〔事例紹介〕

An Image-directed Robotic System for Hip Replacement Surgery

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ABSTRACT

We have developed an image-directed robotic system to augment the performance of human surgeons in precise bone machining procedures in orthopaedic surgery, initially targeted at cementless total hip replacement surgery. The total system consists of an interactive CT-based presurgical planning component and a surgical system consisting of a robot, redundant motion monitoring, and man-machine interface components. In-vitro experiments conducted with this system have demonstrated an order-of-magnitude inprovement in implant fit and placement accuracy, compared to standard manual preparation techniques. A clinical trial on dogs needing hip replacements has begun.

アブストラクト

セメントレス人工股関節置換手術を当初の目標とした整形外科手術において，骨を機械的に精密に処置する外科医の作業能率を上げるために，画像を利用するロボットシステムの開発を行った．全システムは，まず，CTを基本とした手術前用の対話可能な作業計画要素，さらにロボット，付加機能をもつ動作監視装置，マンマシンインターフェース要素からなる手術システムで構成される．このシステムによる生体外の実験では，標準的なマニュアル処置技術に比べて，インプラントの適合性と位置精度において大きな改善が実証された．人工股関節を必要とする犬の臨床試験がすでに始められている．（訳：富田英雄編集委員）

Introduction

One somewhat paradoxical consequence of the development of computed tomagraphy (CT) imaging and computer modelling methods is that the precision available for pre-surgical planning, simulation, and custom implant design greatly exceeds the precision of surgical execution. For example, about half of the 300,000 total hip replacement operations performed each year use cementless implants, where stability of the implant, uniform stress transfer from the implant to the bone, and restoration of the proper biomechanics critically affect efficacy. In turn, these factors 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. Recently repored research confirms that gaps between implant and bone significantly affect bone ingrowth[1]. A recent study[2] of the standard manual broaching method for preparing the femoral cavity found that the gaps between the implant and the bone were 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

人工股関節置換手術のための画像誘導型ロボットシステム

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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. Preliminary studies[3] demonstrated successful machining of shapes in human cadaver bones and 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 have subsequently developed a second generation system suitable for use in an actual operating room, targeted at clinical trials on dogs needing hip implants. This system could provide clinical experience necessary for eventual application to human surgery and (we believe) should also help a number of dogs with severe arthritis. In-vitro experiments with this system (discussed below) confirm that we can achieve an order-of-magnitude improvement in surgical precision. Although the clinical trial is still in progress, early results are quite encouraging.

Requirements and Issues

In developing this system, we were forced to consider (at least by example) a number of issues that seem more generally applicable to reobotic 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 the surgeon to pause execution at any time, modify plan parameters, initiate error recovery actions, and provide positional guidance to the robot.
- "Fusion" of ofline and online models : The surgical plan is based on an ofline CT model of the bone. Sensing must be used to locate the bone during surgery and track its motions.

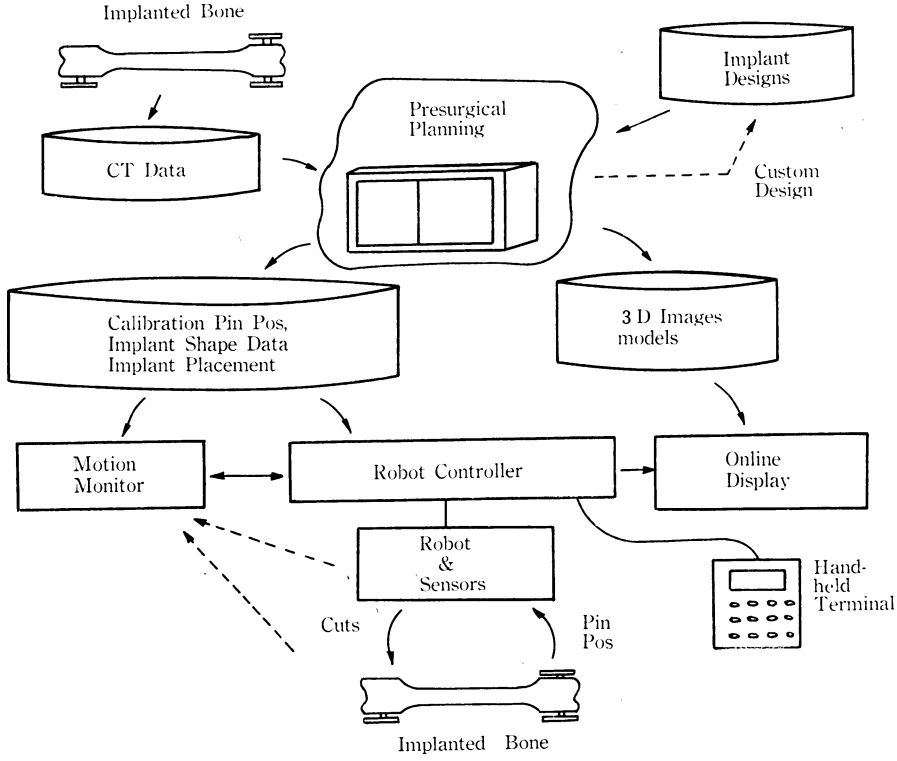


Fig. 1 Applicaton Architecture

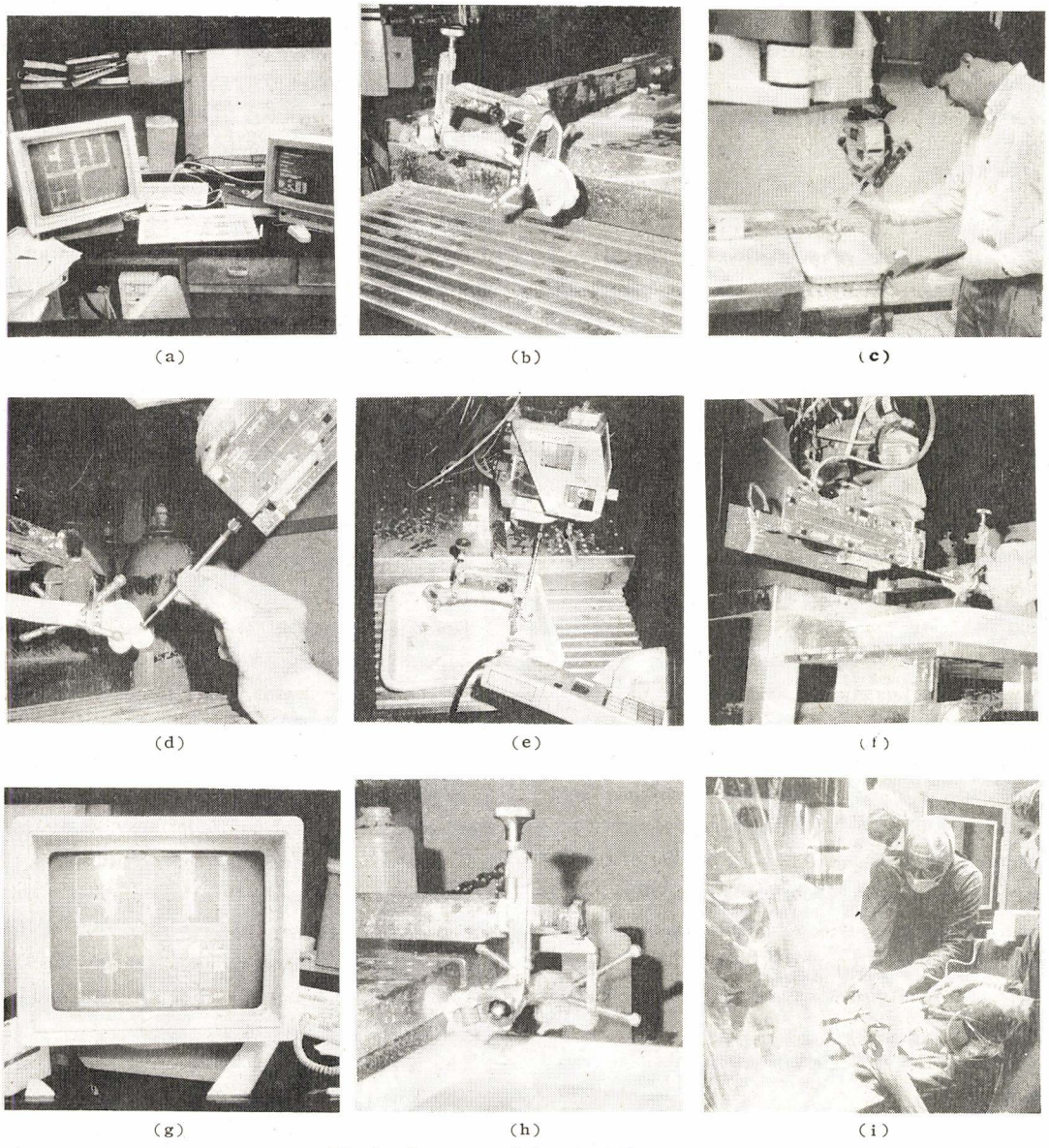


Fig. 2 System and Surgical Sequence

(a) presurgical planning display ; (b) fixated cadaver bone ; (c), (d) manual guiding to approximate pin position ; (e) tactile search for a pin ; (f) cutting the shape ; (g) online display ; (h) final result ; (i) operating room scene for first clinical trial.

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

- Operating room compatibility and sterility : 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 the robot often may 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.

System Architecture and Surgical Procedure

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

Presurgical planning

This component[4] enables the surgeon to select the desired implant shape and determine where the corresponding cavity is to be machined in the femur. It is implemented on an IBM PS/2-80 workstation with an augmented display.

Before surgery, locating pins are inserted into the greater trocanter and femoral condyles, and a computed tomography (CT) scan is made of the leg. The PS/2 processes the image to locate the top center of each alignment pin relative to CT coordinates. The surgeon interactively selects appropriate orthographic cross sectional slices through the CT image of the bone. After selecting the appropriate implant shape from a parts library, he interactively positions the implant model relative to the CT image, while the system generates cross-sectional views. When he is satisfied, the coordinates of each pin, together with the implant identification and desired location are written to a file.

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 is covered by a sterile sleeve ; the end-effector is separately sterilized. The robot controller provides servocontrol, low-level monitoring, sensor interfaces, and higher-level application functions implemented in the AML/2 language. During surgery, the force sensor is used to support redundant safety checking, tactile search to locate the aligning pins, and compliant motion guiding by the surgeon.

The redundant motion monitoring subsystem[5] is implemented on an IBM PC/AT, with specialized IO hardware. It visually tracks the position and orientation of the robot end effector during the cutting phase of the surgery, and checks to verify that the cutter tip never strays more than a prespecified amount outside of the defined implant volume. It also monitors strain gauges which can detect possible shifts of the bone relative to the fixation device. If either condition is recognized, then a "freeze motion" signal is asserted to the robot controller. Once motion is stopped, application code in the robot controller queries the motion monitoring system for more information and then enters an appropriate error recovery procedure in-

teractively controlled by the surgeon.*

The man-machine interface includes an online display system which combines data generated in presurgical planning with data transmitted from the robot controller to show progress of the cutting procedure superimposed on the CT-derived image views used in planning. A gas-sterilized hand-held terminal allows the surgeon to interact with the system during the course of the operation. This terminal supports manual guiding, motion enable, emergency power on/off, and similar functions. It is also 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 and checking computer) is 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 is used to hold the dog's femur firmly to the robot base during the procedure.

Surgical Procedure

The surgical procedure is illustrated for a cadaver bone in **Figure 2** and is discussed at greater length in 6). Briefly, the procedure is as follows :

1. The patient is prepared and draped in the normal manner.
2. The robot is positioned near the patient, draped, and placed in a ready state.
3. The surgery proceeds in the normal (manual) way until after the acetabular component is implanted and the ball of the femur is removed.
4. The robot is placed at the end of the operating table, and the femur is placed in the fixator, which is then attached to the robot base. This prevents further motion of the femur relative to the robot's coordinate system.
5. The three locator pins are exposed manually and are located by a conbination of manual guiding and autonomous tactile search by the robot.
6. The desired implant shape is cut out at the desired position and orientation relative to the pins.
7. The rest of the procedure proceeds in the normal way.

* In his clinical trial (below), the surgeon (Dr. Paul) chose to simplify the operating room setup for the first cases by forgoing use of the bone slip detection hardware and the optical position tracking, although considerable other checking remains. This decision was based on experiments indicating that quite large forces (on the order of 5 kgf) produced only a few microns of bone motion relative to the fixator and on extensive rehearsals with the robot.

Verification Experiments

We have repeated many of the experiments performed on an earlier generation system[3),7)] to verify basic system accuracy. In the "bottom-line" experiment, three pins were implanted in a test fixture with a socket for holding foam test blocks. The positions of 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 approximately 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 placement error of the test shape relative to the pins was found to be less than 0.2 mm, and the dimensional error was less than 0.08 mm. Test pockets in cadaver bone (which is less easily crushed by the test fixture) yielded dimensional errors less than 0.05 mm and placement errors on the order of 0.4 mm.

We have also rehearsed the entire procedure many times with plastic and cadaver dog bones of various sizes. In these experiments, the pins are implanted, the bone is CT-scanned, presurgical planning is performed, and the ball of the femur is removed with a bandsaw. The bone is then placed into the fixation system, the robot locates the pins, and cuts the implant shape. Subjectively, the entire procedure runs smoothly and reliably and produces an excellent "fit" for the implant. A more quantitative study, comparable to 2), is presently under way.

Clinical Trial

A clinical trial, conducted by one of the authors (Paul), has begun on dogs needing hip replacement surgery. By the end of July, 1990, seven

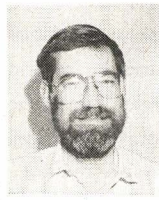
cases had been performed. Although follow-up is continuing, the surgery was successful in every case and the patients have been doing well. The time required for the robotic portion of the procedure is about 30 minutes, including placing the femur into the fixator (5～7 minutes), locating the pins (5～10 minutes), and cutting (about 15 minutes). As experience is gained, the procedure is being refined, and these times may be expected to be reduced somewhat.

Acknowledgements

We wish to thank many people and groups who have contributed to this effort. Those deserving special mention include Techmedica, Inc. (implants), Bill Anspach of The Anspach Effort, Inc. (cutter tools), Steve Lamb, of OSI Inc. (fixation system), Micro-Techmedical Corp (sterile draping), Ken Honeycutt and Kip Harris of IBM Manufacturing Systems Products (robot consultation), Bob Olyha and Tony Castellano of IBM Research (interface electronics) and Jerry Krist and Leon Kehl of Northern Digital (optical tracking).

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Received a B. E. S degree from Johns Hopkins University in 1970 and a Ph. D. in Computer Science from Stanford in 1976. He joined IBM Research in 1976, where he developed the AML language. Following a two year assignment in Boca Raton, he managed robotics research activities at IBM Research from 1982 until returning to full time technical work in late 1988. Since March 1990, he has been manager of Intelligent Robotics. His research interests include robot systems, programming languages, model-based planning, and (most recently) the use of modelbased robotic systems to augment human performance in surgical procedures. He is Editor of the *IEEE Transactions on Robotics and Automation* and has served on many panels, program committees, and advisory boards.

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Joined IBM Research in 1983 as a Research Staff Member woking in robotics. In 1985, he was named manager of Integrated Automation Systems, Manufacturing Research, working in flexible manufacturing systems, robotics, course-fine positioning, end-point sensing, and industrial machine vision. During this time be initiated the robotics work in the medical field. In 1987, Mr. Musits became Semiconductor Programs Manager in Manufacturing Research, where he was responsible for development, coordination and program management of work between GTD(East Fishkill, Burlington and Manassas) and Manufacturing Research.

In 1988 he was named to his present position asTechnical Assistant to the Diretor of the Researcth Division.

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