Factors influencing the surgical process during shoulder joint replacement

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Published in:
Medical Science Monitor

© Med Sci Monit, 2005; 11(1): CR14-20
PMID: 15614190

Received: 2004.02.12
Accepted: 2004.07.13
Published: 2005.01.01

Factors influencing the surgical process during shoulder joint replacement: Time-action analysis of five different prostheses and three different approaches

Authors' Contribution:
A Study Design
B Data Collection
C Statistical Analysis
D Data Interpretation
E Manuscript Preparation
F Literature Search
G Funds Collection

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Source of support: This research is part of the DIPEX (Development of Improved endo-Prostheses for the upper Extremites) program of the Delft Interfaculty Research Center on Medical Engineering (DIOC-9).

Summary

Background: To evaluate the per-operative process of shoulder joint replacement, time-action analysis can be used.

Material/Methods: Forty procedures performed by 7 surgeons with different experience using 5 different prostheses and 3 different surgical approaches were analyzed.

Results: The surgical procedures showed a large variation in, for example, duration, tasks of team members, and protocol used. The surgical procedure was influenced by several factors, such as the prosthesis used, the surgical approach, the patient's condition, and the experience of the surgeon. Exposure of the glenoid was difficult and several retractors were needed, which were held 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 allowed the surgeon to make major errors.

Conclusions: Better alignment instruments, pre-operative planning techniques, and operation protocols are needed for shoulder prostheses. 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. Evaluating the surgical process using time-action analysis can be used to determine the limitations during surgical procedures. Furthermore, it shows the large variation in factors affecting surgical performance, indicating that a system approach is needed to improve surgical outcome.

key words: **joint replacement • guiding instruments • shoulder prosthesis • time-action analysis**

Full-text PDF: http://www.medscimonit.com/abstract/index/idArt/13871

Word count: 3659
Tables: 1
Figures: 2
References: 16

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BACKGROUND

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 (see review by Magermans [1]). Important factors influencing the results of shoulder joint replacements are the diagnosis and the surgeon's experience in accurately inserting the prosthesis and repairing and balancing the soft tissues. The prosthesis design is a less important factor for the functional outcome [1,2]. However, post-operative evaluation studies give no insight into the actual surgical process. This can be obtained using time-action analysis, which 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 [3]. In contrast to industry, such as nuclear power plants [4], few time-actions studies have been performed in the medical field, the majority of them in laparoscopic surgery [5–8] and cardiac surgery [9].

A time-action analysis method has been developed for the evaluation of humeral head replacement [10]. 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 cannot be used to predict surgical outcome. The time-action method was used to evaluate surgical procedures of a single surgeon using one surgical approach and one prosthesis design [10]. However, different surgical approaches and prosthesis designs exist, all of which may influence the surgical procedure.

The goal of this study is to evaluate the per-operative process during shoulder joint replacements using time-action analysis [10]. 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.

MATERIAL AND 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 our previous study [10] are also included. Two surgeons were resident surgeons. Seven surgeons gave permission to record their operations. All shoulder prostheses placed by these surgeons in patients with rheumatic arthritis or osteoarthritis during the course of this study were included in this study. These seven surgeons used three different approaches: a deltopectoral approach, a clavicular osteotomy approach [11], and a postero-superior approach with an acromion osteotomy [12]. Two surgeons used 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 prosthesis 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 stabilized 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.

Time-action 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 recordings and sound were recorded simultaneously using a video mixer. The recordings did not interfere with the surgical process and were analyzed off-line. For the video recordings permission was obtained from both the patient and the surgeon.

The time-action method used has been described previously [10] and will be shortly described here. Each procedure was divided into an exploration, a humerus, a glenoid, and a closure phase, and each phase was subdivided in several steps (Table 1). The duration of all phases and steps was measured. 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. The term 'error' does not mean a complication.

After the analysis, the results were discussed with the surgeons, during which the surgeons commented on the results. These discussions with the surgeons are a very important aspect of the method, because both the researcher and the surgeons learn from them. For example, some action classified by the researcher as a repeated action and unnecessary could be explained by the surgeon and were, in fact, important actions. Other actions, such as the variable order of steps, were recognized by the surgeon as confusing for the nurses and assistants and were changed to a stricter order of steps.

Table 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 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 until 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

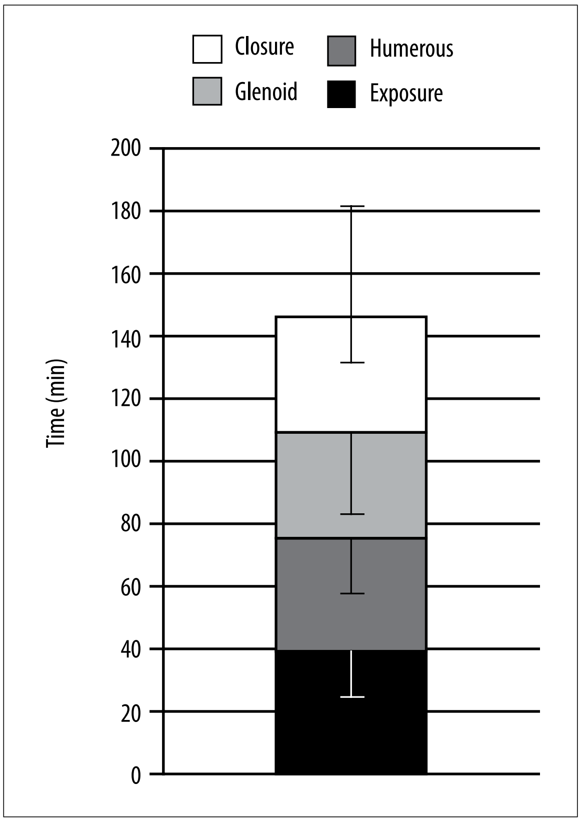

Figure 1. The average duration ±S.D. of a shoulder joint replacement.

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 were 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 1).

General observations

Surgical team

All surgeons were assisted by a scrub nurse and an assistant, normally a resident surgeon. Three surgeons were also assisted by a junior surgeon and had, therefore, a larger surgical team. 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 assist in shoulder replacements on a regular basis gave advice to the surgeon. In one hospital, the nurse assembled the final prosthesis, while in the other hospitals the surgeons did this. 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 assistant. In this case, the experienced surgeon gave advice to the resident surgeon during the procedure.

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 could 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 fixated 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 cutting blocks was clear, although surgical experience was needed. For the Anatomical and Aequalis prosthesis, the anatomical neck is used as a sawing guide, as no further guides exist; one surgeon used the test prosthesis to determine the correct sawing angle. Rasping at the correct angle was sometimes difficult, because the rasp had the ten-

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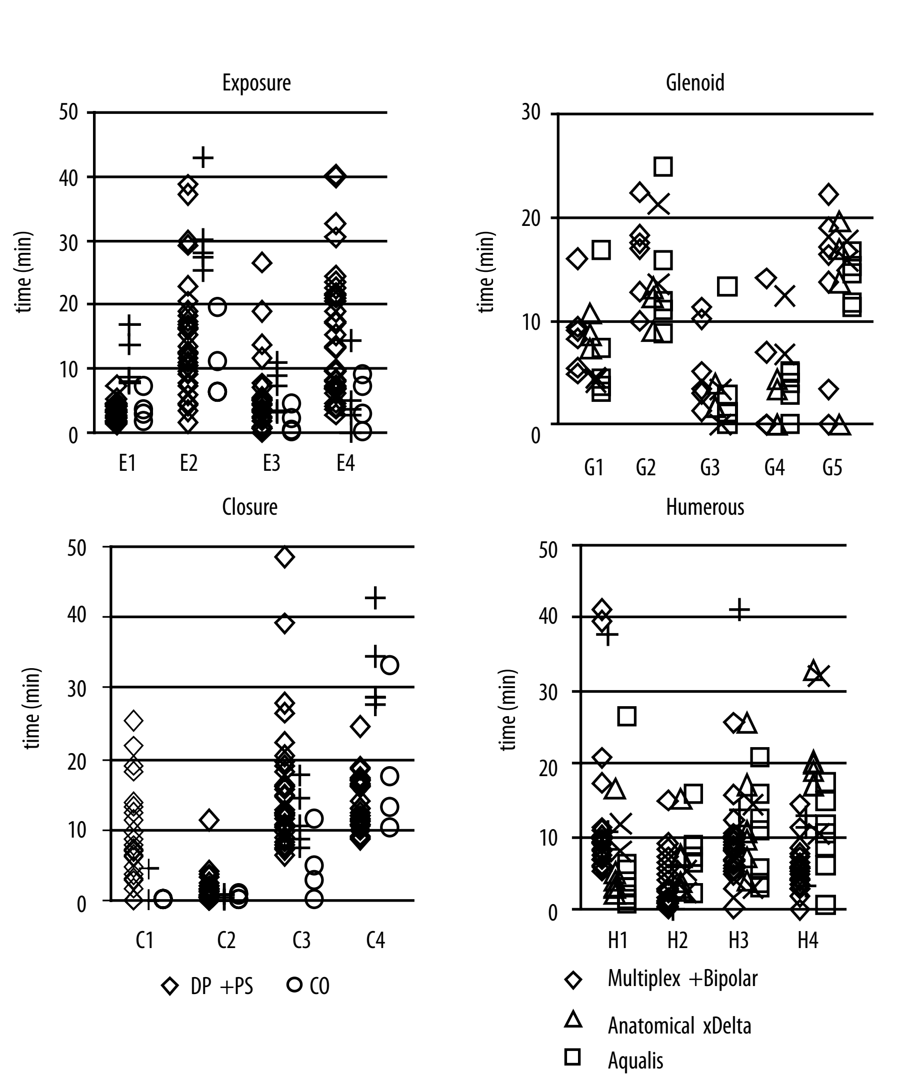

Figure 2. The variation in duration of all steps. For the Exposure and Closure phase, the approach used is marked. For the Humerus and Glenoid phases, the prosthesis used is marked. The steps are explained in Table 1. DP – Deltopectoral; PS – Posterior--superior; CO – Clavicular osteotomy.

dency to displace due to varying bone densities. The assembly 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 a 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 among procedures (Figure 1). Figure 2 shows the variation in the duration of the steps. The steps are explained in Table 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 approach used 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 prosthesis used is marked.

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 with the procedures in which the whole vein is ligated (p=0.004).

E3. Opening the rotator cuff

The duration of this step did not depend on the approach used (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 significantly 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 is 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 cannot 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), dissect the subscapularis (Step E3), align the prosthesis (Step H1), and 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 were observed in all procedures. Waiting occurred in all procedures by all surgeons and took on average 16.3±7.5 minutes (12.3% 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). Repeated action occurs mainly during the alignment of the humerus and glenoid. All surgeons used alignment instruments, but they had to refine the preparation steps often without the help of alignment instruments. The resident surgeons showed a fewer number of repeated actions as their teachers (2.6 for the resident surgeons compared with 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, the stem used was too large 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 replacement was gained by evaluating with time-action analysis the surgical process of forty shoulder joint replacements performed by seven surgeons, using three approaches and five prostheses. The surgical procedures showed a large variation in, for example, duration, tasks of team members, and protocol used, among and within surgeons. The surgical procedure was influenced by the prosthesis used, 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, all of which 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 [11,12] 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 fewer 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 can probably be due to the patient's 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 who was unable to pick the correct instruments. These results confirm the conclusions of time-action analyses of humeral head [10] and of knee joint replacements [13] that better alignment techniques and better pre-operative planning are needed. Waiting time may also be reduced by training the scrub nurses and using a strict operation protocol so that 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, cutting of the biceps, occurred with 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 type, perforation of the humerus during rasping, also occurred with a less experienced surgeon, because no humeral drill guide exists for that prosthesis, so drilling was done by eye. Perforation of the humerus may be prevented by using a correctly sized rasp. The optimal rasp size might be obtained with good pre-operative planning. The third error, 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 by 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 prostheses may decrease the chance of wrongly assembling prostheses in the future.

Recommendations

New instruments

None of the alignment instruments were 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. Guidelines to improve the instruments for shoulder joint replacements can be obtained by examining the instruments for knee or hip joint replacements. These prostheses have special guides which can be placed in relation to the patient's anatomy. After placement of these instruments, the surgeon can safely saw or drill. Besides better conventional instruments, new techniques, such as computer-assisted surgery, have also been developed for hip and knee joint replacements which might also improve shoulder joint replacements.

Exposure

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

Experience surgeon

Shoulder joint replacements are seen by some surgeons as one of the most complicated joint replacements [2]; especially the soft tissue balancing and glenoid alignment are considered difficult procedures. The operation technique may be improved by developing new instruments or by increasing the skills of the surgeon. Developing 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 with hospitals were fewer were placed [14,15]. In this study, four of the five errors were caused by inexperience, indicating that for shoulder replacements, obtaining and retaining experience are as important as in hip and knee replacements to reduce error probabilities and waiting. Complications for the patients might thereby be reduced.

General implication for health care

In the last few years, safety and efficiency became important issues in health care. The US Institute of Medicine (IOM), reporting on errors in health care [16], emphasized that errors are the result of multiple contributing factors and advocated a systems approach to addressing error. The findings from our study support the notion that multiple factors affect surgical performance: the surgical protocol, the design of the alignment instruments, experience of the care providers including the scrub nurse, and the condition of the patient. Therefore, a systems approach is needed to improve surgical performance. In this approach, the total system is evaluated, including the patient, surgical instruments/equipment, surgical team, and hospital logistics.

CONCLUSIONS

The per-operative processes of 40 shoulder joint replacements performed by seven surgeons were evaluated using time-action analysis. The prosthesis used, the surgical approach, and the surgical team all influenced the surgical process. Although this method cannot qualify which approach or prosthesis is better, some general 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 allowed 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.

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