Development of a Surgical Robot for Cementless Total Hip Arthroplasty

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The long-term success of cementless total hip arthroplasty (THA) may depend on bone ingrowth into the porous-fixation surfaces of the implant. The ingrowth process is facilitated when the surgeon achieves a satisfactory fit for the prosthesis. Clinically or roentgenographically visible failure and persistent thigh pain after cementless THA remain significant problems, both of which may be alleviated by more precise preparation of the femoral canal and selection of an appropriately sized prosthesis. The objective of this study was to obtain an exact fit for the prosthesis through the use of an image-directed surgical robot for femoral canal preparation.

The classic technique of preparing the femoral canal for cementless implantation is inherently imprecise: using hand-held reamers and mallet-driven broaches, the orthopedist relies on experience and "surgical feel" to create the cavity. Even the most skilled surgeons cannot consistently achieve dimensional accuracy with these tools. A major consequence of imprecise femoral canal preparation is inadequate contact between prosthesis and bone, with gaps that may prevent bone ingrowth. Studies indicate that gaps between cementless prostheses and bone are a major cause of micromotion[4] and negatively affect the quantity and quality of ingrowth.[2,3,6,7]

These problems motivated the search for an alternative technology for femoral preparation and prompted exploration of the feasibility of using a robot, rather than a mallet and broach, to prepare the canal. The robotic system that has been developed creates cavities with a dimensional accuracy up to 10 times greater than broached cavities, and the system does not produce gaps that may prevent bone ingrowth.

Robotic preparation of a femoral canal presents two separate geometric problems. The first problem is producing a cavity of the appropriate shape and dimensions for the prosthesis. The second is to correctly orient this cavity with respect to femoral anteversion, retroversion, varus–valgus, and leg length.

There is another issue that will not be addressed in detail, but which requires mention here because it is closely related to the two geometry problems: selection of an implant design and size that will function optimally in the particular femur being implanted. More planted. More than 100 implant designs are commercially available, and several manufacturers can machine custom implants based on computed tomography (CT) data of the femur. Implants differ in their bulkiness,

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length, shape, presence of a collar, and location and type of ingrowth surfaces, as well as the location and type of grooves, flanges, indentations, and other surface effects. Definitive clinical evaluation of these features is very difficult, although some general principles are emerging. The robotic surgical system will work with any standard commercial system or with custom prostheses. By allowing the surgeon to view the prosthesis fit to the bone in three dimensions, improvement in prosthesis selection and sizing is expected.

MATERIALS AND METHODS

Shape of the Femoral Cavity

The design and manufacture of hip prostheses uses computer-assisted technologies that define the three-dimensional shape of the prosthesis by a set of digital data. Implant manufacturers can supply these data files in a form appropriate for programming the surgical robot to mill out a corresponding cavity. Despite the potential for some loss of accuracy because of lack of total rigidity in the joints of the robot arm and the cutting tool, experiments involving the reaming of rigid foam materials and anatomic specimen bones have shown that the robot can create a cavity dimensionally accurate to within 0.4 mm (Fig. 1). This is up to 10 times more accurate than the experimental results achieved with manual broaching.

Although no consensus has been reached on acceptable gap size, a recent study indicates that gaps as small as 0.05 mm can prevent bone ingrowth.[1] When studies to determine the feasibility of using the robotic system for canine clinical trials were initiated, the problem of implant tolerances was addressed by measuring each implant. These measurements allow the program to be adjusted for the shape of individual prostheses.

Orientation of the Femoral Cavity

To correctly position the cavity, the robot needs to know where the femur is in space and where the surgeon plans to place the implant. To spatially orient the robot with respect to the bone and the

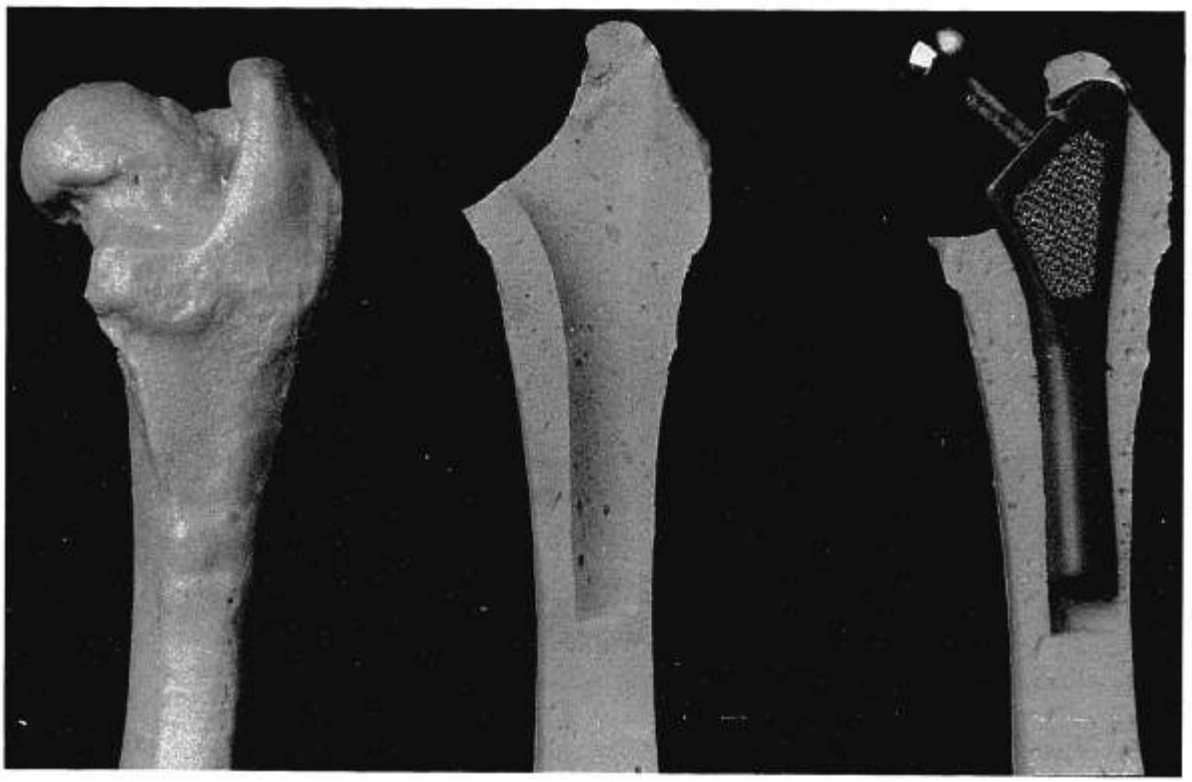

FIG. 1. The robotic system machines dimensionally accurate cavities. This photograph (left to right) shows an intact foam bone, a cut-away view of a robotically reamed foam bone, and a cut-away view of a foam bone with implant inserted.

intended implant position, the femur is preoperatively CT scanned. The CT scan must include three-dimensional identification of certain landmarks on the femur, which the robot can use to construct a bone coordinate system. These landmarks must be present in the initial CT scans so that the surgeon can preoperatively select and template the prosthesis in relation to them. The landmarks must also be identifiable by the robot at the time of surgery.

To serve this purpose, three titanium calibration pins, 2-mm thick and 10 mm in diameter, with screws 12-mm long and 4.5 mm in diameter, are used. The screw portion of a calibration pin is centered on the disk and oriented perpendicular to it. Its purpose is to secure the pin to the bone. The calibration pins are small enough to be percutaneously placed in the femur and large enough that the top center of the disk can be located on the CT scan preoperatively and by the robot, using a force sensor and ball probe at the time of surgery (Fig. 2). Ceramic and titanium pins with disks having 5-, 10-, and 15-mm diameters were evaluated. The titanium pins with 10-mm disks provided the greatest accuracy for localization on the CT data and localization by the robot.[5] Although a small amount of scatter created fuzzy edges, pin images are symmetrical and can be consistently located with submillimeter accuracy.

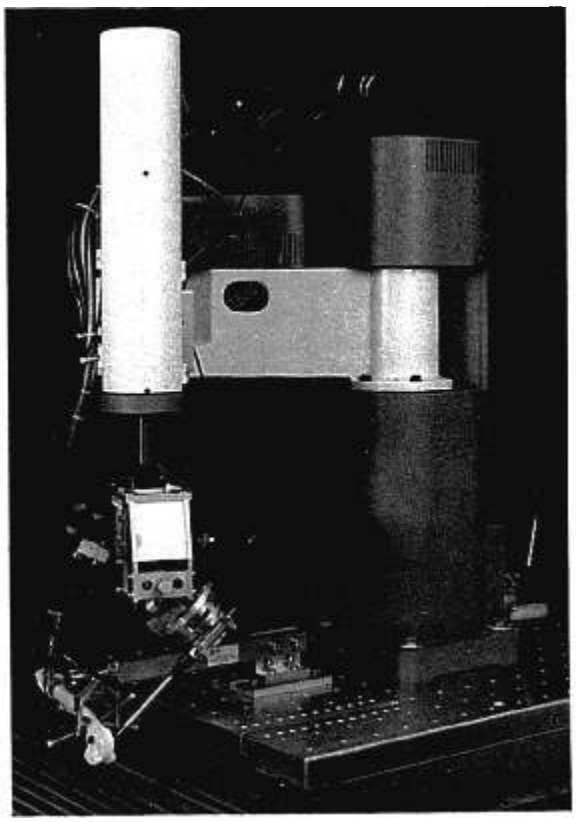

FIG. 2. The robot in a laboratory setting, using its ball probe and force sensor to establish the position of a calibration pin.

Before the CT scan, the surgeon implants the calibration pins through small percutaneous incisions. One pin is placed in each of the femoral condyles, and one in the greater trochanter. The patient is CT scanned, and the CT data is used for preoperative planning and selection of an implant. During surgery, the femur is secured to the robot base with an external fixation device. The "fixator" immobilizes the bone with a clamp at the lesser trochanter and two halo pins, which are inserted just proximal to the calibration pins at the knee. The three calibration pins are then exposed, and the robot's ball probe guided into contact with each one. When a pin is contacted, the robot executes an algorithm to compute the location of the top center point of the disk. The locations of the three pins provide the robot with the coordinate system used during preoperative planning.

After finding the pins, the robot generates a coordinate transform with a dimensional accuracy of 0.1 mm. Combined with the resolution of the CT scan (0.29 mm), the robot's overall accuracy for placement and orientation of the femoral cavity is ±0.4 mm. As the resolution of imaging systems improves, so will the system's capability for precision placement. Currently, the shape of the cavity is reamed at a precision of ±0.05 mm. These tolerances should provide a good fit and immediate mechanical stability.

PREOPERATIVE PLANNING

Traditionally, a surgeon planning a total hip arthroplasty (THA) uses acetate templates as overlays on plain roentgenograms to select an implant and plan its placement within the femur. Because accurate, digital data describing the three-dimensional geometry of the femur (from the CT scan) and the geometry of the implant (from the manufacturer) was readily available, the authors used this data for preoperative planning. A user-friendly program, ORTHODOC, was developed to run on an IBM RS/6000 computer (IBM, Boca Raton, Florida). CT data of the femur was entered into the computer from a nine-track magnetic tape. From this input, the system created sagittal, coronal, and transverse images of the femur (Fig. 3). Differing densities of bone, as determined from the Hounsfield numbers on the CT tapes, are represented by different colors.

The surgeon selects an implant from the computerized library of implant shapes and sizes. The

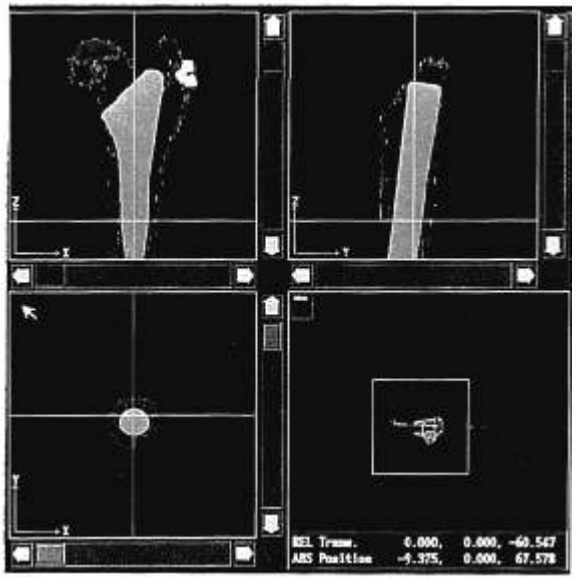

FIG. 3. The preoperative planning system displays sagittal, coronal, and transverse images of a femur and an implant. In a computerized templating session, the surgeon moves and rotates these images to designate the optimal position for the implant within the femur.

dimensional geometry from manufacturer specifications for these implants has been previously entered into the computer. After making a selection, a mouse is used to manipulate an image of the implant and superimpose it on the image of the femur in the desired location for implantation. The computer screen simultaneously displays coronal, sagittal, and transverse views of the femur and implant and allows the surgeon to move, rotate, and change the viewing planes. When the surgeon is satisfied with the selected implant and its orientation, the preoperative plan is saved onto a tape cartridge. The tape cartridge then contained all of the input needed by the robot to machine a cavity that is correctly shaped and oriented with respect to the three calibration pins in the femur.

THE ROBOT

A five-axis Sankyo-Seiki industrial robot was adapted for surgery by adding a six degree-of-freedom force–torque sensor, redundant sensors to assess the robot's position, and a standard high-speed (65,000–75,000 rpm) surgical cutting tool. The torque and speed at which the robot can work was lowered, and the robot was mounted on a movable base, which supports an articulating arm that can position the tool at any angle and location within its effective range. Robot arm movement is controlled by an IBM PC/AT industrial computer.

The robot's machining and cutting tools are sterile; the rest of the robot was draped. During surgery, the robot is wheeled to the operating table and the base rigidly fixed in place. The fixation device secures the femur and immobilizes it in relation to the base. The surgeon has a gas-sterilized hand-held terminal, called a pendant, to interact with the robot during the course of the operation. This terminal supports manual guiding, motion start/stop, emergency power on/off, and other similar functions. It is also used to control the overall sequence of steps and to select preprogrammed error recovery routines, if necessary.

THE SURGICAL PROCEDURE

Before surgery, the robot is calibrated, placed in standby mode, and covered with a sterile draping system. The operation is begun by exposing the femur in the normal manner. A femoral neck osteotomy is then performed 2–3 mm proximal to the desired cut. (The robot mills off the difference.) The acetabulum is prepared in the normal manner, and the acetabular cup is installed.

Proceeding to femoral preparation, the three locator pins are exposed. Then the patient's leg is secured in the femoral fixator. A ball probe is installed in the robot end effector, and the probe is manually guided to the vicinity of each calibration pin. When the probe is close to a pin, the surgeon uses the pendant to initiate a tactile search program that allows the robot to locate the exact center point on the top of the pin. The system performs a transformation between the robot coordinate system and the coordinate system in the preoperative plan. A discrepancy between the relative location of the three pins in the plan data and their actual locations as determined by the robot will signal an error. In this case, an error recovery routine would be activated, which involves relocating the calibration pins. If the discrepancy cannot be resolved, the surgery must be completed manually.

After successful pin finding and coordinate transformation, the surgeon replaces the ball probe with a cutter bit and initiates robotic milling of the femoral cavity. The surgeon carefully monitors the progress of the operation by direct visual observation and through the online display, which shows the cutter position superimposed on the CT images used in the preoperative plan. When the cavity is complete, the robot is moved away from the operating room table, the surgeon inserts the

implant, and the operation is finished in the normal manner.

Safety Features

The system has many features that ensure patient safety and milling accuracy. The pendant requires the surgeon to approve all robotic actions in advance and provides push-button stop and pause functions in case of emergency. A force sensor automatically pauses the cutting action and robot motion if the force applied by the cutter exceeds a certain limit, as would occur if the cutter strayed, unprogrammed, into dense cortical bone. Data integrity of critical files is automatically validated before execution of any surgical procedure. Cutting tool control by the application software ensures that the cutting tool receives power only in the absence of error conditions. Startup diagnostics verify the accuracy of the robot arm and wrist kinematics. If error conditions are detected, the system displays appropriate error messages and will not permit the procedure to begin. Currently under development is a system of redundant sensors that monitor the joint positions of the robot via a back-up computer and automatically pause the cutting action if the cutter strays outside a predefined "safety envelope."

A Laboratory Study

A study was conducted to compare the accuracy of traditional techniques for femoral canal preparation versus robotic milling. The study evaluated three different systems for preparing the femoral canal for cementless total hip implantation. Two of the systems used hand-held broaches and reamers while the third used a robot-controlled rotary cutting tool, similar to the one used in the current system. Nine fresh human femora were roentgenographed to rule out abnormalities and then separated into groups of three.

Group 1—These femora were CT scanned with a GE 9800 scanner (General Electric, Milwaukee, Wisconsin). Based on the CT image data, custom implants were designed for optimal fit and fill of each medullary canal. The implant manufacturer supplied a custom broach and reaming specifications for each bone.

Group 2—These femora were roentgenographed with a scaling marker in the field and templated to determine the appropriate size implant for each bone. A complete set of Zimmer BIAS broaches and reamers (Zimmer, Warsaw, Indiana) were obtained.

Group 3—These femora were roentgenographed with a scaling marker. Based on measurements of the roentgenographic data, custom implants were designed for the optimal fit and fill of each medullary canal. The geometry for each implant design was converted into a cutter control program, which would guide the robot through the appropriate motions. This program specified all of the points necessary to create the cavity and directed the robot to move through consecutive points in a straight line. Executing certain combinations of straight-line moves enabled the robot to approximate curves.

The femora of Groups 1 and 2 were placed in a vice and the femoral heads removed using an oscillating saw. The intramedullary canals were then reamed and broached using techniques specified by the implant manufacturer. These procedures were performed by an orthopedic surgeon who had clinical experience with both implant systems. After broaching, each femur and fully seated broach were potted in a special jig using polymethylmethacrylate (PMMA) (Fig. 4). The position and orientation of the broach relative to the femur/PMMA block was measured and the broach removed. Using a milling machine and a carbide-tipped saw blade, the potted femur was sectioned at 7-mm intervals, beginning at the level of the neck osteotomy and continuing through the cutting portion of the broach, creating eight to ten sections 4-mm thick. Before each section was made, the distance between the base of the block and the section surface was measured using calipers. This value (D2) along with measurements made while the broach/bone was in the fixture (D1) were used to determine the location of the corresponding broach cross section (Fig. 5). Using a height gage, digital calipers, and radius gages (accuracy $\pm$ 0.1 mm), the broach cross section was characterized for each bone section. These measured cross sections of the broach represented the desired shape for each bone section. Each section was photographed with a scaling marker and enlarged by a factor of approximately 3.5. The scaled cross section of the broach was drawn on each photo from its calculated position and in relation to bony landmarks. Every other section (14 mm apart) was then digitized on a Sigma-Scan computerized tablet (Jandel Scientific, Corte Madera, California) to determine the broach and gap areas. The average gap between broach and bone and the percent of the broach surface judged to be in contact with the bone (*i.e.*, no measurable gap) was determined for the medial, anterior, lateral, and proximal broach regions.

The femora of Group 3 were placed in a vice and the femoral heads were removed in the same manner as with Groups 1 and 2. Then, each femur was clamped in a specially designed fixture with

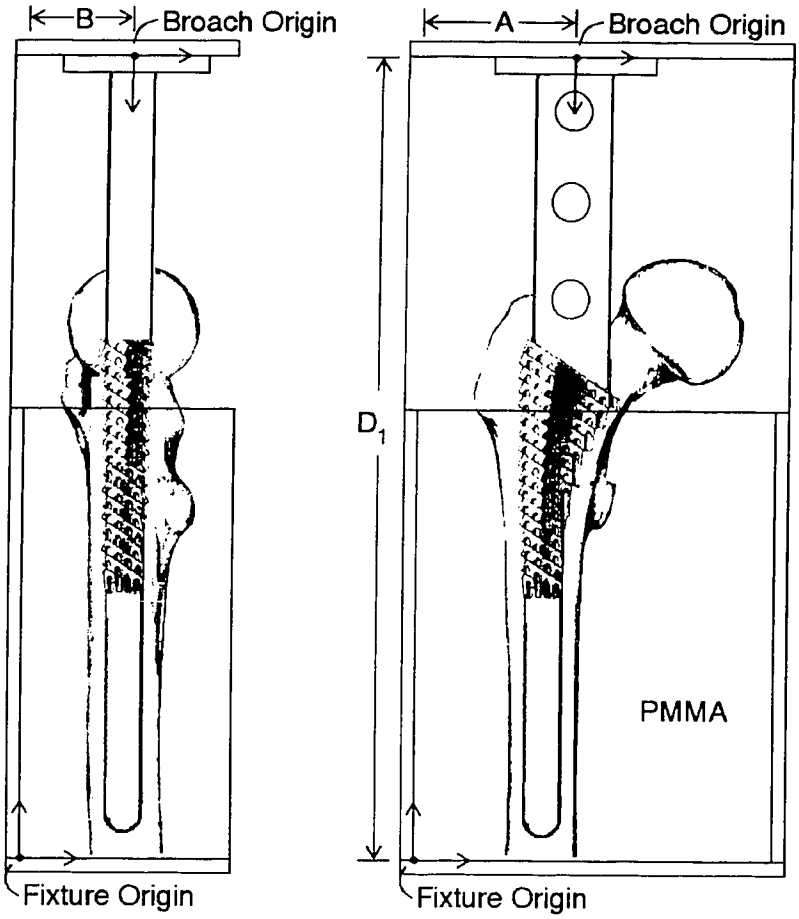

FIG. 4. A broached femur and fully seated broach, potted in a special jig.

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 (Anspach Effort, Lake Park, Florida). Using a contact sensor, the robot located alignment features on the fixture to physically orient itself with respect to the coordinate system in the cutter file. The robot was 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. When the cavity was finished, the fixture, with the bone still attached, was stored for processing.

The femora machined by the robot were processed in the same manner as the broached femora. As mentioned above, each bone was placed in a fixture and aligned with the robot before the machining took place. In addition to this, the start point of the robot tool (which corresponds to the origin of the implant coordinate system) was recorded relative to the fixture. After robotic machining, the bone (still clamped in the fixture) was potted to form rectangular bone/PMMA blocks. These blocks were measured and sectioned as described above. Using the measured value (D2) and the coordinates of the robot start point (D1), the desired cross section for the corresponding bone slice could be determined by evaluating the cutter location file for the appropriate level (H) (Fig. 6).

Each bone section was photographed with a scaling marker and enlarged to approximately 3.5 times its original size. The desired shape, scaled appropriately, was superimposed onto the photograph of each bone section. Each photograph was then digitized using a Sigma-Scan computerized tablet to obtain the following measurements: (1) the area of the actual bone cavity, (2) the area of the desired shape, (3) the percentage of the desired shape's surface, judged to be in contact with the bone (*i.e.*, no measurable gaps), and (4) the average linear gap between bone and desired shape for the medial, lateral, anterior, and posterior regions of each section (*i.e.*, area of the gap divided by its perimeter).

In addition to the above measurements, the bone sections that were machined by the robot were also measured directly using digital calipers.

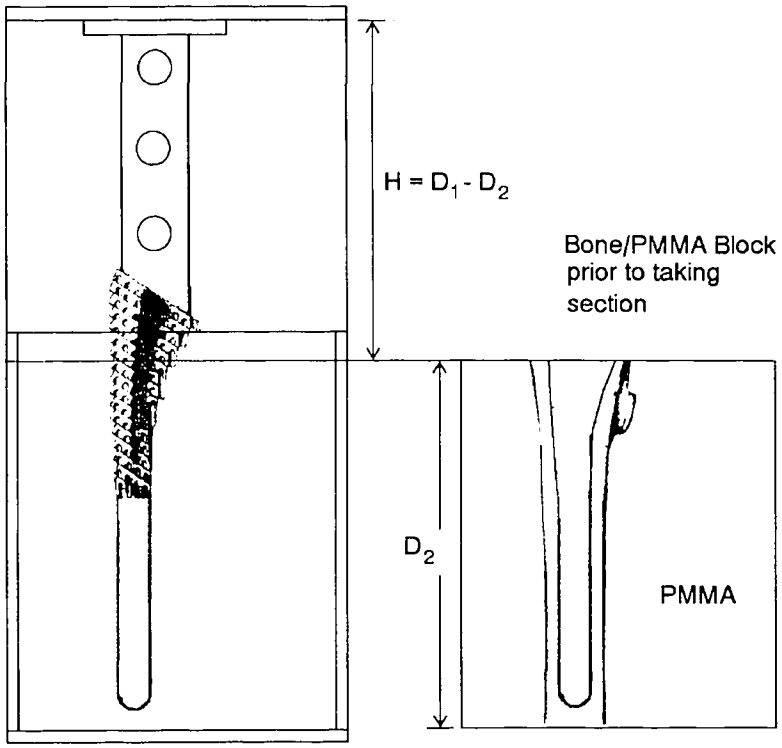

FIG. 5. Measurements were taken to determine the desired cross sections.

RESULTS

Measured gaps between the broach and the bone are reported in Tables 1 and 2. When the broach was used for preparing the femur for cementless implants, the cavity was oversized by an average of 31–33%. On gross examination, it was difficult to determine the intended geometry from most of the bone sections (Fig. 7). The average gap was 0.89 mm for the proximal sections and 1.78 mm for the distal sections ($p < 0.015$). Mean me-

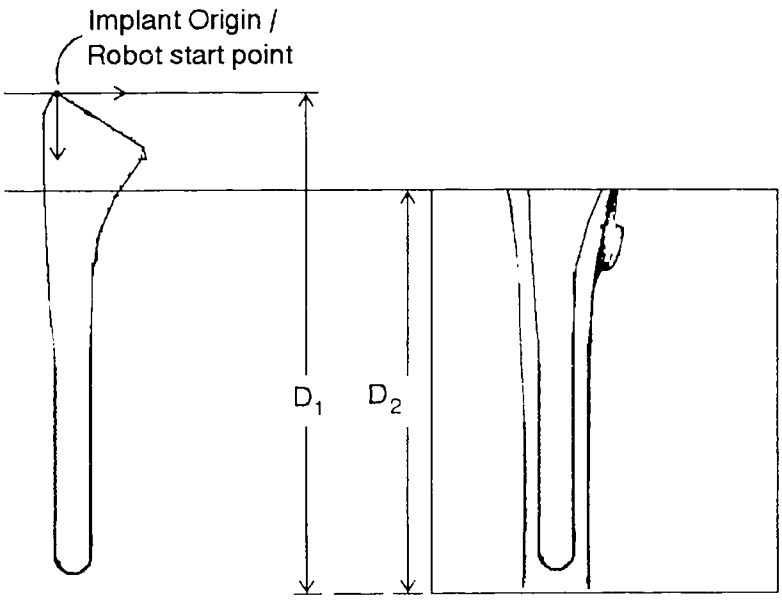

FIG. 6. Measurements were taken to determine the desired cross sections.

TABLE 1. Broached Femora

Cavity oversizing	Mean = 31.33% Range, 22.41–39.62%
Average linear gap	Mean = 1.20 mm Range, 0.96–3.46 mm
Percentage of perimeter in contact with bone	Mean = 20.8% Range, 15.7–29.4%

This table combines the results from Group 1 (custom implants) and Group 2 (Zimmer BIAS implants) because there were no significant differences between these two groups.

dial gaps were less than mean lateral gaps (1.24 mm versus 1.66 mm, respectively, $p < 0.10$). Mean anterior gaps were significantly less than mean posterior gaps (0.66 mm versus 1.74 mm, $p < 0.05$).

The percentage of the broach surface contacting bone was estimated by the perimeter of the broach contacting bone on each scaled photo. These results are presented in Tables 1 and 2. The broach/bone contact percentage was 30.89% for the proximal sections ($p < 0.015$). Medial percentage contact was larger than lateral contact (17.71% versus 6.36%, respectively, $p < 0.08$). Anterior percentage contact was significantly larger than posterior contact (54.63% versus 16.55%, $p < 0.02$).

In contrast, the sections machined by the robot clearly revealed the desired geometry (Fig. 8). Gaps were measured by superimposing the desired shape over a photograph of the section. No gaps were present in any of the proximal and distal areas of the metaphysis along the anterior, posterior, lateral, and medial regions. When these sections were measured directly using calipers, the difference between planned and actual dimensions were found to be less than 0.1 mm.

TABLE 2. Robotically Machined Femora

Cavity oversizing	Mean = 0.54% Range, 0.40–0.70%
Average linear gap	Mean = 0.05 mm Range, 0.03–0.08 mm
Percent of perimeter in contact with bone	Mean = 95.75% Range, 94.10–97.60%

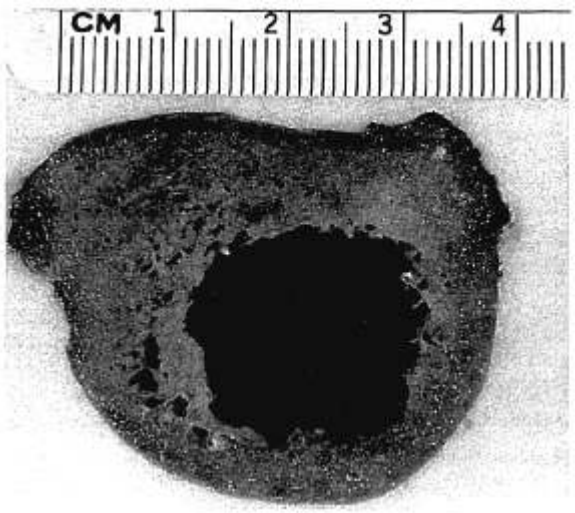

FIG. 7. Cross section of a manually broached femur. The large irregular gaps were created when trabecular bone was torn out by the teeth on the broach.

The accuracy at which the robot was able to machine the bones was one order of magnitude greater than the accuracy obtained when hand-held broaches and reamers were used.

The safety and efficacy of using a surgical robot for THA was tested in a veterinary clinic where 25 successful robot-assisted sur-

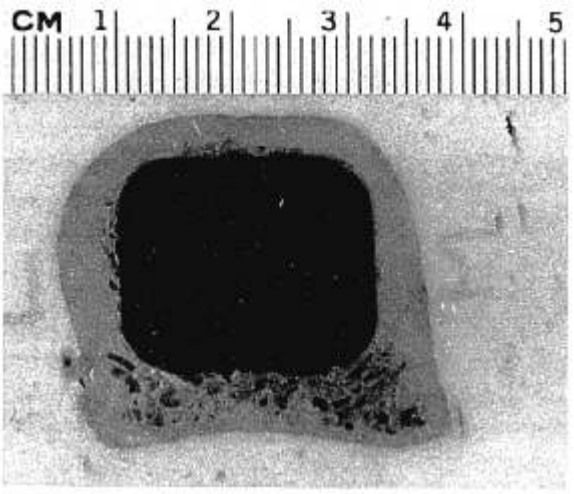

FIG. 8. Cross section of a robotically machined femur.

geries were performed on canine patients with severely disabled hip joints caused by arthritis, femoral neck fractures, or failed pelvic osteotomies.

The study demonstrated that the robot can be easily positioned in the operating room; the fixation device can effectively stabilize the femur during robotic milling; the user interface (computer screen and hand-held pendant) provide the surgeon with adequate control throughout the procedure; and the system has appropriate safeguards and warning features.

None of the dogs in the study suffered any intraoperative complications, such as femoral cracks or fractures, and there were no postoperative infections. The surgeon's impression at the time of implantation was that all of the implants were easily inserted and fitted precisely, providing immediate mechanical stability. Postoperative roentgenograms confirmed the impression that all implants were well positioned.

DISCUSSION

Three of the broaches used in the laboratory study were custom-designed to correspond to a custom implant that would maximize the fit and fill of the endosteal canals in the bones for which they were intended. The other bones were prepared with off-the-shelf broaches supplied by the manufacturer. However, the act of manually broaching the canal created average regional gaps of up to 4 mm. Although the results of this experiment clearly illustrate the relative inaccuracy of current techniques for femoral canal preparation using hand-held broaches and reamers, clinical results may be even worse, because a femur is not rigidly fixed during an actual operation.

Examination of broached sections revealed that gaps were present where it was geometrically impossible for the broach to have made direct contact. These gaps were created when the broach tore out chunks of trabecular bone instead of cutting bone at the point of contact with the broach tooth. The tendency of the broach to bounce when it makes contact with dense trabecular or cortical bone may also produce gaps.

Another potential source of gaps is the initial orientation of the broach when femoral canal preparation begins. Unless the expected end position of the broach is accurately projected at the beginning of the procedure, the interior surface of the bone can exert forces on the broach and redirect its path. This problem may cause proximal gaps, especially when a long, curved stem prosthesis is used.

Many surgeons are aware of the problems associated with broaching and attempt to compensate by using oversized prostheses. Because some of a broached envelope is usually correct, driving an oversized prosthesis into the bone can impinge on the high points, causing either a fracture of the bone or malposition of the prosthesis.

None of these problems occurred during robotic femoral canal preparation, and regardless of whether the bone section was performed in trabecular or cortical bone, the results were consistently accurate. The consistency may be due in part to the fact that cutter reaction forces can be reduced to a negligible value by adjusting the feed rate. This allows the robot to machine trabecular and cortical bone with the same degree of precision. This study also indicated that the robot's high-speed cutting tool cuts, rather than tears, bone. However, the most significant difference between traditional THA techniques and the robotic system is the direct link between the preoperative plan and its surgical implementation.

The use of the robotic system in a human clinical trial is scheduled for 1992. Meanwhile, an application for robot-assisted total knee arthroplasty is under development. Future applications may include placement of distal cross-locking screws for intramedullary nails; placement of pedicle screws in the spine; osteotomies; and sports medicine operations.

The results of extensive laboratory testing and clinical experience in the canine study indicate that the robot is a surgical tool that can greatly increase the accuracy and precision with which a surgeon plans and executes a joint replacement procedure. Whether total joint arthroplasties performed with the robot will have a better long-term success rate remains to be seen; bone is an adaptive tissue that may ultimately compensate for surgical inaccuracies. Nonetheless, it seems logical that greater surgical precision will produce better results in the short and long term.

It should be noted, however, that the ultimate application of this technology is as a tool for improving surgical accuracy and not as a substitute for the surgeon's judgment and skill.

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