ROBODOC® System for Cementless Total Hip Arthroplasty Clinical Results and System Enhancements

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ABSTRACT

The ROBODOC® System brings the accuracy of computer-based planning and computer-controlled machining to surgical procedures. This paper presents the clinical results of using the first generation ROBODOC System for over 300 cementless total hip replacement surgeries in the United States and Germany. This clinical experience has also identified enhancements that are necessary for widespread commercial acceptance of the system.

KEYWORDS: Medical Robotics, Computer Assisted Surgery, Orthopedics, Hip Replacement, Clinical Results

INTRODUCTION

The ROBODOC® System has been developed to address an existing void in cementless total hip replacement (THR) surgery. In THR surgery, the surgeon replaces the articulating surfaces of the ball and socket hip joint using an acetabular cup and femoral stem. Clinical success of the procedure is dependent on achieving long term fixation of the artificial components to the patient's host bone. There are two main approaches for attaching the implants to the bone. These approaches differ depending on whether or not bone cement is used to fix the components. Implant designs which do not require the use of cement (cementless) have evolved in an attempt to create a biologic interface between the implant and the host bone that will, in theory, last for the life of the patient. Current cementless femoral implant designs are often based on large human CT and x-ray databases to create a geometry which optimally fits the internal structure of the proximal femur. The implant designs are then accurately fabricated using advanced computer aided manufacturing technologies. The deficiency or void in the overall process is related to the conventional tools that are used to plan and carry out the surgical procedure. Conventional planning uses plane x-rays and two dimensional overlays to determine component size and placement, and conventional bone preparation uses hand held broaches and reamers to prepare the implant cavity.
Our belief is that this void in technology can be eliminated using image-guided computer-assisted surgery techniques where CT data are used to accurately plan the case and a precise surgical robot is used to prepare the femur for the implant. The primary goal of this development has been to significantly improve implant selection and sizing, improve positioning accuracy of the implant within the bone and improve the accuracy of preparation of the bone cavity to accept the implant. Research indicates that these improvements may result in a consistently improved success rate and an increased useful life of the implant/bone aggregate.

The first generation of the ROBODOC System has been clinically used to assist with hip surgery since 1992. This system was designed with an emphasis on ensuring that accuracy and safety requirements were reliably satisfied. Because this was one of the first active robot systems to operate on human subjects, the primary focus of the system development was to fully characterize system performance, develop and test redundant safety mechanisms and to develop a simple man/machine interface. The first generation system and its evolution has been the subject of numerous publications [1-5].

The development approach for ROBODOC has been to complete the implementation and testing for all safety and performance components (without completely addressing OR time and ease of use) and then install these systems in selected hospitals where they can be closely monitored. This approach has allowed for the installation of systems in highly competent centers and then the collection of clinical use feedback. This information is then used to refine the system for more widespread use. Another advantage to this development approach is that it allows for an early start of long term clinical studies that can lead to documented differences between conventional and robotic surgical techniques.

This paper describes the clinical results with the first generation system in addition to the enhancements that are being developed to support widespread acceptance of the ROBODOC system. To aid with system understanding, a short overview of the surgical protocol is included in the following section.

ROBODOC THR PROTOCOL

For the ROBODOC surgical protocol, patients undergo a separate procedure where three titanium locator pins are implanted in the affected femur under local anesthesia. These pins (two at the knee and one at the proximal femur) are used for registering preoperative planning coordinates with intraoperative coordinates during the robotic procedure. After the pins are installed, a CT scan of the femur is taken and loaded into the ORTHODOC presurgical planning workstaton (ORTHODOC). Using ORTHODOC, the surgeon manipulates three dimensional implant models relative to reconstructed CT data of the femur to determine the optimum implant size and position. The planning data, along with pin locations, are then transferred to the surgical robot system (ROBODOC).

During surgery, after manual preparation of the acetabular cup, the femur is secured in a stabilization device (the femoral fixator) and the three locator pins are exposed. Bone movement during the robotic procedure is sensed using a bone motion detection device. This device measures bone movement and causes an interrupt if the displacement is outside a defined limit. The next step involves using a sterile ball probe, attached to the
robot, to determine the robot (surgical) coordinates for each locator pin. These data, along with the corresponding ORTHODOC data, are used to compute a rigid body transformation which can relate pre-surgical plan coordinates to intraoperative surgical coordinates. Following registration, a high speed, pneumatically-powered cutting tool is installed and the robot machines the cavity in the femur. Following cavity preparation, the surgeon disconnects the robot, installs the implant, and completes the surgery in the standard fashion. More detailed descriptions of the procedure, user interface and the safety systems have been previously published [6-8].

CLINICAL RESULTS

To date, over 300 patients have been successfully operated on using the ROBODOC system. These surgeries have been done in the United States and Germany.

United States Clinical Trial

In 1992, the first patient was operated on using the ROBODOC system as part of an FDA (Food and Drug Administration) authorized ten patient clinical pilot study. The goal of this single-center clinical trial was to collect data to justify that the system was safe to operate on humans. In 1993, following successful completion of this study, a randomized multi-center clinical trial was started. For this study, any patient meeting the enrollment criteria is randomly assigned to either receive a hip replacement using the ROBODOC system or one using conventional instrumentation (control group). The purpose of this study is to collect data which could be used to evaluate differences between conventional and robot cases. Three centers have contributed to this study, where each center had 2-4 surgeons participating. As of January 1, 1996, 116 patients with 131 hips have been enrolled in the study and 127 hips (67 ROBODOC and 60 Control) have completed a minimum 3 month follow-up. Two different implants systems have been used so far in the study, the OSTEOLOCK (Howmedica) and the AML (DePuy).

The patients were evaluated using the modified Harris Hip Scale, the Hip Society Rating System, and the SF 36 Health Status Questionnaire. Surgical time, blood loss, length of stay and complications were also recorded. Three month post-operative radiographs were reviewed in a blinded fashion using a strict objective criteria to grade fit, size selection, implant position and reaming defects.

The results for these patients are the following. When the Harris Hip Scale results were broken into total score and pain score, there were no significant differences at 3 months. However, of the patients who had one year follow up results, statistically more patients from the ROBODOC group fell into the "no pain" category. Average length of stay was not significantly different but surgical time and the associated blood loss was significantly greater for the ROBODOC cases. The post-operative complication rate was not significantly different, but the control group included 3 acute intra-operative femoral fractures (cracks) versus 0 for the ROBODOC group.

The most significant differences were seen in the analysis of the post operative x-rays. For both implant designs, the ROBODOC hips had consistently improved alignment and positioning. For the OSTEOLOCK cases, where there was a greater sample size, the implant to bone fit, implant alignment and size selections were all significantly better for the ROBODOC cases.
German Clinical Use

In Germany, regulations required the TÜV testing of the System, which, contrary to the FDA procedure, did not challenge the efficacy of the system, but put emphasis on its technical safety. Regarding the System as a tool in the surgeon’s control, its use and evaluation of its benefits were left to the surgeon’s judgment.

Following development of system modifications necessary to support the surgical approach used in Germany, the first successful surgery was completed in August 1994 at the Berufsgenossenschaftliche Unfallklinik in Frankfurt, Germany. At this site, the ROBODOC system is not being used in a regulated clinical study, but instead as indicated by the surgeons. As a result, there are no control data that can be used for direct comparison. Results can, however, be evaluated based on previous series of patients done with conventional techniques.

The first 120 cases were successfully completed by one surgical team. Results for this series are the following. The OR time for the first 15 cases averaged 180 minutes, whereas for the remaining 105 cases, the average time was 120 minutes with the fastest time being 99 minutes. The overall complication rate was lower than in comparable cementless series previously published.

As of February 1996, a total of 235 patients have been successfully operated on using the ROBODOC System. A number of clinical observations have been noted. There have been no acute intra-operative fractures in any of the patients. This is compared to reported rates that range from 10 - 25%. All post operative x-rays revealed correct (as planned) implant position and orientation. The post operative recovery was significantly improved and allowed for full weight bearing in 3-5 days as compared to the common practice of 4-6 weeks. This occurred in spite of persistent complaints of knee pain due to pin implantation. The knee pain, also common in the United States patients, is not severe and dissipates within 4-6 weeks.

SYSTEM ENHANCEMENTS

During the early part of the above clinical testing, a number of system enhancement were identified. These enhancements were not related to accuracy or safety but were primarily focused on refining the system for widespread acceptance where OR time and ease of use would be critical factors. The clinical feedback identified the following problem areas:

- The time required to set-up and perform the diagnostics was too long.
- Bone fixturing during surgery was time consuming and difficult for the occasional user.
- Implant cavity machining time, which ranged from 25 - 50 minutes depending on implant size, was too long.
- Pin implantation and robotic location was not desirable due to patient discomfort and the required additional surgical procedure.

The system enhancements to address these and other concerns are being implemented and tested in two separate phases.
Phase One Enhancements

The first phase of improvements focuses on reducing set-up and cutting time yet still require implantation of three locator pins. For safety reasons, the ROBODOC system runs extensive start-up diagnostics to verify that all safety and performance-related components are functioning within specified tolerances. After detailed analysis of the data collected during the early clinical cases, we were able to significantly reduce the time required to perform these tests (from 25 to 10 minutes) without any compromise in safety.

Another item that was addressed in the first phase of enhancements was the time required for the robot to machine the cavity. The first generation system machined the cavity in 25 - 50 minutes, depending on implant size. This time was reduced to 15 - 30 minutes by optimizing the tool paths and changing the tool design. One aspect of this change was to use cutters with larger diameters when possible. This allowed for reduction in time for some of the larger stems.

The final area addressed in this phase was the improvement of the bone fixturing approach. The previous design utilized a proximal clamp attached to a frame that used sharp pins at the distal end to penetrate the soft tissue and secure the distal femur. This distal fixation was often difficult to install and required incisions that would not normally be done in a conventional THR surgery. The new design corrects these problems by using a soft tissue constraint applied below the knee to stabilize the distal femur, coupled with an improved proximal bone clamp which increases stabilization.

Phase Two Enhancements

The second phase enhancements which are currently under development involve the removal of the need for locator pins, additional reduction of robotic cavity machining time, and an improved design of the ROBODOC surgical component to address manufacturability, serviceability, and European regulatory requirements for commercial products (CE marking).

A new method for registering the pre-operative data and the surgical robot has been developed and is currently being clinically tested and compared to the pin-based method. This approach involves collecting intra-operative canal center point data and femur neck surface data during surgery and then using optimization techniques to determine the transformation which causes agreement with similar data collected from the ORTHODOC CT-based pre-surgical planning system. Laboratory testing and early clinical results have shown that this new method of registration can produce results that are comparable to the pin-based technique. Additional work is underway to evaluate the repeatability and robustness of this approach.

The second phase reduction in robot cavity preparation time has focused on the implementation of a force control cutting strategy which continuously adjusts the feed rate of the tool based on the sensed cutting force [6]. Previously, the feed rate for each portion of the cavity was set at a fixed value based on the worst-case assumption that the entire cavity was being machined in dense bone. This was done to ensure high dimensional accuracy in all cases. In reality, there is a significant amount of implant volume which is machined in the softer trabecular bone. The new algorithm is designed
to take advantage of this by increasing the feed rate when there is reduced resistance. This method should reduce the cavity machining time to approximately 10 - 20 minutes.

The final major development for this phase is the redesign of the OR component to address the European regulatory standards that have recently been enacted; in particular the standards for electromagnetic emissions and susceptibility. The new design also represents a significant improvement to the packaging of the system, including a reduction from three to two physical units, a reduction in the number and size of the interconnecting cables, and improvements to the maneuverability of the components. A more detailed description of the commercial version of the system is presented in [9].

CONCLUSION

The successful linking of the fields of imaging and robotics has resulted in a new tool for precision in surgery. The original application of this device to cementless total hip replacement has shown the technology to be of benefit. It is through the development of additional applications that this new category of surgical “smart tools” will allow the operating room of the future to provide improved outcomes that make this technology cost effective.

REFERENCES


