

Education and Research on Sound-Guided 3D CAS Navigation System for Problem Based Learning and Assessment

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ABSTRACT: *Computer assisted surgery (CAS) becomes crucial issue to improve the surgical quality, accuracy and efficiency. Based on the increasing clinical applications of the CAS, the universities need to educate students to have capability in developing the CAS systems. However, the development of the CAS system needs to learn multi-disciplinary knowledge and skills such as computer software, mechanics, robotics, electronics, etc. In addition, the CAS applications are widely varying, such as neurosurgery, orthopaedic, craniofacial reconstruction, and so on. Different CAS applications require different surgical protocol. Therefore, it is difficult to train the students to develop the CAS system in a regular course in university. In this paper, we propose a problem based learning and assessment (PBLA) hands-on practice course for the CAS system. We also present the example of sound-guided 3D CAS navigation system for the tibial intramedullary interlocking nail distal locking screws fixations. Since the effective CAS system requires firm connections between the surgeons and engineers, the proposed PBLA describes not only the educations within the integrations and developments of the computer software, mechanics, robotics, and electronics topics, but also the architectural CAS formulation during the system design stage. Especially, how to transform the clinical and surgical problem to the engineering problems is the most important issue to educate the interested students. In summary, this paper is organized following the PBLA hands-on practice course. Initially, the CAS design concepts and strategies are introduced, and then the CAS system requirement definitions are proposed based on the engineering transformations between the surgeons and engineers. Subsequently, the theorems and technologies within the proposed CAS problem such as computer software, mechanics, robotics, and electronics are presented. And then, the experiment designs for hands-on practice are illustrated. At the end of the course, the experimental evaluation of a CAS system is also included. Based on the proposed PBLA, the students attending this course learn the design concepts, strategies, techniques, and evaluations of the CAS system. Finally, the learning effects are also promoted and discussed in this paper.*

1 INTRODUCTION

The problem-based learning (PBL) [Mayo 1993; Aspy 1993] is a new teaching methodology, and it changes the traditional teaching formula. The PBL is a student-centered and faculty-facilitated teaching methodology for teaching and learning real world problems. Basically, the PBL is capable of teaching and training the students to learn the content knowledge and problem-solving skills in terms of posing the significant, contextualized, real world situations, and providing resources, guidance, and instruction. The PBL teaching is unlike the traditional instruction, the students brainstorm and collaborate to study and discuss the specific problem to stimulate the creativity and to learn the problem in more detail in a group. Therefore, the PBL strategy is to train the students having abilities to think critically, analyze problems, find and use appropriate learning resources.

In this paper, the education and research on sound-guided 3D CAS navigation system for problem based learning and assessment (PBLA) is proposed. Due to the development of the CAS system needs to learn multi-disciplinary knowledge and skills such as computer software, mechanics, robotics, electronics,

etc., improving the efficiencies of think and learn of students becomes the most important issue of this work. In this paper, the PBLA teaching methodology is used to help the students to improve the efficiencies of think and learn.

The proposed course, named “medical mechatronics” is designed for the students in the Graduate Institute of Medical Mechatronics. The backgrounds of the students in the Graduate Institute of Medical Mechatronics, Chang Gung University, widely vary from the mechanical engineering, electrical engineering, medical technology, medicine, etc. The students who take the hands-on “medical mechatronics” course are grouped in the combinations of distinct backgrounds. Typically, the students who graduated from mechanical engineering, electrical engineering, medical technology, and medicine are suggested to arrange in a group. Such a cooperative working group is advantageous for the students to seek solutions to real clinical medical mechatronics problems.

In addition to the specialized grouping mechanism, the hands-on course topics are formalized as a series of medical mechatronics system development problems. Each engineering problem is fitted into a clinical case study. In this paper, an example for teaching the student to solve the clinical case of the tibial intramedullary interlocking nail distal locking screws fixations is introduced. The learning problems are divided into the learning of using 3D digitizer arm, developing the 3D coordinate registration / transformation module and designing the sound-guided navigation module.

The 3D digitizer is a 5 DOF passive robotic arm, and it is used to measure the coordinates of proximal landmarks (three positions on the handle) during operation. The measured coordinates are compared with coordinates of the proximal and distal landmarks (three positions on a registration rod perpendicular to the axis of distal screw holes), which are registered just before placement of the nail into the bone to calculate transformation matrix and these data are subsequently computed for real-time navigation. In addition, the sound-guided navigation module was designed with an audio guiding mechanism through the sound with different tones and intermittence frequencies, as the probe of the digitizer navigates toward the location of distal screw holes. Finally, we provide the physical system to promote the students for practical hands-on exercise based on the tibial intramedullary interlocking nail distal locking screws fixations with cadaveric donor bones. The students can realize the physical meanings and procedures of developing the sound-guided 3D CAS navigation system based on specially designed hands-on courses and the group discussion and brainstorming of the PBAL.

2 CAS SYSTEM REQUIREMENT DEFINITIONS

In order to identify the system requirement definitions of the proposed CAS course, the example of developing the clinical case of the tibial intramedullary interlocking nail distal locking screws fixations is introduced. Initially, this course introduces the traditional tibial intramedullary interlocking nail distal locking screws fixations surgery. In this portion, we invite the skilled surgeons to describe the traditional surgical procedures. The standard treatment for the adult simple tibial shaft fracture is internal fixation with an intramedullary interlocking nail [Schmidt 2003; Sabboubeh 2003] in terms of inserting a metal rod into the medullary canal of the fractured bone, for the purpose of obtaining a good alignment and stability (Figure 1A). [Chen 1996; Selvakumar 2001]. The components of an interlocking nail consist of a cylindrical rod in various diameter and length with two retaining holes on each end for the fixation of locking screws, to prevent rotation of the fractured bone [Roberts 2002; Gorczyca 2002]. For the proximal locking screws, there are guiding tunnels located on the handle with high accuracy to assist the localization procedure (Figure 1B). Unfortunately, once the nail is inserted within the bone, the location of the distal screw hole becomes invisible, and there is no proper guiding tool for such procedure. Currently, to identify the location of the distal screws, most of the solutions are through “trial-and-error”, which may take some length of time [Gugala 2001]; on the other hand, the surgeon can decide to use a mobile X-ray machine, so called “C-arm” to accomplish this task. The surgery using the C-arm is shown in Figure 2. However, the “C-arm” results in the high exposure of radiation hazard for the patient and surgeons [Coetzee 1992; Sanders 1993]; therefore, the clinical problem is to develop a real-time navigation system that is precise and user friendly in the process of localizing the position of screw holes.

Based on the descriptions of the traditional surgeries, we can conclude that the traditional surgery has the following disadvantages:

1. The traditional surgery is time consuming.

2. The traditional surgery is not precise.
3. The traditional surgery makes the surgeons and doctors to be in high and frequent X-ray radiation environment.
4. Due to the traditional surgery is operated based on the trial-and-error method, it increases the number of lacerations during the surgery.
5. The quality of traditional surgery depends on the experience of the surgeon.

Therefore, the CAS system can be formulated as a series of engineering problems to improve the surgical quality. In this course, the problems are formulated as six major categories, and they are shown in Figure 3. These major categories form the newly designed computer-based surgical protocol, and they are further classified into the “before-nail-insertion” and “after-nail-insertion” stages.

3 CAS DESIGN CONCEPTS AND STRATEGIES

The design concepts of the proposed hands-on course follow the PBLA teaching strategy, and they are categorized into the learning of using 3D digitizer arm, developing the 3D coordinate registration / transformation module and designing the sound-guided navigation module. The proposed navigation system is developed based on the concept of medical mechatronics system integration. Figure 4 shows the architecture of the system operation of the sound-guided 3D navigation system, which is composed of the mechanical device, software component, and audio guidance device. The main design concept of this system is to use an audio guiding mechanism to help the surgeon to identify the exact position of the distal screw holes. Before insertion of the nail into the bone, registrations are done by any three chosen positions on the handle, and another three positions on the axis of the distal locking screw, indicated by a registration rod placed at the screw hole perpendicular to the nail, as shown in Figure 5. In this manner, the system design strategies can be defined as follows:

1. Realize the traditional surgical procedures by investigating the surgery videos, visiting the real operations, and discussing with the surgeons.
2. Define the missions, goals and desired targets to improve the performance of traditional methods.
3. Divide the surgical problem into the several segmental sub-problems in terms of the domain knowledge such as mechanical engineering, electrical engineering, medical technology, medicine, etc.
4. Transform the clinical problems to the engineering problems.
5. Integrate the proposed components and modules within the medical mechatronics.
6. Evaluate the proposed system based on the engineering specifications.
7. Evaluate the proposed system based on the clinical specifications.

4 THEOREMS AND TECHNOLOGIES WITHIN THE CAS

In this section, the theorems and technologies within the developing the CAS system are illustrated following the previously described design concepts, strategies, and system requirement definitions.

4.1 Hardware Component Designs

The proposed navigation hardware components consist of a 3D digitizer, a control foot paddle, and a notebook computer run by Windows 98® or higher version. The model of digitizer to be used is MicroScribe® from the Immersion Corporate, consisting of 5 optical rotatory sensors, and angular measurements, with an accuracy of 0.05mm. It can be communicated with a personal computer through the RS-232 serial port. The tip of the probe is of cone shape, and the arm span is 25 inches. The model is complemented with a double foot paddle that functions as foot buttons for data recording.

Additional modifications need to be done. A registration metal rod is designed, bearing the diameter of the screw hole. It has multiple conical holes, with the tips oriented in a straight line passing through the center of the axis. An autoclavable adaptor for the probe tip is mandatory since the system is to be performed aseptically. The original adaptor has a cone shaped tip on one end, and a threaded bud on the opposite end be screwed to the arm of digitizer. Since the apparatus is to be covered entirely with a sterile plastic cover, the design may easily cause contamination of the operation field. Therefore, a tip is designed to have the exact length as the original one, so that the given position will not be distorted. It can also be easily placed onto the end effector of the digitizer in a sterile environment, and difficult for the plastic cover to slip off once in use, by adding a disc at the bud end, shown in Figure 6.

4.2 Landmark Coordinates Transformation

Based on the newly designed surgical protocol, the landmark coordinates transformation is the key theorems of the proposed course. In this portion, the transformation matrix of the robotics course can be applied here. In the before-nail-insertion stage, registrations are done by any chosen three positions on the proximal handle of nail, and another three positions on the axis of the distal locking screw, determined by a registration rod placed at the screw hole perpendicular to the nail. The “registration landmarks” are defined as the points on the nail that must be clearly and easily identified. Special precaution needs to be taken is that these landmarks have to be non-collinear, in order to define a unique plane, hence the coordinate transformation matrix can be calculated. The transformed coordinates of the axis of the distal locking screw can be further calculated from the transformation matrix and the axis of the distal guiding rod measured prior to nail insertion. Figure 7 shows the details of the coordinate transformation relationships.

In the after-nail-insertion stage, the surgeon acquires the coordinates of the registration landmarks on the proximal handle of nail using the 3D digitizer. The 3D digitizer arm is a five-degree-of-freedom passive robotic arm with a resolution of 10^{-3} inch. The coordinates of the end point can be calculated using the forward kinematics. In this study, a windows-based software application program is developed for the system to guide the surgeons to reach the registered landmarks using the Microsoft® Visual C++®. The software application program is designed to enable the communication of 3D digitizer arm, to calculate the coordination transformation matrix, and to guide the arm to the position of distal locking screw hole. In addition, a speaker is incorporated with this system to provide audio guidance during navigation. Different audio sounds are designed to inform the surgeon, while the frequency of beeps increases as the distance between the tip of probe and target decreases.

In this course problem, specific landmarks are chosen to identify the 3D coordinates of the registration and implant locations in the before-/ after-nail-insertion stages. The coordinate transformation matrix can be described as following: the objective is to determine N4, N5, and N6 as shown in Figure 7, based on the given M1, M2, M3, M4, M5, M6, N1, N2, and N3. The formula can be referred to [Kuo 2003], and it is not derived here. Finally, the mathematical calculation of the coordinates is accomplished by matrix transformation. In the initial registration, three proximal reference points are recorded as M1, M2 and M3, and the distal three points recorded from the guiding rod are registered as M4, M5 and M6. After insertion of the nail into the intramedullary canal of the bone, the three proximal reference points re-registered are identified as N1, N2, and N3, and the three imaginary coordinates on the axis of locking screw, N4, N5 and N6 are calculated immediately. However, in order to make navigation easier along the axis of the guiding rod, additional 9 points (N7~N15) on the axis are also derived by the linear interpolation method, as shown in Figure 8.

4.3 Software Interface Structure and Program Design

The proposed software system is a windows-based application program. The modules of application program have been developed using the Microsoft® Visual C++®. The software modules include the 3D digitizer communication, data acquisition, pre-registered landmark loading, coordinate transformations, error calculation, and sound-guided navigation. The navigation application program is shown in Figure 9, where the control icons indicate the operation procedures of this system, which consists of the functions in sequences as connection of the 3D digitizer, enabling of registration, storage of the coordinate data, initiation of a new operation, reloading of the pre-stored data, matrix calculation, start of navigation, stop of navigation, setting of the error range, and finally, calling for online help. Additionally, the coordinates are displayed at the same time on the screen for surgeon’s reference, and the unit of these data is expressed in inch. The error range can be adjusted by the user as to how close the distance will be between the tip of the probe and the target, for the beep to be initiated.

5 EXPERIMENTAL EVALUATION OF A CAS SYSTEM

In this course, the students can practice the proposed system, and they can also validate this system based on the engineering and clinical specifications. Due to the specially designed grouping mechanism of the proposed PBLA, the members of each group can submit their observations and opinions based on their individual background (mechanical engineering, electrical engineering, medical technology, medicine, etc.) and domain knowledge. The hands-on experiment is carried out with a cadaveric donor bone, as shown in Figure 10. Experimental procedures are simulated as in the clinical setting, and the

accuracy as well as feasibility is evaluated. The main goal of this experimentation is to place a stainless steel made cylindrical hollow rod, known as the intramedullary nail into the medullary canal of the long bone, from the proximal end, through the fracture site to the distal fragment, and the locking screws are then applied onto both ends in a perpendicular fashion to the nail itself, from the medial cortex through the holes of the nail to the opposite cortex, in order to obtain a better stability.

The proposed experimentations are integrated based on the surgical protocol, as shown in Figure 11. In order to use the 3D digitizer in the aseptic environment, the original tip of the probe is redesigned, so that the sterile socket can be fixed on the probe tip. The experiment was performed in the operation room with original surgical instrument. The nail was inserted into the medullary canal as in the real surgical procedures. A total of three trials were performed, bearing the accuracy within 1 mm. The photos of the experimentation results are shown in Figure 12. In addition, the experimental results of these trials are summarized as indicated in Table 1. In this table, the actual positions are identified using the 3D digitizer based on the pre-given markers; the computational positions are obtained in terms of the computation of the transformation matrix; and the sound navigated positions are determined using the different tones and intermittence frequencies of the sound. The errors are calculated as the comparisons of the computational positions with the actual positions and the sound navigated positions with the actual positions, respectively.

Table 1 Experimental validations based on three trials

First Trial		X (cm)	Y (cm)	X (cm)	Error (cm)
	Actual Position	-11.68	25.81	0.30	-----
	Computational Position	-11.39	25.18	0.48	0.71
	Sound Navigated Position	-11.24	24.93	0.41	0.99
First Trial		X (cm)	Y (cm)	X (cm)	Error (cm)
	Actual Position	-12.09	14.97	0.84	-----
	Computational Position	-12.04	14.33	1.01	0.66
	Sound Navigated Position	-12.27	14.91	0.95	0.22
First Trial		X (cm)	Y (cm)	X (cm)	Error (cm)
	Actual Position	-12.48	5.88	0.75	-----
	Computational Position	-12.34	5.66	0.80	0.26
	Sound Navigated Position	-12.87	5.42	0.94	0.63

6 CONCLUSIONS

This paper proposes a problem based learning and assessment (PBLA) hands-on practice course for the CAS system of the sound-guided 3D CAS navigation system for the tibial intramedullary interlocking nail distal locking screws fixations. Such a course is challenging to the faculty, since it need to integrate the multi-disciplinary knowledge, backgrounds and skills such as computer software, mechanics, robotics, electronics, etc. in a course. The normal teaching method cannot cover such a course. Based on the specially designed hands-on courses and the group discussion and brainstorming of the proposed PBAL, this course was successfully finished. The students of different backgrounds not only learn the techniques of the medical mechatronics, but also identify their role in developing the medical mechatronics system. Finally, the course design and related research engineering are all described in this paper. In the future, the other surgeries, such as the neurosurgery, orthopaedic, craniofacial reconstruction, and so on., can be included in such courses to train the students to have the capacity for developing the CAS systems.

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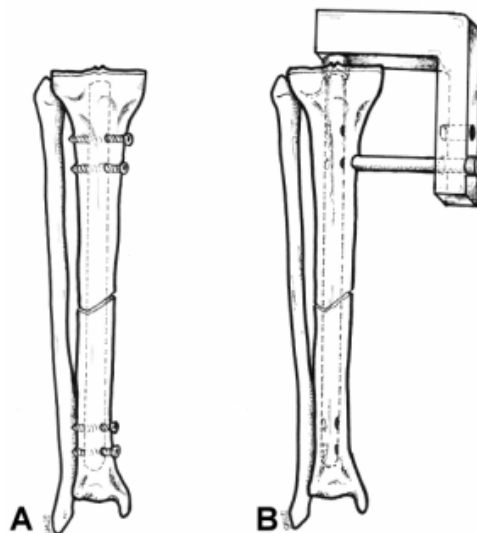


Figure 1. A) Tibial shaft fracture post intramedullary interlocking nail fixation; B) proximal guide on the handle for fixation of proximal locking screws

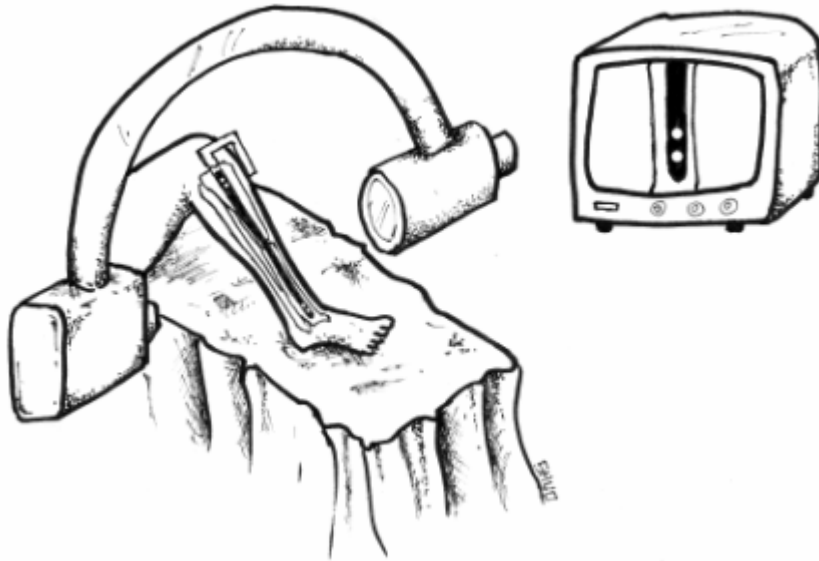


Figure 2. Fluoroscopic assisted localization of the distal screw holes

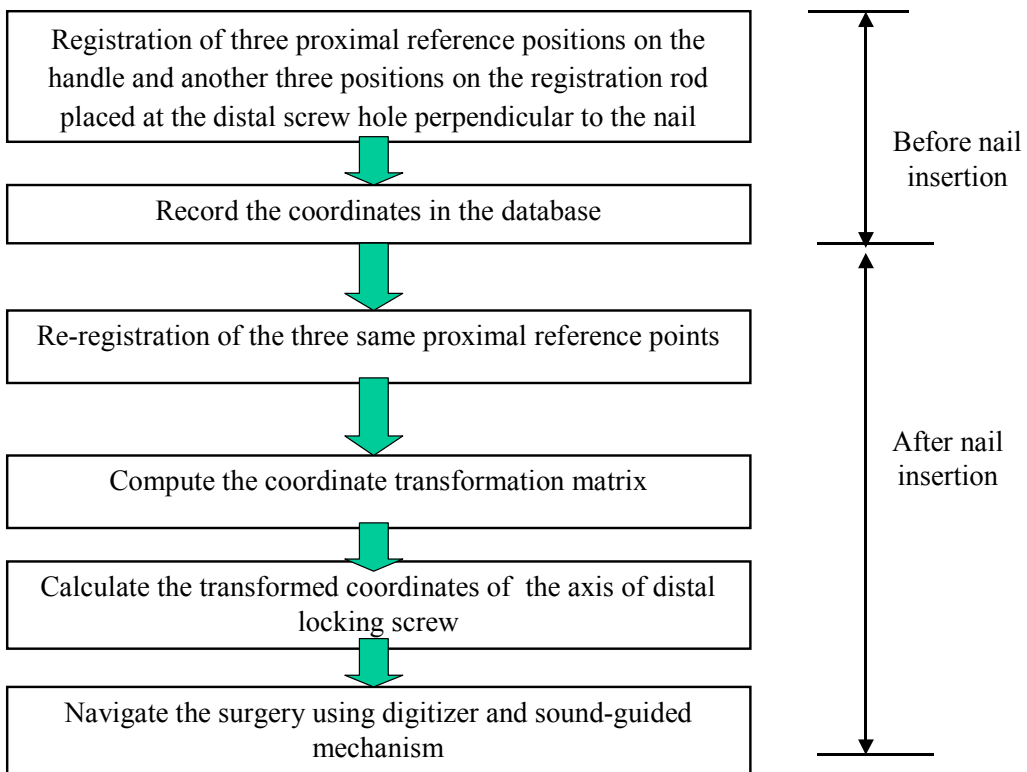


Figure 3. System operation protocol

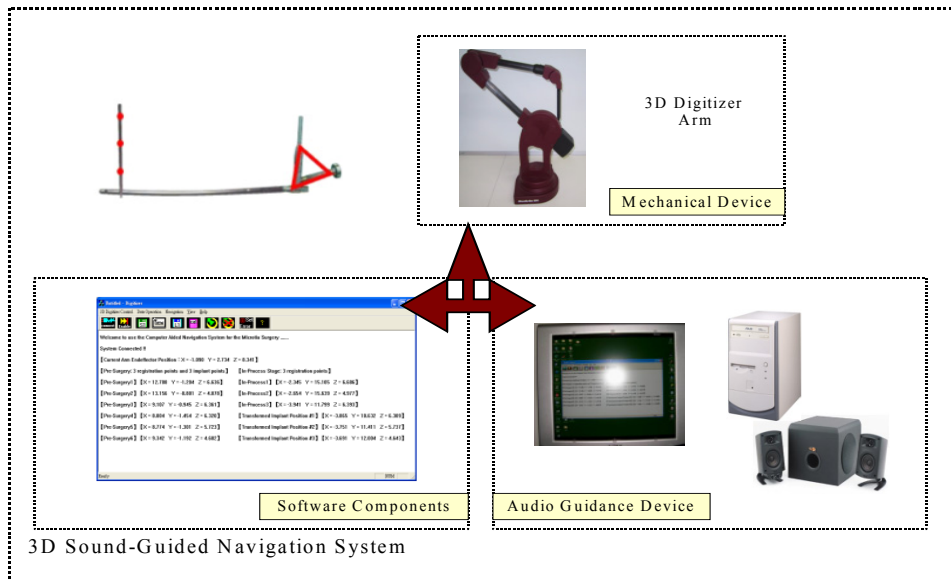


Figure 4. Architecture of system development of the sound-guided 3D navigation system



Figure 5. Registration rod for the axis of screw holes



Figure 6. A) Modified tip on the probe; B) close-up view of the tip

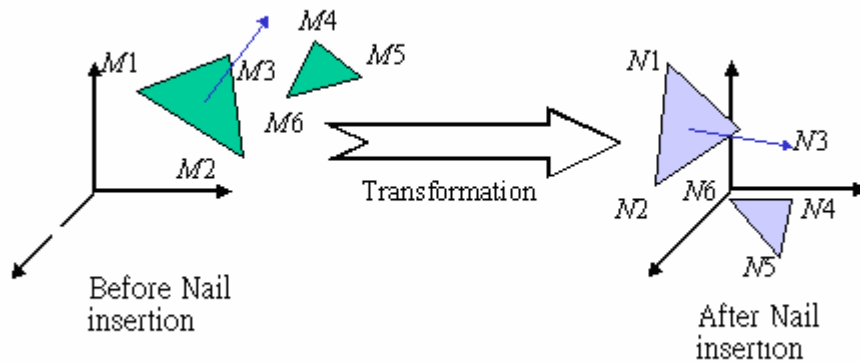


Figure 7. Coordinate transformation relationship



Figure 8. Coordinate transformation markers

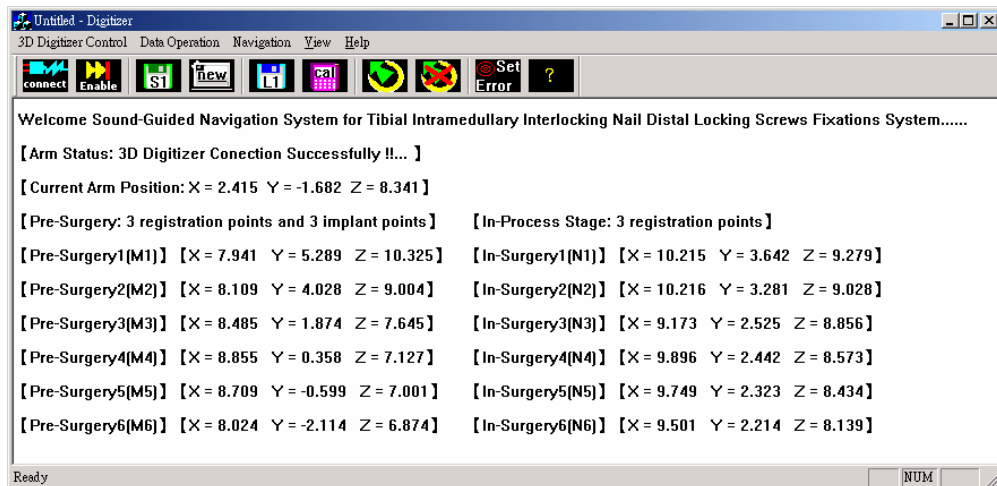


Figure 9. Windows-based user interface of the navigation application program

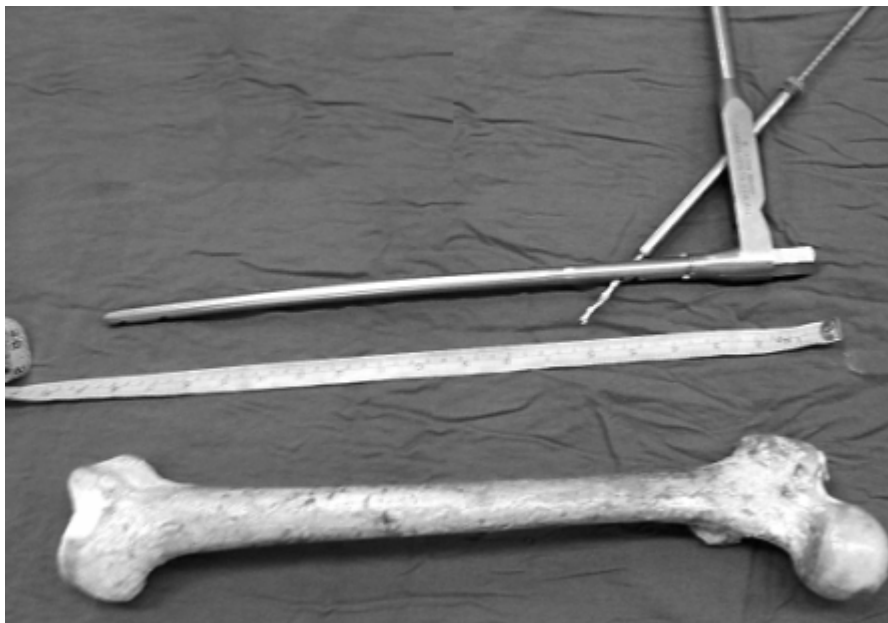


Figure 10. System experimentation using cadaveric donor bone

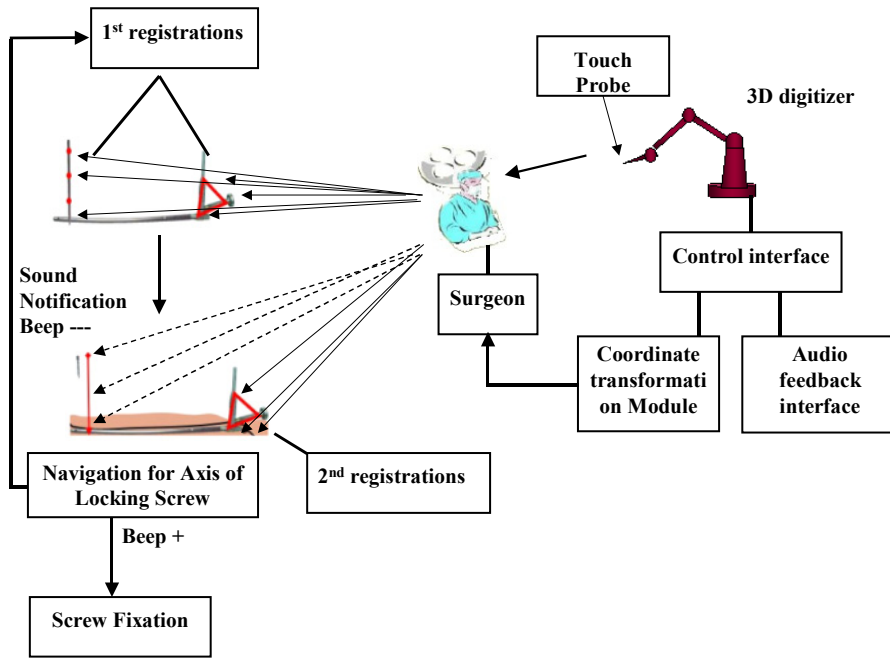


Figure 11. Experimentation procedures of sound-guided navigation system

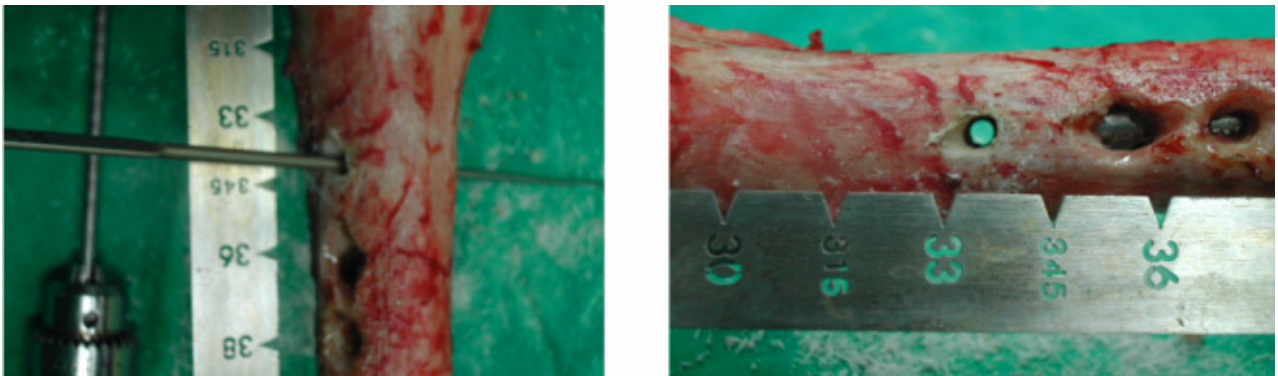


Figure 12. Photos of result during in vitro trial