Proceedings of the 1992 IEEE
International Conference on Robotics and Automation
Nice, France - May 1992

# A Surgical Robot for Total Hip Replacement Surgery

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## Abstract

*Surgical robots may represent the next major advance in total hip replacement (THR) surgery, replacing the hand-held reamers and mallet-driven broaches that are currently used to prepare a cavity in the femur for implantation of a prosthesis. Advances in prothesis technology include the development of porous-coated components that encourage bone ingrowth and do not rely upon bone cement for fixation and stability. Orthopaedic surgeons have discovered that uncemented prostheses are especially suitable for younger, more active patients who are likely to loosen cement and require revision surgery. However, the long-term benefits of an uncemented prosthesis can only be achieved by the biological interlock of bone ingrowth into the fixation surfaces on the prosthesis--and this requires extremely precise preparation of the femoral cavity to minimize the size and number of gaps between bone and prosthesis. With current manual preparation techniques, prosthesis loosening following cementless THR is a significant clinical problem. This paper describes a robotic surgical system that has been designed to create femoral cavities that are precisely shaped and positioned for implantation of uncemented prostheses.*

## 1: Introduction

The success of cementless total hip replacement (THR) surgery is closely associated with the surgeon's ability to precisely prepare and position a cavity with the exact dimensions of the prosthestic implant. A good fit provides immediate mechanical stability, ensures adequate stress transfer from prosthesis to femur, and promotes the growth of bone into or onto fixation surfaces of the prosthesis. Lack of substantial bone ingrowth due to inaccurate preparation of the cavity can cause cementless components to loosen. Research indicates that gaps between the prosthesis and the femur are a major cause of micromotion and negatively affect both the quantity and quality of bone ingrowth (1,5,10,11).

The current technique for cementless THR involves preparing the cavity with hand-held reamers and mallet-driven broaches. The surgeon relies on experience and "surgical feel" to correctly shape and position the cavity, but even the most skilled surgeon cannot completely compensate for the inherent inaccuracies of this method.

These problems motivated us to seek an alternative technology for femoral preparation and explore the feasibility of using a robot, rather than a mallet and broach to prepare the cavity. The robotics system we developed creates cavities with a dimensional accuracy more than 50 times greater than broached cavities, exceeds the tolerances to which implants are manufactured, and does not produce gaps that prevent bone ingrowth (10).

## 2.0: Development of a Surgical Robot

Today's industrial robots are more than sufficiently accurate for the task of preparing a femoral cavity. However, modifying an industrial robot for a surgical application presented a number of technical difficulties.

### 2.1: Two geometry problems

Precise preparation of a femoral canal presents two separate geometric problems: 1) Creating a cavity with the exact shape and dimensions of the prosthesis; and 2) Orienting the cavity with respect to femoral anteversion, retroversion, varus-valgus, and length.

Shape and dimension: Cavity geometry is determined by prosthesis size and shape. Over 100 designs are commercially available in a wide range of sizes; in addition, several manufacturers can machine custom implants based on CT data of the femur. Prostheses differ in bulkiness, length, shape, and presence of a collar. They also feature different surface effects, including ingrowth mesh pads, grooves, flanges, and indentations. Clinical evaluation of these features is not yet definitive, although some general principles are emerging. Our robotics system may be used with any standard commercial system or with custom prostheses.

The design and manufacture of femoral components uses computer-assisted technologies in which the three-dimensional shape of the prosthesis is defined by a set of digital data. Prosthesis manufacturers have provided us with these data files for use in programming the robot to mill a cavity of the precise size and shape of the prosthesis. Even with a slight loss of accuracy due to lack of total rigidity in the joints of the robot arm and in the cutting tool, we have experimentally determined by reaming rigid foam materials and cadaver bones, that the robot can create a cavity with a dimensional accuracy of

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±.05mm.

Orientation: In order for the robot to correctly orient and position the cavity, it has to locate the femur in space and implement the surgeon's preoperative plan for placement. Spatial orientation of the robot with respect to the patient's anatomy requires placing landmarks on the femur. The landmarks that spatially orient the robot are three titanium locator pins that are implanted into the patient's femur through small percutaneous incisions. After locator pin implantation, the patient is CT scanned. The CT data serves as input to the image-driven preoperative planning system, which finds the locator pins and establishes their position within its coordinate system. During surgery, the pins are exposed and the robot performs a tactile search to physically locate the top center point of each pin. The robot then executes an algorithm to compute pin location. This data enables the robot to generate a coordinate transform of the preoperative planning data with a dimensional accuracy of 0.1 mm. When combined with the resolution of the CT scan (0.29 mm), the overall accuracy of placement and orientation of a robotically reamed cavity in the femur is ±0.4 mm.

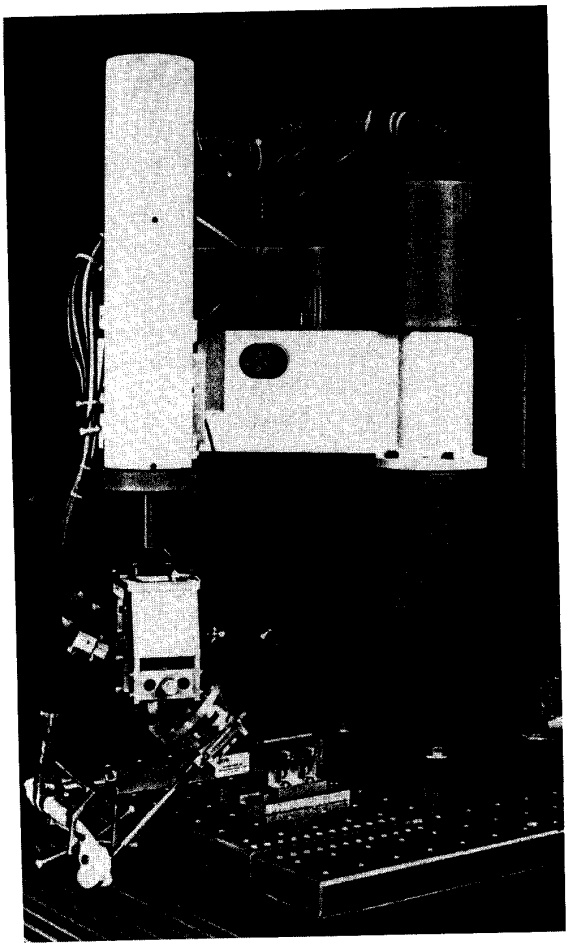
The shape of the cavity is reamed at a precision of ±.05 mm, as is required for a good press fit and initial stability of the component. The orientation or placement of the cavity, as determined by the surgeon during a preoperative planning session is ±0.4 mm. As the resolution of imaging systems improves, so will the system's ability to precisely position the cavity.

### 2.2: Preoperative planning

Using current techniques for THR planning, surgeons overlay acetate templates on plain radiographs to select a prosthesis and determine its placement. Our system uses CT scan data to determine femur size and shape and manufacturer's data to describe prosthesis geometry. The front end to the surgical robot is a preoperative planning workstation, which we call ORTHODOC. Running on an IBM RS/6000 computer, the software graphically presents CT data and gives surgeons the precision of computer-aided tools for prosthesis selection and templating.

ORTHODOC uses the CT data, which is input from a nine-track magnetic tape, to display sagittal, coronal, and transverse images of the femur on the screen. Different colors represent different densities of bone.

After loading patient data, the surgeon selects a prosthesis from the system's library. Using a mouse to manipulate the images, the surgeon moves the superimposed implant imaged into the desired position within the femur. When satisfied with prosthesis selection and orientation, the surgeon saves the data on tape.



***The robot in a laboratory setting, sensing locator pins in a bone model.***

### 2.3: The surgical robot

We adapted a Sankyo Seiki industrial robot for use in surgery by adding a fifth pitch axis and many safety features. The robot has a moveable base, which supports an articulating arm that can position the tool at any angle and location within its effective range. Its movement is controlled by an IBM/AT industrial computer using programs written in AML-X and C++.

The specialized machining and cutting tools for this surgical application are pre-sterilized and single use. They are driven by a standard high-speed (65000-75000 rpm) motor.

To ensure patient safety, the robot is equipped with a set of redundant position encoders; motors and gearing which limit the robot's speed and force; a roll axis that minimizes deflection during cutting; a six-axis force-moment sensor mounted between the fifth joint and the cutting tool, which disables motor power if torque exceeds a certain limit (as would occur if the cutter strayed into dense cortical bone); and a pendant that gives the surgeon pause and emergency stop capabilities.

During surgery, an external fixation device firmly clamps the femur to the robot base, immobilizing the bone and securing its position relative to the robot base. The fixator attaches to the femur by two halo pins just above the knee and a modified bone clamp placed at the level of the lesser trochanter. Movement of the bone in the fixator was experimentally found to be less than 15 microns in any direction when a 10 pound load was applied. Once the robot performs the tactile search to find the locator pins, a bone motion monitor relays motion from the femur to the position sensors and will pause the robot if motion exceeds a predefined threshold.

The system includes a VGA monitor that guides the surgeon and operating room staff through the procedure by displaying a series of prompts, menus, and informational messages. During robotic milling of the femur, the monitor graphically shows the progress of the robot (i.e., the intended path of the cutter within the femur).

## 3.0: The Surgical Procedure

1. A technician prepares the robot for surgery by performing non-sterile calibration and diagnostic procedures.

2. The surgeon begins the operation by exposing the femur in the normal manner.

3. The femoral neck osteotomy is 2-3 millimeters proximal to the desired cut because the robot will mill off the difference.

4. The surgeon exposes the locator pins and secures the femur in the fixator.

5. The surgeon installs a ball probe in the robot's end effector and guides the probe to each locator pin. When the probe senses a pin, it executes a tactile search program that locates the top center point and computes its location in the robot's coordinate system. The transformation is then calculated between the robot coordinate system and the femur coordinate system. A discrepancy between the relative location of the three pins in the CT data and their locations as determined by the robot will signal an error.

6. The surgeon replaces the ball probe with a cutter bit and initiates robotic milling. The surgeon monitors the progress of the operation by direct visual observation and by watching the monitor, which shows the cutter position superimposed on the CT images used in the preoperative plan.

7. When the cavity is complete, the robot is moved away from the operating room table and placed in standby position while the surgeon inserts the prosthesis and finishes the operation in the normal fashion.

## 4.0: A Laboratory Study

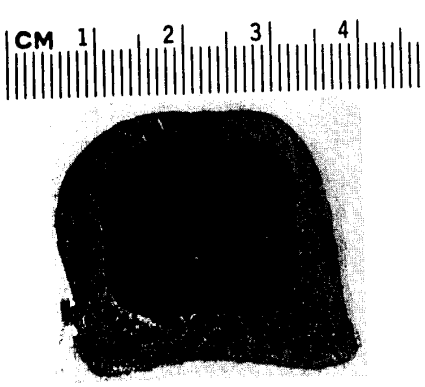
Three systems for preparing a femoral cavity for implantation of a cementless total hip prosthesis were evaluated using nine fresh human femora: two of the systems utilized hand-held broaches and reamers, while a third used a robot-controlled rotary cutting tool. The femora were radiographed to rule out abnormalities, and separated into three groups of three.

The femora of groups 1 and 2 were placed in a vice and the femoral head was removed using an oscillating saw. The intramedullary canal was then reamed and broached using techniques specified by the implant manufacturer. These procedures were performed by an orthopaedic surgeon, who had clinical experience with both implant systems. After the broaching was completed, the broach was fully seated in the bone and saved for processing.

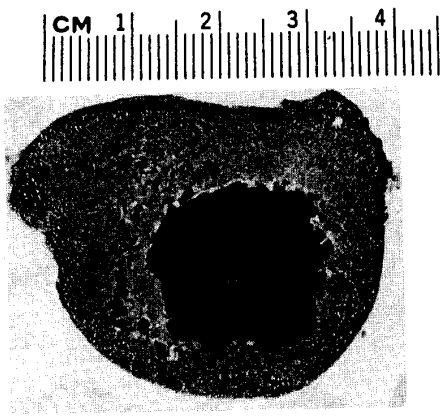
For group 3, following femoral head removal, each femur was clamped in a specially designed fixture with the axis of the bone parallel to the axis of the fixture. The fixture and bone were then placed in the workspace of a five-axis robot (IBM 7576) which had been fitted with a rotary cutting tool (Anspach 65K). Using a contact sensor, the robot located features on the fixture which allowed it to align itself to a coordinate system defined relative to the bone fixture. The robot was then guided to the appropriate start point and the tool tip was measured relative to the fixture. The robot then proceeded to machine the implant cavity.

All groups were evaluated to determine: 1) Area of the actual bone hole; 2) Area of the desired shape; 3) Percentage of the desired shape's surface judged to be in contact with the bone (i.e., no measurable gap); and 4) Average linear gap between bone and desired shape for the medial, lateral, anterior and posterior regions.

When the broach was used for preparing the femur for cementless components, the hole was oversized by an average of 31%. On gross examination, it was difficult to determine the intended geometry. The average linear gap between the desired shape and the bone was 1.2 mm and ranged from 1.0 to 3.5 mm. Gaps were present over 79% of the desired shape's surface, with only 21% of the




*Cross section of a robot-prepared femur*




*Cross section of a broached femur. Large irregular gaps appear where the broach has torn out trabecular bone*

prosthesis in direct contact with bone.

In contrast, the robot-prepared femora clearly revealed the desired geometry. No gaps were present in the proximal and distal areas of the metaphysics along the anterior, posterior, lateral and medial regions. When the sections from the robot-prepared femora were measured directly using calipers, the difference between the desired and actual dimensions were found to be ±0.5 mm.

The dimensional accuracy achieved by the robot was one order of magnitude greater than the accuracy obtained with hand-held broaches and reamers. All differences between the robot and manual broaching techniques were significant to $p<0.01$. These results indicate that the current technique of femoral cavity preparation using hand-held broaches and reamers is inaccurate.

When examining sections from the manually prepared femora, gaps were clearly present where it was geometrically impossible for the broach to have made contact. These gaps probably result when the broach tears out a chunk of trabecular bone instead of cutting it at the broach tooth contact point. The broach also tends to rebound after making contact with dense trabecular or cortical bone, which also causes undesirable gaps. It is possible that a significant amount of the surgical error associated with using a broach is related more to the intrinsic characteristics of the tool than to an individual surgeon's abilities.

Another potential source of surgical error was associated with the initial orientation of the broach for manual preparation. Unless the expected end position of the broach was accurately projected to determine where to begin the procedure, the interior surface of the bone might exert forces on the broach which can redirect its path and cause proximal gaps.

In contrast, none of these problems occurred when the robot-controlled cutting tool was used. Both trabecular and cortical bone sections were consistently accurate, possibly due to the fact that the cutter reaction forces can be reduced to a negligible value by adjusting the feed rate. By doing so, the robot can machine trabecular and cortical bone with the same degree of precision. Examination of the robotically prepared femora also revealed that the trabecular bone appeared to be cut and not torn.

## 5.0: A Canine Clinical Study

A canine study was undertaken to evaluate the prosthesis fit and placement achieved by employing a surgical robot to prepare the femur. This study compared the results achieved on 15 dogs undergoing THR with manual broaching techniques and 25 dogs undergoing robotically-assisted surgery. The manually broached cases were the last 15 THR cases performed at the Sacramento Animal Medical Group prior to installation of the robot (between October 1989 and May 1990). The 25 robot cases were performed between May 1990 and May 1991.

The objective of the study was to demonstrate that the system was safe and efficacious in a clinical setting. A comparison was made between the dogs in the standard-of-care control group whose femurs were hand broached and the dogs whose femurs were machined with the surgical robot. The two groups were evaluated for prosthesis fit and placement, as well as the incidence of intraoperative cracks, fractures, and complications.

All dogs in the control group of manually broached femurs underwent preoperative radiographs with magnification markers. The surgeon then chose the appropriate prosthesis based on the use of acetate overlay templates of nine different sizes of femoral prostheses.

*The robot in action during a canine clinical trial*

Dogs in the study group underwent a computed tomogram study on the operated femur. This information was then imported into the ORTHODOC workstation and the principal investigator, Dr. Howard Paul, used the system to select the size and plan the placement of the prosthesis in the operative femur. The same nine sizes of femoral prostheses were available for both groups.

Consideration was given to randomly assigning subjects to either the control group or the group undergoing treatment with the surgical robot. However, due to the vast improvement in results with the robot, the principal investigator was reluctant to return to the manual method and decided to use the previous 15 cases as historical controls.

The use of actual clinical cases enabled assessment of certain feasibility parameters, including the ease of positioning of the surgical robot in the operating room, the effectiveness of the user interface with the system control software, the suitability of the fixator for femur stabilization, and the sensitivity of various alarm and warning conditions in the system.

### 5.1: Control group results

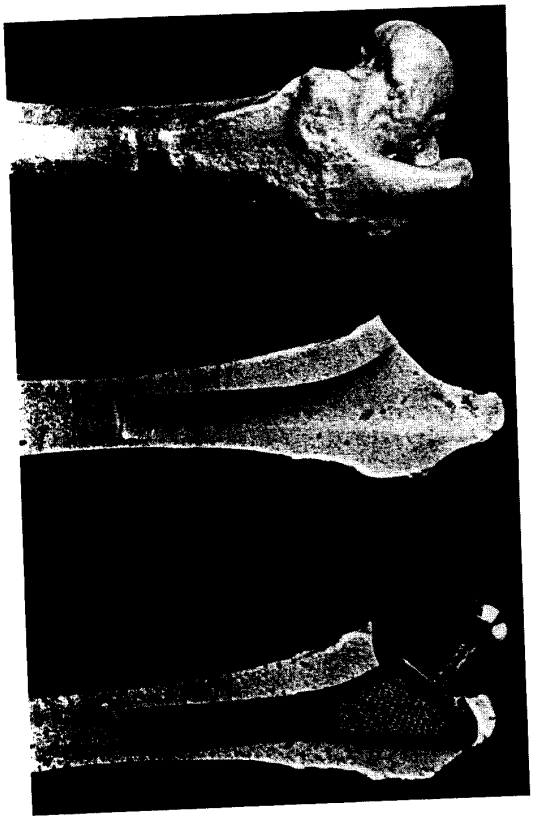
Among the 15 dogs, which ranged in age from two to 12 years, there were no deaths and no infections. Five intraoperative cracks/fractures of the femur occurred either during broaching or upon installation of the femoral prosthesis. All were repaired using one or more cerclage wires around the affected bone. There were three dislocations in this group that needed to be reoperated. One of the dogs in this group has a femoral component that appears loose, perhaps as a result of delamination of the mesh pads on the prosthesis surface. The final choice of prosthesis always occurred during surgery as a function of the surgeon's impression of how the broach was seating in the femur. The femoral prosthesis never sat below the osteotomy cut, but frequently sat above it.

### 5.2: Study group results

Among the 25 dogs, which ranged in age from 2 1/2 to 11 years, there were no deaths, no infections, and no intraoperative complications. Four dogs had early dislocations of the hip. Upon reviewing the three-dimensional ORTHODOC images and evaluating the post-operative radiographs, it was determined that the acetabulum in each of these cases was too retroverted in relationship to the version angle of the femoral head. Dr. Paul had been positioning the acetabular component for the study group in the manner customary for manual cases. This positioning proved to be inadequate because robotic milling increased prosthesis-to-bone contact to such an extent that the final version angle varied widely. Thus, it is necessary to look at the 3D view of the femur to assess the degree of anteversion of the femoral prosthesis and adjust the position of the acetabular component after using ORTHODOC to establish the final position of the prosthesis. One dog's prosthesis needed revision due to delamination of the mesh pads. When this was determined to be the reason for surgical failure, prostheses with this type of ingrowth surface were no longer selected.

No cracks or fractures occurred in the study group. The clinical impression at the time of implantation was that all of the prostheses were easily inserted and were a precise press fit with immediate mechanical stability, much more so than is typically experienced with broached cavities.

It was noted that the implants medial arc always ended flush with the neck cut finished by the automated process. For the study group, final placement of the prostheses, as judged from radiographs, was considered to be an optimal match to the position planned preoperatively. Thus, no implants sat too proud or too low at the time of surgical closure and this was confirmed by postoperative radiographs. Average surgery time for the study and control groups was about the same. A year after surgery, radiographs indicated that the prostheses remained in good position with no loss of bone density around the prosthesis.



***Three views of a canine bone model: 1) Uncut, 2) Cut-away view with a robot-prepared cavity, and 3) Cut-away view with prosthesis inserted. Note the machined surface and line-to-line fit of the prosthesis.***

## 6.0: Human Applications

The first robot-assisted human total hip replacement surgery is scheduled for 1992. The second surgical application for the robot, which is currently under development, will be total knee replacement. Other applications are under consideration, including placement of distal cross-locking screws for intramedullary nails, placement of pedicle screws in the spine, and osteotomies.

The results of our experimental and clinical canine studies indicate that the robot can greatly increase the accuracy and precision with which a surgeon plans and executes a joint replacement procedure. Whether robot-assisted joint arthroplasties will provide better long-term prognoses remains to be determined; bone is an adaptive tissue that can sometimes compensate for surgical inaccuracy. Nonetheless, we predict that robotic systems such as ours will provide surgeons with an unprecedented degree of precision for procedures such as THR.

## Acknowledgments

We wish to thank the following institutions and individuals who have contributed to the work described here: The Anspach Effort; Microtechmedical Corporation; Techmedica; Orthopaedic Systems, Incorporated; IBM; Michael Madison; Sacramento Animal Medical Group.

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