EVALUATION OF THE SURGICAL PROCESS DURING JOINT REPLACEMENTS

Proefschrift

ter verkrijging van de graad van doctor
aan de Technische Universiteit Delft,
op gezag van de Rector Magnificus prof.dr.ir. J.T. Fokkema,
voorzitter van het College voor Promoties,
in het openbaar te verdedigen

op maandag 10 mei 2004 om 15.30 uur

door

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doctorandus in de medische biologie
geboren te Leiderdorp

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Title:	Evaluation of the surgical process during joint replacements. PhD-thesis, Delft University of Technology, Delft, The Netherlands, 2004
Author:	Joanne Minekus
ISBN:	90-

Cover:	Bas Bloemsaat
Print:	Ponsen en Looijen BV.

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Chapter 1:

Introduction

Goal of this thesis

In the last two centuries, technology has become an essential part of life and it has become indispensable for many industries such as aviation, nuclear plants and medicine. But technology is not always user-friendly and it can lead to high work load and unsafe situations. Therefore, in several industries such as aviation, research has been performed on the man-machine interaction to analyse unsafe situations and accidents. Accordingly, machines were adapted and personnel was trained, which resulted in a decrease in the workload for the operators and in an improvement of the safety and efficiency.

The medical world, e.g. surgery, also becomes more dependent on technology, but research on the man-machine interactions in that field is uncommon. Surgeons are assumed to adapt easily to new situations and to make no errors (Kohn, 1999; Schaefer et al. 1995). However, studies concerning human-machine interactions show that surgeons do make errors (Joice et al. 1998), that medical instruments are sometimes wrongly used (Cook et al. 1996; Randell et al. 2002) and that careful analysis of human performance in medical settings could help to reduce errors and to improve safety and efficiency (den Boer et al. 2002b; Sjoerdsma 1998). The results of these human performance studies can be used to improve existing techniques and to develop new technologies for the medical environment.

The goal of this thesis is to give recommendations for improvements of the surgical process during shoulder and elbow joint replacements. Therefore, two common methods used in the man-machine interaction studies, i.e. time-action and error analysis, are adapted to evaluate the surgical process during joint replacements. Shoulder and elbow joint replacements are difficult procedures with a large number of complications and inferior results, compared to knee and hip joint replacements. These results can be explained by the larger range of motion needed for the elbow and shoulder and by the smaller amount of research spent on the shoulder and elbow joints. In this thesis, knee replacements are also evaluated to derive recommendations for the improvement of shoulder and elbow joint replacements.

This project is part of a larger research programme called DIPEX, Development of Improved endoProstheses for the upper EXtrimity, executed by the Delft University of technology which goal is to develop new prostheses and new operation techniques for the upper extremities. In the DIPEX project, 10 researchers are working in 6 different projects: evaluation, image processing, functional assessment, glenoid, prosthesis and instruments. This thesis concerns the results of the evaluation project.

The following paragraphs give background information concerning shoulder, elbow and knee joint replacements, followed by a description of time-action and error analyses.

Shoulder joint replacements

During a total shoulder joint replacement, the humeral head and the glenoid (part of the scapula) are replaced (Figure 1.1). Shoulder joint replacements give pain relief, but they only slightly improve the motion and they yield a complication rate between 10 and 50 percent within 5 years (Magermans et al. 2003). The main complications are glenoid loosening, instability and rotator cuff tears (Magermans et al. 2003; Skirving 1999; Wirth et al. 1996). The glenoid is only a small part of the scapula, which is in rheumatoid patients often affected by the disease. The amount of bone stock in the glenoid may be insufficient for a good fixation of the glenoid component (Boyd et al. 1991). Because most complications depend on the glenoid, several surgeons only replace the humeral head (Boyd et al. 1990; Gartsman et al. 2000; Rahme et al. 2001; Rodosky et al. 1996; Sperling et al. 1998). The instability is caused by the joint anatomy. The shoulder is a ball-and-socket joint with a small socket. Therefore, the joint is unstable and the rotator cuff muscles are needed to stabilize the joint. The rotator cuff muscles are often weakened, especially by patients with rheumatoid arthritis. The weakened muscle can not stabilise the joint sufficiently (Boyd et al. 1991; Waldman et al. 1998; Wirth et al. 1996). To improve shoulder prostheses, the complication change should be reduced by a better fixation of the glenoid, improved stability of the prosthesis and a better functionality.

The shoulder joint replacement is seen as a complicated surgical procedure (Boyd et al. 1991; Neer et al. 1982; Romeo 1995; Skirving 1999). During the standard, deltopectoral approach (Rockwood, Jr. 1990; Romeo 1995), the interval between the deltoideus and the pectoralis muscles is explored and the subscapularis muscle is divided to reach the joint (Figure 1.1). Because the exposure of the glenoid is difficult, it is hard and sometimes even impossible to make a reliable alignment of the glenoid. Therefore, other approaches, like the transacromial approach (Rozing et al. 1998) and the clavicula osteotomy approach (MacKenzie 1993) have been developed (Figure 1.1). These approaches show a larger view of the glenoid, but they are technically more complicated, so only few surgeons use them. Objective evaluation of shoulder joint replacement can give guidelines to improve the procedures.

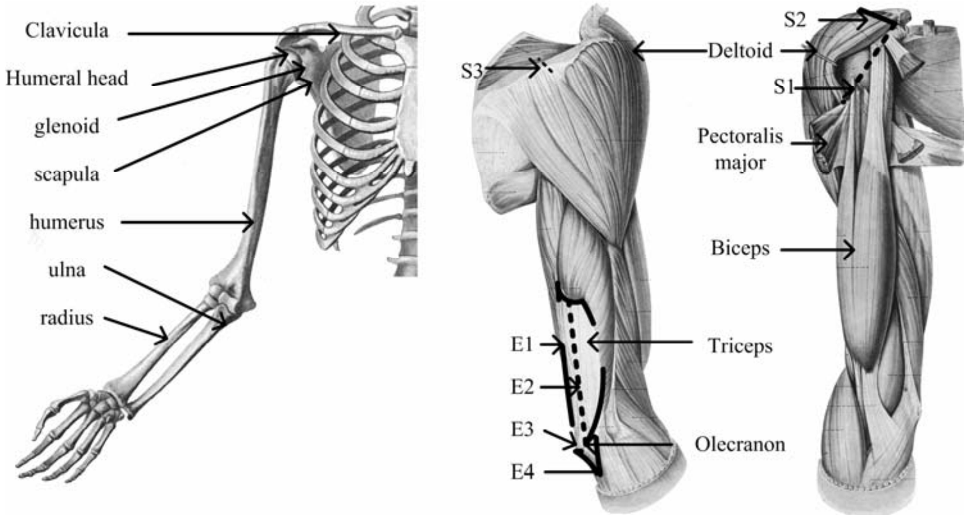


Figure 1.1*: The anatomy of the left arm. The left panel shows the bones of the arm. The middle and right panel show the superficial muscles of the arm. The middle panel shows the anterior or front side and the right panel shows the posterior or back site of the arm. This figure shows the main muscles discussed in this thesis. The figure is adapted from the atlas of Sobota (2003).*

The surgical approaches to the shoulder and the elbow are drawn in the figure.

Shoulder approaches:	*Elbow approaches:*
S1: Deltopectoral.	*E1: Triceps lip.*
S2: Clavicula osteotomy	*E2: Triceps split.*
S3: Transacromial.	*E3: Triceps sparing (cutting the olecranon).*
	E4: Lateral (between anconeus and triceps).

Elbow joint replacements

Similar to shoulder replacements, elbow joint replacement have inferior results compared to hip and knee replacements. Elbow replacements give pain relief, but only a small improvement in motion and have a high complication rate (Ferlic 1999; Gschwend 2002). During an elbow joint replacement, the humeral and ulnar part of the elbow joint are replaced (Figure 1.1). The main complications of an elbow joint replacement are nerve injury, infection, loosening and fracture (Ferlic 1999). The ulnar nerve lays close by the joint and may already be damaged by the disease or may accidentally be hit or retracted too roughly during the surgical procedure. The elbow joint replacements might be improved by increasing the fixation and alignment of the prosthesis.

Several approaches are possible to place an elbow prosthesis (Gallay et al. 2000). Most approaches use a lateral incision but vary in the way the triceps muscle is opened, e.g. midline incision, tendon removal or osteotomy of the olecranon (Figure 1.1). Also, a medial approach can be used: exploring the space between the triceps and anconeus muscles. All approaches have their advantages and disadvantages and no standard method exists. Although the operation procedure for an elbow prosthesis is less complicated than the procedure for a shoulder prosthesis, it is expected that objective evaluation of the elbow joint replacements may also result in guidelines for improvements.

Knee joint replacements

Knee joint replacements are far more common than shoulder or elbow joint replacements and have better results with a 10 year survival rate of 85-100 percent (Callaghan et al. 2000; Fetzer et al. 2002; Keating et al. 2002; Nelissen 1995; Robertsson et al. 2001). During a knee joint replacement, the tibia and femur joint surfaces and sometimes the patella are replaced. The success of a total knee arthroplasty is influenced by the complex interaction between the geometry of an implant design, the active and passive soft-tissue structures that surround the articulation and the correct surgical technique (Elias et al. 1990; Figgie, III et al. 1986; Stulberg et al. 2002; Thoma et al. 2000). It has been estimated that errors in tibial and femoral alignment of more than three degrees occur in at least ten percent of total knee arthroplasties, even when surgeons use mechanical alignment systems of modern design (Stulberg et al. 2002). Even the most elaborated mechanical instrumentation systems rely on visual inspection to confirm the accuracy of the implant alignment and, therefore, depend on the experience of the surgeon (Stulberg et al. 2002). New methods, e.g. computer assisted surgery, have been developed to improve the alignment of knee prostheses.
Computer assisted surgery improves the alignment of the prosthesis, but also increases the operation time with approximately 20 minutes (Jenny et al. 2001; Siebert et al. 2002; Stindel et al. 2002; Stulberg et al. 2002). Nowadays, computer assisted surgery is only used in few research hospitals. To make computer assisted surgery usable for all hospitals, the post-operative results should be tested in a random clinical trial and the system should be easy and fast to use in the operation theatre. In this study, the effect of computer assisted surgery on the per-operative process during knee joint replacements will be addressed.

Time-action analysis in surgery

Time-action analysis can be used to gain insight into the actions and the cognitive processes of people performing specific tasks. Several methods are possible, e.g. inquiries, interviews, observations, modelling, simulated experiments and accident analyses (Kirwan et al. 1992). In cases of aviation and nuclear and chemical plants, time-action analysis studies have improved the work tasks and decreased the risks for accidents. In the medical field, only few time-action analysis studies have been performed, mostly in the field of anaesthesiology (Kohn 1999; Staender et al. 1997), laparoscopy (den Boer et al. 1999; Sjoerdsma 1998) and emergency rooms (Hoyt et al. 1988; Ritchie et al. 1999).

A simple form of time-action analysis is observing the surgical procedure and on-line counting the number of performed actions and measuring the operation time (Dessole et al. 2000). This method can be used for broad comparison of different techniques and has as advantage that little equipment is needed, but this method is limited to the memory capacity and writing velocity of the observer and the events can not be repeated. Therefore, this method is not suitable for more detailed evaluation.

More detailed analysis can be made using video-recordings, because the recordings can be analysed off-line at slow speed. Video-analyses have shown to be a good method for the assessment of team performance in trauma centres. Deficiencies of the procedures could be identified and feedback could be given to the surgeons (Hoyt et al. 1988). Because the surgeons became aware of the inefficiencies, video-analysing has also led to more efficient work (Ritchie et al. 1999; Townsend et al. 1993). In laparoscopic surgery, the operation time could be reduced because the operation protocol was improved (Sjoerdsma 1998). Time-action analysis based on video analysis can also be used to compare different operation techniques and to evaluate new instruments (den Boer et al. 1999; den Boer et al. 2002a; den Boer et al. 2002b).
In this thesis, the time-action analysis method used by den Boer en Sjoerdsma (den Boer et al. 2002b; Sjoerdsma 1998) has been adapted for the evaluation of joint replacements. Because of the differences between joint replacements and laparoscopic surgery, e.g. the size of the incision and the hand eye coordination (Sjoerdsma 1998), several changes were needed in the time-action analysis method e.g. introducing a head mounted camera and a new thesaurus of functions.

Critical step and error analysis

During a surgical procedure, several successive steps are performed. Although, the number and order of the surgical steps differ between surgeons, some steps are critical for the procedure. Dunbar and Gross (1995) defined for knee arthroplasty four criteria needed for a step to be called a critical step: A critical step:

1. must be performed by all surgeons in all procedures;
2. must require significant longer time to complete than other steps;
3. must be revised more often than other steps; and
4. must require a significantly greater percentage of total operation time to revise.

The choice of these criteria may be questioned, especially Criteria 2 and 4, because short steps may be equally important and may cause equal problems if performed incorrectly as long steps. An alternative description of critical steps could be: steps needed to complete the procedure, which are more difficult and have a higher risk of complications than other steps. In this study, critical steps during shoulder and elbow surgery will be determined.

Critical steps might be more vulnerable to errors. Reduction of error probabilities can also improve a surgical procedure. An error is defined as a failure of a planned action to be completed as intended (error of execution) or the use of a wrong plan to achieve an aim (error of planning) (Reason 1990). In industries, such as nuclear power plants and aviation, error analysis is an accepted method to reduce error probabilities and to improve safety. In medicine, error analysis is not often used, because it is not commonly accepted that surgeons make errors. In laparoscopic surgery, human reliability analysis demonstrated a large amount of errors, fortunately none of them lead to a complication (Cuscheri 2000; Joice et al. 1998). Some medical errors can lead to an adverse event. An adverse event is defined as an injury caused by medical management rather than the underlying condition of the patient (Kohn, 1999) and is a major cause of deaths and disabilities in the United States (Kohn, 1999). Normally not a single error, but a combination of errors leads to an adverse event. In this thesis, error paths in joint replacements are identified and guidelines to reduce the error probabilities are given.

Outline of the thesis

The goal of this thesis is to give recommendations for improvements of shoulder and elbow joint replacements. Therefore, the surgical process during shoulder and elbow joint replacements is evaluated using time-action and error analyses. All chapters in this thesis are written as articles and can be read independently, however, some overlap between the chapters exists.

In this thesis, two approaches have been used to get requirements for improving the placement of shoulder prostheses: a written inquiry (Chapter 2) and per-operative evaluation (Chapter 3 and 4). In Chapter 2, the Dutch shoulder surgeons are asked for their experiences with shoulder prosthesis. In Chapter 3, the time-action analysis method has been used to evaluate the placement of one type of shoulder prosthesis and in Chapter 4 the time-action analysis method has been used to evaluate the placement of different prostheses and surgical approaches.

In Chapter 5, the time-action analysis method has been expanded with an error analysis method and both knee and elbow replacements have been evaluated with the combined method. Knee joint replacements are more common procedures than elbow or shoulder joint replacements. Knee and elbow joints are comparable in the fact that both joints are mainly hinge joints and the stability depends on the ligaments. By comparing these procedures recommendations for improvement of knee and elbow prostheses can be obtained.

One of the most important and difficult parts of a joint replacement is the alignment of the prosthesis. In Chapter 6, the literature concerning the alignment instruments is discussed and recommendations for improvements for both shoulder and elbow joint replacements are given. To improve the alignment of a prosthesis, new surgical techniques, e.g. computer assisted surgery have been developed. In Chapter 7, the effect of computer assisted surgery on the per-operative process during knee joint replacements is evaluated.

Finally, in Chapter 8, the used method is discussed and recommendations for further research and improvements of the shoulder and elbow joint replacements are given.

Chapter 2

Shoulder joint replacements in the Netherlands: an inquiry among orthopaedic surgeons.

Based on 'Schouderprothesen: Ervaringen van Nederlandse orthopedische chirurgen'
Joanne PJ Minekus, Piet M Rozing, Jenny Dankelman (Submitted).

Summary

Many different shoulder prostheses exist and several surgical approaches are possible to place a shoulder prosthesis, but a clear overview of the actual use of these different prostheses and approaches is lacking. To get a better insight into the use of shoulder prostheses and into the difficulties and problems that can occur during placement, an inquiry has been performed among Dutch orthopaedic surgeons. Forty-four shoulder surgeons responded, who together placed seventy-four percent of the shoulder prostheses in the Netherlands. Seventy percent of the prostheses were hemi-prostheses and mainly modular, anatomical prostheses were used. The main pathologies were rheumatoid arthritis and acute fracture. Although all surgeons used a deltopectoral or anterior approach, several variations were found, e.g. one third of the surgeons located the nervus axillaris. The alignment of the glenoid component was indicated as the most difficult step in the operation procedure. In conclusion, the questionnaire identified the problems that occurred during shoulder replacements. Furthermore, the questionnaire provided insight in the requirements for a new prosthesis. The glenoid alignment should be simplified and a protocol for pre- and postoperative care should be developed. Finally, the large variation in surgical steps between surgeons indicates that the best approach is unknown and that more research is needed on the surgical approach.

Introduction

Shoulder prostheses give pain relief, but only slightly increase the range of motion and several complications can occur (Magermans et al. 2003; Wirth et al. 1996). The results of the surgical outcome may be affected by several factors, e.g. the used prosthesis, the operation technique and the post-operative care. To improve the results of shoulder prostheses, one or more of these factors should be improved. Many shoulder prostheses have been developed (Mackay et al. 2001; Magermans et al. 2003; Rahme et al. 2001; Rockwood 2000) and several surgical techniques have been proposed (Brodsky et al. 1987; Dumontier et al. 2001; Kadic et al. 1992; Post et al. 1998; Rockwood, Jr. 1990). At this moment, no standard protocol for shoulder joint replacements exists and information on the actual use of shoulder prostheses is lacking. To develop improved shoulder prostheses and surgical techniques, insight into the existing prostheses, operation techniques and the complications is needed.

Several shoulder prostheses have been evaluated in long-term follow-up studies. Magermans et al (2003) have made a literature review concerning the follow up studies of shoulder joint replacements. This literature review showed that the most reviewed prosthesis is the Neer prosthesis and that the main pathologies for a shoulder prosthesis are rheumatoid arthritis or osteoarthritis (Magermans et al. 2003). However, the most commonly used prostheses in 1999 were modular, anatomical prostheses in both Britain (Mackay et al. 2001) and Sweden (Rahme et al. 2001). Because a delay between placement of the prostheses and follow-up studies, the literature is not representative of the actual use of prostheses. Also, only the opinions and experiences of shoulder specialists are presented in literature, which may be different from shoulder surgeons placing less shoulder prostheses.

The goal of our study was to obtain more detailed information about the use of shoulder prostheses in the Netherlands and to obtain the opinion of the surgeons about these prostheses. Therefore, we performed an inquiry among Dutch orthopaedic shoulder surgeons. The questions concerned the patient population, the prostheses used, the advantages and disadvantages of shoulder prostheses, the operation technique and the causes of the poor functional outcome.

Method

All Dutch orthopaedic departments were telephonically contacted to find out which surgeons place shoulder prostheses. Some departments did not tell the name of the shoulder surgeon. Questionnaires were sent to the surgeons personally, if the name was given and otherwise to the orthopaedic department.

The questionnaire consisted of closed and open questions concerning the data in 2001. The questionnaire asked for numbers and percentages of placed shoulder prostheses and patient pathology. The questionnaire also asked for the opinions of the surgeons about e.g. the prosthesis, the indications and possible improvements. Finally, the questionnaire asked for the used surgical steps and the level of difficulty of each step.

The surgeons could respond anonymously. Some surgeons answered only a few questions. Therefore, the number of surgeons who answered a specific question (n_s) varied. Several surgeons used two or three types of prostheses; opinions about these prostheses were evaluated separately, resulting in a number of used prostheses (n_p) larger than the number of surgeons. Both numbers are given in the results section. Correlations between results have been checked using a chi quadrate test; $P<0.05$ was considered as significant.

In the Netherlands, the Prismant organization keeps track of the performed surgical procedures. They provided the total number of shoulder replacements performed in the previous years. These data are used to check the representativeness of our results.

Results

Prismant data.

In the Netherlands, the number of placed shoulder prostheses increased from 439 in 1998 to 511 in 2001. Seventy percent of the shoulder prostheses were hemi-prostheses. Eighty percent of the patients was female and eighty percent of the patients was older than 50 years with a median age between 70 and 74 years. The patient population was equal for all years.

The surgeons.

In total 124 questionnaires were sent to 94 orthopaedic departments in the Netherlands. In thirteen orthopaedic departments, the name of the shoulder surgeon was not given and the questionnaire was sent to the department. Forty-six surgeons responded. These surgeons indicated that they placed 377 shoulder prostheses in 2001, which is 74 percent of all shoulder replacements in the Netherlands. The number of prostheses placed by one surgeon varied between 0 and 30, with a median value of 8 prostheses in one year (Figure

2.1). Thirty-three percent of the surgeons placed less than 5 shoulder prostheses each year. Thirty-five percent of the shoulder prostheses was placed by a surgeon placing over 15 shoulder prostheses each year.
The number of shoulder surgeons in one hospital ranged between 1 and 6; 15 surgeons indicated that they were the only shoulder surgeon in their hospital, 15 surgeons had one shoulder colleague and 15 surgeons had 2 or more shoulder colleagues.

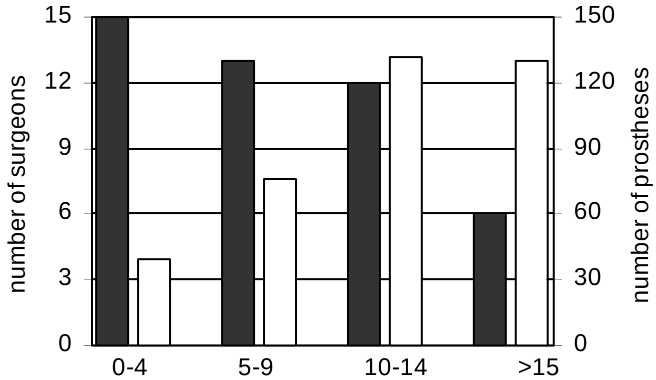


Figure 2.1: *Distribution of placed shoulder prostheses. The x-axis gives the number of prosthesis placed by a surgeon. The black bars show the number of surgeons placing a certain amount of prostheses and the white bars show the total number of prostheses placed by these surgeons.*

The prostheses

Seventeen different shoulder prostheses were used. The most used prostheses were the Aqualis of Tornier and the Biomodular of Biomet (Table 2.1). One surgeon had not yet decided which prosthesis to use and was trying several prostheses. Thirty surgeons used only one type of shoulder prosthesis; 14 surgeons used 2; and one surgeon used 3 different prostheses. The main reasons for using a second prosthesis were:

- a special prosthesis for patients with a rotator cuff arthroplasty (n_s=8);
- a special prosthesis for elder patients (n_s=3);
- a special fracture prosthesis (n_s=3);
- a back up prosthesis (n_s=3).

Table 2.1: *The advantages and disadvantages of shoulder prostheses according to the surgeons. The answers of the open and closed questions are given separately.*

		Total	Aqualis	Biomodular	Neer II	Cofield 2	Eska	Global	Anatomical	Delta	Nottingham	Endo plus	Copeland	Arthrex	Universe	BiglianiFlatow	Stanmore	Bipolar	3M
	Number of surgeons	61	11	11	9	3	2	5	1	7	3	1	2	1	1	2	1	1	1
	Number placed	377	78	58	49	37	30	22	20	20	15	10	7	6	5	4	4	1	1
Satisfied	Satisfied	22	6	4	1	1	1	1	1	1	1	1	2	1		2			
	Mostly satisfied	29	5	5	6	2	1	2		4	1				1		1	1	
	Little bit satisfied	4		1				1		1									1
	Not satisfied	1			1														
Advantages (Closed)	Easy to use	35	6	6	6	2	1	3	1	1	2	1	2			1	1	1	1
	Good literature results	31	6	6	6	2		3	1	2	2					1	1	1	
	Anatomic	30	9	3	3	1	1	3	1	1	1		2	1	1	2	1		
	Stable	28	6	4	3		1	2		4	1		2		1	2	1		1
	Good connection to manufacturer	19	3	5		1		2			2	1	1			2		1	1
	Good price quality relation	14	4	3	4	1					1					1			
	Recommended by known surgeon	15	1	2	1	1	1	2		2	1		1			1	1	1	
	Learned during education	9	1	2	4							1					1		
Advantages (Open)	Modular	15	5	4	2			1			1	1				1			
	Uncemented and cemented fixation	6	1	2	1						1	1							
	Eccentric head	5	2	2												1			
	Few bone removing	3				1	1						1						
	Good trauma reconstruction	3		2				1											
	Revision possible	2				1							1						
	Salvage	2								2									
Disadvantages	Too many possibilities	2	1													1			
	Not anatomical	3		2		1													
	Too few possibilities	4		1	1		1					1							
	Uncertain prognosis	2								2									
	Other prosthesis are better	1																	

Ninety percent of the surgeons were mostly or complete satisfied with their prosthesis (Table 2.1). Only one surgeon was not satisfied with his Neer prosthesis and had just started using a different prosthesis.
According to the surgeons, the main advantages of a prosthesis were that it was easy to place, has good results in the literature and is anatomical, stable and modular (Table 2.1). As main disadvantages of shoulder prostheses, the surgeons indicated the difficult glenoid alignment and the non-anatomical design (Table 2.1).

Forty-one surgeons used special instruments to align and place the prosthesis and they were satisfied with the instruments (Table 2.2). The advantages and disadvantages did not differ between prostheses. The surgeons had different opinions about the same prosthesis, e.g. 5 surgeons found the Aqualis prosthesis easy to use whereas 5 other surgeons found this prosthesis difficult to use.

Table 2.2: *Opinions of the surgeons about the alignment instruments used to place the prostheses. The answers of the open and closed questions are given separately.*

		Total	Aqualis	Biomodular	Neer II	Cofield 2	Eska	Global	Anatomical	Delta	Nottingham	Endo plus	Copeland	Arthrex	Universe	Bigliani Flatow	Stanmore	Bipolar	3M
Satisfied	Satisfied	40	8	5	8		2	4	1	1	2	1	2		1	2	1	1	1
	Partly satisfied	6	2	2		2													
	Not satisfied	3						1		2									
Opinion (Closed)	Easy	27	5	5	2	1	1	2	1		2	1	2	1		2	1	1	
	Needs training	17	7	1	2		1	2		1					1	1			1
	Representative present	11	3	2				2			1		1					1	1
	Puzzle	3	2			1													
Opinion (Open)	Difficult	10	5	1	1			1		1						1			
	Uncertain alignment	8	1	4	1						1							1	
	Difficult to use in the operation field	1				1													
	Coarse instruments	1								1									
	Good instruments	4	1		1			1			1								
	Too easy	2			1														1

For the fixation (n_s=43; n_p=59)

- 19 surgeons used cement;
- 19 surgeons used sometimes cement depending on the patient and the prosthesis;
- 5 surgeons used an uncemented prosthesis.

Glenoid.

Eleven surgeons were always able to expose the glenoid, 15 surgeon usually, 6 surgeons sometimes and 1 surgeon never. The glenoid was replaced

- always by 1 surgeon
- sometimes by 17 surgeons
- never by 25 surgeons.

For the 17 surgeons who sometimes replaced the glenoid, the replacement of the glenoid depended :

- on the patient condition (n_s=17);
- the pathology (n_s=14);
- the condition of the rotator cuff (n_s=8);
- the possibility to reach the glenoid (n_s=6);
- the used prosthesis (n_s=6);
- the age of the patient (n_s=2).

The main reasons for not placing a glenoid component were:

- too many complications with the glenoid component (n_s=7);
- equal literature results for hemi and total shoulders (n_s=6);
- the claim that there were fewer advantages than disadvantages for a total shoulder replacement (n_s=4)

Indications.

The main pathologies according to this study (n_s=43) were rheumatoid arthritis (36%) and acute fracture (27%) and contrasted with the main pathology in the follow up studies, rheumatoid arthritis (Magermans et al. 2003) (Figure 2.2). The inquiry showed a large variation in patient pathology between surgeons, independent of the amount of replacements the surgeon performed.

For all surgeons, pain at rest was the main indication for a shoulder prosthesis. For only half of the surgeons, loss of function was an indication (n_s=41). According to the surgeons, the main contra-indications for a shoulder replacement were

- infection in the joint (n_s=38) ;
- infection in the body (n_s=26);
- high physical demand of the patient (n_s=25);
- a bad rotator cuff (n_s=16).

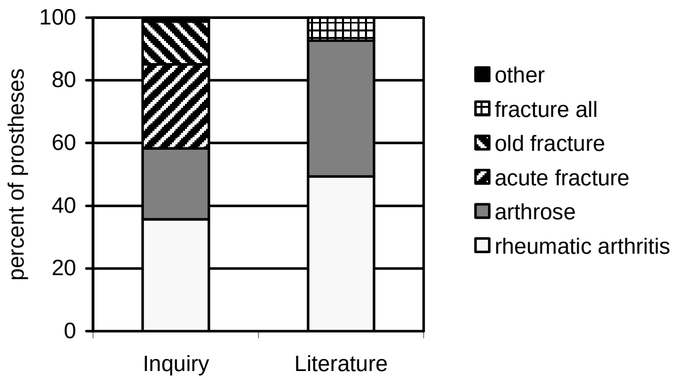


Figure 2 2: *Relative contribution of pathology to the number of shoulder prostheses. The data obtained in this study are compared with the data in the literature (Magermans et al. 2003).*

Pre-operative planning.

Almost all surgeons made a pre-operative X-ray image (98% or n_s=40). Most surgeons used the image for diagnosis (92%) and some observed the images during the procedure (60%). For several prostheses, X-ray images can be used for pre-operative determination of the prosthesis size. This possibility was used by 54% of the surgeons. However, in only 79 percent the size determined in the pre-operative investigation size was actually placed.

The operation procedure.

Although all surgeons used the deltopectoral or anterior approach, several variations could be found. For example, the coraco-humeral ligament was cut by half of the surgeons. An overview of the variations is given in Table 2.3. The surgeons were asked to normalise the level of difficulty of all performed steps on a range from 1-5, with 1 as the easiest step and 5 as the most difficult step. Figure 2.3 shows the relative difficulty of all performed steps. The steps are numbered in the Figure 2.3 for clarity and are described in Table 2.4.

The glenoid phase was seen as the most difficult phase: especially exposing the glenoid; determining the direction of the component; and making the hole for the screw or keel. In the exposure phase, locating the nerves axillaris was judged as a difficult step. In the humerus phase, fixating the sawing directions and determining the position of the head were difficult. The closure phase was indicated as the easiest phase. There was no correlation between the used steps and the experienced difficulty or the possibility to reach the glenoid (chi-test, $p>0.05$).

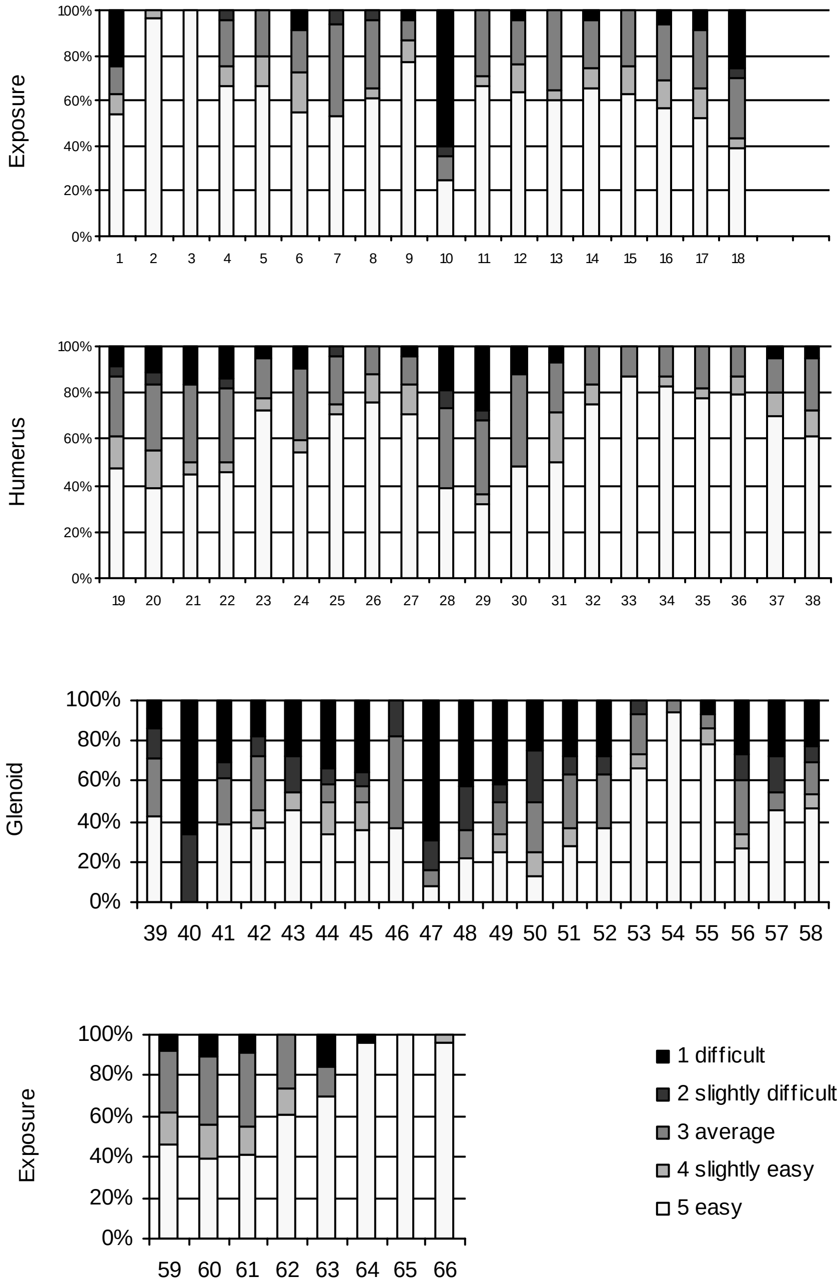
Table 2.3: *Variation in the used surgical steps*

Phase	Always	Never	Sometimes
Exposure			
Detach m. deltoideus off clavicula	9	27	1
Detach m. deltoideus off humerus	3	34	0
Free v. cephalica	25	12	0
Cut off tributaries of v. cephalica	24	11	2
Locate biceps tendon	26	10	0
Locate n. axillaris	11	24	2
Place sutures in m. subscapularis (1)	32	3	0
Place sutures m. subscapularis (2)	25	6	0
Cut coracohumeral ligaments	16	19	0
Cut glenohumeral ligaments	16	12	1
Remove osteophytes	32	1	0
Humerus			
Determine midpoint head	29	8	0
Fixate cutting guide	23	12	0
Refine saw	18	17	1
Place sutures reattachment subscapularis	19	16	0
Remove waste cement	29	4	0
Fixate prosthesis till cement dries	28	5	0
Test movement (1)	35	1	0
Glenoid			
Remove joint capsule	8	14	1
Remove cartilage and labrum	20	3	0
Remove waste cement	22	0	0
Fixate prosthesis till cement dries	21	0	0
Closure			
Repair rotator cuff	26	12	3
Suture ligaments	21	16	0
Suture capsule	31	6	0

Table 2.4: *Surgical steps of a shoulder joint replacement*

Exposure		**Glenoid**	
1	Positioning patient	39	Remove joint capsule
2	Incision skin	40	Expose glenoid
3	Incision subcutus	41	Remove cartilage and labrium
4	Exploration deltopectoral groove	42	Align drill
5	Detach m. deltoideus off clavicula	43	Drill glenoid
6	Detach m. deltoideus off humerus	44	Place the mill
7	Free vena cephalica	45	Mill the glenoid
8	Cut off tributaries of vena cephalica	46	Determine size glenoid component
9	Locate biceps tendon	47	Determine direction glenoid component
10	Locate nervus axillaris	48	Determine place keel or screw
11	Place sutures in subscapularis (1)	49	Make keel or screw hole
12	Detach subscapularis	50	Undercut hole
13	Place sutures subscapularis (2)	51	Test glenoid component
14	Cut joint capsule	52	Test glenoid with the humerus
15	Cut coracohumeral ligaments	53	Rinse glenoid
16	Cut glenohumeral ligaments	54	Make cement
17	Remove humerus from joint	55	Insert cement
18	Remove osteophytes	56	Place glenoid
		57	Remove waste cement
Humerus		58	Fixate prosthesis till cement dries
19	Exposure humeral head		
20	Determine midpoint head	**Closure**	
21	Fixate cutting guide	59	Suture ligaments
22	Saw humeral head	60	Suture capsule
23	Refine saw	61	Suture subscapularis
24	Determine place humeral stem	62	Test movement (2)
25	Place awl in humerus	63	Suture deltoideus to clavicula
26	Rasp humerus	64	Place drain
27	Test stem	65	Suture subcutus
28	Determine head size	66	Suture skin
29	Determine position head		
30	Test head		
31	Place sutures reattachment subscapularis		
32	Clean humerus		
33	Make cement		
34	Insert cement		
35	Place humerus		
36	Remove waste cement		
37	Fixate prosthesis till cement dries		
38	Test movement (1)		

Figure 2.3 *(page 19): Relative difficulty of the surgical steps (ns=34). The difficulty ranges from 1 (easiest step=white) to 5 (hardest step=black). The Y-axis represents the relative number of surgeons giving a rating. On the X-axis, the step numbers are given (Table 2.4). Each diagram represents the steps of a certain phase.*


Exposure
Humerus
Glenoid
Exposure
1 difficult
2 slightly difficult
3 average
4 slightly easy
5 easy

Success.

Fourteen surgeons judged a shoulder replacement successful, if the patient had no or just a little pain afterwards, 30 surgeons judged it successful if the patient had no or just few pain and enough movement for most every day tasks. Eleven surgeons also added that the patient should have no complications.

Table 2.5: *Improvements recommended by the surgeons (ns=37).*

Recommendation	$\mathbf{N_s}$
Prosthesis improvement	14
Better soft tissue reconstruction	11
Earlier procedure	8
Improvement operation technique	7
Post-operative treatment	6
Training surgeon	7
Better indication making	3
Centralisation of procedures	1
Pre-operative treatment	1

Problems and possible solutions.

According to the surgeons, the functional less results of shoulder replacements compared to hip or knee replacements is caused by the rotator cuff and weak tissues (n_s=34) and by the difference in biomechanics between the shoulder and the knee or hip (n_s=16). The surgeons thought that the results can be improved by prosthesis improvement, better soft tissue reconstruction or by replacing the joint in an earlier stage (Table 2.5).

Discussion

To gain insight into the use of shoulder prostheses in the Netherlands and to obtain the opinions of shoulder surgeons about shoulder prostheses, an inquiry was performed among Dutch shoulder surgeons. One third of the Dutch shoulder surgeons responded, they placed 74 percent of the shoulder prostheses in the Netherlands and, therefore, the results are useful as input for further research on shoulder prostheses. The results of this inquiry show that shoulder prostheses have several disadvantages and from the results guidelines for improvements can be obtained.

Restriction of inquiries

Inquiries have several restrictions which should be kept in mind by the interpretation of the results. First, the numbers presented in this study were often based on estimations given by the surgeon. It is expected that some surgeons may have overestimated whereas others may have underestimated their numbers. The overall results are assumed to be representative. Secondly, the given opinions may not always be evidence based. For example, good literature results is considered to be an advantage by several surgeons, but the post-operative results showed no difference between prostheses (Magermans et al. 2003) and for the Bigliani-Flatow and Nottingham prostheses, we could not find any literature evidence although this argument was given. Finally, the surgeons were not randomly selected, but responded voluntarily. Probably, surgeons with an interest for shoulder surgery have responded. In spite of these limitations, the data of this study can be used to give recommendations for further research.

The operation process

Although all surgeons claimed to use the same approach, a large variation of the used steps can be seen. The used steps did not correlate with the experienced difficulties, the possibility to reach the glenoid or the number of prostheses placed by the surgeon. The reason why a surgeon performed a step has not been asked. The variation in used steps can have several causes. Some steps were performed for a better exposure of the joint, but may increase the risk of complications, e.g. detaching the deltoid from the clavicula. Other steps depended on the used prosthesis e.g. determining the midpoint of the humeral head. Some steps were performed to decrease the complication risk, but may be time-consuming e.g. cutting off the tributaries of the Vena Cephalica. Finally, some steps were performed by some surgeons to simplify a later part of the procedure, e.g. placing sutures in the subscapularis. The large variation in surgical steps show that the best surgical approach is not known.

Literature bias

The data about the used prostheses, the pathology of patients and the contribution of hemi prostheses were comparable to studies in the UK and Sweden (Mackay et al. 2001; Rahme et al. 2001), but were in contrast to the follow-up studies (Magermans et al. 2003) indicating a literature bias. In the Netherlands, the UK and Sweden, the most widely used prostheses are anatomical, modular prostheses, while the most reviewed prosthesis is the Neer prosthesis (Magermans et al. 2003), probably because it is the oldest shoulder prosthesis. In the follow-up studies, many more total shoulder replacements are evaluated. This can partly be due to the smaller fraction of fracture patients in the follow-up studies by whom no glenoid component is placed. But it probably also depends on the surgeons publishing their data. Those surgeons may be more experienced and have fewer problems with the glenoid alignment. Furthermore, these surgeons are often connected to a special prosthesis, which they helped developing. Therefore, the patient data of the follow-up studies is not representative for the whole patient population.

Recommendations

New shoulder prosthesis: The surgeons prefer an anatomical, modular and stable shoulder prosthesis, which is easy to use and has a correct alignment. The stability and the function of the shoulder mainly depend on the rotator cuff muscles (Williams et al. 1996). If these muscles do not function, an anatomical prosthesis will be unstable. Therefore, we recommend a new shoulder prosthesis, which is more constrained to keep the head in the socket and which can compensate for the rotator cuff muscles.
New guiding instruments: The surgeons experienced the glenoid alignment as the most difficult part of the procedure. The glenoid component has also the highest complication risk (Wirth et al. 1996). Therefore, attention should be given to the guides used for the glenoid alignment. The glenoid is rather small and is located deep in the wound. A guide or a mill placed on the glenoid, can block the sight of the glenoid. For knee prosthesis, a good alignment improves the post-operative results (Elias et al. 1990). We expect that the results of a glenoid replacement, also depends on the alignment of the prosthesis, but that the existing guiding instruments are not accurate enough. Computer navigation might improve the alignment, but is expensive, time-consuming and the technical possibility is unknown. The use of a patient specific fixture might be a cheaper and less time-consuming solution (Valstar et al. 2002). Still, new developments are needed to improve the alignment of the glenoid.

Muscle status: According to some surgeons, the functional outcome might be improved by operating sooner and by improving the pre and post-operative care. The determination of the best time to perform a shoulder replacement is difficult. An advantage of performing the procedure earlier is that the rotator cuff muscle is in a better shape and, therefore, the result of a shoulder joint replacement is better (Williams et al. 1996; Moeckel et al. 1992; Norris et al. 1995). If a muscle is not used for a longer period of time, the muscle function decreases. Also, pre-operative training may keep the muscle condition better. A second advantage of performing the procedure earlier is that the amount of bone stock for fixation will be larger and of a better quality. A disadvantage of an earlier procedure is that the prosthesis has only a survival expectance of ten years, after which the prosthesis has a large probability of loosening which causes pain and lost motion to the patient. The determination of the optimal operation date depends on a large amount of factors. A shoulder model including the muscle activity and bone quality and adaptable to the patient specific needs, e.g. pathology, age, physical demands, might be useful to determine the optimal operation time.

Shoulder register: The operation technique varied between surgeons. Probably the pre- and post-operative treatment also varies between surgeons, but the inquiry has not asked for these data. An objective evaluation of the treatment protocol might give insight into the different treatment methods. In the Netherlands, none of the hospitals has enough shoulder patients to make a good evaluation possible. In Sweden, all data of hip and knee replacements are kept and evaluated in one database and this database has given important insights into the functioning of these prostheses (Robertsson et al. 2001). In Sweden, also a shoulder database exists, but this database is insufficient to evaluate the effect of the used approach and treatment protocol on the outcome of the surgical process. To evaluate the treatment protocols and prostheses types, a national or even an European database should be founded, which contains general parameters such as used prosthesis and indication, and also contains treatment protocols and objectively measured pre- and postoperative scores.

Centralisation of procedures: In almost all Dutch hospitals, shoulder prostheses are placed, resulting in a low number of shoulder prostheses placed in each hospital. The results of knee and hip replacements depend on the number of prostheses placed in a hospital. Hospitals in which over 15 knee or hip prostheses are placed per year have better results than hospitals in which less prostheses were placed, because both the surgeon and the operation team are more experienced (Kreder et al. 1997). Probably the same holds for shoulder replacements. But only thirty percent of the shoulder prostheses in the Netherlands are placed in hospitals where 15 or more shoulder prostheses are placed yearly (Figure 2.1). Because of the small number of shoulder replacements in the Netherlands, about 500 each year, it might be better to concentrate the procedures in 20 to 30 hospitals, with at least 15 shoulder replacements a year.

Conclusion

An inquiry about shoulder prostheses was performed among Dutch shoulder surgeons. The mostly used shoulder prostheses were modular, anatomical prostheses. In seventy percent of the patients only the humeral head was replaced and the main pathology of the patients was rheumatoid arthritis or acute fracture. Most surgeons used a deltopectoral or anterior approach, but several variations were found, e.g. osteotomy of the clavicula and cutting the coraco-acromial ligament. The alignment of the glenoid was seen as the most difficult part of the procedure. The functional outcome was ascribed to problems with the rotator cuff and weak tissues. The results of this study indicate that additional research is needed to develop new prostheses, glenoid guiding instruments and a shoulder model. Besides, a Dutch database of shoulder prosthesis can give valuable information about factors influencing the results. Finally, a discussion should be started whether the procedures should be concentrated in less hospitals, so the surgeons and operation team of these hospitals will retain enough experience.

Acknowledgements

We would like to thank all surgeons who filled in the inquiry for their time and co-operation.

Chapter 3

Evaluation of humeral head replacements using time-action analysis

Based on: Evaluation of humeral head replacements using time-action analysis.
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Journal of Shoulder and Elbow Surgery 2003. 12: 152-157

Summary

New surgical technologies are often introduced without objective evaluation of their efficiency. Commonly, their results are only related to surgical outcome and risk of complications. In this study, time-action analysis was applied to evaluate the per-operative process and to measure the surgical performance during eight humeral head replacements. An overview of the operation theatre and a detail view of the operative field were recorded on video simultaneously. Duration and number of actions, grouped to functions, limitations and repeated actions were determined. The duration and the number of performed actions varied between procedures. The efficiency of the procedure, defined as the percentage of goal-oriented functions, was about 55 percent. Repeated actions were frequently observed during the alignment and insertion phase. We conclude that time-action analysis can be used to objectively evaluate surgical performance. Limitations of the surgical process that can be improved could be identified. These findings enable the evaluation of new operation techniques, protocols and instruments.

Introduction

Although humeral head replacements provide pain relief and increase the range of motion (Boyd et al. 1990; Field et al. 1997; Hattrup et al. 2000; Sperling et al. 1998; Stoffel et al. 2000; Wakitani et al. 1999), their number of complications is still of a great concern (Alund et al. 2000; Brown et al. 2000). The outcome of a humeral head replacement is influenced by several factors, such as the type of disease, the condition of the rotator cuff, the prosthesis used, the instruments used, the surgical technique and the experience of the surgeon (Boyd et al. 1990; Brown et al. 2000; Sperling et al. 1998). For an enhanced functional outcome, one or more of these factors should be improved. For improvement of the per-operative technique, insight in the existing operation technique is needed. This insight can be obtained by evaluating the operation process using time-action analysis.

Time-action analysis is a quantitative method, which measures the number and duration of the actions needed for an operator to achieve his goal, and the efficiency of these actions (Kirwan et al. 1992). In contrast to industry and aerospace, only few time-actions studies have been performed in the medical field, the majority of them in laparoscopic surgery (Cuscheri 2000; den Boer et al. 1999; Joice et al. 1998; Sjoerdsma 1998). For example, in diagnostic laparoscopic surgery, time-action analysis showed that 52 percent of the actions were efficient (den Boer et al. 1999). After discussing the outcome of time-action analysis with the surgeon, the operation technique of laparoscopic colon resections could be improved and the operation time could be significantly decreased (Sjoerdsma 1998). Joice et al (1998) used a similar method and found that in laparoscopic cholecystectomies a large number of errors occurred, fortunately none of these errors resulted in a complication. These studies show that time-action analysis can be used to gain insight in the operation process. Although the results of these studies do not predict the surgical outcome, the insight obtained can be used to improve the operation procedure and instrumentation.

The goal of our study is to investigate whether time-action analysis is a useful technique to evaluate orthopaedic surgical procedures. In this study, eight humeral head replacements will be evaluated by measuring the duration and number of all performed actions. These parameters are grouped with respect to function, and the percentage of goal-oriented functions will be determined. Limitations of the procedure will be described and quantified and recommendations will be given to improve the operation technique. Finally, the limitations and advantages of time-action analysis will be discussed.

Materials and methods

Surgical procedure:

Eight humeral head replacements were evaluated; they were performed by one experienced surgeon (PMR) in six patients with rheumatic arthritis and in two patients with osteoarthritis. The joint was reached by a deltopectoral approach. The tributaries of the cephalic vein were ligated; the vein itself was left intact. The subscapularis tendon was split and reattached afterwards. When needed, ruptures of the rotator cuff were repaired. During the procedure, two resident surgeons and one experienced scrub technician assisted the surgeon. An uncemented Multiplex shoulder prosthesis and Multiplex alignment instruments (ESKA implants, Lübeck, Germany) were used in all cases. The alignment instruments consisted of an instrument to determine the centre of the humeral head; an instrument to determine the sawing direction; an instrument to drill the hole in the humerus; and several test prostheses.

Table 3.1 *The three phases of the humeral head replacements and their subsequent steps*

	Phase		Steps
1	Exposure	1.1	Open the skin and connective tissue
		1.2	Explore the deltopectoral groove
		1.3	Cut the subscapularis and place the sutures for reattachment the subscapularis
		1.4	Release the ligaments and subscapularis of humeral head and dislocate the humeral head
2	Alignment and insertion of the prosthesis	2.1	Mark the geometric centre of the humeral head
		2.2	Cutting off the humeral head
		2.3	Open the humeral shaft
		2.4	Place the trial prosthesis for the humeral stem
		2.5	Place the sutures for reattachment in the bone
		2.6	Place the humeral stem prosthesis
		2.7	Place the trial prosthesis for the humeral head
		2.8	Place the humeral head prosthesis
		2.9	Test the range of motion
3	Closure	3.1	Suture the subscapularis
		3.2	Insert the drain
		3.3	Suture the deltopectoral groove
		3.4	Suture the connective tissue
		3.5	Suture the skin

Time-action analysis:

Video recordings of the procedure were made using two cameras, one giving an overview of the total operation field and one placed on the head of the surgeon giving a detailed view of the hands of the surgeon. The two images and the sound were recorded simultaneously using a videomixer. The recordings did not interfere with the surgical process and were analysed off-line. The medical ethical committee of the Leiden University Medical Center approved the research.

Each procedure was divided into an exposure, a prosthesis and a closure phase and each phase consisted of subsequent steps (Table 3.1). The time-action analysis started by the first knife incision in the exposure phase and stopped when the last suture was placed in the closure phase. During each step, several actions were performed, e.g.: cutting with a knife or scissors, coagulating, moving the arm and waiting. All performed actions and their duration were scored using a thesaurus of 68 strictly defined actions. These actions were grouped by their function in order to get a better overview (Table 3.2). Goal-oriented functions are defined as those functions that contribute directly to the advancement of the operation. The percentage of goal oriented functions is a measure of the efficiency of the operation (Sjoerdsma et al. 2000).

Table 3.2: *Taxonomy of orthopaedic surgical functions*

	Function	Definition
Goal-oriented	Preparing	Dissection using e.g. a knife, or a saw.
	Alignment and inserting of the prosthesis	Determination of the position of the prosthesis using alignment instruments and placement of the prosthesis.
	Suturing	Placement of sutures
Additional	Stop bleeding	Checking for bleedings and stopping them using e.g. coagulating, or swamping
	Observing	Watching the wound, palpating or moving the arm
	Exposing	Placement of hooks to expose the humeral head.
	Waiting	Actions that do not contribute to the operation like teaching, waiting for instruments or talking.
	Miscellaneous	Actions that could not be identified or classified within the other functions.

In a perfect procedure, all steps would be performed without any need for corrections or repetitions and without unintentional damage to the surrounding tissue. However, repetitions and corrections are needed in most procedures due to the complexity of the surgical approach, the limitations of the instruments, or the experience of the surgeon. Five classes of limitations can be distinguished: repeated actions, instrument failure, unintentional tissue damage (bleeding or fracture), incorrect timing of a step, and omitted action.

Results:

In none of the eight humeral head replacements, a per-operative complication occurred. The median duration of a humeral head replacement was 105 minutes (range 83 to 136 minutes) and the median number of performed actions was 437 (range 352 to 593).

Number and duration of actions

The exposure phase had a relatively large number of actions and a large variation, because of short actions like swabbing and coagulating and the different number of actions needed to obtain a good exposure (Figure 3.1). The outlier was caused by an operation in which a large number of small bleedings occurred.

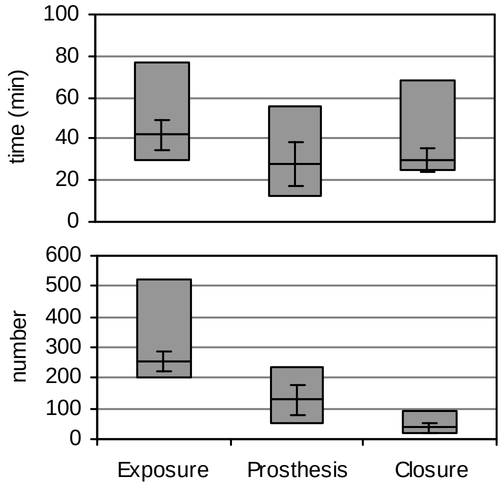

Figure 3.1: *Duration and number of actions per phase. The upper panel shows the duration of the phases and the lower panel the number of actions (lower panel). The middle line represents the median value and the vertical lines the standard deviation. All data lay within the boxes (n=8).*

The prosthesis alignment and insertion phase had the largest variation, both in the duration and the number of actions. This variation was caused by the variable number of necessary refinements, the varying bone quality among patients and the different number of actions needed to obtain a good exposure.

The closure phase had the smallest number of actions, because the most time-consuming action, suturing, was hardly interrupted.

Functions

In the exposure phase, both preparing and stopping bleedings were time consuming functions, 51% of the functions was goal-oriented (Figure 3.2).

In the prosthesis insertion and alignment phase, both the preparing, and the prosthesis aligning and inserting were time consuming; 56% was goal-oriented.

In the closure phase, suturing was the main function and 85 % was goal-oriented.

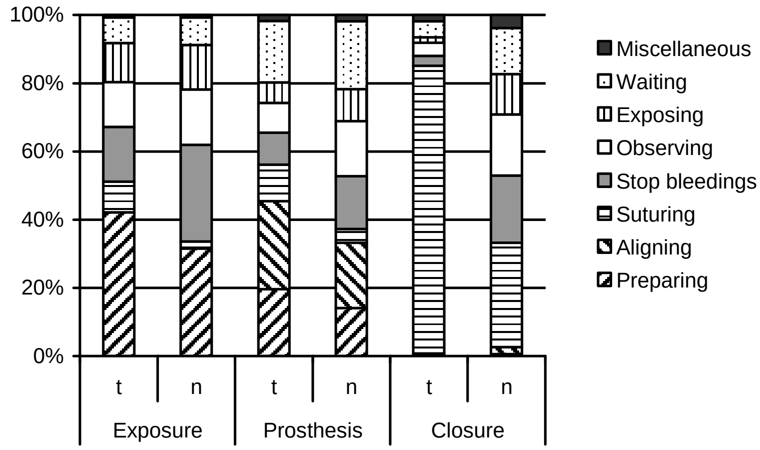

Figure 3.2: *Average percentage of duration (t) and number (n) of the functions per phase. The striped boxes represent the goal-oriented functions.*

A large part (11%) of the operation time was spent on waiting (Figures 3.2). In the exposure phase, the waiting time varied between 1.3 and 6.7 minutes, in the prosthesis phase between 3.7 and 7.2 minutes and in the closure phase between 0.0 and 3.5 minutes (Table 3.3). The main cause for waiting was changing of instruments (39%).

The prosthesis alignment and insertion phase

The prosthesis alignment and insertion phase consists of several steps. The most time-consuming steps were sawing off the humeral head and testing the stem. The shortest step was testing the range of motion (Table 3.1, Figure 3.3). The placement of the sutures for reattachments was the most goal-oriented step. During placement of the stem and placement of the head, a rather large waiting time was observed, caused by the fact that the size of the prosthesis had to be determined during the procedure and the surgeon was waiting, while the correct prosthesis was unpacked.

Table 3.3: *Causes and duration of waiting (seconds).*

Cause \ Phase	Exposure	Prosthesis	Closure	Total
Inevitable	3.2	10.6	5.2	19.1
Teaching	54.0	55.3	7.7	117.0
Unnecessary	47.5	115.5	28.8	191.8
Unknown	1.8	6.0	0.0	7.8
Prosthesis	0.0	71.7	0.0	71.7
Instrument change	90.1	143.0	24.6	257.8
Total	196.6	402.1	66.3	665.2

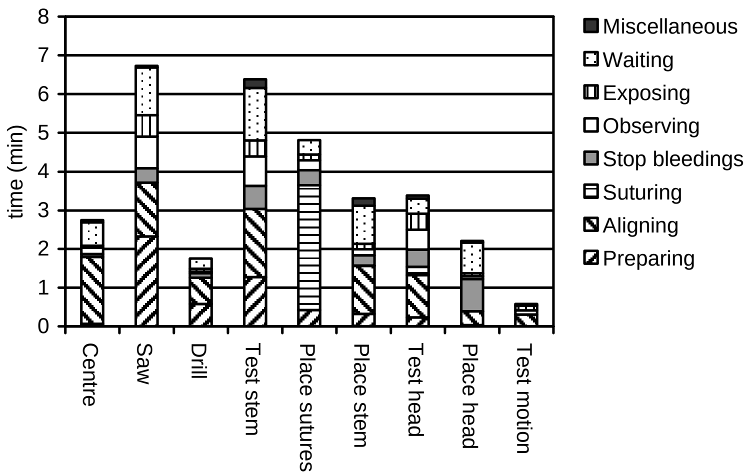

Figure 3.3: *Average duration of functions for the steps during the alignment phase. The striped boxes represent the goal-oriented functions.*

Table 3.4: *Limitations occurring in 8 procedures.*

Phase	Nr	Class	Time (s)	Description
1.1	1	damaging	25	Cut through vein
1.2	1	timing	13	Assistant released a clamp too early
	1	damaging	210	Insufficient coagulation
	1	timing	20	Delayed suturing of vein
1.3	3	timing	0	Delayed suturing (in alignment phase)
1.4	1	repeating	3	Replacing of a clamp
2.1	5	repeating	62	Second determination of geometric centre
2.2	6	repeating	62	Sawing again with an alignment instrument
	6	repeating	56	Sawing again without an alignment instrument
	1	instrument	22	Sawing blade was loose
2.3	1	instrument	48	Wrong drill
	2	repeating	48	Wrong placement drilling alignment device.
	2	repeating	64	Drilling again without an alignment instrument
2.4	4	repeating	170	Nibbling instead of sawing again
	4	repeating	50	Using a chisel
	4	repeating	121	Sawing again
2.5	1	timing	115	Sutures were placed after waiting for the prosthesis instead of during this waiting time
2.6	2	repeating	42	Sawing again
2.7	15	repeating	48	Wrong size test prosthesis
3.1	1	instrument	56	Broken suture
3.1	1	damaging	152	Blood vessel hit
3.4	1	instrument	5	Needle drops

Phase: Tthe phase in which the limitation occurred; numbers are defined in Table 3.1.

Nr.: Number of times a limitation occurred during a step

Class:Ttype of limitation

Time: Average time in seconds needed for restoration

Description: Description of the limitations

Limitations

In the exposure phase, three limitations resulted in a bleeding with a restoration time varying between 0.2 and 3.5 minutes (Table 3.4). In the prosthesis phase, fifty limitations were repeated actions. The duration of the repeated actions varied between 0.2 and 6 minutes. The total time used for repeated actions varied between 2.1 and 11 minutes (14-35% of the duration of the prosthesis phase). In the closure phase, only three limitations were observed with a restoration time varying between 0.1 and 2.5 minutes.

Discussion

A relatively complicated orthopaedic surgical procedure was evaluated using time-action analysis. The analysis gave a detailed insight into the per-operative process and the results prove that this method can be used successfully to measure the efficiency of an operation procedure and to identify the limitations of the surgical process that need further investigation.

Limitations of this study

Surgical procedures have mostly been analysed with respect to functional outcome and/or post-operative complications. These analyses, however, provide hardly any insight into the problems of the actual complex per-operative procedures. Our evaluation method gives this insight, but it gives only partial information about functional outcome and the risk of complications. It may well be that a more efficient surgical procedure jeopardises postoperative course. For example, the exposure phase may have a shorter duration when a different approach is used, e.g. ligating the whole cephalic vein instead of ligating the tributaries. Ligating this vein, however, could decrease the functional outcome for the patient by decreasing the blood drainage of the lower arm, which might result in a light oedema of the arm. Therefore, a more time consuming approach may have a better functional outcome. We emphasise that time-action analysis measures neither the quality of the surgery nor the quality of the surgeon. A longer operation time can be the result of the inexperience of the surgeon, who needs more time to think and to observe. But it may also happen with an experienced surgeon, who knows that more time spent on tissue balancing or aligning the prosthesis will improve the functional result for the patients. Therefore, this evaluation method should be used with care, especially when different surgeons or different surgical techniques are compared.

Time-action analysis can be used to identify problems and limitations of the operation procedure. A limitation did not imply a complication: in none of these eight humeral head replacements a per-operative complication occurred. Some of the limited actions can be made on purpose, when for example, the surgeon wants to replace the centre of the humeral head, the original centre is identified and used to determine the new centre for the prosthesis. During the time-action analysis, this is seen as a repeated action. Some of the limitations can be caused by the condition of the patient. For example, a pin placed to mark the centre of the humeral head may be displaced, because of the variable bone density. Therefore, the surgeon has to replace the pin. Finally, a limitation may be caused by the operation procedure, inadequate alignment instruments or the surgeon. Time-action analysis can not determine the real causes of these limitations.

The outcome of time-action analysis depends on the thesaurus of actions used. In this study, we used 68 actions to described the entire procedure. Suturing, for example, was defined as one action. This action could have been divided in smaller tasks like putting the thread in the needle, placing the suture, making a knot, cutting the thread; which would have resulted in more, shorter actions, but also in more time needed for the evaluation. In further research directed to certain limitations or phases of a procedure, it may be useful to define the actions related to these limitations or phases in more detail.

The main limitation of the time-action analysis method is that the reason of the surgeon for a certain approach or action can not be determined. Therefore, for a good interpretation of the results, interaction with the surgeon is very important. The surgeon is aware of certain limitations and inefficiencies, which he can explain. He may also be not aware of other limitations or inefficiencies and after recognising them, he can try to reduce them. Also, for the development of new instruments, it is important to know why a surgeon uses certain actions and approaches. Time-action analysis gives insight into surgical procedures, but for a good interpretation, discussion of the outcome with the surgeon is needed.

Recommendations for humeral head replacements

Per-operative evaluation of humeral head replacements provided a detailed insight into the limitations delaying the per-operative process. Most of the 64 limitations were repeated actions during the prosthesis alignment and insertion phase. An incorrect alignment of the prosthesis may lead to decreased functional outcome (de Leest et al. 1996). New alignment instruments, especially computer-guided instruments (Habermeyer et al. 1999), may reduce the number of repeated actions and may improve the alignment of the prosthesis.

Time-action analysis can be used for comparison of different prostheses with their alignment systems. In this study, the Multiplex prosthesis and alignment tools were used. The Multiplex prosthesis was selected, because it has an instrument to determine the centre of the humeral head, whereas most other prostheses do not have such a tool. Time-action analysis does not show whether the prosthesis is placed correctly. However, assuming that finally the prosthesis is placed correctly, it can be used for evaluating the efficiency of the alignment instruments in terms of repeated actions, or time spent on using the instruments. More research is needed to measure differences between instruments.

Improving the efficiency may be difficult, because some non-goal oriented functions are needed e.g. to obtain enough view on the glenohumeral joint. The efficiency may be improved by using bipolar scissors, which may lead to less bleedings and, therefore, decrease the time spent on checking for and stopping of bleedings (Dessole et al. 2000). The efficiency may also be improved by decreasing the waiting time, which accounted for 10 percent of the total operation time (11 min). The change of instruments caused 39 percent of the waiting time; a more efficient instrument table may decrease this time. Searching and unpacking the prosthesis caused 23 % of the waiting time (2 min). Before the procedure, an estimation of the appropriate prosthesis size is made, but this has to be checked during the operation. Therefore, the prosthesis is looked for and unpacked late in the operation while the surgeon has to wait. A better pre-operative estimation of the prosthesis size can reduce this time, because the prosthesis can be unpacked earlier during the procedure.

This time-action analysis method can also be used for training resident surgeons. Their results can be compared with recordings of an experienced surgeon, who used the same instruments and operation procedure. It will provide information about the learning curve of surgical skills. Furthermore, it elucidates the steps on which training of the resident should be focussed.

Conclusion

Time-action analysis can be used for an objective evaluation of the per-operative surgical process during humeral head replacements. This method gives insight into the most frequently used actions and the number of goal-oriented and additional functions. Also, limitations can be identified with this method. In the future, this evaluation method can be used to evaluate the improvements of new surgical instruments and/or alternative surgical procedures.

Chapter 4

Factors influencing the surgical process during shoulder joint replacements:

Time-action analysis of five different prostheses and three different approaches.

Joanne PJ Minekus, Edward R Valstar, Piet M Rozing, Maarten J de Vos, Ron L Diercks, W Jaap Willems, Jenny Dankelman (Submitted)

Summary

The per-operative processes of 40 shoulder joint replacements have been evaluated using time-action analyses. The procedures were performed by 7 surgeons with different experience using 5 different prostheses and 3 different surgical approaches. The surgical procedures showed a large variation in e.g. duration, tasks of team members and used protocol. The surgical procedure was influenced by several factors, such as the used prosthesis, the surgical approach, the patient condition and the experience of the surgeon. The exposure of the glenoid was difficult and several retractors were needed, which were hold by an extra assistant or clamped to the table or the surgeon. Two main limitations were seen in all procedures: repeated actions and waiting. Also, five errors could be identified. None of the alignment instruments was completely reliable and they did allow the surgeon to make major errors. Therefore, better alignment instruments, pre-operative planning techniques, and operation protocols are needed for shoulder prostheses. The training of resident surgeons should be focussed on the exposure phase, the alignment of the humeral head, the exposure of the glenoid and the alignment of the glenoid.

Introduction

Post-operative evaluation studies show that shoulder joint replacements give good pain relief, but only a small improvement in range of motion and a rather high complication rate (reviewed by Magermans et al. 2003). Important factors influencing the results of shoulder joint replacements are the diagnosis and the surgeon's experience for accurately inserting the prosthesis and for repairing and balancing the soft tissues. The prosthesis design is a less important factor for the functional outcome (Magermans et al. 2003; Skirving 1999). However, post-operative evaluation studies give no insight into the actual surgical process.

Insight into the actual surgical process can be obtained using time-action analysis. Time-action analysis is a quantitative method, which measures the number and duration of the actions needed for an operator to achieve his goal, and the efficiency of these actions (Kirwan et al. 1992). In contrast to industry such as nuclear power plants (Swain & Guttmann, 1983), only few time-actions studies have been performed in the medical field, the majority of them in laparoscopic surgery (Cuscheri 2000; den Boer et al. 1999; Joice et al. 1998; Sjoerdsma 1998).

A time-action analyses method has been developed for the evaluation of humeral head replacement (Chapter 3). This study showed that time-action analysis can be used to determine the limitations of the surgical procedure and to give recommendations for improvements, although time-action analysis can not be used to predict the surgical outcome. The time-action analysis method was used to evaluate surgical procedures of one surgeon using one surgical approach and one prosthesis design. However, different surgical approaches and prosthesis designs exist, which all may have their influence on the surgical procedure.

The goal of this study is to evaluate the per-operative process during shoulder joint replacements using time-action analysis (Chapter 3). Therefore, 40 shoulder joint replacements performed by 7 surgeons using 5 different prostheses and 3 different approaches were evaluated. From these evaluations, factors influencing the surgical process will be determined and guidelines for improvements of the surgical procedure will be extracted.

Method

Procedures:

Forty shoulder joint replacements have been analyzed. These procedures were performed by seven surgeons stationed in four different hospitals. The surgeons placed 24 hemi and 16 total shoulder arthroplasties. The data of Chapter 3 are also included. Two surgeons were resident surgeons.

These seven surgeons used three different approaches: a deltopectoral approach, a clavicular osteotomy approach (Redfern et al. 1989) and a postero-superior approach with an acromion osteotomy (Rozing et al. 1998). Two surgeons were using two approaches.

The prostheses

The surgeons used five different prosthesis designs: the Multiplex from ESKA Implants (Lübeck, Germany); the Bipolar from Biomet (Warsaw, Indiana, USA); the Anatomical from Sulzer Orthopaedics (Zürich, Switserland); the Delta from DePuy (Leeds, UK); and the Aequalis from Tornier (Grenoble, France). Two surgeons were using two different prosthesis designs.

The Multiplex, Aequalis and Anatomical prostheses are anatomical prostheses. The humeral component of the Multiplex has uncemented fixation. The humeral components of the Aequalis and Anatomical prostheses have cemented fixation. The Multiplex and Aequalis prostheses have keeled glenoid components and the Anatomical prosthesis has a pegged glenoid. All glenoid components are cemented.

The Bipolar and Delta prostheses are non-anatomical prostheses and are used in case of rotator cuff deficiency. The Bipolar prosthesis consists of a humeral component with a small head articulating in a larger head, which is stabilised against the scapula. The Bipolar prosthesis is an uncemented prosthesis. The Delta prosthesis is a reversed prosthesis meaning that a ball is fixed on the glenoid and the humerus is the socket. The humeral component is cemented and the glenoid component is fixed with screws and cement.

Video analysis:

Video recordings of the procedures were made using two cameras, one giving an overview of the total operation field and one placed on the head of the surgeon giving a detailed view of the hands of the surgeon. The two video images and sound were recorded simultaneously using a video mixer. The recordings did not interfere with the surgical process and were analyzed off-line using the time-action method described in Chapter 3.

Table 4.1: *The phases and steps of a shoulder joint replacement.*

Phase	Step	Description
Exposure	E1	Incision skin and subcutus
	E2	Exploring the deltopectoral groove and preparing the cephalic vein
	E3	Opening off the rotator cuff
	E4	Preparing the humeral head
Humerus	H1	Sawing off the humeral head
	H2	Rasping the shaft
	H3	Testing the humeral head
	H4	Placing the prosthesis
Glenoid	G1	Preparing till the glenoid is reached and visible
	G2	Preparing the glenoid
	G3	Testing the glenoid component
	G4	Testing the glenoid component with the humeral head
	G5	Placing the glenoid component
Closure	C1	Placing sutures in the bone for reattachment
	C2	Testing the final prosthesis and muscle attachments
	C3	Suturing the rotator cuff
	C4	Suturing the remaining wound

Phases, steps and limitations:

Each procedure was divided into an exposure, a humerus, a glenoid and a closure phase and each phase was subdivided in several steps (Table 4.1).

In a perfect surgical procedure, all tasks would be performed without any need for corrections or repetitions and without unintentional damage to the surrounding tissue. However, repetitions and corrections are needed in most procedures due to the complexity of the surgical approach, the deficiencies of the instruments, or the experience of the surgeon. Some limitations may be classified as errors. Errors are defined as unintended, preventable actions of a surgeon, which may lead to damage if they are not corrected.

Statistical analysis

The data are compared for statistical differences using the Anova and Student t-test. $P<0.05$ was assumed to be significant.

Results

Forty shoulder replacements performed by seven surgeons have been recorded and evaluated. Sixteen procedures were total shoulder replacements and twenty-four were hemi shoulder replacements. The duration of the placement of a hemi shoulder prosthesis varied between 70 and 210 minutes and of a total shoulder prosthesis between 93 and 220 minutes (Figure 4.1).

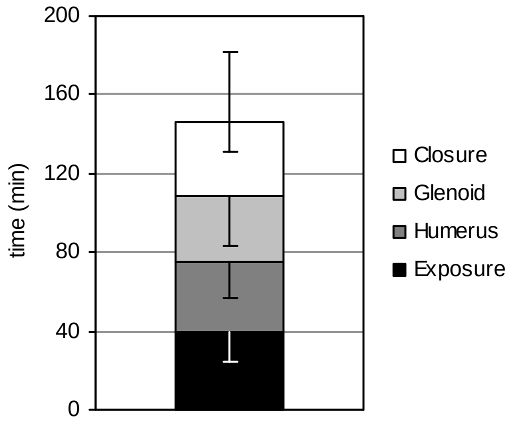

Figure 4.1: *The average duration of a shoulder joint replacement. The downward lines give the standard deviation of the duration of each phase and the upward line the standard deviation of the total operation time.*

General observations

Surgical team: All surgeons were assisted by a scrub nurse and by an assistant, normally a resident surgeon. Three surgeons were also assisted by a junior surgeon and had, therefore, a larger surgical team. The assistants were mainly holding clamps but also helped preparing and suturing during the exposure and closure phases. Two surgeons were resident surgeons with an experienced surgeon as the assistant. In this case, the experienced surgeon gave advice to the resident surgeon during the procedure. The nurses were responsible for the instruments. All scrub nurses were senior nurses. However, not all of them were experienced with shoulder surgery. The inexperienced shoulder nurses needed help in choosing the correct guiding instruments. The nurses who assisted on regular basis by shoulder replacements gave advice to the surgeon. In one hospital, the nurse assembled the final prosthesis, while in the other hospitals the surgeons assembled the prosthesis.

Exposure: Good exposure was quite difficult to obtain; therefore, all surgeons needed several refinements to position the retractors and the arm. Because normally one assistant can not hold the arm and all retractors, other methods were used to fixate the arm and retractors. In two hospitals, the junior surgeon also held some retractors or the arm. In other hospitals, the retractors were fixed to the surroundings using tape or a clamp, or the arm was clamped to the surgeon or the instrument table. The less experienced assistants often needed help from the surgeon to place the retractors to obtain a better exposure.

Humerus alignment: For the Multiplex, the Biomodular and the Delta prostheses, sawing and rasping guides were used for the alignment. The use of the cutting blocks was clear, although surgical experience was needed. For the Anatomical and Aequalis prosthesis, the anatomical neck is used as sawing guide and no guides exist. One surgeon used the test prosthesis to determine the correct sawing angle for the Aequalis prosthesis. Rasping in the correct angle was sometimes difficult, because the rasp had the tendency to displace due to varying bone densities. The assembling of the Bipolar, Anatomical and Aequalis humeral component was quite complicated because of the large number of prosthetic components to build a single prosthesis.

Glenoid alignment: For the glenoid, only few guiding instruments exist. Normally a drill guide and K-wire to drill the first hole and a guide to drill the slot or the remaining holes for respectively the keel and pegged type. The main problem was the exposure, because the glenoid is located deep in the surgical field. Using the drill guide, the workspace became even narrower and the visibility decreased; therefore, some surgeons only oriented themselves with the guide and then drilled without the drilling guide. The assessment of the Delta glenoid component was complicated because of the large number of prosthetic components.

Factors influencing the per-operative process

The duration of the four phases varied largely between procedures (Figure 4.1). Figure 4.2 shows the variation in the duration of the steps. The identification of the steps is given in Table 4.1. The exploration and closure phases are expected to depend on the approach used; therefore, in the plots of the exploration and closure phases, the used approach is marked. The humerus and glenoid phases are expected to depend on the prosthesis; therefore, in the plots of the humerus and glenoid phases, the used prosthesis is marked.

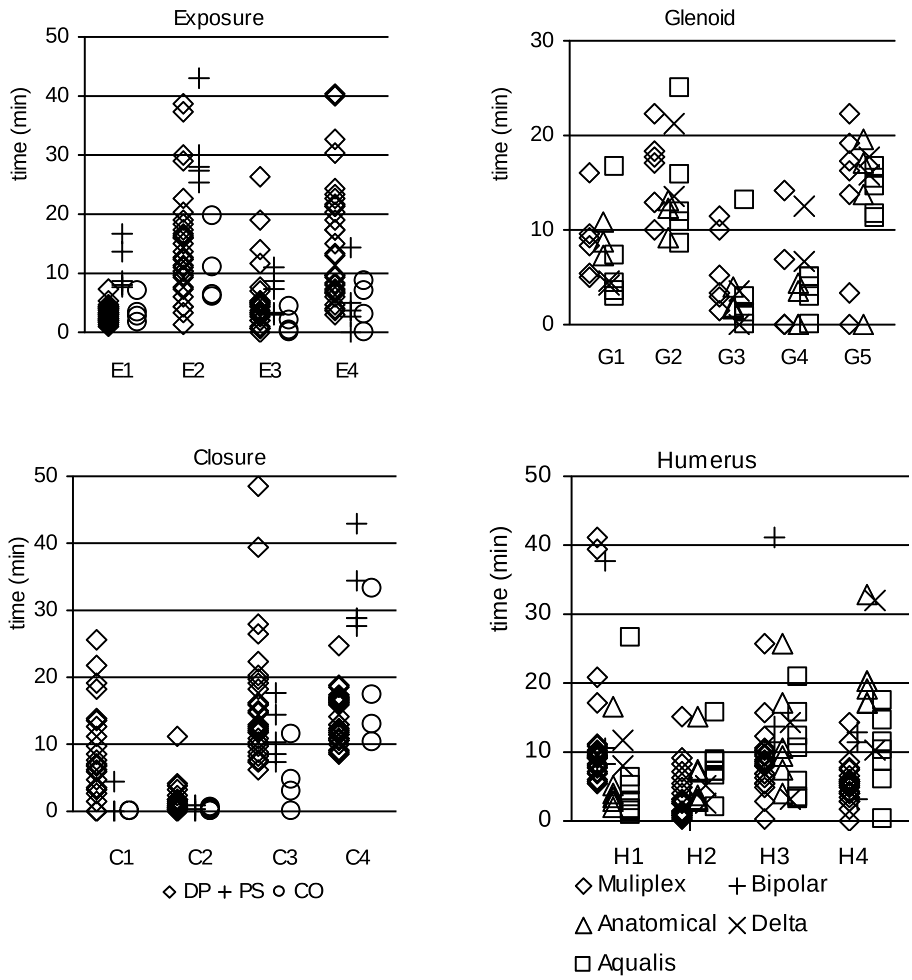

Figure 4.2: *The variation in duration of all steps. For the Exposure an Closure phase, the used approach is marked. For the Humerus and Glenoid phases, the used prosthesis is marked. The steps are explained in Table 4.1.*

DP= Deltopectoral;PS= Posterior-superior;CO= Clavicular osteotomy

Exploration phase

E1 Incision skin and subcutus: The duration of this step took on average 7 minutes longer for the posterior-superior approach ($p<0.001$).

E2 Exploring the deltopectoral groove: This step was different in the postero-superior approach. For the posterior superior approach, the acromion osteotomy to expose the rotator cuff took on average 15 minutes longer than exploring the deltopectoral groove in the other two approaches ($p=0.001$). Exploring the deltopectoral groove took 5 minutes longer for the procedures in which the tributaries of the cephalic vein were ligated, while the vein itself was left intact compared to the procedures in which the whole vein is ligated ($p=0.004$) .

E3 Opening off the rotator cuff: The duration of this step did not depend on the used approach ($p=0.32$).

E4 Preparing the humeral head: The duration of this step took on average 10 minutes longer for the deltopectoral approach than for the other two approaches ($p=0.02$).

Humerus phase

Only step H4, placing the prosthesis, depended significant on the used prosthesis and more specifically on the used fixation method. The use of bone cement took approximately 10 minutes extra. If the duration was corrected for the use of bone cement, the placement of the prosthesis was longer for the anatomical prosthesis, because of the assessment of the final prosthesis ($p=0.01$).

Glenoid

The variation of the five steps in the glenoid phases can not be ascribed to either the used prosthesis or the used approach.

Closure

C1 Placing sutures in the bone for reattachment: This step was not needed for the postero-superior approach or for the Delta and the Bipolar prostheses. For the other prosthesis this step took on average 10 ± 6 minutes.

C2 Testing the final prosthesis and muscle attachments: The duration of this step did not depend on the used approach ($p=0.35$).

C3 Suturing the rotator cuff: This step was not needed for the Delta and the Bipolar prostheses. Suturing the rotator cuff took on average 10 minutes shorter for the clavicular osteotomy approach than for the other two approaches ($p=0.048$)

C4 Suturing the remaining wound: This step took on average 16 minutes longer for the posterior-superior approach ($p<0.001$).

Influence of experience

Two surgeons were resident surgeons. They needed more time than the senior surgeon in the same hospital to perform the surgical procedure to identify the anatomical structures within the deltopectoral groove (Step E2); to dissect the subscapularis (Step E3); to align the prosthesis (Step H1) and to place sutures in the humerus for reattachment of the subscapularis (Step C1). If the procedures became too complicated, the senior surgeon took over, which occurred in 4 of the 8 procedures during the humerus phase.

Limitations and errors

The main limitations were waiting and repeated actions. Both limitations have been observed in all procedures. Waiting occurred in all procedures by all surgeons and took on average 16.3 ± 7.5 minutes (12.3 percent of the operation time). Most waiting occurred in the humerus and glenoid phases. The main causes for waiting were the nurse needing time to find and give the correct instruments and to unpack the prosthesis (8.1±4.5 minutes) and waiting for the cementing process (5.2±3.6 minutes). The surgeon had to wait on average 47±18 times for the nurse to find and give the correct instruments and to unpack the prosthesis.

Repeated actions occurred on average 4.8 ± 2.7 times and took on average 3.9 ±3.5 minutes (3 % of the operation time). The repeated actions occurred mainly during the alignment of the humerus and glenoid. All surgeons used alignment instruments, but they had to refine the preparing steps often without the help of alignment instruments. The resident surgeons showed fewer number of repeated actions than their teachers (2.6 for the resident surgeons compared to 5.9 for the experienced surgeons), because the teacher checked the alignment before the cutting started.

Five errors could be identified. In two procedures, the biceps tendon was cut in the exposure phase; which could be reattached in the closure phase. In one procedure, the humerus was perforated while rasping with a rasp that was too large, which could be restored using bone cement. In two procedures, the prosthesis was wrongly copied from the test prosthesis. In the first case, a stem too large was used, because an inexperienced nurse, who was not aware that different stem sizes exist, unpacked the wrong prosthesis. After re-rasping, this prosthesis could be inserted. In the second case, the head was wrongly placed on the stem, because a small piece of bone was confused with the mark sign on the prosthesis; this could not be repaired and a new prosthesis was unpacked. These errors were time consuming (up to 15 minutes).

Discussion

In this study, insight into the surgical process during shoulder joint replacements was gained by evaluating the surgical process of forty shoulder joint replacements performed by seven surgeons, using three approaches and five prostheses using time-action analysis. The surgical procedures showed a large variation in e.g. duration, tasks of team members and used protocol between and within surgeons. The surgical procedure was influenced by the used prosthesis, the surgical approach and the experience of the surgeon. The main limitations, repeated actions and waiting, were found in all procedures and took 15.3 percent of the total operation time. Five errors could be identified, which all could be restored.

Factors influencing the surgical procedure

The approach: The standard surgical procedure for a shoulder joint replacement is the deltopectoral approach, but several variations in this approach exist. All surgeons evaluated in this study used a different variation of this approach. Three surgeons used a different approach (Redfern et al. 1989; Rozing et al. 1998), because they found the view of the glenoid too limited with the deltopectoral approach. These different approaches did improve the view on the joint and made the glenoid alignment easier, but also increased the operation time.

The prosthesis: Although a large variation in humeral alignment guides exists, only the assessment of the prosthesis and the fixation method influenced the operation duration.

Experience: Inexperienced surgeons needed more time than their teachers, especially for the exposure phase, the alignment of the humeral head, the exposure of the glenoid and the alignment of the glenoid. These differences indicate that those phases are difficult. The resident surgeons showed less repeated actions because an experienced surgeon assisted them. The experienced surgeon improved the view by good placement of hooks and gave advice to the resident surgeon. The inexperienced surgeons were also more vulnerable to errors (see below).

Surgical team: If the surgical team was more experienced, the surgeon needed less time to instruct the team members and even got feedback from the team.

Patient condition: Part of the variation in duration could be attributed to the prosthesis, the approach, the surgical team and the experience of the surgeon. The remaining variation is probably due to the patient condition, e.g. the disease and the state of the rotator cuff.

Limitations and errors

Two limitations, waiting and repeated actions, were found in all procedures independent of the prosthesis or approach used. The repeated actions were mainly caused by the inability of the guiding instruments to make a correct alignment. Waiting was mainly caused by the cementing technique and by the scrub nurse which was unable to pick the correct instruments. These results confirm the conclusion of time-action analysis study for humeral head (Chapter 3) and a study of knee joint replacements (Dunbar et al. 1995) that better alignment techniques and better pre-operative planning are needed. Besides, waiting time may also be reduced by training of the scrub nurses and by using a strict operation protocol, so the nurses are better able to pick the correct instruments.

Besides these limitations, three types of errors were observed: cutting of the biceps tendon; humerus perforation; and wrong assembly of the prosthesis. The first error type, cutting of the biceps, occurred by two less experienced shoulder surgeons. The chance of cutting the biceps may be reduced by identifying the biceps tendon in an earlier stage of the procedure using a more standardized protocol. The second error type, perforation of the humerus during rasping, also occurred by a less experienced surgeon, because no humeral drill guide exists for that prosthesis, so drilling was done by eye. The perforation of the humerus may be prevented by using a correct size rasp. The maximum rasp size might be obtained with good pre-operative planning. The third error, the mal-assembly of the prosthesis, occurred with two different prosthesis designs. The first case was caused by an inexperienced nurse and may be prevented by pre-operative training of nurses, good checking of the surgeon or clearer packaging. The second wrongly assembled prosthesis was caused by a small piece of bone on the surface of the test prosthesis, which was confused with the sign on the prosthesis needed for the alignment. Clear marks on the test and final prosthesis may in the future decrease the change of wrongly assembling prostheses.

Recommendations

New instruments: None of the alignment instruments was adequate to align the prosthesis correctly at once, causing a lot of repeated actions and a reduced view of the glenoid. The existing instruments should be improved, or new techniques, like computer-assisted surgery, should be adapted for shoulder surgery.

Exposure: The exposure of the glenoid is quite complicated and often a shortage of hands exists to hold retractors and the arm. A mechanical assistant may be used to hold the retractors or the arm. Several mechanical assistants already exist, but these were not used, probably, because they are quite complicated, expensive and not well known.

Experience of the surgeon: Shoulder joint replacements are seen by some surgeons as one of the most complicated joint replacements (Skirving 1999), especially the soft tissue balancing and the glenoid alignment are considered as difficult procedures. The operation technique may be improved by developing new instruments or by increasing the operation skills of the surgeon. Development of an instrument for soft tissues balancing is very difficult and may even be impossible. Surgical skills may be improved by performing an adequate number of procedures and, thereby, increasing the experience of the whole surgical team. For both knee and hip joint replacements, the results were better in hospitals in which more prostheses were placed annually compared to hospitals were less prostheses were placed (Kreder et al. 1997; Robertsson et al. 2001). In this study, four of the five errors were caused by inexperience, indicating that for shoulder replacements, obtaining and retaining experience is equally important as for hip and knee replacements to reduce error probabilities and waiting. Thereby, the complications for the patients might be reduced.

Conclusions

The per-operative processes of 40 shoulder joint replacements performed by seven surgeons were evaluated using time action analysis. The used prosthesis, the surgical approach and the surgical team all influenced the surgical process. Although this method can not qualify which approach or prosthesis is better, some overall comments on the operation process during shoulder prostheses were given. The training of new surgeons should be focused on the exposure phase, as well as alignment of the humeral head, exposure of the glenoid and alignment of the glenoid. None of the alignment instruments were reliable and they did allow the surgeons to make major errors, therefore better guiding instruments are needed.

Acknowledgements

We would like to thank A.L. Boerboom, MD and F. Breukelman, MD of the University Hospital Groningen and S. J. Eekhoudt, MD and J.B. van Lent, MD of the Leiden University Medical Center for their co-operation in this project.

Chapter 5

Time-action and error analysis applied to elbow and knee joint replacements

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Summary

The goal of this study is to gain insight into the surgical process during elbow and knee joint replacements, to identify bottlenecks and to give guidelines for improvements. Therefore, an existing time-action analysis method has been extended with an error analysis method. Five knee and eleven elbow joint replacements performed by two experienced surgeons have been evaluated. Time-action analysis showed a large variation in duration between procedures. The main limitation for both procedures is waiting caused by the cementing process and waiting caused by inexperienced scrub nurses. For the error analysis, an error chart is made. For elbow replacements, the main error is caused by the inadequate instruments. For the knee replacements, the main error is caused by the large number of guiding instruments leading to confusion of the inexperienced nurses. The placement of both prostheses will benefit from new fixation techniques, better pre-operative planning, more experienced nursing staff, and better instrument tables.

Introduction

Adverse events, defined as an injury caused by medical management rather than the underlying condition of the patient, are within the top 10 of death causes in the United States (Brennan et al. 1991, Kohn et al. 1999). Half of the adverse events can be attributed to medical errors and are called 'preventable adverse event' (Brennan et al. 1991). Medical errors have become an important issue, especially after the publication of the report 'To err is human, building a safer health care system' (Kohn et al. 1999). The health care industry can learn from high risk industries e.g. aviation and nuclear power plants, where human factors studies have contributed to the increase of the efficiency and safety by reducing errors.

Surgical procedures are technically demanding and their outcome has great impact on the patient. Several instruments and procedures are used in the operation theatre without a thorough evaluation of their effect on the per-operative process. Insight in their effect on a surgical procedure can be obtained using time-action and error analysis. For laparoscopic colon resections, time-action analysis helped to improve the operation technique and to decrease the operation time (Sjoerdsma 1998) and time-action analysis was used to compare different instruments (den Boer et al. 2002a) and surgical techniques (den Boer et al. 1999b). Error analysis for laparoscopic cholecystectomies showed a large amount of errors; fortunately none of them resulted in an adverse event (Joice et al. 1998). For shoulder and knee joint replacements, time-action analysis studies have shown a large number of repeated actions and long waiting times (Dunbar et al. 1995; Chapter 3). For open surgical procedures, error analysis studies have not yet been published.

The goal of this study is to develop a method to gain insight into the surgical process during elbow and knee joint replacements, to identify bottlenecks and to give guidelines for improvements. Therefore, the time-action analysis method used to evaluate shoulder joint replacements (Chapter 3) is expanded with an error analysis method. This study will compare the surgical process of knee and elbow joint replacements. Knee joint replacements are common orthopaedic procedures which give pain relief and restoration of function and have a small complication rate (Rand et al. 2003; Ritter 2002; Robertsson et al. 2001). Elbow joint replacements are less common procedures, which give pain relief, but only a limited restoration of function and have a large complication rate (Ferlic 1999; Gschwend 2002; Rozing 2000). Two procedures are evaluated to analyse if some general rules can be found and furthermore if instruments and methods used in the one procedure can be used to derive guidelines for improvements in the other procedure.

Method

Procedures and surgical team

Total knee and elbow joint replacements performed by two experienced surgeons were evaluated. Five cemented NexGen knee prostheses (Zimmer, Warsaw, USA) and eleven cemented Souter-Strathclyde elbow prostheses (Stryker Howmedica Osteonics, Limerick, Ireland) were placed in patients with rheumatoid arthritis. During the knee replacement, the femur, tibia and patella joint surfaces were replaced. During the elbow replacement, the humerus and ulna joint surfaces were replaced. For knee replacements, the pre-operative condition was used to classify the difficulty of the procedure. Two knees had a neutral alignment and were classified as standard procedures. The remaining three knees had a large valgus angle or flexion contracture and were classified as difficult, because additional soft tissue release was needed. For the elbow such classification was not made.

The surgical team consisted of 5 team members: the surgeon, the assistant, the scrub nurse, the walking nurse and the anaesthesiologist. This study mainly focussed on persons in the sterile field: the surgeon, the assistant and the scrub nurse. The knee and the elbow replacements were performed by two different surgeons. This study has been performed in a hospital with teaching facilities for both nurses and surgeons. During the knee replacements, the scrub nurse was twice a junior nurse and three times a senior orthopaedic nurse. During the elbow replacement, the scrub nurse was always a senior orthopaedic nurse, although not always experienced with elbow prosthetic surgery. Some nurses assisted by both procedures. The assistant was in all procedures a resident surgeon.

Time-action analysis

Recordings: Video recordings of the procedures were made using two cameras. The first camera gave an overview of the total operation field and the second camera, placed on the head of the surgeon, gave a detailed view of the hands of the surgeon (Chapter 3). The images and the sound were recorded simultaneously using a mixing device and were analysed off-line. The recordings did not interfere with the surgical process. The medical ethical committee of the Leiden University Medical Center approved the study protocol.

Surgical steps: For the evaluation of the surgical tasks, the procedure was divided in four subsequent phases: the exposure phase, the bone preparation phase, the prosthesis insertion phase and the closure phase. Each phase was subdivided in several steps. Figure 5.1 gives a schematic overview of the different steps during a joint replacement. The steps are explained in Table 5.1. In the bone preparation phase, several steps were repeated, which are indicated by arrows in Figure 5.1:

Arrow 1: For each bone, the alignment, preparation and testing were performed separately.

Arrow 2: For certain bones, successive guides were used and the aligning and preparing steps were alternated.

Arrow 3: The alignment of each bone was tested using a trial prosthesis and when the surgeon was not satisfied, refinements were made.

Arrow 4: The combined prosthesis was tested and when the surgeon was not satisfied, refinements were made.

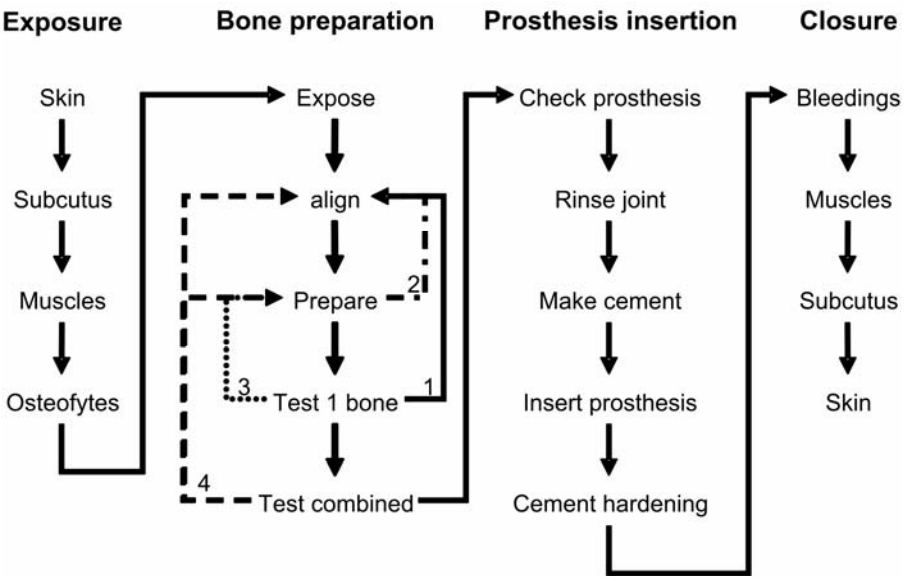

Figure 5.1: *Steps of a joint replacement. The steps are explained in Table 5.1 and the arrows are explained in the text.*

Functions: The actions performed by the surgeon, the scrub nurse and the assistant were analysed using a thesaurus of 55 actions and grouped into eight different functions (Table 5.2). The tokens in the taxonomy were discussed with the surgeon. The use of a strictly defined taxonom y resulted in observer independent results in a previous study (den Boer et al. 1999a).

Limitations were defined as repetitions and corrections needed due to the complexity of the surgical approach, the limitations of the instruments, or the experience of the surgeon.

These factors included waiting, repeated actions and instrument failure. Some of the limitations might be an error or an indication of an error.

Table 5.1: *Definition of steps in a joint replacement (see also Figure 5.1).*

Step	Description
Exposure phase	
Skin	Open the skin
Subcutus	Open the subcutus
Muscles	Split and cut muscles covering the joint
Osteofytes	Remove osteofytes of the joint
Bone preparation phase	
Expose	Expose the bone surface
Align	Place the cutting guide
Prepare	Prepare the bone
Test bone	Test the alignment of one bone using the trial prosthesis.
Test combined	Test the alignment of the combined prosthesis using the trial prosthesis
Prosthesis insertion phase	
Check prosthesis	Check the size and model of the real prosthesis, before unpacking
Rinse joint	Rinse the joint with tissues and salt water
Make cement	Make cement by the scrub nurse
Insert prosthesis	Insert the prosthesis and remove waste cement.
Cement hardening	Wait till the cement has hardened
Closure phase	
Bleedings	Release the pneumatic control and check for remaining bleedings
Muscles	Reattach the muscles to the bone and to themselves
Subcutus	Close the subcutus
Skin	Close the skin

Guiding instruments: Most prostheses have their own guiding instruments. For the Souter-Strathclyde elbow prosthesis, one guide exists and was used to draw the shape of the prosthesis with ink on the humerus (Figure 6.9). The inside of the shape was removed by sawing and drilling. For the NexGen knee prosthesis, different guiding systems exist (Figure 6.4). The surgeon in our study used an extramedullar guide for the tibia; an intramedullar guide for the femur (IM block) after which a multitude of different cutting blocks is used; and a saw and drill guide for the patella. Therefore, six boxes with instruments were needed, which were partly placed on top of each other on the instrument tables. Four types of NexGen knee prostheses were available in this hospital. The different types required partly the same and partly different instruments. The type of prosthesis used during the operation was determined.pre-operatively.

Table 5.2: Thesaurus of functions for the surgeon, scrub nurse and assistant.

Function	Definition
Preparing	Dissecting the wound
Aligning	Aligning the bones and placing the prosthesis.
Suturing	Placing sutures or a drain.
Observing	Watching the wound, palpating or observing the operation.
Exposing	Placing and holding retractors to expose the wound.
Stop bleeding	Checking for bleeding and stopping them using e.g. coagulating or swamping.
Instruments	Getting, positioning or cleaning instruments.
Waiting	Not performing a surgical action.
Miscellaneous	Actions that could not be identified or classified within the functions given.

Error analysis

Before the error analysis method is introduced, the term 'error' should be defined and some general comments on errors should be given, because the term 'error' has multiple and negative associations. A standard definition of an error is: 'A failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (i.e. error of planning) ' (Reason 1990). An error is not the same as an adverse event, but may lead to an adverse event, when the error is uncorrected or occurs in combination with other errors. An error can be caused by a human, by instruments or by the system. Errors may be active and latent. Active errors occur at the level of the frontline operator, and their effects are felt almost immediately and, therefore, they are easily identified and corrected (e.g. bleedings). Latent errors are errors within the system which occur in specific situations. They are tend to be removed from the direct control of the operator and, therefore, they are harder to identify (e.g. faulty maintenance and poorly structured organizations) (Reason 1990). Error analyses give insight into the error paths and such insight can be used to reduce and to restore adverse events. In each system errors will be made. The systems can improve significantly by learning from the errors.

An error analysis consists of 4 different steps:

A. Evaluation of all possible errors During this step, all possible errors are identified. These errors do not have to be observed in the operation theatre, nor do these errors have to result in complications for the patient. For all possible errors, pathways are invented how the errors can be restored. For example an electrical instrument may be defect. This can be restored by repairing the instrument, by unpacking a new instrument or by using a different instrument.

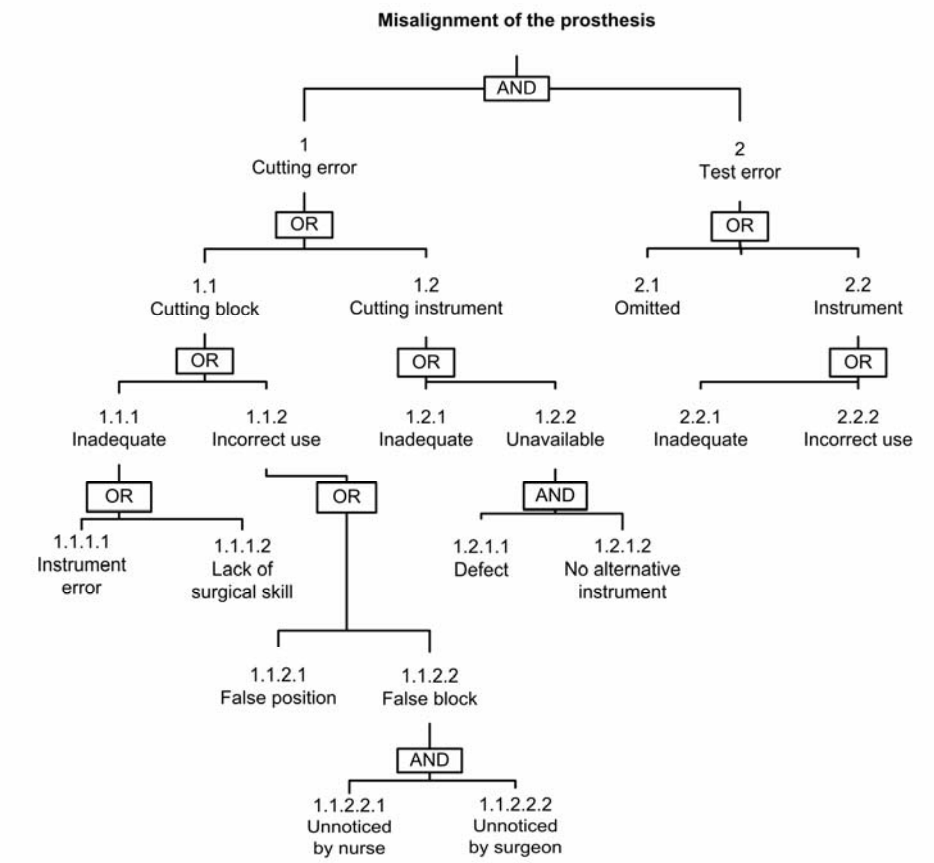

Figure 5.2: *Error chart of a joint replacement. The chart is explained in the text.*

B.. Representation of errors In this step, the error paths are analysed using an error chart. Figure 5.2 shows an example of an error chart. At the top of the chart, the possible adverse events are placed, in this case misalignment of the prosthesis. At the lowest level the actions, or groups of actions are placed which may cause the adverse event. With the terms 'or' and 'and' it is indicated whether a single event or a combination of events could have led to the error. For misalignment of the prosthesis, both the Cutting Error (1) and the Testing Error (2) should occur. The Cutting Error may occur by either an error of the Cutting Block (1.1) or an error in the Cutting Instrument e.g. saw or drills (1.2). The remaining chart can be read using the same method. The chart given in Figure 5.2 is just an example. The chart can be further extended and also other choices are possible.

C. Quantification of errors Some of the error probabilities at the lowest level in the error chart can be estimated from the result of the time-action analysis. For example the error probability of Nurse Unnoticed (1.1.2.2.1) is the number of false unpacked cutting blocks divided by the total number of unpacked cutting blocks. These error probabilities can be used to calculate the error probabilities at the higher levels. The probability of a step for which two errors are needed (‘and’ connection) is the product of the two separate errors probabilities. For example the probability of misalignment of the prosthesis (P(top)) is the product of the probabilities of a Cutting Error (P(1)) and the independent Test Error (P(2)): P(top)=P(1)*P(2). The probability of a step for which one of several independent errors need to occur ('or' connection) is one minus the product of the probabilities that no error occurs. For example the probability of a Cutting Error (1) is one minus the product of the probabilities of a good placement of the cutting block and a good cutting instrument: e.g. P(1)=1-(1-P(1.1))*(1-P(1.2)).

For a good quantification of errors, at large number of procedures should be evaluated, which is very time-consuming. In this study, only a small number of procedures is evaluated. Therefore, no error probabilities can be determined. However, the chart can be used to show bottlenecks of the procedures.

D. Impact assessment In this step, the effect of a specific error is evaluated. Error reduction should focus on those errors with the highest probability and which may lead to the worst adverse events.

Results

Time-action analysis

The duration of a knee replacement varied between 88 and 140 minutes (average 111±20 minutes) and the duration of an elbow replacement varied between 87 and 168 minutes (average 132±21 min). The duration of all phases varied largely between the procedures (Figure 5.3), especially in the bone preparation phase. The bone preparation phase during the elbow replacements showed a larger variation than during the knee replacements. The two standard procedures with neutral knees had a shorter exposure phase than the complex knees with the valgus and flexion contracture knees. In none of the eleven observed elbow joint replacements and five knee joint replacements, an intra-operative complication occurred.

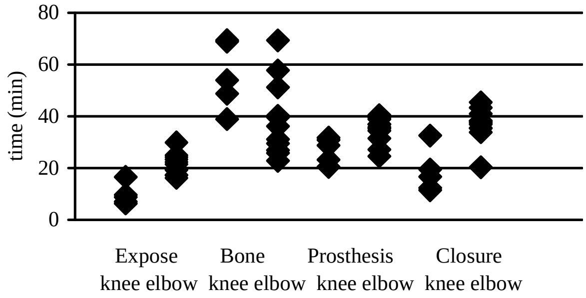

Figure 5.3: *Duration of the phases of 5 knee and 11 elbow replacements.*

Functions

The surgeon spent most of the time with preparing and aligning the prosthesis (Figure 5.4). During a knee joint replacement, the surgeon spent more time aligning the prosthesis in the bone phase, whereas during an elbow joint replacement, the surgeon spent more time preparing in the exposure phase. For the knee replacement, a larger number of guiding instruments was used. Once a guide was placed, the sawing and drilling was performed without repetition. For the elbow replacement, most alignment was performed with the use of the test prosthesis. This resulted in a large number of small refinements alternated with testing to prevent removing too much bone.

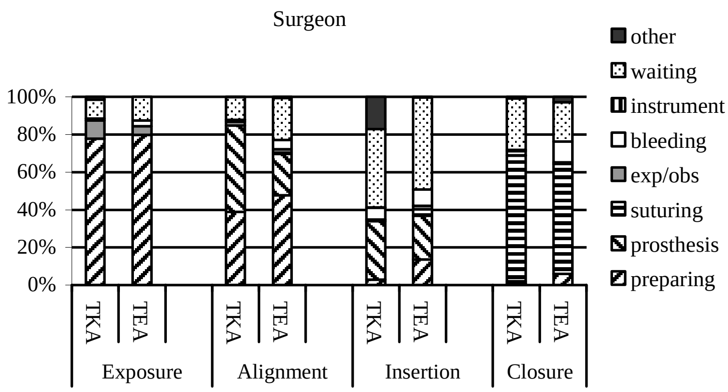

Figure 5.4: *Average duration of the functions of the surgeon.*
TKA: Total knee prosthesis; TEA: Total elbow prosthesis.

The assistant often used the two hands for different functions and, therefore, these were scored separately. The assistant used one hand mainly to hold retractors and the second hand for small tasks, which were alternated by large waiting periods (Figure 5.5).

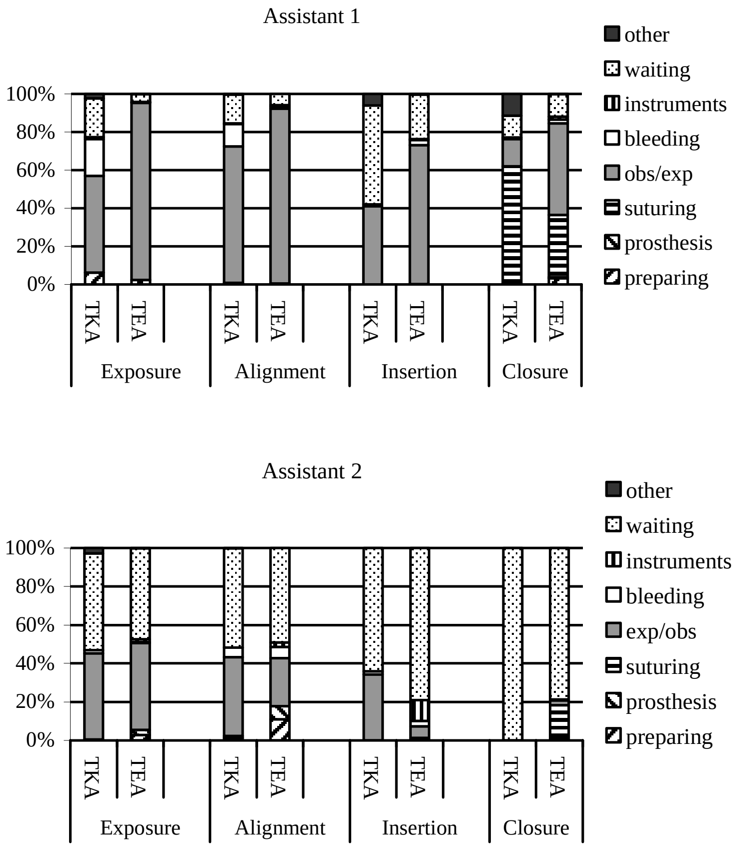

Figure 5.5: *Average duration of the functions of the assistant in each phase. Because the assistant used sometimes two hands for different functions, two functions are counted for the assistant. TKA: Total knee prosthesis; TEA: Total elbow prosthesis.*

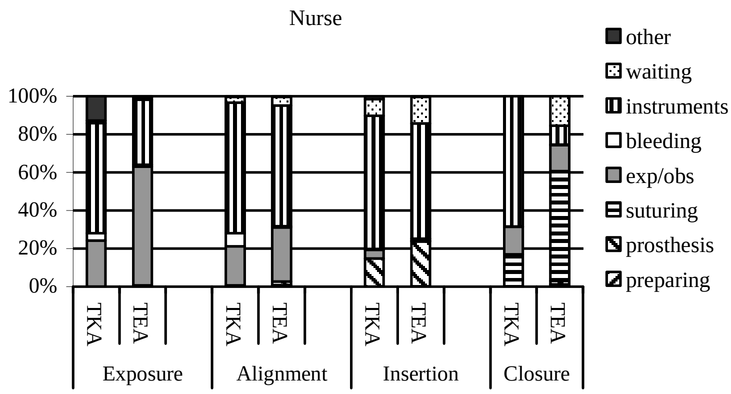

Figure 5.6: *Average duration of the functions of the scrub nurse in each phase. TKA: Total knee prosthesis; TEA: Total elbow prosthesis.*

The scrub nurse spent most of the time organizing and cleaning instruments (Figure 5.6). During the bone alignment phase, the scrub nurse spent much time observing the surgeon to be able to hand over the needed instruments. During a knee replacement, the scrub nurse needed more time to arrange the instruments because of the larger number of knee guides. The less experienced nurses had difficulties to predict which knee instrument would be needed next.

Limitations The main limitations were waiting, repeated actions and instrument problems (Table 5.3). Waiting occurred in all knee and elbow procedures. Before the wound could be closed, the surgeon had to wait until the cement was dry, otherwise the prosthesis would have an inadequate bone fixation. When the nurse was unable to predict the next instrument for the surgical procedure, the surgeon also had to wait. During a knee replacement, the surgeon had to wait longer when assisted by inexperienced nurses. After the trial prosthesis was implanted and the surgeon was satisfied with the prosthesis size, the walking nurse had to find and unpack the prosthesis. In two evaluated knee procedures, the walking nurses could not find the prosthesis, resulting in long waiting times. In one procedure, a senior nurse from another operation theatre came to help. In the other procedure, the surgeon left the operation table to aid the walking nurse and the surgeon had to rescrub to continue the procedure. Since the hospital has a nursing school, these events are part of daily practice.

Repeated actions occurred in all elbow and in two knee joint replacements and were caused by the difficult alignment of the prosthesis. For the knee prosthesis, the alignment guides could be placed unambiguously on the bone and once placed, the sawing or drilling could be done correctly at once. Two repeated actions during the knee joint replacements occurred, because the trial knee prosthesis was too tight, resulting in a less optimal performance. Therefore, more bone had to be removed from the tibia. For the elbow prosthesis, the shape of the prosthesis was drawn on the bone using ink. This was not a very accurate method and, therefore, the surgeon deliberately removed too small pieces of bone and had to make refinements afterwards, while checking the alignment with the trial prosthesis.

Although the type of knee prosthesis was known pre-operatively, the instruments of an other knee prosthesis were unpacked twice, because the nurses confused them with another type.

Table 5.3: *Average duration (in minutes) and number of limitations for both knee (n=5) and elbow (n=11) procedures.*

		Knee		**Elbow**	
		t (min)	**number**	**t (min)**	**number**
Waiting for	Cement	5.8	1	12.7	3
	Teaching	5.7	3	0.9	3
	Instruments	4.8	35	7.9	56
	Prosthesis	3.7	1	0.1	1
	Bleedings	0	0	6.3	1
	Miscellaneous	1.6	4	2.9	6
Repeated actions		0.9	0.4	17.1	10
Instrument failure		2.8	0.8	0.7	1
Miscellaneous		0.5	1.2	1.0	1.7

Error analysis

A. Evaluation of all possible errors: Table 5.4 lists several possible errors for joint replacements. For a joint replacement, both instrumental and human errors may occur. Fortunately, most of these errors can be recovered

B. Error tree: The error tree given in Figure 5.2 shows that misalignment of prosthesis occurs when both a cutting and a test error occur. Both errors have an instrumental and a human component, e.g. the cutting block may be inadequate or may be used incorrectly.

Table 5.4: Possible errors during joint replacements

Error type	Error	Recovery path
Instrument error	Inadequate	Testing
	Unavailable	Using a different instrument
	Defect	Unpacking a new instrument
		Using a different instrument
Human error	Insufficient knowledge	Better training
		With a supervisor
	Incorrect performed action	Warning of other team member
		Recovery action
	Omitted action	Warning of other team member
	Wrong position guide	By eye
		Testing
	Incorrect use of guide	Testing
	Use of wrong guide	Warning of other team member
		Testing

C. Error probability: Because of the small number of evaluated procedures, the error probabilities could not be calculated. However, the observations do give insight into which errors have a higher error probability. Because the error probability of the lowest error blocks (Figure 5.2) can be used to calculate the error probabilities for the higher blocks, only the errors in the lowest blocks in the error tree are discussed:

1.1.1.1 Instrument error Ideally, after placement of a cutting block, the surgeon should be able to cut the bone correctly at once. During two knee replacements, the tibia alignment was repeated. During all elbow replacements, the humerus and the ulna alignment steps were repeated. These data indicate that the instrument error probability is higher for the tibia guide than for the femur and patella guides. The instrument error probability is higher for the elbow alignment than for the knee alignment and a large amount of surgical skill is needed to compensate for the instrument errors.

1.1.1.2 Lack of surgical skill. To place a cutting block and to see if the cut is correct needs surgical skill. If the guides are inadequate, the surgeon should compensate for it, e.g. by repeating a step. During an elbow joint replacement, the surgeon could not trust the alignment guide and therefore cut less bone than needed and made a refinement after testing. The surgical skill and its error probability could not be measured in this study. Because the surgeons were experienced, the error probability is expected to be small.

1.1.2.1 False positioned cutting block The surgeon used the instruments as described by the developers. The error probability could not be measured in this study, but is expected to be small.

1.1.2.2.1*False block, unnoticed by nurse* In two knee procedures, the nurse had unwrapped the wrong instruments. In the elbow procedures always the right instruments were unpacked. These data indicate that the probability that the nurse unpacks the wrong instruments is higher for the knee replacements than for elbow joint replacements.

1.1.2.2.2*False block, unnoticed by surgeon.* The surgeon noticed the wrong instruments for the knee prosthesis indicating a small error probability.

1.2.1 *Cutting instruments inadequate* The standard cutting instruments, e.g. saws, drills and scissors were adequate for the preparation indicating a small error probability.

1.2.2.1 *Defec tcutting instruments* For both knees and elbows, similar preparing instruments were used. In all procedures, both a pneumatic and an oscillating electrical drill and saw systems were used. The data for both procedures of the two electrical systems were grouped leading to a total of 32 electrical systems. Ten of the electrical cutting systems did not work properly during the procedures and therefore the error is roughly around 1/3.

1.2.2.2 *No alternative instruments* When an instrument was defect, a new instrument was unpacked or alternative instruments were used, showing a small error probability.

2.1 *Testing omitted* The surgeons always tested the alignment showing a small error probability.

2.2.1 *Testing instruments inadequate* The test prosthesis had the same shape and dimensions as the prosthesis, therefore, the error probability is expected to be small.

2.2.2 *Testing instruments used incorrectly* The test prosthesis could only be used in one way and, therefore, this error probability is expected to be small.

D. Error impact: For the Souter-Strathclyde elbow prosthesis, a large number of repeated actions is needed for the alignment of the prosthesis, indicating a large error probability for the Cutting Blocks (1.1.1.1). The Instrument Error should be compensated by a good Surgical Skill (1.1.1.2). Less experienced surgeons may lack enough surgical skill and have a larger probability to misalign the prosthesis. Besides, the human skills might be insufficient, because e.g. the human eye can not distinguish small rotations and movements. To reduce possible misalignment, better guides are needed.

For the NexGen knee prosthesis, the tibia alignment guides show larger error probability as the femur blocks. Also, the unwrapping of instruments of the nurse have a higher error probability for knees than for elbows. The tibia alignment was always tested by the surgeon and misalignment was easily detected. The unwrapping of the wrong instruments was caused by inexperience of the nurses. In these procedures, the surgeon noticed the wrong instruments, but with only a small lack of attention of the surgeon, this error may lead to misalignment of the prosthesis with a high error probability.

The electrical cutting instruments (1.2.2.1) have an error probability of about 1/3. These errors are easily identified and corrected by unpacking new instruments or using mechanical instruments. Therefore, these errors will probably not lead to adverse events for the patients.

Discussion

Advanced instruments are introduced in the operation theatre, but their use and their effect on the operation process itself are generally not evaluated. In this study, a time-action and error analysis method is introduced and used to evaluate the effect of surgical instruments on the surgical process during elbow and knee joint replacements. Time-action analysis showed that the operation time for both elbow and knee joint replacements varied largely between procedures and depends on the surgical team and the patient’s preoperative joint deformity. The surgeon's main tasks are preparing and aligning the prosthesis; the nurse's main task is arranging instruments and the assistant's main task is holding retractors for exposure. The main limitations were repeated actions and waiting. Error analyses showed that the main error for the elbow prosthesis occurs due to inadequate guiding instruments and for the knee prosthesis due to less experienced nursing staff because of the teaching facility.

Time-action analysis

This study showed that time-action analysis can be used to evaluate joint replacements. The time-action analysis method has some limitations. The main parameter of this method, time, is not necessarily correlated to the functional outcome (Chapter 3). A good functional outcome, i.e. no pain, no complications and a large range of motion, is preferable above a short operation time for the patient. Furthermore, the method can not be used to distinguish cognitive processes and the reason of the surgeon for a certain approach or action. Therefore, for a good interpretation of the results, communication with the surgeon is important. Despite these limitations, time-action analysis gives insight into operation procedures and can be used to show the bottlenecks of surgical procedures.

Error analysis

This study introduced an error analysis method to evaluate surgical errors. The goal of error analysis is to determine the probability of an error during surgical procedures and to find the cause of the error. The goal is not to blame people for making errors. All people make errors and people can learn from errors. Error analyses are performed to learn from errors. This study showed that an adverse event is normally the result of both an instrumental and a human error.

Instruments should be able to prevent human error, but remain at this time only an adjunct for the surgeon. For knee instruments, several studies have been performed on the reliability of the instruments (Laskin 2003; Otani et al. 1993; Plaskos et al. 2002). These studies show, that the cutting guides should be used with care, that the placement of the cutting guides varied between and within surgeons and that even when the cutting guides are placed correctly, the saw can deviate due to differences in bone hardness. The data in this study show that especially the cutting guide for the elbow has a large error probability and, therefore, should be improved.

For deeper insight into the human errors, more surgeons including resident surgeons should be evaluated. Such research can give insight into the learning process and might help to improve the learning curve of resident surgeons. For even better predictions of human errors, a human reliability method should be used. Human reliability studies measure how reliable humans are in their actions; when the human skill fails to perform the correct actions; and how humans can detect and correct errors. In nuclear power plants, a large amount of research has been performed on the human reliability (Swain et al. 1983), predicting many human error probabilities. To get a better insight into human error in surgery, additional research is needed.

Improving the instruments for the Souter-Strathclyde elbow prosthesis

A good alignment and fit of the prosthesis improves the fixation and the range of motion and decreases the probability of a complication (Stulberg et al. 2002; Thoma et al. 2000). For the alignment of the prosthesis, cutting guides are used. These guides should be unambiguous and easy to use. For the humeral alignment of the Souter Strathclyde elbow prosthesis, the shape of the prosthesis is drawn with the help of a guide on the bone. The drawing method is not very accurate and the drill or saw can easily be displaced. An experienced surgeon will probably have enough skills to place this prosthesis correctly, but inexperienced surgeons have a large risk of misalignment of the prosthesis. A guide fixated on the bone, such as the extrameddular guides for the knee, can increase the accuracy and can decrease the number of repeated actions. For the ulna alignment, the surgeon did not use an alignment guide and, therefore, the ulna alignment requires a large amount of surgical experience and the alignment might be improved by the development of alignment guides.

Decreasing the complexity of the NexGen prosthesis

The NexGen prosthesis is very complex because of the large amount of possibilities to adapt the prosthesis to the patient's anatomy. In contrast to the elbow, for the knee prosthesis a left and right type exists. Furthermore, in this hospital, the prosthesis has four different types: flex mobile, flex fixed, posterior stabilized mobile and posterior stabilized fixed. The four types were often mixed-up by the nurses. Due to the large number of instruments and the nurse training setting, the nurses lack an overview of the instruments and they sometimes needed advice of the surgeon. Therefore, the prostheses and guiding instruments themselves should be made less complex by e.g. less confusing names and better distinguishable instruments.

Waiting

Waiting affects the efficiency of the surgical procedure and, thereby, the duration of anaesthesia, the risk of infection and the number of procedures which can be planned in the OR. It can also decrease the concentration of the operation team and, hence increases human error probability. Waiting occurs mainly while unwrapping the prosthesis, changing instruments and during cement hardening. Waiting time needed for unwrapping the prosthesis may be reduced by improving the pre-operative planning. When the needed prosthesis size is known pre-operatively, the prosthesis can be searched for at the beginning of the procedure, thus no time is lost. However, unpacking the prosthesis earlier increases the infection probability. Waiting time needed to change instruments may be reduced by a smaller number of instruments. The evaluation of the logistic process in the operation department might help to reduce the waiting times caused by finding the right prosthesis and the instruments. To reduce the waiting time for cementing more research is needed to develop faster hardening cement or to develop other fixation methods, such as screws or glues.

Conclusion

The time-action and error analysis method can be used to gain insight into the surgical process. The result of this study can be used to reduce the error probability of the elbow and knee procedures. The placement of the Souter Strathclyde elbow prosthesis can be improved by the development of alignment guides for both the humerus and ulna. The NexGen knee prosthesis can be improved by a better understanding of the instruments by the nursing staff. It should be mentioned that a training facility was used for this study. Both types of prostheses will benefit from new fixation techniques, better pre-operative planning, more experienced nursing staff, and better instrument tables.

Chapter 6

Instruments for joint replacements

Summary

The goal of this study was to give recommendations for improvements of the elbow and shoulder joint replacements by evaluating the alignment instruments for knee, elbow and shoulder joint replacements. The literature showed that a correct alignment of a joint consists of three steps: correct placement of the alignment instrument in relation to the bone, fixation of the guide and the preparation of the bone. All three steps can lead to an error: correct placement because of differences in bone geometry between persons; fixation because of displacement of the pins and movement possibilities of the guide; and the preparation because of displacement of the surgical instruments in relation to the guide. For knee joint replacement, a large number of studies have been performed on the alignment instruments and the best alignment axis. These studies have lead to a range of successive alignment instruments. For shoulder and elbow prostheses, few studies concerning the alignment instruments have been performed and less alignment instruments are available. For the shoulder replacement, the humerus is probably aligned accurately enough. However, the glenoid alignment is more difficult and crucial. The glenoid alignment might be improved by patient specific fixtures or computer assisted surgery. For the elbow, the alignment is also important and guides comparable to knee guides might be used.

Introduction

Correct alignment of a prosthesis is crucial for the post-operative results. The needed accuracy for the alignment depends on the joint. For hip replacements, an accuracy of 10 degrees is accepted as sufficient (Harris 1980), whereas for knee replacements an accuracy of 4 degrees is needed (Mont et al. 1997; Novotny et al. 2001; Otani et al. 1993). For shoulder and elbow prostheses, the needed accuracy is not determined. For the alignment, special alignment instruments are available to help the surgeon. Ideally, these instruments should be placed easily and unambiguously, and when placed, the saw cuts and drill holes should be made correctly at once. During elbow and shoulder joint replacements, a large number of repeated actions is needed to align the prosthesis, indicating that the elbow and shoulder alignment instruments are inadequate to make an unambiguous and correct alignment (Chapters 3, 4, 5). Knee replacements showed less repeated actions indicating that knee alignment instruments are more reliable (Chapter 5).

The goal of this chapter is to derive recommendations to improve shoulder and elbow prostheses by evaluating the literature and the available instruments for knee, elbow and shoulder joint replacements. Firstly, some general principles and problems concerning alignment guides will be specified. Secondly, general characteristics and examples of available guides for knee, shoulder and elbow prostheses will be described. Finally, recommendations will be given to improve shoulder and elbow joint replacements. This chapter will only study instruments used to align a prosthesis placed by patients with bone diseases like rheumatic arthritis and osteoarthritis. Because in fracture patients, the joint anatomy is destroyed. Therefore, different surgical techniques and instruments are required depending on the damage encountered.

General alignment rules

Alignment guides should help the surgeons to align the prosthesis in relationship to the anatomy of the joint and to make a correct saw or drill cut. For the alignment, a single instrument, or a range of successive instruments can be used. Errors that can occur during the use of these alignment instruments are: misalignment, changed position during fixation and displacement of the preparing instruments.

Alignment in relationship to the patient anatomy

The prosthesis is aligned with the help of anatomical landmarks. These landmarks vary in size and in relative distances between persons (Berger et al. 1993). Furthermore, these landmarks can be affected by diseases such as rheumatic arthritis. With help of the alignment guides, the surgeon should be able to adapt the prosthesis to the different anatomy of patients. For the alignment, different anatomical landmarks can be used:

– *Bone characteristics*, e.g. muscle attachments and bone shapes. Pre-operatively some characteristics can be seen on roentgen photos or MRI scans and during the procedures, these characteristics are visible or palpable in the wound. Because of the small wound size, only few bone characteristics can be used and they might have been affected by the disease.
– *The rotation axis*. Most prostheses try to restore the rotation axis of the joint. The rotation axis can be estimated from anatomical characteristics or by moving the joint. The anatomical characteristics are often used to align the guides and the movement to test the placement of the prosthesis.
– *The shaft of the bone.* By long bones, the shaft can be used to determine the direction of the prosthesis. The prostheses are often partly placed in the shaft for a better fixation and force distribution. Pre-operatively, the shaft can be defined with the X-rays scans, and angles and distances related to the shaft can be measured. For some bones, the adjoining joint can also be used to get insight into the direction of the bone. The shaft is not useable or available in small bones, such as the glenoid, because the shaft is too small and is not visible or palpable during the surgical procedure.

Correct placement of the guide

For the alignment of long bones, two guiding systems are available: intramedular and extramedular guides. The intramedular guides are placed in the shaft of the bone. First, a small hole is made in the bone. The canal is widened using a rasp or drill, so the cutting guide can be placed. The reliability of an intramedular guide depends on the accuracy of the insertion point, the rod length and diameter (Novotny et al. 2001; Nuno-Siebrecht et al. 2000; Reed et al. 1997). The intramedular guide is easily placed; minimizes the number of operation steps; and is considered to be most reliable. However, the intramedular guide increases the risk of pulmonary fat emboli; needs a plug when using bone cement; its proper position depends on patients non-deformed bony structures such as the condyles; and it cannot be placed in small and bent bones (Simmons, Jr. et al. 1991).

The extramedular guides are placed outside and parallel to the bone. With the extramedular guide, the adjoining joint can be used as reference. For example, for the extramedular tibia guide, the base is placed on the ankle joint. On the X-ray images, the direction of the bones and the distance between affected and adjoining joint can be measured. The extramedular guides are universal in use in both deformed and non-deformed patients and have smaller rotation errors. However, the extramedular guide can be displaced because of fat tissue and surgical draping.

Fixation of the guide

After the alignment, the guides are fixed to the bone with pins or clamps. During the fixation, the pins have the tendency to move to the softer bone (Plaskos et al. 2002) and, thereby, displace the guide. Different fixation methods are possible, like clamping, pins or an internal rod. Measurements of possible displacements after fixation showed that all fixation methods allowed the cutting block to displace. The best fixation method was a combination of a tight rod fixation in combination with large pins; the worst method was clamping the guide to the bone. Clamps show a displacement over 1.5 mm (Otani et al. 1993). The block can also displace because of the oscillating saw; especially by higher vibration energies and when the vibration is in the direction of the pins (Otani et al. 1993).

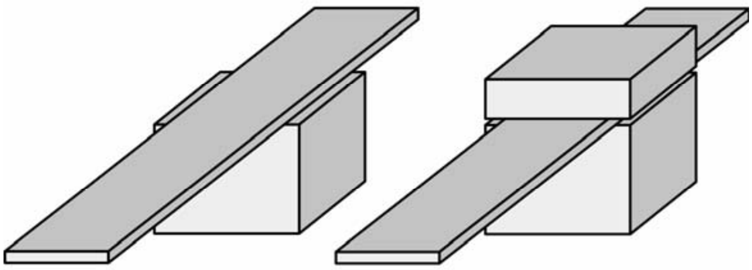

Figure 6.1: *Open and slotted guides. The left figure shows an open guide and the right figure a slotted guide.*

Correct preparing

Once the alignment guide is placed, the surgeon should be able to prepare the bone without errors. However, a large variation of cutting angles has been shown for both experienced and resident surgeons preparing with a fixed guide (Plaskos et al. 2002). The guides have holes to align the drill and pins and planes to align the saw. For the alignment of the saw, two methods can be used: open and slotted guides (Figure 6.1). By an open guide, the saw is guided by a single plane either above or below the saw. By a slotted guide, the saw is guided between two planes. When using an open guide, the surgeon can hold the saw in a large range of angles and still keep contact with the guide. To prevent for sawing too much bone, the surgeons had a tendency to leave bone at the back of the saw cut for refinements. With slotted types, the preparing instrument has less motion possibilities (Plaskos et al. 2002). The cutting error with slotted guides depends on the slot distance and the saw blade thickness. The slots allow a small variation in insertion angle. With a regular blade of 1.2 mm thickness and 1.5 mm slot, the saw can have a deviation of 0.6 mm after 3 cm of drilling (Otani et al. 1993). The slotted guides did not improve the accuracy of all cutting planes. The accuracy of the open guide was better if the surgeon had to hold the saw down in stead of up (Plaskos et al. 2002). Both type of guides, open and slotted, allow errors in the positioning of the saw blade.

Few studies have evaluated the preparation process itself. Several preparation techniques are possible e.g. sawing, milling or reaming. Milling causes a smaller temperature increase than sawing and, therefore, a smaller change of bone necrosis (Dueringer et al. 1996). Milling is also more accurate as sawing, but involves more cumbersome equipment and may increase the risk of injury (Van Ham et al. 1998). Reamers with tooth were safer and gave less fractures (Kold et al. 2003). After a month use, all saw blades showed damage to the angle and size of the teeth of the blades; half of the blades could even be classified as significantly damaged. Because of the damage, the old blades required more force in drilling and showed irregular saw surfaces with broken trabercula, torn edges and debris, which was not seen with new blades. The irregular surfaces may decrease the in-growth possibilities of the bone in the prosthesis (Wevers et al. 1987). The accuracy of preparation depends on the used preparation method and the life time of the instrument.

Knee:

Prosthesis design:

The knee is mainly a hinged joint with about 130 degrees of flexion and has only limited motion in other directions. Most knee prostheses try to restore the normal movement axis. Several types of knee prostheses are available:

- Non-constrained prostheses restore the joint surfaces.

– Posterior stabilized prostheses restore the joint surfaces and give additional stability.
– Mobile bearing prostheses have a loose bearing like a meniscus and can be used for both constrained and non-constrained prostheses.

Alignment methods:

The success of knee prostheses depends on a correct alignment. Achieving accurate positioning of the knee requires the surgeon to identify and register the tibia and femoral mechanical axis and to align and mount the cutting guides to these axes to perform the bone cuts (Plaskos et al. 2002). The mechanical axes are not visible during the procedure and, therefore, additional landmarks are used to estimate the mechanical axes. The femur has several good visible anatomical landmarks and a large shaft (Figure 6.2). Four methods have been defined for the alignment of the prosthesis: the anterior-posterior axis, the posterior condylar axis, the transepicondylar axis and the femoral component rotation necessary to form a symmetric flexion gap of the ligament balance in complete extension (Berger et al. 1993; Olcott et al. 2000). Studies concerning the best alignment method for knees have shown that the best method depends on the pre-operative varus/valgus angle of the knee (Figure 6.3).

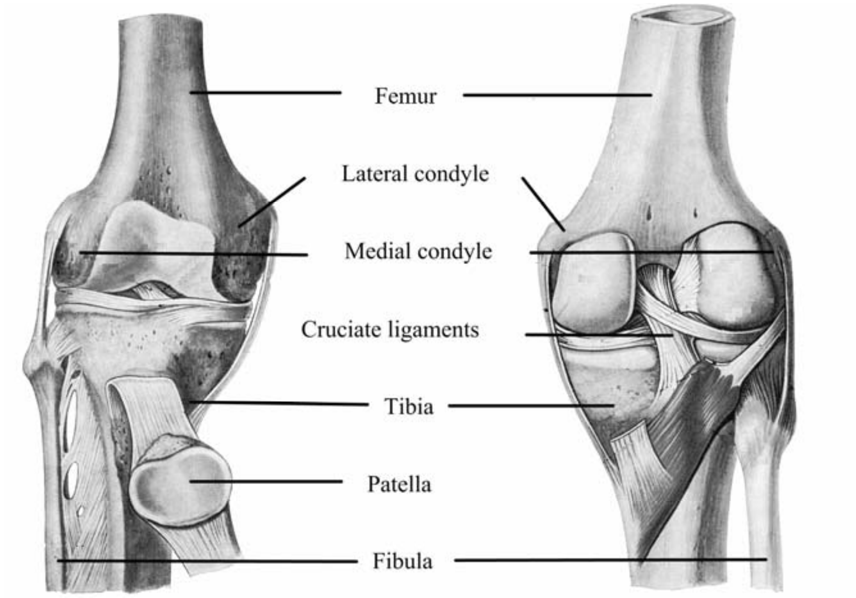

Figure 6.2: *Anatomy of the knee. The left figure shows the posterior view and the right figure shows the anterior view. The figures are adapted from the atlas of Sobotta (Sobotta 2003).*

Uni-compartment prostheses replace only the medial or lateral side, to conserve the healthy side by patients with asymmetric destruction of the joint. The posterior condyles axis connects the two condyles. Its location can only be determined reliably in 75% of the patients (Plaskos et al. 2002) and can be used for neutral and varus knees (Nagamine et al. 1998; Olcott et al. 2000) but this axis is not reliable for valgus knees (Pagnano et al. 2001).

- The anterior-posterior lies between the two condyles and is almost perpendicular to the posterior condyles axis. This axis is less reliable in normal and varus knees, but better for valgus knees (Nagamine et al. 1998; Olcott et al. 2000).
- The transepicondylar axis connects the two epicondyles and is unreliable with an interobserver variation in determining this axis of 23 degrees (Berger et al. 1993; Jerosch et al. 2002; Olcott et al. 2000), although a different study claims that this axis is reliable and can be used for extramedular guides (Luo et al. 2001).
- The ligament balancing method is mainly performed in combination with one of the other methods.

The tibia has less distinguished anatomical landmarks because the surface is flatter (Figure 6.2). To estimate the mechanical axis, different axes are defined in the direction of the shaft. For the alignment of an intramedular guide, the insertion angle did not depend on the used axes, because the variation in insertion angle was larger than the variation between the three axes (Denis et al. 2002). Both intra- and extramedular guides exist to align the tibia. The intramedular rods were more accurate for varus knees, but could only be placed in 80 percent of the varus and in 37 percent of the valgus knees, because of the bowing of the tibia. (Simmons, Jr. et al. 1991).

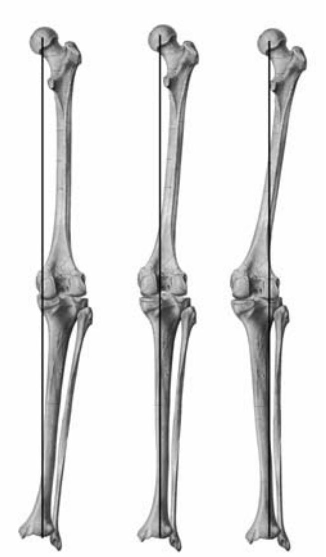

***Figure 6.3**: Varus/valgus angle of the knee. Three legs are shown and in each leg the anatomical axis (the line between the centers of the hip to the center of the ankle) is drawn. In the valgus knee (left), the anatomical axis passes the centre of the knee joint lateral, in the neutral knee (middle) in the middle and in the varus knee (right) medial Figures adapted of Sobotta (Sobotta 2003).*

Available instruments

All knee prostheses have a large number of alignment instruments. Figure 6.4 shows an example of knee instrumentation for the NexGen knee. Other knee prostheses have comparable instrumentation sets. For the femur, most prostheses have an instrument to align the guides to the patient anatomy; the cutting blocks are placed over the alignment guides, or over pins placed using these guides. For the tibia, one guide is used for both the alignment and the cutting.

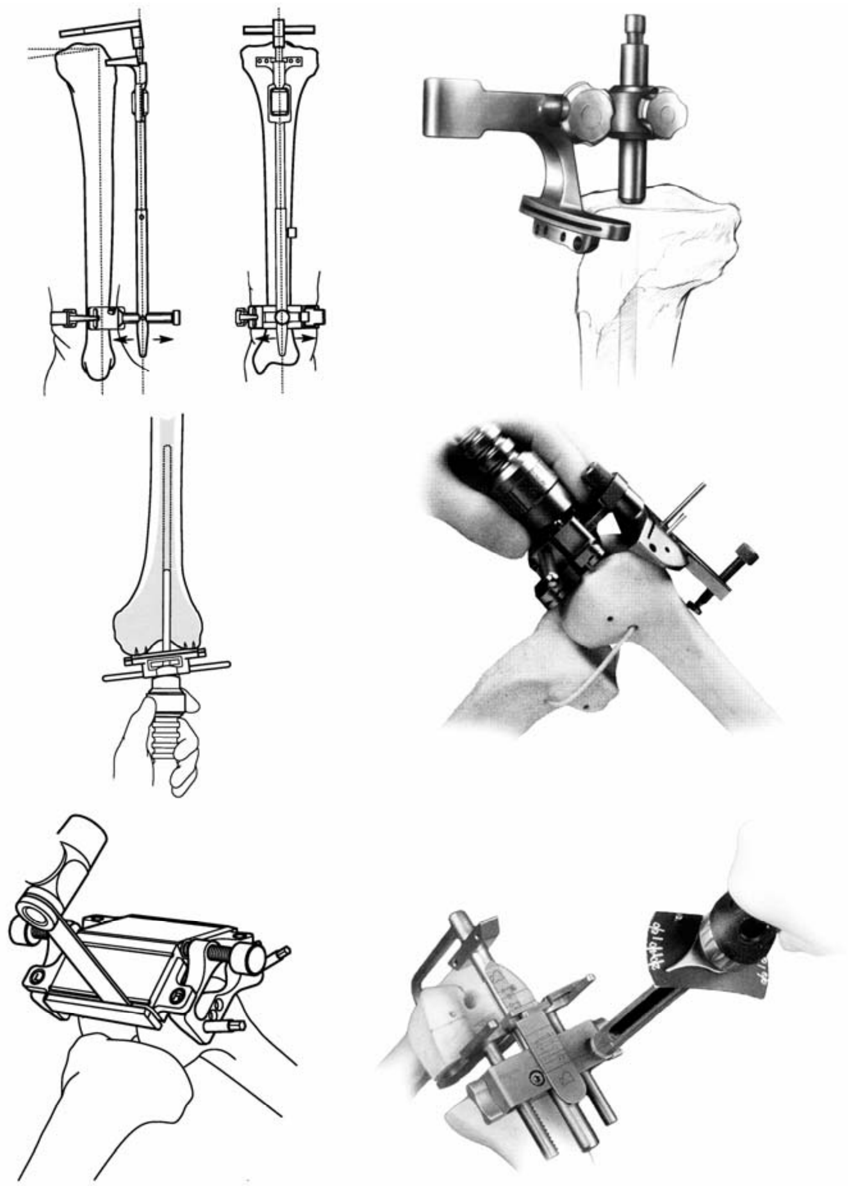

Figure 6.4*: Knee alignment guides. The top row shows the extra- (left) and intramedular guide (right) for the tibia. The second row shows the first two steps of the femur alignment: intramedular alignment guide and, transposing to the cutting block. The third row shows the femur cutting block (left) and the possibility to the check the ligament balancing (right). All instruments are from the NexGen knee prosthesis (Zimmer).*

Several studies have compared the accuracy of intra and extramedular guides for knee replacements. Some studies have shown better results for intramedular tibia guides (Maestro et al. 1998; Reed et al. 1997) and some studies have shown comparable results (Ishii et al. 1995; Teter et al. 1995a; Teter et al. 1995b). In spite of these results, 75 percent of the British surgeons showed a preference for extramedular guides (Philips et al. 1996)

In 5-10 percent of the knee prostheses, the required accuracy was not reached even when modern guides were used (Stulberg et al. 2002). Optimal placement of the prosthesis may not be achieved when the patient bone geometry differs from the geometry assumed by the designer (Teter et al. 1995a). Also, in most mechanical systems, some degrees of freedom like the rotation and positioning of the patella component are aligned by visual inspection (Teter et al. 1995a). Few possible solutions for these inaccuracies were proposed and tested. Firstly, an intramedular goniometer could decrease the range of outliers, because the surgeon has a better mechanical insight (Mont et al. 1997). Secondly, computer assisted surgery also reduced the number of outliers (Jenny et al. 2001; Stulberg et al. 2002).

The shoulder:

Prosthesis design

The shoulder is a ball- and socket-joint with the humeral head as ball and the glenoid as socket (Figure 6.5). Most shoulder prostheses are anatomical and restore the existing anatomy. A computer simulator study showed that the humeral heads of commercial available anatomical prostheses were sufficient to match the anatomical parameters of almost all humeral heads to within a couple of millimetres, although with some reduction of articular surface area (Pearl et al. 2002). Several model and cadaver studies have evaluated the effect of the position and size of the humeral head on the range of motion and muscle forces. The range of motion is affected by the size of the humeral head (Blevins et al. 1998), the position of the centre of rotation, the posterior offset (de Leest et al. 1996) and the conformity between the humerus and the glenoid (Karduna et al. 1997). The position of the humeral head is less important, misalignment of less as 8 mm did not change the rotation movement (McMahon et al. 2003; Williams, Jr. et al. 2001).

Alignment method

The humeral head is good visible during the surgical procedure and several anatomical landmarks can be used (Figure 6.5): the anatomical neck, the humeral shaft, the epicondylar axis of the elbow, the forearm and the bicipital groove. The anatomical neck is the border between the humeral head and stem and is normally the line in which the head is sawn off. The anatomical neck can be hard to determine because of osteofytes (Post et al. 1998). The humeral axis is defined in relation to the epicondilar axis of the elbow. The epicondylar axis can be used as an anatomical reference for a well designed externally attached reference guide. Because of the relationship between the epicondylar axis of the elbow and the humeral version, a bent forearm can be used to determine the amount of rotation of the humeral head. The bicipital groove can also be used as an indication of the retroversion angle for some prostheses (Post et al. 1998), but due to a large variation of the angle of the bicipital groove in relation to the transepicondylar axis, the bicipital groove is not always a reliable landmark (Kummer et al. 1998)

For the alignment of the glenoid component, less anatomical characteristics can be used because most of the scapula is covered by muscles and other soft tissues and is, therefore, invisible during the procedure. The only visible part of the scapula is the glenoid surface, which is rather small and is located deeply in the wound. A pre-operatively CT, roentgen or MRI scan gives insight into the position of the glenoid towards the scapula.

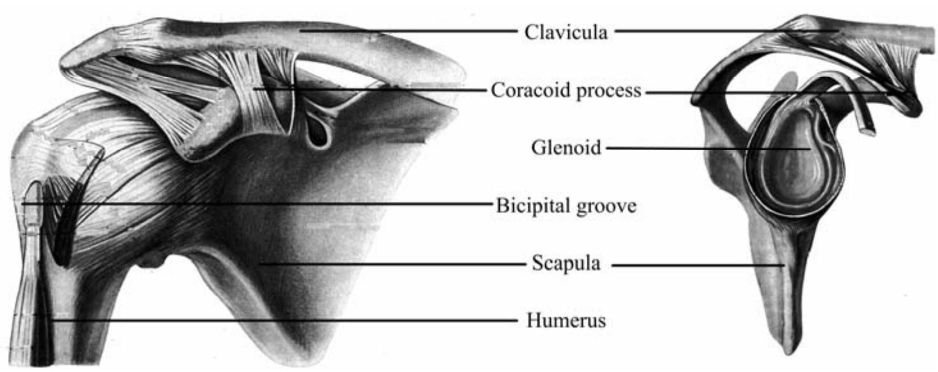

***Figure 6.5**: Anatomy of the shoulder. The left figure shows the anterior view and the right figure a detailed view of the glenoid. The figures are adapted from the atlas of Sobotta (Sobotta 2003).*

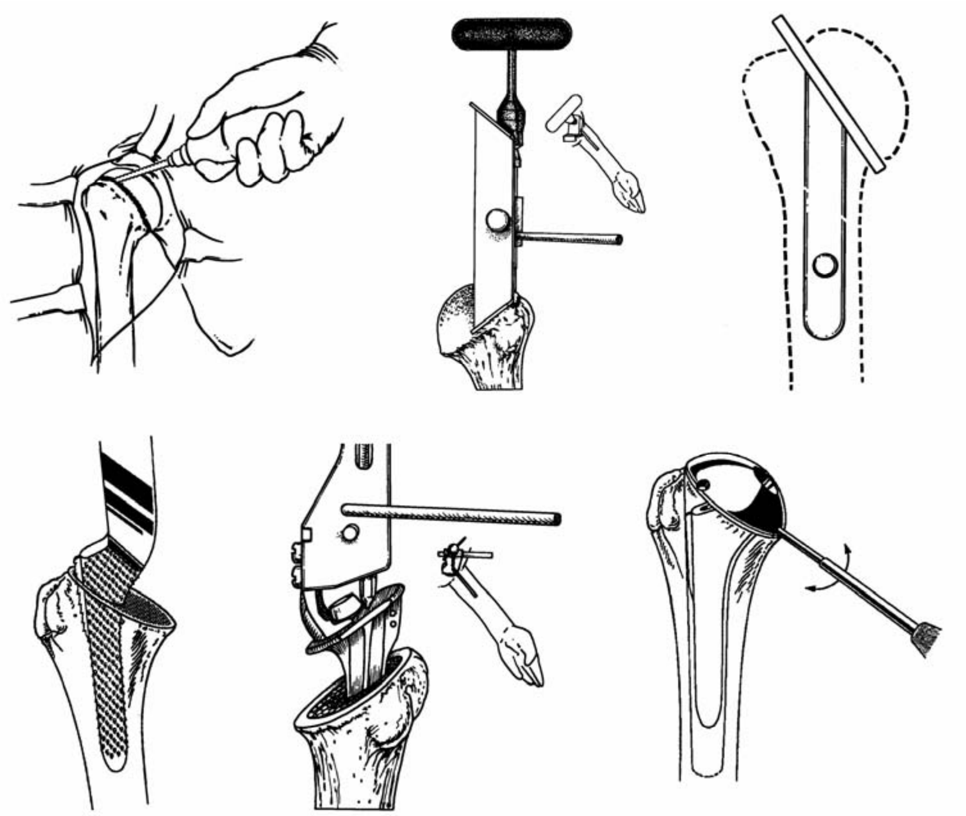

***Figure 6.6**: Humeral alignment guides of different shoulder prostheses. The top row shows different sawing methods: free hand, intramedular guide and extramedular guide. The second row shows two rasp methods: free hand and guided raping ands a possibility to adapt the humeral head to the saw cut. The figures are adapted from different prosthesis. In the upper row respectively from the Biomet shoulder, the 3M shoulder and the Biomet shoulder; and in the last row from the Anatomical shoulder, the Kirschner shoulder and the Anatomical shoulder.*

Available instruments

Figures 6.6 and 6.7 show examples of the different alignment instruments used for shoulder joint replacements. Several similarities can be seen between the different instruments and these will be described in the text.

The humerus: The alignment of the humerus consists of three steps: sawing of the head, preparation of the canal and determining of the head size and position (Figure 6.6). For sawing of the humeral head, two different methods can be used. For the first method, the head is sawn off by eye and the prosthesis can be adapted to variations in the angle of the saw cut. For the second method, the head is sawn off in a fixed angle and intra or extramedular guides are used to determine the sawing angle. For the intramedular guide, a rasp is placed in the stem and the cutting guide is attached to the rasp and fixated to the bone. The extramedular guide is placed outside the bone on the humerus and can use the middle point of the head or the epicondylar axis of the elbow as alignment marker. On some guides, a rod can be placed which should be perpendicular with the forearm to determine the angle of rotation of the humerus, before the saw cut is made.

The preparation of the humerus is important for prostheses with large stems; the humeral shaft is prepared with a series of rasps and broaches according the prosthesis size. Observation studies showed that rasping in the correct angle was sometimes difficult, because the rasp had the tendency to displace due to varying bone densities (Chapter 4). For prostheses with small stems, e.g. the Eska and the Copeland, the direction of the stem is less important, because the stem stays inside the humeral head.

Finally, the humeral head size is determined. Most prostheses have a special measurement device to measure the size of the original head, so the surgeon can place a prosthetic head with a comparable size.

The glenoid: For the alignment of the glenoid, only a small variation in instruments exists (Figure 6.7). For most prostheses there is a guide which is placed over the glenoid to drill the holes. The hole made with the first guide can be used to align the next instruments like the broach. Finally, a guide is placed to align the holes for the pegs or the keel. Some prostheses have rasps in the shape of the keel, to rasp the right shape and size hole. For the Delta prosthesis, the surgeon drills a hole for a pin in the middle of the glenoid without a guide and all other instruments are guided by this pin.

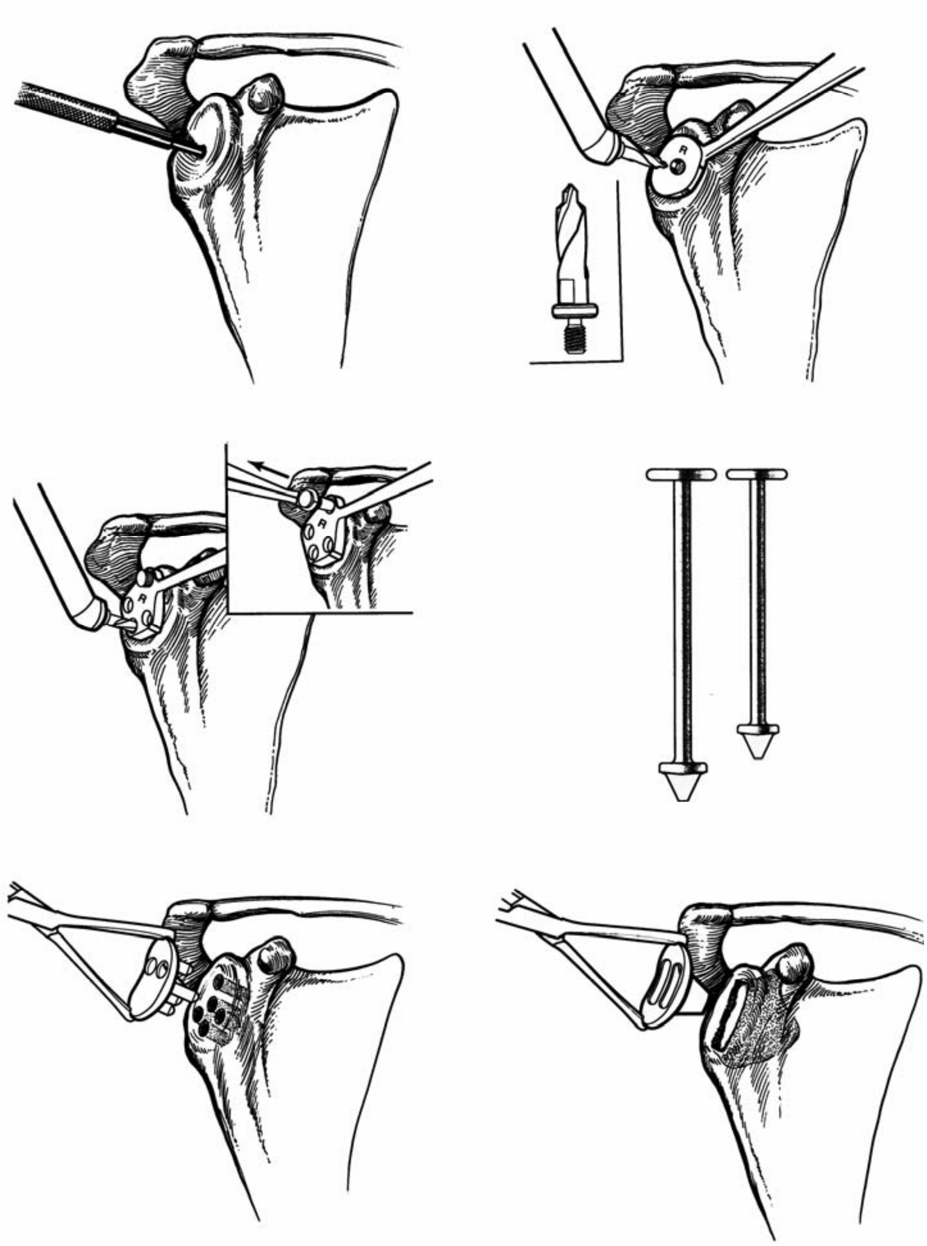

Figure6.7: *Glenoid alignment guides. The top row shows the drilling of the central hole with or without a guide. The second row shows the preparation of the glenoid for the pegged or keel type. The bottom row shows the testing of both type of glenoid prosthesis. All figures are adapted for the Global prosthesis (DePuy).*

The elbow

Prosthesis design:

The elbow is a hinged joint, with 130 degrees flexion around one axis. Only in the extreme positions, the axis is not strictly defined. Three types of elbow prostheses can be distinguished:

- Linked prostheses allow only flexion movement and because of the high forces, they have a high risk of loosening rates and are not commonly used.
- Semi-constrained prostheses allow small deviation of the flexion movement.
- Non-constrained elbow prostheses allow more movements but their stability depends on the quality of the ligaments.

For the alignment of the elbow prosthesis, the direction of the flexion axis is more important than the position of the component (Schuind et al. 1995). Small displacement of the humerus component did not change the movement pattern (King et al. 1993; Schuind et al. 1994; Schuind et al. 1995) but placement of the humeral component in a false rotation angle significantly changed the motion pattern and muscle moment arms, which might lead to high stresses at the bone-cement-implant interfaces and thereby to early aseptic loosening (Schuind et al. 1994, Schuind et al. 1995; Stokdijk et al. 2003).

Alignment methods

The elbow joint surfaces are rather small, but with several clear landmarks (Figure 6.8). Also, the rotation axis of the elbow can be identified by moving the elbow, although for patients with bone diseases like rheumatic arthritis, the rotation axis may have become unclear (Stokdijk et al. 2003).

Available instruments

A large number of elbow prosthesis designs exists and all prostheses have their own alignment instruments. In this study, the alignment instruments of five prostheses will be discussed: the Souter-Strathclyde, the iBP, the Kudo, the Solar and the Coonrad-Morrey.

The humerus: For the humerus component, two types of prostheses are available: an intramedular and a surface replacement (Figure 6.9). For the intramedular prostheses, the epicondyles are preserved. The Souter-Strathclyde and the Solar are intramedular prostheses. For the Souter-Strathclyde elbow prosthesis, a template is used to draw the shape of the prosthesis with ink on the humerus. The inside of the shape is removed by sawing and drilling. Most of the bone preparations for the Souter-Strathclyde prosthesis is performed by eye and with help of the trial prosthesis and, therefore, a large amount of surgical experience is needed. The Solar prosthesis also uses a template and methyl blue to remove the first part. Once the first bone is removed, a cutting guide is placed intramedular for the final adjustment of the humerus alignment.

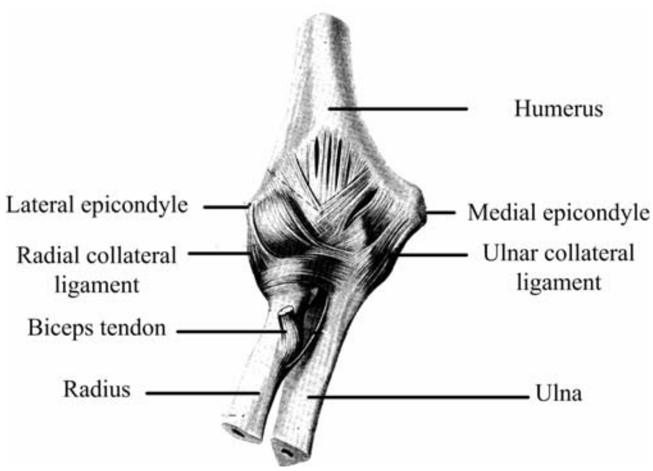

Figure 6.8: *Anatomy of the elbow. The figure is adapted from the atlas of Sobotta (Sobotta 2003).*

The iBP, the Kudo and the Coonrad-Morrey replace the surface of the humerus. For the Coonrad-Morrey, the midportion of the trochlea is prepared with a rongeur or saw to identify the canal, so the reamer can enter. A humeral alignment guide is placed into the humeral canal and the humerus is sawed accordingly. For the Kudo prosthesis, a special two blade saw is used to drill a hole in the humerus. The remaining preparation is performed by eye. For the iBP prosthesis an intramedular guide is placed to align the position of the component and a template is used to remove bone for the bearing of the prosthesis.

The ulna: For all five prostheses, the ulna part is mainly prepared by eye with the help of test prostheses (Figure 6.9). Only a shaped rasp is available to align the stem for most elbow prostheses. For the Coonrad-Morrey prosthesis, a special handle can be attached to the rasp, to determine the orientation of the shaft.

For elbow replacements, two studies have been performed concerning the accuracy of the instruments. The instruments of the iBP elbow allow the surgeon to place the prosthesis with the same direction of the axis, although the position changed. Therefore, the instruments should be changed, by adding a control point for the distal alignment, for example the relation between the lateral epicondyli humeri and the average kinematical elbow axis in vivo (Stokdijk et al. 2003). The instruments of the Norway elbow (not discussed above) also allow the surgeon to correctly align the humerus, but the orientation of the ulna component was highly variable for the Norway elbow, because of the difficult reproducibility of the anatomical axis (King et al. 1993).

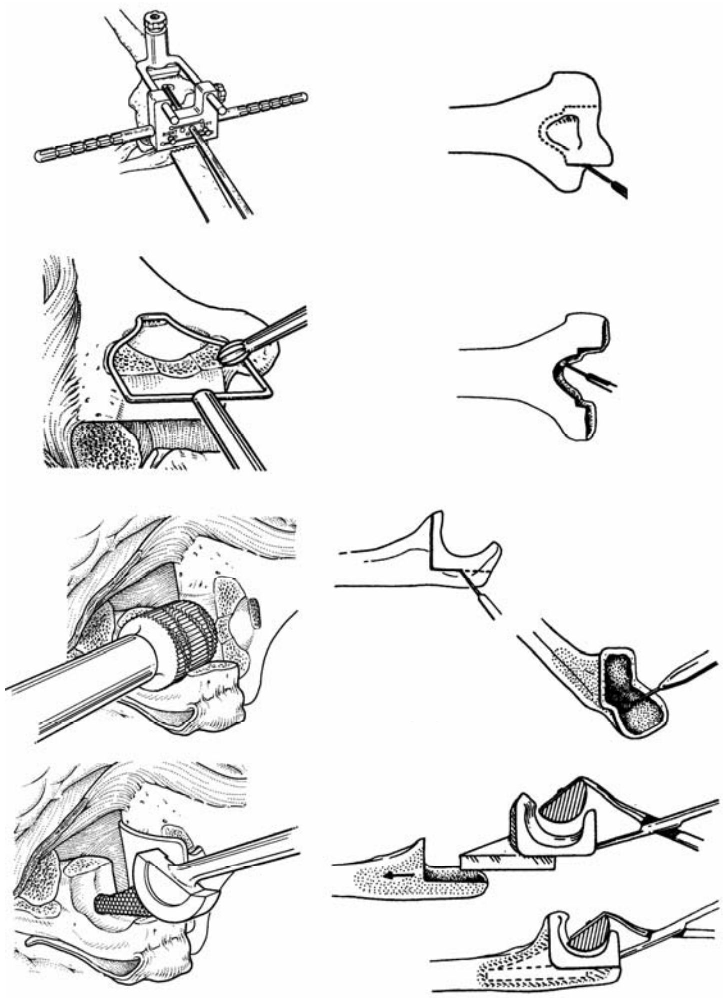

Figure 6.9: *Elbow alignment guides. For the elbow, figures of the iBP (Biomet) and the Souter-Strathclyde (Howmedica) elbow are shown in respectively the left and right column. The upper four figures show instruments for the alignment of the humerus, the lower four figures for the ulna.*

Discussion and recommendations

In this study, alignment instruments for knee, elbow and shoulder joint replacements have been evaluated to get a better insight into the available alignment instruments. The literature showed that a correct alignment of a joint consists of three steps: correct placement of the alignment instrument in relation to the bone, fixation of the guide and preparation of the bone. All three steps are vulnerable for errors. The alignment because the bone geometry varies from person to persons. The fixation because the pins can displace during insertion and because movement possibilities of the guide after fixation. The preparation because the preparation instrument can displace in the guide. For knee joint replacement, a large number of studies has been performed on the alignment instruments and the best alignment axis. These studies have lead to a range of successive alignment instruments. For shoulder and elbow prostheses, less studies concerning the alignment instruments have been performed and less alignment instruments are available.

Similarities and differences between the joints

The alignment of a prosthesis consisted of three steps: alignment, fixation and preparation. For knee joint replacement, studies have been performed concerning all three steps. Some of the conclusions and rules derived from these studies might be useful for elbow and shoulder replacements, where other rules are joint dependent.

The first step, the alignment of the alignment instrument in relation to the bone, depends on the anatomy of the joint. Joint surfaces with small variation between subjects and clear landmarks are easier to align than joint surfaces with high variation between subjects or flat surfaces. Also, the size and the visibility of the joint surface influence the possibility for misalignment. Some advantages and disadvantages of alignment methods like intra- or extramedular guides and the use of adjoining joints might be comparable for all joint. However, to determine the best alignment method for the shoulder and elbow more research is needed.

The second step, the fixation of the guide is less joint dependent, because for all joints equal fixation techniques, e.g. pins and clamping, are used. In all joints, the pins and drills will have the tendency to move to the softer bone (Plaskos et al. 2002) and a combination of fixation methods will probably result in the strongest fixation (Otani et al. 1993). However, for some joint surfaces not all fixation methods can be used. For example large pins may be too large for small bones e.g. the ulna and the glenoid.

The third step, the preparation is independent of the joint, because for all joints similar preparing instruments e.g. saws and drills are used.

Recommendations for the shoulder alignment

The shoulder joint is more similar to the hip than to the knee joint. For the hip, a larger alignment error is allowed than for the knee (Harris 1980; Kummer et al. 1999; Lewinnek et al. 1978) Probably, for the humeral head also a larger alignment error is acceptable (McMahon et al. 2003; Williams, Jr. et al. 2001). The alignment error for the humeral head guides has not been determined, but the small risk of loosening for humeral heads (Wirth et al. 1996) indicates that the error is probably acceptable.

For the glenoid, the alignment is probably more crucial, because the glenoid is smaller and the inclination angle of the glenoid affects the force required to subluxate the humeral head and, thereby, the possibility of subluxations (Wong et al. 2003). Several authors (Post et al. 1998; Rockwood, Jr. 1990) have described how the glenoid should be aligned, but no studies have been performed to analyze whether these rules are right and how accurate the glenoid is actually placed. In hip replacements, eighty-two percent of the acetabular cups were not placed as intended (DiGiolia et al. 2002). For glenoid alignment, the same results can be expected, because of equal problems: the bone is deep in the wound, the bone can not be fixed and the orientation of the bone is unknown per-operatively.

The development of instruments for glenoid components is difficult, because of the small size of the glenoid, the difficult assessment and the movable scapula. The placement of one K-wire in the middle of the scapula is probably sufficient to align the remaining instruments, because they can be placed over this K-wire (Figure 6.10). Two options are available for the alignment of this K-wire: mechanical fixtures or computer assisted surgery. Valstar (unpublished data) developed patient specific fixtures for the alignment of the glenoid, but the accuracy of placement was comparable between glenoids placed using a mall and glenoids placed without a mall. Further research will be performed Computer assisted surgery has shown to improve the accuracy and repeatability of the placement of the acetabulum cup, but has up till now not been used for glenoids.

For computer assisted surgery, two additional steps are introduced: placement of reference markers on the bone and recording of the bone shape to match the computer model with the patient's anatomy. Both steps may cause problems for the glenoid. For the placement of the reference markers, the size of the glenoid is too small and additional incisions are needed to place the markers on a different part of the scapula. The registration of the glenoid can be insufficient, because of the small amount of available palpable bone which is covered with soft tissue. In addition, the operation area is small and, therefore, the reference marker might hinder the surgeon during preparation actions. Likewise, the surgeon or other team members might get in the way of the camera and, thereby, block the camera's views of the reference markers. No studies have been published about the use of computer assisted surgery for shoulder joint replacements. However, the two problems can be solved by e.g. a good placement of the markers. Computer assisted surgery can be useful to accurately place the glenoid prosthesis.

Figure 6.10 *(right figure): K-wire for the glenoid. In the center of the glenoid a K-wire (small iron bar) is placed, which can be used to align future instruments. The figure is adapted from the atlas of Sobotta (Sobotta 2003).*

Figure 6.11 *(left figure): Possible alignment instrument for elbow prostheses. A frame can be places along the ulna, fixed on the wrist and the olecranon. The figure is adapted from the atlas of Sobotta (Sobotta 2003)*

Recommendations for the elbow

The elbow joint resembles the knee joint. Both joints have one major movement axis and small rotation in different directions and both joints have long bones. The direction of loading is different for both joints and also the pathology of the patient may vary. Still, the similarities between the bones indicate that the knee alignment instruments may be example for the elbow alignment instruments.

The humeral instrumentation of the iBP elbow prosthesis already has an alignment instrument comparable to the femur alignment instruments and this instrument was also reliable for the alignment (Stokdijk et al. 2003). Also, the instruments for the Norway elbow were sufficient (King et al. 1993). For the other elbow prostheses comparable humeral instruments are needed.

For the ulna, all instruments were mainly based on visual inspection. An intramedular instrument might be difficult for the ulna, because of its small size. An extramedular guide might be possible. For the tibia, the guide is aligned with the help of the ankle joint. For the ulna, the guide might also be aligned with help of the wrist (Figure 6.11). Both the wrist and the elbow can be seen on roentgen photos, so the surgeon can pre-operatively determine this distance. Also the wrist can help to determine the rotation of the component, but more research is needed.

Conclusion

The knee alignment guides and the studies concerning knee alignment have been evaluated to give guidelines for improvement of the alignment of shoulder and elbow prostheses. Some of the alignment rules for knee prostheses are general for all joints, were other rules are joint dependent. For the shoulder, the glenoid alignment can be improved with mechanical fixtures or computer assisted surgery. For the elbow, alignment instruments comparable to the knee alignment instruments can be developed.

Chapter 7

Evaluation of the peroperative

Process of knee joint replacements with computer assisted surgery

Joanne PJ Minekus; Rob GHH Nelissen; Mike JA van Steijn; Jenny Dankelman (Submitted)

Summary

Time-action analysis was used to study the first experiences of two surgeons using computer-assisted surgery for knee joint replacements. For the first surgeon, five traditional knee replacements and the first 7 computer-assisted knee joint replacements using the Brainlab system (Munich, Germany) were evaluated. For the second surgeon, two traditional and two computer-assisted knee joint replacements (Stryker, Freiburg, Germany) were evaluated. The second surgeon had performed 20 computer-assisted procedures before this study. Computer-assisted surgery increased the operation time with approximately 40 minutes. The first computer-assisted procedures took even longer. Besides the extra actions needed to calibrate the computer, the Brainlab system increased the femur phase because of the difficult positioning of the cutting block and the Stryker system increased the testing phase because of the ligament balancing. In the future, training methods should be developed to reduce the learning curve. The additional operation time can be reduced by development of easier alignment instruments.

Introduction

Knee joint replacements are common procedures in orthopaedic surgery. Knee joint replacements give pain relief, function restoration and have a survival fraction of 90-100% in 10 years (Rand et al. 2003; Ritter 2002; Robertsson et al. 2001). The results depend on the condition of the patient, the used prosthesis and the alignment of the prosthesis (Elias et al. 1990; Figgie, III et al. 1986; Rand et al. 2003; Stulberg et al. 2002; Thoma et al. 2000). For good functional results, the prosthesis should be placed with an accuracy of 4 degrees (Mont et al. 1997; Novotny et al. 2001; Otani et al. 1993). Achieving accurate positioning of the knee prosthesis requires the surgeon to identify and mark the tibia and femoral mechanical axis and to align and mount the cutting guides to these axes to perform the bone cuts (Plaskos et al. 2002). In about 5 to 10 percent of the knee prosthesis, the required accuracy was not reached even when modern guides were used (Stulberg et al. 2002). The accuracy of the alignment can be improved by using computer assisted surgery (CAOS) (Jenny et al. 2001; Sparmann et al. 2003; Stulberg et al. 2002).

This study evaluates the first experiences of two surgeons using computer-assisted surgery for knee joint replacements analysis. The two surgeons used different navigation systems. The surgical process of the computer-assisted knee joint replacements was compared with the surgical process of traditional knee joint replacements using time-action analysis (Chapter 3). The results are used to give guidelines for improvements for computer-assisted surgery.

Methods

Surgical procedure

Sixteen knee joint replacements of two experienced knee surgeons in two hospitals were evaluated. Surgeon A had no previous experiences with computer-assisted surgery. Surgeon B had performed 20 computer-assisted knee joint replacements before the start of this study. Both surgeons worked in a training hospital for nursing staff.

Surgeon A placed five knees prostheses using the traditional method (Trad A) and seven knee prostheses using the Brainlab computer-assisted system (Brainlab, Munchen, Germany). For the first four computer-assisted procedures, surgeon A used the CT-based method (CAS A, CT-based). For the following three procedures, surgeon A used the CT-free method (CAS A, CT-free). Surgeon A used the NexGen knee prosthesis (Zimmer, Warsaw USA). All patients of surgeon A had rheumatoid arthritis. During the computer-assisted procedures, all alignment steps were checked using the traditional mechanical instrumentation for knee replacement surgery.

Surgeon B placed two knee prostheses using the traditional method (Trad B) and two knee prostheses using the Stryker CT-free computer-assisted surgery system (Stryker, Freiburg, Germany) (CAS B, CT-Free). Surgeon B used the Stryker knee prosthesis (Stryker Leibinger, Freiburg, Germany) for one traditional and the two computer-assisted procedures. He used the NexGen knee (Zimmer, Warsaw, USA) for the second traditional knee replacement. All patients of surgeon B had arthrosis.

Two types of CAOS systems are used: CT-based and CT-free. For the CT-based procedures, a CT-scan is made. Pre-operatively, the CT-scan is used to make a patient-specific knee model and to determine the optimal position of the prosthesis. Therefore, the surgeon marked several anatomical landmarks on a CT-scan of the patient. Per-operatively, the surgeon placed the navigation marker trees on the bones and calibrated the CT-model with the patient anatomy by locating the anatomical landmarks on the patient with a special pointer. For the CT-free procedure, no additional pre-operative planning is needed. Per-operatively, a general knee model was adapted to the patient’s knee by marking several anatomical landmarks and bony surfaces with the pointer. The computer calculates the best position of the prosthesis, but this position can be adapted by the surgeon.

According to the pre-operative condition of the knee, knee joint replacements can be classified as standard or complicated procedures. Knees with a neutral alignment are classified as standard knees. Knees with deformities of more than 15 degrees (varus, valgus or flexion contracture) are classified as complicated because additional soft tissue release is needed. For surgeon A, five knee replacements (2 traditional and 3 CT-based) were classified as standard and the remaining seven knees were classified as complicated. For surgeon B, two knees (one traditional and one CT-free) were classified as standard and the remaining two knees were classified as complicated.

Time-action analysis

Video recordings of the surgical procedure were made using two cameras, one giving an overview of the total operation field and one placed on the head of the surgeon giving a detailed view of the hands of the surgeon. The images were recorded simultaneously with the sound using a mixing device. The procedures were analysed off-line with a time-action analysis method (Chapter 3). The recordings did not interfere with the surgical process; the medical ethical committee of the Leiden University Medical Center approved the research.

Each procedure was divided into eight phases (Table 7.1). In all phases, the surgeon performed several actions, which were identified with a thesaurus of 50 actions. For clarity, the actions were grouped into eight different functions (Table 7.2). The durations of all phases and functions were measured.

Statistics

The duration of the different phases and the duration of the used tasks were compared using a student t-test. A p-value smaller than 0.05 was considered to be significant.

Table1: *The phases during a knee joint replacement.*

Phase	Definition
Exposure	Open the skin and soft tissue
Calibration	Place navigation markers and match the patient's anatomy to the computer model.
Tibia	Prepare and align the tibia component
Femur	Prepare and align the femur component
Patella	Prepare and align the patella component
Test	Test the prosthesis
Prosthesis	Insert the prosthesis
Closure	Close the wound

Table 7.2*: Taxonomy of functions*

Function	Definition
Preparing	Preparing the bone and soft tissues with e.g. knives and saws
Aligning	Aligning and placing of the prosthesis
Suturing	Placing of sutures
Observing	Observing the wound or the surgeon
Exposing	Placing and retaining retractors to expose the wound.
Bleeding	Checking for bleedings and stopping them.
Miscellaneous	Actions that could not be identified or classified within the other functions
Waiting	Not performing actions or performing actions which do not contribute to the surgical procedure.

Results

Traditional knee replacements

The traditional knee replacement of surgeon A took on average 106 minutes (range 84-136 minutes) and of surgeon B 104 minutes (range 88-120 minutes) (Figure 7.1). No significant differences between the traditional knee replacements performed by both surgeons could be found. The duration of the total operation time, the different phases and the used functions varied largely between procedures. The duration of the exposure phase was longer for knees which were classified as difficult procedures according to the preoperative condition. The other phases did not depend on the pre-operative situation of the knee.

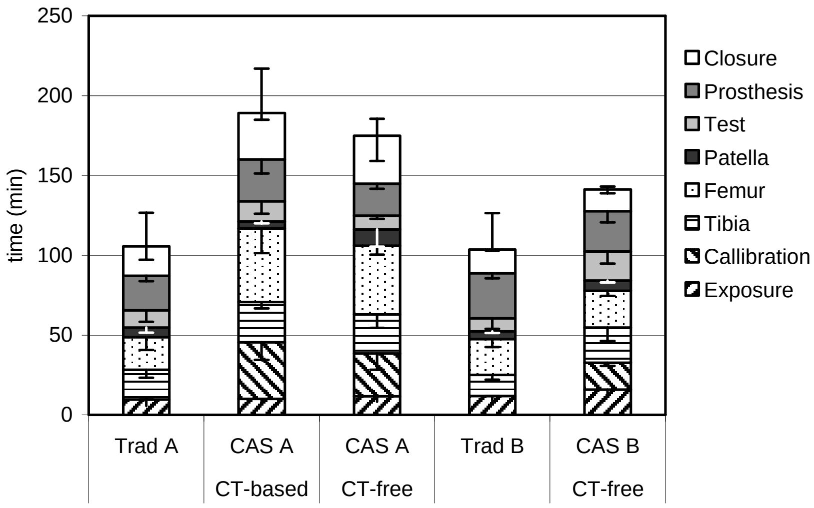

Figure 7.1: *Average duration of the traditional (Trad) and computer assisted (CAS) procedures performed by the two surgeons (A and B). The CT-based procedures are indicated with + and the CT-free procedures with a -. The phases are explained in Table 7.1.*

Computer assisted surgery

Surgeon A: The first seven computer-assisted procedures of surgeon A took on average 83±28 minutes longer for CT-based and 65±11 minutes longer for CT-free procedures compared to traditional knee joint replacements (Figure 7.1). Four phases showed an increase in duration (Figure 7.2):

1. The calibration phase. For computer-assisted procedures, an additional phase was needed to calibrate the patient's anatomy to the computer model. The calibration for the CT-free procedure was more extended, because the surgeon had to mark more anatomical landmarks. In the second and fourth CT-based procedure the calibration had to be repeated because of insufficient correlation between the CT-model and the patient's anatomy.

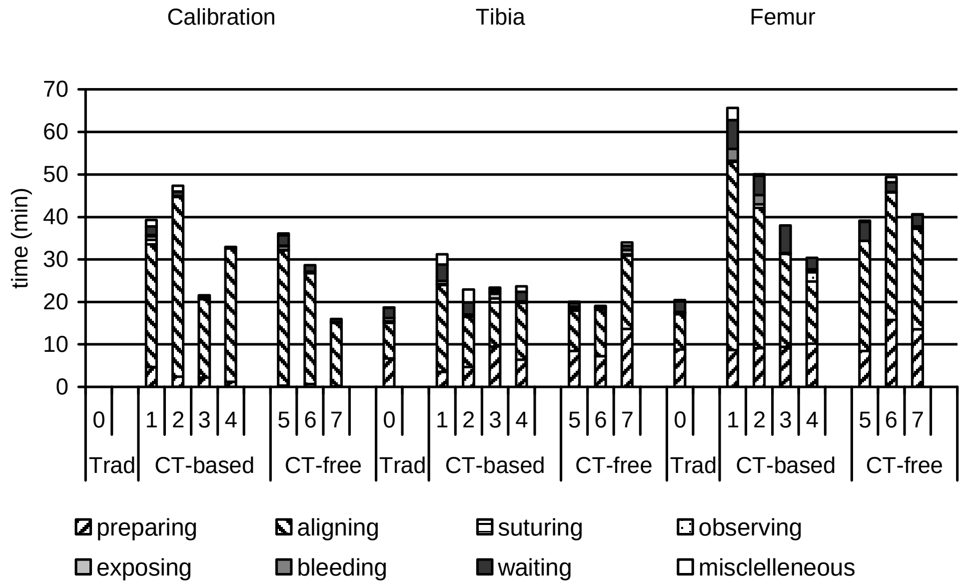

Figure 7.2: *The effect of computer navigation on the operation process during the first seven knee joint replacements of surgeon A. The numbers give the order of the procedures. The CT-based procedures were performed prior to the CT-free procedures. The Functions are explained in Table 7.2.*

2. The tibia phase. The tibia phases of computer-assisted procedures were comparable to traditional knee replacement, except for the first CT-based and the last CT-free procedure. In the first CT-based procedure, the surgeon checked the alignment of the computer using the traditional approach. In the last CT-free procedure, the surgeon sawed less bone than the computer advised. After testing, the advice of the computer was found to be correct and the tibia cut was repeated according to the computer's proposal.

3. *The femur phase.* During computer-assisted procedures, the alignment of the femur took longer. During the traditional knee replacements, an intramedular guide was used to place the femur cutting block. During the navigated procedures, the surgeon placed the cutting block with help of the computer and had to control 4 degrees of freedom while

watching the monitor instead of his hands. This resulted in easy displacement of the cutting block and, therefore, in a longer duration for the alignment. Also this step was double checked with the traditional -mechanical axis- alignment method.

4. *Closure phase.* The procedures were performed under pneumatic control. Because the computer-assisted procedures took over 120 minutes, the pneumatic control had to be released with a pressure bandage. This caused an extra waiting time and extra actions needed to stop the bleedings.

Surgeon B: The computer assisted procedures of surgeon B took 38 minutes longer compared to traditional knee joint replacements (Figure 7.1), because of the additional calibration phase and an increased duration of the test phase (Figure 7.3). The test phase was increased, because the computer was used to measure the ligament tension and to balance the ligaments.

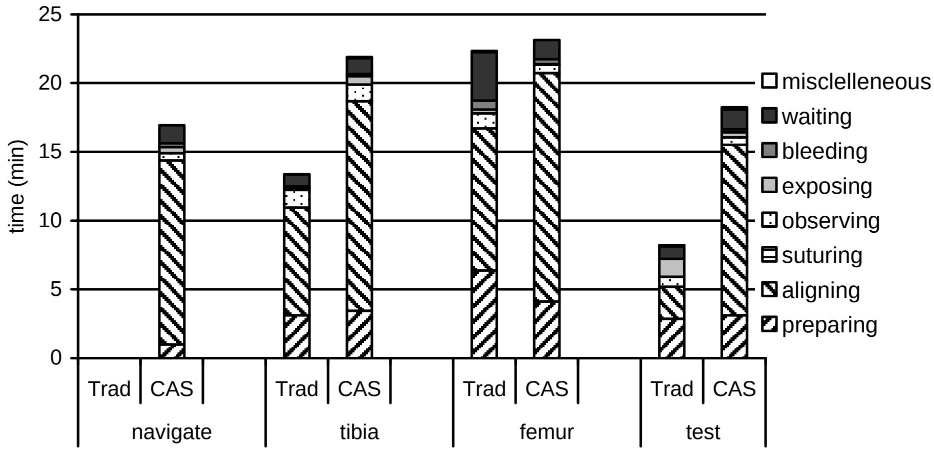

Figure 7.3: *The effect of computer navigation on the operation process during joint replacements for surgeon B. The Functions are explained in Table 7.2.*

Waiting: In all procedures, the surgeons had to wait for the cementing process and the scrub nurse needing time to find and hand over the needed instruments (Table 7.3). The computer-assisted procedures for surgeon A showed longer waiting times for instruments handling, because the nurses were inexperienced with the navigation system and needed more time to find and set up the navigation instruments. The navigation also caused extra waiting to adjust the positioning of the camera. The time needed to adjust the camera position decreased when the surgeons and nurses became more experienced with the camera system. No differences were found in the waiting times for surgeon B.

Table 7.3: *Occurrence of waiting*

	Trad A		**CAS A CT-based**		**CAS A CT-free**		**Trad B**		**CAS B CT-free**	
Waiting for:	**t**	**n**	**t**	**n**	**t**	**n**	**t**	**n**	**t**	**n**
Instruments	4.9	39	10.3	46	6.9	31	5.5	35	7.2	42
Cement	5.3	5	6.8	4	5.7	4	7.4	6	7.5	3
Prosthesis	4.3	5	5.4	4	0.0	0	0.9	2	0.4	2
Navigation	0.0	0	1.2	3	5.1	2	0.0	0	0.2	1
Miscellaneous	2.2	11	7.5	3	7.8	3	3.0	7	1.2	6
Total	16.7	60	31.2	60	25.0	41	16.9	49	16.4	53

Legend:

t: average duration in minutes

;n: average number of occurrence

Trad A and Trad B: Traditional procedure of surgeon A and B, respectively.

CAS A and CAS B: Computer-assisted procedure of surgeon A and B, respectively.

Discussion

The use of a computer navigation system for a knee replacement increased the operation time with approximately 40 minutes because of extra actions needed to calibrate the computer. During the first experiences with computer-assisted procedures the operation time was even higher. In this study, two different navigation systems, Stryker and Brainlab, were evaluated. Both systems increased the operation time because of an additional calibration phase. Additionally, the Brainlab system also increased the femur phase because the prosthesis manufacturer (Zimmer) did not provide instruments for computer assisted surgery. This made the surgical procedure more difficult in positioning of the cutting block. The Stryker system has special instruments for computer assisted surgery, because it is a navigation system made by the prosthesis manufacturer (Stryker). However, the Stryker system increased the testing phase because of the ligament balancing.

The additional calibration phase during computer-assisted procedures is needed to relate the patient’s anatomy to the computer model. This phase consists of several additional steps: placement of the marker tree, palpating anatomical landmarks and computer calculating to adapt the model to the patient's anatomy or to determine the optimal prosthesis position for the CT-free system. The time needed for the calibration decreases when the surgeon gets more experienced, but will take approximately 15 minutes. The navigation system might reduce the time needed to align and test the tibia and femur phases, although for neither surgeon the time needed to align the prosthesis was reduced by using the navigation system. The tibia, femur and test phases of the traditional knee replacements had an average duration of 45 minutes, of which twenty minutes were used for the alignment. Based on the tasks that have to be performed during the alignment of the prosthesis, it is expected that the additional duration of the calibration phase can not be compensated by reduction the duration of the other phases.

The alignment of the prosthesis is important for a good functional outcome (Mont et al. 1997; Novotny et al. 2001; Otani et al. 1993) and this is supposed to be improved by CAOS in knee surgery (Sparman 2003). For both evaluated computer-assisted systems, markers were placed on the mechanical alignment instruments. For the Stryker system, the guides were roughly aligned by eye and then fine tuned using screws with help of the navigation system. For the Brainlab system, the guides have to be placed correctly at once since the prosthesis manufacturer (Zimmer Inc) did not provide CAOS instruments to the Brainlab system. Therefore, the surgeon had to control four degrees of freedom, while looking at the screen and not at the guide that had to be positioned. Therefore, a good CAOS software system (i.e. the virtual presentation of the surgical field) should go hand in hand with good surgical instrumentation tools.

Ligament balancing is important for the outcome of a knee replacement. Both CT-free navigation systems can measure the ligament balance. For the Stryker system, the measurement took approximately 5 minutes additional operation time, because the ligament tension is calculated during several steps of the flexion movement. For the Brainlab system, measuring of ligament tension is less extensive and took no additional operation time. The measured ligament tension is used to determine the amount of needed soft tissue reconstruction (Nizard 2002). The possibility to measure the ligament tension is an advantage of the CT-free navigation system; however, it does increase the operation time for one tested system.

The first computer-assisted procedures increased the waiting time, because the nurses needed time to find and prepare the instruments. Both surgeons worked in a hospital with teaching facilities for nurses. Junior nurses experienced knee replacements as complicated procedures, because of the large number of necessary instruments. The computer navigation increased the number of instruments and, thereby, made the procedures even more complicated for the junior nurses. Probably with more training of the nurses, waiting for instruments will be reduced.

If a new technique is introduced into surgery, the surgeons and nurses get an introduction course and then the technique is used on the patients. This study showed a learning curve needed to get familiar with the system. Therefore, the patient had a longer anaesthesia time, with additional risk for co-morbidity. However, in none of the cases this was experienced. Based on our observations, it is recommended that the surgical team starts with training on a sawbones model, or even better, since soft tissue is present, on a cadaver specimen. Also, a simulator model might be developed in which the surgical team can train the procedure (De Siebenthal et al. 2003). Training can reduce the duration of the first surgical procedure on a patient with approximately 15 minutes.

Two navigation systems are in use: CT-free and CT-based. The CT-based system requires a CT-scan and extra time for the pre-operation planning of approximately 10 minutes. The pre-operative planning is normally scheduled the day before the procedure. However, delays in the program or emergencies can reduce the time available for the pre-operative planning. Randomized studies comparing the accuracy of both studies have not been published. From a time management point of view, the CT-free system is preferable above the CT-based system. But abnormal anatomy might be the indication for a CT-based knee prosthesis, since the models used in the CT-free software modules are based on normal anatomy.

Conclusion

The computer-assisted procedure increased the operation time with approximately 40 minutes, because of an additional calibration phase and more time needed to arrange the instruments by training nurses. Depending on the used navigation system, also more time is needed to align the cutting blocks or the ligament balancing. During the first experiences with computer-assisted procedures, the operation time was higher, but a quick learning curve was observed. In the future, training methods should be developed to reduce the learning curve. The additional operation time should be reduced by development of easier alignment instruments. Thus the development of CAOS software should be paralleled with the development of instrumentation by the prostheses manufacturer, which should be focused on the possibility of fine adjustment of three degrees of freedom. A CT-free system is, from a time management point of view, preferable above a CT-based system.

Chapter 8

General discussion

Main findings

The goal of this thesis was to give recommendations to improve the surgical process of shoulder and elbow joint replacements. Therefore, an inquiry has been performed among shoulder surgeons (Chapter 2) and shoulder, elbow and knee joint replacements have been evaluated using time-action analysis enhanced with error analysis (Chapter 3, 4 and 5). The inquiry showed that the surgeons experience the alignment of the glenoid component as the most difficult part of the procedure. The inquiry also showed a large variation in surgical techniques between the surgeons, which indicates that the best technique has not been established. The time-action analysis studies showed that the main limitations for shoulder and elbow joint replacements were repeated actions and waiting. Repeated actions were caused by the alignment instruments inadequate to align the prosthesis correctly at one. Waiting was caused by the cementing process, the logistics and inexperience of scrub nurses. For traditional knee joint replacements, waiting is also a limitation. However, repeated actions are less common compared to shoulder or elbow replacements, because the alignment instruments for knee replacements are more sophisticated.

The post-operative results of a joint replacement depend on the alignment of the prosthesis (Mont et al. 1997). For knee replacements, a large amount of research has been spent on the alignment and newer techniques, e.g. computer assisted surgery, became available. By evaluating and comparing the alignment instruments for knee, shoulder and elbow joint replacements, recommendations to improve the shoulder and elbow alignment instruments could be obtained (Chapter 6). Computer assisted surgery improves the alignment of the prosthesis, but also increases the operation time by adding an operation time and by more time spent on the alignment because of the complex instruments (Chapter 7).

This general discussion will give some remarks concerning the time-action and error analysis method. Also, new research areas for time-action and error analysis should aim to explore the possibility to reduce the operation team, the logistic of the operation theatre and the teaching of resident surgeons. Furthermore, this thesis is part of the DIPEX project (Development of Improved Prosthesis for the upper Extremity at the Delft University of Technology) and therefore this thesis will be placed in relationship with the other DIPEX projects. Finally, all the recommendations derived in this thesis for improvements for shoulder and elbow joint replacements and for computer assisted surgery will be summarized.

Time-action analysis

This study showed that time-action analysis can be used to evaluate open surgical procedures such as joint replacements and that the result of this time-action analysis gives insight into the per-operative process. This insight can be used to improve the surgical process during joint replacements and to evaluate the effect of new techniques e.g. computer assisted surgery. Besides these advances, time-action analysis has several limitations (Chapter 3). Firstly, the reason of the surgeon to perform certain actions is not always clear. Therefore, discussion with the surgeons is a very important part of the time-action analysis. Secondly, the result of time-action analysis does not necessarily correlate with the surgical outcome. A longer operation time can improve the surgical outcome and decrease the complication rate, although it also may increase the risk of infection. Time-action analysis gives insight into surgical procedures, but communication with the persons involved and placing the results into the surgical context is needed.

The performance of a time-action analysis is very time consuming. The analysis of one recorded procedure took one to three times the operation time. For regular use of time-action analysis, this time should be reduced. The analysis consisted of 2 steps: collecting the data by observing the videotapes and analysis of the data using computer programs, e.g. excel and matlab. Collection of the data is most time consuming, because often the tape has stopped to make notes. Also, the tape had to be replayed several times, because the beginning of an action was missed, or the action was not correctly identified, e.g. some instruments can be used for different tasks. The analysis of the data is less time consuming and was performed automatically. The duration of the data collection can be reduced by using a video editing system with a direct coupling to the computer (e.g. Observer®). The duration of the evaluation can also be reduced by focusing on fewer research questions. Then, only part of the procedure needs to be evaluated, or the procedure can be evaluated less precise, e.g. on the level of surgical steps instead of on the level of tasks. For a regular use of time-action analysis, it is important to develop a more automatic recording system and focussed research question.

Human error analysis

This study has shown that error analysis can also be used to gain more insight into surgical procedures (Chapter 5). The error analysis showed that most adverse events are caused by a combination of both human and instrumental errors. This thesis has mainly focused on instrumental errors. Chapter 7 discussed the alignment instruments and gave recommendations to improve the alignment instruments for shoulder and elbows. This paragraph discusses the need for future research on human error analysis in medicine.

In several trades such as aviation, research on human errors is common. Incidents like plane crashes have been evaluated to elucidate what went wrong and what should be changed to prevent a repetition of that accident. Also, all persons involved are asked to report errors and erroneous situations, even when no accident has occurred. These data are used to analyze trends and causes of errors (Helmreich 2000; Reason 2000). These studies are not performed to blame or fire people who made an error, because all people make errors. However, the goal of error analysis is to learn from the errors. This knowledge can be used to train personnel and to improve systems.

In the last decade, several studies have been performed concerning human errors in medicine. These studies estimated that medical errors are responsible for 13 percent of hospital deaths (Brennan et al. 1991; Kohn 2000; Vincent et al. 2001) and that theories concerning human performance and errors developed for industries like aviation and nuclear power plants also hold for medical errors (Cuscheri 2003). Only very few studies actually measure human performance and error probabilities in medicine (Joice et al. 1998; Ritchie et al. 1999). More practical and observation studies concerning human error are needed.

To assess error probabilities and to get insight into factors that influence these probabilities, a realistic simulation environment has to be developed and an anonymous incident reporting system should be introduced. Several simulators haven been developed for anaesthesiology (Devitt et al. 2001; Weller et al. 2002) and minimal invasive surgery (Gramopadhye et al. 2000; O'Toole et al. 1999; Taffinder et al. 1998). In the simulators, the test persons should be able to perform realistic actions during critical situations. A simulator model has as advantage, that several tests persons can be exposed to the same situation and those medical personnel can be trained in high risk situations without exposing a patient. The surgical simulators are only available for small tasks and surgical procedures. More research is needed to develop surgical simulators to train complex surgical procedures such as joint replacements. For an incident control system, all medical personnel is asked to voluntarily and anonymous report errors and erroneous situations. Evaluation of all errors gives insight into the occurrence of errors and can result in guidelines to reduce error probabilities. The data of reporting system should be held confident and should not be available for law suits. Practical studies are needed to get more insight into the occurrence of human errors in medicine and to train health care workers to detect errors and to cope with high risk work situations.

Reducing the size of the operation team

In the Netherlands, waiting lists exist for patients needing a surgical procedure. This waiting list is, among other things, caused by a lack of operation nurses. Reduction of the number of personnel needed might increase the number of procedures which can be performed and therefore decrease the waiting list. Changing the operation team might give logistic or other problems during the surgical procedure. Time-action analysis can give insight into the possibilities of reducing the operation team and into the consequences for the surgical procedure.

The surgical team during a joint replacement consists of five team members. The surgeon performs the procedure and is indispensable. The tasks of the two team members in the non-sterile field, the walking nurse and the anaesthesiologist, are beyond the scope of this research, but are probably difficult to combine because different skills are needed. Therefore, the tasks of the assistant and scrub nurse remain to be discussed. In the hospital of our study, the assistant was a resident surgeon, but in non-teaching hospitals she/he can be a surgical nurse. The actions of the nurse and the assistant overlapped on average 64.2% (86.3 min) and 66.7% (76.5 min) of the operation time for respectively the elbow and the knee.

The main overlapping functions are (Table 8.1):

- *Observing by the nurse.* During this time, the nurse is able to perform a different task.
- *Holding retractors by the assistant.* Retractors may also be held by a mechanical assistant (den Boer et al. 2002; Thompson et al. 1997).
- *Suturing.* Suturing can be performed by only two persons.
- *Covering up instruments by the nurse.* Covering up instruments is quite complicated because of the large number of instruments, but is often not time-critical and can be performed pre-operatively or during waiting periods. Also, more efficient instrument

tables can be designed, where the surgeon can seize his own instruments. If the tables are prepared pre-operatively, the walking nurse can change the tables during the procedure.

Table 8.1: *Overlapping functions between the nurse and assistant. The first row gives the duration when both the nurse and the assistant are waiting or observing. The second and third rows give the duration when only the nurse or the assistant is performing a function. The fourth till the sixth four rows give the durations when the nurse or the assistant is performing a specific function and the other person is performing a different function. The last row gives the remaining function*

Person	**Function**	**Elbow** time (min)	**Elbow** time (%)	**Knee** time (min)	**Knee** time (%)
Nurse and assistant	Waiting/observing	9.1	6.8	4.0	3.5
Nurse	Alone	9.9	7.4	17.9	15.6
Assistant	Alone	38.3	28.4	16.4	14.3
Assistant	Exposing	38.1	28.3	46.2	40.2
Nurse and assistant	Suturing	22.4	16.6	3.1	2.7
Nurse	Instruments	10.9	8.1	24.8	21.6
Nurse and assistant	Remaining functions	6.0	4.4	2.4	2.1

Combining the tasks of the assistant and the nurse is possible using a mechanical assistant and more efficient instrument tables, but will increase the operation time with approximately 10 minutes, the tasks of the remaining team members will be more complicated and the flexibility of the operation team will be reduced. Therefore, all team members need to be experienced. If a procedure is used for education, the number of team members can probably not be reduced.

The logistics

The operation theatre is a complex work domain with people of different disciplines, backgrounds and priorities working together. This study showed that the logistics of the operation theatre influenced the surgical process and gave two causes for waiting: the time needed to obtain new instruments by the walking nurse and the time needed to find the needed instrument by the scrub nurse. Besides the waiting time during a procedure, large waiting times were seen between procedures depending on the logistics of the operation department. Probably, this study has only shown a small part of the inefficiency of the logistics.

Several studies have shown (Melnik et al. 1998) that the logistics of the operation theatre can be improved (Krasner et al. 1999). The logistics of the operation department varied in e.g. size of the operation theatre, task division between team members, teaching faculties and storage places. In spite of the large differences in logistic between operation theatres, in all hospitals waiting occurred because of the logistics and some general causes can be identified, e.g. the timing of ordering new patients, the place where patients are prepared for a procedure and the storage place. More studies are needed to determine and improve the general bottlenecks of operation theatres. Besides, each hospital needs a personal logistic evaluation to identify the hospital specific bottlenecks and improvements.

Teaching resident surgeons

Resident surgeons are trained in a master-pupil setting: the resident surgeon first observes procedures of an experienced surgeon and then performs the procedures under guidance of the surgeon. The education of resident surgeons might conflict with the needs of the patients. Inexperienced surgeons need more time to perform a procedure and they have a higher error probability (Chapter 4). Besides ethical concerns about teaching basic skills on patients, the master-pupil situation has as disadvantage that the learning depends on the availability of patients and the occurrence of complications (Anastakis et al. 1999; Reznick et al. 1997). Also, the surgical procedures need to be more efficient because of the financial constraints, which gives less room for teaching (Anastakis et al. 1999; Reznick et al. 1997). Therefore, other methods have to be developed to train resident surgeons.

Different methods can be used to obtain surgical skills: cadavers, live animals, simulators and patients. The training on cadavers has the advantage that it uses a human body, however, the tissues are dead and not many cadavers are available. Training on live animal studies has the advantage that the animals have living tissue. However, the anatomy of animals differs from humans, animals are expensive and there are ethical discussions about animal rights. Training in simulators has as advantage that the actions can be standardized and repeated and all kind of complications may be simulated, however simulators are labour intensive and costly (Anastakis et al. 1999; Reznick et al. 1997; Rogers et al. 2000). Simulator models are only developed for a small number of procedures. For orthopaedic procedures, simulator models do not yet exist. For joint replacements, the computer assisted surgery systems can be used for teaching resident surgeons (Lynch et al. 2001; Nackman et al. 2002). Simulator models are probably the best method to train resident surgeons outside the operation theatre, but a large amount of development is still needed.

To determine which steps should be trained, critical steps of a procedure should be defined (Dunbar et al. 1995). Critical steps are steps needed to complete the procedure, which are more difficult and give more complications than other steps. For NexGen knee replacement, the placement of the tibia alignment instrument might be seen as critical step (Chapter 5). For the Whiteside Ortholoc II knee prosthesis, two steps both related to the femur alignment were classified as critical (Dunbar et al. 1995). The differences in critical steps between the knee prostheses are caused by the different alignment instruments. Therefore, the training will need a general part e.g. the exposure and a prosthesis-specific part e.g. the available alignment instruments. For all shoulder prostheses, the expose and alignment of the glenoid can be seen as the critical steps. For the Souter-Strathclyde elbow prosthesis, all alignment steps can be seen as critical. Resident surgeons should be trained on the critical steps, which can be determined using time-action analysis.

Relation of this thesis with the other DIPEX projects

This thesis is part of the DIPEX-project performed at the Delft University of Technology, which goal is to develop new prostheses and new operation techniques for the upper extremities. In the DIPEX-project 10 researchers of different scientific background worked on 6 different projects: evaluation of the per-operative process, visualization, functional assessment, fixation of the glenoid, design of a new prosthesis and design of new instruments. The first project, evaluation of the per-operative process is the subject of this thesis. This thesis has obtained data about shoulder joint replacements which can be used as input parameters for the other DIPEX projects:

- The opinions of the surgeons on existing shoulder prostheses.
- The patient population which included more fracture patients than expected.
- Insight into the surgical procedure, which could be used as input for the simulations of the post-operative shoulder motion.
- The insufficiency of existing alignment guides.

The results of the other DIPEX projects are not yet available for use in the operation room. If new instruments come available, it will be interesting to evaluate whether these instruments do improve the operation using time-action analysis.

Recommendations

In this thesis several recommendations have been given to improve shoulder and elbow replacements and to improve computer assisted surgery. This section gives a short overview of the main recommendations.

Recommendations for all joint replacements:

- Improved fixation of prosthesis to reduce waiting times (Chapters 3 and 5).
- Improved pre-operative planning to get a better insight into the patient's anatomy and to reduce the waiting needed to find and unpack the prosthesis (Chapters 3 and 5).
- Improved instrument tables to reduce the time needed for the scrub nurse to find the instruments (Chapter 5).

Recommendations specific for the shoulder prosthesis:

- A new shoulder prosthesis which is easy to place and stable (Chapter 2).
- New alignment instruments for the alignment of the glenoid (Chapters 2, 3, 4 and 6).
- A model to determine the optimal operation time and treatment protocol for a patient (Chapter 2).
- National or European shoulder replacement database to objectively evaluate the effect of different treatment protocols and prostheses (Chapter 2).
- Centralization of the procedures to 20 to 30 hospitals with a minimum of 15 shoulder prostheses each year in which the surgeons and nurses can become experienced with shoulder prostheses (Chapters 2 and 4).
- A mechanical assistant to hold retractors to improve the exposure of the joint and to reduce the number of team members (Chapter 4).

Remaining recommendations

- For the elbow prosthesis, improved alignment guides for both the humerus and ulna (Chapter 5 and 6).
- For the knee prosthesis, reduction of the complexity and number of the alignment instruments (Chapter 5).
- For computer assisted surgery, simplification of the alignment instruments and the development of new training methods (Chapter 7).

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Evaluation of the surgical process during joint replacements

Summary

Shoulder and elbow joint replacements are difficult surgical procedures with a high number of complications and inferior results compared to knee and hip joint replacements. To improve the results of shoulder and elbow joint replacements, a research program called DIPEX, Development of Improved endoProstheses for the upper EXtrimity, has been started at the Delft University of Technology. The goal of the DIPEX project is to develop new prostheses and new operation techniques for the upper extremity. The goal of this thesis is to evaluate the surgical technique of shoulder and elbow joint replacements and to give recommendations for improvements.

An inquiry has been performed among Dutch orthopaedic surgeons to gain a better insight into the use of shoulder prostheses, into the difficulties of the surgical technique and into the opinions of the shoulder surgeons. Forty-four shoulder surgeons have filled in the inquiry. These surgeons placed 377 shoulder prostheses, which is seventy-four percent of the shoulder prostheses in the Netherlands in 2001. Seventy percent of the used prostheses were hemi-prostheses and mainly modular, anatomical prostheses were used. The main pathologies were rheumatoid arthritis and acute fracture. Although, all surgeons used a deltopectoral or anterior approach, the used steps varied between surgeons. The alignment of the glenoid component was indicated as the most difficult step in the surgical procedure. The large variation in used steps indicates that more research is needed to optimize the surgical approach.

For the evaluation of the surgical process, a time-action analysis method has been developed. The surgical procedure was recorded on video using an overview camera, a detail view camera and a microphone. The duration and number of actions and limitations were measured. The per-operative processes of 40 shoulder joint replacement have been evaluated using time-action analyses. The procedures were performed by seven surgeons with different experience using five different prostheses and three different surgical approaches. The surgical procedures showed a large variation in e.g. duration, division of tasks between team members and used protocol. The surgical procedure was influenced by several factors: the used prosthesis, the surgical approach, the patient condition and the experience of the surgeon. The exposure of the glenoid was difficult and several retractors were needed, which were (a) held by an extra assistant, (b) clamped to the table, or (c)

clamped to the surgeon. Two main limitations were seen in all procedures: repeated actions and waiting. Also, five errors could be identified: (a) fracture of the shaft by the use of a rasp which was too large, (b) twice the cutting of the biceps tendon and (c) twice incorrect assembling of the prosthesis. None of the alignment instruments was completely reliable and they did allow the surgeons to make major errors. To improve the surgical process of a shoulder joint replacement, better alignment instruments, pre-operative planning techniques and operation protocols are needed. The training of resident surgeons should be focused on the exposure phase, the alignment of the humeral head, the exposure of the glenoid and the alignment of the glenoid.

The DIPEX-project concerned both shoulder and elbow joint replacements. For the evaluation of eleven elbow joint replacements, the time-action analysis method has been expanded with error analysis. For the error analysis, all possible errors were identified and an error tree was made. To obtain recommendations to improve the shoulder and elbow joint replacement, also five knee joint replacements were evaluated. Because knee joint replacements are more common procedures and have been the subject of extensive research, they were evaluated for comparison. Task analysis showed a large variation in duration between procedures for both elbow and knee procedures. The main limitations for both procedures were waiting caused by the cementing process and waiting caused by inexperienced scrub nurses. For elbow replacements, the alignment instruments had the highest error probability, because the surgeons were unable to align the prosthesis correctly at once and, a large amount of surgical skill was needed to use these alignment instruments. For the knee replacements, the guiding instruments gave the highest error probability, because less-experienced nurses were confused by the large number of instruments. Both prostheses will benefit from new fixation techniques, improved pre-operative planning, more experienced nursing staff, and well-arranged instrument tables.

The post-operative result of prostheses depends on the alignment. For knee replacements, a large number of studies concerned the alignment. Guidelines obtained of these studies can also be used to improve the surgical technique for shoulder and elbow joint replacements. A correct alignment of a joint consists of three steps: (1) alignment of the guiding instrument in relation to the bone, (2) fixation of the guide and (3) the preparation of the bone. All three steps can lead to an error, because ad 1) alignment depends on the bone geometry which varies between persons; ad 2) fixation may be inaccurate because of the pins can displace and the guide has still small movement possibilities; and as 3) the preparation may be inaccurate because of displacement of the preparing instrument in relation to the guide. For the shoulder replacement, the humerus causes fewer problems than the glenoid. The glenoid is very small and is difficult to visualize in the wound. The glenoid alignment might be improved by patient specific fixtures or computer assisted surgery. For the elbow, the existing guiding instruments are insufficient and guides comparable to knee guides might be used. However, care should be taken because the complexity of the guiding instruments for some knees prostheses is still too high.

To further improve the alignment for knee joint replacements, a new technique, computer assisted surgery, has been developed. Computer assisted surgery uses a computer model of the knee, special markers placed on the bone and instruments and a camera to registrate the position of the markers in space. The computer calculates the optimal placement and with the navigation system the prosthesis can be placed with an accuracy of a millimetre. Computer assisted surgery might also be useful for shoulder and elbow joint replacements, but such systems are not yet available on the market. However, evaluating the surgical process of knee joint replacements using computer assisted surgery, can give insight into the possibility to use computer assisted surgery for shoulder and elbow joint replacements. Two surgeons using different navigation systems have been evaluated using time-action analysis. Both computer-assisted systems increased the duration of the surgical procedure, because additional actions were needed to calibrate the computer. For the first system, additional time was needed to position the alignment instruments correctly. For the second system, additional time was needed due to the more extensive soft tissue balancing measurements. The surgeons had only limited experience with the navigation system; therefore, extra time was needed for the surgeon to become acquainted with the system. To reduce the learning curve, the procedure should be trained on shell bones or cadavers, or new training methods such as simulators should be developed. Furthermore, the increased complexity of the alignment guides needs to be reduced by the development of new alignment instruments.

In this thesis, a time-action and error analysis method has been developed to evaluate the surgical process of shoulder, elbow and knee joint replacements. This method gave insight into the problems occurring during the surgical procedures and recommendations are given to improve shoulder and elbow joint replacements.

De evaluatie van het chirurgisch proces tijdens het plaatsen van een gewrichtsprothese

Samenvatting

De plaatsing van schouder- en elleboogprothesen zijn technisch moeilijke chirurgische procedures met een grotere kans op complicaties en slechtere resultaten dan heup- en knieprothesen. Om de resultaten van schouder- en elleboogprothesen te verbeteren is het onderzoeksprogramma DIPEX, (Development of Improved endoProstheses for the upperEXtrimity) gestart aan de Technische Universiteit te Delft. DIPEX heeft als doel het ontwikkelen van nieuwe prothesen en operatietechnieken. Dit proefschrift is een onderdeel van het DIPEX-project en heeft als doel inzicht te krijgen in het operatieproces om daaruit richtlijnen te generen voor het verbeteren van het chirurgisch proces.

Om inzicht te krijgen in het gebruik van schouderprothesen, de operatietechniek en de moeilijkheden tijdens de operatie is er een enquête gehouden onder de Nederlandse orthopedisch chirurgen. Vierenveertig chirurgen hebben de enquête ingevuld. Zij plaatsen gezamenlijk 377 schouderprothesen, dat is 74 procent van alle schouderprothesen in Nederland in 2001. Zeventig procent van de geplaatste schouderprothesen waren hemiprothesen. De meest gebruikte prothesen waren modulaire, anatomische prothesen. De belangrijkste reden voor het plaatsen van een schouderprothese was pijn veroorzaakt door reuma en acute fracturen. Alle artsen gebruikten de deltopectorale benadering echter met een grote variatie in gebruikte stappen. Deze variatie wijst erop dat meer onderzoek nodig is om het chirurgisch proces te optimaliseren. De artsen beschouwden het uitrichten van het glenoidcomponent als de moeilijkste stap in de operatie.

Inzicht in het chirurgisch proces tijdens het plaatsen van de prothese is verkregen door middel van een taakanalysemethode. Daarvoor is het operatieproces opgenomen op video met een overzichtscamera, een gedetailleerde camera en een microfoon. Na de operatie zijn de duur en het aantal acties gemeten en de problemen geanalyseerd. De procedures van 40 schoudervervangingen uitgevoerd door zeven artsen met verschillende ervaring zijn geëvalueerd. De artsen gebruikten vijf verschillende prothesen en drie verschillende benaderingen. De totale operatietijd en de tijd van de verschillende fasen varieerden tussen zowel operaties van dezelfde als operaties van verschillende artsen. Het operatieproces werd beïnvloed door verschillende factoren zoals de gebruikte prothese, het chirurgisch protocol en de conditie van de patiënt. De moeilijkste stap van de operatie was het zichtbaar maken van het glenoid, waarvoor verscheidene haken gebruikt werden.

De haken werden (a) vastgehouden door een extra assistent, (b) vastgeklemd aan de tafel, of (c) vastgeklemd aan de arts. Twee beperkingen werden gezien in alle operaties, namelijk wachten en het herhalen van acties. Ook konden er drie fouten worden geïdentificeerd: (a) fractuur van de schacht door het gebruik van een te grote rasp, (b) tweemaal het doorsnijden van de bicepspees en (c) tweemaal het verkeerd assembleren van de prothese. Elke prothese heeft zijn eigen uitrichtinstrumenten en geen daarvan bleek volledig betrouwbaar te zijn. Het chirurgisch proces van schouderprothesen kan verbeterd worden door het verbeteren van de uitrichtinstrumenten, de preoperatieve planning en de operatieprotocollen. De training van arts-assistenten moet zich focussen op de moeilijkste stappen van de operatie: (a) het benaderen van het gewricht, (b) het uitrichten van de humeruskop, (c) het zichtbaar maken van het glenoid en (d) het uitrichten van het glenoid.

Het DIPEX-project richt zich naast schouderprothesen ook op elleboogprothesen. Voor de evaluatie van het operatieproces van de plaatsing van elf elleboogprothesen is de taakanalysemethode uitgebreid met een foutanalysemethode. Voor de foutanalyse zijn alle mogelijke fouten geanalyseerd en is er een foutenboom gemaakt. Omdat het instrumentarium voor de knieprothesen verder ontwikkeld is, is tevens het operatieproces van vijf knieprothesen geëvalueerd. De operatieduur van zowel knie- als elleboogvervangingen varieerde sterk tussen operaties. Voor beide procedures zijn de belangrijkste beperkingen: wachten vanwege het cementeerproces en wachten op de minder ervaren operatiezuster. Deze studie is uitgevoerd in een opleidingsziekenhuis voor zowel artsen als operatiezuster. De zusters die nog in training waren, hadden meer tijd nodig om de goede instrumenten te vinden en deze in elkaar te zetten. De grootste kans op fouten tijdens het plaatsen van een elleboogprothese werd veroorzaakt door onnauwkeurigheden in de uitrichtinstrumenten. Deze onnauwkeurigheden moesten gecompenseerd worden door goede chirurgische vaardigheden. De grootste kans op fouten tijdens het plaatsen van de knieprothese werd veroorzaakt door het grote aantal instrumenten. De instrumenten werden door de operatiezusters in opleiding door elkaar gehaald. Beide prothesen kunnen profijt hebben van nieuwe fixatietechnieken, betere preoperatieve planning, meer ervaren operatiezusters en eenduidige instrumentnetten.

Een goede uitrichting van de prothese is nodig voor goede postoperatieve resultaten. Voor knieprothesen is veel onderzoek gedaan naar het precies uitrichten van de prothese. De resultaten hiervan kunnen gebruikt worden voor richtlijnen om de instrumenten voor schouder- en elleboogprothesen te verbeteren. Een correcte uitrichting van een prothese bestaat uit drie stappen: (1) het positioneren van het uitrichtinstrumentarium ten opzichte van het bot, (2) het fixeren van het uitrichtinstrumentarium en (3) het prepareren van het bot. Elke stap heeft een foutkans:

1. Het positioneren, vanwege de variatie in botgeometrie tussen personen.
2. Het fixeren, omdat de fixatiepinnen kunnen verplaatsen tijdens het vastzetten en omdat zelfs na fixatie beweging mogelijk is tussen het instrument en het bot.
3. Het prepareren, omdat verschillende hoeken mogelijk zijn tussen het prepareerinstrument en het uitrichtinstrument.

Voor de schouderprothese is het uitrichten van het glenoid moeilijker en onnauwkeuriger dan het uitrichten van de humerus, omdat het glenoid klein is en diep in de wond ligt. Het uitrichten van het glenoid kan verbeterd worden door het ontwikkelen van mechanische mallen of het gebruik van computernavigatie. Het uitrichten van de elleboogprothese kan worden verbeterd met instrumenten lijkende op het knie-instrumentarium. Echter het instrumentarium van sommige knieprothesen is erg complex door het grote aantal instrumenten en mogelijkheden.

Om de nauwkeurigheid van het uitrichten van knie-instrumentarium te verbeteren is een nieuwe operatietechniek ontwikkeld: computernavigatie. Computernavigatie maakt gebruik van een computermodel van de knie, speciale markers die op het bot geplaatst worden en een camerasysteem dat de markers lokaliseert in de ruimte. De computer berekent de ideale positie van de prothese en met behulp van het navigatiesysteem kan de prothese op de millimeter nauwkeurig geplaatst worden. De evaluatie van het gebruik van computernavigatie voor het plaatsen van knieprothesen kan inzicht geven in de mogelijkheden voor computernavigatie voor schouder- en elleboogprothesen. Twee ervaren kniechirurgen plaatsen knieprothesen met zowel de traditionele instrumenten als met computernavigatie. De artsen gebruikten verschillende navigatiesystemen. Beide systemen verlengden de operatietijd vanwege extra operatiestappen vanwege het kalibreren van de computer. Daarbij was voor een systeem extra operatietijd nodig vanwege de complexe uitrichtinstrumenten en voor het andere systeem vanwege de uitgebreidere mogelijkheden om de weke delen te reconstrueren. De artsen hadden nog maar beperkte ervaring met computernavigatie. De eerste operaties met behulp van het navigatiesysteem kostten extra tijd, omdat de arts onbekend was met het systeem en extra controlestappen uitvoerde. Geadviseerd wordt om de leercurve te verkorten door te trainen op kadavers of kunststof botten en door het ontwikkelen van nieuwe trainingsfaciliteiten zoals simulators. Tevens moeten de uitrichtinstrumenten vereenvoudigd worden.

In dit proefschrift is een taak- en foutanalysemethode ontwikkeld en gebruikt om inzicht te krijgen in de problemen die optreden in het operatieproces tijdens het plaatsen van schouder- en elleboogprothesen. De resultaten van de analyse hebben geleid tot aanbevelingen om de schouder- en elleboogprothesen te verbeteren.

Dankwoord

Met dit boekje is een einde gekomen aan vier jaar leuk, uitdagend en afwisselend werk op de rand van de techniek en de geneeskunst. Ik had dat werk niet kunnen doen zonder de hulp en inspiratie van velen.

Mijn onderzoek speelde zich grotendeels af in operatiekamer. Ik wil de meewerkende artsen, Breukelman, Boersma, Diercks, Van Eckhart, Eigendahl, Van Lent, Nelissen, Rozing, Van Stein, De Vos, De Waal-Malefeit en Willems, bedanken dat ze de camera op hun hoofd hebben gezet, zodat ik op hun handen heb kunnen kijken. De heren Nelissen en Rozing wil ik tevens bedanken voor de medische en wetenschappelijke bijdragen aan mijn manuscripten. Ook de instrumenterenden, assistenten en anesthesisten in de operatiekamers wil ik bedanken voor al hun hulp, ondanks dat ik hun soms in de weg stond. Gelukkig hebben Janneke en Map uit het LUMC mij wegwijs in de operatiekamer en zijn gebruiken gemaakt. Tevens wil ik alle secretaresses, met namen Petra en Thea, bedanken voor de moeite van het opzoeken van de operatieschema’s van de artsen.

In Delft heb ik veel inspiraties opgedaan tijdens de pauzes, werkbesprekingen en in de kantoortuin. Ik wil graag alle collega’s bij MMS bedanken voor de gezellige en inspirerende tijd. Een paar collega’s wil ik graag bij namen noemen. Jenny, door je rust en inzicht hielp je me verder als ik vast zat met mijn gedachten. Frans, jouw enthousiasme was aanstekelijk. Henk, jouw lange ervaring met onderzoek heeft mij regelmatig verder geholpen. Eveline, we zijn samen begonnen en konden veel ervaringen uitwisselen. Dank je wel dat je mijn paranimf wil zijn. Dennis en Ed, als naaste DIPEX collega’s heb ik erg veel steun van jullie gehad met algemene schoudervragen en mijn engels. Edward, bedankt dat je zo vaak tijd vond om mijn werk te bekijken en bespreken. Alle DIPEX-collega’s, bedankt voor de discussies over schouders en voor de gezellige etentjes met elkaar.

Voor onderzoek is goede apparatuur natuurlijk erg belangrijk, in mijn geval is dat de video-unit. Ik wil Frits, Michiel en Ruud van MTO in het AMC bedanken voor al hun moeite en tijd die ze in de unit gestoken hebben.
Mijn werk stopte niet ’s middags om vijf uur. Gelukkig kon ik ook buiten werktijden bij familie en vrienden terecht voor een luisterend oor en goede op en aanmerkingen. Janine, Judith en Maaike door jullie eigen band met onderzoek begrepen jullie mijn verhalen goed en had ik veel steun aan jullie. Oom Kees, bedankt dat u mijn proefschrift op het engels hebt willen controleren. Nico, jij was een goede stimulans voor mij om verder te komen

met leren. Dank je wel dat je mijn paranimf wil zijn. Papa en mama, jullie bijdrage aan dit boekje begon al veel eerder. Papa, bedankt dat jij mij hebt geïnteresseerd voor de techniek. Mama, bedankt voor al je hulp bij mijn taalvaardigheid. Bas, jij hebt het hele traject naast me gestaan van het vroeg op staan om mij naar het station te brengen tot het ’s avonds luisteren naar mijn verhalen. Dank je voor je steun en relativerende commentaar.

Curriculum Vitae

I was born June 16th, 1974 in Leiderdorp, The Netherlands. After graduating from my secondary school, Het Vlietland College, in Leiden, I started to study Medical Biology at the Rijksuniversiteit Leiden. In 1997, I gained my master degree and started to work as a researcher at the urodynamics department at the Erasmus University in Rotterdam. This research concerned the contractility of the urinary bladder. In 2000, I switched to the Delft University of Technology to start my PhD project, which is described in this thesis. I have now just started to work as a clinical researcher for Ortomed in Dordrecht, The Netherlands.