The Surgical CAD/CAM Paradigm and an Implementation for Robotically-Assisted Percutaneous Local Therapy

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Abstract

Computer-integrated surgery represents a growing segment of our national healthcare system. These systems transform preoperative images and other information into models of individual patients, assist clinicians in developing an optimized interventional plan, register this preoperative data to the actual patient in the operating room, and then use a variety of means, such as robots and image overlay displays, to assist in the accurate execution of the planned interventions. Finally, they perform complex postoperative analysis of the interventions. Borrowing analogies from industrial production systems, the process was named surgical CAD/CAM. Percutaneous ("through skin") local therapies represent a significant portion of minimally invasive procedures. They involve the insertion of tubular therapy devices (needles, catheters, bone drills, screws, tissue ablating devices, etc.) into the body, with the guidance of intra-operative imaging devices, like CT, MRI, ultrasound, or fluoroscopy. Percutaneous systems also depend on sophisticated image acquisition and analysis tools. This paper provides an introduction to the surgical CAD/CAM paradigm and also presents an implementation of the paradigm for percutaneous local therapies.

1. Introduction

Computer-integrated surgical (CIS) systems will have the same impact on our health care system over the next two decades as computer aided design and manufacturing (CAD/CAM) has had on our economy over the past twenty years. In general, CIS systems are able to provide new capabilities that transcend human limitations in surgery. When fully developed, they will increase the consistency and quality of surgical treatments, promote better outcomes and more cost-effective processes in surgical practice. The primary role of CIS is integration of information with surgical action, where information must be understood in a broad sense. CIS systems apply suitable combination of medical imaging and sensory data, collected before, during, and after surgery. The scope of CIS, therefore, spans over the pre-, intra-, and postoperative phases of surgery.

2. The Surgical CAD/CAM Paradigm

Although CIS systems show great variability over the healthcare spectrum, they all follow the generic logic and flow of information shown in Figure 1.

In the preoperational phase, CIS systems transform preoperatively collected image data and other information such as statistical anatomical atlases and pre-existing surgical plans into computer models of individual patients, then assist clinicians in developing an optimized interventional plan. This phase is analogous to the computer aided design (CAD) feature of industrial production systems.
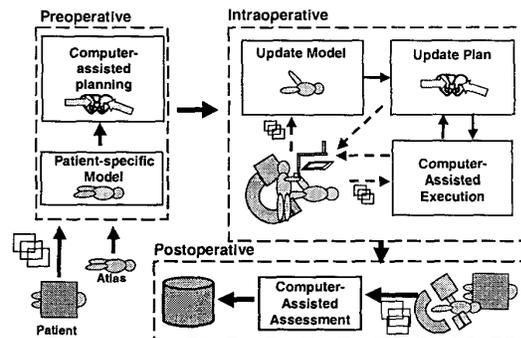

Figure 1: Flow of information in computer-integrated surgical systems

Next, the patient is brought into the operating room and the interventional plan is also transferred to the central computer controlling and overseeing the procedure in the operating room. New images are collected about the patient and the CIS system combines this date with the preoperative plan. In many ways, intraoperative and preoperative planning are conceptually identical. In the operating room, however, accuracy, reliability and overall speed emerge as critical factors. The actual surgery may begin once the refined surgical plan is ready. The physician carries out the plan with the help of surgical devices and robots under the direct control or surveillance

of a central computer. The physician monitors the progress of surgery with the help of intraoperative imaging devices and various sensors. This information, correlated with internal systems status information, is stored for postoperative analysis. The patient stays within a closed intraoperative control and surveillance loop until the surgical plan is carried out. In a well-functioning CIS system, the patient must not be released from the operating room without sufficient evidence that the planed intervention was carried out. Sufficient intraoperative information must also be collected for the assessment of trauma and collateral damage caused by the intervention itself. This information can be of critical importance in prescribing postoperative rehabilitation regimen. In summary, the intraoperative phase of CIS systems is analogous to the computer-aided manufacturing (CAM) process of industrial production systems.

In the postoperative phase, follow-up imaging studies and examinations are performed. Using the same or similar methods as developed for modeling and surgical planning, we create postoperative patient specific models and register them to preoperative models, allowing the physician to follow the progress of recovery. Also postoperatively, CIS systems can assemble statistical anatomical atlases from data collected before and during surgery. Those atlases capture inter-patient variability in anatomy, pathology, physiology and also store a statistical record of actual surgical procedures. Like real physicians, CIS systems can accumulate surgical experience. This information can be exploited in both planning and execution of procedures. In the planning phase, the CIS system can suggest a statistically optimal placement or trajectory for the surgical devices, as well as provide statistical analysis of the physician's current choice. The end-effectors of surgical robots are often equipped with sensory devices, typically with force sensors. Force measurement data can be collected during surgery and combined with a statistical anatomical atlas, thus providing a statistical procedural atlas. During surgery, the robot is spatially registered to the atlas, so the robotic system has a statistical knowledge about the contact forces typically encountered in a given surgical situation. If the expectation of the robotic system is substantially different from the sensory input of the robot, then the robot will halts and the system request the physician to resolve the conflict. The above outlined postoperative activities show analogy with the process of total quality management (TQM), known in industrial production systems. CIS systems that implement the chain-linked phases of CAD, CAM and TQM are simply called "Surgical CAD/CAM Systems" (Figure 2.)
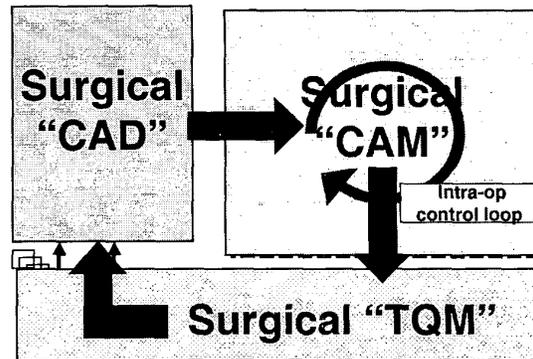

Figure 2: The Surgical CAD-CAM paradigm

Percutaneous local therapy as surgical CAD/CAM

Percutaneous ("through skin") procedures are ideal candidates to implement the CIS paradigm. These procedures involve the insertion of tubular therapy devices (needles, catheters, bone drills, screws, tissue ablating devices, etc.) into the body, typically through the skin. Just as any CIS system, percutaneous systems heavily depend on sophisticated image acquisition and analysis tools. The most frequently used imaging modalities are CT, MRI, ultrasound, or fluoroscopy.

In percutaneous surgical CAD/CAM systems, autonomous robots are applied to orient the surgical device (simply referred to as "needle" herein). The robots are navigated computationally using some form of intraoperative imaging. In this process, the robot is registered to the coordinate system of the imager. The intervention is planned out in anatomic coordinates, i.e. in the coordinate system of the imager. For execution, the interventional plan is transformed into the robot's frame of reference and the robot is instructed to carry out the plan.

3. System for Robotically Assisted Percutaneous Therapy

The robotic subsystem

Manual needle punctures typically include the following three decoupled tasks: (1) touch down with the needle tip on the skin entry point, (2) orient the needle by pivoting around the skin entry point, (3) insert the needle into the body along a straight trajectory. Inserting a needle to an arbitrary location requires six independent

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stages of motion, also called degrees-of-freedom or DOF. First, three independent Cartesian motions (3-DOF) are necessary to move the needle tip from its current location to the skin entry point. Then two independent rotations (2-DOF) are necessary to aim the needle by pivoting around a fulcrum point at the skin entry point. Finally, one-directional translation (1-DOF) is necessary to insert the needle into the body through the skin. This above kinematic sequence can be achieved by the basic robotic system shown in Figure 3.

The basic components of the robot seen in Figure 3 have been developed by primarily Stoianovici, Taylor, Whitcomb at the Johns Hopkins University [5,6,7].
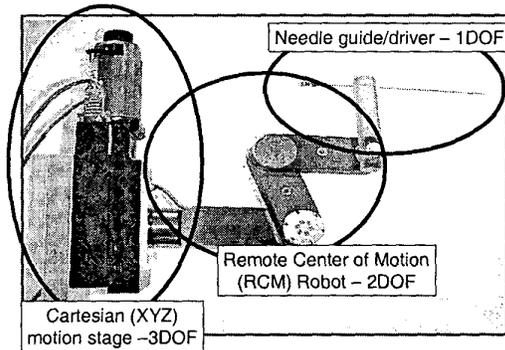
Figure 3: Modular percutaneous robot with decoupled stages (Taylor, et al., 1999)

The system consists of a 3-DOF Cartesian motion stage, a 2-DOF rotational stage, and a 1-DOF needle insertion stage. The motion stages are operated sequentially. Only one stage moves at a time while motion power is turned off on the two other inactive stages. This scheme prevents insertion before proper alignment is confirmed and also prevents an accidental change in the needle path during insertion. The stages are kinematically constrained and each stage is able to perform only one kind of motion. For example, the rotation stage cannot translate and the translational stage cannot rotate. The system also applies non-backdrivable transmission that preserves configuration when the robot is deactivated or in the event of power failure. Over-travel of the stages is also a concern that is addressed extensively in the control software and by placing hard-stop blocks on the hardware. For example, accidental over-travel of the needle can be prevented by placing a sterile clamp on the needle shaft above the driving gear at the maximum insertion depth. These safety features guarantee that the robotic system performs only the prescribed motion and each component stays within the set kinematic constraints. All motion stages are powered by DC motors. The remote center of motion robot employs a miniature parallelogram structure driven by

chain drive that provides full 360 degree rotation around both axes.

Several needle driver mechanism have been developed in our laboratories. The clinically tested devices have one degree of freedom and employ the principle of friction transmission with axial loading, patented by Stoianovici (Figure 4.A,B,C,D). A frictionless 2-DOF model has also been developed, it provides independent bi-directional spin and insertion of the needle (Figure 4.E.)
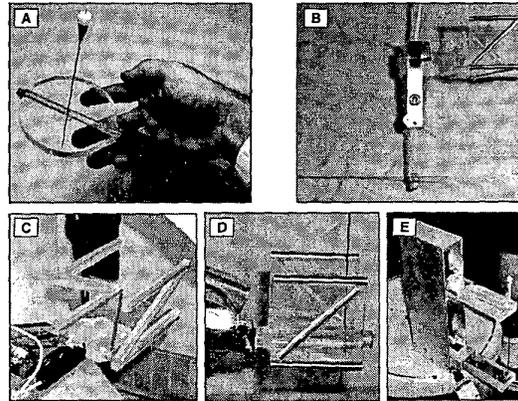

Figure 4: X-ray compatible needle drivers. (Stoianovici at al., in collaboration with Susil (C), Masamune (D), and Wiard (E), 1999-2001)

Both the RCM and needle driver components have been used in multiple clinical scenarios by Dr. Louis R. Kavoussi et al. in the Brady Urological Institute [5,6,7]. The engineering characteristics of these devices were also published [2]
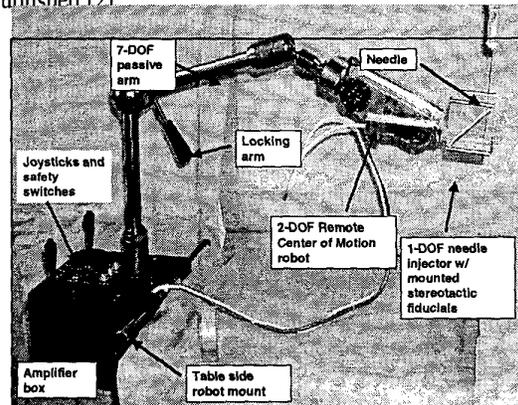

Figure 5: Prototype of the percutaneous robotic system (Stoianovici et al., 1999)

The actual pre-clinical prototype is shown in Figure 5. Here the robotic system is mounted on the OR table. In order to promote encapsulation of robotic components, the amplifiers and power supplies are built inside the robot

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mount. Temporarily, the Cartesian motion stage was replaced by an un-encoded passive mounting arm. The arm locks and unlocks easily with a handle. The arm is unlocked and the robot is moved manually to the skin entry point, then the arm is locked. The rotational stage is attached to the arm, and the radiolucent motorized needle insertion device (needle driver) is linked to the rotational stage. The combined weight of the system is about 15 kg. One reasonably skilled technician can set up and take down the system in ten minutes. The entire robotic system, including the passive mount, rotational stage, and needle driver folds conveniently into a carry-on suitcase.

Image guidance

Image guidance is a critical aspect in CIS systems. Ideally, percutaneous robotic systems apply purely image-based registration between the robot and the image space. In order to achieve this objective, we must identify traces of the robot in the intraoperative medical images, then reconstruct the location of the robot with respect to the patient. One typical solution is to attach rigid body fixtures to the robot's end-effector, which leave marks in the image. Figure 6 shows surgical planning with the device shown in Figure 4.D. With the use of such a stereotactic fixture, registration and targeting can be accomplished with a single image slice, as opposed to taking volumetric data. This feature promotes lower
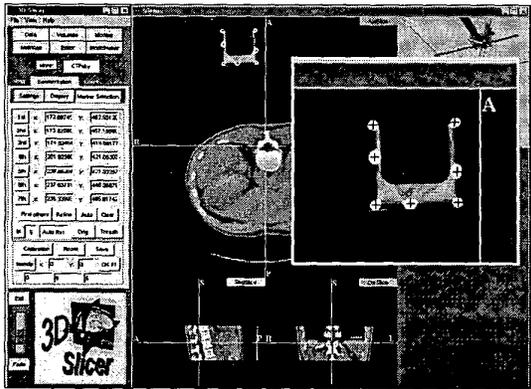

Figure 6: Treatment planning display and CT image of a the end-effector shown in Figure 4D. (Tanacs et al., 2001)

radiation exposure and shorter procedure. The fundamentals of stereotactic registration of robotic-end-effectors have been published by Susil [4] based on the prototype shown in Figure 4.C. Lee et al.[11] expended on the concept and developed clinically applicable robust mathematical methods that support a plurality of such devices and can also handle incomplete input data. Masamune created the first clinically practical version of

the device shown in Figure 4.D. Registration in X-ray fluoroscopy images is also very important, given this is the primary imaging modality in orthopedic surgery and cardio-vascular interventions. Figure 7 shows a registration fixture for fluoroscopy guidance allowing accurate registration from a single fluoroscopic image, as published by Yao et al. [12].
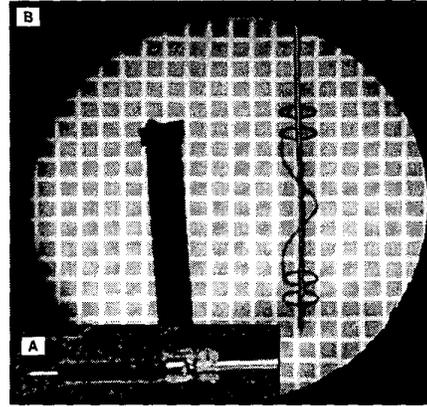

Figure 7: Rigid body registration fixture for fluoroscopy guidance (A) and its image (B) (Yao, Taylor et al., 2000)

Systems software and integration

A schematic drawing of the overall configuration of the prototype system is presented in Figure 8. The CT images are transferred across a local area network (LAN) in DICOM format to a Pentium-II 333 MHz personal computer equipped with a 17" flat panel display. The computer runs a "simple storage" DICOM server, installed from the public domain source at http://www.erl.wustl.edu/DICOM [8]. The operator of the scanner pushes DICOM images from the CT console through the LAN to the DICOM server.
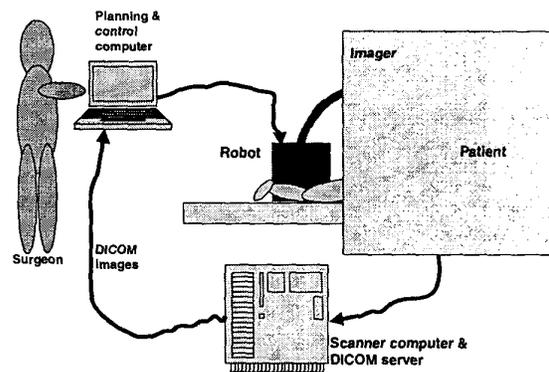

Figure 8: Schematic drawing of the system

The central computer performs intra-operative image processing, motion planning, remote actuation, and control of the robotic components. These services are provided in the 3D Slicer software system, which is jointly developed with MIT Artificial Intelligence Laboratory and the Surgical Planning Laboratory at the Brigham and Women Hospital [9]. The surgeon uses an interactive display to execute the intervention step-by-step (Figure 9/A). Upon completing each step, the computer waits for confirmation before continuing. The interactive software completes an intra-operative control loop, thus implementing a simplified variant of the surgical CAD/CAM paradigm. Figure 9 also shows screenshots from the 3D Slicer-based path planning and visualization. Stereotactic fiducials are picked and the prostate is contoured semi-automatically (Figure 9/C). The robot and patient are registered, and the path and pattern of the needles are planned in three dimensions (Figure 9/B).
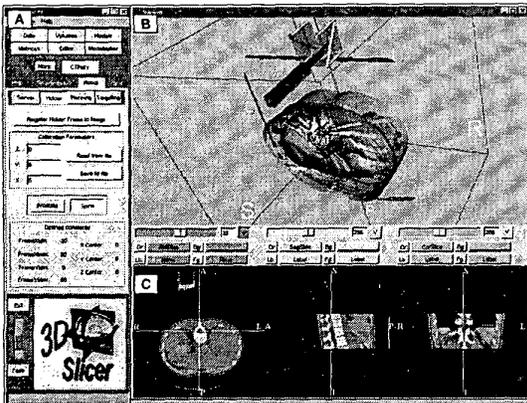

Figure 9: Visualization and treatment planning display for CT-guided robotically assisted spinal nerve blocks, using the end-effector shown in Figure 4D (Tanacs et al., 2001)

Robot Control (MRC) library previously developed by Taylor et. al. at the Johns Hopkins University. The MRC library, which is fully integrated with the 3D Slicer system, is a set of portable C++ classes for distributed and modular robot control. The system does not depend on any vendor-specific hardware or software feature and is deployable on any scanner that has DICOM interface.

4. Clinical Applications

The X-ray compatibility of the end-effectors and the highly modular nature of the robotic system made it possible to deploy the device with several imaging modalities with minor or negligible modification. Historically, the first application area was urology, where the system was used in kidney biopsy procedures under

fluoroscopy guidance by Stoianovici et al. (Figure 10.) Currently, the system is being adapted for CT-guided prostate biopsy by Fichtinger et al. [13] (Figure 11.)
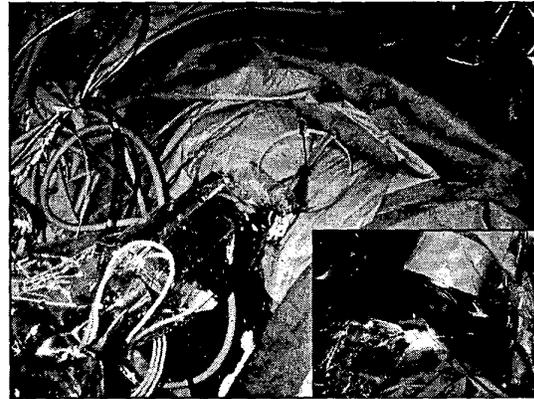

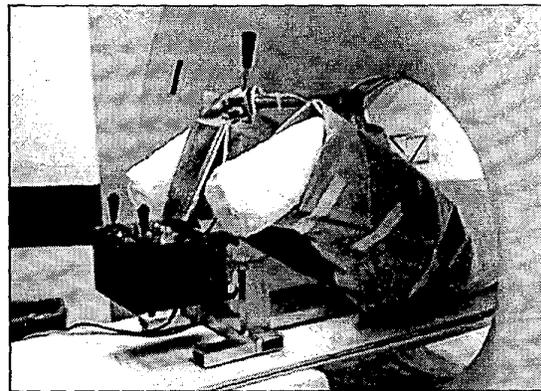**Figure 10: Robotic kidney biopsy with fluoroscopy guidance (Stoianovici et al., 2000)**

Figure 11: Robotic prostate biopsy with CT guidance, phantom experiment (Fichtinger et al., 2001)

5. Summary and Conclusions

Computer-integrated surgical systems using image-guided robots are beginning to gain acceptance by the medical community. It is expected that this process will accelerate and in short time these systems will become standard parts of the national healthcare system. It is imperative that new systems engineering frameworks be formulated for scientifically sound design and analysis of CIS systems. In this article, we introduced the paradigm of Surgical CAD-CAM, as well an implementation of the paradigm for percutaneous local therapy procedures. We also presented several embodiments of this general-purpose percutaneous system. All variants used the same modular surgical robot deployed with multiple intra-

operative imagers in various clinical scenarios. The presented generic system has been serving as a versatile engineering and pre-clinical testbed for our research center and it is expected to continue being a most productive conduit between engineering prototyping and clinical applications.

6. Acknowledgments

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