Robotic Total Hip Replacement Surgery in Dogs

Russell H. Taylor (1), Howard. A. Paul (2), Brent D. Mittelstadt (2),
Edward Glassman (1), Bela L. Musits (1), William L. Bargar (2)

(1) Manufacturing Research Department
IBM T. J. Watson Research Center
Yorktown Heights, New York 10598
Csnet: rht at ibm.com
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(2) Orthopaedic Research Laboratories
UC Davis School of Medicine
Davis, Ca. 95616

Abstract

Approximately half of the over 120,000 total hip replacement operations performed annually in the United States use cementless implants. The standard method for preparing the femoral cavity for such implants uses a mallet-driven hand-held broach whose shape matches that of the desired implant. In-vitro experiments have supported the possibility that a more accurate (and, we expect, more efficacious) result can be achieved by using a robot to machine the cavity. We are now developing a second-generation system suitable for use in an operating room, targeted at clinical trials on dogs needing hip implants. This summary describes the background, objectives, architecture, and surgical procedure for this system. It also provides brief descriptions of key results from our earlier experiments and of some of our planned future work.

Introduction

About 120,000 total hip replacement operations are performed each year in the United States, and over 300,000 world wide. About half of these operations use cementless implants that rely on a press fit and/or bone ingrowth for fixation [1]. Stability of the implant, uniform stress transfer from the implant to the bone, and restoration of the proper biomechanics critically affect efficacy and, in turn, are significantly affected by the proper placement of the implant relative to the bone and by the accuracy with which the femoral cavity can be prepared to match the implant shape. The development of computed tomagraphy (CT) imaging and modelling has made it possible to design custom implants for individual patients. One somewhat paradoxical consequence is that the precision of design and planning now greatly exceeds the precision of surgical execution.

Recently reported research confirms that gap between implant and bone significantly affects bone ingrowth [4]. The standard surgical method for preparing the femoral cavity uses a hand-held mallet-driven broach matching the implant shape This rather violent procedure is less than optimal; one recent study [2] found that the the gap between the implant and the bone was commonly 1-4 mm and that the overall hole size was 36% larger than the broach. Only 18-20 percent of the implant actually touches bone when it is inserted in the hole. Furthermore, the placement of the implant cavity in the bone (which affects restoration of biomechanics) is as much a function of where the broach "seats" itself as of any active decision on the part of the surgeon.

These considerations have led us to explore the use of a robot to mill out the desired shape. The positional accuracy of present-day industrial robots is more than sufficient for this task, and (indeed) robots are frequently used in low-precision material removal tasks. However, successful application of a robot to bone shaping nevertheless presents some challenges. These include determination of appropriate material removal process parameters (cutter design, speed, feed rate, etc.) for cutting both cortical and trabecular bone, development and verification of reliable means to relate the image-based surgical plan to physical reality (e.g., location of the bone relative to the robot), solution of a host of "clinical" and practical problems (sterilization, safety, etc.), and gaining actual clinical experience.

In earlier studies (summarized below and in [3]) we have demonstrated successful machining of shapes in cadaver bones and have also demonstrated the feasibility of using pre-operatively implanted calibration pins to accurately define a bone coordinate system both in the CT images and in the robot's workspace.

We are now developing a second-generation system suitable for use in an actual operating room, targeted at clinical trials on dogs needing hip implants. This system will provide clinical experience necessary for eventual application to human surgery and (we believe) should also help a number of dogs with severe arthritis. In developing this system, we must also consider (at least by example) a number of issues that seem more generally applicable to robotic surgery. These include:

- *Man-machine interaction in a surgical situation*: We want the robot to function as an uncannily precise, if narrowly specialized, assistant to the surgeon. Although the surgeon *must* rely on the robot and sensing system to cut the right shape, the surgeon's comprehension of (and responsibility for) the total situation is clearly much greater than the machine's. Suitable interfaces must be provided to allow him to pause execution at any time, modify plan parameters, initiate error recovery actions, and provide positional guidance to the robot.
- *"Fusion" of off-line and online models*: The surgical plan is based on an offline CT model of the bone. Sensing must be used to locate the bone during surgery and track its motions. Although the use of aligning pins allows us to simplify the problem considerably in the instant case, we still must verify that our solution works reliably. Beyond this, our goal is to provide a robust enough structure to permit development of more general and less invasive sensing schemes for other applications and to permit active use of the online model in facilitating man-machine interactions.
- *Verification*: Since the surgeon must rely on the precision of the robot, it is extremely important that no single failure cause an undetected loss of accuracy. Consequently, we must provide redundant sensing checks wherever possible. In this case, we especially want to verify that the robot's end effector does not stray out of the volume it is supposed to be cutting and that the bone does not slip relative to the robot's base after the pins are located. It is especially important that systematic shifts be detected early. A sin-

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gle misplaced cut can usually be repaired, but it may much harder to correct for misplacing the entire cavity.

- *Operating room compatibility and sterilization*: It must be possible to bring the robot into the operating room and set it up without requiring extensive fit-ups or permanent installations, since the operating room must be available for other procedures, as well. This consideration led us to rule out some configurations (such as a cartesian manipulator suspended from the ceiling) that might otherwise have been attractive. Similarly, acceptable means of preserving sterility must be provided.
- *Safety, error recovery, and backup*: Many of these points have been covered already. Clearly, redundant safety mechanisms are very important, both for the protection of the patient and of the surgeon. Emergency pause and power-off functions are a must. Wherever possible, error conditions must be anticipated and recovery procedures provided. Although many times, the robot will be able to continue with the procedure, it is also prudent to provide a reliable means of stopping the robot, removing it from the surgical field, and continuing the operation with manual backup.

Our approach to some of these issues is discussed below.

Application Architecture and Surgical Procedure

The overall application architecture is illustrated in Figure 1 and may be broken down, roughly, into (offline) presurgical and (online) surgical components.

Presurgical planning

Before surgery, locating pins will inserted through small incisions into the greater trocanter and femoral condyles, and a computed tomography (CT) scan will be made of the leg. The CT data will be used to select the correct size off-the-shelf femoral implant and to determine the desired position of the implant relative to a bone coordinate system (BCS) determined from the three pin locations. Data to control the cutter path relative to the BCS and for the online display will be precomputed. Initially, we plan to select one of nine off-the-shelf Techmedica canine implants. Eventually, we plan to develop custom implants based on the CT data and optimized for robotic surgery.

Operating Room System

The operating room system consists of several components:

- The five-axis *robot* is an IBM 7576 SCARA manipulator with an added pitch axis, six degree-of-freedom force sensor, and a standard high-speed (65000 rpm) Anspach surgical cutting tool. During surgery, all but the robot's end-effector will be covered by a sterile sleeve; the end-effector will be separately sterilized. The robot will sit at the end of the operating table, as shown in the sketch.
- The *robot controller* provides servocontrol, safety monitoring, sensor interfaces, and higher-level application functions implemented in the AML/2 language.
- The *vision subsystem* will track the position and orientation of the robot to provide a redundant check on the robot's motion and (possibly) as a tool for volumetric calibration of the robot [5].
- The *cell control and online monitoring system* provides general supervisory control over the application and (more importantly) provides the surgeon with an online display of the progress of the operation, based on realtime sensing and information derived from the CT data.
- The surgeon will have a gas-sterilized *hand-held terminal* to interact with the robot during the course of the operation. This terminal will support manual guiding, motion enable, emergency power on/off, and similar functions. It will also be used to control the overall sequence of application steps and to select appropriate pre-programmed error recovery procedures should the need arise. Each of the major control components (robot controller, vision system, and cell controller) will be able to freeze (inhibit) all robot motion or to turn off manipulator and cutter power in response to recognized exception conditions. If this happens, the surgeon must explicitly re-enable motion from the hand-held terminal.
- A *fixation system* will be used to hold the dog's femur firmly to the robot base during the procedure.

Surgical Procedure

1. Prior to surgery, a special calibration probe will be inserted into the cutter collet and the robot calibration will be checked using both the vision system and sterile calibration points on the robot base. Finally, the robot will be placed in a standby mode and covered with a second drape until the robotic part of the operation.
2. The dog will be brought into the operating room and the surgery will proceed normally until the point where the femoral cavity must be created. I.e., the hip will be opened and dislocated, the ball of the femur will be cut off, and the acetabluar cup will be installed.
3. The three aligning pins will be exposed and the bone will be placed into the fixation system, which will lock it firmly to the robot base.
4. A combination of guiding and tactile search will be used to locate the top center of each aligning pin in the robot's coordinate system. This data will be used to compute the transformation between CT-based bone coordinates and robot cutter coordinates. Proximity sensors may be positioned to detect any subsequent motion of the pins (and, hence, of the bone) relative to the robot base.
5. A cutter bit will then be placed into the cutter and a further calibration check will be made to verify that it is installed correctly.
6. The robot will then mill out the correct shape to receive the implant. The surgeon will carefully monitor the progress of the operation both by direct visual observation and through the online display.
7. Once the shape has been cut out, the robot will withdraw to a standby position and manipulator power will be turned off. The femoral implant will be installed, and the femoral fixator and aligning pins will be removed. The operation will then proceed normally.

Summary of Previous Experimental Work

Our early experiments were performed with an ASEA IRB-6 five axis manipulator interfaced to an IBM PC running AML/X (an experimental version of AML/2). Although we have concluded that a different robot would be more appropriate for operating room use, this configuration served us well for in-vitro experiments.

We have tried a number of different cutter shapes and cutting strategies for both cortical and trabecular bone. Based on these studies, we have settled on a simple cutting strategy using a cylindrical cutter. On human bones, coarse cuts produced by successively cutting out 2.5 mm-deep slices of the desired shape, with finish cuts performed by the side of the cutter, and a uniform feed rate of 6.4 mm/sec works well. Figure 2 compares slices of broached and milled bone.

We have performed many experiments to assess the contribution of each element (from CT data acquisition to pin location to robot motion and calibration) determining the overall accuracy of placement and shape dimensions of the implant cavity relative to a bone [3]. We have also performed a "bottom-line" experiment using a delrin test fixture with a socket for holding a foam test block and with three alignment pins implanted at the same relative positions that they would occupy on an actual bone. The positions of the the pins were measured both on a coordinate measuring machine (CMM) accurate to 0.0127 mm (0.0005 inches) and on CT images. The fixture was placed approxiimately in the robot's workspace and the pin positions were found by tactile sensing. The robot then cut a test shape into the foam block and the shape was measured on the CMM. This procedure was repeated for several blocks. The total error in placement in placement of the test shape relative to the pins was found to be less than 0.4 mm, and the dimensional error was less than 0.13mm.

Although we need to repeat this experiment with the next generation system, we are encouraged by these results. The new system should be at least as precise as the old. More importantly, the experiment verifies that the *total* error introduced in the path from CT-based surgical plan to robotic execution can be limited to a small value and provides us with a good benchmark procedure to evaluate future generations ot the system.

Status and Plans

At this time (May 1989) we are continuing integration of our surgical system. The augmented robot is complete and AML/2 software for cutter motion control and basic calibration have been developed. We expect to complete other components of the system and integrate them with the robot over the spring and summer. Before beginning clinical trials, we must repeat a number of our earlier experiments using the new system on dog bones to verify system integrity. We must also rehearse the procedure repeatedly both on plastic and cadaver bones and (in "dress rehearsals") on cadaver dogs. Although it is hard to predict how long all this will take, we are hopeful that our first clinical case can be done in the not-too-distant future.

We have also begun to consider future extensions of our work. As mentioned earlier, clinical experience with dogs is clearly very useful in considering whether and how to apply similar methods to people, although it is premature to speculate on how such a system will evolve. We have begun to consider what would be required to modify the hip-replacement system for use in other procedures. One obvious candidate is knee replacement, although we have begun to speculate about other applications as well, including femoral rodding, other trauma repair, hip implant revision, etc. Other important areas are better pre-surgical planning and modelling (including such topics as optimal placement and design of implants, bone remodelling simulations, etc.), incorporation of better sensing methods for locating and tracking bone positions relative to the robot end-effector, incorporation of better force feedback and adaptive control for bone machining, identification and removal of acrylic bone cement, and more advanced man-machine interfaces.

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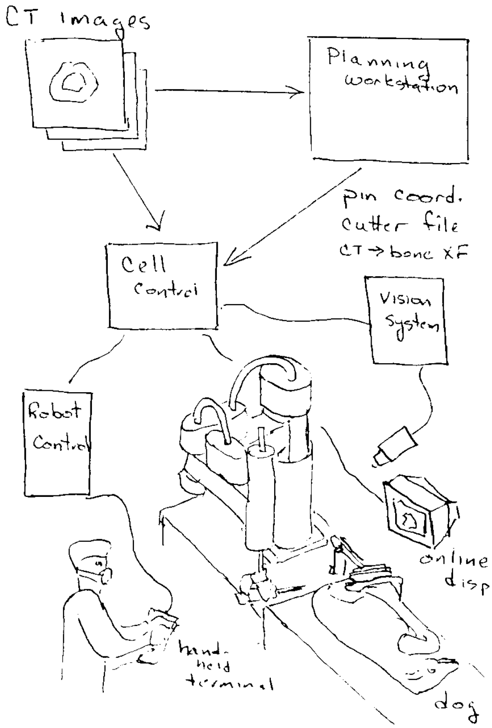

Figure 1: Application Architecture

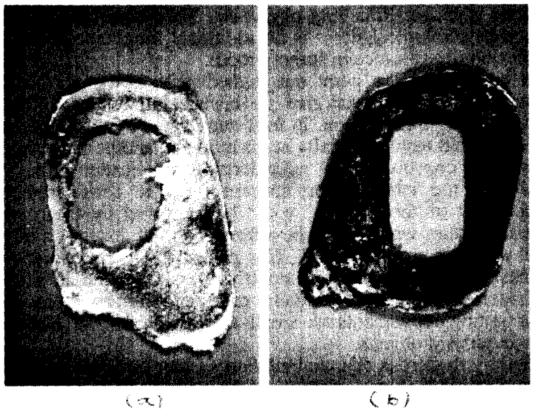
(a) (b)

Figure 2: Slices of human cadaver femur cut (a) with a broach and (b) with the robot