally come together in the distal joint in a much cleaner rotating motion than along the length of the forearm. If the natural anatomy were to be replicated by extending the abutments to the point of the patient's wrist, this clean rotation could allow for a much simpler attachment device.

Initially it did not seem that more categories would follow from these definitions. However, after reformulating these groups of solution this had become possible. The two first categories were combined, resulting in the following formulations:

1. Extend & free both abutments;
2. Keep short & fix one abutment.

This abstract reformulation created a situation where a number of categories could be added until a logical maximum was reached, indicating that the entire design space was considered. They are:

3. Extend & fix one abutment;
4. Extend & fix both abutments;
5. Keep short & free both abutments;
6. Keep short & Fix both abutments.

Not all of these categories are valid for the generation of viable sub-solutions. For example: "Keep short & fix both abutments" describes the current attachment device that

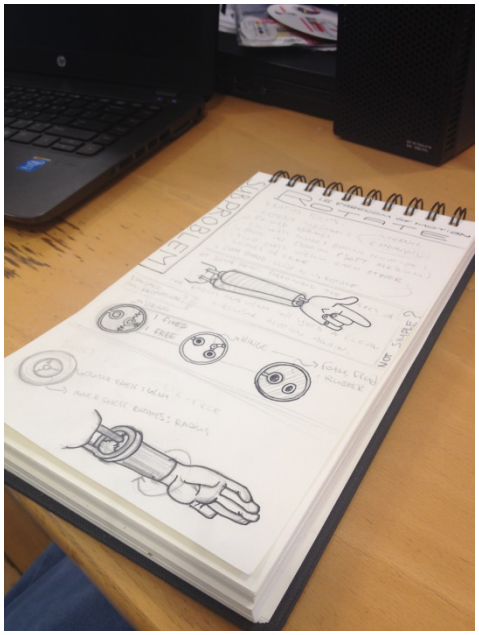


Figure 13: Sketches for the "free" category.

osseointegrated TRA patients use, which causes the problem that is being solved in this thesis. Solutions belonging to this category would involve body-powered cables or electric motors. Still, exploring all of these categories resulted in the generation of a number of new sub-solutions.

Analysis & concept choice

To be able to choose between many concept solutions, it's often opted for to put them in a table with all wishes and requirements and create a scoring system that reveals an optimal concept [30], [31]. In practice finding an objective, prioritized and truly substantiated scoring method is often very difficult and time-consuming.

When the approach is taken to use clear categorization of concepts like described up to this point, it is possible to take a different route. A structured discussion can be held with the client or design team members about what the weak and strong points are for a representative concept of each category of concepts, closely keeping in mind the program of requirements and wishes. The strong points of each category can be taken to see if combinations can be made to form an "ideal" concept that spans across categories or optimizes a specific one. This new concept can be discussed again after which it can be optimized and reiterations can be made until the designer and client decide that a satisfactory point has been reached to move forward. If no "ideal" concept can be found, it can always be opted for to fall back to a scoring system.

In this case, the two sub-functions were mostly independent from each other: Nearly any method chosen for freeing the abutments with respect to each other could be combined with a large number of attachment solutions. In order to prevent that some combinations were overlooked before narrowing down the possible concepts, the functions were kept separated for a while longer. Furthermore, it was decided that the sub-solution for the *Free* function was the most crucial and unique aspect of the design solution. The most promising ideas from each category were explored and developed further until each relevant category had a representative solution. These solutions were prototyped using the company's 3D printer (Figure 14) and discussed. The representative solutions are described in Figures 15, 16 and 17. It should be kept in mind that these are not the only concept solutions that were developed, but they were selected for discussion because of the large differences in functionality among them.

Figure 14: Functional prototypes made with 3D printing.

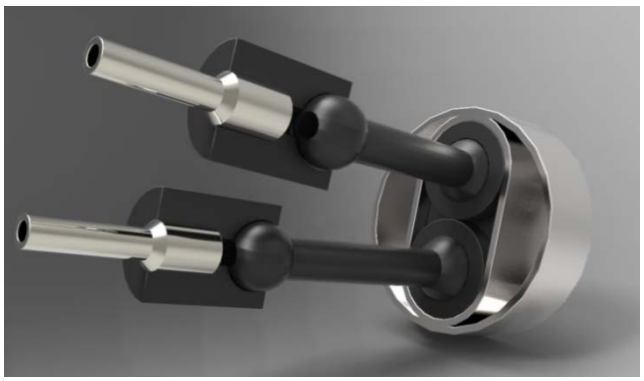


Figure 15: The concept of the extended abutments. The patient's abutments can be attached to what can be considered as artificial forearm bones. Both ends of these "bones" are shaped as spheres that form the studs of ball joints. At the distal end the balls are enclosed within a base which is in turn connected to the prosthetic hand. At the proximal end they are clamped together with the abutments in separate holders, and when configured to the patient they can be (partially) locked in a specific position. The hope is that any motion that the abutments make with respect to each other will result in a rotation of the "base" part due to the enclosure of the ball joint in the artificial distal joint.

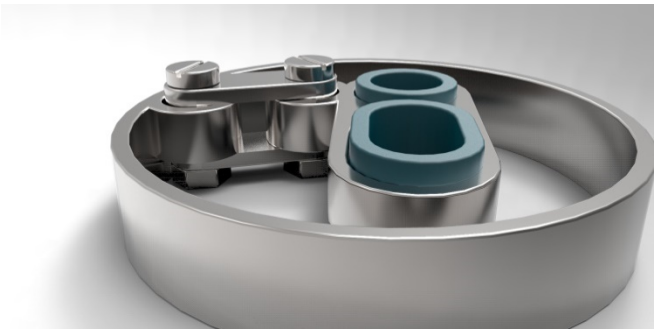


Figure 16: The track motion concept. Both abutments are attached to a holder of which the orientation can be changed within the rest of the attachment device with hinges. Within the holder, one abutment is free to move in a track while the other is not. By allowing this motion, the device will rotate when the forearm of the patient does. In order to allow deviations in the angles and translations of the abutments, the holder must incorporate some elastic elements to which the abutments are attached (green in the image).

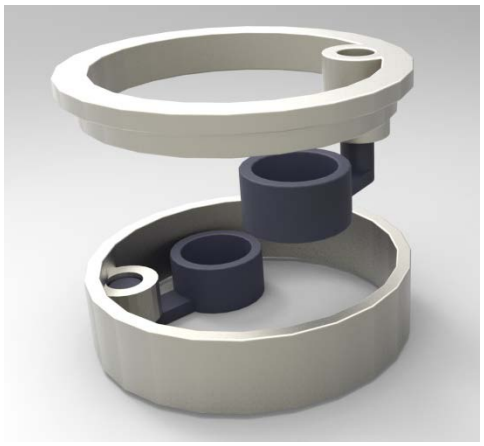


Figure 17: The concept of the separate holders. By attaching each abutment to a separate cup (purple in the Figure) and connecting each of these cups to a holder of their own, the abutments are fully independent from each other. However, by fitting one holder into the other and enabling it to rotate, each motion of the abutments will be translated into a rotation of the top holder. The abutment connected to the non-rotating cup can be fixed by locking the hinge in a certain position, while the hinge connected to the other abutment can remain free to move. This way the abutment which is connected to the rotating holder is free to move away and towards the other abutment, while the top holder remains to rotate in the bottom one.

Although the solutions discussed showed promise, each had uncertainties about their functionality or properties that made them suboptimal for implementation. Still, a number of conclusions could be drawn from the discussion. The most intriguing aspect about the solution of the extended wrist was the inclusion of ball joints. The stud of a ball joint is free to rotate around its own axis and change its angle with respect to the cup. This means that two of the motions that the abutments make with respect to each other can be accommodated with this solution. However, simulating the patient's anatomy and extending the forearm bones to the wrist would result in a custom made product for every patient, which strays from the company's wish for this to be a product which is as reliable and easy to produce as possible. Consequently, in order to keep the advantages of the ball joints while keeping the producibility of the other solutions, a new design should be created that combines properties of multiple categories.

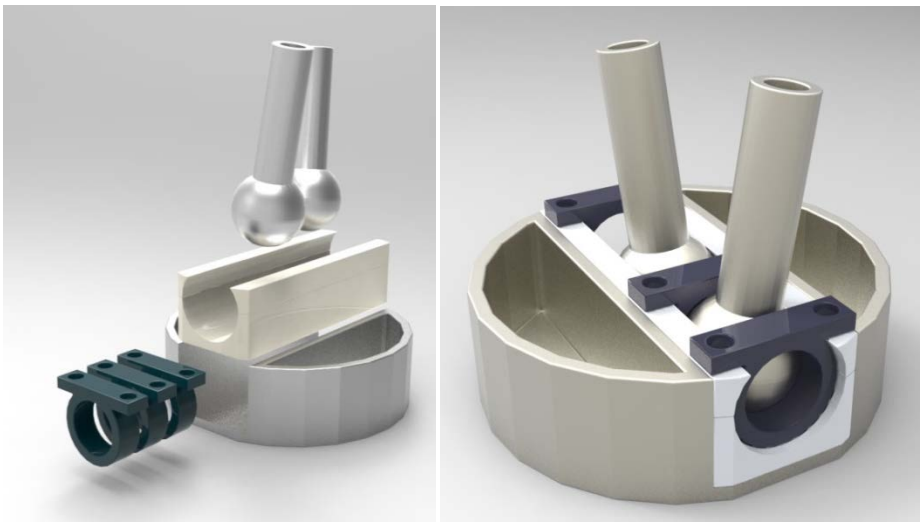


Figure 18: The short ball-joint concept. The abutments can be attached to tubes ending in spherical elements. Both of these spherical elements form ball joints, but one of them can also slide in a plastic track, enabling the abutments to move towards and away from each other. The position of the "fixed" ball joint can be altered by sliding small walls into the track and fixing them at positions which should be adapted to an individual user.

Some time was taken to translate these conclusions into a tangible concept solution. After some discussion and reiteration, a new concept was presented which combined the use of ball joints and the track motion of a single abutment (see Figure 18).

This concept was decided to be a good starting point as a solution for the "Free" function. Selection of the "Fix" function could now be based on compatibility with this concept. Many options were considered and discussed. Initially, one of the most producible and reliable methods was decided to be locking of the abutment into the cylindrical holder using a pin that could be screwed onto a bevel that is located on the abutment, preventing it from exiting the holder. This attachment would only require a threaded hole to be made in the holder and an additional pin to be produced. This pin could be screwed into the holder either with a tool or by hand. Combining the two functions and optimizing the design with respect to assembly and functionality resulted in the creation of the device depicted in Figure 19. Prototypes of this concept revealed promise in its functioning. Furthermore, the design was highly modular and consisted of few parts, which is beneficial for producibility.

Figure 19: The optimized ball-joint concept. The working principle is identical to the concept explained in Figure 17, but was made smaller and detailed further. The abutments are attached to the holders by means of a screw that is inserted into the holder and clamps the abutment in place. The device can be attached to the prosthesis with screws that are positioned to fit to a standard prosthetic sleeve.

A meeting was held about this concept with a prosthetist and the R&D manager of the company. The reactions in this meeting were generally positive, but a few points of criticism were made. First of all, even though the attachment to the abutments was very simple and producible, it was stressed that requiring the patient to use a tool in order to lock the device should be avoided at all costs, and producing buttons big enough to operate by hand would most likely impair the functioning of the device because the holders should be free to rotate around their own axes. The second remark was that the device was quite tall because of the ball joints, and this meant that adjustments would need to be made to the prosthetic limbs of patient to prevent that the artificial hand sticks out further than the natural one. If possible, the device should be as flat as possible for this reason.

Another optimization was performed. Following more brainstorm sessions, the discovery was made that the degrees of freedom that a ball joint yields could be reproduced with a cylindrical holder that can rotate around its own axis and can accommodate angular deviations and translations by being placed on top of an elastic element. This discovery enabled the functionality of the device to remain roughly the same, but made it much flatter. Furthermore, the attachment mechanism that made use of a screw clamping the abutment into the holder was replaced with a locking mechanism. This device is shown in Figure 20.

Figure 20: The flatter alternative for the ball joint concept. Plastic locks take the place of the screw attachment of the abutments, and the ball joint is replaced with a cylindrical holder (indirectly) placed on an elastic element.

Figure 21: The machined prototype of the new attachment device attached to a prosthetic limb.

The company considered this concept to be an acceptable solution. Subsequently it was prototyped by the company's instrument maker (see Figure 21). This prototype was used in the tests evaluating the device as described in the rest of the thesis. It should be noted that the experienced instrument maker had some remarks regarding the producibility of the device. These remarks lead to another round of optimization. No major changes were made to the functioning of the concept. This last optimization, shown in Figure 22, makes the device easier to produce and assemble, and no longer contains sharp edges. A patent was filed for this concept and it was named the "Rotador".

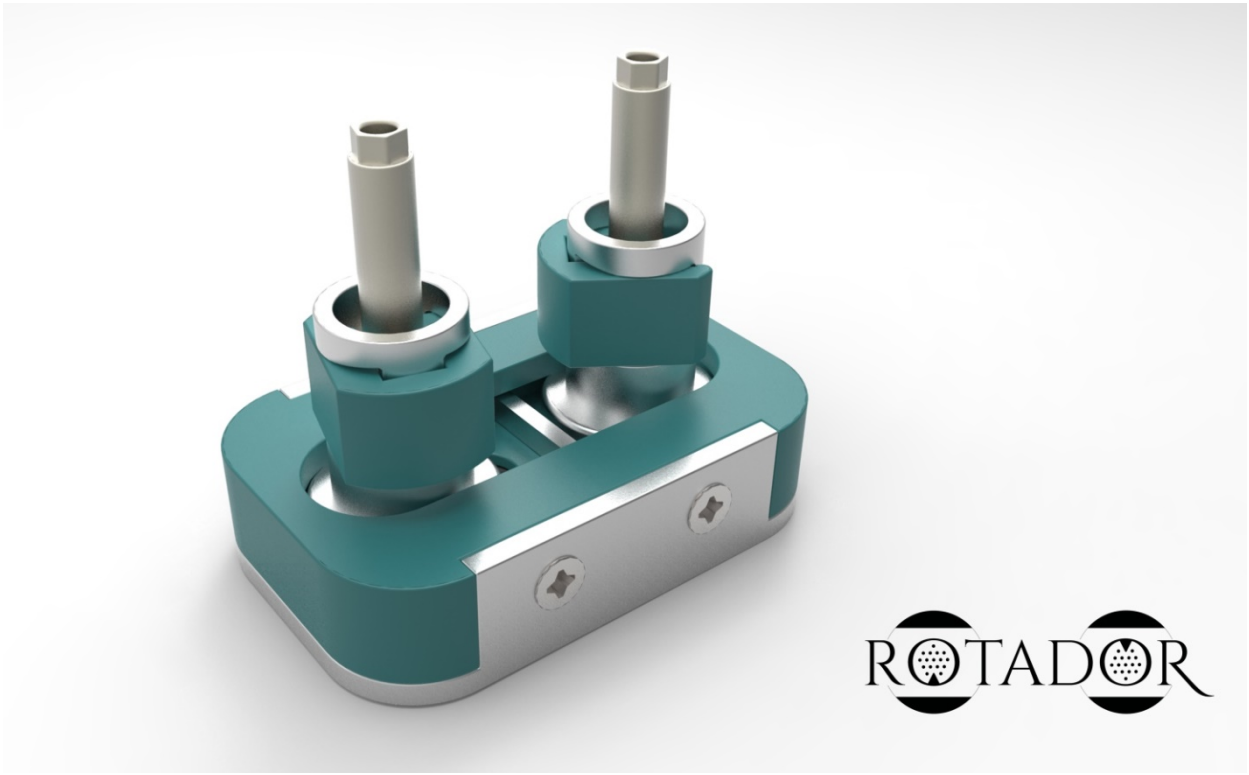


Figure 22: The concept chosen to move forward with: the "Rotador".

TESTING

User experience

Range of motion

The first and perhaps the most logical evaluation of the attachment device is examining how much of the motion of forearm rotation that the patient has left after his amputation is preserved when the attachment device is connected to his abutments. In other words: How effectively does the Rotador preserve pronation and supination?

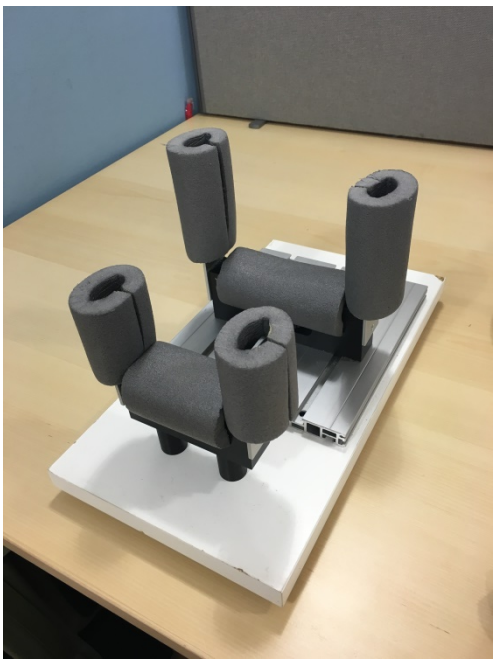


Figure 23: The rig that the patient placed his arm in for the analysis of the motion.

To this end, a rig was used in which a single TRA patient with osseointegration placed his arm (Figure 23). A camera was placed facing the ends of the patient's abutments in a frontal and a sagittal view. Keeping his upper arm in the same position, the patient was asked to rotate his forearm slowly, starting from a neutral position and first going to full supination and then to full pronation in three conditions: First the motion was recorded when the patient had no prosthetic device attached to examine the remaining range of forearm rotation. Then the task was repeated with the attachment device attached, and once more with a prosthetic limb attached via the attachment device. The process is illustrated in Figure 24. The video clips were analyzed. The frames where the patient's forearm was positioned in maximal pronation and supination were extracted for all three conditions. Using photo editing software the angular deviation between pronation and supination of the forearm was determined for only the abutments and when the designed device was attached. The third condition, in which a prosthetic limb was attached, was also analyzed but due to changes in the camera setup quantitative analysis was considered to be unreliable.

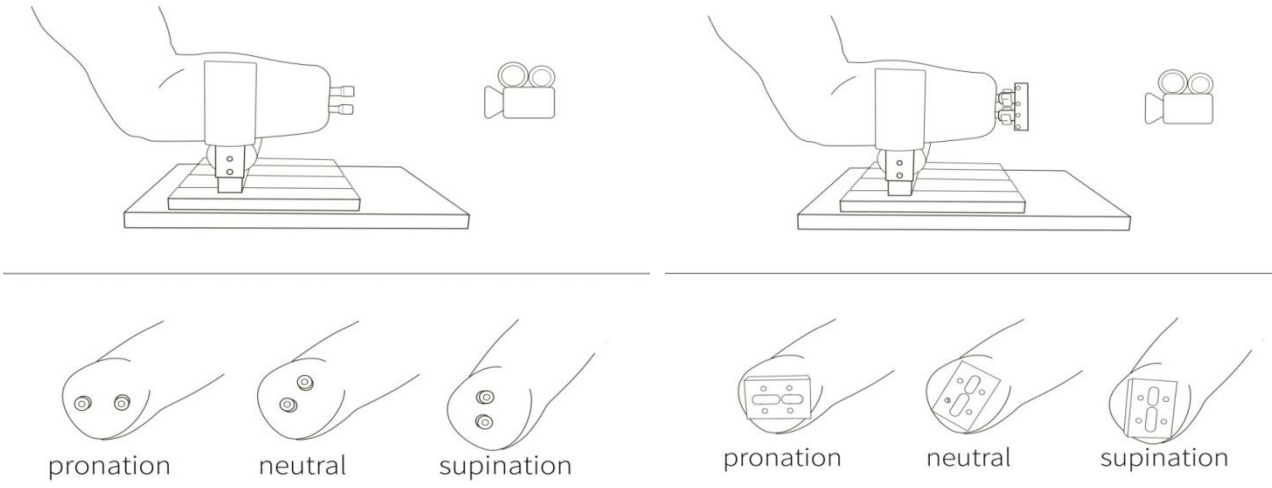


Figure 24: The setup for the analysis of the range of motion.

Task performance:

Another question of importance was: How do these changes in ability translate to actual everyday task performance?

In order to determine this, two different tests that are used to assess general hand functioning were performed on a single male TRA patient with osseointegrated implants at a prosthetics center in Gothenburg. The tasks were conducted by a prosthetic specialist who for each task noted the time it took to be completed. The patient performed a practice run of each test with and without forearm rotation before the actual experiment to decrease any learning effects present between conditions.

The tests with were performed with a VariPlusSPeed hand from Ottobock. Electrodes were placed on the patient's arm on the same positions as the electrodes of his own prosthesis are placed and were then fixed in place using skin-friendly tape. When using his personal prosthesis, the surface electrodes are clamped onto the skin of the patient with some force to ensure the acquisition of proper signals. To simulate that condition, a bandage was applied around the electrodes with a light pressure. To power the prosthesis a portable battery was used, which was attached to the patient's arm with a flexible armband. The cables from the electrodes and the battery were guided through a custom made connecting component between the attachment device and the prosthetic limb. This component was attached to the attachment device between the abutments and the prosthesis with four screws. In the tests without rotation this attachment device was the puck system which is currently used by osseointegrated upper limb amputation patients. For the

Figure 25: Setup of the prosthesis with the puck (left) and the Rotador (right)

Figure 26: The SHAP test [39].

Figure 27: Materials for the turning task in the MMDT [41].

test with rotation, the puck was replaced with the prototype of the Rotador. This setup is shown in Figure 25.

The patient first performed both tests with the puck (so without the ability to pronate and supinate the forearm), and then with the Rotador. For each task with the Rotador it was assessed whether the subject made noticeable use of forearm rotation. For each test with the puck careful attention was paid to whether the subject was compensating noticeably for forearm rotation by the use of shoulder movements.

The first test that was performed was the Southampton Hand Assessment Procedure (SHAP). This test requires the patient to perform a number of tasks which are divided in two parts. During the first part the subject is asked to pick up objects of various shapes, such as a sphere, a cylinder, and a block, and put them back down a few centimeters further. This part of the test is called “Abstract Objects”. The second part is called “Activities of Daily Living” and involves the subject performing (simulations of) everyday tasks including turning a page, cutting food, pouring water in a cup, using a screwdriver, and undoing buttons. The performance of each task is translated into a compound score for six different grips. These six scores are then used to create the Index of Function score, which can be used as an overall measurement of hand functioning. The SHAP procedure is used not only used for prosthetics but also for assessment of healthy hand functioning and in individuals with motor impairment. This means that the test is not specifically designed to be used for prosthetics, thus certain tasks may be extra difficult for amputees to perform. It has been shown that learning effects should be taken into account for novice prosthetic users [32], though the subject in this test had had around 12 years of experience using prostheses. The items used in the SHAP test can be seen in Figure 26.

The second test that was performed was the turning task within the Minnesota Manual Dexterity Test (MMDT). This test focuses more specifically on rotation of the arm [40]. In this test the subject is asked to pick up a number of small disks which are black on one side and red on the other with one hand and turn them over with that same hand, then take them with the other hand, and finally place them in a dot raster with this second hand row by row. There are four rows in total. The set-up for this test can be seen in Figure 27.

Load distribution

Aside from task performance, a second crucial part of the validation of the Rotador was evaluating the distribution of loads over the two implants. To this end it was examined whether the differences in strain between the radius and the ulna are acceptable during use of the prosthesis in various positions. An important consideration here is the fact that one of the abutments can move in a track while the other is fixed: It was to be assessed whether the fixed one takes considerably more load than the other one when subjected to bending loads due to its fixation. Lastly, it was examined whether the alignment of the abutments has an impact on the load distribution.

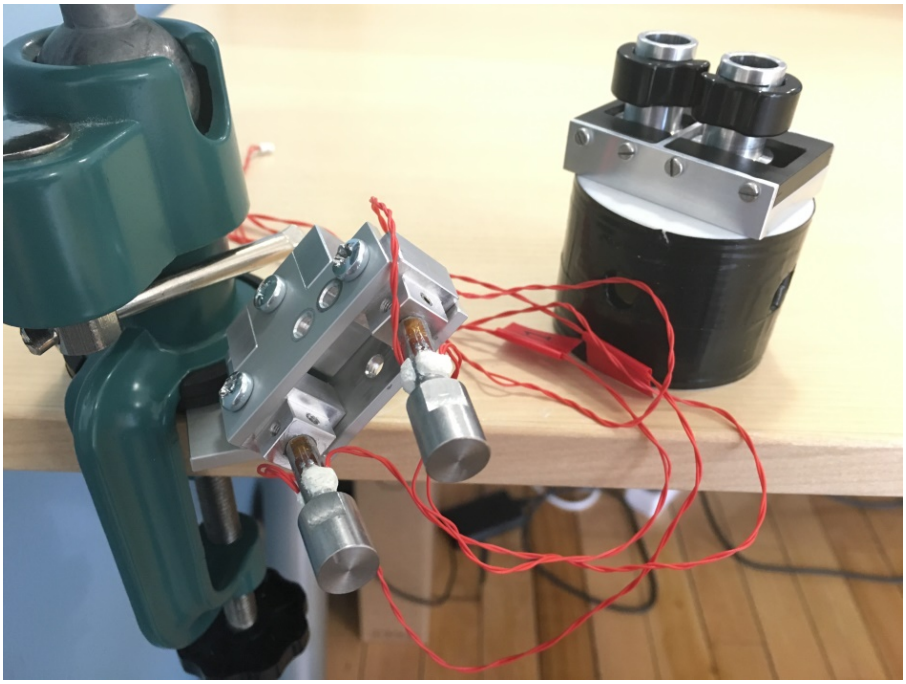


Figure 28: Test rig with abutments and strain gauges (Left) and the Rotador attached to a custom component that carried the weight during tests (right).

Load distribution in the forearm bones is very difficult to test in vivo, so a test rig was produced to function as a model of two fixtures of an osseointegrated TRA patient. In this rig, which can be seen in Figure 28, the abutments could be placed in various positions, simulating the different configurations of implants which are possible in patients.

This test rig consisted of a number of parts: Two fixtures in which the abutments could be fixated, two flat holders which acted as a clamp keeping the fixtures in place, a base to which the holders were attached and which could rotate around an axis simulating the range of pronation and supination, and a platform that was used to connect the rig to the surface by which it was

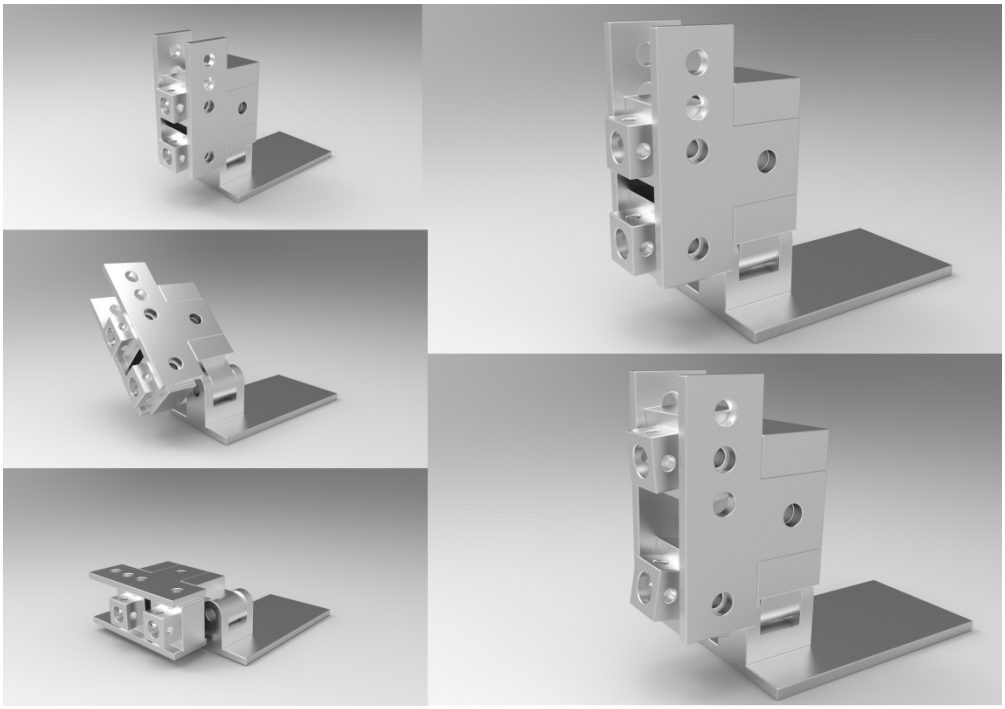


Figure29: Various configuration of the test rig used for the load distribution tests.

supported. Some different possible configurations of the rig can be seen in Figure 29.

Instead of by means of a press-fit which is used in the actual OPRA system, abutments were clamped inside custom fixtures using set screws. The positioning of these fixtures could be adjusted in two ways. Firstly, the distance between the fixtures could be varied. Secondly, the angle between the fixtures was adjustable. The range of pro-and supination was simulated with a hinge connection between the base and the platform.

Strain gauges were used to be able to measure the distribution of stresses in the implants. The gauges were attached to the abutments as close to the connection as possible. The change in strain that occurred in the gauges during these tests resulted in a change of voltage being picked up by a measuring board provided by the company. As the bending stress varies over the cross section of the object (see Figure 30), it was important to have the strain gauges in the same position for all of the tests. The abutments were able to rotate within the fixtures when the set screws were loosened, so that the gauges could be rearranged depending on the position of the rig.

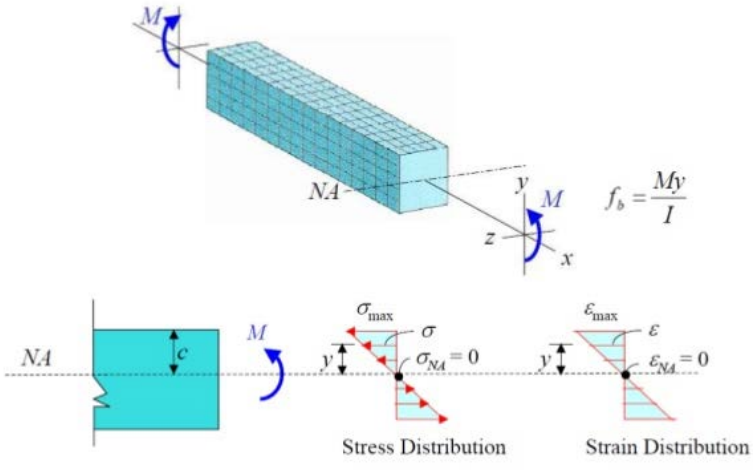


Figure 30: Bending stress and strain distribution [45]

The strain gauges used were of the type LY11-06/120 and were produced by HBM. This type of gauge is used to measure bending, which was decided to be the most interesting type of loading for these tests. Even though axial forces have been the subject of past research concerning load distribution in the forearm, with the Rotador as well as the puck system no difference in the magnitude of axial forces are expected since both abutments are constrained identically in the longitudinal direction. Shear forces will depend on the degree of forearm rotation: in a horizontal position of the rig it will be identical for both abutments, but in a vertical position only one abutment will be loaded due to the fixation in the track. These stresses should be considerably smaller than the bending stresses due to the presence of a moment arm, which is why they are not a matter of investigation here. Rotation of the prosthesis will result in bending of both abutments in opposite directions rather than actual torsion stresses in each implant; for that reason and to save space on the small abutments, no extra gauges specifically for torsion were used.

A bag with a content weighing around 5 kg was attached to the abutments through the Rotador. The strain was measured during 30 seconds for each test, during which the full weight of the bag was put on the Rotador for ten seconds, then lifted for ten seconds, and then put on the Rotador again for the last ten seconds. This change in voltage translates to the bending moment in a linear fashion:

$$M = \frac{2\Delta V_0}{V_{EX} \times S_E} \times E \times S \quad (1)$$

In this formula ΔV_0 is the change in voltage and V_{EX} , S_E, E, and S are constants. The derivation of this formula is shown in appendix C.

The bending moment is in turn linearly related to the normal stress due to bending σ_b [34]:

$$\sigma_b = \frac{M \times y}{I} \quad (2)$$

Here, y and I are constants and the same for both abutments. This means that the ratio between the changes in voltage measured in both abutments is representative for the stress distribution in the Rotador.

Measurements were done in various set-ups. First of all, tests were done with the rig placed in one of three different angles: with the abutments placed vertically, diagonally in an angle of approximately 45 degrees, and horizontally. Secondly, the alignment of the abutments was either parallel to each other or in a converging position. Lastly, it was alternated which abutment was attached to the fixed holder. In total 9 different positions were tested:

1. Abutments straight, rig vertical, the ulna fixed;
2. Abutments straight, rig vertical, the radius fixed;
3. Abutments straight, rig diagonal, the ulna fixed;
4. Abutments straight, rig diagonal, the radius fixed;
5. Abutments straight, rig horizontal, the radius fixed;
6. Abutments angled, rig vertical, the ulna fixed;
7. Abutments angled, rig vertical, the radius fixed;
8. Abutments angled, rig diagonal, the ulna fixed;
9. Abutments angled, rig diagonal, the radius fixed.

4. RESULTS

ATTACHMENT DEVICE

Functioning

The main thought behind the concept of the Rotador is that each of the abutments are attached to their own cylindrical “holders”, and while these holders are enclosed by the rest of the device their position is not completely fixed. Rather, they are each placed loosely on a rigid surface that provides low friction. Those rigid surfaces are in turn placed on top of elastic elements, which are placed in a metallic base. To keep the abutments on these surfaces, the holders are enclosed from the top by a “locking plate”. The base is connected to this locking plate and to the prosthetic limb with screws. There is a partition located between the two abutments and the surfaces that they are placed on, which allows one of the abutments to slide in a track while the other cannot. Figure 31

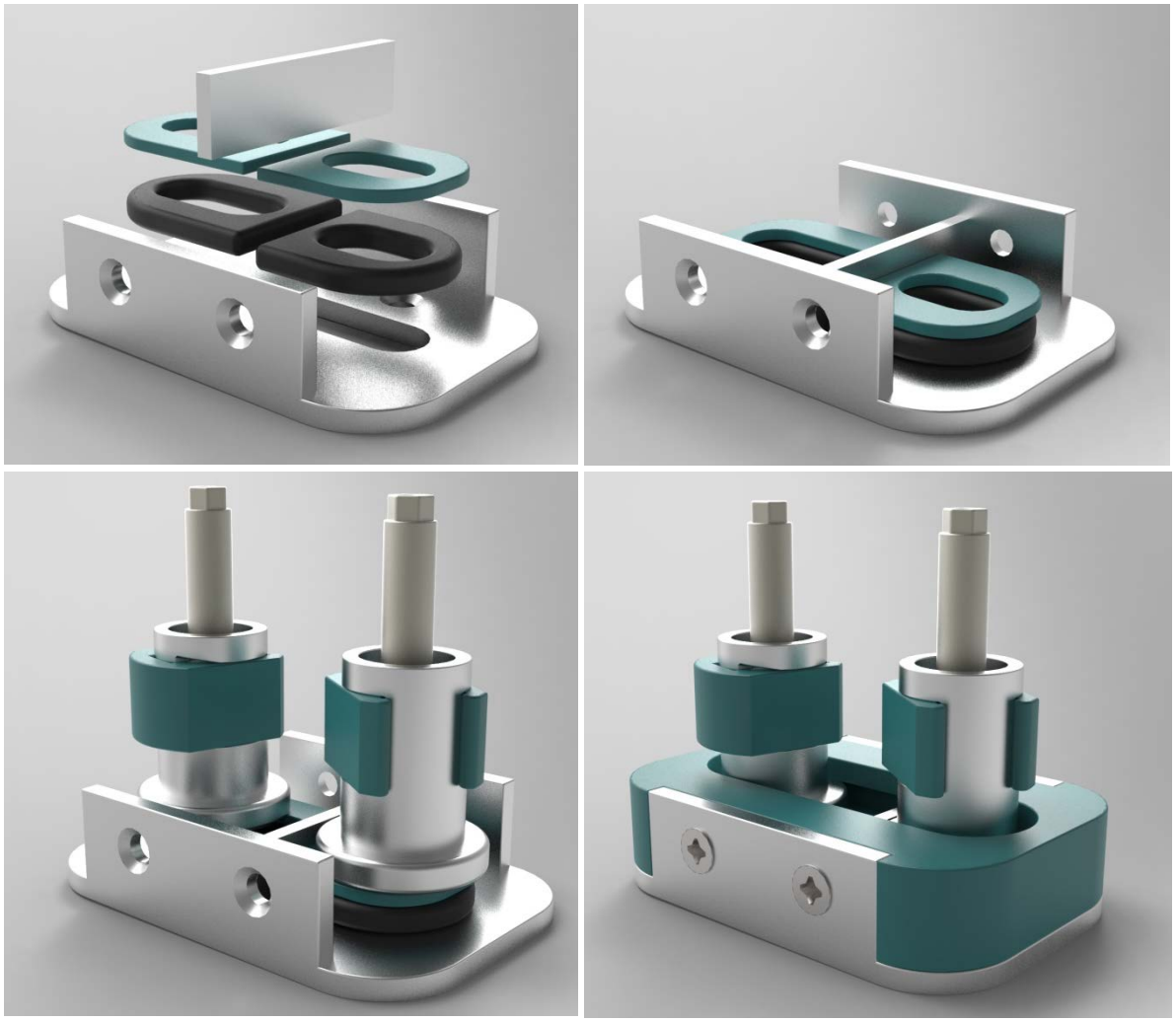


Figure 31: Top left: The rigid metallic base accommodates a partition, rigid “sliding surfaces” (green) and elastic mats (black). Top right: These are placed loosely inside the base. Bottom left: The holders containing the abutments are placed loosely on the sliding surfaces. Bottom right: A “locking plate” encloses the other parts and keeps them in place, and is attached to the base using screws.

shows these different parts making up the device.

In the introduction and in the requirements section it was mentioned that the Rotador must make the forearm bones free to move with respect to each other in a number of ways: Axial rotation, variable distance between abutments, angular deviation, and distal translation.

These motions are made possible by the device in the following ways. Axial rotation is possible because the holders are circular and are placed loosely between the locking plate and sliding surfaces. The abutments cannot rotate within the holders because they are kept in place by locks, but the holders can rotate freely within the base. Distance between abutments can be varied because one of the holders has the possibility to not only rotate freely, but also slide in a track formed by the partition, which is kept in place by the locking plate. Angular deviations are possible because the sliding surfaces are loosely placed on elastic mats, which deform under pressure. This means that when the abutments are positioned in an angle, the holders will adapt this position and subsequently exert a force on the sliding surfaces. These in turn will also adapt to this angle by causing the elastic mats to deform. Still, the holders will always be sliding and rotating on a flat surface, since the sliding surfaces themselves are relatively rigid. Small height differences are also possible because of the elastic mats, which deform when forces are exerted on them.

The attachment of the abutments to the holders is realized by the use of locks that snap around a notch that is already present on the abutments of current osseointegrated TRA patients. The attachment mechanism is shown in Figure 32, where it is illustrated how the abutment can be placed into the holder, after which the holes in the holder can be aligned with the notch of the abutment. Then the lock can be snapped around the abutment. The walls of the holder around which the lock is placed have slightly different thicknesses; it is slightly thinner on the side where the lock contacts the holder first. The lock only fits into the holder when it is inserted in the right direction, which is starting from the side with the thinner wall. The shapes of the lock and the holes

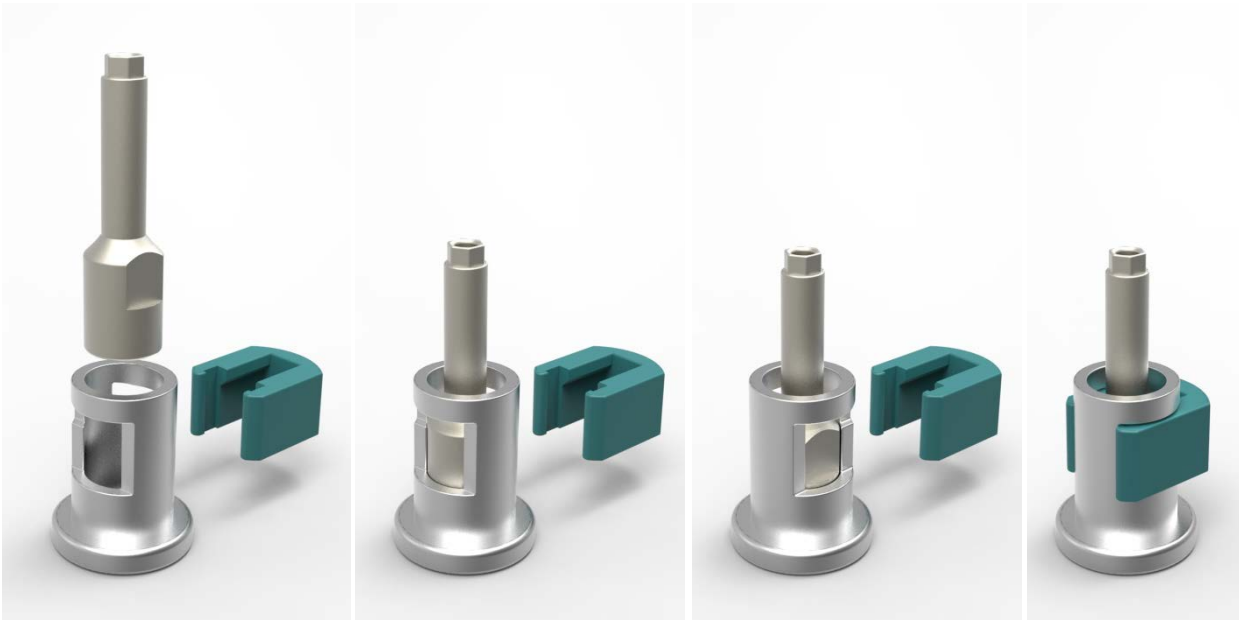


Figure 32: Left: The abutment, holder, and lock. Second from left: The abutment is placed within the holder. Second from right: The holder is turned until the holes align with the notch in the abutment. Right: The lock is snapped around the abutment.

in the holder do not allow the user to insert the lock the wrong way around, so it will always pass by the thinner portion first and snap around the thicker portion when it is placed correctly. The reason for this snap fit is to provide the user with feedback concerning a correct connection and to secure the attachment.

Materials and production

The working principle of the ball-joint concept (Figure 17) was inspired by Total Hip Replacement (THR) implants, which are used across the world and commonly last longer than 20 years [43]. Commonly these implants are made from a metallic stem and a plastic acetabular cup, often made from High Density Polyethylene (HDPE). The ball joints don't require lubrication but rely on the bearing properties of the combination of metal balls sliding and rolling within plastic cups (Figure 33). The Rotador does not consist of an identical interface since the metal ball is replaced with a cylinder. Furthermore, rather than only rotating, one of the abutments can also slide in a track-motion. Still, since the design is modular and the sliding surfaces can easily be replaced in case of wear, this combination of materials was decided to be adapted to the Rotador. The holders represent the hip stems in THR's and are made from a metallic material and the sliding surfaces and locking plate could consist of plastic, simulating an acetabular cup.

Concerning the plastic parts of the Rotador, which are the locking plate, the sliding surfaces, and the locks, different materials could be used. One of the most versatile and often used polymers is polyethylene (PE) which, as discussed before, in a high-density grade is also used in medical products. However, this plastic is most often associated with shaping processes that include large batch sizes such as injection molding. Due to a small number of TRA patients currently treated with osseointegrated prostheses (12), the components of the Rotador will most likely be produced using a process more suitable for small batch sizes, like machining or 3D printing. Integrum uses an experienced instrument maker who machines most of their parts and prototypes through processes such as milling and turning. With these currently used facilities it is possible to machine the plastic parts using either Polyoxymethylene (POM) or polyvinylchloride (PVC) as the material. 3D printing of products is usually done by a producer outside of the company, since the 3D printer at the company is not suitable for high quality products. Common materials for this process are materials with properties close to Polyamide (PA) or Acrylonitrile butadiene styrene (ABS).

Figure 33: A Total Hip Replacement (THR) [43].

A material study comparing the possible materials can be found in Appendix B, where properties like price, density, fracture toughness, yield strength and Young's modulus were compared for the materials suited for both machining and 3D printing, with PE added as a reference material for commonly used plastic products. The most suitable material was found to be PA, as it has good mechanical

properties and can be used with high quality 3D printing, which in this case is a less costly process than machining.

The metallic parts of the Rotador cannot be manufactured with rapid prototyping methods using current suppliers. These parts will have to be machined, which can be done with various metals. Most parts made for Integrum are machined from titanium, though many housings and prototypes have been made with aluminum. A similar material study for the metallic parts (the base and the holders) as the one conducted for the plastic parts can be found in the Appendix B. Since the attachment device needs to be as light as possible, it won't be implanted, and costs should remain as low as possible, aluminum was decided to be the best material for the base and holders. When machining parts, the aim is to design them in such a way that the instrument maker can produce each part as quickly as possible. That means each feature of the parts should be easily accessible and as many features as possible can be made within the same fixture, meaning that the producer has to remove the part and then fix it in another angle into the milling machine as few times as possible. This was taken into account when designing the metal components of the device.

The prototype that was used for the tests conducted in this thesis was machined entirely, with the plastic parts made from POM and the metallic parts from aluminum.

TESTING

Range of motion

Figure 34 shows the patient's abutments and the prototype of the Rotador when the patient was asked to move his forearm from full pronation to full supination slowly.

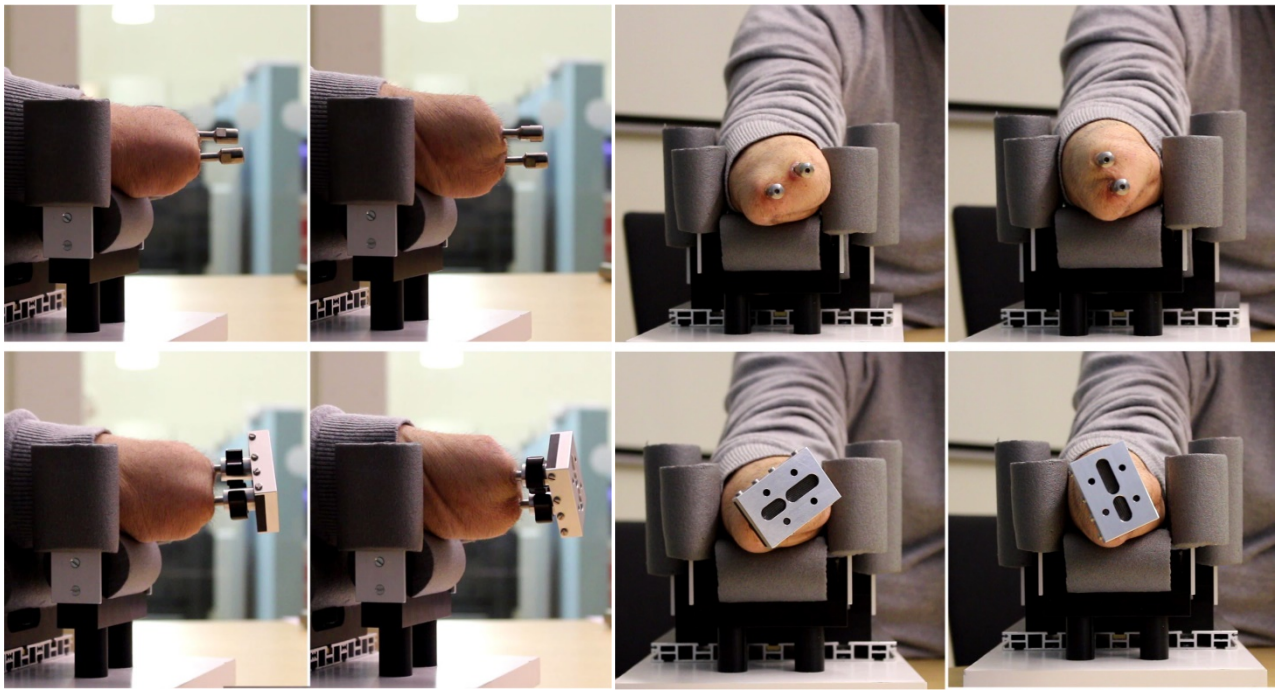


Figure 34: Top: the position of the patient's abutments when in full pronation and supination. Bottom: The position of the prototype of the Rotador when the patient's forearm is in full pronation and supination.

For both conditions (with and without the Rotador) the moment is captured when full pronation is reached and when full supination is reached. It is visible that at least a large portion of the motion is preserved, as the position of the abutments in the top images is very similar to the positions of the Rotador in the lower images in both supination and pronation. When asked about it, the patient expressed that the motion of his abutments felt natural and unrestricted throughout the entire motion with the prototype attached. However, while the entire motion of his abutments translated to a rotation of the Rotador during supination, there was a small portion of pronation that did not result in a rotation of the device. In this small range both abutments could still move freely, but the device did not follow the motion. Rather, the holder connected to the radius was observed to rotate around its own axis and slide in the track with the rest of the device remaining in the same position. This observation could explain the fact that when the device was attached, the angle between full pro- and supination was 8 degrees smaller than when it was not attached, which is illustrated in Figure 35.

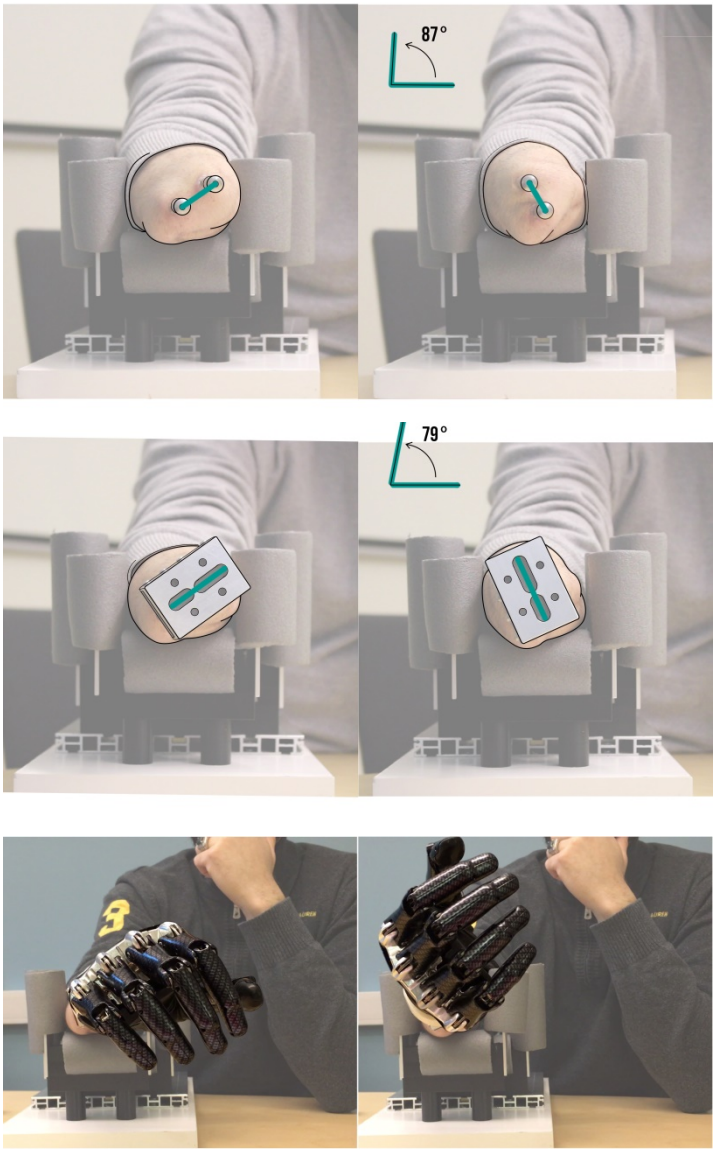


Figure 35: Top: the range of forearm rotation when no device is attached to the abutments. Middle: the range of forearm rotation when the prototype of the Rotador is attached. Bottom: The range of forearm rotation when a prosthesis is attached to the Rotador. Quantification of the angle was considered to be unreliable here, since the camera set-up had changed. The same analysis yielded an angle larger than the initial 87 degrees, which is highly unlikely.

This corresponds to a loss of forearm rotation range of around 9%. This loss was no longer observed in the pictures of the motion with the prosthetic hand attached, though this is likely due to a change in the camera set-up or the shape of the prosthesis.

Task performance

SHAP

The results of the Southampton Hand Assessment Procedure are listed in Table 5 (Abstract Objects) and in Table 6 (Activities of Daily Living). In both tables it is indicated which tasks were observed to involve considerable pro-or supination when using the Rotador. When the puck system was used an indication is present when distinct shoulder movements were observed that compensate for forearm rotation.

Table 5: Tasks performed in the first part of the SHAP procedure (abstract objects): Completion time in seconds.
†: Distinct pro- or supination observed with the Rotador, and/or noticeable compensation for pro-or supination by means of shoulder movements observed with the Puck.

SHAP (Abstract Objects)	Sphere light	Sphere heavy	Tripod Light †	Tripod Heavy †	Cylind. light	Cylind. heavy
Puck	3,4	3,5	4,4	3,9	2,9	2,4
Rotador	3,2	7,2	3,9	3,4	2,8	2,8
	Lateral light	Lateral heavy	Tip Light †	Tip heavy †	Extend light †	Extend heavy †
Puck	3,5	4,8	2,8	2,5	3,1	2,5
Rotador	4,2	3,4	2,8	3,4	2,9	3,2

Table 6: Tasks performed in the second part of the SHAP procedure (Activities of Daily Living): Completion time in seconds.
†: During this tasks distinct pro- or supination was observed with the Rotador, or noticeable compensation for pro-or supination by means of shoulder movements observed with the Puck.

SHAP (Daily Living)	Coins †	Full jar	Buttons †	Empty tin	Food cutting	Tray lifting †	Page turning †
Puck	16,8	5,1	56,0	3,6	12,7	12,1	6,3
Rotador	18,9	6,0	24,2	3,5	18,9	4,2	5,1
	Key turning †	Lid opening	Zipping	Jug pouring †	Screwing †	Carton pour †	Door handle †
Puck	8,0	5,2	13,9	9,8	32,8	14,2	5,6
Rotador	1,35	5,4	9,1	12,7	16,8	13,6	6,6

Figure 36: Posture of the patient during task performance without the ability to perform forearm rotation (upper row) and with it (bottom row). The tasks are from left to right: Lifting a tray, turning a door handle, turning a key, and using a screwdriver. The pictures show the same completion level for the tasks for both with and without forearm rotation.

For the first part of the SHAP test, Abstract Objects, 5 out of 10 tasks were performed faster with forearm rotation and in 6 out of the 10 tasks (compensation for) forearm rotation was observed. In the "Daily Living" portion of the test, 7 out of 14 tasks were performed faster with the Rotador. For half of the tasks (7 out of 14) forearm rotation or shoulder movement replacing forearm rotation was observed. Figure 36 shows a number of instances where the ability to perform forearm rotation changed the execution of the task: For 4 tasks the same moment is captured with forearm rotation (bottom images) and without it (upper images). The Index of Function score improved from 61 points without forearm rotation to 71 with it.

MMDT

The results of the turning task of the Minnesota Manual Dexterity Test are presented in Table 7. Each run was performed faster with the Rotador, with a mean time of 231 seconds with the ability of rotation versus 258 seconds without it. The use of forearm rotation was not especially noticeable with the Rotador, but shoulder movements were observed with both the puck and the Rotador in order to compensate for wrist flexion. This was needed in order to be able to pick up the disks used in the test.

Table 7: Completion times of all runs and mean results of the turning task within the Minnesota Manual Dexterity Test for both with forearm rotation (with the Rotador) and without it (with the puck system). Times are in seconds.

Minnesota Manual Dexterity Test (MMDT): Turning task	Run 1	Run 2	Run 3	Mean
Puck	301,9	244,2	228,0	258,0
Rotador	255,6	226,4	210,8	230.9

Load distribution

Appendix C shows plots of the change in voltage measured during each of the load distribution tests.

A summary of the results of can be seen in Table 8. For each test the bending moment is given for both abutments, as well as how much of the total bending moment was accounted for by the ulna. The last two columns state which of the two abutments was connected to the fixed holder and what the configuration of the test rig and the alignment of the abutments were.

Table 8: Results of the load distribution tests.

Load distribution					
Test	Moment in Radius (Nm)	Moment in Ulna (Nm)	% Ulna	Fixed abutment	Configuration
1	0,30	0,97	76	Ulna	Straight alignment, vertical position
2	1,1	0,1	8	Radius	Straight alignment, vertical position
3	0,75	0,90	54	Ulna	Straight alignment, diagonal position
4	1,11	0,57	33	Radius	Straight alignment, diagonal position
5	1,23	1,22	50	Radius	Straight alignment, horizontal position
6	0,30	0,74	71	Ulna	Angular alignment, vertical position
7	0,54	0,19	25	Radius	Angular alignment, vertical position
8	0,64	0,81	56	Ulna	Angular alignment, diagonal position
9	0,90	0,60	40	Radius	Angular alignment, diagonal position

In every test the abutment connected to the fixed holder was subjected to more strain. The only exception was the fifth test, in which the rig was placed horizontally. That test resulted in an approximately equal strain in both abutments. Positioning the rig diagonally as opposed to vertically lowered the strain in the fixed abutment in all instances. No consistent influence was observed of the position of the abutment with respect to each other: In one case the angular alignment resulted in a slightly higher strain in the fixed abutment (with the ulna fixed in a vertically positioned rig), while in three other cases the strain was reduced when the abutments were not parallel.

5. DISCUSSION

USER EXPERIENCE

Preservation of pronation and supination

Having the ability to naturally perform pronation and supination appealed to the single patient that performed tests with the Rotador, as he expressed that using the prosthesis looked and felt more natural. However, sometimes not the entire motion of pronation was translated when using the new attachment device. This was not always the case, but when it happened the patient expressed that it made the prosthesis feel like “less of a part of him”. Possibly this is related to which of the abutments is fixed, as it was noticed later on that each time the patient expressed this feeling, his ulna was connected to the fixed holder. However, this has not yet been tested specifically.

When asked to briefly carry a bag with a content of around 5 kg, the patient described the feeling he experienced as “strange”. It was decided not to take any risks at that time and the patient did not try to carry more weight. A possible explanation for this phenomenon is the fact that the bones are now free to move with respect to each other, likely even more than is the case with a healthy limb. Due to the missing stability of the wrist joint and the dysfunctional or absent interosseous membrane, along with not having used the forearm rotation muscles since the amputation, the newly gained freedom of the forearm bones could result in forces on the soft tissues around the radius and ulna that are uncomfortable or even harmful to the patient. Training protocols with the Rotador could possibly solve this issue. However, if heavy lifting turns out to be a serious issue in the future, a locking mechanism can be added to the Rotador that can be activated when carrying large weights. A possible redesign of the Rotador that incorporates this function is described in Appendix F.

SHAP

A number of interesting observations were made during the Southampton Hand Assessment Procedure.

The most noticeable and perhaps most important one was a decrease in the use of shoulder movements when using the prosthesis with the Rotador. Even though the patient had not used pronation and supination with his missing limb for over a decade, having the possibility to do so quickly became the natural thing to do in several tasks. It should be noted that not all tasks which involved forearm rotation were performed faster when using the Rotador. Possibly this is due to the fact that the subject has had a wealth of experience with a prosthesis that does not allow for this motion; a large number of tasks can be performed quite well by using compensatory shoulder movements, even if it looks less natural.

Another statement that can be made after having done this test is that the addition of pronation and supination alone is not always enough to drastically change the way the prosthesis is used. Not all tasks that were expected to change when using the Rotador actually did; In order to

naturally perform some of the more complicated tasks like pouring a cup of water or cutting food, additional degrees of freedom would be needed. The cup of water could not be held by the handle in a comfortable position when pouring its content using only forearm rotation, and in order to cut food as a natural hand does the knife would need to be held in a way that is not comfortably possible with the prosthesis the subject was using. Because of these limitations these tasks were performed nearly identically with and without the ability to perform forearm rotation and often included many compensatory shoulder movements.

Because of the elastic components of the Rotador it was observed that more compliance of the prosthesis was present with forearm rotation then without it, especially when exercising a lot of force, like when trying to close and open an old zipper. In order to make the attachment device adjustable for variable patients some of this compliance is probably unavoidable, though it is perhaps larger than necessary in the current prototype. A redesign that incorporates less compliance for angular deviation could be desirable, though research should be conducted concerning how much is needed in order to have multiple patients be able to use the device.

At times combining pronation and supination with opening and closing of the prosthesis resulted in difficulties with prosthetic control. One likely explanation is that muscle activity due to movement of the forearm during pro-and supination occasionally got picked up by the surface electrodes and was mistaken for the intention of opening or closing the hand. Another probable factor is the fact that the surface electrodes are placed on fixed locations. This means that when forearm rotation occurs, the placement of the electrodes does no longer align with the forearm muscles in the same way.

MMDT

The Minnesota Manual Dexterity test mainly showed the need of the addition of degrees of freedom other than pronation and supination, specifically wrist flexion. Even with the possibility to perform forearm rotation, in order to be able to grasp the disks used in the MDDT the prosthetic hand needed to be positioned slightly vertically, which would have been achieved in a healthy limb with wrist flexion. However, now that performing that motion was not possible, shoulder movements were needed in order to compensate for flexion. When the disk was picked up and lifted, the necessary adduction of the shoulder already resulted in the disk being turned over. This meant that the use of pro-and supination was no longer needed. Still, all tests with the Rotador were performed faster than with the puck system. This could be partially due to learning effects as the tests with forearm rotation were done after the tests without it, but subtle differences in posture possibly improved the performance as well.

DEVICE

Load distribution

When reflecting on the way stresses are distributed over the abutments when attached to a weight through the Rotador, a number of observations should be taken into consideration.

In each of the tests conducted the abutment that was attached to the fixed holder, which is not able to move in a track, was shown to experience more strain than the abutment attached to the free holder. Depending on the position of the rig and the alignment of the abutments, the share of the load in the fixed holder ranged from 54 to 92%. This does not take into account the condition where the rig was placed horizontally: in that case the strains were shown to be approximately equal in both abutments, which was expected due to the fact that no forces acted in the direction in which the fixed holder was constrained uniquely. The notion that it can now be predicted which holder transfers the highest stresses to the abutments can be used in the patient's advantage: As research has shown that in healthy limbs the radius generally carries more load than the ulna [29], the abutment connected to the radius can be attached to the fixed holder as a ways of simulating the natural situation. Research in this area seems to be limited to axial forces and limbs that have not had an amputation, so this matter should be investigated in the future with more patients.

It seems that the distribution of stresses changes over the range of forearm rotation. In the tests performed in this thesis, having the rig in a position so that one abutment was positioned exactly above the other showed an increased in the difference between the measured voltages in all cases when compared to having the rig in a diagonal position. For patients using the Rotador this could have implications for the use of the device: When carrying a large weight, in order to try and get an as even load distribution as possible they could aim to keep their abutment in an as horizontal position as possible. Based on the results of these tests the radius will still receive the majority of the loads as long as it is connected to the fixed holder. Not a lot is known about how the loads should be distributed in the forearm bones of a TRA patient, but in this way at least some safety considerations are made.

No clear conclusions can be drawn about the alignment of abutments, as in some of the tests the difference between loads increased when switching from parallel abutments to misaligned ones and in some tests the difference decreased. More testing is needed to accurately describe the impact of differences in the alignment of the abutments on the load distribution. However, for functional purposes it would be beneficial to have the abutments aligned. This would make it easier to adjust the Rotador to more patients, and when less variation is present in the alignment of abutments then the device could be designed to be less compliant. For current patients this is not relevant, but it could be a guideline for surgeons treating TRA patients with osseointegration in the future.

MEETING OF REQUIREMENTS & WISHES

Tables 9 and 10 show the requirements and wishes that were set up in the concept development phase. After a prototype has been made and tested, this section should be revisited in order to evaluate if the created device is in fact an acceptable solution.

Table 9: Evaluation of how well the Rotador meets the requirements defined early in the design process. A check-mark indicates that the requirement has been met. A check-mark with an asterisk indicates that the requirement is met for the most part, but some issue is present.

FUNCTIONAL REQUIREMENTS	VERDICT
1. The initial position of the abutments within the device must be adjustable.	✓ Track motion
2. Both abutments must be able to rotate around their own axis.	✓ Loose holders
3. The prosthesis must not make unintended motions when loaded.	*✓ Some compliance is observed with high loads
4. The abutments must be able to move distally with respect to each other.	✓ Track motion
5. The device must be usable for trans-radial OHMG users in the future.	✓ Feed through is present for cables
6. The ulna must not carry more than 50% of the loading on the device at any time.	✓ When the radius is fixed
GENERAL REQUIREMENTS	**VERDICT**
7. Donning and doffing the prosthesis must be possible using one hand.	✓ Patient was able to do this
8. It must be possible to make a prototype with currently used facilities.	✓ Has been done
9. The product must be usable in cold and warm weather.	✓ No indication otherwise
10. The product must be usable in rain and snow.	✓ No indication otherwise
11. The product must be usable in dirty and dusty environment.	✓ No indication otherwise
12. Flammable materials must not be used.	✓ Not the case
13. Attaching the device must result in an indication of completion (user feedback)	✓ Snapping of the mechanism
14. It must be possible to clean the product regularly.	✓ Easy to disassemble
15. The product must not contain sharp or protruding components with respect to the rest of the prosthesis.	✓ Smaller diameter than prosthesis, no sharp edges in the design

Table 10: Evaluation of how well the Rotador fulfills the wishes defined early in the design process. A check-mark indicates that the wish has been fulfilled. A check-mark with an asterisk indicates that it is partially fulfilled. An "x" means that the wish is not (yet) fulfilled.

FUNCTIONAL WISHES	VERDICT
1. Loading should be distributed over the abutments in the following way: a. The ulna should carry between 25% and 50% of the load when handling large weights. b. The radius should carry between 50% and 75% of the load when handling large weights.	*✓ Testing showed that this was the case for all but two configurations, where the radius seemed to carry more than 75% of the loads.
GENERAL WISHES	**VERDICT**
2. It should be possible to attach the prosthesis to both abutments simultaneously.	✓ Shown in SHAP and MMDT.
3. The product should enable the user to carry as much as he can with his current attachment device.	× To be determined
4. The product should be able to carry as much loads as possible.	× To be determined
5. The product should enable the user to handle items with the at least the same precision as his current attachment device does.	✓ Shown in SHAP and MMDT.
6. Cleaning the product should be as easy as possible.	✓ No indication otherwise
7. Cleaning the product should be possible using one hand.	✓ No indication otherwise
8. The product should not include a protruding clamp.	✓ Not included
9. The attachment to the prosthesis should be as reliable as possible.	✓ Low risk of failure due to simplicity and compliance
10. The product should be usable for as long as possible.	× To be determined
11. The product should shield any connectors of the OHMG system from water or dirt during use.	× No shielding included yet
12. The dimensions of the product should be minimal.	✓ Smaller than the prosthesis
13. The weight of the product should be as low as possible.	*✓ While being reliable
14. The product should be as easy to produce as possible.	*✓ While being reliable
15. The product should cost as less as possible.	*✓ Considering small batches
16. The product should contain standard parts wherever possible.	✓ M3 & M4 thread connection
17. Materials used should be as resistant to wear and corrosion as possible.	✓ Material study took this into account
18. The product should be as comfortable in use as possible. It should:	
a. Minimize the number of user actions;	✓ Snap-fit connections
b. Minimize the number of repeated motions;	✓ Repeat once (two snap-fits)
c. Be used with minimal forces;	× To be determined
d. Be used in as little time as possible;	✓
e. Have reachable components.	✓
19. The product should be as safe to use as possible. It should:	
a. Minimize the chance of injury to the patient;	✓ Compliance
b. Minimize the chance of injury to the patient's environment.	✓ No sharp or protruding edges

When looking at these tables some conclusions can already be drawn concerning the successfulness of the attachment device. In principle the Rotador has been shown to meet the requirements that were defined: all ranges of motions are accounted for without compromising the rigidity of the prosthesis to the point that it considerably hinders task performance, space is available in the device to allow the feed through of cables for the OHMG system, load distribution has been shown to be satisfactory if the device is used properly (the radial abutment should be fixed), and a patient was successful in easily donning and doffing the prosthesis and using it in everyday tasks. Furthermore, due to the modular and robust design of the device it is usable in various environments and cleaning should be possible regularly without much trouble.

Some of the wishes that were formulated are not yet or not completely accounted for. For example, carrying loads has not been tested extensively with the Rotador and therefore it is not certain how much the preserved freedom of motion of the forearm bones affects the patient's ability to handle heavy objects.

Because of the modularity of the device and the fact that it is easy to assemble and disassemble, when the plastic parts exhibit wear to the point that it hinders performance of the device, it should be easy to quickly replace those parts. However, fatigue testing has not yet been performed and would be necessary to make well-founded claims about the durability of the device. Cleaning of the device also should be easy to do but since the product has not been used for a long time or outside of a testing environment, it is hard to formulate conclusions about how easily dirt will accumulate in the Rotador and hinder its performance. For future trans-radial OHMG users it will possibly be necessary to develop an addition to the device that serves to shield the connectors from dirt and water.

Weight, costs and producibility have been taken into account when developing the Rotador, although compromises have been made to optimize the functionality of the device.

Lastly, no extensive testing has been done concerning the forces necessary to operate the product. The snap connection of the locks has not yet been optimized as only one prototype has been made and used. The connection works well, but does at times require some force to put into place due to the alignment of the abutments.

6. CONCLUSIONS

This project has yielded a solution to the problem that gave rise to it: With the current prosthetic attachment device it is not possible for osseointegrated TRA patients to use their artificial limb while preserving the range of pronation and supination of the forearm they have left, while with the Rotador it has been shown that it is. The device is considered to be a successful solution as its requirements have been met and some improvements have been observed in task performance. However, there is more to be said about the development of this novel attachment device.

LIMITATIONS

Testing with more patients should be done to verify the versatility of the device. The device was not designed for the specific patient that tested it and it still performed well, but in order to truly test its adjustability more possible users should try it. Additionally, more rigorous mechanical testing needs to be done: It is important to have a better understanding of the fatigue properties of the product and how it handles extreme use.

When looking at the tests that were performed to evaluate task performance, other options could be of interest. The Minnesota Manual Dexterity test is not the most suitable assessment of forearm rotation, because in order to perform it a lot of shoulder movements are needed to compensate for wrist flexion.

The load distributions tests also had a significant limitation: The fixture that was used to hold the abutments was very rigid, while it is likely that exerting force on the abutments of the patient will result in movement of the soft tissues and possibly of the abutments with respect to each other. These movements might have an impact on the stress distribution, and the force exerted on the soft tissues might be a risk for the patient in itself.

APPLICABILITY

Thanks to the tests performed with the Rotador it was possible to make an important observation: Pronation and supination results in considerable movement of the forearm muscles, even in the case of trans-radial amputees. This means that if the patient is using surface electrodes that are clamped onto the stump in fixed positions, as is the case for most current patients, this movement will make the electrodes slide, possibly resulting in control issues. This could be solved by changing the way the electrodes are attached to the patient. However, another issue remains for patients using surface electrodes. Because of muscle activity during forearm rotation, the surface electrodes could mistake the intention to pronate and supinate for the intention to open and close the hand. These problems were not anticipated to occur to this extent beforehand: Only after solving the problem that was the subject of this thesis and enabling a patient to perform everyday tasks with this solution, these new issues became evident. It should be noted that they will most likely be non-existent for patients using the OHMG system, since those patients will not use surface electrodes and the signals to control the prosthesis will be retrieved from individual muscles.

There are plans to implement this system to multiple trans-radial patients within a couple of years. Especially for these patients the Rotador could be of great value, as it would add a degree of freedom to the artificial limb that can be controlled naturally and simultaneously with other motions without needing to occupy any electronics from the OHMG system.

Having the ability to perform forearm rotation will enable more precise and effective handling of objects. However, another important subject of investigation is the patient's ability to carry heavy loads with the device. If the device results in a better prosthetic experience for light or small objects but makes life more difficult for heavy ones, the overall purpose of the product is put in question. Future testing with multiple patients is needed to further explore this phenomenon. However, it stands to reason that if the increased freedom of motion of the forearm bones indeed poses this threat, locking the abutments with respect to each other when carrying large weights as described in Appendix F could be a solution.

SCOPE

In practice upper extremity amputees are often able to partly compensate for the lack of forearm rotation with shoulder maneuvers. Flexion and extension of the wrist, on the other hand, is a movement that cannot be compensated for in many situations and would add great value to prosthetic function. Various patients talked to during this project stressed the importance of this latter motion when talking about wrist functionality. In fact, the improvements in task performance associated with restoring pronation and supination are quite possibly smaller than improvements that would be achieved by enabling effortless wrist flexion and extension. Thus, pro-and supination might not be the most crucial motion to upper extremity amputees. However, an important difference is present between these motions: TRA patients often still have the natural ability to rotate their forearm, but no longer possess the ability to flex and extend the wrist since the wrist joint is completely absent. Preserving the remaining natural functionality of forearm rotation through a prosthetic attachment device means that the development of the prosthesis itself can remain unchanged. The added functionality could be performed simultaneously with other prosthetic actions like grasping or releasing, while not complicating or slowing down the use of the device in any way.

The goal of prosthetics can be defined as to try to restore as much natural ability as possible to a person suffering from an amputation. The attachment device developed in this thesis not only seems to improve daily task performance but also restores a more natural appearance and feeling to TRA patients with osseointegrated prostheses, without having to make adjustments to the prosthesis itself and without putting the implants at risk. While prosthetic upper limbs are still a long way from being as functional as healthy arms, the development of the Rotador is one of many positive developments working towards that goal.

7. APPENDIX

A. PROCESS TREE

EMERGENCE

1. Product development
    a. Problem analysis
    b. Concept generation
    c. Prototype production
    d. Preliminary testing
    e. User & specialist feedback
    f. Reiteration (possibly)
    g. Final testing
2. Production process development
    a. Material & process selection
    b. Supplier selection
    c. Supplier agreements
3. Production final product
4. Assembly (possibly)
5. Packaging

DISTRIBUTION

6. Shipping
    a. To company or clinic, or
    b. To user
7. Transporting
8. Delivering
9. Repeat 6-8 if delivered to company before delivered to patient.

USE

10. Unpacking
11. Read instructions
12. Assembly (possibly)
13. Attach to abutments
14. Lock mechanism
15. Perform daily tasks
    a. Have breakfast

b. Maintain personal hygiene
    i. Shower
    ii. Brush teeth
    iii. Comb hair
    iv. Use toilet
    v. Use toiletries
c. Put on clothes
    i. Put on pants, shirt(s), socks, shoes
    ii. Fasten buttons, shoelaces, zippers
d. Leave home
    i. Pack bag
    ii. Carry items
    iii. Use public transportation
    iv. Drive car
    v. Ride bicycle
    vi. Etc.
e. Handle big, heavy items
    i. Use (power) tools
    ii. Carry cargo
    iii. Etc.
f. Handle small, precise items
    i. Typing
    ii. Using office supplies
    iii. Using electronics
    iv. Etc.
g. Travel home
    i. Transportation (see
h. Do groceries
    i. Handle trolley
    ii. Handle groceries
    iii. Handle payment
i. Take off shoes, coat
j. Drop and stow away work items
k. Prepare dinner
l. Have dinner
m. Get ready for bed

16. Unlock mechanism
17. Disconnect prosthesis
18. Stow away prosthesis

END OF LIFE

19. Package product
20. Send broken/worn out product to company for inspection
21. Inspection of product
22. Disposal/storage/restoration of product

B. MATERIAL STUDY

When choosing a material for the plastic parts of the Rotador, it was mentioned that the first reduction of the number of choices resulted from examining which materials would be available depending on the most commonly used materials in production processes applicable to the Rotador. Two common and available materials were selected for each of the processes of machining and 3D printing. For machining these materials were POM and PVC, for 3D printing they were ABS and PA. As a reference, a commonly used plastic for plastic products in large batch sizes was added to the analysis as well. Properties of these materials were compared using the program Cambridge Engineering Selector.

First of all, the selected materials were compared based on their price and density (Figure 37). A solution is sought after which is as light as possible, and even though the material costs of the plastic parts will probably not be very high compared to the tooling costs, it should aim to be as cheap as possible.

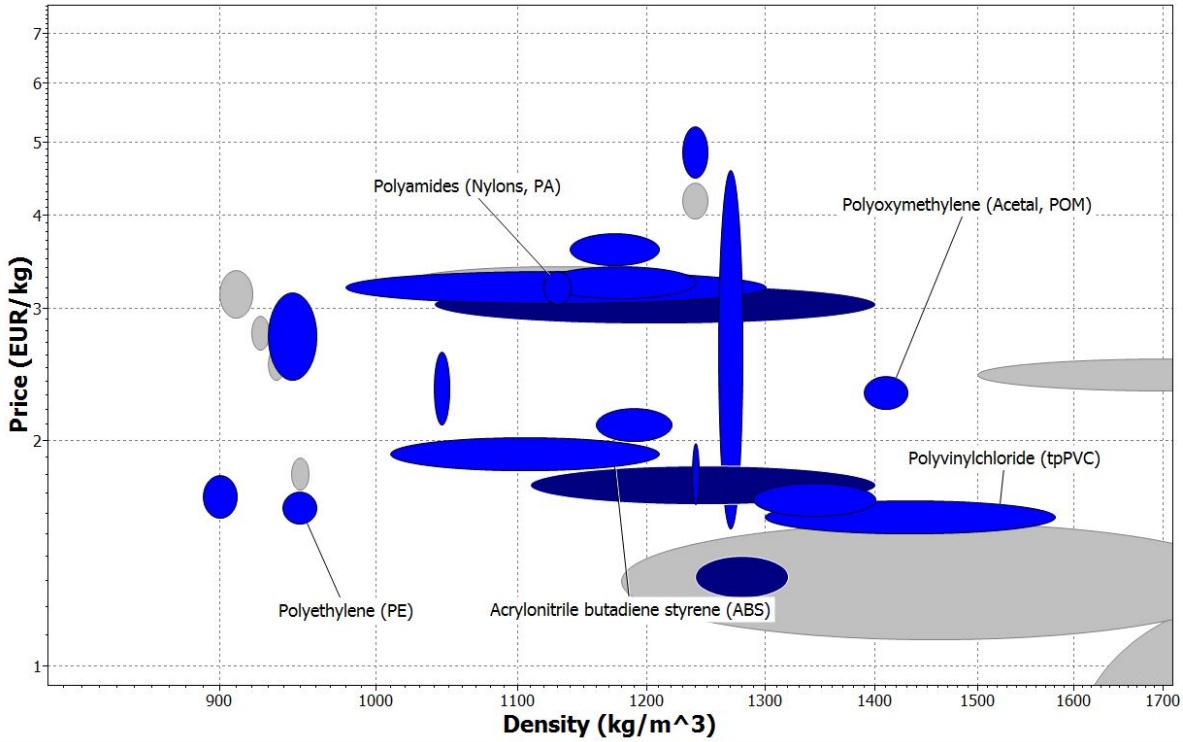


Figure 37: Comparison of price and density for plastic materials [44].

Figure 36 shows that when looking only at these two qualities, the commonly used PE would be the optimal choice. Slightly heavier materials are ABS and PA, with ABS being the cheaper material out of those two. The plastics that can be machined (PVC and POM) are heavier still, but generally cheaper than the 3D printing plastics.

There are a number of other material properties that are important for the plastic parts of the Rotador. They must be strong and stiff so the holders are constrained by the locking plate well and the sliding surfaces remain straight when the holders are pressed down with force. Furthermore the fracture toughness should be as high as possible: It is likely that wear due to the sliding

motions will affect the plastic parts. The wear itself might not necessarily impact the effectiveness of the device right away, but it will make the plastic parts more vulnerable to fracture.

When looking at fracture toughness and yield strength (Figure 38), PA seems to be the optimal choice with both of these properties being the highest of the options regarded. Furthermore it has a high stiffness, similar to that of POM and PVC (Figure 39). It is the most expensive of the materials, though the material costs will probably be almost negligible compared to the process costs of both 3D printing and machining.

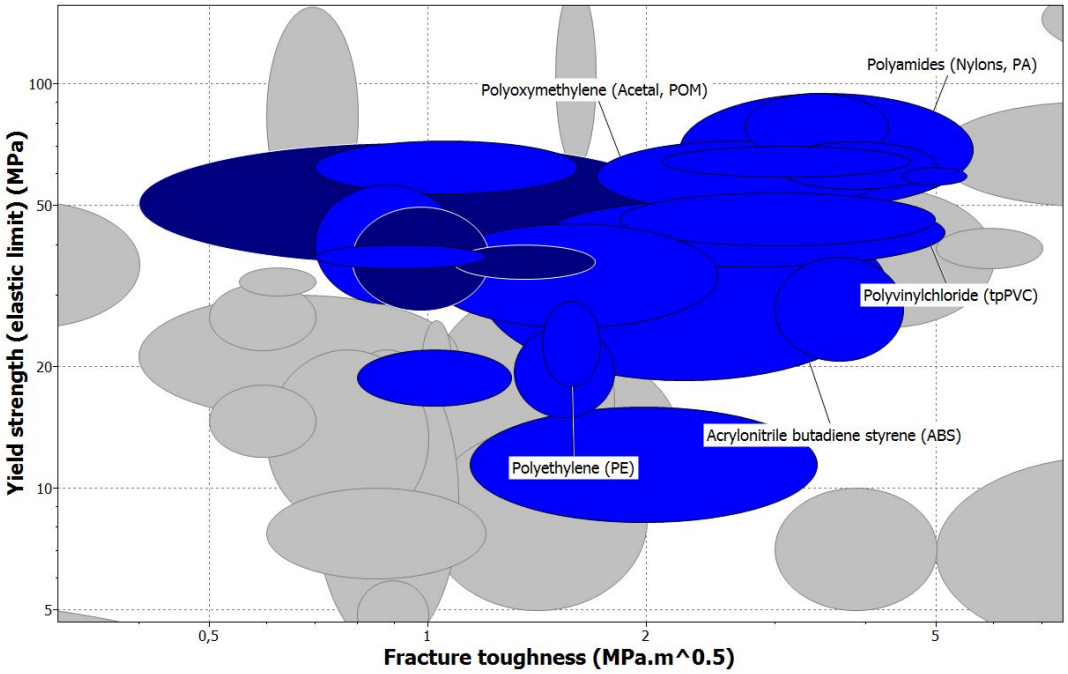


Figure 38: Comparison of yield strength and fracture toughness for plastics [44].

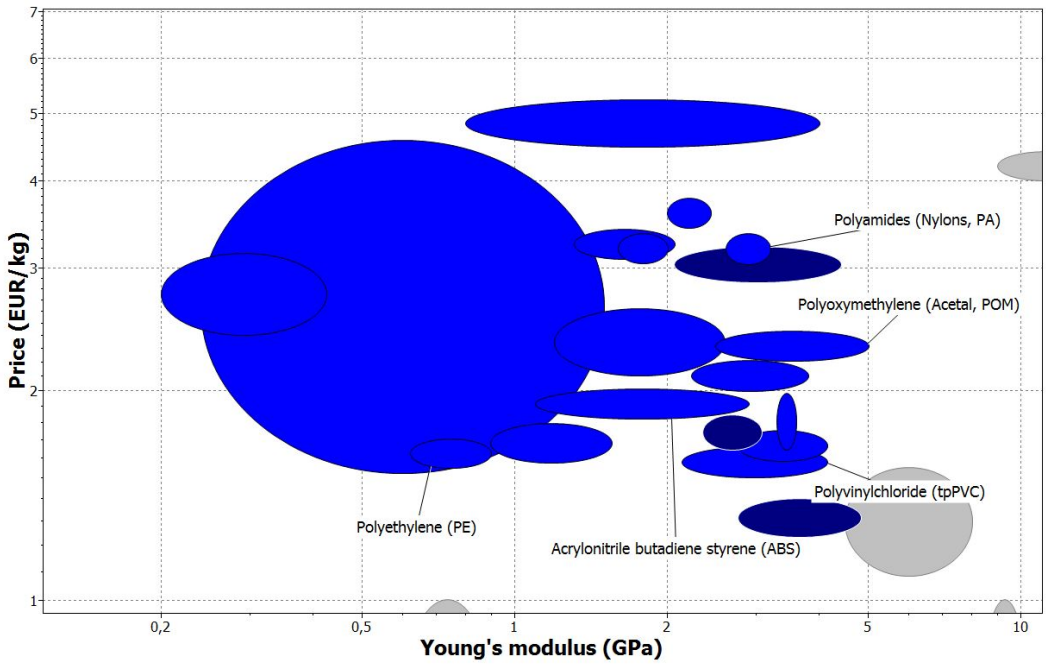


Figure 39: Comparison of price and Young's modulus for plastics [44].

Similar properties matter when looking for a suitable metal. Again costs are somewhat relevant: Most likely the material costs will be small compared to the costs associated with the machining process, but the design should aim to reduce costs where possible and without compromising the quality of the mechanism. Since metal is in general a heavier material than plastic, weight becomes more of importance as the device should be as light as possible. Weight and price of metals are compared in Figure 40. Furthermore, yield strength is a factor since the base will be connected to the full weight of the prosthesis through a set of screws. Yield strengths of various

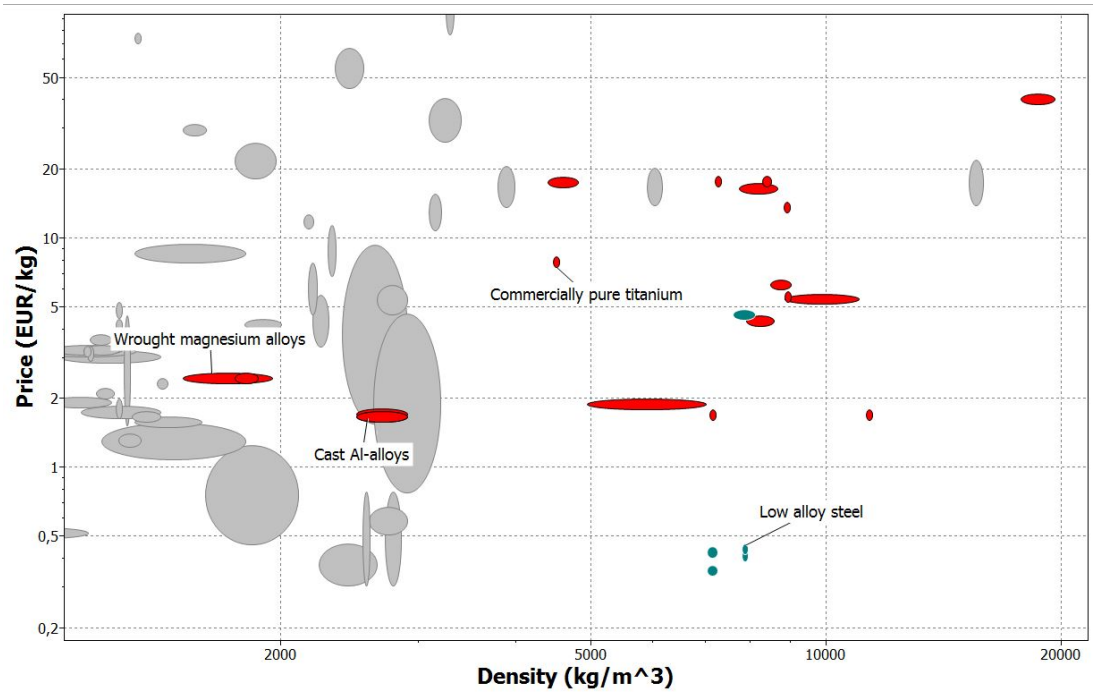


Figure 40: Comparison of price and density for metals [44].

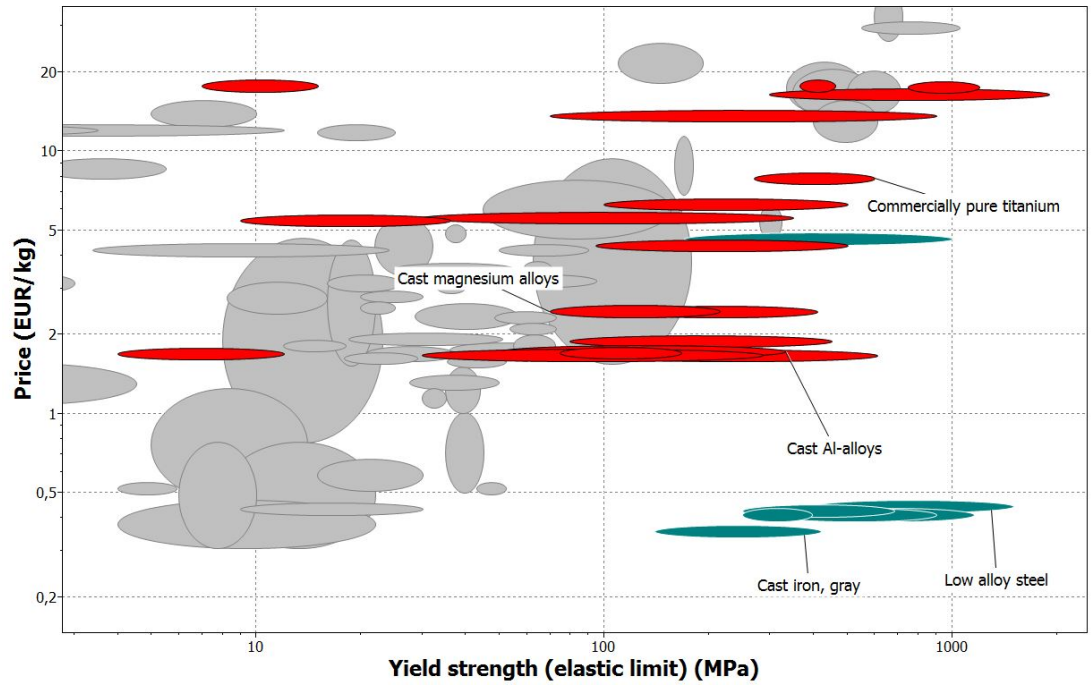


Figure 41: Comparison of Price and yield strength for metals [44].

metals are shown in Figure 41. Most likely, fracture due to wear has less importance here as the metal holders are only in contact with plastic and the abutments are fixed in place within the holders. Elasticity will be negligible for most metals compared to the plastic and rubber parts and is not specifically considered here.

A light, cost efficient, and easily machinable metal is aluminum. Titanium is the material used for the fixtures, abutments and abutment screws and has a higher strength. For these components, strength is a highly important factor because of the fact that they are implanted and mechanical failures must be addressed in the form of surgical revisions. Even so, no mechanical issues have been reported with the upper limb implants due to the relatively low stresses compared to the lower limb. For the attachment device this means that a compromise can be made between mechanical properties and efficiency in the production process and use of the device. Following this rationale, aluminum is a most suitable material for the Rotador.

C. STRAIN GAUGE TESTS

Unit conversion

In order to translate the voltage that was measured by the board to moments in the abutments, a number of formulas were used. A difference in voltage is measured between the moments when the load is applied on the attachment device and when the load is released. This difference can be expressed as V_0. With the set-up that was used in this experiment, this relates to the strain in the gauges e in a linear fashion [46], [47]:

$$e = \frac{2\Delta V_0}{V_{EX} \times S_E}$$

In this formula, V_{EX} is the excitation voltage and S_E is the gauge factor; both are constants inherent to the set-up.

Using Hooke's law, from this strain the stress in the material σ can be calculated when the material's Young's modulus E is known:

$$\sigma = e \times E$$

This stress can also be calculated with the bending moment M_B, the distance from the neutral axis to the point of measurement y and the moment of inertia I [34]:

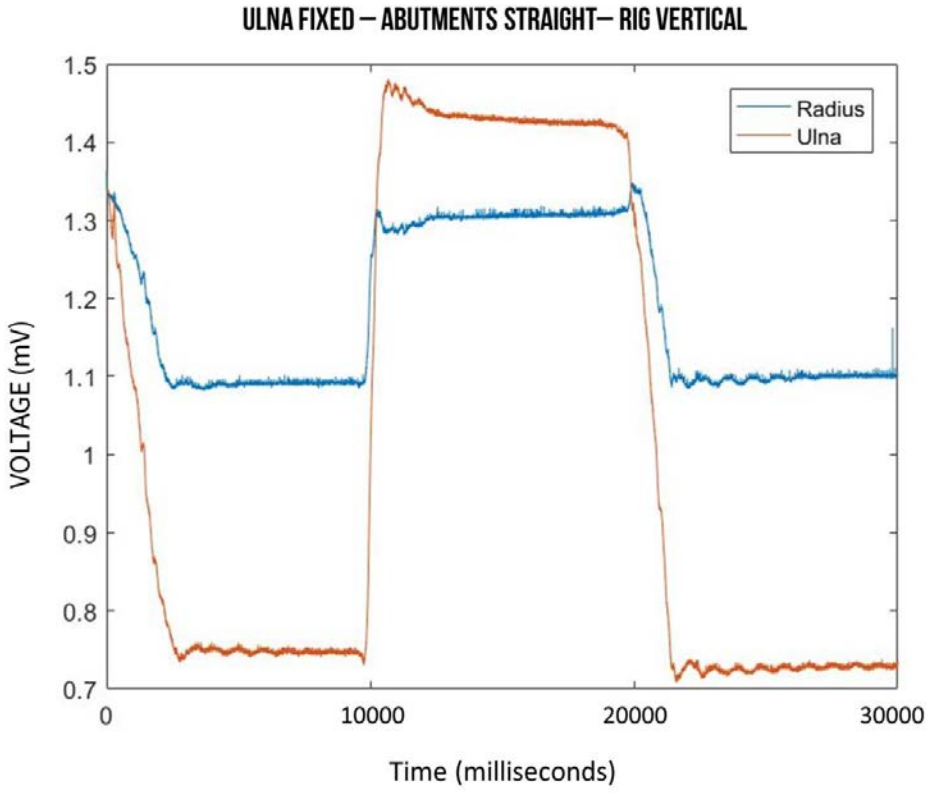
$$\sigma = \frac{M_B \times y}{I}$$

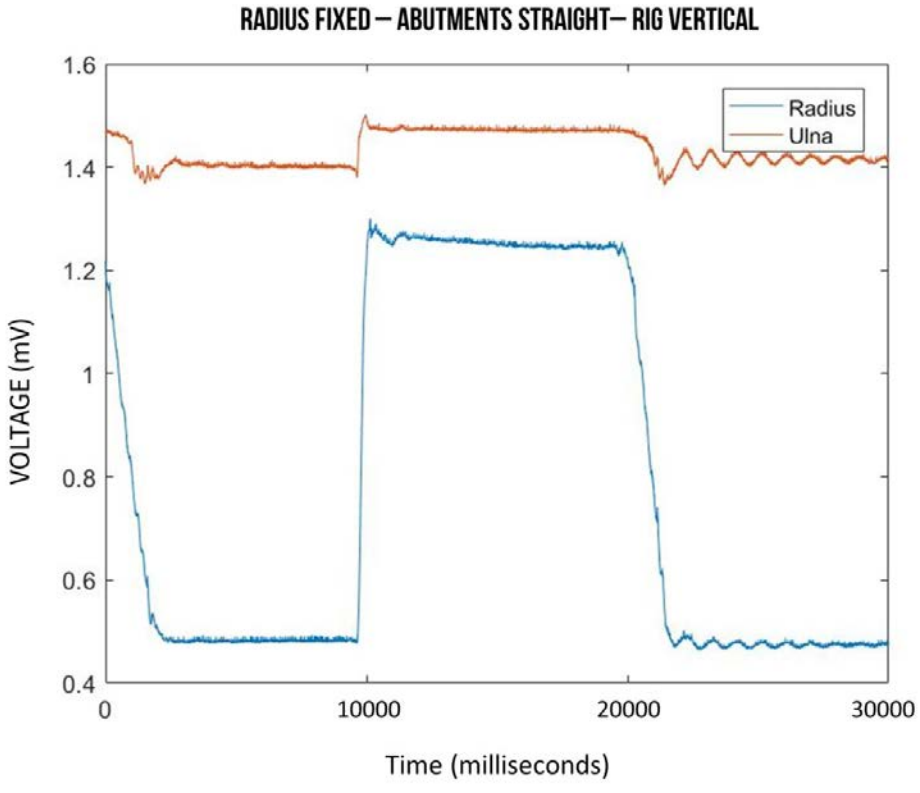
When the geometry of the abutments is known and the stresses are calculated from the measured differences in voltage, the moment in the abutment is the only unknown variable in this last equation and can therefore be calculated. The previous equations can be combined into a general formula for the bending moment M_B:

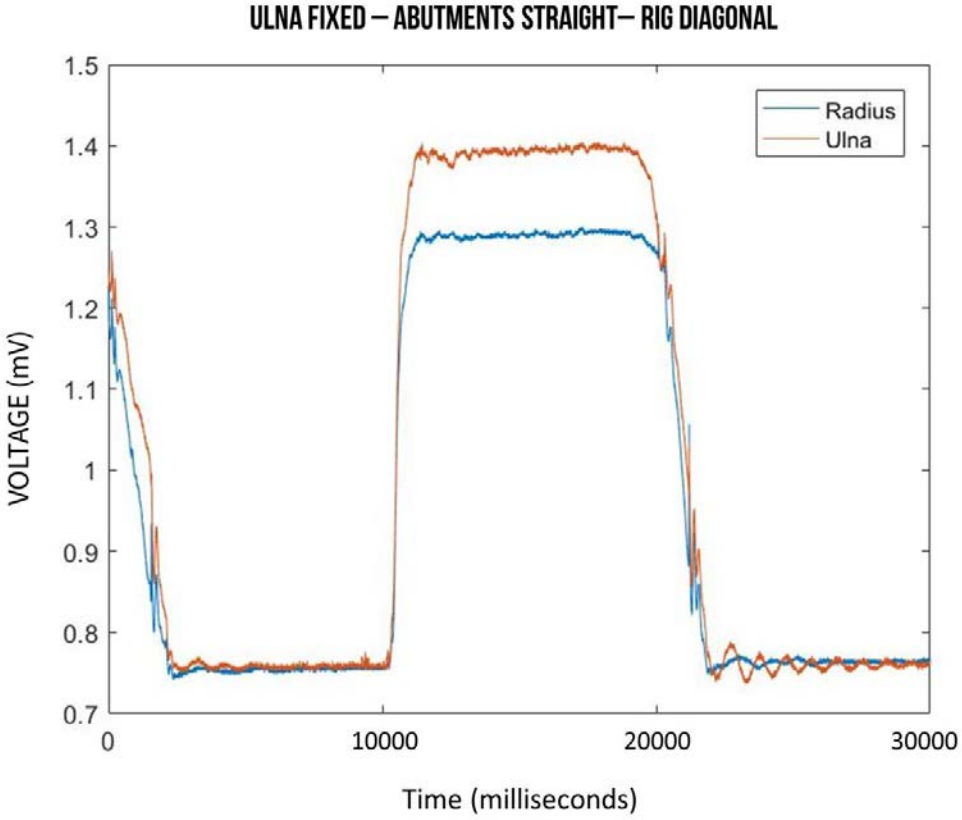
$$M_B = \frac{2\Delta V_0}{V_{EX} \times S_E} \times E \times S$$

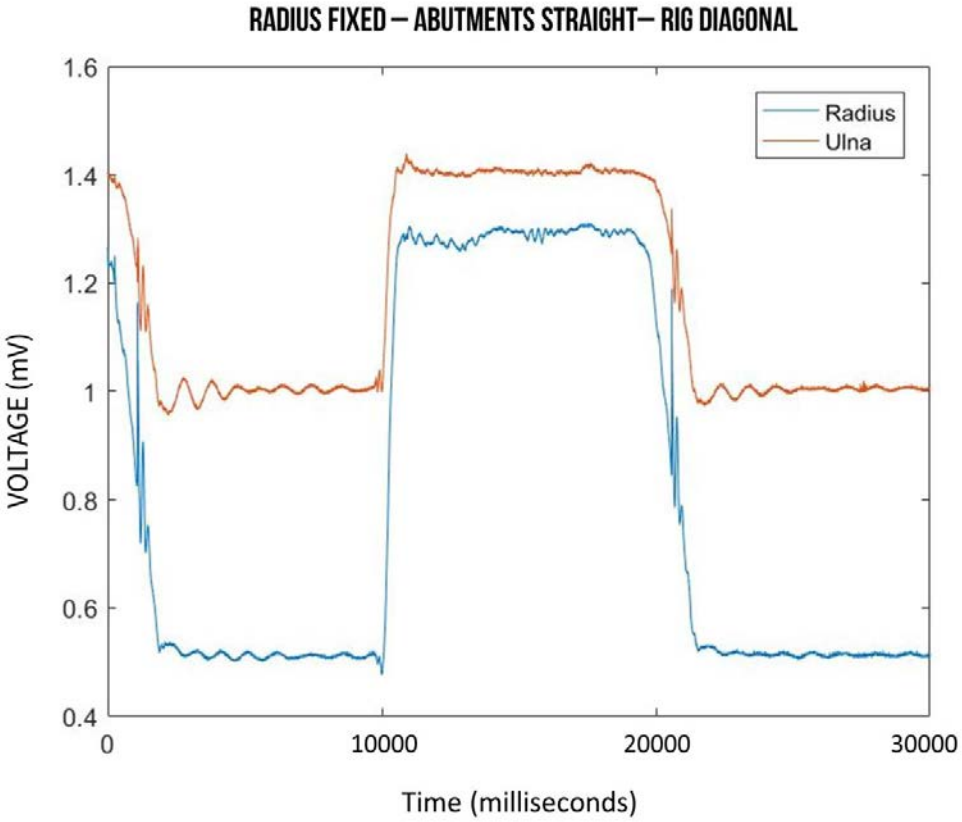
In this formula the sectional modulus S is used, which is calculated by dividing I by y.

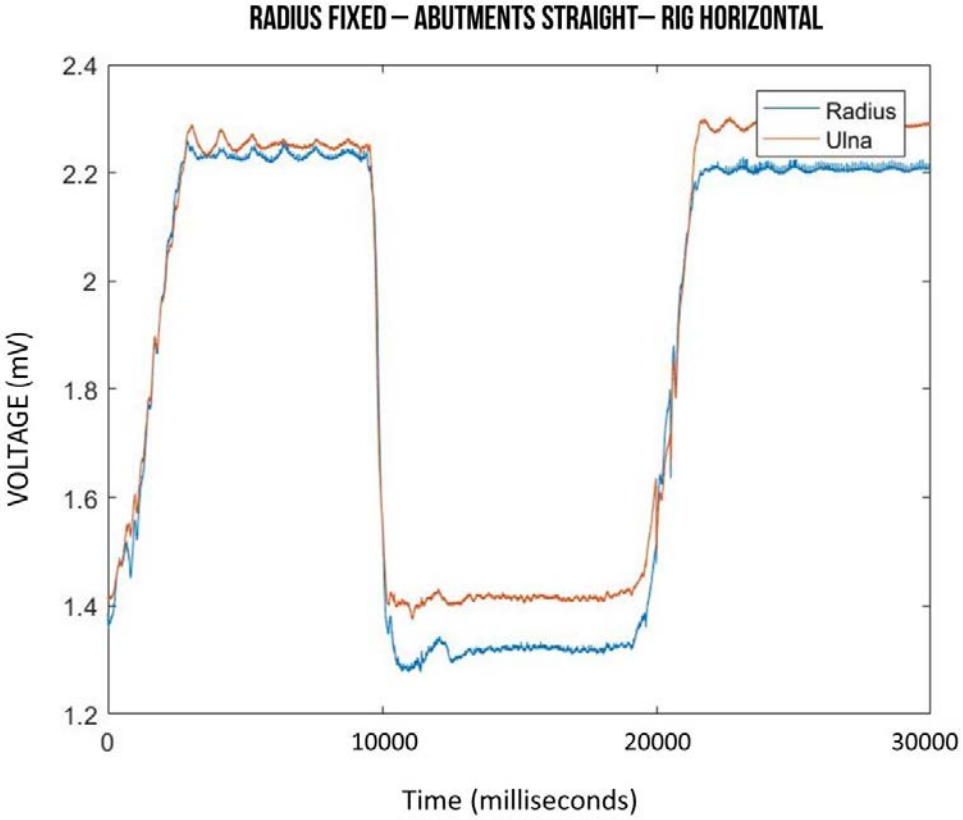
Plots

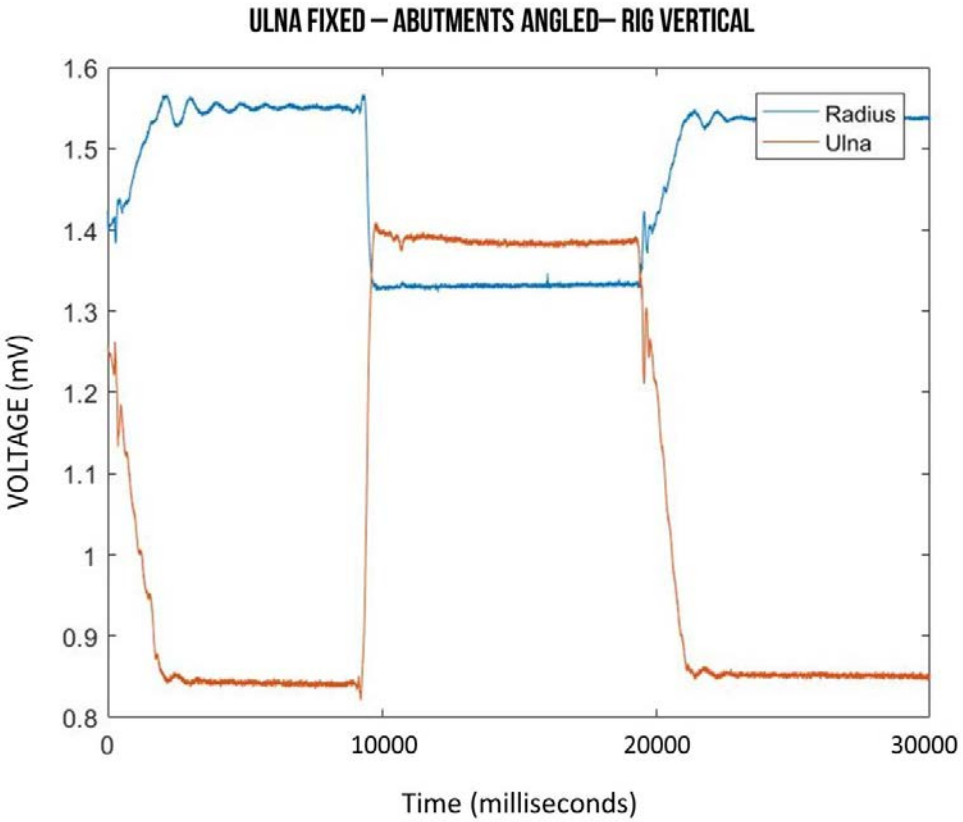

ULNA FIXED – ABUTMENTS STRAIGHT– RIG VERTICAL
Radius
Ulna
VOLTAGE (mV)
1.5
1.4
1.3
1.2
1.1
1
0.9
0.8
0.7
0
10000
20000
30000
Time (milliseconds)

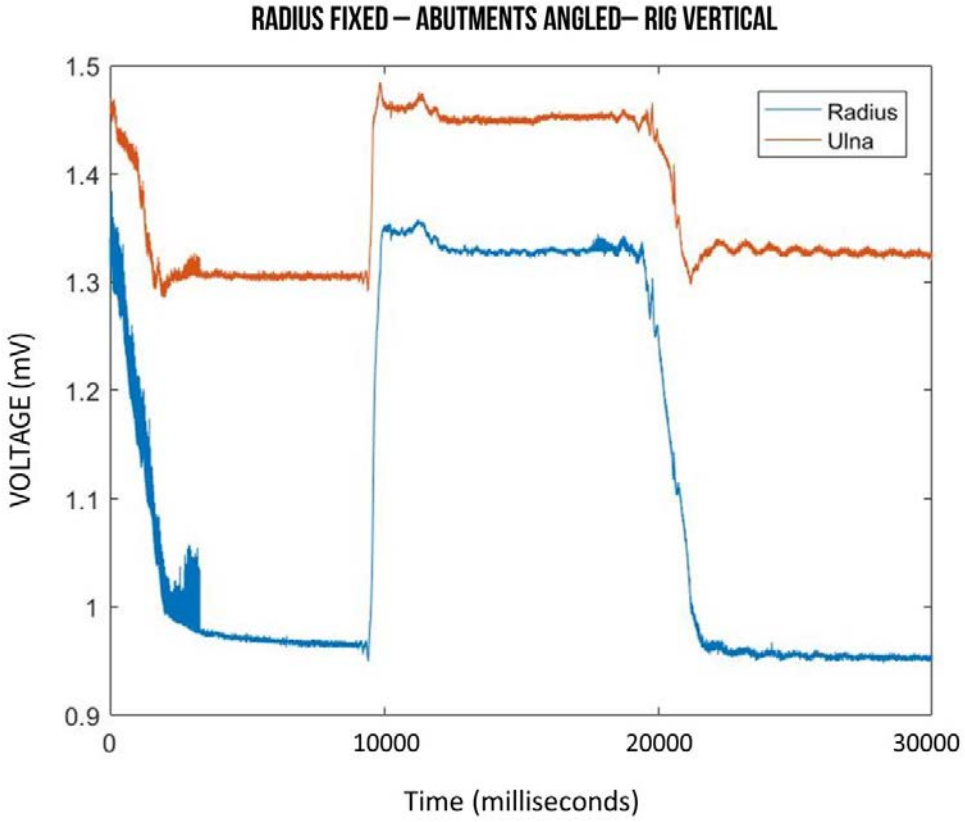

RADIUS FIXED – ABUTMENTS STRAIGHT– RIG VERTICAL
Radius
Ulna
VOLTAGE (mV)
1.6
1.4
1.2
1
0.8
0.6
0.4
0
10000
20000
30000
Time (milliseconds)

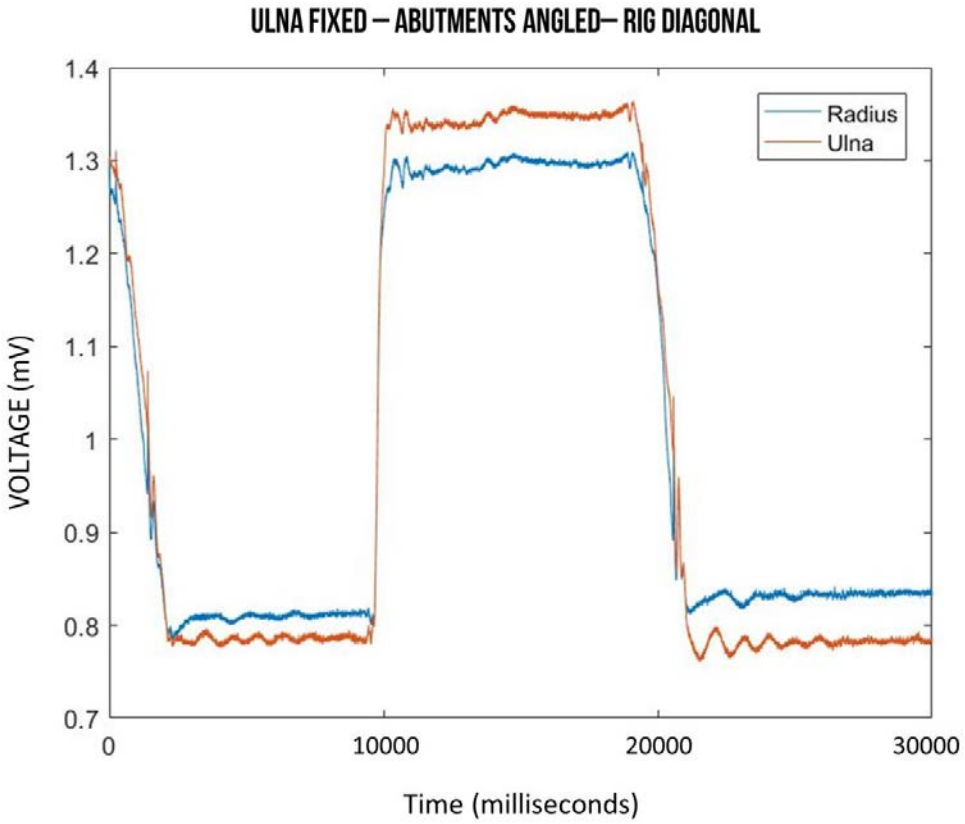

ULNA FIXED – ABUTMENTS STRAIGHT– RIG DIAGONAL
Radius
Ulna
VOLTAGE (mV)
1.5
1.4
1.3
1.2
1.1
1
0.9
0.8
0.7
0
10000
20000
30000
Time (milliseconds)

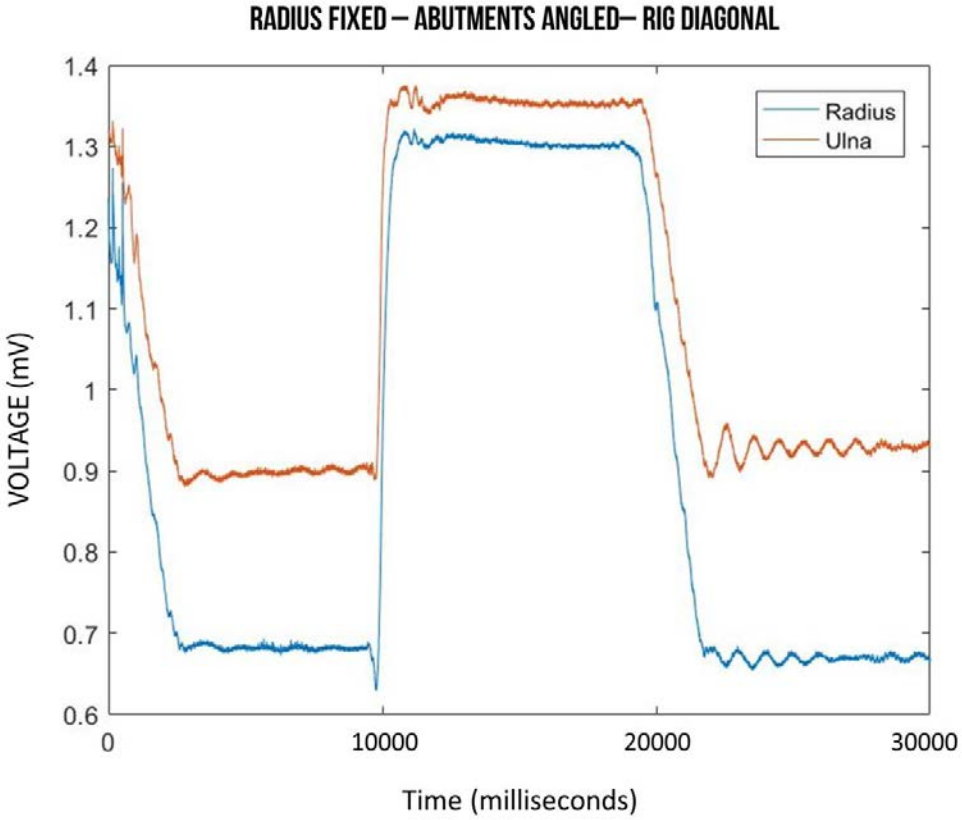

RADIUS FIXED – ABUTMENTS STRAIGHT– RIG DIAGONAL
Radius
Ulna
VOLTAGE (mV)
1.6
1.4
1.2
1
0.8
0.6
0.4
0
10000
20000
30000
Time (milliseconds)


RADIUS FIXED – ABUTMENTS STRAIGHT– RIG HORIZONTAL
Radius
Ulna
VOLTAGE (mV)
2.4
2.2
2
1.8
1.6
1.4
1.2
0
10000
20000
30000
Time (milliseconds)


ULNA FIXED – ABUTMENTS ANGLED– RIG VERTICAL
Radius
Ulna
VOLTAGE (mV)
1.6
1.5
1.4
1.3
1.2
1.1
1
0.9
0.8
0
10000
20000
30000
Time (milliseconds)


RADIUS FIXED – ABUTMENTS ANGLED– RIG VERTICAL
Radius
Ulna
VOLTAGE (mV)
1.5
1.4
1.3
1.2
1.1
1
0.9
0
10000
20000
30000
Time (milliseconds)


ULNA FIXED – ABUTMENTS ANGLED– RIG DIAGONAL
Radius
Ulna
VOLTAGE (mV)
1.4
1.3
1.2
1.1
1
0.9
0.8
0.7
0
10000
20000
30000
Time (milliseconds)


RADIUS FIXED – ABUTMENTS ANGLED– RIG DIAGONAL
Radius
Ulna
VOLTAGE (mV)
1.4
1.3
1.2
1.1
1
0.9
0.8
0.7
0.6
0
10000
20000
30000
Time (milliseconds)

D. LITERATURE REVIEW

Table 2 shows what was found to be relevant literature regarding the kinematics of the forearm and the specific motion of forearm rotation. Depending on the study various topics are explored, such as description of the motion in the DRUJ, description of the motion in the PRUJ, description of the motion along the forearm, methods to measure the range of forearm rotation in healthy subjects, and ways of modeling or simplifying the motion.

Table 11: Articles found in the literature survey that focused on forearm kinematics.

STUDY	Motion of DRUJ	Motion of PRUJ	Motion along forearm	Measuring methods	Modeling of motion	Goal of study
Weinberg et. al (2000) [A]					✓	Develops a mathematical model to simulate pro/ supination
Reich et al. (2000) [B]					✓	Develops a rigid body model to assess dynamic properties of the forearm.
Kasten et al. (2004) [C]			✓			Quantifies axial rotation of the ulna in pro/supination.
Baeyens et al. (2006) [D]	✓	✓				Evaluates the motion of the radial head in the PRUJ & DRUJ during pro/supination.
Tay et al. (2008) [E]	✓	✓	✓	✓		Develops a method for describing the axis of rotation of pro/supination.
Fürnstahl et al. (2009) [F]	✓				✓	Predicts and simulates the rotational axis based on CT measurements of DRUJ.
Colaris et al. (2010) [G]				✓		Evaluates ways for estimating the range of pro/supination.
Tay et al. (2010) [H]	✓	✓	✓			Uses a new method [44] to describe the rotational axis of pro/supination.
Matsuki et al. (2010) [I]	✓		✓			Assesses the kinematics of the DRUJ &PRUJ in dynamic conditions.
Fohanno et al. (2013) [J]					✓	Develops a model that improves estimations of forearm kinematics.
Chen et al. (2013) [K]	✓					Analyzes how the ulna moves in the DRUJ during forearm rotation.
Fraysse et al. (2014) [L]				✓		Compares methods for the estimation of rotational axes in the forearm.
Omori et al. (2016) [M]		✓				Explores elbow kinematics during forearm rotation.

Table 3 categorizes found literature regarding the forearm and the motion of forearm rotation. This group of studies focuses on force exertion, load distribution, or dynamics.

Table 12: Articles found in the literature survey that focused on forces acting on the forearm.

STUDY	Force exertion	Load distribution	Dynamics	Goal of study
De Serres et al. (1992) [N]	✓			Explores EMG activity of elbow flexors with a semi-pronated forearm, when pro/supination tasks in various elbow angles are performed.
Birbeck et al. (1997) [O]		✓		Explores the impact of the interosseous membrane on load distribution in the forearm.
Gordon et al. (2004) [P]	✓			Compares EMG data from rotator muscles during pro/supination tasks.
O'Sullivan et al. (2005) [Q]	✓			Measures maximum forearm torques and discomfort in pro/supination tasks.
Bremer et al. (2006) [R]	✓			Determines moment arms of the forearm rotator muscles.
Shaaban et al. (2006) [S]		✓		Describes load distribution between the radius and ulna in axial compression.
Di Domizio et al. (2010) [T]	✓			Explores how various tasks alter forearm muscle activity.
Charles et al. (2011) [U]			✓	Presents a model of wrist rotation dynamics and discusses kinematic data with this model.
Peaden et al. (2014) [V]			✓	Presents equations of motions describing torques in complex forearm movements.
Ibáñez-Gimeno et al. (2014) [W]	✓			Provides an in-depth analysis of the role of the pronator teres muscle.

References literature

[A] Weinberg A.M., Pietsch I.T., Helm J., Hesselbach J., and Tscherne H. (2000) **A new kinematic model of pro-and supination of the forearm.** *Journal of Biomechanics*, 33, 487-91

[B] Reich J. and Daunicht W.J. (2000) **A rigid body model of the forearm.** *Journal of biomechanics*, 33, 1159-68.

[C] Kasten P., Krefft M., Hesselbach J., Weinberg A.M. (2004) **Kinematics of the ulna during pronation and supination in a cadaver study: implications for elbow arthroplasty.** *Clinical Biomechanics*, 19, 31-35.

[D] Baeyens J.P., Van Glabbeek F., Goossens M., Gielen J., Van Roy P., Clarys J.P. (2006) **In vivo 3D arthrokinematics of the proximal and radioulnar joints during active pronation and supination.** *Clinical Biomechanics*, 21, s9-s12.

[E]Tay S.C., Van Riet R., Kazunari T., Koff F., et al. (2008) **A method for *in-vivo* kinematic analysis of the forearm.** *Journal of Biomechanics*, 41, 56-62.

[F] Fürnstahl P., Schweizer A., Nagy L., Székely G., Harders M. (2009) **A morphological approach to the simulation of forearm motion.** *31st Annual International Conference of the IEEE EMBS*, Minneapolis, Minnesota, USA, September 2-6, 2009.

[G] Colaris J. Van der Linden M., Selles R., Coene N., Allema J.H., Verhaar J. (2010) **Pronation and supination after forearm fractures in children: Reliability of visual estimation and conventional goniometry measurement.** *Injury Int. J. Care Injured*, 41, 643-46.

[H] Tay S.C., Van Riet R., Kazunari T., Amrami K.K., et al. (2010) ***In-vivo* kinematic analysis of the forearm rotation using helical axis analysis.** *Clinical Biomechanics*, 25, 655-59.

[I] Matsuki K.O., Matsuki K., Mu S., Sasho T., et al. (2010) **In vivo 3D kinematics of normal forearms: Analysis of dynamic forearm rotation.** *Clinical Biomechanics*, 25, 979-983.

[J] Fohanno V., Lacouture P., Colloud F. (2013) **Improvement of upper extremity kinematics estimation using a subject-specific forearm model implemented in a kinematic chain.** *Journal of Biomechanics*, 46, 1053-59.

[K] Chen Y.R., Tang J.B. (2013) ***In vivo* Gliding Contact Characteristics of the Sigmoid Notch and the Ulna in Forearm Rotation.** *Journal for Hand Surgery*, 38(A), 1513-19.

[L] Fraysse F., Thewlis D. (2014) **Comparison of the anatomical, functional and regression methods for estimating the rotation axis of the forearm.** *Journal of Biomechanics*, 47, 3488-93.

[M] Omori S., Miyake J., Oka K., Tanaka H., et al. (2016) **In vivo three-dimensional elbow biomechanics during forearm rotation.** *Journal for Shoulder and Elbow Surgery*, 25, 112-119.

[N] De Serres S.J., Henert L.J., Arsenault A.B., Goulet C. (1992) **Effect of pronation and supination tasks on elbow flexor muscles.** *Journal of Electromyography and Kinesiology*, 2(1), 53-58.

[O] Birbeck D.P., Failla J.M., Hoshaw S.J, Fyhrie D.P., et al. (1997) **The interosseous membrane affects load distribution in the forearm.** *Journal of Hand Surgery*, 22A(6), 975-980.

[P] Gordon K.D., Pardo R.D., Johnson J.A., King G.J.W., et al. (2004) **Electromyographic activity and strength during maximum isometric pronation and supination efforts in healthy adults.** *Journal of Orthopaedic Research*, 22. 208-13.

[Q] O'Sullivan L.W., Gallwey T.J. (2005) **Forearm torque strengths and discomfort profiles in pronation and supination.** *Ergonomics*, 48:6, 703-721

[R]Bremer A.K., Sennwald G.R., Favre P., Jacob H.A.C. (2006) **Moment arms of forearm rotators.** *Clinical Biomechanics*, 21, 683-91.

[S] Shaaban H., Giakis G. Bolton M., Williams R., et al. (2006) **THE LOAD-BEARING CHARACTERISTICS OF THE FOREARM: PATTERN OF AXIAL AND BENDING FORCE TRANSMITTED THROUGH ULNA AND RADIUS.** *Journal of Hand Surgery*, 31(3), 274-79.

[T] Di Domizio J., Keir P.J. (2010) **Forearm posture and grip effects during push and pull tasks.** *Ergonomics*, 53(3), 336-43.

[U] Charles S.K., Hogan N. (2011) **Dynamics of Wrist Rotation.** *Journal of Biomechanics*, 44, 614-621.

[V] Peaden A.W., Charles S.K. (2014) **Dynamics of wrist and forearm rotations.** *Journal of Biomechanics*, 47, 2779-85.

[W] Ibáñez-Gimeno P., Galtés I., Jordana X., Malgosa A., Manyosa J. (2014) **Biomechanics of Forearm Rotation: Force and Efficiency of Pronator Teres**. *PLoS ONE*, 9(2), e90319.

E. LOCKING MECHANISM

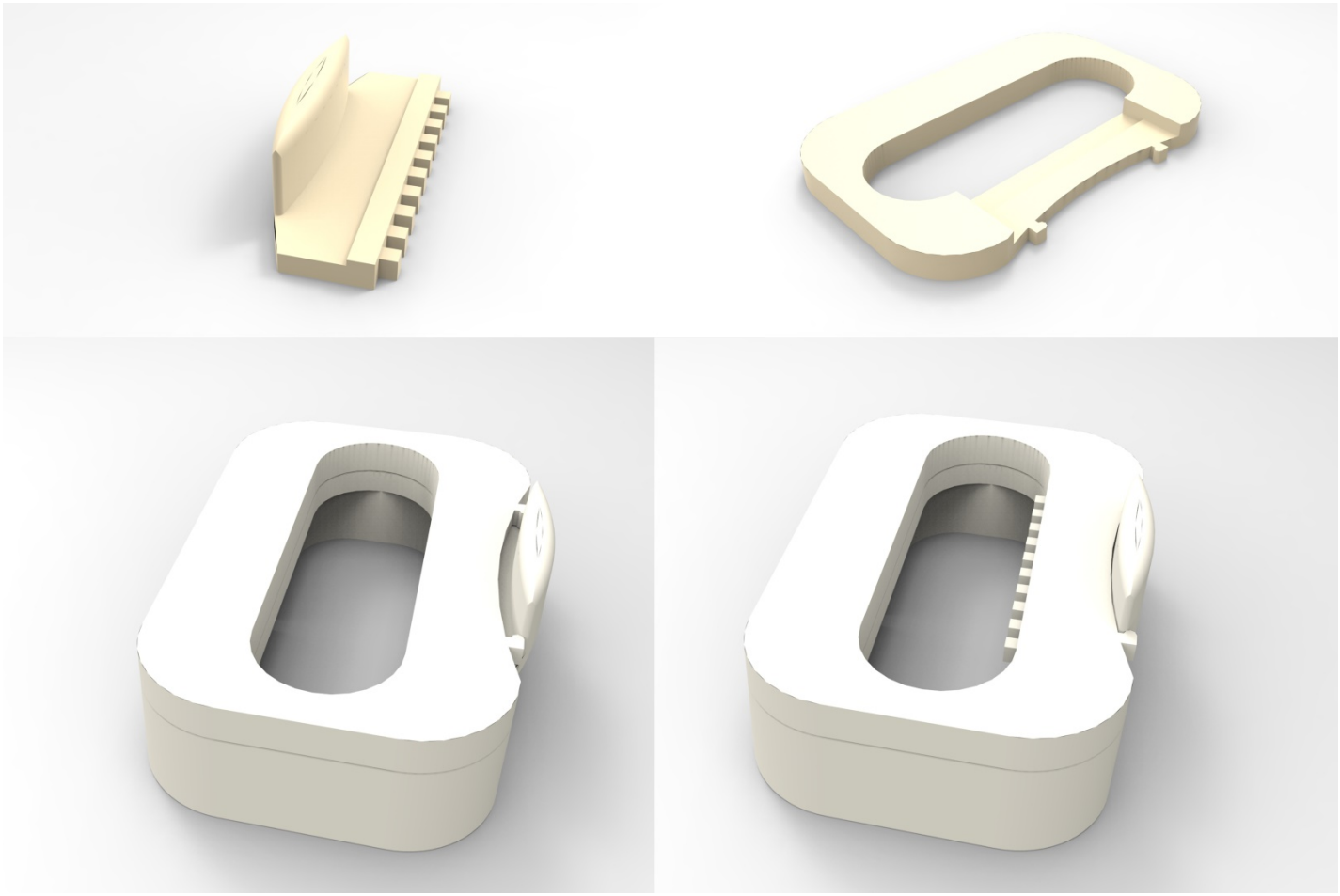


Figure 42: Concept of the locking mechanism for the Rotador. Top left: the locking part. Top right: the extension of the locking plate the holds the locking part. Bottom left: The mechanism unlocked. Bottom right: the mechanism locked.

Due to the limited amount of research available in the area of load distribution in the forearm in TRA patients and the fact that preliminary testing with the Rotador indicated that issues might be present when carrying heavy loads, a redesign of the attachment device was made that includes the option to lock the holders for the abutments in place when the patients chooses to do so. In this redesign, a plastic extension is attached to the top of the locking plate (Figure 42, top right image). This extension accommodates a second plastic part that serves as a lock. This has small “teeth” which, during normal use of the Rotador, are stowed away within the locking plate. However, when this lock is pushed into the center of the Rotador it snaps into a position where the teeth push against the holders. In order for this redesign to be functional adjustments would also have to be made to the holders themselves: the teeth of the lock would have to be machined into these components at the right height. This way, when the locking mechanism is snapped into place, the teeth lock into the holders, preventing them to rotate and slide in the track.

It is not yet certain that the implementation of this redesign will be necessary in the future. Still, if carrying large weights with the Rotador will give rise to complications it will be beneficial to have a functional concept for a safety measure at hand.

8. BIBLIOGRAPHY

[1] NLICC staff (2008). **Amputation Statistics by Cause Limb Loss in the United States.** *National limb loss Information Center.* Amputee Coalition of America, Knoxville, TN.

[2] Kristin Østlie, Ola H. Skjeldal, Beate Garfelt & Per Magnus (2011) **Adult acquired major upper limb amputation in Norway: prevalence, demographic features and amputation specific features. A population-based survey.** *Disability and Rehabilitation*, 33 (17-18), 1636-49.

[3] Ziegler-Graham K., MacKenzie E.J., Ephraim P.L, Travison T.G., and Brookmeyer R. (2008). **Estimating the Prevalence of Limb Loss in the United States: 2005 to 2050.** *Arch Phys Med Rehabil*, 89, 422-29.

[4] Barmparas G., Inaba K., Teixeira P.G.R., Dubose, J.J, et al. (2010). **Epidemiology of Post-Traumatic Limb Amputation: A National Trauma Databank Analysis.** *The American surgeon*, 76, 1214-22.

[5] Stansbury L.G., Lallis S.J., Branstetter J.G, Bagg M.R., and Holcomb, J.B. **Amputations in U.S. Military Personnel in the Current Conflicts in Afghanistan and Iraq.** *J Orthop Trauma*, 22 (1), 43-46.

[6] Jönsson, S., Caine-Winterberger, K., Brånemark, R. (2011). **Osseointegration amputation prostheses on the upper limbs: methods, prosthetics and rehabilitation.** *Prosthetics and Orthotics International*, 35(2), 190–200

[7] Tillander, J., Hagberg, K., Hagberg, L., Brånemark, R. (2010). **Osseointegrated titanium implants for limb prostheses attachments – Infectious complications.** *Clin Orthop Relat Res*, 468, 2781-88.

[8] Brånemark, R., Berlin, Ö., Hagberg, K. et al. (2014) **A novel osseointegrated percutaneous prosthetic system for the treatment of patients with trans-femoral amputation: A prospective study of 51 patients**. *The bone & joint journal*, 96(1), 106-13.

[9] Biddiss E.A., and Chau T.T. (2007) **Upper limb prosthesis use and abandonment: A survey of the last 25 years.** *Prosthet Orthot Int,* 31(3), 236-257.

[10] Hagberg, K., Brånemark, R. (2009). **One hundred patients treated with osseointegrated trans-femoral amputation prostheses – Rehabilitation perspective.** *Journal of Rehabilitation Research & Development*, 46(3), 331-44.

[11] Adell R., Lekholm U., Rockler B., and Brånemark P.I. (1981). **A 15-year study of osseointegrated implants in the treatment of the edentulous jaw.** *Int. J. Oral Surg.*, 10, 387-416.

[12] Brånemark P.I. (1983) **Osseointegration and its experimental background.** *The journal of prosthetic dentistry*, 50 (3), 399-410.

[13] Hagberg, K., Hansson, R.R., Brånemark, R. (2014). **Outcome of Percutaneous 9Year Follow-Up.** *Archives of Physical Medicine and Rehabilitation*, 95, 2120-7

[14] Van de Meent, H., Hopman, M.T., Frölke, J.P. (2013). **Walking Ability and Quality of Life in Subjects With Trans-femoral Amputation: A Comparison of Osseointegration With Socket Prostheses.** *Archives of Physical Medicine and Rehabilitation*, 94, 2174-8

[15] Häggström E., Hagberg K., Rydevik B., Brånemark R. (2013) **Vibrotactile evaluation: Osseointegrated versus socket-suspended trans-femoral amputees.** *JRRD*, 50(10), 1423-34.

[16] Lundberg M., Hagberg K., Bullington J. (2011) **My prosthesis as a part of me: a qualitative analysis of living with an osseointegrated prosthetic limb.** *Prosthetics and Orthotics International*, 35(2), 207-214.

[17] Häggström E., Hansson E., and Hagberg K. (2012) **Comparison of prosthetic costs between osseointegrated and conventional suspended trans-femoral prostheses.** *Prosthetics and Orthotics International*, 0, 1-9.

[18] Weinberg A.M., Pietsch I.T., Helm J., Hesselbach J., and Tscherne H. (2000) **A new kinematic model of pro-and supination of the forearm.** *Journal of Biomechanics*, 33 , 487-91

[19] Reich J. and Daunicht W.J. (2000) **A rigid body model of the forearm.** *Journal of biomechanics*, 33, 1159-68.

[20] Ortiz-Catalan M., Håkansson B., Brånemark R. (2014) **An osseointegrated human-machine gateway for long-term sensory feedback and motor control of artificial limbs.** *Science Translational Medicine,* 6 (257), 257-66.

[21] Taylor C.L. (1955) **The Biomechanics of Control in Upper-Extremity Prostheses.** *Artificial limbs - A review on current developments.* Washington: Advisory Committee on Artificial Limbs, 4-25.

[22] Matsuki K.O., Matsuki K., Mu S., Sasho T., et al. (2010) **In vivo 3D kinematics of normal forearms: Analysis of dynamic forearm rotation.** *Clinical Biomechanics*, 25, 979-983.

[23] Colaris J. Van der Linden M., Selles R., Coene N., Allema J.H., Verhaar J. (2010) **Pronation and supination after forearm fractures in children: Reliability of visual estimation and conventional goniometry measurement.** *Injury Int. J. Care Injured*, 41, 643-46.

[24] Baeyens J.P., Van Glabbeek F., Goossens M., Gielen J., Van Roy P., Clarys J.P. (2006) **In vivo 3D arthrokinematics of the proximal and radioulnar joints during active pronation and supination.** *Clinical Biomechanics*, 21, s9-s12.

[25]Tay S.C., Van Riet R., Kazunari T., Koff F., et al. (2008) **A method for *in-vivo* kinematic analysis of the forearm.** *Journal of Biomechanics*, 41, 56-62.

[26] Tay S.C., Van Riet R., Kazunari T., Amrami K.K., et al. (2010) **I*n-vivo* kinematic analysis of the forearm rotation using helical axis analysis.** *Clinical Biomechanics*, 25, 655-59.

[27] Gordon K.D., Pardo R.D., Johnson J.A., King G.J.W., et al. (2004) **Electromyographic activity and strength during maximum isometric pronation and supination efforts in healthy adults.** *Journal of Orthopaedic Research*, 22. 208-13.

[28] Birbeck D.P., Failla J.M., Hoshaw S.J, Fyhrie D.P., et al. (1997) **The interosseous membrane affects load distribution in the forearm.** *Journal of Hand Surgery*, 22A(6), 975-980.

[29] Shaaban H., Giakis G. Bolton M., Williams R., et al. (2006) **THE LOAD-BEARING CHARACTERISTICS OF THE FOREARM: PATTERN OF AXIAL AND BENDING FORCE TRANSMITTED THROUGH ULNA AND RADIUS.** *Journal of Hand Surgery*, 31(3), 274-79.

[30] Van Boeijen, A., Daalhuizen, J., Zijlstra, J., Van der Schoor, R. (2013). **Delft Design Guide.** Amsterdam: BIS Publishers.

[31] Roozenburg, N.F.M., Eekels, J. (1998). **Productontwerpen, structuur en methoden (2e druk).** Den Haag: *Lemma BV.*

[32] Vasluian E., Bongers R.M., Reinders-Messelink H. et al (2014). **Learning effects of repetitive administration of the Southampton Hand Assessment Procedure in novice prosthetic users.** *J. Rehabil Med.*, 46, 788-97.

[33] Szychlinski, L. (2012). **Prosthesis attachment device for individuals with trans-radial amputations.** *Master's Dissertation by Lukasz Szychlinski,* Lund University, Division of Solid Mechanics.

[34] Hibbeler, R.C. (2008). **Mechanics of Materials: Seventh edition.** Singapore: PEARSON EDUCATION SOUTH ASIA PTE LTD.

Verbal & electronic

[35] Integrum. **Rehabilitation of individuals with amputations since 1990.** *Web: www.integrum.se.* Retrieved 11-01-2016.

[36] Max Ortiz, R&D Manager Integrum AB

[37] Rickard Brånemark, founder Integrum AB.

[38] Stewe Jönsson, Leg. Orthopedic engineer, CPO TeamOlmed.

[39] Southampton Hand assessment Procedure. **About SHAP**. *Web: http://www.shap.ecs.soton.ac.uk/* . Retrieved 21-03-2016.

[40] Lafayette Instrument. **Minnesota Manual Dexterity Test.** *Web: http://www.lafayetteevaluation.com/product_detail.asp?itemid=164.* Retrieved 21-03-2016.

[41] North Coast. **Minnesota Manual Dexterity Test.** *Web: https://www.ncmedical.com/item_741.html*. Retrieved 21-02-2016.

[42] Chalmers.. **Natural control of artificial limb through an osseointegrated implant.** *Web: https://www.chalmers.se/en/projects/Pages/Natural-control-of-artificial-limb.aspx*. Retrieved 24-02-2016

[43] Hip Joint Surgery. **Hip Implants.** *Web: http://hipjointsurgery.co.uk/hips/hip-implants/.* Retrieved 24-02-2016.

[44] Software: **Cambridge Engineering Selector.**

[45] Slideshare. **Unsymmetrical bending of beams.** *Web: http://www.slideshare.net/VenkateshCa/unsymmetrical-bendingppt.* Retrieved 24-02-2016

[46] Tokyo Sokki Kenkyujo Co., Ltd. **Strain gauge connections and bridge circuits.** *Web: http://www.tml.jp/e/product/strain_gauge/bridge_list.html*. Retrieved 30-03-2016].

[47] National Instruments. **Strain Gauge Configuration Types**. *Web: http://www.ni.com/white-paper/4172/en/#toc5*. Retrieved 30-03-2016.