

Abdel-Malek, K., McGowan, D., Goel, V.K., Kowalski, D., and Smith, S., (1997), "Bone Registration Method for Robot-Assisted Surgery: Pedicle Screw Insertion," *IMechE Journal of Engineering in Medicine*, Vol. 211, Part H, pp. 221-233.

Bone registration method for robot-assisted surgery: pedicle screw insertion

K Abdel-Malek, BSc, MSc, PhD

Department of Mechanical Engineering, The University of Iowa, Iowa City, Iowa, USA

D P McGowan, BSc, MSc, MD

Department of Surgery, Veteran's Administration Medical Center, Des Moines, Iowa

V K Goel, BE, ME, PhD, **D Kowalski**, BSc

Department of Biomedical Engineering, The University of Iowa

A Hager, Bsc, Msc

Department of Mechanical Engineering, The University of Iowa, Iowa City, Iowa, USA

S B Smith, BSc, MD

Department of Orthopaedic Surgery, Indiana University, Indianapolis, Indiana

SUMMARY

A registration method that identifies bone geometry with respect to a robotic manipulator arm is presented. Although the method is generally applicable to many orthopaedic internal fixation, it was only demonstrated for the insertion of pedicle screws in vertebral bodies for spine fixation. The method relies upon obtaining an impression of the vertebral bodies. Computed Tomography scans of both vertebrae and mold are reconstructed using a computer-aided-engineering (CAE) system. From the reconstructions, the surgeon is able to do pre-operative planning including selection of pedicle screw diameter, direction of screw through pedicle, point of entry, and length of

engagement. The three-dimensional models are then meshed to determine positions of the surgeon's preoperative plan relative to the mold. Intra-operative positions are defined in space by a mechanical fixture rigidly attached to the mold and designed to allow a manipulator end-effector to recognize the global coordinates of the in-vivo spine. The theory and methodology were validated using a five-axis manipulator arm. This initial presentation assumes and allows no relative motion between vertebrae in-vivo.

Key words: robotic-assisted surgery, orthopaedics, pedicle-screws, internal fixation, pre-operative planning, registration.

1 INTRODUCTION

Robots have had a significant impact on the manufacturing environment, yielding higher productivity and improved quality. Robots, however, have not yet made a significant impact in health care. The application of robots in medical practice is limited by a lack of tools yet to be developed. These tools are different from those in the manufacturing environment. Better visualization and control of the manipulator, as well as the opportunity for detailed pre-operative planning simulations, are of great interest to a surgeon conducting robot-assisted surgery.

The work presented in this paper is aimed at developing robotic registration and control systems that will allow robotic manipulators to safely assist surgeons in placing pedicle screws. Identification of bone geometry with respect to the manipulator is called registration. This research is the result of a collaboration between the University of

Iowa's Biomechanics laboratory, the Center for Computer Aided Design, and the Veteran's Administration Medical Center in Des Moines, IA.

In spine surgery, spinal instrumentation is often used to apply forces to correct deformity or to stabilize an injured spine. Spine instrumentation may also improve the rate and quality of biologic fusion. Spine instrumentation systems may attach to vertebrae by some combination of hooks, wires, or screws. Pedicle screw fixation is the best choice for short-segment rigid fixation or when posterior-elements are absent.

One of the most critical issues to success is the exact insertion of pedicle screws. Pedicle screws may be inserted by anatomic land marks as proposed by Magerl or Camille, by extensive use of fluoroscopy which exposes both the patient and surgical team to significant radiation, by extensive dissection of the pedicle, or by some combination of these techniques. However, knowledge of the ideal positioning is one thing and accurately achieving it physically is quite another. The space where each screw can be inserted is extremely limited and is close to major vascular structures, dural tube, and nerve roots.

With the advent of robotic manipulator arms, the medical industry has endeavored to automate many procedures that require high accuracy. Total hip and knee replacements, stereotactic brain surgery, and resection of brain tumors are some of the procedures that have met with some success. In recent years, robotic technology has seen many advances that allow for accuracies of 0.0001" and repeatabilities 0.0005" .

The long-term objective of the presented research is to develop a general systematic method for robot-assisted surgery. Robot-assisted insertion of pedicle screws is a challenging, yet achievable, problem. This work is aimed at developing an integrated system comprised of: (1) a CT/MRI scanning system to delineate three-dimensional bone geometry, (2) a manipulator arm to accomplish the correct placement of a screw, and (3) a computer-aided engineering interface to model the geometry and perform the necessary calculations. Such a system provides the surgeon with a tool for improved control of screw insertion.

A systematic and accurate method of pedicle-screw insertion should decrease the fraction of procedures which progress to clinical failure. With approximately 200,000 new cases presenting annually with up to 25% complication rate and 1% morbidity rate, This unique tool to assist the surgeon will improve outcomes and contribute to a reduction of cost in the health care system.

Long-term, there are several other areas where the technology proposed will be of interest and use. For spine surgeons, percutaneous pedicle screws could be precisely, quickly, and accurately placed with the aid of robotics and would be a minimally invasive and safe procedure.

Brain, spine, and endoscopic surgery were some of the applications discussed recently in the First International Symposium on Medical Robotics and Computer Assisted Surgery (MRCAS '94). It is also worth noting that the National Science Foundation has recently

awarded a Grand Challenge grant for the researchers using a robot that assists in a total hip replacement surgery “Robodoc.”

2 LITERATURE REVIEW

Because of the multidisciplinary content of this research, this section will review two main bodies of literature: (a) Work related to screw fixation mechanisms including screw placement; and (b) work related to robotic-assisted surgery and bone registration methods.

2.1 Pedicle Screw Insertion

The holding power of screws in bone is affected by the density to the second power, the surface area of thread-bone contact and the configuration of the thread relative to the structure of bone. Tapping of the drill hole is another source of possible loss of fixation. Frictional forces between threads and bone can have an impact on the tendency of screws to back out (**1, 2**). It is possible to extrapolate and surmise that imprecise drill holes or tapping could compromise the stability of fixation. A concise review of screw insertion methods was presented by Goel (**3**). A recent issue of *Spine* was dedicated to the use of bone screws in the vertebral pedicles (**4**). A comprehensive literature review and surgical treatment alternatives as well as pedicle screw fixation mechanisms are discussed.

In 1941, Lyons noted that the orthopedic literature had not addressed the subject of hole preparation for screw placement (**2**). In this review of the current literature, it is deduced again that this issue has not been adequately addressed. Two studies were

published from 1989-1991 which addressed the hole preparation technique in pedicle screw placement. Both studies compared a hand drilling technique to a hand probing technique (5, 6).

Pedicle screws are used for fixation in degenerative spondylolisthesis, stenosis and spinal fractures. They have been found to have nearly a 20% greater rate of fusion than non-instrumented controls. There have been multiple studies reviewing pedicle screw use and complications cited have included screw loosening, pullout, migration and loss of reduction. In a recent review of 3498 cases, screw loosening was found to range from 1.7 to 2.3% depending on the indication for placement and the chronological relationship to its surgical placement (AAOI, 1994).

The anatomy of the pedicle in the thoracic and lumbar spines has been quantified for a skeletal mature population (6-13). Anatomic points on the vertebral bodies for entry into the pedicle have also been defined (14-16).

Pedicle screw systems are available which should fit within the cortex of pedicles in the lower thoracic, lumbar, and sacral pedicles. Image intensification and simple radiographs have been used to guide pedicle screw placement, but radiographic assessment of pedicle screw placement has been demonstrated to show up to 8.1% false positives and up to 14.5% false negatives (16). Radiographically imaging the position of the screw tip relative to the anterior cortex is also difficult and misleading (17, 18) because of the convexity of the anterior body. More recently, Amiot et al. (82) presented a

feasibility study for a computer-assisted pedicle screw fixation method with a targeted accuracy of $\pm 1.1 \text{ mm}$ and angular precision of $1.6^\circ \pm 1.2^\circ$ based on 964 measurements in 90 sessions. Measurements were taken by two observers on one artificial object. Various errors due to sensor calibration ($\pm 2.5 \text{ mm}$) and 3D reconstruction ($\pm 1.0 \text{ mm}$) are addressed.

Similarly, a single CT image in the longitudinal plane of the pedicle may falsely imply the best path for a given diameter screw through the pedicle. From the unpublished work of Berlemann, the best path through the pedicle is determined from the three-dimensional reconstructions of the pedicle **(19)**.

Studies have shown, however, that screws are placed outside the pedicle in 25% of cases **(20)**, 21% **(16)**, 10% Roy-Camille, **(14)**, and 6% **(21)**. Post-operative complications have been reported as high as 25% and mortality as high as 1%.

Measuring forces and torques to verify robot performance in surgery has not been done to date. Torque of pedicle screw insertion has been correlated with bone density and strength of fixation **(22, 23)**. Bone strength in compression is correlated with the bone density to the second power **(24, 25)**.

Pedicle screw fixation has also correlated with bone density **(22, 26-33)**. Bone density and strength may be calculated from a quantified CT scan **(27, 28, 34-37)**.

2.2 Work related to robotic-assisted surgery

There have been numerous reports of using robots in surgery, some of which have been very successful (reviews of such works can be found in Kassler (38) and Priesing (39)).

Although robotic-aided pedicle screw placement in the operating room has not been attempted to date, a real time non-x-ray guidance system has been developed and accurized in the laboratory (19). Results show 91% exact pedicle screw placement and no violation of the pedicle cortex. Registration was accomplished with a vertebral marker on the spinous process and registration of paired skeletal landmarks. This system would allow for vertebral motion during instrumentation, but depends on accurate registration of the landmarks by the surgeon.

There have been numerous reports of using robots in other surgical applications. Successful applications of robots in surgery have included reports by Lavalley et al. (40), Benabid (41), and Cinquin (42), at Grenoble University in France, who have reported the utilization of a robot for more than 200 interventions in the field of neurosurgery. A computer reconstructed a 3-dimensional image of the brain, and a surgeon supplied the coordinates to specify the trajectories using an IBM personal computer. The motion was decomposed into sequences of linear actions. Currently those authors are organizing to extend their technology to spine surgery.

Kwoh et al. (43) and Young et al. (44), at the Memorial Medical Center in Long Beach, California, have used a PUMA 200 robot for automating the manual adjustments

of a stereotactic frame. In 1985, the robot assisted in surgery of a patient who had a suspicious brain lesion. The robot calculated precise trajectories for each incision. The controller eliminated errors in calculating stereotactic frame settings and in transferring calculated settings to a mechanical frame.

Another successful robot (called Minerva) is used in surgery at the Swiss Federal Institute of Technology. Glauser et al. (45) and Flury et al. (46) reported the design of this stereotactic thalamotomy robot. The robot was used with a CT scanner to define trajectories. The target point and trajectory were determined from a CT scan. The redundancy in the manipulator was used to compute two solutions as close as possible to the tool-skin contact area. Its developers report "adding speed, accuracy, and security" by robotization.

In the orthopaedic field, probably the most well-known application is Robodoc, an image-directed surgical robot that was developed to help surgeons prepare a cavity for a prosthesis in a total hip replacement (THR) surgery. Human clinical trials are ongoing at ten centers. The system uses digital data from CT scans of the femur. The developers (47-55), currently at Integrated Surgical Systems, report a great increase in accuracy and precision of the joint replacement procedure. Robodoc uses a framed method (fixator and pins) to immobilize the femur. Pins are inserted into the bone to retrieve a coordinate system and achieve registration. The manipulator used is a four degree-of-freedom manipulator of the Selective Compliance Articulated Robot Arm (SCARA) type.

Other robots currently performing surgery are the Automated Endoscopic System for Optimal Positioning (AESOP) developed by Wright **(56)**, the Surgeon Assistant Robot for Prostatectomy (SARP) developed by Davies et al. **(57)**, and the Surgeon Assistant Robot Acting on the Head (SARAH) developed by Finlay **(58)**. Others are reported by Ng, et al. **(59)** for transurethral resection and Matsen, et al. **(60)** for distal femoral arthroplasty.

In order to compute manipulator joint variables to follow a specified screw-path trajectory, the kinematics of the manipulator have to be defined. The formulation of an inverse kinematic solution for manipulators, in the general sense, is well established. Solutions of the kinematics problem for manipulators have been studied as early as 1968 **(61)**. The inverse kinematics problem has been solved by various methods, e.g., algebraic transforms **(62)**, screw algebra **(63)**, dual matrices **(64)**, dual quaternion **(65)**, iterative **(66)**, and geometric approaches **(67)**. More recently, Pohl and Lipkin **(68)** presented a new method using complex numbers, while Raghavan and Roth **(69)** reported a method for calculating the inverse kinematic solution for any series chain manipulator and closed-loop linkage.

One of the most challenging aspect of robotic-assisted surgery is bone registration. There has been many reports of registration methods. At the Rizzoli Institute, a registration method has been developed using markers positioned in the bone to perform a total knee arthroplasty **(70)**. A frameless patient registration method was reported by Ault and Siegel **(71)** at Carnegie Mellon University that uses ultrasound imaging. The locations of target features relative to the reference features are identified. Another frameless

guidance method was reported by Grimson et al. (72) at MIT to register clinical data, such as CT reconstructions of the patient's head. Simon et al. (73) presented two techniques for registration: high-speed pose tracking and intra-surgical data selection in order to perform a surface-based meshing of the data. At Northwestern University, (74, 75) reported a registration method used in Total Knee Replacement. This system uses Fiducials (reference features located on both the computer-based model and the bone). The coordinates are then matched to register the bone surface. A more recent report of using a robot in inserting a guide-wire was reported by Bouzza-Marouf, et al. (76) where the bone is secured using a fixation mechanism.

3 IDENTIFYING REFERENCE FRAMES

The major difficulty in robot-assisted surgeries is the computer identification of bone geometry with respect to an invariant reference frame, that is the global coordinate system known by the robotic arm. Several methods exist for identifying coordinate points such as that reported by Nolte (19), where the coordinates of three to six characteristic anatomic landmarks are captured for an operative paired point matching procedure. In the work presented by DiGioia, et al. (77), the registration method still requires pins or frames to determine the position and orientation of femoral bone. The markers are visible in medical images and are still attached to the patient at the time of surgery.

In this paper, a unique method for bone registration is presented that does not insert any markers into the bone or require exact identification of a point on a bone. Therefore, this method does not expose the patient to additional trauma and risk associated with the

implantation of markers or require the surgeon to locate an exact point on a vertebrae surface which could never be done consistently. This method is based upon obtaining a partial mold of the vertebral bodies. Rather than defining a minimum of 3 non-collinear points, the mold defines all complex three-dimensional surfaces of the posterior elements.

After experimentations with different types of material, dental impression material called *Reprosil type I* (Dentsply International Inc., Milford, DE) was selected. The material is composed of Vinyl Polysiloxane and is used in the reconstruction of dentistry. Reprosil was selected due its very low viscosity, inert and non-toxic to human tissues, and ease of handling on fresh bone surface. After several test experiments with fresh cadaver spines, it is noticed that Reprosil can be removed from the vertebral bodies without damage to tissues and without the mold material breaking. The material is laid inside a especially made fixture (called registration fixture). A partial impression of the posterior elements, already dissected, is taken. Once the material starts to solidify (2-3 minutes), it is removed. It is emphasized that this mold, which is an infinite number of points on the surface of the bone, replaces the invasive methods using frames and pins. It should also be emphasized that this procedure can be done in the operating room and does not require any further surgery. The registration fixture serves two main purposes.

(1) Provides a standard reference frame for the impression material.

In order to secure the impression material inside the fixture, T-shape indentation inside the cylindrical part of the fixture is machined. The registration fixture is depicted in Fig. 1.

This will secure the mold from rotating and will allow the mold to be disassembled and assembled freely.

(2) Aids in establishing a reference frame for the manipulator end-effector.

To be able to identify the fixture's coordinate reference frame, it is necessary to establish a systematic method for acquiring its position and orientation. The method employed is to have the manipulator end-effector manually guide its end-of-arm tooling into a unique machined groove in the top as shown in Fig. 1. This groove is machined such that the end-of-arm tooling is inserted only in one unique configuration (see Fig. 1). Once this is accomplished, the position of the mold and the three-dimensional in-vivo spine are defined in the robot's global coordinate system. By computing the direct kinematics of this manipulator, the orientation and position of the end-effector are known. Using a simple transformation matrix, the coordinate system associated with the fixture (coordinate system B in Fig. 2) is also identified. An illustration of the coordinate reference frames is depicted in Fig. 2.

For this initial investigation, the impression material is laid on two to three consecutive vertebral bodies. The impression material is inside the fixture. The robot end-of-arm tooling is shown being guided to the end-effector reference groove in Fig. 3. Once the arm is in position, joint coordinates are registered and the coordinate system associated with the fixture is computed. Note that the end-of-arm tooling is an especially manufactured tool that would fit into the groove in one unique configuration.

4 COMPUTER MESHING OF MODELS

In order to register bone geometry, it is necessary to digitize the bone surfaces onto the computer. Computed Tomography scans have the ability to identify a wide range of bone densities at a minimum of 1.0 mm cross-sectional slices. Therefore, CT scans of the vertebrae are obtained. Only boundary surfaces of the bone geometry are identified as shown in Fig. 4.

Each cross sectional slice is entered into a three-dimensional computer aided engineering (CAE) system. The digitized slices are mapped into graphical entities.

Computed Tomography scans of the impression material (mold) are also obtained. The slices are also reconstructed using the CAE system into a three-dimensional model. A top view of the reconstructed mold is shown in Fig. 5.

Note that both models are entered into the same CAE system and therefore, appear on the same computer screen. It is now necessary to establish a meshing criteria for the two models. The simplest method is to identify the spinous process in both models. This criteria is simple and does converge to an accurate meshing. However, in many cases where the medical intervention is a revisit, spinous processes are removed, thus causing the meshing procedure to be prolonged. If this is the case, contour lines of the mold should be identified with those of the vertebral bodies. This is not an impossible task, but it is more difficult. Figure 6 depicts two views of the meshing screen (cross-sectional slices were taken every 1.5 mm).

It is obvious that meshing accuracy will increase with smaller scanning thickness. It is also obvious that without the spinous process, it will be difficult to ascertain an accurate meshing. Therefore, the acquired accuracy using this method is 1.0 mm which is the distance between two cross-sections of a CT scan.

5 PLANNING PEDICLE SCREW PLACEMENT

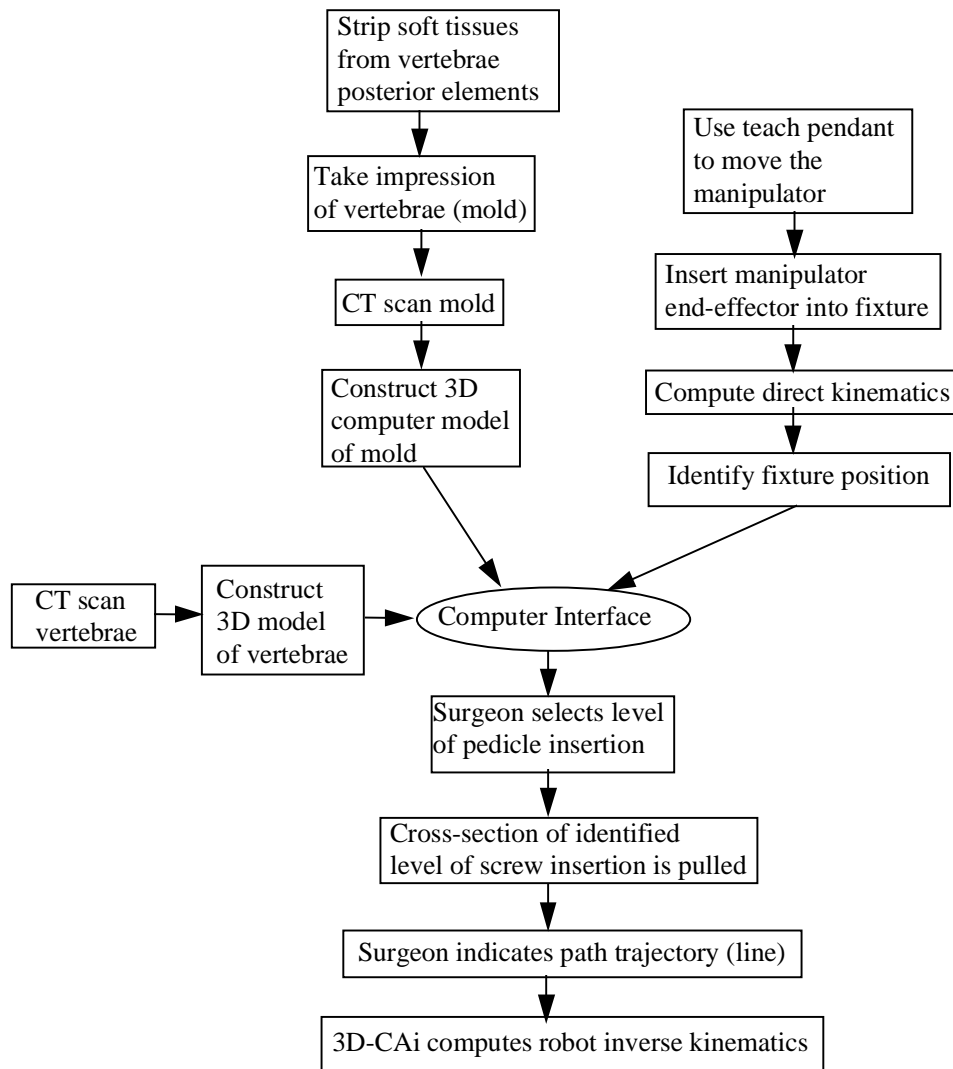
The software that encompasses the computer-aided-engineering system, the reconstruction of three-dimensional models, computing manipulator direct inverse kinematics, computing manipulator trajectories from graphical entities, and the system for allowing a surgeon to manipulate cross-sectional slices has been called the three-dimensional Computer-Aided Interface (3D-CAi) (78, 79).

In order for the surgeon to indicate an exact location for the pedicle screw, a system for manipulating the models has also been developed. A slice representing a cross-section can be pulled from the stack.

It is important to notice that the drill trajectory does not have to be in the plane of the slice. Using 3D-CAi, the surgeon may “draw” a line indicating the required path. 3D-CAi transforms this graphical entity into manipulator joint coordinates. Figure 7 depicts a snapshot from the computer code written inside a computer-Aided-Engineering system that allows a user to indicate a path trajectory on projected views. A line indicating the drilling

trajectory is drawn by the surgeon. Note that the line is drawn in three-dimensions (not in the plane of the cross-section).

In order to summarize the registration procedure, a block diagram is presented below.



6 A NOTE ON COMPUTER IMPLEMENTATION

Computer-aided engineering software was used to provide a visual link between the surgeon and the robotic arm. This system was developed using AutoCAD (AutoDesk

Corp.) (80) that provides an artificial intelligence language called AutoLisp. This language allows for the development of commands, mathematical formulations, and interface with other programs from within AutoCAD. Although the specific language and commercial software used does not affect the ideas presented here, nevertheless, it provides the reader with the means for implementation. The experimental codes developed at Iowa within AutoCAD comprises four additional menu items to the regular AutoCAD menu. The menu under 'Robot' provides the user with the ability to manipulate the arm, manipulate each individual joint, and the ability to register the joint coordinates (the modified AutoCAD screen is showed in Fig. 8). The 'Registration' menu allows the user to compute the direct and inverse kinematics for the manipulator, register the mold, and allows the CAD system to retrieve different spine data files stored in graphical format.

The 'Pre Operative Simulation' menu provides the user with the ability to simulate a specific set of motions planned by the previous commands. This set of commands will depict a robot arm undergoing a sequence of preplanned motion to help the surgeon visualize the procedure before proceeding with the surgical intervention. This menu also allows the user to load different data-files for various robotic manipulator arms. The Denavit-Hartenberg data sets (81) are needed to describe the geometry and kinematics of the manipulator. The 'Trajectory' menu allows the user to indicate a specific CT-scan slice, allows the user to view this slice from different views, and transfers the graphical entity into robotics data. Figure 9 depicts a snap shot of a simulated manipulator arm and the fixture.

It should be emphasized that this system is experimental and a different choice of CAD system and programming language is recommended since this system has been developed using a personal computer that limits the real-time capabilities needed for safety considerations in terms of monitoring the arm.

6 ACCURACY

Possible error contributions of various subsystems are addressed.

6.1 Manipulator Accuracy and Repeatability

Accuracy: Although optical encoders mounted on the arm provide a closed-loop positioning accuracy of 1000 encoder lines per revolution, and magnified through the use of harmonic drives with a reduction ratio of 1:60 with zero backlash (i.e., an accuracy of 0.006°), the educational robot used in our early studies has an end-effector accuracy of 0.01-0.03 inches at average velocities. Accuracies of 0.001" can readily be achieved using the new NASA arm provided for this research by the NASA Goddard Space Research Center (accuracy of 0.005").

Repeatability: Although repeatability of a manipulator in an industrial application is of great importance due to high velocities, accelerations, and the high number of repeatable tasks, it is not a concern in this work. The robot arm is required to drill the hole only once and at very low velocities and accelerations.

6.2 Accuracy of the Learning Method

Registration of the fixture (i.e., determining its coordinates in space) is achieved through inserting a tool into a specific groove in the fixture. Upon manually guiding the manipulator arm to insert the tool into the fixture (using a teach pendant), the manipulator joint coordinates are recorded (encoder accuracy are in the order of $\pm 0.006^\circ$ with zero backlash due to harmonic drives).

However, the greatest error contribution results from obtaining a stressed (deflected) link configuration when fitting occurs. It is evident that the manipulator end-effector be in the machined groove of the fixture while one of the links is deflected. The deflection may occur in some links depending on their lengths. An estimated maximum deflection of ~ 2 mm and $\sim 2^\circ$ may occur.

6.3 Accuracy of the Tooling and Fixture

The accuracy of the fit between the tool and fixture depends on the manufacturing process of both parts. Both parts were manufactured using CNC and EDM machines with a close tolerance $\pm 0.0005''$. Therefore, this aspect of the method does not contribute any errors.

6.4 Meshing

Computed Tomography (CT) scans are taken at a thickness of 1.0 mm. This is the maximum accuracy possible due to CT machine limitation, it presents adequate resolution for the meshing procedure. Digitized slices are mapped into graphical entities (lines connecting surface points). These entities of the impression material and of the vertebral bodies are then meshed on the screen. The meshing is currently performed using

commands issued in the CAD system to geometrically align the models. Although parametric surface patches can be developed and an algorithm for 3D-meshing can be implemented, it was deemed sufficient to manipulate 3 views of the two models to obtain a relatively accurate mesh. The use of the term meshing in finite element analysis (FEA) is accurate, however, the term is also used in the context of aligning two solids such that their geometries match.

6.5 Modeling Accuracy of the Anatomy

Modeling of the anatomy is extracted from CT scans. The most dense bone is electronically traced using a camera-projection system where only light passing through dense bone (white areas of the scan) are registered. Digital resolution of the system is estimated at 0.2 mm. Outer surfaces of the bone and impression material are then entered into the CAE system.

6.6 Impression Material

The impression material used called “Reposil Putty” (Vinyl Polysiloxane) is a very high viscosity material consisting of two pastes which harden to form a base for final impressions. The material is not soluble in water and is used to obtain *very accurate* impressions of dental works. The manufacturer’s reported accuracy of the material is adequate for obtaining impressions of miniature cavities in teeth of the order of 0.05 *mm*.

6.7 Required Registration Accuracy

An ideal pedicle screw positioning system is one that is able to position and orient the screw such that it does not perforate anterior cortex, yet maintain a solid fusion. The depth of penetration is also important to increase pull-out strength. Placement of the screw using a manipulator is important in achieving a circular hole rather than an elliptical one resulting from manual preparation. In terms of registration, a required accuracy of $\pm 1 \text{ mm}$ is a goal with an orientation accuracy of two to three degrees. According to practicing orthopaedic surgeons who perform this type of fusion, a manual accuracy of $5 \pm 2 \text{ mm}$ and $3 \pm 2^\circ$ is reported. The main problem in this type of surgery is not the accuracy of the surgeon's hand or the manipulator's end-effector, but is in the accuracy the data provided to the manipulator's controller. The data represents the position and orientation of the screw location with respect to a vertebral coordinate system embedded in the fixture. Typically, a surgeon is guided by intermittent fluoroscopic snap shots of the cross-sectional view of the spine. In addition, in many instances, these x-ray snap shots do not adequately represent the true configuration of the screw or K-wire.

Published works using computer methods (Amiot et al. 1995) have reported an accuracy of $4.5 \pm 1 \text{ mm}$ and $1.6 \pm 1.2^\circ$. Commercial mechanisms used to aid a surgeon in placing the screws are also available which may improve accuracy.

7 FUTURE ENDEAVORS

The authors are currently endeavoring to develop a feedback scheme where the manipulator would measure forces induced at the tip of the drill in real time. The forces would be fed back to the arm controller so that the predicted position of the drill may be

further confirmed. For pedicle screws, cortical bone will be machined only at the point of entry. In reality, a surgeon hand is guided through the pedicle by a touch feedback and this real-time system incorporates the surgeon's feel into the robot.

The authors are continuing to enhance the 3D-CAi system to include a more elaborate simulation capability of the arm and vertebral bodies. The complete procedure will be simulated before execution.

A study is currently underway to validate that a hole drilled by a robotic manipulator has many more advantages than that performed by a human hand. A number of tests are conducted including screw pullout tests to verify the proposed method are planned.

The relative motion of the spine due to breathing has not been accounted for. It is planned, however, to study the effect of this lateral motion. It is contemplated that the rigid mold once rigidly fixed, can act as a fixator to two or more vertebral bodies.

8 CONCLUSIONS

A general registration method that identifies bone geometry with respect to a robot's fixed reference frame has been presented. The method has been applied to a robot-assisted procedure for inserting pedicle screws. It has been shown that this method is not invasive. It has also been shown that this method achieves a high accuracy of registration and highly depends on the accuracy of the CT scans.

This method has exhibited feasibility since it does not require further surgical procedures and it can be performed inside the operating room with minimal loss of time. It has been shown that this method replaces the need for frames and pins inserted into the bone which require further surgical intervention.

The uniqueness of using impression material to obtaining a partial mold has been shown to achieve a high resolution registration. Difficulties in meshing the three-dimensional models of the vertebral bodies and the impression material may arise especially if an adequate subperiosteal dissection has been accomplished. This difficulty is especially visible when the spinous process is removed. Adequate testing of any reactive effects due to the mold's material interaction with tissues has not been performed. It is believed, however, that since this material is used in dental applications, with often times open wounds, it is suitable for interaction with human tissue. It has been shown that removal of this material from the vertebrae once it is solidified, causes no disruption to tissues. The material is removed without any parts left on the vertebrae.

ACKNOWLEDGMENTS

The authors thank the University of Iowa CARVER Scientific Research award committee for funding this research. The authors thank the Lutheran Hospital in Des Moines, Iowa, for granting the use of the CT scanning machine. The authors also acknowledge NASA Goddard space center for granting of a robotic arm to continue conducting this research.

REFERENCES

- 1 **Bray, T.J., Templeman, D.C.**, Principles of screw fixation *Operative Orthopaedics*, 2nd Edition, J.B. Lippincott Co. Philadelphia, 1993.
- 2 **Lyons, W.F., Cochran, J.R., Smith, L.**, Actual holding power of screws in bone. *Annals of Surgery*, 114(3):376-384, 1941.
- 3 **Goel, V.K.**, *Biomechanics of the spine: Clinical and Surgical Prospective*, CRC Press, Boca Raton, FL (1990).
- 4 Spinal Fusion: The Use of Bone Screws in the Vertebral Pedicles, *Spine*, Vol. 19, No. 20S.
- 5 **George, D C., Krag, M., Johnson, C.C., et.al.**, Hole preparation techniques for transpedicle Screws: effect on pull-out strength from human cadaveric vertebrae. *Spine*, 16:181-4, 1991.
- 6 **Moran, J.M., Berg, W.S., Berry, J.L., et.al.**, Transpedicular screw fixation. *JOR*, 7:10714, 1989.
- 7 **Bernard, T.N., Seibert, C.E.**, Pedicle diameter determined by computed tomography: Its relevance to pedicle screw fixation in the lumbar spine." *Spine*, (17), 6:S160-3, 1992.
- 8 **Krag, M.H., Beynnon, B.D., Pope, M.H., et.al.**, "An internal fixator for posterior application to short segments of thoracic, lumbar, or lumbosacral spine. Design and testing. *CORR*, 203:75-98, 1986.
- 9 **Krag, M.H., Weaver, D.L., Beynnon, B.D., et.al.**, Morphometry of the thoracic and lumbar spine related to transpedicular screw placement for surgical spinal fixation. *Spine*, 13(1):2732, 1988.
- 10 **Marchesi, D., Schneider, E., Glauser, P., et.al.**, Morphometric analysis of the thoracolumbar and lumbar pedicles, anatomical-radiologic study. *Surg. Radiol. Anat.*, 10:317-322, 1988.
- 11 **Misenhimer, G.R., Peek, R.D., Wiltse, L.L., et.al.**, Anatomic analysis of pedicle cortical and cancellous diameter as related to screw size. *Spine*, 14:367-72, 1989.
- 12 **Sailant, G.**, Etude anatomique des pedicules vertebraux, applications chirurgicales. *Rev. Chir. Orthop. Traumatol*, 62:151-7, 1976.
- 13 **Zindrick, M., Wiltse, L., Dornick, A., et. al.**, Analysis of the morphometric characteristics of the thoracic and lumbar pedicles. *Spine*, 12:160-6, 1987.
- 14 **Roy-Camille, R., Saillant, G., Mazel, C.**, Internal fixation of the lumbar spine with pedicle screw plating. *CORR*, 203:7-17, 1986.
- 15 **Magerl, F.P.**, Stabilization of the lower thoracic and lumbar spine with external skeletal fixation. *CORR*, 189:125-41, 1984.
- 16 **Weinstein, J.N., Spratt, K.F., Spengler, D., et.al.**, Spinal pedicle fixation: reliability and validity of roentgenogram-based assessment and surgical factors on successful screw placement. *Spine*, 13(9) :1012-1018.
- 17 **Krag, M.H., Van Hal, M.E., Beynnon, B.D., et.al.**, "Placement of transpedicular vertebral screws close to anterior vertebral cortex. *Spine*, 14:879-83, 1989.
- 18 **Whitecloud, T.S., Skalley, T.C., Cook, S.D., et.al.**, Roentgenographic measurement of pedicle screw penetration. *CORR*, 245:57-68, 1989.
- 19 **Nolte, L.P., Zamorano, L.J., Jiang, A. et.al.**, "Image-guided insertion of transpedicular screws. *Spine*, 20(4):497-500, 1995.

- 20 Gertzbein, S.D., Robbins, S.E., Accuracy of pedicle screw placement in vivo. *Spine*,15(1):114, 1990.
- 21 McGowan, D.P., Ruffin, G., Stanistic, M., et.al., Percutaneous placement of pins for external spine fixation—a laboratory assessment *Proceedings of the International Society for the Study of the Lumbar Spine*, 1991.
- 22 Okuyama, K.O., Sato, K., Abe, E., et.al., Stability of transpedicle screwing for the osteoporotic spine: An in vitro study of the mechanical stability. *Spine*, 18(15):2240-5, 1993.
- 23 Lim,T.H., An, H.S., Evanich,C., et.al., “Strength of anterior vertebral screw fixation in relationship to bone mineral density. *J. of Spinal Disorders*, 8(2):121-5, 1995.
- 24 Carter, D.R., Hayes, W.C., Bone compressive strength: the influence of density and strain rate. *Science*, 194:1174-6, 1976.
- 25 Carter, D.R., Hayes,W.C., The compressive behavior of bone as a two-phase porous structure. *JBJS*, 59A:954-62, 1977.
- 26 Coe, J.D., Warden, K.E., Herzig, M.A., et.al., Influence of bone mineral density on the fixation of thoracolumbar implants. *Spine*,15(9):902-907.
- 27 McGowan, D.P., Hipp, J.A., Takeuchi, T., et.al., Strength reductions from trabecular destruction within thoracic vertebrae. *Journal of Spinal Disorders*, 6(2)130-6, 1993.
- 28 Mosekilde, L., Mosekilde, L., Normal vertebral body size and compressive strength: relations to age and to vertebral and lliac trabecular bone compressive strength. *Bone*, 7:207-12, 1986.
- 29 Ruland, C.M., McAffee, P.C., Warden, K.E., et.al., Triangulation of pedicular instrumentation: a biomechanical analysis. *Spine*,16(6):S270-6, 1991.
- 30 Sell, P., Collins, M., Dove, J, Pedicle screws: axial pullout strength in the lumbar spine. *Spine*,13:1075-6, 1988.,
- 31 Soshi,S., Shiba,R., Kondo,H., et.al., An experimental study on transpedicular screw fixation in relation to osteoporosis of the lumbar spine. *Spine*,16(11):1335-41,1991.
- 32 Wittenberg, R.H., Shea, M., Swartz, D.E., et.al., Importance of bone mineral density in instrumented spine fusions. *Spine*,16(6):647-52,1991.
- 33 Zindrick,M.R., Wiltse,L.L., Widell,E.H., et. al., A biomechanical study of intrapeduncular screw fixation in the lumbosacral spine. *CORR*, 203:99-112, 1986.
- 34 Lang, S.M., Moyle,D.D., Berg,E.W., et.al. Correlation of mechnaical properties of vertebral trabecular bone with EMD as measured by computed tomography. *JBJS*, 70A:1531-8, 1988.
- 35 McBroom, R.J., Hayes, W.C., Edwards, W.T., et.al., Prediction of vertebral bony compressive fracture using quantitative computed tomography. *JBJS*, 67A:1206-14, 1985.
- 36 Silva, M.J., Hipp, J.A., McGowan, D.P., et.al., Strength reductions of thoracic vertebrae in the presence of transcortical osseous defects: effects of defect location, pedicle disruption, and defect size. *European Spine Joournal*, 2:118-25, 1993.
- 37 Weaver, J.K., Chalmers, J., Cancellous bone: its strength and changes with aging and an evaluation of some methods for measuring it mineral content. *JBJS*, 48:289-98, 1966.

- 38 **Kassler, M.**, Robotics for health care: a review of the literature. *Robotica*, v.11, 6:495-516, 1993.
- 39 **Priesing, B., Hsia, T.C., and Mittelstadt, B.**, A literature review: robots in medicine. *IEEE Engineering in Medicine and Biol.*, June 1991, pp. 13-22
- 40 **Lavallee, S., and Cinquin, P.**, Image guided operating robot. *Fifth International Conference on Advanced Robotics*, Pisa, Italy, 1991
- 41 **Benabid et al.**, Computer-driven robot for stereotactic surgery connected to CT scan and magnetic resonance imaging: technological design and preliminary results." *Applied Neurophysiology* (50), Nos. 1 -6, 153-154, 1987.
- 42 **Cinquin, P., Lavallee, S., and Troccaz, J.**, IGOR: Image Guided Operating Robot, methodology, applications. *Proceedings of IEEE Engineering in Medicine and Biology 14 Annual Conference*, (3), 1992.
- 43 **Kwoh, Y.S., Hou, J., Jonckheere, E.A., and Hayaty, S.**, "A robot with improved absolute positioning accuracy for CT guided stereotactic brain surgery. *IEEE Trans. on Biomedical Engineering*, vol. 35, No.2, pp. 153-160, 1988.
- 44 **Young et al.**, Application of robotics to stereotactic neurosurgery. *Neurological Research* 9, No.2, pp.123-128, 1987;.
- 45 **Glauser, D., Flury, P., and Burkhardt, C.**, Mechanical concept of the neurosurgical robot 'Minerva'." *Robotica*, vol.11, no.6, pp.567-575, 1993.
- 46 **Flury, P., et al.** Minerva, a robot dedicated to neurosurgery operations. *Proceedings of the 23rd Int. Symposium on Industrial Robots*, Barcelona, pp. 729-733, 1992.
- 47 **Mittelstadt, B., Paul, H., Kazanzides, P., et al.**, Development of a surgical robot for cementless total hip replacement, *Robotica*, vol 11, 1993, 6:553-560.
- 48 **Mittelstadt, B.D., Kazanzides, P., Zuhars, J., et al.**, The evolution of a surgical robot from prototype to human clinical use, *Proc. of the First Int. Symposium on Medical Robotics and Computer Assisted Surgery*, 1994, Pittsburg, PA.
- 49 **Taylor, R., Paul, H., Mittelstadt, B., et al.**, An image-based robotic system for hip replacement surgery, *Journal of the Robotics Society of Japan*, 1990, pp. 111-116.
- 50 **Hanson, W.A., Taylor, R.H., Paul, H.A., and Williamson, W.** ORTHODOC--an image driven orthopaedic surgical planning system, *Proc. 12th IEEE Medicine and Biology Conf.*, 1990, Philadelphia, PA.
- 51 **Kazanzides, P., and Zuhars, J., Mittelstadt, B.D., Taylor, R.H.**, Force sensing and control for a surgical robot, *Proc. IEEE Conf. on Robotics and Automation*, 1992, Nice, France.
- 52 **Cain, P., Kazanzides, P., Zuhars, J., Mittelstadt, B.D., Paul, H.A.**, Safety considerations in a surgical robot, *Biomedical Sciences Instrumentation: Proc. of the 30th Annual Rocky Mountain Bioengineering Symp.*, 1993, San Antonio, TX.
- 53 **Bargar, W.L., Taylor, J.K., Leathers, M., and Carbone, E.**, Report of human pilot study: 3-D imaging and robotics for cementless total hip replacement, *Proceedings of the First International Symposium on Medical Robotics and Computer Assisted Surgery*, 1994, Pittsburg, PA.
- 54 **Bargar, W.L., Taylor, J.K., Leathers, M., and Carbone, E.J.**, Preoperative planning and surgical technique for cementless femoral components using 3-D imaging and robotics: reports of human pilot study," *Proc. American Academy of Orthopaedic Surgeons Annual Meeting*, 1994, New Orleans, LA.

- 55 **Taylor, R.H., Mittelstadt, B.D., Paul, H.A., et al.,** An image directed robotic system for precise orthopaedic surgery, 1994, *Computer Integrated Medicine*, MIT Press, Boston, MA.
- 56 **Wright, J.,** Mission accomplished: robotics for safer surgery, *NASA Tech Briefs*, vol.18, No.1, 1994.
- 57 **Davies, B.L., Hibberd, R.D.,** Coptcoat, M.J., and Wickham, J., A surgeon robot prostatectomy - a laboratory evaluation. *Journal of Medical Engineering and Technology*, (13), No.5, 1991.
- 58 **Finlay, P.A.,** The development of advanced medical robotics. *Proceedings of the 215th International Symposium on Industrial Robots*, Copenhagen, Germany, 1990.
- 59 **Ng, W.S., Davies, B.L., Hibberd, R.D., and Timoney, A.G.,** Robotic surgery: a first-hand experience in transurethral resection of the prostate, *IEEE Engineering in Medicine and Biol.*, 1993, Vol. 12, No. 1, pp. 120-125.
- 60 **Matsen, F.A., Garbini, J.L., Sidles, J.A., et al.,** Robotic assistance in orthopaedics: a proof of principle using distal femoral arthroplasty, *Clin. Orthop. Related Res.*, 1993, No. 296, pp. 178-186.
- 61 **Pieper, D.L.,** The kinematics of manipulators under computer control. Stanford Artificial Intelligence Laboratory, Stanford University, AIM 72, 1968.
- 62 **Paul, R.P.,** *Robot Manipulators: Mathematics, Programming, and Control*. MIT Press, Cambridge, Massachusetts, 1979.
- 63 **Kohli, D., and Soni, A.H.,** Kinematic analysis of spatial mechanisms via successive screw displacements. *J. Engr. for Industry Trans. ASME*, (2 B.) pp. 739-747, 1975.
- 64 **Denavit, J., and Hartenberg, R.S.,** A kinematic notation for lower-pair mechanisms based on matrices. *Journal of Applied Mechanics*, ASME, (22), pp. 215-221, 1955.
- 65 **Yang, A.T., and Freudenstein, R.,** Application of dual; number quaternion algebra to the analysis of spatial mechanisms, *Trans. ASME, J. Appl. Mech.*, vol. 31, series E, pp. 152157, 1 964.
- 66 **Uicker, J.J. Jr., Denavit, J. and Hartenberg, R.S.,** An iterative method for the displacement analysis of spatial mechanisms. *Trans. ASME, J. Appl. Mech.*, vol. 31, Series E.pp. 309314,1964.
- 67 **Lee, C.S.G. and Ziegler, M.,** UA geometric approach in solving the inverse kinematics of PUMA. *IEEE Trans. Aerospace and Electronic Systems*, vol. AES-20, no. 6, pp.695-706, 1984.
- 68 **Pohl, ED, and Lipkin, H.** Complex robotic inverse kinematic solutions. *J. of Mechanical Design*, 115:509-514,1993.
- 69 **Raghavan, M., and Roth, B.,** Inverse kinematics of the general 6R manipulator and related linkages. *Transactions of the ASME*, 115:502-508, 1993.
- 70 **Fadda, M., Martelli, S., Dario, P., Marcacci, M., Zaffagnini, S., and Visani, A.,** First steps towards robot-assisted discectomy and arthroplasty, *Innov. Tech. Bio. Med.*, Vol. 13, No. 4, 1992.
- 71 **Ault, T., and Siegel, M.W.,** Frameless patient registration using ultrasonic imaging, *Proceedings of the First International Symposium on Medical Robotics and Computer Assisted Surgery*, 1994, Pittsburg, PA.

- 72 Grimson, E., Lozano-Perez, T., Wells, W., et al.,** Automated registration for enhanced reality visualization in surgery, *Proc. of the First Int. Symposium on Medical Robotics and Computer Assisted Surgery*, 1994, Pittsburg, PA.
- 73 Simon, D., Hebert, M., and Kanade, T.,** Techniques for fast and accurate intra-surgical registration, *Proceedings of the First International Symposium on Medical Robotics and Computer Assisted Surgery*, 1994, Pittsburg, PA.
- 74 Lea, J., Watkins, D., Mills, A., et al.,** Immobilization and registration for robot-assisted discectomy and arthroplasty, *Proceedings of the 1st Int. Symp. on Medical Robotics and Computer Assisted Surgery*, Sept. 22-24, 1994.
- 75 Lea, J.T., Mills, A., Watkins, D., et al.,** Registration and immobilization for robot-assisted orthopaedic surgery, *Proceedings of the First International Symposium on Medical Robotics and Computer Assisted Surgery*, 1994, Pittsburg, PA.
- 76 Bouazza-Marouf, K., Browbank, I., and Hewit, J.R.,** Robotics-assisted internal fixation of femoral fractures, *IMechE Journal of Engineering in Medicine*, 1995, Vol. 209, No. H1, pp. 51-58.
- 77 DiGioia, A.M., Jaramaz, B., and O'Toole, R.V.,** An integrated approach to medical robotics and computer assisted surgery in orthopaedics, *Proceedings of the First International Symposium on Medical Robotics and Computer Assisted Surgery*, 1994, Pittsburg, PA.
- 78 Abdel-Malek, K.,** "The TR-Graphical Interface Robotics Control Environment." US Copyright ©1992, registration number TXU-561 981, 1992.
- 79 Abdel-Malek, K.,** *Off-Line Programming Using Commercial CAD Systems, and Design Criteria for Manipulators with Inherent Accuracy*, PhD Dissertation, Department of Mechanical Engineering, University of Pennsylvania, Philadelphia, PA., 1993.
- 80** AutoDesk Corporation, AutoCAD reference manual.
- 81 Fu, K.S., Gonzalez, R.C., and Lee, C.S.,** *Robotics: Control Sensing, Vision, and Intelligence*, McGraw-Hill, NY., 1987
- 82 Amiot, L.P., Labelle, H., DeGuise, J.A., Sati, M., Brodeur, P., and Rivard, C.H.,** "Computer-Assisted Pedicle Screw Insertion", *Spine*, Vol. 200, No. 10, pp. 1208-1212, 1995.

CAPTIONS TO ILLUSTRATIONS

- Fig. 1** Registration fixture and end-of-arm tooling
- Fig. 2** Operational setup
- Fig. 3** Registering the fixture coordinate system
- Fig. 4** Digitized cross-sections of vertebral bodies
- Fig. 5** Contour lines of the partial mold
- Fig. 6** Two snap shots of the meshing procedure
- Fig. 7** A snap shot from the computer screen (indicating trajectories)
- Fig. 8** Menus in the CAD system
- Fig. 9** Simulations of a robotic arm

ILLUSTRATIONS

Mold

Tooling

Fixture

Fig. 1

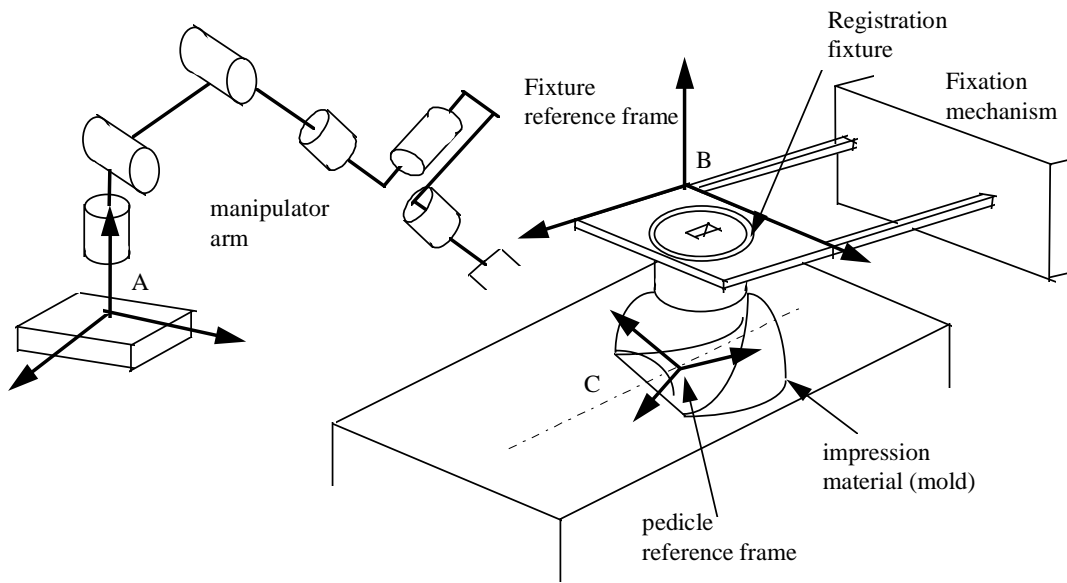


Fig. 2

Fixture

Robot

Mold

Spine

Fig. 3

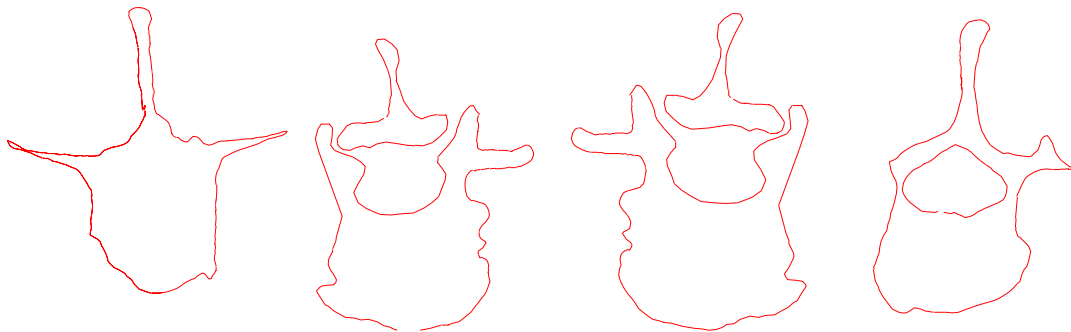


Fig. 4

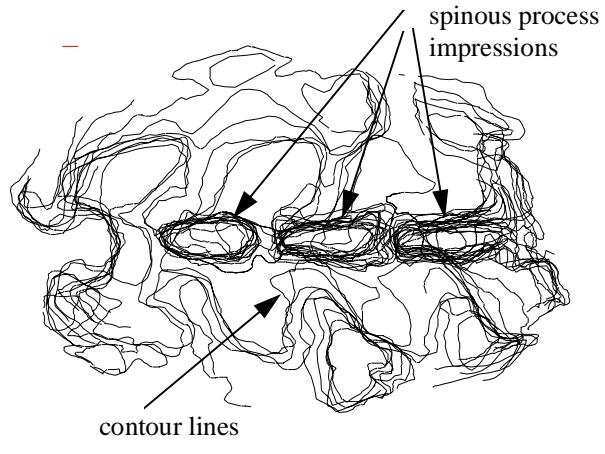


Fig. 5

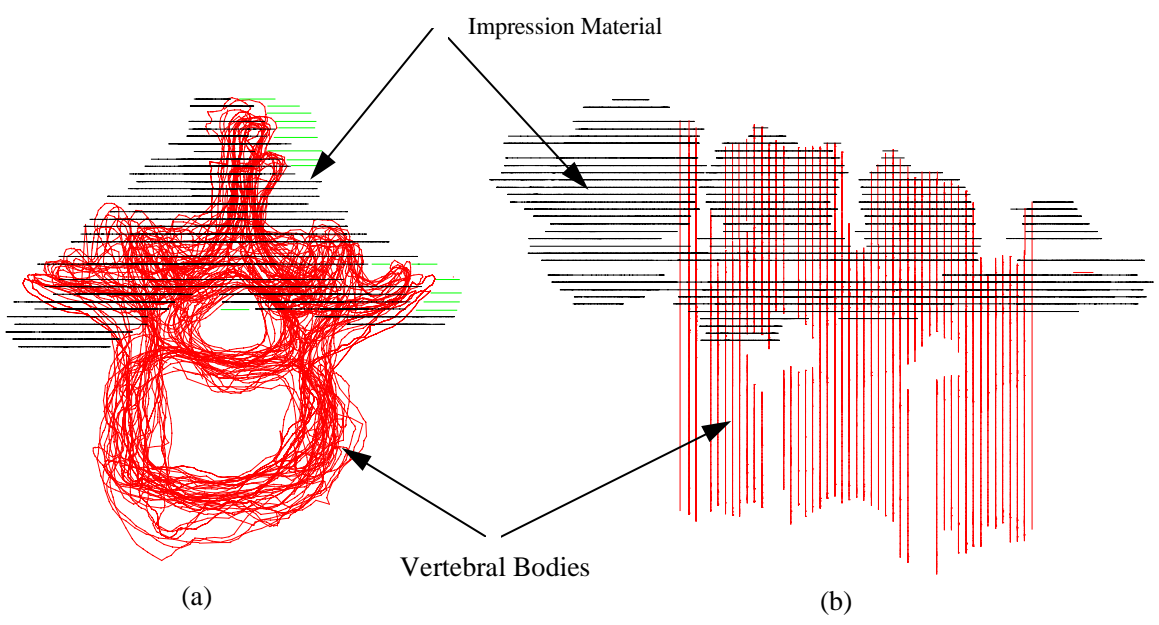


Fig. 6