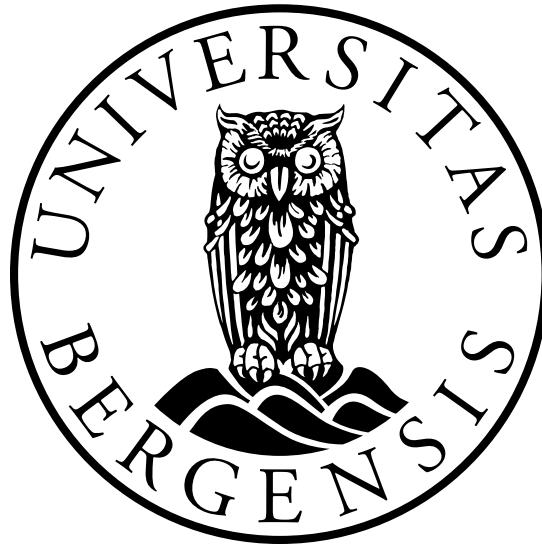UNIVERSITY OF BERGEN

DEPARTMENT OF INFORMATION SCIENCE AND MEDIA
STUDIES

Knee Alignment Tool for Total Knee Arthroplasty: Contribution to a Clinical Decision Support System

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Abstract

This master thesis presents a design science research-based development of *Knee Inspection Tool (KIT)* and *Arthroplasty X-ray Registry (AXR)*, two prototypes for extracting and utilizing key parameters from short-leg x-ray images. The prototypes are contributing to an envisioned clinical decision support system designed to assess and follow-up a patient both pre- and postoperative in the context of Total Knee Arthroplasty.

Development of the system prototype was a multidisciplinary iterative process following the design science research paradigm. The priority was on creating KIT, a working prototype for measuring anatomic alignment of a patient's knee. AXR was created as a proof of concept for utilizing the data generated from KIT, i.e. for user friendly presentation of features, archiving, and contributing to the existing arthroplasty registry. The prototypes were tailored to suit particular clinical needs and to be included as a part of a wider clinical decision support system.

The clinical expertise was considered in formulating requirements and during the two design iterations. Evaluation of the final prototype was two folded: one was carried out with clinical users and the other with IT experts. The results show that the KIT system performs correctly and AXR could provide expected user support, and enable integration with already existing clinical information systems.

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Chapter 1

Introduction

As the Norwegian elderly population is steadily growing in size, the number of knee replacement surgeries are growing parallel with it. Evidence can be found in the statistics; between 2006 and 2016 the number of knee replacement surgeries more than doubled - from 3109 to 6466 [31, 16]. If these numbers hold up, we can expect a doubling - if not more - of knee replacement surgeries within the next 10 years [31, 16]. These surgeries relive the patient of much pain, and help restore quality of life back to the patient. However, knee implants today have a finite lifespan as they are posed to many possible complications. In the event of a complication, a revision surgery is in order. It will restore the implant, but at a cost of more pain and less maneuverability than before.

Within the field of Orthopedics, research to accurately map the direct cause of these knee implant complications and how to combat them is still ongoing [15]. Each patient case is different, so the complexity of the research is high. Since removing the complications out of the picture is not a solution yet, the solution for the oncoming elderly wave is in more effective and accurate treatment of patients. Some risk factors can be tied to improper alignment of the implant, such as instability, aseptic loosening, pain and malalignment [31].

Today, clinicians at Haukeland University Hospital are using commercially licensed software to manually mark-up, measure, and align an implant on digital radiographs of the patients knee before surgery. The quality of this time-consuming task is directly tied to the knowledge and intuition of the surgeon. Therefore, most patient cases are overseen, if not all done by a senior consultant

in Orthopedics. The supply of such personnel is limited, which is alarming given the current growth of demand.

This study will be a part of the ongoing Painless project founded by Helse Vest. They have envisioned a program that in the future will be able to automatically extract key parameters in total knee arthroplasty, on both pre- and postoperative radiographs. This program will then serve as an input for a wider clinical decision support system that will help clinicians assess a patient both pre- and postoperative, e.g. which implant would suit the patient's anatomy best, optimal positioning of implant, and warn if there is alarming change in the implants positioning.

This study will lay the foundation for the envisioned clinical decision support system, by creating a program for manual alignment measurement that allow for extracting data, together with a proof of concept of a web application for utilising this data in combination with relevant patient data.

1.1 Users Group

User groups in this study are clinicians and researchers within Orthopedics. Clinicians are assessing patient status prior to surgery and afterwards to follow up patients periodically to check the state of the implant. In general, most of the knee replacement surgeries are assessed by a senior consultant. Researchers are interested in the outcomes, especially in the cases when revision surgeries are needed. They aim at a deeper understanding of the impact prostheses have on the surrounding bone tissue, specific features of the various prostheses, and how to improve their longevity.

1.2 Data

Data of interest for this project are clinical x-ray images of knee as they are used by the above mentioned user groups. That means that the focus for this study is on the assessment of the x-ray images rather than processing them by means of pattern recognition. The source of data is Haukeland University Hospital's Personalised Archiving and Communication System.

1.3   Research Questions

The research questions that this study will try to answer are:

RQ1: How can design science research methods be used to create an artifact for measuring alignment on a x-ray image in the domain of total knee arthroplasty?

RQ2: How can we include such an artifact as a part of a clinical decision support system to benefit various user groups?

RQ3: Can tailor made artifacts provide solutions that allow more freedom and accuracy to the users as compared to commercially available systems?

1.4 Thesis Outline

Chapter 2 - Literature Review

Present the literature and theory relevant for this study.

Chapter 3 - Methods and Methodologies

Introduce the framework, methods, and methodologies used throughout this study.

Chapter 4 - Requirements

Introduce the requirements for the created prototypes.

Chapter 5 - Prototype Development

Present the development tools, and the development iterations resulting in the created prototypes.

Chapter 6 - Evaluation

Present the results from the evaluation of the prototypes.

Chapter 7 - Discussion

Considers the methods used, prototypes created, and answers the research questions.

Chapter 8 - Conclusion

Present what this study has achieved, together with future work.

Chapter 2

Literature Review

In this chapter the related research is presented. First, an introduction of the clinical field of Orthopedics that is concerned with alignment measuring in total arthroplasty. Then, commercial products for measuring alignment is presented. Then, an introduction to the main research field, along with the relevant student projects, will be presented.

2.1   Medical Informatics

Medical informatics, including Clinical Informatics, is the field where information science, computer science, and health care meet. It is the application of resources, devices, and methods to improve the acquisition, storage, retrieval, and use of information in health and bio-medicine. The field consists of researchers and developers from different disciplines, backgrounds, and experience, collaborating to create innovative applications to improve patient health [50].

In this study, the collaboration with experts from the medical field has been vital for understanding the medical theory and requirements for creating the prototypes of this project. Clinicians and researchers within the field of Orthopedics were involved to evaluate the prototype development, and of the final prototypes together with IT-experts.

2.2 Clinical Decision Support System

Clinical Decision Support System (CDSS) is defined by Kawamoto et al. [29] as any electronic or non-electronic system that aids in direct clinical decision making, where patient specific data is used in assessment or recommendations [29]. Furthermore, Alther and Reddy [1] define CDSS as *"computer systems designed to assist clinicians with patient-related decision making, such as diagnosis and treatment"* [1]. There are two main types of CDSS: **Knowledge-based**, which funnels the input through predefined IF-ELSE sentences to generate the output, and **Nonknowledge-based**, which use machine learning methods to generate the output.

This study presents preliminary work for a knowledge-based CDSS for decision making in total knee arthroplasty, by extracting data from x-ray images based on well known alignment methods for pre- and postoperative clinical assessment, and utilising the data visually in a proof of concept web application.

Figure 2.1: General Knowledge-based CDSS ([1] P. 631)
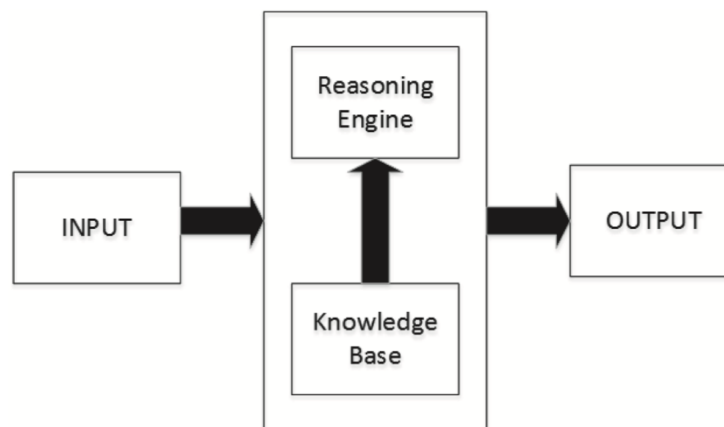
Knowledge-based Clinical Decision Support System

Knowledge-based CDSS derives from early expert systems, in which the human decision making in medical sciences are applied in a decision making system. These systems rely on a user-defined knowledge base of medical information, rules, and conditions [1]. A knowledge-based CDSS is built up by three main parts (Figure 2.2):

Inference engine

Is that part of the CDSS that incorporate a user's input with any necessary data to create a list of assessments back to the user [1].

Knowledge base

Is concerned with determining the condition of the patient based on which information the user inputs. Most often, the knowledge base consist of IF-THEN rules trickling down the input resulting sorted outcomes [1].

User communication

Is concerned with presenting the user with a front-end for inputting data, displaying actions and the suggested solutions [1].

2.3   Radiographs

Radiographs, or X-ray images, are produced by imaging techniques based on the use of X-rays - Computer Axial Tomography (CT), Ultrasound, Magnetic Resonance Imaging (MRI), Positron-Emission Tomography (PET), and Radiophotography [47]. In clinical work, radiographs are typically used because it is a cost-effective way of gaining insight of the patient's body. Although radiographs offer a detailed view of the patient's inner workings, radiographs expose the patient to radiation, varying depending on the imaging technique and body part. The amount of natural radiation the average Norwegian is exposed to in a year is 3.2 mSv, however in radiography, the patient is exposed to between approximately three hours to two months worth of natural radiation [24].

This project is concerned with x-ray images produced by radiophotography, as it is the most cost-effective imaging technique when comparing quality of the image and the amount of radiation the patient is exposed to.

2.3.1   Knee Radiograph Views

For radiographs of the knee the three short-leg views most commonly performed are anterior-posterior, lateral, and axial (Figure 2.2). Each view gives a greater

(a) Anterior Posterior [48]   (b) Lateral [48]   (c) Axial [48]
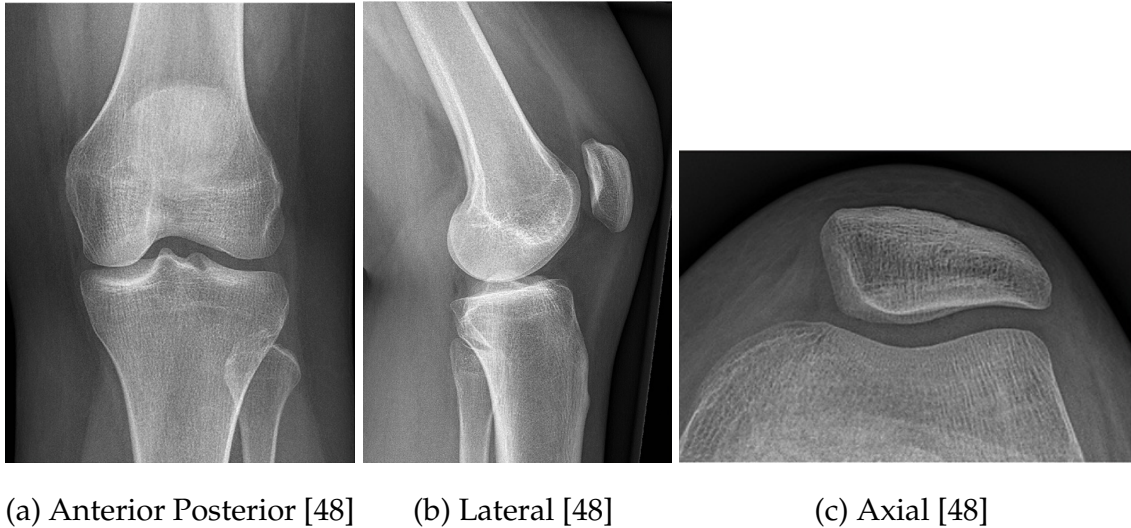
Figure 2.2: Short-leg Radiographic Views

insight to the inner workings of a patient's knee, and helps clinicians assess the most optimal treatment for the patient.

This project is concerned with using anterior-posterior and lateral views as its data.

Anterior-posterior view (AP)

Is taken from the center of the front of a fully extended knee - with the patient either laying or standing. The X-rays pass through the knee joint from front to back. The reverse version of this view, posterior-anterior are also performed, but less common [48]. Figure 2.2a shows AP view.

Lateral view (LAT)

Is taken from the side of a knee flexed to 30°, with the patient laying down on the side. The X-rays pass through the knee joint from the inside of the knee to the outside. Lateral view from various angles are also performed, but are less common [48]. Figure 2.2b shows LAT view.

Axial view

Is taken from the underside of a knee flexed to 40-45°, with the patient laying down on the back. This view is typically used to investigate the patient's patella. This view is not used in this study, but is common in the clinical patient assessment [48]. Figure 2.2c shows axial view.

Long-leg view

Are x-ray images taken of the patient's entire lower body. Contrary to the other views, long-leg view gives clinicians an overview of the patient's anatomical condition as a whole. Typically, this view is used for determining whether the patient is curved in varus or valgus and by how much. This is typically a part of the preoperative planning, however it does also occur in postoperative assessment [48]. Figure 2.3 shows long-leg view.

Figure 2.3: Long-leg Radiographic View [6]

2.3.2 Personalised Archiving and Communication System (PACS)

PACS is an electronic system for storing, sharing, and viewing radiographs within the hospital. The system is developed for use in imaging diagnostics in radiologic departments, and support x-ray images from techniques such as radiophotography, CT, MR, and ultrasound. These images are stored as DICOM-files [46].

2.4 Degenerative Joint Disease

Preliminary to the next section, the most common degenerative joint diseases are:

Osteoporosis (OP)

OP is a disease where the person has weaker bones, making it more prone to where it can easily break. It is often referred to as a "silent disease" as there are no symptoms before a bone breaks [20].

Osteoarthritis (OA)

OA on the other hand is caused by natural wear and tear of the cartilage in joints. The severity of the disease is parallel with the condition of the cartilage - the more severe, the less cartilage. At critical levels of severity the bones starts to grind in to each other leaving bone fragments around the joint. This can in turn cause inflammation which reduce maneuverability and create a lot of pain. The main demographic affected by OA are elderly people as their joints have been exposed to prolonged wear and tear over the years [19].

Rheumatoid Arthritis (RA)

RA is an autoimmune disorder, meaning that the person's immune system is sort of fighting itself. In this disease, the immune system is attacking the person's healthy joint tissues, causing pain, swelling, stiffness, and reduced functionality [21].

2.5 Total Knee Arthroplasty

For some patients affected by degenerative joint disease, the damage to the joints can be so severe that a replacement surgery is the only option to relive the patient of constant pain. In the surgery, the patient will have the damaged bone and cartilage replaced by an artificial part (prostheses) - which will restore most of its function and reduce the pain considerably. Within orthopedics this procedure is known as arthroplasty and is most commonly performed on hip or knee [36].
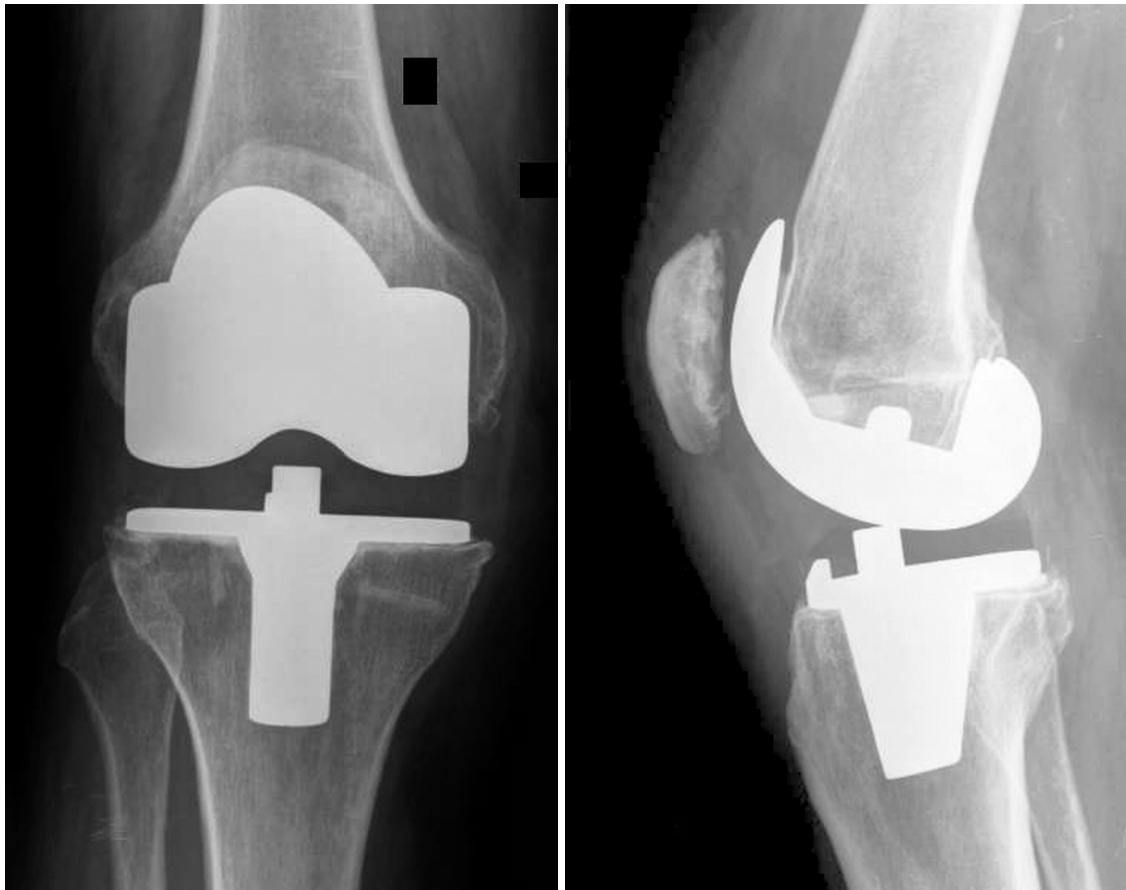
(a) Anterior posterior view [2]   (b) Lateral view [2]

Figure 2.4: Postoperative Radiographs of LPS-Flex Mobile Knee Implant [2]

In total knee arthroplasty (TKA), or Knee Replacement Surgery, the tip of the femoral- and tibial bone and the cartilage is removed and replaced by components of titanium alloy and ultra-high molecular weight polyethylene (PE) [31]. Components of other materials or compounds do occur, but are less common. Most implants are cast around a 3- to 5mm thick layer of cement to glue it to the bone - keeping the prostheses in place and stopping it from grinding away the surrounding bone [30]. As a side-note; there are implants placed into the the bone without cement but they are far less common [31]. In between the femur- and tibia-component is a layer of PE that acts as a artificial cartilage to stop the prostheses components from grinding in to each other. Although the most common implant is with PE, metal-to-metal implants do exist [31]. However, due to the increased heat generation, metal-to-metal implants are not preferred. Moreover, the patella is removed in most implants nowadays, but there are still some

cases where the patella is kept. For these surgeries, the backside of the patella is typically replaced by a component of titanium alloy [31].

2.5.1 Alignment of Implant

According to Cherian, et al. [13] proper alignment of the knee is one of the most influential factors in determining the long-term outcomes after TKA[13]. Today, there are two main alignment techniques in TKA; mechanical, and anatomical. There is little to no agreement in the field of orthopedics on what technique is the most optimal, or which one leads to the best result [13].

Anatomic Alignment

Anatomic alignment was first introduced by Hungerford and Krackow [25] who purposed that the optimal alignment position for an implant would be to recreate the joint line anatomically [13]. According to Luo, Cong-Feng [34] measuring anatomic alignment on a short-leg x-ray image is done by measuring four lines;

Figure 2.5: Short-leg Alignment [34]

Anatomical axes of femur and tibia, and tangential lines of femur and tibia. Drawing anatomic axes of femur and tibia is done by locating the middle of the length and width of the femoral/ tibial bone, and place a mark. On a short-leg x-ray image this is done by placing a marker about 10cm from the center of the knee. From that mark, a line is drawn from to the center of the knee on the femural/ tibial bone. Furthermore, drawing the tangential lines of femur and tibia is

done by setting a line on the outermost knobs on the plateau of femur and tibia.

In Figure 2.5 the anatomical axes and tangential lines are presented. The axes and lines are used to measure the distal condylar angles of femur and tibia, as well as the condylar-plateau angle. The distal condylar angles are measured by the angle between the anatomic axis and the tangential line, of femur and tibia. The condylar-plateau angle is measured by the angle between the tangential lines of femur and tibia [34].
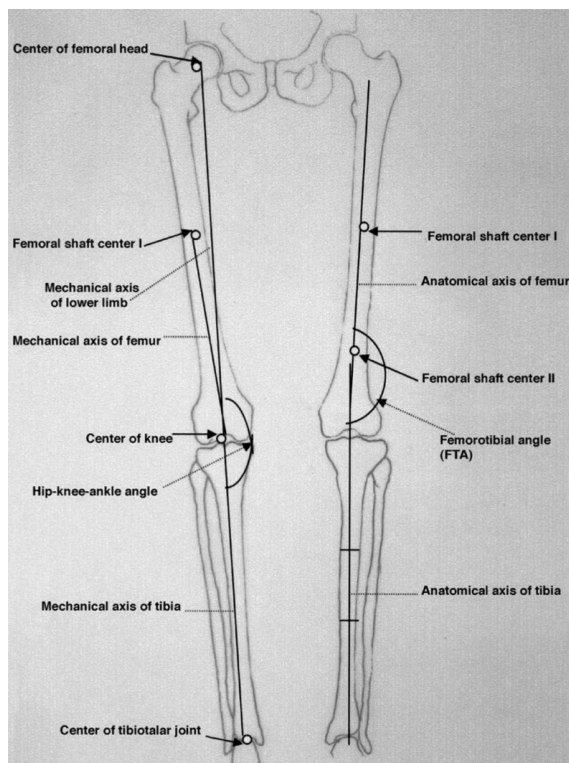
Figure 2.6: Long-leg Alignment [34]

Mechanical Alignment

Mechanical alignment was first introduced by John Insall [45] as an alternative alignment method to anatomical alignment. Insall argued that anatomical alignment would lead to component failure due to the increased pressure across the medial joint component. In contrast, he proposed that mechanical alignment would restore even distribution of pressure across the medial joint component, lowering the chances of failure. Furthermore, a key parameter in mechanical alignment is the mechanical axis which is determined by drawing a line from the center of the femoral head in the hip, to the center of the ankle joint. This requires the use of a long-leg x-ray image which is less commonly performed because of the increased radiation, hassle for the patient, and overall cost [13]. In Figure 2.6, mechanical alignment is presented.

(a) Illustration of Implant design [51]   (b) Lateral View with Depth [49]

Figure 2.7: LCS Complete Implant

2.5.2   Knee Implant Design

Over the last decade implant material, thickness, length and overall design has been subject to change. This means that today, there are a lot of manufacturers with many different implant designs. Moreover, the choice of implant and its positioning is done by a clinician in preoperative planning, with help of radiographs and the history of the patient. Furthermore, the seven most common implant-brands in Norway during period of 2013 to 2017 are as following [31]:

- NexGen (11 455)

- LCS Complete (3 418)

- PFC-Sigma (3 367)

- Legion (2 775)

- Triathlon (1 872)

- PROFIX (1 169)

- Vanguard TM (301)

The various implant-brands are constantly shifting in popularity as brands improve upon their products. The past few years, the LCS Complete implant have been the first choice of implant in Norwegian hospitals. In Figure 2.7 the implant is presented.

2.5.3 Postoperative Complications and Revision Surgery

Every implant has a finite lifespan. It is not a question of if the implant is going to break down, but rather when it will wear out or even break. Most implants rarely break down due to internal complications such as poor construction of the components, but rather to external complications [31]. As of 2017, in Norway, the most common external complications in knee implants are as follows [31]:

- Infection (27%)

- Instability (15%)

- Aseptic loosening of tibia (15%)

- Unexplained pain (13%)

- Malalignment (11%)

In case of an external complication, a revision surgery is necessary to restore the implant. This restoration can either be to partly change something about the implant, or to perform another total knee replacement. According to the Norwegian Arthroplasty Registry's (NAR) rapport for 2018 [31], revision surgery cannot guarantee to restore the quality of life back to the patient, in contrast to the primary surgery as it leaves the patient with a lesser functioning knee and the possibility of more pain than before. Moreover, a revision surgery is highly costly for the Norwegian hospitals - in 2016 there were 583 surgeries, costing the Norwegian hospitals approximately NOK 110 M. Although revision surgery is in most cases the best choice for the patient - the ideal situation would be to prevent it from ever being necessary.

2.6 Related Works

2.6.1 Relevant Literature

Presented below is the literature central for this study. It includes preliminary research for the efforts of this study, as well as the most relevant research on knee alignment.

Individual Patient Outcome Tool For Joint Replacement Patients

In the study, Ellison et al. [16] outline a method for integrating existing data sources to a prediction model, such as data from clinical total knee arthroplasty work. Utilising existing data would mean minimal burden on both the patient and the healthcare system, making it easier such a prediction model to be implemented. Furthermore, the prediction model would be a part of a bigger tool for patient specific forecasting to combat the upcoming demand in TKAs [16].

Lower Limb Alignment Measures

Sled et al. [44], studied the reliability of alignment measures using a customized computer software program. The study used an established method for alignment measures, landmark-based method, using 10 femoral and tibial bone landmarks. In conclusion, the study found that alignment measures using the computer program was highly reliable between multiple participants [44].

Comparison of Measuring Mechanical Axis Alignment

Mündermann et al. [39], studied whether the mechanical axis alignment could be predicted from skin markers on anatomical landmarks, and alignment measurements using computer-based programs. The study found that the method relying on skin markers was promising, only reviling a small, but significant difference between the methods, leaning towards the computer-based programs. However, a skin-marker-based method would allow for no radiation harm to the patient while indicating functional variables, such as dynamic joint loading in degenerative joint disease [39].

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Frontal Plane Knee Alignment

Cooke et al. [15] present in their study, a call for a standardised measurement method for frontal plane alignment. Their work is towards a standard approach that can be used by researchers and clinicians, and is based on geometric analysis of femur, tibia, and the knee joint surfaces. In conclusion, the study present two methods for frontal plane knee alignment measuring, one based on long-leg view which utilises the mechanical axes, and the other based on short-leg view which utilises anatomic axes.

2.6.2 Relevant Master Theses

Previous master theses at the Department of Information Science and Media Studies at the University of Bergen, have been concerned with work within the research field. Following are short summaries of these:

Postmarket Surveillance of Total Joint Prostheses

Berntsen [9] developed and implemented a database of revision patient records and an application to manage it, intended in the first place for the Biomaterials lab at Haukeland University Hospital. The system allows for integration of data from several sources such as registry data, patient record, and biomaterial measurements. It is possible to view, edit, and export data for further statistical analysis. The system was developed in a .NET architecture, with a Microsoft SQL database [9].

Postmarket Surveillance of Orthopedic Implant

Patient knee and hip prostheses that fail are sent to the Biomaterials lab to identify the reason for the device failure. Ertkjern [17] developed a prototype for gathering relevant medical data about prostheses that have failed, and combine that information with external sources, outputting summaries and statistics based on user queries. This study builds on the work of Berntsen, in that the prototype is built from the system created by Berntsen. In addition to this, the system fetches data from the MAUDE database, an international web system of surveillance of all Orthopedic implants [17].

HALE: Hip Arthroplasty Longevity Estimation system

Longberg [32] present a model for predicting longevity of an implant in total hip arthroplasty. The dataset was based on data generated from Ertkjern's system, and contained biomaterial measurements of hip implants, as well as the actual longevity of the implant [32].

2.6.3 Relevant Commercial Products

Presented below are products that offer measuring alignment of implants in total arthroplasty:

mdesk

mdesk is an orthopedic system for preoperative planning and templating of joint replacement, trauma, and deformity correction surgery. The system is made by RSABiomedical, a Swedish firm specialising in products and measuring systems within digital medical imaging [10].

mediCAD Classic

mediCAD Classic is a orthopedic system for preoperative planning and templating of joint replacement and trauma on 2D radiographs. Contrary to mdesk, the system has more focus on automatic detection of bone contour and key parameters. The system is made by mediCAD, a German firm specialising in products and measuring systems within digital medical imaging [35].

Agfa HealthCare Enterprise System

AGFA HealthCare is a global health informatics firm that provides an enterprise system for digital medical images. Among the products they provide is a digital radiograph viewer that is connected to the hospitals PACS, which has tools for viewing in both 2D and 3D [22].

TraumaCAD

TraumaCAD is an Orthopedic preoperative planning system that specialises in automatic planning of joint replacement surgery. The system is made by Brainlab, a global firm specialising in health informatics [52].

Chapter 3

Methods and Methodologies

This chapter present the methods and methodologies used in creating the prototype of this study.

3.1 Design Science

Design science, according to Hevner et al. [23], is a research framework that requires the development of an artifact in information systems that is innovative and purposeful for the problem domain. The methodology is problem solving oriented, focused on creating and evaluating information system artifacts which solve problems for a specific domain. Creating an artifact in design science is an iterative process continually improving on the developed innovative prototype, based on feedback from the evaluations. The evaluation gives the researcher a greater perspective and understanding of the artifact's current state [23].

This study is following the seven guidelines for conducting and evaluating design science. The focus of the guidelines is that the artifact created must be innovative and meaningful for a specific problem domain. At the end of each iteration the artifact is evaluated to confirm that the artifact fills its purpose. A created artifact solve an unknown problem, or a known problem in a better way. Hevner et al. [23] discuss the importance of a well structured representation of the artifact and issues. This ensures that the artifact can be a foundation for further research and that the artifact is suitable for implementation in the problem domain. In Figure 3.1, the guidelines for design science research are presented.

Table 1. Design-Science Research Guidelines	
Guideline	**Description**
Guideline 1: Design as an Artifact	Design-science research must produce a viable artifact in the form of a construct, a model, a method, or an instantiation.
Guideline 2: Problem Relevance	The objective of design-science research is to develop technology-based solutions to important and relevant business problems.
Guideline 3: Design Evaluation	The utility, quality, and efficacy of a design artifact must be rigorously demonstrated via well-executed evaluation methods.
Guideline 4: Research Contributions	Effective design-science research must provide clear and verifiable contributions in the areas of the design artifact, design foundations, and/or design methodologies.
Guideline 5: Research Rigor	Design-science research relies upon the application of rigorous methods in both the construction and evaluation of the design artifact.
Guideline 6: Design as a Search Process	The search for an effective artifact requires utilizing available means to reach desired ends while satisfying laws in the problem environment.
Guideline 7: Communication of Research	Design-science research must be presented effectively both to technology-oriented as well as management-oriented audiences.

Figure 3.1: Overview of the guidelines for Design Science Research ([23] P. 83)

Design as an Artifact

"Design-science research must produce a viable artifact in the form of a construct, a model, a method or an instantiation. [23]

Hevner et al. [23] describe an IT artifact as a broad definition covering instantiations, constructs, models, and methods. They argue that the capabilities of the instantiations, constructs, models, and methods are important for the production of research in the field of information systems [23].

Problem Relevance

"The objective of design-science research is to develop technology-based solutions to important and relevant business problems." [23]

Hevner et al. [23] define a problem as the difference between the current state of the system and the wanted state for the system.

Design Evaluation

"The utility, quality, and efficacy of a design artifact must be rigorously demonstrated via

well-executed evaluation methods." [23]

Hevner et al. [23] argue that the evaluation of the prototype is one of the core parts of research in design science, because the results of the evaluation dictates the further quality of the artifact. The artifact can be evaluated by testing the functionality, completeness, consistency, precision, performance, stability, usefulness, and other relevant measurements [23].

Research Contribution

"Effective design-science research must provide clear and verifiable contributions in the areas of the design artifact, design foundations, and/or design methodologies."[23]

Hevner et al. [23] clarify that contribution of a design science research must be clear. This can be in the form of the designed artifact, new methodologies, using creative evaluation methods, build upon existing knowledge in that particular research field, or a combination of them all. Most commonly the artifact is the main contribution of design science [23].

Research Rigor

"Design-science research relies upon the application of rigorous methods in both the construction and evaluation of the design artifact." [23]

The quality of the contribution of research in design science is grounded in the researchers rigor for the knowledge base and selected methods in creating the artifact [23]. Hevner et al. [23] stress that for the study to be valid, participants of the evaluation must be representative of the user group or have relevant ties to the research field.

Design as a Search Process

"The search for an effective artifact requires utilizing available means to reach desired ends while satisfying laws in the problem environment." [23]

Hevner et al.[23] argue that apart from being a product, design is also an iterative search process to discover an effective solution to a problem. The process is a cycle in which the researcher is always trying to find improvement to be made, referring to both the knowledge base and the problem domain for the answer [23].

Communication of Research

"Design-science research must be presented effectively both to technology-oriented as well as management-oriented audiences." [23]

Hevner et al. [23] state that design science must be presentable for a technology- and management audience. This means that for the technology audience, sufficient details of the artifact within its problem domain must be presented. As for the management audience, the research should bring sufficient knowledge about the resources it would take for the construction of it.

3.2 System Development

Nunamaker et al. [40] present System Development as a research methodology for developing artifacts within information systems. They clarify that system development can be used in combination with other methodologies in information system research. In this study System Development was used as a formulation of process in the artifact development. The methodology is divided into five parts:

Construct a Conceptual Framework

Researchers must advocate the importance of the project's intention, by declaring meaningful research questions that give a clear understanding of the research through the development process. The research questions must be discussed in the context of a conceptual framework, which will help ground the project in relevant theories of the knowledge base [40].

The requirements and functionalities for the system were defined in collaboration with this thesis's co-supervisor and research- and medical-personnel at Haukeland University Hospital, presented in Section 4.1. That formed the basis of the research questions central for this project.

Develop a System Architecture

In the development process, a well defined system architecture will act as a road map for the project, putting the to-be product's components and functionalities into perspective while also declaring their structural relationship [40].

Analyze and Design the System

The nature of the project may be driven by new functionalities envisioned by the researcher, or influenced by representatives from the problem domain. A conceptualised design based on theory and abstraction will be used as a blueprint for the implementation of the system [40].

Build the System

Implementation of the designed prototype will demonstrate the feasibility of its design and the usability of the functionalities of a system development research project [40].

Observe and Evaluate the System

Development is an evolutionary process, where evaluation of the prototype is a determining factor for further improvements of the prototype. In evaluation, the test results must be interpreted based on the conceptual framework and requirements the project set out with. New theories or models may be developed as a result of the development.

3.3 Interaction Design

According to Preece et al. [42], Interaction design deals with the development of effective solutions for a given problem domain. These solutions must have the user in focus, creating the solution with a good user experience. In this thesis, methods of Interaction Design has been utilised to ensure good user experience of the created prototypes.

3.3.1 Usability Goals

As a part of the process of understanding the user group, usability goals ensure that the developed prototype is easy to learn, effective to use, and enjoyable from the user's perspective. The Usability goals are as follow:

- Effective to use (effectiveness)

- Efficient to use (efficiency)

- Safe to use (safety)

- Having good utility (utility)

- Easy to learn (learnability)

- Easy to remember how to use (memorability)

By elaborating usability into these goals, the researcher has a tool to alert of potential design flaws and conflicts that was not thought of beforehand [42].

3.3.2 Design Principles

To conceptualise the usability, Preece et al. [42] suggest the use of design principals. These principals are generalised abstractions aimed at guiding designers to think broaden the perspective on the aspects of their design. The principals are meant as a tentative plan of how to design an interface, and not a strict methodology the designer must follow. The design principles are as follow:

Visibility

Of the product's functionality will increase the likelihood that the user know what to do next. The more functionality left invisible, the more difficult it is for users to navigate, or complete actions in the system [42].

Feedback

Refers to keeping the user informed about what action has been performed and the results of it. This allows the user to continue and complete the activity. As a concept, feedback is related to visibility because giving feedback to the user the right way will enhances visibility of the product [42].

Constraints

Refers to not over-complicating the functionality that the users have at their disposal. This will reduce the likelihood that the user make mistakes during a given activity since the options at hand are only relevant to what the user want to accomplish [42].

Consistency

Of functionality, operations, and elements for the designed interface will make the product easier to learn and use. By having consistent design, the users will only have too learn a single mode of operation which is then applicable to all objects within the product[42].

Affordance

Refers to the attributes of an object that lets its users know how to use it. This can, for example, be a door-handle by which the user intuitively know that this it the object for opening and closing the door. Popular in digital design is to take users knowledge from the real world and apply it to the digital domain [42]. For example, the user is familiar with a button in real life, so when it is seen in the digital domain, the user knows it has the same attributes.

3.3.3 Prototype

A prototype is an expression of the envisioned product's design that offers limited functionality, but users can interact and evaluate it [42]. Prototypes therefor make it possible to collect data about a certain feature-set without developing the entire program. A prototype can be anything from a paper-based schematic to a fully functional program [42].

The purpose of using prototypes is to bring in user feedback earlier in the development process. Prototypes are quicker to make than an entire program, but are often based around a specific set of features. Prototypes are classified into three different categories:

Low-fidelity

Is usually made after the user requirements. Since it is quick to make and has simple functionality, this type of prototype is often represented as a schematic on paper.

Medium-fidelity

Offers more functionality than the low-fidelity, and offers more detailed informa-

tion about the navigation, content, and layout, but is still lacking some features from giving the full experience of the envisioned program.

High-fidelity

Makes it possible to simulate the envisioned program. Its feature-set is nearly identical to that of the envisioned program, and all that is needed is some last finishing touches. The prototype can then be tested with users as if it was the envisioned program, enabling feedback for the program as a whole. After this prototype is completed, the consequent step is its full implementation.

3.4 Development Methodology

The development methodology chosen for this study was an applied version of the Scrum methodology for a single developer. Scrum is a well known agile methodology for software development [43]. Development that uses Scrum puts the end-user in focus by having a set of user-stories represent the requirements of the system. These user-stories are used by the project manager to create a sprint; a collection of user-stories relevant for the artifact development. The whole development process may consist of multiple sprints depending on the time and resources available, each sprint typically lasting up to 30 days. As with all agile methodologies, the focus is not on knowing everything beforehand, but rather on being able to act on the inevitable changes that occur. Furthermore, requirements in scrum are represented as user stories with the who-what-why-format: "As a *who*, I want *what*, so that *why*". The sentences may vary, but must be constructed with this format. Moreover, the user stories fill up the product backlog, which in turn is portioned out over the various sprints through the sprint backlogs.

From the first sprint, a burn-down chart is made in order to predict how much time it will take before completion, which is based on how much work has been done that far. Each day start with a scrum meeting to update team members on how well the development is going and what is to be done next [43]. In Figure 3.2, the Scrum framework is presented.

Since this was a single developer scrum, adjustment were made accordingly. For example, there is no reason to communicate with other team members, in-

SCRUM FRAMEWORK
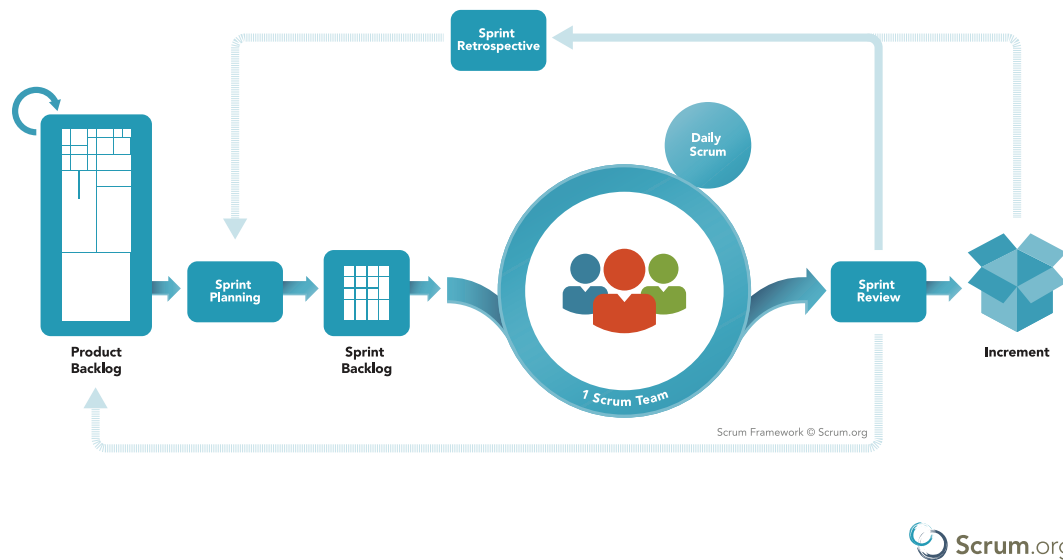
Figure 3.2: Scrum Framework Model [43]

stead the progress is represented through a Trello board. In addition, all roles were filled by the researcher. Furthermore, the product backlog consist of user stories, which will be presented in more detail in Section 5.2.1.

3.5 Evaluation

In the evaluation, the quality of the system or product developed is judged [42]. In the evaluation data is collected about the participants understanding and how they experience the system or product [42]. Feedback during this process helps improve functionality and design of the system or product in the next design-iteration [42].

There are many evaluation methods to chose from, and it is up to the researcher to select the methods that best suit the study [42]. Evaluation can be a part of development iterations to reaffirm that the project is on the right track. At the end of the last development iteration a larger evaluation is done to measure its overall quality and if the research goals have been achieved [42].

3.5.1 Expert Evaluation

Expert evaluation is used to identify as many usability and availability problems as possible, in order to eliminate these before an evaluation with the user group. Expert evaluation involves experts within a a certain domain, or experts within usability and availability to determine the state of the system. Once a prototype is ready, one can perform expert evaluation. There are many reasons as to why one would use this type of evaluation of a system; problems getting participants representative of the user group, not having enough time to perform a more extensive testing, or simply only needing an expert's verdict of the system.

3.5.2 Observation

The value of observation is to capture non-verbal impressions of how participants interact with the system. At times participants have a hard time explaining their own actions, and why or how they solved a task [42]. Using the observation method will allow for greater insight into the actions of the participants and how they perceived the system.

Observing the participants can be done in a active or passive manner. The active manner is when the observant is actively participating in the evaluation of the system, where as the passive manner is when the observant is not participating in the evaluation of the system. These manners both have their practical and ethical limitations, and it is up to the researcher in choosing what manner is right for the given situation [42].

3.5.3 Semi-structured Interviews

Semi-structured interviews are central part of evaluating a prototype, as they allow participants to freely respond to the asked questions. This way, it is possible to gather users thoughts about the prototype, and their experience using the prototype.

The questions are following a tentative plan which cover all aspects of the evaluation, all of which is prepared. The main advantage with a semi-structured interview, compared to other types of interview, is that they allow for a broader

conversation than the pre-planned questions. It is possible for the interviewer to ask follow-up questions outside of the pre-planned questions, allowing for collection of relevant data that was not thought of beforehand.

In this study, semi-structured interviews were used to evaluate the created prototypes using the following set of questions:

1. How was it using the prototype?

2. What did you think about the layout of the system?

3. Which features of the system did you appreciate?

4. What additional features would you like to have?

5. What limitations do you experience with the prototype?

6. What advantages would the system provide for you in your job?

7. How does the prototypes developed compare to the commercial product you are using now?

Together with the observation, the questions are designed to uncover the user's honest thoughts about the system and how it felt using it. Follow up questions were done ad hoc, and changed for each participant as they had different backgrounds and different challenges using the prototype.

3.5.4   System Usability Scale

System Usability Scale (SUS) is a form of ten statements that give a global view in assessing the usability of a system. SUS use a Likert scale, meaning that respondents can express their feelings of agreement or disagreement to each of the statements, on a scale from one (disagree) to five (agree) [11]. These ratings are: Strongly disagree, disagree, neutral, agree, and strongly agree. The ten statements are as follow:

1. I think that I would like to use this system frequently.

2. I found the system unnecessarily complex.

3. I thought the system was easy to use.

4. I think that I would need the support of a technical person to be able to use this system.

5. I found the various functions in this system were well integrated.

6. I thought there was too much inconsistency in this system.

7. I would imagine that most people would learn to use this system very quickly.

8. I found the system very cumbersome to use.

9. I felt very confident using the system.

10. I needed to learn a lot of things before I could get going with this system.

Respondents generally answers the questionnaire after they have had the opportunity to use the system that is being evaluated. When interpreting the scores each answer is converted to their representative number, the odd-numbered questions are then removed one point from, while the even-numbered questions are used to subtract from five points. After this, the score numbers are added together and multiplied by 2.5 which gives a score between 0 and 100. Based on empirical research, the average SUS score is 68, meaning that anything above that will be above average, and anything below will be below average [11]. However, according to an empirical study of SUS score system by Bangor et al. [7], any score above 70 is an acceptable score and the created product is considered good. If the score is between 50 and 70, the product is not satisfactory and needs some more tweaking. Below 50 is not acceptable and the product must be improved.

In this study, SUS was used to determine the usability of the created prototypes. The scoring system used was the one presented by Bangor et al. [7] because it offered a more detailed view of the scores.

3.6 Ethical Consideration

Research that includes eliciting knowledge from users and experts should be conducted according to ethical norms. Norwegian Center for Research Data
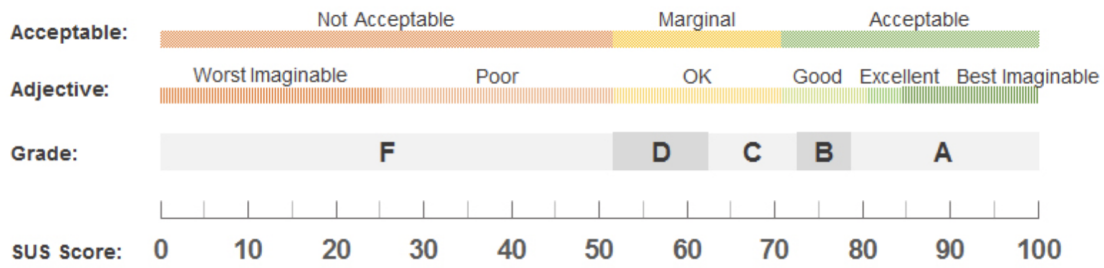
Figure 3.3: In-depth SUS score analysis [7].

(NSD) has established procedures for evaluating ethical consequences that research might have on all participants involved. Research projects are submitted and approved based on the purpose of the research and submitted documents, such as research plan and informed consent.

3.6.1 Informed consent

Informed consent is a document consisting of information about the study and expectations on the participants, what kind of data is collected and what happens with the data once the study is done. The consent can be withdrawn at any point without providing any reason.

All data collected in this study was done with a written consent by the voluntary participants. A written consent form was given to all participants before any data was collected. Prior to evaluation, an additional information about the study and what happens with the data, was given together with the possibility to ask further questions. All participants gave their consent to evaluate the prototypes, undergoing a semi-structured interview, and fill out a System Usability Scale. The informed consent form submitted to NSD is presented in Appendix B.

Chapter 4

Requirements

In this chapter the requirements for this study is presented. The prototype developed in this study for measuring x-ray images of the knee must serve both clinical and research purposes.

4.1 Background

Requirements for the system were established during two sessions, one with a senior surgical consultant, and one with biomaterial researcher, at the Haukeland University Hospital. They have demonstrated how they work with similar commercial products, presented in Section 2.6.3, showcasing their typical work tasks and discussing strength and limitations they experienced with the commercial systems. They have communicated some expectations regarding the future system, such as better measuring accuracy and the ability to export the data. Data was not collected during these meetings because the intent of the meetings was to inform the researcher of the functionality of the commercial products the department had at their disposal.

4.2 Establishing Requirements

A requirement is defined by Preece et al. [42] as a description of the behavior and traits of the envisioned program or product. Normally requirements are split up into two parts: Functional, and non-functional. The functional require-

ments express the expected functionality of the program or product, while the non-functional requirements express the limitations of the program, product, or development of it [42].

Based on the observations with both the clinicians and biomaterial researchers at Haukeland University Hospital, both the functional and non-functional requirements for the system were established as following.

Functional Requirements

The system should:

- Load and display an x-ray image of the patient's knee.

- Present the user with an alignment method to assess the knee.

- Allow for alignment of each of the radiographic views of the patient's knee.

- Allow the user to chose the position of the assessment points.

- Present the user with the measured data.

- Allow users to manipulate the image through zooming, panning and altering lightning conditions.

- Present visualisation of the measured data.

- Be able to export, save, and load the assessment.

Non-functional Requirements

The system should:

- Combine measured data with the rest of the patient record.

- Enable the user to search for a specific patient.

- Present data of all the patient-consultations.

- Allow measured data to be implemented in a prediction model, and present the processed data visually.

- Alert the user if an x-ray image has not been analysed, as well as inform about completion of analysis.

- Allow integration with existing registry developed within previous studies.

Chapter 5

Prototype Development

In this chapter the prototype development of this project is presented, along with the various tools used in the development process.

Creating the prototypes was done through three development iterations. The first iteration was centered around creating a working prototype of the of the knee alignment measurement program. This was the biggest of the iterations. The second iteration was smaller and was centered around improving the prototype based on the results of feedback from evaluation, and updating the requirements for the project. In the third iteration the focus was on implementing a web application.

5.1 Development Tools

The development tools used for developing and planning the prototype are presented below.

5.1.1 Programming Languages

In this section the programming languages used to make the prototypes are presented. Java was used to develop the measuring application, while JavaScript and React.JS was used to develop the web application.

Java

Java is a programming language designed to be a general-purpose, class-based,

and object-oriented language. It compiles to bytecode and runs on its Java Virtual Machine (JVM), making it highly portable in that it can be used on any operating system [41].

Java was chosen as the programming language because of the powerful third-party libraries, and personal experience and familiarity, but most importantly because of Haukeland University Hospitals preferences for software. Other programs made by the Biomaterials lab were developed in Java, making use of the same language allows for integration between the prototype of this study and theirs. Also, Java because coffee.

JavaScript

JavaScript is a well-known scripting language for Web pages. It is a lightweight programming language used in collaboration with HTML and CSS. JavaScript is ran on the user's web-browser, and can be used to alter a web-page's functionality and behavior. Although similar in name, JavaScript has no ties to the programming language Java [38].

ReactJS

ReactJS is a library in JavaScript created by the Facebook engineer Jordan Walke. The main part of the library and its power, derives from its use of Components; small pieces of HTML code containing what the creator wants the user to see. These are centralised and rendered in one of the HTML-documents. JavaScript can be utilised on this rendering, allowing for functionality such as conditional rendering, and displaying dynamic content. React supports external libraries, giving the creator more tools to work with [14].

In this study, React was used to create a working prototype of a web application to centralise the most vital information about a patient undergoing a knee replacement surgery. React allowed for a quick implementation with vast functionality, i.e. dynamically displaying patient information based on measurements of different consultations.

5.1.2 Open-source Software

Open-source software (OSS) is software that is open and free to use by all. In this project, the ImageJ source code was used as a template for the radiograph measuring prototype - Knee Inspection Tool. By utilising the functionality of an OSS, complex functionality did not need to be developed from scratch, thus saving development time.

ImageJ

ImageJ is a public domain Java image processing program which was inspired by NIH Image for the Macintosh. The software was first developed by Wayne Rasband in the 70s and has since evolved into the OSS that it is today [26]. The current version of the software was initiated in 2015, and it is this source code the project will be based upon. The program can display, edit, analyze, process, save and print 8-bit, 16-bit and 32-bit images, runs on Windows, Mac OS X and Linux [26].

5.1.3 Git and Bitbucket

Git is a free, open-source distributed version control system used for system development. Bitbucket is an online service that offers hosting of Git repositories [4]. Git was used in conjunction with Bitbucket to allow for continuous development on several workstations as well as enabling instantaneous sharing of any state of the system during development [3].

5.1.4 Trello

Trello is a free and flexible planning tool that makes it possible to organize, prioritize, and keep track of tasks in a project. Trello utilizes boards that contain multiple lists with as many cards as the user wants. The cards can be anything from user stories to tasks that need to be done. The different lists show how far in the development a certain card is, and each card can be moved freely between the lists. The cards offer color coding which can represent its importance or difficulty - it is up to the user to decide how the colors should be utilised. This way Trello

provides transparency of the development process [5].

In this study, Trello was used together with personalised scrum methodology. The lists kept track of the different parts of the prototypes. The cards were color coded; ranging from red (important), to yellow, and green (least important). Based on feedback during the first iteration new cards were added and some were modified.

5.1.5 Draw.io

Draw.io is an open-source technology stack for building diagramming applications. Draw.io use an extensive shape library and a template library to enable users to build their own diagram for their projects [33].

5.1.6 IntelliJ

The IntelliJ Integrated Development Environment (IDE) was used for all Java coding during the development process. It was chosen because of its extensive integrated development tools, as well as, good personal experience and familiarity with the tool. IntelliJ is not restricted to Java development only, as it has support other languages that utilise JVM, the major application servers, and the most popular web frameworks [28].

5.1.7 Visual Studio Code IDE

Visual Studio Code IDE support a vast majority of the programming languages currently available. It offers built-in git commands, debugging, syntax highlighting, built-in terminal, and a lot of extensions.

The IDE was used for web development and was chosen because of its extensive integrated development tools, as well as personal experience and familiarity [37].

5.2 First Development Iteration

The first development iteration describes the process from a conceptual design, to the creation of the first version of the prototype. The goal was to create a working prototype that gave the user tools to annotate clinical x-ray images of the knee.

5.2.1 Backlog

The iteration began by generating a product backlog of the functional and non-functional requirements for the system. This backlog was generated in collaboration with this project's co-supervisor, Dr. Peter Ellison, and was based on the feedback from the orthopedic clinicians and researchers of the biomaterial lab at Haukeland University Hospital - as presented in Section 4.1. Figure 5.1, displays the product backlog created in Trello.
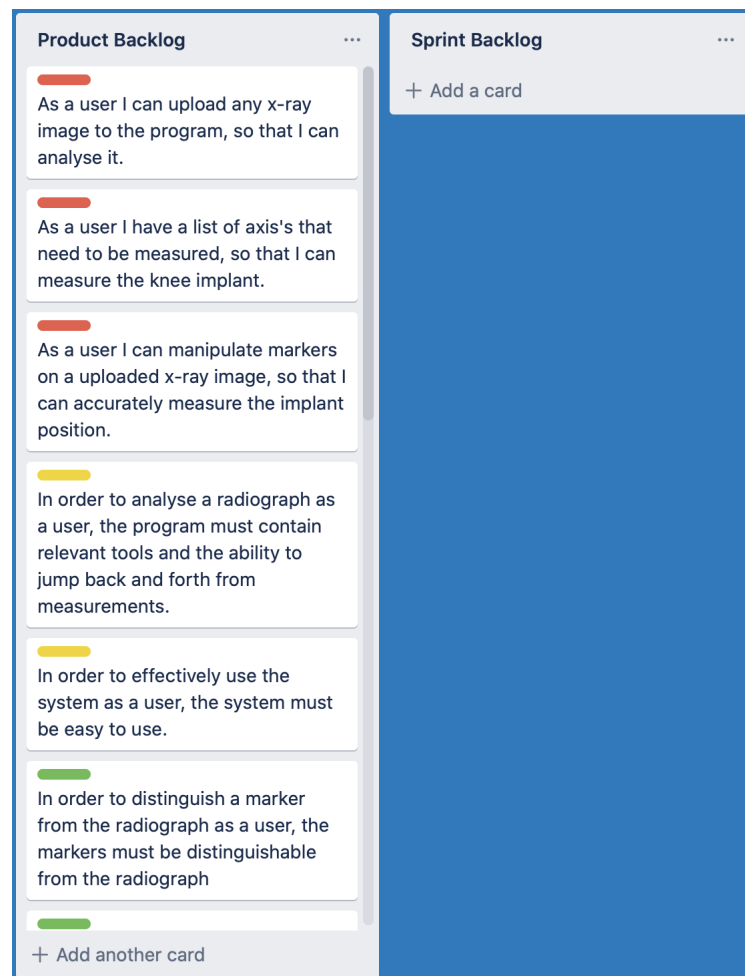
Figure 5.1: Product Backlog in Trello

5.2.2 Low-fidelity Prototype

Based on the backlog, a low-fidelity prototype was created using sketching to conceptualise the design. Sketching is a technique used to quickly make low-fidelity prototypes that demonstrate the functionality of the envisioned product [42].
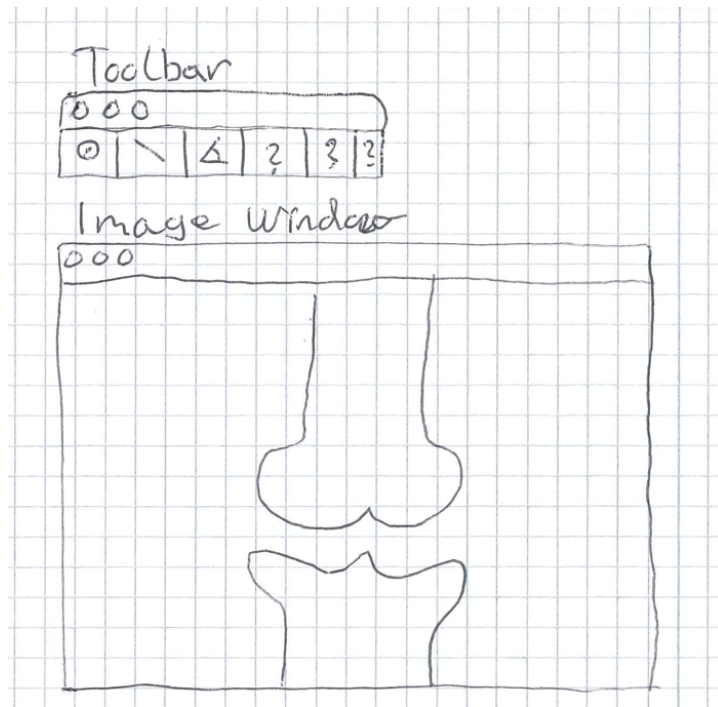
Figure 5.2: Sketch of conceptual design

In Figure 5.2 the conceptualised design is presented. At this point in time, the focus was based on keeping the design simple. The toolbar and image window are independent and separated, so that the entire screen could make up the image. Furthermore, on the toolbar, the button icons would resemble their functionality such as *Placing dots, drawing up lines, measuring angles, zooming, and panning.*

5.2.3 Choice of Open-source software

Within OSS for medical image processing there are three main contenders, each offering the features the envisioned program would need. Those three are:

MIPAV

Medical Image Processing, Analysis, and Visualization, as the name implies, is a java-application that offers visualization and deep analysis of bio-medical images - such as X-ray, PET, MRI, CT, or microscopy [18].

ImagePy

The medical image processing program - ImagePy - is inspired by and modeled after the ImageJ's user experience. It is built on libraries of the PyData software stack, including NumPy, SciPy, Scikit-Image, pandas and others [27].

ImageJ

has been presented in Section 5.1.2, as it was the choice of OSS for this project. At the end, the choice stood between ImagePy and ImageJ. ImagePy was a good candidate because of Python's popularity within machine learning, and down the road automating functionality of the prototype could be desirable. However, as presented below, the biomaterials lab had previously developed a tool - Hip X-ray Inspection Tool (HIT) - using source code from ImageJ. That suggested that ImageJ would be a good choice for the development of the prototype in this study.

5.2.4 Hip X-ray Inspection Tool

Hip X-ray Inspection Tool (HIT) is a tool used for the research purposes at the Biomaterials lab at Haukeland University Hospital, for performing radiostereometric analysis of clinical hip x-ray images. The program is a high fidelity prototype that was developed in-house using Java, and utilising some functionalities of the ImageJ framework.

In Appendix C the tool is presented with a clinical x-ray image of a double hip implant. On the right hand side of the program is the toolbar. It offers measurement of position, wear, migration, and Osteolysis. When a given measurement is selected, its markers are displayed in the Markers-list. Also implemented are tools for opening images, zooming, panning, and altering the brightness and contrast of the image. Furthermore, the load and save functionalities for the markers on the image has been disabled, needing further development.

Due to the familiarity of the HIT system, the development has taken it as the starting point. Further development would thus focus on implementing new functionality to fit the user requirements of the project.

5.2.5 Prototype Functionality

Since it was decided to use HIT as a baseline for the project, it was a natural choice to continue with the same design and functionality as seen in the prototype.

GUI

HIT is built up using Swing, a popular GUI webkit toolkit for Java. This makes up the image window and its processing functionality derived from the ImageJ library, as well as the toolbar on the right hand side, that come directly from the Swing library. Various listeners are implemented in the toolbar, as well as in the image window, to track the user's actions.

Regions of Interest

The main functionality of HIT comes from its utilisation of the regions of interest (ROI) classes in ImageJ. ROIs in ImageJ are objects that represent various shapes. In HIT, the ROIs are used in measurements of size, angle, and distance to determine the situation of the patient's prostheses. ROIs are placed in the image window when a given measurements is selected, and are handled by the Image-Processor class in ImageJ.

Image processing

HIT utilises the various image processing functionalities from ImageJ such as zooming, panning, and controlling brightness and contrast of the image.

These functionalities also represent the requirements of the new prototype to be developed in this study. However, they are modified according to the specific needs of this project. This would ensure the consistency and affordance of the design and remain user friendly.

5.2.6 Choice of Alignment Method

As presented in Section 2.5.1, the two most used methods for digitally measuring alignment of the knee, are mechanical- and anatomic alignment. The goal of this research is to create a tool for utilizing the x-ray images taken in the clinical domain. Given that Short-leg x-ray images are more common, anatomic alignment was chosen as the first alignment method to be integrated. Ideally, both methods would be implemented, but given time constraint of the prototype development, anatomic alignment was the only method implemented. In collaboration with co-supervisor, the approach of determining anatomic alignment was based on research by Luo, Cong-Feng [34] - as presented in Section 2.5.1.

5.2.7 Implementation of Alignment Method

The plan going forward was to apply Luo's [34] anatomic alignment method, presented in Section 2.5.1, by using the ROIs in ImageJ. Since the various axis's need to be lines, the natural choice of ROI was the Line-ROI, a subclass of the ROI-superclass. When the user selects anatomic alignment, four Line-objects are created and placed on the image. These Line-objects represent the anatomical axis's of femur and tibia, and tangential lines of femur and tibia.

5.2.8 First Iteration Prototype

The prototype at this point consisted of a design inspired by the HIT prototype. Under the hood, the ROIs of the HIT prototype was replaced with four Line-objects from ImageJ with functionality for saving their position.

In Figure 5.3, the prototype so far is presented. The toolbar now contains the modules: View, Measure, and Markers. The View module enables the user to annotate whether the x-ray image is a front- or side-view. The Markers, Line-objects, are conditionally rendered based on whether Anatomic Alignment has been selected in the Measure module. Figure 5.3a show the Line-objects "Anatomical Axis Femur", and "Tangential Line Femur".

Furthermore, "Show labels" activate labels for each of the Line-object on the image, display the names as shown in the Markers-list. A "Calculate"-button
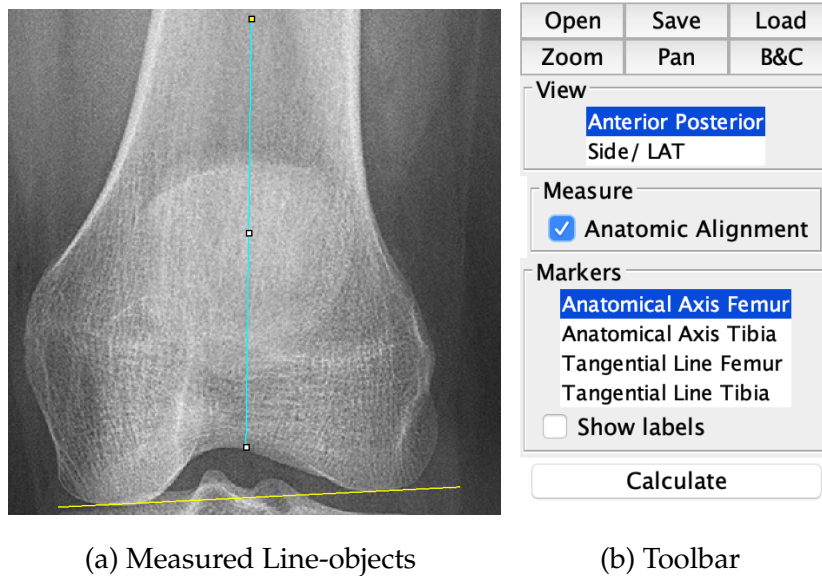
(a) Measured Line-objects   (b) Toolbar

Figure 5.3: First Iteration Prototype with Knee Measurements

has been added, but without functionality. Open, Zoom, Pan, and B&C work as intended. In addition, Save and Load work for saving and loading the position of the ROIs on the image.

5.2.9 Evaluation

The prototype from the first development iteration was evaluated with an expert from the orthopedic department through Skype. The evaluation consisted of a demonstration of the prototype, with feedback regarding the implemented functionality and what the future development should focus on.

Because the prototype could be considered of medium-fidelity, feedback concerned the design of the program and functionalities of the ROIs. One big flaw with the way the anatomical axis's would be placed on the image was observed. Namely, the position of the axis's were difficult to reproduce since it required eyeballing the middle of the bone. As a solution, the expert thought that a more accurate method of deciding this point would be to utilise the bone contour. As such, two point would be placed on the outsides of the bone and the middle point between them would be the point of interest.

5.3 Second Development Iteration

In the second development iteration the focus was on improving the prototype, both based on feedback from the evaluation in the first iteration, and further functionality needed to measure anatomic alignment. Here, the design for the architecture of the system as a whole was outlined together with a proposed web application. Evaluation was not performed on this iteration because it would require real users feedback, so it was decided it would be done in the final evaluation with the most complete prototype.

5.3.1 Improving Functionality of the First Prototype

After the first iteration evaluation, it was clear that the prototype had problems reproducing the position of the anatomical axes. Although the commercial products let the user place the position of the axes freely, this would not work for this project. The prototype that was developed in this study is intended for both clinical and research environments, which means that precision and repeatability of the anatomic alignment are functional requirements.

It became clear that placing the anatomical axis freely could impact the degree of the axis up to one degree. In this context changing in one degree could pose certain risk for uneven pressure on the prostheses, which could affect longevity of the prostheses.

As a solution to the problem, it was instead proposed to implement four dots for each of the anatomical axis's. The four dots would be placed, by the user, on the outside contour of both femur and tibia at the same height as before. From there, a line in middle the topmost dots and through to the lowermost dots would appear. This ensured that the center of the bone would always remain the same, regardless of the user's possible bias. Consequently, the axis's position could be repeated with great accuracy.

Implementing the solution was performed using the Point-ROI class, instead of the Line class. The two PointRoi objects were initialised with four dots each, two for the top of the bone, and two for the bottom. Furthermore, the next part was to locate the center between the topmost dots, and lowermost dots. This was

done by figuring out which dots had the highest Y-coordinates on the image, using .getHeight() method from ImagePlus class. Based on which of the dots had the lowest X-coordinates, the distance from that dot, to the next one was divided in two and added to that X-value. This was then repeated for the Y-values. Moreover, the values were then used in creating a new Line-object for both the femur and tibia dots. These Line-objects represented the anatomical axis of femur and tibia. To create them, a "create axis"-button was added to the toolbar, together with a listener holding the functionality for creating the new anatomical axes. Once created, the axes were put into the list of markers, and the user could alter their position by selecting them from the Markers-list. Furthermore, a "remove"-button was added so that the user could remove the created axes, if needed.

5.3.2 Calculating Anatomic Alignment

The angles and axes were implemented, as presented in Section 2.5.1.

In ImageJ, the ROI superclass has a method called .getAngle(), which returns a double value between 0.0 and 180.0, thus representing the angle at which the ROI is positioned. For the *distal condylar angle*, the angle of the tangential line of femur was subtracted off the anatomical axis of femur, which was then subtracted off of 180.0. This approach was repeated also for tibia in calculating the *tibia plateau-tibial shaft angle*. Calculating the *condylar-plateau angle*, the angle of either tangential line was subtracted off the other one, and that value was then subtracted off 180.0.

A listener was then implemented to the "Calculate"-button, referring to methods for calculating the angles. As for now, the result of the calculations is exported as a .CSV-file, while the user is notified through a pop-up notification that the calculation was complete. In Figure 5.9b, the Pop-up window is presented.

5.3.3 Architectural Design

Since the prototype for measuring anatomic alignment was now beginning to take shape, it was time to look at the system-prototype as a whole.

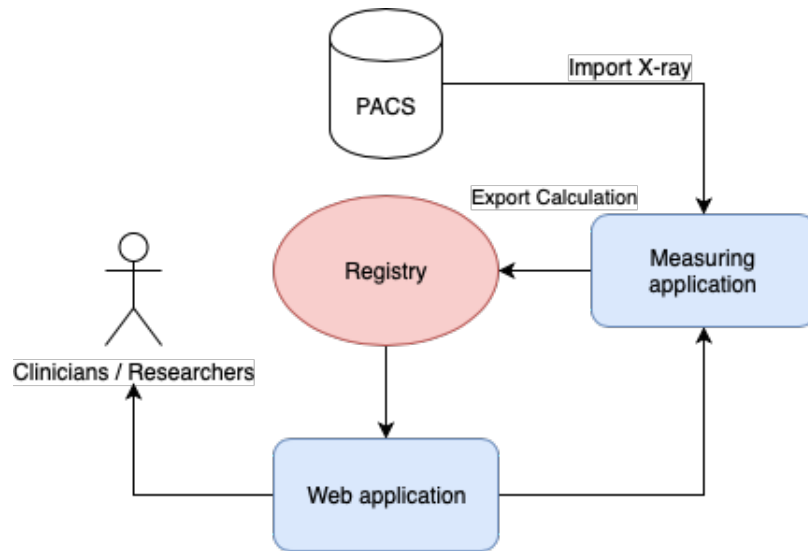A high-level architectural design for the system was created using Draw.io

Figure 5.4: High-level Architectural Design

- presented in Figure 5.4. This was based on the feedback presented in Section 4. When establishing the requirements for this project, the research personnel at the orthopedic department expressed their wish for a web application to perform the alignment measurements. A web application for the front-end of the system, managing the patient data was therefore contemplated. Although creating a web application for managing the patient data could not be fully developed and implemented the users had wished to think about web-application.

The thought behind the architecture was that the prototype for measuring alignment, now named **Knee Inspection Tool (KIT)**, could be used for measuring clinical x-ray images directly from the PACS. Because of the privacy concerns the system could not be fully implemented, but rather as a high-level architecture to demonstrate one possible solution. Furthermore, assessment of x-ray images would be triggered by commands from the web application, giving the user better control over patient records. Highlighted in blue are the applications developed in this study, while highlighted in red is the contrary.

5.3.4   Conceptual Design of Web application

A low-fidelity prototype using sketching was used to design main functionalities of the web application. This prototype is meant as a proof of concept prototype to demonstrate how the patient data could be applied and utilised in combination

with information from KIT, the prototype developed for measuring alignment. The envisioned system would require engagement of Helse Vest, which is beyond the requirements of the current project.

In Figure 5.5 the conceptual architecture is presented - divided into three main components: landing page 5.6, search page 5.7, and patient page 5.8. For all three pages, the header would remain the same. Since the prototype was inspired by the design of Helse Bergen's website [8], the logo and the hamburger-menu was positioned the same place as Helse Bergen's website.
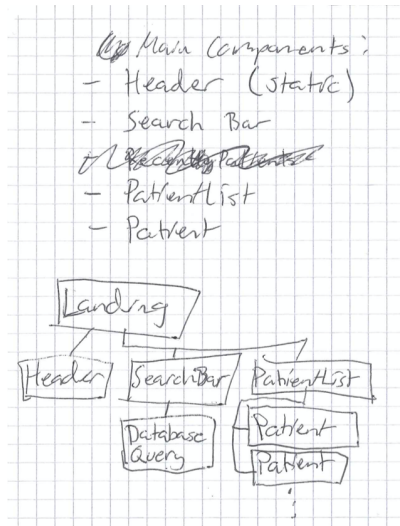
Figure 5.5: Conceptual Architecture

Landing page

Other than the header, the landing page had a *basic search bar* that when used would take the user to the *Search Page*. Below the *basic search bar*, every patient is presented in their own box, vertically, based on their ID number. The age and sex of the patient is displayed under their names and each patient-box would have a button for redirecting the user to the specific *Patient Page*.

Figure 5.6: Landing Page

Figure 5.7: Search Page

Search page

Based on the query, a *search page* with that specific information would open. Each *patient-box* is similar to that of the landing page and once the arrow button has been pressed, the user is taken to that specific *patient page*. The *advanced search bar* was planned to have more extensive functionality than the basic one presented at the landing page 5.7.

Patient page

The *patient page* contains basic patient information at the moment. Further development would include clinicians and researchers that would define content. In this phase the web application is a proof of concept to demonstrate feasibility.
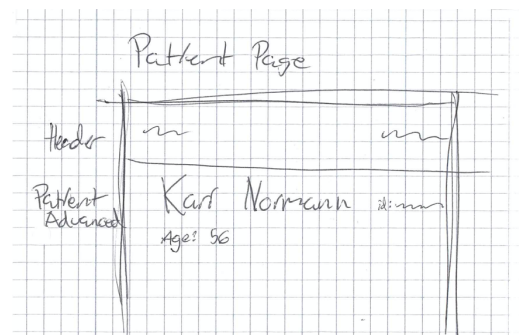
Figure 5.8: Patient Page

5.3.5 KIT prototype Finalised

At this point in the development the measuring prototype, KIT, was finalised. The anatomic alignment had been implemented and was working properly together with all the functionality. In Figure 5.9, KIT is presented together with the Pop-up notification informing that the calculation was completed. In Appendix D a bigger view of the KIT prototype is presented.
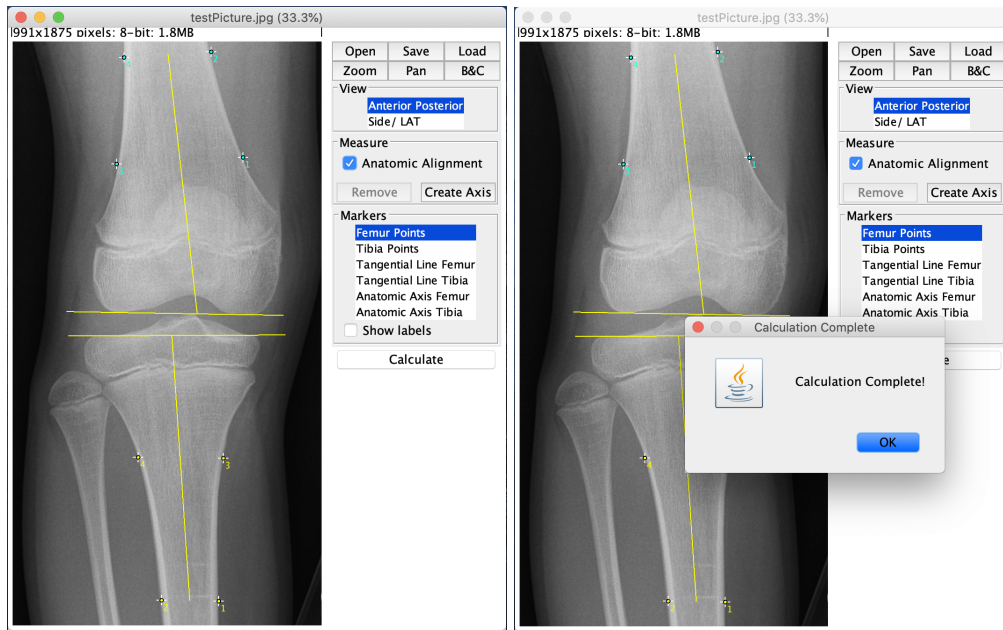
(a) Knee Inspection Tool (KIT)   (b) KIT with Pop-up

Figure 5.9: Finalised Prototype of Measuring Prototype

5.4 Third Development Iteration

In the third development iteration the focus was on developing the web-application for managing the patient data together with data extracted from KIT.

5.4.1 Preliminary

Based on the conceptual design presented in Section 5.3.4, the development of the web application started. The programming language of choice was React.js, a library for JavaScript that makes it easier to develop front-ends with vast functionality - presented in Section 5.1.1. React.js is built up using instantiations of Components - Objects that hold HTML/CSS/JavaScript functionality - rendered through a main file. This is typically called a single-page application, where everything is dynamically rendered through a single page.

5.4.2 Web Application Prototype

The web application was named **Arthroplasty X-ray Registry (AXR)**. In Figure 5.10 the landing page of the application is presented. Although in the conceptual

ARTHROPLASTY X-RAY REGISTRY
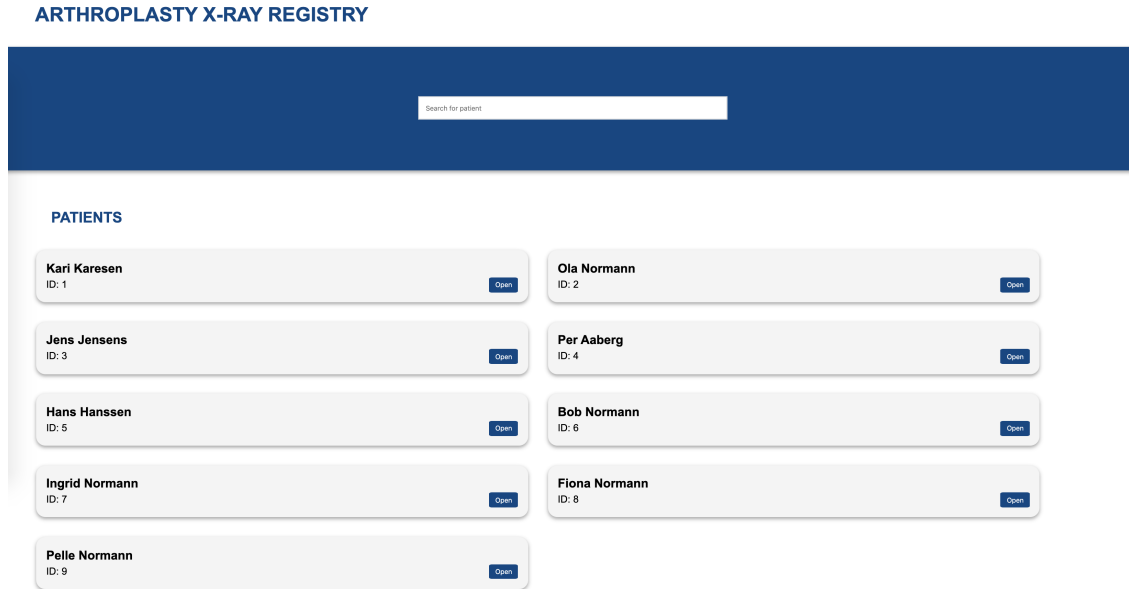
Figure 5.10: Web Application: Arthroplasty X-ray Registry

design, the plan was to have multiple rendered pages for the patients and the user queries, the developed prototype consisted only of a single page, serving as a proof of concept. Thereby, the importance of the web application prototype was to demonstrate how the data could be applied. Currently, the dataset used in this prototype is a list with JSON-objects representing patients (Figure 5.11.

These *patient-objects* hold an id, name, sex, birth date, and a list of consultations. The list of consultations hold *consultation-objects* which hold an id, date for the consultation, type of consultation (preoperative or postoperative), and a list of radiographs. The list of radiographs then hold *radiograph-objects* which hold an id, the radiographic view, the body part, type of alignment was performed, type of implant, and a *result-object* holding the results from the alignment measure-

Figure 5.11: Patient-objects

ments.

On the landing page there are four main Components running: *Header*, *Search-Bar*, *PatientList*, and *Patient*.

Header

Holds the logo - "Arthroplasty X-ray Registry" and nothing else at the moment. In the conceptual design, a hamburger-menu was contemplated, but omitted due to the limited functionality of the application.

Searchbar

Consists of a background in blue and a entry form. Here, the user can type in their query which is checked against the first variables in the *patient-objects*. This lets the user search for patient based on id, name, sex, and birth date. Given the query, the patient list is conditionally rendered. This happens on run-time so once the user starts typing the list of patients changes.

Figure 5.12: Searchbar Component

PatientList

Holds the list of *Patient Components* rendered based on the query from the search bar. If the search bar is empty, all patients are rendered.

Patient

This Component has two different states that change based on whether the "open" button on the right of the patient component has been pressed or not. In Figure 5.13 the opened patient component is presented. Here, all the data from the patient-object is applied. There are three more Components running within the Patient Component:
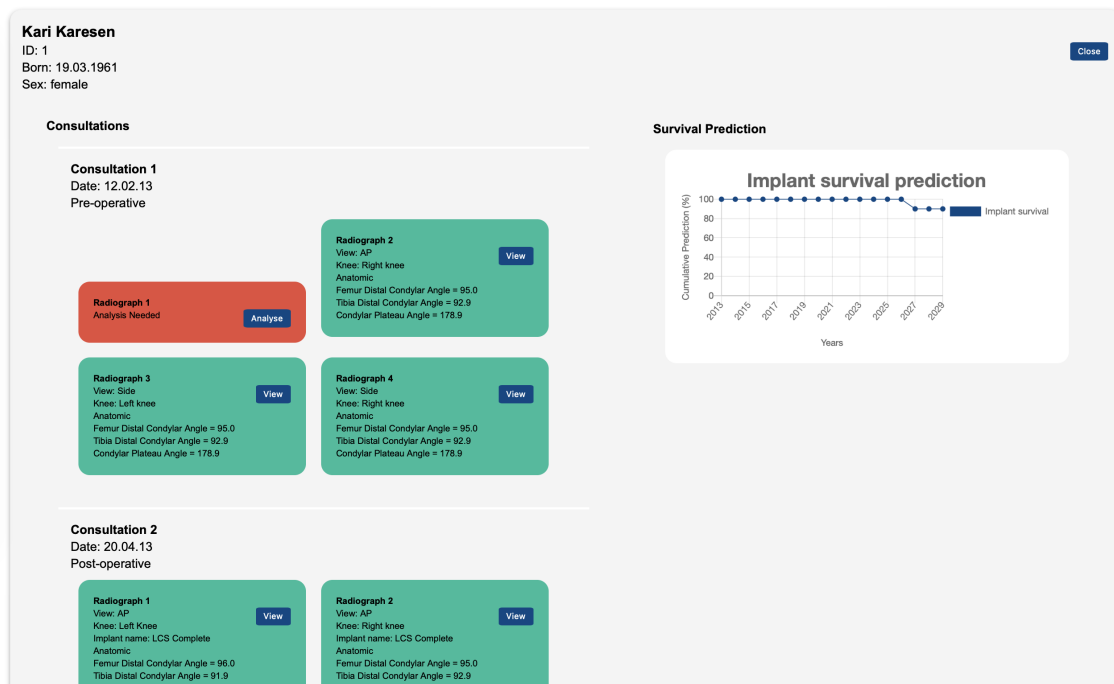
Figure 5.13: Web Application: Patient Box Opened

Consultation

Holds information of the given consultation-object: id, date, type, and Radiograph Components for that Consultation.
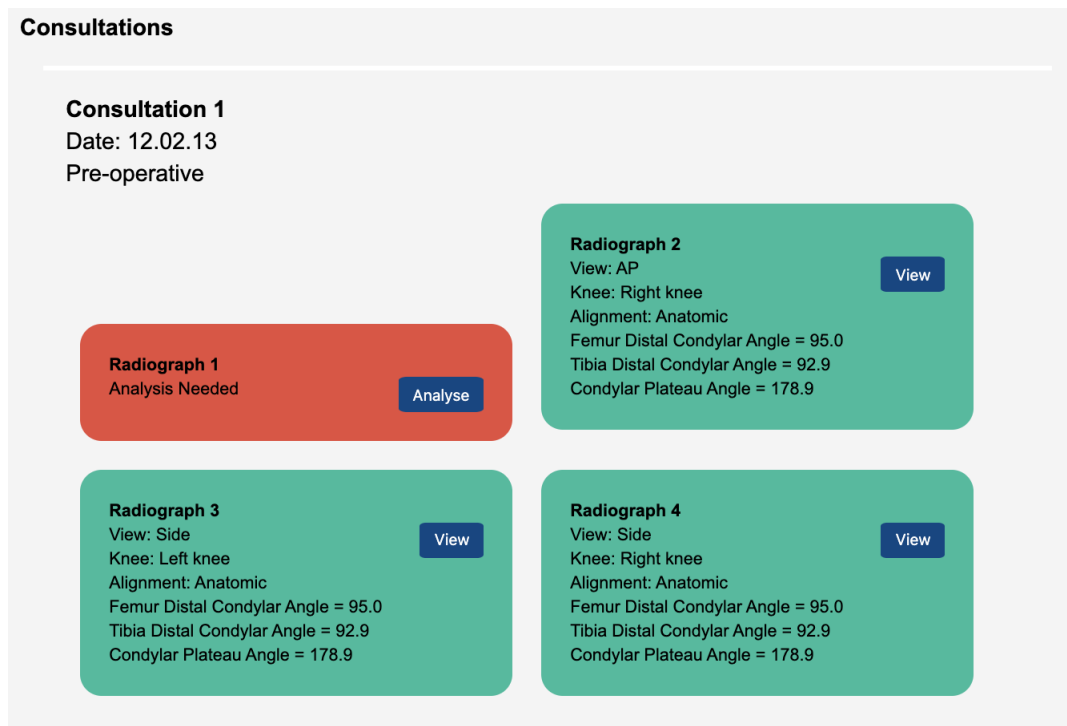
Figure 5.14: Consultation Component

Radiograph

Holds information about that given radiograph: id, view, body part, alignment, implant, and information from the result-object. Depending on whether the radiograph has been measured or not, the background is conditionally rendered between green (analysed) and red (not analysed). The button on each Radiograph is supposed to take the user to KIT and open that specific x-ray image, however implementation towards a back-end has not been done yet.

Chart

This is a Line chart from the React.js version of the Chart.js library [12]. The dataset in the Chart Component is static and demonstrates a rendered implant survival prediction, again serving as a proof of concept.
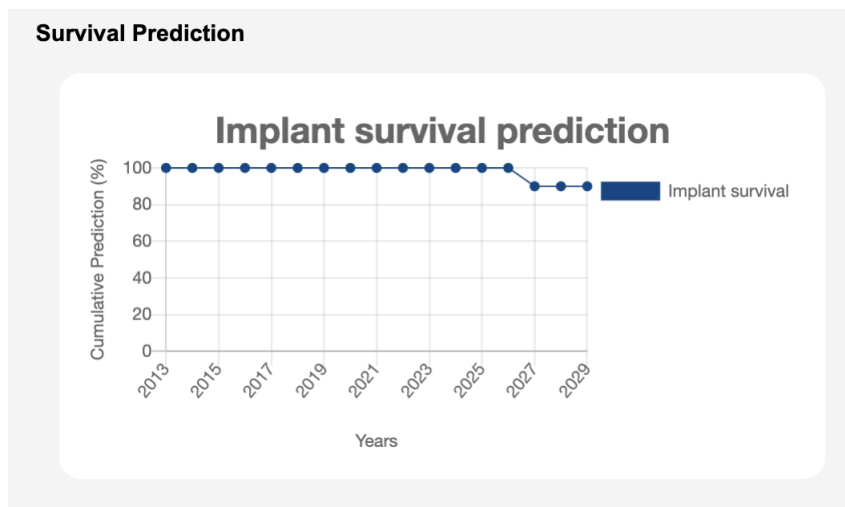
Figure 5.15: Chart Component

5.4.3 Use of Design Principles

The Design principles presented in Section 3.3.2 were used throughout the process of developing the web application prototype.

Visibility

All buttons and inputs have text that describe their functionality. Each element of the web page is distinctive through the use of clear colors, white space, and natural grouping with elements that are similar - signalising their relationship. The blue colors were inspired by Helse Bergen's website, since blue and white were the main colors of their site. Radiograph-components are rendered based on their result, if there analysis is needed then the button is turned to "analyse" and the background color is red. Already analysed radiographs are colored green and the button is turned to "open", so that the user can go back and view the radiograph in the measuring prototype. This example is also applicable for the next principle, **feedback**.

Feedback

The site is changing in appearance to signalise to the user when actions are performed. Buttons change text, patient-components are rendered in run-time through queries, and the patient-components change size and display more information when opened. This way the users have a clear feedback of their actions after interacting with the system.

Constraints

Are realised by restricting the user to only being able to do correct actions. As this prototype is currently focus on managing patient data, the actions the user can perform are limited. Since the actions the user can perform are visible, and the information of each patient is confined within its patient-component, making a mistake such as assessing the wrong patient will be difficult.

Consistency

Is used to make it easier for the user to learn and use the web application. The prototype is inspired by the website of Helse Bergen, a website the user group is already familiar with. Furthermore, each of the patient-components are similar in their layout and design, even though patient specific information is unique.

Affordance

In connection with **visibility**, affordance is utilised to construct a prototype that is easier for the user to learn and use. Users are familiar with the actions of buttons from previous online and real life interactions, as well as entering queries into the search bar.

5.4.4   Final User Evaluation

Final user evaluation has involved representatives of intended user group, as well as IT-experts. For this purpose, a high-fidelity prototype was used to enable a proper user experience. The results will be given in Chapter 6.

Chapter 6

Evaluation

This chapter present the evaluation of the created prototypes, namely KIT and AXR. The evaluation was performed with the intended user group, and IT-experts, using the evaluation methods described in Section 3.5.

6.1 Users Evaluation

Since the user group for this project were clinicians and researchers, their perspective on the state of the prototype was essential to evaluate the prototypes. User testing was performed with researchers from the Biomaterials lab, and a senior consultant at the Orthopedic department, both within Haukeland University Hospital. The evaluation included observation, semi-structured interview, and System Usability Scale - presented in Sections: 3.5.2, 3.5.3, and 3.5.4.

6.1.1 Goal of evaluation

The goal with the user testing was to answer if the prototypes could be a good tool for measuring x-ray images in both preoperative and postoperative assessment of the patient's knee, in the context of knee replacement surgery. Moreover, the evaluations were also used to explore how the prototypes could be improved. To guide the evaluation the following questions were defined:

- What are the participants perspective on the use of the prototypes?

- How are the prototypes as compared to the commercially available products?

- How can the prototypes be improved in design and functionality?

- In their opinion, will the system require special training?

6.1.2 Participants

The participants in the user testing were coded as P1, P2, and P3, in the following sections the participants will be addressed as such. Furthermore, each participant was given an informed consent form explaining the purpose of the evaluation and which data would be collected. General information about what the purpose of the system was and how the prototypes were linked together, was presented orally prior to the testing. The informed consent given to the participants is shown in Appendix B.

6.1.3 Observation

Observation took place at their respective workplaces. Ideally, the programs would be used on their own computers to simulate the real scenario. However, since the state of the system was still a prototype, the system was showcased on computer used for development.

Tasks

During the observation the participants were given tasks to solve. If they were stuck, or could not solve the task, then they would be instructed on how to continue. In such a case, the problem the participant was having would be noted. The following tasks were handed out on a sheet of paper:

1. Locate the patient "Kari Karesen" on the web page.

2. Find out which radiograph needs to be analysed and open the radiograph.

3. Measure the anatomical axis of femur and tibia.

4. Measure the tangential line of femur and tibia.

5. Perform a calculation of anatomic alignment.

6. Find the results of the alignment in the patient-box.

The participant's performance would be observed and noted. However, the time spent solving was not recorded since the tasks were concise and fairly easy. Before the participants went on with the solving, they were told to navigate around the system and familiarise themselves. This would ensure that the participants were comfortable using the system, which would better simulate a real world scenario.

Results

All the participants managed to solve the tasks, but P1 and P2 seemed to have some problems with performing the anatomic alignment in KIT. P1 exclaimed that she was not familiar with this way of measuring the alignment. Once she was given a clue about where to place the four dots for each of the bones, as well as which button would create the axes, she managed to calculate the angles. P2 on the other hand, had problems locating the button to create the axis. Once P2 were instructed where the button was, he too managed to calculate the angles.

P2 stated that the design of the program reminded them of software they used previously in their work.

None of the participants had problems with navigating through the website, but none of them used the search-bar to navigate to the given patient. This was probably because the patient "Kari Karesen" was the first one in the list of patients and therefore easily seen. Furthermore, the participants seemed confused about every patient-component having the same dummy data in them. In retrospect, the data could have been created uniquely for each patient.

P3 had no problems aligning the four dots on each of the bones and managed to find the button to create the axes. He seemed more familiar with the alignment method in general. Although he managed to perform the calculation on his own, he noted he prefer a different location of the dots on the image. Currently they would just appear on the top left of the image, but he wanted them to appear closer to the bone they were meant for - femur and tibia. He also declared that the way of activating the given markers were tedious. In the current state of KIT, to drag around the lines or the dots, the marker corresponding to that dot/line needed to be activated first. Allowing the users to freely drag around

any dot/line would make it easier and faster for the user to perform the alignment, P3 said.

6.1.4 Semi-structured Interview

After the observation took place the interviews were conducted. In contrast to the observation, the interview was aimed at explicitly uncovering the participant's general impression of the system; how good or bad it was, what improvements could be made, and how the system could be compared to the commercially available products. Moreover, the audio was recorded to keep track of the conversation with the participants. The audio was transcribed, analysed, and summarized. The full transcript of the interviews can be found in Appendix E (Norwegian).

Results

Here is a summary of the main findings from the interviews:

How was it to use the AXR?

All participants answered positively to the question. P1 also remarked that the application was straightforwardly, while P2 remarked that the layout was simple and it was easy to solve the tasks given.

What was your experience using KIT?

P1 and P2 had some difficulties in solving the tasks. P1 answered that the program was okay, and that it would be easier to understand once she had used it some more. P2 thought the program was very good to use, but he acknowledged that it was beneficial to get help solving some tasks. P2 added that the interface was nice, the symbols clear, but that a little help text could have been nice to see, referring to instructions on positioning the markers. In a follow-up question, P2 suggested that he would have the markers flash during their activation, to make the user's action more transparent. He also added that the start position of the markers could have been moved closer to their respective bones. Furthermore, P3 thought program was good to use, but he thought that dragging the dots was

not intuitive. On a follow-up question, he thought that the measuring functionality in this program was better than in the commercial program they were using routinely.

What did you think about the layout of both the systems?

All participants said that they liked the layout of both prototypes, and P2 added that he thought they were clear as well.

Were there any additional features you would like to have?

P1 added that she wanted some guidelines to inform which sub-measurement would be done next. P2 wanted text directly on the image of its radiographic view, which is something that P3 mentioned as well. P3 also wanted the ability to measure mechanical alignment as well.

What advantages would the system provide for you in your job?

All participants stated that the program would be beneficial in the context of knee alignment measuring, both in their clinical and research work.

How does the system compare to the commercial product(s) you are using?

P2 expressed that although the system and the commercial products were similar, the latter was more complex and had more features. P3 had previously said the the measuring in the system was better as compared to the commercial products he was using. He explained that in the commercial products the angles calculated would be readily available on the image itself, something that P2 had also previously expressed.

6.1.5 System Usability Scale (SUS)

Final part of the evaluation was a SUS form. In Section 3.5.4, SUS was introduced together with how to calculate the scores. A SUS form was handed out for each of the prototypes, to get a separated view of their usability. After the participants had filled out the form they could add some additional comments and criticism about the system, if they wanted.

Participant	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	SUS Score
P1 (AXR)	5	1	4	1	5	1	5	1	4	1	95
P1 (KIT)	5	1	4	4	5	1	5	1	4	5	90
P2 (AXR)	4	1	5	2	4	1	5	1	5	2	90
P2 (KIT)	4	3	4	4	4	4	4	2	3	2	60
P3 (AXR)	4	2	4	3	3	2	3	3	2	3	57,5
P3 (KIT)	4	2	4	4	3	2	4	3	3	3	60

Table 6.1: SUS Scores of User Testing

Results

The SUS score of the user testing is presented in Table 6.1. Since the participants were handed out a SUS form for each of the prototypes, each participant has a SUS score for each of the prototypes. The average SUS score for KIT was 70, while the average for the AXR was 80,83. Combined, the total SUS score was 75,42.

As previously presented in Section 3.5.4, this project employs the score system by Bangor et al. [7]. That means that KIT has a good, acceptable score with a grade of C, while the AXR has an excellent, acceptable score with a grade of B. Combined the system has a good, acceptable score with a grade of C. Furthermore, the scores suggest that although the system is at a good state, some more polishing of functionality can be performed to improve it.

Additional Comments

One of the evaluation participants entered comments into the SUS form. On the SUS of the AXR he added that he liked the inclusion of the color-coding of the radiograph boxes - red and green - but would like to see information somewhere about what the color actually meant - like an information box. Furthermore, on the SUS form of KIT he added that he would have given a higher score on question four if the program had some help text about the functionality of the markers - something he had previously commented during the semi-structured interview.

6.2 Evaluation with IT Experts

In evaluation with Information Technology (IT) experts, an observation was performed together with a SUS form. First the participants were given a small presentation of the domain and scope of the project, and afterwards an informed consent was handed out. It was assumed that the IT experts had no knowledge about the medical theory in advance, so the presentation was considered a reasonable introduction.

6.2.1 Participants

Participants in this evaluation were IT experts of the Department of Information Science and Media Studies at the University of Bergen. In total there were four participants, continuing the numbering from the user group - P4, P5, P6, and P7. As IT-experts, these participants would be able to give a greater insight into the functionality and design of the system.

6.2.2 Observation

During the observation with each of the IT-experts, a discussion about the functionality and design of the system was conducted. There were no difficulties in understanding the system, however during measuring the alignment all participants needed further explanation.

The tasks the IT-experts solved was the same as the user group. However, as mentioned, since none of the IT-experts had domain knowledge they would be guided to perform the alignment method. As with the participants from the user groups, the users were first tasked to navigate around and familiarise themselves with the system - exploring both the prototypes. After which the participants went on to solve the tasks.

Results

All participants managed to solve the tasks, but with help during the anatomic alignment. None of the participants had anything they immediately wanted to comment on or criticise about the system. After the testing was done, P7 noted

Participant	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	SUS Score
P4 (AXR)	4	1	4	2	4	1	5	1	5	1	90
P4 (KIT)	4	2	4	1	4	1	5	2	5	2	85
P5 (AXR)	5	1	5	2	5	1	5	1	4	2	92,5
P5 (KIT)	5	1	5	2	5	1	4	1	5	2	92,5
P6 (AXR)	4	2	4	3	3	2	4	3	3	4	65
P6 (KIT)	3	2	3	2	4	2	4	2	3	3	65
P7 (AXR)	4	2	4	2	4	2	4	1	4	2	77,5
P7 (KIT)	4	2	4	2	4	1	4	1	4	2	80

Table 6.2: SUS Scores of IT-experts

that she liked the layout of the patient boxes and the colors used to signalise if a radiograph needed to be analysed. None of the participants had anything they wanted to add about KIT.

6.2.3 System Usability Scale (SUS)

After the observation, the IT-experts were given a SUS form for both the prototypes. They were also encourage to leave any additional comments about the state of the system.

Results

The SUS scores of the IT-experts is presented in Table 6.1. The average SUS score for KIT was 80,62 while the average for the AXR was 81,25. Combined, the total SUS score was 80,93. All scores were excellent and passable of a grade of B, according to Bangor et al. [7].

Additional Comments

Out of the IT-experts, only P7 added additional comments about the system. For KIT, she stated that further information about the functionality of the various components in the toolbar should be added. She suggested to use small information boxes explaining functionality, to better explain to the user how to utilise it. This is something that P2 also discussed in his additional comments. Fur-

thermore, for AXR, P7 would like to see additional effects on the buttons, like a hoovering effect or button press effect, to give a more complete user experience.

6.3 Summary

(a) SUS scores of AXR

(b) SUS scores of KIT
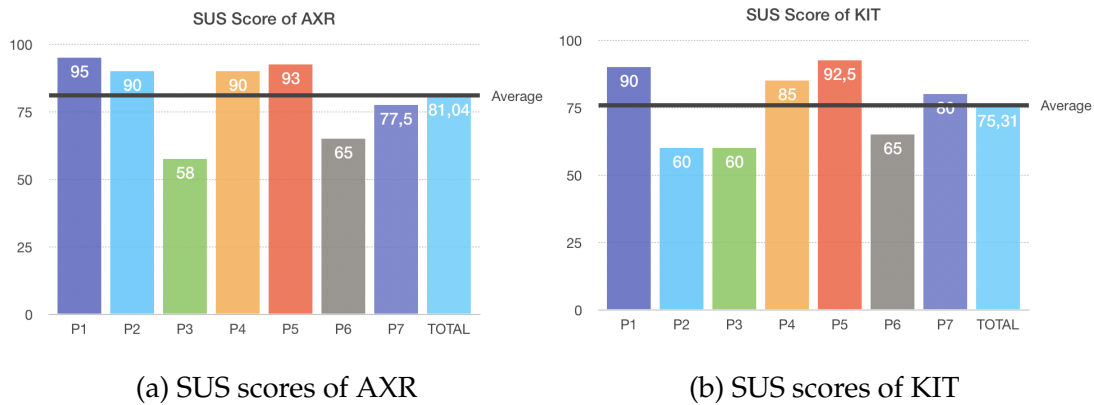
Figure 6.1: Total SUS scores

After all the evaluations were complete, the total SUS score of both users and IT experts were combined. The mixed total for KIT was 75,31, while the mixed total for AXR the total was 81,04. The overall total score is 78,57. According to Bangor et al. [7], the scores mean that KIT has a good, acceptable score with a grade of C, while AXR has reached an excellent, acceptable score with a grade of B. In overall total, the system has a good, acceptable score with a grade of C.

6.3.1 Additional features

Based on the feedback from the participants, the following list of features was defined to be included in future development.

- Add guidance to KIT that explain how to conduct the alignment.
- Have information about the x-ray additionally displayed on the image.
- Immediately give the user feedback on calculation results.
- Let users activate markers by clicking on them on the image.
- Implement the system into the registry for more accurate user testing.
- Give the user information about what the color scheme of the radiograph-boxes means.

Chapter 7

Discussion

This chapter present the discussion of the created prototypes.

7.1 Methods and Methodologies

7.1.1 Design Science

Throughout this study the Design Science framework was used to integrate the methods that were used following seven guidelines within Design Science that ensure the research is carried out efficiently. In Section 3.1, the steps which resulted in the artifact are presented. The framework is recommended for domains where different types of experts and methods have to be involved.

Design as an artifact

A working prototype of the Knee Inspection Tool (KIT), a program that allows the users to measure anatomic alignment on radiographs of the knee, was created first. Then, a proof of concept prototype, Arthroplasty X-ray Registry (AXR), was created to demonstrate feasibility of managing extracted data. These two prototypes make up the input and output modules of a clinical decision support system that will help clinicians follow-up patients who have their knee replaced and recommend patient specific treatment.

Problem Relevance

The Orthopedic department have problems with their commercial software prod-

ucts for measuring radiographs of the knee. This problem is two folded, firstly these programs are licensed, and as such they become constricted from working together with solutions from other companies or from the hospital's in-house information systems. Secondly, the users feel the lack of standardised alignment method which produce different interpretations of the measures. A new study might be around the corner where another alignment method is presented, or the some new key parameters for complications in knee replacement are identified.

The prototype created in this project will give the users the same possibility for measuring knee alignment, but will confine the alignment approach in a standardised way. This will give the department more freedom regarding the technologies they want to implement in the future, while also standardising the measures produced.

Design Evaluation

Evaluation of the prototypes were done in collaboration with the Orthopedic department and the Biomaterials lab, both located at Haukeland University Hospital. In addition to IT experts from the Department of Information Science and Media Studies, University of Bergen. The participants were users and experts within their respective fields. The purpose of the evaluations was to see how well the prototypes fitted the intended user groups, and whether the prototypes were relevant and useful. Evaluation with a medical expert was done at the end of the first development iteration, using demonstration over Skype. The evaluation with the intended user groups and IT experts were done in the final evaluation, using observation, semi-structured interview, and System Usability Scale.

Research Contribution

For this study, the main research contribution are two artifacts, i.e. a prototype for measuring alignment in total knee arthroplasty on short-legged clinical x-ray images, and a web application for managing relevant patient data together with results from the first prototype. The prototypes were developed in accordance with defined user needs through three development iterations.

Research Rigor

The main artifact was developed based on the knowledge of procedures for measuring alignment of the knee on x-ray images, which is well a documented and established scientific field. The second artifact was developed using contemporary web technologies. Single Developer Scrum was used as a system development method, combined with appropriate development tools. Evaluation was conducted using known methodology, such as observation, semi-structured interview, and System Usability Scale. All these methods and methodologies are well documented in the literature.

Design as a Search Process

The developed prototypes build upon the current knowledge of several research fields, refraining the study from duplicating existing work. Following the agile system development methodology ensured contact with users and experts from the problem domain. The prototypes were modified and improved through the development iterations, using the feedback from experts to ensure the prototypes quality and usefulness to the problem domain.

Communication of Research

To meet the demand of the technology audience, Chapter 4 goes through the established requirements for the system, and Chapter 5 goes through how the solution was implemented. These chapters will give the technology audience sufficient information to be able to reconstruct the prototypes. Furthermore, to meet the demand of the management audience, Chapter 6 goes through the results of the evaluation of the created prototypes. This chapter will give the management audience sufficient information about benefits of the prototypes, to decide whether this solution should be considered for clinical- and research work.

The main communication of the research will be the thesis published on the open-source portal of University of Bergen - *www.bora.uib.no*. The thesis contains technical details for the technical audience, as well as background and results for the general and management audience.

7.1.2 System Development

In this project, system development was used in creating KIT and AXR prototypes. The methodology was used to control and advance development, by providing a clear view of the current point in development and what needs to be done next.

7.1.3 Interaction Design

Interaction Design contributed with tools that were used in developing KIT and AXR, to help convey a better user experience. Interaction Design was introduced in Section 3.3.

7.1.4 Usability Goals

In Section 3.3.1, the usability goals were introduced. These goals were used as guidance throughout the development of both prototypes. In the evaluation with participants from the user groups and IT experts, the results suggested the prototypes were useful to a satisfactory degree. Although the usability goals were not the only focus of the evaluation, observations of these goals were performed together with some feedback from the participants.

Effectiveness and Efficiency

All of the participants managed to solve the tasks they were given, however, some participants had problems with performing the alignment measurements. This was due to lack of knowledge about the alignment method from the participants, as well as lack of guidance from the program. Once they were shown how to perform it, all of the participants managed to accomplish the task. A full clinical evaluation would be needed to demonstrate the clinical usefulness of the prototypes.

Safety

Given the results of the evaluation, the prototypes are seen as safe to use. None of the participants made any unexpected mistakes, but throughout the evaluation

it has became clear that measuring anatomic alignment in KIT could be somewhat difficult for inexperienced users. This is related to positioning the various markers on the image. A possible solution to the problem, commented by participants, was to change the starting position of the markers to be closer to their related bones. However, alignment methods such as the one found in KIT will require special training for the users to perform it optimally, as with any other alignment method.

Utility

All participants stated that the prototypes would be beneficial in the context of knee alignment measuring. In addition, one of the participants commented that the accuracy of alignment measuring in KIT was more accurate than in the commercial products he used on a daily basis. This was based on the approach of the alignment, using the bone contour as reference points for aligning the anatomic axes, rather than eyeballing their placement.

Learnability

All of the participants seemed to have a fairly easy time learning how to use the prototypes. Again, the problem area seemed to be centered around KIT, and how to place the markers. Some participants commented that they would like some guidance in how to position the markers properly, which would make the prototype even easier to use.

Memorability

Memorability was not tested in this study, however, since KIT was based on the design of HIT prototype (Section 5.2.4), some participants expressed that the design felt familiar. Such response suggest that the design of KIT is easy to remember.

7.1.5   Design Principles

In Section 3.3.2, the design principles were introduced. The principles were used as guidelines in designing the prototypes. Since the design of KIT is based on HIT,

the design principles applied for KIT were not explicitly introduced in Section 5. For AXR however, the use of the design principles were introduced in Section 5.4.3, because this was a new prototype made from scratch in this study.

7.1.6 Knowledge-based Clinical Decision Support System

In this study, the user communication method was constructed. Development of a prototype for outputting high quality data from measuring clinical x-ray images of a patient's knee was carried out. In addition a web-application that enables user management of patients was created to allow production of data, as well as visualisation of the output. This work contributes to the construction of a knowledge-based CDSS in TKA, at Haukeland University Hospital, as it is seen as a continuation of the work of Ellison et al. [16].

7.1.7 Development and Prototyping

The development process in this study was performed with a single developer Scrum framework in combination with Trello, presented in Sections 3.4 and 5.1.4. Trello was used for visualising the development process, keeping track of the product backlog, and portion the user stories to the sprints. The product backlog was mainly focused on the functionality of KIT, as it was the main focus of this study.

Low-fidelity prototypes were used to create conceptual design of both prototypes (Sections 5.2.2 and 5.3.4). Medium fidelity prototype was used in the expert evaluation (Section 5.2.9). The high fidelity prototypes that were introduced to the participants allowed for detailed feedback and a clearer presentation of the envisioned state of the prototypes (Chapter 6).

In the development process, several tools were used for creating the prototypes. A central tool was ImageJ (Section 5.1.2), which allowed for an effective creation of KIT while still maintaining vast functionality. Furthermore, Draw.io was used for high level modelling of the conceptual architecture of the system, while Bitbucket in combination with Git (Section 5.1.3) was used for version control during development of both the prototypes. Visual Studio Code (Section

5.1.7) and IntelliJ (Section 5.1.6) were used as IDEs.

7.1.8 Evaluation

The evaluation of the prototypes was performed with participants from the user groups as well as IT experts. Three well known methods were used for the evaluation of the prototypes: Observation, Semi-structured Interview, and System Usability Scale, but for the IT experts the semi-structured interview was not performed. The various evaluation methods were introduced in Section 3.5. The data collected in this study involves both qualitative and quantitative data, giving a high degree of validity to the evaluation.

Expert Evaluation

After the first prototype development iteration, expert evaluation was used to make sure that the prototype developed, KIT, was on the right track, as well as to test the alignment approach. The feedback gathered was very useful, especially to increase the accuracy of the alignment approach. Expert evaluation was not performed for AXR, as this prototype was created as a proof of concept, demonstrating the possibilities of managing patient data together with the measured data.

Participants

In total there were seven participants in the evaluation, made up of clinicians, researchers, and IT experts. Although the number of participants can be seen as limited, Virzi [53] argue that a sample size of 4-5 participants could detect around 80% of the usability problems with a system. In addition, IT experts were used which generally have more experience with detecting usability problems. Furthermore, because the clinicians and researchers were quite busy it was difficult to introduce evaluation earlier in the prototype development. Therefore, these participants were not introduced until the final prototype evaluation.

Observation

Observation was introduced in Section 3.5.2, and was performed in a direct man-

ner. This gave participants an option to ask questions underway and it made the communication between the observant and the participants easier. Given that some participants were not IT experts, using the direct manner was thought to help these participants feel more confident in their evaluation of the prototypes. The value of using observation was to capture the non-verbal impressions of the participant's interaction with the prototypes. Through observing the participants some usability issues were noted, which helped establishing additional features to be implemented in future development.

Semi-structured Interview

Semi-structured interviews (Section 3.5.3) were conducted to gather the participants explicit impressions of the prototypes. The feedback was valuable to evaluate the prototypes usefulness, and to uncover additional features that could be added. The interviews were designed to be short with open ended questions, lasting about 15 minutes for each participant.

System Usability Scale

SUS (Section 3.5.4) was performed with all participants, and was given for each of the prototypes. Although filling out two SUS forms instead of one would be more time consuming, this approach was thought to bring about a better picture of each of the prototypes. At the bottom of the SUS form there was an "additional comments" section where the participants could more freely express their thoughts about the given prototype.

7.1.9 Ethical Consideration

The collection of data in this study was approved by NSD (Appendix A), meaning that the conduct of the study was informed and ethical. All participants were given an informed consent (Section 3.6.1 and Appendix B) form before the evaluation began, together with an oral presentation about the information. Their identities would remain anonymous, and at any point during the study the participants could withdraw their participation, without any reason.

7.2 Prototype

In this section, different aspects of the high fidelity prototypes will be discussed. The prototypes developed had limitations since some of the requirements were not implemented. However, the prototypes demonstrate the concept well, but some additional features could be implemented based on the requirements and feedback gathered during the evaluation.

Technical Features

KIT was developed in Java together with ImageJ, based on the HIT prototype. AXR was developed using ReactJS. Both prototypes have not been implemented in the hospital domain given privacy concerns. This would require further polishing of the prototypes, a working back-end, and approval from the IT-department at Helse Vest. Furthermore, KIT gives the user the possibility to measure anatomic alignment on short-leg x-ray images and extract this data to be used elsewhere. The data is extracted as a CSV-file, with the three angles measured in anatomic alignment. Moreover, AXR gives the user a visual overview of the patients with their specific data and together with data extracted from KIT. Currently all the data displayed in AXR is dummy data to serve as a proof of concept for further development.

Design

The evaluation in Section 6 revealed a few weaknesses in the design of both prototypes. Firstly, almost all participants had problems with the alignment approach of KIT, although it was said to be more accurate than the commercial products used on a daily basis. The participants expressed that some kind of guidance in the program would help, such as help text. Secondly, again in KIT, the markers were somewhat problematic. The participants wanted to be able to activate the markers by clicking directly on the image. This was thought of during the development, but was not prioritised. Moreover, the participants also wanted the starting position of the markers to be closer to their respective bones. Lastly, the implementation of a back-end was desired to give a more complete user experience to that of the envisioned system.

The combined total SUS-score was acceptable with a grade of B (Section 6.3). Implementing the features presented here will most likely result in a higher SUS-score, as they are a solution to the problems the participants were having.

Content

The content of KIT derives from the requirements that was established together with a senior consultant, and a biomaterial researcher, both experts within their respective fields. Their knowledge and experience ensured the high quality of the content in KIT, which was then confirmed later on during the final evaluation of the prototypes.

7.3 Limitations

This study has some limitations. The evaluation of the prototypes could have included more participants from the user groups. The time constraint on the study reduced the scope of the functionality in KIT. Ideally, mechanical alignment would be implemented as well, since it is a widely used alignment method that give a more general view of the patient's lower anatomy.

Because of time constraints, after the AXR prototype was developed the project development was deemed finished. Ideally, the prototype development would last another iteration to explore the implementation of a database for the prototypes, or integrating the prototypes in the already existing back-end from previous master theses. That could deem a more feasible and comprehensive system-prototype, yielding more extensive and in-depth feedback from the evaluations.

Another in-depth evaluation that would be needed is a clinical study to be carried as a separate trial with selected images and two sets of participants, and possibly including comparison with other alignment systems. An illustration of such work is demonstrated in [44]. This kind of work could not be performed in a master project.

7.4 Research Questions

This study seeks to answer the three research questions presented in Section 1.3.

How can Design Science research methods be used to create an artifact for measuring alignment on x-ray images in the domain of total knee arthroplasty?
First step is to think about user requirements since they define what is relevant for the problem domain, as demonstrated in the Chapter 4. Then it is important to consider methods that could offer solutions (Chapter 3). After that the design process can start following the design science principles given in the Section 3.1.

Since this is multidisciplinary project, relevance of the resulting artifact through the iterations could be evaluated with domain experts and IT experts, where it was appropriate. In the final evaluation, clinicians and researchers responded that the layout gave them a clear overview, and that the alignment method was accurate (Section 6.1). The IT experts responded positively towards the design and functionality of the prototypes (Section 6.2). Both groups judged the prototypes as feasible and a welcoming solution.

How can we include such an artifact as a part of a clinical decision support system to benefit various user groups?
This could be done in several ways: the alignment measuring tool, KIT, creates accurate, high quality data to serve as input to a CDSS (Section 2.2). Currently, AXR serves as a proof of concepts for a web-application managing in- and output of an envisioned CDSS. The prototypes can be connected to a back-end, either the registry created in previous master projects, or to the wider hospital information system.

In the conceptual architecture, integration with the hospital's PACS is proposed (Section 5.3.3). According to Ellison et al. [16], such a solution has the potential to be cost efficient by reusing clinical X-ray images (Section 2.6.1).

Clinicians and researchers can both draw benefits from the envisioned system. Clinicians benefit from having a more strict approach to the alignment measures which will reduce the measuring bias from clinician to clinician. A clear overview of the patients information, together with a set of possible treatments will raise

the quality and effectiveness of the clinicians work. Furthermore, the researchers also benefit from the more strict alignment approach since it will produce more accurate data for them in their research. In addition, such a system might inspire research into the correlation between measured data, suggested treatment, and potential outcome.

Can tailor made artifacts provide solutions that allow more freedom and accuracy to the users as compared to commercially available systems?
The research has demonstrated that this is possible. The prototype demonstrated how user can take advantage of the tailored solution by assigning markers on the bones, following a well known alignment method for short-leg radiographs of the knee, anatomic alignment (Section 2.5.1). The alignment approach presented in KIT is more strict than what is demonstrated in the literature and used in the commercial products. Because of this, the alignment measured will be more accurate, and less affected by human bias, than compared to the commercially available systems. Although the alignment approach is more strict, the user can freely change the position of the markers if it is preferred (Section 5.3.1).

Chapter 8

Conclusion

This chapter present the conclusion of this study, together with a section about future work.

8.1 Achievement

The Design Science framework requires development of an artifact to serve as a solution for a specific problem domain, and its intended user groups. As a part of this study, two prototypes were developed as a contribution to a clinical decision support system (CDSS). The first prototype, *Knee Inspection Tool (KIT)*, enables the user to measure alignment on short-leg x-ray images in total knee arthroplasty (TKA), producing accurate, high quality data that serves as input. The second prototype, *Arthroplasty X-ray Registry (AXR)*, manages patient data together with the extracted data, and handles in- and output in the CDSS. This study demonstrates how Design Science can be used to create digital solutions for clinicians and researchers in the domain of total knee arthroplasty, how created artifacts can be included in as a part of a CDSS, and how tailor made artifacts can better benefit users compared to commercially available products.

Developing the prototypes was a multidisciplinary process consisting of three iterations. Preliminary to the development process, user requirements were defined, serving as a precursor to the product backlog. The first development iteration was focused on around utilising an existing prototype design as a baseline for the alignment measuring program, KIT. This iteration resulted in a medium

fidelity prototype that was evaluated with a domain expert. The second development iteration was focused on improving the functionality of KIT, conceptual architecture, and preliminary work for the web application, AXR. The third development iteration focused on developing the web application for patient data management and handling in- and output of the envisioned CDSS.

After the development process, an extensive evaluation with participants from the user groups and IT experts was conducted. All participants were observed solving tasks using the prototypes, and their performance would be noted. All participants solved the tasks, but some of them had problems with performing the alignment properly because of limited knowledge about this specific alignment method. After the observation, semi-structured interviews were conducted with the participants from the user groups. The result of which was a satisfactory view of the prototypes with suggestions for additional features. Lastly, a System Usability Scale (SUS) was performed with all participants for each of the prototypes. This resulted in a overall score of the prototypes of an acceptable, grade B.

8.2 Future Work

There are several focus areas the future work can have. Presented below are suggestions based on the findings in this study.

Further Development of the Prototypes

In Section 6.3.1, a list of features for further development is presented. This list is mainly focused around some improvement or additional features the participants would like to see in the final state of the prototypes. Implementing these features is thought to have a positive impact on the user experience of the prototypes, possibly yielding even better SUS scores.

Out of this list, the most natural progression would be to implement the prototypes into a back-end, as was discussed in Section 7.3. From then, implementing guidance to cater new users of the prototypes would help users understand how they should approach the alignment.

Creating the Knowledge Base and Reasoning Engine

Since this thesis has been a contribution to an envisioned CDSS for TKA, the natural progression is to start research into constructing the knowledge base and reasoning engine. The data produced from the prototypes in this study must be analysed to determine the weight of these variables. This is an effort that leans more towards the medical research domain, but the results of such a study could be used to construct the knowledge base and reasoning engine.

Automating the Alignment Measures

For now, the prototype lets users manually measure alignment on short-leg radiographs. A possible direction for further research could explore automating the alignment approach, which would enable a more effective way of generating input for the CDSS. This is made possible by KIT, since the program allows for generation of labeled data, which is beneficial for machine learning. In the envisioned automated alignment program, radiographs could be measured immediately after they have been taken, possibly reducing time spent treating each patient without cost of quality.

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Appendix A

NSD Evaluation

NSD NORSK SENTER FOR FORSKNINGSDATA

NSD sin vurdering

Prosjekttittel

Development of a Clinical Decision Support Tool for Total Knee Arthroplasty

Referansenummer

264769

Registrert

23.09.2019 av Ruben Mikal Skartveit - Ruben.Skartveit@student.uib.no

Behandlingsansvarlig institusjon

Universitetet i Bergen / Det samfunnsvitenskapelige fakultet / Institutt for informasjons- og
medievitenskap

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Type prosjekt

Studentprosjekt, masterstudium

Kontaktinformasjon, student

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Prosjektperiode

01.01.2019 - 01.12.2019

Status

24.09.2019 - Vurdert med vilkår

Vurdering (1)

24.09.2019 - Vurdert med vilkår

SIMPLIFIED ASSESSMENT WITH CONDITIONS
Having reviewed the information registered in the Notification Form with attachments, we find that this

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project presents a low risk to the rights and freedoms of data subjects. This assessment is based on the project not processing special categories of personal data or personal data relating to criminal convictions and offences, and not including vulnerable groups. The duration of the project is reasonable and the processing of personal data is based on consent. We have therefore given a simplified assessment with conditions.

You have an independent responsibility to meet the conditions and follow the guidance given in this assessment. If you meet the conditions and the project is carried out in line with what is documented in the Notification Form, the processing of personal data will comply with data protection legislation.

CONDITIONS
Our assessment presupposes:
1. That you carry out the project in line with the requirements of informed consent
2. That you do not collect special categories of personal data or personal data relating to criminal convictions and offences
3. That you follow the guidelines for information security as set out by the institution responsible for the project (i.e. the institution where you are studying/carrying out research)
4. That you upload the revised information letter(s) for each sample in the Notification Form and select "Bekreft innsending" (Confirm submission) so that documentation is correct. NSD will not carry out a new assessment of the revised information letter(s).

1. REQUIREMENTS FOR INFORMED CONSENT
The data subject should receive written and/or oral information about the project and consent to participation. You must ensure that the information at least includes the following:
- The purpose of the project and what the collected personal data will be used for
- Which institution is responsible for the project (the data controller)
- What types of data will be collected and how the data will be collected
- That participation is voluntary and that participants may withdraw their consent, without giving a reason, as long as their personal data are being processed
- The end date of the project and what will happen with the collected personal data; whether it will be erased, anonymised or stored for further use
- That you will be processing personal data based on the consent of the data subject
- The right to request access , correction, deletion, limitation and data portability
- The right to send a complaint to The Norwegian Data Protection Authority (Datatilsynet)
- Contact information for the project leader (or supervisor and student)
- Contact information for the Data Protection Officer (Personvernombudet) at the institution responsible for the project

On our website you will find more information and a template for the information letter:
http://www.nsd.uib.no/personvernombud/en/help/information_consent/information_requirements.html

It is your responsibility to ensure that the information given in the information letter corresponds to what is documented in the Notification Form.

2. TYPE OF DATA AND DURATION OF PROJECT
The project will be processing general categories of personal data until 01.12.2019.

3. FOLLOW YOUR INSTITUTION'S GUIDELINES
NSD presupposes that the project will meet the requirements of accuracy (art. 5.1 d), integrity and confidentiality (art. 5.1 f) and security (art. 32) when processing personal data.

If you will be using a data processor in the project, the processing of personal data must meet the legal requirements for use of a data processor, cf. arts. 28 and 29.

To ensure that these requirements are met you must follow your institution's internal guidelines and/or consult with your institution (i.e. the institution responsible for the project).

NSD's ASSESSMENT
Our assessment of the legal basis for processing personal data, of the principles relating to this processing and of the rights of data subjects, follows below, but presupposes that the conditions stated above are met.

LEGAL BASIS
The project will gain consent from data subjects to process their personal data. Presupposing that conditions 1 and 4 are met, we find that consent will meet the necessary requirements under art. 4 (11) and 7, in that it will be a freely given, specific, informed and unambiguous statement or action, which will be documented and can be withdrawn. The legal basis for processing personal data is therefore consent given by the data subject, cf. the General Data Protection Regulation art. 6.1 a).

PRINCIPLES RELATING TO PROCESSING PERSONAL DATA
Presupposing that conditions 1-4 are met, NSD finds that the planned processing of personal data will be in accordance with the principles under the General Data Protection Regulation regarding:
- lawfulness, fairness and transparency (art. 5.1 a), in that data subjects will receive sufficient information about the processing and will give their consent
- purpose limitation (art. 5.1 b), in that personal data will be collected for specified, explicit and legitimate purposes, and will not be processed for new, incompatible purposes
- data minimisation (art. 5.1 c), in that only personal data which are adequate, relevant and necessary for the purpose of the project will be processed
- storage limitation (art. 5.1 e), in that personal data will not be stored for longer than is necessary to fulfil the purpose of the project

THE RIGHTS OF DATA SUBJECTS
So longs as data subjects can be identified in the collected data, they will have the following rights: transparency (art. 12), information (art. 13), access (art. 15), rectification (art. 16), erasure (art. 17), restriction of processing (art. 18), notification (art. 19), data portability (art. 20).

Presupposing that the information meets the requirements in condition 1, NSD finds that the information given to data subjects about the processing of their personal data will meet the legal requirements for form and content, cf. art. 12.1 and art. 13.

We remind you that if a data subject contacts you about their rights, the data controller has a duty to reply within a month.

NOTIFY CHANGES
If you intend to make changes to the processing of personal data in this project it may be necessary to notify NSD. This is done by updating the information registered in the Notification Form. On our website we explain which changes must be notified. Wait until you receive an answer from us before you carry out the changes.

FOLLOW-UP OF THE PROJECT
NSD will follow up the progress of the project at the planned end date in order to determine whether the

processing of personal data has been concluded.

Good luck with the project!

Contact person at NSD: Karin Lillevold
Data Protection Services for Research: +47 55 58 21 17 (press 1)

Appendix B

Informed Consent Form

Informed Consent Form: Interview
Request of participation in research project
"Development of a Clinical Decision Support Tool for Total Knee Arthroplasty"

Background
This research project is a part of a master studies within the Department of Information Science and Media Studies in University of Bergen. The research project seeks to answer if a system made from open-source software is sufficient in measuring alignment of the knee in total knee arthroplasty, and how it compares to commercial off-the-shelf software for clinical and research work.
To form the best possible opinion about the system created, senior consultants, medical research personell, and information technology experts will be interview. These will be chosen based on their position as well as contacts from my own network.

What does participation in the study mean?
Participation in the study means to participate in an observation test where the participants are testing the created system, which will take about 15 minutes. From there on an unstructured interview will be performed to gather the participants opinion, which will take about 15 minutes. This will be recorded audio of. Finally, the participants will fill out a System Usability Scale (SUS) to determine the usability of the system, which will take about 10 minutes.

What happens with the information about you?
All the personal information gathered will be processed confidentially.
Only the student, supervisor, and co-supervisor will have access to this information.
Personal information (both written and in the audio recording) will not be stored with direct name, name is swapped out with a key number. List of names with key number will be stored on an external storage device. The thesis or any other material with the key number is not stored on this device. Participation in this study will not be approved in the publication unless the participant approves the use of his/her name in the publication.

Interview Informed Consent Form
The project will end 1. December 2019. On that date, all files with personal information will be deleted (expect from the names of participants who approved to have their names in the publication). List of names and key numbers will be deleted, as well as audio recordings and notes done under the interviews.

Voluntary participation
Participating in the study is voluntary and you can redraw your approval anytime without giving a reason.
If you redraw your approval, all information about you will be anonymised.

If you have any questions to the study, please contact:
Student: Ruben Mikal Skartveit - 41670365 - rsk014@uib.no
Supervisor: Ankica Babic - 55589139 - Ankica.Babic@infomedia.uib.no
This study is approved by Personvernombudet for forskning, Norsk samfunnsvitenskapelig datatjeneste AS.

Approval of participation in the study
I have received information about the study, and I agree to participate.

(Signed by project participant, date)
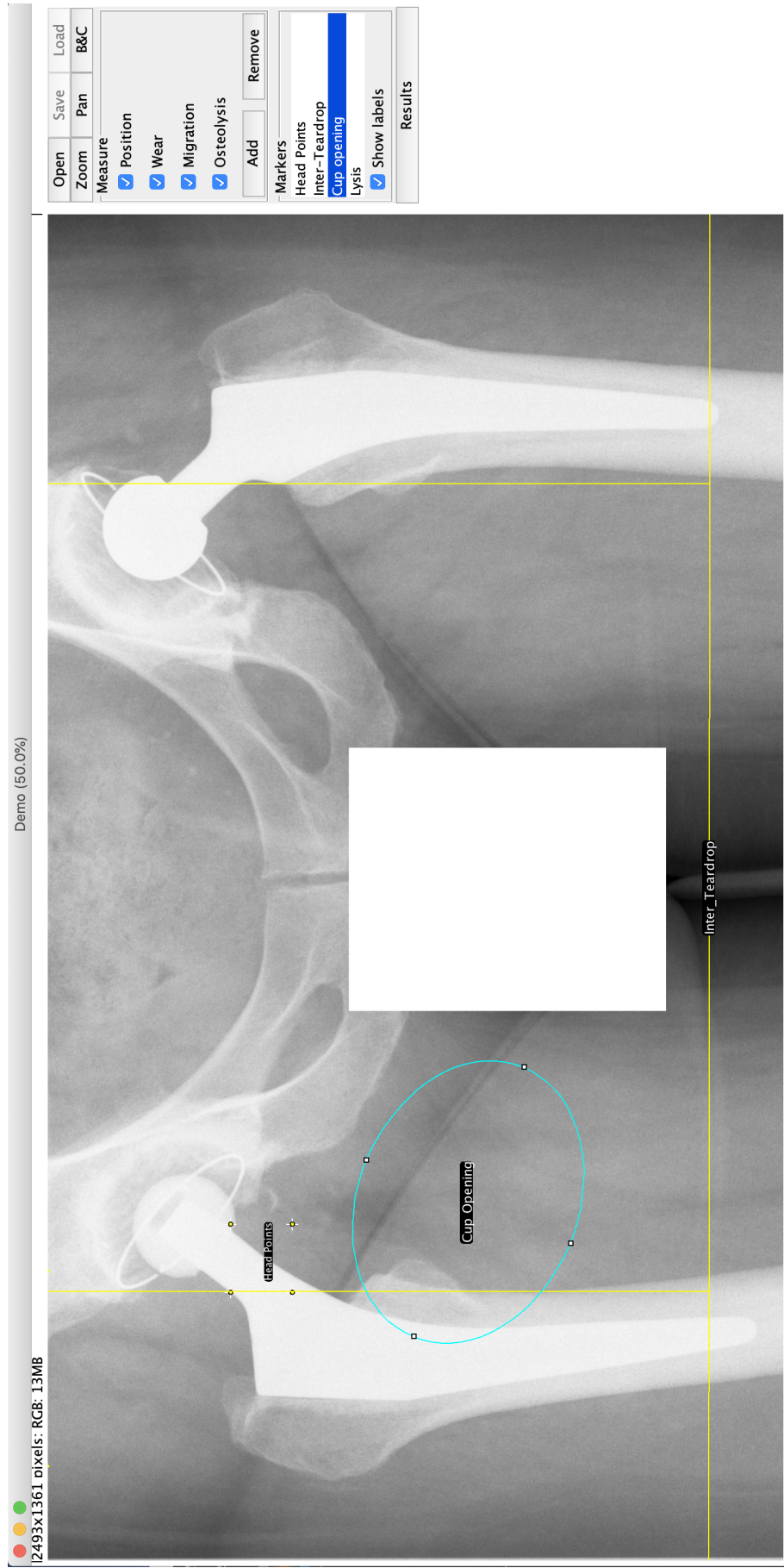I give my consent to participate in an observation.
I give my consent to participate in an interview.
I give my consent to participate in system usability scale task.
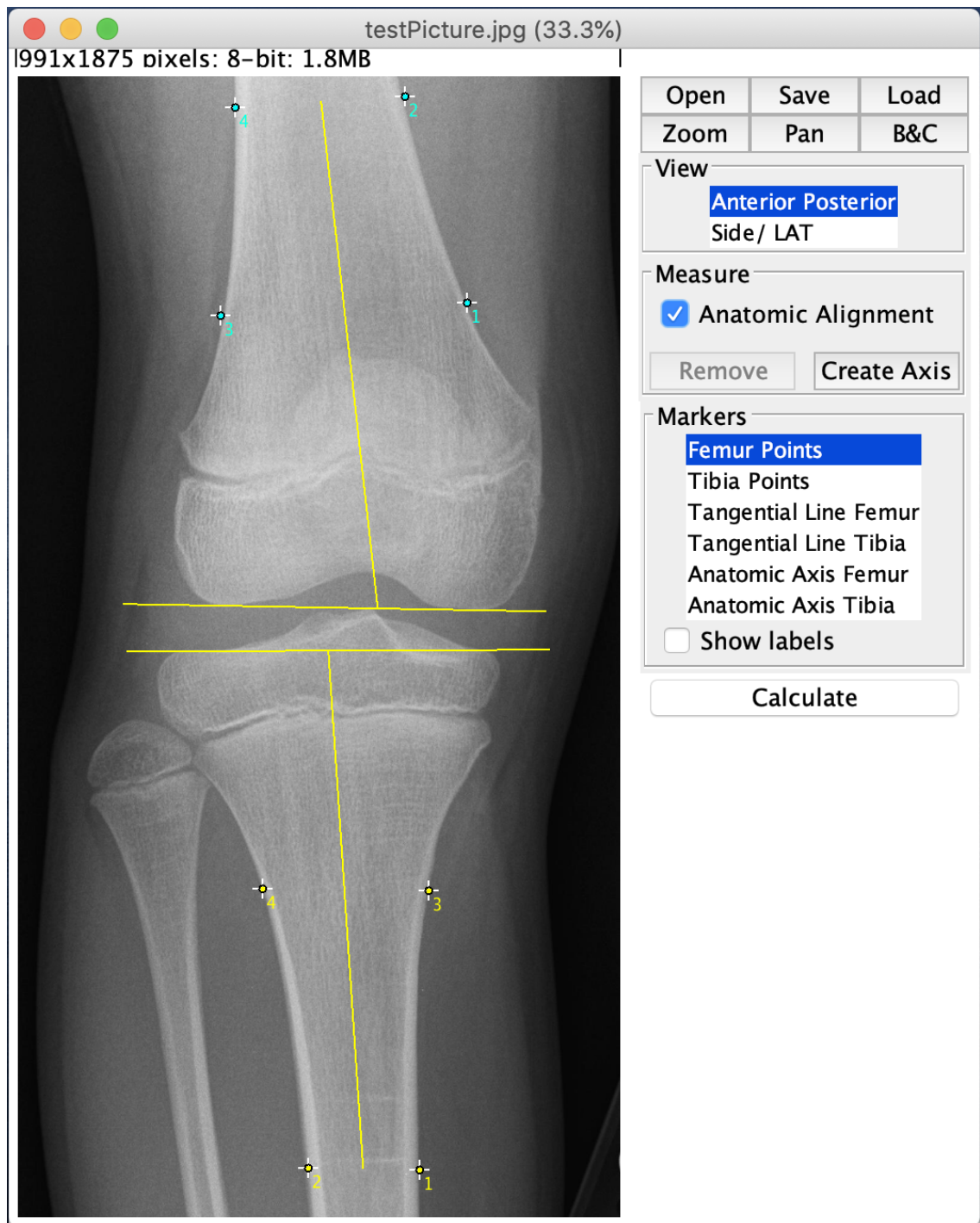I give my consent that my name can be shown in the publication.

Appendix C

Hip X-ray Inspection Tool

Appendix D

Knee Inspection Tool

Appendix E

Highlights of the Semi-structured Interviews (in Norwegian)

Deltaker 1

Hvordan syntes du det var å bruke prototypen?

Det var oversiktlig.

Hvordan syntes du det var å bruke det webinterfacet?

Det var den første..? Haha, ja, nei det var oversiktlig, men jeg tenker at hvis du har grådig mange pasienter blir det då ordnet alfabetisk da eller? For å finne frem på den måten? Hvis du hadde hatt hundre pasienter?

Hvordan syntes du java programmet (KIT) var?

Det og var greit å følge og tenker at når du har gjort det en gang så er det sikkert lettere å gjøre mer effektivt.

Men det var litt vanskelig å bruke første gangen?

Ja.. jo.. det var litt var litt vanskelig å bruke første gangen, men det hjalp å ha deg ved siden av... hehe.

Så hvis du hadde vært helt på egenhånd så hadde det vært litt vanskelig?

Ja. Det kunne vært noe retningslinjer for hvordan å gå frem med målingene.

Hvordan syntes du oppsettet på webinterfacet var?

Oversiktlig.

Hvordan syntes du oppsettet på KIT var?

Det var veldig greit at markørene var på bildet så man slipper å huske på det av en selv.

Noen ting med systemet som en helhet at du likte?

Jeg likte røntgenbildet som lyste opp rødt når det trengtes å redigeres.

Var det noen funksjoner du følte du manglet?

For mitt vedkommende måtte det være at jeg hadde en oversikt som viste hva jeg skulle måle.

Hvilke fordeles kan et sånt type program gi deg i din jobb?

Hvis jeg er med i et studie (forskning) på knær så ser jeg for meg at dette kunne vært et nyttig verktøy.

Deltaker 2

Hvordan var det å bruke websiden?

Det var enkel layout og det var enkelt å utføre oppgavene som du ba meg om å gjøre.

Hvordan var det å bruke java-programmet?

Med litt hjelp og støtte underveis var det veldig greit å bruke... fin interface, klare symbol, men litt hjelpetekst kunne det jo vært (samme poeng som P1). Med små sånne hjelpebokser. For å hjelpe deg inn mot funksjonene til programmet og hvordan du skulle plassere markørene, eller aktivere punktene.

Var det noe funksjoner som kunen vært brukt for å hjelpe med dette?

Hvis punktene hadde flashet opp når de ble aktivert så hadde jeg visst hvilke jeg kunne flytte på.. På bildet viste deg seg at punktene for tibia var lagt til på bildet over femur punktene. De (femur punktene) burde kanskje vært plassert over... til å begynne med.. du kunne til og med hatt enda større avstand mellom dem, og plassert tibia punktene nede (nedforbi femur punktene)... Da hadde det blitt enda mer intuitivt..

Så plassert nærmere der de hører hjemme? Ja, rett og slett. Da blir det på en måte bombsikkert.

Websiden var intuitivt og greit?

Ja, det var navn i hver boks og det var en søkefunksjon.. du fikk mer info om

pasienten når du kom inn på boksen. Det virker klart.. og så står det også et result av vinkelmålingen.. det var noen som hadde aktivt brukt java-programmet (KIT) til å gjøre målingene. Det var greit måten de målte og de ikke målte var avskilt på.

Hvilke funskjoner var det du likte med systemet?

Det var relativt kjapt å gjøre vinkelmålingen.

Noen funksjoner du følte du manglet?

Legge til tekst på bildet.. skrive sånn AP (view) direkte på bildet sånn at det ikke kan mistforstås. For man ser vanligvis ikke så lett om det er lateralt eller medialt bildet.

Er det noen fordeler med et slikt program i din jobb?

Ja, det er jo at man kan gjøre vinkelmålinger.. eh.. det brukes til kirurgisk planlegging, men også til postoperativ kontroll av endringer i vinkelen... i vår lab er vi interessert i å se på endringer over tid.. om komponentene flytter på seg.. om de beveger seg inn i beinet eller om de tilter på seg er vi interessert i å måle.

Vi bruker noen lignende programmer i forskningen vår i dag... som røntgenstereometrisk analyse (HIT)... som sikkert X snakket om... der de (seg selv) noen ganger plasserer markører på et bilde for målingene.

Hvordan syntes du systemet stacker seg opp mot de kommersielle programmene? Noen fordeler eller ulemper du ser?

De er mer komplekse selvfølgelig... du har mer funksjoner.. nå kjenner jeg ikke til verktøyet (mDesk) de bruker i klinikken (ortopedisk avdeling), men det er samme firma (RSABiomedical) som leverer det.. [forklarer funksjonene i programmet].

Deltaker 3

Syntes du det var greit å bruke systemet som en helhet?

Det så jo greit ut da, men det var vel kanskje ikke så intuitivt at jeg måtte hente

(dra) målemarkørene. Og så vil jeg at informasjonen skal dukke opp på bildet, slik man ikke trenger å gå via databasen for å finne resultatene.. ikke at de ikke skal i databasen for det er jo selvfølgelig viktig at de også havner i databasen..

Syntes du det var vanskeligere å bruke programmet med å flytte på punktene fremfor å dra streker slik som i det programmet du bruker?

Nei, jeg tror at det blir riktigere sånn som du gjør det der enn slik som vi gjør i klinikken med at vi ... i hvert fall i dette enkle kliniske programmet så kan vi ikke trekke linjene slik som det er beskrevet (forskning) at man skal gjøre. Så det er veldig bra hvis man kan få det frem slik som du har gjort da, men i en klinisk hverdag så vil vi jo ha vinklene (på bildet).. min erfaring er jo at det blir ganske korrekt når man bare tegner det opp (finner midten av beinet med øyemål).. rett på røntgenbildet.. på nære bildet så blir det ikke så nøyaktig, men på lange akse bilder så blir det ganske nøyaktig.

Hvordan syntes du layouten og knappene på java programmet var oversiktlig og greit?

Ja, det virker greit det.

Noen funksjoner du følte du manglet?

Ja, jeg ville jo hatt den der mekaniske aksen til pastienten da (mekanisk måling på long-leg røntgenbilder).. [han forklarer hvordan den måles opp. Oppsummert: Viktighet av å ha bilder av hele nedre del av pasienten for å måle mekanisk måling].. Vi vil jo at beinet skal se rettest mulig ut (90 grader)...

[Jeg legger til: det har jeg sett det er litt uenighet om i forskningen, det er noen som vil gjenopprette 90 graders vinkling og noen som vil gjenopprette den naturlige vinkelen på beinet]:

Det er det jo en del diskusjon om det.. problemet er jo at vi er veldig individuelle og at når du kommer til operasjonen og de har et helt utslitt kne så er det jo litt skjevt da.. [han viser bilde av pasient på sin pc].. hva skal de måle på (hva er det egentlige vinkelen på beinet?).. skal de måle på andre beinet?.. det er jo ikke sikkert at den er riktig (opprinnelig vinkel) heller.. det er ikke så lett å vite hva man skal sikte på, så det blir lettere hvis man prøver å gjøre pasienten rett

(90 graders vinkling).. Det er vanskelig og dette her vet ikke helt enda da.. Gode randomiserte studier viser ikke forskjell på dem.. så derfor velger jeg å sikte på mekanisk akse.

Ser du noen fordeler dette programmet kunne gitt deg i din jobbsammenheng?

Ja, jeg ser jo at dette kan være bra hvis det kan bli brukt slik Pete (med-veileder) har sett det for seg, i sammenheng med å automatisere slike målinger.

Hvordan syntes du dette programmet er sammenlignet med de kommersielle programmene du bruker i dag?
Bra program, men på de programmene vi bruker så får vi i hvert fall opp direkte vinkelmål på bildet.. det vil være en fordel.