Taming the Bull: Safety in a Precise Surgical Robot

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Abstract

Over the past several years, we have developed an image directed robotic system for orthopaedic bone machining applications, aimed initially at cementless total hip replacement surgery. A clinical trial in dogs needing such surgery has begun. The fact that our application requires a robot to move a tool in contact with a patient has motivated us to implement a number of redundant consistency checking mechanisms. This paper provides a brief system overview and outlines the requirements defined by the veterinary surgeon who uses the system. It then describes our approach to implementing these requirements and concludes with a few remarks about our experience so far and possible extensions of our work.

Introduction

The precision of image-based pre-surgical planning often greatly exceeds that surgical execution. Typically, precise surgical execution has been limited to procedures (such as brain biopsies) for which a suitable stereotactic frame is available. The inconvenience and restricted applicability of these devices has led many researchers to explore the use of robots to augment a surgeon's ability to perform geometrically precise tasks planned from computed tomography (CT) or other image data (e.g., [1], [2], [3], [4], [5]).

Safety is a fundamental issue in these applications. We are essentially developing a partnership between a man (the surgeon) and a machine (the robot) that seeks to exploit the capabilities of both to do a task *better* than either can do alone. The robot is very precise and untiring. It can be both strong and fast and can be equipped with any number of feedback sensors. Since it is numerically controlled, it can move a surgical instrument through an exactly defined trajectory with precisely controlled forces. On the other hand, the surgeon is very dexterous. He is also quite strong, fast, and is highly trained to exploit a variety of tactile, visual, and other cues. "Judgementally" controlled, he understands what is going on in the surgery and uses his dexterity, senses, and experience to execute the procedure. By nature, he wants to be in control of everything that goes on. However, he *must* rely on the robot to provide precision. How can he trust it not to harm the patient?

The most obvious way to prevent a robotic device from making an undesired motion is to make it incapable of moving of its own accord. Motor-less manipulators have been implemented, in which joint encoders are used to provide feedback to the surgeon on where his instruments are relative to his image-based surgical plan (e.g., [4]). One important limitation of this approach is that it is often very difficult for a person to align a tool accurately in six degrees of freedom with only positional feedback.

In cases where only a single motion axis is required during the "in contact" phase of the surgery, the robot may be used essentially as a motorized stereotactic frame ([1], [2], [6], et al). A passive tool guide is placed at the desired position and orientation relative to the patient; brakes are applied; and robot power is turned off before any instrument touches the patient. The surgeon provides whatever motive force is needed for the surgical instruments themselves and relies on his own tactile senses for further feedback in performing the operation. This approach ameliorates, but does not entirely eliminate, the safety issues raised by the presence of an actively powered robot in close proximity to the patient and operating room personnel. Furthermore, maintaining accurate positioning is not always easy, since many robots tend to "sag" a bit when they are turned off or to "jump" when brakes are applied. Leaving power turned on and relying on the robot's servocontroller to maintain position introduces further safety exposures. Finally, the approach is limited to cases

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where a passive guide suffices. The surgeon cannot execute a complex pre-computed trajectory.

Over the past several years, we have developed an image-directed robotic system to augment the performance of human surgeons in precise bone machining procedures in orthopaedic surgery, with cementless total hip replacement surgery as an initial application. In-vitro experiments conducted with this system have demonstrated an order-of-magnitude improvement in implant fit, compared to standard manual preparation techniques ([7], [8]) and a clinical trial on dogs needing hip replacement operations is underway. This application inherently requires computer controlled motion of the robot's end-effector while it is in contact with the patient. Thus, we have had to pay considerable attention to safety checking mechanisms. Subsequent sections of this paper will discuss these mechanisms in somewhat more detail.

System Architecture and Surgical Procedure

The total system (illustrated in Figure 1) 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.

Presurgical planning

This component [9] enables the surgeon to select the desired implant shape and determine where the corresponding cavity is to be machined in the femur. 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 pins are located by image processing and the surgeon uses interactive graphics to position a CAD model of the implant relative to arbitrary orthographic cross sectional views through the CT data set. 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 architecture of the operating room system is illustrated in Figure 2. It 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. A *fixation system* holds the femur rigidly to the robot's base during surgery. 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. The surgeon can also guide the robot by placing it in a force compliant mode and grabbing its end effector. The *motion monitoring subsystem* is discussed in greater detail in a subsequent section.

Surgical Procedure

The surgical procedure is illustrated for a cadaver bone in Figure 3 and is discussed at greater length in [10]. Briefly, the surgeon removes the ball of the femur manually and places the bone in the fixator. A combination of manual guiding and tactile search is used to locate the three aligning pins. Finally, the implant shape is cut out at the desired position and orientation relative to the pins. The robot is turned off and the rest of the procedure is completed manually.

Safety Requirements

The principal requirements were defined by one of the authors (Paul) who is the veterinary surgeon who uses the system. They are:

1. *The robot should never "run away."* No single-mode hardware (or system) error should cause the application software to lose control of its motions. Furthermore, the application software should only request proper motions.
2. *The robot should never exert excessive force on the patient.* Normal cutting forces are quite light (usually on the order of 1 kgf). Anything substantially more than that means something may be wrong, and the robot better stop what it is doing.
3. *The robot's cutter should stay within a pre-specified positional envelope relative to the volume being cut.* For hip replacement surgery, the really important goal is to prevent a systematic shift in the placement or shape of the hole; a single "gouge" is generally reparable, although undesirable. Of course, other surgical procedures (like brain surgery) may be less forgiving.
4. *The surgeon must be "in charge" at all times.* This is, of course, the fundamental dilemma. He has to trust the system to some extent. Nevertheless, the system should keep him informed about its status, and he should be able to "freeze" motion at any time. Once robot motion is stopped, he should be able to further query the robot's status, to manually guide it, to select an appropriate recovery procedure to con-

tinue the surgery, or to completely terminate use of the robot and continue manually.

Safety Checking and Recovery Implementation

Robot Controller

The robot controller routinely performs many safety and consistency checks, including such standard features as position and velocity deadbands in the joint servos, monitoring of external signals, and a safety timeout monitor which turns off arm power if the controller does not affirmatively verify system integrity every 18 ms. In addition to a basic power-enable relay (external to the controller), controller software provides facilities for disabling manipulator power, for "freezing" motion, for resuming interrupted motions, and for transferring control to user-written recovery procedures.

Many conditions (externally signalled consistency checks, force thresholds, pushbutton closures, and the like) interrupt the application program and cause motion to be frozen or (occasionally) power to be dropped. Menus on the hand-held terminal then permit the surgeon to interrogate system status, to select local actions (such as manual guiding or withdrawal of the cutting tool), to continue the present motion, to discontinue or repeat the present step of the procedure, or to restart at some earlier phase altogether. One very common case is a simple "pause" to allow the surgeon to satisfy himself that all is well or to perform some housekeeping function like refilling an irrigation bottle.

Force Monitor

The microprocessor interface to a wrist-mounted force sensor computes forces and torques resolved at the cutter tip. If any tip force component greater than about 1.5 kgf is detected, the controller is signalled to freeze motion. Forces greater than about 3 kgf cause arm power to be dropped. Experiments in which a sudden large motion is commanded in the middle of cutting confirm that these checks are quite effective in detecting many "run away" conditions. They are also effective in detecting such conditions as the cutter stalling or hanging up in improperly retracted soft tissue.

Motion Monitoring Subsystem

A separate PC/AT with special input-output hardware provides an independent check that the cutter tip stays within a defined volume relative to the bone. This is done by checking (a) that the bone does not move relative to the fixator, which is rigidly affixed to the robot base and (b) that the end effector never strays from a defined volume in space.

Bone motion is sensed by strain gauge sensors attached to the fixator and bone. Experiments with bench versions of the sensors have demonstrated that motions on the order of 0.1mm are easily detectable. Furthermore, experiments with the fixation system have indicated that even rather large forces (5 kgf) have produced only a 16 microns of motion, which would be negligible in the context of this application.

Tracking of the robot's end effector is performed by a Northern Digital Optotrak system, which tracks LED beacons to accuracies of 0.1 mm or better over a 1 meter cube. We fabricated a rigid PC card with eight such beacons and affixed it to the robot's wrist, as shown in Figure 3f. Northern Digital-supplied software is used to compute a coordinate system from the beacon locations. The robot-to-camera and cutter-to-beacon transformations were computed by ordinary least squares estimation from data taken with the robot in various known positions, using appropriate linearized models. Constructive solid geometry (CSG) tree "check volumes" corresponding to implant and cutter selection were constructed from primitives bounded by quadric surfaces located a defined distance (1 mm) outside the furthest nominal excursions of the cutter. During surgery, the PC/AT reads the beacon plate coordinates from the Optotrak and computes the cutter location. If this location is outside the check volume, it signals an "out-of-bounds" condition through an optically isolated digital port to the robot controller, which freezes motion and then obtains more detailed information through a serial port.

Preliminary experiments demonstrated that this system could reliably detect when a motion crossed a threshold to about 0.2 mm precision with constant orientation, and about 0.4 mm with cutter reorientation. Checking rates of approximately 3-4 hz were obtained. At typical cutter speeds, the total excursion before motion is frozen is about 2 mm after all latencies are accounted for. This number could be reduced by using faster computers and making certain modifications in the controller software.

Experience and Discussion

In Vitro

Extensive rehearsals were conducted on plastic and cadaver bones and on foam test blocks, in order to verify basic system accuracy and to gain confidence in overall system behavior [8]. In one "bottom line" experiment, three pins were implanted into a test fixture and located on CT images of the fixture. Test shapes were machined in foam blocks held in the test fixture and measured on a coordinate measuring machine. The total placement error of the was found to be less than 0.2mm and the dimensional error was found to be less than 0.08 mm. Similar experiments in cadaver bone (which is less easily crushed) yielded dimensional errors of 0.05mm and placement errors on the order of 0.4 mm. A quantative study similar to [11] of actual implant shapes in cadaver bone is underway.

Except for bone motion detection, the redundant checking mechanisms discussed above were all integrated with the prototype surgical system. During in-vitro rehearsals on cadaver bone, the most common "error" condition detected has been an excessive cutting force causing a motion "freeze" when the cutter encounters unusually hard bone. Continuation from this condition was almost always easily achieved by backing off 1-2 mm and retrying the current cut.

Once communications protocols were ironed out, both the motion display and motion tracking systems proved to be surprisingly useful in application debugging. Even though the display was essentially a "cartoon," it provided useful information about exactly where the robot was and what the controller thought it was doing. The motion tracker provided a useful consistency check to the calibration procedures. It also caught a real bug in the shape cutting code that might otherwise have been very hard to find.

In Vivo

A clinical trial on dogs needing hip replacement surgery was begun in May, 1990. By November, approximately 15 cases had been performed. All were successful.

In surgery, the system has worked very well. There have been very few "glitches," so that there has been little actual use of any of the error recovery capabilities of the system. This is as it should be. The force monitor has occasionally frozen motion when an unusually hard section of cortical bone at the proximal end of the femur was encountered. In these cases, the surgeon simply commanded the robot to proceed with cutting. On two other occasions (once when the cutter became entangled in some suture material and once when it got caught in an assistant's glove) it was necessary for the robot to withdraw from the bone. The surgical team cleared the entanglement and resumed the application without incident.

The surgeon (Dr. Paul) has found the online display to be very useful in surgery. It is possible to tell when the cutter is in contact with hard bone by listening to the sound it makes. When he hears a change in pitch, he checks the surgical display to verify that what he is hearing is consistent with where the robot claims to be cutting. One interesting possibility for future work would be to automate this (and similar) checking.

The separate motion checking system is not presently being used in surgery, although parts of it are expected to be used in the very near future. The surgical field is rather crowded, since a technician must constantly irrigate the bone while the robot is cutting it. It proved to be very difficult to place the vision system sensors in the veterinarian's operating room so that they would always have a clear view of the end effector. One possibility would have been to mount the cameras overhead. Another would have been to use the system for occasional "spot checks" of the robot. However, one consequence of the confidence gained from the in-vitro rehearsals was that the surgeon concluded that the additional redundancy gained was not worth the added complexity for veterinary cases.

Future Work

We anticipate incorporating the bone motion monitoring system into the clinical system in the very near future. Although experience has shown that the bone fixator is very reliable, an additional check would still be useful, since it could detect cases when the fixator somehow gets loosened from the bone or perhaps was not tightened down properly.

We have also been considering a number of possible measures both to reduce the robot's top speed and acceleration and to provide alternatives to the present visual endpoint motion monitoring. The former might be accomplished either by mechanical modifications to the manipulator or by electrical limits on motor voltage or current. The latter would include incorporation of redundant position and velocity encoders, which would be monitored by a separate computer, preferably electrically isolated from the robot controller. If an out-of-tolerance or out-of-control condition was detected, this computer would take appropriate action, such as raising a "freeze" signal or turning off power.

Conclusions

In conclusion, the fact that our application requires a robot to move a tool in contact with a patient has motivated us to implement a number of redundant consistency checking mechanisms. We believe that this is an important subject even in applications involving less active motions. It is one that will merit considerable attention as robotic devices become increasingly common in operating rooms.

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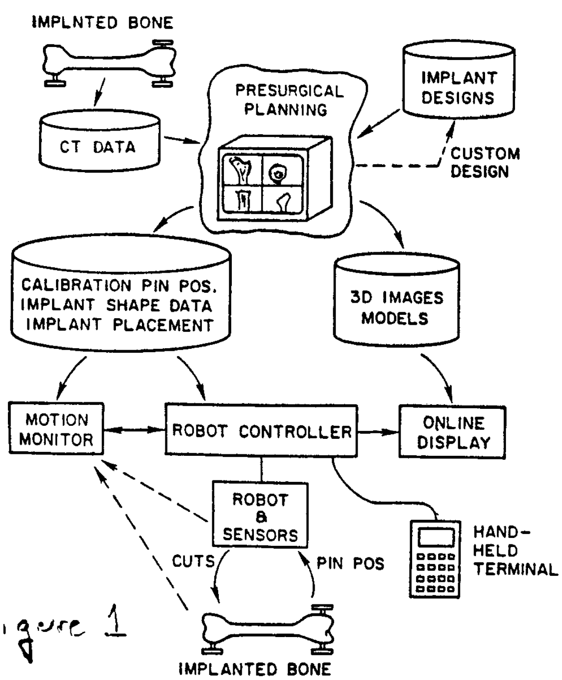

Figure 1

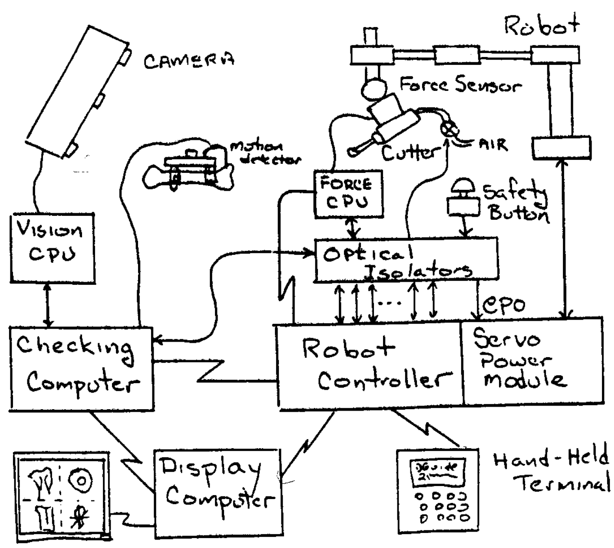

Figure 2

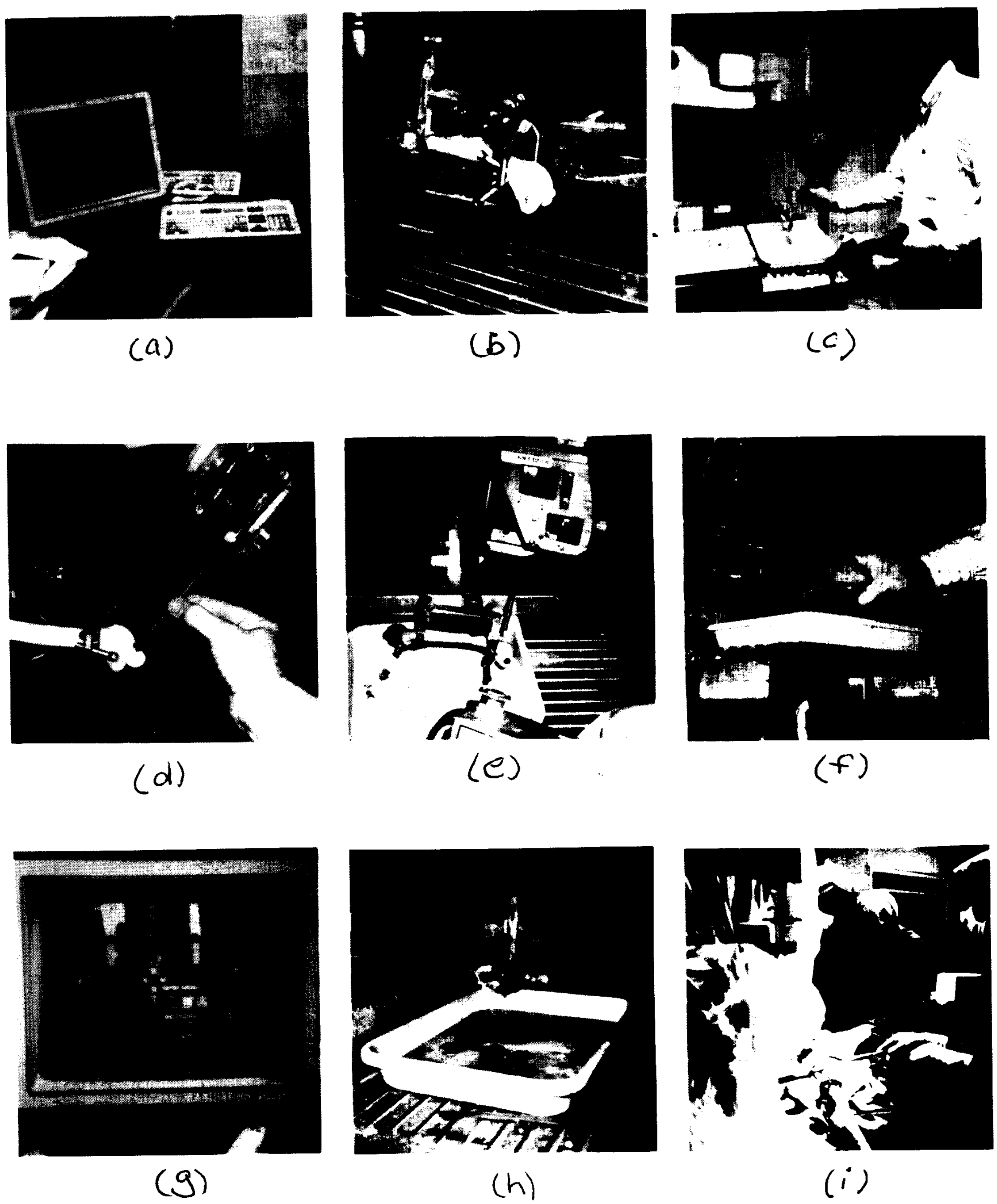

Figure 3: System and Surgical Sequence. (a) presurgical planning display; (b) fixated cadaver bone; (c); (d) manual guiding to approximate pin position; (e) tactile search for a pin; (f) cutting the shape; (g) online display; (h) final result (i) operating room scene for first clinical trial.