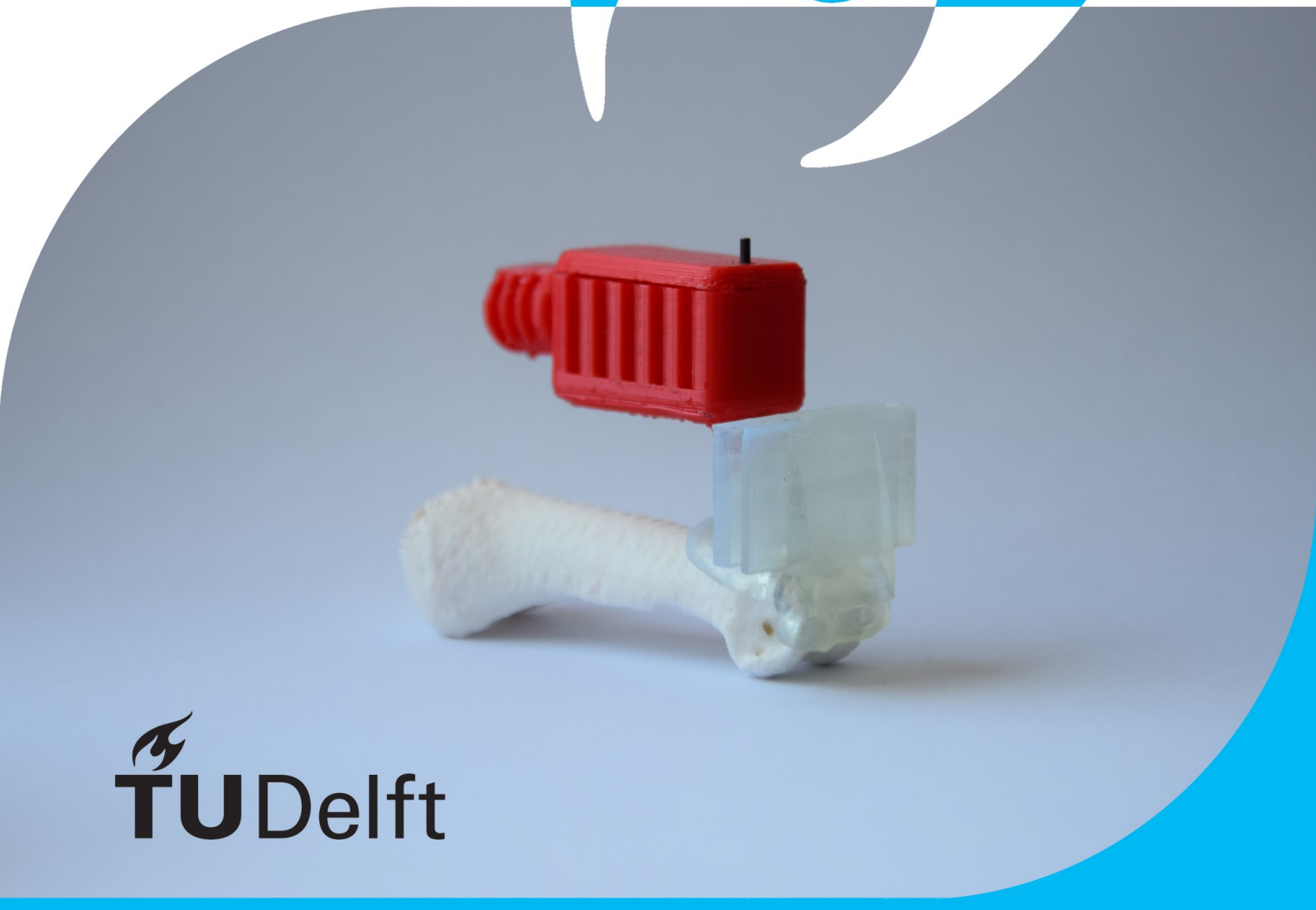
A Clear Cut Case

The Development of a Surgical Instrument for Orthopaedic Surgery

by Menno Schijf



TU Delft

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The Development of a Surgical Instrument for Orthopaedic Surgery

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Menno Schijf

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TU Delft reinier haga orthopedisch centrum

Abstract

Introduction - Arthritis is a condition causing pain, deformations and loss of motion in human joints. The surgical instruments used to place a specific unconstrained prosthesis that is used to treat an arthritic joint are difficult to use. The objective for this thesis is to improve the current placement procedure by carrying out an analysis on the procedure and by developing a novel (set of) instrument(s). **Analysis -** Analysis displayed which instruments used during the placement procedure fall short, and in what way. The analysis forms the basis for a list of design criteria. **Concept design -** A concept was generated for the part of the procedure in which the bones are prepared such that the prosthesis can be placed. **Final design -** One of the surgical instruments that is part of the concept was designed in detail and a prototype was made. **Evaluation -** An evaluation study was carried out on cadaveric joints. The efficacy of the working principle of surgical instrument was demonstrated. **Discussion -** It is not possible to make a statistically significant comparison between the performance of the surgical instrument and the performance of the conventional instruments used for the same procedure. **Conclusion -** The surgical instrument could be an improvement to the current placement procedure. A comparative study between the surgical instrument and the conventional instruments should be carried out.

Preface

Throughout my many years as a student, writing a masters thesis always was this small spot on the horizon. However, in the beginning of 2021 this spot became bigger and bigger, and it was up to me to transform this vague spot into something concrete. I told my professor -Prof. dr. ir. Paul Breedveld- I enjoyed working on surgical instruments during my internship, after which Paul put me in touch with hand surgeon Dr. Gerald Kraan. I have never been as happy with a referral to a doctor as this one time. Gerald had a problem with placing a finger joint prosthesis, something that immediately interested me. I got the amazing opportunity to witness all sorts of orthopaedic surgeries at the Reinier Haga Orthopaedic Center. After many hours in the operating room, it was time to convert the acquired knowledge and inspiration into an engineering design. It was both fun and educational to combine medical and engineering knowledge into something people could actually benefit from in the future. I want to explicitly thank Gerald for all his support during the project. Gerald is one of the most driven and passionate people I know, a quality that reflects on other people. It motivated me to keep pushing myself, especially in difficult times.

The most satisfying part of the project was to see two pairs of hands -of which none were my own- work with the prototype of the design in the dissecting room, and to see the prototype work the way we hoped for. I want to thank Gerald and Mieke Schildmeijer, who sacrificed their evening off for this moment. This thesis could not have been finished without it. As far as I am concerned, that sacrifice is characteristic of the passion of people working in healthcare. I also want to thank Ian Blom, who was always willing to send me yet another CT-scan.

I want to thank Paul for his help and critical attitude. Paul often held up the mirror to me, which allowed me to zoom-out and see the bigger picture. I will never forget the conversations we had, in which all sorts of parallels were brought to the table: the way a car is put together - painting a fence - mother duck trying to count her children - the express train; you name it. I want to thank my daily supervisor Dr. ir. Gerwin Smit for sharing his insights, for always providing me with practical advise and for asking me the right questions. The conversations we had were very helpful and often contained an entertaining anecdote that was somehow related to the here and now.

Last but not least I want to thank my family and friends for their unconditional support. I could not have done it without them. I learned a lot about both engineering and life during my time at Delft University of Technology, and cannot wait to start the rest of my life.

Menno Schijf
Rijswijk, April 2022

Nomenclature

Term/abbreviation	Meaning
AOM	Arc Of Motion.
Arthritis	Painful condition that causes decreased motion and deformity of a joint.
Arthroplasty	Surgical treatment to restore the function of a joint.
Articulating surfaces	The surfaces of the bones that are in contact with each other as part of a joint.
Base	Proximal end of a bone.
CAD	Computer Aided Design
Cancellous bone	Spongious structure inside of a bone.
Collateral ligaments	Soft tissue on both the radial- and the ulnar side of the PIP joint that hold the joint together and provide stability. See Figure 1.2.
Condyles	Spherical structures at the end of a bone. See Figure 1.2.
Coronal plane	Medical term to indicate a geometric plane with respect to the hand. See Figure 1.1.
Cortex	Dense outer surface of a bone.
CT	Computer tomography, an imaging technology.
Digit	Finger
Distal	Medical term to indicate a direction with respect to the hand. See Figure 1.1.
DOF(s)	Degree(s) Of Freedom
Dorsal	Same as volar. Medical term to indicate a direction with respect to the hand. See Figure 1.1.
Epicondylar axis	Axis that goes through the origins of the collateral ligaments, associated with the AOR of a joint.
Fluoroscopy	An imaging technology.
FDM	Fused Deposition Modelling, a 3D-printing technology.
FP	Final Placement (of the prosthesis), phase 3 of the placement procedure.
FT	Functionality Test (of the prosthesis), phase 2 of the placement procedure.
Head	Distal end of a bone.
K-wire	Kirschner wire. A sterilized stainless steel pin that can be fixated into bone.
MCP joint	MetaCarpoPhalangeal joint. The joint at the base of the proximal phalanx, connecting the proximal phalanx to the hand.
Modulator	Instrument used to prepare the head of the proximal phalanx for a precision fit with the CapFlex prosthesis. See Figure 2.11.
OA	OsteoArthritis. Arthritic disease causing destruction the cartilage of the joint and osteophytic outgrowth on the periphery of the joint surface.
Osseointegration	Structural connection between living bone stock and the surface of an implant.
Osteophyte	Unwanted piece of bone that grows on the periphery of the joint surface as a consequence of OA: osteotphytic outgrowth.
Osteotomy (osteotomies)	Surgical procedure during which a piece of bone is cut.
Palmar	Medical term to indicate a direction with respect to the hand. See Figure 1.1.
Phalanx (phalanges)	A bone in the finger.
PIP joint	The Proximal InterPhalangeal joint. The joint at the head of the proximal phalanx, connecting the proximal- and middle phalanx.
PLA	PolyLactic Acid, filament often used in FDM printers.
PP	Preparing Phalanges, phase 1 of the placement procedure.
Proximal	Medical term to indicate a direction with respect to the hand. See Figure 1.1.
PSSG(s)	Patient Specific Surgical Guide(s)
RA	Rheumatoid Arthritis. Arthritic disease in which the patients joint is inflamed causing deformations that make the joint unstable.
Radial	Medical term to indicate a direction with respect to the hand. See Figure 1.1.
Resection	Surgical procedure during which bone stock or other human tissue is removed.
RFCAL	Requirements For Correct Alignment List.
ROM	Range Of Motion.

Term/abbreviation	Meaning
Sagittal plane	Medical term to indicate a geometric plane with respect to the hand. See Figure 1.1.
Shaft	Part of the bone in between the head and the base.
Sizer	Instrument used to determine the right size of the CapFlex prosthesis and to pierce channels in the phalanges.
SLA	Stereolithography, a 3D-printing technology.
SR	Surface Replacement prostheses are unconstrained prostheses that only require the articulating surfaces of the joint to be removed in order for the prosthesis to be placed.
Surgical guide	Surgical instrument used to guide another instrument -such as a saw or a drill- along a certain path.
TKA	Total Knee Arthroplasty
Transverse plane	Medical term to indicate a geometric plane with respect to the hand. See Figure 1.1.
Ulnar	Medical term to indicate a direction with respect to the hand. See Figure 1.1.
Volar	Same as dorsal. Medical term to indicate a direction with respect to the hand. See Figure 1.1.

Contents

1 Introduction

1.1. Background

1.1.1. The Proximal InterPhalangeal (PIP) joint

This thesis describes the development and evaluation of a novel surgical instrument that finds its application in hand surgery. See Figure 1.1 for a drawing of the hand, including the anatomical names of the planes and directions that are defined with respect to the hand. The human hand consists of 27 bones, of which 14 can be found in the fingers of the hand. These bones are called the *phalanges*. The proximal end of a phalanx is called the *base*, the distal end the *head* and the part in between the *shaft*. The locations at which the head and the base of two adjacent phalanges connect, are called joints. Joints allow for motion between the adjacent phalanges, and keep the bones connected to each other at the same time [18].

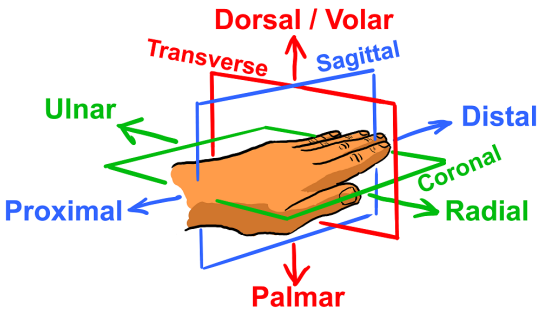


Figure 1.1: Drawing of a left hand showing the anatomical planes and directions defined with respect to the hand, according to standard conventions [4].

The Proximal InterPhalangeal (PIP) joint can be found in the index-, middle-, ring- and little finger, also called *digit* II, III, IV and V respectively. The PIP joint consists of the head of the proximal phalanx, the base of the middle phalanx, the surrounding soft tissue and is encapsulated by the joint capsule, see Figure 1.2. The PIP joint is a hinged joint that primarily allows for flexion-extension movement in the sagittal plane between the proximal- and middle phalanx. The Arc Of Motion (AOM) is approximately 100° [36]. The surfaces of the phalanges that are in contact with each other as part of the joint are called the *articulating surfaces*. They are covered in hyaline cartilage. The hyaline cartilage provides smooth rotation and absorbs shocks between the phalanges. Due to the the incongruity of the articulating surfaces, the axis of rotation is not fixed but slightly varies over the AOM [12]. Small movements outside of the sagittal plane are possible [36]. The phalanges are held together by the volar plate and the *collateral ligaments*. Additional stability comes from the joint capsule and the central slip. The central slip is part of the tendon responsible for extension of the PIP joint [18].

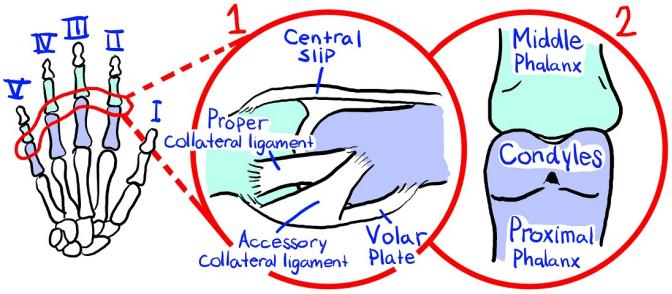


Figure 1.2: A schematic drawing of the bones of the hand and wrist is drawn to the left. The Proximal InterPhalangeal (PIP) joint can be found in finger number II, III, IV and V, in between the bone of the finger that is closest to the body, and the adjacent finger bone: the proximal- and middle phalanx respectively. In enlarged drawing **1**, the soft tissues surrounding the PIP joint are indicated in the sagittal plane. In enlarged drawing **2** the morphology of the bones that form the PIP joint is displayed in the coronal plane as seen from the palm of the hand (soft tissue is not drawn this time). The ridge at the base of the middle phalanx is positioned in between the *condyles* of the head of the proximal phalanx.

PIP joint *arthritis* is a painful condition that causes decreased motion of the joint and deformity. Arthritis of the PIP joint is most commonly caused by OsteoArthritis (OA) or post-traumatic arthritis, but also by Rheumatoid Arthritis (RA) [28]. OA destroys the hyaline cartilage of the joint. New, unwanted pieces of bone start to grow at the periphery of the joint: osteophytic outgrowth [21], see Figure 1.3. OA is the most common musculoskeletal condition [33], due to an ageing population. In RA patients, part of the joint is inflamed, causing parts of the joint to swell. Next to deformations of the joint and fingers, RA also makes the joint unstable as surrounding soft tissue is degenerated. The collateral ligaments are stretched by the swelling, which reduces lateral stability in the coronal plane [36].

1.1.2. Proximal interphalangeal joint prostheses

In case non-operative treatments such as anti-inflammatory drugs, physical therapy, corticosteroid injections or bracing do not treat an arthritic joint satisfactory, surgery might be an outcome [32]. One option is arthrodesis: a procedure in which the phalanges of the joint are fused together. Arthrodesis provides pain relief, however it leaves a non-

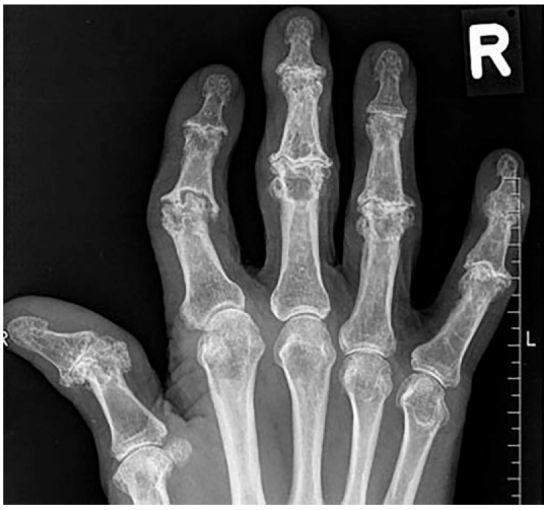


Figure 1.3: X-ray image displaying deformations and unwanted bone growth (osteophytic outgrowth) in the joints of the fingers of a patient suffering from osteoarthritis. The joint between the proximal- and middle phalanx of the index finger -the proximal interphalangeal joint- is severely deformed. Source: [11].

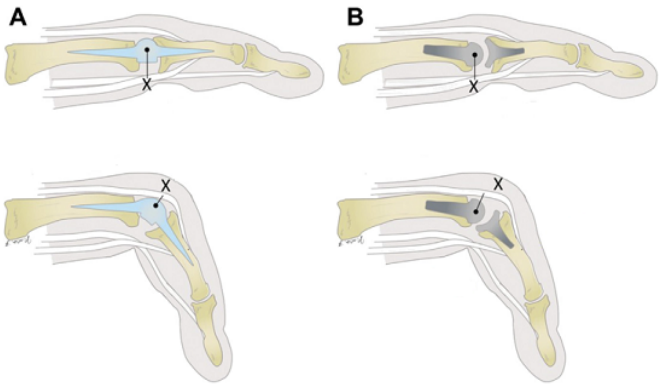


Figure 1.4: Arthritic joints can be treated by means of prostheses in order to reduce pain and (partially) restore joint function. In **A** a silicone constrained prosthesis is placed at the location of the proximal interphalangeal joint. **B** Displays the use of an unconstrained prosthesis. The black dots indicated by an *x* highlights the axes of rotation of the joints. Source: adapted from [36].

functional joint [28]. A prosthesis can also be placed to surgically restore the function of the joint. This is called *arthroplasty* by means of a prosthesis. The golden standard in PIP joint arthroplasty is the use of a one-piece constrained silicone prosthesis. The compliant hinge element of the prosthesis only allows in-plane rotation of the joint[36], see Figure 1.4. The prosthesis is recommended for patients having degenerated soft tissue [23], and requires the collateral ligaments to be removed. Long-term follow-up studies show satisfactory results regarding pain relief, patient satisfaction and revision rates. However, restore of joint function is limited and the prosthesis suffers from many cases of breakage and dislocation as a consequence of poor lateral stability [25].

Unconstrained and semi-constrained prostheses such as surface replacement (SR) and pyrocarbon prostheses entered the playfield as early as 1979 [35], see Figure 1.4. These prostheses consist of two parts and thus do not constrain out of plane motion, hence their names. SR means that only the articulating surfaces of the joint are replaced by the prosthesis. Pyrocarbon, or pyrolytic carbon, is a material with similar mechanical properties to that of bone. Unconstrained and semi-constrained prostheses rely on the intrinsic stability of the soft tissue surrounding the joint; the collateral ligaments are maintained during the placement procedure [28]. Placing them also allows to correct for frontal- and longitudinal axis deviation of the phalanges, which contributes to the stability of the joint [25]. Unconstrained prostheses have been proven to perform better regarding post-op range of motion (ROM) than constrained silicone prostheses [8]. They also more stable [10].

1.1.3. The CapFlex prosthesis

Unfortunately, also unconstrained and semi-constrained prostheses showed many imperfections. Pyrocarbon and ceramic SR prostheses fail in properly connecting to living bone stock. This is called poor *osseointegration*. This causes migration of the prosthesis and leads to high revision rates. In order for the phalanges to match the shape of the base of the prosthesis, several pieces of bone need to be cut of the phalanges. This process is called *resection*. Cutting of a piece of bone is called *osteotomy*. SR and pyrocarbon prostheses still require much of bone to be resected, making it hard to execute revision surgery. There simply is almost no bone stock left to anchor the new prosthesis into [25]. In 2015 the CapFlex PIP Prosthesis was introduced by the German company KLS Martin, see Figure 1.5. From this point on it is referred to as the CapFlex prosthesis.

Figure 1.5: The company KLS Martin from Germany developed an unconstrained surface replacement prosthesis to restore the function of the Proximal InterPhalangeal (PIP) joint. This prosthesis is called the CapFlex PIP prosthesis. Source: [9].

The CapFlex prosthesis is an unconstrained SR modular gliding PIP joint prosthesis. The proximal component is a bicondylar cap of cobalt-chrome alloy. The distal component has an articulating surface of ultra high molecular weight polyethylene, containing a ridge in the middle. The bicondylar cap and the ridge mimic the anatomical shape of the PIP joint, increasing lateral stability [25, 36]. The design requires minimal resection due to its size, and distinguishes itself from other SR prostheses by the short stems used for secondary fixation [35]. The stems and base of both compo-

nents are made of porous titanium, stimulating cement-free osseointegration. The first method of fixation is a press-fit [26]. The ideal tension on the collateral ligaments can be found in an iterative manner inter-operatively, as the surgeon can choose from three different thicknesses for the distal component. This optimizes joint stability [25]. Mid-term follow-up shows favourable clinical performance and patient reported outcome measures, as well as lower revision rates than pyrocarbon and other SR prostheses [23].

1.1.4. Misalignment of the prosthesis

A call from the field

Dr. G.A. Kraan -an experienced orthopaedic hand surgeon at the Reinier Haga Orthopaedic Center in Zoetermeer- experiences difficulty in placing the CapFlex prosthesis. The resection process requires four osteotomies. Dr. G.A. Kraan experiences that the instruments used to assist in making well-aligned and straight osteotomies -so called *surgical guides*- are difficult to use. Only experienced hand surgeons perform the procedure at the Reinier Haga Orthopaedic Center. This means that inexperienced surgeons in training cannot practice this procedure. Not only do these instruments cause longer operation times, sometimes the prosthesis is even malpositioned. In Dr. G.A. Kraan's experience, this leads to shorter lifetime of the prosthesis, and thus to unnecessary early revision of the prosthesis.

Misalignment of unconstrained prostheses

A prospective case series on the CapFlex prosthesis also mentions complications caused by slight malpositioning of the proximal component of the prosthesis during the placement procedure [25]. This caused the prosthesis to have an axial deviation relative to the proximal phalanx. Axial deviation causes the articular surfaces to slide over each other under an angle. The collateral ligaments pull the phalanges together. When the contact surfaces between the phalanges are under a slight angle, this force can cause the phalanges to slide past each other: dislocation of the joint. Dislocation appears to be a more frequently seen complication in patients having an unconstrained prosthesis. Researchers reported on dislocation between 14% and 17% of all cases after placing an unconstrained prosthesis [7, 8, 30]. Dislocation can lead to reoperation [30], and was reported to be the cause for reoperation in 2 out of 3 cases in a study on reoperation after unconstrained arthroplasty [19]. Another study on reoperation after unconstrained arthroplasty investigated 76 cases [22]. 80% of the causes were soft-tissue related. 22 times the cause for reoperation was one that can directly be tackled by improving either the way of fixation or the placement procedure. Four of those 22 fixable causes were misalignment of the prosthesis, a significant part.

The placement procedure

A short analysis of the placement procedures of unconstrained prostheses [2, 9, 29] learns that the osteotomies made to resect the phalanges are either performed using surgical guides or freehanded. Validation of the alignment of these osteotomies is done in an indirect manner. A test-prosthesis is placed on the phalanges, radiographs are made and the surgeon judges whether the prosthesis is aligned correctly or not. The surgical guides that are used during the placement procedure of the CapFlex prosthesis specifically, are not fully constrained relative to the phalanges. They all allow for multiple Degrees Of Freedom (DOFs) between the surgical guide and the phalanx at the moment they are being used. This means that the orientation of a cut could change during the execution of the cut. It is not clear how the surgeon should know how to align the surgical guides relative to the phalanges, let alone how the surgical guides provide in correct alignment of the prosthesis. A more detailed analysis of the placement procedure and accessory instruments is needed in order to completely understand and improve them.

1.2. Problem definition

The instruments used to place the CapFlex prosthesis should help the surgeon in such a way that they align the proximal and middle phalanges anatomically correct. The current set of instruments to place the CapFlex prosthesis is difficult to use and does not guarantee correct alignment of the prosthesis relative to the phalanges, and thus of the phalanges involved. The success of the alignment procedure is subject to the skill and eye of the surgeon. Not being able to guarantee correct alignment of the proximal and middle phalanges is a problem, because the alignment influences the stability of the prosthesis and thus its lifetime.

1.3. Objective of this Thesis

The objective of this thesis is to improve the placement procedure of the CapFlex prosthesis by:

- Performing an analysis on the current placement procedure and accessory instruments to display their shortcomings.
- Developing a novel (set of) instrument(s) for improved alignment of the prosthesis.

1.4. Layout of this Thesis

Before the first steps of designing a new (set of) instrument(s) can be taken, a deeper, more thorough analysis of the problem has to be made. In what phase of the placement procedure would an addition or improvement to the instrument set be most effective for improved alignment of the phalanges? In Chapter 2, first the requirements for correct alignment of the prosthesis are discussed. The current placement procedure is divided into phases and sub-phases and is described in detail. The functions and working principles of the instruments involved are discussed and their shortcomings are displayed. Once it is clear what would be the most effective way to improve the placement procedure, the design direction is set out. Then the design criteria are defined. They function as the foundation for the conceptual design. The novel concept for an improved placement procedure is presented, explained and motivated in Chapter 3. How does it work, why does it work, and why does it work better than other concepts that were generated? The chapter is concluded by a description of the instruments that have to be designed in detail, along with additional design criteria.

In Chapter 4 the final design of the novel instruments is presented. The production process is also discussed. In Chapter 5 a study evaluating the novel instruments is presented. The evaluation is cut up into two parts: a test on artificial bone and a test on a cadaveric hand. It is explained what is evaluated, why it is evaluated and how it is evaluated. The results are presented after. In Chapter 6 the results of the evaluation are discussed. The performance of the design is judged according to the design criteria. An analysis of the design and the test environment clarifies the performance of the design. The performance is compared to the performance of the current placement procedure and to state-of-the-art technology. Strengths and limitations of the study are presented, after which a recommendation on future research follows. This thesis ends by presenting an overview of what can be concluded from this thesis in Chapter 7.

2

Analysis

2.1. Requirements for correct alignment of the prosthesis

In this chapter a thorough analysis of the current placement procedure of the CapFlex prosthesis is carried out. To understand every step of the placement procedure, it is important to understand how the prosthesis should be placed such that the phalanges are aligned correctly. In order to be able to define a list of requirements for correctly aligned placement of the prosthesis, it is important to keep in mind what the PIP joint should allow for. Ideally, there is only one DOF between the proximal and middle phalanx: the rotation for flexion/extension movement. In order to do so, **the axis of rotation should be orthogonal to the sagittal plane** (see Figure 2.1) **of both the proximal and middle phalanx**. To achieve this, **the prosthetic components should be placed on the phalanges such that these sagittal planes coincide**.

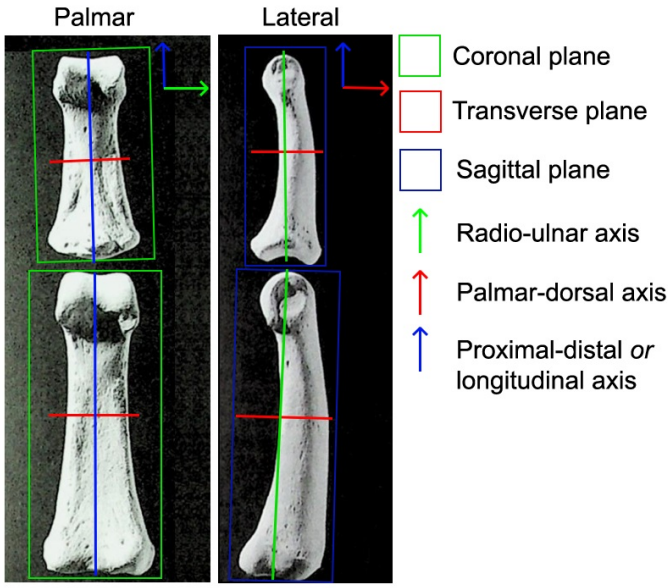


Figure 2.1: Figure illustrating the geometric planes and axes of the two phalanges that are involved in the proximal interphalangeal joint. The bone at the bottom is called the proximal phalanx, the one at the top the middle phalanx. The planes are called and chosen such that the orientation matches the standard conventions as used for a hand with all fingers in an extended position [4]. Source: adapted from [34].

The titanium base of the proximal component consists of two stems located on a flat surface and two 45° angled surfaces. The base of the distal component consists of three stems located on a flat surface, see Figure 2.2.

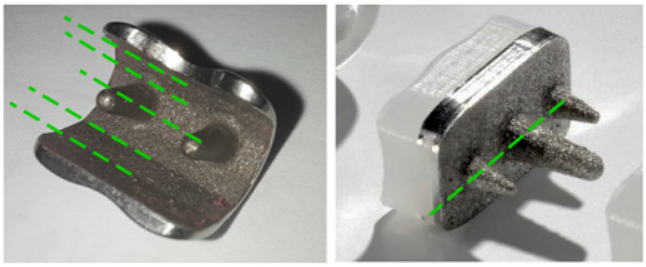


Figure 2.2: The two components of the CapFlex prosthesis. The proximal component is depicted on the left side, the distal component on the right side. The axes on which the stems and the edges of the 45° angled surfaces are located, are indicated with a green dotted line. The axes are all parallel to each other. Source: adapted from [9].

The axis of rotation of the CapFlex prosthesis is parallel to the axis on which the stems of both components of the prosthesis are located. The edges of the 45° angled surfaces on the base of the proximal component of the prosthesis are also parallel to this axis, see Figure 2.2. This means that for correct axial alignment of the phalanges, the prosthetic components should be placed on the head and base of the phalanges such that the following requirements are met:

1. The normal vector of the flat surface of the base of the proximal component should be parallel to the longitudinal axis of the proximal phalanx, see Figure 2.3. The longitudinal axis is the intersection of the coronal and the sagittal plane as can be seen in Figure 2.1.

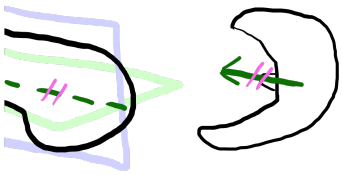


Figure 2.3: The first requirement for correct alignment of the prosthesis. The light-green and light-blue frames indicate the coronal and sagittal plane of the proximal phalanx respectively. The dark-green dotted line indicates the longitudinal axis of the proximal phalanx, the dark-green arrow indicates the normal vector of the flat surface of the base of the proximal component. The pink signs indicate these axes should be parallel.

2. The flat surface of the base of the proximal component should be approximately 4 mm proximal to the original most distal point of the head of the proximal phalanx, see Figure 2.4.

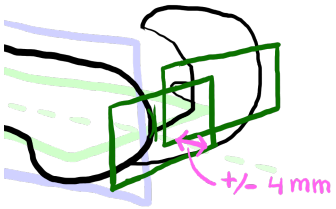


Figure 2.4: The second requirement for correct alignment of the prosthesis. The light-green and light-blue frames indicate the coronal and sagittal plane of the proximal phalanx respectively. The dark-green frames indicate the flat surface of the base of the proximal component and the most distal point of the head of the proximal phalanx. The pink arrow indicates that the distance between them should be approximately 4 mm.

3. The middle of the flat surface of base of the proximal component should coincide with the longitudinal axis of the proximal phalanx, see Figure 2.5.

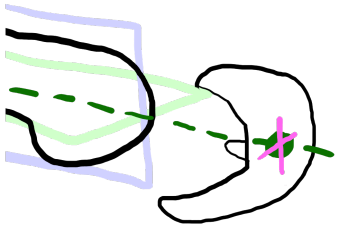


Figure 2.5: The third requirement for correct alignment of the prosthesis. The light-green and light-blue frames indicate the coronal and sagittal plane of the proximal phalanx respectively. The pink cross indicates that the middle of the flat surface of the base of the proximal component should coincide with the longitudinal axis -indicated by a dark-green dotted line- of the proximal phalanx.

4. The axis on which the stems of the proximal component are located, should be in the coronal plane of the proximal phalanx, see Figure 2.6. This automatically means that the axes on which the edges of the 45° angled surfaces of the proximal component are located, should be parallel to the the coronal plane, as these axes are parallel (See Figure 2.2.

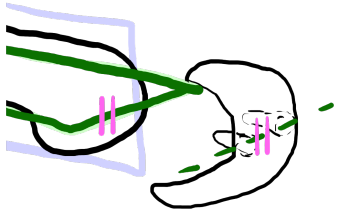


Figure 2.6: The fourth requirement for correct alignment of the prosthesis. The light-blue plane is the sagittal plane of the proximal phalanx. The dark-green dotted line is the axis on which the stems of the proximal component lie. This axis should lie within the the coronal plane of the proximal phalanx, indicated with a dark-green frame. The pink sign indicates this geometric equality.

5. The normal vector of the flat surface of the back of the distal component should be parallel to the longitudinal axis of the middle phalanx, see Figure 2.7.

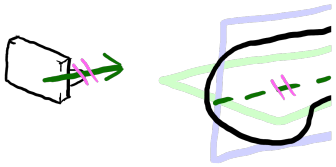


Figure 2.7: The fifth requirement for correct alignment of the prosthesis. The light-green and light-blue frames indicate the coronal and sagittal plane of the middle phalanx respectively. The dark-green dotted line indicates the longitudinal axis of the middle phalanx, the dark-green arrow indicates the normal vector of the flat surface of the base of the distal component. The pink signs indicate these axes should be parallel.

6. The flat surface of the base of the distal component should be at a maximum of 1 mm distal to the most proximal point of the base of the middle phalanx, see Figure 2.8. **Note:** This is not exact because the surgeon can vary in thickness of the distal component, so that the prosthesis functions well. This is explained in more detail in Appendix D.

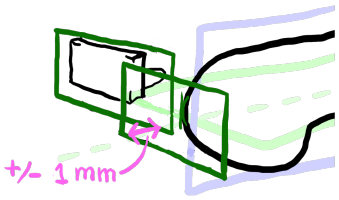


Figure 2.8: The sixth requirement for correct alignment of the prosthesis. The light-green and light-blue frames indicate the coronal and sagittal plane of the proximal phalanx respectively. The dark-green frames indicate the flat surface of the base of the distal component and the most proximal point of the base of the middle phalanx. The pink arrow indicates that the distance between them should be approximately 1 mm.

7. The middle of the flat surface of the base of the distal component should coincide with the longitudinal axis of the middle phalanx, see Figure 2.9

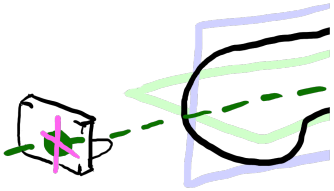


Figure 2.9: The seventh requirement for correct alignment of the prosthesis. The light-green and light-blue frames indicate the coronal and sagittal plane of the middle phalanx respectively. The pink cross indicates that the middle of the flat surface of the base of the distal component should coincide with the longitudinal axis -indicated by a dark-green dotted line- of the middle phalanx.

8. The axis on which the stems of the distal component are located, should be in the coronal plane of the middle phalanx, see Figure 2.10.

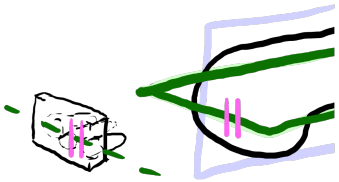


Figure 2.10: The eighth requirement for correct alignment of the prosthesis. The light-blue plane is the sagittal plane of the middle phalanx. The dark-green dotted line is the axis on which the stems of the distal component are located. This axis should lie within the the coronal plane of the middle phalanx, indicated with a dark-green frame. The pink sign indicates this geometric equality.

In this thesis, this list is referred to as the Requirements For Correct Alignment List (RFCAL). The shape of the head of proximal phalanx and the shape of the base of the middle phalanx have to match the shape of the base of the prosthetic components in order for the prosthesis to be placed on the phalanges. Therefore the phalanges are resected in such a way that when the prosthetic components are placed on the phalanges, the requirements of the RFCAL are fulfilled. The steps that are currently taken in order to do so are described in the next section.

2.2. Current placement procedure of the CapFlex prosthesis

2.2.1. Overview of the placement procedure

Dividing the placement procedure in phases and sub-phases

Before a detailed analysis of the individual steps of the placement procedure is made, an overview of the procedure is presented first. This is done so that there is an understanding of what role every individual step plays in the overall process. To give a better overview of the placement procedure, the procedure is divided into phases and sub-phases. This self-made division is made after analysis of the procedure using a dorsal approach, as prescribed by KLS Martin in their user manual [9]. Since the relevant steps are the ones concerning alignment of the prosthesis, the first phase starts at the point the joint is already exposed. Everything before that point is standard surgical procedure and has nothing to do with the alignment of the prosthesis. The names for the three phases are:

1. Phase 1: **Preparing phalanges**, see Figure 2.11.
2. Phase 2: **Functionality test** of the prosthesis, see Figure 2.12.
3. Phase 3: **Final placement** of the prosthesis, see Figure 2.13.

Each phase consists of a number of sub-phases with corresponding instruments supplied by KLS Martin. To clearly visualize this, see an overview per phase in Figure 2.11, 2.12 and 2.13. The schematic pictures on top of the schematics

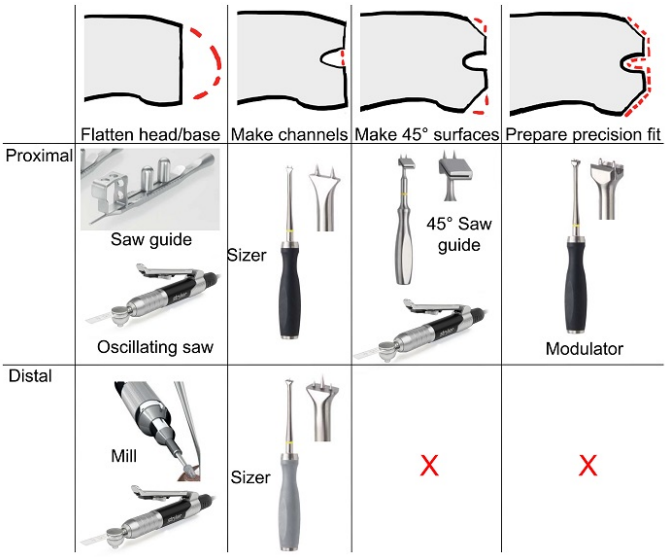


Figure 2.11: Phase 1: **Preparing phalanges** and all of its sub-phases with corresponding instruments [9]. Note the difference between the instruments used for the preparation of the proximal- and middle phalanx. For the drawings in the top row, lines in black indicate the part that remains in that sub-phase and lines in red indicate parts that are removed in that sub-phase. Source: adapted from [9].

give an indication of what is done in the corresponding sub-phase.

Before a more detailed analysis is carried out, a brief explanation corresponding to the sub-phases in Figure 2.11, 2.12 and 2.13 will follow so there is a general idea of the procedure and the instruments that are used, before the details are presented.

As stated before, the CapFlex prosthesis is a surface replacement prosthesis, meaning only the outer end of the phalanges is resected and the collateral ligaments are maintained. Initially it is fixated by a press-fit and secondary by osseointegration due to the porous titanium base of both components [26]. In order for the press-fit to be successful, the resected surfaces at the end of the phalangese have to match the shape of the prosthesis. The prosthesis uses the shape of the head of the proximal phalanx and the base of the middle phalanx for its orientation. Therefore it is extremely important that the resected surfaces align with the planes of the phalanges in the same manner as the surfaces of the prosthesis should, as described in the RFCAL in Section 2.1.

Phase 1: Preparing phalanges

The goal of the first phase of the procedure is to manipulate the phalanges such that they have the shape and orientation described in Section 2.1. In this thesis this phase is called: **Preparing Phalanges** (PP), see Figure 2.11. In the first sub-phase of PP the bone is cut such that the flat surfaces of the prosthetic components are matched by the phalanges. This is done using a so called *surgical guide* and an oscillating saw for the proximal phalanx. For the middle phalanx special bone cutting pliers, an oscillating saw and/or a mill are used to flatten the base. No guiding instruments are used for the middle phalanx. This sub-phase contributes to Requirement **1, 2, 5** and **6** of the RFCAL and forms the basis for

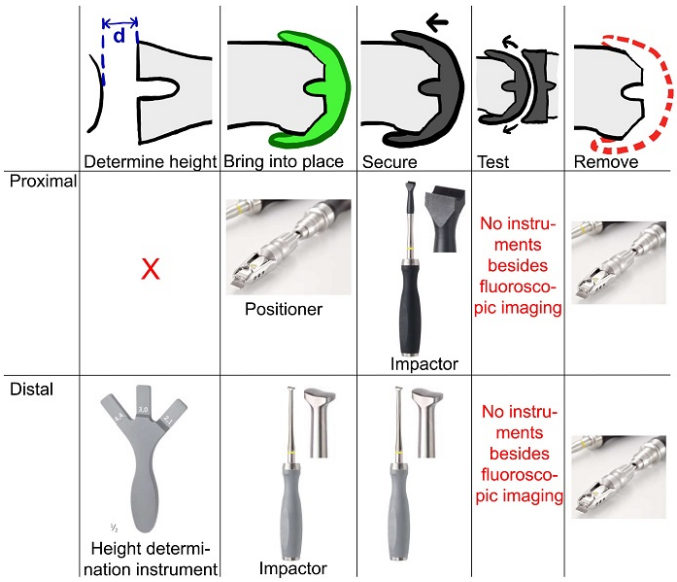


Figure 2.12: Phase 2: **Functionality test** of the prosthesis, and all of its sub-phases with corresponding instruments [9]. Note the difference between the instruments used for the placing and removing of the proximal- and distal components. For the top row, lines in black indicate the part that remains in that sub-phase, lines in red indicate parts that are removed in that sub-phase, and lines in green indicate parts that are added in that sub-phase. Source: adapted from [9].

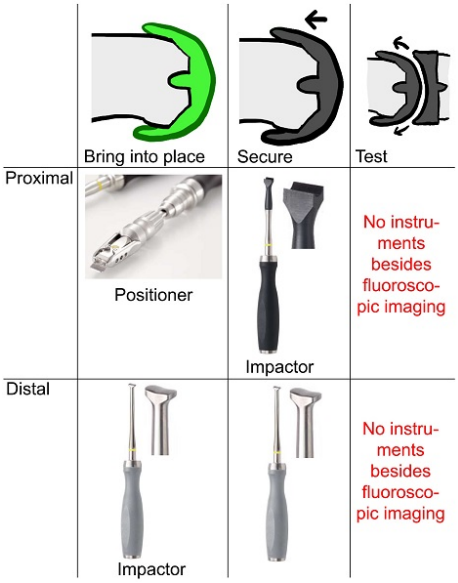


Figure 2.13: Phase 3: **Final placement** of the prosthesis, and all of its sub-phases with corresponding instruments [9]. Note the difference between the instruments used for the placing and removing of the proximal- and distal components. For the top row, lines in black indicate the part that remains in that sub-phase, lines in red indicate parts that are removed in that sub-phase, and lines in green indicate parts that are added in that sub-phase. Source: adapted from [9].

Requirement **2, 3, 4, 6, 7** and **8**. In the second sub-phase of PP the channels for the stems are made using a *sizer*. This instrument also allows the surgeon to pick the right size for the prosthesis. This sub-phase contributes to Requirement **3, 4, 7** and **8** of the RFCAL. The preparation of the middle phalanx is now done. However, the proximal component of the prosthesis has a more complicated shape, and two more manipulations need to take place. In the third sub-phase of PP the 45° angled surfaces are made using a surgical guide and an oscillating saw. This sub-phase contributes to Requirement **4** of the RFCAL. In the fourth sub-phase of PP the *modulator* is placed over the surfaces that were created in the steps before. The head of the modulator matches the outer contour of the head of the proximal phalanx. The modulator is then hammered so that the soft bone is compressed, making it stiffer and ensuring it matches the base of the proximal component of the prosthesis so that it allows for a press-fit. This sub-phase already relies on coverage of all the requirements of the RFCAL. Now both phalanges are fully prepared.

Phase 2: Functionality test of the prosthesis

The goal of the second phase is to test whether the phalanges are prepared such that the test prosthesis (and thus the final prosthesis) functions well. This is accompanied by picking the right thickness of the distal component. This phase is called: Functionality test of the prosthesis, or short: **Functionality Test** (FT), see Figure 2.12. Although the shape of the bone created in PP seems to fully determine the orientation of the prosthetic components (and thus alignment of the phalanges), FT also plays a roll in alignment of the phalanges. In the first sub-phase of FT the thickness for the distal component is determined. Chronologically speaking, first the proximal test prosthesis is placed, which is then used as a reference using the height determination instrument. The proximal component has no varying thickness, so this sub-phase does not exist for the proximal component. In the next sub-phase the test prosthesis is brought into place; for the proximal component using the *positioner*, for the distal component using the *impactor*. After the prosthesis is brought into place, it needs to be secured by press-fit. This is done by placing the head of the impactor over the test prosthesis and by hammering it. Once the test components of the prosthesis are placed, alignment is evaluated by *fluoroscopy* (an imaging technology) and joint motion is tested by passively flexing and extending the finger. Now the test prosthesis can be removed using the positioner again. If the surgeon was satisfied during testing and evaluating using fluoroscopy, he or she proceeds to the final phase. If not, he or she redoes (elements of) PP.

Phase 3: Final placement of the prosthesis

The goal of the third phase is to place and test the final prosthesis, hence its name: Final placement of the prosthesis, or short: **Final Placement** (FP), see Figure 2.13. FP is a repetition of FT, however this time without determining the correct thickness of the distal component, as that has already been done in TP. Next to that, the prosthesis is not removed this time, since the final prosthesis is being placed. In the first sub-phase the final prosthesis is brought into place using the positioner for the proximal component and the impactor for the distal component. In the next sub-phase the prosthetic components are secured utilizing a press-fit using the impactors in the same manner as before. Then again testing using fluoroscopy and by passively flexing and extending is done. If everything is in order the finger can be closed again. If not, the surgeon redoes (elements of) PP.

The order in which the phases are divided is not entirely chronological compared to the actual surgical procedure.

However, it is more insightful as it groups the different steps on its essence and gives a direct insight in the differences in the placement procedure between the proximal and distal component. The order in which the procedure usually takes place would be to first prepare the bone of the proximal phalanx, place the test prosthesis and make a fluoroscopic image. Then this would be repeated for the middle phalanx, after which the finger can be tested on extension and flexion. Then the final prosthesis would be placed on both phalanges.

Now that we know about all the phases of the dorsal placement procedure of the CapFlex prosthesis, what its subphases cover and what their goals are, we can go into the specifics and start analysing.

Since this thesis discusses the development of a novel (set of) instrument(s) used for the dorsal approach, only an analysis of this procedure can be found in this chapter. In case you want to know more about the palmar approach and the differences with the dorsal approach, please see Appendix C. Unfortunately this procedure does not offer any advantages regarding alignment of the phalanges. The most commonly used implants for SR arthroplasty are the Stryker/Small Bone Inventions SR PIP prosthesis and the Ascension PyroCarbon prosthesis [35]. An analysis of the placement procedures for these prostheses was also made. Unfortunately, these procedures did not offer any notable advantages regarding alignment of the phalanges and the analyses were therefore left out of the main body of this thesis. The analyses of the placement procedures for these prostheses can be found in Appendix A and B.

2.2.2. Detailed analysis of Phase 1: Preparing Phalanges

Flattening of the head/base of the phalanges

The first surgical guide provided by KLS Martin used to align the prosthesis is the *saw guide*, see Figure 2.14. Once the joint is exposed by making incisions in the soft tissue (See Figure 2.15a), the saw guide is used as can be seen in Figure 2.15b. The saw guide has three functions:

1. Position the saw blade such that the normal vector of the cutting surface is parallel to the longitudinal axis of the proximal phalanx (Requirement **1** of the RFCAL).
2. Make sure the cutting surface is constrained relative to the proximal phalanx according to Figure 2.18 during the osteotomy, such that there is no play during the osteotomy.
3. Allow the surgeon to vary the amount of bone he/she wants to remove from the head of the proximal phalanx (Requirement **2** of the RFCAL).

Usually the surgeon has to cut approximately 4 mm of the head of the proximal phalanx. This number is related to the thickness of the prosthesis. However, not every phalanx is the same, so there should be some freedom differentiate in this number. The saw guide consists of a so called "guide rail" indicated with number (1) in Figure 2.14. This thin rod is pushed beneath the proximal phalanx, in between the condyles of the proximal phalanx, see Figure 2.16. The shape of the condyles is used as a reference to align this guide rail with the longitudinal axis of the proximal phalanx. The guide rail of the saw guide is pushed beneath the proximal phalanx until the surface indicated with number (2) hits the head of the proximal phalanx. By unscrewing the knobs indicated with number (4), the surface indicated with number (3) can be pushed over the proximal phalanx until it is offset by 4 mm of the head of the proximal phalanx. This distance corresponds with the thickness of the proximal component of the CapFlex prosthesis. The knobs are tightened again and the surface indicated with (3) can now be used as a surface to guide the oscillating saw blade in order to resect the proximal phalanx, as can be seen in Figure 2.15b.

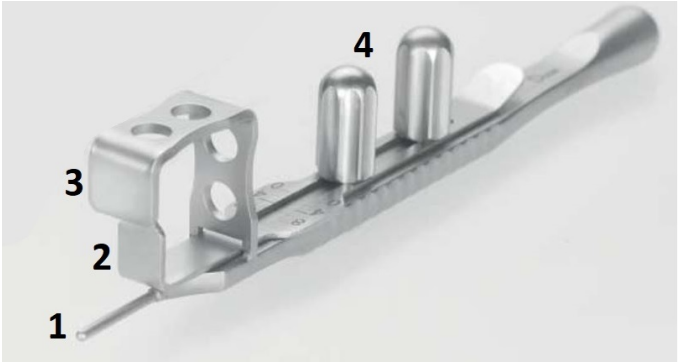
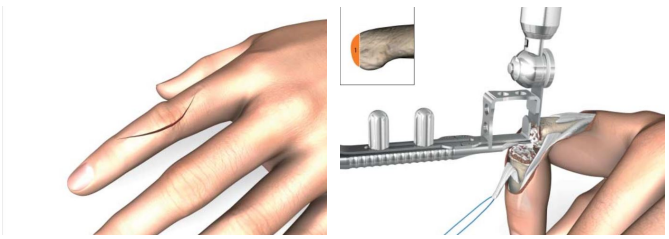


Figure 2.14: The saw guide used to perform the first cut of the head of the proximal phalanx, used in the dorsal approach of the placement procedure of the CapFlex prosthesis. The numbers indicate the: guide rail (1), the surface that should be placed against the head of the proximal phalanx (2), the surface that guides the cut (3), and the knobs to set the distance over which should be cut (4) [9]. Source: adapted from [9].

The first two functions of the saw guide are of great importance for correct alignment of the prosthesis. The surface created in this sub-phase completely determines whether Requirement **1** and **2** of the RFCAL are fulfilled.

However, the condyles that should help the surgeon in the initial positioning of the saw guide, only create two point contacts with the guide rail, which allows the longitudinal axis of the saw guide to deviate from the longitudinal axis of the proximal phalanx during initial positioning and during the osteotomy. See the rotation indicated in red (over the palmar-dorsal axis) in Figure 2.17. Also, there are no other forces besides reaction forces that constrain the instrument during the osteotomy. The reaction force provided



(a) Incision for the dorsal approach.

(b) Flattening of the head of the proximal phalanx. The saw guide is placed such that the oscillating saw should make a straight cut perpendicular to the longitudinal axis of the proximal phalanx.

Figure 2.15: Images of the incision for the dorsal approach and the flattening of the head as part of the first phase of the placement procedure of the CapFlex prosthesis. Source: [9].

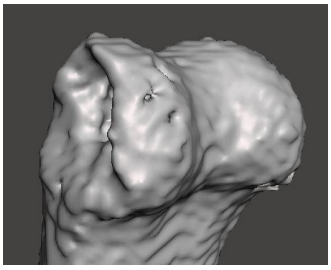


Figure 2.16: Image of the head and part of the body of the proximal phalanx as seen from a palmar perspective. The images shows the spherical condyles on the head of the proximal phalanx. The condyles are used as a reference by the guide rail of the saw guide used to flatten the head of the proximal phalanx.

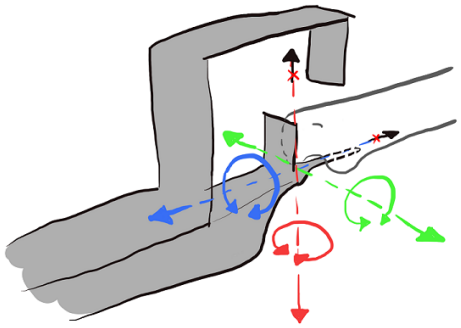


Figure 2.17: The degrees of freedom of the saw guide that are constrained relative to the proximal phalanx are black and are marked with a red "x", the other ones are free.

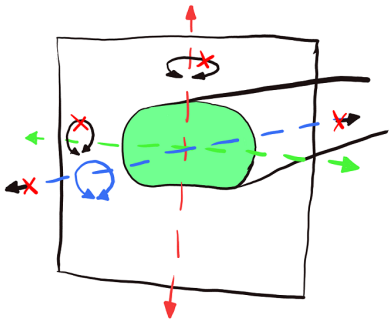


Figure 2.18: Picture indicating what Degrees Of Freedom (DOFs) of the cutting surface should be constrained during the cutting relative to the proximal phalanx. The DOFs that are black and are marked with a red "x" should be constrained, the others are free. The green surface indicates the cutting surface.

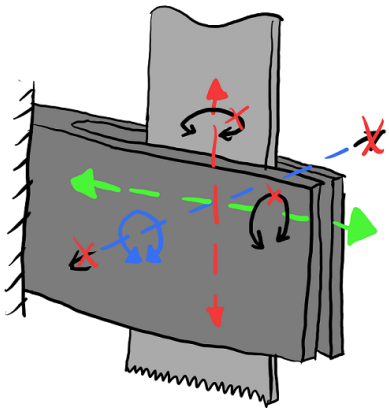


Figure 2.19: The guiding slot is connected to the rigid world (in this case the rest of the guiding instrument) to the left, the oscillating saw blade is drawn within it. The allowed degrees of freedom are drawn in color, the constrained ones in black marked by a red "x".

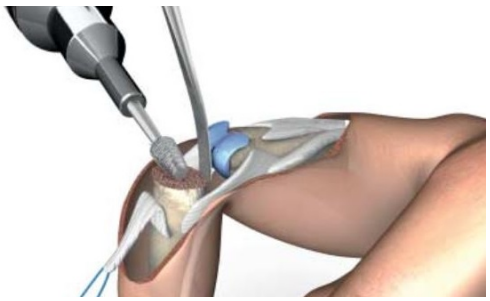


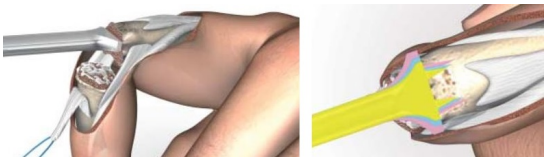
Figure 2.20: Flattening the head of the middle phalanx. A mill and/or an oscillating saw and a pair of pliers specially designed to cut bone are used to remove the bone. Source: [9].

by the proximal phalanx in combination with the force exerted by the surgeon constrain two translations, being the arrows marked with a red "x" in Figure 2.17. This results in four free DOFs: all translation and rotations that have no crosses through them in Figure 2.17. In stead of four, there should be only three free DOFs between the proximal phalanx and the cutting surface during cutting as can be seen in Figure 2.18. These are: translations over both the radio-ulnar and palmar-dorsal axes and rotation over the proximal-distal (from now on: longitudinal-) axis. In other words: in-plane movement. However, the guiding slot should already allow for these DOFs as depicted in Figure 2.19. This means that the saw guide itself should be constrained in all DOFs relative to the proximal phalanx. In other words, this instrument shoots short in two out of three functions: positioning the saw blade and constraining the cutting surface. Then we did not even mention that the surface past which the saw moves is in fact not a slot but a single surface. This means it only constraints translation orthogonal to the cutting surface in one direction, as it only offers a reaction force in one direction.

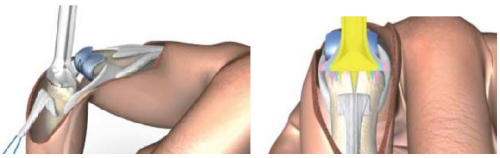
The flattening of the the base of the middle phalanx is done a little differently, see Figure 2.20. An oscillating saw or a pair of pliers specially designed to cut bone (such as the Luer Bone Rongeur) can be used to cut away the largest part. For the flattening usually a small hand mill is used, but an oscillating saw can do the job as well. Enough bone has been removed when the inside of the bone -a spongeous structure called *cancellous bone*- comes to the surface and the *cortex* disappears. The cortex is the dense outer surface of the bone. This is approximately 1 mm at most. This number is related to the thickness of the prosthesis. However, not every phalanx is the same, so there should be some freedom differentiate in this number. No specific instruments to guide this operation are supplied by KLS Martin. In arthritic patients, *osteophytes* may have grown on the margins of the joint. As osteophytes are unwanted pieces of bone, they are first removed, after which the middle phalanx is flexed to almost 90°. The collateral ligaments should be kept as intact.

In order to make sure the surface the cutting surface is flat the surgeon has to rely on his or her eyes and hands. In order

to make sure the normal vector to this surface is parallel to the longitudinal axis of the middle phalanx according to Requirement **5** of the RFCAL, again the surgeon has to rely on his or her eyes and hands. During the flattening of the surface the same DOFs should be constrained as during the flattening of the proximal phalanx as indicated in Figure 2.18. This should all come from the hand of the surgeon as there are no guiding instruments in place to assist in doing so. However, there is a technique that can help the surgeon in aligning this surface, called ligament based osteotomy. This technique uses the collateral ligaments in combination with the height determination instrument in order to help align the middle phalanx relative to the proximal phalanx, in an iterative way. However, this technique relies on the fact that the osteotomies performed on the proximal phalanx are executed in a well-aligned manner. The technique is explained in detail in the first paragraph of Appendix D.



(a) The proximal sizer is used to determine the size of the proximal component and pierces the cancellous bone with two spikes.



(b) The distal sizer is used to determine the size of the distal component and pierces the cancellous bone with three spikes.

Figure 2.21: Images of the making of the channels in both the proximal and the middle phalanx as part of the first phase of the placement procedure of the CapFlex prosthesis. For both sizers, three possible sizes are available: S, M and L indicated with yellow, blue and red respectively. Source: [9].

Making the channels

If everything went right, the normal vector of the surface that was just created on the head of the proximal phalanx is now parallel to the longitudinal axis of the proximal phalanx. The CapFlex prosthesis offers three sizes: S, M and L. Different combinations of sizes can be used for the proximal and the distal component. To determine the right size of the proximal component, an instrument called the proximal sizer is used, see Figure 2.21a. Just like with the prosthesis, there are also three sizes of this instrument that correspond with the size of the prosthesis. The width of the head of the instrument and the width of the bone are used to determine the right size, see Figure 2.21a. The size of the prosthesis should be chosen as small as possible in order to prevent soft-tissue irritation. Next to determining the right size of the proximal component, the sizer also pierces the cancellous bone in the proximal phalanx with two small channels that will later be used to place another surgical guide, the test prosthesis and the final prosthesis. The channels have to be pierced into the proximal phalanx such that Requirement **3** and **4** of the RFCAL are fulfilled. However, the way the surgeon has to ensure proper alignment is by eye and hand (!). None of the DOFs oft he sizer is constrained during the piecing of the bone, while the only possible DOF should be translation over the longitudinal axis. Next to that, the surgeon can feel if the head of the instrument out of which the spikes originate is flush against the surface of the bone, which provides a little extra tactile feedback.

For the middle phalanx a repetition of steps is taking place. Three small channels are pressed in the cancellous bone of the middle phalanx with the distal sizer, see Figure 2.21. That is also one of the two differences compared to sizing of the proximal phalanx: three instead of two channels, corresponding to the three stems on the base of the the distal component of the prosthesis. These have to be pressed into the proximal phalanx such that Requirement **6** and **7** of the RFCAL are fulfilled. The second difference is that this component should be chosen as large as possible to protect the prosthesis against subsidence. Yet again, alignment relies on the the eyes and hands of the surgeon, and there is some additional tactile feedback just like with the proximal component. None of the DOFs of the sizer are constrained during the piercing of the bone, while the only DOF that should be allowed is translation over the longitudinal axis.

The preparation of the middle phalanx is now completed, however for the proximal phalanx there are a few more steps to be fulfilled before the bone is fully prepared.

Making the 45° angled surfaces

The titanium base of the proximal component has two 45° angled surfaces, therefore the head of the resected proximal phalanx also needs these angled surfaces in order to match the base of the prosthesis. This step is called pre-contouring. The two channels pierced by the sizer are now used to outline the 45° saw log, see Figure 2.22. This instrument has three functions:

1. Position the saw blade such, that the normal vector of the surface along which the osteotomy is made is under a 45° angle relative to the coronal plane of the proximal phalanx (Requirement **4** of the RFCAL).
2. Position the saw blade such, that the edge of the 45° angled surface starts at the right position from the coronal plane such that the head of the proximal phalanx matches the base of the proximal component.
3. Make sure the cutting surface is constrained relative to the proximal phalanx according to Figure 2.24 during the osteotomy so that there is no play during the osteotomy.

The saw log has a 45° angled guide slot of 0.5 mm through which the oscillating saw is guided such that the angle of the cut is ensured. The dimensions of the saw log are such that the edge of the 45° angled surface starts at the right distance from the coronal plane, such that the head of the proximal phalanx matches the inside of the proximal component. Once the dorsal side is cut, the saw log is removed, flipped upside down, and used again such that the osteotomy on the palmar side can be made, see Figure 2.22. After the precontouring, the osteophytes can be removed.

The first two functions we identified for the saw log are of great importance for correct alignment of the prosthesis. The surfaces created in this sub-phase partially determine

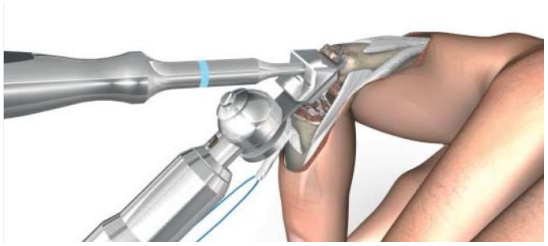


Figure 2.22: The 45° saw log and the oscillating saw are used to perform the angled cuts as part of the first phase of the placement procedure of the CapFlex prosthesis. Source: [9].

whether Requirement **4** of the RFCAL is fulfilled, as they influence the orientation of the edges of the 45° angled surfaces. The channels pierced in the previous sub-phase guide the saw log in its position/orientation using the spikes on top of the saw log. The interface between the cancellous bone and these spikes prevents the saw log from rotating over the longitudinal axis of the proximal phalanx, given the small diameter of the handle of the saw log. The rotation over the blue axis in Figure 2.23 (the longitudinal axis) is constrained. This means it succeeds in its first function.

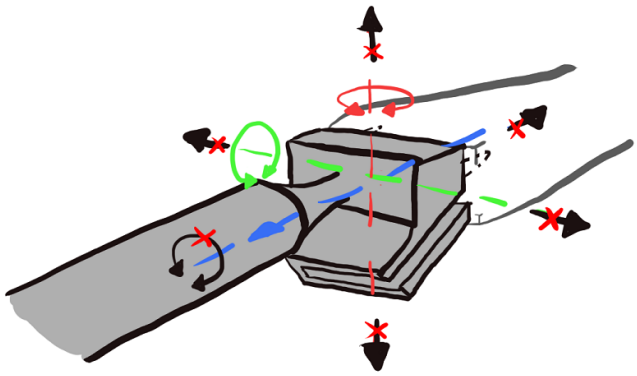


Figure 2.23: The degrees of freedom of the saw log that are constrained relative to the proximal phalanx during the execution of the cut are black and are marked with a red "x", the other ones are free.

All translations of the instrument relative to the proximal phalanx are constrained by the interface between the spikes of the saw log and the cancellous bone, and by the interface between the flat side of the instrument and the cancellous bone. See the arrows marked with a rex "x" in Figure 2.23. However, due to the high ratio between the long moment arm of the handle of the instrument over the green axis in Figure 2.24 (radio-ulnar axis) and the relatively short moment arm of the counteracting reaction force coming from the interface between the cancellous bone and the spikes, rotation is free over that axis. The same goes for the rotation over the red axis in Figure 2.24 (palmar-dorsal axis). Since the slot guiding the oscillating saw already allows three DOFs (see Figure 2.19) that can be free during the cutting as indicated in Figure 2.24, the guiding instrument itself should be constrained in all DOFs relative to the proximal phalanx. This means the saw log shoots short in two out of three functions: positioning the saw blade such that the cut is made at the right distance from the coronal plane and constraining the cutting surface. Contrary to the saw guide discussed

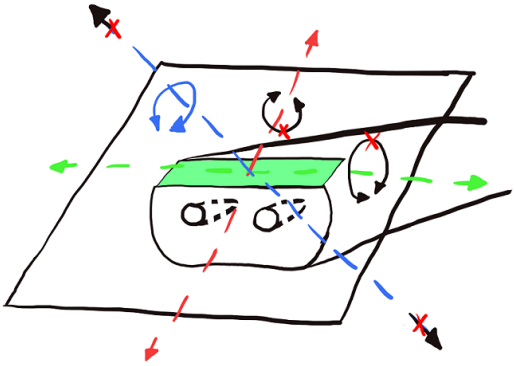


Figure 2.24: Drawing indicating what Degrees Of Freedom (DOFs) of the surface along which the angled cut is made should be constrained during the execution of the cut, relative to the proximal phalanx. The DOFs that are black and are marked with a red "x" should be constrained, the others are free. The green surface indicates the cutting surface.

earlier, the slot through which the oscillating saw is moved offers a reaction force in both directions of the DOF it should constrain.

Preparing for precision fit

The proximal component of the prosthesis is initially fixed with a press-fit. The cancellous bone is soft, and the precision fit asks for a high tolerance. Therefore the cancellous bone has to be compressed to make it stiffer. The modulator is the instrument used for this, see Figure 2.11. The modulator also helps to reduce errors in alignment of the newly created surfaces relative to each other. The internal contour of the head of this instrument is made such that once it is impacted by a hammer onto the proximal phalanx, a precision-fit prosthesis seat is prepared and modeled, see Figure 2.25.

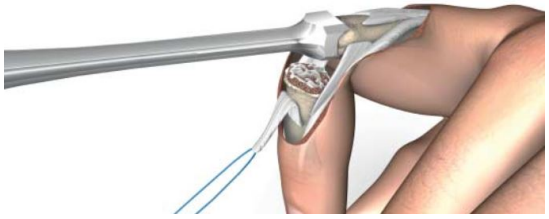


Figure 2.25: Preparation of precision fit as part of the first phase of the placement procedure of the CapFlex prosthesis. The modulator is impacted onto the proximal seat of the prosthesis using a hammer. Source: [9].

Ideally, the modulator would be guided by the outer contour of the proximal phalanx, and be aligned properly. That is: the inner contour of the head of the modulator should align exactly as the proximal prosthetic component according to Requirement **1, 2, 3** and **4** of the RFCAL. However, given the fact that there is quite some space for error in the previous sub-phases, this outer contour gives no guarantee in aligning the modulator correctly at all. Besides, the cancellous bone is soft, and given the long moment arm of the handle of the instrument, deviations can occur easily. The modulator is not guided by any instrument at all, nor is it constrained during hammering: its alignment depends completely on the eye and hand of the surgeon.

Detailed analysis of Phase 2 and 3: Functionality Test and Final Placement
As can be read in more detail in Section 2.3, analysis of the different phases displayed that improvements can be made most efficiently in Phase 1: PP. Therefore, the main body of this thesis will only contain a detailed analysis of Phase 1: PP. For a more detailed analysis of Phase 2: TP and Phase 3: FP, please see Appendix D.

2.3. Design direction

This thesis aims to develop a new (set of) instrument(s) for improved alignment of the proximal and middle phalanges. Given the limited time available, the most efficient approach is to only improve the elements of the procedure that offer the greatest gain. Hence the preceding analysis. In this section it is motivated what would be the most efficient improvement for improved alignment of the phalanges, and why it is the most efficient way. It sets the design direction used to define the design criteria in Section 2.4.

Despite the fact that in all three phases there are sub-phases that contribute to correct alignment of the phalanges, the greatest contribution is done in PP. Preparing the phalanges forms the foundation for correct alignment of the prosthesis. If this is done right, the outer contours of the head and base of the phalanges should guide the prosthetic components in place aligned correctly. Therefore it was decided to zoom-in further on PP.

In what sub-phases of PP could the most gain be achieved? Must the focus be only on the proximal or distal component? The quality of the preparation of the middle phalanx relies on correct alignment of the proximal component. Using ligament based osteotomy the surgeon can align the osteotomy of the middle phalanx in an iterative way. However, if the proximal component is already misaligned, alignment of the distal component is going to be even more difficult. Alignment of the proximal prosthetic component relative to the proximal phalanx is the foundation for correct alignment of the phalanges. Next to that, preparing the base of the middle phalanx is easier than aligning the head of the proximal phalanx, simply because there is less room for error. For the proximal phalanx, three surfaces (one flat surface and two 45° angled surfaces) need to be correctly aligned relative to each other **and** to the proximal phalanx. For the middle phalanx, the flat surface only needs to be correctly aligned relative to the middle phalanx itself. This is probably what KLS Martin figured as well, since they provide only two surgical guides for the preparation of the proximal phalanx, and non for preparation of the middle phalanx. However, the analysis displayed that these surgical guides fall short in aligning, while they should be the key to correct alignment of the proximal component.

All four sub-phases of PP contribute to correct alignment of the proximal prosthetic component relative to the proximal phalanx, as they combined fully cover Requirement **1, 2, 3** and **4** of the RFCAL. In order to fulfill these requirements, the procedures and instruments should be able to do the following four things:

1. Identify the important axes and planes to which should be aligned to in that sub-phase.
2. Position and orientate the instrument in order to make the manipulation to the proximal phalanx.
3. Constrain the instruments relative to the proximal phalanx during the manipulation of the proximal phalanx such, that there is no room for deviation during the manipulation.
4. Allow another instrument to manipulate the proximal phalanx.

The analysis showed that although the saw guide used for the first osteotomy tries to identify the longitudinal axis using the guide rail, it shoots short. The instrument lacks in positioning and especially in constraining relative to the proximal phalanx. The saw log identifies the important planes and positions the instrument correctly in case the previous sub-phases have been executed correctly, however fails in constraining relative to the proximal phalanx. The sizer also gives no guarantee that the important planes are identified, that the instrument is orientated and positioned correctly and it is not constrained at all during the manipulation. The modulator should be able to be positioned and orientated correctly in case the previous sub-phases are not executed properly, however it is not constrained relative to the proximal phalanx during the moment it is impacted. This leads to the fact that the quality of the execution of all sub-phases of PP for the proximal phalanx is very dependent on the eye, the hand -in other words- the skill of the surgeon.

Therefore the assignment for this thesis is limited to only improve the procedure and instruments for all sub-steps of the first phase: PP, and only focuses on the proximal phalanx. Requirement **1, 2, 3** and **4** of the RFCAL are used as a baseline to define the functional requirements in Section 2.4. In theory, a solution could be expanded to do the same for the distal component and the middle phalanx, involving Requirement **5, 6, 7** and **8** of the RFCAL. The design developed in this thesis will assist in aligning the instruments that are currently used for manipulation of the phalanx; there will not be a re-invention of the oscillating saw, the sizers or the modulator. They are instruments already suitable to execute the desired manipulations, just not to do it well-aligned. The design will guide the instruments such that they prepare the proximal phalanx for correct alignment of the CapFlex prosthesis relative to the proximal phalanx.

2.4. Design criteria

2.4.1. Functional requirements

The main function the novel (set of) instrument(s) should fulfill is:

Guide the instruments that are currently used for the preparation of the proximal phalanx (oscillating saw, sizer, modulator) such, that when the proximal component of the CapFlex prosthesis is placed on the head of the proximal phalanx, it is aligned relative to the proximal phalanx according to Requirement 1, 2, 3 and 4 of the RFCAL as defined in Section 2.1.

To succeed in this function, four sub-functions should be fulfilled by this novel (set of) instrument(s). The sub-functions and corresponding function trees can be found in Figure 2.26. A brief summary of the four sub-functions with-

out their function trees follows:

1. Guide the oscillating saw for the flattening of the head of the proximal phalanx, such that when the prosthesis is placed Requirements **1** and **2** of the RFCAL are fulfilled.
2. Guide the sizer for the making of the channels, such that when the prosthesis is placed Requirements **3** and **4** of the RFCAL are fulfilled.
3. Guide the oscillating saw for the cutting of the two 45° angled surfaces, such that when the prosthesis is placed Requirements **1, 2, 3** and **4** of the RFCAL are fulfilled..
4. Guide the modulator for preparing the head of the proximal phalanx for a precision fit, such that when the prosthesis is placed Requirements **1, 2, 3** and **4** of the RFCAL are fulfilled.

In order to be able to measure how well the novel (set of) instrument(s) perform(s) these sub-functions during an evaluation study, allowable tolerances should be defined. These tolerances indicate how far off the manipulations that are performed using the novel (set of) instrument(s) are allowed to be from the desired positions and orientations.

Tolerances

When we take a closer look at the function trees, we can identify ten items to which a geometric tolerance can be assigned. These tolerances determine the quality of the alignment of the proximal prosthetic component relative to the proximal phalanx. There is no data available on acceptable tolerances for PIP joint arthroplasty. A rule of thumb from the world of Total Knee Arthroplasty (TKA) is that the femoral component of the prosthesis may deviate $+/-3°$

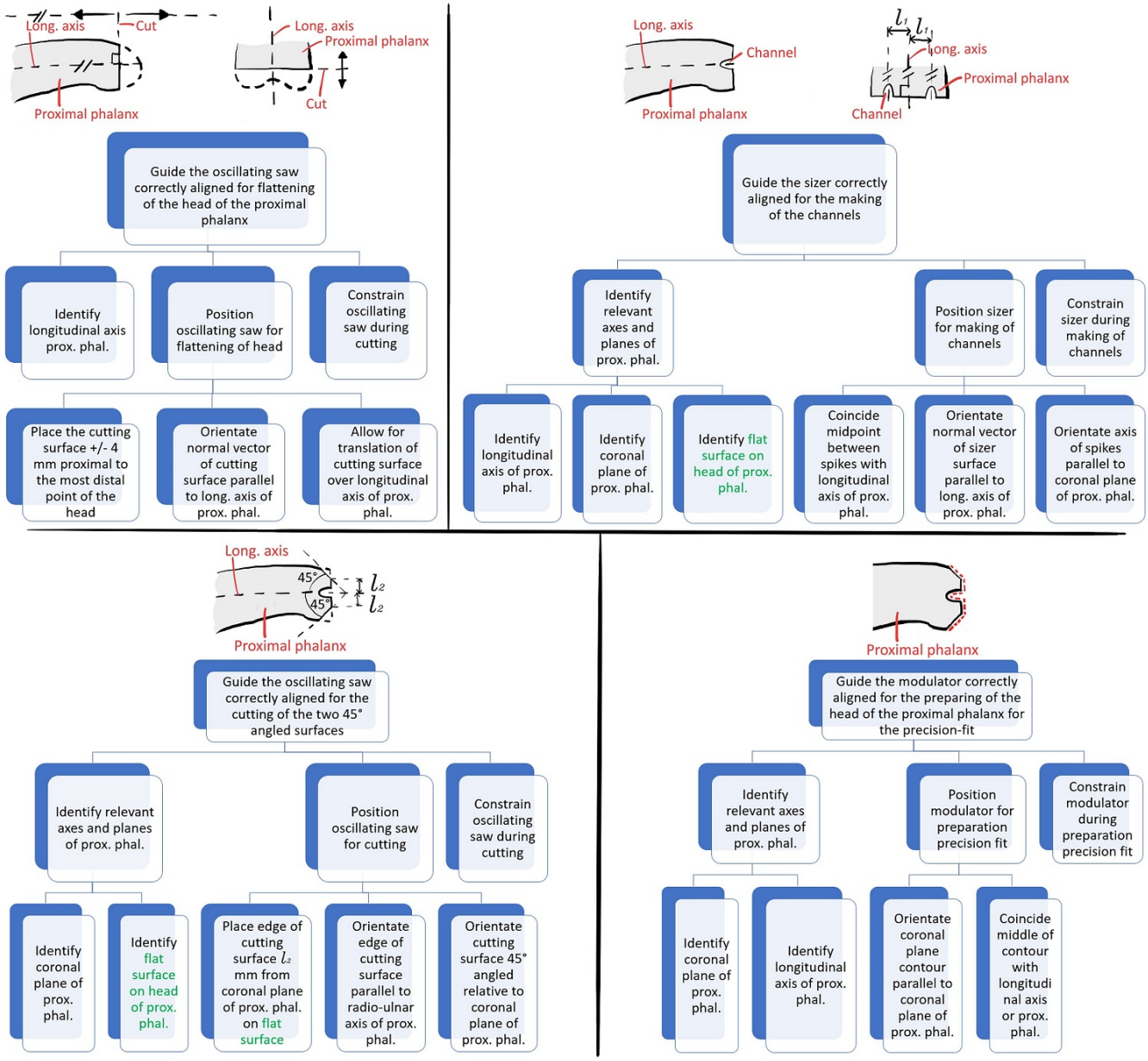


Figure 2.26: The four sub-functions the novel (set of) instrument(s) should fulfill, accompanied by their function trees. The drawing above the function tree illustrates the corresponding sub-function. The green-colored texts in the function tree refer to a geometry of the proximal phalanx that has been created in an earlier stage of the placement procedure; it is not a part of the natural anatomy of the proximal phalanx.

from the theoretical axis of rotation [16]. After consultation with Dr. G. A. Kraan it was decided to stick to this rule of thumb and also apply it to this design case. The other tolerances are determined in consultation with Dr. G. A. Kraan.

Now follows a list repeating the items from the function trees that demand a tolerance, followed by the tolerance:

- Place the first cutting surface 4 mm proximal to the anatomical end of the proximal head. **Tolerance:** $+/-0.5$ mm on longitudinal axis.
- Orientate normal vector of first cutting surface parallel to longitudinal axis of proximal phalanx. **Tolerance:** $+/-3°$ on both palmar-dorsal and radio-ulnar axis.
- Coincide midpoint between spikes with longitudinal axis of proximal phalanx **Tolerance:** $+/-0.5$ mm on both palmar-dorsal and radio-ulnar axis.
- Orientate normal vector of sizer surface parallel to longitudinal axis of proximal phalanx. **Tolerance:** $+/-3°$ on both palmar-dorsal and radio-ulnar axis.
- Orientate axis of spikes parallel to coronal plane of proximal phalanx. **Tolerance:** $+/-3°$ on longitudinal axis.
- Place edge of the 45° angled cutting surface l_2 mm (see Figure 2.26) from coronal plane of proximal phalanx on flat surface. **Tolerance:** $+/-0.5$ mm on both palmar-dorsal and radio-ulnar axis.
- Orientate edge of cutting surface parallel to radio-ulnar axis of proximal phalanx. **Tolerance:** $+/-3°$ on both longitudinal and palmar-dorsal axis.
- Orientate angled cutting surfaces 45° angled relative to coronal plane of proximal phalanx. **Tolerance:** $+/-1.5°$ on radio-ulnar axis (lower and upper part summed is $+/-3°$ total).
- Orientate coronal plane contour of modulator parallel to coronal plane of proximal phalanx. **Tolerance:** $+/-3°$ on both longitudinal and radio-ulnar axis.
- Coincide middle of contour modulator with longitudinal axis of proximal phalanx. **Tolerance:** $+/-0.5$ mm on both palmar-dorsal and radio-ulnar axis.

2.4.2. Design specifications

This list presents a number of items with design choices that are prescribed. The design will be according to these items.

- The design will consist of bio-compatible materials.
- The design will be suitable for digit II, III, IV and V.
- The design will be suitable for the dorsal approach.
- The design will either be usable for every patient, or easily be made patient specific.
- The design will use a physical reference –from the patient- for alignment.
- The design will be designed such that it guides the oscillating saw (specifically the Electric Pen Drive by the company called DePuy Synthes utilizing a 0.38 mm thick and 10 mm wide blade), the sizer and the modulator without blocking the movement demanded during the manipulations.
- The design will be disposable, as a re-usable instrument would greatly limit the design possibilities given the fact that it should be completely cleanable.

2.4.3. Design constraints

This list presents a number of items the design cannot do. The design is limited by these constraints.

- The design will not break when it is subject to the maximum force exerted by the surgeon.
- The stiffness of the design will be such that the maximum displacement within the design will not transcend the set tolerances when it is subject to the maximum force exerted by the surgeon.
- The design will not leave room for any DOFs between the design and the proximal phalanx once it is installed properly by the surgeon.
- The design will not block any DOFs of the middle phalanx relative to the proximal phalanx.
- The design will not block sight at the collateral ligaments.
- The design will not harm the ligaments, nerves and vessels.
- The design must fit within the space between the proximal and middle phalanx once the PIP joint is exposed.
- The design dimensions will not exceed the limits as drawn in in Figure 2.27.
- The design will weigh no more than 100 g.

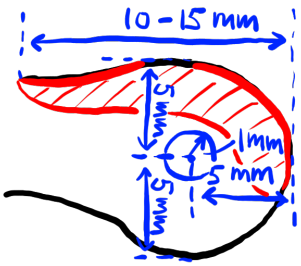


Figure 2.27: The red-hatched area indicates the area of the proximal phalanx that is exposed during the current placement procedure. It is very important that the collateral ligaments are not harmed. The area was determined in consultation with Dr. G. A. Kraan and based on data regarding the position of collateral ligament attachment [17]. The dimensions are based on a phalanx with a head of approximately 10 mm diameter. They are simply scaled for every phalanx in order to determine the available area.

2.4.4. Performance and evaluation criteria

The items on the following list can be used to evaluate how good or bad a design is. They can motivate design choices, but do not prescribe or constrain the design in any way.

- Degree of alignment (see tolerances in Subsection 2.4.1).
- Time it takes to use the instrument(s).
- Amount of steps it takes to use the instrument(s).
- Executability of these steps.
- Degree of invasiveness.
- Production time.
- Production cost.

3

Concept design

3.1. The new placement procedure

3.1.1. Introduction

A brief recap: the concept to be developed needs to assist in making three osteotomies, making two channels and compressing the resulting shape such that it has the exact dimensions for a precision fit with the prosthesis. This chapter first presents the overall concept generated to solve for all of these functions. A total of five surgical guides are developed. The guides have in common that they all cover three main functions: **identification** of relevant anatomical geometries, **positioning** the instrument needed for the specific manipulation of the phalanx and **constraining** the manipulating instrument relative to the proximal phalanx during this manipulation. The generation of these five instruments and their core working principles are all the same, as will become clear in the next paragraph. Therefore it was only develop and test one of these instruments. Developing all of them would prove nothing new as they are simply an extension of the first one. Doing so would only take more time. The guiding instrument that was chosen to be developed is the one used to guide the first osteotomy. After the explanation of the overall concept for the renewed part of the placement procedure, a detailed description of the first surgical guide follows. How does it work? Why does it work? How is it constructed? And why was it chosen over other concepts?

3.1.2. Overview of the new procedure

Pre-operative CT-scan

See Figure 3.1 and 3.2 for a visualization of the concept. The concept utilizes Patient Specific Surgical Guides (PSSGs). Therefore the new procedure also contains three pre-operative steps, in order to design and produce these instruments. To make these PSSGs, first computed tomography (CT) imaging technology is employed to obtain a precise and complete 3D-image of the patient's hand in the pre-operative situation.

Identification of anatomical geometries

The *epicondylar axes* (see Subsection 3.2.1), longitudinal axis, coronal plane, sagittal plane and transverse plane are drawn in the 3D-model of the proximal phalanx digitally, utilizing morphological landmarks. Based on this identification the correctly aligned cutting surfaces and locations for the channels can be drawn in the 3D-model.

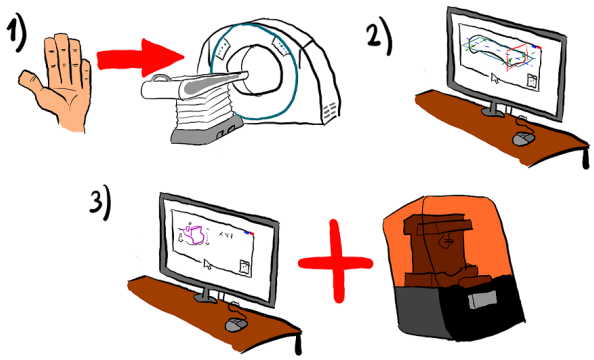


Figure 3.1: Schematic drawing illustrating the first three steps of the new placement procedure. First a pre-operative CT-scan is made of the hand of the patient. Then a digital identification of the osteotomy planes and positions of the channels is made. Based on this identification and the shape of the proximal phalanx, patient specific surgical guides are designed and produced using computer-aided design software and 3D-printing technology.

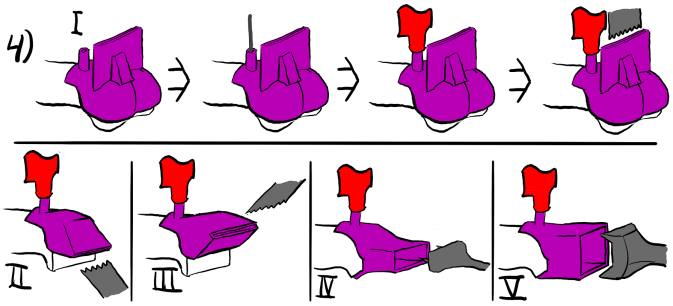


Figure 3.2: Schematic drawing illustrating the fourth step of the new placement procedure. First surgical guide I (purple) is placed on the head of the proximal phalanx. A pin is drilled into the phalanx, the clamp (red) is placed and the manipulation to the phalanx is made through the guide. The clamp and the guide can now be removed. The process is repeated for the remaining guides, while keeping the pin in place.

Digital design of patient specific surgical guides

A negative mold of the part of the head of the phalanx that is exposed during surgery is digitally generated, see Figure 3.2 for a visualization. The first PSSG can be digitally constructed using Computer Aided Design (CAD) software, physically connecting the negative mold to a slot that guides the first cut according to the previously made identification. For the construction of the second PSSG, the part of the phalanx that is cut away in the first osteotomy is now subtracted from the 3D-model of the phalanx, and a new negative mold can be digitally generated. Like before, the new negative

mold is connected to a slot that guides the first 45° cut. This process is repeated for all of the manipulations, so that five PSSGs are generated. See Figure 3.2 for a visual representation. These PSSGs are then 3D-printed using a resin printer.

Using the patient specific surgical guides

All surgical guides contain a vertical channel. After the PSSG is placed on the phalanx, the channel of the first PSSG is used to drill a sterilized pin made of stainless still into the dorsal side of the proximal phalanx. This pin is called a Kirschner wire, or short: *K-wire*. The K-wire is drilled until halfway the cancellous bone, It should not penetrate the cortex on the palmar side of the phalanx. The guide can only be placed on the proximal phalanx in one unique way, as it is a negative mold. This ensures the PSSG is placed exactly as planned pre-operatively. A clamp is then placed over the K-wire, pressing the guide against the phalanx, so that all DOFs are constrained. The first cut is made through the slot, the clamp is loosened, and the PSSG can be removed. The next surgical guide can now be placed over the K-wire, such that it encloses the head of the proximal phalanx. The clamp is placed like before, and the guide can now be used for the next osteotomy. This process is repeated for all of the PSSGs. After the final manipulation, the K-wire is removed as well and the placement procedure can continue in the usual manner as described in Section 2.2.

3.2. Identification of anatomical geometries

3.2.1. Used definitions of anatomical geometries

Although there is a general understanding of how the anatomical geometries are defined within the hand [4] as described in Section 2.1, there is no definition relating these geometries to morphological landmarks. In TKA, the clinical epicondylar axis is considered to coincide with the fixed flexion-extension axis of the knee, and is used as a reference by surgeons performing a TKA [1, 16]. This axis is thus perpendicular to what we considered to be the longitudinal axis in 2.1. The epicondylar axis coincides with the origins of the collateral ligaments [17] of the distal femur. The origins coincide with the outer most radial and end of the condyles of the joint, see Figure 3.3. A descriptive anatomical study on the axis of rotation (AOR) of the PIP joint concludes that -just like for the distal femur- the origins of the collateral ligaments of the proximal phalanx coincide with the AOR [17].

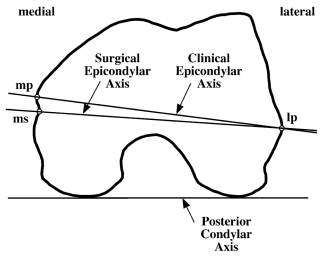


Figure 3.3: Schematic drawing of the distal femur -a bone part of the knee joint- relating the clinical epicondylar axis to anatomical landmarks, being the origins of the collateral ligaments at the outermost radial and ulnar points of the head of the bone. Source: [1].

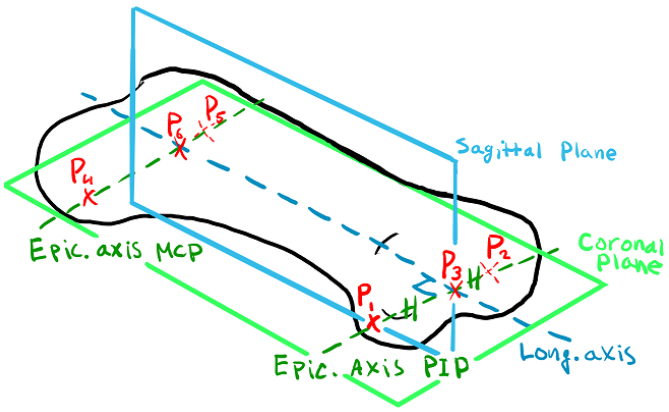


Figure 3.4: Schematic drawing indicating the identification of the anatomical geometries of the proximal phalanx. First the outermost radial and ulnar points on both the head and the base of the phalanx are identified, P_1, P_2, P_4 and P_5 respectively. The line between P_1 and P_2 is the epicondylar axis of the Proximal InterPhalangeal (PIP) joint. The midpoint of this line is called P_3. The line between P_4 and P_5 is the epicondylar axis of the MetaCarpoPhalangeal (MCP) joint. A line originating from P_3, orthogonal to the epicondylar axis of the PIP joint is constructed such that it intersects with the epicondylar axis of the MCP joint in P_6. This line is the longitudinal axis. The surface spanned by the longitudinal axis and the epicondylar axis of the PIP joint is the coronal plane.

In consultation with Dr. G.A. Kraan it was decided to take over these definitions, and apply them to the PIP joint to align the prosthesis correctly. When the the on which the stems of the prosthesis lie is parallel to the epicondylar axis, its axis of rotation would be parallel to the epicondylar axis and thus the assumed AOR of the joint. The epicondylar axes of the PIP and MetaCarpoPhalangeal (MCP) joint -the joint at the base of the proximal phalanx- can easily be identified via morphological landmarks. The longitudinal axis and the coronal plane are then constructed using these epicondylar axes. See Figure 3.4 and the caption for the way the construction of these axes is done.

3.2.2. Identification process

Inter-operative identification

Now that there is a definition of the anatomical geometries, somehow the morphological landmarks need to be identified on the actual patient's proximal phalanx. Then the surgeon can place the surgical guides relative to these axes and planes.

The first option would be to do this inter-operatively. Remember, the collateral ligaments are maintained in surface replacement arthroplasty. The morphological landmarks that are key to the identification -P_1, P_2, P_4 and P_5 in Figure 3.4- are covered by these collateral ligaments. For the MCP joint they are also covered by skin, as this joint is not exposed during the surgery. An estimation of these points based on visual and tactile information could deviate up to a couple of millimeters easily. In a scenario in which the estimations for P_1 and P_2 would deviate 2 mm in opposed direction over a PIP joint that is 13 mm wide, the estimated epicondylar axis would deviate $\arctan\frac{2+2}{13} \approx 17°$ from the true epicondylar axis. This number exceeds the set tolerance of 3 mm almost by a factor of 6. One of the generated concepts relied on a CT-scan in combination with this inter-operative

identification method. Because of this possible deviation of the epicondylar axis, it was not chosen. See Appendix F for a more detailed description of this concept.

Pre-operative identification

Another option would be to pre-operatively identify these morphological landmarks (and thus the anatomical geometries) by means of a CT-scan, and then somehow relate this pre-operative identification to the inter-operative situation. Using the Aquilion One CT by Canon, a 3D-image with increments of 0.25 mm between the separate slices that form the model can be made. This is a reliable, accurate and precise method and therefore the method of choice. The CT-scan generates an STL-file as output, which can be closely analysed and manipulated in CAD-software such as Solidworks. In Solidworks, we simply identify the morphological landmarks as described in Figure 3.4, after which all the anatomical geometries can be constructed. See Figure 3.5.

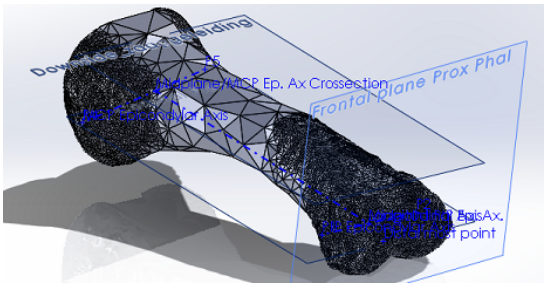


Figure 3.5: Screenshot taken from Solidworks. The relevant anatomical geometries of the proximal phalanx are constructed. Note that the density of the mesh has been reduced in the parts of the phalanx that are irrelevant for identification of the anatomical geometries and positioning of the patient specific surgical guide.

3.3. Positioning the surgical guide

3.3.1. Guiding the saw blade along the cutting surface

Now that the identification is done, the the exact orientation and position of the cutting surface can be digitally drawn in the 3D-model, according to the first two items of the RFCAL (see Section 2.1). It is chosen to guide the blade of the oscillating saw past this cutting surface through a slot. The thickness of the slot is easily adaptable. The slot constraints all DOFs except for in plane motion of the saw blade. Different saw blades could be used using the same slot. If for example the entire saw would be guided in stead of just the blade, a completely new guiding system of much greater size would have to be developed for every kind of oscillating saw. See the picture to the left in Figure 3.6 for the standardized part of the PSSG, containing the guiding slot. Using the identification done before, the standardized part can be oriented and positioned according to the first two items of the RFCAL, as can be seen in the picture to the right of Figure 3.6.

Another option to guide the saw past the cutting surface based on the previously done identification would be to use a robot and a reflective marker system. This is a method used in TKA in systems like the MAKO [27]. However, this would be a much more complex solution, and was therefore not chosen.

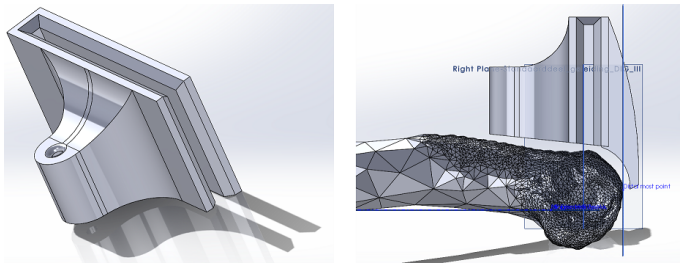


Figure 3.6: To the left: digital drawing in Solidworks of a 1 mm thick slot, used to guide the oscillating saw blade. To the right: digital drawing in which the guiding slot of the patient specific surgical guide floats 4 mm proximal to the end of the proximal phalanx along the longitudinal axis.

3.3.2. Positioning the surgical guide relative to the proximal phalanx

The use of a negative mold

The previously made digital identification and the resulting digital placement of the standardized part of the saw guide needs to be translated to the inter-operative situation. The way this is done is by (digitally) placing a negative mold of the head of the proximal phalanx over the head of the proximal phalanx, and by connecting this mold to the standardized part of the PSSG. See Figure 3.7. This negative mold can only be placed in one unique way on the phalanx, due to the shape of the head of the proximal phalanx. Since there is a rigid connection between this negative mold and the standardized part of the PSSG, the slot can only be positioned in one orientation and position relative to the proximal phalanx: as pre-operatively planned like in Figure 3.6. After digitally cutting away some material of the negative mold, the PSSG is finished and ready for production. See Figure 3.7.

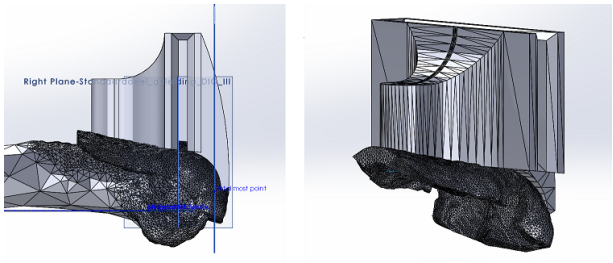


Figure 3.7: To the left: the negative mold of the proximal phalanx is connected to the standardized part of the Patient Specific Surgical Guide (PSSG). The PSSG can now only be positioned relative to the proximal phalanx in one unique way: as pre-operatively planned! To the right: the final digital model of the finished PSSG.

The use of a reproducible clamping orientation

Another concept was worked out to reproduce the pre-operatively planned situation in the inter-operative situation. This concept uses a clamp that clamps on all of the outermost points of the proximal phalanx, see Appendix E. However, it turned out to be difficult to exactly reproduce the pre-operaively planned orientation as there were multiple orientations possible. The flexibility of the skin was also an issue. Next to that, the concept relied on the placement of a K-wire that would pierce a tendon. This resulted in the concept not being viable.

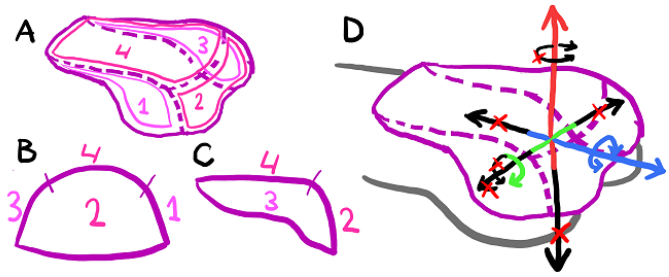


Figure 3.8: **A)** 3D-drawing indicating the four directionally distinguishable contact surfaces of the negative mold. Note that the standardized part of the Patient Specific Surgical Guide (PSSG) is left out of the drawing. **B)** Rear view of the negative mold **C)** Cross-sectional view in the coronal plane of the negative mold **D)** Grey indicates the proximal phalanx, purple the negative mold as part of the PSSG. The degrees of freedom of the PSSG to the proximal phalanx that are black and have a red cross through them are constrained, the other ones are free.

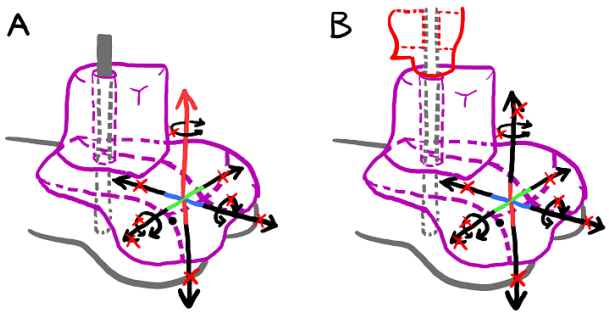


Figure 3.9: **A)** A pin is drilled through a channel of the Patient Specific Surgical Guide (PSSG) into the proximal phalanx. Grey indicates the proximal phalanx and the pin, purple the negative mold as part of the PSSG. The degrees of freedom of the PSSG relative to the proximal phalanx that are black and have a red cross through them are constrained, the other ones are free. **B)** A clamp (red) is pushed over the pin until its flush against the PSSG.

3.4. Constraining the surgical guide

3.4.1. Remaining degrees of freedom to constrain

Once the PSSG is placed on the head of the proximal phalanx, there are four directionally distinguishable contact surfaces between the head of the phalanx and the negative mold. See Figure 3.8. These surfaces are close to orthogonal with respect to each other. These four contact surfaces constrain the following DOFs of the negative mold and thus the PSSG relative to the phalanx: translation over the green axis (radio-ulnar axis), translation in proximal direction over the blue axis (proximal-distal or longitudinal axis), translation in palmar direction over the red axis (dorsal-palmar axis), counter-clockwise rotation over the green axis and rotation in both directions over the red axis. This means one DOF is free completely, and three DOFs are free in one direction. Extra constraints need to be added in order to constrain all six DOFs of the PSSG completely during the osteotomy.

3.4.2. Solution using a pin and a clamp

To constrain the remaining DOFs, two elements are added. See Figure 3.9. Once the PSSG is placed on the head of the phalanx, a K-wire is drilled through a channel parallel to the red axis. This K-wire fixates itself in the proximal phalanx. The K-wire disables both translation and rotation of the PSSG over the blue and green axes. Only one DOF remains, being translation in dorsal direction over the red axis. By pushing a clamp over the K-wire, flush against the PSSG, this DOF is also constrained. The clamp fixates itself relative to the K-wire and thus to the phalanx. The PSSG is now fully constrained.

3.5. Instruments to design

3.5.1. Patient specific surgical guide

To conclude this chapter a brief overview of what needs to be designed in detail is given. Now that the specifics about the concept to be designed are known, extra design specifications should be added to the list provided in Section 2.4. The PSSG is the first instrument to design in detail. For the evaluation described in Chapter 5 the intention was to test with the oscillating saw that is used during the actual placement procedure. Unfortunately it was not possible to borrow the Electric Pen Drive by DePuy Synthes, or any other oscillating saw used for small-bone-osteotomy. Therefore a Bosch Multitool was used in stead, having a greater evasion of the blade and a different blade. Constraining the PSSG is done using a K-wire. These two choices lead to the following adaptions/additions to the **design specifications:**

- The design will contain a 1 mm diameter channel parallel to the palmar-dorsal axis to guide the drilling of the K-wire.
- The design will be designed such that it guides the blade of a Bosch Multitool through a slot. The blade has a 0.78 mm thickness and is 10 mm wide. The Bosch Multitool oscillates over an arc of 2.8° and the distance from the center of rotation to the tip of the blade is 70 mm.

3.5.2. Clamp

The clamp is the second instrument to design in detail. The clamp must be easy to mount and dismount over the K-wire on top of the PSSG by hand. In theory the oscillating saw blade does not exert a force on the PSSG in the dorsal direction, so the clamping force does not have to be high. It should be just high enough to prevent the PSSG from moving as a consequence of vibrations transmitted by the oscillating saw blade. The design of the clamp must comply with the design criteria defined in Section 2.4, however a couple of specific design criteria for the clamp must be added to that list.

The following **functional requirements** for the clamp are defined:

- The clamp must keep the PSSG in place when vibrations from the saw blade are transmitted through the phalanx and PSSG at a maximum power of 130 W at a maximum frequency of 250 Hz.

The following **design specifications** for the clamp are defined:

- The clamp will fit around a 1 mm diameter K-wire.
- The clamp will be mounted and dismounted by hand.
- The clamp will either be disposable or completely cleanable.

4

Final design

4.1. Patient specific surgical guide

4.1.1. Digital design of the surgical guide

Design of the negative mold

Most of the steps that need to be fulfilled in order to generate the CAD design of the PSSG are already explained in Section 3.3, as they were necessary to understand the overall concept. However a few details have not been highlighted so far.

Naturally the surface on the radial and ulnar side of the head of the proximal have a concave feature, as can be seen in Figure 4.1. If the negative mold would simply be generated based on this shape and left unmanipulated, it would not be possible to place the negative mold over the head of the phalanx, assuming the negative mold is infinitely stiff, see Figure 4.2. This problem can be solved in two ways: either make the negative mold compliant enough so that it "snaps" around the head of the phalanx, or: remove this concave shape from the negative mold in CAD software. It was chosen to do the latter, as for every uniquely shaped phalanx a different amount of compliance would need to be calculated and applied. Simply removing the material is a very straightforward solution, and the unique fit of the negative mold is maintained.

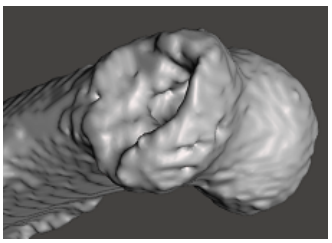


Figure 4.1: Digital image of the head of the proximal phalanx of the middle finger, generated using a CT-scan. The concave feature in the surface of the radial side of the head of the phalanx can clearly be seen.

Design of the guiding slot

The distance from the center of rotation of the oscillating blade, until the tip of the blade is 70 mm. The blade oscillates over an angle of 2.8° total, so with an amplitude of 1.4°. This results in an amplitude of $\tan 1.4 * 70 \approx 1.7$ mm at the tip of the blade. The slots are designed such that if the most ulnar located piece of bone is cut away by the 10 mm wide blade, there is still a 5 mm space between the side of the blade and the PSSG. The walls of the slot are -just like the walls of the negative mold- 1.5 mm thick. The slot itself is 1 mm thick, so that it leaves a total of 0.22 mm play between the blade and the saw guide in the direction orthogonal to the cutting surface.

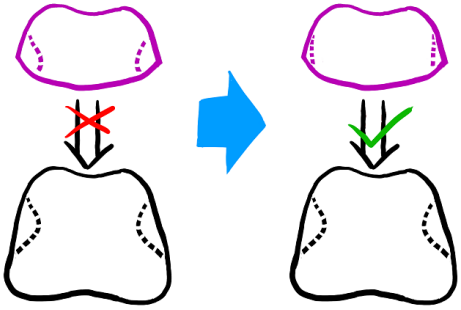


Figure 4.2: Two drawings from a frontal perspective. Purple indicates the negative mold as a part of the patient specific surgical guide, black indicates the head of the proximal phalanx. If the negative mold would contain the concave shapes from the head on the phalanx on the radial- and ulnar side (the situation to the left) it cannot be placed over the phalanx. Removing these shapes from the negative mold solves this problem (situation to the right).

The Bosch Multitool is not such a refined piece of equipment as the the Electric Pen Drive by DePuy Synthes which is equipped with torque control. The distance between the tip of the blade and the position at which the saw is held by the surgeon's hand is also much larger using the Bosch. This results in the surgeon having to deliver a greater counter-torque once the blade gets into contact with the phalanx. Therefore it was requested by Dr. G.A. Kraan to leave the radial side of the slot open, see Figure 4.3. By this way it is easier to avoid vibrating the side of the blade against the PSSG once the blade hits the phalanx. Using the DePuy Synthes Electirc Pen Drive this would be a lot easier, and it would be chosen to close the slot on both sides to increase the overall stiffness of the PSSG.

4.1.2. Physical production of the surgical guide

To assure the best possible quality for the shape of the negative mold, the PSSGs were 3D-printed using the Formlabs 3B SLA-printer. This resin printer can print layers as thin as 25 microns (!), has a laser resolution of 25 microns and a laser-spot size of 85 microns. Another advantage of this printer is that it can print in the BioMed Amber Resin, which is suitable for short-term skin or mucosal membrane contact and is compatible with common solvent disinfection and

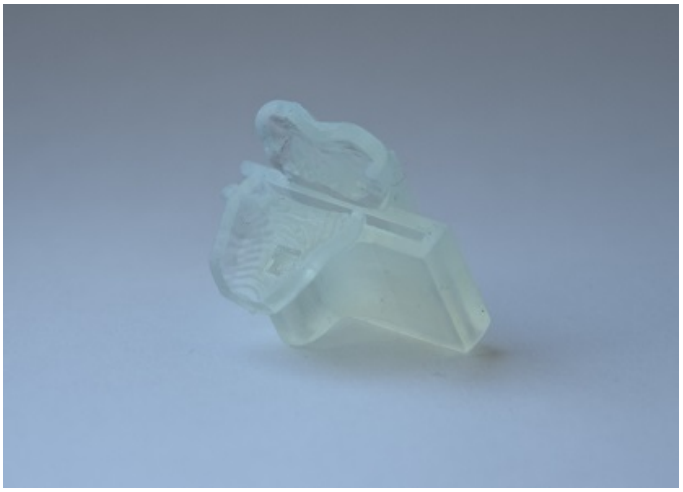


Figure 4.3: Photograph of the patient specific surgical guide turned upside-down. The negative mold of the head of the proximal phalanx, the channel through which a pin is drilled and the slot to guide the saw-blade are clearly visible.

sterilization methods. Buying this resin and an accessory tank was rather expensive. The advantages regarding biocompatibility and sterilization did not matter for our testing purposes, being a cadaveric study. Therefore it was chosen to use a material that was already available within the university: Clear V4. This is a transparent material. Printing one mold took around two and a half hours. See Figure 4.3. The weights of the PSSGs are: 2.41 g (digit II), 2.56 g (III), 2.52 g (IV), 1.72 g (V). The average amount of resin to produce one PSSG including support material was 2.6 mL, which comes down to a price of €0.59 per PSSG on material.

In case the CT-scans or production method is somehow not precise enough and the negative mold will not fit exactly around the head of the phalanx, a backup plan is needed. Therefore it was chosen to print an extra set of PSSGs, of which the dimensions of the negative mold are scaled up by 5%, which should compensate for small errors. Printing the PSSGs including their scaled versions for all four fingers took around six and a half hours. See Figure 4.4.

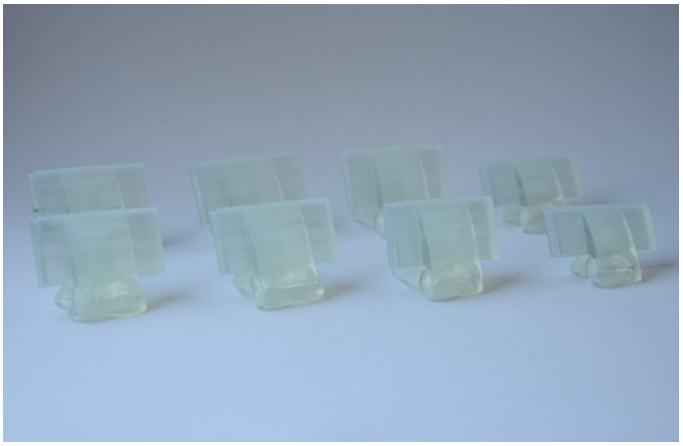


Figure 4.4: Photograph of the Patient Specific Surgical Guides (PSSGs) used to cut the proximal phalanx of the of the index-, middle-, ring- and little finger from left to right respectively. The front row consists of PSSGs that have an exact fit with the head of the proximal phalanx. The back row consists of PSSGs of which the dimensions of the negative mold are scaled by 5%.

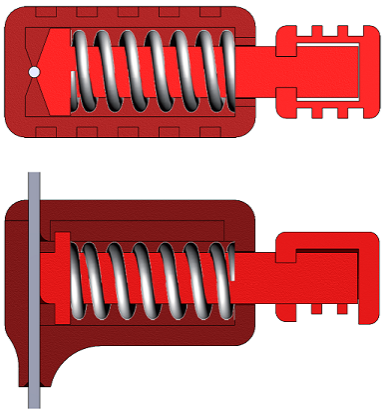


Figure 4.5: Two screenshots from Solidworks showing cross-sectional drawings of the clamp that keeps the surgical guide in place, from a top- and side view respectively. The compression spring clamps the pin between the inner part (light-colored red) and the outer part (dark-colored red) of the clamp. The clamp is opened by pulling the handle to the right. Notches were added to both parts to increase grip when opening the clamp.

4.2. Clamp

4.2.1. Digital design of the clamp

The design of the clamp is kept as simple as possible. See Figure 4.5 for two cross-sectional drawings and a brief explanation of the clamp. The clamp is designed such that it can be assembled without the use of tools. The top part remains stuck in the bottom part by the precision fit principle.

4.2.2. Physical production of the clamp

For the prototype of the clamp it was chosen to 3D-print the clamp out of PolyLactic Acid (PLA) filament using a Fused Deposition Modeling (FDM) 3D-printer called the Creality 3D Ender-3 V2. Printing using a layer height of 0.12 mm took around one and a half hour and 5.82 g of filament including support material. This comes down to €0.11 per clamp. Different production techniques can be chosen as well. See Figure 4.6a and 4.6b for photographs of the 3D-printed clamp and the accessory spacer. This spacer can be placed prior to the placement procedure to open the clamp, and can easily be pulled out once the clamp is placed correctly. This makes the process of placing the clamp easier and faster.

(a) A photograph of the clamp and the spacer that can be placed on the handle of the clamp to keep the clamp open.

(b) A photograph of the clamp with the spacer in place. The clamp can now easily be placed over the pin, without anyone having to apply force to keep the clamp open at the same time.

Figure 4.6: Photographs from different angles of the clamp and the accessory spacer, used to keep the surgical guide in place.

The spring has an uncompressed length of 20 mm, an outer diameter of 8 mm and a stiffness of 3 N/mm. The spring costs €0.55 when ordering a small batch. The clamp

exerts a clamping force of 12 N on the K-wire. The complete clamp weighs 4.60 g and costs €0.66 on material. The clamp can be disassembled by hand and consists of surfaces that are all easily cleanable. However, the production costs for this clamp are so low that cleaning them might be more of an effort than simply buying/producing a new one.

4.3. The finished prototype

See Figure 4.7 and 4.8 for photographs of the prototype. The PSSG and clamp combined weigh no more than 7.2 g and cost around €1.30 on materials. In the design method described in this thesis the identification and design is done manually by an engineer in CAD software. Making the CT-scan as well as designing and printing of one PSSG can be done within a working day of eight hours. For a full set -so for all four digits, including scaled versions- scanning and designing can be done during the eight hour working day and the print can run during the night. The final product can be delivered within 24 hours.

Figure 4.7: Photograph of the Patient Specific Surgical Guide (PSSG) (transparent) on top of an 3D-printed proximal phalanx of the middle finger. The PSSG is constrained to the bone by a pin and a clamp (red).

Figure 4.8: A photograph from the side of the Patient Specific Surgical Guide (PSSG) (transparent) on top of an 3D-printed proximal phalanx of the middle finger. The PSSG is constrained to the bone by a pin and a clamp (red).

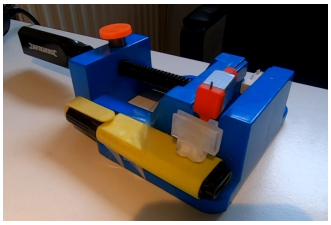
5

Evaluation

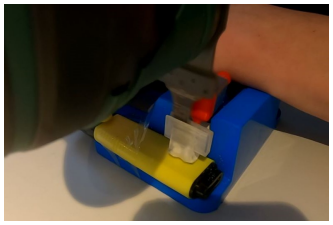
5.1. Evaluation on artificial bone

5.1.1. Proof of the working principle of the surgical guide

In the end the goal is to evaluate the designs in a small cadaveric study, in a clinical environment. For this test, one hand with four suitable fingers is available. All PSSGs are made for this particular hand. The osteotomies can only be performed once, therefore the risk of failure has to be minimized. The working principle has to be tested on artificial bones first. This is done by clamping 3D-printed proximal phalanges in a table clamp, see Figure 5.1a. The phalanges are 3D-printed with a Creality 3D Ender-3 V2 with a layer height of 0.12 mm and an infill of 100%. The material used is white Jupiter series PLA. In stead of a K-wire a 1.0 mm drill was drilled in the phalanx using a Bosch drill. The osteotomy was performed using the Bosch Multitool with the blade described in Section 3.5. See Figure 5.1b. The goal of the test is to see whether a clean straight cut can be made, without loosening of the PSSG due to vibrations or any other causes. The test is done twice for Dig. II, III, IV and V. No quantitative measurements are made. All eight cuts were successful. All cuts had a straight cutting surface, none of the PSSGs loosened during the cut. See Figure 5.2a and 5.2b.

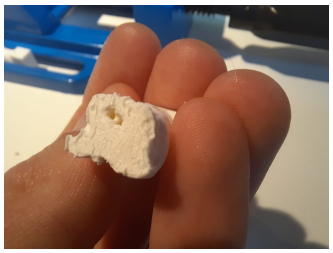


(a) The 3D-printed phalanx is clamped in a table clamp. The patient specific surgical guide and the clamp that holds the guide in place, are placed on top of the phalanx.

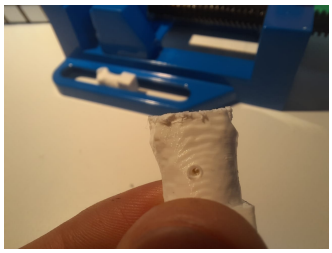


(b) The oscillating saw is cutting through the 3D-printed bone and guided by the patient specific surgical guide.

Figure 5.1: Two photographs of the artificial test set-up.



(a) A photograph of the head of the 3D-printed proximal phalanx of the middle finger after part of it was cut off.



(b) Photograph of the same 3D-printed phalanx from another angle.

Figure 5.2: Two photographs of the head of the 3D-printed proximal phalanx of the middle finger after part of it was cut off as part of the evaluation study on artificial bone.

5.2. Evaluation on cadaveric bones

5.2.1. Fit of the negative mold on the head of the bone

Test protocol

The second part of the evaluation is done on a cadaveric hand. The hand was from a healthy person, meaning the hand did not show any sign of arthritic symptoms. The core of the concept relies on the unique fit between the negative mold and the head of the proximal phalanx. This principle is validated first in the evaluation on cadaveric bones. To quantify how well this principle works, methylene blue and a questionnaire were used. The questionnaire was filled out by the surgeon and the operation assistant. Once the PIP joint is exposed, methylene blue is applied to the negative mold, after which it is pressed against the head of the proximal phalanx, see Figure 5.3. The methylene blue leaves a print on the proximal phalanx, which visualizes where the contact areas between the mold and the head of the phalanx are. After the PSSG is removed from the head of the phalanx again, pictures of the prints are made.

Expected outcome measures

The expected outcome measures from this part of the evaluation do not display whether the novel instrument fulfills the (sub-)functional requirements as defined in Section 2.4. They should help give more insight in the success or failure of the execution of the cuts performed later.

1. Coordinates of contact points between the four negative molds and the heads of the four phalanges: (x, y, z) [mm]
2. Total contact area between the four negative molds and the four heads of the proximal phalanges: A [mm^2]
3. Question 3 of the questionnaire specifically aims to evaluate the fit of the PSSGs on the heads of the proximal phalanges, in both a quantitative (Scale 1-10) and qualitative manner, see Table 5.5.

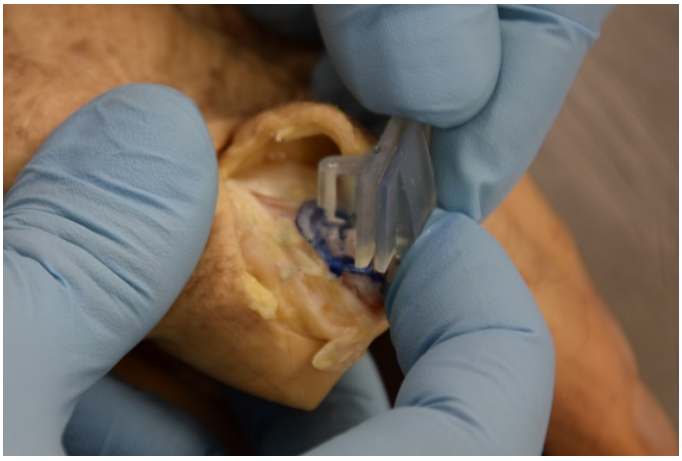
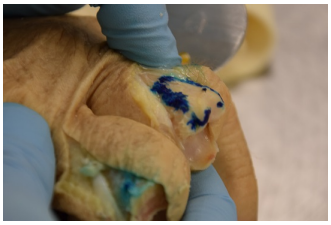


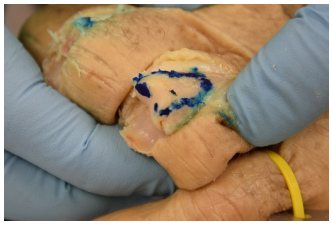
Figure 5.3: Photograph of the Patient Specific Surgical Guide (PSSG) being pressed against the head of the phalanx of the index finger. Methylene blue is applied to the negative mold of the PSSG in order to highlight the contact areas between the negative mold and the head of the phalanx.

Test results

It turned out to be rather difficult to equally cover the entire surface of the negative mold with methylene blue. For all of the four fingers the print on the head of the phalanx looked approximately the same, see Figure 5.4a and 5.4b. The periphery of the surface of the negative mold is visible on all of the four heads. The test using methylene blue was too inaccurate and too hard to properly execute to derive more specific data from it. Both the surgeon as well as the operation assistant stated that they could feel when the PSSG was in the right position and orientation very clearly, grading that aspect by a 9 and a 10 out of 10. See Table 5.5. For none of the joints the PSSG was too small, so none of the scaled version had to be used.



(a) A photograph from a radial point of view of the cadaveric ring finger.



(b) A photograph of the same situation from an ulnar point of view.

Figure 5.4: To visualize how well the shape of the Patient Specific Surgical Guides (PSSGs) enclosed the proximal phalanges, a test was carried out on the cadaveric fingers. The PSSGs were pressed against the head of the proximal phalanges after which they were removed again, while methylene blue was applied at the surfaces of the negative molds. Blue parts indicate contact areas between the negative mold and the proximal phalanx.

5.2.2. Quality of the execution of the cuts

Test protocol

The objective of this study was to develop instruments for improved alignment during the placement procedure. Therefore this part of the evaluation is the most important one; an osteotomy on an actual human phalanx is made using the PSSG, and the degree of alignment is measured after. The degree of alignment is determined by putting the hand in the CT-scan again after the procedure. A digital analysis is then made, in order to compare the post-operative situation with the pre-operative plan. Next to the quantitative parameters indicating the deviations from the planned cut, also the deviations from the planned drill channel and the time for the procedure per finger are measured. The time it takes to perform the procedure is measured and questions related to the user experience of the surgeon and the operation assistant were added to the questionnaire.

The procedure is as follows: the operation assistant pushes the PSSG on the head of the phalanx of the exposed joint by hand. The assistant exerts force in both proximal and palmar direction. The surgeon drills the K-wire into the phalanx, through the channel of the PSSG. The operation assistant then shoves the clamp over the K-wire and pushes it against the PSSG. The operation assistant then removes the spacer so that the PSSG is constrained. The hand is held stable by the operation assistant and the surgeon performs the osteotomy by manoeuvring the saw blade through the PSSG. The clamp is then removed, after which the PSSG can be pulled off. Since only one osteotomy is made per finger, the K-wire is also removed. For the surgical procedure a Bosch drill and a Bosch Multitool (as described in Section 3.5) are used. See Figure 5.5 for a photograph of the saw blade being guided past the cutting surface by the PSSG.

The CT-scan used for the generation of the negative mold, the generation of the 3D-printed bone and for the post-operative analysis is an Aquilion One CT by Canon (previously Toshiba). The DICOM data generated by the CT-scan is then segmented using IntelliSpace Portal (software by ISP, Philips) and exported as an STL-file. The scan parameters can be found in Table 5.1.

Expected outcome measures

The outcome measures following from this part of the evaluation determine whether the novel instrument fulfills the (sub-)functional requirements and how well the instrument performs on part of the performance and evaluation criteria as defined in Section 2.4. The expected outcome measures are:

1. Angular deviation of the four cuts over the palmar-dorsal axis: α_1 [°]. See Table 5.3 for a visualization.

Table 5.1: To evaluate the quality of the execution of the cuts using the patient specific surgical guides, a CT scan of all fingers of the cadaveric hand was made before and after the procedure as part of the evaluation study. The CT-scan used was the Aquilion One CT by Canon using the following scan parameters:

Tube voltage $[kV]$	**Tube current** $[mA]$	**Rotation time** $[s]$	**mAs-number** $[mAs]$	**Iterative reconstruction**	**Kernel**	**Window-width** $[Hu]$	**Window-level** $[Hu]$	**Slice thickness** $[mm]$	**Increment** $[mm]$
120	100	0.5	50	AIDR 3D Mild	FC30	2500	850	0.50	0.25

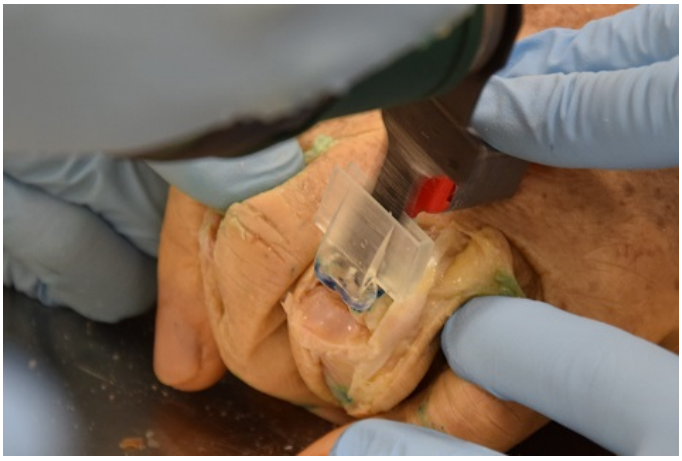


Figure 5.5: Photograph of the patient specific surgical guide for the ring finger in action; the guide is constrained to the head of the phalanx and guides the oscillating saw blade past the cutting surface as it is cutting the head of the proximal phalanx.

2. Angular deviation of the four cuts over the radio-ulnar axis: β_1 [°]. See Table 5.3 for a visualization.
3. Positional deviation of the four cuts along the longitudinal axis: x_1 [mm]. See Table 5.3 for a visualization.
4. Angular deviation of the four channels over the radio-ulnar axis α_2 [°]. See Table 5.4 for a visualization.
5. Angular deviation of the four channels over the longitudinal axis β_2 [°]. See Table 5.4 for a visualization.
6. Positional deviation of the origin of the four channels along the longitudinal axis: x_2 [mm]. See Table 5.4 for a visualization.
7. Positional deviation of the origin of the four channels along the radio-ulnar axis: y [mm]. See Table 5.4 for a visualization.
8. Time it takes to perform the four procedures: *Time* [s]
9. The questionnaire contains 14 questions that are all related to the execution of the procedure. The questionnaire should provide both quantitative (scale 1-10) and qualitative answers in order to validate the executability of the procedure, and to compare the use of the PSSG to the instruments provided by KLS Martin. See Table 5.5 for an overview of the questions.

Test results

All of the four cuts succeeded. As can be seen in Figure 5.6, all four osteotomies resulted in a straight surface. An overview of the time the procedure took for all four digits can be seen in Table 5.2. It should be noted that digit II was constrained using a K-wire without cutting surfaces on the end, the rest of the digits were constrained with a 1.0 mm drill since there was no K-wire with cutting surfaces available. It should also be noted that constraining the PSSG for digit III failed the first time. The K-wire was drilled such that the PSSG was still able to move. It was removed and the procedure was started over. The time corresponding to that try was noted in the table.

The results of the CT-analysis, comparing the positions and orientations of the cutting surfaces and K-wire channels as pre-operatively planned with the actual execution, can be seen in Table 5.3 and 5.4. For digit II and IV, no data on the angular deviation of the channel is available. The CT-scan only images the outer surface of the phalanx. For digit III and V, the surgeon drilled all the way through the phalanx, making it possible to draw a line from the dorsal to the palmar side of the phalanx, which illustrated the channel of the K-wire. For digit II and IV the surgeon did not. The means are all calculated using the absolute values of the deviations from the desired position/orientation. The standard deviations were calculated using the raw data. This displays the accuracy and precision of the PSSGs in the best way.

Table 5.2: The time it took to perform the cut using the Patient Specific Surgical Guide (PSSG) was measured as part of the evaluation study on the cadaveric bones. This table presents an overview of the time it took to complete the procedure for the index-, middle-, ring- and little finger, called digit II, III, IV and V respectively. The time ran from the moment the PSSG was picked up until the moment it was removed from the phalanx again after the cut had been completed.

	Digit II	**Digit III**	**Digit IV**	**Digit V**
Time	5 m 15 s	4 m 2 s	2 m 8 s	3 m 59 s

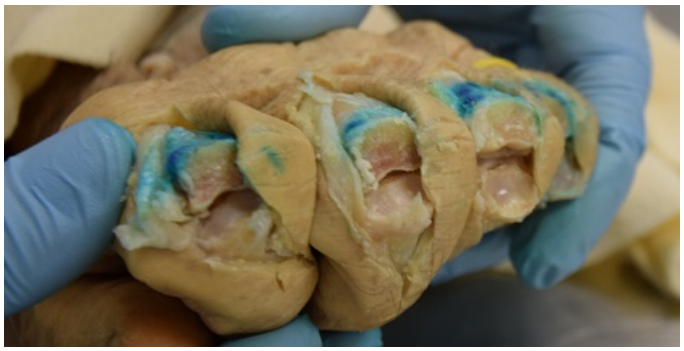


Figure 5.6: Photograph of the heads of the proximal phalanges of the index-, middle-, ring- and little finger of the cadaveric hand, after the patient specific surgical guides were used to cut off part of the head of the phalanges as part of the evaluation study.

Table 5.3: Table displaying the deviations of the performed cuts on the cadaveric fingers (red-dotted line) compared to the pre-operatively planned cuts (black-dotted line). Digit (Dig.) II, III, IV and V correspond to the index-, middle-, ring- and little finger respectively. α_1 is the angular deviation over the palmar-dorsal axis, β_1 the angular deviation over the radio-ulnar axis and x_1 the positional deviation along the longitudinal axis. The blue-dotted line indicates the longitudinal axis of the proximal phalanx. The deviations are followed by the means of the absolute values of the deviations and the standard deviations of the raw data.

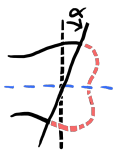
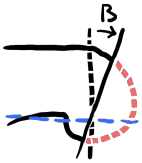
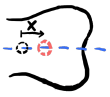
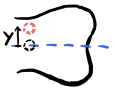
	 α_1 [°]	 β_1 [°]	 x_1 [mm]
Dig. II	-2.0	-8.6	2.3
Dig. III	0.20	3.6	-0.62
Dig. IV	5.2	-13	1.4
Dig. V	10	-20	2.4
Mean of abs. val.	4.4	11	1.7
σ	5.5	9.7	1.4

Table 5.4: Table displaying the deviations of the drilled channels (red-dotted line) in the cadaveric fingers for the pin that is used to constrain the surgical guide compared to the pre-operatively planned channels (black dotted line). Digit (Dig.) II, III, IV and V correspond to the index-, middle-, ring- and little finger respectively. α_2 is the angular deviation over the radio-ulnar axis, β_2 the angular deviation along the longitudinal axis, x_2 the positional deviation of the origin of the channel along the longitudinal axis and y the positional deviation of the origin of the channel along the radio-ulnar axis. The blue-dotted line indicates the longitudinal axis. For digit II and IV the angular deviations could not be retrieved from the CT-images. The deviations are followed by the means of the absolute values of the deviations and the standard deviations of the raw data.

	 α_2[°]	 β_2[°]	 $x_2[mm]$	 $y[mm]$
Dig. II	/	/	1.1	0.58
Dig. III	-9.0	-5.3	-0.38	-1.0
Dig. IV	/	/	-0.29	-0.83
Dig. V	-9.2	-5.7	-0.29	-0.96
Mean of abs. val.	9.1	5.5	0.51	0.84
σ	0.16	0.29	0.69	0.76

The mean deviations of α_1, β_1 and x_1 of the made osteotomies all fall outside of the set tolerances of $+/-3°$, $+/-3°$ and $+/-0.5$mm. Even if one of mean deviations would have been within the set tolerances, the precision would still have been too low. Only two individual deviations fall within the set tolerances, being α_1 for digit II and III with $-2.0°$ and $0.20°$ respectively. Using a one-tailed T-test it can be calculated that the chances at cutting within the set tolerance for α_1, β_1 and x_1 are 35%, 15% and 18% respectively.

The questionnaire displayed that the procedure using the PSSG was considered to be an improvement to the procedure using the saw guide by KLS Martin, see Table 5.5. The greatest advantage was considered to be the control of the orientation of the cut relative to the longitudinal axis, and the sight at the cut. The only disadvantage compared to the current instruments was considered to be that the procedure consists of more steps. The new procedure was considered to be a procedure that is much easier taught to inexperienced surgeons in training. The operation assistant considered it difficult to hold the PSSG stable in the right position while the K-wire was drilled. No difference was experienced between the different fingers using the PSSG. The greatest inconvenience was considered to be the open slot. Desired improvements to the PSSG are: the slot being closed on both sides, and an instrument with a handle to hold the PSSG, so that drilling and cutting can be performed more stable.

Table 5.5: Questionnaire filled out by the surgeon and the operation assistant on their experience using the patient specific surgical guides on four cadaveric fingers to perform a cut as part of evaluation study. The questions that are not related (to the activities of) the operation assistant contain a "/" in the answer box.

#	Question	Surgeons answer	Operation assistants answer
1	On a scale of 1-10, how realistic did you consider the test environment and executed procedure to the actual procedure in the operating room?	10	10
2	What would you consider the most important difference?	Accuracy	/
3	On a scale of 1-10, how well were you able to determine whether the Patient Specific Saw Guide (PSSG) was in the right position and orientation?	9	10, Very well. There was really only one way in which the mold fitted the patients bone.
4	On a scale of 1-10, how well were you able to stably drill the K-wire through the channel of the PSSG into the proximal phalanx?	8	6. It was difficult to hold the mold while at the same time having to position the K-wire. The K-wire (without cutting blades) was hard to drill into the cadaveric phalanx. In the future a K-wire with cutting blades should be used.
5	On a scale of 1-10, how well were you able to stably place the clamp?	8	8
6	On a scale of 1-10, how well were you able to stably cut the head of the proximal phalanx through the slot of the PSSG?	7	9
7	If you compare the method to perform the first osteotomy as it is done right now using KLS Martins saw guide to the new procedure using the PSSG, how would you grade both methods overall on a scale of 1-10?	KLS Martin saw guide: 3 PSSG: 9	/
8	On a scale of 1-10, how suitable would you consider both the procedure using the KLS Martin saw guide and the PSSG to teach to surgeons in training?	KLS Martin saw guide: 2 PSSG: 8	/
9	What did you consider the greatest advantage using the PSSG compared to the KLS Martin saw guide?	Using the KLS Martin saw guide, in axial direction no controll at all. PSSG axial and frontal good control and sight.	/
10	What did you consider the greatest disadvantage using the PSSG compared to the KLS Martin saw guide?	Only an extra manoeuvre, but that is necessary.	/
11	Did you notice any difference using the PSSG between the different fingers? In case of a “yes”, what difference did you notice?	None.	None.
12	What was the greatest inconvenience while using the PSSG?	Open slot.	/
13	What would you like to see improved or added to the PSSG or to the procedure using the PSSG?	Closed slot and a handle to stabilize the PSSG.	/
14	Do you have any final remarks?	None.	None.

6

Discussion

6.1. Interpretation of evaluation results

6.1.1. Performance related to design criteria

The efficacy of the working principle of the PSSG has been demonstrated. Using the PSSG, straight and clear cuts were performed on the cadaveric phalanges. However, the PSSG does not yet meet the set demands related to the tolerances for the functional requirements. The PSSG was neither accurate nor precise enough. The PSSGs performed best for the angular deviation over the longitudinal axis (α_1). This deviation could be considered the most important one, as longitudinal axis deviation is assumed to cause dislocation of the prosthesis [25]. The chance of the osteotomy to be within the defined tolerance for α_1 is 35%. However, only looking at these percentages would be misleading. The large mean angular deviation over the radio-ulnar axis (β_1) causes the positional deviation on the longitudinal axis (x_1) to be far more off than necessary. If β_1 increases, x_1 automatically increases as well, this can clearly be seen in Table 5.3. That x_1 would not have been so far off without β_1 being off is confirmed by the deviations of the channel for the K-wire as well. The mean deviation over the longitudinal axis is only 0.51 mm with a standard deviation of 0.69 mm. If this number would be responsible for the deviation on the longitudinal axis of the cutting plane alone, the chance the tolerances would have been met increases from 18% to 53%, using a one-tailed T-test.

6.1.2. Possible explanations for performance

Lack of data

As a start it should be said that a lot more data has to be collected in order to get a better image of the true accuracy and precision of the guides, and to make statistically significant correlations. It would also be interesting to have the means and standard deviations per deviation parameter per finger available, in stead of placing the deviation parameters under the same heading for all fingers, as is done now. The greatest influence on the performance is probably one that is not to be distracted from the data; it is the test setting.

Deviations caused by cutting

In stead of the intended Electric Pen Drive by DePuy Synthes, the Bosch Multitool was used as an oscillating saw. This led to the decision to leave the slot open on the radial side, see Subsection 4.1.1. This results in a reduction of the stiffness and the distal end of the PSSG being able to slightly flex when the blade is pushed against it. This allows the blade to rotate out of the planned cutting plane, increasing the mean values of α_1 and β_1. In case the blade pushes against the distal end of the PSSG, this force is even greater using the Bosch in stead of the Electric Pen Drive. The torque delivered by the surgeon is greater due to the greater distance between the tip of the blade and the position at which the Bosch is held by the surgeon. Next to that the Bosch is heavier, its center of gravity is further away from the blade, the tool is unpractical to hold and allows for less tactile feedback.

Deviations caused by drilling

The operation assistant stated in the questionnaire that it is difficult to hold the PSSG stably during drilling of the K-wire. This is a shortcoming of the current prototype: the assistant has to hold the PSSG in place with his/her fingers. Not only is the surface that allows the operation assistant to hold the PSSG in place small, it is even harder to counteract the torque the surgeon exerts on the PSSG. When the K-wire comes into contact with the inside of the channel, force is exerted on the inner walls of the channel. This happens when the surgeon is not drilling exactly aligned with the direction of the channel. The distance between the PSSG and the position at which the drill is held by the surgeon amplifies the torque on the PSSG as a consequence of the force that is applied by the surgeon. This could cause the PSSG to rotate. This results the drilled channel to deviate from the the preoperatively planned channel, as can be seen on the values for α_2 and β_2 in Table 5.4. An easy fix would be to design an instrument that makes it easier for the assistant to push the PSSG onto the head of the phalanx. Give this instrument a handle of the appropriate length, and the torque coming from the surgeon can easily be counteracted, preventing the PSSG to rotate.

Fit between mold and the proximal phalanx

Another cause for the lack in performance of the PSSG could be that the fit between the negative mold and the proximal phalanx leaves room for different orientations. However, the questionnaire showed that for both the surgeon and the operation assistant it was very obvious when the PSSG was placed in the correct manner. The evaluation of the fit with mythelene blue did not entirely give the desired result, however it shows that the entire periphery of the negative mold is in contact with the head of the phalanx once the PSSG is placed. This means it can offer a reaction force in the four

distinguishable directions as planned in Section 3.4. These arguments combined make the chance of the fit contributing to the deviation of the cuts unlikely.

A minor contribution to the deviation might be the post-op analysis. The pre- and post-op CT-scans showed small differences, which caused the overlap between the two .STLs not to be a 100% exact.

6.2. Comparison with state-of-the-art technology

6.2.1. Current placement procedure of the CapFlex prosthesis

Even though the defined tolerances for the functional requirements were not met, the objective for this thesis was to develop a new (set of) instrument(s) for the placement procedure that would improve alignment of the phalanges. Unfortunately it was not possible within the scope of this project to execute a proper comparison study between the performance of the saw guide provided by KLS Martin and the novel PSSG.

A prospective study on CapFlex prostheses with five year follow-up outcomes report on longitudinal axis deviation between the proximal- and middle phalanx using antero-posterior radiographs [23]. The longitudinal axis deviation defined in that prospective study is comparable to what is called angular deviation α_1 in this thesis. The numbers reported on do not say anything about the longitudinal axis deviations of the osteotomies explicitly. However, it is a safe assumption to say that when the longitudinal deviation between the phalanges is $x°$, the longitudinal deviation of the osteotomy of the proximal phalanx is at least equal to, or less than $x°$. Five years after surgery, 75% of the treated proximal- and middle phalanges had an axial deviation of less than 5°, 22% between 5° and 15° and 3% of more than 15°.

Another follow-up prospective study on CapFlex prostheses reports that none of the 89 PIP joints had a longitudinal axis deviation greater than 15% two years after surgery [3]. The definitions used were the same as those of the previous article.

A prospective study on CapFlex prostheses with a median follow-up time of three years yet again reports on this longitudinal axis deviation between the phalanges [10]. Out of the ten joints that were analyzed, 50% had a deviation smaller than 5°, 40% between 5° and 15° and 10% of more than 15°.

Unfortunately no studies reporting specifically on the accuracy of the osteotomies using the guiding instruments provided by KLS Martins were found.

6.2.2. Freehand- and conventionally guided phalangeal osteotomy

Almost no literature is available on the accuracy of freehand phalangeal osteotomy or osteotomy using conventional guides such as the guides provided by KLS Martin (Chapter 2), Ascension (Appendix A) and Stryker (Appendix B).

A study comparing freehand osteotomy to robot-assisted osteotomy provides some insight in freehand performance [6]. 156 Cuts were performed freehanded on a $40x40x85$ mm rectangular shaped block. Deviations from the intended cut were reported to have a mean value of: α_1 and β_1 that are either $5.43° +/- 4.39°$ or $3.66° +/- 3.16°$ (the article is vague on which deviation relates to what angle) and $x_1 = 5.19\,\text{mm} +/- 3.44\,\text{mm}$. Although the size of the block is somewhat comparable to a proximal phalanx, the shape makes it impossible to compare the performance to the performance of the PSSG. The rectangular shape makes it easy to estimate the orientation the cut needs to have, compared to an only partially exposed proximal phalanx.

A 2014 cadaveric study involving 152 PIP joints evaluated the placement of the Ascension Pyrocarbon prosthesis [14]. The critical osteotomy is similar to the one for the CapFlex prosthesis, see Appendix A. Only 33% of the prostheses were placed such that the frontal- and sagittal plane of the prosthesis were within acceptable tolerances. No mention was made about the specifics of the tolerances.

Nothing of any statistical significance can be said to compare the accuracy and precision of the cuts made using the PSSG to those made during freehand osteotomy or using conventional guides. The mean deviation of α_1 of 4.4° is close enough to the best reported deviations mentioned in literature of 5° and 3.66° for the PSSG to be more accurate, but it might as well be not. At least all mean deviations are in the order of magnitude of the deviations found in literature. Independent of the quantitative performance of the PSSG, the PSSG was considered to be easy to use by the surgeon and the operation assistant. They consider the PSSG to be an improvement to the saw guide currently provided by KLS Martin. Inexperienced surgeons are expected to be able to use the PSSG more easily than the guiding instrument that is currently used. Without the PSSG, surgeons might have had to redo the osteotomy a few times before reaching a satisfying result, evaluating it by eye every single time. Using the PSSG, the influence of the eye and skill of the surgeon is greatly reduced.

6.2.3. State-of-the-Art patient specific surgical guides

What can be said about the performance of the novel PSSG compared to state-of-the-art PSSGs? PSSGs proved their value in other orthopaedic procedures such as high tibial osteotomy as part of a TKA, with mean deviations of 0.72° from the planned cut [20]. PSSGs have also been proven to be successful in corrective osteotomies of the forearm, reaching mean deviations from the planned cuts up to 1.8°, 1.4° [5], 1.7° and 2.0° [24] from the relevant planes, and deviations of 0.8 mm on the relevant axes[24]. However, comparing the performance of the PSSG to these surgical guides is unfair, as the surface of bone to connect the PSSG to is much smaller in phalangeal surgery, and more specifically in PIP joint arthroplasty.

There are multiple reports on 3D-printed PSSGs to correct the malunion of intra-articular fractures of the phalanges. A case report describes the satisfactory application of such a guide at the base of the proximal phalanx [31]. However, nothing is mentioned about the accuracy of the cut. Yet another case study reports on the successful application of such a guide, yet again mentioning nothing about the accu-

racy of the cut it assists in performing [15]. Another study reports on eight corrective osteotomies, also using 3D-printed PSSGs [13]. With a mean follow-up time of six months, the researchers report on a mean residual deviation of 2.3° and 0.4 mm. Ignoring statistic significance, this guide seems to perform more accurate than the PSSG developed in this thesis. However, it should be said that much more bone area was available for guide-bone contact. All of the guides required at least three and at most seven screws/K-wires to constrain the guides. The performed cut was also a different type of cut. No reports were found on PSSGs for osteotomies in PIP joint arthroplasty. Yet again, nothing of any statistical significance can be said to compare the performance of the novel PSSG to state-of-the-art PSSGs.

6.3. Strengths and limitations of this study

The greatest limitation of this study is the lack of a statistically significant quantitative comparison between the novel PSSG and the saw guide provided by KLS Martin that is currently used in the placement procedure. The evaluation study performed as part of this thesis only involved four fingers of a non-arthritic hand, while this procedure would usually be performed on the joint of a patient suffering from arthritis. Osteophytes might influence the performance of the PSSG and the ease of fixation.

Another limitation is that the evaluation performed in this study probably gives a worse image of the performance of the PSSG than it truly is. The use of heavy equipment like the Bosch Multitool gives a distorted picture of the performance, and makes it difficult to compare the results to other studies.

Besides that, the pursued tolerances for the osteotomy are rather arbitrary. The only scientific motivation behind the tolerances is that some of them are appropriate in TKA. Even though the knee joint also provides a flexion-extension movement, it is a completely different joint. The same goes for the definitions of the anatomical axes and planes that are used.

A strength of this study, is that the chosen path for improvement of alignment is one that can also be applied to PIP arthroplasties using different unconstrained prostheses. The PSSG helps in making the osteotomy orthogonal to the longitudinal axis. The alignment of both the Stryker and Ascension Pyrocarbon prosthesis greatly depend on the same osteotomy. For both placements procedures there are no proper guiding instrument available. See Appendix A and B .

6.4. Future research

The novel PSSG that was developed and evaluated was only a first prototype. The evaluation on the cadaveric hand and the questionnaire both show the potential improvement to the current placement procedure of the CapFlex prosthesis that lies within this concept. Especially given the fact that small adjustments in the design and evaluation environment might highly increase the PSSG its performance.

A proper comparison study between the novel PSSG and the saw guide provided by KLS Martinn used to perform the first osteotomy of the placement procedure of the CapFlex prosthesis should be carried out. This test should be done within an environment where the osteotomy is performed using the Electric Pen Drive by DePuy Synthes. Using this oscillating saw allows the guiding slot to be closed on both the radial- and ulnar side, increasing the stiffness of the PSSG and thus the quality of the osteotomy. Next to that, an instrument that assists in keeping the PSSG in place when the surgeon drills the K-wire should be developed, as it will make the drilling more stable and thus more accurate.

If the potentially improved performance is proven, a clinical trial should be started. Only part of the novel concept for the placement procedure was designed in detail in this thesis. The remaining four PSSGs should be designed as well, so that the entire preparation of the proximal phalanx can be done according to the concept for the novel procedure. The concept should be extended for preparation of the middle phalanx as well.

Research to the definition of the anatomical geometries should be done, as well as for acceptable tolerances for the osteotomies. To speed-up the production process of the PSSGs, an algorithm that identifies the cutting planes and automatically generates .STL files for the PSSGs should be developed.

7

Conclusion

Analysis shows that the most effective way to improve the placement procedure of the CapFlex prosthesis, is to improve part of the first phase of the procedure. In this part, the proximal phalanx is prepared such that the head of the phalanx matches the shape of the prosthesis. The current instruments fall short in identifying the relevant anatomical geometries, and it cannot be guaranteed that the instruments are properly aligned relative to these geometries. During manipulation of the proximal phalanx, the DOFs of the manipulating instruments are not properly constrained relative to the phalanx.

The efficacy of the working principle of the Patient Specific Surgical Guide (PSSG) that was developed in this thesis was demonstrated. The cuts performed using the PSSG do not meet the demanded accuracy and precision as defined in the design criteria. The mean of the absolute deviations from the planned orientation and position of the cut are 4.4 °, 11 ° and 1.7 mm. The outcome of the evaluation is likely to be negatively influenced by the oscillating saw used during this evaluation.

The surgeon and operation assistant that carried out the evaluation considered the PSSG to be an improvement to the guiding instruments currently used. However, it is not possible to make a statistically significant quantitative comparison between the PSSG and the guiding instruments currently used regarding accuracy and precision of the cut. Therefore it cannot be said whether the PSSG improves alignment of the prosthesis, and neither whether it improves the current placement procedure as a whole.

It is recommended to carry out a comparative study between the PSSG and guiding instruments currently used to perform the first osteotomy as part of the placement procedure of the CapFlex prosthesis. To improve performance of the PSSG, the slot of the PSSG that guides the saw blade should be closed on both the radial- and the ulnar side. Next to that, an additional instrument should be developed which holds the PSSG in place when it is being constrained to the proximal phalanx.

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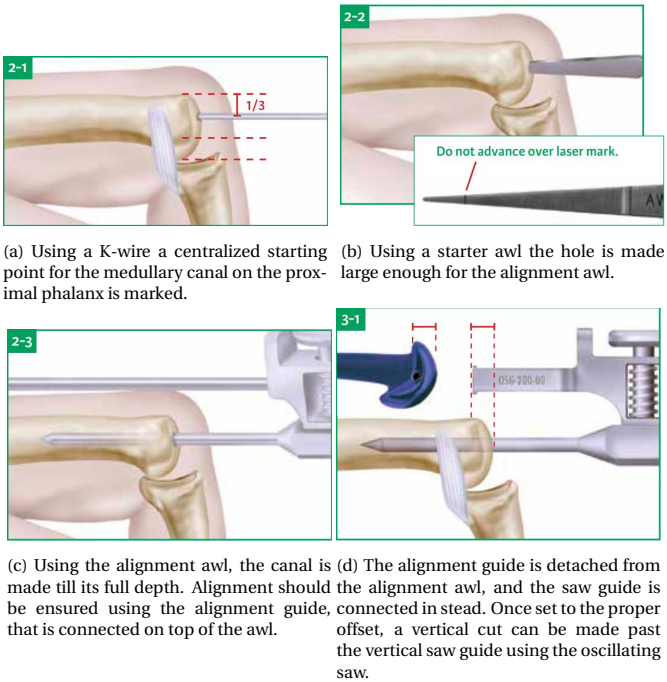
A

Placement procedure of the Ascension Pyrocarbon prosthesis

A.1. Medullary canal opening of proximal phalanx, alignment and vertical cut

After the joint has been exposed, osteophytes are removed and the canal used for intramedullary fixation in the proximal phalanx is opened. This canal is first used for alignment, and ultimately for the fixation of the proximal component of the prosthesis. The opening of the canal is done in three sub-steps. First a mark is made at about 1/3 from the dorsal side and horizontally seen in the middle of the proximal phalanx using a K-wire, see Figure A.1a. This is done to have a centralized starting point for the canal. Yet again, the precision depends on the eye of the surgeon. The position is confirmed using X-ray, after which the hole is enlarged using the starter awl, see Figure A.1b. The hole is made just large enough for the insertion of the alignment awl, which is ultimately used to make the canal to its full depth. That is the last sub-step to open the medullary canal. In this step, alignment starts to play a role. The canal has to be made parallel to the longitudinal axis of the proximal phalanx. For this the alignment guide is attached to the alignment awl, see Figure A.1c. The alignment guide is a rod that passes the finger dorsally, and the surgeon can actually see whether this guide is parallel to the proximal phalanx, contrary to the saw guide for the CapFlex prosthesis. Still, the quality of the alignment depends of the eye of the surgeon. Just like with the first sub-step, the centralized position is checked using X-rays.

Ideally, the alignment awl is now inserted parallel to the longitudinal axis of the proximal phalanx. This property is used in a smart way. The alignment guide is removed from the alignment awl and replaced by the saw guide, see Figure A.1d. This guarantees the saw guide to be orthogonal to the longitudinal axis of the proximal phalanx, and so should be the cut made past the surface of the saw guide. The cut is made using a micro sagittal saw, which is an oscillating saw like used for the procedure to place the CapFlex prosthesis. An advantage compared to the CapFlex prosthesis is the intramedullary fixation. The canal can be used to align the saw guide. Unfortunately that is an intrinsic disadvantage of the CapFlex prosthesis, as it used extramedullary fixation and an intramedullary canal is not available for alignment.



(a) Using a K-wire a centralized starting point for the medullary canal on the proximal phalanx is marked.

(b) Using a starter awl the hole is made large enough for the alignment awl.

(c) Using the alignment awl, the canal is made till its full depth. Alignment should be ensured using the alignment guide, that is connected on top of the awl.

(d) The alignment guide is detached from the alignment awl, and the saw guide is connected in stead. Once set to the proper offset, a vertical cut can be made past the vertical saw guide using the oscillating saw.

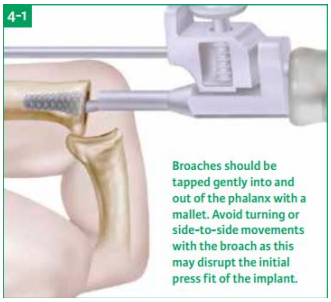
Figure A.1: Step 2-1, 2-2, 2-3 and 3 of the surgical procedure to place the Ascension Pyrocarbon Prosthesis. Source: [2].

A.2. Proximal component broaching and oblique cut

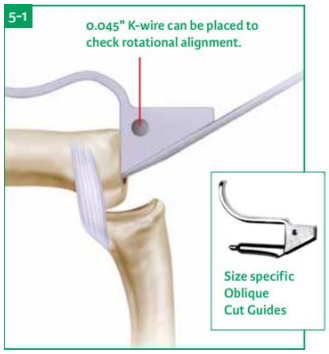
The next step is to bring the canal to its final size, such that the largest implant stem possible is fit into it. The stem should be aligned centralized, so the alignment guide is connected to the different broaches used, see Figure A.2a.

Once the canal is at size, the oblique saw guide is inserted into the medullary canal of the proximal phalanx. The size of the guide corresponds to the final broach size, see Figure A.2b. The frontal surface of the oblique saw guide is pushed flush against the surface on the head of the proximal phalanx created in the previous step. The function of the oblique saw guide is to guarantee the angle of the cut relative to the longitudinal axis of the proximal phalanx, such that the oblique of the proximal phalanx is removed and the prosthesis fits on top of the head of the proximal phalanx. Again the cut is made with a sagittal saw. The proximal end is done, the trial prosthesis can now be tested and possible adaptions to

the channel and articular surface can be made as a consequence.



(a) Broaching of the intramedullary canal till the largest implant can be fit into it.



(b) The oblique cut is made using a oblique saw guide.

Figure A.2: Step 4 and 5 of the surgical procedure to place the Ascension Pyrocarbon Prosthesis. Source: [2].

A.3. Distal surface preparation and broaching

Now that the proximal side is finished, the procedure is done again for the distal end, however slightly different. Again a K-wire is used to mark the starting point for the medullary canal, and again the mark should be at 1/3rd of the height seen from the dorsal side, see Figure A.3a. This should be checked by X-ray. The hole is now enlarged by the starter awl and enlarged even further using a side cutting burr, see Figure A.3b. Just like with the CapFlex prosthesis, no attention is paid to alignment in preparing the distal surface. A small end cutting burr is used to remove the articular surface of the middle phalanx, and alignment is all done by eye, see Figure A.3c.

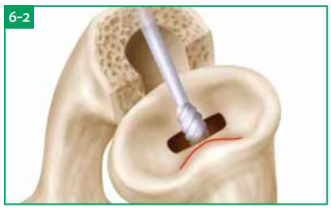
Finally the distal canal should be brought to its final size, the size matching the stem of the distal component of the prosthesis. This is done using the distal broach with the alignment guide attached to it, see Figure A.3d. Just like with the proximal component, the alignment guide slides over the phalanx, and alignment is as good as the eye of the surgeon. The largest possible implant should be chosen. A distal sizing template is used to check whether the distal component of the prosthesis will match the smoothed surface or that additional removal is required, see Figure A.4. After the smallest broach is used, correct alignment is confirmed by X-rays, after which a larger size broach is used. In case aligment is incorrect, a side-cutting burr is used to correct for this.

Both canals are now fully prepared and the trial prosthesis is also inserted in the middle phalanx. A function test is done, the trial prostheses are removed and the final prostheses are press-fitted into the canals. The finger is closed and the procedure is done.

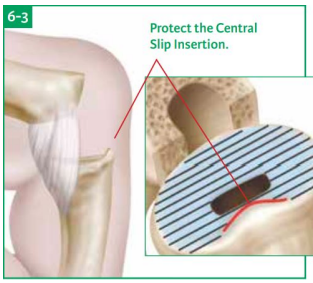
A.4. Conclusion for Ascension Pyrocarbon prosthesis

The saw guide for the placing of the Ascension Pyrocarbon prosthesis already has one advantage over the one for the CapFlex prosthesis: it is (intramedullary) fixated. The same

(a) Using a K-wire a centralized starting point for the medullary canal on the middle phalanx is marked.



(b) Using a starter awl and a side-cutting burr the hole is enlarged till the distal broach fits into it.



(c) Using a small end cutting burr the articular surface of the middle phalanx is removed.

(d) Using distal broaches with the alignment guide attached, the distal medullary canal is enlarged till its final size.

Figure A.3: Step 6-1, 6-2, 6-3 and 7 of the surgical procedure to place the Ascension Pyrocarbon prosthesis . Source:[2].

Figure A.4: The distal sizing template used to determine if the distal component of the Ascension Pyrocarbon prosthesis will match the smoothed surface. Source: [2].

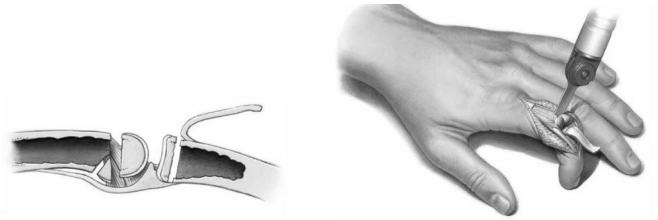
goes for the angled saw guide. However the way the middle of the channel for these saw guides is determined is by the eye. The way the alignment awl is properly aligned with the longitudinal axis is also by the eye, and thus subject to errors.

Just like for the CapFlex prosthesis, the distal seat is prepared completely on the eye by a small mill. Not a single surgical guide is used.

B

Placement procedure of the Stryker prosthesis

B.1. Resection and intramedullary cavity preparation of the proximal phalanx



(a) A total of three cuts have to be performed for the proximal- and middle phalanx combined.

(b) Using a small oscillating saw the head of the proximal phalanx is cut without any sort of surgical guide.

Figure B.1: Step 2 and an overview of all saw cuts of the surgical procedure to place the Stryker Prosthesis. Source: [29].

After the joint has been exposed, resection of the proximal phalanx begins. A total of three osteotomies have to be performed, just like with the Ascension Pyrocarbon prosthesis, see Figure B.1a. While the procedures discussed earlier involved special instruments to guarantee a straight cut, orthogonal to the longitudinal axis of the proximal phalanx, this procedure has a complete lack of such instruments. Resection of the proximal phalanx is done by a small oscillating saw and $2-3$ mm should be cut off, see Figure B.1b. As can be seen, the cut is made entirely on the eye. Guidance for the osteotomy is not available at all. The osteotomy entirely relies on the hand and eye of the surgeon. Just like with all surface replacement prostheses, the collateral ligaments are protected as much as possible.

The second cut made is the oblique cut. However, for this osteotomy a surgical guide that is fixated in the intramedullary cavity is used, see Figure B.2. Therefor, first the intramedullary cavity has to be opened and prepared. This is done using a small awl, see Figure B.3. A powered burr might be needed in case a small awl does not succeed in opening the cavity. After the cavity is opened, the hole is enlarged with reamers until the size matches that of the stem of the trial component. All alignment is done on the eye.

Now that the intramedullary cavity is made free, it can be used to fixate the surgical guide, such that the oblique cut can be made past it. The surgical guide consists of an angled surface past which the oscillating saw can be moved such that the demanded oblique cut can be made straight under the right angle relative to the longitudinal axis. In order to make sure this instrument is aligned properly, the guide handle should be parallel with the longitudinal axis of the proximal phalanx. It should be pulled into the intramedullary cavity till it is seated flush against the surface created during the first resection. Now the volar lip can be cut off, such that the head of the proximal phalanx will match the inside of the proximal component of the Stryker Prosthesis.

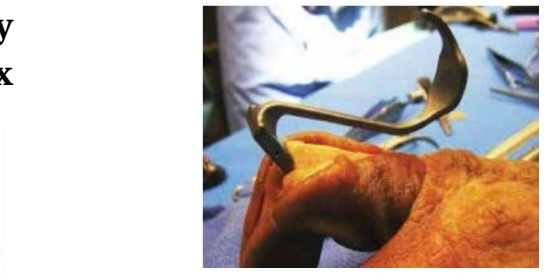


Figure B.2: The saw guide used to perform the oblique cut as part of the surgical procedure to place the Stryker Prosthesis. Source: [29].

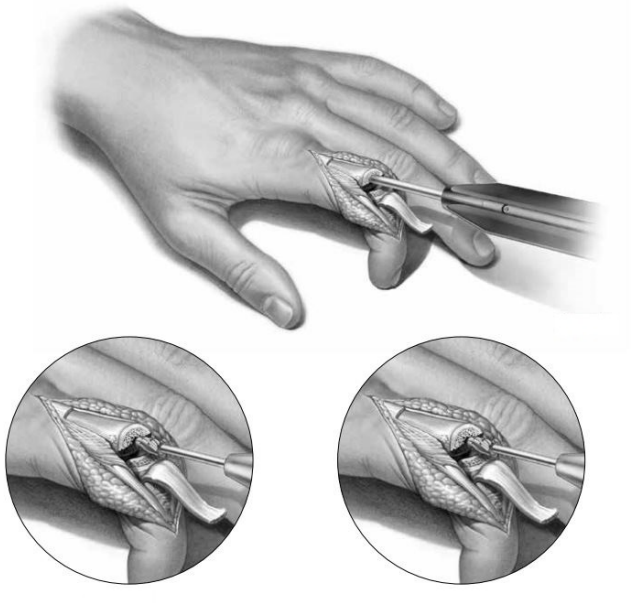
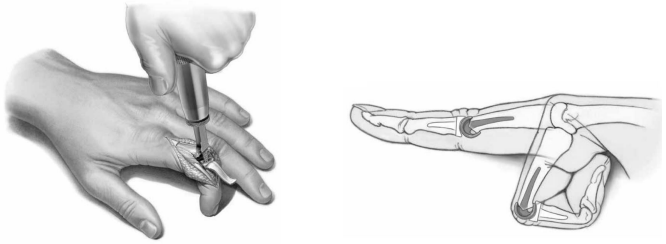


Figure B.3: Step 3 of the surgical procedure to place the Stryker Prosthesis. Source: [29].

B.2. Resection and intramedullary cavity preparation of the middle phalanx and finishing up

Resection of the middle phalanx is also done without a cut guide, and should be done as can be seen in Figure B.1a. The intramedullary cavity is opened and prepared in the same way as that of the proximal phalanx, also without any surgical guides, see Figure B.4a. All steps that were relevant to proper alignment are now done. After the trial components are inserted, a function test is done, see Figure B.4b. Once the surgeon is satisfied, the trial components are removed, the final prosthesis components are placed and the finger is closed again.



(a) The intramedullary cavity of the middle phalanx is opened using an awl and enlarged using burrs.

(b) Executing the functionality test.

Figure B.4: Step 5 and 7 of the surgical procedure to place the Stryker Prosthesis. Source:[29].

B.3. Differences between the dorsal- and palmar approach

Of course the procedure for the palmar approach differs in a lot of ways from the palmar approach. However to describe those differences for all prostheses is not relevant, and therefor only the differences regarding alignment are described in this appendix. After the joint is exposed from the palmar side, the first difference regarding alignment comes to light. The order in which the cuts are made is different compared to the dorsal approach, see Figure B.5. First the oblique cut is made. As the vertical cut has not been made yet, the intramedullary cavity has not been opened either. Therefor the saw guide cannot be place which causes all cuts for the palmar approach to be unguided. This makes this approach even more difficult for the surgeon, as another step relies on his eye and muscle control. After the oblique cut has been made, the vertical cut of the proximal phalanx is made and later on the vertical cut for the middle phalanx, see Figure B.6. Besides these differences regarding alignment, there are no other differences worth mentioning.

B.4. Conclusion for Stryker SR PIP Prosthesis

The instrument set used for placing and aligning the Stryker Prosthesis does not offer a single improvement compared to the instruments for the CapFlex prosthesis. Only one surgical guide is used during the entire procedure. The advantage of this surgical guide is that it is intramedullary fixated. The channel in which this guide is fixated is made without any guiding instrument. However, in case the surgical guide is not aligned with the longitudinal axis of the proximal phalanx properly, corrections can be made based on X-rays.

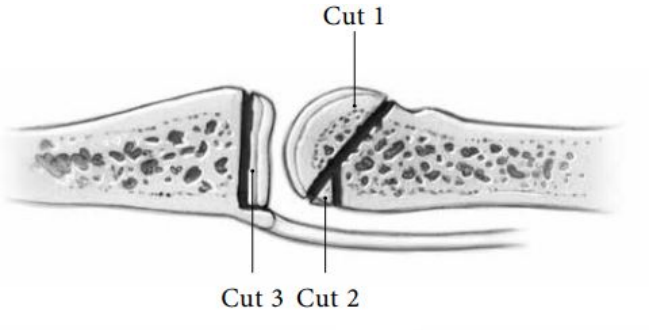


Figure B.5: The order of the cuts for the palmar approach of the surgical procedure to place the Stryker Prosthesis. Source: [29].

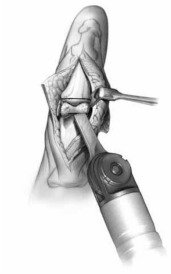


Figure B.6: Resection of the middle phalanx as part of the palmar approach of the surgical procedure to place the Stryker Prosthesis. Source: [29].

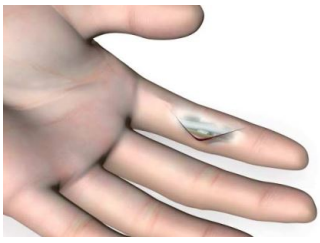
C

Differences between dorsal- and palmar approach for the CapFlex Prosthesis

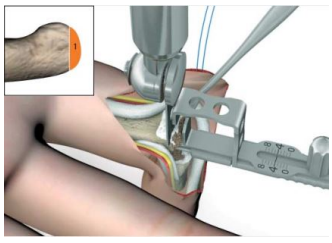
C.1. Introduction

In some cases the surgeon may prefer the palmar approach over the dorsal approach. The prosthesis and instruments supplied by KLS Martin allow for this approach. Roughly the same procedure has to be carried out, but then from the palmar side. All steps will quickly be mentioned, but the focus will be on the differences compared to the dorsal approach.

In case it is still not entirely clear what *palmar approach* means, see Figure C.1a. Once the joint has been exposed, the first difference comes to light. Like stated before, the steps are approximately the same. Just like with the dorsal approach a saw guide is used to make the first osteotomy on the head of the proximal phalanx orthogonal to the longitudinal axis of the proximal phalanx. However, the saw guide slightly differs from the one used during the dorsal approach. This saw guide has two guide rails on the head in stead of one. The reason for that is the shape of the bone the guide rail utilizes to guide the instrument: the guide rail for the palmar approach slides over the dorsal side of the proximal phalanx, which is concave in stead of convex. The guide rails encloses this shape and therefor there are two of them. The first osteotomy is performed using the saw guide and the oscillating saw in the same manner as before, see Figure C.1b.



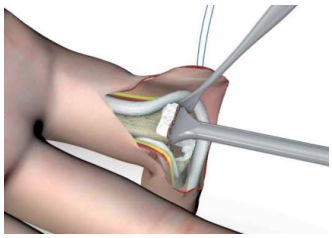
(a) Incision for the palmar approach.



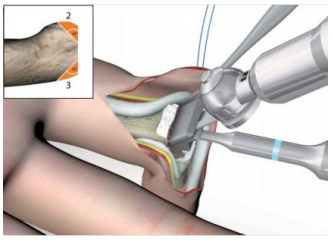
(b) Resection of the proximal phalanx, the saw guide is placed such that the oscillating saw should make a cut perpendicular to the longitudinal axis of the finger.

Figure C.1: Step 1 and 2 of the surgical procedure to place the CapFlex Prosthesis using the palmar approach. Source: [9].

Yet again a repetition of steps, but mirrored. The sizer is used to determine the size of the proximal component prosthesis and to pierce the channels, see Figure C.2a. The saw log is then used to guide the oscillating saw with the same goal as before: to make sure the angle between the cut and the longitudinal axis is 45°, see Figure C.2b.



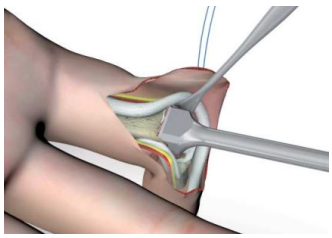
(a) The distal sizer is used to determine the size of the palmar component and pierces the cancellous bone with two spikes.



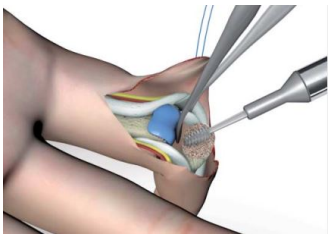
(b) The 45° saw log and the oscillating saw are used to precontour the proximal prosthesis seat.

Figure C.2: Step 3 and 4 of the surgical procedure to place the CapFlex prosthesis using the palmar approach. Source: [9].

The modulator is used to match the prosthesis seat with the inside of the proximal component of the prosthesis, see Figure C.3a. The test prosthesis can now be placed using the positioner and the impactor. The preparation of the proximal seat is finished once the surgeon is satisfied with the fluoroscopic images. Now the preparation of the distal seat starts, again using the Luer bone rongeur. After the osteophytes are removed the base of the middle phalanx is turned into a flat surface, all on the and wrist eye of the surgeon, see Figure C.3b.



(a) The modulator is impacted onto the proximal seat of the prosthesis such that a precision-fit seat is prepared and modeled.

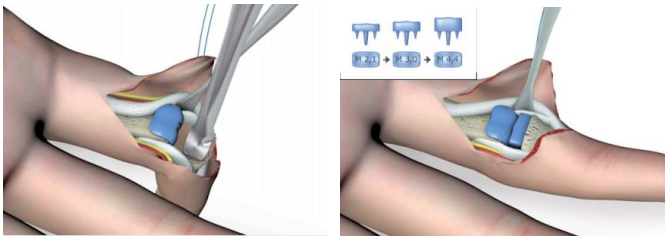


(b) The Luer bone rongeur is used to flatten the base of the middle phalanx.

Figure C.3: Step 5 and 7 of the surgical procedure to place the CapFlex prosthesis using the palmar approach. Source: [9].

The distal sizer is now used to determine the right size for the distal component and to pierce the cancellous bone with three spikes that will later house the stems of the distal component of the prosthesis, see Figure C.4a. Just like before, alignment depends on the hand and the eye of the surgeon. Now the second actual difference comes to light,

being that the height determination instrument cannot be used to determine the proper thickness for the distal component. It is advised to start with the smallest height available, being 2.1 mm. The height should be scaled up till the tension on the joint is only moderate, see Figure C.4a. If even using the lowest component the tension is too high, slightly more bone should be resected from the base of the middle phalanx. Once the correct test prosthesis is inserted, a function test is done and the position and orientation are finally checked under fluoroscopic control. Once the surgeon is satisfied, he or she removes the test prostheses using the positioner, and places the final prosthesis with the positioner and impactors. The finger is closed and postoperative treatment can start.



(a) The distal sizer is used to pierce the middle phalanx. There are three possible sizes for the sizer: S, M and L.

(b) To determine the right height for the distal component of the prosthesis, the different heights are tried starting at the lowest height available.

Figure C.4: Step 8 and 9 of the surgical procedure to place the CapFlex prosthesis using the palmar approach. Source: [9].

D

Detailed analysis of Phase 2 and 3: Functionality test and final placement

D.1. Phase 2, Functionality Test: detailed analysis

D.1.1. Determine height

A concept from the world of knee prosthetics is that the lateral bands should be under the same tension in all angles of flexion/extension. That can be achieved by choosing the right thickness of the distal component. The thickness of the proximal component cannot be varied. The instrument used to pick the right thickness is the height determination instrument (HDI), see Figure 2.12 and D.1. There are three possible heights to choose from: 2.1, 3.0 and 4.4 mm. The surgeon knows he or she has the right size, when lateral play is at a minimum with the instrument in between the proximal component and the distal bone surface when the finger is in full extension. In order to determine the correct height of the distal component, the proximal test component should already be placed. Like stated in the introduction of this Section, this sub-phase does not come chronologically first in the placement procedure. However, since bringing the distal component into place can only happen after the correct height is determined, it was chosen to discuss this sub-phase first.

Now comes the second application of the HDI, referred to earlier in Subsection 2.2.2. The HDI can also be used to align the vertical saw cut on the middle phalanx such, that Requirement **5** of the RFCAL is fulfilled. Remember, Requirement **5** of the RFCAL is: the normal vector of the flat surface of the distal prosthetic component is parallel to the longitudinal axis of the middle phalanx. The surgeon had to do this all by the eye and the hand. The HDI can be used in helping aligning this surface correctly in an iterative way. This is called *ligament based osteotomy* of the middle phalanx. By putting the HDI in between the proximal component and the flat base of the middle phalanx, he or she brings the ligaments under tension as described before, hence the name of the technique. The surgeon can now evaluate the way the middle phalanx is aligned with respect to the proximal phalanx in both flexion and extension, as the HDI simulates the distal component. Evaluation can be done both by the eye as using fluoroscopy. If the surgeon is not satisfied, he or she quickly removes the HDI, makes an adjustment using the oscillating saw or mill to the surface, and checks again using the HDI. This is a quick, iterative and -in case done correctly- reliable technique to align the sagittal planes of both phalanges. Take in mind that in order for this technique to be fully effective, the proximal prosthetic component should be aligned in the correct manner.

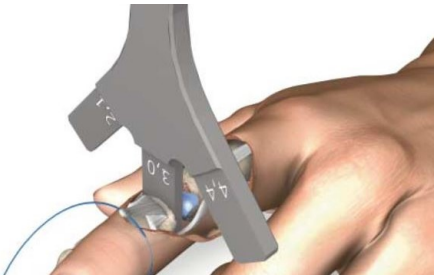


Figure D.1: Using the height determination instrument the proper thickness for the distal component of the CapFlex prosthesis is chosen. Source: [9].

D.1.2. Bring test prosthesis into place and secure it

In the next sub-phase, first the proximal component of the test prosthesis is brought into place. The first instrument used is the positioner, see Figure 2.12 and D.3. The positioner both holds the prosthesis and prevents the prosthesis from tilting downwards. If all previous steps went correct, the outer contour of the head of the proximal phalanx guides the prosthesis such that it should be aligned correctly. Since the prosthesis has a dorsal and a palmar side, it is very important that the condyles are pointed towards the dorsal side. Once the test prosthesis is seated correctly, the wheel on the handle of the positioner is turned clockwise, such that the mouth of the positioner opens and releases the test prosthesis, see Figure D.2. The modulator (see Figure D.3b) is now placed on the test prosthesis and hammered until the prosthesis is press-fitted on the head of the proximal phalanx.

Just like with the proximal component, a test component is placed for the distal component, see Figure D.4a. It is brought into place using the impactor. The channels and the flat surface created in PP should make sure the test prosthesis is placed correctly aligned.

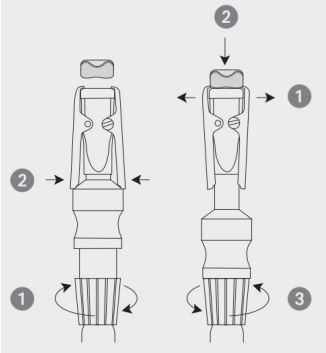


Figure D.2: By turning the wheel on the handle of the positioner clockwise, the mouth moves outwards. The mouth moves inwards by turning the wheel counter-clockwise. Source: [9].

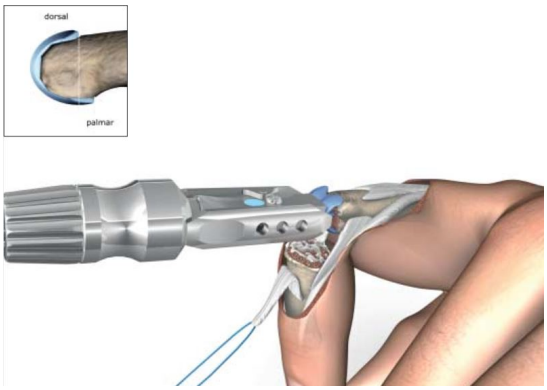
D.1.3. Test and remove the test prosthesis

After each of the prosthetic components is placed, fluoroscopy is used to check whether the components are correctly aligned relative to the corresponding phalanges. Now follows a function test, see Figure D.4b. The central slip is pulled proximally, and the finger should be able to extend completely. In case the finger cannot fully extend, apparently there is a lack of space and a thinner distal component should be used until the extension deficit is gone. Meanwhile, if the finger can overextend, a thicker distal component should be chosen. Lateral play should be 10° at most and alignment of both prostheses is yet again checked by fluoroscopoy. When the surgeon is not satisfied, he or she will have to redo (elements of) PP until he or she is satisfied with the result. Either way the surgeon has to remove the test prostheses again by using the positioner. The mouth is placed over the prosthetic components, the wheel is turned counter-clockwise until it has a grip on the component after which it is pulled out.

D.2. Phase 3, Final placement

D.2.1. Placing and testing of the final prosthesis

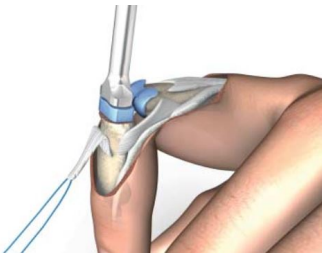
Once the surgeon is satisfied with the result of FT, the final prosthetic components with the same sizes as the test components are placed using the positioner and impactors. This is done the same way as in FT, but then using the final prosthesis. The outer contours of the phalanges guide the placing of the components, tests take place using fluoroscopy and by evaluating flexion and extension movements. Yet again, if the surgeon is unsatisfied he or she has to redo (elements of) PP. In case everything is as it should be, the soft tissue structures are repaired, the skin is closed and postoperative treatment can start. A fluoroscopic picture of a finger containing the CapFlex prosthesis can be seen in Figure D.5.



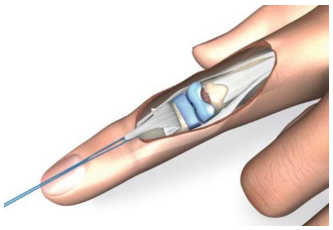
(a) The test prosthesis is placed by means of the positioner. This instrument can both be used to place as to detach the test prosthesis from the phalanges. On the top-left the matching 45° angled edges on both the head of the proximal phalanx and on the inside of the proximal component of the CapFlex prosthesis can be seen.

(b) The proximal impactor (left) and the positioner (right) used for insertion of the test prosthesis.

Figure D.3: Image of the placing of the proximal component of the test prosthesis and the instrment used. Part of FT of the placement procedure of the CapFlex Prosthesis. Source: [9].



(a) The test distal component is inserted using the distal impactor.



(b) The function test is done with the test prostheses in place.

Figure D.4: Placing the distal component of the test prosthesis and testing the function of the finger. Source: [9].

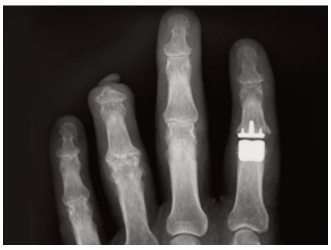


Figure D.5: After the placement of the CapFlex prosthesis is done, the finger in which the prosthesis is placed looks like this in a fluoroscopic image. Source: [9].

E

Concept 1

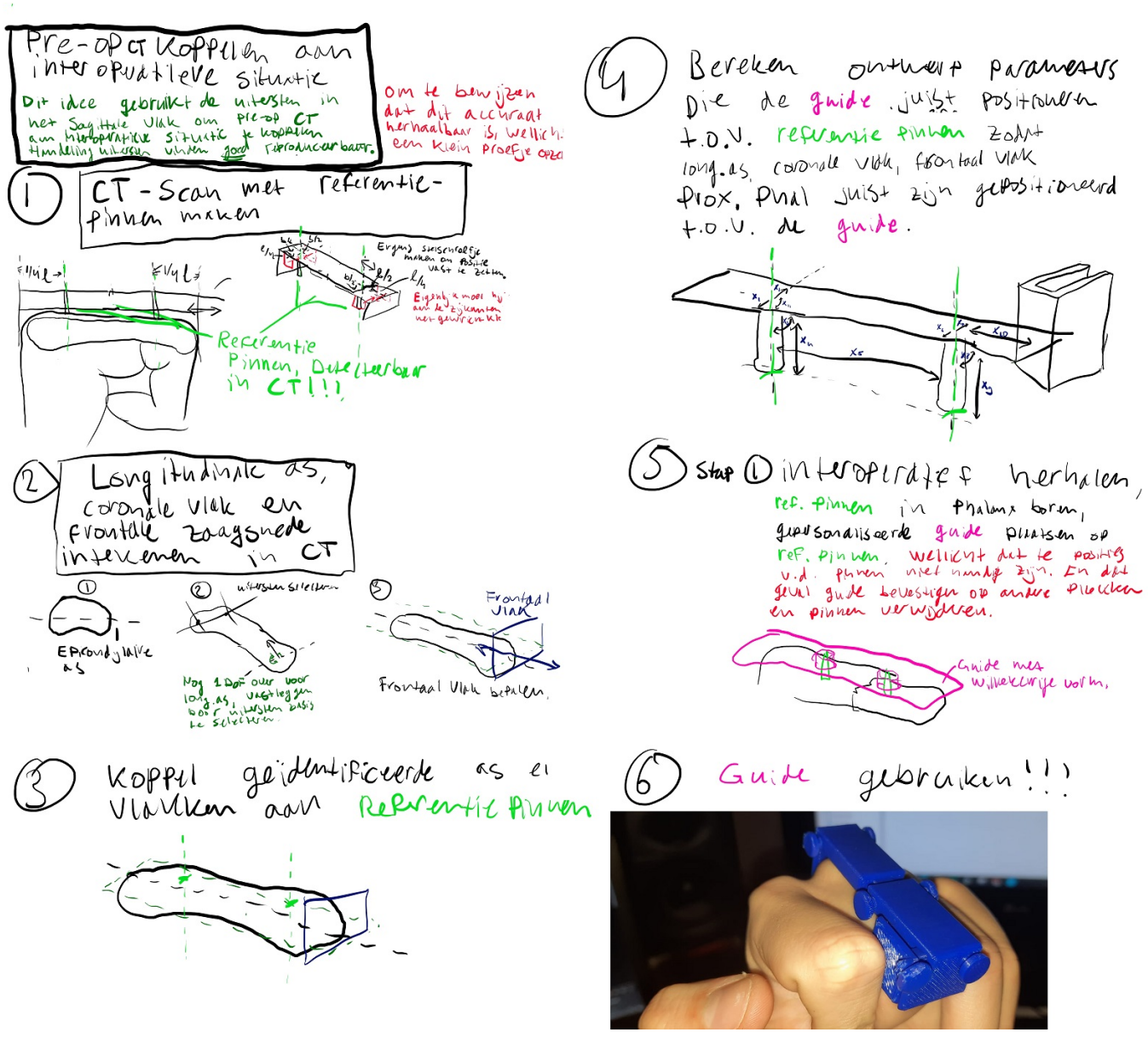


Figure E.1: Concept 1 including a photograph of a 3D-printed photograph of the clamp.

F

Concept 2

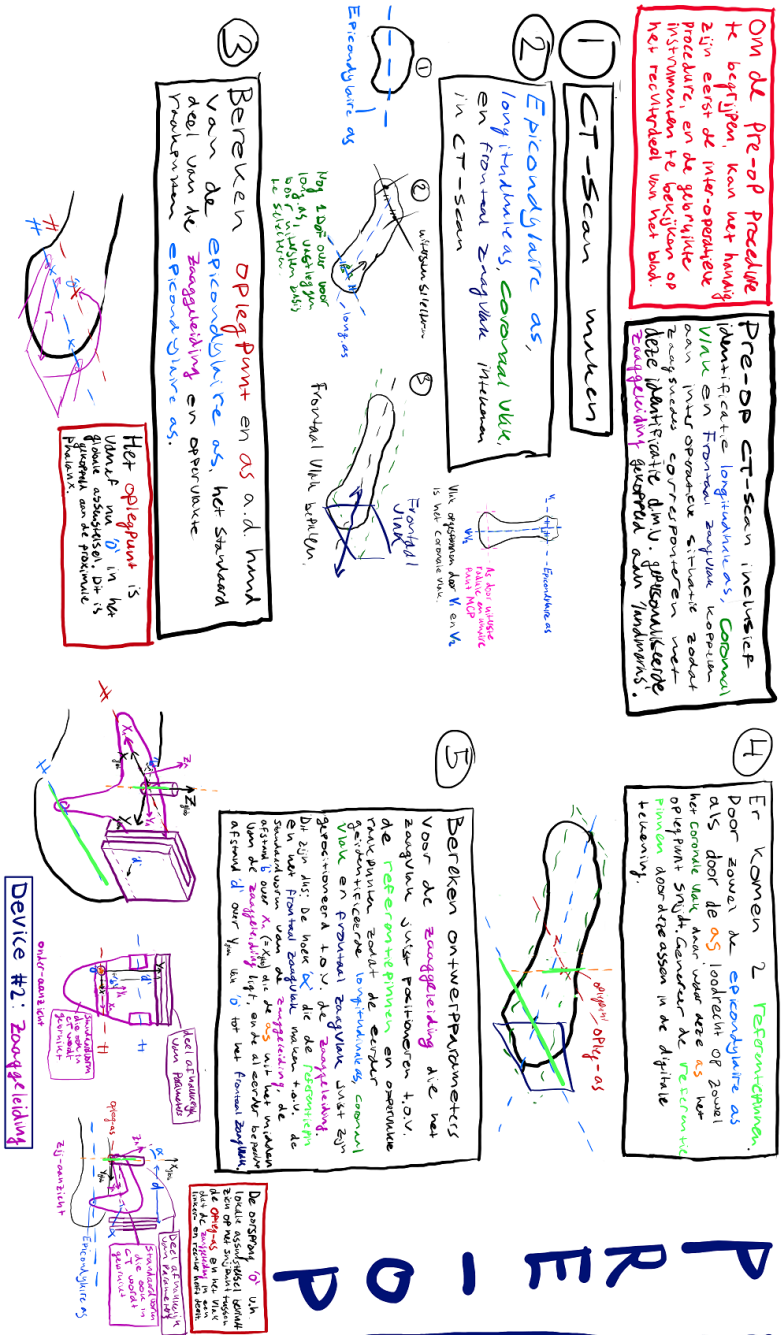


Figure F.1: Concept 2: pre-operative steps

Figure F.2: Concept 2: inter-operative steps

Device 1 — Epicondylar Identifier (EpID)

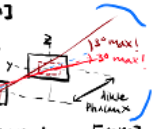
Functie: Boring K-Draad door epicondylaire as geleiden

Uitgangspunt: Er wordt geklemd op de radiale en ulnaire uitsteken van de condylen: morfologische landmarks goed te herkennen én deel van de ep.as

Functional Requirements:
- Geleiden K-Draad door Epicondylaire as
- Klemmen/constrainen op Epicondylaire as
- Verstelbaar

Specifications:
- Bio-compatible X Steriliseerbaar
- Disposable óf makkelijk schoonmaakbaar
- Verwijderbaar na Plaatsing K-Draad

Constraints:
- Klemmen binnen bereik van ... t/m ... [mm]
- Klemkracht binnen een bereik van ... t/m ... [N]
- Niet groter dan ... x ... x .. [mm]
- Maximale afwijking: ± 3° over beide assen
  - Y,Z-afwijking afhankelijk van dikte proximale phalanx



- Onder maximale klemkracht maximale vervorming van: .. [mm]
- Mag niet breken of plastisch deformeren onder maximale klemkracht
- Mag zicht op uitsten condylen niet blokkeren tot hij is geklemd.

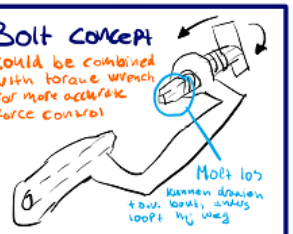
Performance criteria:
- Cost
- Manufacturability
  - Hinspanningen Frees/Draaibank
  - # Printtijd
  -
- Controlability of applied force

Belangrijke ontwerpvariabelen
- Opspanlocaties
- Type opspanningen
-

Clamping of EpID

Bolt concept

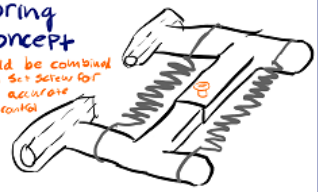
Could be combined with torque wrench for more accurate force control



Advantage: line of ext. force collinear with normal force: No bending moment to be compensated for.

Spring concept

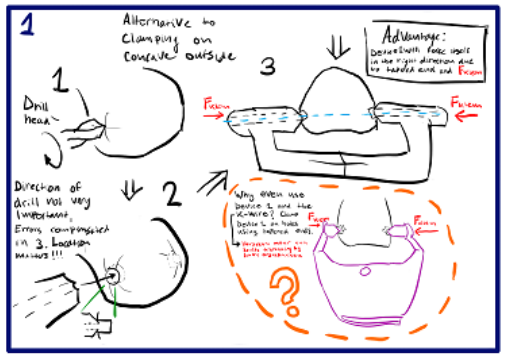
Could be combined with Set Screws for more accurate Force control



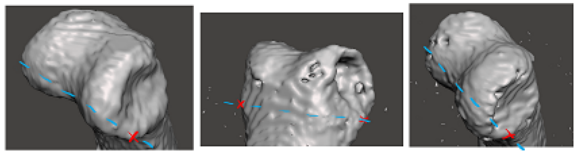
Disadvantage: less control on clamping force, Force line not in line with contact points

De Vraag is: in hoeverre valt er te klemmen op dit gladde bot? Zijn deze contacten afdoende? Loopt de EpID weg op het bot?

Alternatieve klem Principes



Klemkr borgen vermindert zicht drastisch.



Inhammen benutten voor klemmen EpID?

Figure F.3: Concept design of Device 1 of Concept 2.

Device 2

Functie: zaag juist uitgelijnd geleiden n.a.v. pre-operatieve CT-scan.

Functional requirements:

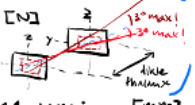
- Geleiden oscillerende zaag over vooraf bepaald Frontaal zaagvlak
  - ↳ Instelbaar naar in CT-scan bepaalde parameters
- Alle 6 DOFs tussen Frontaal zaagvlak en proximale phalanx constrainen

Specifications:

- Vorm deel 1 volledig bepaald na invoeren 3/4 parameters, te bepalen in analyse CT-scan, zijnde: a, b, d (wellicht ook breedte 1e deel)
- Montabel op eerder geplaatste referentie (K-Draad)
- Bevat geleiding voor boring K-Draad dorsale zijde proximale Phalanx boven opleggPunt
- Begeleiding oscillerende zaag op kop instrument
- Bio compatible x Steriliseerbaar
- Disposable ⇒ 3D-Printbaar

Constraints:

- Dorsale K-Draad niet verder dan 15 [MM] proximaal van "cupula"
- klemmen binnen bereik van ... t/m ... [mm]
- klemkracht binnen een bereik van ... t/m ... [N]
- Niet groter dan ... x ... x .. [mm]
- Maximale afwijking: ± 3° over beide assen
  - Y,z-afwijking afhankelijk van dikte proximale phalanx

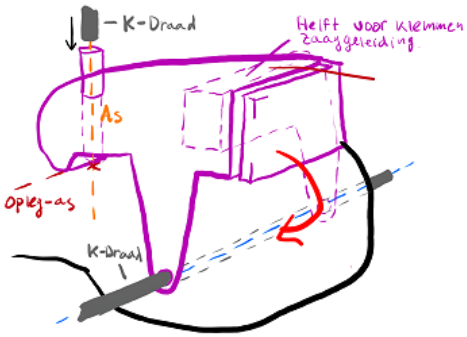


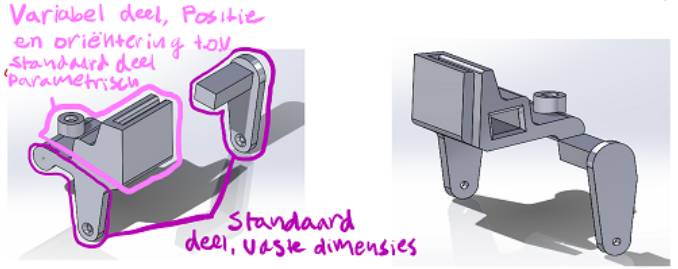
- onder maximale klemkracht maximale vervorming van: .. [mm]
- Mag niet breken of plastisch deformeren onder maximale klemkracht
- onder maximale loodrechte belasting zaggeleidingsvlak maximale vervorming van ... [mm]

Performance criteria:

- Cost
- Manufacturability
  - # inspanningen Frees/Draaibank
  - # Printtijd
- Controllability of applied force

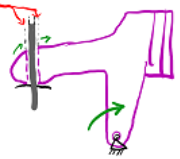
Veel van dit instrument ligt al vast door principe van het concept





Er moeten nog 2 DOFs worden geconstrained:

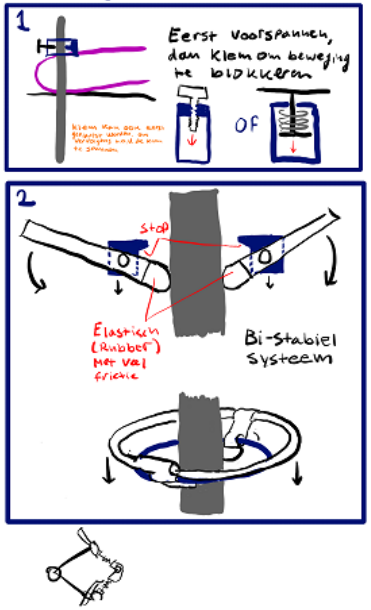
Maar door speling zal ook hier minieme rotatie moeten worden tegen gegaan



2 opties: 1) Druk de zaaggeleiding op de phalanx/andere zaaggeleidingshelft en plaats een klemmetje op de K-Draad (Niet écht een actieve klemkracht op de zaaggeleiding, meer rotatiek/axiale constraint)

2) Genereer klemkracht tussen de zaaggeleiding en de phalanx/andere zaaggeleidingshelft

Kracht genereren t.o.v. K-Draad



Kracht genereren t.o.v vinger/ander zaaggeidingsdeel

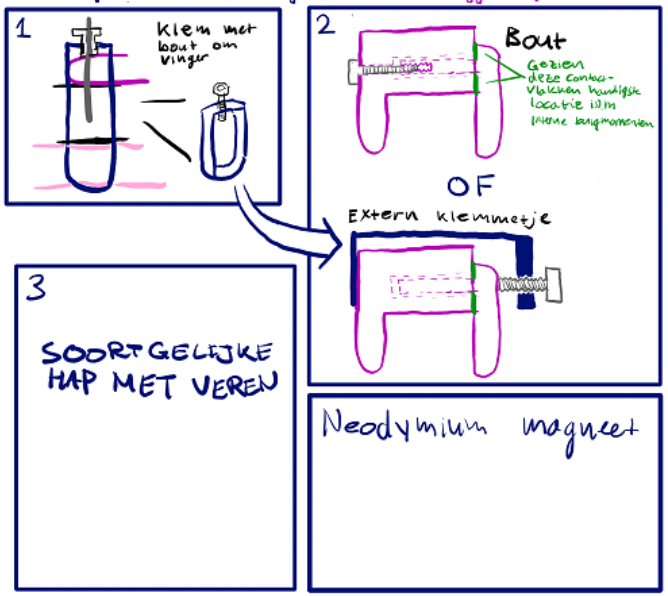


Figure F4: Concept design of Device 2 of Concept 2, including possible designs for a clamp.

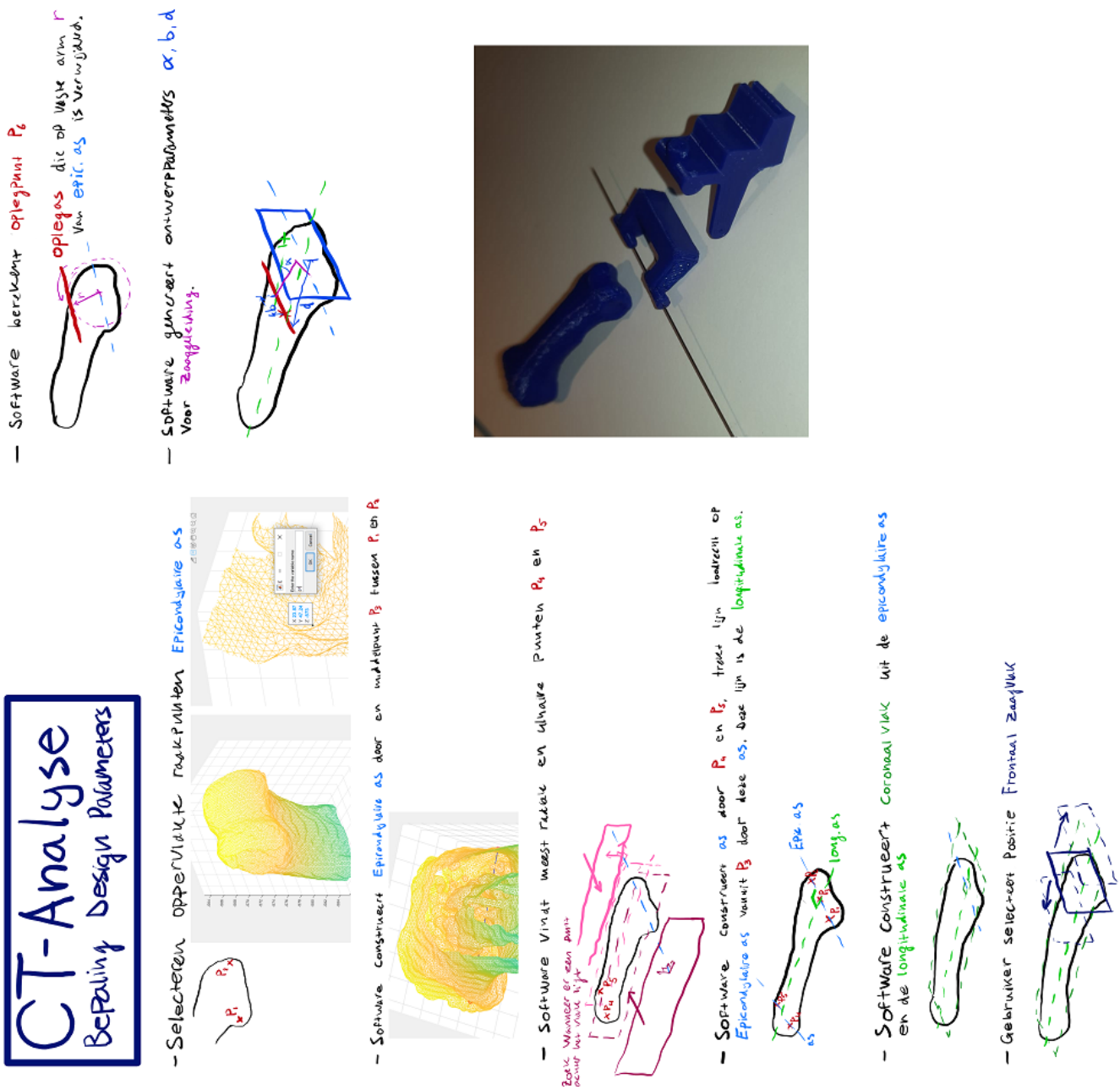


Figure F.5: Concept design of the CT-analysis of Concept 2, including a photograph of a 3D-printed prototype of Device 1 and 2.