An Image Guided Navigation System for Accurate Alignment in Total Hip Replacement Surgery

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Abstract

Dislocation following total hip replacement surgery (THR) remains a significant clinical problem. Malposition of the acetabular component increases the occurrence of impingement, reduces the “safe” range of motion and increases the risk of dislocation. Not fully understanding the interaction between pelvic orientation and final acetabular cup alignment may be one of the main contributing factors in the continued significant incidence of dislocations following total hip replacement.

There has been little clinical research to examine the effects of patient positioning and pelvic motion on the alignment of the acetabular implant during total hip replacement surgery. Until now, no tools were capable of accurately measuring these variables during the actual procedure. As part of a broader program in medical robotics and computer assisted surgery, we have developed several enabling technologies that provide surgeons with a new class of image guided measurement tools and assist devices. These surgical navigation tools provide position and alignment information never before available intraoperatively. Our Hip Navigation system (HipNav) continuously and precisely measures and tracks pelvic location and relative implant alignment. HipNav technology is used to gauge current clinical practice and provide intraoperative feedback to surgeons in order to improve the precision and accuracy of acetabular alignment during THR. These tools were successfully introduced into the clinical practice of surgery with results showing that: a) there exist unpredictable and large variations of the initial position of patients’ pelvii on the OR table as well as significant pelvic movement during surgery and during intraoperative range of motion testing; b) current mechanical acetabular alignment guides do not account for these variations, and result in variable and in some cases unacceptable acetabular alignment; and c) press fitting oversized acetabular components influences the final cup orientation.

Keywords

total hip replacement, dislocation, acetabular implant alignment, computer assisted surgery, image guided surgery, navigational guidance.

I. Introduction

A. Issues and Current Practice

With approximately 200,000 primary and 40,000 revision total hip replacement surgeries performed each year in the United States, dislocation following total hip replacement (THR) due to malposition of components remains a significant clinical problem. Dislocation is the most common early postoperative complication following THR, resulting in significant distress to the patient and surgeon, with decreased patient satisfaction, worse clinical outcomes, and significant additional treatment costs.[5, 6, 8, 9, 12, 20, 35, 41, 47, 51, 63] In the early days of THR, the incidence of dislocation was as much as ten percent. More recent studies have reported a reduction in the incidence of dislocation to approximately one to five percent in primary THR. However, the magnitude of the problem is significant since the majority of these dislocations require a general anesthetic for reduction and a significant number of patients go on to become recurrent dislocators who require reoperation.[9-11, 63] Despite clinicians' and researchers' attempts to understand and prevent dislocation, its incidence following primary THR remains a significant problem.

The causes of dislocation are multifactorial and include patient related positional factors, soft tissue or bone impingement, soft tissue laxity and implant design parameters such as the head/neck ratio of the femoral implant.[3, 4, 8, 9, 18] However, malalignment of one or both components is responsible for the majority of dislocations with the acetabular cup being the component more likely to be malpositioned[8, 20, 30] and is the most sensitive variable in predisposing to dislocation.[9, 30, 52] Of all the factors associated with dislocation, component malposition is the most easily correctable and when corrected, yields a good postoperative result.[8, 9, 43] In addition, prevention of malalignment is important since nearly all patients with recurrent dislocation associated with malposition require revision surgery.[8, 9, 20, 50]

In addition to frank dislocations, impingement between the neck of the femoral implant and the rim of the acetabular implant can also lead to advanced polyethylene wear resulting in the generation of debris which may accelerate loosening.[53, 54, 56, 67] Though improvements continue in the design of implants and methods of fixation, little effort has been made to provide surgeons with more accurate tool guides or strategies to improve implant alignment and bone preparation.

One important factor affecting alignment is the orientation of the pelvis on the operating room table and its impact on cup alignment.[39, 66] McCollum and Gray[39] pointed out that special precautions should be taken using the lateral decubitus position. They hypothesized that significant flexion and potential lateral tilt of the pelvis in this position could lead to improper cup alignment. In the lateral decubitus position the pelvis is flexed; thus, an increased implant flexion is likely necessary to achieve the desired (true) anatomic anteversion of the acetabular component. Their results suggested that to achieve a relative cup position of 20-40 degrees of anteversion from the horizontal plane, significant implant flexion needs to be introduced at the time of surgery. With a strategy of using bony landmarks to assist in alignment, their dislocation rate was reduced to 1.14 percent using the posterolateral approach in a consecutive series of 441 patients. These results indirectly show that considering "functional" pelvic positions may be an important consideration for optimal implant alignment.

Clinical reports of patient outcomes have yielded conflicting conclusions when examining component alignment as a risk factor in dislocations. Although it is intuitive to surgeons that component alignment is an important factor, several large clinical series have concluded that component orientation is not associated with the risk of dislocation.[6, 24, 36, 44, 49, 50] Other studies have shown a more direct relationship between malalignment and the risk of dislocation.[9, 12, 13, 30, 33, 41, 66] In a recent report, Paterno[44] detected no association between the risk of dislocation and version or abduction angle measured from standard AP pelvis and shoot through lateral X-rays. In addition, the majority of patients who experienced dislocation had acetabular alignment in the "safe zone" of 15±10 degrees anteversion and 40±10 degrees abduction.[35]

However, these studies and nearly all prior clinical series have been limited to using radiographic measures of acetabular alignment as opposed to true anatomic alignment.[6, 9, 12, 24, 30, 35, 44, 48-50, 66] Radiographic measures of cup alignment are dependent on the position of the pelvis on the X-ray table and the angle of the X-ray beam with respect to the pelvis. These errors can lead to potentially significant variations in measured component alignment.[14-16, 22, 23, 35, 48, 55, 56, 68] Radiographic measurements of version are especially sensitive to the position of the patient on the X-ray table.[14, 15, 23, 55, 64, 68] Only Lewinnek and coworkers[35] attempted to standardize the position of the patient with respect to the X-ray table and beam. They developed a technique to level the anterior pelvic plane defined by the anterior superior iliac spines and the symphysis pubis in order to maintain a standardized pelvic alignment permitting consistent measurements of radiographic alignment. The inability to accurately measure true acetabular alignment from the radiographic measures of alignment may be the reason that we have not been able to detect the influence of component position on dislocation in some of these large clinical series. In addition, researchers have shown that there is significant motion of the human pelvis during activities of daily living like sitting, standing and lying supine.[28, 39] These functional positions of the pelvis may also play an important role in instability following THR. Therefore, clinicians and researchers need to know the true alignment of the acetabular component and account for functional changes of pelvic position during normal activities in order to ultimately relate implant alignment to patient outcomes.

Current planning for acetabular implant placement and size selection is performed using acetate templates and a single anterior-posterior X-ray of the pelvis. Traditional acetabular templating is most commonly performed to determine the approximate size of the acetabular component with little effort to optimize the orientation of the implant, leaving it to be determined at the time of surgery. Intraoperatively, bony landmarks of the pelvis are somewhat obscured and most surgeons will admit that it is very difficult to know precisely how the patient's pelvis is oriented, despite many techniques of pelvic positioning and stabilization on the OR table. Mechanical intraoperative guides provided by implant manufacturers attempt to align the acetabular component with respect to the longitudinal and coronal planes of the patient. However, these devices assume that the patient's trunk and pelvis are aligned in a known orientation to the operating room table, and do not take into account individual variations in a patient's anatomy or the actual position of the pelvis on the operating room table. In addition, the surgeon may be faced with conflicting objectives during surgery choosing between maximizing peripheral press fit and maintaining adequate alignment of the acetabular component.[31, 32, 37] We hypothesize that the use of these types of acetabular guides as the sole source of intraoperative alignment will lead to a wide variation between the desired and actual implant placement resulting in reduced range of motion, impingement and possible dislocation.

B. New Technologies and Opportunities to Improve Clinical Measurements

The overall objective of our comprehensive program in computer assisted surgery is to couple a patient-optimized preoperative plan with intraoperative tools to accurately implement that plan. The clinical challenges faced by the surgeon during THR lend themselves to this approach. We have developed a system called HipNav, for Hip Navigation system, which:

- provides preoperative simulations of range of motion and implant impingement to optimize the surgical plan;
- provides a pelvic orientation and motion measurement tool;
- improves the accuracy and precision of acetabular alignment during THR.

HipNav includes three components: a preoperative planner, a hip range of motion simulator, and an intraoperative tracking and guidance system (Figure 1). The preoperative planner allows the surgeon to interactively specify the size, position and orientation of the acetabular component within the pelvis model based upon preoperative CT images. The simulator provides feedback which can aid the surgeon in determining optimal, patient-specific acetabular implant alignment. The simulator can be used to predict a safe envelope of range of motion based upon the implant geometry and orientation provided by the preoperative planner. Implant impingement is used as a conservative predictor of dislocation. The simulator enables the surgeon to adjust the plan away from orientations where impingements are likely to occur for daily functional motions of the leg.

The intraoperative tracking and guidance system is used to measure the position of the pelvis and acetabular component at all times during surgery. With this information the surgeon can accurately orient the implant in the planned optimal alignment regardless of the position of the patient on the operating room table. In addition, these navigation technologies provide the clinical researcher with an interactive and unique intraoperative measurement tool. Surgeons, for the first time, can precisely measure intraoperative variables such as pelvic orientation and motion, and examine cup alignment strategies that could not previously be measured or validated.

Our hypotheses are:

- There is significant variation in the initial orientation and position of patients' pelvii at the start of THR.
- There is significant change in pelvic orientation during THR from the initial position and during various steps of surgery including after dislocation and femoral osteotomy, during acetabular preparation and alignment and during range of motion testing for stability.
- Current mechanical acetabular alignment guides are imprecise and unreliable when used alone. Additional alignment cues based on pelvic anatomy are necessary to improve acetabular alignment and minimize the variation from optimal.

This report focuses on the benefits of HipNav technology and its transition from a laboratory prototype to its introduction into the operating room both as a measurement tool and as a system to improve the alignment of acetabular cups. As a proof of concept, to aid the introduction into a clinical setting and to test accuracy, HipNav was first tested in a cadaver trial. A clinical trial was then undertaken to test the feasibility and safety of the system within an actual operating room environment and to collect information on current clinical practice.

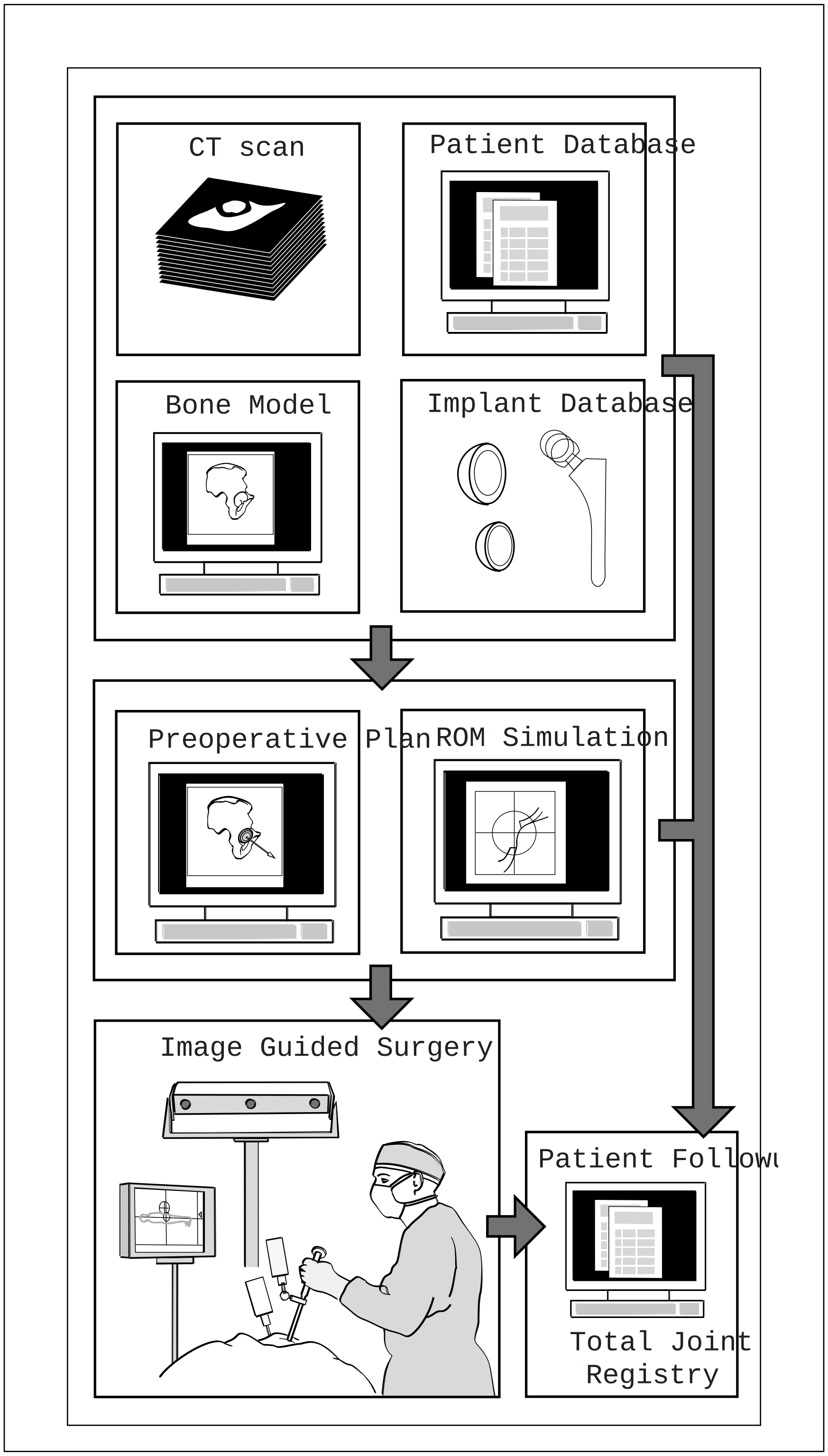

Figure 1. HipNav: Coupling preoperative planning with intraoperative measurements and navigational guidance.

II. Materials and Methods

A. HipNav System Description and Technology Development

The HipNav preoperative planner uses CT data as well as a three-dimensional surface model of a patient's pelvis generated from the CT data (Figure 2). The interactive planner allows the surgeon to determine the appropriate implant size and orientation. To specify the implant's center of rotation and diameter, the surgeon positions cross sections of an implant upon orthogonal views of the pelvis. The surgeon then specifies cup orientation using three-dimensional surface renderings of the pelvis that can be viewed from any perspective. Once the implant size and orientation is selected, the plan can be tested for anterior and posterior instability using functional leg motion paths (e.g., flexion of 90 degrees, adduction and maximum internal rotation or maximum extension and external rotation) with the range of motion simulator integrated into the planner. Positions of impingement are determined for the specified implant design and orientation within the bone. The range of motion simulator determines an envelope of the safe range of motion for any selected leg motion paths (Figure 2). A more complete description and validation of the range of motion planner and simulator appear in previous reports.[26, 27] Based upon the range of motion information, the surgeon can modify the orientation of the cup to achieve an "optimal" implant alignment (i.e., maximizing stability while minimizing impingement for specific functional positions such as sitting in a chair or lying supine in bed).

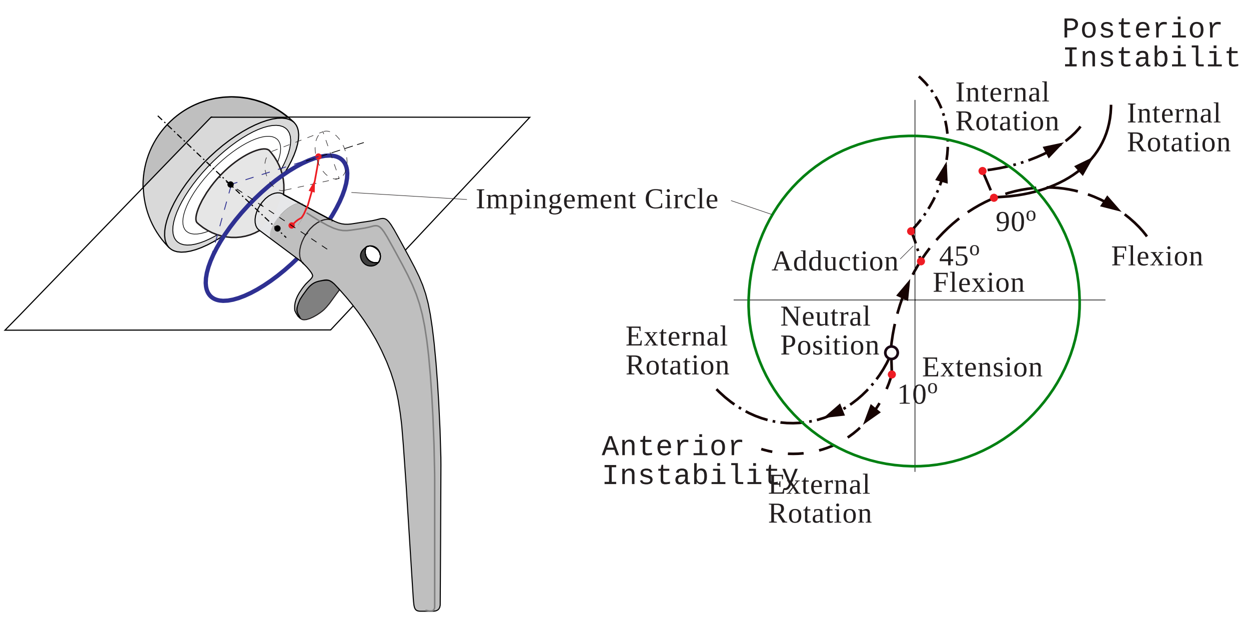

Figure 2. Preoperative planner and range of motion simulator that defines an envelope of "safe" range of motion.

The patient-specific plan is used by HipNav during surgery to help the surgeon guide the implant into the optimal position. HipNav measures the location of the pelvis at all times during surgery. Knowing the position of the pelvis during surgery, and especially during preparation and implantation of the acetabular implant, permits the surgeon to accurately and precisely measure and align the cup according to the preoperative plan. Alternatively, HipNav can also help the surgeon align the implant to an accepted standard such as 45 degrees of abduction and 20 degrees of anteversion.

Several new technologies are used intraoperatively to allow the surgeon to accurately measure cup alignment and execute the preoperative plan. One important component of the system is an optical tracking camera (Optotrak, Northern Digital Inc., Ontario) which is used to track the position of special targets with light emitting diodes. These targets are attached to the pelvis and surgical tools to allow highly reliable position tracking (Figure 3). Optotrak targets are attached to a pointer (digitizing probe), the wing of the ilium and the handle of an acetabular cup holder (HGP II and Trilogy,® Zimmer, Inc., Warsaw, IN). One additional Optotrak target (which is only needed during system setup and calibration) is used to establish an operating room coordinate system at the beginning of surgery (i.e., left, right, up and down with respect to the surgeon).

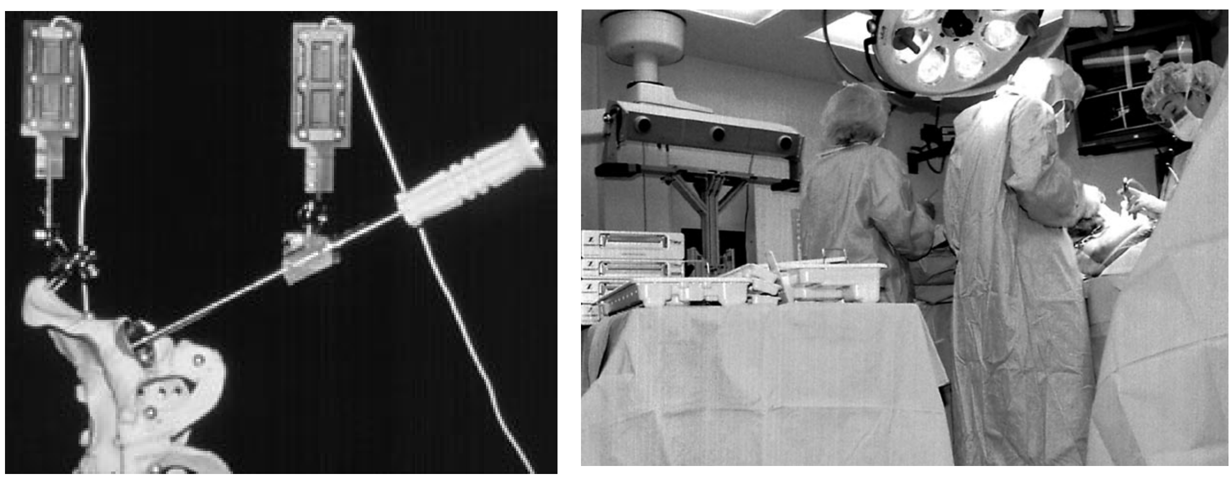

Figure 3. Intraoperative tracking of the pelvis and surgical tools using Optotrak™ and targets.

Several key software components are necessary to use the HipNav intraoperative guidance system. One of the most important components is the software which registers (locates and orients) the preoperative information (i.e., the CT scan and preoperative plan) to the position of the patient on the operating room table. A limitation of most registration systems currently used in orthopaedics and neurosurgery is the need for fiducial pins or screws that are surgically implanted into bone before preoperative images are acquired.[45, 46, 61, 62] An alternative technique applied by our group uses surface geometry to perform registration.[7, 17, 21, 34, 42, 57, 59, 60] Multiple points on the surface of the pelvis are collected with a digitizing probe during surgery. These intraoperative data create a cloud of points which is then matched to a geometric description of the bony surface derived from the CT images already used to plan the surgery. Using this approach, the unique surfaces of a bone (such as the pelvis) can be used to accurately align the intraoperative position of the patient to the preoperative plan without the use of pins or other invasive procedures.

The overall registration process is illustrated in Figure 4. The pelvic surface model is constructed from CT data. To accelerate the procedure, an initial estimate of the registration transformation is first determined using specified anatomical landmarks (anterior superior iliac spine, sciatic notch and superior acetabular rim). Once this initial estimate is determined, the surface-based registration algorithm uses the pre- and intraoperative data to refine the initial transformation estimate.[57] The goal of the process is to determine a "registration transformation" which best aligns the discrete points with the surface model. Much of our registration research has focused on the accuracy of this approach and the intelligent selection of these intraoperative data points in a manner which maximizes registration accuracy while minimizing the number of points needed and therefore, surgical time required for data collection.

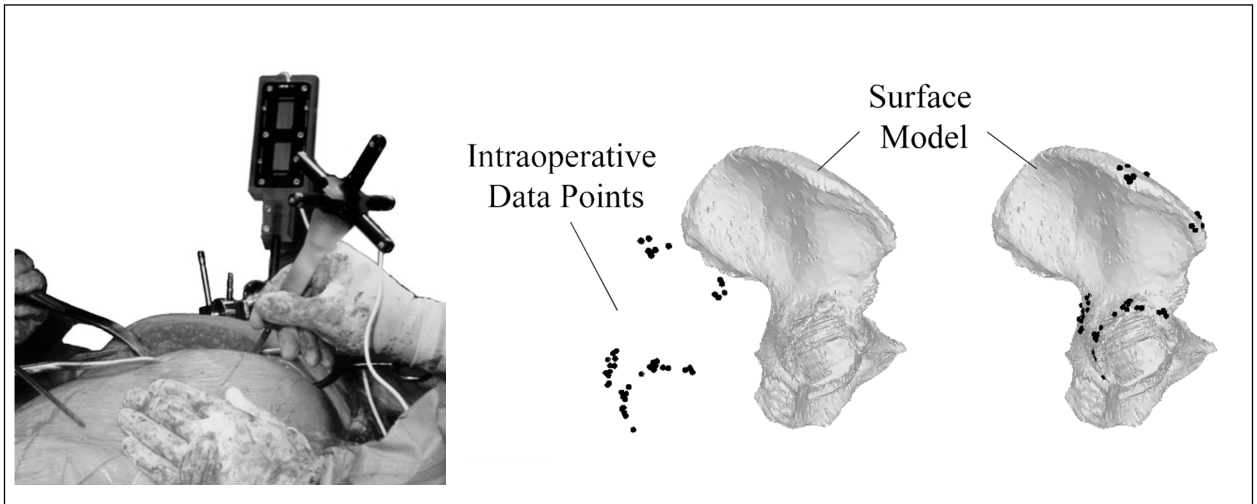

Figure 4. Registration process showing intraoperative data collection with the probe and matching of points to the surface model allowing final registration of the preoperative plan and patient position on the OR table.

After registration, the movement and position of the pelvis and any of the instrumented surgical tools can be continuously monitored during all phases of surgery, which eliminates the need for rigid fixation of the pelvis. In addition, this tracking ability allows recording of the position of the pelvis and acetabular implant at any time during surgery, and especially at key times such as during acetabular alignment and range of motion testing.

Navigational feedback is provided on a television monitor (Figure 5). To place the cup within the acetabulum in the orientation determined by the preoperative 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 these cross hairs are aligned, the implant is in the preoperatively planned orientation. On the same screen, a digital display continuously reports the actual measurement of abduction and anteversion of the implant which the surgeon can also use to align the cup. By using this system as a measurement tool, strategies of cup alignment can be tested and validated during surgery.

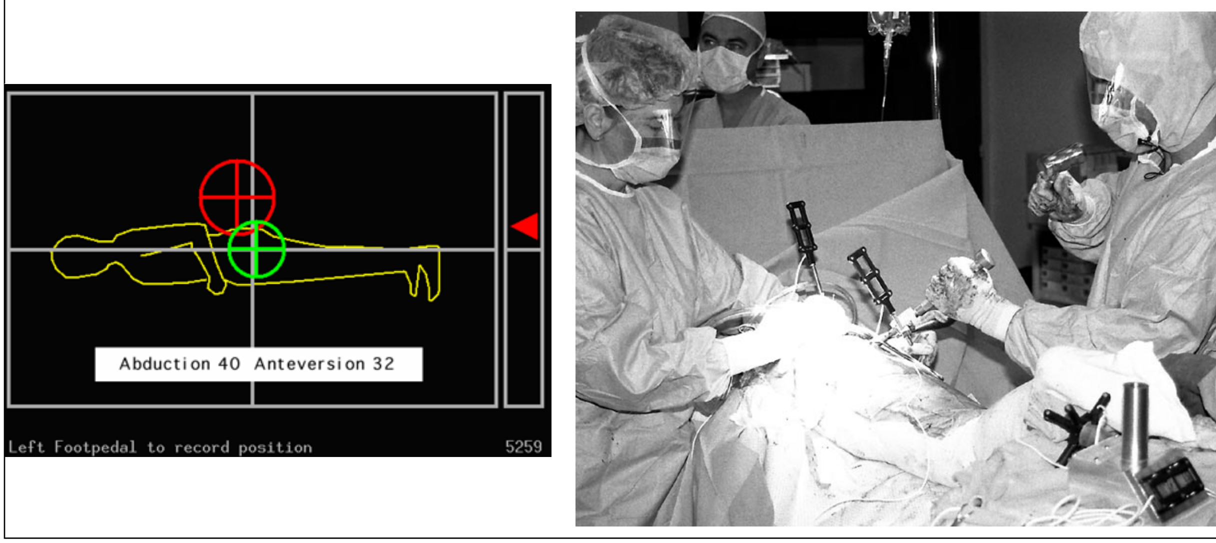

Figure 5. Intraoperative navigational feedback provided to the surgeon to measure and align the acetabular component and OR setup.

B. Experimental Set Up and Cadaver Trial

Initial evaluation of the prototype HipNav system was performed in the laboratory under controlled conditions. As development progressed, a number of cadaver trials were performed, increasingly more realistic in replicating operating room conditions.[58] A total of six cadaver trials were performed with the last three tests as full OR mock-ups. The goal of the cadaver trials was to validate the various system components in terms of robustness, usability, safety and registration accuracy. These trials were extremely helpful in the later design of clinical procedures and protocols.

For this part of the study, the six cadaveric pelvii, including soft tissues, were scanned on a GE High-Speed Advantage CT scanner with 0.5 millimeter in-plane resolution, 3.0 millimeter table increments, and 1.0 millimeter slice thickness. Surface model reconstruction was performed using custom contour extraction and surface reconstruction software. Discrete point data were collected during the test using the digitizing probe. Surface-based registration was performed using the software described.

In order to estimate the accuracy of surface-based registration, it was necessary to determine a highly accurate "ground truth." For the cadaver study, a fiducial-based registration method was used to provide this ground truth. The fiducial markers, 0.5 inch in diameter aluminum spheres mounted on plastic stand-offs, were carefully designed to maximize the accuracy with which they could be localized in CT images and during the actual surgical setups using a digitizing probe. A series of six fiducials were fixed to the inner wing of the cadaveric pelvii. After determining the locations of the markers in the CT and surgical coordinate systems, a corresponding point registration method was used to establish the ground truth registration transformation.[25]

C. Clinical Trial Protocol

After obtaining appropriate Institutional Review Board (IRB) approval and obtaining informed consent from patients, a limited clinical trial was initiated using the HipNav system. All patients enrolled in the trial were candidates for unilateral, primary THR with the principal diagnosis of degenerative arthrosis (Table I). Preoperatively, a CT scan was used to generate a three-dimensional model of the pelvis for each patient. The computerized preoperative planner and simulator of hip range of motion were then used to size and position the acetabular component and determine the "optimal" cup alignment. Standard radiographs were obtained and included an AP pelvis and lateral of the involved hip. To aid in preoperative planning, standing and sitting lateral pelvic X-rays were also obtained to quantify changes in pelvic tilt for each patient in these functional positions. These X-rays provide a measurement of the range of pelvic flexion and extension which directly influences version of the cup.[39]

Intraoperatively, all patients were positioned and stabilized on the OR table according to the surgeon's typical routine which included aligning the patient's trunk with the longitudinal axis of the OR table and stabilizing the pelvis with a series of anterior and posterior blocks and a bean bag. The non-operative leg was secured to the table in approximately 45 degrees of flexion. A posterolateral approach to the hip was performed in all cases and by one surgeon (AMD). The posterior soft tissue structures including the capsule and short external rotators were re-attached to the proximal femur during closure. No patient underwent a greater trochanteric osteotomy. Femoral implant version was measured manually. The anterior capsule was generally left intact except for an occasional limited inside-out capsulectomy performed if a severe flexure contracture was present. Oversized cementless acetabular components (HGP II and Trilogy,® Zimmer, Inc., Warsaw, IN) were press fit into the acetabulum to achieve initial fixation which was supplemented by additional screws as needed (refer to Table III). The amount of press fit varied from two to four millimeters and was dependent on the diameter of the native acetabulum and quality of reamed bone.

Table I: Demographics and Patient Information

Patient ID	Age	Surgery	Type of Acetabular Implant	Diagnosis
1	61	Uncemented left hip	HGP II	OA
2	59	Hybrid left hip	Trilogy	Psoriatic Arthritis
3	60	Hybrid left hip	Trilogy	OA
4	72	Hybrid right hip	Trilogy	OA
5	64	Uncemented left hip	Trilogy	OA
6	75	Hybrid left hip	Trilogy	OA
7	65	Hybrid right hip	Trilogy	OA
8	72	Hybrid right hip	Trilogy	OA
9	72	Hybrid left hip	Trilogy	OA
10	68	Hybrid right hip	Trilogy	OA
11	63	Uncemented right hip	Trilogy	OA
12	69	Hybrid left hip	Trilogy	OA
13	65	Hybrid left hip	Trilogy	OA
14	75	Hybrid right hip	Trilogy	OA
15	76	Hybrid right hip	Trilogy	OA
16	76	Hybrid left hip	Trilogy	OA
17	50	Uncemented right hip	Trilogy	OA
18	64	Hybrid right hip	Trilogy	OA
19	57	Uncemented right hip	Trilogy	OA
20	49	Uncemented right hip	Trilogy	OA/CDH

Data were collected to determine the variations of the alignment and motion of a patient’s pelvis on the OR table during THR. With pelvic motion being tracked, it was possible to measure the actual orientation of the acetabular component when the cup was positioned using the following methods: traditional acetabular guides provided by the implant manufacturer; the surgeon’s own technique; the “optimal” position as determined by a patient-specific preoperative plan; and the final cup alignment measured after press fitting the acetabular component. Implant orientation was quantified with respect to the anterior pelvic plane defined by the two anterior superior iliac spines and the symphysis pubis (Figure 6). This plane, easily identifiable both radiographically and by physical exam, is used to define the standard pelvic coordinate system to determine pelvic and acetabular cup alignment.

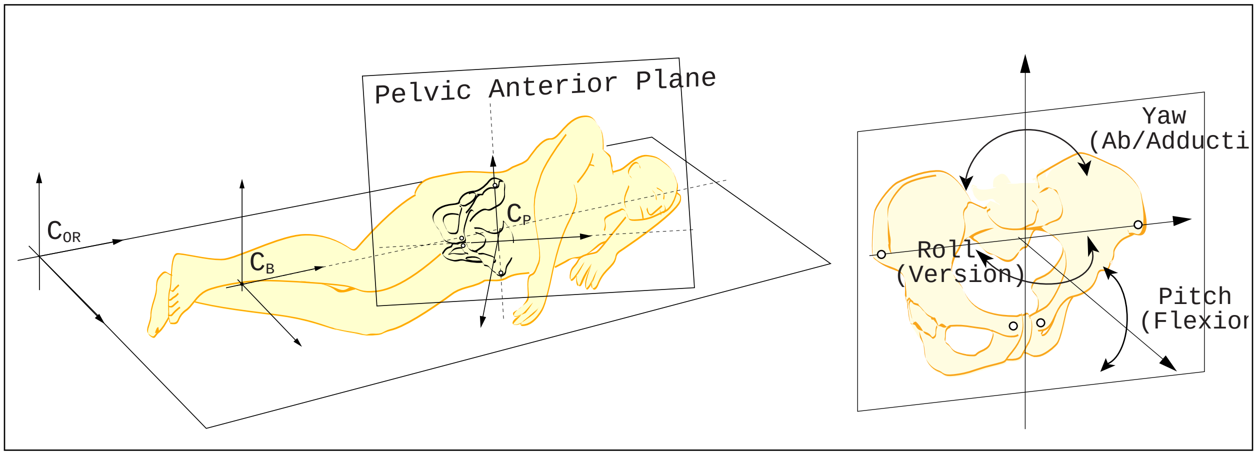

Figure 6. Definitions of pelvic motion and the pelvic coordinate system using an anterior pelvic plane defined by the anterior superior iliac spines and symphysis pubis.

Each patient was enrolled in our clinical database. Clinical evaluations are performed prospectively and by independent evaluators, preoperatively and at regular postoperative intervals. Data collected during these intervals include the Harris Hip Score, SF-36 survey, and Modems Hip/Knee Outcomes Data Collection Instruments (AAOS) standard data used to measure patient outcomes and will be reported in future studies as the length of follow up increases.[1, 29, 38, 65]

III. Results

A. Experimental Study and Cadaver Trial

All surface data points collected from the cadaveric pelvii were in clinically accessible regions within the sterile surgical field used routinely for THR. Iliac wing points were collected percutaneously. Based on our initial registration accuracy studies, data collection was concentrated in three regions: the acetabular rim, the anterior iliac wing and the sciatic notch. Forty to fifty points were collected from these regions in approximately three to five minutes.

Table II: Registration Errors for Cadaver Trials

Cadaver Trial	RMS Translation Error	RMS Rotation Error
1	0.96 mm	0.79 degrees
2	0.69 mm	1.31 degrees
3	0.24 mm	1.19 degrees

The error measures, reported in Table II for the cadaveric pelvii, are with respect to the ground truth provided by the fiducials and are the root mean square (RMS) values of the translation and rotation components of the registration error transformation. Errors are represented about a coordinate system with an origin at the center of rotation of the acetabulum and with the z-axis pointing straight out of the cup (i.e., normal to the plane of the rim). The small values in Table II indicate that the registration transformations of surface based registration are similar to those of pin-based registration. Since pin-based registration is accepted as a gold standard, one can infer that the accuracy provided by surface based registration approaches that of pin-based.

B. Technology Integration into Clinical Practice

The HipNav system was successfully deployed for the first time in the OR with minimal impact on current surgical routine. The only deviations from the surgeon’s current routine were the installation of the pelvic tracking device and surface data point collection used for registration. These steps typically took 10 to 15 minutes additional OR time. The OR staff was able to quickly calibrate the digitizing probe and acetabular cup holder while the surgeon performed the surgical approach to the hip. A standard posterolateral surgical approach was utilized and there was no need to extend soft tissue dissection in order to collect any data points. Points on the wing of the ilium were collected percutaneously. No cases were aborted due to system or component failure and there were no adverse events related to the use of the system. Although a direct line of sight is required for tracking, there were no difficulties with integrating the Optotrak system into the OR environment.

C. Clinical Trial

Although the follow up period is currently too short and the number of patients too small to provide statistically significant clinical outcomes data, an abundant amount of information and important trends arise from the analysis of the intraoperative measurements collected from the first ten patients. Figure 7 shows one example of the importance of lateral pelvic X-ray series in preoperative planning. In these X-rays, the patient is standing (A) and sitting (B). The patient’s involved hip is placed next to the cassette with the wing of the ilium perpendicular to the beam of the X-ray. In this specific case (Patient #6), the pelvis was tilted anteriorly (+10) degrees while standing and posteriorly (-15) degrees when assuming the sitting position resulting in a total relative change of 25 degrees. From our series of twenty patients (Table III), lateral pelvic X-ray series showed the wide variation of pelvic tilt between each patient. Among all patients, the pelvic tilt varied from 16 degrees posterior to 27 degrees anterior in the standing position and 50degrees posterior to 5 degrees anterior in the sitting position. In addition, there was a significant amount of change in each individual patient’s pelvic tilt moving from the standing to sitting position (range 3-57 degrees). The use of the three-dimensional planner with preoperative simulator resulted in an optimal cup orientation angle which was slightly increased in abduction and moderately increased in anteversion with respect to the orientation angles commonly quoted. Femoral component version measured during surgery was within the expected range of 15-30 degrees of anteversion.

Table III: Preoperative functional Pelvic Tilt, Acetabular Implant Size and Pressfit

Patient ID	Pelvic Tilt[a] (degrees) Standing	Pelvic Tilt[a] (degrees) Sitting	Pelvic Tilt[a] (degrees) Change	Final Acetabular Implant Size (mm)	Amount of Pressfit (mm)	# Screws
1	-16	-13	3	54	2	1
2	+27	-30	57	54	2	0
3	n/a[b]	n/a[b]	n/a[b]	56	2	1
4	+5 to +17 (midpoint +11)	-34	45	54	2	0
5	+17	-34	51	64	4	0
6	+10	-15	25	54	2	0
7	+8	-30	38	50	2	1
8	+4	n/a[b]	n/a[b]	52	2	2
9	+20	+5	15	50	2	0
10	0	-25	25	48	2	1
11	0 to +14 (midpoint +7)	-7 to -12 (midpoint -10)	17	60	2	1
12	0	-45 to -55 (midpoint -50)	50	66	2	2
13	-8 to +5 (midpoint -1)	-47	48	50	2	1
14	-6	-15	9	62	2	1
15	+5 to +25 (midpoint +15)	-20	35	54	2	1
16	n/a[b]	n/a[b]	n/a[b]	52	2	2
17	+5	-30 to -42 (midpoint -36)	41	60	2	0
18	+3 to -10 (midpoint -3)	-17 to -20 (midpoint -18)	15	54	2	1
19	+3 to + 7 (midpoint -2)	-30	28	60	2	1
20	+20	-14	34	52	2	2

a. Anterior tilt from neutral upright position is positive (+),
Posterior tilt from neutral upright position is negative (-).

b. Measurement not available.

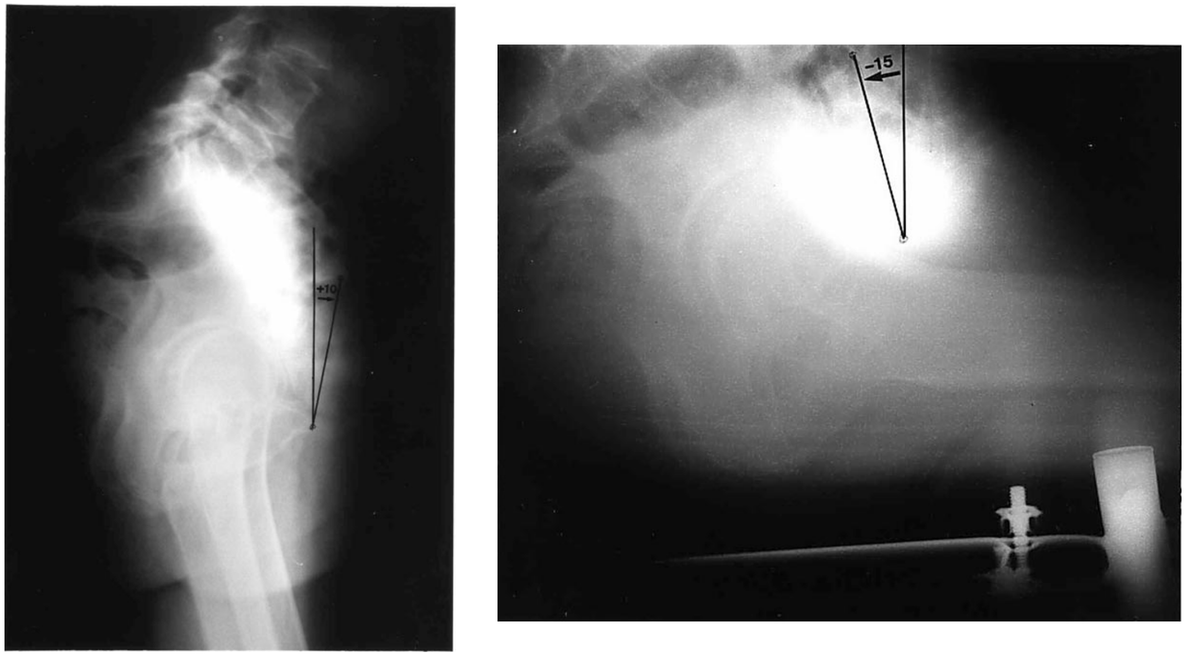

Figure 7. Standing and sitting lateral pelvic radiographs with measurements of pelvic tilt ("+" is anterior tilt and "-" is posterior tilt).

Pelvic Orientation and Position

The measured pelvic rotations are expressed in terms of roll, pitch, and yaw rotational components relative to a baseline coordinate system as illustrated in Figure 6. These rotations can be generally interpreted as anteversion/retroversion, flexion/extension and abduction/adduction, respectively. Figure 8 displays a representative sample of one patient's pelvis initial alignment on the OR table and the change of orientation during various stages of surgery. The baseline pelvic orientation in the top of Figure 8a is set in the position that surgeons would assume as optimal, in which the anterior plane of the pelvis is parallel to the longitudinal axis and perpendicular to the plane of the operating room table. This assumed pelvic position is then presented as the white line drawing in all subsequent figures. The pelvic data are presented in the AP and lateral projections. If the patient's pelvis was initially aligned in the expected neutral baseline position and there were no changes in pelvic orientation during surgery, the pelvic images would be coincident. Figure 8A shows the alignment of the pelvis just prior to dislocation, during acetabular alignment and after pressfitting the acetabular component. Figure 8B presents similar projections of pelvic alignment during range of motion testing for hip stability commonly performed by surgeons after implantation of the final components. The measured pelvic position is shown with the leg in neutral alignment (zero degrees of flexion or extension); then at maximal extension coupled with external rotation; flexion of 90 degrees, neutral adduction and maximal internal rotation; and finally with maximal flexion.

From the series of twenty patients as illustrated in this demonstration, the intraoperative measurements show that there is significant variation of the initial position of the pelvis from patient to patient even while employing the identical surgical routine (maximum differences of 36 degrees version, 19 degrees flexion/extension and 14 degrees adduction/abduction). In addition, there was no specific pattern for the surgeon to rely on with respect to pelvic position during acetabular alignment. The position of the pelvis changed throughout the course of each case and especially during the intraoperative range of motion testing for stability.

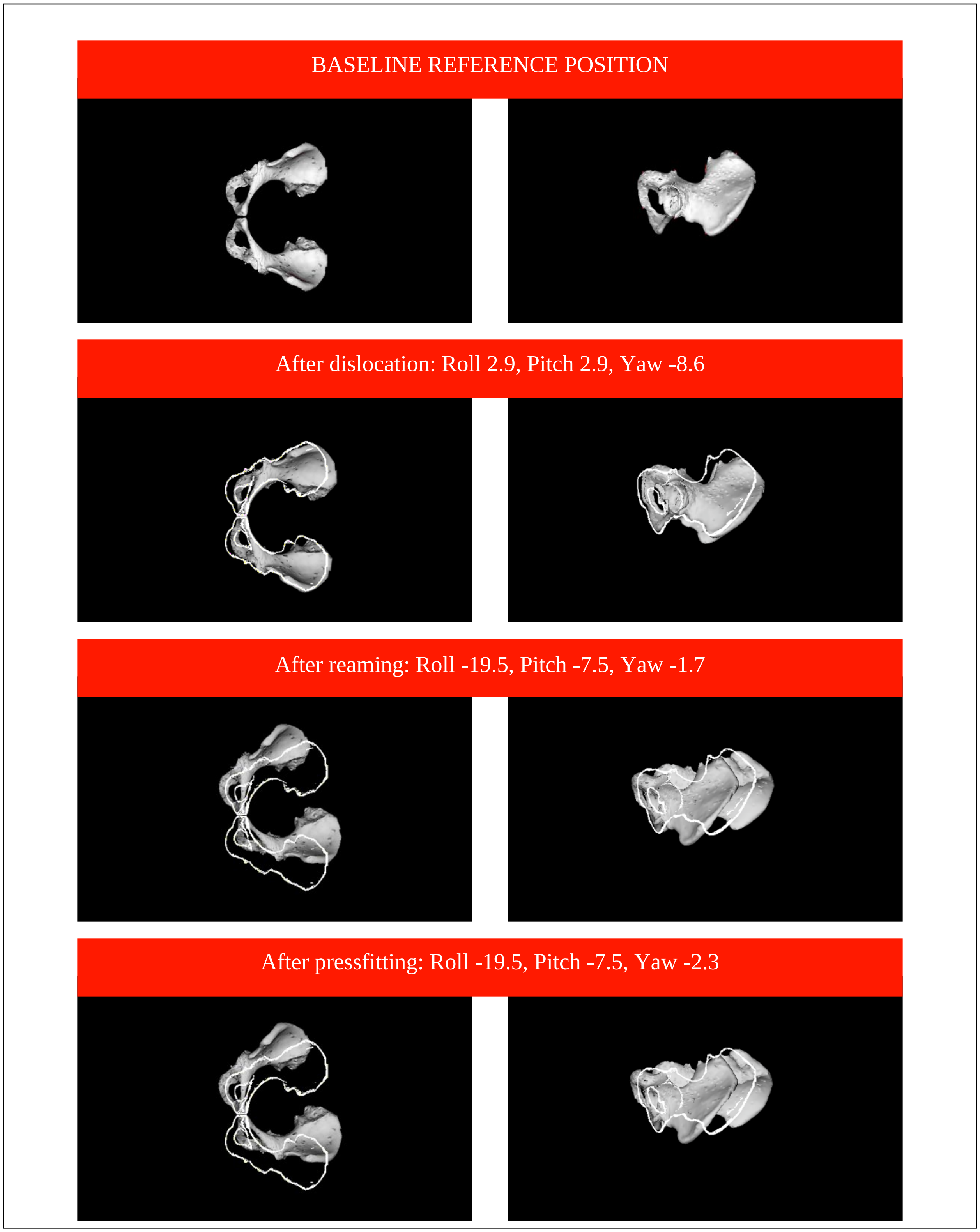

Figure 8a. A demonstration of pelvic orientation. The assumed neutral position is depicted in the AP and lateral projections (top) and then the actual patient's pelvis is displayed during the steps of surgery.

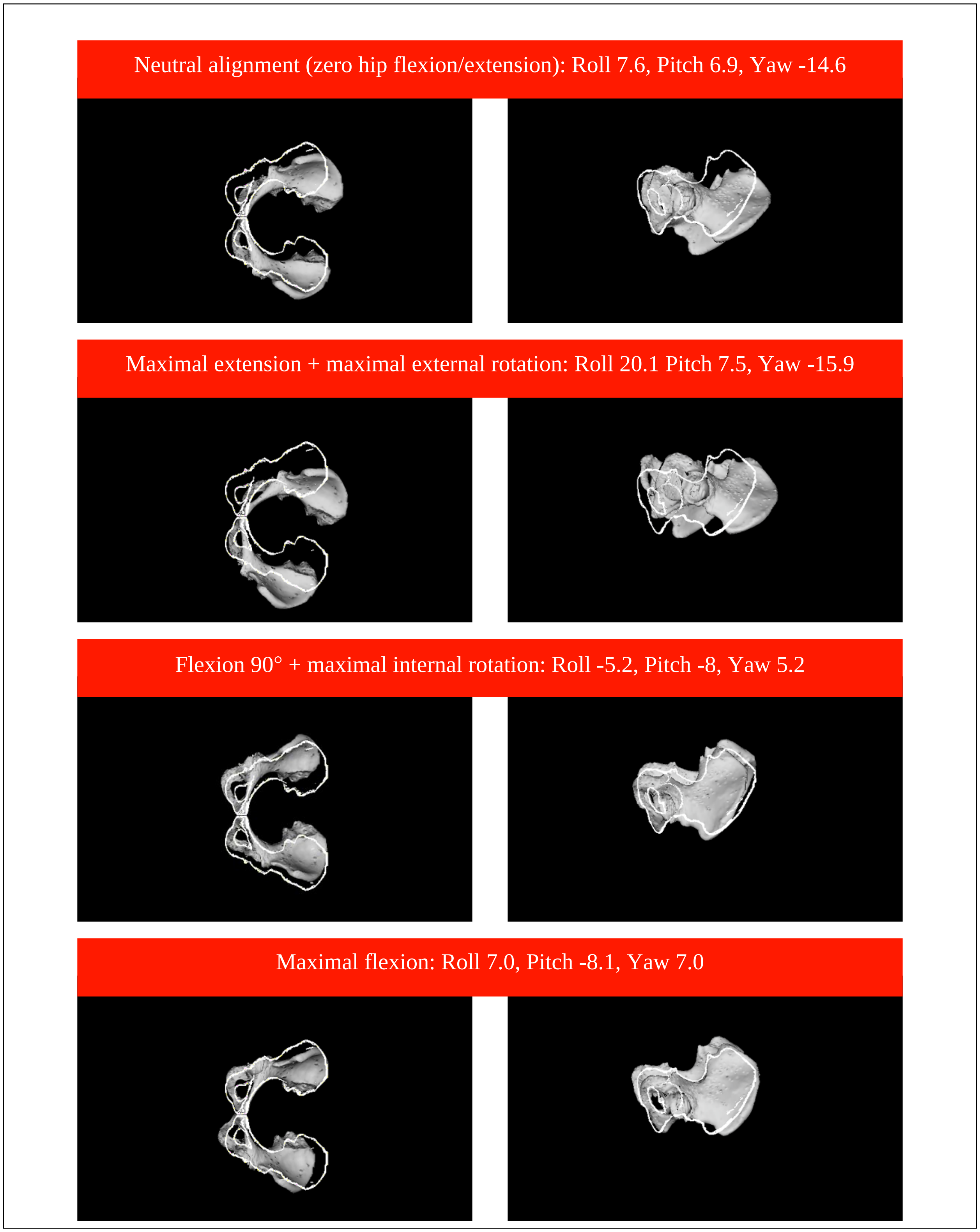

Figure 8b. The alignment of the pelvis is displayed during intraoperative range of motion testing for anterior and posterior instability following implantation of the actual THR components.

Acetabular Implant Alignment

Table IV presents the measured true orientation of the acetabular component during surgery in abduction and anteversion angles (see Appendix A for definitions of alignment) using the following strategies:

- the mechanical guide
- the surgeon's own technique
- preoperatively determined optimal HipNav plan
- final implant orientation after press fitting (with the changes from optimal that occurred with the press fit)

Table IV: Acetabular Implant Orientation Using Different Alignment Strategies[a]

Patient #	Manufacturer's Guide	Surgeon's Position	Optimal Position Prior to Pressfit	Final Implant Position	Change in Final Position from Optimal after Pressfit
1	40/-9	50/16	48/19	48/26	0/+7
2	42/-2	48/24	54/20	51/27	-3/+7
3	41/9	54/26	54/20	61/24	+7/+4
4	n/a[b]	56/23	53/16	54/22	+1/+6
5	48/-7	48/16	55/21	52/16	-3/-5
6	43/19	54/37	56/23	58/33	+2/+10
7	36/1	45/32	56/23	47/20	-9/-3
8	44/3	51/21	54/20	48/20	-6/0
9	44/20	54/33	56/23	53/16	-3/-7
10	44/5	54/28	54/20	52/27	-3/+2
11	48/12	53/22	56/23	44/33	-12/+10
12	40/-6	43/17	54/20	45/14	-9/-6
13	40/-10	50/7	56/23	54/22	-2/-1
14	45/7	53/18	54/20	51/24	-3/+4
15	46/13	58/29	56/23	n/a[b]	n/a[b]
16	40/-5	49/21	56/23	55/25[c]	n/a[b]
17	43/-3	59/28	56/23	55/26	-1/+3
18	46/4	56/21	54/20	54/23	0/+3
19	40/7	47/23	54/20	52/19	-2/-1
20	38/1	64/24	52/27	56/25	+4/-2

a. Measurements listed as abduction/anteversion.
b. Measurement not available.
c. Measurement taken verbally.

The goal of the mechanical guide is to place the cup in 45 degrees of abduction and 20 degrees of anteversion. However, because of the unknown relative position of the pelvis, the actual cup alignment was variable with abduction ranging from 36 to 48 degrees and from 9 degrees of retroversion to 20 degrees of anteversion. The trend was towards neutral alignment and retroversion which will increase posterior instability. Figure 9 plots the points depicting alignment using the manufacturer's guide superimposed on the "safe zone".[35] Overall, the alignment measurements for 12out of 19 patients would have resulted in unacceptable alignment.

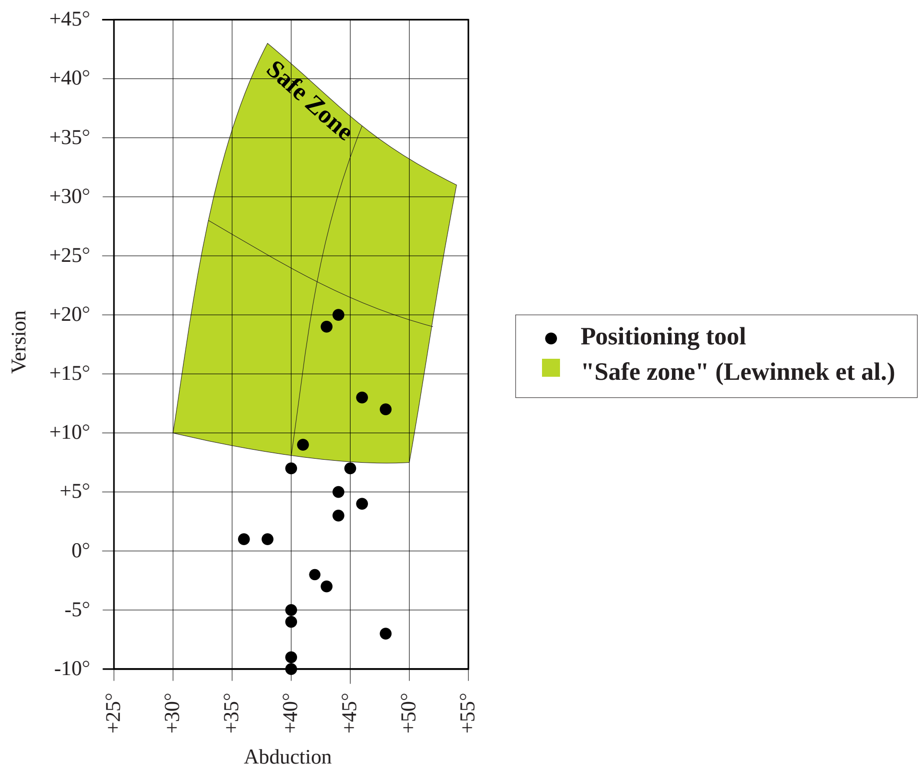

Figure 9. Plot of measured alignment using the mechanical guide provided by the manufacturer plotted in the "safe" zone.

Figure 10 plots all alignment strategies normalized relative to the optimal HipNav plan. The greatest variation from optimal for both abduction and version occurred with the mechanical guide. Although the surgeon's strategy for alignment was felt to be relatively consistent, the actual measures of alignment were quite variable from patient to patient (ranges: 45-56 degrees of abduction and 16-37 degrees of anteversion). The optimal HipNav alignment could be established very easily during surgery using the cross hair-type "aim and shoot" interface. However, during the course of the trial, it became clear that press fitting oversized acetabular cups affected the ability to maintain this optimal alignment during the process of malleting the component into place. Furthermore, the process of press fitting more significantly affected the ability to maintain version alignment than it did abduction alignment, and tended to introduce more anteversion in six out of ten cases. Maximum variations of up to six degrees of abduction and 10 degrees of anteversion were directly attributed to the press fit process.

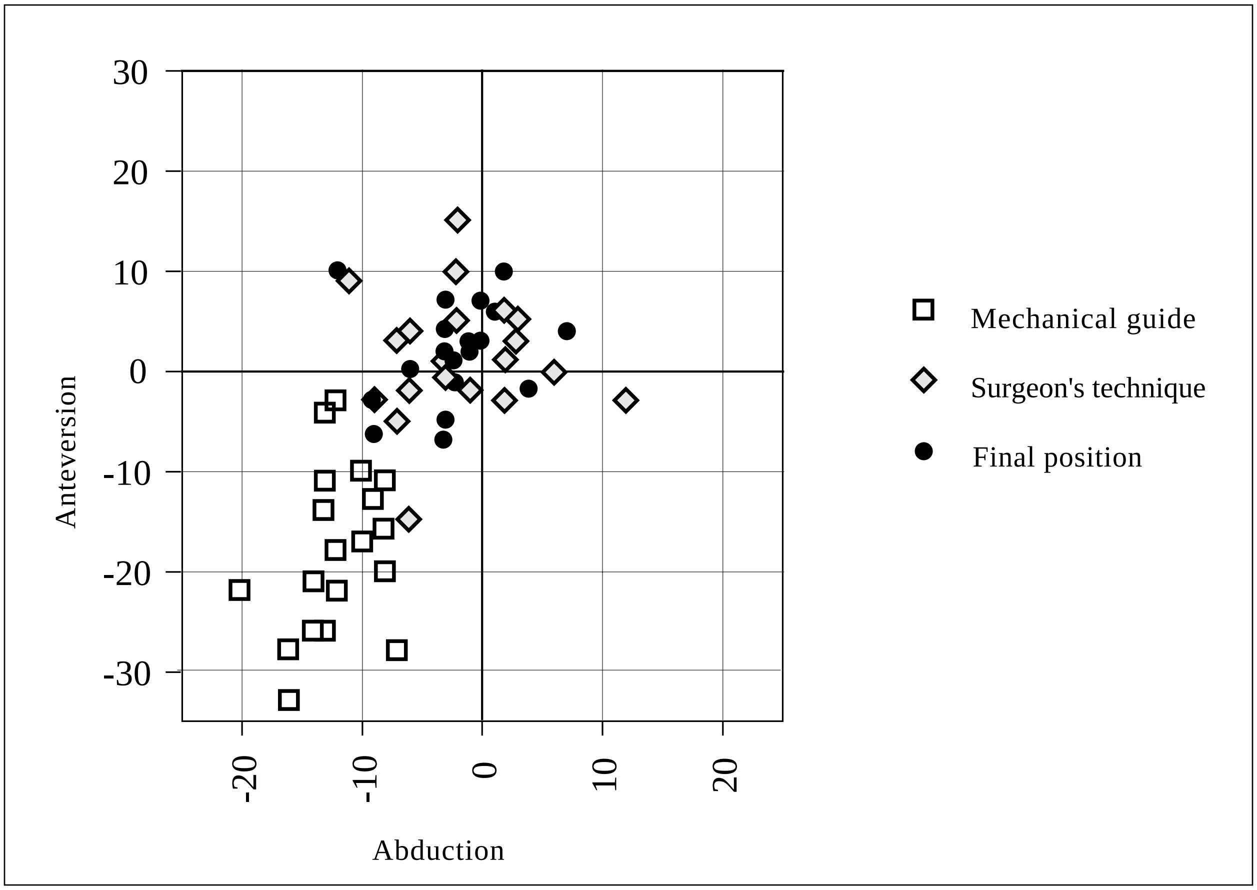

Figure 10. Plot of acetabular implant alignment using various strategies, normalized to the optimal plan.

IV. Discussion

HipNav represents a new class of technologically advanced measurement devices and sensors, blending the fields of computer science, robotics and engineering to solve real clinical problems. We believe that this is the first surgical navigation tool ever used clinically that can intraoperatively and accurately measure pelvic position and motion, and acetabular alignment during surgery. With its basis in image guided technologies, the system represents a new generation of preoperative and intraoperative tools available for surgeons and researchers to measure current practice, with the potential to impact the way surgery is planned, simulated, and executed. A potential major advantage of computer assisted surgery is a reduction in the variation of surgical practice[10, 12, 19] and improved precision and accuracy of commonly performed procedures which will reduce complications and improve patient outcomes.

A. Technology Validation and Accuracy

Many factors contribute to overall system accuracy of an image guided surgical system. During HipNav validation, we studied the accuracy of registration, surface model generation, and tool calibration steps. In past work, we described a method for validating the accuracy of surface-based registration and the need for task-specific measures of accuracy. We have validated the accuracy of HipNav's registration system using this methodology. The registration accuracy reported for the cadaver trial was on the same scale as those reported for the pin-based registration of a human femur.

During the six cadaver trials, three of which were replications of the OR environment, registration orientation errors varied between roughly 0.5 degrees and 1.5 degrees. If there were no other error sources contributing to implant malalignment, these measurements suggest that HipNav could position the acetabular implant within a 1.5 degree cone centered at the desired orientation. We feel that the surface-based registration used in our system provides a clinically and technologically viable alternative to pin-based methods and will be more readily accepted clinically.

In general, the maximum tolerable error for any surgical navigation system is a function of the procedure and task being performed. Every surgical procedure will have its own acceptable level of error based on the clinical tasks that the surgeon faces. Contributing factors include anatomic constraints (i.e., the size of spinal pedicles versus sacrum) and system requirements (like translation versus rotation accuracy). In practice, there may also be other technical factors which affect alignment error such as imaging, segmentation and target sensing errors which need to be quantified in order to determine an end-to-end system accuracy.

B. Clinical Trial

We present our initial clinical experience using HipNav. For the first time, surgeons can intraoperatively track and monitor, in real time, the position of the acetabulum and the orientation of the acetabular implant during THR. Intraoperative measurements showed wide variations in both the initial position of patients' pelvii on the OR table and during various stages of surgery. During range of motion testing for implant stability there was also significant pelvic motion which, in effect, changes the true measurement of range of motion.

Traditional acetabular alignment guides, used according to the manufacturer's specifications, resulted in less than optimal alignment and did not reliably achieve 45 degrees of abduction and 20 degrees of anteversion of true anatomic alignment. Somewhat surprisingly to the surgeon, there was significant variation in final cup orientation using the surgeon's current technique of alignment. In addition, for all cases, version alignment appeared to be most sensitive to changes in pelvic orientation, which is expected to directly impact the risk of impingement and dislocation. New surgical strategies to improve alignment and reduce variability will likely need to be based on anatomic landmarks coupled with mechanical guides. HipNav is now capable of testing and validating any new strategies.

During the course of the trial we found that the process of press fitting the acetabular cup component significantly affected its final orientation. This phenomenon occurred despite both the use of minimal press fit and increasingly aggressive attempts by the surgeon to control alignment as the cup was inserted. We hypothesize that this relative change in alignment is caused by either the acetabular guide design, the patient's bony anatomy, or both. The current implant holder has a rounded impaction surface which may drive the guide off alignment when hit with the mallet (Figure 11). In addition, the final shape of the reamed acetabulum may force the cup orientation to conform to the reamed cavity and change the final alignment as impaction occurs or significant changes in pelvic orientation occur with each blow of the mallet. We have begun to test these hypotheses using HipNav since we can now collect the shape and location of the final reamed acetabulum intraoperatively using the digitizing probe. We have also begun to track the position of the pelvis and acetabular guide during the impaction process at speeds of twenty measurements per second so that we can examine this phenomenon. We hope to be able to quantify this press fit effect and develop and test alternative alignment strategies or impaction tools to assist the surgeon.

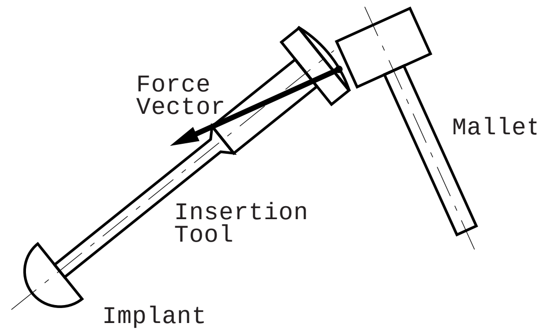

Figure 11. One possible mechanism for the change in acetabular cup alignment during pressfit.

Although the HipNav system has focused on the problem of acetabular cup alignment, the potential cause of dislocation is malposition of both implanted components. We measured femoral version manually and the measured angle of version versus desired version was less variable than for acetabular alignment. By flexing the knee at 90 degrees and orienting off of the flexed knee (much like a protractor) the surgeon can achieve relatively accurate rotational alignment of the femoral component. In addition, cementless femoral component version is more constrained by the fit of the implant within the native proximal anatomy of the femur.

To more accurately measure the effect of femoral alignment, we have begun to develop a femoral tracking and guidance system that will extend the current HipNav capabilities to include intraoperative tracking of the femur, broaches, and implant position. By extending surgical navigation to the femoral side, we will then be able to simulate and execute plans for the alignment and orientation of both the acetabular and femoral implants. We can then provide the surgeon with real time feedback not only on optimal alignment but also on accurate intraoperative measurements of leg length and hip offset. In addition, the effect of femoral implant alignment can be measured during intraoperative functional range of motion testing permitting the surgeon to make adjustments in neck lengths or version during surgery.

The initial clinical trial admittedly represents the quantification of measurements from one surgeon’s practice and techniques. However, we believe that the problems of determining pelvic orientation and obtaining reproducible and accurate acetabular alignment are ubiquitous in the performance of THR surgery. Our clinical trial is ongoing and we continue to collect intraoperative data and expand our database. Plans are also underway to expand the number of sites to include two to four sites in the United States and Europe in order to gauge clinical practice of multiple sites and surgeons. We continue to prospectively collect functional and clinical data using the Harris Hip Scores, SF 36 Survey and Modems Hip/Knee Outcomes Data Collection Instruments (AAOS) in order to follow dislocation rates and patient outcomes.

Although the ultimate risk of dislocation depends on many factors, the most important first step is to provide optimal alignment. In the case of acetabular alignment, these navigational tools will permit us to challenge commonly held assumptions of optimal alignment. They will also provide for a new class of intraoperative measurement tools that, when coupled with three-dimensional preoperative planners, may permit accurate and reproducible orientation of acetabular components and establish and validate more reliable, anatomic-based alignment strategies to assist surgeons in cup alignment.

C. Future Clinical Studies

Access to this new technology opens up many opportunities for clinical researchers. With the ability to precisely measure intraoperative alignment and position information, these tools will permit examination of the following critical issues:

- development of new alignment strategies using anatomically based landmarks for acetabular alignment to be used in conjunction with mechanical guides;
- design and analysis of more accurate tools for bone preparation including drills, reamers and impaction devices;
- intraoperative measurement of the reamed bone surface to gauge the accuracy of the reamers and preparation strategies currently used;
- intraoperative measurement of bone/implant gaps after press fitting oversized implants;
- comparison of true anatomic cup alignment with radiographic measures of alignment; and
- more accurate examination of the incidences of dislocation, wear debris and loosening related to the initial component alignment.

D. Other Clinical Utilities of HipNav Technology

The knowledge provided by this experience is not limited to intraoperative and patient outcome data. The preoperative planner and simulator also provides surgeons and researchers with the ability to perform “functional” preoperative planning for acetabular alignment using pelvic tilt measurements made from preoperative X-rays in positions like standing and sitting. The range of motion simulator coupled with an accurate alignment tool allow us to examine and optimize the effects of the functional positions of the pelvis and minimize the risk of dislocations during daily activities. The current simulator incorporates the effect of implant to implant impingement. However, to improve fidelity of the system to represent the actual clinical problem, work is underway to improve the planner and simulator by including the effect of soft tissue and bone impingement and capsular restraints on impingement and dislocation.

The technologies used in HipNav also provide the surgeon with a powerful intraoperative visualization tool. By using the digitizing probe as a pointer, the patient's pelvic anatomy can be localized and navigated on the TV monitor. This gives the surgeon, in effect, an on-line, real-time registered CT scan and "X-ray vision" without the need for further ionizing radiation. In addition, by knowing the absolute position of the pelvis and surgical tools, HipNav can measure and provide feedback on the position of any tracked surgical tool relative to the pelvis during surgery.

As clinicians begin to better understand the concept of image guided technologies and the potential of coupling optimized preoperative plans with accurate intraoperative tools, many more clinical applications can be developed. Surgical procedures such as percutaneous screw fixation of fractures, pelvic and sacroiliac screw placement, arthroscopic ligament reconstructions around the knee and total knee replacement surgery are some of the procedures that may benefit with the adaption of image guided technologies. Eventually, this approach will lead to less invasive surgical techniques.

E. Impact on Surgical Practice

The purpose of HipNav and similar navigational systems is to provide accurate real-time information to the surgeons through their routine clinical use. By providing intraoperative feedback such as tool alignment and anatomic visualization during surgery, a synergistic coupling of the capabilities of the surgeon and the system is likely to improve the outcome achieved by either the surgeon or the system independently. Ultimately, to prove its clinical utility, HipNav, as well any new image navigational guided system, will need to show the improvement of clinical outcomes while being cost-effective.

The utility of HipNav's technology, however, goes beyond the scope of individual surgeons who have the opportunity to routinely use the system. HipNav offers a set of measurement tools which can be used to evaluate and validate not only implant systems and alignment strategies, but more importantly, the currently held assumptions which all surgeons use as a basis for cup alignment. For instance, with HipNav, for the first time, a tool exists to test the often quoted optimal alignment strategy of 45 degrees abduction and 20 degrees anteversion.

With such a tool, information validated at clinical test sites, such as improved alignment strategies, can quickly be passed on to a larger surgical audience. This application of the information from HipNav is likely to have a wider clinical impact in a shorter period of time than widespread clinical use of the system itself. It will also provide developers of image guided systems with end user feedback necessary to integrate these technologies into widespread clinical practice.

Appendix A

Definitions of Pelvic Alignment and Implant Orientation

The discussion of acetabular alignment can be a confusing subject for surgeons and researchers alike. Descriptive alignment terms like cup anteversion and flexion are used interchangeably and often incorrectly. In addition, measures of true anatomic alignment and radiographic alignment are also different. For any hip navigation system, these definitions become critical.

Acetabular cup alignment is traditionally measured by describing two angles: one for inclination and one for version.[2, 40, 55, 68] Description of alignment can be defined as anatomic (or true), radiographic (or planar) and operative based on a chosen sequence of rotations (Figure 12). The most general description is the true or anatomic alignment which assumes a general pelvic origin and can describe any combinations of cup alignment. Operative alignment is the measurement that surgeons depend on for cup alignment in the OR. The proper description of this measure of rotation is acetabular component flexion (and not version). Cup flexion is introduced in surgical practice on the OR table using the mechanical guides provided by implant manufacturers and is a combination of abduction and version. Radiographic measures of alignment are dependent on the position of the patient's pelvis and the orientation of the X-ray beam. True anatomic version and operative version cannot be directly measured from a standard radiograph.

In general, the description of cup abduction is more straightforward and less variable than measurements of version for any of these measures of alignment.[2, 14-16, 23, 48, 55, 68] Similar to the work of Lewinnek[35], we propose the use of an anterior plane defined by the anterior superior iliac spines and symphysis pubis as the standard pelvic coordinate system. Once this baseline pelvic coordinate system is established, acetabular alignment can be universally presented in any combination of surgical alignment (abduction and flexion), true anatomic alignment (abduction and version) or radiographic (planar) alignment. The utility of a common pelvic coordinate system is reinforced because this anterior plane:

- is based on standard anatomic landmarks easily identified by physical exam;
- is readily apparent on lateral pelvic X-rays used to measure pelvic tilt;
- in general, is nearly vertically oriented in standing patients;[64]
- provides for a universal plane in order to better measure changes in pelvic tilt during functional positions like sitting, standing, lying down.

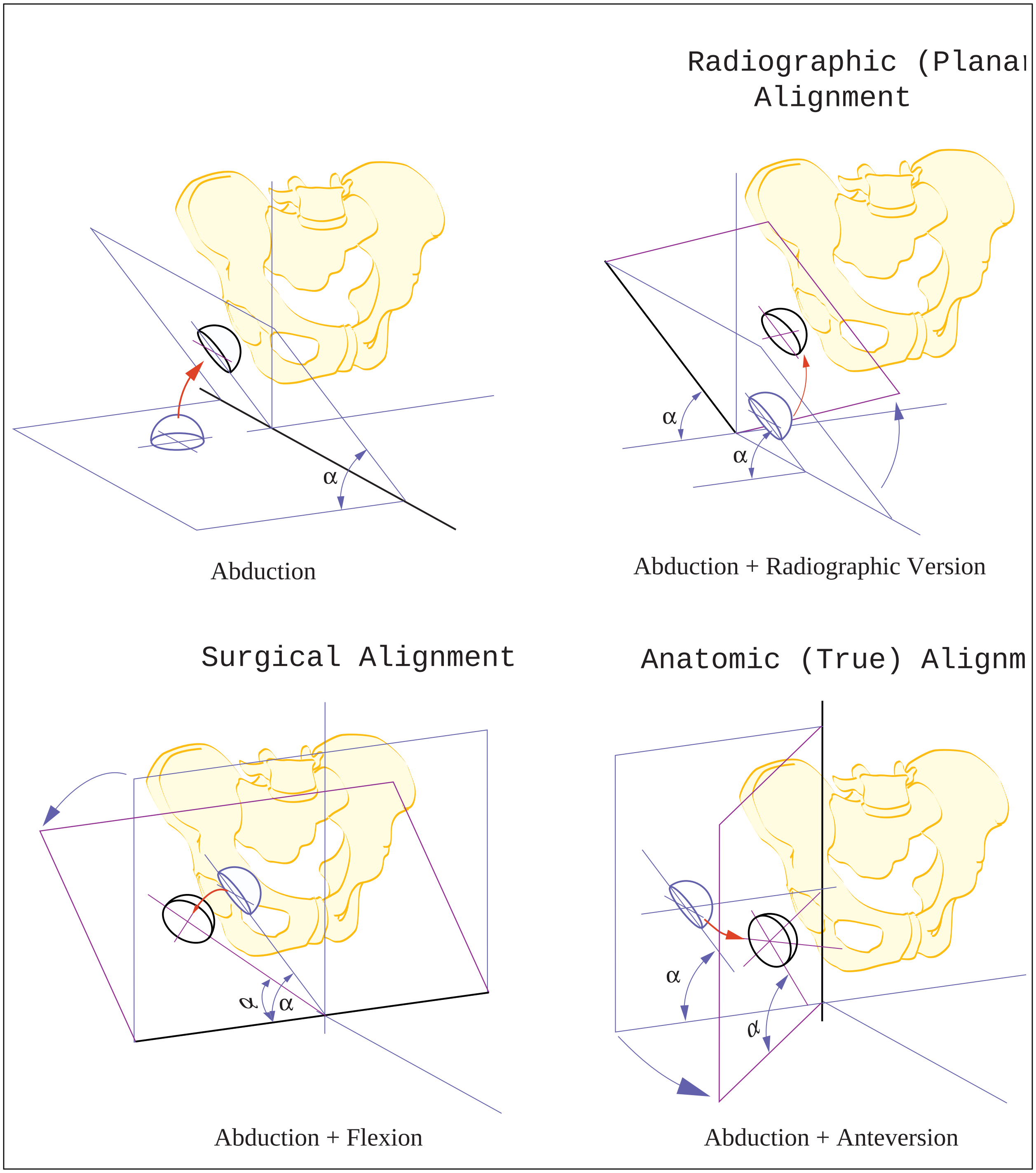

Figure 12. Definitions of acetabular implant alignment and neutral anterior pelvic plane.

V. Acknowledgments

Many people played a significant role in the development of HipNav as we moved from the design phase to prototype development, to laboratory testing, to the cadaver trial and now during the ongoing clinical trial. Only through the collaboration between Carnegie Mellon University and several clinical departments at Shadyside Hospital has this project succeeded. We would like to especially thank Gretchen Daniels, RN and Joanne Redondo, RN, and other members of the operating room staff, for contributing their time, energy and suggestions during the development and implementation of the system in the OR; to Rich Wallace and the Radiology Department for their assistance and time in obtaining the CT scans; to David Zorub, MD, Chairman, Department of Surgery and Henry Mordoh, President, Shadyside Hospital for providing support of our program over the last five years; to Zimmer, Inc. for providing tools and implant information; to Dr. Michael Miller for reviewing and providing comments on this manuscript; and especially to Joni Ropelewski for her efforts in putting together this manuscript.

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