Computer Aided Surgery

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Online Publication Date: 01 January 2003

To cite this Article: Schneider, Jörg and Kalender, Willi (2003) 'Geometric Accuracy in Robot-Assisted Total Hip Replacement Surgery', Computer Aided Surgery, 8:3, 135 — 145
To link to this article: DOI: 10.3109/10929080309146048
URL: http://dx.doi.org/10.3109/10929080309146048

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Geometric Accuracy in Robot-Assisted Total Hip Replacement Surgery

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ABSTRACT
Objective: Robot-Assisted Surgery in Total Hip Replacement (RAS-THR) has become a fairly widespread procedure for hip replacement surgery in Europe. However, data on the geometric accuracy of the overall process have so far been unavailable. The equipment manufacturers have only published data on the accuracy of certain elements of the procedure (e.g., the accuracy of the robot system). This study aimed to investigate the overall geometric accuracy of the complete process of RAS-THR, as well as the influence of some of the individual component steps.

Materials and Methods: An anthropomorphic phantom has been developed representing the hip and upper leg region of a human body. The entire RAS-THR procedure can be carried out using this phantom. Studies were conducted to investigate the overall accuracy of the process, as well as the influence of some individual steps in the procedure, using both the ROBODOC and CASPAR systems.

Results: Overall geometric accuracy of the RAS-THR process was found to be within a standard deviation of 0.5 mm and 0.3° in the critical directions. Most individual steps in the process make similar contributions to the overall variation. The two robot systems examined offer comparable accuracy.

Conclusion: Initial results seem to indicate that the RAS-THR process is acceptably accurate. However, acceptance criteria for the necessary geometric accuracy have not yet been defined.

Key words: robot-assisted surgery, computer-assisted surgery, total hip replacement, geometric accuracy

INTRODUCTION
In recent years, the use of robot systems to assist in total hip replacement (THR) surgery has spread quickly. Whereas less than 10 systems were in use just a few years ago, well over 100 systems are now available in operating rooms, mostly in Europe. Using these systems, several thousand robot-assisted THR surgeries have been carried out successfully. In a few cases, however, the actual position of the implanted prosthesis has been found to differ significantly from the planned position.

As of the time of writing, there are no data available concerning the geometric accuracy of the overall process of Robot-Assisted Surgery in
THR (RAS-THR). System manufacturers sometimes advertise the accuracy of their robot systems, and the quoted values of (typically) 0.1-0.2 mm are quite impressive. However, the accuracy of the overall process is not determined by the accuracy of one component of the system alone. All the components involved in the process exert influence on the accuracy and need to be taken into account when evaluating the overall accuracy.

This study aimed to examine the overall accuracy of RAS-THR and to investigate the influence of different steps in the process.

Steps Involved in RAS-THR

There are currently two commercially available robot systems for RAS-THR: ROBODOC (Integrated Surgical Systems (ISS), Davis, CA) and CASPAR (formerly available from ortoMaquet, Rastatt, Germany, and now distributed by Universal Robot Systems (URS), Parchim, Germany). Both systems operate in a similar manner and are used for milling the femoral cavity for the prosthesis stem according to the preoperative plan. The overall process can be broken down into four major steps:

Marker Pin Insertion

In the first step, typically two marker pins are implanted in the patient's femur: a shorter pin in the trochanter major, and a longer pin in one of the condyles. This procedure is normally carried out the day before the actual operation. These pins serve as a reference frame to register the preoperative plan, which is based on a computed tomography (CT) dataset (see below), with the actual patient femur in the operation room (OR). ROBODOC has now introduced a method for pinless registration, though this method was not examined in the present study.

CT Scan

Step two is the acquisition of a three-dimensional (3D) dataset of the patient's anatomy using CT. The protocol for CT scanning is prescribed by the system manufacturers and varies slightly depending on the robot system and CT scanner used. A typical protocol would use spiral CT acquiring data from approximately 10 mm proximal to the femoral head to approximately 250 mm distal to the femoral head. A second set of data including the condyles and the distal pin is acquired during the same session. The protocols for a Siemens Somatom Plus 4 scanner (Siemens AG, Erlangen, Germany) are shown in Figure 1. To detect any unwanted patient movement during the CT scan, a rod is fixed to the leg of the patient and can be seen in all the acquired images. After scanning, the CT data are transferred to the planning station.

Preoperative Planning

The third step is the preoperative planning of RAS-THR based on the CT data on the planning station. First, some security checks are performed automatically. The scan protocol is checked, as well as the representation of the rod fixed to the patient's leg. If the patient has not moved, the data are accepted for preoperative planning. If movement is detected, but does not exceed a certain threshold, the data are still accepted, although this may lead to inaccuracies. Only if the movement exceeds the threshold are the data rejected. Segmentation of the marker pins is performed automatically and must be confirmed by the operator. Once this is done, the actual planning is executed. The anatomy of the patient is displayed on the screen, typically in three orthogonal planes. The operator chooses a prosthesis from a database and virtually places it in the femur. The prosthesis can be moved and tilted in

Fig. 1. Prescribed scan protocol for a Siemens Somatom Plus 4 for ROBODOC and CASPAR.
all six degrees of freedom. Further functions are available for repositioning image planes, zooming, panning and measuring. When positioning the prosthesis, the operator takes into account the anatomy of the patient as well as the guidelines of the prosthesis manufacturer and his own experience. Should the first choice of prosthesis prove unsuitable, a different prosthesis can be selected at any time. Once the planning is completed to the operator's satisfaction, the plan data and the results of the pin segmentation are transferred via a medium to the robot system.

**Operation**

The fourth and last step of the process is the operation itself. The patient is prepared and the approach to the hip joint is opened in the conventional way, except that the incision for RAS-THR is larger. The implantation of the prosthesis cup is also done conventionally. Meanwhile, the robot is prepared for milling the cavity for the prosthesis stem. Calibrations and self-tests are performed, the planning data are loaded, and the robot is covered completely with sterile wrapping.

When the surgeon is ready to prepare the femoral cavity, the robot is moved close to the patient. The femur is fixed to the base of the robot using a clamp, and the shank is affixed to a special support.

Using a special keying tool, the robot interactively determines the positions of both marker pins, as well as the orientation of the condyle pin. To obtain the position of the pins, the spherical keying tool is inserted into a corresponding indent on each one. To determine the direction of the longer marker pin in the condyle, the two robot systems follow different approaches. With CASPAR, an extension is screwed to the condyle pin, pointing along its axis. The keying tool is then inserted into an indent in this extension to determine the orientation of the pin. With ROBODOC, several points on the flat surface of the head of the condyle pin are acquired to calculate the orientation of the pin, which is perpendicular to the head plane.

The positions of the pins are registered with the result of the pin segmentation performed during preoperative planning. From this matching, the robot can calculate the position of the femoral cavity by referring to the known positions of the marker pins. After replacing the keying tool with a drilling tool, the cavity is prepared.

A bone-motion sensor is attached to the femur to detect movements of the patient during the robot-assisted operation. The same rules apply as for motion during CT scanning: Movements below a certain threshold are acceptable, although they may cause inaccuracies, but movements above the threshold result in the milling procedure being aborted. In the latter case, milling only resumes after the pins have been re-registered.

Once milling of the cavity is completed, the robot is removed from the patient and the marker pins are removed from the bone. Subsequent insertion and assembly of the prosthesis, as well as the remaining steps of the operation, are done in the conventional way.

**Factors Influencing Geometric Accuracy**

Each of the four steps outlined above can influence the accuracy of the overall process to a varying degree.

Insertion of the marker pins has little significance, so long as a rigid fixation of the pins is secured.

The CT scan can influence the accuracy of the overall process in various ways. The parameters of the scan determine the spatial resolution and image quality of the dataset used for planning, while the physics of the scanner may cause artefacts that can reduce image quality. As for the mechanical properties of the CT scanner, table bending, undetected gantry tilt or non-linear table movement during spiral CT may also lead to distortions in the dataset.

The influence of the preoperative planning is closely linked to that of the CT scan. Resolution and image quality influence the visibility of fine structures and sharp edges during the planning process. They may also have an impact on marker pin segmentation. Of course, the segmentation algorithm can have an impact on the accuracy itself. Another feature influencing the accuracy is the man-machine interface. Two aspects should be considered here: first, whether the representation of the dataset is appropriate, allowing the operator to receive all the relevant information; and second, whether the control mechanisms are adequate to ensure optimal positioning of the prosthesis according to the operator's aims.

During the actual operation, the geometric accuracy of the robot system is one aspect that needs to be considered, as well as the determination of the marker pins, the registration algorithm and the patient fixation. All have an impact on the position of the femoral cavity.
MATERIALS AND METHODS
To determine the overall geometric accuracy of RAS-THR, a special procedure and a dedicated phantom have been developed. The procedure is outlined in Figure 2. All the relevant steps of RAS-THR can be carried out on the phantom. A cavity for the prosthesis stem can be milled in the femur part, then its position measured and compared to the desired position, which is defined by the design of the phantom. This yields data on the geometric accuracy of the overall process of RAS-THR.

Phantom Design
The phantom has an anthropomorphic design in terms of geometry as well as in the materials used. It was developed in cooperation with QRM GmbH (Möhrendorf, Germany). The materials selected have CT values (Hounsfield Units) representative of the anatomic structures involved (soft tissue, cortical bone, spongious bone). The phantom consists of several parts, as displayed in Figure 3. Two major parts represent the soft tissue structures of the human hip and upper leg. These structures enclose two modularly designed femora. This form of construction is necessary due to the multiple requirements that the proximal part of the femur must satisfy. For preoperative planning, structures need to be included to indicate the desired prosthesis position to the surgeon, and these structures must be visible in the CT dataset. Drilling of the cavity is performed in the same region, so the material needs to have mechanical properties equivalent to those of bone. Also, as the phantom is intended to enable the procedure to be repeated many times, replacing the milled femur should not be excessively expensive.

To meet these broad requirements, the central proximal part of the femur (Fig. 3: inserts) is available in two different versions. For milling of the cavity, a milling insert is used which does not have any inner structures and consists of polyurethane foam with mechanical properties similar to those of human bone. Each milling insert can only be used for milling one cavity and must then be replaced.

For the CT scan and preoperative planning stages, a scan insert is available. This has the same outer form as a milling insert, but is made of different material and has a guiding structure included. This guiding structure is visible in the CT dataset due to the materials used. It has been designed to represent the outer form of a commonly used prosthesis (Howmedica Osteolock size 3, sleeve 14, Howmedica Inc., Rutherford, NY), as shown in Figure 4.

The scan insert was designed using AutoCAD 13 and the electronic description of the Osteolock 3/14 prosthesis. The guiding structure consists of several geometric parts clearly outlining the prosthesis. The insert was manufactured using a computer numeric-controlled industrial milling machine and vacuum-casting techniques.

The aim of the planning is to position the prosthesis exactly on the guiding structure. To avoid any possible misinterpretation as to how this was to be accomplished, an instruction leaflet that clearly defined the method of positioning the prosthesis was given to everyone performing a surgical plan on the phantom during the study. The combination of a guiding structure and instruction leaflet defined an objective aim that left no room for interpretation.

The design of the phantom ensures that the scan insert and milling insert are positioned in exactly the same place within the phantom. The inserts are pressed against the lateral wall of the femur part of the phantom by means of two screws in the medial femur wall. Also, a groove construction at the distal end of the inserts secures them in the correct location.

The whole process is designed around the aforementioned prosthesis. In this study, no other prostheses were included. It was, of course, necessary to use the Howmedica Osteolock 3/14 in the preoperative planning as well.

Performing RAS-THR on the Phantom
A general procedure to examine the overall geometric accuracy of RAS-THR has been established. By performing only parts of the general procedure and varying certain steps, the influence
of these steps on the overall accuracy can also be determined. The general procedure is described in this section. The variations of the procedure used to examine the influence of specific steps are described in the section below entitled Studies Conducted.

**Marker Pin Insertion**

The first step of RAS-THR, the insertion of the marker pins, was actually performed during the manufacture of the phantom. This was done to avoid the gradual destruction of the phantom as a result of repeatedly changing the position of the pins for each experiment. As the influence of pin insertion on accuracy can be regarded as negligible in comparison to the other steps in RAS-THR, this simplification is considered to be acceptable. To examine both robot systems, one femur was fitted with the ROBODOC pins, the other with the CASPAR pins. The pins were inserted at the usual locations; the short one in the trochanter major, the longer one in the condyle.

**CT Scan**

The CT scan was performed on the fully assembled phantom using the scan insert. To take into account the effect of CT table bending, weights were distributed on the table around the phantom to simulate the load of a typical patient. The total load of weights and phantom was 70 kg. The CT protocol was chosen as prescribed by the robot system manufacturer for the CT scanner used. An example of scan protocols required for a Siemens Somatom Plus 4 scanner is shown in Figure 1. Following the normal procedure for a patient, the CT scan was conducted and the data were then transferred to the planning station.

**Preoperative Planning**

To perform preoperative planning, the security checks were carried out and pin segmentation was performed. The actual planning was conducted by experienced surgeons, who were asked to position the prosthesis (Howmedica Osteolock 3/14) on
Fig. 4. The scan insert contains a guiding structure. This structure was designed to represent a Howmedica Osteolock 3/14 prosthesis. To enable identification of the guiding structure in the CT dataset, different materials were chosen to achieve a contrast between the structure and the surrounding insert.

the guiding structure. To eliminate any possibility of misinterpretation, they were given the leaflet explaining the aim of the experiment. The leaflet stated which prosthesis was to be used (Howmedica Osteolock 3/14) and how it was to be placed on the guiding structure. This combination of an objective, clearly defined aim for the planning and the design of the phantom itself in turn defined the desired position of the prosthesis. The use of an instructional leaflet ensured that all plans were performed with the same aim. Figure 5 shows a planning station with the phantom dataset and the positioned prosthesis. After the surgeons were satisfied with the planning, the data for the robot were generated.

**Operation**

The actual operation was performed using clinical robot systems. To prepare the femur, the scan insert was replaced by a milling insert. Only the femur was needed for the operation. After the robot had loaded the planning data and performed its self-tests and calibrations, the femur was attached to the base of the robot by means of the standard femur fixator. The marker pins were registered according to the normal procedure and drilling of the cavity was performed. Once milling was completed, every step that could influence the geometric accuracy of the RAS-THR process had been carried out on the phantom. The actual insertion of the prosthesis into the milled cavity is possible, but was not necessary for the purposes of the present study.

Measurement of the cavity position was performed on the milling insert using a 3D coordinate measuring machine (PRIMAR MX4, Mahr GmbH, Göttingen, Germany). This machine measures coordinates and geometric features of bodies by tactilely acquiring points, lines or other geometrical forms. The features are acquired with a sphere fixed to a stylus that is manipulated by the machine (Fig. 6a). The contact of the sphere with the object is used to digitize points in three dimensions.

In the measuring procedure, several lines on the exterior of the milling insert were acquired, as shown in Figure 6b. These lines define a coordinate system (outer system). Analogously, some features of the cavity were measured (Fig. 6c), defining a second coordinate system (inner system). By calculating the transformation from the outer to the inner coordinate system, the position of the cavity within the insert is derived. Because the position of the scan insert in the phantom during scanning is exactly the same as the position of the milling insert during the operation, the position of the cavity can be compared to the position of the guiding structure in the scan insert to
determine the deviation of the actual cavity position from the desired position (i.e., the position of the guiding structure).

The accuracy of the measuring procedure itself was determined by performing repetitive measurements, measuring reference objects, and taking into account the specification of the measuring machine. It was found to be accurate to 0.02 mm.

Studies Conducted

The established procedure is not only suitable for determining the overall geometric accuracy of RAS-THR: By varying some parameters while leaving others unchanged, the influence of individual steps on the overall process can be evaluated. To this end, three studies were conducted as described below.

Inter-Operator Variation in Preoperative Planning

This study aimed to evaluate differences in prosthesis positioning during preoperative planning conducted by different surgeons. A CT dataset of the phantom was acquired according to the ROBODOC scan protocol using a SOMATOM Plus 4 CT scanner. The preoperative planning was conducted on the ImpactCappa planning station (Vamp GmbH, Möhrendorf, Germany). This station features a slightly different planning procedure than the one used with ROBODOC or CASPAR. This particular procedure was used since it exports the plan in an easily accessible and readable format, whereas the plans exported from the CASPAR or ROBODOC systems can only be read with special hardware and knowledge of the planning files that were unavailable to us.

Six experienced surgeons carried out a preoperative planning using the dataset. For planning on the phantom, the surgeons were introduced to the objective aim of planning for the phantom via the guidelines in the brochure. They conducted the plan with a view to achieving the prescribed aim using the Howmedica Osteolock prosthesis.

The result of the preoperative plan, i.e., the position of the prosthesis in the datasets, was exported from the planning station. For each
dataset, the medium position was calculated as well as the deviation of each individual position from the medium position. This part of the study was carried out to determine the technical limitations of the planning process. The planning process during normal clinical routine is not only influenced by the technical limitations, but also by the experience and opinion of the operator.

To evaluate the influence of the operator as well, a second phase of this study was carried out in which the variation in preoperative planning on a patient dataset was examined. A CT dataset of the patient was acquired according to the ROBODOC scan protocol using a SOMATOM Plus 4 CT scanner. The preoperative planning was conducted on the ImpactCappa planning station again. The prosthesis of choice for that clinic was used in all cases (Erlanger Prothese 13, Peter Brehm GmbH, Weisendorf, Germany) for reasons of comparability. Otherwise, each of the six surgeons followed the usual clinical planning procedure without being influenced.

Using this procedure, the planning based on the patient dataset was carried out following a subjective aim each time—the individual surgeon's opinion. This is in contrast to the study on the phantom, where an objective aim was followed and it was determined how precisely this aim could be achieved due to the technical limitations of the process.

Repeatability of Operation

The second study assessed the repeatability in the OR of the actual operation, i.e., the process of femur fixation, keying of marker pins and milling of the femoral cavity. Both robot systems were evaluated in this study.

To prepare for the experiment, two datasets of the phantom were acquired on a SOMATOM Plus 4 CT scanner, one according to the ROBODOC protocol, the other according to the CASPAR protocol. The datasets were transferred to the respective planning stations for each system. One preoperative plan was conducted on
each station, following the written guidelines provided in the leaflet. Each plan was carried out four times without any changes for both robot systems. The positions of the cavities were measured on the PRIMAR MX4. For each robot system, the mean position and the deviation of the single positions from the mean position were calculated.

**Overall Geometric Accuracy (CT Scan, Preoperative Planning, Operation)**

To evaluate the overall geometric accuracy, the entire RAS-THR process was carried out on the phantom several times. Seven measurements were performed using the ROBODOC system: five at the department for trauma surgery at the University Hospitals Erlangen, and two at the Berufsgenossenschaftliche Unfallklinik Frankfurt. At both sites, SOMATOM Plus 4 CT scanners were used for the CT scans. The preoperative planning was done on the ROBODOC planning stations in both clinics. Each planning session was conducted by a different surgeon, who followed the guidelines in the leaflet. The operations were performed according to the plan in the ORs at the two sites, using their respective clinical robot systems.

For CASPAR, the process was carried out on the phantom four times. All CT scans were acquired on a SOMATOM Plus 4 CT scanner. Four preoperative plans were conducted on the CASPAR planning station by different persons, according to the written guidelines. The operations on the phantom were carried out in a special milling cabinet at ortoMaquet GmbH, the manufacturer of CASPAR, using a clinical robot system.

The milling inserts of both systems were measured with the PRIMAR MX4, and the deviation of the actual position of the cavity from the desired position was calculated.

**RESULTS**

The results of all three studies are presented in Figure 7. The translational deviation of the actual position from the desired position is shown in the three major anatomical directions (medial-lateral, anterior-posterior, proximal-distal). These values refer to the most distal point of the prosthesis stem. The rotational deviation around the same point is displayed in the three major anatomical planes (sagittal, coronal, transversal).

When interpreting these results, it should be kept in mind that a deviation perpendicular to the femur shaft axis indicates milling of the cavity into the cortical bone, resulting in possibly severe damage. On the other hand, deviations along and around the femur shaft axis (proximal-distal, antetorsion) have much less severe consequences.

**Inter-Operator Variation in Preoperative Planning**

In the results for the phantom dataset (objective aim), the deviation was approximately 0.25 mm in both directions perpendicular to the femur shaft axis and 0.45 mm in the proximal-distal direction. The values for the rotational deviation were less than 0.2° for varus-valgus and flexion, and less than 0.8° for the antetorsion angle.

For the patient dataset (subjective aim) the
intra-operator variation showed a much larger deviation - a translational deviation of 0.75-1.0 mm in both directions perpendicular to the femur shaft axis. The deviation in the proximal-distal direction was approximately 5 mm. The rotational deviation was found to be approximately 0.7° for varus-valgus and flexion angle, and 1.1° for the antetorsion angle.

**Repeatability of Operation**

For the repeatability of operation, both robot systems were found to have similar deviations: approximately 0.25 mm in all linear directions and better than 0.2° for the rotational direction, except for the antetorsion angle, where a deviation of > 0.5° was found.

**Overall Geometric Accuracy (CT Scan, Preoperative Planning, Operation)**

The overall geometric accuracy was found to be similar for both systems. They showed translational deviation of approximately 0.5 mm, except for the proximal-distal axis (CASPAR: 0.3 mm; ROBODOC: 1.6 mm). The rotational deviation was approximately 0.3°, except for antetorsion (0.6° for CASPAR; 0.9° for ROBODOC). The apparent differences between the systems are probably due to both the statistical uncertainty in the data collected and the motivation and experience of the various people participating in the study during the preoperative planning stage.

**DISCUSSION AND CONCLUSIONS**

The phantom described in this paper proved to be a suitable means of investigating the geometric accuracy of robot-assisted THR surgery. It permitted examination of the accuracy of the overall procedure, as well as the accuracy of individual steps.

Inter-operator variation was much greater in planning based on the patient dataset than with the phantom dataset. When conducting planning on the patient dataset, the physician is guided by the anatomy of the patient, the guidelines of the prosthesis manufacturer, and also, strongly, by his own experience. He is therefore following a subjective aim, and must often compromise, as the prosthesis may not fit the patient's anatomy. Obviously, the subjective aims of the preoperative planning and the necessary compromises vary between operators.

With the special design of the phantom and the objective aim for the planning being described in the written leaflet provided to operators, the desired result of the planning is clearly defined and is not dependent on opinion, interpretation or compromise. The remaining deviation found when different physicians conducted the planning on the phantom was predominantly caused by the technical limitations of the CT dataset and the planning station, e.g., resolution and image quality of the CT dataset and man-machine interface of the planning station.

When analyzing the data for the repeatability of the operation, it can be concluded that the accuracy of the operation process is determined not only by the accuracy of the robot system but also by the accuracy of the pin registration. The higher deviation for the antetorsion is based on the way the orientation of the prosthesis is derived from the position of the pins. While the varus-valgus and flexion angles are determined by the connecting line between the two pins, the antetorsion is derived from the orientation of the condyle pin. Due to the geometric settings, this orientation cannot be determined with the same certainty as the connecting line between the two pins. It should be considered that a deviation in the antetorsion angle is less critical than deviations in the other two orientations.

When comparing the variation caused by the user's subjective opinion (inter-operator variation when conducting planning on the patient dataset) with the overall deviation caused by the technical components (planning on the phantom, objective aim), it may be stated that the technical components contribute less than the user's subjective opinion to the overall deviations. However, one must take into account the fact that the deviation caused by the user's subjective opinion is based on an intelligent decision, while the deviation caused by the technical components is purely random.

From a technical viewpoint, it can be concluded that each of the three critical steps (CT scan, preoperative planning, operation) of a RAS-THR procedure contributes approximately the same amount to the overall geometric error. With a deviation of 0.5 mm and 0.3°, the overall geometric accuracy of the technical components of RAS-THR seems to be sufficient. The influence of the robot system on the overall accuracy during the actual operation is less than 0.25 mm. However, a threshold for an acceptable error for the placing of the prosthesis has yet to be defined.

Future studies will investigate the influence of the single steps of RAS-THR further. The in-
fluence of new registration methods (e.g., “pinless” registration) and the use of navigation systems in combination with surgical robots for THR should be examined. The method introduced in this article is also suitable for evaluating future developments in RAS-THR, such as automatic positioning of the prosthesis.

We recommend that manufacturers of surgical robots for RAS-THR and responsible operators use phantoms and procedures like those described here as a means of quality assurance for their surgical systems. The ever-increasing demand for quality control, and the need to prove that all possible measures were taken to ensure proper performance, should warrant such efforts.

REFERENCES