Experiences with the ROBODOC® system in more than 1000 cases

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Introduction

Early attempts of cementless fixation were less successful (7), and only after Charnley's invention of bone cement (1), THR proved to be a safe and reliable method that soon would be performed by thousands of surgeons. The use of bone cement showed a lot of advantages:

1. The cancellous bone in the proximal femur, itself to soft to give enough support to the implant, was fortified by the cement.
2. The cavity could be prepared without high accuracy, as the cement would fill any gaps between bone and implant.
3. The use of cement allowed immediate weight bearing, as fixation was perfectly tight after hardening of the cement.

In addition, the cement itself created problems: one more interface was added, creating new problems through different elasticity modules. And finally, in the event of loosening and revision, all the cement had to be removed, this itself being in many cases a major undertaking. Although alterations in cement preparation, cement placement and implant design improved the cemented technique a lot (2), there still is the desire amongst many surgeons for cementless fixation and primarily healing between bone and implant.

In the development of cementless techniques, numerous variations in design of the implant and surface modelling were performed. Although reaming techniques were constantly improved, studies showed the poor performance and the lack of tight contact between bone and implant (5, 6). Planning was performed with acetate templated. During surgery, the surgeon had to rely on certain landmarks in order to orient the implant and try to transform the preop plan. This orientation was impeded by the fact, that only small parts of the bone were actually visible and the most of it hidden under soft tissue. Many studies showed, that the attempt of tight fixation of the implant in the femur led to a significant number of femur fractures, this fact in itself being a major factor for early failure of the implant (8). Despite various techniques and designs, certain principals in cementless THR were established (3):

1. To achieve primarily healing between implant and bone, close initial contact between prosthesis and bone, preferably strong bone is crucial. (7).
2. As important is the correct placement of the implant. Varus or valgus orientation have to be strictly avoided, the proper anteverision has to be considered.
3. Femur fractures must not occur.
Obviously it is hard to meet these principals using the traditional techniques. Therefore, the rationale for the use of a robotic system was given (6).

**Materials and methods**

The ROBODOC® Surgical Assistant consists of three major components: the planning workstation, called ORTHODOC®, the robot itself and the workstation, that guides and controls the robot.

**ORTHODOC®**

The data used in ORTHODOC® to create the image come from CT Data. The process of registration requires the implantation of three small metal pins into the patient's condyles and greater trochanter prior to the CT Scan. CT data of the patient's femur are then loaded into ORTHODOC®. ORTHODOC® creates an image of the patient's femur in three levels:

- lateral
- cross section.

The images can be turned on the screen, zoomed in and the cross section moved to any desired level. A routine identifies the pins in the femur and detects any motion of the patient during scanning. Also included in ORTHODOC® is an implant library. Any implant can be chosen by the planning surgeon and placed into position on the screen. Implants can be moved in any direction, tilted and turned. Especially the proximal loading can be monitored. Once the surgeon is satisfied with the chosen size of the implant and its position in the bone, he creates the ROBODOC® file. This tape is loaded into the workstation that controls the robot.

**ROBODOC®**

The robot itself is a modification of a standard industrial robot, armed with either a probe or a high speed cutter. Surgery starts in the conventional fashion with preparation of the joint, resection of the capsule and femoral head. The cementless acetabular cup is placed by hand. The first step of the robotic procedure is the tight connection between patients leg and robot, controlled by a bone motion monitor. This step is followed by the registration, where the surgeon exposes the two pins and guides the probe at the robot arm to the pin centre. The distances between the pins and their relative orientation is compared by the computer to the data derived from ORTHODOC®. Only if these data match with high accuracy, the procedure can be continued. After successful registration the probe will be replaced by the cutter. Cutting is done fully automatically,
the surgeon on the screen of the workstation. The surgeon can interrupt the procedure anytime by pressing a halt button on the sterile remote control, with which he controls the menu. If a bone motion is monitored by the computer, cutting will stop and registration has to be repeated. The cutting procedure will take, depending on the type and size of implant, between 20 and 40 minutes. At the end of cutting the robot will be disconnected, moved away from the OR table and the surgeon can insert the implant without any problems into the cavity. As the cavity form matches exactly the implant size, no major force is necessary to introduce the implant. Reducing of the joint, closure of soft tissue layers and skin terminate the procedure. The ROBODOC® system was installed at the Berufsgenossenschaftliche Unfallklinik Frankfurt am Main in July 1994. First surgery was attempted in August 1994. From that time until today, 1065 surgeries were performed

Results

The first two surgeries in August 1994 had to be aborted, as pin registration could not be successfully executed. Reason for this was not a surgical mistake or a system error, but a rather unlikely failure in the CT the table motion in CT was inaccurate, so wrong data were transmitted to ORTHODOC® and ROBODOC®. Yet these two cases, as frustrating as they were, proved the safety and accuracy of the system.

After installation of a new scanner, 1000 surgeries were performed between November 1994 and February 1998. In all these cases, preop planning could be transformed with highest accuracy. The chosen implants were inserted without problems, not in one case was a change in size necessary. No femur fractures occurred. OR time in the beginning was more than 3 hours, compared to an average of 1.25 hours in conventional THR. But, after 20 cases, OR time declined to an average of 2.25 hours, with the fastest surgery at about 1.5 hours. The half hour that robotic surgery now takes longer than conventional surgery is consumed by time for connecting the patient to the robot, registration and the cutting.

As complications we saw some pulmonary embolism (n=9 0.9%), deep vein thrombosis (n = 25 2.5%), and 29 (2.9%) cases of postoperative luxation, which were not connected to the robot work but to errors in cup placement. Overall complication rate was lower than in comparable series. After the first 30 patients we changed the postop regimen: patients were allowed to immediate weight bearing on the operated leg. This is in contrast to conventional cementless regimen, where weight bearing starts between week 8 and 10. We were encouraged to change the regimen by the good clinical results of the first patients and the postop x-rays which showed a perfect proximal support of the implant by strong bone. Although full weight bearing was encouraged, no sinking of the implant was detected.

Discussion

Lasting cementless fixation of the femoral component in the bone is impaired by primary instability of the implant. Micro motion promotes bone resorption and development of a
fibrous membrane between implant and bone. Rotational instability, enhanced by poor proximal fixation and/or inadequate positioning of the implant, is responsible for delayed bone healing and possible aseptic loosening. Therefore, close primary fit of the implant within the bone, overall tight contact and exact orientation are mandatory prerequisites (4). The ROBODOC® procedure was designed to help the surgeon in reaching these goals. The procedure consists of two main parts: the planning stage on ORTHODOC®, and the stage of transformation of the plan by ROBODOC®. The planning itself is a revolution compared to traditional templating: there was no chance to consider all the details that are at hand by working with ORTHODOC®. Traditional templating was restricted to determine the size of the implant and roughly the varus/valgus orientation plus the appr. site of the implant. ORTHODOC® planning supplies the surgeon with an abundance of details regarding the fit of the implant, the bone density, the anteversion, the necklength and the offset. While traditional templating took about five minutes and was often neglected by surgeons, ORTHODOC® planning takes at least 20 minutes and is a mandatory routine in the whole procedure.

While the planning on of ORTHODOC® itself is more precise and effective than conventional templating, this advantage gains even more importance by the fact that ROBODOC® transforms the planning during surgery with highest accuracy. Our results show that in all cases the proop plan was fulfilled without any error or deviation. While the conventional procedure offered pitfalls both in planning and transforming of the plan, the robot assisted procedure guarantees the a thorough planning and a consequent execution of the plan.

Although the ROBODOC® technique seemed very complex and demanding in the begining, it proved to be a reliable and not to complicated procedure. Provided good training of the team, consistency within the team, sound motivation to work with new technology and an adaptable surgical environment, robot technology can improve surgeons performance in THR.

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