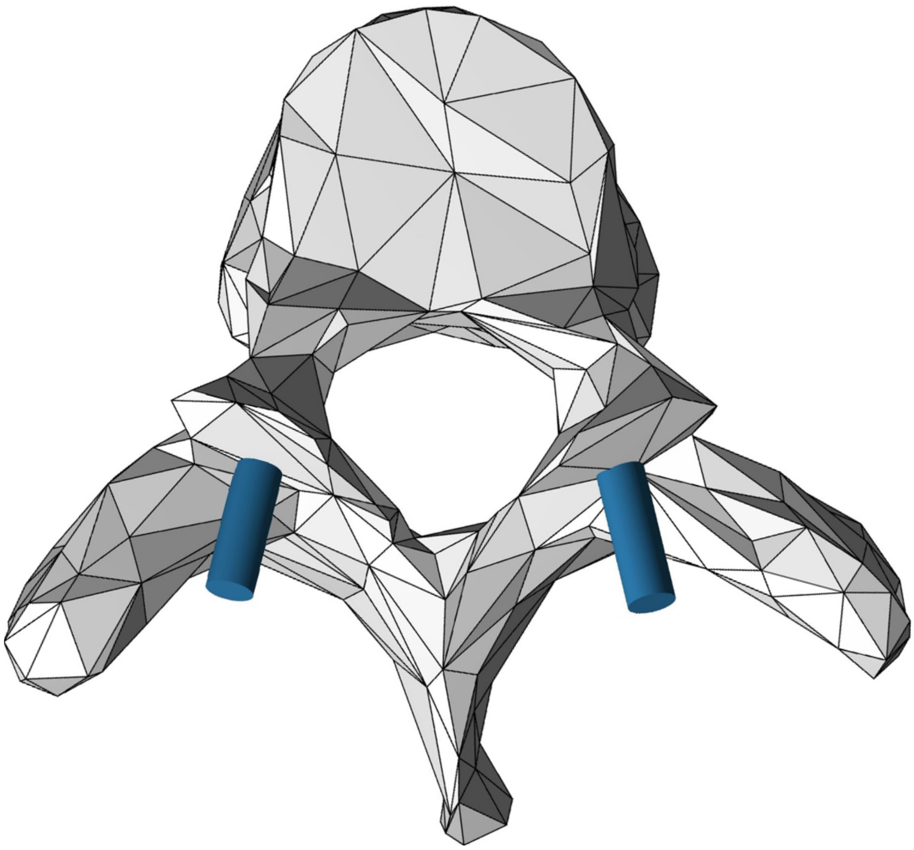
UNIVERSITY OF TWENTE.

Patient specific pre-operative plan for orthopedic surgery: from software to guides



Jasper W. van der Graaf

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Supervisors:
Prof. dr. ir. N Verdonschot
Dr. ing. S van de Groes
Dr. D. Janssen
Drs. R. Haarman
Ir. H. Dunning

University of Twente
P.O. Box 217
7500 AE Enschede
The Netherlands

Preface

In September 2011 begon ik aan de bachelor Bewegingswetenschappen in Groningen. Na drie en een half jaar met heel veel plezier hier gestudeerd te hebben had ik toch het gevoel dat ik iets anders wou. Ik miste hier vooral de technische kant en de praktische toepasbaarheid van het onderzoek. Na lang wikken en wegen heb ik toen besloten om de stap te maken naar Technische Geneeskunde met het idee om mij te blijven focussen op het bewegingsapparaat. Hier heb ik met vijf andere studenten een jaar lang heel hard moeten werken om de pre-master succesvol af te ronden, wat ons alle zes gelukt is. Na ook het eerste jaar van de master afgerond te hebben was ik klaar om aan mijn stages te beginnen. Hier bleek ik al snel een onbewuste voorkeur te hebben voor de chirurgische wereld. Na een stage bij de thoraxchirurgie, orthopedie, kaakchirurgie en een bedrijfsstage bij Demcon besloot ik terug te keren naar orthopedie in het Radboudumc. Een afdeling die ik al kende, waar ik mij goed bij voelde, en een klinische specialisatie die bij mij en mijn achtergrond past.

Afgelopen jaar heb ik hard gewerkt om een mooi onderzoek neer te zetten, maar vooral om er achter te komen wie ik als TG'er ben. Ik heb de kans gekregen om mijn eigen weg te vinden in mijn onderzoek en in mijn klinische ontwikkeling. Tijdens deze stage heb ik geleerd waar mijn kwaliteiten liggen, wat mij motiveert en wat ik na mijn afstuderen wil doen. Met trots kijk ik terug op het werk wat ik heb geleverd de afgelopen tijd, maar dit was absoluut niet in mijn eentje gelukt.

Bij deze wil ik iedereen bedanken die mij ondersteund heeft het afgelopen jaar. Dennis en Nico hebben mij geholpen het onderzoek in de juiste richting te sturen om het tot een goed einde te kunnen brengen. Op technisch gebied werd ik het meest begeleid door Hans. Op papier was Hans geen begeleider, en zo heeft de samenwerking ook nooit gevoeld. Hij heeft een erg groot aandeel gehad in het eindresultaat, waar ik hem erg dankbaar voor ben. Sebastiaan stond altijd voor mij klaar en heeft mij de vrijheid en het vertrouwen gegeven om mijn eigen weg te kiezen. Verder wil ik Rian bedanken voor de begeleiding, en de leuke, constructieve gesprekken die we de afgelopen twee jaar gevoerd hebben. Ook wil ik alle stafleden en arts-assistenten bedanken, en dan met name Marinus. Zijn enthousiasme zorgde er voor dat ik nieuwe dingen durfde te proberen en mijn grenzen op ging zoeken. Als laatste wil ik natuurlijk mijn vrienden en familie bedanken, en in het bijzonder mijn ouders en Erin. Jullie onvoorwaardelijke steun heeft er voor gezorgd dat ik deze studie af heb kunnen ronden.

In mei 2020 zal ik starten als promovendus op deze afdeling. Ik zal software gaan ontwikkelen die doormiddel van kunstmatige intelligentie de ideale behandeling voor lage rugklachten zal voorspellen. Ik vind het een enorme eer dat ik kan blijven werken in het Radboud. Het feit dat ik aangenomen ben voor deze functie, ondanks dat ik geen ervaring heb met kunstmatige intelligentie, is in mijn ogen het grootste compliment wat ik kon krijgen.

Abstract

With the increasing complexity of current day surgery, a 3-dimensional surgical plan is often needed. These can be difficult and time consuming to make. The current study aims to improve the workflow of creating pre-operative plans in orthopedic surgery. For this purpose, a graphical user-interface (GUI) was created in which a surgical plan can be manipulated by the physician. First, four clinical cases were described in which a preoperative surgical plan is created in combination with patient specific instrumentation (PSI). The four cases were used to obtain input for the different user and system requirements for the GUI. Three different types of visualization (2D, 3D and hybrid) were evaluated to determine the most suitable method for a physician to interact with a 3D surgical planning. The usability and accuracy of the software was investigated.

MeVisLab was used to create software in which pedicle screws can be planned for spinal fusion surgery. In total 15 users were included in this research. The participants had to place six pedicle screws in three different vertebrae. Two criteria were given for the screw placement: 1. the screw must be placed inside the pedicle; 2. the screw must be placed parallel to the vertebral body. The time needed per screw was recorded. A system usability scale (SUS) was filled in as well as a confidence score, to determine how confident the user is, that the planning is correct. The screw position was evaluated automatically, calculating the angle between the screw and the vertebral body. Screws that penetrated the pedicle wall or the vertebral body were automatically found.

An average SUS of 78,5 was found for all three visualization methods, scoring between good and excellent. However, no significant differences in usability (SUS) and confidence score were found. In total time needed, the hybrid method worked significantly faster than the 2D method. The screw angle was significantly larger in 3D compared to hybrid. All other results were not statistically different.

In this research four cases are presented in which a PSI surgical guide was successfully used. This research proves it is possible to create an intuitive user interface which allows physicians to create a surgical plan. A better visualization can be made of a surgical plan for PSI's. With a combination of the 2D and hybrid method all information is clearly visualized to assess whether screws are correctly placed.

Contents

Chapter 1

Introduction

Making a preoperative plan is an essential process within orthopedic surgery. Whether it's simple lines on an x-ray or a complex 3-dimensional visualization, it enables a surgeon to thoroughly prepare for surgery. This ultimately reduces the operating time with better patient outcomes [1]. Potential complications can be anticipated on and precautionary measures can be taken if necessary. Furthermore, there is a growing application of new technologies, such as robotic surgery, surgical navigation or 3D-printed patient specific implants and surgical guides. These all require a precise preoperative plan. Methods of surgical preparation differ within orthopedics. Different imaging modalities are used to make a surgical plan, such as CT, MRI or X-ray. Although the approach might differ, it all serves the same goal, to reduce surgery time and costs, as well as improving patient outcomes. Whether it is joint alignment in arthroplasty surgery or cutting planes in tumor resection surgery, sufficient preparation is key. With the increasing complexity of current day surgery and the demand for patient specific treatment, often a 3-dimensional surgical plan is needed.

In the field of orthopedic surgery several examples exist where a three dimensional (3D) preoperative planning improves the surgical accuracy. Sariali et al. (2012) showed the added benefit of 3D computerized planning of total hip arthroplasty (THA) compared to the conventional 2D templating [2]. Not only did it prove that 3D planning gives a higher accuracy, it also states it shortened the learning curve for a low-experience surgeon. Furthermore, in total shoulder arthroplasty the use of 3D pre-operative planning makes the surgery more precise and more reliable [3]. In the field of craniomaxillofacial surgery 3D analysis and planning is already widely used for several different surgical procedures and can be considered the gold standard in mandibular reconstruction [4].

A prime example for which a complex 3D surgical plan is needed is the use of patient specific instrumentation (PSI) during surgery. First, a plan is created after which a guide is designed that enables the surgeon to directly translate the surgical plan to the operating room (OR). The guide has a unique fit to the bone and has pre-defined cutting planes or drill shafts determined in preoperative plan. Victor and Premanathan (2013) described the options of PSI to perform correction osteotomies around the knee [5]. They showed that surgical guides are a valuable concept which makes the surgery more accurate. Also in spinal surgery PSI is emerging. Research shows patient specific drilling guides for pedicle screw placement improve the accuracy and reduce surgery time [6]. Lastly, PSI is also rising within orthopedic oncology surgery. Ma et al. (2016) reported that using PSI led to more precise resections, less blood loss, shorter surgery time and reduced radiation exposure during surgery [7].

1.1 Current problem

As stated earlier, orthopedic surgery is becoming increasingly complex, creating a demand for an accurate 3-dimensional surgical plan. Depending on the expertise and background of the physician, these are possibly difficult and time consuming to make. Commercial companies offer services where a surgical plan is created with a fitting surgical guide. However, the physician is not able to directly interact with this surgical plan to tailor it to his/her demands. It is sent to the user, most commonly in a .pdf file, which sometimes can be rotated in 3D. If adjustments are needed, these need to be communicated back to the company, resulting in a prolonged back-and-forth interaction to adjust the surgical plan to the physician's preferences. This process can be time consuming, and therefore needs to be optimized.

1.2 Research goal

This research aims to improve the workflow of creating pre-operative plans in orthopedic surgery. For this purpose, a user-interface will be created in which a surgical plan can be adjusted by the physician. Three different types of visualization will be evaluated to determine the most suitable method for a physician to interact with a 3D surgical planning.

1.3 Thesis outline

In the first four chapters different cases are presented in which a surgical guide was created for various types of orthopedic surgery. These case studies describe the medical background and the design process of the surgical guide. First some anatomical background information on the knee is given after which two cases are presented. The first case study is of a 20 year old male with a chronically fixed lateral patella luxation, who underwent extensive reconstructive surgery for which a cutting guide was created. For the second case study a cutting guide was designed for a tumor resection in the distal femur. During this surgery the guide was combined with surgical navigation to assess the positioning of the cutting guide. Thereafter a brief introduction in spinal fusion surgery is given. This is followed by two case studies in which drilling guides were used for pedicle screw placement in scoliosis correction and kyphosis correction surgery.

The four cases were used to obtain input for the different user requirements for the planning software. These user requirements were subsequently used to develop 3D planning software with three different interface options for visualization. Finally, the usability and accuracy of the software was investigated in a study with 17 end-users with different backgrounds and skill levels.

Chapter 2

Anatomical background of the knee

The knee is one of the largest and most complex joint of the human body [8], [9]. It consist of three bones: the femur, tibia and patella. Together they form the tibiofemoral and patellofemoral joint. The tibiofemoral joint consists of the lateral and medial femoral condyles, articulating with the corresponding tibial plateaus. The knee allows for flexion and extension as well as a slight internal and external rotation. During flexion and extension the patella runs through the femoral trochlea, which is a cartilaginous groove on the distal femur. The patella is the largest sesamoid of the human body and increases the moment arm of the extension musculature. The main extensor muscles are the quadriceps. This is a muscle group consisting of the rectus femoris and the vastus lateralis, medialis and intermedius. The main flexor muscles of the knee are: sartorius; biceps femoris; semitendinosus; semimembranosus; gastrocnemius; plantaris and popliteus.

Two of the four major ligaments that give stability to the knee are the medial and lateral collateral ligament (MCL and LCL). The main function of these two ligaments is to resist valgus and varus stress respectively. This means it prevents the tibia being pushed outward or inward compared to the femur. The other two major ligaments of the knee are the anterior and posterior cruciate ligament (ACL and PCL). The ACL prevents anterior tibial displacement where the PCL prevents posterior tibial displacement. Apart from all the aforementioned structures, the knee is characterized by its bilateral menisci. These are crescent shaped fibrocartilaginous structures present between both femur condyles and the tibial plateau. The purpose of both menisci is to disperse the friction between the femur and tibia. Figure 1 shows the various different anatomical structures [9].

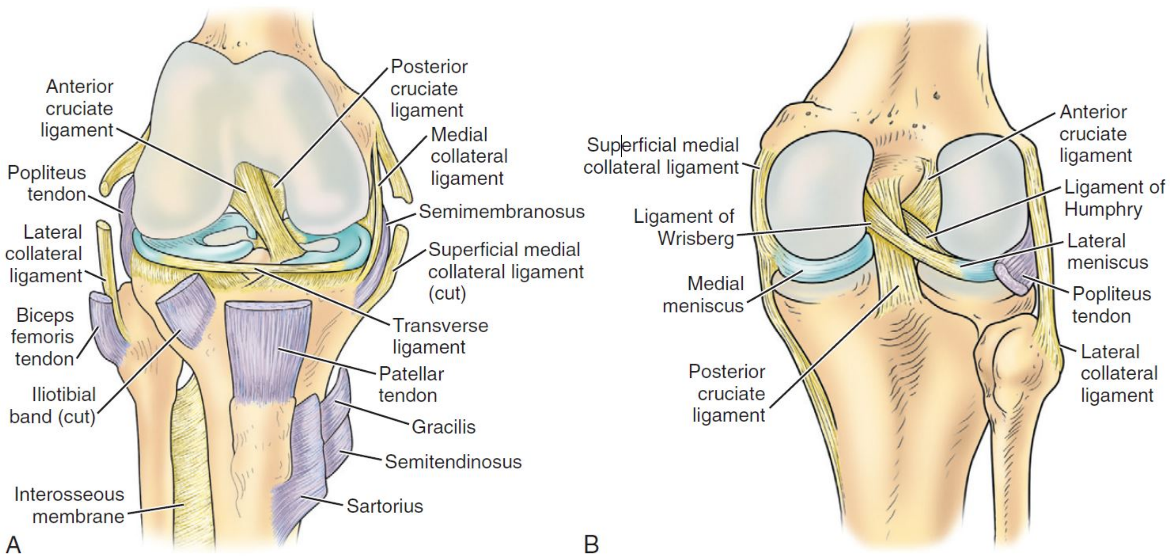

Figure 1: Schematic drawing of the various structures around the knee. In image A the knee is shown from an anterior perspective where image B is shown from an posterior perspective [9].

The insertion point of the patellar tendon on the tibia is called the tibial tubercle. The patella is stabilized in front of the trochlear groove by four ligaments: the medial and lateral patellofemoral ligament (MPFL and LPFL), and the medial and lateral patellotibial ligament (MPTL and LPTL). The medial ligaments prevent lateral dislocation where the lateral ligaments prevent medial dislocation. In full extension the patella is located just proximal and lateral of the trochlear groove. Within the first 0-20 degrees of flexion, 60% of the total restraining force when the patella is moved laterally is provided by the MPFL [10]. In patients suffering from a lateral traumatic patella luxation, 70%–100% of the cases show a MPFL rupture [11]. Once the knee is flexed, the patella will enter the trochlea, giving major medial and lateral stability.

Chapter 3

Tibial tubercle transposition

Traumatic patellar luxation is a common knee injury. The incidence of primary patellar dislocation is 31:100.000 (ages between 10-20), 11:100.000 (ages between 20-30) to 2:100.000 (ages between 30-50) which shows a predominance in adolescents [12]–[15]. Usually after a traumatic luxation the patella quickly snaps back in place or is relocated by putting medial force on the patella while extending the knee [16]. However in rare cases the patella is not reduced and remains lateral of the trochlea. Treatment of these patients can be challenging. During tibial tubercle transposition (TTT) an osteotomy of the tibial tubercle, insertion of the patella tendon, is performed after which its position is either medialized, distalized or both [9]. TTT surgery is considered when the origin of the patellofemoral instability is mispositioning of the tibial tubercle [17]. The goal of TTT surgery is to realign the patella, and therefore the quadriceps, such that the patella nicely glides through the femoral trochlea. Its new position should reduce the knee pain and the risk of recurrent patellar dislocation.

In 2018 a case was presented to the Radboudumc with a chronic dislocated patella. Similar to the case-study described by Xinning Li et al. (2013), a patient specific surgical plan was created [18]. The goal of the surgery was to place the patella back in the trochlea. It was a large and invasive surgery containing various different interventions, including TTT. For the TTT a PSI cutting guide was created. In this case report the surgical plan is described as well as the process of creating the 3D printed cutting guide.

3.1 Case description

A 20 year old man was referred to the Radboudumc Nijmegen with progressive chronic left knee pain. In 2010 (at 10 years of age) the patient fell during snowboarding and twisted his left knee. Directly after the trauma an X-ray was taken and no abnormalities were seen. The patient received a knee-brace as treatment since a medial crucial ligament rupture was suspected, which was continued by the general physician after returning home together with physiotherapy for over a year. Pain was slightly reduced but one and a half year later, two and a half years after the initial incident, the patient was referred to the orthopedics department with pain after prolonged walking or standing. During physical examination a chronic luxated patella was observed in the left knee. Also a flattened patella and a underdeveloped trochlear groove where described based on the CT-images alongside a osteochondral lesion in the lateral femur condyle. No further treatment or surgery was done at that point since the dislocation was ruled as congenital. The current situation had to be accepted and controlled with the use of physiotherapy.

Six years later the patient returned to the Radboudumc with sudden worsening of knee pain. The diagnosis was recognized as being a traumatic patellar luxation because of the significant osteochondral lesion which clearly indicates the traumatic event (Figure 2). Also a secondary deformity of the

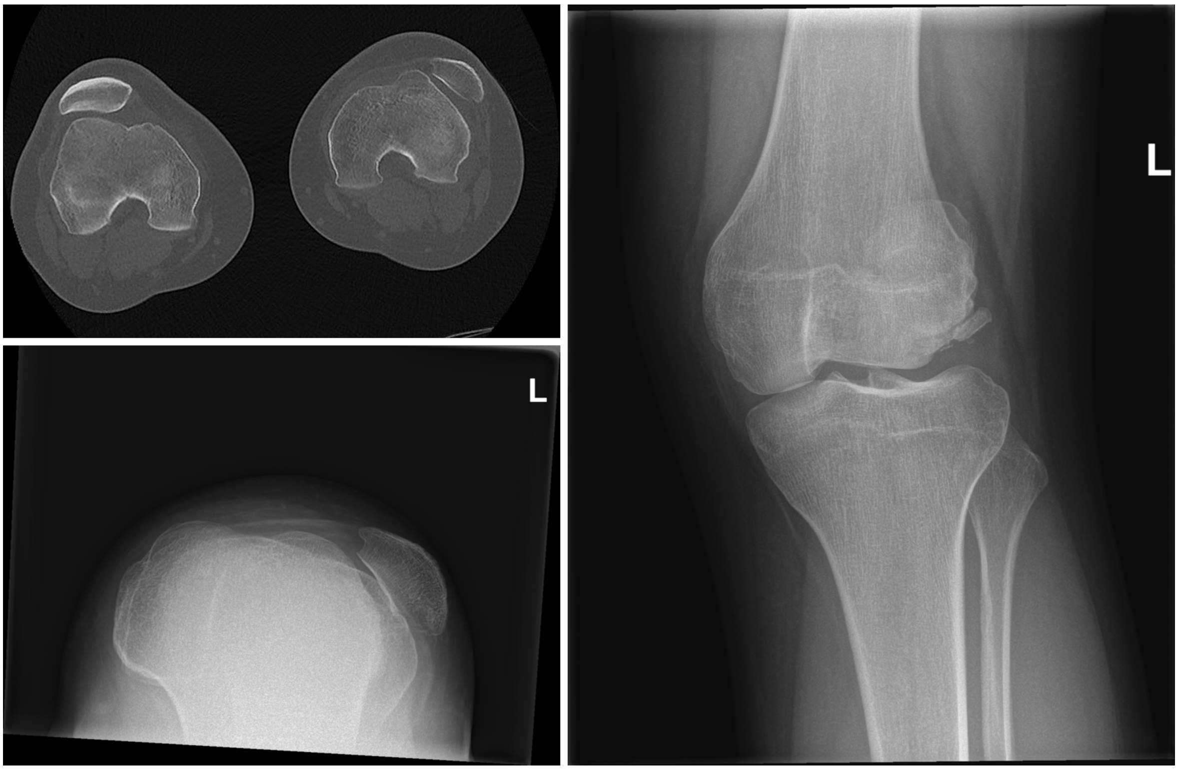

Figure 2: Pre-operative images of the left knee. In the top left image a axial slice of the trochlea and patella is shown, clearly depicting the chronic patellar luxation. The lower left image is a skyline Laurin view X-ray. The right image is an AP X-ray image in which the osteochondral lesion of the lateral condyle is seen.

lower limb was described with a dominant external tibial torsion, originated since the patellar luxation occurred before the growth spurt. The lateral position of the patella pulled the tibia in external rotation, causing valgus deformation of the tibia as well as rotational deformity of the lower leg. A CT-scan was made and a knee arthroscopy surgery was scheduled. During the arthroscopy the patella could be repositioned onto the lateral trochlea. Both the medial and lateral compartment showed healthy cartilage apart from minor damage laterally. The medial meniscus was intact whereas the lateral meniscus was completely ruptured and disappeared for the most part. The corpus liberum was a split fracture and showed a vital cartilage layer, thus it was decided not to remove it. Subsequently, a valgus angle of 6 degrees was measured in the left leg while a normal alignment is seen in the right leg.

3.2 Surgical planning and cutting guide

In standard tibial tubercle transfer surgery the preoperative plan is, among other factors, based on the tibial tubercle to trochlear groove (TT-TG) measurement, which in this case was 40 mm (TT-TG between 11-15 mm is considered normal [13]). This measurement however is not applicable in this case because of the severe proximal tibial external rotation. The tibial tubercle was rotated laterally making a simple linear measurement over the lateral-medial axis insufficient. Moreover, Yao, L. et al. (2014) stated the TT-TG measurement is strongly influenced by the knees orientation within the CT bore [19]. This study concluded that a 5 degrees of simulated femur abduction could lead to an average 3.4 mm change of TT-TG measurement. Since there is a valgus deformity the TT-TG measurement therefore is less reliable. A new method had to be found to determine the new ideal position of the tibial tubercle.

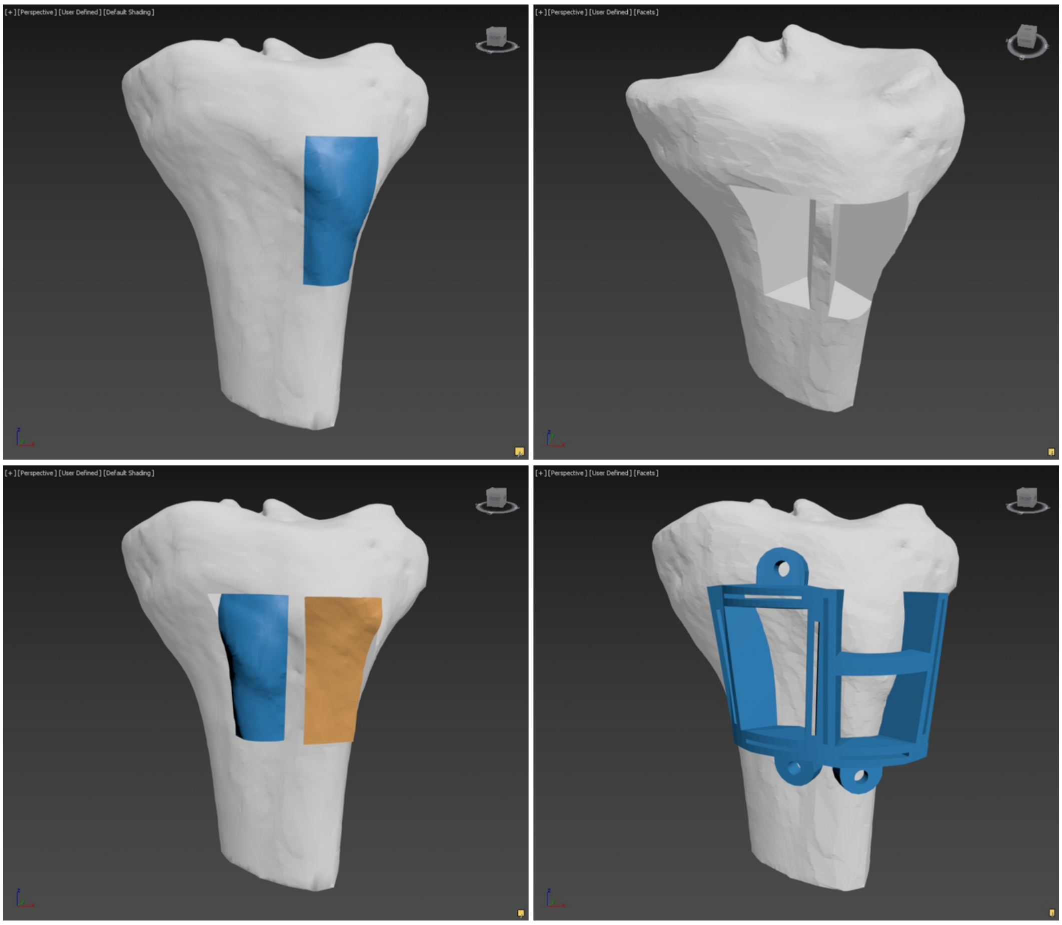

Figure 3: Different steps of the preoperative planning. Top left: The tibia is shown with in blue the tibial tubercle. Top right: The tibia is shown with the double V-shaped osteotomy. Bottom left: The tibial tubercle is placed in the medial osteotomy while the medial bone-piece is moved laterally. Bottom right: The guide is shown with in total 7 cutting planes and 3 fixation points.

We decided to use the normal right knee as the reference for the reconstruction of the left knee. The femur, tibia, patella and patellar tendon of both left and right were segmented from the preoperative CT-scan. First the right side was mirrored over the sagittal plane. To determine the new ideal position of the tibial tubercle, first the valgus osteotomy of the distal femur was virtually performed. Based on the measured valgus angle of 3.5° a lateral opening wedge osteotomy of the distal femur was simulated whereafter both femora were again superimposed. The reasoning behind finding the new position of the tibial tubercle was to reproduce the mechanical properties of the unimpaired knee. By virtually performing a V-shaped osteotomy (Figure 3) on the tibial tubercle, its new position could be determined. This was done by rotating and translating the tibial tubercle, patellar tendon and patella as a whole until it matched the right patella and patellar tendon. Once the preferred position was chosen, the decision was made to perform the transposition with a double V-shaped osteotomy as depicted in (Figure 3). With the osteotomy planes needed to perform the transposition, a patient specific cutting guide was created using 3ds Max (Autodesk, San Rafael, CA, USA) (Figure 3). The guide was printed by KLS Martin (Tuttlingen , Germany).

3.3 Surgery

Based on the findings of the arthroscopy a surgical plan was made which was executed two months later. A anterolateral incision was made which was extended down to the tibial tubercle. The osteotomy of the tibial tubercle was done with the use of the 3D printed patient specific cutting guide. The bone from the medial osteotomy was fixated in the original location of the tibial tubercle whereas the tubercle itself was left detached from the bone to assure the range of motion of the patella during the procedure. An extensive release of the lateral retinaculum and the quadriceps muscles was done by manually mobilizing to muscles to assure the medialization of the patella. The osteochondral defect was fixated using three headless compression screws. Thereafter a valgus osteotomy of the distal femur was performed with the use of an external alignment rod. A lateral opening wedge was created in which a six millimeter thick tricalcium phosphate block was inserted and the osteotomy was fixated using a titanium plate. The tibial tubercle was fixated in the intended position created earlier with the cutting guide. The patella now tracks anteriorly through the trochlea with a maximal flexion of 40 degrees. A reconstruction of the MPFL is done with the tissue of the gracilis tendon. Lastly the iliotibial tract was lengthened by roughly two centimeter with a Z-plasty.

3.4 Outcome

A post-operative CT-scan was made to determine the accuracy of the tibial tubercle transposition. The CT-scan was manually segmented and registered on the preoperative planning. Both the tubercle and the medial osteotomy where manually extracted from the bone based on the CT images and the 3D segmentation. Compared to the planning, the performed transposition was 1.4 mm to far medial, 1.7 mm to far anterior and 2.7 mm to far distal. When looking at the rotational differences between the pre- and post-OR, only in the z-direction (axial plane) a disagreement of 7° was found. Also it was made clear that the chosen position of the cutting guide intraoperatively was about 7 mm more distal than planned.

Seven weeks after surgery the patient returned to the outpatient clinic. He stated his knee felt good considering the circumstances and he was able to reach 90° flexion. The patella nicely tracked through the trochlear groove. The patient clearly experienced pain once pressure was applied on the tibial tubercle. When looking at the new CT-scan it showed displacement of the tibial tubercle to cranial of 5 mm with possible signs of bone consolidation. However since already 90° flexion was possible and the tubercle only moved 5 mm no further action was taken. Three months after surgery the patient was still able to easily reach 90° flexion and the pain in the knee was reduced compared to last visit. The patella still nicely tracked through the trochlea and also the palpation pain at the tibial tubercle was less compared to six weeks before. When comparing the new CT-scan with earlier ones the position of the tibial tubercle did not change and clear signs of consolidation were seen in the images.

Six months after the initial surgery the knee looks normal with good patella tracking and a maximal flexion angle of 120°. He can now start witch physiotherapy training to regain power in his leg. Figure 4 shows the 6 months post-OR X-ray images.

3.5 Discussion

All in all this surgery can be considered successful. The patient came with a chronically fixed lateral patella dislocation which occurred more than 8 years ago, resulting in a secondary rotational

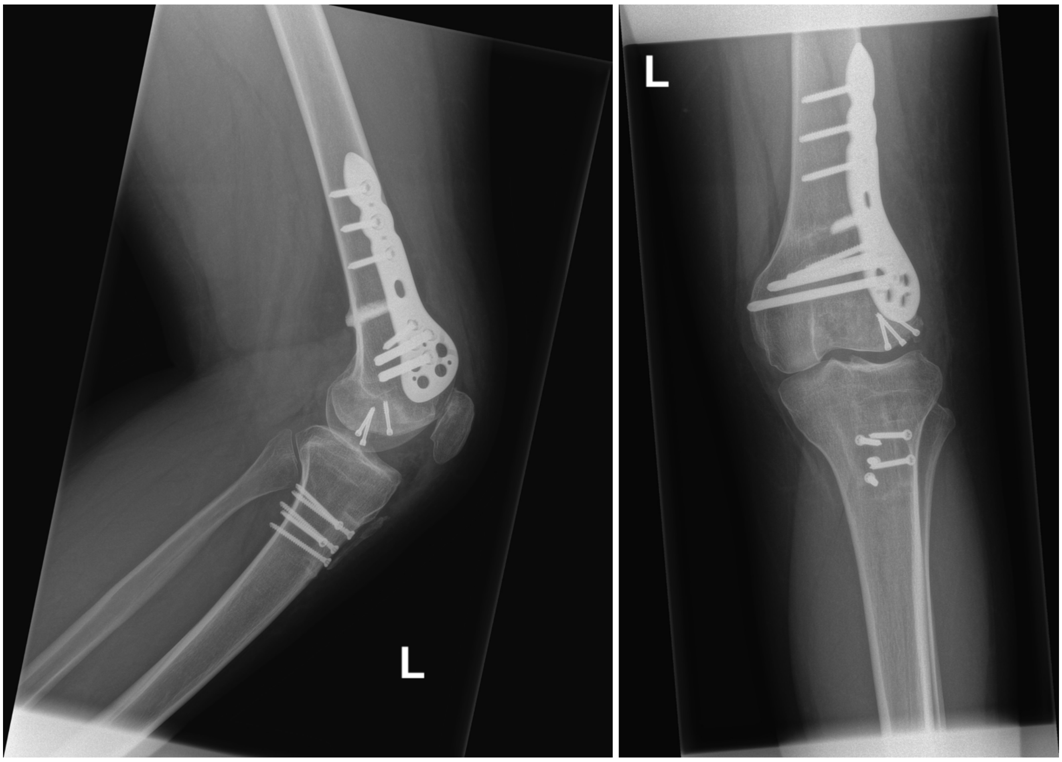

Figure 4: 6 months post-OR X-ray images. On the left an AP view of the knee is seen and on the right the lateral view. The patella is situated in front of the trochlear groove.

deformity of the lower limb and a painful knee. Six months after surgery the patients is reintegrating his job with less pain and a patella that tracks through the trochlear groove. However, some valuable lessons were learned during this treatment. There were some differences between the planned transposition and the actual performed surgery, mainly in the proximal-distal direction. This was partially caused by the absence of one cutting plane in the surgical guide. The most proximal cut of the tibial tubercle (behind the patellar tendon) had to be done manually. This cut ended up being a few millimeters more proximal compared to the planning which resulted in the tubercle osteotomy being slightly taller. Subsequently, this piece did not fit in the new created cavity which ended up being manually adjusted.

Additionally, the guide was positioned more distally than planned despite seemingly good fit intraoperatively. With the design of the guide a margin of 0.4 mm was taken of the guide to account for the thickness of the periosteum layer. However on the proximal side the soft tissue layer was thicker than expected which resulted in the guide being moved downwards. As mentioned, the fit was good and since the complete transposition of the tibial tubercle was embedded in the guide, a slight misplacement on the longitudinal axis would not affect the overall result. In future surgical guide designs for tibial tubercle surgery the proximal soft tissue layers should be accounted for to a larger extend.

Furthermore, the overall size of the cutting guide was smaller than expected. The initial osteotomy of the tibial tubercle during planning was done manually in such a way that looked correct visually. No actual measurements of the length were done, which usually is around 5 cm. In this case the length would be 4 cm tall which was just big enough for three screws. The actual size was overestimated since the preoperative plan only showed the 3D model. No clear scale was visible which easily could cause misjudgment. In this case it would have been beneficial if a scaled image was created. In future cases, if more time is available, a test phase could be implemented with an actual printed prototype.

Lastly, the tibial tubercle showed proximal displacement of 5 mm when the patient returned for the 6 week follow-up. As stated earlier, the performed transposition was 2.7 mm to far distally which caused extra tension on the patellar tendon. Also the created surgical plan perhaps was not sufficient enough. The current position of the tibial tubercle after being displaced shows a Caton-Deschamps index of 0.9 (measured on the six month post OR x-ray). A Caton-Deschamps index is considered normal between 0.8-1.2 [17]. Considering the patellar tendon insertion moved 5 mm proximately the post-OR Caton-Deschamps must have been lower than the current measurement. This shows that the current method of finding the ideal insertion point of the patellar tendon can be improved. More research is needed on new methods to create a surgical plan for TTT.

Chapter 4

Osteosarcoma resection

Osteosarcoma is the most common primary bone malignancy, mainly presented in the distal femur, followed by the proximal tibia [20]. Surgical treatment may vary, yet complete surgical resection is proven to be essential [21]. Since surgery is needed, often close to the knee joint, essential structures of the joint cannot always be saved. In an effort to minimize the damage done to the joint, while still resecting the complete lesion, various technological advancements are being used intraoperatively. One new approach is intraoperative navigation where a given instrument can be shown in the existing CT-images relative to its actual position [22]. Another emerging tool is the use of patient specific cutting guides [22]. Bosma at al. (2018) stated the difference between computer assisted surgery (CAS), PSI and free hand methods [23]. Both CAS and PSI proved to more accurate compared to free-hand, with PSI being superior compared to CAS. This research also describes that CAS can be used as intraoperative quality control tool for PSI. This case presents a patient with low grade osteosarcoma in the distal femur for which surgical navigation was combined with a patient specific cutting guide.

4.1 Case description

A 56 year old female patient was first referred to Radboudumc with nagging pain of the right knee. The pain increased with higher loads on the joint, mainly situated on the posterior-lateral side. A normal functioning knee was described with minimal hydrops and no evident palpation pain around the knee. On the X-ray images a intraosseous lesion was described with malignant characteristics (Figure 5). A biopsy was taken, with CT guidance, showing a low grade osteosarcoma. Further analysis showed no metastases. Surgical treatment was proposed existing of local resection which would be filled with bone cement. Since the proximity of the lesion to the knee joint, surgical navigation would be used as well as a patient specific cutting guide.

4.2 Surgical planning and cutting guide

First the femur and tumor are segmented separately. The surgical plan was made in 3ds Max. A bounding box was built around the tumor representing the 5 needed cutting planes. These planes were placed in such a way that the lateral condyle would remain unaffected. A guide was designed around these planes with a saw-thickness 1.3 mm. For three planes (proximal, distal and anterior), a slot was created for the oscillating saw. For the cutting planes on the condyle and the posterior cutting plane, the saw had to be put on the edge of the guide. Not only was it impossible to create a wide enough slot in these areas, it would be challenging to reach these planes, let alone maneuver through the guide.

Figure 5: Images from left to right: The first two images show a pre-operative AP X-ray and CT slice of the knee. A low-grade osteosarcoma van be seen in the lateral side of the distal femur. The third and fourth image are post-operative X-ray images (AP and sagittal). The cavity is completely filled with bone cement. It is clear that the posterior part of the lateral condyle was saved.

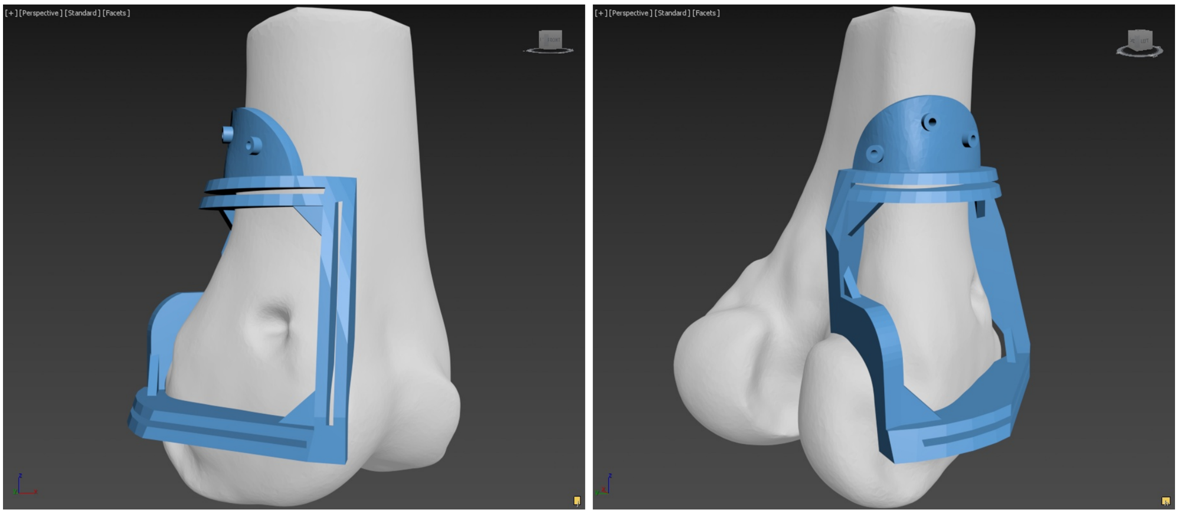

Figure 6: A 3D model the distal femur with in blue the patient specific surgical guide. In the left image the proximal, distal and anterior cutting slots can be seen. The right image shows the sides of the guide used to make the anterior cut and the condylar cut.

Three holes of 1.7 mm diameter were added proximally to fixate the guide with K-wires. A margin of 0.2 mm was taken of the guide to account for the periosteum layer. In certain areas of the guide, such as the most distal edge and around the trochlea, a larger margin was taken to account for extra soft tissue layers. The surgical plan and guide were both created by a technical physician and checked by the orthopedic surgeon. Once the complete plan was finished it was combined with the Brainlab Curve surgical navigation (spine/trauma module). Specific target points were added to easily assess the guides position intraoperatively. The guide was printed by KLS Martin. In Figure 6 images are shown of the designed guide.

4.3 Surgery

An incision was made around the biopsy scar and prolonged proximally and distally. The femur was exposed and soft tissue was removed to place the cutting guide. This had to be done with care, since the insertion of the LCL was very close to the distal border of the guide. The femur was registered using a point cloud registration method. The guide was inserted and the position was checked with the navigation tool. Once the position was correct the guide was fixated using two K-wires. Four out of five cuts were made with the guide. Only the most distal cut was made using the outside ridge of the guide. This was done to create a larger resection margin distally of the tumor. The guide was removed and with an osteotome the osteotomy was completed after which the tumor was removed as a whole. Macroscopically all resection margins were clean, meaning no clear signs of remaining malignant tissue were seen. Figure 5 shows two post operative X-ray images.

4.4 Discussion

This case study describes the first surgery within the orthopedics department of the Radboudumc where a patient specific surgical guide was used alongside surgical navigation software for a tumor resection. The post-operative pathology results on the resection margins have yet to be returned. Still the surgery was considered successful since the complete osteosarcoma was removed with seemingly clean resection margins. Also the patient specific surgical guide in combination with the navigation software was a new experience for the whole team with good results. Nevertheless, some valuable lessons were learned during this surgery.

First of all, the posterior cutting plane was difficult to reach. Flexing the knee made it easier yet it was still not possible to completely see the specific edge of the guide. Therefore it was challenging to determine if the angle of the saw was parallel to the guide. A cut was made but it was not entirely certain that it was similar to the planning. There was no risk that the cut would go through the tumor since the saw-blade was tilted away from the lesion. Nevertheless, while making the surgical plan, the size of the incision should be accounted for more precisely.

The fixation to the bone could be improved. In the current design, the guide is only fixed on the proximal side of the guide. This was done since it was uncertain how much space would be available on the anterior and posterior side. No fixation points were added on the distal side because of the lateral collateral ligament and the joint capsule. Yet extra fixation was needed, preferably on the opposite side of the current fixation points. However these fixation points cannot be on the inside of the guide since it would penetrate the tumor. Additionally, it was preferred to keep the outside edges of the guide clear to enable the surgeon to use this as guide when an extra margin of 3-4 millimeters was desired. This was the case for the distal cutting plane. The plane was planned really close to the lesion to save as much of the ligaments and capsule as possible. Using the navigation the posterior margin looked close to the lesion. No risks were taken and the decision was taken to use the outside edge of the guide instead of the defined slot. With current knowledge the best position for extra fixation points would have been alongside the anterior plane.

The combination of a surgical guide alongside surgical navigation seemed to work well. The guide had a clear unique fit to the bone and with the pre-defined reference points on the guide it was fairly easy to confirm whether this position was correct. However, the out of plane motion was not completely accurate. The camera module was placed at the foot end of the OR table. When the pointer was placed in the proximal plane the pointer was projected one millimeter higher. When the pointer was placed in the distal plane the pointer was projected one millimeter lower. This means that either the software performs scaling during the registration or it illustrates the flaws of out of plane motion. To prevent these inaccuracy's a more accurate system should be used with more cameras at different angles.

An actual assessment of the accuracy of the resection has not been done. Since the tumor was sent to the pathologist and no post-OR CT-scan was available, no further analysis was done. However, this specific case shows the collaboration between two emerging technological advancements within orthopedic surgery. Despite the aforementioned recommendations this case shows the potential of these modalities working together.

Chapter 5

Introduction in spinal fusion surgery

The human spine consists of 24 vertebrae (7 cervical, 12 thoracic and 5 lumbar), the sacrum and coccyx (tail bone). All vertebrae have different shapes, but the same anatomical features. A vertebra consists of a vertebral body and a posterior vertebral arch (Figure 7). The body of the vertebra is the primary area of weight bearing. The posterior arch is formed by the laminae, transverse processes, spinous process and the pedicles, which are the connection between the vertebral arch and body. The laminae cover the vertebral foramen, which is the spinal canal. The spinous process points dorsally and caudally and serves to attach muscles and ligaments. The transverse processes serve the same purpose. The main ligaments on the spinous process are the intraspinous and supraspinous ligament. The different vertebral bodies are separated by intervertebral discs. They connect the vertebrae and serve as shock absorber for the spine. The discs consists of fibrocartilaginous tissue which allows slight movement between the vertebrae. On the posterior side adjacent vertebrae are connected by two facet joints. These are plane joints between the articular processes (Figure 7) of two vertebrae [24].

A common surgery performed by an orthopedic spinal surgeon is spinal fusion surgery (also known as spondylodesis). With the use of surgical instrumentation two or more vertebrae are joined. With titanium screws and rods a construction is built which fuses the vertebrae. Screws are placed through the pedicles from posterior into the vertebral body after which they are connected with rods. Often extra bone grafts, either autograft or allograft, are added to ensure the vertebrae grow together. Spinal fusion surgery can be used to treat various conditions such as vertebral fracture, spinal tumor

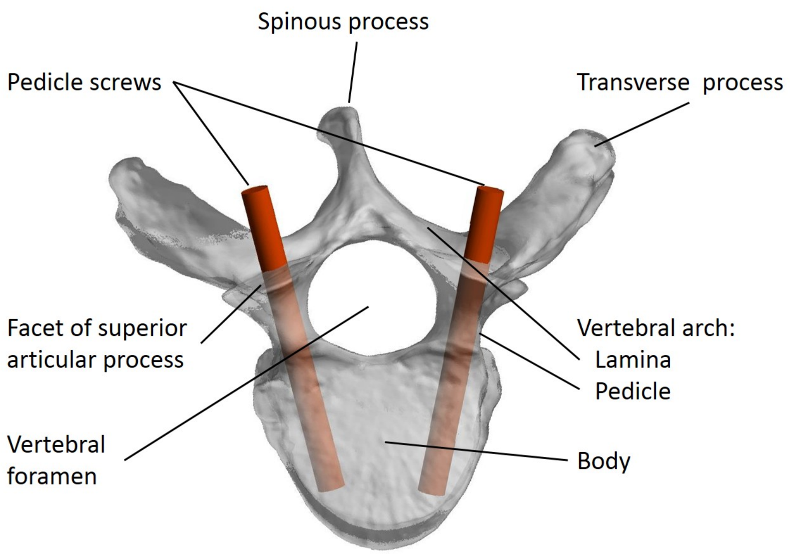

Figure 7: A 3D model of a vertebra with its different anatomical features. Two red cylinders are shown which depict the ideal position of pedicle screws.

or spinal deformities (e.g. scoliosis or kyphosis).

Placement of pedicle screws in spinal surgery is always challenging with the risk of damaging the spinal cord. An example of pedicle screw placement is seen in Figure 7. Currently the screw position is not planned but determined intraoperatively with additional imaging. With identification of anatomical landmarks the entry point is determined whereafter a thick K-wire is inserted a few millimeters. X-ray imaging is used to confirm whether the entry point and the direction of the inserted K-wire are correctly chosen such that the eventual screw will cross the pedicle as desired. This is a time-consuming method that requires a lot of experience, with possibly a high radiation dose for the patient.

To make the process of placing pedicle screws faster and safer, drill guides for pedicle-screw placement can be considered. They are currently being used in various institutions for different surgical indications within spinal surgery [25]–[27]. Such surgical guides are commercially available at different companies which offer a surgical planning with fitting drill-guides. Sugawara et al. (2018) proved that patient specific drilling guides improve the accuracy of pedicle screw placement and reduce surgery time and radiation exposure during spinal fixation surgery [6]. In the following two chapters, cases are presented in which PSI drilling guides are used for pedicle screw placement for spinal fusion surgery.

Chapter 6

Neuromuscular scoliosis correction

Scoliosis is a deformity of the spine characterized by a S- or C- shaped curvature in the coronal plane. The cause of such deformities differ. In 65% scoliosis is idiopathic, meaning no actual cause is found. In 15% of the cases the deformity is congenital (birth defect) and in the remaining 10% it is secondary to a neuromuscular disease [28]. Although neuromuscular scoliosis is less common compared to idiopathic scoliosis, it often causes a more progressive and severe spinal deformity [29]. These deformities cause symptoms such as back pain, impaired sitting balance and pelvic obliquity which can lead to apparent leg length discrepancy. In some cases the curvature can lead to alterations of the thorax's dimension, possibly causing respiratory or cardiac problems.

The first treatment usually is nonoperative, which is either done by bracing or seating modifications [29]. In severe cases, spinal fusion surgery can be performed to ultimately reduce pain, improve sitting balance and improve posture. This can possibly also improve the pulmonary function. During surgery the scoliosis will be corrected and, as explained in the previous chapter, the spine is fused in a fixed position. The deformity will be reduced and the progression will be stopped. In this case study a patient is presented that underwent spinal fusion surgery for neuromuscular scoliosis correction. During this surgery two PSI drilling guides were used for pedicle screw placement.

6.1 Case description

An 18 year old male was presented at the Radboudumc with progressive neuromuscular scoliosis which at that time was still treated with a corset. The patient had a known history of epilepsy for which he had a hemispherectomy (rare neurological procedure where half of the brain is removed) at the age of 4. This caused an imbalance in his spinal musculature instigating the scoliosis. He had a right convex scoliosis with a Cobb angle of approximately 75°, which is a measurement of the severity of the scoliosis (Figure 9). Because of the progressive nature of the scoliosis the decision was made to perform spondylodesis surgery from vertebra thoracic 4 to lumbar 2.

6.2 Surgical planning and drilling guide

The goal of this surgery was not to completely correct the scoliosis, but to "balance the spine" which in this case meant to reduce the scoliosis from a Cobb angle of 75° to approximately 50° with a fusion from thoracic 4 to lumbar 2. Several CT-scans were already available which meant a surgical planning could be made based on 3-dimensional images without extra radiation load. The decision was made to create a surgical plan and PSI drilling guides for Th11 and L1 since these had large and clear pedicles.

MeVisLab 3.1 (MeVis Medical Solutions AG, Fraunhofer MEVIS, Bremen, Germany) was used to develop a visualization tool in which cylinder shapes (representing pedicle screws) could be added

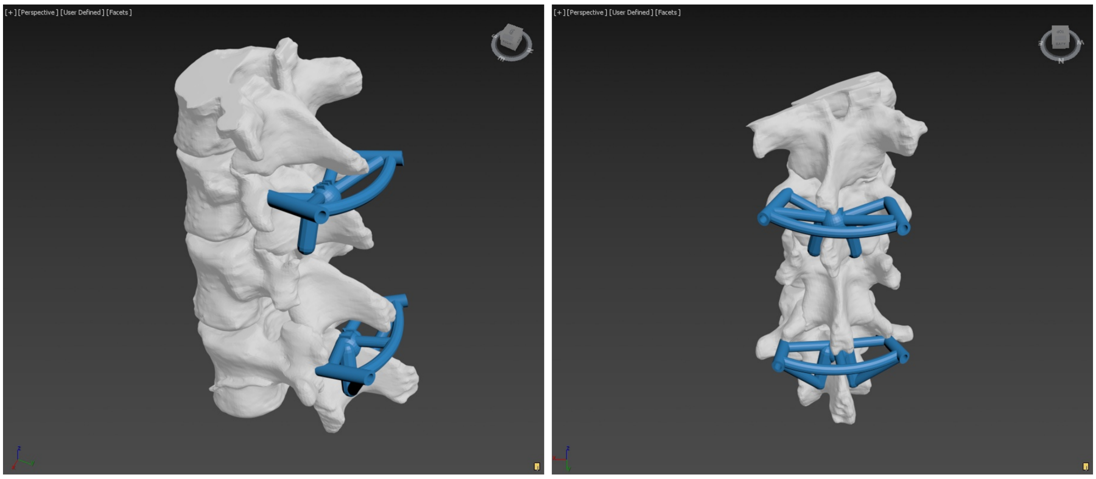

Figure 8: A 3D model of the vertebrae Th10-L1 is seen from two different angles. On both Th11 and L1 the patient specific surgical guide is shown.

and moved within a CT-scan. The screw position was planned by the physician assistant and checked by the surgeon. From the same CT-scan the vertebra Th10 to L1 were segmented. To ensure correct placement of the pedicle screws, surgical guides were designed using 3ds Max 2017 (Autodesk, San Rafael , United States). The design was based on research done in the UMC Groningen by P. Pijpker MSc [26]. The guide designed for Th11 was identical to the one described in the aforementioned paper whereas for L1 extra sidebars were added to make it more rigid and stable. Both guides are designed in such a way that the only contact points are on the spinous process and het entry points of the pedicle screws which will account for a precise and unique fit. An extra margin of 0.2 mm was chosen to take the remaining soft tissue and periosteum layer into account and ensure proper fit of the guides. The guide tubes were designed to fit a 2.7 mm drill with a tube length of 20 mm. Both guides were printed by KLS Martin (Figure 8).

6.3 Surgery and outcome

In total, 16 pedicle screws and one pedicle hook were placed during surgery. Pedicle screws in Th11 and L1 were placed using the guides, all other screws were placed using the conventional method. The point of entry was chosen based on anatomical landmarks. With a pedicle awl and pedicle probe the trajectory through the pedicles was created while verifying it regularly using intra-operative X-ray images. Pedicle screws were inserted and checked using X-ray images.

For Th11 and L1 the supraspinous and interspinous ligaments had to be removed as well as all other soft tissue that might be in between the bone and the guide. The guide was put in position and a small hole was drilled through the guide using a 2.7 mm drill. K-wires were inserted and an X-ray image was made to verify the trajectory. The K-wires were removed and drilling was continued through the pedicle. The pedicle probe was inserted in the created holes to check and feel the trajectory and pedicle screws were insert. Two titanium rods were bend and inserted into the screws. The correction was done by giving compression or traction in certain areas. The surgery was performed with no complications and all screws were placed in the correct position. Six days after surgery a routine X-ray image is made which shows a Cobb angle 50° which was the preoperative target (Figure 9).

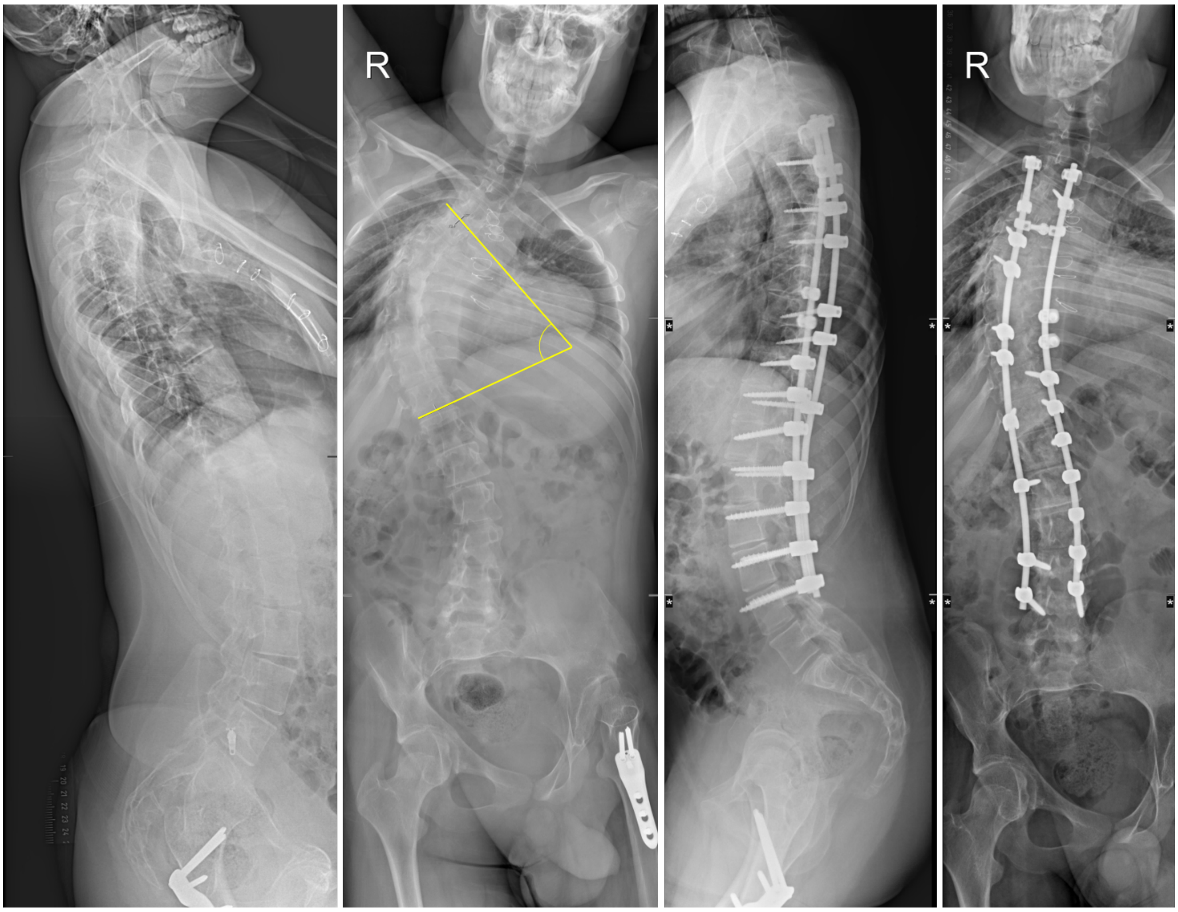

Figure 9: Pre- and post-operative X-ray images, described from left to right. In the left a AP view of the total spine is seen with a clear scoliosis (Cobb angle of approximately 75°, shown with the yellow lines). The second shows a sagittal view of the total spine is seen. The third and fourth image are 6 weeks post-operative X-ray's. The third is an AP view of the total spine in which a clear reduction of the scoliosis (Cobb angle of approximately 50°) is seen. In the fourth image a sagittal view of the total spine is seen.

6.4 Discussion

At this point the surgery can be considered successful. This was the first case in the Radboudumc where drill guides were used for pedicle screw placement. The fit on the bone of both guides was excellent, there was a clear identical fit for one specific location and the margin of 0.2 mm proved to be sufficient. Both the surgeon as well as the technical physician were satisfied with the created guides, yet some improvements can be made for future designs.

As stated earlier, there were some slight differences in the design of both guides. These differences we clearly noticeable during usage. The Th11 guide was substantially more flexible compared to the L1 guide. Once pressure was applied at the arc (circular tube connecting both drill shafts, seen in Figure 8) both drill-shafts diverged. However, when the pressure was too low it was difficult to keep the guide in place. This did not happen in the Th11 guide since extra reinforcement was added between the arc and the center of the guide. This connection piece was not in the original design, as proposed in the previously cited paper, yet it was of great value in this case. The polyamide material proved to be rather flexible, therefore all extra reinforcements are highly recommended.

The planning created using MeVisLab 3.1 showed to be sufficient. With K-wires and intraoperatively X-ray images, a check was done to confirm the preoperative plan. No abnormalities were seen and the guides were used to drill completely through all four pedicles. However some improvements can be made in future surgical plans. The entry point of the left L1 pedicle screw was planned on a "slope". The angle between the drill and the bone at the point of entry was around 45°. This caused a slight slippage of the guide once drilling started which was immediately noticed and drilling stopped. To prevent this from happening a large amount of pressure needed to be put on the guide to keep it in place during drilling. In future surgical plans the point of entry should be chosen such that the drill is perpendicular to the bone.

No precise assessment of screw-placement was done. A CT-scan has to be made to clearly determine whether the Th11 and L1 screws are placed similar to the preoperative plan. Assessment will be done in a later stage when a new CT-scan is present. Still, this first iteration of drill guides for pedicle screws proved their potential in reducing the surgery time and the radiation dose.

Chapter 7

Kyphosis correction

Ankylosing spondylitis (AS), also known as Bechterew's disease, is a common inflammatory rheumatic disease. It mainly affects the vertebral column and sacroiliac joints, causing stiffness and back pain [30]. The incidence is between 0.5 and 14 per 100.000 people per year depending on the country [30]. The disease causes large spinal remodeling by ligamentous ossification, vertebral joint fusion, osteoporosis, and kyphosis [31]. Kyphosis is a spinal deformity with an abnormally excessive convex curvature of the spine. In this case study a patient is presented suffering from AS with severe "chin on chest" deformity for which a cervical osteotomy was performed [32]. For this surgery, two patient specific drill guides were used for placement of 10 pedicle screws.

7.1 Case description

A 73 year old male was presented at the Radboudumc with severe cervical kyphosis. The patient had a known history of AS and wanted to know whether there were any options for surgical correction. The patient described the progressive nature of the deformity and the severe decrease in quality of life. The cervical kyphosis was clearly visible and on CT-images ankylosis of the spine was described (Figure 12). In spite of several comorbidities (overweight and a known cardiac history) a surgical cervicothoracic kyphosis correction was proposed. This would be done via a cervical correction osteotomy. In this surgery first the lamina and pedicles of C7 would be removed to enable the head to be extended after which it would be fixated in its new position. Figure 10 illustrates the correction osteotomy. This surgery has a severe risk of major complications. Since the cervical spine is heavily manipulated there is the danger of high spinal cord injury. Despite the known risks of complications the patient chose to undergo this surgery.

7.2 Surgical planning and drilling guide

A surgical plan was made to perform an open-closing wedge osteotomy on C7. Therefore pedicle screws had to be placed in C3-4-5 (possibly also C6), Th2 and Th4. Screw positions were planned using a self-created user-interface (created with MeVisLab 3.1) and checked by a neurosurgeon. Since no movement was possible between the vertebrae it was possible to create a single cervical guide (for 6-8 pedicle screws) and a single thoracic guide (for 4 pedicle screws) instead of one guide per vertebra. This would possibly make it easier to position the guide correctly.

For the cervical guide 8 drill-shafts were added (two for C3-4-5-6). All shafts were connected horizontally as well as vertically to make the guide as rigid as possible without making it too bulky. The guide rested on all drill-shafts as well as the lamina of C3-4-5 and the spinous process of C5. The thoracic guide rested on all four drill shafts, the lamina of Th4 and the spinous process of Th2. In both guides a margin of 0.2 mm was taken of the guide to account for the periosteum layer. The

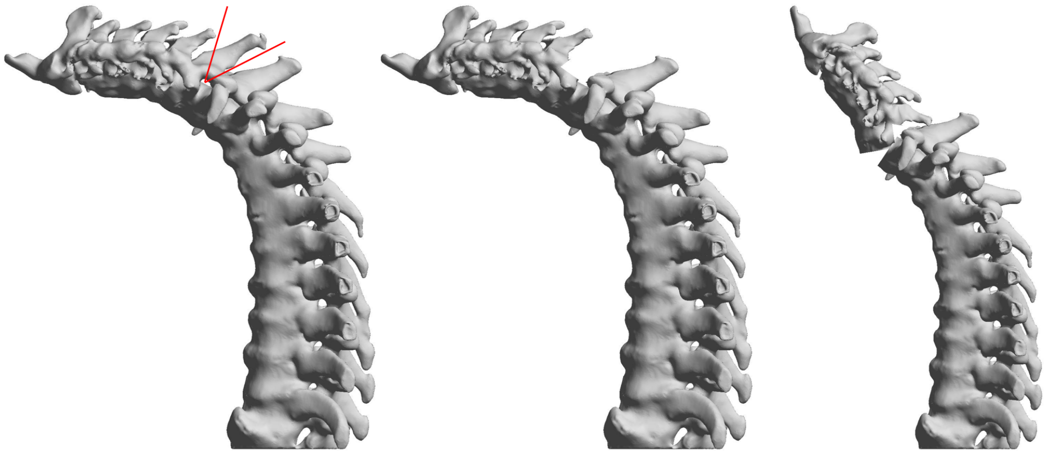

Figure 10: 3D model of a kyphotic spine. On the left the osteotomy is visualized with two red lines. In the middle the osteotomy of C7 is performed. The vertebral arch of C7 is removed. On the right the end result is seen where the cervical spine is extended.

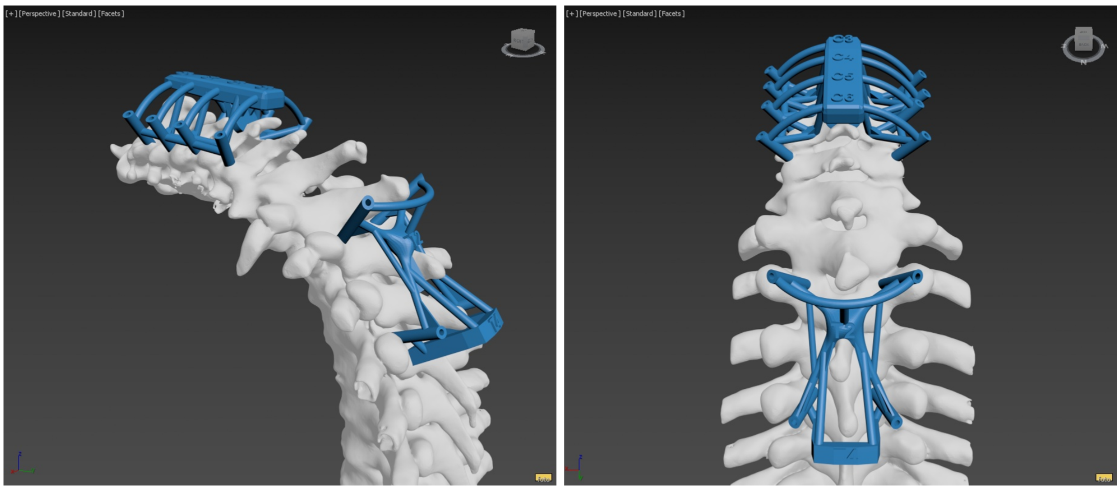

Figure 11: A 3D model of the cervical and thoracic spine is seen from two different angles. Two surgical guides are placed on the spine. One guide for C3-6 and one guide for Th2 and Th4.

guide tubes were designed to fit a 2.7 mm drill with a tube length between 20 and 30 mm. Both guides were printed by KLS Martin (Figure 11).

7.3 Surgery

The spine was exposed from C3 to Th4. With the created patient specific drilling guides bilateral pedicle screws were placed in C4-5-6, Th2 and Th4. Two extra small incisions needed to be made to reach the drill shafts of C4. Excision of the spinous process and a laminectomy of C7 was performed. The pedicles were removed until the corpus was reached. The spinal cord and bilateral foramen of the C7 and C8 nerves were fully exposed. The corrective extension maneuver was done by one surgeon, lifting and tilting the head. A second surgeon checked the head movement and position from under the sterile drapes. Once satisfied with the clinical position of the head, all pedicle screws were attached to manually bent titanium rods. The correction resulted in the osteotomy being nearly

Figure 12: Left: Sagittal slice of a pre-operative CT-scan. A clear kyphosis is visible as well as ankylosis of the spine. Right: Sagittal slice of a post-operative CT-scan. A clear reduction of the kyphosis is visible.

completely closed. The last remaining opening between C6 and Th1 was covered by the split spinous process of C7. Extra bone chips were added posterior over the lamina.

7.4 Discussion

The presented case was the first within the Radboudumc where 3D printed patient specific drilling guides were used in cervicothoracic kyphosis correction surgery. Clinically the results were great (Figure 12). Surgical guides were needed because of the complex positioning of the patient. The usual approach would require intra operative X-ray images which would have been challenging in this case. The cervical guide proved to be highly effective, yet the thoracic guide had several points of improvement.

First the thoracic guide was used. The fit on the bone was good. A large amount of pressure could be put on the arc of the guide to keep it in place. However the guide was too flexible. There was too much rotation possible in the middle of the guide which resulted in movement of the Th4 drill shafts. Also the drill shafts were longer, compared to the guides from the previous chapter. This was a result of the design choice to make one guide for two vertebrae. However since the drill shafts were longer, the moment arm was larger once the drill was tilted within the shaft. It was fairly easy to bend the guide while drilling which would result in a different trajectory than planned. Because of the noticeable movement and flexibility of the guide, it was only used to drill a few millimeters to create the point of entry. The actual trajectory through the pedicle was created using a pedicle probe. In future designs, where one guide is created for multiple vertebrae, the guide needs to be substantially stiffer without becoming bulky. This can be accomplished by making the drill shafts shorter and adding more reinforcements. Yet it can also be recommended not to combine multiple vertebrae in one guide when they are not adjacent.

In contrast with the thoracic guide, the cervical guide worked almost perfectly. The fit on the bone was again good. After the trajectory through the pedicle was drilled, the drill bit would remain in the bone, through the guide. This was repeated for all six pedicle screws. Thereafter, one by one the drill shafts were cut with a bone cutter to enable a pedicle screw to be placed while the rest of the guide would stay in place. This workflow proved to be highly effective. The high amount of cross connections made the guide more rigid compared to the thoracic guide. Yet it was still possible to easily cut through these cross connections to make room for the screw placement. The only improvement would be to make the guide less bulky. No screws were placed in C3 which means the guide could have been substantially smaller. However, the size enabled the usage of the C4 drill shafts which were not reachable without extra small incisions.

A post-operative CT-scan was made to assess the screw placement. The preoperative plan was superimposed on the new CT-scan to compare the plan to the actual positions of the pedicle screws. Figure 13 depicts the placed screws connected with the titanium rods. The planned screw position is superimposed to compare the placed screws with the original plan. When looking at the post-OR imaging it was seen that all cervical screws were correctly positioned. All were centrally placed through the pedicles, but not all were identical to the surgical plan. The left screws of both Th2 and Th4 showed to be placed more lateral. The right Th4 screw was placed more medially than planned, just missing the spinal cord. The slight mispositioning of the thoracic screws could possibly be explained by the flexibility of the guide. Additionally, the thoracic guide was only used to create the entry points after which the actual trajectory was created manually. This makes it difficult to determine the actual effectiveness of the thoracic guide. Yet the cervical guide clearly proved to be effective. It was fully used as planned and the screw-positions turned out close to perfect.

This case illustrates the added value of drill guides for pedicle screw placement in complex surgery. Different design choices prove their effectiveness but also valuable lessons were learned for future surgical guides.

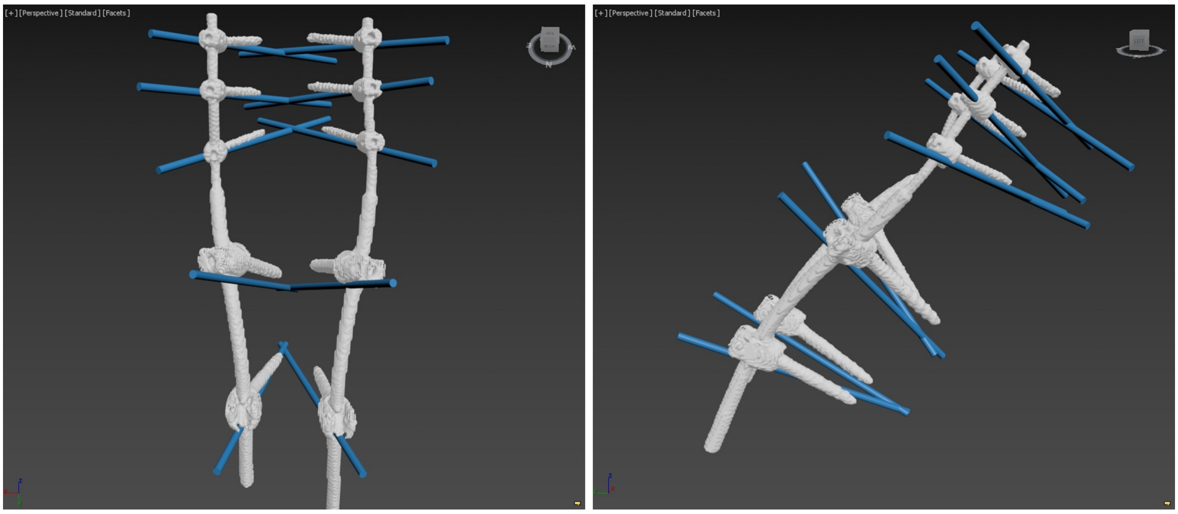

Figure 13: A 3D model of all placed screws, connected with the titanium rods. In blue the planned screw positions are superimposed based on the post-OR CT-scan. This image visualizes the differences between the surgical plan and the actual execution.

Chapter 8

User Requirements surgical software

The previously presented cases were used to obtain an overview of the user requirements of a surgical planning system for orthopedic applications. In all four cases the surgical plan was made by a technical physician and presented to the surgeon using different methods.

In the first case (tibial tubercle transposition) the surgical plan was visualized using only a virtual 3D model that could be rotated. All stages of the surgery were shown: the preoperative knee joint, both osteotomies with the patient specific cutting guide, and the actual end result. The 3D models provided a good overview of the surgical plan, but lacked some relevant information. No visualization was made to relate the fit of the guide with the surrounding soft tissue. When the planning was presented to the physician the question was asked if it was possible to see a cross section of the model, as if it was a CT-scan. As stated in chapter three, the size of the guide and the osteotomy were overestimated. No extra information was given on the widths and heights during the visualization.

In the second case (tumor resection), 2D and 3D visualization was available of both the planning and the guide, but yet again improvements could be made. The surgical plan was made in 3ds Max using primitive shapes (in this case a cube) to define the cutting planes. To visualize the cutting planes in the original CT-images, the cube had to be exported from 3ds Max and imported into MeVisLab. This workflow did not allow for quick and simple adjustments, illustrating the relevance of this research. In the third and fourth case (scoliosis and kyphosis correction respectively) the surgical plan was made solely based on the orthogonal views of CT images. This gave an accurate representation of the trajectory of all pedicle screws, and whether they crossed the pedicle correctly. However, it was difficult to determine the actual point of entry of the screw without a 3D representation. Once a 3D model was shown, and the point of entry visualized the surgical planning could be confirmed and accepted by the physician.

From these aforementioned cases valuable lessons were learned on the information needed for a surgeon to critically evaluate a surgical planning. From these interactions several user requirements were extracted which were translated to system requirements (Table 1).

Table 1: overview of all user requirements and system requirements

User requirement	**System requirement**
The system should show the original CT images	Superimpose a .stl tri-mesh file or cutting planes in the orthogonal CT images
The system should give an overview from different angles	Incorporate a 3D viewer in which the surgical plan can be rotated
The system should incorporate different visualization methods	The 2D CT-viewers should be linked to the 3D viewer and vice versa. Once the planning is adjusted it should be translated to the other modality effortlessly.
The system should give the sizes of the surgical plan	The scaling of the eventual implant or guide should be made visible or adjustable
The system should to be easy to use and intuitive	All buttons should get a medical description to make it easy to understand for a medically trained user

Chapter 9

Methods

Based on the system requirements, a planning software package was developed with three different visualization methods. The usability of these three visualization methods was evaluated by providing surgeons with a specific test case. Pedicle screw placement was chosen as use case scenario, as such a planning would be relatively simple, yet still a relevant representation of a surgical planning. A large portion of a visualization tools were previously created in MeVisLab for the earlier presented spine-cases. These tools were used to write software in which pedicle screws could be added and adjusted with the three different visualization methods.

9.1 Visualization methods

The first visualization method (2D method) was solely based on 2D axial, coronal and sagittal views of CT-images (Figure 14A). The physician could scroll through the three orthogonal projections of the CT scan, in which the location and orientation of the screws was visualized in cross-sections of the 3D objects. The second method (3D method) consisted of a 3D model of the spine, which could be rotated and translated by the user to evaluate the screw positions from different angles (Figure 14B). Additionally, the transparency of the bone could be adjusted to analyze the complete trajectory of the planned screws. Lastly, a visualization method was created in which a 3D model of each separate vertebra was shown from three different viewpoints (hybrid-method)(Figure 14C). The models were fixed in three orthogonal orientations (axial, sagittal and coronal), so rotation of the vertebra for different viewing angles was not needed. The transparency was fixed at 50% to assure visibility of the screws at all times.

Manipulation (i.e. rotation and translation) of the screws was similar for all three methods to assure possible differences between the three methods were solely based on the visualization. The side panel consisted of four different boxes (Figure 14): (1) adding screws with a list of already added screws; (2) rotation; (3) translation; (4) saving of the surgical plan. Only with the 3D method, an extra field was added in which the transparency could be adjusted. The rotation and translation boxes had three buttons for manipulation in the X, Y, and Z direction. Medical terms were given to these fields, instead of naming them X, Y or Z, to make it more intuitive for the physician to use. For each field adjustment was done by clicking on one of the two up or down arrows. Each click represented a movement or rotation of 0.5 mm or 1° for the single arrows, and 10 mm or 10° for the double arrows. To enable movement of a screw it first needed to be selected by clicking its name in the list of screws, which would cause the specific screw to turn green.

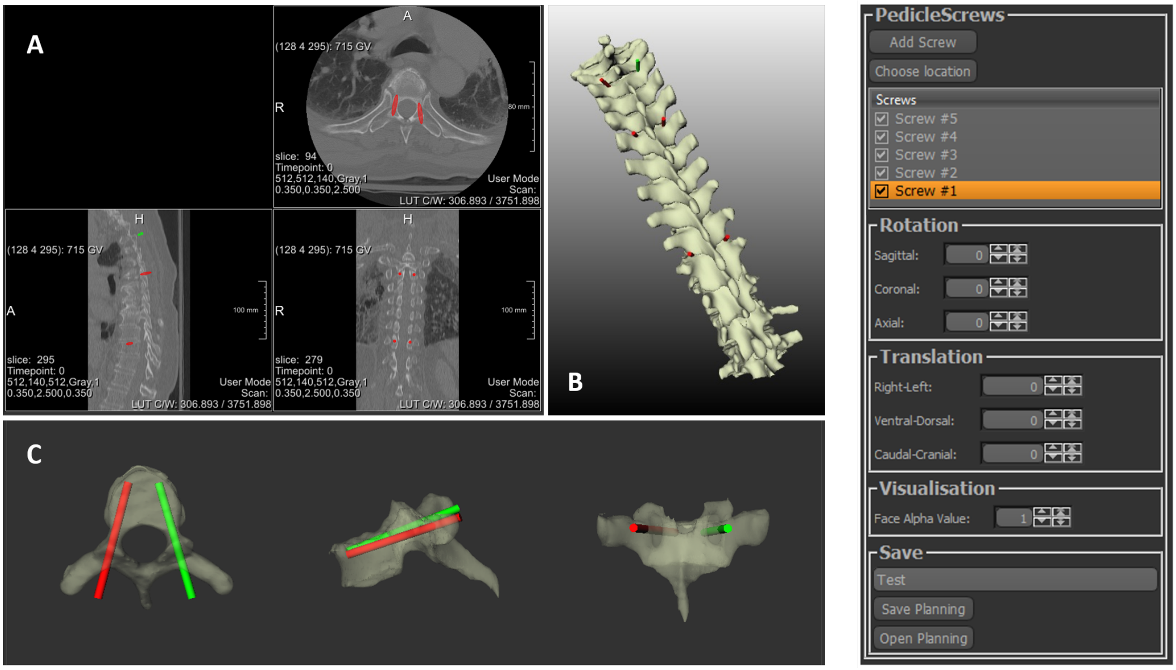

Figure 14: This figure consists of four images. The three images on the left show all three visualization methods. Top left (A) shows the 2D CT visualization. Top right (B) depicts the 3D method and on the bottom (C) the hybrid method is visualized. In all three the screws are represented as cylinders. The selected screw is green where all other screws are red. The right image is a image of the side panel used to manipulate the screws.

9.2 Data collection

In total 10 physicians, 6 residents and 1 physician assistant participated in this research. The participants were asked to place six pedicle screws: one in each pedicle of thoracic 2, 6 and 11. The screws were already placed in the correct vertebra yet in a random position, which was similar for all users. The users were given instructions to rotate and translate the screws until they were satisfied. Two criteria were given for the screw placement: each screw had to be placed inside the pedicle, and it had to be oriented parallel to the vertebral body. Once the user was pleased with the screw-position he/she could continue to the next screw. Based on the randomly selected visualization method the participant would receive written instructions, which had to be read first (appendix A). Additional oral instructions were given to each participant on how to select a specific screw, since this proved to be unintuitive during testing. Similarly for the 2D and 3D visualization, additional explanation was given on what was meant by “clicking on the mouse wheel”, which was needed for zooming or panning the view.

After all instructions were clear the user could start, which meant the instructor was not allowed to answer further questions on the controls of the user interface. The participant was allowed to keep the instruction sheet during the process. Once the first screw was selected the time needed for each screw was recorded automatically. When the user was satisfied with all screw positions, the coordinates, Euler angles and time used were saved in a .csv file.

A system usability scale (SUS) was filled in by the participant, which gave a score between 0 and 100 [33]. This scale related to whether the system was seen as: worst imaginable (SUS $<$ 25); awful (SUS $\pm$ 32); poor (SUS $\pm$ 39); OK (SUS $\pm$ 52); good (SUS $\pm$ 73); excellent (SUS $\pm$ 86) or best imaginable (SUS = 100) [34]. Likewise, the participant’s confidence in the created surgical planning had to be expressed on a scale from 1 (no confidence) to 10 (100% confident). An informal evaluation followed, in which the user was able to express his/her experience, and propose changes to the user interface. All suggestions were collected to create an overview of the desired adjustments. Finally, the other two visualization methods (those not used during their session) were shown, after which the user was asked which method he/she deemed the most useful.

9.3 Analysis of screw position

The assignment was to place the pedicle screws through the pedicle, parallel to the vertebral body. Therefore, assessment of the pedicle screw position was only based on these criteria. First, all screws that were not completely inside the pedicle were scored as misplaced screws. All screws were exported from MeVisLab as .stl file and imported into MATLAB 2019a (MathWorks, Natick, Massachusetts, USA). A ray-triangle intersection algorithm was used to determine whether there were multiple intersections between the screw and the vertebra. If there were more intersections than just the point of entry, it meant that it either went outside of the pedicle or that it penetrated the vertebral corpus. These screws were considered misplaced. For all misplaced screws it was checked whether it penetrated the pedicle wall, corpus or both.

Secondly, the angle between the screw and the vertebral body was calculated. A plane was created on the vertebral body by selecting 3 points (points A, B and C) as seen in Figure 15. Subsequently, the center of mass and the inertial axis of each individual screw was calculated. This gave a point (D) and a vector (E), representing the screw placement. The normal vector (N) of the plane was calculated using equation 1. The angle between the screw and the vertebral body ($screwAngle$) was calculated using equation 2.

$$N = (B - A) \times (C - A) \quad (1)$$

$$screwAngle = |\frac{\pi}{2} - \cos^{-1} \frac{E \cdot N}{\|N\| / \|E\|}| \quad (2)$$

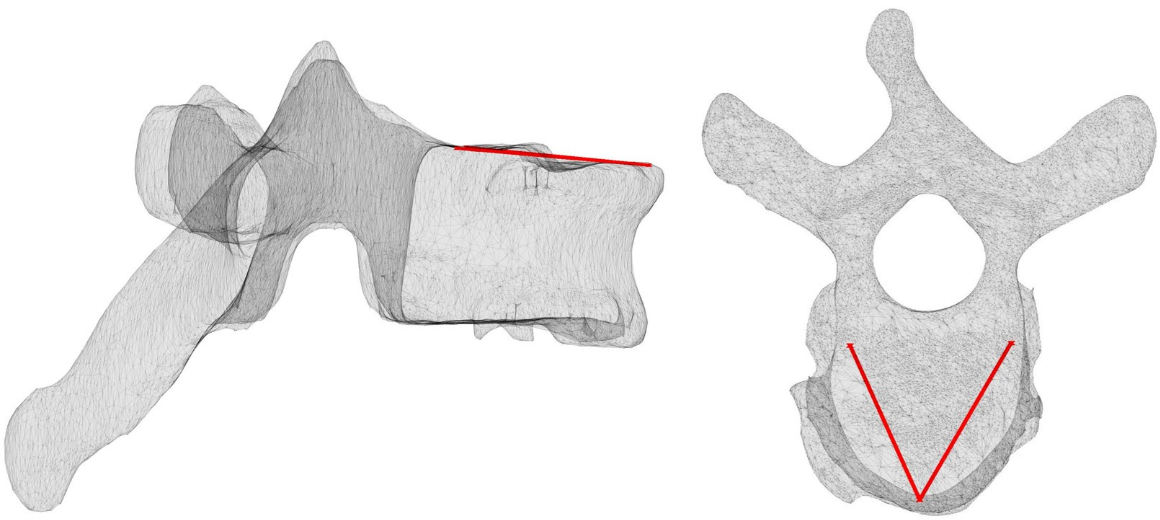

Figure 15: 3D model of Th6 seen from a sagittal (left) and axial (right) perspective. The three points used to create a plane parallel to the vertebral body are plotted and connected with red lines.

9.4 Statistical analysis

For statistical analysis, first, a Shapiro-Wilk test was performed to determine if the data was normally distributed. If the variables were normally distributed, a one-way ANOVA test was done to test if there were significant differences between the visualization methods. The Tukey's range test showed the different relations between all three methods. A non-parametric Kruskal-Wallis test was performed if data was not normally distributed.

Chapter 10

Results

In total 17 participants of the orthopedic surgery department at the Radboudumc were asked to contribute to this research (2 female and 15 male). Two users were excluded from this research. One user was excluded due to a software malfunction. The selected screws did not turn green when selected, therefore the user had more difficulty determining which screw was being manipulated. A second participant was excluded since the task was not completed. This user had to work with the 3D visualization and did not feel confident using such a system and therefore ended his session. He did not want to further cooperate and no SUS was obtained.

All average scores of the SUS, confidence score and the total time used are displayed in Table 2. The data of both the SUS and the total time were normally distributed, while this was not the case for the confidence score. Of these three variables, only the total time showed significant differences between the visualization methods (p=0.021). With the Tukey test the different relationships between the three methods were tested, showing only a significant difference between the 2D and the hybrid method (p = 0.018). In Figure 16A the time per screw is plotted. The SUS and the confidence score were both not significant, with p=0.564 and p=0.353, respectively.

An overview was created of all comments, suggestions and recommendation from the formal evaluation. Of the 15 users, five stated they would prefer to have a “drag and drop” system, where it would be possible to click a specific screw and drag it to the correct position. Such a system would work more intuitively and it would require less time to learn compared to the current system. Eight out of 15 users stated they had some difficulties with getting used to the screw controls. Either the buttons were too small or the function of certain buttons was illogical. Four out of five participants from the 2D group stated the controls of the DICOM viewer needed some getting used to. When the question was asked which method the user would prefer to use, 10 users stated they would prefer the hybrid method, yet often in combination with either the 2D or 3D viewer.

In total 36 out of 90 screws (40%) penetrated the pedicle wall, the vertebral body or both. The most screws were misplaced in 3D (53.3%), followed by hybrid (43.3%) and 2D (23.3%). Of these 36 screws, 7 were critically placed, meaning the screw penetrated the pedicle wall on the proximal,

Table 2: Average values of all results including the standard deviation. A * accent is added to the results that were significantly different.

	SUS ± SD	Confidence score ± SD	Total time ± SD	Screw angle ± SD
2D	76.0 ± 6.70	8.8 ± 1.1	*17.7 ± 5.8	8.2 ± 3.8
3D	82.0 ± 13.04	7.3 ± 2.6	15.0 ± 2.3	*11.7 ± 7.5
Hybrid	77.5 ± 6.12	8.0 ± 1.0	*9.4 ± 2.1	*7.3 ± 5.3
Average	78.5 ± 8.52	8.0 ± 1.7	14.1 ± 3.6	9.1 ± 6.0

distal or medial side. Table 3 shows the results of all misplaced screws. Figure 16B shows the average screw angles per method and per vertebra (also seen in Table 2). The 3D method showed to have significant higher angles in screws placed in Th6, Th11, and in all screws combined compared to the hybrid method ($p = 0.027$, $p < 0.001$ and $p = 0.014$ respectively). Only in Th11 a significant difference between 2D and 3D was found ($p < 0.001$). Th2 showed no statistical differences between the visualization methods.

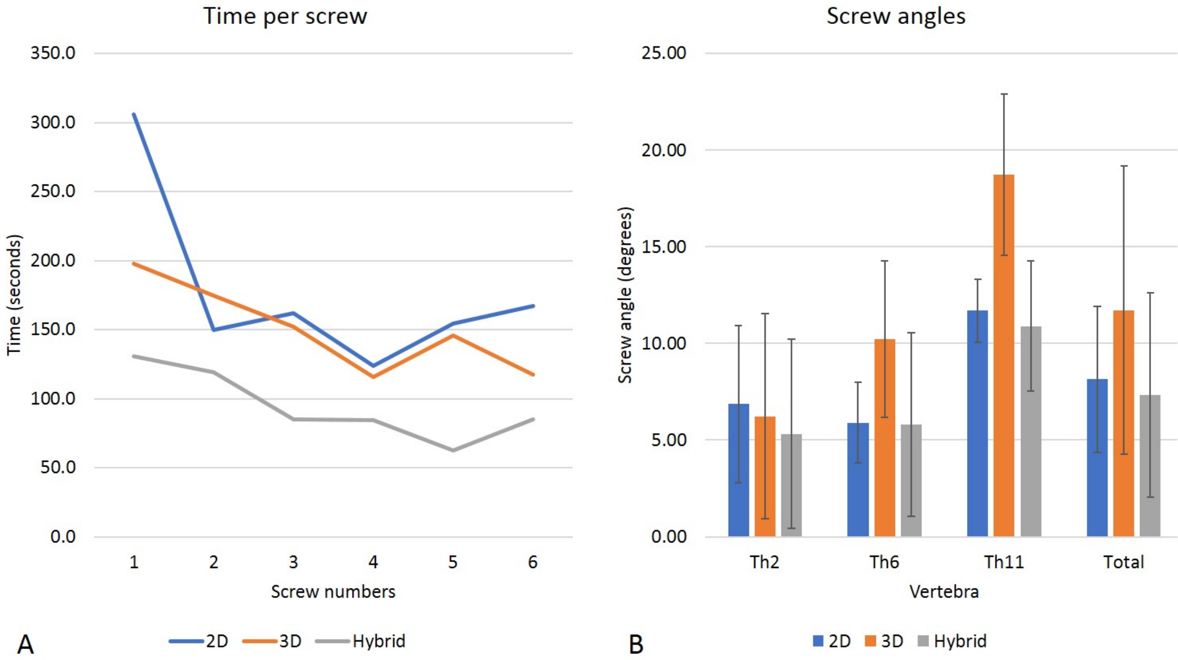

Figure 16: This figure consists of two graphs. **A:** Graph of the average time used per screw for all three visualization methods. **B:** Bar chart of average screw angle (in degrees) for all three visualization methods per vertebrae. The error bars represent the respective standard deviation.

Table 3: Results of all misplaced screws per visualization method.

	2D	3D	Hybrid
Pedicle (critically placement)	4 (3)	8 (3)	9 (2)
Corpus	3	5	2
Both	0	3	2
Total (percentage)	7 (23.3%)	16 (53.3%)	13 (43.3%)

Chapter 11

Discussion

The goal of this research was to determine which visualization method is preferred by physicians, residents and physician assistants to make a preoperative surgical plan for placement of pedicle screws. In the first section of this thesis four different cases were presented in which PSI surgical guides were used. In these cases lessons were learned in relation to the requirements a visualization of a surgical plan should meet. Reflecting on the actual guides itself reveals there is still room for improvement. Some guides were too flexible, making it susceptible to change the direction of the drill or saw while usage. Other guides needed slight adjustments to better account for the presence of soft tissue layers. However, these first experiences with PSI surgical guides were promising and showed the surgeons the potential of using such instruments. More knowledge is gained with each iteration of patient specific designs. In the future these designs can be perfected by learning from these previous cases.

Considering the user requirements a system was created which was supposed to fit the user's needs. On average a system usability scale of 78.5 was found for all three visualization methods, scoring between good and excellent. However, no significant differences in usability (SUS) were found. This can possibly be explained by the fact that all three methods used the same system to change the screw position. During the follow-up evaluation, 8 out of 15 users stated they had some difficulties with getting used to the screw controls. Most users learned how to use the rotation and translation buttons by trial and error. Especially with the rotation buttons the direction of the rotation was not clearly understood from the names given to the buttons. Rotation was possible in the axial, coronal and sagittal plane, yet these terms did not give enough information on resulted changes to the screw position. Since this was one of the main issues users experienced with the software, which was similar for all three methods, less difference can be seen in the SUS.

No statistical differences were found between the confidence scores of the three methods. On average a difference between the visualization types can be seen, yet the difference is not large enough to show significant results with the low number of participants. However, when during the informal evaluation all three types of visualization were shown, all users from the 3D and hybrid group used the 2D CT-images to evaluate their planning. These are the images physicians are familiar with, which enables the user to confidently conclude whether a screw is placed correctly. This could possibly explain the higher average in confidence score for the 2D visualization. The confidence score of 3D was the lowest of all three, largely because of one participant that gave 3.0 for his planning. This user explained that he needed a better visualization of the pedicles to confirm whether the planning is 100% correct. Once the hybrid method was shown he stated he would score a 10 on the confidence score with this visualization method, illustrating the clear overview this method gives.

When looking at the total time needed, the hybrid method worked drastically faster than both other methods. Compared to the 2D and 3D method, the hybrid visualization was 1.9 and 1.6 times faster, respectively. Time needed to create a surgical plan does not directly relate to the most intuitive and usable visualization, but it can give a clear indication. Furthermore, the participants using the hybrid method didn't have to get used to a new viewer. Since it existed of three different static images, no manipulation was needed to adjust viewpoints or scroll through the CT-scan. All information needed to plan the pedicle screws was visible in one overview.

The average angular error of the 3D visualization method was larger compared to both other methods. These differences can possibly be explained by two reasons. First, several users did not change the transparency. If the user kept this value at 1, the spine model was solid and the trajectory of the screw was not completely visible. The screw angle could only be assessed by the part of the screw that sticks out the vertebra. This possibly also explains why the screw angle is even larger in Th11 with the 3D method: since this vertebra is bigger, a smaller part of the screw sticks out posteriorly which gives less information on the screw angle. A second possible explanation could be that the 3D method is the only method were the entry point is clearly visualized in relation to other vertebrae. The point of entry was often close to the lamina of the adjacent vertebra. The user therefore often chose a more distal entry point, which automatically results in a larger screw angle.

In total, 40% of all screws penetrated the pedicle wall, the vertebral body or both. The 2D method showed the best results with 23.3% of the screws being misplaced. However, these numbers should be put in the right perspective. Only 7 screws (7.8%) were critically placed, penetrating the pedicle wall on the proximal, distal or medial side. Several users purposely placed the screws as close to the lateral side of the pedicle as possible, and accepted it when it was clear the screw went outside of the cortex. A known technique for pedicle screw placement is the "in-out-in" technique, which means the screw penetrates the lateral side of the pedicle on purpose [35]. The assignment stated the screw had to be placed through the pedicle, but did not specify the specific manner. Also no instructions were given on the length of the screw. Some participants placed the end of the screw halfway in the corpus while others pushed the screw close to the anterior edge.

To get a clear indication of the actual screw placement, qualitative assessment of all screws needs to be done. This was not done during this research, due to the heterogeneity of the group. The current participants were either physician, resident, or physician assistant at the Radboudumc orthopedics department. Of the 17 participants, only three were specialized spine surgeons who place pedicle screws on a daily basis. All others were capable of planning pedicle screws, but were not specifically trained in the procedure. If an assessment would be made of a surgical plan, it would be challenging to determine whether a faulty planning was caused by a visualization method, or by the limited experience of the user. To ultimately identify the most accurate placement method, an investigation should be conducted where only trained spinal cord surgeons use one of the three visualization methods. Thereafter, all screws should be assessed by a panel of spinal surgeons, using all possible types of visualization.

Additionally, several changes can be made to make the software more intuitive and easy to use. Firstly, to translate a screw, a drag and drop system should be implemented when using the 2D or the hybrid visualization as proposed by five different participants. This would make the user interface easier to learn and more intuitive. Several users tried to grab a certain screw with their mouse, showing the potential added benefit and intuitiveness of such an adjustment. However, in 3D, drag and drop manipulation is difficult to control, and additional experience with similar software is needed. Furthermore, the process of rotating a screw should be simplified. Rotation in the coronal plane should be removed since it was not needed and only made the screw placement increasingly difficult. Instead of having two fields for rotation in the sagittal and axial plane, more intuitive buttons should be considered. For example, the axial rotation buttons could be named converge and diverge which gives a more clear description of the rotation. Also a drag and drop system could be proposed for rotating the pedicle screw, however adding multiple click functions within the same field could also over-complicate the system.

Although there were several features of the user interface that need adjustments, 16 out of 17 users completed the surgical plan. All screws were placed in the intended vertebra while crossing the pedicles. This system was new to all users and on average 14.1 minutes were needed to adjust six pedicle screws. Once the user is more familiar with such a system this time will only improve. With an average SUS of 78.5 over all three methods, the system scored between good and excellent while still being the pilot version. Considering the aforementioned improvements this system has the potential to get an excellent SUS score, proving such a planning tool possibly has added value when creating a surgical planning.

11.1 Conclusion

In this research four cases are presented in which PSI surgical guides were successfully used. System requirements for a surgical planning system were derived from the interactions with orthopedic surgeons. Three different user interfaces were created to make a surgical plan for pedicle screw placement. The hybrid method proved to be the fastest method to learn and to use, while the 3D method proved to be the least accurate. Furthermore, this research proves it is possible to create an intuitive user interface which allows physicians to create a surgical plan. Now a better visualization of a surgical plan for PSI drilling guides can be made. With a combination of the 2D and hybrid method all information is clearly visualized to assess whether screws are correctly placed.

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Appendix A

Questionnaire and instructions

Naam: ....   Datum:..

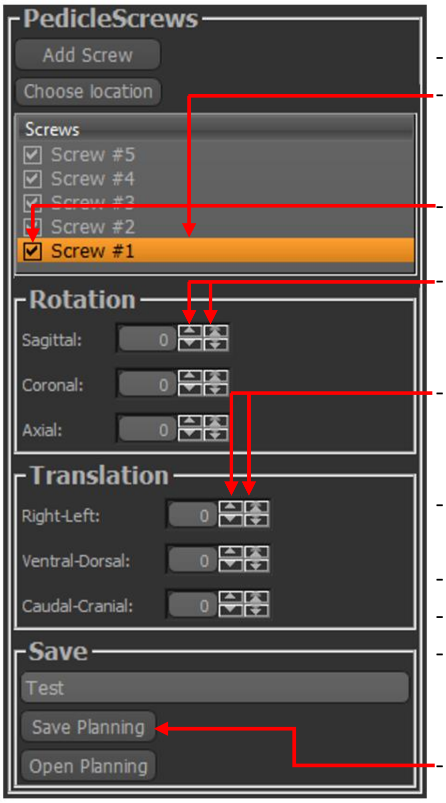
System Usability Scale:

		Strongly Disagree				Strongly Agree
1.	I think that I would like to use this system frequently.	1	2	3	4	5
2.	I found the system unnecessarily complex.	1	2	3	4	5
3.	I thought the system was easy to use.	1	2	3	4	5
4.	I think that I would need the support of a technical person to be able to use this system.	1	2	3	4	5
5.	I found the various functions in this system were well integrated.	1	2	3	4	5
6.	I thought there was too much inconsistency in this system.	1	2	3	4	5
7.	I would imagine that most people would learn to use this system very quickly.	1	2	3	4	5
8.	I found the system very awkward to use.	1	2	3	4	5
9.	I felt very confident using the system.	1	2	3	4	5
10.	I needed to learn a lot of things before I could get going with this system.	1	2	3	4	5

Hoeveel vertrouwen heb je in de zojuist gemaakt planning?
(1 = geen vertrouwen; 10 = ik vertrouw 100% op deze planning)

Instructies 2D:

In de CT scan zijn 6 pedikelschroeven geplaatst (thoracaal 2, 6 en 11). Deze zitten in de juiste wervel maar nog niet in de goede positie. Het is de opdracht om de schroeven zo te verplaatsten en roteren tot ze goed door de pedikels lopen, evenwijdig aan de dekplaat. **Dit moet schroef voor schroef gedaan worden!** Hiermee wordt bedoeld dat de volgende schroef pas aangepast mag worden als u volledig tevreden bent met de huidige schroef. Als u doorgaat naar de volgende schroef mag de vorige niet meer aangepast worden.

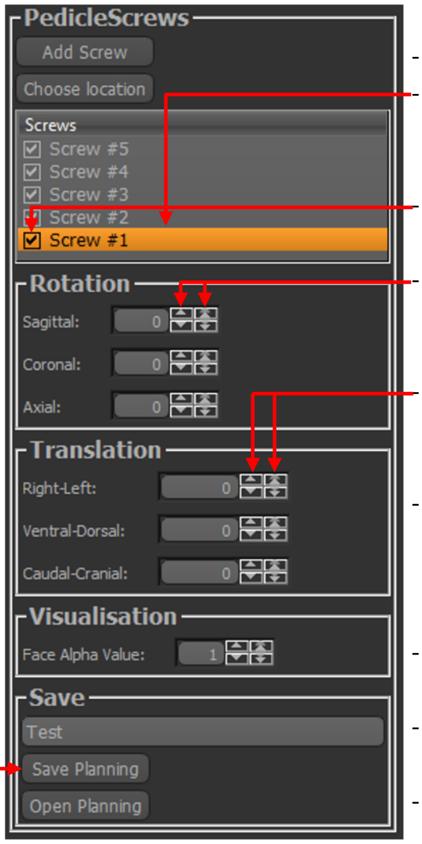


Handleiding:

- Verslepen van de schroef is niet mogelijk
- **Selecteren**: voordat een schroef verplaatst kan worden moet hij geselecteerd worden. Dit moet door hem aan te klikken in het lijstje 'Screws'. **De schroef zal dan groen worden.**
- De schroef kan zichtbaar/onzichtbaar gemaakt worden door hem aan of uit te vinken.
- **Schroef Roteren**: Als de juiste schroef geselecteerd is kan hij in alle drie de richten geroteerd worden (de linker knopjes zijn 1 graden en de rechter 10 graden).
- **Schroef Verplaatsten**: Als de juiste schroef geselecteerd is kan hij in alle drie de richten verplaatst worden (de linker knopjes zijn 0.5 mm en de rechter 10 mm).
- **Helderheid/contrast aanpassen:** Dit kan gedaan worden door de rechter muis knop ingedrukt te houden en te verslepen.
- **Inzoomen:** Ctrl + scrol wieltje indrukken.
- **Beeld verplaatsen:** Shift + scrol wieltje indrukken.
- **Aanzicht aanpassen:** Als het aanzicht van de CT beelden aangepast moet worden (naar bijvoorbeeld alleen sagittaal) kan dat bij het knopje Layout (boven de CT beelden)
- **Opslaan:** Pas onder het kopje save de naam aan en klik op Save Planning.

Instructies 3D:

In de CT scan zijn 6 pedikelschroeven geplaatst (thoracaal 2, 6 en 11). Deze zitten in de juiste wervel maar nog niet in de goede positie. Het is de opdracht om de schroeven zo te verplaatsten en roteren tot ze goed door de pedikels lopen. **Dit moet schroef voor schroef gedaan worden!** Hiermee wordt bedoeld dat de volgende schroef pas aangepast mag worden als u volledig tevreden bent met de huidige schroef. Als u doorgaat naar de volgende schroef mag de vorige niet meer aangepast worden.



Handleiding:

- Verslepen van de schroef is niet mogelijk
- **Selecteren**: voordat een schroef verplaatst kan worden moet hij geselecteerd worden. Dit moet door hem aan te klikken in het lijstje 'Screws'. **De schroef zal dan groen worden.**
- De schroef kan zichtbaar/onzichtbaar gemaakt worden door hem aan of uit te vinken.
- **Schroef Roteren**: Als de juiste schroef geselecteerd is kan hij in alle drie de richten geroteerd worden (de linker knopjes zijn 1 graden en de rechter 10 graden).
- **Schroef Verplaatsten**: Als de juiste schroef geselecteerd is kan hij in alle drie de richten verplaatst worden (de linker knopjes zijn 0.5 mm en de rechter 10 mm).
- **Transparantie aanpassen:** De mate van transparantie van de 3D wervelkolom kan aangepast worden door de Face Alpha Value aan te passen. Hierbij is 1 volledig zichtbaar en 0 volledig onzichtbaar.
- **Beeld draaien:** Het 3D beeld kan gedraaid worden met de Linker muis knop.
- **Beeld inzoomen:** Er kan ingezoomd worden door middel van het scrol wieltje.
- **Beeld verplaatsen:** Het beeld kan verplaatste worden door te klikken op het scrol wieltje en te slepen.
- **Centreren van het beeld:** Dit kan gedaan worden door aan de rechter kant van het scherm op dit knopje te klikken: 
- **Opslaan:** Pas onder het kopje save de naam aan en klik op Save Planning.

Instructies Hybrid:

In de CT scan zijn 6 pedikelschroeven geplaatst (thoracaal 2, 6 en 11). Deze zitten in de juiste wervel maar nog niet in de goede positie. Het is de opdracht om de schroeven zo te verplaatsten en roteren tot ze goed door de pedikels lopen. **Dit moet schroef voor schroef gedaan worden!** Hiermee wordt bedoeld dat de volgende schroef pas aangepast mag worden als u volledig tevreden bent met de huidige schroef. Als u doorgaat naar de volgende schroef mag de vorige niet meer aangepast worden.

Handleiding:

- Verslepen van de schroef is niet mogelijk
- **Juiste wervel selecteren:** Bovenin kan de juiste wervel geselecteerd worden (T2, T6 of T11).
- **Selecteren**: voordat een schroef verplaatst kan worden moet hij geselecteerd worden. Dit moet door hem aan te klikken in het lijstje 'Screws'. **De schroef zal dan groen worden.**
- De schroef kan zichtbaar/onzichtbaar gemaakt worden door hem aan of uit te vinken.
- **Schroef Roteren**: Als de juiste schroef geselecteerd is kan hij in alle drie de richten geroteerd worden (de linker knopjes zijn 1 graden en de rechter 10 graden).
- **Schroef Verplaatsten**: Als de juiste schroef geselecteerd is kan hij in alle drie de richten verplaatst worden (de linker knopjes zijn 0.5 mm en de rechter 10 mm).
- **Opslaan:** Pas onder het kopje save de naam aan en klik op Save Planning.