A Configurable Guide for Knee Arthroplasty

The design of a configurable patient specific surgical guide for the alignment of bone resections in total knee arthroplasty

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ABSTRACT. In total knee arthroplasty (TKA) the contact surfaces of the knee are replaced with prosthetic components. In order to fit the prosthetic components, the bones are shaped by making bone cuts. Patient specific surgical guides (PSSGs) are guides made from CT or MRI images to fit the patient’s anatomy. They guide the bone cuts. When bone deviations disturb the fit, commercially available PSSGs cannot be adjusted. Our goal is to design a reusable PSSG for TKA which can be configured for a planned alignment and corrected during surgery when unplanned bone deviations occur.

Concepts for the functional problems are developed and combined into a final design consisting of three components: the guide, contact points and setting tool. The setting tool configures the contact points. The contact points are magnetically fixated to the guide’s base and can be removed when the fit is disturbed. Pins protrude from the contact points, indicating contact with the bone to evaluate the fit.

We assess the ability of inexperienced and experienced subjects to recognize surface disturbances using the protruding pins. Subjects position the guide and are tasked to recognize if and where disturbances occur. With inexperienced users, the disturbed contact point is correctly recognized for 7 out of 26 disturbed experiments. A significant increase is found in the rotational error for placements with a disturbance. No significant increase is found for the translational error. With experienced users, the disturbed contact point is correctly recognized for 18 out of 26 disturbed experiments. No significant increase is found in the rotational and translational error for placements with a disturbance.

Inexperienced users cannot recognize disturbances and reconfigure the guide. Experienced users can better recognize disturbances and reconfigure the guide. When disturbances were not correctly recognized by experienced users, the disturbance had only a small effect on the alignment. We recommend to correct the perceived backlash of the contact points and stiffen the guide design. Training of the test subjects is suggested when new experiments are performed.
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1. Introduction

1.1. Background

Osteoarthritis is a joint disease that damages cartilage which subsequently may lead to decreased movement of the joint and pain. In 2011 there were 53,000 new cases of knee osteoarthritis in the Netherlands [1], and arthrosis in general is expected to increase with almost 40% by 2030 [2]. An osteoarthritic knee can be treated by replacing the contact surfaces of the joint with prosthetic components. This is called knee arthroplasty. In total knee arthroplasty (TKA) the entire joint is replaced. TKA is a common surgical procedure, in 2010 close to 20,000 procedures were carried out in the Netherlands [3].

Prior to placement of the components, the distal femur and proximal tibia are prepared with bone resections. The distal femur is shaped to match the geometric shape inside the prosthetic component as seen in Figure 1.

![Figure 1: The distal femur is shaped to match the geometric shape inside the prosthetic component.](image)

The first femoral cut is the distal cut. The alignment of the subsequent cuts is influenced by the alignment of this first resection. Hence, alignment of this first resection heavily determines the alignment of the femoral component. The tibia is prepared with a single resection and this plane determines the alignment of the tibial component greatly. To align the cutting planes, blocks with cutting slots are used. To align the cutting blocks, a reference is needed during surgery. With conventional instruments (CI), this is done for the femur using a rod that is inserted into the medullary canal. For the tibia, an external rod that clamps to the ankle is often used. However, alternative referencing tools are available.

Computer navigation (CN) is such an alternative. As the name implies, it uses a computer system to help with navigation during surgery. It requires registration of specific points on the bone surface, landmarks, to create a virtual bone model. Marker trees on the leg and on the instrumentation are tracked by a camera to calculate their alignment according to the bone. The cutting blocks are placed using visual feedback of the computer which presents the alignment of the resulting cut to the user. CN has showed to more accurately reach the planned alignment [4], but there has been no sign of a resulting decrease of revision surgeries [5]. Because CN increases the cost of the procedure, a decrease in revision surgeries is necessary to make the approach cost-effective. Furthermore, registration of the bone landmarks is done with the bone exposed and therefore elongates the procedure [6], [7].

Another alternative is patient specific surgical guides (PSSGs). These positioning guides are tailor made to fit the anatomy of the patient. They are introduced to have the advantages of a computer aided planning without the disadvantage of intraoperative registration and with less added costs. CT or MRI images are used to create a virtual model of the anatomy and to determine a preoperative alignment plan. The guides facilitate in cutting the bone directly by incorporating a cutting slot, or by placing pins using pin holes after which a cutting block is placed. Since PSSGs remove the use of the femoral canal as a reference for the femur, the procedure is simplified and slightly shorter compared to CI. Results in obtaining the planned alignment are mixed. Compared to CI, PSSGs are reported to increase [8], [9], decrease [10] and get similar alignments [11]. PSSGs are designed to support on several areas on the bone. CT-based PSSGs tend to support more on bone outside of the cartilage, whereas MRI-based PSSGs often support on cartilage as well. When a bump or soft tissue occurs under the support area, placement can be disturbed as seen in Figure 2.
PSSGs are disposable and are produced according to an alignment determined on the virtual bone model. The guides are rigid and thus the alignment cannot be adjusted intraoperatively. This can be a disadvantage, as intraoperative adjustments are reported to be often needed [12]. The disposable guides are made by an external company according to high specifications. This means that the surgeon can give feedback on the design of the guide, but doesn’t have full control. Average lead times for production are around 20 to 30 days [13], during which the cartilage surface may have been damaged more and thus changed compared to the original image. Attempts have been made to develop a guide that can be customized to the patient’s anatomy, and is reusable and configurable. This keeps the surgeon in control and allows for adjustments during surgery. The goal of this thesis, which is explained in detail later, is a further development of such guides. The previous designs are discussed to show what the direction is of the development for configurable PSSGs, and to formulate a goal that builds upon these developments.

1.2. Guide designs

The Exactech Advanced Surgical Instrumentation seen in Figure 3 uses landmark registration as is done with computer navigation. This places it closer to the CN approach than PSSGs, but it has a feature that is interesting for the intraoperative configurability of guides. The guide base is fixed to the bone first, and then the location of pin slots are configured using several screws. It shows how a guide that is placed first can be corrected intraoperatively.

In 2012, Haselbacher [14] proposed a concept of using a screw-based plate seen in Figure 4 to configure a patient specific fit. This can be used as a configurable and reusable guide that can be set by the surgeon according to the preoperative plan, regaining control of the whole planning process.
To evaluate the contact interface of the pins with the bone, Van den Borne [16] redesigned the guide to have a curved surface. This follows the lateral contour of the femur as seen in Figure 6. The prototype was used to test the effect of rigid and compliant contact points on the orientation of the guide when bony deviations occur on the contact surface. The rotational errors were found to be lower when compliant contact points are used, but there were no significant differences in translational errors [16].

Mattheijer explored the design of patient-specific surgical guides and the effect of contact locations on docking robustness as seen in Figure 7 [17] [18]. A minimum of contact points means you have a minimal chance of encountering a bony deviation that was not predicted by the preoperative CT or MRI. The results show information on the placement of contact points on the bone, valuable for choosing contact point locations on the guide.

**1.3. Goal**

The goal of this thesis is to design a new reusable PSSG for TKA which can be set to a planned alignment and can be corrected when small unplanned bony deviations affect the alignment.

We evaluate the guide by answering two research questions regarding the user-guide interaction:

1. If users are able to evaluate the contact of the guide with the bone, can they recognize where unplanned bony deviations occur?
2. If users are able to evaluate the contact of the guide with the bone, can they position it according to a planned alignment?
2. Analysis

In order to define a list of requirements we create a function structure. This is an abstract model of the user tasks for a general configurable guide. From these user tasks we can also derive technical requirements, for instance the placement of the guide by the user results in requirements on stability and accuracy. A functional analysis is done to further specify these user tasks. Limitations are introduced by the design of the project and delimitations are chosen to define a scope. Finally, the requirements are presented.

2.1. Function analysis

The function structure visible in Figure 8 is described in user tasks. First, the surface of the guide is configured to match the bone of the patient it has to dock with. This configuration is verified to be according to the planning. Then it is placed on the bone perioperatively, and is checked whether or not it docks correctly with the bone surface. If not, it has to be reconfigured to correct for errors and is then placed on the bone again. When it is verified that the guide surface docks correctly with the bone surface, it is held into place by the surgeon’s docking force while reference holes are drilled into the bone. After this the reference holes are used for alignment of cutting tools and surgery proceeds without the guide. After the procedure the guide is disassembled, sterilised and assembled for its next use. For this project we look at the use of the guide perioperatively up until a verified alignment is achieved.

These tasks are used to organize the function analysis described in the next section after which this structure is described with more specific tasks in Figure 12. We describe these more specified tasks because certain design choices have altered them and they will be used to generate ideas for.

2.1.1. Configure & reconfigure guide

Alignment

The reason for designing a configurable guide is to ultimately obtain a good alignment for every patient. Conventionally, the alignment of the prosthesis is determined with preoperative planning using only radiographs, and thus the alignment of the necessary bone cuts are determined. With patient specific approaches, CT or MRI images are used to determine the anatomy of the patient. There are different methods for alignment, and the long held standard and most widely accepted is mechanical alignment. The mechanical axis of the femur runs from the femoral head to the central distal femur, and the mechanical axis of the tibia runs from the centre of the proximal tibia to the centre of the ankle [19]. The angular difference of these axes can be corrected by a varus/valgus cutting angle needed to place them in line with each other and obtain mechanical alignment, as seen in Figure 9.

![Figure 8: Functional structure of a general configurable guide. The flowchart shows the user tasks. Tasks that fall in the scope of this thesis are within the grey area.](image-url)
Figure 9: An unaligned knee (a) can be corrected to obtain a mechanically aligned knee (b) by a varus/valgus cutting angle. This is preoperatively planned using radiographs (c).

Having a postoperative malalignment of more than 3 degrees is associated with loosening of the implant [20]–[22]. However, this is the postoperative alignment of the implant, not the alignment of the cutting planes. It could be that there is a difference between the alignment of the resected plane and the alignment of the implant due to bone cement interfering with the placement. Conteduca [10] evaluates PSSGs by checking the error of the actual resection plane with a computer navigation system. They accept alignment when the rotational error is no more than two degrees in all planes to account for cumulative errors in three dimensions.

Van den Borne [16] explored the interface between the bone and the contact points. The alignment error was measured when a bony deviation occurred under a contact point. It showed that a pin based guide is able to remain well under 3 degrees rotational and 3mm translational errors when using twelve contact points. The goal of this project is to improve on this and plan to stay under 2 degrees and 2 millimetres.

**Contact points**

Using contact points to connect with an arbitrary surface has two big advantages over using contact surfaces. First, it is much easier to make a set of contact points adaptable than it is for contact surfaces. This is especially powerful when designing a configurable guide. Second, when there is a small mismatch between the physical surface and the virtual surface the guide is set to, the chance of encountering the mismatch is smaller with contact points. Thus, contact points are chosen as the approach for the configurable guide. Because changing and checking configurations intraoperatively is too tedious, we decide to correct for mismatches by removing a contact point from the set. To create a deterministic fit on an arbitrary three-dimensional surface, we need six contact points because we have six degrees of freedom. However, since we want to have a unique fit of which we are sure that the position of the guide is the position we planned it to be, we want to create an over-determined fit. This means we want to use at least seven contact points at all times, to be sure we have positioned the guide correctly. Taking into account that up to two contact points may have to be removed, the minimum number of configured contact points in the guide has to be nine. A unique fit however, is not a stable fit.

Mattheijer et al. define docking robustness as the allowed variation in the line of action of the surgeon’s docking force [17] [18]. The greater the allowed variation for a certain contact set, the higher the docking robustness. They explored the design of patient specific surgical guides and the effect of contact point locations on docking robustness as seen in Figure 7. In a guide where the contact point locations on the bone can be freely chosen, the placement for 6 to 18 contact points to support on the bone is optimized for maximum docking robustness. This enables the guide to have the advantages of using contact points while maintaining stability. When robustness of a completely enclosing surface is 1.0, a guide with 12 contact points can be optimized to get a robustness of 0.74. Increasing the number of contact points will gain only a small increase in robustness but losing one has great negative impact on the robustness. Therefore we plan to use at least 12 contact points at all times. If we wish to account for the removal of two contact points, the planned goal is 14 configurable contact points. The resulting locations of the contact points also show that the edges of the cartilage are important places for support in order to get a high docking robustness.

The guide design of van den Borne [16] has a fixed grid with threaded holes. The contact points are also threaded and can be placed in the grid after which they are fixed with a nut. This is easy to
produce with standard parts, but not user friendly. Setting of the contact points, as well as placing or removing them, is a tedious job. It can take over 30 seconds per contact point and requires multiple tools for fixating, setting and measuring. The time needed for placing, setting and removing the contact points has to be reduced greatly.

**Specified function for configure & reconfigure guide**

Because we have chosen to design a contact-point based guide, configuring the guide can be specified as configuring the contact points. We want to generate ideas for the mechanical solution of how to place contact points in the desired position, but also generate separate ideas for the interaction of the user with the guide during the configuration of the contact points. This resulted in the further subdivisions ‘configure mechanism’ and ‘configure method’.

When a contact point can be configured for different settings, it introduces the extra function of locking the positions of the contact points before placing it on the bone.

We have also chosen to instead of reconfigure the guide perioperatively, just allow removal of contact points, specifying ‘reconfigure’ as ‘remove contact points’.

2.1.2. Verify configuration

**Specified function for verify configuration**

As this function is already self-explanatory, there is no need to specify it further.

2.1.3. Place on bone

**Contact area**

Kroes [15] visualized the area that is deemed accessible during surgery as seen in Figure 10. While observing a video documented procedure done with CT-based PSSGs, the author verified that the area indicated in the image was well accessible.

**Guide shape**

Van den Borne [16] designed a prototype for the experiments, and did a redesign of the guide. He designed the guide to follow the lateral contour of the distal femur, allowing for support on and around the whole joint surface. It also makes the grid finer at the cartilage because the contact surface is closer to the centre of the contour as seen in Figure 11.

Furthermore, it positions the pushing force exerted on the guide as close to the bone as possible, allowing for more deviation in pushing direction and making the fit more robust. Following the lateral contour will be used in our guide design to enable support onto the accessible bone during surgery.

**Specified function for place on bone**

The placement on bone function results in specific requirements, but remains unchanged as a function.

2.1.4. Verify placement

In the video documented procedure done with CT-based PSSGs, placement of the guide was often checked with the printed bone model to verify if the fit on the actual bone matched the planned fit on the model. This shows it is important to ensure the planned position is reached and be able to verify this.

**Specified function for verify placement**

The maximum information we can get from a contact point consists of three things. The first is whether or not it is making contact with the bone. Second, when not in contact with the bone, what the distance between the point and the bone is. Third, the location of the contact point on the bone. For knowing the location, a computer system with reference points is needed so we will not incorporate that function. The distance of a contact point from the bone seems to add relatively little value of information compared to just knowing if a
contact point makes contact, while more complex mechanisms are required. Just verifying the contact can have simple solutions, so it is chosen that users need to be able to verify for each contact point separately if it is making contact with the bone, specified as the function ‘verify contact’.

2.1.5. Hold
While the goal of the design used by Kroes [15] was to test an algorithm for choosing contact pin locations, the experience with the prototype leads to conclusions about the locking mechanism. All pins are locked by tightening a middle baseplate that clamps the pins between the outer plates and the middle baseplate. When enough force is exerted on the guide however, pins would slide despite being locked. The clamping force was insufficient to sustain the load and this would change the alignment of the guide. When a guide is designed that has configurable contact points, it is important that they can hold a good amount of pushing force when locked.

**Specified function for hold**
This function also remains unchanged.

As some functions have been altered, a more specified function structure is visible in Figure 12, as well as the connection between the tasks and the conceptual development of chapter 3.

2.2. Scope
Limitations in time and approach of the project combined with chosen delimitations define the scope of the project.

2.2.1. Delimitations
- The need for a configurable guide is found in previous research and projects, but no user research is conducted to verify this need.
- Aligning drill holes for the bone is not taken into account when designing the guide, the goal is to be able to align a guide base. Future development can translate this into aligning drill holes.
- Postoperative processing of the guide is not taken into account. This includes the disassembly and sterilization.
- Rigid contact points are chosen, even though a compliant contact point based guide proved to decrease rotational errors when disturbances occur. However, compliant contact points can introduce additional problems when the docking force fluctuates and the pushing force is insufficient.
direction varies, which is the case when conducting user experiments.
- We choose to design a guide which can be reconfigured for a robust fit only when two or less contact points are affected. If more points are affected, this may indicate the errors are more than just small unrecognized bony deviations.
- We are not looking at production methods or material specifications. This means no cost analysis will be done as well.
- For user experiments using the designed guide, we choose a convenience population consisting of various orthopaedic staff members and PhD students in the Leiden University Medical Centre. These are not end users which are orthopaedic surgeons, because it would result in a very small population given the time schedule for the experiment.

2.2.2. Limitations
- Time limits us from evaluating the design on all requirements. Instead, user experiments are done to evaluate a core design goal.

2.3. Requirements
A list of requirements is created using a simplified version of the Tom Gilb method [23]. These are ‘hard’ requirements, meaning they can be verified. It describes how to determine (HTD) if the requirement is met, and describes the rationale behind it. To introduce a scale to which degree a requirement has been met, they are defined with three goals: a minimum (must do) target, a planned target and an ideal wished target. The minimum target is self-explanatory and is the hard requirement for the design, if this is not met the design fails. The planned target is a desired target, it is also a reachable goal but due to combinations of solutions or necessary compromises this may not be met for all requirements. The ideal wished target is a reach further and may not even be possible, but is the target that can be met in an ideal world. It is a direction for further development.

**Target, must do:** Minimum nine contact points to account for the removal of two and still have an overdetermined fit.

**Target, plan:** Fourteen contact points to account for the removal of two and have a fit with high robustness.

**Target, wish:** -

**Rationale:** With seven contact points the fit on the bone is over determined. This is necessary to identify the placement of the guide on the correct position. When disturbances on the bone surface occur, removal of a contact point may be necessary. To account for this and still have an over determined fit, nine contact points are at least needed.

**References:** [18].

**Title:** Configuration time.

**Description:** Setting the contact points to their planned positions preoperatively must be done within a certain amount of time.

**Scale:** Minutes.

**HTD:** Subjects are presented with a guide and a planned fit. Time for setting the guide to the fit is measured.

**Target, must do:** ≤10min.

**Target, plan:** ≤5min.

**Target, wish:** ≤1min.

**Rationale:** When the setting time of the guide is long it will disturb the daily workflow of the medical professional and acceptance of the design by the user is less likely.

**References:** -

**Title:** Configuration accuracy.

**Description:** The contact points must be placed in their planned positions with a certain accuracy.

**Scale:** Millimetres.

**HTD:** When contact points are brought to their planned position, the difference between the actual position and planned position is measured.

**Target, must do:** An error of ≤0.5mm.

**Target, plan:** An error of ≤0.3mm.

**Target, wish:** An error of ≤0.1mm.

**Rationale:** Inaccurately placed contact points will lead to a malalignment of the bone cuts and thus malalignment of the prosthesis.

**References:** -

**Title:** Verifying configuration.

**Description:** The positions of the contact points have to be verified preoperative with a certain accuracy.

**Scale:** Millimetres.

**HTD:** The options for measurement in the design are selected to have specifications that meet the accuracy target.
Target, must do: An error of ≤0.2mm.
Target, plan: An error of ≤0.1mm.
Target, wish: An error of ≤0.01mm.

Rationale: When contact points are placed, they have to be verified in order to avoid errors in the final position.

References: -

Title: Locking contacts.
Description: The contact points have to withstand the force applied to the guide without changing position.
Scale: Newton.
HTD: The guide is placed in its planned position and a force is exerted pushing it towards the centre of the epicondyles. The amount of force that can be exerted under which the contact points remain in their configuration is measured.
Target, must do: The contact points retain their position under a force of 500N.
Target, plan: The contact points retain their position under a force of 700N.
Target, wish: The contact points retain their position under a force of 1000N.

Rationale: The adjustable contact points have to be locked in position to create a rigid guide. The guide is pushed on the bone to ensure a docked position while drilling holes through the pin slots.
References: Intuitive sufficient pushing force was exerted and measured.

Title: Support area.
Description: The guide has to support on the bone during surgery. Only a limited area is available. Additionally, when a smaller area can be used to support on, the incision necessary for the procedure can be smaller resulting in a less invasive procedure.
Scale: Visual reference.
HTD: Available contact area during surgery is specified by orthopaedic surgeons. The size of the guide has to fit over this area, but not exceed it with more than one centimetre. When the guide is configured, it is evaluated if all necessary contact point locations are within this area.

Target, must do: The area visible in Figure 10.
Target, plan: The area visible in in Figure 10.
Target, wish: -

Rationale: Due to the size of the incision and the soft tissue covering part of the bone, only limited contact area with the cartilage and bone is available for the contact points to support on.
References: [15], [18].

Title: Docking accuracy.
Description: The guide must remain stable in the planned position when pushed on the bone.

Scale: Translation in millimetres and rotational angles in degrees.
HTD: After the guide is prepared for a planned fit, the guide is placed with a force towards the centre of the condyles. The resulting position is compared to the planned position of the guide, with a coordinate system that has its origin in the centre of mass of the guide base. Angles are taken from an axis-angle representation and translations are taken from the length of the translational vector.

Target, must do: Errors of ≤2mm translational and ≤2° rotational.
Target, plan: Errors of ≤1mm translational and ≤1° rotational.
Target, wish: Errors of ≤0.5mm translational and ≤0.5° rotational.

Rationale: When the guide shows signs of rocking in its planned docking position, it can affect the placement and rotation of the eventual bone cuts. An accurate placement of the bone cuts is needed for accurately aligned prosthesis components.
References: [10].

Title: Removal time.
Description: Removing a contact point perioperatively must be done within a certain amount of time.
Scale: Seconds.
HTD: Subjects are presented with a guide set to a planned fit and a bone model with two deviations on two contact points. Time for recognizing the faulty contact points and removing them is measured.

Target, must do: ≤120sec.
Target, plan: ≤60sec.
Target, wish: ≤10sec.

Rationale: When the fit is inaccurate due to bone disturbances, the affected contact points have to be identified and removed. If this is a tedious effort, surgeons may be prone to use conventional guides due to their adjustability for intraoperative changes.
References: -

Title: Verify contact.
Description: The contact points need to be evaluated if they are making contact with the surface perioperatively.

Scale: -
HTD: The guide is pre-set to a planned fit. The surgeon places the guide on the bone and verifies if all points make contact.

Target, must do: Yes, the surgeon can verify what contact points are making contact.
Target, plan: Yes, the surgeon can verify what contact points are making contact.
**Target, wish:** Yes, the surgeon can verify what contact points are making contact.

**Rationale:** When the guide is placed on the bone, it may be possible that a deterministic fit is found using six contact points that does not result in the planned orientation. When the over determined fit is obtained where all contact points make contact, there is more certainty that the planned orientation is reached. The surgeon should be able to validate this placement.

**References:** [17].
3. Synthesis

The most important tools resulting from the analysis are the individual functions and the requirements. The functions are used to generate ideas for, and the requirements are used to evaluate the ideas with. Ideas are evaluated with Harris scores which can be viewed in Appendix A. The selected ideas of the different functions are combined into concepts. These are concepts of one or two functions however, and not overall concepts. It is chosen to do it this way, because when several overall concepts were developed, it was recognized that certain specific solutions could still be seen and evaluated separate from each other. This gives us the freedom to make a selection of the best conceptual solution to different problems and combine them into a final concept. This process, and how it connects with the functions from section 2.1, can be seen in Figure 12.

3.1. Conceptualization

The partial concepts are created for: positioning contacts, configuration, placement and removal of the contact points and contact indication. For each of these four problems, two to four concepts are made as seen in Table 5-8. The decisions for the concepts are made using the weighted objectives method [24]. This shows how high the importance of the different objectives is regarded during the selection.

3.1.1. Positioning contacts concepts

Ideas for the configuration mechanism are combined into the positioning contacts concepts visible in Table 5. The simplest ideas scored highest, resulting in combinations of simple one degree of freedom ideas. The solutions are all based on a placement in a two dimensional surface, in which contact points are inserted that will determine the depth setting for the third dimension. The weighted objectives scores can be seen in Table 1.

<table>
<thead>
<tr>
<th>Placement freedom</th>
<th>Grid regions</th>
<th>Sliders</th>
<th>Discrete rows</th>
<th>Fixed grid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight</td>
<td>5</td>
<td>6</td>
<td>8</td>
<td>7</td>
</tr>
<tr>
<td>Mechanism simplicity</td>
<td>2</td>
<td>4</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Setting time</td>
<td>4</td>
<td>6</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Human error proof</td>
<td>3</td>
<td>6</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Total</td>
<td>80</td>
<td>72</td>
<td>103</td>
<td>102</td>
</tr>
</tbody>
</table>

The simple approaches score highest because simplicity also decreases the chance for human error. Continues movements enhance the freedom but increase the chance for a small error and most likely setting time as well. A trade-off must be made between the freedom and the simplicity, and the discrete rows concept does this the best.

3.1.2. Configuration concepts

The ideas for the method for setting the configuration of the guide and the method for verifying the settings are combined into the configuration concepts visible in Table 6. Since manually interacting with the contact points would be too time consuming and installing additional systems in the guide would require extra space and diminish the placement options, an external tool is chosen for both concepts. The weighted objectives scores can be seen in Table 2.
Table 2: Weighted objectives scores for the configuration concepts.

<table>
<thead>
<tr>
<th>Setting concept</th>
<th>Weight</th>
<th>Accuracy</th>
<th>Simplicity</th>
<th>Setting time</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bench that sets the contact points outside the guide</td>
<td>4</td>
<td>9</td>
<td>5</td>
<td></td>
<td>88</td>
</tr>
<tr>
<td>Setting head that automatically configures one-for-one</td>
<td>5</td>
<td>8</td>
<td>7</td>
<td></td>
<td>76</td>
</tr>
</tbody>
</table>

Although both concepts increase the accuracy from setting with manual tools, a fully automated tool can check every possible manual handling involved. This eliminates human error and because the entire setting process is outsourced to the setting tool, there is no extra time involved.

3.1.3. Placement and removal of contact points concepts

Ideas for locking the contact point settings and for removing contact points are combined into concepts visible in Table 7. Although locking is in all cases based on a bolt and nut principle, the solution for using an insert or to use two bolts as a mechanical stop have a different approach. The weighted objectives scores can be seen in Table 3.

Table 3: Weighted objectives scores for the removal of contact points concepts.

<table>
<thead>
<tr>
<th>Removal concept</th>
<th>Weight</th>
<th>Contracting tip with quick release</th>
<th>Magnetic insert with quick release</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Removal time</td>
<td>5</td>
<td>7</td>
<td>8</td>
<td>45</td>
</tr>
<tr>
<td>Required space</td>
<td>4</td>
<td>7</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>63</td>
<td>68</td>
<td>45</td>
<td></td>
</tr>
</tbody>
</table>

Simplicity and compactness lead to the higher score of a magnetic fixation with a pre-set stop.

3.1.4. Contact indication concepts

Ideas for verifying contact are translated directly into concepts for contact indication seen in Table 8. All three concepts are based on visual feedback. The weighted objectives scores can be seen in Table 4.

Table 4: Weighted objectives scores for the contact indication concepts.

<table>
<thead>
<tr>
<th>Contact indication concept</th>
<th>Weight</th>
<th>Protruding head</th>
<th>Protruding insert</th>
<th>Force sensor with light</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Space efficient</td>
<td>4</td>
<td>7</td>
<td>3</td>
<td>2</td>
<td>58</td>
</tr>
<tr>
<td>Visibility</td>
<td>4</td>
<td>3</td>
<td>5</td>
<td>7</td>
<td>50</td>
</tr>
<tr>
<td>Simplicity</td>
<td>3</td>
<td>6</td>
<td>6</td>
<td>5</td>
<td>51</td>
</tr>
</tbody>
</table>

Added required space in the guide is undesirable because it results in less options for placement of the contact points. This is the main reason for the protruding head to win because the other concepts have low scores on this objective. Its visibility is a weak point, and has to be evaluated with a prototype.
Table 5: Figures and descriptions for the positioning contacts concepts.

<table>
<thead>
<tr>
<th>Grid regions</th>
<th>Sliders</th>
<th>Discrete rows</th>
<th>Fixed grid</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Image" /></td>
<td><img src="image2.png" alt="Image" /></td>
<td><img src="image3.png" alt="Image" /></td>
<td><img src="image4.png" alt="Image" /></td>
</tr>
<tr>
<td>There are several regions that have a fixed grid for placement of the contact points. The regions can move separately from each other to position contact points accurately on key support points.</td>
<td>Rows of sliders allow for placement of the contact points. In one direction this placement is discrete, but the sliders have continuous movement to accurately position the contact points on key support points.</td>
<td>The rows of overlapping holes result in discrete placement in both directions. The distance in the rows between the holes is smaller than with a fixed grid, giving a better freedom to position the contact points.</td>
<td>A simple grid resulting in discrete options in both directions. The freedom is limited but its simplicity makes it easily adaptable to every design choice.</td>
</tr>
</tbody>
</table>

Table 6: Figures and descriptions for the configuration concepts.

<table>
<thead>
<tr>
<th>Setting head that automatically configures one-for-one</th>
<th>Bench that sets the contact points outside the guide</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image5.png" alt="Image" /></td>
<td><img src="image6.png" alt="Image" /></td>
</tr>
<tr>
<td>A setting head that moves in one direction and a holding bay for the guide moves in the perpendicular direction. This allows the setting head to access all locations for the contact points. The head will have an interface to dock with the contact points depending on the design, for instance with a hex key. With this solution, the user can let the instrument do all the work and spend no extra time in setting each contact point.</td>
<td>An external bench is used in which a contact point can be placed. The setting of the contact point is then set, either with the bench aiding in precise measurements, or with an automated bench doing the setting.</td>
</tr>
</tbody>
</table>
Table 7: Figures and descriptions for the placement and removal of contact points concepts.

<table>
<thead>
<tr>
<th>Contracting tip with quick release</th>
<th>Magnetic</th>
<th>Insert with quick release</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Diagram" /></td>
<td><img src="image2.png" alt="Diagram" /></td>
<td><img src="image3.png" alt="Diagram" /></td>
</tr>
<tr>
<td>The contact points are fixed on the guide. The tip of the contact point is connected to a protruding bar that is pushed towards the head of the contact point. The head prevents the bar from shooting out, until it is turned and the tip of the contact points shoots up.</td>
<td>The contact points sit loose in the guide. A magnetically charged stop on the contact point connects with the guide to keep it in place.</td>
<td>The guide has inserts in which the contact points are fixed. They are held in place with a quick release hook that can be pressed to remove the insert with its contact point.</td>
</tr>
</tbody>
</table>

Table 8: Figures and descriptions for the contact indication concepts.

<table>
<thead>
<tr>
<th>Protruding head</th>
<th>Protruding insert</th>
<th>Force sensor with light</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image4.png" alt="Diagram" /></td>
<td><img src="image5.png" alt="Diagram" /></td>
<td><img src="image6.png" alt="Diagram" /></td>
</tr>
<tr>
<td>The head of the contact point is connected to the tip. When the tip is pressed, a coloured sleeve protrudes from the top of the contact point visible for the user.</td>
<td>The guide has inserts in which the contact points are fixed. When the contact point is pressed, the insert protrudes on the top of the guide with a coloured sleeve visible to the user.</td>
<td>The guide has inserts in which the contact points are fixed. The inserts cannot move in the guide, and a force sensor sits between the guide and the insert. When the contact point is pressed, the force sensor sends a signal that will activate a light embedded on the guide.</td>
</tr>
</tbody>
</table>
4. Materialization

In the materialization section the result of the concept choices is presented. The separate components and their mechanisms are explained and a user scenario is shown of the whole product. A prototype is developed to evaluate functions, further described in chapter 5. The final concept consists of three main components: The guide, the contact points and the setting tool. The guide consists of a base that allows for positioning of the contact points. Its shape and design determine the options where contact points can be placed. The contact points can be set to a certain height, and they include a mechanism to show the user when they are making contact with the bone. The setting tool is an external instrument with a bay in which the guide with inserted contact points can be placed. The tool adjusts the contact point heights to their planned position, and it checks the grid location of the contact points.

4.1. Final concept

The components of the final concept are described in detail in the following three subsections. In subsection 4.1.4, a user scenario is presented of the typical use of the design.

4.1.1. Guide

The guide’s base has the same shape as the prototype of van den Borne [16]. The lateral contour follows the cartilage surface. The placement of the contact points is different. They are inserted from the inside of the guide and connect with the magnetic layer that keeps them from falling out as seen in Figure 13. This allows for quick removal of the contact point. The contact points can be placed in a grid which consists of rows with overlapping holes (Figure 14). This allows for precise placement on key support points like the cartilage edge for a wide variety of shaped knees, without using overcomplicating mechanisms.

Figure 13: The guide base has a magnetic inner surface that is used to hold the contact points.

Figure 14: Multiple contact points can be inserted in the rows of overlapping holes.
4.1.2. Contact points
Contact points are designed to show when they are in contact with the bone. This is done with a protruding coloured pin end that is connected to the tip as can be seen in Figure 15. A light spring prevents the pin from protruding due to gravity or movement.

The tip of the contact points connects with a cut-out to the sleeve, as seen in Figure 15. This transfers the torque when the setting tool accesses the tip to adjust the depth setting.

4.1.3. Setting tool
The setting tool is an external instrument that will set and verify the contact point settings (Figure 16). The user will have to insert contact points in the correct grid hole of the guide before using the setting tool. The setting tool can verify the grid locations and indicate if correction is needed. A bay in the setting tool will hold the guide and a setting head will interact with the contact points. The bay can rotate around the central axis of the guide’s cylindrical curvature and in this way the row that needs to be accessed is selected. The setting head accesses the contact points from the inside as seen in Figure 16, and can move linear to select the column of the contact point that needs to be accessed.

![Figure 15: a) Components of the contact points, b) partial section view of contact point when not in contact with the bone, c) partial section view of contact point when in contact with the bone.](image)

![Figure 16: The setting tool contains a bay in which the guide is placed (a). This can rotate the guide around the centre of its curvature. A head inside the setting tool (b) can move linear. With these two movements all contact points can be accessed.](image)
The three nuts with radial teeth are accessed by three tubular parts of the setting head as seen in Figure 17. The outer part is the reference head as it docks with the reference nut. The middle part is the locking head as it docks with the locking nut and it can rotate to lock or unlock the nuts. The innermost part is the tip head as it docks with the tip. When the nuts are unlocked, and the tip head is rotated it will change the depth setting of the contact point.

The tip head is pushed upwards using a spring. This way it automatically docks with the contact point tip when the reference head docks and it also remains docked when the setting is changed.

Figure 17: Cross section of the setting head and the interaction with the contact point during setting. The setting head has three main tubular components that dock with the contact points. These components reside in the slider that moves linear along the rows of the guide. The three components are all moved in position by gears that can be driven by actuators. The steps are shown for changing the depth setting of a contact point.

Thesis: A configurable guide for knee arthroplasty
4.1.4. **User scenario**
The user scenario in Figure 18 shows the typical interaction of the user with the guide and the setting tool. The scenario runs from receiving a planning up to the aligned placement of the guide on the bone. Note that drilling holes are not incorporated in the design, as stated in section 2.2.1.

![User scenario images](image)

**Figure 18**: User scenario of the configurable guide.
4.2. Prototype

To evaluate the ability of reconfiguring the guide and verify its placement, a prototype is produced of the guide and the contact points. The setting tool is not prototyped to simplify the evaluation and focus on the use of the guide during surgery. The design of the prototype is altered from the concept to enable use of standard parts and basic production techniques.

The guide itself is produced with three-dimensional printing. In the final concept the inner surface is covered with a magnetic layer (Figure 13). In the prototype, magnetic strips are used between the rows of overlapping holes as seen in Figure 19.

![Figure 19: Prototype of the guide.](image)

The tip of the contact point is a metal ball welded to the protruding pin with green end (Figure 20). The round nuts with radial teeth are replaced by standard nuts that can be fixed with wrenches.

![Figure 20: Prototype of the contact point.](image)

The prototype is developed for user experiments, but other design choices can be evaluated using the prototype as well. It develops a feeling for replacing contact points using the magnetic connection and for the placement in the overlapping holes.
5. Evaluation

Experiments are performed with the prototype to evaluate the ability of users to recognize deviations from a fit and reconfigure the guide to correct the alignment. This section first presents the research questions raised in the introduction. Then the materials are described, the method of user testing is described, and the results are presented. Finally, we present the evaluation of the design requirements.

5.1. Research questions

**Question 1:** If users are able to evaluate the contact of the guide with the bone, can they recognize where unplanned bony deviations occur?

**Question 2:** If users are able to evaluate the contact of the guide with the bone, can they position it according to a planned alignment?

5.2. Materials

A 3d-printed femur model is used to place the guide on. The shape is the mean of a statistical shape model from a study by Baka et al. [25].

The guide is tracked by the Optotrak Certus system for which a marker tree is attached to the guide as seen in Figure 21. Markers are also placed on the bone to correct for possible displacements of the bone model between measurements.

Two sets of contact points are available. One set is without a disturbance, that is, with settings exactly as described in Table 9. The locations of the contact points reference to their grid positions from a top view of the guide (Figure 22). This is a configuration of 14 contact points which is optimized for docking robustness [18] as described in section 2. Their algorithm determines the location of the contact points and the depth setting. Because the print of the guide base deviates from the digital model and also bends slightly, the settings are altered manually in such a way that all pins protrude when the correct alignment is reached. Contact point two is moved from J01 to H01 and contact point five is moved from L02 to J02.

The other set of contact points is with disturbances introduced. These contact points all have a depth setting which is 1mm deeper than the settings from Table 9.

![Figure 21: Subjects place the guide on the bone model. When the desired fit is reached, the alignment of the Optotrak markers is recorded.](image)

![Figure 22: Grid of the guide in top view.](image)

**Table 9:** The configuration of the guide for optimal docking robustness. The locations refer to the grid positions in Figure 22. The settings in mm are measured from the nut that connects with the guide to the tip of the contact point.

<table>
<thead>
<tr>
<th>Contact point</th>
<th>01</th>
<th>02</th>
<th>03</th>
<th>04</th>
<th>05</th>
<th>06</th>
<th>07</th>
<th>08</th>
<th>09</th>
<th>10</th>
<th>11</th>
<th>12</th>
<th>13</th>
<th>14</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location</td>
<td>B01</td>
<td>H01</td>
<td>Q01</td>
<td>Z01</td>
<td>J02</td>
<td>P05</td>
<td>X05</td>
<td>J07</td>
<td>I09</td>
<td>X09</td>
<td>L11</td>
<td>O11</td>
<td>P12</td>
<td>V12</td>
</tr>
<tr>
<td>Setting(mm)</td>
<td>15.53</td>
<td>14.60</td>
<td>18.04</td>
<td>11.68</td>
<td>18.29</td>
<td>13.04</td>
<td>11.28</td>
<td>11.63</td>
<td>11.28</td>
<td>12.98</td>
<td>17.22</td>
<td>18.55</td>
<td>14.07</td>
<td></td>
</tr>
</tbody>
</table>
The guide is fitted with the first set by default. Contact points can be switched with the ones from the second set to mimic the presence of a bump on the knee model.

5.3. Method

The experiments are performed with two different target groups. User tests are performed to validate if people inexperienced with the guide can successfully detect the disturbances using the protruding pins mechanism. Expert tests are performed to evaluate if people that are experienced with the guide can successfully detect the disturbances using the protruding pins mechanism.

5.3.1. User tests

The participants completed a scenario consisting of two tasks. The first task was to recognize if and where disturbances were located. The second task was to reconfigure the guide and place it in the planned position. This was done for six configurations. Three of these configurations were with the contact points of set one, without disturbances. The other three configurations had one contact point switched with a disturbed contact point. For each participant, the disturbed contact point was also randomized. Pins one to four were omitted from the disturbance selection. They showed a lot of backlash and were fixed on the guide with an additional nut. This would require extra time to replace with a disturbed contact point, which could hint the participant for the location of the disturbance prior to placement.

When inexperienced users are presented with a disturbance first, it is difficult to judge the required force to protrude the pins and get a feeling what a good fit feels like. For that reason, all participants started with a configuration without disturbance. The order of the remaining five configurations was randomized to diminish the learning effect in the rest of the placements. The first placement without disturbance and the first placement with a disturbance were used to gain familiarity with the use of the guide. These measurements are omitted from the data.

When subjects believed they reached the desired fit, the alignment of the markers was recorded for two seconds with the Optotrak Certus system. The mean of the marker coordinates during this time are the coordinates used to determine the alignment.

The fourteen subjects that were tested are all staff and PhD students of the orthopaedic department of the Leiden University Medical Center. Results of one subject are rejected as contact points were switched during testing, changing the entire fit of the guide. The total number of measured placements is 52, of which 26 are with a disturbance and 26 are without.

5.3.2. Expert tests

Expert tests were performed with two subjects highly experienced with the guide; the author and Joost Mattheijer, the supervising PhD student. They performed the same tasks as done with the user tests. A random series of configurations was generated for both subjects until at least 13 undisturbed and 13 disturbed configurations are present in the series. The total number of measured placements is 52, of which 26 are with a disturbance and 26 are without.

5.3.3. Data analysis

For research question one the resulting data is dichotomous, participants either fail or succeed in recognizing the disturbed contact point.

For research question two we present the alignment error as translations and rotations. The author placed the guide five times prior to testing, using the undisturbed settings. The mean of the marker coordinates for these placements is the baseline.

Placements during the experiments are compared to the baseline, with the centre of mass of the guide without pins and magnets as the origin. A translation error vector and a rotation error matrix are calculated from a measured placement. The length of the translation error vector is the resulting translation error. The rotation matrix is converted to an axis-angle representation, consisting of the rotation magnitude and the axis under which the rotation takes place. Since we are only interested in the rotation error and not in the direction, we only use the rotation magnitude from the axis-angle representation.

For both rotational and translational errors we can compare between the groups of placements with and without the disturbance introduced. We expect that the data is not normally distributed, so a
nonparametric test will be used. If a difference in the errors is found between placements with and without disturbances, we assume the error to increase with disturbances. This means a one-tailed test can be performed to increase power. The differences are highly skewed, making the Wilcoxon signed rank test invalid. The alternative is the paired-samples one-tailed sign test, of which the hypotheses are:

\[ H_0 = \text{The translational/rotational error when placing the guide with a disturbance is equal to placing the guide without a disturbance.} \]

\[ H_1 = \text{The translational/rotational error when placing the guide with a disturbance is greater than placing the guide without a disturbance.} \]

Disturbances can be corrected for by removing the affected contact point from the guide. Therefore we assume the errors to be equal and thus we expect to reject \( H_1 \) and accept \( H_0 \). By accepting \( H_0 \) we verify the adaptability of the guide to disturbances.

5.4. Results

5.4.1. User tests

From the 26 placements where a contact point was disturbed, 7 times the affected contact point was recognized. Additionally, in 9 out of 26 placements where no contact point was disturbed, one was removed. This shows it was not clear for users where disturbances took place. During tests, subjects often didn’t use the protruding pins to full extend to determine if the planned alignment was met. Instead, alignment was often considered to be correct even when not all pins were protruding. This is also reflected by the high outliers in both the cases with and without disturbances seen in Figure 23.

The distributions of the user tests can be seen in Figure 23 as well. The increase in the translational error median from 0.8mm to 1.2mm when disturbances were introduced is not significant (\( \alpha=0.05, p=0.084 \)). A significant median increase from 1 to 2.1 degrees in the rotational error is found when disturbances were introduced (\( \alpha=0.05, p=0.038 \)).

The fact that a significant increase is found means that users were not able to correct the guide when disturbances were introduced. Even though the difference in translational errors is not found to be significant, there is a small increase in the data with the disturbances. These results are expected, as only in seven cases the disturbance was correctly recognized

Figure 24 shows the distributions of the seven cases with disturbances where correct contact points were recognized.

\[ H_0 \]

\[ H_1 \]

Figure 23: Distributions of the translational errors (left) and rotational errors (right) of guide placements that had no disturbance and that had a disturbance under one contact point when placed by subjects inexperienced with the guide. Subjects could evaluate for contact points if they are in contact with the bone, and correct for disturbances by removing a contact point.
Both translational and rotational errors are smaller than the errors for the total population with disturbances introduced. The translational error is exceptionally small in these cases, with the highest being 1.55mm.

This indicates that users were able to reach the planned alignment when the disturbance was correctly recognized, but the population is too small to generalize.

5.4.2. Expert tests

From the 26 placements where a contact point was disturbed, 18 times the affected contact point was recognized. Additionally, in 2 out of 26 placements where no contact point was disturbed, one was removed.

This shows the experience with the guide leads to a much better recognition of the disturbances, and recognition when no disturbances are present. However, there are still 8 out of 26 placements where the disturbance was not recognize correctly.

The distributions of the expert tests can be seen in Figure 25. The increase in the translational error median from 0.6mm to 0.7mm when disturbances were introduced is not significant ($\alpha=0.05$, $p=0.423$). The increase in the rotational error median from 1.0 to 1.4 degrees when disturbances were introduced is also not significant ($\alpha=0.05$, $p=0.423$).

The fact that no significant increase is found for both rotational and translational errors, the fact that these medians are so low, and the fact that there are no outliers, show us that a good alignment was obtained in all cases. This means that in the cases where the disturbance was not recognized correctly, the disturbance did not affect the overall alignment greatly. This can be due to the fact that disturbances in some locations have a greater effect on the alignment than others and are accordingly easier to recognize.
5.5. Requirement evaluation

The evaluation of the design for each requirement can be seen in Table 10.

There is sufficient space in the guide to place the 14 contact points. The locking nuts on the contact points have no chance of loosening when pressed on the bone. The shape of the guide allows for placement of contact points on the support area. For the removal of contact points, no additional parts need to be loosened and removal can be done within a second. Contact of contact points can be verified, and thus this requirement is met, but it should be noted that it has not shown to result in a correct recognition of disturbances of the fit yet.

The setting tool is not prototyped, and thus no verification is done on the configuration time, accuracy or the verification of the configuration.

The guide did not meet the docking accuracy requirement during tests.

Table 10: Evaluation of the requirements for the design.

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Must</th>
<th>Plan</th>
<th>Wish</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of contacts</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Configuration time</td>
<td></td>
<td>?</td>
<td></td>
</tr>
<tr>
<td>Configuration accuracy</td>
<td></td>
<td>?</td>
<td></td>
</tr>
<tr>
<td>Verifying configuration</td>
<td></td>
<td>?</td>
<td></td>
</tr>
<tr>
<td>Locking contacts</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Support area</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Docking accuracy</td>
<td></td>
<td>✗</td>
<td></td>
</tr>
<tr>
<td>Removal time</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Verify contact</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>
6. Discussion

6.1.1. Goal
The goal of the thesis is to design a new reusable PSSG for TKA which can be set to a planned alignment and can be corrected when small unplanned bony deviations affect the alignment. The goal has partially been reached. The contact point based guide is reusable and can be set to different knees. The proposed setting tool can configure the guide as late as the day of the procedure. Current PSSGs require weeks of waiting for production and leaves the final control in someone else’s hands. In the proposed design, contact points can easily be removed to correct the guide when small unplanned bony deviations affect the alignment. To select the correct contact points to remove, it is important that the deviations are correctly recognized. The contact points have a protruding pin that is visible when the tip is pressed on the bone. This can aid in the recognition of these bony deviations.

6.1.2. Research questions
The protruding pins however, proved to be insufficient for users to recognize the deviations. In only seven out of 26 placements with a disturbance, the correct contact point was recognized by inexperienced users. It is safe to say that the subjects were not able to locate the disturbed contact points. The protruding pins do not directly point out a deviation because other contact points will still make contact with the bone. It does show that when all pins are protruding, the correct alignment is reached. Because some contact points would affect the alignment more than others when disturbed, and some are clustered together while others are more apart, there is no standardized method for recognizing a disturbed contact point. As experienced users, the author and supervising PhD student also performed 26 placements with guide settings where one contact point was disturbed. In 18 out of 26 placements, the correct contact point was recognized. This ratio is higher than the recognized contact points with inexperienced users, but lower than expected from experienced users. The protruding pin mechanism in the prototype is not sufficient to recognize every disturbed contact points and thus bony deviations.

From the resulting alignment errors we can evaluate if disturbances that affect the alignment greatly are successfully recognized. The alignment errors of the inexperienced user tests have high outliers for both translational and rotational errors for placements with, and without a disturbance. This shows it was sometimes difficult to evaluate a correct alignment even when no disturbances were introduced. No significant increase in translational errors was found when disturbances are introduced and both medians are well under the required maximum of 2mm. However, the highest errors that are not outliers are far over the required 2mm and 2 degrees. The rotational error median is significantly greater for the placements with a disturbance and errors are also a lot wider distributed. This is consistent with the low ratio of correctly recognized disturbed contact points. It means the subjects were not able to correct the disturbance and reach the planned alignment. Furthermore, the increased rotational error median is higher than the required maximum of 2 degrees. This could be caused by the inexperience with the guide. Low alignment errors are found in the small number of samples where the correct contact point was recognized, but the sample size is too small to generalize. A small pilot test was performed with five subjects where they got a brief hands-on instruction prior to the placement to see if this would increase the recognition rate of disturbed contact points. This proved unsuccessful.

When the author and supervising PhD student were presented with randomized configurations, no significant increases is found in the rotational and translational errors and the medians are well under the minimum requirements of 2mm and 2 degrees. There are no outliers and the highest rotational error was 3 degrees, the highest translational error was 2mm. The required maximum is 2mm and 2 degrees, but the planned for requirement is an error under 1mm and 1 degree. The median translational errors are well under 1mm, but the rotational error median was not under 1 degree. Because the disturbances were not always successfully recognized but the alignment errors are very low, we can conclude that in the cases where the disturbance was not recognized during the expert user tests, it did not affect the alignment much. Because these expert user tests showed it is possible to recognize disturbances that affect the alignment greatly, and inexperienced user tests did
not, we think that training can make the difference. Because the small pilot tests with a brief hands-on instruction proved unsuccessful, training needs to be more extensive.

6.1.3. Current available PSSGs
If we look at the early development of current available PSSGs, the initial idea was tested with alignment errors under 1mm and 1 degree [26]. When further development led to experiments on cadaver bone, a maximum error of 2.5 degrees was found with a mean of 0.67 degrees [27]. The results of our expert tests with no disturbances do not match those. Now that the PSSGs are in practice, alignment results are not reported to always improve when compared to conventional instruments. Results of both better [8], [9], [28] and worse [10]–[12] alignments are reported. Our experiments were performed on a printed bone model and we did not use cadaveric specimens. Because our setup is a more ideal situation but the resulting errors are higher than the initial PSSG tests, the design has to be improved before it can enter next development stages like clinical testing. The configurable guide is a promising view on the patient specific approach and addresses issues regarding the intraoperative adjustments and surgeon control, but cannot match in terms of alignment accuracy.

6.1.4. Additional findings
Aside from the planned evaluation of the guide, its prototype has revealed additional findings about the guide design. The overlapping holes in the base provide extra freedom for placement of contact points, but the backlash in the direction of the rows felt like too much in certain conditions.

For instance when contact points are placed on a location where they make contact with the bone under an angle of thirty degrees, they can be pushed to the side in some occasions. Prior to making the base, we tested this connection with a block that had the overlapping holes machined, and the backlash was much smaller in these samples. It could be the resolution of the printed guide base that causes the larger backlash because it was not the case in the samples. It has to be researched if a higher resolution print removes this effect, or if a grid without overlapping holes is necessary to ensure a rigid placement of the contact points.

When optimizing the configuration for robustness, we used a constraint for the contact point locations. We disregarded locations where the contact points make contact with the bone under an angle of less than 50 degrees. Aside from the mentioned backlash, the protruding pins do not work always when this angle is smaller. This constraint means there are less options to optimize for robustness. Because we also moved two contact points, the used configuration is less robust than would be possible with rigid contact points that to not need the angular constraint.

The springs in the contact points also felt too stiff. Pressing the contact point enough takes between 1 and 2N. Because the protrusions of the pins are only meant to indicate contact and not contribute in the docking, this is too much.
7. Conclusion

In the introduction issues with PSSGs are raised regarding the disturbed alignment when a bump occurs in the contact area, the inability to make intraoperative adjustments, the lack of full control by the surgeon and the production time of PSSGs. These issues can be addressed with a guide similar to the proposed design in this thesis. The configurable guide is reusable. The guide can be reconfigured intraoperatively because pins can be taken out of the contact set easily. It leaves the surgeon and supporting staff in full control over the guide and the alignment, and it can be made ready as late as the day of the procedure. However, our tests found no evidence that untrained users can recognize deviations or evaluate if the correct alignment has been reached with the incorporated protruding pins. It may be sufficient to improve the prototype and provide users with proper training as suggested before, but it has to be recognized that this system could also fall short.

Experienced users are better able to recognize the disturbances unless they are of minor influence on the alignment. We are convinced the protruding pin mechanism can be used to successfully locate the disturbances, but the prototype design may need to be changed to make the pins more clearly to the user. Now the stroke is not exactly the same for all pins, making it harder to see if a pin is completely or only partially protruding. Less stiff springs in the contact points and removing backlash when they are inserted in the guides can also make recognizing disturbances easier, because the user can better combine haptic feedback of a rocking guide with the visible protruding pins. These improvements together with tests that include extensive training could lead to validation of the protruding pins.

In terms of alignment, the design cannot match the early results of prototypes that led to the currently available PSSGs. This may be resolved when contact indication is clearer, because then it is clearer when the correct alignment is reached.
8. Recommendations

For the overall concept it should be checked if the backlash in the prototype occurred due to inaccuracy of the holes or because the design choice for overlapping holes. We checked this up front with sample blocks where the overlapping holes are drilled and there is only small backlash in these samples. However, there is also wear in the guide due to constant removal and reinsertion of the contact points. It may be necessary to produce a guide with regular holes to ensure a better fit of the contact points.

Aside from the backlash, the current prototype shows more drawbacks. The tracks that are made to insert the magnetic strips in make the guide base more flexible. It started showing little cracks around these tracks due to the concentrated stress on the corners. If a new prototype is to be produced, it is advised to close the tracks at the sides to make the guide stiffer (Figure 26).

Figure 26: The prototype had open tracks (left) to insert magnet strips. They can be closed (right) to stiffen the guide base.

The inability for inexperienced users to detect disturbances has been addressed several times now. Because the expert tests showed a high alignment accuracy, and because the cases where users detected contact points correctly also showed a high alignment accuracy, follow-up tests can be done with extensive training to fully verify the protruding pin mechanism. However, the proposed improvements on the design have to be done to make the correct fit clearer for the users.

Finally, the setting tool is not prototyped and now only developed on a conceptual level. However, this is of secondary interest as the detection of disturbances by users is directly related to misalignment during the procedure.
9. Bibliography


Appendix A: Idea generation

For the different functions ideas are generated and evaluated according to the requirements deemed applicable for that function. Table 11 presents three different stages of the idea generation.

First, it shows the generated ideas themselves. The rows represent the different functions in which ideas are presented with sketches and titles.

Second, it shows the evaluation of the ideas based on their likeliness to succeed for the requirements. Due to sizing of the table, keywords are used to appoint the different requirements on which are evaluated:

- Number of contacts.
- Configuration time.
- Configuration accuracy.
- Verifying configuration.
- Locking contacts.
- Support area.
- Docking accuracy.
- Removal time.
- Verify contact.

Because of the number and abstract level of ideas, they are evaluated with Harris profiles. With Harris-profiles, ideas are evaluated with scores of $\pm 2$, $\pm 1$, $+1$ and $+2$. The colour matching of the scores for each requirement serve a purpose, the higher scoring ideas are easily separated from the lower scoring ideas on first glance. They are sorted in Table 11 based on their scores for each problem statement, the best ideas are shown first.

Third, the selection of ideas are shown that are developed into concepts. For each problem, two or three highest scoring ideas are selected for the concepts. These are depicted with a blue (blue box), red (red box) and yellow (yellow box) in the lower right corner. In case of the first problem statement, this is a combination of separate ideas indicated by connecting lines.
Table 11: Three stages of idea generation. First it presents the generated ideas for each function in separate rows. Second it shows their evaluation with Harris scores based on the requirements. Third it shows the ideas selected for the conceptualization.

<table>
<thead>
<tr>
<th>Configure mechanism: Three degrees of freedom</th>
<th>Flexible surface</th>
<th>Bean bag</th>
<th>Liquid fit</th>
<th>Free arm</th>
<th>Gooseneck</th>
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<td>Ball joints</td>
<td>Sets on ball joints</td>
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<td>Grouped track</td>
<td>Pre-set stop</td>
<td>Single track</td>
<td>Telescopic</td>
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<td>Controller</td>
<td>Direct on contact point</td>
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</table>

Verifying settings:
- Automatic box
- External tool
- Meters on contacts
- Meters on guide
- Computer nav.

Verifying:
- Total

Verifying contact:
- Passive visual
- Active visual
- Blind
- Tactile
- External tool

Verifying contact:
- Total

Removing contact:
- Loose
- Break off
- Jump out
- Pen principle
- Fold out

Removing contact:
- Total