Computer assistance in orthopaedic surgery

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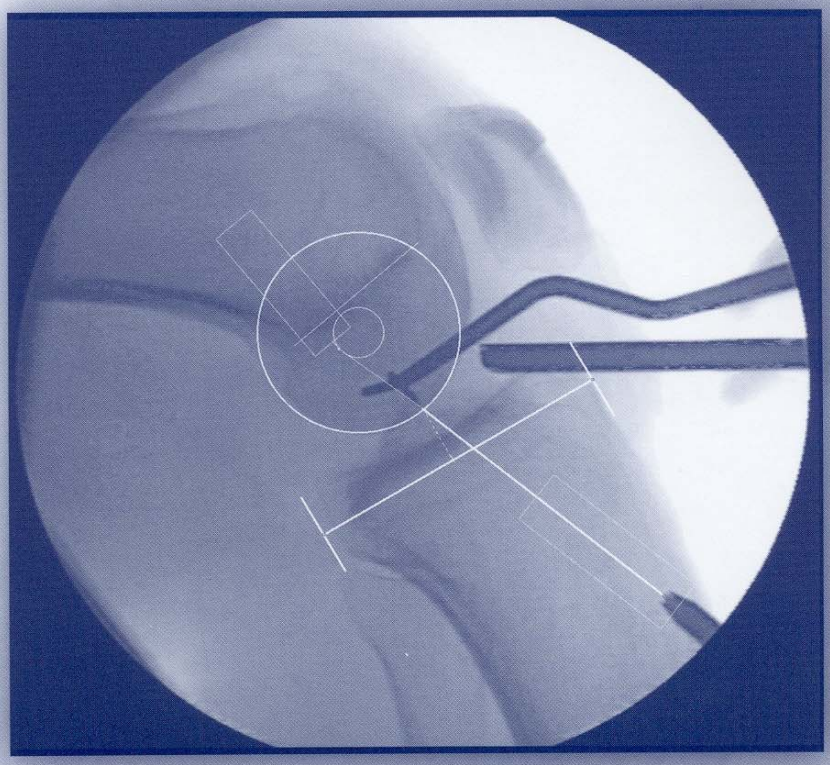
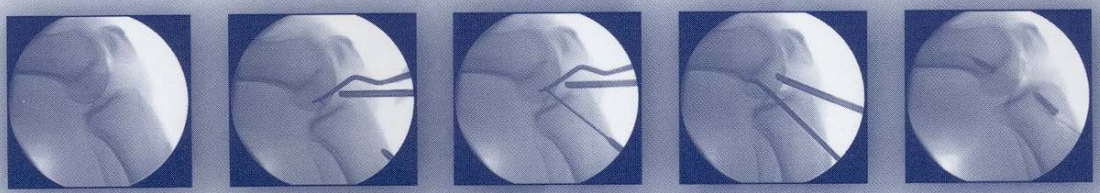


Raymond Habets



Stellingen

behorende bij het proefontwerp

Computer assistance in orthopaedic surgery

door

Raymond J.E. Habets

1. Achter een goede chirurg staat steeds vaker een goede ingenieur.
   (*Technologiethema nr. 9, Medische technologie, TU Delft*)

2. De korte iteratietijd van een *rapid prototyping* aanpak is zeer waardevol bij het ontwerpen van medische systemen. (*dit proefontwerp*)

3. Het ontwerp van de gebruikersinterface van een computerondersteund systeem voor kruisbandreconstructie kan heel intuïtief en eenvoudig zijn.
   (*dit proefontwerp*)

4. Ondanks het feit dat de optimale plaats van de voorste kruisband niet bekend is, is de hoge nauwkeurigheid van het computersysteem dat deze plaatsing ondersteunt relevant. (*dit proefontwerp*)

5. Een computerondersteund chirurgiesysteem dat volledig voldoet aan de wensen van één chirurg zal uitsluitend gebruikt worden door die chirurg.
   (*dit proefontwerp*)

6. Voor veel computerondersteunde chirurgiesystemen is het gebrek aan een eenvoudige integratie in de orthopaedische praktijk het belangrijkste struikelblok voor routinematig gebruik.

7. Volwassenen ontbreekt het vaak aan de kinderlijke inventiviteit die nodig is om kindveilige sluitingen te openen.

8. Na langdurig redigeren van een proefschrift levert elke nieuwe suggestie zeer waarschijnlijk weer een oude versie op.

9. De soms slechte betrouwbaarheid van de opiniepeilingen voor de verkiezingen is niet te wijten aan de gebruikte meetmethodes.

10. De recente ontwikkeling dat filmproducenten films gaan maken die voorafgaan aan een bestaande film ontneemt de kijker de hoop op een onvoorspelbaar einde al op voorhand.

11. In het heffen van ecotaks op groene stroom zit een dusdanige tegenstrijdigheid, dat het wel zo moet zijn dat òf de naamgeving òf de regelgeving niet klopt.

12. Met de introductie van een draadloos toetsenbord, een draadloze muis en een draadloze telefoon verschuiven de knopen van de draden onder het bureau naar de ether.

Computer assistance in orthopaedic surgery

Raymond Habets

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Habets, Raymond J.E.

Computer assistance in orthopaedic surgery / by Raymond J.E. Habets. -
Eindhoven : Technische Universiteit Eindhoven, 2002.
Proefontwerp. - ISBN 90-386-1940-5
NUR 954
Trefw.: biomedische computertoepassingen / orthopedische chirurgie / gewrichtsbanden /
biomedische beeldverwerking / knieen.
Subject headings: computer aided orthopaedic surgery / anterior cruciate ligament / orthopaedics /
medical image processing / knee.

Druk: Universiteitsdrukkerij TU Eindhoven

Computer assistance in orthopaedic surgery

PROEFONTWERP

ter verkrijging van de graad van doctor
aan de Technische Universiteit Eindhoven,
op gezag van de Rector Magnificus, prof.dr. R.A. van Santen,
voor een commissie aangewezen door het College voor Promoties
in het openbaar te verdedigen
op maandag 4 november 2002 om 16.00 uur

door

Raymond Joseph Elisabeth Habets

geboren te Houthem - St. Gerlach

De documentatie van dit proefontwerp is goedgekeurd door de promotoren:

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Stan Ackermans Instituut, Centrum voor Technologisch Ontwerpen.

Financial support for publication of this design thesis was kindly provided by
Philips Medical Systems Nederland B.V. (MIMIT EasyVision Advanced Development)
and the Technische Universiteit Eindhoven.

Voor Carin

Life is what happens to you while you're busy making other plans
John Lennon, 1940-1980

Summary

Measuring is a recurring task in the clinical setting. Surgeons perform measurements in diagnostic, surgical as well as research tasks. To assist surgeons in these tasks computer-assisted measurement systems can be developed. Over the last years several researchers and companies developed computer-assisted surgery (CAS) systems. CAS systems were developed (among other applications) for brain surgery and for pedicle screw placement in orthopaedics. The commercially available computer-assisted orthopaedic surgery (CAOS) systems for pedicle screw placement provide 'live' three-dimensional (3D) navigation in a 3D patient model based on CT imaging. The clinical use of this kind of systems requires changes in the clinical set-up: additional CT imaging is necessary and some surgical instruments must be equipped with trackers. Conventionally, surgeons accomplish their tasks by using 2D imaging and their experience. 2D systems require no additional imaging. Except for adding a computer, a 2D CAOS system requires no changes in the clinical set-up. This facilitates integration of such systems into the clinical setting.

This design thesis explores the possibilities of the use of 2D computer-assisted measurement systems and CAS systems for the orthopaedic surgery practice. These systems will use intra-operative fluoroscopic images and knowledge about the surgical procedure to compensate for the absence of a full three-dimensional patient model. In order to design and build 2D CAOS systems close co-operation with orthopaedic surgeons is an absolute necessity. This research was conducted in co-operation with the Catharina Ziekenhuis in Eindhoven. The computer-assisted systems were developed by using a rapid prototyping design strategy. To facilitate the prototyping process we developed software tools to capture and display images, to locate the surgical instruments and the bony anatomy within the images, to take measurements, and to display overlay graphics. First, the software tools were used to develop several computer-assisted measurement programs. These programs enable the surgeon to perform clinical measurements electronically on digitised films. Next, the tools were used to develop a CAOS system for anterior cruciate ligament (ACL) reconstruction. In this procedure the surgeon uses arthroscopic and single plane fluoroscopic imaging. This CAOS system assists the surgeon in the preoperative planning phase and in the intra-operative positioning of the tunnels that are used to insert the new ACL graft into the patient's knee. To investigate the limits of this '2D-plus approach' we tried to develop a CAOS system for hip fracture surgery, in which fluoroscopic images taken from two directions are used. The surgeon combines these two images and positions a guide wire in the centre of the femoral head. Using a 2D-plus CAOS system in combination with a mechanical guide that is visible in both images, the surgeon can place the guide wire more accurately.

The computer-assisted measurement systems reduce the measurement times and thus save costs. Besides this, the accuracy of the measurements can be improved and the automatic data storage enables direct statistical analysis. The time saved with our measurement

systems justified the time spent to develop them. The CAOS system for anterior cruciate ligament reconstruction was used in more than 350 surgical cases. In this trial the system significantly improved the accuracy of the reconstruction procedure. Also it reduced the number of staple fixations, and thus the need for a second procedure to remove this staple. The CAOS system prototype for hip fractures showed that the 2D-plus approach could be used to assist the surgeon in procedures that use fluoroscopic imaging in two planes.

We demonstrated that with our approach computer-assisted measurement systems and 2D-plus computer-assisted surgery systems could be developed. CAOS systems that are based on single plane fluoroscopy, such as the ACL reconstruction system, can be integrated successfully into the clinical practice. For more complex CAOS systems, such as the hip fracture system that use fluoroscopy for multiple directions, extra guiding instruments are necessary to couple the computer planning and the surgical actions. Because the recently developed (and now commercially available) freehand navigation systems based on fluoroscopic images show great potential without having to develop new surgical instruments, we decided not to continue with the development of the hip system.

Contents

Chapter 1

Introduction

1.1 Computer-assisted surgery

Over the past few years a growing activity can be noticed in the development and use of computer-assisted orthopaedic surgery (CAOS) systems. What is computer-assisted orthopaedic surgery? DiGioia described CAS in the following way [DiGioia, 1998a]:

"*Computer-assisted surgery is much broader than medical robotics and also includes image guided surgical devices, surgical navigation systems, preoperative planners and simulators, and augmented reality or hybrid reality computer interfaces. One working definition for computer-assisted surgery is that a machine's capability is coupled with a human's judgment to perform a task better than either could do alone. Only by this synergistic action between a computer driven device and the physician can the potential promised by these enabling technologies be fully reached.*

The clinical goals of these computer-assisted surgery technologies are:
1. *to develop interactive, patient specific preoperative planners and simulators to optimise the performance of surgery and the subsequent biologic response.*
2. *to develop more precise and ultimately less invasive "smart" tools to assist in the actual measurement and performance of a surgical task.*

One of the most important features of the technology is the ability to permit surgeons to tightly couple and integrate preoperative planning and medical imaging with surgical execution. "

The first work on CAS systems was focused on tumour location in neurosurgery, based on the principles of stereotaxy [Brown, 1979]. In orthopaedics, Robodoc was the first robotic system used to assist in performing part of a total hip replacement in 1992 [Paul, 1992], [Bargar, 1998]. The first three-dimensional (3D) surgical navigation system in orthopaedics was developed for the spinal surgery procedure of placing pedicle screws [Nolte, 1995], [Lavallée, 1995], [Foley, 1996]. For a long time this computer-assisted orthopaedic surgery (CAOS) system for pedicle screw placement was the only clinically available orthopaedic application. Nowadays, CAOS systems are available for total hip replacement (THR) [DiGioia, 1998c], [Langlotz, 1999] and total knee replacement (TKR) [Fadda, 1994], [Fadda, 1997], [Delp, 1998]; nail locking [Suhm, 2000], [Suhm, 2001]; tibial [Ellis, 1999],

femoral and pelvic [Langlotz, 1998] osteotomies; and knee ligament reconstruction [Dessenne, 1995], [Sati, 1997], [Julliard, 1998], [Sati, 2000], [Petermann, 2000], [Picard, 2001]. CAOS systems are being developed for shoulder surgery, trauma procedures, repositioning of pelvic ring and acetabulum fractures and shaft navigation. To increase the benefit to cost ratio of these systems several manufacturers offer systems that support several procedures [Brainlab], [Muacevic, 2001], [Braun Aesculap], [Orto Maquet], [Medtronic Sofamordanek].

Most contemporary computer-assisted orthopaedic surgery systems provide navigation in a 3D patient model based on preoperative CT or MR imaging [Taylor, 1996]. The 3D patient model is used for preoperative planning. Intra-operatively this model is matched to the actual patient position with a stereotactic camera system and a special pointer equipped with light emitting diodes (leds). This matching process is known as registration. The patient model and reality are matched based on anatomic references or markers (point to point matching), entire anatomical surfaces (surface matching) or a combination of both. If the surgical instruments are also modelled and equipped with leds, they can be tracked during the surgical procedure and their position can be displayed in the computer model. The surgeon can thus align the instruments according to the preoperative plan. If the patient is not completely immobilized, additional effort must be made to track patient movements and thus preserve the match between patient and 3D model. For this purpose an additional tracking device can be attached to the part of the patient's anatomy that is being operated upon.

The latest developments in CAOS are fluoroscopic navigation systems and 3D fluoroscopic systems. With fluoroscopic navigation systems fluoroscopic images from multiple view angles are used instead of CT images. These fluoroscopic images are made with a tracked C-arm just before surgery. Intra-operatively the surgical instruments are tracked, as was the case in the CT based systems, and their actual position is overlaid on all fluoroscopic views. These systems thus provide 'virtual' continuous fluoroscopic views from multiple directions, without the actual C-arm being in the operating room during the procedure.

With the 3D fluoroscopic systems an isometric C-arm system is used to take about 100 fluoroscopic images covering a 190-degree angle (in the operating room just before surgery). These images are than used to make a CT-like 3D reconstruction [Euler, 2000]. These systems offer intraoperative 3D imaging capabilities. When these systems are coupled to navigation systems, it is possible to build a 3D CAOS system without the need of preoperative imaging and intraoperative registration.

All 3D CAOS systems provide real time instrument navigation without the need of continuous intra-operative imaging in order to execute the preoperative plans. However, using these systems requires changes in preoperative imaging, clinical set-up, surgical technique and the surgical instrumentation.

Many orthopaedic procedures are performed while using arthroscopy. Additionally a fluoroscope can be used to image the positions of bones and the instruments and thus assist in navigating the bony anatomy (2D images). The surgeon's expertise and anatomical

knowledge is the key to success for performing the 3D surgical tasks with 2D imaging. If this expertise and anatomical knowledge is 'captured' and used by a computer it would be possible to create CAOS systems based on 2D imaging. Systems that use a-priori information in combination with 2D images are often referred to as 2D-plus systems. This thesis investigates the possibilities of developing 2D-plus CAOS systems for procedures that use 2D fluoroscopic imaging. In contrast to the 3D systems, these 2D-plus systems will not use 3D images and will not provide real time instrument navigation. To develop CAOS systems we need software to capture images, to locate the surgical instruments and the bony anatomy, to display overlays and more. An important task is to gather the requirements for the system. We need to extract the essential knowledge about the procedure from the surgeon.

Close co-operation with orthopaedic surgeons is an absolute necessity to design and build successful CAOS systems. This research was conducted in the Catharina Ziekenhuis in Eindhoven, where Klos, an orthopaedic surgeon, did a Ph.D. study to explore the possibilities of a CAOS system for anterior cruciate ligament (ACL) surgery [Klos, 2000d]. My thesis mainly focuses on the design of the computer-assisted tools. For the specific medical consequences of the computer-assisted tool for ACL reconstruction, I would like to refer the reader to Klos's thesis. In this thesis I often use 'we' to describe my part of our work on computer-assisted orthopaedic surgery tools.

Anterior cruciate ligament reconstruction is one of the most frequently performed orthopaedic procedures in young people. This procedure restores the stability of the knee-joint. If the ACL is ruptured other ligaments and the menisci take over its primary function, which is controlling anterior movement of the tibia relative to the femur. However, these other knee structures can be damaged in an uncontrolled movement. Reconstructive surgery therefore not only restores knee stability but also prevents secondary injuries. Conventionally, the ACL reconstruction procedure was an open procedure. Nowadays, the procedure can be performed with minimally invasive surgery by using arthroscopic imaging. Postoperatively, X-ray imaging is used to evaluate the position of the ACL graft relative to previously defined anatomical landmarks [Klos, Habets et al., 2000b]. To improve the accuracy of the procedure, additional fluoroscopic imaging was introduced to visualize the position of the surgical instruments. However, the interpretation of the fluoroscopic images still depends on the expertise of the orthopaedic surgeon. With the help of a CAOS system the surgeon can measure the position of the instruments and thus disclose the position of the ACL graft during the procedure. With this intra-operative feedback the surgeon can realize the tunnels for the graft at the desired location.

In a pilot project, the anatomical landmarks that were described in the previous section were incorporated into a pilot-prototype [Lambregts, 1995]. This pilot-prototype was used in a cadaver study (a series of 5 human knee's) to evaluate the possibilities of a CAOS system for ACL reconstruction.

In a subsequent graduation project of the two-year design course in Information and Communication technology of the Stan Ackermans Institute, a clinical prototype was constructed that was used to evaluate the approach clinically [Habets, 1997],

[Habets, 1998]. This project was performed in the Catharina Ziekenhuis in Eindhoven in co-operation with the former section of Medical Electrical Engineering of the Electrical Engineering department of the Technische Universiteit Eindhoven. It was partly financed by the Technology Foundation (STW).

This clinical prototype was able to acquire fluoroscopic images, identify anatomical landmarks and surgical instruments and to display the desired locations for the drill tunnels in a graphics overlay. The clinical prototype was designed in the clinical setting by using a rapid prototyping strategy. Rapid prototyping allows the designer and the orthopaedic surgeon to develop a computer-assisted surgery system in close co-operation.
After a successful clinical evaluation of the clinical prototype the work was continued as a designer thesis project. The goal of this latter project was to build the clinical CAOS system for ACL reconstruction and to further explore the possibilities and limitations of the rapid prototyping design approach that was used in the previous project. For successful rapid prototyping of CAOS systems the developer needs a toolbox (a software library) that contains all the basic functionality to build them. This toolbox enables the designer to quickly implement ideas and verify the method. Quick development is one of the most important benefits of rapid prototyping. In traditional design the specifications for the system are obtained from the client before the design and implementation process is started. The client will not be involved again until the developer is ready to test the final system. This process only works if the client is able to provide the exact specifications.

In most cases the requirements will not be crystal clear and the first thing the designer will hear from the client after a demonstration of the system will be: “That’s very nice…but what I actually want is…”. To collect requirements successfully the designer and the client must understand each other. They must have (or build) some common knowledge. The designer should understand the medical procedure and terminology. The physician should have an idea about the current state of technology and know what can and cannot be done. In some cases requirements collection can be difficult because the client’s goals are not settled yet (moving target). In a rapid prototyping design the designer will quickly implement part of the system and show it to the client. The client can then test this part of the system and refine the requirements.

1.2 Outline of the project

The first part of the thesis project is to analyse the use of rapid prototyping in the clinical setting and to construct a rapid prototyping toolbox. The toolbox must contain software to acquire, process and display fluoroscopic images (live images and films); define, draw, save, load and manipulate graphic overlays; measure angles and relative and absolute distances; and collect, store, load and analyse procedure data. In the second part of the thesis project the toolbox and the rapid prototyping design approach are used to design the final prototype of the CAOS system for ACL reconstruction. This final prototype contains all elements to make it a CAOS application. The clinical application supports the surgeon with the ACL reconstruction procedure and also collects and stores patient information and clinical results. Its user interface must be designed to accommodate the OR technicians who are the operators of the system. In the third part of the thesis project the usability of the

toolbox and the design method to create clinical applications are investigated further. Besides other computer-assisted surgery programs the design approach can be used to develop programs for all tasks in which X-rays or other types of images are used to perform measurements.

X-rays are not only used in diagnostic tasks but also in preoperative planning, surgery, postoperative scoring and medical research. Measurement programs can be designed for all tasks for which an observer draws on an image and measures something. Computer-assisted measurement has several advantages over manual measurements. The computer-assisted measurement programs can offer image handling functions like save, store, print, zoom, flip and rotate; non-destructive drawing and image annotation; functions for measuring distances and angles as absolute or relative values; or determine more complex relations between anatomical landmarks that were defined by the user. These programs can handle a large number of images, support different sets of measurements and deal with multiple observers. They also enable automatic data collection, calculations, storage and export of data to statistical analysis programs. The data can be used for diagnostic purposes, to generate knowledge about the procedure, and to improve its quality. Measurement programs can save time and enable tasks that could not be afforded before.

In order to investigate the limits of the toolbox and the design approach with respect to the 3D possibilities we developed a CAOS system for hip pinning. With this procedure the surgeon has to drill a guide-wire through the femoral neck while using X-rays from two directions. We explored the possibilities to visualize the drill path to assist the surgeon to reach the desired location. To couple the information of the two images and assist in placing the guide wire it was necessary to develop a special guiding instrument.
We will also discuss the impact that the new generation of freehand X-ray navigation systems will have on our 2D-plus design approach.

1.3 Outline of the thesis

This thesis describes the work that has been done to build a toolbox and use a rapid prototyping design approach to develop CAOS systems, in particular a clinical CAOS system for ACL reconstruction. Chapter 2 provides some necessary medical terminology and definitions together with an overview of developments in the fields of anterior cruciate ligament surgery, hip surgery, and 3D CT based CAOS systems. Chapter 3 describes the rapid prototyping design method. Chapter 4 describes the development of the toolbox that was used to develop CAOS systems. Chapter 5 discusses the use of the rapid prototyping toolbox in the design of measurement applications. Chapter 6 discusses the design of the CAOS system for ACL reconstruction. Insight is provided in the design process from the initial idea up to the final prototype. In addition, a detailed description of the final ACL system is given. Chapter 7 explores the limits of our approach with the design of a CAOS system for hip pinning. Chapter 8 discusses the concurrent developments in the field of CAOS systems. Finally, the conclusions and recommendations are presented.

Chapter 2

Medical and technical background

2.1 Introduction

To communicate with surgeons it is very important to understand the medical terminology and the medical procedures for which CAOS systems are developed. This chapter provides an overview of the medical terminology and definitions that are used in this thesis. It also discusses the developments in the fields of anterior cruciate ligament (ACL) surgery and hip fracture surgery. Section 2.2 introduces the medical terminology for position and movement. Section 2.3 describes the knee and introduces the function of the anterior cruciate ligaments. Section 2.4 provides an overview of ACL reconstruction techniques. Section 2.5 explains the currently used reconstruction techniques. Section 2.6 discusses hip fractures. Section 2.7 introduces several techniques for hip fracture surgery. Section 2.8 discusses the currently used DHS procedure in detail. Section 2.9 provides an introduction into 3D CAS systems. Section 2.10 presents the principles of 3D based CT CAS systems. Section 2.11 presents the conclusions for this chapter. The appendix presents a list of medical terms and abbreviations.

2.2 Terminology: position and movement

In medicine, terms like left and right are always referred to from the patient's point of view. Positions and movements in the human body are defined relative to the part of the body that is under consideration. The X, Y and Z planes through the human body are also defined relative to the patient (standing in an upright position). The vertical plane from left to right is called the coronal plane, the vertical plane from front to back is called the sagittal plane and a horizontal cross section at a certain height is called the transversal plane.

Medical terms for (relative) position and direction are defined for the extremities and for the complete body. As with the definitions of the planes these positions and directions are also defined relative to the part of the anatomy considered respectively relative to the entire patient. As an example of the position and movement (which can be divided into translations and rotations) we will use the knee as an example.

The knee has two cruciate ligaments. The ligament in the front is called the *anterior* cruciate ligament and the one in the back is called the *posterior* cruciate ligament. If the

lower-leg (tibia) moves towards the front in the sagittal plane this is called anterior translation. It is also possible to describe a translation by using a combination of terms and describe the origin and the direction of the motion. For example if the lower-leg moves from the back to the front (in the sagittal plane) this is called posterior to anterior or PA motion. The term's flexion and extension are used to describe rotation in the sagittal plane. Flexion is posterior rotation (bending the knee) and extension is anterior rotation (stretching the knee). A complete list of position, translation and rotation terms are presented in appendix 2.

2.3 The knee

2.3.1 Anatomy and function

The knee is a very complex joint (see Figure 2-1). There are three bones in the knee-joint, the lower leg or tibia, the upper leg or femur and the kneecap or patella. The knee-joint has six degrees of freedom for motion: three translations and three rotations.

The translations are:
- Anterior-posterior describes a translation in the sagittal plane. Anterior is towards the front of the patient and posterior is to the back.
- Medial-lateral describes a translation in the coronal plane. Medial is towards the body main axis, lateral is away from this axis. For example, in a right knee, medial is to the left and lateral is to the right.
- Distal-proximal describes a translation perpendicular to a transversal plane. Distal is the furthest from the body centre and proximal is closest to the body centre.

The three rotations are:
- Flexion-extension describes rotation in the sagittal plane. Flexion is posterior rotation (bending the knee) and extension is anterior rotation (stretching the knee).
- Abduction-adduction describes rotation in the coronal plane. Abduction is towards the lateral side and adduction is towards the medial side.
- External-internal describes rotation in the transversal plane. External rotation is towards the lateral side and internal rotation is towards the medial side.

To control these complex movements the knee comprises two cruciate ligaments (the anterior cruciate ligament and the posterior cruciate ligament), the medial and the lateral collateral ligament, the medial and the lateral meniscus and the knee capsule. A detailed description of the knee's mechanism can be found in [Blankevoort, 1991], [Daniel, 1990], [Lambregts, 1995] and [Müller, 1983].

The primary role of the anterior cruciate ligament (ACL) is to restrain anterior translation of the tibia relative to the femur. Both ligaments are hourglass-shaped (Figure 2-2). Because of this shape, different sets of fibres within the ligaments are used during the full range of knee movement.

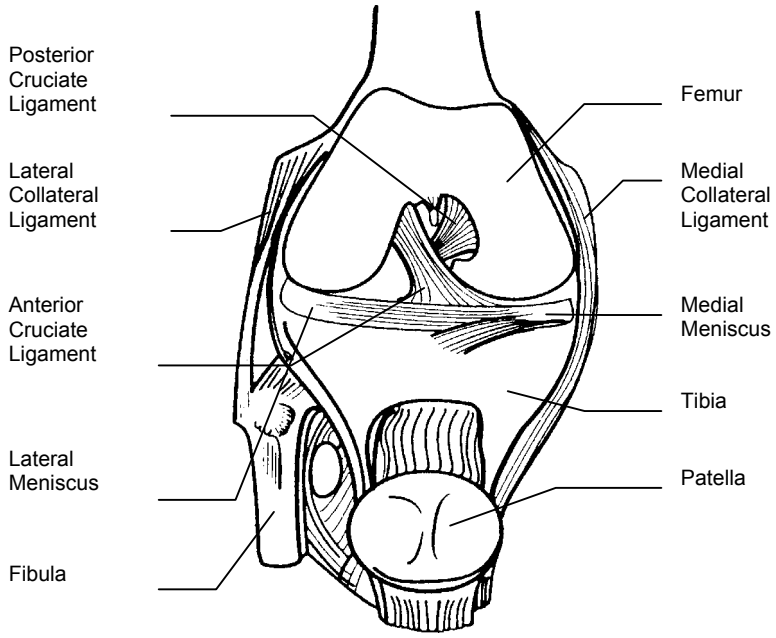


Figure 2-1: The knee-joint; adapted from [Meins, 1995]. The patella is loosened to show the cruciate ligament.

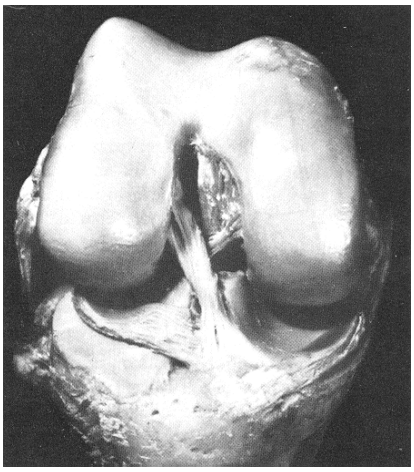


Figure 2-2: View of the anterior and posterior cruciate ligaments [Müller, 1983].

2.3.2 The ACL attachment sites

The tibial attachment site of the ACL is located on the tibial eminentia (Figure 2-3). A study of 64 lateral MRI's [Klos, Habets et al., 2000a] has shown that the centre of the tibial attachment site is located at 46% ± 3% of the distance from the most anterior point to the most posterior point on the tibial cortex (see Figure 2-3). The femoral attachment site of the ACL is located on the inside of the lateral condyle (see Figure 2-4). A recent study showed that this site corresponds to a point 25% of the radius of the condylar circle posterior to the condylar circle centre in the direction of Blumensaat's line (see Figure 2-4). A study of 48 lateral fluoroscopic images has shown that the centre of the condylar circle is projected at 66% ± 5% of the length of Blumensaat's line [Klos, Habets et al., 2000a]. The centre of the femoral attachment site is projected at about 80 % of the length of Blumensaat's line (see Figure 2-4).

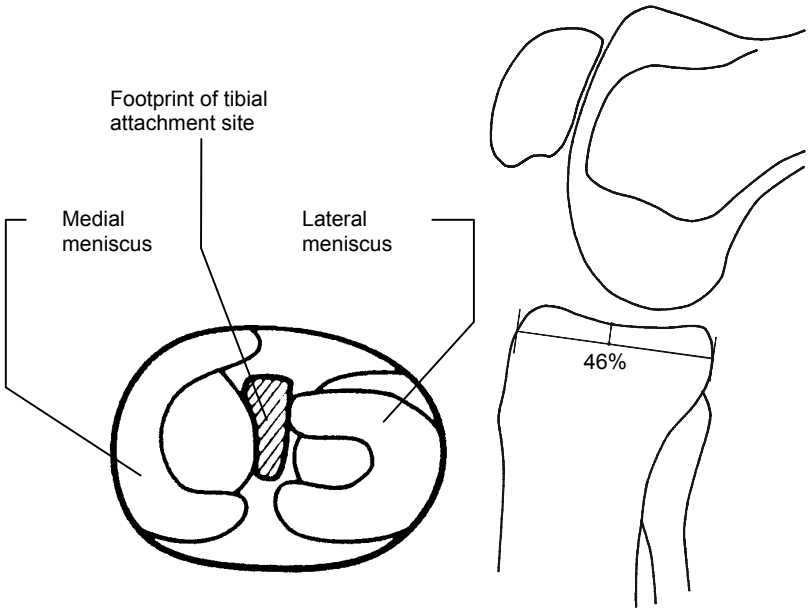


Figure 2-3: Left: footprint of tibial attachment site (top view of the tibial plateau); Right: position of the centre of the tibial attachment site relative to a line from the anterior to the posterior tibial cortex (lateral cross section of the knee).

When sports like soccer, American football, rugby, ice hockey, motor sports and skiing are being practiced the knee-joint can receive severe blows. Excessive force in the anterior-posterior (AP) direction (often in combination with an internal rotation of the tibia) can cause the ACL to rupture. ACL ruptures are often associated with meniscus injuries. The ACL reconstruction procedure will be discussed in the following section.

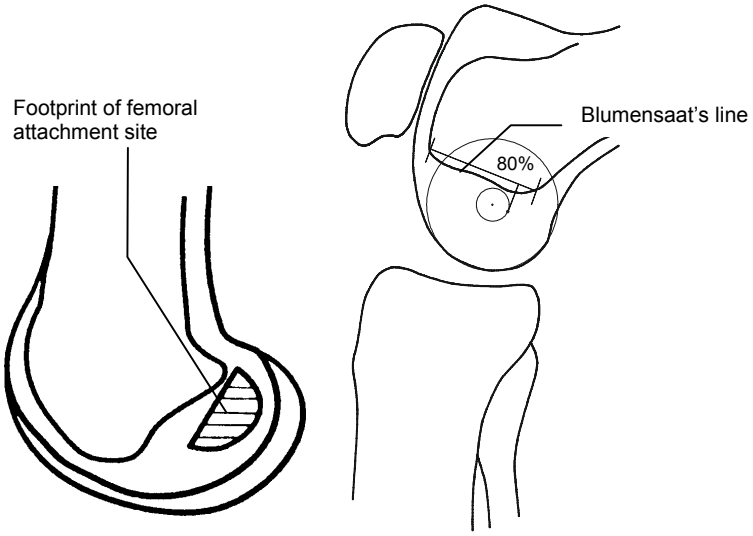


Figure 2-4: Left: footprint of femoral attachment site (lateral cross section of the knee); Right: position of the femoral attachment site relative to Blumensaat's line (lateral cross section of the knee).

2.4 The ACL reconstruction procedure

2.4.1 Introduction

Since the first diagnosis of Anterior Cruciate Ligament (ACL) rupture, many have sought a means for repairing the injured knee. Repairing the knee is important because unstable knees tend to deteriorate (further injury to the menisci and other ligaments can occur). Many different types of material have been used to repair the ACL. At first kangaroo tendons were popular. For a while artificial tendons were used, but these tendons were frequently not 'accepted' by the patient's body. Nowadays, most surgeons use patellar tendon bone (PTB) grafts or hamstring tendon grafts.

ACL reconstruction is intended to restore knee stability. With this reconstruction the ACL's functionality will be restored, not the original anatomy. The term *stability* in this context is unclear, however. It is not easy to define stability for each patient. During the last decade a number of factors have been identified and investigated with respect to their impact on the success of the reconstruction procedure: graft selection, choice of allograft versus autograft material, graft fixation, graft tensioning, tibial and femur tunnel positioning, rehabilitation protocols and the condition of secondary stabilizing structures as the menisci and the other ligaments [Johnson, 1992]. These factors are not all surgery related; the co-operation of the patient in the rehabilitation process is just as important for the stability of the knee. Several of these factors will be discussed here.

2.4.2 Success factors

Graft selection
In the current surgical practice two types of autografts are used for ACL reconstruction. The most commonly used graft is the patella tendon bone (PTB) graft. This type of graft consists of a bone-tendon-bone structure. This graft is harvested from the middle third of the patella bone, the patella tendon and the tibia as is depicted in Figure 2-5.

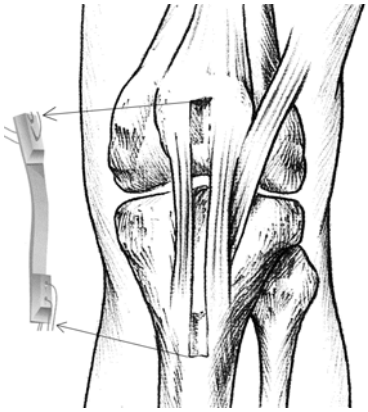


Figure 2-5: Harvesting a patella tendon bone graft.

Figure 2-6: Hamstring tendon stripper (7 mm) [Artrex, 1995].

The second frequently used graft type is the hamstring graft that is harvested from the semitendinosus and gracilis tendon. These tendons are harvested through a four-cm incision with a special tendon stripper that is depicted in Figure 2-6. The grafts are folded double to obtain a stronger graft and stitched together to form the new ACL graft.

Isometric placement
The original ACL is hourglass shaped. During the normal range of knee movement different sets of fibres within the ACL are fully flexed while others are lax. The anterior cruciate ligament actually consists of two functional bundles, the antero-medial and the postero-lateral bundle. The antero-medial bundle is functional in flexion; the postero-lateral bundle is functional in extension. For ACL reconstruction it is not known if it is better to restore one of the bundles, both or to aim for a central position (between both bundles). Because these graft shapes can never exactly restore the original anatomical situation, fully isometric sites may thus be impossible to realize. The objective of the procedure therefore is to restore the ACL's functionality and to create a stable knee.

To assure that the graft provides stability while flexing and extending the knee, the attachment sites of the graft will have to be isometric as best as possible. Isometric means in this case that the distance between the tibial and the femoral attachment site remains constant during the full range of normal knee movement.

To locate the isometric positions for each individual patient, dynamic studies of the knee-joint are necessary. The greatest problem is that the identification of the isometric positions should be performed while the knee is healthy. The ACL-deficient knee does not behave normally during movement, so isometric attachment sites identified pre-operatively may not be truly isometric when the graft is in place. To ensure isometric positioning intra-operative measurements are necessary during the fixation of the graft.

The determination of the location of isometric attachment sites has been the subject of many studies [Odensen, 1986], [Good, 1987], [Goble, 1988], [Sidles, 1988], [Hefzy, 1989], [Cazenave, 1990], [Brand, 1992], [Feller, 1993], [Jackson, 1994]. In all cases it proved very difficult to obtain isometric attachment sites. Collette states that there are no unique isometric points [Collette, 1996]. For every possible tibial attachment site there is a corresponding femoral attachment site that is isometric to that selected tibial attachment site.

Collette developed a radiological method in which two images (one in flexion and one in extension) are used to determine a transition line between the impingement free zone and the impingement zone for the ligament's femoral attachment site given the selected tibial attachment site. The femoral attachment site should never be positioned anterior to this transition line independent of the shape, size or dynamics of the knee.

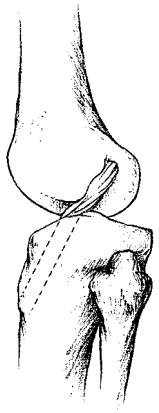


Figure 2-7: Roof-impingement.

Roof-impingement
Roof-impingement occurs when the graft touches the anterior edge of the intercondylar roof near full extension of the knee-joint (see Figure 2-7). This problem often occurs in patients with hyperextension. Roof-impingement occurs when the tibial attachment site is too anterior. In extreme cases, roof-impingement can result in a rupture of the graft. The femur bone can act as a guillotine and sever the graft. If the graft touches the roof after it is fixated, notchplasty is performed to widen the intercondylar cavity. However, it is better to avoid roof-impingement.

Sidewall-impingement
Sidewall-impingement occurs when the graft touches the lateral femoral condyle during normal knee motion. Sidewall-impingement can occur when the graft is positioned too laterally, when the patient has a very narrow intercondylar notch or when both occur. Like roof-impingement sidewall-impingement can result in graft failure. If sidewall-impingement can not be prevented notchplasty can be performed.

Graft-Tunnel mismatch
A normal ACL is approximately 30 mm long. In reconstructive surgery while using a patellar tendon bone (PTB) graft, the graft is approximately 90 to 120 mm long. The

proximal block of this bone-tendon-bone graft is placed entirely in the femur. The tendon, which is approximately 40 to 60 mm long, will reside partly inside the intercondylar groove and partly inside the tibia tunnel. The distal block should be placed inside the tibia tunnel. If the tibia tunnel is not sufficiently long, the distal block will stick out (graft-tunnel mismatch). For an adequate bone interference fixation a minimum of 20 mm of distal block must reside inside the tibia tunnel. Graft-tunnel mismatch is discussed in [Shaffer, 1993]. They found that for a series of 34 endoscopic PTB reconstruction procedures mismatch occurred in 26% of the cases. Mismatch occurred more frequently for patients whose patellar tendon lengths exceeded 50 mm.

In reconstructive surgery with the hamstring tendon graft, the graft (after it has been folded) is approximately 110 to 130 mm long. The graft passes through the intra-articular space into the tibia tunnel. The graft should at least protrude 15 mm from the tibia tunnel in order to be able to fixate it externally with staples.

Graft fixation

For the PTB technique the graft is normally secured by means of two interference screws. These metal screws must be placed parallel to the bone blocks. In order to avoid damage it is important that the screws do not touch the tendon. Since the minimum screw-length is 20 mm a screw cannot be used for fixation when graft-tunnel mismatch occurs (see previous section). In this situation staples are used. Staples have a major disadvantage: because they are not placed inside the drill tunnel the patient will feel them through the skin. In cases where a patient has problems with these staples they can be removed when the graft is ‘grown in’.

For the hamstring technique the graft is secured in the femur tunnel with a transverse intra-osseous implant (see Figure 2-8). With this type of implant the tendon wraps around a metal pin. In time the tendon will grow into the femoral bone. For the tibial side the graft is normally fixated with low profile ligament staples (see Figure 2-9). As an alternative the graft can be fixated inside the tibia tunnel with a bio-interference screw. In this case the graft-tunnel requirement of 15-mm extrusion is no longer needed.

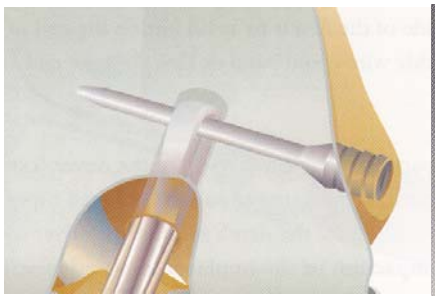


Figure 2-8: Transverse intra-osseous implant [Artrex, 1995].

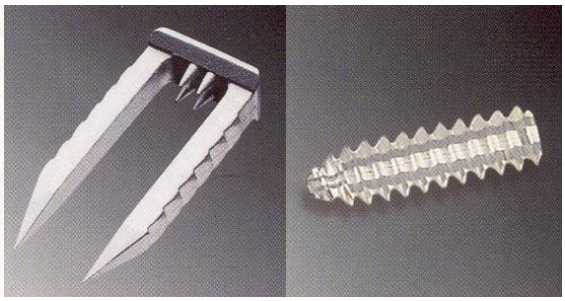


Figure 2-9: Tendon fixation devices: staple (left) bio-interference screw (right) [Artrex, 1995].

Expertise of the surgeon
It is the expertise of the surgeon that determines how well the procedure is performed. Some surgeons only use arthroscopic feedback during reconstructive surgery. With this technique the surgeon relies on experience when placing the tunnels. Using fluoroscopic imaging as extra feedback will increase the reproducibility significantly. The use of Computer-Assisted Surgery systems will further increase the possibilities for the surgeon to control the factors that determine the success of the operation.

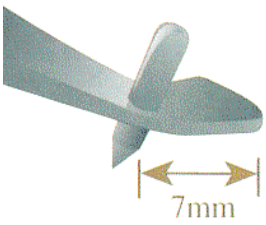
Rehabilitation
The surgeon is not the only person affecting the outcome of the reconstruction process, however. Most of the work has to be done by the patient. The patient will have to do exercises from the first day after surgery, wear a brace, participate in an intensive physiotherapy program and constantly be on guard not to over-stress the knee. The fact that the revalidation efforts of the patient have such a large effect on the outcome of the reconstruction obscures any objective study into the effect of the intra-operative parameters on the outcome of the process.

2.4.3 The 'optimal' graft position

Many surgical techniques are used to deal with the intra-operative factors that determine the success of the procedure. Because of the difficulty of determining the effects of each of these factors on the final outcome of the procedure there is no generally accepted technique. Hence, any real comparison between the techniques is fraught with difficulties. A combination of methods will most likely lead to the best results. Although there is no technique that provides an optimal solution for all factors discussed in the previous section, the graft position is considered the most important factor for the success of the procedure. In this section a number of techniques for locating the tibial and the femoral attachment sites will be discussed. The selection of these attachment sites does not depend on the type of graft used.

2.4.3.1 Tibial attachment site

PCL-oriented



The tibial attachment site of the anterior cruciate ligament in the normal knee is about seven mm anterior to the tibial attachment site of the posterior cruciate ligament (PCL). With the PCL-oriented technique a location seven mm in front of the PCL is aimed at for the tibial attachment site. An example of a surgical instrument based on this technique is the Arthrex tibial guide (see Figure 2-10) [Artrex, 1995].

Figure 2-10: Detail of the POP hook of the Arthrex tibial guide [Artrex, 1995].

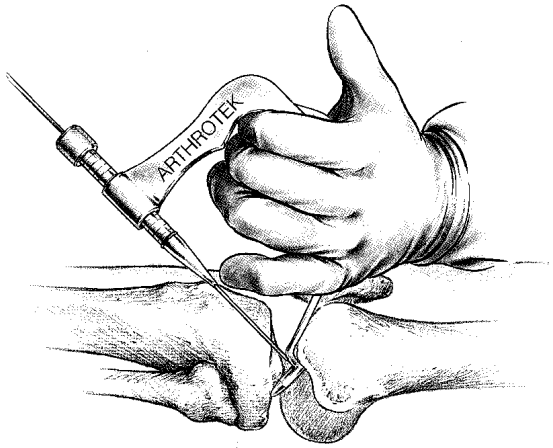


Figure 2-11: Roof-oriented positioning using the Arthrotek drill guide [Arthrotek, 1996].

Roof-oriented
This technique focuses on avoiding roof-impingement. With this technique the tibial drill tunnel is drilled in extension. An instrument that is positioned along the intercondylar roof is used to locate a suitable tibial attachment site. An example of instrumentation based on this technique is the Arthrotek tibial drill guide (see Figure 2-11).

Centre of original ACL footprint oriented
In [Klos, Habets et al., 2000a] lateral MRI's of 60 healthy knees were analysed to determine the normal location of the tibial attachment site. They showed that the centre of the tibial attachment site was located at 46% ± 3% of the distance from the most anterior to the most posterior point on the tibial cortex (see Figure 2-3).

2.4.3.2 Femoral attachment site

Isometric
The importance of isometric attachment sites was discussed in the previous section. Several instruments have been developed for measuring the intra-articular distance (the distance between the tibial and femoral attachment sites) during surgery. It has already been explained that there is no guarantee that the selected sites are still truly isometric after graft fixation.

Condylar circle-oriented
In [Klos, Habets et al., 2000a] Klos postulated that the femoral attachment site could be positioned in the middle of the condylar circle (a circle touching the inferior and posterior aspects of the lateral femoral condyle). Forty-eight lateral fluoroscopic images were analysed to determine the relationship between the centre of the condylar circle and Blumensaat's line. They showed the centre to be at 66% ± 5% of the length of Blumensaat's line from the most anterior point of the line.

Further research has shown that the hypothesis that the centre of the condylar circle could be used as target for the femoral attachment site was wrong [Klos, Habets et al., 1998]. The femoral attachment site must be located further towards the back. Therefore, the femoral attachment point is positioned a further 25% of the radius of the condylar circle posterior to the centre in the direction of Blumensaat's line.

Centre of original ACL footprint oriented
The natural femoral attachment site is located at the posterior side of the lateral condyle (Figure 2-4). In an arthroscopic view of the knee joint this location is referred to as 'over-the-top'. The 'over-the-top' position is located beyond the end of Blumensaat's line (see Figure 2-12) in the posterior aspect of the original anatomical attachment site. The proximal block must be fixated in the femoral bone. The condyle itself is not thick enough to hold the proximal block. To achieve the same effect as an over-the-top positioning the proximal block can be positioned from the back. However, the position of the patient in our transtibial operating technique excludes the possibility of drilling such a femur tunnel.

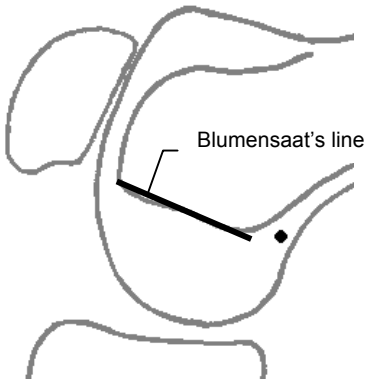


Figure 2-12: Over-the-top position (dot).

Cortical back wall-oriented
A femoral attachment site as far posterior as possible on Blumensaat's line resembles the natural site as closely as possible. It is important to ensure that the proximal block can be safely fixated in the femur tunnel. The tunnel must be placed in such a way that cortical back wall blowout is prevented. Arthrex has developed a femoral drill guide to ensure a constant cortical back wall thickness.

2.4.4 Surgical instrumentation

Arthrex
The Arthrex set is developed to drill the tunnels when the knee is flexed. The set supports the complete reconstruction procedure. The tibia tunnel is placed PCL-oriented and the femur tunnel is positioned cortical back wall-oriented. A description of the Arthrex set, which is used in the current reconstruction procedure, will be given in the next section.

Arthrotek
The Arthrotek set (see Figure 2-11) is developed to drill the tibia tunnel when the leg is extended. The tibia tunnel is placed roof-oriented.

CARAD
The CARAD tibial guide as described in Chapter 6 of [Lambregts, 1995] was developed to aim for the centre of the condylar circle. This drill guide can be used to drill a tibia tunnel that 'passes through' the centre of the condylar circle. Because this femoral aim is no longer used this experimental drill guide has not been utilized in our research.

2.5 Current ACL reconstruction technique

The current reconstruction technique in the Catharina Ziekenhuis is based on the Arthrex instrumentation [Arthrex, 1995] and a combination of arthroscopic and fluoroscopic feedback. The complete procedure takes about three hours. The different steps in the procedure will be discussed below. The steps concerning the grafting and the graft fixation differ for the PTB and the hamstring technique.

Step 1 Preparation

First of all, the patient is anaesthetised. Next, the fluoroscope is positioned in order to obtain a truly lateral image of the joint. In such an image the contours of the medial and the lateral condyle overlap exactly. The fluoroscope is locked into the correct position. Next, the sterile area is draped and the rest of the equipment is placed. Finally, the table with the surgical instruments is wheeled in. A layout of the OR can be seen in Figure 2-13.

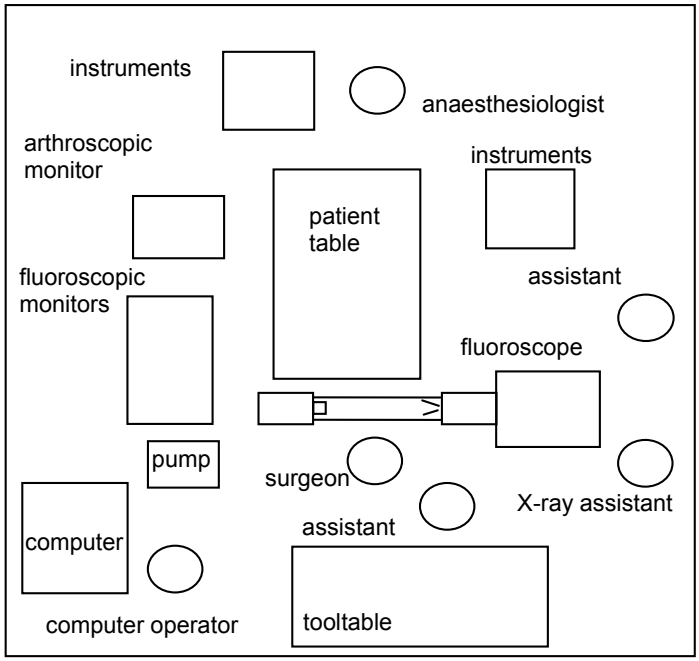


Figure 2-13: Layout of the OR for ACL reconstruction procedure (right knee). At least 6 people are present in the OR. The computer operator and the X-ray assistant only have to be present when the tunnels are drilled. In this situation the surgeon uses 4 different monitors: arthroscope, fluoroscope (2) and the computer.

Step 2 Cleaning the joint

After making the incisions the surgeon cleans the inside of the knee-joint. All scar tissue and the remnants of the ruptured ligament are removed. This is necessary to create sufficient space for inserting the graft. In case of a small notch, which could lead to roof-impingement, notchplasty may be performed.

Step 3 Grafting

Patella tendon bone graft:

First, an incision is made from the patella to the top of the tibia. Next, the proximal block is cut out of the middle third of the patella. Then, the middle third of the tendon is harvested. Next, the distal block is cut out of the tibia. The graft and the graft site are depicted in Figure 2.5. After the graft has been harvested the bone blocks are prepared to fit in a tunnel with a constant diameter between 9 and 12 mm. Then, the graft is measured. The diameter of the proximal block determines the femur tunnel diameter while the distal block diameter determines the tibia tunnel diameter. Because the femur tunnel is drilled through the tibia tunnel, the proximal block diameter must be smaller than or equal to the distal block diameter.

Hamstring tendon graft:

First, the landmarks for harvesting the semitendinosus and gracilis tendons are identified. Both tendons can be harvested through a 4-cm incision. After harvesting, the tendons are mounted on the graft workstation base by looping the tendons around the workstation's adjustable post at their midpoint and clipping the free ends together with Kocher clamps (see Figure 2-14). These clamps are inserted through stationary posts to tension the graft. The parts of the graft that will be placed in the tibia are sewed together for a length of 25 mm.

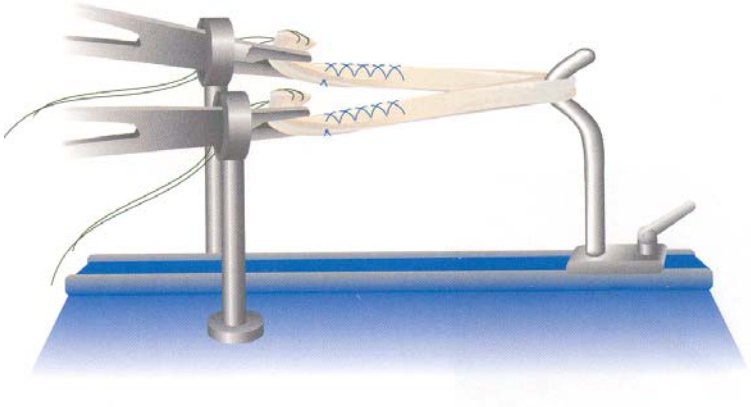


Figure 2-14: Graft workstation with hamstring graft [Artrex, 1995].

Step 4 Drilling the tibia tunnel

After the graft has been harvested the tibia tunnel will be drilled. The Arthrex tibial drill guide is inserted into the joint (see Figure 2-15). This drill guide consists of two parts: an aim-part with a hook that references the PCL and a hollow guide-part that contains a guide wire (Kirschner wire or K-wire). Both parts are connected to a metal arc that is constructed in such a way that a K-wire inserted through the guide part will touch the tip of the hook of the aim part. The back of the hook (called the Posterior Oriented Placement or POP hook) is pressed firmly against the PCL. The tip of the K-wire in the guide part is placed against the tibial cortex. The surgeon verifies the position of the POP hook visually by using arthroscopic and fluoroscopic imaging. If the surgeon is satisfied with the position the guide wire is drilled into the tibia (see Figure 2-15).

The position of this K-wire is then verified fluoroscopically. If the surgeon is satisfied the K wire is over-drilled with a cannulated burr of the correct diameter. Finally, the K-wire is removed. Because the tibia can be very firm and because the surgeon must apply some pressure to drill in the K-wire, the wire does not always exit the tibia at the location of the POP hook [Goble, 1995]. For this reason, visual verification after the K-wire has been inserted is necessary.

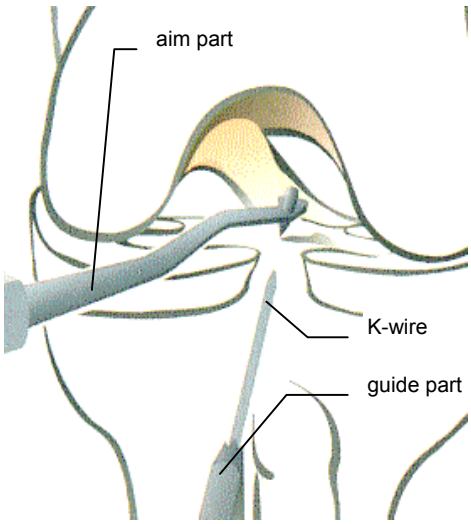


Figure 2-15: Drilling the K-wire into the tibia.
Adapted from [Artrex, 1995].

Step 5 Drilling the femur tunnel

After the tibia tunnel has been over-drilled the femur tunnel can be made. The femoral drill guide is inserted through the tibia tunnel and placed in the over-the-top position. The position of the femoral drill guide is verified visually with arthroscopic and fluoroscopic imaging. If the surgeon is satisfied with the femoral attachment site and the resulting

cortical back-wall thickness, the K-wire is drilled (see Figure 2-16). The position of the femoral K-wire can be verified fluoroscopically. For the PTB technique the K-wire is drilled through until it penetrates the skin of the upper leg. Finally, the K-wire is over-drilled with a mushroom-shaped drill. For the PTB technique the femur tunnel will be made just long enough to hold the proximal block of the graft. For the hamstring technique the tunnel will always be made 35 mm long.

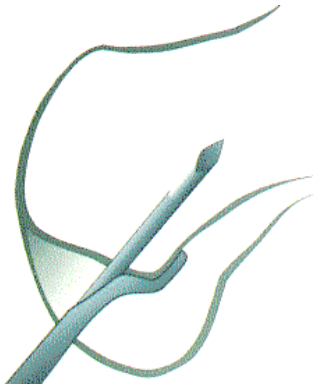


Figure 2-16: Drilling the K-wire into the femur [Artrex, 1995].

Step 6 Graft fixation

After both tunnels have been drilled, loose bone fragments are flushed out of the knee and the sharp edges of the drill tunnels are rounded.

Patella tendon bone graft:

The graft is tied to the distal end of the K-wire, which is still in the knee. By pulling the K-wire out at the proximal side, the graft is pulled into the knee. Under arthroscopic imaging the proximal block is manoeuvred around the PCL and into the femoral drill tunnel. The bone-tendon transition at the proximal end of the graft was marked with a special pen (after preparing the graft) in order to verify arthroscopically that the block is completely inside the femur tunnel. Next, a wire is inserted parallel to the proximal block in order to guide an interference screw. The position of this guide wire is verified fluoroscopically. When satisfied, the surgeon will secure the proximal block with a sheathed screw to prevent damage to the PCL (see Figure 2-17).

After the screw is placed, the surgeon will test the graft to check that it is sufficiently secured. Next, the surgeon will extend and flex the knee several times to settle the ligament in the joint and to confirm the absence of roof-impingement. If roof-impingement is noticed, additional notchplasty can still be performed. Next, the surgeon will insert a wire parallel to the distal block to guide the distal screw. The position of the guide wire is verified visually and fluoroscopically. When the surgeon is satisfied with the position of the guide wire the distal block is secured with a screw. The graft will now be fully secured (see Figure 2-18)

Hamstring tendon graft:

A transfix tunnel hook of the correct diameter is inserted in the femur tunnel and attached to the C-ring guide. With this guide a guide wire is drilled in the femur until it exits the knee on the medial side (see Figure 2-19). A five mm drill and a dilator are inserted over

the guide wire to create the tunnel for the transfix implant that will secure the graft. Once the transfix-tunnel is prepared a graft passing wire is attached to the guide wire and pulled through the joint. A loop of the graft passing wire is then pulled down through the tibia tunnel. The hamstring graft is placed evenly over the wire loop that is then retracted back into the femur tunnel by pulling the wires on both sides of the knee joint. Then the transfix-implant is inserted to secure the graft on the femoral side (see Figure 2-20). Finally, the graft is secured distally with staples or a bio-interference screw).

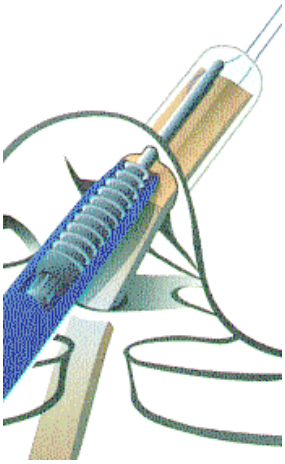


Figure 2-17: Proximal block fixation [Artrex, 1995].

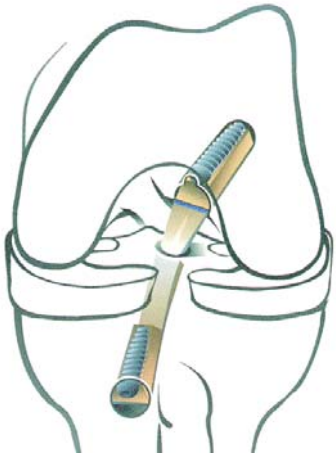


Figure 2-18: Fully secured PTB graft [Artrex, 1995].

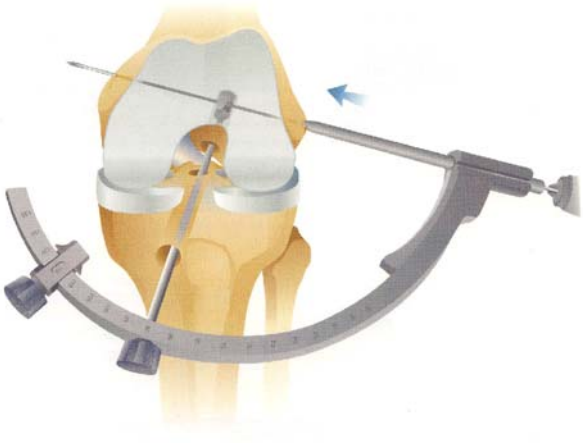


Figure 2-19: Drilling the transversal tunnel [Artrex, 1995].

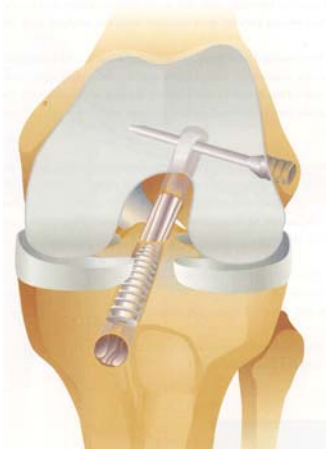


Figure 2-20: Fully secured hamstring graft [Artrex, 1995].

Step 7 Finishing up

After the graft has been inserted and secured the insertion sites are closed. A mixture of painkillers is injected into the knee-joint. A fluid drain is left at the tibial donor site. Finally, the knee is taped and a cooling-bag is wrapped in the bandages. This cooling-bag is connected to an ice-water machine. Patients will start directly with therapy. A Continuous Passive Motion (CPM) machine will automatically flex and extend the knee at regular intervals. It is important that the patient fully extends the knee regularly to prevent build-up of scar tissue in the knee.

2.6 Hip fractures

One of the most frequent injuries in the elder population is the hip fracture (the actual fracture location is the proximal femur). The two most important risk factors are age and sex. With increasing age the risk of osteoporosis increases, the protective responses decrease, the muscle mass decreases, and the walking speed decreases (people collapse to the side instead of falling to the front where they can land on their hands). All these factors increase the risk for a hip fracture. Besides this, women have a greater risk of hip fracture than men (because they have a greater risk for osteoporosis). As the average age of our population increases so will the occurrence of these fractures. Detailed information can be found in [Parker, 1997].

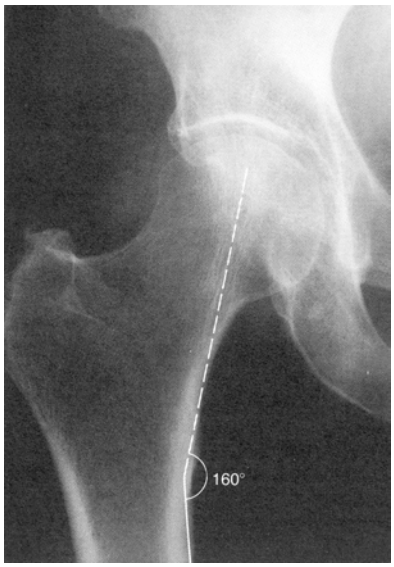


Figure 2-21: The trabecular angle is defined as the angle between the trabeculae of the femoral head and the shaft of the femur [Parker, 1997].

Generally, the diagnosis of a hip fracture is made without difficulty. Typically it concerns an elder person complaining of a painful groin or thigh with problems when rising or walking following a fall. A set of X-rays can be used to support this diagnosis. Mostly this

set contains two antero-posterior (AP) views (one of the pelvis showing both hips and one detail view of the injured hip) and a lateral view showing the femoral neck. These views should be studied to determine breaks in the continuity of the cortical margins, any changes in appearance or a distortion of the normal trabecular angle of 160 degrees (see Figure 2-21).

Once the diagnosis is confirmed the fracture can be classified based on the location of the fracture (see Figure 2-22). First, the fractures are divided into intracapsular or extracapsular fractures. Intracapsular fractures are fractures in the femoral neck. Extracapsular fractures are subdivided into trochanteric fractures and subtrochanteric fractures. Trochanteric fractures are located in a region between the greater trochanter and the lesser trochanter. Subtrochanteric fractures are fractures located below lesser trochanter. Each category can be subdivided even further based on whether or not the fracture is displaced, the shape of the fracture and the presence of loose bone fragments.

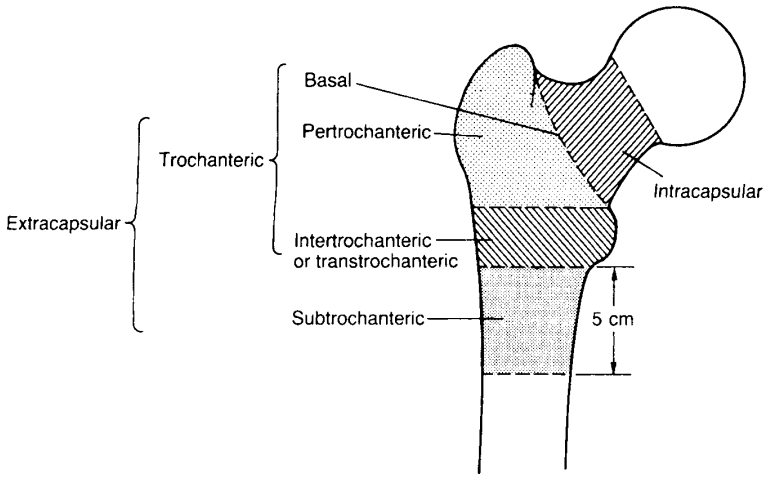


Figure 2-22: Hip fracture location classification [Parker, 1997].

2.7 Hip fracture procedures

There are several ways to treat hip fractures. For most types of fractures a surgical approach is recommended. Only with undisplaced intracapsular fractures sometimes a conservative (non-surgical) approach is selected. For the undisplaced or minimally displaced intracapsular fractures an internal fixation can be used. With an internal fixation two or more screws are placed inside the femoral neck. If the intracapsular fracture is diagnosed late or the fracture is associated with bone disease or arthritis the fracture can be treated with arthroplasty (a hip implant). For the basal, trochanteric and high subtrochanteric extracapsular fractures an extramedullary fixation can be used. These implants have a screw or a pin connected to a plate that is attached to the lateral side of the femur. The low subtrochanteric fractures and femoral shaft related extracapsular fractures are treated with an intramedullary fixation. With this fixation a nail is inserted via the greater trochanter into

the intramedullary canal of the femur. For patients with extracapsular fractions who refuse to have surgery or those who are unfit for any form of anaesthesia or just when there is a lack of surgical facilities or experienced surgeons the fracture can be treated with traction. This however causes a prolonged hospital stay (which can lead to other problems for the elderly patients). There will also be a very small group of patients who are not treated at all because their life expectancy does not justify the procedure or for patients that were already completely immobilized before the injury.

The available surgical techniques enable patients to be on their feet again a few days after surgery. From all options discussed above the internal fixation and the extramedullary and intramedullary fixation systems will be discussed further.

2.7.1 Internal fixation of intracapsular fractions

With the internal fixation a set of two or three parallel pins or screws is inserted into the femoral neck and head. The screws are placed parallel to the longitudinal axis of the femoral neck (see Figure 2-23).

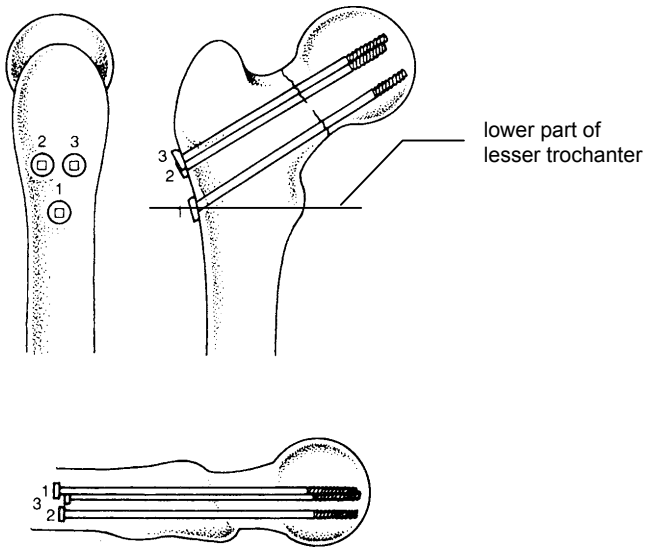


Figure 2-23: Intracapsular fixation with three parallel screws adapted from [Parker, 1997].

The entry point for the most distal screw is selected on the lateral femoral cortex at the height of the lower part of the lesser trochanter (horizontal line in Figure 2-23). Most screws are cannulated to insert them over a guide wire. The three parallel guide wires can be placed by using a drill guide that uses a centrally placed guide wire positioned exactly central in the femoral neck. Once this central guide wire is positioned the guide will be used to drill three parallel tunnels. Over these three guide wires the cannulated screws are inserted. The central wire is drilled freehand under fluoroscopic vision while using an axial

as well as an AP view (not simultaneous). Placing a guide wire on top of and along the femoral neck assists the freehand navigation. This wire is positioned with fluoroscopic images from two directions.

2.7.2 Extramedullary fixation of extracapsular fractures

With the extramedullary fixation methods a central pin or screw that is placed through the femoral neck and head is connected to a plate that is attached to the lateral femoral cortex. The Dynamic Hip Screw (DHS) is the most commonly used implant for this type of fixation. The DHS is also known as a compression hip screw or sliding hip screw. The DHS is called dynamic because it allows a limited collapse at the fracture site as the bone heals. This dynamic behaviour has eliminated several of the healing complications (non-union, joint penetration, cutting out the femoral head and breaking) that were experienced with the static fixation systems.

To create the tunnel for the screw of the DHS implant a guide wire must be positioned somewhat distal to the central axis of the femoral neck. This guide wire is placed in a similar way as with the internal fixation. Fluoroscopic images from the axial and the AP direction are used to control the guide wire placement. The angle between the inserted guide wire and the lateral side of the femur has to match the angle between the central screw and the femur plate of the DHS implant. The available DHS implant configurations are 135 and 150 degrees. To ensure an exact angle of 135 or 150 degrees a drill guide is used to position the guide wire (see Figure 2-24). To obtain a stable position the tip of the guide wire should engage subchondral bone. After the guide wire is placed the tunnel can be drilled and the screw is inserted. After inserting the screw the plate is attached and fixated onto the femur. The surgical technique of placing a DHS implant (in the Catharina Ziekenhuis) is discussed in detail in section 2.8.

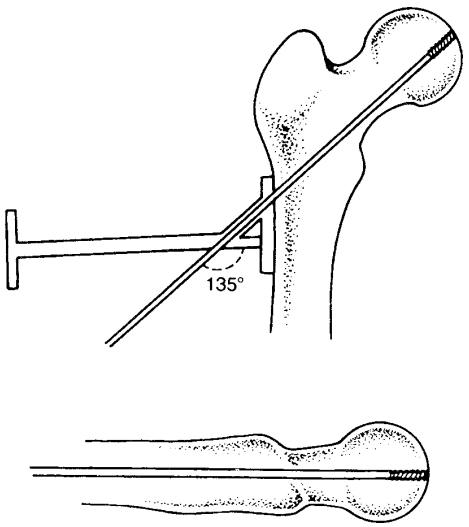


Figure 2-24: The DHS guide wire is positioned using the 135º guiding instrument [Parker, 1997].

2.7.3 Intramedullary fixation of extracapsular fractures

A common type of intramedullary fixation is the IntraMedullary Hip Screw (IMHS). The IMHS consists of a nail inserted via the greater trochanter with one or more cross screws inserted through the femoral neck and into the femoral head. The cross screw should be placed somewhat more distal to the centre of the neck in order to obtain better stability. Intramedullary nails are available in various types and shapes. After the intramedullary nail has been inserted the cross screw will be placed. This screw is inserted over a guide wire. This guide wire is placed with an external drill guide that is secured to the intramedullary nail (see Figure 2-25). The drill guide assures that the guide wire passes though the corresponding opening of the intramedullary nail with the correct angle. Thus, positioning the intramedullary pin itself controls the position of the wire relative to the femoral neck. The depth to which the nail is inserted determines the position of the cross screw on an AP fluoroscopic image. Rotating the nail controls the screw's position in the axial fluoroscopic view.

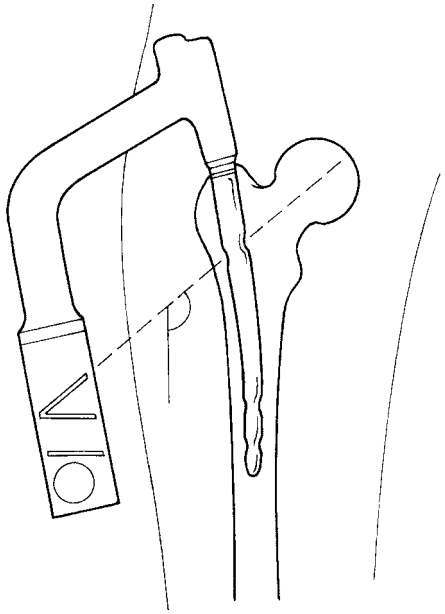


Figure 2-25: IMHS guiding instrument for guiding the lag screw and the cortical screws [Parker, 1997].

The distal part of the intramedullary nail is secured with screws. For shorter nails the external guide can be used to position the screws exactly though the nail (see Figure 2-25). For longer nails a mechanical guide will not work anymore to position distal locking screws. In this case the screws are placed under fluoroscopic vision. The C-arm is positioned so that the screw holes appear exactly round. Then a radiolucent drill is used to drill a pilot hole for the screw exactly through the nail.

2.8 Current DHS technique

The current DHS technique in the Catharina Ziekenhuis is based on the Synthes DHS system [Stratec Medical, 1995]. The complete procedure takes about two hours. The different steps in the procedure will be discussed below.

Step 1 Preparation
First of all, the patient is anaesthetised (general or spinal anesthesia). The patient is placed in a supine position and the legs are placed in a traction extension. Then the fluoroscope is positioned in order to obtain AP and axial views of the hip joint. Next, the sterile area is draped and the rest of the equipment is placed.

Step 2 Reduction
After the incision is made the proximal femur is exposed. With the traction extensions and (optionally) Kirschner wires the fracture is reduced.

Step 3 Positioning the central guide wire
Based on the location of the fracture the surgeon selects a DHS implant with a screw angle of 135 or 150 degrees. The corresponding insertion point will be at a distance of 2.5 to about 6 cm from the innominate tubercle (see Figure 2-26). Once the insertion point is selected the DHS angle guide (see Figure 2-27) is mounted in the lateral femoral cortex. An additional guide wire is placed on top of and along the femoral neck to assess the anteversion of the proximal femur. While using fluoroscopic vision from two directions the guide wire is placed in the postero-inferior quadrant of the femoral head. The guide wire is positioned in the subchondral bone. Once the guide wire is in place the surgeon measures the length of the guide wire in the bone and selects a corresponding screw length. The guide wire is left in place during the rest of the procedure.

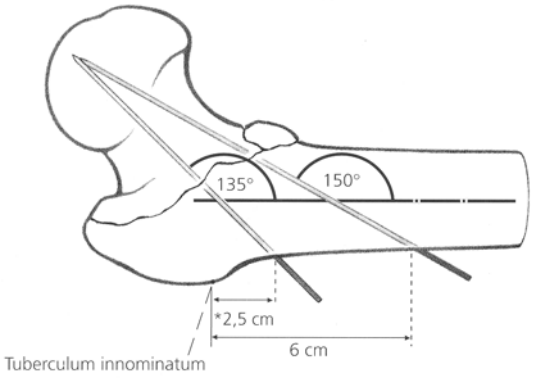


Figure 2-26: Guide wire insertion points for the 135º and 150º DHS screw relative to the tuberculum innominatum [Stratec, 1995].

Figure 2-27: DHS angle guide (135º model) [Stratec, 1995].

Step 4 Placing the screw

Once the guide wire is in place a tunnel is made with a special drill (DHS triple reamer, see Figure 2-28). This drill creates a tunnel with three different diameters: one for the screw, one for the plate barrel and one for the junctions between the plate and the barrel. After drilling the tunnel is tapped and the screw is inserted by using a centring device and a wrench. The plate can only be inserted correctly if the wrench handle is turned parallel to the femoral shaft (see Figure 2-29).

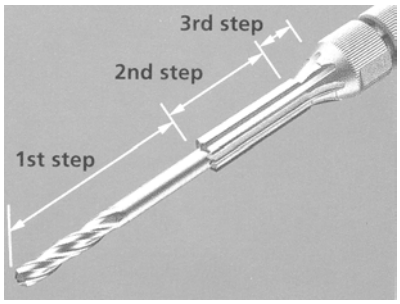


Figure 2-28: DHS triple reamer [Stratec, 1995].

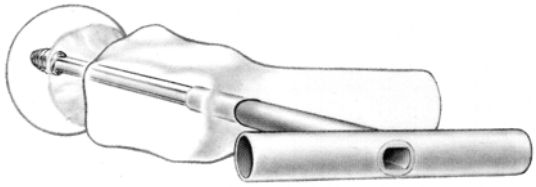


Figure 2-29: DHS wrench handle parallel to femoral shaft [Stratec, 1995].

Step 5 Mounting the plate

After the screw is in place, the surgeon slides the DHS plate over the guide wire. Next, the guide wire can be removed. The plate is hammered into the tunnel with an impactor and thus the fracture is impacted.

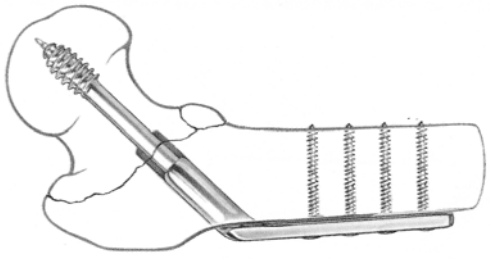


Figure 2-30: Completed DHS plate fixation with four cortical screws [Stratec, 1995].

Step 6 Screwing the plate onto the femoral shaft
After the plate has been positioned it is secured with a number of cortex screws of appropriate length (see Figure 2-30). The holes for these screws are predrilled with a 3.2-mm drill bit. As an alternative for the fracture impaction the fracture can be compressed by inserting a compression screw.

Step 7 Finishing up
After a fluoroscopic check of the final implant position (see Figure 2-31) a drain is inserted and the insertion site can be closed. The leg is placed in a padded splint and the bed-end is elevated. The patient will start directly with therapy (small exercises). Weight bearing exercises are started the second day after surgery. A routine radiological check is performed after two, six and twelve weeks and finally after one year.

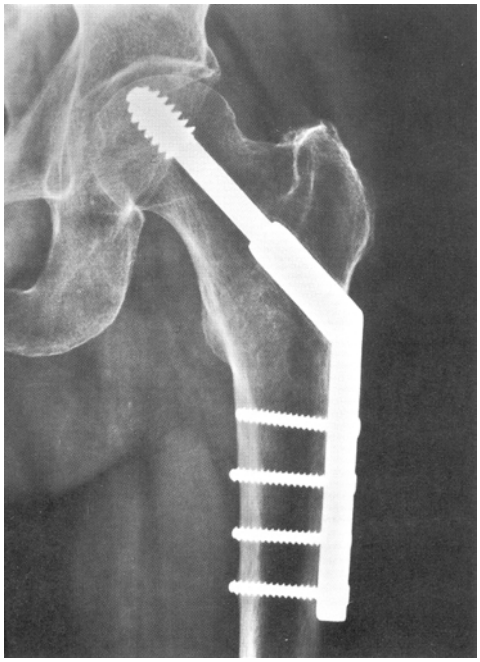


Figure 2-31: Postoperative X-ray one year after DHS surgery [Stratec, 1995].

2.9 Introduction into CAS systems

Computer-assisted surgery (CAS) systems first appeared in the neurological discipline. In cranial procedures the head is mounted in a frame before making the CT or MR images. During the procedures this frame can be used to match the operating room coordinate system with the 3D CT image coordinate system (a process called registration). An optical (stereotactic) positioning system can then be used to track surgical instruments and display

their location in the 3D CT image. If the frame's position is not fixed relative to the operating room coordinate system, the frame itself is tracked to assure the registration is not lost. Instead of using frames or markers that were already available during imaging, also anatomical landmarks or markers glued to the patient's skin can be used for the registration process (frameless registration).

Using CAS systems for orthopaedic surgery is a logical next step, because the rigid bony anatomy is also well suited for registration and tracking. At the time our project started back in 1996 some manufacturers of computer-assisted surgery systems had just made the step from the neurological field to the orthopaedic field. The first field application for computer-assisted orthopaedic surgery (CAOS) systems was the positioning of pedicle screws [Nolte, 1995], [Lavallée, 1995], [Foley, 1996]. With this system, the stereotactic positioning system assists the surgeon to accurately place screws in vertebra.

DiGioia describes the current surgical practice as a relatively loosely connected and sometimes uncoupled sequence of events: diagnosis and planning, execution of a surgical plan and postoperative measurement of the results of the surgical action [DiGioia, 1998b]. CAS systems provide a means to couple the preoperative planning to the surgical execution. CAS systems also provide an exact record of the surgical procedure itself. These measurements are used postoperatively to relate the surgical practice to patient outcome. If we know the effects of surgical actions on patient outcome we can improve our preoperative planning and thus link all formerly uncoupled sequences of surgical events. Thus, the use of a CAS system closes the loop in the surgical practice.

During this project, the number of commercially available computer-assisted surgery systems grew rapidly, especially in the field of orthopaedic surgery. Section 2.10 presents a general overview of CT-based 3D CAS systems technology.

2.10 CT-based 3D CAS systems

Preoperatively a set of CT slices is acquired. After these images are acquired the following steps are performed:

Segmentation
Optionally each image (slice) is segmented. For example, in orthopaedic applications the bone and soft tissues are distinguished to obtain a 3D model containing only the bony anatomy.

Rendering
The segmented images are combined into a three-dimensional patient model. With multi-modal images the information from different imaging modalities (for example CT and MR) is combined to form a more complete 3D patient model that contains not only bony anatomy but also soft-tissue information. The most difficult step in using the multi-modal images is to match (fuse) the information in both images (a process called image registration). The matching is difficult because the position of the soft tissue relative to the bony anatomy will differ in each image set (and perhaps even in each slice).

Planning
The 3D patient model is used to plan the surgery. This step provides tools to perform virtual surgery on the 3D patient model. If the patient model is combined with functional models (for example models describing bone and soft tissue interaction), even the surgical outcome can be predicted for the virtual surgery.

Registration
Registration is the process of matching the 3D patient coordinate system in the computer to the actual patient coordinate system in the operating room. Once the registration is complete all tracked instruments can be displayed in the 3D patient model. The gold standard for registration processes is the use of implanted markers (also called fiducial markers). These markers are implanted before the actual images are taken. During the registration process the surgeon selects a marker in the 3D data set and then simply touches the corresponding markers on the actual patient with a tracked pointer. Because using fiducial markers requires an extra surgical procedure to place the markers two other registration techniques are commonly used.

The first registration technique is paired point matching. With paired-point matching a set of reference points (for example anatomical landmarks) is determined in the 3D patient model. The surgeon is then asked to touch these reference points on the actual patient with a tracked pointer. From the set of paired points (a point in the 3D patient model and the corresponding point on the actual patient) the registration is calculated. The second registration technique is surface matching. With surface matching the surgeon digitises an area (surface) of the patient's anatomy by palpating that area with a tracked pointer and collecting a few dozen points for that area. The computer then matches the digitised area with the corresponding areas of the 3D patient model in the computer.

In most CAS systems a combination of paired point and surface matching is used to do the registration. Recently, several manufacturers explored the use of ultrasound to do the surface matching. Another development is the registration with a tracked C-arm system. The fluoroscopic image is matched to digitally reconstructed radiograph (DRR) images created from the 3D patient model.

If the matching process of the registration method assumes that the anatomy cannot change the registration is called is rigid. In case the surgical procedure concerns a single bone, the assumption of non-changing anatomy is true. To cope with soft tissue or several bones that are connected (for example several vertebrae) the matching process should weaken this assumption. Registration techniques that can deal with this are called non-rigid or elastic.

To avoid the need to repeat the registration process every time the patient moves, the patient (the parts of the anatomy that are under consideration) is also tracked. This tracker is used to compensate for patient movements.

Instrument calibration
Once the optical tracker is attached to the surgical instrument the tracking system needs to know the position of the tracker relative to the shape of the instrument. The instrument's shape can be loaded into the system by using its construction drawing (for example an AutoCAD file). Mostly the shape of the instrument is simply modelled by its mechanical axis and the position of the tip of the instrument. Almost all surgical instruments have a straight main axis and a clearly defined tip (for example screwdrivers, drills, pedicle ors, scissiles etc.). These instruments can be calibrated in a calibration station. A calibration station is a block of metal with a clamp that can hold the instrument in the direction of its main axis. The calibration station itself is tracked by the optical system. The tip of the instrument is pressed firmly against the bottom of the calibration station. Once the optical tracker is attached to the instrument the tracking system knows the relation between the optical tracker, the instrument's main axis and its tip.

Navigation
Intraoperatively, the location of the surgical instruments will be tracked and their position will be displayed in the 3D patient model. The tracking is performed with an optical tracking system. Early attempts to use electromagnetic (em) tracking systems failed because the operating room's permeability is not constant. Recently, some manufacturers have made em-systems that compensate for these distortions. Besides the optical and electromagnetic trackers, also mechanical and ultra sound trackers have been used. There are two ways of optical tracking: active or passive.

With active optical tracking a tracking plate with three or four LEDs (light emitting diodes) is attached to the instrument. This kind of tracker is called active because the LEDs need power. The light these LEDs emit is observed by two or more cameras. These cameras produce images from slightly different angles. With these images it is possible to calculate the active tracker's position in space.

With passive optical tracking a tracking plate with three of more reflective markers is attached to the instruments. This tracker is called passive because no power source is needed for the tracker. The camera system that is the same as for the active LED trackers has an additional infrared light source that transmits light in the direction of the trackers. The cameras register the light that is reflected by the markers and then calculate the tracker's position in space.

Once the instruments are calibrated and the system is registered the navigation can start. The positions of all surgical instruments are tracked and a digital representation of the instruments are displayed in the 3D patient model. The actual instrument positions can be compared to positions obtained in the preoperative planning. Some systems offer special user interface tools to realize the planning. A frequently used interface to position a drill along a previously planned trajectory (starting point and direction) is the use of a view along this planned trajectory and two circles. First, the 3D images are used to create a view along the planned drill tunnel. The centre of this image corresponds to the entry point of the planned drill tunnel. The planned direction is now perpendicular to the image plane. The actual instrument position is displayed by using two circles. The centres of these circles

represent respectively the tip and the end of the surgical instrument (or any other point along the instrument main axis). When both circles are exactly aligned (centres overlapping) in the centre of the image, the actual instrument position corresponds exactly with the predetermined direction.

2.11 Discussion

The medical background for the ACL reconstruction surgery and the hip fracture surgery provides a good first step to understand the problems that will be encountered when developing CAOS systems for these procedures. Because a CAOS system will be used intraoperatively it is very important to analyse the surgical procedure in the operating room itself. The CAOS system must be integrated seamlessly into the clinical workflow. Descriptions of the problems tackled by the CAOS systems as well as descriptions of the design of the CAOS systems will be discussed in the next chapters of this thesis.

Because we initially did not intend to include real time navigation, we decided to explore the use of 2D CAOS systems. The concurrent developments on 3D CAOS systems are described in chapter 8. This chapter will also discuss the similarities and differences between the 2D and 3D development approaches.

Chapter 3

Design methodology

3.1 Introduction

To find the best method to design computer-assisted surgery systems for orthopaedic procedures (CAOS systems) we will first look at the traditional design process and discuss the usability of several design methods (Section 3.2). Section 3.3 discusses some special considerations when designing systems for clinical practice. In section 3.4 rapid prototyping will be introduced along with its advantages especially for the design of medical systems. For successful rapid prototyping we developed a toolbox that contains all essential building blocks (discussed in chapter 4). This toolbox will be tested in several ways. First, the toolbox will be used to create computer-assisted measurement systems (chapter 5). Next, we will construct a prototype computer-assisted surgery system for anterior cruciate ligament surgery (chapter 6). Finally, we will try to develop more complex CAOS systems that use imaging information from multiple directions (chapter 7).

3.2 Traditional design

3.2.1 Design phases

Traditional design methods are based on a five-phase approach: analysis, specification, design, implementation and testing.

Analysis
In the analysis phase (or feasibility phase) the product as well as the environment in which the product has to operate are analysed. It must be clear what must be designed and what not. Results of the analysis phase are descriptions of the environment in which the product will be used, a detailed description of the product itself and a clear goal for the design process. As soon as a clear goal has been set designers should ensure they are not reinventing the wheel. This holds for the entire system as well as for parts. Reusing existing software components is not always the way to go. As Cluitmans states in his thesis [Cluitmans, 1999] reinventing the wheel is not necessarily bad. Sometimes adapting existing software takes more time than completely redesigning it. There is also a risk that an existing component may work now, but will give problems when you want to make changes later.

Specification
All functional and operational requirements are collated in the specification phase. Functional requirements are requirements derived from the *way* in which the product will be used. Functional requirements thus describe what the product has to do (the application requirements). They include the users' requirements. Operational requirements are requirements derived from the *environment* in which the product will be used. These requirements comprise legal, environmental, organizational, ergonomic, economic and social aspects. The result of the specification phase is a detailed description, often in a formal language, of the product. This description has to be completely independent of the implementation of the product. It describes *what* must be designed rather than *how* it will be designed.

Design
In the design phase the specifications will be grouped into modules. Specifications that obviously belong together or are related in some way can be grouped. The modules are constructed so that connections and communication between them are reduced to a minimum. The relations between these modules are described in their interfaces. Next, the interior of each module is designed. It is decided how the module will realize the behaviour described in its interface. The result of the design phase is a modular design of the product. Concurrent with the product design the user manuals, testing programs and maintenance programs can be designed.

Implementation
In the implementation phase the design is implemented in hardware, software or both. All modules are constructed and tested separately. Finally all modules are assembled and the complete product is built. The implementation phase will result in the actual product.

Testing
In the testing phase the complete product is tested. Errors are eliminated and small adjustments in the design may be necessary. The result of this phase is the final product complete with all necessary documentation.

3.2.2 Design methods

There are many design methods available. Some of these methods have been developed specifically for a certain type of product (e.g. integrated circuits, digital filters), others are developed based on the designer's discipline (mechanical engineering, electrical engineering, etc). However, all design methods contain the design phases described in the previous paragraph in some way. The names of the phases may be different and there can be some additional phases. The educational background of the designer often influences the choice for a certain design method. For example a mechanical engineer will search for a mechanical solution to a problem and select a design method that supports this point of view.

In the field of electrical engineering and information technology (IT), products often consist of a combination of hardware and software (often embedded). In this sector functional design methods such as Structured Analysis and Structured Design (SASD) are often used.

The application of a design method results in a prescription that is intended to lead to a solution that meets the requirements. These methods are used to control the design process. Traditional design methods do not have built-in design cycles. However, one never gets it right first time, so there will always be some alterations. It is very important to phase out errors quickly because, as the design process continues, it becomes increasingly difficult and more expensive to correct them. Thus, it is very important to get the specifications right before continuing with the next phases of the design process. To facilitate communicating between designer and client, the specifications should be made in a form that is understandable to the client.

Because our project will contain hardware as well as software components the design methods from the IT business and Software Engineering branches can be helpful. The design method should support the development of user-interfaces because this is an important part of a computer-assisted surgery system.

3.3 Designing medical systems

As with all designs, it is very important to keep the design of the medical system simple and straightforward. Many designs fail because the product is overloaded with features and the original goal of the product is lost. For medical systems, especially those designed for use in the operating room, it is imperative that no time is lost on non-essential features. A good product needs to function as designed, it needs to be simple in use and thus fast to learn. We can define the following criteria for a successful computer-assisted surgery system:

Besides being as simple as possible, a CAS system should:

- not be more accurate than necessary.
- be aimed at solving a real clinical problem that has no satisfactory solution yet.
- be tested with a large enough patient population.
- (eventually) support multiple applications within different surgical subspecialties.
- be designed to be an aid or instrument. It is very important that the environment defines the system, not the other way around. The design must not drastically change the current operating technique or the instruments used nor should it unnecessarily complicate other tasks in any aspect.
- introduce a minimum of extra hardware into the operating room.
- be designed in close cooperation with the different users, the orthopaedic surgeons and the OR technicians who actually operate the system. The surgeon is the most important source for functional requirements; the technician should be the most important source for operational requirements.
- leave complete control to the surgeon who has the final responsibility for the procedure. However, a system must ‘know’ its limitations and never produce false results when outside the limits it was designed for.
- comply with all safety and legal rules applicable to medical equipment.
- be designed for robustness and serviceability.

- only use additional information that can be collected at acceptable costs.
- always improve the quality of service to the patient and eventually show to be cost effective.

3.3.1 Design steps

For the design process of hardware or software for the medical field the first four phases can alternatively be described as:

1. Identification and analysis of the medical problem. Without an exact understanding of the problem there is a risk of building a system that solves the wrong problem.
2. Translating the problem from the medical to the technical domain. Medical problems are often presented in a way a technical designer does not understand. A typical example would be "we need to improve the reproducibility of surgical procedure x".
3. Creating a technical solution (if a technical solution appears to be the best solution).
4. Translating the solution from the technical to the medical domain. In this last and most important step the technical solution needs to be implemented so that the designed system can be integrated into the clinical setting without problems.

3.3.2 CAS system classification

Computer-assisted surgery systems can be classified according to the way they interact with clinical practice.

Critiquing systems
The simplest approach is the design of a critiquing system. Critiquing systems observe actions and comment on these actions only in case the results of that action are different from previously defined (expected or desired) results. Critiquing systems do not interfere directly with the surgical process. The surgeon is in complete control of the procedure. Critiquing systems can best be compared with a colleague, teacher, trainer or specialist who comments on actions and may advise an alternative course of action.

Guidance systems
A more radical approach is the design of a guidance system. In this case the computer will guide the surgeon in placing the instruments. This approach requires real-time feedback concerning the position of the surgical instruments and the anatomy. The actual situation must continuously be compared with the model situation. The system will inform the surgeon when instrument position is in agreement with model position. However, to provide real time instrument and anatomy feedback it is not necessary to have continuous fluoroscopic imaging. Instruments and anatomy (patient) position can be tracked with an optical system and then displayed in pre-operative CT, MR or X-ray images.

Robot systems
The most advanced approach would be a robot surgery system. This is a combination of the guidance system described above and a robot (mechanical arm). The robot would operate surgical instruments (e.g. a drill) guided by the guidance system. Besides visual information from medical images surgeons also use tactile information to perform the surgery. In order to perform equally well a robot system must be able to use these sources of information

also. Using a robot surgery system does not imply that the robot completely replaces the surgeon. The robot system can be seen as an 'intelligent instrument' that facilitates a certain task. The surgeon, who controls the system, stays responsible for the procedure.

3.3.3 Software design

An essential part of the design of computer-assisted surgery systems will be the software design. According to Rosen [Rosen, 1998] writing software for the clinic is no different than writing any other software if you are already using good software development practices. He advises to keep the software design simple and straightforward. Rosen states that when writing software for the clinic the designer is often under pressure to deliver a product before he even understands all of the problems or how to solve them. In these situations he advises to use an incremental development approach. Create a simple operating version of the software with few features, then add functionality in steps such that there is always a tested operating version of the software.

As described in section 3.2 software design contains the steps: analysis, specification, design, implementation and testing. The most important and difficult step in the design is the specification. Rosen mentions that statistics indicate that 60% of all software faults are really specification errors. Obtaining software specifications from medical specialists resembles knowledge acquisition for the design of expert systems. Designers of expert systems use tools (models of domain) to extract all relevant information from the expert. In a similar way, prototyping tools can be used to facilitate communication between the specialist and the designer and thus extract the specifications. For clinical software it is important that the design plan includes a hazard analysis. A designer should expect the software to be used in unintended ways. For clinical software maintainability, portability, reliability and execution-speed are important properties. To create a maintainable system proper documentation is very important. To make it portable the designer should use operating system defaults and try to avoid hardware specific code.

3.3.4 Design specificity

One of the potential pitfalls of designing medical systems is a too specific design. If a system is based on the expertise of a single specialist there is a risk to build a system that has only one client. Ideally, a system would be optimally commercially viable if it is usable by many surgeons, for many techniques, for many procedures, in several medical disciplines and in all hospitals. On the other hand systems must not be too generic. Generic systems often have a complex user-interface to provide access to all its functions. The importance of the user interface will be explained in the next section. To provide a balance between a tailor made and a generic application the developer should focus on the surgical procedure. A CAS system should support all techniques and instrumentation commonly used for a surgical procedure, and offer a way to expand this set. In this way every surgeon who performs the procedure can benefit from its use. Supporting several techniques and instruments does not mean designing different systems since the final goal of the procedure will be the same for all different combinations. For example, in ACL reconstruction there are several surgical techniques based on the type of graft (patella tendon and hamstring), the access technique (transtibial, rear entry), the number of bundles (one or two) and the referenced anatomic landmarks (condylar roof, tibial spine, the PCL). Every technique has

it own set of surgical instruments. In all cases the goal is the same: make a tunnel and insert a new ACL graft.

Another way to make CAS systems usable in different situations is to focus its design on a specific surgical action. A frequent surgical action in the field of orthopaedics is drilling a guide wire. Drilling guide wires is often the first step to drill tunnels, place screws or position implants. To make the system useful for this action it should support drill path planning using all sorts of pre-operative images. It should also contain a surgical navigation system that guides the surgeon in executing the plan. The system should be able to work with all types of guiding instruments and drills. This approach can be seen in stereotactic navigation systems. These systems provide real time instrument tracking and they can also display the position of the instruments in the medical images.

3.3.5 Designing user interfaces

In the operating room everyone needs to be fully concentrated on his or her job. A user interface should therefore be simple and straightforward. The user interface should only contain the essential elements necessary for the job at hand. A good design should be based on the requirements of the user. As discussed before it is important to define who the user is. If the surgeon controls the system the user interface may need to be completely different than when an operating room technician controls the system.

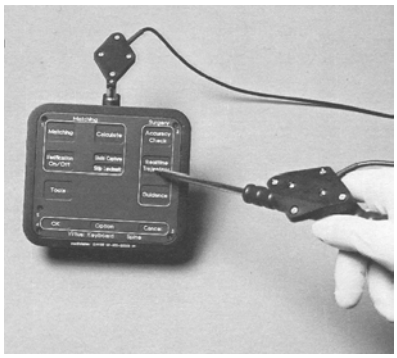


Figure 3-1: Virtual keyboard.

The surgeon is in the sterile operating field and thus the user interface controls must be sterile too. There are several ways to make sterile controls. First of all, it is possible to pack standard non-sterile controls in a sterile package. If the controls are not too complex, pedals can be used. Pedals do not have to be sterile since they are put on the floor. If a 3D positioning system is available it is possible to design special 'virtual' keyboards. Such a virtual keyboard does not have actual buttons. The keyboard is tracked with the 3D positioning system and the surgeon can select options by touching the virtual buttons with a pointer or other surgical instrument that is tracked by the same system (see Figure 3-1). Since the keyboard itself can be an engraved metal plate it can be sterilized easily. Another way to create a sterile way to control is voice recognition. Voice recognition, in the old fashioned way, is the oldest way to create a sterile control: the surgeon just tells an assistant

what to do. Nowadays, it is possible for computers to be controlled with the human voice. This technology enables the surgeon to pass instructions to the equipment directly. Finally, there have been attempts to control robot arm systems with a head mounted control. A motion sensor in this device translates the surgeons head motion into robot motion. To prevent unwanted robot motion the surgeon had to press a pedal simultaneously. As these controls expect the surgeon to make extra and perhaps even unnatural movements, they will not be accepted easily.

If the surgeon is too busy with surgical tasks or the necessary controls become too complex for a simple sterile user interface, the system has to be controlled by an operating room technician. In this case the surgeon's influence on the user interface will focus on the functional requirements of the system, that is the surgeon controls the functionality the user interface provides at a certain time. The actual system operator, in this case the operating room technician, will provide the operational requirements of the system. As described in the previous section it is dangerous to focus user interface design on one single user. However, the user interface provides means to tailor an application to an individual user. If the program is equipped with an adaptable user interface it is possible to create an individual interface for each user. Customizing the user interface to meet an individual user's demands is quite common in software. Microsoft's word processor Word for example has adjustable toolbars that allow the user to customize the interface. Frequently used functions can be made available on the top level of the interface.

Modern programming languages, such as Borland Delphi, provide many components to build user interfaces. All standard user interface elements like menus, toolbars, boxes, panels and buttons are available in a graphical development environment. The programmer just draws the user interface and then adds the functionality. Such a development tool enables rapid prototyping of user interfaces and allows the programmer to try out user interface ideas quickly. User interfaces designed with these tools can be tested before the actual functionality of the program is available.

Every surgical procedure has a protocol. The protocol describes the steps of the procedure, the necessary equipment and instrumentation. This surgical protocol can be used to design the user interface. If the computer system encompasses the surgical protocol, the user interface can restrict its available options to those tasks that need to be performed in that step of the procedure. All user interface (UI) controls for essential tasks of the computer-assisted surgery system that are not relevant in the active step of the protocol can be hidden. This provides a simple, dynamic user interface driven by the surgical protocol itself. This protocol driven user interface can be implemented as a state machine or Petri net. Each state corresponds to a step in the surgical protocol. In a state the user interface only displays controls for the system tasks in that step. The active state can be presented to the user in a UI control such as a drop down box. State changes are invoked by the user by selecting the next state from the state transition box (a user interface element) or by completion of a certain task.

3.3.6 Market pull vs. technology push

In a market pull situation the development of a product will be initiated when customers signal a problem and ask for a product that solves their problem. In the technology push situation a company develops a product and tries to convince customers they need it. In the latter case the product idea will have originated in the market too, so it is not easy to make a clear distinction between the two. In the development of medical products we also see both mechanisms. In our case (the development of a computer-assisted surgery system for anterior cruciate ligament surgery) the question came from within the medical community. An orthopaedic surgeon wanted to improve the reproducibility of the reconstruction procedure and he wanted this improvement implemented in some sort of computer-assisted surgery system. As this surgeon was familiar with the general concepts and possibilities of CAOS systems he knew what to ask for. Often customers do not know the full potential of the current state of technology. In this case designers present the state of the art possibilities to a small group of customers and together they start looking for possible application areas. This is also the way most medical systems are developed. Before any medical system prototype can be turned into an actual product it is necessary to prove its clinical relevance in a trial series. These trial series are impossible to realize if companies do not cooperate with surgeons. So, even if the first idea to start making a new product originates from the company side the clients will be involved in the development process before the final product is marketed.

3.4 Rapid prototyping

The use of prototypes is well known from the motorcar industry. Manufacturers display their concept cars at every motor show. This is not only because they want to show their customers what they can do. Newly designed cars are used to trigger feedback from customers. Based on the customers' reaction to all aspects of their cars, the design team will select some of these aspects for the construction of future models. The development of these cars entails much time and effort. For the development of a software package the timeframe and budget requirements are much stricter.

3.4.1 Why prototyping?

In traditional design methods the client is expected to provide the designer with all requirements for the final program. To do this the client needs a clear idea of what the final program should do and how it must do it. In normal circumstances, however, the client has a problem and he hires a software designer to solve this problem. By using a prototype the designer can get all necessary feedback from the client, collect all requirements and define the final specifications. The prototype is a very suitable instrument to facilitate communication between developers and clients. The designer can use the final prototype as a 'living' specification.

3.4.2 What is rapid prototyping?

Every company wants to produce higher-quality products on shorter schedules. The use of a prototyping process can help ensure that a program meets the customer's needs and that the developers understand all the requirements. Isensee and Rudd list the following

characteristics as descriptive of a software prototype [Isensee & Rudd, 1996]:

- quickly functional
- a miniature model of the final system
- easy to modify
- a working model written in a fourth-generation language
- often rewritten in a procedural language for implementation
- a model to determine design correctness
- a quick way to approximate a problem solution
- often discarded
- something that models human interfaces to computers
- something that promotes communication between developers and users
- the nucleus of an evolving system
- not operating at high-performance levels
- not intended to be the final system
- not having advanced system features
- a display mock-up of reports and screens
- a feasibility study
- always used with 'real' data
- a requirements definition strategy
- a blueprint for programmers to follow in writing the final program
- a vehicle for conducting early usability testing
- a marketing tool for early customer demonstrations
- a method of creating a clear and understandable interface specification
- a method of comparing alternative implementations
- an early aid for writing user documentation and help information

Isensee and Rudd define six types of prototypes. Factors that influence the choice what prototype to use are: available development time, programming skills of the designer, the degree to which the prototype must resemble the actual program and the re-usability of code from the prototype. Of these six types, two are suitable for our project: the domain-specific prototype and the language prototype.

Domain-specific prototype
Domain-specific prototypes are constructed using tools that are designed specifically for building special kinds of applications. They focus on a narrow domain and provide facilities for constructing applications very quickly. For the CAOS domain (computer-assisted orthopaedic surgery) no commercially available tools existed. It is possible however to use a general prototyping tool in combination with a domain-specific library. Such a library could for example contain components for: image-acquisition from fluoroscopes, image processing and storage, overlay generation, object-recognition routines, calibration and distortion correction of fluoroscopic images, measurements, and data collection and analysis.

Language prototype
Language prototypes are written in the same programming language as used for the final product. This type of prototyping is also called incremental prototyping. These prototypes aim at performance and a high level of functionality in the prototype. For our project it is very important to have a fully functional prototype which can be used to collect data. These data are necessary to validate our approach. Rapid Application Development (RAD) is a form of language prototyping in which the prototype evolves into the final product.

3.4.3 Advantages of prototyping

Prototyping offers many advantages. For our project the following advantages will be especially helpful:

Improved collection of user requirements
As discussed earlier, a prototype provides excellent means of communication between the designer and the customer. The designer can incorporate all known requirements into the prototype. By using the prototype and giving comments, the client can fill in missing requirements or suggest changes or corrections.

Evaluation of new interface techniques and functions
A prototype is an excellent environment in which to test new interface techniques and new program functionality. The designer can receive immediate feedback from the customers about new ideas.

Demonstration of feasibility
A prototype gives the designer the opportunity of demonstrating the feasibility of a product. The prototype can be used to investigate if there is a market for the product without the expense of developing the final product.

Early testing
Testing the prototype can begin in the first stage of the design process. This implies that errors will be discovered quickly, when they are still easy to correct. In our case testing can also be combined with the early collection of data.

A clear specification
In the software engineering branch specifications have to be crystal clear. If the specifications are ambiguous the final program will not be precisely defined. Therefore, large documents filled with formal descriptions are produced. In these formal languages, however, it is extremely difficult to describe such aspects as user-interface and program navigation. It is impossible for most customers to understand this document and review the specification. If a prototype is used as a specification this problem disappears. The ‘living specification’ (prototype) will also be much easier to understand for the programmers who will implement the final product.

Marketing demonstrator
Besides these advantages the prototype can serve as a sales tool. If customers can participate in the design of the product they are likely to find that it meets their demands.

Because this customer-designer interaction starts directly, errors are more frequently corrected in the beginning of the design process. Correcting errors as soon as possible saves money. Another advantage of rapid prototyping is the fact that customers can see that their suggestions are being implemented directly. Prototyping thus not only helps to improve design but it also helps to satisfy customers.

3.4.4 Prototyping pitfalls

Prototyping also has disadvantages. Designers need to learn about the prototyping process and the possibilities of the prototyping tools. Because learning to use the prototyping approach takes time, it will not immediately yield an increase in productivity. Choosing the representativeness and the fidelity of the prototype (the level at which the prototype resembles the actual product) is not an easy task. Unless rapid application development is used, it is also very important to remind the customer that the prototype is not the final product. After the prototyping process the final product must still be developed by using a traditional design process. Designers must also guard against the never-ending prototype. It is important to stop prototyping as soon as all specifications have been defined and met.

3.4.5 Requirements for the rapid prototyping process

The key elements in successful prototyping as described in [Isensee & Rudd, 1996] are speed, iterative or incremental design, domain expertise and early completion. Prototyping must be done fast and therefore it is essential to use a modular design approach and to re-use software where possible. All re-usable software components can best be collected in a software library. Prototyping is an acknowledgment of the fact that one never gets it right the first time. For successful prototyping it is also essential to use the expertise of a domain expert. Domain experts know best when the program is ready. Finally, it is important to complete the prototyping process before the actual coding starts. In this way we have customer-approved specifications and the final product can be developed without further delay.

3.4.6 The rapid prototyping process

The rapid prototyping process consists of three phases: identification of customer requirements, concept validation, and final prototype development (see Figure 3-2).

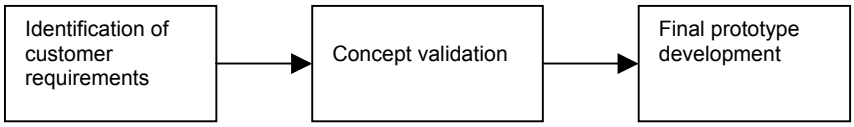


Figure 3-2: Rapid prototyping design process.

In the first phase the problem and the problem environment are explored, the initial customer requirements are collected and all constraints are identified. In the second phase, which is an iterative process, the key concepts of the application are explored. In this phase user-interface elements and different approaches and techniques are tested and compared to extrapolate what the essential functionality of the final application must be. This phase results in an initial prototype, test data and an initial design specification. The third phase is

the development of the final prototype. During this phase, which is also iterative, all functionality will be prototyped as completely as possible. The user-interface and all functions will be prototyped completely with help facilities and error handling. The result of this phase is a 'living specification' of the final product. The prototyping process will provide the developers of the final product with all the information they need. The final prototype is usually not the final product. Although the final prototype demonstrates all functionality it has not been optimised for stability, neither completeness nor execution speed. In the case of rapid application development (RAD) the final prototype is the product. RAD development tools therefore have an optimised toolbox and offer a stable application framework.

The selection of a rapid prototyping tool is an essential part of the design. The tool must support the kind of functionality that is needed for the product. However, the more specific a tool is, the harder it will be to find it. After the first phase (identification of customers' requirements) an appropriate tool can be selected. The efficiency of a prototyping process is based on the available library. For rapid development a modular approach and software re-use is an absolute must.

3.5 Rapid prototyping of CAOS systems

As rapid prototyping has proven to be effective to develop medical systems we will use this design approach to develop computer-assisted surgery tools for orthopaedic procedures in which fluoroscopic imaging is used intra-operatively. The prototypes will provide a means of communication between developer and medical specialist and make it possible to create a clear specification. In this section we will present a way to perform the first phase of rapid prototyping for designing medical systems. We will present a step-by-step description of a process that can be used to find a procedure that can benefit from a CAOS system and identify the first set of user requirements. This process is based on our experience with developing software for the clinic. After collection of the initial user requirements we can select a prototyping tool.

3.5.1 Select a surgical procedure

- Learn the basic medical terms and brush up the anatomical knowledge.
- Search for orthopaedic procedures in which pins, wires or screws are positioned and in which fluoroscopic imaging can be (or are already) used.
- Select a surgical procedure from the set of possible procedures for which a computer-assisted surgery system would be beneficial.
- Search a surgeon who is willing to cooperate with new research. The surgeon should be open-minded for improvements in a technique that is generally considered to be adequate. Besides all this the surgeon must have experience with the selected procedure.
- Demonstrate the development toolbox (preferably via a demo program or a previously developed computer-assisted surgery system) during an initial conversation and explain how it may be exploited to create a prototype. By discussing the possibilities and limitations of computer-assisted surgery systems it is possible to form some common knowledge on the subject. Make sure the developer understands the surgeon and vice versa.

- Discuss if there are any tasks in the procedure that might be a candidate for improvement. If there are no apparent problems or no indications that some part of the procedure is sub-optimal the selected procedure is unsuitable for a CAOS system. If there is no actual medical problem one should not try to improve the procedure. It should be the surgeon's responsibility to decide if there is a problem that can be tackled by a CAOS system.

3.5.2 Analyse the selected procedure

The result of the first step should be an idea about which surgical procedure to consider and which surgeon to cooperate with. In the next step the developer will need to learn more about the selected procedure.

- Read the instruction manual for the surgical instruments used. These manuals often contain an accurate description of the surgical technique.
- Read the procedure protocol. In every operating room there will be a protocol book that describes all procedures and the instrumentation used.
- Perform a thorough literature review. Focus not only on technical literature about computer systems for this type of surgery but also on medical literature describing surgical techniques, instrumentation and equipment. Medical research often focuses on trials describing techniques and materials. Concerning the medical and technical articles the designer should not only focus on the exact type of surgery selected, but also should study similar procedures.
- Ask the surgeon to explain the procedure, by using the collected literature, anatomical models and miniatures, sawbones and if possible the surgical instrumentation.
- Visit the operating room and observe the procedure first hand. Observe the general operating room layout, observe the intra-operative images, look at pre-operative images, listen to the surgeon and, if possible, ask for a step-by-step explanation of the procedure as it is performed. The least intrusive time to visit the operating room is when the surgeon is training an assistant. During these sessions he explains elaborately what the difficult steps in the procedure are. In the latter case it is very important to study all medical terms relevant to the procedure because otherwise you won't understand the explanation.
- Ask 'why' whenever the surgeon does something that differs from the description in the instruction manual. Surgeons hardly ever follow procedures exactly as they develop their own techniques. Also whenever possible the surgeon will combine procedures if necessary. As with the construction of expert systems the knowledge elicitation is one of the most difficult steps. Make sure not to overdo the 'why-ing' because the line between curious and annoying is very narrow, and concentration is a must for surgeons.
- Operating room technicians and assistants are an excellent source of information. They are very familiar with the procedure and they have more time to explain the procedure. For minimal invasive surgery with local anaesthesia the assistants often explain the procedure to the patients and thus their vocabulary is less medical. The assistants also assist in the surgery itself and thus they are familiar with all aspects of the procedure. They are also the most important source for information about operating room layout, organization, surgical instruments and procedure time.

- The X-ray technicians are an excellent source of information for all image-related questions. They are familiar with the bony anatomy and know how to display it. X-ray technicians can explain what influences image quality and what problems can be expected with these images. Experienced assistants also know which images the surgeon uses and why.
- All operating room personnel described above can provide the designer with an impression of the essential and difficult tasks during surgery. They will certainly not make the same remarks. The surgeons will comment based on their own technique. The operating room assistants can compare the techniques of different surgeons and thus comment on differences and conclude which parts of surgery are most difficult.

3.5.3 Define the essential tasks

The first few procedures a developer visits will provide a general impression about the surgery. Especially during the first procedure one may not see anything useful because one does not know what to look for and everything is new and exciting. The next step in the design is to look for essential or difficult tasks where a CAS system could assist the surgeon. In this process it is important to remember the benefits of computer-assisted surgery systems. CAS systems enable image acquisition, enhancement, analysis, calibration, correction and storage. They provide means to measure distances (relative or absolute), angles and radii. CAS systems also enable displaying of overlays for anatomical references and instrument locations, they can extend drill paths and virtually place grafts, instruments or prosthetics. Many orthopaedic and trauma procedures have an essential task in positioning a tunnel in which a graft, screw or guide wire is inserted.

Study medical literature and try to find if there is consensus about the optimal drill positions for the procedure at hand. If there is no consensus, because there are several surgical techniques for the procedure, it may be possible to make an adaptable system that supports all commonly used drill positions.

3.5.4 Define the models (graphics overlays)

A CAOS system should help the surgeon to place the tunnels or at least to help evaluate the position of the proposed tunnels intra-operatively. The location of the proposed tunnel can be detected from intra-operative fluoroscopic images by analysing the actual position of the guiding instruments. To perform this intra-operative measurement of tunnel position the designer needs to know how a surgeon judges the position of the aiming instrument. In a next step the designer must implement this judging in the CAS system. Aiming devices reference anatomical landmarks (soft tissue or bony landmarks). In case bony landmarks are used one should try to create a model (overlay) that derives desired guide-wire locations from these anatomical references. Also models for instruments and implants can be included. Try to make a virtual-placement based on the locations of the anatomy, the guiding instruments and the implant models.

Summarizing we can create the following models:

- Anatomical models: for fluoroscopic images these will often consist of bony anatomical landmarks. Select those anatomical landmarks the surgeon uses to locate the desired drill paths and to perform implant positioning.

- Instrument models: Instruments consist of mechanical parts that reference the anatomical landmarks (soft tissue or bone) and parts that guide the drill wire. For a drill guide there will be a drill entry and a drill exit point (or a drill direction). These two points can be used to predict and display a virtual version of the drill path.
- Implant models: These models contain a model overlay of the implant. The implant can be a screw, graft, prosthesis, pin or plate. The implant model (overlay) is positioned according to the position of the anatomic and instrument models. This model will thus display the virtual result of the procedure.
- Combined models: Most drill guides reference anatomical landmarks and guide the drill wire to an aiming position (incorporated in the shape of the instrument). Overlay models for anatomic references and drill direction can often be combined.

The overlays of the measurement tools (distances and angles) are connected to or integrated with the other models. They take care of displaying the intermediate surgery results.

3.5.5 Check constraints and requirements

- Analyse all constraints (medical, technical, legal, organizational, ergonomical, financial and temporal).
- Collect all user requirements. Ask the different users what functionality they expect to find in the program. Also ask how they would want the results to be presented.

After the analysis it is time to build a first prototype. It is important to focus on essential tasks and not to spend time on optimising parts or on making it fully automatic.

3.6 Discussion

In this chapter several aspects of designing medical applications were discussed. Considering the design process, the medical field does not differ from other areas. The most difficult part of the development process is the definition of the specifications. Rapid prototyping proved to be an excellent way to communicate with the client and build a ‘living specification’. We used evolutionary prototypes that contained the complete functionality for the system under construction. In this way, the CAOS systems could be evaluated clinically with the prototype itself. To make the rapid prototyping process effective we implemented a toolbox that contains generic as well as domain specific libraries.

Chapter 4

The rapid prototyping toolbox

4.1 Introduction

Based on our previous experience with developing software for the clinic and the analysis presented in the previous chapter we will use the rapid prototyping design approach for the development of the computer-assisted measurement and surgery systems. It was explained in section 3.4 that the prototyping cycles must be carried out quickly. It was also explained that starting all over is common in a rapid prototyping process but that this does not imply that nothing is re-used from the previous-generation prototype. Re-using software is one of the essential aspects of prototyping. It is therefore necessary to develop, implement and maintain a toolbox (module library) with re-usable software components. The module library should contain general as well as domain-specific components. The general components should include all user interface elements to create windows, menus, toolbars, buttons and input controls. These general component-libraries are provided with the prototyping tool or in the programming language. Examples of programming languages with rapid prototyping support are Borland Delphi, Borland C++Builder, Microsoft Visual C++ and Microsoft Visual Basic.

Besides these general component-libraries we also need domain-specific component-libraries (libraries for the construction of CAOS applications for orthopaedic procedures). Our domain-specific library comprises modules for image acquisition, display, and processing; for graphics overlay generation and interaction; and for measuring distances (relative or absolute), angles and radii. For each of these modules the requirements will be presented. We will discuss what was already available and what we developed ourselves. Finally, a generic CAOS program will be constructed to test all individual library components. This generic program can then be used as a prototyping tool (development tool) or as a basis to develop more specific CAOS programs.

4.2 Image handling

During surgery an orthopaedic surgeon routinely uses arthroscopic, fluoroscopic and preoperative images.

The most important means of navigation for the surgeon are the arthroscopic images. The arthroscope is a miniature camera system used during minimal invasive surgery. It provides the surgeon with live video from within the joints. Because arthroscopic images are not easy to interpret even for a human observer, the main source of image information for a 2D-plus computer-assisted surgery system for orthopaedic surgery is the fluoroscope.

The fluoroscope, also called a C-arm because of its C-like shape, is a mobile X-ray device suitable for intra-operative use. The fluoroscope consists of an X-ray tube and an image intensifier. The image of the image intensifier is recorded with a CCD camera. The images from the CCD camera can be stored on an internal hard disk and they can be transferred to magneto-optical disks, for storage or printing. Most fluoroscopes have two monitors, one for the "live" and one that holds the last stored image. These monitor signals can be made available externally.

With most modern fluoroscopes the manufacturer can provide a DICOM interface that can be used to transfer images via a network. DICOM is a standard for medical images. DICOM is more than an image format; it is also a protocol that allows hardware to access, provide and store the images.

Pre-operative X-ray, CT or MR images can also provide valuable information for a CAOS system. Pre-operative images are used for diagnosis and for surgical planning. In radiology departments there is a trend to go ‘filmless’. Most pre-operative images are still on film but with the growing number of PACS in hospitals, the digital availability of these images will increase. Most new imagers and computer equipment can be integrated in a digital network.

4.2.1 Acquisition

In this section the possibilities will be discussed for image acquisition of pre-operative and intra-operative images.

The pre-operative images can be acquired directly from the image modality if this supports network access, for example via DICOM. If the images are only available on film a special high-resolution film scanner can be used. Instead of these special scanners it is also possible to use a ‘standard’ flatbed scanner that is equipped with a transparency adapter. Transparency adapters are available for several types of ‘standard’ scanners. To handle all film sizes the scanner needs to be able to handle at least A3 size films. To integrate the scanner control directly with the CAOS application the TWAIN protocol can be used. TWAIN is a universal image capture API for Microsoft Windows and Apple Macintosh that supports functions for selecting an image source and acquiring the images.

The intra-operative fluoroscopic images have to be obtained via the video outlet of the C-arm since the available C-arm is not equipped with a network interface. The video signal, which is a standard PAL signal, can be captured with a framegrabber. A framegrabber is a personal computer expansion board that can digitise standard or non-standard video signals. Capturing video can also be done with some modern videoboards (which contain a framegrabber). Manufacturers provide drivers and programming libraries to control the image acquisition.

Requirements
When the framegrabber board is replaced by another model we do not want to change the CAOS program itself. To keep the CAOS program independent of the hardware we need a generic framegrabber interface layer that supports all necessary image acquisition functions (select input, grab single image, grab continuous images, save image). Besides the framegrabber interface we need libraries for image import and export in various file formats (like Bitmap, JPEG and TIFF). To support our HP scanner (with transparency adapter) we can use its TWAIN interface. In our CAOS application we want to store all single images that were digitised (to create a patient record with intra-operative images that were used during the procedure). For this we need a function that combines the acquisition of a single image and a save action.

Available libraries
With our Matrox Meteor framegrabber board the manufacturer delivered several drivers and a small programming library, called MIL-Lite (Matrox Imaging Library). This library supports all required acquisition functions, several image display and processing functions and file handling for Bitmap and TIFF images. For the Borland programming environments many component libraries are available. A suitable library for image processing is ImageEn by Encomps. This shareware component library supports the file import and export functions for images (JPEG, TIFF, PNG, BMP, PCX, GIF, WMF, EMF, ICO and CUR) as well as image acquisition from TWAIN scanners with full control of the scanner capabilities (optionally without the default scanner user interface).

Own developments
Based on the framegrabber library the following generic interface functions are developed:

- **open_framegrabber** / **close_framegrabber**
- **select_input**
- **grab_single** / **grab_continuous**
- **save_single**

The CAOS program uses this generic framegrabber interface. If the framegraber is replaced these four functions have to be created for the new board (on top of the programming library provided by the manufacturer). Our framegrabber board does not have memory of its own. Instead it shares memory with the host computer. With the **open_framegrabber** function the framegrabber is initialised and the shared memory is allocated. The **close_framegrabber** function closes the board and frees the shared memory. With the **select_input** function one of the four video inputs can be selected. The **grab_single** and **grab_continuous** functions store the raw images in this shared memory. The **save_single** function takes the last stored image in shared memory and saves it to disk. For file transfer the framegrabber driver supports several image formats including the Windows bitmap. Bitmaps are the native image format in Windows. A bitmap contains an uncompressed two-dimensional pixel array so they are very suitable for image manipulation.

As an extra option a remotely controlled grab mechanism was developed. The framegrabber board has a trigger input that can be used to start a single image acquire cycle automatically. We developed an infrared remote control unit that triggers a function that

grabs a singe image and stores it to disk. With this remote control the surgeon can use the system from the sterile operating area without the need for an extra operator.

4.2.2 Display

After acquiring the images they must be displayed. For single images the framegrabber driver can save the raw image data to file (**save_single** function) or transfer it directly to the computer display. For live images the framegrabber can transfer the image data directly to the display memory. In order to display live video at 25 frames per second, the framegrabber driver communicates directly with the display drivers by using direct memory access (DMA).

Requirements
As with the acquisition functions we want to develop generic framegrabber interface functions that support the display functions (display a single image, display images continuous). The single image display function should be able to display the most recent image from shared memory or display a previously stored image. The continuous display function should provide 'live' video in a separate window.

Available libraries
Every general programming tool for the Windows environment provides components to display images. Display functions are included in the Borland development environment itself but also in the ImageEn component library. A library for displaying continuous images was provided with the framegrabber board.

Own developments
Based on the framegrabber and the Borland libraries the following generic interface functions were developed:

- **display_single**
- **display_continuous**

The **display_single** function displays a saved digitised image by using the Borland TImage component. This TImage component implements a drawing surface (Canvas) that can display bitmap images and manage their colour palette. The **display_continuous** function provides a wrapper for the corresponding framegrabber's library function. In Windows, programs can access the display memory via a device context. The **display_continuous** function passes the identifier of the live display window (a Windows handle) to the framegrabber library. The framegrabber library then uses this handle to allocate a device context to the corresponding part of the display memory and draws the live images directly into that window.

4.2.3 Processing

The raw image data usually have to be processed before the image is displayed. The imaging modality itself will pre-process the images. After digitising the image it can be processed further. This processing can consist of simple image manipulations such as setting brightness and contrast or more complex processing such as automatic detection of the surgical instruments.

Requirements
The basic processing library should include functions to select a part of the images for further use (clipping / region of interest); functions to flip, mirror or resize an image; functions for brightness and contrast settings and histogram manipulations.

When imaging joints with a C-arm, often the field of view is larger then the joint itself. On the borders of the image the X-ray beam falls directly on the image intensifier and thus the image will show signs of over-exposure. This effect can be compensated in the C-arm with the use of shutters. Most C-arms also have some form of automatic control system that adapts the current and voltage of the X-ray tube to prevent over-exposure. Sometimes these measures against over-exposure will result in fairly dark images. In this case histogram functions such as equalize and stretch can be helpful to redistribute the available greyscale values and provide a better image.

More challenging image processing tasks such as bone contour recognition, surgical instrument recognition and tracking fall outside the generic scope of the toolbox. To create a robust automatic contour recognition algorithm for intra-operative surgery images may not be possible without using a-priori information about the surgical procedure and instrumentation. Therefore, it does not concern generic functionality. However, it is possible to include the building blocks for these algorithms into the toolbox. Contour recognition and tracking algorithms will need filters for edge detection and gradient analysis. Developing these automatic contour recognition and instrument tracking techniques is an essential part when developing systems that don't need an extra human operator. If a system has 'the intelligence' to detect the bony anatomy and the surgical instruments itself, the user interface can be simplified even further and the surgeon can control the system from within the sterile area. However, when building prototypes it is important to get the functionality right before trying to automate processes.

Available libraries
The MIL-Lite library provides functions to clip, flip, mirror and resize images and functions to set the brightness and contrast. Matrox also provides a more sophisticated image-processing library, called MIL (Matrox Image Library) for their range of framegrabbers. This extensive library contains all components necessary to build vision systems (including tools for character recognition, object recognition, camera interfacing and many more). However, this kind of library exceeds our requirements. Thus we decided to use the MIL-Lite library and optionally the ImageEn library. The latter also contains the tools for histogram manipulation.

Own developments
Since the image-processing components directly interface with the display components (both from the MIL-Lite library) we do not need to develop generic functions to control the processing functions.

4.3 Graphics overlay and measurement tools

4.3.1 Requirements

In order to present visual feedback to the surgeon we need to draw a graphics overlay on top of the fluoroscopic images. These graphic overlays (models) will be used to visualize the anatomical landmark positions and the surgical instrument positions and display the measurement tools for distances, angles and radii. To realize such a graphics overlay we need a graphics library that contains basic shapes to visualize points, lines, contours, rectangles, ellipses, circles and text. These basic shapes will be used to construct the complex graphics that visualize the anatomical landmarks and surgical instrument models and measurement tools. An example of such a complex graphic is a ruler tool for measuring distances.

The basic graphic shapes should support a rich set of arithmetic functions that can be used to construct the measurement tools. All graphic object should implement functions to report their size (length, width or diameter), area or orientation relative to the coordinate system (angles) if applicable. These arithmetic functions should also include functions for translation, rotation, scaling and functions to calculate projections and intersections between the shapes.

The user must be able to create, select, modify, save and load the models and the measurement tools. Some of these models should be under direct control of the user while others are derived from other models. For example, in case of a virtual-placement of an ACL graft the user will position the instrument and anatomical models. Based on the locations of these models the position of the graft model will be calculated and then displayed (as a graphics overlay).

Besides the basic shapes and the user interaction a layering mechanism is needed. The background layer will contain the X-ray image. On top of the background layer one or more overlay layers with graphics (models) can be displayed.

Thus for our graphics overlay system we need:

- a set of basic shapes
- a mechanism to define complex shapes
- a layering mechanism
- user interaction mechanism: create, enter, select and modify
- save and load functions
- functions to derive shapes from other shapes
- arithmetic functions

4.3.2 Available programs and libraries

The requirements for the graphics overlay resemble those of a multi-layer vector oriented drawing program. In a drawing program basic shapes are combined to form complex graphical shapes. However, these drawing programs do not have features to define relations

between shapes. A simple example of relations between shapes required by an application is depicted in Figure 4-1. The centre of the smaller circle is defined to be half the diameter of the bigger circle to the left of the bigger circle's centre while its radius is half of the radius of the bigger circle. If the user changes the size or location of the bigger circle, the smaller circle will also change according to the defined relation.

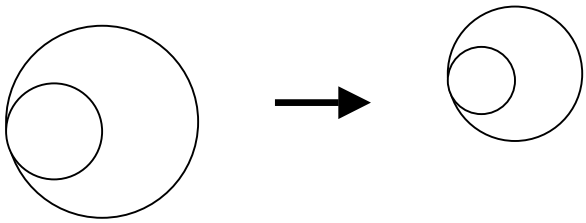


Figure 4-1: Related graphics shapes: the size and the position of the smaller circle are related to the size and position of the bigger one.

Besides impossibility to define relations between graphics shapes available drawing programs also lack the ability to define the way in which the user interacts with the shapes. In drawing programs a circle is always drawn via its bounding box, which is entered from the upper left corner to the bottom right corner. A circle can be resized by moving one of the bounding box corners while the opposite one stays in place. Because we want to have complete control over the shapes and the overlay and interaction mechanism we cannot use a 'standard' drawing program. However, this does not imply that we have to program everything ourselves. Our graphics shapes will be based on the graphics library of the Borland programming environment. This library offers functions to draw basic shapes and text on a canvas (drawing surface).

4.3.3 Own developments

The graphic overlay system implements a layering system that supports three types of visible layers (see Figure 4-2). First, a background layer that holds the X-ray image. Second, the control layer that manages graphic shapes (graphic objects) that are under direct control of the user. Third, the dependent layer that manages all derived graphic

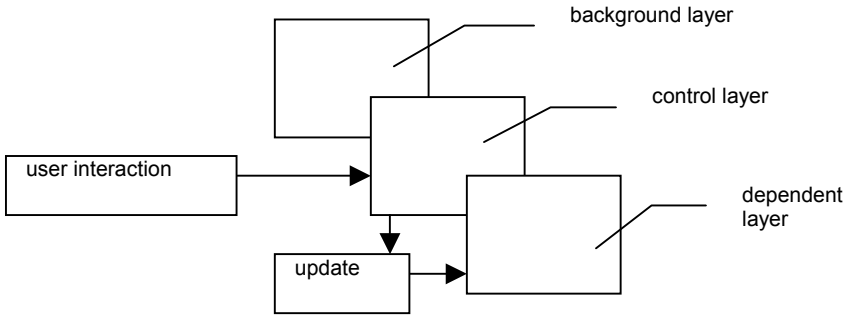


Figure 4-2: Layering mechanism containing three layers (background, control, dependent); user interaction with the control layer; and an update block between the control layer and the dependent layer.

objects. The user can interact with the graphic objects in the control layer. There are four states of graphics interaction: creating objects, entering objects, calibrating objects and selecting objects (the default state). The user can switch states by pressing the appropriate buttons in the user interface. The update block calculates the position of the graphic objects in the dependent layer by using the position of the objects in the control layer (according to the defined relations). A design diagram of the graphics overlay toolbox is presented in Figure 4-3.

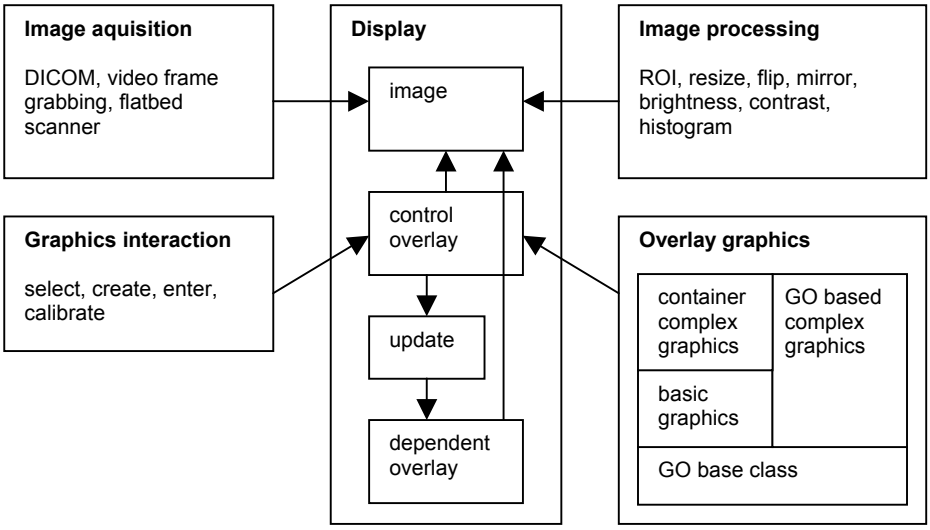


Figure 4-3: Design diagram of the graphic overlay system.

The design of the graphics objects is split into three parts: the design of the general graphics object behaviour (discussed in sections 4.4), the design of the individual basic graphics objects like point, lines and circles (section 4.5), and the design of more complex graphics objects like rulers (section 4.6). The layers are implemented as containers for graphics objects. The layers pass the user interaction (mouse clicks) on to the selected graphics object. Each object keeps track of the user-interaction state it is in (create, enter, calibrate or select mode). The layering mechanism is discussed in detail in section 4.7. The user interaction is discussed in section 4.8.

4.4 Graphics objects base class

For the design and implementation of the graphics objects (graph objects) object-oriented techniques will be used. The general properties (members) of a graph object will be realized in a base class. The individual graph objects will then inherit the general properties from the base class and define the shape-specific properties themselves. Similarly, the base class contains the definitions for the general functionality of the graph objects in its methods. Each individual graph object must override these general base class methods and optionally

define additional shape-specific methods. For example: each graph object must be able to draw itself. The prototype for the draw method is defined in the base class. Each derived class (child) must implement its own version of the draw method. The class hierarchy is depicted in Figure 4-4.

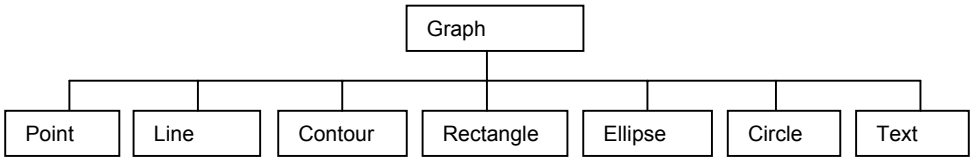


Figure 4-4: Class hierarchy of the graph objects.

The definition of the graph object base class is presented in textbox 4-1. Class GraphObject (GO) only has virtual methods (methods that can be overridden). Only the **saveToFile** and **loadFromFile** methods have a default implementation. Thus, the GO class is not intended to make an object (instance). This is called an abstract class. Every derived class (child) must implement all virtual functions. An object of (an instance of) a class can be created like any other variable.

4.4.1 Members

The members (variables) of the GO class are divided into three categories: definition, interaction and representation. The four definition members identify the object. The first, **object_type** defines which type of object (shape) it is. The seven types of graph objects are the point, line, contour, rectangle, ellipse, circle, and text. Optionally, **object_name** can be used to name the object. The name, which is used when storing the object, can be any string. The *boolean* **dynamic** member signals if the graph object was defined dynamically (using the **new** operator). If the object is defined dynamically the owner of the GO (normally this will be the overlay) is responsible for destroying the object. Finally, the *boolean* **valid** member indicates whether the GO contains valid information.

The interaction members control the user interaction with the object. The value **nearDistance** indicates how close the user should click with the mouse near the object in order to select it. The **selectable** member indicates if the GO can be selected (whether the user can interact with the GO) and the **selected** member indicates if it is. The index **interactionMode** indicates in what way the graph object is selected for interaction. The meaning of this index differs for each type of graph object and will be discussed in the section about the individual graph objects. The **entering** member signals that the user is entering coordinates for the object. With the internal **enteredPoint** index the GO keeps track of the coordinates the user is entering. The use of this index will be discussed for the individual objects. Finally, the **moving** member indicates whether the object is currently being moved.

The representation members control how the graph object is visualized. The **visible** member indicates whether the graph object is visible. The **pen** member controls the graph object outline (it describes the colour, line width and line type). The **brush** member controls the graph object interior (it describes the fill colour and fill style).

```
class GraphObject
{

    // Members

    object_type                  // definition
    object_name
    dynamic
    valid

    nearDistance                 // interaction
    selectable
    selected
    interactionMode
    entering
    enteredPoint
    moving

    visible                      // representation
    pen
    brush

    // Virtual methods

    bool near(mouse location)
    bool selectInteractionMode(mouse location)

    enter(mouse location)
    move(mouse location)
    rotate(rotation centre, angle)
    zoom(factor)

    draw(drawing surface, draw style)
    saveToFile(filename)
    loadFromFile(filename)

};
```

Textbox 4-1: Graph object base class definition.

4.4.2 Virtual methods

There are two basic levels at which a GO can be selected. At the top level an object is selected by clicking the mouse near the object. The **near** method determines whether the mouse was pressed near the object (near is defined as within **nearDistance** of the object). If an object is selected its interaction handles will appear. The bottom level of selection is controlled by the **selectInteractionMode** method. This function determines in what way the user wants to interact with the selected object. The user can interact with one of the

handles or with the entire object. This interaction mode is stored in the **interactionMode** member. For example: a line can be selected at the begin point, the end point, and as a whole.

When the **entering** member signals that a GO is being entered the mouse coordinates are passed to the GO via the **enter** method. This method uses the **enteredPoint** index to determine which point is entered. Graph objects have three basic methods to alter their appearance: **move**, **rotate** and **zoom**. All these methods can be used interactively (with the mouse) or directly from within other functions. The move method uses the **interactionMode** member to determine its behaviour. All rotate methods are passed a rotation centre and a rotation angle. The **zoom** method is used for scaling the GOs relative to the coordinate system origin.

The **draw** method handles the drawing of graph objects. If the object is selected the **draw** method will draw the handles. Every programming language for the Windows environment offers support to draw to the screen. At the lowest level Windows uses the Graphics Device Interface (GDI) to draw inside a window. The GDI accesses the window via a Device Context (DC). A device context for a window can be obtained via the identifier of that window (a window handle). In most high level programming languages the window handle and the device context are combined in a drawing surface. This drawing surface supports drawing of the basic shapes such as a line or an ellipse. The GOs **draw** methods are implemented on the level of these drawing surfaces. In our case we use Borland C++Builder in which the drawing surface is called a canvas. This makes the **draw** method of our graphics library tied to the Borland library. However, using the GDI functions directly would make the library unnecessarily complex. The **draw** method supports destructive and non-destructive drawing. Non-destructive XOR-drawing can be used to visualize real time interaction with overlay objects.

The **saveToFile** and **loadFromFile** methods handle the storage and retrieval of the graph objects to and from a file. These files (ASCII format text files) store the properties of each graph object. Only properties that are different from the default implementation are stored in these files. The properties defined in the base class are stored and loaded by the default implementation of these functions. Every overridden function in a derived class should call the base class implementation first.

The data files use the Windows ini-files format. Standard functions provide a way to write and read the values of the members to and from files. If a member that is not present in the file is read from an ini-file, the function returns a default value. An example of a GO data file can be seen in textbox 4-2. This file contains a red circle named ‘CondyleCircle’ with its centre coordinate and a radius; a blue line named ‘AngleLine’ that is selected at the begin point; and a label named ‘AngleText’ which is located near the end point of ‘AngleLine’ and that displays the line’s angle.

```
[CondyleCircle]
GOType=gotCircle
Name=CondyleCircle
Color=red
Radius=50
Centre.x=222
Centre.y=286

[AngleLine]
GOType=gotLine
Name=AngleLine
Selectedpoint=1
IsSelected=1
Color=blue
Direction.x=58
Direction.y=57
BeginPoint.x=243
BeginPoint.y=203
Linepiece=1

[AngleText]
GOType=gotText
Name=AngleText
Color=yellow
Text=44.5°
Position.x=301
Position.y=260
```

Textbox 4-2: File format for storing graphics objects. This file contains three different graphic objects (a circle, a line and a text label).

4.5 Basic graphic shapes

In the next sections the design of the individual graph objects will be discussed. First, the members of the GO (shape) are discussed. Then, all constructors, operators and other methods are explained. Finally, the interaction with the GO is described. This interaction is realized in the overridden versions of the virtual methods. As their implementation is straightforward, the **zoom, saveToFile** and **loadFromFile** methods will not be discussed further. The first section describes the supporting vector class.

4.5.1 Vector

The vector class represents a 2D direction (dx, dy). As the vector class is not a visible shape it is not derived from the GO base class. The vector class resembles the point class (described next). Mathematically, any point with coordinates (x, y) can be interpreted as a vector (x, y) relative to the origin. The vector class also resembles the Windows TSize class, which is based on the (*integer*) pixel coordinate system. To make a general vector class the **dx** and **dy** members will be stored as floating-point *(double)* values.

A vector object can be constructed from another vector, from two values, a TSize structure or a point. In order to calculate with vectors, all necessary mathematical methods (operators) were implemented for the vector class. These operators include:

`a == b`	test equality
`a != b`	test inequality
`a = -a`	invert (both for dx and dy)
`a = b`	assignment
`a += const`	positive offset (both for dx and dy)
`a -= const`	negative offset (both for dx and dy)
`a + b`	addition
`a - b`	subtraction
`a × b`	vector multiplication (dot product)
`a × const`	scaling (both for dx and dy)
`a / const`	scaling (both for dx and dy)

Testing if two vectors are the same by testing if the **dx** and **dy** values are the same does not work adequately. Only if the floating-point values were exactly the same the two vectors would be considered to be equal. To make a more useful definition for the equality of floating-point number based members it is better to weaken the definition for the equality in such a way that two values are considered equal if they differ no more then some small constant value (epsilon).

Besides the basic operators the vector class supports methods for controlling the length of the vector, reporting its angle relative to the orientation of the horizontal axis or another vector, rotating the vector and returning the normal vector.

4.5.2 Point

The point class realizes a coordinate (x, y). The point class is a visible graph object so it is derived from the GO base class. The Windows API contains the TPoint class, which is based on the *integer* pixel coordinate system. To make a point coordinate system that is more generally applicable, a floating-point version was created. The coordinate is stored in two *double* members **x** and **y**. The way in which the point is visualized is stored in the **style** member. A point can be selected with the mouse by clicking near the point. If the point is selected the point will be visualized as a handle (a hollow square, five pixels wide).

A point object can be constructed from another point, from two values (x and y), a TPoint structure, and a vector or a TSize object. The point class contains operators to test equality and inequality (similar to the equality test of the vector class). It contains operators for positive and negative offset of a point with a vector, addition and subtraction of a point with a vector, subtraction of two points (returning a vector), assignment, and negation (mirror relative to the coordinate system origin). The point class also has a method to calculate the distance between two points. Because the point class is derived from the GO base class all virtual methods must be overridden.

A mouse coordinate is considered to be near the point if it is located in a square region around the point's coordinate (**near** method). The size of this square is two times

nearDistance. The selection procedure of the point class is trivial: there is only one point to select. The **selectInteractionMode** method just checks whether the mouse coordinate passed to it is near the point. The **move** and **enter** methods set the new location of the point to the current mouse position. A point can be rotated counter clockwise around the provided rotation centre over the provided angle. A point can be visualized in several ways. The point can be drawn as a single pixel, a cross, and a small square or circle (both with transparent or solid interior). The drawing style is stored in the **style** member. The **draw** method uses the Borland canvas→Pixels and canvas→LineTo methods to draw the point in the selected style.

4.5.3 Line

The line class is derived from the GraphObject base class. The **point** and the **direction** member (a point and a vector object) define a line. The **linePiece** member indicates if the line should be interpreted as a line piece or an infinite line. In case of a line piece, **point** is interpreted as the starting point of the line. The endpoint is calculated from the starting point and the direction vector **direction**. The length of the direction vector equals the length of the line. For infinite lines, **point** is interpreted as a base point: the line contains that point. For infinite lines the length of the direction vector is ignored.

A line object can be constructed from another line, from two points, and from one point and a vector. Besides the assignment operator the line class supports methods to set and get the base (begin) point, the direction vector and (indirectly) the endpoint. The line class has methods that return the line's normal vector; to calculate the point which is the result from an orthogonal projection from any given point on the line; to calculate the length; to calculate the distance of any given point to the line; to calculate the line's angle relative to the horizontal axis or any other line; to test if two lines are parallel (at a fixed precision); that determines if a point is on, below or above a line (above is defined as a counter clockwise rotation less than 180 degrees from the direction vector); and that returns the intersection point with another line.

A line can be selected with the mouse by clicking near the line. A selected line shows two handles one located at **point** and one located at the endpoint. Both handles can be moved to a new location altering the **point** and the **direction** member. If the selected line is picked up at another point the entire line is moved without altering its direction. Infinite lines will also show both handles in order to change its direction. The user can enter a line by placing a begin point and an end point. Rotating a line equals rotating **point** and **direction.** In case of a line piece the **draw** method draws a line from **point** to the end point. In case of an infinite line the drawing is cropped relative to the size of the drawing area. The **draw** method uses the Borland canvas→LineTo method to draw the line. Optionally, the **draw** method can visualize a line piece as a rectangle. The line piece is then used as the centreline of a rectangle of a certain width (stored in the **rectWidth** member).

4.5.4 Contour

A contour is defined by the **pointList** member, which is an ordered list of points (coordinates). The **closed** member determines whether the contour is open or closed. By default the points will be connected by lines. For a closed contour an extra line will be

drawn between the last and the first point in the list. As an alternative a contour can be constructed with a base point and a list of vectors giving the displacement from the previous point. This vector implementation would make moving the entire contour trivial: just move the base point. Because all other methods would become more complex we discarded this alternative. To make a contour appear smoother it is possible to use the points in the array as control points for a spline or bezier contour. With the use of these interpolation algorithms it is possible to make smooth shapes with only a few points.

A contour object can be constructed from another contour or from a list of points. The contour has methods to add, insert or delete points and to report the number of points it consists of. There are also methods to upsample (interpolate) or downsample (segment) the contour. The most simple interpolation technique is the linear interpolation. With linear interpolation a new point is inserted halfway between two adjacent points. Smoother contours can be obtained when using the spline or bezier interpolation. The contour also has methods to calculate the contour length (along the contour edge) and the area. If the contour is used as a representation of a three-dimensional object it is also be possible to create a method that estimates the volume of that object. Finally, there is a method that can be used to calculate a set of intersection points with a line.

A contour can be selected by clicking somewhere on the contour border. Once selected all points are displayed with handles. The user can then pick up a contour point by its handle and move it. The user can pick up the entire contour by the line segments between two handles. The user can enter a contour point by point. The entry procedure can be finished in two ways:

- if the user enters two points on approximately the same spot the contour is finished and defined to be an open contour
- if the user enters a point which is near (within a few pixels) the begin point, the contour is finished and defined to be a closed contour

Rotating a contour equals rotating every individual point. The **draw** method uses the Borland canvas→LineTo method to draw the contour.

4.5.5 Rectangle

A **baseline** and a **width** member define a rectangle object. The direction of the rectangle's width is parallel to the normal vector of the **baseline** member. A line object can be visualized as a rectangle so it seems unnecessary to have a separate rectangle class. However, a line visualized as a rectangle does not provide a way of (interactively) adjusting the rectangle width. In object oriented design it is advised to keep the classes as simple as possible. It is better to create a new class if some of its behaviour is fundamentally different. With the line class the rectangle option was intended as a way of drawing a line, not to create an actual rectangle object. Windows also has a rectangle definition (TRect). The main problem with this definition is that rectangles are oriented along the horizontal and vertical axis of the screen, just like windows.

A rectangle object can be constructed from another rectangle or from a line and a width. In contrast with the line's rectangle visualization, the line in the rectangle class is the border of

the rectangle. The rectangle class has an assignment operator and methods to return its bounding box. The bounding box is defined as the smallest Windows-style rectangle (TRect) that exactly contains the rectangle. The rectangle class also contains a method that determines if a point is located inside the rectangle and methods to position a rectangle object at the starting point or end point of a line with its direction parallel to that line.

A rectangle can be selected by clicking with the mouse near the rectangle's border. A selected rectangle has three handles, two in the corners of the side that corresponds to the base line and one in the corner closest to the begin point of the baseline. Moving the baseline handles alters the orientation of the rectangle. The third handle controls the width of the rectangle. If the rectangle is picked up somewhere inside the rectangle, the entire rectangle is moved. The user can enter a rectangle by placing the base line and then the opposite corner point. Rotating a rectangle equals rotating the base line. The **draw** method uses the Borland canvas→LineTo method to draw the rectangle.

4.5.6 Ellipse

The ellipse class implements an ellipse shape that fits exactly into a rectangle. This implies that the two ellipse axes are the two perpendicular lines that connect the midpoints of two opposite sides of the rectangle. Internally, an ellipse is defined with the same members as the rectangle class (**baseline** and **width**). Windows also has an ellipse definition but this is based on the Windows rectangle definition and thus the axes of the Windows ellipses are oriented along the horizontal and vertical axis of the screen.

An ellipse object can be constructed from another ellipse or from a rectangle. The ellipse class has methods to get the ellipse axes and the centre (crossing of the two axes), to calculate the bounding box, to determine whether a point is located inside the ellipse, to calculate the angle of a border point relative to its centre and to provide the border point located at a certain angle.

An ellipse can be selected with the mouse by clicking near the edge. A selected ellipse shows four handles at all ends of its axes. When selected, any point within the ellipse can be used for a drag and drop procedure that moves the entire ellipse. The two handles of the axis that is parallel to the **baseline** (the main axis) can be used to change the orientation and the size of that axis (just like the two handles of a line). The size of the other axis (width axis) does not change. However, the position and orientation of the width axis changes so that it is still perpendicular to the main axis and passes the main axis's midpoint. The handles of the width axis can be used to change the length of that axis (symmetrical relative to the main axis).

The user can enter an ellipse by placing the main axis line and then one point of the width axis. Rotating a rectangle equals rotating the main axis line (and thus actually the **baseline**). The **draw** method cannot use the Borland canvas→Ellipse method to draw the ellipse. Instead, the ellipse equation is used to calculate a set of border points. These border points are then drawn as a contour. If the ellipse border points are close to each other, a smooth ellipse can be drawn.

4.5.7 Circle

The circle class is derived from the GO base class. Two members define a circle: **centre** and **radius**. The **centre** member is a point object so all the operators defined for the point class can be used on the circle centre. The **radius** member contains a *double* value. The *boolean* **crosshair** member defines whether a crosshair is drawn within the circle.

A circle object can be constructed from another circle or from a centre point and a radius. The circle class supports an assignment operator that makes the circle a copy of another circle. A 'test equality' operator for the circle object can be defined by using the 'test equality' operator for both the **centre** as well as the **radius** member. The circle class has methods to set and get the centre and the radius, to calculate the bounding box (a square which exactly contains the circle), to determine whether a point is located inside the circle, to calculate the angle of a border point relative to its centre and to provide the border point located at a certain angle.

A circle can be selected with the mouse by clicking near the circle edge. A selected circle shows four handles at 12, 3, 6 and 9 o'clock. When selected, any point within the circle can be used for a drag and drop procedure that moves the entire circle. If the drag and drop procedure is performed with a point on the circle's border (all points except a handle) the circle can be resized relative to the circle centre. The resizing behaviour via the handles is different. If the user picks up a handle the opposite handle's location is fixed and the circle resizes relative to that fixed location. This way of interaction is very helpful when positioning a circle along a circular shaped edge in the image. A circle can be entered in two steps. First, the centre is placed and then a point along the border. Rotating a circle around an arbitrary point has the same effect as rotating its centre point around that point. The **draw** method uses the Borland canvas→ellipse method to draw the circle. The **draw** method has an extra option to display a cross hair inside the circle.

4.5.8 Text

The last basic shape derived from the GO class is the text class that implements a label that can be used to make annotations in images. Three members define the text class: **text** that contains a text string, **font** that contains the text font, and a **location** that determines the coordinates for the label. The text background is made transparent in order to show the image beneath.

A text object can be constructed from a string and a location. A text label can be selected with the mouse by clicking on the text. A selected text box will display a handle in the upper left corner of the text box. The textbox can be picked up with the mouse (anywhere inside the box) and dragged to a new location. The user can enter a text label in a dialog box and then position the text in the image (with a single mouse click). Rotating a text label equals rotating the text labels position. The text itself is not rotated. The **draw** method uses the Borland canvas→TextOut method to draw the contour.

4.6 Complex graphic shapes

Using the basic shapes it is possible to create more complex graphical shapes. There are two ways to define these shapes. First, we can derive the shapes directly from the base class just like the basic graphics shapes discussed in section 4.5. In this case the complex shapes are derived classes from GO that contain other GO objects. Second, we can build a container class that is not derived from the GO base class itself but which does contain other GO objects. The main difference is that if the complex shape is derived from the GO based class we can define a specific behaviour for it (we can define selection, enter, and modify behaviour as well as handles). If the complex shape is just a container for GO objects each element of the complex shape will show its generic behaviour. The relations between the individual GO objects of the container class can be defined in the **update** method. To create the individual GO objects and register the update method (place the **update** method in the update block between the dependent and the control layer) the container class has a **create** method. Destroying the objects and the relation is done in the **destroy** method.

As an example of the GO derived complex shapes we will discuss the ruler class. A ruler (see Figure 4-5) is a line with a moving slider (a point). The line and the slider should behave as one object and thus we derived the ruler class from the GO base class. The ruler class is discussed in section 4.6.1. As an example of the container type complex shapes we will discuss the angle measurement tool, which consists of two lines and an angle label. The container type is chosen because the lines should behave as two individual lines. However, the value for the text label is determined by the angle between the two lines (in the **update** method). The angle class is discussed in section 4.6.2. These two types of complex graphic shapes will be used for building the models for the CAOS systems (that were discussed in section 3.5).

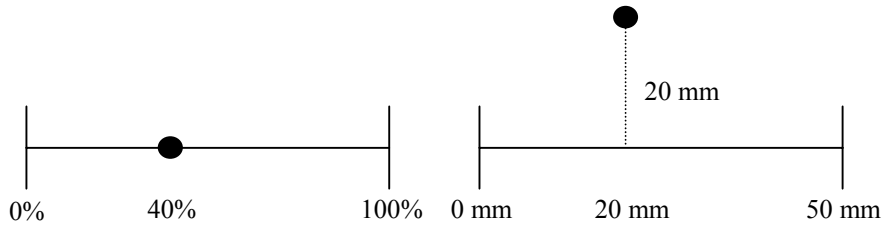


Figure 4-5: Left: relative scale ruler with a slider bound to the ruler baseline; Right: relative scale ruler with a freely movable slider.

4.6.1 GO based complex shapes: ruler class

The ruler class implements a tool to measure distances. This class, which is derived from the GO base class, implements a ruler with a movable slider. The movable slider (a point object) is defined relative to the ruler baseline (a line object). The slider position is defined by two parameters (**sliderPosition, sliderDistance**). The first slider parameter

(**sliderPosition**) is the relative position of the projection of the slider onto the baseline. The second slider parameter (**sliderDistance**) is the signed distance to the baseline (in pixels). For example: the begin point of the ruler corresponds to a slider position of (0, 0); the end of the ruler to a slider position of (1,0); and a point halfway the ruler at a distance of 50 pixels would have a slider position of (0.5, 50). Because the slider is defined relative to the baseline, changing the baseline will also change the slider. To use the ruler for absolute measurements the ruler class has a member **calibrationValue** that translates the pixel value to the actual value. The unit of the actual value is stored in the **unit** member. The boolean member **absoluteScale** signals if the ruler is used for relative or absolute measurements.

A ruler can have three different slider configurations. This slider configuration is stored in the **sliderType** member. The first slider type is **no_slider**. In this case the ruler does not have a slider. It is just a baseline that can display its length. The length is displayed according to the ruler's **calibrationValue** member. The second slider type is **bound_slider** (see Figure 4-5 on the left). In this case the ruler has a slider that is bound to the baseline. The motion of the slider is limited along an infinite line that contains the baseline. This slider type can be used either with an absolute or with a relative scale. For relative measurements the beginning and the end of the ruler correspond to 0% respectively 100%. In this case the **sliderPosition** is also expressed as a percentage. As an extra option the slider movement can be limited to the baseline itself. The third slider type is **unbound_slider** (see Figure 4-5 on the right). In this case the ruler has a slider that is not bound to the baseline. This type of ruler can be used absolute as well as relative. As an extra option the slider movement can be limited to above or below the baseline.

A ruler object can be constructed from another ruler object, from a line (baseline) and a point (slider), or from a line and two slider coordinates. Via the baseline the ruler can access all line methods. The ruler class contains several methods to calculate distances (ruler length, slider distance to baseline, relative slider position, etc.)

A ruler object can be selected with the mouse by clicking near the baseline or near the handle. The selected ruler shows three handles, two at the baseline and one at the slider. The baseline handles behave as normal line handles. The slider position is moved along with the line. If the slider is picked, it can be moved to a new location (according to the slider type).

The user can enter a ruler by placing the begin point and end point of the baseline and optionally a slider (only if the selected ruler type has a slider). If the slider is bound, the entered point will be projected onto the baseline. Rotating the ruler equals rotating the baseline. The **draw** method draws the baseline and the slider (if any). The **draw** method has an extra option to display tickmarks (small perpendicular lines centred on the baseline) at the beginning and end of the ruler and at the projected slider location. The size of these tickmarks can be controlled via the ruler's **tickLength** member. It is also possible to hide or show all four text labels for the ruler (begin and end of the baseline, the relative slider position and the slider distance to the baseline).

4.6.2 Container based complex shapes: angle class

The angle class implements a tool to measure angles. The angle class is not derived directly from the GO. Instead, the angle class is a container that holds three GOs, two lines and a text label. The two lines, called baseline and angle-line, can be selected with the mouse and moved independently. The text label cannot be moved interactively. As an option the lines can be joined in the begin points to form a protractor.

The relations between these three objects are implemented in the **update** method. This method calculates the angle between the two lines and stores it in the label. The method also updates the label's position. If the angle tool is used as a protractor the begin point of the angle line is set to the begin point of the baseline. The label position can be coupled to the begin or end point of one of the lines. The **create** method adds the two line elements to the control overlay layer, it adds the text label to the dependent overlay layer and it registers the **update** method with the update block between the layers.

4.7 Layering mechanism

As explained in section 4.3 we need to create a multi-layer overlay for the radiographic images. The background layer is used to display the radiographic image (image acquisition and display was discussed in section 4.2). The background layer is implemented with the standard Borland TImage component. To implement the two overlay layers (control layer and the dependent layer) the overlay class was created. The definition of the overlay class is depicted in textbox 4-3.

```
class Overlay
{

    // Members

    graphObjectList
    selectedObject
    visible

    // Functions

    add(graph object)
    delete(graph object)
    clear()
    freeAllObjects()
    select(mouse location)
    draw(drawing surface)
    drawNSO(drawing surface)
    zoom(factor)

};
```

Textbox 4-3: Definition of the overlay class that implements a graphics objects layer

4.7.1 Members

The basis for the overlay class is the **graphObjectList** member, a dynamic list that contains graph objects. This list can hold all child classes of the GO base class. Thus, the overlay does not know exactly what objects are stored in the list, only that they are graph objects and that they implement all the virtual functions of the GO class. The selected object, if any, is stored in the **selectedObject** member. This pointer is also declared as a pointer to a GO object and can point to all graph objects derived from the GO base class (one object at a time). The type of object to which **selectedObject** points, is accessible via the **object_type** member that was defined in the GO base class. The third member variable of the overlay class is **visible** that controls the visibility of the entire overlay.

4.7.2 Methods

The overlay class has methods to add objects (**add**) to or delete objects (**delete**) from the overlay. These methods just add or remove the GO pointer of the object at hand to or from the **graphObjectList**. With the **clear** method all GOs can be deleted from the overlay. The **clear** method only destroys the overlay's references to the graph objects, not the graph objects themselves. The **freeAllObjects** method actually destroys all the objects that are managed (owned) by the overlay (all object which have the **dynamic** member set) and frees the occupied memory.

In section 4.4.2 the two level selection process was mentioned. The top-level selection process is implemented in the overlay class. The overlay's **select** method takes the mouse location of the last mouse click and checks if this location is near one of its graph objects. In fact the overlay cycles through the **graphObjectList** and passes the mouse coordinate to the **near** method of each individual GO. If one of the **near** methods returns true, the pointer to this object is stored in the **selectedObject** member. For the second level of selection the mouse coordinates are passed directly to the selected object.

The Overlay class has two methods to draw the overlay: **draw** and **drawNSO**. The **draw** method cycles through **graphObjectList** and draws all GOs (actually it calls the **draw** methods of the individual objects). The **drawNSO** method also draws the GOs from the list except the selected object. The **drawNSO** method is used to realize the visualization of a drag and drop procedure of a selected object. When visualizing a moving GO, the background including all other GOs is drawn only once. The selected GO is drawn in an eXclusiveOR (XOR) drawing mode. When drawing XOR, the object is not drawn in its defined colour, but in a colour that results from a logical XOR operation of the GO colour and the background colour. Drawing the GO twice at the same location completely restores the background image. Moving an object without redrawing the entire image is then possible by just drawing two times: once to erase the object at the previous location and then again to draw it at the new location. Drawing the selected GO twice is much faster then redrawing the entire image and it also prevents the 'flickering effect' that occurs if a complete image is drawn repeatedly. The overlay's **zoom** method just passes the zoom factor to all individual GOs.

The control layer and the dependent layer are implemented as two overlay objects (**controlLayer** and **dependentLayer**). If the user alters a GO in the control layer, the update block (that contains all the update methods) is called and the GOs in the dependent layer are updated.

4.8 User interaction

4.8.1 Mouse interaction

The user can interact with the graphics objects using the mouse. The mouse can be used in four ways, called mouse modes. In the startup mode (M_SELECT) the mouse can be used to select an object. The selected object can then be edited (moved or resized). The mouse can also be used to create an object (M_CREATE), to enter coordinates for the created object (M_ENTER), or to enter calibration points (M_CALIBRATE). To store the current mouse mode for the application the **mouseMode** member is used. The state machine depicted in Figure 4-6 controls the mouse interaction.

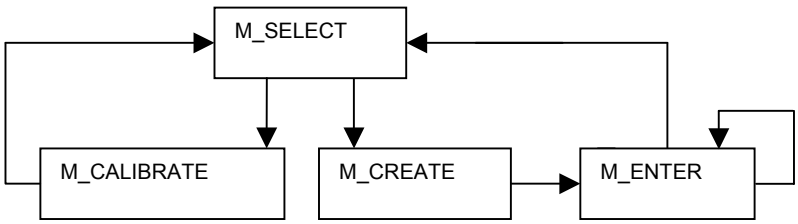


Figure 4-6: Mouse interaction state machine.

If the user selects to draw a new graph object the state will be set to M_CREATE. When the user positions the first point of the object the state will change to M_ENTER. When the last point of the object is entered the state will change back to M_SELECT.

In the Borland C++Builder environment the mouse interaction is controlled via five events: **MouseDown**, **MouseMove**, **MouseUp**, **Click** and **DoubleClick**. These events are provided for all window controls (all controls that have a visible area that can be clicked with the mouse). Besides positions these events also contain the status of all mouse buttons and of some keyboard buttons (shift, alt and control). The first three events are the basic mouse events. The **Click** event is generated after a combination of **MouseDown** and **MouseUp** within a certain time. The **DoubleClick** event is generated after two subsequent clicks within a certain time. For our user interaction we will use the three basic events. The **onMouseDown** method can be seen in textbox 4-4 and the **onMouseMove** and **onMouseUp** methods are described in textbox 4-5. The **onMouseDown** method contains code for all four mouse states. The **onMouseMove** method only works in the M_SELECT and M_ENTER states. The **onMouseUp** method only contains code for the M_SELECT state.

```
onMouseDown (mouseposition)
{
    if the mouseMode is M_SELECT
    {
       if (Level1 selection & Level2 selection)
       {
            set object state to moving;
            draw background image;
            draw overlay without selected object;
            move the selected object;
            draw the selected object in XOR mode;
       }
       else
       {
           do Level1 select;
           redraw the image;
       }
    }
    else if the mouseMode is M_CREATE
    {
         create object stored in objectToCreate;
         store this object in objectToEnter;
         set object state to entering;
         add the object to the overlay;
         set mouseMode to M_ENTER;
    }
    if the mouseMode is M_ENTER
    {
       if (pass mouseposition and test if entering is ready)
       {
            set mouseMode to M_SELECT;
            make this object the selected object
       }
       else draw point at mouseposition
    }
    else if the mouseMode is M_CALIBRATE
    {
       if (pass mouseposition & test if calibration is ready)
       {
            set mouseMode to M_SELECT;
            pass the calibration value to the selected object;
       }
       else draw point at mouseposition
    }
};
```

Textbox 4-4: Implementation of the OnMousedown method.

In the M_SELECT state, objects can be selected for a drag and drop procedure to alter the appearance of the object. For the M_SELECT state the **onMouseDown** method implements the first level (selecting the object itself) and second level (selecting the part of the object

that will be changed) selection process. Once the second level selection is completed, the selected object is marked as moving. The background and overlays are drawn without the selected object and the selected object itself is drawn in XOR for the first time. The drag and drop procedure is continued in the **onMouseMove** method that erases the object at the old location, moves the object and draws it again at the new location. Finally, in the **onMouseUp** method the moving object is erased and moved for the last time. Then the update block is called to update the relations that were defined for the objects. Finally, the entire overlay is redrawn.

```
onMouseMove(mouseposition)
{
   if there is a moving object or mouseMode is M_ENTER
   {
        draw the object in XOR mode (erase old object);
        move the object;
        draw the object in XOR mode (draw at new location);
   }
};

MouseUp(mouseposition)
{
   if there is a moving object
   {
        draw the object in XOR mode (erase old object);
        move the object;
        call all update functions;
        redraw the entire image;
   }
};
```

Textbox 4-5: Implementation of the onMouseMove and onMouseUp methods.

The M_CREATE state is entered when the user presses one of the shape buttons (a button that signals that the user wants to draw a certain shape). The object that the user wants to create is stored in the **objectToCreate** member. The actual object is created the first time the mouse is clicked somewhere inside the drawing area. A pointer to the new object is stored in the **objectToEnter** member. This first mouse coordinate is also used as first coordinate for the graph object and immediately the state changes to M_ENTER. In the M_ENTER state as many coordinates are passed to the object as needed. For example a line only needs one more coordinate. During the M_ENTER state the temporary object is drawn in the **onMouseMove** method. Once all coordinates are entered, the state will change back to M_SELECT. The M_CALIBRATE state is entered when the user presses the calibrate button that appears when an object (that can be calibrated) is selected. For example: to calibrate a ruler the user selects the ruler, enters a length in the calibration dialog box, and presses the calibrate button. Next, two coordinates are collected in the **onMouseDown** method. Once both coordinates are entered, the calibration factor is calculated and passed to the selected ruler. The state then changes back to M_SELECT.

4.8.2 Property pages

The user can change properties of a graph object during run time using the property pages. If the user presses the property page button the property page window is displayed for the selected object (if that type of object has a property dialog). The dialog displays all current settings. After closing the property page the overlay is redrawn using the new settings. Property pages were defined for the line, circle and the ruler GOs. The line property page allows the user to switch between the three visualizations of a line (line piece, infinite line and rectangle). The circle property page allows the user to switch the crosshair on or off. The ruler property page allows the user to switch between the three slider types, select which text labels are visible, set the absolute or relative ruler mode, and control the clipping bounds for the slider.

Besides this property dialog page, there are two general property pages. The first, the line width page, controls the pen width for the selected object. The second, the colour page, enables the user to change the object's border colour.

4.9 Testing the toolbox

First, all image acquisition and display functions and the graphics overlay functions from our toolbox were tested individually. Then all components were integrated into a demonstration program. This program supports:

- image acquisition via framegrabber
- live preview window for video source
- image retrieval and image storage from and to files (with and without overlays)
- zoom in and out, centre image and cancel zoom
- create and edit graphics shapes (point, line, contour, rectangle, ellipse, circle, text, ruler and the protractor)
- the property pages for the colour and pen width
- the property pages for the implemented graphics objects

This program can be used as a prototyping tool or as a template to develop CAOS programs. For this purpose Borland C++ builder has an object repository that can hold forms, dialogs, data modules and even entire projects and thus enable to reuse them.

4.10 Discussion

4.10.1 Implementation choices

At the start of the first project we did not have a toolbox. Therefore, we decided to take the feasibility prototype and use this as the basis for the evolutionary prototyping process. The software modules written for this prototype were used as a prototyping toolbox. Within two months, the first clinical prototype was operational and the first clinical trials were started. Although this approach worked, adding new functionality to the prototype proved very difficult. Thus, adding new functionality to our computer-assisted orthopaedic surgery prototypes was postponed until the rapid prototyping toolbox was ready.

The toolbox is a collection of C++ routines that are based on the Borland C++Builder environment. The Borland environment provides a visual component library (VCL) that is build on top of the Windows API's. All graphical and system functions are performed by these Borland components. Not only does this save a lot of time; it also makes it possible to expand our toolbox with all commercially available components developed for the Borland environment (like the ImageEn toolbox discussed in section 4.2.1). Using the Borland components also has some disadvantages. Because the Borland C++ implementation has extended the C++ language with extra keywords and because of the additional VCL layer, the code cannot be used directly by other C++ compilers.

To increase the speed of development the toolbox was used to build a test program that contains all basic functionality to build CAOS programs (see section 4.9). This generic program was used as the initial prototype to test the different concepts that are defined in the concept validation phase of the prototyping process. This approached proved very successful as new prototypes could be developed in a few days.

4.10.2 Develop or buy

As discussed in section 4.3.2 our toolbox implements functionality also present in a standard drawing program. Our test program that implements all standard functions for a computer-assisted surgery system closely resembles such a drawing program. However, we could not use a standard drawing program because we need relations between graphic objects and because we need complete control over the behaviour of all these graphic objects.

Changing the functionality of an existing drawing program (if the source is available) would take more time than developing a graphics library from scratch. We decided to use commercially available components only if they meet our requirements and need no additional changes (for example framegrabber drivers, TWAIN support and image file format conversions). All manufacturers that build CAOS systems have a well-equipped toolbox. These toolboxes, that are the basis for all their products, are not commercially available.

4.10.3 Usability

As suggested in section 4.9, the test program can be used as a prototyping tool. When discussing the possibilities of a CAOS system with a surgeon the program can be used to visualize the generated ideas directly. However, the test program does not support interactive definition of dependencies between graph objects. If this functionality is added the test program can grow to be a rapid application development tool that can be used by medical specialists themselves.

In its present form the test program is suitable as a basis to develop two-dimensional CAOS systems. First, we will show the use of the toolbox and the test program to develop measurement programs (Chapter 5). Then we will use them to build a 2D-plus CAOS system for anterior cruciate ligament surgery (Chapter 6). Finally, we will test if our toolbox can be used to construct a CAOS system for hip pinning (Chapter7).

Chapter 5

Computer-assisted measurement systems

5.1 Introduction

Measuring is an essential part of diagnostic, surgical and research tasks: to measure is to know. Surgeons draw on transparent sheets that are overlaid on X-ray images and measure distances and angles. As hospitals install PACS systems and replace films (hardcopies of medical images) with digital images, also a digital way of measuring is needed. The digital alternative for drawing on films is to use the graphic overlays from our rapid prototyping toolbox discussed in chapter 4. This toolbox includes all necessary tools to implement graphic overlays and measurement tools. In this chapter the toolbox and the test program will be used to create computer-assisted measurement programs. These programs assist a physician to perform measurements, calculate results and store the data.

A measurement protocol is a prescription how to perform (a set of) clinical measurements. These prescriptions contain all relevant aspects for the clinical measurement (image requirements, observers, measurement tools and techniques, data storage, and user interface). Measurement protocols are developed in two stages. The first stage is to determine the best way to measure a certain effect. To accomplish this, several measurement techniques will be compared and evaluated with multiple observers. Developing new clinical measurements is a typical medical research task. In the second stage the technique that was selected in the first stage will be used to define a measurement protocol for a diagnostic or surgical task. Each stage can be supported by a computer-assisted measurement system. For measurement protocols that are already well accepted in clinical practice, a diagnostic or surgical computer-assisted system that supports that measurement protocol can be developed directly.

As diagnostic and surgical measurements differ from research measurements the computer-assisted measurement systems that support them will also be different. Diagnostic and surgical measurement systems implement a clearly defined measurement protocol. The user interface will be focused on its usability in clinical practice, as is the case with any CAS system. The measurement results are reported to the user immediately. In addition, a research measurement system often deals with multiple measurements on large series of images with several observers. The user interface is optimised to reduce the number of tasks an observer has to perform. The data is most likely stored directly into a database.

This chapter explains how the rapid prototyping toolbox can be used for building computer-assisted measurement systems. Section 5.2 describes current ways of measuring and related problems. In section 5.3 several clinical measurements are discussed. They comprise diagnostic as well as research measurements. From these examples the requirements for both types of computer-assisted measurement programs are derived (section 5.4). Section 5.5 discusses the design of computer-assisted measurement systems. In section 5.6 the accuracy computer-assisted measurement systems is discussed. Section 5.7 discusses the evaluation of measurement systems. In section 5.8 two measurement systems are presented that we developed for validating our approach. The first is a research measurement system that helps to assess the best way to measure the knee laxity with stress radiographs. The second is an intra-operative measurement tool for knee laxity. This measurement tool is integrated into the computer-assisted surgery system for ACL reconstruction (described in chapter 6). Finally, the clinical integration of these systems is discussed in section 5.9.

5.2 Aspects of clinical X-ray measurements

In this section the clinical measurement practice using X-ray images and its problems will be discussed. Because X-ray images are projections, measurements in X-ray images will be more complex than measurements in CT and MR images (which provide 3D image slices). The radiographic imaging system will be explained as well as the differences between radiographic and fluoroscopic X-ray systems. Finally, some possible advantages and disadvantages of computer-assisted measurement systems are presented.

5.2.1 Current measurement practice

In current practice a physician or surgeon uses a light box to display the radiographic images. A pen will be used to mark certain features on the images. If the image should not be altered the drawings will be made on a transparent sheet that overlays the image. Measurements will be made with a transparent ruler (distances) and protractor (angles). The results of the measurements will be jotted down on a piece of paper and later transferred to a spreadsheet. Sometimes, more complicated measurements require some calculations before the final result is written down. If more than one measurement must be made for each image or the measurement will be done more that once (for intra-observer tests), or several observers will do the same measurement (for inter-observer tests) the transparent sheets have to be changed after each measurement to prevent writing on the images.

Errors can occur because the transparent sheets can shift, the drawings are covering the underlying image, and the rulers can be misread. Besides this, errors can be made in the calculations or when writing down the results or when entering the results into a spreadsheet program. Besides these errors, this way of measuring also takes a lot of time.

5.2.2 Radiographic imaging system

The radiographic imaging system contains a single X-ray source (focus) and an image plane (film). Radiographic images are projection images. In projection images the size of an object in the image increases if the object is placed closer to the focus. The two objects a and b in Figure 5-1 have the same size. Because b is closer to the image plane its projection b' is smaller. This magnification effect must be considered when measuring. Another

important effect when measuring distances in projection images is shortening. Consider for example a small metal pin with a length of 5 cm and a diameter of 2 mm. If the pin is aligned with the main axis of the imaging system, the pin will be projected as a dot. If the pin would be located in a plane parallel to the image plane, the pin would be projected at its full length. So, the length of an object in the image depends on its position between focus and film and its orientation in space. The same problem arises when measuring angles for objects that are not parallel to the image plane. Angle measurements are only correct for objects parallel to the image plane. Out of plane measurements can produce smaller as well as larger values than the actual angle value.

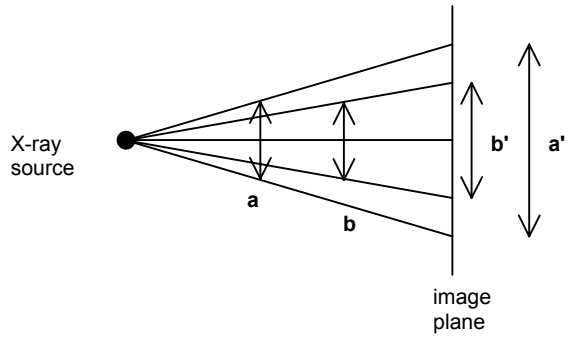


Figure 5-1: X-ray magnification: two identical objects a and b and their projections a' and b'.

In order to make accurate measurements we need to know the orientation and position of the measured object relative to the imaging system. In clinical practice this information will almost never be available. However, it is possible to do accurate measurements when the X-ray image is taken from an 'optimal' position and calibration is applied. Using anatomical knowledge it is possible to position the measured object parallel to the image plane as best as possible (by aligning patient and X-ray camera). This is why radiography departments have imaging protocols for all possible X-ray studies.

Sometimes it is possible to derive information about object orientation from the X-ray image by using geometrical knowledge. For instance, if an object in the image looks elliptical and it is actually round, the tilt of the object relative to the image plane can be calculated from the ratio of the length of the two axes of the ellipse (see Figure 5-2). However this tilt measurement is not unambiguous: the measured tilt can be in two possible directions (tilted towards the reader or tilted away from the reader). It is also possible to use images from different directions to derive orientation information.

A spherical or cylindrically shaped calibration object of known diameter inserted at the same focus-film distance as the measured object can be used to calibrate the measurement. Spherical and cylindrical calibration objects are used because the diameter of the projected object is independent of the orientation of the object. To measure distances in a direction not parallel to the image plane a calibration object of known size in that same direction can

be used to calibrate the measurement. An example of such a calibration is the tunnel length measurement in the CAOS program for anterior cruciate ligament surgery (Chapter 6). In this system the metal hook of the tibial drill guide, which is aligned with the proposed drill tunnel, is used to calibrate the system to measure distances in the direction of the tunnel.

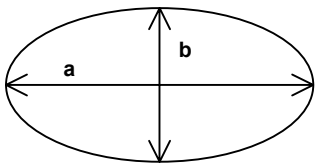


Figure 5-2: A circle projected as an ellipse: the ratio of the two axes can be used to determine the tilt angle.

5.2.3 Fluoroscopy

In fluoroscopic X-ray systems an image intensifier is used instead of film. Fluoroscopic imaging adds two additional types of image distortion that will affect measurements. First, the slightly spherical shape of the image intensifier causes pincushion distortion. Second the earth's electromagnetic field causes S-shape distortion. Both distortions are non-linear. The S-shape distortion depends on the position and orientation of the fluoroscope, and thus will be different for images taken from different directions. The pincushion distortion is related to the construction of the image intensifier (II) and thus does not depend on the orientation of the fluoroscope itself.

Fluoroscope manufacturers try to reduce these distortion effects as much as possible. The distortions are smallest in the centre of the field of view. For most fluoroscope applications (angio, DSA, surgical feedback) these distortions are acceptable. However, for measurement purposes these effects should be corrected. To assess the magnitude of these errors a test was done to extrapolate the path of a guide wire during hip surgery. In a fluoroscopic image about three centimetres of guide wire was visible in the lower left corner. A line object was overlaid on the drill guide and then extrapolated (see Figure 5-3) not taking the image distortion into account. Then the guide wire was drilled to its final position (an advancement of about 12 cm) and the obtained drill path was compared with the predicted one (the line overlay). At its final position the tip of the wire was already located 5 mm above the predicted location. This confirms the experience of the surgeon who explained that normally for this procedure he aims a little bit lower than the place he wants to be.

In the clinical setting surgeons use their experience to compensate for image distortions. If the C-arm would be rotated slightly in the previous example the distortions would cause the drill path to deviate down instead of up. These experience-related corrections only work if the images are always taken in the same way. The same holds for computer-assisted surgery and measurement systems. For the CAOS program for anterior cruciate ligament surgery the models for the attachment sites were based on 'true lateral' X-rays with overlapping

condyles. If the used image is ‘close’ to this ‘optimal image’, measurement errors will be small. The system should never be used for images that clearly show non-overlapping condyles. CAOS systems cannot interpret the radiographic images themselves and decide if it can be used. It is the responsibility of the system operator and the surgeon to decide if an image is suitable for measurement.

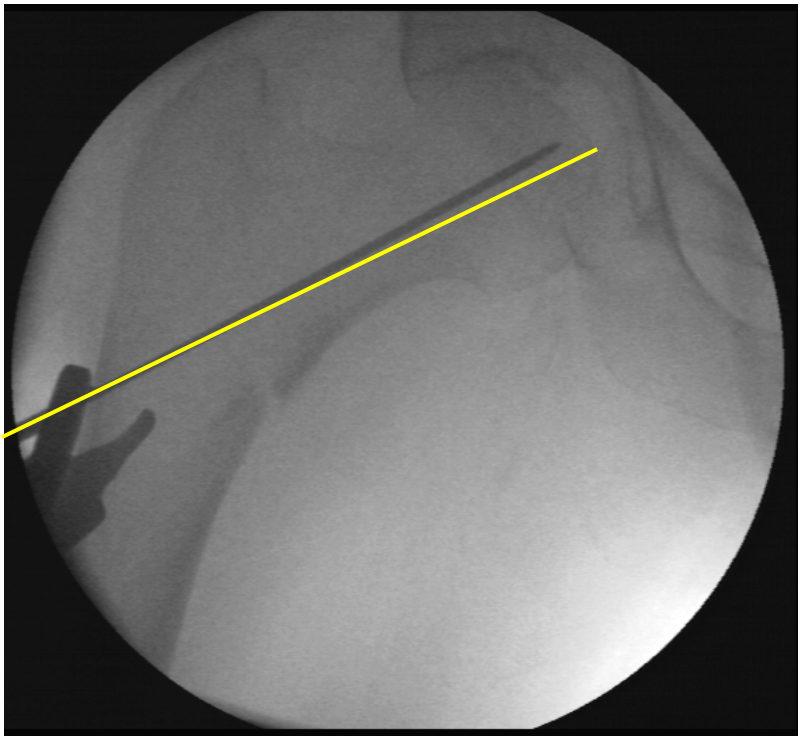


Figure 5-3: Deviation of the actual drill path (in black) compared to a extrapolated drill path (in white) based on the observed orientation of the guiding instrument.

To correct image distortions (for a certain orientation in space) a calibration plate is attached to the image intensifier (II). The calibration plate is a Perspex plate with a grid of steel bullets, one inch apart. Distortion correction techniques with these kinds of calibration plates are described in [Banks, 1992], [Banks, 1996], [Hofstetter, 1999], [Gronenschild, 1997], [Gronenschild, 1999]. The methods start with identifying the location of the steel bullets in the distorted image. Then the locations of the bullets as they would be in an undistorted image are determined. Some techniques are based on the assumption that the steel bullets in the centre of the image are free of distortions (Hofstetter, Gronenschild); others (Banks) use two plates at different distances from the II and the geometry of the imager to calculate the position of the balls in case the system would be distortion-free. From these two coordinate sets a transformation matrix is determined that transforms the

distorted image into the corrected image. The matrix only holds correction vectors for the grid itself. Corrections for the other pixels are determined by interpolating the correction vectors.

The interpolation techniques can be divided into global schemes that use all balls or a local scheme that use only the four nearest vectors for pixels that reside inside a region. The most commonly used interpolation technique is the bilinear interpolation. Gronenschild presented a comparison between global and local correction techniques. He showed that the global techniques are more accurate than the local techniques. All methods report a final accuracy of about one millimetre. A distortion correction tool for fluoroscopic images would be a valuable expansion of our toolbox.

5.2.4 Pros and cons of computer-assisted measurement

Computer-assisted measurement systems

- provide measurement tools (non-destructive overlays) that can be positioned and altered easily
- offer several image enhancement functions (simple functions to change brightness and contrast but also more complex functions for image filtering and histogram manipulation)
- perform calculations necessary for more complex measurements
- eliminate errors in reading ruler results and writing down or copying results
- help with all sorts of image calibrations, distortion corrections and coordinate transformations
- automatically store all results into a database or spreadsheet
- not only store the final results but also all measurement tool coordinates and thus all anatomical markers used in the measurement process
- facilitate statistical analysis of the measurement method itself
- store all images with separate overlays for each measurement and observer

Besides these advantages a computer-assisted measurement approach would also have some disadvantages.

- digitising images that are available on film takes time
- interfacing image modalities requires cooperation of the manufacturers
- transporting images over a network requires additional effort/time
- a light box can be found in every specialist's office; this is not yet true for a personal computer

Most of these disadvantages will disappear when the hospital modernizes and 'digital' picture archiving and communication systems (PACS) are introduced.

5.3 Clinical measurements

To collect the requirements for computer-assisted measurement systems several clinical measurements will be analysed. They will be divided into diagnostic, surgical measurements and research measurements. The presented examples are not limited to

orthopaedic measurements. Our work on computer-assisted systems sometimes triggered other specialists in our hospital to suggest projects covering their own field. After explaining the measurements the requirements to implement them in a computer-assisted measurement system are presented. Some of the diagnostic and surgical measurement systems and all research measurement systems were actually implemented during the course of this thesis project.

5.3.1 Diagnostic and surgical measurements

CDH (Congenital Dislocation of the Hip)
If a surgeon suspects a congenital dislocation in an infant's hip an AP pelvic X-ray will be made. On these X-rays the positions of the femoral and pelvic bones are marked [Hensinger, 1979]. The surgeon identifies Hilgenreiner's horizontal line, Perkins' vertical line, and the line of the acetabular roof and Shenton's curve. From the acetabular roof and Hilgenreiner's line the acetabular index (Dutch: pandak hoek) is calculated. Depending on the gender and the age of the infant this angle has to be within a certain range. These angle ranges are tabulated for an AP pelvic X-ray with the hips extended, the lower extremities normally aligned and in neutral rotation. This however is not a 'normal' position for an infant. Often the pelvis will be tilted and the angle tables will not be valid. If the pelvic tilt could be estimated the tables could be recalculated to make the values usable again.

Requirements: import large X-rays; draw lines; draw curved contours; make annotations; calculate angles; store and access tables; estimate tilt.

Cup migration in total hip replacement
Aseptical release of the acetabulum component (the cup) is a known problem with total hip replacement. Early diagnosis is very important to assure a successful re-intervention. Normally patients will not have complaints in the early stages of release. To assess if there is release the position and orientation of the cup are measured on follow-up X-rays. These positions are measured relative to the pelvic bones. As the movements will be very small these measurements are very difficult. To compare measurements accurately all follow-up X-ray images will have to be oriented the same.

Requirements: import large X-rays; draw lines; draw circle/ellipse; measure distances and angles; calibrate measurements; store and access positions.

Isometry measurements in ACL surgery
In ACL reconstruction surgery it is preferable to have isometric attachment sites for the graft (see section 2.4.2). This implies that the graft will function during the full range of knee motion. Collette [Collette, 1996] described a method to locate a femoral attachment site that is isometric to a realized tibial attachment site. The method is based on two measurements, one on an X-ray with the knee in flexion and one with the knee in extension. In both measurements the position of the intercondylar roof is measured relative to the tibia position. Based on the intersection of the extension of Blumensaat's line and the tibia plateau, an isometric zone at the femur site is determined.

Requirements: handle multiple images; draw lines; intersect lines.

Stroke volume estimation in echocardiography
The stroke volume of the heart can be roughly estimated from an echocardiograph of the left ventricle. Based on the left ventricle's boundary contour and its axis the volume can be calculated with Simpson's rule. Before any measurements can be made the echo-image should be calibrated. Echocardiography equipment provides calibration marks in the images.

Requirements: import echo images; draw line; draw contours; calculate border, area and volume; calibrate distance measurements.

Brachytherapy quality control in radiotherapy
After dilating a blood vessel with a balloon the vessel does not always remain open. In some cases the vessel will clot again. To prevent this a stent can be inserted into the vessel. Even in case a stent is used the formation of scar tissue can cause problems. To prevent the vessel from clotting again it is possible to irradiate the tissue with a small radiation dose. The dose is administered with radioactive bullets, which are inserted through the same catheter that was used for the balloon and the placement of the stents. The procedure will only be effective if the complete area in which the balloon was located is irradiated. To determine this match the position of the stent, the balloon and the radioactive bullets have to be measured.

Requirements: import (live) X-ray images; handle multiple images; combine overlays of two images; draw contours; rotate and resize contours; mark positions and areas; measure distances and region-overlap.

Head shape measurements
To check if a head has deformities a photo (or digitised video image) is analysed. The head contour is traced and the differences to a circular or elliptical form are determined. From these differences the degree of deformity can be determined.

Requirements: import (live) video images; draw contours; fit circular or elliptical models.

5.3.2 Research measurements

Tibia reponation during femoral tunnel drilling
During ACL surgery two tunnels are drilled in the knee. With the currently used transtibial ACL reconstruction technique the femur tunnel is drilled through the tibia tunnel with the knee in about 90 degrees flexion. The femoral drill guide is positioned in the 'over the top' position and rests against the backside of the tibia tunnel. During the virtual-placement this femoral drill guide is not present in the knee (see Section 6.3.4.3). The orthopaedic surgeon wants to check if the femoral drill guide forces the tibia in an unnatural posterior position. If the tunnels were drilled in an unnatural position, this would affect the functionality of the graft. To measure if this unwanted effect occurs the position of the tibia relative to the femur has to be measured in two sets of images: first a set consisting of pre-operative images without the femoral drill guide, second a set consisting of intra-operative images taken during drilling of the femoral tunnel.

Requirements: import X-ray images; draw lines and circles; measure distances; handle two series of images; store measurements.

Intercondylar roof angle vs. outcome
The clinical result of cruciate ligament knee surgery is assessed via Biodex testing, questionnaires and laxity testing. One of the factors that might influence the clinical outcome is the intercondylar roof angle. This angle is measured relative to the femoral axis. The femoral axis can be derived from the anterior or posterior femoral cortex or from both. To investigate the relation between clinical outcome and the intercondylar roof angle a set of intra-operative and post-operative images are selected for roof angle measurements.

Requirements: import X-ray images; draw lines; measure angles; handle series of images; store measurements.

Measuring knee laxity with stress radiography
The main functionality of the anterior cruciate ligament is to provide anterior-posterior stability to the knee joint. In the normal clinical situation knee laxity is assessed manually or with an arthrometer. Intra-operatively it is possible to assess knee laxity from radiographic images by directly measuring the displacement of the tibia relative to the femur when force is applied (stress radiography measurements).

Requirements: import X-ray images; draw lines and circles; handle series of images; store measurements.

Measuring the position of the DHS screw in the femoral head
The dynamic hip screw (DHS) is used to stabilize a hip fracture. A correct position of the DHS screw relative to the femoral head is very important for the success of the procedure. The position of this screw is determined in an AP as well as an axial radiographic image. In both images the DHS screw is modelled with a straight line; the femoral head is modelled with a circle. The smallest diameter of the femoral neck is modelled with a line (perpendicular to the femoral neck axis). The position of the tip of the DHS screw is measured with two relative measures:

- the distance to the centreline (the diameter of the circle that is parallel to the axis of the DHS screw) expressed as a percentage of the circle diameter
- the distance to the circle edge in the direction of the centreline expressed as a percentage of the circle diameter

The position of the DHS screw relative to the femoral neck is measured by intersecting the DHS screw line with the femoral neckline. This intersection point is reported as relative to the length of the neckline (0% being the most proximal point of the neck line).

Requirements: import X-ray images; draw lines and circles; create parallel and perpendicular lines; handle series of images; measure distances (relative), store measurements.

5.4 Requirements for computer-assisted measurement programs

In the previous section several measurement tasks were presented and a list of requirements was collected. Summarizing, a computer-assisted measurement program should comprise modules for:

- importing all types of images (X-rays, echography, video, CT, MR)
- handling multiple images and image series
- drawing points (mark positions), lines, contours (mark areas), circles and ellipses
- making annotations
- creating non-destructive overlays
- measuring distances, angles, rotation, area, region-overlap and volume
- calculations such as projections and intersections
- storing and accessing data (database or spreadsheet)
- exporting the data to statistics programs

Next, the consequences for the image acquisition and processing, the calibration and distortion correction, the user interface, and possible extensions will be discussed.

Image acquisition and processing
To use a computer-assisted measurement program the physician or surgeon has to digitise the radiograph with a scanner or digitise the image directly from the video output of an image modality. In a growing number of hospitals the radiographs are available digitally and can be accessed via a network (DICOM). If it is necessary for a good measurement, the user should be able to alter image intensity and contrast to improve the image quality. It should also be possible to zoom in and look at details in the image.

Calibration and distortion
As discussed in section 5.2 a computer-assisted measurement system should provide calibration tools for magnification and shortening effects. To support measurements in different directions each measurement tool must have its own calibration value. For accurate measurements on fluoroscopic images also distortion correction should be implemented.

User interface
For diagnostic and research measurements the specialist will be the user of the computer-assisted measurement system. For the surgical measurement tasks the specialist can perform the pre-operative and the post-operative measurements but not always the intra-operative measurements. The intra-operative measurements will be under control of an OR technician (as with the anterior cruciate ligament CAOS system). The requirements and specifications for the computer-assisted measurement system's user interface should thus be defined in close cooperation with the specialist (for functional and operational requirements) and the OR technician (for operational requirements).

The diagnostic and surgical measurements are simple measurements that are performed during a normal day's work. Research measurements mostly consist of many measurements on large image sets with multiple observers. The validity and reliability of the measurement

technique can be evaluated by using inter- and intra-observer testing. The research measurements will be carried out during occasional pauses or after office hours. The measurement system should thus be able to cope with highly fragmented measurement sessions. For all measurements it is important that the system's user interface is designed to carry out the measurement task at hand as efficiently as possible. Extra or non-essential features should never complicate this task.

Extensions
Initially, we focused on measurements for radiographic and fluoroscopic images. However, all two-dimensional images can be used for measurements (for example video images of a person's head and single CT or MR slices). Besides this, the approach can be extended to include measurements in three-dimensional images.

5.5 Design of a computer-assisted measurement system

In order to develop computer-assisted measurement programs quickly, the rapid prototyping strategy and toolbox as described in chapters 3 and 4 will be used. The design of the computer-assisted measurement system consists of two parts: a generic part and an application specific part. The generic part contains functionality to acquire the image from scanner, video source or network; functions to display, enhance and resize the images; and functions to display and interact with the measurement tools. The application specific part contains the measurement protocol, the measurement tools, and a module for the data storage.

For research measurements the control for executing the measurement protocol can also be implemented in the generic part. Several specialists will conduct a set of measurements on a list of images. The interface should have controls to select the measurement and identify the observer. Measuring will often take place in very fragmented measurement sessions so the user must be presented with an option to stop measuring at any time. The generic measurement user interface will thus contain the following controls:

- select measurement
- select observer
- next measurement
- quit

No corrections or backtracking will be allowed. As soon as the user selects a measurement the corresponding measurement protocol is loaded. This measurement protocol contains:

- a list of images
- a list of observers
- a list of measurements to be performed in each image
- a list of measurement tools
- a database to store the information for this measurement

The list of images contains all (radiographic) images on which measurements have to be performed according to the selected measurement protocol. The list of the observers contains the names of all people who perform the measurements. This list will be shown via the **select observer** control. Once the observer selects his or her name from the observer box the database is accessed to retrieve the last entry of this observer. The system then switches to the next measurement and displays the corresponding measure tools. The observer can proceed to the next measurement by pressing the **next measurement** button. All measured values are stored in the database before each actual switch to a next measurement. At any given time the observer can decide to quit and continue the measurements at a later time by pressing the **quit** button.

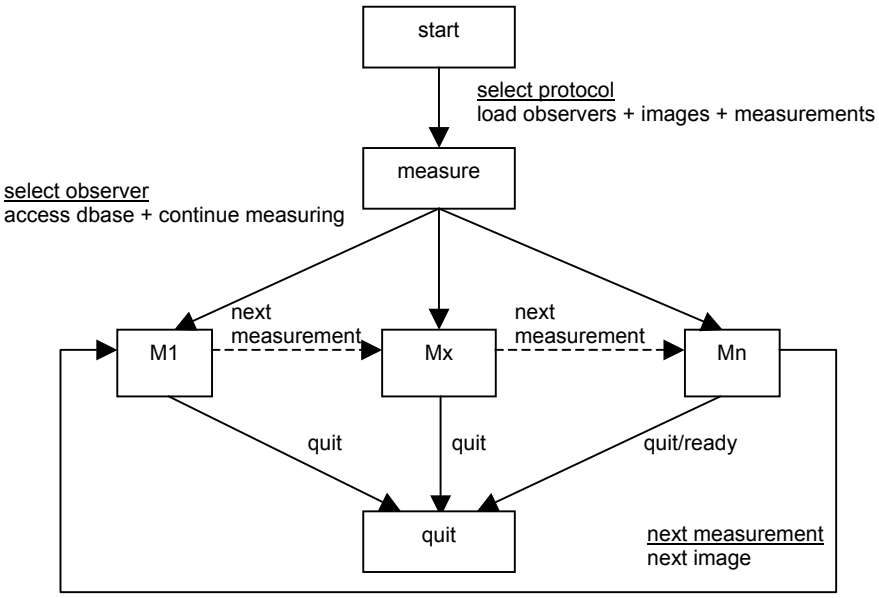


Figure 5-4: State machine representing a measurement protocol that has Mn measurements per image. The quit state and start state are the same. If the user does not exit the measurement program, a new protocol can be selected.

The measurement protocol is implemented as a state machine (see Figure 5-4). Let us assume that there are n measurements (M1 to Mn) to be performed on each image. Each time the user presses ‘next’ the measured values are saved and the tools for the next measurement are displayed. After pressing next in state Mn the system will load the next image. If there is no next image the measurements for this observer are ready and the state will return to start.

5.6 Accuracy

In order to analyse the accuracy of a measurement system it is important to look at the accuracy of each of its components and the overall accuracy. We are interested in the accuracy expressed in mm in the patient.

5.6.1 Technical details of our computer-assisted measurement system

The following technical details of our fluoroscopic system and imaging system are important when investigating accuracy:

image intensifier (II) size:	230 mm
source to II distance:	896 mm
collimator to II housing distance:	675.5 mm
source to skin distance:	202.5 mm
digital image storage:	512 × 512 pixels
framegrabber mode:	PAL video system 768 × 576 pixels
field of view:	actual image area of a digitised fluoroscopic image measures 566 × 522 pixels
mouse pointer:	cross shaped mouse pointer, ten pixels long, line width of one pixel
graphic overlays:	line width of one pixel, point marked as a small square (hollow or solid) of five by five pixels.

5.6.2 Accuracy considerations

In our CAOS system the mouse is used to enter landmarks. The accuracy of placing landmarks will depend more on finding the correct location than on marking it. Positioning landmarks in a digitised X-ray image can be done with a one pixel accuracy. With our framegrabber settings, the size of the image intensifier (230 mm) corresponds to 566 pixels. Thus, in the image 1 pixel corresponds to 0.41 mm. To investigate the accuracy we need to know the size of a pixel related to the patient, not the to the image. The relation between image-mm and patient-mm depends on the position and orientation of the measured object (part of the patient) relative to the X-ray source and the image intensifier.

For an object parallel to the image intensifier plane that is located in the centre of the C-arm the source to object distance is 540.25 mm (= 202.5 + 0.5 × 675.5). The X-ray magnification factor (source-II distance / source-object distance) than equals 1.66. Thus, 0.41 mm in the image corresponds to 0.25 mm in the patient.

If the digital image is zoomed, an individual pixel can be picked with the mouse more easily. The ‘smoothness’ of a zoomed image can be increased if interpolation filters are used, but for diagnostic tasks it is considered unwanted to use manipulated images. Zooming the images when selecting anatomical landmarks (features) seems helpful. However, if the image is zoomed too much, finding the anatomical landmarks becomes more difficult. An observer needs some anatomical context in order to trace contours and thus determine where the landmarks are.

When developing a measurement system the type of anatomical landmark and the kinds of complex measurement tools that are used to mark these anatomical sites influence the accuracy. Therefore it is important to analyse the accuracy of the measurement tools for each measurement system. Especially measurement tools that use projections can cause errors. The accuracy of measurement tools can be improved by using extra (3D) anatomical information.

We will now discuss how several aspects influence the accuracy of measuring the length of small metal pin in the X-ray image. We assume that the absolute measurement error equals 2 pixels. The relative measurement error is defined as: 2 / #lengthinpixels × 100%, with #lengthinpixels the total length of the object in (image)pixels.

Size of the image intensifier
If the size of the image intensifier increases, the size of the pixels in the image and in the patient increases and thus the absolute measurement error increases.

Source-object distance
If the source-object distance decreases (moving the object closer to the X-ray source) the X-ray magnification for the object increases. The object will be projected larger (more pixels). In this case the absolute measurement error does not change but the relative measurement error decreases. When imaging object for measurements we should always use the full range of view. However, the closer the object is to the source, the more blurred the image will be (the source is no ideal point-source).

Image intensifier resolution
Increasing the resolution of the imaging system (the CCD camera that captures the X-ray image from the image intensifier) will decrease the size of the pixels and also provide more pixels for the object. Thus, the absolute as well as the relative measurement error will decrease. However, when increasing the resolution, the blurring will affect more pixels.

Match between the working plane and the projection plane
Objects located in a plane that is aligned with the image intensifier plane will be projected without shortening. In this case, small changes in C-arm alignment will only have small effects in length change, because the projected length of an object in an image is calculated as the cosine of the angle between the object and the image intensifier plane times the actual length. Thus, if the projection (image) and the working (object) planes match, measurement errors due to movements of the patient and the instruments will be minimal.

Calibration
To measure the length of an object we can calibrate these measurements with an object of known size that has the same orientation as the object to measure. The relative measurement error decreases with the size of the calibration object. Thus a calibration object should be as large as clinically possible. To measure objects in an X-ray image that have a different orientation in space each measurement should be calibrated separately. If objects have almost the same orientation it is possible to use only one single calibration value. However, this introduces an extra measurement error.

Feedback of the surgeon's actions
Our CAOS and measurement systems can only collect information from X-ray imagers and direct user input. Because we do not use continuous fluoroscopy or 3D instrument tracking, our systems cannot deal with changes in instrument or patient movements after taking the X-ray. It is the user's responsibility to make a new image if the situation changes significantly. The accuracy of our systems is also directly affected by the accuracy of manually entered data.

Image distortion correction
Another important aspect that affects the accuracy is the image distortion caused by the fluoroscopy system (discussed in section 5.2.3). For measurement systems based on fluoroscopy images distortion correction should be implemented if a high (1 mm or below) accuracy is required.

5.7 The evaluation of measurement systems

With the toolbox we can create a computer-assisted measurement system for most measurements a physician can think of. However, the essential part is to create a measurement system that provides correct and accurate results. In section 5.6 we discussed some technical aspects of computer-assisted measurement systems that are related to accuracy. When designing measurement procedures it is also important to verify the reliability, validity and the responsiveness of the measurement tool [Deyo, 1991].

- Reliability comprises the internal consistency of a scale and the reproducibility of the scores. Deyo describes the internal consistency as a term for the correlation among items comprising an instrument, by using statistics such as split half comparisons or the more general Cronbach's alpha. The reproducibility can be determined with two similar measurements at different times (test-retest) or by using two similar measurements made by different observers. Reproducibility can be assessed with the product-moment (Pearson) correlation or the intraclass correlation coefficient (ICC).

- Validity means that a measurement actually measures what one wants to measure. The validity of a measurement can be determined by comparing it to a 'golden standard' measurement (if this is available).

- The responsiveness is the ability of a measurement to detect the smallest relevant clinical changes. Responsiveness is also known as sensitivity to change. The responsiveness can be assessed with the t-test, effect size, Guyatt's responsiveness statistic or the ROC method [Deyo, 1991].

To support such a statistical evaluation of the measurement procedures the measurement prototypes must supports the storage of all intermediate and final results. The actual statistical analysis can then be performed with appropriate statistical programs.

5.8 Computer-assisted stress radiography

As discussed in chapter 2, the main functionality of the anterior cruciate ligament is to provide anterior-posterior stability to the knee joint. The amount of knee laxity can be measured in several ways. For all laxity tests anterior force is applied to the tibia while restraining the femur (mostly via the patella). Laxity is then defined as the amount of anterior shift of the tibia relative to the femur. Knee laxity can be measured manually. However, applying force manually to the tibia while holding back the femur by pressing against the patella only provides a qualitative measure. Manual tests, such as the Lachman- or the anterior drawer test are used in the diagnosis of instability. There are several instruments (arthrometers), such as the KT1000, the KT2000 [Daniel, 1985, 1993] and Rolimeter [Balasch, 1999] that assess the actual magnitude of the instability. These arthrometers measure the displacement of the tibia relative to the femur for a predetermined flexion angle, pull-direction and force. All arthrometers have to deal with the displacement of soft tissue, which can cause measurement errors.

The displacement of the bones under anterior force can be measured directly via radiographic imaging. The radiographic images of the bones while applying an anterior force are called (radiographic) stress images. Stäubli first introduced the measurement of knee laxity in this way [Stäubli, 1990]. Stäubli measured the displacement between the most posterior aspects of the tibial plateau and the femoral condyles both on the medial and on the lateral side. Laxity is then defined as the average displacement. If these measurements are performed on ‘perfectly lateral’ radiographs (exactly overlapping femoral condyles) of the knee joint, the medial and lateral results will be the same and only one measurement is necessary. Klos proposed the use of a circle overlapping the condyles in order to determine the femoral position [Klos, Habets et al., 1998]. Amis was the first who discussed the use of a circular model to determine femoral positions [Amis, 1994]. Three methods to measure laxity with stress radiography were defined and compared to stress measurements performed with the KT2000 arthrometer. The most reliable method of measuring knee laxity with stress radiography will be built into the anterior cruciate ligament CAOS system.

Laxity is determined by the position of the tibia and the femur. The position of the tibia on lateral stress radiographs is determined with a ruler (discussed in section 4.6.1) that is positioned on the anterior and posterior cortices of the tibia. This ruler will be called the AP ruler. The position of the femur is determined in three different ways. First, the position of the femur can be defined as the most posterior point of the femoral condyles (relative to the direction of the tibial ruler). If the condyles are not overlapping the average of the most posterior position for the medial and the lateral condyle is used. This resembles the femoral position as used by Stäubli. Second, the femoral position can be defined as the centre of a circle overlaying the femoral condyles. This is the approach as proposed by Amis and Klos. Third, separate circles can be used for the medial and lateral condyle taking into account that the femoral condyles do not overlap perfectly. The femoral position is then defined as the midpoint of the line connecting both circle centres. This line is anatomically known as the Hollister line.

Based on these femoral positions three methods were defined to measure knee laxity on the stress images. The laxity for all three methods will be expressed as the AP position (in % AP) of the projection of the femur position as discussed above. The tangent method is based on the most posterior point position (Stäubli). For this method the projection line (perpendicular to the AP ruler) is a tangent line to the circularly shaped posterior aspect of the femoral condyles. The single circle method is based on the femoral position according to Amis and Klos. Finally, the dual circle method is based on the femoral position as defined by the Hollister line. The dual circle method takes into account the possibility of femoral rotations (and thus non-overlapping condyles). The three measurement methods are presented in Figures 5-5a, 5-5b, and 5-5c.

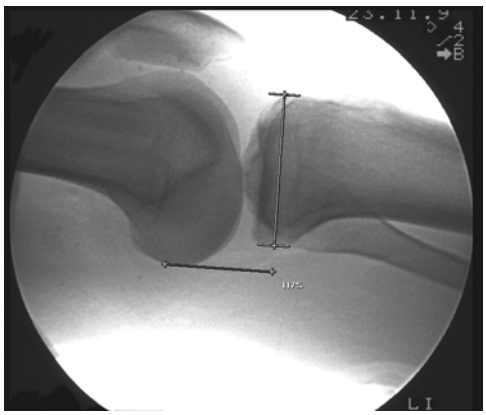


Figure 5-5a: Tangent method. Femoral position is determined by the tangent to the posterior aspect of the femoral condyle.

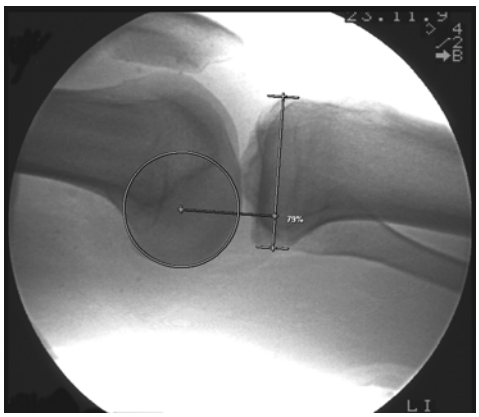


Figure 5-5b: Single circle method. Femoral position is determined by a single circle modelling both femoral condyles.

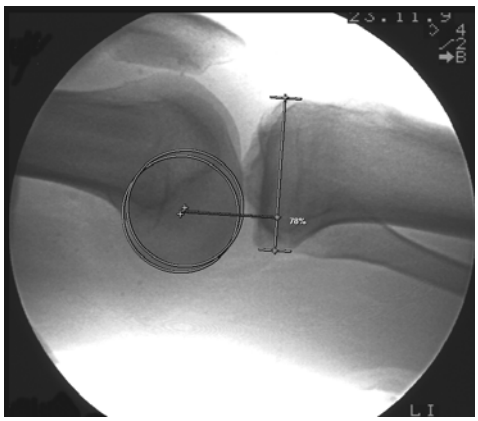


Figure 5-5c: Dual circle method. Femoral position is determined by two circles each modelling a femoral condyle.

5.8.1 Evaluation of three methods for stress radiography

The three studies discussed below were performed in cooperation with Caroline Slits in the context of her graduation project of the Human Movement Science study at the University of Maastricht, the Netherlands. A detailed description of the tests and the statistical analysis is provided in her graduation report: Computer-assisted stress radiography for intra-operative guidance in anterior cruciate ligament reconstruction [Slits, 1999]. The results of the validation study were published in co-operation with Klos [Klos, Habets et al., 2000c].

First, a reliability study was done to assess which method is the most suitable to determine stress laxity. A measurement program called Stressrad was developed to implement the three measurement methods. In total 56 images (14 subjects, four images per patient: two pre-operative and two post-operative images) were assessed by 5 observers (two students, two orthopaedic surgeons and one orthopaedic assistant). Developing the measurement program took about one week (by using the generic measurement program discussed in section 5.5). The user interface is presented in Figure 5-6. The list of images contains 28 radiographs with the knee in 90 degrees flexion and 28 radiographs with the knee in extension. The list of observers contains the names of the five observers. The list of measurements contains three entries: tangent, single circle and dual circle. The list of measurement tools contains three sets of tools corresponding to the three methods (AP ruler; AP ruler + circle1; AP ruler + circle1 + circle2). For the tangent measurement the x and y coordinates of begin point (A) and endpoints (P) of the AP ruler (Ax, Ay, Px, Py) will be stored together with the AP percentage of the femoral location (AP%T). For the single circle method the x and y coordinates of the circle centre and radius (Cx, Cy, Cr) will be stored along with the AP percentage of the circle centre (AP%SC). For the dual circle method the coordinates and the radii of both circles will be stored (C1x, C1y, C1r, C2x, C2y, C2r) along with the AP percentage of the midpoint of the line connecting both circle centres (AP%DC).

The inter-observer reliability was assessed with the Intraclass Correlation Coefficient (ICC) between observers. The ICC is described in [Landis, 1977] and [Shrout, 1979]. A high value for the ICC value indicates that the differences in the measurements are caused by differences in patients and not by measurement errors. Our interpretation of the ICC values will be based on the scale of interobserver agreement published by Landis and Koch (Table 5-1).

Table 5-1: Landis and Koch scaling of agreement for Intraclass coefficient values.

Agreement	Values
slight	0.0 to 0.2
fair	0.21 to 0.4
moderate	0.41 to 0.6
substantial	0.61 to 0.8
(almost) perfect	0.81 to 1.0

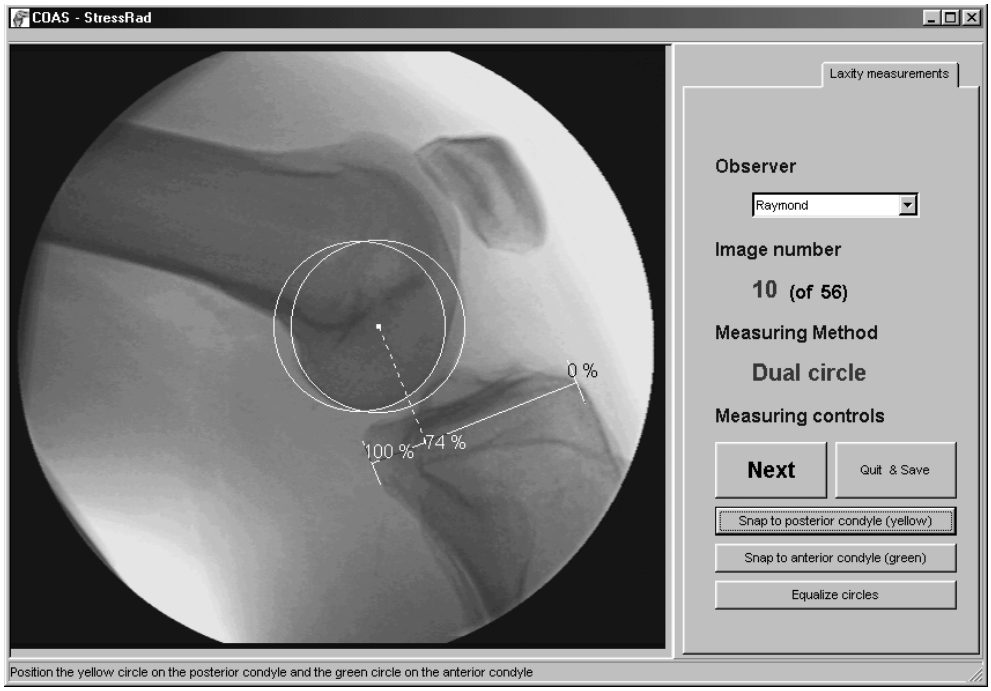


Figure 5-6: User interface of the stress radiography computer-assisted measurement system.

To assess the accuracy of placing the landmarks used for our measurement tools the variability of placing each landmark was measured between observers (inter-observer) and within one observer (intra-observer). For a group of five observers we will analyse the distance of each landmark to the average position (calculated from all observers). The intra-observer variability will be assessed by repeating a set of measurements five times. We also compared the inter- and intra-observer variability of the AP ruler angle.

Second, a validation study was done to assess if stress radiography results agree with the KT2000 scores, which are considered the 'golden standard'. Besides this, we will assess if the results of both methods can be used to determine an increase in knee stability (pre/post comparison). For the validation study a group of 27 patients was assessed with stress radiography and KT2000 testing. The stress radiography scores were compared to KT2000 scores in several ways:

- pre-operative Stressrad with 20° and 80° of knee flexion and pre-operative KT2000 both under anesthesia (KT2000 pre).
- post-operative Stressrad with 20° and 80° of knee flexion (under anaesthesia) and post-operative KT2000 without anaesthesia (KT2000 post)
- pre-operative KT2000 without anaesthesia (KT2000 pre) and pre-operative KT2000 under anaesthesia (KT2000 peri)

For the pre-operative comparison the KT2000 system was also used under anaesthesia (just before surgery after spinal or full anaesthesia). To investigate if the KT2000 results are comparable with and without anaesthesia the pre-operative test was done for both situations.

5.8.2 Measurement protocol

For the reliability study the observers were instructed to use the following measurement protocol:

- Select your name from the select observer list. The system will access the database and show the next image and measurement. The next measurement will be one of the methods described in section 5.6 (the tangent method, the single circle method and the dual circle method).

- For the tangent method: Position the anterior point of the AP ruler on the most anterior position of the tibial cortex and then the posterior point of the ruler on the most proximal position of the tibial cortex. The AP ruler must be positioned parallel to the tibial plateau. Finally, the slider of the AP ruler must be positioned at the most posterior location of the femoral condyles. In case the condyles are not overlapping a point exactly between the medial and lateral condyle should be selected. The system will automatically project the slider position onto the ruler and calculate the AP percentage. Press next if you are satisfied with the selected locations. The position of the AP ruler will be 'frozen' for both circular methods. It is not possible to change the location of the AP ruler during the two circle methods because we want to investigate which of the three femoral positions is best for determining laxity. The system thus assures that there are no differences in tibial landmarks between the three measurements.

- For the single circle method: Position the circle to match the posterior and inferior aspects of the femoral condyles. In case the condyles do not overlap, position the circle between the medial and the lateral condyle as best as possible (again based on the posterior and inferior parts of the condyles).

- For the dual circle method: Position both circles, one on each condyle, and make sure the circles again match the posterior and inferior aspects of the condyles. In case the condyles do overlap, position the circles on top of each other. This can be accomplished easily by pressing the **equalize circles** button. Initially both circles are presented with the same diameter. Make sure that both circles remain roughly the same size.

5.8.3 Results

Reliability study
Table 5-2 shows the inter-observer reliability (ICC scores) of the different methods between the five observers. The results are divided into pre-operative (pre) and post-operative (post) and for flexion (flex) as well as near extension (ext).

Table 5-2: Intraclass correlation coefficients for joint laxity measurements by using stress X-rays by 5 observers.

method	pre-ext	pre-flex	post-ext	post-flex
tangent	0.67	0.44	0.65	0.52
single circle	0.81	0.89	0.81	0.77
dual circle	0.83	0.87	0.80	0.75

Table 5-3 shows the inter-observer variability of the landmark positions. The table shows the average distance of each individual landmark determined by each observer to the mean landmark positions (the average over all observers). The average difference in AP ruler angle (tilt) for observer 1 and 2 was 2.4 degrees. Table 5-4 shows the intra-observer variability for the landmark positions and the AP ruler angle for observer 3.

Table 5-3: Inter observer variability of the individual landmark positions relative to the mean landmark position (in pixels).

A: anterior landmark

P: posterior landmark

C(single): centre of the circle in the single circle method

C1(dual) and C2(dual): centres of both circles in the dual circle method

Observer	A	P	C (single)	C1 (dual)	C2 (dual)
1	4.37	4.75	7.53	9.20	7.71
2	6.76	9.56	6.25	9.28	5.89
3	6.57	4.19	3.37	5.44	5.76
4	6.33	7.28	4.87	6.01	5.50
5	10.07	10.39	3.12	4.58	4.01

Table 5-4: Intra observer variability values (average range) of the individual landmarks for observer 3. The reported values are averages of the range (max_val - min_val) of the five repeated measurements.

Ax, Ay: range in x- and y coordinate of the anterior landmark (in pixels)

Px, Py: range in x- and y coordinate of the posterior landmark (in pixels)

angle: range in AP ruler angle in degrees

%tan: range in laxity measured with the tangent method (as a percentage of the length of the AP ruler)

Cx, Cy: range in x coordinate and y coordinate of the centre of the condylar circle (in pixels)

Cr: range in radius of the condylar circle (in pixels)

%C: range in laxity measured with the single circle method (as a percentage of the length of the AP ruler)

Ax	Ay	Px	Py	Angle	%tan	Cx	Cy	Cr	%C
7.6	2.9	7.1	4.6	2.5	4.0	4.4	5.4	3.9	4.4

Validation study
Table 5-5 shows the Spearman correlation coefficients for the agreement between the Stressrad and the KT2000 results.

Table 5-5: Correlation between KT-200 and stressradiography laxity measurements; *Correlation is significantly different from 0 at the 0.05 level.

Relation	Spearman correlation coefficient
Stressrad 20° peri - KT2000 pre	0.22
Stressrad 80° peri - KT2000 pre	0.24
Stressrad 20° post - KT2000 post	0.45*
Stressrad 80° post - KT2000 post	0.23
KT2000 pre - KT2000 peri	0.47*

Timesavings
Measuring laxity with the three methods on the 56 images took an average of 1.5 hours per observer. For each observer 896 (56×16) parameters were stored in the database so a total of 4480 values were recorded. When measuring by hand (with transparent sheets) measuring one image takes about five minutes (drawing, measuring and calculating the percentages). For the complete set of 56 images this would mean four hours and forty minutes. Measuring the coordinates of the tools themselves would take another two minutes per image (one hour and fifty-two minutes). Copying 896 values into a spreadsheet (at about twenty entries a minute) would take another 45 minutes. Measuring by hand would thus take about seven hours and fifteen minutes, almost five times as long as with the computer-assisted measure system.

5.8.4 Accuracy of the measurement tool

The overall accuracy of the stress radiography measurements depends on the type of anatomical references (for example landmarks), the accuracy of placing them and on the design of the complex measurement tools. For the single circle stress laxity measurements the anatomical references consist of the AP ruler and the condylar circle.

The measurement protocol states that AP ruler should be positioned from the most anterior point to the most anterior point or the tibial cortex parallel to the tibia plateau. As the tibial cortex is almost perpendicular to the tibia plateau the AP ruler's position can still vary in the proximal distal direction along the proximal-distal cortex. The femoral landmark, which is the centre of the condylar circle, is projected onto the AP ruler. If the AP ruler is moved in proximal distal direction but parallel to the tibia plateau, the projected percentage will be constant. However, if the AP ruler is moved in anterior-posterior direction or if the ruler tilts, the projected percentage will change.

To estimate the measurement tool's sensitivity to ruler tilt we investigated the inter-observer and intra observer variability of the individual landmarks and the ruler angle. From table 5-3 we can learn that the inter observer variability of the most anterior and posterior points on the tibial cortex is about 7 pixels. 7 pixels corresponds to an offset of about 2 mm. If we assume this 7-pixel offset to be along the tibial cortex and assume it to

be in different directions for the anterior and the posterior point the maximum tilt error would be about 4 degrees (with an average AP length of 191 pixels). For an average femoral position of 73% AP with an average distance of 119 pixels to the ruler, a 4 degree rotation error will cause a 4% change in reported percentage (see Figure 5-7). If the 7-pixel shift would be in anterior-posterior direction, the maximum error would be around 3%. Misplacing the condylar circle will have a similar effect. The condylar circle can be placed with an average accuracy of about 5 pixels, which corresponds to 1.5 mm. If this shift in the femoral position were entirely in an AP direction (along the ruler) a 5-pixel shift would also correspond to a 2.6% change in projected percentage.

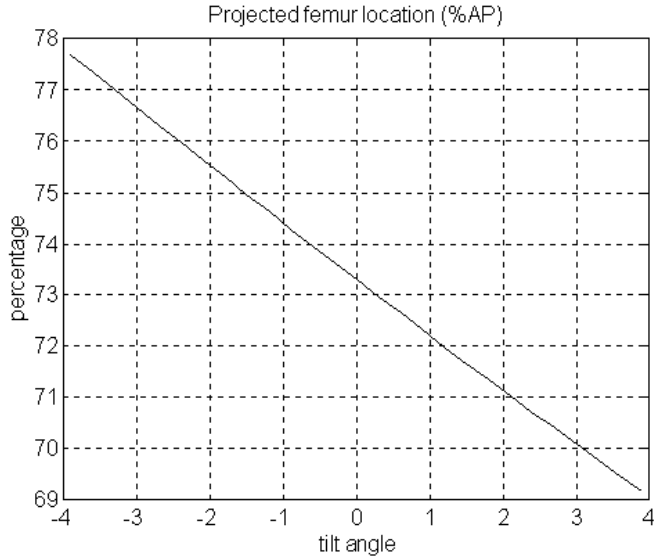


Figure 5-7: Relation between the AP ruler tilt angle and error in projected percentage for the single circle method.

The analysis in the previous paragraph is a worst-case situation based on measurements from different observers. The average inter-observer tilt difference was 2.4° (stdev 1.7°). The average range of the intra-observer tilt angles was 2.5°. The expected error due to AP ruler tilt will thus be around 2.5% AP.

KT2000 research has shown that a laxity difference of about 2 mm between the two knees (corresponding to 3.6% AP) is relevant to decide on ACL insufficiency. To measure these differences the ruler will have to be positioned very accurately in order to have usable stress laxity measurements.

5.8.5 Clinical evaluation

The results of the reliability study (ICC scores from table 5-2) show that both circle methods perform better than the tangent method to measure knee laxity. The high ICC scores for the circular methods imply that the circular methods can be used reliably to assess knee laxity. From the accuracy analysis in section 5.8.4 we can learn that the

measurements are very sensitive to AP ruler tilt so extra care should be taken to position the AP ruler exactly parallel to the tibia plateau.

For the validation study the observers were instructed to position the AP ruler accurately by following the measurement protocol precisely. The single circle method was selected for the validation study because it is faster and easier to use (position one circle instead of two). As the data was not normally distributed the Spearman correlation coefficient was selected to compare the stress laxity results with the KT2000 scores. As the KT2000 test is performed in extension and the reconstructed anterior cruciate ligament functions mainly in extension it was expected that the scores in extension would show better correlation than the scores in flexion. From table 5-5 we can see that only the post-operative KT2000 scores and the post-operative stress laxity scores at extension (20°) and the pre-operative KT2000 scores with and without anaesthesia showed a moderate correlation significantly different from zero. All other correlation's were not significantly different from zero. The moderate correlation between pre-operative KT2000 with and without anaesthesia shows that pre-operative KT2000 measurements may not accurately reflect the knee laxity.

The poor correlation results can have several reasons. First, C-arm images were used instead of radiographs (without distortion correction). Expressing the laxity as a relative percentage eliminated errors due to different magnification in the pre-operative and the post-operative images. Second, the stress laxity test is a manual test. The surgeon controls the knee position, knee angle and the magnitude and direction of the force. Thus, the values of all these parameters will differ from measurement to measurement but also from the KT2000 test in which a mechanical device is used to keep all parameters constant. Differences in force direction will influence the measurement because the anatomy is tested in a different direction but also because the (projected) laxity will decrease if the direction of the force is not parallel to the image plane. Third, all measurements are done just before and during the procedure when the condition of the knee can hardly be considered stable. Finally, the poor correlation results can also be caused by the fact that KT2000 results are only reliable if the operator is an experienced tester and the patients completely relax their muscles [Slits, 1999].

For future research comparing stress radiography and KT2000 measurements it is important to keep all parameters constant. It would be best to take the stress X-rays during the KT2000 testing. However, Stäubli and Lerat also found poor correlation between arthrometric (KT1000) tests and the stress laxity tests (tangent method), although they did keep all parameters constant [Stäubli, 1997], [Lerat, 1993]. We thus conclude that the KT-2000 test is not suitable as a golden standard to validate the intra operative laxity scores.

Although the stress radiography results do not correlate with the KT2000 scores, both scores can be used to detect a reduction of laxity after the ACL reconstruction procedure. A paired T-test showed that the mean difference in laxity (pre-post difference) was significantly reduced after the procedure. In a study of 27 patients we found a mean side-to side improvement of 11.5 % [Klos, Habets et al., 2000c].

As the ICC scores were good (> 0.8) and the tests showed that a significant difference in knee laxity could be detected (as can be expected after surgery), we conclude that stress radiography is suitable to measure the change in joint laxity during surgery. We implemented the single circle method in the CAOS system for ACL reconstruction. The system operators will be instructed to keep the ruler parallel to the tibia plateau. To make the stress measurements less sensitive to tilt errors of the AP line this line could be determined relative to the tibia plateau and the tibia axis. By identifying more markers along the tibial cortex, the computer system can determine the position of the AP line automatically. We decided to use the stress radiography in its present form and use the scores as an indication of improvement of knee stability.

5.8.6 Clinical stress laxity measurements

Six stress images are recorded. Pre-operatively both the involved (injured) and the non-involved (normal) knee are tested in flexion as well as in extension. Post-operatively only the involved knee has to be tested again in flexion and extension.

For measuring stress laxity the fluoroscopic stress images are digitised intra-operatively. The interface includes a button to digitise and store each of the six stress images (see section 6.4.2). Each button shows if the corresponding measurement is taken (name is crossed out). Each stress image has a **load** button associated with it, that displays the selected images and displays the measurement tools over the image. After positioning the tools the **calc** button can be used to calculate and store the stress value of the corresponding stress image. The stress laxity is measured as soon as the images are taken. The improvement is then reported back to the surgeon directly and if necessary the surgeon can decide to retension the graft.

5.9 Discussion

Measuring the results of a procedure (outcome) and relating those measurements to surgical actions is an important step in improving the quality of care for our patients. In this chapter we showed that computer assistance can indeed help to make these measurements more easily.

The goal was to assess the usability of the toolbox to create computer-assisted measurement systems in a fast and easy way. Our toolbox proved to have the flexibility to create computer-assisted measurement systems. The toolbox and the generic design for the research measurement systems (presented in section 5.5) provide a means to build a measurement program in a few days. Besides the laxity measurement system we also developed the cup migration measurement program, the tibia reponation measurement program and the intercondylar roof angle program. The tibia reponation measurement program was completed in just one day because this measurement resembles the single circle method of the stress measurement program. The intercondylar roof angle program was completed within three days. The system's users were very pleased with the ease of use, the automated data collection and the significant reduction in the time spent doing the measurements.

5.9.1 Building measurement tools

For most clinical research it would take more time to develop computer-assisted measuring tools systems than it would take to do these measurements by hand. Only for very large studies the automation of the measurements and the data storage can be considered. Besides the time necessary to develop the systems also the availability of a technical staff (designers and software engineers) to do the actual development will be an issue for many hospitals. Finally, developing dedicated systems for small projects can never be cost effective. Our approach to design these computer-assisted measurement systems has eliminated the need for long development times and huge costs.

As an alternative, computer-assisted measurement systems could be provided commercially. All companies that develop clinical application software have development platforms (similar to our toolbox) that can be used to create these kinds of computer-assisted measurement systems. If they would also develop and commercially distribute a platform to create these systems quickly (like the one discussed in this chapter) it could become cost effective to create software for only one or a very small number of clients.

Depending on the complexity of the user interface of such a platform the final development (tailoring) of the computer-assisted measurement systems could be performed by the company's engineers, technical specialists within the hospital (for example the clinical physicists), or even the specialists themselves. A similar trend can be observed with the development of programming languages. Programming languages have evolved from highly hardware dependent languages (such as assembler) that were only suitable for engineers, to graphically oriented functional languages (such as Borland's Delphi).

With our development environment a programmer can build a computer-assisted measurement system in a few days. To make the development environment suitable for physicians we need to develop a user interface that allows them to enter their own measurement protocol. This user interface should support building measurement tools in a graphic and interactive way (drawing of graphical objects and the definition of relations between these graphical objects). Besides the measurement tools, the interface should also support the specification of the list of images and observers and support the creation of a database for storing the measurement results.

A possible implementation would be to create a user interface that allows the surgeon to create a measurement protocol in a visual way. By using building blocks that create graphics, relations and lists, the user could 'draw' the protocol and then execute it. The interface described above resembles interfaces such as the SIMULINK interface of the MATLAB program. MATLAB is a mathematics and visualization program that contains an enormous library of functions. The SIMULINK toolbox contains an interface that allows the user to build mathematical models in a visual way and then to perform simulations. The development of such a visual interface for our CAOS toolbox fell outside the scope of this project.

5.9.2 Integration into the clinical setting

The computer-assisted measurement system for stress radiography (discussed in section 5.8) was installed on an 'all-purpose' computer in the orthopaedics department. One surgeon took the program home and sent the measurement results by e-mail. The measurement images were collected relatively easy with the CAOS system for anterior cruciate ligament surgery. Most observers completed the measurements in a few sessions. Within one week all data was available. After the data was analysed, the best method was integrated into the CAOS system for ACL surgery.

The measurement system for the position of the DHS screw in the femoral head was build in a few days. Collecting the images took more work. We had to select 16 patients and digitise their X-ray films. Because the study finished and the implemented measurements were no routine clinical measurements the system was never used again. The measurement system for measuring cup migration in total hip replacement was developed for an existing research project. We selected a small series of three patients with at least three follow-up X-rays to test the measurement system. Although the test was promising, the measurement system was not used routinely because of the limited time the surgeon could spend on this project and because of the problems associated with digitising the large number of X-ray films (availability of large X-ray scanners and time).

Using computer-assisted measuring systems clinically requires constant technical support. Surgeons simply do not have the time to collect and digitise large series of images, design and set-up measuring systems (even if it is simple) and process all results. If the radiology department can provide the images digitally and if the orthopaedics department has technical support, computer-assisted measurement systems are helpful.

An important issue for a successful clinical integration of the developed computer-assisted measurement systems is how these systems can be used in clinical practice. First, we can place the measurement systems on the physician's desk as a stand-alone program. In order to make this possible the digital images will have to be transported to this computer. Second, we can integrate the measurement functionality into the PACS or HIS systems that manage all digital images within the hospital. PACS systems are available on many workplaces (including the physician's desk) and thus measurement functionality can be offered along with the images. Third, we can integrate measurement functionality into the medical imaging systems. Rulers for distances and simple angular measurements are already incorporated in the latest generation of fluoroscopic imagers. This option would enable intra-operative measurements and provide the link to the computer-assisted surgery systems.

Chapter 6

Computer-assisted anterior cruciate ligament reconstruction

6.1 Introduction

The basics of knee anatomy and the anterior cruciate ligament (ACL) as well as the ACL reconstruction procedure were explained in chapter 2. In 1994, T.V.S. Klos, an orthopaedic surgeon in the Catharina Ziekenhuis in Eindhoven, started his PhD project to improve the reproducibility and the quality of ACL reconstruction surgery [Klos, 2000d]. To accomplish this, Klos wanted to explore the possibility of using a computer-assisted orthopaedic surgery (CAOS) system for the procedure. In 1995 Klos started to cooperate with the Technische Universiteit Eindhoven. In a pilot project Kees Lambregts constructed a prototype that was used to demonstrate the feasibility of the computer-assisted surgery approach [Lambregts, 1995]. This prototype was tested *in vitro* on five cadaver knees.

A second project was then defined that aimed to develop a prototype for clinical use. This prototype must prove the clinical relevance of a CAOS system for the ACL reconstruction procedure. The following requirements were formulated:

- The prototype must be designed in close cooperation with the orthopaedic surgeon to ensure easy integration into the clinical setting.
- The clinical prototype will be developed with the evolutionary rapid prototyping approach described in chapter 3 and the toolbox described in chapter 4.
- The clinical prototype will be tested for a series of 50 patients (realized in half a year).

As described in chapter 3.4.5 the first phase of the rapid prototyping process (the identification of the customer requirements) includes setting a clear objective for this project, analysing all relevant aspects of the assignment and its environment and collecting all requirements and constraints. The second phase is the concept validation phase, an iterative process in which the key concepts of the application will be explored. This phase will result in a first clinical prototype that will be used to evaluate the clinical relevance of a CAOS system for ACL reconstruction. The third phase is the development of the final prototype that will contain all features of a fully functional system for anterior cruciate ligament reconstruction. The final prototype was developed with the toolbox described in chapter 4. This final prototype is still no commercial product, so an additional design effort must be made if a product is desired.

6.2 Identification of the customer requirements - Prototyping Phase 1

6.2.1 Introduction

Rupture of the Anterior Cruciate Ligament (ACL) is a common injury for young people. This affects the anterior to posterior stability of the tibia relative to the femur in an extended knee. To restore knee stability and to prevent secondary injuries to menisci and other structures an ACL reconstruction can be performed. A complete description of the ACL reconstruction procedure is provided in chapter 2. Below the main issues are summarised.

The two most common reconstruction techniques are the patella tendon technique and the hamstring technique. With the patella tendon technique the graft consists of a bone-tendon-bone structure. The proximal bone block is harvested from the middle third of the patella, the tendon is the middle third of the patella tendon and the distal bone block is harvested from the tibia. For the hamstring technique a hamstring tendon is used as a graft.

Under arthroscopic vision, two tunnels are drilled, one in the lower leg (tibia) and one in the upper leg (femur). The tunnel diameters are determined by the size of the graft. The tunnels are drilled with a drill guide. With the transtibial technique the femoral drill guide is inserted through the tibial tunnel. First, the tunnels are predrilled with a 2 mm Kirschner wire (K-wire). Then the K-wire is over-drilled with a cannulated burr to produce a tunnel of the correct diameter. The graft is inserted into the tunnels and fixated against the tunnel walls with cannulated interference screws. Graft position is considered the most important parameter for the success of the procedure. Some surgeons use additional fluoroscopic feedback in the sagittal plane to check the location of the drill guides in a true lateral image of the knee joint (an image in which both femoral condyles overlap exactly).

6.2.2 Assignment

The assignment in medical terms is stated as “increase the reproducibility of the ACL reconstruction procedure”. By *reproducibility* the surgeon means achieving a constant level of positioning of the new ACL graft for each patient. The position of the ACL graft is determined by the location of the drill tunnels. Therefore, our assignment is to develop a CAOS system that helps the surgeon to place the drill tunnels more reproducible.

6.2.3 Project goal

Section 3.3.2 provides a classification for CAS systems according to the way they interact with clinical practice: critiquing (measurement) systems, guidance systems and robotic systems. Each of these approaches can be used to design a system that provides more accurate positioning of the drill tunnels.

The simplest approach is the use of a measurement system to verify the tunnel positions. For this approach the system operator analyses the lateral X-ray image, detects the drill guides and verifies their positions against planned positions. The system reports the differences in positions to the surgeon. How this information is used is the surgeon’s responsibility.

A more sophisticated approach is the design of a guidance system. In this case the computer guides the surgeon in placing the drill guides. This approach requires real-time measurement, localization and display of both knee and instrument positions. The system continuously informs the surgeon if the current instrument position is in agreement with the planned one.

The most advanced approach is a robot surgery system. This is a combination of the guidance system described above and a robot (mechanical arm). The robot operates the drill guided by the guidance system. A surgeon uses arthroscopic and fluoroscopic feedback as well as tactile feedback. In order to perform equally, a robot system should use all these sources of information. Using a robot surgery system does not imply that the robot replaces the surgeon. The robot system can be seen as an additional instrument that holds the drill and the drill guide. The robot will be under the control of the surgeon assisted by the computer system.

In this project we designed a *measurement system*. The choice for this option is based on the following considerations:

- the surgeon does not have to alter the operating technique significantly
- the existing surgical instruments can be used
- the Medical Ethics Committee can quickly approve the project because the operation technique itself does not need significant changes
- a simple approach provides a testable application more quickly so we can start collecting data sooner and validate our method
- a measurement system is the logical first step, also for the other two approaches
- we do not have the time and the resources (personnel, finances, equipment, computing power) to aim at the other two approaches

We did not intend to develop a complete product; we wanted to produce a prototype suited for clinical use. First, this prototype was used to provide the data for assessing our method. Then the prototype was used as a clinical CAOS system for anterior cruciate ligament surgery in our hospital.

6.2.4 Sources of information

To obtain a clear definition of the assignment and to find solutions that are suitable for integration into the clinical setting, we do not focus solely on the assignment itself but also on the process from which the assignment originates and the environment of the assignment and process. In this case the process is described in the OR protocol for the ACL surgery. The environment analysis will encompass all aspects that are not under the direct control of the designer but do influence the assignment and the process. This implies that all relevant aspects will be investigated from the actual positioning of drill tunnels to the organization structure of the OR. We have several sources that we can use for information.

Pilot project
The report of the pilot project [Lambregts, 1995] describes medical nomenclature, knee anatomy, the principles of knee kinematics, the ACL reconstruction procedure, a set of initial requirements for the computer-assisted ACL reconstruction method, the design of the pilot-prototype and a design of the CARAD drill guide for the reconstruction procedure. The pilot-prototype was designed as a 2D-plus system that uses a model based on X-ray landmarks to

define the location for the new attachment sites. We will use the same approach for the clinical prototype. The pilot-prototype can be used as a 'living specification'. It contains the requirements and constraints that were gathered in the pilot project.

Literature
Although there is still no consensus in this field about the optimal position for the new ACL, there are many publications stressing the importance of the selection of the attachment sites for the graft. A recent article by Kohn shows that realizing the planned graft position is difficult (especially for the femoral site) even for experienced surgeons [Kohn, 1998]. The relevant details concerning the ACL reconstruction procedure are surveyed in chapter 2. To the best of our knowledge there were no other CAOS systems for ACL reconstruction in use at the start of this project. During this project several research facilities and companies started developing CAOS systems for this purpose [Dessenne, 1995], [Sati, 1997], [Juliard, 1998], [Sati, 2000], [Petermann, 2000], [Picard, 2001], [Sati, 2002]. An overview of these concurrent developments is presented in chapter 8.

Instrument manuals
Klos uses Arthrex surgical instruments for both the patella-tendon-bone technique as well as the hamstring tendon technique [Arthrex, 1995]. The ACL reconstruction procedures are described in chapter 2. We use the 'old style' tibia guide for both techniques because this guide clearly shows the tibial attachment site on a lateral X-ray and because it can be used to calibrate the system.

Observing surgeons at work
To form a realistic impression of the ACL reconstruction procedure and the OR situation it is necessary to observe the surgeons at work. Attending several operations is essential for understanding the different steps in the reconstruction procedure. Understanding the fluoroscopic images and especially the arthroscopic images requires more time. The procedure as used by Klos is slightly different from the one described in the Arthrex manual. The graft is harvested manually (without the described block-cutting guide), no hollow burr is used for the tibial tunnel and only one size of transtibial guide for the femur drill tunnel is used.

Interviews with the surgeons
In a number of conversations with the surgeons the project priorities, the changes necessary in the pilot-project design and the use of the CARAD drill guide were discussed. The priority was to start a clinical trial as soon as possible in order to assess the usability of CAOS systems for ACL reconstruction surgery. The fastest way realize this was to adapt the earlier pilot-prototype for OR use. The first generation clinical prototype therefore has the same functionality as the pilot-prototype. The pilot-project design was changed on two points. First the acquisition of fluoroscopic images had to be added. The second change concerned the target for the femoral attachment site. The femoral attachment site in the pilot-prototype was positioned at the centre of the condylar circle. Further research showed this location to be too far anterior. The new target for the femoral attachment site should be located 25% of the condylar circle radius more posteriorly in the direction of Blumensaat's line. It was decided not to use the CARAD drill guide for the clinical prototype because it was based on the old femoral target and because it was decided not to alter the instruments for the first clinical trials.

6.2.5 Requirements and constraints

We want a computer-assisted surgery system (a clinical prototype) that shows the fluoroscopic image and a graphics overlay that displays the relationship between the actual position of the drill tunnels and the 'optimal' targets. The actual position of the drill tunnels can be identified from the position of the surgical instruments, and the 'optimal' targets can be identified from anatomical landmark models. It is important to realize a working prototype as soon as possible in order to start collecting data that can be used to evaluate the use of a CAOS system for the ACL procedure. In this section requirements and constraints are presented in the categories: medical, technical, legal, organizational, financial and time.

Medical requirements and constraints
The available instrumentation from Arthrex is described in section 2.4.4 and 2.5. In order to test the prototypes the integration of the system into the clinical setting must be as easy as possible. Thus, it is important not to change the instrumentation before the method has been proven right and the CAOS system has been shown to be helpful.

The currently used operation technique must be the basis for the CAOS system. Small changes are acceptable in order to test the prototype. To use the arthroscopic system effectively the surgeon must be able to move the patient's knee freely. Immobilization of the knee-joint will be unacceptable. During the ACL reconstruction procedure a fluoroscope provides a lateral image in which the lateral and the medial femoral condyle overlap. The CAOS system only provides positional feedback for the sagittal plane. The locations of the drill tunnels in the coronal plane will be under the control of the surgeon.

Default target positions for the attachment sites were determined from the average ACL location in a large group of persons with no knee complaints (tibia target 46% AP; femoral target 80% Blumensaat's line). However, since every individual knee is different these target positions can be overruled based on the patient's anatomy: both the location of the Posterior Cruciate Ligament (PCL) and the position of the intercondylar roof in extension can require different targets. Therefore, it is necessary that the surgeon retains complete control.

The tibia-aiming guide can be placed (the tip of the drill guide is pressed into the cartilage) with an accuracy of about 2 mm. Thus, a 2 mm deviation in placement from the tibial target is considered acceptable. With an average AP length of 55 mm (corresponding to 100% AP), positioning the pop hook within 3.6 % of the 46% aim is acceptable. In case of the PTB technique the distal bone block of the graft must be placed at least 20 mm inside the tunnel to obtain an optimal graft fixation. With the hamstring technique the graft must be placed at least 15 mm outside the tunnel in order to obtain an optimal graft fixation. Smaller values are undesirable (although alternative fixation solutions are available). The femoral tunnel should have at least 1 mm of back wall.

The CAOS system will incorporate the expertise of the orthopaedic surgeons in the Catharina Ziekenhuis. However, the system does not replace an orthopaedic surgeon. It must be designed as a tool the surgeon uses to simplify his or her work.

Technical requirements and constraints
The Catharina Ziekenhuis uses a Siemens Siremobil 2000 fluoroscope. This fluoroscope is equipped with two 100Hz monitors. The Siremobil is also equipped with an additional module that provides a standard PAL video signal. The fluoroscope has no sensors that can report its position in space (gantry position and gantry angle).

For the development of the CAOS system we want to use the available hardware in the Catharina Ziekenhuis (Windows95 based PC platform). The computer system will be equipped with a framegrabber board for digitising the PAL video signal from the fluoroscope. The system must not depend on a specific type of PC or framegrabber board.

Legal requirements and constraints
A description and justification of our project must be submitted to the Medical Ethics Committee together with copies of the patient information and informed consent forms. Testing the prototype may not affect the current reconstruction procedure.

Several organizations have developed guidelines for the design and the development of medical products. In the USA the Federal Drugs Administration (FDA) has developed a set of guidelines for medical software. In the Netherlands KEMA has developed a set of quality guidelines. The International Electrotechnical Commission (IEC) developed guidelines for the electrical safety and electromagnetic compatibility of medical equipment (IEC 601-1 respectively IEC 801). The European community also has a CE marking concerning medical equipment (93/42/EEG). However, because our CAOS prototype is a research system we only considered the electrical safety of our system.

Organizational requirements and constraints
A layout of the OR during an ACL reconstruction procedure (right knee) is depicted in Figure 2-13. For a left knee the layout around the operation table will be a mirror image. Because the operating table is not exactly in the middle of the OR there is less space available for the computer when the left-knee is being treated. The arthroscopic console contains one monitor and the fluoroscope has two monitors. Together with the PC-monitor, used for the feedback of the CAOS system, the surgeon must be able to see four different monitors. For the surgeon this is not an ergonomically optimal situation. The possibility of combining monitors should be considered for a later CAOS product. In [Lambregts, 1995] the use of a separate technical room next to the OR was suggested. This solution is ergonomically superior but the infrastructure of our operating rooms does not permit this situation.

During an ACL reconstruction about seven people are present in the OR (see Figure 2-13). The surgeon, a co-assistant and a surgical nurse occupy the sterile operating area. Besides these three people we have one anaesthetic assistant, two general assistants and an X-ray assistant. The orthopaedic surgeon will be the CAOS system's user but not the system operator. The CAOS system is positioned at the same side of the OR as the monitors of the fluoroscope.

The X-ray assistant is located at the other side of the OR because the fluoroscope's controls are on this side. X-ray assistants would be the logical choice to operate the CAOS system because they are responsible for the imaging system and have the necessary knowledge to interpret the

fluoroscopic images. The general assistants are also familiar with the procedure and the interpretation of images, so they can also be trained to operate the CAOS system. A third option would be to let a technical OR assistants to operate the CAOS system. Such technical assistants are trained to assist with all types of new systems.

Once the use of a system can be considered a standard procedure the operation of a system must be transferred to the medical personnel. During the prototyping process, the system will be under the control of the designer who is familiar with the technical details of the CAOS system under construction.

The X-ray assistants and the general assistants circulate through all functions in their department. There are about 30 X-ray assistants and about 60 general assistants. It is not feasible to train this number of people since this takes a lot of time and because they would only assist once or twice a year, their knowledge about the CAOS system would need to be constantly refreshed. If the system's operator has to come from one of these groups we must train a small selected group of people as operators. It is also possible (and perhaps more efficient) to train the selected group of technical assistants. This group consists of only four or five people who are all trained in operating a diversity of medical and technical equipment. The technical assistants also have the necessary experience in operating computer systems and solving problems with them.

Financial requirements and constraints
The Catharina Ziekenhuis provides all the necessary hardware and software: the computer system with the C++ development environment, the framegrabber board and the module to obtain standard video signals from the fluoroscope. The Stan Ackermans Institute of the Eindhoven University of Technology finances the position of the technological designer. A part of the project costs is financed by the Technology Foundation (STW).

Timing requirements and constraints
The development of the first clinical prototype that was used to evaluate the CAOS approach for ACL reconstruction had to be built during the graduation project of the two-year developers course. The graduation project started June 1996 and had to be finished on May 30, 1997. It takes about eight months to collect the data from 50 procedures so the first working version of the clinical prototype had to be operational in October 1996. Subsequently, a period of half a year was available to write manuals and train the operating room technicians (two technicians were trained to be trainers themselves). The final prototype was built in the subsequent thesis project that started in May 1998.

6.3 Concept validation - Prototyping Phase 2

In this second phase of the prototyping process the key concepts on which our clinical prototype of the CAOS system would be based were identified. Different user-interface elements, techniques and approaches were tested and compared. Before we could start with this phase we needed to select a prototyping tool. Next, we needed to determine a way to acquire the X-ray images. With the image acquisition tools and the pilot-prototype the first version of the clinical prototype could be built. Initially this clinical prototype had the same functionality

as the pilot-prototype. Then, we started the search for the key concepts of the clinical CAOS application for ACL reconstruction and upgraded the clinical prototype. The evolving prototype was used to evaluate the clinical relevance of the CAOS approach, as requested by the surgeon.

6.3.1 Selection of prototyping tools

The pilot-prototype was constructed with Microsoft Visual C++ 2.0 (MSVC++) with use of the Microsoft Foundation Classes (MFC) [Nicolaisen, 1994]. The only visual element about MSVC++ is the construction of dialogs. MFC introduces a program organization called the document-view structure. In this structure the program data is stored in a document class. Each document class is connected to a view class. This view class takes care of the interaction with the user and it displays the data.

For the first generations of the clinical prototype we decided to use an evolutionary prototyping approach by using the pilot-prototype and the MSVC++ programming environment. This choice was based on the following considerations:

- MSVC++ is suitable for constructing a language prototype (as explained in chapter 3). A high level of functionality of the language prototype was needed because collecting data with the prototype was a project priority.
- The report of the previous designer did not contain a detailed description of the pilot-prototype. We had to analyse the source code to learn more about the design on which it is based.
- The prototyping library (chapter 4) was not available at this time. The code from the pilot-prototype could be re-used in the construction of the clinical prototype.
- The software for the framegrabber board was also written in MSVC++.
- Starting with a different programming environment would involve too much time.

In every prototyping process there is a point at which it is necessary to start all over again. All previously collected specifications are used for the next generation prototype. Expanding and changing a prototype (evolutionary prototyping) remains effective until extensive changes in the design of the program are necessary. In that case, the changes necessary to make the next-generation prototype will take as much time as starting from scratch. This does not imply that no modules are re-used. Starting all over again can be done quickly if the programmer has a good prototyping library.

6.3.2 Image acquisition

To digitise the fluoroscopic images the computer system is equipped with a Matrix PCImage SVGS framegrabber board [Matrix, 1996]. To test the module on the fluoroscope that provides the video signal without bringing the computer to the OR, a video-recorder was used to tape the fluoroscopic images made during several anterior cruciate ligament reconstruction procedures. The images were digitised with the Matrix demonstration program and transferred to the pilot-prototype. For the first clinical prototype the images were transferred in the same manner. The 32-bit drivers for the framegrabber were not available so integrating the framegrabber control into the clinical prototype was not possible. There are several ways of realizing the communication between the two programs. Windows programs can communicate via Object Link Embedding (OLE), Dynamic Data Exchange (DDE), shared-memory blocks

and files. Examples of OLE communication are the copy-and-paste functions that copy an object via the Windows clipboard. We selected communication via files because collecting data is an important task of the prototype anyway. This also eliminates the need to implement OLE or DDE features in both the CAOS and the demonstration program.

To store and exchange the fluoroscopic images between the two programs quickly, the demonstration program is changed slightly. The **save bitmap** option is adapted so it will save each new image with an automatically generated name (automatic numbering). The CAOS program is extended with a **snap** function that automatically loads the last saved image. Exchanging images and saving them thus necessitates three actions. The first action is to select **save bitmap** in the Matrix demonstration program. The second action is a task switch between the two programs. The final action is to select **snap** in the CAOS program.

6.3.3 Transform the pilot-prototype into a clinical prototype

The pilot-prototype could display the condylar circle, the femoral target, the femoral axis, the tibia contour, the tibial axis, the tibial target and the tibial and femoral tunnel axes. The pilot-prototype contained several small errors that were corrected. To create the first generation clinical prototype the following changes were made to the pilot-prototype:

- the femoral target was moved backwards by a distance equal to 25% of the radius of the condylar circle in the direction of Blumensaat's line as described in chapter 6.2.4.
- the **save bitmap** / **snap** combination explained in the previous section was implemented.

6.3.4 Key concepts of the application

As discussed before, the accuracy of the anterior cruciate ligament reconstruction is mainly determined by the location of the graft. The key concepts (essential features) for the clinical CAOS system can be found by analysing the way in which the surgeon evaluates the results of the procedure and the considerations determining graft placement.

6.3.4.1 Measurements

Post-operative X-rays are normally used to measure tunnel positions. Klos recently showed that tunnel position measurements taken from post-operative X-rays have low inter- and intra-observer reliabilities. Measuring tunnel positions on intra-operative images with the drilling instruments in place is easier and more accurate [Klos, 1999]. Measuring intra-operatively also provides the ability to change the position of the instruments to a more favourable position.

The tibial attachment site, determined from a lateral fluoroscopic image, is defined as the location where the K-wire breaks through the tibial cortex and enters the knee joint. This location (the proximal end of the tibial tunnel) can be expressed relative to the AP line (a line that connects the most anterior point with the most posterior point of the tibial cortex and which is parallel to the tibial plateau). The tibial attachment site position is projected onto the AP line and then reported as a percentage (the anterior point being 0%). The femoral attachment site, determined from a lateral fluoroscopic image, is defined as the location where the K-wire from the trans-tibial drill guide enters the femoral cortex. Its position is expressed relative to the length of Blumensaat's line (the line from the most anterior to the most posterior point of the intercondylar roof) as depicted in Figure 2-4).

6.3.4.2 Calibration

Our computer-assisted system performs intra-operative measurements (based on the position of the surgical instruments) and presents this information to the surgeon. In order to determine the tunnel lengths and the distance between the tibial and femoral attachment sites (in millimetres) and to overlay the ACL graft graphics correctly, we need to calibrate the system. Because the X-ray image is a projection image, the size of every object shown will depend on its position between the X-ray source and the image intensifier (see Figure 5-1) and on its orientation relative to the projection plane (shortening effect).

To determine the length of the drill tunnel we need to calibrate the system for this direction. The calibration is done with an object of known size having this direction. In this case the POP hook of the tibial drill guide is used. This hook, which has the direction of the resulting drill tunnel, is 9.7 mm long. In the digitised X-ray image the hook is about 40 pixels long (see Figure 6-9). We can locate the beginning and the end of the hook (in the digitised image) with an accuracy of about 1 pixel (see section 5.6.2). The total calibration error will thus be 2 pixels or 5% (i.e. 6 mm on an average graft length of 120 mm). This calibration error is fairly large. Increasing the size of the calibration object would result in a smaller error but it is considered undesirable to insert a bigger object into the knee.

As an alternative the surgical instrumentation could be adapted to provide a mechanical reading of the tunnel length (the distance from the tip of the POP hook to the sleeve of the K-wire guide). Identifying these points in the image and entering the actual length manually would enable a calibration over a distance of about 70 mm. This would decrease the calibration error a factor of seven to about 0.7%. Because this alternative approach introduces changes to the surgical instruments and extra actions for the surgeon we decided not to do this.

The calibration is only valid if the orientation of the knee and the instruments does not change once the calibration has been performed. Normally, during surgery the orientation of the knee and the instruments does change somewhat, because the surgeon moves the knee to visualize the anatomy with the arthroscope. During the drilling of the tunnel the orientation of the knee and thus the orientation of the drill tunnel will not change more than 10 degrees (in the flexion-extension direction and in the abduction-adduction direction). The movements are limited to about 10 degrees because the portals (the incisions through which the instruments are inserted into the knee) are kept as small as possible with minimal invasive surgery. Calculations based on the average position of the hook during surgery (relative to the projection plane) and the possible variations in tunnel direction have shown an additional error of 2% in tunnel length. We decided to not re-calibrate the system for each individual X-ray image.

6.3.4.3 Graft position

There is still no consensus on the optimal position for the graft. Many surgeons advocate anatomical placement and some surgeons believe the ACL should be reconstructed by using two grafts (see section 2.4.3). With the transtibial technique it is not possible to reach the anatomic location for the ACL attachment on the femur. The most posterior position that can be reached without breaking through the back wall of the femur is just inside the antero-medial bundle. Some surgeons advocate isometric placement, which means that the distance between the tibial and the femoral attachment site should not change when the

knee flexes or extends. This assures that the graft will function during the full range of knee motion. However, realizing isometric attachment sites with a graft is hardly possible. Other surgeons advocate impingement-free placement. If the tibial attachment site is positioned too far anteriorly the femur will impinge on the graft near extension (roof impingement).

A difficult task in placing the graft is to obtain graft-tunnel match. The attachment sites should be selected so that the graft fits in the tunnel. For the patella tendon bone (PTB) technique the distal bone block should be positioned inside the tibial tunnel for at least two centimetres. This enables fixating the bone block with an interference screw without the screw touching the tendon. For the hamstring technique the tendon has to protrude at least 1.5 centimetres from the tunnel in order to fixate it with a staple on the tibial cortex.

With the currently used operating technique in our hospital the tibial attachment site is positioned at 46% on the AP line. If this location would cause roof impingement, the tibial attachment site is moved posterior. The position of the femoral attachment site is determined with Blumensaat's line and a circle drawn in continuation of the posterior and inferior contours of the femoral condyles (a circle touching the back and bottom of the border of the femoral condyle). The entry point for the femoral tunnel and thus the femoral attachment site for the new ACL is located at 1/4 of the circle's radius, posterior (in the direction of Blumensaat's line) to the centre of the circle. This point is located at 80% of Blumensaat's line (perpendicular projection).

6.3.4.4 Essential tasks

The essence of the CAOS system is to provide feedback to the surgeon about the location of the tunnels and thereby the position of the graft. The clinical prototype focuses on three essential parts of feedback.

1. The tibia tunnel position and roof impingement.
   The CAOS system should report the tibial attachment site (expressed in %AP) given the present location of the tibial drill guide. This location has to be verified against the roof impingement zone.

2. The virtual-placement of the graft and the inside-outside prediction.
   The CAOS system should check if the harvested graft fits if the tunnels are drilled at the current location of the drill guide. To verify this, the system needs to know the size of the graft, the location of the femur in the fluoroscopic image, the model for the femoral attachment site, the tibial attachment site (from 1) and the location of the drill guide. This information is presented to the surgeon by displaying a virtual graft on the fluoroscopic image as well as by providing a prediction whether the graft protrudes from the tibia tunnel (the inside-outside prediction).

3. The femoral tunnel position and back wall blowout.
   The CAOS system reports the femoral attachment site (expressed in % Blumensaat's line) for the current location of the femoral drill guide. Based on this current location, the system also displays a virtual proximal block overlay that the surgeon can use to prevent cortical back-wall blowout.

The tibia tunnel position and roof impingement

If a graft is positioned too far anteriorly the femur can impinge on or even guillotine the graft when the knee is extended completely. This effect is called roof impingement (see section 2.4.2). The most anterior impingement free location is determined by intersecting the tibial plateau with Blumensaat's line (the projection in an X-ray image of the intercondylar roof). The most anterior position a tendon graft can have in a drill tunnel is the anterior tunnel wall. If this wall is posterior to the impingement zone the graft will never touch the intercondylar roof, whatever its shape. Thus, the centre of the drill tunnel should be placed more than half the tunnel diameter posterior to the intersection point of the tibial plateau and Blumensaat's line (see Figure 6-1).

The roof impingement test described above may not be accurate for normal weight bearing conditions. When force is applied to the joint, the position of the tibia relative to the femur can change. Being close to the roof in extension (not touching) may again lead to impingement. If the angle between the roof and the femoral axis is small (steep slope) the graft will be positioned close to the roof when the knee is extended.

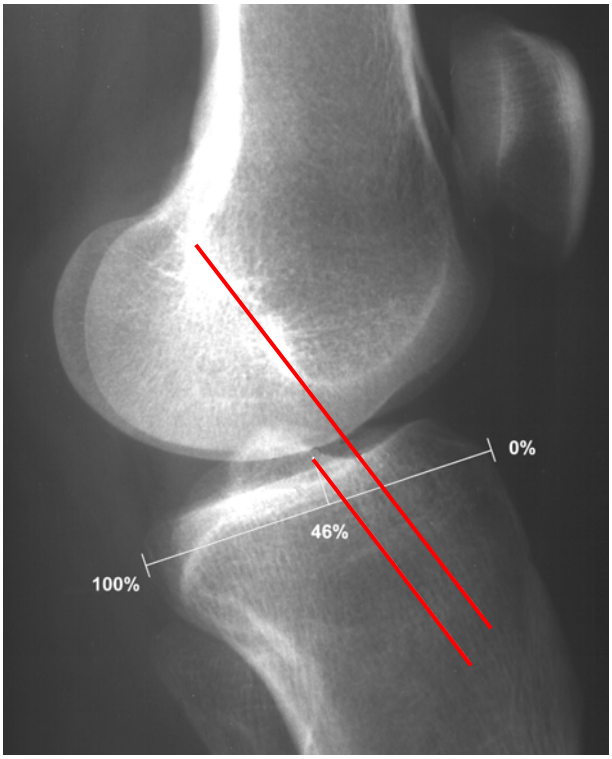


Figure 6-1: Determining the most anterior impingement free tibial attachment site on a lateral X-ray. The centre of the drill tunnel (which intersects the tibia plateau at 46% AP) is placed at least half the tunnel diameter anterior to Blumensaat's line.

One would expect people with steep slopes to have a higher risk of injuring their ACL. However, for our ACL patient group we did not observe steeper intercondylar roof slopes than for those people who had a normal functioning anterior cruciate ligament. Thus, there was no reason to position the graft more posteriorly.

The graft-positioning problem is not two-dimensional. The graft is not positioned in a plane parallel to the fluoroscopy plane. The graft, like the anatomical ACL, is positioned between a medial position on the tibial plateau and the inside of the lateral condyle. In an AP view the femoral attachment site would be located at 11 (or 1) o'clock (if clock were imagined inside the intercondylar cavity). The medio-lateral position of the drill guide cannot be verified on a lateral X-ray image. The CAOS system's X-ray based roof impingement test method only prevents impingement by the intercondylar roof. If the tibial attachment site is positioned too medially, sidewall impingement can still occur. Selecting the medio-lateral position of the graft is left to the surgeon.

The virtual-placement of the graft and the inside-outside prediction
The virtual-placement is based on the prediction of the femoral attachment site and the 'proposed' tibial attachment site of the graft. The prediction of the femoral attachment site is derived from the positions of Blumensaat's line and the femoral condyle model. The femoral attachment site for the new ACL can be found at 1/4 of the condylar circle's radius, posterior (in the direction of Blumensaat's line) to the centre of the circle. The 'proposed' tibial attachment site can be found by identifying the exit point of the tibial tunnel by using the position of the tibial drilling guide that is visible in the X-ray image.

After identifying the attachment sites the system must be calibrated for measuring distances in the direction of the drill tunnel. This calibration uses the tip of the POP hook of the drill guide, which is mechanically aligned with the tibial part of the drill tunnel. When drilling the femoral part both tunnels will be exactly aligned (because a trans-tibial technique is used). However, when drilling the tibial tunnel (assisted by the virtual graft placement) both tunnels are not exactly aligned. The graft's tendon and the distal bone block are virtually attached to the femoral attachment site and then guided via the tibial attachment site into the tibial tunnel. The virtual positioning should take into account that the surgeon prefers to positions the proximal block two millimetres inside the femur.

The 'virtual' graft consists of three parts: a part that is located in the tibia tunnel (the direction for which the system was calibrated); a part in the intra-articular cavity, which actually is the new ACL; and a part in the femoral tunnel. The length of the new cruciate ligament (the intra-articular distance or IAD) is on average about 28 mm. The position of the knee during the procedure is about 80 degrees flexion. As the direction of the new graft is about the same as the direction of the tibia tunnel the tibial tunnel calibration value will be used for the entire graft. After calibration the visual overlay can be shown over the X-ray image.

For a patella-tendon-bone graft:
Besides showing this visual overlay the system also reports the prediction of the position of the distal block to the surgeon. The system provides the values 'inside' (mm of distal block

inside the tibia tunnel), 'outside' (mm of distal block outside the tibia tunnel) and 'extra' (mm of empty tunnel when the distal block is entirely inside the tibia tunnel). The virtual overlay is displayed on the X-ray that shows the tibial drill guiding instruments and subsequently on the X-ray that shows the position of the tibial drill guiding instruments with the inserted K-wire.

To secure the distal block with an interference screw the block must be at least 20mm inside the tibia tunnel. This 20 mm limit is derived from the fact that the smallest interference screw measures 20 mm and the fact that the screw must be positioned along the bone block and not along the tendon. If 20 mm of bone block inside is not available the graft will be secured with a staple. Screw fixations are superior to screw-staple fixations because the latter type of fixation sometimes requires an extra procedure to remove the staple in case of knee complaints.

The femoral tunnel position and back wall blow-out
After drilling the tibia tunnel the trans-tibial femur guide is inserted and positioned in the 'over the top' position. The femur guide mechanically provides a 7 mm distance between the femoral attachment site and the back wall of the femoral bone. This back wall of the femur is the place where Blumensaat's line ends and the femoral bone starts to curve upwards. The name 'over the top' refers to the fact that this location cannot be seen arthroscopically. Because this location is not visible arthroscopically it is difficult to place the guide. With a CAOS system the position (relative to Blumensaat's line) and orientation of the femur guide can be verified on an X-ray image.

First the location of the guide is verified against the planned attachment site. Next, the attachment site is reported as a percentage of Blumensaat's line. Finally, a virtual femoral tunnel is displayed. The virtual-placement and resulting femoral back wall is checked visually by the surgeon. The width of the virtual tunnel is determined with the same calibration factor that is used for the tibia tunnel. This introduces a small but acceptable error. Using this calibration factor prevents introducing a time consuming extra calibration step (see section 6.4.3).

6.3.4.5 Prototyping cycle

Once the essential tasks of our computer-assisted surgery system are clearly defined the user interface concepts that implement these tasks have to be designed. From our previous experiences with building user interfaces for clinical software we expect it will take a few prototyping cycles (iterations) to find the best user interface (UI) concept to realize the essential tasks. The following cycle is repeated several times:

- Implement new user-interface concepts, new functionality and alternative approaches and construct the new prototype.
- Test the new prototype and collate comments, suggestions for changes and new ideas from its users.
- Analyse these data.
- Define new user-interface concepts, functionality or alternative approaches for the next-generation prototype.

Besides the application-specific UI concepts for the three essential tasks described in section 6.3.4.3 some general application UI concepts are presented. These general UI concepts concern the image acquisition and the interaction with the graphical overlay models. The UI concepts for the application are presented in the order in which the tasks occur during an anterior cruciate ligament reconstruction procedure.

6.3.4.6 General user interface concepts

Image acquisition
The CAOS system must be able to acquire and display a fluoroscopic image quickly with a single action, as the surgeon has to wait for the results of the CAOS system. The most suitable action would be clicking a speed-button with the mouse or selecting a hot key from the keyboard. This could not be realized at that time because the correct framegrabber drivers were not available. As soon as these drivers were provided, the image acquisition was integrated into the CAOS program and the adapted Matrix demonstration program became obsolete.

Graphic overlay interaction
The CAOS system must be able to display the models, the attachment sites and the graft on top of the fluoroscopic image. The tools necessary to create these overlays are discussed in chapter 4. The knee is not secured because the surgeon must be able to move it freely. Each subsequent image will show the knee in a slightly different position. Thus, fast editing of the graphical overlays (models) is essential for a clinical prototype. The UI must allow the user to directly interact with the graphics. The graphical overlay system presented in chapter 4 provides all the necessary tools to quickly manipulate the graphical models.

As operation time is limited the user interaction with the graphics should be reduced to a minimum. Optimally, the graphical models would be positioned automatically. This would imply that the bony contours and the instruments must be detected and tracked automatically. In the first prototypes some contour recognition algorithms based on edge detection and active contours (snakes) were tested. It became clear quickly that robust, automatic detection would not be easy to build. The detection algorithms had to cope with all other surgical instruments, the electrical cables, and the water tubes from the arthroscopic system that obstruct the contours of the drill guide and the knee. Besides this, the intensity and the contents of images are changing with every new image. Even if these algorithms would perform quite well the surgeon would need the possibility to overrule the automatically determined contour positions. As development time and resources are limited and as there will be an extra person present in the OR to assist using the system we decided not to implement automatic contour detection in the clinical prototype. Automatic contour detection will be considered for the final clinical application if the prototype proves to be clinically relevant.

6.3.4.7 Application user interface concepts

Procedural information
The user must provide whether the reconstruction procedure is to be performed on a left or a right knee in order to define the anterior and posterior directions. This information is entered in the procedure dialog box. This dialog box is presented at the start of a computer-assisted procedure. This dialog can also be used to enter other procedure and patient information.

Graft size
The size of the graft is entered in a dialog box. For a PTB graft this dialog box must contain edit-boxes for the lengths and diameters of the proximal and the distal block as well as edit-boxes for the tendon length and the total graft length. One of the two latter boxes can be left empty as the missing length can be calculated from the other three lengths. Because of the shape of the proximal and distal block it is difficult to measure the tendon length, so this is the most suitable field to be left blank. The proximal block diameter must always be equal to or smaller than the distal block diameter because the femoral drill must be inserted through the tibial tunnel. For a hamstring graft the dialog contains a single edit box for the tendon length.

Calibration
The calibration process involves marking the location of the POP hook in the X-ray image. The UI will provide a zoom window centred at the current mouse location, so the user can easily mark both ends of the hook.

Tibia location and tibial drill guide position
The location and orientation of the tibia and the position of the tibial drill guide are modelled with the tibia tool. The tibia tool is depicted in Figure 6-2. The tibia tool references the most anterior and most posterior points on the tibial cortex and the entry point and exit point of the drill guide. The tibia tool is a complex graphic shape (see section 4.6). It is a combination of a ruler object (AP ruler) and a line object (drill tunnel line). The AP ruler is used to model the most anterior and most posterior points of the tibial cortex. The drill tunnel line is used to model the tibia tunnel (from the tip of the drill to the tip of the POP hook).

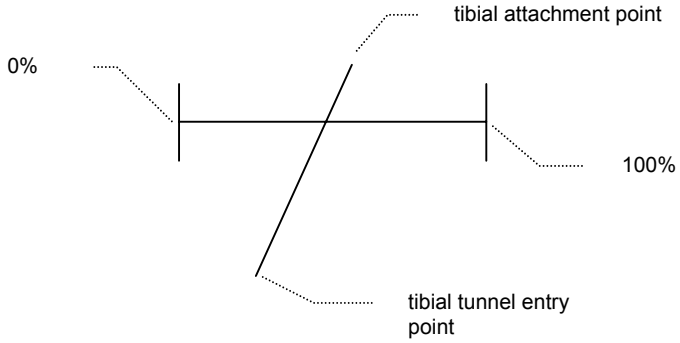


Figure 6-2: Tibia tool.

The tibia tool has four movable points: the 0% anterior point, the 100% posterior point, the tibial attachment point (tip of the POP hook) and the tibia tunnel entry point (tip of the drill). The drill tunnel line is coupled to the AP ruler. The begin point of the drill tunnel line (the tibial attachment site of the new ACL) is attached to the movable slider of the AP ruler. The position of the drill tunnel line is stored by using the drill tunnel length and its angle relative to the AP ruler. The drill tunnel endpoint is calculated via these parameters. Moving the AP ruler will thus also move the drill tunnel line without changing the slider reading of the AP ruler or the direction of the drill tunnel line relative to the direction of the

AP ruler. Moving the tibial attachment point will change the slider reading. The tibial tunnel entry point will be altered accordingly. The position of the selected tibial attachment point is reported as a percentage relative to the AP line. The tibia tunnel entry point can be moved without moving the other points.

Because of this construction the movable points of the tibia tool must be positioned (dragged and dropped with the mouse) in a certain order. First, the AP ruler must be positioned (the 0% anterior point is positioned at the most anterior point of the tibial cortex and the 100% posterior point is positioned at the most posterior point of the tibial cortex). Next, the tibial attachment point is positioned at the tip of the POP hook. Finally, the tibial tunnel entry point is positioned at the tip of the drill. The slider reading of the AP ruler displays the realized location for the tibial attachment site for the selected position of the drill guide (expressed in %AP). Once the system has been calibrated the total drill tunnel length (tibia- tunnel length + distance between tibial and femoral attachment sites + femur-tunnel length) can be compared with the total graft length in order to determine if the graft will fit.

Femur location and femoral attachment site
The location and orientation of the femur is modelled with the condylar circle and the intercondylar roof line (Blumensaat's line). This model is developed for a fluoroscopic image in which the lateral and the medial condyle exactly overlap. The circle is positioned with the mouse by dragging the circle to the posterior and distal edge of the condyle. Blumensaat's line is positioned with the mouse by selecting two points along the intercondylar roof. The location of the femoral attachment site is then determined from the condylar circle and Blumensaat's line as described before. The virtual position of the femur tunnel is displayed with the femur tool (see section 6.4.2). The femur tool is a line that is positioned on top of the drill guide. The beginning of the line is positioned with the mouse at the tip of the K-wire that can be seen inside the transtibial drill guide (see Figure 6-14). The endpoint of the femur tool line is positioned somewhere on the axis of the drill guide. The resulting position of the femoral tunnel is then displayed virtually.

6.3.5 CAACLRec: technical evaluation

Before a system can be evaluated clinically it is imperative to evaluate if a system is sufficiently accurate and safe to perform the tasks it is designed for. In this evaluation it is checked if the design requirements concerning accuracy and safety, provided by the surgeons, are met. These design requirements are presented in section 6.2.5.

The required accuracy for the tibial attachment site is 2 mm (3.6 % AP). The tibial attachment site is expressed as a percentage of the AP line in the same way as the position of the femur relative to the tibia in the stress laxity measurements (section 5.8). As we learned from 5.8.4 the AP ruler can be positioned with a maximum tilt error of 4 degrees. For an average femoral position of 46% AP and an average distance of this position of 30 pixels to the ruler, a 4 degree rotation error will cause a 1% change in reported percentage (see Figure 6-3). Even with rotation errors of around 8 degrees the position error would be less than the acceptable 3.6%.

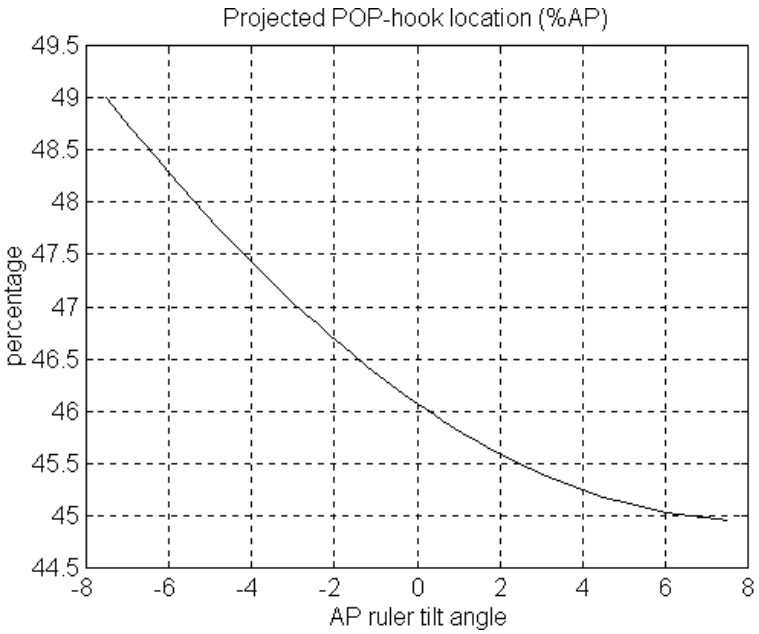


Figure 6-3: Relation between the AP ruler tilt angle and the error in the reported tibial attachment site (the position of the POP hook) expressed as a percentage of the length of the AP ruler.

For a PTB graft the distal block has to be inside the tunnel for at least 20 mm. More is no problem, less is. For the hamstring graft the tendon should protrude 15 mm from the tunnel. Again: more is no problem, less is. From section 6.3.4.2 we learned that the calibration error was 5% resulting in a 6 mm error for an average tunnel length of 120 mm. With the virtual-placement the virtual graft is attached to the femoral target and then drawn through the tibia tunnel. The accuracy of placing the femoral target is determined by the accuracy of placing the condylar circle. The condylar circle can be placed with an average accuracy of 5 pixels (as was discussed in chapter 5.8), which corresponds to 1.5 mm. The average tunnel length (from the femoral target to the tibial entry point) is about 90mm and thus a 5% calibration error could result in a 4.5 mm tunnel length error. For a worst-case situation our graft-tunnel match prediction could be 6 mm off for the average graft length. If we always take an extra 6 mm of precaution when placing the tunnel this error will not be a problem.

The femoral tunnel is displayed by using the calibration factor determined for the tibia tunnel (see section 6.3.4.3). For the tunnel diameter this will introduce an error. To assess the magnitude of this error several femoral screw diameters are measured (while using the tibial calibration factor). On average the measured screw diameter differs 0.3 mm from the true diameter (corresponding to a 4.3 % error in diameter). The femoral virtual-placement is used to visually check if there the femoral tunnel has a sufficient cortical back wall.

Because the shape of the femur is concave the actual back wall will always be thicker. As the femoral guide mechanically provides 1 mm back wall and the virtual-placement is only used as extra feedback we decided to accept this error and use the calibration value determined for the tibial tunnel. As discussed in this section the error in the virtual-placement can be quite large (up to 6 mm). However, if we plan on the safe side, the method can be used clinically.

6.3.6 CAACLRec: a first clinical evaluation

The prototype CAOS system for ACL reconstruction resulting from the concept validation process is named CAACLRec (Computer-assisted Anterior Cruciate Ligament REConstruction). CAACLRec implements the essential tasks described in this section. CAACLRec is evaluated in a series of 50 patients. It has been evaluated from September 1996 to May 1997. This evaluation, which mainly focuses on the resulting graft position, has been presented in [Klos, Habets et al., 1998]. The attachment sites are determined with fluoroscopic images that are made during the procedure. We use intra-operative images because the position of the instruments makes it easy to locate the position of the drill tunnels and thus the location of the attachment sites.

The clinical evaluation compares the location of the ACL attachment sites for three series of procedures. The first 29 procedures were performed with arthroscopic imaging. The next 53 procedures were performed with arthroscopic and fluoroscopic imaging. The third series consists of 50 procedures with arthroscopic and fluoroscopic imaging and the use of the prototype CAACLRec system. The ACL attachment sites for these three series were measured and compared. For the arthroscopic series we had no intra-operative images, so the position data from the first group may be less accurate. However, as most investigators still use post-operative X-rays to determine graft position, we will use these results in our comparison.

The tibial and femoral targets are the same for all series. The mean positions for the tibial and the femoral site for the three series were compared as well as their standard deviations. Another way of comparing the scores for the three series is to compare the range of the series. The range is defined as the difference between the minimum and maximum location (expressed in %AP). This range will give an impression of the worst case situation in each set. The results for the tibia placement are presented in table 6-1. The tibial attachment site is expressed as a percentage of the AP line as proposed by Stäubli [Stäubli, 1994]. The results for the femoral placement are presented in table 6-2. The femoral attachment site is expressed as a percentage of the Blumensaat's line as proposed by Harner [Harner,1994].

Although the mean tibial graft position did not change, the standard deviation and the range decreased significantly for both the AF and the AFC approach when compared to the original approach A. For the femur the introduction of fluoroscopy resulted in a more posterior femoral attachment site (closer to the original anatomical position). The increased feedback provided means to position the tunnel more posterior without risking back wall blow-out. Besides this, the standard deviation and the range decreased significantly. Klos states that these results are not only statistically significant but also clinically relevant [Klos, 2000d].

Table 6-1: Results of tibial graft placement according to criteria by Stäubli.
A = Arthroscopic (29 cases)
AF = Arthroscopic with Fluoroscopy (53 cases)
AFC = Arthroscopic with Fluoroscopy and Computer assistance (50 cases)

	Tibia		
	A	AF	AFC
Mean	45%	46%	46%
Stand.Deviation	5.9%	4.2%	2.7%
Minimum	37%	38%	38%
Maximum	60%	58%	51%
Range	23%	20%	13%

Table 6-2: Results of femoral graft placement according to criteria by Harner.
A, AF and AFC defined as defined in Table 6-1

	Femur		
	A	AF	AFC
Mean	73%	79%	80%
Stand.Deviation	9.0%	5.1%	2.8%
Minimum	46%	65%	71%
Maximum	90%	89%	86%
Range	44%	24%	15%

6.4 Final prototype development - Prototyping Phase 3

As explained in section 3.4.5 final prototype development is the last phase in the rapid prototyping process. In this phase all functionality must be prototyped as completely as possible. The final prototype will look exactly like the final program. It can be used as a 'living specification' for the developers of the final product. In the final prototype phase most feedback will be provided by the system users (the OR technicians). First, all new functionality will be described. Second, a detailed description of the surgical procedure with the use of the CAOS system will be presented. In a final section the final prototype will be evaluated. In this evaluation the overall accuracy of the system will be discussed as well as the clinical relevance of the CAOS system for ACL reconstruction.

6.4.1 New functionality

The concept validation prototype was used clinically to validate the approach. The reactions of users on the concept validation prototype already revealed some of the functionality that should be added in the final prototype. This section describes the changes made to the concept validation prototype as well as the requested new functionality.

6.4.1.1 Changing the development tool

In the concept validation phase evolutionary prototypes were used. New ideas and functionality were simply built into the existing software. From a software point of view this will probably not provide structured and maintainable code. Since speed of development is so important little extra effort is put into writing optimally structured code. The only way to bring structure back into the software is starting all over. The MSVC++ environment provides a fast compiler but it lacks the tools to quickly develop user interfaces. Since user interface development is an important task in the final prototype development we changed to the Borland C++Builder environment to continue our design. The Borland environment offers many standard controls to develop user interfaces in a visual way. The rapid prototyping toolbox described in chapter 4 was also built with the Borland environment. The development of the final prototype for computer-assisted ACL reconstruction will be a thorough test for the toolbox and the design approach.

Similar to the concept validation prototype, the new implementation of the toolbox is not independent of the developed environment. Like MSVC++ with its Microsoft Foundation Classes the Borland environment has its own library to provide wrappers for the basic Windows API functions. Besides these wrappers the environment also provides some additional features that enhance the standard object oriented C++ language. An example of the additional features is the use of properties. Properties provide an indirect access mechanism to variables (see Borland documentation for a detailed description of these features). By using these features instead of the standard C++ and Windows API decreases development times significantly, which is very important in a rapid prototyping process.

6.4.1.2 Integration of the image acquisition

To increase the usability of the CAOS system, image acquisition from the fluoroscope must be integrated into the system. In the concept validation prototype the images were acquired via the demo program of the framegrabber board. In the final prototype acquiring an image will be a single button action. With this button action the image will be digitised, displayed and stored. The framegrabber controls were discussed in the description of the toolbox. The layered design of the image acquisition controls allowed us to change the framegrabber hardware without changing the CAOS software itself. For the final prototype the Matrix MVSG framegrabber board was replaced by a Matrox Meteor Board. Matrox provides a universal image library, called MIL (Matrox Image Library), that can control all framegrabber boards from the Matrox family. The high-level image acquisition functions of our toolbox are now based on the low-level MIL functions, which enable us to use all Matrox boards without changing the CAOS software or changing our library functions.

The OR layout prohibits the CAOS operator from seeing the monitors from the fluoroscope. In order to know when a new fluoroscopic image comes available for measurement the final prototype will be equipped with a ‘live view window’ that shows the content of the fluoroscope’s monitor. This greatly improves the ergonomic situation for the system operator. However, the surgeon’s attention is still divided between four displays: one from the arthroscope, two from the fluoroscope and one from the computer.

6.4.1.3 Hamstring tendon support

The concept validation prototype only supported ACL procedures with PTB grafts. Because of patella complications, especially for female patients, a growing number of procedures are performed with hamstring grafts. Therefore, the final prototype also had to support the hamstring tendon technique. From the perspective of the CAOS system the main difference between the hamstring and the PTB technique is the virtual-placement. For the PTB the goal is to drill tunnels so that the distal block is located inside the tibia tunnel at least two centimetres, in order to be able to fixate it with an interference screw. For the hamstring technique the tunnel must be drilled so that the tendon extrudes at least two centimetres from the tibia in order to fixate it externally with a staple. Optionally the tendon can be secured with a bio-absorbable interference screw. Adding hamstring support affects the graft entry dialog, the virtual graft placement and the data storage.

The femoral fixation of the hamstring is also different from the PTB technique (explained in chapter 2). For the hamstring technique the surgeon drills a femoral tunnel of 35 mm depth. The medio-lateral pin is inserted 5 mm for the end of this tunnel. In this way the graft can be placed while keeping a safe distance to the end of the tunnel. For the virtual graft placement the CAOS system uses a fixed femoral tunnel length (containing tendon) of 32 mm (assuming a 4 mm tendon diameter).

6.4.1.4 Integration of stress laxity measurements

The development of a computer-assisted stress radiography tool is described in section 5.7. Stress measurements are performed directly before surgery (but after the spinal anaesthesia is administered) as well as directly after surgery as soon as the ACL graft is secured. When the user selects the stress radiography function the dialog presented in section 5.7.6 is shown.

6.4.1.5 Electronic patient record

The concept validation prototype automatically stores all intra-operative images indexed on OR dates. However, as it is possible to have two procedures on one day, this way of indexing does not work. A better way to index is the combination of patient identification number (IP number) and the procedure date. The IP number alone would not suffice because some patients undergo an ACL procedure more than once (other knee or a revision). The final prototype of the CAOS system is extended with an electronic patient record (EPR). The EPR stores information about the procedure: OR date, surgeon, operator, ACL deficient knee (left or right), and surgery type (PTB or hamstring); and information about the patient: name, date of birth, gender and IP number. This information is collected via the patient information dialog (Figure 6-4).

Besides this pre-operative data the EPR also collects and stores intra-operative data. The EPR stores all ‘raw’ fluoroscopic images, all intra-operative images with overlays (to document the situation on which medical choices were based), the knee laxity scores as well as the dimensions of the screws or staples used for fixation. To store extra information about the procedure a remarks section is included into the EPR. Besides storing data the EPR also includes data that can be used to assess the quality of the CAOS system. The

'virtual graft placement' predicts the position of the distal bone block (with a PTB) or the distance the tendon protrudes from the tibia (with a hamstring). At the end of the procedure the user can enter the true position of the bone block or the tendon as reported by the surgeon. At the end of the procedure the EPR record can be transferred to a removable disk (in our case an Iomega ZIP disk).

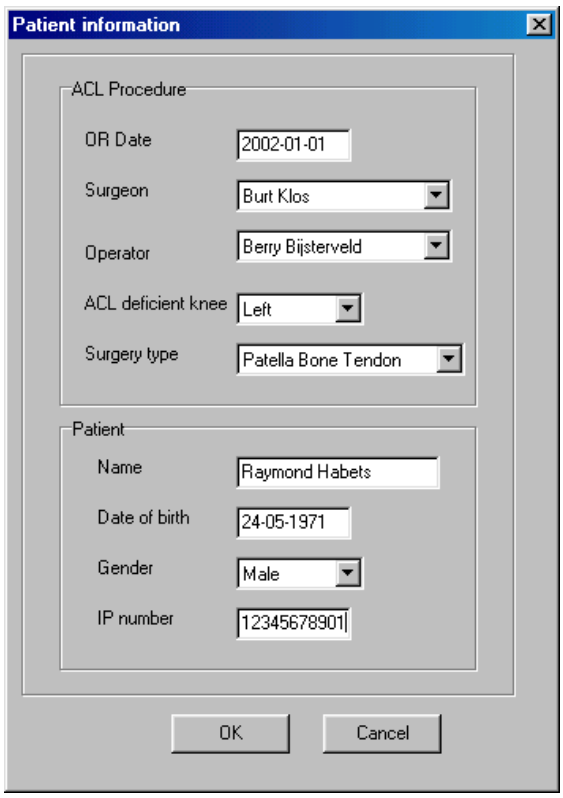


Figure 6-4: Patient information dialog with procedure and patient information.

6.4.1.6 Protocol driven – single button user interface

In section 3.3.4 it is explained that a clinical user interface must be organized according to the surgical protocol the system is designed for. In the user interface of the final prototype for ACL reconstruction the surgical protocol is implemented as a state machine. The following states have been defined: new patient, pre-op drawer testing, enter graft data, calibration, tibia drilling, femur drilling, and post-op drawer testing. The user can switch to the next state by pushing a single button (the arrow in the upper right corner of Figure 6-5).

For some states the transition to the next state in the protocol can be done automatically on completion of the task for the current state. The states can also be accessed directly via the

protocol listbox (Figure 6-5) enabling to go back to an earlier state. In each state the user interface is adapted to perform the tasks for that step of the protocol. The protocol and the user interface will be discussed in section 6.4.2.

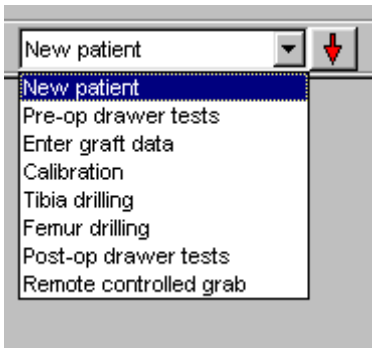


Figure 6-5: Protocol based single-button style user interface.

6.4.1.7 Restore function

If the system crashes it is important to restart as soon as possible. All functions that store data in the EPR write directly to disk. The system never uses temporary data. If the system is restarted it offers the user a restore function. This function retrieves the last patient record that was active and loads all available data. Based on this data the system switches to the last 'active' state. The user only has to reposition the overlay models and continue with the procedure. A restart of our Windows95 based CAOS system takes about two minutes. The time it takes to restart a computer depends heavily on the type of computer, its operating system, and the number of memory resident programs that are installed on it.

6.4.2 The CAACLRec2 design

In chapter 4 we discussed the design of the rapid prototyping toolbox for the graphic overlay system. The design of the first CAACLRec (Computer-Assisted Anterior Cruciate Ligament Reconstruction) prototype is described in [Habets, 1997]. The design of our CAOS system prototype for anterior cruciate ligament surgery will be a combination of the graphic overlay design (section 4.3), the measurement tools and the electronic patient record described in this chapter, and the protocol driven user interface. A design diagram of the CAACLRec system is presented in Figure 6-6.

The image acquisition, graphics interaction, image processing and display blocks in Figure 6-6 are already explained in chapter 4. The ACL measure tools block contains Borland C++ dialogs and complex graphic objects for the measurement tools (such as the tibia tool from Figure 6-2). With the single button user interface the user can switch between the different steps in the ACL protocol. Each protocol step will show the appropriate dialogs and measurement tools and switch to the corresponding tab of the EPR. A detailed description of the CAACLREC2 workflow is presented in the next section.

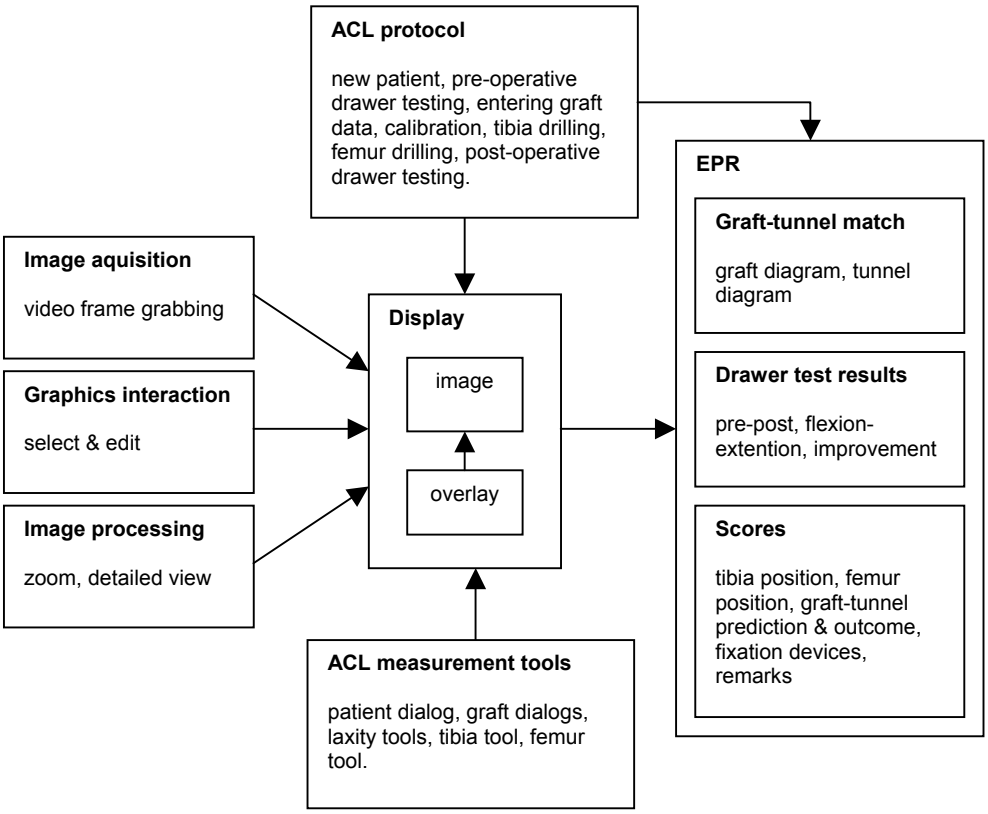


Figure 6-6: Design diagram of the CAACLRec2 system.

For the design and implementation of the prototypes we used the rapid application development environment offered by the Borland C++ Builder. Because of this, the design of the prototype is not independent of the implementation. Therefore, we will not discuss the design and the implementation in detail and just present the final prototype as a 'living specification' for an eventual commercial product version.

6.4.3 The CAACLRec2 prototype

This section describes step-by-step the computer-assisted anterior cruciate ligament reconstruction procedure as performed with the CAACLRec2 prototype. Differences between the patella tendon bone technique and the hamstring tendon technique will be discussed in the individual steps.

Step 1 Set-up
The computer is connected to the video output of the fluoroscope. On start-up, the computer will automatically start the CAACLRec2 program. To restore the last known state the **restore** button can be pressed (if it concerns a restart after a crash). To test if the C-arm is properly connected and the framegrabber is working the 'live view' window can be used to check if the current fluoroscopic image is digitised and displayed correctly.

Step 2 Enter patient information
If the operator clicks the **next state** button the system will go to the **new patient** state and launch the EPR dialog (see Figure 6-4). The fields for patient name, date of birth, and gender are optional; the IP number field must be entered. Once the IP number is entered the OK button is enabled allowing the user to continue. The information fields for the procedure date, surgeon and operator are also optional. The default value for the procedure date is the current date. The surgery and operator fields can be used to enter the surgeon and the operator that perform the current procedure. These fields contain two lists that contain the names of all surgeons and operators qualified to use the system. The fields for the ACL deficient knee (left or right), and surgery type (PTB or hamstring) must be entered in order to set the orientation of the coordinate system (medial-lateral) and determine the type of graft used.

Step 3 Pre-operative drawer testing
Once the EPR dialog is closed the user can proceed with the pre-operative stress laxity testing (drawer test). This state can be skipped by selecting the next state directly from the protocol listbox. In the **pre-operative drawer** state the user interface switches to the **stress images** tab (see Figure 6-7). As described in section 5.7.6 the interface now shows 4 buttons to digitise and display each of the pre-operative stress radiography images. If a stress image is digitised the corresponding **load** button (lower part of tab) is enabled. Each **load** button loads the corresponding stress image and overlays the measurement tools over the image. If the user is finished with positioning the measurement tools the **calc** button can be pressed to calculate the position of the tibia relative to the femur and store the results in the EPR. At the bottom of the tab two buttons (**display scale** and **remove scale**) are provided to show and hide the measurement tools.

The four pre-operative stress radiography images are made during a short imaging session just before the actual surgery. The actual measurements are done after all images are collected when the surgeon is preparing (washing) and while the OR assistants drape the knee and clean it with iodine.

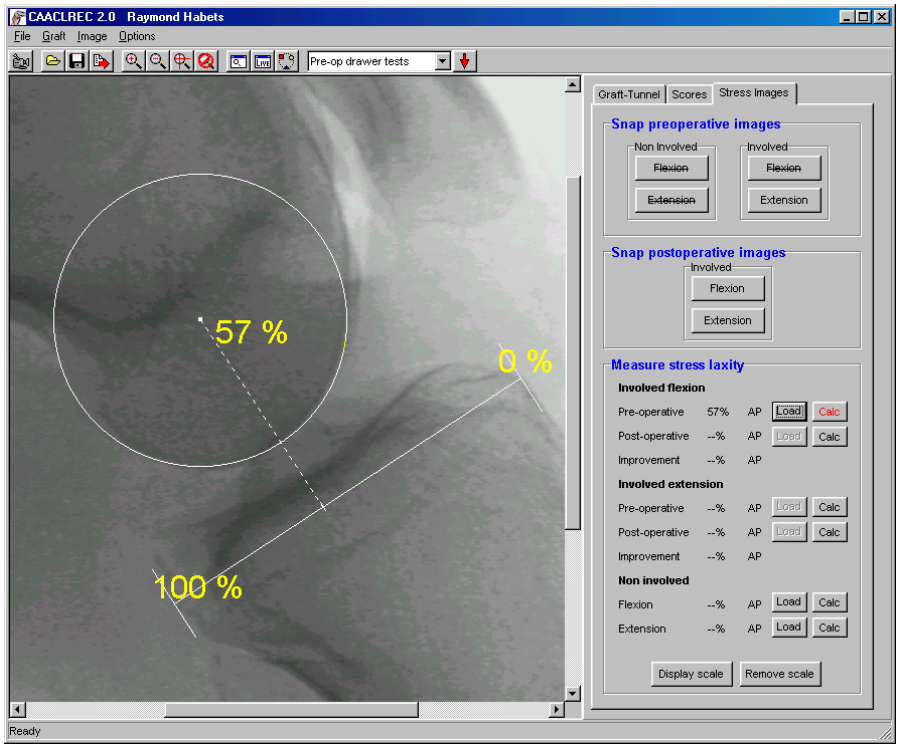


Figure 6-7: Pre-operative drawer testing using the single circle stress laxity method (see section 5.8). The relative femur position (57%AP) is stored in the EPR.

Step 4 Enter graft data

When the stress radiography images are digitised and measured the user can switch to the next state: **enter graft data**. The surgeon will first clean the joint arthroscopically before starting with harvesting the graft. This part of the procedure will take about 45 minutes. During this part the system operator can attend other duties.

After the surgeon has harvested and prepared the ACL graft its dimensions can be entered into the system. Depending on the surgery type the PTB or the hamstring graft dialogs will appear (Figure 6-8). The left dialog is for the PTB procedure, the right one for the hamstring procedure. In the PTB dialog the block dimensions (length and diameter), the tendon length and the total graft length can be entered (all in mm). As explained before the tendon length and the total graft length are linked: only one has to be entered. It is advised to enter the total graft length (see section 6.3.4.6). The user interface will also prevent the user from entering impossible block combinations (the distal block diameter must be larger than the proximal block diameter). In the hamstring dialog box the user can enter the total length of the prepared hamstring tendon (after folding) and the selected drill diameter. After the values are entered and the dialog is closed, the system's graft-tunnel tab will show a graphic representation of the graft with all its dimensions (actual size).

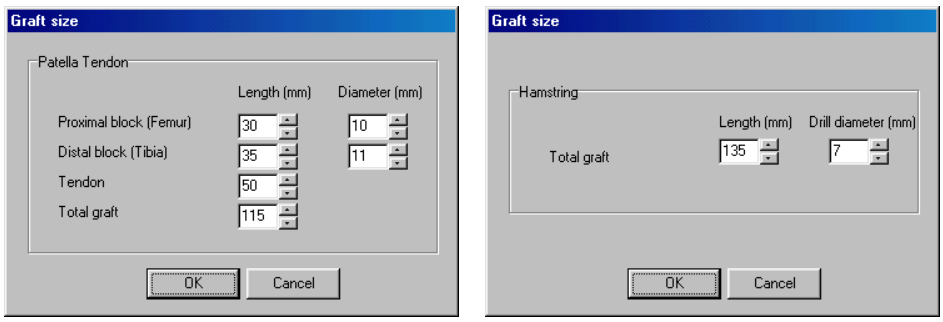


Figure 6-8: Graft dialogs; left: patella tendon bone (PTB); right: hamstring tendon

Step 5 Calibration

As soon as the graft data has been entered the user can switch to the **calibration** state. The user interface will enable the calibrate button (see Figure 6-9). Calibration is possible as soon as the fluoroscopic image with the drill guide in place is available. After pressing the **calibration** button the user must enter the beginning and the end of the POP hook (with the mouse). To facilitate this process and increase the accuracy of the calibration process the **detail zoom** window can be used to enlarge the image around the mouse cursor. This detailed zoom window contains a crosshair that corresponds to the position of the cursor (see Figure 6-9).

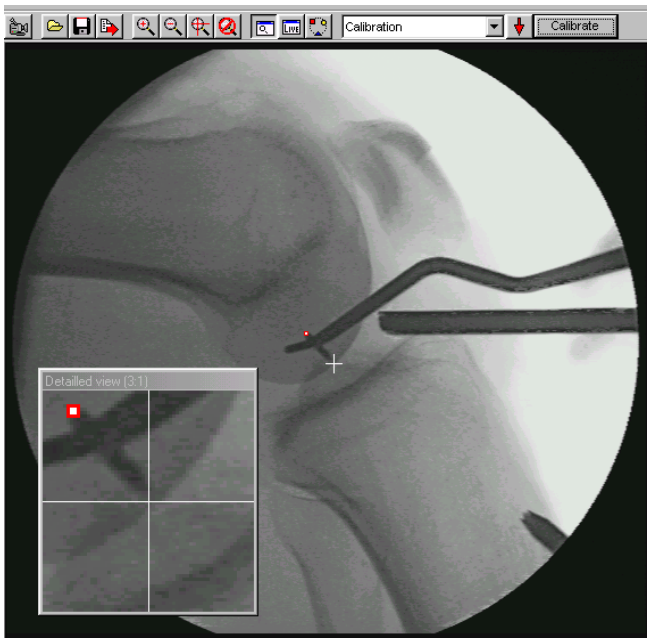


Figure 6-9: Calibration using the POP hook and the detailed view window.

Calibrating the system is only done once for the direction of the drill tunnel as discussed in section 6.3.4.6 If the surgeon moves the tibial guide instrument substantially (more than 10 degrees) it is advised to recalibrate the system.

Step 6 Tibia drilling

Once the system is calibrated the user can switch to the **tibia drilling** state. The user interface will display the tibial and femoral models and the virtual graft overlay and switch to the graft-tunnel tab. First, Blumensaat's line and the femoral condyle circle must be positioned. Then the tibia tool is positioned. Once all tools are positioned the virtual graft placement can be evaluated (see Figure 6-10 and 6-11). The position of the tibial ACL attachment for the current location of the drill guide (expressed in %AP) can be read from the tibia tool. The graft-tunnel match can be read from the graft-tunnel tab that displays the graft (on the left) and the graft-tunnel relation (on the right). The graft-tunnel match depends on the type of graft (PTB or hamstring).

Figure 6-10 shows the graft-tunnel match for a PTB graft. The left panel on the tabsheet displays the PTB graft. The right panel displays the tunnel graph. This tunnel graph extracts the tunnel dimensions from the virtual graft placement and displays it 'unfolded' along the graft. The different parts of the tunnel are presented in different colours. A green-blue part on top represents the femoral tunnel. The femoral tunnel is drilled two millimetres deeper than the length of the proximal bone block in order to assure the bone block will not protrude from the femoral tunnel. Just below the femoral tunnel, a cyan part represents the part of the graft that is located in the intra-articular cavity. This part, which is called intra-articular distance (IAD), is the length of the new ACL. A second green-blue part represents the part of the tendon that is located in the tibia tunnel. The next parts contain the actual information for the graft tunnel match. The part of the tunnel that corresponds to the part of the distal block that fits in the tunnel is colored green. If the tunnel is longer than the graft the size of the green tunnel part equals the distal block length. The part of the tunnel that contains no block is colored yellow. If the tunnel is shorter than the graft the part of the tunnel that corresponds to the part of the distal block that protrudes from the tunnel is colored red. This red part is appended at the end of the physical tunnel length. If more than 20 mm of distal block is located inside the tunnel, the block can be adequately secured with an interference screw.

Figure 6-11 shows the graft-tunnel match for a hamstring graft. The left tabsheet panel displays the hamstring graft. The right tabsheet panel displays the colour-coded tunnel graph. A green-blue part on top represents the femoral tunnel. The proximal tunnel is always drilled to 35 mm and thus 32 mm of graft will be located inside the femoral tunnel (explained in section 6.4.1.3). As with the PTB graft, a cyan tunnel part represents the new ACL graft (IAD). A second green-blue part represents the part of the tendon that is located in the tibia tunnel. With a hamstring graft the tendon has to protrude from the tibia tunnel at least 15 mm in order to fixate the graft externally with a staple. The part of the graft that protrudes from the tunnel is drawn in green. If the graft is shorter than the tunnel the part of the tunnel without graft is colored red.

If the surgeon is satisfied with the actual tibial attachment site and with the graft-tunnel match the K-wire is drilled, otherwise the tibial drill guide is repositioned and this step is repeated. As the K-wire does not always end exactly at the tip of the POP hook it is important to verify its position by using an X-ray image (see Figure 6-12). If the surgeon is satisfied with the position of the K-wire (and thus the tibia tunnel position) the K-wire is over-drilled with a cannulated burr of the correct diameter (i.e. the diameter of the distal block). If not, the K-wire can be repositioned.

After the K-wire position is approved the user can switch to the scores tab (see Figure 6-15). The obtained tibial attachment site (expressed in %AP) and graft-tunnel match data (PTB: block position prediction; Hamstring: tendon position prediction) are stored in the EPR by clicking the **set** button.

Step 7 Femur drilling

When the tibia tunnel is drilled and the scores are stored the user can switch to the **femur drilling** state. The user interface will display the femoral model, the femur tool (see section 6.3.4.3) and switch to the scores tab (see Figure 6-13). The user interface also offers three buttons to show or hide the two femoral models (Blumensaat's line and the condylar circle) and the femur tool. First, the X-ray image in which the femoral drill guide is visible is digitised. Then, Blumensaat's line and the femoral condyle are positioned. If the condyles no longer overlap exactly the circle is positioned between the medial and the lateral condyles. The position of the tip of the K-wire inserted through the femoral drill guide (the new femoral attachment site of the ACL graft) can then be checked against the model determined attachment site (that is derived from the condylar circle and Blumensaat's line). If the surgeon is satisfied with the position of the attachment site, the femur tool is positioned on top of the drill guide (see Figure 6-14). The system will then display the position of the femoral attachment site expressed as a percentage of the length of Blumensaat's line. Besides this, the system also provides the user with a virtual-placement of the femoral tunnel. The surgeon can use this virtual-placement to check the tunnel position relative to the cortical back wall. The diameter of the virtual proximal block is calculated with the calibration value that was determined for the direction of the tibia tunnel (as discussed in section 6.3.4.3).

If the surgeon is satisfied with the realized femoral attachment site and the direction of the femur tunnel, the K-wire is drilled. If not the femoral guide can be repositioned. As with the tibia drilling, the position of the guide wire can be verified after the surgeon has drilled a couple of centimetres (this check is not always performed). If the surgeon is satisfied with the position, the K-wire is drilled completely through the femur until it passes through the skin. The user can then store the position of the obtained femoral attachment site location in the EPR by pressing the corresponding **set** button on the scores tab.

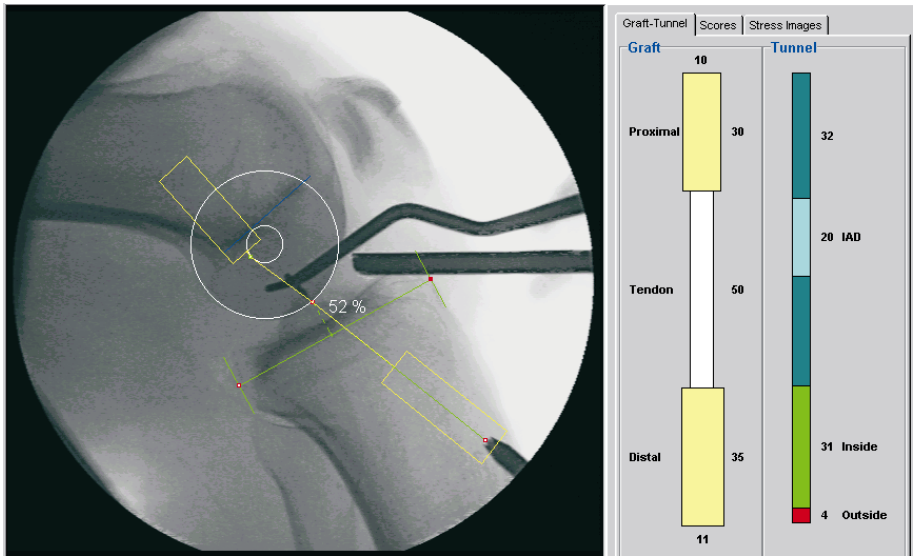


Figure 6-10: Graft-tunnel match for the PTB technique (tibia drilling state). X-ray image (left): tibial and femoral models and the virtual graft overlay; Tabsheet (right): graft-tunnel match graphics.

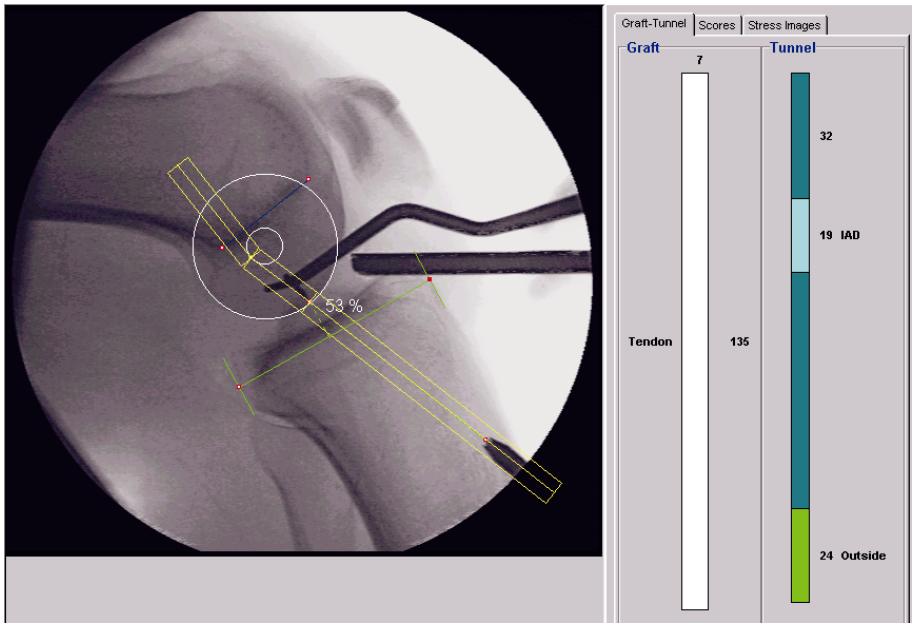


Figure 6-11: Graft-tunnel match for the hamstring technique (tibia drilling state). X-ray image (left): tibial and femoral models and the virtual hamstring graft overlay; Tabsheet (right): graft-tunnel match graphics.

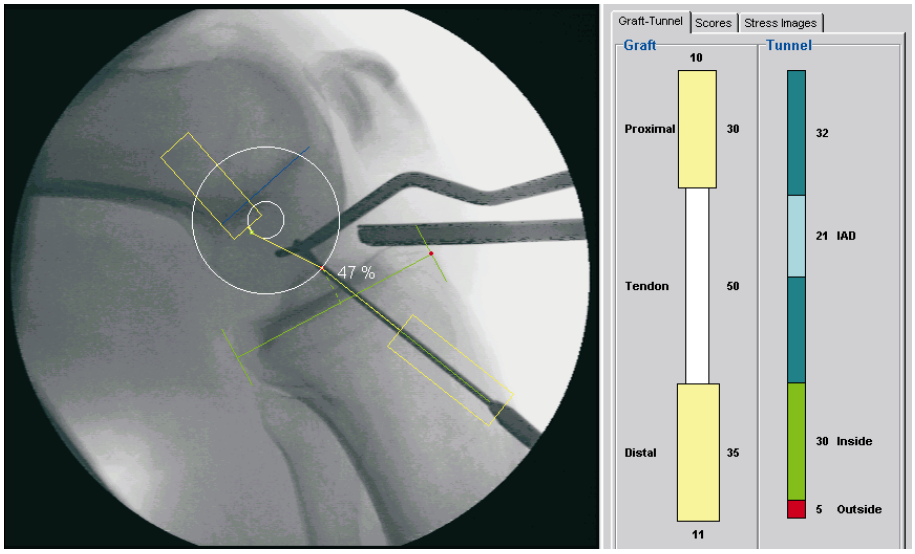


Figure 6-12: Verifying the virtual-placement (tibia drilling state) with the K-wire in place. The final tibial attachment site is 47% AP.

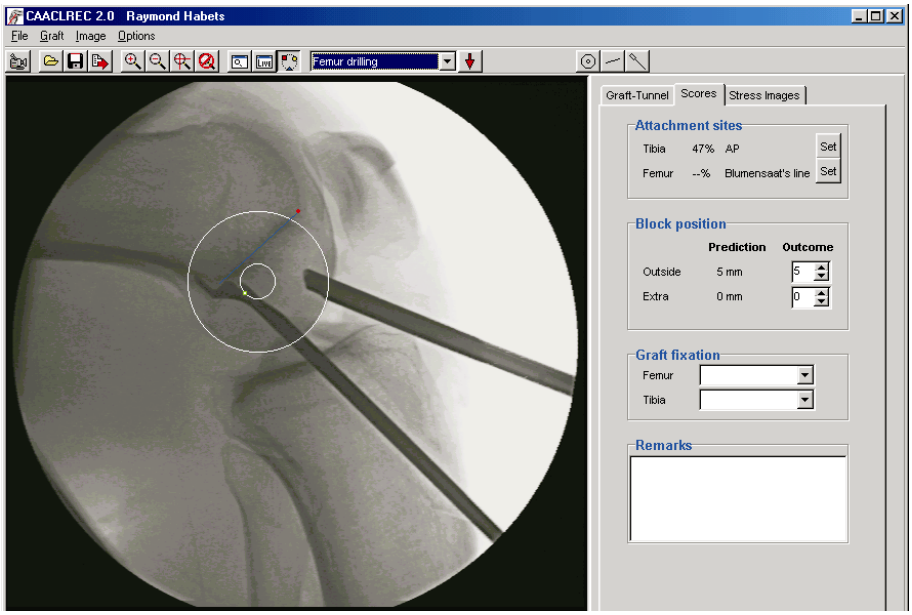


Figure 6-13: Femur drilling state with femoral model. The actual position of the guiding instrument (the femoral attachment site) is compared to the planned position (green dot on small circle).

Finally, the surgeon will over-drill the femoral tunnel with a cannulated burr of the correct diameter. For a PTB graft the burr diameter equals the diameter of the proximal block, for a hamstring graft the burr diameter will normally be 7 mm. For the PTB graft the tunnel is made 2 mm longer than the length of the proximal block, for the hamstring graft the femoral tunnel will always be 35 mm. The tunnel length can be read (arthroscopically) from the scale printed on the burr. If the system would be calibrated for the direction of the femur tunnel it could provide feedback about the actual tunnel depth. As this computer-assisted reading will not bring any extra or more accurate information but only introduce the need for extra actions and more fluoroscopic images it will not be used.

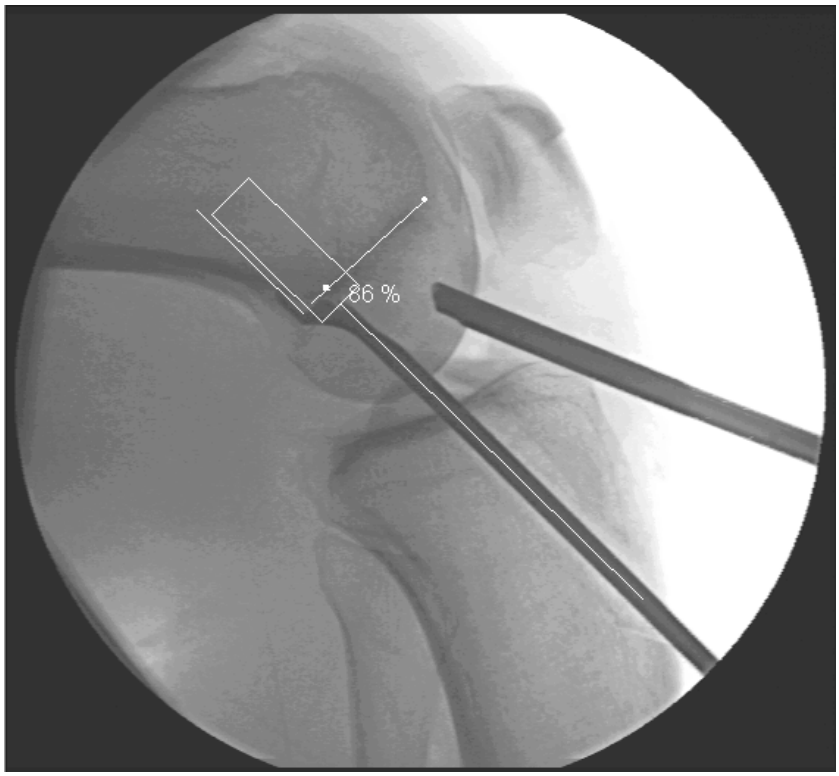


Figure 6-14: Femur drilling state with virtual femoral tunnel placement. The final femoral attachment site is 86% Blumensaat's line.

Step 8 Enter data into EPR

When both tunnels are drilled the surgeon will insert the ACL graft. As soon as the surgeon has decided on the size of the interference screws (or staples) these sizes can be entered into the EPR (see Figure 6-15). After the graft is secured the surgeon will verify the block position prediction (or tendon position prediction in case of a hamstring graft) by visually checking the actual position of the graft relative to the tunnel. The actual position is stored

in the outcome field of the EPR. This data provides an indication about the accuracy of the virtual-placement and the graft-tunnel match prediction. The EPR contains an extra field for remarks. This field can be used to enter any extra relevant information about the procedure (for example to describe a complication).

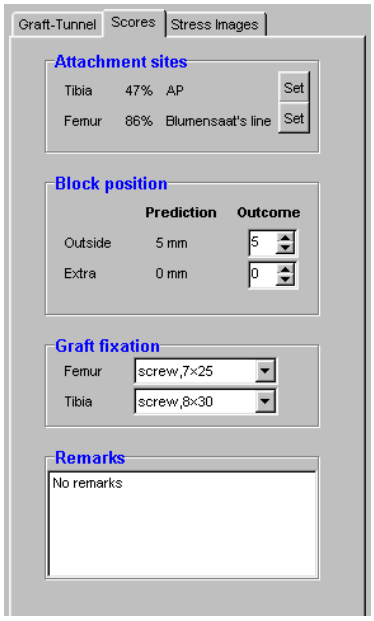


Figure 6-15: EPR scores dialog with attachment site positions, predicted and realized block positions, fixation details and remarks.

Step 9 Post-operative drawer test

In the **post-operative drawer** state the user interface switches back to the **stress images** tab (see Figure 6-7). The user can then digitise the two post-operative images of the involved knee (in flexion and in extension) and calculate the knee laxity scores. The system will store these values and calculate the improvement in extension and in flexion. In case the improvement is not sufficient the surgeon may decide to repeat the graft fixation applying more tension to the graft.

Step 10 Finishing up

After the post-operative drawer tests the ACL reconstruction procedure is finished. The surgeon will close the knee joint and the patient is moved to the recovery room. Before the CAACLRec2 system is shut down the current EPR record can be transferred to removable disk (ZIP, Iomega). This file transfer can be accomplished with the **store** button.

6.4.4 Evaluating CAACLRec2

The technical and clinical evaluation of the initial CAACLRec system are discussed in section 6.3.5 and 6.3.6. We showed the system provided a significant improvement in tunnel position accuracy. Additionally, the overall accuracy of the improved CAACLRec2 system is analysed by comparing the predicted graft-tunnel match with the actually realized graft-tunnel match (as recorded in the EPR). The average prediction error for 50 surgical cases was 3 mm. Because the estimation of the final position of the graft is done with the naked eye and because both tunnel and block are not 'straight' the measurements will be accurate to about 1 or 2 mm. As we always take an extra 6 mm of tunnel length (as discussed in section 6.3.5) a prediction error of 3 mm is considered clinically acceptable.

Another way to score the overall accuracy (for the PTB technique) is to calculate the fraction of screw-screw fixations. For the arthroscopic series 59 % of 29 PTB procedures were realized as two-screw fixations. Of the first 155 surgical PTB procedures performed with the CAACLRec2 system 91% were two-screw fixations. Thus, we expect that the computer-assisted system will significantly reduce the number of reinterventions to remove staples.

6.5 Discussion

6.5.1 Graft placement

The first clinical evaluation (section 6.3.6) compares the graft placement of procedures with arthroscopy (A) to that of arthroscopy and fluoroscopy (AF) and to that of the procedures with the computer-assisted orthopaedic surgery system (AFC).

As can be seen in Tables 6-1 and 6-2 the standard deviation of the realized attachment site decreased from 5.9% (A) to 4.2% (AF) to 2.7% (AFC) for the tibia and from 9.0% (A) to 5.1% (AF) to 2.8% (AFC) for the femur. The range of realized tibia attachment site locations decreased from 23% (A) to 20% (AF) to 13% (AFC) and the range of realized femur attachment sites decreased from 44% (A) to 24% (AF) to 15% (AFC). These data show that the accuracy and thus the reproducibility of the reconstruction procedure has increased first by introducing fluoroscopic feedback and then again by introducing the CAOS system.

From the same tables it can be observed that the mean tibial attachment site has not changed. However, the introduction of fluoroscopic feedback did shift the mean femoral attachment site posteriorly. Adding the CAOS systems had only a very small effect on the mean femoral position. The introduction of fluoroscopic feedback thus provides a means to approach the anatomical femoral attachment site more closely. The extra feedback concerning the cortical back-wall thickness makes the surgeon more confident in choosing a location as posteriorly as possible.

In the surgical cases with fluoroscopic feedback but without the CAOS system we observed that the variability in position was larger in the first half of the procedures than in the

second half. This effect demonstrates the surgeon's learning curve during the use of fluoroscopic feedback. Such a learning curve can also be observed for the surgical cases in which the CAOS system is used. Because the prototype changed significantly during the first 30 procedures a decrease in variability can also be explained by improvements in the prototype itself. Later in the series the variability slightly increased again. This occurred because the surgeons stopped repositioning the instruments in case of small and acceptable deviations from the planned position. In the beginning they tried to position as 'optimal' as possible, sometimes repositioning the drill guide to gain 2 %. As the acceptable placement accuracy is about 2 mm (corresponding to 3.6%) and because repositioning takes extra time, in later procedures the guide was only repositioned if the obtained location differed more than 2 mm from the target.

6.5.2 Virtual-placement accuracy

The required accuracy for the tibial attachment site was 2 mm (3.6 % AP). As discussed in section 6.3.5, the variability in placing the landmarks can cause a 4-degree rotation error, which corresponds to a 1% change in reported percentage. A worst-case analysis showed the graft-tunnel match prediction could be off by 6 mm. In the clinical evaluation we found a mean prediction error of 3 mm. This predicted tunnel length error seems very large. However, using the virtual-placement in a 'safe way' by always taking between 5 and 10 mm extra room proved to be very helpful. This is possible as the average distal block length is 35 mm and only 20 mm of the block has to be inside the tibial tunnel.

6.5.3 Clinical relevance

The first clinical prototype for the ACL reconstruction system was introduced in October 1996. At that time it was, to our knowledge, the first CAOS system for ACL reconstruction that was used routinely in a clinical setting. The system provided a significant improvement in graft placement accuracy at the tibia and the femur site (section 6.3.6). It also significantly increased the number of two-screw fixations and thus reduces the number of additional surgical interventions to remove staples from the knee (section 6.4.3). Besides these 'hard facts', the surgeons find it helpful and decided to continue the use of the system after the trials. The additional feedback of the system has been greatly appreciated by the surgeons already for more than 5 years. The additional features like the EPR provide means to document the actions of an individual procedure. This data will, amongst others, help the search for the optimal graft position.

Assessment of clinical relevance is important for all new techniques and instruments in the medical field, and thus also for CAOS systems. There must be benefits to the patients or the physician that justify the use of the system. The CAOS system reduces the number of extra procedures and this is a direct benefit for the patient. The relation between increased placement accuracy and patient outcome is hard to investigate for the following reasons:

- Although graft position is considered the most important factor for the success of the reconstruction procedure, it is not the only one. Graft fixation, graft tensioning and the entire revalidation procedure also influence the outcome of the procedure.

- The available scores for patient outcomes are very subjective. A frequently used system to assess knee function is the IKDC test. One of the more objective scores in this test is the knee-stability measured with the KT2000 system. However, there are patients who have low KT2000 scores (a stable knee) and still state that their knee feels unstable but also patients with high KT2000 scores who do perceive their knee as stable.

We expect there will be a range of graft positions that can be considered adequate. For the patients in this group other parameters than the graft position will be the determining factors for the patient outcome. For our patient group we found no clear correlation between the knee stability measured with the KT2000 (as a measure for the patient outcome) and the graft position as reported by the ACL CAOS system. The fact that we do not find a direct relation between our position scores and patient outcome parameters suggests that the placement accuracy we obtained with our CAOS system is sufficient to position all grafts in the safe range.

The short-term benefits of the system have been demonstrated by reducing the number of staple fixations. However, five years is a short period when compared to the intended lifetime of the graft (about 50 years). Thus, it is not possible yet to address long-term results.

For all clinical systems it is imperative that the benefits for the patient outweigh the costs involved to use these systems. We feel this is the case for our system: the placement accuracy and the decrease of staple fixations is important for our patients. The results indicate that the CAACLRec system is a valuable addition to the treatment of anterior cruciate ligament deficiency.

6.5.4 Clinical acceptance

Clinical relevance is the most important condition for acceptance of this CAOS system in the clinical setting. During all of our demonstrations of the CAOS system in our hospital and during conferences (e.g. at the AAOS conference where we demonstrated the system to more than 100 orthopaedic surgeons) we interviewed surgeons and asked them to comment on our system. This resulted in a list of questions comprising topics of alternative graft positions, clinical integration, the responsibility of operating the system, the use of fluoroscopy, the choice of a 2D-plus system, and system maintenance. In this section we will discuss several of the issues that were raised during these interviews.

6.5.4.1 Optimal graft position

There is still no consensus about the ‘optimal position’ for the ACL graft. As discussed in section 6.5.3 this optimal position will actually be an optimal area (range). One could argue that it is illogical to use a CAOS system that enables accurate placement of the graft if it is not exactly known where this graft should be placed. However, in order to find the optimal area we need to investigate the relation between the placement of the graft and the patient outcome. Without measuring the realized position for each patient, it is not possible to find the optimal area. Therefore, the use of CAOS systems is a first step in relating surgical intervention to patient outcome.

The ACL reconstruction system uses a general target based on landmarks that can be overruled by a patient-specific situation. Only for patients who have a hyper-extended knee, it might be necessary to change the target for the graft position to prevent impingement. To see if this is the case, an impingement test was implemented. Besides impingement free, the graft should also be placed isometric. As an addition to our system, the radiographic isometry test described by Colette [Colette, 1996] can be implemented. If a graft is not placed in an isometric position the graft can shorten or stretch during the normal range of motion of the knee.

Because the graft has a completely different shape when compared to the original ACL, we think it will never be possible to obtain truly isometric attachment sites. Besides this, all isometry measurements are performed on an ACL deficient knee. The missing ACL, the intraoperative swelling and anaesthesia all influence the dynamic behaviour of the knee. The isometric graft positions determined in this situation may not be isometric after the graft has been placed. Therefore, we decided not to consider the isometry of our graft placement.

6.5.4.2 Integration into the clinical setting

The prototype could easily be integrated into the clinical setting because no significant changes were required in the reconstruction procedure itself or in the surgical instruments. The critiquing system approach (providing feedback only) is very suitable for CAOS-system prototypes. A surgeon will not risk testing a prototype in the clinical setting if he is not in complete control.

The prototype CAOS system is based on the 2D information from the fluoroscope. The targets for the attachment sites are based on anatomical references defined on a truly lateral X-ray of the knee joint. Thus, the CAOS system should only be used if the intra-operative X-ray images show overlapping condyles. As the system is only calibrated once, the user has to keep in mind not to change the orientation of the knee or the fluoroscope more than 10 degrees. For these 2D-plus based CAOS systems the user always has to take into account the limitations of the system and the range of situations in which it can be used safely.

For the final product the ergonomic situation for the surgeon should be improved as well. One possibility would be to use one of the three existing displays to present the feedback from the CAOS system. It is also possible to design a new display system for the operating room. This new display system must be able to display information from all available sources, including the computer. Currently, display technology is an area of attention for the clinical physics department.

6.5.4.3 Responsibility issues

The surgeon is responsible for the procedure. This also implies that the surgeon uses tools that are inherently safe. For a surgical knife the responsibility issue is simple. Nobody would hold the manufacturer of the knife responsible for accidentally making a wrong incision. However, if the knife would break under normal working conditions the manufacturer could be held responsible for delivering poor quality instruments.

For more complex systems, like CAOS systems, the responsibility question is more difficult. The surgeon relies on his or her own expertise, the expertise of the hospital's clinical physics department that approved the use of such systems and the manufacturer's competence to deliver a system that can be used safely for the procedure. When using the system the surgeon also depends on the expertise of the system operator, the maintenance engineer and the OR crew. The responsibility for safely using the system is now shared between all these parties. Thus, when a CAOS system is introduced in the clinical setting it is very important to document the individual responsibilities of all parties involved.

6.5.4.4 Using a fluoroscope for the ACL procedure

Most surgeons perform the ACL procedure with the standard arthroscopic technique. Halbrecht suggested the use of a fluoroscope [Halbrecht, 1993]. Table 6-3 contains some of the concerns expressed by surgeons when additional fluoroscopic feedback is suggested for the ACL reconstruction procedure.

Table 6-3: Surgeon's concerns to use fluoroscopy for anterior cruciate ligament surgery.

Surgeons concerns about fluoroscopy	Situation with our CAOS system
The fluoroscope is not necessary for the procedure.	For our system, the fluoroscope is necessary.
It takes an extra person and extra time to set-up and operate the fluoroscope.	The fluoroscope is set up when the surgeon scrubs, so no time is lost. The radiology assistant only has to be present when the tunnels are drilled (last 30 minutes).
The entire OR team must wear a lead jacket during the procedure.	Lead jackets are only necessary when the tunnels are drilled. The surgeon can put on the lead jacket and re-scrub when the assistant is preparing the graft.
The fluoroscope will limit the OR team's freedom of motion during surgery.	With our set-up two people can reach the operating area without interference from the fluoroscope.
The fluoroscope introduces extra radiation exposure to the patients and the OR team [Larson, 1995].	We use about 12 single-shot fluoroscopic images for the entire procedure (the total X-ray exposure is always less than half a minute). Thus, the radiation exposure for patient and OR team is very low.

6.5.4.5 Using a 2D-plus instead of a 3D CAOS system

Almost all commercially available CAOS systems are 3D systems. All these systems need extra tracking hardware and optionally CT images. As the ACL procedure can be performed arthroscopically, surgeons will have a hard time accepting such a 3D system. We developed a CAOS system based on 2D fluoroscopic images that would not make the procedure more complex. This 'simple' system requires no preoperative CT images and no changes to the operation technique or to the surgical instruments normally used for this procedure. The system runs on a standard Pentium computer, so the costs are minimal.

After every demonstration of the system, we asked if the orthopaedic surgeons would consider the use of such a system for their ACL surgery if it were an actual product. Many reacted positively. Unless they only reacted positive out of politeness, our system thus demonstrates it is possible to create a CAOS system that can be accepted for anterior cruciate ligament reconstruction.

6.5.4.6 Maintenance tasks concerning the CAOS system

The normal maintenance of the ACL system consists of making a backup of the electronic patient record (EPR). This backup is made about four times per year. In addition, the CAOS system's EPR is cleared yearly (all old patients are removed from the system and transferred to CDROM storage). All backups are stored in the archives of the technical department. To prevent loss of data due to computer crashes all data is saved directly to disk. After a crash all data of the current procedure can be restored by pressing a single button. For extra safety and for the surgeons personal records a backup of the EPR record of each individual patient is made after every procedure.

At least five technical assistants are trained to operate the system and solve small problems. At least two of them can train new operators. All hardware can be replaced without changing the software. The software for the CAOS system is available on CDROM in case it has to be reinstalled. This CDROM also contains the source code and the documentation. This should provide a software engineer with everything needed to make changes to the program without the assistance of the system's designer.

6.5.5 Other developments

The system from the Müller institute discussed in section 8.2.2.3 uses a lateral fluoroscopic image of the knee in combination with a 3D model of the knee made by digitising the knee with a tracked palpation hook [Sati, 2000], [Sati, 2002]. The tibia, femur and all instruments are also tracked with an optical system. The system provides 3D impingement testing, isometric placement, 3D virtual-placement and instrument navigation.

The CASPAR system is a CT based 3D system that uses a surgical robot to drill the tunnels [Petermann, 2000]. The planning for the ACL injured knee is based on information from the non-injured knee. The system offers notch as well as wall impingement testing. During drilling with the surgical robot the knee is temporarily immobilized. The KneeNav system is a 3D CT based system with freehand navigation [Picard, 2001]. The Vector Vision ACL system is a 3D freehand fluoroscopy based system. To the best of our knowledge none of the systems described in this section are widely used in the clinical setting.

All 3D systems can guide the surgeon to a 3D location when placing the ACL graft. In follow-up studies that relate patient outcome to surgical action, we demonstrated that with our 2D-plus system we could place all grafts in a 'safe area' and that we could not relate an individual position within that area to better patient outcome. We expect that the 3D systems, that offer even a higher placing accuracy, will encounter this same problem. In combination with the need for an additional optical tracking system (with trackers that have to be implanted in the bones), this will make the clinical acceptance of 3D ACL CAOS systems more difficult than our 2D-plus system.

In the most recent computer-assisted ACL surgery system developed at the M.E. Müller Institute for Biomechanics [Sati, 2002] graft fixation assistance similar to our graft-tunnel match was included. In their comment on our system they mention that the advantage of our system is that it allows 2D X-ray anatomy-based preoperative planning of both ligament position and bone-block length. They state our system seeks an anatomical placement of the ligament with respect to radiographic landmarks using intraoperative fluoroscopic guidance in the sagittal plane. They argue that it does not provide direct computer-assisted guidance of the planned tunnel insertion, or a truly 3D analysis of ligament placement, impingement and elongation measurement. They also state that a fluoroscopy-based approach cannot be used to consider cartilage geometry.

We demonstrated that the combination of arthroscopic and fluoroscopic imaging provides a good ligament position. In section 6.5.3 we mentioned that the lack of correlation between patient outcome and graft position suggests that all our grafts are placed in a 'safe range'. We feel it will be hard to clinically justify the extra effort needed to add 3D navigation tools to provide a truly 3D analysis. In our approach the cartilage geometry is considered arthroscopically by the surgeon.

6.5.6 Our place in the market

Did industry overtake us? Our 2D-plus system aims to help the surgeons with their current ACL surgery technique. The system is designed to comment on observed surgical actions (by using single-shot fluoroscopic images) and predict the location for the graft from the actual instrument position. The commercial 3D systems aim to help the surgeon with the planning and the surgical execution of that plan (guidance systems). As the design goals are different the industry did not overtake us; they followed a different strategy. Both strategies provide a CAOS system accurate enough to place the ACL graft in a target zone that provides good clinical results.

Will our ACL system ever be a commercial product? Because 2D-plus CAOS systems like our ACL system only use fluoroscopic images they could be integrated into a fluoroscope. In this case the radiology assistant could be the system operator. Another possibility would be to combine our approach with a freehand fluoroscopy based navigation system.

6.5.7 Recommendations

From the prototype we learned which landmarks in the X-ray images must be detected. Automatic detection of the surgical instruments (the POP hook and the tip of the tibial drill guide) is possible. Automatic detection of bone contours is more difficult but some a-priori information can be used:

- the fluoroscopic images always show the knee in a similar position (a truly lateral image as required for our models)
- the possible knee motion from one to the next image is limited
- the location of the knee is directly related to the location of the surgical instruments
- the user can provide an initial position of the overlay tools for the first image
- the shape of the bony anatomy (bones) does not change during the anterior cruciate ligament procedure

If a fully automatic detection can be realised the feedback can be provided more timely. However, an additional operator would still be necessary. Sterile interfaces are available that allow the surgeons to operate the CAOS systems but in this case the surgeon cannot hold the drill guides and simultaneously operate an interface (even a very simple one). Speech recognition systems may be a solution to this problem. As automatic detection can increase the usability of a CAOS system it should be considered if an actual clinical CAOS product is made.

Chapter 7

Computer-assisted hip pinning

7.1 Introduction

In many orthopaedic procedures multi-plane fluoroscopic feedback is used. In these procedures several (mostly orthogonal) views are made with a single fluoroscope. The surgeon uses these images in combination with the anatomical knowledge to perform a three-dimensional surgical task. A frequently performed procedure that uses fluoroscopic images from two different directions (anterior-posterior and axial) is the treatment of a hip fracture with a dynamic hip screw (DHS). A main problem in this procedure, that was explained in section 2.8, is the positioning of a guide wire somewhat distal to the centre of the femoral head.

To explore the limits of the 2D-plus approach of the rapid prototyping toolbox we investigate the possibility to create computer-assisted tools for multi-plane procedures. We design a computer-assisted surgery system for hip pinning (DHS procedure) that assists the surgeon in placing the guide wire. This guide wire is drilled freehand by using a guiding instrument that mechanically provides the correct angle between DHS screw and plate. Fluoroscopic images from the axial and the AP direction are used to control the guide wire placement. As there is only one C-arm available that has no positional feedback, these images can not be made available at the same time.

First, we provide the surgeon with a graphic overlay that shows the target drill path in both views individually. Next, we provide a ‘virtual’ path, that displays a prediction of the drill path based on the current location of the surgical instruments (as with the ACL reconstruction system described in Chapter 6). This ‘virtual’ path is presented in both fluoroscopic views. Finally, we assist the surgeon in positioning the guiding instrument in such a way that the entry point and the entry direction match the target path in both the AP and axial direction. To realize independent positioning in two directions we need an extra mechanical guide to couple the information from both images.

7.2 Identification of the customer requirements - Prototyping Phase 1

7.2.1 Introduction

The main task of the CAOS system for ACL reconstruction is to position a guide wire and drill the tibia tunnel based on single-plane fluoroscopy. The DHS procedure is an excellent candidate to develop a CAOS system that uses two-plane fluoroscopy. As with the ACL system, the basic task is positioning a guide wire at a previously defined position. More importantly, the orthopaedic surgeons in our team state that a system that can help place a DHS screw more accuracy is clinically relevant. Misplacement of the DHS screw is one of the main reasons for complications. In the current situation, the placement of the guide wire is a trial and error procedure and it takes an experienced surgeon to position the wire with a minimum number of fluoroscopic images.

7.2.2 Identifying the problem

The most difficult surgical task in the DHS procedure is the positioning of the guide wire. Only the entry point for the guide wire at the femoral cortex a few centimetres below the innominate tubercle is visible. As was explained in chapter 2, the drill guide mechanically provides a guide wire position that assures a correct angle between the DHS screw and the femur plate. The two remaining degrees of freedom in positioning the guide wire are:

1) the entry point of the guide wire, which can be controlled by moving the drill guide in the cranial-caudal direction along the femoral cortex, and
2) the anteversion angle of the guide wire, which can be controlled by tilting the drill guide in the ventral-dorsal direction.

Both the target for the entry point position and the target for the anteversion angle of the drill guide can be determined with an extra guide wire that is placed on top of and along the femoral neck. Fluoroscopic images from the AP and the axial view are used to assist the positioning of this extra guide wire. By using the extra guide wire and experience, the surgeon positions the drill guide and drills the guide wire for the screw (see section 2.7). The obtained position of the guide wire is then verified fluoroscopically in the axial and AP direction (sequentially). It is very difficult to position the screw guide wire while using two sequential fluoroscopic images, because the surgeon must change the orientation of the drill guide in the currently observed image without changing the orientation of the guide in the other image. Even experienced surgeons will need a few iterations to obtain an adequate guide wire position.

The femur contact surface of the drill guide is slightly curved to match the femoral contours. This curved surface is equipped with four small sharp pins (fixation pins) that are pressed into the femoral bone to prevent the plate from slipping. The hollow metal cylinder that is mounted on the curved plate holds the guide wire with the correct angle. As explained before manipulating the guide is very difficult. Making small position adjustments is extra difficult because the fixation pins on the contact surface prevent the guide from moving. The problem with this guide is that positioning and fixation are tightly coupled. During surgery we noticed that the surgeon controlled the anteversion angle of the guide wire by tilting the guide in ventral-dorsal direction over two of the four fixation pins.

Another problem that complicates positioning of the guide wire is the image distortion of the fluoroscope (see section 5.2.3). According to the imaging protocol, the AP fluoroscopic image of the hip is taken with the femoral axis shown vertical. In this situation, the drill will enter on (for the 135 degree DHS) or somewhat below (for the 150 degree DHS) the image diagonal and travel in the direction of the opposite top corner (see Figure 5-3). Due to image distortion, this straight drill (guide wire) will appear to be curving downward in the fluoroscopic image. During one of the procedures we observed that an experienced surgeon advised a trainee to aim a little bit lower than he would expect when extrapolating the current drill direction. This demonstrates that surgeons use their experience to compensate for image distortion. As long as the imaging protocols are followed strictly this 'correction by experience' will work. Any change in image protocol, imaging hardware of surgical technique can make these corrections useless and even completely wrong (see Figure 5-3 where the drill enters above the image diagonal and thus curves upwards).

7.2.3 Project goal

One of the most important features of computer-assisted surgery systems is to couple the preoperative planning and the surgical intervention. The CAOS system for anterior cruciate ligament surgery only verifies the actions of the surgeon. The system compares the obtained drill tunnel positions (the tunnel that would result assuming the current instrument position) to the target tunnel positions. The system does not actually guide the surgeon. Initially, for the hip CAOS system we will do the same: the target guide wire position is compared to the 'virtual' guide wire position. However, to explore the limits of our approach we will also guide the surgeon in placing the drill guide at this target position.

In 3D CAOS systems, the preoperative planning and the surgical execution are coupled by using an optical tracking system. This system tracks the instrument positions and patient movements and shows the actual instrument positions in the planning data. We propose to use an extra mechanical guide in addition to the surgical instruments currently used for the DHS procedure. The design of this additional guide is discussed in section 7.3.3.3.

We aim at developing a CAOS system that helps the surgeon in placing the central guide wire more accurately central in the femoral neck. This CAOS system will help the surgeon to determine the entry point and a correct direction for the guide wire using the two fluoroscopic images. The use of an additional guide should enable a surgeon to change the position of the drill guide in one image plane, while maintaining its position in the other plane (before drilling). In this way, we want to reduce the number of fluoroscopic images used in the current trial and error positioning of the guide wire.

7.2.4 Sources of information

Section 6.2.4 discussed several sources of information that can be used to gather the requirements for developing a CAOS system. An introduction into hip pinning surgery was presented in chapter 2. Information about the surgical procedures was collected from instrument manuals, from observing the surgeons at work and during personal interviews with the surgeons.

7.2.5 Requirements and constraints

Medical requirements and constraints
During the development and the testing of the prototype the current DHS procedure should not be altered severely. The currently used surgical instrumentation should not be altered. It should always be possible to abort a CAOS trial and continue the surgery with the 'old' operating technique.

The DHS procedure is an unscheduled trauma procedure. Both orthopaedic and general surgeons in our hospital perform this procedure. During the development phase, we select a small number of surgeons that are interested and willing to cooperate in the design of a CAOS system for DHS surgery.

The CAOS system must be based on the two fluoroscopic images that are routinely used in a DHS procedure: the AP and the axial view. The target guide wire position in the axial view is slightly dorsal to the centre of the femoral neck. The target guide wire position in the AP view is slightly distal to the centre of the femoral neck. The guide wire should pass through the centre of the femoral head. The tip of the wire is drilled to about 5 mm from the cortex of the femoral head. The CAOS system should provide graphical overlays showing the femoral head and the optimal wire position. On both sides of the central femoral neck axis, error margins (lines parallel to the axis) should be displayed. These error margin lines should be spaced with a distance of a quarter radius of the femoral head.

The entry point for the guide wire on the femoral cortex can be derived from the target guide wire positions in both fluoroscopic views. The CAOS system should assist (guide) the surgeon in locating this entry point on the patient. To realize this, it is necessary to use an additional guiding instrument that is visible in both fluoroscopic images.

The CAOS system should provide a graphical overlay showing the 'virtual' drill path. This 'virtual' path is a prediction of the drill tunnel based on extrapolating the guide wire as it is observed in the fluoroscopic image. This prediction of the guide wire position can then be compared to the target guide wire position.

The guide wire should be placed with an accuracy of about 2mm. The prototype CAOS system will be tested by one of the orthopaedic surgeons that participated in the trial. The final prototype will be evaluated clinically in a series of 50 DHS procedures.

Technical requirements and constraints
The CAOS system for hip pinning will be constructed with the rapid prototyping toolbox. For the 'virtual' drill path prediction the small part of the guide wire that is visible in the fluoroscopic image (a few centimetres) is extrapolated over the entire length of the tunnel (about 12 cm). This will not be possible without implementing a distortion correction tool for the toolbox.

The CAOS system for hip pinning should be implemented with the same hardware (computer, framegrabber and fluoroscope) as used for the CAOS system for anterior cruciate ligament surgery.

Legal requirements and constraints
As with the ACL system permission from the Medical Ethics committee will be obtained before the clinical trials will start.

Organizational requirements and constraints
During the development phase the CAOS system will be under control of the designer. The final system will be operated by the medical technical assistants that are trained in using the ACL system.

The OR layout for a DHS procedure is shown in Figure 7-1. The surgical team and the patient are separated by a 'plastic curtain'. The involved hip is accessible via an opening in the curtain. The involved leg is fixed in a traction system that allows the surgeon to control the position and orientation of the femur. The fluoroscope is positioned on the patient side of the curtain. The fluoroscope can be rotated freely to obtain the AP and axial X-ray images. The monitors of the fluoroscope are placed at the end of the curtain next to the traction system. The computer for the CAOS system is placed next to the fluoroscopic monitors.

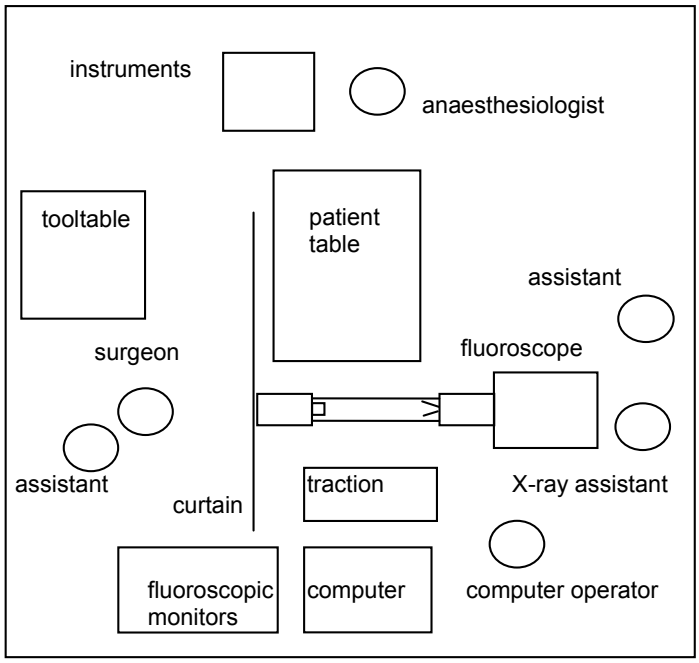


Figure 7-1: OR layout during a DHS procedure.

During a DHS procedure at least six people are present in the OR. The surgeon and a surgical nurse occupy the sterile operating area. Optionally, there will also be an extra surgical assistant. There will be one anaesthetic assistant, at least one general assistant and a radiological assistant. The team is completed with the computer operator.

Financial requirements and constraints
The Stan Ackermans Institute of the Eindhoven University of Technology financed the position of the technological designer. The section of Signal Processing Systems of the faculty of Electrical Engineering of the Eindhoven University of Technology financed a workplace and provided the project management.

The Catharina Ziekenhuis provided all necessary hardware, a workplace and all support necessary to develop and create the additional surgical guide.

Timing requirements and constraints
The development of the CAOS system for hip pinning had to be built during the PhD project following the two-year developers course. The PhD project started in May 1998 and had to be finished by May 2000. The DHS system would be constructed in the second part of this project.

As will be discussed in chapter 8, others (in research and industry) are working on computer-assisted surgery systems. Because the development of new surgical instruments will be expensive, we will introduce a decision moment at the end of the concept validation phase. Based on the developments in the field we will then decide if we should continue with our project.

7.3 Concept validation - Prototyping Phase 2

In the concept validation phase of the rapid prototyping process the key concepts of the CAOS system for hip pinning are determined. This step focuses on the design of the user-interface elements for the target and the 'virtual' path overlay and on the design of the additional surgical guide. For this phase, we assume that a DHS screw with a 135 degrees angle is used.

7.3.1 Selection of prototyping tools

The rapid prototyping toolbox from chapter 4 will be used to develop the CAOS system for DHS surgery. The system will be developed with the Borland C++ Builder environment. The generic CAOS program (see Section 4.9) will be used as a starting point for the DHS system. From the generic CAOS program we inherit image acquisition, the live preview window, all image retrieval and image storage functionality, zoom functionality, and the generic drawing tools.

7.3.2 Data acquisition

To start the concept validation phase we needed representative X-ray images of hip pinning procedures. These images were acquired with the generic CAOS program installed on the computer system developed for the ACL CAOS system. During four DHS procedures and one IMHS procedure five sets of about 30 images were collected. Table 7-1 shows the statistics for the four DHS procedures. For each of these procedures we determined the total number of X-ray images, the number of X-ray images used for aiming and the number of orientation changes of the C-arm.

Table 7-1: DHS statistics: total number of X-rays, nr of x-rays used in aiming procedure, and the number of orientation changes of the C-arm.

DHS procedure	Total nr. of X-rays	nr. of X-rays for aiming	C-arm orientation changes
1	31	19	2
2	24	11	4
3	34	27	5
4	26	15	2

7.3.3 Key concepts of the application

As discussed before, the accuracy of the dynamic hip screw procedure is mainly determined by the position of the DHS screw. The key concepts (essential features) for the clinical CAOS system can be found by analysing the way in which the surgeon evaluates the results of the procedure and the considerations determining screw placement.

7.3.3.1 Screw position

The position of the DHS screw is measured by using an AP and an axial X-ray image. For this, a measurement system that measured the position of a screw relative to the femoral head was implemented (discussed in section 5.3.2). This measurement system uses three anatomical references that can be determined in both X-ray views:

- the axis of the DHS screw: modelled with a straight line
- the femoral head: modelled with a circle
- the smallest diameter of the femoral neck: modelled with a line perpendicular to the femoral neck axis

The measurement system measures the position of the tip of the DHS screw and the position of the screw in the smallest part of the femoral neck. The position of the tip is measured with two relative measures:

- the distance to the centreline (the circle diameter that is parallel to the axis of the DHS screw) expressed as a percentage of the circle diameter
- the distance to the circle border in the direction of the centreline expressed as a percentage of the circle diameter

The position of the DHS screw relative to the femoral neck is measured by intersecting the DHS screw line with the femoral neck line. This intersection point is reported as relative to the length of the neck line (0% being the most proximal point of the neck line). Examples of these measurements are presented in Figure 7-2 (the left image shows the AP X-ray; the right image shows the axial X-ray).

From the available DHS surgery data the data of 16 patients, with correctly placed DHS implants, were selected. The DHS screw position was measured in both the AP and the axial images. The mean values and the standard deviations are presented in Table 7-2.

Table 7-2: DHS screw positions in the AP and axial view relative to the femoral head and the femoral neck.

		Distance to border (% circle diameter)	Distance to axis (% circle diameter)	Position in neck (% neck diameter)
AP	Mean	23%	0%	57%
	Std	8%	9%	10%
axial	Mean	24%	2%	57%
	Std	7%	9%	12%

The distance of the screw tip to the circle border is measured along the circle centreline (projection). Thus, if the screw is positioned off axis it is actually closer to the femoral head cortex. The distance of 23% (with a femoral head diameter of 3 cm this corresponds to about 7 mm) is somewhat larger than expected, but considering the explanation presented above it meets the requirement (5 mm for the cortex). As expected the screw axis passes through the centre of the femoral head and it crosses the femoral neck slightly distal (AP) and slightly dorsal (axial) to the femoral neck axis.

7.3.3.2 Target path and 'virtual' path

AP view target path

Figure 7-3 shows an AP image taken during a DHS procedure. The femoral head is modelled with a circle (in yellow). This circle will be called FH-AP circle (femoral head in the AP view). The top of the drill guide (the plate parallel to the femoral axis), is modelled as a straight line (in cyan). The drill path will be modelled as a line (in cyan), called targetpath-AP line. The targetpath-AP line makes a 135 degrees angle (corresponding to the DHS screw-plate angle) with the femoral axis (the drill guide) and passes through the centre of the FH-AP circle. On both sides of the targetpath-AP, parallel error margins (red lines) are displayed. These error margin lines are spaced with a distance equal to a quarter of the femoral head radius.

Because the fluoroscopic image is a projection image the screw-plate angle will only measure 135 degrees if the fluoroscope is positioned exactly perpendicular to a plane through the femoral shaft and neck. In this procedure the patient is positioned on his or her back with the foot of the involved leg in traction. With the foot in a normal position the femoral head will point somewhat upward and out of the coronal plane (femoral anteversion). Thus, in a truly AP image of the hip joint the screw-plate angle will appear to be greater than 135 degrees. If the AP image shows the guiding instrument the correct screw-plate angle for the targetpath-AP line can be copied from the instrument's guide wire cylinder (which is exactly 135 degrees). The intersection of the targetpath-AP line with the femoral cortex is the target entry point in the AP view.

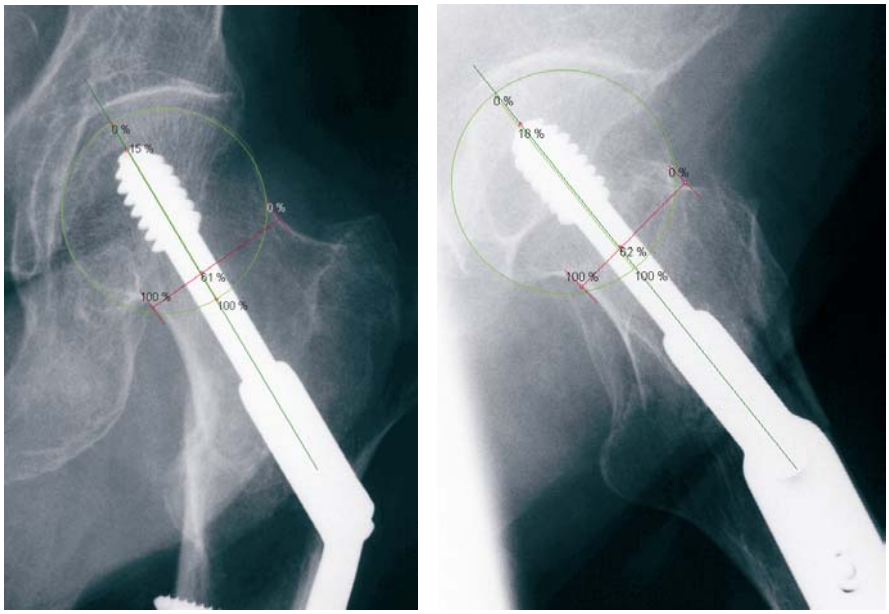


Figure 7-2: Measuring the relative position of the DHS screw. AP(left) DHS screw tip: 0% to centreline, 15% to border; 61% neck. Axial (right) screw tip: 0% to centreline, 16% to border; 62% neck.

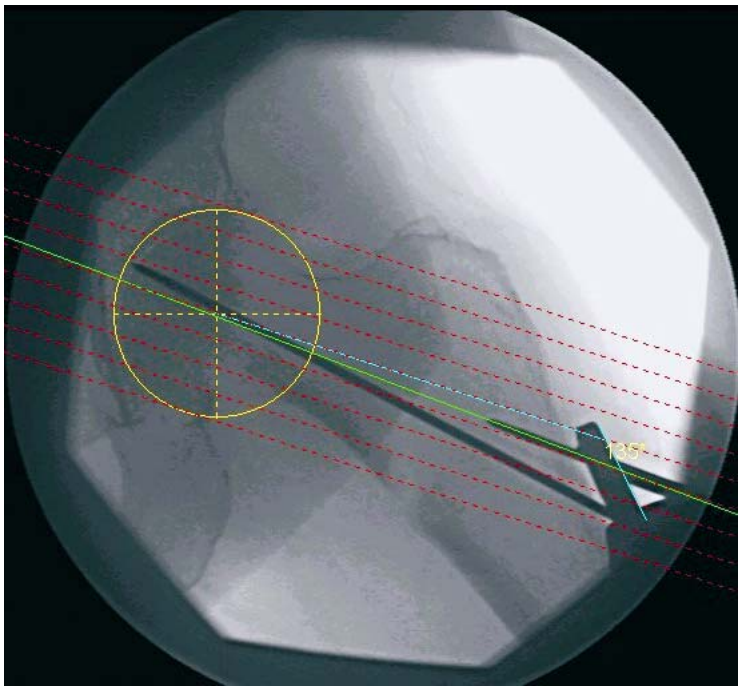


Figure 7-3: Target path (cyan line and yellow circle) and virtual path (in green) in the AP X-ray image.

AP view 'virtual' path
The targetpath-AP line is the planned 'optimal' position for the dynamic hip screw (in the AP view). The 'virtual' path of the drill can be determined from the current position of the guiding instrument. A green line, named virtualpath-AP, is placed on the central axis of the hollow cylinder that guides the k-wire. By extrapolating the virtualpath-AP line in the direction of the femoral head we can determine the drillpath that would be realized with the current instrument position. To provide an accurate drillpath prediction it is necessary to correct the image for pincushion and s-curve distortions as will be discussed in section 7.3.3.4.

Axial view target path
Figure 7-4 shows an axial image taken during a DHS procedure. In this image the pelvic bones mask (part) of the femoral head. If the femoral head is visible, it is modelled as a circle (similar to the AP image), named FH-axial circle. The drill path will be modelled as a line, called targetpath-axial line. This targetpath-axial line passes through the centre of the FH-axial circle and the centre of the femoral neck (optionally slightly dorsal). The intersection of the targetpath-axial line with the femoral cortex is the target entry point in the axial view (not visible in Figure 7-4).

Axial view 'virtual' path
The targetpath-axial line is the planned 'optimal' position for the dynamic hip screw (in the axial view). Similar to the AP view 'virtual' path, a virtualpath-axial line is constructed for the drill path prediction in the axial view. If the drill guide is not visible the guide wire has to be inserted over a small distance to determine the extrapolated drillpath.

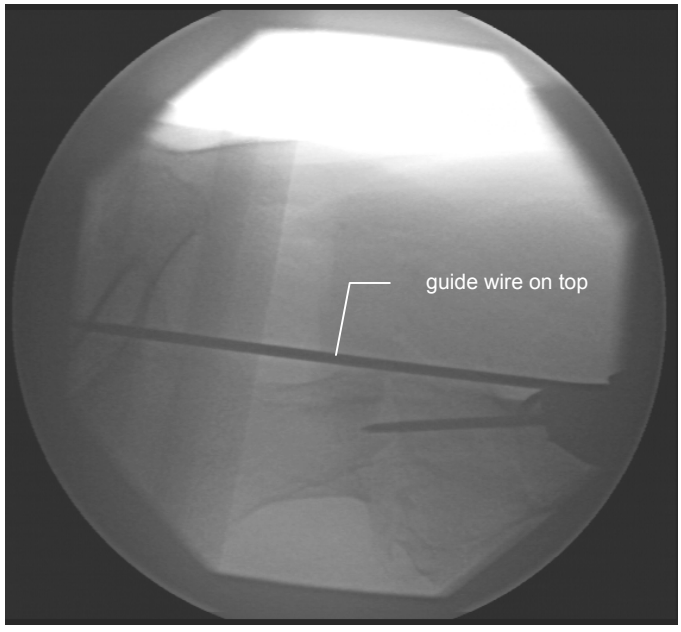


Figure 7-4: Axial X-ray image during DHS surgery with guide wire on top of the hip joint and a partially inserted guide wire.

7.3.3.3 A guide for the CAOS hip system

We have collected the following requirements for the guide:

- it should be used in combination with the standard DHS guiding instrument discussed in section 2.7.2.
- it should make the positioning tasks in the AP and the axial view independent of each other
- it should guide the surgeon to realize the target drill tunnel
- it should be (partly) visible in a fluoroscopic image
- it should not obscure the standard guiding instruments in the fluoroscopic images
- it should be simple and easy to manufacture
- it should be sterilisable

A schematic drawing of the proposed guide is depicted in Figure 7-5. The standard guide will be positioned on top of this guide (and no longer directly on the femoral cortex). The guide was developed in close cooperation with the surgeons and a medical instrument designer. The basis of the guide is a rectangular plate. The top of the plate contains a rectangular opening. Below this opening is a six by four grid of small holes. The horizontal spacing between every other hole (1-3, 2-4, 3-5 and 4-6) matches the distance between the lower two fixation pins of the standard DHS guide. Based on the accuracy requirements, the vertical spacing of the holes is selected to be 2-mm. The standard guide's distance between the cylinder and the lower two fixation pins allows four rows (assuring sufficient stability for the standard guide). If the top row of holes is used the upper rim of the plate supports the upper part of the standard DHS guide. If the standard guide is positioned on the plate (lower fixation pins in a combination of two holes) the hollow cylinder with the 135-degrees bus will be positioned over the rectangular hole. Thus, a guide wire inserted into the hollow cylinder will pass through the rectangular opening.

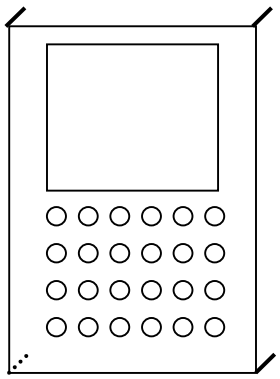


Figure 7-5: The additional DHS guide offering 16 possible positions for the standard DHS guide.

The plate will be made from a radiolucent material so it will not obscure the view of the standard guide. To make the plate itself visible in a radiographic image its rim and the four fixation pins (at the corners of the plate) will be made of metal. As an alternative to the four small pins the plate could also be fixated with two k-wires (this would require two extra holes in the corner of the plate with the diameter of a k-wire).

The plate offers 16 different positions for the standard guide. With the selected spacing of the grid, this guide offers an 8 by 8 mm area of variation. As the plate is flat, all 16 tunnel options will be parallel. To assure a correct direction of the drill tunnels the plate must be placed exactly perpendicular to the targetpath-axial line (in the axial view). The surgeon should assure (visually) that the long axis of the plate is parallel to the femoral axis and that the plate touches the femoral cortex along its entire length. If these conditions are met, the plate offers 16 possible guide wire positions varying in the proximal-distal direction (rows) and the ventral-dorsal direction (columns).

After obtaining a correct axial view an AP view is made. This AP view must be perpendicular to the plate showing the plate as a line having a length equal to the height of the plate (The AP view should be parallel to a plane through the femoral shaft and neck). The plate now enables the surgeon to move the standard drill guide independently in the two x-ray planes. Changing the row will move the guide in the AP view without changing the position in the axial view and vice versa.

Once the plate is attached correctly and the two fluoroscopic images are available the target drillpath models described in section 7.3.3.2 are created. In both views, the plate is then modelled as a line positioned on top of the border of the plate. These lines are called plate-AP line and plate-axial line. Intersecting the targetpath-AP line with the plate-AP line will provide the cranial-caudal position of the entry point. Intersecting the targetpath-axial line with the plate-axial line will provide the ventral-dorsal position of the entry point. The row and column number corresponding to that entry point are then calculated by using the known size of the plate. The surgeon can then position the standard guide in the calculated position and drill the tunnel with a guide wire. In this way, no trial and error procedure with all related extra fluoroscopic images will be necessary to place the guide wire.

If the CAOS system using this new ‘simple’ guide is evaluated and if it proves to be clinically relevant, a completely new guide can be developed, integrating the hollow cylinder from the standard guide (providing the 135 degree angle) with a mechanism that allows independent movement in the AP and in the axial plane.

7.3.3.4 Image distortion correction

As mentioned before the ‘virtual’ path prediction will require image distortion correction. Figure 5-3 showed a fluoroscopic image (AP view) from our DHS image data. The image shows the proximal femur with the guide wire for the DHS screw already in place. A line is positioned centrally on the metal cylinder (for the guide wire). The thin line is extrapolated. It can be seen clearly that the predicted drill path deviates from the actual drill path. Without the distortion correction, prediction errors above 5 mm were observed. Changing the image protocols in such a way that the guide wire is positioned horizontally in the

image will reduce this error, but this will not be an option for a clinical CAOS system. Thus, we have to implement distortion correction.

7.3.4 Proposed CAOS procedure

Once the key concepts of section 7.3.2 are implemented, the resulting CAOS procedure for the DHS procedure could be:

Step1 Axial fluoroscopic image
Acquire the axial fluoroscopic image.

Step 2 Positioning the plate
The plate must be placed exactly perpendicular to the targetpath-axial line (in the axial view). The surgeon should assure (visually) that the long axis of the plate is parallel to the femoral axis and that the plate touches the femoral cortex along its entire length. This is possible because the femur bone is visible trough the incision. If the plate is positioned properly, it can be fixated.

Step 3 AP fluoroscopic image
Acquire the AP fluoroscopic image. Assure the image is parallel to a plane through the femoral shaft and neck.

Step 4 Determine the 135º angle
Once the plate has been set up, the standard guide is positioned on the plate and an AP image is made. Any position will do as long as the hollow cylinder is visible in the resulting image. From this image, the screw-plate angle is copied.

Step 5 Create the target and the plate models
After the FH-AP circle and the femoral axis are defined, the screw-plate angle is used to create the targetpath-AP line. The position of the plate is determined by positioning the plate-AP line. In the axial view the FH-axial circle and the targetpath-axial line are determined. The position of the plate is determined by positioning the plate-axial line.

Step 6 Calculate the entry position
Intersecting the targetpath and the plate lines provides the entry point for the guide wire. The row (AP) and column (axial) number for the determined entry point are calculated and reported to the surgeon.

Step 7 Verify the drillpath
After the surgeon has placed the standard guide it is possible to define the virtualpath-AP and virtualpath-axial lines and verify the entry point position of the guide wire. If the surgeon is satisfied with the predicted drill path, the tunnel can be drilled. After drilling, the position of the guide wire can be checked again. Finally, the guide wire is overdrilled with the triple reamer (see section 2.8) to create the final screw tunnel.

7.4 Project continuation

The goal of this project was to explore the possibilities and limitations of our rapid prototyping toolbox. We demonstrated that our toolbox is suited to develop and implement the user interface for a multi-plane fluoroscopic procedure. The proposed DHS CAOS system can determine the 'optimal' drill path and provide a 'virtual' drill path prediction in both X-ray views. An extra guiding instrument was designed (not implemented) to provide independent navigation in both X-ray images and guide the surgeon to the target entry point. This extra instrument should be used in combination with the standard surgical instruments used in the DHS procedure allowing the surgeon to continue the surgery in the normal way at all times. However, before we decide to continue and start manufacturing a new surgical instrument we will consider the present situation:

- The orthopaedic trainee who assisted in the design of the system moved to another hospital to continue his education.
- Our current budget does not allow developing the guiding instrument (costs were estimated at about fl.10.000).
- Issues concerning the fixation of the new guiding instrument to the patients bone still had to be solved. This fixation is a new surgical step that was not necessary before. Changing the surgical procedure will require permission from the Medical Ethics committee.
- Positioning the new guiding instrument and maintaining that position during the fixation could be as difficult as the drill-positioning task we are trying to simplify.
- Before the system can be tested clinically, the distortion correction module must be implemented in the toolbox. The distortion correction process itself would involve another action during the surgical procedure.
- The DHS procedure is an unscheduled trauma procedure that would make it difficult to obtain sufficient test cases in the time left for this project.
- The newly developed freehand x-ray navigation systems as discussed in section 8.2.1 offer excellent possibilities to implement our CAOS system for hip pinning without adding new surgical instruments.

In combining the information from the two planes and assisting the surgeon in the execution of the surgical plan, we appear to be near or even have crossed the boundary to the functionality of the 3D real time navigation systems. The freehand x-ray navigation systems have already solved the problems surrounding navigation in several x-ray planes without having multi plane fluoroscopes present in the OR continuously. These systems have also implemented the necessary distortion correction. Therefore, we did not continue the development of the extra guiding instrument. However, our efforts are not lost. The system discussed in this chapter can be used to plan the drill path for the guide wire. The navigation assistance can then be implemented with one of the commercially available x-ray freehand navigation systems.

7.5 Discussion

In this chapter we presented the design of a computer-assisted surgery system for the DHS procedure. This system assists the surgeon in placing the guide wire for the DHS screw. A good position of this screw is essential to provide a stable hip. Besides commenting on the position of the instruments, we intended to guide the surgeon to obtain a correct guide wire position. For this guidance an additional surgical guide and extensions to our toolbox would have been necessary.

In section 7.4 we discussed several reasons why the development of our CAOS system for hip pinning was stopped. The goal of the CAOS system for hip pinning was to explore the possibilities and limitations of our toolbox. In combining the information from the two image planes and assisting the surgeon in the execution of the surgical plan, we passed the current limits of our toolbox. Instead of expanding our toolbox to include this functionality, it is best to combine our toolbox with existing freehand navigation system.

The ‘virtual’ fluoroscopy of the freehand navigation system reduces the radiation exposure to the patient and the surgeon. Manufacturers of these systems advertise that the C-arm can be removed after the images are taken. However, if the C-arm is removed the surgeon looses the ability to verify the final position of the guide wires. Besides this, if the C-arm is removed and the tracking is lost there is no way to continue navigation. As with all optical tracking systems the OR set-up must provide a line of sight between the camera system and the tracked instruments. This will be especially difficult if the C-arm needs to be draped for the procedure.

Chapter 8

Concurrent developments and discussion

8.1 Introduction

This thesis project consists of two subsequent parts. The first part started in June 1996 as a graduation project of the two-year design course in Information and Communication Technology of the Stan Ackermans Institute at the Technische Universiteit Eindhoven [Habets, 1997]. In this project, we developed a clinical prototype of a computer-assisted surgery system for anterior cruciate ligament reconstruction.

The second part started in May 1998, as a designer thesis project. In this project we designed and implemented a rapid prototyping toolbox that can be used for developing computer-assisted orthopaedic surgery systems. This toolbox was used to create several computer-assisted measurement systems (chapter 5), the final prototype of the CAOS system for anterior cruciate ligament surgery (chapter 6), and a CAOS system for dynamic hip screw surgery (chapter 7).

At the start of the first project, computer-assisted orthopaedic surgery systems were just emerging. Based on the CAS technology for the neuro-surgery field, these CAOS systems used pre-operative CT imaging and intra-operative navigation with optical trackers. The placement of pedicle screws was a popular orthopaedic surgical task. Pedicle screw insertion requires very accurate 3D navigation, which is ideal to demonstrate the usefulness of these CAOS systems.

This chapter presents the developments in the field of computer-assisted orthopaedic surgery that have taken place parallel to our study. First, the freehand navigation systems are discussed. Next, the CAOS systems that became available during our project are presented. Then, we will discuss the selected design approach and our experiences with the design of computer-assisted orthopaedic surgery systems. We will also discuss the effects other developments had on our project. Finally, we will make some general conclusions and present possible future developments.

8.2 Concurrent developments

8.2.1 X-ray based 3D CAS systems

At the end of the previous millennium researchers started to explore the possibilities of fluoroscopy based computer-assisted navigation for orthopaedic procedures [Hofstetter, 1999]. These systems, which are also called freehand X-ray navigation systems, provide 'real time' navigation assistance during surgery while using X-ray images taken just before surgery (but inside the OR). The images are taken from different directions with a fluoroscope that is tracked with an optical positioning system. The fluoroscopic images are corrected for distortion as explained in chapter 5. The surgical instruments are also tracked and their current position is displayed in the X-ray images. To compensate for patient movement the patient must also be tracked. These systems provide 'virtual real-time multi-plane fluoroscopy' during surgery. The imaging is called virtual because the actual X-ray imager is removed after taking the images and the surgical instruments are just overlay graphics on the location where the actual instruments would have been visible if the imager was still there. These systems appear to be suitable for orthopaedic and trauma surgery for example when placing guide wires or screws. Hofstetter reported a mean positioning error of 0.55 mm with a standard deviation of 0.48 mm [Hofstetter, 1999].

When compared to CT based systems freehand navigation systems:

- do not require CT images (do not need segmentation nor rendering)
- can acquire the images during the procedure itself
- provide intra-operative planning (just before the procedure)
- do not need an extra registration step because the images are made with a C-arm tracked by the same system that tracks the patient and the surgical instruments

The first step with freehand navigation systems is the acquisition of the fluoroscopic images. Then, the images are corrected for distortion (mostly performed automatically). Once the C-arm is removed, the surgeon can start navigating (the instruments need to be calibrated as was described with the CT based systems). Freehand navigation systems are mostly used to support a surgical task (for example placing a guide wire). The planning for these systems often consists of displaying a 'target' (overlay graphics) that is derived from anatomical landmarks. Together with this target, these systems display overlay graphics showing the current location of the tracked instrument.

A freehand navigation system can be easily combined with the computer-assisted surgery tools we developed. Our CAOS systems (for ACL and DHS surgery) could provide the targets as discussed above. The use of these systems would also eliminate the need to have the C-arm available during the entire procedure.

8.2.2 CAOS applications in clinical practice

Computer-assisted Orthopaedic Surgery (CAOS) is a fast growing field. Two annual symposia report on the latest developments in the field. The first is the international CAOS symposium that was first held in 1995 in Bern, Switzerland. The second is its American counterpart CAOS/USA that was first held in 1997 in Pittsburgh, USA. The organizers of

the symposium started publishing their own magazine called CAOS. In this section of the thesis the latest developments and application fields of CAOS systems are discussed.

8.2.2.1 Spinal surgery

Pedicle screw insertion was the first orthopaedic procedure that was considered for computer assistance with a 3D CT-based CAS system. For conventional methods of screw insertion perforation rates between 21.1% and 39.9 % have been reported in clinical series. Laine presented several randomised controlled clinical trials (total of 100 patients) with the Medivision CAS system. They found perforation rates from 4.3 to 14.3 %, which is a significant improvement over the traditional insertion methods [Laine, 2000]. Schwarzenbach also investigated the accuracy of the Medivision system. They showed an overall reduction of malpositioned screws to 2.7% [Schwarzenbach, 1997]. They state that due to the size of the pedicles avoiding perforations altogether will be impossible. However, the most dangerous deviations in medial direction (towards the spinal chord) can be limited to a minimum. It is expected that the benefits for the patients will be significant. Recently fluoroscopy based CAOS systems for pedicle screw insertion were introduced [Nolte, 2000].

8.2.2.2 Hip and pelvic surgery

There are many recent developments in computer-assisted Total Hip Replacement (THR). Most systems focus on the acetabular component placement (the cup). Traditionally the cup is placed with a mechanical alignment guide. These guides do not provide an accurate placement of the cup. DiGioia reports that 82% of all cups they measured were placed outside the 'safety zone' as defined by Lewinnek [Lewinnek, 1978]. DiGioia's group developed the HipNav system that assists the surgeon in performing the THR procedure [DiGioia, 1998c]. Their most recent developments are the incorporation of dynamic models that allow dynamic testing (range of motion and impingement testing) in the planning phase. The first efforts to use medical robots in total hip replacement were undertaken in 1992 with the Robodoc system [Paul, 1992]. Robot systems are especially helpful for reaming the femur to insert the femoral component of the THR implants. The Robodoc system has also been used to ream cemented femurs in revision cases, where it is very important (and extremely difficult) to remove all the old cement. Researchers from the Müller institute in Bern have created a CAOS system that helps the surgeon in planning the procedure, the preparation of the acetabulum and the placement of the cup [Langlotz, 1999]. The Bern system was tested in four different clinics with more than 25 cases.

In pelvic surgery, computer-assisted surgery systems have been developed for acetabular fractures and pelvic (ring) osteotomies. A CAOS system can help with three-dimensional repositioning of the different bone fragments, and help to reduce the risk of injuring the hip joint or the vascular and neural structures while performing pelvic osteotomies. The pelvic osteotomy is a routine procedure to reposition the acetabulum in order to treat a dysplastic hip. The Bern group developed a CAOS system for computer-assisted pelvic osteotomies, that was first tested in a 14-patient trial in 1995 [Langlotz, 1998]. The system proved to be helpful visualizing the orientation of the fracture components. The system also reduces the need for many intraoperative X-rays and it can play a role in the education and training of medical professionals.

8.2.2.3 Knee ligament reconstruction

Concurrent to our development several other research groups were working on 3D computer-assisted surgery systems for anterior cruciate ligament surgery [Dessenne, 1995], [Sati, 1997], [Juliard, 1998]. The Müller institute also developed a CAOS system for anterior cruciate ligament reconstruction using the patellar tendon technique [Sati, 2000] [Sati, 2002].

The latter system uses a preoperative lateral-medial (LM) X-ray image; no intraoperative images are used. With a computer tracked palpation hook several points at the femoral groove, the intercondylar roof, a line from the medial to the lateral condyle at the height of the notch entrance and the deepest point in 90 degrees flexion are identified. With these digitised points a 3D knee model is constructed. By using this knee model the orientation of a LM X-ray relative to this model can be determined. Then, the end of the intercondylar roofline can be located in this image. After 'digitising' the tibial plateau and the anterior tibial axis in a similar way, the landmarks for the graft placement can be displayed. The system supports 3D 'virtual' graft placement and allows dynamic testing of the proposed graft with respect to impingement and elongation. The movements of the knee bones are tracked with LED trackers that are attached to tibia and femur.

Orto Maquet developed a 3D CT based CAOS system in combination with a robotic system. This system, called the CASPAR system, uses the non-involved knee to derive the optimal graft location [Petermann, 2000]. Brainlab experimented with an ACL module called Vector Vision ACL [Brainlab]. Also the HipNav team expanded their system with a knee module KneeNav that can assist the surgeon in placing ACL grafts [Picard, 2001].

8.2.2.4 Total knee reconstruction

In case knee arthritis cannot be treated with an osteotomy procedure, a total knee reconstruction (TKR) can be considered. With a TKR the complete knee joint is replaced by an artificial one. As with osteotomies it is very important to obtain a correct joint alignment. CAOS systems have been developed to assist in the planning and surgical execution of the TKR. Drilling and cutting the bones can be performed manually under computer navigation or with a surgical robot. The CASPAR robot system (Orto Maquet) has a module for TKR. The Casper system supports the 3D planning of the procedure. This planning is then transferred to the surgical robot that accurately mills the necessary planes and holes for the prosthesis. This system offers the surgeon a highly controlled and accurate positioning system for the knee prosthesis. Other system that can perform a total knee arthroplasty are the Orthopilot system by Braun Aesculap [Jenny, 2001], the VectorVision knee system by Brainlab and the TREON system by Medtronic / SofamorDanek.

8.2.2.5 Trauma (C-arm) surgery

Computer-assisted fluoroscopy based systems were discussed in section 8.2.1. As with CT based systems, one of the first applications that were implemented with these systems was the placement of pedicle screws [Nolte, 2000]. Three single fluoroscopic images are made of the vertebra in different projections with a tracked C-arm. Once the images are taken the C-arm can be removed from the operating room. The surgical instruments are tracked with

LED markers and their live position is displayed in each of the three fluoroscopic images. Patient movements are also tracked with LED markers. Medivision implemented this fluoroscopy-based system in the Surgigate trauma module.

Suhm used the Medivision system for intramedullary nail locking in the treatment of long bone fractures [Suhm, 2000]. Intramedullary nailing is necessary for the treatment of fractured hips with intramedullary hip screws (IMHS). With the IMHS a pin is placed inside the femur. The pin is fixated with screws that are inserted from outside the leg. A CAOS system can help in aiming the screw through the screw holes in the pin. Besides nail locking the systems can also be used for shaft navigation (positioning the pin in the femoral bone). Similar trauma systems can be developed to assist in positioning the guide wire used in the dynamic hip screw (DHS) and the cannulated screw procedures (see Chapter 2).

Besides Medivision also Brainlab offers a fluoroscopy based trauma system called Vector-Vision trauma [Brainlab]. The system supports navigation for the treatment of fractures with screws, nails or plates.

8.2.2.6 Osteotomies

A tibial osteotomy is performed for patients with severe knee arthritis. Correction of the joint alignment is realized by placing or removing a wedge in a transversal cut in the tibia. As the corrected mechanical axis angle and tibial plateau angle can still differ significantly from the planned angles while using a traditional tibial osteotomy technique, a 3D CAS system was used to assist the surgeon with the planning and surgical execution of the tibial osteotomy. An initial in-vitro study by Ellis showed a significant reduction of the correction error (planned angle versus realized angle) [Ellis, 1999]. The maximum correction error measured was 1.5 degrees.

8.2.2.7 Other application areas

Besides the application areas described in the previous sections, CAOS systems can be used for other orthopaedic fields like shoulder surgery and ankle surgery. CAOS systems can be developed for all surgical interventions that require some sort of positioning or navigation task. CAOS systems aim at providing increased accuracy of the surgical procedures while making the surgery less invasive. The incorporated data acquisition will also provide the surgeon with an exact record of the surgical actions. This is essential when trying to relate surgical actions to patient outcome. On the downside, CAOS systems may need extra imaging (especially CT imaging) and require severe changes to the clinical practice. The manufacturers of these CAOS systems closely cooperate with medical professionals to assure systems will be clinically relevant.

Many of the 3D computer-assisted surgery systems have been developed in research institutes, universities and clinical centres. To assure the research efforts will finally lead to actual products the developers often seek alliances with the manufacturers of medical equipment. To gain easy access to the orthopaedic practice these alliances are strengthened by including implant manufacturers who have the networks to reach the individual surgeons. An example of such an alliance is the Müller institute (research) that cooperated with Medivision (CAOS manufacturer) and Synthes (implant manufacturer).

8.3 Designing CAOS systems

8.3.1 Design method and toolbox

Rapid prototyping design proved to be very helpful in the clinical setting. Prototyping helped to facilitate the communication between the physician and the developer so that the CAOS system's requirements could be collected quickly. The interactive prototyping process helps the surgeon to understand the technical possibilities of computer-assisted surgery systems. Simultaneously, the prototyping process helps the developer to understand the actual medical problem and the clinical setting in which this problem exists. This mutual understanding is essential to build a clinically relevant system.

To support the prototyping process we developed a toolbox that contains all necessary building blocks (software) to build CAOS systems. As was demonstrated in chapter 5 and chapter 6 the toolbox functionality was sufficient to construct measurement systems and a CAOS system for anterior cruciate ligament surgery. In chapter 7 we presented a CAOS system to assist a DHS procedure. To assure an accurate drill path prediction for this type of surgery our toolbox should be extended with a distortion correction module. In chapter 7 we also explored the possibility to actually guide the surgical intervention (navigation) by introducing and extra guiding instrument. The reasons not to continue to build this instrument were set out in section 7.4. To create CAOS systems that include intra-operative navigation our toolbox could be combined with a freehand fluoroscopy based navigation system (discussed in section 8.2.1).

Our toolbox is intended to create CAOS systems that provide quality control for the surgical procedures as they are performed in current clinical practice. These systems measure the surgical actions intra-operatively on 2D fluoroscopic images and provide feedback to the surgeon. The 3D CAOS systems provide a 3D planning of the surgical procedure and intra-operative real-time guidance to execute this surgical plan. These systems thus change the current clinical practice by introducing a new operating technique. These 3D systems can be combined with simulators that test the dynamic and functional effect of the selected planning. This simulation will require modelling, not only of the bones but also of the muscle and soft tissue of the patient.

The orthopaedic surgeons will have to decide what approach is suitable for each of the procedures that are considered for a CAOS system. This decision will be a trade-off between patient benefit, complexity of the procedure and the procedure costs. For example: does the increased positioning accuracy justify the additional costs and extra radiation doses for the patient caused by the necessary CT images?

8.3.2 Selecting surgical procedures

A well-equipped toolbox proved to be an important factor in creating a CAOS system. However, it is more important to select suitable surgical procedures for a CAOS system approach. Only consider surgical procedures in which there is a clearly defined medical problem that has no satisfactory solution. A CAOS system should improve the quality or the efficiency of a procedure (or both).

Measurement systems decrease the time spent on measuring. They increase the accuracy and assist in the processing and storage of the measurement data. The measurement system thus improves the quality as well as the efficiency of the clinical measurement tasks. The CAOS system for anterior cruciate ligament reconstruction improved the positioning accuracy of the new ACL graft. It also decreased the number of (less optimal) staple fixations. Thus, the ACL system improved the quality of the ACL reconstruction procedure.

8.3.3 CAOS system evaluation

As explained in section 5.6 every system should be analysed for accuracy and sensitivity and validated before it can be used clinically. This technical validation is the responsibility of the developer. After a CAOS system has passed the technical validation the clinical validation can start. In the clinical evaluation the system will have to prove its relevance in clinical practice. Clinical relevance is often tested by comparing the new approach to the golden standard (the generally accepted surgical technique) for that procedure.

During the clinical tests also other relevant aspects like the ergonomics of the CAOS system will be tested. Many surgeons are concerned about introducing computers into the OR. What about the electrical safety? Will it be connected to other medical equipment? Who will operate the system? Does this mean yet another screen to look at? Where will the system be placed? All these questions were addressed for our ACL system (chapter 6).

If a commercial product is based on our CAOS prototype attention must be paid to the ergonomic aspects of the system (the information display and the way the system is operated). For a commercial version, it would be best to combine the computer display with the right screen of the fluoroscope. Not only would this improve the ergonomic situation, it would also solve the problems of connecting the system to the fluoroscope. The system could then be operated by the radiology assistant.

Another possibility would be to introduce two general-purpose displays that can be used to display all images used in the OR. In case of the anterior cruciate ligament reconstruction procedure this would be the arthroscopic images, the fluoroscopic images, the images from the computer system and the preoperative images normally presented on a light box in the corner of the OR. The same displays could be used to present lab results and for communicating with other physicians (remote consulting with the possibility to discuss the procedure while using all available images).

8.4 Closing remarks

Orthopaedic surgery is a fast changing discipline. New operation techniques, minimal invasive surgery, arthroscopy, new imaging techniques and the growing number and increasing complexity of surgical implants put the surgeons capabilities to the test. The accuracy requirements for some of these new surgical techniques exceed the humanly possible. By using the available imaging equipment we can measure and plan procedures on a sub-millimetre accuracy. But what sense does it have to plan things that are impossible to realize?

Similar to the developments in the field of neurosurgery, computer-assisted surgery systems were introduced to tackle this problem. Surgeons should see these CAS systems as tools that help them to do their job not as something intended to replace them. The surgical dexterity and the experience gained in many years of training will never become obsolete and the computer systems will never take over the surgeon's job.

Similar developments have taken place in air traffic industry. Almost all planes have become so complex that no pilot is able to control it directly. Pilots control the computer systems that operate the plane, and they are still in complete control. Similarly, the surgeon will always stay in complete control in the operating theatre.

New technology like computer-assisted surgery systems, tele-surgery systems, robot surgery systems and virtual reality not only provides new tools to help during surgery. The increased accuracy and the exact documentation of the surgical action is also very important for the post-operative evaluation of the surgical intervention, follow-up studies and the development of new surgical techniques. Besides this, these technologies have also introduced the possibility to develop surgical simulators that allow validation of surgical planning and which can assist in training new surgeons.

The CAOS systems described in section 8.2.2 all promise an improved surgical quality and thus a reduction of the possible clinical complications. If they can deliver, the computer-assisted orthopaedic surgery systems are here to stay. Besides the increased quality, clinical CAOS systems should support a diversity of procedures; they should be very flexible and easy to use. Preferably they should decrease the duration of the procedure, reduce the radiation dose to the patient and finally save costs.

The improvements in quality and efficiency of the surgical interventions are not the only factors in the acceptance of these techniques. Another important driving force are the patients themselves. Directly, patients can demand the best and most modern care available independent of whether or not that is relevant for them. Indirectly, because patients tend to start malpractice cases more frequently, the insurance companies can force the surgeons to use a CAOS system to document their actions.

With a prototyping approach and our computer-assisted surgery toolbox we succeeded to create a clinical CAOS system for anterior cruciate ligament surgery. To support our research on cruciate ligament reconstruction several computer-assisted measurement systems were designed. The technical and clinical evaluation of these systems is described in this thesis. A frequent question following this kind of clinical research is: what happens to the system after the research project finished?

As writing this thesis took a little longer than expected I have an opportunity to answer this question. Two years later, the two surgeons involved with the development of the system still use the computer-assisted ACL reconstruction system routinely for every procedure. The system has been used for over 350 patients. Lately, patients from outside the region come to the Catharina Ziekenhuis for a computer-assisted anterior cruciate ligament reconstruction. The group of technical assistants is still operating the system and they can

train new operators themselves. No problems have been encountered for more than a year except for a loose connection in the cable to the C-arm.

In an interview the surgeon explained that the range of acceptable tibial graft positions has slightly increased (42%-56%). For hamstring tendons the femoral graft site has even moved further posterior as back wall blow-out is no complication in this case. The system accuracy for the 'virtual' graft placement prediction, as observed by the surgeon, is about 3 mm. The surgeon repositions the guiding instruments in about 50% of the cases so the feedback is still actively used. Staple fixations have not been necessary for over a year now. In addition, the stress radiography is now used routinely to assess the knee laxity improvement of the procedure (on a side to side basis).

In conclusion we were able to build a clinically successful CAOS system. During our project the field of computer-assisted orthopaedic surgery grew rapidly. All major companies of medical equipment are investing in CAOS technology. In the year to come we will see the CAOS technology introduced in mainstream clinical practice. Considering history, the future will bring more than we can ever expect today.

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Samenvatting

Meten is een steeds terugkerende handeling in de medische wereld. Een chirurg gebruikt metingen bij het stellen van de diagnose, bij de voorbereiding van de chirurgische behandeling en voor het ondersteunen van hun onderzoek. Om de chirurg bij deze taken te helpen kunnen computer ondersteunde meetsystemen ontwikkeld worden.

De laatste jaren is er veel onderzoek gedaan naar computer ondersteunde chirurgie (CAS) systemen. Geënt op de CAS systemen uit de neurochirurgie, werden orthopaedische CAS systemen ontwikkeld voor het plaatsen van wervelschroeven. Zo'n computer ondersteund orthopedisch chirurgie (CAOS) systeem voor wervelschroeven biedt de chirurg de mogelijkheid om te navigeren in een 3D patiënt model dat is verkregen uit CT beelden. Het gebruik van deze systemen vereist enkele veranderingen in de normale klinische werkwijze, zoals het maken van extra CT opnamen en het uitrusten van de chirurgische instrumenten met trackers.

In de huidige klinische werkwijze gebruiken de chirurgen naast hun ervaring vooral 2D (röntgen) beelden. Voor 2D-plus computer ondersteunde chirurgie systemen zouden hierin, behalve het introduceren van een computer, geen andere wijzigingen nodig zijn.

Dit proefontwerp onderzoekt de gebruiksmogelijkheden van 2D-plus computer ondersteunde meetsystemen en computer ondersteunde chirurgie systemen voor de orthopaedische praktijk. Deze systemen zullen de chirurg ondersteunen met zijn (3D) werkzaamheden, gebruik makend van intra operatieve röntgenbeelden en kennis over de chirurgische ingreep. Een intensieve samenwerking met de orthopedisch chirurg is een absolute voorwaarde om dergelijke 2D-plus CAOS systemen te kunnen ontwerpen en realiseren. Dit onderzoek is uitgevoerd in nauwe samenwerking met het Catharina Ziekenhuis in Eindhoven.

Bij het ontwerp van de CAOS systemen is gebruik gemaakt van een rapid prototyping strategie. Om dit proces te ondersteunen is er een software bibliotheek (toolbox) ontwikkeld die medische beelden kan digitaliseren en tonen, gebruikt kan worden om modellen te maken voor het lokaliseren van medische instrumenten en de anatomie, het mogelijk maakt te meten in de gedigitaliseerde beelden, en deze beelden kan voorzien van grafische overlays.

In eerste instantie werd deze toolbox gebruikt voor het bouwen van enkele computer ondersteunde meetprogramma's. Deze programma's bieden de chirurg de mogelijkheid om metingen te doen in gedigitaliseerde beelden.

Vervolgens werd de toolbox gebruikt voor het bouwen van een computer ondersteund chirurgie systeem voor voorste kruisband (VKB) reconstructie. Bij de voorste kruisband

reconstructie gebruikt de chirurg arthroscopie en röntgendoorlichting in één vlak. Dit systeem ondersteunt de chirurg bij de preoperatieve planning en, tijdens de operatie, bij het maken van de boorkanalen waarin de nieuwe VKB geplaatst word.

Om de grenzen van onze 2D-plus aanpak te onderzoeken is een computer ondersteund systeem voor dynamische heupschroeven ontworpen. Bij het plaatsen van een dynamische heupschroef (DHS) wordt röntgendoorlichting in twee richtingen gebruikt. De chirurg gebruikt deze opnames om een schroef in het midden van de femurkop te plaatsen. Met behulp van het computersysteem en een boorgeleider, die zichtbaar is in beide beelden, kan de chirurg de voerdraad voor de schroef nauwkeuriger plaatsen.

De computer ondersteunde meetsystemen besparen veel tijd, en dus ook kosten. Daarnaast worden de metingen nauwkeuriger en door de automatische data opslag kunnen de gegevens direct gebruikt worden voor statistische analyse. De tijdsbesparing die het computer ondersteunde meten en verwerken van de gegevens oplevert, overtreft ruimschoots de tijd die nodig is om deze systemen te ontwikkelen.

Het voorste kruisband systeem is gebruikt voor een groep van ruim 350 patiënten. Niet alleen vergrootte dit systeem de nauwkeurigheid van plaatsing, ook het aantal fixaties met krammen is aanzienlijk gereduceerd. Dit betekent dat er minder vervolgoperaties nodig zijn voor het verwijderen van krammen.

Het prototype voor heupschroeven liet zien dat de 2D-plus aanpak ook gebruikt kan worden voor procedures die gebruik maken van doorlichting uit twee richtingen.

We hebben laten zien dat onze 2D-plus aanpak geschikt is voor het ontwikkelen van computer ondersteunde meetsystemen en computer ondersteunde chirurgie systemen. CAOS systemen die gebruik maken van doorlichting uit één vlak, zoals het VKB systeem, kunnen eenvoudig in de huidige klinische werkwijze ingezet worden. Voor meer complexe systemen, zoals het DHS systeem, zijn extra richtinstrumenten noodzakelijk om de planning te koppelen aan de chirurgische uitvoering. Aangezien de recentelijk ontwikkelde freehand-navigation systemen navigatie bieden, zonder dat extra instrumenten nodig zijn, hebben we het DHS prototype niet verder ontwikkeld.

Dankwoord

Een ontwerp zoals ons voorste-kruisbandreconstructie programma kan onmogelijk gerealiseerd worden zonder intensieve samenwerking tussen technische en medische specialisten. Vanaf deze plaats wil ik dan ook graag alle mensen bedanken die aan mijn onderzoek hebben meegewerkt.

Enkele mensen wil ik ook persoonlijk bedanken. Van de Technische Universiteit Eindhoven allereerst Professor Jan Beneken voor het leggen van de initiële contacten. Vervolgens Hans Blom die al vanaf de ontwerpersopleiding bij dit project betrokken is als begeleider. Bedankt voor je vertrouwen in de goede afloop van dit project. Vervolgens Arie Hasman,die in het promotietraject mijn eerste promotor wilde zijn. Bedankt voor de vele discussies en je geduld. Tot slot Frans Gerritsen die als tweede promotor met zijn jarenlange ervaring in het vakgebied het onderzoek kritisch heeft doorgelicht. Sorry, het was inderdaad nog iets meer dan een paar weken werk. Van het Catharina Ziekenhuis allereerst Burt Klos, de orthopedisch chirurg die voor zijn eigen promotie met het voorste kruisbandonderzoek begonnen was. Vervolgens Roger Devilee, die het prototype ook bij elke kruisbandoperatie gebruikt en getest heeft. Berry Bijsterveld en Jos Verbeek, zonder wie het nooit gelukt was het prototype in de operatiekamer te krijgen.

Verder een algemeen dankwoord voor het Catharina Ziekenhuis, met name de afdelingen orthopaedie, klinische fysica, medische instrumentatie, radiodiagnostiek, fysiotherapie en de OK. Daarnaast voor de afdeling radiotherapie voor het bieden van onderdak.

En natuurlijk wil ik ook nog al de patiënten bedanken die hebben meegedaan. Zonder hun medewerking was dit onderzoek niet mogelijk geweest.

Raymond Habets

Curriculum Vitae

Raymond Habets was born in Houthem-St. Gerlach, The Netherlands, on May 24th 1971. In 1989 he finished secondary school (Gymnasium B, Scholengemeenschap Stella Maris in Meerssen) and started with his study Electrical Engineering at the TU/e.

He obtained his masters degree in March 1995 at the group of Medical Electrical Engineering with his work entitled “Improving the Dynamic Response of Catheter-Manometer Systems; Automatic Correction of Distorted Blood Pressure Measurements”. Subsequently he started a two year design course in Information and Communication Technology at the Stan Ackermans Institute at the TU/e. He obtained his designer’s degree in June 1997 with his work entitled “Rapid Prototyping Design of a Computer-Assisted Surgery System for Anterior Cruciate Ligament Reconstruction”.

After a short period during which he worked for the Catharina Ziekenhuis in Eindhoven he started with his PhD design study in March 1998. In February 2001 he continued his work in the field of medical application development at Philips Medical Systems in the EasyVision Advanced Development department of the Medical Imaging IT group.

Appendix: terms and abbreviations

Position and movement

The terms are divided into terms used for the extremities and terms used for the complete body. As discussed in the examples the terms are often combined to describe movements.

For the extremities the following positions and movements are defined:

Anterior	the part in front / motion to the front
Posterior	the part in the back / motion to the back
Medial	the part closest to the body main axis / motion towards the body main axis
Lateral	the part farthest from the body main axis / motion away from the body main axis
Proximal	the part closest to the body / motion towards the body
Distal	the part farthest from the body / motion away from the body
Superior	the part on top / upwards motion
Inferior	the part on the bottom / downwards motion

For the complete body the following positions and movements are defined:

Ventral	the part in front / motion towards the front
Dorsal	the part in the back / motion towards the back
Cranial	the part closest to the head / motion towards the head
Caudal	the part closest to the feet / motion towards the feet
Sinister	the part to the left / motion towards the left
Dexter	the part to the right / motion towards the right

For the extremities the following rotations are defined:

Flexion	posterior rotation in the sagittal plane (bending the knee)
Extension	anterior rotation in the sagittal plane (stretching the knee)
Abduction	medial rotation in the coronal plane
Adduction	lateral rotation in the coronal plane
External	lateral rotation in the transversal plane
Internal	medial rotation in the transversal plane

Anteversion	directed to the front

Knee

Tibia	lower leg (anterior bone)
Fibula	lower leg (posterior bone)
Femur	upper leg
Patella	knee cap
Condyles	the circular shaped structures at the knee side of the femoral bone
Intra-articular	inside the knee joint
Intercondylar roof	the surface of the intra articular cavity between the condyles
Notch	the intercondylar cavity viewed from an anterior to posterior direction.
Ligament	tendon structure that connects a bone to a muscle or to another bone
Graft	a tissue implant
Allograft	graft that is taken from another person
Autograft	graft that is taken from the patient's own body
Harvesting	the process of extracting a graft from the patient
Grafting	see Harvesting
Semitendinosus	hamstring tendon
Gracilis	hamstring tendon
Meniscus	cartilage between tibia and femur
Tibial spine	the bony 'knob' in the centre of the tibial plateau
Eminentia	see tibial spine
Tuberositas	the bony 'knob' on the front side of the tibia just below the knee at which the patella tendon attaches to the tibia

Bone

Cortical bone	dense outer layer of a bone
Cancellous bone	soft inner part of a bone
Chondral bone	cartilage
Subchondral bone	bone just below the cartilage

Surgical instruments and procedures

Dilator	instrument used to compress the cancellous bone within a tunnel creating a more dense and harder surface
Kirschner wire	guide wire (2-3 mm diameter) with a small drill shape tip that is used to predrill tunnels
K-wire	Kirschner wire
Reaming	drilling large tunnels in bone tissue
Notchplasty	removing bone from the walls of the inter articular cavity in order to increase the space available for the new ligament
Arthroscopic	minimal invasive joint surgery using a pinhole camera system
Kocher clamp	clamp in the form of a pair of scissors that is used to hold or clamp something

Abbreviations

2D	Two-dimensional
3D	Three-dimensional
ACL	Anterior Cruciate Ligament
AP	Anterior-Posterior
API	Application Programmer Interface
CAACLREC	Computer-Assisted Anterior Cruciate Ligament REConstruction
CAS	Computer-Assisted Surgery
CAOS	Computer-Assisted Orthopaedic Surgery
CCD	Charge Coupled Device
CT	Computer Tomography
DICOM	Digital Imaging and Communications in Medicine
DHS	Dynamic Hip Screw
EPR	Electronic Patient Record
EM	Electro Magnetic
GDI	Graphics Device Interface
IMHS	Inter Medullary Hip Screw
K-wire	Kirschner wire
LED	Light Emitting Diode
LM	Lateral-Medial
MIL	Matrox Imaging Library
ML	Medial-Lateral
MRI	Magnetic Resonance Imaging
OR	Operating Room
PA	Posterior-Anterior
PACS	Picture Archiving and Communication System
PCL	Posterior Cruciate Ligament
POP	Posterior Oriented Placement
PTB	Patella Tendon Bone
THR	Total Hip Replacement
TKR	Total Knee Replacement
UI	User Interface
XOR	eXclusive OR