Development and Validation of a Navigational Guidance System for Acetabular Implant Placement*

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Abstract. During the past year our group has been developing HipNav, a system which helps surgeons determine optimal, patient-specific acetabular implant placement and accurately achieve the desired implant placement during surgery. HipNav includes three components: a pre-operative planner, a range of motion simulator, and an intra-operative tracking and guidance system. The goals of the current HipNav system are to: 1) reduce dislocations following total hip replacement surgery due to acetabular malposition; 2) determine and potentially increase the "safe" range of motion; 3) reduce wear debris resulting from impingement of the implant's femoral neck with the acetabular rim; and 4) track in real-time the position of the pelvis and acetabulum during surgery.

The original implementation of the HipNav system was a proof-of-concept prototype which was useful for demonstrating the efficacy of this technology in-vitro. As the HipNav system progressed towards a clinical implementation, our efforts focussed on several practical development and validation issues. This paper describes our experience transforming HipNav from a proof-of-concept prototype into a robust clinical system, with emphasis on technical development and validation. Despite the highly applied nature of this endeavor, many fundamental research issues exist. The benefits of tightly coupling fundamental research together with applied development in our work are discussed.

Keywords: computer-assisted surgery, total hip replacement, navigational guidance, system validation.

1 Introduction

Each year in the United States, approximately 200,000 primary and 40,000 revision total hip replacement (THR) surgeries are performed. The most common early post-operative complication following THR is dislocation of the femoral implant from the acetabulum, resulting in significant distress to the patient and surgeon, worse clinical outcome, and associated additional treatment costs. The approximate dislocation rate in the first year following primary THR is between 2 and 6 percent [10], and the most common cause of early dislocation is malposition of the acetabular component [11].

The causes of dislocation following total hip replacement are multi-factorial and include not only malposition of the implants causing impingement, but also soft tissue and bone impingement, and soft tissue laxity [11]. Impingement between the neck of a fem-

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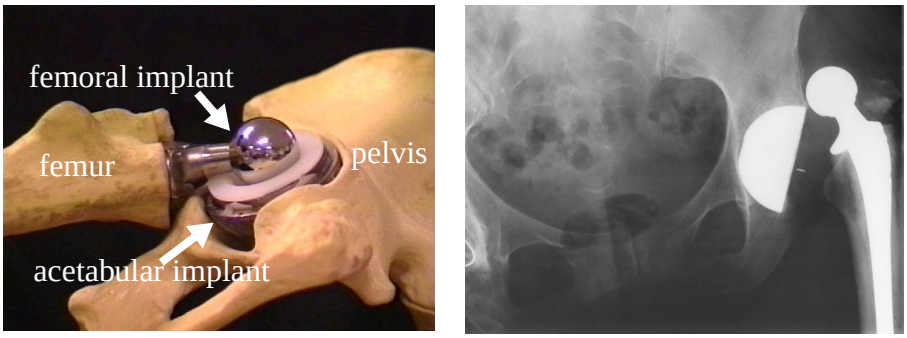

Fig. 1. Femoral and acetabular implants in impingement, and X-Ray of dislocation.

oral implant and the rim of an acetabular implant is shown in Fig. 1. Impingement can lead to advanced wear of the acetabular implant rim resulting in polyethylene wear debris which may accelerate loosening of implant bone interfaces. The position of impingement is determined by implant design and geometry, and more importantly by the placement of the femoral and acetabular implants. In certain cases, impingement may result in dislocation, as seen in the X-ray of Fig. 1.

The HipNav system has been developed to permit accurate placement of the acetabular component during surgery [3]. HipNav includes three components: a pre-operative planner, a range of motion simulator, and an intra-operative tracking and guidance system. The pre-operative planner allows the surgeon to manually specify the position of the acetabular component within the pelvis based upon pre-operative CT images. The range of motion simulator estimates femoral range of motion based upon the implant placement parameters provided by the pre-operative planner. Feedback provided by the simulator can aid the surgeon in determining optimal, patient-specific acetabular implant placement. The intra-operative tracking and guidance system is used to accurately place the implant in the planned optimal position regardless of the position of the patient on the operating room table.

By accurately placing the acetabular component in an optimally selected position, the HipNav system has the potential to reduce the risk of dislocations, reduce the generation of wear debris caused by impingement resulting from malpositioned components, and increase the “safe” range of motion. This paper focuses on the transition of the HipNav system from a laboratory prototype into a robust clinical system.

2 HipNav System Description

Pre-operative planning in HipNav is based upon a CT scan of the patient’s pelvis. The pre-operative planner allows the surgeon to determine the appropriate implant size and placement. In the current version of the planner, the surgeon positions cross sections of a sphere (i.e., circles) upon orthogonal views of the pelvis to specify the implant’s center of rotation and size, as seen in Fig. 2. The surgeon specifies implant orientation using 3-D surface renderings of the pelvis and the implant. We are currently evaluating

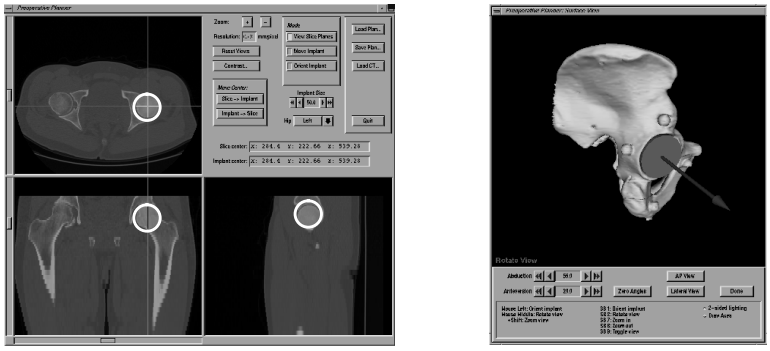

Fig. 2. Pre-operative planner - center of rotation and orientation components.

several methods for presenting CT data to the surgeon, and for updating implant placement based upon surgeon input [1].

Once the surgeon has selected the implant placement and size, the range of motion simulator is used to determine the femoral positions (in terms of extension/flexion, abduction/adduction, and internal/external rotation) at which impingement would occur for the specific implant design and placement. Based upon this range of motion information, the surgeon may choose to modify the selected placement in an attempt to achieve an "optimal" implant orientation (in terms of range of motion) for the specific patient. The range of motion simulator performs a kinematic analysis which determines an envelope of the safe range of motion, as seen in Fig. 3. More detailed descriptions of the range of motion simulator appear in [7] and [8].

The optimal patient-specific plan is used by the HipNav System in the operating room on the day of surgery. HipNav permits the surgeon to determine where the pelvis and acetabulum are in "operating room coordinates" at all times during surgery. Knowing the position of the pelvis during all phases of surgery, and especially during preparation and implantation of the acetabular implant, permits the surgeon to accurately and precisely position the cup according to the pre-operative plan. Alternately, using HipNav

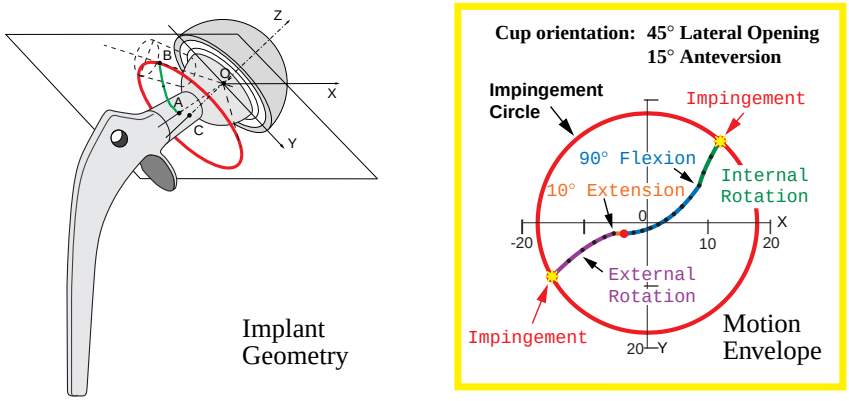

Fig. 3. Kinematic range of motion simulation.

the surgeon can align the implant to an accepted standard such as 45 degrees of abduction and 15 degrees of anteversion.

Several devices are used intra-operatively to allow the surgeon to accurately execute the pre-operative plan, as seen in Fig. 4. One device is an Optotrak optical tracking camera (Northern Digital Inc., Ontario) which is capable of tracking the position of special light emitting diodes (targets). These targets can be attached to bones, tools, and other pieces of operating room equipment to allow highly reliable tracking. Optotrak can achieve accuracies of roughly 0.1mm at speeds of 100 measurements per second or higher.

In order to determine the locations of the pelvis and the acetabular implant during surgery, Optotrak targets are attached to several conventional surgical tools, as seen in Fig. 5. In the laboratory prototype of HipNav, the pelvis was tracked by attaching a target to the pelvic portion of a Harris leg length caliper (Zimmer, Inc., Warsaw, IN), and inserting this device into the wing of the ilium. The acetabular implant was tracked by attaching a second target to the handle of an HGP II acetabular cup holder and positioner (Zimmer, Inc., Warsaw, IN). A third Optotrak target (which is only needed during system setup and calibration) is used to establish an operating room coordinate system (i.e., left, right, up and down with respect to the surgeon).

Several key steps are necessary to use the HipNav intra-operative guidance system. One of the most important is the registration of pre-operative information (i.e., the CT scan and pre-operative plan) to the position of the patient on the operating room table. A limitation of some registration systems used in orthopaedics is the need for fiducial pins to be surgically implanted into bone before pre-operative images are acquired (e.g., see [16]). An alternative technique which has been applied by several groups including ours uses surface geometry to perform registration [2][5][9][12][13][15]. Using this approach, the surfaces of a bone (such as the pelvis) can be used to accurately align the intra-operative position of the patient to the pre-operative plan without the use of pins or other invasive procedures. Using this technique, it is necessary to sense multiple points on the surface of the bone with a digitizing probe during surgery. These “intra-operative data points” are then matched to a geometric description of the bony surface of the patient derived from the CT images used to plan the surgery. A major focus of

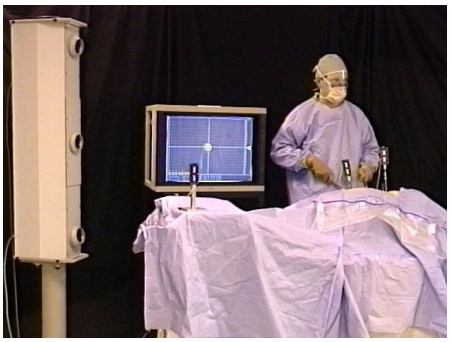

Fig. 4. Intra-operative execution.

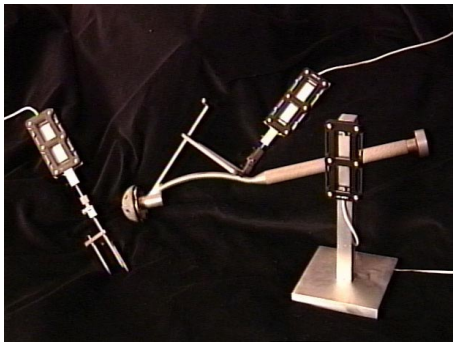

Fig. 5. Surgical tools instrumented with tracking targets.

our registration research is the intelligent selection of these intra-operative data points in a manner which maximizes registration accuracy while minimizing the quantity of data [13].

The registration process is illustrated in Fig. 6. The pelvic surface model was constructed from CT data using techniques similar to those described in [4]. The discrete points were collected using an Optotrak digitizing probe which was physically touched to the indicated points. The goal of the process is to determine a "registration transformation" which best aligns the discrete points with the surface model. An initial estimate of this transformation is first determined using manually specified anatomical landmarks to perform corresponding point registration [6]. Once this initial estimate is determined, the surface-based registration algorithm described in [15] uses the pre- and intra-operative data to refine the initial transformation estimate.

Once the location of the pelvis is determined via registration, navigational feedback can be provided to the surgeon on a television monitor, as seen in Fig. 7. This feedback is used by the surgeon to accurately position the acetabular implant within the acetabular cavity. To align the cup within the acetabulum in the placement determined by the pre-operative plan, the cross-hairs representing the tip of the implant and the top of the handle must be aligned at the fixed cross hair in the center of the image. Once aligned, the implant is in the pre-operatively planned orientation.

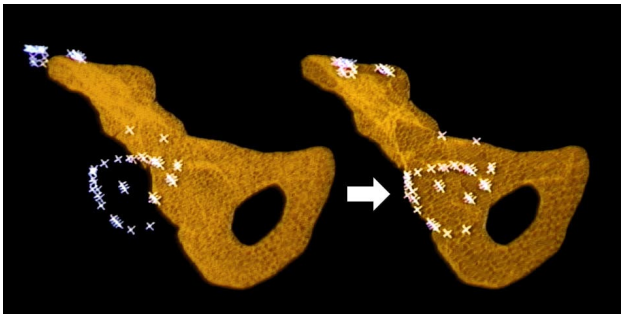

Fig. 6. Surface-based registration.

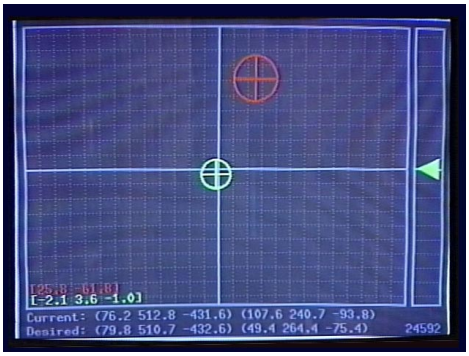

Fig. 7. Navigational feedback.

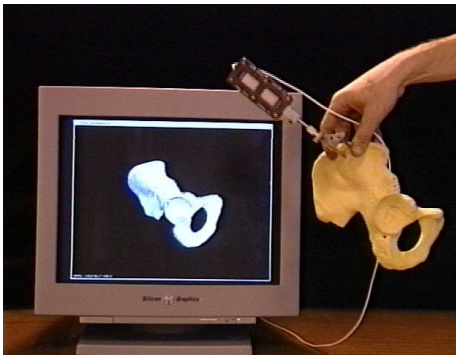

Fig. 8. Real-time tracking of the pelvis.

Registration also allows the position of the pelvis to be tracked during surgery using the Optotrak system, as demonstrated in Fig. 8. This eliminates the need for rigid fixation of the pelvis. In addition, this tracking ability allows us to record the position of the pelvis during surgery, and especially at key times such as during the implantation of the acetabular component or during range of motion testing.

3 Development and Validation

Initial evaluation of the prototype HipNav system was performed in the laboratory under controlled conditions. As development progressed, we performed a series of evaluation trials which were progressively more realistic (i.e., similar to the clinical environment). At the time this paper was written, we had performed 4 cadaver trials in an operating room, with two additional cadaver trials scheduled before initiation of preclinical patient trials. The goal of the cadaver trials is to validate the various system components in terms of robustness, usability, safety and accuracy. The trials have been extremely helpful in the design of clinical procedures and protocols.

We have classified development and validation issues into four categories: hardware, software, system and accuracy. A summary of the most interesting issues in each of these categories is presented below.

3.1 Hardware Issues

We attempted to use as many off-the-shelf hardware components in the HipNav design as possible. Many of these components are low-technology devices which are deceptively simple. Despite their simplicity, poor selection or design can have serious consequences in terms of usability, reliability, accuracy and safety. For example, as seen in Fig. 8, it is necessary to rigidly fasten a tracking target to the pelvis. The initial device used for this purpose was an off-the-shelf component used for measuring leg lengths before and after surgery. The device consists of three spikes attached to a rigid platform (the device on the left in Fig. 5) which are driven in to the iliac wing during surgery. In HipNav, it is crucial that this device remains fixed relative to the pelvis once data collection for registration has begun. However, during the later stages of cadaver testing we noticed small motions (2-3 mm) of the target fixator relative to the pelvis, necessitating a re-design of this component. The new design uses threaded screws, instead of smooth spikes, to ensure stability.

Ergonomics plays an important role in component design. For example, our initial data collection probes were poorly balanced and excessively heavy, factors to which surgeons are keenly sensitive. Data collection probe tips must be designed in a manner which allows data collection in a variety of anatomical locations (e.g., sciatic notch, percutaneous iliac wing, acetabular rim). Selection of a single probe tip which satisfies multiple accessibility constraints was important to eliminate the need for multiple probes or for probe re-calibration during surgery.

Later stages of hardware validation focussed on practical problems such as:

- Component sterilization requiring reactivity testing with the sterilization gas (ethylene oxide).

- Electrical isolation of tracking targets.
- Evaluation of material biocompatability.
- Electrical cable routing within the operating room to preserve sterility.

Hardware development benefited greatly from the cadaver trials. In certain cases, hardware limitations would not have been identified without multiple trials (e.g., slippage of the pelvic target fixator, accessibility limitations of data collection probe tips).

3.2 Software Issues

Software development and evaluation are large fields of study encompassing many design and evaluation philosophies. Two areas of software evaluation which are particularly relevant to computer-assisted surgical applications are functionality and usability testing. Functionality testing attempts to answer the question, “does the software correctly perform the operation for which it was designed?” Usability testing attempts to determine whether the software can be *efficiently* operated by intended target users to complete a given task. Ensuring functional and usable software is paramount in computer-assisted surgical applications.

The HipNav system consists of three primary software components: the pre-operative planner, the range of motion simulator, and the intra-operative control software. Extensive functionality and usability testing has been performed on all three components, and highlights of these activities are summarized below.

Large-scale, pre-operative planner usability tests are currently being performed by our group [1]. The goal of these tests is to compare several competing user interface designs to determine the best design for accomplishing the HipNav pre-operative planning task. Evaluation criteria are task accuracy, task completion time, and subjective factors such as user fatigue and confusion. In these experiments, test users are asked to reproduce particular acetabular implant orientations using the pre-operative planner, based upon a physical pelvic model and coupled implant which are presented to them. A complete description of this work appears in [1].

For the range of motion simulator, we have concentrated our validation efforts on functional testing [8]. In these tests, physical bone models are used to validate the accuracy of the computational kinematic simulator. The results of this validation process have been very encouraging, and suggest that our simulator is accurate to sub-degree tolerances [8].

The intra-operative control software provides a user interface to the HipNav system for use by surgeons. It is crucial that this software be reliable, easy to use, and easy to understand. Simple factors such as selection of type fonts and font sizes, selection of background and foreground colors, display layouts, and mechanisms for providing feedback to the surgeon regarding software state can have a profound impact on the acceptance of the HipNav system by clinicians. The software usability evaluations which we have performed were based on anecdotal feedback from two surgeons and a usability expert during and following the cadaver trials.

3.3 System Issues

System issues are those which are not associated with a particular hardware or software component of the system, and which are not directly related to system accuracy.

A crucial step in developing a clinical version of HipNav is the design of efficient CT scanning protocols. Initial cadaver trials were performed without regard to radiation exposure, monetary costs or scan time. The primary goal was to maximize the quantity and quality of information available for the planning and registration processes. For clinical use, it is desirable to minimize radiation exposure, monetary costs and scan time, while ensuring sufficient CT data. Two important parameters of the scanning protocol include: inter-slice spacing, and extent of the imaged volume. The effects of varying these parameters on the pre-operative planning and registration processes is currently being studied.

The duration of the CT scanning process is primarily a function of the number of cross-sectional images required. The relation between scan time and number of images is not necessarily linear, and may depend on factors such as the rate of X-ray tube cooling. As the duration of scan time increases, so does the probability of patient motion during the scanning process resulting in significant artifacts or errors. We plan to investigate this problem by attaching a non-invasive fixturing device to patients receiving CT scans of the pelvis (not necessarily HipNav patients). Coupled to the brace are a series of rods, similar to those used in stereotactic neurosurgical head frames, which will allow us to assess and potentially correct for patient motion during the scanning process. Based upon the results of this study, we may include motion correction or patient immobilization as a routine component of the HipNav CT scanning protocol.

The method which we currently use for generating *accurate* surface models of bones from CT data is labor intensive. The process requires a trained individual to semi-automatically extract bone contours from each of the CT slices, a time-consuming task. Depending upon the number of CT slices, this procedure can take from 1 to 4 hours. If systems such as HipNav are to be used routinely, the amount of manual labor required to construct accurate surface models must be reduced. We are pursuing parallel research with the goal of automatically generating accurate surface models of bones from CT images.

During surgery, the clock is always running. Therefore, minimizing procedural times and complications, and improving usage efficiency are important. Shifting setup and calibration procedures to the time period before the patient enters the operating room has obvious advantages. Additional time savings may be possible via intelligent design of hardware components which require assembly during surgery (e.g., the pelvic target tracker). Efficiency can also be improved by careful design of procedural transitions between conventional portions of the total hip replacement surgery, and those performed using HipNav.

Physical space is at a premium in the operating room. Therefore, it is important to minimize the real-estate used by the hardware components of the system. The largest component of the HipNav system is the tracking camera. During cadaver trials, the camera

was positioned on a floor mounted stand, although we are considering a ceiling mounted camera for clinical use.

Since the tracking camera requires line-of-sight between the sensor and the tracking targets, it is crucial to know when a target is being obscured. This is especially important since tracking accuracy may degrade significantly as a function of the number of obscured LEDs. Therefore, the guidance software continually tests for obscured LEDs during the procedure and provides a warning when not enough LEDs can be seen.

3.4 Accuracy Issues

A major advantage of computer-assisted surgery is improvement in procedure execution accuracy. In HipNav and related systems, there are many factors which contribute to system accuracy [14]. During HipNav validation, we have studied registration accuracy, surface model generation accuracy, and tool calibration accuracy.

In [14], we described a method for validating the accuracy of surface-based registration and the need for task-specific measures of registration accuracy. For the HipNav task, it can be shown that only *orientation* errors in registration are relevant to the implant placement task. This is because the system only provides feedback regarding implant orientation. Implant position is determined by a reaming process during which HipNav is not currently used.

We have validated the accuracy of HipNav's registration system using the techniques described in [14]. During the four cadaver trials which have been performed to date, registration orientation errors have varied between roughly 0.5 degrees and 1.5 degrees. If there were no other error sources contributing to implant misalignment, these measurements suggest that HipNav could position the acetabular implant within a 1.5 degree cone centered at the desired orientation. In practice, insertion error may be larger due to other sources of inaccuracy such as tool calibration errors, deviation of implant alignment during the insertion (impaction) process, and target sensing errors. Additional validation of HipNav registration is being done in the context of intelligent selection of intra-operative data points which maximize registration accuracy using minimum-sized data sets [13].

4 Conclusions

Many of the issues addressed during the development of HipNav have strong technical research components which may have broad application. These issues include:

- Automatic generation of bone surface models from CT-images, and validation of the accuracy of these models.
- Optimization of registration accuracy as a function of the collected data [13], and subsequent validation of this accuracy [14].
- Design of complex software interfaces to maximize usability for a target user group [1].

In addition to these technical issues, there are many *clinical* research problems related to HipNav, including demonstration of efficacy and cost-effectiveness.

It has been our experience that performing technical research together with system development in a tightly coupled manner has several advantages. Perhaps the most important effect is to focus the research towards the solution of *real* problems. Experience gained during system development and validation tends to focus research efforts away from contrived problems and non-issues. For example, in the area of accuracy validation it is important to define task-specific accuracy requirements to ensure that time is not spent achieving unnecessary accuracy.

The HipNav system holds the promise of reducing dislocation rates in primary and revision total hip replacement by optimizing the placement of acetabular implants and minimizing impingement. It also provides a set of tools that will be useful for examining assumptions made by conventional methods of total hip replacement surgery.

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